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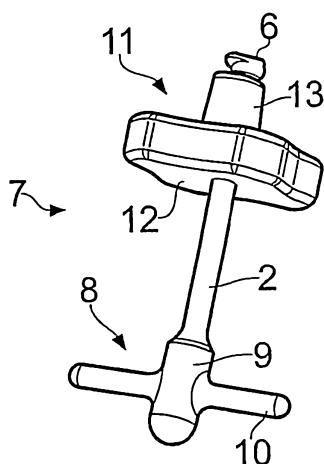
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(54) Title: SEPARATION DEVICE



(57) Abstract: A device (1, 7) for separating a sleeve from an implant head, comprising a drive shaft (2) having a proximal end (3) and a distal end (4), the distal end having a cam (6), wherein the cam is disposed such that when, in use, a torque is applied to the drive shaft via the proximal end the cam acts in a direction substantially parallel to the axis of the drive shaft. A method of separating a sleeve from an implant head using such a device.

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SEPARATION DEVICE

5 The present invention relates to a separation device, and particularly a device for separating a sleeve from an implant head. For example, if an incorrect selection (either the head or sleeve) is made the sleeve can become stuck within an implant head, such as a hip implant head. In such circumstances, manual force applied directly by a user, i.e. without the aid of a device/tool, can be insufficient to remove the sleeve. Accordingly, a suitable device is required.

10 Existing taper sleeves have an internal screw thread at the base of the taper. To remove such taper sleeves, a device with a threaded spigot is used to thread through the bottom surface of the taper sleeve and bear against the recessed internal face of the implant head, thereby forcing the sleeve and the implant head apart. Such a device will not work with a sleeve lacking a screw thread.

15 Such sleeves require there to be sufficient space for a bottom surface at the base of the sleeve. In some cases where space is limited there is not sufficient space and therefore such sleeves cannot be used.

20 Sleeves having threaded portions are more difficult to manufacture than those without threaded portions.

Sleeves having threaded portions are prone to failure due to thread burring caused by the threaded spigot separation device.

25 The present invention seeks to provide a device that can efficiently separate a sleeve from an implant head, regardless of whether the sleeve has a screw thread or not, without causing any damage to the sleeve, and/or at least provide a useful alternative

30 According to a first aspect of the present invention, there is provided a device for separating a sleeve from an implant head, comprising a drive shaft having a proximal end and a distal end, the distal end having a cam, wherein the cam is

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disposed such that when, in use, a torque is applied to the drive shaft about an axis of the drive shaft via the proximal end, the cam rotates and acts in a direction substantially parallel to the axis of the drive shaft, whereby on rotation of the drive shaft, the cam locates in a cavity space between a leading face of the sleeve and an internal face of the implant head, and forces the sleeve and the implant head apart.

The device can remove both threaded and non-threaded sleeves from an implant head. The device is simple to use and requires minimal force in order to effect separation of the sleeve and implant head. The device does not damage the sleeve. The device enables a surgeon to use non-threaded sleeves, which are easier to manufacture than threaded sleeves, less prone to damage than threaded sleeves (when removed by a threaded spigot separation device), and which can be utilised where space is limited and closed tapers are not possible.

15

The drive shaft may have a length in the range 40-80 mm. The drive shaft may have a length in the range 50-70 mm. The drive shaft may have a length in the range 55-65 mm.

20 The drive shaft may have a diameter in the range 4-8 mm. The drive shaft may have a diameter in the range 5-7 mm.

The cam may have an angle in the range 10-14° measured relative to the plane that is perpendicular to the axis of the drive shaft. The cam may have an angle in the range 11-13°. The cam may have an angle of approximately 12°.

The cam is sized so that the leading edges are smaller than the gap size of the cavity space. The cam is sized so that as the cam is rotated the cam increases to greater than the gap size. The cam may be sized so that as the cam is rotated through 180° the cam increases to greater than the gap size.

The proximal end of the device may have a handle, such that, in use, a torque is applied to the drive shaft via the handle.

5 The handle may comprise a bar disposed perpendicular to the proximal end of the drive shaft. The bar may be disposed such that the bar and the drive shaft form an L-shape. The bar may be disposed such that the bar and the drive shaft form a T-shape.

