

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INVENTOR(S):                    Nguyen et al.  
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TITLE:                            Intraoral Device  
CONFIRM. NO.:                  5030  
ATTY.DKT.NO.:                 INCEP-001COF

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PRELIMINARY AMENDMENT

Prior to examination of the present application, please enter the following **amendments** to the **claims**, which commence on **page two**. The **remarks** appear beginning on **page eleven**.

## CLAIMS

### WHAT IS CLAIMED IS:

1. (original) A mouthpiece comprising:

a main body having a first end opposite a second end that is narrower than the first end,  
the main body comprising:

a first wall having a plurality of first edges and extending from the first end to the second end,

a second wall having a plurality of second edges and located at a distance from the first wall, the distance corresponding to an interior space between the first wall and the second wall, wherein the second wall also extends from the first end to the second end,

a connecting wall that connects one of the first edges of the first wall to one of the second edges of the second wall across the distance between the first wall and the second wall, and

a bridge structure that includes a plurality of spaced protrusions integral with and protruding from an interior surface of the second wall, the bridge structure extending through the interior space towards the first wall.

2. (currently amended) The mouthpiece of claim 1, wherein one or more of the first edges of the first wall and the second edges of the second wall include a superior edge and an inferior edge.

3. (original) The mouthpiece of claim 2, wherein the superior edge is formed so as to appear as the inferior edge in a different orientation, and wherein the inferior edge is formed so as to appear as the superior edge in the different orientation.

4. - 5. (cancelled)

6. (original) The mouthpiece of claim 1, further comprising a suction connector extending from the first end of the main body, wherein an evacuation conduit within the suction connector is in communication with the interior space between the first wall and the second wall.

7. (original) The mouthpiece of claim 6, wherein a wall thickness of the suction connector is greater than a wall thickness of the first wall or the second wall of the main body.

8. (cancelled)

9. (currently amended) The mouthpiece of claim [[8]] 6, wherein the suction connector further includes a cutout configured to interlock with a corresponding protrusion of [[the]] a vacuum adapter, wherein a shape of the cutout follows a shape of a shield logo.

10. - 15. (cancelled)

16. (currently amended) The mouthpiece of claim 1, further comprising a stability bar corresponding to a thickened area of the main body, the stability bar extending along a longitudinal axis of the main body between the first wall and the second wall, wherein a thickness of the stability bar reinforces at least a portion of the main body.

17. – 19. (cancelled)

20. (original) The mouthpiece of claim 1, wherein the main body further includes a slit that extends along at least a portion of the main body, and wherein the slit opens into the interior space between the first wall and the second wall to assist in cleaning.

21. (new) An isolation mouthpiece for use with a suction system in a dental procedure, the mouthpiece comprising:

a main body portion having a first end and a second end, the main body portion including:

a first wall having a first edge and a second edge extending from the first end of the main body portion towards the second end of the main body portion, the first wall including a first plurality of perforations formed adjacent to and extending along a portion of the first edge and a second plurality of perforations formed adjacent to and extending along a portion of the second edge,

a second wall having a third edge and a fourth edge extending from the first end of the main body portion towards the second end of the main body portion, the second wall including a first plurality of perforations formed adjacent to and extending along a portion of the third edge, and a second plurality of perforations formed adjacent to and extending along a portion of the fourth edge, wherein the second wall further includes a plurality of protrusions extending from an interior surface of the second wall towards the first wall in a shape having one or more crests and one or more troughs, and

a third wall connecting the first wall and the second wall such that the first wall is spaced from the second wall to define an inner cavity, wherein a portion of the first wall has a first width adjacent to the first end of the main body portion and a second width adjacent to the second end of the main body portion and a portion of the second wall has a third width adjacent to the first end of the main body portion and a fourth width adjacent to the second end of the main body portion, wherein the first width is greater than the second width and the third width is greater than the fourth width;

a suction connector portion extending from the first end of the main body portion, the suction connector portion including:  
a generally tubular conduit including:  
an opening extending through the conduit and in fluid communication with the inner cavity, the opening being configured to receive a vacuum portion of the suction system therein, and  
a cutout configured to engage a protrusion on the suction system to aid in coupling the mouthpiece to the suction system;  
a mouth prop including a first side and a second side that are inwardly tapered from a top surface of the mouth prop towards a bottom surface of the mouth prop, the first side and the second each including a plurality of ridges; and  
a cheek retractor portion having a first cheek-retractor end coupled to the second end of the main body portion and a second cheek-retractor end, the first cheek-retractor end and the second cheek-retractor end each having rounded edges.

22. (new) The mouthpiece of claim 21, wherein the cutout has a shield shape.

23. (new) The mouthpiece of claim 21, wherein the cutout is generally triangular and has a top edge, a first curved edge, and a second curved edge.

24. (new) The mouthpiece of claim 21, wherein a wall thickness of the conduit is greater than a wall thickness of the first wall or the second wall of the main body.

25. (new) The mouthpiece of claim 21, wherein the first plurality of perforations of the first wall and the second plurality of perforations of the first wall each include at least five perforations.

26. (new) The mouthpiece of claim 25, wherein the first plurality of perforations of the second wall and the second plurality of perforations of the second wall each include at least three perforations.

27. (new) The mouthpiece of claim 21, wherein the first plurality of perforations of the first wall and the second plurality of perforations of the first wall each include at least seven perforations.

28. (new) The mouthpiece of claim 27, wherein the first plurality of perforations of the second wall and the second plurality of perforations of the second wall each include at least four perforations.

29. (new) The mouthpiece of claim 21, wherein the third wall connects the first edge of the first wall to the third edge of the second wall.

30. (new) The mouthpiece of claim 21, wherein the third wall connects the second edge of the first wall to the fourth edge of the second wall.

31. (new) The mouthpiece of claim 21, wherein the first wall and the second wall are shaped such that the first edge of the first wall corresponds to the third edge of the second wall and the second edge of the first wall corresponds to the fourth edge of the second wall.

32. (new) The mouthpiece of claim 21, wherein the mouth prop is removably coupled to the generally tubular conduit of the suction connector portion.

33. (new) An isolation mouthpiece for use with a suction system in a dental procedure, the mouthpiece comprising:

a main body portion having a first end and a second narrower end that is narrower than the first end, the main body portion including:

a first wall having first and second edges extending from the first end towards the second narrower end of the main body portion, the first wall having a first-wall width defined between the first and second edges, the first-wall width being at a maximum in a region between the first and second ends and being at a minimum at the second narrower end, the first wall including a first plurality of perforations formed adjacent to and extending along a substantial portion of the first edge and a second plurality of perforations formed adjacent to and extending along a substantial portion the second edge, at least one of the first plurality of perforations and at least one of the second plurality of perforations being located adjacent to the minimum width of the first wall at the second narrower end of the main body;

a second wall spaced apart from the first wall to define an inner cavity of the main body between the second wall and the first wall, the second wall having third and fourth edges extending from the first end towards the second end of the main body portion, the second wall having a second-wall width defined between the third and fourth edges, the second-wall width being at a maximum in a region between the first and second ends and being at a minimum at the second narrower end, the second wall including a third plurality of perforations formed adjacent to and extending along a substantial portion of the third edge and a fourth plurality of perforations formed adjacent to and extending along a substantial portion the fourth edge, at least one of the third plurality of perforations and at least one of the fourth plurality of perforations being

located adjacent to the minimum width of the second wall at the second end of the main body;

a stability bar located along a center of the first wall at least adjacent to the second narrow end of the main body, the at least one of the first plurality of perforations being positioned on one side of the stability bar and the at least one of the second plurality of perforations being positioned on another side of the stability bar; and

a bridge structure extending from an interior surface of the first wall toward the second wall, the bridge structure including a plurality of wave-like protrusions to ensure the first wall remains separated from the second wall during suction from the suction system;

a suction-connector portion extending from the first end of the main body portion, the suction connector portion including:

a generally tubular conduit including an opening extending through the conduit and in fluid communication with the inner cavity of the main body, the opening being configured to receive a vacuum portion of the suction system therein for providing suction to the inner cavity; and

a mouth prop that extends away from the tubular conduit, the mouth prop at least partially defined by a first side and a second side that generally taper inwardly in a direction away from the tubular conduit towards a bottom surface of the mouth prop, the first side and the second side including a plurality of ridges; and

a cheek-retractor portion connected to the second narrower end of the main body portion and expanding outwardly away from the second narrower end, the first and second walls of the main body transitioning into and being connected in the cheek-retractor portion to form the cheek-retractor portion.

34. (new) The mouthpiece of claim 33, wherein the generally tubular conduit of the suction-connector portion includes a cutout configured to engage a protrusion on the suction system to aid in coupling the mouthpiece to the suction system.

35. (new) The mouthpiece of claim 34, wherein the cutout is on the same side of the suction-connector portion as the mouth prop.

36. (new) The mouthpiece of claim 33, wherein the first plurality of perforations of the first wall and the second plurality of perforations of the first wall each include at least five perforations.

37. (new) The mouthpiece of claim 33, wherein the stability bar extends upwardly from the first wall toward the second wall.

38. (new) The mouthpiece of claim 37, wherein the stability bar does not contact the second wall.

39. (new) The mouthpiece of claim 33, wherein the bridge structure is located centrally in the main body.

40. (new) The mouthpiece of claim 33, wherein the narrower second end is part of a rectangular portion of the main body.

41. (new) The mouthpiece of claim 33, wherein the first and second walls of the main body that transition into the cheek-retractor portion remain unconnected from each other for a distance within the cheek-retractor portion before being connected to each other in the cheek-retractor portion.

42. (new) The mouthpiece of claim 41, wherein the at least one of the first plurality of perforations and the at least one of the second plurality of perforations located adjacent to the second narrower end of the main body are near the unconnected portion of the first and second walls within the cheek-retractor portion.

## REMARKS

The Applicants have amended claims 2, 9, and 16; cancelled claims 4, 5, 8, 10-15, and 17-19; and added new claims 21-42. The amended/new claims concern subject matter fully supported by the specification and drawings, and to which the Applicant believes that it is entitled to claim. As such, no new matter has been added, and entry and consideration of the same is respectfully requested.

Applicant submits that the claims are in a condition for allowance and action toward that end is earnestly solicited. The Examiner is invited to contact the Applicant's undersigned representative with any questions concerning the present amendment.

Applicant is submitting excess claim fees (10 claims in excess of 20 x \$40) herewith. It is believed that no additional fees are due; however, should any additional fees be required (except for payment of the issue fee), the Commissioner is authorized to deduct the fees from deposit account 50-1662.

Respectfully submitted,

**August 11, 2023**

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Table with columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO., EXAMINER, ART UNIT, PAPER NUMBER, NOTIFICATION DATE, DELIVERY MODE. Includes application details for Thien Nguyen and examiner APONTE, MIRAYDA ARLENE.

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocketing@polsinelli.com
sfpatent@polsinelli.com

# Office Action Summary

Application No.

18/217,304

Applicant(s)

Nguyen et al.

Examiner

MIRAYDA A APONTE

Art Unit

3772

AIA (FITF) Status

No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 11 August 2023.

A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on \_\_\_\_\_.

2a)  This action is **FINAL**.

2b)  This action is non-final.

3)  An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_\_; the restriction requirement and election have been incorporated into this action.

4)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims\*

5)  Claim(s) 1-3,6-7,9,16 and 20-42 is/are pending in the application.

5a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

6)  Claim(s) \_\_\_\_\_ is/are allowed.

7)  Claim(s) 1-3,6-7,9,16,20-30,32-37 and 39-40 is/are rejected.

8)  Claim(s) 31,38 and 41-42 is/are objected to.

9)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement

\* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see [http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto:PPHfeedback@uspto.gov).

## Application Papers

10)  The specification is objected to by the Examiner.

11)  The drawing(s) filed on 30 June 2023 is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

## Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

### Certified copies:

a)  All      b)  Some\*\*      c)  None of the:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

1)  Notice of References Cited (PTO-892)

3)  Interview Summary (PTO-413)

Paper No(s)/Mail Date \_\_\_\_\_.

2)  Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)

4)  Other: \_\_\_\_\_.

Paper No(s)/Mail Date \_\_\_\_\_.

## DETAILED ACTION

### *Notice of Pre-AIA or AIA Status*

1. The present application is being examined under the pre-AIA first to invent provisions.

### *Drawings*

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: the reference number 320 of Fig. 3A is not found.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Claim Objections*

3. **Claim 21** is objected to because of the following informalities: In lines 21-26 is considered a run-on sentence. The sentence in question is grammatically faulty **sentence** in which two or more main or independent clauses are joined without a word to connect them or a punctuation mark to separate them. Where on type of run-on sentence is a polysyndeton, that is when a sentence uses too many conjunctions or more

conjunctions than necessary. Wherein lines 21-26 uses the “and” conjunction more than necessary. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of 35 U.S.C. 112(b):  
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claim 21** is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.
6. **Regarding claim 21**, in line 39 uses the term “second”, in which it is confusing. It is not understood what structure the term “second” refers to. For examination purposes, the recitation will be treated as the term “second” refers to the “second side”, described in line 37 of the claim.

