(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
02 September 2021 (02.09.2021)

(10) International Publication Number
WO 2021/171277 A2

(51) International Patent Classification:
Not classified

(21) International Application Number:
PCT/IB2021/056708

(22) International Filing Date:
26 July 2021 (26.07.2021)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
00937/20 28 July 2020 (28.07.2020) CH

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(81) **Designated States** *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,

(54) Title: SPINAL CORRECTION TOOL ASSEMBLY

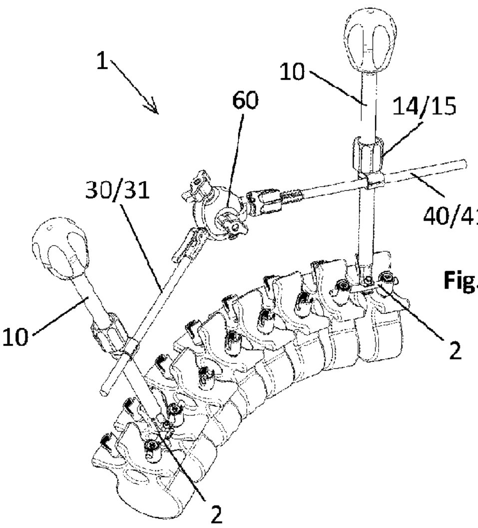

Fig. 1A

(57) Abstract: A spinal correction tool assembly (1) is proposed comprising two manipulation tools (10), at least one articulation joint (60), and at least one elongated connection instrument (30, 40). The spinal correction tool assembly (1) may be used in combination with spinal implants, such as pedicle screws and/or posterior rods, for a controlled correction of a deformed spinal column in the case of scoliosis, for instance. The spinal correction tool assembly (1) is intended for gradually correcting the spinal column and for stabilising the spinal column before placement of a rod implant into pedicle screws.

WO 2021/171277 A2

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EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

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— *in black and white; the international application as filed contained color or greyscale and is available for download from PATENTSCOPE*

SPINAL CORRECTION TOOL ASSEMBLY

TECHNICAL FIELD OF THE INVENTION

The present invention relates to a spinal correction tool assembly. The spinal correction tool assembly may be used in combination with spinal implants, such as pedicle screws and/or posterior rods, for a controlled correction of a deformed spinal column in the cases of scoliosis, for instance. The proposed assembly provides a surgeon with a better control of the process. The assembly also provides the ability of independently managing/correcting coronal, and/or sagittal deformities, and independently being able to de-rotate and adapt a translation or length of one or more of the involved elements. The present invention also relates to a method for gradually correcting combined deformities.

BACKGROUND OF THE INVENTION

In orthopaedic surgery around the spine, posterior spinal stabilisation systems are often placed to a target site to realign, correct and/or stabilise the spinal column to compensate for malalignment caused by for example degeneration of the spine, born malalignments, such as excessive lordosis, kyphosis and scoliosis, and for example trauma, such as fractures. A typical posterior spinal stabilisation system consists of multiple pedicle screws that are connected by a rod. In a first step, at different levels of the spinal column, the pedicle screws are screwed through the pedicle bone into vertebral bodies. In a second step, the pedicle screws are connected by a rod, having a desired shape or curvature. Normally, using a spinal column persuading instrument, the vertebral bodies including the pedicle screws are forced towards the rod (or vice versa). When the rod has reached its end position within a rod receiving head of the pedicle screw, the rod is rigidly fixated by tightening a set screw against the rod.

In the cases of severe deformities, longer trajectories including multiple segments need to be corrected. The correction requires high forces and needs to be made gradually for the spine to adapt to the correction, and to the surrounding soft tissue. Also the nerve roots and the spinal cord needs to be managed with great care to prevent from pinching or damaging these structures.

According to an exemplary correction technique, in all vertebral bodies of the target spinal column section, two pedicle screws are implanted at both sides of the vertebral body. At one side (ipsilateral side), the last two segments at each end of the target spinal column section are connected by means of a temporary rod and set screws. In a next step, a manipulation handle is attached to each of the temporary rods. By means of the manipulation handles, the operating surgeon can apply corrective forces to each end of the target spinal column section and correct these segments and all intermediate segments.

During the procedure, repetitively one or more temporarily rods is/are placed and fixated on the contralateral side. These rods are individually manually bent and shaped. The shape is based on a correction that has been obtained in a given correction step. After preparation of the next correction step, the rod(s) is/are removed, and by manipulating the handles, the spine is further corrected towards the planned physiological shape. Now, a next temporary rod needs to be placed.

The above-described step is repeated several times. The surgeon manually controls corrections in different anatomical planes, and further controls the rotational shape of the spine. One further important aspect to be controlled is the length of the spine. When a curved spine is made more straight, the length is influenced which causes tensile or compressive stresses to the nerve structures and the spinal cord. Larger corrections of the spine must be considered critical, and these corrections are time consuming surgeries due to the step-by-step correction and the repeatedly placed temporary rods.

Thus, in view of the above, there is a need for an improved spinal correction tool assembly that provides a surgeon with a gradual and independent control of the procedure for independently managing coronal, and/or sagittal deformities, and for independently being able to de-rotate and adapt a translation or length of the involved elements in the cases of severe deformities. Furthermore, for less severe deformities, a spinal correction tool assembly is needed that allows the surgeon to control all correction directions at once, and instantaneously and rigidly fixate the desired and achieved correction.

SUMMARY OF THE INVENTION

It is an object of the present invention to overcome at least some of the problems associated with the correction or restoration of the alignment of the spinal column prior to the final fixation of posterior spinal stabilisation constructs. There is a need for a spinal correction tool assembly that provides the ability and flexibility of correcting the spinal column in the cases, where an instrument-based gradual and controlled correction is necessary prior to the placement of the final rod implant.

According to a first aspect of the invention, there is provided a spinal correction tool assembly as recited in claim 1.

The spinal correction tool assembly is intended for gradually correcting the spinal column and for stabilising the spinal column before placement of a rod implant into pedicle screws. The spinal correction tool assembly comprises two manipulation tools, at least one articulating joint, and at least one elongated connection instrument or member. The manipulation tools are configured as elongated handles to be attached to an in-situ spinal stabilisation system, and they each comprise a lockable coupling for connecting to the elongated connection instrument or to the articulating joints. In one example, the lockable coupling may be configured as a freely rotatable and lockable sphere, which forms an articulating joint with three rotational degrees of freedom. The articulating joints are sized and shaped to receive the elongated connection instrument. According to a second example, the attachment is fixed and the articulating joint including three rotational degrees of freedom is an integral element of the connection instrument and arranged between the manipulation tools. In this example, the articulating joint is configured as a universal joint or Hooke's joint and it comprises securing mechanisms for independently locking at least one axis of rotation. The spinal correction tool assembly provides the surgeon with the ability and flexibility to correct the spinal column in the cases, where an instrument-based gradual and controlled correction is necessary prior to the placement of the final rod implant.

According to a second aspect of the invention, there is provided a method of operating the spinal correction tool assembly according to the first aspect to thereby gradually correct combined deformities. The method includes the ability of independently controlling and fixating coronal, and/or sagittal corrections, and of independently being able to correctively de-rotate the spinal column and adapt a translation or length of the involved elements.

Other aspects of the invention are recited in the dependent claims attached hereto.

BRIEF DESCRIPTION OF THE DRAWINGS

Other features and advantages of the invention will become apparent from the following description of non-limiting example embodiments, with reference to the appended drawings, in which:

- Figures 1A and 1B depict a correction tool assembly according to a first embodiment of the invention;
- Figures 2A to 2E depict the articulating joint member including the elongated connecting instruments in multiple perspective views;

- Figures 3A and 3B depict a translation and rotation mechanism of the correction tool assembly in a planar cross-sectional view, and in a perspective partial cross-sectional view, respectively;
- Figures 4A to 4D depict the operation of a dial to limit maximal rotation;
- Figures 5A to 5L depict a surgical procedure using the correction tool assembly according to the first embodiment of the invention;
- Figures 6A and 6B depict a correction tool assembly according to a second embodiment of the invention;
- Figures 7A and 7B depict the manipulation tool according to the second embodiment of the invention in two perspective views;
- Figures 8A and 8B depict a clamping sphere and an elongated connecting member in two perspective views;
- Figures 9A to 9D depict the activation of a toggle clamp mechanism in cross-sectional and perspective views;
- Figure 10 depicts a mobility control mechanism in detail;
- Figures 11A to 11M depict a surgical procedure using the second example correction tool assembly; and
- Figures 12A to 12 D depict the functionality and importance of the sliding capability of the example correction tool assemblies in a practical example.

DETAILED DESCRIPTION OF THE INVENTION

The embodiments of the present invention will now be described in detail with reference to the attached figures. The embodiments are described in the context of a spinal correction tool assembly and a posterior spinal stabilisation construct, used to correct a scoliotic spinal column. Although the invention is specifically described in this context, the teachings of the invention are not limited to this environment. When the words first and second are used to refer to different elements, it is to be understood that this does not necessarily imply or mean that the first and second elements are somehow structurally substantially different elements or that their dimensions are substantially different unless specifically stated. A bone fastener in this context means a structural element, which can be brought into the target bone, and forms a stabile connection between the target bone and the remaining spinal construct. Most often, a bone fastener is a fastening element, such as a pedicle screw. Identical or corresponding functional and structural elements which appear in the different drawings are assigned the same reference numerals.

Figures 1A and 1B show a first example surgical spinal correction tool assembly 1 according to the first embodiment in an assembled view, and in a disassembled view, respectively. The correction tool assembly 1 comprises a manipulation tool 10, a first elongated connection member or instrument 30, a second elongated connection member or instrument 40, and an articulating joint member 60. The articulating joint member is arranged between the manipulation tools, and the first and second elongated connection members 30, 40 connect the articulating joint member to the manipulation tools. The first and second elongated connection members 30, 40 are in this example configured as a first rod 31 and a second rod 41, and collectively form an elongated connection arrangement.

The manipulation tool 10 comprises an elongated tool shaft 11 extending between a handling end 12 and an attachment end 13 for attachment to an in-situ spinal stabilisation system 2 or possibly directly to a pedicle screw. Furthermore, the manipulation tool 10 comprises a lockable coupling 14 having a locked and unlocked state for connection to the elongated connection members 30, 40. In the depicted example, the lockable coupling 14 is configured as a clamping mechanism 15 sized and shaped to rigidly fixate the elongated connection members 30, 40 to the manipulation tool 10. The clamping mechanism may be arranged in a fixed orientation in relation to the tool shaft 11, but alternatively, it may be flexible or rotatably linked to the tool shaft and have multiple rotational degrees of freedom. In this example, the lockable coupling 14 includes a threadedly engaged grooved knob 16 for locking and unlocking the clamping mechanism. The manipulation tool 10 further comprises an ergonomic grip 17 at a first handle end 18 for manipulation and applying forces and torques to the spinal construct 2 and vertebral bodies, as described in greater detail later.

Figures 2A to 2E depict the articulating joint member 60 together with the elongated connection members 30, 40 in multiple perspective views. A disassembled view 2B depicts the multiple single components of the articulation joint. The exploded views 2D and 2E depict details of certain components, which are formed of multiple parts, and which after assembly are inseparably connected together. The articulating joint member 60 is configured as a modified universal joint, gimbal joint or Hooke's joint, and it comprises three articulating sections 65, 66, 67, each providing different mechanical degrees of freedom to the correction tool assembly 1. In the present example, a first articulating section 65 of the articulating joint is formed as a pinned-sphere coupling. The articulating joint 60 comprises a central sphere 61 forming the base 62 of the articulating joint. A first rotation member or bracket 63, and a second rotation member or bracket 64 have or define a first axis of rotation AR1, and a second axis of rotation AR2, respectively, and which are rotatably coupled to the base 62. In this example, the first and second brackets extend along the circumference of the central sphere over a rotation angle of approximately 180 degrees. Moreover, the first and second axes of rotation AR1, AR2 are oriented orthogonally or substantially orthogonally to each other. According to the present example, the first and second axes of rotation intersect in a rotation centre area or region ”C”.

The first and second brackets can be locked by a first securing mechanism 68, and a second securing mechanism 69, respectively. In this example the securing mechanisms are configured as a first threaded wing nut mechanism 70, and a second threaded wing nut mechanism 71. The first and second wing nut mechanisms are engaged over a first threaded projection 72, and a second threaded projection 73, respectively. In this example, the first and second threaded projections 72, 73 are monolithically connected to the central sphere and align with or form the first and second axes of rotation AR1, AR2. By tightening the wing nuts, a portion of the brackets will mate in a forceful manner with the central sphere and motion of the brackets is inhibited. Alternatively, the secured state can be achieved by a form-fit over meshing teeth, rough structures, etc., or by combinations thereof. Each axis comprises or defines a secured or locked and unsecured or unlocked state. Alternatively, other mechanisms can be used for securing and releasing, such as lever mechanisms, eccentric mechanisms, toggle mechanisms, bayonet mechanisms, etc. Furthermore, the first bracket is engaged over a third threaded projection 74, which is arranged at the opposite side of the central sphere. The third threaded projection is also configured to receive the first wingnut. This way the articulating joint member can be assembled in a mirror image manner, depending on the preferences of the user.

As depicted in more detail in the exploded view of Figure 2D, the first bracket 63 comprises a first extension 76 with a first extension axis EA1, which extends away from the bracket. The first extension is sized and shaped to receive the first connection member 30 and forms the second articulating section 66 of the articulating joint member 60. In this example, the first connection member 30 is rotatably-free coupled with the first extension 76 and can rotate around a third axis of rotation AR3. The third axis of rotation is oriented substantially orthogonally to the first axis of rotation AR1 and intersects the rotation centre region “C”. It is to be noted that the axes can be numbered in any other manner instead, for example so that the third axis is referred to as AR1 or AR2 in the drawings, and the second axis could be referred to as AR1 or AR3 in the drawings. Moreover, one end the first connection member 30 comprises an integrated third securing mechanism 34, which is configured as an eccentric latching mechanism 35, having a swivelable lever 36. The lever is made to forcefully engage against the first extension 76 by moving the lever, and in this manner, the rotation of the first elongated connection member 30 around the third central axis AR3 can be inhibited. The first extension 76 and the first connection member 30 are coupled by a pin-in-groove coupling 78, to inhibit any translational movement but to provide rotational freedom. Alternative coupling mechanisms, such as snap mechanisms, etc., may provide the same effect. Alternatively, other mechanisms can be used for securing and releasing, such as lever mechanisms, eccentric mechanisms, toggle mechanisms, bayonet mechanisms, etc. The articulating joint 60 can comprise at least one scale or marking 77 (as shown in Figure 3B) to give feedback on the rotation or translation of the elongated connection members 30, 40.

The second bracket 64, as depicted in more detail in the exploded views of Figures 2D and 2E, comprises a second extension 80 with a second extension axis EA2, which extends away from the second bracket. The second extension is sized and shaped to receive the second connection member 40 and forms the third articulating section 67 of the articulating joint member 60. The second connection member 40 is axially movably coupled with the second extension 80 and can translate along a first axis of translation AT1. The first axis of translation is oriented substantially orthogonally to the second axis of rotation AR2. According to the present example, the first axis of translation AT1 intersects the rotation centre region “C”.

In order to provide a means for a controlled translation of the second connection member 40, the correction tool assembly, and in this example in particular the second extension 80 comprises an integrated translating mechanism 81 configured as a spindle mechanism. A rotatable knob 83 is arranged at the end of the second extension, and it comprises an internal spindle thread or helix 84 (shown in Figure 3B). The second connection member 40 comprises a spindle end 42 including a counter-feature or a complementary-shaped feature, which is configured as an external spindle helix 43. The rotatable knob is coupled to the second extension 80 by means of a second pin-in-groove connection 87 (shown in Figure 3B). A spindle mechanism is defined as two helically coiled elements, having a defined complementary shape, where upon rotating one element, the other element translates along a defined path. As depicted, the spindle end 42 comprises at least one rotationally asymmetric face 43. The spindle end 42 is sized and shaped to engage in an at least partly complementary-shaped channel extending in the second extension 80. The internal spindle helix 84 and the external spindle helix 43 are configured to simultaneously mesh or to be engaged with each other. The integrated translating mechanism 81 forms a fourth securing mechanism 86, inhibiting unwanted translation in any direction. In this example, the second elongated connection member 40 can be disassembled for cleaning and reprocessing reasons. Furthermore, the central sphere comprises a recess 85 extending through the central sphere.

The recess provides a clearance for the spindle end 42 with the purpose of reducing the overall size of the correction tool assembly.

Figures 3A and 3B show the previously described mechanisms in a planar cross-sectional view, and a perspective partial cross-sectional view, respectively.

Figures 4A and 4D show an additional mechanism. In this example, the articulating joint comprises a stop mechanism 100 for limiting the maximal angular rotation from a first position into a second position around at least one of the axes of rotation. In this example, the rotation around the second axis of rotation AR2 is limited. The stop mechanism is configured as a dial 101 including a curved slot 102. The curved slot is configured to encompass a stop pin 103 which protrudes from the second bracket 64. The curved slot for example extends over a twenty-degree path and could limit the motion to maximally twenty degrees. The curved slot comprises a first slot end seat 106 and a second slot end seat 107. Furthermore, the dial 101 is engaged over a third threaded projection 104 (shown in Figure 2B) extending from the central sphere 61. The third threaded projection is configured to receive a third wing nut 105, and the dial is thus arranged between the third wing nut 105 and a mating area 106 of the central sphere 61. By tightening the wing nuts, the dial will mate in a forceful manner against the central sphere and any motion of the dial is inhibited.

Figures 4A to 4D also depict the operation of the dial 101. Figure 4A shows the first and second connection members 30, 40 being oriented in a start angle in relation to each other. The dial is in a unlocked state. All other securing mechanisms are secured. Figure 4B shows the rotation of the dial towards an end position, in which the first slot end seat 106 engages with the stop pin 103. Tightening of the third wing nut locks the dial in the end position. The curved slot is free between the second slot end 107 and the stop pin. Figure 4C depicts the release of the second securing mechanism, providing freedom for the second connection member to rotate around the second rotation axis. The dial remains arranged in a fixed spatial relationship with the central sphere. During this motion, the stop pin travels within the curved groove towards the second end seat 107 which forms the limit for the maximal rotation, as depicted in Figure 4D.

According to a variant of the invention, the correction tool assembly comprises a plurality of modular stop mechanisms for limiting the maximal angular rotation from a first position into a second position, where the modular stop mechanisms define different maximal rotation angles.

Figures 5A to 5L depict example surgical steps utilising the correction tool assembly 1 according to the first embodiment. Figure 5A depicts a spinal column portion having eight vertebrae having a combined deformity of a scoliosis and an excessive kyphosis. In each vertebra, two pedicle screws 3a, 3b, 3x are implanted. Figures 5B and 5C depict the placement of two temporary rods 4, linking the last two vertebrae at each end of the spinal column portion. The temporary rods are rigidly fixated into the pedicle screw heads by using set screws 5.

Figure 5D shows the attachment of two manipulation tools 10 to the temporary rods 4. The attachment end 13 is fixated to the rod. In the present example, a locking bolt, integrated in the attachment end, fixates the temporary rod and the manipulation tool in relation to each other. Figure 5E shows the assembly of the first and second connection members 30, 40 including the articulating joint 60 arranged between the first and second connection members 30, 40, which are secured in the clamping mechanisms 15 in a neutral position, representing the pathological situation of the spinal curvatures.

