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MDE



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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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**Patente de Invención: TORNILLOS ENDOÓSEOS Y DISPOSITIVO
ORTOPÉDICO PARA ASISTIR LA OSTEOSÍNTESIS RÍGIDA DE
FRACTURAS.**

Atentamente se dirige a usted **JAIME EDUARDO DELGADO VILLEGAS**, Abogado, mayor y vecino de Bogotá D.C., e identificado como aparece al pie de mi firma, me dirijo a su Digno Despacho para manifestarle lo siguiente:

1. En mi condición de apoderado de la sociedad ORTHOFIX S.R.L., domiciliada en BUSSOLENGO - ITALIA, presenté ante su Digno Despacho la solicitud de registro de la Patente de Invención mencionada en la referencia.
2. Debido a lo anterior, y con el fin de dar cumplimiento al requerimiento hecho por su Despacho mediante Oficio No. 13670 del 2 de Septiembre de 2011, me permito expresar lo siguiente:

- El Capítulo reivindicatorio de la solicitud presentada ante el PCT contiene 13 reivindicaciones. El solicitante presentó ante el PCT modificaciones a este capítulo el día 20 de Julio de 2010, el cual consta solamente de once (11) reivindicaciones tal como se observa en el informe de examen de patentabilidad del 27 de Septiembre de 2010. (ver adjunto).

Por lo anterior, en el momento de radicar la solicitud PCT Fase Nacional en Colombia se anexaron los recibos de caja No. 11 – 0063543 por valor de \$ 571.000 correspondiente a la tasa de presentación y 11 – 0054359 por valor de \$ 27.000 correspondiente a la tasa por una reivindicación adicional.

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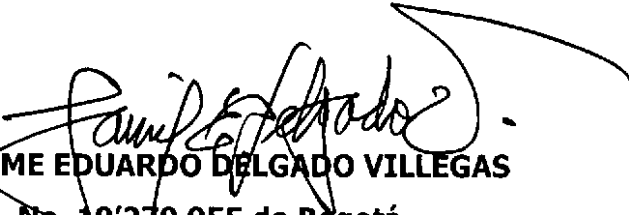
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Por lo expuesto, solicitamos que se tenga en cuenta para el examen de patentabilidad las reivindicaciones modificadas que incluyen once (11) reivindicaciones.

Con la documentación adjunta, doy cumplimiento dentro de término hábil a lo requerido por su Digno Despacho, por lo que comedidamente solicito se continúe con el trámite normal de registro de la Patente de Invención que se enuncia en la referencia.

Atentamente,



JAIME EDUARDO DELGADO VILLEGAS
C.C. No. 19'270.955 de Bogotá

T.P. No. 43.308 del Consejo Superior de la Judicatura.

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (PCT Rule 71.1)

To:

Paglia, Pietro
Botti & Ferrari S.r.l.
Piazza dei Martiri 5
I-40121 Bologna
ITALIE

Date of mailing
(day/month/year)

27.09.2010

Applicant's or agent's file reference
OFX092BWO

IMPORTANT NOTIFICATION

International application No.
PCT/IB2009/007856

International filing date (day/month/year)
22.12.2009

Priority date (day/month/year)
23.12.2008

Applicant
Orthofix S.r.l.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international
preliminary examining authority:



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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference OFX092BWO		FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/IB2009/007856		International filing date (day/month/year) 22.12.2009	Priority date (day/month/year) 23.12.2008	
International Patent Classification (IPC) or national classification and IPC INV. A61B17/80				
Applicant Orthofix S.r.l.				
1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. ☒ sent to the applicant and to the International Bureau a total of <u>4</u> sheets, as follows: ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see paragraph 3b1s of Annex C of the Administrative Instructions).				
4. This report contains indications relating to the following items: ☒ Box No. I Basis of the report ☐ Box No. II Priority ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability ☐ Box No. IV Lack of unity of invention ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement ☐ Box No. VI Certain documents cited ☐ Box No. VII Certain defects in the international application ☒ Box No. VIII Certain observations on the international application				
Date of submission of the demand 2010-07-20		Date of completion of this report 27.09.2010		
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Fax: +49 89 2399 - 4465		Authorized officer Fernández Arillo, J Telephone No. +49 89 2399-8495 		

