(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
13 October 2005 (13.10.2005)

PCT

(10) International Publication Number
WO 2005/094705 A2

(51) International Patent Classification[7]: A61B 17/72

(21) International Application Number:
PCT/EP2005/003392

(22) International Filing Date: 31 March 2005 (31.03.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

04007787.7	31 March 2004 (31.03.2004)	EP
04007785.1	31 March 2004 (31.03.2004)	EP
04007788.5	31 March 2004 (31.03.2004)	EP
04007789.3	31 March 2004 (31.03.2004)	EP
04007790.1	31 March 2004 (31.03.2004)	EP

(71) Applicant *(for all designated States except US)*: **ORTHOFIX INTERNATIONAL B.V.** [NL/NL]; Johannes Vermeerplein 11, NL-1071 Amsterdam (NL).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **COATI, Michele** [IT/IT]; Via A. Vivaldi, 2, I-37029 San Pietro in Cariano (IT). **MARAZZI, Giancarlo** [IT/IT]; Via Strà Favia 1/A, I-21047 Saronno (IT). **MARINI, Graziano** [IT/IT]; Via IV Novembre, 74/A, I-37060 Castel D'Azzano (IT). **ROSSI, Graziano** [IT/IT]; Via L. de Besi, 22, I-37139 Verona (IT). **ROSSI, Luigi** [IT/IT]; Via Forte Laghetto, 8, I-37019 Peschiera del Garda (IT). **VENTURINI, Daniele** [IT/IT]; Via dei Carpini, 36, I-37064 Povegliano Veronese (IT).

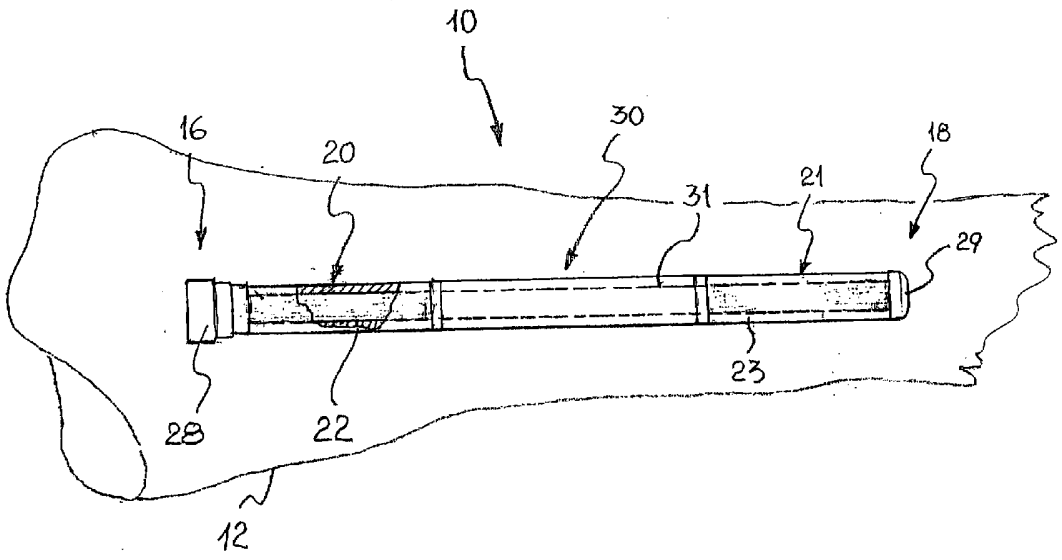
(74) Agents: **BOTTI, Mario** et al.; Botti & Ferrari S.r.l., Via Locatelli, 5, I-20124 Milano (IT).

(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, SM, 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, IS, IT, LT, 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).

[Continued on next page]

(54) Title: INTRAMEDULLARY NAIL PROVIDED WITH EXPANSION FIXING MEANS OPERATED BY ONE OR MORE DRIVING ELEMENTS



(57) Abstract: An intramedullary nail (10) suitable for insertion in a fractured elongate bone (12) and for an unusually simple fixation therein comprises a substantially straight stem (14, 114, 214, 314) extending between a proximal end (16, 116, 216, 316) and a distal end (18, 118, 218, 318), one of said ends (16, 18; 116, 118; 216, 218; 316, 318) comprising expansion means (20, 120, 220, 320) for the nail fixation to the bone, said expansion elements (20, 120, 220, 320) comprising at least an element (20a, 120a, 220a, 320a) realised with a shape-memory material.

WO 2005/094705 A2

Published:

— *without international search report and to be republished upon receipt of that report*

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.

Title: "Intramedullary nail provided with expansion fixing means operated by one or more driving elements"

DESCRIPTION

FIELD OF APPLICATION

The present invention relates in its more general aspect to an intramedullary nail suitable for insertion in a fractured elongate bone and an application method of said nail in said bone.

In particular, the invention relates to an intramedullary nail suitable for insertion in a fractured elongate bone, such as a femur or a tibia, comprising a substantially straight stem extending between a proximal end and a distal end.

PRIOR ART

Intramedullary nails are known, which, during a surgical operation, are inserted in a fractured elongate bone and fixed therein, in order to reconstruct the original bone shape and in the meantime to recover the bone solidity, so that callus regeneration mechanisms can correctly occur.

The stems of these intramedullary nails are generally substantially cylinder-shaped and they can be both solid and hollow.

In order to fix the intramedullary nail to the bone portions to be reconstructed, two or more offset holes are usually provided on the nail, having axes lying on parallel or crossing planes and extending diametrically across the stem, in correspondence with the nail distal end, and two or more similar offset holes, having axes not necessarily lying on parallel planes, in correspondence with the nail proximal end. Said holes are suitable for housing bone screws, which are inserted, after a convenient bone drilling, in the bone, with the subsequent fixation of the intramedullary nail to the bone portions.

Although advantageous under different points of view, intramedullary nails being structured as above schematically described have known drawbacks mainly occurring when bone drillings are to be performed for

bone screw insertion. This step is particularly critical since it is known that a good nail fastening essentially depends on the correct realisation of these bone drillings, obviously made in correspondence with the holes of the inserted intramedullary nail.

However the precise location of the intramedullary nail holes is made difficult by the fact that the holes are no more visible, being the nail inserted in the bone. It is then worth underlining a further location problem, i.e the fact that the intramedullary nail can be, when being inserted, slightly bent, so that the holes at the nail distal end are no more, with respect to the proximal end, in the same position as before installing the nail.

The traditional technique for locating the holes of an inserted intramedullary nail provides the use of X rays, involving however the well known risks of cumulative exposure of the operating staff, besides being quite awkward during the surgical operation.

Specific mechanical devices have thus been studied and realised, such as for example the one described in the European patent no. EP 772 420 in the name of the same Applicant.

These devices do not require the use of X rays, but they have the drawback of requiring several operational steps, all to be performed quite carefully and precisely.

An intramedullary nail being fixed without using bone screws is also known from the international patent application no. WO 0134045,

The fixation is performed through a radial expansion of two nail portions, positioned near the distal and proximal end of the nail stem. In other words, at least one of said ends comprises expansion means for the nail fixation to the bone.

These portions are sleeves provided with longitudinal slots: the sleeve radial expansion is performed by applying an axial compression mechanical action to the ends of said sleeves. The compression is performed through an axial movement of a further stiff sleeve, which is moved by screwing it by hand on the stem.

Although advantageous under different points of view with respect to the above-mentioned prior art, the intramedullary nail structured as schematically above described has well-known drawbacks.

First, rotations of the nail in the bone can actually occur, since only the friction of the expansion portions against the bone causes the nail fixation.

Moreover, as a result of the expansion step of the two nail portions, with the subsequent shortening thereof in the axial direction, an undesired shortening of the bone whereon operation occurs is obtained, since the two sleeves equipped with slots are approaching to each other.

Still further, in the case of bone lyses in the contact area between the expanded sleeves and the bone, the nail fixation becomes insecure and it is necessary to operate from the outside to recover, as much as possible, a proper pressure in this contact area.

SUMMARY OF THE INVENTION

The problem underlying the present invention is to provide an intramedullary nail suitable for insertion in a fractured elongate bone, capable to meet the above-mentioned requirement, meanwhile overcoming, in a simple and effective way, all the drawbacks mentioned with reference to the prior art.

This problem is solved, according to the present invention, by an intramedullary nail suitable for insertion in a fractured elongate bone, as above described as defined in the independent claims.

Further features and the advantages of the intramedullary nail suitable for insertion in a fractured elongate bone, as well as of the application method of said nail in said bone, according to the present invention, will be apparent from the following description of some embodiments thereof made with reference to the attached drawings, given by way of non-limiting example.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic perspective view of a first embodiment of an

intramedullary nail, suitable for insertion in a fractured elongate bone, according to the present invention.

Figure 2 is a schematic perspective view of a second embodiment of an intramedullary nail, suitable for insertion in a fractured elongate bone, according to the present invention.

Figure 3 is a schematic enlarged-scale perspective view of a portion of the nail of figure 2.

Figure 4 is a schematic perspective view of a third embodiment of an intramedullary nail, suitable for insertion in a fractured elongate bone, according to the present invention.

Figure 5 is a schematic enlarged-scale perspective view of a portion of the nail of figure 4.

Figure 6 is a schematic enlarged-scale perspective view of a further portion of the nail of figure 4.

Figure 7 is a schematic enlarged-scale perspective view of a component of the nail of figure 4.

Figure 8 is a schematic perspective view of an alternative embodiment of a portion of an intramedullary nail according to the present invention.

Figure 9 is a schematic perspective view of a further alternative embodiment of the nail portion of figure 8.

Figure 10 is a schematic plan view of an alternative embodiment of the nail portion of figure 8.

Figure 11 schematically shows a side-elevation cross-section of the nail of figure 10, taken according to the traced V-V plane.

Figure 12 is a further schematic enlarged perspective view of a further embodiment of the nail portion of figure 8.

Figure 13 is a schematic perspective view of the entire nail of figure 12.

Figure 14 is a schematic perspective view of an intramedullary nail

suitable for insertion in a fractured elongate bone, according to the present invention.

Figure 15 is a schematic front-elevation view of the nail of figure 14.

Figure 16 is a schematic front-elevation view of a first alternative embodiment of the nail of figure 15.

Figure 17 is a schematic perspective view of a alternative embodiment of an intramedullary nail according to the present invention.

Figure 18 is a schematic front-elevation view of the nail of figure 17.

Figure 19 is a schematic front-elevation view of a further alternative embodiment of an intramedullary nail according to the present invention.

Figure 20 is a schematic perspective view of a further alternative embodiment of an intramedullary nail according to the present invention.

Figure 21 is a schematic perspective view of a further alternative embodiment of an intramedullary nail according to the present invention.

Figure 22 is a schematic perspective view of a further alternative embodiment of an intramedullary nail according to the present invention.

Figure 23 is a schematic perspective view of the intramedullary nail of figure 22, in a different configuration.

Figure 24 is a schematic perspective view of a further alternative embodiment of an intramedullary nail according to the present invention.

Figure 25 is a schematic perspective view of an intramedullary nail, suitable for insertion in a fractured elongate bone, according to the present invention.

Figure 26 is a schematic perspective exploded view of the nail of figure 25.

Figure 27 is a schematic perspective view of an alternative embodiment of an intramedullary nail according to the present invention.

Figure 28 is a schematic perspective exploded view of an portion of an intramedullary nail, suitable for insertion in a fractured elongate bone,

according to the present invention.

Figure 29 is a schematic side-elevation view of the nail of figure 28, in a different configuration.

Figure 30 is a schematic plan view from above of the nail of figure 29.

Figure 31 schematically shows a detail of the nail of figure 28.

Figure 32 schematically shows a detail of the nail of figure 29.

Figure 33 is a schematic plan view from above of an alternative embodiment of a nail according to the present invention.

Figure 34 schematically shows a cross-section of the nail of figure 33, taken according to the traced VII-VII plane of figure 33.

Figure 35 is a schematic plan view from above of the nail of figure 33, in a different configuration.

Figure 36 schematically shows a cross-section of the nail of figure 35, taken according to the traced IX-IX plane of figure 35.

Figure 37 is a schematic perspective view of a portion of an alternative embodiment of the intramedullary nail according to the present invention.

Figure 38 is a schematic perspective view of an alternative embodiment of an intramedullary nail according to the present invention.

Figure 39 is a schematic perspective view of the intramedullary nail of figure 38, in a different configuration.

Detailed description

Referring first to figure 1, an intramedullary nail according to the present invention is shown and globally indicated with 10, suitable for insertion in a fractured elongate bone 12, such as for example a femur or a tibia.

The nail 10 comprises a substantially straight stem 14 extending between a proximal end 16 and a distal end 18.

The stem 14 is preferably composed of a cylindrical tube, realised for

example with a titanium alloy. The stem 14, according to an aspect of the present invention, comprises, near said proximal 16 and distal 18 ends, expansion means 20 and 21 respectively for the fixation of the nail 10 to the bone 12, said expansion means 20 and 21 being operated by at least one driving element 30, interposed between said expansion means 20 of said proximal end 16 and said expansion means 21 of said distal end 18 and realised with a shape-memory material.

Shape memory material means a material having a given initial starting shape and taking, under predetermined external conditions (for example a temperature rise and/or drop) or undergoing a predetermined activation condition, i.e. after a so-called "material instruction" step, a given new shape.

Known shape-memory material, which are suitable for use in the present invention, are, for instance, certain nickel-titanium alloys.

The invention is based on the following principle: subjecting an element realised in a shape memory material, having a predetermined initial shape at rest, to said so-called "material instruction" step (for example to a predetermined temperature variation), said element takes a shape being maintained as long as the "instruction" step effect persists; said shape, being different from the initial shape, can be called transient shape and it is temporary or unstable. When the "instruction" step effect stops, the element leaves said transient shape and, coming back towards the initial shape, takes a working shape. Depending on the type of material and on the working temperature, in the working shape, said material can arrive at the initial shape or it can go further on the initial shape, arriving at a final shape. It is worth pointing out that the more this final shape is far from the initial shape, the more the available shape memory energy of the material is high.

The invention has been reached as result of the intuition that an element realised in a shape memory material, in the passage from the transient shape towards the working shape, can create the fixing of the intramedullary nail in the bone.

Expansion means 20 of the proximal end 16 comprise a cylindrical sleeve 22 which is worn around the stem 14. The cylindrical sleeve 22,

undergone an axial compression, buckles taking a cask configuration, outside the stem 14, even taking an almost spherical configuration.

Expansion means 21 of the distal end 18 comprise a cylindrical sleeve 23 which is worn around the stem 14. Also the cylindrical sleeve 23, undergone an axial compression, buckles taking a cask configuration, outside the stem 14, even taking an almost spherical configuration.

Said at least one driving element 30 is interposed between the cylindrical sleeve 22 and the cylindrical sleeve 23. The driving element 30 comprises an intermediate cylindrical sleeve 31, worn around the stem 14, with a radial dimension being substantially equal to the radial dimension of the two sleeves 22 and 23 and realised with a shape-memory material: in the final shape, causing the fixation of the nail 10 to the bone 12, said intermediate cylindrical sleeve 31 undergoes an extension.

The stem 14 has at the distal end 18 or at the proximal end 16 an thickening 28, a front end of the cylindrical sleeve 23 or a front end of the cylindrical sleeve 22 respectively abutting on a surface thereof. The intermediate cylindrical sleeve 31 and the cylindrical sleeve 22 (or the cylindrical sleeve 23 respectively) are then mounted on the stem 14, said two cylindrical sleeves 22 and 23 abutting on the two front ends of the intermediate cylindrical sleeve 31.

The stem 14 has, in correspondence with the proximal end 16 or the distal end 18 respectively, a thread wherein a retaining ring 29 of the series of the first 22, second 23 and intermediate cylindrical sleeve 31 is screwed. Preferably, the ring 29, which is realised for example with a titanium alloy, is screwed on the stem 14 up to exert a slight pressure on the series of the sleeves 22, 23 and 31, i.e. said sleeves 22, 23 and 31 are positioned with an axial preload.

In order to screw the ring 29, two or more side flats (preferably parallel at a calibrated distance) are provided thereon for using a suitable control spanner.

At the top of the stem 14, on the side wherein the ring 29 is mounted, for example an hexagon-shaped profile is advantageously obtained, to fasten the stem 14 (with respect to the ring 29) by means of a spanner for socket

hexagonal head.

The intermediate cylindrical sleeve 31 undergoes an instruction step causing it, in the final shape, to axially extend: this deformation causes on the first sleeve 21 and on the second sleeve 23 said axial compression buckling the first 22 and second 23 sleeve as above described.

In an alternative embodiment, the intermediate cylindrical sleeve 31 is realised with a titanium alloy, while the driving element 30 is composed of the stem 14, which is realised with a shape-memory material: in the final shape, causing the fixation of the nail 10 to the bone 12, said stem 14 undergoes a shortening. In other words, the stem 14 undergoes an instruction step causing it, in the final shape, to axially shorten: this deformation causes on the first sleeve 22 and on the second sleeve 23 said axial compression buckling the first 22 and second 23 sleeve as above described.

