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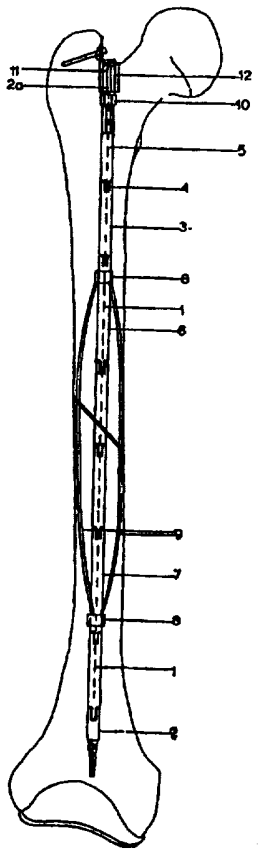
(54) Title: INTRAMEDULLARY, FLEXIBLE FRACTURE FIXATION DEVICE, USING BI-AXIAL PRESTRESSING

(57) Abstract

The invention refers to a prosthetic device for the application of simultaneous axial and tranversal prestressing to obtain stable and elastic osteosynthesis of fractures. The device focuses on the concept of internal fixation with consideration for the natural frequency of the bone. The device for fracture fixation comprises a "tendon" (i.e. a tensionable wire) least one deformable element at the focus of the fracture, with the tendon and the deformable element being disposed almost parallel, whereby the device further comprises compression means to apply a compression force to the deformable element(s), so that the deformable element(s) deform(s) laterally. The device described can be used for fractures of long bones as well as for proximal femoral fractures. When used for long bone fractures, the device is an intramedullar flexible bar, with which we apply adjustable and measurable axial prestressing in order to compress the bone fragments and preload the bone. When used for proximal femoral fractures, the device is the same intramedullar flexible bar, with which we apply adjustable and measuring lateral prestressing while anchoring it on the femoral shaft exterior. By doing so we compress the bone fragments in order to neutralize the tension forces on the fracture and to avoid interfragmentary motions. The terms "axial prestressing" and "lateral prestressing" refer to axis of the long bone. The device allows us to achieve predetermined and measurable intramedullar transversal prestressing, which is a prerequisite for the application of axial prestressing.



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Intramedullary, Flexible Fracture Fixation Device, using bi-axial prestressing.

The invention refers to a prosthetic device for the application of simultaneous axial and transversal prestressing to preload the bone and obtain stable and elastic osteosynthesis of fractures. The device focuses on the concept of biological internal fixation with minimal damage and with consideration for the natural frequency (Hz) of the bone.

Each of the well established fixation methods (rigid compression plating, reamed intramedullary nailing, with or without interlocking of the fracture fragments, external fixation and dynamic hip screw) has advantages and disadvantages as well as special biomechanical characteristics. Vast clinical experience combined with the data produced from theoretical and experimental studies have described many of the problems related to the biomechanics of these fracture fixation devices.

Today's understanding of bone biology has led us to a new approach to bone fixation. This approach considers the importance of the preservation of the soft tissue and of careful protection of the viability of bone.

This invention aims to add to the theory and practice of bone fixation the concept that the fracture fixation device introduces into the broken bone equilibrium tensions to restore the intraosseous forces and make the bone capable of receiving the load stresses and muscle-spasm stresses right at the beginning of the healing period, as opposed to the prior concept that it is the device that receives these stresses.

A first attempt towards these goals is disclosed by Protogirou in WO 91/19461 (title : Device for Osteosynthesis with Axially Guided Prestressing Elements). This device was also trying to solve some of the problems related to the biomechanics of bone fixation using axial prestressing to achieve stable and elastic osteosynthesis thus restoring the

intraosseous forces. The resetting of the fragments remains stable by the medullary guide and the axial prestressing is applied through the tendons.

According to the invention the device for fracture fixation comprises, a tendon and at least a deformable element at the focus of the fracture, whereby the deformable elements may be 2, 3, 4, 5, or more, with the tendon and the deformable element being disposed almost along the same direction, whereby the device further comprises compression means to apply a compression force to the deformable elements, so that the deformable elements deforms laterally. The device described can be used for fractures of long bones as well as for proximal femoral fractures. When used for long bone fractures, the device is an intramedullar flexible bar, by which we apply adjustable and readable axial prestressing in order to compress the bone fragments and preload the bone, and not a supportive intramedullar nail as the devices used sofar for fracture fixation. When used for proximal femoral fractures, the device is the same intramedullar flexible bar, by which we apply adjustable and readable lateral prestressing when anchoring it on the external femoral shaft. By doing so we compress the bone fragments in order to neutralize the tension forces on the fracture and to avoid the interfragmentary motions. The terms "axial prestressing" and "lateral prestressing" refer to the axis of the long bone.

