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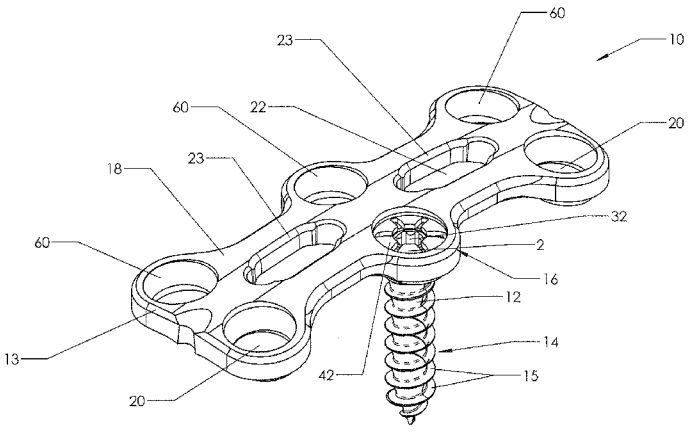

Fig. 1

(57) Abstract: A bone screw assembly includes a bone screw having a shaft portion and a head portion. The shaft portion bears threads oriented in a first direction. The head portion has an internal bore, which has a first portion and a second portion. The second portion is adapted to engage a driver and has a diameter less than that of the first portion. The surface of the first portion bears threads oriented in a second direction which is opposite that of the first direction. The bone screw assembly also includes a set screw adapted to engage the surface of the first portion and having a bore adapted to engage the driver. The assembly also includes a collar adapted to engage the head portion and having a bore with a diameter that is less than the diameter of the set screw. A method includes the use of the bone screw assembly.

LOCKING CERVICAL SCREW AND METHODS OF USE THEREOF

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 and a bone plate wherein the bone screw is locked into place and methods of use thereof. Even more particularly, this invention relates to a bone screw and an associated cervical 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 rod is disposed longitudinally along the length of the spine in the region of concern. The rod is arranged according to the anatomy and the correction desired. In this system, the rod is aligned along the spine and engages various vertebrae along its length. The rod engages, or more typically, a pair of parallel rods engage the spine using fixation elements, such as anchors, attached to vertebral bodies by a bone screw that is inserted into the pedicle and penetrates into the body of the vertebra.

[0005] In another technique, 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 loosening 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 an apparatus and prevent their loosening over time.

[0006] One such prior technique involves the use of a pair of cervical plates. A first cervical plate is attached to the vertebrae with bone screws and then a second plate is overlaid on top of the first plate and the heads of the bone screws and secured in place by a second set of screws, thereby preventing or at least delaying the loosening of the bone screws.

[0007] A variety of other 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] Anatomy and correction frequently require aligning of correcting rods, plates or screws at various angles along the length of the portion of correction. In order to provide this alignment, polyaxial screws/anchors have been developed. Many variations of bone screw and fixation systems exist on the market today. However, prior systems have been limited in the amount of angulation permitted relative to the place of attachment to the spine.

[0009] Therefore, there is a need for a bone screw assembly that permits a wide range of angulation relative to the place of attachment to the spine while providing an effective and secure lock of the screw and plate in the desired position.

SUMMARY OF INVENTION

[0010] It is, therefore, an aspect of the present invention to provide a screw assembly that requires the use of only one tool for insertion and securing of a screw in a plate adapted to receive the screw.

[0011] It is another aspect of the present invention to provide a bone screw and plate that provides for polyaxial orientation of the screw relative to the plate.

[0012] It is still another aspect of the present invention to provide a cervical plate system that provides for polyaxial orientation of one or more bone screws while securing the bone screws in a simple manner.

[0013] It is yet another aspect of the present invention to provide a method of securing a cervical plate to the cervical region of the spine.

[0014] In general, the present invention provides a bone screw assembly that includes a bone screw having a shaft portion and a head portion. The shaft portion bears threads oriented in a first direction. The head portion has an internal bore, which has a first portion and a second portion. The second portion is adapted to engage a driver and the second portion has a diameter less than the diameter of the first portion. The surface of the first portion of the bore bears threads oriented in a second direction which is opposite that of the first direction. The bone screw assembly also includes a set screw adapted to engage the surface of the first portion of the bore and having a set screw bore adapted to engage the driver. The assembly also includes a collar adapted to engage the head portion and having a collar bore with a minimum diameter that is less than the maximum diameter of the set screw. The bone screw assembly may additionally include a bone plate, such as a cervical plate, having one or more apertures adapted to receive a bone screw.

[0015] The bone screw assembly may have a head portion that extends away from the shaft portion in a generally arcuate manner around the entire circumference of the head portion,

forming an arcuate section. An outer surface of the collar abuts the arcuate section and has a generally arcuate configuration that complements and continues the arcuate configuration of the arcuate section. One or more apertures have an inner surface that forms an arcuate seat. Optionally, the arcuate section may additionally comprise one or more projections on the surface of the arcuate section, configured to prevent the bone screw from rotating beyond a predetermined point.

[0016] The bone screw assembly is arranged such that the bone screw is capable of rotating in a cone of up to about 5, 10 or even 20 degrees around a perpendicular orientation relative to the plate. To aid in such a freedom of rotation, a lower edge of the one or more apertures may be chamfered.

[0017] The bone screw assembly includes a collar that is adapted to be able to flex inwardly in response to radial pressure when the set screw is fully engaged in the first portion of the internal bore of the head portion of the bone screw. This allows the assembled bone screw, set screw and collar to be inserted into a plate aperture, where the minimum diameter of the aperture is slightly smaller than the maximum diameter of the collar. The collar flexes inwardly as the screws and collar pass the point of minimum diameter in the plate, but once past this point, the collar then relaxes back into a relaxed position. The collar may also comprise slits that extend from the collar bore and partially through the collar to aid in the ability of the collar to flex in response to radial pressure. The collar and the bone screw it engages are fixed in place when the set screw is partially removed from the first portion of the internal bore of the head portion of the bone screw, such that the set screw contacts the collar, keeping the collar from flexing inwardly. For the bone screw to be able to loosen, the assembled bone screw, set screw and collar would need to pass the point of minimum diameter in the reverse direction as described above. However, with the set screw preventing the collar from flexing inwardly, this is not possible, as the collar maintains a maximum diameter that is greater than the minimum diameter of the plate aperture. In one example, the set screw does not cause the collar to spread outwardly but rather prevents the collar from flexing inwardly. In another example, the collar and the head portion of the bone screw each comprise a flange and a groove adjacent the flange, and wherein flange of the head portion of the bone screw engages the groove of the collar and the flange of the collar engages the groove of the head portion of the bone screw.

