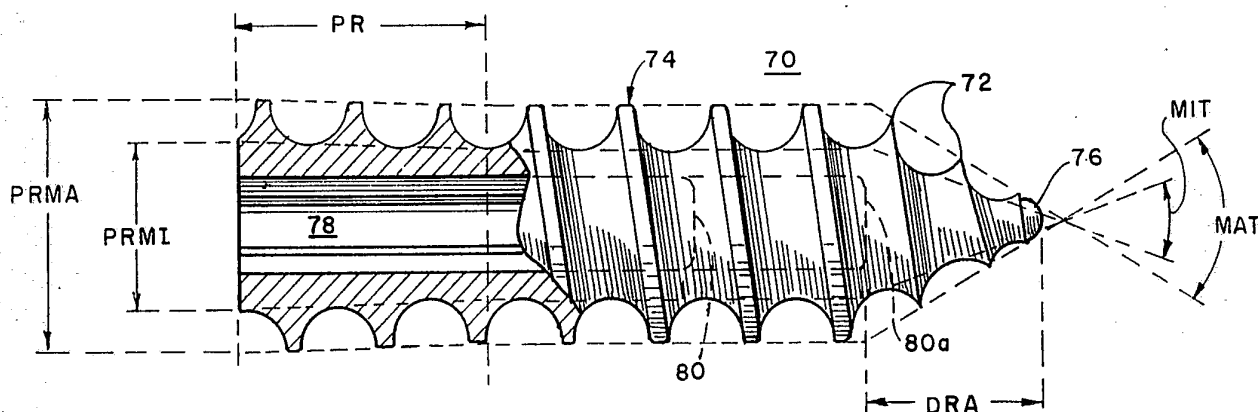




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(21) International Application Number: PCT/US93/01284 (22) International Filing Date: 12 February 1993 (12.02.93) (30) Priority data: 07/836,674 14 February 1992 (14.02.92) US (71) Applicant: AMERICAN CYANAMID COMPANY [US/US]; 1937 West Main Street, Stamford, CT 06904 (US). (72) Inventors: SMALL, Alan, Attridge ; 131 Richdale Road, Needham, MA 02194 (US). CARLOZZI, Gerard, Stephen ; 79 Tilden Road, Weymouth, MA 02190 (US). REGO, Richard, P., Jr. ; 13 Bonney Lane #5, Mansfield, MA 02048 (US). JARRETT, Peter, Kendrick ; 1063 Georges Hill Road, Southbury, CT 06488 (US).		(74) Agent: STONE, Mark, P.; 1100 High Ridge Road, Suite 205, Stamford, CT 06905 (US). (81) Designated States: AU, CA, FI, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: POLYMERIC SCREWS AND COATINGS FOR SURGICAL USES**(57) Abstract**

Polymeric preferably bioabsorbable, interference screws (30, 70, 90) having increased helical thread thickness (TT) and decreased thread depth (TD) relative to corresponding metal insertion screws (10, 50) to provide increased wall thicknesses, which enhances overall rigidity and strength of the absorbable interference screw (30, 70, 90). A proximal region (PR) of the screw (30, 70, 90) increases gradually in diameter (MA, MI) proximally to increase the bite and holding power of the screw (30, 70, 90) as well as to increase wall thickness. The proximal region (PR) increases proximally in at least one of a proximal region minor diameter (PRMI) and a proximal region major diameter (PRMA). Also featured are screws (90) having an absorbable coating (92).

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POLYMERIC SCREWS AND COATINGS FOR SURGICAL USES

FIELD OF THE INVENTION

5 This invention relates to polymeric screws and absorbable screw coatings, and more particularly to improved absorbable screws and coated screws for surgical use.

