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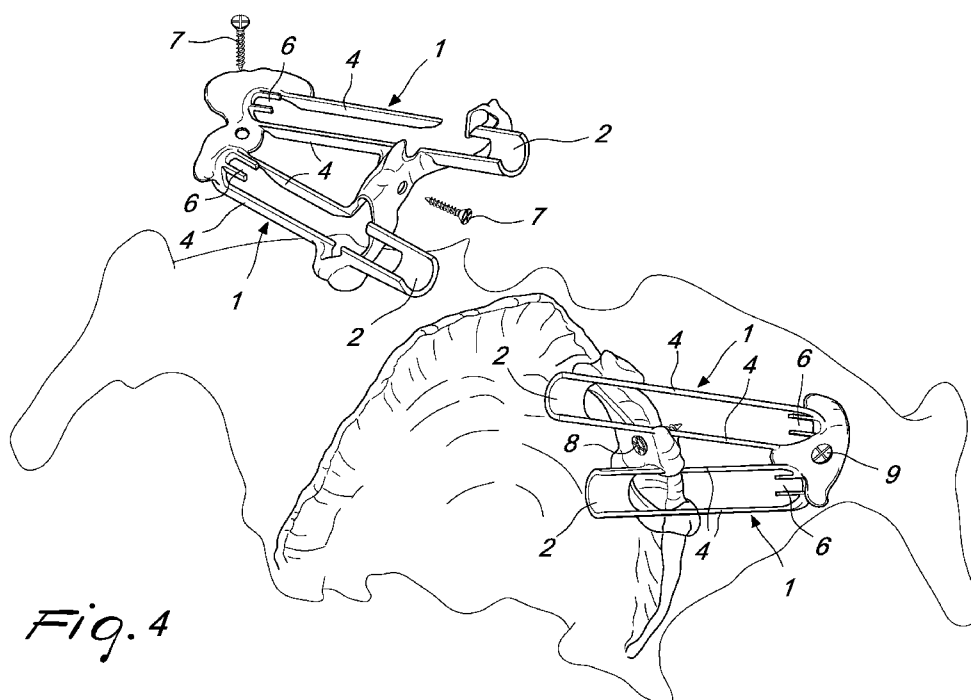


Fig. 4

(57) Abstract: A guide for guided surgery on zygomatic bone implants for dental prostheses, characterized in that it includes a half-bushing and a complementary half-bushing which are connected by a pair of bars, the half-bushings and the bars defining a common longitudinal median axis between them; the half-bushings have a U-shaped or semicircular cross-section with mutually opposite concavities directed toward the median axis; the half-bushings and the bars form a seat in which it is possible to insert a work member, such as a burr and a subsequent implant, which can move only along the median axis and rotates about an axis of rotation that coincides with the median axis.



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SURGICAL GUIDE FOR ZYGOMATIC BONE IMPLANTS

The present invention relates to a guide for guided surgery on zygomatic bone implants for dental prostheses.

5 Implant- and prosthetic-based rehabilitation has developed considerably over the years, solving increasingly critical oral conditions.

Rehabilitation surgery by using zygomatic bone implants is the most modern solution for patients affected by severe maxillary atrophy.

10 This method uses intra-bone dental implants of considerably increased length which are not inserted exclusively in the maxillary bone, as in traditional implants used so far, but are anchored to the zygomatic bone.

The requirement of special anatomical and surgical knowledge, however, has limited the diffusion and use of this method in the field of everyday dentistry routine, making it usable almost exclusively by a maxillofacial surgeon.

15 The need to simplify zygomatic bone surgery and render it usable also by the dental surgeon has therefore pushed to evolve the current technique, improving the surgical passages and entrusting it to so-called guided surgery, i.e., a technique which relies on the most modern software to study and simulate beforehand each individual burr pass until the implant is inserted, by means of a guide which rests against the bone, with fixation by means of synthetic screws or pins.

20 Guided surgery is already known for traditional implants but is not used for zygomatic bone implants.

For example, EP2060240 discloses a kit which includes a surgical guide for guiding the insertion of a dental implant into a desired location in a patient's mouth. The implant includes a non-rotational structure. The surgical guide includes a structure and a master tube. The structure has a negative impression surface to be fitted on and placed
25 over gingival tissue, bone, and/or teeth in the patient's mouth. The structure includes an opening through which the dental implant is placed. The master tube is located at the opening. The master tube includes indicia for alignment with the non-rotational structure on the implant such that the non-rotational structure of the implant is at a known angular
30 orientation with respect to the master tube.

US2010/0256649 discloses a method for providing a three-dimensional solid reproduction of the anatomical zone of implantation and, by means of this reproduction, a device for assisting drilling, which includes a rigid base provided with a guide for a drill. The three-dimensional solid reproduction consists of a reproduction of an internal and peripheral portion of the bone structure that is free, at least in the vicinity of each hole of the implant, from the surrounding non-osseous tissues and mucosa. The rigid base has a contact surface adapted to make contact with a portion of the external surface of the three-dimensional solid reproduction and therefore also later with a peripheral surface portion of the bone structure.

10 The aim of the present invention is to provide a surgical guide which can be used for zygomatic implants.

Within the scope of this aim, an object of the invention is to provide a surgical guide that allows to precisely guide the burr passes in order to create the receptacle of the implant and the insertion in the bone receptacle of the implant, designed beforehand.

15 Another object of the invention is to provide a surgical guide with intimate osseous resting contact that is provided specially for each patient.

A further object of the present invention is to provide a structure which, by virtue of its particular constructive characteristics, is capable of giving the greatest assurances of reliability and safety in use.

