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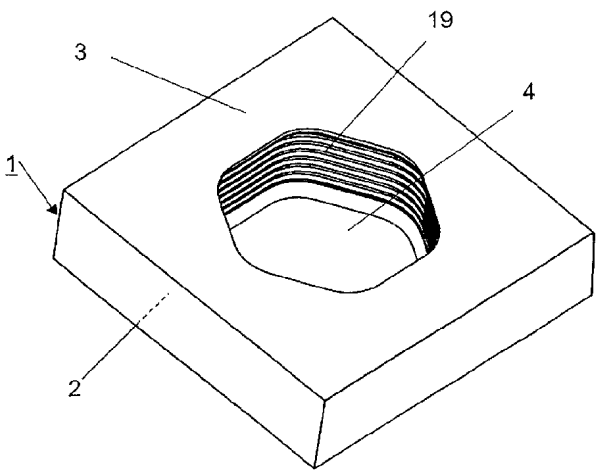
*[Fortsetzung auf der nächsten Seite]*

(54) Title: DEVICE FOR PERFORMING OSTEOSYNTHESIS

(54) Bezeichnung: VORRICHTUNG FÜR DIE OSTEOSYNTHESE




(57) Abstract: The device for performing osteosynthesis comprises a bone plate (1) with an underside (2), which is intended for resting against the bone, with an upper side (3), at least one passage (4), which joins the underside (2) to the upper side (3) and is provided for accommodating a multiaxially pivotal insert (10) for a bone screw (20), whereby the passage (4) has a central axis (5). The inventive device also comprises an insert (10), which can be inserted into the passage (4), is provided with a central boring (11) for accommodating a bone screw (20), whereby the boring (11) has a longitudinal axis (12), and the insert has a peripheral outer surface (17) intended for placing in contact with the passage (4). The insert (10) is designed so that it can be radially compressed and radially expanded, and the cross-section (6) of the passage (4), which is orthogonal to the central axis (5), is non-circular. The cross-section (16) of the insert (10) that is orthogonal to the longitudinal axis (12) has a shape that essentially corresponds to the cross-section (6) of the passage (4) of the bone plate (1), and the insert (10) inserted in the passage (4) is fixed so that it does not rotate in relation to the longitudinal axis (12) thereof but, inside the passage (4), remains pivotal in relation to the bone plate (1).

*[Fortsetzung auf der nächsten Seite]*

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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.*

**(57) Zusammenfassung:** Die Vorrichtung für die Osteosynthese umfasst eine Knochenplatte (1) mit einer Für die Anlage zum Knochen bestimmten Unterseite (2), einer Oberseite (3), mindestens einem die Unterseite (2) mit der Oberseite (3) verbindenden Durchgang (4) zur Aufnahme eines multiaxial schwenkbaren Einsatzes (10) für eine Knochenschraube (20), wobei der Durchgang (4) eine Zentralachse (5) aufweist, sowie einen in den Durchgang (4) einsetzbaren Einsatz (10) mit einer zentralen Bohrung (11) zur Aufnahme einer Knochenschraube (20), wobei die Bohrung (11) eine Längsachse (12) aufweist, sowie einer peripheren Aussenfläche (17), welche zum Kontakt mit dem Durchgang (4) bestimmt ist. Der Einsatz (10) ist radial komprimierbar und radial expandierbar ausgebildet und der orthogonal zur Zentralachse (5) stehende Querschnitt (6) des Durchgangs (4) ist unrung ausgebildet ist. Der orthogonal zur Längsachse (12) stehende Querschnitt (16) des Einsatzes (10) weist eine zum Querschnitt (6) des Durchganges (4) der Knochenplatte (1) im wesentlichen korrespondierende Form auf und der im Durchgang (4) eingesetzte Einsatz (10) ist relative zu seiner Längsachse (12) rotationsfest, bleibt aber innerhalb des Durchgangs (4) relativezur Knochenplatte (1) schwenkbar.

1917/PCT

**Re: International Patent Application No. PCT/CH01/00740**
**"Vorrichtung für die Osteosynthese"**

I .....
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do hereby certify that I am conversant with the English and German languages, and am a competent translator thereof, and I further certify that to the best of my knowledge and belief the attached document is a true and correct translation made by me of the documents in the German language attached hereto.

Signature of translator: .....

