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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 April 2012 (19.04.2012)

PCT

(10) International Publication Number
WO 2012/050424 Al

(51) International Patent Classification:
A61B 17/68 (2006.01)

(21) International Application Number:
PCT/MY20 11/000213

(22) International Filing Date:
2 1 September 201 1 (21 .09.201 1)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
PI201000485 1 14 October 2010 (14.10.2010) MY

(72) Inventor; and
(71) Applicant : LEONG, Sai Yeong [MY/MY]; 11, Man Perusahaan Jelutong 3, Fortune Park, Bandar Sri Pinang, 11600 Penang (MY).

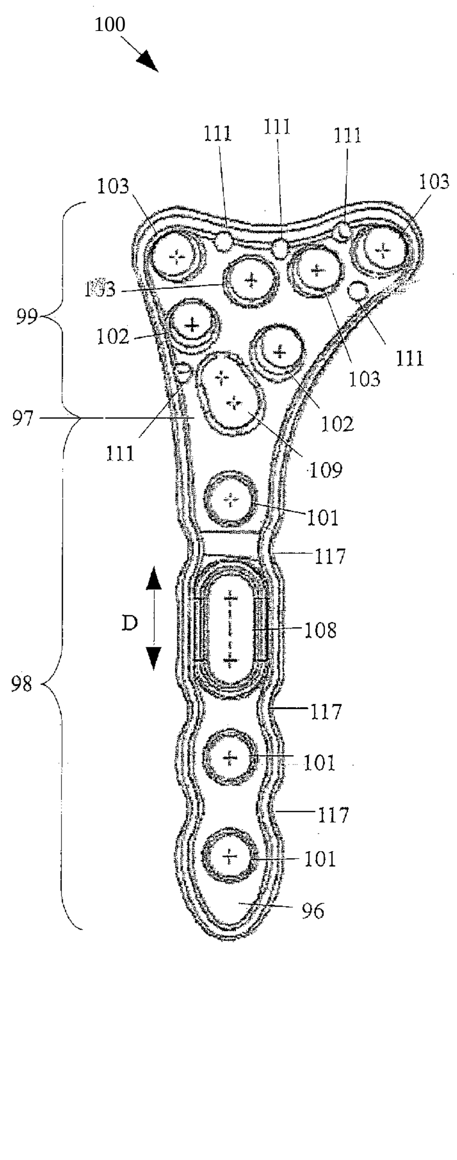
(72) Inventors; and
(75) Inventors/Applicants *(for US only):* **TAN, Boon Cheong** [MY/MY]; 11, Jalan Perusahaan Jelutong 3, Fortune Park, Bandar Sri Pinang, 11600 Penang (MY). **TAN, Bee Keong** [MY/MY]; 11, Jalan Perusahaan Jelutong 3, Fortune Park, Bandar Sri Pinang, 11600 Penang (MY).

(74) Agent: LOK, Choon Hong; Pintas IP Group SDN BHD, Suite 6.03, 6th Floor, Wisma Mirama, Jalan Wisma Putra, 50460 Kuala Lumpur (MY).

[Continued on nextpage]

(54) Title: A DISTAL RADIUS PLATING SYSTEM

Figure 1



(57) Abstract: A bone plate (100) for fixing distal radius (405) fracture comprising a volar-shaped head (99) to be positioned at the distal radius (405); a shaft (98) inclinedly extending from the head (99); a plurality of K- wire openings (111) distributed over the head (99) for receiving K- wires (118) to temporarily secure the plate (100); and a plurality of fastening means openings (101, 102, 103, 108) distributed over the head (99) and the shaft (98) for receiving fastening means (104, 105, 106, 107) to fix the plate (100) to the distal radius (405); characterized by an insertion cavity (109) formed at the junction of the head (99) and the shaft (98) in such a manner as to provide an accessible space for efficient insertion of bone graft material.

WO 2012/050424 A1

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

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available):* ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

A DISTAL RADIUS PLATING SYSTEM

FIELD OF INVENTION

The present invention relates to a plating system for internal fixation of bone fracture. In more particular, the present invention provides a bone plate for the fracture fixation and management of intra or extra-articular fracture of the distal radius bone, which effectively promotes the healing of the bone fracture.

BACKGROUND OF THE INVENTION

A distal radius fracture is a common bone fracture occurred at the radius of the forearm, which is positioned proximately to the wrist joint. It is sometimes known as Colles's fracture, Smith's fracture, Barton's fracture or Chauffeur's fracture, or generally known as wrist fracture. As the distal end of human radius is made up of cancellous bone, any fracture occurred at this region will usually give rise to the collapse of this structure in the later phase. Therefore, proper treatment methods are necessary to be applied for fixing and managing the fracture.

One of the contemporary treatment options for distal radius fracture is the surgery approach. During the orthopeadic surgery, an internal fixator, such as a bone plate, can be implanted into the bone at the fracture region. This internal fixation technique is capable of facilitating the healing of the fracture. Therefore, the configuration and performance of a bone plate is vital to the cure of this injury.

There are several patented technologies disclosed in the prior arts relating to the distal radius plating systems. Of interest in connection with a distal radius plate is disclosed in U.S. Patent No. 2007265629. The distal radius plate comprises a head portion and a proximal plate portion, wherein the head portion has a palm shaped profile having a complex topography that is substantially free from any planar areas. The plate also has at least one fixed peg hole which is threaded and at least one variable angle peg hole with a locking mechanism that permits a variable angle peg to be locked into a desired position.

Another highly-versatile variable-angle bone plate system is disclosed in U.S. Patent No. 2008140130. This bone plate system includes a plurality of holes constructed to receive either a non-locking, locking, or variable-angle locking bone screw. The holes have discrete columns of teeth or thread segments arranged around the inner surface of the hole for engaging threads on the heads of locking and variable-angle locking bone screws. Variable-angle locking bone screws can engage the bone plate at within a range of selectable angles. The head of the variable-angle locking screw is at least partially spherical, and the thread thereon has a profile that follows the arc-shaped radius of curvature of the spherical portion of the screwhead.

U.S. Patent No. 2006004362 also discloses a distal radius bone plating system with locking and non-locking screws. This bone plate can be applied for the fixation of distal or proximal ends of long bones. It also has a head portion and a shaft portion having a plurality of plate holes and a plurality of locking and non-locking screws. The locking bone screws can be threaded and the non-locking cancellous bone screws are configured and dimensioned to have a particularly useful dimensional relationship.

There is another U.S. Patent No. 2005065524 relating to an anatomical distal radius fracture fixation plate with fixed-angle Kirschner wire (K-wire) holes which define a three-dimensional surface, This fixation plate includes a set of threaded peg holes adapted to individually receive fixation pegs therethrough and non-threaded alignment holes having a relatively smaller diameter than the peg holes and preferably sized to closely receive a K-wire. The alignment holes are located between the peg holes, in which one alignment hole is configured for aligning the plate, while other alignment holes are configured for use after fracture reduction and receive K-wires to temporarily stabilize the fracture and secure the plate to the bone. The head of the plate has a shape and contour which provide bone support and a low profile which minimizes the potential for soft tissue irritation.

To further strengthen the fixation bone fracture, bone graft can be applied together with the bone plate as a filler material. Generally, there are several types of bone grafts used, namely autograft, allograft, xenograft and synthetic bone graft. Autograft and synthetic bone graft are commonly used in distal radius fracture. The bone graft can be inserted and packed into the fracture region. The bone graft will fill up the gaps and spaces caused by the fracture and interdigitate the spaces within the cancellous bone. However, the process of packing the bone graft after fixing the fracture with plate and screws can be challenging. This is because the screw holes on the bone plate are usually small and not designed to adapt for the efficient insertion of bone graft. Thus, the volume of bone graft that can be inserted at the fracture region are limited and wastage of bone graft can occur as most of the bone graft, especially the paste form, will spill out from the fracture region.

As revealed by the patented technologies, most of the prior arts disclose a low profile design of the bone plate. Besides, various types of screws including fixed angle and variable angle screws have also been described by the existing technologies. However, none of the existing technologies discloses a distal radius bone plate which is designed and configured to adapt for the efficient insertion of bone graft during the internal fixation process. It is therefore desirable for the present invention to provide a distal radius bone plate having innovative design and configuration which are capable of overcoming the drawbacks of the prior arts and providing a more efficient surgery treatment for distal radius fracture.

SUMMARY OF INVENTION

The primary object of the present invention is to provide an innovative bone plate for fixing distal radius fracture which is designed and configured to allow and to ease the insertion and packing of bone graft into the fracture region during the internal fixation process, thus enhancing the fixation of the bone fracture and promoting healing thereof.

Another object of the present invention is to provide a distal radius bone plate which has anatomic low profile design that matches with the topography of the distal radius, and comparable with the existing distal radius bone plating technologies.

Still another object of the present invention is to provide a distal radius bone plate with optimum fixed angle construct for maximum fracture stability.

Yet another object of the present invention is to provide a distal radius bone plating system which is incorporated with specifically-designed screws that are .capable of reducing stress within the bone of the patient and providing ease of screw purchasing for the surgeon.

Further object of the present invention is to provide a kit for fixing distal radius fracture which includes an innovative bone plate and variable effective fastening and fixing means.

At least one of the preceding objects is met, in whole or in part, by the present invention, in which one of the embodiments of the present invention describes a bone plate (100) for fixing distal radius (405) fracture comprising a volar-shaped head (99) to be positioned at the distal radius (405); a shaft (98) inclinedly extending from the head (99); a plurality of K-wire openings (111) distributed over the head (99) for receiving K-wires (118) to temporarily secure the plate (100); and a plurality of fastening means openings (101, 102, 103, 108) distributed over the head (99) and the shaft (98) for receiving fastening means (104, 105, 106, 107) to fix the plate (100) to the distal radius (405); characterized by an insertion cavity (109) formed at the junction of the head (99) and the shaft (98) in such a manner as to provide an accessible space for efficient insertion of bone graft material.

