Title: JOINT PROSTHESIS WITH REMOVAL DEVICE

Abstract: Joint prosthesis (100) with removal device comprising a first portion (10) suitable to be implanted in a bone structure and suitable to couple with a second portion (50) characterised in that said second portion (50) houses within it a removal element (70) suitable to interact with at least one of said first and second portions (10, 50) and in that said removal element (70), is configured to be operated in translation with respect to the second portion (50), and to generate a detachment force such as to uncouple the first portion (10) from the second portion (50) of the joint prosthesis (100).


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DESCRIPTION

"JOINT PROSTHESIS WITH REMOVAL DEVICE"

The present invention discloses a joint prosthesis with removal device. In the state of the art, there are known surgical prostheses adapted to be implanted in the body of a patient in order to replace the original joint, affected by particular pathologies and/or wear. Due to said pathologies or wear affecting the joints, the patient perceives pain during movement and the replacement of said joints makes it possible for him/her to return to a normal life, unburdened by pain during movements.

The surgical operation for the replacement of the natural joint with a new artificial joint involves specific intervention passages on the patient's bones in order to implant artificial bone coating surfaces and articulation elements between the two implanted artificial surfaces. Said artificial surfaces comprise essentially two parts: a first part, in contact with the patient's bone, and a second part, not in contact with the patient's bone but articulating with a joint element. The first part in contact with the bone is responsible for correctly securing the artificial surface to the patient's body and can present a portion thereof adapted to be inserted in a bone seat formed by the surgeon during implantation. Said artificial surface can also be fixed to the bone by means of various techniques; for example, it may be cemented or, alternatively, non-cemented.

The state of the art has a plurality of joint prostheses of this type for the main joints of the human body. For example, document US8246687 by Biomet Manufacturing Corporation can be mentioned about the shoulder joint; document WO2013074700 by Maxx Orthopedics Inc can be mentioned about knee joint; document US2014135939 by Wright Medical Tech Inc can be mentioned about ankle joint; and so on.

After replacing the natural joint as needed with a known prosthetic joint, the patient can resume his/her normal activities. Of course, it is possible that the normal activities of the patient can lead to wear of the joint prosthesis implanted or that, with time, said joint prosthesis requires
operation of total or partial replacement. It will therefore be necessary to perform another surgery aimed at partial or total replacement of the previously implanted joint prosthesis.

As is clear, in this new surgery it will be necessary to disassemble the joint prosthesis from the patient's bone where it is implanted and replace it, possibly in part, with a new one. Depending on the methodology used for prosthesis implant, the removal operations of the same may be more or less invasive but, in any case, it will be necessary to act on the bone by means of appropriate instruments, such as, for example, burrs, saws or the like, in order to detach the joint replacement by said bone. It is clear to the skilled in the art that said replacement surgeries involve remarkable stresses transmitted to the bone, up to the removal of bone material in order to disassemble the prosthesis.

This type of procedure may be considered as a drawback to what known in the art. In fact, generally, the stresses imposed by the surgeon to detach the previously implanted prosthetic joint can damage the bone structure and cause issues to the patient.

Another drawback to what known in the prior art is the difficulty for the surgeon to uncouple the joint prosthesis from the patient's body. In fact, the surgeon has to operate in the presence of body fluids such as blood, and in confined spaces, due to the need to minimize the invasiveness of the surgery, circumstances that do not allow for optimal performance of the operations of detachment of the joint prosthesis from the bone.

A further drawback to what known in the prior art is the possibility that the surgeon exerts an excessive force during the operations of detachment of the prosthetic joint, therefore damaging the bone.

Another drawback to what known in the prior art is the need to employ a relatively long time to obtain an optimal detachment of the prosthetic joint, using different sterile surgical instruments with a consequent increase in costs for the structure and prolongation of the time required to complete the surgery.
Said drawbacks are common to all main joint prostheses i.e., for example, shoulder, elbow, wrist, knee, hip and ankle joint prostheses. In its general aspects, the present invention intends to solve the drawbacks of the known state of the art with reference to each type of joint prosthesis.

Thus, an object of the present invention is to provide a joint prosthesis removal device that can be uncoupled without damaging the patient's bone structure.

