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Declarations under Rule 4.17:

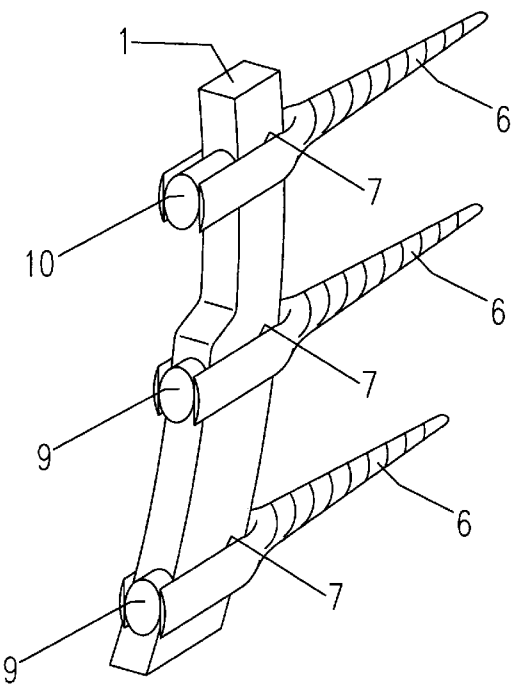
— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report (Art. 21(3))*

(54) Title: SPINAL IMPLANT SET FOR THE DYNAMIC STABILIZATION OF THE SPINE

FIG. 6



(57) Abstract: A connection element (1) for stabilizing vertebral bodies that has a variable stiffness along its longitudinal axis in that particularly the cross-section of the connecting element varies along its longitudinal axis and extends over a plurality of bone screws (6). In spite of the varying cross-section (h1, h2), in a preferred embodiment, the same bone screws (6) may be used in all locations by inserting clamping elements (9, 10) of different lengths.

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Spinal Implant Set for the Dynamic Stabilization of the Spine

The present invention relates to a spinal implant set for the dynamic stabilization of the spine according to the preamble of claim 1 and a use thereof.

The present invention allows to realize an elastic connecting rod having different degrees of stiffness along its longitudinal axis and usable for dynamically stabilizing vertebral bodies. Elastic connecting rods are typically used in conjunction with bone screws (pedicle screws) for the dynamic stabilization of the spine. If such a rod is provided with a section of higher stiffness, the possible indications can be substantially extended. Thus, a section of higher stiffness may e.g. be used for the fusion of a vertebral body while a section of lower stiffness may be used for the elastic connection of a neighboring segment.

The "golden standard" in spinal surgery today still consists in the fusion (stiffening) of pathologic vertebral bodies. However, the stiffening often leads to premature degeneration of the segments adjacent to the fusion. Therefore, attempts are being made to provide rods having different degrees of stiffness and to include the neighboring segments in the surgical treatment.

As shown below, the approaches that are known in the art relate to combinations of metal and plastic rods, on one hand, and to plastics rods having variable cross-sections, on the other hand.

The invention according to patent application EP 1 719 468 connects a metal bar to a textile band that is intended to act as an inner traction structure in an outer plastic cushion to form a connected dynamic stabilization.

The invention according to patent specification EP 1 815 812 provides, at the end of a metal rod, a part for receiving a connectable plastic rod.

The invention according to patent application US 2009/0118767 shows a connecting element having variable flexibility along its longitudinal axis. Here the variable flexibility is limited to the area between two anchoring elements, and only the outer body of the connecting element is varied in its stiffness.

The invention according to patent application US 2009/0248083 shows connecting rods having areas of different stiffness along their longitudinal axis which only extend over one motion segment, however, i.e. act between two consecutive fastening screws.

The invention according to patent application WO 97/32533 shows (rigid) connecting rods varying in diameter along their longitudinal axis, which is however limited to the area between two fastening screws.

The invention according to patent application WO 2007/038429 shows a stack of load-bearing elements that should be stiff in the longitudinal direction and elastic in the transversal direction. However, the intended difference in stiffness is only achieved between two respective fastening screws.

The invention according to patent application US 2005/0203513 aims to achieve different degrees of stiffness between respective motion segments or pairs of fastening screws. However, the suggested solution provides no continuous variation over the respective fastening screws so that the connecting element necessarily requires predetermined graduations of the fastening locations, which may result in considerable difficulties for the surgeon in multisegmental applications.