The device according to the invention presents a different approach to the problem of fracture fixation in that it allows us to achieve predetermined and readable intramedular transversal prestressing, which is a prerequisite for the application either of axial prestressing or of lateral prestressing. The transversal prestressing holds in place the repositioned bone fragments and contributes to the neutralization of the bending moments and the shearing forces between the fracture angle and the mechanical axis of the bone caused by the axial prestressing in the case of long bone fractures. In the case of proximal femoral fractures the transversal prestressing diminishes the

interfragmentary motions. The term "transversal prestressing" refers to the "axial prestressing" and the "lateral prestressing" and is vertical to them.

Moreover, because the transversal prestressing can diminish the bending moments and the shearing forces caused by muscular spasm, the same device can be used as bone distractor for unstable long bone fractures.

The ability to compress the bone ends uniformly, In the case of long bone fractures, can be achieved through intramedullary axial prestressing. But the fractured bone cannot receive compression forces if it is not repositioned in a stable way, because of bending and shearing forces occurring as a result of compression. The resetting of the fragments remains stable and allows for the application of axial prestressing because of the prior application of intramedullary transversal prestressing. In order to achieve this bi-axial prestressing we need a tendon, inserted intremedullarly and anchored in the one end of the bone. The tendon is passing through cylindrical bodies, which fit into one another and form a flexible bar. At least one pair of cylindrical bodies bear attachment means for deformable elements. By applying compression to the cylinders by the compression nut we bring the cylinders together and compress the deformable elements, which deform laterally and exercise pressure on the inner wall of the bone (transversal prestressing). As the tendon is already anchored in the one end of the bone, we exercise tension on the tendon by a screw bolt with support on an anchor means, which is anchored into the other end of the bone (axial prestressing). In spite of the application of tension, the flexible bar does not become a straight bar, but on the contrary it follows all the curvatures of the bone.

The neutralization of tension forces on the fractured proximal femoral bone can be achieved through lateral prestressing (tension band). The application of lateral prerstressing becomes more efficient if we diminish the interfragmentary motions. This

is achieved by the prior application of transversal prestressing. In order to achieve this double prestressing we need an anchor screw, which is anchored in the head of the femur. The other end of this anchor screw is formed as a cylinder with attachment means at both its ends for the deformable elements. By applying compression to a compression means at the end of the cylinder other than the end bearing the screw, we compress the deformable elements, which deform laterally and exercise pressure on the inner wall of the bone (transversal prestressing). The one end of the tendon is anchored at the end of the cylinder other than the end bearing the screw. The tendon is anchored by a ball means in order to form an articulation at this point and thus diminish the motion between implant and bone. The tendon bends on the lateral femoral shaft with support on a fulcrum attached on a plate, which plate is screwed in the lateral femoral shaft. The other end of the tendon passes through a cylinder fixed to the plate. We exercise tension on this end of the tendon with support on the cylinder fixed to the plate and we then anchor the tendon on the plate (lateral prestressing). In some cases of unstable fractures we add to the above described device a second tension band (wire). We introduce both ends of the wire in the form of a slip knot into the bone from the opening made for the anchor means 2b, towards the base of the femoral neck. We then anchor the slip knot on the anchor screw, we tighten it over the greater trochanter, and we then anchor both its ends on the plate.

The following advantages can be observed compared with the previous fixation methods (rigid compression plating, reamed intramedullary nailing with or without interlocking of the fragments, external fixation and dynamic hip screw) :

- The resetting of the fragments is supported by the transversal prestressing.
- One does not have to operate at the fracture area because the device is inserted intramedullary by the same technique as any intramedullary nail in the cases of long bone fractures, and it is inserted from the lateral femoral shaft by the same technique as the present devices in the cases of proximal femur fractures.

- The device is introduced without any reaming, and fills up the intramedullar area, thus allowing for early bearing.
- The device is inserted easily and it does not affect the shape of the bone because it is flexible and self guided and follows the curves of the bone.
- Friction between device and bone is minimal because of small and firm contact between them.
- The infection possibility and other complications are minimised.
- The time of medical attendance and recovery is minimised.
- The removal of the device is very easy.
- Moreover, because the transversal prestressing can neutralise the bending moments and the shearing forces caused by muscular spasm, the same device can be used as bone distractor for unstable fractures.
- The possible mistakes are very few because the method is easy to learn and apply.
- The use of x-rays is not necessary in many cases, and when indispensable, the time of use is minimized.
- The device does not affect the E-modulus and the blood circulation of the bone.
- It is possible to assemble individual device components of different lengths, so as to achieve adjustment according to the geometry of the specific bone (Universal and Modular).