10 According to a preferred embodiment of the present invention, the device further comprises a body for engaging with the sleeve, the body having a bore for receiving the drive shaft.

15 The diameter of the bore may be greater than the diameter of the drive shaft, thereby enabling translation of the cam in a plane substantially perpendicular to the axis defined by the bore.

20 The bore may have a diameter in the range 4-12 mm. The bore may have a diameter in the range 4-10 mm. The bore may have a diameter in the range 4-8 mm. The bore may have a diameter in the range 5-7 mm.

The axis of the bore may be offset from the main axis of the body so that rotation of the drive shaft results in eccentric motion of the cam with respect to the body.

25 The body may be tapered so that it can engage with a tapered sleeve.

30 The body and the drive shaft may have guide marks such that when the guide marks on the body and the drive shaft are aligned, this indicates to a user that the cam is optimally oriented with respect to the body in order to enable insertion into the sleeve.

The body may have a first portion and a second portion, the first and second portions being cylindrical, the first portion having a greater diameter than the second portion, the first and second portions being aligned such that their

centre-points are coaxial and the body is substantially T-shaped when viewed in cross-section. The bore extends through both the first and second portions.

5 The first portion may have a diameter in the range 25-75 mm. The first portion may have a diameter in the range 35-65 mm. The first portion may have a diameter in the range 45-55 mm.

10 The second portion may have a diameter in the range 10-20 mm. The second portion may have a diameter in the range 10-15 mm. The second portion may have a diameter in the range 11-13 mm.

15 The combined length of the first and second portions measured along the bore axis may be in the range 20-50 mm. The combined length may be 20-40 mm. The combined length may be 20-30 mm. The combined length may be 25-30 mm.

20 The first portion of the body may be shaped so that it can be gripped by a user. For example, the first portion may be based on a cylinder with parts of the periphery removed in order to provide indentations that can act as gripping points. The first portion may have at least two gripping points. The first portion may have two opposing gripping points. The first portion may have three gripping points disposed equidistantly around its periphery. The first portion may have four gripping points disposed equidistantly around its periphery.

25 The second portion of the body may be tapered so that it can engage with a tapered sleeve.

30 The drive shaft/cam may be made of plastic. Preferably, the drive shaft/cam is made of metal. The metal may be aluminium, titanium, stainless steel or a metal alloy. Preferably, the metal is stainless steel.

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The handle may be made of plastic. Preferably, the handle is made of metal. The metal may be aluminium, titanium, stainless steel or a metal alloy. Preferably, the metal is stainless steel.

- 5 The body may be made of metal. The metal may be aluminium, titanium, stainless steel or a metal alloy. Preferably, the body is made of plastic. Preferably, the plastic is polyacetal.

According to a second aspect of the present invention, there is provided a method
10 of separating a sleeve from an implant head, comprising:

providing a device comprising a drive shaft having a proximal end and a distal end, the distal end having a cam, wherein the cam is disposed such that when a torque is applied to the drive shaft about an axis of the drive shaft via the proximal end, the cam rotates and acts in a direction substantially parallel to the
15 axis of the drive shaft;

inserting the distal end into a cavity space between the leading face of the sleeve and the internal face of the implant head so that the cam engages with the leading face of the sleeve and the internal face of the implant head;

applying a torque to the drive shaft via the proximal end so that the cam
20 rotates and thereby forces the sleeve and the implant head apart.

Preferably, the proximal end of the device has a handle and torque is applied to the drive shaft via the handle.

- 25 The handle may comprise a bar disposed perpendicular to the proximal end of the drive shaft. The bar may be disposed such that the bar and the drive shaft form an L-shape. The bar may be disposed such that the bar and the drive shaft form a T-shape.

- 30 According to a preferred embodiment of the present invention, the device further comprises a body for engaging with the sleeve, the body having a bore for receiving the drive shaft, and wherein the body is disposed so that it engages with the sleeve.

The diameter of the bore may be greater than the diameter of the drive shaft, thereby enabling translation of the cam in a plane substantially perpendicular to the axis defined by the bore, so that when the cam is moved within the cavity space it engages with the leading face of the sleeve and the internal
5 face of the implant head.

