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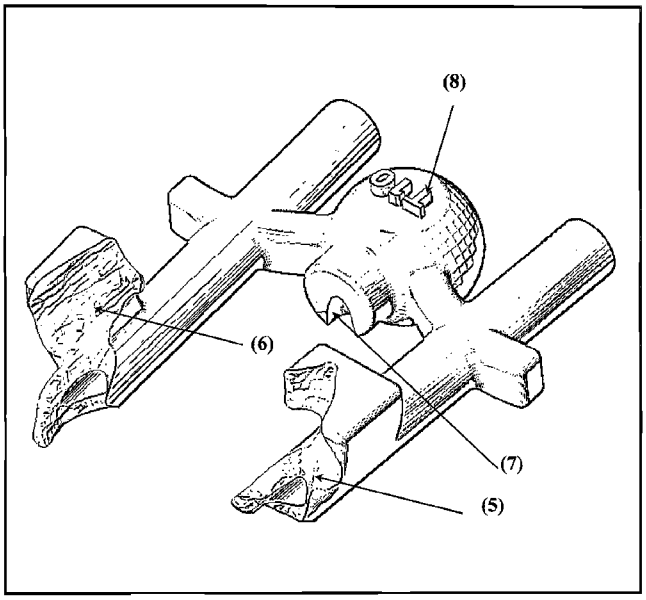
(54) Title: PATIENT-SPECIFIC TEMPLATES FOR PEDICAL SCREW INSERTION IN CORRECTIVE SCOLIOSIS SURGERIES



(57) Abstract: This invention relates to a surgical device for the detection of the pedicle screws trajectories of a patient undergoing to scoliosis or spondylosis correction. The device is a patient specific and has information about screw size and position. The increased use of pedicle screws in scoliosis creates a challenge for accurate and safe placement of screw within the pedicle during the scoliosis surgery. Patient-specific templates (PST), is an alternative method to guide the surgeons for detecting the positions and trajectories of pedicle screws in scoliosis and spondylosis fixation surgery. This 3D model constructed during PST process can be also 3D printed as a physical model, which can help surgeons to develop an accurate and safe position of pedicle screws and its trajectories. This device has the ability to customize the placement and the size of each pedicle screw based on the unique morphology and landmarks of the vertebrae.

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Patient-Specific Templates for Pedical Screw Insertion in Corrective Scoliosis Surgeries

This application claims the benefit of Egyptian Provisional application No. 25/2017 filed on September 14, 2017 and Egyptian Patent Application No. 448/2018 on March 13, 2018

The Technical Field

The present invention relates to a device and a method for determining the position, the path, and the size of pedicel screws used in corrective scoliosis surgeries. The device is a patient-specific template with data about the size, path, and position of the screw.

Prior Art

Disadvantages of Current Technologies

The increasing use of pedicel screws in corrective scoliosis surgeries has posed a challenge to surgeons, especially those of limited experience. This kind of surgery is critical and should be conducted by professional surgeons. The major issue in corrective scoliosis surgery is determining the right position and path of the pedicel screw in the vertebra. Mislocating the pedicel screw leads to unsatisfactory results for both the surgeon and the patient. For example, if the screw gets out of its path it may cause compression of the nerves connected to the spine, difficulty of leg motion after surgery or loss of contact with the aorta artery behind the spine. According to previous studies and researches, more than 25% of pedicel screws are mislocated in corrective scoliosis surgeries.

Accordingly, there is a dire need for a new method that uses guides and patient-specific electronic templates for accurately determining the path, location, and size

of the pedicel screw. The inventive method's error ratio is zero, as the template is designed to match the patient's vertebrae topology.

Detailed Description of the Invention

The current invention relates to a device and method for determining the position, the path, and the size of pedicel screw used in corrective scoliosis and spinal disc herniation surgeries. The device is a patient-specific template used for single patient only with data about the size, path and position of the screw. The template is designed according to anatomical indicators and markers of the spinal vertebrae. The template includes two hollow cylinders with flanks for vertebrae matching and template fixation. It also contains a central hollow sphere that matches the topology of the spinous process of the vertebrae on which the template would be fixed. The said sphere is connected to the cylinders by two nerves (Figures no. 1, 2, 3, 4 & 6).

The electronic template is manufactured according to a pre-operative planning using a special software program.

The surgery is planned according to the program's data input. The patient undergoes a computed tomography scan (CT scan) that is converted to three-dimensional scan of the patient's spine. Each vertebra appears independent from the other, hence ensuring accurate surgery planning and correct determination of the position and path of the pedicel screw for each vertebra.

Pre-surgery planning is made depending on the anatomic form of the vertebra, putting into consideration the shape of the spinous process, the internal plate and the transverse process as anatomic indicators for the fixation of the electronic template on the vertebra. In the planning process, the degree of the spine curvature is determined as well as the position of each vertebra, its degree of rotation and

inclination relative to the vertebral column axis. In this way, the position, the path, the inclination angle and all data related to the pedicel screw are determined. The position of the electronic template on the vertebra is determined by the aid of this data as well as surface topologies of the spinous process, the transverse process and the plate that are moved to the outer surface of the hollow cylinders and the flanks at the cylinders' ends (see figures 4, 5, 6 & 7).

The said electronic templates are fixed on the vertebra depending on its outer surface's topology, according to which the template's internal surface is formed at the end of the hollow cylinders and their flanks. Hence, the template is only fitted into one location on the vertebra's surface during the pre-planned surgery. This makes it easier for surgeons, especially of limited experience, to accurately determine the position, the path and the size of the pedicel screw to be fixed on the vertebra. It is impossible for the template to be mislocated. It cannot be displaced since its unique design makes the surface of the hollow cylinder end identical to the vertebra's surface on which it is to be fixed (see figure no. 5 & 7).

