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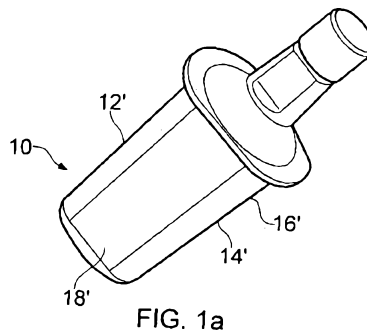
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(54) **Title:** A FEMORAL NECK PROSTHESIS



(57) **Abstract:** A femoral neck prosthesis (10) with a cross-section defined by a perimeter comprising: first and second arcuate portions (12, 14) disposed opposite one another; and first and second substantially straight portions (16, 18) disposed opposite one another and in between the first and second arcuate portions, wherein the first and second straight portions are non-parallel with respect to one another.

A FEMORAL NECK PROSTHESIS

This invention relates to a femoral neck prosthesis and particularly but not exclusively relates to a femoral neck prosthesis with a trapezoidal cross-section.

5

Background

Arthritis of the hip primarily affects the articulation between the femoral head and the acetabulum. If surgery is required, the primary objective is to replace the articulating surfaces. To achieve this it is desirable to obtain a homogeneous transfer of forces to the proximal femur. This is best provided by retention of the femoral neck. Early attempts to achieve a conservation of the femoral neck and more physiological loading were betrayed by poor materials, inadequate fixation and failure of the articulation. Despite the high level of survivorship of cemented and uncemented stemmed femoral components, there is a need for a joint prosthesis that does not invade the femoral canal. The above mentioned prosthesis would be useful in treating younger and more active patients, in whom the use of such a design would usefully prolong the time where a conventional total joint replacement design is necessary.

20 While the more frequent use of hard-hard articulations and the highly cross-linked polyethylenes in total hip replacement are anticipated to lead to a reduction of osteolysis, in addition to wear, stress shielding is expected to become a more targeted cause of bone reduction. The reduction of stress and strain in the proximal femur following total hip replacement is hypothesized to be one reason of proximal bone loss, which may lead to a reduction of implant support, progressive implant subsidence and periprosthetic bone fracture. Even though it is not clear if the resorption of the proximal femoral bone stock is directly related to the survival of implants, an excessive bone loss around a primary prosthesis can reduce the longevity of a revision prosthesis by compromising the bone stock available at the revision procedure. Thus, conservation of bone stock is a vitally important principle, especially in young patients where the chances of revisions during the patients' lifetime are high. Particularly in uncemented total hip replacement, which is often favored in young patients, the stem geometry is believed to play an important role in the load transfer to the femur and, consequently, in femoral remodeling. As canine studies, periprosthetic bone mineral density measurements and clinical observations have indicated, implantation of different

femoral stems lead to a bone reaction specific for the geometry, surface finish and stiffness of the implants used.

5 The main problem with the replacement procedure is the survival rate and the revision options. At a revision there is a considerable amount of bone of the upper femur destroyed in the loosening process, and during the removal procedure of the existing femoral component. The subsequent revision implant is necessarily larger and longer in order to gain sufficient fixation. The survivorship of such devices is usually less than that of the primary procedure. Moreover, should that device fail, the prognosis is very
10 poor indeed. Hence, there is a strong rationale for use of a "conservative" device at the primary stage, which involves interfacing with far less of the femur than does a conventional total hip. The goals of such a conservative device are that it will be easy to insert and will have a survivorship similar to that of a conventional total hip. Even if the survivorship was slightly less, there is still a justification for its use. If a
15 conservative hip is suitably designed and if it were to fail by loosening or other reason, then its removal would involve little destruction of the femoral bone. The revision procedure would then be equivalent to the use of a primary total hip. Thereby, the patient would have gained a substantial time period, say ten years or more. The high probability of revision in these younger more active patients has been one of the main
20 factors driving the quest for more bone sparing conservative options at a total hip replacement. The present invention therefore seeks to address this issue.

It is to be clearly understood that mere reference herein to previous or existing apparatus, products, systems, methods, practices, publications or other information, or
25 to any problems or issues, does not constitute an acknowledgement or admission that any of those things individually or in any combination formed part of the common general knowledge of those skilled in the field, or that they are admissible prior art.

Statements of Invention

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According to a first aspect of the present invention there is provided a femoral neck prosthesis with a cross-section defined by a perimeter comprising: first and second arcuate portions disposed opposite one another; and first and second substantially straight portions disposed opposite one another and in between the first
35 and second arcuate portions, wherein the first and second straight portions are non-parallel with respect to one another wherein a substantial portion of the femoral neck

2b

prosthesis is configured for placement within the metaphyseal cancellous bone between a femoral head and the cortical bone, and wherein the femoral neck prosthesis is configured such that in an installed configuration a rigid fixation between the femoral neck prosthesis and the femur which withstands all the forces and moments transmitted from the femoral head is provided.

The first and second arcuate portions may have the same radius of curvature. The first and second arcuate portions may have the same centre of curvature.

10 The perimeter may be symmetrical about a line of symmetry intersecting the first and second arcuate portions. The distance between first and second straight portions

along a line perpendicular to the line of symmetry and passing through a midpoint in the line of symmetry may be substantially two-thirds of the distance between the first and second arcuate portions along the line of symmetry.

- 5 The first and second arcuate portions may be provided on medial and lateral sides of the patient respectively. The first and second substantially straight portions may be provided on anterior and posterior sides of the patient respectively. The first and second substantially straight portions may converge such that the distance between the first and second substantially straight portions may be greater at the lateral side
10 than the medial side.

The cross-sectional area of the femoral neck prosthesis may vary along the length of the prosthesis. The cross-sectional area of the femoral neck prosthesis may taper along the length of the prosthesis. A locus defined by a midpoint between the first and
15 second arcuate portions along the length of the femoral neck prosthesis may be substantially straight.

As mentioned above, a substantial portion of the femoral neck prosthesis may be suitable for placement within the metaphyseal cancellous bone between the femoral
20 head and the cortical bone.

The corners between the first and second arcuate portions and the first and second substantially straight portions may be rounded off.

- 25 A femoral neck prosthesis assembly may comprise the femoral neck prosthesis as described above. The femoral neck prosthesis assembly may further comprise a neck portion for engaging a femoral head portion. The neck portion may be modular and may have first and second ends adapted to selectively engage corresponding openings in the prosthetic femoral neck and the femoral head portion respectively. The
30 prosthetic assembly may further comprise a modular collar. The modular collar may have an opening to selectively engage the neck portion of the prosthetic assembly.

According to a second aspect of the invention there is provided a method of manufacturing the femoral neck prosthesis as described above, wherein the method
35 comprises: providing a workpiece having a cross-section with an at least partially curved perimeter; and removing first and second portions from the workpiece such that

first and second segments are removed from the cross-section of the workpiece. The cross-section of the workpiece may be circular.

5 A femoral neck prosthesis according to an example of the present invention may be based on the principle of transmitting physiological load through the trabeculae between the femoral head and different endosteal regions of the proximal femur as naturally as possible. The prosthesis may provide rigid fixation that would withstand all the forces and moments transmitted from the femoral head. The prosthesis may further leave the femur sufficiently intact if the prosthesis had to be removed. In that case, a conventional hip replacement stem may be inserted with minimal compromise. 10 Based on the anatomical shape of the neck of the femur, a trapezoidal cross section may provide optimum fit and fill allowing for loading on to the calcar region. A tapered section along the length of the prosthesis may produce compressive and shear forces down the axis of the femoral neck. The forces may be transmitted from the shaft of the prosthesis to the cortical and cancellous bone in the region of the femoral neck. The femoral neck may then further distribute the loading in the distal part of the femur. 15

Brief Description of the Drawings

20 For a better understanding of the present invention, and to show more clearly how it may be carried into effect, reference will now be made, by way of example, to the accompanying drawings, in which:-

Figure 1 shows a femoral neck prosthesis according to an example of the present invention in a perspective view (Figure 1(a)) and a plan view (Figure 1(b)); 25

Figures 2(a)-(d) shows a sectional view of the femoral neck prosthesis according to an example of the present invention;

30 Figures 3(a)-(d) show a sectional view of the femoral neck prosthesis according to an example of the present invention at various stages during manufacture;

Figures 4(a)-(c) show a femoral neck prosthesis assembly comprising a neck portion according to an example of the present invention;

Figures 5(a)-(c) show a femoral neck prosthesis assembly comprising a collar according to an example of the present invention;

Figure 6 shows a femoral neck prosthesis assembly comprising a neck portion and a collar according to an example of the present invention; and

Figure 7 shows a perspective view of the femoral neck prosthesis according to an example of the present invention once installed in the femur.

10 **Detailed Description**

With reference to Figure 2 a femoral neck prosthesis 10 according to an example of the present invention comprises a cross-section defined by a perimeter comprising first and second arcuate portions 12, 14 and first and second substantially straight portions 16, 18. Accordingly, the perimeter has four sides. The first and second arcuate portions 12, 14 are disposed opposite one another. The first and second substantially straight portions 16, 18 are disposed opposite one another and in between the first and second arcuate portions 12, 14. The first and second straight portions 16, 18 converge. In other words they are not parallel.

20

As shown in Figure 2(a), the first and second arcuate portions 12, 14 may have different radii of curvature and/or different centres of curvature. For example, the first and second arcuate portions may have radii R_1 and R_2 respectively and their centres of curvature may be separated by a distance L . Furthermore, the first and second arcuate portions 12, 14 need not be circular in shape and may be elliptical or any other curved shape. However, with reference to Figure 2(b), the first and second arcuate portions 12, 14 may have the same radius and centre of curvature. In other words, the first and second arcuate portions 12, 14 may be arcs from the same circle.

30 Referring to Figures 1(a) and 2(a), the cross-section described above extends in a lengthwise direction so as to generate first and second arcuate surfaces 12', 14' and first and second substantially straight surfaces 16', 18'. The first and second substantially straight surfaces 16', 18' may be straight in the plane of the above described cross-section, but may be curved or straight in a lengthwise direction.

35 Similarly, the first and second arcuate surfaces 12', 14' may be curved in the plane of the above described cross-section, but may be curved or straight in a lengthwise

direction. The first and second substantially straight surfaces 16', 18' resist rotation of the femoral neck 10 when in situ, whilst also maximising the amount of bone remaining.

5 The first and second arcuate surfaces 12', 14' are provided on lateral and medial sides of the patient respectively and the first and second substantially straight surfaces 16', 18' are provided on posterior and anterior sides of the patient respectively. The first and second substantially straight portions 16, 18 converge such the distance between the first and second substantially straight portions is greater at the lateral side than the medial side.

10 The cross-sectional area of the femoral neck prosthesis 10 may vary along the length of the prosthesis and the femoral neck prosthesis may taper towards its distal end. Alternatively, the cross-sectional area may be constant along the length of the femoral neck prosthesis. A locus defined by a midpoint between the first and second arcuate portions 12, 14 along the length of the prosthesis is substantially straight. In the particular case of the first and second arcuate portions 12, 14 having the same radii and centres of curvature, the midpoint corresponds to the centre of curvature.

15 With reference to Figure 2(c), the cross section of the perimeter of the prosthesis is symmetrical about a line of symmetry 20 intersecting the first and second arcuate portions 12, 14. In the particular case of the first and second arcuate portions being defined by a common circle, the line of symmetry corresponds to a diameter of the circle. The distance between the first and second straight portions 16, 18 along a line 22 perpendicular to the line of symmetry and passing through a midpoint in the line of symmetry 20 is substantially two-thirds of the distance between the first and second arcuate portions along the line of symmetry. In other words, the ratio of the lengths of the lines CD:AB shown in Figure 2 is 2:3.

20 As shown in Figure 2(d), the corners between the first and second arcuate portions 12, 14 and the first and second substantially straight portions 16, 18 may be optionally rounded off.

25 With reference to Figures 3(a)-(d) the femoral neck prosthesis 10 described above may be manufactured by providing a workpiece 30 having an at least partially curved cross-section, which may in one particular example be a circular cross-section as shown in Figure 3(a). The workpiece may for example be tubular, frustoconical or cylindrical.

First and second portions 32, 34 are then removed from the workpiece 30 by cutting, milling, grinding or any other removal process (Figure 3(b)). The first and second portions 32, 34 have a cross-section such that first and second segments are effectively removed from the cross-section of the workpiece. The net result is that the first and second substantially straight portions 16, 18 are formed (Figure 3(c)).
5 Alternatively, the femoral neck prosthesis may be formed in a mould. However, the mould may be formed in a manner similar to that described above, i.e. from an at least partially curved cross-section workpiece with segments removed. In either case, manufacturing the femoral neck prosthesis 10 is straightforward as the cross-section of the workpiece may form two of the four sides of the perimeter and the remaining two straight edged sides are readily formed. The corners may subsequently be rounded off as shown in Figure 4(d). (Figure 3(d) contrasts with Figures 3(a)-(c) in that it shows a workpiece cross-section comprising first and second arcuate portions with different centres and radii of curvature.)
10

15 With reference to Figures 4(a)-(c) a femoral neck prosthesis assembly 100 according to an example of the present invention comprises the femoral neck prosthesis 10 as described above and a neck portion 110 for engaging a femoral head portion (not shown). The neck portion 110 is removable from the femoral neck prosthesis 10 and femoral head. In other words the neck portion 110 is modular. The neck portion 110 has first and second ends 112, 114 adapted to selectively engage corresponding openings in the femoral neck prosthesis and the femoral head portion respectively. For example, the femoral neck prosthesis 10 comprises an opening 116 for receiving the first end 112 of the neck portion 110. The opening 116 and first end 112 of the neck portion 110 may be correspondingly tapered in order to provide a tapered fit. The first end 112 of the neck portion 110 and the corresponding opening 116 may comprise a circular cross-section (Figure 5(a)), an elliptical cross-section (Figure 5(b)), a trapezoidal cross-section (Figure 5(c)) or any other suitable cross-section. The second end 114 of the neck portion 110 may comprise a similarly tapered connection.
20
25
30

The neck portion 110 may further comprise an abutment shoulder 118 at the first end 112 of the neck portion which may abut against the femoral neck prosthesis 10.

35 With reference to Figures 5(a)-(c) a femoral neck prosthesis assembly 200 according to an example of the present invention comprises the femoral neck prosthesis 10 as described above and a collar 220 for engaging a resected portion of the femur. The

collar 220 is disposed about a neck portion 210 of the femoral neck prosthesis 10 which may or may not be removable. The collar 220 is removable from the femoral neck prosthesis 10. In other words the collar 220 is modular. The collar 220 comprises an opening 222 shaped to selectively engage the neck portion 210 of the prosthetic assembly. The collar may comprise an additional opening 224 such that the opening 222 is only partially enclosed by the collar. The collar may then be installed onto the neck portion 210 from a anterior or posterior side (as shown in Figure 5(a)) or a medial or lateral side (as shown in Figure 5(b)). The additional opening 224 may be tapered such that the collar 22 snaps into position about the neck portion 210.

Alternatively, the collar 220 may not comprise the additional opening 224 such that the opening 222 is enclosed by the collar (Figure 5(c)). The collar may then be installed from the femoral head end of the neck portion 210. As shown in Figure 1(b), the collar 220 may have a cross-section similar to the cross-section of the femoral neck prosthesis 10. The collar 220 may have a larger cross-sectional area than the femoral neck prosthesis 10 so as to protrude beyond the femoral neck prosthesis 10 and provide an abutment surface for abutment with the femoral neck.

With reference to Figure 6 a femoral neck prosthesis assembly 300 according to an example of the present invention comprises the femoral neck prosthesis 10 as described above, a removable collar 220 for engaging a resected portion of the femur and a removable neck portion 110 for engaging a femoral head portion (not shown). In other words, the prosthetic femoral assembly 300 may comprise both the modular collar 220 and the modular neck portion 110 described above. Advantageously, modular collars and/or modular neck portions allow different sized or shaped collars or neck portions to be used to suit the requirements of the patient. It also permits a greater variation in the femoral assembly with the minimum number of parts required.

With reference to Figure 7 a perspective view of the femoral neck prosthesis 10 once installed in the femur is shown. As is shown, a substantial portion of the femoral neck prosthesis is suitable for placement within the metaphyseal cancellous bone 400 between the femoral head and the proximal cortical bone 410. The amount of bone remaining is therefore maximised, thereby facilitating revision surgery.

Anatomical forces are transmitted through the trabeculae between the femoral head and different endosteal regions of the upper femur. A rigid fixation which withstands all the forces and moments transmitted from the femoral head is therefore provided. The

resultant force on the femoral head produces a compressive force down the axis of the neck portion and a perpendicular shear force. The compressive force is transmitted by the collar of the implant to the cut surface of the femoral neck. The shear force will be transmitted by the femoral neck prosthesis from adjacent the collar to the cortical and cancellous bone in that region of the medial neck. Furthermore, the femur is left sufficiently intact so that, if the prosthesis had to be removed, a conventional hip replacement stem could be inserted with minimal compromise.

In the present specification and claims (if any), the word 'comprising' and its derivatives including 'comprises' and 'comprise' include each of the stated integers but does not exclude the inclusion of one or more further integers.

Reference throughout this specification to 'one embodiment' or 'an embodiment' means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment of the present invention. Thus, the appearance of the phrases 'in one embodiment' or 'in an embodiment' in various places throughout this specification are not necessarily all referring to the same embodiment. Furthermore, the particular features, structures, or characteristics may be combined in any suitable manner in one or more combinations.

In compliance with the statute, the invention has been described in language more or less specific to structural or methodical features. It is to be understood that the invention is not limited to specific features shown or described since the means herein described comprises preferred forms of putting the invention into effect. The invention is, therefore, claimed in any of its forms or modifications within the proper scope of the appended claims (if any) appropriately interpreted by those skilled in the art.

Claims

1. A femoral neck prosthesis with a cross-section defined by a perimeter comprising:
- 5 first and second arcuate portions disposed opposite one another; and
first and second substantially straight portions disposed opposite one another and in between the first and second arcuate portions, wherein the first and second straight portions are non-parallel with respect to one another,
wherein a substantial portion of the femoral neck prosthesis is configured for
10 placement within the metaphyseal cancellous bone between a femoral head and the cortical bone,
and wherein the femoral neck prosthesis is configured such that in an installed configuration a rigid fixation between the femoral neck prosthesis and the femur which withstands all the forces and moments transmitted from the femoral head is provided.
- 15
2. A femoral neck prosthesis as claimed in claim 1, wherein the first and second arcuate portions have the same radius of curvature.
3. A femoral neck prosthesis as claimed in claim 1 or 2, wherein the first and
20 second arcuate portions have the same centre of curvature.
4. A femoral neck prosthesis as claimed in any one of the preceding claims, wherein the perimeter is symmetrical about a line of symmetry intersecting the first and second arcuate portions.
- 25
5. A femoral neck prosthesis as claimed in claim 4, wherein a distance between the first and second straight portions along a line perpendicular to the line of symmetry and passing through a midpoint in the line of symmetry is substantially two-thirds of the distance between the first and second arcuate portions along the line of symmetry.
- 30
6. A femoral neck prosthesis as claimed in any one of the preceding claims, wherein the first and second arcuate portions are provided on lateral and medial sides of the patient respectively and the first and second substantially straight portions are provided on posterior and anterior sides of the patient respectively.
- 35

7. A femoral neck prosthesis as claimed in claim 6, wherein the first and second substantially straight portions converge such that the distance between the first and second substantially straight portions is greater at the lateral side than the medial side.
- 5 8. A femoral neck prosthesis as claimed in any one of the preceding claims, wherein the cross-sectional area of the femoral neck prosthesis varies along the length of the femoral neck prosthesis.
9. A femoral neck prosthesis as claimed in any one of the preceding claims,
10 wherein a locus defined by a midpoint between the first and second arcuate portions along the length of the femoral neck prosthesis is substantially straight.
10. A femoral neck prosthesis as claimed in any one of the preceding claims,
15 wherein the corners between the first and second arcuate portions and the first and second substantially straight portions are rounded off.
11. A femoral neck prosthesis assembly comprising the femoral neck prosthesis as
claimed in any one of the preceding claims, wherein the assembly further comprises a
neck portion for engaging a femoral head portion.
20
12. A femoral neck prosthesis assembly as claimed in claim 11, wherein the neck
portion is modular and has first and second ends adapted to selectively engage
corresponding openings in the femoral neck prosthesis and the femoral head portion
respectively.
25
13. A femoral neck prosthesis assembly as claimed in claim 11 or 12, wherein the
assembly further comprises a modular collar, the modular collar having an opening to
selectively engage the neck portion of the femoral neck prosthesis assembly.
- 30 14. A method of manufacturing the femoral neck prosthesis of claim 1, wherein the
method comprises:
 providing a workpiece having a cross-section with an at least partially curved
perimeter; and
 removing first and second portions from the workpiece such that first and second
35 segments are removed from the cross-section of the workpiece.

15. A femoral neck prosthesis or assembly, substantially as described herein, with reference to and as shown in the accompany drawings.

16. A method of manufacturing a femoral neck prosthesis , substantially as described
5 herein, with reference to and as shown in the accompany drawings.

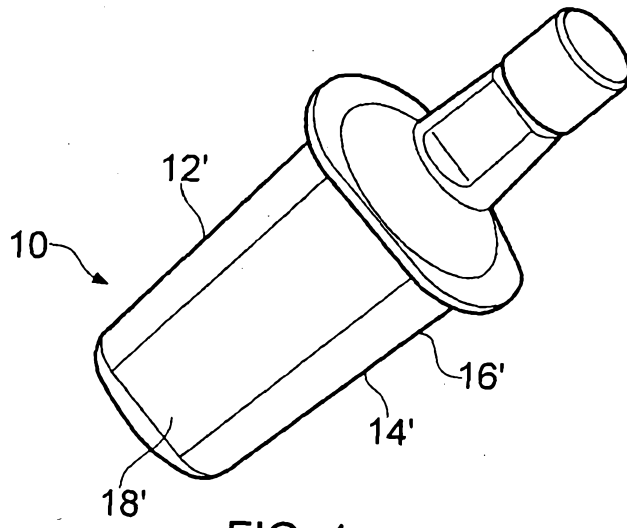


FIG. 1a

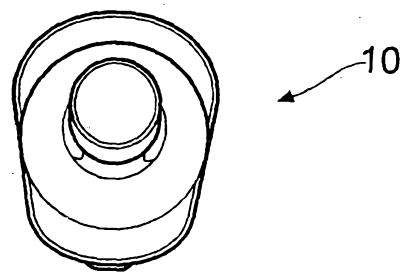


FIG. 1b

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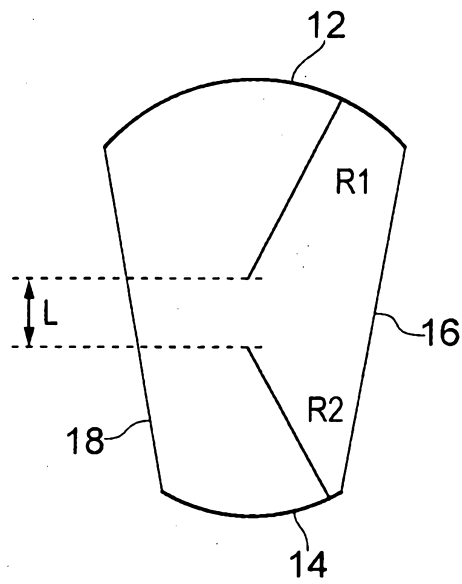


FIG. 2a

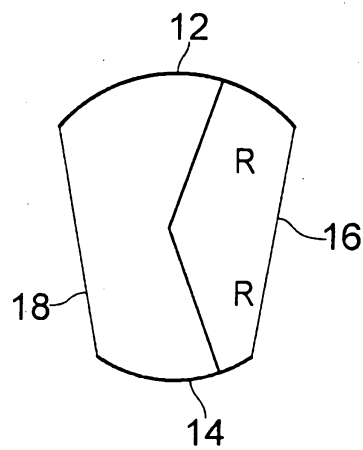


FIG. 2b

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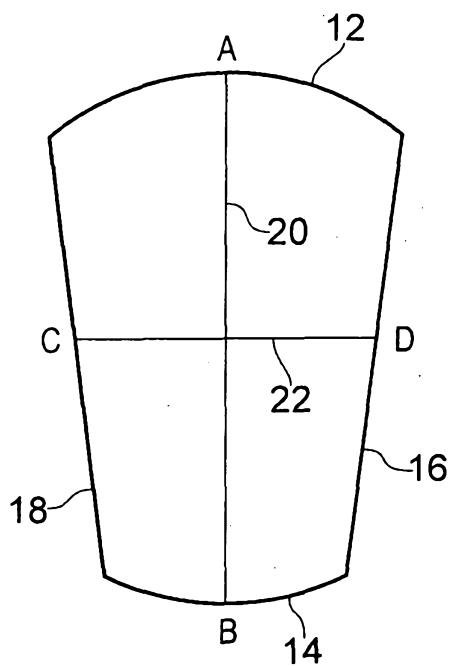


FIG. 2c

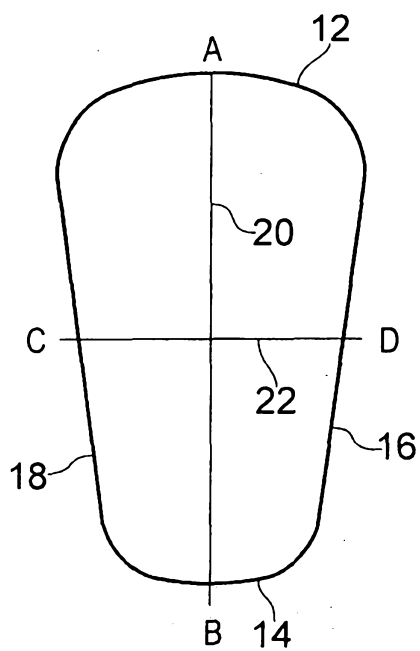


FIG. 2d

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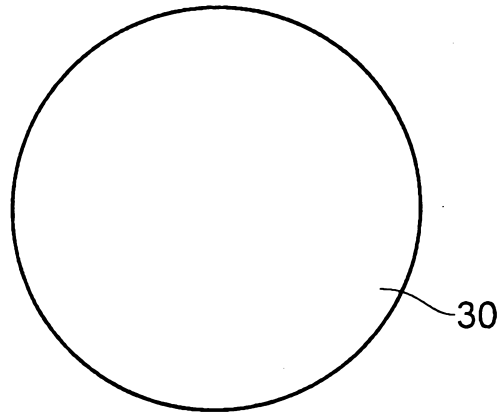


FIG. 3a

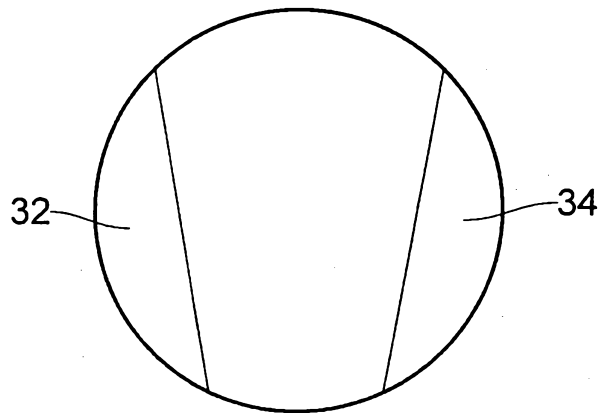


FIG. 3b

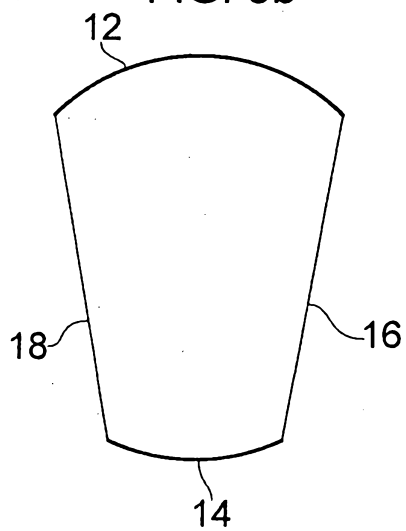


FIG. 3c

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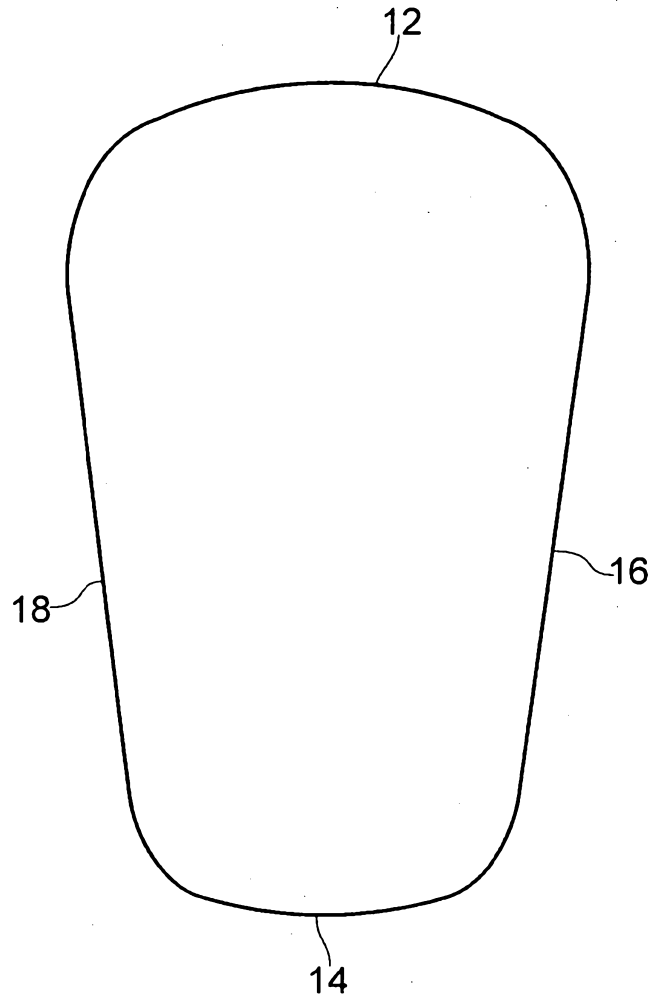


FIG. 3d

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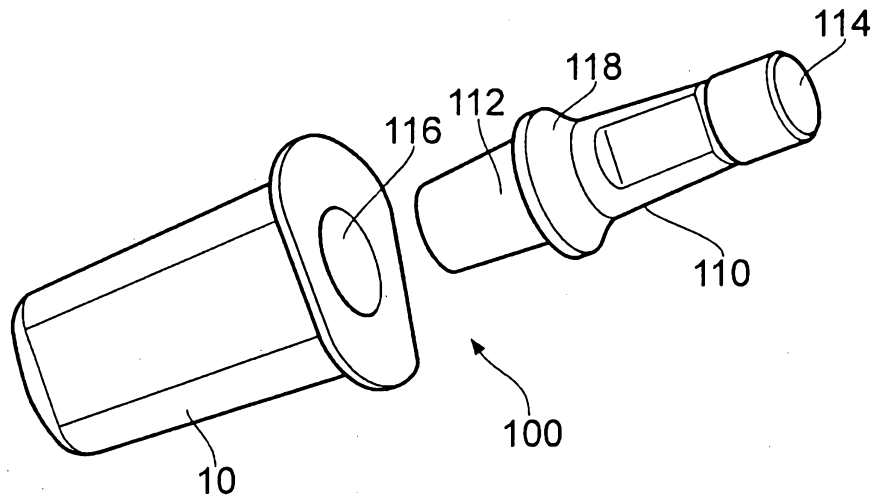


FIG. 4a

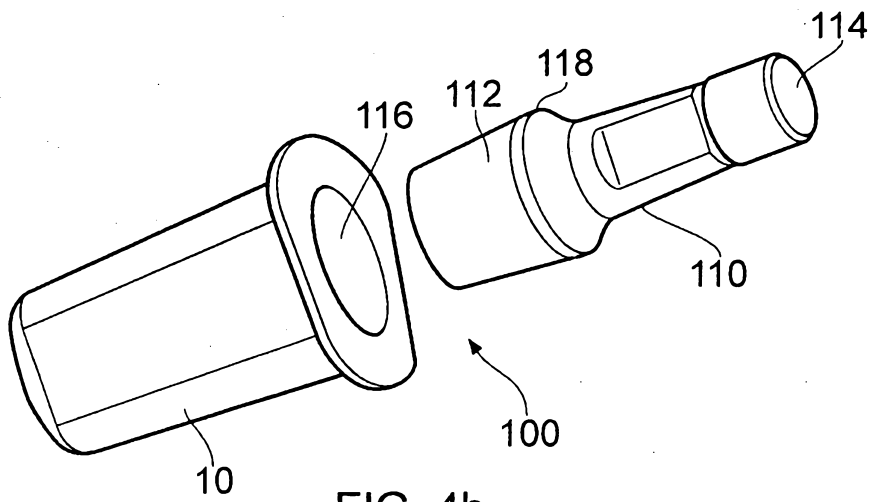


FIG. 4b

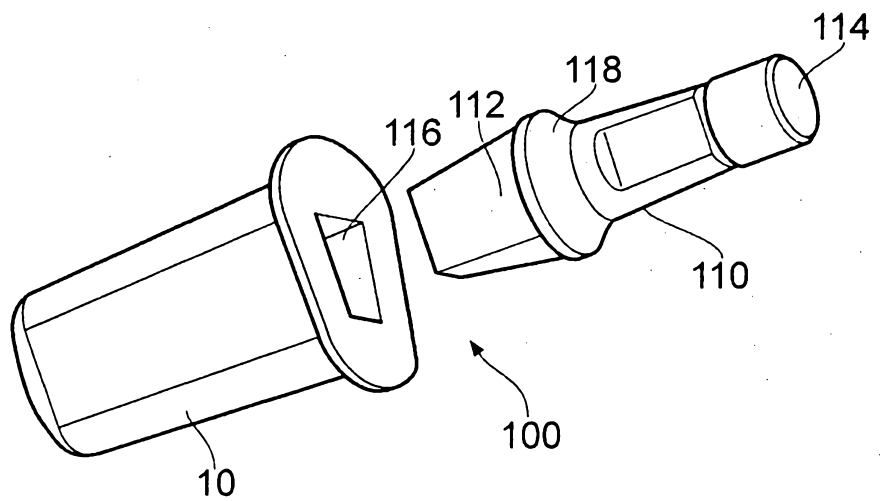
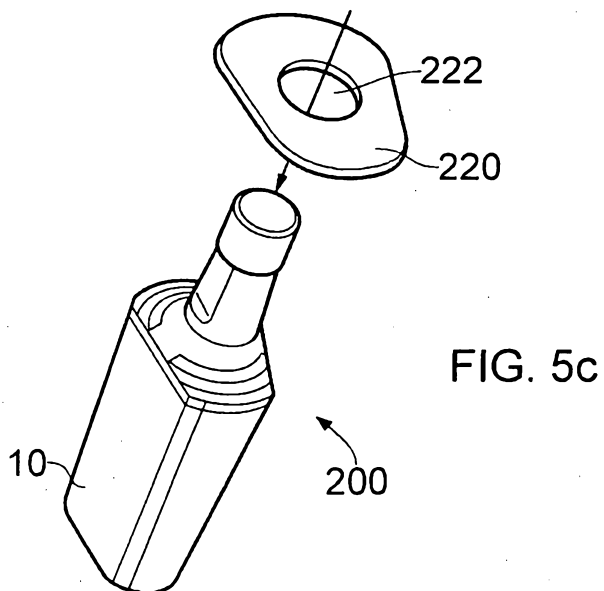
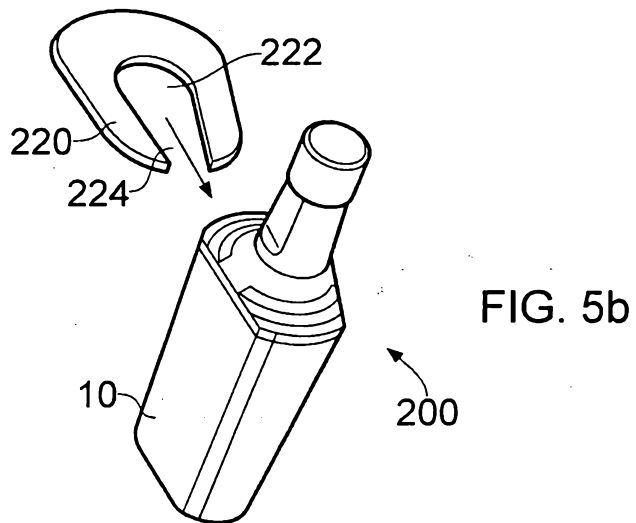
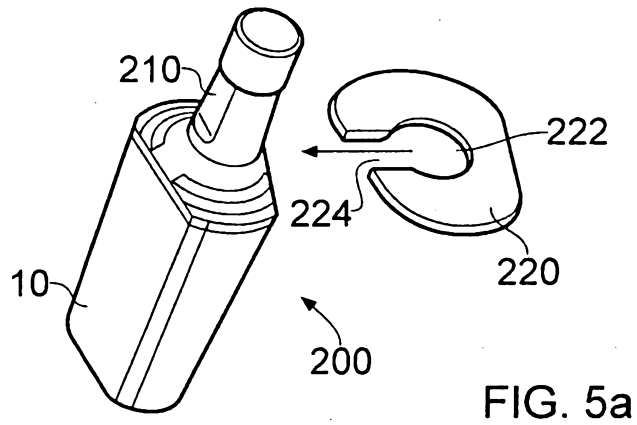


FIG. 4c

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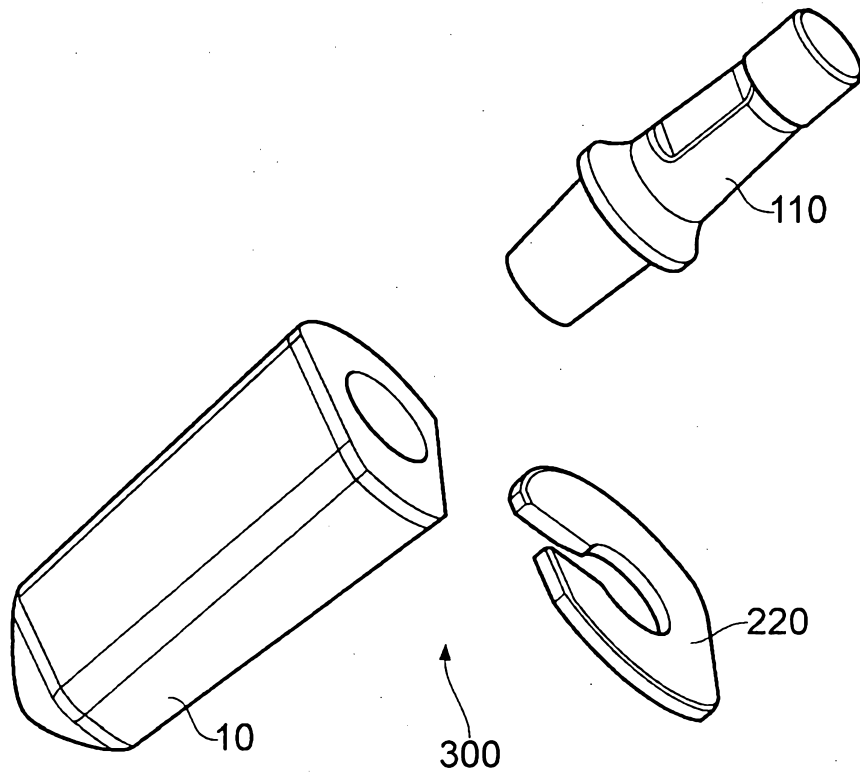


FIG. 6

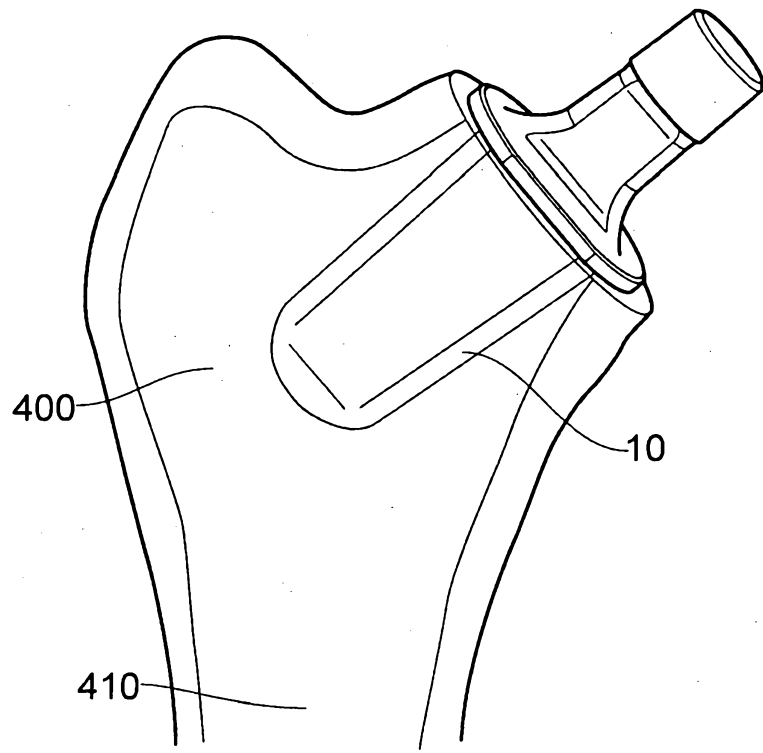


FIG. 7