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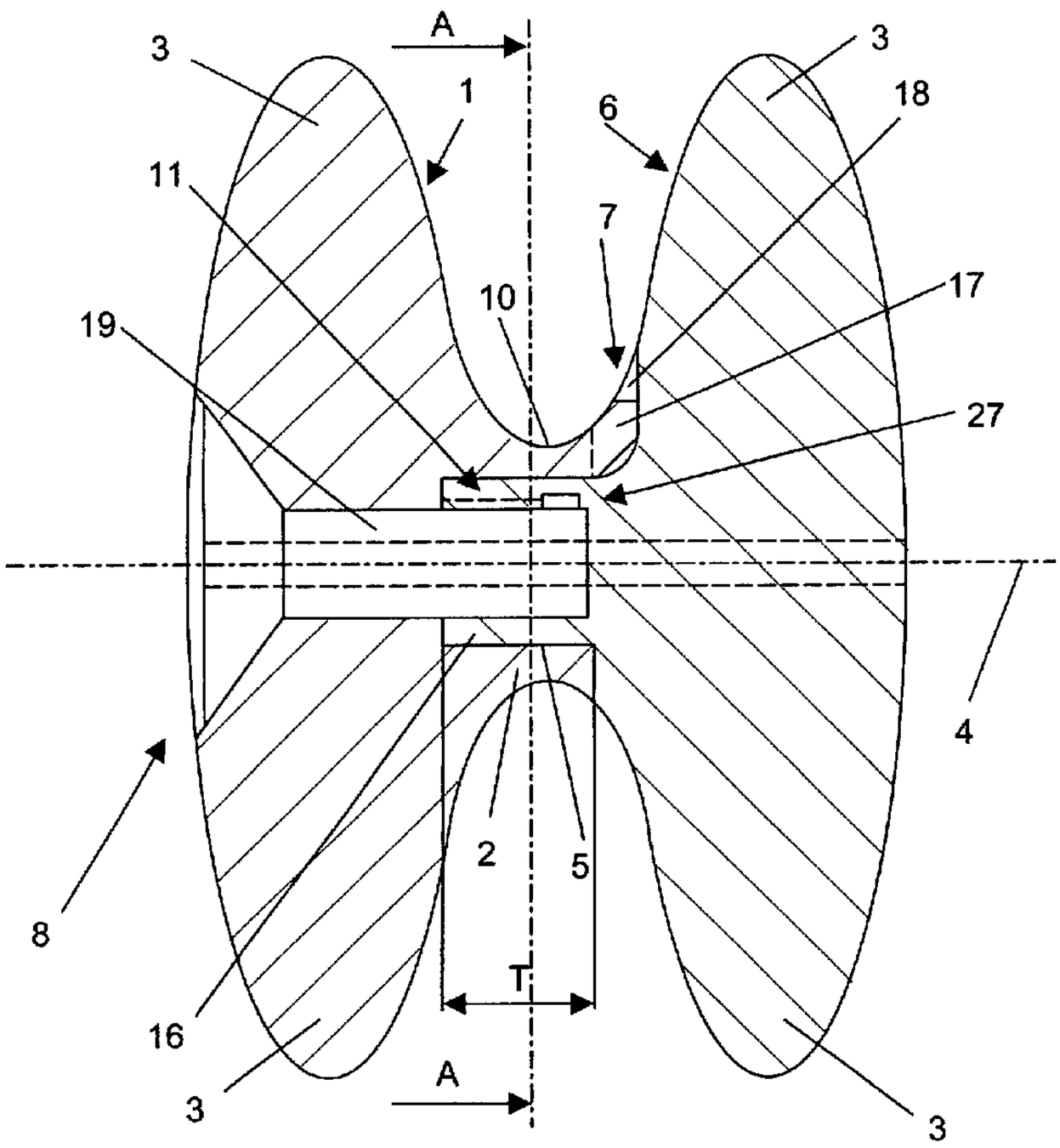
(54) Title: INTERSPINAL PROSTHESIS



(57) Abrégé/Abstract:
An interspinal prosthesis (1) comprising a middle piece (2) which can be introduced into the interspinal area and which has a center axis (4), an inner end (7) and an outer end (8) in addition to two extensions (3) extending radially and diametrically with respect to the center axis (4), originating from the outer end (8), said extensions being able to be introduced into the interspinal area of two adjacent bodies of the vertebra. The inner end (7) of the middle piece (2) opposite the extensions (3) has an axial recess (5) for receiving a counter piece (6) which is substantially symmetrical with respect to the prosthesis (1).

