

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
23 March 2006 (23.03.2006)

PCT

(10) International Publication Number
WO 2006/030460 A1

(51) International Patent Classification⁷: A61B 17/17

(21) International Application Number:
PCT/IT2004/000502

(22) International Filing Date:
16 September 2004 (16.09.2004)

(25) Filing Language: English

(26) Publication Language: English

(71) Applicant (for all designated States except US): ALFA PLASTIC S.R.L. [IT/IT]; 5 Via F. Turati, I-42010 Rio Saliceto (IT).

(72) Inventors; and

(75) Inventors/Applicants (for US only): FERRARI, Luigi [IT/IT]; 37 Via Toscanini, I-41049 Sassuolo (IT). SACCHI, Edo [IT/IT]; 4/A Via San Pellegrino, I-42015 Correggio (IT).

(74) Agents: CORRADINI, Corrado et al.; 4, Via Dante Alighieri, I-42100 Reggio Emilia (IT).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,

MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

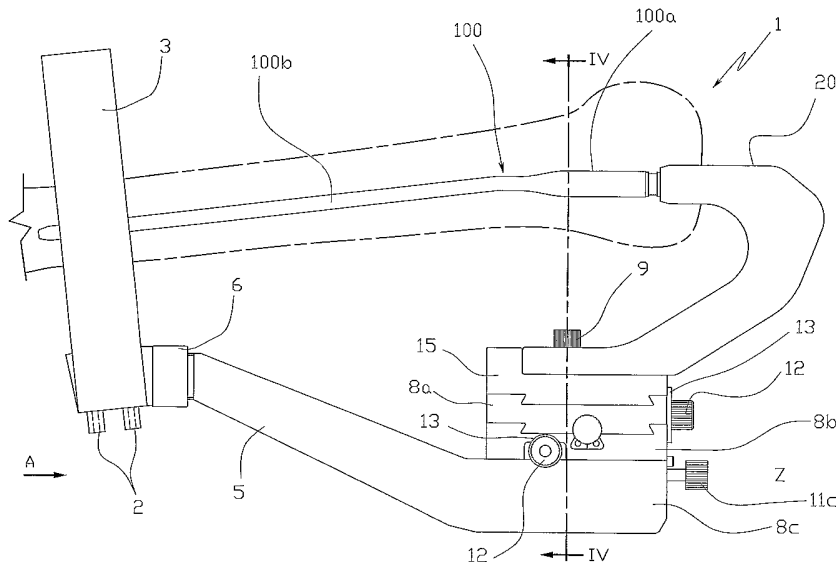
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ,

[Continued on next page]

(54) Title: ALIGNING DEVICE FOR CORRECTLY INSERTING SCREWS INTO HOLES OF ENDOMEDULLARY PROSTHESES, AND RELATIVE ALIGNMENT METHOD



(57) Abstract: An aligning device (1) for correctly inserting a screw into a respective through hole (10) of an endomedullary prostheses (100) implanted in a bone tissue, comprising support means (3) associated with said prosthesis (100) and carrying guide means (2) defining an intervention aiming line (X-X) for perforation means for said bone tissue, said guide means (2) being detectable by selective detection means, and further comprising orientation means (5, 8) for spatially orientating said support means (3), said support means (3) further carrying a target (4) with sight (4') detectable by said detection means and positioned aligned with said aiming line (X-X), said hole (10) being interposed between said guide means and said target, with its axis disposed on said aiming line (X-X).

WO 2006/030460 A1



BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— with international search report

DESCRIPTION

ALIGNING DEVICE FOR CORRECTLY INSERTING SCREWS INTO
HOLES OF ENDOMEDULLARY PROSTHESES, AND RELATIVE
ALIGNMENT METHOD

5

TECHNICAL FIELD

The present invention relates to an aligning device for correctly inserting screws into through holes provided transversely in an endomedullary prosthesis, and the relative alignment method

10

PRIOR ART

In the case of a comminuted bone fracture, a prosthesis, commonly known as a nail, has to be inserted and locked into the bone through which it passes.

15 The intramedullary nail is locked by inserting two screws percutaneously and passing them through holes provided in the proximal and/or distal end of the nail.

Inserting the screws through both ends of the nail fixes the proximal and distal fragments, preventing them from sliding along the nail.

20 This type of synthesis is defined as "static".

Alternatively the screws can be inserted through only one end of the nail, to fix only one of the larger fragments.

This type of synthesis is defined as "dynamic".

Before nailing, generally of closed roof type, pre-operative radiography
25 must be carried out on the healthy bone to determine the correct nail size, the degree of boring and the final length of the nail in seriously

comminuted fractures.