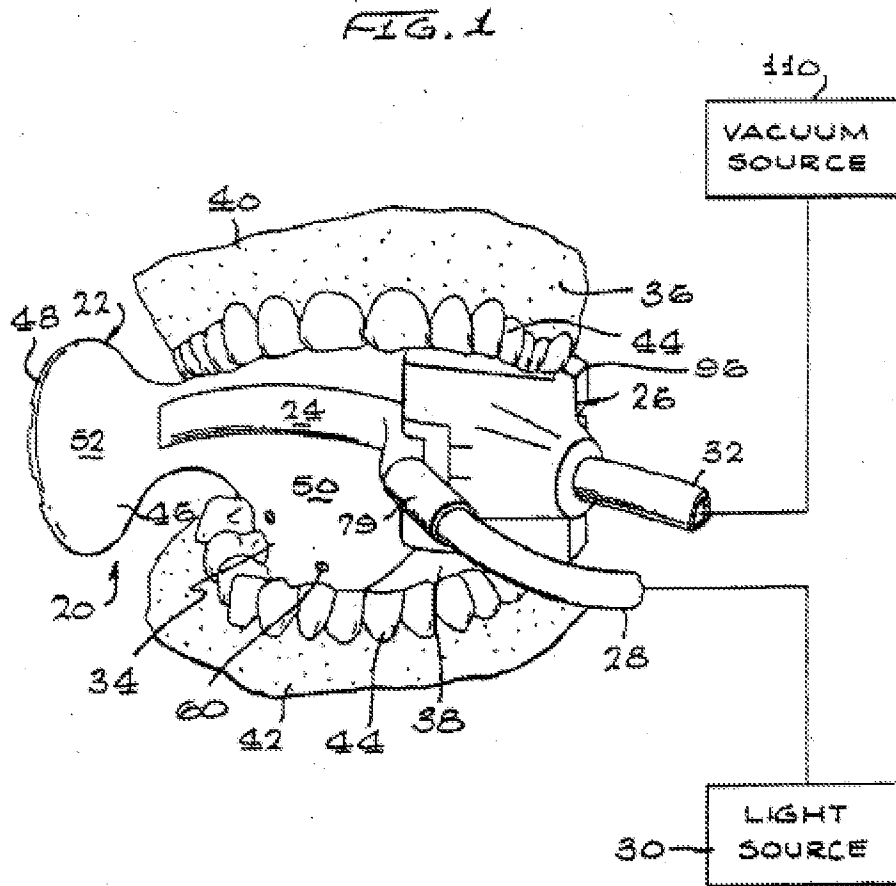
***Claim Rejections - 35 USC § 102***

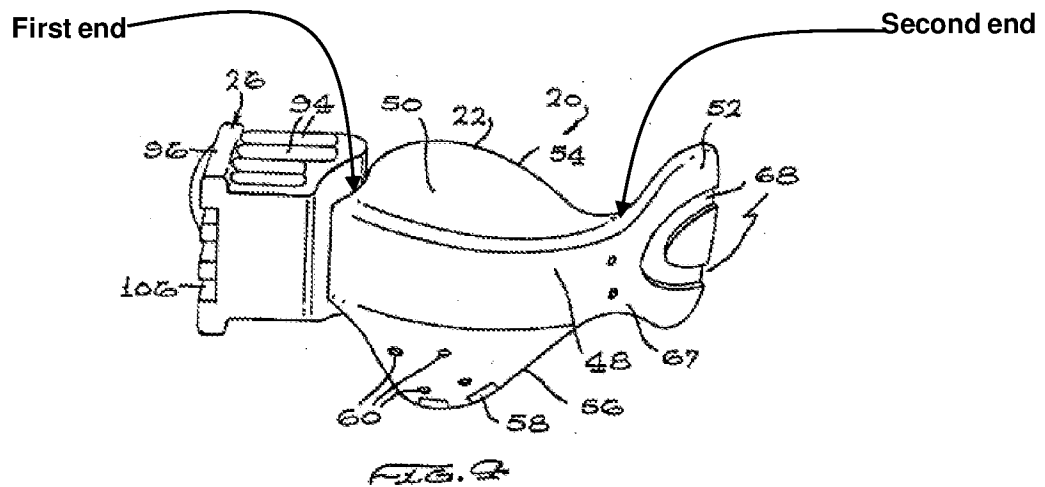
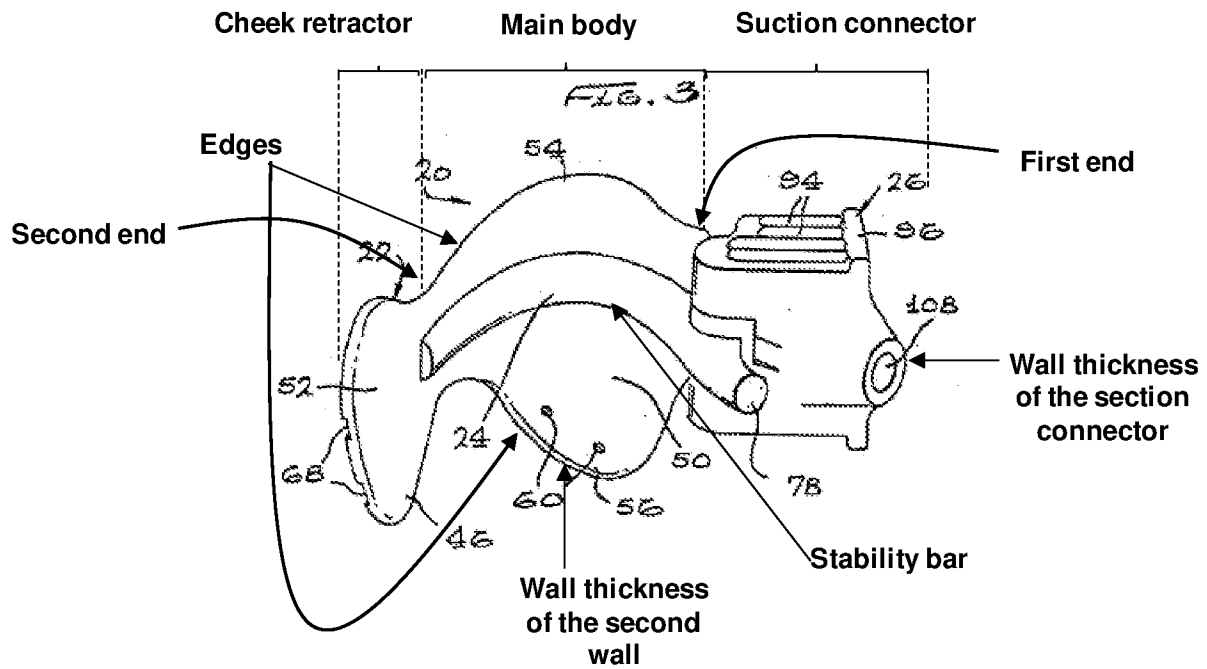
7. The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 1-3, 6, 7, 16 and 20 are rejected under pre-AIA 35 U.S.C. 102(a) as being anticipated by Hirsch (US 20030134253 A1).





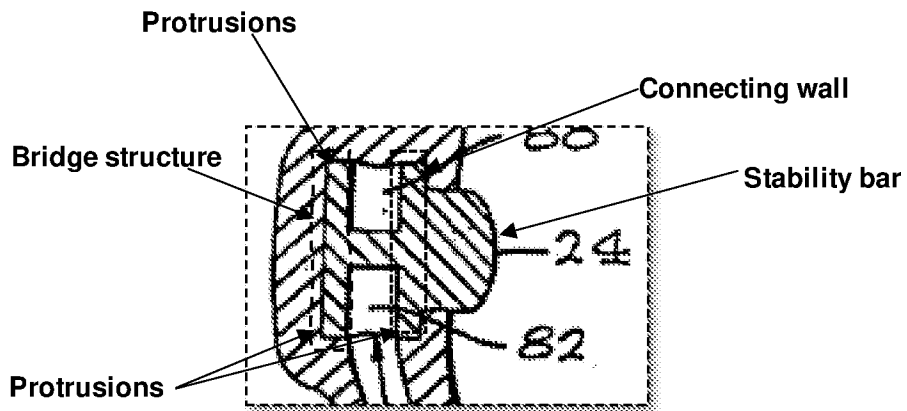
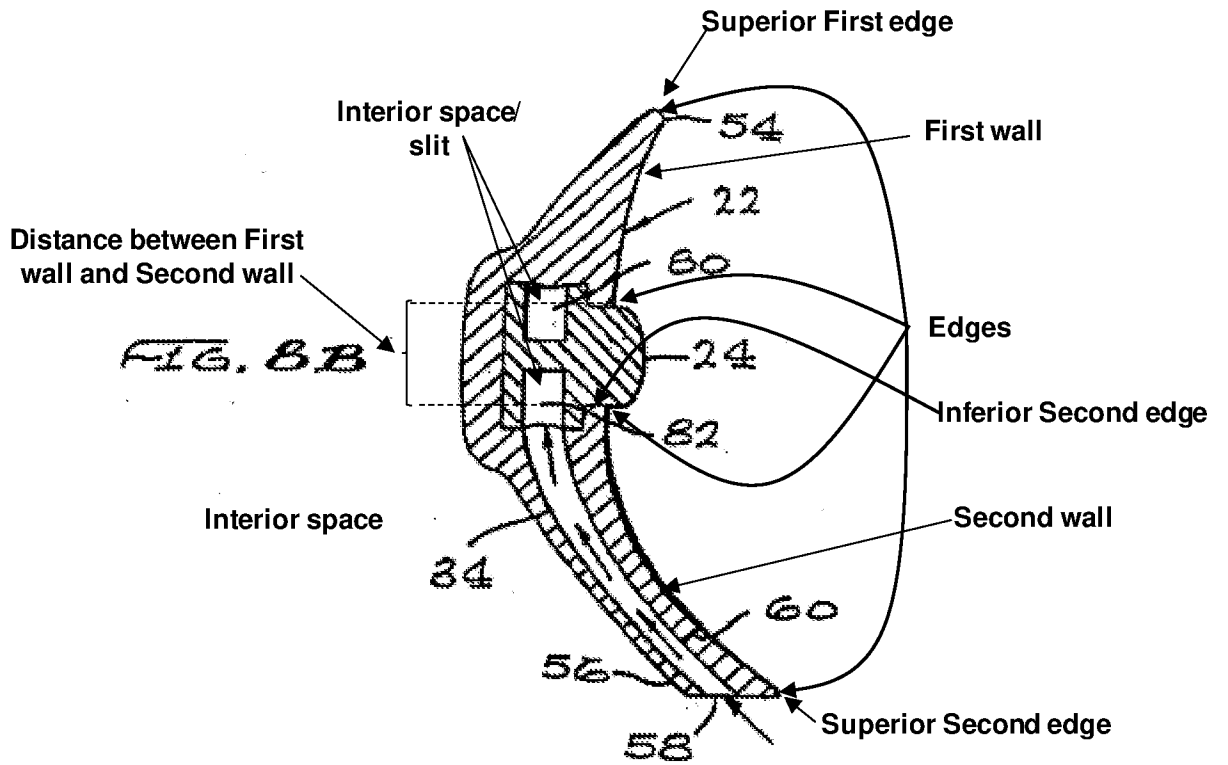


Fig. 8B zoomed portion

9. **Regarding claim 1**, Hirsch et al. discloses a mouthpiece including:  
a main body having a first end opposite a second end that is narrower than the first end (see annotated Fig. 3 above), the main body including:  
a first wall having a plurality of first edges and extending from the first end to the second end (see annotated Fig. 3 and 8B above),  
a second wall having a plurality of second edges and located at a distance from the first wall (see annotated Fig. 8B above), the distance corresponding to an interior space between the first wall and the second wall, wherein the second wall also extends from the first end to the second end (see annotated Fig. 8B above),  
a connecting wall (see enclosed portion in element 24 highlighted in Fig. 8B zoomed portion above) that connects one of the first edges of the first wall to one of the second edges of the second wall across the distance between the first wall and the second wall (see annotated Fig. 8B and 8B zoomed portion above), and  
a bridge structure that includes a plurality of spaced protrusions integral with and protruding from an interior surface of the second wall, the bridge structure extending through the interior space towards the first wall (see the half of the H internal structure of element 24 enclosed in the annotated Fig. 8B zoomed portion).
10. **Regarding claim 2**, Hirsch et al. discloses that one of the one or more of the first edges of the first wall and the second edges of the second wall include a superior edge and an inferior edge (see annotated Fig. 8B above).
11. **Regarding claim 3**, Hirsch et al. discloses that the superior edge is formed so as to appear as the inferior edge in a different orientation, and wherein the inferior edge is

formed so as to appear as the superior edge in the different orientation (see annotated Fig. 8B above – where the edges change the superior and inferior orientation when the device changes its orientation when the first wall is a down location and the second wall is in the superior location).

12. **Regarding claim 6**, Hirsch et al. discloses further including a suction connector extending from the first end of the main body (see annotated Fig. 3 above), wherein an evacuation conduit (ending in tube 32 see Fig. 1 above) within the suction connector is in communication with the interior space between the first wall and the second wall (through the interior spaces 80 and 82 shown in Fig. 8B above).

13. **Regarding claim 7**, Hirsch et al. discloses that a wall thickness of the suction connector is greater than a wall thickness of the first wall or the second wall of the main body (see annotated Fig. 3 above).

