Provided herein is a total endoprosthesis, comprising (a) a first prosthetic component for comprising a spherical dome and an anchor peg; and (b) a second prosthetic component, comprising a cup configured for receiving said spherical dome, and a fixation stem.

Fig. 7

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ENDOPROSTHESIS

FIELD OF THE INVENTION
The present invention is situated in the field of medical devices, more particularly in the field of (endo)prosthetic devices. Provided herein are sternoclavicular and radiocarpal endoprostheses and methods for the manufacture thereof. Further provided is a method of implanting a sternoclavicular and radiocarpal endoprosthesis.

BACKGROUND OF THE INVENTION
10 The sternoclavicular joint is the only joint between the axial skeleton and the upper limbs and is composed of two portions separated by an articular disc which is made from fibrocartilage. More particularly, the joint is composed of the sternal end of the clavicle, the clavicular notch of the manubrium sterni, and the cartilage of the first rib. Symptomatic degenerative sternoclavicular arthritis is uncommon and typically involves an anterior subluxation of the clavicle. If conservative treatment fails, a medial clavicle resection (claviculectomy) can be performed. However, also this type of treatment shows a significant risk failure. In some cases, a too extensive clavicular resection results in a seriously impaired function of the upper arm, which causes significant pain and discomfort to the patient. Currently there is no effective treatment for these cases.

20 Indeed, although a number of sternoclavicular implants are currently available, these implants typically do not sufficiently reduce pain and can involve significant risks of loosening of the sternal component, with possible lethal consequences. For example, European patent EP737454 describes an endoprosthesis for replacing a joint between bones which cannot be distracted easily, such as the sternoclavicular joint. However, the prosthesis is sensitive to destabilizing forces which may lead to joint distraction. US patent US4367562 describes a joint prosthesis which may be used for replacing a sternoclavicular joint, comprising a single flexible part which is connected to the bones of the joint. However, such prosthesis results in a significantly reduced mobility of the joint.

30 Thus, there is a need for implants and methods for treating sternoclavicular joint lesions, which mitigate at least one of the problems stated above.

SUMMARY OF THE INVENTION
The present inventors have found that the provision of a reverse prosthesis, forming a ball-and-socket joint with the socket positioned on the sternal end of the clavicle and the ball positioned on the clavicular notch of the manubrium, can allow for correcting the
subluxation of a clavicle and can result in a significantly increased stability of the joint compared to known prostheses. More particularly, the prosthesis described herein may result in a complete neutralization of the lever arm exerted on the sternal component, which can lead to an improved bone ingrowth and reduced implant loosening.

5 Accordingly, in a first aspect, provided herein is an endoprosthesis comprising a first prosthetic component for positioning on the manubrium and (b) a second prosthetic component for positioning on a clavicle.

More particularly, provided herein are the following aspects:

10 Aspect 1. A sternoclavicular endoprosthesis comprising:
   (a) a first prosthetic component configured for positioning on the manubrium comprising:
      - a spherical or ellipsoidal dome; and
   - an anchor peg provided at the base of said dome; and
   (b) a second prosthetic component comprising:
      - a cup comprising a concave surface configured for receiving said dome;
      - a base configured for attachment to the diaphysis of a clavicle; and
      - optionally, a fixation stem provided at said base, configured for fixation of said second prosthetic component in the diaphysis of a clavicle.

   Aspect 2. The endoprosthesis according to aspect 1, wherein said dome has a radius between 5 mm and 20 mm.

25 Aspect 3. The endoprosthesis according to aspect 1 or 2, wherein the base of said dome is provided with a central notch having a width at least equal to the radius of the base of said dome.

Aspect 4. The endoprosthesis according to aspect 3, wherein said notch runs along the entire width of said dome.

Aspect 5. The endoprosthesis according to any one of aspects 1 to 4, wherein said first prosthetic component is at least partially made of titanium, cobalt, chrome, or an alloy thereof; or polyethylene. Optionally, the interacting surface of said first prosthetic component with said second component is coated with polyethylene.
Aspect 6. The endoprosthesis according to any one of aspects 1 to 5, wherein said second prosthetic component is at least partially made of titanium, cobalt, chrome, or an alloy thereof; or polyethylene. Optionally, the interacting surface of said second prosthetic component with the first component is coated with polyethylene.

Aspect 7. The endoprosthesis according to any one of aspects 1 to 6, wherein said stem and said cup are provided on separate parts, which are or can be assembled together. Preferably, said assembly can be through a morse-taper interaction, through screw-thread, or through screws or pins.

Aspect 8. The endoprosthesis according to any one of aspects 1 to 7, wherein said first prosthetic component is free from surfaces having an intersection forming an angle of less than 100° wherein the radius of curvature at the intersection is less than 100 μm.

Aspect 9. The endoprosthesis according to any one of aspects 1 to 8, wherein said at least one anchor peg is received in an anchor hole in the manubrium.

Aspect 10. The endoprosthesis according to any one of aspects 1 to 9, wherein said fixation stem (11) has a shape that prevents the fixation stem from rotating around its longitudinal axis. Preferably, said shape is rectangular, triangular, or star-shaped and optionally can have one or more fin(s). Alternatively, said shape is circular but provided with one or more fin(s).

Aspect 11. The endoprosthesis according to any one of aspects 1 to 9, wherein said fixation stem (11) is additionally fixed into the clavicular with one or more screws, preferably perpendicular to the clavicula.

Aspect 12. In a further aspect, the present application provides a method of generating a sternoclavicular endoprosthesis as described herein, comprising:

(i) providing a three-dimensional (3D) model of the sternoclavicular joint of a patient;
(ii) providing a plan for a reconstructive sternoclavicular joint surgery;
(iii) generating a patient-specific sternoclavicular endoprosthesis as defined herein based on the three-dimensional model obtained in step (i);
(iv) optionally, manufacturing the endoprosthesis generated in step (iii) at least partially via additive manufacturing.
Aspect 13. In yet a further aspect, the present invention provides a method of implanting a sternoclavicular endoprosthesis in a patient, comprising:

(1) accessing a sternoclavicular joint defined by a clavicle and a clavicular notch on the corresponding side of the sternum;

(2) positioning a first prosthetic component as defined herein on said clavicular notch, said first prosthetic component comprising a spherical or ellipsoidal dome facing said clavicle; and

(3) positioning a second prosthetic component as defined herein on said clavicle, said second prosthetic component comprising a cup comprising a concave surface configured for receiving said dome.

Aspect 14. In a preferred embodiment of aspect 13, the positioning step (2) also includes the preparation of the surface of the clavicular notch, e.g. by reaming the surface of the notch so as to enable stable positioning of the first prosthetic component on said notch.

Although the prostheses and methods are described herein mostly with respect to sternoclavicular joint reduction, these devices and methods may, mutatis mutandis, also be used for reduction of other joints with limited movement, such as the wrist joint (radiocarpal joint).