10 BACKGROUND OF THE INVENTION

There are a number of surgical procedures in which a fastener such as a screw or nail is inserted
15 into a tissue of a patient. One surgical use involves insertion of an interference screw into a bone tunnel to secure a bone plug in place to attach an end of an anterior cruciate ligament (ACL) replacement. ACL
20 reconstruction procedures and interference screws are disclosed for example in U.S. Patent Nos. 5,062,843, 4,950,270 and 4,927,421 and in the following articles: Matthews et al., "Pitfalls in the Use of Interference
25 Screws for Anterior Cruciate Ligament Reconstruction: Brief Report", J. Arthroscopic and Related Surgery 5(3):225-226 (1989) and Kurosaka et al., "A Bio-mechanical Comparison of Different Surgical Techniques
30 of Graft Fixation in Anterior Cruciate Ligament Reconstruction", Am. J. Sports Medicine 15:225-9 (1987).

Surgeons and patients desire absorbable implants which will be partially or completely absorbed

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by the body. An absorbable lag screw for fracture fixation and having a rounded head, for example, is disclosed in German Patent DE 3,811,345.

5 A relatively large amount of torque must be applied to an interference screw during insertion. A screw formed from a bioabsorbable material is likely to have a significantly lower strength, however, and therefore should not be subjected to high torque during insertion. It would be desirable to improve the configuration of the screw or to lower the amount of torque which must be applied to the screw.

10 Coatings having a low coefficient of friction have been applied to a number of surgical devices including suture needles and hypodermic needles (U.S. Patent No. 2,814,296), and surgical staples (U.S. Patent No. 4,655,222). Typically, most or all of the exterior surface of these devices are coated with a low coefficient of friction material such as Teflon, available from E. I. du Pont de Nemours & Co.

20 Other uses of a Teflon-type material include incorporation into surgical sutures (U.S. Patent No. 4,362,162), on razor blades (U.S. Patent No. 4,012,551) and on screws to provide self-sealing fasteners (U.S. Patent No. 3,494,243). Other uses include application of absorbable or nonabsorbable plastics (including polytetrafluoroethylene) to staples as disclosed in U.S. Patent No. 4,275,813. Use of Teflon and other resins for resisting corrosion has been disclosed for dental implants in U.S. Patent No. 3,977,081 and for threaded fasteners in U.S. Patent No. 4,835,819.

SUMMARY OF THE INVENTION

35 Therefore, it is an object of the present invention to provide improved interference screws formed of a polymeric material which preferably is bioabsorbable.

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It is a further object of the invention to provide such screws which can withstand relatively high insertion torques.

A still further object of the invention to provide an absorbable interference screw having increased bite and increased wall thickness to accommodate relatively high edge loads placed on the screw during insertion, and to provide sufficient strength during bioabsorption of the screw until surrounding tissue regenerates sufficiently.

Yet another object of the invention is to provide an absorbable coating for screws to modify the coefficient of friction of the screw, to promote bone ingrowth, or to deliver a medicament or growth factor.

This invention features polymeric interference screws having increased thread thickness and decreased thread depth relative to corresponding metal insertion screws. The increases in screw thicknesses enhance overall rigidity and strength of the absorbable interference screw. A proximal region of the screw increases gradually in major and/or minor diameter proximally to increase the bite and holding power of the screw as well as to increase wall thickness. A distal region of the screw may define a helical thread having one or more revolutions with a sharp peak at the thread crest; alternatively, the distal region completely lacks a thread and is a smooth, frustoconical section, and the proximal region is threaded and begins increasing in diameter immediately thereafter.

This invention also features surgical screws having an absorbable coating wherein the base screw is formed of a biocompatible material where the coating is selected to raise or lower the coefficient of friction of the screw, to preferentially biodegrade to promote bone ingrowth, or to serve as a delivery vehicle for a substance such as a pharmaceutical or a growth factor.

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BRIEF DESCRIPTION OF THE DRAWINGS

Other objects, features and advantages will occur from the following description of preferred embodiments and the accompanying drawings, in which:

Fig. 1 is a side view of a conventional metal 5.5mm interference screw;

Fig. 2 is a side view of a novel 5.5mm absorbable interference screw according to the present invention;

Fig. 3 is a side view of a conventional metal 7mm interference screw;

Fig. 4 is a side view of a novel 7mm absorbable interference screw according to the present invention; and

Fig. 5 is a side, partial cross-sectional view of a novel 9mm interference screw which is coated according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

This invention may be accomplished by novel polymeric interference screws such as screws 30, 70 and 90 shown in Figs. 2, 4 and 5 and described below.