A further object of the present invention is to provide a joint prosthesis removal device which is easy to use for the surgeon, minimizing the invasiveness of the surgical operation.

A further object of the present invention is to provide a joint prosthesis removal device that is able to minimize the force imparted by the surgeon on the joint prosthesis to be removed.

A further object of the present invention is to provide a joint prosthesis removal device that is able to minimize the number of sterile surgical instruments which must be employed by the surgeon for decoupling the present invention from the patient's bone.

The final object of the present invention is to provide a joint prosthesis removal device that is able to reduce surgery costs and duration and is easy and cost-effective to use and implement.

In view of these objects, the present invention provides a joint prosthesis removal device, the essential feature of which constitutes the subject of claim 1.

Further advantageous features are listed in the dependent claims.

All claims are considered as described.

The present invention will be described in greater detail by way of example only with the aid of the accompanying drawings, in which:

Figure 1 is a ¾ front view of the upper portion of a joint prosthesis with removal device according to a preferred embodiment of the present invention,

Figure 2 is a ¾ backside view of the upper portion of a joint prosthesis with
removal device according to a preferred embodiment of the present invention,

Figure 3 is a ¾ front view of a lower portion of a joint prosthesis with removal device according to a preferred embodiment of the present invention,

Figure 4 is an axial sectional view of a joint prosthesis with removal device according to the preferred embodiment of the present invention,

Figure 5 is an axial, partially exploded sectional view of a joint prosthesis with removal device according to the preferred embodiment of the present invention;

Figure 6 is a sectional view of a joint prosthesis with removal device put in place in a bone agglomeration;

Figure 7 is a sectional view of a joint prosthesis with removal device during a first step of the disassembly process;

Figure 8 is a sectional view of a joint prosthesis with removal device during a second step of the disassembly process;

Figure 9 is a detail view of the particular A of Figure 8;

Figure 10 is a side elevational view of a variant of the preferred embodiment of the present invention.

In the drawing, 100 refers to a joint prosthesis with removal device according to the present invention. In the following description, explicit reference will be made to a glenoid joint prosthesis, as depicted in the accompanying drawing only by way of example, however not limiting the scope of the present invention only to this type of prosthesis.

In the present description, the terms “medial” and “side” will be also used to denote the parts of the joint prosthesis 100 with removal device that are located in medial or side position with respect to the bone structure on which said device is implanted, as shown in Figures 6 to 9. The terms “upper” and “lower” will be used with respect to the assembly direction of the device 100 as shown in Figure 5.

The joint prosthesis 100 with removal device essentially comprises: a first
portion, designated in the following as lower portion 10, a second portion, designated in the following as upper portion 50, and a removal element 70, made, for example, of a metal material, preferably cobalt-chromium alloys, titanium alloys and/or the like.

The upper portion 50 has two parts: a medial stem part 51 and a side part 52, having a substantially elliptical section. Said two parts are mutually integrally connected. The side part 52 is characterised by two faces: a medial face 52.2 and a side face 52.1. Said side face 52.1 in the side part 52 has a substantially elliptical shape, with a tapered lip 53 tapered and a concave, circular-section central area 54. Said central area 54 substantially has a spherical-cap shape and is adapted to receive a leaning humeral head (not shown). The medial face 52.2 in the side part 52 of the upper portion 50 has a housing area 52.3 and, outside of it, one edge 53.1 of lip 53. Said medial face 52.2 is integrally connected, in its central area, to the medial stem part 51.

The medial stem part 51 has a cylindrical shape with an axial cavity 51.4 and two ends: a lower end 51.6, open to ensure access to said axial cavity 51.4, and an upper end 51.5, integrally connected to the medial face 52.2 of the side part 52. Said axial cavity 51.4 of the medial stem part 51 has, therein and for a substantial part of its axial extension, a thread 51.1. At the free end 51.6 of the stem medial part 51 there are two blunted guides 51.2 and 51.3.

It should be noted that the stem medial part 51 is positioned such that the end 51.5 of the through axial cavity 51.4 is centrally aligned with the side part 52, so that the central axis of the axial cavity 51.4 is aligned with the centre of the central area 54.