One of the preferred embodiments of the present invention is a bone plate (100) wherein the head (99) has a thickness of 1.5 mm to 2.5 mm, and is tapered from the junction of the head (99) and the shaft (98), towards the distal end of the plate (100).

Another preferred embodiment of the present invention discloses that the shaft (98) has a thickness of 2.0 mm to 3.0 mm. Preferably, the shaft (98) has at least one waisted region (117) for uniform distribution of stresses.

Still another preferred embodiment of the present invention discloses that the pre-bended angle of inclination between the head (99) and the shaft (98) lies within the range of 20° to 30", most preferably 23°.

Yet another preferred embodiment of the present invention discloses that the plurality of K-wire openings (111) and fastening means openings (101, 102, 103, 108) are chamfered outwardly towards the bottom surface of the plate (100) to allow flexible movement of the K-wires (118) and the fastening means (104, 105, 106, 107).

In yet another preferred embodiment of the present invention, it is disclosed that the fastening means (104, 105, 106, 107) are locking screws (104), cortical screws (105), smooth pegs (106), threaded pegs (107) or a combination of any two or more thereof.

Preferably, the plurality of fastening means openings (103) at the distal end of the head (99) are aligned in an arc (400) to allow the fastening means (104, 105, 106, 107) to engage subchondral regions of the distal radius (405). Further, others of the fastening means openings (102) are aligned on the head (99) in such a manner as to allow the fastening means (104, 105, 106, 107) to engage volar and medial subchondral regions of the distal radius (405).

Another preferred embodiment of the present invention also discloses that still further fastening means openings (101, 108) are aligned along the longitudinal axis of the shaft (98). Preferably, the plurality of fastening means openings (101, 102, 103, 108) are round or oblong in shape.

According to another preferred embodiment of the present invention, the insertion cavity (109) is gourd-shaped, pear-shaped or kidney-shaped. Preferably, a chamfer (200) is outwardly formed around the insertion cavity (109) toward its bottom surface (95) to allow maximum reach of a bone graft syringe at any angle through the cavity (109).

Further embodiment of the present invention is a bone plate (100) for fixing distal radius (405) fracture which is made of titanium, titanium alloy or stainless steel.

Still further embodiment of the present invention is a kit (300) for fixing distal radius (405) fracture comprising a plurality of K-wires (118); a plurality of fastening means (104, 105, 106, 107) and a bone plate having a volar-shaped head (99) to be positioned at the distal radius (405); a shaft (98) inclinedly extending from the head (99); a plurality of K-wire openings (111) distributed over the head (99) for receiving K-wires (118) to temporarily secure the plate (100); and a plurality of fastening means openings (101, 102, 103, 108) distributed over the head (99) and the shaft (98) for receiving fastening means (104, 105, 106, 107) to fix the plate (100) to the distal radius (405); characterized by an insertion cavity (109) formed at the junction -of the head (99) and the shaft (98) in such a manner as to provide an accessible space for efficient insertion of bone graft material.

One skilled in the art will readily appreciate that the present invention is well adapted to carry out the objects and obtain the ends and advantages mentioned, as well as those inherent therein. The embodiments described herein are not intended as limitations on the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

For the purpose of facilitating an understanding of the invention, there is illustrated in the accompanying drawing the preferred embodiments from an inspection of which when considered in connection with the following description, the invention, its construction and operation and many of its advantages would be readily understood and appreciated.

Figure 1. is a top view of the distal radius bone plate (100) as described in one of the preferred embodiments of the present invention.

Figure 2 is a bottom view of the distal radius bone plate (100) of Figure 1 showing the longitudinal A-A axis of the plate (100).

Figure 3 is a perspective view of the distal radius bone plating kit (300) as described in one of the preferred embodiments of the present invention, showing the positioning of the K-wires (118) and various types of fastening means (104, 105, 106, 107) on the plate (100).

Figure 4 is a front view of the distal radius bone plating kit (300) of Figure 3, showing the head (99) of the plate (100) and the angulations of the fastening means (104, 106, 107).

Figure 5 is a side view of the distal radius bone plating kit (300) of Figure 3, showing the angle of inclination, a, formed between the head (99) and the shaft (98).

Figure 6(a) is a partial top view of the distal radius bone plate (100) of Figure 1.

Figure 6(b) is a cross-sectional view through the B-B axis of Figure 6(a), showing the head inclination angle, β, of the head (99) of the bone plate (100).

Figure 7 shows the top view of the distal radius bone plate (100) of Figure 1 when it is positioned on the distal radius (405).

Figure 8(a) is a top view of the distal radius bone plate (100) of Figure 1 showing the angular definition of the fastening means openings (101, 102, 103, 108).

Figure 8(b) is a cross-sectional perspective view through the C-C axis of Figure 8(a) showing the contact threads between the fastening means (104, 106, 107) and the plate (100).

Figure 9(a) is a side view of a locking self-tapping screw of the distal radius bone plating kit (300) as described in one of the preferred embodiments of the present invention.

Figure 9(b) is a top view of the locking self-tapping screw of Figure 9(a).

Figure 9(c) is a cross-sectional view of the locking self-tapping screw of Figure 9(a).

Figure 9(d) is a side perspective view of the locking self-tapping screw of Figure 9(a).

Figure 10(a) is a side view of a cortical self-tapping screw of the distal radius bone plating kit (300) as described in one of the preferred embodiments of the present invention.

Figure 10(b) is a top view of the cortical self-tapping screw of Figure 10(a).

Figure 10(c) is a cross-sectional view of the cortical self-tapping screw of Figure 10(a).

Figure 10(d) is a side perspective view of the cortical self-tapping screw of Figure 10(a).

Figure 11(a) is a side view of a locking self-tapping threaded peg of the distal radius bone plating kit (300) as described in one of the preferred embodiments of the present invention.

Figure 11(b) is a top view of the locking self-tapping threaded peg of Figure 11(a).

Figure 11(c) is a cross-sectional view of the locking self-tapping threaded peg of Figure 11(a).

Figure 11(d) is a side perspective view of the locking self-tapping threaded peg of Figure 11(a).

Figure 12(a) is a side view of a locking smooth peg of the distal radius bone plating kit (300) as described in one of the preferred embodiments of the present invention.

Figure 12(b) is a top view of the locking smooth peg of Figure 12(a).

Figure 12(c) is a cross-sectional view of the locking smooth peg of Figure 12(a).

Figure 12(d) is a side perspective view of the locking smooth peg of Figure 12(a).

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a plating system for internal fixation of bone fracture. In more particular, the present invention provides a bone plate for the fractui-e fixation and management of intra or extra-articular fracture of the distal radius bone, which effectively promotes the healing of the bone fracture.

Hereinafter, the invention shall be described according to the preferred embodiments of the present invention and by referring to the accompanying description and drawings. However, it is to be understood that limiting the description to the preferred embodiments of the invention and to the drawings is merely to facilitate discussion of the present invention and it is envisioned that those skilled in the art may devise various modifications without departing from the scope of the appended claim.

The present invention discloses a bone plate (100) for fixing distal radius (405) fracture comprising a volar-shaped head (99) to be positioned at the distal radius (405); a shaft (98) inclinedly extending from the head (99); a plurality of K-wire openings (111) distributed over the head (99) for receiving K-wires (118) to temporarily secure the plate (100); and a plurality of fastening means openings (101, 102, 103, 108) distributed over the head (99) and the shaft (98) for receiving fastening means (104, 105, 106, 107) to fix the plate (100) to the distal radius (405); characterized by an insertion cavity (109) formed at the junction of the head (99) and the shaft (98) in such a manner as to provide an accessible space for efficient insertion of bone graft material.

Figure 1 and Figure 2 respectively show a top view and a bottom view of the distal radius bone plate (100) as described in one of the preferred embodiments of the present invention. This bone plate (100) is designed and configured into a unique anatomic low profile that provides optimum fixation support for the distal volar radius (405). The bone plate (100) shown in Figure 1 and Figure 2 is designed and configured for the right volar. It is to be noted that a left distal radius bone plate shall be substantially a mirror image of the plate (100) shown in Figure 2 which is having a longitudinal A-A axis.

As shown in Figure 1 and Figure 2, the distal radius bone plate (100) is made up of a head (99) and a shaft (98). The junction of the head (99) and the shaft (98) is considered as a neck (97). The wide V-shaped neck (97) with a radius curvature is capable of providing substantial strength to support the head (99) from the shaft (98).

One of the preferred embodiments of the present invention is a bone plate (100) in which the head (99), which is also known as the buttress head, has a thickness of 1.5 mm to 2.5 mm in order to maintain low profile of the plate (100). This design is capable of easing contouring or bending of the plate (100), thus reducing soft tissue irritation. Preferably, the thickness of the head (99) is gradually tapered from the junction of the head (99) and the shaft (98), towards the distal end of the plate (100), in which the shaft (98) has a thickness of 2.0 mm to 3.0 mm. The width of the head (99) is preferred to be approximately 20 mm to 30 mm, depending on the size of the user's volar. Most preferably, a standardized width of 25mm is generally made. However, the present invention does not intend to limit the width of the head (99), even though a wider plate is generally preferred for larger bone at a scale approximately 15% to 35% depending on the underlying bone size.

According to the preferred embodiment of the present invention, the length of the plate (100) is preferably 55 mm to 65 mm, most preferably 60 mm, for a shaft (98) with 4 fastening means openings (101, 102, 103, 108). However, it is to be noted the present invention does not intend to limit length of the plate (100). A longer plate (100) with more number of fastening means openings (101, 102, 103, 108) is preferred depending on the surgeon discretion on fracture pattern. Preferably, the shaft (98) has a few waisted regions (117) therealong for uniform distribution of stresses. More preferably, the edge of the shaft (98) volar shaped head (99) are fabricated into a smooth round shaped in order to reduce soft tissue irritation.