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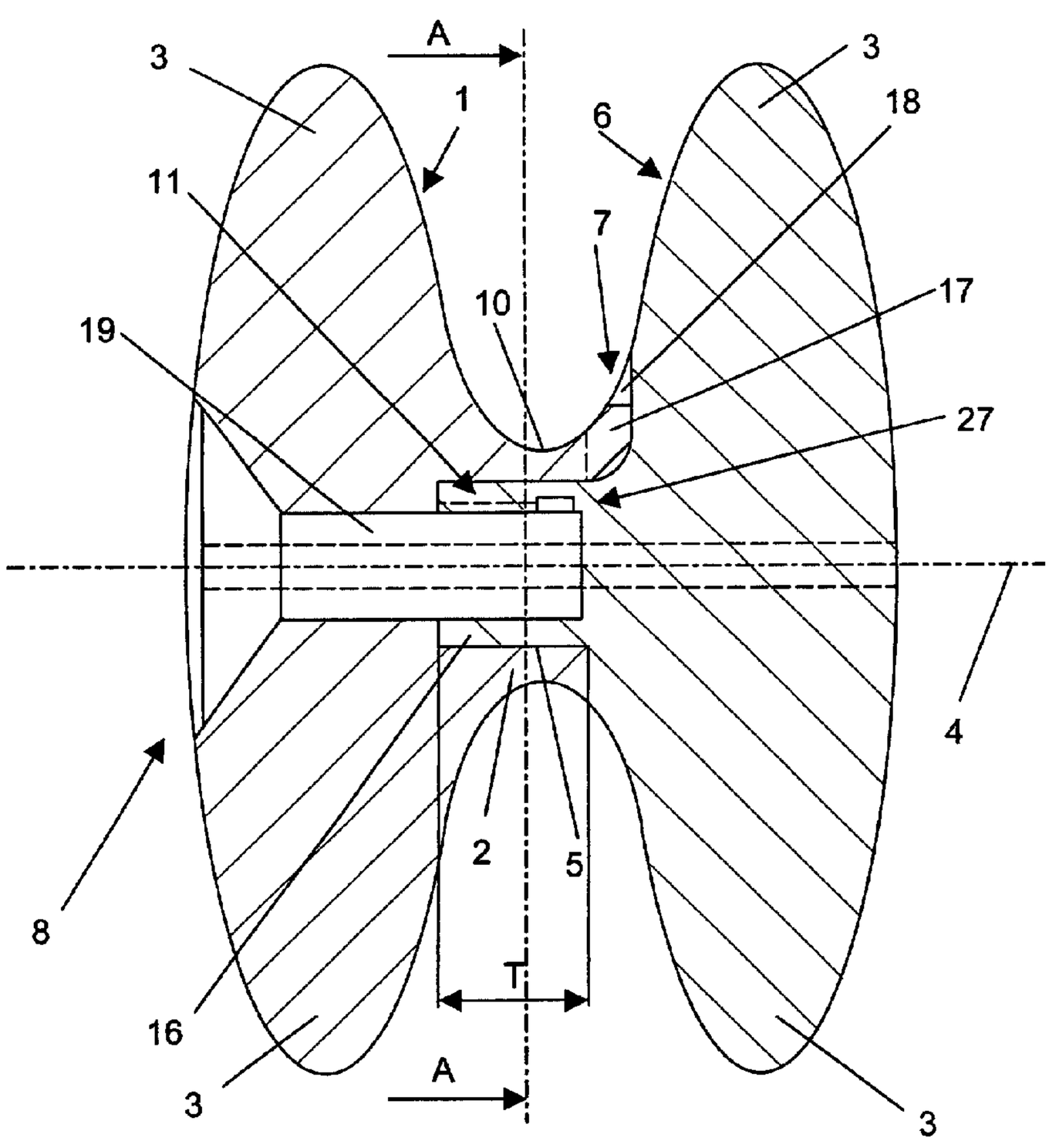
[Fortsetzung auf der nächsten Seite]

(54) Title: INTERSPINAL PROSTHESIS

(54) Bezeichnung: INTERSPINALE PROTHESE



(57) Abstract: An interspinal prosthesis (1) comprising a middle piece (2) which can be introduced into the interspinal area and which has a center axis (4), an inner end (7) and an outer end (8) in addition to two extensions (3) extending radially and diametrically with respect to the center axis (4), originating from the outer end (8), said extensions being able to be introduced into the interspinal area of two adjacent bodies of the vertebra. The inner end (7) of the middle piece (2) opposite the extensions (3) has an axial recess (5) for receiving a counter piece (6) which is substantially symmetrical with respect to the prosthesis (1).

(57) Zusammenfassung: Interspinale Prothese (1) mit einem in den Interspinalraum einführbaren Mittelteil (2) mit einer Zentralachse (4), einem inneren Ende (7) und einem äusseren Ende (8) sowie zwei am äusseren Ende (8) entspringenden, radial und diametral zur Zentralachse (4) verlaufenden Fortsätzen (3), welche in den Raum zwischen den Dornfortsätzen zweier benachbarter Wirbelkörper einführbar sind, wobei das Mittelteil (2) an seinem den Fortsätzen (3) abgewandten, inneren Ende (7) eine axiale Vertiefung (5) aufweist, zur Aufnahme eines zur Prothese (1) im wesentlichen symmetrischen Gegenstücks (6).

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Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

INTERSPINAL PROSTHESIS

The invention relates to an interspinal prosthesis of the introductory portion of claim 1, a counterpart thereto as well as to a multi-part interspinal prosthesis combined therefrom.

Such prostheses function as spacers for two adjacent vertebrae in the case of a defective disk, which would otherwise reduce the distance between the vertebrae. The stress on the facet joints is also relieved by the enlarged distance.

The W099/42051 discloses an interspinal prosthesis of this type, which includes a central piece, which is to be introduced into the interspinal space and from which a pair of ears arises cranially and caudially to the right and to the left of the central piece, in order to hold the central piece in the space between the spinous processes (processus spinosus) of two adjacent vertebrae after an implantation. A disadvantage of this known prosthesis is the fact that the latter is in one piece, which makes the implantation more difficult, so that it is necessary to remove the supraspinal ligament. The removal of this ligament has the disadvantage that the prosthesis is not held securely in the dorsal direction. For this reason, it is proposed in the WO99/42051 that the prosthesis be drilled through in the interspinal central piece, in order to pass a tape through the borehole, with which tape the prosthesis can be tied to the spinous processes of the adjacent vertebrae. This procedure is very time-consuming and complicated

The above discussion of the state of the art is given only to explain the environment of the invention and does not mean that the cited state of the art was also actually published or publicly known at the time of this application or its priority.

The invention is to provide a remedy here. It is therefore an object of the invention to provide an interspinal prosthesis, which can be implanted while the

supraspinal ligament is retained, so that the operation, as a whole, can be carried out more gently and the implant secured dorsally without additional means.

Pursuant to the invention, this objective is accomplished with a multi-part, interspinal prosthesis, the individual parts of which may have different mechanical properties.

The inventive, interspinal prosthesis includes essentially a central piece with a central axis, which can be introduced into the interspinal space, and two processes, which arise at the outer ends and extend radially and diametrically to the central axis and can be introduced into the space between the spinous processes of two adjacent vertebrae. Furthermore, at the inner end of the central piece, averted from the spinous processes, there is an axial depression, which accommodates an essentially symmetrical counterpart to the prosthesis.

In a preferred embodiment, the central piece has coupling means, with which the counterpart can be fixed to the prosthesis. The coupling means therefore are constituted so that the positions of the processes at the prosthesis and the positions of the processes at the counterpart are determined relative to one another when the counterpart is fixed in position. Preferably, the coupling means consist of a slide lock, which has a stop, so that, when the counterpart is attached to the prosthesis, the processes assume their desired positions at the prosthesis and the counterpart. Instead, of with a slide lock, the two parts can also be fixed to one another by a screwed or conical connection. In this case, the prosthesis and the counterpart preferably have a twisting safeguard, so that the counterpart can be introduced only in a particular position into the axial depression at the prosthesis. A different configuration of the coupling means consist of at least one elastically deformable cam, which, after the prosthesis and counterpart are assembled, can be locked or snapped into position in the latter.

In a different, preferred embodiment of the inventive prosthesis, the coupling means comprise at least one elastically deformable cam, which, when the prosthesis and counterpart are being assembled, can be deformed elastically and, after the prosthesis and counterpart are assembled, can be locked in position in a complementary depression.