According to a further alternative embodiment of the invention, the two cylindrical sleeves 22 and 23 are realised with a shape-memory material: said cylindrical sleeves 22 and 23 undergo an instruction step causing them, in the final shape, to take a cask configuration, outside the stem 14, even taking an almost spherical configuration.

Therefore, in this alternative embodiment, both expansion means 20 and 21, and the intermediate cylindrical sleeve 31 are realised with shape-memory materials. The intermediate cylindrical sleeve 31 undergoes an instruction step causing it, in the final shape, to axially extend: this deformation causes on the first sleeve 22 and on the second sleeve 23 a compression load tending to further increase the deformation of the first 22 and second sleeve 23.

Referring now to figures 2 and 3, a second embodiment of intramedullary nail is shown, according to the present invention, and globally indicated with 110, suitable for insertion in a fractured elongate bone 112. In this embodiment, the elements being structurally or functionally similar to the elements of the intramedullary nail 10 are indicated with the same reference number increased by 100 and the detailed description thereof is not repeated hereafter.

The nail 110 comprises a substantially straight stem 114 extending between a proximal end 116 and a distal end 118.

The stem 114 is preferably composed of a cylindrical tube, realised for example with a titanium alloy. The stem 114, according to an aspect of the present invention, comprises, near each of said proximal 116 and distal 118 ends, expansion means 120 and 121 respectively for the fixation of the nail 110 to the bone 112, said expansion means 120 and 121 being operated by at least one driving element 130, interposed between said expansion means 120 of said proximal end 116 and said expansion means 121 of said distal end 118 and realised with a shape-memory material.

Expansion means 120 and 121 of the proximal 116 and distal ends are of a same type; they comprise a plurality of inserts 122 and 123, sliding in corresponding openings 124 and 125 provided around the cylindrical sleeve of the stem 114 between an initial position, wherein an upper end 122a and 123a of the inserts 122 and 123 is substantially positioned below or on the outer side surface of the stem 114, and a final position, wherein the upper end 122a and 123a of the inserts 122 and 123 is positioned outside the outer side surface of the stem 114. The final position of said inserts 122 and 123 is defined by striker elements 122b and 123b abutting on a surface of the stem 114 positioned around the openings 124 and 125, inside the stem 114.

The upper end 122a and 123a of the inserts 122 and 123 is, for example, flat or slightly convex.

A flare 122c and 123c respectively is also preferably realised above the inserts 122 and 123, for example countersunk at 45°, towards the central part of the stem 114.

A housing groove 122d and 123d respectively of an elastic clamping ring (not shown in the figures) is also provided above the inserts 122 and 123, joining together the plurality of inserts 122 and 123 respectively.

The inserts 122 and 123 have a lower sloping surface 126 and 127, preferably flat, sloping from the side positioned towards the two ends of the stem 114 respectively.

Each of the expansion means 120 and 121 also comprises a driving element 132 and 133 to bring said inserts 124 and 125 in said final position: each of said driving elements 132 and 133 slides in the cylindrical sleeve of the stem 114 and it is equipped with a plurality of sloping surfaces, sloping from the opposite side with respect to the two respective ends of the stem 114, each of said sloping surfaces being conjugated to a corresponding lower sloping surface 126 and 127 of the inserts 122 and 123.

More precisely, the plurality of sloping surfaces of the driving elements 132 and 133 is realised, in the example of the figures, with a single frustum conical surface 134 and 135 respectively.

Said at least one driving element 130 is interposed between the two driving elements 132 and 133, in the cylindrical sleeve of the stem 114. The driving element 130 comprises a spring 131 realised with a shape-memory material: in the final shape, causing the fixation of the nail 110 to the bone 112, said spring 131 undergoes an extension along the direction of the axis of the stem 114.

Preferably, the inserts 122 and 123 and the driving elements 132 and 133 are realised with a titanium alloy.

Referring now to figures 4, 5, 6 and 7, a third embodiment of intramedullary nail is shown, according to the present invention, and globally indicated with 210, suitable for insertion in a fractured elongate bone 212. In this embodiment, the elements being structurally or functionally similar to the elements of the intramedullary nail 10 are indicated with the same reference number increased by 200 and the detailed description thereof is not repeated hereafter.

The nail 210 comprises a substantially straight stem 214 extending between a proximal end 216 and a distal end 218.

The stem 214 is preferably composed of a cylindrical tube, realised for example with a titanium alloy. The stem 214, according to an aspect of the present invention, comprises, near each of said proximal 216 and distal 218 ends, expansion means 220 and 221 respectively for the fixation of the nail 210 to the bone 212, said expansion means 220 and 221 being

operated by at least one driving element 230, interposed between said expansion means 220 of said proximal end 216 and said expansion means 221 of said distal end 218 and realised with a shape-memory material.

The expansion means 220 of the proximal end 216 comprise a cylindrical sleeve 222 which is worn around the stem 214. The cylindrical sleeve 222 preferably comprises a plurality of longitudinal slots 222a, for example equally spaced around the cylinder of the first sleeve 222, the slots 222a defining a plurality of staves 222b.

Moreover, the first sleeve 222 comprises at least one first tongue-shaped appendix 222c extending, in a longitudinal direction, outside the stem 214: the appendix 222c is housed in a corresponding first tongue housing 222d provided on an thickening 228 of the stem 214, realised at the proximal end 216 of the stem 214, beyond the cylindrical sleeve 222.

The thickening 228, having a cylindrical shape and a radial dimension being substantially equal to the dimension of the cylindrical sleeve 222, preferably comprises holes 228a for bone screws, for example two.

In the final shape, causing the fixation of the nail 210 to the fractured bone 212, said cylindrical sleeve 222, undergoing an axial compression, takes a cask configuration outside the stem 214, with a subsequent shortening of the longitudinal dimension of the sleeve 222; in the preferred embodiment with the staves 222b, in the final shape, the staves 222b take the cask stave configuration, with a subsequent shortening of the longitudinal dimension of the sleeve 222.

The first tongue-shaped appendix 222c, when passing from the initial shape to the final shape, slides in the first tongue housing 222d and also in said final shape the first tongue-shaped appendix 222c is inserted in the corresponding tongue housing 222d.

The expansion means 221 of the proximal end 218 comprise a cylindrical sleeve 223 which is worn around the stem 214. The cylindrical sleeve 223 preferably comprises a plurality of longitudinal slots 223a, for example equally spaced around the cylinder of the first sleeve 223, the slots 223a defining a plurality of staves 223b.

Moreover, the first sleeve 223 comprises at least one second tongue-shaped appendix 223c extending, in a longitudinal direction, outside the stem 214: the appendix 223c is housed in a corresponding second tongue housing 223d provided on an thickening 229 of the stem 214, realised at the proximal end 218 of the stem 214, beyond the cylindrical sleeve 223.

The thickening 229, having a cylindrical shape and a radial dimension being substantially equal to the dimension of the cylindrical sleeve 223, preferably comprises holes 229a for bone screws, for example two.

In the final shape, causing the fixation of the nail 210 to the fractured bone 212, said cylindrical sleeve 223, undergoing an axial compression, takes a cask configuration outside the stem 214, with a subsequent shortening of the longitudinal dimension of the sleeve 223; in the preferred embodiment with the staves 223b, in the final shape, the staves 223b take the cask stave configuration, with a subsequent shortening of the longitudinal dimension of the sleeve 223.

The second tongue-shaped appendix 223c, when passing from the initial shape to the final shape, slides in the second tongue housing 223d and also in said final shape the second tongue-shaped appendix 223c is inserted in the corresponding tongue housing 223d.

Said at least one driving element 230 is interposed between the cylindrical sleeve 222 and the cylindrical sleeve 223. The driving element 230 comprises an intermediate cylindrical sleeve 231, worn around the stem 214, with a radial dimension being substantially equal to the radial dimension of the two sleeves 222 and 223 and realised with a shape-memory material: in the final shape, causing the fixation of the nail 210 to the bone 212, said intermediate cylindrical sleeve 231 undergoes an extension.

Preferably, as shown in the example of the figures, the thickening 229 comprises a cylindrical sleeve and the distal end 218 of the stem 214 has a thread. A retaining ring 232 of the series of the first 222, second 231 and cylindrical sleeve 223 is screwed on said thread. Preferably, the ring 232 is screwed on the stem 214 up to exert a slight pressure on the series of the sleeves 222, 223 and 231, i.e. said sleeves 222, 223 and 231 are positioned with an axial preload. In this shape, the cylindrical sleeve of the

thickening 229 is fixed to the stem 214, for example by positioning, in a radial direction, a pin 229b between the sleeve and the stem 214.

The intermediate cylindrical sleeve 231 undergoes an instruction step causing it, in the final shape, to axially extend: this deformation causes on the first sleeve 222 and on the second sleeve 223 said axial compression buckling the first 222 and second sleeve 223 as above described.

According to an alternative embodiment of the invention, the two cylindrical sleeves 222 and 223 are realised, at least partially, with a shape-memory material: said cylindrical sleeves 222 and 223 undergo an instruction step causing them, in the final shape, to take a cask configuration, outside the stem 214.

More precisely, the staves 222b and 223b are realised with a shape-memory material. By way of example, nitinol can be used, which, as it is well known, is a nickel-titanium alloy created in 1962 by Buehler, a metallurgist at the U.S. Naval Ordinance Laboratory. The staves 222b and 223b can thus comprise nitinol fillets.

Instead of nitinol, a superelastic material can be used, i.e. allowing considerable constant-load deformations: such a material is a nickel-titanium alloy and it differs from nitinol only for the percentages of these components.

It must be underlined that the staves 222b and 223b can also comprise wires made of nitinol or other shape-memory material, instead of said nitinol fillets.

Therefore, in this alternative embodiment, both the expansion means 220 and 221 and the intermediate cylindrical sleeve 231 are, at least partially, realised with shape-memory materials. The intermediate cylindrical sleeve 231 undergoes an instruction step causing it, in the final shape, to axially extend: this deformation causes on the first sleeve 222 and on the second sleeve 223 a compression load tending to further increase the deformation of the first 222 and second sleeve 223.

It is specified that, in the third embodiment of the nail 210 of the invention, the positions of the components of the nail 210 can be

obviously inverted with respect to the proximal 216 and distal 218 ends of the stem 214, in the sense that the ring 232 can be positioned at the proximal end 216 rather than at the distal end 218.

Referring now to figure 8, a further embodiment of intramedullary nail, according to the present invention, is shown and globally indicated with 310, suitable for insertion in a fractured elongate bone 312. More precisely in figure 8, only a portion of the nail 310 is shown.

The nail 310 comprises a substantially straight stem extending between a proximal end 316 and a distal end.

The substantially straight stem preferably comprises a cylindrical sleeve, while expansion means 320 are provided in correspondence with at least one of the two ends for a fixation of the nail 310 to said fractured bone 312.

More precisely, according to an aspect of the present invention, these expansion means 320 comprise at least an element 320a realised with a shape-memory material.

In particular, expansion means 320 of the same type are provided both at the proximal end 316 and at the distal end.

The elements 320a realised with a shape-memory material of the expansion means 320 are, in this case, each of the proximal 316 and distal ends, whereon a plurality of longitudinal cuts 324 are provided, said cuts 324 cutting the thickness of the cylindrical sleeve of the stem 314. The cuts 324 are preferably equally spaced around the stem cylindrical sleeve and they define a plurality of foils 324a. The cuts 324 abut in grooves 324b being shaped according to a circumference arc.

It is specified that the stem cylindrical sleeve is bounded, at the proximal 316 and distal ends, by a bevelled surface 340, split by said cuts 324, said bevelled surface 340 being for example a portion of a spherical cap.

Referring now to figures 10 and 11, an alternative embodiment of said intramedullary nail 310 is shown.

The elements 320a realised with a shape-memory material of the

expansion means 320 are, in this case, two inserts 344 positioned the one at the proximal end 316 and the other at the distal end of the nail 310, in correspondence with respective lowered-cross-section portions of the stem 314.

Each insert 344 is shaped as a cylindrical sleeve comprising, at the end outside the stem 314, a plurality of longitudinal cuts 324, said cuts 324 cutting the thickness of the cylindrical sleeve of the insert 344. The cuts 324 are preferably equally spaced around the cylindrical sleeve of the insert 344 and they define a plurality of tongues 346. In the case shown in the figures the tongues 346 are four. In the initial shape, starting from the cylindrical sleeve without cuts 324, each tongue 346 has a first bend 348 outside the nail 310 and a following second bend 350 inwards the nail 310, so that the end section of the tongue 346 is positioned in a substantially axial direction with respect to the stem 314.

In a further alternative embodiment of said intramedullary nail 310, shown in figure 9, ring-shaped grooves 342 are provided, realised in correspondence with the two ends of the stem cylindrical sleeve: said ring-shaped grooves 342 are broken, along the circumference, by the cut 324 crossing.

The above description corresponds to the initial shape of the expansion means 320 realised with a shape-memory material. In the final shape, the free ends of the foils 324a or of the tongues 346 bend outside the stem, the foils 324a or the tongues 346 thus positioning in a substantially radial way.

Referring now to figures 12 and 13, a further embodiment of intramedullary nail, according to the present invention, is shown and globally indicated with 410, suitable for insertion in a fractured elongate bone 412.

The nail 410 comprises a substantially straight stem extending between a proximal end and a distal end.

The substantially straight stem is preferably composed of a cylindrical tube, while expansion means are provided in correspondence with at least one of the two ends for a fixation of the nail 410 to said fractured bone.

An element 420a consist of a first cylindrical sleeve 423 comprising a plurality of longitudinal cuts crossing the thickness of the cylindrical sleeve 423, said cuts starting from an end of the sleeve 423 and abutting in corresponding grooves 425b. The cuts are preferably equally spaced around the cylindrical sleeve 423 and they define a plurality of foils 425a. In the example of the figures, the foils 425a are four; the grooves 425b of the cuts 425 are shaped according to a circumference arc. Ring-shaped grooves 443 are also provided, realised in correspondence with the free ends of the foils 425a: said ring-shaped grooves 443 are broken, along the circumference, by the cut crossing.

The cylindrical tube of the stem has, in correspondence with the proximal end, a first narrow section, wherein the cylindrical sleeve is worn, so that the free end of the foils 425a is turned towards a stem central portion and it abuts in correspondence with the stem outer diameter change, wherein the first narrow section is provided. Preferably, the first narrow section has an outer prismatic shape corresponding to an inner conjugated prismatic shape of the central hole of the first cylindrical sleeve 423.

The foils 425a are not realised with a shape-memory material. In this case, in the final shape, the first cylindrical sleeve 423 is moved towards a stem central portion by driving means 444, so that the foils 425a are bent outside the first narrow section.

Driving means 344 are realised for example with a cylinder 346, made of a shape-memory material, which shortens in the final shape, inserted in the stem hole and fixed in said stem and in said first cylindrical sleeve 323.

It must be noticed that the cylinder 446 of the driving means 444 is, in the example of figure 13, realised enbloc with the second cylindrical sleeve 423, and it is practically an extension thereof. In this case, the cylinder 446 is obviously not directly fixed to the stem, since the fixation indirectly occurs by means of the second cylindrical sleeve 423 which, as already mentioned, is directly fixed to the narrow section of the stem.

With reference to figures 14 to 24, an intramedullary nail according to the invention which is suitable for insertion in a fractured elongate bone 12, such as for example a femur or a tibia, comprises a substantially straight stem extending between a proximal end and a distal end. The stem is

preferably composed of a cylindrical tubular body.

According to an aspect of the present invention, the stem comprises at least a substantially longitudinal distribution of expansion means for the nail fixation to the bone. The substantially longitudinal distribution comprises at least an element realised with a shape-memory material, a free end of said at least one element positioning outside the stem to perform said fixation.

In the example of figures 14 and 15, the substantially longitudinal distributions 520 are three and they are angularly equally spaced around the side surface of the cylindrical tubular body of the stem 514

The element 522 made of a shape-memory material of each distribution 520 shapes in a substantially rectangular tongue 526, with the longest side being longitudinally developed with respect to the stem 514 and about as long as the stem 514. The tongue 526 is connected outside the stem 514 by a longest side thereof, while the opposite longest side is the free end 524 of said element 522.

In the final shape, i.e. when the shape-memory material is activated, the tongues 526 are positioned in a substantially tangential way with respect to the cylindrical tubular body of the stem 514, the tongues 526 being all positioned with a same rotation direction, i.e. the free ends 524 of the tongues 526 being all for example arranged in an angular position preceding (once the clockwise direction is set) the angular position of the longest side connected to the stem 514.

In the initial shape the tongue 526 is bent towards the side surface of the stem 514, it abuts for example on the side surface of the stem 514, and according to the width thereof, it can partially abuts on the adjacent tongue 526 (i.e. the tongue being arranged in an angular position preceding the angular position of the tongue 526 being concerned, the clockwise direction being always set).

The tongues 526 have connection arcs with the stem 514 being such as to reduce the stress concentration; meanwhile, these arcs have a limited extension, since it is worth allowing the deformation of most of each tongue 526.

