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S&N Exhibit 1109 S&N v. Arthrex



PTO/SB/17 (11-01)

Approved for use through 10/31/2002. OMB 0651-0032

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CORKSCREW SUTURE ANCHOR

This application is a continuation of U.S. Application Serial No. 09/823,988, filed April 3, 2001, which is a continuation of U.S. Application Serial No. 09/588,065, filed June 5, 2000, now U.S. Patent No. 6,214,031, which is a continuation of U.S. Application Serial No. 08/954,206, filed October 20, 1997, now U.S. Patent No. 6,117,162, which is a continuation of U.S. Application Serial No. 08/905,393, filed August 4, 1997, now abandoned. This application also claims the benefit of U.S. Provisional Application Serial No. 60/023,011, filed August 5, 1996.

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BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to an apparatus and method for anchoring surgical suture to bone. More specifically, the present invention relates to arthroscopic apparatus and methods for anchoring suture to cancellous bone using a suture anchor having an auger-like configuration.

20 2. Description of the Related Art

When soft tissue tears away from bone, reattachment becomes necessary. Various devices, including sutures alone, screws, staples, wedges, and plugs have been used to secure soft tissue to bone. Recently, various types of threaded suture anchors have been developed for this purpose.

Suture anchors have been developed that are designed to be inserted into a predrilled hole. Other suture anchors are self-tapping. Self-tapping screws are shown, for example, in U.S. Pat. No. 4,632,100, which discloses a cylindrical suture anchor. The

suture anchor of the '100 patent includes a drill bit at a leading end for boring a hole in a bone, followed by a flight of threads spaced from the drill bit for securing the anchor into the hole created by the drill bit. U.S. Pat. No. 5,370,662 discloses a self-tapping suture anchor having a flight of threads around a solid body. U.S. Pat. No. 5,156,616 discloses a similar suture anchor having an axial opening for holding a knotted piece of suture.

All of the above-noted suture anchors rely on a flight of threads disposed on the outer surface of a shank to secure the anchor to the bone. They all provide a relatively easy method of suture fixation in hard, cortical bone.

Recent studies indicate, however, that the above-noted suture anchors may have problems related to inadequate "pull-out" strength. This is true especially in softer bone sites, such as cancellous bone, or in bone tissue that has become compromised, such as in osteoporotic bone sites. The structure of cancellous, or cancellated, bone is lattice-like, or spongy. Osteoporotic bone is the result of a condition that reduces the quantity of bone or atrophies skeletal tissue, causing a porous condition of the bones. These bone types may present a limited range of specific fixation points that are available to the surgeon.

Also, certain known suture anchors also have a tendency to "back out" of the implantation site. Moreover, substantial bone loss is incurred simply upon installation of the above-described prior art suture anchors. This problem is acute particularly during procedures that require removal or relocation of suture anchors.

Accordingly, a need exists for a suture anchor that can be secured easily and effectively, especially in softer types of bone. A need also exists for a suture anchor that displaces a minimum amount of bone upon insertion. In addition, a need exists for a suture anchor having exceptional pull-out strength, especially in soft bone. A need also exists for a suture anchor that is averse to "backing out" of the insertion site.

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SUMMARY OF THE INVENTION

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The suture anchor of the present invention overcomes disadvantages of the prior art, such as those noted above, and achieves the foregoing objectives by providing a corkscrew suture anchor having preferably a single thread spiralling helically around a central body.

The corkscrew suture anchor has a central body, a distal end, and a proximal end. The central body preferably tapers from the proximal end to terminate in a point at the distal end. The distal point preferably is rounded to avoid possible breakage sometimes encountered when using a sharp point. The point is approached by a concave cone having a taper more pronounced than that of the central body.

The proximal end of the corkscrew suture anchor body has a hex drive head incorporating a slotted suture eye for receiving one or more pieces of suture. At the junction between the hex drive head and the central body, the circumference of the central body advantageously is larger than the outer circumferential dimension of the hex drive head. Accordingly, the enlarged body adjacent the hex drive head forms a hole sufficient to accommodate a hex driver disposed over the hex drive head. The hex driver is described more fully below. This allows the suture anchor to be at least partially countersunk below the surface of the bone upon installation by preventing impingement of the distal end of the hex driver on the bone surface.

Advantageously, the threads of the suture anchor of the present invention provide an increased percentage of thread surface area for each turn of the screw, as compared with known suture anchors, thus providing increased pull-out strength, and a decreased tendency for back-out. The increase in the surface area of the thread is achieved in part by increasing the ratio of the outer diameter of the threads to the inner diameter of the threads. Preferably, the ratio is between 2.25 and 2.75. Most preferably, the ratio of the outer diameter to the inner diameter is 2.5.

In addition, the suture anchor has a higher thread pitch than prior art screws, thus increasing the area of thread for each turn of the screw, which also leads to greater pull-out strength. Significantly, due to the increased pitch, fewer turns of the corkscrew screw thread are required to advance the suture anchor into position. Accordingly, the suture

anchor is easy to install, and displaces less tissue material upon insertion than known suture anchors.

The pull-out strength and minimal tissue damage are enhanced by the relatively compressed cross-sectional aspect of the thread, particularly in relation to the broad axial faces of the threads. The distal and proximal faces of the threads preferably form a square or rounded break edge at the outer diameter of the thread. In addition, the thickness of the thread increases proximally, such that at least the most proximal flight is thicker than each of the more distal flights.

Increased back-out resistance is enhanced by surface features, such as radial ridges, on the top and/or bottom faces of the screw threads. The surface features augment the engagement between the thread surfaces and the surrounding tissue once the suture anchor is installed.

The present invention also provides a suture anchor and driver assembly for driving the corkscrew suture anchor into bone. The driver is formed of a cannulated tube secured to a cannulated handle. A hexagonal socket formed on the distal end of the tube holds the suture anchor for rotation and installation into the bone. The outer diameter of the tube is equal to or less than the outer diameter of the proximal end of the suture anchor's central body.

The driver is provided with a cleat on the side of the handle. Consequently, suture threaded through the cannulated driver can be wrapped around the cleat and fixed for shipping in a slot in the cleat using adhesive foam. One or more sutures, threaded through the suture anchor eye and up through the cannulated driver, can be pulled and secured around the cleat, whereby the suture is pinched under tension. Advantageously, the tensioned suture helps to hold the suture anchor in place at the distal tip of the driver. The suture anchor and driver assembly can be shipped, pre-loaded with suture, as a sterile, surgery-ready unit.