[0018] It will be appreciated that the screw assembly does not rely on plastic deformation of any component to secure the one or more screws. Therefore, the screws can be removed, relocated and reused, even after a screw has been previously locked in place, since none of the components have been permanently deformed when locked into place.

[0019] The present invention also provides a method for attaching a bone plate to one or more bones. The method includes providing a bone screw assembly and a bone plate as provided above. The bone screw assembly comprises a bone screw having a shaft portion and a head portion, the shaft portion bearing threads oriented in a first direction, and the head portion having an internal bore with a first portion and a second portion. The second portion of the bore space is adapted to engage a driver and has a diameter less than the diameter of the first portion. The surface of the first portion of the bore space bears threads oriented in a second direction which is opposite that of the first direction. A set screw adapted to engage the surface of the first portion and having a bore adapted to engage the driver is also provided. A collar adapted to engage the head portion and having a bore with a diameter that is less than the diameter of the set screw is likewise provided. The bone plate includes one or more apertures.

[0020] The bone screw, set screw and collar are assembled with the set screw fully inserted into the first portion of the internal bore and with the collar engaged with the head portion of the bone screw. The assembled bone screw, set screw and collar are inserted as a single piece through an aperture of the bone plate and a driver is inserted through the collar bore to engage the set screw bore and the second portion of the internal bore. The driver is rotated in a first direction to drive the bone screw into the bone until the assembled bone screw, set screw and collar contact the bone plate. Rotation of the driver is continued, driving the bone screw until the driving force causes the collar to flex inwardly, allowing the assembled bone screw, set screw and collar to pass into the aperture of the bone plate. The collar may have one or more slits extending from the collar bore into and partially through the collar to facilitate inward flexing in response to radial pressure. When fully seated and not subject to radial pressure, the collar expands and is flush with the interior aperture of the plate. The driver is then partially removed from the bone screw, such that the driver only contacts the set screw at the set screw bore. Rotation of the driver in the first direction is continued to retract the set screw through the collar bore until the set screw

contacts the collar, thereby preventing the collar from flexing inwardly and locking the bone screw, the set screw and the collar to the bone plate. In one example, the bone plate is a cervical plate and the one or more bones are cervical vertebrae.

[0021] In another example, the head portion extends away from the shaft portion in a generally arcuate manner around the entire circumference of head portion, forming an arcuate section. An outer surface of the collar abuts the arcuate section and has a generally arcuate configuration that complements and continues the arcuate configuration of the arcuate section. The one or more apertures have an inside surface that forms an arcuate seat. In such an example, the bone screw is capable of rotating in a cone of up to about 5, 10 or even 20 degrees around a perpendicular orientation relative to the plate, depending on the thickness of the plate and other structural considerations. The arcuate section may additionally comprise one or more projections on the surface of the arcuate section, wherein the projections are configured to prevent the bone screw from rotating beyond a predetermined point.

[0022] In one particular example, the collar and the head portion of the bone screw each comprise a flange and a groove adjacent the flange. The flange of the head portion of the bone screw engages the groove of the collar and the flange of the collar engages the groove of the head portion of the bone screw.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0023] Fig. 1 is a plan view of a screw system including a bone screw and a bone plate according to the present invention.

[0024] Fig. 2A is an exploded plan view of a bone screw, set screw and collar of the present invention.

[0025] Fig. 2B is a partial, cross-sectional view of a bone screw according to the present invention.

[0026] Fig. 2C is a cross-sectional view of a set screw adapted to be used in the present invention.

[0027] Fig. 2D is a cross-sectional view of a collar adapted to engage the bone screw of the present invention.

[0028] Figure 3 is a cross-sectional view of a bone screw assembly inserted into a bone plate in an unlocked condition; and

[0029] Figure 4 is a cross sectional view of a bone screw assembly inserted into and secured in a bone plate in a locked condition.

PREFERRED EMBODIMENT FOR CARRYING OUT THE INVENTION

[0030] The present invention is directed toward a screw system and an associated plate that provides polyaxial orientation of the one or more screws secured to the plate. The following examples should not be viewed as limiting the scope of the invention. The claims will serve to define the inventions.

[0031] In one embodiment, shown in Figs. 1, 2A and 2B, the cervical plate with screw system 10 comprises a screw 12 having a shaft portion 14 and a head portion 16. Shaft portion 14 contains threads 15 that are oriented in a first direction. That is, the threads located on shaft portion may be either right-handed or left-handed. Screw 12 is configured to be inserted through a first aperture 20 in plate 18. First aperture 20 is configured such that head portion 16 contacts the side wall 60 of aperture 20, which forms an arcuate seat for screw 12 as described more fully below.

[0032] Plate 18 may also contain one or more second apertures 22. In the case of plate 18 being used as a cervical plate, second apertures 22 permit the surgeon to view or monitor structures lying beneath the plate 18. Alternatively, second apertures 22 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. To this end, second apertures 22 may include one or more chamfers 23 on the upper edge of second apertures 22 to at least partially accommodate a bone screw head. The peripheral edge 13 of plate 18 may also be chamfered to prevent the cervical plate 18 from damaging or irritating tissues surrounding the plate 18.

[0033] Plate 18 may be described as being generally flat. However, a predetermined amount of curvature may be present to conform to anatomical requirements. Plate 18 is shown in Figure 1 as having 6 apertures in a pattern of 3 sets of connected pairs of apertures. However, any number or pattern of apertures may be present, depending on the requirements of a particular application.

[0034] Head portion 16 of screw 12 is configured with an internal bore 24. Bore 24 has a first upper portion 26 and a second, lower portion 28. Lower portion 28 has a width or diameter that is less than the width or diameter of upper portion 26. Lower portion 28 of bore 24 may be configured to accept a driver such as a hexagonal driver, a star-shaped driver or a similar tool. The inner surface of upper portion 26 of bore 24 contains threads 30 having an opposite orientation from threads 15 of shaft portion14. That is, if the threads 15 of shaft portion 14 have a right-handed orientation, then the threads 30 of upper bore portion 26 have a left-handed orientation. Conversely, if the threads 15 of shaft portion 14 are left-handed in orientation, then the threads 30 of upper bore portion 26 are right-handed in orientation.

[0035] Head portion 16 extends away from shaft portion 14 in a generally arcuate manner around the entire circumference of head portion 16 forming arcuate section 36. Head portion 16 also has a top flange 38 separated from arcuate section 36 by a first head section groove 40. As with arcuate section 36, both top flange 38 and head portion groove 40 extend uninterrupted around the circumference of head portion 16. Top flange 38 is defined by the upper surface 17 of head portion 16 and by a lower flange surface 19. Head section groove 40 is defined by lower flange surface 19 and arcuate section upper surface 37.

[0036] As illustrated in Figs. 2A-2C, a generally cylindrical set screw 32 is adapted to engage upper portion 26 of bore 24. Set screw 32 contains threads 34 on its outer surface that are adapted to engage upper bore portion threads 30. Threads 34 may also comprise a lip 31 or similar structure to engage collar 42 upon partial withdrawal of set screw 32, as more fully described

below. Threads 34 may be of any configuration or shape so as to secure set screw 32 firmly within screw 12, for example, by configuring the thread to include a major and a minor thread, each having a diameter designed to hold the set screw in place in screw 12. The height of set screw 32 may generally correspond to the height of upper bore portion 26 such that when set screw 32 is fully engaged within upper portion 26 of bore 24, an upper surface 35 of set screw 32 is flush with or only slightly protrudes or slightly recedes from an upper surface 17 of head portion 16. Set screw 32 also contains a bore 33 through the axis of the set screw and having a substantially similar configuration as that of lower portion 28 of bore 24 so as to allow bore 33 and lower portion 28 of bore 24 to be engaged by the same driver or similar tool.

[0037] A collar 42, shown in Figs. 1, 2A, 2D, and 3 is adapted to engage head portion 16. In one example, collar 42 is generally cylindrical with a bore 43 through the center of the cylindrical shape. In another example, collar 42 is C-shaped. Collar 42 may optionally also have slits 41 that extend from collar bore 43 but do not penetrate through the entirety of collar 42. Slits 41 provide increased flexibility of collar 42, as explained more fully below. Regardless of any of these variations, collar 42 contains a first top flange 44 defined by a top collar surface 46 and a bottom surface 48 of first collar flange 44. Collar 42 also contains a second bottom flange 50, which is defined by a bottom collar surface 52 and a top surface of second collar flange 54. First top flange 44 of collar 42 is separated from second bottom flange 50 of collar 42 by collar groove 56. Additionally, collar groove 56 and top flange 38 of head portion 16 are adapted to engage each other. Likewise, head portion groove 40 and second collar flange 50 are adapted to engage each other. Outer surface 58 of collar 42 has a generally arcuate configuration that abuts arcuate section 36 and continues the arcuate configuration of arcuate section 36 to create a partially hemispherical combined outer surface of arcuate section 36 and outer surface 58.

[0038] The assembly of screw 12 with collar 42 and set screw 32 in plate 18 may be described with reference to Figs. 1, 3 and 4. Aperture 20 may have an inside surface that is adapted to engage screw 12. In this example, the adaptation may be described as forming an arcuate seat 60. When inserted into first aperture 20, collar 42 and arcuate section 36 of head portion 16 cooperate to engage arcuate seat 60 together to form a continuous arcuate surface. In use, this continuous arcuate surface allows bone screw 12, together with collar 42, to rotate within aperture 20 in either or both of two dimensions. In one example, screw 12 can rotate

within a cone of up to about 5, 10, 15 or even 20 degrees around a perpendicular orientation relative to plate 18. To facilitate rotation of screw 12 within first aperture 20, a lower edge 21of aperture 20 may be chamfered. Arcuate section 36 of head portion 16 may also have one or more projections 39 extending from the surface of arcuate section 36. These projections can act as "stops" to prevent screw 12 from rotating beyond a desired point. For example, projections 39 may prevent screw 12 from rotating to a point at which screw 12 is no longer secured in aperture 20.

[0039] Collar 42 has a resilient bias outward and is configured such that, when fully seated in arcuate seat 60 of aperture 20, top flange 38 of head portion 16 only partially fills collar groove 56 and bottom collar flange 50 only partially occupies head portion groove 40. Stated differently, a gap exists between collar 42 and head portion 16 at both collar groove 56 and head portion groove 40 when the collar 42 and screw 12 are inserted into aperture 20. However, because of the resilient nature of collar 42, in response to radial pressure, at least a portion or even substantially all of collar 42 may be caused to flex inwardly, lessening or even eliminating the gaps between collar 42 and head portion16. The presence of optional slits 41 may facilitate such a flexing inwardly of collar 42.

[0040] At least a portion of top collar flange 44 extends inwardly to an extent sufficient to contact set screw 32 when set screw 32 is not fully engaged in upper portion 26 of bore 24. Stated differently, collar bore 43 has a minimum diameter that is less than the outside diameter of set screw 32.Top collar flange 44 may have an angled configuration such that its configuration complements the threads of set screw 32. In examples where a lip 31 is present in threads 34 of set screw 32, flange 42 may be configured to engage lip 31.

[0041] In one example, aperture 20 is 5.9 mm in diameter at the surface of plate 18. However, the assembled screw 12, set screw 32 and collar 42 have a maximum diameter of 6 mm. Therefore, once fully secured, screw 12 can not loosen from plate 18 without outside intervention.

[0042] The screw system 10 may be used in a method of securing a plate to a substrate, such as securing bone plate such as a cervical plate to one or more bones such as cervical vertebrae, as follows. A screw 12, set screw 32, and collar 42 are assembled with the set screw fully inserted into upper portion 26 of bore 24 of screw 12 and with collar 42 engaged to head portion 16 of screw 12 such that second bottom collar flange engages head portion groove 40 and top flange 38 of head portion 16 engages collar groove 56. The assembled screw 12, set screw 32 and collar 42 are inserted as a single piece through aperture 20 of plate 18. A driver such as a star-driver or hexagonal driver mentioned above is inserted through collar bore 43 to engage set screw bore 33 and lower portion 28 of bore 24. The driver is used to drive the screw 12 into the substrate (for example, a bone) until the assembled screw 12, set screw 32 and collar 42 contact plate 18. As the driving force continues, collar 42 flexes inwardly, allowing the assembled screw 12, set screw 32 and collar 42 to pass into aperture 20 of plate 18. Once seated in aperture 20, collar 42 is no longer forced to flex inwardly and therefore returns to its original configuration, forming a continuous arcuate surface with arcuate section 36 of head portion 16 of screw 12 (see Fig. 3). This continuous arcuate surface is capable of permitting the assembled screw 12, set screw 32 and collar 42 to rotate in one or both of two dimensions. Once the assembled screw 12, set screw 32 and collar 42 are fully inserted into the substrate, the driver is partially removed, such that it only contacts the set screw 32 at set screw bore 33 and no longer contacts lower portion 28 of bore 24. The rotation of the driver is then continued. Because the set screw threads 34 have an opposite orientation as threads 15 of screw 12, as mentioned above, continuing rotation of the driver in the same direction as previously results in set screw 32 being partially retracted through collar bore 43. However, as also mentioned above, collar bore 43 has a smaller minimum diameter than set screw 32. Also, set screw 32 may include a lip 31 that engages a surface of top collar flange 42. Therefore, when set screw 32 engages top collar flange 44, it immobilizes top collar flange 44 in place, preventing collar 42 from flexing inwardly (Fig. 4). By preventing collar 42 from flexing inwardly, the assembled screw 12, set screw 32 and collar 42 are locked into place. Additionally, where set screw 32 includes a lip 31 that engages bottom surface 48 of collar flange 44, the set screw may also be secured in place in bore 24, thereby preventing the set screw from being removed from the assembled screw 12, set screw 32 and collar 42.

[0043] This provides a surgeon with a method for attaching a cervical plate using only one driver tool, simplifying and consequently shortening the time required to perform the procedure. While the above descriptions have been provided with reference to a cervical plate, other medical and even non-medical applications are also contemplated for the screw assembly provided herein.

[0044] Based upon the foregoing disclosure, it should now be apparent that the screw assembly will carry out the aspects set forth hereinabove. 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

We claim:

1. A bone screw assembly comprising:

a bone screw having a shaft portion and a head portion, the shaft portion bearing threads oriented in a first direction, and the head portion having an internal bore, the internal bore having a first portion and a second portion,

wherein the second portion is adapted to engage a driver and the second portion has a diameter less than the diameter of the first portion, and

wherein the surface of the first portion bears threads oriented in a second direction which is opposite that of the first direction;

a set screw adapted to engage the surface of the first portion and having a bore adapted to engage the driver; and

a collar adapted to engage the head portion and having a bore with a minimum diameter that is less than the maximum diameter of the set screw.

2. The bone screw assembly of claim 1, additionally comprising a bone plate, the bone plate having one or more apertures adapted to receive a bone screw.

3. The bone screw assembly of claim 2, wherein the head portion extends away from the shaft portion in a generally arcuate manner around the entire circumference of head portion forming an arcuate section, and wherein an outer surface of the collar abuts the arcuate section has a generally arcuate configuration that complements and continues the arcuate configuration of the arcuate section, and further wherein the one or more apertures have an inside surface that forms an arcuate seat.

4. The bone screw assembly of claim 3, wherein the bone screw is capable of rotating in a cone of up to about 20 degrees around a perpendicular orientation relative to the plate.

5. The bone screw assembly of claim 3, wherein a lower edge of the one or more apertures is chamfered.

6. The bone screw assembly of claim 3, wherein the arcuate section additionally comprises one or more projections on the surface of the arcuate section, wherein the projections are configured to prevent the bone screw from rotating beyond a predetermined point.

7. The bone screw assembly of claim 2, wherein the collar is adapted to flex inwardly in response to radial pressure as the collar passes through an aperture.

8. The bone screw assembly of claim 7, wherein the collar is fixed in place when the set screw is partially removed from the first portion of the internal bore of the head portion of the bone screw, such that the set screw contacts the collar.

9. The bone screw assembly of claim 8, wherein the set screw comprises a lip which is configured to engage a surface of the collar in such a way as to prevent passage of the set screw though the bore of the collar.

10. The bone screw assembly of claim 7, wherein the collar also comprises slits that extend from collar bore partially through the collar.

11. The bone screw assembly of claim 7, wherein the collar is C-shaped.

12. The bone screw assembly of claim 7, wherein the collar and the head portion of the bone screw each comprise a flange and a groove adjacent the flange, and wherein flange of the head portion of the bone screw engages the groove of the collar and the flange of the collar engages the groove of the head portion of the bone screw.

13. A method for attaching a bone plate to one or more bones, the method comprising:
providing a bone screw assembly and a bone plate, wherein the bone screw assembly comprises:
a bone screw having a shaft portion and a head portion, the shaft portion bearing threads oriented in a first direction, and the head portion having an internal

bore, the internal bore having a first portion and a second portion,

wherein the second portion is adapted to engage a driver and the second portion has a diameter less than the diameter of the first portion, and

wherein the surface of the first portion bears threads oriented in a second direction which is opposite that of the first direction;

a set screw adapted to engage the surface of the first portion and having a bore adapted to engage the driver; and

a collar adapted to engage the head portion and having a bore with a diameter that is less than the diameter of the set screw

and wherein the bone plate comprises one or more apertures having a minimum diameter that is less than the maximum diameter of the collar;

wherein the bone screw, set screw and collar are assembled with the set screw fully inserted into the first portion of the internal bore and with the collar engaged with the head portion of the bone screw;

inserting an assembled bone screw, set screw and collar as a single piece through an aperture of the bone plate;

inserting a driver through the collar bore to engage the set screw bore and the second portion of the internal bore and rotating the driver in a first direction to drive the bone screw into the bone, whereupon a driving force applied by the rotating of the driver causes the collar to flex inwardly upon contact of the collar on the bone plate, allowing the assembled bone screw, set screw and collar to pass into the aperture of the bone plate and to become seated in the aperture of the bone plate;

partially removing the driver from the bone screw, such that the driver only contacts the set screw at the set screw bore; continuing rotation of the driver in the first direction to retract the set screw through the collar bore until the set screw contacts the collar, thereby preventing the collar from flexing inwardly and locking the bone screw, the set screw and the collar to the bone plate.

14. The method of claim 13, wherein the bone plate is a cervical plate and the one or more bones are cervical vertebrae.

15. The method of claim 13, wherein the head portion extends away from the shaft portion in a generally arcuate manner around the entire circumference of head portion, forming an arcuate section, and wherein an outer surface of the collar abuts the arcuate section has a generally arcuate configuration that complements and continues the arcuate configuration of the arcuate section, and further wherein the one or more apertures have an inside surface that forms an arcuate seat.

16. The method of claim 15, wherein the bone screw is capable of rotating in a cone of up to about 20 degrees around a perpendicular orientation relative to the plate.

17. The method of claim 14, wherein the arcuate section additionally comprises one or more projections on the surface of the arcuate section, wherein the projections are configured to prevent the bone screw from rotating beyond a predetermined point.

18. The method of claim 13, wherein the collar additionally comprises slits that extend from the collar bore partially through the collar.

19. The method of claim 13, wherein the collar and the head portion of the bone screw each comprise a flange and a groove adjacent the flange, and wherein flange of the head portion of the bone screw engages the groove of the collar and the flange of the collar engages the groove of the head portion of the bone screw.

20. The method of claim 13, wherein the set screw comprises a lip which is configured to engage a surface of the collar in such a way as to prevent passage of the set screw though the bore of the collar.

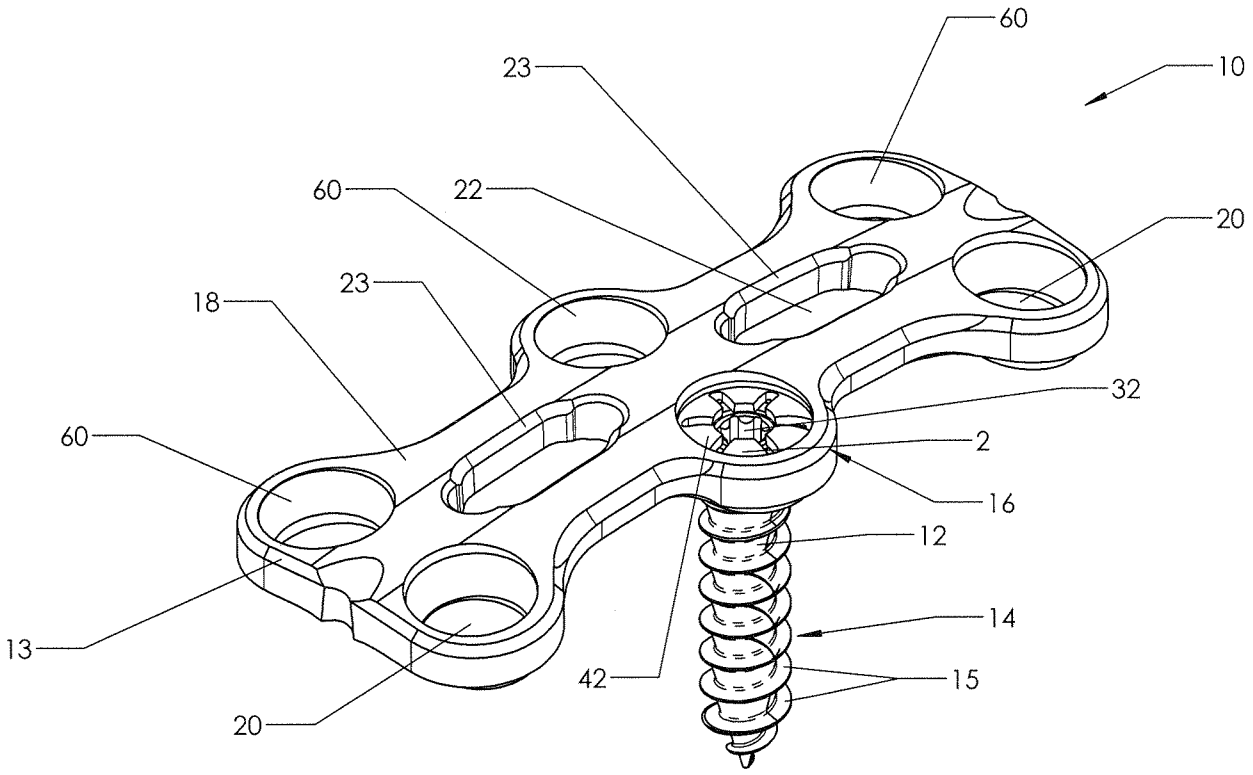

Fig. 1

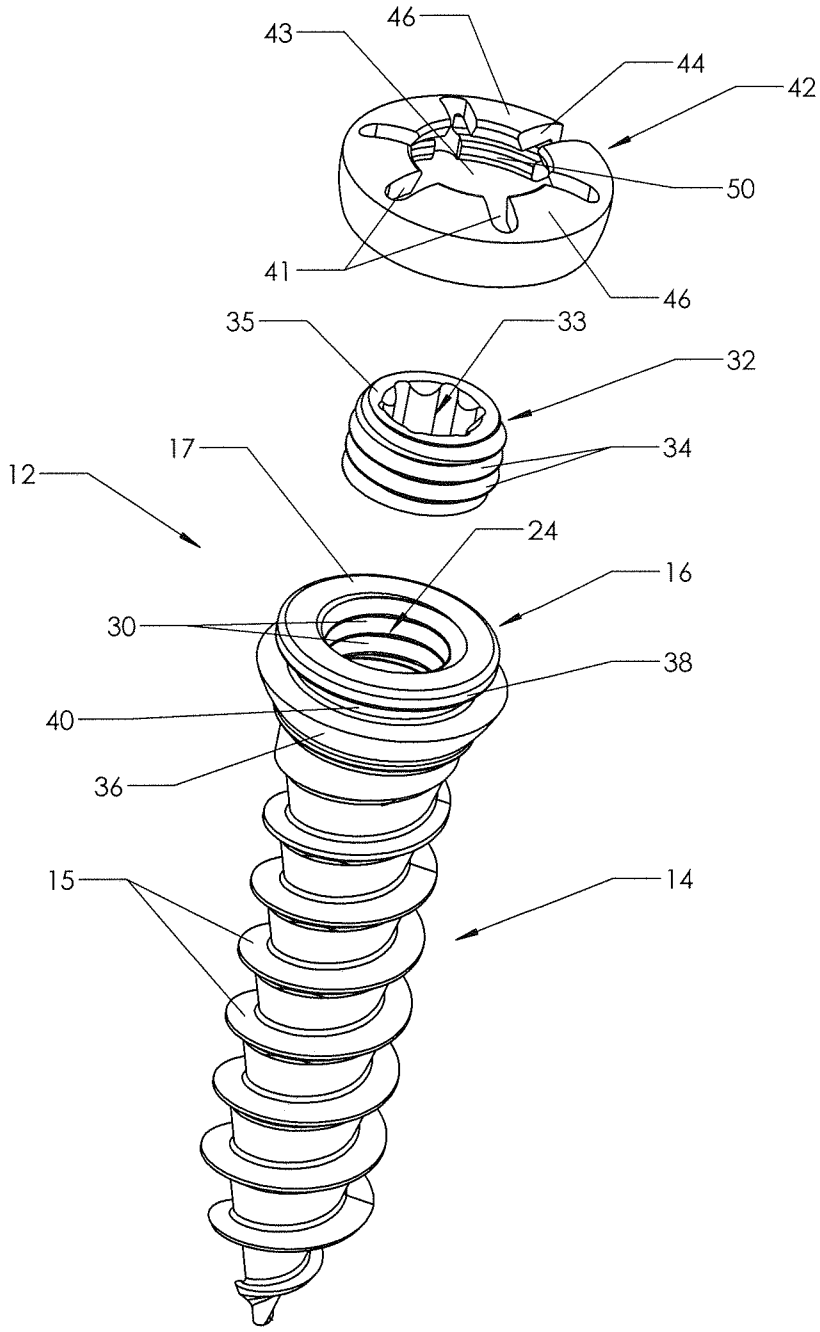

Fig. 2A

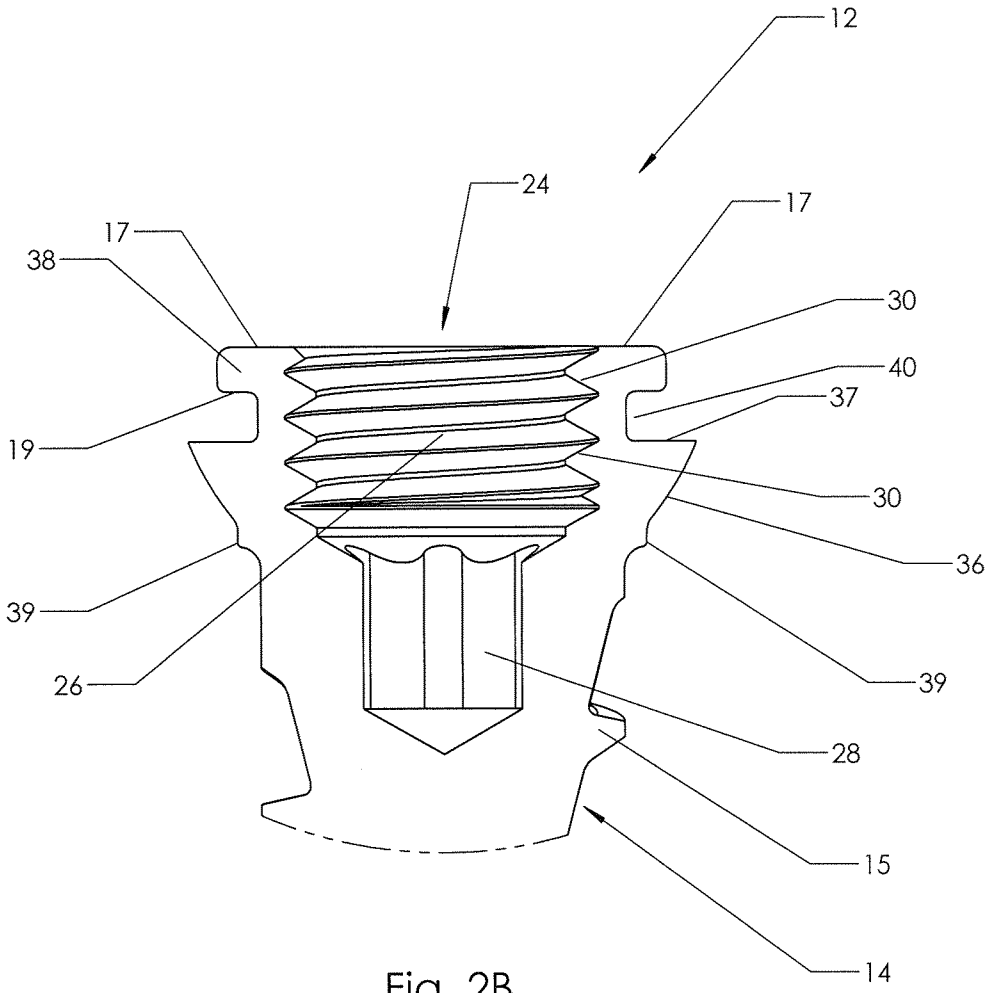

Fig. 2B

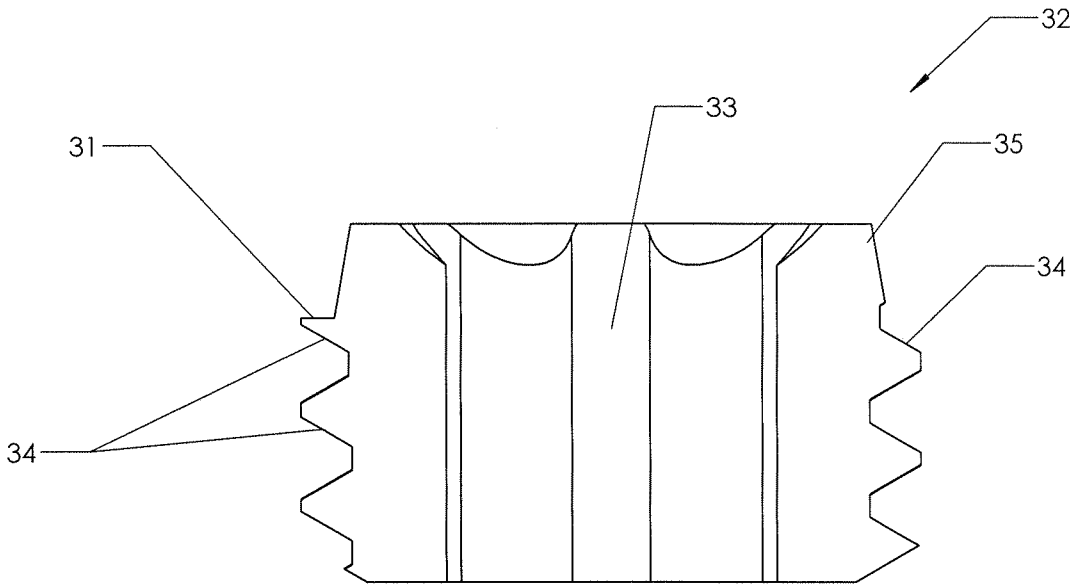

Fig. 2C

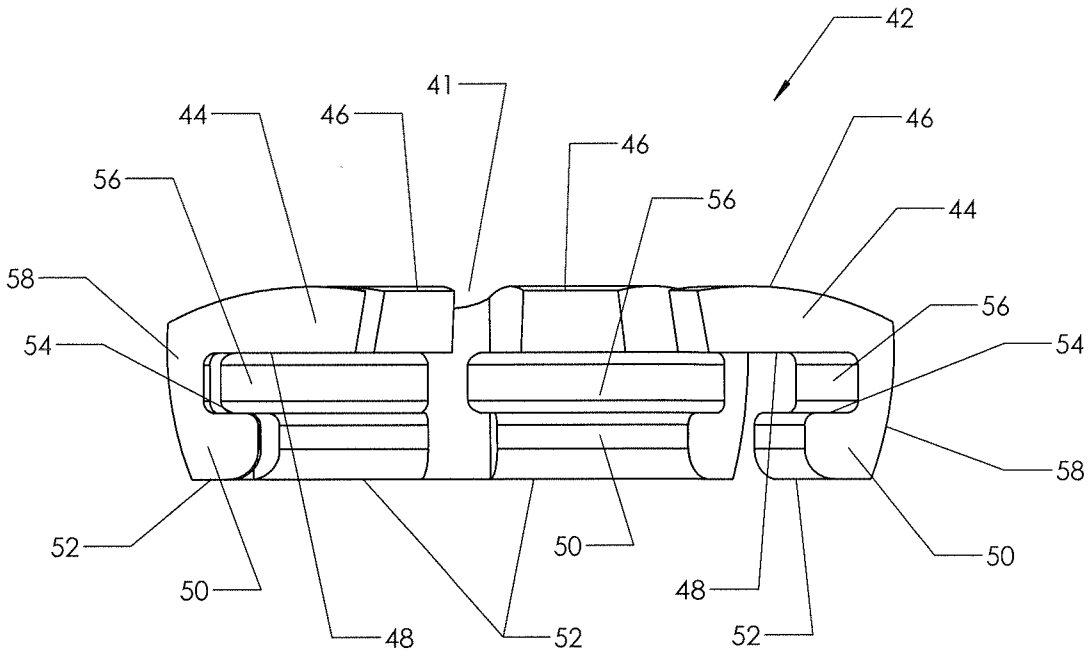

Fig. 2D

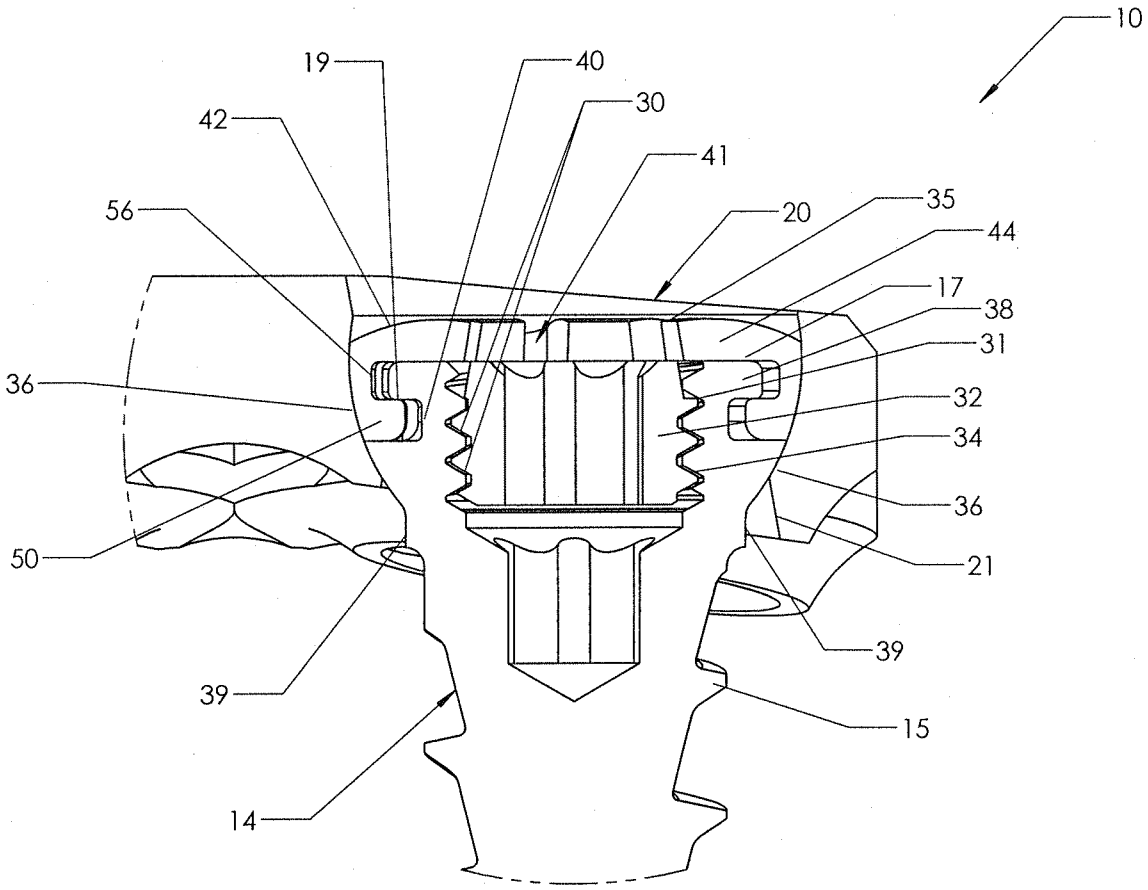

Fig. 3

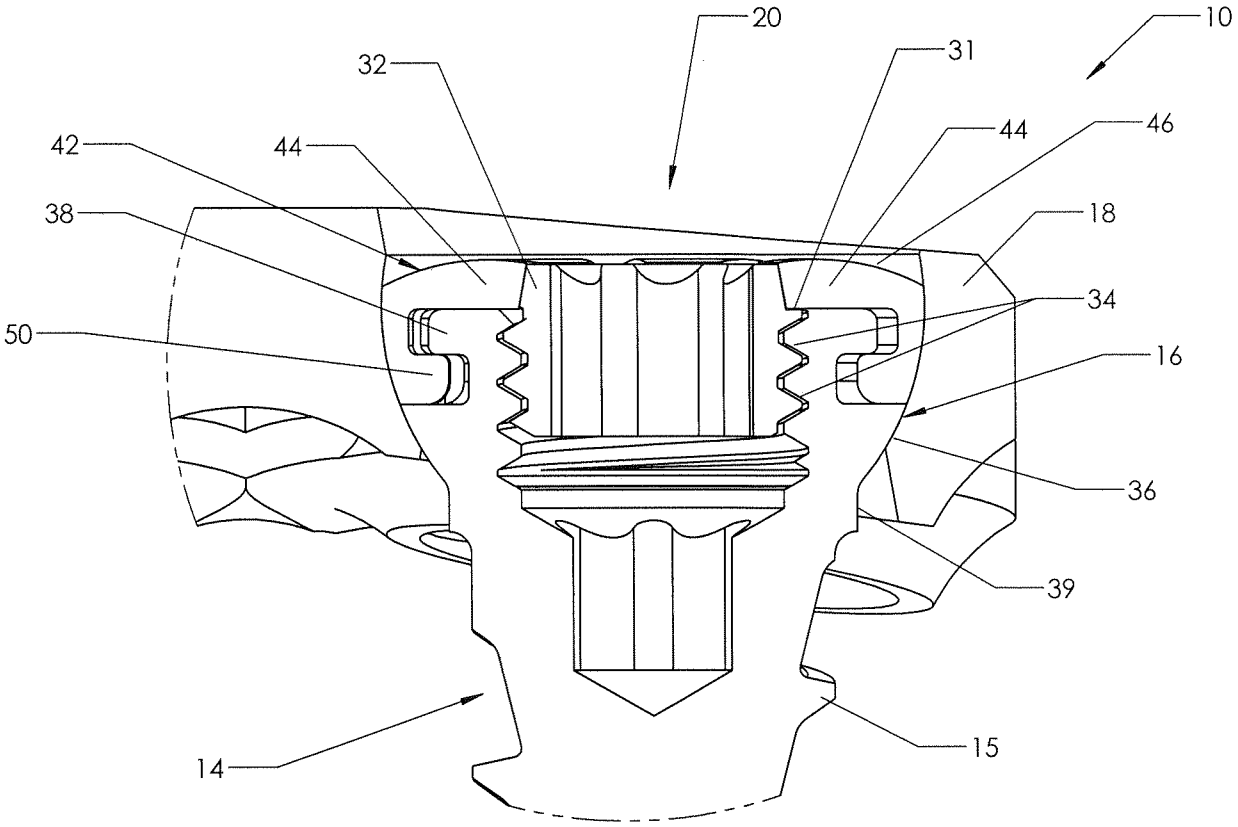

Fig. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/056770

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/70(2006.01)i, A61B 17/58(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 8: A61B

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)

eKIPASS(KIPO Internal) "bone", "screw", "collar", "polyaxial", "bore"

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6235033 B1 (MICHAEL BRACE et al) 22 May 2001 See claim 1, column 4, lines 7-26, figure 6	1-12
A	US 7048739 B2 (DAVID D. KONIECZYNSKI et al) 23 May 2006 See claims 1, 5 and 6, column 2, line 46 - column 3, line 27, figure 1A	1-12
A	US 6613053 B1 (SIMON NICHOLAS COLLINS et al) 2 September 2003 See claims 1 and 2, column 1, lines 26-45, figure 1	1-12
A	US 6893443 B2 (ROBERT FRIGG et al) 17 May 2005 See claims 1, 12 and 13, column 7, lines 56-59, figure 1	1-12

☐ 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
27 NOVEMBER 2008 (27.11.2008)	**27 NOVEMBER 2008 (27.11.2008)**

Name and mailing address of the ISA/KR

Korean Intellectual Property Office
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Facsimile No. 82-42-472-7140

Authorized officer

JEON, CHANG IK

Telephone No. 82-42-481-8303

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/056770

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.: 13-20
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 13-20 pertain to methods for treatment of human or animal 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) PCT.

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/US2008/056770

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US 6235033 B1	22.05.2001	AU 2001-39088 A1	30.10.2001
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		EP 1306058 A2	02.05.2003
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		US 2003-0171753 A1	11.09.2003
US 6893443 B2	17.05.2005	US 2003-0036758 A1	20.02.2003