The stem 514, at one end, has a head 528 having a substantially cylindrical shape and an axis substantially coinciding with the stem 514 axis: said head 528 has traditional means for hooking the nail 510, during the insertion thereof in the bone 12, with a traditional external guide device.

In the alternative embodiment of figure 16, the nail 610 according to the invention is shown, having a similar structure to the structure of the nail 510 of figure 14, with an additional covering element 630 enveloping the tongues 526 of the stem 514.

The covering element 630 shapes in a flat spiral spring which is preferably constrained to the free end 524 of a tongue 526.

The flat spiral spring, being longitudinally developed with respect to the stem 514, has a rest inner diameter being substantially equal to the cylindrical dimension of the tongues 526 in the initial position thereof. When the tongues 526 are operated, the inner diameter of the spiral spring is expanded according to the position taken by the free ends 524 of the three tongues 526.

Preferably, the spiral spring has outwardly a considerably rough surface.

In the alternative embodiment of figures 17 and 18, the nail 710 according to the invention is shown, wherein the substantially longitudinal distributions 520 are four and they are angularly equally spaced around the side surface of the cylindrical tubular body of the stem 14

Similarly to the nail 510, the element 522 made of a shape-memory material of each distribution 520 shapes in a substantially rectangular tongue 526, with the longest side being longitudinally developed with respect to the stem 14 and about as long as the stem 514. The tongue 526 is connected outside the stem 514 by a longest side thereof, while the opposite longest side is the free end 524 of said element 522.

In the final shape, i.e. when the shape-memory material is activated, the tongues 526 are positioned in a substantially tangential way with respect to the cylindrical tubular body of the stem 514, the tongues 526 being all positioned with a same rotation direction, i.e. the free ends 524 of the

tongues 526 being all for example arranged in an angular position preceding (once the clockwise direction is set) the angular position of the longest side connected to the stem 514.

In the final shape shown in figures 17 and 18, the tongues 526 are bent outside the stem 514: more precisely, the tongue concavity is the one deriving from the fact that the free end 524 of the tongue 526 is arranged in an angular position following (once the clockwise direction is set) the angular position of the respective tangent to the cylindrical tubular body of the stem 514.

In the initial shape the tongue 526 is bent towards the side surface of the stem 514, it abuts for example on the side surface of the stem 514, and according to the width thereof, it can partially abuts on the adjacent tongue 526 (i.e. the tongue being arranged in an angular position preceding the angular position of the tongue 526 being concerned, the clockwise direction being always set).

The tongues 526 have connection arcs with the stem 514 being such as to reduce the stress concentration; meanwhile, these arcs have a limited extension, since it is worth allowing the deformation of most of each tongue 526.

The stem 514, at one end, has a head 528 having a substantially cylindrical shape and an axis substantially coinciding with the stem 514 axis: said head 528 has traditional means for hooking the nail 510, during the insertion thereof in the bone 512, with a traditional external guide device.

In the alternative embodiment of figure 19 the nail 810 according to the invention is shown, wherein the elements 522 made of a shape-memory material of the substantially longitudinal distributions 520 shape in a plurality of corrugations 832 of a tubular structure 834 realised with a shape-memory material. The corrugations 832 are continuously distributed along the side surface of the tubular structure 834, which is internally constrained to the cylindrical tubular body of the stem 514. Alternatively, the tubular structure 834 is self load-bearing.

More precisely, the tubular structure 834 undergoes an instruction step of

the shape-memory material wherein, starting from a tubular structure with a circular outer profile (final shape of the nail 810), a tubular structure with a more reduced outer dimension is obtained (initial shape of the nail 810), by forming successive corrugations 832.

It is evident that in this alternative embodiment the free ends 524 of the corrugations 832 are practically the grooves of the corrugations 832, which, in the final shape of the nail 810, are positioned outside the initial dimension of the tubular structure 834, to perform the nail fixation to the bone.

By way of example, the outer diameter of the tubular structure 834 in the final shape (shown with dotted lines in the figure) can be of 20 mm, while the thickness of the tubular structure 834 can be of 0,4 mm.

In the alternative embodiment of figure 20 the nail 910 according to the invention is shown, wherein the element 522 made of a shape-memory material of the substantially longitudinal distribution 520 shapes in a covering element 930 enveloping the stem 514.

The covering element 930 shapes in a flat-spiral-shaped bent plate.

An end of said plate is connected to the stem 514 through traditional connection means, such as welding or mechanical joint, so to be substantially tangent to the cylindrical tubular body of the stem 514.

An opposite end of the bent plate is the free end 524 of the shape-memory element 522. In the final shape, this free end 524 is positioned, with respect to the stem 514, far outside than in the initial shape of the nail 910. In other words, the plate flat spiral enlarges, i.e. it radially expands when passing from the initial shape to the final shape.

The bent plate can also be split into pieces, to limit the risk of rotation of the nail 910 in the bone in the plate expansion step.

In the alternative embodiment of figure 21 the nail 910 according to the invention is shown, wherein the element 522 made of a shape-memory material of the substantially longitudinal distribution 520 shapes in a covering element 930 enveloping the stem 514.

The covering element 930 shapes in a flat-spiral-shaped bent plate.

An end of said plate is connected to the stem 514 through traditional connection means, such as welding or mechanical joint, so that the flat spiral strays in a substantially radial direction with respect to the stem 514 and it is preferably developed for about a turn and a half.

An opposite end of the bent plate is the free end 524 of the shape-memory element 522. In the final shape, this free end 524 is positioned, with respect to the stem 514, far outside than in the initial shape of the nail 910. In other words, the plate flat spiral enlarges, i.e. it radially expands when passing from the initial shape to the final shape.

In the alternative embodiment of figures 22 and 23 the nail 1010 according to the invention is shown, wherein the substantially longitudinal distributions 520 shape in two shaped plates 1036 and 1038, realised with a shape-memory material.

The shaped plates 1036 and 1038, in the final shape, are substantially flat and they are substantially rectangle-shaped, with the longest side being developed with the axis of the stem 514 and about as long as the stem 514.

More particularly, each of said shaped plates 1036 and 1038 is connected to the stem 514, along an intermediate line between the rectangle longest sides of the respective plates 1036 and 1038, in a substantially tangential way to the stem 514, for example by welding.

The intermediate connection lines are positioned substantially parallel to the axis of the stem 514, and they are for example offset on the outer surface of the stem 514 by about a right angle.

The planes of the two so-arranged plates 1036 and 1038 intersect: respective material lacks 1040 and 1042 allowing such an arrangement are thus provided.

More precisely, in the first shaped plate 1036, these lacks 1040 shape in rectangular slits, positioned in series in the direction of the longest side of the rectangle of the plate 1036. In the second shaped pate 1038, these lacks 1042 shape in rectangular slots, positioned in series in the direction

of the longest side of the rectangle of the plate 1038. The slots are realised starting from a longest side of the rectangle of the plate 1038 and they thus define a series of teeth 1044, being positioned in correspondence with the rectangular slits and having suitable dimensions for passing through these slits.

The above description corresponds to the final shape of the two shaped plates 1036 and 1038 having thus globally four series of free ends 524 for the fixation and i.e. the two longest sides of the rectangle of the plate 1036, the teeth 1044 and the longest side of the rectangle of the plate 1038 being opposite to the teeth 1044.

In the initial shape, the two plates 1036 and 1038 are bent with the concavity towards the stem 514; in other words, they lie enveloped on the outer surface of the stem 514.

By way of example, in the final shape, the plates 1036 and 1038, intersecting with each other as above described, have an outer dimension equal to a cylinder with a diameter of 19 mm.

It must be noticed that it is possible to have two plates 1036 and 1038 with free ends 524 distributed only in some areas (for example close to the ends of the stem 514), conveniently selecting for example the position of the teeth 1044.

A ferrule 1046 is preferably positioned at one end of the stem 514 to improve the insertion of the nail 1010. This ferrule shapes in an ellipsoid portion, centrally drilled in correspondence with the axis of the stem 514.

In the alternative embodiment of figure 24 the nail 1110 according to the invention is shown, wherein the substantially longitudinal distributions 520 shape in three plates 1148, 1150 and 1152, realised with a shape-memory material.

In the final shape, the three plates 1148, 1150 and 1152 are substantially flat and rectangular, with the longest side along the axis of the nail 1110.

They are connected to each other, by means of welds and/or joints. The connection occurs by joining a longest side of a plate to an intermediate and parallel line to the longest sides of the rectangle of the adjacent plate.

In other words, an equilateral-triangle-shaped section exists, with each of the three sides extending on a same side with respect to the single side being considered.

In the initial shape, the plates 1148, 1150 and 1152 are bent in correspondence with the respective intermediate lines of the mutual connection, so that, reasoning in the section terms, the extension of each side of the equilateral triangle is bent towards the side connected to the side being considered.

The stem 514 is inserted in the three so-connected plates 1148, 1150 and 1152 and it is constrained thereto.

With reference to figures 25-27, an intramedullary nail according to the present invention is shown.

The nail, in the embodiment described at first, is globally indicated with 1210, while in the alternative embodiment the nail of the invention is indicated with 1310.

The nail 1210 shown in figures 25 and 26, which is suitable for insertion in a fractured elongate bone 12, such as for example a femur or a tibia, comprises a substantially straight stem 1214, having a predetermined X-X axis, extending between a proximal end 1216 and a distal end 1218. The stem 1214 is preferably composed of a cylindrical tubular body.

According to an aspect of the present invention, the nail 1210 comprises an helical element 1220 realised in a shape-memory material, said helical element 1220 being positioned along said axis X-X and elongation-constraint means 1221 being provided in correspondence with said proximal 1216 and distal 1218 ends, said helical element 1220 elongating in the helical development thereof so that coils thereof 1222 are positioned outwards said axis X-X for the nail fixation to the bone.

In the embodiment of figures 25 and 26, the helical element 1220, for example with circular cross-section, is positioned in the cylindrical tubular body of the stem 1214.

More precisely, the stem 1214 is elastically deformable in a direction being substantially radial to the axis X-X. Preferably, a plurality of longitudinal

slots 1224, developed for example for most of the length of the stem 1214 and angularly equally spaced, are provided around the cylindrical tubular body.

In correspondence with each of the two proximal 1216 and distal 1218 ends, said elongation-constraint means 1221 shape in a closing element 1226 which is connected to the cylindrical tubular body of the stem 1214: said closing element 1226 closes the central hole of the cylindrical tubular body of the stem 1214. Preferably, the closing element 1226 is cylinder-shaped.

In the initial shape, the helical element 1220 is inserted in the cylindrical tubular body of the stem 1214 and it has a longitudinal development being lower or substantially equal to the distance between the two closing elements 1226. The radial dimensions of the coils 1222 or the helical element 1220 are such as to be comprised in the cylindrical tubular body of the stem 1214, without causing a deformation thereof.

In the final shape, i.e. when the shape-memory material of the helical element 1220 is activated, the helical element 1220 is elongate: being however constrained to the longitudinal elongation by the constraint means 1221, it results that the radial dimensions of the coils 1222 increase and consequently the cylindrical tubular body of the stem 1214 is radially expanded.

In the alternative embodiment of figure 27, the nail 1310 according to the invention is shown, wherein the helical element 1220, for example with quadrilateral cross-section, is positioned outwards the stem 1214.

More precisely, the stem 1214 is composed of a cylindrical tubular body.

Said elongation-constraint means 1221 in correspondence with an end of the stem 1214, for example in correspondence with the distal end 18, shape in an enlargement 1328 of the stem 1214. The enlargement 1328 is equipped, on the side towards the centre of the stem 1214, with a beat collar 1330 for an end of the helical element 1220. Preferably, the enlargement 1328 is tapered on the opposite side with respect to the beat collar 1330, to help in inserting the nail 1310.

At the opposite end, i.e. for example at the proximal end, the elongation-constraint means 1221 shape in a further enlargement 1329 of the stem 1214. Similarly to the enlargement 1328, the enlargement 1329 is equipped, on the side towards the centre of the stem 1314, with a beat collar 1331 for the opposite end of the helical element 1220. Preferably, the enlargement 1329 is cylinder-shaped.

In the initial shape, the helical element 1220 is put around the cylindrical tubular body of the stem 1214 and it has a longitudinal development being lower or substantially equal to the distance between the enlargement 1328 and the further enlargement 1329.

In the final shape, i.e. when the shape-memory material of the helical element 1220 is activated, the helical element 1220 is elongate: being however constrained to the longitudinal elongation by the constraint means 1221, it results that the radial dimensions of the coils 1222 increase.

With reference to figures 28-39, an intramedullary nail according to the present invention is shown.

The nail 1410 shown in figures 28, 29 and 30, which is suitable for insertion in a fractured elongate bone 12, such as for example a femur or a tibia, comprises a substantially straight stem 1414, having a predetermined axis X-X, extending between a proximal end 1416 and a distal end 1418.

According to an aspect of the present invention, the nail 1410 comprises expansion means 1420 for the nail fixation to the bone, said expansion means 1420 being operable by at least one driving element 1422 realised with a shape-memory material.

In the example of figures 28, 29 and 30, the stem 1414 comprises a plurality of longitudinal portions 1424 forming, close to each other, a cylindrical tubular body.

In other words, the longitudinal portions 1424 have a circular-crown-sector-shaped section. In the case being shown, the longitudinal portions 1424 are four and the angle at the circular crown sector centre is a right

angle.

Expansion means 1420 shape in said longitudinal portions 1424, which can be radially spaced apart from the axis X-X of the stem 1414.

Said at least one driving element 1422, for example in the shape of a V-or-U-bent cylindrical body 1426, is provided between the longitudinal portions 1424. The cross section of the cylindrical body 1426 can be, for example, circular or square.

The cylindrical body 1426 is fixed, at the two opposite ends, to two longitudinal portions 1424, generally in correspondence with surfaces being turned towards the axis X-X.

Preferably, recesses 1428, being accessible from the axis X-X, are provided in said longitudinal portions 1424. Said recesses 1428 of the longitudinal portions 1424 are conjugate to each other: in other words, when the longitudinal portions 1424 are close to each other, said recesses 1428 define an area 1430 comprising said bent cylindrical body 1426 which is connected, at two opposite ends, to the two longitudinal portions 1424 being concerned.

In the case of the four longitudinal portions 1424 being shown, four cylindrical bodies 1426 are provided in correspondence with each end 1416 and 1148 of the stem 1414. Preferably, the four cylindrical bodies 1426 of each end 1416 and 1418 are symmetrically positioned with respect to the axis X-X, generally at a same height with respect to the axis X-X.

In the initial shape, shown in figure 28, the longitudinal portions 1424 are close to each other and the cylindrical bodies 1426 are bent.

In the final shape, shown in figures 29 and 30, i.e. when the shape-memory material of the cylindrical bodies 1426 is activated, the cylindrical bodies 1426 tend to straighten, i.e. the angle between the directions of two opposite ends tends to increase, as it can be seen by comparing figures 31 and 32 showing a cylindrical body 1426 in the initial shape and in the final shape. As a consequence of this straightening, the longitudinal portions 1424, connected by means of the cylindrical bodies 1426, are

spaced apart, having moved in a substantially radial direction with respect to the axis X-X.

In the alternative embodiment of figures 33, 34 and 35, the nail 1510 according to the invention is shown, wherein at least one driving element 1422, shaping in a X-shaped structure 1526, is provided between the longitudinal portions 1424.

The structure 1526 has thus four ends 1526a, 1526b, 1526c and 1526d: in correspondence with two first adjacent ends 1526a and 1526b, the structure 1526 is fixed to two longitudinal portions 1424, generally in correspondence with surfaces being turned towards the axis X-X. The fixation is performed for example through buckling with plastic deformation.

Preferably, grooves 1528, being accessible from the axis X-X, are provided in said longitudinal portions 1524. Said grooves 1528 of the longitudinal portions 1424 are conjugate to each other: in other words, when the longitudinal portions 1424 are close to each other, said grooves 1528 define an area 1530 comprising said structure 1526 when being bent, i.e. when the two first adjacent ends 1526a and 1526b are close to each other and when also the two remaining adjacent ends 1526c and 1526d are close to each other.

The two remaining ends 1526c and 1526d are able to slid in said grooves 1528.

In the case being shown, the longitudinal portions 1424 are four and four structures 1526 are provided in correspondence with each end 1416 and 1418 of the stem 1414. Preferably, the four structures 1526 of each end 1416 and 1418 are symmetrically positioned with respect to the axis X-X, generally at a same height with respect to the axis X-X.

In the initial shape, shown in figures 33 and 34, the longitudinal portions 1424 are close to each other and the structures 1526 are bent as above described.

In the final shape, shown in figures 35 and 36, i.e. when the shape-memory material of the structures 1526 is activated, the first two adjacent

ends 1526a and 1526b tend to space apart, as the remaining adjacent ends 1526c and 1526d tend to space apart by sliding in the grooves 1528, i.e. the structures 1526 become X-shaped. As a consequence of this straightening, the longitudinal portions 1424, connected by means of the structures 1526, are spaced apart, having moved in a substantially radial direction with respect to the axis X-X.

