Industria y Comercio
SUPERINTENDENCIA

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PETITORIO

SUPERINDUSTRIA Y COMERCIO
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Tramite : 011 PCT-PATENT 379 FASE NACT 411 PRESENTAC
Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

FORMULARIO UNICO DE SOLICITUD DE PATENTE
PCT
ENTRADA EN FASE NACIONAL

1 **SOLICITUD DE:**

☒ Patente de Invención. ☐ Patente de Modelo de Utilidad.

☐ Capítulo I. ☒ Capítulo II.

2 **SOLICITANTE (71)**	Nombre: **SYNTHES AG CHUR** sociedad constituida y existente bajo las leyes de Suiza. Dirección: Grabenstrasse 15, CH-7002 Chur, Suiza. Domicilio: Chur, Suiza.	**IDENTIFICACION** C.C. ☐ NIT ☐ C.E. ☐ Otro ☐ Cual_____ Número: _____
3 **REPRESENTANTE O APODERADO**	Nombre: EMILIO FERRERO Dirección: Carrera 4ª. No. 72-35 Teléfono: 347 36 11 Fax:: 217 92 11 E-mail: clientes@camvp.com. Domicilio: Bogotá, Colombia.	**IDENTIFICACION** C.C. ☒ NIT ☐ C.E. ☐ Otro ☐ Cual_____ Número: 438.019 T.P. 31.929

4 **INVENTOR (ES) (72)**

1- James M. GREEN
6720 S.W. Canyon Drive,
Portland, Oregon 97225
Estados Unidos de América.

2- Stanley J. KMIEC Jr.
663 W. Fairmount Street
Coopersburg, Pennsylvania 18036,
Estados Unidos de América.

5 **PCT (86)**

Solicitud Internacional No. PCT/CH01/00258 Fecha: 25 de abril de 2001
Publicación Internacional No. WO 01/91659 A1 Fecha : 06 de diciembre de 2001

6 **Título (54)** HOJA ESPIRALADA HUMERAL

7 **Clasificación Internacional (51)** A61B 17/74

8 **Prioridad** SI ☒ NO ☐	(33) País de Origen	(32) Fecha	(31) Número de Solicitud
	US.	31 de mayo de 2000	09/584.381

9 Comprobante de pago No.: 02-65,105 Fecha: 30 de Sepbre. 2002

10

Anexos:

- [x] Comprobante de pago de la tasa de presentación de la solicitud por $ 378.000.oo.
- [ ] Comprobante de pago por reivindicación de prioridad.
- [x] Documento que acredita la existencia y representación legal cuando el solicitante sea persona jurídica.
- [x] Poderes, si fuere el caso.
- [ ] Documento de cesión del inventor al solicitante o a su causante.
- [ ] Declaraciones.
- [x] Copia de la solicitud internacional. (Resumen, descripción, reivindicaciones, dibujos)
- [x] Traducción de la solicitud internacional al castellano. (Resumen, descripción, reivindicaciones, dibujos)
- [x] Copia del examen preliminar efectuado por la IPEA.
- [ ] Traducción del examen preliminar efectuado por la IPEA.
- [ ] De ser el caso, copia del contrato de acceso.
- [ ] De ser el caso, documento que acredite la licencia o autorización de uso de conocimientos tradicionales de las comunidades indígenas.
- [ ] De ser el caso, certificado de depósito del material biológico.
- [x] Arte final 12x12
- [ ] De ser el caso, información sobre otras solicitudes de patente o títulos obtenidos en el extranjero por el mismo titular o su causante, relacionadas parcial o totalmente con la invención de esta solicitud.
- [ ] Otros

11

FIGURA CARACTERISTICA:

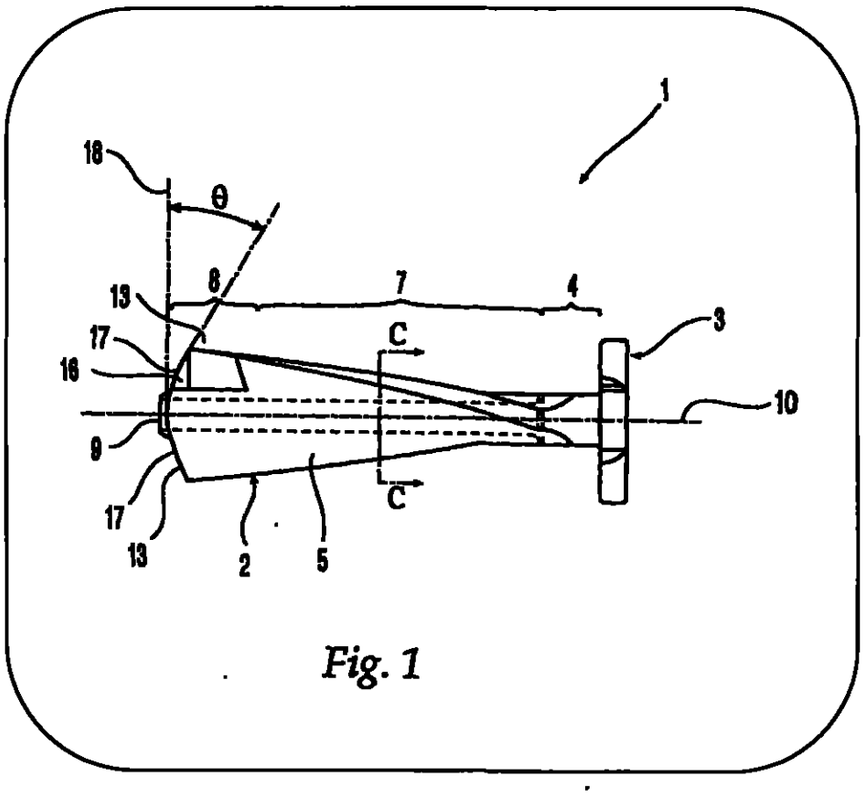


Fig. 1

12 Solicito la concesión de la patente,

NOMBRE: EMILIO FERRERO

FIRMA:

C.C. 438.019 de Usaquén T.P. 31.929

M-210/CO

03261
01618

801304-8
005-5

Y

CAVELIER
ABOGADOS

EDIFICIO SIMEX
CARRERA 4ª Nº 72-35
BOGOTA, 8 - COLOMBIA

For patents, utility designs, trademarks, service marks, commercial names, insignia.

Para patentes, modelos y dibujos industriales, marcas de fábrica y de servicio, nombres comerciales y enseñas.

REPRESENTACION Y PODER

REPRESENTATION AND POWER OF ATTORNEY

I (we), the undersigned / Yo (nosotros), abajo firmado(s)
Synthes AG Chur

of / domiciliado(s) en Grabenstrasse 15
CH-7002 Chur

por el presente nombramos a GERMAN CAVELIER, tpa. 832; GONZALO PERDOMO, tpa. 831; ERNESTO CAVELIER, tpa. 11519; y EMILIO FERRERO, tpa. 31929; domiciliados en la Carrera 4ª Nº 72-35, Bogotá, Colombia, en obedecimiento a lo dispuesto en el parágrafo 1º del Artículo 543 del Código de Comercio, el primero como principal y los demás como suplentes, en su orden, como nuestros representantes en todos los asuntos de propiedad industrial con facultad para recibir notificaciones y nombrar apoderados judiciales o extrajudiciales. El primer representante suplente reemplazará al principal en caso de ausencia o impedimento temporal o definitivo de aquél. La misma regla se aplicará cuando el segundo representante suplente haya de reemplazar al primero, o el tercero al segundo. En tales casos, el representante principal, o el primero, o segundo suplente, en su caso, o ambos, declararán su intención de no ejercer la representación mediante declaración autenticada por Notario Público en Colombia, o por Notario u otro Funcionario Público, o Cónsul de Colombia, en el extranjero; y si se tratare de impedimento, con el certificado respectivo. Si alguno de los nombrados faltare definitivamente, el siguiente tomará su lugar. Cuando cesare la ausencia o impedimento del representante principal, o de su primero o segundo suplente, en su caso, podrán ejercer la representación, en su orden, uno u otros según el caso, asumiéndola por el solo hecho de ejercerla, cesando en ese momento el ejercicio de la representación por el primero, segundo o tercer suplente en su caso.
Además, y bajo las mismas reglas, conferimos poder a los abogados arriba nombrados, para obtener la protección de mi (nuestra) propiedad industrial y contra la competencia desleal, a cuyo efecto autorizo(amos) a los dichos apoderados para que me(nos) representen ante cualesquiera entidades o personas, ejerzan o no jurisdicción, especialmente ante las del orden administrativo, contencioso-administrativo y judicial, en todo lo concerniente a los siguientes asuntos: a) Obtención de patentes de invención, modelos y dibujos industriales; el registro de marcas de fábrica, colectivas, defensivas y de servicios; el depósito de nombres comerciales y enseñas; su renovación, traspaso, cambio de nombre o domicilio, cancelación voluntaria; y el registro de licencias de uso de esos derechos; b) Las acciones de oposición, cancelación, nulidad, medidas cautelares, concesión de licencias y en general los juicios civiles, penales, administrativos o contencioso-administrativos relacionados con estos derechos; acciones y juicios que promuevamos o se nos promuevan. Y para que en todos los asuntos arriba determinados, puedan sustituir este mandato, transigir, desistir, cancelar, recibir, renunciar, y ratificar los actos hechos por agentes oficiosos.

in due compliance with the terms of paragraph 1st. of article 543 of the Commercial Code, do hereby appoint GERMAN CAVELIER, tpa. 832; GONZALO PERDOMO, tpa. 831; ERNESTO CAVELIER, tpa. 11519; and EMILIO FERRERO, tpa. 31929; domiciled at Carrera 4ª Nº 72-35, Bogotá, Colombia, the first as principal and the others as alternates, in the order of their appointment, as our representatives for all industrial property matters with faculty to receive notifications and to appoint attorneys in and out of Court. The first alternate shall replace the principal in case of his absence or of temporal or definitive impediment. The same rule will apply when the second alternate representative is to replace the first one, or when the third is to replace the second. In such cases, the principal representative, or the first or second alternates in their turn, or both of them, shall state their intention not to act as representatives through a declaration given before a Notary Public in Colombia, or before a Notary or another Public Official or a Colombian Consul abroad; and in case of impediment, the appropriate certificate shall suffice. If any of the appointees were to be definitely absent, the following alternate shall take his place. When the absence or impediment of the principal representative, or of the first or second alternate in their turn ceases, the representation can be taken again in their sequence, by the principal, the first or second alternate depending on case, and the mere fact or its exercise will suffice. The exercise of the representation by the first, second or third alternates in their turn shall end at such time. In addition, we grant a Power of Attorney in favor of the above-named attorneys-at-law so that they may obtain the protection of my (our) industrial property and against the unfair competition, for which purpose I (we) authorize the said attorneys to represent me (us) before any authorities or persons, with or without jurisdiction, specially those administrative, administrative contentious and judicial, in all matters concerning the following: a) Obtainment of patents, models and designs; the registration of trademarks, collective, defensive and service marks; the deposit of commercial names and insignia; its renewal, assignment, change of name or domicile, voluntary cancellation; and the registration of licenses of use of the above rights; b) Actions of opposition, cancellation, nullity, infringement, granting of licenses; and in general the civil, penal, and administrative suits relating to those rights; actions and suits instituted by me (us) or against me (us). And [illegible] they may substitute this [illegible] desist, cancel, rece[illegible] by representatives without [illegible]

Given and signed this / Dado y firmado hoy
July 21, 1998

in / en Bad Ragaz

Firma / Signature

SYNTHES AG CHUR
Grabenstrasse 15
CH - 7002 CHUR

07 OCT 2002
JUAN MANUEL BOTERO MEDINA
NOTARIO

TRADUCCION No.:
M[illegible] VIVA MARTELO
Traductora e Intérprete Oficial
Inglés - Español - Inglés
Res. No. 2879 Min. Justicia

LEGALIZACION

El *Señor Cónsul* de Colombia debe expedir un *certificado consular* sobre (1) la existencia legal de la compañía que otorga el poder, (2) que ésta ejerce su objeto social, y (3) que las personas que otorgan el poder están autorizadas para darlo. A este efecto les solicitamos que muestren al Señor Cónsul las pruebas que acreditan esos hechos (1), (2) y (3).

LEGALIZATION

The Colombian Consul *must issue a consular certificate*, on (1) the legal existence of the company which grants the Power-of-Attorney, (2) that it is in actual exercise of its company purposes, and (3) that the persons who execute the Power of Attorney are authorized to do so. To this effect, please show the Consul the evidence to prove the above facts (1), (2) and (3).

Eva Bertossa-Bertschi, notary public of the Canton of Berne (Switzerland), with office at Berne, Zeughausgasse 29

certifies:

The foregoing signature "ppa M. Jacques" on behalf of Synthes AG Chur, with registred office in Chur (Switzerland), was written by Mrs Margrit Jaques-Baumann, born on 5th March 1940, of Sainte-Croix and Flawil (Switzerland), director, divorced, Blockweg 8, 3007 Berne, who has single signature on behalf of Synthes AG Chur and is known to the notary personally.

Certified at the office of the notary public on the twenty-third of July ninteenhundert and ninety eight.

