

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD  
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IMPERATIVE CARE, INC.,  
Petitioner,  
INARI MEDICAL, INC.,  
Patent Owner.

Case No. IPR2025-00156  
U.S. Patent No. 11.697-012

VIDEOTAPED DEPOSITION OF PAUL J. ZALESKY, Ph.D.  
LOS ANGELES, CALIFORNIA  
AUGUST 27, 2025

Reported by: Leslie A. Todd, CSR No. 5129 and RPR

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DIGITAL EVIDENCE GROUP  
1730 M Street, NW, Suite 812  
Washington, D.C. 20036

(202) 232-0646 *Imperative Care v. Inari Medical*  
US Patent 12,109,384  
**Imperative Care Ex. 1017**

1                   Deposition of PAUL J. ZALESKY, Ph.D.,  
2 held at the offices of:

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PERKINS COIE

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1888 Century Park East

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Suite 1700

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Los Angeles, California 90067

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Pursuant to notice, before Leslie Anne  
Todd, California Certified Shorthand Reporter in  
and for the State of California, who officiated in  
administering the oath to the witness.

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A P P E A R A N C E S

ON BEHALF OF PETITIONER:

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ON BEHALF OF RESPONDENT:

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ALSO PRESENT:

JINAH CHOI, Videographer

1 C O N T E N T S

2 EXAMINATION OF PAUL J. ZALESKY PAGE

3 By Mr. Stowell 7, 187

4 By Mr. Hamilton 183

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8

9 E X H I B I T S

10 (Attached to transcript)

11 ZALESKY DEPOSITION EXHIBITS PAGE

12 No. INARI- Declaration of Paul J. Zalesky,  
13 2001 Imperative Care, Inc. v. Inari  
14 Medical, Inc. 27

15 No. INARI- Supplemental Declaration of  
16 2008 Paul J. Zalesky, Imperative  
17 Care, Inc. v. Inari Medical, Inc. 32

18 No. 1001 United States Patent No.  
19 11,697,012 80

20 No. 1005 United States Patent Application  
21 Publication No. 2003/0225379 A1 127

22 No. 1006 United States Patent Application  
23 Publication No. 2003/0116731 A1 150

24 No. 1007 United States Patent  
25 No. 9,980,813 171

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E X H I B I T S C O N T I N U E D

(Attached to transcript)

ZALESKY DEPOSITION EXHIBITS

PAGE

No. 1008 Illustrations - Composite Statis

Valve, Inventors Name: David

Schaffer

129

No. 1013 Portions of Dorland's Illustrated

Medical Dictionary, 32nd Edition

54



1           Knobbe Martens on behalf of the  
2           Petitioner, Imperative Care.

3                     And just to correct the read-on,  
4           the deposition is taking place at 1888  
5           Century Park. Sorry. 1888, three 8s.

6                     MR. HAMILTON: And this is Joe  
7           Hamilton of Perkins Coie, representing  
8           the Patent Owner and the witness.

9                     PAUL J. ZALESKY, Ph.D.,  
10          first having duly been sworn, was  
11          examined and testified as follows:

12                                     EXAMINATION

13   BY MR. STOWELL:

14           Q.        Good morning, Dr. Zalesky.

15                     Can you say and spell your name?

16           A.        So Paul, P-A-U-L, J. Z-A-L-E-S-K-Y.

17           Q.        And what is your home address?

18           A.        124 Gilbert Stuart Drive, East  
19   Greenwich, Rhode Island.

20           Q.        And you understand that you've been  
21   retained to serve as an expert on behalf of the  
22   patent owner, Inari Medical, in this IPR; is that  
23   correct?

24           A.        Yes.

25           Q.        And you understand that today's

1 deposition relates to some declarations that you  
2 have submitted in that IPR?

3 A. Yes.

4 Q. I know you've been deposed before,  
5 but I'll just go over the rules. It's always good  
6 to have a reminder.

7 You understand that you are under  
8 oath today, just as if you were testifying in a  
9 court of law?

10 A. Yes.

11 Q. All of your answers today will need  
12 to be verbal so that the court reporter can  
13 transcribe them. Does that make sense?

14 A. Yes. Understood.

15 Q. We'll try to avoid, as best we can,  
16 talking over each other, so please wait for me to  
17 finish my question. I'll do my best to finish --  
18 to -- or wait until you finish your answer before I  
19 ask another question; is that fair?

20 A. That is.

21 Q. Okay. If at any point today you  
22 don't understand one of my questions, please let me  
23 know. If you don't speak up, the presumption will  
24 be that you understood the question; is that fair?

25 A. Yes.

1 Q. Your counsel may make short  
2 objections today. However, you'll still have to  
3 answer all of my questions to the best of your  
4 ability unless you're specifically instructed not  
5 to answer by your counsel. Do you understand?

6 A. Yes.

7 Q. If you need a break today, just let  
8 me know. The only thing I'll ask is that we finish  
9 the line of questioning we're on before we take the  
10 break; is that fair?

11 A. It is.

12 Q. And is there any reason you can't  
13 provide truthful and accurate testimony today?

14 A. No.

15 Q. Have you had any food, drink, or  
16 medication that would inhibit your ability to tell  
17 the truth or to remember facts?

18 A. No.

19 Q. You were deposed in June in a related  
20 IPR between Imperative Care and Inari, correct?

21 A. Yes.

22 Q. And do you recall that that IPR  
23 related to another patent owned by Inari that we  
24 sometimes refer to as the '011 patent?

25 A. Yes.

1 Q. Have you had an opportunity to review  
2 your transcript from that IPR?

3 A. I have briefly, yes.

4 Q. And when you say briefly, what do you  
5 mean?

6 A. I looked at my declaration, skimmed  
7 over the boilerplate aspects, looked at some of the  
8 basic issues that were raised or addressed.

9 Q. Okay. There may be some confusion,  
10 so I'm asking after your last deposition, there was  
11 a written transcript of everything that was said at  
12 the deposition. Did you get a chance to review  
13 that transcript?

14 A. No, I did not.

15 Q. Okay. After your deposition, did  
16 you -- the prior deposition, did you discuss that  
17 deposition with anybody?

18 A. I think over the last several weeks,  
19 Joe Hamilton and I may have had a brief --

20 MR. HAMILTON: I just want you  
21 to caution you. You can say if you've  
22 discussed it but not reveal --

23 THE WITNESS: Okay.

24 MR. HAMILTON: -- the content of  
25 any communications.

1 THE WITNESS: Right.

2 Just, yes, very briefly.

3 BY MR. STOWELL:

4 Q. Okay. So you discussed your prior  
5 deposition with your counsel, Mr. Hamilton?

6 A. Very briefly, yes.

7 Q. Okay. And have you discussed that  
8 prior deposition with anybody else?

9 A. No.

10 Q. Since your last deposition regarding  
11 the '011 patent, have you given any other  
12 depositions in other matters?

13 A. No.

14 Q. And have you testified in court since  
15 your last deposition relating to the '011 IPR?

16 A. No.

17 Q. What do you consider your area of  
18 expertise?

19 A. The category I generally use is  
20 called medical specialty devices, which are medical  
21 devices with very specific either diagnostic or  
22 therapeutic instructions or indications for use.

23 Q. When you say specific diagnostic  
24 indications, what are you referring to there?

25 A. There are a variety of devices,

1 typically disposable components, with a complex  
2 system associated with it for measuring things like  
3 blood gas, pressures, images, ultrasonic  
4 reflections, and probably 10 or 20 other diagnostic  
5 data that the treating physician will use to  
6 diagnose and treat.

7 Q. And so these diagnostic devices, they  
8 collect data and information that the physician  
9 will then use in a procedure?

10 A. Yes. And I meant to say therapeutic  
11 as well, so not just diagnostic, but also  
12 therapeutic, such as angioplasty, thrombectomy,  
13 stents, and so forth.

14 Q. And why do you refer to these as  
15 specialty devices?

16 A. Typically, I'm working with a  
17 physician specialist: the interventional  
18 cardiologist or an interventional radiologist or  
19 orthopedic surgeon. So the normal state of affairs  
20 in developing medical specialty devices is  
21 collaborating with a specialized physician, not a  
22 general physician.

23 Q. And for the therapeutic devices, you  
24 had mentioned angioplasty devices, stents. Are  
25 there any types of other therapeutic devices that

1 you consider to be part of your area of specialty?

2 A. It's actually pretty broad. I worked  
3 in cardiopulmonary bypass, as an example, where  
4 there's a fairly complex system used for bypassing  
5 the heart while it's stopped for open-heart  
6 surgery. There are probes and adjuncts and various  
7 devices used in that procedure. Similarly for  
8 gastrointestinal, both diagnostic and therapy. So  
9 the list would be quite long.

10 Q. And do you consider yourself to be an  
11 expert in the design of medical specialty devices?

12 A. Yes. I -- almost all of my product  
13 development projects have involved some involvement  
14 in design. In some cases they come from an  
15 external source, in which case the design has  
16 already been completed, but, in general, yes.

17 Q. And do you consider yourself to be an  
18 expert in the use of medical specialty devices?

19 A. Yes.

20 Q. And do you consider yourself to be an  
21 expert in the manufacture of medical specialty  
22 devices?

23 A. Yes.

24 Q. Do you consider yourself to be a  
25 professional expert witness?

1 MR. HAMILTON: Objection.

2 Vague.

3 THE WITNESS: I don't normally  
4 used that term when asked. I usually  
5 say consultant.

6 BY MR. STOWELL:

7 Q. And in your mind, what's the  
8 difference between a professional expert witness  
9 and a consultant?

10 MR. HAMILTON: Objection.

11 Vague.

12 THE WITNESS: Expert witness to  
13 me and to some colleagues is more  
14 limiting than a consultant for medical  
15 specialty technology.

16 BY MR. STOWELL:

17 Q. And how would expert witness be more  
18 limiting?

19 A. Expert witness is typically this  
20 dynamic associated with this current case, where  
21 I'm reviewing patents, intellectual property,  
22 various issues, and opining in the form of a  
23 declaration and, of course, today in a deposition.

24 In a general sense, I consult not  
25 only on intellectual property, but the underlying

1 technology or technology alternatives or  
2 development strategies and plans and so forth.

3 Q. And so when you think of an expert  
4 witness, you're thinking of serving as an expert  
5 witness in a legal capacity; is that accurate?

6 A. Yes.

7 Q. And what percentage of your current  
8 working time is dedicated to expert witness work?

9 A. It certainly varies month to month,  
10 but right now I'd say approximately 50 percent.

11 Q. And looking back at the last four  
12 years of your career, has that 50-percent level  
13 generally remained consistent?

14 A. As I said, it's varied from month to  
15 month. But I think if I looked at an overall  
16 average, yes.

17 Q. And the other 50 percent of your  
18 working time, what is that dedicated to?

19 A. It's probably best if I give an  
20 example.

21 In one case that's ongoing, I needed  
22 to identify, initiate, supervise, and manage --

23 MR. HAMILTON: And I'll just  
24 interject. Objection to the extent the  
25 answer requires confidential

1 information. You don't -- you're not  
2 required to disclose other clients'  
3 information. But if you can talk  
4 generally about it, that's fine.

5 THE WITNESS: Yeah. Just in a  
6 general sense, as I said, initiated,  
7 organized, managed, supervised, testing  
8 at a -- an ISO-certified laboratory to  
9 produce some key technical data for  
10 assessment by the client.

11 BY MR. STOWELL:

12 Q. And so then is it fair to say that 50  
13 percent of your time is dedicated to expert witness  
14 work and 50 percent of your time is dedicated to  
15 assisting your clients with the underlying  
16 technology?

17 A. In general, yes.

18 Q. Does your consulting business have a  
19 name?

20 A. Just my name.

21 Q. Just your name. Okay.

22 And did you enter into a consulting  
23 agreement for this case?

24 A. Yes.

25 Q. And what party did you enter into

1 that agreement with?

2 A. With Perkins Coie.

3 Q. Okay. Did you enter into any  
4 agreements with Inari Medical?

5 A. No.

6 Q. Did you enter into any agreements  
7 with Stryker?

8 A. No.

9 Q. And are you aware that Stryker has  
10 acquired Inari Medical?

11 A. Yes.

12 Q. Who do you submit your invoices to in  
13 this matter?

14 A. For this case, to this gentleman  
15 right here, Joe.

16 Q. Okay. And is it your understanding  
17 that Perkins Coie then pays your invoices?

18 A. Yes.

19 Q. And I understand you're charging \$300  
20 per hour for your work on this matter; is that  
21 correct?

22 A. Yes.

23 Q. And during the course of your  
24 consulting agreement, has that number changed at  
25 all?

1 A. No.

2 Q. And is that the rate that you charge  
3 for all of the consulting work that you do?

4 A. No.

5 Q. Okay. How does it differ?

6 A. That's the low end.

7 Q. Okay. And when you say "the low  
8 end," what is your range of consulting fees that  
9 you charge to your customers?

10 A. 300 an hour being the low end; 750  
11 being the high end.

12 Q. And how do you determine how much you  
13 will charge on any given matter?

14 A. There are various issues involved  
15 including how I'm being recruited or by whom I'm  
16 being recruited. In some cases it's by a  
17 professional organization who will use my rate and  
18 then add significantly to it. In other cases I  
19 just deal directly with the prospective client.

20 Q. For this range, \$300 to \$750 an hour,  
21 does that range apply to the work you perform as an  
22 expert witness in legal matters?

23 A. Yes.

24 Q. Okay. So there are some legal  
25 matters that you work on where your rate is \$750

1 per hour; is that right?

2 A. No. The 750 would apply to non-legal  
3 issues.

4 Q. Okay. So for the expert witness work  
5 you do in legal matters, what is the range of the  
6 amounts you charge per hour?

7 A. 300 to 500.

8 Q. And so for those matters, how do you  
9 decide -- for the legal matters, how do you decide  
10 how much you'll charge in that 300 to \$500 range?

11 A. There's a bit of negotiation or,  
12 depending on the client, how I'm approached. And  
13 it's really a case-by-case basis of determining  
14 that rate.

15 Q. Are there any factors you typically  
16 consider when you're deciding on the rate you're  
17 going to charge to a client?

18 A. I'll usually get some sort of  
19 synopsis of what the case is going to be and what  
20 the likely evolution will be, including the time  
21 and the requirements. And the longer time periods  
22 with semi-minimal requirements would justify a  
23 lower rate.

24 Q. And in this case, why did you decide  
25 that you would only charge \$300 per hour?

1           A.           I was recruited directly by a junior  
2 member of Perkins Coie via telephone, followed up  
3 by e-mail. And I had used that rate for certain  
4 other clients. And she and I quickly agreed that  
5 would be acceptable.

6           Q.           And have you performed expert witness  
7 services for Perkins Coie before?

8           A.           No.

9           Q.           Do you work with any expert witness  
10 organizations to obtain your expert witness  
11 positions?

12          A.           There are a few that come to mind  
13 like Forensis, as an example, will often reach out  
14 in a recruitment. And there are probably four or  
15 five others around the country.

16          Q.           And when you say Forensis, how do you  
17 spell that, just so we have the record clear?

18          A.           F, as in frank, O-R-E-N-S-I-S.

19          Q.           And are there any other expert  
20 witness recruiting firms that you recall working  
21 with?

22          A.           There are, but it's been probably two  
23 years since I've worked with them, and so I don't  
24 have them on the top of my head.

25          Q.           But in this case, you were directly

1 contacted by an attorney from Perkins Coie; is that  
2 correct?

3 A. Yes.

4 Q. How much have you billed Perkins Coie  
5 for your work on the Imperative Care versus Inari  
6 matters?

7 A. Do you mean year to date or project  
8 to date?

9 Q. Why don't we do project to date  
10 first.

11 A. This is just a swag. I would say  
12 maybe \$40,000.

13 Q. Okay. And what about year to date?

14 A. Less than half that.

15 Q. And other than the \$300 per hour that  
16 you're receiving for your work on this case, are  
17 you receiving any other sort of monetary or  
18 financial payment for your work on this case?

19 A. Only reimbursement of travel or  
20 sundry expense.

21 Q. Is there any sort of success fee  
22 attached to your work on this case?

23 A. No.

24 Q. Okay. Have you been offered any  
25 equity in Inari or Stryker as a result of your work

1 on this case?

2 A. No.

3 Q. Have you been promised any additional  
4 work for Perkins Coie based on your performance on  
5 this case?

6 A. No.

7 Q. Have you been promised any additional  
8 work by Inari Medical or Stryker based on your  
9 performance in this case?

10 A. No.

11 Q. Are you aware that there is a  
12 District Court proceeding that is occurring in  
13 parallel to the IPR proceedings between Inari  
14 Medical and Imperative Care?

15 A. I'm aware of it without detail.

16 Q. Okay. What do you know about the  
17 District Court case?

18 A. I know very little other than it  
19 involves the same subject matter.

20 Q. Have you reviewed any articles about  
21 the District Court case?

22 A. I don't recall.

23 Q. Have you reviewed any of the papers  
24 that have been filed in the District Court case?

25 A. I don't believe so.

1           Q.        Have you reviewed any of the  
2    declarations that Inari has submitted or served in  
3    the District Court litigation?

4           A.        Are you talking about declarations by  
5    or from Inari?

6           Q.        Correct.

7           A.        I don't believe so.

8           Q.        Okay. Have you had the opportunity  
9    to inspect Inari's ClotTrievers or FlowTrievers  
10   products?

11          A.        Only virtually.

12          Q.        What do you mean by virtually?

13          A.        Online.

14          Q.        And can you explain how that process  
15   went?

16          A.        I'm not sure what you're asking.

17          Q.        Who participated in the virtual  
18   demonstration of the products?

19          A.        Just myself.

20          Q.        Okay. And what did you do to learn  
21   about the products?

22          A.        Because of my background, I'm  
23   generally familiar with thrombectomy procedures and  
24   associated devices, so this is just a quick review  
25   of Inari's approach.

1 Q. And how did you review their  
2 approach?

3 A. As I said, online.

4 Q. And what websites did you access to  
5 learn about Inari's approach?

6 A. Primary site was Inari, Inari's  
7 website.

8 Q. And why did you decide to go to  
9 Inari's website to look at their product?

10 A. I probably do that in virtually every  
11 case, either just before or at the time of  
12 recruitment to be involved in a project.

13 Q. And did your review of Inari's  
14 products inform your opinions that you've offered  
15 in the declarations in this IPR?

16 A. I would say, in general, no.

17 Q. Did you rely on your review of the  
18 Inari products in forming the opinions that are in  
19 your declarations in this IPR?

20 A. Same answer, in general, no.

21 Q. And you're saying "in general." Is  
22 there a way that they were used in forming your  
23 opinions?

24 A. Only as background of considerations  
25 for the actual procedures associated with

1 thrombectomy, but not directly associated with  
2 opinions on IP.

3 Q. And you say you were familiar with  
4 thrombectomy before you were retained to work on  
5 this case; is that correct?

6 A. Yes.

7 Q. And had you seen procedures similar  
8 to the operation of Inari's device prior to your  
9 retention on this case?

10 A. Over a long period of time, I  
11 certainly have seen certain thrombectomy  
12 procedures, yes.

13 Q. And were those procedures similar to  
14 the procedure that Inari currently does with its  
15 FlowTrievers and ClotTrievers system?

16 MR. HAMILTON: Objection.

17 Vague.

18 THE WITNESS: Similar in a sense  
19 of the basic principles which are  
20 applying some sort of vacuum pressure to  
21 withdraw thrombus volume.

22 BY MR. STOWELL:

23 Q. And as you're thinking back to your  
24 career, what time period are you thinking about  
25 when you learned about thrombectomy procedures?

1           A.           Starting probably in the 1990s, early  
2   1990s.

3           Q.           What were the circumstances of  
4   learning about thrombectomy procedures?

5           A.           I've spent a lot of time in operating  
6   rooms and what are called "specialty procedure  
7   laboratories," like cardiac catheterization labs,  
8   as well as vascular labs and so forth.  And on  
9   occasion, a thrombectomy procedure would be  
10   associated with another device or procedure that we  
11   were developing.  So I was there as an observer.

12          Q.           And if I understand correctly, you  
13   have not been able to -- or you have not had the  
14   opportunity to physically inspect Inari's  
15   ClotTrievers and FlowTrievers; is that correct?

16          A.           Yes.  That's correct.

17          Q.           Have you inspected any of Imperative  
18   Care's products either virtually or in person?

19          A.           I believe quite a while back I did a  
20   cursory look at their website as well, but very  
21   briefly.

22          Q.           And did you -- did you rely on your  
23   view of the Imperative Care website in forming any  
24   of the opinions in your declarations in this IPR?

25          A.           No, not really.

1 Q. You have prepared two declarations  
2 for this IPR, correct?

3 A. Yes.

4 Q. I'll hand you what's been previously  
5 marked in this IPR as Inari-2001; and that's the  
6 exhibit number.

7 (Exhibit No. Inari-2001 was  
8 previously marked for  
9 identification.)

10 MR. STOWELL: Thank you.

11 BY MR. STOWELL:

12 Q. Dr. Zalesky, do you recognize Exhibit  
13 Inari-2001?

14 A. Yes.

15 Q. And what is Exhibit 2001?

16 A. It's my declaration dated  
17 February 25th of this year.

18 Q. And on the cover of your declaration,  
19 there's a reference to U.S. patent number 11697012.

20 Do you see that?

21 A. Yes.

22 Q. Okay. And is it your understanding  
23 that the IPR that we're conducting this deposition  
24 about today relates to U.S. patent number  
25 11,697,012?

1 A. Yes.

2 Q. And for shorthand, is it okay if we  
3 refer to that as the '012 patent today?

4 A. Yes.

5 Q. If we turn to page 109 of your  
6 declaration, which is the last page before the  
7 attachments, is that your signature?

8 A. Yes.

9 Q. And did you sign this document on  
10 February 25, 2025?

11 A. Yes, I did.

12 Q. And where were you when you signed  
13 this document?

14 A. In East Greenwich, Rhode Island.

15 Q. And is that your handwritten  
16 signature on this page?

17 A. Yes.

18 Q. When you signed the declaration, you  
19 attested that all the statements made in the  
20 declaration, to your knowledge, were true and the  
21 statements were made on the -- made on information  
22 and belief that the statements are true. Is that  
23 still true today?

24 A. Yes.

25 Q. Do you still believe that all the

1 statements in this first declaration, Exhibit 2001,  
2 are correct and accurate?

3 A. Yes.

4 Q. Are you aware of any errors or  
5 misstatements in the first declaration,  
6 Exhibit 2001?

7 A. I'm not aware of misstatements. When  
8 you say "errors," I may have not expanded as much  
9 on certain areas as I might have, but I wouldn't  
10 call that an error.

11 Q. Are you aware of anything in the  
12 declaration that is inaccurate?

13 A. No.

14 Q. Do you wish to change any of the  
15 opinions that you've offered in this first  
16 declaration, Exhibit 2001?

17 A. No.

18 Q. Other than working with counsel, did  
19 you work with anyone else to create Exhibit 2001?

20 A. Only with Perkins' counsel.

21 Q. In drafting Exhibit 2001, did you  
22 rely on any conversations with anybody besides  
23 counsel?

24 A. No.

25 Q. In preparing Exhibit 2001, did you

1 have any conversations with anyone at Inari Medical  
2 or Stryker?

3 A. No.

4 Q. Do you know anyone that works at  
5 Inari Medical?

6 A. No.

7 Q. Do you know anyone that works at  
8 Stryker?

9 A. Not that I'm aware, no.

10 Q. And what was the process for creating  
11 your declaration, Exhibit 2001?

12 MR. HAMILTON: Objection.

13 Vague.

14 THE WITNESS: It started with my  
15 reviewing basic materials which, of  
16 course, were the patents -- or the  
17 patent I went to in particular for this  
18 declaration.

19 MR. HAMILTON: I'll just, again,  
20 object to the extent the question calls  
21 for communications or drafts or anything  
22 between us that I'm instructing you not  
23 to answer on. But if you can answer the  
24 question otherwise, please.

25 THE WITNESS: I then put down my

1           own outline and worked with counsel to  
2           draft the contents.

3       BY MR. STOWELL:

4           Q.           And roughly how long did you spend  
5       working to draft Exhibit 2001?

6           A.           I'm guesstimating, 30 hours.

7           Q.           And did you exchange drafts of the  
8       declaration with counsel?

9           A.           Yes.

10          Q.           Was there any information in the  
11       drafts that you relied on in forming your opinions  
12       that does not appear in Exhibit 2001?

13                       MR. HAMILTON:  Objection.  I'm  
14       instructing you not to answer to the  
15       extent the question relates to  
16       information in any draft between  
17       counsel.

18                       THE WITNESS:  So could you  
19       repeat that?

20       BY MR. STOWELL:

21          Q.           Sure.  Was there any information in  
22       the drafts that you relied on in forming the  
23       opinions that are in Exhibit 2001 that's not  
24       referenced or mentioned in Exhibit 2001?

25          A.           No.

1 Q. I will hand you what's been marked in  
2 this case as Exhibit Inari-2008.

3 Thank you.

4 (Exhibit No. Inari-2008 was  
5 previously marked for  
6 identification.)

7 BY MR. STOWELL:

8 Q. Dr. Zalesky, do you recognize  
9 Exhibit 2008?

10 A. Yes.

11 Q. And what is Exhibit 2008?

12 A. It's a supplemental declaration  
13 regarding the '012 patent that I signed on  
14 July 15th of this year.

15 Q. And if we look at page 109 of Exhibit  
16 2008, is that your signature on that page?

17 A. Yes.

18 Q. And did you sign this declaration on  
19 July 15th, 2025?

20 A. Yes.

21 Q. And where were you located when you  
22 signed the declaration?

23 A. In East Greenwich, Rhode Island.

24 Q. And again, on this declaration, you  
25 attested that the statements in the declaration

1 were true or that they were based on a belief that  
2 they were true; is that correct?

3 MR. HAMILTON: Objection. The  
4 document speaks for itself.

5 THE WITNESS: Yes.

6 BY MR. STOWELL:

7 Q. Okay. And do you still believe that  
8 the statements that you made in this supplemental  
9 declaration, Exhibit 2008, are true and accurate?

10 A. Yes.

11 Q. Are you aware of any errors or  
12 misstatements in the declaration?

13 A. No.

14 Q. Are you aware of any opinions or  
15 statements that are inaccurate in the declaration?

16 A. No.

17 Q. Why did you provide a supplemental  
18 declaration?

19 A. It was requested by the client.

20 Q. Okay. Had your opinions changed  
21 between your first declaration, Exhibit 2001, and  
22 this supplemental declaration, Exhibit 2008?

23 A. No.

24 Q. What was the process for creating  
25 Exhibit 2008?

1                   MR. HAMILTON:  Objection.  I'm  
2                   instructing the witness not to answer  
3                   with respect to content of  
4                   communications or drafts or any other  
5                   communication between counsel and the  
6                   witness.

7                   THE WITNESS:  So similar to the  
8                   first declaration, my composing an  
9                   outline and then exchanging  
10                  communications with counsel.

11  BY MR. STOWELL:

12                  Q.           And so you recall for Exhibit 2008  
13                  that you created your own outline for the  
14                  supplemental declaration?

15                  A.           Yes.

16                  Q.           And how did you go about creating the  
17                  outline?

18                  MR. HAMILTON:  Objection, again.  
19                  I'll instruct the witness not to reveal  
20                  the content of any communication or  
21                  information relating to drafts or the  
22                  preparation of the declaration.

23                  THE WITNESS:  Just a general  
24                  review, again, of the patent followed by  
25                  a list.

1 BY MR. STOWELL:

2 Q. And the reason I ask is that  
3 Exhibit 2001 is quite similar to Exhibit 2008. Did  
4 you use Exhibit 2001 as a roadmap for your outline  
5 for Exhibit 2008?

6 A. To a limited extent, yes. Just to  
7 make sure I remembered the key issues in the  
8 original declaration.

9 Q. But is it fair to say you did a new  
10 analysis to generate Exhibit 2008?

11 A. I would call it incremental, not  
12 generally new because some of the same issues were  
13 on the docket, if you will.

14 Q. Would it be fair to say that Exhibit  
15 2008 contains all of the opinions that you have  
16 regarding this IPR?

17 MR. HAMILTON: Objection.

18 Vague.

19 THE WITNESS: I believe so. You  
20 know, I -- as I understand your  
21 question, you're asking could there be  
22 some other issue that I did not address?  
23 Is that your question?

24 BY MR. STOWELL:

25 Q. Well, as you sit here today, you have

1 opinions about this IPR. Are all of those opinions  
2 set forth in Exhibit 2008?

3 A. I believe so.

4 Q. Does Exhibit 2008 supersede  
5 Exhibit 2001?

6 MR. HAMILTON: Objection.

7 Vague.

8 THE WITNESS: That wasn't my  
9 interpretation. I thought the  
10 supplemental descriptor was accurate.

11 BY MR. STOWELL:

12 Q. Okay. Are there any opinions you're  
13 aware of that appear in Exhibit 2008 that don't  
14 appear in Exhibit 2001?

15 A. I don't believe so.

16 Q. And how much time do you recall  
17 spending to prepare Exhibit 2008?

18 A. Probably a bit less than the original  
19 declaration, so I'd approximate 15 hours.

20 Q. And other than working with counsel  
21 at Perkins Coie to prepare Exhibit 2008, did you  
22 work with anybody else to prepare the supplemental  
23 declaration?

24 A. No.

25 Q. And did you have any conversations

1 with anybody at Inari Medical or Stryker regarding  
2 the supplemental declaration, Exhibit 2008?

3 A. No.

4 Q. Did you have any conversations with  
5 anyone else regarding the supplemental declaration,  
6 Exhibit 2008?

7 A. No.

8 Q. Can you turn to paragraph 64 of  
9 Exhibit 2008, and just let me know when you're  
10 there.

11 A. Okay.

12 Q. In paragraph 64, you state, "I do not  
13 analyze the details of Garrison."

14 Is that an accurate statement?

15 A. Yes.

16 Q. Okay. And in the next sentence, in  
17 paragraph 64, it says that you reserve the right to  
18 further assess any reason -- any independent  
19 reasons of patentability for the claims and view of  
20 Garrison.

21 Have you made any such further  
22 assessment of Garrison?

23 A. Only to myself.

24 Q. And have you formed any opinions  
25 about Garrison as they relate to this IPR?

1           A.           Not specifically opinions, no.

2           Q.           And so is it fair to say that with  
3   respect to this IPR relating to the '012 patent  
4   that you do not have any opinions about the  
5   Garrison reference?

6           A.           That's a very broad question.  In  
7   terms of opinions related to the -- to the  
8   associated patent, not directly, no.

9           Q.           And in your supplemental declaration,  
10   you do not offer any opinions regarding the  
11   Garrison reference, correct?

12          A.           If memory serves, I think I had a  
13   sentence related to Garrison in some other part of  
14   the text, but I'd have to go back and look at it.

15          Q.           Okay.  And so do you believe that the  
16   statement in paragraph 64 where you say "I do not  
17   analyze the details of Garrison" is not completely  
18   accurate?

19          A.           That's not what I'm saying.

20                        I had looked at the Garrison patent.  
21   At first glance, I didn't understand how it had any  
22   association with the case; hence, my comment about  
23   a broad question, but did not express an opinion in  
24   that regard.

25          Q.           If we could turn to paragraph 75 of

1 Exhibit 2008, and let me know when you are there.

2 A. Okay.

3 Q. In paragraph 75, you state that you  
4 do not analyze the construction of aspiration in  
5 the preamble of Claim 1. Is that an accurate  
6 statement?

7 A. Yes.

8 Q. You then say that you may, if asked,  
9 further review and assess the proper construction  
10 of this term.

11 Have you been asked to assess the  
12 construction of aspiration?

13 A. No.

14 Q. And so is it fair to say that in this  
15 IPR relating to the '012 patent, that you have not  
16 offered an opinion regarding the construction of  
17 aspiration?

18 A. That's correct.

19 Q. Can we turn now to paragraph 165, and  
20 let me know when you get there.

21 A. Okay.

22 Q. In paragraph 165, you say that you  
23 have not rendered any opinions on secondary  
24 considerations of non-obviousness at this time.

25 I understand the "at this time" to

1 refer to the date that you signed the supplemental  
2 declaration; is that accurate?

3 A. Yes.

4 Q. And was it a correct statement that  
5 you did not offer any opinions on secondary  
6 considerations of non-obviousness?

7 A. Yes.

8 Q. You then go on and you say that you  
9 reserve the right to analyze evidence of secondary  
10 considerations if asked to do so.

11 Have you been asked to evaluate or  
12 analyze evidence of secondary considerations in the  
13 IPR relating to the '012 patent?

14 A. No, I have not.

15 Q. And so is it fair to say that in this  
16 IPR, you do not have any opinions regarding the  
17 secondary considerations of non-obviousness?

18 A. That's correct.

19 Q. While we're at the back of Exhibit  
20 2008, there is an Attachment 1 that I understand  
21 includes your resume. Is that what's reflected in  
22 Attachment 1?

23 A. Yes.

24 Q. And is this version of your resume  
25 current?

1 A. Yes. I believe so.

2 Q. Okay. Is there anything that you  
3 would update or change on the resume?

4 A. No. Not at this time.

5 Q. Okay. If we can turn just to the  
6 last page of your resume, there's a heading towards  
7 the bottom that says "Other."

8 Do you see that?

9 A. Yes.

10 Q. And underneath that it says, "During  
11 the past five years, 2015 to 2020."

12 Do you see that?

13 A. Yes, I do.

14 Q. Okay. And obviously that -- the past  
15 five years are not 2015 to 2020, so is this an  
16 older section from your resume?

17 A. Yes. I failed to catch that.

18 Q. Have you served as an expert witness  
19 during the past five years from 2020 to 2025?

20 A. Yes.

21 Q. And do you keep a list of your expert  
22 witness engagements?

23 A. In my home office, I have an  
24 abbreviated list, yes.

25 Q. And does that list cover the last

1 five years, 2020 to 2025?

2 A. Yes.

3 Q. And is that something that you could  
4 easily retrieve if you were asked to retrieve it?

5 A. Yes.

6 Q. In the last five years, 2020 to 2025,  
7 roughly how many depositions do you think you've  
8 sat for?

9 A. I would say at least six.

10 Q. And in this other section, you  
11 mention testifying in arbitrations. Have you  
12 testified in any arbitrations in the last five  
13 years?

14 A. I have to go back to my records.  
15 There was an arbitration case involving a Stanford  
16 start-up, and I just don't recall the exact dates  
17 from beginning to end. I think it may have, in  
18 fact, gone beyond 2020, but I'd have to check.

19 Q. Have you given any court testimony in  
20 the last five years?

21 A. No.

22 Q. In the last five years, have any of  
23 your legal engagements involved hemostasis valves  
24 other than the current set of matters?

25 A. No.

1 Q. Have any of your engagements in the  
2 past five years involved catheters?

3 A. Yes.

4 Q. Okay. And the matters that have  
5 involved catheters, what type of catheters were  
6 involved?

7 A. The most significant case is called a  
8 guide extension catheter which is used in  
9 interventional cardiology procedures.

10 Q. And what is the guide extension  
11 catheter used for?

12 A. It's used in conjunction with what's  
13 called a standard guide catheter that's placed in  
14 the ostium of the coronary arteries. The guide  
15 extension goes inside that catheter, is advanced  
16 into the coronary vasculature to enable the  
17 interventionalist to access more distal lesions and  
18 to navigate difficult anatomy.

19 Q. There is an Attachment 2 to your  
20 declaration, Exhibit 2008.

21 Do you see that?

22 A. Yes.

23 Q. And the title of this attachment, or  
24 at least at the top of the chart, it says  
25 "Materials Considered."

1 Do you see that?

2 A. Yes.

3 Q. So what is Attachment 2 intended to  
4 reflect?

5 A. Basically a summary of the sources of  
6 information for me to review prior to expressing an  
7 opinion.

8 Q. And did you review all of the  
9 documents that are listed in Attachment 2?

10 A. I believe so.

11 Q. And do you believe that you read each  
12 of the documents cover to cover?

13 A. I honestly don't know, but I believe  
14 so.

15 Q. Okay. And I --

16 A. Excuse me. I didn't read the  
17 Collegiate Dictionary cover to cover.

18 Q. Okay. So when you say the Collegiate  
19 Dictionary, you're referring to Exhibit 2002?

20 A. Yes.

21 Q. And there are other dictionaries  
22 listed here. It's fair to say you didn't read the  
23 entire dictionary for all the dictionary references  
24 or exhibits; is that fair?

25 A. That's fair.

1 Q. Okay. There are a number of  
2 deposition transcripts of Troy Thornton listed on  
3 the second page. Did you review those deposition  
4 transcripts?

5 A. I don't recall if I reviewed all  
6 three. I certainly reviewed some portion.

7 Q. And when you say "some portion," how  
8 did you determine what portion of the deposition  
9 transcript to review?

10 A. I honestly don't recall.

11 Q. One of the papers listed in this list  
12 is paper six, it's on the first page, and it says  
13 "Institution Decision."

14 Do you see that?

15 A. Yes.

16 Q. And do you recall reviewing the  
17 institution decision for this '012 IPR?

18 A. I recall seeing a document that I  
19 didn't pay much attention to, quite frankly, since  
20 it's in the legal frame and not the technical  
21 frame.

22 Q. Okay. So is it fair to say you did  
23 not review that document in depth?

24 A. Yes.

25 Q. Are you aware that the Board in that

1 institution decision disagreed with some of the  
2 opinions you offered in Exhibit 2001?

3 MR. HAMILTON: Objection.

4 Mischaracterizes the document.

5 THE WITNESS: I only know some  
6 limited comments from counsel.

7 BY MR. STOWELL:

8 Q. Okay. Do you recall reviewing any  
9 portions of the institution decision where the  
10 Board disagreed with your opinions?

11 A. I recall reviewing a paragraph or  
12 two, yes.

13 Q. And what did those paragraphs relate  
14 to?

15 A. I'd have to go back and look, quite  
16 honestly.

17 Q. And how was it that you identified  
18 those specific paragraphs to review?

19 A. Probably just blatant disagreement on  
20 my part.

21 Q. Blatant disagreement meaning you  
22 disagreed with what the Board was saying?

23 A. In very selected cases, yes.

24 Q. And if you didn't review the  
25 institution decision in detail, how was it that you

1 identified the portions of the decision where you  
2 had disagreement?

3 A. When you've got numerous documents,  
4 you have to pick and choose which ones you're going  
5 to scrutinize versus really dwell on. And 95  
6 percent of my action was on the patent language and  
7 patent issues; 5 percent on other documents such as  
8 the one you're referring to. So very skimming kind  
9 of review.

10 Q. Is there any document that you  
11 considered in forming the opinions in Exhibit 2008  
12 that is not listed in Attachment 2?

13 A. Not that I'm aware of at the time.

14 Q. Are there any documents not listed in  
15 Attachment 2 that you considered in preparation for  
16 your deposition today?

17 A. No.

18 Q. And what did you do to prepare for  
19 your deposition today?

20 A. I reviewed the declaration probably  
21 over a period of two or three hours.

22 Q. And when you say "the declaration,"  
23 are you referring to the supplemental declaration,  
24 Exhibit 2008?

25 A. Yes.

1 Q. Did you also review Exhibit 2001 in  
2 preparation for your deposition?

3 A. Briefly I did, yes.

4 Q. And when you say "briefly," how much  
5 time do you think you spent reviewing Exhibit 2001?

6 A. About an hour and a half on an  
7 airplane.

8 Q. Okay. So an hour and a half on  
9 Exhibit 2001 and two to three hours on Exhibit  
10 2008; is that correct?

11 A. I think that's appropriate, yes.

12 Q. Did you spend time reviewing any  
13 other documents besides your declaration in  
14 preparation for your deposition today?

15 A. I reviewed, again, the patent  
16 specific language and figures, yes.

17 Q. And when you say "the patent," are  
18 you referring to the '012 patent?

19 A. Yes.

20 Q. Did you also review any of the prior  
21 art patents that are at issue in this IPR?

22 A. Not in preparation for this depo, no.

23 Q. And when I refer to "prior art," is  
24 that a term that you are familiar with?

25 A. Yes.

1 Q. And what's your understanding of what  
2 "prior art" is?

3 A. In general, publications prior to the  
4 patent application that we're talking about, '012,  
5 that involve patents, publications, scientific  
6 journal articles, and the like.