Dated 25/11/2002

1917/PCT

21.12.2001

English translation of the International Patent Application No. PCT/CH01/00740 "Device for osteosynthesis" in the name of Synthes AG Chur

**Device for osteosynthesis**

The invention relates to a device for osteosynthesis as claimed in the precharacterising part of claim 1.

Assemblies of this type serve for screwing together elements such as pedicle screws or pedicle hooks in a polyaxial, rigid manner, and are used in particular in the area of the spinal column. However, they may also be employed for plating in general. Additional fields of application include their use in combination with external fixators and intervertebral implants.

A device of this type is known already from US 6 235 033, in which the screw head and the bore of the bone plate are held together by an angularly adjustable, annular bushing which is compressible and expansible by means of a slot so as to achieve an improved fastening of the screw in the plate. This known device, however, suffers from the disadvantage that the bushing used is of circular shape so that it may rotate together with the screw as the screw is screwed in, thus preventing it from becoming locked within the plate. The bushing may even turn around completely within the plate hole, so that the wrong side thereof faces upward (the inner cone tapering in the wrong direction).

The discussion of the state of the art as set out above is merely intended to illustrate the background of the invention and does not mean that at the moment of filing the present application or its priority the cited state of the art was actually published or otherwise known to the public.

The invention is intended to provide a remedy for this. It is accordingly an object of the invention to create a device for osteosynthesis in which the bone screws are polyaxially movable and lockable in an angularly stable manner relative to the bone plate without necessitating any additional mechanical members.

According to the invention, this object is achieved by means of a device which shows the features of claim 1.

In the following, the term "non-circular" will have to be understood as meaning any cross section deviating from an exactly circular surface, and refers in particular to prismatic and elliptical cross sections.

The advantage achieved by this consists in the fact that the bushing can no longer turn about its own axis while the bone screw is screwed in. The turning of said bushing would in fact entail that no relative movement between the bushing and the screw would take place any more, that the bushing would, therefore, not be spread apart and, consequently, a locking of the screw would not be possible. A further advantage consists in the fact that, unlike in the device according to US 6 235 033, no additional locking screw is necessary.

In one particular embodiment, the cross section of the through hole formed in the osteosynthetic device, which is preferably realised in the form of a bone plate, is polygonal, preferably hexagonal, so that said through hole has the form of a prism, preferably a hexagonal prism. In the case of the hexagonal embodiment, the bone screw may be simultaneously moved in three planes within the hexagonal through hole, making it possible to adjust and fix the screw at any desired angle. Said angle is only limited by the plate thickness and by the abutment of the bushing on the reduced cross section. It is of course also possible to use bone plates having a plurality of through holes.

In a further embodiment, the diameter of the central bore of the bushing tapers in one direction and the bore is preferably shaped in the form of a cone. This configuration permits the bushing to be spread apart by means of a corresponding counter cone. However, the bore formed in the bushing may also be realised in a circular cylindrical shape.

Preferably, the bore of the bushing is provided with an internal screw thread. This permits a locking of the bushing.

Extending orthogonally to the central axis, the cross section of the through hole formed in the osteosynthetic device, which is preferably realised as a bone plate, may also be of elliptical shape.

In a specific embodiment, the cross section of the through hole consists of two incomplete semicircles connected to one another by means of non-circular lines. In this case, the bushing is provided with two protrusions formed on its outer surface which may be inserted into the grooves formed in the through hole by the non-circular lines.

In order to be radially compressible and radially expansible, the bushing may be provided with a continuous slot preferably extending parallel to the longitudinal axis of the bushing. In an alternative embodiment, the bushing may also have a plurality of non-continuous slots preferably extending parallel to the longitudinal axis.

The surface of the bushing, preferably in the area of its peripheral, outside face, is suitably roughened, e.g. by means of grit blasting. The through hole formed in the bone plate may correspondingly be roughened, e.g. by means of grit blasting. However, the surface of the bushing, preferably in the area of its peripheral, outside face, may also be provided with a macrostructured portion, e.g. in the form of peripheral ridges. The through hole may then be correspondingly provided with a macrostructured portion, e.g. in the form of

peripheral ridges. The advantage of this configuration lies in the positive engagement between the bushing and the bone plate which is thus achievable.

In another specific embodiment, the through hole formed in the osteosynthetic device, which is preferably realised as a bone plate, tapers towards the bottom surface and preferably also towards the top surface, thus resulting in reduced cross sections which prevent the bushing from falling out or from being pressed out. Suitably, the reduced cross section of the through hole and the compressibility of the bushing are selected adequately so that it is still possible to introduce the compressed bushing into the through hole.

