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(54) **Title**: A FITTING TOOL FOR A PEDICULAR ANCHORING SYSTEM

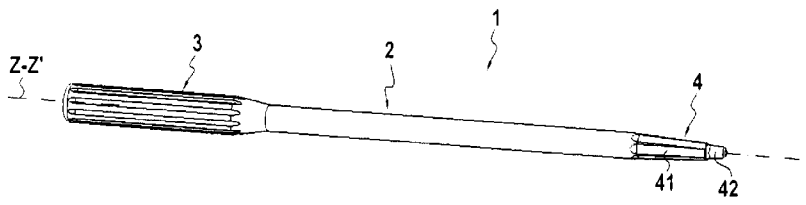

FIG.1

(57) **Abstract**: The present invention relates to a fitting tool (1) to fit and secure a screwable stopper into the head of a pedicular bone screw by means of screwing, said fitting tool (1) comprising an elongate shaft (2).at a first end of which is formed a handle part (3) and at a second end of which is formed an engaging part (4) configured to engage a longitudinal bore in a screwable stopper, wherein the engaging part (4) is configured to engage said longitudinal bore in said screwable stopper such that the fitting tool is automatically released from the screwable stopper once it has been screwed in a said head for a determined length.

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A FITTING TOOL FOR A PEDICULAR ANCHORING SYSTEM

Technical Domain

The present invention relates to the field of medical devices and more particularly to a fitting tool for adjusting and setting a vertebral anchoring system in connection with distraction rods in the surgical treatment of spinal pathologies.

Description of the prior art

In the field of spine defaults correction vertebral anchoring devices like pedicular bone screw are often used to secure fixedly correction devices such as distraction rods into vertebrae along the spinal column. Other anchoring devices like pedicular hooks can also be implemented to secure correction devices.

Pedicular screws typically have a threaded shank configured for implantation into a pedicle or vertebral body of a vertebra. They further comprise a head designed to extend beyond the vertebra, said head generally defining a channel or a U-shaped recess in the head's body to receive a rod or other implant. The head may further be open or closed at its top depending on the design chosen for accommodating a rod or other implant. If the head is open, a closure member such as a locking screw must be used to close between opposite sides of the head once a rod or other implant is placed therein. If the head is closed, a rod or the like implant is threaded or inserted through the head of the bone screw.

It is sometimes difficult to proceed to adjustment of the rod or implant in the body of a patient, particularly when it is necessary to bend the rod and fix it by a second pedicular bone screw to another vertebra of the spine with the aim of correcting a bending of the spine for example.

The bone screws with an open head allow locking of rods by use of locking screws, which can be tightened onto a rod positioned in the U-shaped recesses of the head to prevent it from slipping out of the recesses while the surgeon is bending it. However, the surgeon sometimes needs to adjust the position of the rod relative to the pedicular bone screw by sliding it into the head of the bone screw while maintaining or adjusting the bending of the rod. Such adjustments become

extremely difficult when the locking screw of the head of the pedicular bone screw has been tightened too much, which is often the case to prevent the locking screw from loosening and disassembling from the head of the bone screw to fall into the patient's body.

Description of the invention

The present invention aims at providing a reliable solution for pre-locking locking screws in the head of a pedicular anchoring device to allow a surgeon proceed to in-situ bending of rods before definitive locking of the locking screws in the head of the pedicular bone screws.

The present invention further aims at providing a solution for surgeons for automatically setting a locking screw in the head of a pedicular anchoring device at a predetermined depth in said head.

Such a solution consists according to the present invention in a fitting tool to fit and secure a screwable stopper or locking screw into a head of a pedicular anchoring device by means of screwing, said fitting tool comprising an elongate shaft at a first end of which is formed a handle part and at a second end of which is formed an engaging part configured to engage a longitudinal bore formed in a screwable stopper, wherein the engaging part is configured to engage said longitudinal bore in said screwable stopper such that the fitting tool is automatically released from the screwable stopper once it has been screwed in a said head for a determined length.

According to the invention, the engaging part comprises a coupling section to engage the shape of the longitudinal bore in the screwable stopper and screw said stopper into the head of a pedicular anchoring device, said coupling section being terminated by a tip.

Preferably, the tip of the fitting tool of the invention is thinner than the coupling section of the engaging part.

Preferably, the coupling part and the tip of the fitting tool are joined by a fillet.

In a preferred embodiment of the fitting tool of the invention, the tip is longer than the longitudinal bore in the screwable stopper such that the fitting tool and the stopper are automatically disengaged from each other when the tip comes in

abutment against an obstacle inserted into the head of the pedicular anchoring device.

Advantageously, the coupling section of the engaging part is preferably tapered. Such geometry of the coupling section of the engaging part prevents from blocking of the engaging part into the longitudinal bore of the screwable stopper. Furthermore, the tapered shaped of the coupling section is advantageously chosen for the contact between said coupling section and said longitudinal bore of a screwable stopper to be linear, to ease disconnection between the two when the tip of the fitting tool touches an obstacle such as a rod seated in the head of a pedicular bone screw.

Moreover, still preferably, the transverse shape of the coupling section of the engaging part and of the longitudinal bore in the stopper is hexagonal. This helps transmitting easily a screwing torque applied by a surgeon during pre-locking operation to the screwable stopper to reliably secure it in the head of a pedicular bone screw.

Description of drawings

The features of the fitting tool of the present invention will be presented hereinafter in the detailed description, with references to the enclosed drawings into which:

- **Figure 1** is a preferred embodiment of the fitting tool of the invention in a perspective view;

- **Figure 2** shows the engagement of the engaging part of the fitting tool of the invention into a screwable stopper of a pedicular bone screw;

- **Figure 3** shows a front section view of the head of a pedicular bone screw into which a screwable stopper is inserted by means of a fitting tool according to the present invention;

- **Figure 4** shows a front section view of the linear engagement of the coupling section of the fitting tool of the invention in a screwable stopper of a pedicular bone screw for adjusting said stopper in the head of said screw;

- **Figure 5** shows a similar view as Figure 4 where the coupling section of the fitting tool of the present invention is disengaged from the screwable stopper of a pedicular bone screw.

Best mode for carrying out the invention

With reference to **FIGS. 1-3**, the reference number **1** generally represents a fitting tool according to the present invention. That fitting tool **1** is very like a screwdriver and basically comprises an elongate cylindrical shank **2** at a first end of which a handle part **3** is formed and at a second end of which an engaging part **4** is formed opposite to the handle part **3**.

The handle part **3**, the elongate shank **2** and the engaging part **4** of the fitting tool **1** all extend coaxially along a longitudinal axis Z-Z'.

Preferably, the handle part **3** is substantially cylindrical and has larger diameter than the elongate shank **2**, which in turn also has a larger diameter than the engaging part. The handle part **3** further preferably comprises a corrugated or rough external surface **31** to provide an easy and firm grip by hand and a good transmission of rotation efforts from a hand to the fitting tool **1**.

Moreover the engaging part **4** of the fitting tool **1** comprises a coupling section **41** extending from the elongate shank **2** and terminated by a cylindrical tip **42** joined to the coupling section **41** by a fillet **43**.

Preferably, the coupling section **41** of the engaging part **4** has a non-revolutional tapered shape, and more preferably a pentagonal or hexagonal tapered shape. Such a shape is preferably chosen to help efficient torque transmission from the fitting tool **1** to a rotating part of a device such that a closure screwable stopper **5** for the head **9** of a pedicular bone screw **7** as shown in fig. **2** and fig. **3**, said screwable stopper **5** comprising a central longitudinal bore **6** with a corresponding pentagonal or hexagonal shape for inserting the coupling section **41** therein.

According to the invention, the conic shape of the coupling section **41** and the dimensions (width, depth) of the longitudinal bore of the stopper **5** are chosen such that the contact between said coupling section and said longitudinal bore **6** is linear and not planar, i.e. the peripheral contact on the coupling section **41** is linear when

said coupling section is inserted in the longitudinal bore **6**. The geometry of a transverse section of the coupling section **41** can be of any type usually encountered such as a triangular, square, pentagonal, hexagonal or octagonal section.

Still preferably, the cylindrical tip **42** of the engaging part **4** of the fitting tool **1** is thinner than the coupling section **41**, i.e. the tip **42** has as smaller diameter than the smallest dimension of the coupling section **41** taken in a plane perpendicular to the longitudinal axis **Z-Z'** of the fitting tool **1**. As shown in the figures, the end of the cylindrical tip **42** can be flat but it can also be round or adopt any other form.

According to the invention, the fitting tool **1** is specifically designed for screwing a closure screwable stopper **5** in the head of a pedicular bone screw **7** up to a pre-locking position as shown in fig. **3**, said screwable stopper **5** having an inner longitudinal bore **6** with a corresponding shape to the coupling section **41** of the engaging part of the fitting tool **1**.

As it is commonly known in the field of spine surgery and represented, a pedicular bone screw **7** includes a shank **8** and a head **9**. The shank **8** further is integral with an upwardly extending end **10** holding the pedicular bone screw head **9**.

The shank **8** is elongate, with a helically wound bone engaging thread extending substantially from end **10** to near a tip and projecting radially outward therefrom. The helically wound thread thereby allow for gripping and advancement of the pedicular bone screw in the bone of a vertebra to allow a surgeon secure an implant or rod **11** to the spine of a patient for correcting a deformation or pathology in the spine such as scoliosis.

The pedicular bone screw head **9** has a substantially cylindrical shape with peripheral cylindrical walls **91** delimiting a central longitudinal bore **92**. The head **9** comprises a top part **93** and a bottom part **94**. The inner surface of the walls **91** in the top part **93** include a helically wound track or thread **12** extending from the top rim **95** of the longitudinal bore **92** downwardly therefrom.

The track or thread **12** is configured to mate under rotation with a corresponding external thread **51** of the screwable stopper when said stopper **5** is

introduced and rotated by means of the fitting tool **1** into the longitudinal bore **92** at the top rim **95**. It should be noted that the corresponding shapes of the track or thread **12** in the top part **93** of the head and the external thread **51** of the screwable stopper **5** can be configured with any type of structure conventionally known such as V-shaped thread, a buttress thread, a reverse angle thread or other thread-like or non-thread-like helically wound mating shapes for operably guiding under rotation and advancing the screwable stopper **5** in the head **9** of the pedicular bone screw **7** when the stopper is torqued in the longitudinal bore **92** of the head with the fitting tool **1** of the invention.

The closure screwable stopper **5** is aimed for biasing a correction member such as a rod **11** for correction of spinal deformities against the bottom of a U-shaped channel **13** defined by two U-shaped recesses **97** casted or machined in opposite positions in the walls **91** of the head **9** of the pedicular bone screw **7.** The two U-shaped recesses **97** extend symmetrically about the longitudinal axis Z-Z' of the socket and bone screw **7** from the top rim **95** of the socket to beneath the middle of the socket.

As illustrated in **FIGS. 1** and **2**, the screwable stopper **5** has a generally cylindrical body **50**, with a helically wound external thread **51** configured to mate the internal track or thread **12** of the top part of the head **9** to provide for rotating advancement of the stopper **5** into the head **9** when rotated clockwise and, in particular, to cover the top or upwardly open portion of the U-shaped channel **13** to capture the rod **11** within the head **9** of the pedicular bone screw **7.**

The screwable stopper **5** further includes a base or bottom **52** formed by an annular collar **53** of smaller diameter than the body **50** to frictionally engage the rod **11**, thereby applying pressure to the rod **11** under torquing, so that the rod **11** is urged downwardly into the channel **13**.

Screwing of the screwable stopper **5** in the head **9** of the pedicular bone screw **7** up to frictional engagement of the collar **53** onto the rod is achieved by means of a conventional pentagonal or hexagonal pan screwdriver, not shown in the figures and not part of the present invention, introduced in the longitudinal bore **6** formed in the screwable stopper **5**.

One of the main problems encountered by the surgeons when implanting patients with rods or the like is that classical pedicular bone screws with screwable stoppers like previously described herein before are incompatible with in-situ rod bending technique or in-situ derotation technique because it is necessary to lock the rods in translation into the head of pedicular bone screws by tightening the screwable stoppers against the rods to prevent said stoppers from disassembling from the head of the pedicular screws and falling into the patient's body.

The present invention proposes a fitting tool **1** as previously described and illustrated in **FIGS.1** to **5**, which allows for automatic setting of the screwable stopper **5** in a predetermined position within the head of the pedicular bone screw where a small gap **S** is managed between a rod inserted in the head of the anchoring device (pedicular screw for instance) and the screwable stopper **5**. The fitting tool **1** of the invention allows for pre-tightening of the stopper **5** at a pre-determined distance from the rod thus making correction manoeuvres possible without conflicts due to friction between the rod and the screwable stopper **5**.

The fitting tool **1** of the invention is particularly advantageous when used in combination with a self-retaining screwable stopper **5**.

According to the invention, the engaging part **4** of the fitting tool **1** is configured to engage the longitudinal bore **6** in the screwable stopper **5** of a pedicular bone screw **7** as previously presented such that the fitting tool **1** is automatically released from the screwable stopper **5** once it has been screwed in the head **9** of the pedicular bone screw **7** for a determined length corresponding to the length of the tip **42** of the fitting tool **1**.

Advantageously the tip **42** is made longer than the longitudinal bore **6** in the screwable stopper **5** such that the coupling section **41** of the fitting tool **1** and the stopper **5** are automatically disengaged from each other when the tip **42** comes in abutment against a rod **11** positioned into the U-shaped channel **13** in the head **9**. The tip **42** being thinner that the coupling section **41** and therefore thinner than the longitudinal bore **6** in the screwable stopper **5**, said stopper **5** loses contact with the pentagonal or hexagonal pans of the coupling section **41** of the fitting tool **1** as soon as the tip **42** touches the rod **11** in the U-shaped channel **13**, releasing the stopper

5 from torquing engagement with the fitting tool **1** just a few tenth of millimetres before it touches the rod **11** as well.

Thus the tip **42** touches the rod's surface before the collar **53** of the stopper **5** comes into frictional engagement with the rod **11**, thereby allowing translation of said rod **11** within the U-shaped channel **13** in the head of the pedicular bone screw **7**. In the same time, the screwable stopper **5** is almost completely screwed into the head **9** and the surgeon can exercise bending of the rod **11** in-situ with said rod inserted in the head **9** of the screw **7**.

As shown in **FIGS. 4** and **5**, the conic shape of the coupling section **41** of the fitting tool and the length of the tip **42** are chosen to ensure that the contact between the coupling section **41** and the stopper **5** is linear (**Fig. 4**) and that a clearance or gap **S** is left between the collar **53** of the stopper **5** and the rod **11** when the tip **42** touches said rod and the coupling section **41** is disengaged from the stopper **5**. Advantageously, the gap **S** is determined such that:

$$S \geq D - (H + d)$$

Where **D** is the depth of the U-shaped channel **13**, **H** is the height of the stopper **5** and **d** is the diameter of the rod **11**.

So the conic shape of the coupling section **41** and length of the tip **42** of the fitting tool **1** of the invention are configured and chosen such that a linear contact between the coupling section and the stopper **5** is achieved when inserting the fitting tool **1** in the stopper **5**, said linear contact intervening on the at a distance T_0=H+S from the end of the tip **42**.

The fitting tool **1** of the present invention thereby allows a pre-locking of a rod **11** in the head **9** of a classical pedicular bone screw **7** without preventing it from sliding and translating into the head **9** by managing a gap **S** between the rod **11** and the stopper **5** to allow bending in-situ and other position adjustments of the rod **11** by the surgeon performing implantation prior to definitive locking of the stopper **5** onto the rod **11**.

CLAIMS

1. A fitting tool (**1**) to fit and secure a screwable stopper (**5**) into a head of a pedicular anchoring device (**7**) by means of screwing, said fitting tool (**1**) comprising an elongate shaft (**2**) at a first end of which is formed a handle part (**3**) and at a second end of which is formed an engaging part (**4**) configured to engage a longitudinal bore (**6**) in a screwable stopper (**5**), **wherein** the engaging part (**4**) is configured to engage said longitudinal bore (**6**) in said screwable stopper such that the fitting tool is automatically released from the screwable stopper (**5**) once it has been screwed in a said head (**9**) for a determined length.

2. A fitting tool according to claim **1**, **wherein** the engaging part (**4**) comprises a coupling section (**41**) to engage the shape of the longitudinal bore (**6**) in the screwable stopper (**5**) and screw said stopper into the head (**9**) of the anchoring device, said coupling section being terminated by a tip (**42**).

3. A fitting tool according to claim **2**, **wherein** said tip (**42**) is thinner than the coupling section (**41**) of the engaging part (**4**).

4. A fitting tool according to any of claims **2** or **3**, **wherein** the coupling part (**41**) and the tip (**42**) are joined by a fillet (**43**).

5. A fitting tool according to any of claims **2** to **4**, **wherein** said tip (**42**) is longer than the longitudinal bore (**6**) in the screwable stopper (**5**) such that the fitting tool and the stopper are automatically disengaged from each other when the tip comes in abutment against an obstacle inserted into said head (**9**).

6. A fitting tool according to any of claims **2** to **5**, **wherein** the coupling section of the engaging part (**4**) is tapered.

7. A fitting tool according to claim **6**, **wherein** the transverse shape of the coupling section (**41**) of the engaging part (**4**) and of the longitudinal bore (**6**) in the stopper is hexagonal.

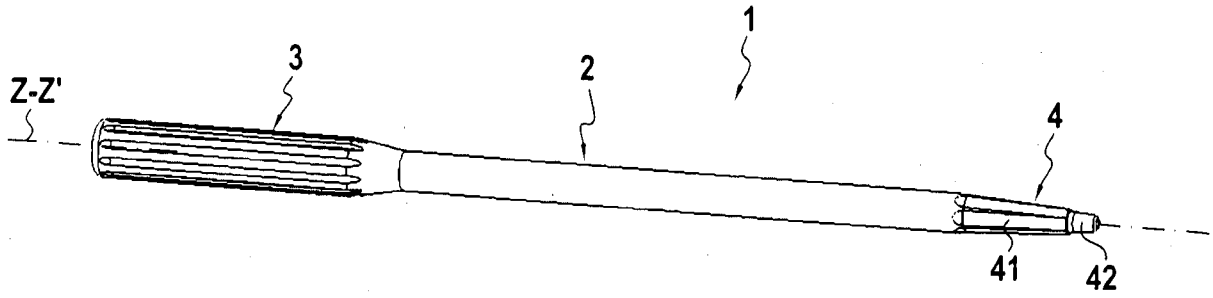

FIG.1

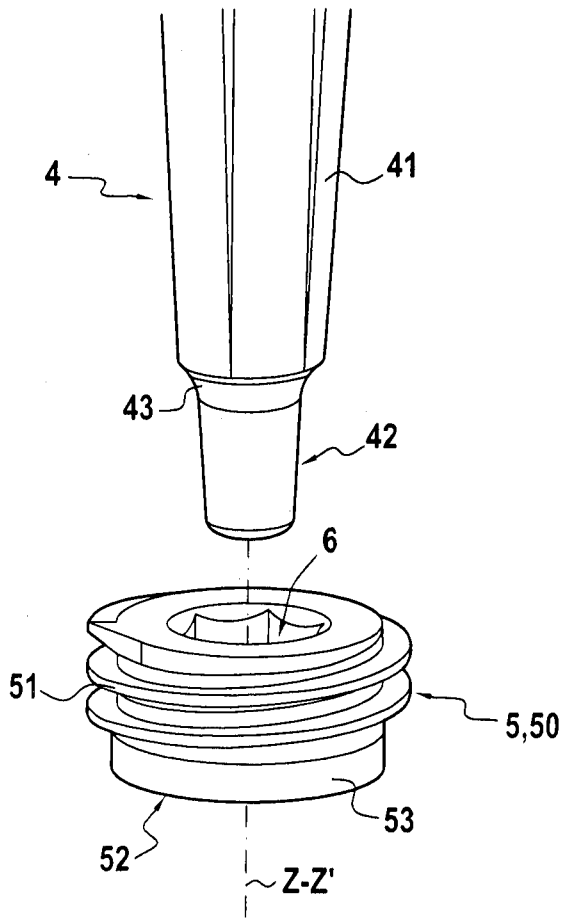

FIG.2

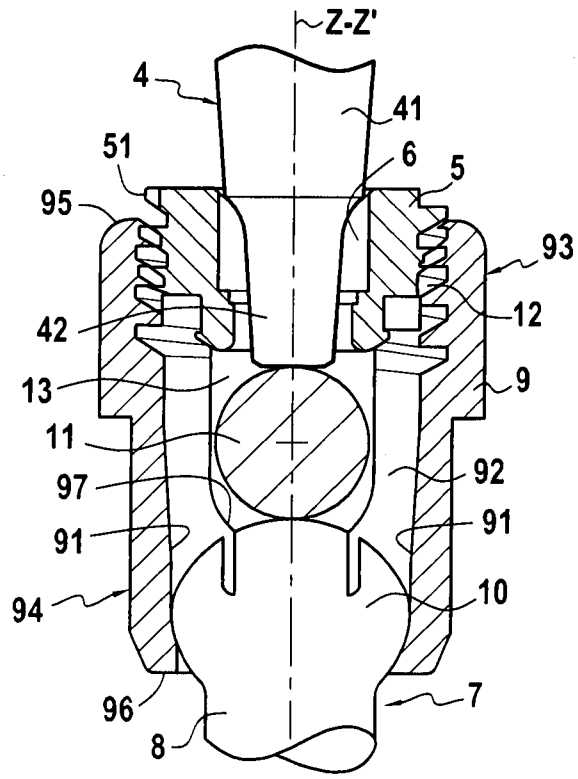

FIG.3

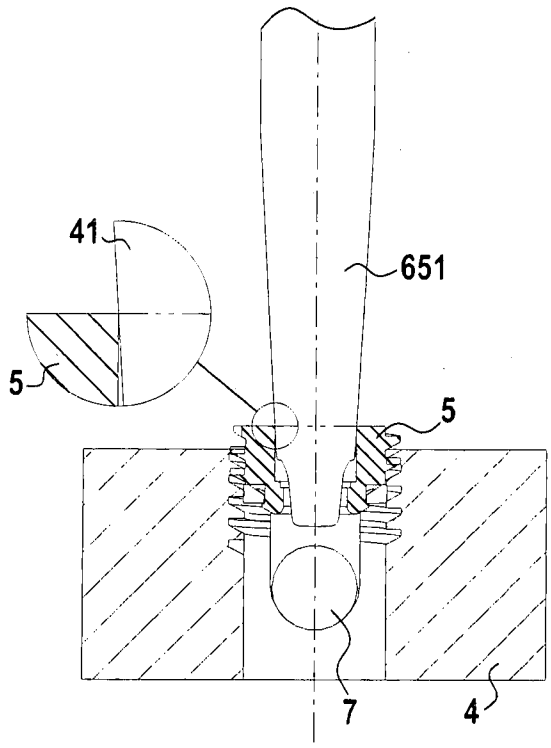

FIG.4

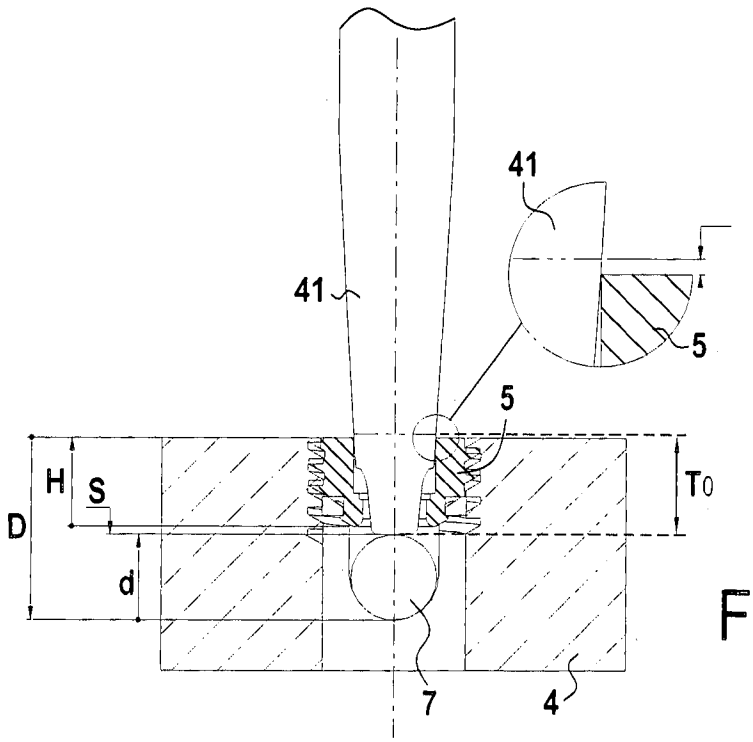

FIG.5

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2011/001127

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	WO 2006/029373 A1 (NUVASIVE INC [US]; COPP MATTHEW [US]; CAMPBELL CHRISTOPHER M [US]; COR) 16 March 2006 (2006-03-16)	1-4
A	page 13, paragraph 2 - page 14, paragraph 1; figure 1 page 16, paragraph 1; figure 5 page 19, paragraph 2 - page 20, paragraph 1; figures 8A-9D	5-7

X	WO 2007/021588 A1 (STRYKER SPINE [FR]; CHIN KINGSLEY RICHARD [US]; FALLIN T WADE [US]; BU) 22 February 2007 (2007-02-22)	1-3
A	paragraph [0070] - paragraph [0073]; figures 9-11	4-7

X	FR 2 880 254 A1 (NEURO FRANCE IMPLANTS SARL [FR]) 7 July 2006 (2006-07-07)	1-3
A	the whole document	4-7

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

☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
6 December 2011	15/12/2011

Name and mailing address of the ISA/	Authorized officer
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1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2011/001127

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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