Still another embodiment of the present invention is a kit (300) for fixing distal radius (405) fracture comprising a plurality of K-wires (118); a plurality of fastening means (104, 105, 106, 107) and a bone plate as set forth in the foregoing description. Illustrated in Figure 3 is a perspective view of the distal radius bone plating kit (300) as described in the preferred embodiment, showing the positioning of the plurality of K-wires (118) and various types of fastening means (104, 105, 106, 107). The K-wire openings (111) are configured and dimensioned to receive K-wires (118) for temporarily stabilizing the fracture and securing the plate position during the fracture fixation process. As shown in Figure 4 and Figure 5, the K-wires (118) can be rotatably fitted on the plate (100) at the K-wire openings (111) in variable angles which provides flexibility to the movement of the K-wire during the positioning of the plate (100).

According to another preferred embodiment of the present invention, the plurality of fastening means openings (101, 102, 103, 108) are retrofittable for various types of fastening means (104, 105, 106, 107). It is also disclosed in the preferred embodiment that these fastening means (104, 105, 106, 107) can be locking screws (104), cortical screws (105), locking smooth pegs (106), locking threaded pegs (107) or a combination of any two or more thereof. The dimensions of these fastening means (104, 105, 106, 107) are further illustrated in Figure 9(a)-(d), 10(a)-(d), ll(a)-(d) and 12(a)-(d). Figure 4 shows the optimum exclusive angulations of the different types of fastening.

As illustrated in Figure 5, an angle of inclination, a, is formed between the head (99) and the shaft (98) at their junction, or the neck (97). According to the preferred embodiment of the present invention, the angle of inclination, a, is ranging from 20° to 27°. Most preferably, the pre-bended angle of inclination is 23°. However, the present invention does not intend to limit the size of the angle a as it can be varied depending on the underlying bone. In one of the preferred embodiments, the head (99) of the plate (100) can be inclined or skewed approximately 1° to 5° at the radial side in order to rest perfectly near to the volar ridge of the radial styloid. However, the present invention does not intend to limit the size of the angle, β, as it can be varied depending on the underlying bone. A cross-sectional view of the bone plate (100) showing the head inclination angle, β, of the head (99) is illustrated in Figure 6(b), which is obtained from the partial top view of the bone plate (100) through the B-B axis of Figure 6(a).

Referring to Figure 7, the plurality of fastening means openings (103) at the distal end of the head (99) are aligned in an arc (400), forming a first set of fastening means openings (103), to allow the fastening means (104, 106, 107) to engage subchondral regions of the distal radius (405). The fastening means (104, 106, 107) applied at this first set of fastening means openings (103) are primary supporting screws, angled specifically in the longitudinal and lateral direction, which as the first set of angular definitions (500, 501, 503, 507) as shown in Figure 8(a) which perfectly engage the entire subchondral regions of the distal radius (405), including the area of radial styloid, palmarulnar and dorsoulnar.

Further, a second set of fastening means openings (102) is also formed on the head (99) and preferably positioned in a in an oblique line (403) as shown in Figure 7, in such a way that it provides secondary support to the first set of fastening means (104, 106, 107) as set forth in the foregoing description. The second set of fastening means (104, 106, 107) can be placed at the second set of fastening means openings (102) located close to the neck (97) of the plate (100) to cover the volar and medial aspect of the subchondral regions of the distal radius (405). The second set of angular definitions (502, 508) are also shown in Figure 8(a).

Another preferred embodiment of the present invention also discloses that the plurality of fastening means openings (101, 108) are aligned along the longitudinal axis of the shaft (98), which is the A-A axis as shown in Figure 1. The fastening means (104, 105) to be placed at this third set of fastening means openings (101, 108) are meant for low profile locking and low profile cortical screws (105). Several shapes of the fastening means openings (101, 102, 103, 108) can be provided. Preferably, these fastening means openings (101, 102, 103, 108) are round in shape, as shown by the first fastening means openings (101) of the shaft (98); or oblong in shape, as shown by the second fastening means openings (108) of the shaft (98) in Figure 1 to Figure 3. Oblong openings (108) allow the fixation and longitudinal translation of low profile cortical screw (105) in the direction D as illustrated in Figure 1 for plate positioning. This opening (108) also allows the low profile cortical screw (105) to translate within 15° laterally (left-right), and approximately 50° longitudinally.

Accordingly, the screws threads and combination angle of screw angulations provide a minimum of 2 to 3 threads intact (514) in all the fastening means openings (101, 102, 103), thus resulting in a strong locking mechanism. Figure 8(b) is a cross-sectional view through the C-C axis of Figure 8(a) showing the contact threads between the fastening means (104, 106, 107) and the plate (100). Locking smooth pegs (106) and locking threaded pegs (107) are preferred for plate head (99) on osteoporotic bones. However, low profile locking screws (104) can be used on the same location as well.

Yet another preferred embodiment of the present invention discloses that the plurality of K-wire openings (111) and fastening means openings (101, 102, 103, 108) are chamfered outwardly toward the bottom surface (95) of the plate (100) to avoid sharp edges, thus to reduce interference with ligaments and soft tissue, in order to avoid tissue irritation. Besides, there is a limited contact base of the shaft (98) designed, therefore the periosteal vascularity underneath the bone plate (100) can be improved. In other words, the design and configuration of this bone plate (100) is capable of avoiding devascularization.

As set forth in the preferred embodiment, the present invention is characterized by the incorporation of an insertion cavity (109) at the neck (97) of the plate (100). This insertion cavity (109) is preferably gourd-shaped, pear-shaped or kidney-shaped. This uniquely shaped cavity (109) formed on the plate median allows option for easy and accessible space for the insertion of bone graft, positioned in the longitudinal and lateral direction as shown in the angle definitions (504, 505, 506) in Figure 8(a). Preferably, a wide bottom chamfer (200) is provided and outwardly formed around the insertion cavity (109) toward its bottom surface (95) to allow maximum reach of a bone graft syringe at any angle through the cavity (109).

The insertion cavity (109) is specially designed to ease the surgeon in inserting the bone graft. This cavity (109), with its flexible shape, is sufficiently large and convenient for the accession of the surgeon to create the window for bone graft insertion and packing during the internal fixation process. It is also capable of preventing the wastage of the bone graft material. Moreover, the presence of this cavity (109) does not compromise the overall strength of the plate structure.

Further embodiment of the present invention is a bone plate (100) for fixing distal radius (405) fracture which is made of titanium, titanium alloy or stainless steel. An example for titanium alloy which can be used is Ti6A14V; whereas the stainless steel preferably applied is 316LVM. The materials used for fabricating the plate (100), as well as the fastening means (104, 105, 106, 107) coupled therewith, are to be sterilized. However, the present invention does not intend to limit the use of other suitable bio compatible materials in the aforementioned fabrication.

Figure 9(a) to 9(d) shows a custom designed locking screw (104) which can be used with the distal radius plate (100). The locking screw (104) is made up of a locking head (618) and a threaded shaft (617). The threaded shaft (617) of the locking screw (104) is preferably having a core diameter (612) which is approximately 70% to 80% of the major diameter (620) which maintains the core strength of the locking screw ;(104). The thread of the locking screw (104) has a thrust face (605) that forms an angle of .approximately 30° to 40° to a plane transverse to the longitudinal axis of the locking screw (104). This thread has a trailing face (604) which has an angle of approximately 5° to 11° to the same plane. This self tapping locking screw (104) has a tip with a radius (609) of approximately 0.5mm to 1.5mm and a point angle (621) of approximately 117° to 123°. The neck of the screw has a reinforced profile with a combination of chamfer (610) which increases the stiffness and a radius (611) that improve the deflection; resulting in a fastening means with optimum strength.

On the other hand, Figure 10(a) to 10(d) shows a custom designed low profile cortical screw (105) which contains a low profile screw head (718) designed with a combination of 3 different radiuses (701, 702, 703) and a threaded shaft (717). The threaded shaft has a core diameter (712) which is approximately 63%> to 73% of the major diameter (720). The thread of the low profile cortical screw (105) also has a thrust face (705) that forms and angle of approximately 30° to 40° to a plane transverse to the longitudinal axis of the screw, similar to that of the locking screw (104). This thread has a trailing face (704) angled approximately 0° to 6° to the same plane. This self tapping cortical screw's tip has a radius (709) of approximately 0.5mm to 1.5mm with a point angle (721) of approximately 85° to 95°. The neck of the screw has a reinforced profile with a radius (711) that improve the deflection; resulting in a fastening means with optimum strength.

As shown in Figure 11(a) to 11(d) is a locking threaded peg (107) which can be used with the plate (100). This locking threaded peg (107) is also having a locking head (818) and a threaded shaft (817), wherein the core diameter (812) of the shaft (817) is approximately 50% to 60% of the major diameter (820). The thread has a thrust face (805) that forms and angle of approximately 20° to 30° to a plane transverse to the longitudinal axis of the screw, and it has a trailing face (804) which has an angle of approximately 2° to 8° to the same plane. The self tapping threaded peg tip has a radius (809) of approximately 0.5mm to 1.5mm with a point angle (821) of approximately 117° to 123°. The neck of the screw has a reinforced profile with a combination of chamfer (810) which increases the stiffness and a radius (811) that improve the deflection; resulting in a fastening means with optimum strength.

Illustrated in Figure 12(a) to 12(d) is a custom designed locking smooth peg (106). This locking smooth peg (106) possesses a locking head (918) and smooth shaft (917). The smooth peg shaft (917) has a core diameter which is in the same dimension as the major diameter (920) a tip (909) radius similar to the radius of the peg's diameter. The neck of the screw has a reinforced profile with a combination of chamfer (910) which increases the stiffness and a radius (911) that improve the deflection; resulting in a fastening means with optimum strength.