In femur fractures, the nail length must be such that its proximal end lies at the apex of the greater trochanter and its distal end between the upper pole of the patella and the distal epiphyseal cicatrix of the femur.

- 5 The intramedullary nail is inserted into the centre of the direct continuation of the medullary channel in the anteroposterior and laterolateral projections using a handle suitably associated, in a removable manner, with the proximal end of the nail.

When inserted, the nail forms an angle of 5°-10° open laterally to the
10 sagittal plane of the femur, such as to be aligned with the femoral axis.

On termination of nail insertion it is locked by inserting screws.

To enable the screws to be inserted, a cutter is generally used applied to a drill, to drill the femur by passing through the holes in the nail.

To ensure that the cutter is correctly centered on the holes present in the
15 nail, the axis on which the cutter operates and the axis of the corresponding hole in the nail must be aligned and consequently coinciding.

This correct centering can be achieved using an aligning device comprising a support associated with the nail handle and carrying a guide
20 bush within which the cutter slides as an exact fit and which is aligned with the corresponding hole before inserting the nail into the femur, recording the position so achieved.

After recording the position the aligning device is removed to allow easier nail insertion, and then is again associated with the handle by which the
25 nail is thrust.

If the nail does not undergo any bending, the alignment between the bush

and the corresponding hole is correct, as the holes have not undergone any spatial displacement from their position recorded prior to insertion. Instead, as the nail inserted into the medullary bone cavity undergoes a certain bending to comply with the natural shape of the endomedullary path and as this bending is more marked the further from the proximal end of the nail with which the insertion handle is associated, a misalignment often occurs between the bush and the corresponding hole, particularly for the distal holes.

In this respect, while the orientation and spatial disposition of the proximal holes remains substantially unchanged, so enabling centering of the proximal holes to be easily achieved as bending there is irrelevant, the spatial disposition of the distal holes can undergo a relatively substantial shift because of the albeit slight bending undergone by the nail at the distal end.

In practice, centering of the proximal holes is relatively simple to achieve because nail bending at that distance is irrelevant, whereas this is not the case with the distal holes.

Consequently, the spatial disposition of the guide bush has to be corrected to bring it into correct alignment with the corresponding hole which has shifted.

Radiography is generally used to verify perfect alignment between the hole and the corresponding bush.

This technique enables the extent of misalignment to be ascertained between the hole in the nail and the guide bush which is rigidly connected to the head of the nail by the handle.

Even though from the images it may appear that the cutter guide bush and

the corresponding hole are aligned, they are in reality often misaligned. In this respect, alignment between the guide bush of traditional aligning devices and the corresponding hole cannot be ascertained accurately by radiography or any other detection method of the known art because the
5 resultant images are not sufficiently accurate to allow detection of slight displacements from perfect alignment, with a consequent substantial error in the subsequent drilling with the cutter.

This means that on the one hand a multiplicity of radiographs have to be taken, with in the limit a continuous radiograph during drilling, in order to
10 follow the cutter path through the bone and continuously verify alignment with the corresponding hole, while on the other hand, in the case of error, drilling has to be done at several points in order to correctly "centre" the corresponding hole.

In this manner not only is the time required to achieve complete locking of
15 the nail to the bone increased, but there is the risk of further damaging the already fragile bone by the continuous attempts to centre the hole with the cutter.

There is therefore a strongly felt requirement for an aligning device for correctly inserting screws into the holes of a prosthesis which enables the
20 detection means, such as radiographic means, to determine exactly and without error when perfect hole centering has been achieved, so preventing further damage to the bone concerned and/or lengthening of the time required to completely lock the nail.

DISCLOSURE OF THE INVENTION

An object of the present invention is to provide an aligning device for correctly inserting screws into the holes of an endomedullary prosthesis having structural and functional characteristics such as to satisfy the
5 aforesaid requirements while at the same time obviating the stated drawbacks of the known art.

A further object is to provide a method for the relative alignment.

These objects are attained by an aligning device for correctly inserting screws into the holes of a prosthesis in accordance with claim 1 and by a
10 method in accordance with claim 11.

The dependent claims define preferred and particularly advantageous embodiments of the device and relative method of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

15 Further characteristics and advantages of the invention will be apparent on reading the ensuing description given by way of non-limiting example with reference to the figures of the accompanying drawings, in which:

Figure 1 is a side view of an aligning device in accordance with the present invention;

20 Figure 2 is a view in the direction of the arrow A of Figure 1;

Figure 3 is the section on the broken line III-III of Figure 2;

Figure 4 is the section on the line IV-IV of Figure 1.