The form of the peripheral outside face of the bushing is suitably convex, and preferably cylindrical.

Preferably, the osteosynthetic device - at least in the area of its through hole - and the bushing - equally at least in the area of its peripheral outside face - consist of different materials, preferably of materials differing from each other in hardness. The bushing may, for example, consist of a biocompatible plastic material and the osteosynthetic device (e.g. a bone plate) of a biocompatible metal. However, the bushing may also be made of metal and the device of a plastic material, preferably a reinforced plastic material. The different materials cause a plastic deformation of the surfaces and thus lead to a positive engagement.

The height of the bushing measured in the direction of its longitudinal axis should be inferior to the height of the through hole formed in the bone plate as measured in the direction of its central axis. The height of the bushing is suitably between 40 and 85 percent, preferably between 45 and 65 percent of the height of the through hole.

The bone screws to be introduced into the bushing preferably have a conical screw head which is provided with an external screw thread. The advantage of

this configuration is that the spreading and the locking of the bushing may thus be realised in a single step.

In the following, the invention and improvements of the invention will be illustrated in greater detail with reference to the partially diagrammatic representations of several embodiments. All the embodiments relate to an osteosynthetic device realised in the form of a bone plate. Analogous applications for pedicle screws, pedicle hooks, external fixators, or intervertebral implants are possible.

In the drawings:

Fig. 1 is a perspective view of a device for osteosynthesis realised in the form of a bone plate;

Fig. 2 is a cross section of the bone plate according to Fig. 1 with a bushing introduced therein;

Fig. 3 is a perspective view of a bushing to be used with the device for osteosynthesis;

Fig. 4 is a horizontal cross section of the bushing according to Fig. 3;

Fig. 5 is a perspective view of a bushing to be used with the device for osteosynthesis;

Fig. 6 is a horizontal cross section of a variant of the bone plate;

Fig. 7 is a perspective view of a bushing for the osteosynthetic device which mates the bone plate according to Fig. 6; and

Fig. 8 is a longitudinal section of a bone screw to be used with the device for osteosynthesis.

The device for osteosynthesis represented in Figs. 1 to 4 consists of a bone plate 1 including a bottom surface 2 designed to bear against the bone, a top surface 3, and a through hole 4 connecting the bottom surface 2 with the top surface 3, designed to receive a multiaxially adjustable bushing 10 for a bone screw 20 (Fig. 8), the through hole 4 having a central axis 5. The bushing 10 (Fig. 3) insertable into the through hole 4 includes a central bore 11 designed to receive the bone screw 20 (Fig. 8), the bore 11 having a longitudinal axis 12, as well as a peripheral outside face 17 designed to be in contact with the through hole 4.

The bushing 10 has a continuous slot 13 so as to be radially compressible and radially expansible. The through hole 4 of the bone plate 1 is provided, toward the bottom surface 2 and toward the top surface 3 thereof, with a reduced cross section 9 so as to prevent the bushing 10 from falling out or from being pressed out. Suitably, the reduced cross-section 9 of the through hole 4 and the compressibility of the bushing 10 are selected adequately so that it is still possible to introduce the compressed bushing 10 into the through hole 4.

As shown in Fig. 3, the surface of the bushing 10 is provided, in the area of its peripheral, outside face, with a macrostructured portion in the form of peripheral ridges 18. Correspondingly, the through hole 4 of the bone plate 1 is provided with a macrostructured portion in the form of peripheral ridges 19 (Fig. 2).

As shown in Fig. 4, the cross section 6 of the through hole 4 extending orthogonally to the central axis 5 is shaped in an approximately hexagonal, i.e. non-circular form. The cross section 16 of the bushing 10 extending orthogonally to the longitudinal axis 12 has a form corresponding substantially to that of the cross section 6 of the through hole 4 of the bone plate 1, so that the bushing 10 which is placed in the through hole 4 is rotationally stable

relative to its longitudinal axis 12, while remaining adjustable within the through hole 4 as to its angular orientation relative to the bone plate 1.

As shown in Fig. 2, the diameter of the bore 11 tapers in the direction of the bottom surface 2 of the bone plate 1, so that the bore 11 has a conical shape. In addition, the bore 11 is provided with an internal screw thread 15.