7 Q. And so in preparation for your  
8 deposition today, other than the two declarations  
9 in Exhibit 1001, the '012 patent, did you review  
10 any other documents?

11 A. No, I don't believe I did.

12 Q. Other than conversations with  
13 counsel, did you discuss your deposition with  
14 anyone else?

15 A. No.

16 Q. Did you meet with counsel to prepare  
17 for your deposition today?

18 A. Yes.

19 Q. And how many times did you meet with  
20 counsel?

21 A. We met virtually briefly and then in  
22 person once.

23 Q. And "virtually briefly," what do you  
24 mean by that?

25 A. A video conference call for

1 significantly less than an hour.

2 Q. And when was that virtual meeting?

3 A. Last week.

4 Q. And who participated in that virtual  
5 meeting?

6 A. Just Joe Hamilton and myself.

7 Q. And then you also met with counsel in  
8 person one time; is that correct?

9 A. Yes.

10 Q. And when was that meeting?

11 A. Yesterday.

12 Q. And who was present at that meeting?

13 A. Again, just Joe and myself.

14 Q. And how long did that meeting last?

15 A. Approximately four hours.

16 Q. And did you review any documents  
17 during that meeting that refreshed your  
18 recollection about any of your opinions?

19 A. Yes. We specifically looked at --

20 MR. HAMILTON: Just, you can  
21 reveal the identity of documents but not  
22 the content of our communications.

23 THE WITNESS: Yeah. We just  
24 reviewed certain selected aspects of  
25 both declarations.

1 BY MR. STOWELL:

2 Q. And were there any other documents  
3 you reviewed during that meeting that refreshed  
4 your recollection about your opinions?

5 A. The '012 patent and one or two of the  
6 prior art patents.

7 Q. And do you remember what prior art  
8 patents?

9 A. Hartley and Eller, in particular.

10 Q. What about the Schaffer reference, do  
11 you remember --

12 A. Oh, sorry. And Schaffer.

13 Q. Any other documents you remember  
14 reviewing that refreshed your recollection about  
15 your opinions?

16 A. A couple dictionary excerpts.

17 Q. Okay. Do you remember reviewing any  
18 documents that refreshed your recollection about  
19 your opinions that are not listed in Attachment 2  
20 of Exhibit 2008?

21 A. No.

22 Q. Have you had the opportunity to  
23 review Mr. Thornton's declaration that was  
24 submitted for this '012 IPR?

25 A. Yes.

1 Q. And did you review that declaration  
2 prior to preparing your declarations, Exhibits 2001  
3 and 2008?

4 A. I can't honestly recall the sequence  
5 of events, but certainly I responded to his  
6 declaration.

7 Q. Did you review Mr. Thornton's  
8 declaration in preparation for your deposition  
9 today?

10 A. Not in any detail, no.

11 MR. STOWELL: Okay. We've been  
12 going a little over an hour. Why don't  
13 we take a break.

14 MR. HAMILTON: Sounds good.

15 THE VIDEOGRAPHER: We're off the  
16 record at 10:12 a.m.

17 (Recess.)

18 THE VIDEOGRAPHER: This marks  
19 the beginning of media number 2. We're  
20 on the record at 10:24 a.m.

21 BY MR. STOWELL:

22 Q. Dr. Zalesky, did you talk to anybody  
23 about the subject matter of your deposition during  
24 the break?

25 A. No.

1 Q. And did you review any documents  
2 during the break?

3 A. No.

4 Q. I understand from your previous  
5 deposition that you served as the director of R&D  
6 at Boston Scientific; is that correct?

7 A. Yes.

8 Q. Okay. And during what years were you  
9 the director of R&D?

10 A. 1984 to '86.

11 Q. And I understand that during that  
12 time, one of the projects you were involved with  
13 was for a guide catheter; is that right?

14 A. Yes.

15 Q. What is a catheter?

16 A. In general, a catheter is a -- is a  
17 tube made of various polymers with a lumen, or in  
18 some cases, multiple lumens, for the conveyance of  
19 either secondary devices or blood withdrawal or  
20 tissue sampling, that sort of thing.

21 Q. And are all catheters made with  
22 polymers?

23 A. Probably 99 percent.

24 Q. And based on your experience, what  
25 are the other one percent made of?

1           A.           There are certain limited devices  
2   made from, as an example, stainless steel  
3   hypotubing. And there's probably a related metal  
4   alternative I'm not thinking of right now. But  
5   very limited.

6           Q.           I'm going to hand you what has been  
7   previously marked in this IPR as Exhibit 1013.

8                       (Exhibit No. 1013 was  
9                       previously marked for  
10                      identification.)

11 BY MR. STOWELL:

12           Q.           Dr. Zalesky, did you have an  
13   opportunity to review Exhibit 1013 as part of your  
14   work on this case?

15           A.           I honestly don't recall looking at  
16   this.

17           Q.           Okay. Are you familiar with  
18   Dorland's Illustrated Medical Dictionary from your  
19   time in the medical field?

20           A.           Yes.

21           Q.           Okay. Is it a dictionary that you've  
22   used before?

23           A.           On limited occasions, yes.

24           Q.           And is it generally accepted in the  
25   field as a reputable dictionary for medical

1 devices?

2 A. I think -- I believe so, yes.

3 Q. Okay. At the bottom of each page,  
4 there are some page numbers. If you could turn to  
5 page 306 of the Dorland's Medical Dictionary, and  
6 let me know when you're there.

7 A. I'm there.

8 Q. Okay. In the upper right-hand  
9 corner, there is a definition for "catheter" that  
10 reads, "A tubular, flexible, surgical instrument  
11 that is inserted into a cavity of the body to  
12 withdraw or introduce fluid."

13 Do you see that?

14 A. I do.

15 Q. And is that definition consistent  
16 with your understanding of what a catheter is?

17 A. I think that's one limited aspect of  
18 what a catheter is.

19 Q. Okay. Would your definition of  
20 catheter be more expansive?

21 A. Yes.

22 Q. And what -- how would your definition  
23 be different than the definition that's shown on  
24 page 306?

25 A. It would include a much broader

1 category of uses in addition to withdrawing or  
2 introducing fluid. As I mentioned a moment ago,  
3 the introduction of therapeutic devices or  
4 secondary diagnostic devices or adjunct devices.  
5 So much broader.

6 Q. Okay. Would you make any other  
7 changes to this definition beyond expanding the  
8 identified uses?

9 A. I think tubular and flexible are  
10 certainly accurate. Surgical is a bit difficult to  
11 interpret. Most people would associate that with  
12 an operating room. A large number of catheters are  
13 not used just in an operating room but bedside,  
14 special procedure labs, and even at home. So,  
15 again, in my opinion, it would be broadened.

16 Q. And is there a word you would use  
17 that you would suggest replacing surgical with?

18 A. Perhaps medical.

19 Q. Other than broadening the identified  
20 uses and broadening the term "surgical," are there  
21 any other changes you would make to the definition  
22 of catheter on page 306?

23 A. I mean, not offhand, no.

24 Q. Okay. So at Boston Scientific, when  
25 you were working on the guide catheter, what is a

1 guide catheter?

2 A. As the name suggests, it's really a  
3 conveyance tool. And so in the great majority of  
4 interventional procedures, whether it's coronary,  
5 cerebral, or peripheral vascular, the guide  
6 catheter is inserted, either with or in adjunction  
7 with a guide wire to approximate the treatment site  
8 that's going to be managed by the physician.

9 In the case of coronary artery  
10 disease or heart disease, the guide catheter is a  
11 100-plus-centimeter long hollow tube basically; has  
12 a sandwich construction that is inserted in the --  
13 either the groin or the radial artery of the arm,  
14 advanced to the ostium of the coronary arteries,  
15 and left there as a guide for other devices to be  
16 advanced through it or inside of it.

17 And that same general procedure  
18 applies to cerebral vascular, peripheral vascular,  
19 and other procedures.

20 Q. And so is it fair to say that the  
21 guide catheter acts as a conduit for other devices  
22 or catheters to be inserted through?

23 A. Yes. I think that's a good word.

24 Q. Are -- does the term "guide catheter"  
25 suggest to you any specific structural features for

1 the catheter?

2 A. They can be quite diverse, from a  
3 simple single polymer tube to a -- also a typical  
4 sandwich construction which has a layer of polymer,  
5 a coil of stainless steel, followed by another  
6 layer of polymer, which it adds the resistance and  
7 kinkability to the device. But lots of variations  
8 on a theme.

9 Q. In your mind, is there any difference  
10 between a catheter and a guide catheter?

11 A. Per our recent dictionary discussion,  
12 catheter is a broader term. A guide catheter,  
13 using your word conduit, is used in certain  
14 procedures. A guide catheter is not used, for  
15 instance, in urethral applications, but a catheter  
16 is used in that indication.

17 Q. Do you still consider guide catheters  
18 to be catheters, based on the definition of  
19 catheter we previously discussed?

20 A. Yes. It's a subdivision of the  
21 broader category of catheters.

22 Q. I believe that you testified that the  
23 guide catheter you had worked on while you were at  
24 Boston Scientific was 6 to 8 French; is that  
25 correct?

1           A.           Yes, that's my recollection.

2           Q.           And did you have two sizes, one 6,  
3 and one 8 French?

4           A.           Actually, three: 6, 7, and 8.

5           Q.           Okay. And were there any challenges  
6 that you faced in enlarging the 6 French catheter  
7 to an 8 French catheter?

8           A.           Not specifically, no. It's the  
9 same -- the same technology, the same process used  
10 in all three sizes.

11          Q.           In your experience, when you were at  
12 Boston Scientific, was it common to have multiple  
13 sizes of catheters for a specific product line?

14          A.           The user required that, depending on  
15 what procedure and what other device he was  
16 planning on using in a procedure.

17          Q.           And why would the user require  
18 multiple sizes of catheters?

19          A.           Smaller is better in most procedures.  
20 But there are certain procedures or certain patient  
21 categories where either a larger therapeutic device  
22 is going to be used or more than one device will be  
23 advanced through that same guide catheter; hence,  
24 the need for a larger lumen.

25          Q.           While you were at Boston Scientific,

1 was an 8 French catheter the largest catheter you  
2 worked on?

3 A. I believe so.

4 Q. In your time in industry, have you  
5 ever worked on catheters that were larger than 8  
6 French?

7 A. You know, I'm trying to go through a  
8 memory here. But at Baxter and working in  
9 cardiopulmonary bypass, there were certain adjunct  
10 cannulas, for instance, that were larger than that,  
11 yes.

12 Q. What do you mean by an "adjunct  
13 cannula"?

14 A. So the way bypass works is you're  
15 pulling blood from the heart and injecting it into  
16 the aorta distal to the heart. And, typically, a  
17 cannula, which is another catheter of sorts, it's a  
18 hollow tube, is used on both ends of that process.

19 Q. And so based on the definition of  
20 catheter we looked at previously, would the  
21 cannulas you worked with at Baxter be considered a  
22 catheter?

23 A. Yes.

24 Q. And what was the size of the cannulas  
25 you worked on while you were at Baxter?

1           A.           There was a range, depending on the  
2 patient category, from pediatric through adults. I  
3 do remember certainly 16 and 18 French devices  
4 being involved.

5           Q.           And what years did you work at  
6 Baxter?

7           A.           1990 to 1994.

8           Q.           And were you aware of 16 French and  
9 18 French catheters being used in other  
10 applications before you used them for the cannulas  
11 at Baxter?

12          A.           You know, I honestly don't recall.

13          Q.           Do you believe that Baxter invented  
14 the 16 French or 18 French cannula?

15          A.           I don't know the history of the  
16 development of those cannulas. They were fairly  
17 commonplace at that point in time.

18          Q.           Is the 18 French catheter the largest  
19 catheter that you've worked on in your career?

20          A.           As I said, I recall specifically 16  
21 and 18s, but there may -- there may well have been  
22 a 20 or even larger French catheter in that  
23 cardiopulmonary bypass setting.

24          Q.           And why do you suspect that there  
25 could have been a larger catheter in that setting?

1           A.           There was the occasional extremely  
2 large patient with large volumes of blood involved  
3 that would require even larger lumens; hence, the  
4 larger size.

5           Q.           And in making or in increasing the  
6 size of a catheter from 16 French to 20 French,  
7 were there any particular hurdles or challenges  
8 that Baxter faced in creating those devices?

9           A.           As I recall, the only real concern  
10 was the wall thickness that would minimize kinking  
11 of such a large catheter.

12          Q.           And so in moving from a 16 French  
13 catheter to a 20 French catheter, would the wall  
14 thickness of the catheter change?

15          A.           Not necessarily, but it could.

16          Q.           The modification of wall thickness of  
17 a catheter, was that something that a catheter  
18 engineer would routinely try to optimize during  
19 catheter design?

20          A.           Yes. In the spirit that smaller is  
21 better, the proverbial requirement that we  
22 engineers have responded to is they want an  
23 infinite ID and a zero OD. So the challenge is  
24 always to minimize that wall thickness while  
25 retaining certain handling and physical properties.

1 Q. And so at this time in the 1990s,  
2 would a person of ordinary skill in the art have  
3 possessed the knowledge to make those changes to  
4 catheter thickness?

5 A. Yes.

6 Q. We've talked about your experience at  
7 Baxter. Are there any other experiences you can  
8 recall where you worked with a catheter that was 16  
9 French or larger?

10 A. Not offhand, no.

11 Q. I understand from the prior  
12 deposition that while you were at Boston Scientific  
13 working on the guide catheter that there were some  
14 physicians who used that guide catheter to aspirate  
15 material from a patient. Is my understanding  
16 correct?

17 A. I don't recall specifying that level  
18 of detail, no.

19 Q. Okay. Do you ever recall the guide  
20 catheter that you worked on with Boston Scientific  
21 being used as an aspiration catheter?

22 A. No, I do not. Its primary indication  
23 was as a conduit.

24 Q. Okay. Have you ever worked on any  
25 catheters that were used as aspiration catheters?

1           A.           I'm sure I have. But I'd have to dig  
2 through my memoirs to figure out exactly when that  
3 was and what that was. And I say that because  
4 physicians are always entrepre- -- not always,  
5 they're often entrepreneurial, and can take a  
6 catheter with another indication and use it for  
7 their own indications, such as taking a standard  
8 hollow single-lumen catheter and using it for a  
9 thrombectomy procedure.

10           Q.           And in your experience, do you recall  
11 observing that, where a physician would take a  
12 catheter intended for some other purpose and use it  
13 for aspiration thrombectomy?

14                       MR. HAMILTON: Objection.

15           Vague. Mischaracterizes the testimony.

16                       THE WITNESS: I saw that happen  
17 on a few occasions in a special  
18 procedures lab, yes. I can't recall the  
19 details, but I do recall the general  
20 sense.

21 BY MR. STOWELL:

22           Q.           What is a special procedures lab?

23           A.           Typically, it involves a patient  
24 table, not different from an operating room table,  
25 with x-ray equipment and additional imaging

1 equipment used to both diagnose and to guide the  
2 procedure such as angioplasty or stent placement.

3 Q. And these procedures you observed in  
4 the special procedures lab, what time period  
5 would -- would this have taken place?

6 A. All the way from 1984 through 2015 or  
7 so.

8 Q. And during those years, you recall  
9 instances where a physician would use a catheter  
10 intended for a different purpose for aspiration  
11 thrombectomy?

12 MR. HAMILTON: Objection.  
13 Mischaracterizes the testimony.

14 THE WITNESS: I recall some  
15 occasions where that was done, yes.

16 BY MR. STOWELL:

17 Q. And in those occasions, do you recall  
18 if the physicians needed to make any modifications  
19 to the catheters in order to use them for  
20 aspiration?

21 MR. HAMILTON: Objection.  
22 Vague.

23 THE WITNESS: The only  
24 modification I can recall is taking a  
25 catheter or two, in certain

1           circumstance, and adjusting its  
2           geometry. So some of these catheters  
3           are formable in the sense that you can  
4           modify the tip geometry to a curvature.

5 BY MR. STOWELL:

6           Q.           And how does the doctor make that  
7           modification to the geometry?

8           A.           Simply with his hands.

9           Q.           So the physician physically bends the  
10          catheter; is that right?

11          A.           Yes. Pretty much.

12          Q.           In the aspiration thrombectomy  
13          procedures that we're talking about, how was the  
14          suction or negative pressure created for the  
15          catheter?

16          A.           Simply with a syringe.

17          Q.           And how would the syringe be  
18          connected to the catheter?

19          A.           In virtually every case, there's a  
20          Tuohy Borst connector, and within that is a  
21          hemostasis valve, which is an axial valve, if you  
22          will. And the catheter is simply inserted through  
23          that Tuohy Borst into the patient.

24          Q.           And then how is the syringe attached  
25          to the catheter to generate the negative pressure?

1           A.           I recall seeing a stopcock proximal  
2   to the Tuohy Borst and then the syringe attached to  
3   the two-way stopcock.

4           Q.           And did the stopcock have some sort  
5   of connector on it that the syringe could be  
6   attached to?

7           A.           The stopcock would have at least two  
8   ports, one of which would be attached to the  
9   syringe.

10          Q.           And would the stopcock have some sort  
11   of standard connector that could be used to attach  
12   other devices to it?

13          A.           As I said, it would have at least two  
14   ports so the secondary port could be utilized for  
15   something else. I don't recall seeing that, but it  
16   could be.

17          Q.           But you recall the syringe being  
18   attached to one of the ports of the stopcock; is  
19   that correct?

20          A.           Yes.

21          Q.           And do you recall if that connector  
22   was a standard lure-type connector?

23          A.           Yes. There was nothing specialized  
24   about it.

25          Q.           When I say "lure-type connector," do

1 you know what type of --

2 A. Yes.

3 Q. -- connecter I'm referring to?

4 And in this time period from the  
5 mid-1980s through 2015, did you have experience  
6 using lure connectors in the medical devices that  
7 you worked on?

8 A. Probably as routine as the Tuohy  
9 Borst.

10 Q. So very common?

11 A. Yes, very common.

12 Q. Okay. Were there any other types of  
13 standard connectors that you dealt with frequently  
14 between the mid-'80s and 2015, other than a  
15 lure-type connecter?

16 A. No. None that -- not that I can  
17 recall.

18 Q. Okay. Have you ever worked with  
19 barbed connectors?

20 A. I don't believe so.

21 Q. And do lure connectors come in  
22 different sizes?

23 A. Yes. Because of their need to mate  
24 with the other device or devices.

25 Q. When do you first remember using

1 lure-type connectors?

2 A. That same time period. So going back  
3 to 1984.

4 Q. On the aspiration procedures we were  
5 talking about that you observed between the  
6 mid-'80s and 2015, do you ever remember any other  
7 devices used to create negative pressure, other  
8 than a syringe?

9 A. Not in the clinical setting, and by  
10 that I mean patient setting, no.

11 Q. What about in the experimental  
12 setting?

13 A. I recall seeing -- but I couldn't  
14 tell you precisely when or where -- a small pump  
15 being used in an animal study.

16 Q. And the pump would be used to create  
17 negative pressure for an aspiration catheter?

18 A. Yes.

19 Q. And would that experience have been  
20 before, say, 2015?

21 A. Yes.

22 Q. The term "aspiration catheter," does  
23 that term make you think of any specific structural  
24 features of the catheter?

25 MR. HAMILTON: Objection.

1           Beyond the scope.

2                   THE WITNESS:   No.   No.

3                   MR. HAMILTON:   I'm also going to  
4           add an objection, vague, to the last  
5           question.

6   BY MR. STOWELL:

7           Q.       In your experience, can most  
8           catheters be used as an aspiration catheter if the  
9           catheter has the appropriate connector and there's  
10          no syringe available?

11                  MR. HAMILTON:   Objection.

12           Vague.   Beyond the scope.

13                  THE WITNESS:   I don't think I'd  
14           say most catheters, no.

15   BY MR. STOWELL:

16           Q.       And why not?

17           A.       As I mentioned earlier, there's a --  
18          a large variety of specialized catheters for  
19          specialized indications with one lumen, multiple  
20          lumens, various tip designs, various indications  
21          for use.   Whereas, aspiration requires at least one  
22          channel that's clean and clear from one end to the  
23          other.

24   BY MR. STOWELL:

25           Q.       Would you agree that most single

1 lumen catheters could be used as an aspiration  
2 catheter?

3 MR. HAMILTON: Objection.

4 Beyond the scope. Vague.

5 THE WITNESS: I think most, yes.

6 BY MR. STOWELL:

7 Q. Let's look at paragraph 16 of your  
8 supplemental declaration, which is Exhibit 2008.  
9 Why did you feel it was important to include  
10 paragraph 16 in this section of your report?

11 A. I prepared this background statement  
12 for, frankly, multiple uses with -- obviously,  
13 tailored to each particular client. But this to me  
14 was part of the pertinent background.

15 Q. And this paragraph focuses on the  
16 years 1995 to 2005.

17 Is there a reason that you focus on  
18 that time period in this paragraph?

19 A. That's when I was most directly  
20 involved with angioplasty procedures and  
21 angioplasty devices, all of which required a guide  
22 catheter.

23 Q. In the angioplasty procedures that  
24 you worked on between 1995 and 2005, were any other  
25 subcategories of catheters used in those procedures

1 besides a guide catheter?

2 A. There were diagnostic catheters, of  
3 course, which included blood sampling or electrode  
4 catheters to measure electrical activity in various  
5 parts of the heart, as well as infusion of  
6 pharmaceuticals or special agents, dye for contrast  
7 angiography studies, diagnostic what's called  
8 intervascular ultrasound to characterize the inside  
9 of a diseased vessel. And I'm sure I could come up  
10 with 10 or 20 others. Quite a lot.

11 Q. And in the typical angioplasty  
12 procedure, were all of those ancillary catheters  
13 inserted through the guide catheter?

14 A. Almost all, I would say.

15 Q. In paragraph 16, you list some of the  
16 catheter configurations that were developed and  
17 tested. Was the size or the, let's say, the  
18 diameter of the catheter one of the configurations  
19 that was developed or changed between these  
20 catheters?

21 A. The size was driven primarily by the  
22 indication for use. A peripheral venous catheter  
23 would almost always be larger than an  
24 interventional coronary catheter as an example.

25 Q. And so the -- during this time

1 period, 1995 to 2005, the catheter size would  
2 typically be chosen based on the procedure?

3 A. It would be based primarily on the  
4 procedure and what the physician intended to treat  
5 with.

6 Q. And who would make the decision about  
7 what catheter to use to treat a patient?

8 A. Always the treating physician.

9 Q. And do you know what factors the  
10 treating physician would consider in selecting the  
11 size of catheter in this time period, 1995 to 2005?

12 A. The same two factors I mentioned,  
13 which is the patient's anatomy and his intended  
14 therapeutic or diagnostic device for that  
15 particular patient.

16 Q. You indicate in paragraph 16 that  
17 variations in thrombectomy were being developed in  
18 this time period of 1995 to 2005. What do you mean  
19 by thrombectomy?

20 A. Simply the removal of thrombus in  
21 vasculature.

22 Q. And during this time period, was --  
23 were variations of aspiration thrombectomy being  
24 developed?

25 A. I don't recall specific attention to

1 just aspiration. I recall more attention to  
2 dislodgement or fragmentation of the thrombus.

3 Q. And those methods to dislodge the  
4 thrombus, would there have been an aspiration  
5 component to those systems?

6 A. Typically, a single-lumen catheter  
7 could deliver a disruptive device, such as an  
8 ultrasonic probe or mechanical device or a chemical  
9 agent like a thrombo lysine, and then that same  
10 catheter being used to apply suction to remove the  
11 remains of the thrombus.

12 Q. And during this time period, 1995 to  
13 2005, do you remember observing catheters being  
14 used to aspirate emboli from a patient?

15 A. Yes. In a special procedures lab.

16 Q. And so do you consider the use of an  
17 aspiration catheter to remove a blood clot from a  
18 patient a thrombectomy procedure?

19 A. Yes.

20 MR. HAMILTON: For that last  
21 question, I'm going to add an objection.

22 Vague. Calls for a legal conclusion.

23 BY MR. STOWELL:

24 Q. Have you ever performed an aspiration  
25 procedure yourself?

1 A. No.

2 Q. And have you ever designed an  
3 aspiration system for a thrombectomy procedure?

4 A. No, I have not.

5 Q. The aspiration thrombectomy  
6 procedures you recall seeing in 1995 to 2005, what  
7 parts of the body was the blood clot being  
8 aspirated from?

9 A. Primarily the coronary arteries of  
10 the heart.

11 Q. Do you recall seeing procedures in  
12 any other parts of the body?

13 A. I recall seeing, you know, a limited  
14 number of procedures involving the peripheral  
15 veins.

16 Q. Do you ever remember seeing any  
17 procedures where aspiration was performed in the  
18 cerebral vasculature during the 1995 to 2005 time  
19 period?

20 A. I believe I saw a small number of  
21 those in a Boston hospital in that time period.

22 Q. Do you recall seeing any aspirational  
23 procedures to remove blood clots that were done in  
24 the pulmonary vasculature during the 1995 to 2005  
25 time period?

1           A.           I only saw images taken on videotape,  
2 but not the actual procedure.

3           Q.           But was it your understanding that  
4 blood clots were removed from the pulmonary  
5 vasculature in the proceedings where you viewed the  
6 video?

7           A.           Yes.

8           Q.           And in these aspiration procedures  
9 that you witnessed from 1995 to 2005, were the same  
10 types of catheters used in each procedure?

11                       MR. HAMILTON:  Objection.

12                       Vague.

13                       THE WITNESS:  I honestly don't  
14 recall.

15 BY MR. STOWELL:

16           Q.           Do you recall if all of the  
17 procedures involved a single-lumen catheter?

18           A.           I honestly don't recall.

19           Q.           Do you recall whether the sizing of  
20 the catheter differed at all between the  
21 procedures?

22           A.           Certainly the coronary procedures  
23 were smaller catheters and peripheral venous, and  
24 the cerebral vascular were even smaller.

25           Q.           And when you say the coronary was

1 smaller, what size are you thinking?

2 A. Six French would be big for a  
3 coronary procedure.

4 Q. And what about for peripheral?

5 A. Eight or 10 French would not be  
6 extreme.

7 Q. And what about cerebral?

8 A. Probably less than 5 French.

9 Q. And the catheters that were used in  
10 the aspiration procedures you observed between 1995  
11 and 2005, were those catheters specifically  
12 designed for aspiration thrombectomy?

13 A. I honestly don't know.

14 Q. Could they have been catheters  
15 designed for another purpose that the doctor  
16 decided to use for aspiration?

17 MR. HAMILTON: Objection. Asked  
18 and answered.

19 THE WITNESS: Yes.

20 BY MR. STOWELL:

21 Q. You mentioned that in some of the  
22 procedures you observed, there was a stopcock that  
23 would be used to connect the syringe to the  
24 aspiration catheter; is that accurate?

25 A. Yes.

1 Q. And how would the stopcock be used in  
2 the procedure?

3 A. The stopcock essentially allowed the  
4 connection of a syringe to put in line with a  
5 catheter, and could be open or closed depending on  
6 what was going on.

7 Q. And were there specific instances  
8 where you recall the stopcock being closed during  
9 the procedure?

10 A. Yes. Typically during manipulation  
11 of the catheter.

12 Q. And do you ever recall the stopcock  
13 being closed while the syringe was pulled back and  
14 pressurized?

15 A. I don't recall the details, to be  
16 honest.

17 Q. Were you familiar with Y-arm  
18 connectors during this period, 1995 to 2005?

19 A. It's not ringing a bell. I may have  
20 but it's not ringing a bell.

21 Q. Okay. You're not -- why I say the  
22 term a "Y-arm connector," that doesn't mean  
23 anything?

24 A. Not a term that I used, no.

25 Q. Okay. Let's look at paragraph 78 of

1 Exhibit 2008.

2 So I understand that in rendering the  
3 opinions in Exhibit 2008, you have applied the  
4 Petitioner's definition of a person of ordinary  
5 skill in the art; is that correct?

6 A. Yes. With the disclaimer that's in  
7 this paragraph 78.

8 Q. And what disclaimer is that?

9 A. Even under this too low definition of  
10 ordinary skill.

11 Q. Okay. So you think that the  
12 definition of a POSITA that was proposed by the  
13 Petitioner is too low; is that correct?

14 A. I don't know if "low" is the right  
15 phrase, but I didn't believe it was sufficient.

16 Q. Okay. You believe that the person of  
17 ordinary skill in the art would have had more  
18 experience than is reflected in Petitioner's  
19 definition; is that correct?

20 A. Yes. In particular with regard to  
21 medical procedures and medical devices.

22 Q. Okay. And then despite that  
23 difference of opinion, when you were rendering the  
24 opinions in Exhibit 2008, you still applied the  
25 definition of a POSITA that the Petitioner used,

1 right?

2 A. Yes.

3 Q. Okay. I'm going to hand you what has  
4 been previously marked in this IPR as Exhibit 1001.

5 (Exhibit No. 1001 was  
6 previously marked for  
7 identification.)

8 BY MR. STOWELL:

9 Q. Dr. Zalesky, do you recognize  
10 Exhibit 1001?

11 A. This is the '012 patent which is the  
12 subject matter of my supplemental declaration.

13 Q. Okay. And is this a patent that you  
14 have reviewed in preparing your supplemental  
15 declaration, Exhibit 2008?

16 A. Yes. I believe so.

17 Q. Okay. And do you believe this to be  
18 a complete copy of the '012 patent that you  
19 reviewed?

20 A. Again, I believe so.

21 Q. And how many times do you think  
22 you've reviewed this patent?

23 A. Probably 10 or 12 times.

24 Q. When you've reviewed this patent,  
25 have there been any portions of it that you have

1 not understood?

2 A. I don't believe so.

3 Q. The -- there are some inventors  
4 listed on the first page of the patent. Have you  
5 ever spoken to any of the inventors?

6 A. No.

7 Q. Have you ever reviewed any literature  
8 other than this patent, that was authored by any of  
9 the inventors?

10 A. I don't believe so.

11 Q. Prior to becoming involved in the  
12 matters between Imperative Care and Inari Medical,  
13 were you aware or familiar with any of these  
14 inventors?

15 A. No.

16 Q. If you could turn to Figures 6 and 7  
17 of the '012 patent.

18 And let me know when you're there.

19 A. Okay.

20 Q. So starting with Figure 6, what does  
21 Figure 6 show?

22 MR. HAMILTON: Objection.

23 Vague.

24 THE WITNESS: It depicts a  
25 single filament in a configuration of a

1           loop.

2       BY MR. STOWELL:

3           Q.       And there's an area, 604, identified  
4       with an arrow.

5                       Do you see that?

6           A.       Yes.

7           Q.       And am I correct in stating that in  
8       the actual device, the tubular element would extend  
9       through that area 604?

10                      MR. HAMILTON:  Objection.

11                      Vague.

12                      THE WITNESS:  Yes.

13       BY MR. STOWELL:

14           Q.       And in Figure 6, the tubular element  
15       is not shown, correct?

16           A.       Yes.

17           Q.       And is it your understanding that the  
18       filament shown in Figure 6 would circumferentially  
19       constrict a tubular member that's extending through  
20       that opening 604?

21                      MR. HAMILTON:  Objection.  Calls  
22                      for a legal conclusion.

23                      THE WITNESS:  It would  
24                      circumferentially constrict around the  
25                      outside of that tubular member.

1 BY MR. STOWELL:

2 Q. Okay. And do you see at the top how  
3 the -- of Figure 6, how the filaments are parallel  
4 to each other?

5 A. Yes.

6 Q. If the gap between those two portions  
7 of the filament were wider, say a couple of  
8 centimeters, do you believe that the filament would  
9 still constrict or circumferentially constrict a  
10 tubular member going through opening 604?

11 MR. HAMILTON: Objection.

12 Vague. Calls for a legal conclusion.

13 THE WITNESS: I'm not sure what  
14 you're referring to as "the gap."

15 BY MR. STOWELL:

16 Q. Sure. So at the top of the figure,  
17 there's a place where the filament is parallel to  
18 each other, correct?

19 A. Correct.

20 Q. Okay. So if there were a gap between  
21 those two portions of the filament that are  
22 parallel to each other a few millimeters so that  
23 it's observable --

24 Are you with me?

25 A. Yes.

1 Q. Okay.

2 If there was a gap between those two  
3 portions of the filament, would you still opine  
4 that the filament circumferentially constricts a  
5 tubular member going through opening 604?

6 MR. HAMILTON: Objection.

7 Incomplete hypothetical. Beyond the  
8 scope.

9 THE WITNESS: With a significant  
10 gap, I don't expect it to be  
11 circumferential.

12 BY MR. STOWELL:

13 Q. And why is that?

14 A. Circumferentially, of course, implies  
15 a circle or a circular configuration. With a  
16 significant gap, you would lose the circular  
17 configuration.

18 Q. And how big would the gap have to be  
19 between the portions of the filament for the  
20 filament to no longer circumferentially constrict  
21 the tubular member?

22 MR. HAMILTON: Objection.

23 Incomplete hypothetical. Beyond the  
24 scope.

25 THE WITNESS: I honestly don't

1 know how to answer that. I -- I think  
2 the only word I can use is  
3 "significant."

4 BY MR. STOWELL:

5 Q. And in your mind, does significant,  
6 within the context of this invention, have any  
7 specific measurements or dimensions?

8 MR. HAMILTON: Objection.

9 Incomplete hypothetical. Beyond the  
10 scope.

11 THE WITNESS: No. I can't  
12 honestly think of a particular  
13 dimension. It would be very small.

14 BY MR. STOWELL:

15 Q. And what do you mean by "very small"?

16 MR. HAMILTON: Objection.

17 Incomplete hypothetical. Beyond the  
18 scope.

19 THE WITNESS: I think a  
20 millimeter would be very small.

21 BY MR. STOWELL:

22 Q. And so is it your opinion that if the  
23 two -- the filament -- the two portions of the  
24 filament in Figure 6 were more than a millimeter  
25 apart, that the filament would not

1 circumferentially constrict a tubular member going  
2 through the opening 604?

3 MR. HAMILTON: Objection.

4 Incomplete hypothetical. Beyond the  
5 scope.

6 THE WITNESS: Frankly, my answer  
7 can only be pure speculation.

8 BY MR. STOWELL:

9 Q. Would it be correct to say that you  
10 don't have an opinion on how far apart the portions  
11 of the filament would need to be for the filament  
12 not to circumferentially constrict a tubular  
13 member?

14 MR. HAMILTON: Objection.

15 Incomplete hypothetical. Beyond the  
16 scope.

17 THE WITNESS: I think it's a  
18 theoretical question; hence, my  
19 reluctance to speculate.

20 BY MR. STOWELL:

21 Q. Earlier you had testified that the --  
22 you believe that the filament that is pictured in  
23 Figure 6 would circumferentially constrict a  
24 tubular member going through opening 604, correct?

25 A. Yes.

1 Q. And what led you to that conclusion?

2 MR. HAMILTON: Objection.

3 Vague.

4 THE WITNESS: The combination of  
5 the figures -- this particular figure  
6 and the written description in the claim  
7 all speak to the ability of a thin, for  
8 lack of a better term, flexible filament  
9 to decrease its radius as either -- and  
10 it's pulled around a tubular element, is  
11 consistent with a circumferential  
12 reduction around the tubular element.

13 BY MR. STOWELL:

14 Q. In Figure 6, are you interpreting  
15 Figure 6 to show that the two portions of the  
16 filament at the top of the figure are touching each  
17 other?

18 MR. HAMILTON: Objection.

19 Vague.

20 THE WITNESS: I would say yes,  
21 in general, to that.

22 BY MR. STOWELL:

23 Q. Okay. Why do you say "in general"?

24 A. When you say "touching," it implies  
25 absolutely no spacing, whatsoever, not even a

1 micron. Because of the nature of physical  
2 structures, they might be one micron apart so  
3 they're not actually touching, but to the naked  
4 eye, that would be undetectable.

5 Q. And so if there were a very small  
6 space between the portions of the filaments at the  
7 top of Figure 6, you would still consider the  
8 filament to circumferentially constrict a tubular  
9 member extending through opening 604?

10 MR. HAMILTON: Objection.  
11 Incomplete hypothetical.

12 THE WITNESS: As I said, this is  
13 just speculation. In general, I  
14 perceive this as them touching or just  
15 about touching; hence, the term  
16 "garrotte."

17 BY MR. STOWELL:

18 Q. When you were forming your opinions  
19 about the '012 patent, what did you understand the  
20 term "circumferentially constrict" to mean?

21 MR. HAMILTON: Objection.  
22 Vague.

23 THE WITNESS: The word  
24 "circumferential" means precisely that:  
25 It includes a complete circumference or

1 a full 360-degree circle, and the  
2 reduction or compression, or whatever  
3 term you want to use, is associated with  
4 an equal force coming from that entire  
5 circumference.

6 BY MR. STOWELL:

7 Q. And so are you understanding the term  
8 "circumferentially constrict" to require the device  
9 that is constricting to form a circle?

10 MR. HAMILTON: Objection.  
11 Vague.

12 THE WITNESS: Yes. With  
13 reference to Figure 6, yes.

14 BY MR. STOWELL:

15 Q. And do you believe that Figure 6  
16 illustrates a circle?

17 A. Yes, I do.

18 Q. When you were forming your opinions  
19 about the '012 patent, what did you understand the  
20 term "loop" to mean?

21 A. My understanding of "loop" is a  
22 complete circle; hence, the word "circumferential"  
23 associated with a complete circle.

24 Q. In your understanding of the term  
25 "loop," is there any difference between a "loop"

1 and a "circle"?

2 MR. HAMILTON: Objection.

3 Vague.

4 THE WITNESS: Not in this

5 particular context. In another context,

6 a loop could have a different geometry.

7 In this context, it's a circle.

8 BY MR. STOWELL:

9 Q. And so in the context of the '012  
10 patent, you understand the term "loop" to be  
11 synonymous with "circle"; is that correct?

12 MR. HAMILTON: Objection.

13 Mischaracterizes the testimony. Vague.

14 THE WITNESS: Yes.

15 BY MR. STOWELL:

16 Q. And outside of the '012 patent, you  
17 would agree that "loop," the term "loop," could  
18 mean configurations other than only a circle,  
19 correct?

20 MR. HAMILTON: Objection.

21 Vague. Beyond the scope.

22 THE WITNESS: I've seen the word  
23 used with respect to things like  
24 jewelry, as an example.

25 BY MR. STOWELL:

1 Q. And when you refer to jewelry, are  
2 you referring to examples of jewelry where the loop  
3 in the jewelry does not form a perfect circle?

4 A. In that context, outside of this,  
5 yes.

6 Q. And is it your opinion that a person  
7 of ordinary skill in the art, in September of 2017,  
8 reviewing the '012 patent would have viewed the  
9 term or would have understood the term "loop" to be  
10 synonymous with "circle"?

11 MR. HAMILTON: Objection.

12 Mischaracterizes the testimony.

13 THE WITNESS: Yeah, I believe  
14 the specification makes it clear cut.

15 MR. HAMILTON: For that last  
16 question, also vague. Objection.

17 Vague.

18 BY MR. STOWELL:

19 Q. Do you believe that the filament  
20 depicted in Figure 6 of the '012 patent has a loop?

21 MR. HAMILTON: Objection. Asked  
22 and answered.

23 THE WITNESS: Yes.

24 BY MR. STOWELL:

25 Q. And is there a portion of the

1 filament that's pictured in Figure 6 that you would  
2 consider to be the loop?

3 A. The loop is a central circular  
4 depiction.

5 Q. So if we look at Figure 6 and we look  
6 at the top of the figure, there are two little  
7 lines at the top there where the filament portions  
8 are parallel to each other. Would the portion of  
9 the filament that is between those two lines be the  
10 loop in your opinion?

11 MR. HAMILTON: Objection.

12 Vague. Beyond the scope.

13 THE WITNESS: If I understand  
14 your question correctly, I don't believe  
15 so. The loop is where the 360-degree  
16 completion occurs with the two ends of  
17 the filament.