The present invention also provides a method of anchoring suture in bone using the suture anchor of the present invention. The method includes threading suture through the suture eye on the proximal end of the suture anchor. The driver is then turned to advance the suture anchor into the bone.

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The anchors of the present invention can be used for arthroscopic procedures. Advantageously, the suture anchor can be installed using a hollow, cannulated grasper as described in U.S. Pat. No. 5,466,243 to Schmieding, the disclosure of which is incorporated herein by reference. The anchors also are advantageous for open and miniopen surgical procedures, such as open rotator cuff repair, as described in U.S. Pat. No. 5,575,801 to Habermeyer et al.

Other features and advantages of the present invention will become apparent from the following description of the invention, which refers to the accompanying drawings.

10 BRIEF DESCRIPTION OF THE DRAWINGS

- FIG. 1 is a side view of a corkscrew suture anchor according to the present invention.
 - FIG. 2 is a proximal end view of the corkscrew suture anchor of FIG. 1.
- FIG. 3 is a distal end view of the suture anchor of FIG. 1.
 - FIG. 4 is a side view of a suture anchor assembly including a suture anchor, threaded with suture, and a driver according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

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Referring to FIG. 1, the suture anchor 2 of the present invention includes a body 4 provided in the shape of a tapered cylinder. A continuous thread 6 wraps around body 4 in a clockwise direction, as shown.

Suture anchor 2 is provided at a proximal end 8 of body 4 with hexagonal drive head 10 having a suture eye 12. The suture eye 12 preferably is in the form of an oval aperture in the drive head for holding at least one, and preferably two or more pieces of braided suture. Channels 14, also shown in FIG. 2, are formed along either side of the drive head 10 to accommodate the suture, such as when the suture anchor is held in a suture anchor driver, set forth more fully below.

A tip 18 is provided. Tip 18 terminates in a rounded point 20, which is approached by a concave, conically tapered surface 22. Conical taper 22 begins at the distal end of the screw thread, and features an angle of taper deeper than the taper of body 4.

The body preferably is formed of a biocompatible material such as stainless steel or titanium alloy. The central core preferably is circular in cross-section, and tapers from a maximum diameter near proximal end 8 to a minimum diameter toward distal end 14.

Corkscrew thread 6 has a proximal face 24, a distal face 26 and a break edge 28. Referring to FIG. 2, suture anchor 2 is shown from the proximal end. Radial ridge lines 30 are shown on proximal face 24 of corkscrew thread 6.

The major, outside diameter of the suture anchor thread of the present invention preferably is about 2.5 times the minor, inner diameter of the thread, or the minor diameter of the body toward distal end 16. Accordingly, on a 5 mm. diameter suture anchor, for example, where central core 4 is approximately 2 mm. in diameter, the outer diameter of the thread is 5 mm.

Preferably, between two and three flights or turns of thread 6 are provided along body 4, between proximal end 8 and distal end 16. The thickness of the thread increases proximally, such that at least the outer edge of the most proximal flight is thicker than the edge of each of the more distal flights, as shown in Fig. 1. Adjacent sections of each flight are separated by a gap that is determined by the number of turns per inch of the suture anchor thread. For example, a 5 mm. suture anchor preferably has about 6 turns per inch, while a 3.5 mm. suture anchor preferably has about 9. Accordingly, on a 5 mm or 6.5 mm suture anchor, the pitch distance A from flight to flight is 0.167 inches. On a 3.5 mm suture anchor, pitch distance A typically is 0.118 inches.

Referring again to FIG. 1, proximal thread surface 24 forms a 10.degree. angle .alpha. with an axial perpendicular to the central axis of the body 4, in the case of a 3.5 or 5.0 mm suture anchor, and a 5.degree. angle .alpha. in a 6.5 mm suture anchor. Distal thread surface 26 preferably forms a 20° angle β with an axial perpendicular to the central axis of the body 4, in the case of a 3.5 or 5.0 mm suture anchor, and a 15° angle β in a 6.5 mm suture anchor, as shown in Table I, as follows:

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TABLE I
Suture Anchor Dimensions and Features

Size		3.5	5.0	6.5
	No.	2.5	2	2
Thread Flights	Pitch (A) (mm)	3.0	4.24	4.24
	Major	3.5	5.0	6.5
Diameter (mm)	Minor	1.22	1.40	1.40
Thread		10	10	5
Angle (°)	β	20	20	15

FIG. 4 shows suture anchor 2 threaded with two pieces of suture 32 and held on a cannulated suture anchor driver 34. The suture is wrapped around cleat 36. Tension on the suture aids in retaining the suture anchor in the distal end of the driver. The suture is held in place in slot 38 using a foam adhesive, for example, during shipping. The assembly is provided as a sterile unit ready for surgical application.

Table II shows the results of various pullout tests performed with suture anchors according to the present invention, as follows:

TABLE II
Pull-out strength of corkscrew suture anchors

	5.0 mm	anchor	6.5 mm anchor
Test No.	20 lb. bone	30 lb. bone	20 lb bone
	block	block	block
1	N/A	112.2 (wire	98.4 (wire
		break)	break)
2	116.1	106.9 (wire	119.2 (wire
	(pulled out)	break)	break)
3	95.4 (pulled	111.5 (wire	125.1 (wire
	out)	break)	break)
4	104.9 (pulled	99.6 (wire	99.7 (slot
	out)	break)	break)
5	125.1	84.7 (wire	125.2 (wire
	(pulled out)	break)	break)
Avg.	110.375	103.0	113.52
St. dev.	13.0	11.4	13.4

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Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. Therefore, the present invention is to be limited not by the specific disclosure herein, but only by the appended claims.

What is claimed is:

- 1. A method of anchoring suture in bone, comprising inserting a suture anchor into bone, the suture anchor comprising:
- a central body having a central axis, a distal end and a proximal end, the central body having a diameter, the central body being tapered from a maximum diameter near the proximal end to a minimum diameter toward the distal end, and a tip portion disposed at the distal end of the central body;
 - a drive head disposed on the proximal end of the central body; an eyelet for receiving at least one strand of suture; and
 - a continuous thread disposed in a spiral around the central body and having an inner diameter, an outer diameter, and a thickness, the thickness of the thread at the outer edge of the thread increasing proximally along a portion of the thread, the outer diameter of the thread being at least twice the inner diameter of the thread along a portion of the thread.
 - 2. The method of claim 1, wherein the bone is in the shoulder.
 - 3. The method of claim 2, wherein the anchor is used for rotator cuff repair.
- 4. The method of claim 1, wherein the bone is soft or cancellous bone.
 - 5. The method of claim 1, wherein the suture anchor is installed arthroscopically.
- 6. The method of claim 1, wherein the thread has a distal and a proximal face, the proximal face forming a radial angle of about 5 to about 10 degrees from a perpendicular to a central axis of the suture anchor.