The template's design is based on the use of two hollow cylinders (figure no. 1) through which the wire or surgical drill passes forming the void space of the pedicel screw in the vertebra. There is an interfacial angle between the cylinders that varies according to the interfacial angle between the specific paths of the concerned pedicel screws (see figure no. 8). In detail, each vertebra has its own template that contains two hollow cylinders of fixed diameter. Each cylinder has a central sphere with a fixed diameter, and ends with two flanks. The interfacial angle between the cylinders differs from one template to another according to the vertebra's number that indicates its location, whether it is lumbar vertebra or thoracic vertebra (figure no. 9), and according to the path inclination of the pedicel screw as a main component of the invention (see figure no. 5).

As previously mentioned, the topology of the cylinders' ends (the surface that contacts the vertebra's surface) matches that of the vertebra's surface (figure no. 4). The template has a central sphere with a cavity that matches the outer surface of the spinal process for fixing the template on its pre-designed location on the vertebra only (see figures no. 5 & 7). In other words, the surgeon cannot fix the template in a position other than that assigned during the computer-assisted surgical planning (see figures no. 5 & 7).

The template contains two flanks at the end of each cylinder whose surface matches the outer surface of the vertebral plate. They are used for keeping the template fixed to help the surgeon to determine the pedicel screw's position and path in the vertebra. The template includes two middle nerves between the central sphere and the hollow cylinders to increase the space of the template and make it tolerant to the forces exerted by surgical instruments. In this way, the template is kept safe from breakage or displacement.

The template is produced through three-dimensional printing techniques.

Description of the Figures

Figure no. 1: represents a three-dimensional perspective for the patient-specific electronic template used for determining the position, the path, and the size of the pedicel screw. The template appears with two hollow cylinders (1), each ends with a flank (3). It also includes a central sphere at its centre (2).

Figure no. 2: represents a two-dimensional front view for the patient-specific electronic template for determining the position, the path, and the size of the pedicel screw. The template appears with two hollow cylinders (1), each ends with a flank (3). It also includes a central sphere at its centre (2).

Figure no. 3: represents a two-dimensional plan view for the patient-specific electronic template for determining the position, the path, and the size of the pedicel screw. The template appears with two hollow cylinders (1), each ends with a flank (3). It also includes a central sphere at its centre (2). The middle nerves appear between the central sphere and the hollow cylinders (4).

Figure no. 4: represents a two-dimensional plan view for the patient-specific electronic template for determining position, the path, and the size of pedicel screw after the planning process. The end of the hollow cylinders' surface (5) appears with a topology that matches that of the plate surface and the transverse process of the targeted vertebra. The flanks at the end of each cylinder (6) have the same topology. The central sphere has a cavity that fits the outer surface of the spinal process (7). The number of the vertebra to be provided with the template is registered on the flanks to avoid confusion during surgery (8).

Figure no. 5: represents a two-dimensional plan view for the patient-specific electronic template for determining the position, the path, and the size of pedicel screw fixed on the targeted template. The figure illustrates the location of the cylinders' ends, the plate's flanks, the transverse process (10), and the location of the centre sphere's cavity on the spinal process (9). A phantom axis for the pedicel screw path inside the template and the vertebra (11) appears in the figure.

Figure no. 6: represents a three dimensional perspective for the patient-specific electronic template for determining the position, the path, and the size of pedicel screw after the planning process. The end of the hollow cylinders' surface (5) appears with a topology that matches that of the plate surface and the transverse process of the targeted vertebra. The flanks at the end of each cylinder (6) have the

same topology. The central sphere has a cavity that fits the outer surface of the spinal process (7). The number of the vertebra to be provided with the template is registered on the flanks to avoid confusion during surgery (8).

Figure no. 7: represents a three dimensional perspective for the patient-specific electronic template for determining the position, the path, and the size of pedicel screw to be fixed on the targeted vertebra. The figure illustrates the location of the cylinders' ends, the plate's flanks and the transverse process (10).

Figure no. 8: represents a two-dimensional front view for a number of electronic templates fixed on their proper positions on the targeted vertebra.

Figure no. 9: represents a front view of the spine in which some vertebrae appear with conventional numbers that is registered on the template for avoiding confusion during surgery.

Claims

1- A patient-specific electronic template for determining the path, the location and the size of the pedicel screws. It is designed for patients undergoing corrective scoliosis and spinal disc herniation surgeries. The template is designed for single-patient use only. It contains two hollow cylinders for determining the position, the size and the path of the screws. At the end of each cylinder, there is a surface that resembles and matches the shape of the vertebra on which the template would be fixed using specific anatomical indicators and markers on the vertebra's surface. The template includes a central sphere at its centre.

2- The template according to claim 1, whereas it is provided with a sphere at its centre and two hollow cylinders extending on the vertebra's surface. Each cylinder is provided with two flanks at its end.

3- The template according to claim 1, whereas it is provided with a sphere at its centre with a cavity that fits the upper surface of the spinal process for fixing the template and preventing its displacement or rotation around the vertebra's axis.

4- The template according to claim 1, whereas it is provided with two hollow cylinders, each with a surface at its end resembling the internal vertebra's surface in topology (the plate and the transverse process). In this way, the template would be fixed on the vertebra and the pedicel screw's path would be accurately determined.

5- The template according to claim 1, whereas it is provided with two hollow cylinders through which the wire or surgical drill passes for opening the path of the pedicel screw.