23rd July 1998

The notary public:

E. [signature]

Reg. No. 094

CUARTO NOTARIO SESTO DEL CIRCULO DE BOGOTA, HAGO CONSTAR QUE LA FOTOCOPIA CORRESPONDE CON EL ORIGINAL QUE HE TENIDO A LA VISTA

07 OCT 20[illegible]

JUAN MANUEL BOTERO MEDINA NOTARIO

EVA BERTOSSA-BERTSCHI NOTARIN DES KANTONS BERN

CANTÓN DE BERNA * CANCILLERÍA DE ESTADO *

Visto para la legalización de la firma que precede de

Eva Bertossa-Bertschi

notario del cantón de Berna

Número: 2093 - Cancillería de Estado del cantón de Berna

28/7/98 Carmen Isabel

Tasa: CHF 15.—

NOTA PARA EL SEÑOR CONSUL DE COLOMBIA: Según los artículos 65 del C. de P. C. y 840 del C. de Co., si el poderdante es una sociedad, el Señor Cónsul debe certificar que tuvo a la vista las pruebas de su existencia, que ejerce su objeto social y que quien confiere el poder es su representante.

5

Consulado de Colombia

Berna

TRADUCCION No.:
MARIA ELVIRA MARTELO
Traductora e Interprete Oficial
Inglés - Español - Inglés
Res. No. 2879 Min. Justicia

AUTENTICACION DE FIRMA No. 1405

BERNA, 11 DE AGOSTO DE 1.998

EL SUSCRITO SEGUNDO SECRETARIO ENCARGADO DE LAS FUNCIONES CONSULARES DE LA EMBAJADA DE LA REPÚBLICA DE COLOMBIA

CERTIFICA :

COMO NOTARIO SEXTO DEL CIRCULO DE BOGOTA, HAGO CONSTAR QUE LA FOTOCOPIA COINCIDE CON EL ORIGINAL QUE HE TENIDO A LA VISTA
07 OCT 2002
JUAN MAN... MEDINA

Que la señora **CARMEN ISELI** que autoriza el presente documento, ejercía legalmente en la fecha expresada, las funciones de Oficial del Oficial de la Cancillería de Estado del Cantón de Berna y que la firma y sello que en el documento aparecen como suyos, son los que usa y acostumbra en sus actos oficiales, de acuerdo con el registro que se lleva en este Consulado.

El Suscrito Segundo Secretario Encargado de las Funciones Consulares de la Embajada, no asume responsabilidad alguna por el contenido del documento autenticado.

CONFRONTA APARECE EN EL DOCUMENTO DESEMPEÑA LAS FUNCIONES INDICADAS

MINISTERIO DE RELACIONES EXTERIORES

7889

Rafael Antonio Torres Martín.

- Pagado Impuesto de Timbre: U$ 6.00
- Pagado Derechos Consulares: U$ 15.00

98 AUG 28 AM 11:59
JEFE DE LEGALIZACIONES SANTAFE DE BOGOTA, D.C.

NO SE ASUME RESPONSABILIDAD DEL TEXTO

Consulado de Colombia

Berna

TRADUCCION No.:
MARIA ELVIRA MARTELO
Traductora e Interprete Oficial
Inglés - Español - Inglés
Res. No. 2879 Min. Justicia

CERTIFICACIÓN NO.000388

EL SUSCRITO SEGUNDO SECRETARIO ENCARGADO DE LAS FUNCIONES CONSULARES DE LA EMBAJADA DE LA REPUBLICA DE COLOMBIA

C E R T I F I C A

Que la compañía **SYNTHES AG CHUR** domiciliada en Grabenstr. 15, Chur/Suiza, existe y esta organizada de conformidad con las leyes de Suiza y que esta cumple con su objeto legal.

Que la señora **MARGRIT JAQUES-BAUMANN** desempeña el cargo de representante de la sociedad y tiene facultad suficiente para otorgar poderes y nombrar apoderados en el exterior.

Que todos los hechos anteriores constan por haber tenido a la vista los documentos respectivos (Certificado de Registro de la Cámara de Comercio de Friburgo expedido el 05 de agosto de 1998).

El Suscrito Segundo Secretario Encargado de las Funciones Consulares no asume responsabilidad por el contenido del documento.

Dado y firmado en Berna, a los once (11) días del mes de agosto de mil novecientos noventa y ocho (1998).

MINISTERIO DE RELACIONES EXTERIORES
177860
COTEJA FIRMA QUE APARECE EN EL DOCUMENTO DE SEMEJANZA
LAS FORMALIDADES INDICADAS

Rafael Antonio Torres Martín

- Pagado impuesto de timbre: u$ 6.00.
- Pagado derechos consulares: u$ 100.00:

JEFE DE LEGALIZACIONES
SANTAFE DE BOGOTA
98 AUG 28
NO SE ASUME RESPONSABILIDAD DEL CONTENIDO DEL DOCUMENTO
07 OCT 2002
JUAN MANUEL BOTERO MADINA
NOTARIO

CHF15.

TRADUCCION OFICIAL No. 16.08/98 preparada por María Elvira Martelo, Traductora Oficial debidamente aprobada por el Ministerio de Justicia de Colombia por Resolución 2879 de 1995 y reconocida por el Ministerio de Relaciones Exteriores.

(A continuación se traducen los sellos y legalizaciones de un documento escrito en inglés y español, por el cual **SYNTHES AG CHUR** otorga poder a **GERMAN CAVELIER, GONZALO PERDOMO, ERNESTO CAVELIER Y EMILIO FERRERO**). Dado y firmado en Berna, Suiza, el 21 de julio de 1998. (Firma) ppa. M. Jacques SYNTHES AG CHUR, Grabenstrasse 15, CH - 7002 CHUR.

Eva Bertossa-Bertschi, notario público del Cantón de Berna (Suiza), con oficina en Berna, Zeughausgasse 29, certifica: la firma que antecede "ppa M. Jacques" a nombre de Synthes AG Chur, con oficina registrada en Chur (Suiza), fue impuesta por la Sra. Margrit Jaques-Baumann, nacida el 5 de marzo de 1940, de Sainte-Croix y Flawil (Suiza), directora, divorciada, Blockweg 8, 3007 Berna, quien tiene firma única a nombre de Synthes AG Chur y es conocida personalmente por el notario público

Certificada en la oficina del notario público el veintitrés de julio de mil novecientos noventa y ocho.

23 de julio de 1998, Reg. B. No. 994 El notario público. (Firma ilegible). (Sello notarial en tinta de Eva Bertossa-Bertschi)

(En español) Legalización de la firma que antecede expedida la Cancillería de Estado del Cantón de Berna el 28 de julio de 1998 bajo el No. 2093, firmado por Carmen Iseli. Pagada tasa por CHF15.

(En español) Certificación de la firma que antecede expedida por el Consulado de Colombia en Berna el 11 de agosto de 1998, bajo el No. 1405. Firma RAFAEL ANTONIO TORRES MARTIN. Pagado impuesto de timbre y derechos consulares.

Legalización de la firma que antecede expedida por el **MINISTERIO DE RELACIONES EXTERIORES** bajo el No. 177889 del 28 de agosto de 1998, firmado por el Jefe de Legalizaciones.

(En español) Certificación de la existencia legal de SYNTHES AG CHUR y de la capacidad legal de MARGRIT JAQUES-BAUMANN para otorgar poder expedida por el Consulado de Colombia en Berna el día 11 de agosto de 1998, bajo el No. 000388. Firmado por RAFAEL ANTONIO TORRES MARTIN. Pagado impuesto de timbre y derechos consulares.

Legalización de la firma que antecede expedida por el **MINISTERIO DE RELACIONES EXTERIORES** bajo el No. 177890 del 28 de agosto de 1998, firmado por el Jefe de Legalizaciones.

Es traducción fiel y completa de la cual se deja copia en esta oficina para su confrontación.

COMO NOTARIO SEXTO DEL CIRCULO DE BOGOTA, HAGO CONSTAR QUE LA FOTOCOPIA COINCIDE CON EL ORIGINAL QUE HE TENIDO A LA VISTA
07 OCT 2002
JUAN MANUEL BOTERO MEDINA
NOTARIO

COLO 3261-701-001-5
Id. 4
Ago. 31/98

TRADUCCION No.: 16.08.98
MARIA ELVIRA MARTELO
Traductora e Interprete Oficial
Inglés - Español - Inglés
Res. No. 2879 Min. Justicia

COMO NOTARIO SEXTO DEL CIRCULO DE SANTAFE DE BOGOTA, HAGO CONSTAR QUE LA(S) FIRMA(S) QUE APARECE(N) EN EL PRESENTE DOCUMENTO

COINCIDE(N) CON LA FIRMA REGISTRADA POR EL (LOS) EN ESTA NOTARIA

SANTAFE DE BOGOTA, 02 SET 1998

NOTARIO SEXTO

COMO NOTARIO ... DE BOGOTA, HAGO ... FOTOCOPIA CORRESPONDE ... QUE HE TENIDO A ...

07 OCT 2 ...

JUAN MANUEL BOTERO MEDINA
NOTARIO

MINISTERIO DE RELACIONES EXTERIORES

26-8-711

MARIA ... CUYA FIRMA APARECE EN EL DOCUMENTO DESEMPEÑA LAS FUNCIONES INDICADAS

NO SE ASUME RESPONSABILIDAD DEL TEXTO

98 SEP 11 PM 12:23

JEFE DE LEGALIZACIONES
SANTAFE DE BOGOTA D.C.

CAVELIER
ABOGADOS

WEB SITE: www.cavelier-abogados.com
E-MAIL: cavelier@colomsat.net.co

EDIFICIO SISKI
CARRERA 4 No. 72 - 35
BOGOTA 8, COLOMBIA

TELEFONO: (571) (1) 347-3611
TELEFAX: (57) (1) 217-9211 (571) (1) 310-4995

Señor Jefe de la
DIVISION DE NUEVAS CREACIONES
Superintendencia de Industria y Comercio
E. S. D.

Poderdante: SYNTHES AG CHUR

Poder conferido el: 21-07-1998

Yo, GERMAN CAVELIER, obrando en mi calidad de apoderado principal del poderdante arriba mencionado, atentamente manifiesto a Usted que sustituyo el poder que me ha sido conferido en la persona del doctor EMILIO FERRERO, Abogado con Tarjeta Profesional No. 31.929, con todas las facultades que me fueron conferidas.

Hago la anterior sustitución conforme al artículo 66 del Código de Procedimiento Civil ya que los otros sustitutos faltan en este momento.

Señor Jefe,

GERMAN CAVELIER
T.P.A. No. 832
C.C. No. 2.877.924 de Bogotá

Acepto:

EMILIO FERRERO
T.P.A. N° 31.929
C.C. No. 438.019 de Usaquén

COMO NOTARIO SEXTO DEL CIRCULO DE BOGOTA, HAGO CONSTAR QUE LA FOTOCOPIA CORRESPONDE CON EL ORIGINAL QUE HE TENIDO A LA VISTA
07 OCT 2002
JUAN MANUEL BOTERO MEDINA
NOTARIO

2e-780-2

NOTARIA SEXTA DE BOGOTA

RECONOCIMIENTO Y PRESENTACION PERSONAL

Bogotá,.D. C. Diciembre 14/2001

Ante Mí, PABLO MENDEZ BARAJAS

NOTARIO SEXTO ENCARGADO DEL CIRCULO DE BOGOTA

Compareció(eron)

quien(es) exhibió(eron) la(s) C. C. 4358019 2877924

y la(s) Libreta(s) Militar(es) 832 3192

domiciliado(s) en Bogotá y declaró(aron) que la(s) firma(s) que aparecen(n) en el presente documento es(son) la(s) suya(s) y que el contenido del mismo es cierto.

En constancia se firma esta Diligencia.

COMO NOTARIO [illegible] DE BOGOTA, HAGO CONSTAR QUE LA FOTOCOPIA COINCIDE CON EL ORIGINAL QUE HE TENIDO A LA VISTA

07 OCT 2002

JUAN MANUEL BOTERO MEDINA
NOTARIO

NOTARIA SEXTA
PABLO MENDEZ BARAJAS
Notario Sexto Encargado

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 December 2001 (06.12.2001)

PCT

(10) International Publication Number
WO 01/91659 A1

(51) International Patent Classification[7]: A61B 17/74

(21) International Application Number: PCT/CH01/00258

(22) International Filing Date: 25 April 2001 (25.04.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/584,381 31 May 2000 (31.05.2000) US

(71) Applicant *(for all designated States except CA, US)*: SYNTHES AG CHUR [CH/CH]; Grabenstrasse 15, CH-7002 Chur (CH).

(71) Applicant *(for CA only)*: SYNTHES (U.S.A.) [US/US]; 1690 Russell Road, P.O. Box 1766, Paoli, PA 19301-1222 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: GREEN, James, M. [US/US]; 6720 S.W. Canyon Drive, Portland, OR 97225 (US). KMIEC, Stanley, J., Jr. [US/US]; 663 W. Fairmount Street, Coopersburg, PA 18036 (US).

(74) Agent: LUSUARDI, Werther; Dr. Lusuardi AG, Kreuzbühlstrasse 8, CH-8008 zürich (CH).