Aspect 15. The present application further provides a radiocarpal endoprosthesis, comprising:

(a) a first prosthetic component for positioning on a radius comprising:

- a spherical or ellipsoidal dome or partial sphere; and
- a fixation stem provided at the base of said dome or partial sphere; and

(b) a second prosthetic component comprising:

- a cup comprising a concave surface configured for receiving said dome or partial sphere;
- a base configured for positioning the cup on the diaphysis of a carpus; and
- optionally, an anchor peg provided at the base of said cup for fixation of said second prosthetic component in the carpus, e.g. with extra angulated screws in the carpus, preferably with a fixation stem in the third metacarpal (metacarpal three).
Aspect 16. The radiocarpal endoprosthesis according to aspect 15, wherein said dome or partial sphere has a diameter between 10 mm and 35 mm.

Aspect 17. The endoprosthesis according to any one of aspects 15 to 16, wherein said first prosthetic component is at least partially made of titanium, cobalt, chrome, or an alloy thereof; or polyethylene. Optionally, the interacting surface of said first prosthetic component with said second component is coated with polyethylene.

Aspect 18. The endoprosthesis according to any one of aspects 15 to 17, wherein said second prosthetic component is at least partially made of titanium, cobalt, chrome, or an alloy thereof; or polyethylene. Optionally, the interacting surface of said second prosthetic component with the first component is coated with polyethylene.

Aspect 19. The endoprosthesis according to any one of aspects 15 to 18, wherein said stem and said dome or partial sphere are provided on separate parts, which are or can be assembled together. Preferably, said assembly can be through a morse-taper interaction, through screw-thread, or through screws or pins.

Aspect 20. The endoprosthesis according to any one of aspects 15 to 19, wherein said first prosthetic component is free from surfaces having an intersection forming an angle of less than 100° wherein the radius of curvature at the intersection is less than 100 μm.

Aspect 21. The endoprosthesis according to any one of aspects 12 to 20, wherein said fixation stem has a shape that prevents the fixation stem from rotating around its longitudinal axis. Preferably, said shape is rectangular, triangular, or star-shaped and optionally can have one or more fin(s). Alternatively, said shape is circular but provided with one or more fin(s).

Aspect 22. The endoprosthesis according to any one of aspects 15 to 20, wherein said fixation stem is additionally fixed into the clavicular with one or more screws, preferably perpendicular to the clavicle.

Aspect 23. In a further aspect, the present application provides a method of generating a radiocarpal endoprosthesis as described herein, comprising:

(i) providing a three-dimensional (3D) model of the radiocarpal joint of a patient;
(ii) providing a plan for a reconstructive radiocarpal joint surgery;
(iii) generating a patient-specific radiocarpal endoprosthesis as defined herein based on the three-dimensional model obtained in step a);
(iv) optionally, manufacturing the radiocarpal generated in step (iii) at least partially via additive manufacturing.

Aspect 24. In yet a further aspect, the present invention provides a method of implanting a radiocarpal endoprosthesis as defined herein in a patient, comprising:

(1) accessing the radiocarpal joint comprising the radius and the carpals;
(2) positioning a first prosthetic component as defined herein on the radius, said first prosthetic component comprising a spherical or ellipsoidal dome or partial sphere facing said clavicle; and
(3) positioning a second prosthetic component as defined herein in or on the carpals, whereby optionally the lunatum and/or the scaphoid carpals are removed.

Aspect 25. The method according to aspect 24, wherein the first prosthetic component is inserted in the radius through an anchoring peg, and wherein the second prosthetic component is inserted into the carpal and one or more metacarpal bones, through pins or screws.

The above and other characteristics, features and advantages of the concepts described herein will become apparent from the following detailed description, which illustrates, by way of example, the principles of the invention.

25 BRIEF DESCRIPTION OF THE DRAWINGS
The drawings depicted herein are merely for illustrative purposes and are not to be seen as limiting the invention in any particular way.

Fig. 1 Illustration of a particular embodiment of the sternoclavicular endoprosthesis as described herein, comprising a first prosthetic component (1) and a second prosthetic component (2), respectively positioned on a sternum (3) and clavicle (4) of a sternoclavicular joint.

Fig. 2 Lateral view of a first prosthetic component (1) of a particular embodiment of the sternoclavicular endoprosthesis as described herein, positioned on a sternum (3). The first prosthetic component (1) comprises a dome (5) and a base (5', not visible in this figure), and is configured to be positioned on the sternum (3). It further
comprises an anchor peg (6) with a hole (7) which can be used to receive a transversal pin or button (9) for locking the prosthesis to the sternum (3). The dome (5) can have one or more wings (8) overlapping with the sternum for increasing the fixation stability.

5 **Fig. 3** Schematic view of one embodiment of the sternoclavicular endoprosthesis as described herein: a) Left panel: Lateral projection of a first prosthetic component (1) positioned on the sternum; Middle panel: Top view of the first prosthetic component, showing the dome (5) and the wings (8); Right panel: side view of the first prosthetic component, showing the dome (5), the base of the dome (5'), the anchoring peg (6), the pin or button-receiving hole (7) in said peg (6) and the wings (8) of the dome. The tip of the peg (7) can be screw-like for ease of insertion into the the sternum (3); b) Left panel: Lateral projection of a second prosthetic component (2), having a base (12) positioned on the clavicle (4) and a cup (13), positioned on the dome of the first prosthetic component (1); Right panel: Isolated view of the second prosthetic component, clearly showing the hollow cup, configured to receive the ball-shaped dome of the first prosthetic component. The fixation stem (11) connected to the base (12) is also depicted inside the clavicle (4); c) Combined isolated view of the first and second prosthetic elements, indicating the interaction of both components, thereby forming a stable reverse prosthesis of the sternoclavicular joint.

10 **Fig. 4** Illustration of the fixation of a first prosthetic component (1) of a particular embodiment of the endoprosthesis described herein, to a sternum (3). A: sternum before treatment; B: indication of planned reaming, indicating the bone to be removed (14); C: preparation of bone surface via reaming with a reamer (15); D: sternum with prepared surface (17) and anchor hole or canal (16); E: sternum with first prosthetic component (1) fixed to it.

15 **Fig. 5** Illustration of the fixation of a second prosthetic component (2) of a particular embodiment of the endoprosthesis described herein, to a clavicle (4). A: clavicle before treatment; B: indication of bone marrow removal forming an intramedullary canal (18); C: clavicle with second prosthetic component (2), anchored into the intramedullary canal (18), through its fixation stem (11).

20 **Fig. 6** Illustration of a specific embodiment of the anchoring peg of the sternoclavicular endoprosthesis as described herein. The anchoring peg (26), can have an indentation for facilitating the suture. A: shows the planes of transversel sections shown in B. Said transversal section can be round, rectangular, triangular, star-shaped or can have any given anti-rotational shape.
**Fig. 7** Illustration of a radiocarpal joint and exemplary positioning of a radiocarpal endoprosthesis on said joint according to one of the embodiments of the invention. A: Radiocarpal joint (20), showing ulna (21), radius (22), carpals (23), and metacarpals I to IV (24). The dotted circle (33) indicates the projection of the circumference of the first prosthetic component (25) and the center of rotation (34) of such a prosthesis, which is located at the edge of the radius or within the radius (arrow from center (34)). B: Radiocarpal endoprosthesis comprising a first prosthetic component (25) and a second prosthetic component (27), respectively positioned on the radius (22) and carpal bones (23) of a radiocarpal joint (20). The first prosthetic component (25) can be inserted in the radius through anchoring peg (22), the second prosthetic component (27) can be inserted into the carpal and one (dark grey) or more (light grey) metacarpal bones, through pins or screws (28). The dotted circle (33) indicates the projection of the circumference of the first prosthetic component (25). The centre of rotation (34) is also indicated.

