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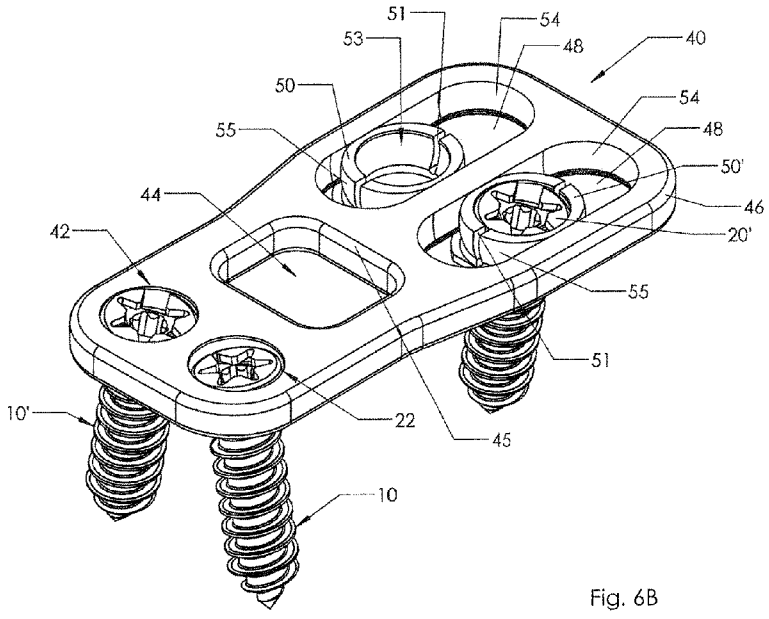


Fig. 6B

(57) Abstract: A locking screw assembly comprises a screw having a shaft and a head. The head extends from the shaft and terminates in a flange. The head includes a column that extends from the flange and contains a bore for engaging a driver. The column has a cross-section that provides a first cross-sectional dimension and a second cross-sectional dimension greater than the first cross-sectional dimension. The assembly also comprises a collar containing a first portion and a second portion. The first portion has a collar aperture defined by aperture walls. The first portion is configured to be seated on the flange and to contact the column at the aperture walls. The second portion extends from the first portion and at least partially overlaps the column. The collar has a first outer diameter in a first position and a second outer diameter, larger than the first outer diameter, in the second position.

SCREW WITH LOCKING MECHANISM AND RIGID/DYNAMIC BONE PLATE

BACKGROUND OF THE INVENTION

[0001] This invention relates to a locking mechanism for a screw and associated methods of its use. More particularly, this invention relates to a bone screw wherein the bone screw is locked into place and methods of use thereof. Even more particularly, this invention relates to a bone screw for an associated bone plate and methods of their use.

[0002] The spine is formed of a series of bones called vertebrae. There are 33 vertebrae, which are grouped as cervical, thoracic, lumbar, sacral, and coccygeal vertebrae, according to the regions of the spine they occupy. A typical vertebra consists of two essential parts, an anterior segment or body, and a posterior part, or vertebral or neural arch. These two parts enclose a foramen, the vertebral foramen. Together, the vertebral foramen of the vertebrae form a canal for the protection of the spinal cord. The vertebral arch consists of a pair of pedicles and a pair of laminae.

[0003] Various techniques and systems have been developed for correcting spinal injuries and/or degenerative spinal processes. Spinal correction frequently requires stabilizing a portion of the spine to facilitate fusing portions of the spine or other correction methodologies. Medical correction of this type is frequently employed for many spinal conditions, such as, for example, degenerative disc disease, scoliosis, spinal stenosis, or the like. Frequently, these corrections also require the use of implants, such as, bone grafts. Stabilizing the spine allows bone growth between vertebral bodies such that a portion of the spine is fused into a solitary unit.

[0004] Several techniques and systems have been developed for correcting and stabilizing the spine and facilitating fusion at various levels of the spine. In one type of system, a bone plate is attached to a plurality of cervical vertebrae by a number of bone screws. A significant problem associated with the use of cervical plates is the rotational back-out of the bone screws over time due to normal movement of the patient. A number of designs have been proposed to secure the bone screws in a spinal plate and prevent their back-out over time.

[0005] One such prior technique involves the use of a pair of plates. A cervical plate is attached to the vertebrae with bone screws and then a second cover plate is overlaid on top of the cervical plate and the heads of the bone screws and secured in place by a second set of screws, thereby preventing the back-out of the bone screws.

[0006] In bone plate systems such as cervical plate systems, bone subsidence can also be a problem. According to Wolf's law, bone grows and remodels in response to stress that is placed on the bone. This is significant, for example, in cervical plate systems used to stabilize vertebrae for spinal fusion. When a cervical plate is used for spinal fusion, a bone graft is placed between adjacent vertebrae. When fusion of the vertebrae begins to occur, a certain amount of compressive stress is required to promote fusion of the adjacent vertebral bodies and bone graft. If subsidence occurs and this compressive stress is removed, bone fusion will not occur any longer causing a failed fusion. Hence, it is desirable to have an automatically adjustable plate or dynamic plate, which stabilizes the vertebral bodies without carrying the entire compressive load, as it is done with static cervical plates. A dynamic cervical plate stabilizes the adjacent vertebrae, but does not carry the axial compressive load, hence allowing the compressive load to be maintained even if subsidence occurs. For example, when the dynamic plate is attached to adjacent cervical vertebrae to facilitate fusion between them, the transfer of the compressive load to the graft material facilitates the growth of bone and the eventual fusion of the cervical vertebrae. Therefore, it is an advantage if a bone plate permits automatic adjustment of the distance between the adjacent vertebrae in response to any bone subsidence that can occur during spinal fusion. Such a system is considered a dynamic bone plate system.

[0007] A variety of designs have been proposed for a locking mechanism for a bone screw. Many of these require the use of a locking washer or collar that is secured within an aperture of the bone plate through which the bone screw passes. These typically require multiple parts that are assembled during surgery with multiple tools.

[0008] Type of correction, anatomy and internal structure of the vertebrae frequently require different angles of the bone screw during the placement of the spinal plate. In order to provide this angulation, polyaxial screws/anchors have been developed. Many variations of bone screw and fixation systems exist on the market today. However, it is a continuing need for alternate systems to address the demands of diverse medical conditions and disease states.

[0009] Therefore, there is a need for a bone screw assembly that provides an effective and secure lock of the screw and plate in the desired position. There is also a need for a dynamic bone plate.

SUMMARY OF THE INVENTION

[0010] It is, therefore, an aspect of the present invention to provide a locking screw assembly. The locking screw assembly comprises at least one screw having a shaft portion and a head portion. The head portion may extend from the shaft portion in an arcuate manner, terminating in a flange portion. The head portion may also include a column portion that extends from the flange portion and contains a bore therein, the bore being adapted to engage a first driver. The column portion may have a non-circular or off-center circular cross-section and thereby have a first cross-sectional dimension and a second cross-sectional dimension greater than the first cross-sectional dimension.

[0011] The locking screw assembly may also comprise at least one collar containing a first collar portion and a second collar portion. The first collar portion has a collar aperture, the collar aperture being defined by collar aperture walls. The first collar portion is configured to be seated on the flange portion and to contact the column portion at the aperture walls. The second collar portion extends from the first collar portion and is adapted to engage a second driver. The collar is adapted to contact the column portion in a first position and in a second position. The collar has a first outer diameter in a first position and a second outer diameter in the second position. The second outer diameter is larger than the first outer diameter. In a particular embodiment, the collar is C-shaped.

[0012] In one embodiment, in the first position, the collar aperture walls having a first cross-sectional dimension contact the column portion in the area of the first cross-sectional dimension, and in the second position the aperture walls contact the column portion only at points of the second cross-sectional dimension, thereby causing the collar to expand outwardly. In one particular embodiment, the column portion has an cross-section that is selected from the group consisting of an essentially rectangular cross-section, an essentially triangular cross-section or an off-center circular cross section. Variations on these cross sections may include those where one or more corners present are rounded corners. In one embodiment, the first and second cross-sectional dimensions may be measured from one side of the column portion to an opposite side of the column portion. For example, when the cross sectional shape is square, a first cross-sectional dimension may correspond to a side of the column portion and a second cross-sectional dimension may correspond to the distance between opposing corners of the column portion, diagonally bisecting the column portion. Alternatively, the first and second

cross-sectional dimensions may be measured from a central axis of the screw to a side of the column portion. The aperture walls may additionally have one or more structures that restrict movement of the collar relative to column portion in the second position. These one or more structures may provide a seat for a part of the column portion contacting the aperture walls in the second position. The second collar portion may also have an internal aperture that is configured to be in communication with the bore.

[0013] The locking screw assembly may additionally comprise a plate having an upper surface and a lower surface and being adapted to accept the screw and collar through at least one orifice. The screw and collar have a first assembled maximum diameter in the relaxed position and a second assembled maximum diameter in the expanded condition. The first assembled maximum diameter is smaller than a dimension of the at least one orifice and the second assembled maximum diameter is larger than the dimension of the at least one orifice. In a particular embodiment, the plate is a cervical plate.

[0014] The plate may include at least one orifice that may comprise at least one first aperture adapted to receive a first screw and collar assembly, at least one elongated second aperture, and at least one carrier slidably engaging the at least one elongated second aperture and having contoured walls adapted to receive a second screw and collar assembly. In one example, the at least one carrier has a lower portion that abuts the lower surface of the plate. The at least one elongated second aperture may have walls that are contoured and the at least one carrier may have an upper portion that conforms to the contour of the walls. A first screw and collar assembly may be inserted into the at least one first aperture and the locking screw assembly may additionally comprise at least a second screw and collar assembly inserted into the carrier.