The invention according to patent application US 2007/0191832 suggests a plurality of bodies having different degrees of elasticity between at most two fastening screws and is therefore limited to at most unisegmental treatments.

The invention according to patent application WO 2007/087476 provides different degrees of stiffness between two fastening screws in that the connecting rods have a longitudinal cavity and different external contours. However, the variable cross-sections are limited to unisegmental treatments and due to the cavities are barely suitable for anchoring e.g. elastic rods in bone screws.

The invention according to patent US 7,326,210 suggests connecting elements having elastic areas between the fastening screws that are either suitable for unisegmental applications only or necessarily subject to the problem of the predetermined graduation.

The invention according to patent application WO 2007/089957 also describes variable cross-sections along the rod axis, however in predetermined segments, which requires an individually adapted rod with corresponding segment lengths for each patient. The flattened sides of the rod are orthogonal to the axis of a potential bone screw. Connections of the rod to the bone are not shown.

The invention according to patent application WO 2009/021116 describes variable cross-sections along the rod axis, too, however only between the fastening screws, therefore again requiring a particular rod with corresponding segment lengths for each patient. The suggested dynamic rod system seems not to be suitable for fusions, i.e. for predominantly compressive forces. Furthermore it is doubtful whether the combination of fibers over a molded core can withstand several millions of load cycles without degradation.

The invention according to patent application EP-A-2047812 describes variable cross-sections along the rod axis, however only between the fastening screws, which is again linked to the problem of predetermined segment lengths. Furthermore, the rod is made of metal and cannot be considered as a dynamic fixation system, neither isolated nor on a transitional segment.

The invention according to patent application US 2010/0114165 shows a round rod having a variable cross-section along the rod axis in that the radius decreases in the cranial direction. However, at the cranial end, the rod is not firmly connected to the vertebral body, especially not by using the same bone screws as used further caudally.

The invention according to patent specification US 5,217,461 also describes two different diameters of the connecting rod along the rod axis, but does not specify how these different rods are connected to the spine, and even less that one single type bone screw can be used therefore.

Accordingly, it is an object of the present invention to provide a spinal implant set comprising a rod of varying stiffness usable in a more extended range of orthopedic situations.

Such a spinal implant set is defined in claim 1. The further claims define preferred embodiments and a use of the implant set.

The implant set according to the invention comprises a connection element or rod the stiffness of which varies over at least two neighboring areas along its longitudinal axis but which is not subject to the disadvantages of a predetermined graduation.

This is accomplished in that the cross-section varies continuously or in at least one step, preferably exactly one step, along the rod axis, preferably in such a manner that the same bone screws with the same seats can be used for the entire connection element.

Preferably, the spinal implant set according to the invention comprises a connecting element having a cross-sectional variation that extends over at least three bone screws.

The present invention is explained in more detail hereinafter by way of preferred embodiments with reference to drawings which do not show all possibilities of varying cross-sections along a rod axis.

The figures schematically show:

Fig. 1 pre-bent rectangular rods having different cross-sections along the longitudinal axis of the rod;

Fig. 2 a straight and two pre-bent longitudinal axes of rods;

Fig. 3 different nose shapes of the rod cross-section in a top view;

Fig. 4 partial longitudinal sections of different screw heads and clamping elements for receiving the rod of varying cross-section;

Fig. 5 partial cross-sections of two versions of a rod with a clamping element in the seat of the bone screw;

Fig. 6 schematized illustration of a pre-bent rod having different cross-sections along the rod axis that is received in a plurality of bone screws of the same type.

An implant set for the dynamic fixation of the spine has been described in the earlier patent application WO 2011/6267 of the applicant. The disclosure of that patent application is incorporated by reference and in particular describes the preferred fastening system for fastening the connection element of the spine implant set to bone screws.

More particularly, a spinal implant comprises a connection rod which has two opposite, plane-parallel faces of which one dimension extends in the direction of insertion in a seat of a bone screw. As explained in WO 2011/6267, this feature allows to circumferentially clamp the rod in a hydrostatic in-plane manner, i.e. the clamping pressure exerted on the whole clamping contour. Thereby, flowing of the rod material in the clamping plane is avoided, and namely rods of polymeric material are therefore held in a long time stable fashion.