It must be noticed that the X-shaped structures 1526 can be alternatively obtained by joining pairs of V-or-U-bent cylindrical bodies 1426, in correspondence with the bent area. It is evident that in this case, in order to achieve the same effect as structures 1526, the cylindrical bodies 1426 will be so instructed as to be bent in the final shape and to be substantially straight in the initial shape.

In the alternative embodiment of figure 37, the nail 1610 according to the invention is shown, which is similar to the nail 1410 and it has thus V-or-U-bent cylindrical bodies 1426. However, in this alternative embodiment the adjacent cylindrical bodies 1426 are positioned with the bend arranged on opposite sides: in other words, in the case of four longitudinal portions 1424 with four cylindrical bodies 1426, the cylindrical bodies 1426, which face to each other, are specular.

It must be noticed that the radial expansion is linked to the length of the cylindrical bodies 1426.

In the alternative embodiment of figures 38 and 39, the nail 1710 according to the invention is shown, wherein expansion means 1720 shape in a rod 1732, two opposite ends 1734 and 1736 of said rod 1732 being spaceable in a substantially radial way from the axis X-X of the stem 14.

More precisely, the rod 1732 is hinged, in an intermediate position thereof, on the stem 1414 by means of a pin 1738. In particular, the rod 1432 is hinged in an intermediate position of the stem 1414.

The rod 1732 is rectangle-shaped and substantially as long as the stem 1414. The rod 1732 is also equipped with a groove 1440, in correspondence with the area wherein the pin 338 is positioned. A torsion spring 1742 realised with a shape-memory material is positioned around

the pin 1738: this is the driving element 1422 of the nail 1710.

An end of the spring 1742 is constrained to the stem 1414, while the opposite end is positioned in front of a wall of the groove 1740, or preferably it is connected thereto.

In the final shape, the spring 1742 is expanded, with an increase in the angle between the two ends of the spring 1742 causing, through the thrust of the opposite end of the spring 1742 on the wall of the groove 1740, a rotation of the rod 1732.

The rod 1732 is preferably equipped, at the two ends 1734 and 1736, with sharp portions for an improved fixation of the nail 1710.

The main advantage achieved by the intramedullary nail suitable for insertion in a fractured elongate bone, as well as by the application method of said nail in said bone, according to the present invention, is the fact of unusually simplifying the fixation step of the intramedullary nail inserted in the bone: the expansion of expansion means occurs in fact without a mechanical manual intervention, the shape-memory material used in the nail of the invention expanding instead by heat absorption. In practise, the nail fixation is obtained simultaneously with the insertion thereof in the bone, since the shape-memory elements, cooled at first to take the initial shape, take in the bone their final shape, due to the heat released by the patient's body.

Another advantage of the intramedullary nail suitable for insertion in a fractured elongate bone, according to the present invention, is to prevent undesired nail torsions or rotations, since the tongue-shaped appendix is held in the housing thereof.

Another advantage of the intramedullary nail according to the present invention is to preserve the length of the bone on which the intervention occurs, since the tongue-shaped appendix slides in the housing thereof, the nail stem thus keeping the starting position thereof.

A further advantage of the intramedullary nail according to the present invention is that, in case of bone lyses in the contact area between the expanded cylindrical sleeves and the bone, the nail fixation is however

ensured, with no need for an external intervention, since the final shape of the cylindrical sleeves realised with a shape-memory material have a higher radial dimension than the radial dimension of the cylindrical sleeves in the fixation step of the nail to the bone, so that a considerable contact pressure is preserved.

A still further advantage of the intramedullary nail according to the present invention is to be easy to produce, because of the reduced number of different pieces (reminding that the two cylindrical sleeves are identical).

Another advantage of the intramedullary nail suitable for insertion in a fractured elongate bone, according to the present invention, is to prevent undesired nail torsions or rotations.

Another advantage of the intramedullary nail according to the present invention, is to prevent undesired nail torsions or rotations in the bone during the application step, due to the structural continuity of the described embodiments.

A further advantage of the intramedullary nail according to the present invention is that the stem in the shape of a cylindrical tubular body allows an easy insertion in the bone by using a guide wire.

In the case of the nail, it must be noticed that the load applied on the medullary canal of the bone by the three tongues is advantageously distributed along the circumference of the stem.

The shortest side of the rectangle of the tongues can be very long, exploiting all the space of the stem lying between one tongue and the other.

Obviously, in order to meet specific and contingent requirements, a skilled in the art could bring several changes to the above-described intramedullary nail suitable for insertion in a fractured elongate bone and application method of said nail in said bone, all however comprised in the scope of protection of the present invention, as defined in the following claims.

CLAIMS

1. Intramedullary nail (10, 110, 210) suitable for insertion in a fractured elongate bone (12, 112, 212), comprising a substantially straight stem (14, 114, 214) extending between a proximal end (16, 116, 216) and a distal end (18, 118, 218), characterised in that said stem (14, 114, 214) comprises, near each of said proximal (16, 116, 216) and distal (18, 118, 218) ends, expansion means (20, 120, 220; 21, 121, 221) for the nail fixation to the bone, said expansion means (20, 120, 220; 21, 121, 221) being operated by at least one driving element (30, 130, 230), interposed along the axis of the stem (14, 114, 214) between said expansion means (20, 120, 220) of said proximal end (16, 116, 216) and said expansion means (21, 121, 221) of said distal end (18, 118, 218) and realised with a shape-memory material.

2. Intramedullary nail (10, 210) according to claim 1, characterised in that said expansion means (20, 220) comprise a cylindrical sleeve (22, 23, 222, 223) which is worn around the stem (14, 214), the cylindrical sleeve (22, 23, 222, 223), undergoing an axial compression, buckling and taking a cask configuration, outside the stem (14, 214).

3. Intramedullary nail (10) according to claim 2, characterised in that, said at least one driving element (30) is interposed between the two cylindrical sleeve (22, 23), the driving element (30) comprising an intermediate cylindrical sleeve (31), worn around the stem (14), with a radial dimension being substantially equal to the radial dimension of the first (22) and second sleeve (23), in the final shape, causing the fixation of the nail (10) to the bone (12), said intermediate cylindrical sleeve (31) undergoing an extension.

4. Intramedullary nail (110) according to claim 1, characterised in that the stem (114) is composed of a cylindrical tube and in that said expansion means (120, 121) of the proximal (116) and distal end respectively comprise a plurality of inserts (122, 123), sliding in corresponding openings (124, 125) provided around the cylindrical sleeve of the stem (114) between an initial position, wherein an upper end (122a, 123a) of the inserts (122, 123) is positioned substantially below or on the outer side surface of the stem (114), and a final position, wherein the

upper end (122a, 123a) of the inserts (122, 123) is positioned outside the outer side surface of the stem (114).

5. Intramedullary nail (110) according to claim 4, characterised in that the inserts (122, 123) have a lower sloping surface (126, 127), sloping from the side positioned towards the two ends (116, 118) of the stem (114), that each of the expansion means (120, 121) comprises a driving element (132, 133) to bring said inserts (124, 125) in said final position and that each of said driving elements (132, 133) slides in a cylindrical sleeve of the stem (114) and it is equipped with a plurality of sloping surfaces, sloping from the opposite side with respect to the two ends (116, 118) of the stem (114), each of said sloping surfaces being conjugated to a corresponding lower sloping surface (126, 127) of the inserts (122, 123).

6. Intramedullary nail (110) according to claim 5, characterised in that said at least one driving element (130) is interposed between the two driving elements (132, 133), in the cylindrical sleeve of the stem (114), the driving element (130) comprising a spring (131) realised with a shape-memory material: in the final shape, causing the fixation of the nail (110) to the bone (112), said spring (131) undergoing an extension along the direction of the axis of the stem (114).

7. Intramedullary nail (210) suitable for insertion in a fractured elongate bone (212), comprising a substantially straight stem (214 extending between a proximal end (216) and a distal end (218), at least one of said ends (218) comprising expansion means (220) for the nail fixation to the bone, characterised in that said expansion elements (220) comprise at least an element (220) realised with a shape-memory material.

8. Intramedullary nail (210) according to claim 7, characterised in that said substantially straight stem (214) is a cylindrical tube and in that said elements (220a) realised with a shape-memory material of the expansion means (220) are each of said proximal (216) and distal ends, whereon a plurality of longitudinal cuts (224) are provided, said cuts (224) cutting the thickness of the cylindrical sleeve of the stem (214), defining a plurality of foils (224a). and abutting in grooves (224b), the free ends of the foils (224a) bending outside the stem (214) in a final shape corresponding to the fixation of the nail (210) to said fractured bone (212).

9. Intramedullary nail (410) according to claims 1 and 7, characterised in that the substantially straight stem (414) is a cylindrical sleeve and in that said driving element (444) is realised with a cylinder (446), made of shape-memory material, which shortens in the final shape, said cylinder (446) being inserted in the stem hole and fixed in said stem.

10. Intramedullary nail (510, 610, 710, 810, 910, 1010, 1110) suitable for insertion in a fractured elongate bone (12), comprising a substantially straight stem (514) extending between a proximal end (516) and a distal end (518), characterised in that said stem (514) comprises at least a substantially longitudinal distribution (520) of expansion means for the nail fixation to the bone, said expansion means comprising at least one element (522) realised with a shape-memory material, a free end (524) of said at least one element (522) positioning outside the stem (514) to perform said fixation.

11. Intramedullary nail (510, 610, 710, 810, 910, 1010, 1110) according to claim 10, characterised in that the element (522) made of a shape-memory material of each distribution (520) shapes in a substantially rectangular tongue (526), with the longest side being longitudinally developed with respect to the stem (514) and about as long as the stem (514).

12. Intramedullary nail (510, 610, 710, 810, 910, 1010, 1110) according to claim 11, characterised in that the tongue (526) is connected outside the stem (514) by a longest side thereof, the opposite longest side being the free end (524) of said element (522).

13. Intramedullary nail (510) according to claim 12, characterised in that it provides a covering element (630) enveloping the tongues (526) of the stem (514).

14. Intramedullary nail (510) according to claim 13, characterised in that the covering element (630) shapes in a flat spiral spring, longitudinally developed with respect to the stem (514).

15. Intramedullary nail (710) according to claim 10, characterised in that the elements (522) made of a shape-memory material of the substantially longitudinal distributions (520) shape in a plurality of corrugations (732)

of a tubular structure (734) realised with a shape-memory material.

16. Intramedullary nail (1210, 1310) suitable for insertion in a fractured elongate bone (12), comprising a substantially straight stem (1214), having a predetermined axis (X-X), extending between a proximal end (1216) and a distal end (1218), characterised in that it comprises an helical element (1220) realised with a shape-memory material, said helical element (1220) being positioned along said axis (X-X) and elongation-constraint means (1221) being provided in correspondence with said proximal (1216) and distal (1218) ends, said helical element (1220) elongating in the helical development thereof so that coils thereof (1222) are positioned outwards said axis (X-X) for the nail fixation to the bone.

17. Intramedullary nail (1210) according to claim 16, characterised in that the helical element (1220) is positioned in the cylindrical tubular body of the stem (1214).

18. Intramedullary nail (1210) according to claim 17, characterised in that the stem (1214) is elastically deformable in a substantially radial direction with respect to said axis (X-X).

19. Intramedullary nail (1310) according to claim 1, characterised in that the helical element (1220) is positioned outwards the stem (1214).

20. Intramedullary nail (1410, 1510, 1610, 1710) suitable for insertion in a fractured elongate bone (12), comprising a substantially straight stem (1414), having a predetermined axis (X-X), extending between a proximal end (1416) and a distal end (1418), characterised in that it comprises expansion means (1420) for the nail fixation to the bone, said expansion means (1420) being operable by at least one driving element (1422) realised with a shape-memory material.

21. Intramedullary nail (1510) according to claim 20, characterised in that at least one driving element (1422), shaping in a X-shaped structure (126) is provided between longitudinal portions (1424) of the stem (1414).

22. Intramedullary nail (1710) according to claim 20, characterised in that expansion means (1420) shape in a rod (1732), two opposite ends (1734, 1736) of said rod (1732) being spaceable in a substantially radial

way from the axis (X-X) of the stem (1414).