14. **Regarding claim 16**, Hirsch et al. discloses a stability bar (24) corresponding to a thickened area of the main body, the stability bar (24) extending along a longitudinal axis of the main body between the first wall and the second wall, wherein a thickness of the stability bar reinforces at least a portion of the main body (see annotated Fig. 3 and 9B zoomed portion above).

15. **Regarding claim 20**, Hirsch et al. discloses that the main body further includes a slit that extends along at least a portion of the main body, and wherein the slit opens into the interior space between the first wall and the second wall to assist in cleaning (see annotated Fig. 8B and [0052-0053]).

***Claim Rejections - 35 USC § 103***

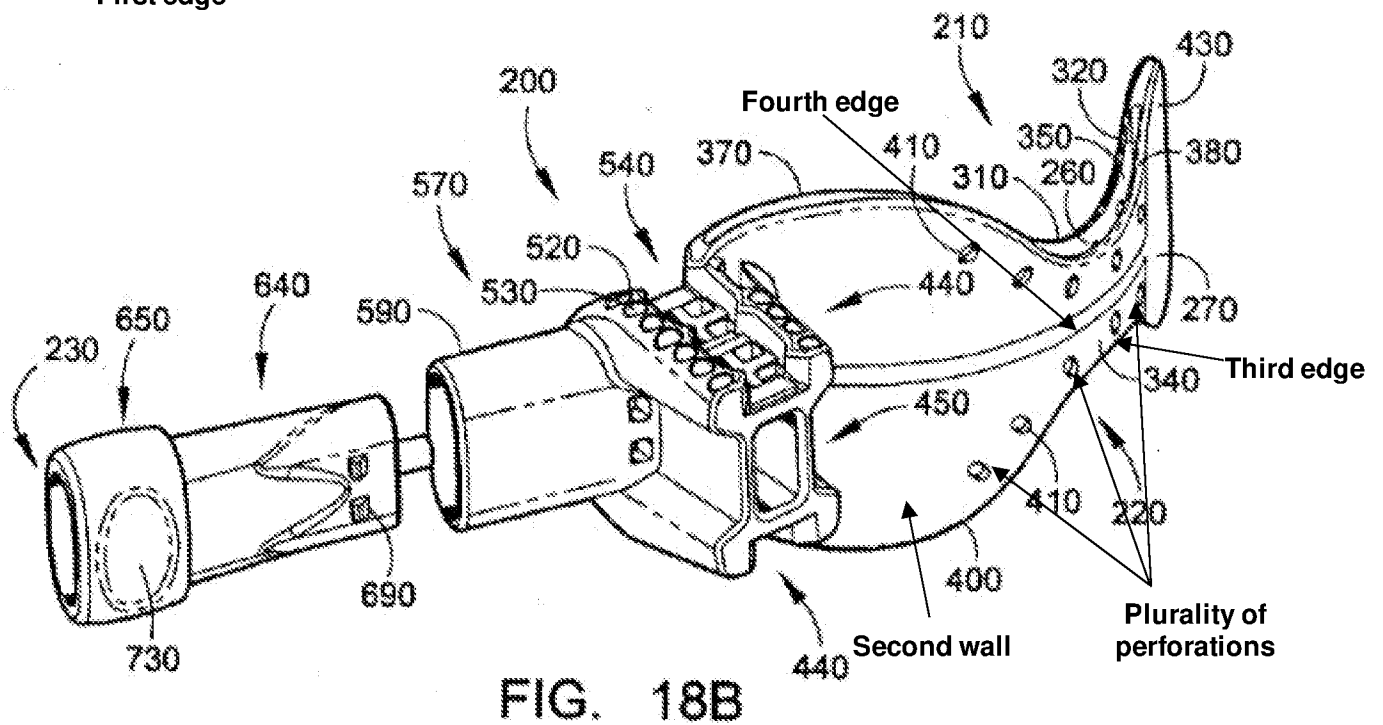
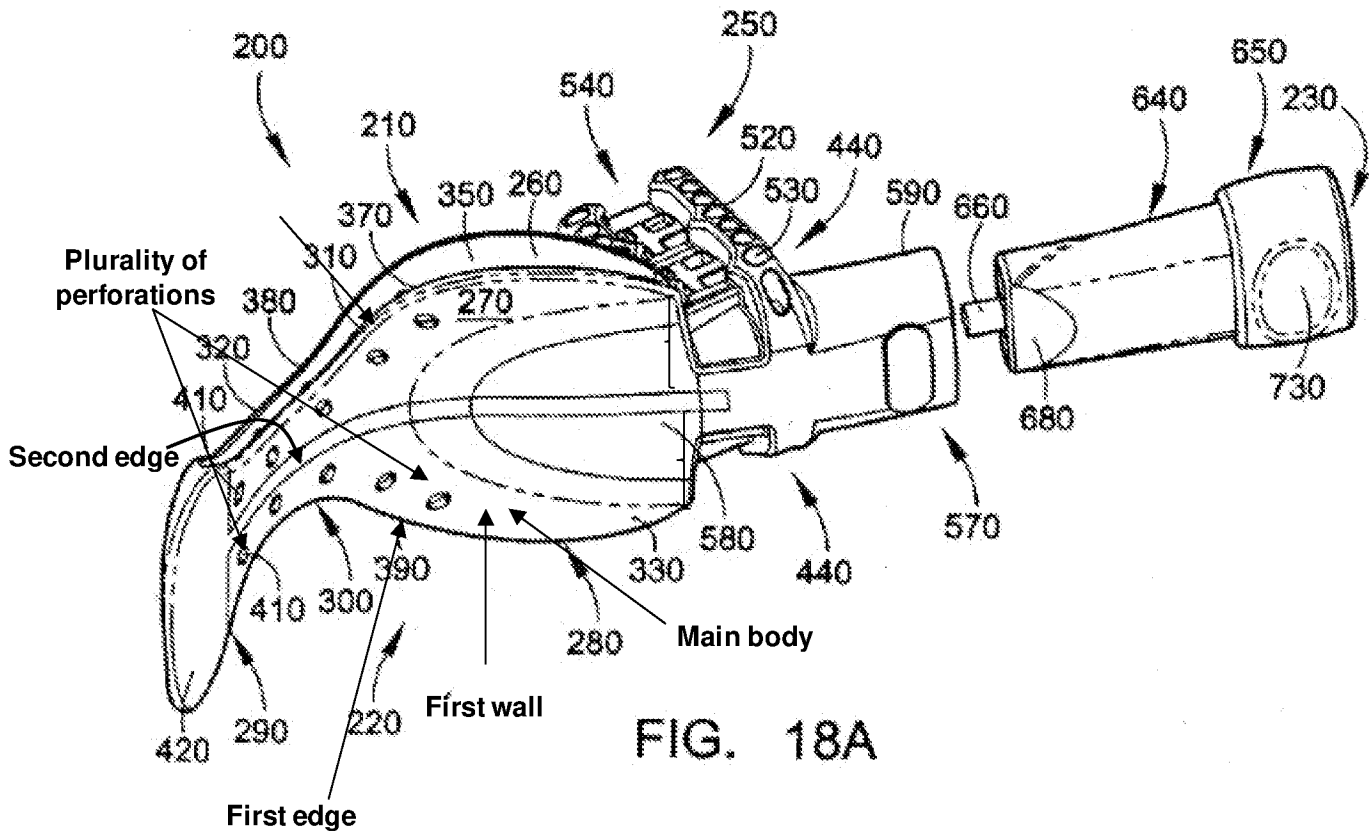
16. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. **Claims 9, 21, 22-30, 32-37, 39 and 40 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Hirsch et al. (US 6974321 B2).**

18. **Regarding claim 9**, Hirsch (1<sup>st</sup> embodiment) discloses the claimed invention substantially as claimed, as set forth above for claim 6.

19. However, Hirsch (1<sup>st</sup> embodiment) does not disclose that the suction connector further includes a cutout configured to interlock with a corresponding protrusion of a vacuum adapter, wherein a shape of the cutout follows a shape of a shield logo.



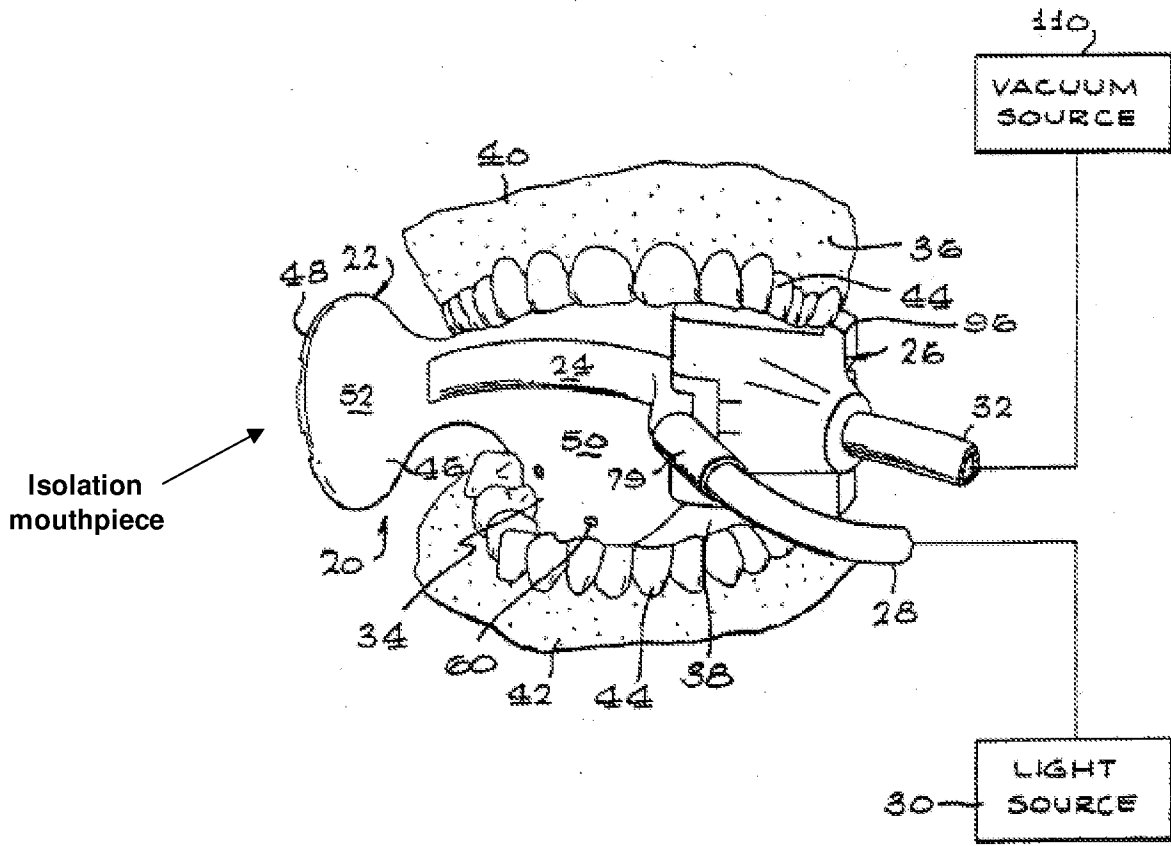
20. On the other hand, Hirsch et al. (aka Hirsch 2<sup>nd</sup> embodiment) also discloses another embodiment in Fig. 18A and 18B including in the area of the suction connector portion includes a cutout configured to engage a protrusion on the suction system to aid in coupling the mouthpiece to the suction system (see annotated Fig. 18A and 18B above and col. 14, lines 46-51 and col. 12, lines 1-17).

21. It would have been obvious to one having ordinary skill in the art before the effective filing date of the claimed invention to modify the engagement of the suction system to the suction connector portion of the embodiment of Fig. 1 of Hirsch, with the cutout on the suction connector portion with a protrusion on the coupling section of the suction system of the embodiment of Fig. 18 of Hirsch, in order for the cutout in the suction connector portion to be able to releasably connect with the protrusions on the external surface of the hose of the suction system and its connection be retained during its use.