In Fig. 1 a pre-bent connection element or rod 1, 12 is depicted whose rectangular cross-section 2 varies in one dimension (h1, h2), preferably in the direction of the curvature radius (R), along the rod axis. Fig. 1a shows a rod 1 wherein the variation is stepwise. Preferably, only one step 32 is present. Fig. 1b shows a rod 12 with a continuous variation of the cross section.

In Fig. 2 a straight longitudinal rod axis, one that is pre-bent according to a radius (R), and one that is bent according to two different radii (R1, R2) are depicted.

In Fig. 3a the rod 1 has no particular nose shape.

In Fig. 3b the rod 1 has a triangular nose shape 3 with a rounded apex 31.

In Fig. 3c the rod 1 has a semicircular nose shape 4.

In Fig. 3d the rod 1 has a semi-elliptical nose shape 5.

The nose shapes according to Figs. 3b to 3d facilitate the insertion of the rod 1 in the seat 7 of the bone screw 6 as explained in WO 2011/6267.

In Fig. 4a a bone screw 6 having a large seat 7 for a large rod cross-section h1 and a short clamping element 9 are depicted.

In Fig. 4b a bone screw 6 having a large seat 7 for a small rod cross-section h2 and a long clamping element 10 are depicted.

In Fig. 4c a bone screw 6 having a small seat 8 for a small rod cross-section h2 and a short clamping element 9 are depicted.

Fig. 5a shows a top view of a rod 1 with a clamping element 9, 10 in the form of a headless screw, in the seat 7, 8 of the bone screw 6.

Fig. 5b shows a top view of a rod 1 with a clamping element 9, 10 in the form of a spacer with an additional external nut 11 in the seat 7, 8 of the bone screw (6). The nut engages in an exterior thread in the head of bone screw 6.

In Fig. 6 a pre-bent rod 1 whose cross-section varies along the rod axis is depicted that is secured in three bone screws 6 of the same type having three identical seats 7 with two short 9 and one long clamping element 10. The bone screws may e.g. be those of WO 2011/6267, yet with clamping elements of varying dimensions.

To realize the invention, countless combinations of embodiments may be contemplated. A few preferred embodiments will be non-exhaustively explained here. The rod cross-section may be rectangular with plane-parallel sides, e.g. according to WO-A-2011/6267. The cross-section may vary along the longitudinal axis of the rod while its height (h), its width (b), or both are varied. The rod may be supplied as a straight rod (R = ∞ (infinite)) or as a pre-bent rod with one or multiple different curvature radii (R1, R2). In the case of a rectangular rod cross-section, one or more sides, preferably at the forward side as seen in the direction of the bone screw 6, may be provided with a particular nose shape. This nose shape may e.g. (cf. Fig. 3) be triangular 3 with a rounded apex 31, semi-circular 4, or semi-elliptical 5. The nose shape may be attached or integrated (in one piece).

In the case of cross-sections that vary in the direction of the screw axis, the same bone screws may be used along the rod axis and clamping elements of merely different lengths are applied. The advantage of bone screws of the same type is that during revision surgery (e.g. extension surgery) screws that are well integrated into the bone may be preserved and sections of merely different rod stiffness can be inserted.

A preferred material for such connecting elements is PCU (polycarbonate-urethane) since it is available in different degrees of stiffness or elasticity, respectively, and has an excellent biocompatibility and outstanding mechanical long-term behavior. However, other polymers may also be contemplated, e.g. those of the PEEK family (polyetheretherketones).

Preferably (cf. Fig. 6), a first or forward side of the connecting rod may follow a line, whereas the opposite or rearward side may be stepped with respect to the first side. The first side will be pushed first in the seats of the bone screws. The continuous shape of the forward side complies with the anatomical situation. Only the spacers or other clamping means pressed on the rearward side of the connection rod need to be chosen to compensate the differing heights, or - more generally - dimensions, of the connection rods. However, even the first side may be shaped unevenly, e.g. stepped, and spacers may be inserted as necessary between the bottom of the seat in the bone screw and the connection rod.

Claims

1. A spinal implant set for the dynamic stabilization of the spine comprising two or more bone screws (6) and at least one elongated connection element (1) having a cross section (2) varying along its longitudinal axis, wherein the cross section has a rearward and a forward side opposed in the direction of insertion in the bone screws and the variation of the cross section is substantially accomplished by the variation of the distance between the rearward and the forward side.