**Fig. 8** Projection of the transversal positioning of the first prosthetic component (25) on the distal end of the radius (right hand side shown only). A: Distal ends of the radius (22) and ulna (21) are shown with their different regions: ulnar facet (29), scaphoid facet (30), lunate facet (31), styloid process (32). The dotted circle (33) indicates the projection of the circumference of the first prosthetic component (25). The centre of rotation (34) of the reverse prosthesis is also indicated. Due to the presence of many canals that harbour tendons, nerves, musles, and blood vessels, the first prosthetic component (25) will typically not be a full sphere, but will have to be a partial sphere, i.e. a sphere cut off by one (B), or two (C) planes. Panels B and C show a typical form of the sphere that is tailored to not interact with the tendons, nerves, musles, and blood vessels running alongside the radius into the carpal region. In each embodiment, the center of rotation (34) needs to be centered as much as possible within the transversal centre of the radius.

**DETAILED DESCRIPTION OF THE INVENTION**

While potentially serving as a guide for understanding, any reference signs used herein and in the claims shall not be construed as limiting the scope thereof.

As used herein, the singular forms "a", "an", and "the" include both singular and plural referents unless the context clearly dictates otherwise.

The terms "comprising", "comprises" and "comprised of" as used herein are synonymous with "including", "includes" or "containing", "contains", and are inclusive or open-ended
and do not exclude additional, non-recited members, elements or method steps. The terms "comprising", "comprises" and "comprised of" when referring to recited components, elements or method steps also include embodiments which "consist of" said recited components, elements or method steps.

Furthermore, the terms first, second, third and the like in the description and in the claims, are used for distinguishing between similar elements and not necessarily for describing a sequential or chronological order, unless specified. It is to be understood that the terms so used are interchangeable under appropriate circumstances and that the embodiments described herein are capable of operation in other sequences than described or illustrated herein.

The values as used herein when referring to a measurable value such as a parameter, an amount, a temporal duration, and the like, is meant to encompass variations of +/-10% or less, preferably +/-5% or less, more preferably +/-1% or less, and still more preferably +/-0.1% or less of and from the specified value, insofar such variations are appropriate to ensure one or more of the technical effects envisaged herein. It is to be understood that each value as used herein is itself also specifically, and preferably, disclosed. Typically, the term "about" should be read in this context.

The recitation of numerical ranges by endpoints includes all numbers and fractions subsumed within the respective ranges, as well as the recited endpoints.

All documents cited in the present specification are hereby incorporated by reference in their entirety.

Unless otherwise defined, all terms used in disclosing the concepts described herein, including technical and scientific terms, have the meaning as commonly understood by one of ordinary skill in the art. By means of further guidance, definitions for the terms used in the description are included to better appreciate the teaching of the present disclosure. The terms or definitions used herein are provided solely to aid in the understanding of the teachings provided herein.

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 envisaged herein. Thus, appearances 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, but may. Furthermore, the particular features, structures or characteristics may be combined in any suitable manner, as would be apparent to a person skilled in the art from this disclosure, in one or more embodiments. Furthermore, while some embodiments described herein include some but not other features included in other embodiments, combinations of
features of different embodiments are also envisaged herein, and form different embodiments, as would be understood by those in the art. For example, in the appended claims, any of the features of the claimed embodiments can be used in any combination.

5 Provided herein is an endoprosthesis comprising first and second prosthetic components suitable for replacing a sternoclavicular or radiocarpal joint (wrist joint). The endoprosthesis described herein is a reverse-type prosthesis. Such prostheses are mainly known for the treatment of shoulder injuries and imply that that the position of the ball and socket of a ball-and-socket joint are reversed. The present inventors have found that the provision a reverse prosthesis is remarkably suitable for the treatment of degenerative and/or sternoclavicular instability lesions. More particularly, whereas the center of rotation of the sternoclavicular joint is naturally located at the sternal end of the clavicle, the provision of a reversed prosthesis allows for shifting the joint's center of rotation closer to the sternum. The present inventors have found that this shift can result in a neutralization of the torque exercised on the sternal component of the prosthesis, thereby leading to an increased implant and joint stability. The implant may further result in an improved bone ingrowth, thereby reducing the risk of implant loosening. This is particularly relevant for sternoclavicular prostheses, since loose components can have lethal consequences due to the proximity of main blood vessels and the trachea. The same applies for radiocarpal joint, which are difficult to treat with an existing endoprosthesis, due to the torque exercised on the radius. By shifting the centre of rotation from within the carpal bones, to a position on or even in the radius, said forces are neutralized.

In a first aspect, the present invention provides in an endoprosthesis comprising:

25 (a) a first prosthetic component comprising a spherical dome and an anchor peg provided at the base of said dome; and
(b) a second prosthetic component comprising:
   - a cup configured for receiving said spherical dome and a base; and
   - optionally a fixation stem provided at said base.

30 This will be explained further herein below.

First prosthetic component
The first prosthetic component provides the ball of a ball-and-socket joint prosthesis. Accordingly, the first prosthetic component comprises an outer convex surface. More particularly, the first prosthetic component can be shaped as a spherical or ellipsoidal dome. In particular embodiments, the dome encompasses at least a hemisphere or hemi-
ellipsoid. The dome can be solid or hollow. In particular embodiments, the (spherical) dome may have a radius between 5 mm and 20 mm. This range is considered suitable for most sternoclavicular joints.

5 There are various possibilities for positioning and fixing a prosthetic component to a bone. In particular embodiments, the first prosthetic component of a sternoclavicular endoprosthesis is provided with an anchor peg. For a radiocarpal endoprosthesis, wherein the first prosthetic component is positioned on a long bone (radius), a fixation stem with or without screw is preferred (see further). The anchor peg typically has a proximal end which is connected to the dome and a distal end for introducing into the bone. The anchor peg typically forms a longitudinal structure such as a rod. The term "longitudinal" as used herein refers to objects having an aspect ratio (length divided by width) of at least 1.5. In preferred embodiments, the anchor peg has a cylindrical shape. The anchor peg can be positioned in an anchor hole which is drilled in the bone, thereby fixing the component to the bone. Preferably, the anchor peg and the dome are manufactured as an integral part to reduce the risk of disconnection.

In particular embodiments, the anchor peg may be provided with a fin, more particularly a fin which is configured to deform when the anchor peg is received in an anchor hole as described above. Suitable anchor pegs having fins are described in European patent EP 1136046, which is hereby incorporated by reference. The presence of one or more fins on the anchor peg can allow for the fixation of the first prosthetic component on the bone via the anchor peg, without the use of bone cement.

