



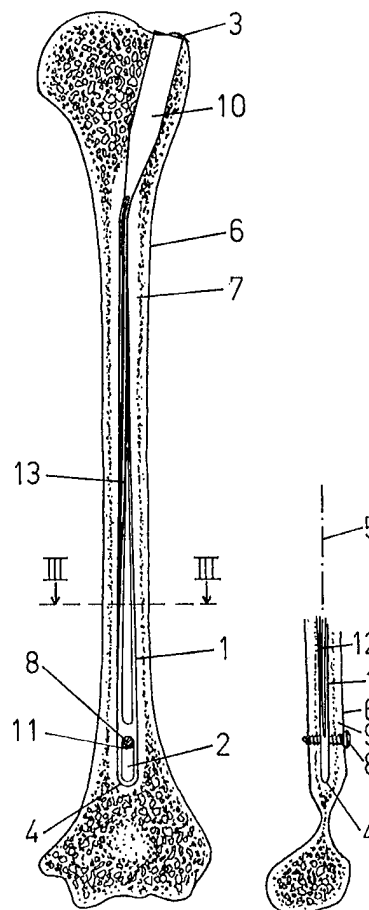
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁶ : A61B 17/72</p>	<p>A1</p>	<p>(11) International Publication Number: WO 98/24380 (43) International Publication Date: 11 June 1998 (11.06.98)</p>
<p>(21) International Application Number: PCT/EP96/05324 (22) International Filing Date: 2 December 1996 (02.12.96)</p> <p>(71) Applicant (for all designated States except CA US): SYNTHES AG CHUR [CH/CH]; Grabenstrasse 15, CH-7002 Chur (CH). (71) Applicant (for CA only): SYNTHES (U.S.A.) [US/US]; 1690 Russell Road, P.O. Box 1766, Paoli, PA 19301-1222 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): FRIGG, Robert [CH/CH]; Färbistrasse 10B, CH-7270 Davos Platz (CH). FILOSO, Silvana [CA/CH]; Obere Strasse 24, CH-7270 Davos Platz (CH). DAESCHER, Peter [CH/CH]; Flurstrasse 7, CH-7270 Davos Platz (CH). (74) Agent: LUSUARDI, Werther; Dr. Lusuardi AG, Kreuzbühlstrasse 8, CH-8008 Zürich (CH).</p>		<p>(81) Designated States: CA, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published With international search report.</p>

(54) Title: FLAT INTRAMEDULLARY NAIL

(57) Abstract

The intramedullary nail for treating a fracture of a long bone (6) has the shape of a helically twisted blade (1) with a flattened cross section extending partially or totally along the longitudinal axis (5) of the nail. The nail is provided with a hole (2) at its distal end (4) for receiving a bone fixation means (8) to be inserted transversally through said hole (2) and at least one cortex of said long bone (6). The nail is made long and thin with the smallest dimension of the cross section being much smaller than the largest dimension, so that it is flexible along the longitudinal axis of the nail.



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FLAT INTRAMEDULLARY NAIL

This invention relates to an intramedullary nail having the shape of a helically twisted blade and at least one hole at one of its free ends. The intramedullary nail is especially suited for the humerus and for other long bones where the insertion plane is different from the locking plane. It is also suited for long bones of young children where the growth plate should not be disturbed.

In recent years, the intramedullary nail has gradually gained importance and is becoming a standard method of internal fixation. Since the development of this method by Küntscher, the intramedullary nail has broadened its range of indications (e.g. locking, Gamma nail, reconstruction nail).

The basic concept behind nailing has remained the same, namely the introduction of a tube or full cylinder into the medullary cavity of a tubular bone. Initially, nailing was used for the femur, but now, its application has been extended to include all large tubular bones. Until now, the cross-sections of intramedullary nails have remained more or less the same. Even the cloverleaf cross-section developed by Küntscher some 50 years ago is still being used today, even though it has been

proven that this shape brings no special advantages. As well, changing the cross-section from the circular or almost circular cross-section was never considered necessary before, since the medullary cavity of the various tubular bones was usually opened using a rotating or circular cutting device.

