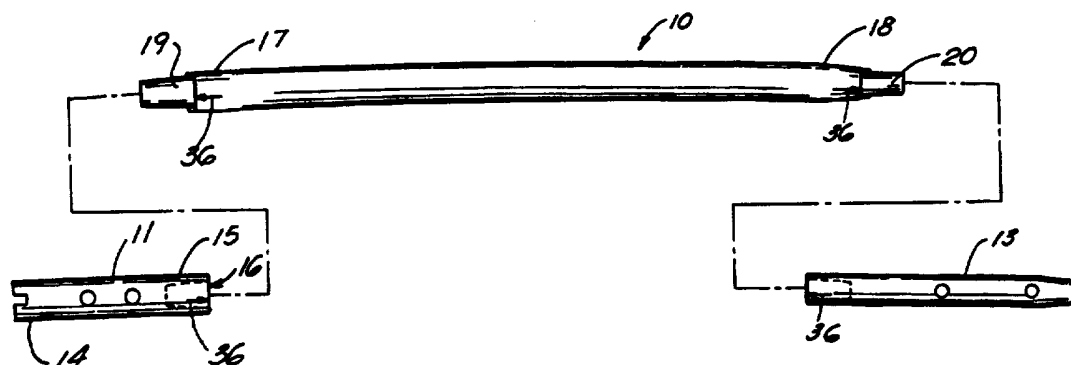




(51) International Patent Classification ⁶ : A61B 17/72	A1	(11) International Publication Number: WO 96/02202
<p>(21) International Application Number: PCT/US95/08875</p> <p>(22) International Filing Date: 14 July 1995 (14.07.95)</p> <p>(30) Priority Data: 08/275,783 15 July 1994 (15.07.94) US</p> <p>(71) Applicant: SMITH & NEPHEW RICHARDS INC. [US/US]; 1450 Brooks Road, Memphis, TN 38116 (US).</p> <p>(72) Inventor: BROSNAHAN, Robert; 2936 Waterleaf, German- town, TN 38138 (US).</p> <p>(74) Agents: KRIEGER, Paul, E. et al.; Pravel, Hewitt, Kimball & Krieger, P.C., 10th floor, 1177 West Loop South, Houston, TX 77027-9095 (US).</p>		<p>(43) International Publication Date: 1 February 1996 (01.02.96)</p> <p>(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published With international search report.</p>

(54) Title: MULTI-SECTION INTRAMEDULLARY NAIL



(57) Abstract

A modular intramedullary nail (10) includes three connectable sections (11, 12, 13) that are connectable end to end. The three sections include an upper proximal nail component (11), a central nail component (12), and a lower distal nail component (13). The nail components are connected using corresponding frustoconical socket (16) and frustoconical projecting end portions (19) of adjoining nail components that can be fitted together with a taper lock or morse taper connection and secured tightly together upon impact. Upon assembly, the connections are self-orienting, providing corresponding key and slot portions (23, 29) adjacent the respective frustoconical socket and frustoconical projecting end portions of the nail components. The interlocking keys and slot align and abut upon assembly so that the adjoining nail components only align in one relative position.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgystan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

TITLE: MULTI-SECTION INTRAMEDULLARY NAIL

Specification

1. Field of the Invention:

5 The present invention relates to an intramedullary nail system for the repair of long bone fractures, which has a multi-section modular design for enabling a surgeon to assemble a nail or related implant during surgery which most closely fits the patient's needs.

10 2. Background of the Invention:

Intramedullary nails have become the preferred implant treatment in many long bone fracture cases. As the use of intramedullary nails has become more popular, the design of the implants has advanced so that there are particular designs for different types of fractures. Nails having a particular configuration are desirable for certain indications. Because of wide variation of the long bones in patients, the particular style of nail is preferably available in a range of lengths, diameters, and shapes. As a result, the surgeon must have at hand a large inventory of styles and sizes to accommodate the variety of indications. Examples of such styles include, but are not limited to femoral reconstruction, intramedullary hip screw, and femur components of total hips. One solution to this variation problem is to provide a modular nail system where a surgeon can select various component parts and assemble them to fit a particular patient's needs.