Cannulated and non-cannulated titanium alloy interference screws having a major diameter of 5.5mm for screw 10, Fig. 1, and major diameters of 7.0mm and 9.0mm for screw 50, Fig. 3, are commercially available in lengths of 20mm to 30mm from Acufex Microsurgical, Inc., Mansfield, Massachusetts. Non-cannulated versions are illustrated in Figs. 1 and 3.

Conventional interference screw 10, Fig. 1, includes an elongated body 12 formed of a titanium alloy which defines a helical thread 14 about its exterior surface extending from distal end 16 to proximal end 18. A hexagonal drive socket 20 is defined at the proximal end 18.

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Several dimensions applicable to all screws described herein are indicated as thread pitch TP, thread thickness TT, thread depth TD, major diameter MA, and minor diameter MI. Each screw further defines a distal region DR, although the thread thickness in this region is substantially less for polymeric interference screws according to the present invention. Over the proximal remainder of the polymeric screw's helical thread, however, the thread thickness is greater than that of conventional metal screws. For all screws illustrated herein, the helical thread in the distal region DR has a major diameter taper angle of MAT and minor diameter angle taper of MIT; the distal region for polymeric screws is referred to as region DRA.

In general, polymeric interference screws according to the present invention preferably are formed of a bioabsorbable material and have an increased thread thickness TT and a decreased thread depth TD to increase overall rigidity and strength of the absorbable interference screw. This improved construction enables use of bioabsorbable materials which are more brittle and have less strength than metal materials. Thread dimensions are compared in Table I below.

The range of ratios of thread thickness to major diameters as shown in Table I is 0.042 (interference screw 90 at a major diameter of 9mm) to 0.069 (interference screw 30 at 5.5mm) for absorbable interference screws according to the present invention, while the ratios for titanium alloy screws range from 0.028 (screw 50 at a major diameter of 9.0mm) to 0.055 (screw 10 at 5.5mm).

The ratios of thread depth to screw diameter range from 0.178 (screw 90 at 9mm) to 0.185 (screw 70 at 7mm) for the absorbable screws, while the metal

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screws range from 0.195 (screw 50 at 9.0mm) to 0.229 (screw 10 at 5.5mm).

TABLE I
COMPARISON OF SCREW THREAD DIMENSIONS (INCHES)

<u>Major Diameter</u>	<u>Thread Thickness(TT)</u>		<u>Thread Depth (TD)</u>	
	<u>Metal</u>	<u>Absorbable</u>	<u>Metal</u>	<u>Absorbable</u>
.218 (5.5mm)	.012	.015	.050	.039
.276 (7mm)	.010	.015	.069	.051
.354 (9mm)	.010	.015	.069	.063

TABLE II
MAXIMUM MAJOR DIAMETER OF PROXIMAL REGION (INCHES)

<u>Major Diameter</u>	<u>Proximal Region Major Diameter (PRMA)</u>		
	<u>By Length</u>		
	<u>20mm</u>	<u>25mm</u>	<u>30mm</u>
5.5mm	.222	.234	.246
7.0mm	.284	.297	.311
9.0mm	.361	.375	.389

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TABLE III
MAXIMUM MINOR DIAMETER OF PROXIMAL REGION (INCHES)

<u>Major</u> <u>Diameter</u>	<u>Minor</u> <u>Diameter</u>	<u>Proximal Region</u> <u>Minor Diameter (PRMI)</u>		
		<u>By Length</u>		
		<u>20mm</u>	<u>25mm</u>	<u>30mm</u>
5.5mm	.138	.183	.195	.207
7.0mm	.174	.233	.246	.260
9.0mm	.228	.298	.312	.326

Absorbable interference screw 30 according to the present invention, Fig. 2, has the same major diameter MA of screw 10 up to boundary 32. From boundary 32 to proximal end 34, the elongated body 31 exhibits an increase in major diameter up to a maximum proximal region major diameter of PRMA. Also, there is an increase in minor diameter in proximal region PR up to maximum proximal region minor diameter PRMI.