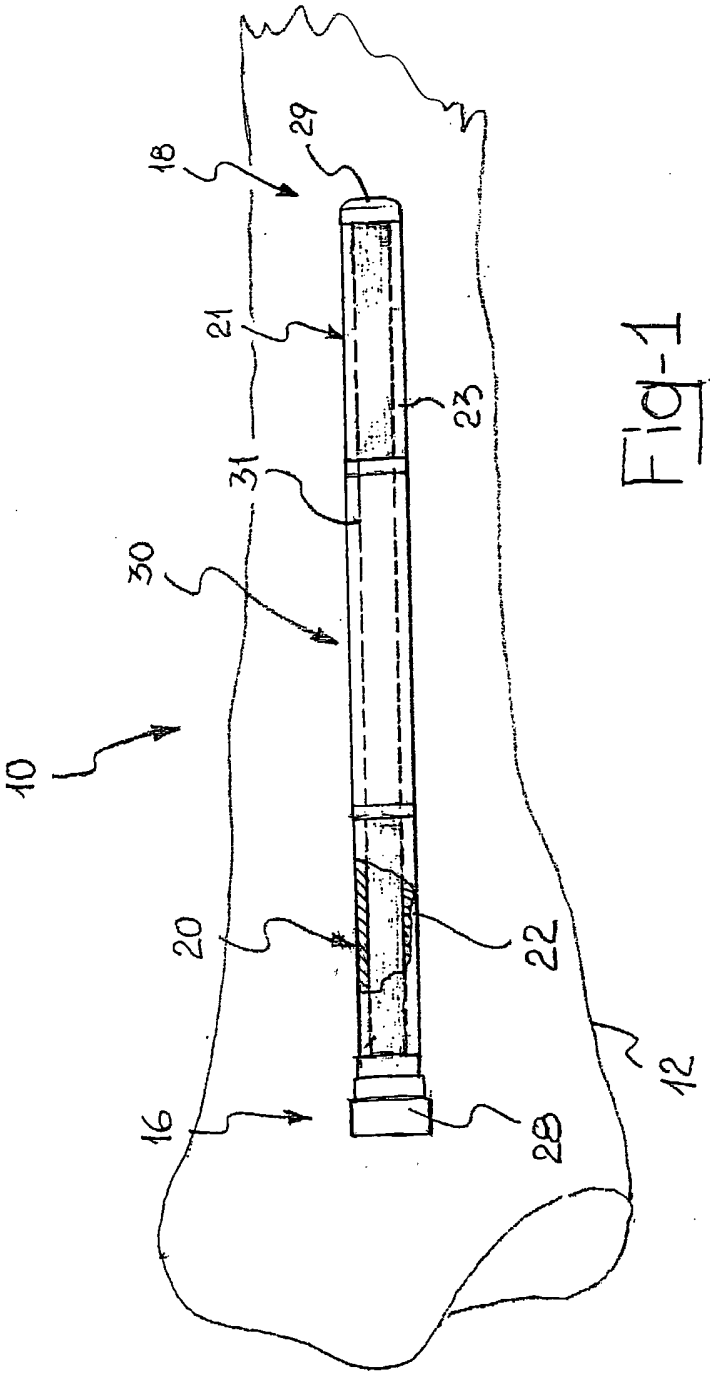


Fig-1

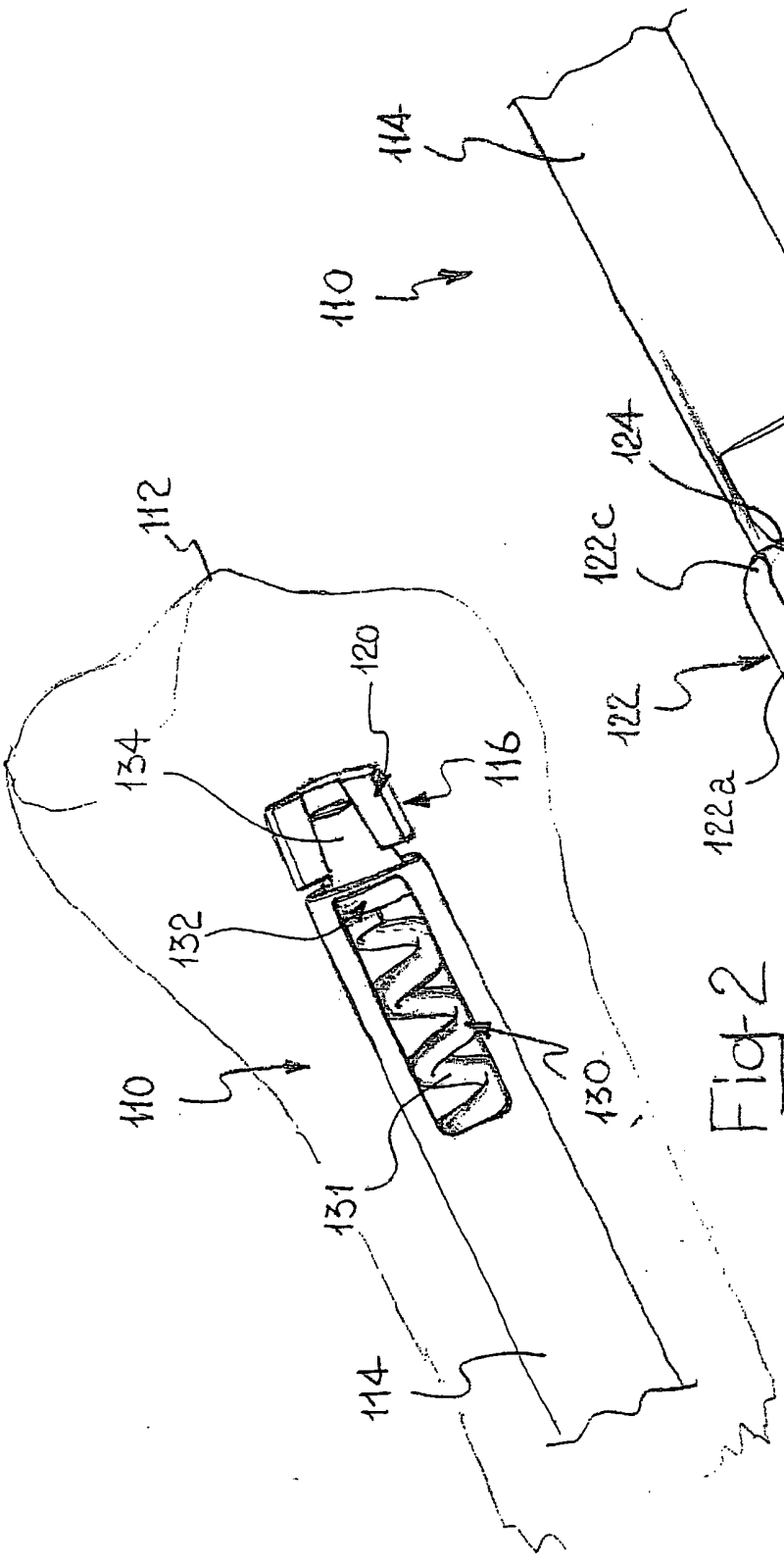

112
120
134
116
132
110
130
131
114

Fig-2

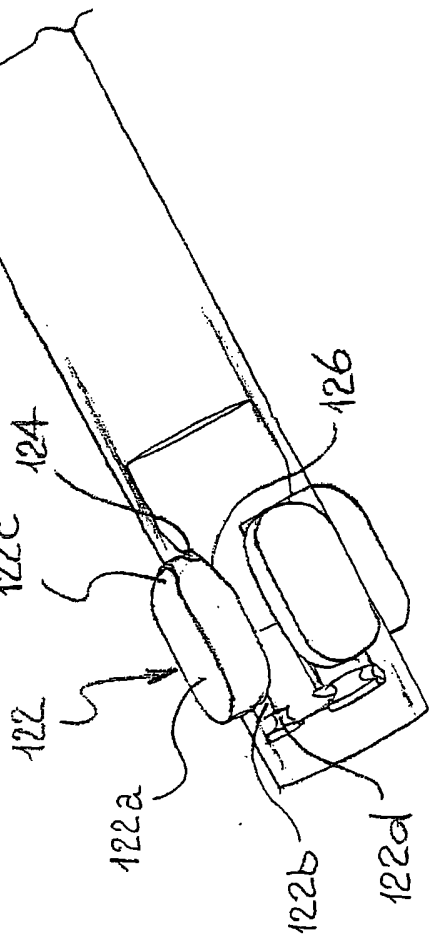

114
110
124
126
122c
122
122a
122b
122d

Fig-3

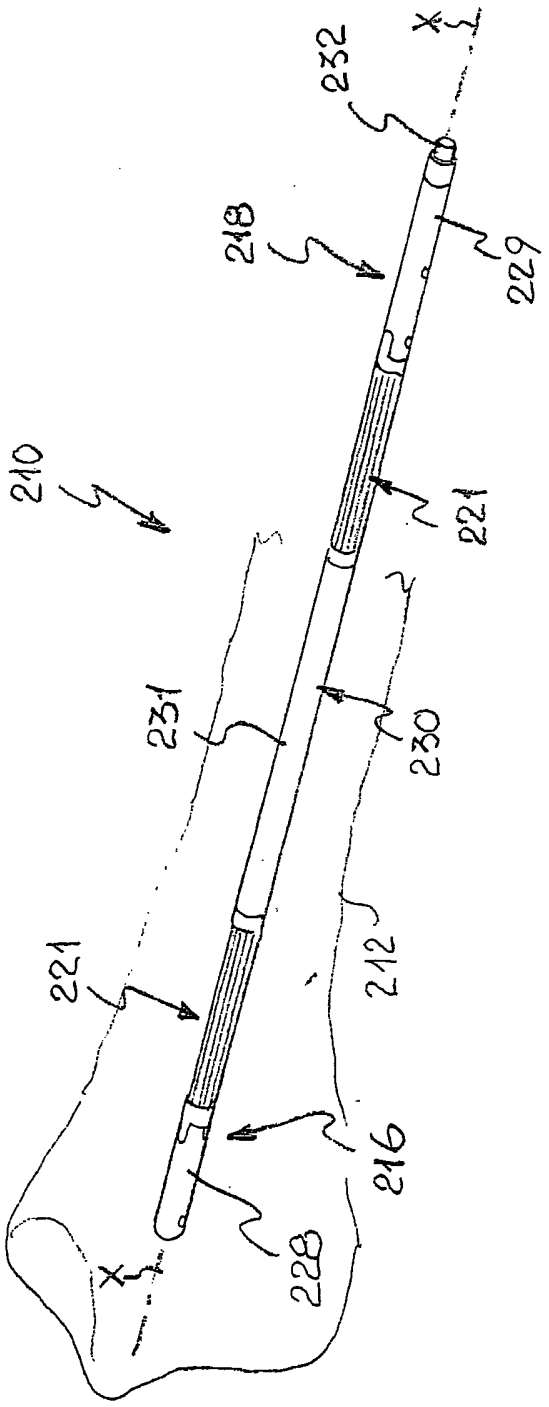


Fig-4

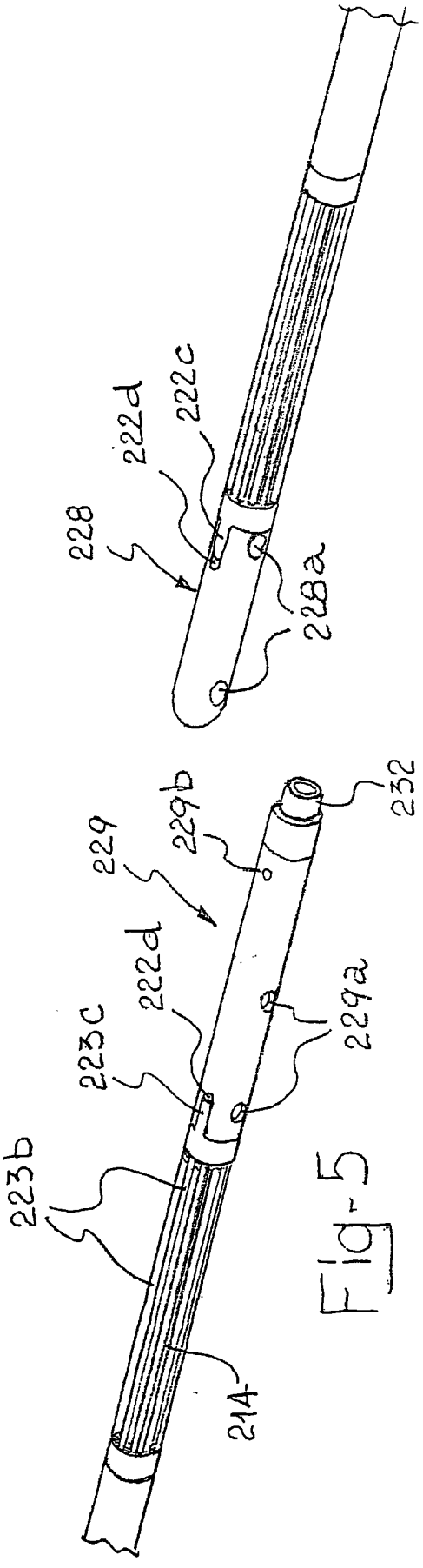


Fig-5

Fig-6

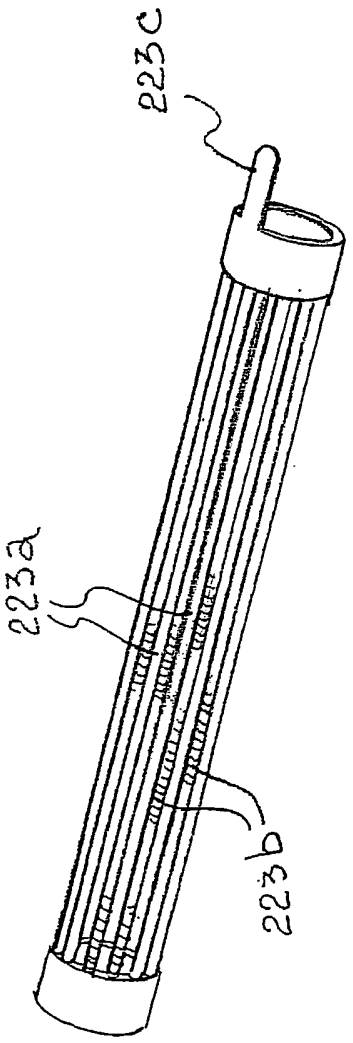


Fig-7

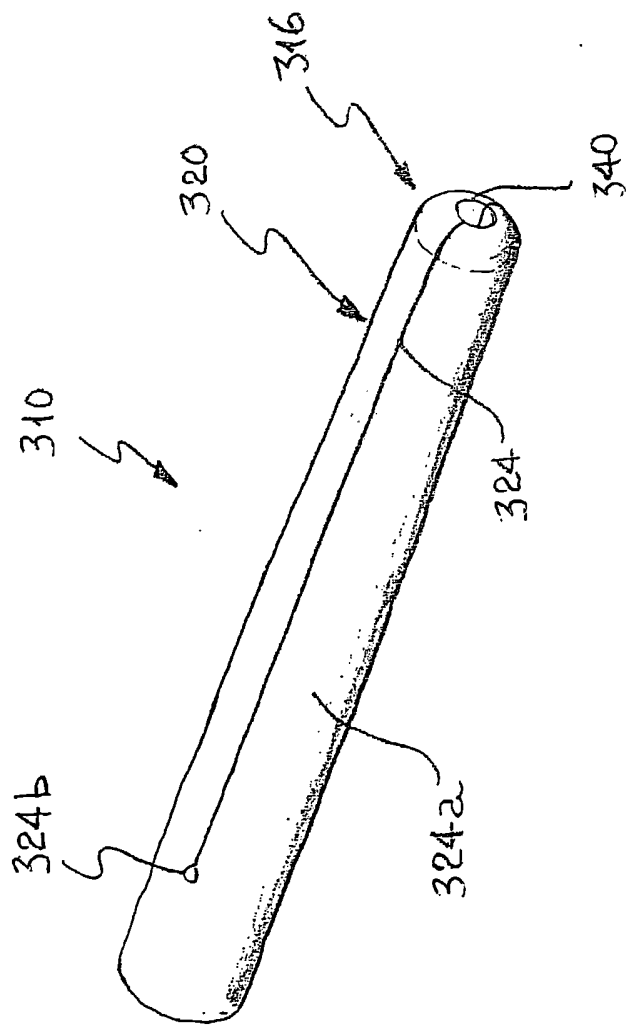


Fig-8

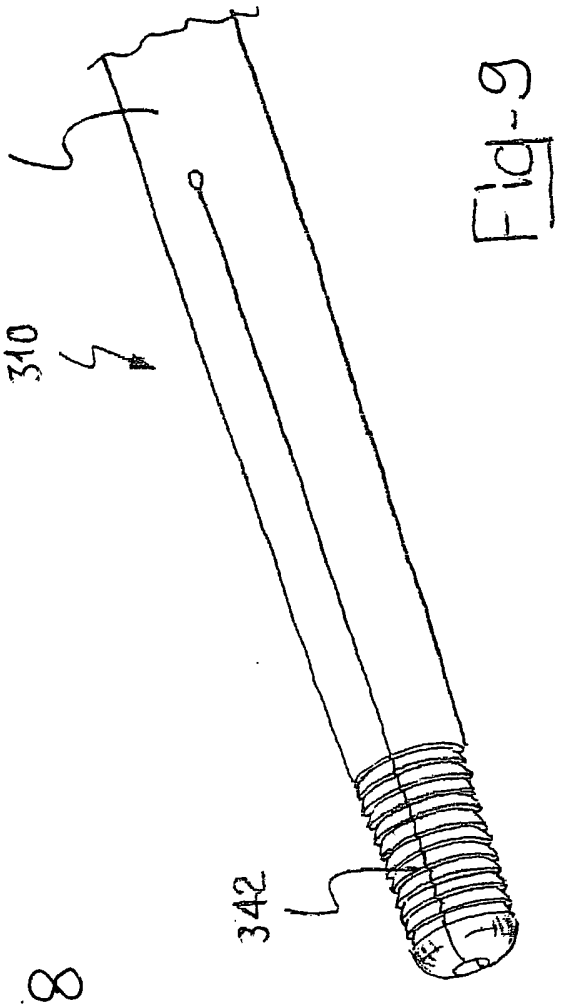


Fig-9