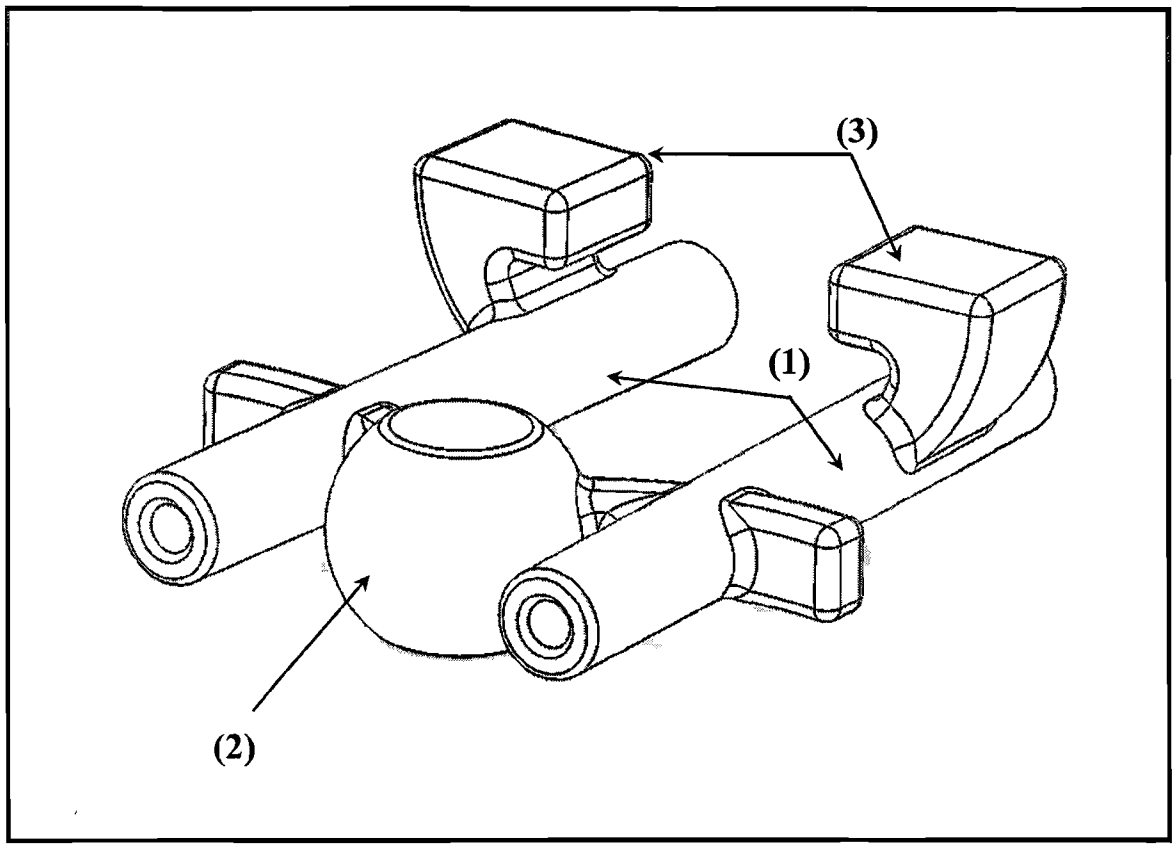
6- The template according to claim 1, whereas it is provided with two hollow cylinders with an interfacial angle that varies according to the inclination of the pedicel screw. The interfacial angle varies according to the vertebra's number and topology.

7- The template according to claim 1, whereas it is provided with two middle nerves between the central sphere and the hollow cylinders for increasing the durability of the template structure and tightly fixing it on the spinal process of the vertebra.

8- The template according to claim 1, whereas it is provided with two flanks at the end of each hollow cylinder. The surface of each flank matches the vertebra's (plate's) topology, hence helping to fix the template on its position on the vertebra that is determined during computer-assisted surgical pre-planning.

9- The patient-specific template according to claim 1, whereas it is used for determining the path, the location and the size of the pedicel screws. It is a computer-designed template designed by converting CT scan into three-dimensional model. The surgery is pre-planned by a special computer program that produces the electronic file of the template.