[0015] A method for attaching a plate to one or more bones includes providing at least one locking screw assembly and a plate, inserting the locking screw assembly through at least one first plate orifice and into a bone, and locking the screw and collar in place by rotating the collar from a first position to a second position. In one embodiment, the plate is a cervical plate and the one or more bones are cervical vertebrae. In this method, the locking screw assembly contains a screw that includes a shaft portion and a head portion. The head portion extends from the shaft portion in an arcuate manner and terminates in a flange portion. The head portion also including a column portion that extends from the flange portion and contains a bore therein. The column portion may have a non-circular

or off-center circular cross-section, thereby having a first cross-sectional dimension and a second cross-sectional dimension greater than the first cross-sectional dimension. The collar may contain a first collar portion and a second collar portion and in one embodiment, is C-shaped.

[0016] The first collar portion has a collar aperture defined by collar aperture walls. The first collar portion is configured to be seated on the flange portion and to contact the column portion at the aperture walls. The second collar portion extends from the first collar portion and is adapted to engage a driver. The collar is adapted to contact the column portion in a first position and in a second position. The collar has a first outer diameter in a first position and a second outer diameter in the second position. The second outer diameter is larger than the first outer diameter, and the plate may have at least one orifice having at least one dimension that is larger than the first outer diameter and smaller than the second outer diameter.

[0017] A bone plate may comprise an upper surface and a lower surface, at least one first aperture adapted to receive a first screw, at least one elongated second aperture, and at least one carrier adapted to slidably engage the at least one elongated second aperture and being adapted to receive a second screw. The at least one elongated second aperture may have walls that are contoured and the at least one carrier may comprise an upper portion and a lower portion. The upper portion may have a shape that conforms to the walls of the at least one elongated second aperture and the lower portion may be adapted to abut the lower surface of the bone plate.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] Figure 1 is a perspective view of an embodiment of a screw and collar providing a locking mechanism;

[0019] Figure 2 is an expanded view of the screw and collar shown in Fig. 1;

[0020] Figure 3A is a side elevational view of the screw and collar shown in Fig. 1;

[0021] Figure 3B is a cross-sectional view of the screw and collar taken along line A-A, which runs along the center axis of the screw, in Fig. 3A;

[0022] Figure 4A is a side elevational view of a screw and collar in a first relaxed configuration;

[0023] Figure 4B is a top cross-sectional view, taken along line B-B, of the screw and collar shown in Figure 4A;

[0024] Figure 4C is a side elevational view of a screw and collar in a second, partially expanded configuration;

[0025] Figure 4D is a top cross-sectional view, taken along line C-C, of the screw and collar shown in Fig. 4C;

[0026] Figure 4E is a side elevational view of a screw and collar in a third, partially expanded configuration;

[0027] Figure 4F is a top cross-sectional view, taken along line D-D, of the screw and collar shown in Fig. 4E;

[0028] Figure 4G is a side elevational view of a screw and collar in a fully expanded configuration;

[0029] Figure 4H is a top cross-sectional view, taken along line E-E, of the screw and collar shown in Fig. 4G;

[0030] Figure 5A is a series of top cross-sectional views showing, from left to right, the progression of the movement of a collar clockwise relative to a square column portion with rounded corners, and transition of the collar from a relaxed to an expanded configuration;

[0031] Figure 5B is a series of top cross-sectional views showing, from left to right, the progression of the movement of a collar clockwise relative to a triangular column portion with rounded corners, from a relaxed to an expanded configuration;

[0032] Figure 5C is a series of top cross-sectional views showing, from left to right, the progression of the movement of a collar clockwise relative to a diamond-shaped column portion with rounded corners, from a relaxed to an expanded configuration;

[0033] Figure 5D is a series of top cross-sectional views showing, from left to right, the progression of the movement of a collar clockwise relative to a off-center circular column portion, from a relaxed to an expanded configuration;

[0034] Figure 6A is an expanded view of a plate and carriers adapted to be inserted therein;

[0035] Figure 6B is a perspective view of an embodiment of a bone plate, with screw and collar assemblies inserted therein;

[0036] Figure 7 is a perspective view of an embodiment of a bone plate, with screw and collar assemblies inserted therein, partially cut-away at the first apertures; and

[0037] Figure 8 is a perspective view of an embodiment of a bone plate, with screw and collar assemblies inserted therein, partially cut-away at the second apertures.

DETAILED DESCRIPTION OF THE INVENTION

[0038] The following examples should not be viewed as limiting the scope of the invention. The claims will serve to define the inventions. Additionally, it should be noted that elements of one example may be combined with elements of another example, except where the function of the components prohibits such combination. The following examples are non-limiting therefore in their arrangements and combinations of elements.

[0039] As shown in Figures 1-3B, a screw and an associated assembly, especially for application in the spinal stabilization arena, comprises an elongated bone screw 10 having central axis with a shaft portion 12 and a head portion 14 and a collar 20. The shaft portion 12 may include threads 13 for inserting screw 10 into a bone or other suitable substrate. Threads 13 located on shaft portion 12 may be either right-handed or left-handed depending on the needs or preferences of associated with a particular application or user. Screw 10 is configured to be inserted through an aperture in a plate, such as a cervical plate. A particular embodiment of a cervical plate is described more fully below.

[0040] Head portion 14 may extend away from shaft portion 12 in a generally arcuate manner around the entire circumference of head portion 14 forming arcuate section 15, terminating in a bottom flange 18. Arcuate section 15 and bottom flange 18 may extend uninterrupted around the circumference of head portion 14. Bottom flange 18 thereby forms a seat for collar 20. A column portion 17 may extend from bottom flange 18 and includes a top flange 30 which is separated from bottom flange 18 by column groove 32. Column portion 17 contains an internal bore 16. Bore 16 may be configured to accept a driver such as a hexagonal driver (also known as an Allen wrench), a hexalobe driver, a star-shaped driver having any number of projections, or a similar tool. In one example, bore 16 is centered at the approximate location of the central axis of screw 10. In another example, bore 16 is displaced from the central axis of screw 10.

[0041] In the examples shown in the Figures, and as described in more detail below, column portion 17 may have a generally polygonal cross-section. For example, column

portion 17 may have a generally non-circular cross section such as a square-shaped, diamond-shaped or triangular-shaped cross section with rounded corners. Other polygon shapes are also possible. In one embodiment, column portion 17 has 4 or fewer sides. It is also possible for column portion 17 to have an off-center circular cross section, that is, column portion 17 may be displaced relative to the central axis of screw 10. Stated differently, column portion 17 may have a circular cross section where the center of the circular cross section is not coincident with the central axis of bone screw 10.

[0042] Collar 20 may be generally cylindrical or disk-shaped with a first collar portion 21 that is configured to be seated on bottom flange 18 and to engage column portion 17 at column groove 32. Collar 20 also includes a second collar portion 23 that is connected to first collar portion 21 and is configured to at least partially overlap column portion 17. In one embodiment, collar 20 is C-shaped by virtue of an opening 24 in the side of collar 20. Opening 24 functions to permit collar 20 to assume an expanded state in use, as described more fully below. Collar 20 has an internal aperture 22 that is oriented to be in communication with bore 16 in use. The aperture walls 26 of first collar portion 21 are shaped to essentially conform to the shape of column portion 17 in a first relaxed state. In one particular embodiment, collar aperture walls 26 fit against column portion 17 in a first relaxed state. In another embodiment, collar aperture walls 26 conform to the shape of column portion 17 but are minimally spaced from column portion 17.

[0043] In one embodiment, collar aperture 22 is centered on the at least approximate location of the central axis of collar 20. Collar 20 may also have one or more additional slits or notches 25 that extend outward from aperture 22. One of slits 25 may be in communication with opening 24 as shown or may extend entirely through collar 20 in place of opening 24. The remainder of slits 25, if any, do not extend through collar 20 completely. Slits 25 are adapted to allow engagement of an instrument that will turn collar 20 relative to column portion 17. Alternatively, collar aperture 22 may have a shape that allows for the engagement of a driver.

[0044] Collar 20 is also configured to be capable of resilient expansion outwardly as follows. Collar 20 is configured to allow it to assume either of at least two positions relative to column portion 17. In a first, relaxed position, as illustrated in Figs. 4A and 5A-5D for example, first collar portion 21 contacts and is immediately adjacent a majority of column portion 17. Collar 20 has a first, narrower diameter and will therefore fit

through a plate having an orifice or bore with a diameter only slightly larger than the diameter of the assemble screw 10 and collar 20. For example, in the relaxed state, screw 10 and collar 20 may have a maximum diameter of about 5.6 mm, which would permit placement of screw 10 and collar 20 through an orifice having a diameter of 5.9 mm.