Fig. 5 shows another embodiment of the bushing 10 which comprises a plurality of non-continuous slots 14 extending parallel to the longitudinal axis 12. This permits the bushing 10 to be radially compressible and radially expansible without having a continuous slot.

Figs. 6 and 7 show another embodiment of the bushing 10 and of the corresponding bone plate 1 in which the cross section 6 of the through hole 4 is defined by two incomplete semicircles 7 connected to each other by means of two non-circular lines 8. Corresponding to this, the bushing represented in Fig. 7 is shaped in the form of a ring the peripheral outside face 17 of which is spherical and which is provided with two diametrically opposed semicircular protrusions 26. The two protrusions 26 are received by the grooves formed by the non-circular lines 8 within the through hole 4 of the bone plate 1, which is equally spherical. When inserted into the bone plate, the bushing 10 is rotatable both about the two protrusions 26 and orthogonally to this axis of rotation, so that adjusting movements are possible in all directions apart from a movement in the plane of the plate (cardan joint).

The bushing 10 may receive the bone screw 20 represented in Fig. 8. The bone screw 20 has a treaded shaft 21 permitting it to be anchored within the bone, a screw axis 23, and a screw head 22 for insertion into the central bore 11 of the bushing 10, which corresponds substantially to the shape of the bore 11. The cross section of the screw head 22, which extends orthogonally to the screw axis 23, has a tapered portion proximal to the screw shaft 21, thus forming a cone. The screw head 22 is provided with an external screw thread 24 which corresponds to the internal screw thread 15 of the bushing 10. In addition, the

screw head 22 is provided with a hexagon socket 15 for receiving an Allen key (not shown in the drawing).

In the following, the clinical utilisation of the device for osteosynthesis will shortly be described.

The bushing 10 of the device comes preassembled in the bone plate 1 or in the jaw. It therefore does not need to be inserted by the surgeon. The bone plate with the preassembled bushings is applied to the bone. This may be done either before or after the reduction of the different bone fragments or vertebral bodies.

There are three possible scenarios for placing the bone screws:

a) drilling, tapping, screwing;

b) drilling, screwing (using self-tapping screws); or

c) screwing (using self-drilling and self-tapping screws).

It is also possible to use aiming devices or drill bushings. It is of course not suitable to use fixed aiming devices, as this would mean to sacrifice the advantage of an angularly adjustable screw, but such an aiming device may nonetheless make sense in cases in which a limitation of the range of adjustment is desirable. Drill bushings are needed in cases in which no self-drilling screws are used and a hole must be drilled prior to inserting the screw. In such cases the drill bushing serves to prevent soft-tissue injury.

There are basically two possible ways of placing a plurality of bone screws:

A) if bone reduction is done prior to the application of the plate, the screws may immediately be fastened; and

B) in cases in which bone reduction is done after the application of the plate, the screws are first turned in only so far as to fix the plate on the bone; after that, the final bone reduction or correction takes place and the screws are subsequently turned in a few more angular degrees so as to become locked within the plate.

Claims

1. A device for osteosynthesis, including
A) a through hole (4) designed to receive a multiaxially adjustable bushing (10) for a bone screw (20), the through hole (4) having a central axis (5);
B) a bushing (10) insertable in said through hole (4) including a central bore (11) designed to receive a bone screw (20), the bore (11) having a longitudinal axis (12), as well as a peripheral outside face (17) designed to be in contact with the interior of the through hole (4),
characterized in that
C) the bushing (10) is realised in such a way as to be radially compressible and radially expansible;
D) the cross section (6) extending orthogonally to the central axis (5) is of non-circular shape; and
E) the cross section of the bushing (10) extending orthogonally to the longitudinal axis (12) is shaped in a form which substantially corresponds to that of the cross section (6) of the through hole (4); so that
F) the bushing (10) inserted in the through hole (4) is secured against rotation relative to its longitudinal axis (12) while remaining adjustable as to its angular orientation relative to the device for osteosynthesis.

2. A device as claimed in claim 1, characterised in that the cross section (6) of the through hole (4) is shaped in a polygonal, preferably a hexagonal form.

3. A device as claimed in claim 1 or 2, characterised in that the through hole (4) is shaped in the form of a prism, preferably a hexagonal prism.

4. A device as claimed in any of the claims 1 to 3, characterised in that the through hole (4) and the bushing (10) are shaped in a form resembling a toothed wheel.