10- The patient-specific template according to claim 1, whereas three-dimensional printers are used for producing the said electronic template.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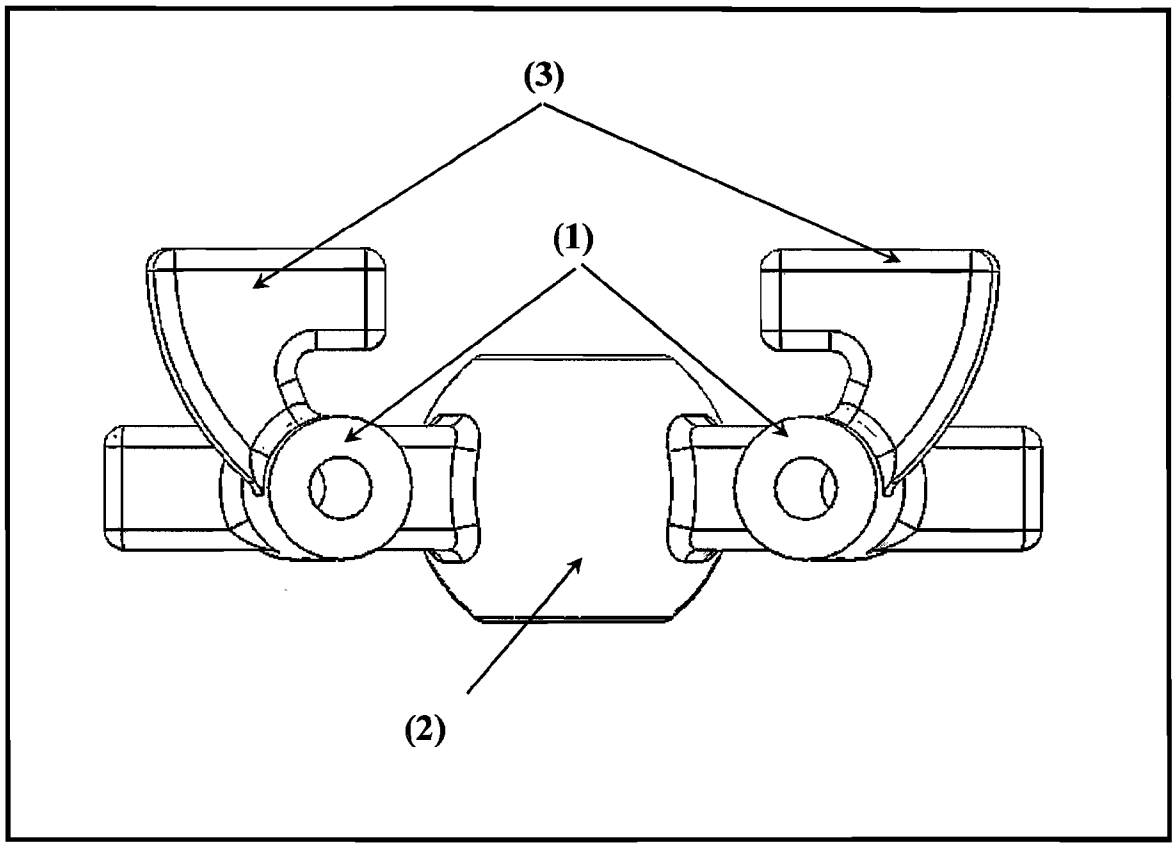
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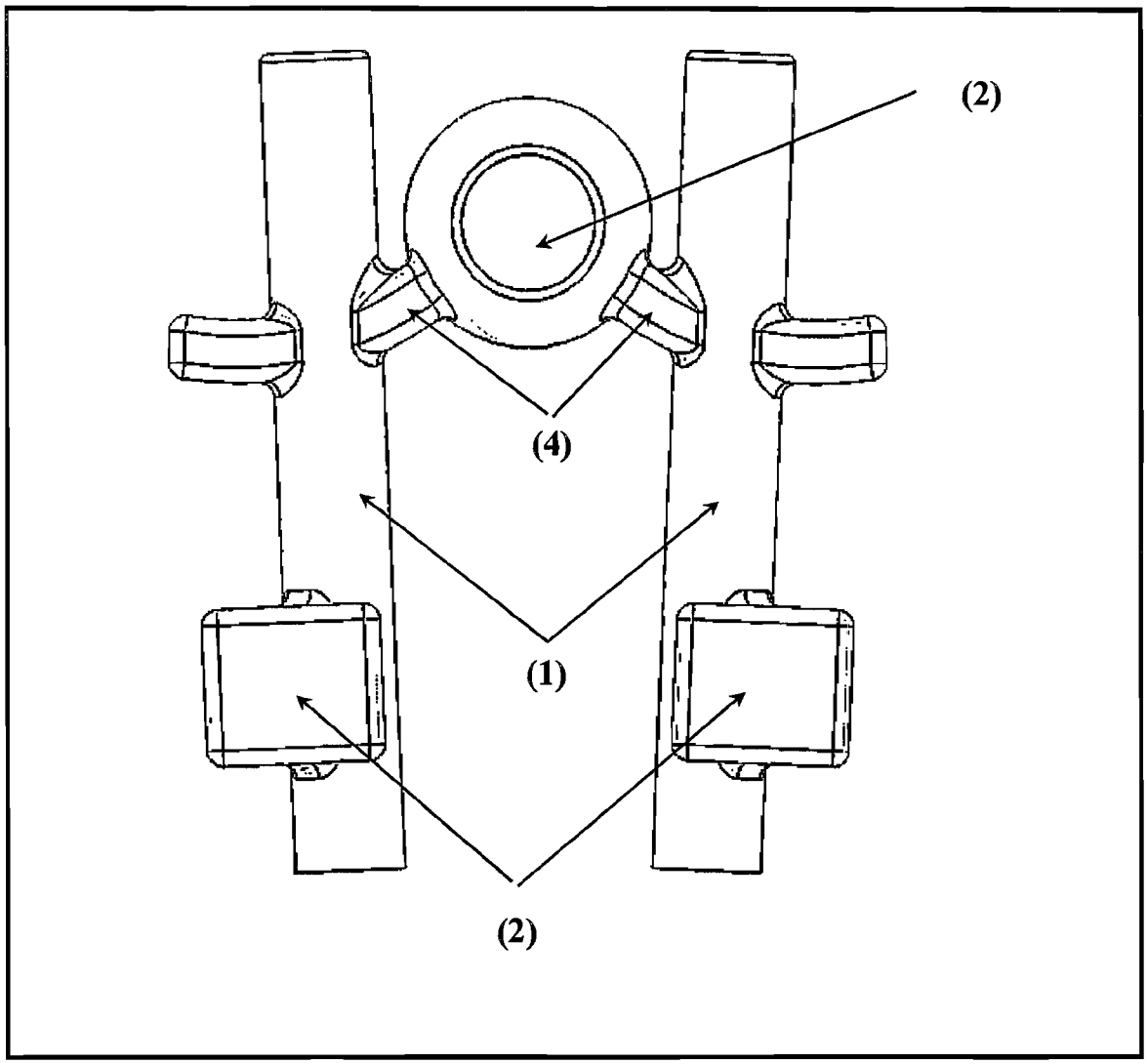
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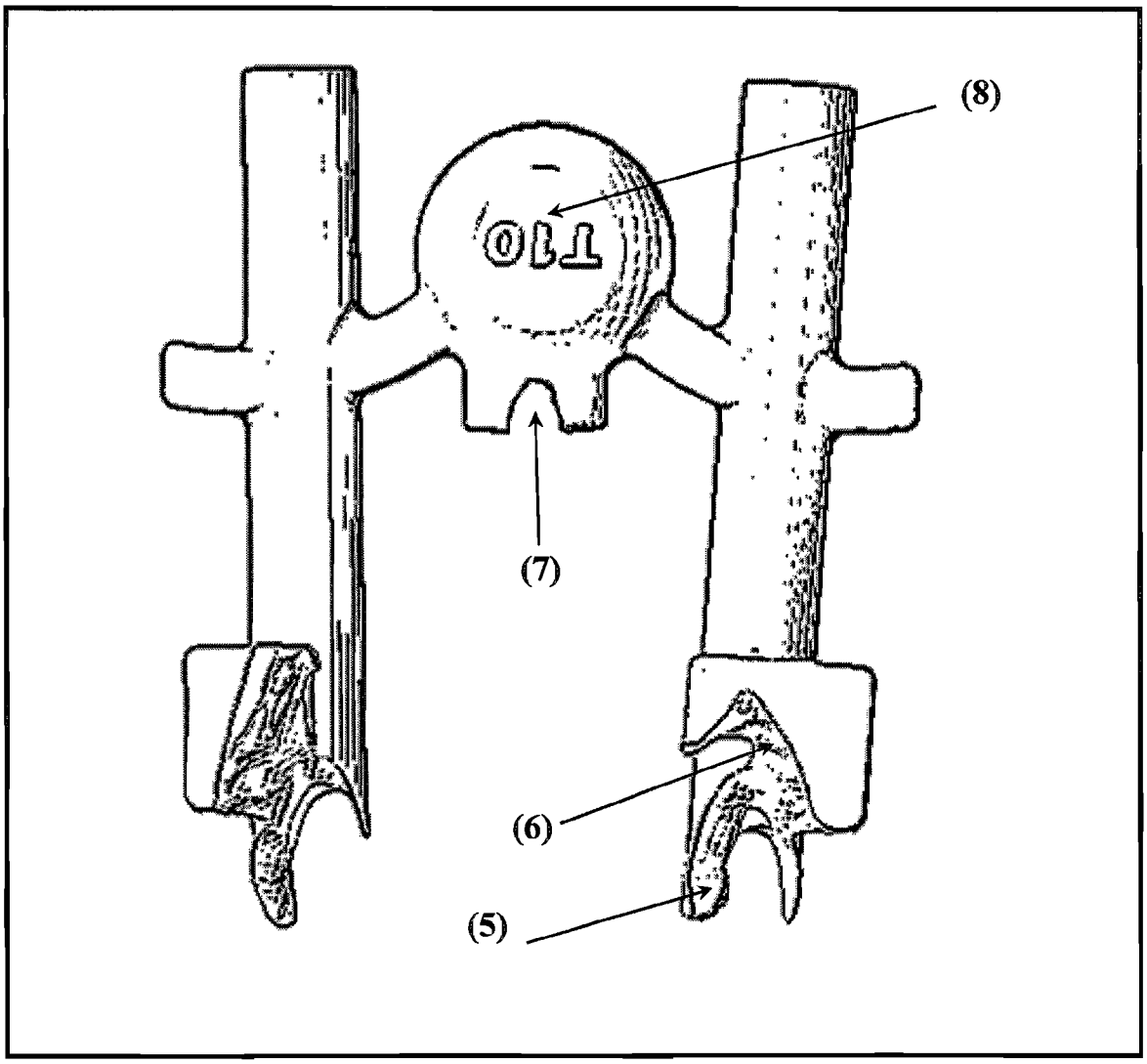