Preferably, the locking heads of all the locking screw (104), the cortical screw (105), threaded peg (107) and smooth peg (106) have the hexalobe recesses (616, 716, 816, 916) for receiving a hexalobe screwdriver. The locking heads of these screws (104, 106, 107) also have external taper threads with a preferred taper angle of approximately 5° to 15° relative to the longitudinal axis of the screw, and a symmetrical included thread angle (602 & 603, 802 & 803, 902 & 903) of approximately 60°. The threads generally have a crest width (601, 801, 901) of approximately 0.02mm to 0.08mm.

According to the preferred embodiment of the present invention, the helical threads of the shafts of the locking screw (104), the cortical screw (105) and threaded peg (107) can have helical threads (625, 725, 825) with a helix angle of approximately 78° to 88°. They can have a crest width (606, 706, 806) of the major diameter which is preferably to be 0.03mm to 0.15mm in order to keep a good strength on the wing of screw thread (624, 724, 824). These can be shown in Figure 9(c), 10(c) and 11(c).

These self tapping screws (104, 105, 107) are preferably 3-fluted and having tips with unique geometry such as a substantially straight flute (613, 713, 813) and taper relieved thread (614, 814) for stress reduction during the self tapping process on the bone. The flute can have a core diameter (622, 722, 822) of 40-50% relative to the core diameter of the thread (612, 712, 812), with a core taper angle (623, 723, 823) of 15° to 25°. As shown in Figure 9(b), 10(b) and 11(b), the rake angle of the screws (615, 715, 815) is preferably 0° to 10°, whereas the taper thread relief angle (619, 819) is preferably 4° to 12° and the helix angle of the flute (613, 713, 813) is preferred to be approximately within the range of 0° to 10°. Minimum of 1 to 2 full turn taper thread (607, 707, 807) at the screw tip is substantially preferred with a taper angle (608, 708, 808) of approximately 10° for the locking screw (104) and the cortical screw (105), or 25° to 35° for the threaded peg (107), per side relative to the longitudinal axis of the screw to ensure easy entry of the screws into the drilled hole during the fixation process.

The bone plate (100) is used in an open reduction internal fixation system for fracture management of the distal radius (405). According to the preferred embodiment of the present invention, the bone fracture fixation process can be initiated by making an incision and dissection, followed by retraction of tendon and arteries. The fracture region is visualized and reduced.

An appropriate size of the implant, which is the distal radius bone plate (100) shall be chosen according to the bone anatomy of the patient. Preferably, the plate (100) is positioned according to the optimum position, which is preferably 5 mm from the distal edge of the radius, or the pronator quadratus line (404) as demonstrated in Figure 7. However, the suitable position can be determined depending on the surgeon's discretion. K-wires (118) can be used for temporarily fixation of the plate (100) while evaluating the placement of the plate (100). A hole of approximately 2.5 mm to 2.7 mm can be drilled on the diaphyseal part of the bone through the oblong-shaped opening (108) of the plate (100) using an appropriate drill guide.

Preferably, the length of the fastening means (104, 105, 106, 107) or the screws applied can be determined using an appropriate depth gauge. For example, a non-locking cortical screw (105) can be placed in the oblong-shaped opening (108) but not completely tightened to allow adjustment of the plate (100) in distal or proximal directions. Under an image intensifier, the correct position of the plate (100) can be determined and the cortical screw (105) can be tightened. Based on the fracture pattern and preference, the procedures of drilling, measuring and placement of other types of fastening means such as the locking threaded pegs (107), locking smooth pegs (106) or locking screws (104) can be repeated by using a drill, a drill sleeve, a measuring gauge and a torque screwdriver. The selection of fastening means (104, 105, 106, 107) are depending on the bone characteristics. Preferably, an approximately 1.9 mm to 2.1 mm drill hole is applied for the coupling of aforementioned screws on the rows of fastening means openings (102, 103) on the head, and preferably a 2.1 mm to 2.7 mm drill hole is used for the remaining openings (101, 108) on the shaft (98).

The bone graft materials are preferably applied through the insertion cavity (109) as an optimal bone void filler. The suitable types of bone graft materials applied herein can be an autogenous bone graft in paste, patty or granuale form. Besides, both autograft or allograft also can be used in the present invention. It is vital to ensure under the image intensifier that all the fastening means (104, 105, 106, 107) are secured in good position, without penetrating the any of the joints. Then, the incision can be closed to complete the fixation process.

The present disclosure includes as contained in the appended claims, as well as that of the foregoing description. Although this invention has been described in its preferred form with a degree of particularity, it is understood that the present disclosure of the preferred form has been made only by way of example and that numerous changes in the details of construction and the combination and arrangements of parts may be resorted to without departing from the scope of the invention.

CLAIMS

1. A bone plate (100) for fixing distal radius (405) fracture comprising:
a volar-shaped head (99) to be positioned at the distal radius (405);
a shaft (98) inclinedly extending from the head (99);
a plurality of K-wire openings (111) distributed over the head (99) for receiving K-wires (118) to temporarily secure the plate (100); and
a plurality of fastening means openings (101, 102, 103, 108) distributed over the head (99) and the shaft (98) for receiving fastening means (104, 105, 106, 107) to fix the plate (100) to the distal radius (405);
characterized by an insertion cavity (109) formed at the junction of the head (99) and the shaft (98) in such a manner as to provide an accessible space for efficient insertion of bone graft material.

2. A bone plate (100) according to claim 1, wherein the head (99) has a thickness of 1.5 mm to 2.5 mm and is tapered from the junction of the head (99) and the shaft (98), towards the distal end of the plate (100).

3. A bone plate (100) according to claim 1, wherein the shaft (98) has a thickness of 2.0 mm to 3.0 mm.

4. A bone plate (100) according to claim 1, wherein the shaft (98) has at least one waisted regiori (117) for uniform distribution of stresses.

5. A bone plate according to claim 1, wherein the angle of inclination between the head (99) and the shaft (98) lies within the range of 20° to 30°.

6. A bone plate (100) according to claim 1, wherein the fastening means (104, 105, 106, 107) are locking screws (104), cortical screws (105), locking smooth pegs (106), locking threaded pegs (107) or a combination of any two or more

thereof.

7. A bone plate (100) according to claim 1, wherein the plurality of fastening means openings (103) at the distal end of the head (99) are aligned in an arc (400) to allow the fastening means (104, 106, 107) to engage subchondral regions of the distal radius (405).

8. A bone plate (100) according to claim 7, wherein others of the fastening means openings (102) are aligned on the head (99) in such a manner as to allow the fastening means (104, 106, 107) to engage volar and medial subchondral regions of the distal radius (405).

9. A bone plate (100) according to claim 8, wherein still further fastening means openings (101, 108) are aligned along the longitudinal axis of the shaft (98).

10. A bone plate (100) according to claim 1, wherein the plurality of fastening means openings (101, 102, 103, 108) are round or oblong in shape.

11. A bone plate (100) according to claim 1, wherein the insertion cavity (109) is gourd-shaped, pear-shaped or kidney-shaped.

12. A bone plate (100) according to claim 1, wherein a chamfer (200) is outwardly formed around the insertion cavity (109) toward its bottom surface (95) to allow maximum reach of a bone grafting device at any angle through the cavity (109).

13. A bone plate (100) according to claim 1 made of titanium, titanium alloy or stainless steel.

14. A kit (300) for fixing distal radius (405) fracture comprising:

a bone plate having a volar-shaped head (99) to be positioned at the distal radius (405); a shaft (98) inclinedly extending from the head (99); a plurality of K-wire openings (111) distributed over the head (99) for receiving K-wires (118) to temporarily secure the plate (100); and a plurality of fastening means openings (101, 102, 103, 108) distributed over the head (99) and the shaft (98) for receiving fastening means (104, 105, 106, 107) to fix the plate (100) to the distal radius (405); characterized by an insertion cavity (109) formed at the junction of the head (99) and the shaft (98) in such a manner as to provide an accessible space for efficient insertion of bone graft material;

a plurality of K-wires (118); and

a plurality of fastening means (104, 105, 106, 107).