Figure 5F shows a first correction step, where the coronal alignment is restored. The first securing mechanism 68 is unlocked, and therefore the first bracket 63 can rotate. By applying force to the manipulation tools, the scoliosis is corrected. After reaching the desired correction, the first bracket is secured to maintain the correction. During the correction, i.e. during the straightening of a curvature, the length of the spine will change. Therefore, during this movement, by means of actuating the translating mechanism 81, the distance between the manipulation tools may be changed, to accommodate this change of length.

Figure 5G shows a second correction step, where the sagittal alignment is restored. The second securing mechanism 69 is unlocked, and therefore the second bracket 64 can rotate. By applying force to the manipulation tools, the kyphosis is corrected. After reaching the desired correction, the second bracket is secured to maintain the correction. During the correction, i.e. during the straightening of a curvature, the length of the spine will change. Therefore, during this movement, by means of actuating the translating mechanism 81, the distance between the manipulation tools may be changed, to accommodate this change of length. It is to be noted that Figures 5F and 5G depict the correction in two steps. Most commonly, multiple small correction steps are required to restore a curvature, and the corrected position needs to be secured and released at several positions. Also during the corrective steps, bony and soft tissue structures need to be managed, for example to prevent nerves from getting pinched. Moreover, during the correction steps, a combined de-rotation may be needed. Therefore, the third securing mechanism 34 of the first elongated connection member may need to be released and secured.

Figure 5H depicts the spinal column portion from the opposite side. A first long rod 6 is inserted into the heads of the pedicle screws. In this example, the rod extends over all the vertebrae and thus links all the vertebrae. Figure 5I depicts the placement of the set screws. Each vertebral body is rigidly locked to the rod. Figure 5J depicts the removal of the correction tool assembly and the temporary rods. Figures 5K and 5L depict the placement of a second long rod and the placement of the set screws. The eight-vertebral-body spinal column portion is corrected and rigidly stabilised. The surgical method as described in connection with Figures 5A to 5L explains the surgical method wherein stepwise different deformity directions are corrected. It is to be noted that the securing mechanisms of the correction tool assembly can be released and secured simultaneously during one correction step to allow for instantaneous corrections in multiple directions.

Figures 6A and 6B show a correction tool assembly 1 according to the second embodiment in an assembled view, and in a disassembled, respectively. The correction tool assembly 1 comprises a first manipulation tool 10, a second manipulation tool 10, a first elongated connection member 30, and a first articulating joint member 60a, and a second articulating joint member 60b. One articulating joint member is arranged within each manipulation tool, and engaged over the first elongated connection member 30 linking the manipulation tools 10. In this example, the first elongated connection member 30 is configured as a square or rectangular rod 31 (having a rectangular, substantially rectangular, square or substantially square cross section orthogonally to the longitudinal axis of the elongated connection member 30), and the articulating joint member is configured as a clamping sphere 110. According to the example configuration shown e.g. in Figures 6A and 6B, the elongated connection arrangement is composed of only one elongated connection member. Thus, in this case, the correction tool assembly is a single connection member correction tool assembly.

Figures 7A and 7B show the manipulation tool 10 according to the second embodiment in two perspective views. The manipulation tool comprises a tool shaft 11 extending between a handling end 12 and an attachment end 13 for attachment to an in-situ spinal stabilisation system 2. The manipulation tool 10 also comprises a lockable coupling 14 for securing or locking the clamping sphere 110 and thus to releasably secure the elongated connection member 30 to the coupling 14. Hence, the lockable coupling defines a locked state and an unlocked state. In the depicted example, the lockable coupling 14 is configured as a clamping mechanism 15 sized and shaped to rigidly fixate the clamping sphere 110. More specifically, the clamping mechanism 15 is in this example configured as a knee lever or a toggle clamp mechanism 120 as shown in greater detail in Figures 9A to 9D. The toggle clamp mechanism 120 allows a theoretically infinite clamping force to be exerted onto the clamping sphere. To operate the toggle clamp mechanism 120, the manipulation tool in this example comprises a locking lever 121, a follower lever 122 and a release button 123 (shown in Figure 9B). For ergonomics and comfort of handling, the locking and follower levers are integrated in the grip 17. To hold the clamping sphere 110, the manipulation tool 10 comprises a socket 123. The socket has an outer periphery OP which is smaller than the major diameter MD of the clamping sphere. The manipulation tool further comprises the grip 17 at a handle end 12 for manipulation and for applying forces and torques to the spinal construct and vertebral bodies, as described in greater detail later.

Figures 8A and 8B depict the clamping sphere 110 and the assembled elongated connection member 30 in detail. The clamping sphere 110 comprises a first or an upper half 111, and a second or a lower half 112, which are separated by a slot 113 almost fully extending through the clamping sphere in a direction orthogonal to the longitudinal axis of the elongated connection member. At one end, the upper and lower halves are connected by a thin elastic hinge 114. The slot is shaped as a thin slot having a larger channel 115 in the middle, which is sized and shaped to receive the elongated connection member 30 in a sliding manner. In this example the channel 115 has a square-shaped cross section, and thus the elongated connection member 30 has a complementary cross-sectional shape. The advantage of the square shape is that rotation within the clamping sphere is inhibited, and a square rod provides increased stability. It is to be noted that other cross-sectional shapes may provide a comparable effect.

Figures 9A to 9C illustrate the operation of the toggle clamp mechanism 120 in three cross-sectional views, and an exploded view of Figure 9D provides better details of the individual components. Figure 9A shows the toggle clamp mechanism 120 in an open or unlocked configuration. The toggle clamp mechanism 120 comprises a first toggle clamp link 125 or locking lever 121 having a first distal end 126, and first proximal end 127, and a second toggle clamp link 128 or follower lever 122 having a second distal end 129, and a second proximal end 130. A toggle clamp frame 124, formed by the tool shaft 11 and the grip 17, holds the second toggle clamp link 128. A centrally arranged first hinge joint 131, and a proximally arranged second hinge joint 132 couple the second toggle clamp link 128 to the frame 124. Furthermore, a third combined hinge and sliding joint 133 couples the first toggle clamp link

125 to the toggle clamp frame 124. The third joint provides a swivelling and translational degree of freedom to the first toggle clamp link 125. In this example, the first toggle clamp link 125 has a first length L1 and the second toggle clamp link 128 has a second length L2, where the first length is greater than the second length. The first toggle clamp link 125 is arranged distally with respect to the second toggle clamp link 128.

The locking lever 121 further comprises a first lever extension 135, which in this example is a curved lever extension, extending proximally from the first toggle clamp link 125, which increases the levering arm for handling purposes. The first lever extension 135 forms a handling area for the user to activate the toggle clamp mechanism 120 by pressing the first lever extension 135 towards and into the grip 17. The extension increases the lever-arm and amplifies the input force to provide a greater output force and clamping force. The lever extension is arranged at a first side of the grip 17. The first toggle clamp link 125 comprises a clamping sphere engagement area or surface 136 at its distal end. This engagement area 136 is configured to press against the clamping sphere in the locked configuration.

The first toggle clamp link 125 comprises a second lever extension forming a release button 123 as explained in greater detail later. The release button 123 extends through the grip 17 towards a second side of the grip 17. In this example, in the unlocked configuration, the release button 123 is arranged inside the grip 17, whereas in the locked configuration the outer surface of the release button 123 is flush or substantially flush with the outer face or surface of the grip 17.

In the depicted example, the clamping sphere 110 is arranged to be received by the socket 123, and it encompasses the elongated connection member. The socket 123 is part of the toggle clamp frame or toggle clamp main body 124.

In the unlocked configuration of Figure 9A, the second and third hinge joints 132, 133 are aligned, and the first hinge joint 131 is misaligned. The joints are thus arranged in a triangular manner. The distal end of the first toggle clamp link 125 is spaced apart from the clamping sphere, and the clamping sphere 110 can rotate within the socket. Furthermore, a play between the clamping sphere 110 and the first toggle clamp link 125 provides translational freedom of motion for the elongated connection member. The release button 123 is arranged within the grip 17 and the locking lever 121 is arranged outside the grip 17.

Figure 9B shows the locked configuration. In the locked configuration, all the elements of the toggle clamp mechanism 120, the clamping sphere 110 and the elongated connection member 30 are rigidly blocked. In the locked configuration, the first, second and third joints 131, 132, 133 are aligned or substantially aligned in a so-called dead centre position, or have minimally exceeded the dead centre position and form a self-restricting state. By aligning the three joints, the triangular arrangement of the unlocked configuration is altered into a linear arrangement. As a result, the distance between the second and third joints 132, 133 is increased, and the clamping sphere engagement area 136 travels towards and against the clamping sphere. Upon engagement, the clamping sphere is deformed towards the elongated connection member and simultaneously pressed into the socket 123. Figure 9C shows the release step. By pressing the release button 123, the toggle clamp mechanism 120 is pressed over the dead centre position, and the mechanism is opened. The advantage of the toggle clamp mechanism 120 is that it works according to the knee lever principle and can be operated with little expenditure of force. Furthermore, locking or self-restriction is guaranteed if the dead centre position (i.e., the alignment of the joints) is exceeded. Very high clamping forces can be achieved with toggle clamps. In theory, when ignoring friction in the joints, at the moment of alignment of the joints, an infinite clamping force is present.

Figure 10 shows a variant of the toggle clamp mechanism 120. After releasing the self-restriction state by pressing the release button 123, all the elements of the toggle clamp mechanism 120 can move freely. In theory, the toggle clamp can be opened completely allowing the clamping sphere 110 to be disengaged out of the socket 123. In order to limit this movability, a control mechanism 137 is integrated in the second toggle clamp link 128. In this example, the control mechanism 137 is configured as a leaf spring 138 that mates with the grip 17 and provides an ergonomic level of friction.

Figures 11A to 11M illustrate example surgical steps utilising the correction tool assembly according to the second embodiment. Figure 11A depicts an eight-vertebral-body spinal column portion having a combined deformity of a scoliosis and an excessive kyphosis. In each vertebra, two pedicle screws 3 are implanted. Figures 11B and 11C depict the placement of two temporary rods 4, linking the last two vertebrae at each end of the spinal column portion. The temporary rods are rigidly fixated into the pedicle screw heads by using set screws 5.

Figure 11D shows the attachment of two manipulation tools 10 to the temporary rods 4. The attachment end 13 is fixated to the rod. In the present example, a locking bolt, integrated in the attachment end, fixates the temporary rod and the manipulation tool in relation to each other. Figure 11E shows the assembly of the first connection member 30, including two clamping spheres 110, encompassing the first connection member 30.

Figure 11F shows a first correction step, where the coronal alignment is restored. The toggle clamp mechanism 120 is unlocked, and therefore the clamping sphere 110 can rotate within the socket 123. The elongated connection member 30 can slide in the clamping sphere. By applying force to the manipulation tools, the scoliosis is corrected. After reaching the desired correction, the toggle clamp mechanism 120 is secured to maintain the correction. During the correction, i.e. during the straightening of a curvature, the length of the spine will change. Therefore, during this movement, the elongated connection member 30 can translate within the clamping sphere 110 to accommodate this change of length.

Figure 11G shows a second correction step, where the coronal alignment is restored. The toggle clamp mechanism 120 is unlocked, and therefore the clamping sphere 110 can rotate within the socket 123. The elongated connection member 30 can slide in the clamping sphere. By applying force to the manipulation tools, the kyphosis is corrected. After reaching the desired correction, the toggle clamp mechanism 120 is secured to maintain the correction. During the correction, i.e. during the straightening of a curvature, the length of the spine will change. Therefore, during this movement, the elongated connection member 30 can translate within the clamping sphere 110 to accommodate this change of length. It is to be noted that Figures 11F and 11G depict the correction in two steps. Most commonly, multiple small correction steps are required to restore a curvature, and the corrected position needs to be secured or fixed and released at several positions. Also during the corrective steps, bony and soft tissue structures need to be managed, for example to prevent nerves from getting pinched.

Figure 11H depicts the corrected spine, where the correction is maintained by instruments only. Figure 11I depicts the spinal column portion from the opposite side. A first long rod 6 is inserted into the heads of the multiple pedicle screws. In this example, the rod extends over all the vertebrae and thus links all the vertebrae. Figure 11J depicts the placement of the set screws. Each vertebral body is rigidly locked to the rod. Figure 11K depicts the removal of the correction tool assembly and the temporary rods. Figures 11L and 11M depict the placement of a second long rod and the placement of the set screws. The eight-vertebral-body spinal column portion is corrected and rigidly stabilised.

Referring to Figures 12A to 12D, the functionality of the sliding capability of the example correction tool assemblies is illustrated. The scenario illustrates a spine that is bent in the coronal plane because of deformity and anomaly related to congenital disorders, trauma, infection or neoplastic disease. In these cases, a three-column osteotomy in the form of a vertebral column resection or pedicle subtraction osteotomy causes a disconnection between the next-adjacent proximal and distal spinal column. To prevent injury to the spinal cord, the disconnected spinal column portions are bridged and stabilised with the spinal correction tool assembly 1. The correction is made by a gradually controlled and tracked correction. By management of the four axes AR1, AR2, AR3 and AT1, the centre of rotation of the correction is precisely definable. As depicted, the centre of rotation COR is ideally arranged at the centre of the spinal cord. Hence, the gradual step-by-step correction of the deformed spine towards a physiologic shape can be achieved without causing significant shortening or distraction of the cord and neural elements. By means of operating the fourth securing mechanism 86, the distance X1, X2, X3 between the manipulation tool 10 and the centre of the articulating joint 60 can be altered. Once the correction is made, the contralateral side is connected with a final rod 6, the correction tool assembly is removed and the ipsilateral side is fixated by another final rod.

To summarise the above teachings, the securing arrangement 14, 68, 69, 34, 86 is configured to inhibit or prevent the rotation of the articulation joint arrangement 60, 60a, 60b or part of it around at least one axis of rotation AR1, AR2, AR3, or in some implementations around at least two of the axes of rotation AR1, AR2, AR3, or the securing arrangement is configured to inhibit or prevent the rotation of the articulation joint arrangement 60, 60a, 60b around at least one of the axes of rotation and the translation of an elongated connection arrangement (comprising one or more connection members 30, 40) along the translation axis AT1. The articulation joint arrangement may comprise one articulating joint 60. Alternatively, the articulation joint arrangement may comprise at least a first articulating joint member 60a and a second articulating joint member 60b, which may define their individual rotation and/or translation axes, but the members may instead be considered to define common rotation and/or translation axes. The rotation axes AR1, AR2, AR3 may be orthogonally arranged, or at least two of these axes may be oriented orthogonally or substantially orthogonally to each other, and they intersect at a respective rotation centre region C, and they provide polyaxiality to the articulation joint arrangement 60, 60a, 60b.

While the invention has been illustrated and described in detail in the drawings and foregoing description, such illustration and description are to be considered illustrative or exemplary and not restrictive, the invention being not limited to the disclosed embodiments. Other embodiments and variants are understood, and can be achieved by those skilled in the art when carrying out the claimed invention, based on a study of the drawings, the disclosure and the appended claims. New embodiments or variants may be obtained by combining any of the above teachings.

In the claims, the word “comprising” or “including” does not exclude other elements or steps, and the indefinite article “a” or “an” does not exclude a plurality. The mere fact that different features are recited in mutually different dependent claims does not indicate that a combination of these features cannot be advantageously used. Any reference signs in the claims should not be construed as limiting the scope of the invention.

CLAIMS

1. A spinal correction tool assembly (1) for realigning and/or stabilising spinal column segments, the correction tool assembly (1) comprising a first manipulation tool (10), a second manipulation tool (10), an articulation joint arrangement (60, 60a, 60b), and an elongated connection arrangement (30, 40), wherein

- the first and second manipulation tools (10) are configured as a tool shaft (11) extending between a handling end (12) and an attachment end (13) for attachment to an in-situ spinal stabilisation system (2), the first and second manipulation tools (10) comprising a first lockable coupling (14), and a second lockable coupling (14), respectively, for connection to the elongated connection arrangement (30, 40) or to the articulation joint arrangement (60, 60a, 60b),
- the articulation joint arrangement (60, 60a, 60b) has at least three axes of rotation (AR1, AR2, AR3) thereby providing polyaxiality to the articulation joint arrangement (60, 60a, 60b), and
- the elongated connection arrangement (30, 40) is connected to the articulation joint arrangement (60, 60a, 60b) to thereby connect the first and second first manipulation tools (10) to each other,

wherein the spinal correction tool assembly (1) comprises a securing arrangement (14, 68, 69, 34, 86) configured to inhibit rotation of the articulation joint arrangement (60, 60a, 60b) around at least one of the axes of rotation (AR1, AR2, AR3).

2. The spinal correction tool assembly (1) according to claim 1, wherein the spinal correction tool assembly (1) comprises a translation mechanism (81, 115) to allow at least a portion of the elongated connection arrangement (30, 40) to translate with respect to the articulation joint arrangement (60, 60a, 60b) along a translation axis (AT1), and wherein the securing arrangement (14, 68, 69, 34, 86) is configured to additionally inhibit translation of the at least a portion of the elongated connection arrangement (30, 40) along the translation axis (AT1), or to inhibit rotation of the articulation joint arrangement (60, 60a, 60b) around at least one further axis of rotation of the axes of rotation (AR1, AR2, AR3).

3. The spinal correction tool assembly (1) according to claim 2, wherein the articulation joint arrangement (60, 60a, 60b) comprises the translation mechanism (81, 115).

4. The spinal correction tool assembly (1) according to any one of the preceding claims, wherein the spinal correction tool assembly (1) comprises a translation mechanism (81) comprising a rotatable knob (83) threadedly engaged with the at least a portion of the elongated connection arrangement (30, 40), and configured such that rotating the knob causes the at least a portion of the elongated connection arrangement (30, 40) to translate with respect to the articulation joint arrangement (60, 60a, 60b) along the translation axis (AT1).

5. The spinal correction tool assembly (1) according to any one of the preceding claims, wherein the elongated connection arrangement (30, 40) comprises at least one elongated rod (31, 41).

6. The spinal correction tool assembly (1) according to claim 5, wherein the at least one elongated rod (31, 41) has a non-circular cross-section orthogonally to a longitudinal axis of the at least one elongated rod (31, 41).

7. The spinal correction tool assembly (1) according to any one of the preceding claims, wherein the securing arrangement (14, 68, 69, 34, 86) comprises a threaded connection (86) or a clamping mechanism (120).

8. The spinal correction tool assembly (1) according to any one of the preceding claims, wherein the articulation joint arrangement (60, 60a, 60b) comprises at least one scale, read-out or indicator (77) indicating the amount of angular rotation of the articulation joint arrangement (60, 60a, 60b) around at least one of the axes of rotation (AR1, AR2, AR3).

9. The spinal correction tool assembly (1) according to any one of the preceding claims, wherein the articulation joint arrangement (60, 60a, 60b) comprises a stop mechanism (100) for limiting the maximal angular rotation of the articulation joint arrangement (60, 60a, 60b) around at least one of the axes of rotation (AR1, AR2, AR3).

10. The spinal correction tool assembly (1) according to any one of the preceding claims, wherein the articulation joint arrangement (60, 60a, 60b) comprises a plurality of modular dials (101) defining different maximal rotation angles for limiting the maximal angular rotation of the articulation joint arrangement (60, 60a, 60b) around at least one of the axes of rotation (AR1, AR2, AR3).

11. The spinal correction tool assembly (1) according to any one of the preceding claims, wherein the articulation joint arrangement (60, 60a, 60b) comprises a first clamping sphere (110) configured to be engaged with the first lockable coupling (14) to thereby form a first ball-in-socket joint, and a second clamping sphere (110) configured to be engaged with the second lockable coupling (14) to thereby form a second ball-in-socket joint.