[0045] Because of the non-circular or off-center cross-section of column portion 17 and collar aperture 22, both of these structures, in the relaxed state, will have a first, minimum cross-sectional dimension d_1 and a second, maximum cross-sectional dimension d_2. Stated differently, in the relaxed state, aperture walls 26 having dimension d_1 engage column portion 17 having dimension d_1, and aperture walls 26 having dimension d_2 engage column portion 17 having dimension d_2. In the example shown in Fig. 5A, column portion 17 has an approximately square cross section with rounded corners. In such an example, a first minimum cross-sectional dimension d_1 is the distance between two opposing sides of column portion 17, and second maximum cross-sectional dimension d_2 is the distance between two opposing corners of column portion 17. Similarly, in Figs. 4A and 5B, where column portion 17 has an approximately triangular cross section with rounded corners, first minimum cross-sectional dimension d_1 is the distance between a corner and the opposing side of triangular–shaped column portion 17, and second maximum cross-sectional dimension d_2 is the distance between two adjacent corners of column portion 17. In the example shown in Fig. 5C, column portion 17 is diamond-shaped. In that example, first minimum cross-sectional dimension d_1 is the distance between the two opposing corners of column portion 17 that lie on the minor axis of the diamond shape. Second maximum cross-sectional dimension d_2 is the distance between two opposing corners of column portion 17 that lie on the major axis of the diamond shape. Finally, in Fig. 5D, where column portion 17 is approximately circular in cross section but is offset relative to the central axis of screw 10, minimum cross-sectional dimension d_1 is the smallest radius from the center of bore 16 (which may be centered on the central axis of screw 10) to the edge of column portion 17 and maximum cross-sectional dimension d_2 is the largest radius from the center of bore 16 to the edge of column portion 17.

[0046] As shown in Figs. 4A-4H and 5A-5D, in the relaxed state, aperture 22 of collar 20 has the same dimensions as column portion 17. As collar 20 rotates relative to column portion 17, aperture walls 26 of collar 20 at minimal dimension d_1 of collar aperture 22 in the relaxed state come in contact with areas of column portion 17 that have a greater

dimension than minimal dimension d_1. To accommodate this larger dimension, collar 20 is pushed outwardly, increasing the maximum diameter of collar 20. When collar 20 rotates a sufficient degree from the relaxed state, aperture walls 26 of collar 20 will contact column portion 17 at a location where column portion 17 has a maximum cross-sectional dimension d_2. However, in the area of contact, aperture walls 26 will be in the regions of aperture 22 that only have the smaller cross-sectional dimension of d_1 in the relaxed state. To accommodate the larger cross-sectional dimension d_2, collar 20 expands outwardly, increasing its outside diameter to a fully expanded position. The increased diameter of collar 20 prevents assembled screw 10 and collar 20 from passing through an orifice or bore in a bone plate in which it is placed, thereby securing screw 10 in place. For example, in the expanded state, screw 10 and collar 20 may have a maximum diameter of about 6.0 or 6.05 mm, which would secure screw 10 and collar 20 in an orifice having a diameter of about 5.9 mm. It should be noted that the examples show collar 20 rotating clockwise as viewed from above as collar 20 moves from a relaxed state to an expanded state, only for purposes of simplifying presentation of the concepts of the invention. It is also possible for collar 20 to be adapted such that counter-clockwise movement of collar 20 occurs as viewed from above as collar 20 proceeds from a relaxed state to an expanded state, even though such embodiments are not shown in the Figures.

[0047] The mechanism of locking is similar for the example shown in Fig. 5D. As stated above, in the example, column portion 17 is approximately circular but is offset relative to the central axis of screw 10. In the example shown, the center of bore 16 is approximately located on the central axis of screw 10 for simplicity in illustration, but this is not required in all embodiments. Column portion 17 and collar aperture 22 are offset relative to the central axis of screw 10 in the relaxed state. Stated differently, in the relaxed state, column portion 17 having dimension d_1 contacts collar 20 at a relatively wider part of collar 20, while column portion 17 having dimension d_2 contacts collar 20 at a relatively narrow part of collar 20. As with previously described embodiments, as collar 20 rotates, the part of aperture 22 having minimal dimension d_1 in the relaxed state comes in contact with areas of column portion 17 that have a greater dimension than minimal dimension d_1. To accommodate this larger dimension, collar 20 flexes outwardly, increasing the maximum diameter of collar 20. When collar 20 rotates a sufficient degree

from the relaxed state, collar 20 will contact column portion 17 at a location where column portion 17 has a maximum cross-sectional dimension d_2.

[0048] As shown in Figs. 4B, 4D, 4F and 4H, aperture wall 26 may have one or more notches 28, 28', 28", 28'" to provide a seat for one or more corners of column portion 17 in the relaxed or expanded positions thereby providing increased resistance to collar 20 rotating without aid from one state to another. Column portion 17 may also cooperate with one or more collar slits 25, such that a part of column portion 17 partially protrudes into collar slits 25 in an expanded or partially expanded state. In Figs. 4A and 4B, collar 20 is seated on bottom flange 18 in a relaxed state. Aperture wall 26 has several notches 28, 28', 28", 28''' into which the corners of triangular shaped column portion 17 may be seated. In the relaxed state, the corners of column portion 17 are seated in notches 28. As collar 20 is rotated clockwise relative to screw 10, the corners of column portion 17 move from notches 28 to notches 28' (Figs. 4C and 4D). The distance between corners of column portion 17 constitute has a maximum cross-sectional dimension d_2 in the triangular configuration of column portion 17. The distance between adjacent notches 28' in the relaxed state is less than maximum cross-sectional dimension d_2. To accommodate the maximum cross-sectional dimension d_2 at this location, collar 20 expands outwardly, increasing its outside diameter to a first, partially expanded position. As collar 20 continues to move clockwise relative to screw 10, the corners of column portion 17 move from notches 28' to notches 28''. In the relaxed state, the distance between adjacent notches 28'' is less than the distance between adjacent notches 28' (Figs. 4E and 4F). Therefore, as collar 20 rotates clockwise and contacts column portion 17 at notches 28'', collar 20 expands outwardly further to a second, partially expanded position. Finally, as collar 20 continues to move clockwise relative to screw 10, the corners of column portion 17 move from notches 28'' to notches 28''' (Figs. 4G and 4H). In the relaxed state, the distance between adjacent notches 28''' is less than the distance between adjacent notches 28'', and is approximately the minimum cross-sectional dimension d_1. As collar 20 rotates clockwise and contacts column portion 17 at notches 28''', collar 20 expands outwardly further to a third fully expanded position. The contour of one or more of notches 28''' may be further modified to provide a lip 29 to secure column portion 17 and to restrict collar 20 from rotating clockwise further beyond a fully expanded condition and back to a relaxed condition due to column 17 contacting notches 28 again. As provided more fully

below, it is possible for screw 10 and collar 20 to be secured in an orifice or similar structure at a less than fully expanded condition, such as when collar 20 contacts column portion 17 at notches 28''.

[0049] Additional examples utilizing different shapes of column portion 17 and collar aperture 22 are shown in Figs. 5A-5D. In the examples shown in Figs. 5A and 5C, column portion 17 has an approximately rectangular cross-sectional shape such as a square or diamond shaped cross-section with rounded corners, and one or more notches 28, 28', 28'', 28''' may be placed in aperture walls 26 to provide a seat for one or more corners of column portion 17 in the expanded position. As described above, as collar 20 is rotated, column portion 17 moves from contacting aperture walls 26 at notches 28 to 28', 28'' and 28''' in series to finally assume a fully expanded state.

[0050] It is not necessary for multiple notches 28, 28', 28'', 28''' to be present in aperture walls 26. For example, as shown in Fig. 5B, only one notch 28 is present in aperture walls 26, terminating in lip 29. Notch 28, in this case, gradually decreases in its dimension rather than having the predetermined positions at notches 28', 28'', 28''. The gradual change will be reduced to the point that collar 20 is essentially locked in place relative to column portion 17. Collar 20 rotates relative to column portion 17, until it assumes a fully expanded state. There are no distinct partially expanded states in such an example.

[0051] It is additionally possible for notches 28 to be dispensed with entirely, as shown in Fig. 5D. In that example, column portion 17 and collar aperture 22 are at least approximately circular but are offset relative to the central axis of screw 10 in the relaxed state. In the relaxed state, column portion 17 has a first minimal cross-sectional dimension d_1 that is measured from the center axis of screw 10 to a side of column portion 17 and a second maximum cross-sectional dimension d_2 that is measured from the center axis of screw 10 to an opposite side of column portion 17 from the side used to determine dimension d_1, because it is offset from the center axis. Because collar 20 is also offset to accommodate column portion 17, the thickness of collar 20 adjoining dimension d_1 of column portion 17 is greater than the thickness of collar 20 adjoining dimension d_2 of column portion 17 in the relaxed state. As collar 20 rotates from the relaxed state, the part of collar 20 having minimal dimension d_1 at collar aperture 22 in the relaxed state comes in contact with areas of column portion 17 that have a greater dimension than minimal

dimension d_1. To accommodate this larger dimension, collar 20 flexes outwardly, increasing the maximum diameter of collar 20. When collar 20 rotates a sufficient degree from the relaxed state, collar 20 will contact column portion 17 at a location where column portion 17 has a maximum cross-sectional dimension d_2.

[0052] Bone screw 10 and collar 20 may be used with a bone plate as previously known or in combination with a bone plate 40 as shown in Figs. 6-8. Bone plate 40 may be described as being generally flat. However, a predetermined amount of curvature may be present to conform to anatomical requirements. Alternatively, the plate may also be formed in sections, which can be used for additional bending during surgery. Bone plate 40 comprises one or more circular first apertures 42, which are adapted to receive bone screw 10 and collar 20. First aperture 42 is configured such that arcuate section 15 on screw 10 and collar 20 contact the side wall 41 of aperture 42. First aperture 42 thereby provides an arcuate seat for assembled screw 10 and collar 20.