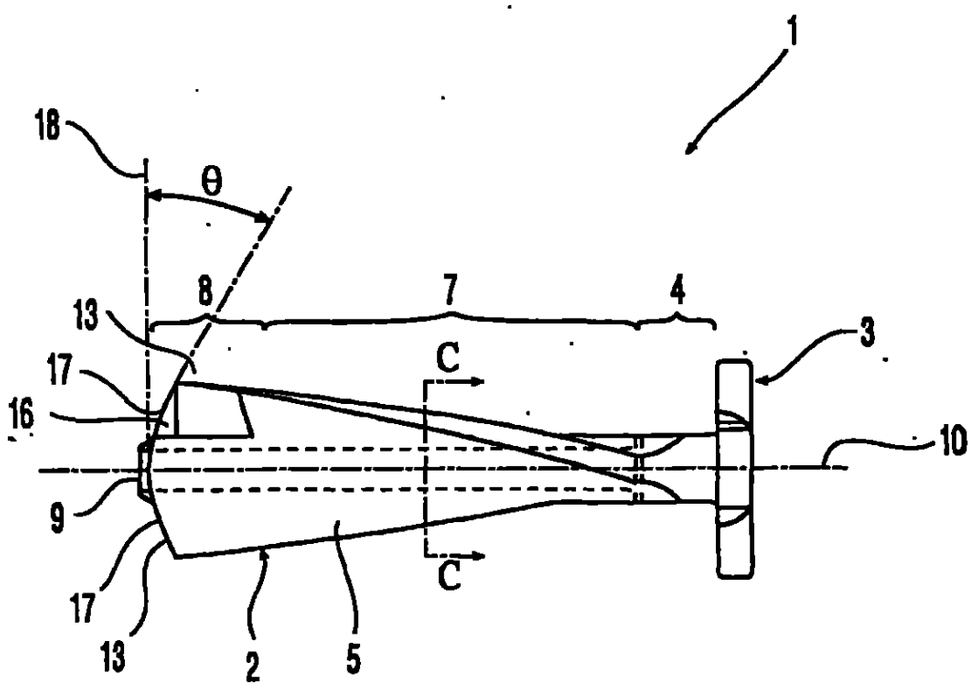
(81) Designated States *(national)*: AE, AG, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

[Continued on next page]

(54) Title: HUMERAL SPIRAL BLADE



(57) Abstract: An osteosynthetic implant for use in treating fractures to the head and neck of the humerus. The implant includes a body, a helically twisted blade (2) having an oblate cross section, and a circumferential collar (3) having a plurality of attachment points for sutures.

WO 01/91659 A1

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

HUMERAL SPIRAL BLADE

The invention relates to an implant for internal fixation of bone and in particular to an implant for internal fixation of diaphyseal and multi-part fractures of the humerus to promote osteosynthesis according to the preamble of claim 1. The invention can be used, for example, in conjunction with an intramedullary device containing a proximal slot for the humeral spiral blade to be positioned and provisionally locked.

Overall between 160,000 and 180,000 individuals suffer fractures of the humerus each year. Approximately seventy five percent of fractures occur in the proximal region of the humerus near the head or cortex, ten percent occur in the mid-shaft region, and fifteen percent occur in the distal region of the humerus.

Diaphyseal humeral fractures involve the humeral shaft. Proximal humeral fractures involve fractures of the head or cortex and often result from a fall that places an axial load on the humerus. In a two-part fracture, the head or a single portion of the head is broken from the humeral shaft. Multi-part fractures involve fracture of the humeral head into two or three fragments that separate from the shaft.

Conventional treatment of diaphyseal and multi-part humeral fractures often involves wiring, suturing, or externally fixing the fragments to one another and/or the humeral shaft. Other known approaches involve inserting one or more screws into the head or shaft of the humerus and fixing the nails or screws to a nail inserted into the medullary canal of the humerus, such as those described in U.S. Pat. Nos. 4,503,847, 5,472,444, 5,697,930, and 5,766,174.

Frequent postoperative complications arise when two or more of the bone fragments are forced together as when the patient applies pressure to the healing bone. For example, a sharp implanted nail or screw may cut out and through the humeral head or neck; or a nail, screw, or intramedullary nail may bend or break under a load. Cut out is particularly problematic in individuals with poor bony stock, such as cancerous or osteoporotic bone. A need exists, therefore, to provide improved osteosynthetic implants for treatment of multi-part and diaphyseal fractures of the humerus.

Femoral fractures have been treated using singl , helical blades, such as disclosed in U.S. Pat. Nos. 4,103,683, 4,978,349, and 5,300,074. These blades are twisted about ninety degrees along their length and have a generally flat rectangular profile with a substantially uniform width and narrow thickness. When implanted in conjunction with an intramedullary nail, these blades are oriented to reduce pressure on cancellous tissue within the femoral head and to provide a high resistance to bending in response to loads along the longitudinal axis of the intramedullary nail.

Because of the aforementioned narrow thickness, however, the prior art single helical femoral blades are fairly compliant in the transverse direction, *i.e.*, in the anterior and posterior directions of the patient. Moreover, the overall flat profile of the blades provides little resistance to cutting through the cancellous bone like a knife in directions aligned with the width of the blade at any station along its length. A need exists, therefore, to provide improved osteosynthetic implants for treatment of multi-part and diaphyseal fractures of the humerus which do not have a tendency to cause such cutting and provides greater resistance to bending in the transverse direction.

Repairing a fractured humerus frequently involves repair of damaged soft tissue surrounding the humerus. Traditional suture anchors suffer from pullout in weakened bone and also require that additional holes be drilled in an already weakened humerus. U. S. Pat. No. 5,766,174 discloses an intramedullary nail having suture holes and a nail cap with suture holes. Suture holes on an intramedullary nail are often not accessible once the nail has been implanted in a fractured humerus. Thus, in repair of a fractured humerus, a need also exists to provide robust, accessible sites for suture attachment that do not require additional drilling of the fractured humerus.

The present invention relates to an implant for a bone. The implant has a body member having a lateral portion, a medial portion, and a helically twisted blade extending along the body and having a longitudinal axis. In a preferred embodiment, the lateral portion of the helically twisted blade is twisted about one fourth turn with respect to the medial portion.

The lateral portion of the body has a circumferential collar extending in a plane perpendicular to the longitudinal axis. The circumferential collar has an attachment element for attaching a tissue fastener for repairing tissue surrounding the bone. In one embodiment, the attachment element comprises a hole for securing the tissue fastener. In another embodiment, the attachment element comprises a threaded hole.

In another embodiment, the body member has a central portion between the lateral and medial portions. The central portion has a cross section and a maximum thickness adjacent the longitudinal axis which gradually tapers to a minimum thickness apart from the longitudinal axis.

In a preferred embodiment, a cannulation extends through the body member along the longitudinal axis from the medial portion to the lateral portion. In another embodiment, the circumferential collar includes a central hole configured with threads to releasably engage a tool for positioning the invention in the bone.

In another embodiment, the medial portion has a medially extending medial end portion having surfaces configured for cutting through the bone. In a preferred embodiment, the medial end portion includes first and second cutting regions and a transverse axis. The first and second cutting regions are asymmetrically disposed about the transverse axis. In a preferred embodiment, the first and second cutting regions further include cutting edges, which form an angle of about thirty degrees to the transverse axis. The first and second cutting regions may include an angled cutting surface. In a preferred, embodiment, the angled cutting surfaces form an angle of from about five to sixty degrees with respect to the longitudinal axis.

The present invention also relates to an osteosynthetic apparatus for fixing a broken humerus. The apparatus includes the implant of the present invention and a securing member comprising an elongated nail having a proximal securing portion configured to occupy a proximal portion of the humeral shaft and a distal portion configured to occupy a distal portion of the humeral shaft. In a preferred embodiment, the proximal securing portion has at least one longitudinal bore configured to accommodate the implant. When the implant is accommodated by the longitudinal bore, a medial portion of the

implant is preferably within the head of the humerus and the implant may be positioned and provisionally locked.

The present invention further relates to a method for fixing a broken humerus. The method includes implanting the implant of the present invention in the humerus with the medial portion of the twisted blade inside the head of the humerus. In a preferred embodiment, the circumferential collar of the implant include a plurality of holes.

Preferred embodiments of the invention will now be described in connection with the attached drawing figures, wherein:

FIG. 1 is a top view of an implant according to the present invention;

FIG. 2 is a side view of the implant shown in Figure 1;

FIG. 3 shows a sectional view of an implant taken along line C-C in Figure 1;

FIG. 4 is a perspective view of the implant;

FIG. 5 shows another perspective view of the implant;

FIG 6 shows a medial view of the implant; and

FIG. 7 shows a cross-sectional side-view of the implant implanted in a humerus in conjunction with an intramedullary nail.

In this description, the terms medial and lateral are defined in relation to the central axis of a patient. Thus, a medial portion of an implanted element according to the invention is located closer to the central axis of a patient. Similarly, the terms proximal and distal are defined in relation to the relative distance from the head of a patient. Thus, a proximal portion of an implanted element is located closer to the head of the patient than a distal portion of the element.

Referring to Figures 1-6, a spiral humeral blade 1 has a helically twisted blade 2 and a circumferential collar 3 adjacent and lateral to a neck portion 4 of blade 2. Blade 2 is formed by bearing surfaces 5 and side surfaces 6. Proceeding medially from neck portion 4, blade 2 also includes a central portion 7 and a medial portion 8. A cannulation 9 extends through blade 2 along a longitudinal axis 10 of spiral blade 1.

Figures 1 and 2 show that central portion 7 and medial portion 8 of blade 2 wind around longitudinal axis 10 of spiral blade 1 in a preferably contiguous manner. Blade 2 covers an angle of rotation that is at least about thirty degrees, preferably from about forty five degrees to one hundred twenty degrees, and most preferably about ninety degrees. Neck portion 4 may extend substantially straight along longitudinal axis 10 of spiral blade 1.

Figure 3 shows a representative cross-section 11 of central portion 7 taken along section C-C in Figure 1. Cross-section 11 is formed by opposing bearing surfaces 5 and opposing side surfaces 6. A distance separating opposing bearing surfaces 5 tapers from a maximum adjacent longitudinal axis 10 to a minimum abutting side surfaces 6. In the embodiment shown, blade 2 has a substantially uniform width at any station along longitudinal axis 10 so that sides 6 are uniformly separated along blade 2. Blade 2 may also be tapered so that a distance separating side surfaces 6 increases or decreases proceeding along blade 2 in the medial direction.

As best seen in Figure 4, neck portion 4 joins circumferential collar 3 by a smooth transition region 12. Smooth transition region 12 reduces stress risers that would otherwise result by a sharp change in geometry.

In Figures 1 and 4 an exemplary embodiment of spiral blade 1 is shown in which medial portion 8 is configured with cutting regions 13 to facilitate implantation of spiral blade 1 into a bone. As seen in Figure 6, cutting regions 13 are asymmetrically disposed about a first transverse axis 14 of spiral blade 1. Cutting region 13 has a first cutting surface 15 gradually tapering to meet a second cutting surface 16. Second cutting surface 16 tapers more steeply to form a medial cutting edge 17. In the embodiment shown, first cutting surface 15 is substantially planar, although first cutting surface 15 may also be

arcuate. As shown in Figure 2, a line substantially parallel to first cutting surface 15 forms an angle θ with respect to longitudinal axis 10 of spiral blade 1. Angle θ is from about five degrees to sixty degrees, preferably from about fifteen degrees to sixty degrees, and most preferably about thirty degrees. As shown in Figure 1, medial cutting edge 17 forms an angle φ with a second transverse axis 18 of spiral blade 1. Angle φ is from about five degrees to sixty degrees, preferably from about fifteen degrees to sixty degrees, and most preferably about thirty degrees.

As seen best in Figures 4 and 5, circumferential collar 3 has a maximum diameter about as great as the width of neck portion 4 of blade 2 and is provided with flat portions 19, which allow spiral blade 1 to be positioned or moved with an auxiliary tool.

In an exemplary embodiment, circumferential collar 3 includes attachment points 20 to facilitate attachment of sutures. In a preferred embodiment, attachment points 20 comprise through-holes to which sutures may be attached. Alternatively, attachment points 20 may be configured to receive one or more auxiliary suture anchors for the fixation of sutures or other means adapted to reconstruct soft tissue, as is known in the art. In a non-limiting example, circumferential collar 3 may be configured with threaded holes to receive a threaded suture anchor.

Cannulation 9 is configured to receive a guide wire to aid in the alignment of spiral blade 1 during implantation, as is known in the art. As seen best in Figures 4 and 5, a central hole 21 extends through circumferential collar 3 and into neck portion 4 of blade 2. Central hole 21 has a diameter greater than the maximum separation distance of bearing surfaces 5 so that central hole 21 breaks through a portion of bearing surfaces 5 of neck portion 4 forming an aperture 22. Central hole 21 is configured with threads 23 to allow releasable attachment of a device to facilitate implantation or removal of spiral blade 1. After implantation, central hole 21 is fitted with a threaded end cap to prevent tissue ingrowth from obscuring central hole 22. The threaded end cap may also be configured with attachment points similar to attachment points 20 on circumferential collar 3.

In use, spiral blade 1 is implanted inside head 24 and neck 25 of the humerus, as shown in Figure 7. Implantation procedures for fixation nails are well known in the art and can be applied with the present invention. Figure 7 shows an embodiment utilizing an intramedullary nail 26 implanted in a humeral shaft 31. A distal portion 32 of nail 26 is configured to occupy a distal portion of humeral shaft 31 and a proximal nail portion 27 is configured to occupy a proximal portion of the humeral shaft. During implantation, intramedullary nail 26 is first inserted into the humerus.

Spiral blade 1 is then implanted through the side of humeral shaft 31 through a hole drilled merely up to the side surface of the intramedullary nail. Proximal nail portion 27 of intramedullary nail 26 includes an oblong bore 28 substantially aligned with a longitudinal axis of proximal nail portion 27. Oblong bore 28 slidably accommodates blade 2 allowing spiral blade 1 to rotate about longitudinal axis 10 as spiral blade 1 is hammered into the bone. Once implanted, longitudinal axis 10 defines an angle with the length of the intramedullary nail of generally being between ninety degrees and one hundred fifty degrees. The angle is adjusted to accommodate the anatomy of the patient.

A proximal bore 29 of intramedullary nail 26 can accommodate, for example by threaded engagement, a locking end cap 30. Engaging locking end cap 30 with proximal bore 29 applies an axial force against medial portion 7 of spiral blade 1 disposed in oblong bore 29. By means of locking end cap 30, axial movement of spiral blade 1 within oblong bore 29 can be either limited or completely prevented.