BEST MODE FOR CARRYING OUT THE INVENTION

25 With reference to said figures, the reference numeral 1 indicates overall an aligning device of the present invention for inserting a screw into a

respective through hole 10 of a prosthesis 100, generally known as an intramedullary nail, inserted into a bone tissue.

Explicit reference will be made hereinafter to a femoral prosthesis and to the insertion of screws through two so-called distal holes, but without
5 being limited to this application.

Said device 1 comprises essentially (Figure 2) support means 3 associated with said nail 100 and carrying respectively guide means 2 to define an aiming intervention line X-X for bone perforation means and a
10 target 4 with sight 4' aligned with said aiming line and intended to be positioned facing the hole 10 on the opposite side to that on which the guide means 2 are disposed during bone perforation, together with orientation means 5, 8 for spatially orientating said support means 3.

According to the preferred embodiment of the present invention, the support means 3 are in the form of an arcuate element to which at its first
15 end 3a the guide means 2 and at its second end 3b the target 4 are fixed. In the illustrated example, said guide means 2 are in the form of a pair of bushes 2a extending along two parallel aiming lines X-X.

Although reference is made to a pair of bushes 2a, a single bush or more than two bushes can be used.

20 In the illustrated example, the arcuate element 3 is fixed at its first end 3a to a bracket 5 by screwing a locking nut 6 able to prevent sliding and rotation of the arcuate element 3 and consequently of the bushes 2a and of the target 4.

The bracket 5 is fixed at its opposite end to the proximal end of the nail
25 100.

According to the invention, the target 4 comprises two punctiform sights 4',

each positioned such as to be always aligned with the respective aiming line X-X of the pair of bushes 2a, i.e. with the direction in which the perforation means travel.

Essentially, each bush 2a is always correctly aligned with the
5 corresponding sight 4' even following any spatial movements of the arcuate element 3.

The perforation means, such as a cutter, this latter applied to a drill in known manner, can slide within the bushes 2a to reach and traverse the distal holes 10.

10 In order to perforate with greater precision along an unequivocal direction, further cylindrical guides 7 can be inserted coaxially into the bushes 2a to abut against the femoral bone tissue after incising the thigh, they being shaped to receive the drilling cutters as an exact fit.

During normal use, the arcuate element 3 is positioned about the thigh
15 with the bushes 2a disposed on one side of the holes 10 and the corresponding sights 4' on the opposite side.

Essentially, the holes 10 lie interposed between the bushes 2a and the target sights 4'.

To achieve correct centering of the distal holes 10 of the intramedullary
20 nail 100, the bracket 5 to which the arcuate element 3 is fixed can be orientated relative to the proximal end of the nail 100 by suitable adjustment means 8, preferably able to transmit millimetric movements. Said adjustment means 8 are interposed between the bracket 5 and the end of a U-shaped handle 20 carrying the intramedullary nail 100
25 associated with its remaining end and prevented from rotating by usual means.

Generally, the nail 100 presents (Figure 3) a first proximal portion 100a associated with the handle 20 and of greater diameter than the prevalent remaining part 100b which presents a 5° - 10° deviation from the first portion 100a to follow the shape of the femoral bone.

5 In the illustrated example, the adjustment means 8 are in the form of three movable elements, an upper 8a, an intermediate 8b and a lower 8c, connected movably together to form a single adjustment block.

The adjustment block is connected by a fixed element 15 to the handle 20, to which it is fixed by a fixing screw 9 with the aid of two centering
10 dowels 14.

The adjustment means 8 enable the bracket 5, and hence its associated arcuate element 3 carrying the bush 2a and the target 4, to be moved spatially.

The movement is adjusted by the micrometric adjustment screws 11a,
15 11b, 11c which enable the bracket 5 to rotate about a rotation axis Y-Y extending in the example substantially parallel to the axis of the proximal portion 100a of the nail 100 and, respectively, to slide along two mutually perpendicular axes, one of which is parallel to the rotation axis Y-Y.

To prevent any undesirable movement of the bracket 5 after attaining
20 correct alignment between the bushes 2a and holes 10, two locking screws 12 with respective washers 13 are used, suitably located on the adjustment block.

By selective tightening or slackening, said locking screws 12 enable the desired movements to be adjusted, in accordance with the known art.

25 In operation, having chosen the nail 100 of appropriate length, it is inserted into alignment with the femoral axis in accordance with the known

art.