2. The spinal implant set of claim 1, wherein the variation of the cross section of the elongated connection element along the longitudinal axis is continuous or with one or more steps.

3. The spinal implant set of one of claims 1 to 2, wherein said elongated connection (1) element is straight or pre-bent with at least one radius (R; R1, R2).

4. The spinal implant set of one of claims 1 to 3, wherein the varying cross section of the elongated connection element (1) comprises a portion of constant cross section (h1) of a length so that the portion is insertable in at least two bone screws (6) when implanted.

5. The spinal implant set of one of claims 1 to 4, wherein the forward side of the elongated connection element is provided with a rounded nose portion.

6. The spinal implant set of claim 5, wherein the cross-section of the rounded nose portion (3, 4, 5) of the

elongated connection element substantially consists of a triangle (3) with a rounded apex (31), a semi-circle (4) or a semi-ellipse (5).

7. The spinal implant set of one of claims 1 to 6, comprising bone screws having a substantially identical seat (7) for the elongated connection element and clamping inserts of differing lengths insertable in the seat of the bone screws (6), so that the clamping inserts (9, 10) are capable to compensate the differing heights of the connection element.

8. The spinal implant set of one of claims 1 to 7, wherein the forward side to be arranged in the seat of the bone screws (6) toward the bone thread extends along a straight or curved line and the cross section variation is exclusively made along the rearward side by one or more steps, preferably by one step (32).

9. The spinal implant set of one of claims 1 to 8, wherein the reduced cross section is at one end of the elongated connection element (1).

10. The spinal implant set of one of claims 1 to 9, wherein the elongated connection element (1) is made of a plastic material.

11. The spinal implant set of claim 10, wherein the plastic material is polycarbonate-urethane (PCU).

12. The spinal implant set of claim 10, wherein the plastic material is of the family of polyetheretherketone (PEEK).

13. The spinal implant set of one of claims 1 to 13, wherein the elongated connection element (1) has two plane-parallel side faces extending in the direction of insertion in a bone screw.

14. Method of applying the spinal set of one of claims 1 to 13, wherein the elongated connection element (1) is inserted in the seats (7, 8) of at least two bone screws (6), preferably at least three bone screws, and clamped therein, and wherein the differing cross sections of the connection element are compensated by using clamping elements (9, 10) of correspondingly varying size and inserted in the seats.