Neck portion 4 of an implanted spiral blade 1 is oriented to present a relatively small surface area normal to loads imposed substantially along humeral shaft 31, thereby, increasing the bending stiffness of blade 2 in response to such loads and also transferring a portion of the load to intramedullary nail 26. Medial portion 8 of an implanted spiral blade 1 is oriented to present a relatively large surface area normal to loads imposed substantially along humeral shaft 31. This reduces pressure on cancellous tissue within humeral head 24 and resists the tendency of blade 2 to cut through further through the bone cortex.

As shown in Figure 7, circumferential collar 3 of an implanted spiral blade 1 remains exposed adjacent to humeral head 24, which allows access to attachment points 20. Configuring circumferential collar 3 of spiral blade 1 with attachment points 20 has several advantages over conventional suture anchors. First, when implanted, circumferential collar 3 is disposed laterally with respect to head 24 of a humerus, which provides a convenient and accessible location for suture attachment. Circumferential collar 3 is large enough to accommodate a plurality of attachment points, which reduces the need to place additional anchors in the bone. Additionally, because spiral blade 1 is firmly implanted in head 24 of a humerus in conjunction with intramedullary nail 26, circumferential collar 3 affords a solid location resistant to movement or pullout.

The thicker cross-section adjacent cannulation 9 of blade 2 seen in Figure 3 reduces flexing of blade 2 in response to loads applied in the transverse direction towards the posterior or anterior of the patients body, whereas the somewhat reduced cross-section adjacent side surfaces 6 allows the blade to be inserted with minimal stripping of tissue. Side surfaces 6 present more surface area than the sides of flat, helical blades known in the art to resist cutting through cancellous bone in directions aligned with the width of blade 2.

It will be appreciated that those skilled in the art may devise numerous modifications and embodiments. It is intended that the following claims cover all such modifications and embodiments that fall within the scope of the present invention.

Claims

1. An implant for a bone said implant comprising:
A) a body member having a lateral portion and a medial portion (8) and a helically twisted blade (2) extending along the body and having a longitudinal axis (10);
B) said lateral portion having a circumferential collar (3) extending in a plane perpendicular to said longitudinal axis (10);
C) said circumferential collar (3) having an attachment element for attaching a tissue fastener for repairing tissue surrounding the bone.

2. The implant of claim 1 wherein the attachment element comprises a hole for securing the tissue fastener.

3. The implant of claim 2 wherein the hole is threaded.

4. The implant of claim 1 wherein the body member further comprises a central portion (7) between the lateral and medial portions (8), the central portion (7) having a cross section and a maximum thickness adjacent said longitudinal axis (10) which gradually tapers to a minimum thickness apart from said longitudinal axis (10).

5. The implant of claim 1 further comprising a cannulation (9) extending through the body member along said longitudinal axis (10) from said medial portion (8) to said lateral portion.

6. The implant of claim 5 wherein said circumferential collar (3) includes a central hole (21) configured with threads to releasably engage a tool for positioning the implant in the bone.

7. The implant of claim 1 wherein the medial portion (8) further comprises a medially extending medial end portion having surfaces configured for cutting through the bone.

8. The implant of claim 1 further comprising a medial end portion extending medially from the medial portion (8), said medial end portion comprising:

a) first and second cutting regions (13); and

b) a transverse axis (18), said first and second cutting regions asymmetrically disposed about said transverse axis (18).

9. The implant of claim 8 wherein said first and second cutting regions further comprise cutting edges (17), said cutting edges (17) forming an angle of about thirty degrees to said transverse axis (18).

10. The implant of claim 9 wherein said first and second cutting regions (13) further comprise an angled cutting surface.

11. The implant of claim 10 wherein said angled cutting surfaces form an angle of from about five to sixty degrees with respect to said longitudinal axis (10).

12. The implant of claim 1 wherein the lateral portion of the helically twisted blade (2) is twisted about one fourth turn with respect to the medial portion (8).

13. An osteosynthetic apparatus for fixing a broken humerus comprising:

A) the implant of claim 1;

B) a securing member comprising an elongated nail having a proximal securing portion configured to occupy an upper portion of the humeral shaft (31) and a distal portion (32) configured to occupy a lower portion of the humeral shaft (31); and

C) the proximal securing portion having at least one longitudinal bore configured to accommodate the implant.

14. The apparatus of claim 13 wherein the circumferential collar (3) includes a plurality of holes suitable for anchoring a suture.

15. A method for fixing a broken humerus having a head comprising:

implanting the implant of claim 1 in the humerus with the medial portion (8) of the twisted blade inside the head of the humerus.

16. The method of claim 15 further comprising anchoring soft tissue to the implant utilizing sutures secured to the attachment element.