20 A further object of the present invention is to provide a structure that can be manufactured easily by using commonly commercially available elements and materials and is also competitive from an economic standpoint.

This aim and these and other objects which will become better apparent hereinafter are achieved by a guide for guided surgery on zygomatic implants for dental prostheses, characterized in that it comprises a first half-bushing and a second half-bushing that are connected by a pair of bars, said half-bushings and said bars defining a common longitudinal median axis between them; said half-bushings having a semicircular cross-section with mutually opposite concavities directed toward said median axis; said half-bushings and said bars forming a seat in which it is possible to insert a work member; said work member being movable along said median axis and

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rotating about a rotation axis that coincides with said median axis; said first half-bushing being arranged in a crestal maxillary position with vestibular concavity, said first half-bushing determining a working depth of said work member, i.e., the vestibulo-palatal penetration; said second half-bushing being arranged at the zygomatic region.

5 Further characteristics and advantages will become better apparent from the description of preferred but not exclusive embodiments of the invention, illustrated by way of non-limiting example in the accompanying drawings, wherein:

Figure 1 is a perspective view of the surgical guide according to the present invention;

10 Figure 2 is a front view of the guide;

Figure 3 is a side view of the guide;

Figure 4 is a schematic perspective view of two double guides, of which one is arranged in the position for use;

Figure 5 is a front view which shows schematically the placement of two guides;

15 Figure 6 is a bottom view of the palate, showing two guides in position;

Figure 7 is a view, similar to the preceding one, showing the application of a burr;

Figure 8 is a view of the step of insertion of an implant;

Figure 9 is a view of an inserted implant;

Figure 10 is a view of the implants inserted and of the removed guide;

20 Figure 11 is a schematic view of the virtual placement of the implants performed by the software.

With reference to the cited figures, the surgical guide according to the invention, designated generally by the reference numeral 1, has a half-bushing 2, in a crestal maxillary position with vestibular concavity, adapted to determine both the working
25 depth, i.e., the vestibulo-palatal penetration, referenced by the segment 3, and the direction of perforation that a burr 100 must follow.

The guide 1 also includes two lateral bars 4 that unambiguously direct the sliding of the burrs 100 and of the implant 101 in space, and a complementary half-bushing 5, which is opposite to the crestal bushing 2 and have a concavity directed medially; the
30 half-bushing 5 is arranged at the zygomatic region.

The complementary half-bushing 5 acts as a guide for the surface direction and orientation of the burrs 100 and of the implant 101.

The mutually opposite half-bushings 2 and 5 have a U shape or semicircular shape with the concavity directed toward the longitudinal median axis of the guide
5 formed between the bars which extend parallel thereto.

In other words, the opposite half-bushings 2 and 5 define the "hole" in which the burr and then the implant are inserted; the burr and the implant represent a "shaft" which, with the "hole", constitutes a "prismatic pair", providing a system with a single degree of freedom, i.e., the motion of the shaft, i.e., the burr 100 and the implant 101,
10 can occur only along one direction, which in this case coincides with the axis of the prismatic cavity formed by the half-bushings 2, 5.

With this system, the axis of the "hole" coincides with the axis of the burr 100 and with the axis of the implant 101.

The half-bushing 2 arranged on the maxillary bone has a U-shaped cross-section
15 and dimensions suitable to guide the work of the burrs 100 and the subsequent positioning of the implant 101.

The complementary half-bushing 5 also has a guide 6 for the first burr 100, the pilot burr, as will be described hereinafter.

The guide 6 is constituted, in this specific case, by a pair of tabs, which extend
20 from the complementary half-bushing 5 in the direction of the half-bushing 2.

The surgical guide according to the present invention is particularly studied to be used in a particular zygomatic implant guided surgery technique which provides, as a first step, the acquisition of a multilayer CT (computerized tomography). This CT is processed by software which allows to virtually position the implants in terms of
25 orientation, position and measurements, as shown schematically in Figure 11.

A second software is used to read the position of the implants, in relation to the bone, decided by the surgeon, and at the same time to virtually build a surgical guide with bone anchoring which allows to reproduce, with the surgical burrs, the exact path and placement of the implants to be inserted, exactly as in the virtual project.

30 In a first step, a pilot mill, preferably constituted by a 2.5 mm diamond mill, is

used, for determining the center of the circumference of the future implant 101 and which will be the insertion point for the drill of the actual burr.

A second burr, termed "cortical burr", allows the erosion of the excess bone level and the forming of the bone hollow for the resting of the future implant. This burr is used
5 by resting its nonworking drill in the spot provided by the pilot burr and by tilting it and pushing it on the bone, consuming the bone with its active part; the final position of the burr is determined by the stop produced by the maxillary half-bushing 2.

The subsequent burrs are guided by the half-bushings 2 and 5 and by the lateral bars 4, which are constituted by two prismatic shapes with a polygonal base; the
10 prismatic shapes have such an extension as to connect the two half-bushings and are arranged tangentially to the ends of the diameter of the implant and parallel to each other.

These features allow to guide the burr 100 and to remove the guide 1 after inserting the implant 101 in the bone.

15 Another feature of the guide 1 is constituted by its extension by means of stabilization flanges in the palate region and the zygomatic fossa; its stabilization occurs by means of self-tapping locking screws or pins 7, which are inserted in maxillary holes 8 and zygomatic holes 9 provided for this purpose.

The files that contain the projects of the customized guides are sent to a center
20 that is specialized in laser melting processes, thus producing the actual titanium guides with a high level of precision.

The surgical technique provides for sculpting a mucosal flap, performing a bone peeling process that is suitable to expose the maxillary and zygomatic anatomical structures, and to accommodate the guide according to the present invention, which is
25 fixed to the bone by means of pins 7.