Different maximum major and minor diameters at the proximal region are provided in Tables II and III for selected lengths of screws 30, 70 and 90 having major diameters of 5.5mm, 7mm and 9mm, respectively. Both the major diameter and minor diameter increase within proximal regions PR at an angle of approximately four degrees to achieve these dimensions. Taper angles of up to ten degrees are desired, with three to five degrees preferred.

The absorbable screw 36 defines a drive socket 36 at its proximal end which extends at least half-way along the length of the elongated body 31 to terminate distally in a socket base 38. In another

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construction, the socket base continues further to socket base 38a. The drive socket 36 is polygonal when viewed from proximal end 34, preferably the shape disclosed in U.S. Patent No. 3,584,667 (Reiland).

Other features of absorbable screw 30 include a length of proximal region PR of 0.089 to 0.483 inch, a distal minor taper MIT of 32° and a distal major taper MAT of 49° . By comparison, metal screw 10, Fig. 1, has a distal minor taper angle MIT of 32° and a distal major taper angle MAT of 60° . The crests 40 of the helical thread 42 within distal region DRA have a shallower thread and culminate in a peak or edge rather than in a thickened crest as is found in the proximal remainder of the thread 42.

Metal screws have a major diameter MA of 7mm and 9mm and a minor diameter MI of 0.138 inch and 0.216 inch, respectively. Both have a configuration of metal screw 50, Fig. 3. Both sizes have a minor distal taper angle MIT of 36° and a major distal angle taper of 60° .

By comparison, absorbable screw 70, Fig. 4, has a minor distal taper angle of 40° and a major distal taper angle of 60° . At least one revolution of the helical crests 72 of helical thread 74 within distal region DRA culminate in an edge, and the distal tip 76 is rounded. The proximal region PR length is 0.106 to 0.50 inch. Other dimensions are described in Tables I-III. Drive socket 78 terminates distally in a socket base 80 or 80a.

Polymeric interference screw 90, Fig. 5, has its exterior surface covered with a coating 92 as described in more detail below. Dimensions for screw 92 include a minor distal taper angle MIT of 51° and a major distal taper angle MAT of 73° . The proximal region PR has a length of 0.106 to 0.50 inch depending on the overall length of the screw 90. Thread crests 94 of helical thread 96 within distal region DRA have a relatively sharp edge and the elongated screw body 97

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terminates in a rounded distal tip 98. Polygonal drive socket 100 terminates distally in a socket base 102 or 102a.

The body of the polymeric screws according to the present invention can be formed of a non-absorbable polymer such as Delrin available from Du Pont or of a bioabsorbable material such as polylactic acid (lactide), polyglycolic acid (glycolide) disclosed in U.S. Patent No. 3,739,773 (Schmitt et al.), or copolymers disclosed in U.S. Patent Nos. 4,300,565 (Rosensaft et al.) and 4,429,080 (Casey et al.), all of which are incorporated herein by reference. A combination of absorbable and non-absorbable materials to form a partially absorbable implant can also be utilized. A polymer such as lactide is preferred for its slower absorption rate and therefore longer retention of structural integrity. Retention of at least fifty percent strength twelve weeks after implantation is preferred for an interference screw used to secure a ligament graft in position.

The absorbable coating 92 preferably has a low coefficient of friction such as polycaprolate. An acceptable polycaprolate copolymer is a random copolymer of 85 weight percent epsilon-caprolactone and 15 weight percent glycolide. Other suitable coatings are disclosed in U.S. Patent No. 4,788,969 (Jarrett et al.), which is incorporated herein by reference. In addition to reducing insertion torque, the absorbable coating can contain a pharmaceutical, a growth factor, or other compound. Additionally, the coating can have a selected absorption property to disappear within a desired period to enhance bone ingrowth and attachment to the screw.