A preferred further development consist therein that the cross-sectional planes, orthogonal to the central axis:

a) have an area of 50 to 300 mm^2 and preferably of 70 to two 250 mm^2 through the central piece at its narrowest site in the area of the inner end and

b) an area of 70 to 500 mm^2 and preferably of 100 to 450 mm^2 through the processes.

Furthermore, the prosthesis is produced preferably from an elastic material, so that the central piece can be elastically deformed radially. A sufficient radial, elastic deformability can be achieved by producing the prosthesis from a plastic or by producing the central piece with cogs, which can be deformed radially and elastically.

The prosthesis may also be produced from an elastomer, silicone or a polymer from the polycarbonate family. It is, however, also possible to produce a prosthesis from a metallic material, if the elasticity of the prosthesis in the region of the central piece, which comes to rest in the interspinal space, can be realized by means of suitable mechanical devices.

In a different embodiment of the inventive prosthesis, the latter is constructed hollow, the hollow walls being collapsible and/or expandable by filling up the hollow spaces. The collapsible hollow walls have the advantage that, as a

result, greater deformation of the prosthesis is made possible than would be permitted by an elastic material.

In the region of the inner end, the outer surface of the central piece can be smooth or roughened. The adhesion of the bone to the prosthesis can be affected by the configuration of the outer surface, being promoted by a rough outer surface and made more difficult or even prevented by a smooth outer surface. The surface of the implant, which is in contact with the bone, can also be protected by embedding hydroxy apatite (HA).

In a preferred embodiment, the inventive counterpart comprises an inner end, an outer end as well as two processes, which arise at the outer end, also extend radially and diametrically and can be inserted in the space opposite the prosthesis and between the spinous processes of two adjacent vertebras. Moreover, a peg, directed toward the inner end, is mounted at the counter part and can be introduced into the depression at the prosthesis. With that, an exact alignment of the prosthesis and the counterpart can be attained during the implantation.

Like the prosthesis, the counterpart can be fitted out with analogous, respectively complementary coupling means. Once again, these coupling means may comprise a slide lock, elastically deformable cams or a screwed or a conical connection. Likewise, an analogous, respectively complementary twisting safeguard is mounted at the counterpart.

The preferred embodiment of the inventive, interspinal prosthesis with a counterpart is distinguished owing to the fact, in the assembled state, it has a plane of symmetry orthogonal to the central axis, the processes of the interspinal prosthesis being at a distance of at least 2 mm and preferably of at least 3 mm from those of the counterpart, when viewed parallel to the central axis. The maximum distance of the

processes of the interspinal prosthesis from those of the counterpart is 15 mm and preferably 12 mm.

The invention and further developments of the invention are explained in even greater detail in the following by means of partially diagrammatical representations of several examples. In the drawings,

Figure 1a shows a section through the preferred embodiment of the inventive, interspinal prosthesis with counterpart,

Figure 1b shows a side view of the preferred embodiment of the embodiment of the inventive prosthesis with counterpart, shown in Figure 1a,

Figure 2 shows a section through a different embodiment of the inventive interspinal prosthesis with a counterpart,

Figure 3 shows a section once again through a different embodiment of the inventive interspinal prosthesis with a counterpart,

Figure 4 shows a section through a further embodiment of the inventive interspinal prosthesis with a counterpart and

Figure 5 shows a view of a further embodiment of the inventive interspinal prosthesis with a counterpart.

In Figure 1, the interspinal prosthesis 1 with the counterpart 6 is shown in the assembled state. The central piece 2 of the prosthesis 1, with the inner end 7 of the prosthesis 1, adjoins the counterpart 6. At the outer end 8 of the prosthesis 1, the two processes 3 are disposed perpendicularly to the central axis 4 and diametrically opposite to one another. In the embodiment shown here, the processes 3 are

constructed as halves of an ellipsoid body. The also radial and diametrically opposite to one another processes 3 of the counterpart 6 are disposed symmetrically to a plane, which is orthogonal to the central axis 4. Three radial cams 17, which are disposed symmetrically when viewed in the cross-section of the prosthesis 1 parallel to the central axis 4, protrude at the central piece 2 at the inner end 7 of the prosthesis and engage complementary grooves 18 at the counterpart 6, function as twisting safeguard between the prosthesis 1 and the counterpart 6. Coaxially with the central axis 4, the central part 2 includes a depression 5, which penetrates from the inner end 7 into the prosthesis 1 up to a depth T. The counterpart 6 has a peg 16, which is constructed to be complementary to the depression 5 and accordingly, during the assembly of the prosthesis 1 and the counterpart 6, can be introduced into the depression 5. Furthermore, the prosthesis 1 comprises a fixing-in-position bolt 19 with a bolt head 26, which can be brought into contact with the outer end 8 of the prosthesis 1. The fixing-in-position bolt can be passed coaxially with the central axis 4 through the prosthesis 1 and locked by means of a slide lock 27 in the peg 16 of the counterpart 6, so that the prosthesis 1 can be locked detachably with the counterpart 6. A borehole 20, coaxial with the central axis 4, passes through the fixing-in-position bolt 19 and the counterpart 6, so that the prosthesis 1 and the counterpart 6 can be collapsed radially.

Figure 2 shows a further embodiment of the prosthesis with the counterpart 6 in the assembled state. The depression 5 passes through the prosthesis 1 coaxially from the inner end 7 up to the outer end 8. During the assembly of the prosthesis 1 and the counterpart 6, the peg 16 at the counterpart 6 is pushed into the through depression until the inner end 7 of the prosthesis 1 comes up against the processes 3 of the counterpart 6. Moreover, a borehole 20 is drilled through the counterpart 6 between the outer end 15 and the inner end 14. The coupling means 11 are constructed as a screwed connection, the screw 21 being passed through the depression 5 at the prosthesis 1 and through the borehole 20 at the counterpart 6 from the outer end 8 of the prosthesis 1 up to the outer end 15 of the counterpart 6 and

bolted with a nut 22. In addition, the prosthesis 1 is provided with a hollow space 12, so that the walls 13 of the hollow space can be collapsed or, by filling the hollow space 12 with a filling material, expanded.