Once the intimate bonding between the bone and the plate has been verified, one proceeds with the sequence of burrs with the goal of providing a bone hollow for guiding the subsequent insertion of the implant.

The seating of the implant is precise because the bone hollow on the maxillary
30 bone and the hole inside the cheekbone (implant neo-receptacle) allow a single

placement in terms of direction and depth and this occurs because during all the surgical steps the operator is guided by the two half-bushings 2 and 5, applying thereon an adequate pressure both with the burrs and with the implant itself at the time of its insertion.

5 The technique thus provided allows to use implants with preset diameter and length and even to prepare a temporary screw-on prosthesis in order to provide an immediate prosthetic load.

An example of execution of the surgical technique based on the guide according to the present invention is described hereinafter.

10 First of all, a multilayer TC acquisition is performed and the file is loaded in the dedicated software, which provides the virtual placement of the implants, in terms of depth and angle, on a CAT in relation to the prosthetic design.

The file is imported in another software in order to design the surgical guide according to the present invention, which is made to size with respect to the bone of the
15 patient and on the basis of the placement of the implant decided in the preceding software.

The file is sent to the manufacturer of the guide, which manufactures it by laser melting.

The guide is tested on a "real model", printed from the files of the CAT (guide
20 project validation), current tolerance 0.2 tenths of a centimeter.

The 0.3 to 0.6 mm multilayer CT is acquired which includes the maxillary bone and the cheekbones in full and is extended up to the complete eye socket; the CT is preferably performed with a barium-based prosthetic radiological guide.

The DICOM file of the CAT is imported into the software for planning and
25 matching the reference points of the files of the digitized radiological guide.

The zygomatic implant is extracted from the library and is positioned in three dimensions with a maxillary/zygomatic orientation, according to the surgical-prosthetic project. The software includes an implant library with diameters and lengths of the implants to be inserted.

30 The placement of the crestal half-bushing 2 is performed by exporting it from the

"bushings" library. The maxillary half-bushing 2 and the complementary half-bushing 5 have different lengths depending on the length of the implant that will be inserted. These two members constitute the guide of the burr in a unique direction.

5 The maxillary half-bushing 2, together with the remaining portion of the complementary half-bushing 5, constitute an ideal prism (hole) through which only and exclusively one trajectory is possible for a zygomatic implant (shaft). Specifically, the "hole" is divided into two equivalent halves, the maxillary half-bushing 2 and the zygomatic complementary half-bushing 5, which are arranged in a mutually opposite manner: the half-bushing 2 with a vestibular concavity and the complementary half-
10 bushing 5 with the concavity directed toward the zygomatic bone plane.

The lateral bars 4 are arranged from the half-bushing 2 to the complementary half-bushing 5. These bars, which have a prismatic shape, are tangent to two opposite points of the circumference of the implant and are mutually parallel. These bars act as an additional guide of the shaft (implant) during its travel from the half-bushing 2 to the
15 complementary half-bushing 5 (hole).

The slot with guiding pin for the first burr is imported.

The slot, half-bushing, complementary half-bushing, lateral bars, zygomatic slot for the first burr are aligned with the designed zygomatic implants.

20 One then proceeds with modeling the guide with bone support, ensuring the stability of the plate, creating a prismatic kinematic pair in which the fixed portion is the guide and the movable portion is the burr.

The guide must have a bone support with an extension from the palate portion, continuing on the maxillary bone, up to the zygomatic portion, extending it to the rear portion of the fossa.

25 In order to fix the guide to the bone portion, holes are used in a number which is variable according to the extension of the guide and are positioned on the maxillary and zygomatic portion thereof.

The holes have a diameter that is capable of accepting a self-tapping screw in order to fix the guide integrally to the bone portion.

30 The burr moves inside the bushings (shaft/hole) with a predefined degree of

tolerance, for example H6/h6 ISO Table, defined as "good" precision, on a scale of four values: high, good, medium, coarse.

Finally, the file is sent to the guide production location and is preferably manufactured in titanium by means of the laser melting method.

5 In practice it has been found that the invention achieves the intended aim and objects, providing a guide that is studied particularly for guided surgery on zygomatic implants for dental prostheses.

An important advantage of the guide according to the present invention is that it is removable after inserting the implant or implants in place.

10 Also, with a single guide it is possible to insert one or more implants, such as in the example shown in Figures 4-10, in which two guides are shown, each of which is configured for the application of two implants.

The materials used, as well as the dimensions, may of course be any according to the requirements and the state of the art.

15 This application claims the priority of Italian patent application No. 102018000006998, filed on 6 July 2018, the content of which is incorporated as reference.

CLAIMS

1. A guide for guided surgery on zygomatic implants for dental prostheses, characterized in that it comprises a first half-bushing and a second half-bushing that are connected by a pair of bars, said half-bushings and said bars defining a common longitudinal median axis between them; said half-bushings having a semicircular cross-section with mutually opposite concavities directed toward said median axis; said half-bushings and said bars forming a seat in which it is possible to insert a work member; said work member being movable along said median axis and rotating about a rotation axis that coincides with said median axis; said first half-bushing being arranged in a crestal maxillary position with vestibular concavity, said first half-bushing determining a working depth of said work member, i.e., the vestibulo-palatal penetration; said second half-bushing being arranged at the zygomatic region.

2. The guide according to claim 1, characterized in that said second half-bushing has a guide for said work member.

3. The guide according to claim 2, characterized in that said guide comprises a pair of tabs which extend from said second half-bushing in the direction of said first half-bushing.

4. The guide according to one or more of the preceding claims, characterized in that it comprises stabilization flanges adapted to allow the fixing of said guide to a bone part.

5. The guide according to claim 4, characterized in that said stabilization flanges allow the fixing of said guide in the palate region and zygomatic fossa.

6. The guide according to claim 4, characterized in that said fixing occurs by means of self-tapping locking screws or pins inserted in maxillary holes provided appropriately.

7. The guide according to claim 4, characterized in that said stabilization flanges mutually connect at least two guides.

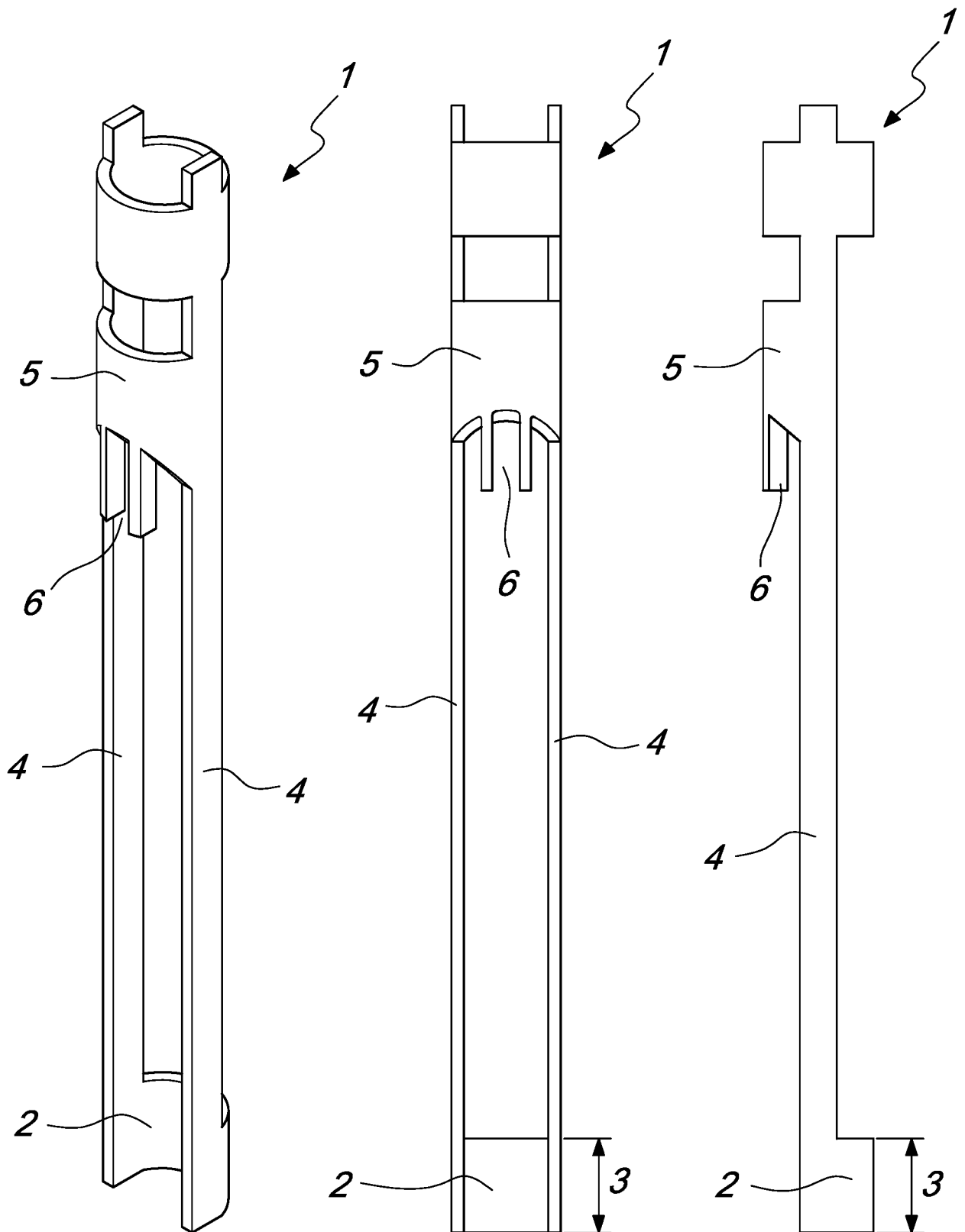


Fig. 1

Fig. 2

Fig. 3

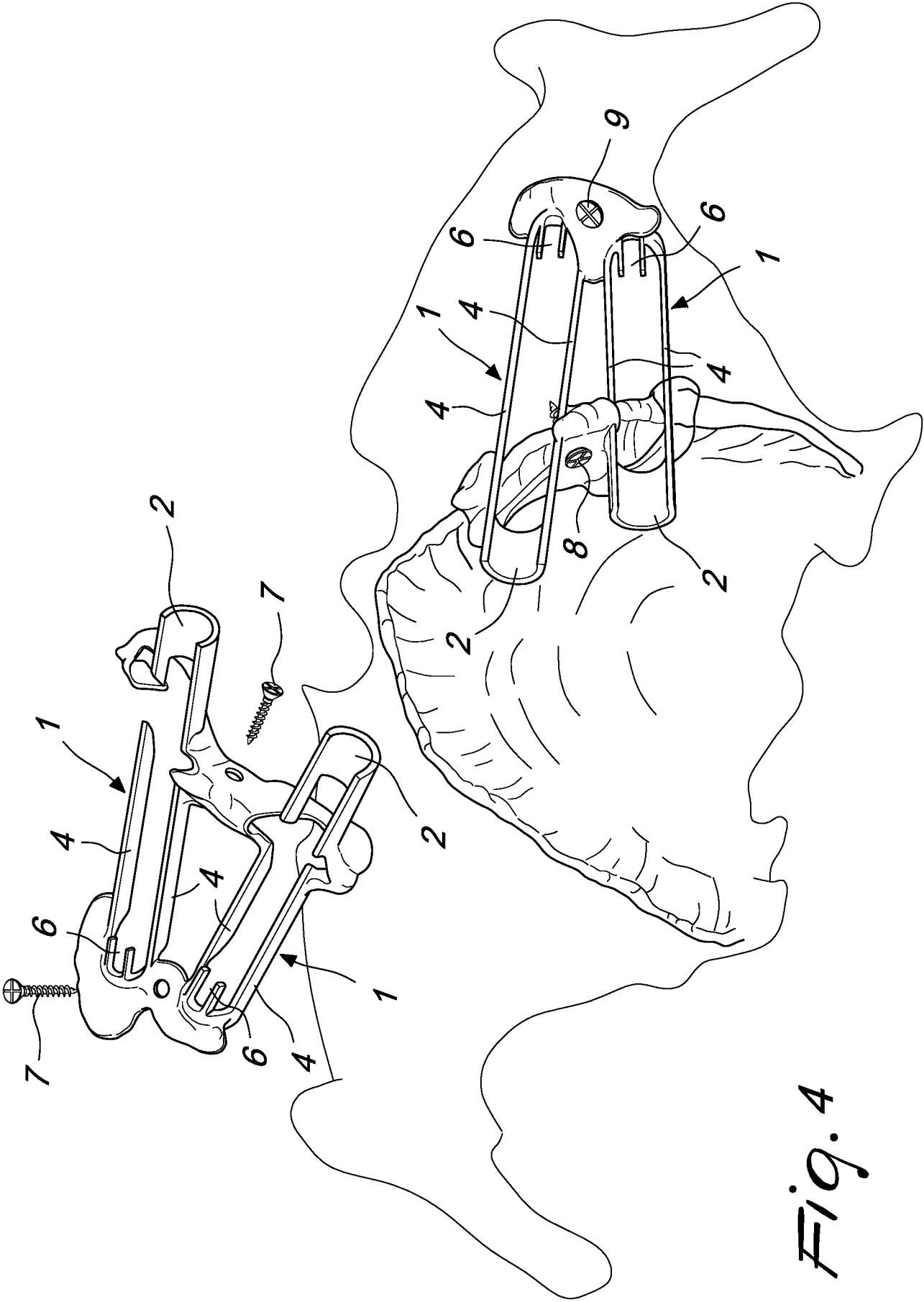
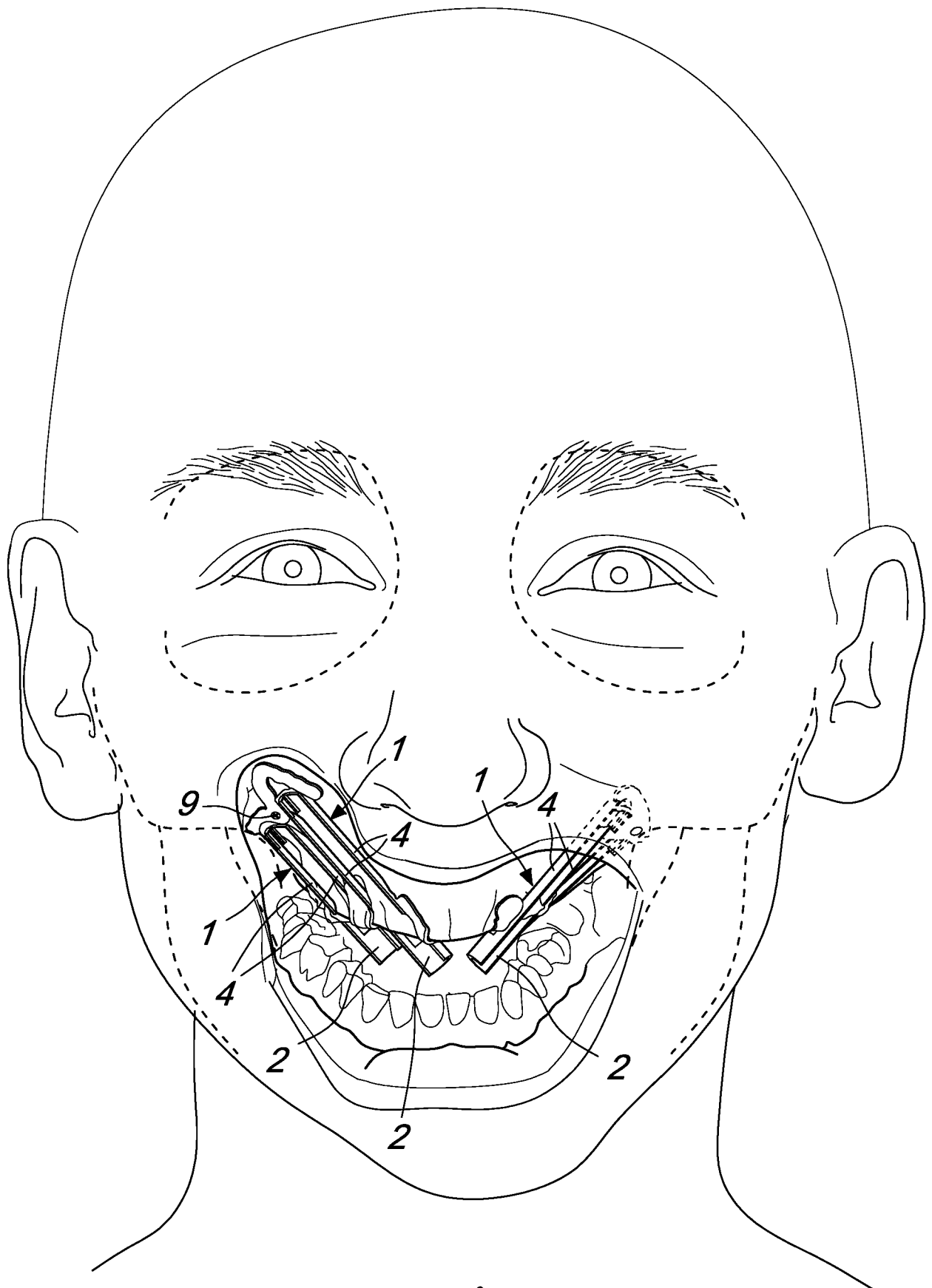
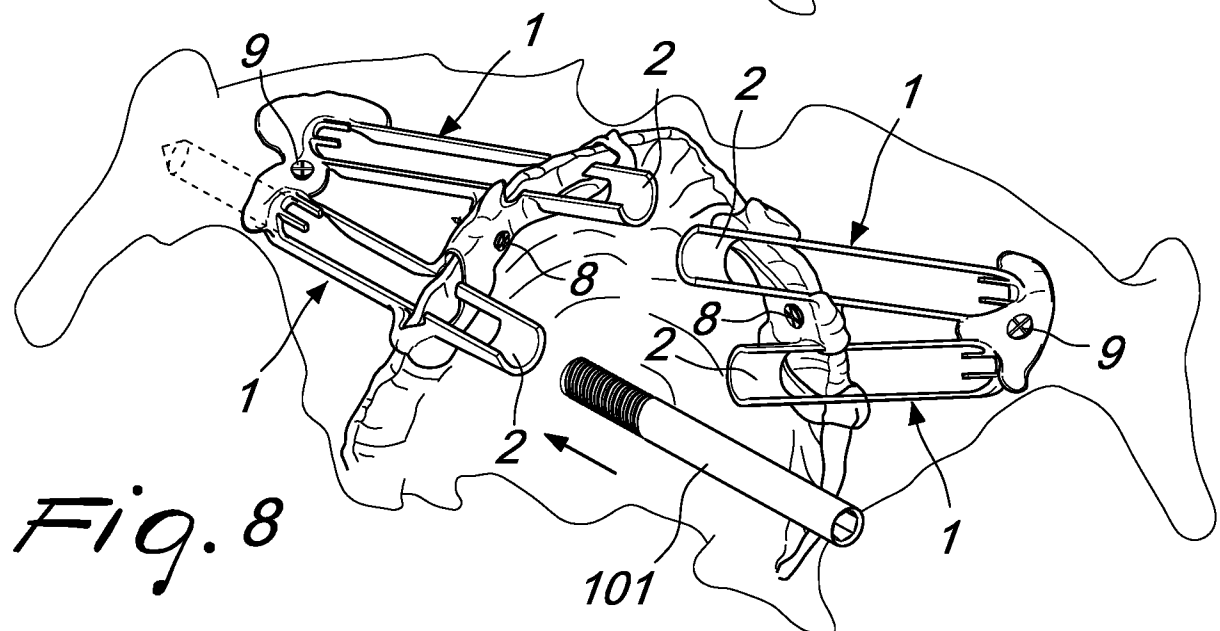
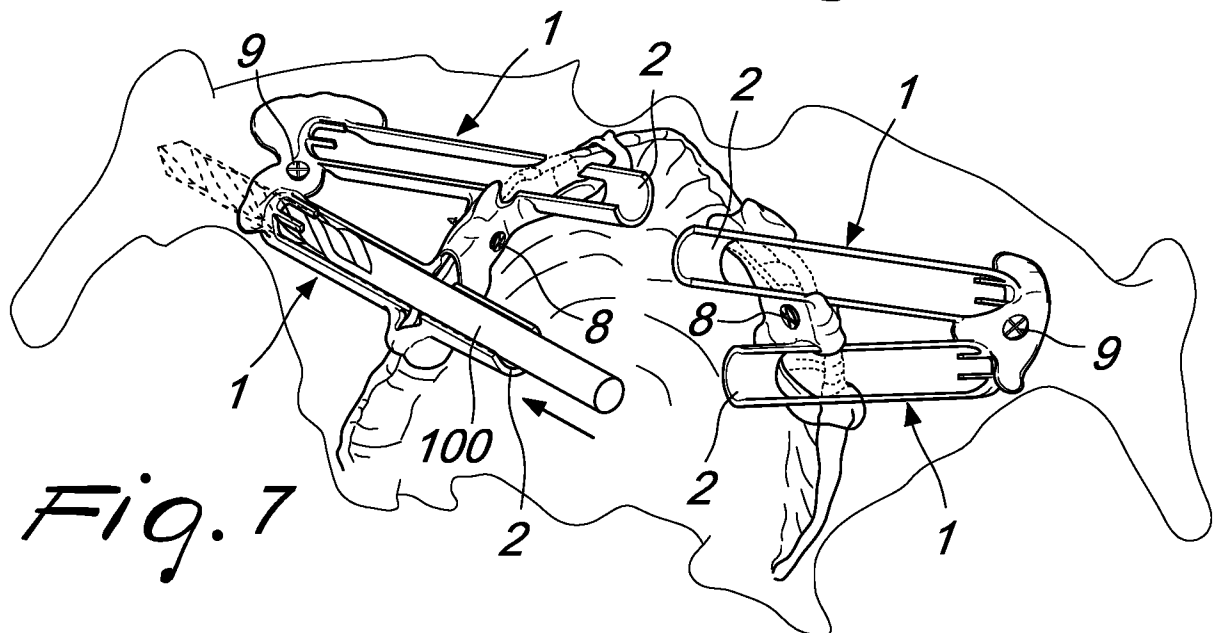
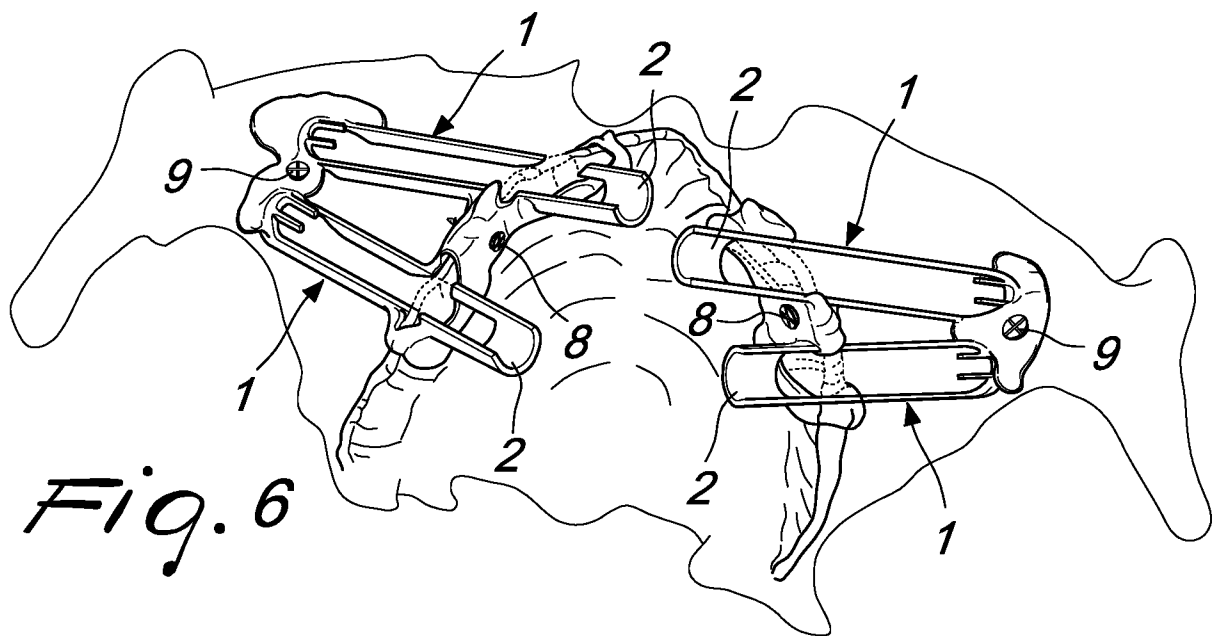
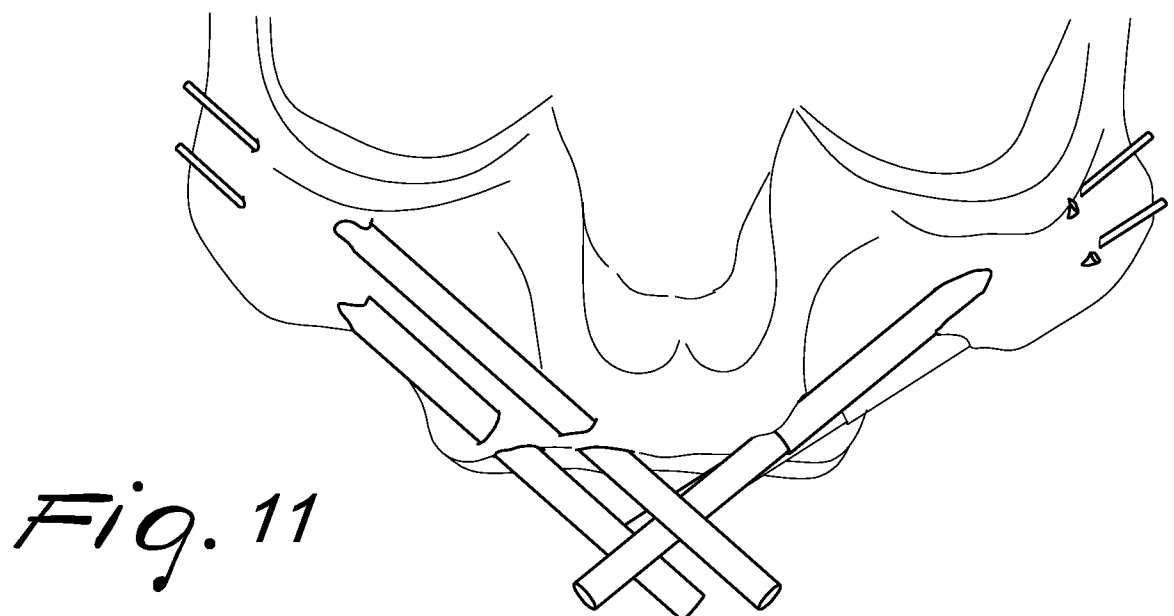
