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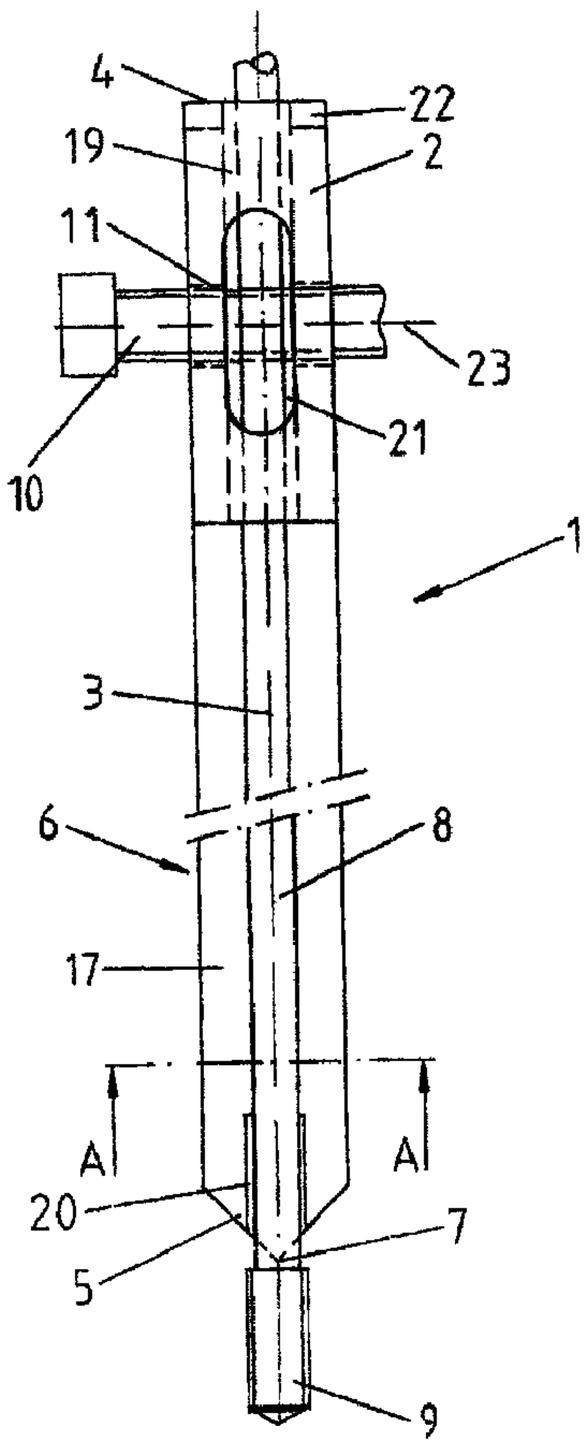
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(54) Titre : CLOU D'OSTEOSYNTHESE INTRAMEDULLAIRE POUR LE TRAITEMENT OPERATOIRE DE FRACTURES DE L'AVANT BRAS

(54) Title: INTRAMEDULLARY NAIL FOR THE OPERATIVE TREATMENT OF FRACTURES OF THE LOWER ARM



(57) Abrégé/Abstract:
A medullary-space nail to surgically treat fracture of thin, tubular bones in the human body, comprising a nail shank (1) having a longitudinal axis (3) and with a prismatic or cylindrical end part (2) at its upper end(4) fitted with connecting means for implements,

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(57) Abrégé(suite)/Abstract(continued):
a longitudinal stem (6) and a nail tip (7) situated at the lower end (5) to simplify implantation, at least the stem (6) comprising channels (15, 16) or boreholes running parallel to the longitudinal axis (3) and receiving locking wires (8), in such manner that the locking wires (8) can be displaced in the channels (15, 16) or boreholes coaxially with the longitudinal axis (3) and beyond the nail tip (7) and be screwed into the bone. Essentially the advantages offered by the Invention are controlled and reliable care of intramedullary fracture of a thin tubular bone, further a flexible implant allowing selecting different entry sites (retrogradely. anterogradely), and allowing correcting for excessively stretching the fracture by retracting the locking wires.