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IB2009/007856

Box No. I Basis of the report

1. With regard to the **language**, this report is based on
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))
2. With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-14 as originally filed

Claims, Numbers

1-11 filed with telefax on 20-07-2010

Drawings, Sheets

1/3-3/3 as originally filed

- ☐ a sequence listing - see Supplemental Box Relating to Sequence Listing.
3. ☒ The amendments have resulted in the cancellation of:
 - ☐ the description, pages
 - ☒ the claims, Nos. 1-13
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
 4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since either they are considered to go beyond the disclosure as filed, or they were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in the Supplemental Box (Rules 70.2(c) and (c-bis)):
 - ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 5. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 70.2 (e)).
 6. ☐ Supplementary international search report(s) from Authority(ies) have been received and taken into account in drawing up this report (Rule 45bis.8(b) and (c)).

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IB2009/007856

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>1-11</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	<u>1-11</u>
	No: Claims	
Industrial applicability (IA)	Yes: Claims	<u>1-11</u>
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the International application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Reference is made to the following documents:

- D1 US 2007/227314 A1 (ERICKSON DAVID R [US] ET AL) 4 October 2007
(2007-10-04)
- D2 US 5 797 918 A (MCGUIRE DAVID A [US] ET AL) 25 August 1998
(1998-08-25)

1 Re ITEM VIII

In claim 1, the "median section" is not uniquely defined, thereby rendering the subject-matter of claim 1 unclear (Article 6 PCT). In line with the description (see page 9 lines 11-15), said "median section" has been understood as a "median **transversal** section **positioned on a plane perpendicular to the longitudinal axis of the screw**".

2 Re ITEM V

2.1 The subject-matter of **claim 1** appears to be new and inventive in the sense of Articles 33(2) and (3) PCT, due to the following reasons:

2.1.1 D1 (see D1, fig. 2) discloses (the references in parentheses applying to this document):

An endosseous screw (100) for fixing a plate (see fig. 4) to a bone site, comprising an at least partially threaded shaft (102), insertion means for inserting the screw into the bone site and a distal portion (101) provided for engaging said plate to fasten it to said bone site and comprising a head (101) having facets (see the facets of the head in figure 2) defining an external peripheral profile provided for engagement with a tubular manipulating wrench (10), to allow the screw to be extracted from the bone site into which it has been inserted, wherein the facets are curvilinear, even in number (see fig. 2) and define an external peripheral profile.

- 2.1.2 The screw of claim 1 differs from the one of D1 in that:
the external peripheral profile defined by the facets has a convex barrel-like shape (see fig. 2), in that
the facets define a regular polygonal section along a median section of the head, said median section being a median **transversal** section **positioned on a plane perpendicular to the longitudinal axis of the screw** and dividing each facet into two internal and external portions, respectively, which mirror each other.
- 2.1.3 The problem solved by these differing features can be seen as how to provide a more stable coupling between a wrench and an endosseous screw, even when said wrench is inclined with respect to the screw.
- 2.1.4 Although D2 (see D2 figs. 2 and 3) discloses such a barrel-like shaped profile 68 and such facets, this profile does not allow a more stable coupling between a tubular manipulating wrench and an endosseous screw. The barrel-like shaped profile 68 of D2 is part of a ball mechanism and D2 is silent as to its use for coupling a wrench to a screw. Therefore the incorporation of these features into the screw of D1 would not be an obvious option to the skilled person.
- 2.2 **Claims 2-11** depend on claim 1. Therefore, they also appear to be new and inventive in the sense of Articles 33(2) and (3) PCT.