18 BY MR. STOWELL:

19 Q. And on Figure 6, where do you believe  
20 that would occur?

21 A. In this figure right where they  
22 appear to be tangential. So just to the left of  
23 the lower mark that you just referenced.

24 Q. So at the top of Figure 6, there's a  
25 mark on the filament that is to the left of the

1 second mark, and you're saying that the place where  
2 the filaments are tangential is just to the left of  
3 that first mark; is that right?

4 MR. HAMILTON: Objection.

5 Vague.

6 THE WITNESS: I think it's  
7 important to note what you're seeing is,  
8 you know, one particular aspect of a  
9 loop formation that is being constricted  
10 over time. And so this is a snapshot of  
11 a particular dimension that changes as  
12 the filaments are tugged or pulled. So  
13 at this particular moment where they  
14 cross is the completion of that  
15 360-degree circuit.

16 BY MR. STOWELL:

17 Q. What are we seeing in Figure 7 of the  
18 '012 patent?

19 MR. HAMILTON: Objection.

20 Vague.

21 THE WITNESS: My understanding  
22 of this is just another embodiment that  
23 involves two loops instead of one loop.

24 BY MR. STOWELL:

25 Q. And based on your review of the '012

1 patent, are there any benefits to having two loops?

2 MR. HAMILTON: Objection.

3 Beyond the scope.

4 THE WITNESS: Only in theory.

5 BY MR. STOWELL:

6 Q. In theory, what would the benefits be  
7 for two loops?

8 MR. HAMILTON: Objection.

9 Vague. Beyond the scope.

10 THE WITNESS: The ability to  
11 apply a greater total amount of force of  
12 constriction.

13 BY MR. STOWELL:

14 Q. And how would two loops apply a  
15 greater amount of force?

16 A. Put a little bit differently, at two  
17 different points in the enclosed tubular structure.

18 Q. And so would the area of constriction  
19 increase with two loops as opposed to one loop?

20 MR. HAMILTON: Objection.

21 Vague.

22 THE WITNESS: No, not  
23 necessarily.

24 BY MR. STOWELL:

25 Q. Okay. And so when you say a greater

1 total amount of force at two different points in  
2 the enclosed tubular structure, what are you  
3 referring to?

4 A. When I say two different points, I  
5 mean axially or longitudinally along the tubular  
6 member.

7 Q. And what would be the benefit of  
8 applying a constricting force at two different  
9 points along the tubular member?

10 MR. HAMILTON: Objection.

11 Incomplete hypothetical.

12 THE WITNESS: In practice, I'm  
13 honestly not sure. In theory, under  
14 some dire high-pressure event going on  
15 inside the tubular structure, there  
16 could be an advantage, but  
17 theoretically.

18 BY MR. STOWELL:

19 Q. And you mentioned a "dire  
20 high-pressure event." What -- why did you specify  
21 a dire high-pressure event?

22 A. If you're dealing with a patient  
23 medicated with a blood thinner, with elevated blood  
24 pressure, and you're dealing with a thrombus in a  
25 high-pressure artery, that would probably be the

1 most challenging valve function case. So "dire" is  
2 probably the wrong word. But a more challenging  
3 circumstance of the pressure inside the tubular  
4 structure.

5 Q. And in that type of procedure, you  
6 could see an advantage to having two loops around  
7 the tubular member of the hemostasis valve?

8 MR. HAMILTON: Objection.

9 Incomplete hypothetical. Vague.

10 THE WITNESS: As I said, in  
11 practice, I'm not at all sure it would  
12 help. I only mention in theory. I  
13 think I could put together an equation,  
14 but theoretical.

15 BY MR. STOWELL:

16 Q. Do you ever recall any instances  
17 where you observed two filaments being used to  
18 constrict or ligate the tubular member?

19 MR. HAMILTON: Objection.

20 Vague.

21 THE WITNESS: No.

22 BY MR. STOWELL:

23 Q. Would including two looped filaments  
24 in the hemostasis valve described in the '012  
25 patent make the valve more difficult to

1 manufacture?

2 A. I could only speculate on that  
3 without seeing a particular configuration.

4 Q. So is it fair to say you don't have  
5 an opinion on whether two loops would make it more  
6 difficult to manufacture?

7 MR. HAMILTON: Objection.  
8 Mischaracterizes the testimony.  
9 Incomplete hypothetical.

10 THE WITNESS: I don't really  
11 have a strong opinion.

12 BY MR. STOWELL:

13 Q. Do you have any opinion?

14 MR. HAMILTON: Again, same  
15 objections. incomplete hypothetical;  
16 mischaracterizes the testimony.

17 THE WITNESS: When you have more  
18 components or more materials, you could  
19 argue you have more structure to deal  
20 with. By that definition, it could be  
21 incrementally more difficult, but not  
22 particularly.

23 BY MR. STOWELL:

24 Q. Do you think it would have been so  
25 much more difficult that it would have discouraged

1 a person of ordinary skill in the art from using  
2 two loops?

3 MR. HAMILTON: Objection.

4 Beyond the scope. Incomplete  
5 hypothetical.

6 THE WITNESS: No.

7 BY MR. STOWELL:

8 Q. Would using two filaments that form  
9 two loops have any advantages for the durability of  
10 the valve that you can think of based on your  
11 experience?

12 MR. HAMILTON: Objection.

13 Incomplete hypothetical. Vague.

14 THE WITNESS: No.

15 BY MR. STOWELL:

16 Q. Would having two filaments forming  
17 two loops create a redundancy in the system that  
18 could be advantageous?

19 MR. HAMILTON: Again, objection.

20 Incomplete hypothetical. Vague.

21 THE WITNESS: As I'm sure you  
22 know, redundancy in any device is an  
23 added protective feature. So in that  
24 sense, yes. But, again, theoretical in  
25 this case.

1 BY MR. STOWELL:

2 Q. Let's look at Figures 8 and 9. Are  
3 these figures that you have reviewed as part of  
4 forming your opinions in Exhibit 2008?

5 A. Yes.

6 MR. HAMILTON: Just for a quick  
7 moment, can we pause for just a second.  
8 My realtime is no longer working.

9 THE VIDEOGRAPHER: We're off the  
10 record at 11:31 a.m.

11 (Recess.)

12 THE VIDEOGRAPHER: This marks  
13 the beginning of media number 3.

14 We're on the record at  
15 11:37 a.m.

16 BY MR. STOWELL:

17 Q. Dr. Zalesky, during the break, did  
18 you review any documents?

19 A. No.

20 Q. And did you talk to anybody about the  
21 subject matter of your deposition testimony?

22 A. No.

23 Q. And do you have Figures 8 and 9 of  
24 the '012 patent in front of you still?

25 A. I do.

1 Q. And based on your review of the '012  
2 patent, what do you understand Figure 8 to depict?

3 MR. HAMILTON: Objection.  
4 Vague.

5 THE WITNESS: From the  
6 specification, these are so-called bites  
7 made from the same filamentous material  
8 in a different configuration.

9 BY MR. STOWELL:

10 Q. And do you understand that the bites  
11 in Figures 8 and 9 are interlocking?

12 A. Yes.

13 Q. And do you understand that the patent  
14 also explains that the bites could be  
15 non-interlocking?

16 A. I recall some reference to that.

17 Q. Do you want to review the reference  
18 to refresh your recollection?

19 A. Can you point me?

20 Q. Yeah. If you look at paragraph 13 --  
21 or sorry, column 13, starting at line 36.

22 A. 13, 36?

23 Q. Yeah.

24 A. Okay. Yes.

25 Q. And is that the portion of the '012

1 patent you were thinking of when you said you  
2 recalled a portion referring to non-interlocking  
3 bites?

4 A. Yes.

5 Q. Okay. In Figures 8 and 9, do you  
6 have an understanding of how these figures would  
7 change if the bites were non-interlocking?

8 MR. HAMILTON: Objection.

9 Incomplete hypothetical.

10 THE WITNESS: I don't understand  
11 the question.

12 BY MR. STOWELL:

13 Q. And what part of the question was  
14 unclear?

15 A. Just -- if you could just restate it,  
16 please.

17 Q. Do you have an understanding of how  
18 Figures 8 and 9 would change if the bites were  
19 non-interlocking?

20 MR. HAMILTON: Objection.

21 Incomplete hypothetical. Vague.

22 THE WITNESS: Without a  
23 particular representation, I believe so.

24 BY MR. STOWELL:

25 Q. And how would, for example, Figure 8

1 change if the bites were non-interlocking?

2 MR. HAMILTON: Objection.

3 Vague. Incomplete hypothetical.

4 THE WITNESS: My interpretation

5 would be they would be positioned

6 parallel and touching each other.

7 BY MR. STOWELL:

8 Q. In Figure 8, there is an area between  
9 the bites that's labeled with an arrow and the  
10 number 814.

11 Do you see that?

12 A. Yes.

13 Q. And I believe the patent refers to  
14 that as an "encircled area." Is that consistent  
15 with your understanding?

16 MR. HAMILTON: Objection. The  
17 document speaks for itself.

18 THE WITNESS: Yes.

19 BY MR. STOWELL:

20 Q. And is it your understanding that the  
21 tubular member would extend through the encircled  
22 area in the valve?

23 A. Yes.

24 Q. In the embodiment pictured in  
25 Figure 8, do you believe that the filaments would

1 circumferentially constrict a tubular member  
2 extending through the encircled area 814?

3 A. Yes. I perceive that where the bites  
4 cross, if you will, they form a circumference  
5 around the tubular member.

6 Q. If the bites were non-interlocking,  
7 would they circumferentially constrict a tubular  
8 member extending through the encircled area?

9 A. Yes. Pretty much the same answer to  
10 the -- the former question.

11 Q. There are some arrows on Figure 8:  
12 810 and 812.

13 Do you have an understanding of what  
14 those arrows reflect?

15 A. The direction of tensioning or  
16 pulling the bites.

17 (Technical interruption.)

18 THE VIDEOGRAPHER: We're off the  
19 record at 11:43 a.m.

20 (Brief pause.)

21 THE VIDEOGRAPHER: We're back on  
22 the record at 11:45 a.m.

23 BY MR. STOWELL:

24 Q. In Figure 8 of the '012 patent, do  
25 you believe that the bites would form a loop around

1 a tubular member extending through the encircled  
2 area 814?

3 MR. HAMILTON: Objection.  
4 Vague.

5 THE WITNESS: It really gets  
6 back to the definition of "loop" which  
7 we identified earlier as a complete  
8 circle. So it certainly creates an  
9 encirclement of an area. I'd have to  
10 think further about does it satisfy the  
11 loop definition.

12 BY MR. STOWELL:

13 Q. Have you formed an opinion on whether  
14 the bite embodiment shown in Figure 8 form a loop  
15 around a tubular member going through the encircled  
16 area?

17 A. I thought I just answered that.

18 Q. What was your answer?

19 A. It forms a circumference, so it does  
20 do a circumferentially constriction of an area, an  
21 enclosed area. But I'm not -- I have to think  
22 further about its consistency with our loop  
23 definition of a 360-degree circle specifically.

24 Q. So as we sit here, you don't have an  
25 opinion on whether the bite embodiments in Figure 8

1 would form a loop around a tubular member that  
2 extends through the encircled area; is that  
3 correct?

4 MR. HAMILTON: Objection.  
5 Mischaracterizes his testimony.

6 THE WITNESS: Let me say this a  
7 different way. I think, again, putting  
8 these in motion as opposed to looking at  
9 a static still shot, at some point you  
10 probably have a complete circle or a  
11 loop. But the bites, by definition, are  
12 bringing two arcs together that are then  
13 circumferentially tightening. And so as  
14 they tighten further, the shape is  
15 probably not circular. So it's an  
16 encirclement shape, but not a loop,  
17 quote/unquote.

18 BY MR. STOWELL:

19 Q. At the stage that's shown in  
20 Figure 8, would you consider the bite embodiments  
21 to form a loop?

22 A. That looks a lot look a circle to me  
23 at that particular stage.

24 Q. And earlier we defined loop to mean a  
25 circle, correct?

1 MR. HAMILTON: Objection.

2 Mischaracterizes the testimony. Beyond  
3 the scope of his opinion in his expert  
4 report.

5 THE WITNESS: Yes.

6 BY MR. STOWELL:

7 Q. If the filaments shown in Figure 8  
8 were non-interlocking but otherwise formed a  
9 similar shape encircled area, would you consider  
10 those filaments to form a loop?

11 A. It's really the same answer.

12 Q. I understand that you have opined  
13 that the filaments depicted in Figures 8 and 9 are  
14 flexible.

15 Do I understand your opinion  
16 correctly?

17 A. Yes.

18 Q. And in reaching your opinion that the  
19 filaments in Figures 8 and 9 are flexible, what  
20 have you relied on to reach that conclusion?

21 A. Both the specification and the  
22 claims -- specification including, of course, the  
23 figures and written description that produce a  
24 circumferential constriction that could only happen  
25 if the filaments were flexible.

1 Q. Is there anything about the drawings  
2 in Figures 8 and 9 that lead you to believe that  
3 the filaments are flexible?

4 A. I look at these figures, again, as  
5 like one snapshot in time. So as I envision  
6 the circumferential constriction, there's inherent  
7 flexibility to achieve that result.

8 Q. Would you agree with me that the  
9 shape of each individual bite does not change  
10 between Figures 8 and 9?

11 MR. HAMILTON: Objection.

12 Vague.

13 THE WITNESS: That's what it  
14 appears to be.

15 BY MR. STOWELL:

16 Q. And would you expect that to be the  
17 case if the filaments were flexible?

18 MR. HAMILTON: Objection.

19 Incomplete hypothetical. Vague.

20 THE WITNESS: I don't know what  
21 you're asking.

22 BY MR. STOWELL:

23 Q. If the filaments were flexible, would  
24 you expect their configuration to change between  
25 Figures 8 and 9?

1           A.           Not necessarily. But this is simply  
2 an embodiment figure, not to scale. No reason to  
3 go either way.

4           Q.           Is it fair to say that simply  
5 reviewing Figures 8 and 9 would not tell you  
6 whether the filaments are flexible?

7                       MR. HAMILTON: Objection.

8           Vague. Mischaracterizes the testimony.

9                       THE WITNESS: In the context of  
10 this patent, flexibility is essential.

11 BY MR. STOWELL:

12          Q.           Right. But looking at Figures 8  
13 and 9, is there anything in the figures that  
14 demonstrate to you that the filaments must be  
15 flexible?

16                      MR. HAMILTON: Objection. Asked  
17 and answered. Vague. Incomplete  
18 hypothetical.

19                      THE WITNESS: As I said, this is  
20 one photo in time. As I envision the  
21 actual dynamic, the figures connote an  
22 inherent flexibility. That's my  
23 interpretation.

24 BY MR. STOWELL:

25          Q.           And what about the figures, what

1 specific feature connotes an inherent flexibility?

2 MR. HAMILTON: Objection. Asked  
3 and answered.

4 THE WITNESS: The fact that they  
5 are going to accommodate the outside  
6 dimension of the enclosed tubular  
7 structure.

8 BY MR. STOWELL:

9 Q. And so are you identifying the arc of  
10 the bite as indicating flexibility?

11 MR. HAMILTON: Objection.  
12 Mischaracterizes the testimony.

13 THE WITNESS: Yes. Sort of. In  
14 a sense that that bite is going to  
15 change its geometry as it accommodates  
16 and circumferentially constricts around  
17 the tubular member.

18 BY MR. STOWELL:

19 Q. And so in Figure 9 we agree that the  
20 geometry of the bite has not changed from Figure 8,  
21 correct?

22 MR. HAMILTON: Objection.  
23 Vague.

24 THE WITNESS: That's what it  
25 appears to be, even though the

1 dimensions are different.

2 BY MR. STOWELL:

3 Q. In an actual device using the  
4 embodiments or the bites in Figures 8 and 9, would  
5 you anticipate Figure 9 to -- or would you  
6 anticipate that the bites in Figure 9 would look  
7 different?

8 MR. HAMILTON: Objection.

9 Incomplete hypothetical. Vague.

10 THE WITNESS: I don't know what  
11 you mean by "would look different."  
12 What would look different?

13 BY MR. STOWELL:

14 Q. Would their geometry be different?

15 A. Would the geometry of the bites be  
16 different --

17 Q. Yes.

18 A. -- because they're in parallel as  
19 opposed to interlocked?

20 Q. No. If this device were used in an  
21 actual valve, would you expect the geometry of the  
22 bites to change between the configuration in  
23 Figure 8 and the configuration in Figure 9?

24 MR. HAMILTON: Objection.

25 Incomplete hypothetical.

1                   THE WITNESS: The radius of  
2                   curvature of the arc of the bites would  
3                   change as the circumferential  
4                   constriction occurs, and that  
5                   necessitates flexibility because  
6                   otherwise the radius of curvature could  
7                   not change.

8 BY MR. STOWELL:

9                   Q.           And you'll agree with me that in  
10                  Figures 8 and 9 the radius of curvature of the bite  
11                  does not change, correct?

12                 A.           These don't depict the actual  
13                  constriction mechanism, so that doesn't make sense  
14                  what you just said. This is just showing one  
15                  particular snapshot of a space in time.

16                 Q.           And in these two snapshots in  
17                  Figures 8 and 9, the radius of curvature of the  
18                  bites is the same, correct?

19                 A.           Because they're not to scale, I can't  
20                  opine on that.

21                 Q.           As we sit here, do you recognize any  
22                  differences in the radius of curvature?

23                 A.           It appears to have a smaller radius  
24                  of curvature in Figure 9 than Figure 8. But since  
25                  they're not to scale, that's speculation.

1 Q. Are there any portions of the  
2 specification that you have relied on for your  
3 opinion that the radius of curvature of the bites  
4 would change as the device constricts the tube?

5 MR. HAMILTON: Objection.

6 Vague.

7 THE WITNESS: The key term used  
8 both in the description or spec in the  
9 claims is there's circumferential  
10 constriction, which implies a reduction  
11 in radius as the constriction dynamic  
12 occurs.

13 BY MR. STOWELL:

14 Q. And so you're relying on the term  
15 "circumferentially constrict" for your  
16 understanding that the radius of curvature of the  
17 bites would change as the device constricts the  
18 tube; is that correct?

19 MR. HAMILTON: Objection.

20 Vague. Asked and answered.

21 THE WITNESS: Those -- those two  
22 words are certainly a driver, in  
23 conjunction with the use of a filament  
24 and the necessary properties of a  
25 filament or filaments.

1 BY MR. STOWELL:

2 Q. If we look at column 14 of the '012  
3 patent -- let me know when you're there.

4 A. Okay.

5 Q. I'm going to read from line 6 where  
6 it says, quote: "The filaments 150 forming the  
7 bites 800 can each apply an arcuate line or narrow  
8 longitudinal zone of pressure to the elongate  
9 member 132."

10 Do you see where I'm at?

11 A. Yes.

12 Q. Okay. And do you have an  
13 understanding of what it means when it says, the  
14 bites can each apply an arcuate line?

15 A. Yes.

16 Q. What does that mean?

17 A. For lack of a better term, "arcuate"  
18 connotes a more diffuse zone of pressure compared  
19 to a line of pressure.

20 Q. And so does that indicate that the  
21 pressure is applied around the arc of the bite?

22 MR. HAMILTON: Objection.

23 Vague.

24 THE WITNESS: That's what this  
25 sentence suggests.

1 BY MR. STOWELL:

2 Q. Now, it also says that the bites can  
3 each apply a "narrow longitudinal zone of  
4 pressure." Do you have an understanding of what  
5 that means?

6 A. My interpretation of that is a more  
7 focused zone of pressure.

8 Q. And so if we flip back to Figure 8,  
9 can you explain how the embodiment in Figure 8  
10 would provide a narrow longitudinal zone of  
11 pressure?

12 MR. HAMILTON: Objection.

13 Vague.

14 THE WITNESS: I'm not the  
15 attorney here, but that seems to be out  
16 of the scope of my opinion.

17 BY MR. STOWELL:

18 Q. Have you considered that portion of  
19 the '012 patent in forming your opinions in your  
20 declaration, Exhibit 2008?

21 A. I didn't pay particular attention to  
22 those two different potential properties, no.

23 Q. And as we sit here today, are you  
24 able to explain to me how Figure 8 would apply --  
25 how the embodiment in Figure 8 would apply a narrow

1 longitudinal zone of pressure to the elongate  
2 member?

3 MR. HAMILTON: Objection. Asked  
4 and answered.

5 THE WITNESS: I can't know what  
6 the authors had in mind here, but  
7 certainly I could envision a  
8 non-circular tubular member inside the  
9 constricting space such that as the  
10 circumferential tightening or  
11 constricting is occurring, there's an  
12 increased pressure at one particular  
13 locus because of the non-circular  
14 geometry of the tubular structure. But  
15 I'm speculating. I don't know what --  
16 if that's exactly what they had in mind.

17 BY MR. STOWELL:

18 Q. Do you believe that the bite could  
19 apply a narrow longitudinal zone of pressure to the  
20 elongate member if the device inserted through the  
21 valve was circular?

22 MR. HAMILTON: Objection. The  
23 document speaks for itself. Vague.  
24 Beyond the scope.

25 THE WITNESS: I don't believe

1           so.

2       BY MR. STOWELL:

3           Q.       So it's your interpretation of this  
4 phrase, "narrow longitudinal zone of pressure" that  
5 that would only apply to instruments inserted  
6 through the valve that are non-circular?

7                       MR. HAMILTON:  Objection.

8           Vague.  Beyond the scope.  Incomplete  
9 hypothetical.

10                      THE WITNESS:  I'm speculating on  
11 that, without really having considered  
12 this in great detail.

13       BY MR. STOWELL:

14           Q.       Is it fair to say you don't have an  
15 opinion on that?

16           A.       That's probably the right answer.

17           Q.       Okay.  Would you agree that the '012  
18 patent explains that the filaments can have a  
19 variety of cross-sectional shapes?

20           A.       Can you point me to a reference?

21           Q.       Column 14 describes the filament, or  
22 it's at least one area that describes the filament,  
23 so that may be a good place to start.  Column 14 at  
24 line 6.

25           A.       Yes.

1 Q. Okay. And so we agree that a  
2 filament, as that term is used in the '012 patent,  
3 could have a rectangular cross-section, correct?

4 A. Between lines 30 and 35, that's what  
5 he has written.

6 Q. If you could turn to column 9 of the  
7 '012 patent.

8 Around line 13, the patent explains  
9 that the filament can be made from a variety of  
10 materials, including, for example, a polymer, a  
11 synthetic, and/or a metal.

12 Do you see where I'm at?

13 A. Yes.

14 Q. And what, if any, role did that  
15 description of the materials play in your  
16 understanding that the filaments disclosed in the  
17 '012 patent are flexible?

18 MR. HAMILTON: Objection. Asked  
19 and answered.

20 THE WITNESS: Again, in the  
21 context of the patent material and the  
22 indication for use, the simple  
23 implication was, no matter the material  
24 used for the construction, either the  
25 processing or the application of that

1 particular material would result in a  
2 small cross-section, very flexible  
3 filament.

4 BY MR. STOWELL:

5 Q. And so is it your opinion that a  
6 polymer can be flexible?

7 A. Yes. There certainly are flexible  
8 polymers.

9 Q. And it also mentions a synthetic. Do  
10 you have an understanding of what it means by  
11 "synthetic"?

12 A. As in a synthesized material, an  
13 artificial material.

14 Q. And would a synthetic differ from a  
15 polymer?

16 A. It could include a polymer.

17 Q. Could a synthetic include other types  
18 of materials?

19 A. Yes. In addition to polymer, yes.

20 Q. Okay. What other types of materials  
21 would be encompassed within a synthetic?

22 A. There could be some small amount of a  
23 metal strand or a carbon strand or some other  
24 material.

25 Q. And is it your opinion that a

1 synthetic could be flexible?

2 A. Yes.

3 Q. Lastly, it identifies a metal. Is it  
4 your opinion that a metal could be flexible?

5 A. In very specialized configurations,  
6 yes.

7 Q. And when you say "specialized  
8 configurations," what do you mean?

9 A. In the form of, for example, an  
10 incredibly small cross-sectional soft metal wire --  
11 keyword being "soft" -- to enable flexibility, or  
12 in a braided or entwined configuration of fibrils,  
13 metal fibrils.

14 Q. Earlier you had testified that it was  
15 your opinion that a polymer could be flexible.  
16 Would the polymer need to have a specialized  
17 configuration to be flexible?

18 A. It would have to be generally small,  
19 but the more important credential would be its  
20 constitution.

21 Q. And when you say "constitution," what  
22 do you mean?

23 A. Is it a high-density polymer, for  
24 instance, or a low-density polymer? To reduce  
25 stiffness, lower is better. Or I should say for

1 increased flexibility.

2 Q. The section goes on to describe some  
3 specific materials. One of those is stainless  
4 steel. Do you consider stainless steel to be a  
5 soft metal?

6 A. The two words that come to mind are  
7 "context" and "configuration." So in general,  
8 stainless steel, we've all observed -- "we" being  
9 POSITAs -- as a semi-rigid or rigid material in its  
10 normal configuration of sheets or struts or similar  
11 things.

12 It's -- it's technically possible to  
13 take a stainless steel in an extremely small  
14 cross-sectional diameter, possibly doped with some  
15 other materials, to give it flexibility.

16 Q. Do you believe that the filaments  
17 illustrated in Figures 8 and 9 would be flexible if  
18 they were made of stainless steel?

19 MR. HAMILTON: Objection.

20 Incomplete hypothetical.

21 THE WITNESS: As I just answered  
22 on the last question, under special  
23 circumstances of constitution and  
24 configuration, yes, they could be.

25 BY MR. STOWELL:

1 Q. Would the circumstances of  
2 constitution and configuration for making stainless  
3 steel flexible have been something that was known  
4 to a POSITA before September 2017?

5 A. I'm speculating, but, yes, I would  
6 think so.

7 Q. The patent also mentions nitinol. Do  
8 you understand nitinol to be a soft metal?

9 A. I think that's a decent  
10 categorization.

11 Q. And do you believe that if the  
12 embodiments in Figures 8 and 9 of the '012 patent  
13 were made of nitinol that they would be flexible?

14 MR. HAMILTON: Objection.

15 Incomplete hypothetical.

16 THE WITNESS: Analogous to the  
17 previous question and answer. There are  
18 different grades of nitinol, most of  
19 which are very temperature sensitive.  
20 So given the right constitution at the  
21 right cross-sectional configuration and  
22 the right temperature, yes.

23 BY MR. STOWELL:

24 Q. At the bottom of the paragraph that  
25 we're looking at, it says, In some embodiments, the

1 filament can comprise one or several threads,  
2 lines, cords, rope, ribbon, flat wire, sheet, or  
3 tape, end quote.

4 Do you see where I am?

5 A. Yes.

6 Q. Okay. And do you agree that any one  
7 of those items listed there could form a filament?

8 MR. HAMILTON: Objection.

9 Vague.

10 THE WITNESS: I struggle with  
11 ribbon and sheet. But, again, via what  
12 I said just a minute ago, given some  
13 unusual construction and a very, very  
14 small cross-sectional configuration, I  
15 think it's conceivable.

16 BY MR. STOWELL:

17 Q. When you say you struggle with  
18 ribbon, why do you struggle with that term?

19 A. The configurations I've seen in that,  
20 you know, metal or other material have not been  
21 very flexible. They would -- they would take a  
22 form, if you will, meaning that if I bend it, it  
23 won't go back to its original form.

24 Q. If you can bend it, doesn't that  
25 indicate, though, that it's flexible?

1 MR. HAMILTON: Objection.

2 Vague.

3 THE WITNESS: "Flexible" is a  
4 very relative term. I think the key to  
5 flexible with regard to the '012 patent  
6 is the context where it's flexibility  
7 around a relatively small dimension  
8 tubular element.

9 BY MR. STOWELL:

10 Q. And when you're using the term  
11 "flexible" in rendering your opinions on the '012  
12 patent, what -- what definition of that term are  
13 you using?

14 MR. HAMILTON: Objection.

15 Vague.

16 THE WITNESS: In general, the  
17 ability to accommodate the external  
18 surface of a small structure.

19 BY MR. STOWELL:

20 Q. And when you say "accommodate the  
21 external surface of a small structure," what do you  
22 mean?

23 MR. HAMILTON: Objection.

24 Vague.

25 THE WITNESS: To achieve the

1 main driver that we've discussed of this  
2 patent, which is a circumferential  
3 constriction -- the keyword being  
4 "circumferential" -- the accommodation  
5 would be the adaptation of a flexible  
6 element or filament to that curved  
7 surface.

8 BY MR. STOWELL:

9 Q. And is it your opinion that a rigid  
10 filament could not conform to a tubular body?

11 A. Again, in -- you know, "rigid" is a  
12 relative term, but a rigid compared to flexible  
13 would not accommodate, or would not accommodate  
14 well.

15 Q. But it could accommodate at least a  
16 little, correct?

17 MR. HAMILTON: Objection.

18 Vague.

19 THE WITNESS. Yeah. I'm just  
20 not sure what that means, "a little."

21 BY MR. STOWELL:

22 Q. You said it "would not accommodate  
23 well." And what do you mean by "would not  
24 accommodate well"?

25 A. Adapting or coopting to a

1 three-dimensional curved or multi-geometry element.

2 Q. You also indicated that you had some  
3 issues with the term "sheet" in that portion of  
4 column 9 that we looked at. Why do you struggle  
5 with the word "sheet"?

6 MR. HAMILTON: Objection.  
7 Mischaracterizes the testimony.

8 THE WITNESS: As a POSITA with  
9 medical device experience, I've not seen  
10 metal sheets utilized in required  
11 flexible medical products.

12 BY MR. STOWELL:

13 Q. When you were rendering your opinions  
14 that are set forth in Exhibit 2008, did you do so  
15 with the understanding that ribbons and sheets  
16 could form flexible filaments?

17 MR. HAMILTON: Objection.  
18 Vague.

19 THE WITNESS: With the  
20 restrictions that I previously limited,  
21 yes.

22 BY MR. STOWELL:

23 Q. In that statement at the bottom of  
24 the paragraph we're looking at in the column lines  
25 9 to 22, are there any examples there that you

1 would cancel out or strike from the list of  
2 materials that can be a filament?

3 MR. HAMILTON: Objection.

4 Vague.

5 THE WITNESS: No.

6 BY MR. STOWELL:

7 Q. And just looking back at Figures 8  
8 and 9, we had talked about the arrows 810 and 812.  
9 Do you see those?

10 A. Yes.

11 Q. And is your -- is it your  
12 understanding that the bites, when tension is  
13 applied to them, will move in the direction of the  
14 arrows?

15 A. Yes.

16 Q. And so, for example, subfilament  
17 150-B in Figure 8 would move in the direction of  
18 arrow 810?

19 A. Yes.

20 MR. STOWELL: So we're going to  
21 transition. Do you want to break for lunch? It's  
22 about 12:20.

23 MR. HAMILTON: That sounds good.

24 THE WITNESS: Sure.

25 MR. STOWELL: Okay. Why don't

1 we break.

2 THE VIDEOGRAPHER: We're off the  
3 record at 12:18 p.m.

4 (Lunch recess.)

5 THE VIDEOGRAPHER: This marks  
6 the beginning of media number 4. We're  
7 on the record at 12:50 p.m.

8 BY MR. STOWELL:

9 Q. Welcome back, Dr. Zalesky. Did you  
10 review any documents during the lunch break?

11 A. No.

12 Q. And did you speak with anybody about  
13 the subject matter of your testimony during the  
14 break?

15 A. No.

16 Q. Okay. I'm going to hand you what has  
17 been previously marked as Exhibit 1005 in this IPR.

18 (Exhibit No. 1005 was  
19 previously marked for  
20 identification.)

21 BY MR. STOWELL:

22 Q. Dr. Zalesky, do you recognize  
23 Exhibit 1005?

24 A. Yes.

25 Q. And what is Exhibit 1005?

1 A. A copy of the Schaffer patent.

2 Q. Okay. And do you recognize this as  
3 one of the prior art references that Petitioner has  
4 relied upon in its petition?

5 A. Yes.

6 Q. Okay. And is this a prior art  
7 reference that you considered in forming the  
8 opinions that are in Exhibit 2008?

9 A. Yes.

10 Q. Okay. And when was the last time you  
11 reviewed the Schaffer reference?

12 A. Only sporadically yesterday, not in  
13 any kind of detail.

14 Q. Okay. And prior to yesterday, had  
15 you reviewed the Schaffer reference?

16 A. I had but it's been some weeks since  
17 I really scrutinized it.

18 Q. There are some inventors listed on  
19 the front of the Schaffer patent. Are you familiar  
20 with any of those individuals?

21 A. No.

22 Q. And the assignee of this patent was  
23 MedAmicus, Inc.

24 Are you -- were you familiar with  
25 that company?

1 A. I'm not. Was not.

2 Q. Okay. And if we refer to this patent  
3 as the Schaffer patent, is that okay for today?

4 A. Yes.

5 Q. You'll understand what patent I'm  
6 referring to?

7 A. Yes.

8 Q. Okay. I'm also going to provide you  
9 with what has been previously marked as  
10 Exhibit 1008 in this IPR.

11 (Exhibit No. 1008 was  
12 previously marked for  
13 identification.)

14 BY MR. STOWELL:

15 Q. Dr. Zalesky, do you recognize  
16 Exhibit 1008?

17 A. I do. I do. I'm not sure what title  
18 it has, but I do recognize it.

19 Q. Okay. Is this a document that you  
20 reviewed in forming your opinions?

21 A. Yes.

22 Q. And do you understand this to be the  
23 figures from the Schaffer patent publication?

24 A. Yes.

25 MR. HAMILTON: Objection.

1 Mischaracterizes the testimony. Vague.

2 BY MR. STOWELL:

3 Q. Okay. And so as I ask you questions  
4 about Schaffer, you're welcome to refer to  
5 Exhibit 1008 if necessary.

6 In this IPR, Petitioner has focused  
7 on Figures 30 through 34 of Schaffer. Have you  
8 reviewed those figures in detail?

9 A. Yes.

10 Q. Okay. And based on your review of  
11 Schaffer, do you understand how the valve in  
12 Figures 30 through 34 operates?

13 A. Yes.

14 Q. And how does -- how is the valve  
15 operated?

16 MR. HAMILTON: Objection.

17 Vague.

18 THE WITNESS: On either side of  
19 the enclosed tubular element is a  
20 hemicylindrical, or half moon, if you  
21 will, rigid structure on either side,  
22 not opposing but staggered. In other,  
23 words side by side.

24 When -- when they are actuated  
25 to press down on the enclosed structure,

1           they create what I would call a pinching  
2           closure effect. And integral to that is  
3           a seal member surrounding the tubular  
4           structure that has compliance properties  
5           that augment the pinching effect.

6       BY MR. STOWELL:

7           Q.           And what is your understanding of the  
8           purpose of the Schaffer valve?

9                       MR. HAMILTON: Objection.  
10           Vague.

11                      THE WITNESS: Its indication for  
12           use is as a hemostasis valve, so the  
13           intention is to occlude an enclosed  
14           structure to prevent back bleed or back  
15           fluid flow or gas flow.

16       BY MR. STOWELL:

17           Q.           And is it your opinion that  
18           Schaffer's valve will seal perfectly regardless of  
19           the diameter of the device that's inserted through  
20           the valve?

21                      MR. HAMILTON: Objection.  
22           Incomplete hypothetical.

23                      THE WITNESS: That wasn't really  
24           part of my assignment and I certainly  
25           wouldn't say perfectly.

1 BY MR. STOWELL:

2 Q. If the device that's inserted through  
3 the valve is much smaller than Schaffer's valve, do  
4 you have an opinion on whether Schaffer's valve  
5 would seal perfectly?

6 A. I have no opinion but, again, I'd be  
7 reluctant to say perfectly.

8 Q. Why would you be reluctant to say  
9 perfectly?

10 A. It connotes that without exception  
11 there's complete closure of any gas or fluid flow.

12 Q. And so can you envision scenarios  
13 where Schaffer's valve would not result in complete  
14 closure to gas or fluid flow?

15 MR. HAMILTON: Objection.

16 Incomplete hypothetical.

17 THE WITNESS: I don't have any  
18 specific scenarios in mind. I'm just  
19 talking about the practicality of  
20 materials, and so certain instruments  
21 and catheters are not uniform. Even  
22 though they look like they might be,  
23 they're not.

24 So it's another way of saying  
25 it's not so much a function of the valve

1 as it is the underlying structure or  
2 deformities, of sorts.

3 BY MR. STOWELL:

4 Q. In your experience working with  
5 hemostasis valves, did you encounter situations  
6 where the instruments inserted through the valve  
7 were not uniform, and that resulted in less than a  
8 perfect seal?

9 MR. HAMILTON: Objection.  
10 Incomplete hypothetical.

11 THE WITNESS: My experience is  
12 almost exclusively with Touhy Borst, and  
13 oftentimes out of roundness is a  
14 characteristic we use often with  
15 catheters and disposable devices that,  
16 on paper, they appear to be completely  
17 round, but, in reality, either because  
18 of extrusion variations or other  
19 fabrication variations, they're slightly  
20 elliptical or otherwise not quite round.  
21 And so they presented a particular  
22 challenge to get a complete seal with  
23 the Tuohy Borst.

24 BY MR. STOWELL:

25 Q. And what would the result be if they

1 didn't provide a complete seal, the Tuohy Borst  
2 valves?

3 A. Well, leakage.

4 Q. Would you anticipate with Schaffer's  
5 valve that if an out-of-round instrument was  
6 inserted through the valve that there could be some  
7 leakage?

8 MR. HAMILTON: Objection.  
9 Incomplete hypothetical.

10 THE WITNESS: Yeah, I really  
11 don't have an opinion on that. I'd have  
12 to touch and feel and test it.

13 BY MR. STOWELL:

14 Q. Okay. So you haven't -- as part of  
15 your forming your opinions in this case, you  
16 haven't considered whether the Schaffer valve would  
17 leak with an out-of-round device inserted through  
18 it; is that correct?

19 MR. HAMILTON: Objection.  
20 Incomplete hypothetical.  
21 Mischaracterizes the testimony.

22 THE WITNESS: Correct. I have  
23 not.

24 BY MR. STOWELL:

25 Q. And as part of forming your opinions

1 in this case, have you considered whether the size  
2 of the instrument inserted through Schaffer's valve  
3 would or could result in leakage?

4 MR. HAMILTON: Objection.  
5 Incomplete hypothetical.

6 THE WITNESS: Indirectly. In  
7 particular -- I mean, we can go to my  
8 supplemental declaration if that makes  
9 sense. But I recall very specifically  
10 looking at a configuration of more than  
11 one instrument inside of a tubular  
12 structure presented a challenge to  
13 complete closure.

14 BY MR. STOWELL:

15 Q. And I'm focused more right now on the  
16 size or, let's say, the diameter of the instrument  
17 inserted through the valve. Did you form any  
18 opinions on how the diameter of the instrument  
19 inserted through Schaffer's valve would impact the  
20 seal created by the valve?

21 MR. HAMILTON: Objection.  
22 Incomplete hypothetical.

23 THE WITNESS: Not explicitly,  
24 no.

25 BY MR. STOWELL:

1 Q. I understand from your prior  
2 deposition that you have experience working with  
3 hemostasis valves, correct?

4 A. Yes.

5 Q. Earlier we had looked at the period  
6 of 1995 to 2005 as a period of your career where  
7 you had a lot of experience with catheters. During  
8 that time period, would you say you also had a lot  
9 of experience using hemostasis valves?

10 A. During that period and significantly  
11 prior to that period, in particularly, the Tuohy  
12 Borst.

13 Q. And did you ever have any experience  
14 designing a hemostasis valve?

15 A. I didn't specifically design a  
16 hemostasis valve such as a Tuohy Borst from  
17 scratch. But on occasion, we would modify the  
18 Tuohy Borst dimensions to accommodate a different  
19 configuration of a catheter and a disposable  
20 device.

21 Q. And when you say "modify the Tuohy  
22 Borst dimensions," what dimensions are you  
23 referring to?

24 A. Primarily length and lumen size.

25 Q. And why would you need to modify the

1 length of the valve?

2 A. There could be some devices that were  
3 not uniform axially or longitudinally. And so one  
4 aspect would be larger, if you will, on the OD than  
5 another aspect.