A removal element 70 is received within said through axial cavity 51.4, for instance by helical coupling with thread 51.1. Said removal element 70 has a substantially cylindrical shape with two free ends: a first free end 70.1, externally projecting through the free end 51.5, and a second free end 70.2, received within the through axial cavity 51.4 of the medial stem part.
51. Both free ends 70.1 and 70.2 respectively have a coupling area 70.6 and 70.5 for coupling to a known fixing device, for example a screwdriver or an Allen wrench.

On a substantial part of the outer surface of said removal element 70 there are engagement/coupling means, for example a thread 70.4 adapted for coupling with thread 51.1, provided inside the through axial cavity 51.4. It should be noted that, in a preferred embodiment of the present invention, said thread 70.4 also extends along the outer side surface of the free end 70.2 and does not extend on the outer side surface of the free end 70.1.

10 The lower portion 10 of the surgical prosthesis 100 with removal device also comprises two parts: a side part 11 and a medial part 12. The side part 11 of the lower portion 10 has a shape allowing it to be received within the housing area 52.3 while in the configuration of use. Particularly, said side part 11 has a central area 14. Said central area 14 has a substantially circular, concave section with a central through hole 15 and a plurality of radial holes 16.1, 16.2, 16.3 and 16.4, also passing through the fitting of said lower portion to the patient's bone by special fixing instruments like, for instance, screws known in the art and not illustrated. Integrally connected to said distal part 11 of the lower portion 10 is a medial part 12. The medial part 12 has a cylindrical shape projecting medially from side part 11 and has a closed free end 12.1. The outer surface 12.3 of medial part 12 has a configuration allowing optimal coupling with a special positioning hole formed into the patient's bone by the surgeon during the implant procedure. For example, the outer surface of medial part 12 can be split and/or coated with porous material suitable for osteointegration such as, for example, a known trabecular metal.

The inner part of said medial part 12 has an axial cavity 12.2, blind and extending throughout the length of said medial part 12 and placed in communication with the central through hole 15 of the central area 14 in the side part 11. Said axial cavity 12.2 is adapted to receive therein, in the configuration of use, the medial stem part 51 and the free end 70.1 of the
removal element 70 projecting therefrom.

**Implant procedure.**

For the implant procedure of the surgical prosthesis 100 with removal device of the present invention, the surgeon provides for an adequate seat into the patient's bone. Said adequate seat can include a substantially cylindrical housing intended to receive the medial part 12 of the lower portion 10, in addition to a spherical cap-shaped housing at least partially adapted to receive the side part 11 of the lower portion 10. In order to secure the lower portion 10, the surgeon proceeds with the insertion of coupling means, e.g. known surgical screws, inside holes 16.1, 16.2, 16.3 16.4, and secures the lower portion 10 to the patient's bone.

In the configuration of use, the upper portion 50 comes already coupled, for example by threaded coupling, with the removal element 70. The surgeon then proceeds with the coupling of the upper portion 50 with the lower portion 10 by sliding the stem part 51 within the axial cavity 12.2 until the proximal edge 53.1 of lip 53 comes into contact with the edge 14.1 of the central area 14 of the lower portion 10. At this point, by an interference fit, for example with a Morse-cone coupling type, known in the art and not further described, the upper portion 50 and the lower portion 10 are integrally connected to each other.

**Operation.**

In order to decouple the upper portion 50 from the lower portion 10, the surgeon uses a special instrument or an instrument known in the art such as, for example, a puncher or a drill and/or the like, making a hole central to the concave central area 54 of the upper portion 50. In this way, thanks to the advantageous positioning of the axial cavity 51.4 of the medial stem part 51, which is aligned axially from said concave central area 54, an access pathway to said axial cavity 51.4 and, thus, to the end 70.2 of the removal element 70 therein contained can be created. Then, by a known instrument such as, for example, a screwdriver C (Figure 7) or an Allen wrench, the surgeon accesses, through the hole just made, the axial cavity
51.4 until engaging the coupling area 70.6 of the removal element 70. At this point, the application of a force to the removal element 70 puts it in relative translation with respect to the medial stem part 51 of the upper portion 50. In this example, the removal element 70 being coupled to the medial stem part 51 by threaded coupling, the surgeon will apply a torque to said removal element 70 to set it in rotation. Said rotation will bring the removal element 70 to translation in the axial direction with respect to the medial stem part 51 in side-medial direction. This translation, however, will be prevented when the removal element 70 comes into contact with the blind medial end of the axial cavity 12.2. The removal element 70 thus comes in abutment against said blind medial end reaching a position known as stop.