The one or more fins are outwardly extending from the peg, and typically surround the peg at least partially. In further embodiments, the one or more fins extend continuously around the entire outer periphery of the anchor peg.

In certain embodiments, the anchor peg may be provided with a plurality of outwardly extending fins. The fins are typically positioned parallel to each other, typically in a position perpendicular to the peg axis. In certain embodiments, the plurality of fins may be arranged in a tapered configuration in which the dimensions of the fins increases along the distal end towards the proximal end of the anchor peg.

The term "perpendicular" as used herein is to be understood as including a certain amount of derivation from its actual precise orientation. More particularly, a fin is considered positioned perpendicular to the peg if the angle between the plane best fitting the fin and the longitudinal axis of the peg is between 85° and 95°, preferably between 87° and 93°, more preferably between 89° and 91°. Similarly, the term "parallel" as used herein is to be
understood as including a certain amount of derivation from its actual precise orientation. More particularly, two fins are considered parallel if the angle between the planes best fitting the fins does not exceed 10°, preferably 5°, most preferably 2°.

5 As an alternative to the fins described above, or in addition thereto, the anchor peg may be provided with a through hole, more particularly a transverse hole which allows for passing a wire. In this way, the peg (and thereby the first prosthetic component) can be fixed to the bone via a suture. More particularly, the suture (19) may pass through the hole (7) in the peg (6) and a button (9) which may be positioned on the exterior of the sternum, e.g. the anterior side of the sternum (cf. Figure 3a, right panel). By pulling the suture, the anchor can be pulled into the bone. Distal to the hole, the peg can also have a indentation a both side for the suture as exemplified in Figure 6. In contrast with fixation via pins or screws, the fixation of the first prosthetic component via sutures (19) reduces the risk of damaging nearby vascular structures in case of loosening of the first prosthetic component, thus increasing patient safety.

Suitable buttons (9) for use with the first prosthetic component described herein typically have a flat shape, and are provided with two or more through holes. In particular embodiments, the button may have a disc-like shape, and be provided with two to four through holes. Examples of suitable buttons are buttons used in the TightRope™ fixation system provided by Arthrex®.

In addition to the anchor peg and/or through holes described above, or as an alternative therefore, the first prosthetic component may be provided with other means for fixing the first prosthetic component to the bone. For example, the tip of the anchor peg can be threaded, such that the component can be inserted in the sternum like a screw. For example, the first prosthetic component may be provided with one or more screw holes for receiving a screw or a pin, thereby allowing fixation of the first prosthetic component on the manubrium via one or more screws or pins.

In certain embodiments, the base of the first prosthetic component may be adapted to cooperate with a corresponding base plate. Indeed, in particular embodiments, the first prosthetic component may be fixed via an intermediary base plate. Typically, the base plate is first fixed to the bone via an anchor pin, screws, or the like. Then, the first prosthetic component is fixed to the base plate, for example via a screw which is provided at the base of the first prosthetic component, matching a corresponding screw hole provided on the base plate. The fixation of the base plate to the bone and the fixation of the first prosthetic component to the base plate can be similar as the fixation of a
metaglene component to a glenoid and the fixation of a bearing component to the metaglene component in a shoulder prosthesis, for example as described in patent application US 2010/0161066, which is hereby incorporated by reference.

5 The first prosthetic component is typically positioned on the bone such that the base of the dome (i.e. the side where a portion of the sphere or ellipsoid is "cut off") faces the bone on which the first prosthetic component is positioned. Accordingly, any element for positioning the first prosthetic component on the bone, such as an anchor peg and or screw as described above, is typically provided at the base of the dome.

10 The optimal dimensions of the prosthetic components may depend on the patient and the type of joint. In particular embodiments, the prosthesis described herein is a prosthesis for replacing a sternoclavicular joint. In these embodiments, the (sphere or ellipsoid defining the) spherical or ellipsoidal dome of the first prosthetic component preferably has a radius between 5 and 15 mm.

In particular embodiments, the dome (5) is provided at its base with a central notch. The notch preferably has a width which is at least equal to the radius of the base of the dome, more preferably at least 70% of the diameter of the base of the dome. The notch preferably runs along the entire width of the base. More particularly, the length of the notch is preferably equal to the diameter of the base. In this way, two opposing wings (8) can be obtained which surround the bone and can provide additional stability when the dome is positioned on the bone (cf. Figure 3a). If the dome is provided with an anchor peg and a central notch, the peg is typically provided within the notch.

25 The edges and/or bottom of the notch may have a rounded shape as to prevent the dome from damaging mediastinal structures upon loosening. For example, the notch may have a U-shaped transversal cross section.

Second prosthetic component

30 The second prosthetic component provides the socket of a ball-and-socket joint endoprosthesis. Accordingly, the second prosthetic component comprises a cup which is configured for receiving the dome of the first prosthetic component. More particularly, the cup comprises a concave surface for receiving the dome. Accordingly, the concave surface of the cup typically has a similar or identical curvature or shape as the dome. However, the surface area of the cup and dome may differ. For
example, the surface area of the concave surface of the cup may be smaller than the outer surface area of the dome.

The second prosthetic component further comprises means for fixing the second prosthetic component to the bone. If the prosthesis is a sternoclavicular endoprosthesis, the base of the second prosthetic component is configured to be fixed to the clavicle, more particularly to the sternal end of the clavicle. Preferably, the second prosthetic component is fixed to the bone via fixation stem. A fixation stem is preferred for fixation of a prosthetic component to the end of a long bone, such as a clavicle or radius. Accordingly, a fixation stem is particularly preferred for a sternoclavicular endoprosthesis, wherein the second prosthetic component is positioned on the clavicle. For a radiocarpal endoprosthesis, an anchor peg as described above is preferred (see further), as the second prosthetic component is positioned on the carpus.

The fixation stem is a longitudinal rod-like structure which can be engaged and fixed in the diaphysis of a long bone, such as a clavicle or the radius, typically after resection. The fixation stem has a proximal and distal end and is or can be connected via its proximal end to the base of the cup. The fixation stem may have a uniform width along its length. However, it is envisaged that in certain embodiments, the diameter of the fixation stem is not uniform. For example, the stem may taper towards the distal end of the stem. The stem typically has a straight shape. However, it is envisaged that in certain embodiments the stem may be curved in order to better suit the curvature of the bone.

The stem typically has a length of at least 2 times, the average thickness of the endosteal diameter of the bone in which the stem will be positioned, i.e. the clavicle or the radius. If the prosthesis described herein is a sternoclavicular endoprosthesis, the stem preferably has a length between 2 cm and 6 cm.