[0053] Plate 40 may also include one or more second apertures 48. Second apertures 48 include a carrier 50. Carrier 50 has an upper portion 52 which is adapted to contact and be seated in second aperture walls 54. For example, when aperture walls 54 are generally arcuate, upper portion 52 is adapted to conform to the shape of second aperture walls 54 with outer carrier walls 55 that have an arcuate shape of approximately the same shape as second aperture walls 54 at the points of contact. Because second apertures 48 may be elongated, carrier 50 may slideably engage plate 40 at second aperture 48. Carrier 50 also has a lower portion or lip 56 which abuts plate 40 on a lower surface 43 of plate 40 thereby restricting movement of carrier 50 upward in the orientation shown in the Figures. In the example shown, the curvature of upper portion 52 restricts the movement of carrier 50 downward in the orientation shown in the Figures once bone screw 10 and collar 20 are placed and the locking mechanism is activated. Carrier 50 may include one or more slots 51 that permit carrier 50 to be compressed temporarily during insertion into second aperture 48.

[0054] Carrier 50 is adapted to receive assembled screw 10 and collar 20. Carrier 50 has an internal bore 53 bounded by an inner carrier wall 57 that is configured such that arcuate section 15 of screw 10 and collar 20 contact inner carrier wall 57 of carrier 50. Carrier 50 thereby provides a seat for assembled screw 10 and collar 20 in second

aperture 48. Carrier 50 may be slightly oval or oblong in shape to prevent or at least inhibit carrier 50 from rotating.

[0055] Carrier 50 may be further adapted to engage second aperture 48 in either of two ways. In a first condition, collar 20 has been partially, but not fully, expanded. Such a state is shown, for example, in Figs. 4C-4F. In this condition, collar 20 has expanded sufficiently to secure screw 10 and collar 20 in carrier 50, but does not significantly inhibit carrier 50 from sliding within second aperture 48. In a second condition, collar 20 has been fully expanded, as seen in Fig. 4G and 4H, for example. In this condition, the expansion of collar 20 is sufficient, not only to secure assembled screw 10 and collar 20 in carrier 50, but also to place stress on upper portion 52 of carrier 50, causing upper portion 52 to expand outwardly and contact second aperture walls 54 in such a way as to prevent carrier 50 from sliding within second aperture 48. In this way, assembled screw 10 and collar 20 may be slidably secured in carrier 50 and plate 40 can be used as a dynamic plate (as in the first condition). Additionally, assembled screw 10 and collar 20 may also be secured in carrier 50 in such a way that no significant movement of screw 10 relative to plate 40 is observed, that is, in the second condition so that plate 40 is used as a static plate.

[0056] Plate 40 may also contain one or more third apertures 44. In the case of plate 40 being used as a cervical plate, third aperture 44 permits the surgeon to view or monitor structures lying beneath the plate 40. Alternatively, third aperture 44 may be also used as a location of a more traditional bone screw or graft screw, for example, when a PEEK (polyetheretherketone) implant is placed in the disc space for fusion purposes or any other bone graft material is used for fusion, know in the art. Third aperture 44 may include one or more chamfers 45 on the upper edge of third apertures 44. The peripheral edge 46 of plate 40 may also be chamfered to prevent plate 40 from damaging or irritating tissues surrounding plate 40. Plate 40 is shown in Figures 6A and 6B as having 5 apertures in a pattern of 2 first apertures 42, two second apertures 48 and one third aperture 44. However, any number or pattern of apertures may be present, depending on the requirements of a particular application.

[0057] In use, screw 10 may be utilized, for example in spinal stabilization, by assembling screw 10 and collar 20 in the relaxed state. The assembled screw 10 and collar 20 are then inserted through plate 40 into a bone (not shown) with a driver for

which bore 16 is adapted. For example, where bore 16 has a hexalobe shape, a corresponding hexalobe driver is used. Once screw 10 is secured in a bone or other suitable substrate, collar 20 is rotated relative to the screw 10 to secure screw 10 and collar 20 in a plate 40. By rotating collar 20, the assembled screw 10 and collar 20 make a transition from a first relaxed state to a second expanded state.

[0058] In Fig. 7, for example, a pair of screws 10 and collars 20, 20' are shown in cross-section as inserted into first apertures 42. A collar in the first relaxed state is shown as collar 20, while a collar in the second expanded state is shown as collar 20'. In particular, collar 20 may be rotated relative to column portion 17. An instrument designed to engage one or more of collar slits 25 may be used to rotate collar 20 relative to column portion 17 may be used. For example, where two collar slits 25 are present on opposite sides of collar aperture 22, a flat headed screw driver might be used to rotate collar 20 relative to column portion 17. Where six collar slits 25 are present as shown in the Figures, an instrument designed to engage a plurality or even all of collar slits 25 may be used to rotate collar 20. When collar 20 has rotated a sufficient degree, it will contact column portion 17 at a location where column portion 17 has a maximum cross-sectional dimension d_2, as described above. However, in the area of contact, the regions of collar 20' making contact will be the regions that previously had the smaller cross-sectional dimension of d_1 in the relaxed state. To accommodate the larger cross-sectional dimension d_2, collar 20' expands outwardly, increasing its outside diameter in a second expanded position. The increased diameter of collar 20' prevents assembled screw 10 and collar 20 from passing through the aperture in which it is placed, thereby securing assembled screw 10 and collar 20' in first aperture 42.

[0059] An assembled screw 10 and collar 20 may be secured in carrier 50 in a similar manner. Carrier 50 is inserted into second aperture 48 as shown in Figs. 6A, 6B and 8. This may be accomplished prior to the start of surgery. An empty carrier 50 is shown on the left side of plate 40 while a carrier 50' with an assembled screw 10 and collar 20' inserted is shown on the right side of plate 40. In carrier 50', collar 20' is in an expanded position. As with first apertures 42, assembled screw 10 and collar 20 are inserted through plate 40 into a bone (not shown). However, assembled screw 10 and collar 20 are seated in carrier 50 instead of being seated directly in second aperture 48. Once screw 10 is secured in a bone or other suitable substrate, collar 20 is rotated relative to the screw 10 to

secure screw 10 and collar 20 in carrier 50. As provided above, rotating collar 20 causes it to make a transition from a first relaxed state to a second, partially expanded state, locking assembled screw 10 and collar 20 into carrier 50 in a dynamic mode. The elongated shape of second aperture 48 allows carrier 50 to move within second aperture 48 along the length of second aperture 48. This movement allows for at least some self-adjustment of the assembled plate system in use and at least partially compensate for bone remodeling that typically may occur in the area of placement of a bone screw and plate. If collar 20 is rotated further relative to screw 10, to fully expand collar 20, the full expansion places additional force on upper portion 52 of carrier 50. This additional force or stress causes upper portion 52 to expand outwardly and contact second aperture walls 54 with sufficient contact to restrict or prevent carrier 50 from sliding within second aperture 48. As provided above, plate 40 may therefore be used as either a dynamic plate or as a static plate.

[0060] As mentioned above, according to Wolf's law, bone can grow and remodel in response to stress placed on that bone. The self-adjusting aspect of the bone screw and plate system allows a certain amount of load to be transferred to a bone graft that is being supported by the plate while the graft fuses adjacent bones. For example, when the plate is inserted into adjacent cervical vertebrae to facilitate fusion between them, the transfer of a portion of the load to the graft material facilitates the growth of bone and the eventual fusion of the cervical vertebrae. The movement of carrier 50 within second aperture 48 permits automatic adjustment of the screws in response to any bone subsidence that occurs during spinal fusion. The resulting bone screw and plate system may therefore be considered a dynamic bone plate system.

[0061] Based upon the foregoing disclosure, it should now be apparent that the locking mechanism may be used with a variety of bone screws or even screws not meant for surgical purposes. It is, therefore, to be understood that any variations evident fall within the scope of the claimed invention and thus, the selection of specific component elements can be determined without departing from the spirit of the invention herein disclosed and described.

CLAIMS

I claim:

1. A locking screw assembly comprising:

at least one screw having a shaft portion and a head portion, the head portion extending from the shaft portion in an arcuate manner, terminating in a flange portion, the head portion also including a column portion that extends from the flange portion and contains a bore therein, the bore being adapted to engage a first driver, wherein the column portion has a non-circular or off-center circular cross-section, wherein the column portion has a first cross-sectional dimension and a second cross-sectional dimension greater than the first cross-sectional dimension; and

at least one collar containing a first collar portion and a second collar portion, wherein the first collar portion has a collar aperture, the collar aperture being defined by collar aperture walls, and wherein the first collar portion is configured to be seated on the flange portion and to contact the column portion at the collar aperture walls, and wherein the second collar portion extends from the first collar portion and is adapted to engage a second driver;

wherein the at least one collar is adapted to contact the column portion in a first position and in a second position, and wherein the at least one collar has a first outer diameter in the first position and a second outer diameter in the second position, wherein the second outer diameter is larger than the first outer diameter and

further wherein the at least one collar and at least one screw together comprise at least one screw and collar assembly.

2. The locking screw assembly of claim 1, wherein, in the first position, the collar aperture walls having a first cross-sectional dimension contact the column portion in the area of the first cross-sectional dimension, and in the second position the collar aperture walls contact the column portion at points larger than the first cross-sectional dimension, thereby causing the collar to expand outwardly.

3. The locking screw assembly of claim 1, wherein the collar aperture walls additionally have one or more structures that restrict movement of the collar relative to column portion in the second position.

4. The locking screw assembly of claim 1, wherein the column portion has cross-section that is selected from the group consisting of an essentially rectangular cross-section, an essentially triangular cross section, an off-center circular cross-section, and variations thereof wherein one or more corners present are rounded corners.

5. The locking screw assembly of claim 1, wherein the second collar portion has an internal aperture that is configured to be in communication with the bore.