Today, more attention is being paid to the rate of fracture healing, and it is believed that healing occurs faster if less damage is done to the bone during placement of an implant in the body. By choosing an appropriate cross-sectional shape for an intramedullary nail which corresponds to the anatomy of the medullary canal, it is possible to eliminate unnecessary removal of bone and tissue from the medullary canal, thus promoting healing by minimizing damage to the medullary canal and its vascularization.

The choice of nail cross-section is particularly relevant for the humerus bone, in which the medullary canal is not round along its entire length but is in fact flat and thin in the distal part. For this bone, a nail with the typical circular or almost circular cross-section would not be appropriate. A nail with a flattened cross-section would be more suited for the distal humerus.

The opening of the medullary canal for insertion of the nail can also cause unnecessary damage to the bone, as well as to the surrounding soft tissue and joint. Intramedullary nails

are typically stiff and are traditionally inserted through an insertion site which is in line with the longitudinal axis of the bone.

For the case of the humerus bone, antegrade insertion (i.e. insertion from the shoulder end of the humerus) typically goes directly through the rotator cuff. This can cause irreparable damage to the joint capsule and instability of the shoulder joint, and can result in post-operative pain and/or loss of range of motion of the limb.

For the case of growing young bones, insertion sites in line with the longitudinal axis of the bone tend to interfere with the growth plate, which can affect the normal development and growth of the bone.

An "ideal" insertion site avoids both the joint for long bones, as well as the growth plate in young patients. For the humerus, an ideal antegrade insertion site is located slightly distal to the greater trochanter on the lateral aspect, thus completely avoiding the joint capsule and rotator cuff at the shoulder. This ideal insertion site cannot not be used with traditionally stiff nails, and could only be used with nails which would be flexible along their length.

The invention as claimed aims at solving the above described problems by providing an intramedullary nail whose flexibility is achieved by relying on the natural mechanical properties (i.e. modulus of elasticity) of the nail material.

The nail is made long and thin with the smallest dimension of the cross-section being much smaller than the largest dimension, so that it is flexible along the longitudinal axis of the nail.

If such a thin, flat nail is inserted into the humerus using the ideal, antegrade, lateral insertion site described above, the distal part of the flat nail will be oriented 90° to the flat distal humerus. In order to correct this orientation problem of the flat distal nail in the flat distal humerus, the nail is twisted 90°, or any multiple of 90°, along its length. This does not significantly affect the local bending properties of the nail (i.e. short length along the axis), since bending can still occur at any one longitudinal section.

Retrograde insertion (i.e. insertion from the elbow end of the humerus) of this flat nail into the humerus is not affected by this twist, since the proximal humerus is relatively large, has a round cross-section, and allows the distal part of the nail to be oriented in any way inside the proximal humerus.

Therefore, this flat, twisted nail is suitable for both antegrade and retrograde insertion into the humerus.

For long, thin, flat nails, the 90° twist of the nail has an additional advantage: to bring added bending stability to the longitudinal device. A flat longitudinal device, after implantation, may bend in the medullary canal under a bending

load. With an added longitudinal twist, however, the device is more stable longitudinally and is, thus, less likely to bend in the canal during normal limb activity.

For thin, flat nails, the 90° twist of the nail has yet another advantage, related to locking for both an antegradely- or retrogradely-inserted nail. For a locking hole to be designed through a nail, the cross-sectional dimension orthogonal to the hole axis must be greater than the diameter of the locking hole. Depending of course on the diameter of the locking bolt, this may not be possible for the thin, flat nail design if the locking hole goes through the largest dimension of the cross-section, i.e. through the thickest wall.

From an anatomical point of view, the presence of nerves and other important tissues can also limit the possibility of locking directions. In the proximal humerus, the brachial plexus nerve group located antero-medially should be avoided during locking. Thus, for a retrograde nail, the safest locking in the proximal humerus is in the lateral-medial direction. In contrast, for an antegrade nail, locking in the flat distal humerus is most commonly done in the posterior-anterior direction, i.e. through the thinnest wall of the humerus.

Therefore, to satisfy anatomical and mechanical requirements for locking, the proximal and distal locking holes and screws should be oriented 90° (or a multiple of 90°) to each other.

For a thin, flat cross-section such as for the invention described here, this can only be achieved with a nail which is twisted 90° , or multiple of 90° , along its length.

For the purpose of closing a fracture gap, a wire or cable loop, as described in US Patent No. 5,034,012, can be added to the nail according to the invention.

The wire/cable can be looped around the entire length of the nail, preferably inset in slots, grooves or other shape of opening on the narrow sides of the flat cross-section of the nail. The closed end of the wire or cable (i.e. the looped part) at the distal tip of the nail is protected from being damaged or deformed during insertion by a metal U-shaped part surrounding it, which is part of the nail. The two ends of the wire/cable at the open end of the loop are fixed inside a nut, which is inside the proximal part of the nail.

To reduce a fracture gap using this wire/cable loop design in the flat, thin nail design, the locking bolt is first placed at the far end of the nail through the locking hole and the loose wire/cable loop. The inner nut is then rotated counter-clockwise with a screwdriver, causing the nut to move upwards and the wire/cable to be pulled upwards. As this is done, the wire/cable loop around the locking bolt at the distal part of the nail becomes smaller, tightly encloses the locking bolt, and finally pulls the locking bolt towards the proximal part of

the nail. This applies a compressive force between the proximal and distal bone fragments, thus reducing the fracture gap.

To summarize the important points, the first main advantage of the flattened, twisted nail is that it is flexible in bending, which allows it be inserted from more anatomical insertion sites not necessarily in line with the longitudinal axis of the bone. As explained above, this is particularly important for the proximal humerus to avoid the shoulder joint capsule and rotator cuff, as well as for pediatric long bones where the growth plate should be avoided.

The twist allows not only locking advantages but also makes the nail generally more stable in bending after insertion into the medullary canal.

Another main advantage of this nail is that its flat, thin cross-section, when used in the humerus, corresponds to the shape of the medullary cavity of the distal humerus. It therefore requires no extra bone or tissue to be removed before nail insertion. As well, the small, anatomical cross-section does not significantly disturb the vascularization in the medullary canal, which is important for fracture healing.

The various features of novelty which characterize the invention are pointed out with particularity in the claims annexed to and forming part of this disclosure. For the better

understanding of the invention, its operating advantages and specific objects attained by its use, reference should be had to the accompanying drawings, examples and descriptive matter in which are illustrated and described preferred embodiments of the invention.

In the drawing:

Fig. 1 is a perspective view of the intramedullary nail according to the invention, shown inserted antegradely into humerus and locked distally with a locking screw;

Fig. 2 is a partial representation of the lower part of the nail according to Fig. 1 seen from an 90° angle;

Fig. 3 is a cross-section of the nail according to Fig. 1 at the line III-III;

Fig. 4 is a modified cross-section of the nail according to the invention;

Fig. 5 is a further modified cross-section of the nail according to the invention;

Fig. 6 is a further modified cross-section of the nail according to the invention;

Fig. 7 is a further modified cross-section of the nail according to the invention;

Fig. 8 is a partial longitudinal cross-section through the upper part of the nail according to Fig. 1; and

Fig. 9 is partial enlarged representation of the lower part of the nail according to Fig. 1 with the cable in the lowest position.

Figures 1 to 3 show an intramedullary nail consisting of a helically twisted blade 1 having a hole 2 at its distal end 4. The nail may have a further hole 2 towards its proximal end 3. The blade 1 is twisted about 90° around its longitudinal axis 5 in a continuous way.

The length L of the blade 1 is in the range of 150 to 300 mm and the ratio T/W between the thickness T and width W of said blade 1 - as represented in Fig. 3 - is in the range of 0,035 to 0,286, preferably in the range of 0,1 to 0,2.

The flat intramedullary nail is used conventionally as shown in Figs. 1 and 2 for treating a fracture of a long bone 6 by inserting it longitudinally into the medulla 7 of a long bone 6, and securing the intramedullary nail to the long bone 6 in its longitudinal position by bone fixation means 8,

preferably in the form of screws, to be inserted transversally through the hole 2 and at least one cortex 9 of the long bone 6.

The head 10 at the proximal end 3 of the intramedullary nail is shown in more detail in Fig. 8 in order to describe how to assemble the intramedullary nail of Fig. 1.

One end of a preferably metallic cable (or wire) 11 is inserted through the head 10 and then threaded through groove 12 on the right side of the nail until it exits into hole 2 as shown in more detail in Fig. 9. The one end of cable 11 pushed into hole 2 is then threaded back up through groove 13 on the left side of the nail until it exits in the head 10.