The embodiment, shown in Figure 3, differs from the embodiments described above in that the peg 16 at the counterpart 6 is passed completely through the depression 5 at the prosthesis 1, so that the inner end 14 of the counterpart 6 aligns with the outer end 8 of the prosthesis 1 furthermore, the counterpart 6 has several boreholes 20, which are continuous from the inner end 14 to the outer end 15 and the axes of which extend parallel to the central axis 4. The cerclage wires 23, by means of which the interspinal prosthesis 1 and the counterpart 6 are fixed in position, can be passed through these boreholes 21.

The embodiment, shown in Figure 4, differs from those shown in Figure 1 owing to the fact that the coupling means 11 comprise a locking bolt 28, which can be passed through the borehole 20, which passes through the prosthesis 1 and the counterpart 6 coaxially with the central axis 4. The locking bolt 28, with its head 29, can be brought into contact with the outer end 15 of the counter part 6 and has, at its tip, radially and elastically deformable cams 31, which, when the prosthesis 1 and the counterpart 6 are assembled, can be locked in an eccentric relief 30, the diameter of which is larger than the diameter of the borehole 20, so that the prosthesis 1 and the counterpart 6 are held together. For introducing the locking bolt 28 into the borehole 20, the cams 31 can be compressed perpendicularly to the central axis 4 by means of axially disposed slots 32, so that the locking bolt 28 can be passed through the borehole 20, while, in the assembled state, the cams 31 spring back elastically and latch into the eccentric relief 30 at the prosthesis 1. A hole is drilled through the locking bolt 28 coaxially with the central axis 4, so that a pin 25 can be passed through it, as a result of which a radial deflection of the cams 31 is prevented

In Figure 5, a further embodiment of the inventive prosthesis 1 with a counterpart 6 is shown. At the outer end 8 of the prosthesis 1 as well as at the outer end 15 of the counterpart 6, the processes 3 are mounted once again perpendicularly to the central axis 4 and diametrically opposite to one another, the processes 3 in this embodiment having a semicircular cross sectional surface parallel to the central axis 4. The depression 5 passes through the prosthesis 1 from the inner end 7 to the outer end 8 coaxially with the central axis 4. In the depression 5, there is an internal thread 36 with a very large pitch. Adjoining the inner end 14, the counterpart 6 once again has a peg 16, which has an external thread 33 that is complementary to the internal thread 36, so that the prosthesis 1 and the counterpart 6 can be fastened detachably to one another by means of this screwed connection. A first saw tooth-like system 34 is mounted at the counterpart 6 between the peg 16 and the processes 3 and can be brought into engagement with a complementary second tooth system 35 at the inner end 7 of the prosthesis 1 during the assembly of the prosthesis 1 and the counterpart 6 so that, due to the asymmetric configuration of the saw tooth systems 34, 35, a safeguard is provided against the unintentional detachment of the prosthesis 1 from the counterpart 6.

Claims

1. Interspinal prosthesis (1) with a central part (2) with a central axis (4), which can be introduced into the interspinal space, an inner end (7) and an outer end (8), as well as two processes (3), which arise at the outer end (8), extend radially and diametrically to the central axis (4) and can be introduced into the space between the spinous processes of two adjacent bodies of a vertebra, the central part (2), at its inner end (7) averted from the processes (3), having an axial depression (5) for accommodating a counterpart (6), which is essentially symmetrical to the prosthesis (1), characterized in that

(A) the interspinal prosthesis is made from an elastic material, which permits an elastic deformation of the diameter of the central part (2) at it narrowest place (10) by 10 to 60% relative to the unstressed diameter and

(B) the cross-sectional plane (9) through the central part (2), orthogonal to the central axis (4), has an area of 50 to 300 mm² at its narrowest place (10) in the region of the inner end (7).

2. The prosthesis (1) of claim 1, characterized in that the central part (2) has coupling means (11), with which the counterpart (6) can be fixed in position thereto.

3. The prosthesis (1) of claims 1 or 2, characterized in that the cross sectional plane (9) through the central part (2), orthogonal to the central axis (4), has an area of 70 to 250 mm^2 at its narrowest place in the region of the inner end (7).

4. The prosthesis (1) of one of the claims 1 to 3, characterized in that the cross sectional plane through the processes (3), orthogonal to the central axis (4), has an area of 70 to 500 mm^2 and preferably of 100 to 450 mm^2.

5. The prosthesis (1) of claims 1 to 4, characterized in that the elastic material permits an elastic deformation of 15 to 50% relative to the unstressed diameter.

6. The prosthesis (1) of claims 1 to 5, characterized in that it consists of a plastic with a Shore hardness of 65A to 90A.

7. The prosthesis (1) of claims 1 to 5, characterized in that it consists of a metallic material and that the central part (2) includes radially elastically deformable cogs.

8. The prosthesis (1) of one of the claims 1 to 7, characterized in that it is constructed hollow, so that its hollow-space walls (13) can either be collapsed or, by filling the hollow space (12) with a filling material, expanded.

9. The prosthesis (1) of one of the claims 1 to 8, characterized in that the central part (2) is constructed in the region of its inner end (7) with a smooth outer surface.

10. The prosthesis (1) of one of the claims 1 to 8, characterized in that the central part (2), in the region of its inner end (7), is roughened at its outer surface.

11. The prosthesis (1) of one of the claims 1 to 10, characterized in that hydroxy apatite (HA) is embedded in the prosthesis material at least on a portion of its surface.

12. The prosthesis (1) of one of the claims 2 to 11, characterized in that the coupling means (11) comprise a slide lock (27).

13. The prosthesis (1) of one of the claims 2 to 11, characterized in that the coupling means (11) comprise elastically deformable cams (10), which, after the prosthesis (1) and the counterpart (6) are assembled, can be locked in position at the latter.

14. The prosthesis (1) of claim 13, characterized in that at least the coupling means (11) are provided with a borehole (20) coaxially to the central axis (4) and that the prosthesis (1) includes a pin, which can be introduced in the borehole (20).

15. The prosthesis (1) of one of the claims 2 to 11, characterized in that the coupling means (11) comprise a conical connection.

16 The prosthesis (1) of one of the claims 2 to 11, characterized in that the coupling means (11) comprise a screw connection.

17. The prosthesis (1) of one of the claims 13 to 16, characterized in that the prosthesis (1) includes a twisting safeguard, which can be accommodated in a counterpart (6).

18. The prosthesis (1) of claim 1, characterized in that the axial depression (5) of the central part (2) is constructed as a continuous borehole passing through the whole of the central part (2).

19. The prosthesis (1) of one of the claims 1 to 18, characterized in that the cross sectional areas of the processes (3), viewed parallel to the central axis (4), are semicircular areas.