In addition to application on polymeric interference screws, an absorbable coating can also be placed according to the invention on a metal screw such as screws 10 and 50, Figs. 1 and 3. The above-

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described advantages of an absorbable coating apply also to these non-polymeric, nonabsorbable surgical screws. Such coated screws are particularly useful for fracture fixation, and can be cannulated or non-cannulated.

As a coating over an absorbable screw body, the absorbable coating can serve as a barrier to body fluids to affect the rate of absorption of the main screw body. An absorbable coating according to the invention has a different composition than the screw body to provide one or more different selected properties such as a different coefficient of friction or rate of absorption.

One example of a metal screw coated according to the present invention is provided by five titanium alloy screws which were dipped in a solution of 10g polycaprolate copolymer (85 weight percent caprolactone, 15 weight percent glycolide) in 80ml of acetone to form a 12.75% solution weight/volume. The screws were alternately dipped and allowed to dry for a total of seven (7) times.

A total of ten screws were tested, five uncoated 7mm by 25mm non-cannulated interference screws supplied by Acufex Microsurgical, Inc. and having the configuration shown in Fig. 3, and five identical screws dip-coated with polycaprolate as described above. One of each screw was inserted into the middle intra-condylar region of a bovine bone, two each in the posterior condylar region, and two each in the anterior condylar region. The results are provided below in Table IV.

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TABLE IV

COATED VERSUS UNCOATED SCREW INSERTION TORQUES (IN.LBS)

Bone		
<u>Region</u>	<u>Coated</u>	<u>Uncoated</u>
Middle Condyle	11.6	19.8
Posterior Condyle	24.6	28.6
	19.0	29.8
Anterior Condyle	22.0	22.8
	21.6	25.4

The average coated screw required 19.8 in. lb. of torque whereas the average uncoated screw required 25.3 in. lb. An average reduction in torque of 22% was therefor provided by the absorbable coating.

Although specific features of the invention are shown in some drawings and not in others, this is for convenience only as each feature may be combined with any or all of the other features in accordance with the invention.

Other embodiments will occur to those skilled in the art and are within the following claims.

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WHAT IS CLAIMED IS:

1. An interference screw insertable into a tunnel drilled in a bone to secure a graft anchor plug in place, comprising an elongated, substantially cylindrical screw body having a distal end and a proximal end, said proximal end defining means for engaging a driver and lacking a head member, said elongated body formed of a polymeric material, said elongated body defining a helical thread about its exterior and having a body major diameter and a body minor diameter, and said elongated body further defining a distal region which decreases in diameter advancing distally and terminates in said distal end, and defining a proximal region which, advancing proximally toward said proximal end, increases to at least one of (a) a proximal region major diameter greater than said body major diameter, and (b) a proximal region minor diameter greater than said body minor diameter.

2. The interference screw of Claim 1 in which said elongated body is formed of a bioabsorbable material and said helical thread extends over said distal region with a substantially narrower thread width, for at least one revolution of said thread, than the thread width of the proximal remainder of said helical thread.

3. The interference screw of Claim 2 in which said elongated body terminates in a substantially rounded distal tip at its distal end.

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4. The interference screw of Claim 1 in which said elongated body is formed of a bioabsorbable material and further including a bioabsorbable coating disposed about the exterior surface of said elongated body, said coating having a coefficient of friction which is lower than that of the exterior surface of said elongated body.

5. The interference screw of Claim 4 in which said coating is a polycaprolate-type material.

6. The interference screw of Claim 5 in which said polycaprolate-type material is a random copolymer of 85 weight percent epsilon-caprolactone and 15 weight percent glycolide.

7. The interference screw of Claim 1 in which said proximal region major diameter tapers outwardly at an angle of up to ten degrees.

8. The interference screw of Claim 1 in which said proximal region major diameter tapers outwardly at an angle of about three to five degrees.