22. However, Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) does not disclose that the cutout has a shield shape.

23. On the other hand, having a particular shape for the cutout is a matter of choice in which a person of ordinary skill in the art would have found obvious by the absent of persuasive evidence in the present application, that the particular configuration of the claimed shape of the cutout is significant. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)

FIG. 1



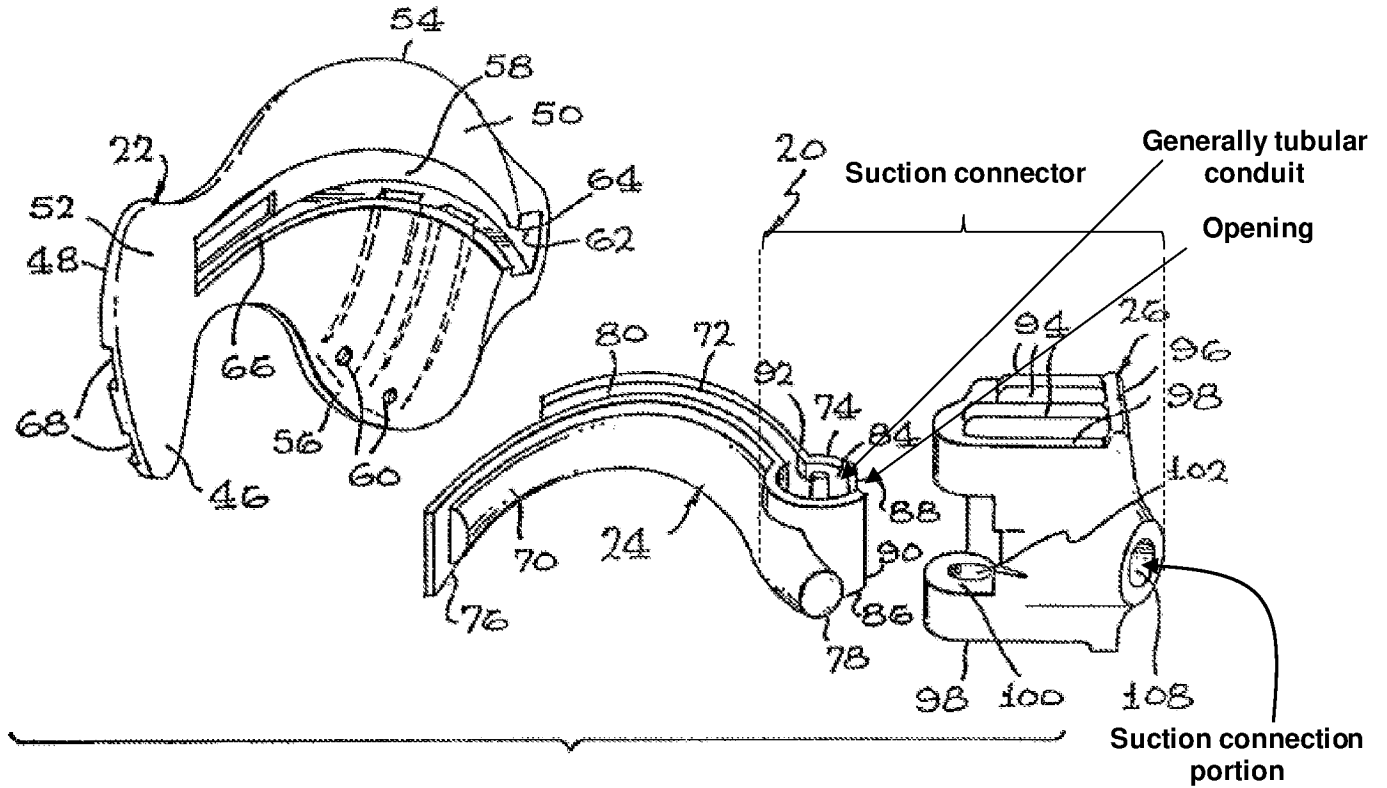
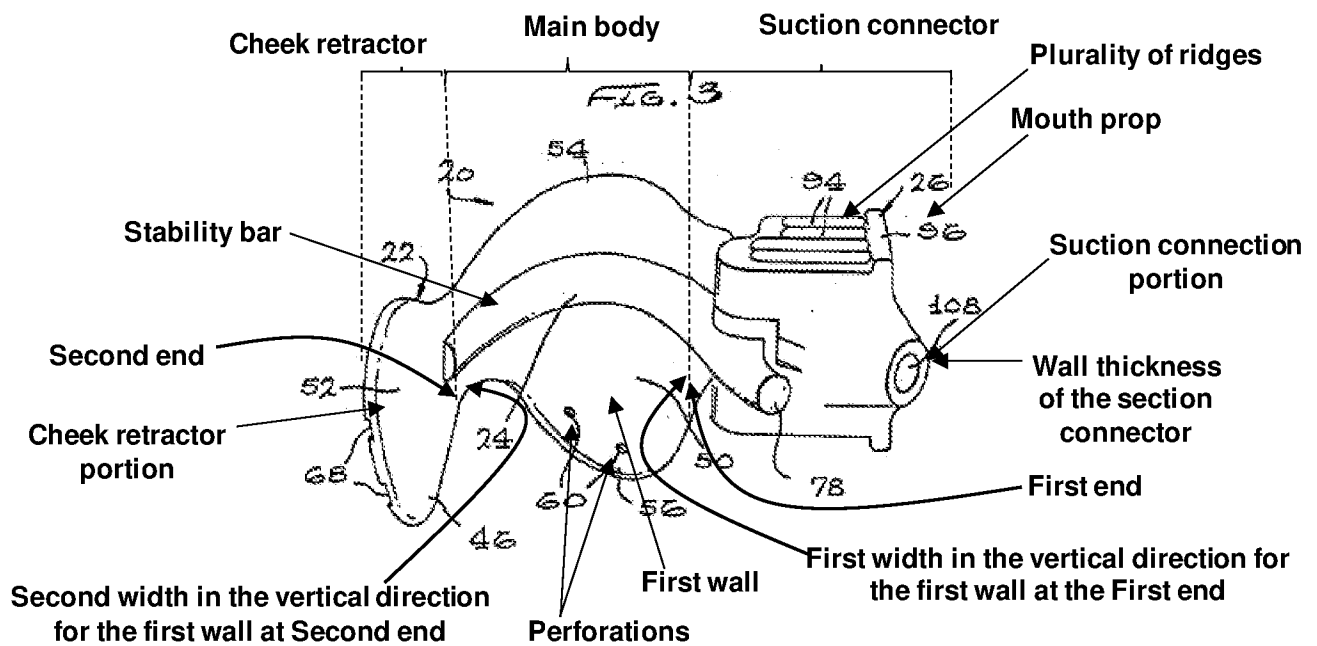
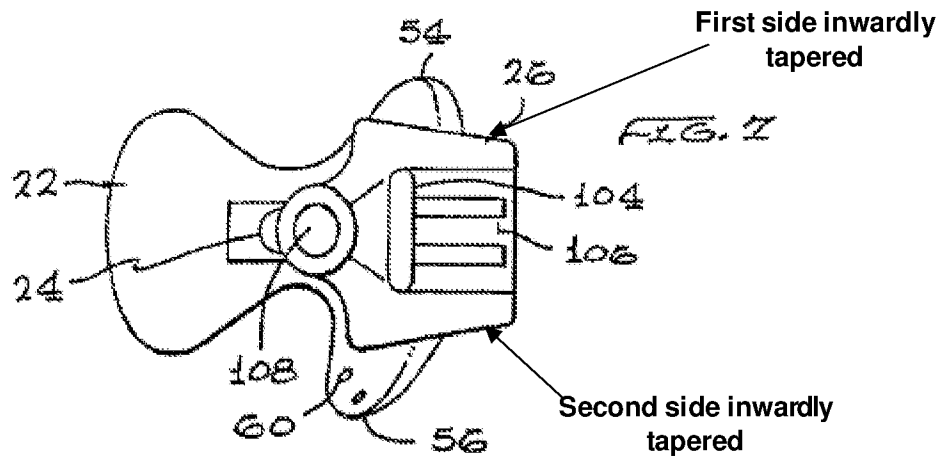
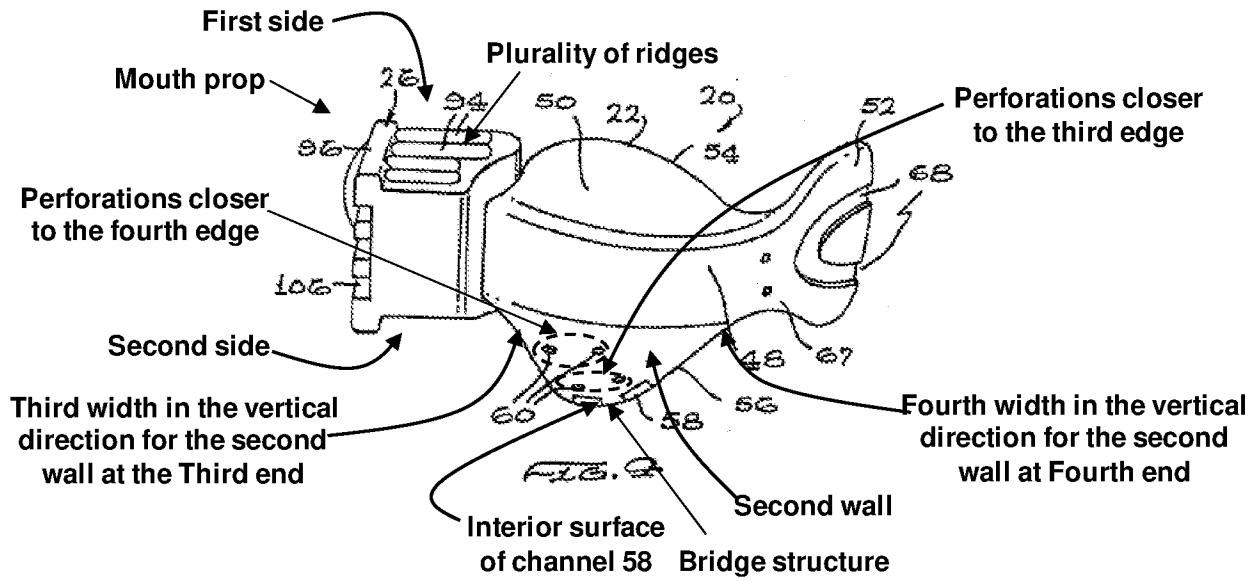
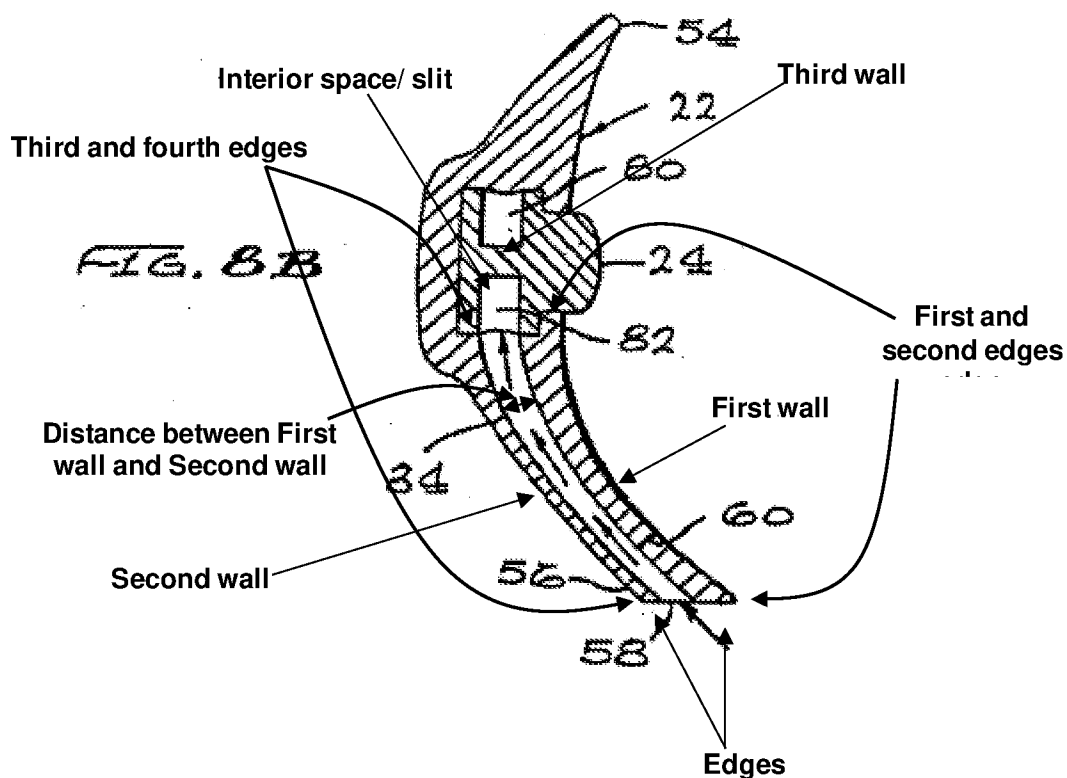


FIG. 2







24. **Regarding claim 21**, Hirsch discloses an isolation mouthpiece (see Fig. 1 above) for use with a suction system (110) in a dental procedure (see annotated Fig. 1 above), the mouthpiece including:

a main body portion having a first end and a second end (see annotated Fig. 3 above), the main body portion including:

a first wall having a first edge and a second edge extending from the first end of the main body portion towards the second end of the main body portion (see annotated Fig. 8B above), the first wall including a first plurality of perforations (60) formed adjacent to and extending along a portion of the first edge (see annotated Fig. 3 above),

a second wall having a third edge and a fourth edge extending from the first end of the main body portion towards the second end of the main body portion (see annotated Fig. 8B above), the second wall including a first plurality of perforations (60) formed

adjacent to and extending along a portion of the third edge, and a second plurality of perforations formed adjacent to and extending along a portion of the fourth edge (see annotated Fig. 8B above), wherein the second wall further includes a plurality of protrusions extending from an interior surface of the second wall towards the first wall in a shape having one or more crests and one or more troughs (see annotated Fig. 4 above – where the channels 58 are formed by interior surfaces extending from one wall to the opposite wall, so that the interior wall extends from a trough to a crest by the distance between the two walls), and

a third wall connecting the first wall and the second wall such that the first wall is spaced from the second wall to define an inner cavity (see annotated Fig. 8B above - where the horizontal wall of element 24 forms a wall, that dictates the space between the first and second wall), wherein a portion of the first wall has a first width adjacent to the first end of the main body portion and a second width adjacent to the second end of the main body portion (see annotated Fig. 3 above), and a portion of the second wall has a third width adjacent to the first end of the main body portion and a fourth width adjacent to the second end of the main body portion (see annotated Fig. 4 above), wherein the first width is greater than the second width and the third width is greater than the fourth width (see annotated Fig. 4 above – where the width in the vertical direction of both first wall and second wall are bigger at the first end than the width in the same direction at the second end);

a suction connector portion (108) extending from the first end of the main body portion (see annotated Fig. 2 and 3 above), the suction connector portion (108) including:  
a generally tubular conduit (84) (see annotated Fig. 3 above) including:

an opening extending through the conduit and in fluid communication with the inner cavity, the opening being configured to receive a vacuum portion of the suction system therein (see annotated Fig. 2 above and col. 7, lines 27-31 – where “fluids are vacuumed from the internal evacuation channel 104 of the bite block 26 through an exit port 108”); and

mouth prop (26) including a first side and a second side that are inwardly tapered from a top surface of the mouth prop towards a bottom surface of the mouth prop, the first side and the second each including a plurality of ridges (94) (see annotated Fig. 3, 4 and 7 above); and

a cheek retractor portion (52) having a first cheek-retractor end coupled to the second end of the main body portion and a second cheek-retractor end, the first cheek-retractor end and the second cheek-retractor end each having rounded edges (see annotated Fig. 3 above).