ABSTRACT

A medullary-space nail to surgically treat fracture of thin, tubular bones in the human body, comprising a nail shank (1) having a longitudinal axis (3) and with a prismatic or cylindrical end part (2) at its upper end (4) fitted with connecting means for implements, a longitudinal stem (6) and a nail tip (7) situated at the lower end (5) to simplify implantation, at least the stem (6) comprising channels (15, 16) or boreholes running parallel to the longitudinal axis (3) and receiving locking wires (8), in such manner that the locking wires (8) can be displaced in the channels (15, 16) or boreholes coaxially with the longitudinal axis (3) and beyond the nail tip (7) and be screwed into the bone. Essentially the advantages offered by the invention are controlled and reliable care of intramedullary fracture of a thin tubular bone, further a flexible implant allowing selecting different entry sites (retrogradely. anterogradely), and allowing correcting for excessively stretching the fracture by retracting the locking wires.

A MEDULLARY NAIL FOR THE SURGICAL TREATMENT OF FOREARM FRACTURES.

The invention relates generally to a medullary-space nail for the surgical treatment of fractures of thin tubular bones in the human body.

Plates and screws are ordinarily used in the surgical treatment of forearm fractures. Contrary to the case of medullary nail treatment in other tubular bones (tibia, femur and humerus), treating the ulna or radius with medullary nails has not been widely accepted so far. In some cases use is made of pairs of thin medullary nails. Some bone splinting is thus made possible. However rotation of the bone fragments cannot be prevented because the nails are not connected to each other. Moreover the medullary nails are affixed only by tensioning in the medullary space and outward migration of thin nails may raise problems. Experiments carried out with conventional locking nails failed because the small nail cross-section admits only minute cross-boreholes which, even when using an image intensifier, may be located only with difficulty. Also, the applicable locking pins are too small to absorb the generated forces.

A medullary space nail is already known from the US Engelhardt patent 4,805,607 which comprises a non-circular, preferably triangular cross-section with concave sides. Using a reamer, this configuration of the medullary nail allows implanting it in the medullary space of a bone without previously drilling open the medullary canal. The triangular nail allows cortical contact along three very thin metal edges. This localized configuration of the cortical contact much reduces the danger that the medullary nail will rotate in the medullary space.

Another medullary nail for the surgical treatment of forearm fractures, comprising a star-shaped nail cross-section, is marketed by Applied Osteo Systems Inc. Walnut Creek, California under the name of Trueflex Nail. Aside splinting the bone, the star-shaped nail cross-section is intended to prevent the main fragments from rotating. However this result is only possible provided the nail be struck as far as possible into

the medullary space in order that the nail tip may anchor in the spongy substance near the joint. However the fracture zone is stretched thereby and fracture healing is interfered with.

Yet, another intramedullary nail having a core and three flexible rods displaceable relative to the core is known from US 5,116,335 HANNON. The core of this known intramedullary nail comprises three grooves, which are situated on the circumference of the core with angles of 120° relative to each other and extending over the whole length of the core. On a length section of the core the grooves are shaped in their cross-section such that they reduce toward the outer surface of the core therewith holding the rods. At the proximal end and at the distal end of the intramedullary nail the cross-sections of the grooves do not taper toward the outer surface of the core, such that the rods may be bent away transversely to the central axis and being anchored within the bone.

Both known medullary nails incur the drawback that they may rotate within the medullary space. This danger is insufficiently precluded by the design of the star-shaped cross-section allowing cortical contact of the edges.

The objective of the invention is palliation. Its purpose is to so configure a medullary nail for forearm fractures that said nail shall be prevented from rotating in the medullary space and that moreover it shall be affixable.

The invention solves the above problem with a medullary nail to surgically treat fractures of thin, tubular human bones comprising a nail shank having a longitudinal axis, an upper end and a lower end, wherein, the nail shank includes an end part at the upper end to engage a tool, a longitudinal stem and a nail tip situated at the lower end for implantation into bone, and the nail shank includes channels extending parallel and excentric to the longitudinal axis for receiving locking wires, and to permit longitudinal movement of the locking wires in the channels and beyond the nail tip. The channels define an opening along a longitudinal portion of an outside

surface of the nail shank and the locking wires are retained within the channels in a direction transverse to the longitudinal axis.

Substantially the advantages offered by the medullary nail of the invention are:

- making possible controlled and reliable intramedullar care of fracture in a thin tubular bone, for instance the radius, ulna or children's tubular bones,
- making available a flexible implant permitting the selection of different entry sites (retrogradely, anterogradely), and
- excessive stretching of the fracture being correctable by retracting the locking wires.

The medullary nail of the invention comprises a nail shank fitted with channels running parallel and excentrically to the longitudinal axis and receiving locking wires running parallel to the medullary nail, two locking wires and one locking screw. The locking wires are rotatable inside the channels and can be shifted in the longitudinal direction of the medullary nail.

Depending on the size of the medullary space, it need not be prepared using a drill previous to the insertion of the medullary nail. If the medullary space diameter is at least 6 mm, the medullary nail may be inserted, absent pre-drilling, into the medullary space. Otherwise and similarly to nailing the humerus, tibia or femur, the medullary space must be bored open.

In a preferred embodiment of the medullary nail of the invention, the locking wires are fitted with threads at their ends near the nail tip. Furthermore the channels are fitted with matching inner threads in the vicinity of the nail tip, so that, when the medullary nail is inserted into the medullary space, the locking wires when screwed into the inside threads will thereby be affixed to the medullary nail. As soon as the proximal nail end is flush with the bone, the two locking wires are screwed sequentially manually or using a drill into the bone in the direction of the bone's end, the threads at the locking wires having been previously rotated out of the channels' inside threads. The metaphysis being very hard distally to proximally in the distal

ulna when nailing the radius in the proximal radius, the locking wires can be well anchored in the bone.

As regards elderly patients and advanced osteoporosis, the lacking bone substance at those sites may be replaced with biodegrading cement, and as a result the locking wires will also be well affixed in that cement.

Once the locking wires have been well anchored in the bone, the fracture gap can be closed by retracting the locking wires while simultaneously holding the nail shank in place. After the last check on the resetting of the fracture, the proximal locking screw will be set using an aiming device or x-ray monitoring. When the locking screw is inserted into the nail shank, the two locking wires at this side are slightly bent outward at this site, being locked in place both rotationally and axially. Once this step has been carried out, the fracture is stabilized. The medullary nail is secured again axially and rotationally by the two locking wires in one of the metaphyses and by the locking screw in the other metaphysis. Thanks to this locking technique, the nail need not be forcefully struck into the bone in order to implement geometric locking. Again small locking holes need not be searched for by x-rays or image intensification in the vicinity of the nail tip, nor need they be locked by a screw.

Aside being applied to the treatment of forearms (radius and ulna), this kind of medullary nail also may be used in children's fractures in the region of the thighs, lower legs and in the upper arm. Depending on the size and design of the thread at the tips of the locking wires, the fracture can be secured against rotation and axial butting while nevertheless permitting the tubular bone to grow because the nail is not locked with respect to traction and hence growth.

Advantageously the channel cross-section narrows where these channels open into the outside surface of the nail body. In this manner the locking wires are prevented from moving out of the channels transversely to the longitudinal axis. This design offers reliable security against the medullary nail rotating in the medullary space.

Further security against rotation and axial shifting of the medullary nail can be implemented by inserting a locking screw running transversely to the said nail. For that purpose a continuous borehole transverse to the longitudinal axis is fitted in the nail body in the region of its upper end.

The channels comprise a clearance in the region of the continuous borehole whereby the locking wires in the vicinity of said borehole can be bent around the locking screw. Because of the locking wires being bent while nevertheless resting against the locking screw, the medullary nail is axially secured additionally by said wires being screwed into the bone. Furthermore, besides the locking screw, additional locking of the nail tip is thus implemented in simple but effective manner and the nail cross-section is kept small.

Advantageously the shank of the nail comprises an oblate cross-section, two segments of parallel chords of a circle of diameter D and apart by a distance x and situated symmetrically to the longitudinal axis having been removed from the surface of said circle. The ratio x/D advantageously shall be 60 to 70 %.

In order to maximally space apart the locking wires at a minimum nail cross-section, the channels are situated in the peripheral arcs of circle of the shank cross-section. In this manner the medullary nail may be made small in spite of controlled locking.

The end part of the medullary nail away from the nail tip advantageously is cross-sectionally circular to allow connection to assembly or disassembly tools. A prismatic or cylindrical cross-section also may be applicable.

Depending on the desired stability, the material of the nail shank may be stainless steel, titanium, or, in the case of required high flexibility, also plastic. Moreover various materials may be combined as regards the nail-shank material and that of the locking wires.

A preferred embodiment of the invention is elucidated below in relation to the drawings.

Fig. 1 is an elevation of the preferred embodiment of the medullary nail of the invention,

Fig. 2 is a longitudinal section of the medullary nail of the invention shown in Fig. 1,

Fig. 3 is a cross-section of the medullary nail of the invention shown in Figs. 1 and 2, and

Fig. 4 is an enlargement of the cross-section of the medullary nail of the invention shown in Fig. 3.

A preferred embodiment of the medullary nail of the invention is shown in Figs. 1, 2 and 3 and consists of a nail shank 1, a locking screw 10 and two locking wires 8. The nail shank 1 further comprises a longitudinal axis 3, an upper end 4 and a lower end 5 and a circular-cylindrical end part 2 at the upper end 4 to connect to an assembly or disassembly tool, an adjoining stem 6 and a nail tip 7 at the lower end to facilitate implantation. The diameter D of the cylindrical part 2 is 6 mm. The stem 6 adjoining the end part 2 comprises an oblate cross-section 12 relative to the end part 2. As shown cross-sectionally in Fig. 4, two segments with parallel chords 14 symmetrical to the longitudinal axis 3 and a distance 4 mm apart have been removed from the circular surface 24 of diameter D and with its origin on the longitudinal axis 3 of the cross-section 12. Two mutually diametrically opposite channels 15, 16 are fitted parallel to the longitudinal axis 3 into the two peripheral arcs of circle 13 of the cross-section 12 remaining between the chords 14 and these receive the locking wires 8. The channels 15, 16 configured symmetrically to the peripheral arcs of circle 13 are situated on a diametrical axis of symmetry 28 and consist of boreholes 23 having a diameter d = 2 mm and being mutually apart by a distance z = 4 mm. The channels 15, 16 are open in the direction of the peripheral arcs of circle 13 by means of parallel lateral surfaces 25, 26 resp. running in the direction of the longitudinal axis 3.

The lateral surfaces 25, 26 are apart by a distance y < d in the direction perpendicular to the longitudinal axis 3 and as a result the channels 15, 16 narrow toward the outside surface 27 of the stem 6 and thereby the locking wires 8 will be displaceable in the direction of the longitudinal axis 3 inside the channels 15, 16 while being precluded from slipping sideways out of them.

The channels 15, 16 are fitted with inside threads 20 in the region of the lower end 5 which cooperate with the outside threads at the threaded tips 9 of the locking wires 8. In this manner the locking wires 8 together with the threaded tips 9 can be rotated back in the channels 15, 16 when the nail shank 1 is inserted into the medullary space and as a result they will not snag during said insertion into the medullary space. Following implantation of the nail shank 1, the locking wires 8 are rotated back manually or by machine out of the nail shank 1 toward the nail tip 7 and are screwed into the spongy substance and/or corticalis of the bone. The locking wires 8 being substantially longer than the nail shank, the depth of penetration in the metaphysis zone can be selected freely. Following the nailing process, the projecting ends of the locking wires will be severed. When tending to porous bones, a bio-cement (for instance Nioran or other degrading cements) may be additionally used. When injected in the diaphysis zone, this cement assures good anchoring of the locking wires 8 which nevertheless can be removed anytime by being rotated backward.