6 Q. And why would you need to modify the  
7 lumen size of the Tuohy Borst valves?

8 A. For that same reason.

9 Q. And when you're talking about these  
10 modifications you made, what time period are you  
11 talking about?

12 A. Between 1987 and probably the early  
13 2000s.

14 Q. And the modifications you made to the  
15 valves, were you using techniques to modify those  
16 valves that would have been available to a person  
17 of ordinary skill in the art at the time?

18 MR. HAMILTON: Objection.

19 Vague.

20 THE WITNESS: Yes. In general,  
21 it was simple machining.

22 BY MR. STOWELL:

23 Q. And so when you modified the  
24 dimensions of the valve to have -- to change the  
25 lumen size, what specifically would you do to the

1 valve; what modifications would you make?

2 A. Using the equivalent of a drill  
3 press, some coring of a certain portion of the  
4 length of the Tuohy Borst.

5 Q. And were you typically, in these  
6 situations, modifying the valve to have a larger  
7 lumen size?

8 A. I would say in all cases it was a  
9 matter of taking a commercially available Tuohy  
10 Borst and increasing the lumen size at least in  
11 some portion.

12 Q. And other than using a drill press to  
13 core a portion of the valve, were there any other  
14 modifications you would need to make to the valve?

15 A. Not that come to mind, no.

16 Q. And was the process of modifying  
17 existing valves to have larger lumens, is that  
18 something that was commonly done in the medical  
19 device industry?

20 A. Commonly done for experimentation  
21 purposes primarily. In other words, preclinical,  
22 which includes bench and animal; and clinical,  
23 which is controlled patient studies, not for  
24 general commercialization.

25 Q. And when you were modifying the

1 valves to increase the lumen size, how did you  
2 determine how large the lumen needed to be?

3 A. Simply measuring the dimensions of  
4 the device that we needed to seal around.

5 Q. And so is it common in using  
6 hemostasis valves to select a valve where the lumen  
7 of the valve approximates the outer diameter of the  
8 device that's going through it?

9 A. That's a fair statement. There,  
10 obviously, has to be some tolerance to allow a  
11 smooth advance and withdrawal of the catheter or  
12 device. But, in general, there's a matching  
13 process.

14 Q. Do you have an opinion on whether  
15 Schaffer's valve will seal perfectly regardless of  
16 the shape of the device that's being inserted  
17 through the valve?

18 MR. HAMILTON: Objection.

19 Incomplete hypothetical.

20 THE WITNESS: Well, first of  
21 all, perfectly, as I've said earlier, I  
22 don't think applies without hands-on  
23 experience. But I didn't opine on that  
24 particular issue.

25 BY MR. STOWELL:

1 Q. Let's turn to paragraph 77 of the  
2 Schaffer reference, which is on page 6 of Schaffer.

3 A. I'm not there. Where are you?

4 Page --

5 Q. Paragraph 77.

6 A. -- 26?

7 Q. Yeah. If you're looking at the pages  
8 at the bottom, yes. Sorry about the confusion.

9 A. Okay.

10 Q. And do you see paragraph 77?

11 A. Yes.

12 Q. And so paragraph 77 in the second  
13 line refers to "in one option." When the Schaffer  
14 patent refers to "in one option," how do you  
15 understand that term?

16 A. One of several potential embodiments.

17 Q. If we look at the next column over  
18 for paragraph 77, there's a sentence that uses the  
19 term "forcibly disengage," and I know you've relied  
20 on this in your report. What was your  
21 understanding of the meaning of the term "forcibly  
22 disengage"?

23 A. Because of the mechanical  
24 configuration with effectively rigid components,  
25 there's an actuation force of release from the

1 constriction.

2 Q. And what do you mean by "an actuation  
3 force of release"?

4 A. A spring created force to bring the  
5 constricting elements away from the tubular  
6 structure.

7 Q. And so do you -- did you understand  
8 the term "forcibly disengaged" to mean "an  
9 actuation force of release"?

10 MR. HAMILTON: Objection. Asked  
11 and answered.

12 THE WITNESS: Yes.

13 BY MR. STOWELL:

14 Q. In Schaffer's valve, when the buttons  
15 are undepressed, would you describe the U-shaped  
16 actuating members as being forcibly engaged with  
17 the tubular member?

18 MR. HAMILTON: Objection.  
19 Incomplete hypothetical.

20 THE WITNESS: There is a  
21 spring-created compressive force bearing  
22 in the direction of the tubular member.

23 BY MR. STOWELL:

24 Q. And would you describe that  
25 spring-created compressive force as meaning that

1 the U-shaped actuating members are forcibly engaged  
2 with the tubular member?

3 MR. HAMILTON: Objection.

4 Vague. Asked and answered.

5 THE WITNESS: I'm unsure about  
6 the use of the word "engaged." There's  
7 creation of a compressive force by those  
8 members from the spring force.

9 BY MR. STOWELL:

10 Q. And do you not understand what the  
11 term "engaged" means?

12 MR. HAMILTON: Objection.

13 Vague. Beyond the scope.

14 THE WITNESS: It can mean  
15 different things. It could include in  
16 contact with the tubular structure.

17 BY MR. STOWELL:

18 Q. In the term "forcibly disengage,"  
19 what did you understand the term "disengage" to  
20 mean in that phrase that's in paragraph 77 of  
21 Schaffer?

22 MR. HAMILTON: Objection. Asked  
23 and answered.

24 THE WITNESS: To pull the  
25 compressive elements away from the

1 surface of the tubular structure.

2 BY MR. STOWELL:

3 Q. Did you understand "disengage" to  
4 mean that the U-shaped actuating members were not  
5 in contact with the actuating member?

6 A. If they're -- if they're being  
7 disengaged, they must have been engaged.

8 Q. Right. But when the actuating  
9 members are forcibly disengaged, do you understand  
10 that to mean that the actuating members are no  
11 longer in contact with the tubular member?

12 MR. HAMILTON: Objection. Asked  
13 and answered.

14 THE WITNESS: That was my  
15 interpretation.

16 BY MR. STOWELL:

17 Q. Okay. And so if "engaged" means in  
18 contact with the tubular member, do you understand  
19 that when the buttons are undepressed, the U-shape  
20 actuating members would forcibly engage the tubular  
21 member?

22 MR. HAMILTON: Objection.  
23 Vague.

24 THE WITNESS: I think that's  
25 reasonable to say that.

1 BY MR. STOWELL:

2 Q. When you reached your conclusion that  
3 "forcibly disengage" means that the U-shaped  
4 actuating members are not in contact with the seal  
5 module, what portions of the specification or  
6 figures were you relying on?

7 A. I would honestly have to go back  
8 through all these, but several of the figures -- my  
9 understanding of what was -- what was being shown  
10 in the figures in particular. And imagine, again,  
11 it's a snapshot in time, analogous to what we  
12 talked about earlier with respect to the '012,  
13 knowing that there's a dynamic involved in  
14 compression and release.

15 Q. If we look at Figures 30 to 34,  
16 specifically, are -- do you believe any of those  
17 figures illustrate the U-shaped actuating members  
18 being forcibly disengaged from the seal module?

19 A. I think Figure 34 comes the closest  
20 to that. And, in particular, comparing it to an  
21 earlier figure, such as 32, going from closure to  
22 opening, suggests that a forcible disengagement has  
23 occurred.

24 Q. And so earlier you had explained  
25 disengagement as being the U-shaped actuating

1 members being out of contact with the seal module.

2 Do you believe that that's shown in Figure 34?

3 A. This is a really ugly figure, but  
4 it's not clear.

5 Q. What if you look at Exhibit 1008,  
6 which has the cleaner image of Figure 34, does that  
7 help you at all answer the question?

8 A. I'm sorry. Which figure?

9 Q. Figure 34.

10 A. As depicted here, the compressive  
11 elements appear to be in contact, but I don't know  
12 that that means this is a complete retraction of  
13 those elements. This could be partly, not  
14 completely.

15 Q. So you believe Figure 34 may only  
16 reflect a partial compression of the buttons and  
17 springs; is that correct?

18 A. Correct.

19 Q. And do you have any basis or any  
20 references in the specification that lead you to  
21 believe that the -- that Figure 34 can be a partial  
22 compression?

23 A. I'd have to re-review the written  
24 description to find a particular clause or sentence  
25 that speaks to that. But from my vantage point, as

1 I mentioned earlier, the figures in particular  
2 suggest a dynamic range, if you will. It's not  
3 simply on or off.

4 Q. Does the lumen of the seal module in  
5 Figure 34 appear to be fully open?

6 A. Hard to know. If you assume that the  
7 rightmost portion of that is a totally relaxed  
8 lumen, then, yes. But that's an assumption.

9 Q. And I think you had indicated that  
10 you thought Figure 34 would be the closest figure  
11 among Figures 30 to 34 to showing the forcibly  
12 disengaged element, correct?

13 A. I think that's correct. You could  
14 argue that Figure 33 shows a potentially partial  
15 disengagement. But it's hard to tell from the  
16 figure.

17 Q. In the Schaffer reference, back in  
18 paragraph 77 -- let me know when you get there.

19 A. Okay.

20 Q. The very last sentence of  
21 paragraph 77 explains that the lumen of the third  
22 seal member 165 is able to retract in an unsealed  
23 configuration.

24 Do you see where I'm at?

25 A. No. Where are you?

1 Q. So the last sentence in paragraph 77.

2 A. Oh, top right?

3 Q. Top right, correct.

4 A. Okay. Say again.

5 Q. It -- that sentence ends, "The lumen  
6 193 of the first seal member 165 is able to retract  
7 to an unsealed configuration."

8 Do you see that?

9 A. Yes.

10 Q. Okay. And do you understand the  
11 mechanism of action for the seal member to be able  
12 to retract to an unsealed configuration?

13 A. I believe it's a characteristic of  
14 that seal member that essentially restores the  
15 lumen as it expands.

16 Q. And so is it your understanding that  
17 the properties of the seal member permit it to  
18 retract to its unsealed configuration?

19 A. Yes. In essence, it's a resilience  
20 of the seal member.

21 Q. If we turn to page 27 of Schaffer,  
22 paragraph 82, the paragraph starts that, "The  
23 stasis valve, in one option, is made from  
24 preexisting amounts of metals and/or plastics."

25 Do you see where I'm at?

1           A.       Yes.

2           Q.       And then it continues that, "The  
3    actuating member and the actuating button, in one  
4    example, is machined from aluminum and, in another  
5    example, it can be machined from plastics."

6                    Do you see that?

7           A.       Yes.

8           Q.       Okay. And so as a person of ordinary  
9    skill in the art, in 2017, what other methods of  
10   making the actuating members would a person have  
11   been aware of?

12          A.       Certainly different molding --  
13                    MR. HAMILTON: Hold on one  
14    second.

15                    Objection. Vague. Beyond the  
16    scope.

17                    THE WITNESS: There are other  
18    molding operations that could be  
19    utilized.

20   BY MR. STOWELL:

21          Q.       Any other methods of making the  
22    actuating members that you think a POSITA would  
23    have known of in 2017?

24                    MR. HAMILTON: Same objections.  
25    Vague. Beyond the scope.

1                   THE WITNESS: I'm most familiar  
2                   with machining and with molding, so it's  
3                   hard to imagine a number of different  
4                   options.

5 BY MR. STOWELL:

6                   Q.           Do you think that the actuating  
7 members could have been drawn?

8                   MR. HAMILTON: Objection.  
9                   Vague. Beyond the scope.

10                  THE WITNESS: I think it's  
11                  technically possible. I'm honestly not  
12                  sure how practical that would be.

13 BY MR. STOWELL:

14                  Q.           Would a person of ordinary skill in  
15 the art, in 2017, have been familiar with drawing  
16 plastics and metals?

17                  A.           It's not an easy question, because a  
18 lot of medical device people would not be involved  
19 in that fundamental operation. That would be from  
20 a vendor. So it's maybe.

21                  Q.           What about in terms of the way we've  
22 identified the person of ordinary skill in the art  
23 in this case, someone with a mechanical engineering  
24 degree with two to four years of experience, would  
25 that person have been familiar with drawing

1 plastics and metals?

2 A. So it's really the same answer.

3 Typically, an engineer with a few  
4 years experience will be familiar and experienced  
5 with secondary operations such as machining or  
6 polishing or trimming or skiving, but not the  
7 fundamental operation of molding or extruding for a  
8 drawing.

9 Q. In paragraph 83, there is an example  
10 of a way to manufacture or to assemble a valve,  
11 correct?

12 A. Yes.

13 Q. Okay. In forming your opinions that  
14 you've expressed in Exhibit 2008, did you consider  
15 other methods of assembling the described valve?

16 MR. HAMILTON: Objection.

17 Vague.

18 THE WITNESS: That wasn't in my  
19 scope, no.

20 BY MR. STOWELL:

21 Q. I'm going to hand you a document that  
22 has been previously marked in this IPR as  
23 Exhibit 1006.

24 (Exhibit No. 1006 was  
25 previously marked for

1 identification.)

2 MR. STOWELL: Thank you.

3 BY MR. STOWELL:

4 Q. Dr. Zalesky, do you recognize  
5 Exhibit 1006?

6 A. Yes.

7 Q. And what is Exhibit 1006?

8 A. It appears to be a copy of the  
9 Hartley patent.

10 Q. Okay. And when you say it appears to  
11 be, is there anything that leads you to believe  
12 that this is not a copy of the Hartley patent?

13 A. Not specifically at this point.

14 Q. Does it look to be a complete copy of  
15 the Hartley patent?

16 A. Without a half-hour review, yes.

17 Q. And -- well, do you have any reason  
18 to believe this isn't a complete copy of the  
19 Hartley patent?

20 A. No.

21 Q. And is this one of the patents that  
22 you reviewed in forming the opinions in your  
23 supplemental declaration, Exhibit 2008?

24 A. Yes.

25 Q. When was the last time you had an

1 opportunity to review the Hartley patent?

2 A. Very cursorily yesterday. In terms  
3 of detail, many weeks ago.

4 Q. When you reviewed the Hartley patent,  
5 did you understand the disclosure?

6 A. Yes.

7 Q. Were there any parts of the patent  
8 that you did not understand?

9 A. No, not specifically.

10 Q. Okay. And would you agree that the  
11 Hartley patent describes a type of rotating  
12 hemostasis valve?

13 A. Yes. In particular, a single  
14 rotating actuator.

15 Q. And do you understand how the  
16 described Hartley valve operates?

17 A. Yes.

18 Q. How does the valve close around a  
19 device inserted through the valve?

20 MR. HAMILTON: Objection.

21 Vague.

22 THE WITNESS: It applies  
23 variable tension to an otherwise  
24 constrained string that is partially  
25 circumscribed in the enclosed

1 tubular element.

2 BY MR. STOWELL:

3 Q. And when you say "variable tension,"  
4 what do you mean by "variable tension"?

5 A. The actuator can be forced down or  
6 released to produce variations in tension.

7 Q. And do you believe that the string,  
8 as you put it, in Hartley circumferentially  
9 constricts the tubular member going through the  
10 string?

11 MR. HAMILTON: Objection.

12 Vague. Calls for a legal conclusion.

13 Beyond the scope.

14 THE WITNESS: I don't believe I  
15 opined on that.

16 BY MR. STOWELL:

17 Q. That's not something you considered  
18 in reaching your opinions in your supplemental  
19 declaration?

20 A. I'd have to go back and look at the  
21 specific words that I use.

22 Q. As we sit here, you don't recall  
23 whether you've opined whether Hartley  
24 circumferentially constricts a tubular member going  
25 through the device?

1           A.           I don't know that I used that  
2 particular phrase.

3           Q.           As we sit here and you're looking at  
4 the figures, do you believe that THE Hartley string  
5 circumferentially constricts the tubular element  
6 going through the filament?

7                       MR. HAMILTON:  Objection.

8           Vague.  Asked and answered.  Beyond the  
9 scope.

10                      THE WITNESS:  It's out of the  
11 scope.  I'm challenged by the figure not  
12 quite representing the reality of the  
13 dynamic effect of the actuator.

14 BY MR. STOWELL:

15           Q.           What if we look at Figures 1 and 2,  
16 does that help you answer the question?

17                      MR. HAMILTON:  Same objections.

18                      THE WITNESS:  No.

19 BY MR. STOWELL:

20           Q.           You would agree, though, that  
21 Figures 1 and 2 show a dynamic effect between  
22 Figure 1 and Figure 2, correct?

23           A.           Correct.

24           Q.           Okay.  And from these figures, are  
25 you unable to determine whether the string

1 circumferentially constricts the cylindrical  
2 diaphragm of a tubular member?

3 A. Because of the angulation of the  
4 ports of the string, it's not clear in looking at  
5 these figures that you get a circumferential  
6 compression.

7 Q. And so that I understand your  
8 position, is it fair to say that today you don't  
9 have an opinion on whether Hartley  
10 circumferentially constricts the cylindrical  
11 diaphragm going through the filament?

12 A. I think it's best to say that.

13 Q. Okay. Paragraph 37 of Hartley, let  
14 me know when you're there.

15 A. Okay.

16 Q. So paragraph 37 states that "It will  
17 be seen that by this invention there is provided an  
18 access or constriction valve arrangement which will  
19 close over a range of diameters of devices passed  
20 through the valve or can close completely down to  
21 be self-sealing."

22 Do you see that?

23 A. I do.

24 Q. And do you agree that the Hartley  
25 valve would close over a range of diameters of

1 devices passed through the valve?

2 MR. HAMILTON: Objection.

3 Vague. Incomplete hypothetical.

4 THE WITNESS: That appears to be  
5 the case.

6 BY MR. STOWELL:

7 Q. Do you have any reason to disagree  
8 with that?

9 A. No. Except that I don't know the  
10 dimensions of his lumen.

11 Q. And how would the dimensions of the  
12 lumen impact your opinion?

13 A. Simple accommodation of size or not.

14 Q. And so how would the dimension of the  
15 lumen impact whether the valve would close over a  
16 range of diameters of devices?

17 A. I'm not saying it wouldn't enclose  
18 over a range. I just don't know what that range  
19 would be.

20 Q. And do you agree with the statement  
21 in paragraph 37 that the device described in  
22 Hartley, the valve, would close completely down to  
23 be self-sealing?

24 A. I'm not sure I understand his  
25 interpretation of "self-sealing."

1           Q.           So when you read the Hartley  
2 reference, you're not -- you don't understand  
3 that -- that phrase there, "can close completely  
4 down to be self-sealing"?

5           A.           I understand "close completely down."  
6 I'm not sure why he added "self-sealing."

7           Q.           What do you understand "close  
8 completely down to mean"?

9           A.           That there is no residual lumen.

10          Q.           And do you believe that that would  
11 occur with the Hartley valve?

12          A.           He claims that it does.

13          Q.           And do you have any reason to  
14 disagree with him?

15          A.           No.

16          Q.           In paragraph 17 Hartley describes  
17 that "The flexible member may be a string, suture,  
18 or band or other suitable material."

19                       Do you see that?

20          A.           Yes.

21          Q.           And when you read the Hartley  
22 reference, what was your understanding of what was  
23 meant by a string?

24          A.           The very common objects that's either  
25 synthetic or cotton or some similar material that

1 we've all used to fly kites and such.

2 Q. And did you understand the term  
3 "string" to describe a device or a structure that  
4 has multiple strands of material?

5 A. I understood that it could encompass  
6 that, yes.

7 Q. Paragraph 17 also mentions a suture.  
8 When you reviewed the Hartley reference, what was  
9 your understanding of what was meant by a suture?

10 MR. HAMILTON: Objection.

11 Beyond the scope.

12 THE WITNESS: I assumed he  
13 intended to describe suture material  
14 commonly used in surgical procedures.

15 BY MR. STOWELL:

16 Q. And what is the material that's  
17 commonly used in surgical procedures for sutures?

18 A. It's quite variable. It ranges from  
19 polypropylene, polyethylene. It's the equivalent  
20 of catgut to synthesize resorbables, so it's quite  
21 a broad range of materials.

22 Q. And when you read Hartley, did you  
23 understand that the use of the term "suture" here  
24 was referring to that broad range of materials?

25 A. No.

1 Q. What did you understand suture in  
2 Hartley to be referring to?

3 A. My interpretation was it would refer  
4 to the stronger family of suture materials.

5 Q. And what materials would you consider  
6 to fall into that stronger family?

7 A. Some versions of polyethylene and  
8 polypropylene.

9 Q. Anything else you can think of?

10 A. It'll come to me, but not at the  
11 moment.

12 Q. Okay. Paragraph 17 also refers to a  
13 band for the flexible member. Did you have an  
14 understanding of what was meant by band?

15 A. I didn't focus on that particular  
16 word, to be frank.

17 Q. Okay. As we sit here, do you have an  
18 understanding of what "band" means in paragraph 17?

19 A. What comes to mind is something like  
20 a rubber band, but I -- again, I didn't really try  
21 to interpret what he was trying to describe.

22 Q. And then it also says "or other  
23 suitable materials." In forming your opinions  
24 about the Hartley reference, did you consider what  
25 other suitable materials could be used for the

1 flexible member?

2 A. I think my declaration shows that my  
3 concentration was on his word of string.

4 Q. And so did you form any opinions  
5 about what other suitable materials could be used  
6 for the flexible member?

7 A. It was out of my scope.

8 Q. Hartley was filed in 2002. Do you  
9 see that, December 2002?

10 A. Yes. Mm-hmm.

11 Q. In December 2002, would a person of  
12 ordinary skill in the art have been familiar with  
13 strings and sutures?

14 A. Yes.

15 Q. Between a string and a suture, would  
16 there have been any advantages to one of those over  
17 the other, based on your experience?

18 MR. HAMILTON: Objection.

19 Incomplete hypothetical.

20 THE WITNESS: I'm speculating,  
21 but small diameter strings, in general,  
22 lots of exceptions, but, in general,  
23 would exhibit better flexibility than  
24 certain suture materials.

25 BY MR. STOWELL:

1 Q. Are there any other advantages that  
2 either a string or suture would have over the other  
3 for use in a hemostasis valve like the one  
4 described in Hartley?

5 MR. HAMILTON: Objection.

6 Vague. Incomplete hypothetical.

7 THE WITNESS: The main advantage  
8 is inherent strength and a small  
9 profile.

10 BY MR. STOWELL:

11 Q. And would -- I think earlier you had  
12 explained that you understood suture in paragraph  
13 17 to refer to some of the stronger suture  
14 materials; is that right?

15 A. Yes.

16 Q. And would you consider a string a  
17 strong material as well?

18 MR. HAMILTON: Objection.

19 Incomplete hypothetical. Vague.

20 THE WITNESS: I think in most  
21 cases in the context of a hemostasis  
22 valve, a string would have sufficient  
23 strength.

24 BY MR. STOWELL:

25 Q. If we look at Figures 3 and 4 of

1 Hartley, there is a spring with a detent pictured.  
2 Do you -- when I say spring in a detent, do you  
3 understand what features in Figures 3 and 4 I'm  
4 referring to?

5 A. Yes, I do.

6 Q. Okay. It looks like the detent  
7 arrangement is described as having a ball 28 and a  
8 spring 29, and it looks like those numbers are  
9 called out in Figure 3, correct?

10 A. Yes.

11 Q. Okay. And you, based on your review  
12 of Hartley, do you have an understanding of the  
13 purpose of the spring and ball detent arrangement?

14 MR. HAMILTON: Objection. The  
15 document speaks for itself.

16 THE WITNESS: Yes. I think I  
17 encompass this in my declaration, but  
18 the detent gives you the ability to  
19 control the tensioning force at  
20 different levels; in other words, fully  
21 compressed, partially compressed, fully  
22 released.

23 BY MR. STOWELL:

24 Q. And what is your understanding of the  
25 purpose of the detent feature?

1 MR. HAMILTON: Objection. Asked  
2 and answered.

3 THE WITNESS: To give the  
4 operator control on the advancement and  
5 withdrawal of devices and/or multiple  
6 instruments.

7 BY MR. STOWELL:

8 Q. When you say "control," what do you  
9 mean by "control"?

10 A. So while he's advancing, he wants  
11 minimal friction to interfere with his advancement  
12 of the device into the target vasculature.  
13 Similarly on withdrawal. But once in position, he  
14 wants -- he wants tight -- as tight sealing as  
15 possible.

16 So the ability to vary, that gives  
17 him control.

18 Q. And so how does the detent feature  
19 contribute to how tight the sealing is?

20 MR. HAMILTON: Objection.  
21 Vague.

22 THE WITNESS: Well, the detent  
23 basically forces the spring into one or  
24 another configuration of tension, and so  
25 it directly affects the force applied to

1           the compressing string.

2       BY MR. STOWELL:

3           Q.       And do you believe that the detent  
4 holds the actuator in a specific position?

5           MR. HAMILTON:  Objection.

6           Vague.  Incomplete hypothetical.

7           THE WITNESS:  Yes.

8       BY MR. STOWELL:

9           Q.       And was that understanding important  
10 to your analysis of the Hartley reference?

11          A.       Yes.

12          Q.       If we could turn to paragraph 33 of  
13 Hartley.

14          A.       Okay.

15          Q.       This paragraph describes the detent  
16 arrangement.  In the last sentence, it says, "The  
17 rotary actuator may be rotated in either direction  
18 to cause constriction of the constriction valve,  
19 and the detents provide tactical feel the action of  
20 the valve."

21                   Do you see that?

22          A.       I do.

23          Q.       Do you understand what it means by  
24 "provide tactical feel"?

25          A.       This relates to the operator control

1 I just described.

2 Q. And so what do you understand  
3 "provide tactical feel" to mean?

4 A. One measure would be the operator  
5 sense a friction in advancing and withdrawing the  
6 device.

7 Q. And how does the operator sense the  
8 friction?

9 A. It's a simple feeling in the hands.  
10 The tension he requires to advance or pull the  
11 device.

12 Q. And how is that feeling of tension  
13 connected to the detent arrangement?

14 A. The detent has imposed one of two or  
15 more forces of constriction which is associated  
16 with two or more forces of friction. And so the  
17 operator senses that when he's advancing or  
18 withdrawing his device.

19 Q. So as you turn Hartley's rotator,  
20 rotary actuator, the ball will fall into one of the  
21 detent holes, correct?

22 A. Yes.

23 Q. And when that happens, will the user  
24 of the actuator be able to feel that ball falling  
25 into the hole?

1 MR. HAMILTON: Objection.

2 Vague. Incomplete hypothetical.

3 THE WITNESS: The operator will  
4 feel the resistance or the lack of  
5 resistance to his manipulation of the  
6 device inside the tubular structure.

7 BY MR. STOWELL:

8 Q. And so when paragraph 33 is talking  
9 about "The detent provides tactical feel," is it  
10 talking about the movement of the ball into one of  
11 the holes, that tactical feedback?

12 MR. HAMILTON: Objection. Asked  
13 and answered.

14 THE WITNESS: No. The tactile  
15 feedback is to the hands of the operator  
16 manipulating the device inside the  
17 structure.

18 BY MR. STOWELL:

19 Q. I guess what is confusing me about  
20 your explanation is that the paragraph 33 says,  
21 "The detents provide tactical feel."

22 In your scenario where the operator  
23 manipulating the device in the structure is getting  
24 tactical feedback, how are the detents involved in  
25 the process?

1 MR. HAMILTON: Objection. Asked  
2 and answered.

3 THE WITNESS: The detents  
4 adjust, if you will, the spring tension  
5 at a certain point. The spring tension,  
6 in response to that, constricts further  
7 or less further of the tubular  
8 structure. More compression means more  
9 friction; less compression means less  
10 friction. So one extreme detent would  
11 be minimum compression, minimum  
12 friction; the other extreme would be  
13 maximum compression, maximum friction.

14 BY MR. STOWELL:

15 Q. And do you believe that the spring  
16 force from the detent arrangement is causing  
17 constriction of the cylindrical diaphragm running  
18 through the valve?

19 MR. HAMILTON: Objection.  
20 Vague.

21 THE WITNESS: Yeah. Your  
22 wording seems awkward to me. All the  
23 detent does is physically impose a  
24 particular state of spring tension and  
25 associated constriction. That's all the

1 detent does.

2 So I don't know if that answers  
3 your question.

4 BY MR. STOWELL:

5 Q. Would it be fair to say the ball and  
6 the detent gives the user feedback about how far  
7 the actuator has been rotated?

8 MR. HAMILTON: Objection.

9 Vague. Asked and answered.

10 THE WITNESS: Yeah, the tactile  
11 feedback to the operator is going to be  
12 during his manipulation of the enclosed  
13 device. It's not going to be tactile  
14 feedback from the detent or the spring.

15 BY MR. STOWELL:

16 Q. And so it's your interpretation that  
17 in paragraph 33, when the specification says "the  
18 detents provide tactical feel," that's referring to  
19 the user pushing or pulling the device through the  
20 valve, correct?

21 A. Yes.

22 Q. Okay. And that opinion that you  
23 have, was that an important opinion to your  
24 evaluation of the Hartley reference?

25 MR. HAMILTON: Objection.

1 Vague.

2 THE WITNESS: Yes.

3 BY MR. STOWELL:

4 Q. And is that an opinion you relied  
5 upon in interpreting Hartley?

6 MR. HAMILTON: Objection.

7 Vague.

8 THE WITNESS: It was more  
9 related to the asserted combination of  
10 inventions that, as I opined, obviated  
11 the value of the detents in the Hartley  
12 patent.

13 BY MR. STOWELL:

14 Q. Do you believe that Hartley requires  
15 the detent arrangement in order to constrict the  
16 cylindrical diaphragm within the valve?

17 MR. HAMILTON: Objection.

18 Vague. Incomplete hypothetical.

19 THE WITNESS: No, I don't -- I  
20 don't believe that it's a requirement.  
21 I think it's an additional feature that  
22 offers an additional level of control.

23 BY MR. STOWELL:

24 Q. Have you considered, in forming your  
25 opinions that are in Exhibit 2008, how Hartley's

1 valve would operate if the detents were not  
2 present?

3 MR. HAMILTON: Objection.

4 Beyond the scope.

5 THE WITNESS: Yeah, it's out of  
6 the scope.

7 BY MR. STOWELL:

8 Q. That's not something you considered?

9 A. No.

10 MR. HAMILTON: We've been going  
11 for a little over an hour. Is this a  
12 good spot to break?

13 MR. STOWELL: Sure.

14 THE VIDEOGRAPHER: Okay. We're  
15 off the record at 1:52 p.m.

16 (Recess.)

17 THE VIDEOGRAPHER: This is the  
18 beginning of media number five. We're  
19 on the record at 2 p.m.

20 BY MR. STOWELL:

21 Q. Okay. Dr. Zalesky, did you speak to  
22 anybody about the subject matter of your testimony  
23 during the break?

24 A. No.

25 Q. Did you review any documents?

1 A. No.

2 Q. Okay. I'm going to hand you what has  
3 been previously marked as Exhibit 1007 in this IPR.  
4 (Exhibit No. 1007 was  
5 previously marked for  
6 identification.)

7 MR. STOWELL: Thank you.

8 BY MR. STOWELL:

9 Q. And do you recognize Exhibit 1007?

10 A. Yes.

11 Q. And what is Exhibit 1007?

12 A. It appears to be a copy of the Eller  
13 patent.

14 Q. Okay. And is this one of the patents  
15 that you studied in preparing your supplemental  
16 declaration, Exhibit 2008?

17 A. Yes.

18 Q. Okay. And when was the last time you  
19 had an opportunity to review the Eller patent?

20 A. Weeks ago.

21 Q. And Eller describes another type of  
22 rotating hemostasis valve, correct?

23 A. Yes.

24 Q. If we look at column 12 of the Eller  
25 patent, at line 37 -- and let me know when you're

1 there.

2 A. Okay.

3 Q. So at line 37 it refers to the  
4 sleeve. Do you understand what the Eller patent  
5 means by "the sleeve 20"?

6 A. Yes.

7 Q. Okay. And what is the sleeve?

8 A. My understanding is a tube that  
9 receives the target structure.

10 Q. And is it the tube that is  
11 constricted by the filament within Eller's valve?

12 MR. HAMILTON: Objection.

13 Vague. Calls for a legal conclusion.

14 THE WITNESS: Yes.

15 BY MR. STOWELL:

16 Q. And in paragraph -- or in that  
17 paragraph we were looking at in column 12, it  
18 explains that the sleeve can be formed of any  
19 suitable material and using any suitable  
20 manufacturing technique. And then it goes on to  
21 state that "Skilled artisans will be able to select  
22 a suitable material and technique to form a sleeve  
23 according to a particular embodiment based on  
24 various considerations, including the materials  
25 that form the housing of an embodiment."

1 Do you see that?

2 A. I do.

3 Q. And do you agree with Eller that a  
4 person of ordinary skill in the art would have  
5 possessed the background and knowledge to select a  
6 suitable material for the sleeve?

7 MR. HAMILTON: Objection.

8 Vague. Beyond the scope.

9 THE WITNESS: It's unclear.

10 BY MR. STOWELL:

11 Q. And why is it unclear?

12 A. Because of the word "suitable."

13 Q. And why does that make it unclear?

14 A. Very nonspecific.

15 Q. And so is it your testimony that a  
16 person of ordinary skill in the art would not have  
17 been able to determine what would be a suitable  
18 material for the sleeve?

19 MR. HAMILTON: Objection.

20 Incomplete hypothetical.

21 THE WITNESS: The POSITA that we  
22 agreed to does not include a great  
23 experience or learning in material  
24 science. And material science would be  
25 involved in that material selection.

1 BY MR. STOWELL:

2 Q. And so the -- the paragraph here goes  
3 on to identify example materials considered  
4 suitable to form a sleeve, and it lists a number of  
5 different materials there.

6 Do you see that?

7 A. Yes.

8 Q. And so is it your position that a  
9 person of ordinary skill in the art, as we've  
10 defined it, would not have been familiar with these  
11 materials that are listed here?

12 A. No. My comment relates to the  
13 suitability of those materials.

14 Q. So would a person of ordinary skill  
15 in the art, in September of 2017, have been  
16 familiar with the specific materials listed in the  
17 paragraph we're discussing on page 12, which  
18 includes things like elastomeric materials,  
19 polymers, polyurethanes, et cetera?

20 A. I think so.

21 Q. And would a person of ordinary skill  
22 in the art have been able to select the appropriate  
23 materials among that list to form sleeve 20 in the  
24 Eller device?

25 A. That's my key question.

1 Suitability's not really defined.

2 Q. And so as you sit here today, do you  
3 have an opinion on whether a person of ordinary  
4 skill in the art, as of September 2017, would have  
5 been able to select a suitable material to form the  
6 sleeve in the Eller device?

7 MR. HAMILTON: Objection.

8 Incomplete hypothetical.

9 THE WITNESS: Yeah, as I said  
10 before, I'm not sure.

11 BY MR. STOWELL:

12 Q. You don't have an opinion on that  
13 today?

14 A. I do not.

15 Q. This paragraph also states that the  
16 skilled artisan would be able to select the  
17 manufacturing technique for the sleeve. And if you  
18 look further down in the paragraph, it gives some  
19 examples of techniques including injection,  
20 molding, casting, and extrusion.

21 Do you agree that a person of  
22 ordinary skill in the art, in September of 2017,  
23 would have been able to select the appropriate  
24 manufacturing technique for the sleeve identified  
25 in the Eller reference?

1 MR. HAMILTON: Objection.

2 Vague. Incomplete hypothetical.

3 THE WITNESS: In general, yes.

4 BY MR. STOWELL:

5 Q. And is there a reason why you think  
6 that the person of ordinary skill in the art would  
7 have been capable of selecting a suitable  
8 manufacturing technique but would not have been  
9 capable of selecting the suitable material?

10 MR. HAMILTON: Objection.

11 Incomplete hypothetical.

12 THE WITNESS: Different  
13 materials are more easily processed with  
14 certain methods than other materials, so  
15 extrusion works with some polymers, not  
16 all polymers, as an example.

17 BY MR. STOWELL:

18 Q. And would a person of ordinary skill  
19 in the art, in September 2017, have known which  
20 materials would work with the manufacturing  
21 techniques identified in the paragraph on  
22 column 12, around line 50?

23 MR. HAMILTON: Objection.

24 Vague. Incomplete hypothetical.

25 THE WITNESS: Yeah, I thought we

1 just asked and answered that.

2 BY MR. STOWELL:

3 Q. And what was your answer?

4 A. Yes.

5 Q. Let's look at column 14, beginning at  
6 line 37. And this is describing an embodiment of  
7 the Eller valve where there's an attachment between  
8 the wire member and a housing or the -- and/or an  
9 actuator.

10 Do you see that?

11 A. I'm not sure which line you're  
12 looking at.

13 Q. Line 37, column 14.

14 MR. HAMILTON: Objection.

15 Mischaracterizes the document. It  
16 speaks for itself.

17 THE WITNESS: So yes, I see the  
18 line.

19 BY MR. STOWELL:

20 Q. And do you remember reviewing  
21 embodiments in the Eller reference where the wire  
22 member was attached to a housing and/or an  
23 actuator?

24 A. Yes.

25 Q. It goes on to explain that "Skilled

1 artisans will be able to select a suitable method  
2 or technique to attach a wire member to a housing  
3 and/or an actuator according to a particular  
4 embodiment based on various considerations."

5 Do you see that?

6 A. Yes.

7 Q. And would you agree that the person  
8 of ordinary skill in the art, in September of 2017,  
9 would have possessed the skills to select a  
10 suitable method to attach a wire member to a  
11 housing or an actuator?

12 MR. HAMILTON: Objection.

13 Incomplete hypothetical.

14 THE WITNESS: Yes.

15 BY MR. STOWELL:

16 Q. The paragraph goes on to identify  
17 some methods or techniques to attach a wire member  
18 to a housing or an actuator, including adhesives,  
19 welding, fusing, providing a friction fit, and  
20 other suitable techniques.

21 Do you see that?

22 A. Yes.

23 Q. Would the techniques of using an  
24 adhesive, welding, fusing, or providing a friction  
25 fit have been techniques known to a person of

1 ordinary skill in the art, in September of 2017,  
2 for attaching a wire to a housing or an actuator?

3 MR. HAMILTON: Objection.

4 Incomplete hypothetical.

5 THE WITNESS: Yes.

6 BY MR. STOWELL:

7 Q. If we look at column 15, line 41 --  
8 let me know when you have a chance to --

9 A. Okay.

10 Q. -- find it.

11 Okay. And there it's describing wire  
12 members. And it says that they can be formed with  
13 any suitable material and using any suitable  
14 manufacturing technique.

15 Do you see that?

16 A. Yes.

17 Q. And do you understand that the wire  
18 members are the filaments that are used to  
19 constrict the sleeve in the Eller valve?

20 A. Yes.

21 Q. And it goes on to explain that the  
22 "Skilled artisans will be able to select a suitable  
23 material and technique to form a wire member  
24 according to a particular embodiment based on  
25 various considerations."

1                   Would you agree that a person of  
2   ordinary skill in the art, in September 2017, would  
3   have possessed the skills and knowledge necessary  
4   to select a suitable wire member to constrict the  
5   sleeve in the Eller device?

6                   MR. HAMILTON:  Objection.

7                   Incomplete hypothetical.

8                   THE WITNESS:  Yes.

9   BY MR. STOWELL:

10                Q.        The paragraph goes on, and if you  
11   read the last sentence, it talks about the  
12   techniques considered suitable to form a wire  
13   member, and it mentions injection, molding,  
14   casting, et cetera.

15                   Would you agree that a person of  
16   ordinary skill in the art, in September of 2017,  
17   would have known of the techniques listed in this  
18   paragraph for forming a wire member?

19                   MR. HAMILTON:  Objection.

20                   Incomplete hypothetical.

21                   THE WITNESS:  Yes.

22   BY MR. STOWELL:

23                Q.        Then in paragraph -- or sorry, in  
24   column 16, there's a paragraph that begins at  
25   line 7.  It starts with "While the selective fluid

1 barrier device."

2 Let me know when you --

3 A. Okay.

4 Q. Did you find it?

5 A. Yes.

6 Q. And there it's listing an embodiment  
7 that has a first wire member, a second wire member,  
8 and a third wire member, right?