The present invention will be better understood with the following detailed description of an embodiment for each type of fracture, long bone and proximal femur fracture, in connection with the accompanying drawings:

FIGURE 1 is a representation of the device implanted into a femur bone.

FIGURE 2 is a representation of the bolt **11**.

FIGURE 3 is a representation of the anchor means **12**.

FIGURE 4 is a representation of the nut **10**.

FIGURE 5 is a representation of the tendon **1** with anchor means **2** at its one end and screw means **2a** at its other end.

FIGURE 6 is a representation of torque means **5**.

FIGURE 7 is a representation of a cylindrical element **3**.

FIGURE 8 is a representation of the two cylindrical elements **6** and **7**, and of the deformable element **9**.

FIGURE 9 is a representation of the device implanted into a proximal femur bone.

FIGURE 10 is a representation of the anchor means **2b**.

FIGURE 11 is a representation of a bolt **18**.

FIGURE 12 is a representation of the end of the tendon **1b**, which end is formed as a ball.

FIGURE 13 is a representation of the deformable elements **9b** attached to the attachment means **8b**.

FIGURE 14 is a representation of the plate **14** with the cylinder **16**.

FIGURE 15 is a representation of the protrusion **15**, which is attached to the head of the plate **14**.

FIGURE 16 is a section of the plate **14**.

Referring now to the drawings the following detailed description of two embodiments, one for a long bone fracture and one for a proximal femur fracture will help understand how we apply the above mentioned principle of bi-axial prestressing.

The tendon **1** for the application of axial prestressing can be a wire-cable. Its one end is incorporated into an anchor means **2**, which may be a self-taping screw, suitable for spongy bone. The head of the anchor means is cylindrical with two slots **4**, dividing the perimeter of the cylinder into two protrusions which fit into the two slots of the preceding cylindrical body **3**. The other end of the tendon is incorporated into a screw means **2a**, for example a threaded bar.

The tendon is passing through cylinders. We have three kinds of cylinders depending on their position on the device and their use. All the cylinders except the last one **5** towards the end of the device near the body have two opposite facing slots **4** at both their ends, dividing the perimeter of the cylinder into two protrusions which fit into the two slots of the nearby cylinder, so as to allow the cylinders first to fit into one another and form a flexible bar, and second to transmit the torsion force which we apply on the torque means **5** to the anchor means **2**.

The two cylinders **6**, **7**, which correspond to the focus of the fracture, have an overdrawn perimeter for part of their length, to provide place for attachment means **8**, in which the deformable laminated springs **9** are adapted. The length of the slots of these two cylinders on the end where they fit into one another is longer, so as to allow them to come closer, compress the laminated springs and let them bow and exercise intramedullary pressure.

The torque means **5**, placed last towards the end of the device near the body is of similar shape to the cylinders **3** along half of its length. The other half of its length, towards the end of the device, has the shape of a screw nut as regards its external shape. A nut screwdriver is adapted to this half of the torque means **5** to screw the anchor means **2**, by screwing the whole device around itself. The internal cylindrical opening of the part of the torque means **5** which fits into the cylinder **3** is of the same diameter as the openings of all the other cylinders so as to allow the tendon to pass through, whereas the part of the internal opening towards the end of the device is larger to let the threaded bar **2a** adapted to the tendon fit into it and be stopped there so as to hold all the cylinders together.

A nut **10** is screwed around the threaded bar **2a** to bring all the cylindrical bodies **3,6,7** and torque means **5** together and compress laminated springs **9**, which by deforming laterally, exercise intramedullar pressure, i.e. transversal prestressing.

The bolt **11** is then screwed around the bar **2a** after the nut **10**, to apply tension to the tendon **1** with support on the anchor means **12** and on the bone, thus exercising axial prestressing, that is pre-loading of the bone.

Bolt **11** may be replaced by element **11a** with grooves on its outer side. In this case the element **11a** when screwed inside the anchor means **12** and by compressing the bar **2a**, it applies compression forces to the device, thus distracting the bone fragments when necessary.

The tendon **1b** for the application of lateral prestressing can be a wire cable. Its one end may have the form of a ball which is attached to a bolt **18**, which bolt is screwed around torque means **5b.** Torque means **5b** is actually the one end of an anchor means **2b**, and serves to screw the anchor means into the bone. The other end of the anchor means **2b** may be a self-taping screw, suitable for spongy bone. The body of the anchor means **2b** is hollow because the anchor means is positioned with the help of a drill guide. Around the cylindrical part of anchor means **2b** deformable elements **9b** are disposed almost along the same direction, which are fixed at both their ends into attachment means **8b**. Before screwing bolt **18** around the one end of anchor means **2b**, we screw a nut **10b**, which compresses the attachment means **8b** between eachother, thus deforming the deformable elements **9b** laterally. The deformable elements **9b** fill up the Ward's Triangle and exercise pressure on the inner side of the bone (transversal prestressing).

A plate **14** is fixed with screws on the lateral cortex of the femur. This plate differs from the usual ones in two points. First it has a protrusion **15** on its head, which serves as a fulcrum for the tendon **1b** to have a smooth change of direction of the tendon. Second, there is a cylinder **16** fixed on the plate' s body. The tendon **1b** is passing through this cylinder.

We exercise tension (lateral prestressing) on the tendon along its axis, with support against the cylinder **16**. This tension may be easily measured and adjusted according to the necessities of the direction of the fracture, the weight of the patient and the form, dimensions and quality of the bone. This tension can be applied by means of a dynamometric tensioner, which in this case plays the role of a tension means. We then anchor the tendon on the plate with a securing means **17**. This securing means 17 may be in the form of a deformable metal clip or cylinder, which can be deformed and pressed on the tendon in a fixed relationship.

CLAIMS

1. Device for fracture fixation comprising, a tendon (1,1b) to apply axial prestressing and lateral prestressing and at least a deformable element (9,9b) at the focus of the fracture, with a tendon (1,1b) with first and second ends and a deformable element (9,9b) being disposed almost along the same direction, whereby the device further comprises compression means (2a,3,5,6,7,10,10b) to apply a compression force to the deformable element, so that the deformable element deforms laterally.

2. Device as in claim 1, whereby the device further comprises tension means (11) to apply a tension force to the tendon (1).

3. Device according to claim 2, whereby the tension means comprises first anchor means (2) at the first end of the tendon (1) and screw means (2a) at the second end of the tendon.

4. Device according to claim 2, whereby the tension means comprises first anchor means (2b) at the first end of the tendon (1b).

5. Device according to claim 1, comprising first anchor means (2,2b) at the first end of the tendon (1,1b) and torque means (5,5b) to apply a torque to the anchor means (2,2b), to turn the device around itself for screwing the first anchor means (2,2b).

6. Device according to claim 1, whereby the compression means comprise first anchor means (2) at the first end of the tendon (1) and screw means (2a) at the second end of the tendon, a plurality of cylindrical elements (3,5,6,7) disposed around the tendon (1), attachment means (8) on two cylindrical elements to attach the two ends of the deformable elements (9) to the two cylindrical elements, and compression means (10) co-acting with the screw means (2a), so that when the

compression means (10) is screwed around the screw means (2a) the plurality of cylindrical elements are brought together to compress the deformable element (9), which by deforming laterally, exercise intramedullary pressure transversal prestressing.

7. Device according to claim 1, whereby the deformable elements (9b) are fixed at both their ends onto attachment means (8b), coacting with the compression means (10b) to compress the deformable elements (9b) and deform them laterally.

8. Device according to claim 6, comprising a bolt means (11) and second anchor means (12) at the end of the tendon carrying the screw means, whereby the bolt means and the second anchor means co-act with the screw means (2a) to apply a tension force to the tendon.

9. Device according to any preceeding claim, further comprising a third anchor means (14,16) and a securing means (17) at the end of the tendon opposite to the first anchor means, whereby the anchor mrans (14,16) and the securing means (17) coact to maintain the tension force applied to the tendon.

10. Device according to claim 6, whereby at least two cylindrical elements have two slots (4) at both their ends, so that at each end of the cylindrical elements there are alternating protrusions and slots, to co-act with corresponding slots and protrusions of the adjacent cylindrical element, so as to allow the cylindrical elements to fit into one another and form a flexible bar.

11. Device according to claims 1, 4, or 5, further comprising a bolt (18) to be screwed around the one end of first anchor means (2b), whereby the first end of the tendon (1b) has the form of a ball enclosed within the bolt (18).

12. Device according to claim 10, whereby two cylindrical elements (6,7) have longer slots (4) on the end where they fit into one another, so as to allow them to come closer and compress the deformable elements.

13. Device according to claim 10, whereby the first anchor means (2) has a cylindrical head with slots (4), so as to fit in to the preceding cylindrical element (3).

14. Device according to any of the preceeding claims, with more than one deformable elements (9,9b), which deformable elements (9,9b) are positioned around the circumference of the anchor means (2,2b) parallel to one another.

15. Device according to any preceeding claim, whereby the third anchor means comprises a plate (14) and a cylinder (16) fixedly attached to the plate (14).

16. Device according to claims 9 and 15, whereby the plate (14) further comprises a protrusion (15) as a fulcrum for the tendon (1b).

17. Device according to any preceeding claim, whereby the whole part of the device, which is outside the bone is covered by a biocompatible plate to provide for a smooth external surface.

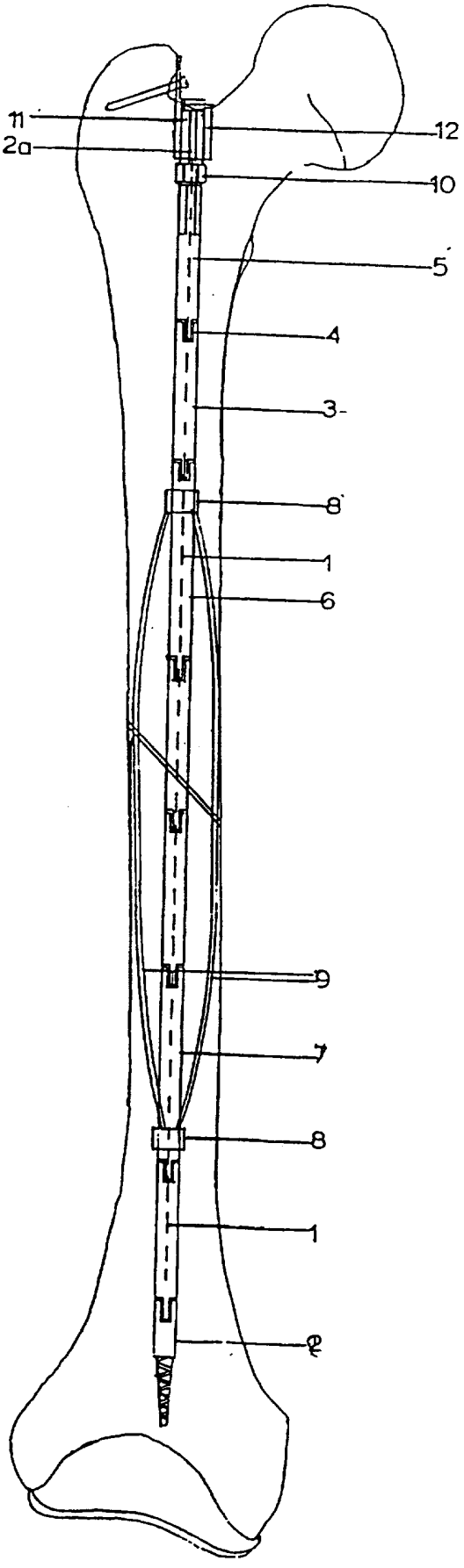


FIG. 1

FIG. 2

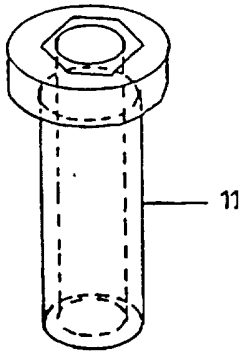


FIG. 3

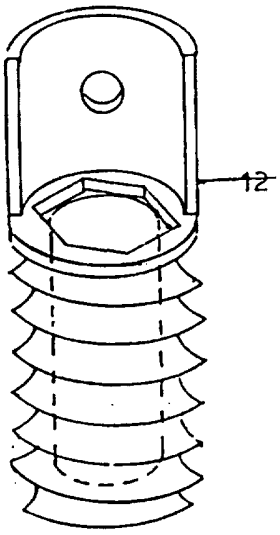


FIG. 4

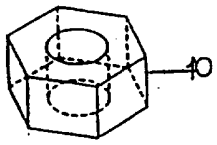


FIG. 5

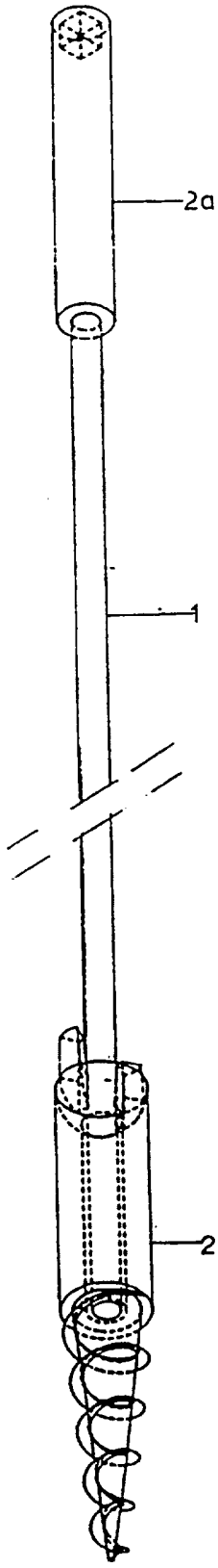


FIG. 6

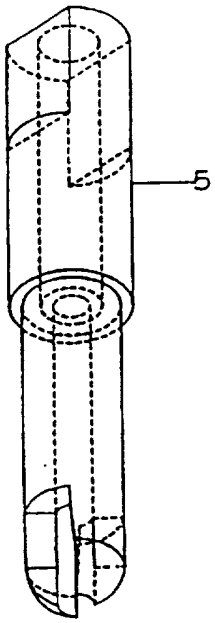
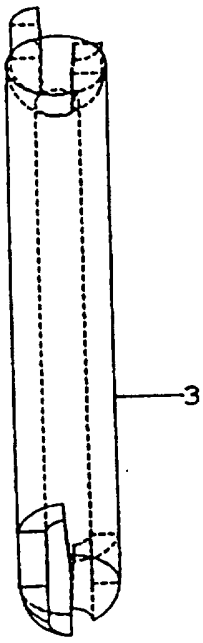


FIG. 7



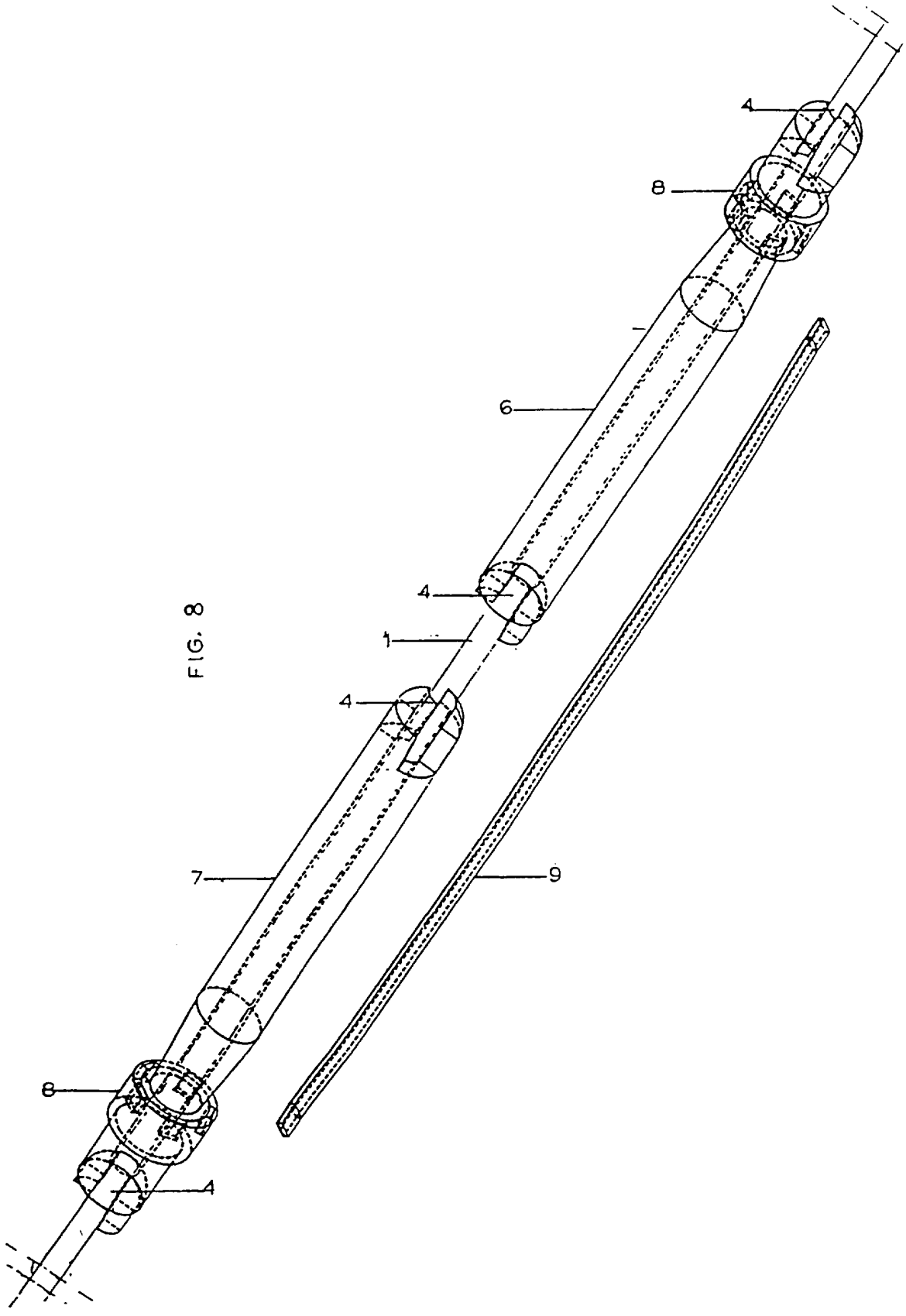


FIG. 8

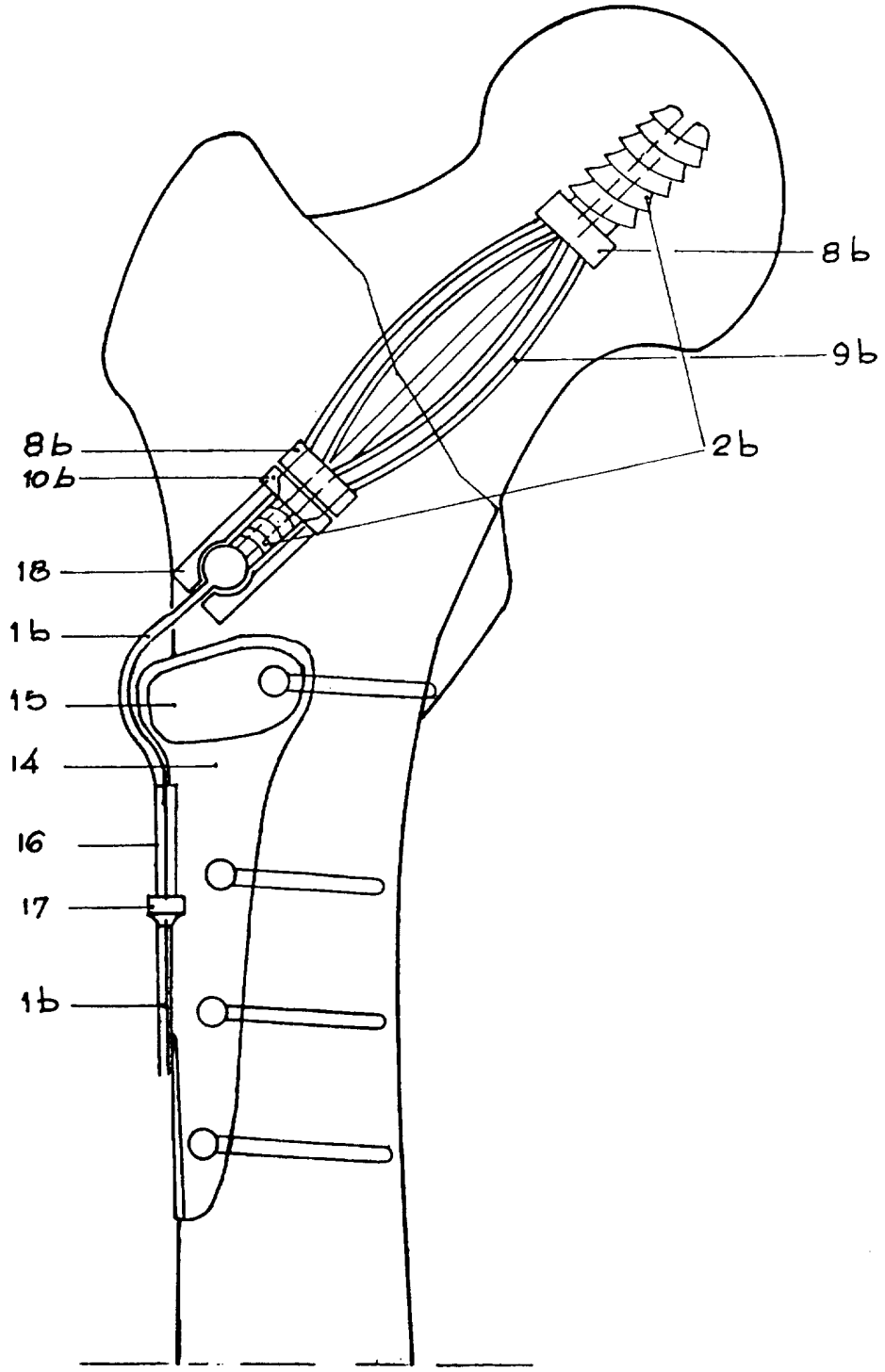


FIG. 9

FIG. 10

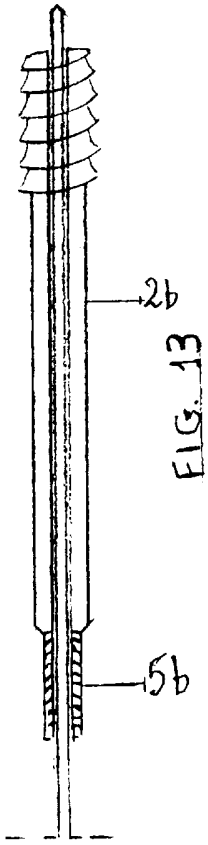


FIG. 13

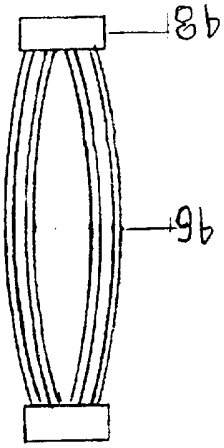


FIG. 15

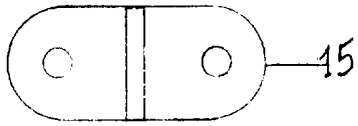


FIG. 14

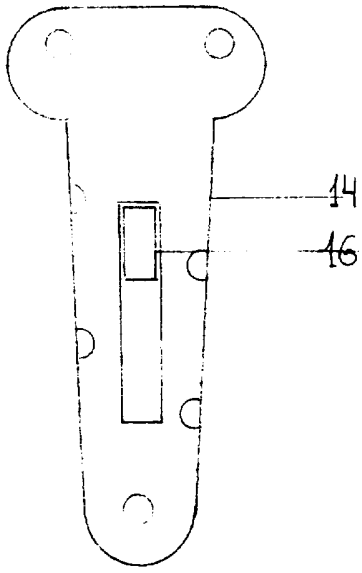


FIG. 11

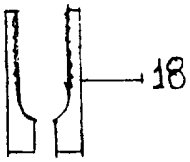


FIG. 12

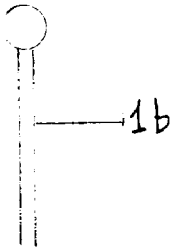
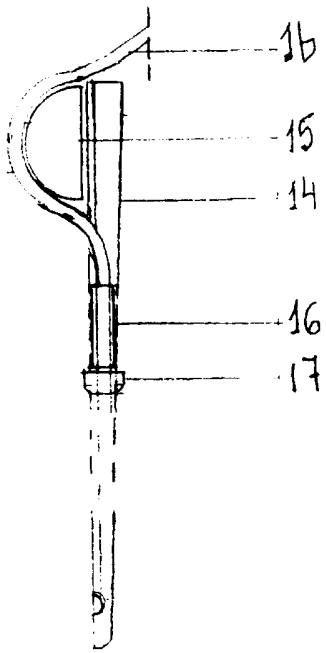


FIG 16



INTERNATIONAL SEARCH REPORT

Interr nal Application No
PCT/GR 97/00026

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/72

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)