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- 7. The method of claim 6, wherein the distal face forms a radial angle of about 15 to about 20 degrees from the perpendicular to the central axis of the suture anchor.
- 8. The method of claim 1, wherein the ratio of the outer diameter to the inner diameter of the thread is between about 2.25 and about 2.75 along a portion of the thread.
 - 9. The method of claim 1, wherein the thread has a pitch between about 6 and about 9 flights per inch.
- 10 10. The method of claim 1, wherein the central body tapers from the proximal end to the distal end.
 - 11. The method of claim 1 further comprising channels for suture on the drive head.

12. The method of claim 1, further comprising two lengths of suture attached to the

- 13. The method of claim 1, wherein the drive head is hexagonal.
- 14. The method of claim 1, wherein the suture anchor is inserted into the bone using a driver formed of a cannulated tube secured to a cannulated handle.
- 15. The method of claim 14, wherein the driver includes a hexagonal socket on thedistal end of the cannulated tube which is inserted over and holds the suture anchor for rotation and installation into bone.
 - 16. The method of claim 14, wherein the cannulated tube of the driver has an outer diameter which is equal to or less than the outer diameter of the proximal end of the suture anchor body.

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suture anchor.

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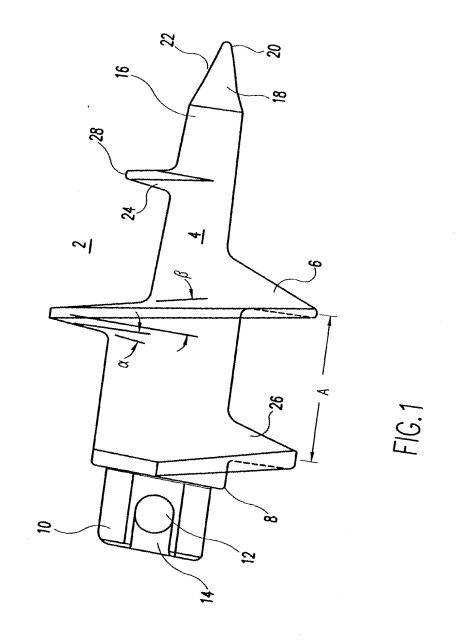
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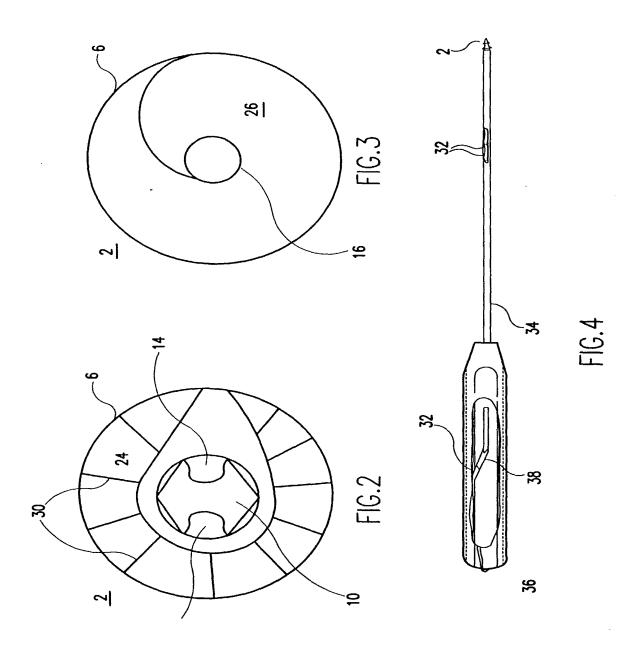
ABSTRACT OF THE DISCLOSURE

A corkscrew suture anchor has a continuous thread spiraling around a tapering central core. At the distal end, the suture anchor terminates in a rounded point. At the proximal end of the suture anchor is an eye for receiving suture. The suture anchor has a large thread surface per turn of thread. Anti-backout ridges can be formed on the front and/or back faces of the threads. A driver for the suture anchor is provided, the driver including a shaft having a central axis, a length, a distal end, and a proximal end. The shaft is provided at its distal end with an opening aligned with the central axis of the shaft, for receiving the hexagonal proximal end of the suture anchor. One or more sutures threaded through the suture eye are threaded through the hollow tubular shaft. The suture is pulled into and captured by V-shaped notches on the proximal end of the handle to hold the suture anchor in place on the distal end of the driver under the tension of the captured sutures.

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UNITED STATES APPLICATION NUMBER	DATE OF FILING (dav. month. vear)		patented	STATUS , pending, abandoned)
08/905,393	August 4, 1997		pending	Ţ
Samuel H. Weiner - Reg. No. 18,510: No. 24,735; Stanley H. Lieberstein - F Soffen - Reg. No. 31,063; James A. F	ABER, GERB & SOFFEN, LLP, and the Lerome M. Berliner - Reg. No. 18,653; R Reg. No. 22,400; Steven I. Weisburd - Reg inder - Reg. No. 30,173; William O. Gray f substitution and revocation to prosecute the ive all correspondence.	lobert C. Faber - Reg. g. No. 27,409; Max M r. III - Reg. No. 30,94	No. 24,322; Edu oskowitz - Reg. N 4 and Louis C. D	vard A. Meilman - Reg. 40. 30,576; Stephen A. rujmich - Reg. No.
SEND CORRESPONDENCE TO:	OSTROLENK, FABER, GERB & SC 1180 AVENUE OF THE AMERICAS NEW YORK, NEW YORK 10036-840	C	DIRECT TE 12) 382-0700	LEPHONE CALLS TO:
believed to be true; and further that the punishable by fine or imprisonment, or	made herein of my own knowledge are in see statements were made with the knowled both, under Section 1001 of Title 18 of the nor any patent assued thereon. R INVENTOR'S SIGNATURE	ige that willful false sta e United States Code,	tements and the I	ike so made are
FULL NAME OF SOLE OR FIRST INVENTOR Reinhold Schmiedin		2_		DATE 11-97
RESIDENCE			COUNTRY OF CT	TIZENSHIP
Naples, FL 33963			U.S.A.	
POST OFFICE ADDRESS 163 Eugenia Drive,	Naples, FL 33963			
FULL NAME OF SECOND JOINT INVENTOR		<i>y</i> -		DATE
R. Donald Grafton	1 Deld AT	7 Ci		10-16-97
RESIDENCE Naples, FL 33942	/		COUNTRY OF CT	MZENSHIP
POST OFFICE ADDRESS	cle, Naples, FL 339	163		
152 Plantation Circulturate of third Boint Inventor	· · · · · · · · · · · · · · · · · · ·	//		DATE
Mark Brunsvold	may Br			10/14/97
RESIDENCE Naples, FL 34116			U.S.A.	TZENSHIP /
POST OFFICE ADDRESS		<u> </u>		-
5224 31st Place S.V	W., Naples, FL 3411	, o		