The locking of the upper end 4 of the nail shank 1 is implemented by a locking screw 10 inserted into the borehole 11 crossing the stem 6 transversely to the longitudinal axis 3. To prevent the locking wires 8 from covering the borehole 11 in latter's vicinity, clearances 21 symmetrical to the borehole 11 are fitted in this vicinity in the channels 15, 16 to allow the locking wires 8 to move out of the channels 15, 16 and so they may be bent around the locking screw 10. This evasive motion of the locking wires 8 leads to further clamping of the locking wires 8. In this manner the fracture is secured not only rotationally but also against axial, longitudinal displacement.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A medullary-space nail for treatment of tubular bones in the human body, comprising:

(a) a nail shank having a longitudinal axis, an upper end and a lower end, wherein;

(b) the nail shank comprises an end part at the upper end to engage a tool, a longitudinal stem and a nail tip situated at the lower end for implantation into bone; and

(c) the nail shank includes channels extending parallel and eccentric to the longitudinal axis for receiving locking wires, and to permit longitudinal movement of the locking wires in the channels and beyond the nail tip;

wherein the channels define an opening along a longitudinal portion of an outside surface of the nail shank and the locking wires are retained within the channels in a direction transverse to the longitudinal axis.

2. The medullary nail of claim 1, wherein the channels have an inside thread proximal the lower end.

3. The medullary nail of claim 1, wherein the nail shank defines a throughbore proximal the upper end, the throughbore having a central axis extending transversely to the longitudinal axis for receiving a locking screw therethrough to preclude displacement of the nail shank relative to the longitudinal axis as well as rotation of the nail shank about the longitudinal axis.

4. The medullary nail of claim 1, wherein the nail additionally comprises locking wires.

5. The medullary nail of claim 3, wherein the channels comprise a recess proximal the throughbore, and the locking wires are bendable around the locking screw.

6. The medullary nail of claim 2, wherein the nail additionally comprises locking wires and the locking wires comprise threaded tips corresponding to the inside threads of the channels, said tips being displaceable parallel to the longitudinal axis beyond the nail tip and screwable into the bone.

7. The medullary nail of claim 1, wherein the stem has an oblate cross-section with a perimeter including two parallel chord segments offset by a first distance and a pair of opposite semi-circular segments having a first diameter.

8. The medullary nail of claim 7, wherein the ratio of the first distance to the first diameter is in a range of about 0.50 to about 0.80.

9. The medullary nail of claim 8, wherein the ratio of the first distance to the first diameter is in a range of about 0.60 to about 0.70.

10. The medullary nail of claim 7, wherein the channels are adjacent the semi-circular segments of the cross-section.

11. The medullary nail of claim 1, wherein the end part has a circular cross-section.

12. The medullary nail of claim 1, further comprising a locking screw.

13. The medullary nail of claim 1, wherein the nail shank is made of titanium.

14. The medullary nail of claim 1, wherein the nail shank is made of stainless steel.

15. The medullary nail of claim 1, wherein the nail shank is made of plastic.

16. The medullary nail of claim 15, wherein the medullary nail is made of a polyether ether ketone (PEEK) plastic.

17. The medullary nail of claim 1, wherein the end part has a prismatic cross-section.

18. A medullary-space nail for treatment of tubular bones in the human body, comprising:

a nail shank having a longitudinal axis extending from an upper end to a lower end, wherein

the nail shank comprises an end part at the upper end to engage a tool, a longitudinal stem and a nail tip situated at the lower end for implantation into bone, and

the nail shank includes channels extending longitudinally through the shank and extending eccentric to the longitudinal axis; and

locking wires insertable into the channels and configured and dimensioned to permit longitudinal movement therethrough, and each locking wire comprises a threaded tip, said threaded tip being displaceable beyond the nail tip and screwable into the bone to preclude rotation of the nail shank about the longitudinal axis.

19. The medullary nail of claim 18, wherein the nail shank defines a throughbore having a central axis extending transversely to the longitudinal axis for receiving a locking screw therethrough to preclude displacement of the nail shank relative to the longitudinal axis.