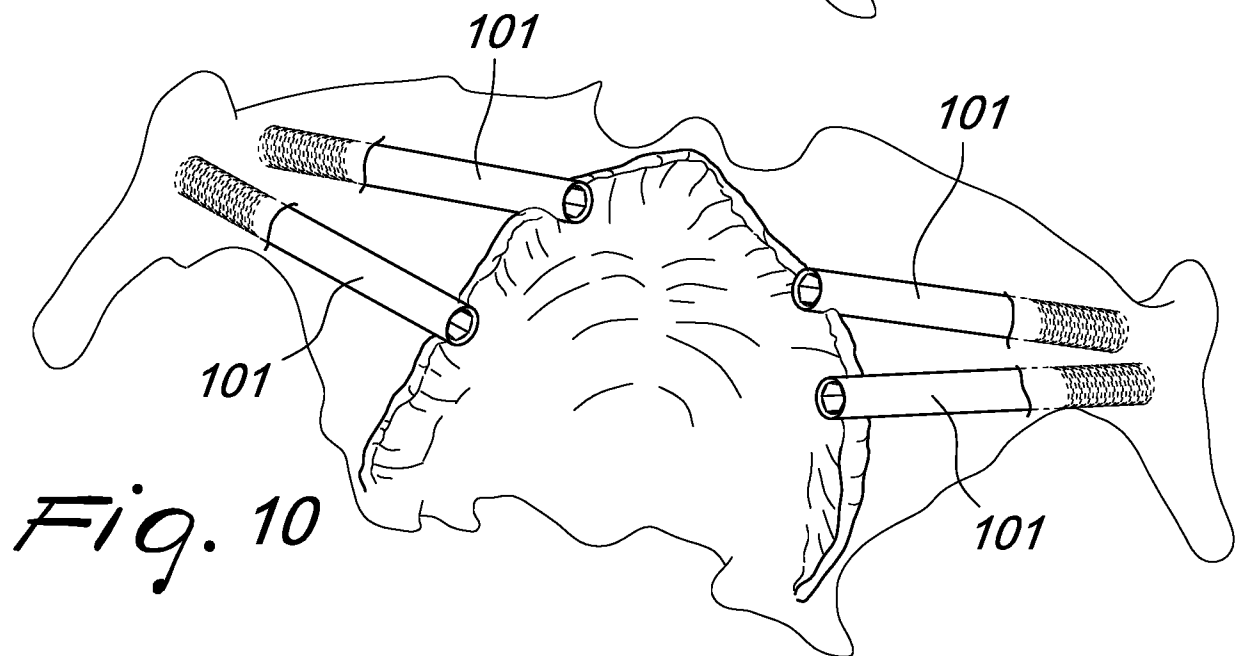
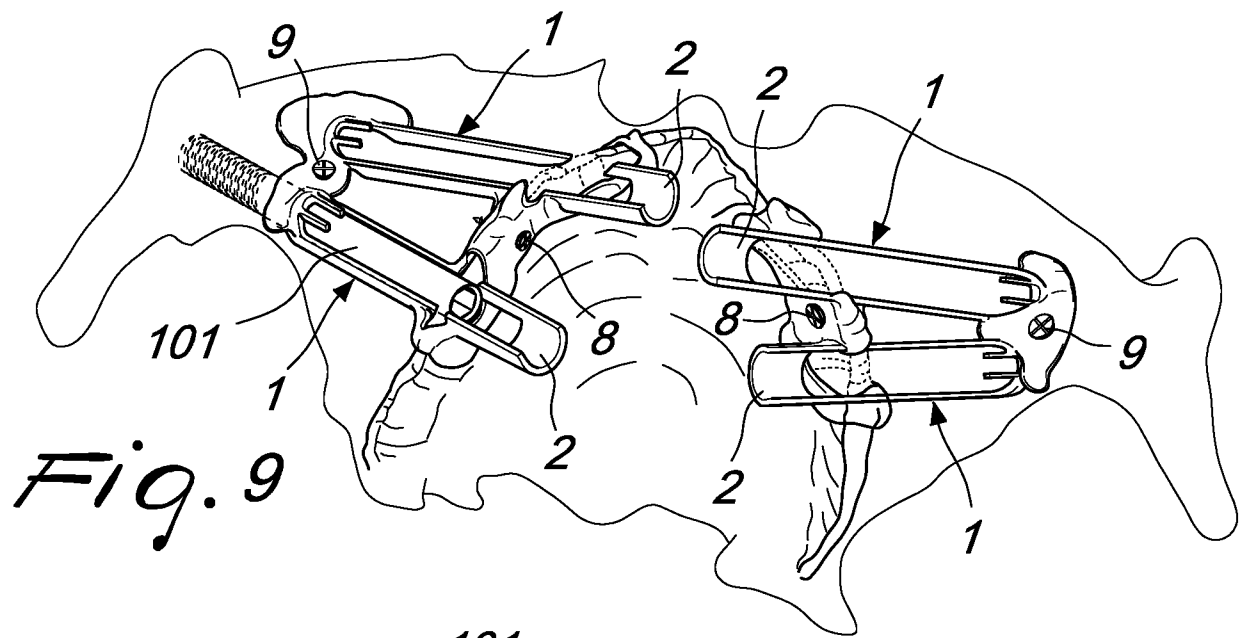


Fig. 4

*Fig. 5*





INTERNATIONAL SEARCH REPORT

International application No
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A. CLASSIFICATION OF SUBJECT MATTER
INV. A61C1/08
ADD. A61C8/00

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)
A61C

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)

EP0-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 2 060 240 A2 (BIOMET 3I LLC [US]) 20 May 2009 (2009-05-20) figures 1A, 5, 6A paragraphs [0008], [0009], [0014] paragraphs [0040], [0041], [0047] - [0050]	1-7
A	----- US 2010/256649 A1 (CAPSAL JEAN [FR] ET AL) 7 October 2010 (2010-10-07) the whole document	1-7
A	----- US 2014/276879 A1 (LIN HSIEH-HSING [TW]) 18 September 2014 (2014-09-18) figures 1-12 paragraphs [0013] - [0015], [0028] - [0045] -----	1-7

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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

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07/10/2019

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2019/055739

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