15
20
25

Such a system is taught in U.S. Patent 4,805,607 to Engelhardt et al. where a modular intramedullary nail system has elongated base nails and extension members of different lengths and diameters. The base nail is the primary structural component of the system and the extension member is designed to fit on the proximal end of a base nail. By selecting various combinations of base nails and extension members, nails of a desired length and diameter can be constructed. The component parts are locked together by a pair of snap lock springs formed on the proximal end of the base nail, which include engagement tongs with locking barbs at the trailing end which are radially depressed in order to engage a counterbore on the extension member. A screw is inserted through a hole in the modular components after the rod has been implanted for preventing the tongs from disengaging.

Another intramedullary nail is disclosed in the Simpson et al. Patent 5,122,141, entitled "Modular Intramedullary Nail". In the Simpson patent, an intramedullary nail system and method for providing a capability of creating intramedullary nails of any desired length includes a combination of a small number of base nail members adapted to be joined to any one of a variety of hollow extension nail members. Any selected extension nail member may be axially connected to any selected base nail member in order to prevent axially separation of the members. Additionally, each extension nail members provided with transverse openings adapted to receive a bone screw to secure the intramedullary nail within the bone to be repaired. The extension nail member is infinitely rotationally adjustable about the axis of the base nail member in order to enable the fixation of the extension member with any desired degree of anteversion prior to

final assembly of the base nail member with the extension nail member.

The Comte et al. Patent 4,875,475 shows a device for treating a bone that includes an intramedullary nail adapted to be driven into a hollow bone. The proximal terminal nail segment includes an internal thread and a transversely penetrating longitudinal slot adapted to receive a screw to penetrate through the nail, and to be screw connected to the bone. A distal terminal nail section comprises two transversely throughgoing bores, each adapted to receive a screw to be screw connected with the bone.

The Chapman et al. Patent 4,776,330 discloses a modular femoral implant system for use in the treatment of femoral disorders resulting from injury, disease, or congenital defects. The modular system includes at least three interconnected components, including an elongated epiphyseal-metaphyseal implant, an intramedullary rod, and an angled side plate having an elongated plate portion adapted to be secured to the outer cortical wall, and a hollow sleeve adapted to extend into the femur.

A French Patent No. 1,031,128 relates to a femoral nail of multiple sections.

The Fischer Patent 3,846,846 discloses a ball-shaped portion to form part of the hip joint and a second portion that extends from the ball-shaped portion into the femur. The second portion is provided with a passage through which an elongated expander rod is extended which is also to be inserted into an opening in the femur and on the expanded rod is arranged a series of expansion elements in the form of a row which as the expander rod is moved longitudinally of the row are all expanded to anchor the prosthesis to the femur.

An adjustable compression bone screw is disclosed in the Glisson Patent 4,858,601 that includes a shaft having first and second sections each with an external thread that may be rotated as a unit or independently. The screw
5 includes means adapted to receive a first driving tool for driving the shaft as unit, and further adapted to receive a second driving tool for rotating the second section independently of the first section.

The Tronzo Patent 4,940,467 discloses a variable
10 length fixation device for insertion into a hole formed in two or more bone fragments and includes a barrel portion and a fastener element. The device is used for repair of the proximal portion of a patient's femur.

The Marcus Patent 4,622,959, entitled "Multi Use
15 Femoral Intramedullary Nail", discloses an intramedullary nail for use in fractures for the left or right femur and includes a body having a head, an intermediate portion, and a distal tip. Transverse openings are provided in the body near the distal tip and in the head for receiving locking
20 screws. One opening in the head has its axis within the femoral neck and another opening has its axis generally transverse thereto. The nail head has a seat with a transverse locating slot for securing a screw insertion tool in a fixed angular position in which the screw guide
25 on the tool is aligned with one of the screw receiving openings.