20. The medullary nail of claim 18, wherein the channels comprise a recess in the region of the thoughbore, and the locking wires are bendable around the locking screw.

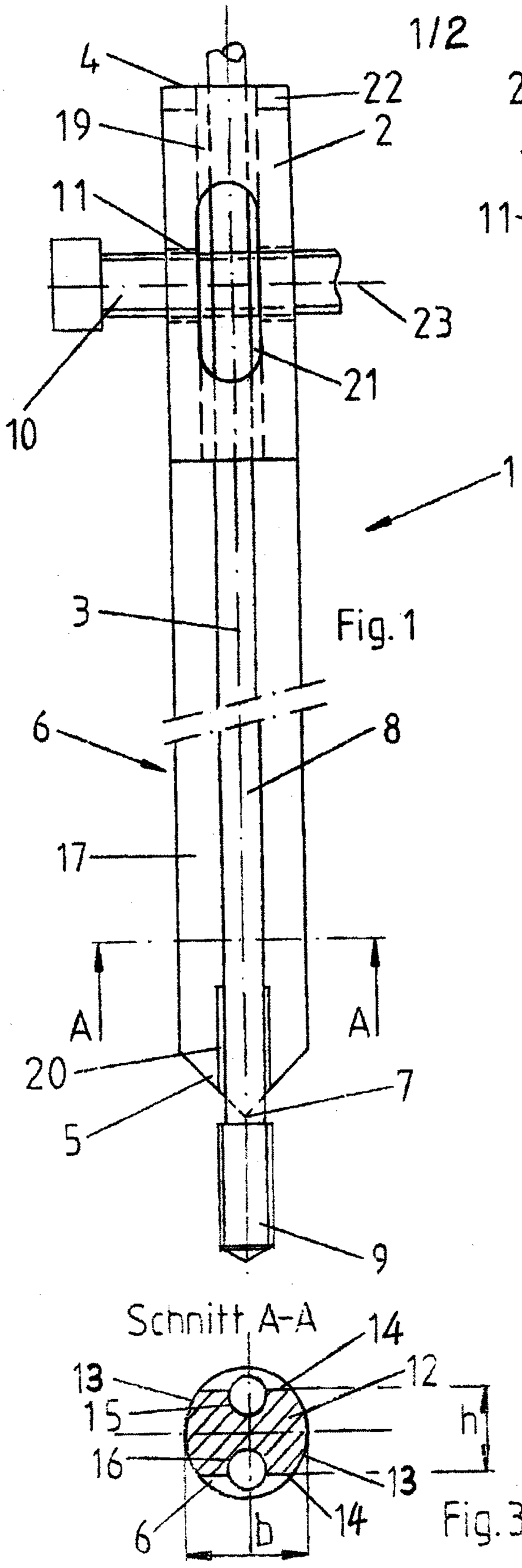


Fig. 1

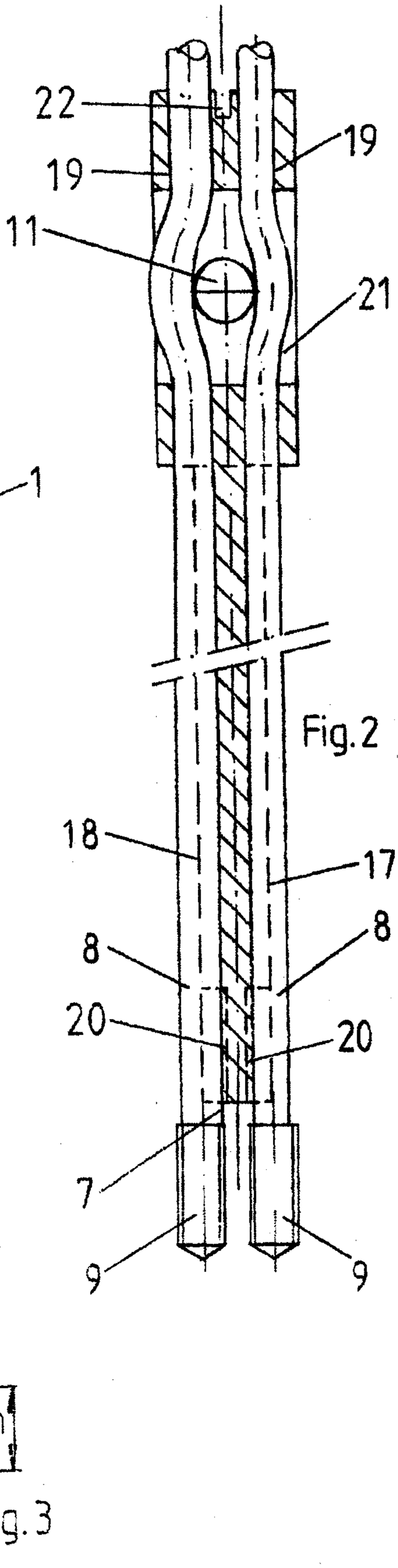


Fig. 2

Fig. 3

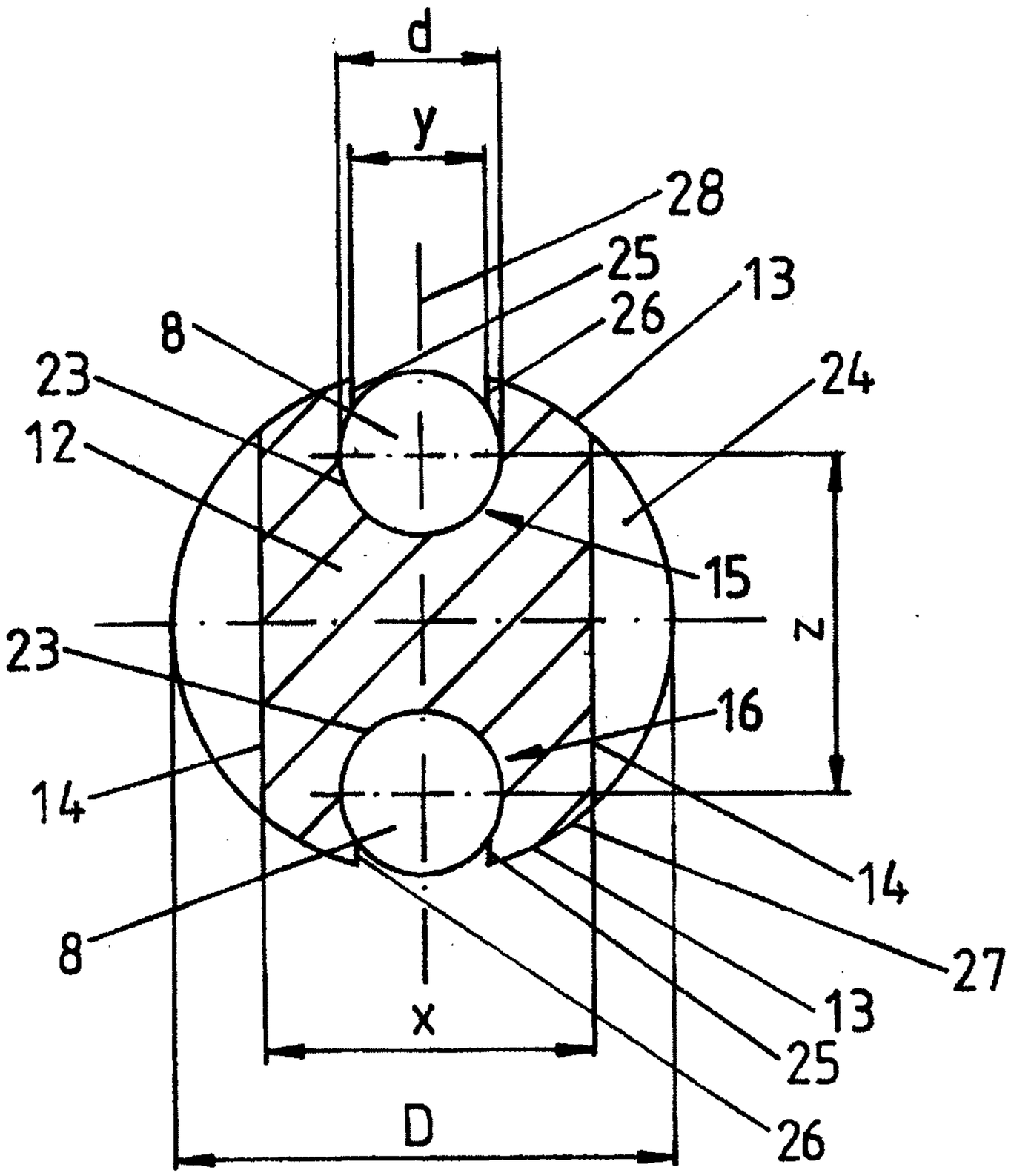
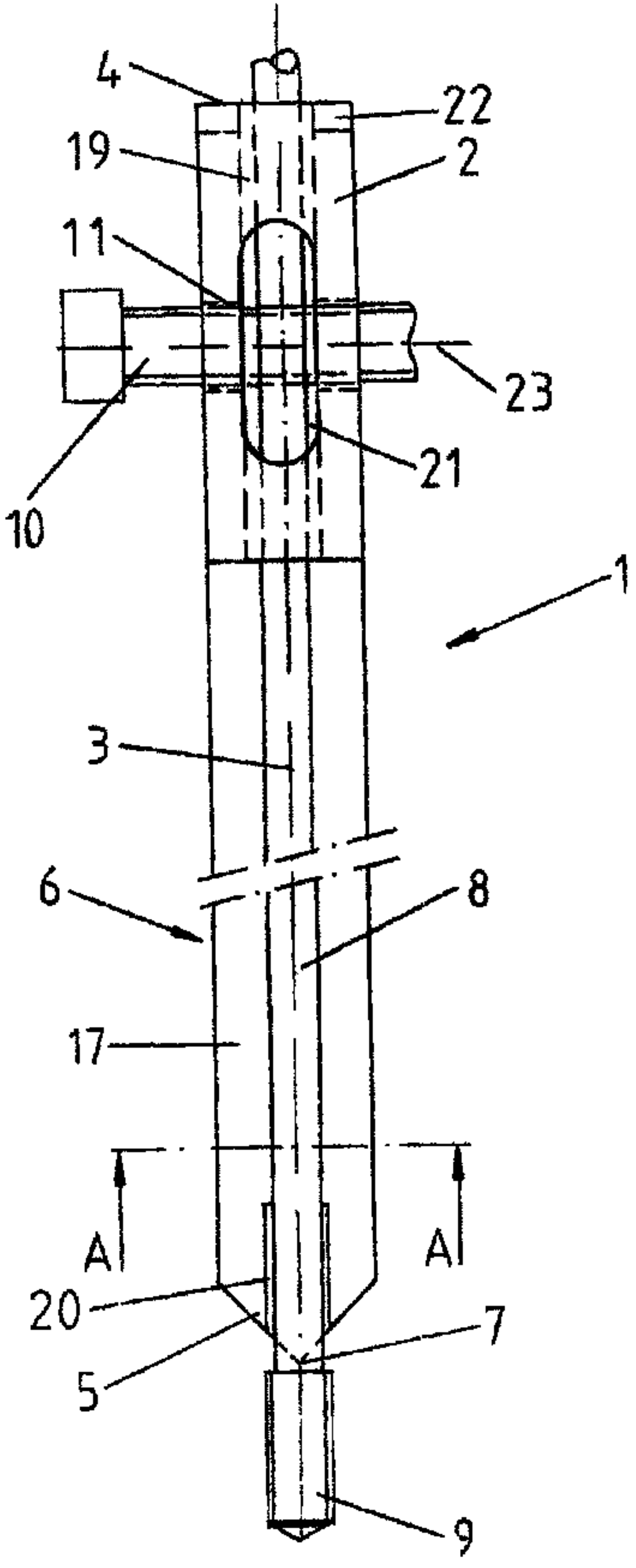


Fig. 4


4
22
19
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