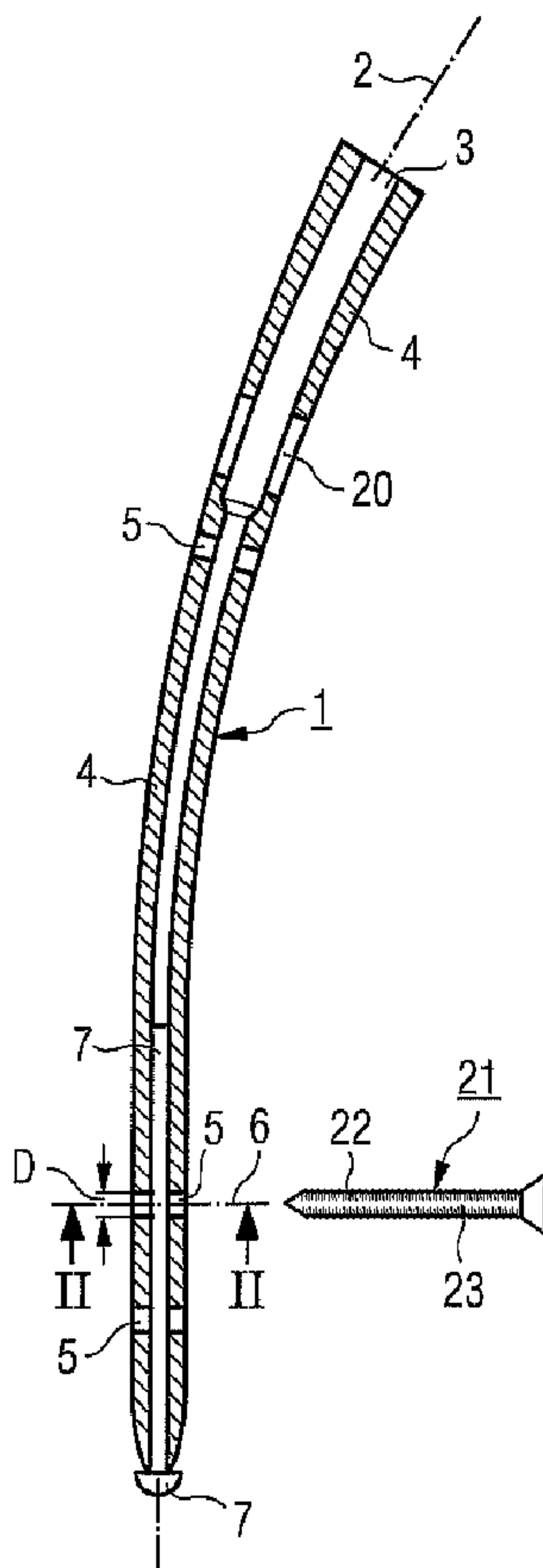




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(57) Abrégé/Abstract:

The invention relates to a surgical nail (1), in the form of an intramedullary nail with a central axis (2), consisting of a material M with the tensile strength  $F_z$ , the compression strength  $F_d$ , the density  $\rho_2$  and the modulus of elasticity E. Said nail (1) has at least at least

(57) **Abrégé(suite)/Abstract(continued):**

one transverse borehole (5), extending transversely to the central axis (2) with the cross-sectional profile F and a transverse axis (6), the cross-sectional profile F having a maximum length a in the direction of the central axis and, perpendicularly thereto, a maximum width b. The nail furthermore has a longitudinal borehole (3), which extends coaxially with the central axis (2), and a wall (4), as well as an insert (7) with the longitudinal axis (13), which can be introduced over the longitudinal borehole (3) into the region of the transverse borehole (5), of a material "m", which has a lower modulus of elasticity  $e < E$  than does the material M.

### Abstract of the Disclosure

The invention relates to a surgical nail (1), in the form of an intramedullary nail with a central axis (2), consisting of a material M with the tensile strength  $F_z$ , the compression strength  $F_d$ , the density  $\rho_2$  and the modulus of elasticity E. Said nail (1) has at least at least one transverse borehole (5), extending transversely to the central axis (2) with the cross-sectional profile F and a transverse axis (6), the cross-sectional profile F having a maximum length a in the direction of the central axis and, perpendicularly thereto, a maximum width b. The nail furthermore has a longitudinal borehole (3), which extends coaxially with the central axis (2), and a wall (4), as well as an insert (7) with the longitudinal axis (13), which can be introduced over the longitudinal borehole (3) into the region of the transverse borehole (5), of a material "m", which has a lower modulus of elasticity  $e < E$  than does the material M.

English Translation of PCT/CH03/00375

## **SURGICAL NAIL**

The invention relates to a surgical nail, especially to an intramedullary nail of the introductory portion of claim 1.