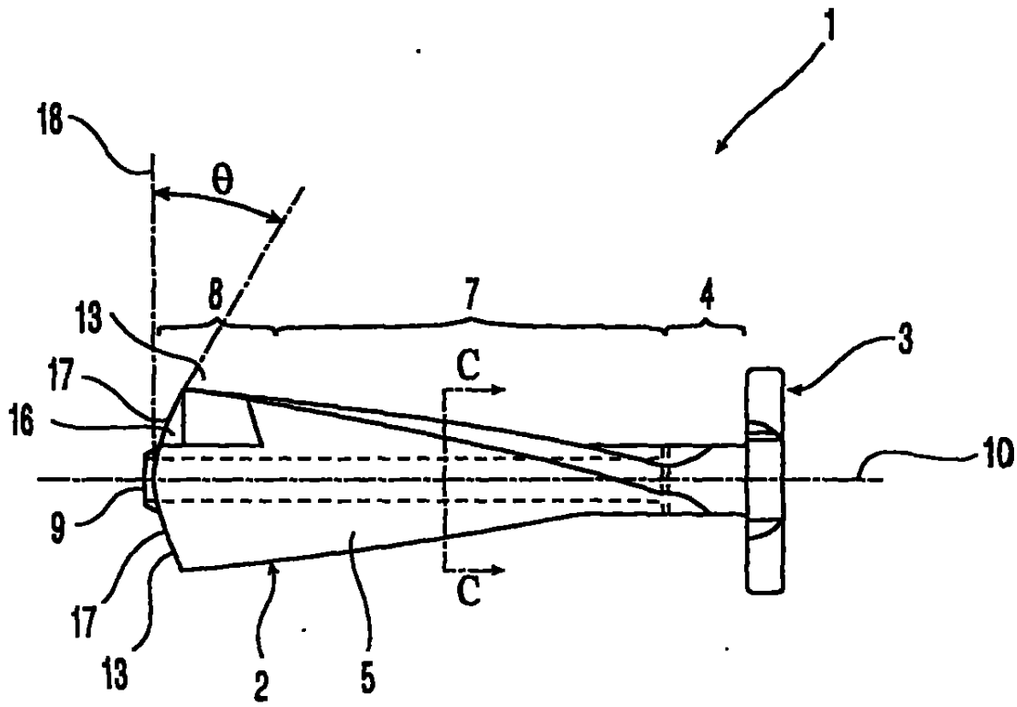


Fig. 1

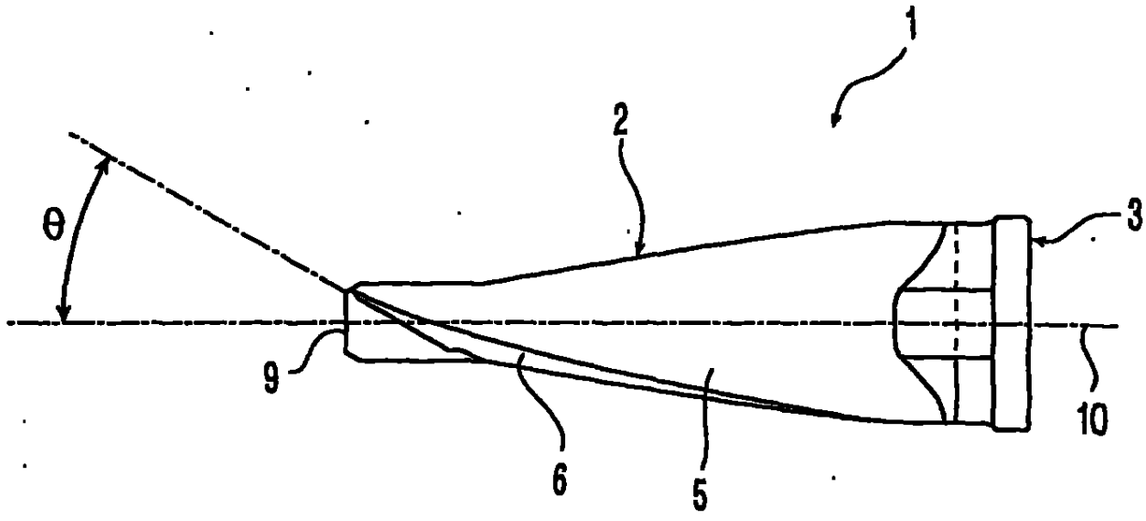


Fig. 2

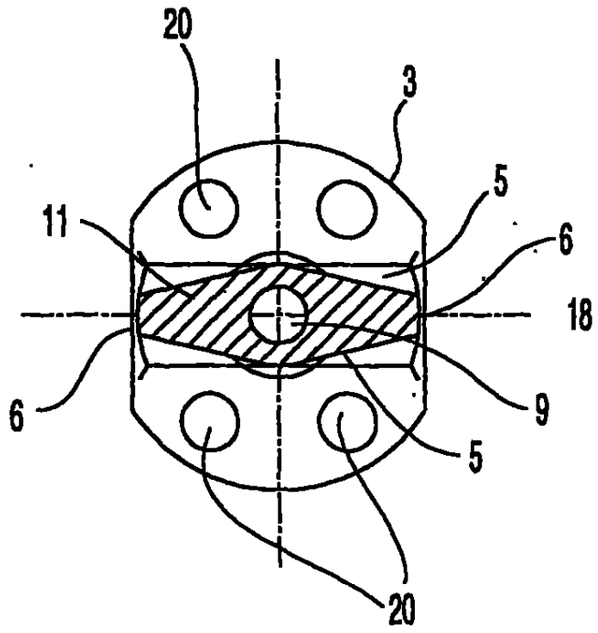


Fig. 3

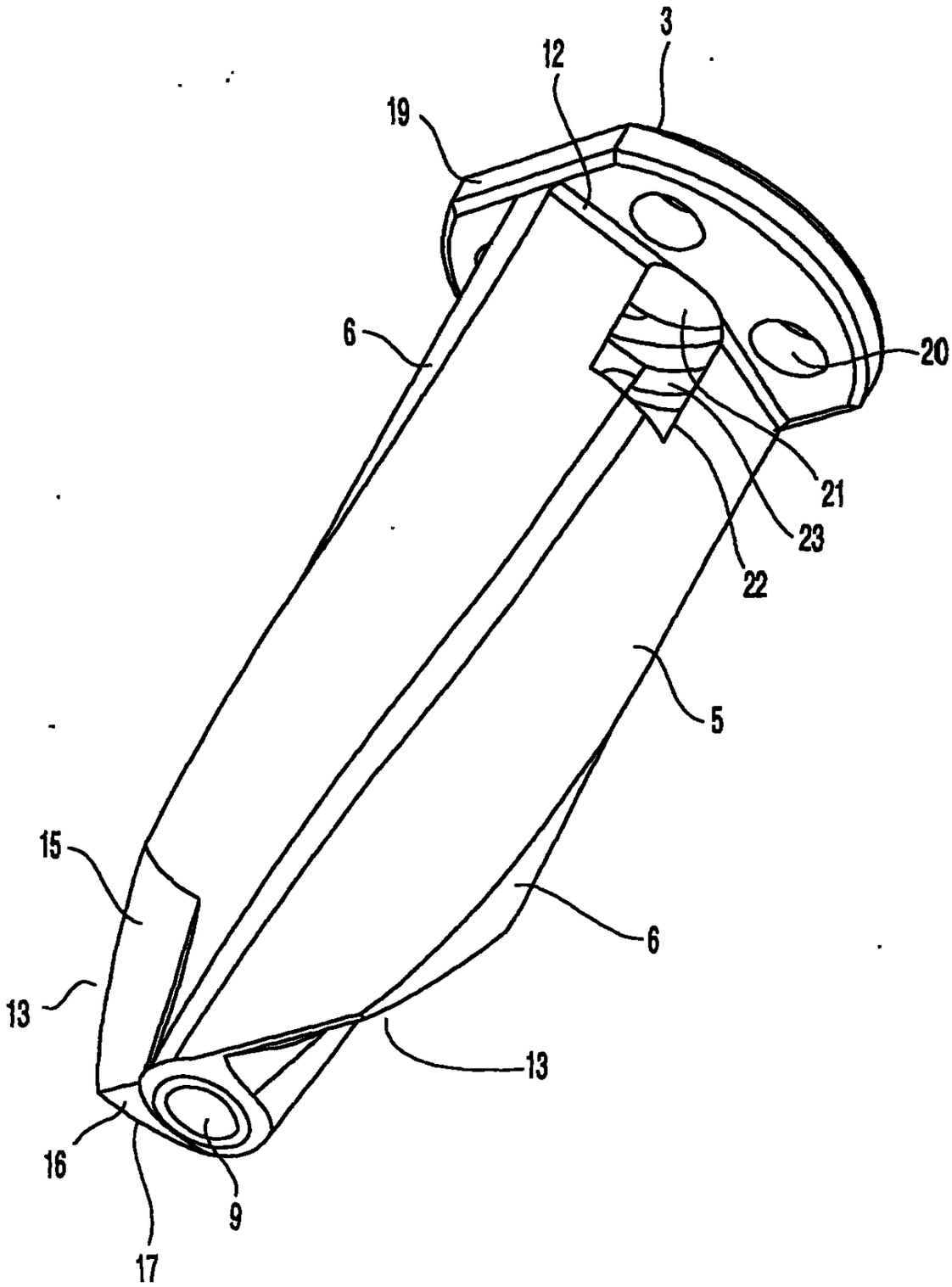


Fig. 4

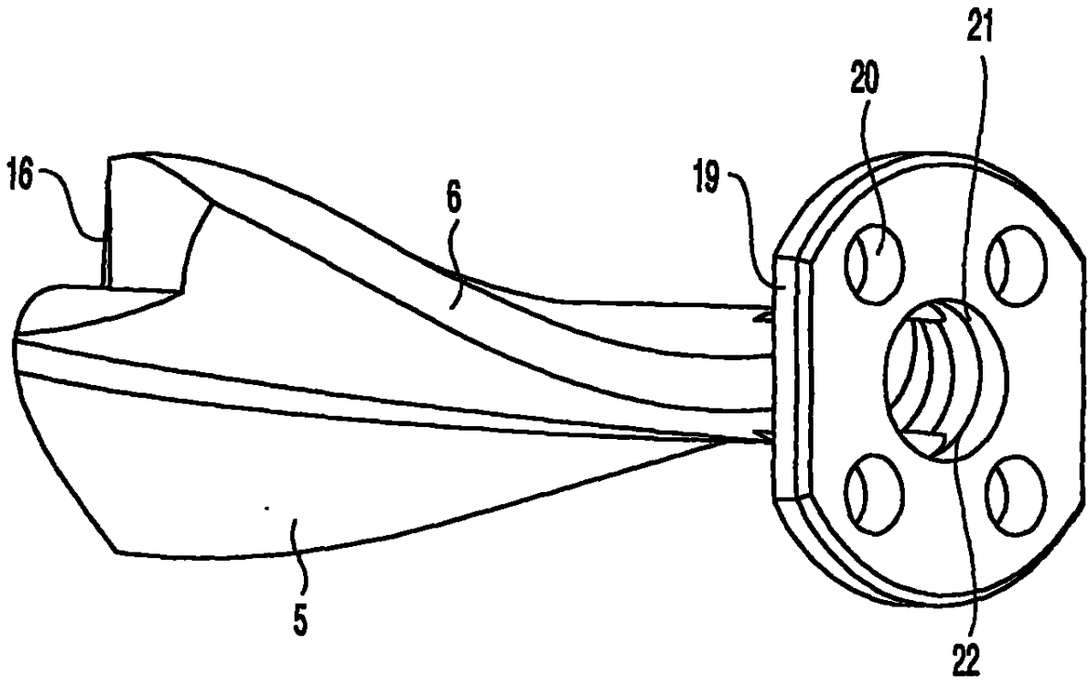


Fig. 5

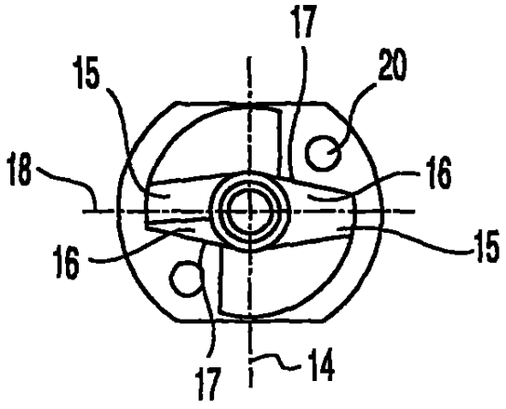


Fig. 6

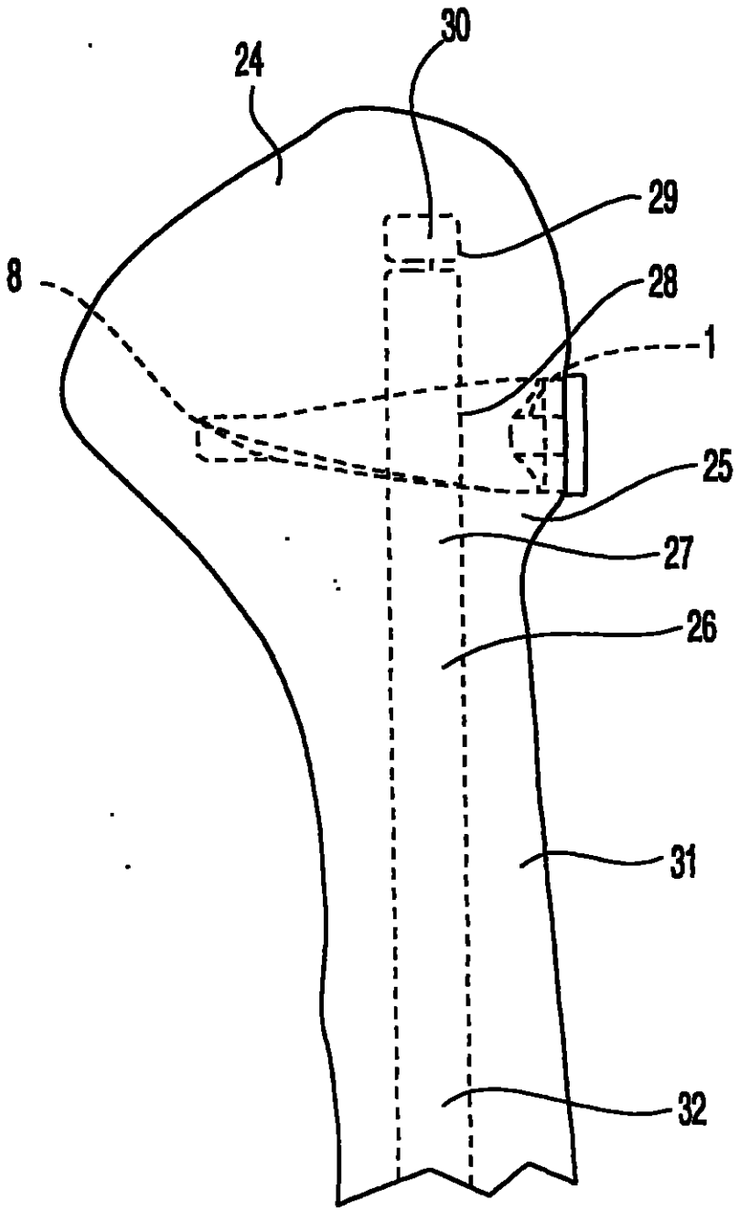


Fig. 7

INTERNATI NAL SEARCH REP RT

Int lonal Application No
PCT/CH 01/00258

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/74

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 300 074 A (FRIGG ROBERT) 5 April 1994 (1994-04-05) cited in the application abstract; figures 1,6,15 claims 1,8,13	1-7, 12-14
Y	WO 98 53746 A (MARTELLO JEANNETTE M D) 3 December 1998 (1998-12-03) abstract; figures 1,3,5	1-7, 12-14
A	EP 0 411 273 A (SYNTHES AG) 6 February 1991 (1991-02-06) cited in the application abstract; figures 1,2 column 2, line 24,25 column 2, line 31,32	1,5,7,8, 12,13

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[X] Further documents are listed in the continuation of box C. [X] Patent family members are listed in 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 document 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
27 September 2001	08/10/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Macaire, S

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REP RT

Int lonal Application No
PCT/CH 01/00258

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	DE 867 274 C (E.A.J. ERICSON) 16 February 1953 (1953-02-16) figure 3	4
A	US 5 571 139 A (JENKINS JR JOSEPH R) 5 November 1996 (1996-11-05) abstract; figures 1,2	1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATI NAL SEARCH REP RT

Information on patent family members

Intl oval Application No
PCT/CH 01/00258

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5300074	A	05-04-1994	CH	682300 A5	31-08-1993
			AT	132725 T	15-01-1996
			CA	2057440 A1	18-06-1992
			DE	59107248 D1	22-02-1996
			EP	0491138 A1	24-06-1992
			JP	2538467 B2	25-09-1996
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			BR	9809908 A	03-10-2000
			EP	0986331 A1	22-03-2000
			US	6168598 B1	02-01-2001
			WO	9853746 A1	03-12-1998
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			CA	2011751 A1	03-02-1991
			DE	69022915 D1	16-11-1995
			DE	69022915 T2	04-04-1996
			EP	0411273 A1	06-02-1991
DE 867274	C		NONE		
US 5571139	A	05-11-1996	NONE		

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Lusuardi, Werther
LUSUARDI AG
Kreuzbühlstrasse 8
CH-8008 Zürich
SUISSE

PCT

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

Date of mailing (day/month/year)	29.08.2002
Applicant's or agent's file reference	IMPORTANT NOTIFICATION
1869/PCT	

International application No.	International filing date (day/month/year)	Priority date (day/month/year)
PCT/CH01/00258	25/04/2001	31/05/2000

Applicant
SYNTHES AG CHUR et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report 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 examination report. 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.

For the purpose of deciding whether the claimed invention is patentable or not, the elected Offices may apply criteria additional to or different from the criteria on which the International preliminary examination report is based (see Articles 27(5), 33(5)). Additional criteria may include e.g. exemptions from patentability and the requirements of enabling disclosure and of clarity and support of claims.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Adams-Gries, I Tel.+31 70 340-2371

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
1869/PCT		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CH01/00258	25/04/2001	31/05/2000
International Patent Classification (IPC) or national classification and IPC A61B17/74		
Applicant SYNTHES AG CHUR et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
19/10/2001	29.08.2002
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Macaire, S Telephone No. +31 70 340 3115

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CH01/00258

I. Basis of the report

1. With regard to the **elements** of the international application *(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 since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-8 as originally filed

Claims, No.:

1-14 as received on 27/02/2002 with letter of 25/02/2002

Drawings, sheets:

1/7-7/7 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

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	1-14
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-14
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-14
	No:	Claims	

2. Citations and explanations
see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

   D1: US-A-5 300 074 (FRIGG ROBERT) 5 April 1994 (1994-04-05) cited in the application
   D2: EP-A-0 411 273 (SYNTHES AG) 6 February 1991 (1991-02-06) cited in the application
   D3: WO 98 53746 A (MARTELLO JEANNETTE M D) 3 December 1998 (1998-12-03)

2. **[claim 1]** Document D1, which is considered to represent the most relevant state of the art, discloses (cf. abstract, fig. 4, 6, 10) an implant for a bone comprising:

   A) a body member(2) having a lateral portion(5) and a medial portion(15) and a helically twisted blade(15) extending along the body and having a longitudinal axis;

   Document D2 also discloses the same features (see fig. 1).

2.1 The subject-matter of claim 1 differs from these known implants in that:

   B) the lateral portion does not have a circumferential collar extending in a plane perpendicular to said longitudinal axis.

   C) said circumferential collar has an attachment element for attaching a tissue fastener for repairing tissue surrounding the bone.

2.2 All the features of the implant of claim 1 are not disclosed by a single document. The subject-matter of claim 1 is therefore novel (Article 33(2) PCT).

2.3 **[claims 2-14]** Claims 2-14 are directly or indirectly dependent from claim 1.The subject-matter of claims 2-14 is therefore novel (Article 33(2) PCT).

3. **[claim 1]** The implant of claim 1 comprises a circumferential collar with an attachment element for attaching a tissue fastener for repairing tissue surrounding the bone. A similar collar can be seem in the tissue anchor disclose in document D3. Nevertheless, nothing in document D1 or D2 suggests the addition of a suture attachment element at the end of the twisted blade.
Moreover the twisted blade of document D1 is used in combination with a bone plate. The blade of document D2 is used in combination with a flat portion along the bone. The addition of a circular collar would alter the fixation of the blade to the plate and alter the fixation of the blade to the bone. The person skill in the art would therefore not add the collar to the implant of document D1 or document D2.

Therefore the solution proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT).

3.1 **[claims 2-14]** Claims 2-14 are directly or indirectly dependent from claim 1. The subject-matter of claims 2-14 does involve an inventive step and does satisfy the criterion set forth in Article 33(3) PCT.

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Claims

1. An implant for a bone with
A) a body member having a lateral portion and a medial portion (8) and a helically twisted blade (2) extending along the body and having a longitudinal axis (10),
characterized in that
B) said lateral portion has a circumferential collar (3) extending in a plane perpendicular to said longitudinal axis (10); and
C) said circumferential collar (3) has an attachment element for attaching a tissu fastener for repairing tissue surrounding the bone.

2. The implant of claim 1 wherein the attachment element comprises a hole for securing the tissue fastener.

3. The implant of claim 2 wherein the hole is threaded.

4. The implant of claim 1 wherein the body member further comprises a central porti n (7) between the lateral and medial portions (8), the central portion (7) having a cross section and a maximum thickness adjacent said longitudinal axis (10) which gradually tapers to a minimum thickness apart from said longitudinal axis (10).

5. The implant of claim 1 further comprising a cannulation (9) extending through th body member along said longitudinal axis (10) from said medial portion (8) to said lateral portion.

6. The implant of claim 5 wherein said circumferential collar (3) includes a central hol (21) configured with threads to releasably engage a tool for positioning the implant in the bone.

7. The implant of claim 1 wherein the medial portion (8) further comprises a medially extending medial end portion having surfaces configured for cutting through the bone.

8. The implant of claim 1 further comprising a medial end portion extending medially from the medial portion (8), said medial end portion comprising:
a) first and second cutting regions (13); and
b) a transverse axis (18), said first and second cutting regions asymmetrically disposed about said transverse axis (18).

9. The implant of claim 8 wherein said first and second cutting regions further comprise cutting edges (17), said cutting edges (17) forming an angle of about thirty degrees to said transverse axis (18).

10. The implant of claim 9 wherein said first and second cutting regions (13) further comprise an angled cutting surface.

11. The implant of claim 10 wherein said angled cutting surfaces form an angle of from about five to sixty degrees with respect to said longitudinal axis (10).