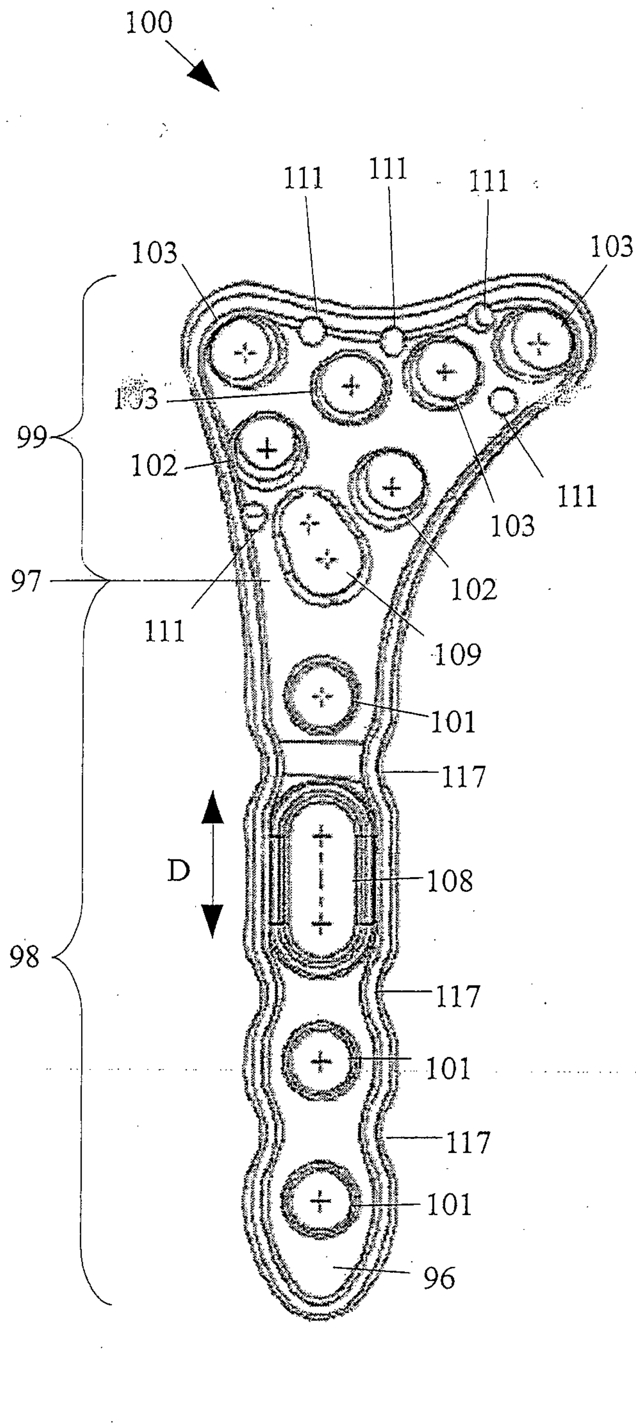


Figure 1

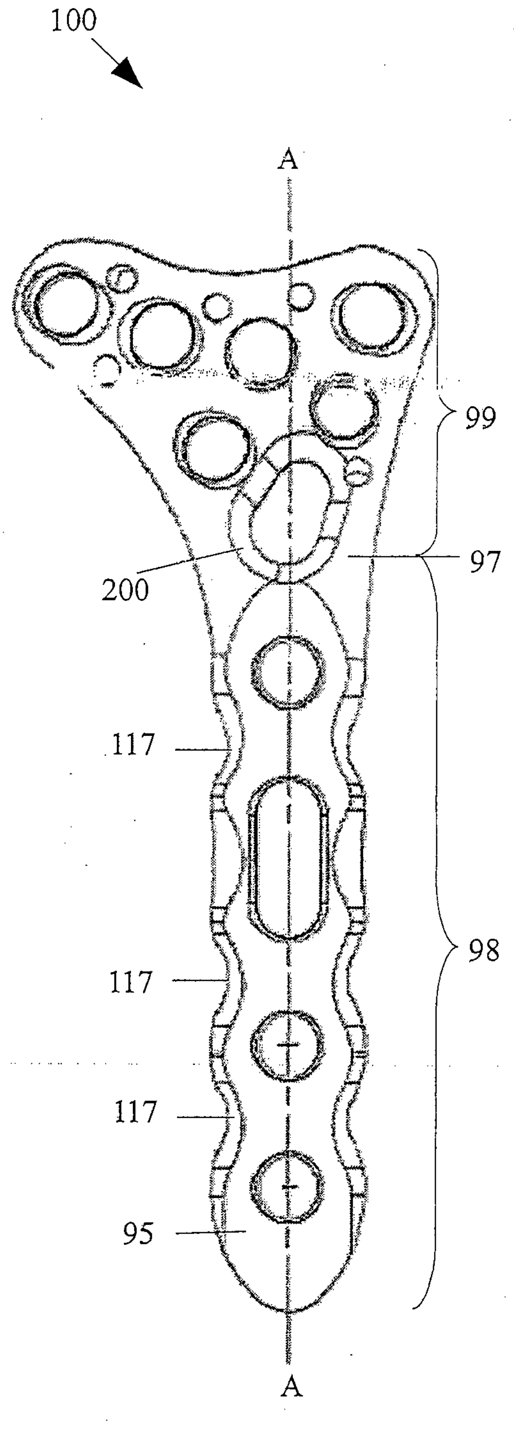


Figure 2

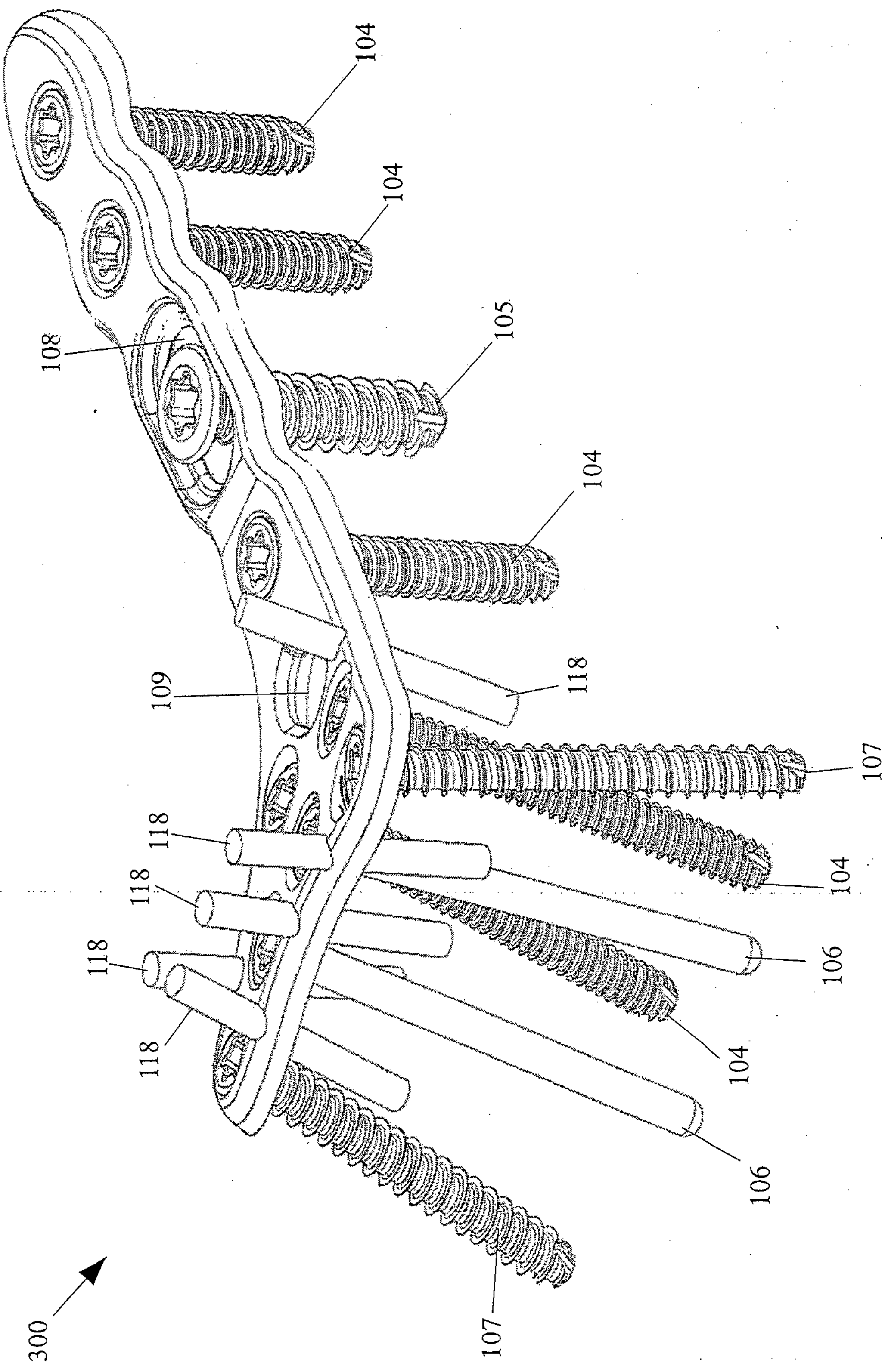

104
104
105
108
104
109
118
107
118
104
118
106
118
104
118
106
107
300

Figure 3

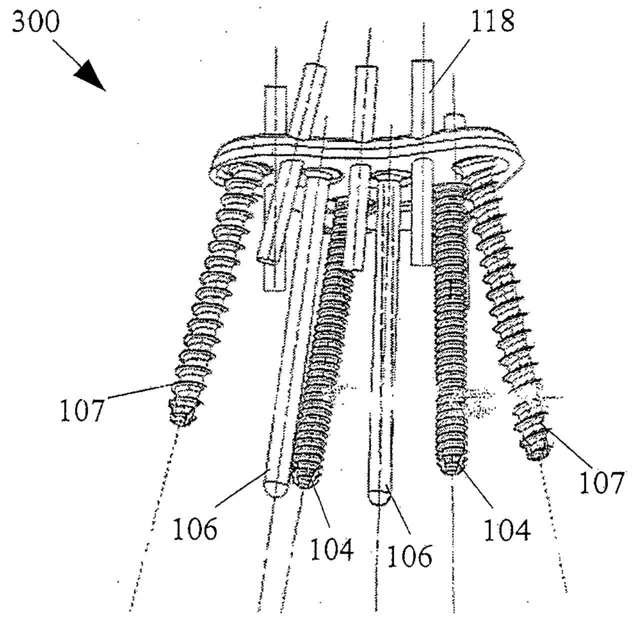


Figure 4

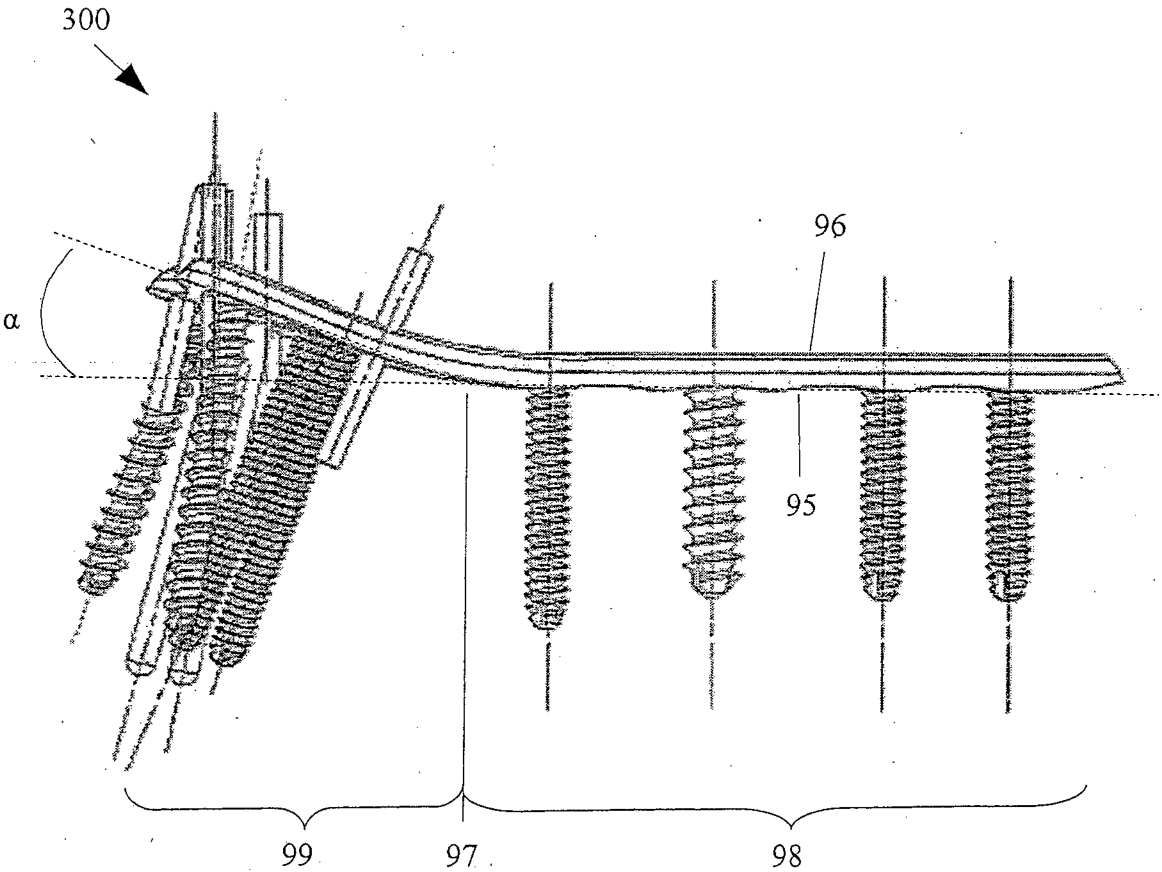


Figure 5