The locking of medullary nails is part of the state of the art. The locking screws or locking bolts (in the following, only the expression, a locking screw, is used; however, it is intended to include also the expression, locking bolt) is inserted into the transverse boreholes of the medullary nail either with the help of an imaging method (X-ray control) or a more or less complicated targeting device. In both cases, a certain targeting inaccuracy cannot be avoided, that is, the tip of the screw cannot be aligned precisely coaxially with the central axis of the transverse borehole and, instead, deviates therefrom by a certain amount. The external diameter of the screw is underdimensioned relative to the diameter of the transverse borehole so that, in spite of this targeting error, the locking screw ends up in the transverse borehole and can be brought through this borehole. If the targeting inaccuracy remains within the scope of this underdimensioning, the locking screw can be passed through the transverse boreholes without any problems in spite of this targeting error. However, because of the underdimensioning, the locking screw now has a certain clearance relative to the transverse borehole.

This clearance defines the amount by which the main bone fragments, which are to be locked by means of the locking screws in the corresponding locking hole, can move relative to the nail and accordingly, because of the rigidity of the nail, also relative to the other main fragments of the bone fastened with the same nail. Admittedly, this clearance is unavoidable in order to guarantee the applicability of the locking for the surgeon. However, it is clinically undesirable for certain indications, for example, in the case of metaphysical fragments.

Even nails with a full cross-section, which may have an internal thread in the locking hole, are not free of clearance. The internal thread merely prevents the nail from shifting axially on the locking screw.

From US patent 6,296,645, a hollow, intramedullary metal nail is known, which has one or two plastic inserts, through which the locking screw can be introduced, in the casing openings of the transverse borehole, which are diametrically opposite to one another and are referred to as windows. It is a disadvantage of this known medullary nail that the window-like plastic inserts can be pressed in under the stresses occurring during clinical use, so that the desired function is lost. However, even if the manipulations are carried out very carefully, the two plastic inserts could be pressed out of their "window" when the locking screw is passed through, which also leads to a loss of function.

The invention is to provide a remedy here. It is an object of the invention to create a surgical nail, especially an intramedullary nail, with which the clearance, existing between it and the locking screw, can be eliminated without risk and an improved holding force between the locking screw and the medullary nail can be achieved, without requiring higher precision from the user during his work.

Pursuant to the invention, this objective is accomplished with a surgical nail, which has the distinguishing features of claim 1.

With these, the following advantages can be achieved:

- a) the targeting accuracy is not affected when the locking screw is introduced;
- b) the nail and the insert can be packaged separately in a sterile manner and the surgeon can elect to use the nail with or without the insert. In the former case, the surgeon himself can introduce the insert into the nail and, optionally, also remove it once again. If the surgeon uses the nail without an insert, the latter remains sterile in its package for a next use. The doctor accordingly can decide during the operation whether or not to use an

angularly stable locking of the locking screw, the concept of "angularly stable" denoting a limitation of certain degrees of freedom.

- c) The possibility of fixing bone fragments angularly stably in certain directions for a certain amount of the load.

In accordance with a preferred further development of the invention, the insert is constructed rod-shaped and can be introduced through the longitudinal borehole of the nail into the region of the transverse boreholes. The surgeon can insert the insert even after the nail has been implanted (without an insert), in that the insert is pushed forward from proximal direction into the longitudinal borehole as far as the region of the transverse boreholes.

The material  $m$  of the insert preferably has a lesser compresses strength  $f_d < F_d$  as well as a lesser tensile strength  $f_z < F_z$  than the material  $M$ . The modulus of elasticity "e" of the insert preferably is less than 0.8 E and typically less than 0.7 E.

For a special embodiment, the material  $m$  of the insert consists of a biocompatible plastic, preferably a polyethylene or a high molecular weight polyethylene (HMWPE). This has the advantage that there is no breakdown of the plastic with unknown breakdown products.

In the case of an alternative, the material of lesser hardness, which is brought into the longitudinal borehole of the hollow nail, consists of a bioabsorbable plastic, which preferably is a polylactide. For this embodiment, initially there is a clearance-free transverse locking of the medullary nail, which then, with increasing absorption of the polymer, is canceled successively once again, so that the transverse locking screw becomes movable once again relative to the medullary nail and, with that, also the bone fragments, which have been taken care of. Accordingly, after the fracture has consolidated, there is a dynamization of the bone fragments.

A further advantage of the bioabsorbable material consists therein that the chips, which result when a locking screw is screwed through the nail, can be broken down by the body.

In the case of a further embodiment, the nail has at least two transverse boreholes and preferably at least three transverse boreholes. One of the transverse boreholes may also be constructed as an elongated hole with the cross-sectional profile of an F, the longer dimension "a" of the elongated hole being disposed in the axial direction of the nail.

The material "m" of the insert preferably also has a density  $\rho_1$ , which is less than the density  $\rho_2$  of the material M,  $\rho_1$  preferably being less than  $0.8 \rho_2$ .

The nail may comprise a locking screw or a locking bolt, which can be introduced into the transverse borehole (with the F-shaped cross-sectional profile) and through the insert, and the external thread or threadless shaft of which has an external diameter "d", which fulfills the condition  $a > d < b$ .

In the case of a further embodiment, the rod-shaped insert has a central longitudinal borehole.

The diameter of the longitudinal borehole of the nail may vary in the direction of its central axis and the longitudinal borehole preferably has a circular offset.

In the case of a further embodiment, the rod-shaped insert may also have a depression, which extends radially and transversely to its longitudinal axis. Due to this depression, a locking screw or a locking bolt can be centered and drilled through the insert more easily and fewer shavings of the material "m" result. The insert may also have several depressions, which are disposed in the same way as the transverse boreholes of the nail.

In the case of a further embodiment, the rod-shaped insert may be constructed conically. Due to this shape, the insert can be introduced more easily from the distal direction into the longitudinal borehole of the nail and, moreover, a press fit is possible.

In the case of a further embodiment, the a rod-shaped insert and the wall of the nail have interacting means, preferably in the form of a groove and an elevation, which fits in to the groove, the interacting means fixing the insert rotatively in a previously specified position relative to the nail.

The rod-shaped insert may have one or more elevations, extending radially and transversely to its longitudinal axis. These elevations may be disposed similarly to the transverse boreholes in the nail. The elevations have a transverse extent "x", which advantageously fulfills the condition  $1 < x/q < 2$ , "q" being the diameter of the insert (7). The advantage of this embodiment consists therein that, when the insert is introduced into the longitudinal borehole of the nail, the elevations snap into the transverse boreholes, so that the insert is positioned unambiguously and securely in the nail. Moreover, the increased displacement volume leads to an improved holding force, that is, to an increased angular stability.

The nail may be made available to the surgeon with an insert, already introduced into its longitudinal borehole up into the region of the transverse boreholes or, alternatively, the nail and insert may be provided as separately packaged parts.

The nail may be used together with a locking screw with a screw shaft and an external thread. For the diameter d of the screw thread,  $a > d < b$ . Preferably, "d" is at least 5% smaller than the smaller of the two dimensions a, b.

To produce the nail, a solid of a material "m" can be introduced into the longitudinal borehole of the nail from the upper or lower end of the latter (made from the material M), so that the solid comes to rest at least in the region of one of the transverse boreholes of the nail.

The invention and further developments of the invention are described in even greater detail in the following by means of partly diagrammatic representations of several embodiments. In the drawing,

Fig. 1 shows a longitudinal section through a hollow medullary nail, partially filled with a softer material,

Fig. 2 shows a cross-section of the medullary nail in the region of the transverse borehole,

Fig. 3 shows an insert of a biocompatible plastic for the introduction into the distal end of a hollow medullary nail with radial countersinkings or boreholes corresponding to the position of the transverse boreholes in the medullary nail,

Fig. 4 shows a transverse section through the medullary nail in the region of the transverse borehole with a rotation-securing insert,

Fig. 5 shows a view of a rotation-securing insert of biocompatible plastic for insertion into the distal end of a hollow medullary nail with radial elevations corresponding to the position of the transverse boreholes in the medullary nail,

Fig. 6 shows a longitudinal section through an insert of biocompatible plastic for introduction into the proximal end of a hollow medullary nail,

Fig. 7 shows a longitudinal section, rotated through 90°, through the insert of Fig 6 and

Fig. 8 shows a view of an insert for introduction into the proximal end of and over the whole length of the hollow medullary nail.

The surgical nail 1, shown in Fig. 1, is an intramedullary nail for tubular bones with a central axis 2, the nail consisting of a material M (metal or metal alloy) and having three transverse boreholes 5, which extend transversely to the central axis 2, a diameter D and a transverse axis 6. A fourth transverse borehole is mounted proximally and constructed as an elongated hole 20, the longer dimension being disposed in the axial direction. Two of the three transverse boreholes 5 are provided in the distal part of the medullary nail 1. Coaxially with the central axis 2, the medullary nail has a longitudinal borehole 3 and, as a result, a wall 4. A rod-shaped insert 7 (Fig. 3), in the form of a one-piece solid of absorbable polylactide, is inserted into this longitudinal borehole 3, so that, in the region of the two distal transverse boreholes 5, the longitudinal borehole 3 is filled with an accurately fitting material m of lower strength, especially with a lower modulus of elasticity (in comparison to the material M of the medullary nail). However, a press fit of the material m is also possible.

As shown in Fig. 1, a locking screw 21 with the shaft 22 and the external thread 23 can be screwed into the transverse borehole 5 and, with that, through the insert 7.

The insert 7 has a longitudinal borehole 8, which extends coaxially with its longitudinal axis 13. At its distal end, it has a hemispherical expansion 11 with a proximally directed stop 10. A secure, axial positioning of the insert 7 in the longitudinal borehole 3 of the medullary nail is guaranteed by the stop 10 of the expansion 11.

The insert 7 has four depressions 12, which extend radially and transversely to the longitudinal axis 13 and are disposed axially, so that they are level with the transverse boreholes 5 of the medullary nail, when the insert 7 is introduced into the longitudinal borehole 3 up to the stop 10. So that the depressions 12 are also aligned radially with the boreholes 5, the insert 7, as shown in Fig. 2, has a profile 15, which corresponds with a profile 16 in the longitudinal borehole 3 of the medullary nail, so that the insert 7 can be introduced into the longitudinal borehole 3 only in a certain rotative position.

As shown in Fig. 4, the insert 7 and the longitudinal borehole 3 of the medullary nail may also have two ribs/grooves 17, 18 instead of the profiles 15, 16 in the form of flattenings. The ribs/grooves 17, 18 bring about the same rotation-blocking effect.

In Fig. 5, an alternative to the insert 7 of Fig. 3 is shown, for which, instead of depressions 12, elevations 14 are present, which, due to their elasticity, can be snapped into the openings of the transverse boreholes 5 in the wall 4, so that an axial and rotative securing of the insert 7 can also be achieved. The transverse extent  $x$  of the elevations 14 is subject to the condition that  $1 < x/q < 2$ ,  $q$  being the diameter of the insert 7.

In Figs. 6 and 7, a further, alternative insert 7 is shown, which can be introduced into the proximal end of , instead of the distal end of the longitudinal borehole 3 of the medullary nail. It has an axial longitudinal borehole 8, as well as an elongated hole 19, which corresponds to the elongated hole 20 in the medullary nail 1. The borehole 19 is approximately elliptical, with a long axis  $a$  and a short axis  $b$ .

A further embodiment of the insert 7 is shown in Figure 8 and has approximately the same length as the medullary nail and, accordingly, covers all transverse boreholes 5 (locking boreholes) of the medullary nail from the proximal to the distal. The insert 7 is fixed by a thread 24 in the proximal region of the

insert 7 in the hollow medullary nail. If necessary, the insert 7 can also be shortened during a surgical procedure.

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

1. An intramedullary nail comprising:

a nail body having a central axis, a proximal end, a distal end, and a wall surrounding a longitudinal bore extending along the central axis, the nail body formed of a material M;

a plurality of transverse boreholes extending transversely to the central axis, each transverse borehole having a cross-sectional profile F and a transverse axis, where the cross-section F has a maximum length  $a$  in the direction of the central axis and a maximum width  $b$  perpendicularly thereto; and

an elongate insert configured and dimensioned for insertion along the central axis into the longitudinal bore of the nail in the area of the transverse boreholes, the insert having a longitudinal axis and formed of a material  $m$  along an entire length thereof, the material  $m$  having a modulus of elasticity  $e$  less than the modulus of elasticity E of the nail material M.

2. The nail of claim 1, wherein the insert is configured and adapted to interface with the wall of the nail to rotationally fix the insert in a predetermined position relative to the nail.

3. The nail of claim 1, wherein the insert includes projections on an outer surface configured to interface with the transverse boreholes in the wall of the nail to secure the insert both axially and rotationally within the nail.

4. The nail of claim 1, wherein the nail includes at least three transverse boreholes.

5. The nail of claim 1, wherein the insert has a central longitudinal bore.

6. The nail of claim 1, wherein at least one of the transverse boreholes is constructed as an elongated slot having a cross-sectional profile F with the longer dimension  $a$  oriented along the central axis of the nail.

7. The nail of claim 1, further comprising a locking screw for introduction into the transverse borehole and through the insert, the locking screw having a shaft with an external diameter  $d$ , where  $a > d < b$ .

8. The nail of claim 1, wherein the longitudinal bore of the nail has a diameter that varies along the central axis of the nail.
9. The nail of claim 1, wherein the insert has at least one radial depression extending transversely to the longitudinal axis of the insert.
10. The nail of claim 1, wherein at least a portion of the insert has a conical shape.
11. The nail of claim 2, wherein the insert includes a projection that mates with a groove on the wall of the nail.
12. The nail of claim 1, wherein the insert includes at least one radial projection extending transverse to the longitudinal axis.
13. The nail of claim 12, wherein the insert includes a plurality of radial projections adapted to interface with the transverse boreholes of the nail.
14. The nail of claim 13, wherein the insert has an outer diameter  $q$ , and the distance from an outer surface of one radial projection to an outer surface of another radial projection is  $x$ , where  $1 < x/q < 2$ , and  $q$  is the diameter of the insert.
15. The nail of claim 1, further comprising a locking screw with a screw shaft and an external thread, the screw thread having a diameter  $d$  where  $a > d < b$ .
16. An intramedullary nail comprising:
  - a nail body having a central axis, proximal end, a distal end, and a wall surrounding a longitudinal bore extending along the central axis, the nail body formed of a material  $M$ ;
  - a plurality of transverse boreholes extending transversely to the central axis, each transverse borehole having a cross-sectional profile  $F$  and a transverse axis, where the cross-section  $F$  has a maximum length  $a$  in the direction of the central axis and a maximum width  $b$  perpendicularly thereto; and
  - an elongate insert configured and dimensioned for insertion along the central axis into the longitudinal bore of the nail in the area of the transverse boreholes, the insert having a longitudinal axis and being formed of a material  $m$  along an entire length thereof, the material  $m$  having a modulus of elasticity  $e$  less than the modulus of elasticity  $E$  of the nail material

M, wherein the insert is configured and adapted to interface with the wall of the nail to rotationally fix the insert in a predetermined position relative to the nail.

17. The nail of claim 16, wherein the insert includes projections on an outer surface configured to interface with the transverse boreholes in the wall of the nail to secure the insert both axially and rotationally within the nail.

18. The nail of claim 16, wherein at least one of the transverse boreholes is constructed as an elongated slot having a cross-sectional profile F with the longer dimension  $a$  oriented along the central axis of the nail.

19. The nail of claim 16, further comprising a locking screw for introduction into the transverse borehole and through the insert, the locking screw having a shaft with an external diameter  $d$ , where  $a > d < b$ .

FIG 1

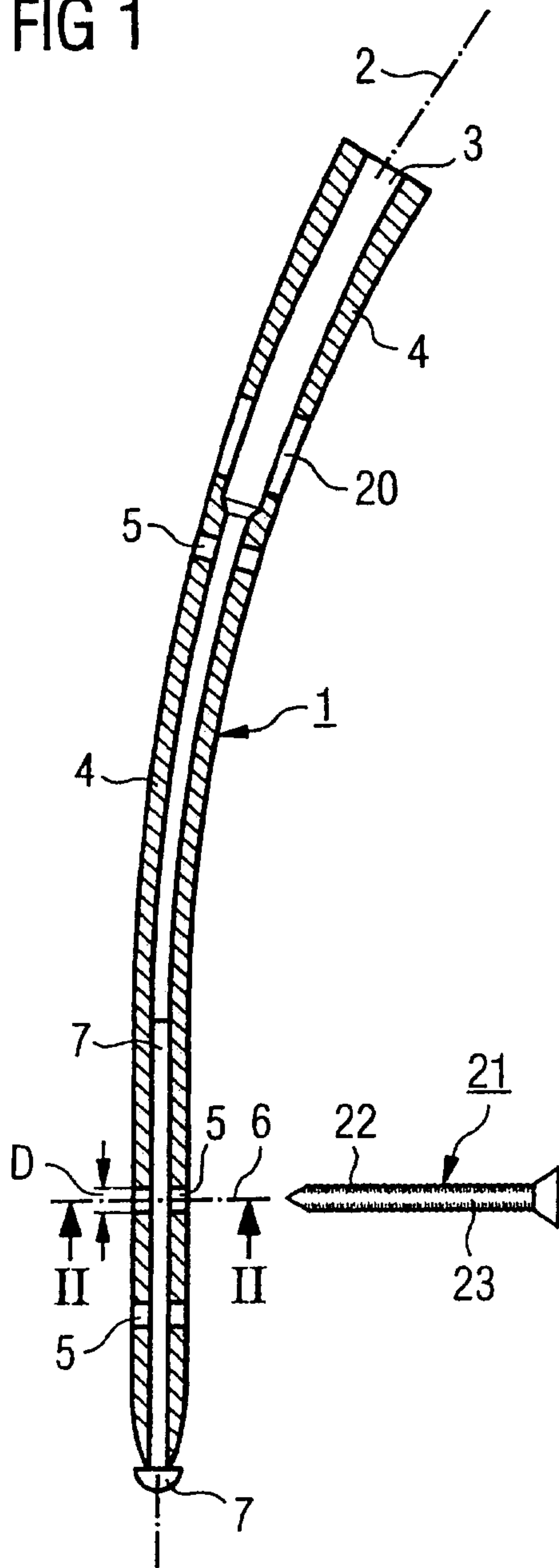


FIG 2

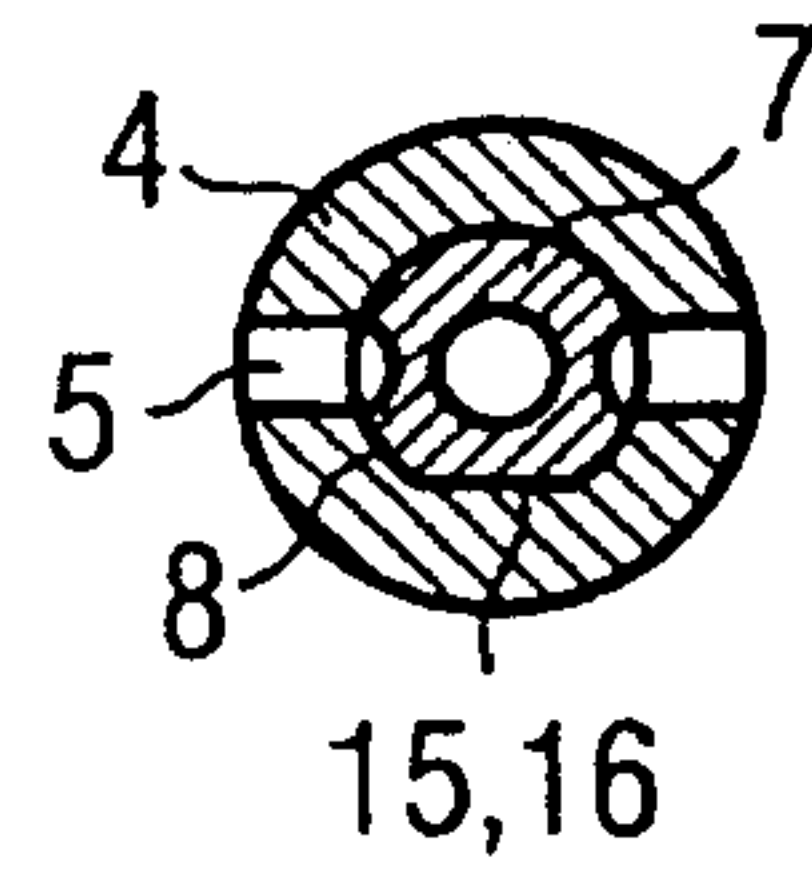


FIG 3

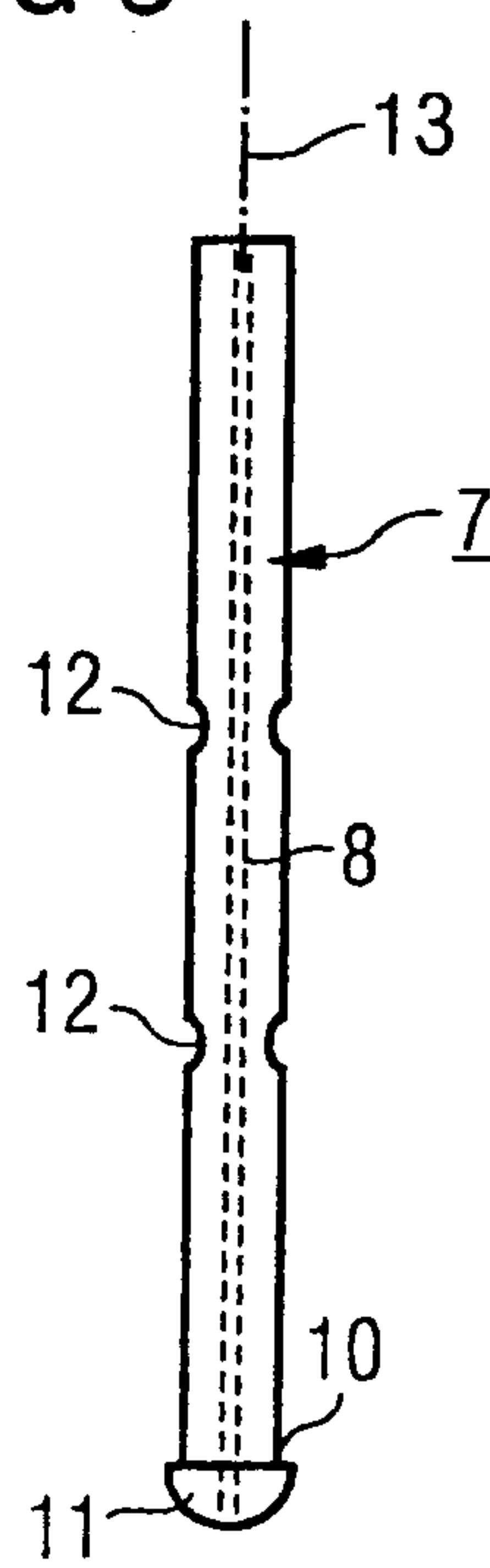


FIG 4

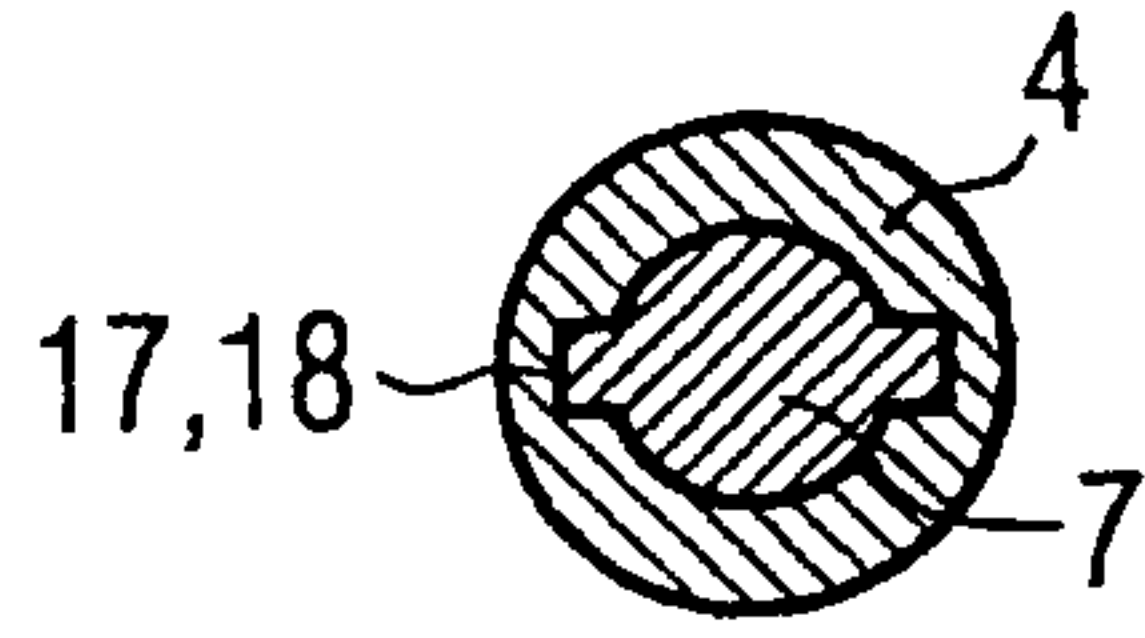


FIG 5

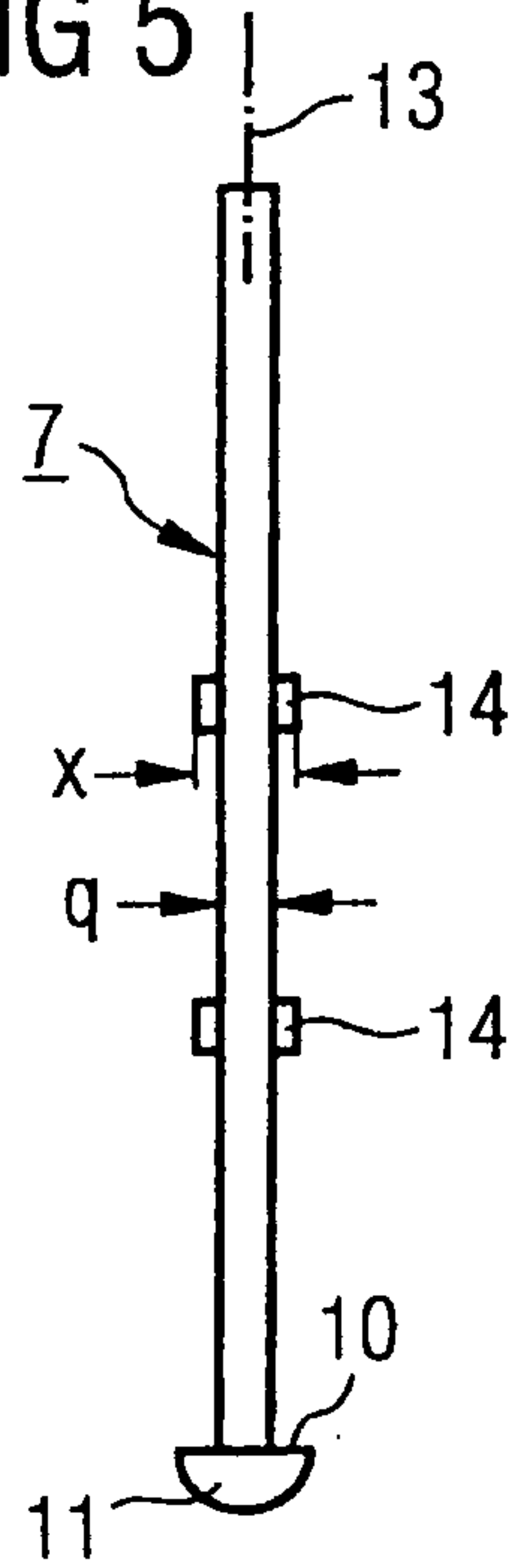


FIG 6

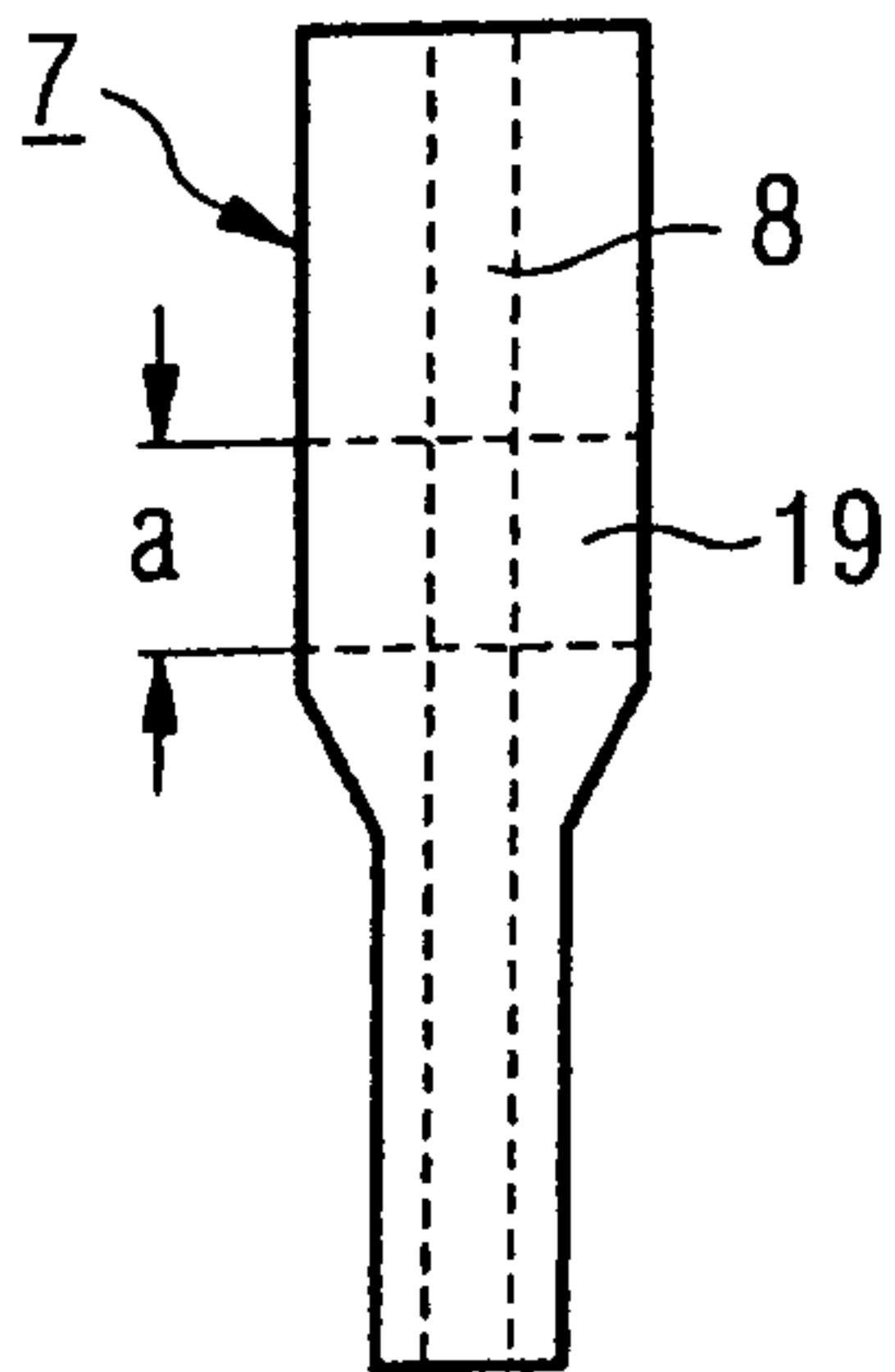


FIG 7

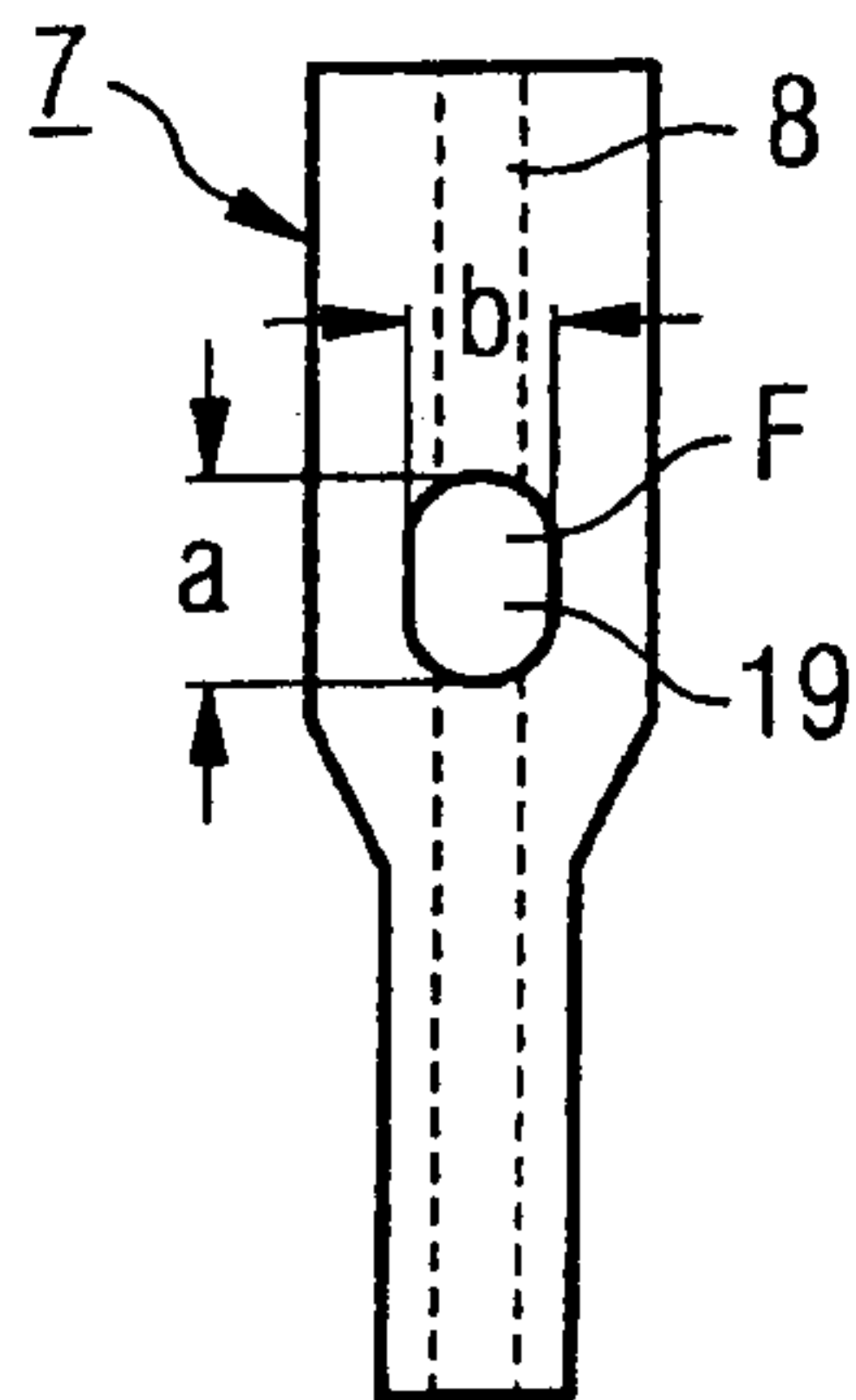


FIG 8