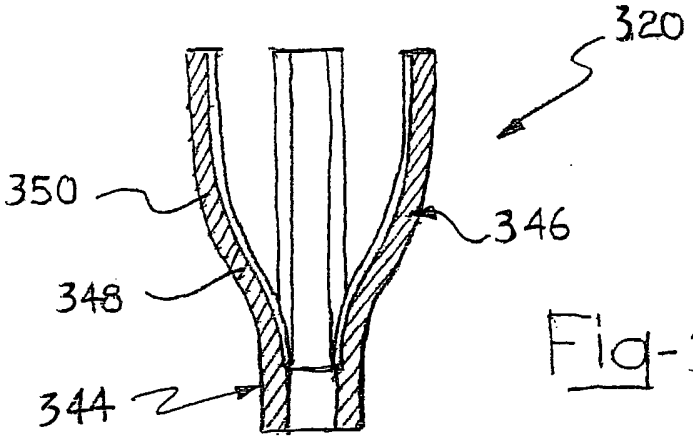


Fig-11

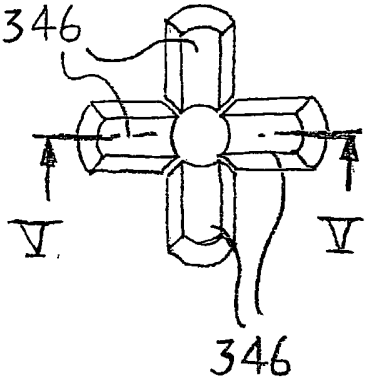


Fig-10

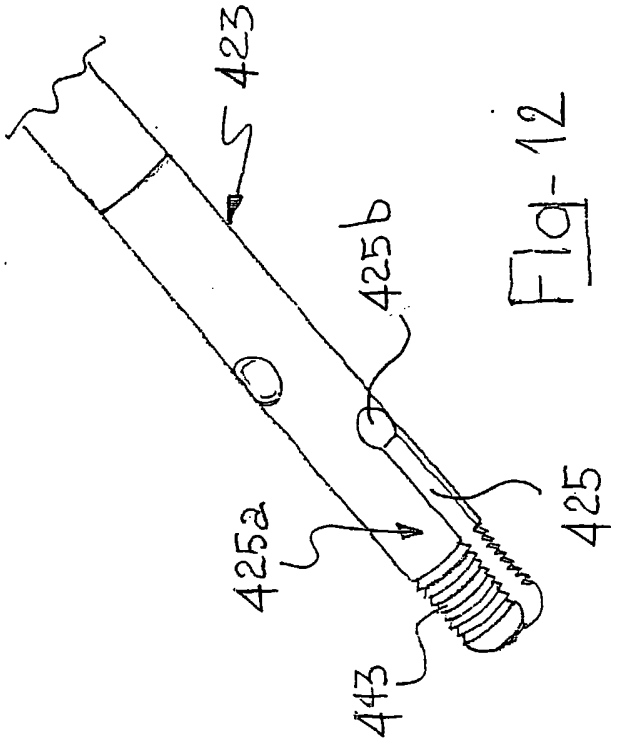


Fig-12

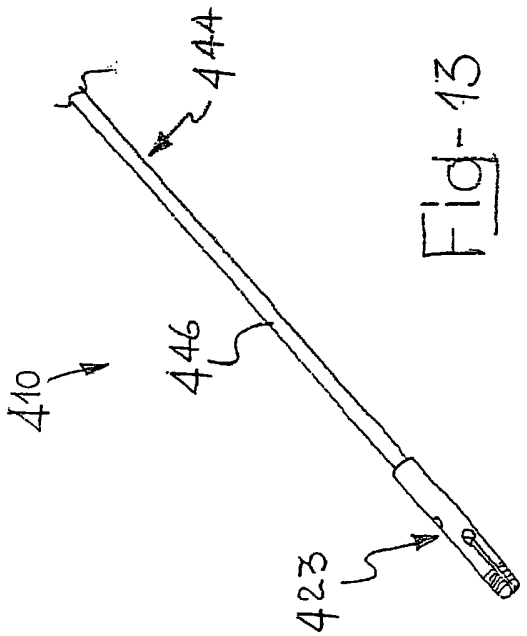


Fig-13

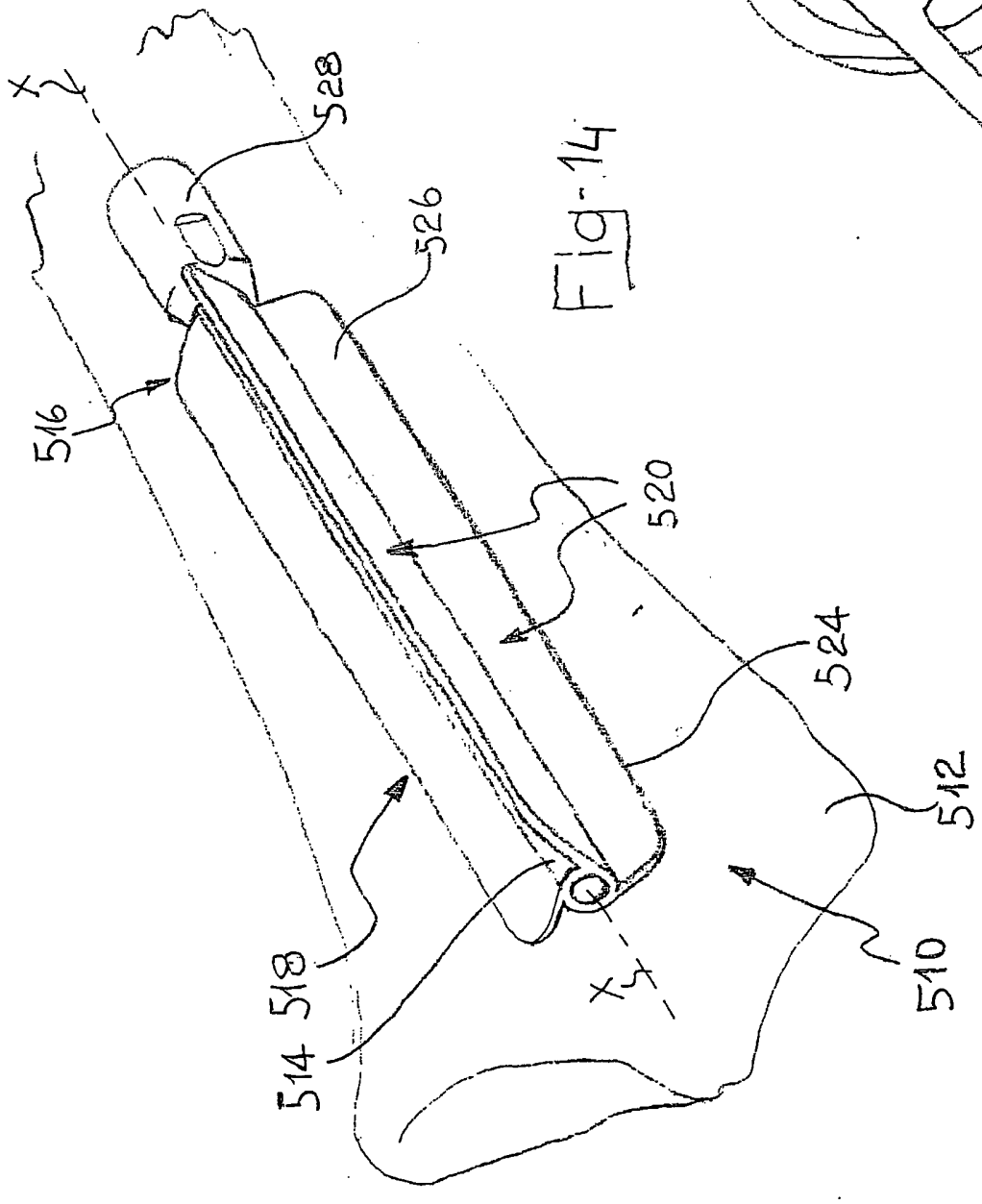


Fig-14

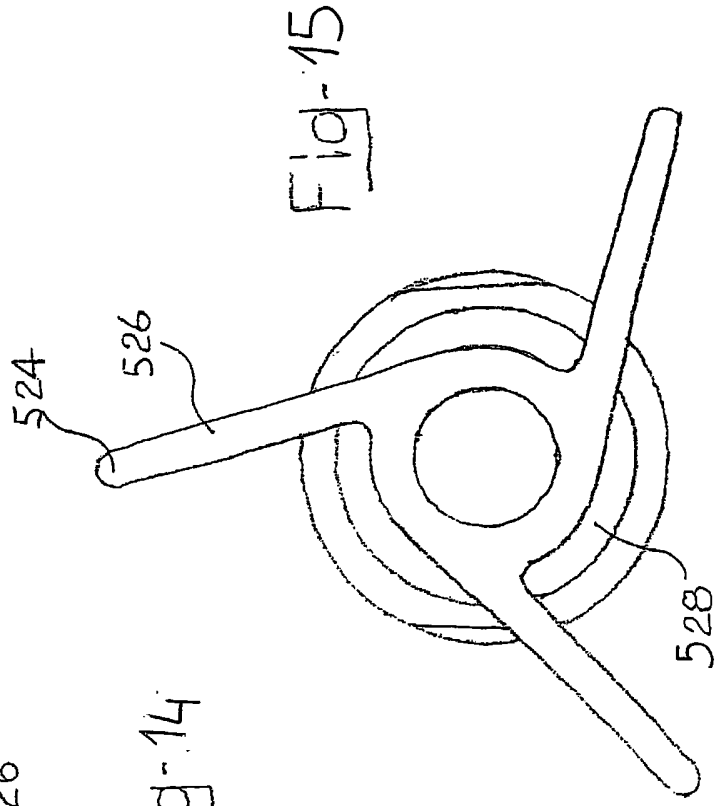


Fig-15

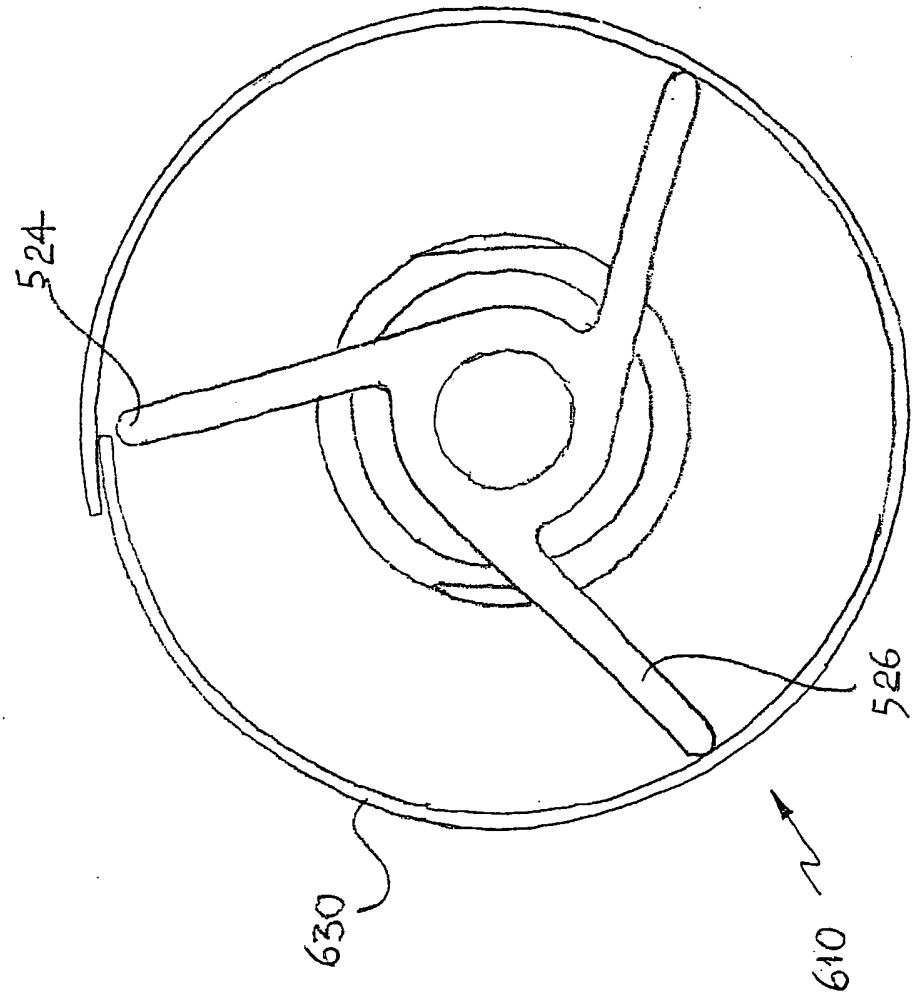


Fig-16

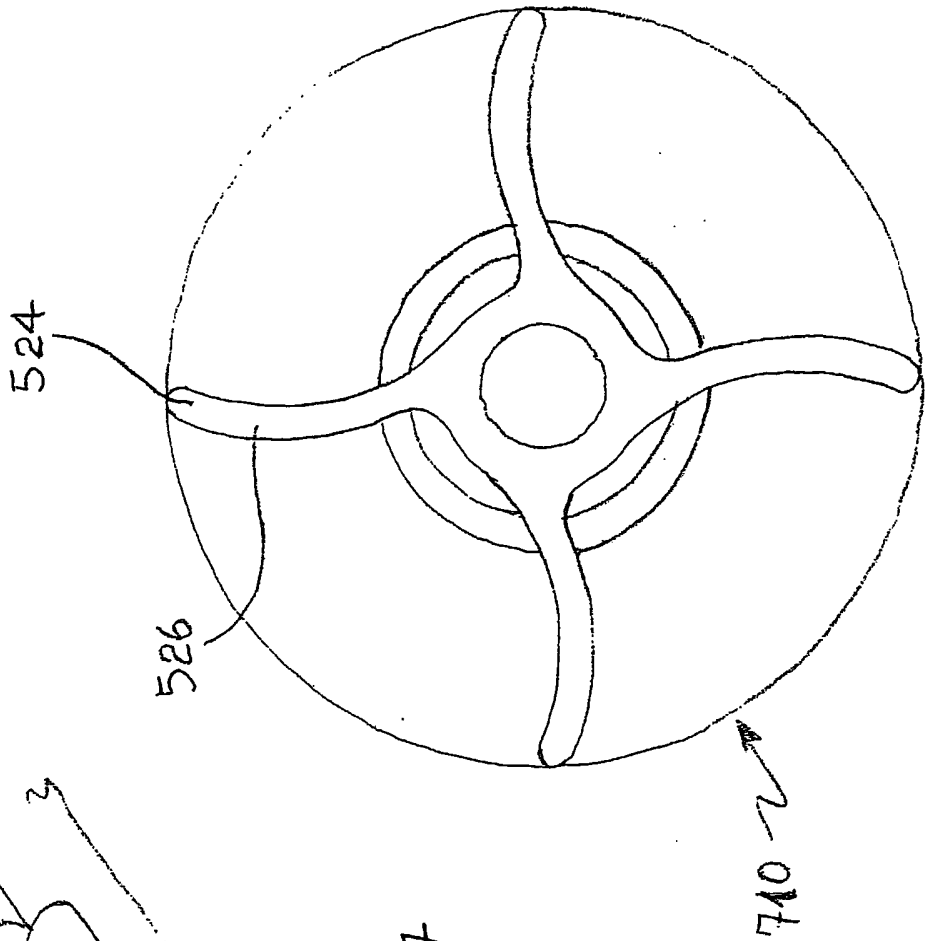


Fig-18

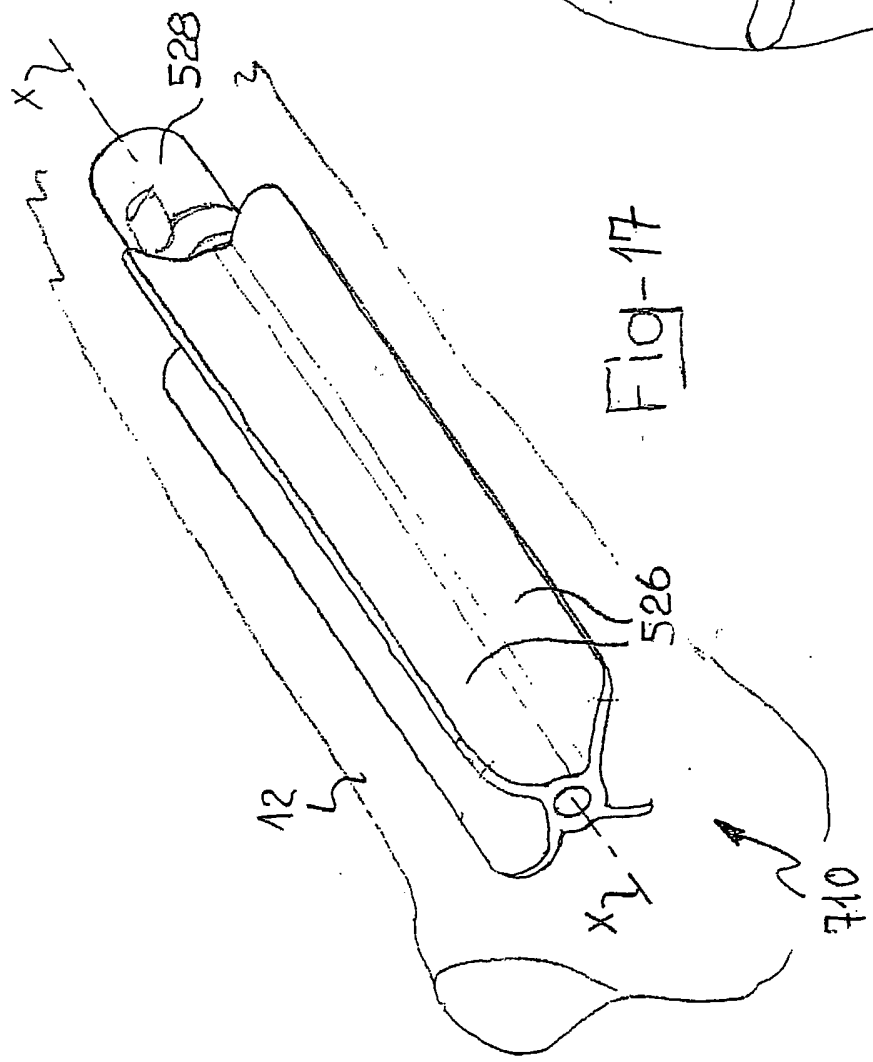
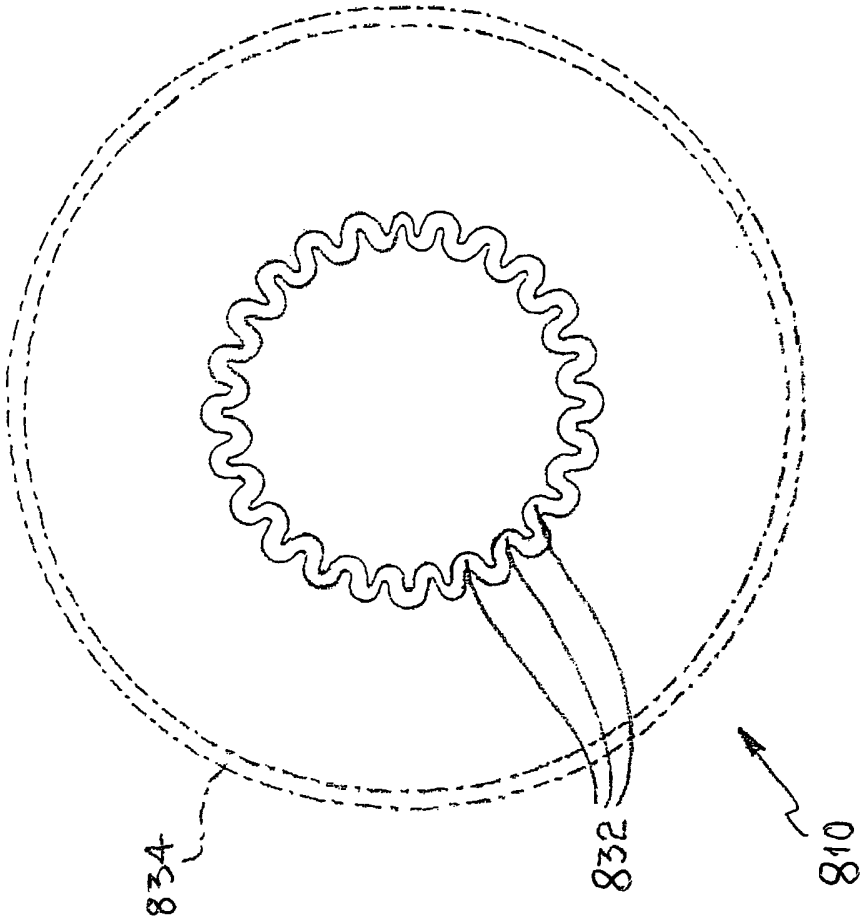