20. The prosthesis (1) of one of the claims 1 to 19, characterized in that it has a counterpart (6), which fits into the axial depression (5) and comprises the following elements:

A) an inner end (14),

B) an outer end (15);

C) two processes (3), which arise at the outer end (15), extend radially and diametrically to the central axis (4) and can be introduced into the space between two spinous processes of two adjacent vertebras and

D) a peg (16), which is directed towards the inner end (14) and can be introduced into the depression (5) at the prosthesis (1).

21. The prosthesis (1) of claim 20, characterized in that the peg (16) of the counterpart (6) includes coupling means (11), with which the prosthesis can be fixed in position thereto.

22. The prosthesis (1) of claim 21, characterized in that the coupling means (11) comprise a slide lock.

23. The prosthesis (1) of claim 21, characterized in that the coupling means (11) comprise elastically deformable cams, which, after the counterpart (6) and the prosthesis (1) are assembled, can be locked in position at the counterpart (6).

24. The prosthesis (1) of claim 21, characterized in that the coupling means (11) comprise a conical connection.

25. The prosthesis (1) of claim 21, characterized in that the coupling means (11) comprise a screw connection.

26. The prosthesis (1) of one of the claims 22 to 25, characterized in that the prosthesis (1) includes a twisting safeguard, which can be accommodated in a counterpart (6).

27. The prosthesis (1) of one of the claims 20 to 26, characterized in that the cross sectional area of a processes (3), viewed parallel to central axis (4), are semicircular areas.

28. The prosthesis (1) of one of the claims 20 to 27, characterized in that, in the assembled state, it has a plane of symmetry, which is orthogonal to the central axis (4).

29. The interspinal prosthesis (1) of one of the claims 20 to 28, characterized in that the processes (3) of the prosthesis (1) are at a distance of at least 2 mm and preferably of at least 3 mm from those of the counterpart (6).

30. The prosthesis (1) of one of the claims 20 to 29, characterized in that the processes (3) of the prosthesis (1) are at a distance of at most 15 mm and preferably of at most 12 mm from those of the counterpart (6).

31. The prosthesis (1) of one of the claims 20 to 30, characterized in that the prosthesis (1) includes a first twisting safeguard and the counterpart (6) includes a second twisting safeguard, complementary to the first twisting safeguard, so that the processes (3) of the prosthesis (1) and the processes (3) of the counterpart (6) can be brought into a mutually aligned position.