In particular embodiments, the stem and the cup may be manufactured as a single part. However, in other embodiments, the stem and cup are provided on separate parts, which are or can be assembled together to form the second prosthetic component. This way the prosthesis can be assembled according to the patient’s anatomy. For example, the cup and/or stem may be manufactured in a number of sizes as standard elements. In such embodiments, the various standard stems may be assembled to any one of the various cups, thereby allowing the surgeon to assemble a second prosthetic component which best fits the patient’s anatomy. The assembly of the stem and cup may further allow for replacement of the cup in a revision surgery, without needing to replace the stem.

Moreover, the manufacture of the second prosthetic component in two or more parts may allow for manufacturing the cup and fixation stem in different materials. For example, the
fixation stem may be made of a material which promotes integration of the component with the bone, whereas the cup may be made of another material which is more durable. The means for assembling the stem and cup are not critical for the prosthesis, as long as they allow for a secure fixation of these parts. For example, the stem and cup may be assembled via interlocking coupling features, and/or via external fastening means such as screws. In particular embodiments, the means for assembling the stem and cup may allow for a removable or reversible assembly of the stem and cup.

The materials used for manufacturing the first and second prosthetic component as described herein typically are materials which are compatible with the human or animal body and provide an adequate durability. In particular embodiments, the first and/or second prosthetic component can be independently formed of one or more materials selected from the group consisting of titanium, titanium alloy, stainless steel, cobalt-chromium alloy, tantalum, tantalum alloy, polyethylene, polyether ether ketone (PEEK), a polyanhydride, a poly(ethylene glycol)-based material (such as poly(ethylene glycol)-diacrylate or poly(ethylene glycol)-dimethacrylate) and bioceramics. These materials are biocompatible and may provide the strength and durability required for implants. Bioceramics are ceramics that are compatible to the human body, such as calcium phosphate ceramic.

The dome is preferably made of a cobalt-chromium alloy, the fixation stem (if present) is preferably made of titanium, and the cup is preferably made of polyethylene. In certain embodiments, the surface of certain parts of the first and second prosthetic component, in particular the anchor peg of the first prosthetic component and/or the fixation stem of the second prosthetic component may comprise a porous metal, preferably porous tantalum, more preferably Trabecular Metal™ (available from Zimmer). Porous metal such as Trabecular Metal™ closely resembles the physical and mechanical properties of bone more and may therefore enable rapid and extensive tissue infiltration and strong attachment.

In particular embodiments, the first and/or second prosthetic component may comprise a hydroxyapatite coating. The use of a hydroxyapatite coating may further improve the biocompatibility of these components. The hydroxyapatite coating may be provided over a part or over the entire surface of the first and/or second prosthetic component.

As indicated above, the prosthesis described herein can provide an increased stability and a reduced risk of loosening. However, implant loosening may still be possible, e.g. due to infection. Implant loosening is particularly problematic for sternoclavicular endoprostheses.
as the loosened implant may damage mediastinal structures such as main blood vessels, possibly with lethal consequences. It is therefore preferred that the first and/or second prosthetic component is free from sharp edges or ridges, to reduce the risk of damaging the mediastinal structures. Preferably, at least the first prosthetic component is free from sharp edges or ridges.

As used herein, the term "sharp ridge" refers to a ridge forming the intersection of two surfaces forming an angle of less than 100°, preferably less than 90°, wherein the radius of curvature at the intersection is less than 100 $\mu m$. Accordingly, in particular embodiments, the first and/or second prosthetic component is free from surfaces having an intersection forming an angle of less than 100° wherein the radius of curvature at the intersection is less than 100 $\mu m$, and preferably less than 250 $\mu m$.

The first and second prosthetic component described herein can be manufactured as standard or as patient-specific parts. Patient-specific parts are parts which are adapted to the specific anatomy of a patient. For example, such parts may be provided with a contact surface which matches a part of the patient's anatomy.

In embodiments wherein the second prosthetic component is made of two separate parts, one part may be standard whereas the other is patient-specific. For example, the fixation stem may be standard, whereas the cup is adapted to the anatomy of a patient.

**Kit**

Further provided herein is a kit comprising:

- two or more first prosthetic components as described herein having a different size; each provided with a separate cup as described herein configured for cooperating with the corresponding prosthetic component; and

- one or more separate fixation stems which can be assembled together with said cups to a second prosthetic component as described herein.

The kit as described herein allows the surgeon to choose the first prosthetic component and corresponding cup which best fits the patient's anatomy, and to assemble (one of the) fixation stem(s) to the chosen cup to the second prosthetic component.

**Method of manufacturing**

Prostheses comprising patient-specific parts are typically designed and manufactured according to a pre-operational plan using a model of the patient's anatomy. Further provided herein is a method for generating a patient-specific endoprosthesis as described herein, comprising:
(i) providing volume information of a patient's joint;
(ii) providing a plan for a reconstructive joint surgery;
(iii) generating a patient-specific endoprosthesis.

Step (i) of the method typically involves providing a three-dimensional (3D) model of the joint, e.g. a sternoclavicular or radiocarpal joint. The model can be based on digital patient-specific image information which can be obtained by any suitable means known in the art, such as for example a computer tomography (CT) scanner, a magnetic resonance imaging (MRI) scanner, an ultrasound scanner, or a combination of Roentgenograms. In certain embodiments, the 3D model of e.g. the radiocarpal or sternoclavicular joint can be based on information obtained from the contralateral, non-injured, radiocarpal or sternoclavicular joint.

Based on the volume information, the surgical intervention can be planned. This can involve determining the type, optimal size, shape, orientation, positioning, etc. of the prosthesis.

Based on the surgical planning, a (virtual model of a) patient-specific endoprosthesis may be generated. In particular embodiments, the endoprosthesis may comprise standard parts and patient-specific parts.

In a further step, the complete endoprosthesis or (patient-specific) parts thereof may be manufactured, preferably via additive manufacturing. Additive Manufacturing (AM) can be defined as a group of techniques used to fabricate a tangible model of an object typically using three-dimensional (3-D), or computer aided design (CAD) data of the object. Currently, a multitude of Additive Manufacturing techniques is available, including Selective Laser Sintering, stereolithography, Fused Deposition Modeling, foil-based techniques, 3D-modeling, 3D-printing, etc.

Accordingly, in particular embodiments, the method described herein may comprise the (optional) step of:

(iv) manufacturing the endoprosthesis generated in step (iii) at least partially via additive manufacturing, e.g. based on the information obtained above.

Surgical method

Further provided herein is a method of implanting a sternoclavicular prosthesis as described herein in a patient. This method comprises:

(1) accessing a sternoclavicular joint of a patient;
(2) positioning the first prosthetic component of the prosthesis on the clavicular notch of the joint, such that the dome of the first prosthetic component faces the (sternal end of) the clavicle of the joint; and

(3) positioning the second prosthetic component on the (sternal end of) the clavicle, such that the concave surface of the cup of the second prosthetic component faces the clavicular notch of the joint.

Steps (2) and (3) as described above may be performed in any order.

In preferred embodiments, step (2) involves providing the clavicular notch with an anchor hole, suitable for accommodating the anchor peg of the first prosthetic component.

Optionally, where needed the surface of the clavicular notch can be prepared or reamed in order to more easily accept the first prosthetic component.