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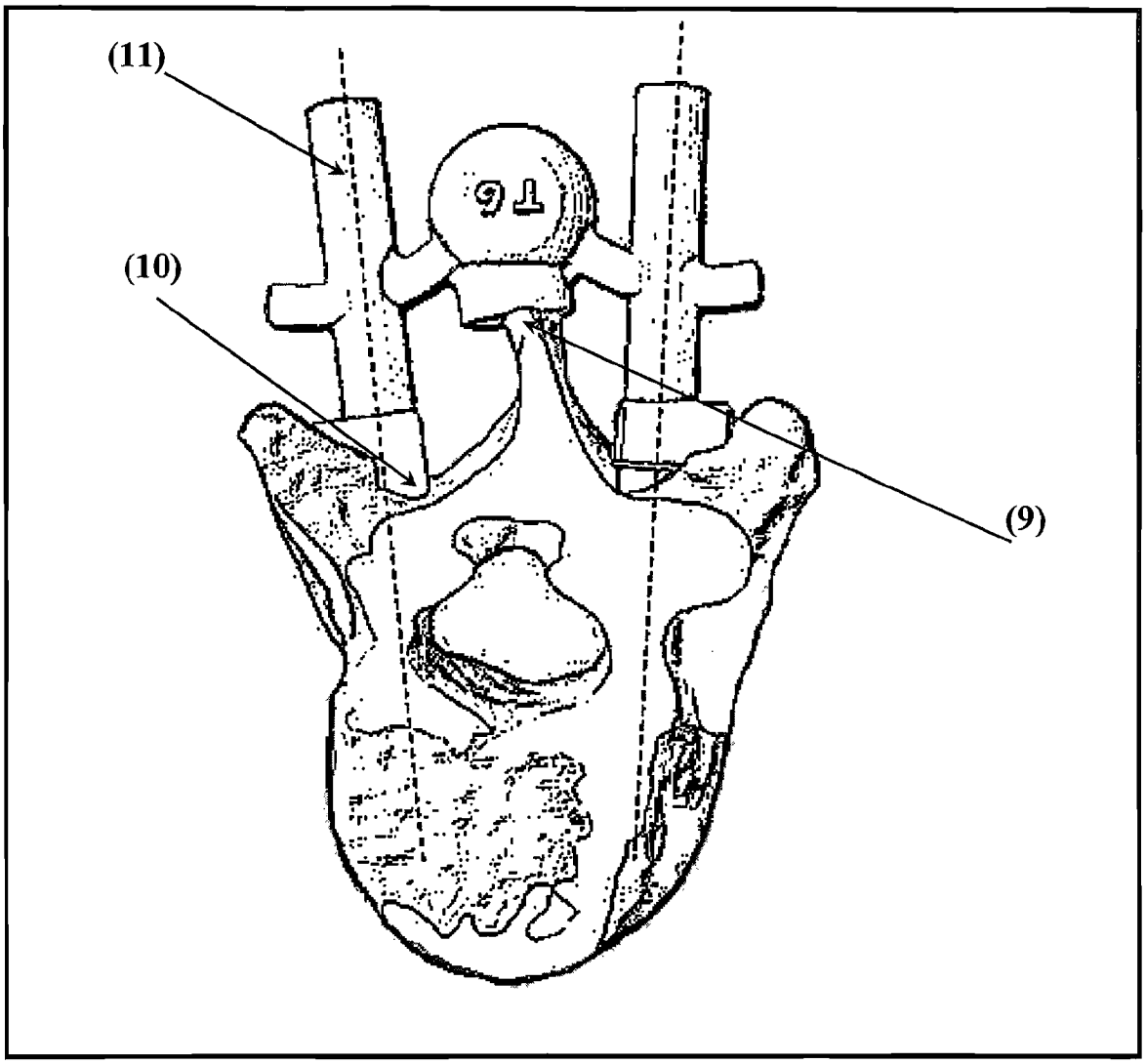
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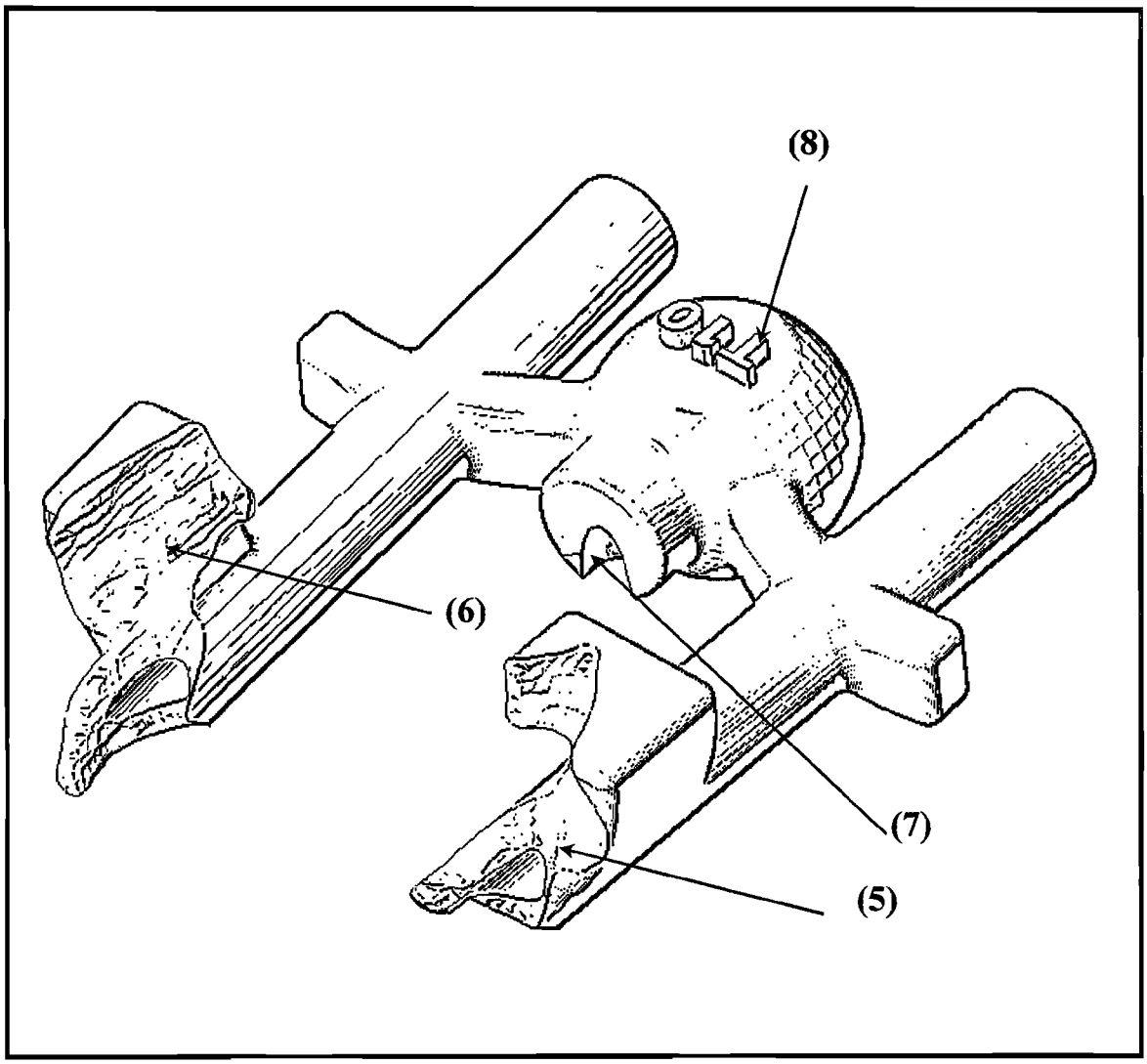