CLAIMS

1. Endosseous screw (1) for fixing a plate (102) to a bone site (300), comprising an at least partially threaded shaft (2), insertion means for inserting the screw into a bone site (300) and a distal portion (33) provided for engaging said plate (102) to fasten it to said bone site (300) and comprising a head (3) having facets (30) defining an external peripheral profile provided for engagement with a tubular manipulating wrench (101), to allow the screw (1) to be extracted from the bone site (300) into which it has been inserted, wherein the facets (30) are curvilinear and the external peripheral profile defined by same facets (30) has a convex barrel-like shape, in order to allow a stable coupling between the tubular manipulating wrench (101) and said profile, which is maintained during the untightening phase of screw from plate, even when said tubular manipulating wrench (101) is oriented in an inclined direction with respect to the longitudinal axis (x) of the endosseous screw (1), characterized in that the facets (30) are even in number and define a regular polygonal section along a median section (A-A) of the head (3), said median section

(A-A) dividing each facet (30) into two internal and external portions (30a, 30b), respectively, which mirror each other,

2. An endosseous screw (1) according to claim 1, wherein each external portion (30b) of a specific facet (30) of head (3) corresponds to a respective internal portion (30a) of another facet, opposite said specific facet, so that at least a segment exists that is normal to both considered portions (30a, 30b), whose length is equal to the distance between the respective opposite facets (30), as measured along the median section (A-A).

3. An endosseous screw (1) according to claim 2, wherein each facet (30) is symmetrical with respect to a plane perpendicular to the longitudinal axis (x) of screw (1) and is defined by a portion of the surface of a cylinder having an axis perpendicularly intersecting said longitudinal axis (x).

4. An endosseous screw (1) according to claim 4, wherein the radius of the cylinder defining the facets (30) is preferably greater than the apothem of the regular polygon defining the shaped profile along the median section (A-A).

5. An endosseous screw (1) according to any of

the preceding claims, wherein the facets (30) are all identical, and are separated by a curvilinear edge (31).

6. An endosseous screw (1) according to any of the preceding claims, wherein the distal portion (33) comprises a conical threaded portion (3c) adjacent to the shaft (2) and suitable for threadedly engaging a hole (103) of the plate (102).

7. An endosseous screw (1) according to claim 6, wherein the conical threaded portion (3c) has a thread with a triangular section, the shaft (2) having a thread with a slotted conical section.

8. An endosseous screw (1) according to any of the preceding claims, wherein the insertion means of the screw comprise a longitudinal stem (4) associated with the head (3) of the screw (1), for manipulating the screw (1) during the insertion phase of the same, and an annular weakening groove (40) interposed between said longitudinal stem (4) and the head (3), said groove (40) being such as to allow the separation by breaking off the longitudinal stem (4) after insertion of screw (1).

9. An endosseous screw (1) according to any of the preceding claims, wherein the shaft (2) of the

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endosseous screw (1) is completely threaded and has an auto-perforating point (2a).

10. Orthopedic device (10) for the osteosynthesis of fractures, of the type comprising a plate (102) with at least a through hole (103) and at least an endosseous screw (1) provided for insertion in said hole (103), said endosseous screw (1) being provided according to any of the preceding claims.

11. System for fixing and extracting an endosseous screw (1) from an orthopedic device (10) for the osteosynthesis of fractures, comprising an orthopedic device (10) according to claim 10 and a tubular manipulating wrench (101) for engaging the external peripheral profile of screw (1).

REIVINDICACIONES MODIFICADAS

1. Un tornillo endoóseo (1) para la fijación de una placa (102) a un sitio óseo (300), que comprende un eje por lo menos parcialmente roscado (2), la medios de inserción para insertar el tornillo en un sitio óseo (300) y una porción distal (33) provista para acoplar la placa (102) asegurándola al sitio óseo (300) y que comprende una cabeza (3) que posee unas caras (30) que definen un perfil periférico externo proporcionado para acoplarse con una llave tubular de manipulación (101), para permitir extraer al tornillo (1) del sitio óseo (300) en el que se ha insertado, en donde las caras (30) son curvilíneas y el perfil periférico externo definido por las mismas caras (30) tiene una forma convexa tipo barril, con la finalidad de permitir un acoplamiento estable entre la llave tubular de manipulación (101) y el perfil, que se mantiene durante la fase de aflojamiento del tornillo de la placa, aún cuando la llave tubular de manipulación (101) esté orientada en una dirección inclinada con respecto al eje longitudinal (x) del tornillo endoóseo (1), caracterizado porque las caras (30) son pares en número y definen una sección poligonal regular a lo largo de una sección mediana (A-

A) de la cabeza (3), la sección mediana (A-A) es una sección mediana transversal situada en un plano perpendicular al eje longitudinal del tornillo y divide a cada cara (30) en dos porciones interna y externa (30a, 30b), respectivamente, que se reflejan mutuamente.

2. El tornillo endoóseo (1) según la reivindicación 1, en donde cada porción externa (30b) de una cara específica (30) de la cabeza (3) corresponde a una porción interna (30a) respectiva de otra cara, opuesta a la cara específica, de forma que al menos existe un segmento que es normal a ambas porciones (30a, 30b) consideradas, cuya longitud es igual a la distancia entre las caras opuestas (30) respectivas, medida a lo largo de la sección mediana (A-A).

3. El tornillo endoóseo (1) según la reivindicación 2, en donde cada cara (30) es simétrica con respecto a un plano perpendicular al eje longitudinal (x) del tornillo (1) y está definida por una porción de la superficie de un cilindro que tiene un eje que intersecta de manera perpendicular al eje longitudinal (x).

4. El tornillo endoóseo (1) según la reivindicación 4, en donde el radio del cilindro que define las caras (30) es preferentemente mayor que el apotema del

polígono regular que define el perfil formado a lo largo de la sección mediana (A-A).

5 5. El tornillo endoóseo (1) de acuerdo con cualquiera de las reivindicaciones anteriores, en donde las caras (30) son todas idénticas, y están separadas por un borde curvilíneo (31).

10 6. El tornillo endoóseo (1) de acuerdo con cualquiera de las reivindicaciones anteriores, en donde la porción distal (33) comprende una porción cónica roscada (3c) adyacente al eje (2) y adecuado para acoplar por roscado a un orificio (103) de la placa (102).

15 7. El tornillo endoóseo (1) según la reivindicación 6, donde la porción cónica roscada (3c) tiene una rosca con una sección triangular, el eje (2) que tiene una rosca con una sección cónica ranurada.

20 8. El tornillo endoóseo (1) de acuerdo con cualquiera de las reivindicaciones anteriores, en donde los medios de inserción del tornillo comprenden un vástago longitudinal (4) asociado a la cabeza (3) del tornillo (1), para manipular el tornillo (1) durante la fase de inserción del mismo, y una ranura anular de ruptura (40) interpuesta entre la vástago longitudinal (4) y la cabeza (3), la ranura (40) permite la

separación por ruptura del vástago longitudinal (4) después de la inserción del tornillo (1).

5 9. El tornillo endoóseo (1) de acuerdo con cualquiera de las reivindicaciones anteriores, en donde el eje (2) del tornillo endoóseo (1) está completamente roscado y tiene un punto de auto-perforación (2a).

10 10. Un dispositivo ortopédico (10) para la osteosíntesis de fracturas, del tipo que comprende una placa (102) con al menos un orificio (103) que atraviesa y al menos un tornillo endoóseo (1), provisto para su inserción en el orificio (103), el tornillo endoóseo (1) se proporciona de acuerdo con cualquiera de las reivindicaciones anteriores.

15 11. Un sistema de fijación y extracción de un tornillo endoóseo (1) de un dispositivo ortopédico (10) para la osteosíntesis de fracturas, que comprende un dispositivo ortopédico (10) según la reivindicación 10 y una llave tubular de manipulación (101) para acoplar el perfil periférico exterior de tornillo (1).

20 1.