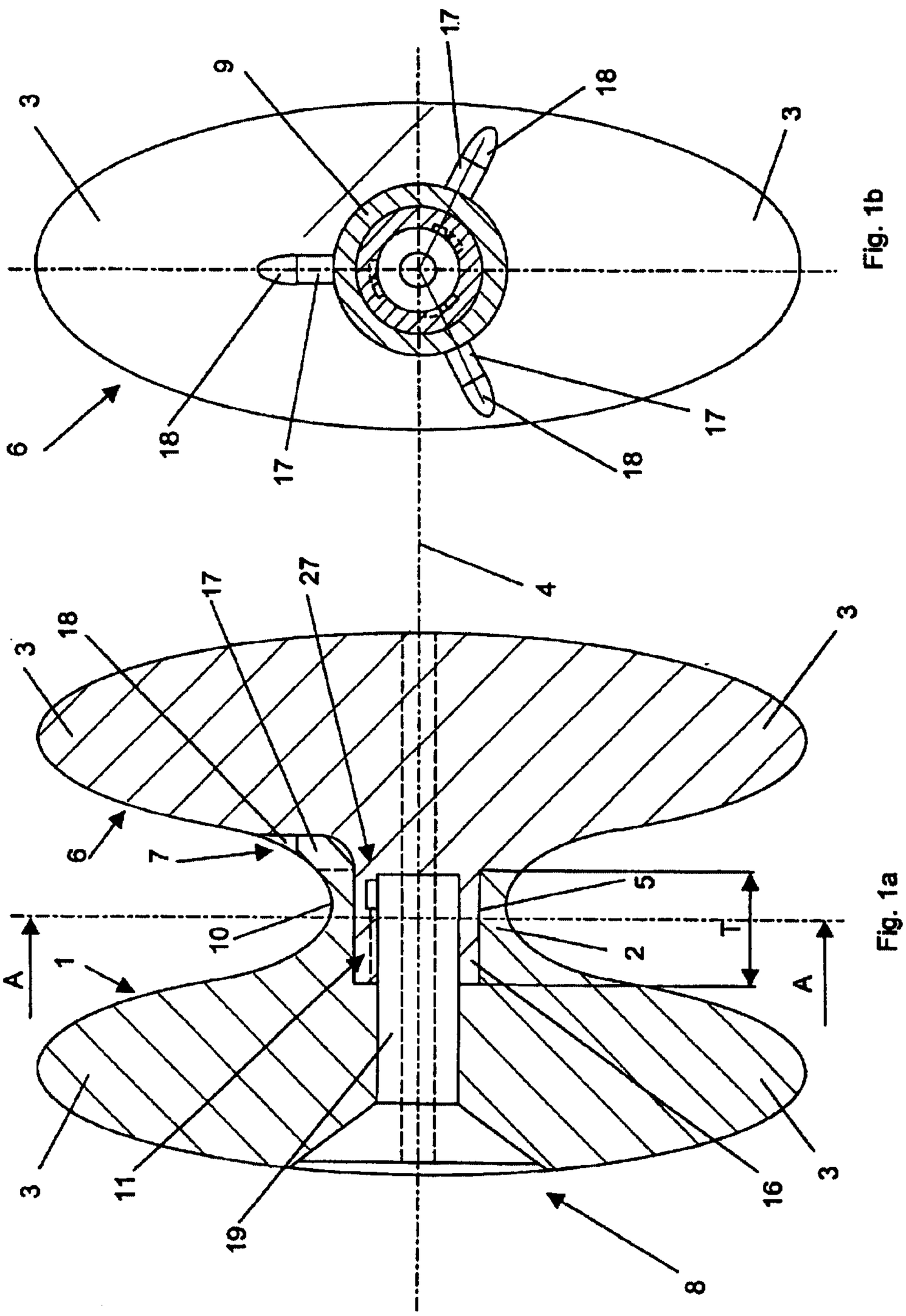


Fig. 1b

Fig. 1a

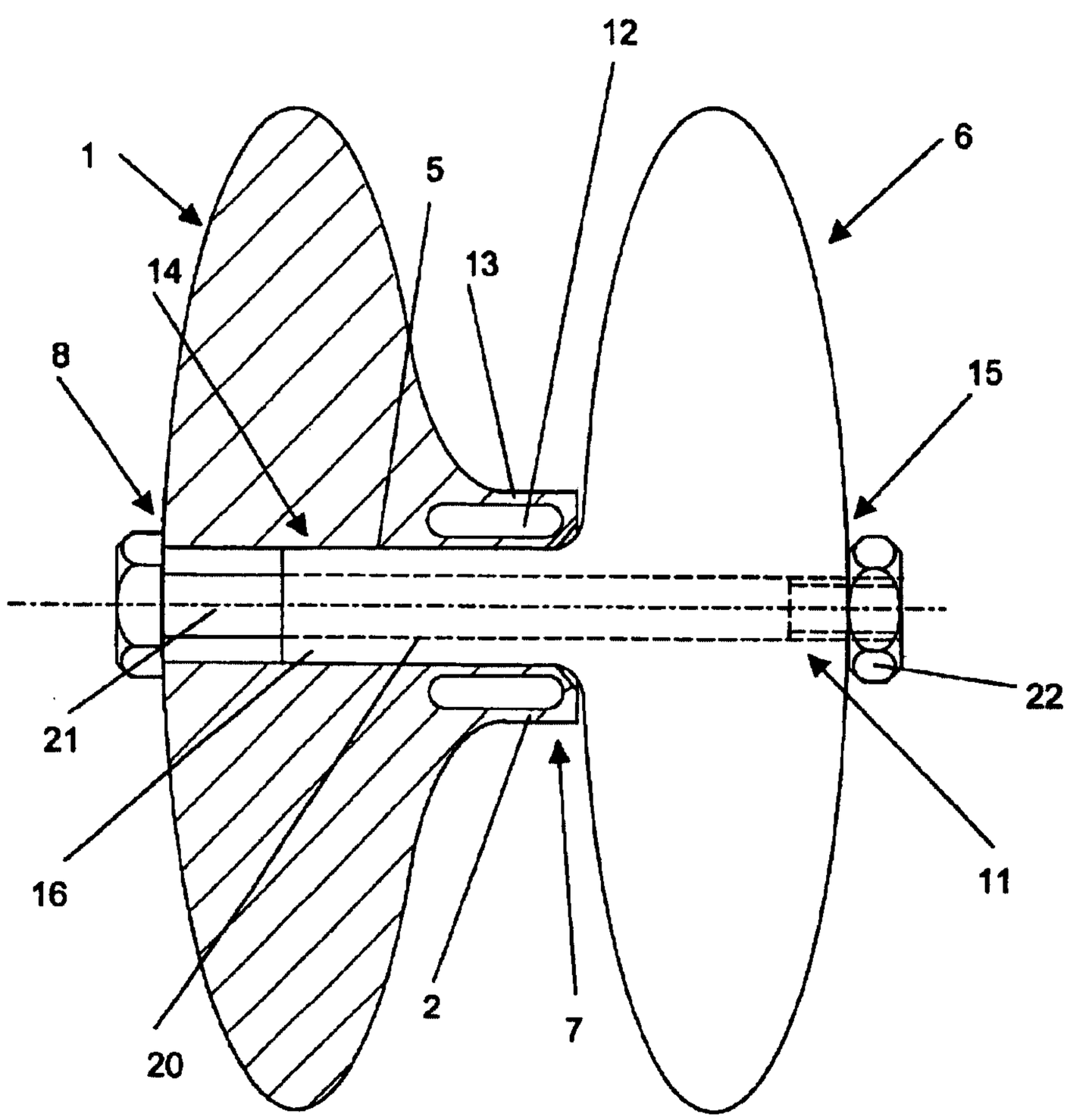


Fig. 2