At this point both ends of cable 11 are protruding out of head 10 at the proximal end of the nail, and towards the distal end 4 of the nail, cable 11 forms a loop at locking hole 2.

Both ends of cable 11 are then inserted into the cavity of an inner hollow tube 15. To secure cable 11 in said inner tube 15 the cable 11 is first adjusted for length and then inner tube 15 is deformed at position 16 in at least on plane. Threaded tube 17 is slid over inner tube 15 and the assembly 15,17 is threaded into the interior threads 19 of hollow head 10 by means of tool geometry 18, resulting in twist of cable 11, until threaded tube 17 is at its lowest position inside head 10. If the cable length was properly adjusted before being fixed inside inner tube 15, the loop 14 of cable 11 will no be

at its lowest position inside slot 2 at the distal end 4 of the nail as shown in Fig. 9. The nail is now assembled and read for implantation in the intramedullary cavity of a long bone.

An insertion handle (not shown) is fixed on head 10 of the nail using the interior threads 19. The nail is implanted in the usual fashion in the humerus of other long bone in the body. The insertion handle is removed. The nail is now ready to be locked distally.

Free-hand distal locking is performed through slot 2 in the usual fashion with a locking bolt or screw 8. The elongated hole or slot 2 is easier to aim for, compared to traditional holes, resulting in easier free-hand locking. After distal locking, a tool (not shown), e.g. a slotted screwdriver is used at tool geometry 18 through open end 20 of head 10 to unthread (or raise) threaded tube 17 until the loop 14 of cable 11 in slot 2 contacts and applies pressure to the locking bolt or screw 8 as shown in Fig. 1.

The advantage of the nail according Fig. 1 over nails according to the state of the art, e.g. 7 mm diameter nails, is the easier free-hand distal-locking due to the elongated hole 2, while still offering the advantage of secure bolt/screw fixation, provided by the loop 14 of cable 11 around the bolt/screw.

The configuration of blade 1 of the nail can be varied in several ways.

Fig. 3 shows the embodiment with lateral grooves 12 and 13 guiding cable 11.

Fig. 4 shows an alternative embodiment in which the grooves 12 and 13 of Fig. 3 are replaced by closed tunnels in which cable 11 is lodged.

Fig. 5 shows a further embodiment which is interesting from a point of view of manufacturing. It consists of a simple metal sheet forming blade 1 the lateral side of which have been curved in order to form lateral tunnels taking up cable 11.

Figs. 6 and 7 are just other variations of the embodiment according to Fig. 5 and which are easy to manufacture.

The advantage of the nail according Fig. 1 over state of the art small-diameter flexible nails, e.g. 2 to 4 mm, is that it offers improved stability due to the interlocking possibilities. Interlocking is usually not possible for small-diameter nails, due to the material limitation. In other words, there is not enough material to insert a locking screw through it.

While the foregoing description and drawings represent the preferred embodiments of the present invention, it will be obvious for those skilled in the art that various changes and modifications may be made therein without departing from the true spirit and scope of the present invention.

CLAIMS

1. Intramedullary nail, characterized in that it has
 - A) the shape of a helically twisted blade (1) with a flattened cross-section extending partially or totally along the longitudinal axis (5) of the nail; and
 - B) it is provided with at least one hole (2) at its proximal end (3) or at its distal end (4).

2. Intramedullary nail according to claim 1, characterized in that the ratio T/W between the thickness T and width W of said blade (1) is in the range of 0,035 to 0,286, preferably in the range of 0,1 to 0,2.

3. Intramedullary nail according to claim 1 or 2, characterized in that said blade (1) is twisted about 30° - 200° around its longitudinal axis (5), preferably in a continuous way.

4. Intramedullary nail according to one of the claims 1 to 3, characterized in that said blade (1) is twisted about 85 - 95° around its longitudinal axis (5).

5. Intramedullary nail according to one of the claims 1 to 4, characterized in that it is provided with means for inserting and removing it from the bone, said means being located at said proximal end (3).

6. Intramedullary nail according to one of the claims 1 to 5, characterized in that it has at least one hole (2) at each of its proximal and distal ends (3,4).

7. Nail according to one of the claims 1 to 6, in which there is one or more round or other locking apertures through the proximal part of the nail.

8. Nail according to one of the claims 1 to 7, in which there is one or more round or other locking apertures through the distal part of the nail.

9. Nail according to one of the claims 1 to 8, in which said at least one hole (2) is elongated in axial direction of the nail.

10. Intramedullary nail according to one of the claims 1 to 9, characterized in that said blade (1) has a length L in the range of 150 to 300 mm, preferably in the range of 200 to 250 mm.

11. Intramedullary nail according to one of the claims 1 to 10, characterized in that it has a flattened or elliptical cross-section extending partially or totally along the length of the nail.

12. Nail according to one of the claims 1 to 11, characterised by the fact that the biggest dimension of the flattened cross-section is 6 - 20 mm, preferably 7 - 15 mm.

13. Nail according to one of the claims 1 to 12, characterised by the fact that the smallest width W of said blade (1) is 0,3 - 5,0 mm, preferably 0,5 - 3,0 mm.

14. Nail according to one of the claims 1 to 13, characterised by the fact that it is made of sheet metal or tubing having a wall thickness of 0,2 - 3,5 mm, preferably of 0,3 - 2,0 mm.

15. Nail according to one of the claims 1 to 14, characterised by the fact that it is made of polymer having a wall thickness of 0,5 - 5,0 mm, preferably of 1,0 - 3,5 mm.

16. Nail according to one of the claims 1 to 15, in which there are two longitudinal canals through or on the sides of the cross-section. The longitudinal canals can be fully closed, or fully or partially open.

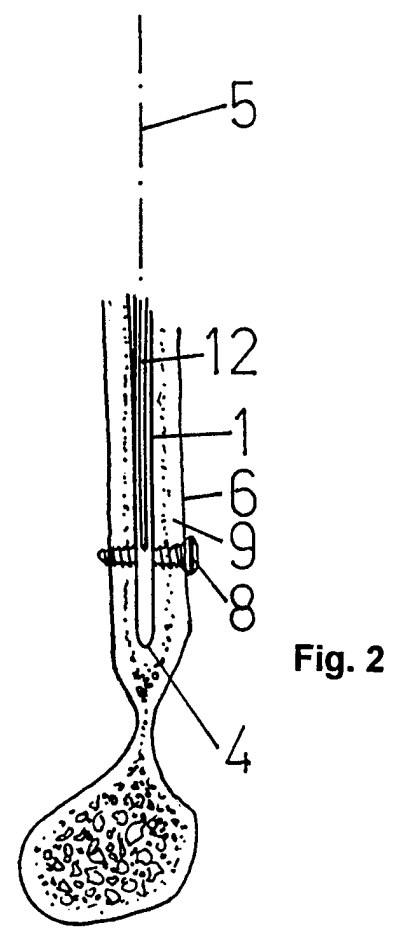
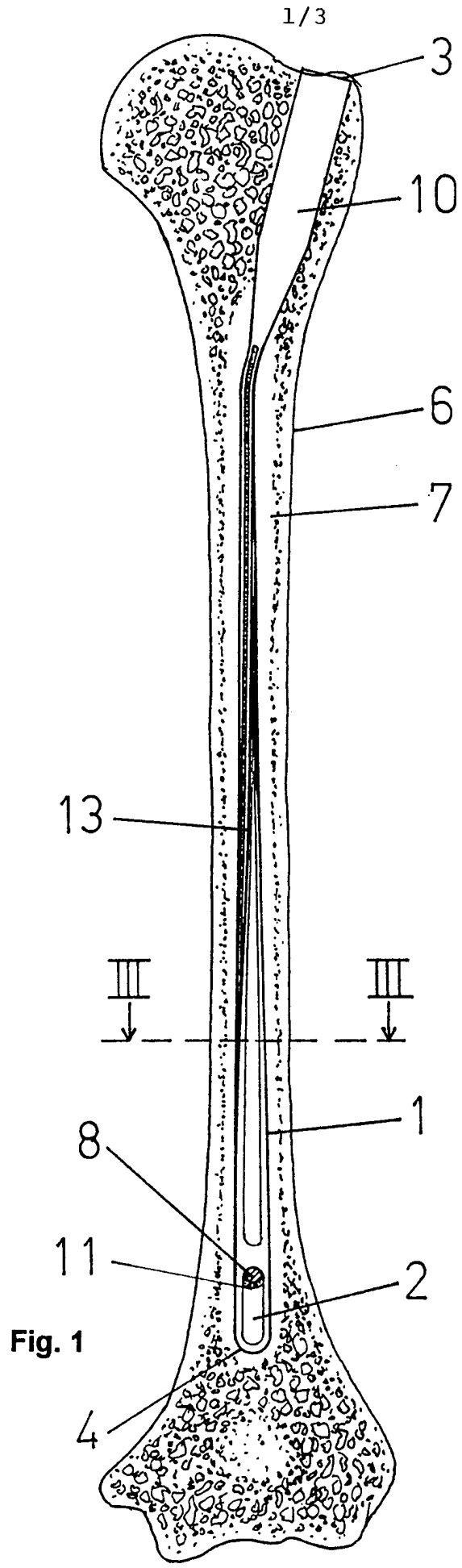
17. Nail according to one of the claims 1 to 16, characterised by the fact that the longitudinal canals have an almost circular cross-section, preferably with a diameter of 0,8-3,0 mm.

18. Nail according to one of the claims 1 to 17, characterised by the fact that a folded wire, cable or other similar longitudinal device is introduced through the longitudinal

canals, the closed loop of which exits at the tip of the intramedullary nail and is used for locking and compressing the fracture gap.

19. Nail according to one of the claims 1 to 18, in which there is a U-shaped metal part at the distal part of the nail to protect the wire or cable loop from damage or deformation during insertion.

20. A method of treating a fracture of a long bone (6) which comprises inserting an intramedullary nail having the shape of a helically twisted blade (1) and at least one hole (2) at one of its free ends (3,4) longitudinally into the medulla (7) of a long bone (6), and securing the nail to the long bone (6) in its longitudinal position by bone fixation means (8) to be inserted transversally through said hole (2) and at least one cortex of said long bone (6).



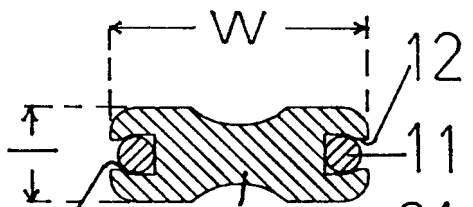


Fig. 3

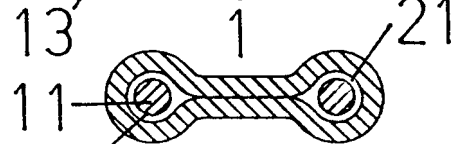


Fig. 4

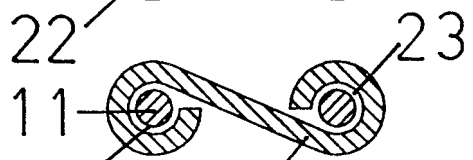


Fig. 5

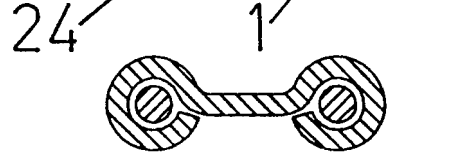


Fig. 6

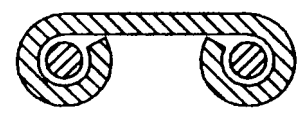


Fig. 7

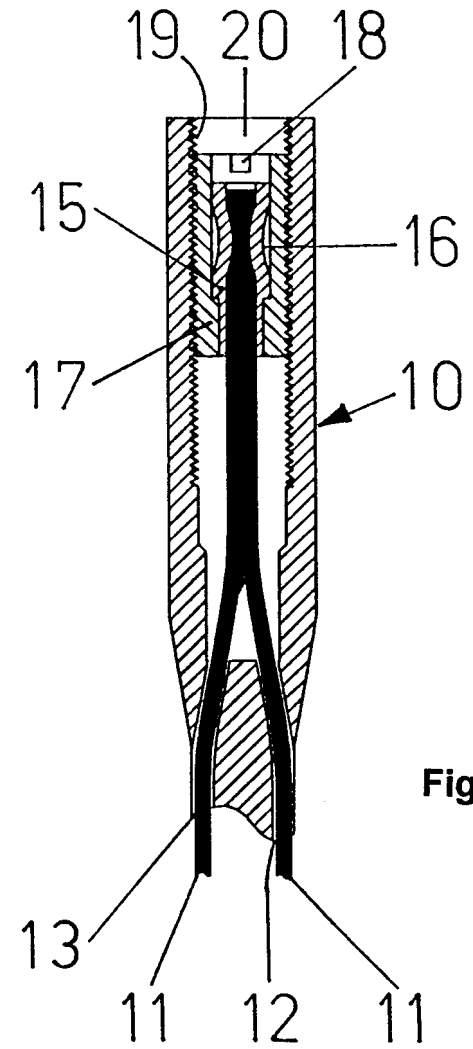


Fig. 8

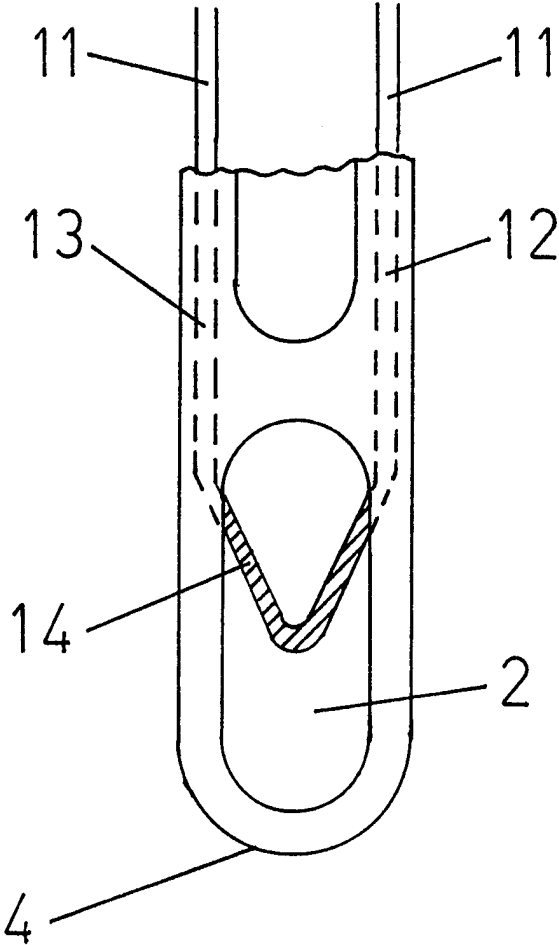


Fig. 9

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 96/05324

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	EP 0 086 552 A (HOWMEDICA) 24 August 1983	1-5,8, 10-14 15		
Y	see abstract see page 6, line 27 - line 31 see page 7, line 7 - line 11 ---	15		
X	EP 0 094 039 A (O.SCAGLIETTI) 16 November 1983 see page 2, line 15 - line 18; figures 1,2 see page 3, line 15 - line 17 see page 4, line 5 - line 8 ---	1-3,5, 9-14		
A	DE 38 35 682 A (R.LABITZKE) 26 April 1990	1,3,4, 6-8,10 15		
Y	see column 1, line 9 - line 10 see column 3, line 6 - line 12; figure 1 --- -/--	15		
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input checked="" type="checkbox"/> Further documents are listed in the continuation of box C.</td> <td style="width: 50%; border: none;"><input checked="" type="checkbox"/> Patent family members are listed in annex.</td> </tr> </table>			<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C.	<input checked="" type="checkbox"/> Patent family members are listed in annex.
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Date of the actual completion of the international search <div style="text-align: center; font-weight: bold;">1 August 1997</div>	Date of mailing of the international search report <div style="text-align: center; font-weight: bold;">11 08. 97</div>			
Name and mailing address of the ISA 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	Authorized officer <div style="text-align: center; font-weight: bold;">Nice, P</div>			

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INTERNATIONAL SEARCH REPORT

Intern. Application No
PCT/EP 96/05324

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 3 025 853 A (C.A.MASON) 20 March 1962 see claim 1; figures 1-3 ---	1-4, 10-14
A	US 5 034 012 A (R.FRIGG) 23 July 1991 cited in the application see the whole document -----	16-19

INTERNATIONAL SEARCH REPORT

International application No.

PCT/EP 96/05324

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 20
because they relate to subject matter not required to be searched by this Authority, namely:
PCT Rule 39.1 (iv) Method for treatment of the human or animal body by surgery, EPC Article 52 (4)
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No PCT/EP 96/05324
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