6. The locking screw assembly of claim 1, wherein the collar is C-shaped.

7. The locking screw assembly of claim 1, additionally comprising a plate having an upper surface and a lower surface and being adapted to accept the screw and collar assembly through at least one orifice, wherein the screw and collar assembly have a first assembled maximum diameter in the first position and a second assembled maximum diameter in the second position, wherein the first assembled maximum diameter is smaller than a dimension of the at least one orifice and the second assembled maximum diameter is larger than the first assembled maximum diameter.

8. The locking screw assembly of claim 7, wherein the plate is a cervical plate.

9. The locking screw assembly of claim 7, wherein the at least one orifice comprises at least one first aperture adapted to receive a first screw and collar assembly, at least one elongated second aperture, and at least one carrier adapted to slidably engage the at least one elongated second aperture and having contoured walls adapted to receive a second screw and collar assembly.

10. The locking screw assembly of claim 9, wherein the first screw and collar assembly is inserted into the at least one first aperture and the locking screw assembly additionally comprises at least a second screw and collar assembly inserted into the carrier.

11. The locking screw assembly of claim 9, wherein the at least one carrier has a lower portion that abuts the lower surface of the plate.

12. The locking screw assembly of claim 11, wherein the at least one elongated second aperture has walls that are contoured and the at least one carrier has an upper portion that conforms to the contour of the walls.

13. The locking screw assembly of claim 12, wherein carrier is adapted such that the second screw and collar assembly inserted into the carrier, in the second position, is secured in the carrier, but does not significantly restrict the carrier from sliding within the second aperture.

14. The locking screw assembly of claim 13, wherein the second screw and collar assembly comprises a collar that is additionally adapted to contact the column portion in a third position, and wherein the collar of the second screw and collar assembly has a third outer diameter in the third position and the third outer diameter is larger than the second outer diameter, and further wherein the third outer diameter causes expansion of the carrier such that the carrier is restricted from moving within the second aperture.

15. A method for attaching a plate to one or more bones, the method comprising:

providing at least one locking screw assembly and a plate,

wherein the at least one locking screw assembly contains:

a screw that includes a shaft portion and a head portion, the head portion extending from the shaft portion in an arcuate manner and terminating in a flange portion, the head portion also including a column portion that extends from the flange portion and contains a bore therein, wherein the column portion has a non-circular or off-center circular cross-section, wherein the column portion has a first cross-sectional dimension and a second cross-sectional dimension greater than the first cross-sectional dimension; and

a collar containing a first collar portion and a second collar portion, wherein the first collar portion has a collar aperture defined by collar aperture walls, and wherein the first collar portion is configured to be seated on the flange portion and to contact the column portion at the collar aperture walls, wherein the second collar portion extends from the first collar portion and at least partially overlaps the column portion, and wherein the collar is adapted to contact the column portion in a first position and in a second position, and wherein the collar has a first outer diameter in the first position and a second outer diameter in the second position, wherein the second outer diameter is larger than the first outer diameter, and

wherein the plate has at least one first plate aperture having at least one dimension that is larger than the first outer diameter and smaller than the second outer diameter;

inserting a locking screw assembly through the at least one first plate aperture and into a bone; and

locking the locking screw assembly in place by rotating the collar from the first position to the second position.

16. The method of claim 15, wherein the plate is a cervical plate and the one or more bones are cervical vertebrae.

17. The method of claim 15, wherein the collar is C-shaped.

18. The method of claim 15, wherein the plate additionally comprises at least one elongated second plate aperture, and at least one carrier, wherein the at least one carrier slidably engages the at least one elongated second plate aperture and is adapted to receive a second screw and collar assembly.

19. A bone plate comprising:

an upper surface and a lower surface;

at least one first aperture adapted to receive a first screw,

at least one elongated second aperture, and

at least one carrier adapted to slidably engage the at least one elongated second aperture and being adapted to receive a second screw.

20. The bone plate of claim 19, wherein the at least one elongated second aperture has walls that are contoured and the at least one carrier comprises an upper portion and a lower portion, the upper portion having a shape that conforms to the walls of the at least one elongated second aperture and the lower portion being adapted to abut the lower surface of the bone plate.