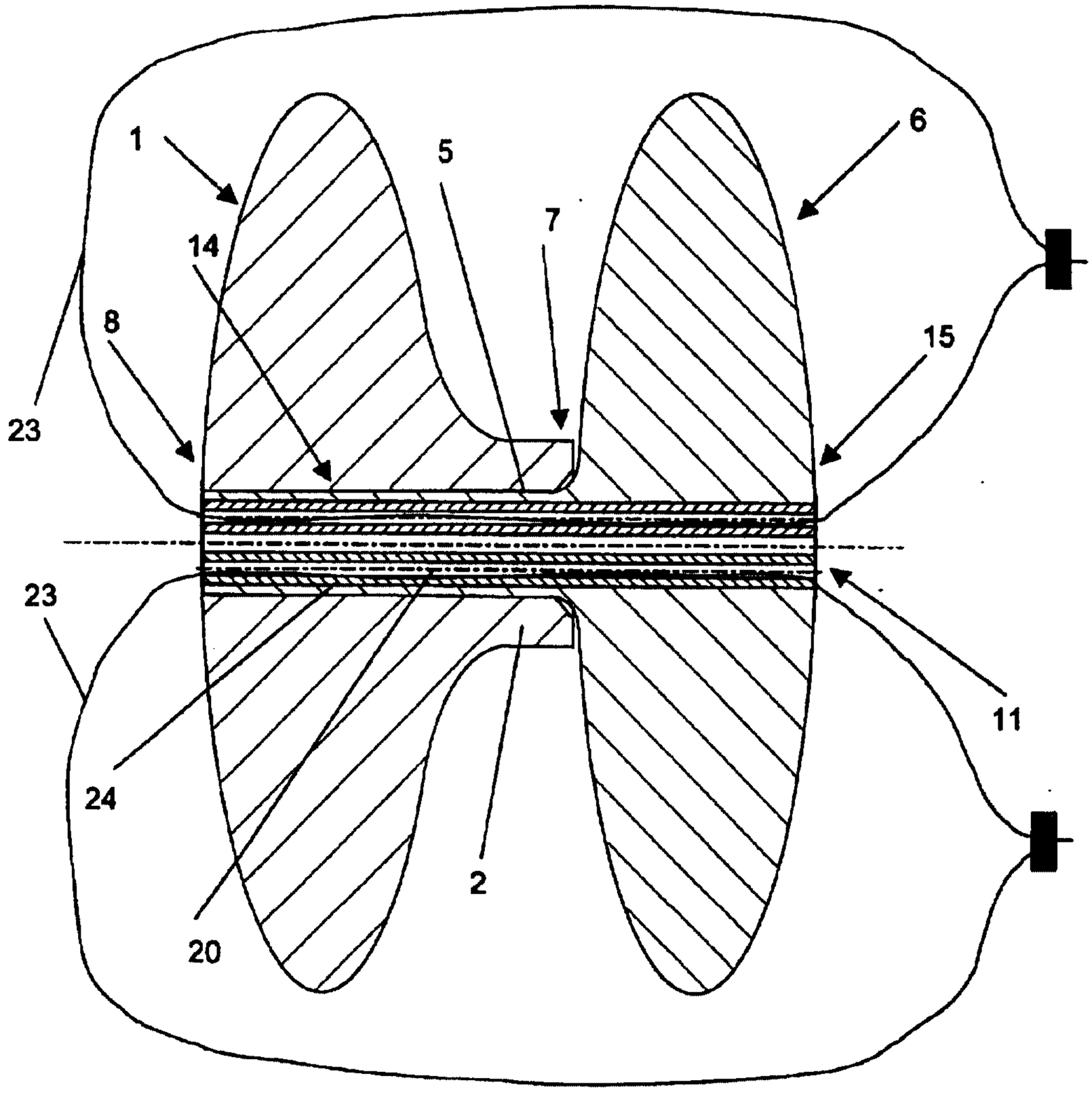


Fig. 3

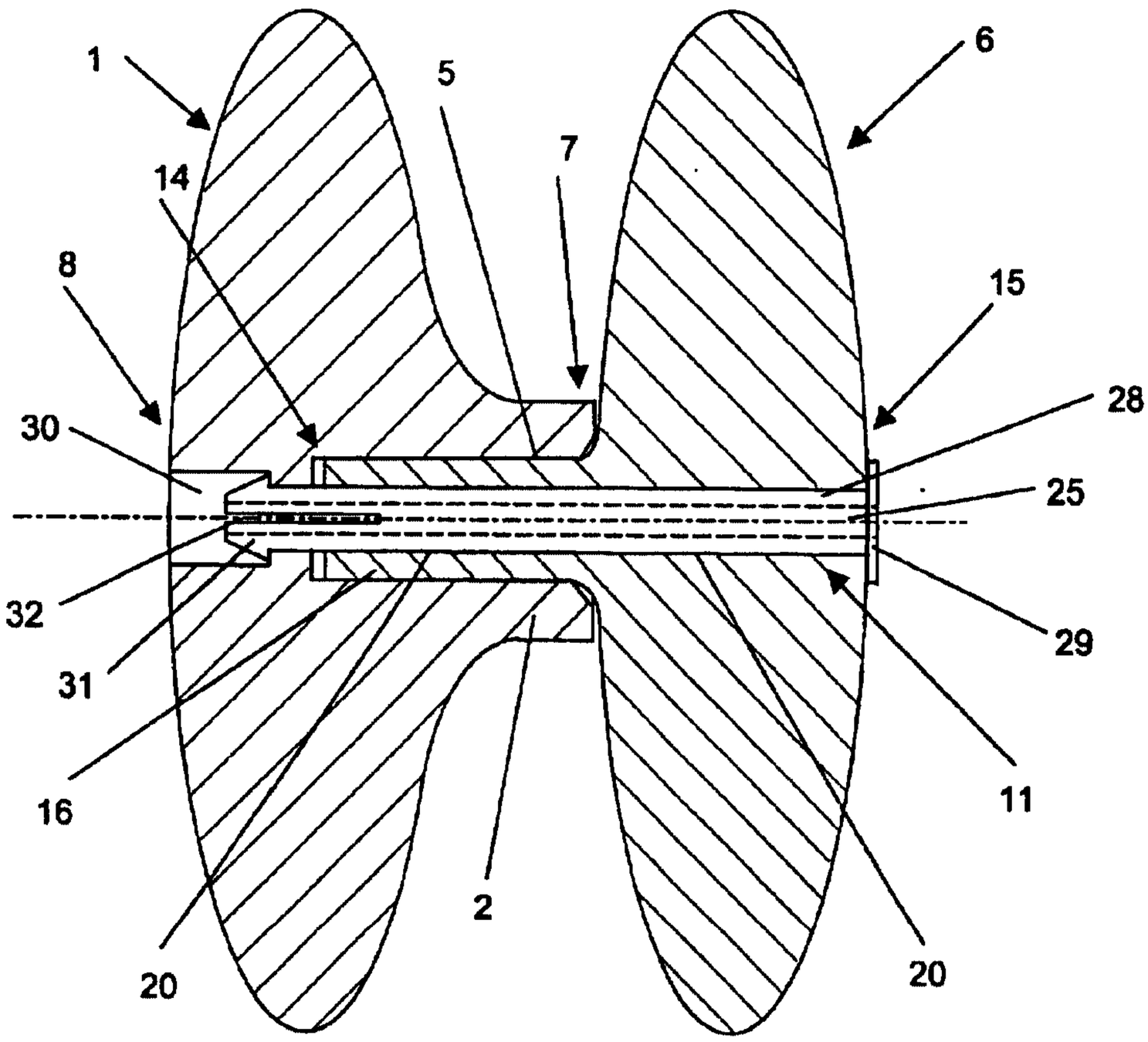


Fig. 4

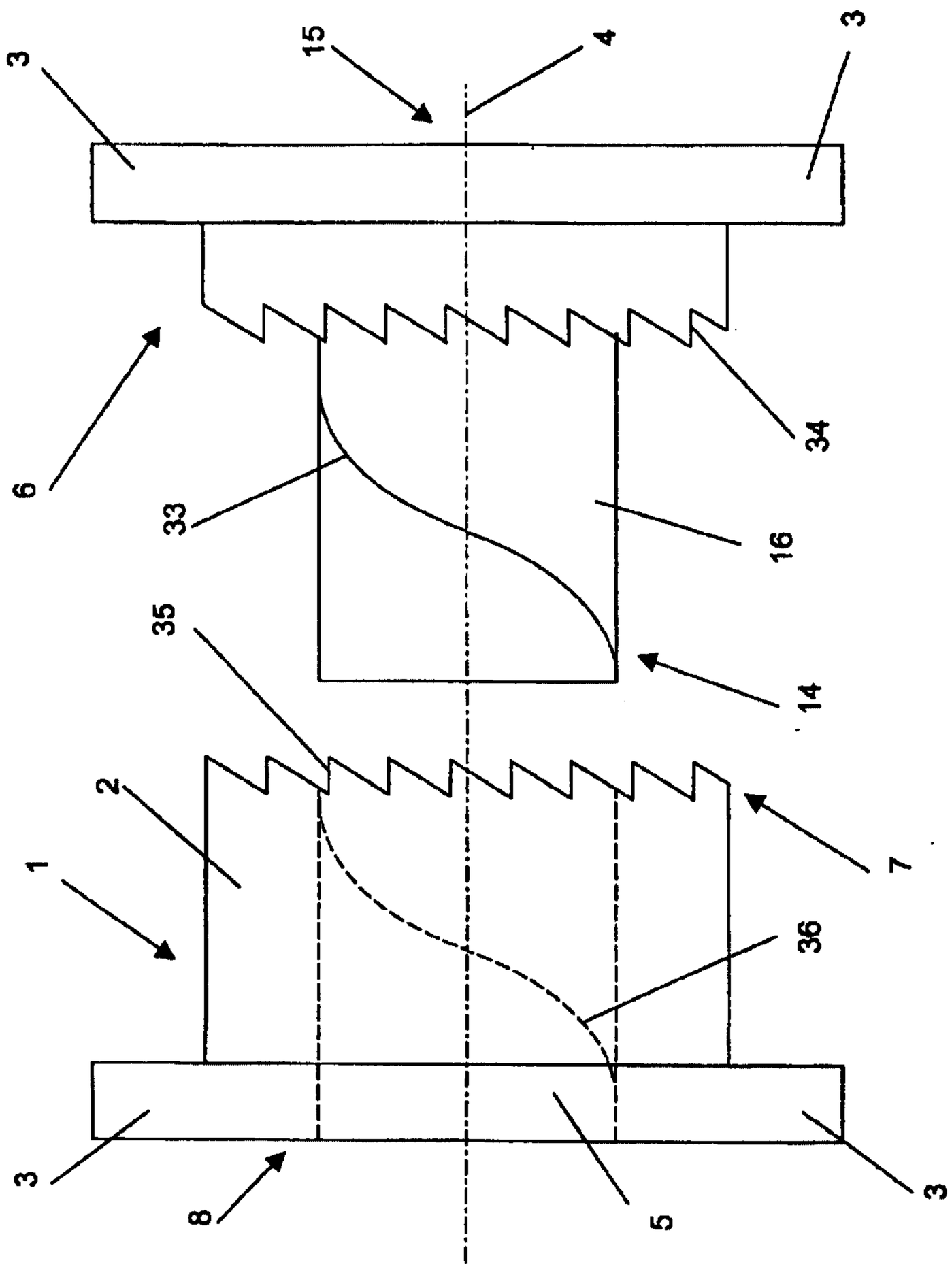