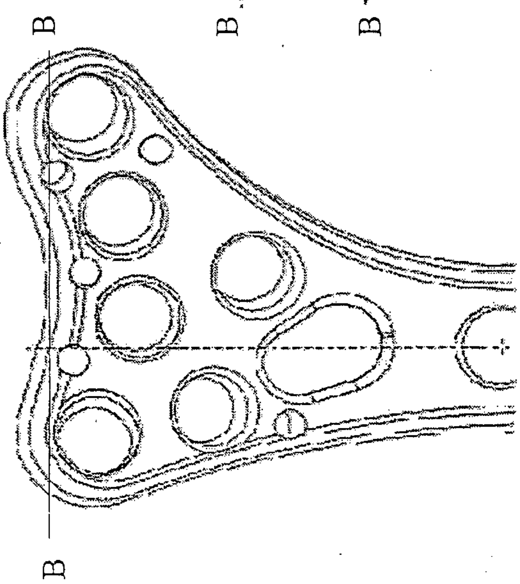


Figure 6(a)

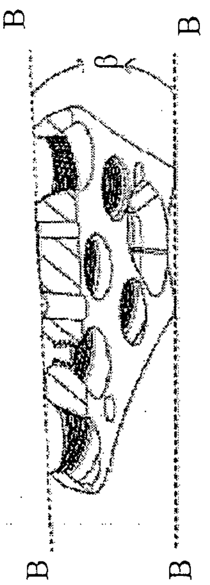


Figure 6(b)

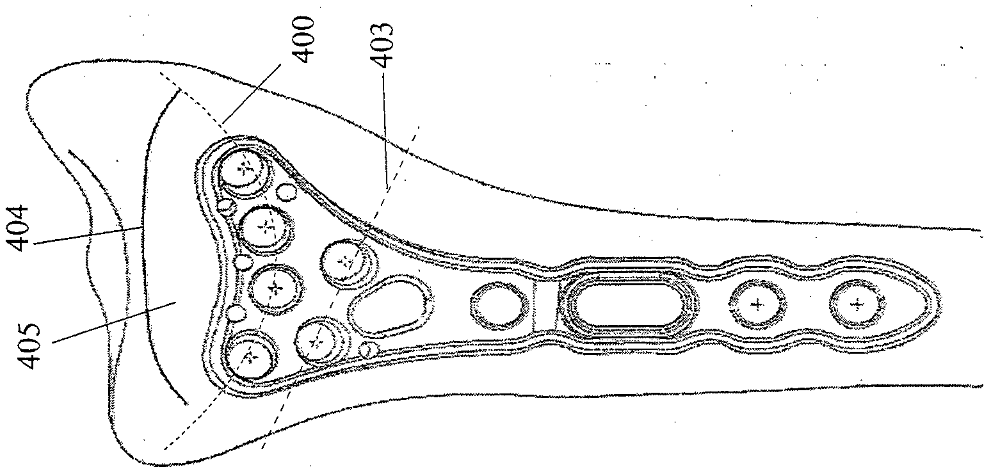


Figure 7

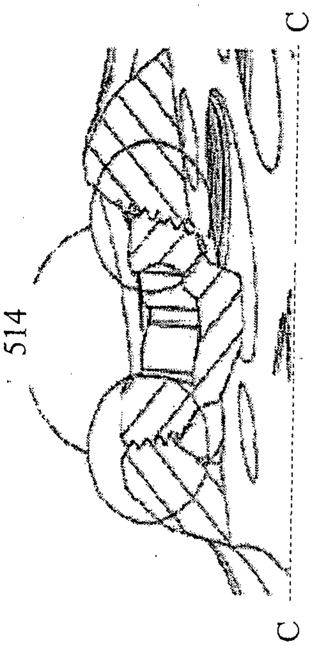


Figure 8(b)

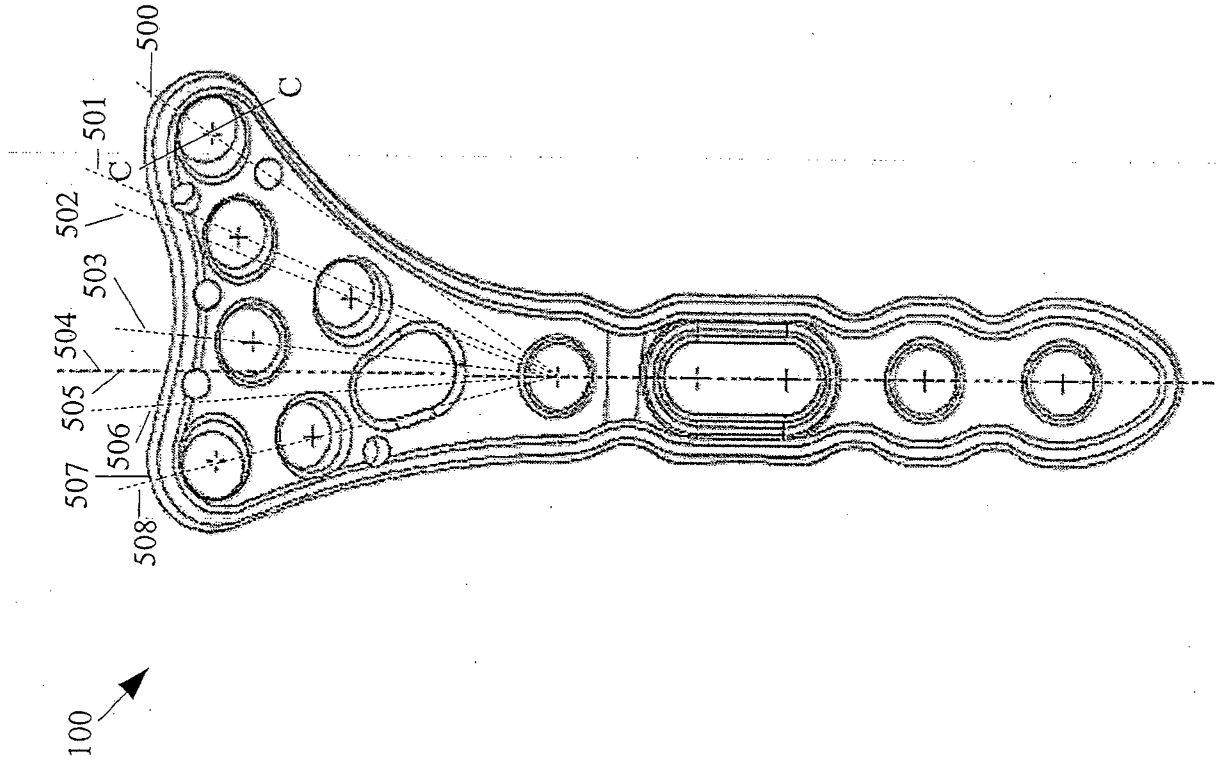


Figure 8(a)

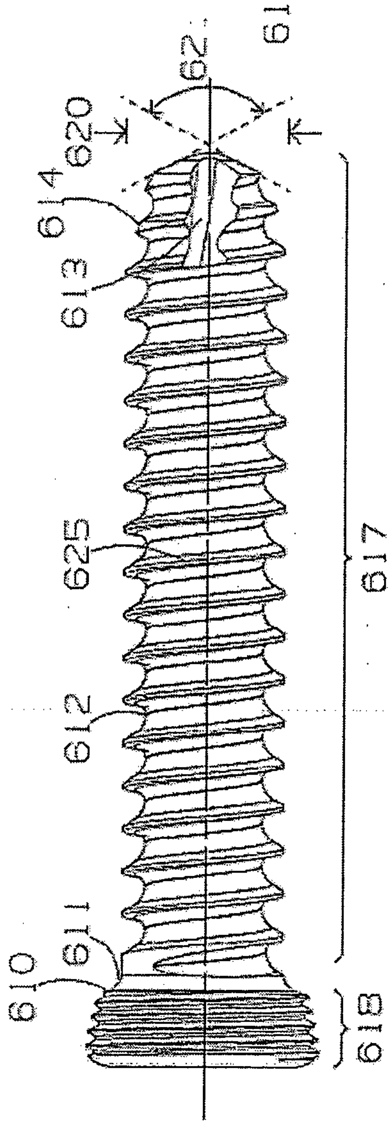


Figure 9(a)