12. The implant of claim 1 wherein the lateral portion of the helically twisted blade (2) is twisted about one fourth turn with respect to the medial portion (8).

13. An osteosynthetic apparatus for fixing a broken humerus comprising:
A) the implant of claim 1;
B) a securing member comprising an elongated nail having a proximal securing portion configured to occupy an upper portion of the humeral shaft (31) and a distal portion (32) configured to occupy a lower portion of the humeral shaft (31); and
C) the proximal securing portion having at least one longitudinal bore configured to accommodate the implant.

14. The apparatus of claim 13 wherein the circumferential collar (3) includes a plurality of holes suitable for anchoring a suture.

PATENT COOPERATION TREATY

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From the INTERNATIONAL BUREAU 11 Dez. 2001

PCT

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:
LUSUARDI, Werther
Dr. Lusuardi AG
Kreuzbühlstrasse 8
CH-8008 zürich
SUISSE

Date of mailing (day/month/year)	
06 December 2001 (06.12.01)	
Applicant's or agent's file reference	**IMPORTANT NOTICE**
1869/PCT	

International application No.	International filing date (day/month/year)	Priority date (day/month/year)
PCT/CH01/00258	25 April 2001 (25.04.01)	31 May 2000 (31.05.00)

Applicant
SYNTHES AG CHUR et al

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this notice:
   KP,KR,US

   In accordance with Rule 47.1(c), third sentence, those Offices will accept the present notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the International application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:
   AE,AL,AM,AP,AT,AU,AZ,BA,BB,BG,BR,BY,CA,CH,CN,CO,CR,CU,CZ,DE,DK,DM,EA,EE,EP,ES,FI, GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MN, MW,MX,NO,NZ,OA,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW

   The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the International application (Rule 49.1(a-bis)).

3. Enclosed with this notice is a copy of the international application as published by the International Bureau on
   06 December 2001 (06.12.01) under No. WO 01/91659

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination (at present, all PCT Contracting States are bound by Chapter II).

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and the PCT Applicant's Guide, Volume II.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer
J. Zahra

Telephone No. (41-22) 338.91.11

Continuation of Form PCT/IB/308

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NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

Date of mailing (day/month/year)	IMPORTANT NOTICE
06 December 2001 (06.12.01)	
Applicant's or agent's file reference	*International application No.*
1869/PCT	PCT/CH01/00258

The applicant is hereby notified that, at the time of establishment of this Notice, the time limit under Rule 46.1 for making amendments under Article 19 has not yet expired and the International Bureau had received neither such amendments nor a declaration that the applicant does not wish to make amendments.

3Y

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* 1859/PCT

Box No. I TITLE OF INVENTION

Humeral Spiral Blade

Box No. II APPLICANT ☐ This person is also inventor

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

Synthes AG Chur
Grabenstrasse 15
CH-7002 Chur
Switzerland

Telephone No.

Facsimile No.

Teleprinter No.

Applicant's registration No. with the Office

State *(that is, country)* of nationality: CH

State *(that is, country)* of residence: CH

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☒ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

Synthes (U.S.A.)
1690 Russell Road
P.O. Box 1766
Paoli, PA 19301-1222
USA

This person is:
☒ applicant only
☐ applicant and inventor
☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☐ the United States of America only ☒ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

LUSUARDI Werther
Dr. Lusuardi AG
Kreuzbühlstrasse 8
CH-8008 Zürich
Schweiz

Telephone No. 01 251 66 92

Facsimile No. 01 251 75 74

Teleprinter No.

Agent's registration No. with the Office

☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

GREEN James M.
6720 S.W. Canyon Drive
Portland, OR 97225
USA

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office:

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of:
- ☐ all designated States
- ☐ all designated States except the United States of America
- ☒ the United States of America only
- ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

KMIEC, Jr., Stanley J.
663 W. Fairmount Street
Coopersburg, PA 18036
USA

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office:

State *(that is, country)* of nationality: US

State *(that is, country)* of residence: US

This person is applicant for the purposes of:
- ☐ all designated States
- ☐ all designated States except the United States of America
- ☒ the United States of America only
- ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- ☐ applicant only
- ☐ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office:

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of:
- ☐ all designated States
- ☐ all designated States except the United States of America
- ☐ the United States of America only
- ☐ the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- ☐ applicant only
- ☐ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office:

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of:
- ☐ all designated States
- ☐ all designated States except the United States of America
- ☐ the United States of America only
- ☐ the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on another continuation sheet.

Box No. V DESIGNATION OF STATES *Mark the applicable check-boxes below; at least one must be marked.*

The following designations are hereby made under Rule 4.9(a):

Regional Patent

- ☒ **AP** **ARIPO Patent:** GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, MZ Mozambique, SD Sudan, SL Sierra Leone, SZ Swaziland, TZ United Republic of Tanzania, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ **EA** **Eurasian Patent:** AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ **EP** **European Patent:** AT Austria, BE Belgium, CH & LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, TR Turkey, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ **OA** **OAPI Patent:** BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

☒ AE United Arab Emirates	☒ GH Ghana	☒ MX Mexico
☐ AG Antigua and Barbuda	☒ GM Gambia	☐ MZ Mozambique
☒ AL Albania	☒ HR Croatia	☒ NO Norway
☒ AM Armenia	☒ HU Hungary	☒ NZ New Zealand
☒ AT Austria	☒ ID Indonesia	☒ PL Poland
☒ AU Australia	☒ IL Israel	☒ PT Portugal
☒ AZ Azerbaijan	☒ IN India	☒ RO Romania
☒ BA Bosnia and Herzegovina	☒ IS Iceland	☒ RU Russian Federation
☒ BB Barbados	☒ JP Japan	
☒ BG Bulgaria	☒ KE Kenya	☒ SD Sudan
☒ BR Brazil	☒ KG Kyrgyzstan	☒ SE Sweden
☒ BY Belarus	☒ KP Democratic People's Republic of Korea	☒ SG Singapore
☐ BZ Belize	☒ KR Republic of Korea	☒ SI Slovenia
☒ CA Canada	☒ KZ Kazakhstan	☒ SK Slovakia
☒ CH & LI Switzerland and Liechtenstein	☒ LC Saint Lucia	☒ SL Sierra Leone
☒ CN China	☒ LK Sri Lanka	☒ TJ Tajikistan
☒ CO Colombia	☒ LR Liberia	☒ TM Turkmenistan
☒ CR Costa Rica	☒ LS Lesotho	☒ TR Turkey
☒ CU Cuba	☒ LT Lithuania	☒ TT Trinidad and Tobago
☒ CZ Czech Republic	☒ LU Luxembourg	☒ TZ United Republic of Tanzania
☒ DE Germany	☒ LV Latvia	☒ UA Ukraine
☒ DK Denmark	☒ MA Morocco	☒ UG Uganda
☒ DM Dominica	☒ MD Republic of Moldova	☒ US United States of America
☐ DZ Algeria		
☐ EC Ecuador		
☒ EE Estonia	☒ MG Madagascar	☒ UZ Uzbekistan
☒ ES Spain	☒ MK The former Yugoslav Republic of Macedonia	☒ VN Viet Nam
☒ FI Finland		☒ YU Yugoslavia
☒ GB United Kingdom	☒ MN Mongolia	☒ ZA South Africa
☒ GD Grenada	☒ MW Malawi	☒ ZW Zimbabwe
☒ GE Georgia		

Check-boxes below reserved for designating States which have become party to the PCT after issuance of this sheet:

☐ ..... ☐ ..... ☐ .....

☐ ..... ☐ ..... ☐ .....

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)*

Supplemental Box *If the Supplemental Box is not used, this sheet should not be included in the request.*

1. If, in any of the Boxes, except Boxes Nos. VIII(i) to (v) for which a special continuation box is provided, the space is insufficient to furnish all the information: in such case, write "Continuation of Box No...." (indicate the number of the Box) and furnish the information in the same manner as required according to the captions of the Box in which the space was insufficient, in particular:

(i) If more than two persons are to be indicated as applicants and/or inventors and no "continuation sheet" is available: in such case, write "Continuation of Box No. III" and indicate for each additional person the same type of information as required in Box No. III. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below;

(ii) if, in Box No. II or in any of the sub-boxes of Box No. III, the indication "the States indicated in the Supplemental Box" is checked: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the applicant(s) involved and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is applicant;

(iii) if, in Box No. II or in any of the sub-boxes of Box No. III, the inventor or the inventor/applicant is not inventor for the purposes of all designated States or for the purposes of the United States of America: in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the inventor(s) and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is inventor;

(iv) if, in addition to the agent(s) indicated in Box No. IV, there are further agents: in such case, write "Continuation of Box No. IV" and indicate for each further agent the same type of information as required in Box No. IV;

(v) if, in Box No. V, the name of any State (or OAPI) is accompanied by the indication "patent of addition," or "certificate of addition," or if, in Box No. V, the name of the United States of America is accompanied by an indication "continuation" or "continuation-in-part": in such case, write "Continuation of Box No. V" and the name of each State involved (or OAPI), and after the name of each such State (or OAPI), the number of the parent title or parent application and the date of grant of the parent title or filing of the parent application;

(vi) if, in Box No. VI, there are more than five earlier applications whose priority is claimed: in such case, write "Continuation of Box No. VI" and indicate for each additional earlier application the same type of information as required in Box No. VI.

2. If, with regard to the precautionary designation statement contained in Box No. V, the applicant wishes to exclude any State(s) from the scope of that statement: in such case, write "Designation(s) excluded from precautionary designation statement" and indicate the name or two-letter code of each State so excluded.

Continuation of box No. II:

Applicant for all States with exception of the United States of America and Canada:

Synrthes AG Chur
Grabenstrasse 15
CH-7002 Chur
Switzerland

Continuation of Box No. III:

Applicant for Canada only:

Synthes (U.S.A.)
1690 Russell Road
P.O. Box 1766
Paoli, PA 19301-1222
USA>

Box No. VI PRIORITY CLAIM

The priority of the following earlier application(s) is hereby claimed:

Filing date of earlier application *(day/month/year)*	Number of earlier application	Where earlier application is:		
		national application: country	regional application:* regional Office	international application: receiving Office
item (1)				
item (2)				
item (3)				
item (4)				
item (5)				

☐ Further priority claims are indicated in the Supplemental Box.

The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of this international application is the receiving Office)* identified above as:

☐ all items ☐ item (1) ☐ item (2) ☐ item (3) ☐ item (4) ☐ item (5) ☐ other, see Supplemental Box

** Where the earlier application is an ARIPO application, indicate at least one country party to the Paris Convention for the Protection of Industrial Property or one Member of the World Trade Organization for which that earlier application was filed (Rule 4.10(b)(ii)):* ....

.....

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):*

ISA / .....

Request to use results of earlier search; reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority):*

Date *(day/month/year)* Number Country *(or regional Office)*

Box No. VIII DECLARATIONS

The following declarations are contained in Boxes Nos. VIII (i) to (v) *(mark the applicable check-boxes below and indicate in the right column the number of each type of declaration)*: Number of declarations

☐	Box No. VIII (i)	Declaration as to the identity of the inventor	:
☐	Box No. VIII (ii)	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	:
☐	Box No. VIII (iii)	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	:
☐	Box No. VIII (iv)	Declaration of inventorship (only for the purposes of the designation of the United States of America)	:
☐	Box No. VIII (v)	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	:

Box No. IX CHECK LIST; LANGUAGE OF FILING

This international application contains:

(a) the following number of sheets in paper form:

request (including declaration sheets)	:	6
description (excluding sequence listing part)	:	8
claims	:	3
abstract	:	1
drawings	:	7
Sub-total number of sheets	:	25
sequence listing part of description *(actual number of sheets if filed in paper form, whether or not also filed in computer readable form; see (b) below)*	:	
Total number of sheets	:	25

(b) sequence listing part of description filed in computer readable form

(i) ☐ only (under Section 801(a)(i))

(ii) ☐ in addition to being filed in paper form (under Section 801(a)(ii))

Type and number of carriers (diskette, CD-ROM, CD-R or other) on which the sequence listing part is contained *(additional copies to be indicated under item 9(ii), in right column)*: .....

This international application is accompanied by the following item(s) *(mark the applicable check-boxes below and indicate in right column the number of each item)*:

		Number of items
1. ☒	fee calculation sheet	:
2. ☒	original separate power of attorney	:
3. ☐	original general power of attorney	:
4. ☐	copy of general power of attorney; reference number, if any:	:
5. ☐	statement explaining lack of signature	:
6. ☐	priority document(s) identified in Box No. VI as item(s):	:
7. ☐	translation of international application into *(language)*:	:
8. ☐	separate indications concerning deposited microorganism or other biological material	:
9. ☐	sequence listing in computer readable form (indicate also type and number of carriers (diskette, CD-ROM, CD-R or other))	
	(i) ☐ copy submitted for the purposes of international search under Rule 13*ter* only (and not as part of the international application)	:
	(ii) ☐ *(only where check-box (b)(i) or (b)(ii) is marked in left column)* additional copies including, where applicable, the copy for the purposes of international search under Rule 13*ter*	:
	(iii) ☐ together with relevant statement as to the identity of the copy or copies with the sequence listing part mentioned in left column	:
10. ☐	other *(specify)*:	:

Figure of the drawings which should accompany the abstract: 1

Language of filing of the international application: English

Box No. X SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

Dr. Lusuardi AG

P. Kaiser April 23,2001

For receiving Office use only

1. Date of actual receipt of the purported international application:

2. Drawings:
☐ received:
☐ not received:

3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:

4. Date of timely receipt of the required corrections under PCT Article 11(2):

5. International Searching Authority (if two or more are competent): ISA /

6. ☐ Transmittal of search copy delayed until search fee is paid

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

PATENT COOPERATION TREATY

05. Okt. 2001

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

To:
DR. LUSUARDI AG
Attn. Lusuardi, Werther
Kreuzbühlstrasse 8.
CH-8008 Zürich
SWITZERLAND

Date of mailing *(day/month/year)*	08/10/2001
Applicant's or agent's file reference: 1869/PCT	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No.: PCT/CH 01/00258	International filing date *(day/month/year)* 25/04/2001

Applicant: SYNTHES AG CHUR et al.