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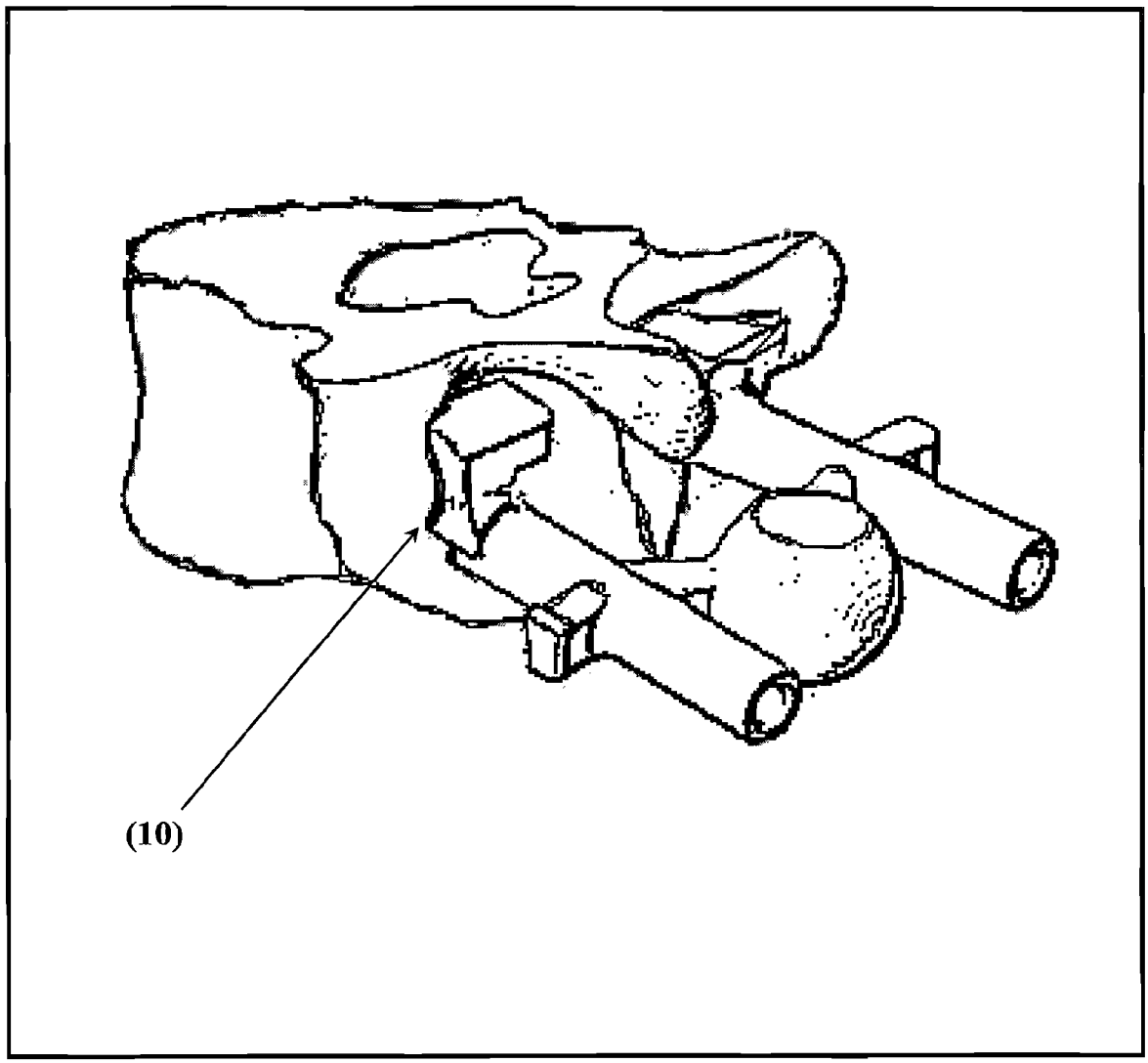
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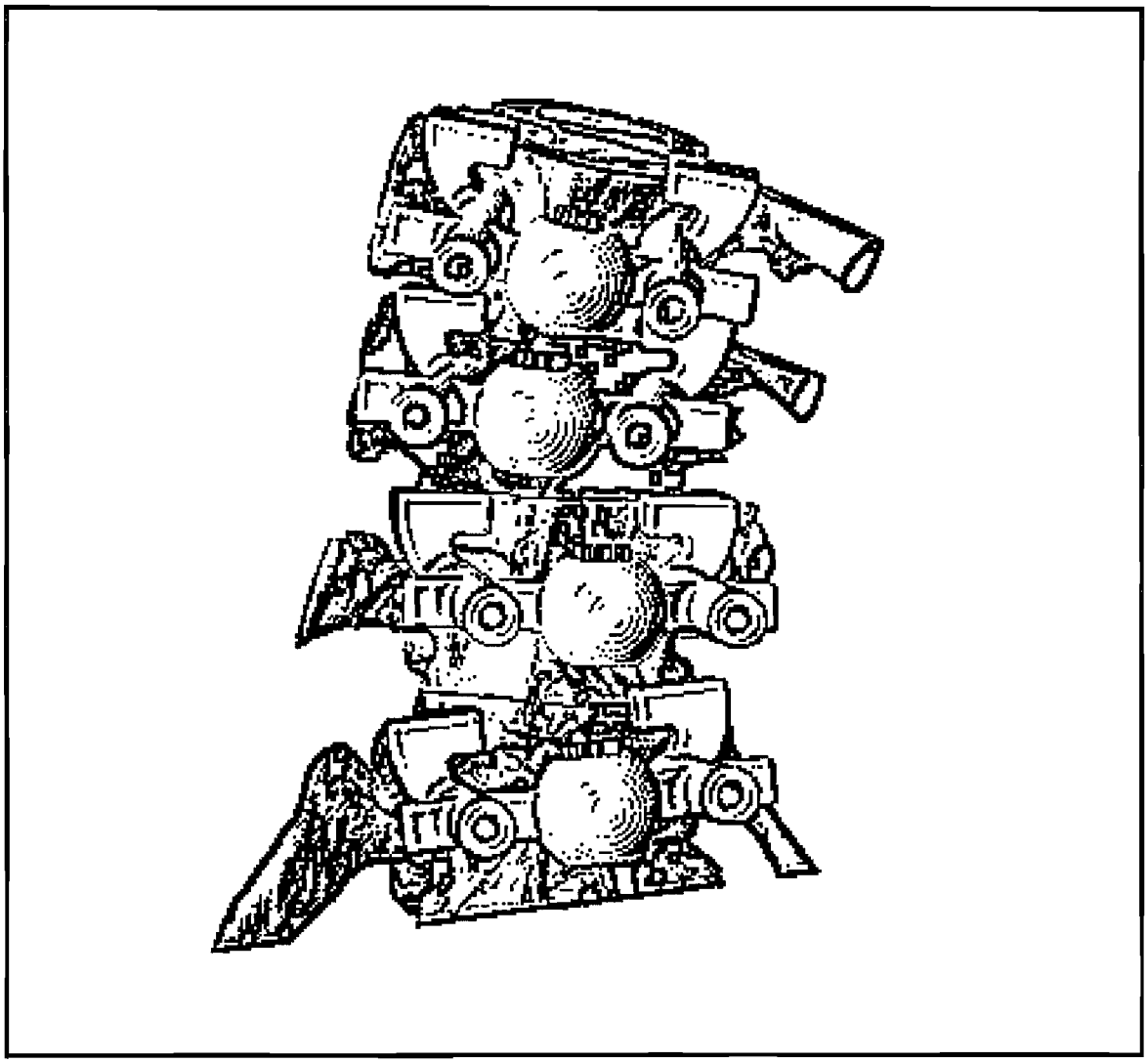