5. A device as claimed in any of the claims 1 to 4, characterised in that the diameter of the bore (11) tapers in one direction and that the bore (11) is preferably shaped in the form of a cone.

6. A device as claimed in any of the claims 1 to 4, characterised in that the bore (11) of the bushing (10) is shaped in a circular cylindrical form.

7. A device as claimed in any of the claims 1 to 6, characterised in that the bore (11) has an internal screw thread (15).

8. A device as claimed in any of the claims 1 to 5, characterised in that the cross section (6) has an elliptical form.

9. A device as claimed in any of the claims 1 to 5, characterised in that the cross section (6) is defined by two incomplete semicircles (7) connected to one another by means of the non-circular lines (8).

10. A device as claimed in any of the claims 1 to 9, characterised in that the bushing (10) has a continuous slot (13).

11. A device as claimed in claim 10, characterised in that the slot (13) extends parallel to the longitudinal axis (12).

12. A device as claimed in claim 10, characterised in that the bushing (10) includes a plurality of non-continuous slots (14) preferably extending parallel to the longitudinal axis (12).

13. A device as claimed in any of the claims 1 to 12, characterised in that the surface of the bushing (10), preferably in the area of its peripheral, outside face (17), is roughened, preferably by means of grit blasting.

14. A device as claimed in any of the claims 1 to 13, characterised in that the surface of the bushing (10), preferably in the area of its peripheral, outside face (17), is provided with a coating made of a harder material than that of the bushing (10).

15. A device as claimed in any of the claims 1 to 14, characterised in that the surface of the bushing (10), preferably in the area of its peripheral, outside face (17), is provided with a macrostructured portion, preferably with peripheral ridges (18).

16. A device as claimed in any of the claims 1 to 15, characterised in that the through hole (4) is roughened, preferably by means of grit blasting.

17. A device as claimed in any of the claims 1 to 15, characterised in that the through hole (4) is provided with a coating made of a harder material than that of the osteosynthetic device.

18. A device as claimed in any of the claims 1 to 17, characterised in that the through hole (4) is provided with a macrostructured portion, preferably with peripheral ridges (19).

19. A device as claimed in any of the claims 1 to 18, characterised in that the through hole (4) is provided, towards the bottom surface (2) and preferably also towards the top surface (3), with a reduced cross section (9) designed to prevent the bushing (10) from falling out or from being pressed out.

20. A device as claimed in claims 10 and 19, characterised in that the reduced cross section (9) of the through hole (4) and the compressibility of the bushing (10) are adequately adapted to one another so that it is still possible to introduce the compressed bushing (10) into the through hole (4).

21. A device as claimed in any of the claims 1 to 20, characterised in that the peripheral outside face (17) of the bushing (10) is shaped in a convex form.

22. A device as claimed in any of the claims 1 to 20, characterised in that the inner surface of the through hole (4) is concave and that the peripheral outside face (17) of the bushing (10) is prismatic.

23. A device as claimed in any of the claims 1 to 22, characterised in that the osteosynthetic device, at least in the area of its through hole (4), and the bushing (10), at least in the area of its peripheral, outside face (17), consist of different materials, said materials being preferably of different hardness.

24. A device as claimed in any of the claims 1 to 23, characterised in that the osteosynthetic device consists of a plastic material, preferably a reinforced plastic material, and that the bushing (10) is metallic.

25. A device as claimed in any of the claims 1 to 14, characterised in that the height of the bushing (10) measured in the direction of its longitudinal axis (12) is inferior to the height of the through hole (4) measured in the direction of its central axis (5).

26. A device as claimed in claim 25, characterised in that the height of the bushing (10) is between 40 and 85 percent, preferably between 45 and 65 percent of the height of the through hole (4).

27. A device as claimed in any of the claims 1 to 26, characterised in that it comprises a bone screw (20) having a threaded shaft (21) for anchoring within the bone, a screw axis (23), and a screw head (22) designed to be introduced into the central bore (11) of the bushing (10), said screw head corresponding substantially to the form of the bore (11).

28. A device as claimed in claim 27, characterised in that the cross section of the screw head (22) extending orthogonally to the screw axis (23) tapers towards the threaded shaft (21), said taper being preferably conical.

29. A device as claimed in claim 27 or 28, characterised in that the screw head (22) is provided with an external screw thread (24).

30. A device as claimed in any of the claims 1 to 29, characterised in that the osteosynthesis device is a bone plate (1) including a bottom surface (2) designed to bear against the bone, a top surface (3), and at least one through hole (4) connecting the bottom surface (2) with the top surface (3).