1. [X] The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

   When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

   Where? Directly to the International Bureau of WIPO
   34, chemin des Colombettes
   1211 Geneva 20, Switzerland
   Facsimile No.: (41-22) 740.14.35

   For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   [ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   [ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

   Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

   Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Johannes Van Brummelen

Form PCT/ISA/220 (July 1998)

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped),whether

(i) the claim is unchanged;

(ii) the claim is cancelled;

(iii) the claim is new;

(iv) the claim replaces one or more claims as filed;

(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international appplication is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
1869/PCT		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/CH 01/00258	25/04/2001	31/05/2000

Applicant

SYNTHES AG CHUR et al.

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [X] Certain claims were found unsearchable (See Box I).

3. [ ] Unity of invention is lacking (see Box II).

4. With regard to the title,

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the abstract,

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No. 1

   [X] as suggested by the applicant.

   [ ] None of the figures.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

INTERNATI NAL SEARCH REPORT

International Application No
PCT/CH 01/00258

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/74

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 300 074 A (FRIGG ROBERT) 5 April 1994 (1994-04-05) cited in the application abstract; figures 1,6,15 claims 1,8,13	1-7, 12-14
Y	WO 98 53746 A (MARTELLO JEANNETTE M D) 3 December 1998 (1998-12-03) abstract; figures 1,3,5	1-7, 12-14
A	EP 0 411 273 A (SYNTHES AG) 6 February 1991 (1991-02-06) cited in the application abstract; figures 1,2 column 2, line 24,25 column 2, line 31,32	1,5,7,8, 12,13

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in 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 document 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
27 September 2001	08/10/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Macaire, S

Form PCT/ISA/210 (second sheet) (July 1992)

International Application No
PCT/CH 01/00258

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	DE 867 274 C (E.A.J. ERICSON) 16 February 1953 (1953-02-16) figure 3	4
A	US 5 571 139 A (JENKINS JR JOSEPH R) 5 November 1996 (1996-11-05) abstract; figures 1,2	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CH 01/00258

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 15,16
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

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

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

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

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/CH 01/00258

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5300074	A	05-04-1994	CH	682300 A5	31-08-1993
			AT	132725 T	15-01-1996
			CA	2057440 A1	18-06-1992
			DE	59107248 D1	22-02-1996
			EP	0491138 A1	24-06-1992
			JP	2538467 B2	25-09-1996
			JP	4292161 A	16-10-1992
WO 9853746	A	03-12-1998	AU	731976 B2	12-04-2001
			AU	7717898 A	30-12-1998
			BR	9809908 A	03-10-2000
			EP	0986331 A1	22-03-2000
			US	6168598 B1	02-01-2001
			WO	9853746 A1	03-12-1998
EP 0411273	A	06-02-1991	US	4978349 A	18-12-1990
			CA	2011751 A1	03-02-1991
			DE	69022915 D1	16-11-1995
			DE	69022915 T2	04-04-1996
			EP	0411273 A1	06-02-1991
DE 867274	C		NONE		
US 5571139	A	05-11-1996	NONE		

YB

TRADUCCIÓN 407

HOJA ESPIRALADA HUMERAL

HOJA ESPIRALADA HUMERAL

La invención se refiere a un implante para la fijación interna de huesos y en particular se refiere a un implante para la fijación interna de fracturas diafisiarias en múltiples partes del húmero para promover la osteosíntesis de acuerdo con el preámbulo de la reivindicación 1. La invención puede ser usada, por ejemplo, conjuntamente con un dispositivo intramedular que contiene una ranura proximal para que la hoja o pala espiralada humeral sea posicionada y trabada provisionalmente.

Entre 160.000 y 180.000 individuos sufren fracturas del húmero cada año. Aproximadamente el setenta y cinco por ciento de las fracturas ocurren en la región proximal del húmero cerca de la cabeza o cortex, el diez por ciento se produce en la región de la mitad del hueso y el quince por ciento ocurre en la región distal del húmero.

Las fracturas humerales diafisiarias involucran la parte alargada del húmero. Las fracturas humerales proximales involucran las fracturas de la cabeza o cortex y frecuentemente resultan a partir de una caída que aplica una carga axial sobre el húmero. En una fractura de dos partes, la cabeza o porción única de la cabeza se rompe desde el eje o vástago del húmero. Las fracturas multi-partes involucran fracturas de la cabeza del húmero que se

parte en dos o en tres fragmentos y que se separan del vástago o cuerpo alargado.

El tratamiento convencional de las fracturas humorales multi-partes y diafisiarias frecuentemente requieren del uso de alambres, suturas, o fijación externa de los fragmentos unos contra otros y/o el cuerpo alargado del húmero. Otros intentos conocidos comprenden la inserción de uno o más tornillos dentro de la cabeza o eje o vástago del húmero y la fijación de clavos o tornillos en relación con un clavo insertado dentro del canal medular del húmero, tal como aquellos descriptos en las patentes norteamericanas Nros. 4.503.847, 5.472.444, 5.697.930 y 5.766.174.

Complicaciones postoperativas frecuentes se producen cuando dos o más de los fragmentos del hueso son forzados uno contra otro cuando el paciente aplica presión al hueso que está curando. Por ejemplo, un tornillo o clavo agudo implantado puede cortar y traspasar el cuello o cabeza del húmero; o un clavo, un tornillo, o una varilla intramedular puede doblarse o romperse bajo el efecto de una carga. El corte es particularmente problemático en los individuos que tienen poco volumen óseo, tal como es el caso de un hueso osteoporótico o canceroso. Por lo tanto, existe la necesidad de proveer implantes osteosintéticos mejorados para el tratamiento de fracturas del húmero diafisiarias y multi-partes.

Las fracturas femorales han sido tratadas utilizando hojas únicas helicoidales tales como aquellas descriptas en las patentes norteamericanas Nros. 4.103.683, 4.978.349 y 5.300.074. Estas palas u hojas están retorcidas en aproximadamente noventa grados a lo largo de su longitud y tienen un perfil generalmente plano y rectangular con un ancho sustancialmente uniforme y un espesor estrecho. Cuando son implantadas conjuntamente con un clavo intramedular, estas palas u hojas son orientadas para reducir la presión sobre el tejido canceloso dentro de la cabeza femoral y para proveer una alta resistencia al doblado en respuesta a las cargas a lo largo del eje longitudinal del clavo o varilla intramedular.

Debido al estrecho espesor anteriormente mencionado, sin embargo, las hojas femorales únicas y helicoidales del arte previo son fácilmente deformables en la dirección transversal, es decir, en las direcciones anterior y posterior del paciente. Mas aun, todo el perfil plano de las hojas provee una pequeña resistencia del corte a través del hueso canceloso como un cuchillo en direcciones alineadas con el ancho de la hoja en cualquier lugar a lo largo de su longitud. Existe la necesidad, por lo tanto, de proveer implantes osteosintéticos mejorados para el tratamiento de fracturas diafisiarias en múltiples partes del húmero que no tengan una tendencia a provocar dicho

corte y provean una mayor resistencia al doblado en la dirección transversal.

La reparación de un húmero fracturado frecuentemente involucra la reparación de tejido blando dañado que rodea el húmero. Los anclajes de sutura tradicionales sufren la falla de ser tirados hacia fuera en el hueso debilitado y también requieren que se perforen orificios adicionales en un húmero ya debilitado. La patente norteamericana No. 5.766.174 describe un clavo o varilla intramedular que tiene orificios de sutura y una tapa de clavo con orificios de sutura. Los orificios de sutura en un clavo intramedular frecuentemente no son accesibles una vez que el clavo ha sido implantado en un húmero fracturado. De esta manera, al reparar un húmero fracturado, existe también la necesidad de proveer sitios robustos accesibles para la fijación de la sutura que no requieran la perforación adicional del húmero fracturado.

La presente invención se refiere a un implante para un hueso. El implante tiene un miembro de cuerpo que tiene una porción lateral, una porción media y una hoja o pala retorcida helicoidalmente que se extiende a lo largo del cuerpo y que tiene un eje geométrico longitudinal. En una realización preferida, la porción lateral de la hoja helicoidalmente retorcida está retorcida alrededor de un cuarto de vuelta con respecto a la porción media.

La porción lateral del cuerpo tiene un collar circunferencial que se extiende en un plano perpendicular al eje geométrico longitudinal. El collar circunferencial tiene un elemento de fijación para fijar un sujetador de tejido para reparar el tejido que rodea al hueso. En una realización, el elemento de fijación comprende un orificio para asegurar el sujetador de tejido. En otra realización, el elemento de fijación comprende un orificio roscado.

En otra realización, el miembro de cuerpo tiene una porción central entre las porciones lateral y media. La porción central tiene una sección transversal y un espesor máximo adyacente al eje longitudinal que se ahúsa o conifica gradualmente hasta un espesor mínimo aparte del eje geométrico longitudinal.

En una realización preferida, una cánula se extiende a través del miembro de cuerpo a lo largo del eje geométrico longitudinal desde la porción media hasta la porción lateral. En otra realización, el collar circunferencial incluye un orificio central que está configurado con roscas para acoplarse liberablemente a una herramienta para posicionar la invención en el hueso.

En otra realización, la porción media tiene una porción extrema media que se extiende a lo largo de la mitad y que

tiene superficies configuradas para cortar el hueso. En una realización preferida, la porción extrema media incluye una primera y una segunda regiones de corte y un eje transversal. Las regiones de corte primera y segunda están dispuestas asimétricamente alrededor del eje geométrico transversal. En una realización preferida, las regiones de corte primera y segunda incluyen además bordes de corte, que forman un ángulo de aproximadamente treinta grados con respecto al eje geométrico transversal. Las regiones de corte primera y segunda pueden incluir una superficie de corte angulada. En una realización preferida las superficies de corte anguladas forman un ángulo que va desde alrededor de cinco a sesenta grados con respecto al eje geométrico longitudinal.

La presente invención también se refiere a un aparato osteosintético para fijar un húmero roto. El aparato incluye el implante de la presente invención y un miembro de fijación que comprende un clavo o varilla alargada que tiene una porción de fijación proximal que está configurada para ocupar una porción proximal del cuerpo alargado o caña humeral y una porción distal configurada para ocupar una porción distal del cuerpo o caña humeral. En una realización preferida, la porción de fijación proximal tiene por lo menos un orificio longitudinal que está configurado para acomodar el implante. Cuando el implante es acomodado mediante el orificio longitudinal, una porción

media del implante queda preferiblemente dentro de la cabeza del húmero y el implante puede ser posicionado y provisionalmente trabado.

La presente invención se refiere además a un método para reconstruir un húmero roto. El método incluye la implantación del implante de la presente invención en el húmero con la porción media de la pala u hoja retorcida dispuesta dentro de la cabeza del húmero. En una realización preferida, el collar circunferencial del implante incluye una pluralidad de orificios.

Las realizaciones preferidas de la invención serán ahora descriptas en relación con los dibujos que se adjuntan en donde:

La figura 1 es una vista tomada desde arriba de un implante de acuerdo con la presente invención;

La figura 2 es una vista lateral del implante que se muestra en la figura 1;

La figura 3 muestra una vista en sección de un implante, tomada a lo largo de la línea c-c de la figura 1;

La figura 4 es una vista en perspectiva del implante;

La figura 5 muestra otra vista en perspectiva del implante;

La figura 6 muestra una vista media del implante; y

La figura 7 muestra una vista lateral en sección transversal del implante ya implantado en un húmero conjuntamente con un clavo o varilla intramedular.

En esta descripción, los términos medio y lateral son definidos en relación al eje geométrico central de un paciente. De esta manera, una porción media de un elemento implantado de acuerdo con la invención está ubicado más cerca del eje geométrico central de un paciente. De manera similar, los términos proximal y distal están definidos en relación con la distancia relativa desde la cabeza del paciente. De esta manera, una porción proximal de un elemento implantado está ubicada más cerca de la cabeza del paciente que una porción distal del elemento.

Haciendo referencia a las figuras 1 a 6, una pala u hoja humeral espiralada 1 tiene una pala helicoidalmente retorcida 2 y un collar circunferencial 3 adyacente y lateral a una porción de cuello 4 de la hoja 2. La hoja 2 está formada mediante superficies de apoyo 5 y superficies laterales 6. Continuando medianamente desde la porción de cuello 4, la hoja 2 también incluye una porción central 7 y

una porción media 8. Una cánula 9 se extiende a través de la hoja 2 a lo largo de un eje geométrico longitudinal 10 de la hoja espiralada 1.

Las figuras 1 y 2 muestran la porción central 7 y la porción media 8 de la hoja 2 que están giradas alrededor del eje geométrico longitudinal 10 de la hoja espiralada 1 en una forma preferiblemente contigua. La hoja 2 cubre un ángulo de rotación que es de por lo menos aproximadamente treinta grados, preferiblemente desde aproximadamente cuarenta y cinco grados a ciento veinte grados, y más preferiblemente alrededor de noventa grados. La porción de cuello 4 puede extenderse sustancialmente en forma recta a lo largo del eje geométrico longitudinal 10 de la hoja espiralada 1.