Failure of further translating in medial-side direction of the removal element 70 causes transmission of a force, known as release force, having a direction parallel to that of translation just described, but in a medial-side direction, through the threaded coupling between threads 51.1 and 70.4, respectively of the medial stem part 51 and the removal element 70, to the upper portion 50. When this force exceeds the force generated by the interference fit by which the upper portion 50 and lower portion 10 are coupled, the upper portion 50 uncouples from the lower portion 10, allowing the surgeon to extract it without acting in any manner on the patient's bone structure.

As appears clearly from the above description, the present invention provides a surgical prosthesis 100 with removal device, able to achieve the above-listed objects.

**First alternative.**

An alternative embodiment of the present invention is illustrated in Figure 10. In said Figure 10 is an instrument 200 incorporating therein the previously described removal element 70. As is readily understandable from mentioned Figure 10, it comprises: a handle 210, sized and shaped to be comfortably grasped by the surgeon, preferably made of a metal
material, having a cylindrical-shaped central portion 220 extending from said handle 210, made of metallic material and having, at its free, integral end, a removal element 700. Said removal element 700 has, for example, engagement/coupling means on its outer surface, for example a thread 704.

**Operation**

In order to decouple the upper portion 50 from the lower portion 10, the surgeon uses a special instrument or an instrument known in the art such as, for example, a puncher or a drill and/or the like, making a hole central to the concave central area 54 of the upper portion 50. In this way, thanks to the advantageous positioning of the axial cavity 51.4 of the stem medial part 51, which is aligned axially with respect to said concave central area 54, an access pathway to said axial cavity 51.4, thus reaching thread 51.1 present therein, can be created. After reaching said thread 51.1 by acting properly on instrument 200, for example placing it in rotation, thread 704 provided on the outer surface of the removal element 700 integral to said instrument 200 engages thread 51.1. Said rotation will cause translation of the removal element 700 in the axial direction with respect to the medial stem part 51 in side-medial direction. The surgeon will maintain the instrument 200 in rotation until the free end of the engagement element 704 comes into contact with the blind end of the cavity 12.1, thereby achieving a stop position.

Failure of further translating in medial-side direction of the removal element 700 causes transmission of a force, known as release force, having a direction parallel to that of translation just described, but in a medial-side direction, through the threaded coupling between threads 51.1 and 704, respectively of the medial stem part 51 and the removal element 700, to the upper portion 50. When this force exceeds the force generated by the interference fit by which the upper portion 50 and lower portion 10 are coupled, the upper portion 50 uncouples from the lower portion 10, allowing the surgeon to extract it without acting in any manner on the
patient's bone structure.
Of course, numerous variations may be made in practice with respect to
those described and illustrated by way of non-limiting example, without
thereby departing from the scope of the present invention and, therefore,
from the domain of the present industrial property right.
CLAIMS

1. Joint prosthesis (100) with removal device comprising a first portion (10) suitable to be implanted in a bone structure and suitable to couple with a second portion (50), characterised in that the second portion (50) houses within it a removal element (70) suitable to interact with at least one of said first and second portions (10, 50) and in that said removal element (70), is configured to be operated in translation with respect to the second portion (50), and to generate a detachment force such as to uncouple the first portion (10) from the second portion (50) of the joint prosthesis (100).

2. Joint prosthesis (100) with removal device according to claim 1 characterised in 10 that the second portion (50) has a housing area (52.3) suitable to house said removal element (70).

3. Joint prosthesis (100) with removal device according to claim 2 characterised in that said housing area (52.3) has means of engagement and/or coupling (51.1) operationally interposed between the second portion (50) and said removal element (70).

4. Joint prosthesis (100) with removal device according to claim 3 characterised in that said means of engagement and/or coupling (51.1) comprise a threading.

5. Joint prosthesis (100) with removal device according to claim 3 characterised in that the removal element (70) has means of engagement/coupling (70.4) suitable to interact with the means of engagement and/or coupling (51.1) present in the housing area (52.3) of the second portion (50) of the joint prosthesis (100).

6. Joint prosthesis (100) with removal device according to claim 1 characterised in that the removal element (70) has a coupling area (70.6) configured to couple with an attachment device, said coupling area being contained inside a housing area (52.3) of the second portion (50).

7. Joint prosthesis (100) with removal device according to one or more
of the previous claims, characterised in that the removal element (70) is contained, at least partially, inside an axial cavity (51.4) of the second portion (50).

8. Joint prosthesis (100) with removal device according to claim 7, characterised in that at least one of the ends of the axial cavity (51.4) is a closed end, when the joint prosthesis (100) is in use.

9. Joint prosthesis (100) with removal device according to claim 1 characterised in that the removal element (70) is coupled to the second portion (50) by means of a helical coupling.

10. Joint prosthesis (100) with removal device according to claim 1 characterised in that the detachment force generated by the removal element (70) imposes on the second portion (50) a translation of the same direction and opposite in orientation to the orientation of the relative translation of said removal element (70) in relation to the second portion (50).

11. Joint prosthesis (100) with removal device according to one or more of the previous claims, characterised in that the first portion (10) and the second portion (50) are coupled by means of an interference coupling.

12. Joint prosthesis (100) with removal device according to claim 11 characterised in that the interference coupling between the first portion (10) and the second portion (50) is of the Morse cone type.

13. Method of removing a joint prosthesis by means of a removal device of a joint prosthesis (100) characterised in that it comprises the following steps:

- opening an access to an axial cavity (51.4) of a second portion (50) of the joint prosthesis;
- operating a removal element (70);
- the relative translation of the removal element (70) in relation to the second portion (50);
- reaching of a stop position by the removal element (70);
- the generation of a detachment force;
- the detachment of the second portion (50) from a first portion (10) of the joint prosthesis.

14. Method of removing a joint prosthesis by means of a removal device of a joint prosthesis according to claim 13 characterised in that said method further comprises the step of inserting an instrument inside the axial cavity (51.4) to operate the removal element (70).

15. Kit for removing a joint prosthesis comprising a joint prosthesis (100) comprising a first portion (10) suitable to be implanted in a bone structure and suitable to couple with a second portion (50), said kit comprising a removal element (700) connected to an instrument (200) suitable to uncouple the first portion (10) from the second portion (50) of the joint prosthesis (100).

16. Kit for removing a joint prosthesis according to claim 15 characterised in that the removal element (700) is integrally connected to the instrument 200.

17. Kit for removing a joint prosthesis according to claim 16 characterised in that the removal element (700) comprises means of engagement/coupling (704) suitable to couple with respective engagement/coupling means (51.4) of the second portion (50) of the joint prosthesis (100).

18. Kit for removing a joint prosthesis 100 characterised in that it comprises a removal element (70, 700) for uncoupling the second portion (50) from the first portion (10) of a joint prosthesis (100) as claimed in the claims 1 or 15.
# INTERNATIONAL SEARCH REPORT

**International application No:** PCT/IB2015/059503

### A. CLASSIFICATION OF SUBJECT MATTER

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According to International Patent Classification (IPC) or to both national classification and IPC

### B. DOCUMENTS SEARCHED

**Minimum documentation searched**: (classification system followed by classification symbols)

A61F

**Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched**

### E. ELECTRONIC DATA BASES CONSULTED DURING THE INTERNATIONAL SEARCH

- EPO-Internal, WPI Data

### C. DOCUMENTS CONSIDERED TO BE RELEVANT

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**Further documents are listed in the continuation of Box C.**

| X | See patent family annex. |

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**Date of the actual completion of the international search:** 1 March 2016

**Date of mailing of the international search report:** 17/03/2016

**Name and mailing address of the ISA/ European Patent Office, P.B. 5018 Patentlaan 2 NL-5200 HV Rijswijk, Tel. (+31-70) 340-2040, Fax (+31-70) 340-3016**

**Authorized officer:** Buchmann, Gerhard

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