After its insertion with the aid of the handle 20, the stage of locking the nail 100 by inserting screws through the proximal and distal holes 10 begins. In this latter case, as stated, hole centering is far more difficult to achieve, hence only the insertion of the screws through the distal holes 10 will be described.

The aligning device 1 of the present invention is fixed to the handle 20 by the fixing screw 9 with the adjustment means 8 interposed, while the arcuate element 3 is positioned about the thigh with the holes 10 of the nail 100 interposed between the target 4 and the bushes 2a.

In practice the aligning device 1 is fixed to the handle 10 before inserting the nail 100, the arcuate element 3 being positioned such that the axes of the nail holes 10 are perfectly aligned and hence coinciding with the aiming lines X-X of the corresponding bushes 2a, the position thus obtained being recorded.

When the nail 100 is to be inserted into the femur and the device 1 again fixed to the handle 20 with the arcuate element 3 embracing the thigh, the bushes 2a will already have an orientation close enough to enable perfect centering between the holes 10 and the cutter.

A radiographic examination enables perfect alignment to be determined between the centres of the bushes 2a through which the aiming lines X-X pass coinciding with the axes thereof and the centre of the holes 10, by virtue of the presence of the sights 4' which constructively lie on the corresponding aiming lines X-X.

In this respect, by using materials which show under radiation, such as metals, for constructing the bushes 2a and the target 4 with the sights 4',

and considering that the nail 100 shows under radiation, when perfect centering has been achieved the radiography plate will show for each hole 10 a first circle of the bush 2a, a second circle of the hole 10, these being concentric, and a point indicating the sight 4' of the target 4 lying perfectly
5 at the centre of the first two circles.

In contrast, if perfect centering of the holes 10 has not been achieved, at least the point indicating the sight 4' of the target 4 will be off-centre to indicate misalignment between the axis of the hole 10 and the aiming line X-X corresponding to the drilling direction.

10 To obtain easily readable images the arcuate element 3 should be constructed of a material which does not show under X-rays.

Alternatively, other systems could be used to display correct positioning such as a brightness amplifier.

The target shape is chosen such as to clearly indicate one or more
15 unequivocal points which become positioned perfectly at the centre of the circles visible on the plates when perfect centering has been achieved.

As will be apparent from the description, the aligning device and the alignment method of the present invention satisfy the requirements and overcome the drawbacks stated in the introduction to the present
20 description with reference to the known art.

In this respect said device enables the holes provided in an endomedullary prosthesis to be perfectly centered at the first attempt, so avoiding compromising the bone structure surrounding the holes.

Numerous modifications and variants can be devised by an expert of the
25 art to satisfy specific contingent requirements, all lying within the scope of protection of the invention as defined by the following claims.

CLAIMS

1. An aligning device (1) for correctly inserting a screw into a respective through hole (10) of an endomedullary prosthesis (100) implanted in a bone tissue, comprising support means (3) associated with said prosthesis (100) and carrying guide means (2) defining an intervention aiming line (X-X) for perforation means for said bone tissue, said guide means (2) being detectable by selective detection means, and further comprising orientation means (5, 8) for spatially orientating said support means (3), characterised in that said support means (3) further carry a target (4) with sight (4') detectable by said detection means and positioned aligned with said aiming line (X-X), said hole (10) being interposed between said guide means and said target, with its axis disposed on said aiming line (X-X).
2. A device (1) as claimed in claim 1, wherein said support means (3) are associated with said prosthesis (100) by way of said orientation means (8).
3. A device (1) as claimed in claim 1, wherein said guide means (2) comprise at least one guide bush (2a) for slidably containing perforation means.
4. A device (1) as claimed in claim 3, wherein said support means (3) comprise an arcuate element (3), to a first end (3a) of which said guide means (2) are rigidly fixed, and to the free second end (3b) of which said target (4) is rigidly fixed.
5. A device (1) as claimed in claim 4, wherein said orientation means comprise a movable bracket (5) and adjustment means (8) to orientate it spatially relative to the prosthesis.
6. A device (1) as claimed in claim 5, wherein said arcuate element (3)

is associated with an end of said movable bracket (5).

7. A device (1) as claimed in claim 5, wherein said adjustment means (8) enable said bracket (5) to rotate about a rotation axis (Y-Y) and to translate along two mutually perpendicular directions (Y-Y, Z-Z).

5 8. A device (1) as claimed in claim 5, wherein said adjustment means (8) comprise mutually cooperating movable elements (8a, 8b, 8c) operated by adjustment screws (11a, 11b, 11c).

