US 20100023019A1

(19) **United States**

(12) **Patent Application Publication**

Fuhrer et al.

(10) **Pub. No.: US 2010/0023019 A1**

(43) **Pub. Date: Jan. 28, 2010**

(54) **PROSTHESIS HOLDER AND APPLICATION THEREOF**

(75) Inventors: **Christophe Fuhrer**, Valliere (FR); **Jerome Levieux**, Versoix (CH)

Correspondence Address:
YOUNG & THOMPSON
209 Madison Street, Suite 500
Alexandria, VA 22314 (US)

(73) Assignee: **SPINEART SA**, Meyrin, Geneve (CH)

(21) Appl. No.: **12/515,787**

(22) PCT Filed: **Nov. 21, 2007**

(86) PCT No.: **PCT/FR2007/052374**

§ 371 (c)(1),
(2), (4) Date: **May 21, 2009**

(30) **Foreign Application Priority Data**

Nov. 28, 2006 (FR) 06 10416

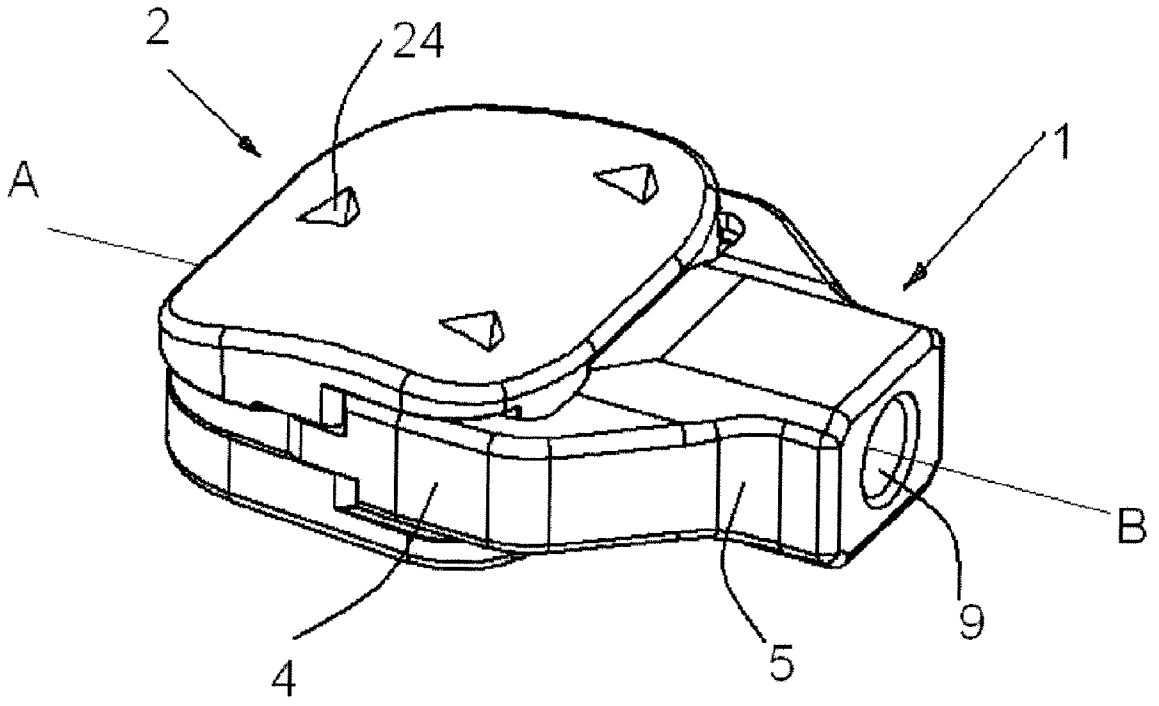
Publication Classification

(51) **Int. Cl.**
A61B 17/58 (2006.01)

(52) **U.S. Cl.** **606/99**

(57) **ABSTRACT**

Prosthesis holder (**1**) made of a radiolucent material for a disc prosthesis (**2**) constituted by at least two parts which are mobile in relation to each another, including, on one side an element (**9**) for coupling to a sleeve and on the other side, an element for reversible coupling to a disc prosthesis, the reversible coupling element is arranged in order to allow decoupling, by simple traction exerted perpendicularly to a spinal column when the disc prosthesis has been correctly impacted between two vertebrae and the retention force of the reversible coupling element on the disc prosthesis is adjusted so as not to allow decoupling by simple traction when the disc prosthesis has not been correctly impacted, and an assembly including a prosthesis holder and a disc prosthesis.



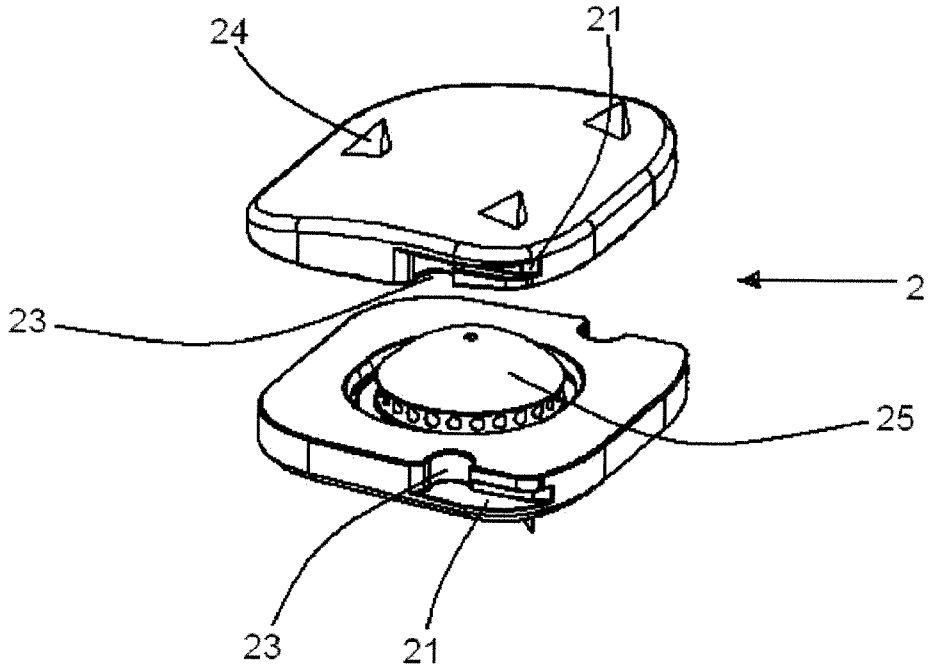


Fig. 1

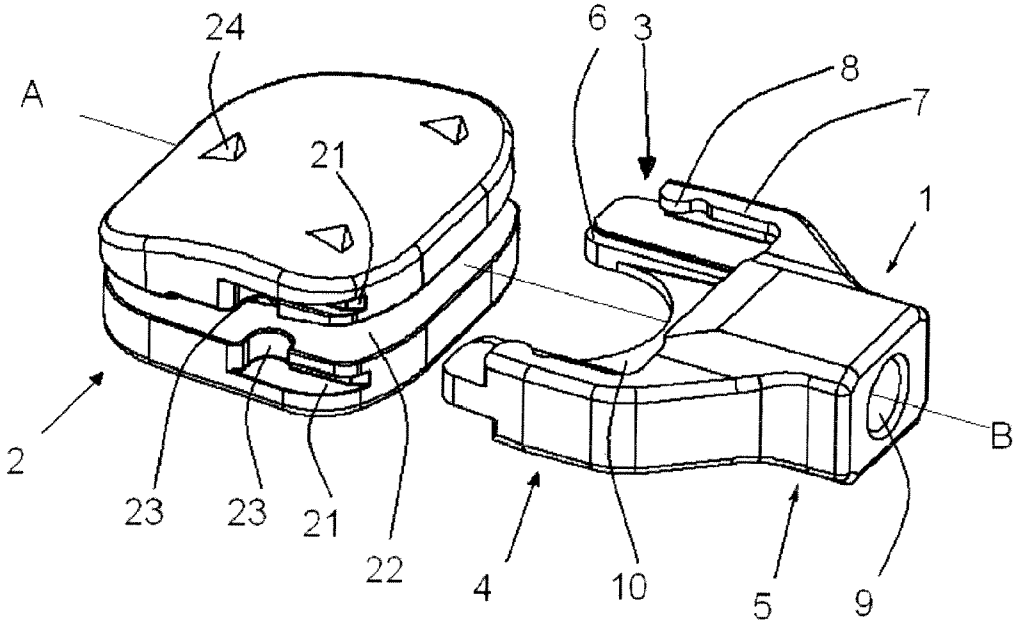


Fig. 2

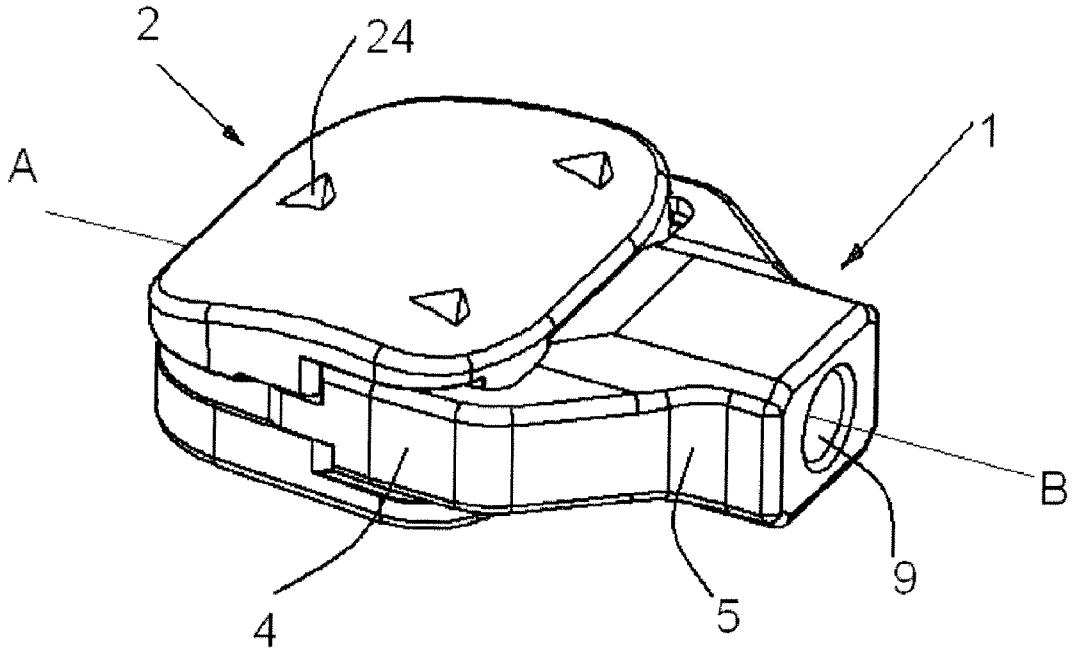


Fig. 3

PROSTHESIS HOLDER AND APPLICATION THEREOF

[0001] The present invention relates to prosthesis holders for discs and applications thereof.

[0002] Pathologies of the spinal column are increasingly treated by so-called "non-fusion" techniques and in particular by the implantation of disc prostheses.

[0003] These prostheses appear to produce good results.

[0004] However, their implantation is a serious and sometimes difficult operation. In fact, the ease and precision of the implantation play a predominant role in the final result, almost as much as the qualities of the disc prostheses themselves.

[0005] In fact, the position of the prosthesis in the disc space must be perfect in order to guarantee correct functioning. The surgeon verifies the position of the prosthesis during the surgical intervention using X-rays.

[0006] A disc prosthesis is a small object which is difficult to handle (of the order of one cm for its largest dimension and a few mm for its thickness). As a result its fitting utilizes a separate instrument called a prosthesis holder or insertion tool. This instrument provided with a sleeve or handle is firmly fixed to the prosthesis in order to allow the surgeon to handle the latter with force. After fitting of the prosthesis, it must be able to be withdrawn and the prosthesis left in place.

[0007] At present, these instruments are often complicated. In particular, the mounting of the prosthesis on the prosthesis holder can prove difficult. Furthermore, these prosthesis holders are made of radio-opaque materials, which does not facilitate the X-ray visualization of the position of the prosthesis.

[0008] Certain prosthesis holders such as Cervidisc prosthesis from Scient'X or the Prestige prosthesis from Medtronics, form a clamp which will grip the prosthesis. When the prosthesis is installed in the correct position, it is released by loosing it from the clamp or pulling on the sleeve.

[0009] These instruments work well, However, the mounting of the prosthesis on its prosthesis holder is difficult and must be carried during the intervention by the surgeon or competent nursing staff. This represents a loss of time and risks of failure. Furthermore these instruments are radio-opaque, generally they are metallic. When the prosthesis is in place, the surgeon checks its position (often in profile) to see whether it is suitable or whether it must still be moved (for example impacted more). This is done by X-rays. It is therefore very difficult for the surgeon to distinguish between the prosthesis and the prosthesis holder; in particular, the surgeon has difficulty in visualizing the position of the front face of the prosthesis which is in contact with the prosthesis holder.

[0010] Moreover, whatever the existing systems (Maverick prostheses from Medtronics, Mobi-c from LDR, Prodisc from Synthes), the disconnection of the prosthesis holder from the prosthesis does not guarantee the stability of the implant in the disc space. In fact, the surgeon loosens the prosthesis holder then withdraws it. Therefore, when it is loosened it can easily be freed even if the prosthesis is not very stable in the space.

[0011] Furthermore, the disc prostheses being constituted by at least two parts which are mobile in relation to each other, it is not easy to fit these prostheses onto their prosthesis holder during the intervention in the operating suite (This is the case in particular for the Prodisc (Synthes), or Prestige (Medtronics), or Cervidisc prostheses (Scient'X).

[0012] The purpose of the invention is to remedy the drawbacks of the above prosthesis holder by proposing a prosthesis holder made of radiolucent material intended to be fixed on the one hand to the prosthesis by a clamp system and having a reversible coupling element with a sleeve such as a threaded or other hole on the other side.

[0013] After lengthy research the Applicant has developed a prosthesis holder which in particular does not interfere with the locating of the prosthesis, is easy to withdraw, and can also make it possible to verify the stability of the prosthesis. Furthermore, the coupling to the prosthesis which is carried out in the operating suite is very easy (simple screwing for example).

[0014] This is why a subject of the present application is a prosthesis holder for a disc prosthesis characterized in that it is made of radiolucent material, in that it comprises, on one side an element for coupling to a sleeve and on the other side, an element for reversible coupling to a disc prosthesis, in that the reversible coupling element is arranged in order to allow decoupling by simple traction exerted perpendicularly to a spinal column when the disc prosthesis is stable between two vertebrae and in that the retention force of the reversible coupling element on the disc prosthesis is adjusted so as not to allow decoupling by simple traction when the disc prosthesis is not stable between the two vertebrae.

[0015] Thus, when the disc prosthesis has been correctly impacted between two vertebrae and stability is correct, the decoupling occurs by simple traction. If on the other hand the disc prosthesis has not been correctly impacted or if the size of the prosthesis is chosen incorrectly (too small) the prosthesis is not stable, in this case, during the traction exerted by the surgeon, withdrawal of the disc prosthesis occurs and the surgeon understands that the disc prosthesis has not been correctly impacted or that its size is not suited to the disc space in question.

[0016] In the present application and in the remainder of the text, the term "reversible coupling" denotes a coupling which can be followed by a decoupling, in particular without using a tool.

[0017] The element for reversible coupling of the prosthesis holder to a disc prosthesis can take numerous forms. Preferably it comprises a follower device of a cam provided on the prosthesis, said follower device being elastically mounted on the prosthesis holder.

[0018] For example, the follower device is a bulge provided on U-shaped arms of the prosthesis holder (forming a fork), said arms being arranged in order to grip a prosthesis and said bulge being directed towards the inside of the U. Preferably the bulge is provided towards the end of the U-shaped arms.

[0019] During the coupling, the follower device is guided for example by a groove or rib constituting the start of the cam then this groove or rib becomes hollow and the follower device (the bulge) will be housed in the recess formed in order to hold the prosthesis firmly.

[0020] Preferably a follower device is provided on each arm, in particular in a symmetrical position with respect to the direction of withdrawal. Advantageously, four follower devices are provided.

[0021] In the example above, the depth of the cam hollow, the length, the thickness of the arms carrying the follower device as well as their geometry (profile in cross section in particular), and the material constituting the prosthesis holder

determine the retention force of the reversible coupling element on the disc prosthesis. A person skilled in the art can, with a few simple experiments, determine the parameters necessary in order to obtain the desired retention force.

[0022] For a prosthesis intended for the cervical region, the retention force, necessary for disengagement, can be from 6 to 30 Newtons, preferably from 8 to 25 N, in particular from 9 to 20 N, quite particularly from 10 to 15 N.

[0023] For a prosthesis intended for the lumbar region, the retention force, necessary for disengagement, can be from 8 to 50 Newtons, preferably from 10 to 40 N, in particular from 12 to 30 N, quite particularly from 15 to 25 N.

[0024] A person skilled in the art understands that the bulges can be placed at various locations on the prosthesis holder as long as they are elastically mounted and corresponding recesses are provided on the prosthesis. Similarly, the bulges can be placed on the prosthesis and the recesses on the prosthesis holder.

[0025] The element for reversible coupling of the prosthesis holder to a disc prosthesis can also comprise studs, preferably cylindrical in shape, intended to be fitted into corresponding holes provided for this purpose in the prosthesis. The studs can be scored and slightly open in order to be fitted with force and to hold the prosthesis by adhesion, a minimum effort also being necessary in order to achieve decoupling.

[0026] Lateral friction surfaces of a fork-shaped prosthesis holder and of the prosthesis can also be practically parallel but slightly trapezoidal (for example with a relative inclination at an angle of 0.5 to 1°, the shorter base being towards the opening of the fork. A web can connect the branches of a fork-shaped prosthesis holder and a bulge or a recess can be provided on the webbed part.

[0027] A person skilled in the art can effortlessly understand when the term "one" signifies "at least one". For example when it says that the reversible coupling element of the prosthesis holder for a disc prosthesis can comprise "a follower device" of a cam provided on the prosthesis, "at least one follower device" is meant.

[0028] Under preferential conditions for implementation of the invention, the above prosthesis holder comprises a separate sleeve and retaining part as well as a system for the reversible coupling of the sleeve to the retaining part.

[0029] The sleeve allows the surgeon to grasp the prosthesis holder, for both insertion and impaction of the prosthesis and for decoupling and verification of the correct insertion thereof.

[0030] The sleeve can be coupled to the retaining part by any means well known to a person skilled in the art. There can be mentioned for example screw-and-thread devices, bayonet, clip devices etc.

[0031] Under preferential conditions for implementation of the invention, the above prosthesis holder comprises two arms forming a U-shaped clamp.

[0032] Each of the two arms preferably comprises a bulge, said bulge being directed towards the inside of the U.

[0033] Under other preferential conditions for implementation of the invention, the above prosthesis holder has as a maximum the same width as the disc prosthesis for which it is intended.

[0034] Under yet other preferential conditions for implementation of the invention, the above prosthesis holder has a length, in the direction of the sleeve, preferably less than 10 cm, in particular less than 5 cm, particularly less than 3 cm, quite particularly less than 2 cm. For a prosthesis intended for the cervical region it has a width preferably of 1 to 3 cm, in particular of 1.2 to 2 cm, particularly of 1.3 to 1.9 cm, quite particularly of approximately 1.5 cm. For a prosthesis intended for the lumbar region it has a width preferably of 2 to 6 cm, in particular of 3 to 5 cm, particularly of 3 to 4 cm, quite particularly of approximately 3.5 cm.

[0035] Under yet other preferential conditions for implementation, the prosthesis holder of the invention has as a maximum the same height as the disc prosthesis for which it is intended. In particular it has as a maximum the same height and as a maximum the same width as the disc prosthesis for which it is intended.

[0036] The prosthesis holder of the invention is radiolucent. It is for example made of thermoplastic resin. The thermoplastic resin is for example high molecular weight polythene, PEEK loaded with glass or carbon fibres or pure, polyphenyl sulphones marketed under the name of Radel® and preferably acetal (thermoplastic homopolymer acetal resin which is reinforced or not reinforced). It can also be made of two or more two different materials. In this case, at least the major part serving to grasp the prosthesis and in contact with said prosthesis is advantageously radiolucent in order to make it possible to visualize the prosthesis in the disc space, whilst the remainder of the prosthesis holder is or is not made of radiolucent material.

[0037] The sleeve can be made of the same materials as the prosthesis holder, or of a different material, for example a metal such as stainless steel which is perfectly suitable.

[0038] The prosthesis holder which is the subject of the present invention possesses very useful qualities.

[0039] The fork being radiolucent, it is easy to visualize the prosthesis in the disc space. Furthermore, given its design, simple traction is sufficient to detach it from the prosthesis. This also has the advantage of verifying the stability of the prosthesis, in fact during traction, if the prosthesis remains connected to the prosthesis holder, it can be considered that its primary stability in the disc space was insufficient and another, larger size must generally be chosen.

[0040] They make it possible to hold together the different parts of a disc prosthesis during the intervention. They also have a reduced space requirement since their height can be less than that of the disc prosthesis and, similarly, their width can be less than that of said disc prosthesis.

[0041] It is also possible to have a prosthesis already fitted to the prosthesis holder in the factory. The mounting of the prosthesis holder thus comes down to screwing a rod into the threaded hole provided for this purpose. This operation is obviously straightforward.

[0042] A subject of the present application is therefore also an assembly (or kit) comprising a prosthesis holder and a prosthesis, preferably pre-mounted as well as, in particular, a sleeve. Preferentially, the various elements of the assembly are sterile and particularly sterile during packaging. The sleeve may not be sterile.

[0043] The arrangement in two parts of the prosthesis holder additionally makes it possible to avoid handling the implant which poses a risk of contamination. As the prosthesis is mounted on its prosthesis holder in the factory, it is even possible to mount the sleeve on the prosthesis holder without ever touching the prosthesis, this is the so-called "no touch"technique, i.e. nothing is touched, which is safest as regards asepsis.

[0044] These properties and qualities are illustrated hereafter in the figures. They justify the use of the prosthesis holders described above, in the fitting of disc prostheses between two vertebrae.

[0045] A subject of the present application is therefore also a method for fitting a disc prosthesis between two vertebrae in which a disc prosthesis is placed between two vertebrae using a prosthesis holder described above.

[0046] A subject of the present application is also method for choosing a disc prosthesis to be inserted between two vertebrae, in which a disc prosthesis is placed between two vertebrae using a prosthesis holder described above, traction is exerted on the prosthesis holder and it is observed whether the disc prosthesis remains in place or comes out with the prosthesis holder.

[0047] The preferential conditions for utilization of the prosthesis holders described above also apply to the other subjects of the invention referred to above, in particular to the assemblies comprising an above prosthesis holder and a disc prosthesis.

[0048] The invention will be better understood by referring to the attached drawings in which

[0049] FIG. **1** shows a perspective view of a disc prosthesis constituted by at least two parts which are mobile in relation to each other, with its parts moved apart from each other.

[0050] FIG. **2** shows a perspective view of a disc prosthesis holder as well as the corresponding prosthesis, separated,

[0051] FIG. **3** shows a perspective view of a disc prosthesis holder as well as the corresponding prosthesis, pre-mounted.

[0052] FIG. **1** shows a disc prosthesis constituted by at least two parts which are mobile in relation to each other, with its pieces moved apart from each other.

[0053] The prosthesis **2** comprises an upper plate and a lower plate, approximately square in shape with rounded corners viewed from above. Each plate of the prosthesis 1 has a size of approximately 1.5 cm by 1.3 cm in this representation. The lower plate comprises a recess in which a dome **25** is housed. The upper plate comprises a concave recess the shape of which corresponds to that of the dome.

[0054] The prosthesis **2** comprises hollowed out elements complementary to raised elements of the corresponding prosthesis holder of FIG. **2**. Each plate comprises in particular along two opposite sides, ribs **21** formant a cam. Recesses **23**, four in number, two on the left and two on the right of the prosthesis i.e. two per plate, are intended to receive the bulges **8** of the prosthesis holder. The dimensions of these elements are suited to those of the corresponding elements of the prosthesis holder.

[0055] The prosthesis **2** comprises, above and below, pointed elements **24** which allow the anchoring of the prosthesis after impaction.

[0056] FIG. **2** shows a disc prosthesis holder **1** as well as the corresponding prosthesis **2**, separated. The prosthesis holder **1** is shown here without its sleeve. It has a general U-shaped fork appearance comprising two branches **3**, **4** and a central part **5**. Each of the branches comprises three ribs, a central rib **6**, two secondary ribs **7** (only one per branch is visible in the figure). The central rib **6** with a significant thickness (from 1 to 5 mm according to the size of the prosthesis and its intended cervical or lumber region) serves as a main guide and gives solidity to the assembly, but does not allow the reversible coupling according to the invention. This is conferred by the secondary ribs **7** (with a thickness of approximately 0.4 to 3 mm) which comprise at their end a bulge **8** projecting towards the inside of the fork. This bulge **8** serves as a follower device. The bulges **8** are elastically mounted thanks to the geometry (profile in cross section in particular), and with the material constituting the prosthesis holder **1** here made of acetal, allowing the two arms to be moved apart from each other.

[0057] The cooperation of the ribs of the prosthesis holder **1** and the prosthesis **2** prevent the moving apart of the parts of the prosthesis **2** and the cooperation of the bulges **8** and recesses **23**, combined with the cooperation of the dome **25** with the concavity of the upper part of the prosthesis **2**, avoids the pieces of the prosthesis **2** sliding on one another, in order to firmly couple the two parts of the prosthesis **2**.

[0058] In its central part **5**, the prosthesis holder **2** comprises a threaded hole **9** into which a sleeve (not shown) can be screwed.

[0059] A web **10** connects the two arms **3** and **4** for good rigidity.

[0060] The prosthesis holder **1** has a height slightly less than that of the disc prosthesis **2**. It has a length, in the direction of the sleeve, of approximately 1.5 cm, a width of approximately 1.5 cm and a height of approximately 6 mm in this representation.

[0061] The prosthesis **2** is here shown with the two plates moved together, the dome **25** in contact with the concave recess in the upper plate.

[0062] The prosthesis **2** comprises hollowed-out elements complementary to raised elements of the prosthesis holder and comprises in particular ribs **21** forming a cam which follows the bulge **8** during the coupling. The web **10** is housed in the space **22** between the upper plate of the prosthesis and the lower plate. Recesses **23**, four in number, two on the left and two on the right of the prosthesis are intended to receive the bulges **8** of the prosthesis holder. The dimensions of these elements are suited to those of the corresponding elements of the prosthesis holder.

[0063] The prosthesis **2** comprises, above and below, pointed elements **24** which allow the anchoring of the prosthesis after impaction.

[0064] During the coupling, shown in FIG. **3**, the secondary ribs **7** are inserted into the ribs **21** serving as corresponding cams. In abutment, the bulges **8** are engaged in the recesses **23** so as to firmly couple the two parts of the prosthesis **2**. A person skilled in the art understands, on examining the figures, that the bulges **8** can be placed at various locations on the prosthesis holder so long as they are elastically mounted and corresponding recesses **23** are provided on the prosthesis. Similarly, the bulges **8** can be placed on the prosthesis and the recesses **23** on the prosthesis holder.

[0065] The prosthesis **1** can be supplied with its prosthesis holder **2** already fitted in the factory as shown in FIG. **3**. The final mounting of the prosthesis holder is thus limited to screwing a sleeve into the threaded hole **9** provided in its central part **5**.

[0066] The depth of the hollow **23** of the ribs **21**, the length, the thickness of the arms **3**, **4** carrying the follower device as well as their geometry (profile in cross section in particular), and the material constituting the prosthesis holder **1** determine the retention force of the prosthesis holder on the prosthesis.

[0067] In order to withdraw the prosthesis holder **1** with a view to leaving the prosthesis **2** in place, and to verify the satisfactory stability of the latter, it is sufficient to pull on the sleeve in the direction AB. If the bulges **8** become disengaged

from the recesses **23** leaving the prosthesis in place, this signifies that the latter is satisfactorily stable. The parts of the prosthesis are released and the plates can be moved in relation to each other, according to the ball joint provided by the dome.

[0068] FIG. **3** also shows that the use of ribs (or elongated slots for the female part) for coupling the two parts of the prosthesis **2** by means of the prosthesis holder **1** makes it possible to appreciably reduce the space requirement of the assembly. The prosthesis holder **1** in fact has the same width as the disc prosthesis **2** as can be clearly observed in the figure. It also has the same height as the disc prosthesis **2**. A reduced space requirement is particularly useful as regards surgery.

1-10. (canceled)

11. A prosthesis holder (**1**) for a disc prosthesis (**2**) constituted by at least two parts which are mobile in relation to each other, said prosthesis holder being made of radiolucent material, and comprising, on one side an element (**9**) for coupling to a sleeve and on the other side, an element for reversible coupling to a disc prosthesis, wherein the reversible coupling element is arranged in order to allow decoupling by simple traction exerted perpendicularly to a spinal column when the disc prosthesis is stable between two vertebrae, wherein the retention force of the reversible coupling element on the disc prosthesis is adjusted so as not to allow decoupling by simple traction when the disc prosthesis is not stable in the intervertebral space, and which is arranged so as to firmly couple the mobile parts of the disc prosthesis.

12. The prosthesis holder according to claim **11**, wherein the arrangement for firmly coupling the mobile parts of the disc prosthesis comprise grooves or ribs (**7**, **21**).

13. The prosthesis holder according to claim **11**, further comprising a follower device (**8**) of a cam (**21**) provided on the prosthesis, said follower device (**8**) being elastically mounted on the prosthesis holder.

14. The prosthesis holder according to claim **13**, wherein the follower device (**8**) is a bulge provided on U-shaped arms (**3**, **4**) of the prosthesis holder, said arms (**3**, **4**) being arranged in order to grip a disc prosthesis (**2**) and said bulge (**8**) being directed towards the inside of the U.

15. The prosthesis holder according to claim **11**, further comprising a separate sleeve and retaining part (**1**) as well as a system for the reversible coupling of the sleeve to the retaining part (**1**).

16. The prosthesis holder according to claim **11**, which is made of thermoplastic resin.

17. An assembly comprising a prosthesis holder as defined in claim **11** and a disc prosthesis (**2**).

18. The assembly according to claim **17**, said assembly being pre-mounted.

19. The assembly according to claim **17**, wherein the arrangement for firmly coupling the mobile parts of the disc prosthesis comprise grooves or ribs (**7**, **21**).

20. The assembly according to claim **17**, wherein the prosthesis holder (**1**) further comprises a follower device (**8**) of a cam (**21**) provided on the prosthesis, said follower device (**8**) being elastically mounted on the prosthesis holder.

21. The assembly according to claim **20**, wherein the follower device (**8**) is a bulge provided on U-shaped arms (**3**, **4**) of the prosthesis holder, said arms (**3**, **4**) being arranged in order to grip a disc prosthesis (**2**) and said bulge (**8**) being directed towards the inside of the U.

22. The assembly according to claim **17**, wherein the prosthesis holder further comprises a separate sleeve and retaining part (**1**) as well as a system for the reversible coupling of the sleeve to the retaining part (**1**).

* * * * *