25. However, Hirsch (1<sup>st</sup> embodiment) does not disclose a second plurality of perforations formed adjacent to and extending along a portion of the second edge on the first wall, and the suction connector portion includes a cutout configured to engage a protrusion on the suction system to aid in coupling the mouthpiece to the suction system.

26. On the other hand, Hirsch et al. (aka Hirsch 2<sup>nd</sup> embodiment) also discloses another embodiment in Fig. 18A and 18B including an isolation mouthpiece, where the main body includes a plurality of perforations (410) in both first and second walls, that a portion of said plurality of perforations on the first wall are adjacent to the first edge and another portion are adjacent to the second edge, and portion of said plurality of perforations on the second wall are adjacent to the third edge and another portion are

adjacent to the fourth edge. Furthermore, in the area of the suction connector portion includes a cutout configured to engage a protrusion on the suction system to aid in coupling the mouthpiece to the suction system (see annotated Fig. 18A and 18B above and col. 14, lines 46-51 and col. 12, lines 1-17).

27. It would have been obvious to one having ordinary skill in the art before the effective filing date of the claimed invention to modify the plurality of perforation of the first wall and the engagement of the suction system to the suction connector portion of the embodiment of Fig. 1 of Hirsch, with additional perforations on the first wall closer to the second edge and a cutout on the suction connector portion with a protrusion on the coupling section of the suction system of the embodiment of Fig. 18 of Hirsch, in order for the plurality of perforation on the first wall to cover a bigger area in the mouth to maintain the working area free of debris and fluids, and for the cutout in the suction connector portion to be able to releasably connect with the protrusions on the external surface of the hose of the suction system and its connection be retained during its use.

**Regarding claims 22 and 23:**

28. **Regarding claim 22**, Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) discloses the claimed invention substantially as claimed, as set forth above for claim 21, and where the cutout has a generally square shape.

29. However, Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) does not disclose that the cutout has a shield shape.

30. **Regarding claim 23**, Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) discloses the claimed invention substantially as claimed, as set forth above for claim 21, and where the cutout has a generally square shape.

31. However, Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) does not disclose that the cutout is generally triangular and has a top edge, a first curved edge, and a second curved edge

32. On the other hand, having a particular shape for the cutout is a matter of choice in which a person of ordinary skill in the art would have found obvious by the absent of persuasive evidence in the present application, that the particular configuration of the claimed shapes of the cutout is significant. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)

33. **Regarding claim 24**, Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) discloses the claimed invention substantially as claimed, as set forth above for claim 21, and where in the 1<sup>st</sup> embodiment of Hirsch discloses a wall thickness of the conduit is greater than a wall thickness of the first wall or the second wall of the main body (see Fig. 3 above).

**Regarding claim 25-28:**

34. **Regarding claim 25**, Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) discloses the claimed invention substantially as claimed, as set forth above for claim 21.

35. However, Hirsch (1<sup>st</sup> embodiment) does not disclose that the first plurality of perforations of the first wall and the second plurality of perforations of the first wall each include at least five perforations.

36. **Regarding claim 26**, Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) discloses the claimed invention substantially as claimed, as set forth above for claim 25.

37. However, Hirsch (1<sup>st</sup> embodiment) does not disclose that the first plurality of perforations of the second wall and the second plurality of perforations of the second wall each include at least three perforations.

38. **Regarding claim 27**, Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) discloses the claimed invention substantially as claimed, as set forth above for claim 21.

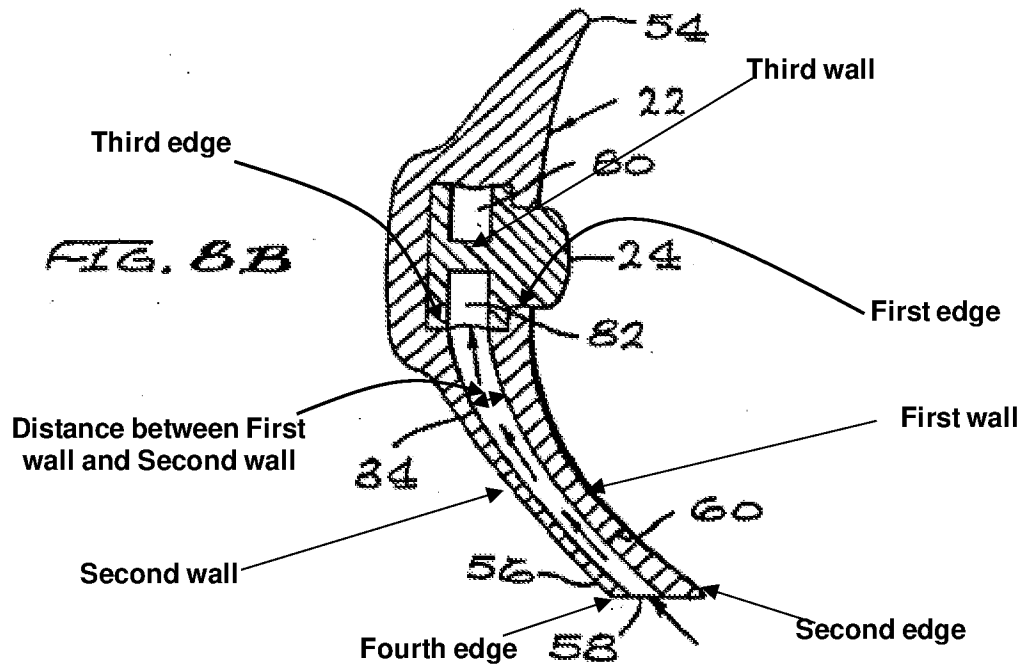
39. However, Hirsch (1<sup>st</sup> embodiment) does not disclose that the first plurality of perforations of the first wall and the second plurality of perforations of the first wall each include at least seven perforations.

40. **Regarding claim 28**, Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) discloses the claimed invention substantially as claimed, as set forth above for claim 27.

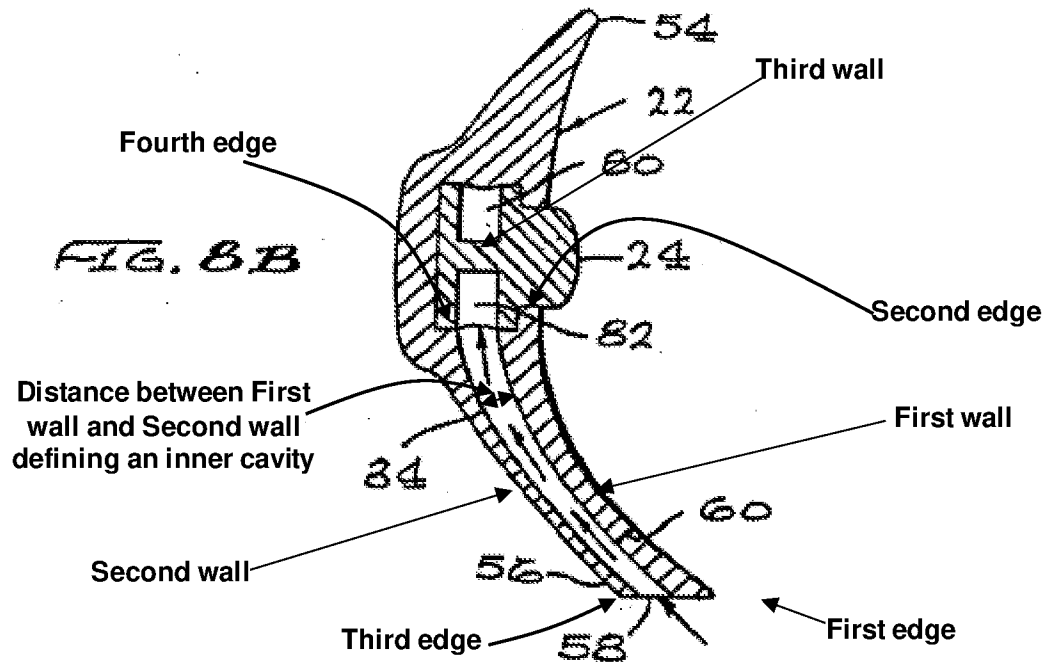
41. However, Hirsch (1<sup>st</sup> embodiment) does not disclose that the first plurality of perforations of the second wall and the second plurality of perforations of the second wall each include at least four perforations.

42. Hirsch, in the 2<sup>nd</sup> embodiment teaches five perforations (410) on each wall (see annotated Fig. 18A and 18B, and that the number of perforations 410 may vary (see col. 12, lines 9-11).

43. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) to include at least five perforations or at least three perforations on each wall, because it has been held that discovering an optimum value of a results effective variable involves only routine skill in the art. See MPEP 2144.05.

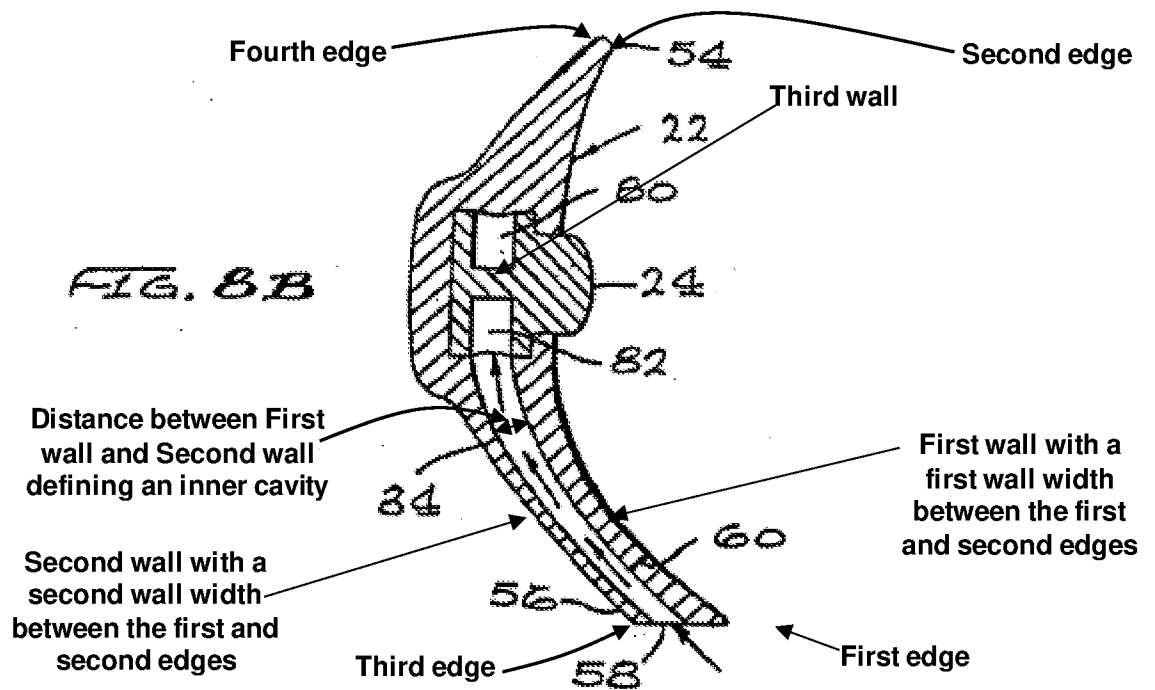


44. **Regarding claim 29**, Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) discloses the claimed invention substantially as claimed, as set forth above for claim 21, and where Hirsch (1<sup>st</sup> embodiment) discloses that the third wall connects the first edge of the first wall to the third edge of the second wall (see annotated Fig. 8B just above).



45. **Regarding claim 30**, Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) discloses the claimed invention substantially as claimed, as set forth above for claim 21, and where Hirsch (1<sup>st</sup> embodiment) discloses that the third wall connects the second edge of the first wall to the fourth edge of the second wall (see annotated Fig. 8B just above).

46. **Regarding claim 32**, Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) discloses the claimed invention substantially as claimed, as set forth above for claim 21, and where Hirsch (1<sup>st</sup> embodiment) discloses that the mouth prop (26) is removably coupled to the generally tubular conduit of the suction connector portion (see annotated Fig. 2 above).