9 A. Yes.

10 Q. Okay. That paragraph, if you go to  
11 the next sentence, it says, "Skilled artisans will  
12 be able to select a suitable number of wire  
13 members, to include in a selective fluid barrier  
14 device, according to a particular embodiment based  
15 on various considerations."

16 Do you see that?

17 A. Yes.

18 Q. And do you agree that a person of  
19 ordinary skill in the art, in September of 2017,  
20 would have been able to select a suitable number of  
21 wire members to include in a selective fluid  
22 barrier device?

23 MR. HAMILTON: Objection.

24 Incomplete hypothetical. Vague.

25 THE WITNESS: I believe so.

1 BY MR. STOWELL:

2 Q. Earlier we had talked about the rate  
3 you charge for your expert witness services in  
4 legal matters.

5 What percentage of your legal matters  
6 do you charge the rate of \$300 an hour?

7 A. This is the only one.

8 Q. So in your other legal matters, you  
9 charge more than \$300 an hour; is that correct?

10 A. Yes.

11 Q. Okay. And what percentage of your  
12 legal matters do you charge \$500 an hour?

13 A. Twenty.

14 Q. And then the roughly other 80 percent  
15 of your legal matters, what -- what range do you  
16 bill those at?

17 A. Three-fifty to four.

18 MR. STOWELL: Okay, Dr. Zalesky,  
19 I have no further questions for you  
20 today.

21 MR. HAMILTON: All right. Why  
22 don't we take a break and I'll see if I  
23 have any follow-up. Thanks.

24 THE VIDEOGRAPHER: We're off the  
25 record at 2:15 p.m.

1 (Recess.)

2 THE VIDEOGRAPHER: We're back on  
3 the record at 2:29 p.m.

4 EXAMINATION

5 BY MR. HAMILTON:

6 Q. Dr. Zalesky, if you could take a look  
7 at Exhibit 2008. This is your supplemental  
8 declaration.

9 A. Yep.

10 Q. And if you could turn to page 48.

11 A. Yep.

12 Q. If you look at the heading B, can you  
13 read that for me.

14 A. "Schaffer does not disclose the first  
15 filament formed into a loop around the collapsible  
16 tubular sidewall of Claim 1."

17 Q. Is it your opinion that Schaffer does  
18 not disclose the first filament formed into a loop  
19 around the collapsible tubular sidewall of Claim 1?

20 MR. STOWELL: Objection.

21 Outside the scope of cross.

22 THE WITNESS: Yes.

23 BY MR. HAMILTON:

24 Q. If you could turn to Exhibit 1008  
25 and turn to Figure 32 on page 17.

1 A. Yep.

2 Q. Does the embodiment in Figure 2 show  
3 side-by-side U-shaped members?

4 MR. STOWELL: Objection.

5 Leading.

6 THE WITNESS: Yes.

7 BY MR. HAMILTON:

8 Q. Do those U-shape members interlock?

9 MR. STOWELL: Objection.

10 Leading.

11 THE WITNESS: No.

12 BY MR. HAMILTON:

13 Q. Take a look at Exhibit 1001. This is  
14 the '012 patent.

15 A. Okay.

16 Q. If you could take a look at the  
17 last -- second-to-last page, page 30.

18 A. Yep.

19 Q. And you see in column 22, about  
20 line 26 --

21 A. Yes.

22 Q. -- you see a reference there to Claim  
23 No. 2?

24 A. Yes, I do.

25 Q. And then if you go down to line 38 of

1 that claim --

2 A. Yes.

3 Q. -- you see the phrase "the filament  
4 circumferentially constricts the valve lumen."

5 Do you see that?

6 A. I do.

7 Q. Do the U-shaped members shown in  
8 Figure 32 of Schaffer that I believe you just said  
9 are side by side, do those circumferentially  
10 constrict the valve lumen as recited in Claim 2?

11 MR. STOWELL: Objection.

12 Leading.

13 THE WITNESS: No, they cannot  
14 physically do that.

15 BY MR. HAMILTON:

16 Q. Okay. Then if you could take a look  
17 at your declaration, paragraph 59, I believe. It  
18 might be page 59.

19 A. The supplemental or the --

20 Q. Sorry. It's page -- page -- the  
21 paragraph beginning on page 59 going into 60.

22 A. My supplemental, yes.

23 Q. Your supplemental declaration, yes,  
24 Exhibit 2008.

25 A. Okay.

1 Q. And if you need to, feel free to take  
2 a minute to read paragraph 110.

3 A. Okay.

4 Q. Do you understand what's depicted in  
5 the Figures 16 through 19 in that paragraph?

6 A. Yes.

7 Q. And does Figure 17 depict -- excuse  
8 me.

9 Are Figures 16 through 19 from the  
10 Schaffer reference?

11 A. Yes.

12 Q. And does Figure 16 -- excuse me.

13 Figure 17, does that depict a lumen  
14 that is completely sealed?

15 A. That's my understanding.

16 Q. And then Figure 19, does that depict  
17 a lumen that is sealed to a very small diameter?

18 A. Yes.

19 Q. And then Figure 18, does that depict  
20 a lumen that is sealed around an irregularly-shaped  
21 item?

22 A. Yes.

23 MR. STOWELL: Objection.

24 Leading. And outside the scope of  
25 cross.

1 MR. HAMILTON: With that, I have  
2 no further questions.

3 FURTHER EXAMINATION

4 BY MR. STOWELL:

5 Q. Dr. Zalesky, did you discuss your  
6 redirect examination with counsel during the break?

7 A. No.

8 Q. Did you discuss any of the topics  
9 that might be raised in redirect with your counsel  
10 during the break?

11 A. No.

12 MR. STOWELL: Okay. I have no  
13 further questions.

14 MR. HAMILTON: Fantastic.

15 THE VIDEOGRAPHER: Mr. Hamilton,  
16 would you like to order a video at this  
17 time?

18 MR. HAMILTON: I would, yes.

19 THE VIDEOGRAPHER: Would you  
20 like the video synced with the  
21 transcript?

22 MR. HAMILTON: Please.

23 THE VIDEOGRAPHER: Okay.

24 This concludes the video  
25 recorded proceeding of Paul Zalesky.

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We're off the record at 2:35 p.m.  
(Whereupon, the deposition of  
PAUL J. ZALESKY, Ph.D. was concluded  
at 2:35 p.m.)

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4 Date of deposition: August 27, 2025  
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9 Witness Name: Paul J. Zalesky, Ph.D.

10 Deposition Date: August 27, 2025

11	Page No.	Line No.	Change
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12

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16

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Signature

Date

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<b>A</b>	147:11 164:19	<b>administering</b> 2:17	<b>aluminum</b> 148:4	117:19 120:21
<b>a.m</b> 6:16 52:16	<b>activity</b> 72:4	<b>adults</b> 61:2	<b>amount</b> 94:11,15	141:11 142:4
52:20 99:10,15	<b>acts</b> 57:21	<b>advance</b> 139:11	95:1 118:22	142:23 143:13
103:19,22	<b>actual</b> 24:25	165:10	<b>amounts</b> 19:6	154:8 163:2
<b>A1</b> 4:21,23	76:2 82:8	<b>advanced</b> 43:15	147:24	166:13 167:2
<b>abbreviated</b>	108:21 110:3	57:14,16 59:23	<b>analogous</b>	168:9 177:1
41:24	110:21 111:12	<b>advancement</b>	121:16 144:11	<b>answers</b> 8:11
<b>ability</b> 9:4,16	<b>actuated</b> 130:24	163:4,11	<b>analysis</b> 35:10	168:2 191:10
87:7 94:10	<b>actuating</b> 141:16	<b>advancing</b>	164:10	191:13
123:17 162:18	142:1 143:4,5	163:10 165:5	<b>analyze</b> 37:13	<b>anticipate</b> 110:5
163:16	143:8,10,20	165:17	38:17 39:4	110:6 134:4
<b>able</b> 26:13	144:4,17,25	<b>advantage</b> 95:16	40:9,12	<b>anybody</b> 10:17
114:24 146:22	148:3,3,10,22	96:6 161:7	<b>anatomy</b> 43:18	11:8 29:22
147:6,11	149:6	<b>advantageous</b>	73:13	36:22 37:1
165:24 172:21	<b>actuation</b> 140:25	98:18	<b>ancillary</b> 72:12	52:22 99:20
173:17 174:22	141:2,9	<b>advantages</b> 98:9	<b>and/or</b> 117:11	127:12 170:22
175:5,16,23	<b>actuator</b> 152:14	160:16 161:1	147:24 163:5	<b>aorta</b> 60:16
178:1 179:22	153:5 154:13	<b>advise</b> 190:10	177:8,22 178:3	<b>apart</b> 85:25
181:12,20	164:4,17	<b>advised</b> 190:6	189:24 190:9	86:10 88:2
<b>absent</b> 190:21	165:20,24	<b>affairs</b> 12:19	<b>Angeles</b> 1:14 2:8	<b>Appeal</b> 1:3 6:10
<b>absolutely</b> 87:25	168:7 177:9,23	<b>agent</b> 74:9	3:16 6:14	<b>appear</b> 31:12
<b>acceptable</b> 20:5	178:3,11,18	<b>agents</b> 72:6	190:2	36:13,14 92:22
<b>accepted</b> 54:24	179:2	<b>ago</b> 56:2 122:12	<b>angiography</b>	133:16 145:11
<b>access</b> 24:4	<b>adaptation</b>	152:3 171:20	72:7	146:5
43:17 155:18	124:5	<b>agree</b> 70:25	<b>angioplasty</b>	<b>appearances</b>
<b>accommodate</b>	<b>Adapting</b> 124:25	90:17 107:8	12:12,24 65:2	6:22
109:5 123:17	<b>add</b> 18:18 70:4	109:19 111:9	71:20,21,23	<b>appears</b> 107:14
123:20 124:13	74:21	116:17 117:1	72:11	109:25 111:23
124:13,15,22	<b>added</b> 98:23	122:6 152:10	<b>angulation</b>	151:8,10 156:4
124:24 136:18	157:6	154:20 155:24	155:3	171:12
<b>accommodates</b>	<b>addition</b> 56:1	156:20 173:3	<b>animal</b> 69:15	<b>applicable</b>
109:15	118:19	175:21 178:7	138:22	190:13
<b>accommodation</b>	<b>additional</b> 22:3	180:1,15	<b>Anne</b> 2:14	<b>application</b> 4:20
124:4 156:13	22:7 64:25	181:18	<b>answer</b> 8:18 9:3	4:22 49:4
<b>accurate</b> 9:13	169:21,22	<b>agreed</b> 20:4	9:5 15:25	117:25
15:5 29:2 33:9	<b>address</b> 7:17	173:22	24:20 30:23,23	<b>applications</b>
36:10 37:14	35:22	<b>agreement</b> 16:23	31:14 34:2	58:15 61:10
38:18 39:5	<b>addressed</b> 10:8	17:1,24	85:1 86:6	<b>applied</b> 79:3,24
40:2 56:10	<b>adds</b> 58:6	<b>agreements</b> 17:4	103:9 104:18	113:21 126:13
77:24	<b>adhesive</b> 178:24	17:6	106:11 116:16	163:25
<b>achieve</b> 107:7	<b>adhesives</b> 178:18	<b>airplane</b> 48:7	121:17 145:7	<b>applies</b> 57:18
123:25	<b>adjunct</b> 56:4	<b>allow</b> 139:10	150:2 154:16	139:22 152:22
<b>acknowledge</b>	60:9,12	<b>allowed</b> 78:3	177:3	<b>apply</b> 18:21 19:2
191:6	<b>adjunction</b> 57:6	190:13	<b>answered</b> 77:18	74:10 94:11,14
<b>acquired</b> 17:10	<b>adjuncts</b> 13:6	<b>alternative</b> 54:4	91:22 104:17	113:7,14 114:3
<b>action</b> 47:6	<b>adjust</b> 167:4	<b>alternatives</b> 15:1	108:17 109:3	114:24,25
	<b>adjusting</b> 66:1		112:20 115:4	115:19 116:5

189:22 <b>applying</b> 25:20 95:8 <b>approach</b> 23:25 24:2,5 <b>approached</b> 19:12 <b>appropriate</b> 48:11 70:9 174:22 175:23 191:9 <b>approximate</b> 36:19 57:7 <b>approximately</b> 15:10 50:15 <b>approximates</b> 139:7 <b>arbitration</b> 42:15 <b>arbitrations</b> 42:11,12 <b>arc</b> 109:9 111:2 113:21 <b>arcs</b> 105:12 <b>arcuate</b> 113:7,14 113:17 <b>area</b> 11:17 13:1 82:3,9 94:18 102:8,14,22 103:2,8 104:2 104:9,16,20,21 105:2 106:9 116:22 <b>areas</b> 29:9 <b>argue</b> 97:19 146:14 <b>arm</b> 57:13 <b>arrangement</b> 155:18 162:7 162:13 164:16 165:13 167:16 169:15 <b>arrow</b> 82:4 102:9 126:18 <b>arrows</b> 103:11 103:14 126:8 126:14	<b>art</b> 48:21,23 49:2 51:6,7 63:2 79:5,17 91:7 98:1 128:3,6 137:17 148:9 149:15 149:22 160:12 173:4,16 174:9 174:15,22 175:4,22 176:6 176:19 178:8 179:1 180:2,16 181:19 <b>arteries</b> 43:14 57:14 75:9 <b>artery</b> 57:9,13 95:25 <b>articles</b> 22:20 49:6 <b>artificial</b> 118:13 <b>artisan</b> 175:16 <b>artisans</b> 172:21 178:1 179:22 181:11 <b>asked</b> 14:4 39:8 39:11 40:10,11 42:4 77:17 91:21 108:16 109:2 112:20 115:3 117:18 141:10 142:4 142:22 143:12 154:8 163:1 166:12 167:1 168:9 177:1 <b>asking</b> 10:10 23:16 35:21 107:21 <b>aspect</b> 55:17 93:8 137:4,5 <b>aspects</b> 10:7 50:24 <b>aspirate</b> 63:14 74:14 <b>aspirated</b> 75:8 <b>aspiration</b> 39:4 39:12,17 63:21	63:25 64:13 65:10,20 66:12 69:4,17,22 70:8,21 71:1 73:23 74:1,4 74:17,24 75:3 75:5,17 76:8 77:10,12,16,24 <b>aspirational</b> 75:22 <b>assemble</b> 150:10 <b>assembling</b> 150:15 <b>asserted</b> 169:9 <b>assess</b> 37:18 39:9 39:11 <b>assessment</b> 16:10 37:22 <b>assignee</b> 128:22 <b>assignment</b> 131:24 <b>assisting</b> 16:15 <b>associate</b> 56:11 <b>associated</b> 12:2 14:20 23:24 24:25 25:1 26:10 38:8 89:3,23 165:15 167:25 <b>association</b> 38:22 <b>assume</b> 146:6 <b>assumed</b> 158:12 <b>assumption</b> 146:8 <b>attach</b> 67:11 178:2,10,17 <b>attached</b> 4:10 5:2 21:22 66:24 67:2,6,8 67:18 177:22 191:11 <b>attaching</b> 179:2 <b>attachment</b> 40:20,22 43:19 43:23 44:3,9 47:12,15 51:19	177:7 <b>attachments</b> 28:7 <b>attention</b> 45:19 73:25 74:1 114:21 <b>attested</b> 28:19 32:25 <b>attorney</b> 21:1 114:15 <b>augment</b> 131:5 <b>August</b> 1:15 6:15 189:15 190:4 191:5 192:10 <b>authored</b> 81:8 <b>authors</b> 115:6 <b>available</b> 70:10 137:16 138:9 <b>average</b> 15:16 <b>avoid</b> 8:15 <b>aware</b> 17:9 22:11,15 29:4 29:7,11 30:9 33:11,14 36:13 45:25 47:13 61:8 81:13 148:11 <b>awkward</b> 167:22 <b>axial</b> 66:21 <b>axially</b> 95:5 137:3	23:22 24:24 71:11,14 173:5 <b>ball</b> 162:7,13 165:20,24 166:10 168:5 <b>band</b> 157:18 159:13,14,18 159:20 <b>barbed</b> 68:19 <b>barrier</b> 181:1,13 181:22 <b>based</b> 22:4,8 33:1 53:24 58:18 60:19 73:2,3 93:25 98:10 100:1 130:10 160:17 162:11 172:23 178:4 179:24 181:14 <b>basic</b> 10:8 25:19 30:15 <b>basically</b> 44:5 57:11 163:23 <b>basis</b> 19:13 145:19 <b>Baxter</b> 60:8,21 60:25 61:6,11 61:13 62:8 63:7 <b>BEAR</b> 3:5 <b>bearing</b> 141:21 <b>becoming</b> 81:11 <b>bedside</b> 56:13 <b>beginning</b> 42:17 52:19 99:13 127:6 170:18 177:5 185:21 <b>begins</b> 180:24 <b>behalf</b> 3:3,11 7:1 7:21 <b>belief</b> 28:22 33:1 <b>believe</b> 22:25 23:7 26:19 28:25 33:7 35:19 36:3,15 38:15 41:1
---	---	--	--	---

44:10,11,13 49:11 55:2 58:22 60:3 61:13 68:20 75:20 79:15,16 80:16,17,20 81:2,10 83:8 86:22 89:15 91:13,19 92:14 92:19 101:23 102:13,25 103:25 107:2 115:18,25 120:16 121:11 144:16 145:2 145:15,21 147:13 151:11 151:18 153:7 153:14 154:4 157:10 164:3 167:15 169:14 169:20 181:25 185:8,17 <b>bell</b> 78:19,20 <b>bench</b> 138:22 <b>bend</b> 122:22,24 <b>bends</b> 66:9 <b>benefit</b> 95:7 <b>benefits</b> 94:1,6 <b>best</b> 8:15,17 9:3 15:19 155:12 <b>better</b> 59:19 62:21 87:8 113:17 119:25 160:23 <b>beyond</b> 42:18 56:7 70:1,12 71:4 84:7,23 85:9,17 86:4 86:15 90:21 92:12 94:3,9 98:4 106:2 115:24 116:8 142:13 148:15 148:25 149:9 153:13 154:8 158:11 170:4	173:8 <b>big</b> 77:2 84:18 <b>bill</b> 182:16 <b>billed</b> 21:4 <b>bit</b> 19:11 36:18 56:10 94:16 <b>bite</b> 104:14,25 105:20 107:9 109:10,14,20 111:10 113:21 115:18 <b>bites</b> 100:6,10,14 101:3,7,18 102:1,9 103:3 103:6,16,25 105:11 110:4,6 110:15,22 111:2,18 112:3 112:17 113:7 113:14 114:2 126:12 <b>blatant</b> 46:19,21 <b>bleed</b> 131:14 <b>blood</b> 12:3 53:19 60:15 62:2 72:3 74:17 75:7,23 76:4 95:23,23 <b>Board</b> 1:3 6:10 45:25 46:10,22 <b>body</b> 55:11 75:7 75:12 124:10 <b>boilerplate</b> 10:7 <b>Borst</b> 66:20,23 67:2 68:9 133:12,23 134:1 136:12 136:16,18,22 137:7 138:4,10 <b>Boston</b> 53:6 56:24 58:24 59:12,25 63:12 63:20 75:21 <b>bottom</b> 41:7 55:3 121:24 125:23 140:8 <b>box</b> 191:9	<b>braided</b> 119:12 <b>break</b> 9:7,10 52:13,24 53:2 99:17 126:21 127:1,10,14 170:12,23 182:22 187:6 187:10 <b>brief</b> 10:19 103:20 <b>briefly</b> 10:3,4 11:2,6 26:21 48:3,4 49:21 49:23 <b>bring</b> 141:4 <b>bringing</b> 105:12 <b>broad</b> 13:2 38:6 38:23 158:21 158:24 <b>broadened</b> 56:15 <b>broadening</b> 56:19,20 <b>broader</b> 55:25 56:5 58:12,21 <b>business</b> 16:18 <b>button</b> 148:3 <b>buttons</b> 141:14 143:19 145:16 <b>bypass</b> 13:3 60:9 60:14 61:23 <b>bypassing</b> 13:4	153:12 172:13 <b>cancel</b> 126:1 <b>cannula</b> 60:13 60:17 61:14 <b>cannulas</b> 60:10 60:21,24 61:10 61:16 <b>capable</b> 176:7,9 <b>capacity</b> 15:5 <b>carbon</b> 118:23 <b>cardiac</b> 26:7 <b>cardiologist</b> 12:18 <b>cardiology</b> 43:9 <b>cardiopulmon...</b> 13:3 60:9 61:23 <b>Care</b> 1:5 4:13,17 6:7 7:2 9:20 21:5 22:14 26:23 81:12 190:3 191:4 192:8 <b>Care's</b> 26:18 <b>career</b> 15:12 25:24 61:19 136:6 <b>case</b> 1:10 6:10 13:15 14:20 15:21 16:23 17:14 19:19,24 20:25 21:16,18 21:22 22:1,5,9 22:17,21,24 24:11 25:5,9 32:2 38:22 42:15 43:7 54:14 57:9 66:19 96:1 98:25 107:17 134:15 135:1 149:23 156:5 190:3 191:4 192:8 <b>case-by-case</b> 19:13 <b>cases</b> 13:14	18:16,18 46:23 53:18 138:8 161:21 <b>casting</b> 175:20 180:14 <b>catch</b> 41:17 <b>categories</b> 59:21 <b>categorization</b> 121:10 <b>category</b> 11:19 56:1 58:21 61:2 <b>catgut</b> 158:20 <b>catheter</b> 43:8,11 43:13,15 53:13 53:15,16 55:9 55:16,18,20 56:22,25 57:1 57:6,10,21,24 58:1,10,10,12 58:12,14,15,19 58:23 59:6,7 59:23 60:1,1 60:17,20,22 61:18,19,22,25 62:6,11,13,13 62:14,17,17,19 63:4,8,13,14 63:20,21 64:6 64:8,12 65:9 65:25 66:10,15 66:18,22,25 69:17,22,24 70:8,9 71:2,22 72:1,13,16,18 72:22,24 73:1 73:7,11 74:6 74:10,17 76:17 76:20 77:24 78:5,11 136:19 139:11 <b>catheterization</b> 26:7 <b>catheters</b> 43:2,5 43:5 53:21 56:12 57:22 58:17,18,21
<b>C</b>				
C 3:1 4:1 5:1 6:1 c/o 190:1 <b>California</b> 1:14 2:8,15,16 3:8 3:16 6:14 190:2 <b>call</b> 29:10 35:11 49:25 131:1 190:15 <b>called</b> 11:20 26:6 43:7,13 72:7 162:9 <b>calls</b> 30:20 74:22 82:21 83:12				

59:13,18 60:5 61:9 63:25,25 65:19 66:2 70:8,14,18 71:1,25 72:2,4 72:12,20 74:13 76:10,23 77:9 77:11,14 132:21 133:15 136:7 <b>cause</b> 164:18 <b>causing</b> 167:16 <b>caution</b> 10:21 <b>cavity</b> 55:11 <b>centimeters</b> 83:8 <b>central</b> 92:3 <b>Century</b> 2:6 6:13 7:5 <b>cerebral</b> 57:5,18 75:18 76:24 77:7 <b>certain</b> 20:3 25:11 29:9 50:24 54:1 58:13 59:20,20 60:9 62:25 65:25 132:20 138:3 160:24 167:5 176:14 <b>certainly</b> 15:9 25:11 45:6 52:5 56:10 61:3 76:22 104:8 112:22 115:7 118:7 131:24 148:12 <b>certificate</b> 189:1 189:13,19 <b>certification</b> 189:21 <b>Certified</b> 2:15 189:1,2 <b>certify</b> 189:3 <b>certifying</b> 189:25 <b>cetera</b> 174:19 180:14	<b>challenge</b> 62:23 133:22 135:12 <b>challenged</b> 154:11 <b>challenges</b> 59:5 62:7 <b>challenging</b> 96:1 96:2 <b>chance</b> 10:12 179:8 <b>change</b> 29:14 41:3 62:14 101:7,18 102:1 107:9,24 109:15 110:22 111:3,7,11 112:4,17 137:24 192:11 <b>changed</b> 17:24 33:20 72:19 109:20 <b>changes</b> 56:7,21 63:3 93:11 191:11 <b>channel</b> 70:22 <b>characteristic</b> 133:14 147:13 <b>characterize</b> 72:8 <b>charge</b> 18:2,9,13 19:6,10,17,25 182:3,6,9,12 <b>charging</b> 17:19 <b>chart</b> 43:24 <b>check</b> 42:18 191:9 <b>chemical</b> 74:8 <b>Choi</b> 3:20 6:17 <b>choose</b> 47:4 <b>chosen</b> 73:2 <b>circle</b> 84:15 89:1 89:9,16,22,23 90:1,7,11,18 91:3,10 104:8 104:23 105:10 105:22,25 <b>circuit</b> 93:15	<b>circular</b> 84:15 84:16 92:3 105:15 115:21 <b>circumference</b> 88:25 89:5 103:4 104:19 <b>circumferential</b> 84:11 87:11 88:24 89:22 106:24 107:6 111:3 112:9 115:10 124:2,4 155:5 <b>circumferenti...</b> 82:18,24 83:9 84:4,14,20 86:1,12,23 88:8,20 89:8 103:1,7 104:20 105:13 109:16 112:15 153:8 153:24 154:5 155:1,10 185:4 185:9 <b>circumsFG87c...</b> 152:25 <b>circumstance</b> 66:1 96:3 <b>circumstances</b> 26:3 120:23 121:1 <b>claim</b> 39:5 87:6 183:16,19 184:22 185:1 185:10 <b>claims</b> 37:19 106:22 112:9 157:12 <b>clause</b> 145:24 <b>clean</b> 70:22 <b>cleaner</b> 145:6 <b>clear</b> 20:17 70:22 91:14 145:4 155:4 <b>client</b> 16:10 18:19 19:12,17 33:19 71:13	<b>clients</b> 16:15 20:4 <b>clients'</b> 16:2 <b>clinical</b> 69:9 138:22 <b>close</b> 152:18 155:19,20,25 156:15,22 157:3,5,7 <b>closed</b> 78:5,8,13 <b>closest</b> 144:19 146:10 <b>closure</b> 131:2 132:11,14 135:13 144:21 <b>clot</b> 74:17 75:7 <b>clots</b> 75:23 76:4 <b>ClotTriever</b> 23:9 25:15 26:15 <b>coacting</b> 124:25 <b>Coie</b> 2:5 3:13 7:7 17:2,17 20:2,7 21:1,4 22:4 36:21 190:1 <b>coil</b> 58:5 <b>collaborating</b> 12:21 <b>collapsible</b> 183:15,19 <b>colleagues</b> 14:13 <b>collect</b> 12:8 <b>Collegiate</b> 44:17 44:18 <b>column</b> 100:21 113:2 116:21 116:23 117:6 125:4,24 140:17 171:24 172:17 176:22 177:5,13 179:7 180:24 184:19 <b>combination</b> 87:4 169:9 <b>come</b> 13:14 20:12 68:21 72:9 120:6 138:15 159:10	190:7 <b>comes</b> 144:19 159:19 <b>coming</b> 89:4 <b>comment</b> 38:22 174:12 <b>comments</b> 46:6 <b>commercializa...</b> 138:24 <b>commercially</b> 138:9 <b>common</b> 59:12 68:10,11 139:5 157:24 <b>commonly</b> 138:18,20 158:14,17 <b>commonplace</b> 61:17 <b>communication</b> 34:5,20 <b>communications</b> 10:25 30:21 34:4,10 50:22 <b>company</b> 128:25 <b>compared</b> 113:18 124:12 <b>comparing</b> 144:20 <b>complete</b> 80:18 88:25 89:22,23 104:7 105:10 132:11,13 133:22 134:1 135:13 145:12 151:14,18 190:6 191:10 191:12 <b>completed</b> 13:16 <b>completely</b> 38:17 133:16 145:14 155:20 156:22 157:3,5 157:8 186:14 <b>completion</b> 92:16 93:14 <b>complex</b> 12:1
--	---	--	--	--

13:4	107:24 110:22	<b>considerations</b>	109:16 112:4	190:8
<b>compliance</b>	110:23 119:12	24:24 39:24	112:17 153:9	<b>Copying</b> 190:21
131:4	119:17 120:7	40:6,10,12,17	153:24 154:5	<b>Copyright</b>
<b>component</b> 74:5	120:10,24	172:24 178:4	155:1,10 167:6	190:20
<b>components</b>	121:2,21	179:25 181:15	185:4	<b>cords</b> 122:2
12:1 97:18	122:14 135:10	<b>considered</b>	<b>construction</b>	<b>core</b> 138:13
140:24	136:19 140:24	43:25 47:11,15	39:4,9,12,16	<b>coring</b> 138:3
<b>composing</b> 34:8	146:23 147:7	60:21 114:18	57:12 58:4	<b>corner</b> 55:9
<b>Composite</b> 5:4	147:12,18	116:11 128:7	117:24 122:13	<b>coronary</b> 43:14
<b>compressed</b>	163:24	134:16 135:1	<b>consult</b> 14:24	43:16 57:4,9
162:21,21	<b>configurations</b>	153:17 169:24	<b>consultant</b> 14:5	57:14 72:24
<b>compressing</b>	72:16,18 90:18	170:8 174:3	14:9,14	75:9 76:22,25
164:1	119:5,8 122:19	180:12	<b>consulting</b> 16:18	77:3
<b>compression</b>	<b>conform</b> 124:10	<b>consistency</b>	16:22 17:24	<b>correct</b> 7:3,23
89:2 144:14	<b>confusing</b>	104:22	18:3,8	9:20 17:21
145:16,22	166:19	<b>consistent</b> 15:13	<b>contact</b> 142:16	21:2 23:6 25:5
155:6 167:8,9	<b>confusion</b> 10:9	55:15 87:11	143:5,11,18	26:15,16 27:2
167:11,13	140:8	102:14	144:4 145:1,11	29:2 33:2
<b>compressive</b>	<b>conjunction</b>	<b>constitution</b>	<b>contacted</b> 21:1	38:11 39:18
141:21,25	43:12 112:23	119:20,21	<b>contains</b> 35:15	40:4,18 48:10
142:7,25	<b>connect</b> 77:23	120:23 121:2	<b>content</b> 10:24	50:8 53:6
145:10	<b>connected</b> 66:18	121:20	34:3,20 50:22	58:25 63:16
<b>comprise</b> 122:1	165:13	<b>constrained</b>	<b>contents</b> 31:2	67:19 79:5,13
<b>conceivable</b>	<b>connector</b> 67:11	152:24	<b>context</b> 85:6	79:19 82:7,15
122:15	67:21,22,25	<b>constrict</b> 82:19	90:5,5,7,9 91:4	83:18,19 86:9
<b>concentration</b>	68:3,15 70:9	82:24 83:9,9	108:9 117:21	86:24 90:11,19
160:3	78:22	84:20 86:1,12	120:7 123:6	105:3,25
<b>concern</b> 62:9	<b>connecters</b> 68:6	86:23 88:8,20	161:21	109:21 111:11
<b>concluded</b> 188:3	<b>connection</b> 78:4	89:8 96:18	<b>continues</b> 148:2	111:18 112:18
<b>concludes</b>	<b>connector</b> 66:20	103:1,7 112:15	<b>contrast</b> 72:6	117:3 124:16
187:24	67:5	169:15 179:19	<b>contribute</b>	134:18,22
<b>conclusion</b> 74:22	<b>connectors</b>	180:4 185:10	163:19	136:3 145:17
82:22 83:12	68:13,19,21	<b>constricted</b> 93:9	<b>control</b> 162:19	145:18 146:12
87:1 106:20	69:1 78:18	172:11	163:4,8,9,17	146:13 147:3
144:2 153:12	<b>connote</b> 108:21	<b>constricting</b> 89:9	164:25 169:22	150:11 154:22
172:13	<b>connotes</b> 109:1	95:8 115:9,11	189:24	154:23 162:9
<b>conducting</b>	113:18 132:10	141:5	<b>controlled</b>	165:21 168:20
27:23	<b>consent</b> 190:22	<b>constriction</b>	138:23	171:22 182:9
<b>conduit</b> 57:21	<b>consider</b> 11:17	94:12,18	<b>conversations</b>	189:11 191:9
58:13 63:23	13:1,10,17,20	104:20 106:24	29:22 30:1	191:12
<b>conference</b>	13:24 19:16	107:6 111:4,13	36:25 37:4	<b>correctly</b> 26:12
49:25	58:17 73:10	112:10,11	49:12	92:14 106:16
<b>confidential</b>	74:16 88:7	124:3 141:1	<b>conveyance</b>	<b>cotton</b> 157:25
15:25	92:2 105:20	155:18 164:18	53:18 57:3	<b>counsel</b> 6:5,21
<b>configuration</b>	106:9 120:4	164:18 165:15	<b>copy</b> 80:18 128:1	9:1,5 11:5
81:25 84:15,17	150:14 159:5	167:17,25	151:8,12,14,18	29:18,20,23
97:3 100:8	159:24 161:16	<b>constricts</b> 84:4	171:12 189:11	31:1,8,17 34:5

34:10 36:20	<b>cursorily</b> 26:20	32:25 33:9,12	<b>depicted</b> 91:20	<b>designed</b> 75:2
46:6 49:13,16	<b>curvature</b> 66:4	33:15,18,21,22	106:13 145:10	77:12,15
49:20 50:7	111:2,6,10,17	34:8,14,22	186:4	<b>designing</b>
187:6,9 190:9	111:22,24	35:8 36:19,23	<b>depiction</b> 92:4	136:14
190:12	112:3,16	37:2,5 38:9	<b>depicts</b> 81:24	<b>designs</b> 70:20
<b>country</b> 20:15	<b>curved</b> 124:6	40:2 43:20	<b>depo</b> 48:22	<b>despite</b> 79:22
<b>couple</b> 51:16	125:1	47:20,22,23	<b>deponent</b> 190:4	<b>detail</b> 22:15
83:7	<b>customers</b> 18:9	48:13 51:23	190:7,9	46:25 52:10
<b>course</b> 14:23	<b>cut</b> 91:14	52:1,6,8 71:8	<b>deposed</b> 8:4 9:19	63:18 116:12
17:23 30:16	<b>cylindrical</b> 155:1	80:12,15	<b>deposition</b> 1:13	128:13 130:8
72:3 84:14	155:10 167:17	114:20 135:8	2:1 4:11 5:3	152:3
106:22	169:16	151:23 153:19	6:4,12 7:4 8:1	<b>details</b> 37:13
<b>court</b> 6:18,23	<b>D</b>	160:2 162:17	10:10,12,15,16	38:17 64:19
8:9,12 11:14	<b>D</b> 5:1 6:1	171:16 183:8	10:17 11:5,8	78:15
22:12,17,21,24	<b>D.C</b> 1:24 191:2	185:17,23	11:10,15 14:23	<b>detent</b> 162:1,2,6
23:3 42:19	192:3	<b>declarations</b> 8:1	27:23 45:2,3,8	162:13,18,25
<b>cover</b> 27:18	<b>data</b> 12:5,8 16:9	23:2,4 24:15	47:16,19 48:2	163:18,22
41:25 44:12,12	<b>date</b> 6:15 21:7,8	24:19 26:24	48:14 49:8,13	164:3,15
44:17,17	21:9,13 40:1	27:1 49:8	49:17 52:8,23	165:13,14,21
<b>create</b> 29:19	189:15 190:4	50:25 52:2	53:5 63:12	166:9 167:10
69:7,16 98:17	191:5,17,22	<b>decrease</b> 87:9	99:21 136:2	167:16,23
131:1	192:10,22	<b>dedicated</b> 15:8	188:2 190:4,12	168:1,6,14
<b>created</b> 34:13	<b>dated</b> 27:16	15:18 16:13,14	191:5,7 192:10	169:15
66:14 135:20	<b>dates</b> 42:16	<b>defined</b> 105:24	<b>depositions</b>	<b>detents</b> 164:19
141:4	<b>David</b> 5:5	174:10 175:1	11:12 42:7	166:21,24
<b>creates</b> 104:8	<b>deal</b> 18:19 97:19	<b>definition</b> 55:9	<b>depth</b> 45:23	167:3 168:18
<b>creating</b> 30:10	<b>dealing</b> 95:22,24	55:15,19,22,23	<b>describe</b> 120:2	169:11 170:1
33:24 34:16	<b>dealt</b> 68:13	56:7,21 58:18	141:15,24	<b>determine</b> 18:12
62:8	<b>December</b> 160:9	60:19 79:4,9	158:3,13	45:8 139:2
<b>creation</b> 142:7	160:11	79:12,19,25	159:21	154:25 173:17
<b>credential</b>	<b>decent</b> 121:9	97:20 104:6,11	<b>described</b> 96:24	<b>determining</b>
119:19	<b>decide</b> 19:9,9,24	104:23 105:11	150:15 152:16	19:13
<b>cross</b> 93:14	24:8	123:12	156:21 161:4	<b>developed</b> 72:16
103:4 183:21	<b>decided</b> 77:16	<b>deformities</b>	162:7 165:1	72:19 73:17,24
186:25	<b>deciding</b> 19:16	133:2	<b>describes</b> 116:21	<b>developing</b>
<b>cross-section</b>	<b>decision</b> 45:13	<b>degree</b> 149:24	116:22 152:11	12:20 26:11
117:3 118:2	45:17 46:1,9	<b>deliver</b> 74:7	157:16 164:15	<b>development</b>
<b>cross-sectional</b>	46:25 47:1	<b>demonstrate</b>	171:21	13:13 15:2
116:19 119:10	73:6	108:14	<b>describing</b> 177:6	61:16
120:14 121:21	<b>declaration</b> 4:12	<b>demonstration</b>	179:11	<b>device</b> 25:8
122:14	4:15 10:6	23:18	<b>description</b> 87:6	26:10 58:7
<b>CSR</b> 1:22 189:18	14:23 27:16,18	<b>depending</b> 19:12	106:23 112:8	59:15,21,22
<b>current</b> 14:20	28:6,18,20	59:14 61:1	117:15 145:24	68:24 73:14
15:7 40:25	29:1,5,12,16	78:5	<b>descriptor</b> 36:10	74:7,8 82:8
42:24	30:11,18 31:8	<b>depict</b> 100:2	<b>design</b> 13:11,14	89:8 98:22
<b>currently</b> 25:14	32:12,18,22,24	111:12 186:7	13:15 62:19	110:3,20 112:4
<b>cursorily</b> 152:2		186:13,16,19	136:15	112:17 115:20