The axis of the bore may be offset from the main axis of the body so that rotation of the drive shaft results in eccentric motion of the cam with respect to the body, thereby enabling the cam to move from a first position within the
10 confines of the body to a second position outside the confines of the body, such that when the cam is in the second position it is disposed in the cavity space so that it engages with the leading face of the sleeve and the internal face of the implant head.

15 The sleeve may be tapered. The sleeve may have two tapers, one internal to engage with the male taper of a hip stem, for example, and one external to engage with the internal taper of the implant head.

The body of the device may be tapered so that it can engage with a tapered
20 sleeve.

The drive shaft/cam may be made of plastic. Preferably, the drive shaft/cam is made of metal. The metal may be aluminium, titanium, stainless steel or a metal alloy. Preferably, the metal is stainless steel.
25

The handle may be made of plastic. Preferably, the handle is made of metal. The metal may be aluminium, titanium, stainless steel or a metal alloy. Preferably, the metal is stainless steel.

30 The body may be made of metal. The metal may be aluminium, titanium, stainless steel or a metal alloy. Preferably, the body is made of plastic. Preferably, the plastic is polyacetal.

The implant head may be part of a hip implant.

According to a third aspect of the present invention, there is provided a kit of parts comprising a device according to the first aspect of the present invention and at least one sleeve, the body of the device and the at least one sleeve
5 being shaped so that they engage one another.

Reference will now be made, by way of example, to the accompanying drawings, in which:

10 Figures 1a-h show various views of a device according to an embodiment of the present invention;

 Figures 2a-e show various views of a device according to another embodiment of the present invention;

 Figures 3a-d show various views of a component of the device shown
15 in Figures 2a-e;

 Figures 4a,b show bottom plan views of the device of Figures 2a-e;

 Figure 5 shows a side view of the device of Figures 2a-e;

 Figure 6 shows a cross-section of an implant head with a sleeve inserted; and

20 Figures 7a-c show various views of the device of Figures 2a-e in use with an implant head and sleeve.

Figures 1a to 1h show a device (1) according to an embodiment of the present invention. The device (1) comprises a drive shaft (2) having a proximal end (3) and a distal end (4). The proximal end (3) has a protuberance (5) that can
25 be gripped by any suitable means (for example a user's fingers or pliers) in order to apply a torque to the drive shaft (2). The distal end (4) of the drive shaft (2) has a cam (6). The cam (6) is disposed such that when a torque is applied to the drive shaft (2) via the proximal end (3) the cam (6) acts in a
30 direction substantially parallel to the axis of the drive shaft (2).

Figures 1a and 1b are side views of the device (1). Figure 1c is a bottom plan view, showing the cam (6). Figures 1d-g show the cam (6) in more detail. Figure 1h shows the protuberance (5) in more detail.

A user can insert the distal end (4) into a cavity space between the leading face of a sleeve and the internal face of an implant head (see Figure 6) so that the cam (6) engages with the leading face of the sleeve and the internal face of the implant head. The user can then apply a torque to the drive shaft (2) via the protuberance (5) on the proximal end (3) of the drive shaft (2) so that the cam (6) rotates and thereby forces the sleeve and implant head apart. The user may apply a torque with his fingers if possible, or with pliers if more force is required. The protuberance (5) may provide an attachment point for a handle, as described herein.

Figures 2a-e show a device (7) according to another embodiment of the present invention. The figures show possible dimensions of the device (7) by way of example only, they are not limiting. The device (7) comprises a drive shaft (2) having a proximal end (3) and a distal end (4). The proximal end (3) has a handle (8) which comprises a body (9) and a cross bar (10). The handle (8) is attached to the protuberance (5) of Figures 1a-h. The handle enables a user to apply a torque to the proximal end (3) of the drive shaft (2). The distal end (4) of the drive shaft (2) has a cam (6). The cam (6) is disposed such that when a torque is applied to the drive shaft (2) via the handle (8), the cam (6) acts in a direction substantially parallel to the axis of the drive shaft (2).

The device (7) also has a body (11) which comprises a first portion (12) and a second portion (13). The body (11) is shown in more detail in Figures 3a-d. The diameter of the first portion (12) is greater than the diameter of the second portion (13). The first (12) and second (13) portions are aligned such that their centre-points are coaxial and the body is substantially T-shaped when viewed in cross-section (see Figures 2a-c, 3b). The first portion (12) has four gripping points (15) disposed equidistantly around the periphery of the first portion (12). The second portion (13) is tapered so that it can engage with a tapered sleeve.

As shown in Figure 3d, a bore (14) extends through both the first (12) and second (13) portions. From Figures 2a,c and 3a,c,d it can be seen that the central axis of the bore (14) is offset from the main axis of the body (11) so that rotation of the drive shaft (2) results in eccentric motion of the cam (6) with respect to the body (11). This is illustrated in Figures 4a,b. As shown in Figures 4a,b, rotation of the drive shaft (in this embodiment in a clockwise direction) causes the cam (6) to move out from within the confines of the second portion (13) of the body (11) in direction Y. As shown in Figure 5, the drive shaft (2) and cam (6) can translate in the direction Z, parallel to the axis of the drive shaft (2).

Figure 6 shows a cross-section of an implant head (17) with a sleeve (16) inserted. As shown, there is a cavity space (18) between the leading face (19) of the sleeve (16) and the internal face (20) of the implant head (17). It is the cavity space (18) that receives the cam (6). The gap size of the cavity space (18) may be 1 mm or more. The gap size of the cavity space (18) may be 2-10 mm. Usually, the gap size of the cavity space is approximately 2 mm.

Figures 7a-c show the device (7) of Figures 2a-e in use with an implant head (17). The distal end (4) of the device (7) is passed into the implant assembly through the rear of the sleeve (16) and allowed to advance until the distal end (4) is inserted into the cavity space (18) between the leading face (19) of the sleeve and the internal face (20) of the implant head (17) (see Figure 7a and Figure 6). The second portion (13) of the body (11) locates in the sleeve (16) and thereby centralises the body (11) in the sleeve (16).

As shown in Figure 7b, a torque is applied to the handle (8) so that the drive shaft (2) rotates. From Figures 4a,b it can be seen that such rotation of the drive shaft (2) causes the cam (6) to move out from within the confines of the second portion (13) of the body (11) in direction Y. Consequently, the cam (6) moves in the cavity space (18) and the leading edges of the cam (6) engage with the leading face (19) of the sleeve (16) and the internal face (20) of the implant head (17) (see Figure 6). As the rotation of the drive shaft (2) and cam (6) continues the cam (6) acts in a direction substantially parallel to the

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axis of the drive shaft (2) (direction Z in Figure 5) such that it forces the sleeve (16) and implant head (17) apart (see Figure 7c).

5 The drive shaft (2)/cam(6) may be made of plastic. Preferably, the drive shaft (2)/cam(6) is made of metal. The metal may be aluminium, titanium, stainless steel or a metal alloy. Preferably, the metal is stainless steel.

10 The handle (8) may be made of plastic. Preferably, the handle (8) is made of metal. The metal may be aluminium, titanium, stainless steel or a metal alloy. Preferably, the metal is stainless steel.

15 The body (11) may be made of metal. The metal may be aluminium, titanium, stainless steel or a metal alloy. Preferably, the body (11) is made of plastic. Preferably, the plastic is polyacetal.

20 Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

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THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A device for separating a sleeve from an implant head, comprising a drive shaft having a proximal end and a distal end, the distal end having a cam, wherein the cam is disposed such that when, in use, a torque is applied to the drive shaft about an axis of the drive shaft via the proximal end, the cam rotates and acts in a direction substantially parallel to the axis of the drive shaft, whereby on rotation of the drive shaft, the cam locates in a cavity space between a leading face of the sleeve and an internal face of the implant head, and forces the sleeve and the implant head apart.
2. A device according to claim 1, further comprising a body for engaging with the sleeve, the body having a bore for receiving the drive shaft.
3. A device according to claim 2, wherein the diameter of the bore is greater than the diameter of the drive shaft, thereby enabling translation of the cam in a plane substantially perpendicular to the axis defined by the bore.
4. A device according to claim 2, wherein the axis of the bore is offset from the main axis of the body so that rotation of the drive shaft results in eccentric motion of the cam with respect to the body.
5. A device according to any preceding claim, wherein the body is tapered so that it can engage with a tapered sleeve.
6. A device according to any preceding claim, wherein the proximal end has a handle, and wherein, in use, a torque is applied to the drive shaft via the handle.
7. A device according to claim 6, wherein the handle comprises a bar disposed perpendicular to the proximal end of the drive shaft.

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8. A device according to claim 7, wherein the bar is disposed such that the bar and the drive shaft form a T-shape.
9. A device according to any preceding claim, wherein the drive shaft/cam is made of metal.
10. A device according to any preceding claim, wherein the handle is made of metal.
- 10 11. A device according to any preceding claim, wherein the body is made of plastic.
12. A method of separating a sleeve from an implant head, comprising:
 providing a device comprising a drive shaft having a proximal end and a distal end, the distal end having a cam, wherein the cam is disposed such that when a torque is applied to the drive shaft about an axis of the drive shaft via the proximal end, the cam rotates and acts in a direction substantially parallel to the axis of the drive shaft;
 inserting the distal end into a cavity space between the leading face of the sleeve and the internal face of the implant head so that the cam engages with the leading face of the sleeve and the internal face of the implant head;
 applying a torque to the drive shaft via the proximal end so that the cam rotates and thereby forces the sleeve and the implant head apart.
- 15 13. A method according to claim 12, wherein the proximal end of the device has a handle, and wherein a torque is applied to the drive shaft via the handle.
14. A method according to claim 12 or 13, wherein the device further comprises a body for engaging with the sleeve, the body having a bore for receiving the drive shaft, and wherein the body is disposed so that it engages with the sleeve.
15. A method according to claim 14, wherein the diameter of the bore is greater than the diameter of the drive shaft, thereby enabling translation of the cam in a

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plane substantially perpendicular to the axis defined by the bore, and wherein the cam is moved within the cavity space so that it engages with the leading face of the sleeve and the internal face of the implant head.

- 5 16. A method according to claim 14, wherein the axis of the bore is offset from the main axis of the body so that rotation of the drive shaft results in eccentric motion of the cam with respect to the body, thereby enabling the cam to move from a first position within the confines of the body to a second position outside the confines of the body, such that when the cam is in the second position it is
10 disposed in the cavity space so that it engages with the leading face of the sleeve and the internal face of the implant head.

17. A method according to any of claims 12 to 16, using a device according to any of claims 5 to 11.

15

18. A method according to any of claims 12 to 17, wherein the implant head is part of a hip implant.

19. A kit of parts comprising a device according to any of claims 2 to 11 and at
20 least one sleeve, the body of the device and the at least one sleeve being shaped so that they engage one another.

20. A device substantially as hereinbefore described with reference to the drawings.

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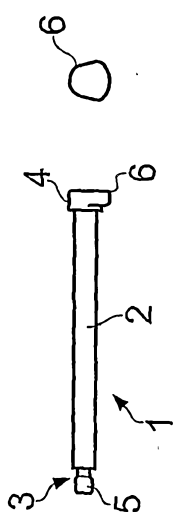


FIG. 1a

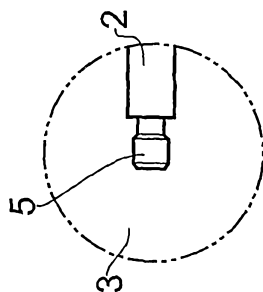


FIG. 1h

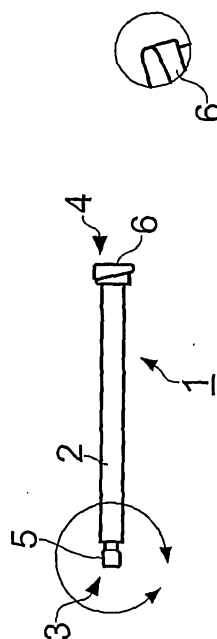


FIG. 1b

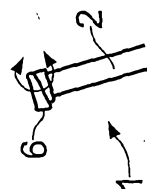


FIG. 1e

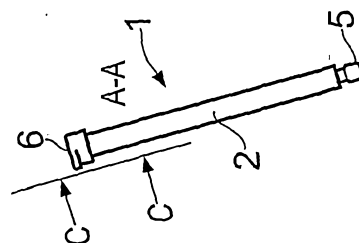


FIG. 1d

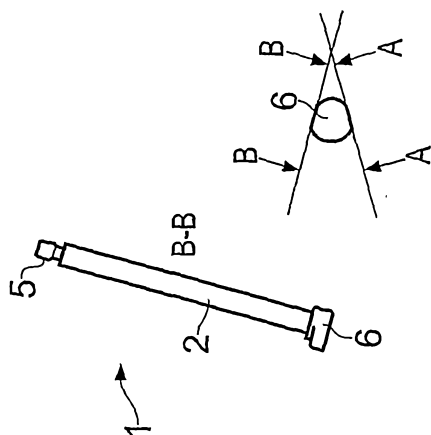


FIG. 1g

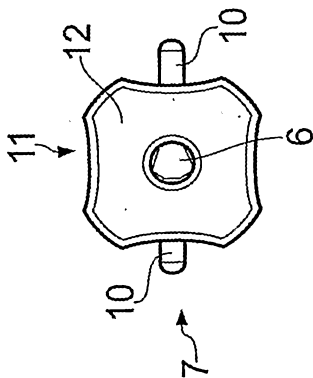


FIG. 2e

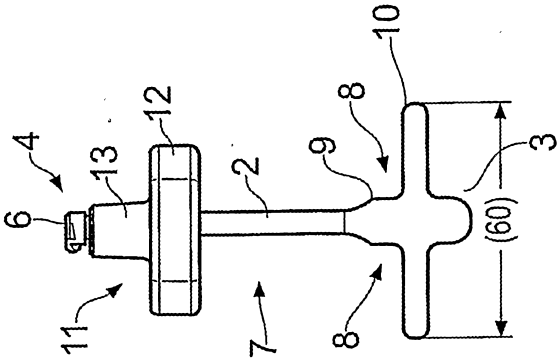


FIG. 2a

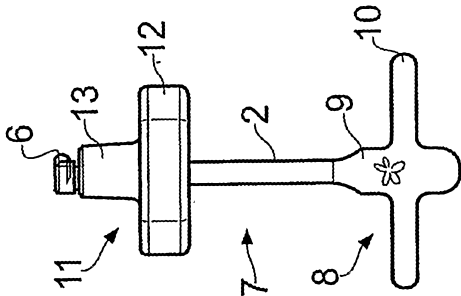


FIG. 2c

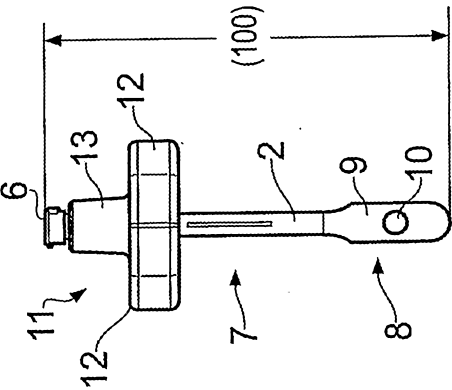


FIG. 2b

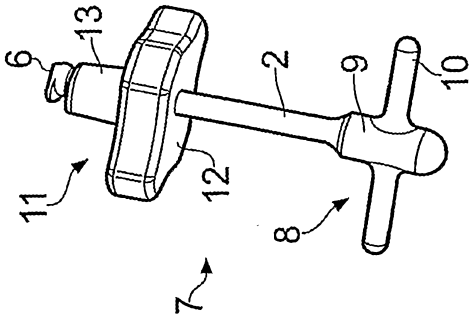


FIG. 2d

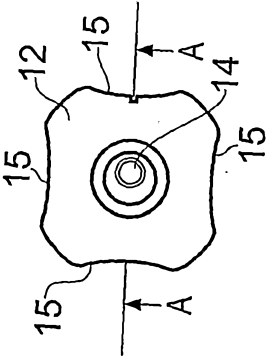


FIG. 3c

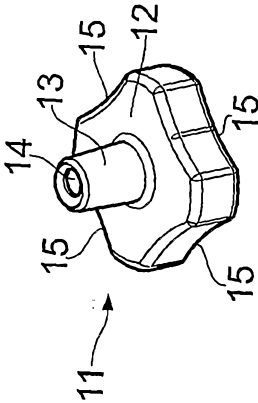


FIG. 3a

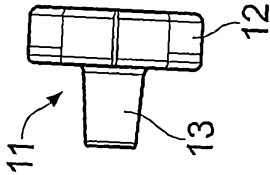


FIG. 3b

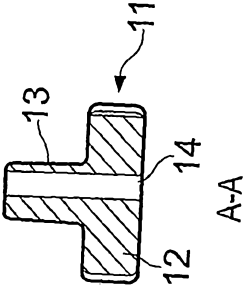


FIG. 3d

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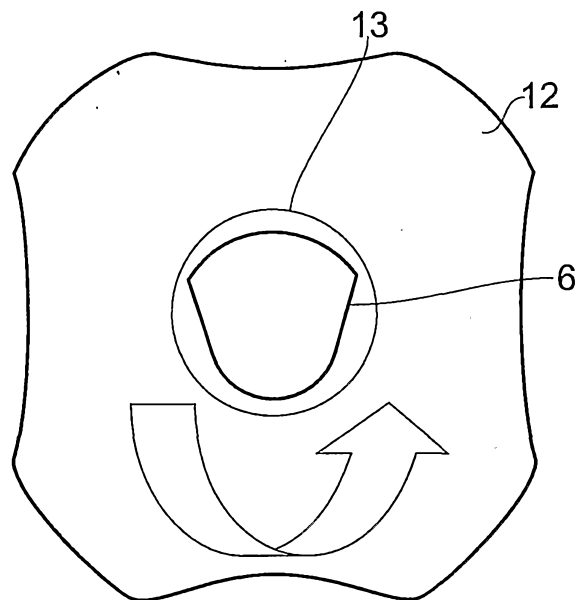


FIG. 4a

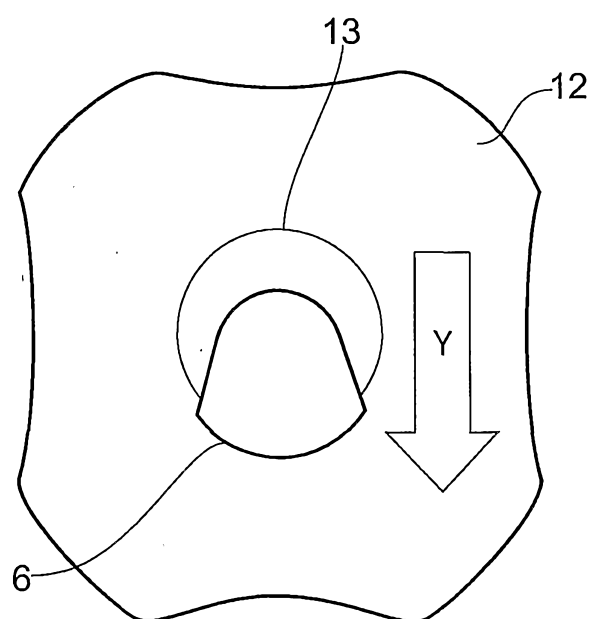


FIG. 4b

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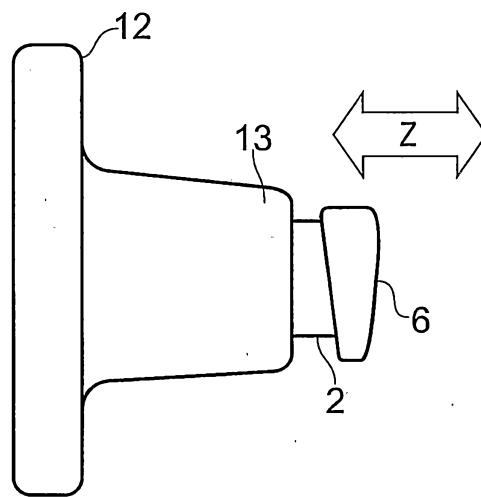


FIG. 5

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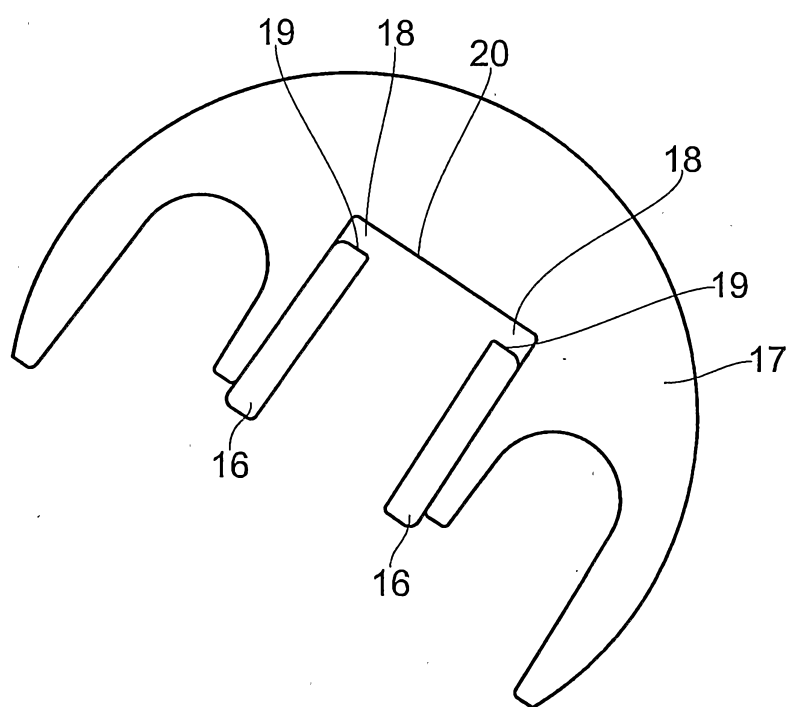


FIG. 6

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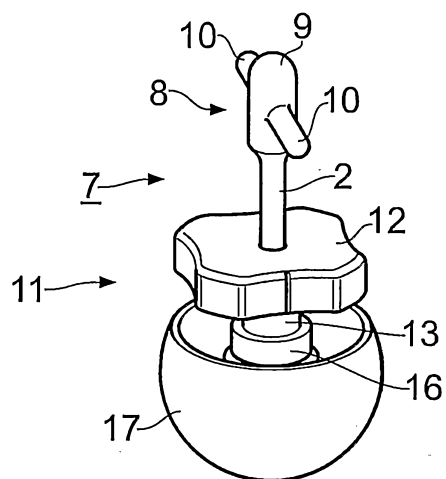


FIG. 7a

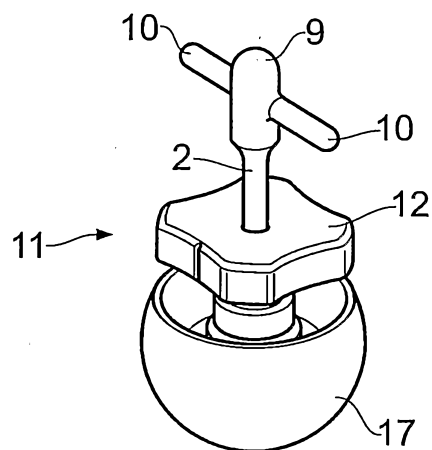


FIG. 7b

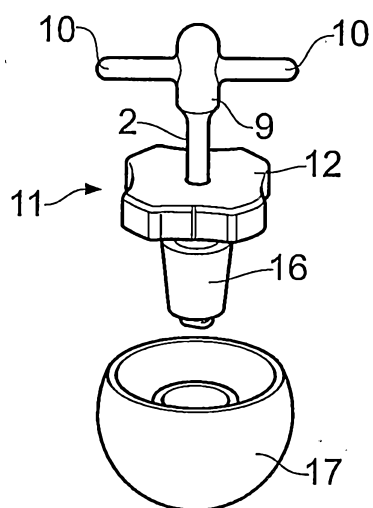


FIG. 7c