Application or Docket Number

PATENT APPLICATION FEE DETERMINATION RECORD

		Effect	ive Octob	er 1, 20	001			1	0,29	8	S§§3	
		CLAIMS AS	S FILED - (Column			mn 2)	SMAL TYPE			OR	OTHER SMALL	THAN
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PATENT	APPLICATION	SERIAL	NO.	

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE FEE RECORD SHEET

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PTO-1556 (5/87)

Docket No.: A8130.0047/P047-A (PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Reinhold Schmieding, et al.

Application No.: Not Yet Assigned

Filed: October 31, 2002

For: CORKSCREW SUTURE ANCHOR

Group Art Unit: N/A

Examiner: Not Yet Assigned

4303

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents Washington, DC 20231

Dear Sir:

Pursuant to 37 CFR 1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement accompanies the new patent application submitted herewith.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached form PTO/SB/08 (facsimile) are not supplied because they were previously cited by or submitted to the Office in a prior Application No. 09/823,988, filed April 3, 2001, which is relied upon in this application for an earlier filing date under 35 U.S.C. 120.

While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR 1.56, it is not intended to constitute an

1514350 v1; WGH@01I.DOC

Application No.: Not Yet Assigned

Docket No.: A8130.0047/P047-A

admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Commissioner is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1073, under Order No. A8130.0047/P047-A.

Dated: October 31, 2002

Respectfully submitted,

Stephen A. Soffen

Registration No.: 31,063

DICKSTEIN SHAPIRO MORIN &

OSHINSKY LLP

2101 L Street NW

Washington, DC 20037-1526

(202) 785-9700

Attorneys for Applicant

PTO/SB/08A (10-01)
Approved for use through 10/31/2002.OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE and to a collection of information unless it contains a valid OMB control number

Sub	stitute for form 1449A/	РТО			Complete if Known	
				Application Number	Not assigned	P. T.
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				Art Unit		22
	(use as many sheets as necessary)		Examiner Name		100	
Sheet	1	of	2	Attorney Docket Number	A8130.0047/P047-A	<u>. 1, </u>

			U.S. PA	ATENT DOCUMENTS	
Examiner	Cite	Document Number	Publication Date	Name of Patentee or Applicant	Pages, Columns, Lines, Where Relevant
Initials*	No.1	Number-Kind Code ² (if known)	MM-YYYY	of Cited Document	Passages or Relevant Figures Appear
		DES 385,352	10-1997	Bales et al.	
		4,175,555	11-1979	Herbert	
		4,870,957	10-1989	Goble et al.	
		4,988,351	1-1991	Paulos, et al	
		5,102,414	04-1992	Kirsch	
		5,139,499	08-1992	Small et al.	
	[5,242,447	9/1993	Borzone	
	Ī	5,364,400	11-1994	Rego, Jr. et al.	
		5,447,401	9-1995	Jones et al	
		5,456,685	10-1995	Huebner	
		5,470,334	11-1995	Ross et al.	
		5,492,442	2-1996	Lasner	
		5,571,139	11-1996	Jenkins, Jr.	
		5,618,314	04-1997	Harwin et al	
		5,626,613	05-1997	Schmieding	
		5,690,676	11-1997	DiPoto et al.	
		5,733,307	3-1998	Dinsdale	
		5,792,142	08-1998	Galitzer	
		5,824,011	10-1998	Stone, et al.	
		5,851,219	12-1998	Goble et al.	

¹ Applicant's unique citation designation number (optional). ² See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ¹ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁵ Applicant is to place a check mark here if English language Translation is attached.

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS							
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²				
		"Implants for Surgery-Metal Bone Screws With Hexagonal Drive Connection, Spherical Under- Surface of Head, Asymmetrical Thread-Dimensions," International Standard ISO 5834, 1991(E), pp. 1-10					
		"Bone Screw Technical Information, " Richards Manufacturing Company, Inc. Tech. Publ. 1980, pp.1-14					
		R.M. Altieri, "Mitek Surgical Products announces fourth-quarter and year-end results, <i>Business Wire</i> (Feb. 24, 1995).					

Examiner	Date
Signature	Considered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (10-01)
Approved for use through 10/31/2002,OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE bond to a collection of information unless it contains a valid OMB control number.

Under the Panerwork Reduction Act of 1995, no persons are required to

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				Art Unit	N/A	95
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Sheet	2	of	2	Attorney Docket Number	A8130.0047/P047-A	

U.S. PATENT DOCUMENTS									
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear				
		4,289,124	9-1981	Zickel					
		4,537,185	8-1985	Stednitz					
		4,631,100	12-1986	Somers et al.					
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		5,738,685	4-1998	Halm et al.					
		5,743,914	4-1998	Skiba					
		5,827,291	10-1998	Fucci et al.					
-		6,117,162	9-2000	Schmeiding et al.					
		6,214,031	4-2001	Schmieding, et al					

	FOREIGN PATENT DOCUMENTS										
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (<i>if known</i>)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T⁵					
		FR 258 8332	4-1987								
		SU 103 4734	8-1983								

¹ Applicant's unique citation designation number (optional). ² See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

	OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS									
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²							
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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS P.O. Dox 19. Alexander Vigginia 22313-1450 www.usplu.gov

Bib Data Sheet

CONFIRMATION NO. 2470

SERIAL NUMBER 10/285,553	FILING OR 371(c) DATE 11/01/2002 RULE	CLASS 606	GRO	GROUP ART UNIT 3731		D	ATTORNEY DOCKET NO. A8130.0047/P047-A				
APPLICANTS Reinhold Schmieding, Naples, FL; R. Donald Grafton, Naples, FL; Mark Brunsvold, Naples, FL; ** CONTINUING DATA **********************************											
which is a COI which is a COI ** FOREIGN APPLIC	which is a CON of 09/588,065 06/05/2000 PAT 6,214,031 which is a CON of 08/954,206 10/20/1997 PAT 6,117,162 which is a CON of 08/905,393 08/04/1997 ABN ** FOREIGN APPLICATIONS ************************************										
met Verified and	yes no no ns yes no no Met af Allowance	STATE OR COUNTRY FL	DRA	ETS WING 2	TOTA CLAI 16	MS	INDEPENDENT CLAIMS 1				
TITLE CORKSCREW SUTU	JRE ANCHOR										
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Cc 37318

Docket No.: A8130.0047/P047-A

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Reinhold Schmieding, et al.