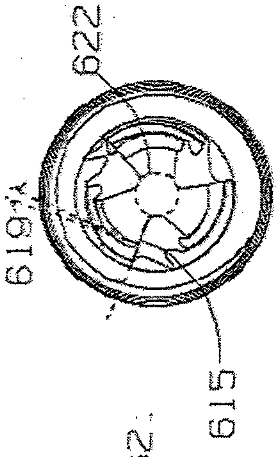


Figure 9(b)

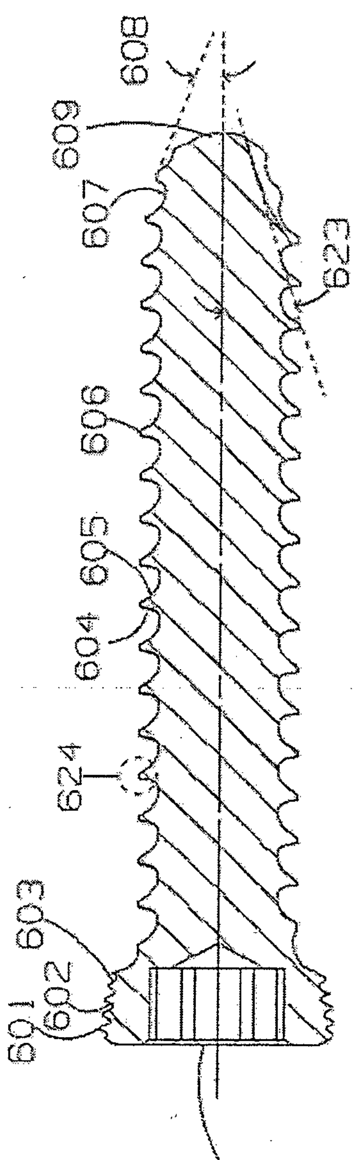


Figure 9(c)

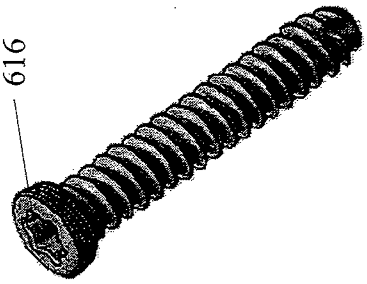


Figure 9(d)

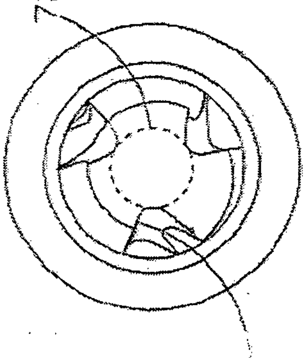


Figure 10(b)

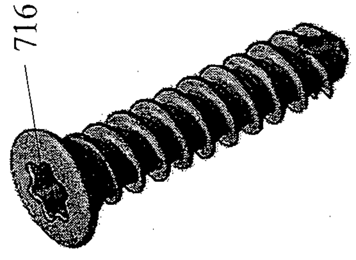


Figure 10(d)

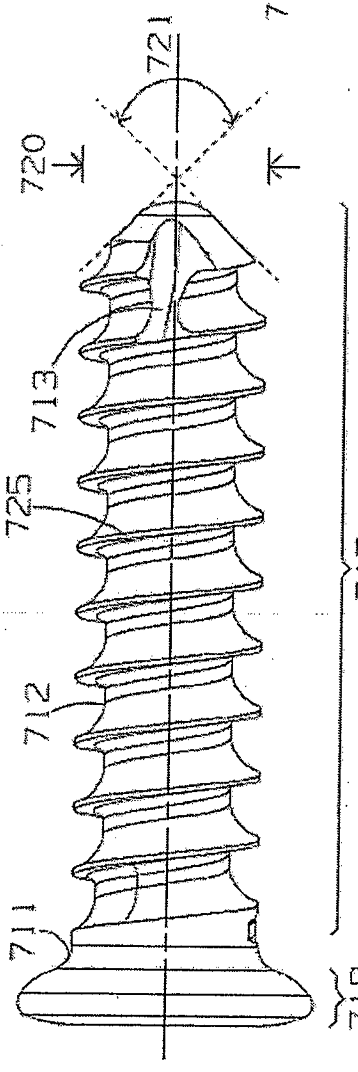


Figure 10(a)

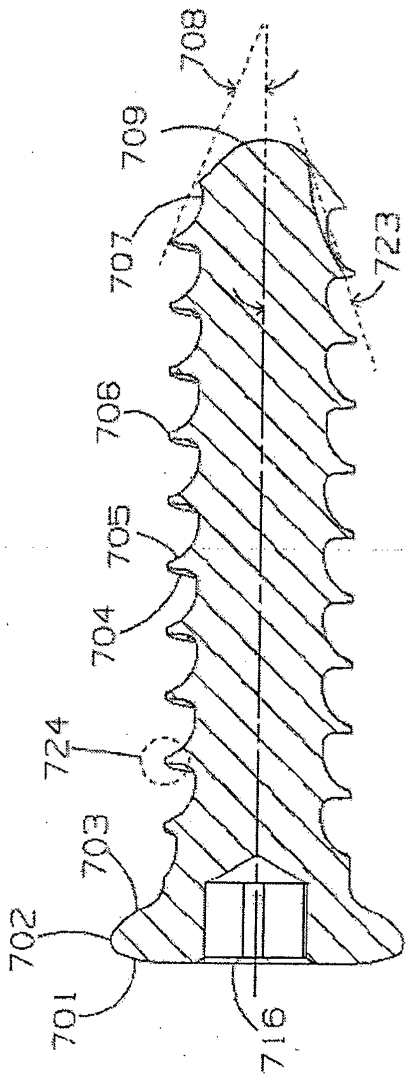


Figure 10(c)

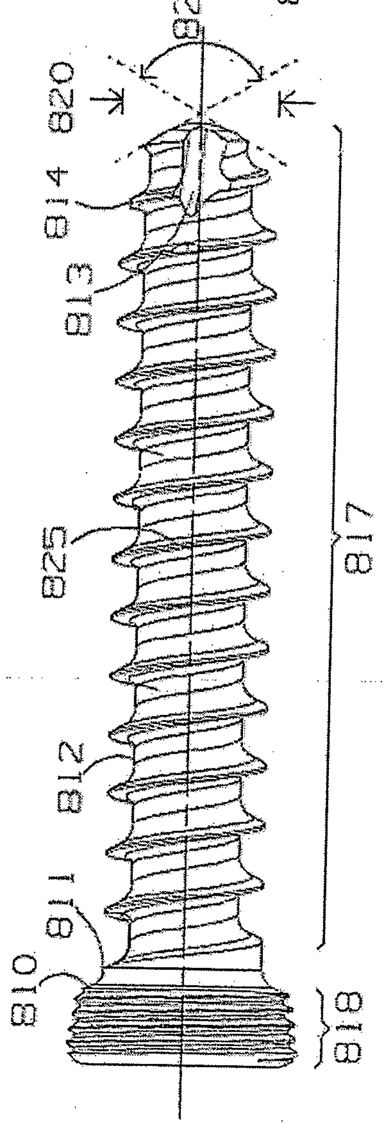


Figure 11(a)

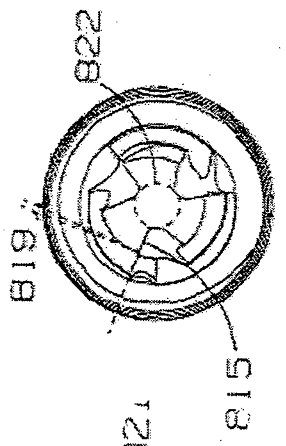


Figure 11(b)

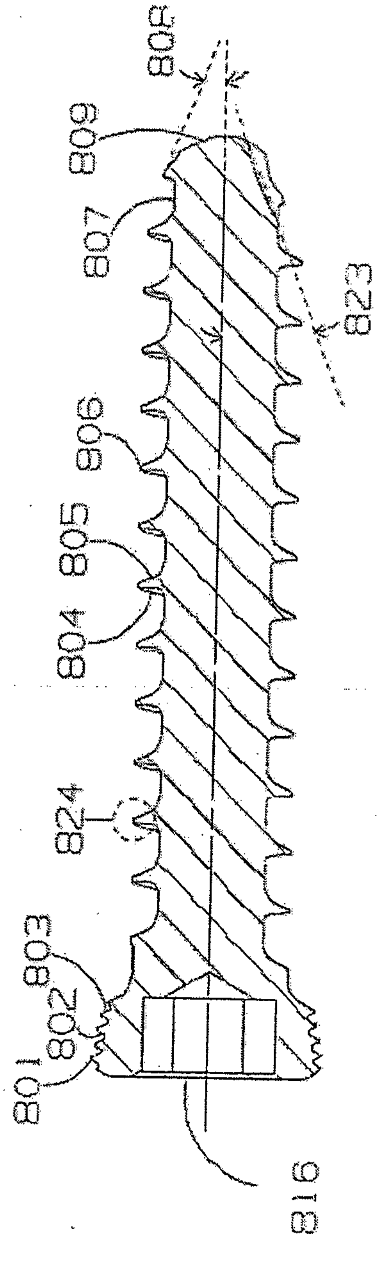


Figure 11(c)

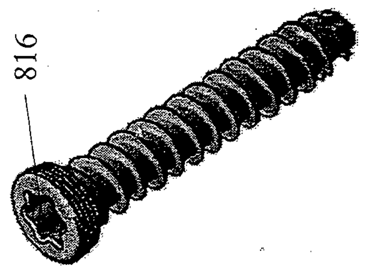


Figure 11(d)