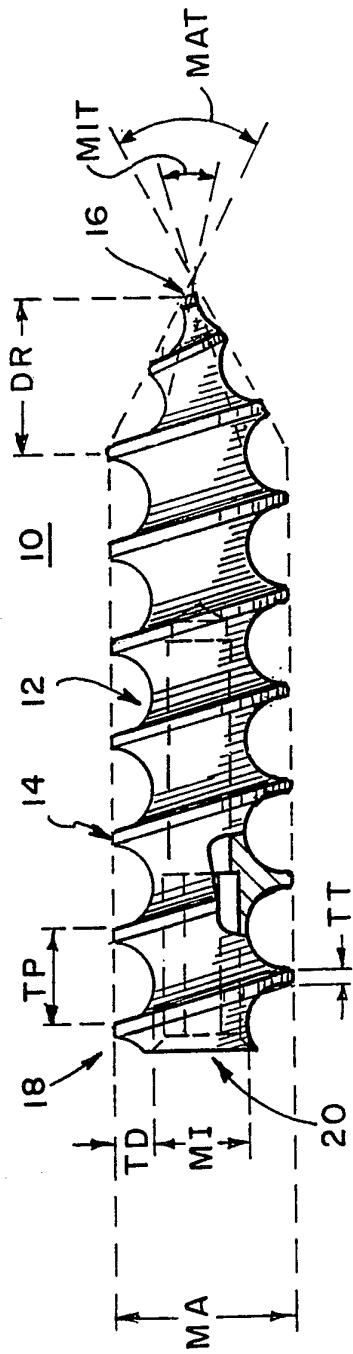


FIG. 1
(PRIOR ART)