12. The spinal correction tool assembly (1) according to claim 11, wherein the first manipulation tool (10) comprises a first knee lever mechanism (120), and/or the second manipulation tool (10) comprises a second knee lever mechanism (120) for closing the first clamping sphere (110), and the second clamping sphere (110), respectively, to thereby inhibit translation and/or rotation of the elongated connection arrangement (30).

13. The spinal correction tool assembly (1) according to claim 11 or 12, wherein the first clamping sphere (110) is seated in a first socket (123) of the first manipulation tool (10), and the second clamping sphere (110) is seated in a second socket (123) of the second manipulation tool (10).

14. The spinal correction tool assembly (1) according to any one of claims 11 to 13, wherein the first clamping sphere (110) comprises a first channel (115) and the second clamping sphere (110) comprises a second channel (115) for receiving a portion of the elongated connection arrangement (30).

15. The spinal correction tool assembly (1) according to any one of the preceding claims, wherein the elongated connection arrangement (30, 40) is composed of only one elongated connection member (30).

16. The spinal correction tool assembly (1) according to any one of the preceding claims, wherein the elongated connection arrangement (30, 40) comprises an elongated connection member (30) connected through a first articulation joint member (60a) and a second articulation joint member (60b) of the articulation joint arrangement (60, 60a, 60b) to the first manipulation tool (10), and the second manipulation tool (10), respectively, or

wherein the elongated connection arrangement (30, 40) comprises a first elongated connection member (30) coupled to the first manipulation tool (10), and a second elongated connection member (40) coupled to the second manipulation tool (10), wherein the articulation tool arrangement (60, 60a, 60b) comprises an articulation joint (60) coupled to the first and second elongated connection members (30, 40), and wherein the articulation joint (60) comprises at least any two of a first securing mechanism (68), a second securing mechanism (69), a third securing mechanism (34), and a fourth securing mechanism (86) for individually inhibiting rotation of the articulation joint (60) around at least two of the axes of rotation (AR1, AR2, AR3), or around one of the axes of rotation (AR1, AR2, AR3) and translation along a translation axis (AT1).

17. The spinal correction tool assembly (1) according to any one of claims 1 to 10, wherein the elongated connection arrangement (30, 40) comprises a first elongated connection member (30) coupled to the first manipulation tool (10), and a second elongated connection member (40) coupled to the second manipulation tool (10), and wherein the articulation tool arrangement (60, 60a, 60b) comprises an articulation joint (60) coupled to the first and second elongated connection members (30, 40).

18. The spinal correction tool assembly (1) according to claim 17, wherein the articulation joint (60) is a universal joint connected to one end of the first elongated connection member (30), and to one end of the second elongated connection member (40).

19. The spinal correction tool assembly (1) according to claim 17 or 18, wherein the articulation joint (60) comprises at least any two of a first securing mechanism (68), a second securing mechanism (69), a third securing mechanism (34), and a fourth securing mechanism (86) for individually inhibiting rotation of the articulation joint arrangement (60, 60a, 60b) around at least two of the axes of rotation (AR1, AR2, AR3), or around one of the axes of rotation (AR1, AR2, AR3) and translation along the translation axis (AT1).

20. The spinal correction tool assembly (1) according to claim 19, wherein the first securing mechanism (68) is configured to block a movement of a first rotation member or bracket (63) around a circumference of the articulation joint (60), and the second securing mechanism (69) is configured to block a movement of a second rotation member or bracket (64) around the circumference of the articulation joint (60).

21. The spinal correction tool assembly (1) according to any one claims 17 to 20, wherein the second elongated connection member (40) is axially movably engaged with the articulation joint (60), and the articulation joint (60) comprises a fourth securing mechanism (86) for blocking translation of the second elongated connection member (40).

22. The spinal correction tool assembly (1) according to any one of claims 17 to 21, wherein the spinal correction tool assembly (1) comprises a translation mechanism (81) configured as a spindle mechanism.

23. The spinal correction tool assembly (1) according to any one of the preceding claims, wherein the axes of rotation (AR1, AR2, AR3) are oriented orthogonally or substantially orthogonally with respect to each other, and/or the axes of rotation (AR1, AR2, AR3) intersect at a rotation centre region (C).

24. A method of realigning and/or stabilising spinal column segments by means of operating the spinal correction tool assembly (1) according to any one of the preceding claims, the method comprising:

- unlocking the articulation joint arrangement (60, 60a, 60b) around a first axis of rotation (AR1, AR2, AR3) of the axes of rotation (AR1, AR2, AR3);
- correcting the spine around the first axis of rotation (AR1, AR2, AR3);
- securing the articulation joint arrangement (60, 60a, 60b) around the first axis of rotation (AR1, AR2, AR3);
- unlocking the articulation joint arrangement (60, 60a, 60b) around a second axis of rotation (AR1, AR2, AR3) of the axes of rotation (AR1, AR2, AR3);
- correcting the spine around the second axis of rotation (AR1, AR2, AR3); and
- securing the articulation joint arrangement (60, 60a, 60b) around the second axis of rotation (AR1, AR2, AR3).

25. The method of realigning and/or stabilising spinal column segments according to claim 24, wherein the articulation joint arrangement (60, 60a, 60b) is unlocked and secured individually around the first and second axes of rotation (AR1, AR2, AR3).

26. The method of realigning and/or stabilising spinal column segments according to claim 24 or 25, wherein the articulation joint arrangement (60, 60a, 60b) is unlocked around

the second axis of rotation (AR1, AR2, AR3) only after the articulation joint arrangement (60, 60a, 60b) has been secured around the first axis of rotation (AR1, AR2, AR3).