125:9 131:19 132:2 134:17 136:20 138:19 139:4,8,12,16 149:18 152:19 153:25 156:21 158:3 163:12 165:6,11,18 166:6,16,23 168:13,19 174:24 175:6 180:5 181:1,14 181:22 <b>devices</b> 11:20,21 11:25 12:7,15 12:20,23,24,25 13:7,11,18,22 23:24 53:19 54:1 55:1 56:3 56:4,4 57:15 57:21 61:3 62:8 67:12 68:6,24 69:7 71:21 79:21 133:15 137:2 155:19 156:1 156:16 163:5 <b>diagnose</b> 12:6 65:1 <b>diagnostic</b> 11:21 11:23 12:4,7 12:11 13:8 56:4 72:2,7 73:14 <b>diameter</b> 72:18 120:14 131:19 135:16,18 139:7 160:21 186:17 <b>diameters</b> 155:19,25 156:16 <b>diaphragm</b> 155:2,11 167:17 169:16 <b>dictionaries</b> 44:21	<b>dictionary</b> 5:8 44:17,19,23,23 51:16 54:18,21 54:25 55:5 58:11 <b>differ</b> 18:5 118:14 <b>differed</b> 76:20 <b>difference</b> 14:8 58:9 79:23 89:25 <b>differences</b> 111:22 <b>different</b> 55:23 64:24 65:10 68:22 90:6 94:17 95:1,4,8 100:8 105:7 110:1,7,11,12 110:14,16 114:22 121:18 136:18 142:15 148:12 149:3 162:20 174:5 176:12 <b>differently</b> 94:16 <b>difficult</b> 43:18 56:10 96:25 97:6,21,25 <b>diffuse</b> 113:18 <b>dig</b> 64:1 <b>Digital</b> 1:23 6:19 190:19,20 191:1 192:1 <b>dimension</b> 85:13 93:11 109:6 123:7 156:14 <b>dimensions</b> 85:7 110:1 136:18 136:22,22 137:24 139:3 156:10,11 <b>dire</b> 95:14,19,21 96:1 <b>direct</b> 189:24 <b>direction</b> 103:15 126:13,17	141:22 164:17 <b>directly</b> 18:19 20:1,25 25:1 38:8 71:19 163:25 <b>director</b> 53:5,9 <b>disagree</b> 156:7 157:14 <b>disagreed</b> 46:1 46:10,22 <b>disagreement</b> 46:19,21 47:2 <b>disclaimer</b> 79:6 79:8 <b>disclose</b> 16:2 183:14,18 <b>disclosed</b> 117:16 <b>disclosure</b> 152:5 <b>discouraged</b> 97:25 <b>discuss</b> 10:16 49:13 187:5,8 <b>discussed</b> 10:22 11:4,7 58:19 124:1 <b>discussing</b> 174:17 <b>discussion</b> 58:11 <b>disease</b> 57:10,10 <b>diseased</b> 72:9 <b>disengage</b> 140:19,22 142:18,19 143:3 144:3 <b>disengaged</b> 141:8 143:7,9 144:18 146:12 <b>disengagement</b> 144:22,25 146:15 <b>dislodge</b> 74:3 <b>dislodgement</b> 74:2 <b>dismantling</b> 189:12 <b>disposable</b> 12:1 133:15 136:19	<b>disruptive</b> 74:7 <b>distal</b> 43:17 60:16 <b>District</b> 22:12,17 22:21,24 23:3 <b>diverse</b> 58:2 <b>docket</b> 35:13 <b>doctor</b> 66:6 77:15 <b>document</b> 28:9 28:13 33:4 45:18,23 46:4 47:10 102:17 115:23 129:19 150:21 162:15 177:15 <b>documents</b> 44:9 44:12 47:3,7 47:14 48:13 49:10 50:16,21 51:2,13,18 53:1 99:18 127:10 170:25 <b>doped</b> 120:14 <b>Dorland's</b> 5:7 54:18 55:5 <b>Dr</b> 7:14 27:12 32:8 52:22 54:12 80:9 99:17 127:9,22 129:15 151:4 170:21 182:18 183:6 187:5 <b>draft</b> 31:2,5,16 <b>drafting</b> 29:21 <b>drafts</b> 30:21 31:7,11,22 34:4,21 <b>drawing</b> 149:15 149:25 150:8 <b>drawings</b> 107:1 <b>drawn</b> 149:7 <b>drill</b> 138:2,12 <b>drink</b> 9:15 <b>Drive</b> 7:18 <b>driven</b> 72:21 <b>driver</b> 112:22	124:1 <b>duly</b> 7:10 189:6 <b>durability</b> 98:9 <b>dwell</b> 47:5 <b>dye</b> 72:6 <b>dynamic</b> 14:20 108:21 112:11 144:13 146:2 154:13,21 <hr/> <b>E</b> <hr/> <b>E</b> 3:1,1 4:1,9 5:1 5:1 6:1,1 <b>e-mail</b> 20:3 <b>earlier</b> 70:17 86:21 104:7 105:24 119:14 136:5 139:21 144:12,21,24 146:1 161:11 182:2 <b>early</b> 26:1 137:12 <b>easily</b> 42:4 176:13 <b>East</b> 2:6 6:13 7:18 28:14 32:23 <b>easy</b> 149:17 <b>Edition</b> 5:8 <b>effect</b> 131:2,5 154:13,21 <b>effectively</b> 140:24 <b>Eight</b> 77:5 <b>either</b> 11:21 24:11 26:18 53:19 57:6,13 59:21 87:9 108:3 117:24 130:18,21 133:17 157:24 161:2 164:17 <b>elastomeric</b> 174:18 <b>electrical</b> 72:4 <b>electrode</b> 72:3
--	---	--	--	---

<b>electronically</b> 190:21	109:6 130:19 130:25 131:13	<b>essence</b> 147:19	30:11 31:5,12	136:2,7,9,13
<b>element</b> 82:8,14 87:10,12 123:8 124:6 125:1 130:19 146:12 153:1 154:5	152:25 168:12 <b>encompass</b> 158:5 162:17	<b>essential</b> 108:10	31:23,24 32:2	139:23 149:24
<b>elements</b> 141:5 142:25 145:11 145:13	<b>encompassed</b> 118:21	<b>essentially</b> 78:3 147:14	32:4,9,11,15	150:4 160:17
<b>elevated</b> 95:23	<b>encounter</b> 133:5	<b>et</b> 174:19 180:14	33:9,21,22,25	173:23
<b>Eller</b> 51:9 171:12,19,21 171:24 172:4 173:3 174:24 175:6,25 177:7 177:21 179:19 180:5	<b>ends</b> 60:18 92:16 147:5	<b>evaluate</b> 40:11	34:12 35:3,3,4 35:5,10,14	<b>experienced</b> 150:4
<b>Eller's</b> 172:11	<b>engage</b> 143:20	<b>evaluation</b> 168:24	36:2,4,5,13,14 36:17,21 37:2	<b>experiences</b> 63:7
<b>elliptical</b> 133:20	<b>engaged</b> 141:16 142:1,6,11 143:7,17	<b>event</b> 95:14,20 95:21	37:6,9 39:1 40:19 43:20 44:19 46:2	<b>experimental</b> 69:11
<b>elongate</b> 113:8 115:1,20	<b>engagements</b> 41:22 42:23 43:1	<b>events</b> 52:5	47:11,24 48:1 48:5,9,9 49:9 51:20 54:7,8 54:13 71:8 79:1,3,24 80:4 80:5,10,15 99:4 114:20 125:14 127:17	<b>experimentation</b> 138:20
<b>embodiment</b> 93:22 102:24 104:14 108:2 114:9,25 172:23,25 177:6 178:4 179:24 181:6 181:14 184:2	<b>engineer</b> 62:18 150:3	<b>evidence</b> 1:23 6:20 40:9,12 190:19,20 191:1 192:1	51:20 54:7,8 79:1,3,24 80:4 80:5,10,15 99:4 114:20 125:14 127:17	<b>expert</b> 7:21 13:11,18,21,25 14:8,12,17,19 15:3,4,8 16:13 18:22 19:4 20:6,9,10,19 41:18,21 106:3 182:3
<b>embodiments</b> 104:25 105:20 110:4 121:12 121:25 140:16 177:21	<b>engineering</b> 149:23	<b>evolution</b> 19:20	127:18,23,25 128:8 129:10 129:11,16 130:5 145:5 150:14,23,24 151:5,7,23 160:23 169:25 171:3,4,9,11 171:16 183:7 183:24 184:13 185:24	<b>expertise</b> 11:18
<b>emboli</b> 74:14	<b>engineers</b> 62:22	<b>exact</b> 42:16	130:5 145:5 150:14,23,24 151:5,7,23 160:23 169:25 171:3,4,9,11 171:16 183:7 183:24 184:13 185:24	<b>explain</b> 23:14 114:9,24 177:25 179:21
<b>enable</b> 43:16 119:11	<b>enlarging</b> 59:6	<b>exactly</b> 64:2 115:16	150:14,23,24 151:5,7,23 160:23 169:25 171:3,4,9,11 171:16 183:7 183:24 184:13 185:24	<b>explained</b> 144:24 161:12
<b>encircled</b> 102:14 102:21 103:2,8 104:1,15 105:2 106:9	<b>enter</b> 16:22,25 17:3,6	<b>examination</b> 4:2 7:12 183:4 187:3,6 189:8	150:14,23,24 151:5,7,23 160:23 169:25 171:3,4,9,11 171:16 183:7 183:24 184:13 185:24	<b>explains</b> 100:14 116:18 117:8 146:21 172:18
<b>encirclement</b> 104:9 105:16	<b>entrepreneurial</b> 64:5	<b>examined</b> 7:11 191:7	150:14,23,24 151:5,7,23 160:23 169:25 171:3,4,9,11 171:16 183:7 183:24 184:13 185:24	<b>explanation</b> 166:20
<b>enclose</b> 156:17	<b>entwined</b> 119:12	<b>example</b> 13:3 15:20 20:13 54:2 72:24 90:24 101:25 117:10 119:9 126:16 148:4,5 150:9 174:3 176:16	150:14,23,24 151:5,7,23 160:23 169:25 171:3,4,9,11 171:16 183:7 183:24 184:13 185:24	<b>explicitly</b> 135:23
<b>enclosed</b> 94:17 95:2 104:21	<b>envision</b> 107:5 108:20 115:7 132:12	<b>examples</b> 91:2 125:25 175:19	150:14,23,24 151:5,7,23 160:23 169:25 171:3,4,9,11 171:16 183:7 183:24 184:13 185:24	<b>express</b> 38:23 190:22
	<b>equation</b> 96:13	<b>exception</b> 132:10	150:14,23,24 151:5,7,23 160:23 169:25 171:3,4,9,11 171:16 183:7 183:24 184:13 185:24	<b>expressed</b> 150:14
	<b>equipment</b> 64:25 65:1	<b>exceptions</b> 160:22	150:14,23,24 151:5,7,23 160:23 169:25 171:3,4,9,11 171:16 183:7 183:24 184:13 185:24	<b>expressing</b> 44:6
	<b>equity</b> 21:25	<b>excerpts</b> 51:16	150:14,23,24 151:5,7,23 160:23 169:25 171:3,4,9,11 171:16 183:7 183:24 184:13 185:24	<b>extend</b> 82:8 102:21
	<b>equivalent</b> 138:2 158:19	<b>exchange</b> 31:7	150:14,23,24 151:5,7,23 160:23 169:25 171:3,4,9,11 171:16 183:7 183:24 184:13 185:24	<b>extending</b> 82:19 88:9 103:2,8 104:1
	<b>errata</b> 190:11 191:11 192:6	<b>exchanging</b> 34:9	150:14,23,24 151:5,7,23 160:23 169:25 171:3,4,9,11 171:16 183:7 183:24 184:13 185:24	<b>extends</b> 105:2
	<b>error</b> 29:10	<b>exclusively</b> 133:12	150:14,23,24 151:5,7,23 160:23 169:25 171:3,4,9,11 171:16 183:7 183:24 184:13 185:24	<b>extension</b> 43:8 43:10,15
	<b>errors</b> 29:4,8 33:11	<b>excuse</b> 44:16 186:7,12	150:14,23,24 151:5,7,23 160:23 169:25 171:3,4,9,11 171:16 183:7 183:24 184:13 185:24	<b>extent</b> 15:24 30:20 31:15 35:6
	<b>ESQUIRE</b> 3:4 3:12	<b>exhibit</b> 27:6,7,12 27:15 29:1,6 29:16,19,21,25	150:14,23,24 151:5,7,23 160:23 169:25 171:3,4,9,11 171:16 183:7 183:24 184:13 185:24	

<p><b>external</b> 13:15 123:17,21</p> <p><b>extreme</b> 77:6 167:10,12</p> <p><b>extremely</b> 62:1 120:13</p> <p><b>extruding</b> 150:7</p> <p><b>extrusion</b> 133:18 175:20 176:15</p> <p><b>eye</b> 88:4</p> <hr/> <p style="text-align: center;"><b>F</b></p> <hr/> <p><b>F</b> 20:18</p> <p><b>fabrication</b> 133:19</p> <p><b>faced</b> 59:6 62:8</p> <p><b>fact</b> 42:18 109:4</p> <p><b>factors</b> 19:15 73:9,12</p> <p><b>facts</b> 9:17</p> <p><b>failed</b> 41:17</p> <p><b>fair</b> 8:19,24 9:10 16:12 35:9,14 38:2 39:14 40:15 44:22,24 44:25 45:22 57:20 97:4 108:4 116:14 139:9 155:8 168:5</p> <p><b>fairly</b> 13:4 61:16</p> <p><b>fall</b> 159:6 165:20</p> <p><b>falling</b> 165:24</p> <p><b>familiar</b> 23:23 25:3 48:24 54:17 78:17 81:13 128:19 128:24 149:1 149:15,25 150:4 160:12 174:10,16</p> <p><b>family</b> 159:4,6</p> <p><b>Fantastic</b> 187:14</p> <p><b>far</b> 86:10 168:6</p> <p><b>feature</b> 98:23 109:1 162:25 163:18 169:21</p>	<p><b>features</b> 57:25 69:24 162:3</p> <p><b>February</b> 27:17 28:10</p> <p><b>fee</b> 21:21</p> <p><b>feedback</b> 166:11 166:15,24 168:6,11,14</p> <p><b>feel</b> 71:9 134:12 164:19,24 165:3,24 166:4 166:9,21 168:18 186:1</p> <p><b>feeling</b> 165:9,12</p> <p><b>fees</b> 18:8</p> <p><b>fibrils</b> 119:12,13</p> <p><b>field</b> 54:19,25</p> <p><b>figure</b> 64:2 81:20,21 82:14 82:18 83:3,16 85:24 86:23 87:5,14,15,16 88:7 89:13,15 91:20 92:1,5,6 92:19,21,24 93:17 100:2 101:25 102:8 102:25 103:11 103:24 104:14 104:25 105:20 106:7 108:2 109:19,20 110:5,6,23,23 111:24,24 114:8,9,24,25 126:17 144:19 144:21 145:2,3 145:6,8,9,15 145:21 146:5 146:10,10,14 146:16 154:11 154:22,22 162:9 183:25 184:2 185:8 186:7,12,13,16 186:19</p> <p><b>figures</b> 48:16</p>	<p>81:16 87:5 99:2,3,23 100:11 101:5,6 101:18 106:13 106:19,23 107:2,4,10,25 108:5,12,13,21 108:25 110:4 111:10,17 120:17 121:12 126:7 129:23 130:7,8,12 144:6,8,10,15 144:17 146:1 146:11 154:4 154:15,21,24 155:5 161:25 162:3 186:5,9</p> <p><b>filament</b> 81:25 82:18 83:7,8 83:17,21 84:3 84:4,19,20 85:23,24,25 86:11,11,22 87:8,16 88:8 91:19 92:1,7,9 92:17,25 112:23,25 116:21,22 117:2,9 118:3 122:1,7 124:6 124:10 126:2 154:6 155:11 172:11 183:15 183:18 185:3</p> <p><b>filamentous</b> 100:7</p> <p><b>filaments</b> 83:3 88:6 93:2,12 96:17,23 98:8 98:16 102:25 106:7,10,13,19 106:25 107:3 107:17,23 108:6,14 112:25 113:6 116:18 117:16</p>	<p>120:16 125:16 179:18</p> <p><b>file</b> 6:3</p> <p><b>filed</b> 6:8 22:24 160:8</p> <p><b>financial</b> 21:18</p> <p><b>find</b> 145:24 179:10 181:4</p> <p><b>fine</b> 16:4</p> <p><b>finish</b> 8:17,17,18 9:8</p> <p><b>firms</b> 20:20</p> <p><b>first</b> 7:10 21:10 29:1,5,15 33:21 34:8 38:21 45:12 68:25 81:4 93:3 139:20 147:6 181:7 183:14,18</p> <p><b>fit</b> 178:19,25</p> <p><b>five</b> 20:15 41:11 41:15,19 42:1 42:6,12,20,22 43:2 170:18</p> <p><b>flat</b> 122:2</p> <p><b>flexibility</b> 107:7 108:10,22 109:1,10 111:5 119:11 120:1 120:15 123:6 160:23</p> <p><b>flexible</b> 55:10 56:9 87:8 106:14,19,25 107:3,17,23 108:6,15 117:17 118:2,6 118:7 119:1,4 119:15,17 120:17 121:3 121:13 122:21 122:25 123:3,5 123:11 124:5 124:12 125:11 125:16 157:17 159:13 160:1,6</p>	<p><b>flip</b> 114:8</p> <p><b>Floor</b> 3:7</p> <p><b>flow</b> 131:15,15 132:11,14</p> <p><b>Flow Trier</b> 23:9 25:15 26:15</p> <p><b>fluid</b> 55:12 56:2 131:15 132:11 132:14 180:25 181:13,21</p> <p><b>fly</b> 158:1</p> <p><b>focus</b> 71:17 159:15</p> <p><b>focused</b> 114:7 130:6 135:15</p> <p><b>focuses</b> 71:15</p> <p><b>follow-up</b> 182:23</p> <p><b>followed</b> 20:2 34:24 58:5</p> <p><b>follows</b> 7:11</p> <p><b>food</b> 9:15</p> <p><b>forbidden</b> 190:21</p> <p><b>force</b> 89:4 94:11 94:15 95:1,8 140:25 141:3,4 141:9,21,25 142:7,8 162:19 163:25 167:16</p> <p><b>forced</b> 153:5</p> <p><b>forces</b> 163:23 165:15,16</p> <p><b>forcible</b> 144:22</p> <p><b>forcibly</b> 140:19 140:21 141:8 141:16 142:1 142:18 143:9 143:20 144:3 144:18 146:11</p> <p><b>foregoing</b> 189:4 189:21 191:7</p> <p><b>Forensis</b> 20:13 20:16</p> <p><b>form</b> 14:22 89:9 91:3 98:8 103:4,25</p>
--	---	--	--	--

104:14 105:1 105:21 106:10 119:9 122:7,22 122:23 125:16 135:17 160:4 172:22,25 174:4,23 175:5 179:23 180:12 <b>formable</b> 66:3 <b>formation</b> 93:9 <b>formed</b> 37:24 104:13 106:8 172:18 179:12 183:15,18 <b>former</b> 103:10 <b>forming</b> 24:18 24:22 26:23 31:11,22 47:11 88:18 89:18 98:16 99:4 113:6 114:19 128:7 129:20 134:15,25 150:13 151:22 159:23 169:24 180:18 <b>forms</b> 104:19 <b>forth</b> 12:13 15:2 26:8 36:2 125:14 189:5 <b>forward</b> 190:11 <b>four</b> 15:11 20:14 50:15 149:24 182:17 <b>fragmentation</b> 74:2 <b>frame</b> 45:20,21 <b>frank</b> 20:18 159:16 <b>frankly</b> 45:19 71:12 86:6 <b>free</b> 186:1 <b>French</b> 58:24 59:3,6,7 60:1,6 61:3,8,9,14,14 61:18,22 62:6 62:6,12,13	63:9 77:2,5,8 <b>frequently</b> 68:13 <b>friction</b> 163:11 165:5,8,16 167:9,10,12,13 178:19,24 <b>front</b> 99:24 128:19 <b>full</b> 89:1 <b>fully</b> 146:5 162:20,21 <b>function</b> 96:1 132:25 <b>fundamental</b> 149:19 150:7 <b>further</b> 37:18,21 39:9 104:10,22 105:14 167:6,7 175:18 182:19 187:2,3,13 <b>fusing</b> 178:19,24 <hr/> <b>G</b> <hr/> <b>G</b> 6:1 <b>gap</b> 83:6,14,20 84:2,10,16,18 <b>Garrison</b> 37:13 37:20,22,25 38:5,11,13,17 38:20 <b>garrotte</b> 88:16 <b>gas</b> 12:3 131:15 132:11,14 <b>gastrointestinal</b> 13:8 <b>general</b> 12:22 13:16 14:24 16:6,17 24:16 24:20,21 34:23 49:3 53:16 57:17 64:19 87:21,23 88:13 120:7 123:16 137:20 138:24 139:12 160:21 160:22 176:3 <b>generally</b> 11:19	15:13 16:4 23:23 35:12 54:24 119:18 <b>generate</b> 35:10 66:25 <b>gentleman</b> 17:14 <b>geometry</b> 66:2,4 66:7 90:6 109:15,20 110:14,15,21 115:14 <b>getting</b> 166:23 <b>Gilbert</b> 7:18 <b>give</b> 15:19 120:15 163:3 <b>given</b> 11:11 18:13 42:19 121:20 122:12 191:10,13 <b>gives</b> 162:18 163:16 168:6 175:18 <b>glance</b> 38:21 <b>go</b> 8:5 24:8 34:16 38:14 40:8 42:14 46:15 60:7 108:3 122:23 135:7 144:7 153:20 181:10 184:25 <b>goes</b> 43:15 120:2 172:20 174:2 177:25 178:16 179:21 180:10 <b>going</b> 19:17,19 47:4 52:12 54:6 57:8 59:22 69:2 70:3 74:21 78:6 80:3 83:10 84:5 86:1,24 95:14 104:15 109:5 109:14 113:5 126:20 127:16 129:8 139:8	144:21 150:21 153:9,24 154:6 155:11 168:11 168:13 170:10 171:2 185:21 <b>good</b> 7:14 8:5 52:14 57:23 116:23 126:23 170:12 <b>governing</b> 190:13 <b>grades</b> 121:18 <b>great</b> 57:3 116:12 173:22 <b>greater</b> 94:11,15 94:25 <b>Greenwich</b> 7:19 28:14 32:23 <b>groin</b> 57:13 <b>Group</b> 1:23 6:20 190:19,20 191:1 192:1 <b>guess</b> 166:19 <b>guesstimating</b> 31:6 <b>guide</b> 43:8,10,13 43:14 53:13 56:25 57:1,5,7 57:10,15,21,24 58:10,12,14,17 58:23 59:23 63:13,14,19 65:1 71:21 72:1,13 <hr/> <b>H</b> <hr/> <b>H</b> 4:9 5:1 <b>half</b> 21:14 48:6,8 130:20 <b>half-hour</b> 151:16 <b>Hamilton</b> 3:12 4:4 7:6,7 10:19 10:20,24 11:5 14:1,10 15:23 25:16 30:12,19 31:13 33:3 34:1,18 35:17	36:6 46:3 50:6 50:20 52:14 64:14 65:12,21 69:25 70:3,11 71:3 74:20 76:11 77:17 81:22 82:10,21 83:11 84:6,22 85:8,16 86:3 86:14 87:2,18 88:10,21 89:10 90:2,12,20 91:11,15,21 92:11 93:4,19 94:2,8,20 95:10 96:8,19 97:7,14 98:3 98:12,19 99:6 100:3 101:8,20 102:2,16 104:3 105:4 106:1 107:11,18 108:7,16 109:2 109:11,22 110:8,24 112:5 112:19 113:22 114:12 115:3 115:22 116:7 117:18 120:19 121:14 122:8 123:1,14,23 124:17 125:6 125:17 126:3 126:23 129:25 130:16 131:9 131:21 132:15 133:9 134:8,19 135:4,21 137:18 139:18 141:10,18 142:3,12,22 143:12,22 148:13,24 149:8 150:16 152:20 153:11 154:7,17 156:2 158:10 160:18
---	--	---	---	---

161:5,18 162:14 163:1 163:20 164:5 166:1,12 167:1 167:19 168:8 168:25 169:6 169:17 170:3 170:10 172:12 173:7,19 175:7 176:1,10,23 177:14 178:12 179:3 180:6,19 181:23 182:21 183:5,23 184:7 184:12 185:15 187:1,14,15,18 187:22 <b>hand</b> 27:4 32:1 54:6 80:3 127:16 150:21 171:2 <b>handling</b> 62:25 <b>hands</b> 66:8 165:9 166:15 <b>hands-on</b> 139:22 <b>handwritten</b> 28:15 <b>happen</b> 64:16 106:24 <b>happens</b> 165:23 <b>hard</b> 146:6,15 149:3 <b>Hartley</b> 51:9 151:9,12,15,19 152:1,4,11,16 153:8,23 154:4 155:9,13,24 156:22 157:1 157:11,16,21 158:8,22 159:2 159:24 160:8 161:4 162:1,12 164:10,13 168:24 169:5 169:11,14 <b>Hartley's</b> 165:19 169:25	<b>head</b> 20:24 <b>heading</b> 41:6 183:12 <b>heart</b> 13:5 57:10 60:15,16 72:5 75:10 <b>held</b> 2:2 6:12 <b>help</b> 96:12 145:7 154:16 <b>hemicylindrical</b> 130:20 <b>hemostasis</b> 42:23 66:21 96:7,24 131:12 133:5 136:3,9 136:14,16 139:6 152:12 161:3,21 171:22 <b>hesitate</b> 190:15 <b>high</b> 18:11 <b>high-density</b> 119:23 <b>high-pressure</b> 95:14,20,21,25 <b>history</b> 61:15 <b>Hold</b> 148:13 <b>holds</b> 164:4 <b>hole</b> 165:25 <b>holes</b> 165:21 166:11 <b>hollow</b> 57:11 60:18 64:8 <b>home</b> 7:17 41:23 56:14 <b>honest</b> 78:16 <b>honestly</b> 44:13 45:10 46:16 52:4 54:15 61:12 76:13,18 77:13 84:25 85:12 95:13 144:7 149:11 <b>hospital</b> 75:21 <b>hour</b> 17:20 18:10,20 19:1 19:6,25 21:15	48:6,8 50:1 52:12 170:11 182:6,9,12 <b>hours</b> 31:6 36:19 47:21 48:9 50:15 <b>housing</b> 172:25 177:8,22 178:2 178:11,18 179:2 <b>hurdles</b> 62:7 <b>hypothetical</b> 84:7,23 85:9 85:17 86:4,15 88:11 95:11 96:9 97:9,15 98:5,13,20 101:9,21 102:3 107:19 108:18 110:9,25 116:9 120:20 121:15 131:22 132:16 133:10 134:9 134:20 135:5 135:22 139:19 141:19 156:3 160:19 161:6 161:19 164:6 166:2 169:18 173:20 175:8 176:2,11,24 178:13 179:4 180:7,20 181:24 <b>hypotubing</b> 54:3	176:21 <b>identifies</b> 119:3 <b>identify</b> 15:22 174:3 178:16 <b>identifying</b> 109:9 <b>identity</b> 50:21 <b>illustrate</b> 144:17 <b>illustrated</b> 5:7 54:18 120:17 <b>illustrates</b> 89:16 <b>Illustrations</b> 5:4 <b>image</b> 145:6 <b>images</b> 12:3 76:1 <b>imagine</b> 144:10 149:3 <b>imaging</b> 64:25 <b>impact</b> 135:19 156:12,15 <b>Imperative</b> 1:5 4:13,16 6:6 7:2 9:20 21:5 22:14 26:17,23 81:12 190:3 191:4 192:8 <b>implication</b> 117:23 <b>implies</b> 84:14 87:24 112:10 <b>important</b> 71:9 93:7 119:19 164:9 168:23 <b>impose</b> 167:23 <b>imposed</b> 165:14 <b>inaccurate</b> 29:12 33:15 <b>Inari</b> 1:7 4:13,17 6:7 7:22 9:20 9:23 17:4,10 21:5,25 22:8 22:13 23:2,5 24:6,18 25:14 30:1,5 37:1 81:12 190:3 191:4 192:8 <b>Inari's</b> 23:9,25 24:5,6,9,13	25:8 26:14 <b>INARI-</b> 4:12,15 <b>Inari-2001</b> 27:5 27:7,13 <b>Inari-2008</b> 32:2 32:4 <b>include</b> 55:25 71:9 118:16,17 142:15 173:22 181:13,21 <b>included</b> 72:3 <b>includes</b> 40:21 88:25 138:22 174:18 <b>including</b> 18:15 19:20 96:23 106:22 117:10 172:24 175:19 178:18 190:21 <b>incomplete</b> 84:7 84:23 85:9,17 86:4,15 88:11 95:11 96:9 97:9,15 98:4 98:13,20 101:9 101:21 102:3 107:19 108:17 110:9,25 116:8 120:20 121:15 131:22 132:16 133:10 134:9 134:20 135:5 135:22 139:19 141:19 156:3 160:19 161:6 161:19 164:6 166:2 169:18 173:20 175:8 176:2,11,24 178:13 179:4 180:7,20 181:24 <b>increase</b> 94:19 139:1 <b>increased</b> 115:12 120:1 <b>increasing</b> 62:5
<b>I</b>				
		<b>ID</b> 62:23 <b>identification</b> 27:9 32:6 54:10 80:7 127:20 129:13 151:1 171:6 <b>identified</b> 46:17 47:1 56:8,19 82:3 104:7 149:22 175:24		

<p>138:10  <b>incredibly</b>                  119:10  <b>incremental</b>                  35:11  <b>incrementally</b>                  97:21  <b>independent</b>                  37:18  <b>indicate</b> 73:16                  113:20 122:25  <b>indicated</b> 125:2                  146:9  <b>indicating</b>                  109:10  <b>indication</b> 58:16                  63:22 64:6                  72:22 117:22                  131:11  <b>indications</b>                  11:22,24 64:7                  70:19,20  <b>Indirectly</b> 135:6  <b>individual</b> 107:9  <b>individuals</b>                  128:20  <b>industry</b> 60:4                  138:19  <b>infinite</b> 62:23  <b>inform</b> 24:14  <b>information</b>                  12:8 16:1,3                  28:21 31:10,16                  31:21 34:21                  44:6  <b>infusion</b> 72:5  <b>inherent</b> 107:6                  108:22 109:1                  161:8  <b>inhibit</b> 9:16  <b>initiate</b> 15:22  <b>initiated</b> 16:6  <b>injecting</b> 60:15  <b>injection</b> 175:19                  180:13  <b>inserted</b> 55:11                  57:6,12,22</p>	<p>66:22 72:13                  115:20 116:5                  131:19 132:2                  133:6 134:6,17                  135:2,17,19                  139:16 152:19  <b>inside</b> 43:15                  57:16 72:8                  95:15 96:3                  115:8 135:11                  166:6,16  <b>inspect</b> 23:9                  26:14  <b>inspected</b> 26:17  <b>instance</b> 58:15                  60:10 119:24  <b>instances</b> 65:9                  78:7 96:16  <b>institution</b> 45:13                  45:17 46:1,9                  46:25  <b>instruct</b> 34:19  <b>instructed</b> 9:4  <b>instructing</b>                  30:22 31:14                  34:2  <b>instructions</b>                  11:22  <b>instrument</b>                  55:10 134:5                  135:2,11,16,18  <b>instruments</b>                  116:5 132:20                  133:6 163:6  <b>integral</b> 131:2  <b>intellectual</b>                  14:21,25  <b>intended</b> 44:3                  64:12 65:10                  73:4,13 158:13  <b>intention</b> 131:13  <b>interfere</b> 163:11  <b>interject</b> 15:24  <b>interlock</b> 184:8  <b>interlocked</b>                  110:19  <b>interlocking</b></p>	<p>100:11  <b>interpret</b> 56:11                  159:21  <b>interpretation</b>                  36:9 102:4                  108:23 114:6                  116:3 143:15                  156:25 159:3                  168:16  <b>interpreting</b>                  87:14 169:5  <b>interruption</b>                  103:17  <b>intervascular</b>                  72:8  <b>interventional</b>                  12:17,18 43:9                  57:4 72:24  <b>interventionalist</b>                  43:17  <b>introduce</b> 55:12  <b>introducing</b> 56:2  <b>introduction</b>                  56:3  <b>invented</b> 61:13  <b>invention</b> 85:6                  155:17  <b>inventions</b>                  169:10  <b>inventors</b> 5:5                  81:3,5,9,14                  128:18  <b>invoices</b> 17:12                  17:17  <b>involve</b> 49:5  <b>involved</b> 13:13                  18:14 24:12                  42:23 43:2,5,6                  53:12 61:4                  62:2 71:20                  76:17 81:11                  144:13 149:18                  166:24 173:25  <b>involvement</b>                  13:13  <b>involves</b> 22:19                  64:23 93:23</p>	<p><b>involving</b> 42:15                  75:14  <b>IP</b> 25:2  <b>IPR</b> 7:22 8:2                  9:20,22 10:2                  11:15 22:13                  24:15,19 26:24                  27:2,5,23                  35:16 36:1                  37:25 38:3                  39:15 40:13,16                  45:17 48:21                  51:24 54:7                  80:4 127:17                  129:10 130:6                  150:22 171:3  <b>IPR2025-00156</b>                  1:10 6:11  <b>irregularly-sh...</b>                  186:20  <b>Irvine</b> 3:8  <b>Island</b> 7:19                  28:14 32:23  <b>ISO-certified</b>                  16:8  <b>issue</b> 35:22                  48:21 139:24  <b>issues</b> 10:8 14:22                  18:14 19:3                  35:7,12 47:7                  125:3  <b>It'll</b> 159:10  <b>item</b> 186:21  <b>items</b> 122:7</p>	<p><b>Joshua</b> 6:25  <b>journal</b> 49:6  <b>July</b> 32:14,19  <b>June</b> 9:19  <b>junior</b> 20:1  <b>justify</b> 19:22</p> <hr/> <p style="text-align: center;"><b>K</b></p> <hr/> <p><b>keep</b> 41:21  <b>key</b> 16:9 35:7                  112:7 123:4                  174:25  <b>keyword</b> 119:11                  124:3  <b>kind</b> 47:8 128:13  <b>kinkability</b> 58:7  <b>kinking</b> 62:10  <b>kites</b> 158:1  <b>Knobbe</b> 3:5 7:1  <b>know</b> 8:4,23 9:8                  22:16,18 30:4                  30:7 35:20                  37:9 39:1,20                  44:13 46:5                  55:6 60:7                  61:12,15 68:1                  73:9 75:13                  77:13 79:14                  81:18 85:1                  93:8 98:22                  107:20 110:10                  113:3 115:5,15                  122:20 124:11                  140:19 145:11                  146:6,18 154:1                  155:14 156:9                  156:18 168:2                  171:25 179:8                  181:2  <b>knowing</b> 144:13  <b>knowledge</b> 28:20                  63:3 173:5                  180:3  <b>known</b> 121:3                  148:23 176:19                  178:25 180:17</p>
--	--	---	--	---

<p style="text-align: center;"><b>L</b></p> <p><b>L.L.C</b> 191:1</p> <p><b>lab</b> 64:18,22 65:4 74:15</p> <p><b>labeled</b> 102:9</p> <p><b>laboratories</b> 26:7</p> <p><b>laboratory</b> 16:8</p> <p><b>labs</b> 26:7,8 56:14</p> <p><b>lack</b> 87:8 113:17 166:4</p> <p><b>language</b> 47:6 48:16</p> <p><b>large</b> 56:12 62:2 62:2,11 70:18 139:2</p> <p><b>larger</b> 59:21,24 60:5,10 61:22 61:25 62:3,4 63:9 72:23 137:4 138:6,17</p> <p><b>largest</b> 60:1 61:18</p> <p><b>Lastly</b> 119:3</p> <p><b>law</b> 8:9</p> <p><b>layer</b> 58:4,6</p> <p><b>lead</b> 107:2 145:20</p> <p><b>Leading</b> 184:5 184:10 185:12 186:24</p> <p><b>leads</b> 151:11</p> <p><b>leak</b> 134:17</p> <p><b>leakage</b> 134:3,7 135:3</p> <p><b>learn</b> 23:20 24:5</p> <p><b>learned</b> 25:25</p> <p><b>learning</b> 26:4 173:23</p> <p><b>led</b> 87:1</p> <p><b>left</b> 57:15 92:22 92:25 93:2</p> <p><b>legal</b> 15:5 18:22 18:24 19:5,9 42:23 45:20 74:22 82:22</p>	<p>83:12 153:12 172:13 182:4,5 182:8,12,15</p> <p><b>length</b> 136:24 137:1 138:4</p> <p><b>lesions</b> 43:17</p> <p><b>Leslie</b> 1:22 2:14 6:19 189:18</p> <p><b>let's</b> 71:7 72:17 78:25 99:2 135:16 140:1 177:5</p> <p><b>level</b> 15:12 63:17 169:22</p> <p><b>levels</b> 162:20</p> <p><b>ligate</b> 96:18</p> <p><b>limited</b> 35:6 46:6 54:1,5,23 55:17 75:13 125:20</p> <p><b>limiting</b> 14:14 14:18</p> <p><b>line</b> 9:9 59:13 78:4 100:21 113:5,7,14,19 116:24 117:8 140:13 171:25 172:3 176:22 177:6,11,13,18 179:7 180:25 184:20,25 192:11</p> <p><b>lines</b> 92:7,9 117:4 122:2 125:24</p> <p><b>list</b> 13:9 34:25 41:21,24,25 45:11 72:15 126:1 174:23</p> <p><b>listed</b> 44:9,22 45:2,11 47:12 47:14 51:19 81:4 122:7 128:18 174:11 174:16 180:17</p> <p><b>listing</b> 181:6</p> <p><b>lists</b> 174:4</p>	<p><b>literature</b> 81:7</p> <p><b>litigation</b> 23:3</p> <p><b>little</b> 22:18 52:12 92:6 94:16 124:16,20 170:11</p> <p><b>LLC</b> 192:1</p> <p><b>LLP</b> 3:5 190:1</p> <p><b>located</b> 32:21</p> <p><b>locus</b> 115:13</p> <p><b>long</b> 13:9 25:10 31:4 50:14 57:11</p> <p><b>longer</b> 19:21 84:20 99:8 143:11</p> <p><b>longitudinal</b> 113:8 114:3,10 115:1,19 116:4</p> <p><b>longitudinally</b> 95:5 137:3</p> <p><b>look</b> 24:9 26:20 32:15 38:14 46:15 71:7 78:25 92:5,5 99:2 100:20 105:22 107:4 110:6,11,12 113:2 132:22 140:17 144:15 145:5 151:14 153:20 154:15 161:25 171:24 175:18 177:5 179:7 183:6,12 184:13,16 185:16</p> <p><b>looked</b> 10:6,7 15:15 38:20 50:19 60:20 125:4 136:5</p> <p><b>looking</b> 15:11 54:15 105:8 108:12 121:25 125:24 126:7 135:10 140:7 154:3 155:4</p>	<p>172:17 177:12</p> <p><b>looks</b> 105:22 162:6,8</p> <p><b>loop</b> 82:1 89:20 89:21,25,25 90:6,10,17,17 91:2,9,20 92:2 92:3,10,15 93:9,23 94:19 103:25 104:6 104:11,14,22 105:1,11,16,21 105:24 106:10 183:15,18</p> <p><b>looped</b> 96:23</p> <p><b>loops</b> 93:23 94:1 94:7,14,19 96:6 97:5 98:2 98:9,17</p> <p><b>Los</b> 1:14 2:8 3:16 6:13 190:2</p> <p><b>lose</b> 84:16</p> <p><b>lot</b> 26:5 72:10 105:22 136:7,8 149:18</p> <p><b>lots</b> 58:7 160:22</p> <p><b>low</b> 18:6,7,10 79:9,13,14</p> <p><b>low-density</b> 119:24</p> <p><b>lower</b> 19:23 92:23 119:25</p> <p><b>lumen</b> 53:17 59:24 70:19 71:1 136:24 137:7,25 138:7 138:10 139:1,2 139:6 146:4,8 146:21 147:5 147:15 156:10 156:12,15 157:9 185:4,10 186:13,17,20</p> <p><b>lumens</b> 53:18 62:3 70:20 138:17</p>	<p><b>lunch</b> 126:21 127:4,10</p> <p><b>lure</b> 68:6,21</p> <p><b>lure-type</b> 67:22 67:25 68:15 69:1</p> <p><b>lysine</b> 74:9</p> <hr/> <p style="text-align: center;"><b>M</b></p> <p><b>M</b> 1:24 191:1 192:2</p> <p><b>machined</b> 148:4 148:5</p> <p><b>machining</b> 137:21 149:2 150:5</p> <p><b>main</b> 3:6 124:1 161:7</p> <p><b>majority</b> 57:3</p> <p><b>making</b> 62:5 121:2 148:10 148:21</p> <p><b>manage</b> 15:22</p> <p><b>managed</b> 16:7 57:8</p> <p><b>manipulating</b> 166:16,23</p> <p><b>manipulation</b> 78:10 166:5 168:12</p> <p><b>manufacture</b> 13:21 97:1,6 150:10</p> <p><b>manufacturing</b> 172:20 175:17 175:24 176:8 176:20 179:14</p> <p><b>mark</b> 92:23,25 93:1,3</p> <p><b>marked</b> 27:5,8 32:1,5 54:7,9 80:4,6 127:17 127:19 129:9 129:12 150:22 150:25 171:3,5</p> <p><b>marks</b> 52:18 99:12 127:5</p>
--	---	--	---	---