Application No.: 10/285,553

Art Unit: 3731

Filed: November 1, 2002

Examiner: G. Jackson

For: CORKSCREW SUTURE ANCHOR

PRELIMINARY AMENDMENT

MS Non-Fee Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

INTRODUCTORY COMMENTS

Prior to examination on the merits, please amend the above-identified U.S. patent application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 5 of this paper.

1763117 v1; 11SFH011.DOC

AMENDMENTS TO THE CLAIMS

1. (Currently amended) A method of anchoring suture in bone, comprising inserting a suture anchor into bone, the suture anchor comprising:

a central body having a central axis, a distal end and a proximal end, the central body having a diameter, the central body being tapered from a maximum diameter near the proximal end to a minimum diameter toward the distal end, and a tip portion disposed at the distal end of the central body;

a drive head disposed on the proximal end of the central body; an eyelet for receiving at least one strand of suture; and

a continuous thread disposed in a spiral around the central body and having an inner diameter, an outer diameter, and a thickness, the thickness of the thread at the outer edge of the thread increasing proximally along a portion of the thread, the outer diameter of the thread being at least twice the inner diameter of the thread along a portion of the thread.

- 2. (Original) The method of claim 1, wherein the bone is in the shoulder.
- 3. (Original) The method of claim 2, wherein the anchor is used for rotator cuff repair.
 - 4. (Original) The method of claim 1, wherein the bone is soft or cancellous bone.
- 5. (Original) The method of claim 1, wherein the suture anchor is installed arthroscopically.
- 6. (Original) The method of claim 1, wherein the thread has a distal and a proximal face, the proximal face forming a radial angle of about 5 to about 10 degrees from a perpendicular to a central axis of the suture anchor.

7. (Original) The method of claim 6, wherein the distal face forms a radial angle of about 15 to about 20 degrees from the perpendicular to the central axis of the suture anchor.

- 8. (Original) The method of claim 1, wherein the ratio of the outer diameter to the inner diameter of the thread is between about 2.25 and about 2.75 along a portion of the thread.
- 9. (Original) The method of claim 1, wherein the thread has a pitch between about 6 and about 9 flights per inch.
- 10. (Original) The method of claim 1, wherein the central body tapers from the proximal end to the distal end.
- 11. (Original) The method of claim 1 further comprising channels for suture on the drive head.
- 12. (Original) The method of claim 1, further comprising two lengths of suture attached to the suture anchor.
 - 13. (Original) The method of claim 1, wherein the drive head is hexagonal.
- 14. (Original) The method of claim 1, wherein the suture anchor is inserted into the bone using a driver formed of a cannulated tube secured to a cannulated handle.
- 15. (Original) The method of claim 14, wherein the driver includes a hexagonal socket on the distal end of the cannulated tube which is inserted over and holds the suture anchor for rotation and installation into bone.

16. (Original) The method of claim 14, wherein the cannulated tube of the driver has an outer diameter which is equal to or less than the outer diameter of the proximal end of the suture anchor body.

REMARKS

By this Preliminary Amendment, claim 1 has been amended.

A Terminal Disclaimer accompanies this submission.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for examination.

Dated: April 30, 2004

Respect/ully submitted

Stephen A. Soffen

Registration No.: 31,063

DICKSTEIN SHAPIRO MORIN &

OSHINSKY LLP

2101 L Street NW

Washington, DC 20037-1526

(202) 785-9700

Attorney for Applicant



Docket No.: A8130.0047/P047-A

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Reinhold Schmieding et al.

Application No.: 10/285,553 Confirmation No.: 2470

Filed: November 1, 2002 Art Unit: 3731

For: CORKSCREW SUTURE ANCHOR Examiner: G. Jackson

TERMINAL DISCLAIMER

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

The undersigned is attorney of record for the assignee of the above-identified application. Arthrex, Inc. certifies that it is the owner of 100% interest in the above identified patent application, as evidenced by the assignment, which was recorded in the U.S. Patent and Trademark Office on October 20, 1997, Reel 8866, Frame 0651.

The owner hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the above-identified application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173, as presently shortened by any terminal disclaimer, of prior U.S. Patent Nos. 6,511,499, 6,214,031, 6,117,162. The owner hereby agrees that any patent that is granted on the above-identified application shall be enforceable only for and during such period that it and the above listed patent are commonly owned. This agreement runs with any patent granted on the above-identified application and is binding upon the grantee, its successors or assignees.

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In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the above-identified application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of the prior patent, as presently shortened by any terminal disclaimer, in the event that it later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminate prior to the expiration of its full statutory term.

Please charge our Credit Card in the amount of \$55.00 covering the fee set forth in 37 CFR 1.20(d). Credit Card Payment Form SB-2038, with a signature from an authorized cardholder, is enclosed. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1073, under Order No. A8130.0047/P047-A.