The Brumfield Patent 4,827,917, entitled "Femoral
Fracture Device," provides an apparatus for treating
30 fractures of the femur that includes a screw and an intramedullary rod. The screw has a threaded portion and a smooth portion. The rod has a head, stem, and longitudinal bore. There is at least one pair of coaxial holes through the stem, transverse to the longitudinal axis

of the rod, for receiving first anchoring means such as a nail, screw, or bolt, to secure the rod within the marrow canal of the femur. There are at least a proximal pair of coaxial holes and a distal pair of coaxial holes in the head of the rod in an angled direction toward the femoral head relative to the longitudinal axis of the rod. The distal pair of head holes are adapted to slidingly receive the screw to permit the threaded portion of the screw, in use, to engage the femoral head and to allow sliding compression of a femoral neck or intertrochanteric fracture. An optional second anchoring means which will also allow sliding and compression and an optional set screw are also provided to adapt the fracture device to a variety of applications.

U.S. Patent No. 4,995,883, issued to DeMane et al. and U.S. Patent No. 5,108,452, issued to Thomas W. Fallin, both entitled "Modular Hip Prosthesis," disclose a modular hip prosthesis that can be custom fitted to a particular patient by a surgeon prior to surgical insertion. The prosthesis features a body having a neck portion for carrying a rounded head element, a transitional mid-section of the prosthesis body includes generally rectangular and generally rounded cross-sectional areas, and a stem section has a generally rounded cross-sectional area. The stem is tapered to receive a tubular extension sleeve with a hollowed portion corresponding in shape to the stem portion of the prosthesis. The tubular extension sleeve has an open end portion receptive of the lower tapering stem of the prosthesis body. The stem portion including an internal bore, and an attachment in the form of an elongated screw is provided for connection to the stem internal bore for securing the extension sleeve and the prosthesis body together, forming a compressive sealed

connection therebetween. Pads can be attached to the transitional midsection of the prosthesis body for increasing the cross-sectional shape of the prosthesis at the transitional midsection. Removable collars can be added to the prosthesis to form a transverse load carrying interface with the upper end of the patient's femur. Frustrorconically shaped extension sleeves can be added to the prosthesis neck for extending the neck length.

U.S. Patent No. 5,047,033, issued to Thomas W. Fallin, entitled "Mill And Guide Apparatus For Preparation Of A Hip Prosthesis," discloses a guide apparatus for preparing the femur of a patient with a rotary mill to receive a femoral hip prosthesis includes a V-shaped guide body having a lower end base portion adapted to extend into the intramedullary canal of the femur and an upper end portion comprised of at least two spaced apart struts so that the overall guide body had a configuration substantially the same as the prosthesis body sought to be implanted in the patient. The lower end of the guide body base provides one or more hemispherical receptacles for holding the hemispherical end portion of a spinning mill bit. A preferably removable transverse guide rail has connection pins at one end portion thereof for forming a connection with the upper end of the guide body at one of the struts, the arm having a curved surface that is adapted to guide the mill bit during preparation of the intramedullary canal of the patient's femur for receiving a hip prosthesis thereafter.

30 SUMMARY OF THE INVENTION

The present invention is directed to improved intramedullary nails providing a modular intramedullary nail system having three modular components. The

components include proximal, central, and distal nail sections. The modular components of the present invention are quickly and easily assembled having joints of high mechanical and torsional integrity.

5 The modular components of the present invention preferably include a locking mechanism for connecting and locking together adjacent modular components which can quickly provide a positive locking fit that resists relative twisting or rotational movement between the
10 components as well as translation.

 Assembly of the modular components of the present invention is achieved by one modular component having a socket with a conical tapered surface adapted to securely engage a cooperating tapered pin or projecting conical
15 surface. The engagement results in a secure taper lock or wedge lock connection which is resistant to translational forces. An example of a modified taper and bore providing such secure connection is a configuration known as a morse
20 taper.

 Resistance to rotational movement between adjacent nail section is achieved by providing a pair of keys adjacent each taper that engage corresponding key slots of the adjoining nail component.