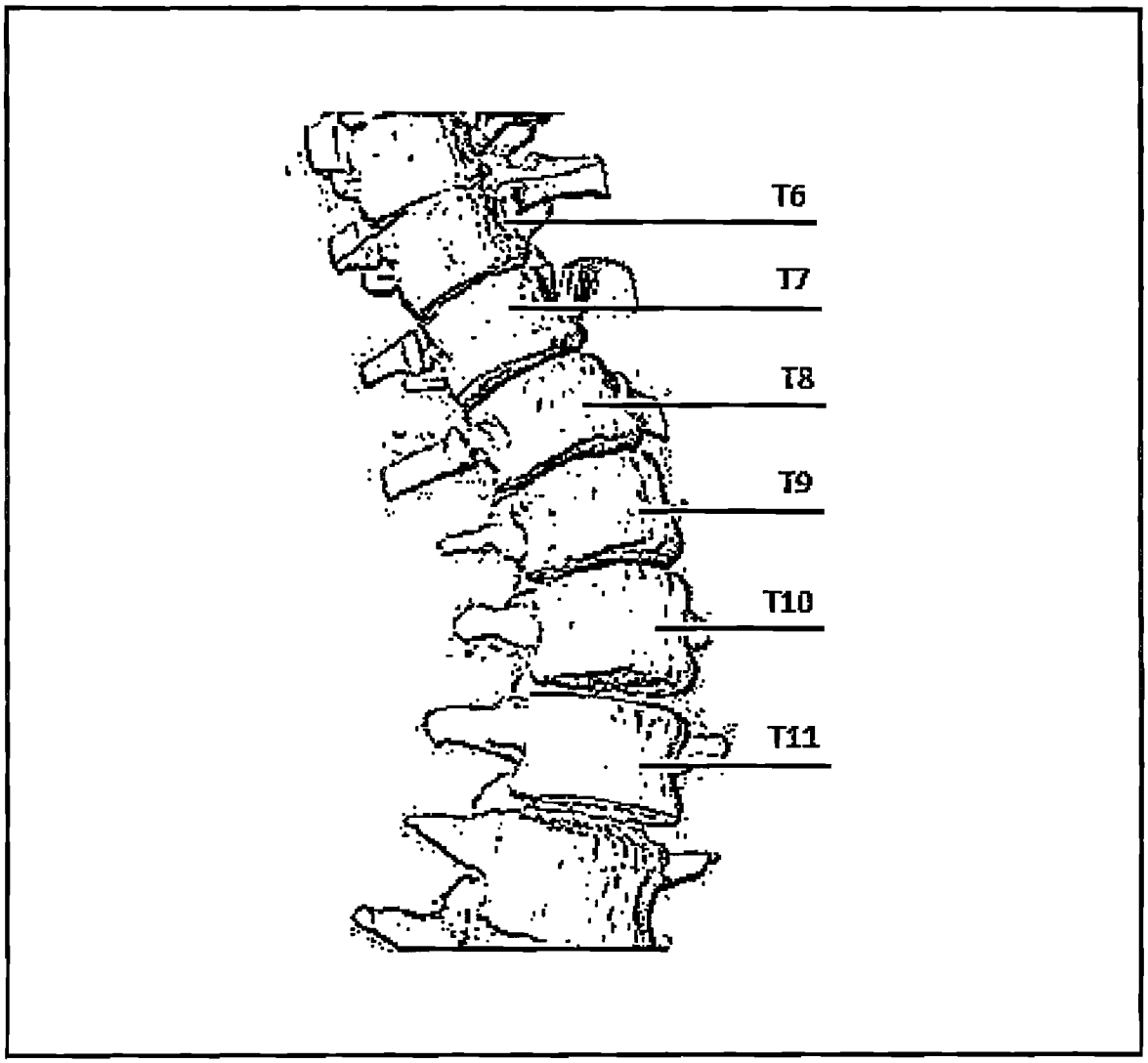
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INTERNATIONAL SEARCH REPORT

International application No
PCT/EG2018/000014

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/17 A61B17/88
ADD. A61B17/56

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 practicable, 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.
A	US 2014/350614 A1 (FREY GEORGE [US] ET AL) 27 November 2014 (2014-11-27) paragraph [0182] - paragraph [0183]; figures 3,4 paragraph [0185] - paragraph [0186]; figure 5 paragraph [0187] - paragraph [0188]; figures 6,7 paragraph [0191]; figure 10 paragraph [0192] - paragraph [0193]; figure 12 paragraph [0215]; figure 30	1-10
A	WO 2016/075581 A1 (MEDACTA INT SA [CH]) 19 May 2016 (2016-05-19) page 3, line 22 - page 6, line 9; figures 1,2	1-10

☐ 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
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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