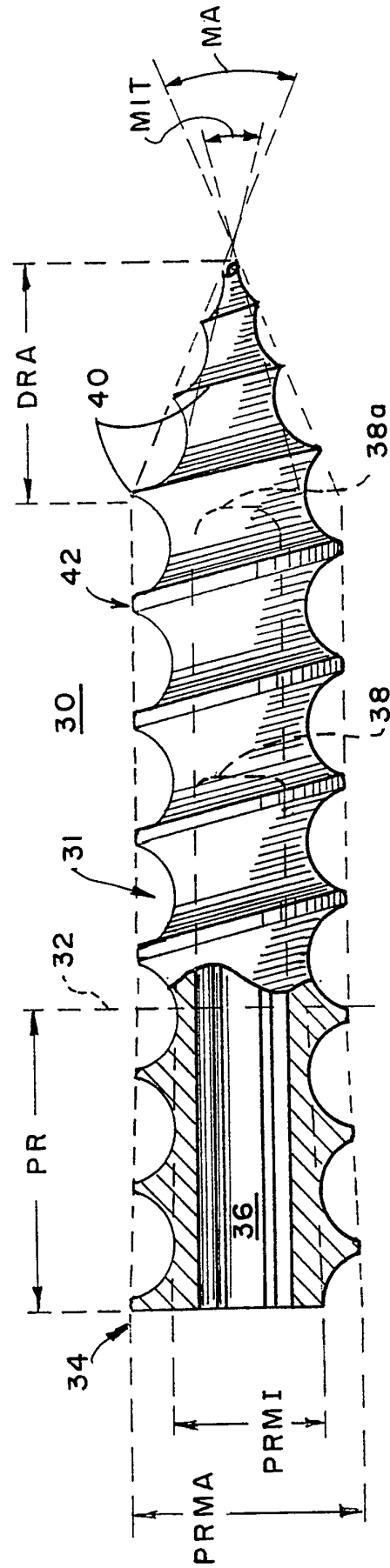


FIG. 2

2/3

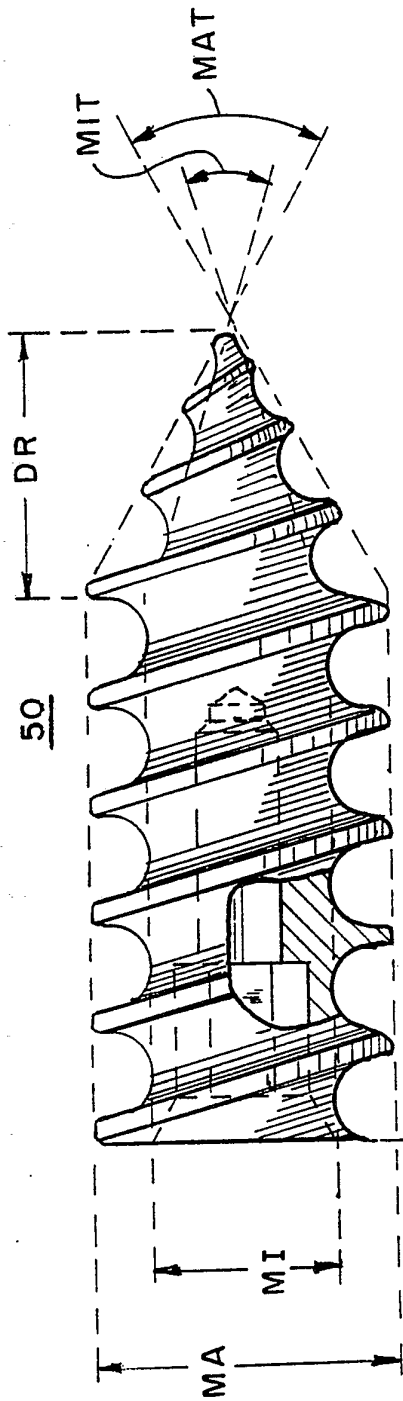


FIG. 3
(PRIOR ART)