<b>Martens</b> 3:5 7:1	69:10 73:18	17:4,10 22:8	181:21 184:3,8	186:2
<b>matching</b> 139:12	78:22 85:15	22:14 30:1,5	185:7	<b>mischaracteri...</b>
<b>mate</b> 68:23	88:20 89:20	37:1 54:18,19	<b>memoirs</b> 64:2	46:4 64:15
<b>material</b> 63:15	90:18 95:5	54:25 55:5	<b>memory</b> 38:12	65:13 90:13
100:7 117:21	105:24 110:11	56:18 68:6	60:8	91:12 97:8,16
117:23 118:1	113:16 119:8	79:21,21 81:12	<b>mention</b> 42:11	105:5 106:2
118:12,13,24	119:22 123:22	125:9,11	96:12	108:8 109:12
120:9 122:20	124:23 135:7	138:18 149:18	<b>mentioned</b> 12:24	125:7 130:1
157:18,25	141:2,8 142:14	190:3 191:4	31:24 56:2	134:21 177:15
158:4,13,16	142:20 143:4	192:8	70:17 73:12	<b>misstatements</b>
161:17 172:19	143:10 153:4	<b>medicated</b> 95:23	77:21 95:19	29:5,7 33:12
172:22 173:6	157:8 163:9	<b>medication</b> 9:16	146:1	<b>Mm-hmm</b>
173:18,23,24	165:3	<b>meet</b> 49:16,19	<b>mentions</b> 118:9	160:10
173:25 175:5	<b>meaning</b> 46:21	<b>meeting</b> 50:2,5	121:7 158:7	<b>modification</b>
176:9 179:13	122:22 140:21	50:10,12,14,17	180:13	62:16 65:24
179:23	141:25	51:3	<b>met</b> 49:21 50:7	66:7
<b>materials</b> 30:15	<b>means</b> 88:24	<b>member</b> 20:2	<b>metal</b> 54:3	<b>modifications</b>
43:25 97:18	113:13 114:5	82:19,25 83:10	117:11 118:23	65:18 137:10
117:10,15	118:10 124:20	84:5,21 86:1	119:3,4,10,13	137:14 138:1
118:18,20	142:11 143:17	86:13,24 88:9	120:5 121:8	138:14
120:3,15 126:2	144:3 145:12	95:6,9 96:7,18	122:20 125:10	<b>modified</b> 137:23
132:20 158:21	159:18 164:23	102:21 103:1,5	<b>metals</b> 147:24	<b>modify</b> 66:4
158:24 159:4,5	167:8,9 172:5	103:8 104:1,15	149:16 150:1	136:17,21,25
159:23,25	189:23	105:1 109:17	<b>method</b> 178:1,10	137:6,15
160:5,24	<b>meant</b> 12:10	113:9 115:2,8	<b>methods</b> 74:3	<b>modifying</b> 138:6
161:14 172:24	157:23 158:9	115:20 131:3	148:9,21	138:16,25
174:3,5,11,13	159:14	141:17,22	150:15 176:14	<b>module</b> 144:5,18
174:16,18,23	<b>measure</b> 72:4	142:2 143:5,11	178:17	145:1 146:4
176:13,14,20	165:4	143:18,21	<b>micron</b> 88:1,2	<b>molding</b> 148:12
<b>matter</b> 6:6 17:13	<b>measurements</b>	146:22 147:6	<b>mid-'80s</b> 68:14	148:18 149:2
17:20 18:13	85:7	147:11,14,17	69:6	150:7 175:20
22:19 52:23	<b>measuring</b> 12:2	147:20 148:3	<b>mid-1980s</b> 68:5	180:13
80:12 99:21	139:3	153:9,24 155:2	<b>millimeter</b> 85:20	<b>moment</b> 56:2
117:23 127:13	<b>mechanical</b> 74:8	157:17 159:13	85:24	93:13 99:7
138:9 170:22	140:23 149:23	160:1,6 177:8	<b>millimeters</b>	159:11
190:6	<b>mechanism</b>	177:22 178:2	83:22	<b>monetary</b> 21:17
<b>matters</b> 11:12	111:13 147:11	178:10,17	<b>mind</b> 14:7 20:12	<b>monitor</b> 6:16
18:22,25 19:5	<b>MedAmicus</b>	179:23 180:4	58:9 85:5	<b>month</b> 15:9,9,14
19:8,9 21:6	128:23	180:13,18	115:6,16 120:6	15:15
42:24 43:4	<b>media</b> 52:19	181:7,7,8	132:18 138:15	<b>moon</b> 130:20
81:12 182:4,5	99:13 127:6	<b>members</b> 141:16	159:19	<b>morning</b> 7:14
182:8,12,15	170:18	142:1,8 143:4	<b>minimal</b> 163:11	<b>motion</b> 105:8
<b>maximum</b>	<b>medical</b> 1:7 4:14	143:9,10,20	<b>minimize</b> 62:10	<b>move</b> 126:13,17
167:13,13	4:17 5:8 6:7	144:4,17 145:1	62:24	<b>movement</b>
<b>mean</b> 10:5 21:7	7:22 11:20,20	148:10,22	<b>minimum</b>	166:10
23:12 49:24	12:20 13:11,18	149:7 179:12	167:11,11	<b>moving</b> 62:12
56:23 60:12	13:21 14:14	179:18 181:13	<b>minute</b> 122:12	<b>multi-geometry</b>

<p>125:1  <b>multiple</b> 53:18                      59:12,18 70:19                      71:12 158:4                      163:5</p> <hr/> <p style="text-align: center;"><b>N</b></p> <hr/> <p><b>N</b> 3:1 4:1,1 5:1,1                      6:1  <b>naked</b> 88:3  <b>name</b> 5:5 6:17                      7:15 16:19,20                      16:21 57:2                      189:15 191:5                      192:9  <b>narrow</b> 113:7                      114:3,10,25                      115:19 116:4  <b>nature</b> 88:1  <b>navigate</b> 43:18  <b>necessarily</b>                      62:15 94:23                      108:1  <b>necessary</b>                      112:24 130:5                      180:3  <b>necessitates</b>                      111:5  <b>need</b> 8:11 9:7                      59:24 68:23                      86:11 119:16                      136:25 137:6                      138:14 186:1  <b>needed</b> 15:21                      65:18 139:2,4  <b>negative</b> 66:14                      66:25 69:7,17  <b>negotiation</b>                      19:11  <b>new</b> 35:9,12  <b>nitinol</b> 121:7,8                      121:13,18  <b>non-circular</b>                      115:8,13 116:6  <b>non-interlocki...</b>                      100:15 101:2,7                      101:19 102:1</p>	<p>103:6 106:8  <b>non-legal</b> 19:2  <b>non-obviousness</b>                      39:24 40:6,17  <b>nonspecific</b>                      173:14  <b>normal</b> 12:19                      120:10  <b>normally</b> 14:3  <b>NOTARY</b>                      191:22  <b>note</b> 93:7  <b>noted</b> 191:11  <b>notes</b> 189:11  <b>notice</b> 2:14  <b>noticing</b> 190:12  <b>noting</b> 190:12  <b>number</b> 6:4                      17:24 27:6,19                      27:24 45:1                      52:19 56:12                      75:14,20 99:13                      102:10 127:6                      149:3 170:18                      174:4 181:12                      181:20  <b>numbers</b> 55:4                      162:8  <b>numerous</b> 47:3  <b>NW</b> 1:24 191:1                      192:2</p> <hr/> <p style="text-align: center;"><b>O</b></p> <hr/> <p><b>O</b> 4:1 5:1 6:1  <b>O-R-E-N-S-I-S</b>                      20:18  <b>oath</b> 2:17 8:8  <b>object</b> 30:20  <b>objection</b> 14:1                      14:10 15:24                      25:16 30:12                      31:13 33:3                      34:1,18 35:17                      36:6 46:3                      64:14 65:12,21                      69:25 70:4,11                      71:3 74:21</p>	<p>76:11 77:17                      81:22 82:10,21                      83:11 84:6,22                      85:8,16 86:3                      86:14 87:2,18                      88:10,21 89:10                      90:2,12,20                      91:11,16,21                      92:11 93:4,19                      94:2,8,20                      95:10 96:8,19                      97:7 98:3,12                      98:19 100:3                      101:8,20 102:2                      102:16 104:3                      105:4 106:1                      107:11,18                      108:7,16 109:2                      109:11,22                      110:8,24 112:5                      112:19 113:22                      114:12 115:3                      115:22 116:7                      117:18 120:19                      121:14 122:8                      123:1,14,23                      124:17 125:6                      125:17 126:3                      129:25 130:16                      131:9,21                      132:15 133:9                      134:8,19 135:4                      135:21 137:18                      139:18 141:10                      141:18 142:3                      142:12,22                      143:12,22                      148:15 149:8                      150:16 152:20                      153:11 154:7                      156:2 158:10                      160:18 161:5                      161:18 162:14                      163:1,20 164:5                      166:1,12 167:1                      167:19 168:8                      168:25 169:6</p>	<p>169:17 170:3                      172:12 173:7                      173:19 175:7                      176:1,10,23                      177:14 178:12                      179:3 180:6,19                      181:23 183:20                      184:4,9 185:11                      186:23  <b>objections</b> 9:2                      97:15 148:24                      154:17 189:7  <b>objects</b> 157:24  <b>observable</b>                      83:23  <b>observed</b> 65:3                      69:5 77:10,22                      96:17 120:8  <b>observer</b> 26:11  <b>observing</b> 64:11                      74:13  <b>obtain</b> 20:10  <b>obviated</b> 169:10  <b>obviously</b> 41:14                      71:12 139:10  <b>occasion</b> 26:9                      136:17  <b>occasional</b> 62:1  <b>occasions</b> 54:23                      64:17 65:15,17  <b>occlude</b> 131:13  <b>occur</b> 92:20                      157:11  <b>occurred</b> 144:23  <b>occurring</b> 22:12                      115:11  <b>occurs</b> 92:16                      111:4 112:12  <b>OD</b> 62:23 137:4  <b>offer</b> 38:10 40:5  <b>offered</b> 21:24                      24:14 29:15                      39:16 46:2  <b>offers</b> 169:22  <b>offhand</b> 56:23                      63:10  <b>office</b> 1:1 6:9</p>	<p>41:23 190:7,15  <b>offices</b> 2:2  <b>officiated</b> 2:16  <b>oftentimes</b>                      133:13  <b>Oh</b> 51:12 147:2  <b>okay</b> 8:21 10:9                      10:15,23 11:4                      11:7 16:21                      17:3,16 18:5,7                      18:24 19:4                      21:13,24 22:16                      23:8,20 27:22                      28:2 33:7,20                      36:12 37:11,16                      38:15 39:2,21                      41:2,5,14 43:4                      44:15,18 45:1                      45:22 46:8                      48:8 51:17                      52:11 53:8                      54:17,21 55:3                      55:8,19 56:6                      56:24 59:5                      63:19,24 68:12                      68:18 78:21,25                      79:11,16,22                      80:3,13,17                      81:19 83:2,20                      84:1 87:23                      94:25 100:24                      101:5 113:4,12                      116:17 117:1                      118:20 122:6                      126:25 127:16                      128:2,6,10,14                      129:2,3,8,19                      130:3,10                      134:14 140:9                      143:17 146:19                      147:4,10 148:8                      150:13 151:10                      152:10 154:24                      155:13,15                      159:12,17                      162:6,11                      164:14 168:22</p>
---	--	--	--	---

171:2,14,18 172:2,7 179:9 179:11 181:3 181:10 182:11 182:18 184:15 185:16,25 186:3 187:12 187:23 <b>older</b> 41:16 <b>OLSON</b> 3:5 <b>once</b> 49:22 163:13 <b>ones</b> 47:4 <b>ongoing</b> 15:21 <b>online</b> 23:13 24:3 <b>open</b> 78:5 146:5 <b>open-heart</b> 13:5 <b>opening</b> 82:20 83:10 84:5 86:2,24 88:9 144:22 <b>operate</b> 170:1 <b>operated</b> 130:15 <b>operates</b> 130:12 152:16 <b>operating</b> 26:5 56:12,13 64:24 <b>operation</b> 25:8 149:19 150:7 <b>operations</b> 148:18 150:5 <b>operator</b> 163:4 164:25 165:4,7 165:17 166:3 166:15,22 168:11 <b>opine</b> 84:3 111:20 139:23 <b>opined</b> 106:12 153:15,23 169:10 <b>opining</b> 14:22 <b>opinion</b> 38:23 39:16 44:7 56:15 79:23 85:22 86:10	91:6 92:10 97:5,11,13 104:13,25 106:3,15,18 112:3 114:16 116:15 118:5 118:25 119:4 119:15 124:9 131:17 132:4,6 134:11 139:14 155:9 156:12 168:22,23 169:4 175:3,12 183:17 <b>opinions</b> 24:14 24:18,23 25:2 26:24 29:15 31:11,23 33:14 33:20 35:15 36:1,1,12 37:24 38:1,4,7 38:10 39:23 40:5,16 46:2 46:10 47:11 50:18 51:4,15 51:19 79:3,24 88:18 89:18 99:4 114:19 123:11 125:13 128:8 129:20 134:15,25 135:18 150:13 151:22 153:18 159:23 160:4 169:25 <b>opportunity</b> 10:1 23:8 26:14 51:22 54:13 152:1 171:19 <b>opposed</b> 94:19 105:8 110:19 <b>opposing</b> 130:22 <b>optimize</b> 62:18 <b>option</b> 140:13,14 147:23 190:9 190:10	<b>options</b> 149:4 <b>order</b> 65:19 169:15 187:16 <b>ordinary</b> 63:2 79:4,10,17 91:7 98:1 137:17 148:8 149:14,22 160:12 173:4 173:16 174:9 174:14,21 175:3,22 176:6 176:18 178:8 179:1 180:2,16 181:19 <b>organization</b> 18:17 <b>organizations</b> 20:10 <b>organized</b> 16:7 <b>original</b> 35:8 36:18 122:23 189:12 190:11 <b>orthopedic</b> 12:19 <b>ostium</b> 43:14 57:14 <b>out-of-round</b> 134:5,17 <b>outer</b> 139:7 <b>outline</b> 31:1 34:9 34:13,17 35:4 <b>outside</b> 82:25 90:16 91:4 109:5 183:21 186:24 <b>overall</b> 15:15 <b>owned</b> 9:23 <b>owner</b> 1:8 7:8,22	<b>page</b> 4:2,11 5:3 28:5,6,16 32:15,16 41:6 45:3,12 55:3,4 55:5,24 56:22 81:4 140:2,4 147:21 174:17 183:10,25 184:17,17 185:18,20,20 185:21 190:12 191:4 192:11 <b>pages</b> 140:7 191:7 <b>paper</b> 45:12 133:16 <b>papers</b> 22:23 45:11 <b>paragraph</b> 37:8 37:12,17 38:16 38:25 39:3,19 39:22 46:11 71:7,10,15,18 72:15 73:16 78:25 79:7 100:20 121:24 125:24 140:1,5 140:10,12,18 142:20 146:18 146:21 147:1 147:22,22 150:9 155:13 155:16 156:21 157:16 158:7 159:12,18 161:12 164:12 164:15 166:8 166:20 168:17 172:16,17 174:2,17 175:15,18 176:21 178:16 180:10,18,23 180:24 181:10 185:17,21 186:2,5 <b>paragraphs</b>	46:13,18 <b>parallel</b> 22:13 83:3,17,22 92:8 102:6 110:18 <b>Park</b> 2:6 6:13 7:5 <b>part</b> 13:1 38:13 46:20 54:13 71:14 99:3 101:13 131:24 134:14,25 <b>partial</b> 145:16 145:21 146:14 <b>partially</b> 152:24 162:21 <b>participated</b> 23:17 50:4 <b>particular</b> 30:17 51:9 62:7 71:13 73:15 79:20 85:12 87:5 90:5 93:8 93:11,13 97:3 101:23 105:23 111:15 114:21 115:12 118:1 133:21 135:7 139:24 144:10 144:20 145:24 146:1 152:13 154:2 159:15 167:24 172:23 178:3 179:24 181:14 <b>particularly</b> 97:22 136:11 <b>partly</b> 145:13 <b>parts</b> 72:5 75:7 75:12 152:7 <b>party</b> 16:25 <b>passed</b> 155:19 156:1 <b>patent</b> 1:1,3,8,10 4:18,20,22,24 6:8,9 7:8,22 9:23,24 11:11
---	--	---	---	--

27:19,24 28:3 30:17 32:13 34:24 38:3,8 38:20 39:15 40:13 47:6,7 48:15,17,18 49:4,9 51:5 80:11,13,18,22 80:24 81:4,8 81:17 88:19 89:19 90:10,16 91:8,20 93:18 94:1 96:25 99:24 100:2,13 101:1 102:13 103:24 108:10 113:3 114:19 116:18 117:2,7 117:8,17,21 121:7,12 123:5 123:12 124:2 128:1,19,22 129:2,3,5,23 140:14 151:9 151:12,15,19 152:1,4,7,11 169:12 171:13 171:19,25 172:4 184:14	191:5 192:9 <b>pause</b> 99:7 103:20 <b>pay</b> 45:19 114:21 <b>payment</b> 21:18 <b>pays</b> 17:17 <b>pediatric</b> 61:2 <b>people</b> 56:11 149:18 <b>perceive</b> 88:14 103:3 <b>percent</b> 15:10,17 16:13,14 47:6 47:7 53:23,25 182:14 <b>percentage</b> 15:7 182:5,11 <b>perfect</b> 91:3 133:8 <b>perfectly</b> 131:18 131:25 132:5,7 132:9 139:15 139:21 <b>perform</b> 18:21 <b>performance</b> 22:4,9 <b>performed</b> 20:6 74:24 75:17 <b>period</b> 25:10,24 47:21 65:4 68:4 69:2 71:18 73:1,11 73:18,22 74:12 75:19,21,25 78:18 136:5,6 136:8,10,11 137:10 190:13 <b>periods</b> 19:21 <b>peripheral</b> 57:5 57:18 72:22 75:14 76:23 77:4 <b>Perkins</b> 2:5 3:13 7:7 17:2,17 20:2,7 21:1,4 22:4 36:21	190:1 <b>Perkins'</b> 29:20 <b>permit</b> 147:17 <b>person</b> 26:18 49:22 50:8 63:2 79:4,16 91:6 98:1 137:16 148:8 148:10 149:14 149:22,25 160:11 173:4 173:16 174:9 174:14,21 175:3,21 176:6 176:18 178:7 178:25 180:1 180:15 181:18 <b>pertinent</b> 71:14 <b>petition</b> 128:4 <b>Petitioner</b> 1:6 3:3 6:6 7:2 79:13,25 128:3 130:6 <b>Petitioner's</b> 79:4 79:18 <b>Ph.D</b> 1:13 2:1 7:9 188:3 190:1,4 191:5 192:9 <b>pharmaceuticals</b> 72:6 <b>photo</b> 108:20 <b>phrase</b> 79:15 116:4 142:20 154:2 157:3 185:3 <b>physical</b> 62:25 88:1 <b>physically</b> 26:14 66:9 167:23 185:14 <b>physician</b> 12:5,8 12:17,21,22 57:8 64:11 65:9 66:9 73:4 73:8,10 <b>physicians</b> 63:14	64:4 65:18 <b>pick</b> 47:4 <b>pictured</b> 86:22 92:1 102:24 162:1 <b>pinching</b> 131:1,5 <b>place</b> 7:4 65:5 83:17 93:1 116:23 189:5 <b>placed</b> 43:13 <b>placement</b> 65:2 <b>planning</b> 59:16 <b>plans</b> 15:2 <b>plastics</b> 147:24 148:5 149:16 150:1 <b>play</b> 117:15 <b>please</b> 8:16,22 30:24 101:16 187:22 190:6 190:10,11,14 <b>point</b> 8:21 61:17 100:19 105:9 116:20 145:25 151:13 167:5 <b>points</b> 94:17 95:1,4,9 <b>polishing</b> 150:6 <b>polyethylene</b> 158:19 159:7 <b>polymer</b> 58:3,4,6 117:10 118:6 118:15,16,19 119:15,16,23 119:24 <b>polymers</b> 53:17 53:22 118:8 174:19 176:15 176:16 <b>polypropylene</b> 158:19 159:8 <b>polyurethanes</b> 174:19 <b>port</b> 67:14 <b>portion</b> 45:6,7,8 91:25 92:8 100:25 101:2	114:18 125:3 138:3,11,13 146:7 <b>portions</b> 5:7 46:9 47:1 80:25 83:6,21 84:3,19 85:23 86:10 87:15 88:6 92:7 112:1 144:5 <b>ports</b> 67:8,14,18 155:4 <b>POSITA</b> 79:12 79:25 121:4 125:8 148:22 173:21 <b>POSITAs</b> 120:9 <b>position</b> 155:8 163:13 164:4 174:8 <b>positioned</b> 102:5 <b>positions</b> 20:11 <b>possessed</b> 63:3 173:5 178:9 180:3 <b>possible</b> 120:12 149:11 163:15 <b>possibly</b> 120:14 <b>potential</b> 114:22 140:16 <b>potentially</b> 146:14 <b>practical</b> 149:12 <b>practicality</b> 132:19 <b>practice</b> 95:12 96:11 <b>preamble</b> 39:5 <b>precisely</b> 69:14 88:24 <b>preclinical</b> 138:21 <b>preexisting</b> 147:24 <b>preparation</b> 34:22 47:15 48:2,14,22
--	--	---	---	---

<p>49:7 52:8  <b>prepare</b> 36:17          36:21,22 47:18          49:16  <b>prepared</b> 27:1          71:11  <b>preparing</b> 29:25          52:2 80:14          171:15  <b>present</b> 3:19          50:12 170:2  <b>presented</b>          133:21 135:12  <b>press</b> 130:25          138:3,12  <b>pressure</b> 25:20          66:14,25 69:7          69:17 95:24          96:3 113:8,18          113:19,21          114:4,7,11          115:1,12,19          116:4  <b>pressures</b> 12:3  <b>pressurized</b>          78:14  <b>presumption</b>          8:23  <b>pretty</b> 13:2          66:11 103:9  <b>prevent</b> 131:14  <b>previous</b> 53:4          121:17  <b>previously</b> 27:4          27:8 32:5 54:7          54:9 58:19          60:20 80:4,6          125:20 127:17          127:19 129:9          129:12 150:22          150:25 171:3,5  <b>primarily</b> 72:21          73:3 75:9          136:24 138:21  <b>primary</b> 24:6          63:22  <b>principles</b> 25:19</p>	<p><b>prior</b> 10:16 11:4          11:8 25:8 44:6          48:20,23 49:2          49:3 51:6,7          52:2 63:11          81:11 128:3,6          128:14 136:1          136:11  <b>probably</b> 12:4          15:19 20:14,22          24:10 26:1          36:18 46:19          47:20 53:23          54:3 68:8 77:8          80:23 95:25          96:2 105:10,15          116:16 137:12  <b>probe</b> 74:8  <b>probes</b> 13:6  <b>procedure</b> 12:9          13:7 25:14          26:6,9,10          56:14 57:17          59:15,16 64:9          65:2 72:12          73:2,4 74:18          74:25 75:3          76:2,10 77:3          78:2,9 96:5          190:14  <b>procedures</b>          23:23 24:25          25:7,12,13,25          26:4 43:9 57:4          57:19 58:14          59:19,20 64:18          64:22 65:3,4          66:13 69:4          71:20,23,25          74:15 75:6,11          75:14,17,23          76:8,17,21,22          77:10,22 79:21          158:14,17  <b>proceeding</b>          22:12 187:25          189:4</p>	<p><b>proceedings</b>          22:13 76:5  <b>process</b> 23:14          30:10 33:24          59:9 60:18          138:16 139:13          166:25  <b>processed</b>          176:13  <b>processing</b>          117:25  <b>produce</b> 16:9          106:23 153:6  <b>product</b> 13:12          24:9 59:13  <b>products</b> 23:10          23:18,21 24:14          24:18 26:18          125:11  <b>professional</b>          13:25 14:8          18:17  <b>profile</b> 161:9  <b>project</b> 21:7,9          24:12  <b>projects</b> 13:13          53:12  <b>promised</b> 22:3,7  <b>proper</b> 39:9  <b>properties</b> 62:25          112:24 114:22          131:4 147:17  <b>property</b> 14:21          14:25  <b>proposed</b> 79:12  <b>prospective</b>          18:19  <b>protective</b> 98:23  <b>proverbial</b> 62:21  <b>provide</b> 9:13          33:17 114:10          129:8 134:1          164:19,24          165:3 166:21          168:18  <b>provided</b> 155:17  <b>provides</b> 166:9</p>	<p><b>providing</b>          178:19,24  <b>proximal</b> 67:1  <b>publication</b> 4:21          4:23 129:23  <b>publications</b>          49:3,5  <b>pull</b> 142:24          165:10  <b>pulled</b> 78:13          87:10 93:12  <b>pulling</b> 60:15          103:16 168:19  <b>pulmonary</b>          75:24 76:4  <b>pump</b> 69:14,16  <b>purchased</b> 190:8  <b>pure</b> 86:7  <b>purpose</b> 64:12          65:10 77:15          131:8 162:13          162:25  <b>purposes</b> 138:21  <b>Pursuant</b> 2:14  <b>pushing</b> 168:19  <b>put</b> 30:25 78:4          94:16 96:13          153:8  <b>putting</b> 105:7</p> <hr/> <p style="text-align: center;"><b>Q</b></p> <p><b>question</b> 8:17,19          8:24 30:20,24          31:15 35:21,23          38:6,23 70:5          74:21 86:18          91:16 92:14          101:11,13          103:10 120:22          121:17 145:7          149:17 154:16          168:3 174:25  <b>questioning</b> 9:9  <b>questions</b> 8:22          9:3 130:3          182:19 187:2          187:13 190:14</p>	<p>191:10,13  <b>quick</b> 23:24 99:6  <b>quickly</b> 20:4  <b>quite</b> 13:9 26:19          35:3 45:19          46:15 58:2          72:10 133:20          154:12 158:18          158:20  <b>quote</b> 113:6          122:3  <b>quote/unquote</b>          105:17</p> <hr/> <p style="text-align: center;"><b>R</b></p> <p><b>R</b> 3:1 6:1  <b>R&amp;D</b> 53:5,9  <b>radial</b> 57:13  <b>radiologist</b> 12:18  <b>radius</b> 87:9          111:1,6,10,17          111:22,23          112:3,11,16  <b>raised</b> 10:8          187:9  <b>range</b> 18:8,20,21          19:5,10 61:1          146:2 155:19          155:25 156:16          156:18,18          158:21,24          182:15  <b>ranges</b> 158:18  <b>rate</b> 18:2,17,25          19:14,16,23          20:3 182:2,6  <b>re-review</b> 145:23  <b>reach</b> 20:13          106:20  <b>reached</b> 144:2  <b>reaching</b> 106:18          153:18  <b>read</b> 44:11,16,22          113:5 157:1,21          158:22 180:11          183:13 186:2          191:6</p>
--	--	---	---	--

<b>read-on</b> 7:3	170:16 183:1	157:2,22 158:8	34:21 38:3	<b>reporter's</b>
<b>reads</b> 55:10	<b>recited</b> 185:10	159:24 164:10	39:15 40:13	189:13
<b>ready</b> 190:6	<b>recognize</b> 27:12	168:24 175:25	<b>relative</b> 123:4	<b>representation</b>
<b>real</b> 62:9	32:8 80:9	177:21 184:22	124:12	101:23
<b>reality</b> 133:17	111:21 127:22	186:10	<b>relatively</b> 123:7	<b>representing</b>
154:12	128:2 129:15	<b>referenced</b> 31:24	<b>relaxed</b> 146:7	6:19 7:7
<b>really</b> 19:13	129:18 151:4	92:23 190:6	<b>release</b> 140:25	154:12
26:25 47:5	171:9	<b>references</b> 44:23	141:3,9 144:14	<b>reproduction</b>
57:2 97:10	<b>recollection</b>	128:3 145:20	<b>released</b> 153:6	189:23
104:5 106:11	50:18 51:4,14	<b>referring</b> 11:24	162:22	<b>reputable</b> 54:25
116:11 128:17	51:18 59:1	44:19 47:8,23	<b>relied</b> 31:11,22	<b>requested</b> 33:19
131:23 134:10	100:18	48:18 68:3	106:20 112:2	<b>require</b> 59:17
145:3 150:2	<b>record</b> 6:22	83:14 91:2	128:4 140:19	62:3 89:8
159:20 175:1	20:17 52:16,20	95:3 101:2	169:4	<b>required</b> 16:2
<b>realtime</b> 99:8	99:10,14	129:6 136:23	<b>reluctance</b> 86:19	59:14 71:21
<b>reason</b> 9:12 35:2	103:19,22	158:24 159:2	<b>reluctant</b> 132:7	125:10
37:18 71:17	127:3,7 170:15	162:4 168:18	132:8	<b>requirement</b>
108:2 137:8	170:19 182:25	<b>refers</b> 102:13	<b>rely</b> 24:17 26:22	62:21 169:20
151:17 156:7	183:3 188:1	140:13,14	29:22	<b>requirements</b>
157:13 176:5	<b>recorded</b> 187:25	159:12 172:3	<b>relying</b> 112:14	19:21,22
<b>reasonable</b>	189:8 191:10	<b>reflect</b> 44:4	144:6	<b>requires</b> 15:25
143:25	191:14	103:14 145:16	<b>remained</b> 15:13	70:21 165:10
<b>reasons</b> 37:19	<b>records</b> 42:14	<b>reflected</b> 40:21	<b>remains</b> 74:11	169:14
<b>recall</b> 9:22 20:20	<b>recruited</b> 18:15	79:18	<b>remember</b> 9:17	<b>reserve</b> 37:17
22:22 34:12	18:16 20:1	<b>reflections</b> 12:4	51:7,11,13,17	40:9
36:16 42:16	<b>recruiting</b> 20:20	<b>refresh</b> 100:18	61:3 68:25	<b>residual</b> 157:9
45:5,10,16,18	<b>recruitment</b>	<b>refreshed</b> 50:17	69:6 74:13	<b>resilience</b> 147:19
46:8,11 52:4	20:14 24:12	51:3,14,18	75:16 177:20	<b>resistance</b> 58:6
54:15 61:12,20	<b>rectangular</b>	<b>regard</b> 38:24	<b>remembered</b>	166:4,5
62:9 63:8,17	117:3	79:20 123:5	35:7	<b>resorbables</b>
63:19 64:10,18	<b>redirect</b> 187:6,9	<b>regarding</b> 11:10	<b>reminder</b> 8:6	158:20
64:19 65:8,14	<b>reduce</b> 119:24	32:13 35:16	<b>removal</b> 73:20	<b>respect</b> 34:3
65:17,24 67:1	<b>reduction</b> 87:12	37:1,5 38:10	<b>remove</b> 74:10,17	38:3 90:23
67:15,17,21	89:2 112:10	39:16 40:16	75:23	144:12
68:17 69:13	<b>redundancy</b>	<b>regardless</b>	<b>removed</b> 76:4	<b>responded</b> 52:5
73:25 74:1	98:17,22	131:18 139:15	<b>rendered</b> 39:23	62:22
75:6,11,13,22	<b>refer</b> 9:24 12:14	<b>reimbursement</b>	<b>rendering</b> 79:2	<b>RESPONDENT</b>
76:14,16,18,19	28:3 40:1	21:19	79:23 123:11	3:11
78:8,12,15	48:23 91:1	<b>relate</b> 37:25	125:13	<b>response</b> 167:6
96:16 100:16	129:2 130:4	46:13	<b>repeat</b> 31:19	<b>restate</b> 101:15
135:9 153:22	159:3 161:13	<b>related</b> 9:19,23	<b>replacing</b> 56:17	<b>restores</b> 147:14
<b>recalled</b> 101:2	<b>reference</b> 27:19	38:7,13 54:3	<b>report</b> 71:10	<b>restrictions</b>
<b>receives</b> 172:9	38:5,11 51:10	169:9	106:4 140:20	125:20
<b>receiving</b> 21:16	89:13 100:16	<b>relates</b> 8:1 27:24	<b>Reported</b> 1:22	<b>result</b> 21:25
21:17	100:17 116:20	31:15 164:25	<b>reporter</b> 2:15	107:7 118:1
<b>recess</b> 52:17	128:7,11,15	174:12	6:18,23 8:12	132:13 133:25
99:11 127:4	140:2 146:17	<b>relating</b> 11:15	189:1,2,25	135:3

<p><b>resulted</b> 133:7  <b>resume</b> 40:21,24              41:3,6,16  <b>retained</b> 7:21              25:4  <b>retaining</b> 62:25  <b>retention</b> 25:9  <b>retract</b> 146:22              147:6,12,18  <b>retraction</b>              145:12  <b>retrieve</b> 42:4,4  <b>reveal</b> 10:22              34:19 50:21  <b>review</b> 10:1,12              23:24 24:1,13              24:17 34:24              39:9 44:6,8              45:3,9,23              46:18,24 47:9              48:1,20 49:9              50:16 51:23              52:1,7 53:1              54:13 93:25              99:18 100:1,17              127:10 130:10              151:16 152:1              162:11 170:25              171:19 190:8  <b>reviewed</b> 22:20              22:23 23:1              45:5,6 47:20              48:15 50:24              51:3 80:14,19              80:22,24 81:7              99:3 128:11,15              129:20 130:8              151:22 152:4              158:8  <b>reviewing</b> 14:21              30:15 45:16              46:8,11 48:5              48:12 51:14,17              91:8 108:5              177:20  <b>Rhode</b> 7:19              28:14 32:23</p>	<p><b>ribbon</b> 122:2,11              122:18  <b>ribbons</b> 125:15  <b>right</b> 11:1 15:10              17:15 19:1              37:17 40:9              53:13 54:4              66:10 79:14              80:1 92:21              93:3 108:12              116:16 121:20              121:21,22              135:15 143:8              147:2,3 161:14              181:8 182:21  <b>right-hand</b> 55:8  <b>rightmost</b> 146:7  <b>rigid</b> 120:9              124:9,11,12              130:21 140:24  <b>ringing</b> 78:19,20  <b>roadmap</b> 35:4  <b>role</b> 117:14  <b>room</b> 56:12,13              64:24  <b>rooms</b> 26:6  <b>rope</b> 122:2  <b>rotary</b> 164:17              165:20  <b>rotated</b> 164:17              168:7  <b>rotating</b> 152:11              152:14 171:22  <b>rotator</b> 165:19  <b>roughly</b> 31:4              42:7 182:14  <b>round</b> 133:17,20  <b>roundness</b>              133:13  <b>routine</b> 68:8  <b>routinely</b> 62:18  <b>RPR</b> 1:22              189:18  <b>rubber</b> 159:20  <b>rules</b> 8:5 190:14  <b>running</b> 167:17</p>	<p><b>S</b></p> <hr/> <p><b>S</b> 3:1 4:1,9 5:1              6:1  <b>sampling</b> 53:20              72:3  <b>sandwich</b> 57:12              58:4  <b>sat</b> 42:8  <b>satisfy</b> 104:10  <b>saw</b> 64:16 75:20              76:1  <b>saying</b> 24:21              38:19 46:22              93:1 132:24              156:17  <b>says</b> 37:17 41:7              41:10 43:24              45:12 113:6,13              114:2 121:25              159:22 164:16              166:20 168:17              179:12 181:11  <b>scale</b> 108:2              111:19,25  <b>scenario</b> 166:22  <b>scenarios</b> 132:12              132:18  <b>Schaffer</b> 5:6              51:10,12 128:1              128:11,15,19              129:3,23 130:4              130:7,11 131:8              134:16 140:2,2              140:13 142:21              146:17 147:21              183:14,17              185:8 186:10  <b>Schaffer's</b>              131:18 132:3,4              132:13 134:4              135:2,19              139:15 141:14  <b>science</b> 173:24              173:24  <b>scientific</b> 49:5              53:6 56:24</p>	<p>58:24 59:12,25              63:12,20  <b>scope</b> 70:1,12              71:4 84:8,24              85:10,18 86:5              86:16 90:21              92:12 94:3,9              98:4 106:3              114:16 115:24              116:8 142:13              148:16,25              149:9 150:19              153:13 154:9              154:11 158:11              160:7 170:4,6              173:8 183:21              186:24  <b>scratch</b> 136:17  <b>scrutinize</b> 47:5  <b>scrutinized</b>              128:17  <b>seal</b> 131:3,18              132:5 133:8,22              134:1 135:20              139:4,15 144:4              144:18 145:1              146:4,22 147:6              147:11,14,17              147:20  <b>sealed</b> 186:14,17              186:20  <b>sealing</b> 163:14              163:19  <b>second</b> 45:3 93:1              99:7 140:12              148:14 181:7  <b>second-to-last</b>              184:17  <b>secondary</b> 39:23              40:5,9,12,17              53:19 56:4              67:14 150:5  <b>section</b> 41:16              42:10 71:10              120:2  <b>see</b> 27:20 41:8              41:12 43:21</p>	<p>44:1 45:14              55:13 82:5              83:2 96:6              102:11 113:10              117:12 122:4              126:9 140:10              146:24 147:8              147:25 148:6              155:22 157:19              160:9 164:21              173:1 174:6              177:10,17              178:5,21              179:15 181:16              182:22 184:19              184:22 185:3,5  <b>seeing</b> 45:18              67:1,15 69:13              75:6,11,13,16              75:22 93:7,17              97:3  <b>seen</b> 25:7,11              90:22 122:19              125:9 155:17  <b>select</b> 139:6              172:21 173:5              174:22 175:5              175:16,23              178:1,9 179:22              180:4 181:12              181:20  <b>selected</b> 46:23              50:24 190:10  <b>selecting</b> 73:10              176:7,9  <b>selection</b> 173:25  <b>selective</b> 180:25              181:13,21  <b>self-sealing</b>              155:21 156:23              156:25 157:4,6  <b>semi-minimal</b>              19:22  <b>semi-rigid</b> 120:9  <b>sense</b> 8:13 14:24              16:6 25:18              64:20 66:3</p>
--	--	--	--	--