 In a preferred embodiment, the keys and slots are pre-
25 positioned to provide an alignment mechanism to ensure the components are properly assembled in a pre-selected position of anteversion.

 In an alternative embodiment, the taper or bore of one component may be adapted to accept more than one type of
30 mated component, with each match corresponding to direct assembly of a specific implant design.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to acquire a better understanding of the invention, reference may be had to a detailed description of exemplary embodiments set forth below, to be considered along with the appended drawings, in which:

5 Figure 1 is a side, partially exploded view of the preferred embodiment of the apparatus of the present invention;

 Figure 2 is an exploded side view of the preferred embodiment of the apparatus of the present invention;

10 Figure 3 is an exploded fragmentary side view of the preferred embodiment of the apparatus of the present invention;

 Figure 4 is a fragmentary end view of the preferred embodiment of the apparatus of the present invention; and

15 Figure 5 is another fragmentary end view of the preferred embodiment of the apparatus of the present invention.

DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

20 Figs. 1 - 5 illustrate the preferred embodiment of the apparatus of the present invention illustrated generally by the numeral 10. Modular intramedullary nail 10 includes three sections that are connectable end-to-end. The three sections include proximal nail section 11, central nail section 12, and distal nail section 13.

 Proximal nail section 11 includes opposing end portions 14, 15. The end portion 14 defines the upper portion of the assembled modular intramedullary nail 10. The numeral 32 designates the proximal end of the entire nail 10 upon assembly. End portion 15 provides a socket 16 that is frustroconically shaped. Socket 16 of nail section 11 connects to central nail section 12 at frustroconical projection 19.

30

Central nail section 12 has opposing end portions 17, 18. A pair of frustroconically shaped projections 19, 20 are carried respectively by end portions 17, 18 as shown in Figure 2. In Figures 3-5, central nail section 12 is shown including opposing frustroconical projecting connector portions 19, 20. The frustroconical projecting connector 19 includes a flat circular surface 21. The frustroconical connector 20 includes a flat circular surface 22. Each of the end portions 17, 18 provides keys 23 that are generally rectangularly shaped and positioned adjacent the frustroconical projections 19, 20 as shown in Figure 3.

Keys 23 extend from annular shoulder 24 of each end portion 17, 18. Each frustroconical projection 19, 20 and its associated keys 23 and annular shoulder 24 cooperate with a similarly configured sockets 16, 25 respectively of proximal section 11 and distal section 13.

In Figure 3, the distal section 13 and its socket 25 are illustrated. However, it should be understood that the end portion 15 of proximal nail section 11 carries a socket 16 that has a configuration and shape like that of the socket 25 shown in Figure 3 for distal rod section 13. In this fashion, the proximal and distal nail sections 11, 13 affix at respective sockets 16, 25 to frustroconical projecting connectors 19, 20 on opposing respective ends 17, 18 of central section 12.

In Figure 3, the socket 25 includes a frustroconical surface 26 that terminates at a flat circular surface 27 defining the inner most portion of the socket 25. Annular shoulder 28 cooperates with and abuts upon assembly of sections 12, 13, the annular shoulder 24.

Keys 23 are configured approximately 180° apart as are key slots 29 adjacent each socket 16, 29. Upon assembly, the frustroconical sections 19, 20 form a taper lock or

morse taper connection with the respective socket 16, 25 of nail sections 11, 13. Upon assembly, the keys 23 align with and register into key slots 29 to provide an automatic indication of proper rotational alignment or a selected degree of anteversion. At the same time, the keys 23 and key slots 29 prevent rotation of one nail section relative to the adjoining nail section upon assembly.