Dated: April 30, 2004

Respectfully submitted

Stephen A. Soffen

Registration No.: 31,063

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Washington, DC 20037-1526

(202) 785-9700

Attorney for Applicant

PTO/SB/17 (10-03)

Approved for use through 7/31/2006. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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1003 530 2003 265 Plant filing fee	1402	330	2402	165		ef in support o	of an appeal	ŀ
1004 770 2004 385 Reissue filing fee	1403	290	2403	145		r oral hearing		t
1005 160 2005 80 Provisional filing fee	1451	1,510	1451	1,510	Petition to	institute a pub	lic use proceeding	Ì
SUBTOTAL (1) (\$) 0.00	1452	110	2452	55	Petition to	revive – unav	oidable	Ī
30B101AL (1) (\$) 0.00	1453	1,330	2453	665	Petition to	revive - uninte	entional	ſ
2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE	1501	1,330	2501	665	Utility issue	e fee (or reissi	ne)	
Extra Fee from Claims below Fee Paid	1502	480	2502	240	Design iss	ue fee		١
Total Claims 16 -20** = x = 0.00	1503	640	2503	320	Plant issue	fee		
Independent 1 -3** = x = 0.00	1460	130	1460	130	Petitions to	the Commiss	sioner	
Multiple Dependent =	1807	50	1807	50	Processing	fee under 37	CFR 1.17(q)	ſ
Large Entity Small Entity	1806	180	1806	180	Submissio	n of Informatio	on Disclosure Stmt	Ī
Fee Fee Fee Fee Fee Description	8021	40	8021	40			ssignment per	t
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1202 18 2202 9 Claims in excess of 20 1201 86 2201 43 Independent claims in excess of 3	1809	770	2809	385	(37 CFR 1	.129(a))	-	1
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SUBMITTED BY						(Complete	(if applicable))	=
Name (Print/Time) Stephen & Soffen	Registr	ration No). 21	,063		Telephone		_
All	(Attorne	y/Agent	101	,000		+	(,	<u>_</u>
						Date	April 30, 2004	

1763181 v1; 11SH901!.DOC

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	6	(("6511499") or ("6214031") or ("6117162")).PN.	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2005/01/09 17:52
L2	43	("4175555" "4289124" "4537185" "4631100" "4870957" "4988351" "5061181" "5067956" "5100417" "5102414" "5139499" "5152790" "5156616" "5180382" "5242447" "5246441" "5364400" "5370662" "5417533" "5443482" "5447401" "5456685" "5470334" "5492442" "5522843" "5571139" "5573548" "5607432" "5626613" "5643269" "5683401" "5690676" "5697950" "5720766" "5733307" "5738685" "5743914" "5792142" "5824011" "5827291" "5851219" "6117162" "6214031").PN.	US-PGPUB; USPAT	OR	ON	2005/01/09 17:53
L3	16	'("0177731" "1693768" "2479730" "4181457").PN. OR ("5643269").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2005/01/09 18:08
L4	735	(606/232).CCLS.	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2005/01/09 18:08
.L5	255	4 and @ad<"19960826"	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/01/09 18:12
L6	132	5 and thread	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/01/09 18:12
L7	9	6 and helical	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/01/09 18:11
L8	1126	(606/73).CCLS.	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2005/01/09 18:12

L9	444	8 and @ad<"19960826"	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/01/09 18:12
L10	412	9 and thread\$2	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR.	ON	2005/01/09 18:13
L11	85	10 and (helical or spiral)	US-PGPUB; USPAT; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2005/01/09 18:13

DL

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

24998

7590

02/02/2005

DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP 2101 L Street, NW Washington, DC 20037 EXAMINER

JACKSON, GARY

ART UNIT

T PAPER NUMBER

3731

DATE MAILED: 02/02/2005

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/285,553	11/01/2002	Reinhold Schmieding	A8130.0047/P047-A	2470

TITLE OF INVENTION: CORKSCREW SUTURE ANCHOR

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$700	\$300	\$1000	05/02/2005

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. <u>PROSECUTION ON THE MERITS IS CLOSED</u>. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is the same, pay the TOTAL FEE(S) DUE shown above
- B. If the status above is to be removed, check box 5b on Part B Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

- A. Pay TOTAL FEE(S) DUE shown above, or
- B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.
- II. PART B FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.
- III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

Page 1 of 3

PTOL-85 (Rev. 12/04) Approved for use through 04/30/2007.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail

Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

			or <u>Fax</u>	(703) 746-4000			
INSTRUCTIONS: This for appropriate. All further corindicated unless corrected by maintenance fee notification	rm should be used for trans respondence including the F below or directed otherwise is.	mitting the ISSU atent, advance or in Block 1, by (a)	E FEE and PUBLI ders and notification) specifying a new of	CATION FEE (if req of maintenance fees orrespondence addres	uired). Blocks 1 through 5 sl will be mailed to the current s; and/or (b) indicating a sepa	hould be completed where correspondence address as trate "FEE ADDRESS" for	
CURRENT CORRESPONDENC	E ADDRESS (Note: Use Block 1 for a	ny change of address)	Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying				
24998 7590 02/02/2005				papers. Each addition have its own certification	nal paper, such as an assignmente of mailing or transmission.	ent or formal drawing, must	
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2101 L Street, NW Washington, DC 20				I hereby certify that States Postal Service addressed to the Ma	this Fee(s) Transmittal is being with sufficient postage for final ail Stop ISSUE FEE address PTO (703) 746-4000, on the d	g deposited with the United st class mail in an envelope above, or being facsimile	
						(Depositor's name)	
						(Signature)	
						(Date)	
APPLICATION NO.	FILING DATE		FIRST NAMED INVE	TOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/285,553	11/01/2002		Reinhold Schmied	ing	A8130.0047/P047-A	2470	
	ORKSCREW SUTURE AND						
APPLN. TYPE	SMALL ENTITY	ISSUE FE	EE P	UBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE	
nonprovisional	YES	\$700		\$300	\$1000	05/02/2005	
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JACKSO	N, GARY	3731		606-232000			
CFR 1.363). Change of correspond Address form PTO/SB/12 "Fee Address" indicat	e address or indication of "Fe dence address (or Change of C 22) attached. ion (or "Fee Address" Indica or more recent) attached. Use	Correspondence	(1) the names of or agents OR, alte (2) the name of a registered attorne	single firm (having as y or agent) and the nat t attorneys or agents. I	a member a 2 mes of up to		
PLEASE NOTE: Unless recordation as set forth in		ow, no assignee of f this form is NOT	data will appear on a substitute for filir	the patent. If an assig g an assignment.	nee is identified below, the d	ocument has been filed for	
(A) NAME OF ASSIGNI . Please check the appropriate	EE assignee category or categor	•		Y and STATE OR CO	DUNTRY) Corporation or other private gro	oup entity 🚨 Government	
4a. The following fee(s) are	enclosed:	4b.	Payment of Fee(s):		-	· · ·	
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Advance Order - # of	Copies		The Director is Deposit Account Nu		charge the required fee(s), or (enclose an extra co	credit any overpayment, to opy of this form).	
	MALL ENTITY status. See 3	7 CFR 1.27.			ALL ENTITY status. See 37 Cl		
The Director of the USPTO i NOTE: The Issue Fee and Pu interest as shown by the reco	is requested to apply the Issuublication Fee (if required) words of the United States Pater	Fee and Publicati ill not be accepted at and Trademark	ion Fee (if any) or to from anyone other to Office.	re-apply any previous han the applicant; a rep	sly paid issue fee to the applica gistered attorney or agent; or th	tion identified above. te assignee or other party in	
Authorized Signature				Date			
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Alexandria, Virginia 22313-1	1430.				the public which is to file (and minutes to complete, includin comments on the amount of tir d Trademark Office, U.S. Depa SS. SEND TO: Commissioner of the displays a valid OMB control		

PTOL-85 (Rev. 12/04) Approved for use through 04/30/2007.

OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE



United States Patent and Trademark Office

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APPLICATION NO.		FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/285,553		11/01/2002	Reinhold Schmieding	A8130.0047/P047-A	2470	
24998	7590	02/02/2005		EXAM	IINER	
DICKSTEIN S 2101 L Street, N		O MORIN & C	SHINSKY LLP	JACKSON, GARY		
Washington, DO				ART UNIT	PAPER NUMBER	
5				3731		
		•	•	DATE MAILED: 02/02/2005		

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 398 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 398 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571) 272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

		$\mathcal{C}\mathcal{D}$
	Application No.	Applicant(s)
	10/285,553	SCHMIEDING ET AL.
Notice of Allowability	Examiner	Art Unit
	Gary Jackson	3731
Th MAILING DATE of this communication app All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85 NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT F of the Office or upon petition by the applicant. See 37 CFR 1.31	S (OR REMAINS) CLOSED in the comment of the comment	n this application. If not included unication will be mailed in due course. THIS
1. This communication is responsive to		
2. The allowed claim(s) is/are <u>1-16</u> .		
3. \boxtimes The drawings filed on <u>11 November 2002</u> are accepted by	the Examiner.	
4. ☐ Acknowledgment is made of a claim for foreign priority of a) ☐ All b) ☐ Some* c) ☐ None of the: 1. ☐ Certified copies of the priority documents have		or (f).
2. Certified copies of the priority documents hav	e been received in Applicati	on No
3. Copies of the certified copies of the priority de	ocuments have been receive	ed in this national stage application from the
International Bureau (PCT Rule 17.2(a)).		·
* Certified copies not received:		
Applicant has THREE MONTHS FROM THE "MAILING DATE noted below. Failure to timely comply will result in ABANDONI THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.		e a reply complying with the requirements
5. A SUBSTITUTE OATH OR DECLARATION must be subminformal PATENT APPLICATION (PTO-152) which gives		
6. CORRECTED DRAWINGS (as "replacement sheets") mu	ist be submitted.	
(a) ☐ including changes required by the Notice of Draftspel	rson's Patent Drawing Revie	w (PTO-948) attached .
1) 🗌 hereto or 2) 🗍 to Paper No./Mail Date		
(b) ☐ including changes required by the attached Examined Paper No./Mail Date	's Amendment / Comment o	or in the Office action of
ldentifying indicia such as the application number (see 37 CFR each sheet. Replacement sheet(s) should be labeled as such in		
7. DEPOSIT OF and/or INFORMATION about the department attached Examiner's comment regarding REQUIREMENT		
Attachment(s)	_	· ·
1. Notice of References Cited (PTO-892)	=	nformal Patent Application (PTO-152)
 Notice of Draftperson's Patent Drawing Review (PTO-948) 	Paper No	Summary (PTO-413), ./Mail Date
 Information Disclosure Statements (PTO-1449 or PTO/SB, Paper No./Mail Date Nov. 1, 2002 		s Amendment/Comment
4. Examiner's Comment Regarding Requirement for Deposit		s Statement of Reasons for Allowance
of Biological Material	9. 🔲 Other	_ ·
		Gary Jackson Primary Examiner Art Unit: 3731

U.S. Patent and Trademark Office PTOL-37 (Rev. 1-04)

Notice of Allowability

Part of Paper No./Mail Date 20050109

Art Unit: 3731

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Stephen A. Soffen on January 10, 2005.

The application has been amended as follows:

Claim 1, line 2, "inserting a suture anchor into bone" has been changed to

-- attaching suture to a suture anchor - -;

The last line after "thread" the following has been inserted:

- -;and

inserting the anchor with the attached suture into bone - -

This amendment places the claims in better condition for allowance.

EXAMINER'S COMMENT

The terminal disclaimer filed April 30, 2004 has been received and placed in the file. The terminal disclaimer makes a double patenting rejection over US Patents 6,511,499, 6,214,031 and 6,117,162 moot issue.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: The art of record closest to the claims fail to teach or suggest a method of anchoring a suture in a bone, wherein the anchor comprises a central body having a head at the proximal end; an eyelet and a

Application/Control Number: 10/285,553

Art Unit: 3731

continuous thread disposed in a spiral around the central body and the thread having a thickness at the outer edge increasing proximally along a portion of the thread and further, wherein the outer diameter of the thread is at least twice the inner diameter of thread along a portion of the

thread.

Allowance."

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

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary Jackson whose telephone number is (571) 272-4697. The examiner can normally be reached on Mon.-Thurs. 7:30 am to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Antoine Nguyen can be reached on (571) 272-4693. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Jackson
Primary Examiner
Art Unit 3731

January 10, 2005

Page 3

PTO/SB/08A (10-01)
Approved for use through 10/31/2002.OMB 0851-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under	the Paperwork Reduction Ac	t of 1995	i, no persons are required to r	espond to a collection of inform	nation unless it contains a valid OMB	control nu	ımber	<u>.</u>
Substitute for form 1449A/PTO					Complete if Known			
				Application Number Not assigned				
INFORMATION DISCLOSURE				Filing Date	October 31, 2002		5	
STATEMENT BY APPLICANT			APPLICANT	First Named Inventor	Reinhold Schmieding	, O	85	
				Art Unit			/2	
(use as many sheets as necessary)			necessary)	Examiner Name		001	#	
Sheet	1	of	2	Attomey Docket Number	A8130.0047/P047-A	, ' ' '	1	

	U.S. PATENT DOCUMENTS					
Examiner	Cite	Document Number	Publication Date	Name of Patentee or Applicant	Pages, Columns, Lines, Where Relevant	
Initials*	No.1	Number-Kind Code ² (If known)	MM-YYYY	of Cited Document	Passages or Relevant Figures Appear	
		DES 385,352	10-1997	Bales et al.		
		4,175,555	11-1979	Herbert		
		4,870,957	10-1989	Goble et al.		
		4,988,351	1-1991	Paulos, et al		
		5,102,414	04-1992	Kirsch		
		5,139,499	08-1992	Small et al.		
		5,242,447	9/1993	Borzone		
		5,364,400	11-1994	Rego, Jr. et al.		
		5,447,401	9-1995	Jones et al	·	
		5,456,685	10-1995	Huebner		
		5,470,334	11-1995	Ross et al.		
		5,492,442	2-1996	Lasner		
		5,571,139	11-1996	Jenkins, Jr.		
		5,618,314	04-1997	Harwin et al		
	L	5,626,613	05-1997	Schmieding		
		5,690,676	11-1997	DiPoto et al.		
		5,733,307	3-1998	Dinsdale		
		5,792,142	08-1998	Galitzer		
<u></u>		5,824,011	10-1998	Stone, et al.		
R	1	5,851,219	12-1998	Goble et al.		