47. **Regarding claims 33 and 39**, Hirsch discloses an isolation mouthpiece for use with a suction system (110) in a dental procedure (see Fig. 1 above), the mouthpiece including:

a main body portion having a first end and a second narrower end that is narrower than the first end (see annotated 3 above), the main body portion including:

a first wall having first and second edges extending from the first end towards the second narrower end of the main body portion (see annotated Fig. 3 and 8B just above), the first wall having a first-wall width defined between the first and second edges (see annotated Fig. 8B just above – where the width is measured in the vertical direction),

the first-wall width being at a maximum in a region between the first and second ends and being at a minimum at the second narrower end (see annotated Fig. 3 just above – where the width is measured in the vertical direction),

the first wall including a first plurality of perforations (60) formed adjacent to and extending along a substantial portion of the first edge (see annotated Fig. 3 above);

a second wall spaced apart from the first wall to define an inner cavity of the main body between the second wall and the first wall (see annotated Fig. 8B just above), the second wall having third and fourth edges extending from the first end towards the second end of the main body portion (see annotated Fig. 4 and 8B above),

the second wall having a second- wall width defined between the third and fourth edges (see annotated Fig. 4 and 8B above), the second-wall width being at a maximum in a region between the first and second ends and being at a minimum at the second narrower end (see annotated Fig. 4 just above – where the width is measured in the vertical direction), the second wall including a third plurality of perforations (60) formed adjacent to and extending along a substantial portion of the third edge (see annotated Fig. 4 above);

a stability bar (24) located along a center of the first wall at least adjacent to the second narrow end of the main body (see annotated Fig. 3 above); and

a bridge structure extending from an interior surface of the first wall toward the second wall, the bridge structure including a plurality of square-like protrusions to ensure the first wall remains separated from the second wall during suction from the suction system (110), and that the bridge structure is located centrally in the main body (for claim 39) (for **claim 39**) (see annotated Fig. 2 and 4 above – where adjacent to the first and third edges includes channels 58 formed by a plurality of square or rectangular protrusions extending from the first wall to the second wall in the center of the main body);

a suction-connector portion (108) extending from the first end of the main body portion (see annotated Fig. 2 and 3 above), the suction connector portion (108) including:

a generally tubular conduit including an opening extending through the conduit and in fluid communication with the inner cavity of the main body (see annotated Fig. 3 above), the opening being configured to receive a vacuum portion of the suction system therein for providing suction to the inner cavity (see col. 7, lines 27-31 – where “fluids are vacuumed from the internal evacuation channel 104 of the bite block 26 through an exit port 108”); and

a mouth prop (26) that extends away from the tubular conduit (see Fig. 3 above), the mouth prop (26) at least partially defined by a first side and a second side that generally taper inwardly in a direction away from the tubular conduit towards a bottom surface of the mouth prop (see annotated Fig. 4 and 7 above), the first side and the second side including a plurality of ridges (94) (see annotated Fig. 4 above); and

a cheek-retractor portion (52) connected to the second narrower end of the main body portion and expanding outwardly away from the second narrower end (see annotated Fig. 3 above), the first and second walls of the main body transitioning into and being connected in the cheek-retractor portion to form the cheek-retractor portion (see annotated Fig. 3 above) (for claim 33).

48. However, the 1<sup>st</sup> embodiment of Hirsch does not disclose a second plurality of perforations formed adjacent to and extending along a substantial portion the second edge, that at least one of the first plurality of perforations and at least one of the second plurality of perforations being located adjacent to the minimum width of the first wall at the

second narrower end of the main body; a fourth plurality of perforations formed adjacent to and extending along a substantial portion the fourth edge, that at least one of the third plurality of perforations and at least one of the fourth plurality of perforations being located adjacent to the minimum width of the second wall at the second end of the main body; that the at least one of the first plurality of perforations being positioned on one side of the stability bar and the at least one of the second plurality of perforations being positioned on another side of the stability bar; and that the protrusions forming the bridge structure includes a plurality of wave-like protrusions.

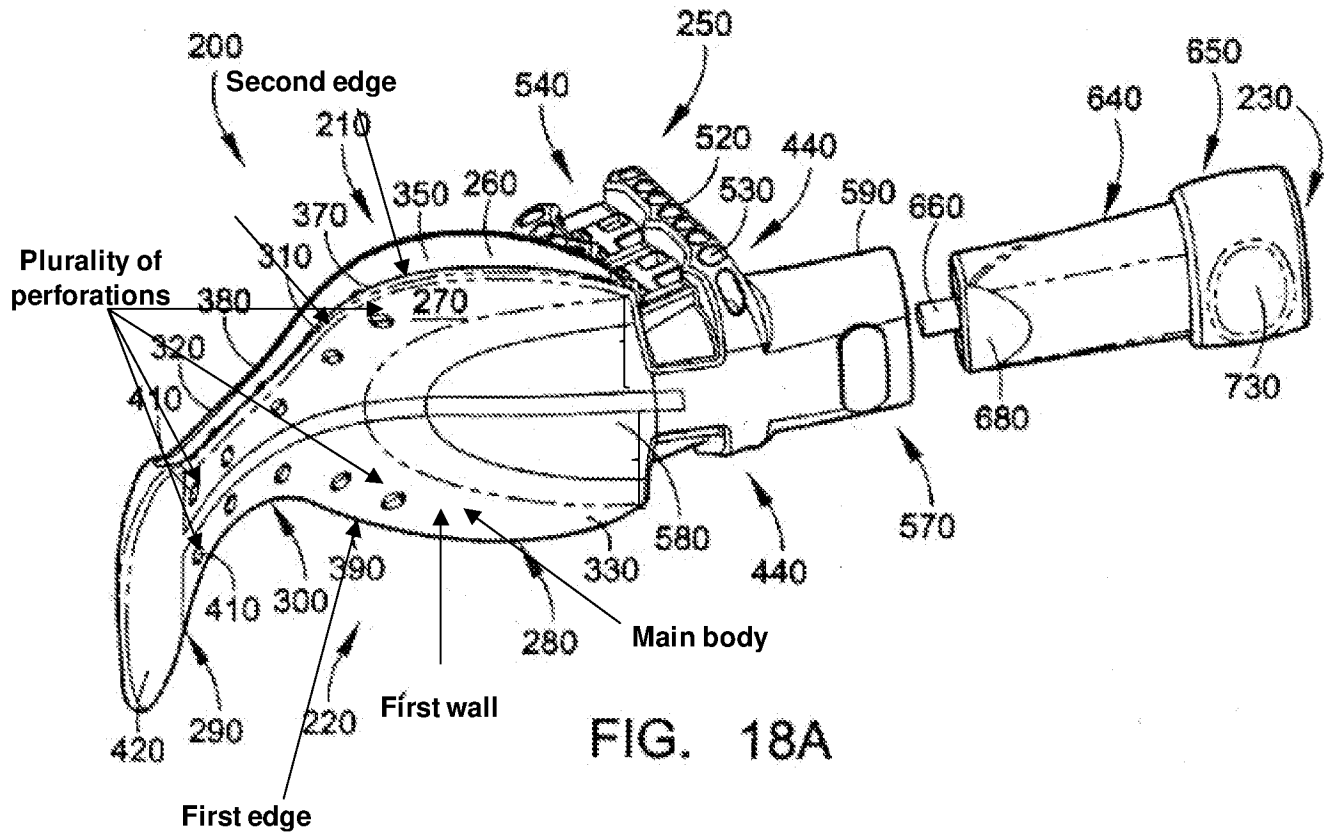
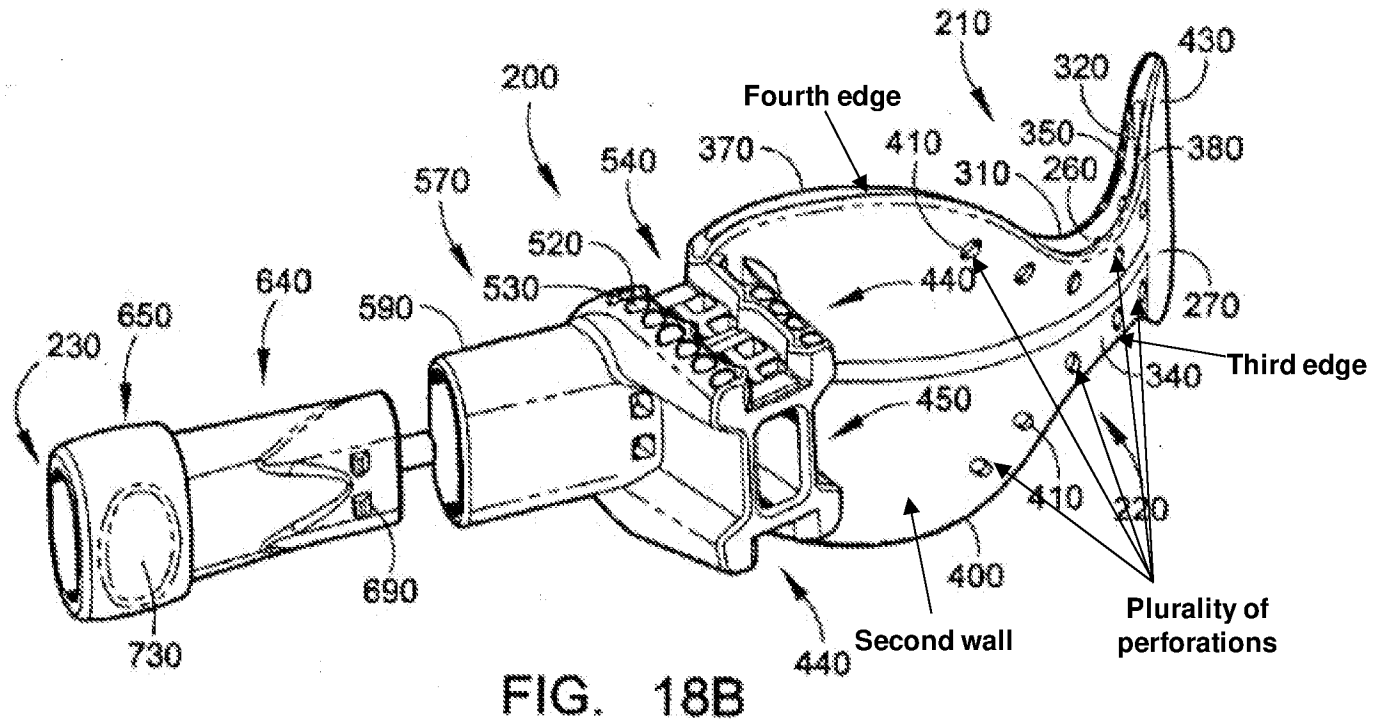


FIG. 18A



49. On the other hand, Hirsch et al. (aka Hirsch 2<sup>nd</sup> embodiment) also discloses another embodiment in Fig. 18A and 18B including an isolation mouthpiece, where the main body includes a plurality of perforations (410) in both first and second walls, where a portion of said plurality of perforations on the first wall are adjacent to the first edge and another portion are adjacent to the second edge, and portion of said plurality of perforations on the second wall are adjacent to the third edge and another portion are adjacent to the fourth edge (see annotated Fig. 18A and 18B above and col. 12, lines 1-17).

50. It would have been obvious to one having ordinary skill in the art before the effective filing date of the claimed invention to modify the plurality of perforations of the first and second walls of the embodiment of Fig. 1 of Hirsch, with additional perforations on the first and second walls closer to the second and fourth edges of the embodiment of

Fig. 18 of Hirsch, in order for the plurality of perforation on the first and second walls to cover an bigger area in the mouth to maintain the working area free of debris and fluids, and by having the plurality of perforations adjacent to both edges located on opposite locations on the walls allows to turn around the mouthpiece so that the vacuum port can be on the left or the right of the mouth of the patient, depending on the necessity of the treatment at hand.

51. However, Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) does not disclose that the protrusions forming the bridge structure includes a plurality of wave-like protrusions.

52. On the other hand, having a particular shape for the protrusions is a matter of choice in which a person of ordinary skill in the art would have found obvious by the absent of persuasive evidence in the present application, that the particular configuration of the claimed shape of the protrusions is significant over other shapes. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)

53. **Regarding claim 34 and 35**, Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) discloses the claimed invention substantially as claimed, as set forth above for claim 33, and where Hirsch (1<sup>st</sup> embodiment) discloses a generally tubular conduit of the suction-connector portion (108).

54. However, Hirsch (1<sup>st</sup> embodiment) does not include a cutout configured to engage a protrusion on the suction system to aid in coupling the mouthpiece to the suction system (for **claim 34**); and that the cutout is on the same side of the suction-connector portion as the mouth prop (for **claim 35**).

55. On the other hand, Hirsch 2<sup>nd</sup> embodiment also discloses an area of the suction connector portion on the same side as the mouth prop that includes a cutout configured

to engage a protrusion on the suction system to aid in coupling the mouthpiece to the suction system (see annotated Fig. 18A and 18B above and col. 14, lines 46-51 and col. 12, lines 1-17).

56. It would have been obvious to one having ordinary skill in the art before the effective filing date of the claimed invention to modify the suction connector portion of Hirsch (1<sup>st</sup> embodiment), with the cutout on the suction connector portion the embodiment of Fig. 18 of Hirsch, in order for the cutout in the suction connector portion to be able to releasably connect with the protrusions on the external surface of the hose of the suction system and its connection be retained during its use.