Typically, step (3) involves engaging the fixation stem of the second prosthetic component in the diaphysis of the clavicle after resection of the clavicle.

15 Radiocarpal endoprosthesis

Although the prostheses and methods are described herein mostly with respect to sternoclavicular joint reduction, these devices and methods may, mutatis mutandis, also be used for reduction of other joints with limited movement, such as the wrist joint (radiocarpal joint). Thus, the present application also provides a reverse prosthesis for replacing a radiocarpal joint.

The elements of such prosthesis are similar as described above. However, given the anatomy of the radiocarpal joint, the first prosthetic component (comprising the dome) preferably is positioned on the radius via a fixation stem with or without screws as described above, whereas the second prosthetic component (comprising the cup) preferably is positioned on the carpus via an anchor peg and/or angulated or non-angulated screws as described above or a fixation stem in the third metacarpal with or without screws.

Thus, in a further aspect, the present application provides a radiocarpal endoprosthesis (cf. Figure 7), comprising:

30 (a) a first prosthetic component for positioning on a radius comprising a spherical or ellipsoidal dome, and an fixation stem provided at the base of said dome; and

(b) a second prosthetic component comprising:
- a cup comprising a concave surface configured for receiving said dome and a base; and

35 - optionally, an anchor peg provided at said base, for fixation of said second prosthetic component or a fixation stem in the third metacarpal.
Similar to the second prosthetic component as described above, the fixation stem and the dome of the first prosthetic component may be manufactured as a single part, or be provided on separate parts, which are or can be assembled together to form the first prosthetic component.

In a further aspect, the present application provides a method of generating a radiocarpal endoprosthesis as described herein, comprising:

(i) providing a three-dimensional (3D) model of the radiocarpal joint of a patient;
(ii) providing a plan for a reconstructive radiocarpal joint surgery;
(iii) generating a patient-specific endoprosthesis
(iv) optionally, manufacturing the endoprosthesis generated in step (iii) at least partially via additive manufacturing.

In yet a further aspect, the present invention provides a method of implanting a radiocarpal endoprosthesis in a patient, comprising:

(1) accessing a radiocarpal joint defined by a radius and a carpus;
(2) positioning a first prosthetic component on said radius, said first prosthetic component comprising a spherical or ellipsoidal dome facing said carpus; and
(3) positioning a second prosthetic component on said carpus, said second prosthetic component comprising a cup comprising a concave surface configured for receiving said dome.

The dimensions of the radiocarpal prosthesis need to be tailored to the dimensions of the radiocarpal joint. The dimensions of the radiocarpal joint differs between male versus female subjects. The distal radius also has a peculiar shape. It roughly has a trapezoid or irregular quadrilateral shape, with the maximal height ranging from 1.8 to 2.0 cm in females and 19 to 22 cm in males and a maximal width ranging from 2.5 to 3 cm in females and 2.8 to 3.5 cm in males. The shape and dimensions of the radiocarpal prosthesis need to be configured to said anatomical shape and the first (dome) component will hence typically not be a complete dome or (hemi)sphere, but will have to be flattened at one or two sides, i.e. it will be a hemisphere that has been cut by one or two planes configured to follow the outer anatomy of the radius.

Typically, the maximal distance between said two planes will be equal to or smaller than the height of the trapezoid shape of the radius. This is depicted in Figure 8. The first component of the radiocarpal prosthesis as defined herein will hence have a partial
sphere shape, having a maximal diameter mimicking the maximal width of the distal radius, which is ranging from 2.5 to 3 cm in females and 2.8 to 3.5 cm in males. In some embodiments, said partial sphere is cut-off by one plane (35). In other embodiments, said partial sphere is cut-off by two planes (35° or 35°), wherein said planes can be parallel, or wherein the angle between both planes ranges from -10 degrees to +20 degrees. Said planes are typically spaced apart by a maximal distance which is mimicking the maximal height of the radius, which is ranging from 1.8 to 2.0 cm in females and 19 to 22 cm in males. Preferably, the center of the partial sphere and hence also the center of rotation of the prosthesis will be centered in the distal radius.

In some embodiments, the diameter of the partial hemisphere can be mimicking the maximal width of the distal radius, which is ranging from 2.5 to 3 cm in females and 2.8 to 3.5 cm in males. In other embodiments, the diameter of the partial hemisphere can be larger than the maximal width of the distal radius. In such a case, the center of rotation will not be at the distal surface of the radius, but will be situated within the radial bone.

In other embodiments, the diameter of the partial (hemi)sphere can be smaller than the width of the distal radius, as long as it is possible to form a sufficiently articulating ball-socket combination with the second component (the cap) of the prosthesis. In all embodiments defined herein, the second component of the radiocarpal prosthesis is configured so as to receive and cap the first partial sphere component. Its shape is typically configured to follow the anatomy of the carpal bones.

The following embodiments are provided for the purpose of illustrating the claimed methods and applications and are by no means meant to limit the scope of the present invention.

Figure 1 shows a particular embodiment of the sternoclavicular endoprosthesis as described herein, comprising a first prosthetic component (1) and a second prosthetic component (2), respectively positioned on a sternum (3) and clavicle (4) of a sternoclavicular joint. The endoprosthesis (cf. Figures 1 to 5) provides a ball-and-socket joint endoprosthesis formed by a dome (5) of the first prosthetic component (1), and a cup (13) of the second prosthetic component (2). The center of rotation of this ball-and-socket joint is located closer to the sternum compared with the natural sternoclavicular joint. This can result in minimizing the torque by neutralizing the lever arm exercised on the sternal component of the prosthesis. More particularly, the center of rotation may be located within the native bone of the sternum as is show in the figure in the form of a dashed circle.
with cross, in the normal situation (right-hand side) or the endoprosthesis situation (left-hand side) of the sternum as depicted in Figure 1.

A detailed lateral view showing the first prosthetic component (1) and its connection to the sternum (3) is shown in Figure 2. The first prosthetic component (1) comprises a spherical dome (5), and an anchor peg (6) provided at the base of the dome. The anchor peg allows fixation of the first prosthetic component via an anchor hole (16) provided in the bone of the sternum, more particularly in the manubrium. The anchor peg is provided with a transverse hole (7) which allows further fixation of the prosthetic component using TightRope™ fixation, e.g. using wires (19) and a (metallic) button (9) as shown in figure 3a, right panel. As shown for example in Figure 6, the anchoring peg (26), can have an indentation for facilitating the suture. Panel A of Figure 6 shows the planes of transversal sections shown in panel B.

The base of the spherical dome is provided with a central notch over the entire width of the dome base, thus creating a dome having two opposing wings (8) which surround the bone of the sternum. This can provide additional stability and avoids the creation of sharp edges which could damage main vessels in the proximity of the sternoclavicular joint. Furthermore, the edges of the first prosthetic component have a rounded shape as to prevent the dome from damaging mediastinal structures such as blood vessels upon loosening.