31. A device as claimed in any of the claims 1 to 29, characterised in that the osteosynthesis device is a pedicle screw or a pedicle hook.

32. A device as claimed in any of the claims 1 to 29, characterised in that the osteosynthesis device is an external fixator.

33. A device as claimed in any of the claims 1 to 29, characterised in that the osteosynthesis device is an intervertebral implant.

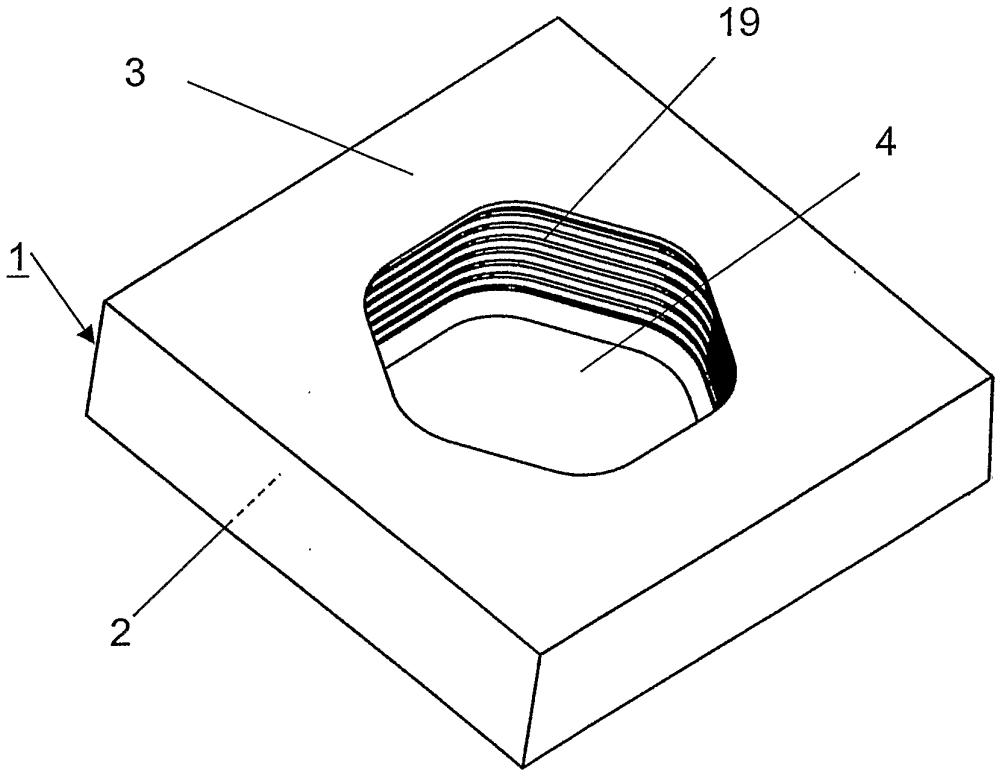


Fig. 1

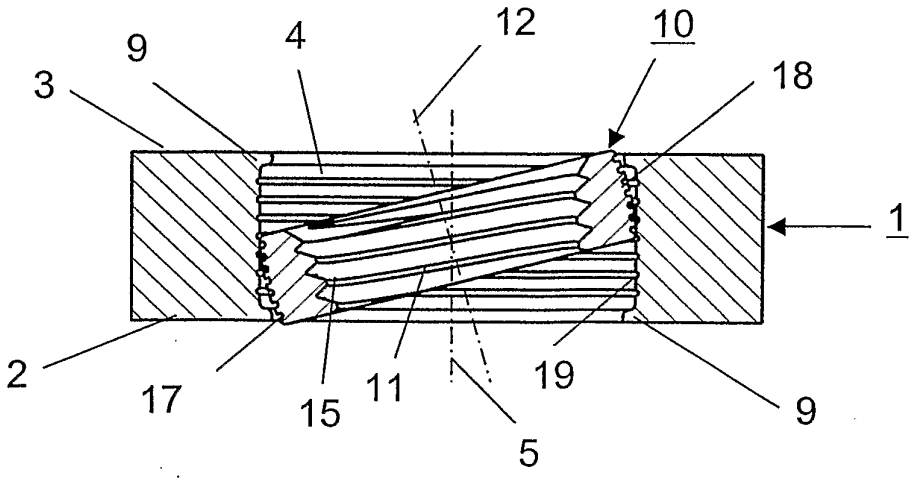


Fig. 2

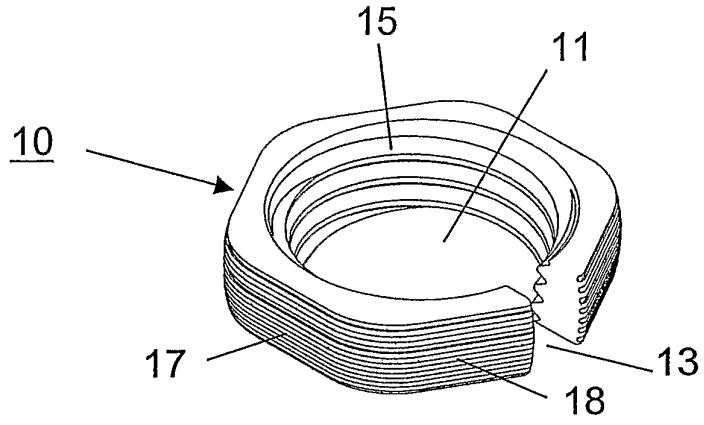