57. **Regarding claim 36**, Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) discloses the claimed invention substantially as claimed, as set forth above for claim 33.

58. However, Hirsch (1<sup>st</sup> embodiment) does not disclose that the first plurality of perforations of the first wall and the second plurality of perforations of the first wall each include at least five perforations.

59. On the other hand, in the 2<sup>nd</sup> embodiment of Hirsch teaches five perforations (410) on each wall (see annotated Fig. 18A and 18B, and that the number of perforations 410 may vary (see col. 12, lines 9-11).

60. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) to include at least five perforations on each wall, because it has been held that discovering an optimum value of a results effective variable involves only routine skill in the art. See MPEP 2144.05.

61. **Regarding claim 37**, Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) discloses the claimed invention substantially as claimed, as set forth above for claim 33, and where Hirsch (1<sup>st</sup> embodiment) discloses that the stability bar (24) extends upwardly from the first wall toward the second wall (see annotated Fig. 8B above).

62. **Regarding claim 39**, Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) discloses the claimed invention substantially as claimed, as set forth above for claim 33, and where Hirsch (1<sup>st</sup> embodiment) the bridge structure is located centrally in the main body (see annotated Fig. 4 above – due to the bridge structure is between the two walls is considered located centrally).

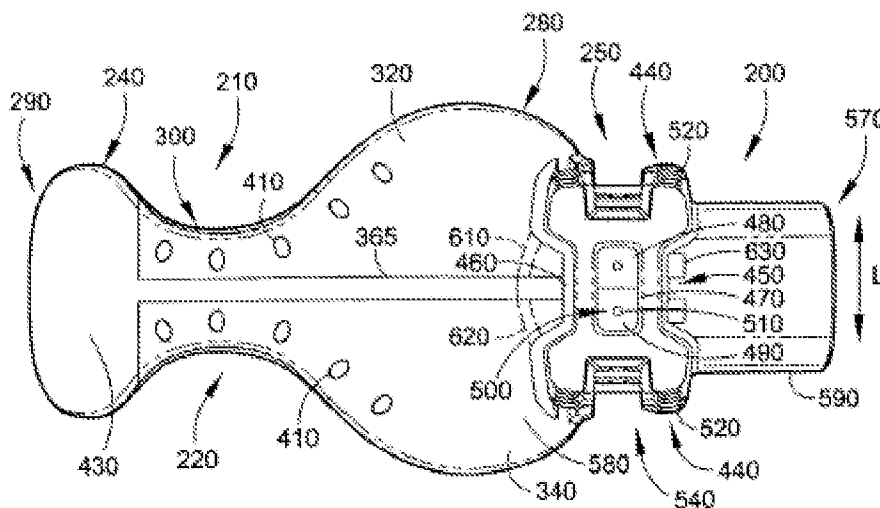


FIG. 19E

63. **Regarding claim 40**, Hirsch (1<sup>st</sup> embodiment)/Hirsch (2<sup>nd</sup> embodiment) discloses the claimed invention substantially as claimed, as set forth above for claim 33, and where Hirsch (1<sup>st</sup> embodiment) discloses that at least a small portion of the isthmus portion between the main body and the check retractor has a small rectangular shape portion.

***Allowable Subject Matter***

64. **Claims 31, 38, 41 and 42** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

65. The following is a statement of reasons for the indication of allowable subject matter:

a. **Regarding claim 31**, the new claim describes that the first wall and the second wall are shaped such that the first edge of the first wall corresponds to the third edge of the second wall and the second edge of the first wall corresponds to the fourth edge of the second wall.

b. **Regarding claim 38**, the new claim describes a stability bar not contacting the second wall, in which is not found in the prior art of Hirsch.

c. **Regarding claim 41**, the new claim describes the first and second walls of the main body that transition into the cheek-retractor portion remain unconnected from each other for a distance within the cheek-retractor portion before being connected to each other in the cheek-retractor portion, in which is not found in the prior arts of Hirsch.

***Conclusion***

66. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MIRAYDA ARLENE APONTE whose telephone number is (571)270-1933. The examiner can normally be reached M-F 8-5.

67. Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

68. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on 571-272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

69. Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MIRAYDA A APONTE/  
Examiner, Art Unit 3772

/RALPH A LEWIS/  
Primary Examiner, Art Unit 3772

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INVENTOR(S): Nguyen et al.  
APPLICATION NO.: 18/217,304  
FILING DATE: June 30, 2023  
TITLE: Intraoral Device  
EXAMINER: Mirayda Arlene Aponte  
ART UNIT: 3772  
CONFIRM. NO.: 5030  
ATTY.DKT.NO.: INCEP-001COF

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**RESPONSE A**

Examiner Aponte:

This responds to the non-final office action mailed September 29, 2023 (*Office Action*). Please enter and consider **amendments to the specification** and **amendments to the claims**, beginning on **page two** and **page three**, respectively. A **summary of examiner interview** begins on **page fourteen**. Remarks begin on **page fifteen**.

## IN THE SPECIFICATION

PLEASE AMEND THE SPECIFICATION AS FOLLOWS:

[0043] The mouthpiece may be used with a mouth prop 160, as illustrated in FIGS. 1 (with a mouth prop 160) and FIGS. 2 (illustrated without the mouth prop 160). FIGS. 3A-E provide different close-up views of an exemplary mouth prop 160. The removable strap 310 may be attached to portion 320 of mouth prop 160, which may be used to prop open a patient's mouth and teeth. In this regard, the suction connector portion 120 may additionally have an external plug 220 (FIG. 2C) protruding from the posterior side of the suction connector portion 120. Such a plug 220 may correspond to and serve to connect with an opening in the mouth prop 160. The mouth prop 160 may be reinforced by the presence of the plug 220 in the opening, thereby resulting in a more crush-resistant, nearly incompressible, and stable mouth prop 160. In some embodiments, the suction connector portion 120 may further have a cutout 230 (e.g., which may be shaped as a logo) providing extra interlocking with a corresponding protrusion (e.g., which may also be shaped as a logo) on an external high-suction vacuum adapter.

## IN THE CLAIMS

PLEASE AMEND THE CLAIMS AS FOLLOWS:

1. (currently amended) A mouthpiece comprising:

a main body having a first end opposite a second end that is narrower than the first end, the main body comprising:

a first wall having a plurality of first edges and extending from the first end to the second end,

a second wall having a plurality of second edges and located at a distance from the first wall, the distance corresponding to an interior space between the first wall and the second wall, wherein the second wall also extends from the first end to the second end,

a connecting wall that connects one of the first edges of the first wall to one of the second edges of the second wall across the distance between the first wall and the second wall, and

a bridge structure that includes a plurality of spaced protrusions integral with and protruding from an interior surface of the second wall, the bridge structure extending substantially across the distance between the first wall and the second wall through the interior space towards the first wall; and

a cheek-retractor portion connected to the narrower second end of the main body portion and expanding outwardly away from the second narrower end, the first wall and the second wall of the main body transitioning into and being connected in the cheek-retractor portion to form the cheek-retractor portion, wherein the first wall and the second wall of the main body portion that transition into the cheek-retractor portion are spaced apart from each other for a distance within the cheek-retractor portion before being connected at a terminal end region of the cheek-retractor portion.

2. (previously presented) The mouthpiece of claim 1, wherein one or more of the first edges of the first wall and the second edges of the second wall include a superior edge and an inferior edge.

3. (original) The mouthpiece of claim 2, wherein the superior edge is formed so as to appear as the inferior edge in a different orientation, and wherein the inferior edge is formed so as to appear as the superior edge in the different orientation.

4. - 5. (cancelled)

6. (original) The mouthpiece of claim 1, further comprising a suction connector extending from the first end of the main body, wherein an evacuation conduit within the suction connector is in communication with the interior space between the first wall and the second wall.

7. (original) The mouthpiece of claim 6, wherein a wall thickness of the suction connector is greater than a wall thickness of the first wall or the second wall of the main body.

8. (cancelled)

9. (previously presented) The mouthpiece of claim 6, wherein the suction connector further includes a cutout configured to interlock with a corresponding protrusion of a vacuum adapter, wherein a shape of the cutout follows a shape of a shield logo.

10. - 15. (cancelled)

16. (previously presented) The mouthpiece of claim 1, further comprising a stability bar corresponding to a thickened area of the main body, the stability bar extending along a longitudinal axis of the main body between the first wall and the second wall, wherein a thickness of the stability bar reinforces at least a portion of the main body.

17. – 19. (cancelled)

20. (original) The mouthpiece of claim 1, wherein the main body further includes a slit that extends along at least a portion of the main body, and wherein the slit opens into the interior space between the first wall and the second wall to assist in cleaning.

21. (currently amended) An isolation mouthpiece for use with a suction system in a dental procedure, the mouthpiece comprising:

a main body portion having a first end and a second end, the main body portion including:

a first wall having a first edge and a second edge extending from the first end of the main body portion towards the second end of the main body portion, the first wall including a first plurality of perforations formed adjacent to and extending along a portion of the first edge and a second plurality of perforations formed adjacent to and extending along a portion of the second edge,

a second wall having a third edge and a fourth edge extending from the first end of the main body portion towards the second end of the main body portion, the second wall including a ~~[[first]]~~ third plurality of perforations formed adjacent to and extending along a portion of the third edge, and a ~~second~~ fourth plurality of perforations formed adjacent to and extending along a portion of the fourth edge, wherein the second wall further includes a plurality of protrusions extending from an interior surface of the second wall towards the first wall in a shape having one or more crests and one or more troughs, and

a third wall connecting the first wall and the second wall such that the first wall is spaced from the second wall to define an inner cavity, wherein a portion of the first wall has a first width adjacent to the first end of the main body portion and a second width adjacent to the second end of the main body portion, wherein ~~[[and]]~~ a portion of the second wall has a third width adjacent to the first end of the main body portion and a fourth width adjacent to the second end of the main body portion, wherein the first width is greater than the second width, and wherein the third width is greater than the fourth width;

a suction connector portion extending from the first end of the main body portion, the suction connector portion including:

a generally tubular conduit including:

an opening extending through the conduit and in fluid communication with the inner cavity, the opening being configured to receive a vacuum portion of the suction system therein, and

a cutout configured to engage a protrusion on the suction system to aid in coupling the mouthpiece to the suction system;

a mouth prop including a first side and a second side that are inwardly tapered from a top surface of the mouth prop towards a bottom surface of the mouth prop, the first side and the second side each including a plurality of ridges; and

a cheek retractor portion having a first cheek-retractor end coupled to the second end of the main body portion and a second cheek-retractor end, the first cheek-retractor end and the second cheek-retractor end each having rounded edges, wherein the first wall and the second wall of the main body portion that transition into the cheek-retractor portion are spaced apart from each other for a distance within the cheek-retractor portion before being connected to each other in the cheek-retractor portion.

22. (previously presented) The mouthpiece of claim 21, wherein the cutout has a shield shape.

23. (previously presented) The mouthpiece of claim 21, wherein the cutout is generally triangular and has a top edge, a first curved edge, and a second curved edge.

24. (previously presented) The mouthpiece of claim 21, wherein a wall thickness of the conduit is greater than a wall thickness of the first wall or the second wall of the main body.

25. (previously presented) The mouthpiece of claim 21, wherein the first plurality of perforations of the first wall and the second plurality of perforations of the first wall each include at least five perforations.

26. (currently amended) The mouthpiece of claim 25, wherein the ~~[[first]]~~ third plurality of perforations of the second wall and the ~~second~~ fourth plurality of perforations of the second wall each include at least three perforations.

27. (previously presented) The mouthpiece of claim 21, wherein the first plurality of perforations of the first wall and the second plurality of perforations of the first wall each include at least seven perforations.

28. (currently amended) The mouthpiece of claim 27, wherein the ~~[[first]]~~ third plurality of perforations of the second wall and the ~~second~~ fourth plurality of perforations of the second wall each include at least four perforations.

29. (previously presented) The mouthpiece of claim 21, wherein the third wall connects the first edge of the first wall to the third edge of the second wall.

30. (previously presented) The mouthpiece of claim 21, wherein the third wall connects the second edge of the first wall to the fourth edge of the second wall.

31. (previously presented) The mouthpiece of claim 21, wherein the first wall and the second wall are shaped such that the first edge of the first wall corresponds to the third edge of the second wall and the second edge of the first wall corresponds to the fourth edge of the second wall.

32. (previously presented) The mouthpiece of claim 21, wherein the mouth prop is removably coupled to the generally tubular conduit of the suction connector portion.