FIG. 1

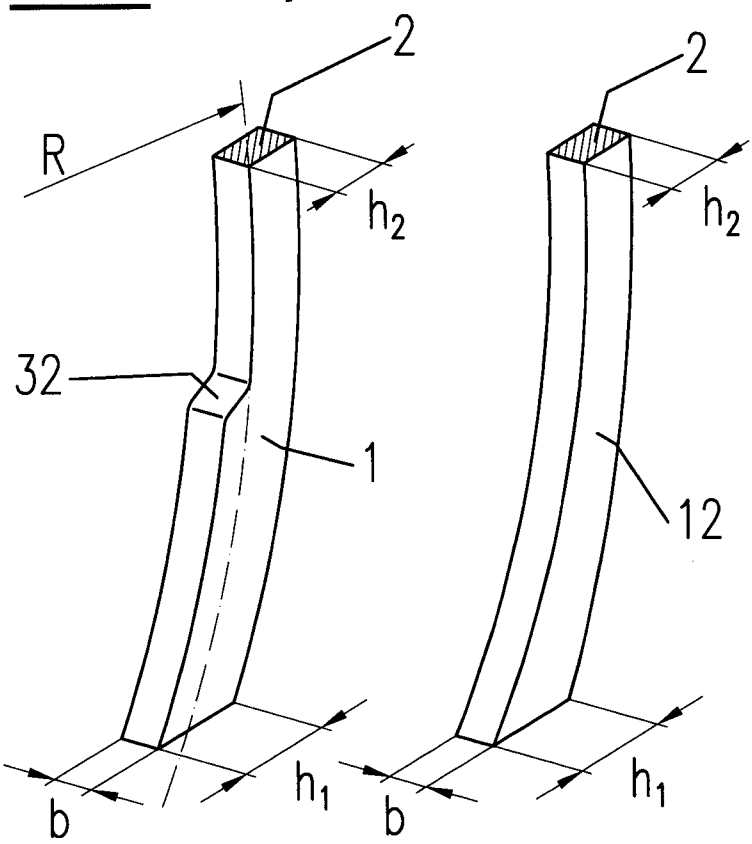


FIG. 2

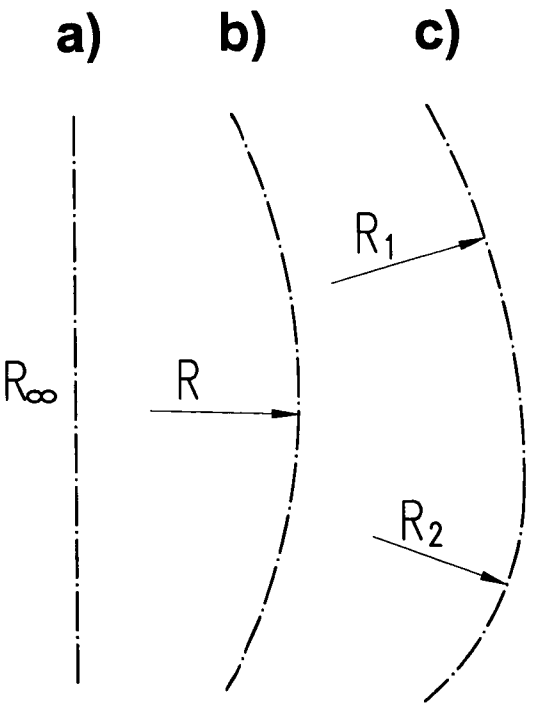


FIG. 3

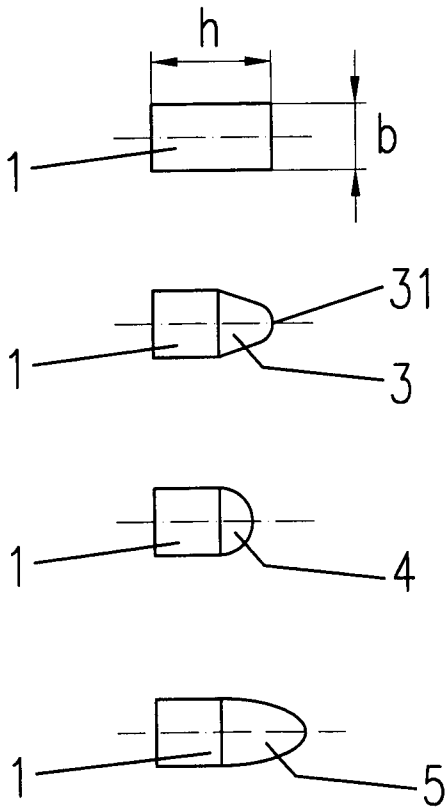
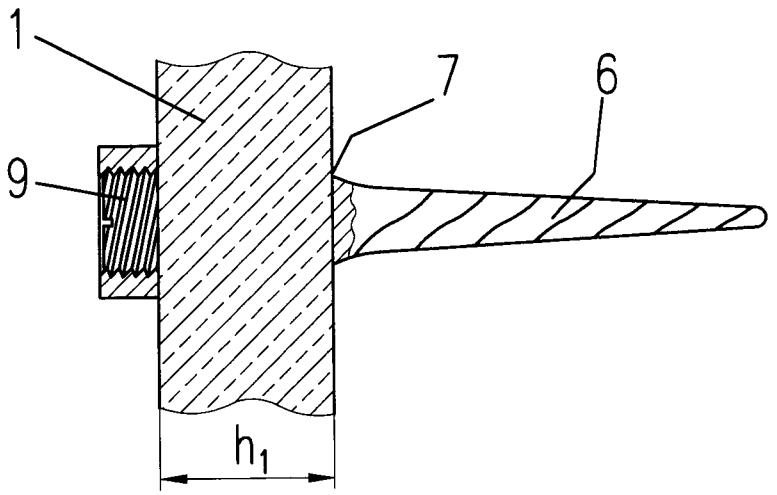
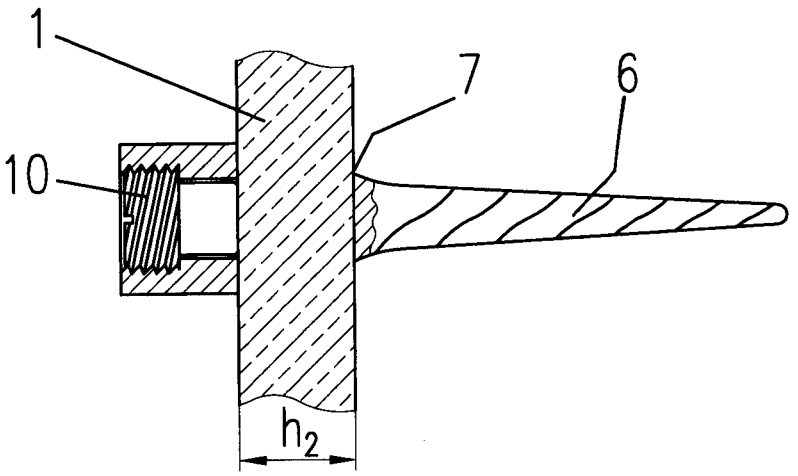