Applicant's unique citation designation number (optional). *See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See attached Kinds Codes of USPTO Patent Documents

	OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²			
10		"Implants for Surgery-Metal Bone Screws With Hexagonal Drive Connection, Spherical Under- Surface of Head, Asymmetrical Thread-Dimensions," International Standard <u>ISO 5834</u> , 1991(E), pp. 1-10				
D		"Bone Screw Technical Information, " Richards Manufacturing Company, Inc. Tech. Publ. 1980, pp.1-14				
28		R.M. Altieri, "Mitek Surgical Products announces fourth-quarter and year-end results, Business Wire (Feb. 24, 1995).				

Examiner Signature	ackson,	Gary	Date Considered	01-09-2005
U	, , , , , , , , , , , , , , , , , , , ,			-

'EXAMINER: Initial if reference considered, whether of not cliation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1514315 v1; WGGB01I.DOC

^{&#}x27;Applicant's unique citation designation number (optional). *Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (10-01)
Approved for use through 10/31/2002.OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO			•	Complete if Kn wn		10
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INF	ORMATI	ON DIS	CLOSURE	Filing Date		S
STATEMENT BY APPLICANT				First Named Inventor	Reinhold Schmieding	75
				Art Unit	N/A	90
(use as many sheets as necessary)			cossary)	Examiner Name	Not Yet Assigned	
heet	2	of	2	Attorney Docket Number	A8130.0047/P047-A	

			U.S. PA	TENT DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (# known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		4,289,124	9-1981	Zickel	
- P		4,537,185	8-1985	Stednitz	
		4,631,100	12-1986	Somers et al.	
		5,0611,181	10-1991	Niznick	·
		5,067,956	11-1991	Buford, III, et al.	
		5,100,417	3-1992	Cerier, et al.	
		5,152,790	10-1992	Rosenberg et al.	
		5,156,616	10-1992	Meadows et al.	
		5,180,382	1-1993	Frigg et al.	
		5,246,441	9-1993	Ross et al.	
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		5,417,533	5-1995	Lasner	
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¹Applicant's unique citation designation number (optional). ² See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³
Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ¹For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ³ Kind of document by the appropriate symbols as Indicated on the document under WIPO Standard ST. 18 If possible. ⁴Applicant is to place a check mark here if English language Translation is attached.

	OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS							
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Application No.	Applicant(s)	
10/285,553	SCHMIEDING ET AL.	
Examin r	Art Unit	
Gary Jackson	3731	

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BIBDATASHEET

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SERIAL NUMB 10/285,553				LASS 606	GROUP ART UNIT			ATTORNEY DOCKET NO. A8130.0047/P047-A							
APPLICANTS	PPLICANTS														
Reinhold Schmie	Reinhold Schmieding, Naples, FL;														
R. Donald Grafton, Naples, FL; Mark Brunsvold, Naples, FL; ** CONTINUING DATA **** This application is a CON of 09/823,988 04/03/2001 PAT 6,511,499 which is a CON of 09/588,065 06/05/2000 PAT 6,214,031 which is a CON of 08/954,206 10/20/1997 PAT 6,117,162 which is a CON of 08/905,393 08/04/1997 ABN															
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X C	harge fee(s) ir	ndicated b	elow		Charge	e fee(s) indi	cated below, e	xcept for t	he filing fee						
	harge any add e(s) under 37		e(s) or underpayme 6 and 1.17	ent of	x Credit	any overpa	yments								
FEE CALCU			_												
1. BASIC FILIN	G, SEARCH,		MINATION FEES		DOUETES	TVANNIN	ATION FFF								
		FILI	NG FEES Small Entity	SEF	RCH FEES Small Entity	EXAMIN	ATION FEES Small Entity								
Application T	<u>ype</u>	Fee (\$)		Fee (\$)		Fee (\$)	Fee (\$)	Fees	<u> Paid (\$)</u>						
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Design Plant		200 200	100 100	100 300	50 150	130 160	65 80								
Reissue		300	150	500	250	600	300 .		······						
Provisional		200	100	0	0	0	0								
2. EXCESS CL	AIM FEES			_	_	-	-		Small Entity						
Fee Description Each claim ove		g Reissue	es)					Fee (\$) 50	Fee (\$) 25						
Each independe	•	•	•					200	100						
Multiple depen	dent claims							360	180						
Total Claims	Extra C	laims	Fee (\$)	Fee P	'aid (\$)	<u>Mu</u>	Itiple Depende	ent Claims	1						
16	- 20 =	×	=			Fee	<u>; (\$)</u>	Fee Paid (<u>\$)</u>						
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3. APPLICATIO															
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4. OTHER FEE		0.00						Fees	Paid (\$)						
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SUBMITTED BY		/	11				_								
Signature	/4	uph	UNIT		Registration No. (Attorney/Agent)	31,063	Telephone	(202) 8	28-4879						

Name (Print/Type)

Stephen A. Soffen

April 13, 2005

Date

Application No.: 10/285,553 Docket No.: A8130.0047/P047-A

Docket No.: A8130.0047/P047-A

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Reinhold Schmieding et al.

Application No.: 10/285,553

Confirmation No.: 2470

Filed: November 1, 2002

Art Unit: 3731

For: CORKSCREW SUTURE ANCHOR

Examiner: G. Jackson

CHANGE OF ENTITY STATUS

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

The patent owner no longer qualifies as a small entity.

In accordance with the change to large entity status, the large entity amount (\$1,715.00) for the Issue Fee is submitted herewith.

Dated: April 13, 2005

Respectfully submitted

Stephen A. Soffen

Registration No.: 31,063

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Attorney for Applicant