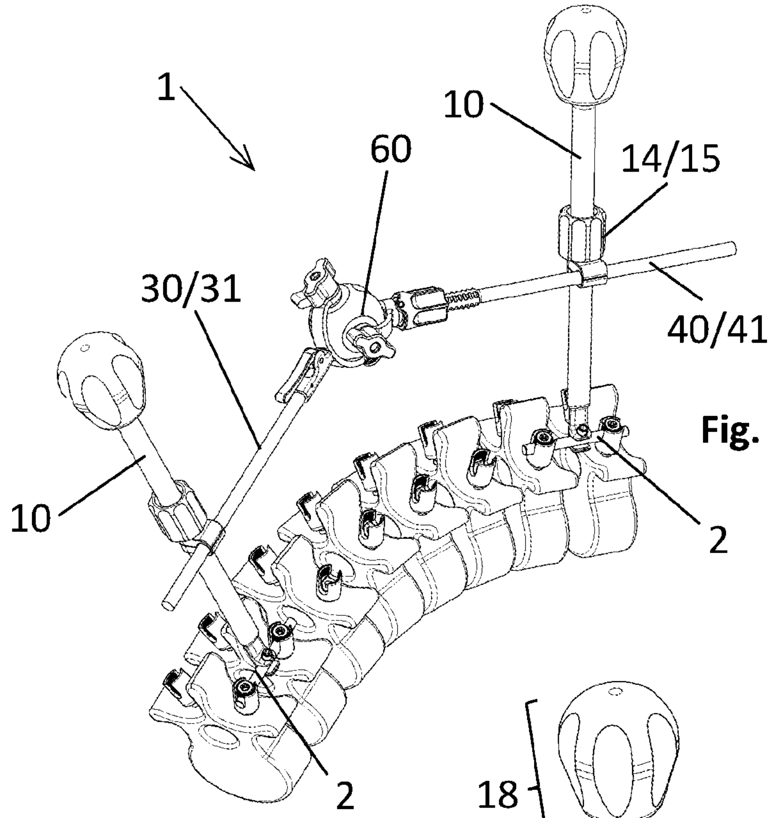

1
10
60
14/15
30/31
40/41
10
2
2

Fig. 1A

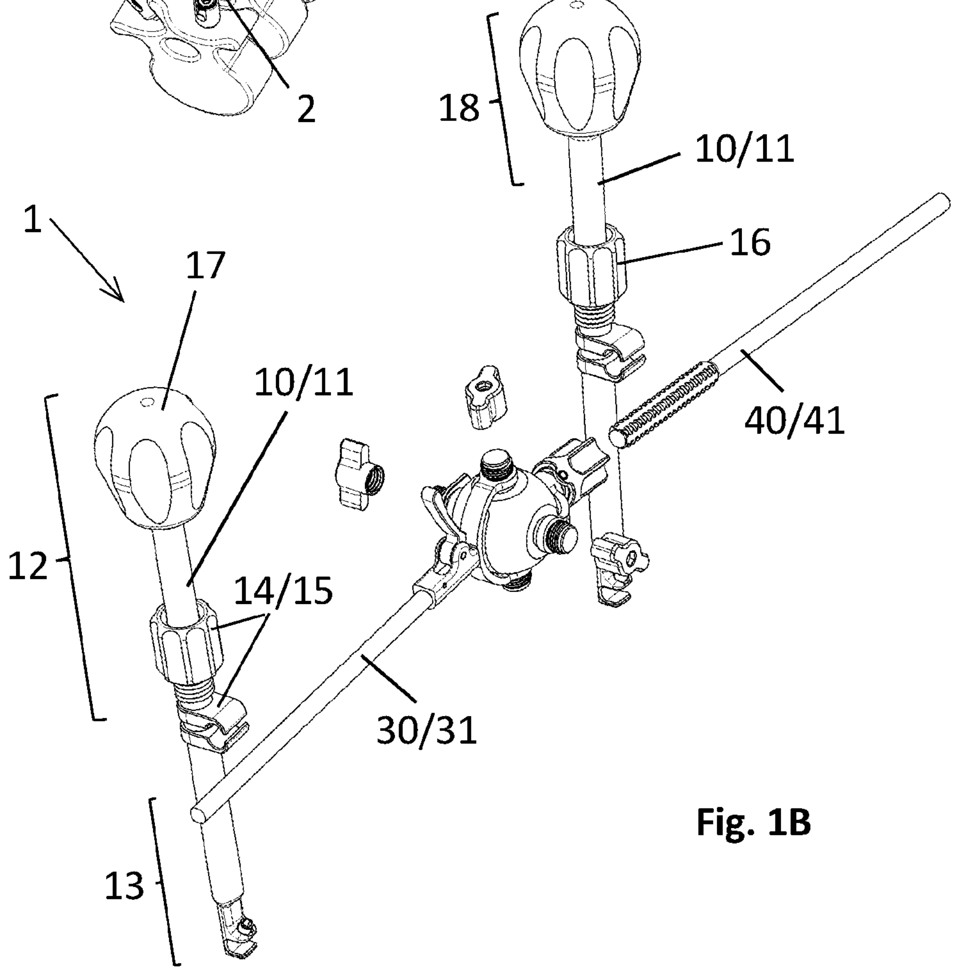

18
10/11
1
16
17
10/11
40/41
12
14/15
30/31
13

Fig. 1B

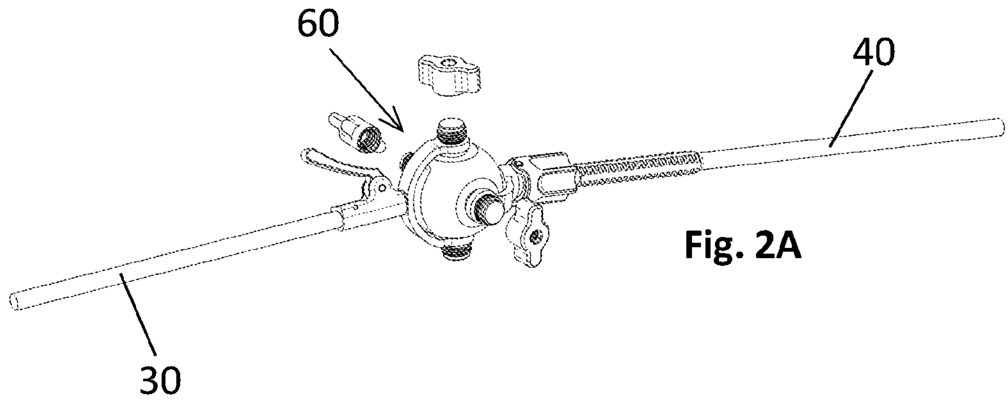


Fig. 2A

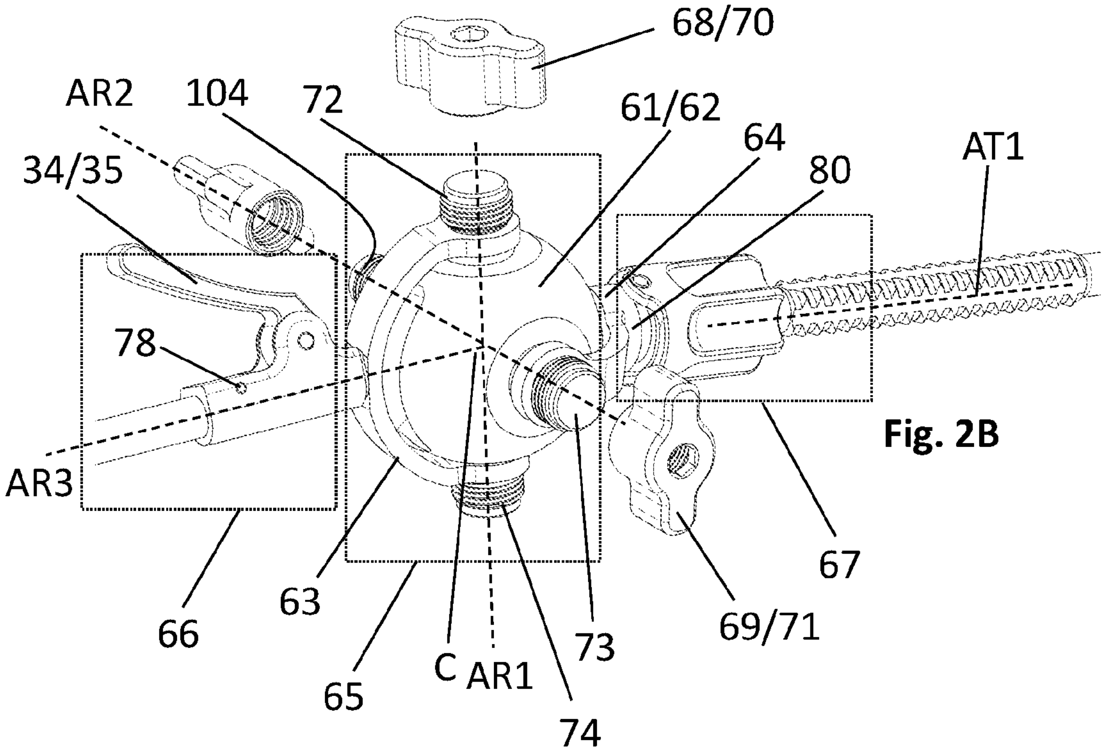


Fig. 2B

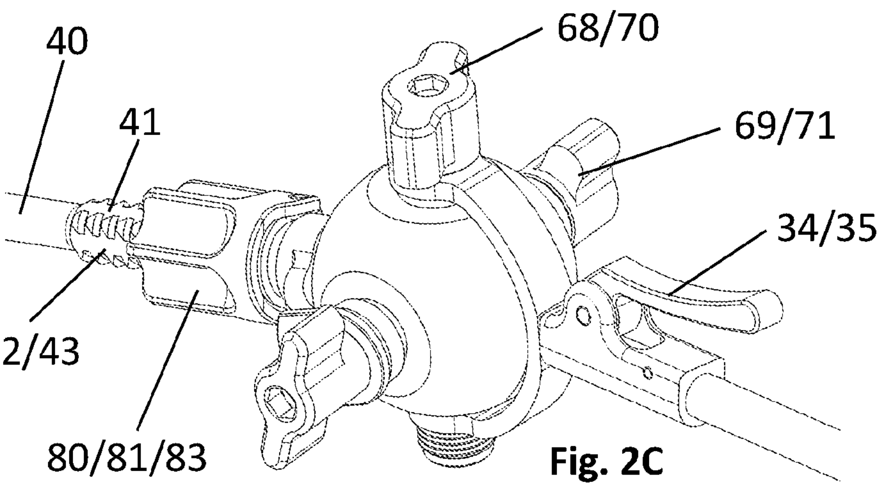


Fig. 2C

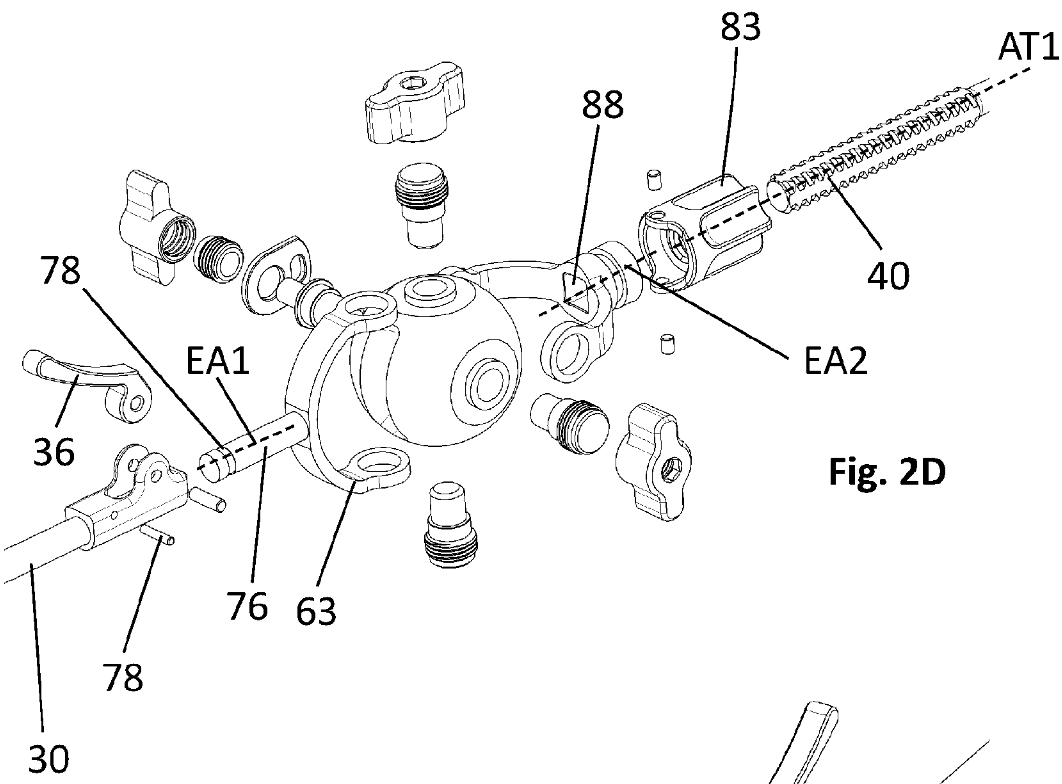


Fig. 2D

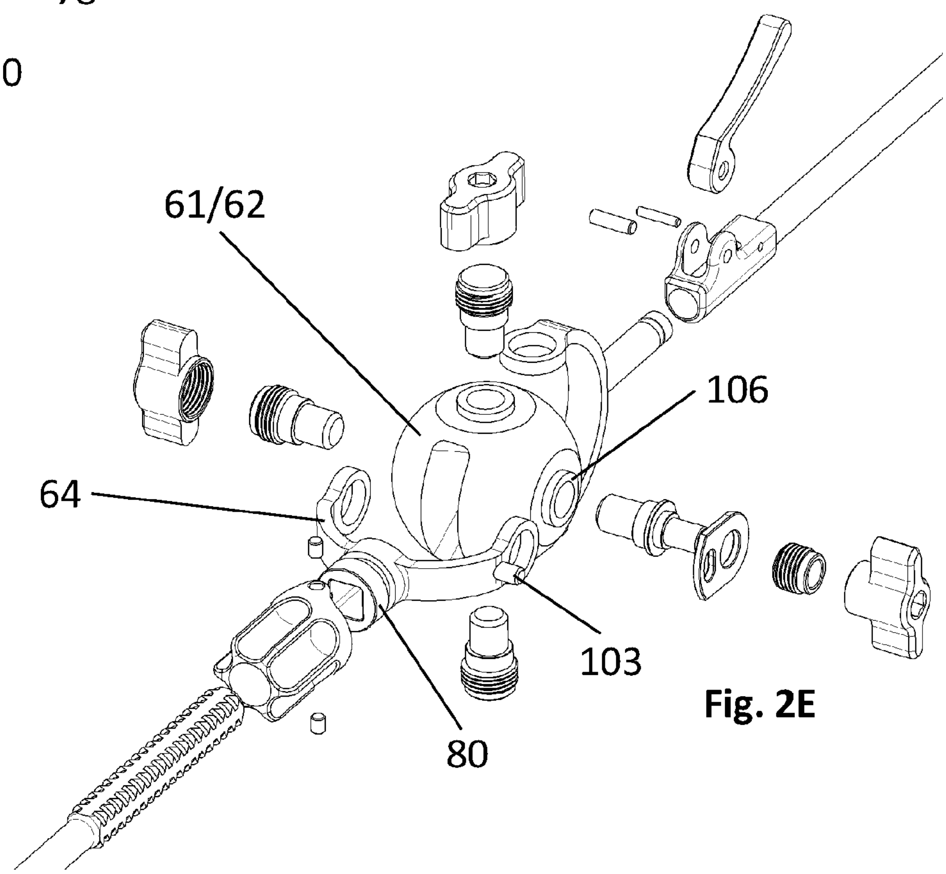


Fig. 2E

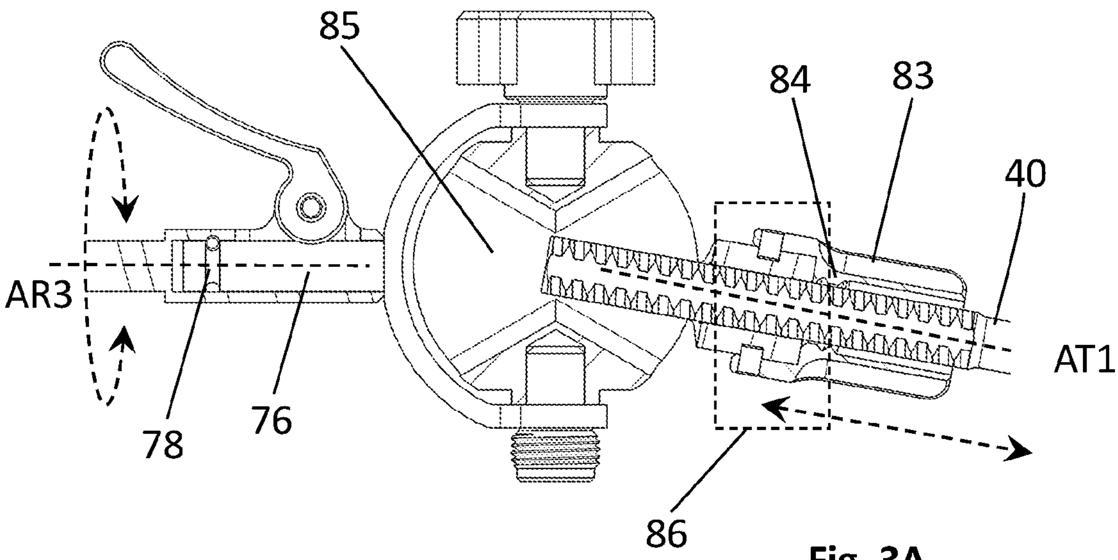


Fig. 3A

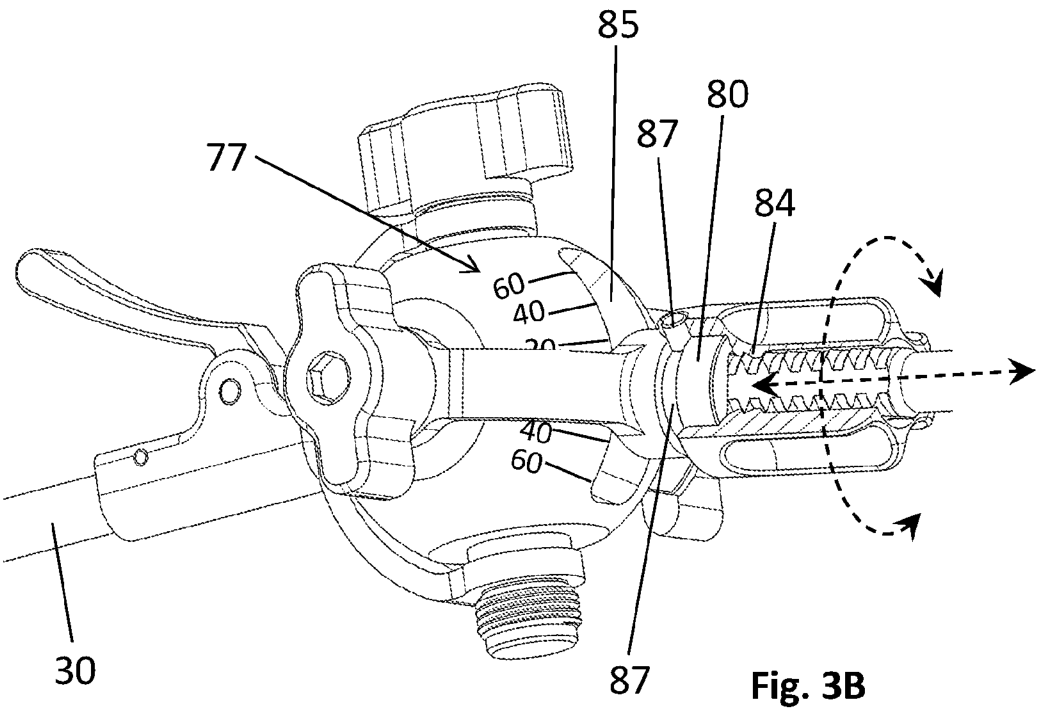


Fig. 3B

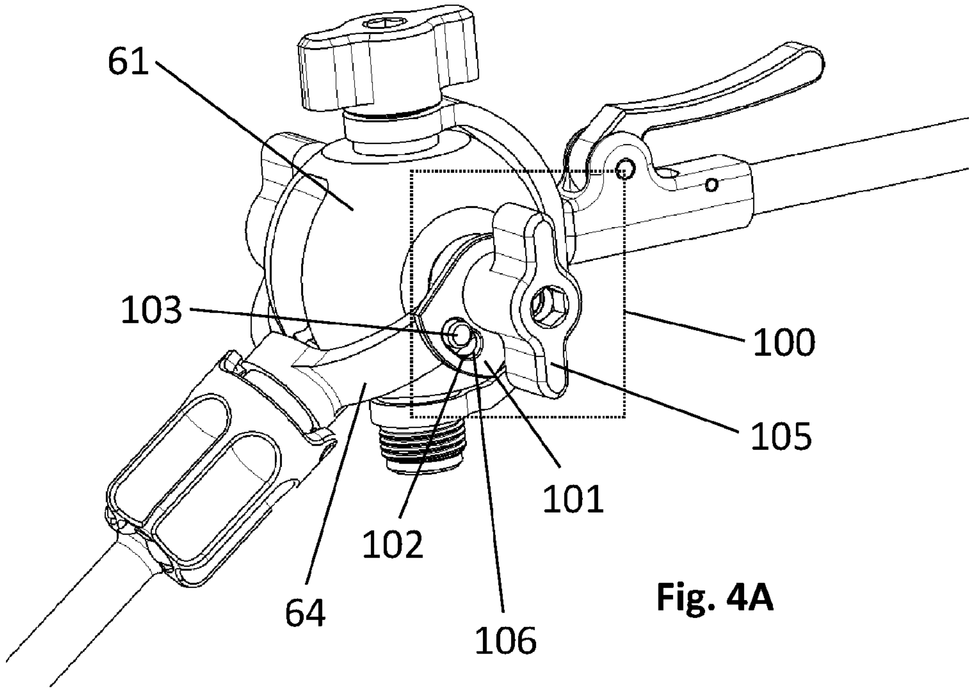


Fig. 4A

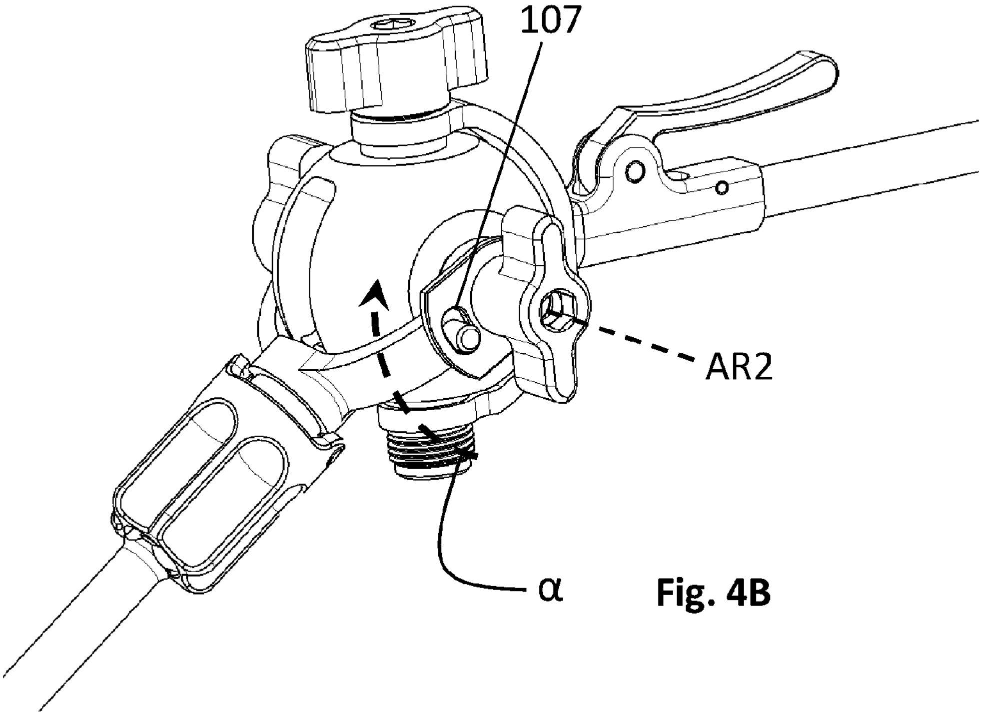


Fig. 4B

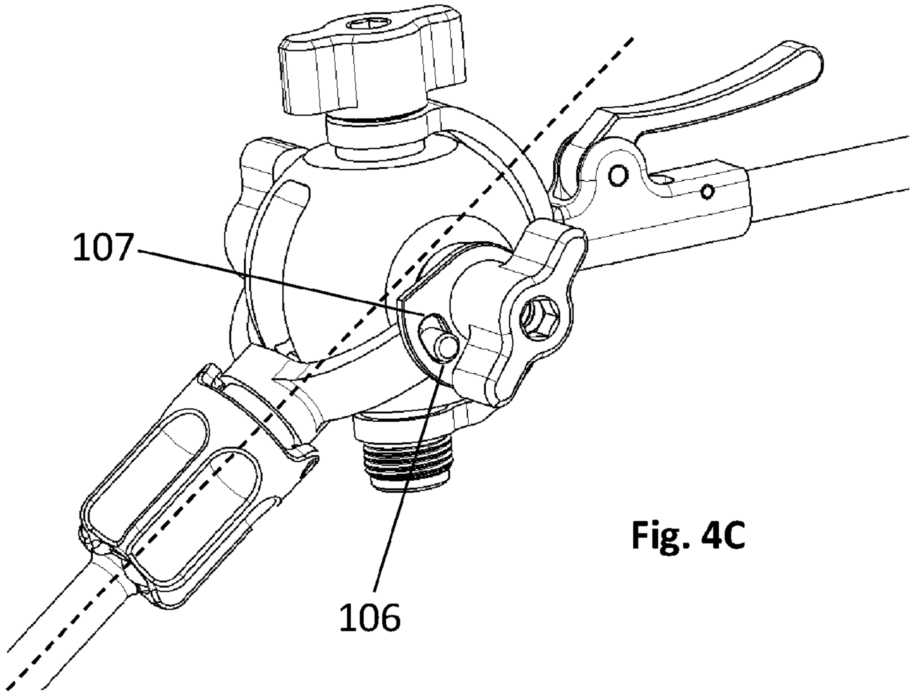


Fig. 4C

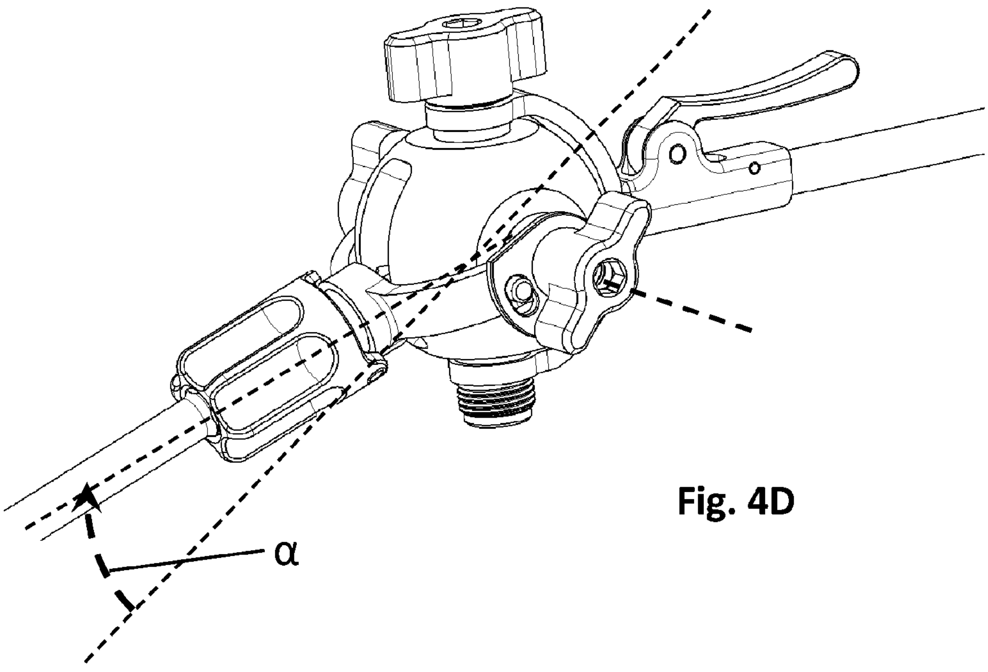


Fig. 4D

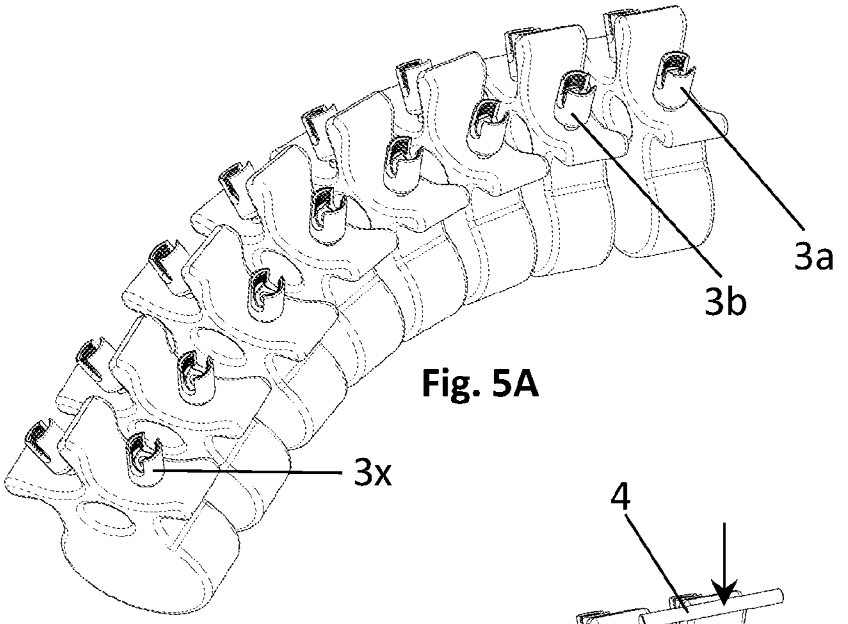


Fig. 5A

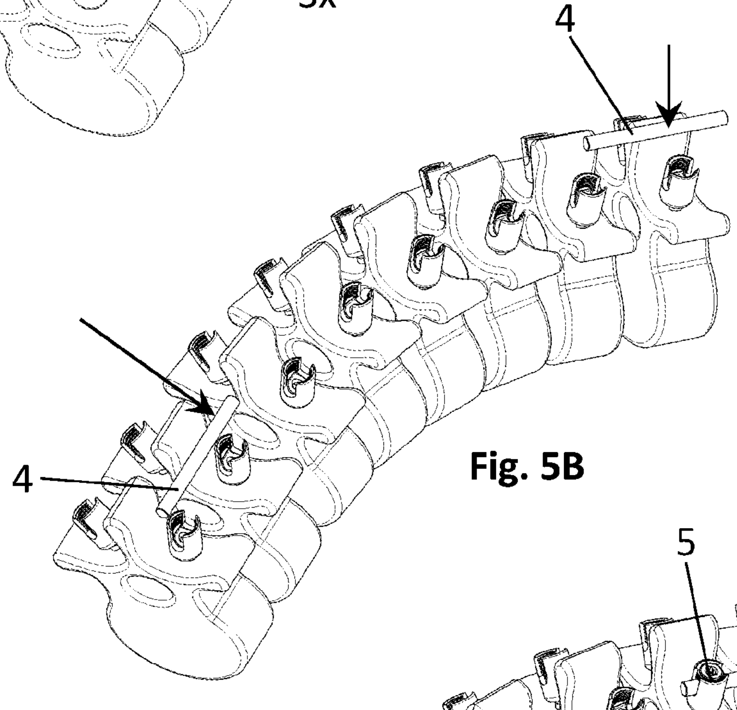


Fig. 5B

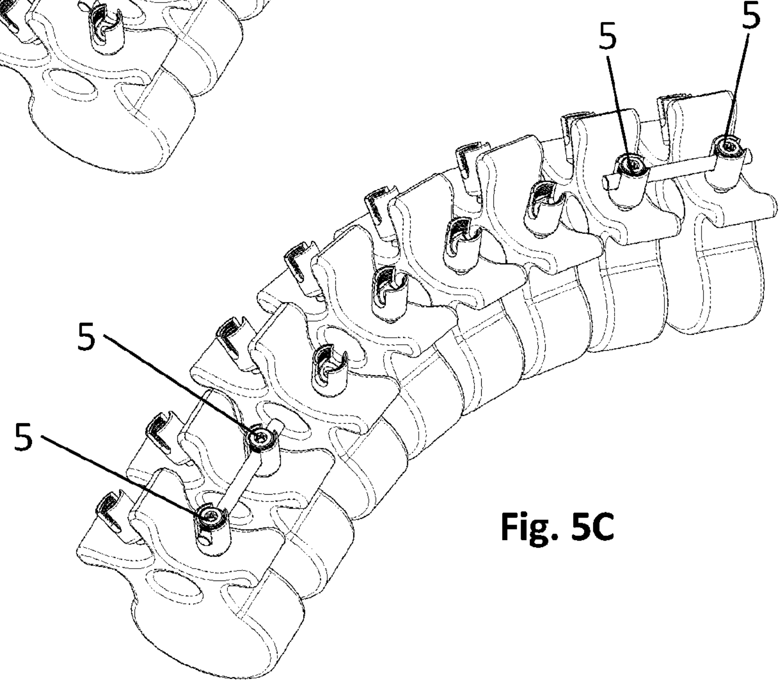


Fig. 5C

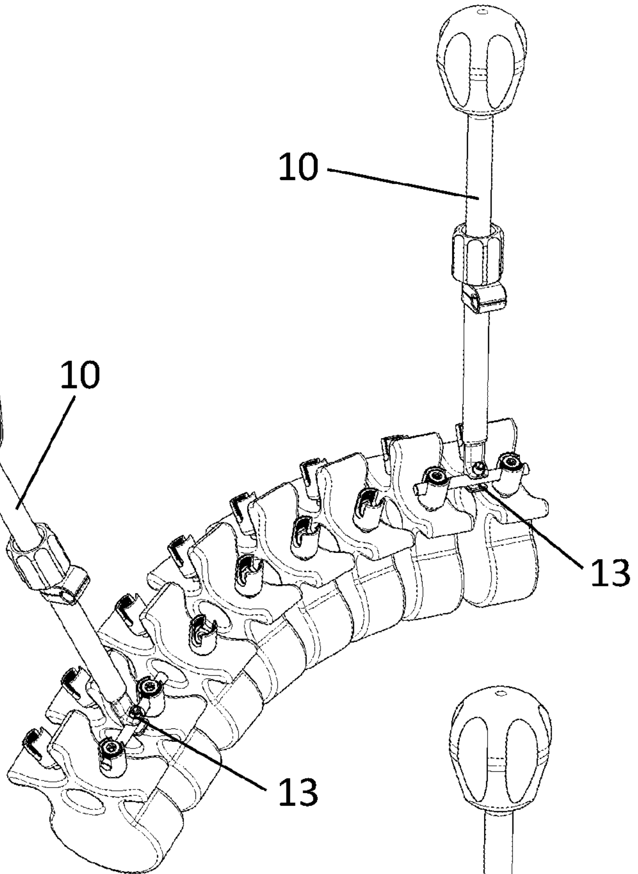


Fig. 5D

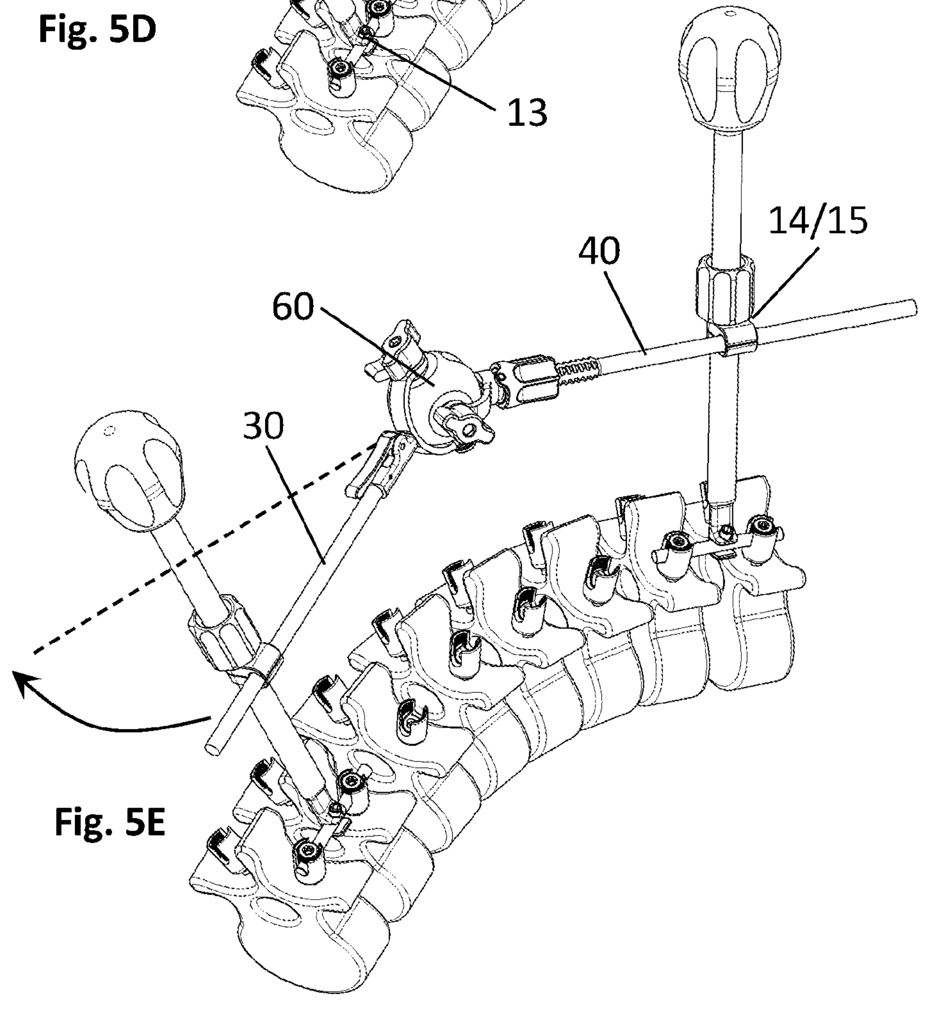
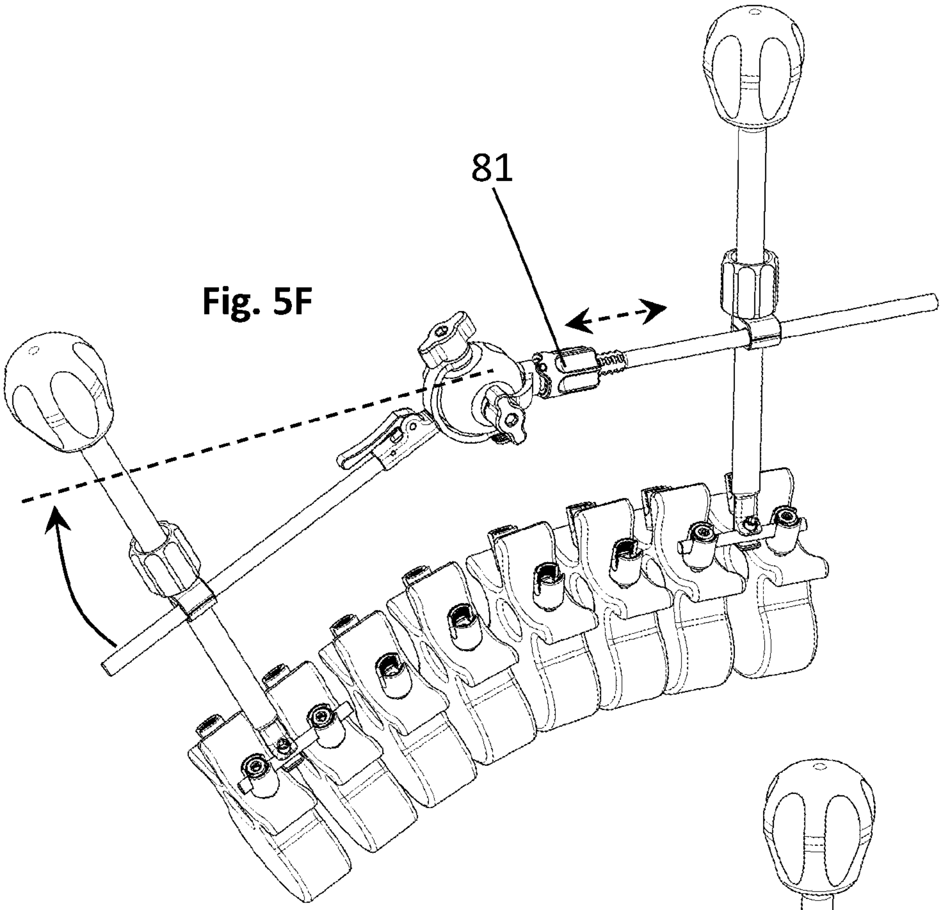


Fig. 5E

Fig. 5F



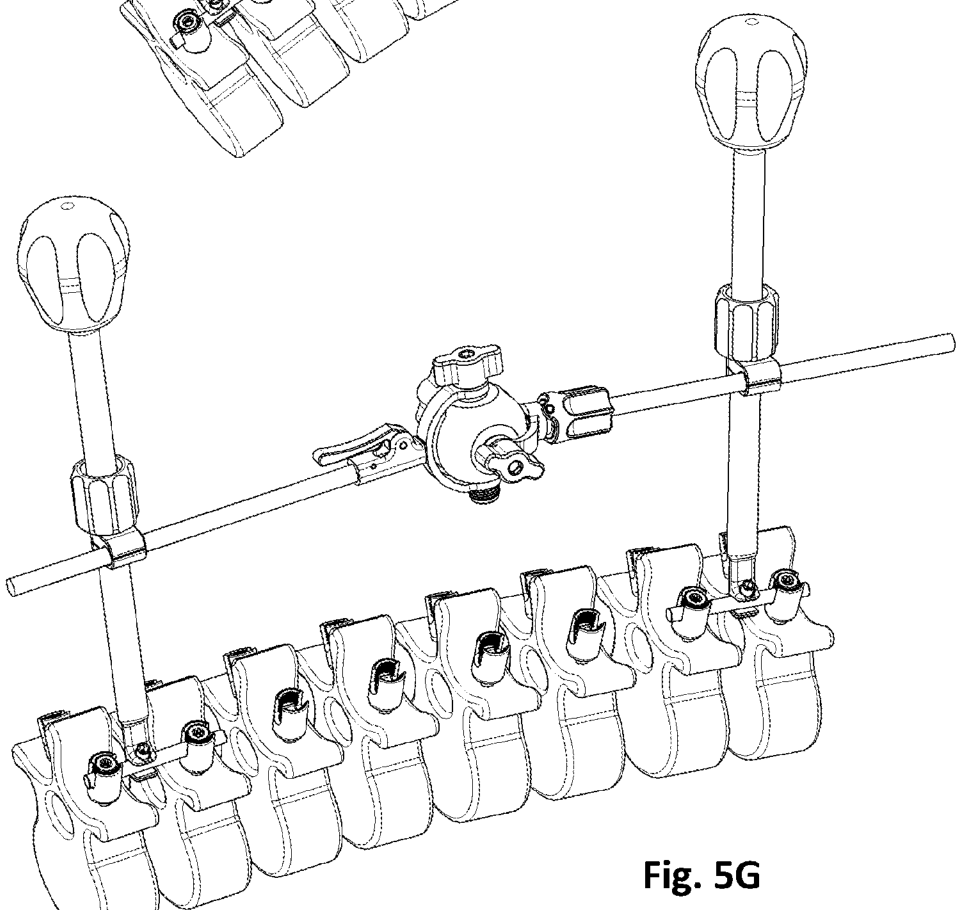


Fig. 5G

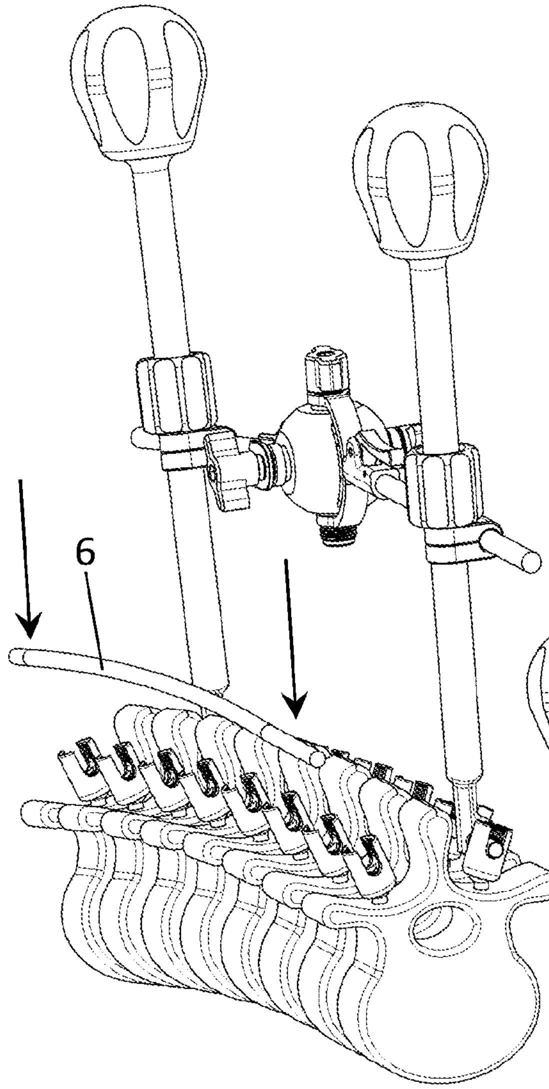


Fig. 5H

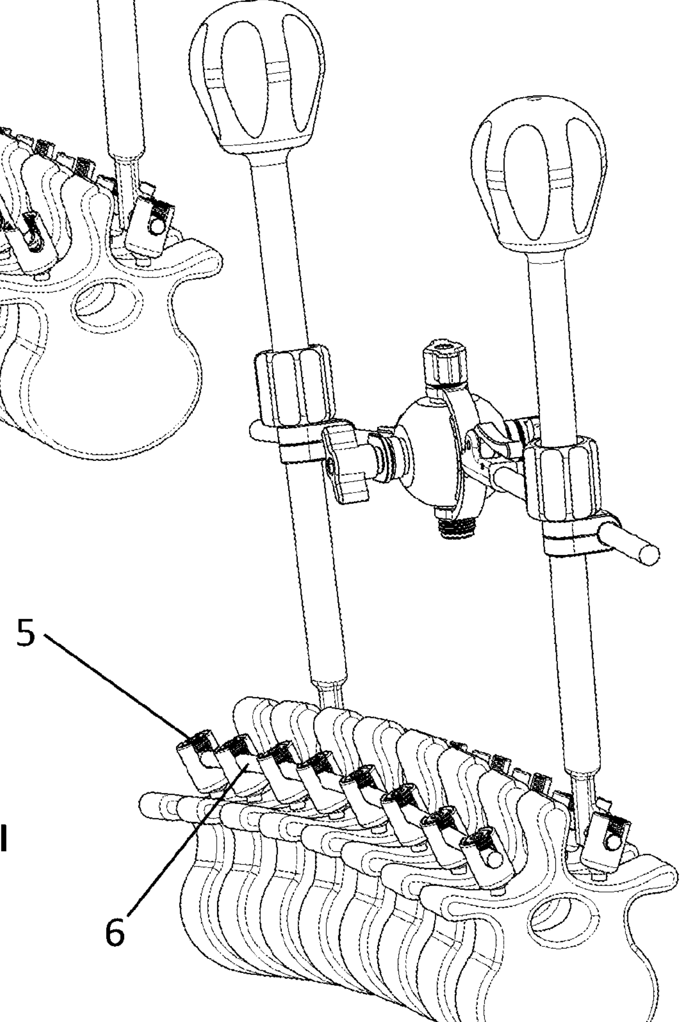


Fig. 5I

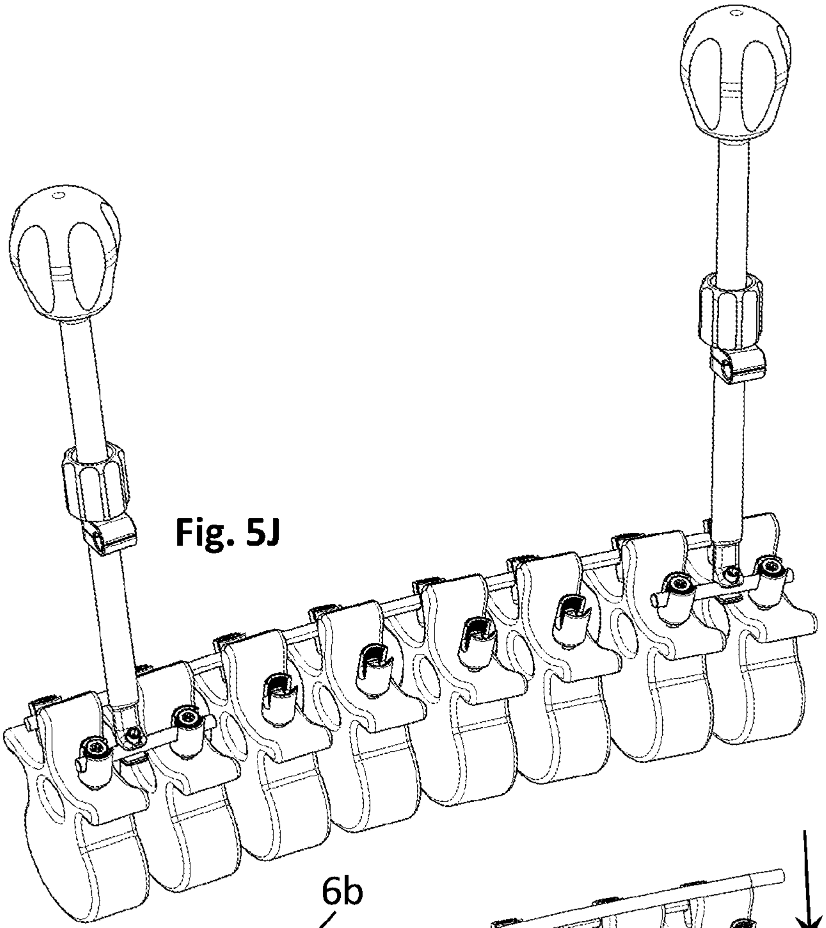


Fig. 5J

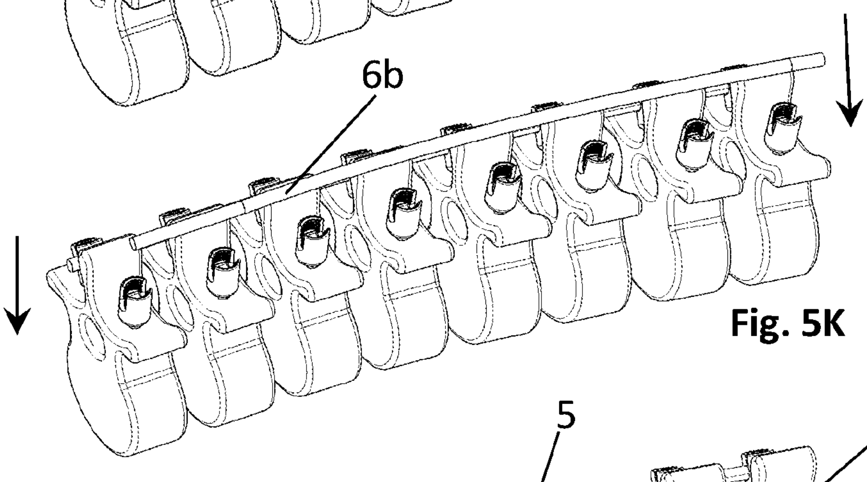


Fig. 5K

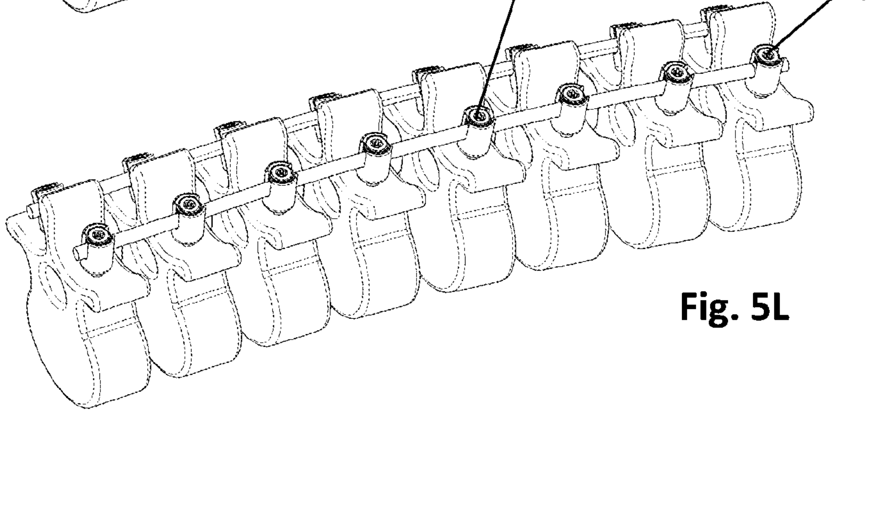


Fig. 5L

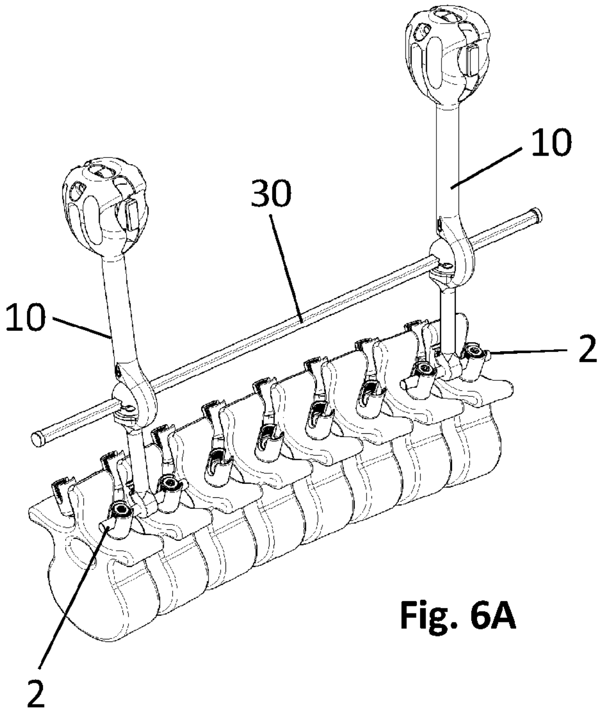


Fig. 6A

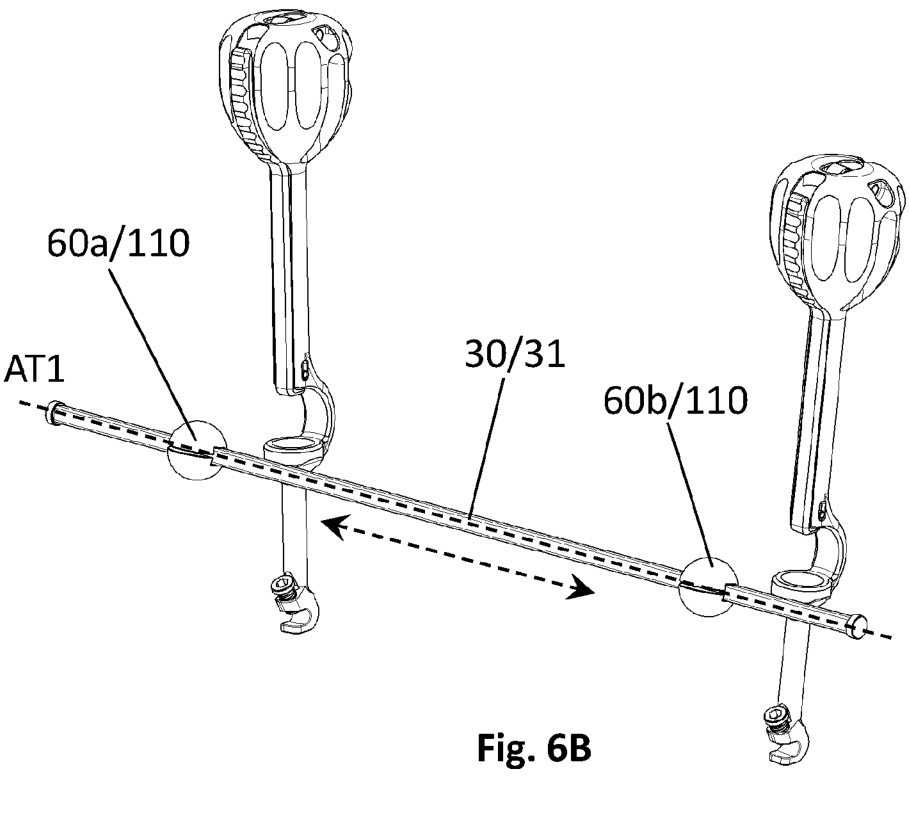


Fig. 6B

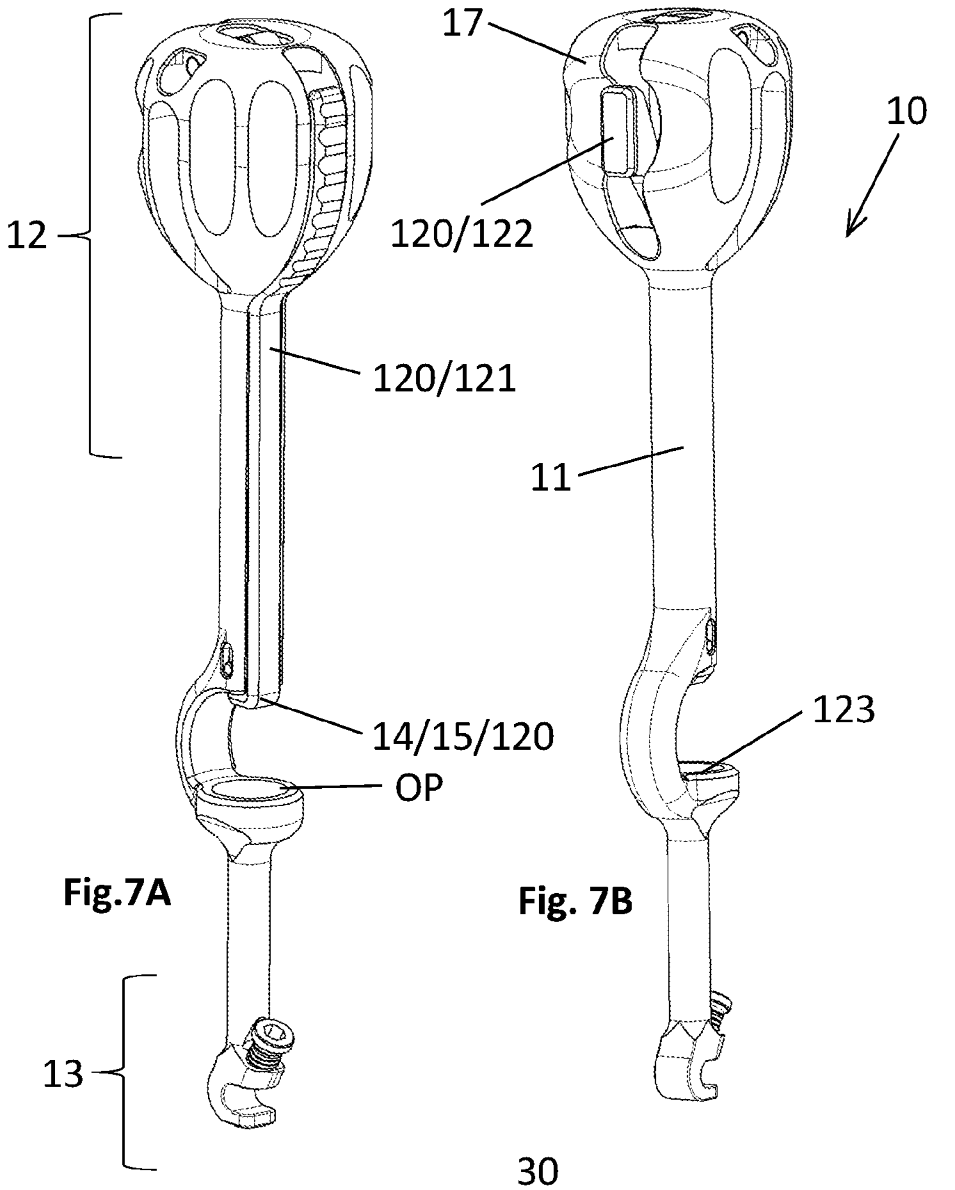


Fig.7A

Fig. 7B

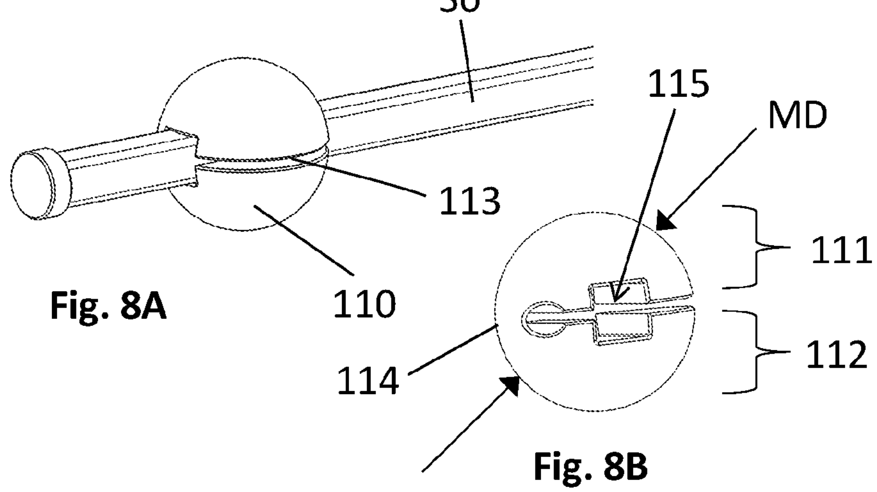
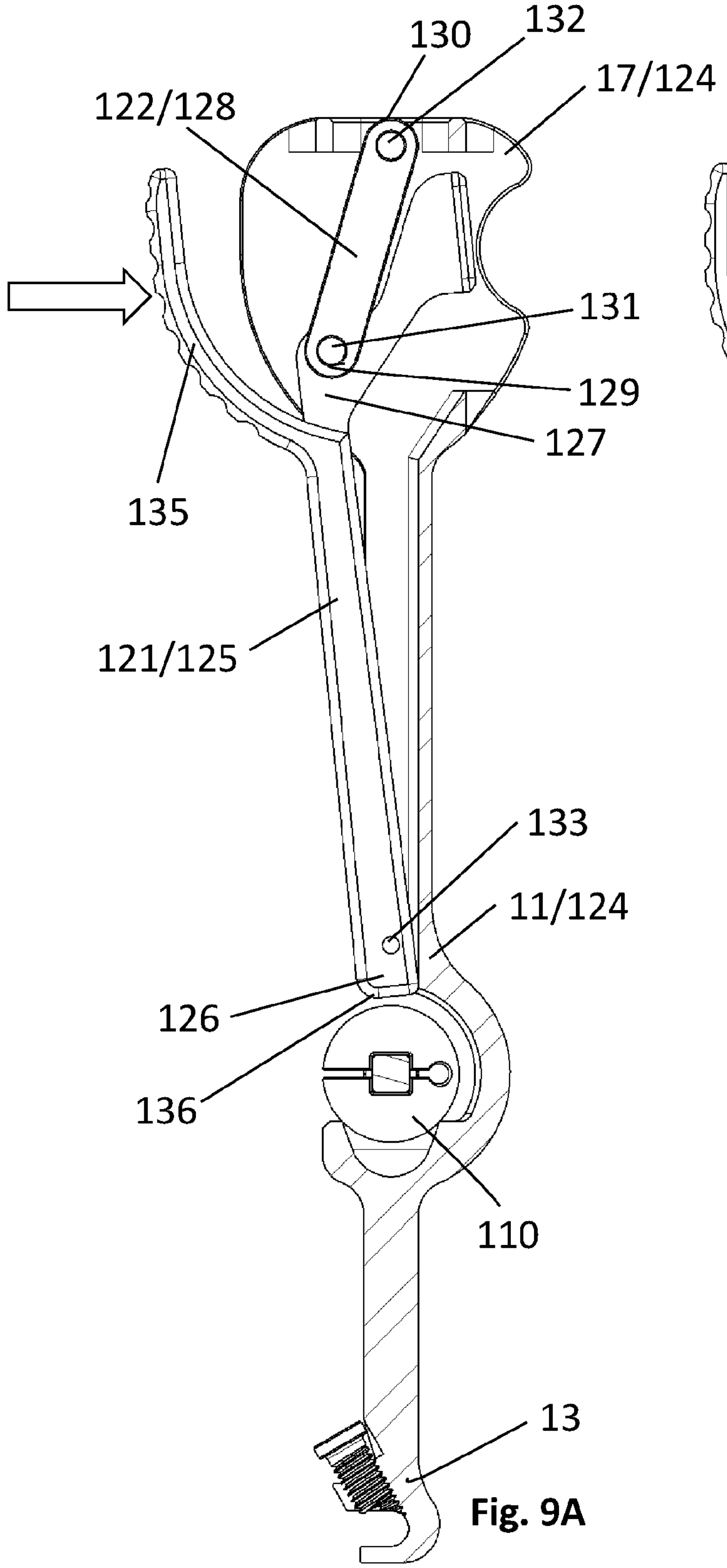


Fig. 8A

Fig. 8B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127
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121/125
133
11/124
126
136
110
13
123

Fig. 9A

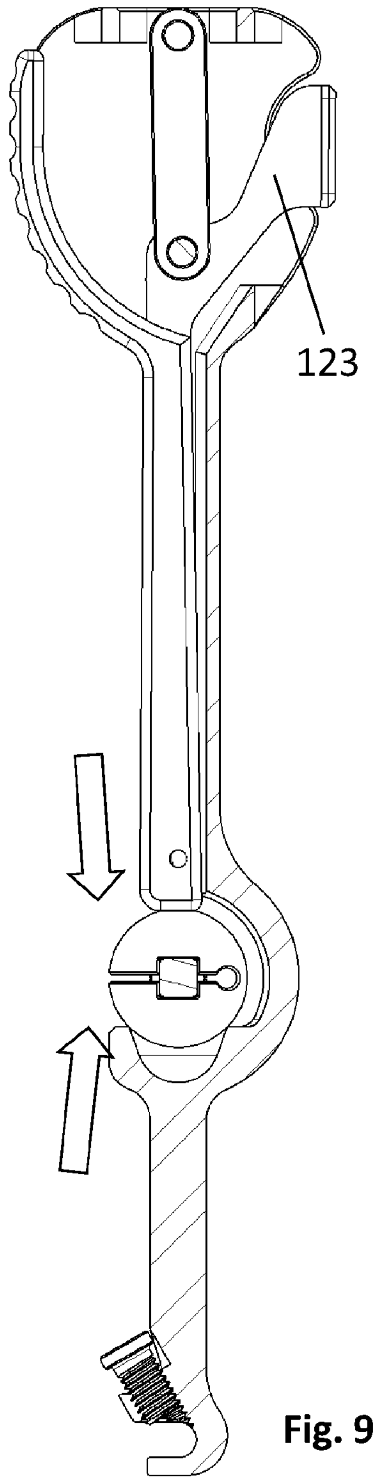

Fig. 9B

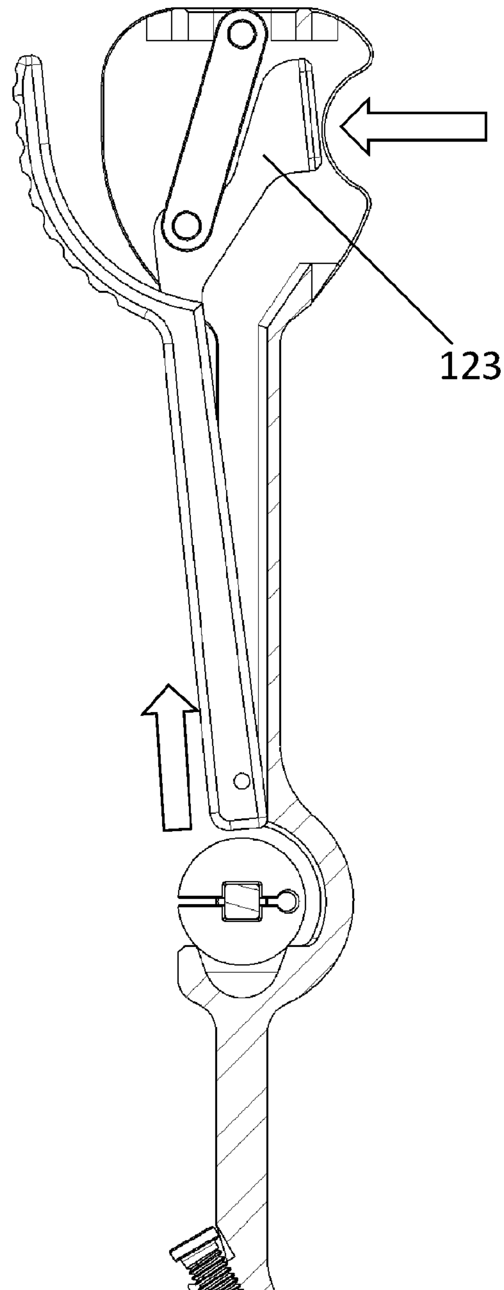

Fig. 9C

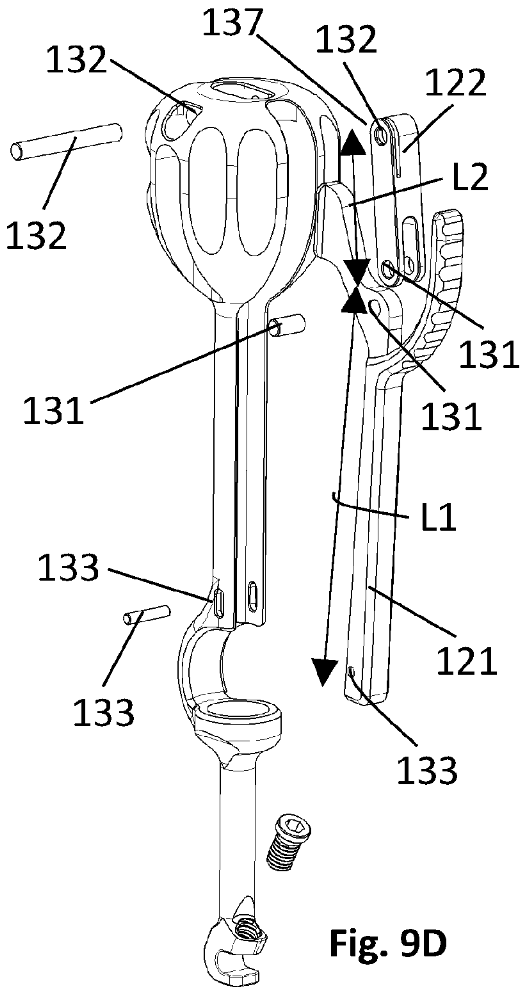

Fig. 9D

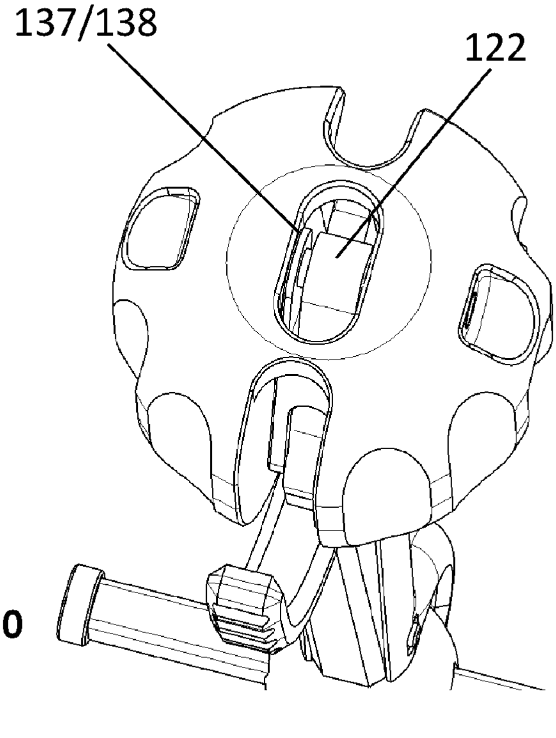

Fig. 10

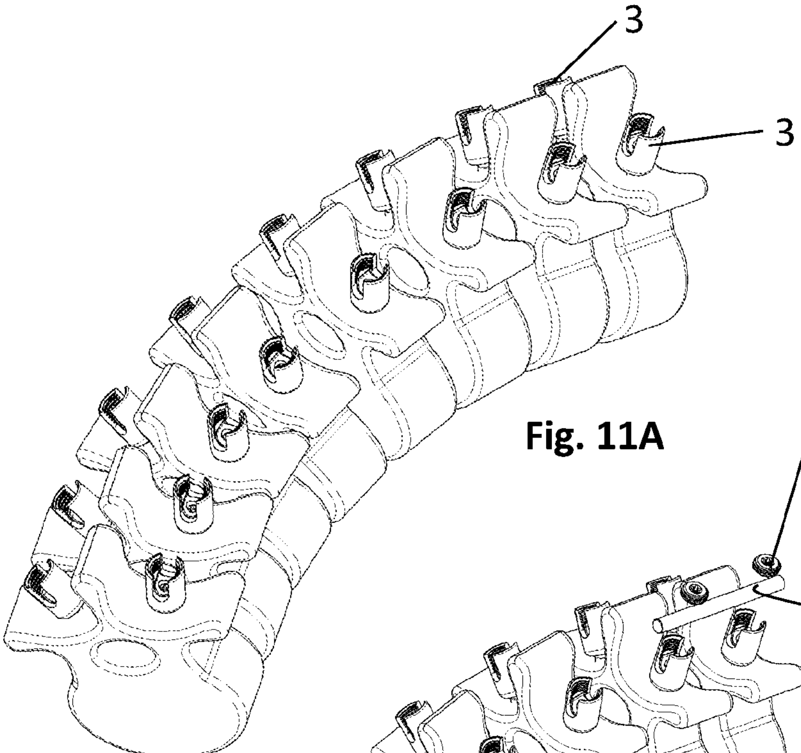

Fig. 11A

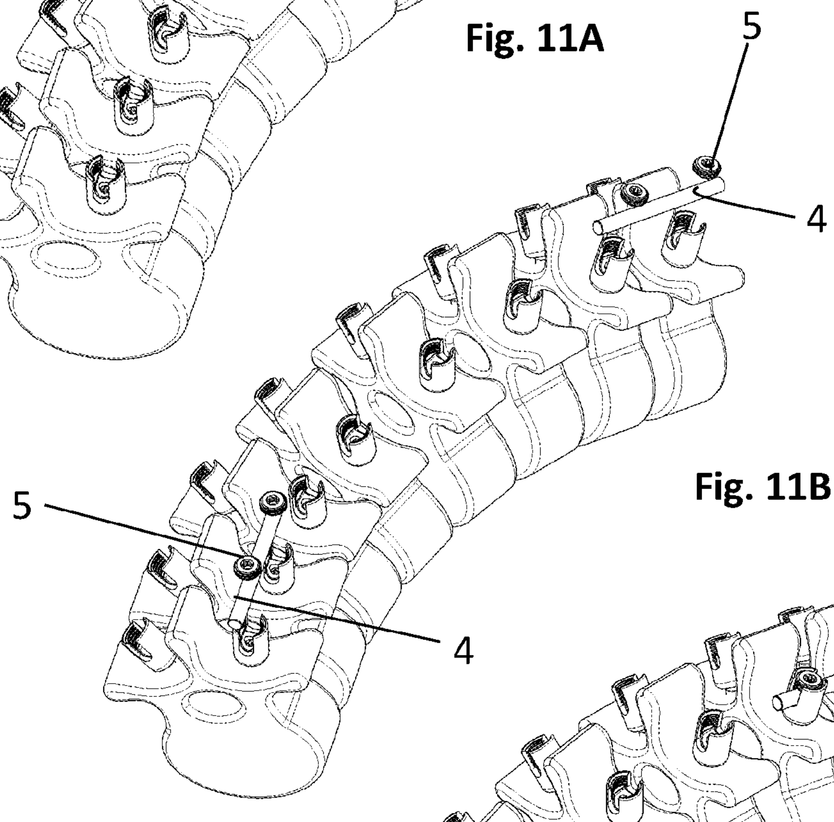

Fig. 11B

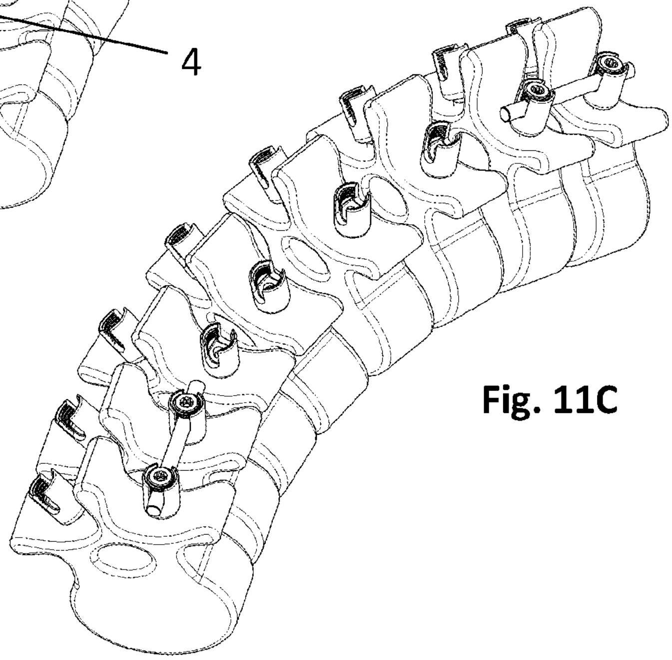

Fig. 11C

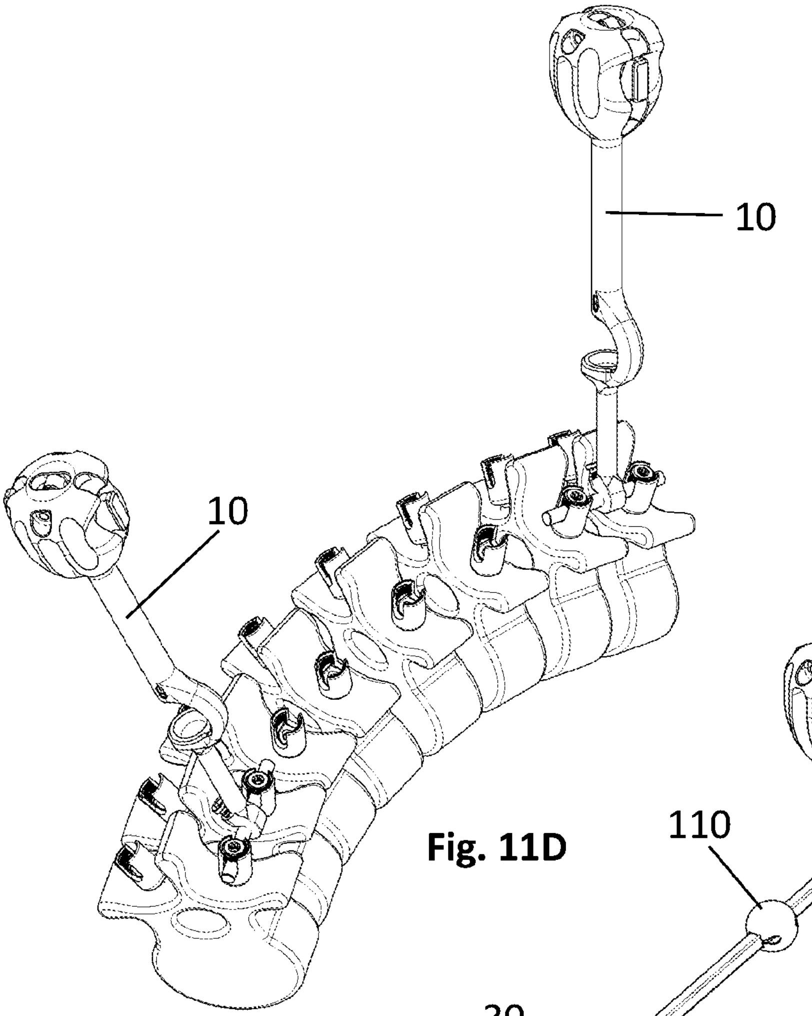

Fig. 11D

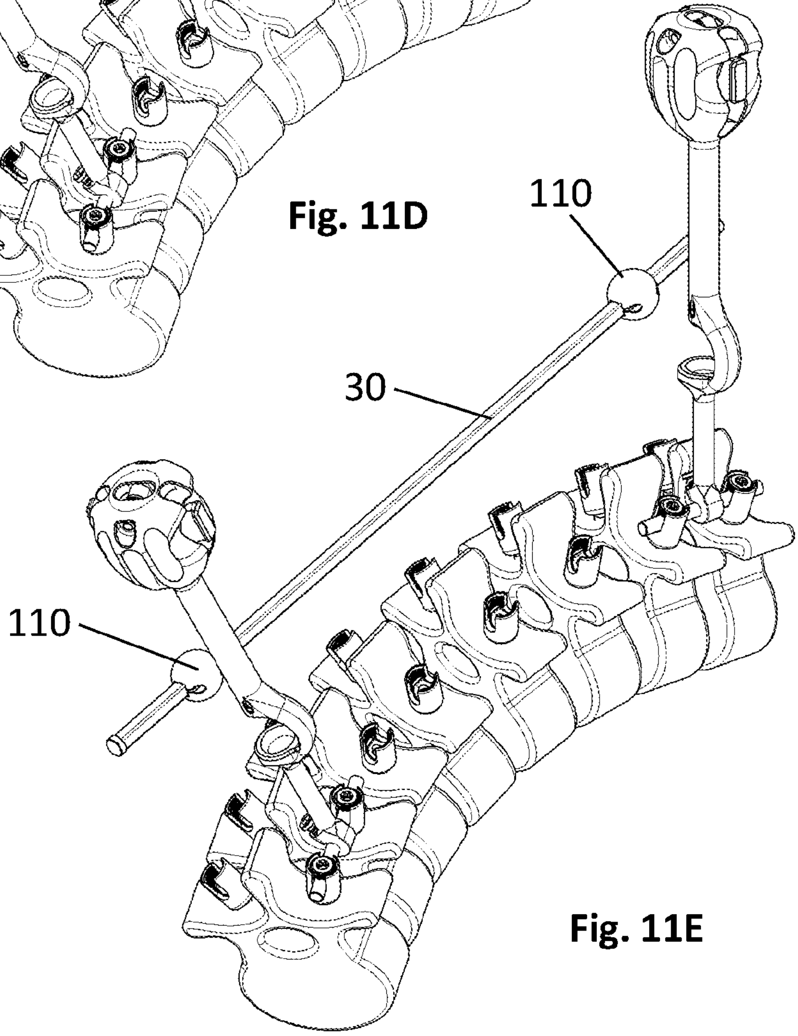

Fig. 11E

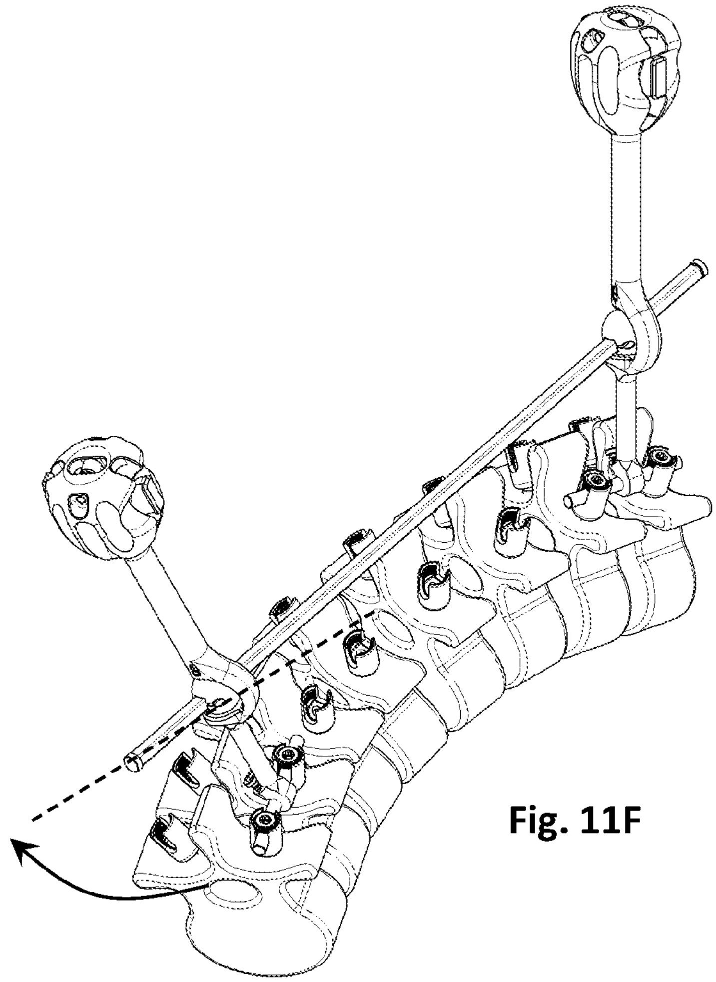

Fig. 11F

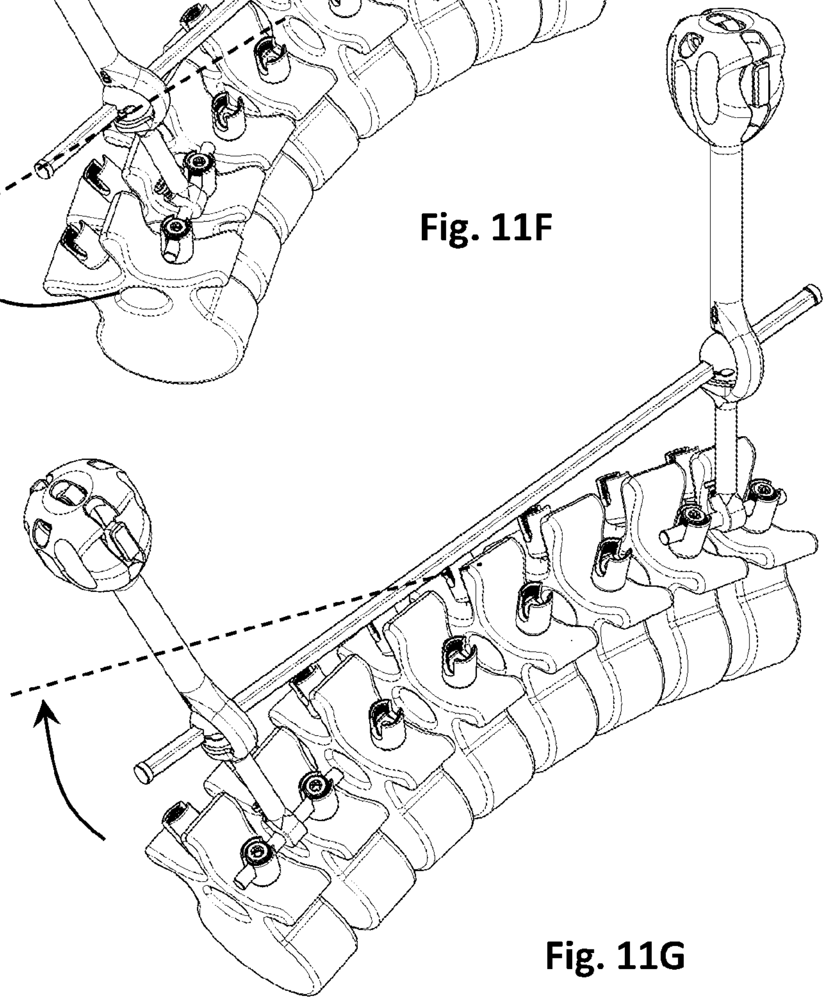

Fig. 11G

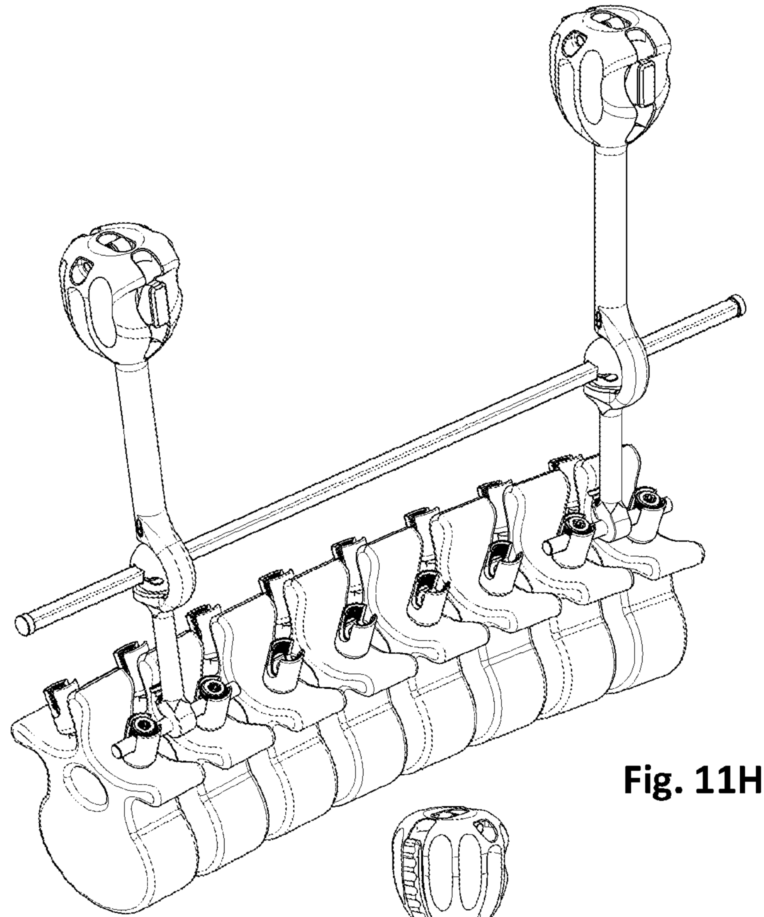

Fig. 11H

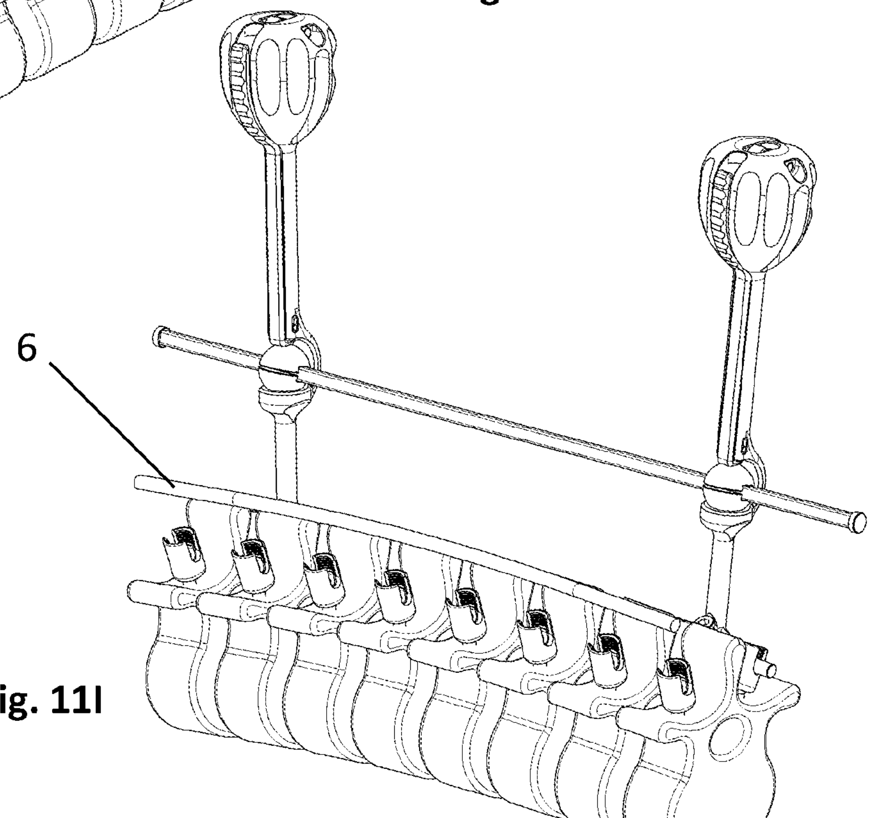

Fig. 11I

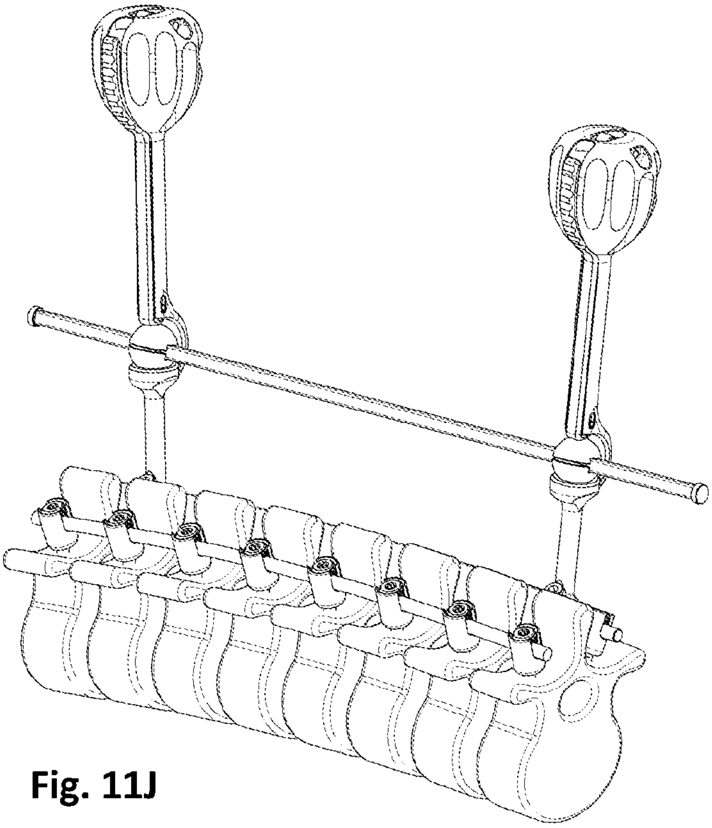

Fig. 11J

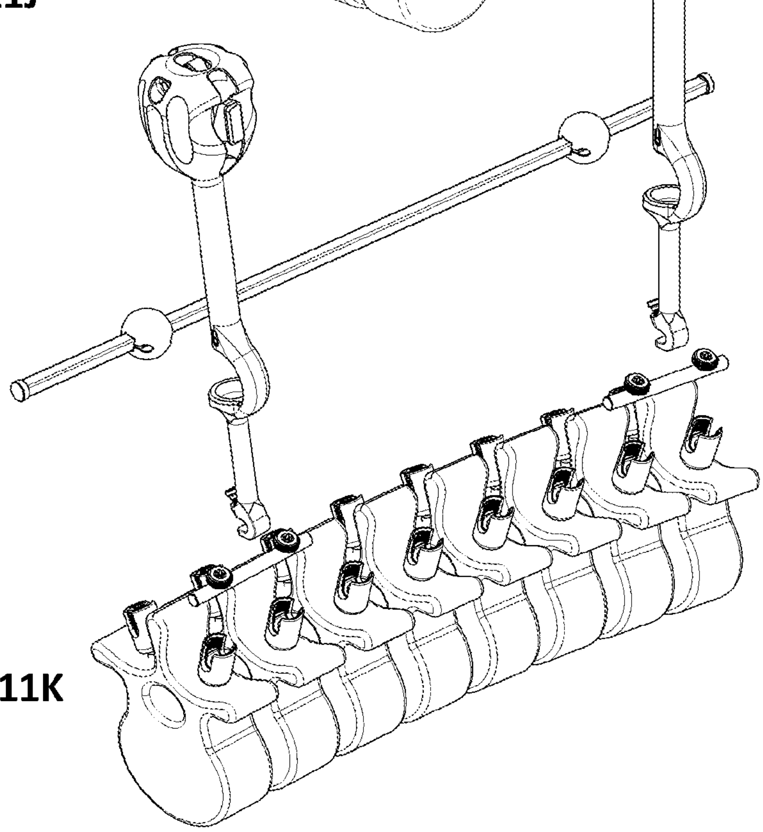

Fig. 11K

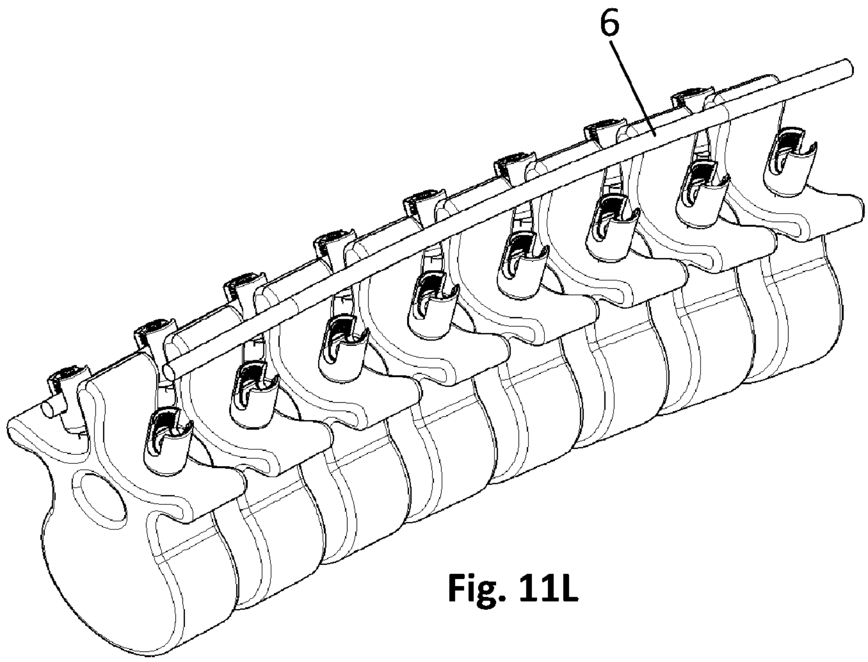

Fig. 11L

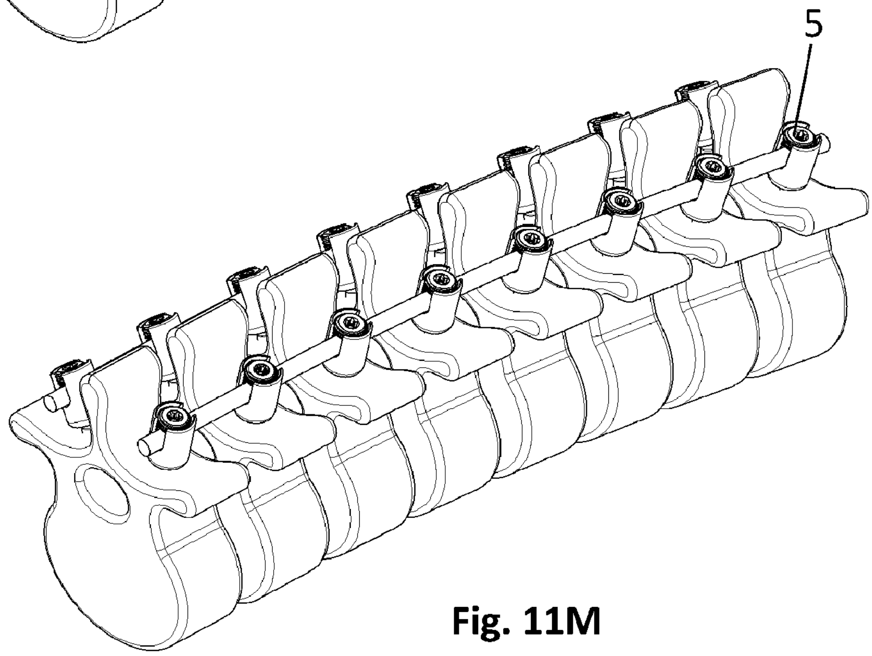

Fig. 11M

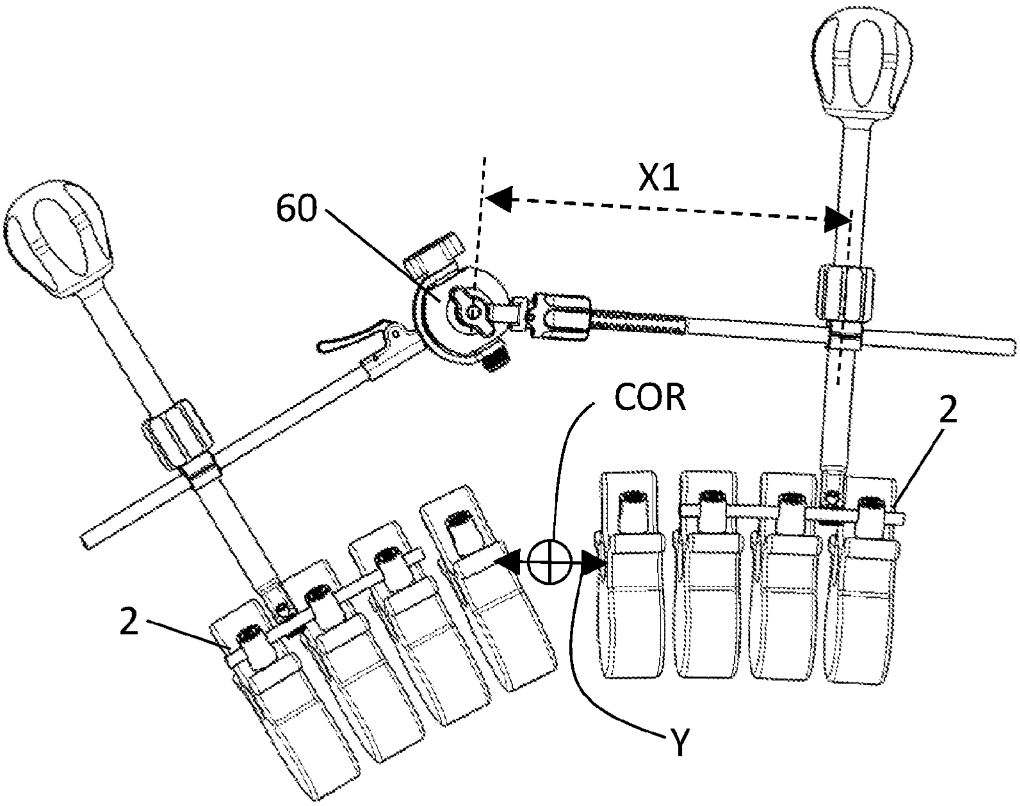

Fig. 12A

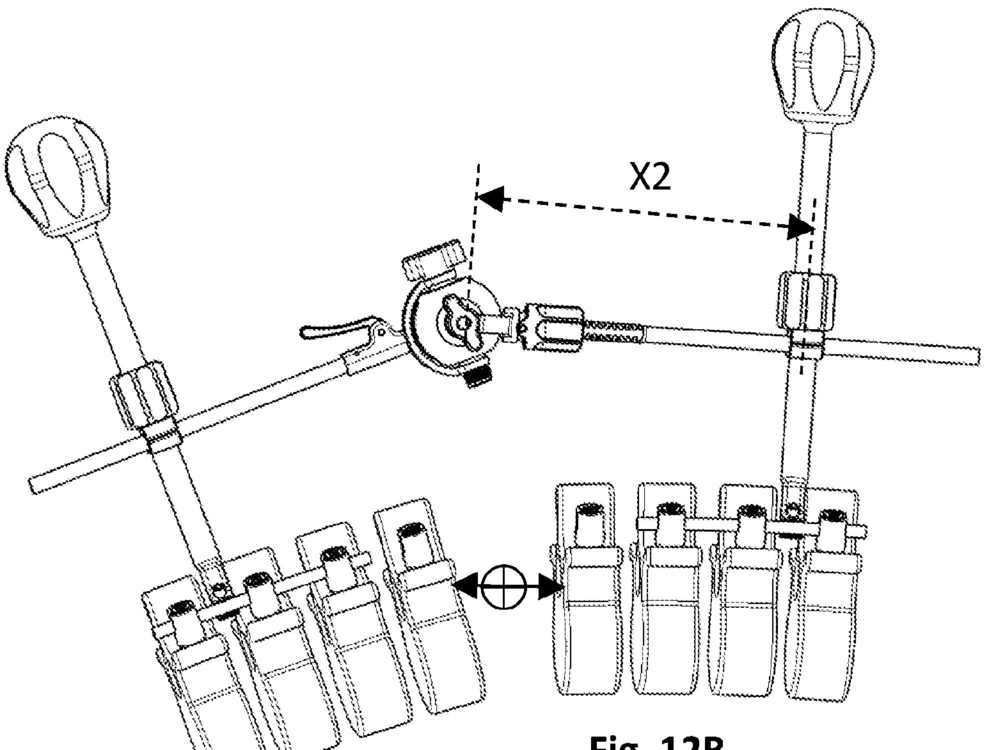

Fig. 12B

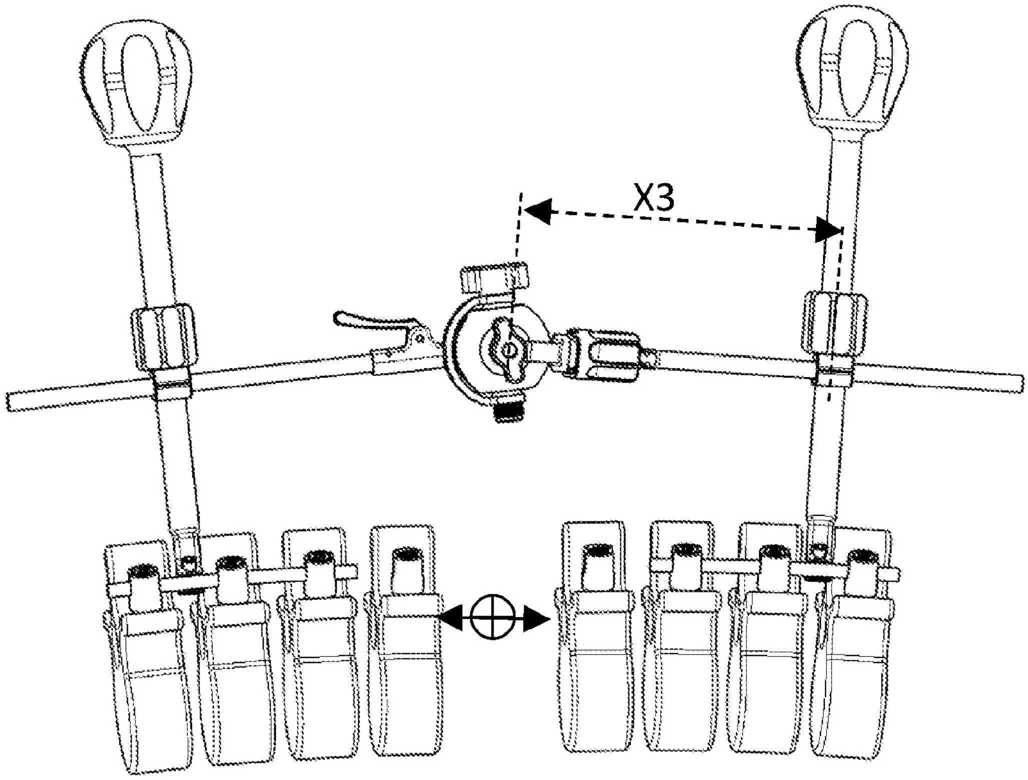

Fig. 12C

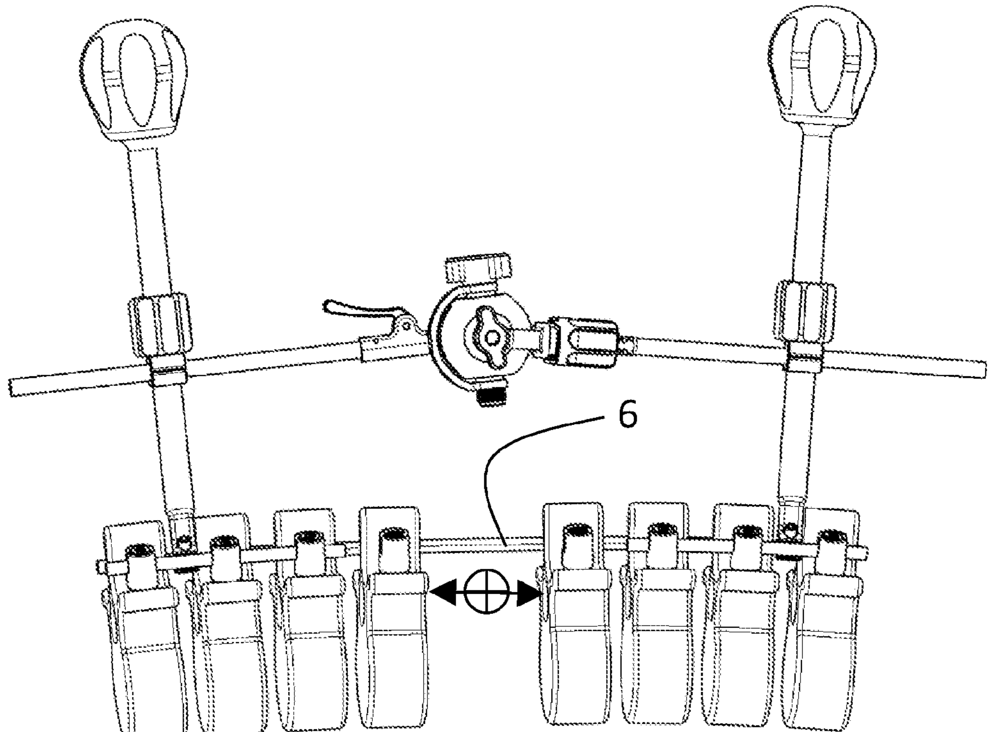

Fig. 12D