Fig. 3

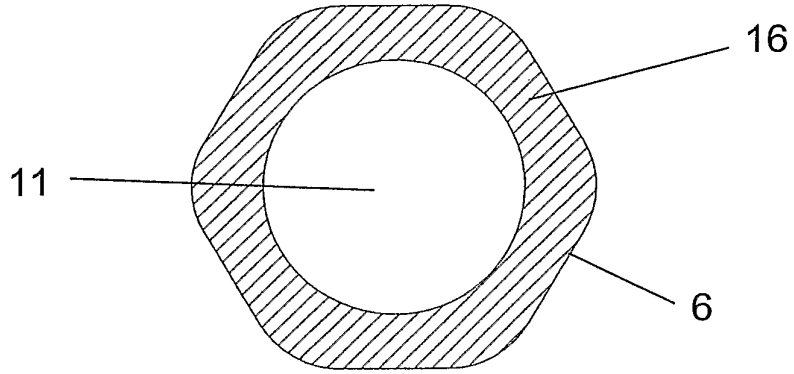


Fig. 4

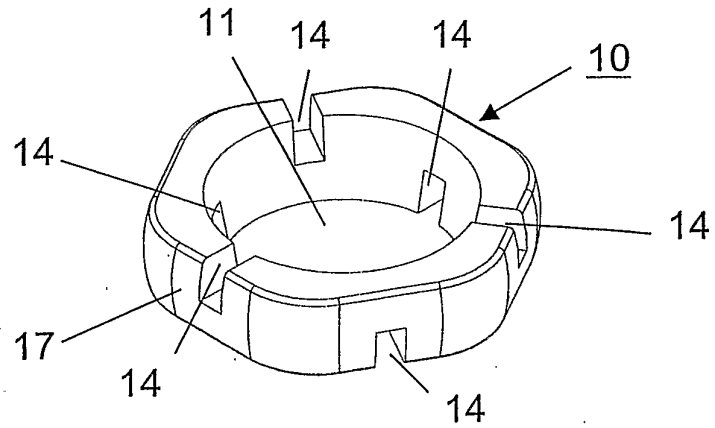


Fig.5

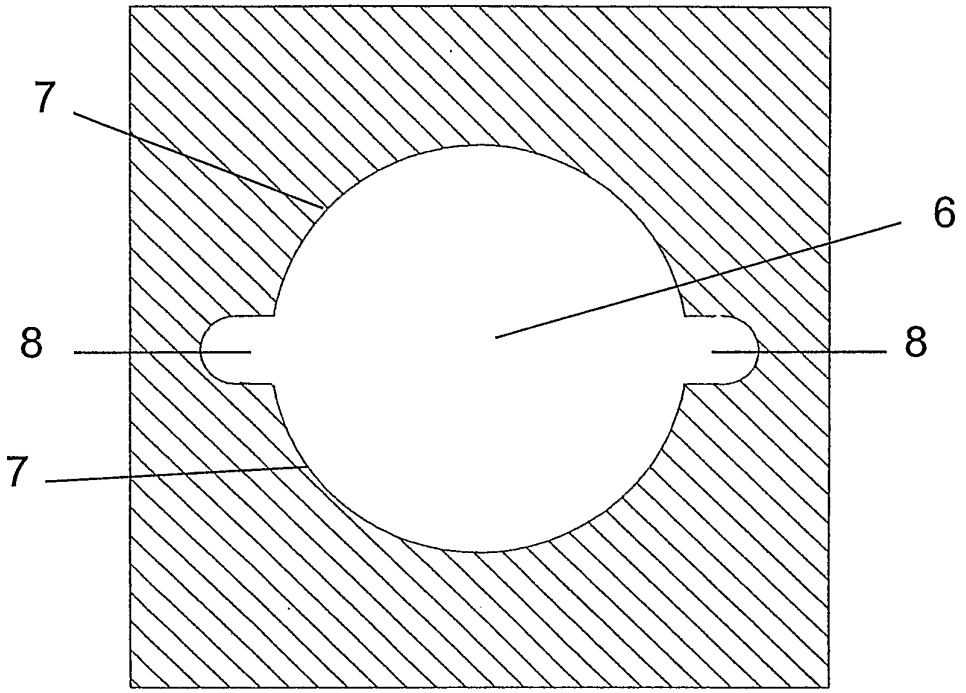


Fig. 6

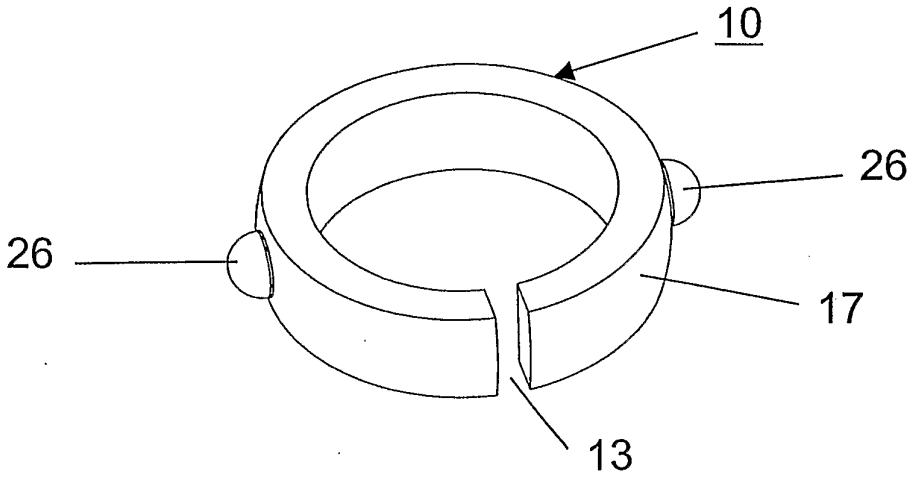


Fig. 7

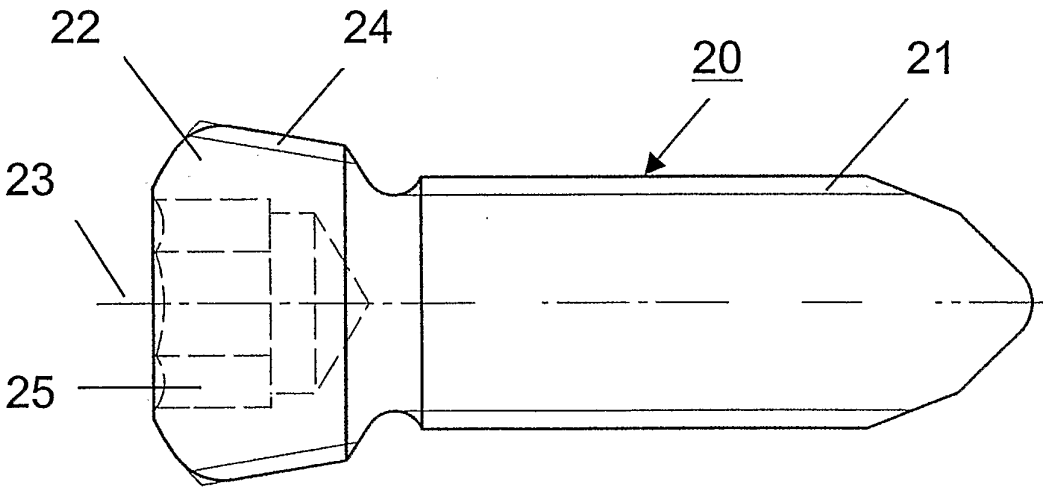


Fig. 8