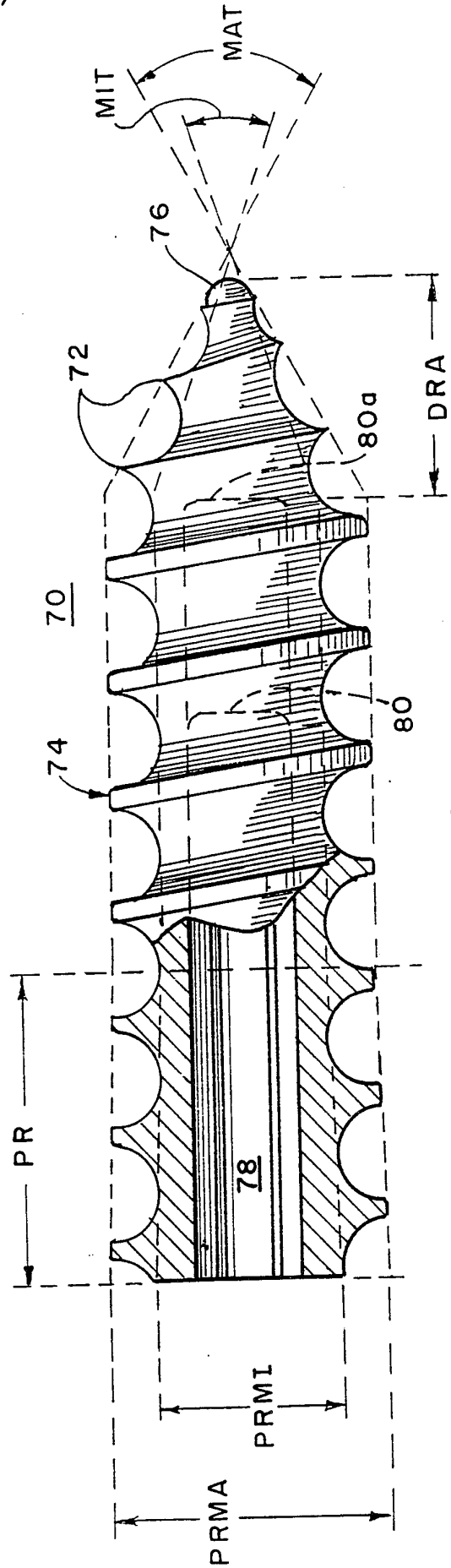
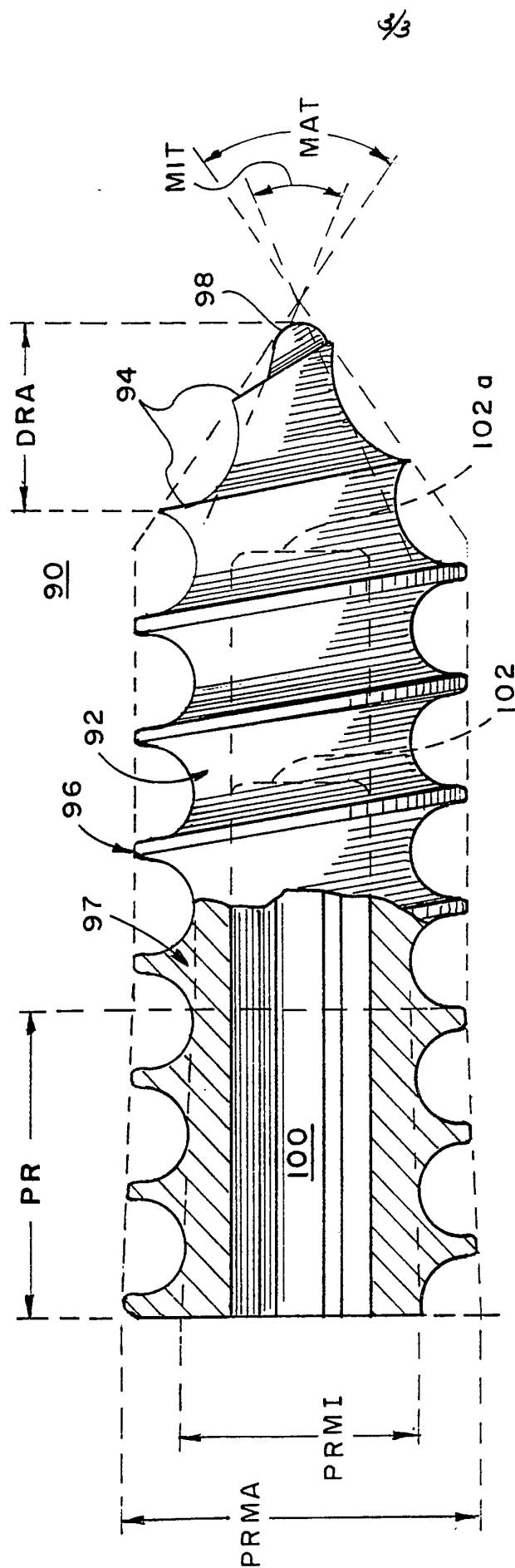


FIG. 4



INTERNATIONAL SEARCH REPORT

PCT/US 93/01284

International Application No

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl. 5 A61B17/58; A61L31/00		
II. FIELDS SEARCHED		
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Classification System	Classification Symbols	
Int.Cl. 5	A61B	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
Y	WO,A,9 008 510 (ACUFEX MICROSURGICAL) 9 August 1990 see page 6, line 3 - page 7, line 15; figure 1 ---	1,2,7
Y	WO,A,8 603 666 (DRAENERT) 3 July 1986 see page 14, line 12 - page 15, line 5; claims 13,21,23; figure 1 ---	1,2,7
A		4-6,8
A	WO,A,8 909 030 (AESCULAP) 5 October 1989 see figures 1,6 cited in the application ---	3
A	EP,A,0 469 441 (MERCK PATENT) 5 February 1992 see figure ---	3
	---	-/--
¹⁰ Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
28 MAY 1993	10.06.93	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	KLEIN C.	

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		Relevant to Claim No.
Category °	Citation of Document, with indication, where appropriate, of the relevant passages	
A	US,A,2 814 296 (EVERETT) 26 November 1957 see column 2, line 24 - line 26; claim 1 cited in the application ---	4
A	US,A,4 791 929 (JARRETT) 20 December 1988 see claims 1,8; example 7 ---	4-6
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**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

US 9301284
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This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
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