9. A device (1) as claimed in claim 1, wherein said support means (3) are insensitive to said detection means.

10 10. A device (1) as claimed in claim 1, wherein said bone tissue is a femur and said through hole (10) is a distal hole.

11. An alignment method for correctly inserting a screw into a respective through hole (100) of an endomedullary prosthesis (100) implanted into a bone tissue, comprising the following steps:

- 15 - providing support means (3) carrying guide means (2) defining an intervention aiming line (X-X) for perforation means for said bone tissue and, respectively, a target (4) with sight (4') aligned with said aiming line (X-X);
- associating said support means (3) with the prosthesis (100), and
- 20 aligning said guide means (2) with the hole (10);
- separating said support means (3) from the prosthesis (100) and inserting this latter into said bone tissue;
- again associating said support means (3) with the prosthesis (100);
- spatially orientating said support means (2) such as to align said hole
- 25 (10), interposed between said guide means (2) and said target (4), with said aiming line (X-X),

said guide means (2) and said target (4) being detectable by selective detection means.

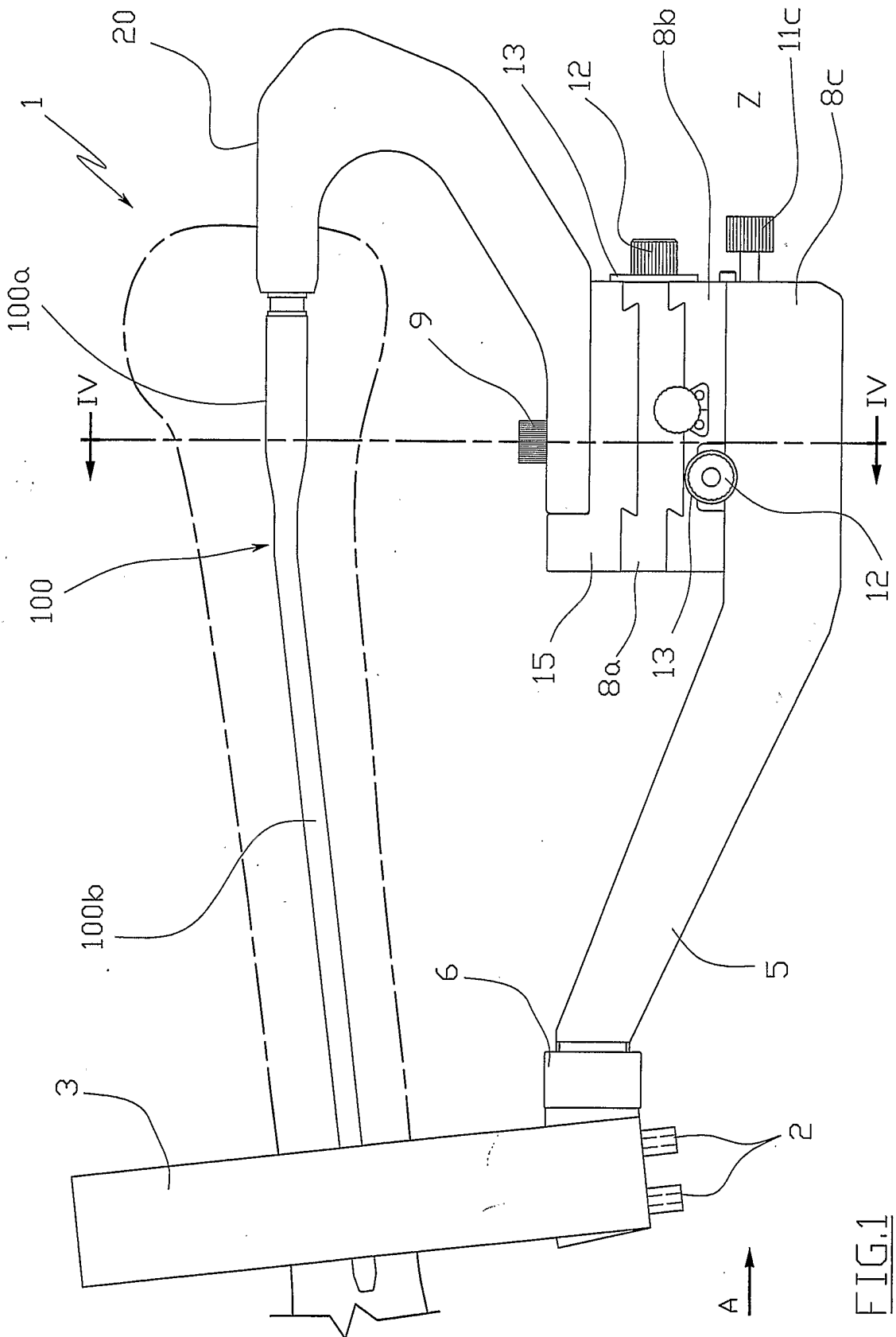


FIG.1

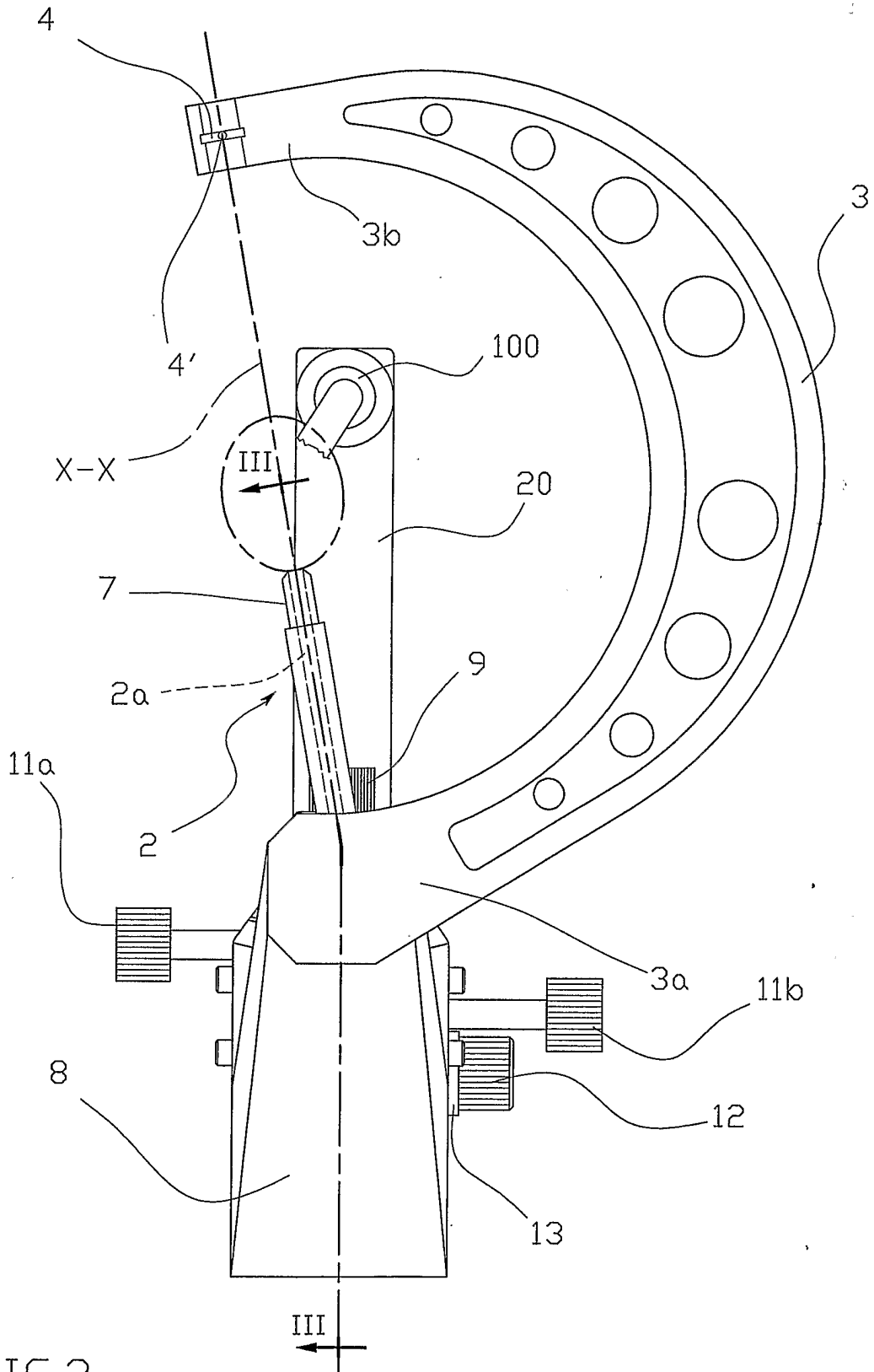


FIG. 2

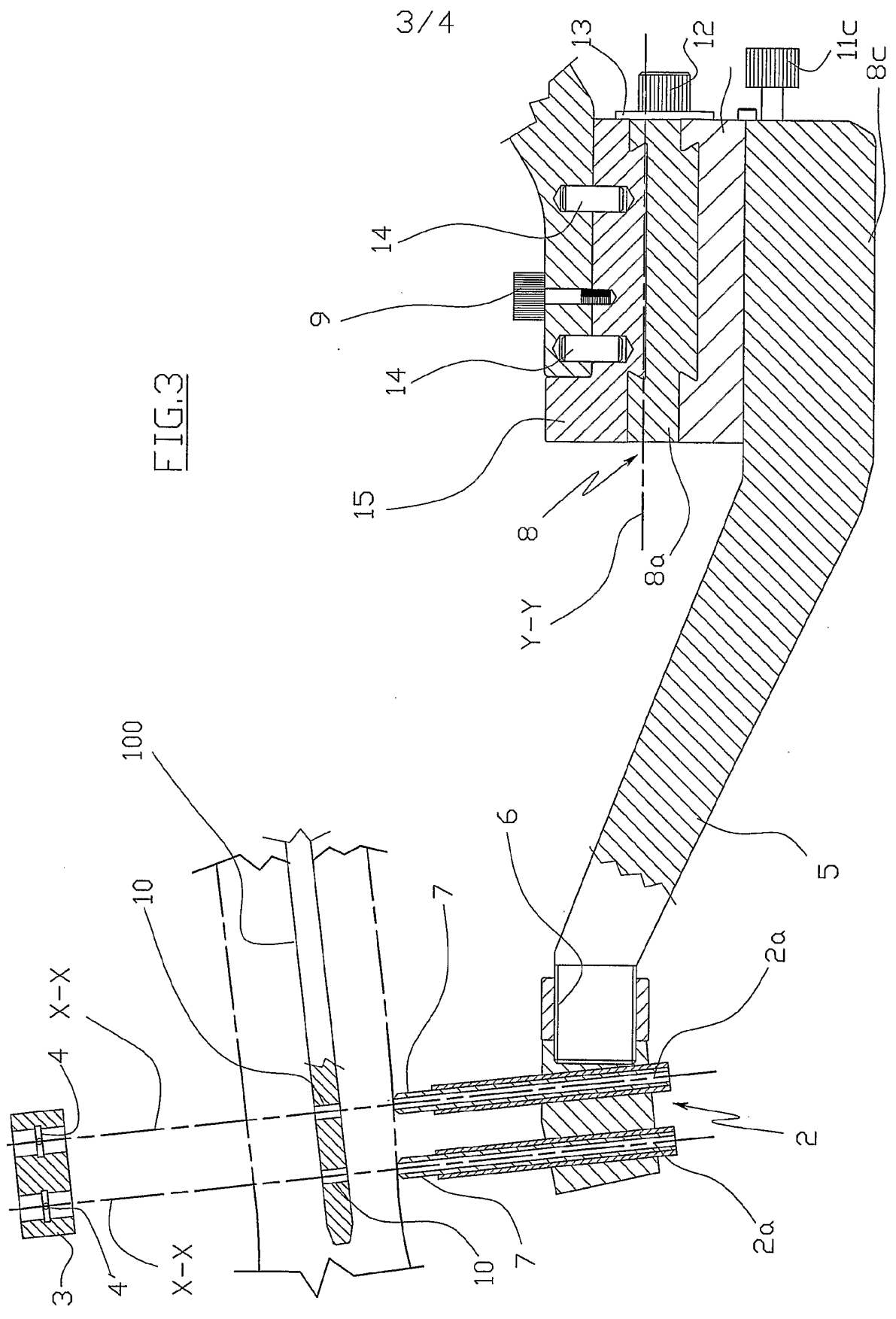


FIG. 3

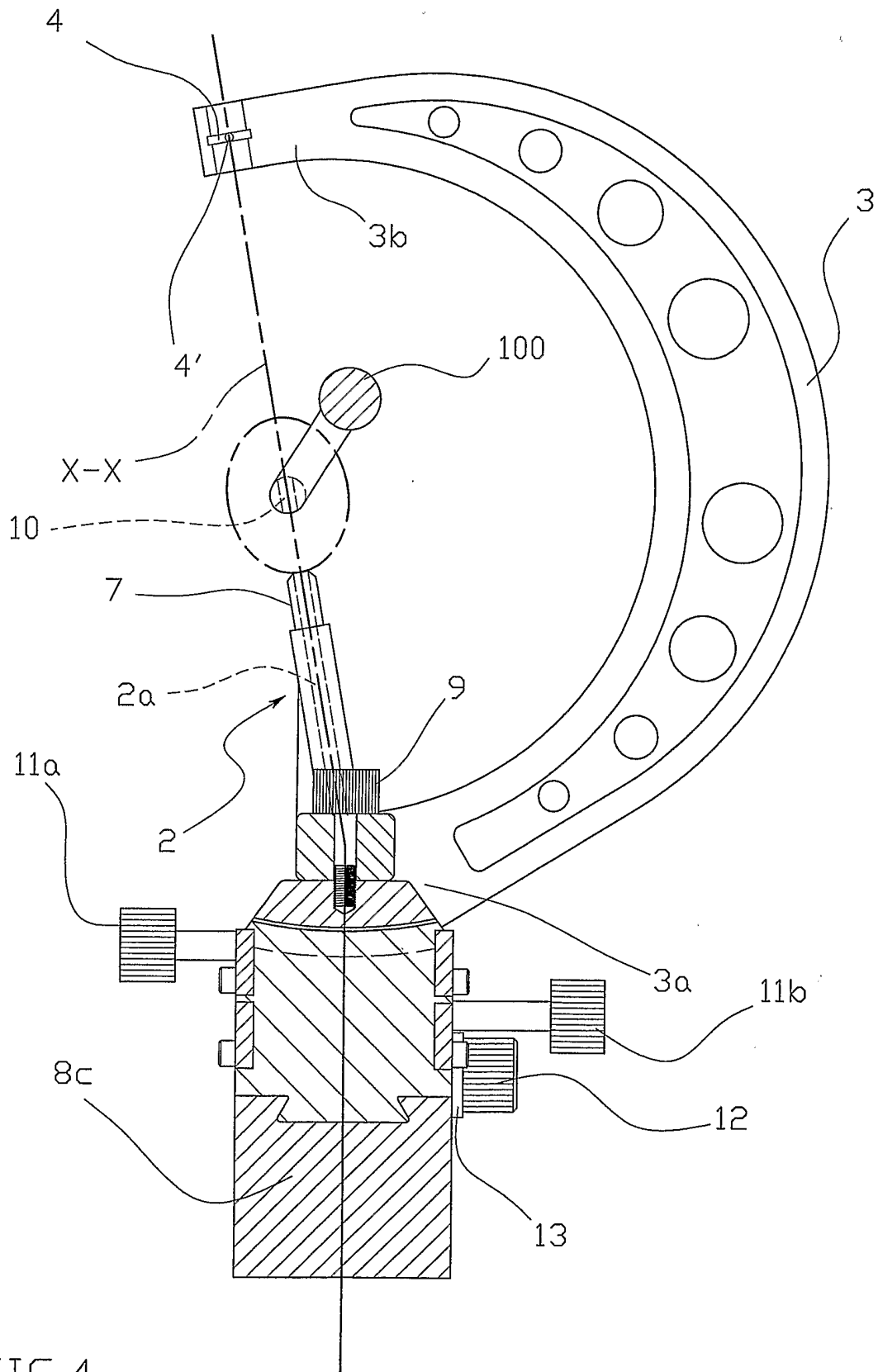


FIG. 4

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IT2004/000502

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/17

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 7 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)