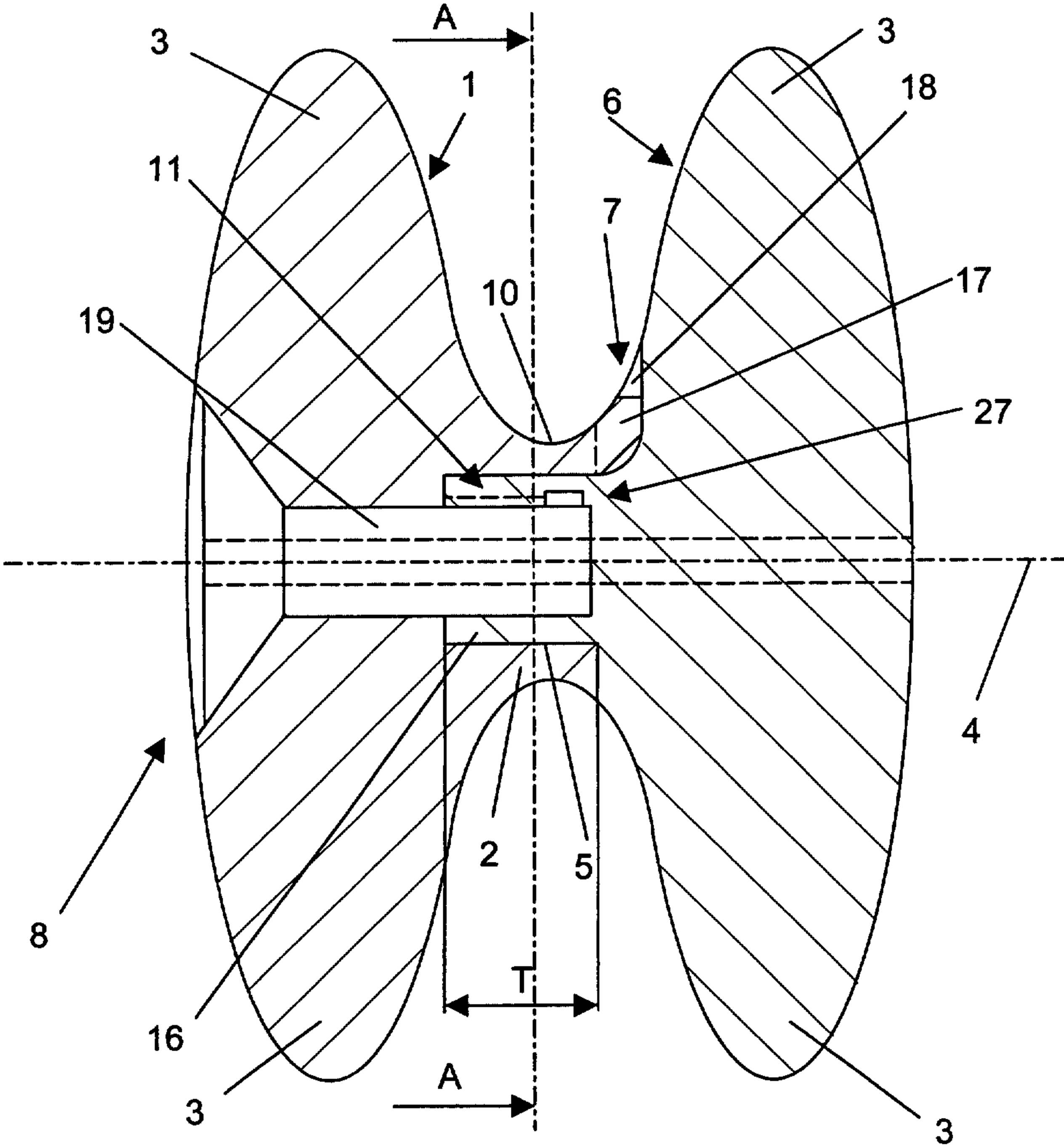


Fig. 5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