Proximal nail section can have a pair of diagonally extending openings 30 that can receive bone screws for forming a connection between the nail 10 and adjoining bone. The proximal nail section 11 can have a central longitudinal bore 35 that intersects diagonal openings 30 at an angle of about 45°, for example. Transverse openings 31 are provided in distal rod section 13 for receiving bone screws therethrough. Similarly, the openings 31 can receive bone screws for affixing distal rod section 13 to adjoining bone tissue. Figure 1 illustrates modular intramedullary nail 10 as assembled. In Figure 1, the assembled nail includes a proximal end 32 and a distal end 33. Circumferentially spaced slots 34 in proximal end 32 of proximal rod section 11 can accept insertion and/or removal tools for transmitting torque to the assembled nail 10 if desired. The central longitudinal bore 35 can include a threaded section for attaching a removal tool, bolt or the like to the proximal section 13 of the assembled nail 10 such as may be required during insertion or removal. Alignment arrows 36 can be used to aid the user in aligning keys 23 and key slots 29. The arrows 36 align as shown in Figure 1. When keys 23 and key slots 29 are properly aligned and engaged.

The following table lists the parts numbers and parts descriptions as used herein and in the drawings attached hereto.

PARTS LIST

	<u>Part Number</u>	<u>Description</u>
	10	modular intramedullary nail
	11	proximal section
5	12	central section
	13	distal section
	14	end
	15	end
	16	socket
10	17	end
	18	end
	19	frustroconical projection
	20	frustroconical projection
	21	flat circular surface
15	22	flat circular surface
	23	key
	24	annular shoulder
	25	socket
	26	frustroconical surface
20	27	flat circular surface
	28	annular shoulder
	29	key slot
	30	diagonal opening
	31	transverse opening
25	32	proximal end
	33	distal end
	34	circumferentially spaced slots
	35	bore
	36	arrows

30 The foregoing description should be considered exemplary of the invention and not restrictive. It should also be understood that improvements and modifications can be made to the invention without departing from the spirit

and scope of the invention as defined in the appended claims.

WE CLAIM:

- 1 1. A modular intramedullary nail, comprising:
2 a) a proximal nail component;
3 b) a distal nail component;
4 c) a central nail component having proximal and
5 distal end portions that are respectively connected during
6 use to the proximal and distal nail components;
7 d) connecting means for securing the proximal
8 and distal nail components to opposing end portions of the
9 central nail component, the connection means including
10 corresponding conical socket and conical projecting end
11 portions of adjoining nail components that can be fitted
12 together and secured upon impact; and
13 e) the connecting means including self
14 orienting portions adjacent the respective conical socket
15 and conical projecting end portions for resisting relative
16 rotational movement between the components.
- 17 2. The modular nail of claim 1, wherein the central
18 nail component has a generally uniform diameter along a
19 majority of its length.
- 20 3. The modular nail of claim 1, wherein the
21 connection means includes corresponding keys and key slots
22 on adjacent and connecting conical socket and conical
23 projecting portions. 4. The modular nail of claim 1,
24 wherein the proximal nail component has a partially
25 internally threaded bore section.
- 26 5. The modular nail of claim 1, wherein the
27 connection means includes male and female connector
28 sections that are generally frustroconical in shape.
- 29 6. The modular nail of claim 1, wherein central nail
30 component has an annular external collar at one end portion
31 thereof.

32 7. The modular nail of claim 1, wherein the
33 connection means includes at least one cooperating key and
34 a cooperating key slot.

35 8. The modular nail of claim 7, wherein at least one
36 key is formed adjacent the conical projecting portion.

37 9. The modular nail of claim 1, wherein the proximal
38 nail component has at least one transverse opening
39 therethrough.

40 10. The modular nail of claim 1, wherein the distal
41 nail section has at least one transverse opening
42 therethrough.

43 11. The modular nail of claim 5, further comprising
44 rotational resistance means that includes a shaped
45 projection on the male connector section and a
46 correspondingly shaped recess on the female connector
47 section, and the projection and recess are shaped to engage
48 for preventing relative rotational movement therebetween.

49 12. The modular nail of claim 1, wherein the central
50 nail section is frustroconically shaped at each of its end
51 portions.