Fig-17

Fig. 19



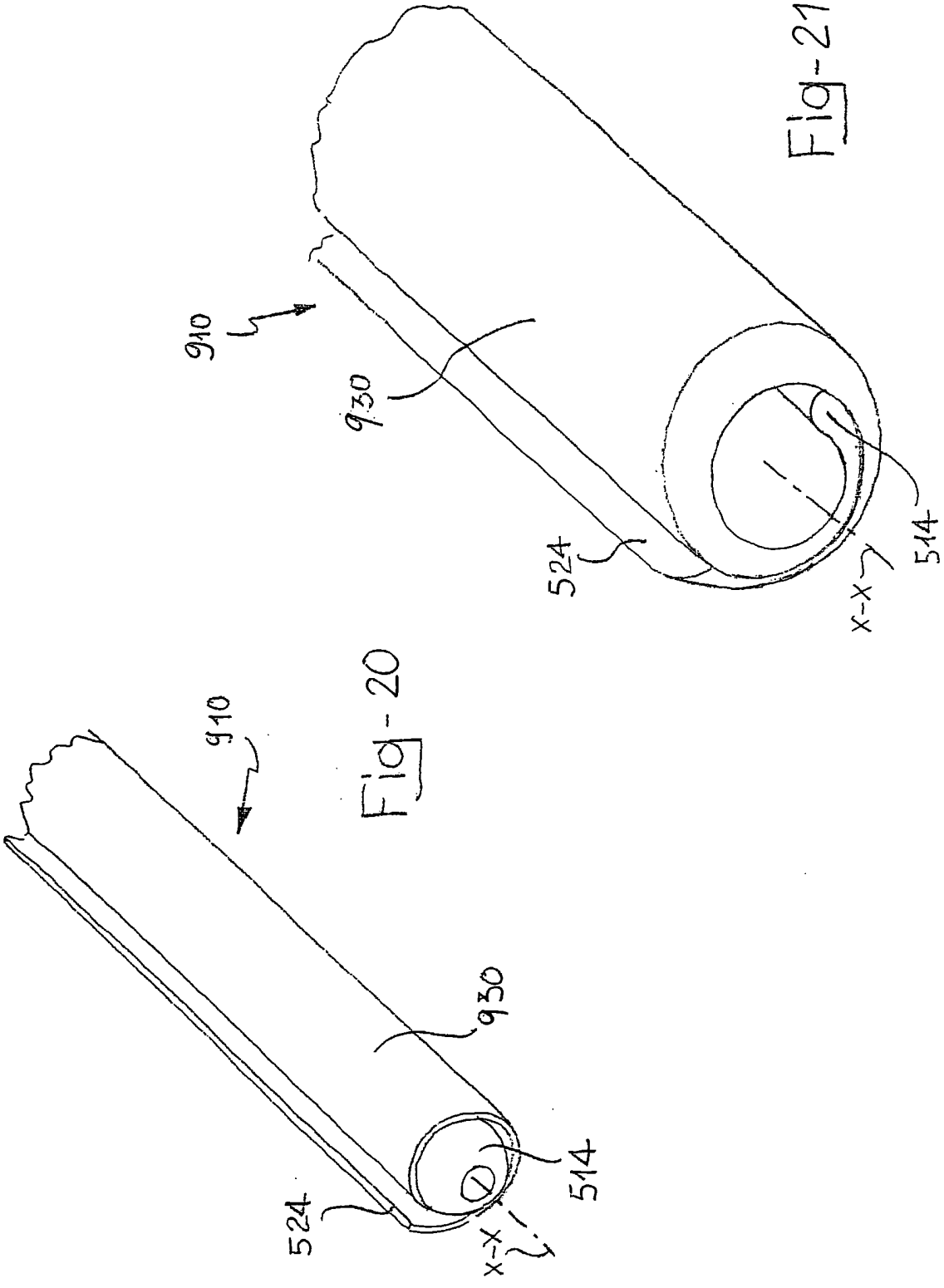


Fig-21

Fig-20

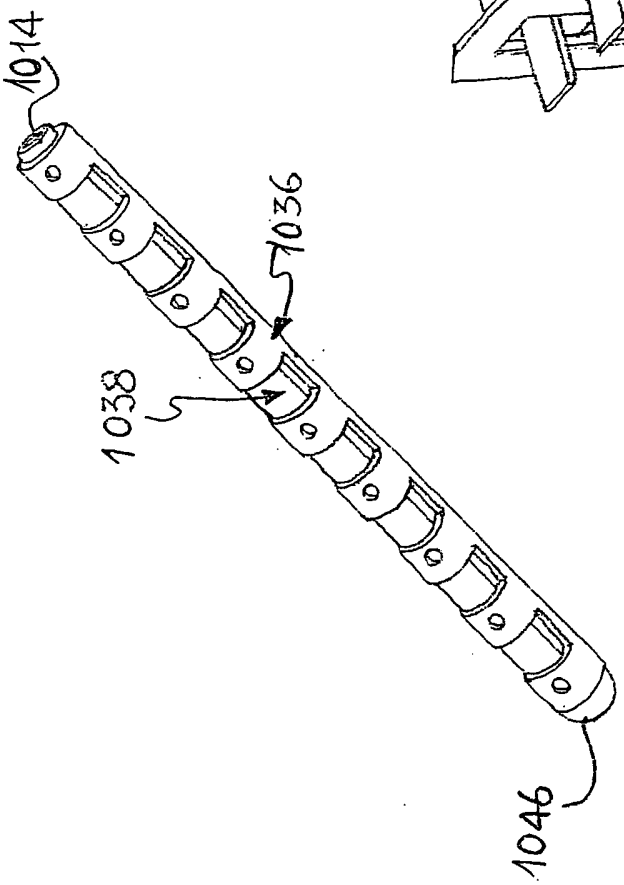


Fig- 22

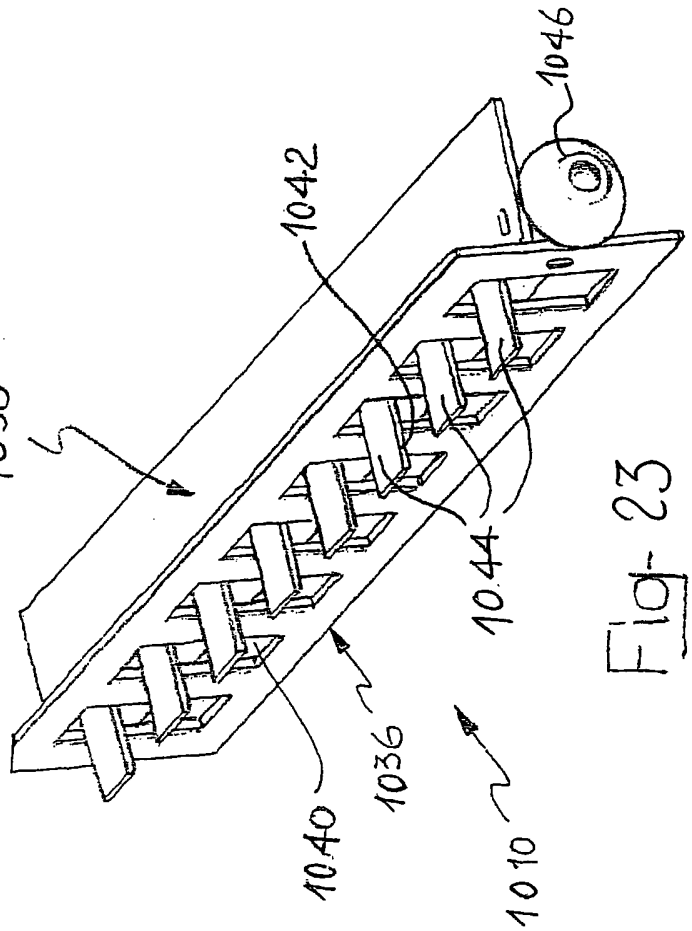


Fig- 23

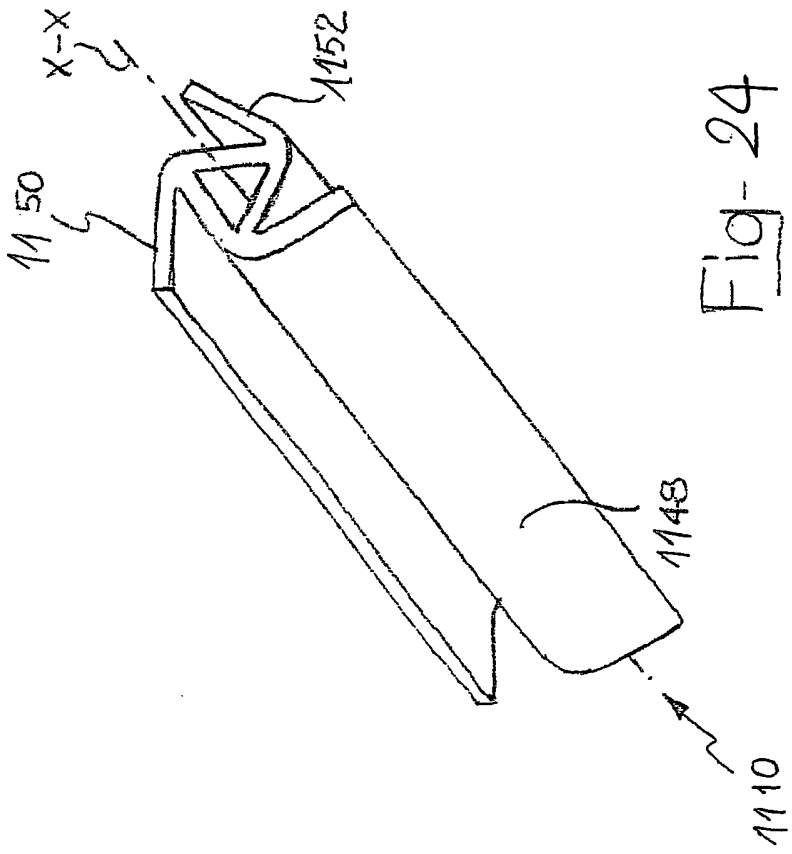


Fig- 24

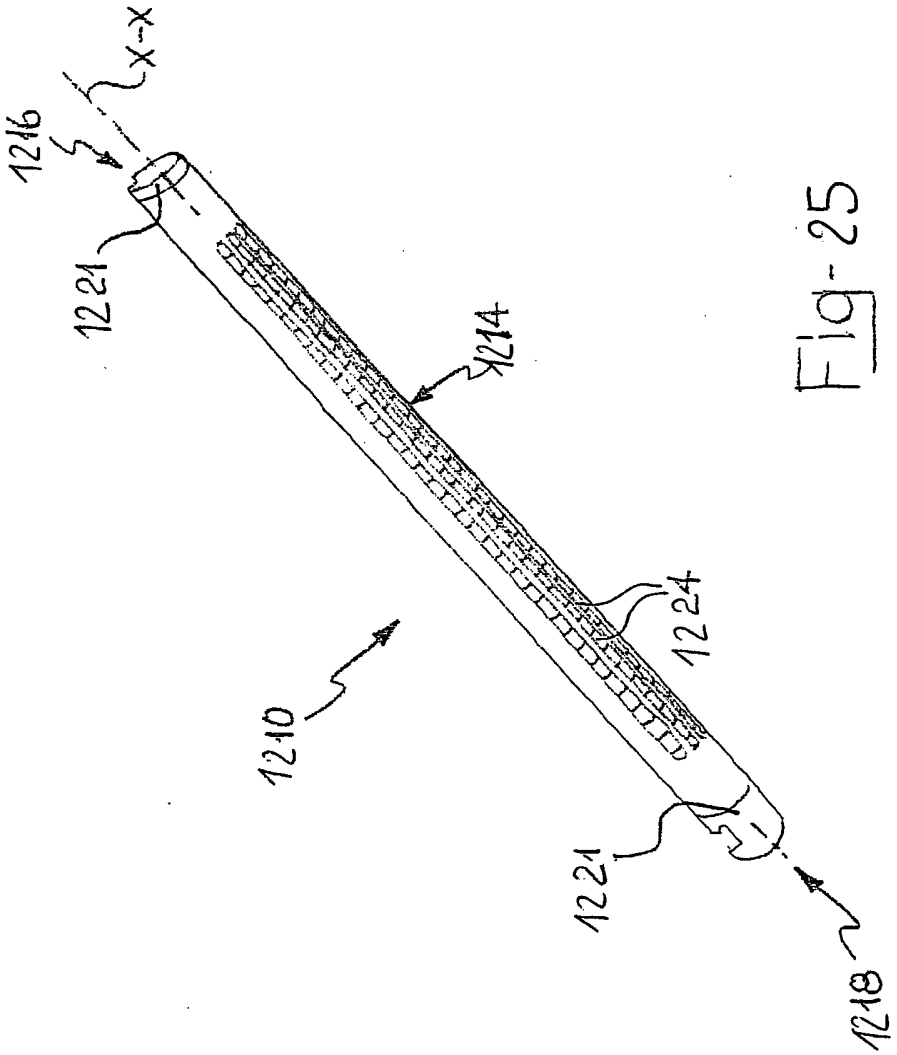


Fig-25

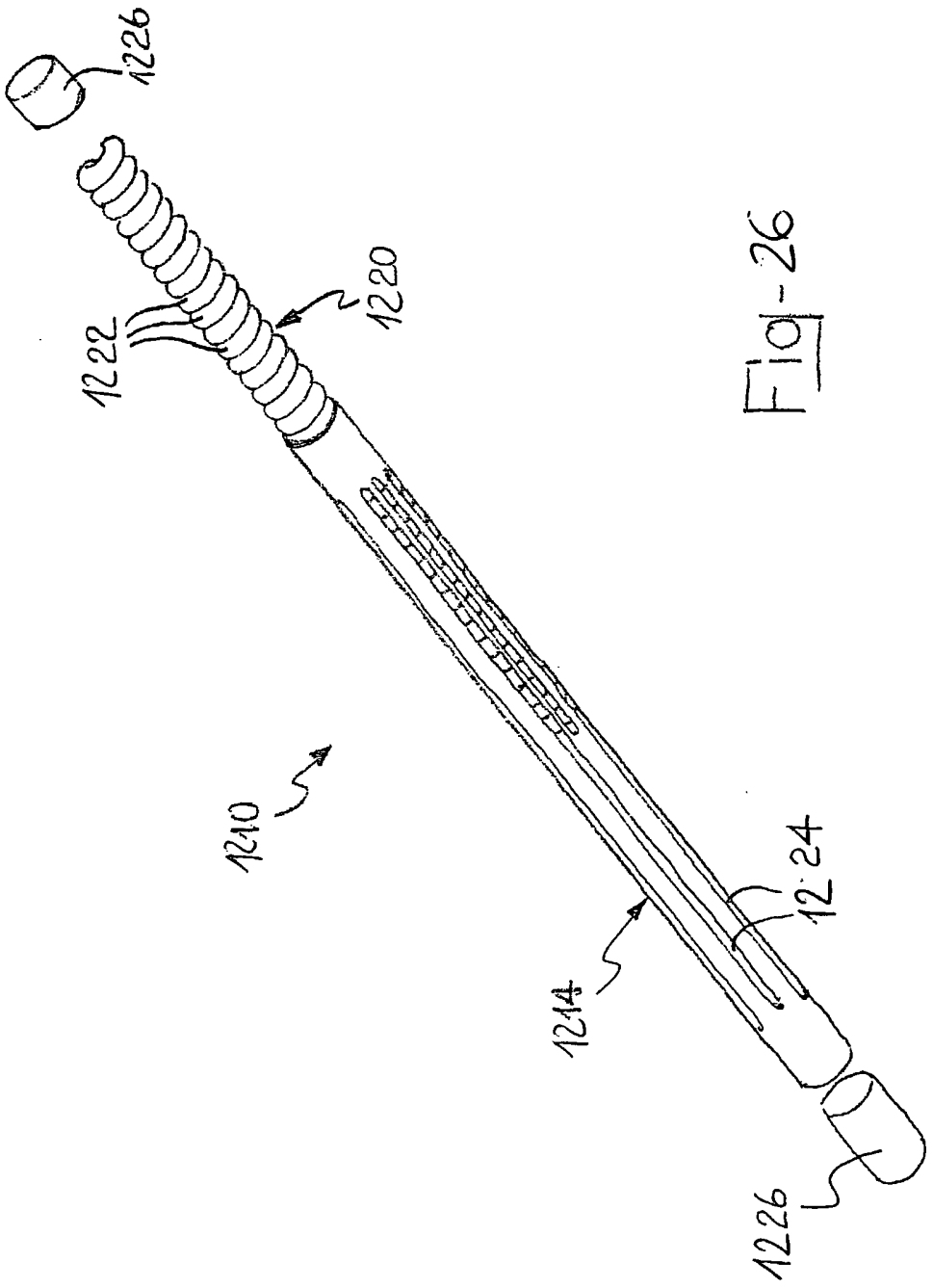


Fig - 26

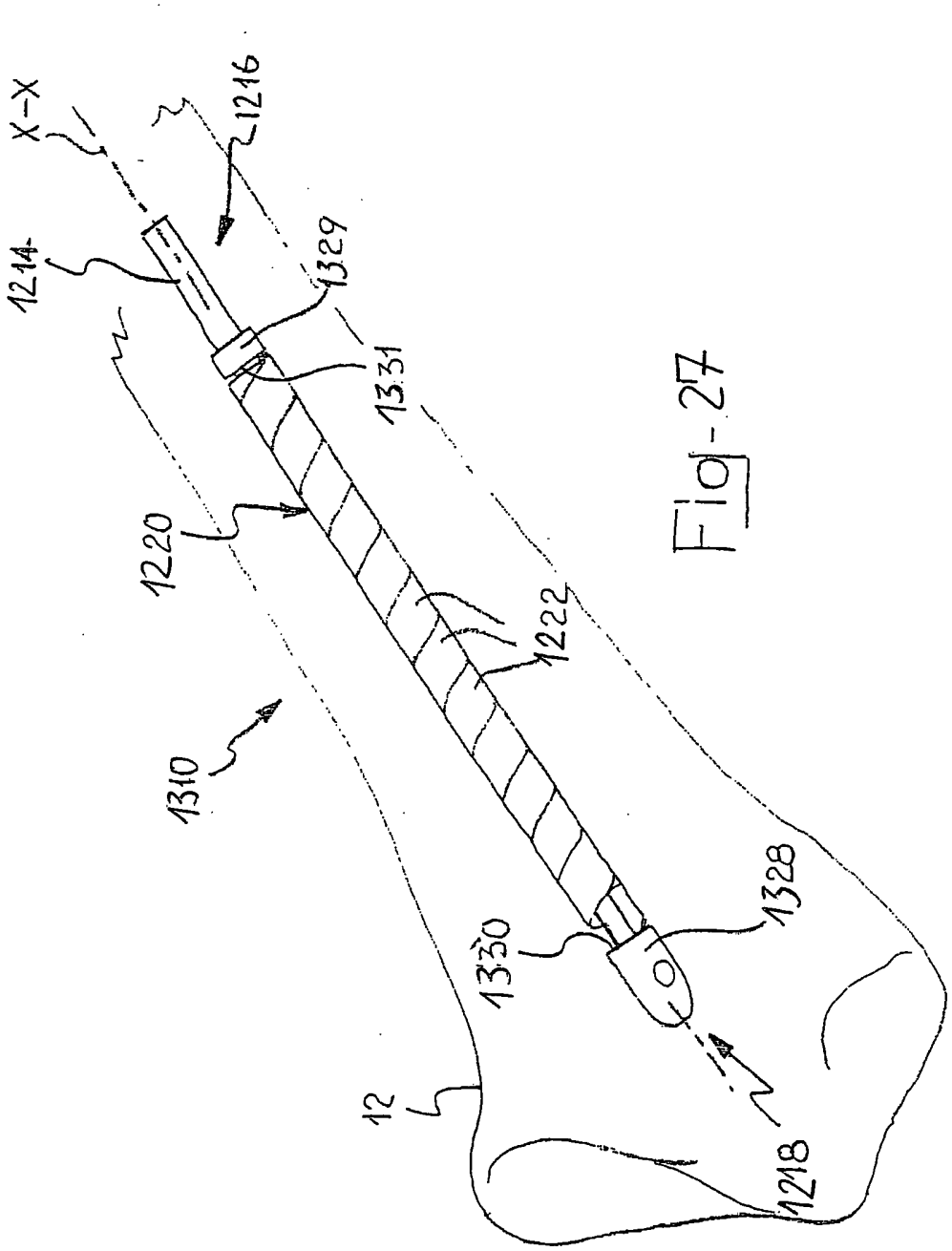
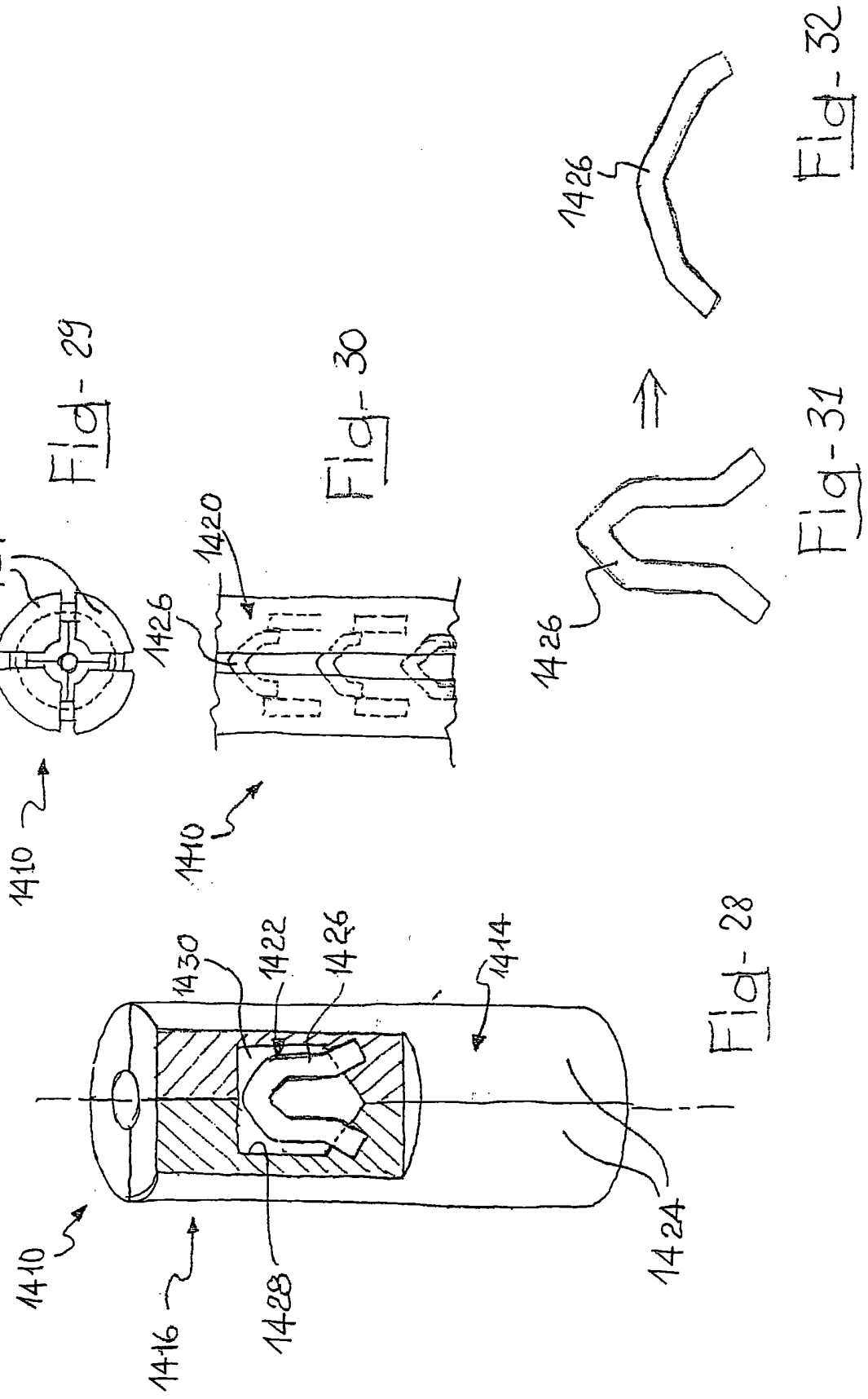


Fig - 27


1410