98:24 109:14 111:13 135:9 165:5,7 <b>senses</b> 165:17 <b>sensitive</b> 121:19 <b>sentence</b> 37:16 38:13 113:25 140:18 145:24 146:20 147:1,5 164:16 180:11 181:11 <b>September</b> 91:7 121:4 174:15 175:4,22 176:19 178:8 179:1 180:2,16 181:19 <b>sequence</b> 52:4 <b>serve</b> 7:21 <b>served</b> 23:2 41:18 53:5 <b>serves</b> 38:12 <b>services</b> 20:7 182:3 <b>serving</b> 15:4 <b>set</b> 36:2 42:24 125:14 189:5 <b>setting</b> 61:23,25 69:9,10,12 <b>shape</b> 105:14,16 106:9 107:9 139:16 <b>shapes</b> 116:19 <b>sheet</b> 122:2,11 125:3,5 190:11 191:11 192:6 <b>sheets</b> 120:10 125:10,15 <b>short</b> 9:1 <b>shorthand</b> 2:15 28:2 189:1,2 189:11 <b>shot</b> 105:9 <b>show</b> 81:21 87:15 154:21 184:2 <b>showing</b> 111:14	146:11 <b>shown</b> 55:23 82:15,18 104:14 105:19 106:7 144:9 145:2 185:7 <b>shows</b> 146:14 160:2 <b>side</b> 130:18,21 130:23,23 185:9,9 <b>side-by-side</b> 184:3 <b>sidewall</b> 183:16 183:19 <b>sign</b> 28:9 32:18 190:7,8 <b>signature</b> 28:7 28:16 32:16 190:6,12 191:4 191:17 192:22 <b>signed</b> 28:12,18 32:13,22 40:1 190:11 <b>significant</b> 43:7 84:9,16 85:3,5 <b>significantly</b> 18:18 50:1 136:10 <b>signing</b> 190:10 <b>similar</b> 25:7,13 25:18 34:7 35:3 106:9 120:10 157:25 <b>Similarly</b> 13:7 163:13 <b>simple</b> 58:3 117:22 137:21 156:13 165:9 <b>simply</b> 66:8,16 66:22 73:20 108:1,4 139:3 146:3 <b>Sincerely</b> 190:18 <b>single</b> 58:3 70:25 81:25 152:13 <b>single-lumen</b>	64:8 74:6 76:17 <b>sit</b> 35:25 104:24 111:21 114:23 153:22 154:3 159:17 175:2 <b>site</b> 24:6 57:7 <b>situations</b> 133:5 138:6 <b>six</b> 42:9 45:12 77:2 <b>size</b> 60:24 62:4,6 72:17,21 73:1 73:11 77:1 135:1,16 136:24 137:7 137:25 138:7 138:10 139:1 156:13 <b>sizes</b> 59:2,10,13 59:18 68:22 <b>sizing</b> 76:19 <b>skill</b> 63:2 79:5,10 79:17 91:7 98:1 137:17 148:9 149:14 149:22 160:12 173:4,16 174:9 174:14,21 175:4,22 176:6 176:18 178:8 179:1 180:2,16 181:19 <b>skilled</b> 172:21 175:16 177:25 179:22 181:11 <b>skills</b> 178:9 180:3 <b>skimmed</b> 10:6 <b>skimming</b> 47:8 <b>skiving</b> 150:6 <b>sleeve</b> 172:4,5,7 172:18,22 173:6,18 174:4 174:23 175:6 175:17,24 179:19 180:5	<b>slightly</b> 133:19 <b>small</b> 69:14 75:20 85:13,15 85:20 88:5 118:2,22 119:10,18 120:13 122:14 123:7,18,21 160:21 161:8 186:17 <b>smaller</b> 59:19 62:20 76:23,24 77:1 111:23 132:3 <b>smooth</b> 139:11 <b>snapshot</b> 93:10 107:5 111:15 144:11 <b>snapshots</b> 111:16 <b>so-called</b> 100:6 <b>soft</b> 119:10,11 120:5 121:8 <b>sorry</b> 7:5 51:12 100:21 140:8 145:8 180:23 185:20 <b>sort</b> 19:18 21:17 21:21 25:20 53:20 67:4,10 109:13 <b>sorts</b> 60:17 133:2 <b>sounds</b> 52:14 126:23 <b>source</b> 13:15 <b>sources</b> 44:5 <b>space</b> 88:6 111:15 115:9 <b>spacing</b> 87:25 <b>speak</b> 8:23 87:7 127:12 170:21 <b>speaks</b> 33:4 102:17 115:23 145:25 162:15 177:16 <b>spec</b> 112:8	<b>special</b> 56:14 64:17,22 65:4 72:6 74:15 120:22 <b>specialist</b> 12:17 <b>specialized</b> 12:21 67:23 70:18,19 119:5 119:7,16 <b>specialty</b> 11:20 12:15,20 13:1 13:11,18,21 14:15 26:6 <b>specific</b> 11:21,23 46:18 48:16 57:25 59:13 69:23 73:25 78:7 85:7 109:1 120:3 132:18 153:21 164:4 174:16 <b>specifically</b> 9:4 38:1 50:19 59:8 61:20 77:11 104:23 135:9 136:15 137:25 144:16 151:13 152:9 <b>specification</b> 91:14 100:6 106:21,22 112:2 144:5 145:20 168:17 <b>specify</b> 95:20 <b>specifying</b> 63:17 <b>speculate</b> 86:19 97:2 <b>speculating</b> 115:15 116:10 121:5 160:20 <b>speculation</b> 86:7 88:13 111:25 <b>spell</b> 7:15 20:17 <b>spend</b> 31:4 48:12 <b>spending</b> 36:17 <b>spent</b> 26:5 48:5 <b>spirit</b> 62:20
--	--	---	--	--

<b>spoken</b> 81:5	<b>stating</b> 82:7	107:15,22	<b>strand</b> 118:23,23	138:23
<b>sporadically</b> 128:12	<b>statis</b> 5:4 147:23	108:11,24	<b>strands</b> 158:4	<b>study</b> 69:15
<b>spot</b> 170:12	<b>steel</b> 54:2 58:5 120:4,4,8,13	109:8,18 110:2	<b>strategies</b> 15:2	<b>subcategories</b> 71:25
<b>spring</b> 141:4 142:8 162:1,2 162:8,13	120:18 121:3	110:13 111:8	<b>Street</b> 1:24 3:6 3:14 190:2	<b>subdivision</b> 58:20
163:23 167:4,5	<b>stenographically</b> 189:9	112:13 113:1	191:1 192:2	<b>subfilament</b> 126:16
167:15,24	<b>stent</b> 65:2	114:1,17	<b>strength</b> 161:8 161:23	<b>subject</b> 22:19 52:23 80:12
168:14	<b>stents</b> 12:13,24	115:17 116:2	<b>strike</b> 126:1	99:21 127:13
<b>spring-created</b> 141:21,25	<b>stiffness</b> 119:25	116:13 118:4	<b>string</b> 152:24 153:7,10 154:4	170:22
<b>springs</b> 145:17	<b>stopcock</b> 67:1,3 67:4,7,10,18	120:25 121:23	154:25 155:4	<b>submit</b> 17:12
<b>stage</b> 105:19,23	77:22 78:1,3,8	122:16 123:9	157:17,23	<b>submitted</b> 8:2 23:2 51:24
<b>staggered</b> 130:22	78:12	123:19 124:8	158:3 160:3,15	<b>subscribed</b> 189:14
<b>stainless</b> 54:2 58:5 120:3,4,8	<b>stopped</b> 13:5	124:21 125:12	161:2,16,22	<b>success</b> 21:21
120:13,18	<b>Stowell</b> 3:4 4:3 6:25,25 7:13	125:22 126:6	164:1	<b>suction</b> 66:14 74:10
121:2	11:3 14:6,16	126:20,25	<b>strings</b> 160:13 160:21	<b>sufficient</b> 79:15 161:22
<b>standard</b> 43:13 64:7 67:11,22	16:11 25:22	127:8,21	<b>strong</b> 97:11 161:17	<b>suggest</b> 56:17 57:25 146:2
68:13	27:10,11 31:3	129:14 130:2	<b>stronger</b> 159:4,6 161:13	<b>suggests</b> 57:2 113:25 144:22
<b>Stanford</b> 42:15	31:20 32:7	131:6,16 132:1	<b>structural</b> 57:25 69:23	<b>suitability</b> 174:13
<b>start</b> 116:23	33:6 34:11	133:3,24	<b>structure</b> 94:17 95:2,15 96:4	<b>Suitability's</b> 175:1
<b>start-up</b> 42:16	35:1,24 36:11	134:13,24	97:19 109:7	<b>suitable</b> 157:18 159:23,25
<b>started</b> 30:14	46:7 51:1	135:14,25	115:14 123:18	160:5 172:19
<b>starting</b> 26:1 81:20 100:21	52:11,21 54:11	137:22 139:25	123:21 130:21	172:19,22
<b>starts</b> 147:22 180:25	64:21 65:16	141:13,23	130:25 131:4	173:6,12,17
<b>state</b> 2:16 6:21 12:19 37:12	66:5 70:6,15	142:9,17 143:2	131:14 133:1	174:4 175:5
39:3 167:24	70:24 71:6	143:16 144:1	135:12 141:6	176:7,9 178:1
172:21	74:23 76:15	148:20 149:5	142:16 143:1	178:10,20
<b>statement</b> 37:14 38:16 39:6	77:20 80:8	149:13 150:20	158:3 166:6,17	179:13,13,22
40:4 71:11	82:2,13 83:1	151:2,3 153:2	166:23 167:8	180:4,12
125:23 139:9	83:15 84:12	153:16 154:14	172:9	181:12,20
156:20	85:4,14,21	154:19 156:6	<b>structures</b> 88:2	<b>Suite</b> 1:24 2:7 3:15 6:13
<b>statements</b> 28:19 28:21,22 29:1	86:8,20 87:13	158:15 160:25	<b>struggle</b> 122:10 122:17,18	190:2 191:1
32:25 33:8,15	87:22 88:17	161:10,24	125:4	192:2
<b>states</b> 1:1 4:18 4:20,22,24 6:8	89:6,14 90:8	162:23 163:7	<b>struts</b> 120:10	<b>summary</b> 44:5
155:16 175:15	90:15,25 91:18	164:2,8 166:7	<b>Stryker</b> 17:7,9 21:25 22:8	<b>sundry</b> 21:20
<b>static</b> 105:9	91:24 92:18	166:18 167:14	30:2,8 37:1	
	93:16,24 94:5	168:4,15 169:3	<b>Stuart</b> 7:18	
	94:13,24 95:18	169:13,23	<b>studied</b> 171:15	
	96:15,22 97:12	170:7,13,20	<b>studies</b> 72:7	
	97:23 98:7,15	171:7,8 172:15		
	99:1,16 100:9	173:10 174:1		
	101:12,24	175:11 176:4		
	102:7,19	176:17 177:2		
	103:23 104:12	177:19 178:15		
	105:18 106:6	179:6 180:9,22		
		182:1,18		
		183:20 184:4,9		
		185:11 186:23		
		187:4,12		

<p><b>supersede</b> 36:4  <b>supervise</b> 15:22  <b>supervised</b> 16:7  <b>supervision</b>              189:25  <b>supplemental</b>              4:15 32:12              33:8,17,22              34:14 36:10,22              37:2,5 38:9              40:1 47:23              71:8 80:12,14              135:8 151:23              153:18 171:15              183:7 185:19              185:22,23  <b>sure</b> 23:16 31:21              35:7 64:1 72:9              83:13,16 95:13              96:11 98:21              124:20 126:24              129:17 149:12              156:24 157:6              170:13 175:10              177:11  <b>surface</b> 123:18              123:21 124:7              143:1  <b>surgeon</b> 12:19  <b>surgery</b> 13:6  <b>surgical</b> 55:10              56:10,17,20              158:14,17  <b>surrounding</b>              131:3  <b>suspect</b> 61:24  <b>suture</b> 157:17              158:7,9,13,23              159:1,4 160:15              160:24 161:2              161:12,13  <b>sutures</b> 158:17              160:13  <b>swag</b> 21:11  <b>swear</b> 6:23  <b>sworn</b> 7:10              189:6</p>	<p><b>synced</b> 187:20  <b>synonymous</b>              90:11 91:10  <b>synopsis</b> 19:19  <b>synthesize</b>              158:20  <b>synthesized</b>              118:12  <b>synthetic</b> 117:11              118:9,11,14,17              118:21 119:1              157:25  <b>syringe</b> 66:16,17              66:24 67:2,5,9              67:17 69:8              70:10 77:23              78:4,13  <b>system</b> 12:2 13:4              25:15 75:3              98:17  <b>systems</b> 74:5</p> <hr/> <p style="text-align: center;"><b>T</b></p> <hr/> <p><b>T</b> 4:1,1,9 5:1,1  <b>table</b> 64:24,24  <b>tactical</b> 164:19              164:24 165:3              166:9,11,21,24              168:18  <b>tactile</b> 166:14              168:10,13  <b>tailored</b> 71:13  <b>take</b> 9:9 52:13              64:5,11 120:13              122:21 182:22              183:6 184:13              184:16 185:16              186:1  <b>taken</b> 6:5 65:5              76:1 189:4  <b>talk</b> 16:3 52:22              99:20  <b>talked</b> 63:6              126:8 144:12              182:2  <b>talking</b> 8:16 23:4              49:4 66:13</p>	<p>69:5 132:19              137:9,11 166:8              166:10  <b>talks</b> 180:11  <b>tangential</b> 92:22              93:2  <b>tape</b> 122:3  <b>target</b> 163:12              172:9  <b>technical</b> 16:9              45:20 103:17  <b>technically</b>              120:12 149:11  <b>technique</b>              172:20,22              175:17,24              176:8 178:2              179:14,23  <b>techniques</b>              137:15 175:19              176:21 178:17              178:20,23,25              180:12,17  <b>technology</b>              14:15 15:1,1              16:16 59:9  <b>telephone</b> 20:2  <b>tell</b> 9:16 69:14              108:5 146:15  <b>temperature</b>              121:19,22  <b>tension</b> 126:12              152:23 153:3,4              153:6 163:24              165:10,12              167:4,5,24  <b>tensioning</b>              103:15 162:19  <b>term</b> 14:4 39:10              48:24 56:20              57:24 58:12              69:22,23 78:22              78:24 87:8              88:15,20 89:3              89:7,20,24              90:10,17 91:9              91:9 112:7,14</p>	<p>113:17 117:2              122:18 123:4              123:10,12              124:12 125:3              140:15,19,21              141:8 142:11              142:18,19              158:2,23  <b>terms</b> 38:7              149:21 152:2  <b>test</b> 134:12  <b>tested</b> 72:17  <b>testified</b> 7:11              11:14 42:12              58:22 86:21              119:14  <b>testifying</b> 8:8              42:11  <b>testimony</b> 9:13              42:19 64:15              65:13 90:13              91:12 97:8,16              99:21 105:5              106:2 108:8              109:12 125:7              127:13 130:1              134:21 170:22              173:15 189:7  <b>testing</b> 16:7  <b>text</b> 38:14  <b>Thank</b> 27:10              32:3 151:2              171:7  <b>Thanks</b> 182:23  <b>theme</b> 58:8  <b>theoretical</b> 86:18              96:14 98:24  <b>theoretically</b>              95:17  <b>theory</b> 94:4,6              95:13 96:12  <b>therapeutic</b>              11:22 12:10,12              12:23,25 56:3              59:21 73:14  <b>therapy</b> 13:8  <b>thereof</b> 189:11</p>	<p>189:14  <b>thickness</b> 62:10              62:14,16,24              63:4  <b>thin</b> 87:7  <b>thing</b> 9:8 53:20  <b>things</b> 12:2              90:23 120:11              142:15 174:18  <b>think</b> 10:18 15:3              15:15 38:12              42:7,17 48:5              48:11 55:2,17              56:9 57:23              69:23 70:13              71:5 79:11              80:21 85:1,12              85:19 86:17              93:6 96:13              97:24 98:10              104:10,21              105:7 121:6,9              122:15 123:4              139:22 143:24              144:19 146:9              146:13 148:22              149:6,10              155:12 159:9              160:2 161:11              161:20 162:16              169:21 174:20              176:5  <b>thinking</b> 15:4              25:23,24 54:4              77:1 101:1  <b>thinner</b> 95:23  <b>third</b> 146:21              181:8  <b>Thornton</b> 45:2  <b>Thornton's</b>              51:23 52:7  <b>thought</b> 36:9              104:17 146:10              176:25  <b>threads</b> 122:1  <b>three</b> 7:5 45:6              47:21 48:9</p>
--	---	--	--	--

<p>59:4,10  <b>three-dimensi...</b>                  125:1  <b>Three-fifty</b>                  182:17  <b>thrombectomy</b>                  12:12 23:23                  25:1,4,11,25                  26:4,9 64:9,13                  65:11 66:12                  73:17,19,23                  74:18 75:3,5                  77:12  <b>thrombo</b> 74:9  <b>thrombus</b> 25:21                  73:20 74:2,4                  74:11 95:24  <b>tight</b> 163:14,14                  163:19  <b>tighten</b> 105:14  <b>tightening</b>                  105:13 115:10  <b>time</b> 6:16 15:8                  15:18 16:13,14                  19:20,21 24:11                  25:10,24 26:5                  36:16 39:24,25                  41:4 47:13                  48:5,12 50:8                  53:12 54:19                  60:4 61:17                  63:1 65:4 68:4                  69:2 71:18                  72:25 73:11,18                  73:22 74:12                  75:18,21,25                  93:10 107:5                  108:20 111:15                  128:10 136:8                  137:10,17                  144:11 151:25                  171:18 187:17                  189:5,6,8                  190:13  <b>times</b> 49:19                  80:21,23  <b>tip</b> 66:4 70:20</p>	<p><b>tissue</b> 53:20  <b>title</b> 43:23                  129:17  <b>today</b> 8:8,11,21                  9:2,7,13 14:23                  27:24 28:3,23                  35:25 47:16,19                  48:14 49:8,17                  52:9 114:23                  129:3 155:8                  175:2,13                  182:20  <b>today's</b> 6:15                  7:25  <b>Todd</b> 1:22 2:15                  6:19 189:18  <b>tolerance</b> 139:10  <b>tool</b> 57:3  <b>top</b> 20:24 43:24                  83:2,16 87:16                  88:7 92:6,7,24                  147:2,3  <b>topics</b> 187:8  <b>total</b> 94:11 95:1  <b>totally</b> 146:7  <b>touch</b> 134:12  <b>touching</b> 87:16                  87:24 88:3,14                  88:15 102:6  <b>Touhy</b> 133:12  <b>Trademark</b> 1:1                  6:9  <b>transcribe</b> 8:13  <b>transcribed</b>                  189:10  <b>transcript</b> 4:10                  5:2 10:2,11,13                  45:9 187:21                  189:10,12,22                  190:6,7 191:7  <b>transcription</b>                  191:10,12  <b>transcripts</b> 45:2                  45:4  <b>transition</b>                  126:21  <b>travel</b> 21:19</p>	<p><b>treat</b> 12:6 73:4,7  <b>treating</b> 12:5                  73:8,10  <b>treatment</b> 57:7  <b>Trial</b> 1:3 6:10  <b>trimming</b> 150:6  <b>Troy</b> 45:2  <b>true</b> 28:20,22,23                  33:1,2,9                  189:10 191:9                  191:11  <b>truth</b> 9:17  <b>truthful</b> 9:13  <b>try</b> 8:15 62:18                  159:20  <b>trying</b> 60:7                  159:21  <b>tube</b> 53:17 57:11                  58:3 60:18                  112:4,18 172:8                  172:10  <b>tubular</b> 55:10                  56:9 82:8,14                  82:19,25 83:10                  84:5,21 86:1                  86:12,24 87:10                  87:12 88:8                  94:17 95:2,5,9                  95:15 96:3,7                  96:18 102:21                  103:1,5,7                  104:1,15 105:1                  109:6,17 115:8                  115:14 123:8                  124:10 130:19                  131:3 135:11                  141:5,17,22                  142:2,16 143:1                  143:11,18,20                  153:1,9,24                  154:5 155:2                  166:6 167:7                  183:16,19  <b>tugged</b> 93:12  <b>Tuohy</b> 66:20,23                  67:2 68:8                  133:23 134:1</p>	<p>136:11,16,18                  136:21 137:7                  138:4,9  <b>turn</b> 28:5 37:8                  38:25 39:19                  41:5 55:4                  81:16 117:6                  140:1 147:21                  164:12 165:19                  183:10,24,25  <b>Twenty</b> 182:13  <b>two</b> 20:22 27:1                  46:12 47:21                  48:9 49:8 51:5                  59:2 65:25                  67:7,13 73:12                  83:6,21 84:2                  85:23,23 87:15                  92:6,9,16                  93:23 94:1,7                  94:14,16,19                  95:1,4,8 96:6                  96:17,23 97:5                  98:2,8,9,16,17                  105:12 111:16                  112:21 114:22                  120:6 149:24                  165:14,16  <b>two-way</b> 67:3  <b>type</b> 43:5 68:1                  96:5 152:11                  171:21  <b>types</b> 12:25                  68:12 76:10                  118:17,20  <b>typical</b> 58:3                  72:11  <b>typically</b> 12:1,16                  14:19 19:15                  60:16 64:23                  73:2 74:6                  78:10 138:5                  150:3</p> <hr/> <p style="text-align: center;"><b>U</b></p> <hr/> <p><b>U</b> 5:1  <b>U-shape</b> 143:19</p>	<p>184:8  <b>U-shaped</b>                  141:15 142:1                  143:4 144:3,17                  144:25 184:3                  185:7  <b>U.S</b> 1:10 27:19                  27:24  <b>ugly</b> 145:3  <b>ultrasonic</b> 12:3                  74:8  <b>ultrasound</b> 72:8  <b>unable</b> 154:25  <b>unclear</b> 101:14                  173:9,11,13  <b>undepressed</b>                  141:15 143:19  <b>underlying</b>                  14:25 16:15                  133:1  <b>underneath</b>                  41:10  <b>undersigned</b>                  189:2  <b>understand</b> 7:20                  7:25 8:7,22 9:5                  17:19 26:12                  35:20 38:21                  39:25 40:20                  53:4,11 63:11                  79:2 88:19                  89:19 90:10                  92:13 100:2,10                  100:13 101:10                  106:12,15                  121:8 129:5,22                  130:11 136:1                  140:15 141:7                  142:10,19                  143:3,9,18                  147:10 152:5,8                  152:15 155:7                  156:24 157:2,5                  157:7 158:2,23                  159:1 162:3                  164:23 165:2                  172:4 179:17</p>
---	--	--	--	--

<p>186:4  <b>understanding</b>                  17:16 27:22                  49:1 55:16                  63:15 76:3                  82:17 89:7,21                  89:24 93:21                  101:6,17                  102:15,20                  103:13 112:16                  113:13 114:4                  117:16 118:10                  125:15 126:12                  131:7 140:21                  144:9 147:16                  157:22 158:9                  159:14,18                  162:12,24                  164:9 172:8                  186:15  <b>understood</b> 8:14                  8:24 81:1 91:9                  158:5 161:12  <b>undetactable</b>                  88:4  <b>uniform</b> 132:21                  133:7 137:3  <b>United</b> 1:1 4:18                  4:20,22,24 6:8  <b>unsealed</b> 146:22                  147:7,12,18  <b>unsure</b> 142:5  <b>unusual</b> 122:13  <b>update</b> 41:3  <b>upper</b> 55:8  <b>urethral</b> 58:15  <b>use</b> 11:19,22                  12:5,9 13:18                  18:17 35:4                  56:16 64:6,12                  65:9,19 70:21                  72:22 73:7                  74:16 77:16                  85:2 89:3                  112:23 117:22                  131:12 133:14                  142:6 153:21</p>	<p>158:23 161:3  <b>user</b> 59:14,17                  165:23 168:6                  168:19  <b>uses</b> 56:1,8,20                  71:12 140:18  <b>usually</b> 14:4                  19:18  <b>utilized</b> 67:14                  125:10 148:19</p> <hr/> <p style="text-align: center;"><b>V</b></p> <hr/> <p><b>v</b> 4:13,17 190:3                  191:4 192:8  <b>vacuum</b> 25:20  <b>vague</b> 14:2,11                  25:17 30:13                  35:18 36:7                  64:15 65:22                  70:4,12 71:4                  74:22 76:12                  81:23 82:11                  83:12 87:3,19                  88:22 89:11                  90:3,13,21                  91:16,17 92:12                  93:5,20 94:9                  94:21 96:9,20                  98:13,20 100:4                  101:21 102:3                  104:4 107:12                  107:19 108:8                  108:17 109:23                  110:9 112:6,20                  113:23 114:13                  115:23 116:8                  122:9 123:2,15                  123:24 124:18                  125:18 126:4                  130:1,17                  131:10 137:19                  142:4,13                  143:23 148:15                  148:25 149:9                  150:17 152:21                  153:12 154:8                  156:3 161:6,19</p>	<p>163:21 164:6                  166:2 167:20                  168:9 169:1,7                  169:18 172:13                  173:8 176:2,24                  181:24  <b>value</b> 169:11  <b>valve</b> 5:5 66:21                  66:21 96:1,7                  96:24,25 98:10                  102:22 110:21                  115:21 116:6                  130:11,14                  131:8,12,18,20                  132:3,3,4,13                  132:25 133:6                  134:5,6,16                  135:2,17,19,20                  136:14,16                  137:1,24 138:1                  138:6,13,14                  139:6,7,15,17                  141:14 147:23                  150:10,15                  152:12,16,18                  152:19 155:18                  155:20,25                  156:1,15,22                  157:11 161:3                  161:22 164:18                  164:20 167:18                  168:20 169:16                  170:1 171:22                  172:11 177:7                  179:19 185:4                  185:10  <b>valves</b> 42:23                  133:5 134:2                  136:3,9 137:7                  137:15,16                  138:17 139:1,6  <b>vantage</b> 145:25  <b>variable</b> 152:23                  153:3,4 158:18  <b>variations</b> 58:7                  73:17,23                  133:18,19</p>	<p>153:6  <b>varied</b> 15:14  <b>varies</b> 15:9  <b>variety</b> 11:25                  70:18 116:19                  117:9  <b>various</b> 13:6                  14:22 18:14                  53:17 70:20,20                  72:4 172:24                  178:4 179:25                  181:15  <b>vary</b> 163:16  <b>vascular</b> 26:8                  57:5,18,18                  76:24  <b>vasculature</b>                  43:16 73:21                  75:18,24 76:5                  163:12  <b>veins</b> 75:15  <b>vendor</b> 149:20  <b>venous</b> 72:22                  76:23  <b>verbal</b> 8:12  <b>version</b> 40:24  <b>versions</b> 159:7  <b>versus</b> 21:5 47:5  <b>verus</b> 6:7  <b>vessel</b> 72:9  <b>video</b> 49:25 76:6                  187:16,20,24  <b>videographer</b>                  3:20 6:3,18                  52:15,18 99:9                  99:12 103:18                  103:21 127:2,5                  170:14,17                  182:24 183:2                  187:15,19,23  <b>videotape</b> 76:1  <b>videotaped</b> 1:13                  6:4  <b>view</b> 26:23 37:19  <b>viewed</b> 76:5 91:8  <b>virtual</b> 23:17                  50:2,4</p>	<p><b>virtually</b> 23:11                  23:12 24:10                  26:18 49:21,23                  66:19  <b>void</b> 189:13  <b>volume</b> 25:21  <b>volumes</b> 62:2</p> <hr/> <p style="text-align: center;"><b>W</b></p> <hr/> <p><b>wait</b> 8:16,18  <b>waive</b> 190:9  <b>wall</b> 62:10,13,16                  62:24  <b>want</b> 10:20                  62:22 89:3                  100:17 126:21  <b>wants</b> 163:10,14                  163:14  <b>Washington</b>                  1:24 191:2                  192:3  <b>wasn't</b> 36:8                  131:23 150:18  <b>way</b> 24:22 60:14                  65:6 105:7                  108:3 132:24                  149:21 150:10  <b>We'll</b> 8:15  <b>we're</b> 9:9 27:23                  40:19 49:4                  52:15,19 66:13                  99:9,14 103:18                  103:21 121:25                  125:24 126:20                  127:2,6 170:14                  170:18 174:17                  182:24 183:2                  188:1  <b>we've</b> 52:11 63:6                  120:8 124:1                  149:21 158:1                  170:10 174:9  <b>website</b> 24:7,9                  26:20,23  <b>websites</b> 24:4  <b>week</b> 50:3  <b>weeks</b> 10:18</p>
---	---	---	---	--

128:16 152:3 171:20 <b>welcome</b> 127:9 130:4 <b>welding</b> 178:19 178:24 <b>went</b> 23:15 30:17 <b>West</b> 3:14 190:2 <b>whatsoever</b> 87:25 <b>wider</b> 83:7 <b>wire</b> 57:7 119:10 122:2 177:8,21 178:2,10,17 179:2,11,17,23 180:4,12,18 181:7,7,8,12 181:21 <b>wish</b> 29:14 <b>withdraw</b> 25:21 55:12 <b>withdrawal</b> 53:19 139:11 163:5,13 <b>withdrawing</b> 56:1 165:5,18 <b>witness</b> 2:17 6:24 7:8 10:23 11:1 13:25 14:3,8,12,12 14:17,19 15:4 15:5,8 16:5,13 18:22 19:4 20:6,9,10,20 25:18 30:14,25 31:18 33:5 34:2,6,7,19,23 35:19 36:8 41:18,22 46:5 50:23 64:16 65:14,23 70:2 70:13 71:5 76:13 77:19 81:24 82:12,23 83:13 84:9,25 85:11,19 86:6	86:17 87:4,20 88:12,23 89:12 90:4,14,22 91:13,23 92:13 93:6,21 94:4 94:10,22 95:12 96:10,21 97:10 97:17 98:6,14 98:21 100:5 101:10,22 102:4,18 104:5 105:6 106:5 107:13,20 108:9,19 109:4 109:13,24 110:10 111:1 112:7,21 113:24 114:14 115:5,25 116:10 117:20 120:21 121:16 122:10 123:3 123:16,25 124:19 125:8 125:19 126:5 126:24 130:18 131:11,23 132:17 133:11 134:10,22 135:6,23 137:20 139:20 141:12,20 142:5,14,24 143:14,24 148:17 149:1 149:10 150:18 152:22 153:14 154:10,18 156:4 158:12 160:20 161:7 161:20 162:16 163:3,22 164:7 166:3,14 167:3 167:21 168:10 169:2,8,19 170:5 172:14 173:9,21 175:9	176:3,12,25 177:17 178:14 179:5 180:8,21 181:25 182:3 183:22 184:6 184:11 185:13 189:6,7,14 190:8 191:5,17 192:9 <b>witnessed</b> 76:9 <b>word</b> 56:16 57:23 58:13 85:2 88:23 89:22 90:22 96:2 125:5 142:6 159:16 160:3 173:12 <b>wording</b> 167:22 <b>words</b> 112:22 120:6 130:23 138:21 153:21 162:20 <b>work</b> 15:8 16:14 17:20 18:3,21 18:25 19:4 20:9 21:5,16 21:18,22,25 22:4,8 25:4 29:19 36:22 54:14 61:5 176:20 <b>worked</b> 13:2 20:23 31:1 58:23 60:2,5 60:21,25 61:19 63:8,20,24 68:7,18 71:24 <b>working</b> 12:16 15:8,18 20:20 29:18 31:5 36:20 56:25 60:8 63:13 99:8 133:4 136:2 <b>works</b> 30:4,7 60:14 176:15 <b>wouldn't</b> 29:9	131:25 156:17 <b>written</b> 10:11 87:6 106:23 117:5 145:23 190:22 <b>wrong</b> 96:2 <hr/> <b>X</b> <b>X</b> 4:9 5:1 <b>x-ray</b> 64:25 <hr/> <b>Y</b> <b>Y-arm</b> 78:17,22 <b>Yeah</b> 16:5 50:23 91:13 100:20 100:23 124:19 134:10 140:7 167:21 168:10 170:5 175:9 176:25 <b>year</b> 21:7,13 27:17 32:14 <b>years</b> 15:12 20:23 41:11,15 41:19 42:1,6 42:13,20,22 43:2 53:8 61:5 65:8 71:16 149:24 150:4 <b>Yep</b> 183:9,11 184:1,18 <b>yesterday</b> 50:11 128:12,14 152:2 <hr/> <b>Z</b> <b>Z-A-L-E-S-K-Y</b> 7:16 <b>Zalesky</b> 1:13 2:1 4:2,11,12,16 5:3 6:5 7:9,14 27:12 32:8 52:22 54:12 80:9 99:17 127:9,22 129:15 151:4 170:21 182:18	183:6 187:5,25 188:3 190:1,4 191:5 192:9 <b>zero</b> 62:23 <b>zone</b> 113:8,18 114:3,7,10 115:1,19 116:4 <hr/> <b>0</b> <b>011</b> 9:24 11:11 11:15 <b>012</b> 28:3 32:13 38:3 39:15 40:13 45:17 48:18 49:4,9 51:5,24 80:11 80:18 81:17 88:19 89:19 90:9,16 91:8 91:20 93:18,25 96:24 99:24 100:1,25 103:24 113:2 114:19 116:17 117:2,7,17 121:12 123:5 123:11 144:12 184:14 <hr/> <b>1</b> <b>1</b> 39:5 40:20,22 154:15,21,22 183:16,19 <b>1:52</b> 170:15 <b>10</b> 12:4 72:10 77:5 80:23 <b>10:12</b> 52:16 <b>10:24</b> 52:20 <b>100-plus-centi...</b> 57:11 <b>1001</b> 4:18 49:9 80:4,5,10 184:13 <b>1005</b> 4:20 127:17 127:18,23,25 <b>1006</b> 4:22 150:23 150:24 151:5,7
---	--	--	--	---

<b>1007</b> 4:24 171:3 171:4,9,11	161:13 183:25 186:7,13	36:5,14 46:2 48:1,5,9 52:2	<b>2020</b> 41:11,15,19 42:1,6,18	<b>35</b> 117:4
<b>1008</b> 5:4 129:10 129:11,16 130:5 145:5 183:24	<b>1700</b> 2:7 6:13 <b>171</b> 4:25 <b>1730</b> 1:24 191:1 192:2	<b>2002</b> 44:19 160:8 160:9,11	<b>2025</b> 1:15 6:15 28:10 32:19 41:19 42:1,6 189:15 190:4 190:20 191:5 192:10	<b>36</b> 100:21,22 <b>360-degree</b> 89:1 92:15 93:15 104:23
<b>1013</b> 5:7 54:7,8 54:13	<b>18</b> 61:3,9,14,18 186:19	<b>2003/0116731</b> 4:23	<b>2032-0646</b> 1:25 191:2	<b>37</b> 155:13,16 156:21 171:25 172:3 177:6,13
<b>109</b> 28:5 32:15	<b>183</b> 4:4	<b>2003/0225379</b> 4:21	<b>2040</b> 3:6	<b>38</b> 184:25
<b>11,697,012</b> 4:19 27:25	<b>187</b> 4:3 <b>1888</b> 2:6 7:4,5	<b>20036</b> 1:24 191:2 192:3	<b>22</b> 125:25 184:19	<hr/> <b>4</b> <hr/>
<b>11.697-012</b> 1:10	<b>18s</b> 61:21	<b>2005</b> 71:16,24 73:1,11,18	<b>232-0646</b> 1:25 191:2	<b>4</b> 127:6 161:25 162:3
<b>11:31</b> 99:10	<b>19</b> 186:5,9,16	74:13 75:6,18	<b>25</b> 28:10	<b>40,000</b> 21:12
<b>11:37</b> 99:15	<b>193</b> 147:6	75:24 76:9	<b>25th</b> 27:17	<b>41</b> 179:7
<b>11:43</b> 103:19	<b>1984</b> 53:10 65:6 69:3	77:11 78:18	<b>26</b> 140:6 184:20	<b>48</b> 183:10
<b>11:45</b> 103:22	<b>1987</b> 137:12	136:6	<b>27</b> 1:15 4:14 6:15 147:21 190:4 191:5 192:10	<hr/> <b>5</b> <hr/>
<b>110</b> 186:2	<b>1990</b> 61:7	<b>2008</b> 4:16 32:9 32:11,16 33:9	<b>27</b> 1:15 4:14 6:15 147:21 190:4 191:5 192:10	<b>5</b> 47:7 77:8
<b>11697012</b> 27:19	<b>1990s</b> 26:1,2 63:1	33:22,25 34:12	<b>28</b> 162:7	<b>50</b> 15:10,17 16:12,14 176:22
<b>12</b> 80:23 171:24 172:17 174:17 176:22	<b>1994</b> 61:7	35:3,5,10,15	<b>29</b> 162:8	<b>50-percent</b> 15:12
<b>12:18</b> 127:3	<b>1995</b> 71:16,24 73:1,11,18	36:2,4,13,17	<hr/> <b>3</b> <hr/>	<b>500</b> 19:7,10 182:12
<b>12:20</b> 126:22	74:12 75:6,18	36:21 37:2,6,9	<b>3</b> 99:13 161:25 162:3,9	<b>5129</b> 1:22 189:19
<b>12:50</b> 127:7	75:24 76:9	39:1 40:20	<b>30</b> 31:6 117:4 130:7,12	<b>54</b> 5:8
<b>124</b> 7:18	77:10 78:18	43:20 47:11,24	144:15 146:11	<b>5850</b> 3:15 190:2
<b>127</b> 4:21	136:6	48:10 51:20	184:17 189:15	<b>59</b> 185:17,18,21
<b>129</b> 5:6	<hr/> <b>2</b> <hr/>	52:3 71:8 79:1	<b>300</b> 17:19 18:10 18:20 19:7,10 19:25 21:15 182:6,9	<b>5th</b> 3:14 190:2
<b>13</b> 100:20,21,22 117:8	<b>2</b> 43:19 44:3,9 47:12,15 51:19	79:3,24 80:15	<b>306</b> 55:5,24 56:22	<hr/> <b>6</b> <hr/>
<b>132</b> 113:9	52:19 154:15	99:4 114:20	<b>310</b> 3:17	<b>6</b> 58:24 59:2,4,6 81:16,20,21 82:14,18 83:3 85:24 86:23 87:14,15 88:7 89:13,15 91:20 92:1,5,19,24 113:5 116:24 140:2
<b>14</b> 113:2 116:21 116:23 177:5 177:13	154:21,22	125:14 128:8	<b>310</b> 3:17	<b>60</b> 185:21
<b>14th</b> 3:7	170:19 184:2	150:14 151:23	<b>32</b> 4:17 144:21 183:25 185:8	<b>604</b> 82:3,9,20 83:10 84:5 86:2,24 88:9
<b>15</b> 36:19 179:7	184:23 185:10	169:25 171:16	<b>32nd</b> 5:8	<b>633</b> 3:14 190:2
<b>150</b> 4:23 113:6	<b>2:15</b> 182:25	183:7 185:24	<b>33</b> 146:14 164:12 166:8,20 168:17	<b>64</b> 37:8,12,17
<b>150-B</b> 126:17	<b>2:29</b> 183:3	<b>2015</b> 41:11,15 65:6 68:5,14 69:6,20	<b>34</b> 130:7,12 144:15,19	
<b>15th</b> 32:14,19	<b>2:35</b> 188:1,4	99:4 114:20	<b>34</b> 130:7,12 144:15,19	
<b>16</b> 61:3,8,14,20 62:6,12 63:8 71:7,10 72:15 73:16 180:24 186:5,9,12	<b>20</b> 12:4 61:22 62:6,13 72:10 172:5 174:23	125:14 128:8	<b>32nd</b> 5:8	
<b>165</b> 39:19,22 146:22 147:6	<b>2000s</b> 137:13	150:14 151:23	<b>33</b> 146:14 164:12 166:8,20 168:17	
<b>17</b> 157:16 158:7 159:12,18	<b>2001</b> 4:13 27:15 29:1,6,16,19 29:21,25 30:11 31:5,12,23,24 33:21 35:3,4	169:25 171:16	<b>34</b> 130:7,12 144:15,19	
		183:7 185:24	<b>32nd</b> 5:8	
		<b>2017</b> 91:7 121:4 148:9,23 149:15 174:15 175:4,22 176:19 178:8 179:1 180:2,16 181:19	<b>33</b> 146:14 164:12 166:8,20 168:17	
		<b>202</b> 1:25 191:2	<b>34</b> 130:7,12 144:15,19	
		<b>202)-232-0646</b> 190:15	<b>34</b> 130:7,12 144:15,19	
		<b>202)232-0646</b> 192:4	<b>34</b> 130:7,12 144:15,19	

38:16	<b>8s</b> 7:5			
<u>7</u>	<u>9</u>			
<b>7</b> 4:3 59:4 81:16	<b>9</b> 99:2,23 100:11			
93:17 180:25	101:5,18			
<b>75</b> 38:25 39:3	106:13,19			
<b>750</b> 18:10,20,25	107:2,10,25			
19:2	108:5,13			
<b>760-0404</b> 3:9	109:19 110:4,5			
<b>77</b> 140:1,5,10,12	110:6,23			
140:18 142:20	111:10,17,24			
146:18,21	117:6 120:17			
147:1	121:12 125:4			
<b>78</b> 78:25 79:7	125:25 126:8			
<b>788-3271</b> 3:17	<b>9,980,813</b> 4:25			
	<b>9:09</b> 6:16			
<u>8</u>	<b>90067</b> 2:8 6:14			
<b>8</b> 58:24 59:3,4,7	<b>90071</b> 3:16 190:2			
60:1,5 99:2,23	<b>92614</b> 3:8			
100:2,11 101:5	<b>949</b> 3:9			
101:18,25	<b>95</b> 47:5			
102:8,25	<b>99</b> 53:23			
103:11,24				
104:14,25				
105:20 106:7				
106:13,19				
107:2,10,25				
108:5,12				
109:20 110:4				
110:23 111:10				
111:17,24				
114:8,9,24,25				
120:17 121:12				
126:7,17				
<b>80</b> 4:19 182:14				
<b>800</b> 113:7				
<b>810</b> 103:12 126:8				
126:18				
<b>812</b> 1:24 103:12				
126:8 191:1				
192:2				
<b>814</b> 102:10 103:2				
104:2				
<b>82</b> 147:22				
<b>83</b> 150:9				
<b>86</b> 53:10				
<b>888</b> 6:13				