La figura 3 muestra una sección transversal representativa 11 de la porción central 7 tomada a lo largo de la porción C-C en la figura 1. La sección transversal 11 está formada mediante la oposición de las superficies de apoyo 5 y la oposición de las superficies laterales 6. Una distancia que separa las superficies de apoyo opuestas 5 se va afinando desde un máximo adyacente al eje geométrico longitudinal 10 hasta un mínimo que se corresponde con las superficies laterales 6. En la realización ilustrada, la hoja 2 tiene un ancho sustancialmente uniforme en cualquier lugar a lo largo del eje geométrico longitudinal 10 de

manera que los lados 6 se encuentran uniformemente separados a lo largo de la hoja 2. La hoja 2 puede también afinarse de manera tal que una distancia que separa las superficies laterales 6 aumenta o disminuye continuando a lo largo de la hoja 2 en la dirección media.

Tal como mejor se ve en la figura 4, una porción de cuello 4 se une al collar circunferencial 3 mediante una suave región de transición 12. La región suave de transición 12 reduce la aparición de tensiones que podrían resultar de otro modo debido a un agudo cambio en la geometría.

En las figuras 1 y 4 se muestra una realización de la hoja espiralada 1 a modo de ejemplo, en la cual la porción media 8 está configurada con regiones de corte 13 para facilitar la implantación de la hoja espiralada 1 dentro de un hueso. Tal como se ve en la figura 6, las regiones de corte 13 están dispuestas asimétricamente alrededor de un primer eje geométrico transversal 14 de la hoja espiralada 1. La región de corte 13 tiene una primera superficie de corte 15 que se afina gradualmente para unirse a una segunda superficie de corte 16. La segunda superficie de corte 16 se afina más rápidamente para formar un borde de corte medio 17. En la realización ilustrada, la primera superficie de corte 15 es sustancialmente plana, aunque la primera superficie de corte 15 también puede ser arqueada.

Tal como se muestra en la figura 2, una línea sustancialmente paralela a la primera superficie de corte 15 forma un ángulo θ con respecto al eje geométrico longitudinal 10 de una hoja espiralada 1. El ángulo θ tiene desde alrededor de cinco grados hasta sesenta grados, preferiblemente desde alrededor de quince grados hasta sesenta grados, y más preferiblemente alrededor de treinta grados. Tal como se muestra en la figura 1, el borde de corte medio 17 forma un ángulo φ con un segundo eje geométrico transversal 18 de la hoja espiralada 1. El ángulo φ tiene desde alrededor de cinco grados hasta sesenta grados, preferiblemente desde alrededor de quince grados hasta sesenta grados y más preferiblemente alrededor de treinta grados.

Tal como mejor se ve en las figuras 4 y 5, el collar circunferencial 3 tiene un diámetro máximo que es aproximadamente tan grande como el ancho de la porción de cuello 4 de la hoja 2 y está provisto con porciones planas 19, que permiten que la hoja espiralada 1 pueda posicionarse o ser movida con una herramienta auxiliar.

En una realización a modo de ejemplo, el collar circunferencial 3 incluye puntos de fijación 20 para facilitar la fijación de suturas. En una realización preferida los puntos de fijación o sujeción 20 comprenden orificios pasantes a los cuales se puede sujetar las

suturas. De manera alternativa, los puntos de sujeción 20 pueden estar configurados para recibir uno o más anclajes de sutura auxiliar para la fijación de suturas u otros medios adaptados para reconstruir el tejido blando, tal como es conocido en el arte. En un ejemplo no limitativo, el collar circunferencial 3 puede estar configurado con orificios roscados para recibir un anclaje roscado de sutura.

La cánula 9 está configurada para recibir un alambre de guía para ayudar al alineamiento de la hoja espiralada 1 durante la implantación, tal como es conocido en el arte. Tal como mejor se puede ver en las figuras 4 y 5, un orificio central 21 se extiende a través del collar circunferencial 3 y hacia el interior de la porción de cuello 4 de la hoja 2. El orificio central 21 tiene un diámetro mayor que la máxima distancia de separación de las superficies de apoyo 5 de manera tal que el orificio central 21 irrumpe a través de una porción de las superficies de apoyo 5 de la porción de cuello 4 formando una abertura 22. El orificio central 21 está configurado con roscas 23 para permitir la sujeción liberable de un dispositivo para facilitar la implantación o la remoción de la hoja espiralada 1. Luego de la implantación, el orificio central 21 se completa con una tapa extrema roscada para impedir el crecimiento de tejido dentro del orificio central 22. La tapa o tapón extremo roscado puede también

estar configurado con puntos de sujeción similares a los puntos de sujeción 20 en el collar circunferencial 3.

Durante el uso, la hoja espiralada 1 es implantada dentro de la cabeza 24 y el cuello 25 del húmero, tal como se muestra en la figura 7. Los procedimientos de implante para la fijación de clavos o varillas es bien conocido en el arte y puede ser aplicado con la presente invención. La figura 7 muestra una realización que utiliza un clavo intramedular 26 implantado en una caña humeral 31. Una porción distal 32 del clavo 26 está configurada para ocupar una porción distal del cuerpo alargado o caña 31 del húmero y una porción de clavo proximal 27 está configurada para ocupar una porción proximal de la caña humeral. Durante la implantación, el clavo intramedular 26 es primeramente insertado dentro del húmero.

La hoja espiralada 1 es luego implantada a través del lateral del cuerpo o caña 31 del húmero a través de un orificio perforado meramente hasta la superficie lateral del clavo intramedular. La porción de clavo proximal 27 del clavo intramedular 26 incluye un orificio oblongo 28 que está sustancialmente alineado con un eje geométrico longitudinal de la porción de clavo proximal 27. El orificio oblongo 28 acomoda deslizablemente la hoja 2 permitiendo que la hoja espiralada 1 gire alrededor del eje geométrico longitudinal 10 a medida que la hoja espiralada

1 es martillada dentro del hueso. Una vez implantada, el eje geométrico longitudinal 10 define un ángulo con la longitud del clavo intramedular que generalmente está entre noventa grados y ciento cincuenta grados. El ángulo es ajustado para acomodarse a la anatomía del paciente.

Un orificio proximal 29 del clavo intramedular 26 puede acomodar, por ejemplo mediante acoplamiento roscado, una tapa o tapón extremo de traba 30. El contacto o acoplamiento de la tapa extrema de traba 30 con el orificio proximal 29 aplica una fuerza axial contra la porción media 7 de la hoja espiralada 1 que está dispuesta en el orificio oblongo 29. Por medio de la tapa extrema de traba 30, el movimiento axial de la hoja espiralada 1 dentro del orificio oblongo 29 puede ser, ya sea limitada o completamente impedida.

La porción de cuello 4 de una hoja espiralada 1 implantada es orientada para presentar un área superficial relativamente pequeña y normal a las cargas impuestas sustancialmente a lo largo del cuerpo alargado o caña 31 del húmero, de modo de aumentar la rigidez al doblado de la hoja 2 en respuesta a tales cargas y también para transferir una porción de la carga al clavo intramedular 26. La porción media 8 de una hoja espiralada implantada 1 está orientada para presentar un área superficial relativamente grande y normal a las cargas impuestas

sustancialmente a lo largo de la caña humeral 31. Esto reduce la presión sobre el tejido canceloso dentro de la cabeza humeral 24 y resiste la tendencia de la hoja 2 a producir un corte adicional a través del cortex del hueso.

Tal como se muestra en la figura 7, el collar circunferencial 3 de una hoja espiralada implantada 1 permanece expuesto adyacentemente a la cabeza humeral 24 lo que permite el acceso a los puntos de sujeción 20. La configuración del collar circunferencial 3 de la hoja espiralada 1 con punto de sujeción 20 presenta diversas ventajas con respecto a los anclajes de sutura convencionales. Primero, cuando está implantado, el collar circunferencial 3 está dispuesto lateralmente con respecto a la cabeza 24 del húmero, lo cual provee una ubicación conveniente y accesible para la fijación de la sutura. El collar circunferencial 3 es suficientemente grande como para acomodar una pluralidad de puntos de sujeción, lo cual reduce la necesidad de disponer anclajes adicionales en el hueso. Adicionalmente, debido a que la hoja espiralada 1 está firmemente implantada en la cabeza 24 del húmero conjuntamente con el clavo intramedular 26, el collar circunferencial 3 provee una ubicación sólida resistente al movimiento o a las fuerzas de tiro hacia fuera.

La sección transversal más ancha de la cánula adyacente 9 de la hoja 2 que se ve en la figura 3 reduce la flexión

de la hoja 2 en respuesta a las cargas aplicadas en la dirección transversal hacia la parte posterior o anterior del cuerpo del paciente, de modo que las superficies laterales 6 adyacentes de sección transversal algo reducida permiten que la hoja sea insertada con un mínimo desprendimiento de tejido. Las superficies laterales 6 presentan una mayor área superficial que los laterales de las hojas planas helicoidales conocidas en el arte para resistir al corte a través del hueso canceloso en direcciones alineadas con el ancho de la hoja 2.

REIVINDICACIONES

Habiendo así especialmente descrito y determinado la naturaleza de la presente invención y la forma como la misma ha de ser llevada a la práctica, se declara reivindicar como de propiedad y derecho exclusivo:

1. Un implante para un hueso, donde dicho implante comprende:

A) un miembro de cuerpo que tiene una porción lateral y una porción media y una hoja helicoidalmente retorcida que se extiende a lo largo del cuerpo y que tiene un eje longitudinal;

B) presentando dicha porción lateral un collar circunferencial que se extiende en un plano perpendicular a dicho eje geométrico longitudinal;

C) presentando dicho collar circunferencial un elemento de sujeción para fijar un sujetador de tejido para reparar tejido que rodea al hueso.

2. El implante de la reivindicación 1, donde el elemento de sujeción comprende un orificio para asegurar el sujetador de tejido.

3. El implante de la reivindicación 2, donde el orificio está roscado.

4. El implante de la reivindicación 1, donde el miembro de cuerpo comprende además una porción central entre las porciones lateral y media, presentando la porción central una sección transversal y un espesor máximo adyacente a dicho eje geométrico longitudinal, el cual se reduce gradualmente hasta un espeso mínimo apartado de dicho eje geométrico longitudinal.

5. El implante de la reivindicación 1, que comprende además una cánula que se extiende a través del miembro de cuerpo a lo largo de dicho eje geométrico longitudinal desde dicha porción media hasta dicha porción lateral.

6. El implante de la reivindicación 5, donde dicho collar circunferencial incluye un orificio central que está configurado con roscas para acoplar liberablemente una herramienta para posicionar el implante en el hueso.

7. El implante de la reivindicación 1, donde la porción media comprende además una porción media extrema que se extiende medianeramente y que presenta superficies configuradas para producir un corte a través del hueso.

8. El implante de la reivindicación 1, que comprende además una porción extrema media que se extiende medianeramente desde la porción media, comprendiendo dicha porción extrema media:

a) regiones de corte primera y segunda; y

b) un eje geométrico transversal, estando dichas regiones de corte primera y segunda asimétricamente dispuestas alrededor de dicho eje geométrico transversal.

9. El implante de la reivindicación 8, donde dichas regiones de corte primera y segunda comprenden además bordes de corte, en donde dichos bordes de corte forman un ángulo de aproximadamente treinta grados con respecto a dicho eje geométrico transversal.

10. El implante de la reivindicación 9, donde dichas regiones de corte primera y segunda comprenden además una superficie de corte angulada.

11. El implante de la reivindicación 10, donde dichas superficies de corte anguladas forman un ángulo que va desde aproximadamente cinco grados a sesenta grados con respecto a dicho eje geométrico longitudinal.

12. El implante de la reivindicación 1, donde la porción lateral de la hoja helicoidalmente retorcida está retorcida alrededor de un cuarto de vuelta con respecto a la porción media.

13. Un aparato osteosintético para reparar un húmero roto, que comprende:

A) el implante de la reivindicación 1;

B) un miembro de fijación que comprende un clavo alargado que tiene una porción de fijación proximal que está configurada para ocupar una porción superior del cuerpo alargado del húmero y una porción distal que está configurada para ocupar una porción inferior del cuerpo alargado del húmero; y

C) presentando la porción de fijación proximal por lo menos un orificio longitudinal que está configurad para acomodar el implante.

14. El aparato de la reivindicación 13, donde el collar circunferencial incluye una pluralidad de orificios adecuados para sujetar una sutura.

15. Un método para reparar un húmero roto que tiene una cabeza, donde el método comprende:

implantar el implante de la reivindicación 1 en el húmero, con la porción media de la hoja retorcida dispuesta dentro de la cabeza del húmero.

16. El método de la reivindicación 15, que comprende además sujetar el tejido blando al implante utilizando suturas aseguradas al elemento de sujeción.

RESUMEN

Un implante osteosintético para ser utilizado en el tratamiento de fracturas en la cabeza y el cuello del húmero. El implante incluye un cuerpo, una hoja helicoidalmente retorcida que tiene una sección transversal achatada y un collar circunferencial que tiene una pluralidad de puntos de sujeción para suturas.

[redacted] **FORMATO DE DIGITALIZACION**
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CAVELIER ABOGADOS	CONSIGNACION	BANCO POPULAR	050-00110-6	7030536	30/09/2002	23,260,000.00

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

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50003-01-01 SOLICITUDES	1 TRAMITES DE SOL. DE PATENTE DE IN	378,000.00
		TOTAL : $	378,000.00

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REQUISITOS NECESARIOS PARA PRESENTACION Y AGILIZACION DEL TRAMITE

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Indicación de que se solicita la concesión de una patente.	( )	(✓)
Datos de identificación del solicitante o de la persona que se presenta la solicitud.	( )	(✓)
Descripción de la invención.	( )	(✓)
Dibujos de ser estos pertinentes.	( )	(✓)
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COMPLETA (✓)	**INCOMPLETA** ( )	( )
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Conmutador 334 12 21
Fax. 281 31 25
Santa Fe de Bogotá, D C Colombia