1416
1428
1430
1422
1426
1414
1424
Fig- 28
1410
1424
Fig- 29
1440
1420
1426
Fig- 30
1426
Fig- 31
1426
Fig- 32

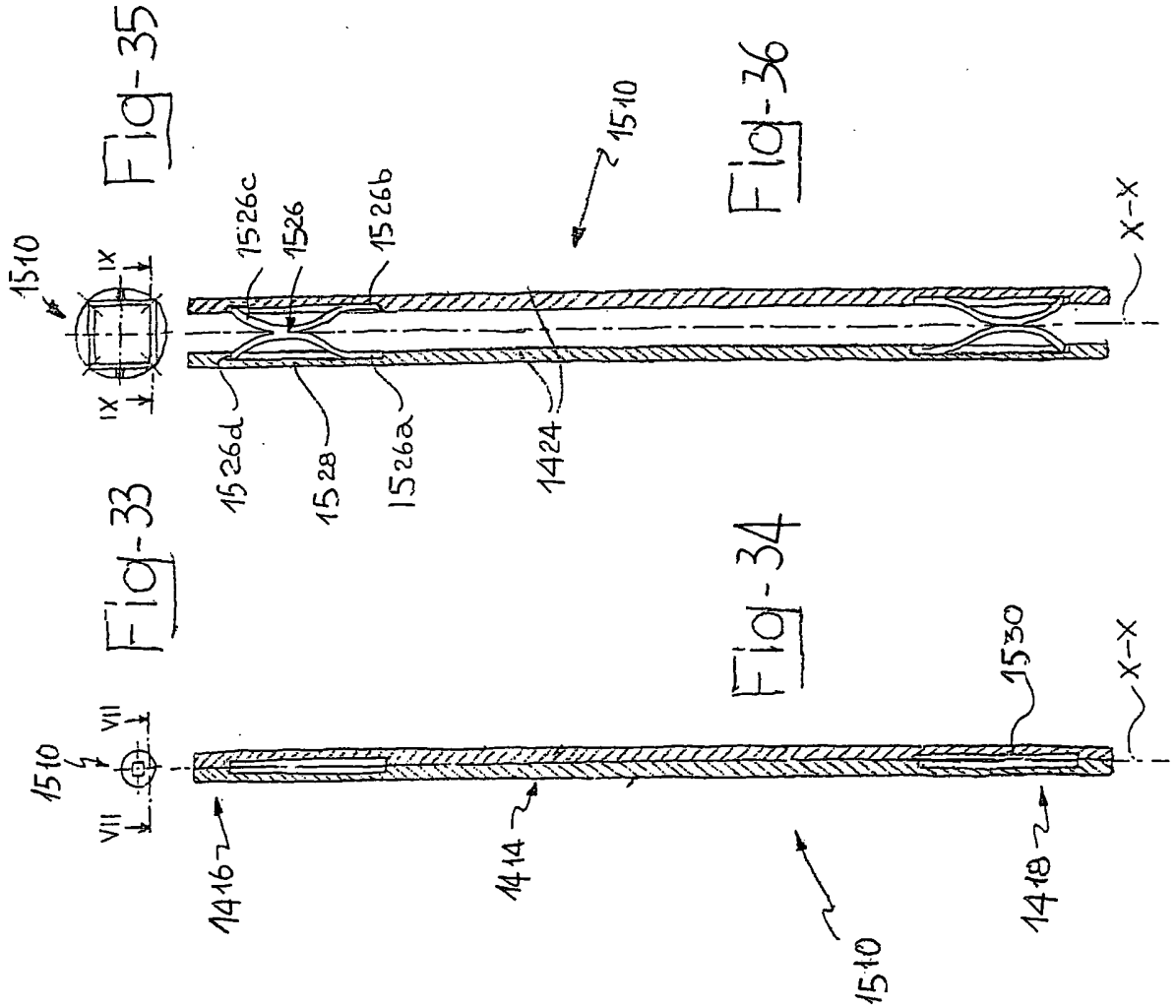
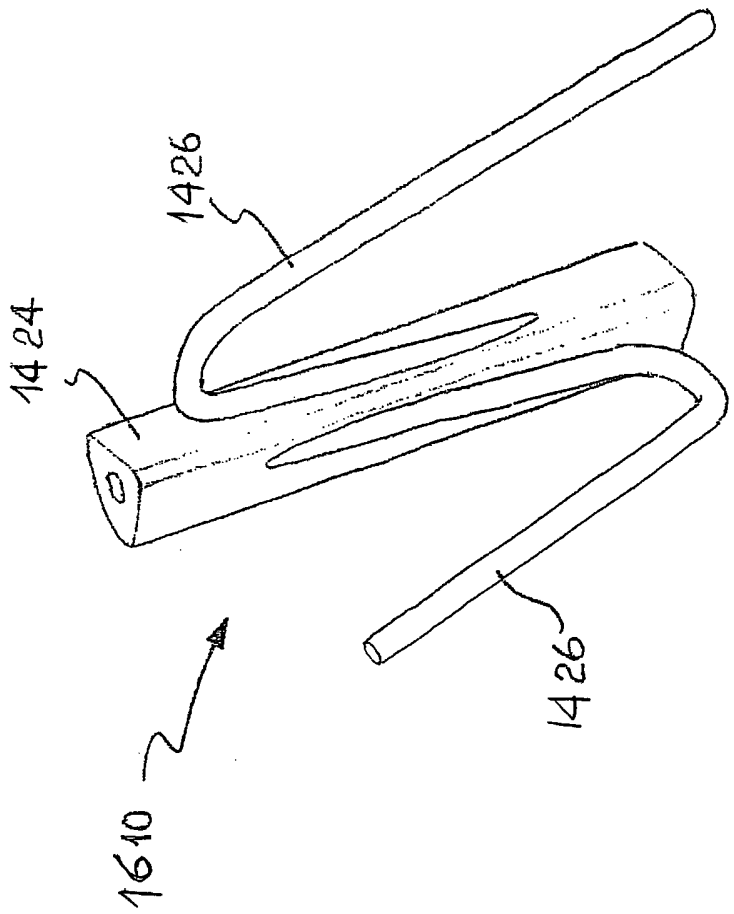


Fig-35
1510
IX
IX
15'26c
1526
15'26b
15'26d
1528
15'26a
Fig-36
1510
1424
X-X
Fig-33
1510
VII
VII
Fig-34
1530
X-X
1416
1414
1510
1418

Fig- 37



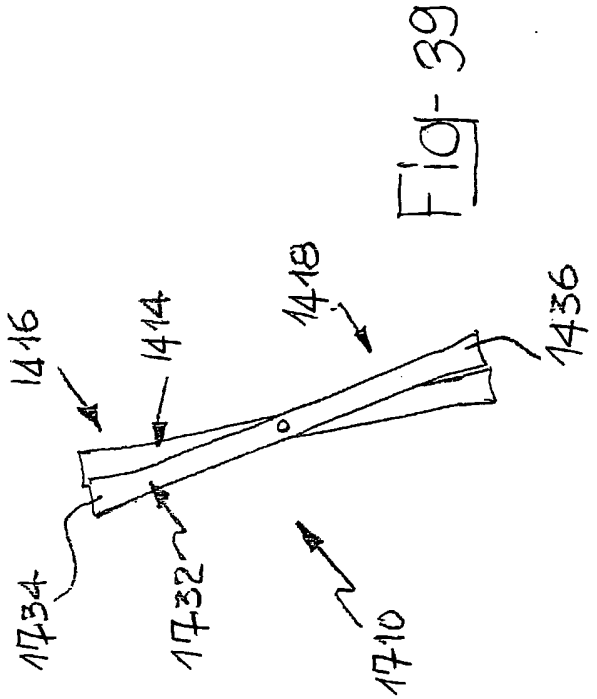


Fig- 39

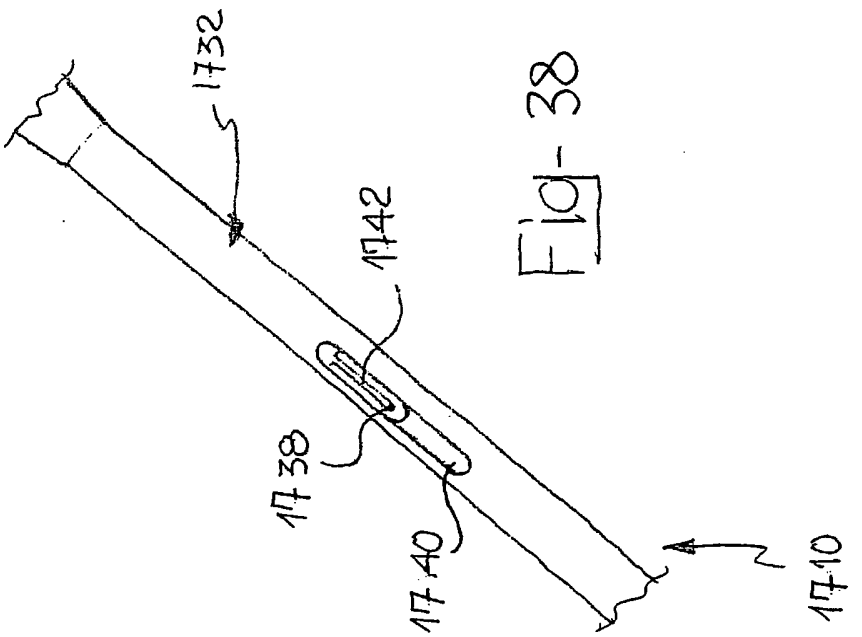


Fig- 38