1/2

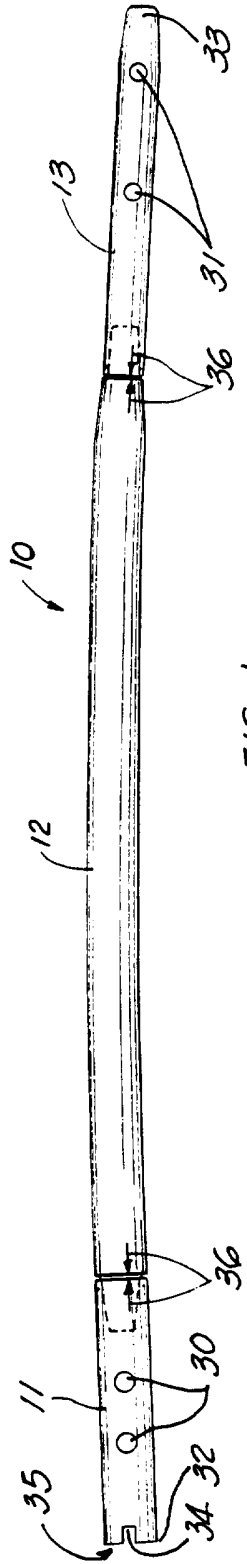


FIG. 1

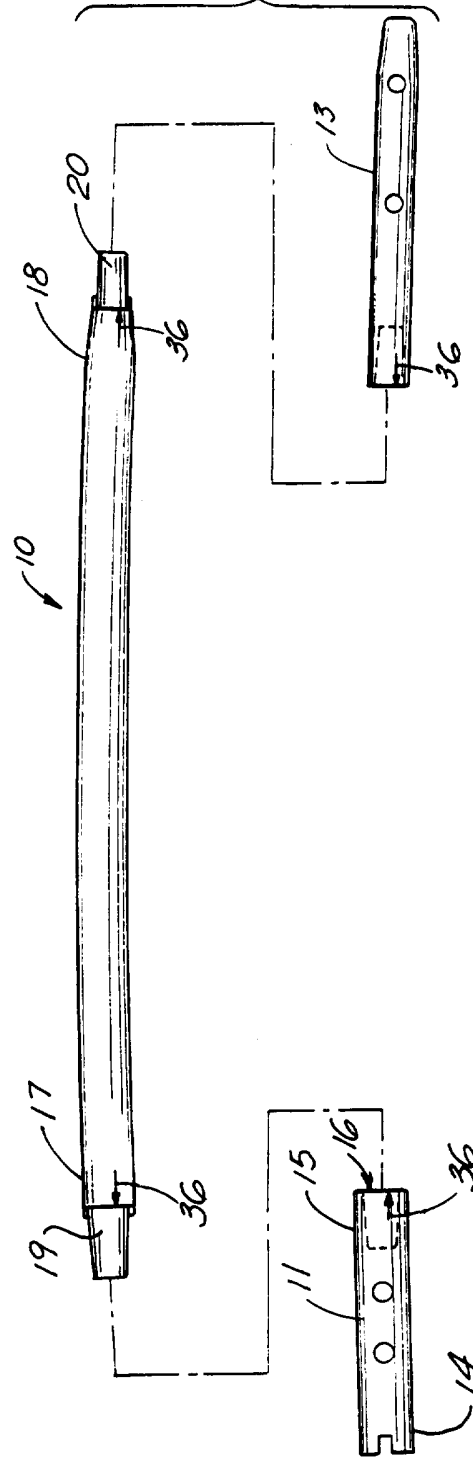
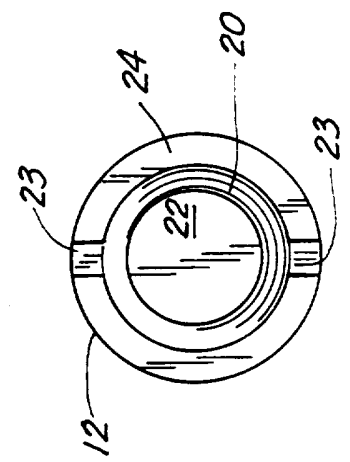
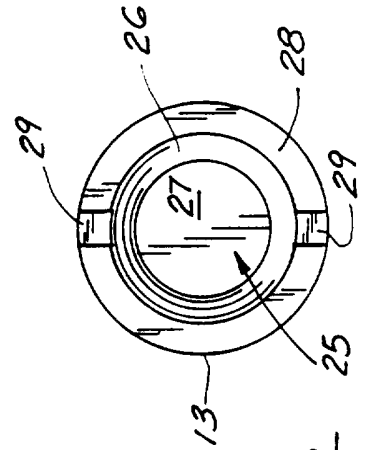
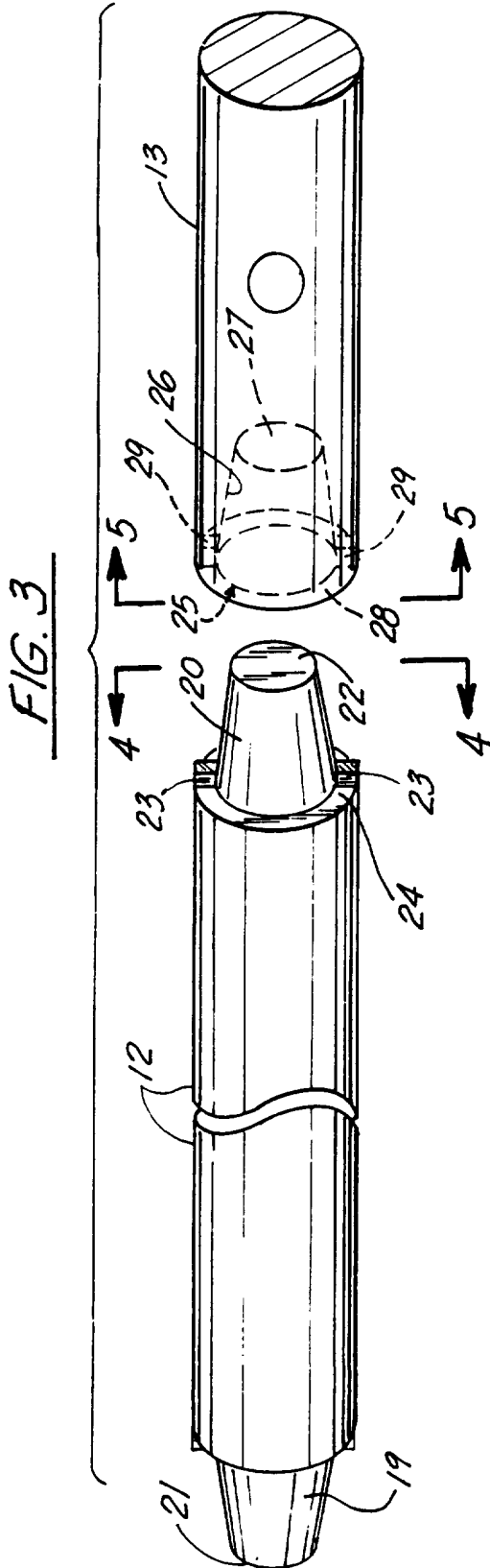


FIG. 2



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US95/08875

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/72

US CL :606/62, 67

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 403/334; 606/62-68; 623/23

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y, P	US, A, 5,352,227 (O'HARA) 04 October 1994, see Fig. 3.	1-12
Y	US, A, 1,542,266 (PALMER ET AL.) 20 June 1921, see Figs. 1 and 2.	1-12
Y	US, A, 4,827,917 (BRUMFIELD) 09 May 1989, see Figs. 1 and 3.	4
Y	US, A, 5,122,141 (SIMPSON ET AL.) 16 June 1992, see Figs. 1 and 2.	9, 10

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:	"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
"A" document defining the general state of the art which is not considered to be part of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"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
"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)	"&" document member of the same patent family
"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	

Date of the actual completion of the international search

29 SEPTEMBER 1995

Date of mailing of the international search report

13 NOV 1995

Name and mailing address of the ISA/US

Commissioner of Patents and Trademarks

Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

SCOTT B. MARKOW
PCL

SCOTT B. MARKOW

Telephone No. (703) 308-3595