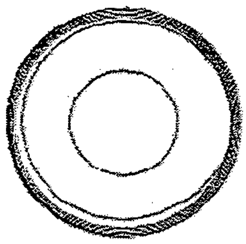


Figure 12(b)

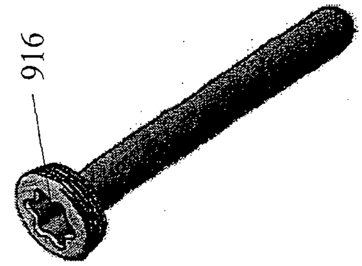


Figure 12(d)

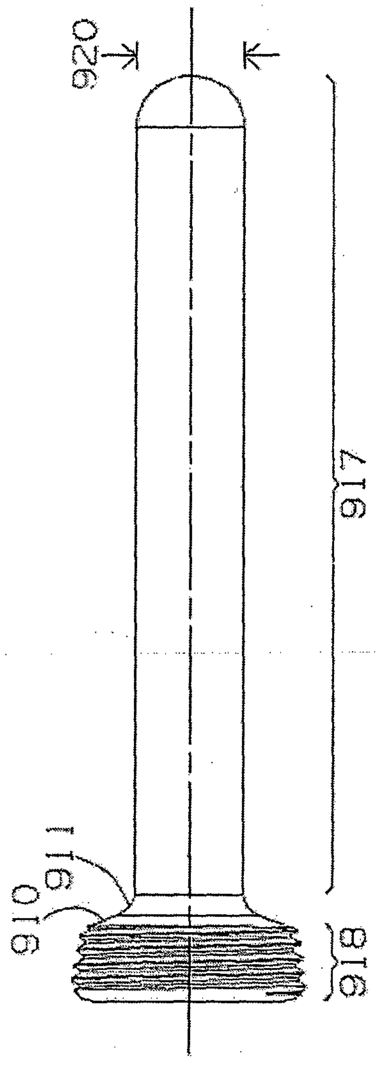


Figure 12(a)

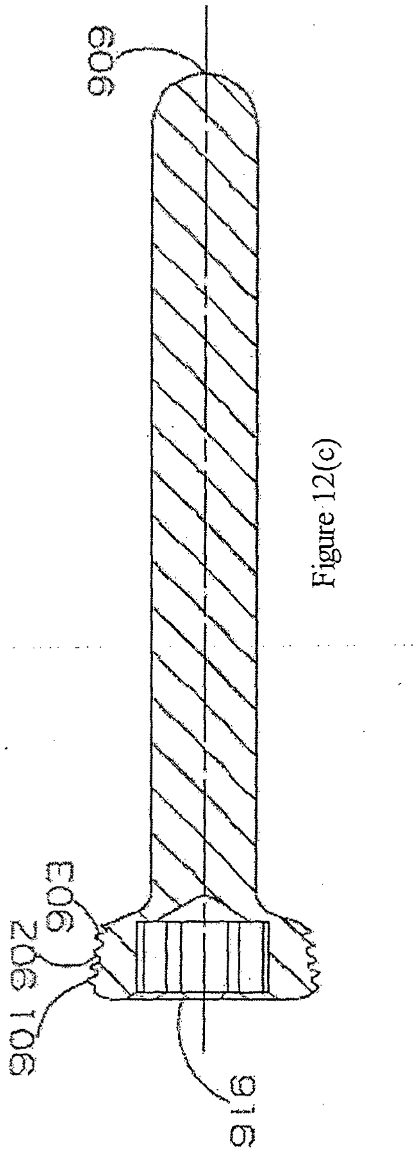


Figure 12(c)

International application No.
PCT/MY201 1/000213

A. CLASSIFICATION OF SUBJECT MATTER

Int. CI.

A61B 17/68 (2006.01)

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)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPI, EPODOC, IPC A61B 17/58, A61B 17/56, A61B 17/68 & KEYWORDS VOLAR, Y, SHAPE, HOLE, OPENING, APERTURE, PASSAGE, GRAFT, MATERIAL, FILLER & OTHERS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	**US 2008/0140127 A1 (VASTA ET AL) 12 June 2008** **see entire specification and figures 1-7**	**1-14**
A	**US 2005/0065524 A1 (ORBAY) 24 March 2005** **see abstract & figure 2**	
A	**US 2007/0265629 A1 (MARTIN ET AL) 15 November 2007** **see abstract & figure 21**	
A	**US 2005/0085818 A1 (HUEBNER) 21 April 2005** **see abstract & figures 2 & 5**	

☐ **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 another 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
09 February 2012	16 February 2012
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. +61 2 6283 7999	Authorized officer **M.S. HAYNES** AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No : +61 2 6283 2170

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	2008140127	AR	064600	AU	2007329398	EP	2099373
		WO	2008070695				
US	2005065524	AU	33015/01	AU	2002323296	AU	2003234384
		AU	2003239525	AU	2003294435	AU	2004226455
		AU	2004279290	AU	2005208810	AU	2005269990
		AU	2005304439	AU	2006207962	AU	2006220382
		AU	2007227098	AU	2007227099	BR	010801 1
		BR	031 1440	BR	PI0408807	BR	PI0513164
		CA	2396850	CA	2487571	CA	2508172
		CA	2519776	CA	2539386	CA	2587373
		CA	2596266	CA	2646726	CA	2647067
		CA	2676225	CN	1878507	CN	1997322
		CN	101022767	EP	1251790	EP	1507486
		EP	1567072	EP	1605842	EP	1677690
		EP	1713409	EP	1713410	EP	1764052
		EP	1768584	EP	1809190	EP	1855605
		EP	1996096	EP	1996120	EP	2258288
		IL	150980	JP	2005527316	JP	2007505682
		JP	2006507898	JP	2003529414	JP	2006521 160
		JP	2007083046	JP	2007518537	JP	2008505700
		JP	2008519664	JP	2008528202	JP	2009530052
		JP	2009530053	MX	PA02007250	NO	20074357
		US	6358250	US	6364882	US	200101 1172
		US	6440135	US	6508819	US	2003083661
		US	6706046	US	2002032446	US	671 2820
		US	2002143337	US	6730090	US	2002143338
		US	6767351	US	2004193163	US	6866665
		US	2003083660	US	6893444	US	2005165395
		US	7001388	US	2005065522	US	7250053
		US	2004193165	US	7282053	US	2005065523
		US	7294130	US	2005065528	US	7425213
		US	2004260292	US	7527639	US	2005283154

		US	7563263	US	7635381	US	2006009771
		US	7695502	US	2006100624	us	7727264
		US	2005182406	US	7744638	us	2005065520
		US	7780664	US	2005182405	us	7780710
		US	2004260294	US	778071 1	us	2004193164
		US	7857838	us	2006189996	us	7896886
		us	2007088360	us	7905909	us	2006200157
		us	7927341	us	2006189987	us	7938850
		us	2004153073	us	2004193155	us	2004260293
		us	2004260295	us	2005159747	us	2005187551
		us	2005240186	us	2005245931	us	2006041260
		us	2006149257	us	2006161 156	us	2010241 173
		us	2010268283	us	201 1166571	wo	0156452
		wo	03020007	WO	03101320	wo	03101321
		wo	2004049903	wo	2004087005	wo	2005034780
		wo	2005055842	wo	2005072284	wo	2005072285
		wo	2006014436	wo	2006053179	wo	2006081483
		wo	2007109436	wo	2007109437	ZA	200409570
		ZA	200507445	ZA	200602225	ZA	200607029
		ZA	200701078	ZA	200705054	ZA	200707231
		ZA	200809015				
US	2007265629	AU	2007223991	BR	PI0708679	CA	2645022
		EP	1993456	us	6509172	US	2003157651
		US	7572885	US	8021402	us	2007219349
		WO	2007103376				
US	2005085818	AU	2003261221	AU	2003291 114	AU	2003294342
		AU	2003294414	AU	2003295749	AU	2004249313
		AU	2006267081	AU	2006304847	CN	1674832
		CN	1835718	CN	101262828	CN	101340851
		EP	1542602	EP	1567074	EP	1572045
		EP	1608276	EP	1643923	EP	1906850
		EP	1948049	EP	2019637	EP	2379016
		GB	2407510	GB	2412590	GB	2412875
		GB	241591 1	GB	2419096	GB	2437441
		GB	2442189	GB	2445346	GB	2451 187
		GB	2451401	GB	2477481	JP	2006506197
		JP	2005533565	JP	2006519662	JP	2006506194

JP	2007275651	JP	2007515990	JP	2009501575
JP	2009512522	JP	2009535129	KR	20050075440
KR	20050083916	KR	20080036082	KR	20080074895
US	2004102778	US	7090676	US	2004181221
US	7147640	US	2004102788	US	7153309
US	2004102777	US	7189237	US	2006106390
US	7235079	US	2004102776	US	7326212
US	2004260291	US	7537596	US	2004127901
US	7537603	US	2004102775	US	7537604
US	2005234472	US	7578825	US	2007276405
US	7704251	US	2007162018	US	7717945
US	2007055251	US	7857836	US	2007123878
US	7914532	US	2006106393	US	7927332
US	2008177291	US	7955388	US	2005101961
US	2005171544	US	2005234458	US	2005240187
US	2006106391	US	2007055249	US	2007173840
US	2007270850	US	2008161861	US	2009069851
US	2009076554	US	2010121390	US	2010324602
US	2011022049	US	2011137351	WO	2004008980
WO	2004045384	WO	2004045389	WO	2004045455
WO	2004080344	WO	2004112587	WO	2005037114
WO	2005046494	WO	2005074580	WO	2005102193
WO	2007009124	WO	2007048038	WO	2007082004
WO	2007127994	WO	2007146165	WO	2008048684
WO	2008057404	WO	2010054400		

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX