BRIGARD& CASTRO
PROPIEDAD INTELECTUAL

CARRERA 7 # 71 – 21 TORRE B – PISO 4
BOGOTÁ – COLOMBIA
TEL: (571) 744 22 00
FAX: (571) 742 22 00 – (571) 3214045
www.bc.com.co

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
No. 06-041471- -00004-0000
Fecha: 2008-02-08 16:29:40 Dep: 2020 NUECREACIONE
Tra: 11 PATENTEYII Eve: 378 FASENACIONALI
Act: 538 PETICION Folios: 2

AS: 101.062

Señores
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES
E. S. D.

REF.: Expediente No. 06 041.471 - Solicitud de Patente FASE NACIONAL
Corresp. a la Solicitud Internacional PCT/IB2003/005243.
a nombre de: **SYNTHES GmbH.**
Titulada: SET DE PLACAS DE OSTEOSÍNTESIS.

JUAN PABLO CADENA SARMIENTO, vecino de Bogotá, portador de la tarjeta profesional No. 57492 del Consejo Superior de la Judicatura, obrando como apoderado de la Sociedad **SYNTHES GmbH**, según lo acredita el documento de poder presentado en esa División, de acuerdo con el Artículo 44 de la Decisión 486 de la Comisión de la Comunidad Andina, me permito solicitar que se examine si la invención contenida en la solicitud en referencia es patentable.

De acuerdo con lo anterior, me permito anexar el recibo oficial de caja No. 08-6,301 por valor de $420.000.

De la Señora Jefe atentamente,

JUAN PABLO CADENA SARMIENTO
C.C. No. 80.410.337 de Usaquén
T.P. No. 57492 del C.S.J.
Cra 7 No. 71-21 Torre B, Piso 4

Bogotá, 08 de febrero de 2008
CHP/MEV/jpg

AS. 101062

112

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
No. 08.041271 .00004-0000
Dep: 0020 NUECREACIONE
Cve: 378 FASENACIONALI
Folios: 2

RECIBO OFICIAL DE CAJA : 08 - 6,301
FECHA : ENERO 23 DE 2008

***** C O N S I G N A C I O N *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
BRIGARD & CASTRO LTDA	CONSIGNACION	BANCO DE BOGOTA	062754387	128206	23/01/2008	31,370,000.00

***** C O N C E P T O *****

CANT.	RENTISTICO	CONCEPTO		TOTAL CONCEPTO
1	50005-01-01 SOLICITUDES	85	EXAMEN DE PATENTABILIDAD DE INVEN	420,000.00
			TOTAL : $	420,000.00

SON: CUATROCIENTOS VEINTE MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No._____

112
113

Industria y Comercio
SUPERINTENDENCIA

DIVISIÓN DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. 06-41471

EL EXTRACTO DE LA PRESENTE SOLICITUD DE **PATENTE DE INVENCIÓN**

FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No **580** DE

FECHA **28 DE SEPTIEMBRE DE 2007** EL TÉRMINO HÁBIL SEÑALADO POR

LA LEY EXPIRA EL **27 DE DICIEMBRE DE 2007**

NOTA: Dentro del plazo de los seis (6) meses siguientes a partir de la fecha de publicación en la gaceta de Propiedad Industrial, deberá solicitar y cancelar el examen de patentabilidad so pena de que la solicitud caiga en abandono, de acuerdo con lo establecido en el Artículo 44 de la Decisión 486/2000.

SE PRESENTARON OPOSICIONES POR PARTE DE TERCEROS.

SI _____ NO ___X___

showing a portion of the femur plate coupled to the femur with the femur plate in cross section and showing the bone screw of Figure 10 positioned in the condyles of the femur;

Fig. 13 is a plan view of a cortical bone screw for attachment to both cortical bone surfaces of a long bone and for engagement with the bone plate for use with the femur plate of Fig. 4;

Fig. 14 is a plan view of a bone screw for engagement with the bone plate installed in a bone plate according to the present invention with a portion of the bone plate and a bushing providing polyaxial rotation shown in cross section;

Fig. 15 is a top view of a bushing for providing polyaxial rotation of the bone screw according to the present invention;

Fig. 16 is a plan view shown in cross section of the bushing of Fig. 15;

Fig. 17 is a plan view of a drill guide instrument installed on a bone plate for use with the fracture repair system of Figures 1-16; and

Fig. 18 is a plan view of a cancellous bone screw for attachment to cancellous bone of a long bone for use with the fracture repair system of Figure 1.

[0017] Referring to the drawings, Figure 6 shows a fracture repair system 10 for engagement with a long bone 12. The long bone 12 may be any long bone, for example, a femur, tibia, fibula, humerus, radius or ulna, but as shown in Figure 1 the long bone is a femur. The fracture repair system 10 includes a plate 14.

[0018] Referring now to Figure 4 the fracture repair system 14 is shown in greater detail. The plate 14 may be made of any suitable durable material and may, for example, be made of a metal, for example, a metal compatible with the human anatomy, for example, cobalt chrome, stainless steel or titanium. The plate 14 includes a body portion 16 and an interior wall 20. The interior wall 20 defines a plate hole 22 through the body portion 16.

[0019] Referring now to Figure 12 the fracture repair system 10 is shown in greater detail. In addition to the plate 14 the fracture repair system 10 includes one or more bushings 24. The bushing 24 includes a radial exterior surface 26 and opposite radial interior surface 30. The opposite radial interior surface 30 defines a passageway 32 through the bushing 24. The exterior surface 26 of the bushing 24 and the interior wall 20 of the plate 14 are configured to permit the polyaxial rotation of the bushing 24 within the plate hole 22 (see Figure 12). Such polyaxial rotation may be permitted by providing an arcuate or spherical surface on the interior wall 20 of the plate 14 and a mating arcuate or spherical surface on the radial exterior surface 26 of the bushing 24.

[0020] The fracture repair system 10 further includes the attachment component 34 includes a distal portion 36 sized for current passage through the passageway 32 and into the long bone 12. The attachment component 34 further includes an opposite proximal portion 40 sized to press the bushing 24 against the internal wall 20 of the plate 14 to form a friction lock between the bushing 24 and the plate 14 in a selected polyaxial position. The attachment component 34 is positionable in an orientation extending divergently from the centre of the plate.

[0021] Referring now to Figures 3 through 6 the fracture repair system 10 is shown as femur plate assembly 10. Preferably and as shown in Figures 3-6, the body portion 16 of the femur plate 14 preferably includes a proximal portion 42 and distal portion 44. To provide for optimal support of the femur, the femur plate 14 has a shape generally conforming to the outer periphery of the femur 12. The proximal portion 42 of the bone plate 14 is generally flat or planer in conforming to the general flat or planer nature of the proximal shaft portion of the femur. The femur plate 14 may have a bow to accommodate the natural anterior/posterior bow of the femur 12. The distal portion 44 of the femur plate 14 has a shape generally conforming to the condylar portion 46 of the femur 12. Since the condylar portion 46 of the femur 12 is arcuate or curved the distal portion 44 of the femur plate 14 is preferably curved to mate with condyles 50 of the condyle portion 46 of the femur 12.

[0022] While the particular size and shape and dimensions of the femur plate 14 may vary widely depending upon the size of the femur on which it is installed, for an adult human femur, the plate 14 may have, for example as shown in Figure 4, an overall length L of about 15.2 to 35.5 cm (6 to 14 inch) and a width W of about 0.64 to 1.9 cm (0.25 to 0.75 inch) or 0.9 to 3.17 cm (0.75 to 1.25 inch) and a thickness T of, for example as shown in Figure 6, about 0.31 to 0.64 cm (0.125 to 0.25 inch). Since the human anatomy is generally symmetrical, the femur plate 14 is either a right hand or left hand femur plate and the right hand and left-hand femur plates are different, but generally symmetrical with each other.

[0023] While the fracture repair system of the present invention includes one or more bushings which cooperates with an attachment component such that the attachment component may be positionable in an orientation diverging from the centre of the plate, it should be appreciated that the fracture system or plate may include a plurality of attachment components. Further these attachment components may be of different styles or types.

[0024] Referring now to Figure 6, the femur plate 14 is shown with three different types of attachment components. Solid, fully-threaded, cortical screws 52 are positioned in elongated openings 54 shown in Figure 4 in the proximal portion 42 of the femur plate 14. The fully threaded cortical screws 52 may, as shown in Figure 6, be self-tapping and cut threads while they are being screwed through the plate into the bone during surgery. The cortical screws 52 are supported primarily by the cortical bone to which they have been secured. While the proximal portion 42 of the bone plate 14 may be so-

cured by a solitary cortical screw 52 preferably and, as shown in Figure 6, the proximal portion 42 of the femur plate 14 is supported by a series of several spaced apart fully threaded cortical bone screws.

[0025] To provide ample support for the proximal portion 42 of the plate 14 and to provide for a standard commercially available femur plate 14, the femur plate 14 preferably includes a uniformly spaced apart pattern of elongated openings 54 shown in Figure 4. The surgeon may choose any of a number of the elongated openings 54 shown in Figure 4 in which to drill and screw the cortical screws. Depending on the position of the fractures as few as two or three cortical screws may be sufficient to support the femur plate 14.

[0026] Continuing to refer to Figure 6, cancellous screws 56 may also be placed in the elongated openings 54 and used to secure the proximal portion 42 of the femur plate 14.

[0027] The screw 56 unlike cancellous screw 70 (see Figure 6) does not include threads on the head of screw 56. The lack of screw threads on the head of screw 56 allows the head to spin on the bushing 24 without locking, thereby achieving a lagging effect. The cancellous screws 56 may be any suitable size and may, for example, be 2 to 6 mm solid, cancellous, partially or fully threaded cancellous screws. The cancellous screws 56, preferably have a length less than the thickness of the femur so that they may not protrude from the opposite surface of the femur.

[0028] Distal portion 44 of the femur plate 14 is designed to follow the general contours of the lateral distal femur while the proximal portion 42 incorporates the natural bow of the femur.

[0029] The femur plate 14 may include one or more tapped openings 60 in the femur plate 14 which may be utilized to secure a drill guide 200 shown in Figure 17 for aligning a drill and a screw driver for the insertion of the screws 52 and 56 into the femur. The drill guide 200 will be described in greater detail later.

[0030] According to the present invention, the plate 14 includes attachment components which are positionable in an orientation diverging from the centre of the plate. The plate 14 thus includes at least one screw 70 which is secured to the plate 14 by means of the bushing 24. The screw 70 may be in the form of a cancellous screw. The cancellous screw is particularly well suited for securing the condylar portion of the distal portion of the femur. The cancellous screw 70 may be partially or fully threaded and may have any suitable length to reach the proper portion of the fractured condylar portion of the distal femur. For example, the cancellous screw may have a length from 20 to 150 millimetres. The cancellous screw may have a suitable diameter to properly secure the fractured portions of the femur. For example, the cancellous screw may have a diameter of 3 to 10 millimetres. The cancellous screw 70 is used to secure the distal portion of the femur plate to the bone.

[0031] The cancellous screws may be rotated from the first position 72 shown in solid to position 74 shown rotated an angle α or to a third position 76 rotated in the opposite direction an angle β (see Figure 6). If the cancellous screw 70 is rotated to the second position 74, the screw 70 will be utilized to secure fragment AA while if the cancellous screw 70 is rotated to position 76, the cancellous screw 70 may be utilized to secure fragment BB. The tip of the cancellous screws 70 can therefore be rotated in a conical pattern.

[0032] The cancellous screw 70 as shown in Figure 6 may include external threads 80 on the head or proximal portion of the screw 70. Alternatively, the head or proximal portion may have a smooth conical head. The external threads 80 mate with internal threads 82 on the bushing 24. Preferably and as shown in Figure 6 the external threads 80 are tapered such that as the external threads 80 of the screw 70 are engaged into the bushing 24 the bushing 24 expands, locking the radial external surface 26 of the bushing 24 to the radial interior surface 30 of the plate 14.

[0033] By permitting the bushing 24 to rotate within the plate 14 and by permitting the bushing 24, the screw 70 and the plate 14 to all be locked securely in place, the screw may be fixedly positioned in many different orientations, while maintaining all components at minimal stress. As shown in Figure 6, the feature of having the positionable screw and plate configuration permits either fragment AA or fragment BB to be secured by the screw 70.

[0034] Referring now to Figure 6A, one or any portion of the locations of the plate 14 may include one or more bushings 124 which may alternatively be utilized with a screw having a non-threaded head. For example, as shown in Figure 6A a cancellous screw 170 is shown similar to screw 70 but not including external threads on the head of the screw. The screw 170 does include cancellous threads 172 for securement to the cancellous bone. The screw 170 includes a head 174 which is secured against face 176 of bushing 124. In this configuration the bushing 124 serves to permit the rotation of the screw 170 in the direction of arrows 100 and 102, thus permitting the orientation of the screw 170. The use of the bushing 124 prevents stress risers on the head 174 or face 176 of the bushing 124.

[0035] The plate 14 may be made of any suitable durable material that is biologically compatible with the human anatomy and preferable made of a high strength metal. For example, the plate may be made of stainless steel, cobalt chrome or titanium. Preferably the plate 14 is manufactured from a forged or wrought titanium alloy. One such suitable alloy complies with test method ASTM F-620-97 and another suitable alloy complies with test method ASTM F-136 ELI.

[0036] Referring to Figure 7, the femoral plate 314 may be secured to the femur 312 during surgery either percutaneously or by conventional open surgery. When the femur plate 314 and screws are implanted in conventional open surgery a longitudinal cut 390 is made

through the skin along the thigh 308 laterally where the femur plate is typically installed. A lateral installation of the femur plate provides for the minimal interference with muscle, ligaments and other soft tissue. A longitudinal cut 306 in the thigh 308 through the skin parallel to the femur 312 is made approximately the length of the femur plate 314 and the soft tissue is pulled apart so that the femur plate may be placed in position. Cancellous and cortical screws are then positioned over their respective openings in the femur plate 314 and secured to the femur 312.

[0037] When performing percutaneous surgery the skin of the thigh 308 is opened laterally near the knee and a transverse cut 392 is made and femur plate 314 is inserted at that opening and guided against the femur 312 proximally toward the hip. The proximal end of the femur plate 314 may include a contoured tip 384 to ease the percutaneous installation of the femur plate 314.

[0038] While the femur plate 314 may be made of any suitable size depending on the size of the human in which the plate is to be installed, the femoral plates 314 may be available in various lengths so that they will be available when trauma strikes. For example, the femoral plates may be provided with varying lengths including for example 5, 8, 11, 14 or 18 screw holes in the shaft.

[0039] The cortical and cancellous screws are manufactured of any suitable durable material that are typically manufactured of a wrought titanium alloy for example which complies with test method ASTM F-136 ELI.

[0040] Referring now to Figure 12A, the femur plate 14 may further include a cannulated cancellous screw for positioning in the condylar portion 46 of the femur 12. The cannulated cancellous screw 62 preferably has a length slightly shorter than the length of the portion of the cancellous bone at the condylar portion 46 such that the cannulated cancellous screw does not contact the opposite cortical bone. The cannulated cancellous screw may, for example, be 8 mm cannulated cancellous and preferably as shown in Figure 12A include external threads 48 located on proximal portion 38 of the cancellous screw 46. The external threads 48 mate with the internal threaded opening 49 of the distal portion 44 of the femur plate 14. The cannulated cancellous screw 62 provides additional structural support to the condylar portion 46 of the femur 12. Alternatively, the head of the cancellous screw 62 may be smooth, thereby allowing the head to spin in the plate without locking. The spinning achieves a lagging effect, i.e. drawing the fragments together.

[0041] Referring now to Figure 10, the cannulated cancellous screw 62 is shown in greater detail. The cannulated cancellous screw may not be in any particular size and may include a diameter D1 of, for example, 4 to 10 millimetres. The cannulated cancellous screw has a length L1 sufficient to occupy most of the condylar portion 46 of the femur or long bone 12. To provide for rigid attachment of the cannulated cancellous screw 62 to the bone plate 14, the cancellous screw 62 preferably includes a head 410 having external threads 412 which may mate with internal threaded opening 49 of the bone plate 14 (see Figure 12A). The cannulated cancellous screw 62 includes external threads 414 and may include an untnreaded shank portion 416. The cannulated cancellous screw 62 may include a self-tapping tip 420 which may also serve as a self-drilling as well as a self-tapping tip. As shown in Figure 10, the threads 412 on the head 410 are tapered to provide for a tight locking fit with the bone plate 14. The cannulated cancellous screw 62 is by definition cannulated or includes a central longitudinal opening 422.

[0042] Referring now to Figure 13 a cortical screw 52 is shown. The cortical screw 52 includes threads 514 which are adapted for securing cortical bone. The cortical screw 52 may include an unthreaded shank portion (not shown). The cortical screw 52 includes a head 552 which may, as shown in Figure 13, have a generally oval shape. The cortical screw 52 may also include a self-tapping tip 520 which may also include self-drilling provisions. The cortical screw 52 has a length L2 which preferably is of sufficient length to engage the cortical bone on the opposite or exit side of the bone. The cortical screw 52 further includes a thread diameter D2 which is of sufficient size to provide sufficient holding power and engagement with the cortical bone. For example and as shown in Figure 13, the cortical screw 52 has a diameter D2 of, for example, 3.5 to 6 millimetres.

[0043] Referring now to Figure 14 an attachment component according to the present invention is showed as cancellous screw 70. The screw 70 includes a distal portion 36 which has an outside diameter OD which is less than the inside diameter ID of the internal wall or surface 30 of the plate hole 22. The screw 70 further includes external threads 80 located on the proximal portion 40 of the screw 70. Preferably and as shown in Figure 14, the external threads 80 are tapered. The external threads 80 are mateably engageable with the internal threads 82 on the bushing 24. The bushing 24 is pivotally engageable with the plate 14. The radially exterior surface 26 of the bushing 24 has a generally spherical shape and is mateably fitted with the interior wall or surface 30 of the plate hole 22. The interior threads 82 of the bushing 24 is larger than the outside diameter of cancellous threads 71 on the screw 70 to permit the distal portion of the 36 of the screw 70 to slidably pass or thread through the plate hole 22. The cancellous threads 71 are adapted for efficient engagement with cancellous bone 96 and the screw 70 has a length L3 which is sized to provide for the cancellous thread 71 to engage a significant portion of the cancellous bone 96.

[0044] Referring now to Figure 18, a fully threaded cancellous screw 56 is shown for use with the bone plate 14. The cancellous screw 56 includes a head 610. The head 610 may have any suitable shape and may, for example, be flat head as shown in Figure 18 or have a pan head shape. The screw 56 unlike cancellous screw

70 (see Figure 6) does not include threads on the head of screw 56. The lack of screw threads on the head of screw 56 allows the head to spin on the bushing 24 without locking, thereby achieving a lagging effect. The cancellous screw 56 has a length L4 to provide for engagement with a suitable portion of the cancellous bone (not shown). The cancellous screw has threads 614 which are adapted for engagement with cancellous bone. The thread 614 has a diameter D4 which is sized for efficient and effective support and engagement with the cancellous bone. For example, the cancellous screw 56 may have a diameter D4 of, for example 2 to 6 mm. The cancellous screw 56 further includes a tip 620. The tip 620 may optionally include self-drilling and/or self-tapping features.

[0045] Referring now to Figure 15, the bushing 24 is shown in greater detail. The bushing or collet is manufactured of any suitable durable material that is compatible with the human body. For example the collet may be made of cobalt chrome, stainless steel or titanium. For example the bushing 24 may be manufactured of a wrought titanium alloy. A suitable wrought titanium alloy is such as complies with test method ASTM F-136 ELI.

[0046] The bushing 24 preferably includes a radial opening or passageway 32 on the periphery of the bushing 24. The passageway 32 extends from the radially exterior surface 55 through the opposite radially interior surface 53. The bushing 24 has a first relaxed position 85 which represents the shape of the bushing 24 when not assembled into the plate 14. The bushing 24 further has an assembled position 87 as shown in the dotted line. The assembled position 87 represents when the bushing 24 is placed within the plate 14 and when the screws are not installed. The bushing 24 further has an expanded position 88 shown in phantom in which the bushing 24 is shown with the bushing 24 installed in the plate 24 and the screws installed within the bushing 24.

[0047] As can be seen in Figure 15, the bushing 24 is contracted when the assembled position 87 to provide for an interference fit between the bushing 24 and the plate 14. Further as shown in Figure 15, the bushing 24 is expanded as it moves from the assembled position 87 to the expanded position 88. This occurs because the tapered threads during engagement cause the bushing 24 to enlarge. The enlarging of the bushing 24 causes a tighter interference between the bushing 24 and the plate thereby securely locking the bushing in its polyaxial oriented position with minimal stress.

[0048] Referring now to Figure 16 a cross-section of the bushing 24 is shown. As shown in Figure 16 preferably the bushing 24 has a spherical radius R_s which defines the radial exterior surface 26 of the bushing 24. By providing a spherical radius R_s the bushing 24 may be oriented into a number of angular positions with respect to the plate.

[0049] Referring to Figure 16 the internal threads 82 of the bushing 24 have a taper defined by an internal angle βββ. The angle βββ may be, for example from 3 to 30°. As shown in Figure 16 the truncated spherical shape of the radial exterior surface 26 may be modified by corner radius R.

[0050] While the fracture repair system of the present invention includes the bushing to provide for positioning of the attachment component in a variety of diverging directions while providing for reduced stress at the plate, when percutaneously securing a bone screw to a bone plate location which does not provide for the pivotal securement of the bushing arrangement, it is critical that the screws in such fixed locations be properly positioned. Referring now to Figure 17 preferably the femur plate 14 is used in conjunction with drill guide 200. Drill guide 200 is installed onto the femur plate 14 during surgery and is utilized to guide drills and screwdrivers to properly orientate the screws that are placed in the proximal portion of the plate 14. The drill guide 200 includes a locating feature 202 in the form of, for example, an elongated pin which closely fits to the elongated slots of a plate. The drill guide includes a riser portion 204 and a bar portion 206 which is positioned parallel and spaced from the plate 14.

[0051] The bar portion 206 includes a series of bushing holes 210 which are in alignment with the centre of the elongated openings 54 in the plate 14. To properly secure the drill guide 200 to plate 14, for example, the drill guide 200 may include a securing screw 214 which may be slidingly fitted to an opening 216 in the riser portion 204 and which may be secured to tapped opening 60 in the plate 14.

[0052] The drill guide 200 may be utilized both in conventional open surgery and in percutaneous surgery. When utilized in percutaneous surgery the bushing holes 210 may be utilized to guide trocars which will open the skin and tissue around the openings permitting the screws to be properly secured. Since the human anatomy is generally symmetrical, the drill guide 200 is either a right hand or left hand drill guide and the right hand and left-hand drill guide are different, but generally symmetrical with each other. It should be appreciated that the drill guide may be utilized for any bone plate for supporting any long bone for example a tibia, humerus, ulna, radius or fibula.

[0053] While the fracture repair system has been described in detail as a femur plate, it should be appreciated that the plate may be utilized for supporting any long bone for example a tibia, humerus, ulna, radius or fibula.

[0054] Referring now to Figures 7 to 9 and 11, a tibia plate 314 for installation onto a tibia 312 is shown. The fracture repair system 310 for use on the tibia 312 includes a tibia plate 314 having a body portion 316. The body portion 316 includes a distal portion 342 and a proximal portion 344. The tibia plate 314 like the femur plate 14 is preferably positioned laterally on the long bone. The lateral position of the tibia plate reduces the amount of soft tissue that must be dislocated to position the tibia plate 314. Since the human anatomy is gener-

ally symmetrical, the tibia plate 314 is either a right hand or left hand tibia plate and the right hand and left-hand tibia plates are different, but generally symmetrical with each other. The proximal portion 344 of the tibia plate 314 is designed to follow the general contours of the lateral proximal tibia. The proximal portion 344 of the plate 314 is contoured to fit the lateral condyle 350 of the condylar portion 346 of the tibia 312. The body portion 316 of the tibia plate 314 like the body portion 16 of the femur plate 14 has a generally arcuate cross-section to conform with the distal shaft of the tibia 312.

[0055] The tibia plate 314 like the femur plate 14 may be made of any suitable durable material that is compatible with the human immune system and may for example be made of a durable non-corrosive material such as stainless steel, cobalt chrome or titanium. For example, the tibia plate may be manufactured from a forged or wrought titanium alloy. For example, such a titanium alloy may be such as complies with test methods ASTM F-620-97 or ASTM F-136 ELI.

[0056] Referring now to Figure 7, the tibia plate 314 may be inserted into the human anatomy percutaneously or by conventional open surgery. When inserted by conventional open surgery, the leg 308 is cut with a longitudinal incision 390 of length roughly equal to that of the tibia plate 314. The soft tissue is moved away from the tibia 312 and the tibia plate 314 is placed against the tibia 312. Screws such as those for the femur plate are utilized to secure the tibia plate 314 to the tibia 312. If the tibia plate 314 is to be inserted percutaneously, a smaller longitudinal incision 392 is made in the skin of the leg 308 near the knee and the distal portion 342 of the body portion 316 of the tibia plate 314 is inserted in the incision 392 in the direction of arrow 306 toward the distal portion of the leg. A contoured tip 384 on the distal portion of the 342 of the tibia plate of the tibia plate 314 is shaped to ease the insertion of the tibia plate along the contour of the tibia 312 in the direction of arrow 306.

[0057] For installation either percutaneously or by conventional open surgery of the tibia plate 314 drill guides (not shown) such as drill guide 200 for the femur plate as shown in Figure 17 are utilized. Again, as with the femur plate, the drill guide may be utilized to guide the drill and the screws whether the plate and screws are inserted percutaneously or by conventional open surgery. It should be appreciated that a left-hand drill guide (not shown) and a right hand drill guide (not shown) are necessary respectively for the right hand and left-hand tibia plates (not shown).

[0058] Referring now to Figure 8, the tibial plate 314 may be made of sufficient dimensions to properly support the tibia 312. The proper dimensions of the tibial plate 314 are dependent thus on the size of the particular tibia to be treated as well as the inherent strength of the material from which the tibial plate 314 is made. For example, the tibial plate 314, if made of titanium, may have a thickness TT (see Figure 9) of, for example, approximately 1.6 to 6.4 mm (0.063 to 0.25 inch) and a WW width of around 6.4 mm to 19 mm (0.25 to 0.75 inch) and a length LL of, for example, from 12.7 to 25.4 cm (5 to 10 inch). To provide for a range of standard tibial plates, the tibial plates may be provided in varying lengths of, for example, a length with a number of elongated openings 354 of, for example, 4, 7, 11, or 14 elongated openings.

[0059] According to the present invention and referring to Figures 7 to 9 and 11, the tibial plate 314 includes the body portion 316 which conforms at least partially to the contour of the tibia 312. The tibia plate 314 also includes an interior wall 320 which defines a tibia plate hole 322 through the body portion 316.

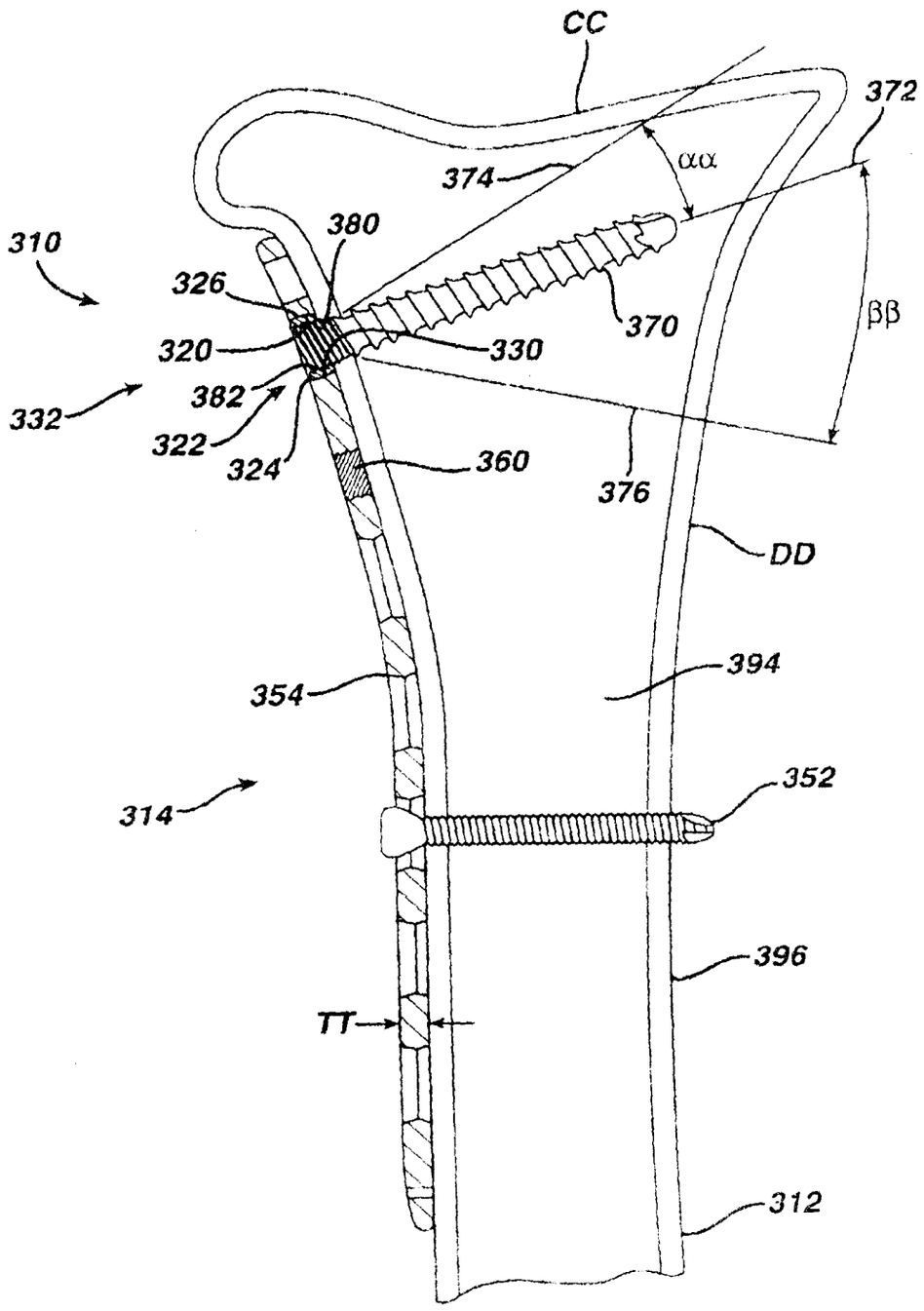
[0060] Referring to Figure 9, the tibial plate 314 further includes one or more bushings 324. The bushing 324 includes a radially exterior surface 326 and an opposite radially interior surface 330. The opposite radially interior surface 330 defines a passageway 332 there through. The exterior surface 326 of the bushing 324 and the interior wall 320 (see Figure 9) of the plate 314 cooperate with each other and are configured to permit polyaxial rotation of the bushing 324 within the plate hole 322. The tibial plate 314 further includes an attachment component 370 in the form of, for example, a cancellous screw. The screw 370 includes a distal portion 336 sized for clearance passage through the passageway 332 and into the cancellous bone 394.

[0061] The screw 370 further includes a proximate portion 340 sized to press the bushing 324 against the inner wall or surface 330 of the plate 324 to form a friction lock between the bushing 324 and the plate 314 in a selected polyaxial position. For example, the cancellous screw 370 may be in a first polyaxial position 372 as shown in solid line 372 (see Figure 11). Alternatively, the cancellous screw 370 may be oriented an angle $\alpha\alpha$ from the first position 372 into a second position 374 as shown in phantom. Alternatively, the cancellous screw 370 may be positioned in, for example, a third position 376 positioned at an angle $\beta\beta$ from the first position 372. The cancellous screw 370 may thus be positioned with a diverging angle $\alpha\alpha$ or $\beta\beta$ from the first position 372.

[0062] Preferably and as shown in Figure 11, the proximal portion 340 of the cancellous screw 370 includes external tapered threads 380 which mate with internal threads 382 located within the bushing 324. By providing tapered threads as the cancellous screw 370 is screwed into the bushing 324, the bushing 324 expands with the radially exterior surface 326 of the bushing seating and securing against the radially interior surface 330 of the plate 314. This provides for stress-free, secure locking of the screw 370 to the plate 314.

[0063] Alternatively, the attachment component which mates with the bushing 324 may be provided without any threads in the proximal portion of the attachment component similarly to the screw 170 of Figure 6A. Such a screw will provide for polyaxial positioning of the attachment component with reduced stress. The screw 56 unlike cancellous screw 70 (see Figure 6) does not in-

FIG. 9


CC
372
αα
374
380
310
326
370
ββ
320
330
382
332
322
324
360
376
DD
394
354
352
314
396
TT
312

121

121

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIRECCION DE NUEVAS CREACIONES

202084

Bogotá, D.C.

Abogado
JUAN PABLO CADENA SARMIENTO
Apoderado

ASUNTO	Radicación	06 – 41471
	Trámite	011
	Evento	378
	Actuación	519
	Oficio	1402
	Folios	010

Patente de Invención	X	Patente de Modelo de Utilidad			
Vía Nacional					
Vía PCT (fase nacional)	X	Cap. I	X	Cap. II	

No. Sol. Internacional IB2003/005243

Fecha de Presentación Internacional 18/11/2003

Como resultado del examen de fondo, realizado con fundamento en el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le comunica:

1. Documentos estudiados

1.1.	Descripción:	Folios	53 a 66
1.2.	Reivindicaciones:	Folios	67 a 78
1.3.	Dibujos:	Folios	80 a 88

2. Objeto de la invención

Título de la solicitud: "SET DE PLACAS DE OSTEOSÍNTESIS"

El problema planteado en esta solicitud se refiere a: una perforación no especifica de las placas requiere un complejo arqueado de las placas, lo que implica una merma en la estabilidad mecánica de la osteosíntesis de placas, pudiendo existir falta de apoyo óseo y de puntos de fijación para los tornillos óseos; una placa que requiere una adaptación a su posición, no se logra la comodidad de un sistema de dos placas preformadas de modo especifico. Cuando están en forma paralela presupone desventajosamente que todos los fragmentos óseos se encuentran en un espacio liso, relativamente plano entre las dos placas de osteosíntesis. Y la inexistencia de un encuentro en ángulo obtuso de los sentidos de introducción de los tornillos originando una carencia de la unión a través del bloque distal, que reduciría el sostén de las placas óseas en el hueso y por lo tanto la estabilidad de la osteosíntesis.

En general se pueden ubicar desventajosamente en la zona de contacto de los tendones y probablemente interferir así en el funcionamiento del codo. Además no se presenta en el lado medial una fijación satisfactoria a través de bloque medial.

Para solucionar este problema técnico la solicitud en estudio proporciona un set de placas de osteosíntesis, que sostiene mejor el hueso y permite una reubicación segura entre sí de mayor cantidad de fragmentos óseos diferentes; esto se logra haciendo una distribución especial de los tornillos óseos que pueden fijarse en las placas de osteosíntesis, respecto de diferentes ubicaciones espaciales de los mismos en estado de montaje.

El objeto de la presente invención se lleva acabo de acuerdo con las características reivindicadas, en las reivindicaciones 1 y 6 a 34 (ver folios 67 a 78).

El objeto de la solicitud definida anteriormente se encuentra en la Clasificación Internacional de Patentes (IPC), A61B17/58; A61B17/76; A61B17/82; A61B17/68.

3. Determinación del Estado de la Técnica

Se buscaron documentos del estado de la técnica relacionados, con fecha de publicación anterior a 2003-09-18, que pueden afectar la patentabilidad del objeto de la presente solicitud, encontrándose:

Nº	Documento	Título	Fecha de Publicación
D1	EP1250892	Polyaxial locking plate	2002-10-23

4. De la solicitud de Patente

4.1. Reivindicaciones (artículo 30 D 486)

Se sugiere fusionar las reivindicaciones las reivindicaciones independientes 1 y 6 a 34; ya que están caracterizando el mismo objeto, esto para dar mayor claridad, sin necesidad de extenderse. También se aconseja que la reivindicación independiente, mencione todas las características conocidas en el estado de la técnica, en el preámbulo, y seguido del término *"CARACTERIZADO POR"* se muestren las características técnicas novedosas propias de la solicitud, y que la diferenciarían del estado de la técnica.

Con lo anterior se busca que la reivindicación independiente de mayor claridad y delimite mejor la invención, para reflejar el verdadero alcance de la protección.

5. Análisis de patentabilidad (artículo 14 D 486)

5.1. Novedad (artículo 16 D 486)

Teniendo en cuenta que el documento ***EP1250892*** (mencionado de ahora en adelante como **D1**), que se refiere a: un "***Polyaxial locking plate***" como se muestra a continuación:

Al comparar elemento por elemento de la invención tal como está definido las reivindicaciones 1 y 6 a 34; con el documento **D1**: vemos que el dicho documento contiene todas las características técnicas:

o Las dos placas de osteosíntesis (2g, h o i) y/o sus orificios (3a, b, c) se

conformaron de modo tal, que los tomillos óseos (12) colocados en estado de implante o bien los orificios (3a, b, c) indican como mínimo hacia cuatro sentidos espaciales distintos. Ver **D1** Capitulo descriptivo, columnas 5 a 15; elementos 10, 14, 310, 314, y Figuras 1 a 18.

- Una de las dos placas de osteosíntesis (2g, h, i) presenta como mínimo dos orificios (3a, b, c) para tomillos óseos (12), cuyos tornillos óseos (12) -estando implantados- cortan o cruzan en forma al menos aproximadamente paralela el eje articular. Ver **D1** Capitulo descriptivo, columnas 5 a 15; elementos 10, 32, 14, 310, 314, 354 y Figuras 1 a 18.

- Una de las dos placas de osteosíntesis (2g, h, i) presenta como mínimo un orificio (3a, b, c) que se dispuso o se conformo de modo tal que su eje o bien un tornillo óseo colocado en la misma (12) corta o cruza al menos de modo prácticamente perpendicular el eje articular en estado implantado. Ver **D1** Capitulo descriptivo, columnas 5 a 15; elementos 10, 32, 14, 310, 314, 354 y Figuras 1 a 18.

Realizada la comparación del documento **D1** con la presente solicitud de patente de invención, se observa que dicho documento contiene todas las características técnicas de las reivindicaciones 1 y 6 a 34; con lo cual quedaría desvirtuada la novedad de esta.

6. Conclusión:

Los requisitos de patentabilidad de la presente solicitud se encuentran afectados así:

N°	Documento N°	Reivindicaciones Afectadas	Requisito que Afecta
D1	EP1250892	1 a 34	Novedad

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de sesenta días contados a partir de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Única N° 10 de 2001.

ALIX CARMENZA CÉSPEDES DE VERGEL
Directora de Nuevas Creaciones (C)

El anterior requerimiento fue notificado por fijación en lista, de fecha 05 FEB. 2010

CONCEPTO TÉCNICO No.393	**EXAMINADOR TÉCNICO** Código No. 84

Fase