FIG. 4

a)



b)



c)

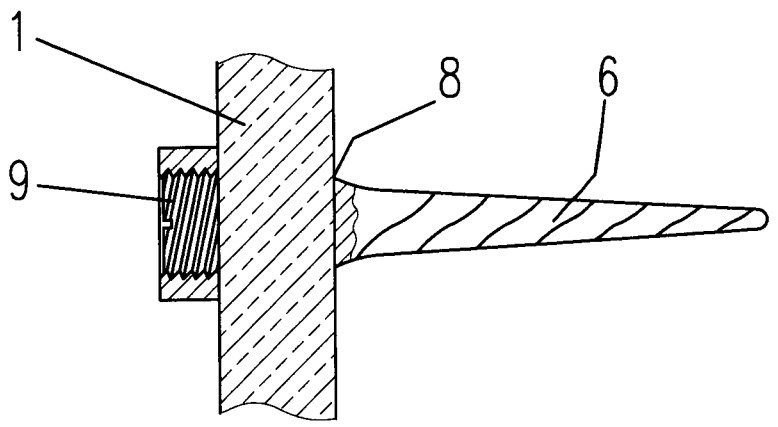


FIG. 5

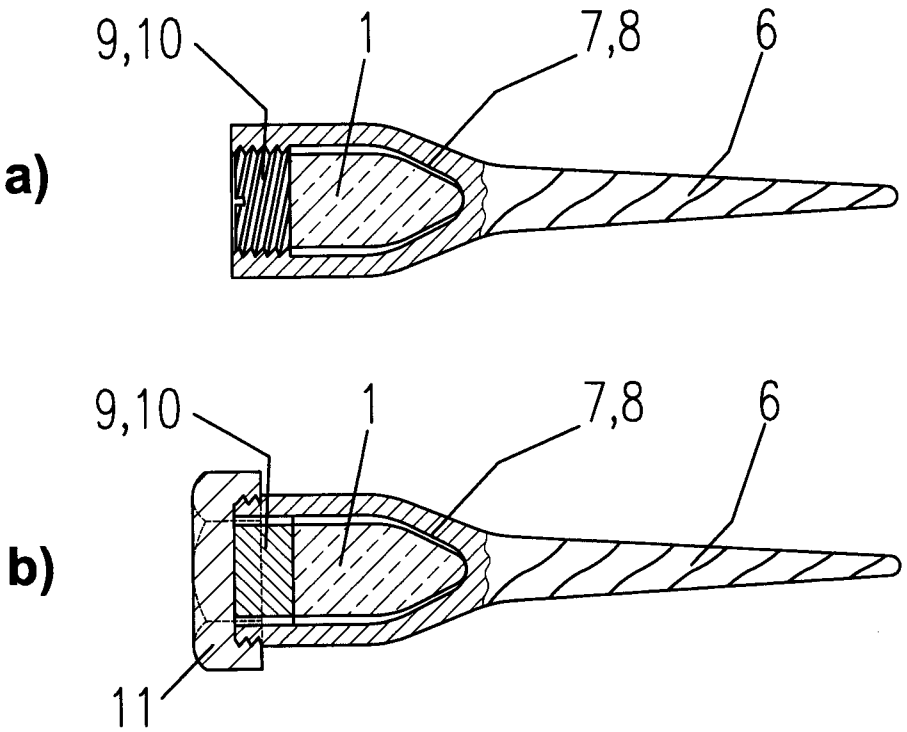
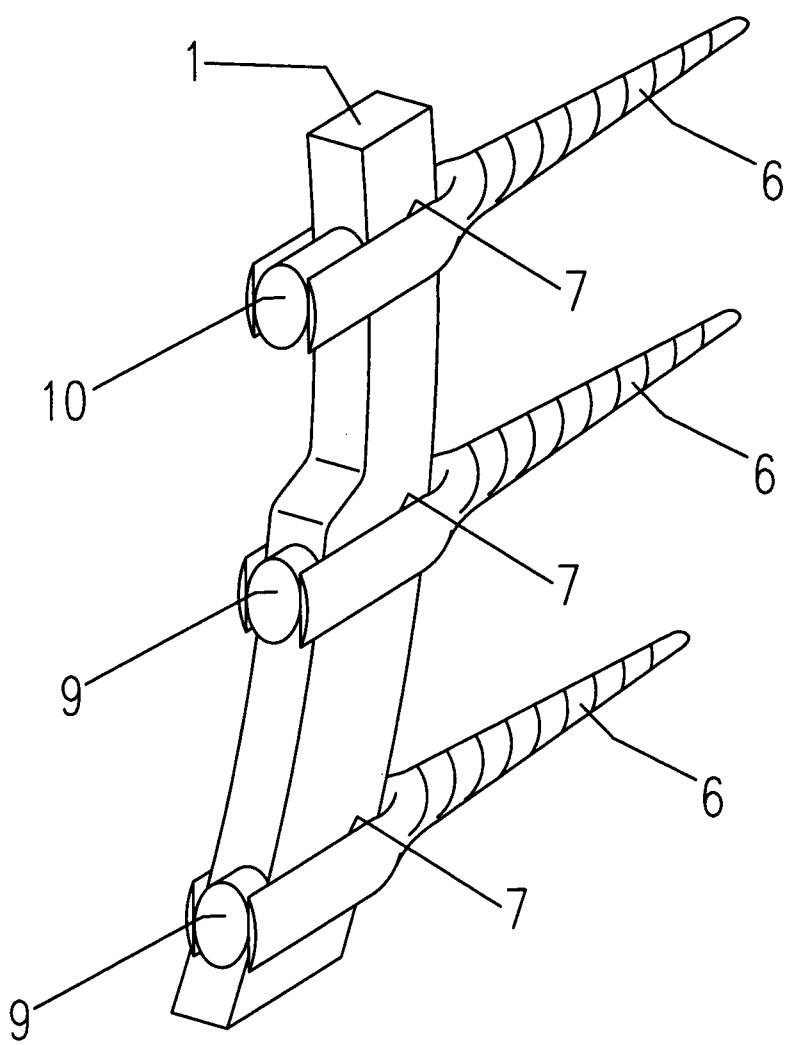


FIG. 6



INTERNATIONAL SEARCH REPORT

International application No
PCT/CH2011/000192

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/70
ADD.

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)
A61B

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/177320 A1 (MCBRIDE LARRY THOMAS [US]) 24 July 2008 (2008-07-24) page 1, paragraph 1 - page 3, paragraph 34 figures 2, 4, 6, 7, 8, 11	1-6,8, 10,12,13
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X	US 2010/114165 A1 (ELY KAMERON SCOTT [US]) 6 May 2010 (2010-05-06) page 2, paragraph 10 page 3, paragraph 33 - page 4, paragraph 40 figures 3, 4	1-6,9, 10,12

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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 document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or 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.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
27 September 2011	06/10/2011

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Kakoullis, Marios

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/CH2011/000192

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 217 461 A (ASHER MARC A [US] ET AL) 8 June 1993 (1993-06-08) column 2, line 18 - column 4, line 55 figures 1-3	1-6,9
X	WO 2009/021116 A2 (SYNTHES USA [US]; SYNTHES GMBH [CH]; ENGELMANN VOLKER [DE]; KRAFT MARK) 12 February 2009 (2009-02-12) page 6, paragraph 23 - page 7, paragraph 26 figure 1	1,5,6, 10-12
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Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CH2011/000192

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
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:

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

2. [ ] 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.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/CH2011/000192

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