Figure 3 shows a more detailed view of both parts of the endoprosthesis. Fig. 3a details the first component of the prosthesis. The left panel depicts a lateral projection of a first prosthetic component (1) positioned on the sternum. The middle panel shows a top view of the first prosthetic component, showing the dome (5) and the wings (8). The right panel shows a side view of the first prosthetic component, showing the dome (5), the base of the dome (5'), the anchoring peg (6), the pin or button-receiving hole (7) in said peg (6) and the wings (8) of the dome. The tip of the peg (7) can be screw-like for ease of insertion into the the sternum (3).

Figure 3b depicts the second component of the endoprosthesis. The left panel depicts a lateral projection of a second prosthetic component (2), having a base (12) positioned on the clavícula (4) and a cup (13), positioned on the dome of the first prosthetic component (1), while the right panel shows an isolated view of the second prosthetic component, depicting the hollow cup, configured to receive the bal-shaped dome of the first prosthetic component. The fixation stem (11) connected to the base (12) is also depicted inside the clavicle (4).
Figure 3c depicts the interaction of both components of the endoclavicular endoprosthesis.

Figure 4 shows the preparation of the sternum (3), and more particularly the manubrium, for the positioning and fixation of the first prosthetic component (1).

Figure 4A shows the sternum (3) prior to treatment. In order to position the first prosthetic component, the surface of the manubrium is prepared by reaming a part of the bone. Fig. 4B shows the same sternum (3), with an indication of the bone to be removed (14). The removal of the bone is conveniently done using a reamer (15). Typically, a hole will be drilled in the bone for guiding the reamer, as shown in Fig. 4C. After reaming, this hole can provide an anchor hole (16) for accommodating the anchor peg of the first prosthetic component. Fig. 4D illustrates the sternum with a reamed surface (17) on which the first prosthetic component can be positioned. The surface (17) is provided with an anchor hole (16). Fig. 4E shows the first prosthetic component when positioned on the surface, wherein the anchor peg is placed in the anchor hole (not shown).

Figure 5 shows the preparation of the clavicle (4) for the positioning and fixation of the second prosthetic component (2). Fig. 5A shows the clavicle before treatment. Fig. 5B shows the same sternum, wherein the bone marrow is partially removed. Thereby, access is provided to the intramedullary canal (18) for the fixation stem (11) of the second prosthetic part (2), as shown in Fig. 5C.

The second prosthetic part may be manufactured as a single piece, or may comprise two or more parts which can be assembled together. Fig. 1 shows a second prosthetic part (2) comprising a base part (12) provided with the fixation stem (not shown), and a cup part provided with the cup (13).

The radiocarpal endoprosthesis as defined herein is, positioned on the radiocarpal joint (cf. Figure 7). The radiocarpal endoprosthesis comprising two main elements: a first prosthetic component (25) and a second prosthetic component (27), respectively positioned on the radius (22) and carpal bones (23) of a radiocarpal joint (20). The first prosthetic component (25) can be inserted in the radius through anchoring peg (22), the second prosthetic component (27) can be inserted into the carpal and one or more metacarpal bones, through pins or screws (28). The metacarpal three (MC-III, or third metacarpal) is targetted preferentially (dark grey in the figure), and the metacarpals two (MC-II) and four (MC-IV) can be targetted optionally (light grey in the figure) when additional stability is needed. In one embodiment, the anchoring is done in metacarpal three (28, III, dark grey pin). Alternatively, e.g. for more complex fractures, additional anchoring means (28) can be inserted to metacarpals II and/or IV, as shown in light grey
on Figure 7. As becomes clear from the figure (cf. panel A), the centre of rotation (smaller grey circle with cross) is shifted (black arrow) from within the carpal bones onto, or into the radius (larger black circle with cross), thereby reducing the forces applied to the prosthesis. Said centre of rotation can further be shifted into the radius (dotte arrow) by adjusting the dome shape. In panel B of the figure, the exemplary reverse prosthesis is depicted with its centre of rotation indicated by the circle with cross.

The radiocarpal prosthesis of the invention comprises again two components, a dome or partial sphere shaped component (25 to be fixed on the distal radius (cf. Figure 8). The centre of rotation (34) of the reverse prosthesis is situated in the on the distal surface of the radius or in the radius. Due to the presence of many canals that harbour tendons, nerves, muscles, and blood vessels, the first prosthetic component (25) will typically not be a full sphere or hemisphere, but will have to be a partial sphere, i.e. a (hemi)sphere cut off by one (cf. Figure 8 B), or two (cf. Figure 8 C) planes. The first prosthetic component will typically have the form of a partial sphere that is tailored not to interact with the tendons, nerves, muscles, and blood vessels running alongside the radius into the carpal region. In preferred embodiments, the center of rotation (34) needs to be centered as much as possible within the transversal centre of the radius.
CLAIMS

1. A radiocarpal endoprosthesis, comprising:

5  (a) a first prosthetic component for positioning on a radius comprising:
   - a spherical or ellipsoidal dome or partial sphere; and
   - a fixation stem provided at the base of said dome or partial sphere; and
(b) a second prosthetic component comprising:
   - a cup comprising a concave surface configured for receiving said dome or partial sphere;
   - a base configured for positioning the cup on the diaphysis of a carpus; and
   - optionally, an anchor peg provided at the base of said cup for fixation of said second prosthetic component in the carpus, e.g. with extra angulated screws in the carpus, preferably with a fixation stem in the third metacarpal (metacarpal three).

2. The radiocarpal endoprosthesis according to claim 1, wherein said dome or partial sphere has a diameter between 10 mm and 35 mm.

3. The endoprosthesis according to claim 1 or 2, wherein said first prosthetic component is at least partially made of titanium, cobalt, chrome, or an alloy thereof; or polyethylene.

4. The endoprosthesis according to any one of claims 1 to 3, wherein the interacting surface of said first prosthetic component with said second component is coated with polyethylene.

5. The endoprosthesis according to any one of claims 1 to 4, wherein said second prosthetic component is at least partially made of titanium, cobalt, chrome, or an alloy thereof; or polyethylene.

6. The endoprosthesis according to any one of claims 1 to 5, wherein the interacting surface of said second prosthetic component with the first component is coated with polyethylene.
7. The endoprosthesis according to any one of claims 1 to 6, wherein said stem and said dome or partial sphere are provided on separate parts, which are or can be assembled together.

8. The endoprosthesis according to any one of claims 1 to 7, wherein said assembly can be through a morse-taper interaction, through screw-thread, or through screws or pins.

9. The endoprosthesis according to any one of claims 1 to 8, wherein said first prosthetic component is free from surfaces having an intersection forming an angle of less than 100° wherein the radius of curvature at the intersection is less than 100 μημ.

10. The endoprosthesis according to any one of claims 1 to 9, wherein said fixation stem has a shape that prevents the fixation stem from rotating around its longitudinal axis.

11. The endoprosthesis according to any one of claims 1 to 10, wherein said shape is rectangular, triangular, or star-shaped, or wherein said shape is circular with one or more fin(s).

12. The endoprosthesis according to any one of claims 1 to 11, wherein said fixation stem is additionally fixed into the clavicular with one or more screws, preferably perpendicular to the clavicula.

13. A method of generating a radiocarpal endoprosthesis according to anyone of claims 1 to 12, comprising:

   (i) providing a three-dimensional (3D) model of the radiocarpal joint of a patient;
   (ii) providing a plan for a reconstructive radiocarpal joint surgery;
   (iii) generating a patient-specific radiocarpal endoprosthesis as defined herein based on the three-dimensional model obtained in step a);
   (iv) optionally, manufacturing the radiocarpal generated in step (iii) at least partially via additive manufacturing.

14. A method of implanting a radiocarpal endoprosthesis according to anyone of claims 1 to 12 in a patient, comprising:

   (1) accessing the radiocarpal joint comprising the radius and the carpals;
(2) positioning a first prosthetic component as defined herein on the radius, said first prosthetic component comprising a spherical or ellipsoidal dome or partial sphere facing said clavicle; and

(3) positioning a second prosthetic component as defined herein in or on the carpals, whereby optionally the lunatum and/or the scaphoid carpals are removed.

15. The method according to claim 14, wherein the first prosthetic component is inserted in the radius through an anchoring peg, and wherein the second prosthetic component is inserted into the carpal and one or more metacarpal bones, through pins or screws.

16. A sternoclavicular endoprosthesis comprising:
   (b) a first prosthetic component configured for positioning on the manubrium comprising:
      - a spherical or ellipsoidal dome; and
      - an anchor peg provided at the base of said dome; and
   (b) a second prosthetic component comprising:
      - a cup comprising a concave surface configured for receiving said dome;
      - a base configured for attachment to the diaphysis of a clavicle; and
      - optionally, a fixation stem provided at said base, configured for fixation of said second prosthetic component in the diaphysis of a clavicle.

17. The endoprosthesis according to claim 16, wherein said dome has a radius between 5 mm and 20 mm.

18. The endoprosthesis according to claim 16 or 17, wherein the base of said dome is provided with a central notch having a width at least equal to the radius of the base of said dome.

19. The endoprosthesis according to claim 18, wherein said notch runs along the entire width of said dome.

20. The endoprosthesis according to any one of claims 16 to 19, wherein said first prosthetic component is at least partially made of titanium, cobalt, chrome, or an alloy thereof; or polyethylene.
21. The endoprosthesis according to any one of claims 16 to 20, wherein the interacting surface of said first prosthetic component with said second component is coated with polyethylene.

22. The endoprosthesis according to any one of claims 16 to 21, wherein said second prosthetic component is at least partially made of titanium, cobalt, chrome, or an alloy thereof; or polyethylene.

23. The endoprosthesis according to any one of claims 16 to 22, wherein the interacting surface of said second prosthetic component with the first component is coated with polyethylene.

24. The endoprosthesis according to any one of claims 16 to 23, wherein said stem and said cup are provided on separate parts, which are or can be assembled together.

25. The endoprosthesis according to any one of claims 16 to 24, wherein said assembly can be through a morse-taper interaction, through screw-thread, or through screws or pins.

26. The endoprosthesis according to any one of claims 16 to 25, wherein said first prosthetic component is free from surfaces having an intersection forming an angle of less than 100° wherein the radius of curvature at the intersection is less than 100 µm.

27. The endoprosthesis according to any one of claims 16 to 26, wherein said at least one anchor peg is received in an anchor hole in the manubrium.

28. The endoprosthesis according to any one of claims 16 to 27, wherein said fixation stem (11) has a shape that prevents the fixation stem from rotating around its longitudinal axis.

29. The endoprosthesis according to any one of claims 16 to 28, wherein said shape is rectangular, triangular, or star-shaped, or wherein said shape is circular, but provided with one or more fin(s).

30. The endoprosthesis according to any one of claims 16 to 29, wherein said fixation stem (11) is additionally fixed into the clavicular with one or more screws, preferably perpendicular to the clavicle.
31. Method of generating an endoprosthesis according to any one of claims 16 to 30, comprising:
   (i) providing a three-dimensional (3D) model of the sternoclavicular joint of a patient;
   (ii) providing a plan for a reconstructive sternoclavicular joint surgery;
   (iii) generating a patient-specific endoprosthesis
   (iv) optionally, manufacturing the endoprosthesis generated in step (iii) at least partially via additive manufacturing.

32. Method of implanting a sternoclavicular endoprosthesis according to any one of claims 16 to 30 in a patient, comprising:
   (1) accessing a sternoclavicular joint defined by a clavicle and a clavicular notch;
   (2) positioning a first prosthetic component on said clavicular notch, said first prosthetic component comprising a spherical or ellipsoidal dome facing said clavicle; and
   (3) positioning a second prosthetic component on said clavicle, said second prosthetic component comprising a cup comprising a concave surface configured for receiving said dome.

33. The method according to claim 32, wherein the positioning step (2) also includes the preparation of the surface of the clavicular notch, e.g. by reaming the surface of the notch so as to enable stable positioning of the first prosthetic component on said notch.
Fig. 6
International Search Report

A. CLASSIFICATION OF SUBJECT MATTER
- A61F2/30
- A61F2/42
- A61B17/84

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

B. FIELDS 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.

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used):
- EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
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<td>GB 2 007 099 A (HAMAS R S) 16 May 1979 (1979-05-16) page 3, lines 31-56</td>
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<td>X</td>
<td>DE 23 09 432 AI (SULZER AG) 29 November 1973 (1973-11-29) pages 2-4</td>
<td>1-3, 5, 7</td>
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<td>WO 2009/076758 AI (UNIV MCGI LL [CA]; RICHARDS COREY [AU]; HACKING ADAM S [CA]; HARVEY EDW) 25 June 2009 (2009-06-25) page 15, line 5 - page 16, line 17</td>
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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents:
- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) on which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed
- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "A" document member of the same patent family

Date of the actual completion of the international search: 17 June 2015

Date of mailing of the international search report: 24/06/2015

Name and mailing address of the ISA:
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Authorized officer: Buchmann, Gerhard
<table>
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<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
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**INTERNATIONAL SEARCH REPORT**

**Box No. II**  
Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. **X** Claims Nos.: 14, 15, 32, 33  
   because they relate to subject matter not required to be searched by this Authority, namely:

   **Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery**

2. **□** Claims Nos.:  
   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. **□** Claims Nos.:  
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III**  
Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. **□** As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. **X** As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. **□** As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. **□** No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

- **□** The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- **□** The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- **□** No protest accompanied the payment of additional search fees.
This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-33
   A prostheses.

1.1. claims: 1-15
   A radiocarpal prosthesis comprising a first component to be positioned on a radius and having a spherical dome and a fixation stem, and comprising a second component to be positioned on the carpus/metacarpus and having a concave cup and a base for positioning on the carpus/metacarpus.

1.2. claims: 16-33
   A sternoclavicular endoprosthesis comprising a first component to be positioned on the manubrium and having a spherical dome and an anchor peg, and comprising a second component to be attached to the clavicle and having a concave cup and a base for attachment to the diaphysis of the clavicle.

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