EPO-Internal, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 214 013 B1 (LAMBRECHT GREG ET AL) 10 April 2001 (2001-04-10) column 8, line 15 - line 37 figures 5a,5b	1-10
A	US 4 803 976 A (FRIGG ET AL) 14 February 1989 (1989-02-14) abstract	
A	EP 0 465 436 A (G. CREMASCOLI S.R.L.) 8 January 1992 (1992-01-08) column 3, line 41 - column 4, line 3 figures	

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° 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 when the document is taken alone
- *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

Date of the actual completion of the international search

17 February 2005

Date of mailing of the international search report

28/02/2005

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

Storer, J

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IT2004/000502

Box II Observations where certain claims were found unsearchable (Continuation of item 2 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.: 11
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
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 III Observations where unity of invention is lacking (Continuation of item 3 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/IT2004/000502

Patent document cited in search report	Publication date	Publication date	Patent family member(s)	Publication date
US 6214013	B1	10-04-2001	US 6036696 A	14-03-2000
			US 2002133172 A1	19-09-2002
			EP 0923906 A2	23-06-1999
			JP 3280631 B2	13-05-2002
			JP 11244300 A	14-09-1999
US 4803976	A	14-02-1989	CH 671873 A5	13-10-1989
			BR 8601918 A	30-12-1986
			CA 1271998 A1	24-07-1990
			EP 0201737 A2	20-11-1986
EP 0465436	A	08-01-1992	IT 1250907 B	21-04-1995
			EP 0465436 A1	08-01-1992