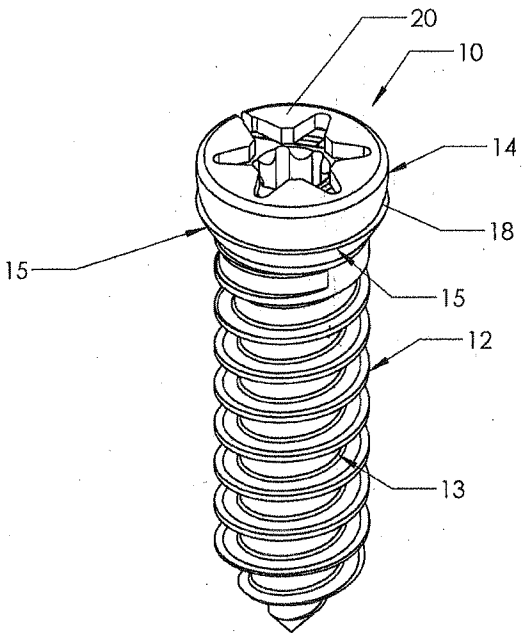

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Fig. 1

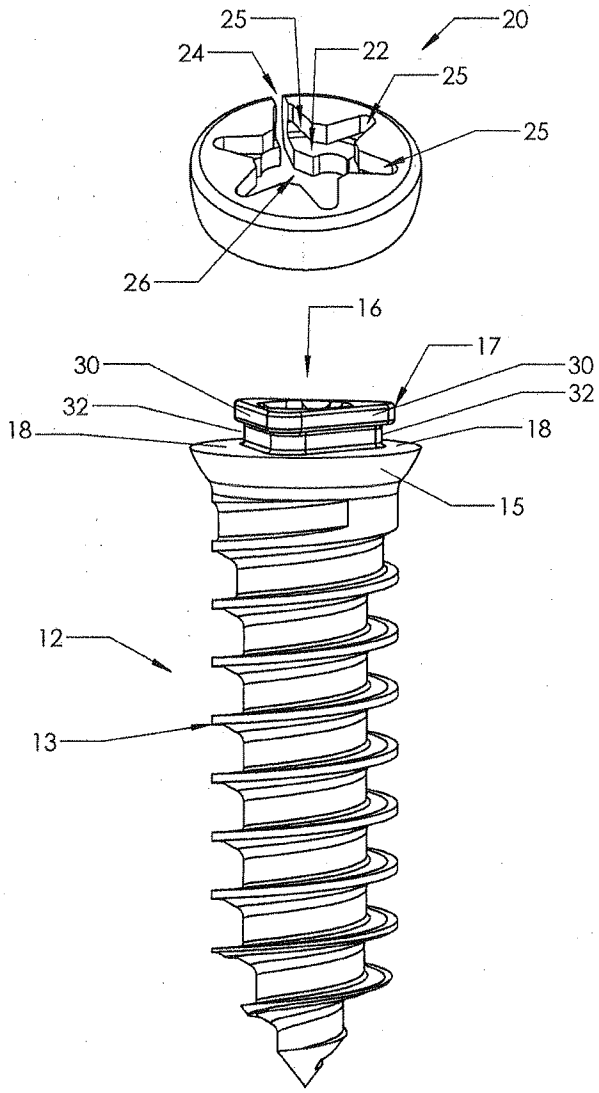

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Fig. 2

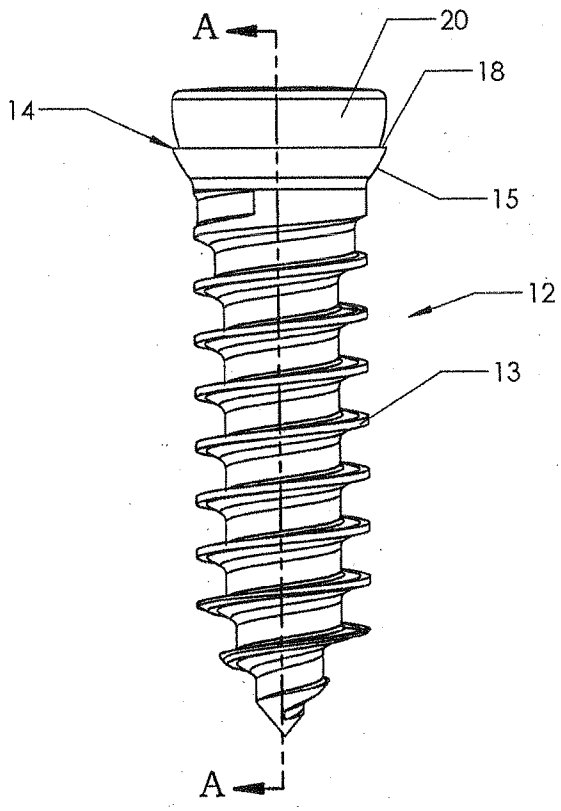


Fig. 3A

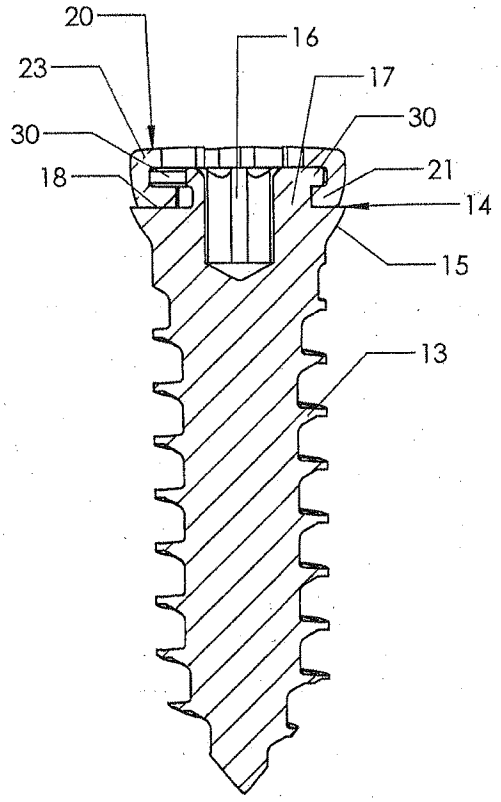


Fig. 3B

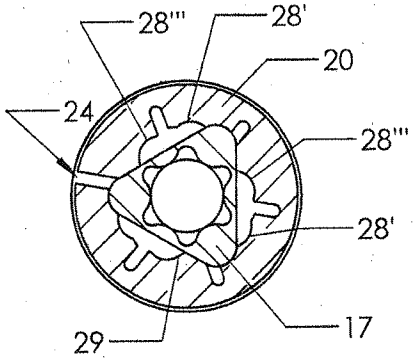


Fig. 4B

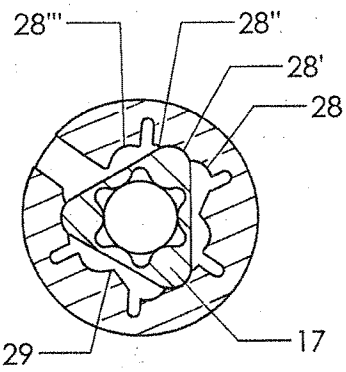


Fig. 4D

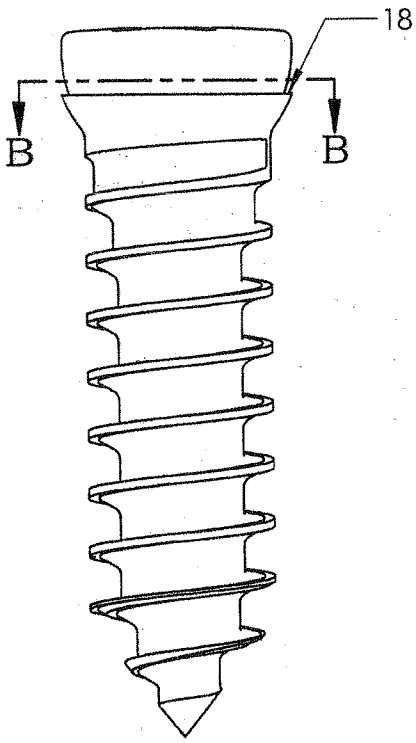


Fig. 4A

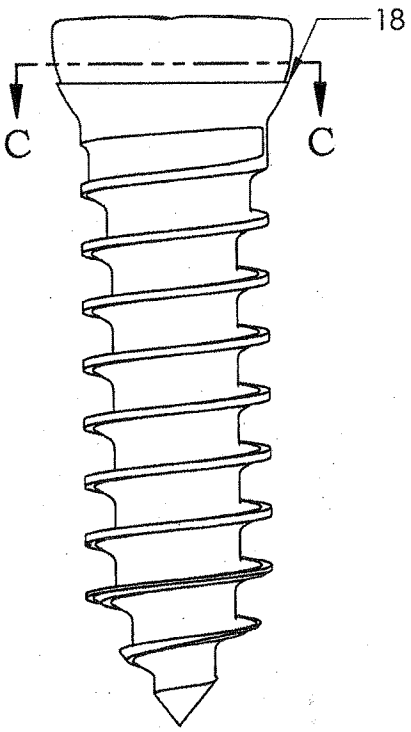


Fig. 4C

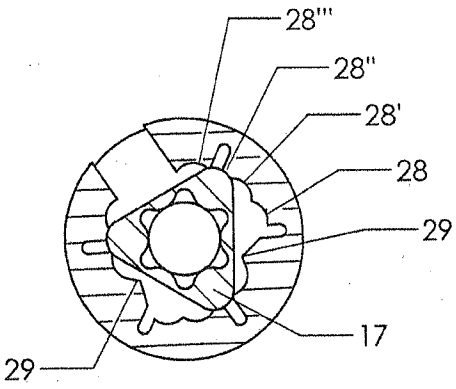


Fig. 4F

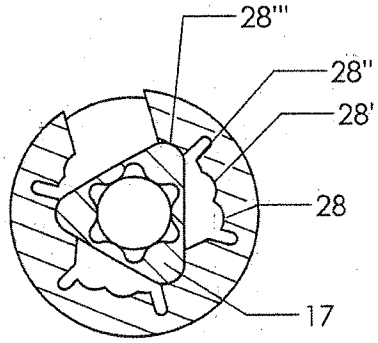


Fig. 4H

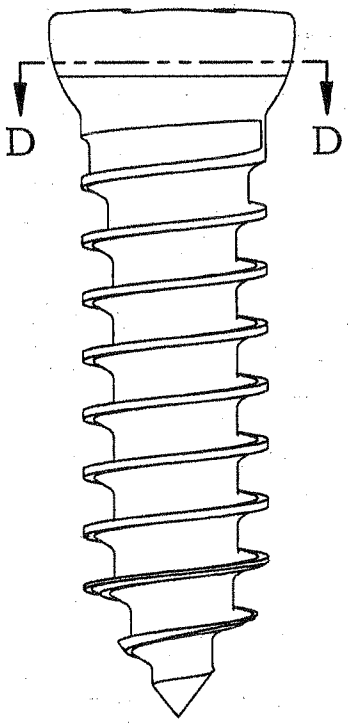


Fig. 4E

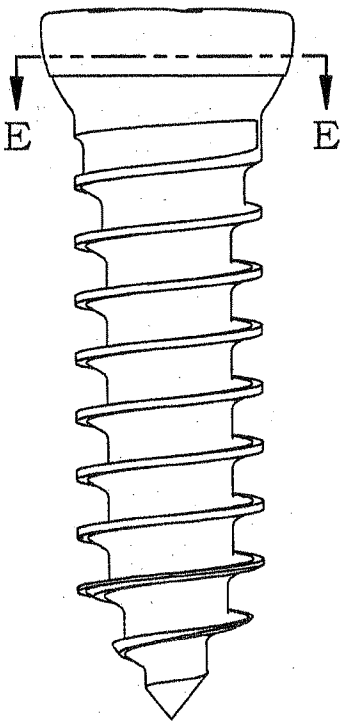


Fig. 4G

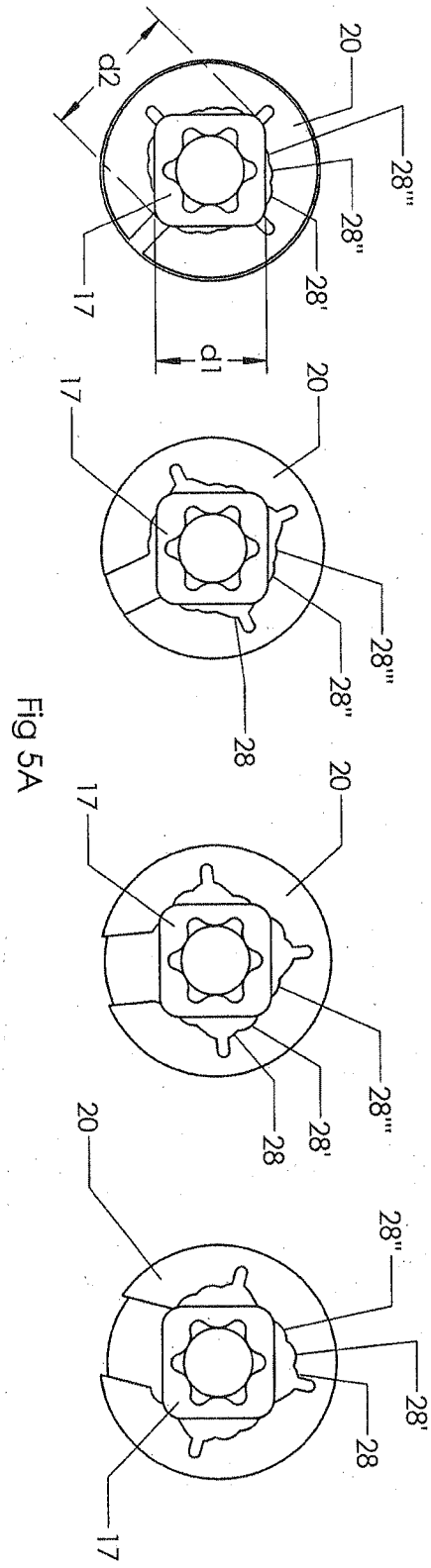

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Fig 5A

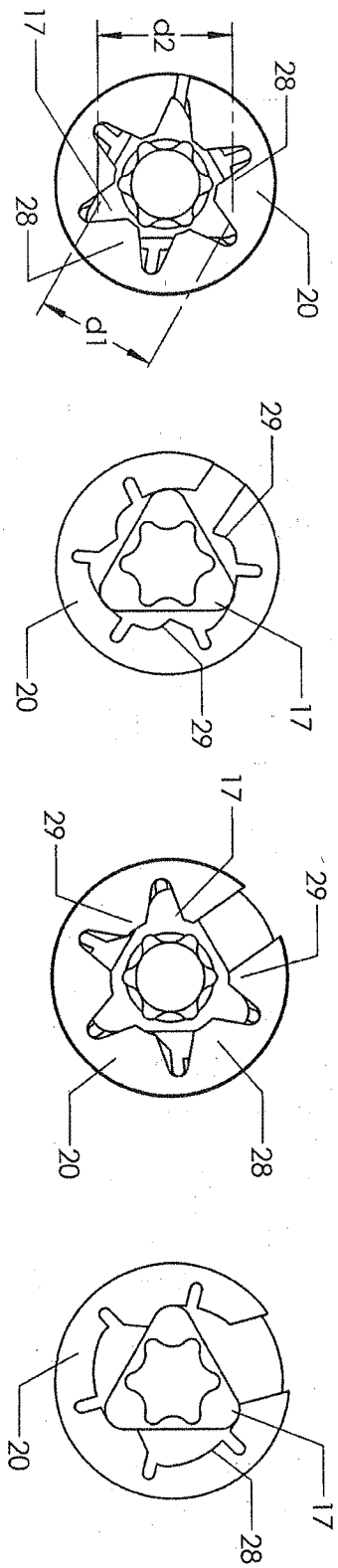

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Fig 5B

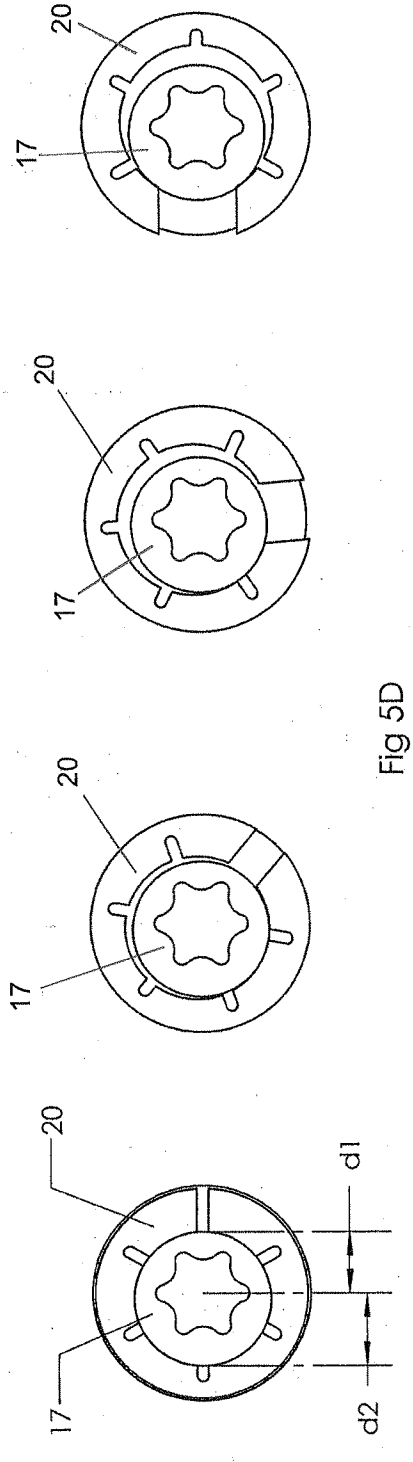


Fig 5D

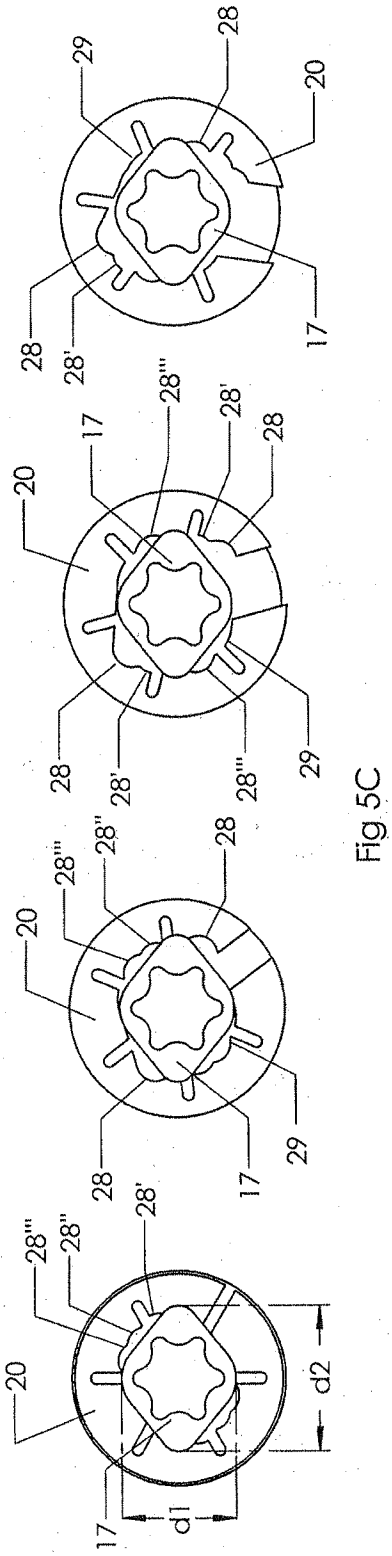


Fig 5C

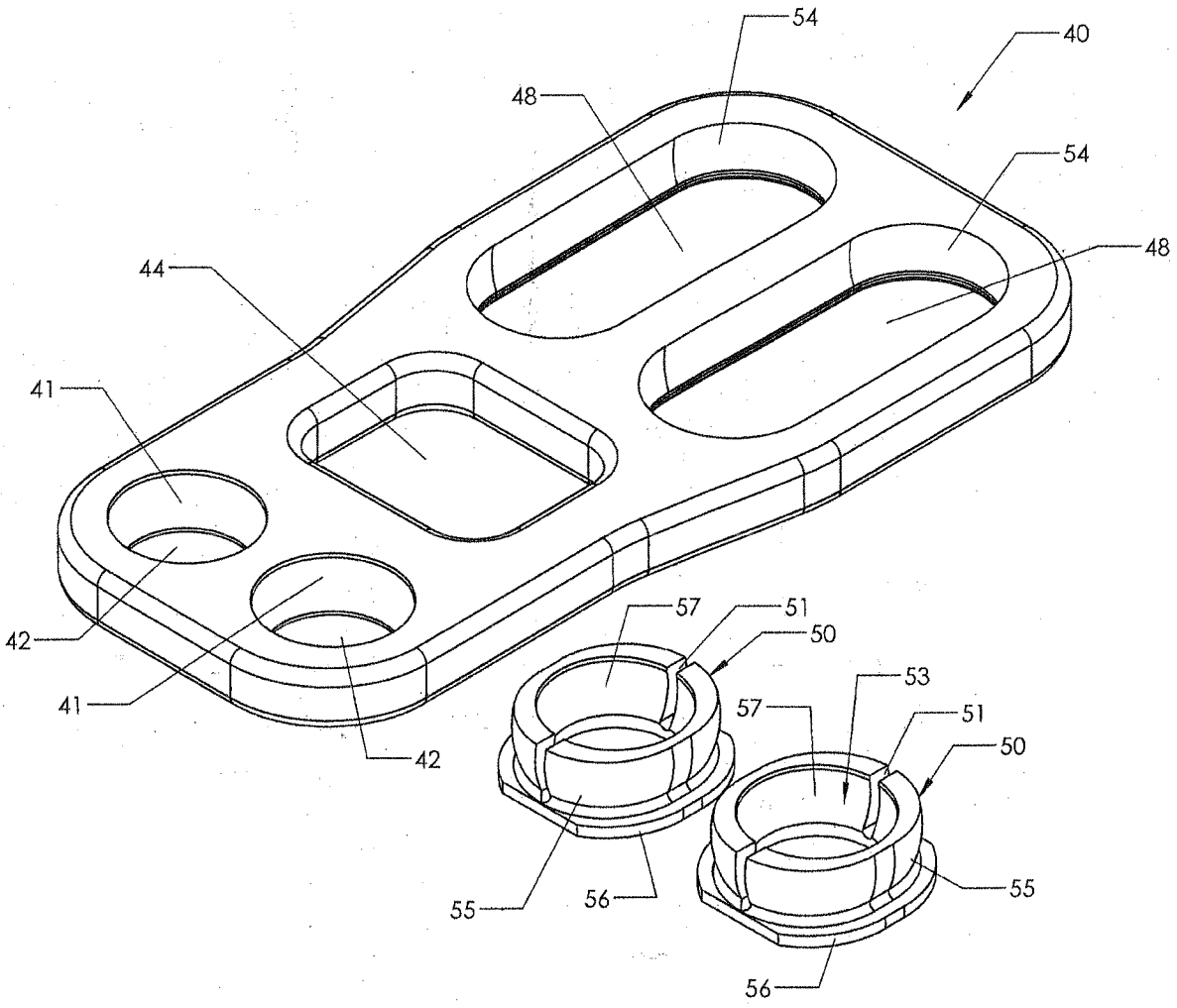


Fig. 6A

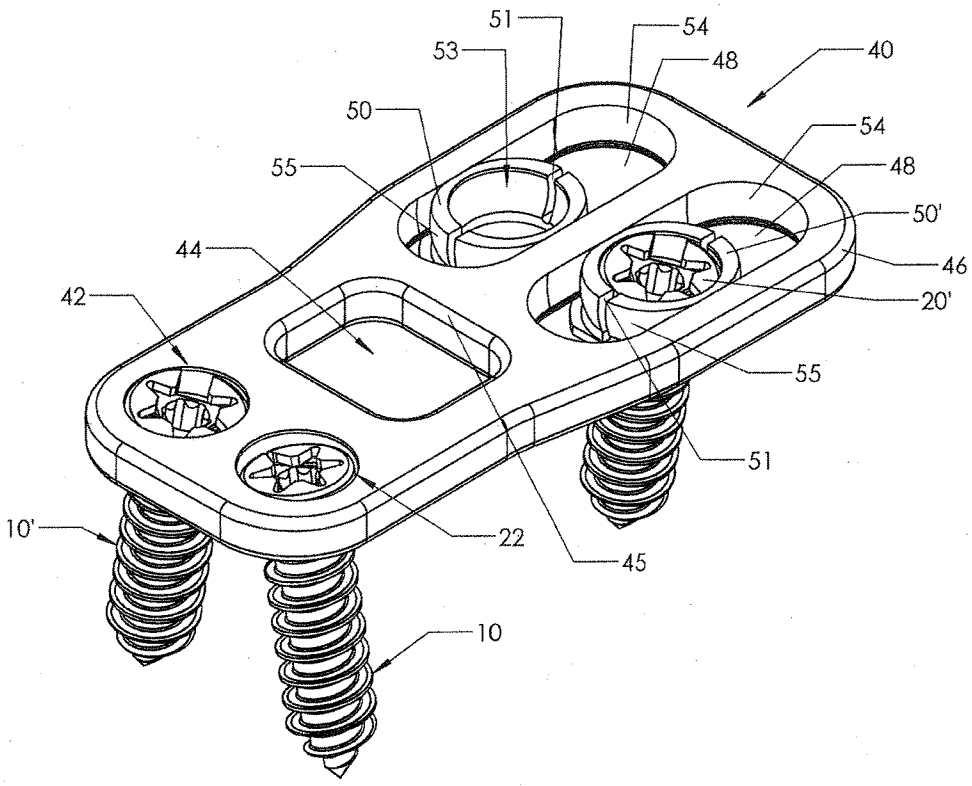


Fig. 6B

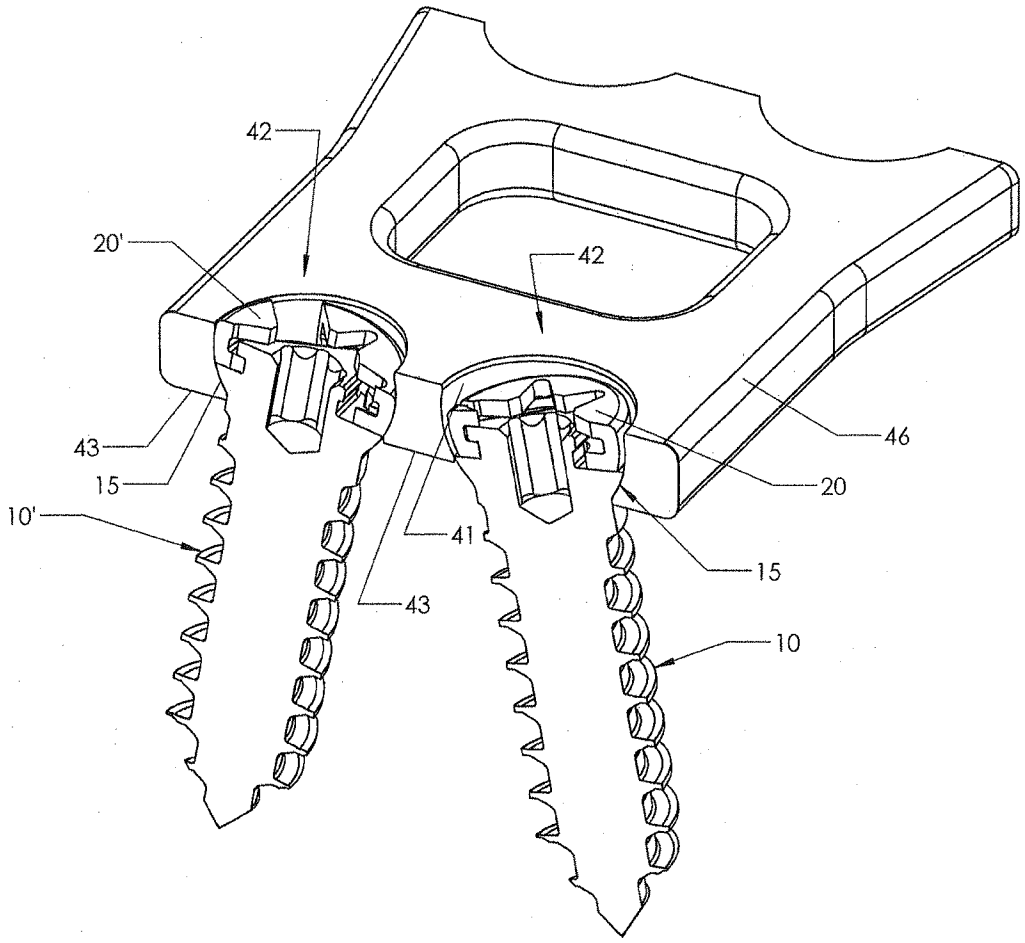


Fig. 7