33. (currently amended) An isolation mouthpiece for use with a suction system in a dental procedure, the mouthpiece comprising:

a main body portion having a first end and a second narrower end that is narrower than the first end, the main body portion including:

a first wall having first and second edges extending from the first end towards the second narrower end of the main body portion, the first wall having a first-wall width defined between the first and second edges, the first-wall width being at a maximum in a region between the first and second ends and being at a minimum at the second narrower end, the first wall including a first plurality of perforations formed adjacent to and extending along a substantial portion of the first edge and a second plurality of perforations formed adjacent to and extending along a substantial portion of the second edge, at least one of the first plurality of perforations and at least one of the second plurality of perforations being located adjacent to the minimum width of the first wall at the second narrower end of the main body;

a second wall spaced apart from the first wall to define an inner cavity of the main body between the second wall and the first wall, the second wall having third and fourth edges extending from the first end towards the second end of the main body portion, the second wall having a second-wall width defined between the third and fourth edges, the second-wall width being at a maximum in a region between the first and second ends and being at a minimum at the second narrower end, the second wall including a third plurality of perforations formed adjacent to and extending along a substantial portion of the third edge and a fourth plurality of perforations formed adjacent to and extending along a substantial portion of the fourth edge, at least one of the third plurality of perforations and at least one of the fourth plurality of perforations being located adjacent to the minimum width of the second wall at the second end of the main body;

a stability bar located along a center of the first wall at least adjacent to the second narrow end of the main body, the at least one of the first plurality of perforations

being positioned on one side of the stability bar and the at least one of the second plurality of perforations being positioned on another side of the stability bar; and

a bridge structure extending from an interior surface of the first wall toward the second wall, the bridge structure including a plurality of wave-like protrusions to ensure the first wall remains separated from the second wall during suction from the suction system;

a suction-connector portion extending from the first end of the main body portion, the ~~suction-connector~~ suction-connector portion including:

a generally tubular conduit including an opening extending through the conduit and in fluid communication with the inner cavity of the main body, the opening being configured to receive a vacuum portion of the suction system therein for providing suction to the inner cavity; and

a mouth prop that extends away from the tubular conduit, the mouth prop at least partially defined by a first side and a second side that generally taper inwardly in a direction away from the tubular conduit towards a bottom surface of the mouth prop, the first side and the second side including a plurality of ridges; and

a cheek-retractor portion connected to the second narrower end of the main body portion and expanding outwardly away from the second narrower end, the first wall and the second ~~walls~~ wall of the main body transitioning into and being connected in the cheek-retractor portion to form the cheek-retractor portion, wherein the first wall and the second wall of the main body portion that transition into the cheek-retractor portion are spaced apart from each other for a distance within the cheek-retractor portion before being connected to each other in the cheek-retractor portion.

34. (previously presented) The mouthpiece of claim 33, wherein the generally tubular conduit of the suction-connector portion includes a cutout configured to engage a protrusion on the suction system to aid in coupling the mouthpiece to the suction system.

35. (previously presented) The mouthpiece of claim 34, wherein the cutout is on the same side of the suction-connector portion as the mouth prop.

36. (previously presented) The mouthpiece of claim 33, wherein the first plurality of perforations of the first wall and the second plurality of perforations of the first wall each include at least five perforations.

37. (previously presented) The mouthpiece of claim 33, wherein the stability bar extends upwardly from the first wall toward the second wall.

38. (previously presented) The mouthpiece of claim 37, wherein the stability bar does not contact the second wall.

39. (previously presented) The mouthpiece of claim 33, wherein the bridge structure is located centrally in the main body.

40. (previously presented) The mouthpiece of claim 33, wherein the narrower second end is part of a rectangular portion of the main body.

41. (cancelled)

42. (currently amended) The mouthpiece of claim ~~[[41]]~~ 33, wherein the at least one of the first plurality of perforations and the at least one of the second plurality of perforations located adjacent to the second narrower end of the main body are near ~~the unconnected~~ a portion of the first wall that is spaced apart from ~~[[and]]~~ the second wall ~~walls within the cheek retractor portion.~~

43. (new) An isolation mouthpiece for use with a suction system in a dental procedure, the mouthpiece comprising:

a main body portion having a first end and a second end, the main body portion including:

a first wall having a first edge and a second edge extending from the first end of the main body portion towards the second end of the main body portion, the first wall including a first plurality of perforations formed adjacent to and extending along a portion of the first edge and a second plurality of perforations formed adjacent to and extending along a portion of the second edge,

a second wall having a third edge and a fourth edge extending from the first end of the main body portion towards the second end of the main body portion, the second wall including a third plurality of perforations formed adjacent to and extending along a portion of the third edge, and a fourth plurality of perforations formed adjacent to and extending along a portion of the fourth edge, wherein the second wall further includes a plurality of protrusions extending from an interior surface of the second wall towards the first wall in a shape having one or more crests and one or more troughs, and wherein the first wall and the second wall are shaped such that the first edge of the first wall corresponds to the third edge of the second wall and the second edge of the first wall corresponds to the fourth edge of the second wall, and

a third wall connecting the first wall and the second wall such that the first wall is spaced from the second wall to define an inner cavity, wherein a portion of the first wall has a first width adjacent to the first end of the main body portion and a second width adjacent to the second end of the main body portion, wherein a portion of the second wall has a third width adjacent to the first end of the main body portion and a fourth width adjacent to the second end of the main body portion, wherein the first width is greater than the second width, and wherein the third width is greater than the fourth width;

a suction connector portion extending from the first end of the main body portion, the suction connector portion including:

a generally tubular conduit including:

an opening extending through the conduit and in fluid communication with the inner cavity, the opening being configured to receive a vacuum portion of the suction system therein, and

a cutout configured to engage a protrusion on the suction system to aid in coupling the mouthpiece to the suction system;

a mouth prop including a first side and a second side that are inwardly tapered from a top surface of the mouth prop towards a bottom surface of the mouth prop, the first side and the second side each including a plurality of ridges; and

a cheek retractor portion having a first cheek-retractor end coupled to the second end of the main body portion and a second cheek-retractor end, the first cheek-retractor end and the second cheek-retractor end each having rounded edges.

## APPLICANT'S SUMMARY OF EXAMINER INTERVIEW

The Applicant's representative spoke with the Examiner on December 6, 2023 and January 26, 2024 ("*Examiner Interviews*") regarding the rejections set forth in the *Office Action* and claim amendments for overcoming the same. During the *Examiner Interviews*, the Applicant's representative discussed the elements of allowable subject matter identified by the examiner and incorporation of the same into the independent claims.

The Examiner agreed that the proposed amendments to the independent claims would place the present application into condition for allowance. Claim amendments in accordance with the *Examiner Interviews* are hereby presented for formal entry. The Applicant and the Applicant's representative thank the Examiner for her time and courtesy during the *Examiner Interview*.

## REMARKS

### *Status of the Claims*

Claims 1, 21, 26, 28, 33, and 42 are currently amended. Claim 41 is cancelled and claim 43 is newly added. All amendments are supported by the specification, including at least paragraphs [0033]-[0042] and associated FIGs. 1-2 and 7. No new matter is added. Applicant respectfully submits that these claims are allowable.

### *Allowable Subject Matter*

The Examiner notes that claims 31, 38, 41, and 42 would be allowed if rewritten in independent form. *Office Action*, 31. The elements of allowable claim 41 are hereby incorporated into all independent claims presented herein. All of the independent claims now recite allowable subject matter and are thus allowable; the respective dependent claims are likewise allowable for at least the same reasons.

### *Objections to the Drawings*

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the reference number 320 of Fig. 3A not found in the specification. *Id.* at 2. Paragraph [0043] of the *Specification* has been amended in compliance with 37 CFR 1.121(b). Clean and marked-up substitute *Specifications* with the amendments are also provided herewith. Withdrawal of the objection to the drawings is respectfully requested.

### *Claim Objections*

The Examiner objects to informalities regarding the sentence structure of claim 21. *Id.* The present claim 21 is amended and no longer include the identified informalities. Thus, the objections are believed to be moot, and Applicant respectfully requests withdrawal of the same.

*Rejections under 35 U.S.C. § 112(b)*

Claim 21 is rejected under 35 U.S.C. § 112(b) as purportedly being indefinite in relation to the term 'second.' *Id.* at 3. To expedite examination, 'second' has been amended to refer to the 'second side' in accordance with guidance in the *Office Action. Id.* The rejections are believed to be moot, and Applicant respectfully requests withdrawal of the same.

*Rejections under 35 U.S.C. §§ 102-103*

Claims 1-3, 6, 7, 16, and 20 are rejected under 35 U.S.C. § 102 as being anticipated by *Hirsch 1* (U.S. Publication No. 2003/0134253). *Id.* at 4. Claims 9, 21, 22-30, 32-37, 39 and 40 are rejected under 35 U.S.C. § 103 as being unpatentable over *Hirsch 1* in view of *Hirsch 2* (U.S. Patent No. 6,974,321). *Id.* at 9.

The Applicant notes that all of the independent claims (including new claim 43) now recite the elements previously recited by claim 41 and identified as allowable by the *Office Action. Id.* at 31. In view of the above remarks, the independent claims are patentable over the cited references. Furthermore, because each of the dependent claims incorporates by reference all the limitations of the independent claim from which it depends, the dependent claims are allowable for at least the same reasons. The Applicant therefore respectfully requests that the rejections of the claims under 35 U.S.C. § 102 and 103 be withdrawn.

## CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

The Examiner is invited to contact Applicant's undersigned representative with any questions or comments as to patentability of the present claims.

Respectfully Submitted,

Date: **January 29, 2024**

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Table with columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
Rows include application details for 18/217,304 and 138718 7590, examiner APONTE, MIRAYDA ARLENE, art unit 3772, and notification date 03/13/2024.

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocketing@polsinelli.com
sfpatent@polsinelli.com



## DETAILED ACTION

### *Notice of Pre-AIA or AIA Status*

1. The present application is being examined under the pre-AIA first to invent provisions.

### *Information Disclosure Statement*

2. The information disclosure statement filed 2 October 2023 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

### *Drawings*

3. The drawings were received on 30 June 2023. These drawings are not acceptable. Fig. 1D indicates a cross section 5A-5A that is not found in the set of drawings.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character not mentioned in the description: The cross section 5A-5A of Fig. 1D, is not found in the specification.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be

labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

5. The amended specification was received on 29 January 2024. This amended specification acceptable.

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: **Claim 1** describes that the "bridge structure include a plurality of spaced protrusions integral with and protruding from an interior surface of the second wall". Where the specific description that the protrusions of the bridge structure are integral with the interior surface of the second wall is not found in the specification.

### ***Claim Rejections - 35 USC § 112(a)***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. **Claims 1-3, 6, 7, 9, 16 and 20** are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventors, at the time the application was filed, had possession of the claimed invention.
9. **Claim 1** describes a “terminal end region” for the “cheek-retractor portion” in the last two lines of the claim, the term “terminal end region” is not found in the specification.

***Claim Rejections - 35 USC § 112(b)***

10. The following is a quotation of 35 U.S.C. 112(b):  
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. **Claims 1-3, 6, 7, 9, 16 and 20** are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.
12. **Regarding claim 1**, the use of the term “substantially” in line 15 of the claim is confusing. The specification or the claim do not provide the metes and bounds of said term in a way to understand its limitations, rendering the claim indefinite.

13. **Regarding claim 1**, the use of the term “terminal end region” used in combination with “cheek-retractor portion” in the last two lines of the claim, is confusing. It is not understood if the said terminal end region is at the proximal end of the “cheek-retractor portion, or the distal end of the “cheek-retractor portion”. For examination purposes, the recitation will be treated as the “terminal end region” is at the proximal end of the “cheek-retractor portion”.

***Allowable Subject Matter***

14. **Claims 21-43** are allowed.

15. The following is an examiner’s statement of reasons for allowance:

a. **Regarding claim 21**, the claim includes similar languages for describing the separation between the first wall and the second wall as the claim 41, in which it was indicated to have allowable subject matter in the last Office action of 29 September 2023.

b. Therefore, the art of record does not teach or render obvious, either alone or in combination, an isolation mouthpiece including first wall and a second wall of a main body portion that transition into a cheek-retractor portion are spaced apart from each other for a distance within the cheek-retractor portion before being connected to each other in the cheek-retractor portion in combination with the elements set forth in the claim.

c. **Regarding claim 33**, the claim includes similar languages for describing the separation between the first wall and the second wall as the claim 41, in which

it was indicated to have allowable subject matter in the last Office action of 29 September 2023.

d. Therefore, the art of record does not teach or render obvious, either alone or in combination, an isolation mouthpiece including first wall and the second wall of the main body portion that transition into the cheek-retractor portion are spaced apart from each other for a distance within the cheek-retractor portion before being connected to each other in the cheek-retractor portion in combination with the elements set forth in the claim.

e. **Regarding claim 43**, the claim includes similar languages for describing the separation between the first wall and the second wall as the claim 41, in which it was indicated to have allowable subject matter in the last Office action of 29 September 2023.

f. Therefore, the art of record does not teach or render obvious, either alone or in combination, an isolation mouthpiece including first wall and the second wall of the main body portion that transition into the cheek-retractor portion are spaced apart from each other for a distance within the cheek-retractor portion before being connected to each other in the cheek-retractor portion in combination with the elements set forth in the claim.

16. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Response to Arguments***

17. Applicant's arguments with respect to **claims 1-3, 6, 7, 9, 16 and 20** have been considered but are moot because the new ground of rejection does not rely on any reference applied in the prior rejection of record for any teaching or matter specifically challenged in the argument.

***Conclusion***

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

19. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MIRAYDA ARLENE APONTE whose telephone number is (571)270-1933. The examiner can normally be reached M-F 8-5.

21. Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an

interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on 571-272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

23. Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MIRAYDA A APONTE/  
Examiner, Art Unit 3772

/RALPH A LEWIS/  
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