IPC 6 A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	GB 2 268 068 A (J.B.C.DAVIES) 5 January 1994 see page 6, line 21 - line 26; figures see page 7, line 22 - page 8, line 13 ---	1,14 2-7,10
X	DE 923 085 C (E.POHL) 3 February 1955 see page 2, line 24 - line 46 see figures 1-4 ---	1,14
Y	EP 0 689 800 A (KESSLER SIGURD) 3 January 1996 see page 4, line 29 - line 42; figure 9 ---	2-7,10
A	DE 26 57 303 A (H.HÄMMERLE) 30 June 1977 see page 14, line 7 - page 15, line 15 see figures 1,2,5 --- -/--	2,5

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 October 1997	17. 11. 97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Nice, P

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INTERNATIONAL SEARCH REPORT

Inter ional Application No
PCT/GR 97/00026

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 236 512 A (J.AGINSKY) 2 December 1980 see abstract; figure 1 ---	1-7, 14-17
A	US 4 632 101 A (Y.FREEDLAND) 30 December 1986 see abstract; figure 10 -----	1-7, 14-17

1

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Interi nal Application No
PCT/GR 97/00026

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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DE 923085 C		NONE	
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DE 2657303 A	30-06-77	AT 353394 A CH 603141 A	12-11-79 15-08-78
US 4236512 A	02-12-80	NONE	
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