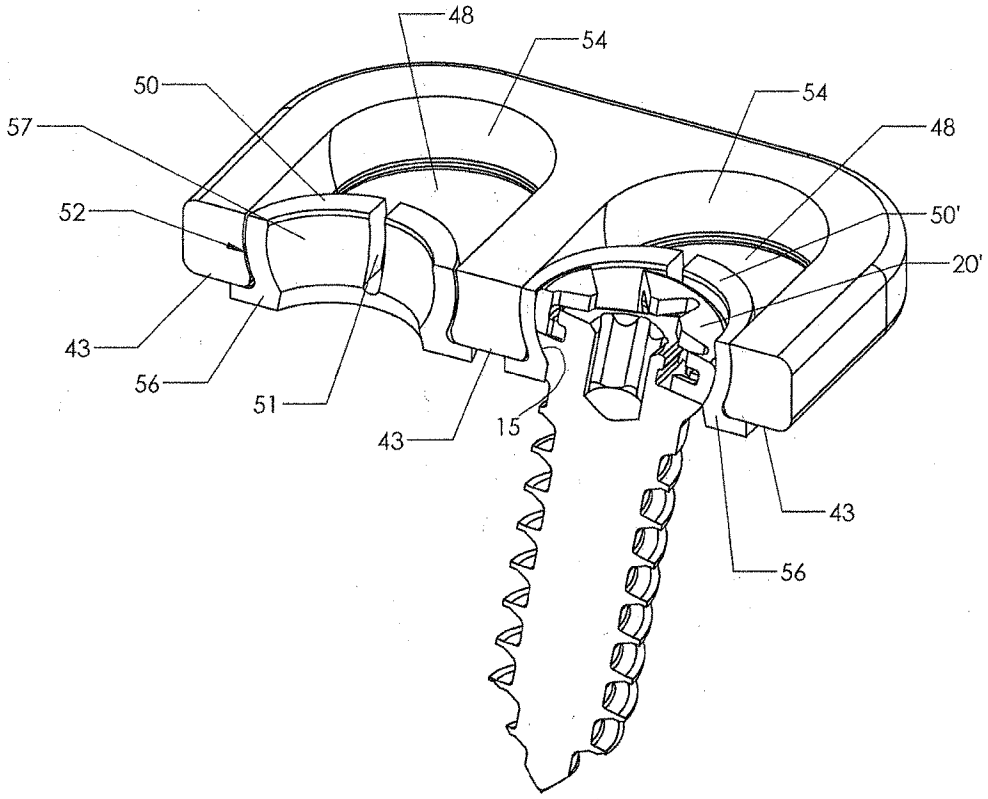


Fig.8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/080616

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/58(2006.01)i, A61B 17/80(2006.01)i

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)
IPC A61B 17/58, 17/70, 17/80

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean Utility models and applications for Utility models since 1975
Japanese Utility models and applications for Utility models since 1975

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO 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 5,578,034 A(BRADLEY) 26 NOVEMBER 1996 See abstract, figs. 1, 2, column 1 lines 14-22, column 4 line 36 - column 5 line 3, column 5 lines 54 - 67, claim 1	1-14, 19, 20
A	US 2008/234750 A1(RICHARD W. WOODS et al.) 25 SEPTEMBER 2008 See abstract, figs. 1B, 2F, paragraphs [28] - [35], claim 1	1-14, 19, 20
A	US 2001/14807 A1(ERIK J. WAGNER et al.) 16 AUGUST 2001 See abstract, figs. 1, 3, 4, 8, paragraphs [12], [35] - [38], [48], claims 1, 17	1-14, 19, 20
A	US 7,175,623 B2(JEFFREY THRAMANN et al.) 13 FEBRUARY 2007 See abstract, figs. 3, 6, 7, column 2 lines 3-14, column 3 line 61 - column 3 line 11, column 3 lines 20 - 62, claims 1, 8	1-14, 19, 20

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

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 JULY 2009 (16.07.2009)	**17 JULY 2009 (17.07.2009)**

Name and mailing address of the ISA/KR
Korean Intellectual Property Office
Government Complex-Daejeon, 139 Seonsa-ro, Seo-gu, Daejeon 302-701, Republic of Korea
Facsimile No. 82-42-472-7140

Authorized officer
KIM, Hee Seung
Telephone No. 82-42-481-8656

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/080616

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 15-18
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 15-18 pertain to methods for treatment of human body by therapy and thus relate to a subject matter which this International Searching Authority is not required to search under Article 17(2)(a)(i) and Rule 39.1(iv) of the Regulations under the PCT, to search.

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

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

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2008/080616

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		US 2002-0058939 A1	16.05.2002
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