(19) World Intellectual Property Organization

International Bureau





PCT

(43) International Publication Date 10 April 2008 (10.04.2008)

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

(21) International Application Number:

PCT/GB2007/003737

(22) International Filing Date: 2 October 2007 (02.10.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

0619534.1 3 October 2006 (03.10.2006) GH

(71) Applicant (for all designated States except US): BIOMET UK LIMITED [GB/GB]; Waterton Industrial Estate, Bridgend, South Wales CF31 3XA (GB).

(72) Inventors; and

(75) Inventors/Applicants (for US only): SINGHAL, Keshav [GB/GB]; Rhiwau, Old Port Road, Wenvoe, Cardiff CF5 6AL (GB). PITKANEN, Heikki, Vilhelm [FI/FI]; Runeberginkatu 46 C 49, FIN-00260 Helsinki (FI).

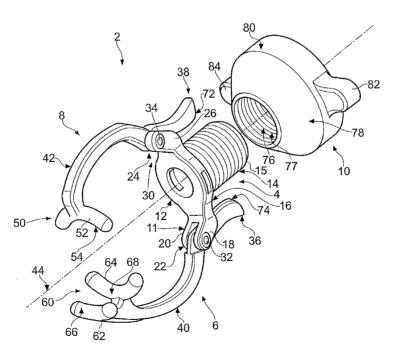
(10) International Publication Number WO 2008/040961 A1

- (74) Agent: GILES, Ashley, Simon; Haseltine Lake, Lincoln House, 300 High Holborn, London WC1V 7JH (GB).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

with international search report

(54) Title: SURGICAL INSTRUMENT



(57) Abstract: An instrument (2) for aligning a surgical tool, the instrument (2) comprising, a body portion (4) having a tool guide (90), first and second arms (6), (8) operatively connected to the body portion (4) and adapted to engage a bone, and urging means (10), acting between the body portion (4) and the first and second arms (6), (8), for urging the first and second arms (6), (8) into engagement with a predetermined portion of a bone, thereby clamping the arms (6), (8) onto the bone and aligning the tool guide (90) with the bone.



1

SURGICAL INSTRUMENT

This invention relates to a surgical instrument and particularly, but not exclusively, relates to an instrument having a tool guide and a clamping arrangement, the clamping arrangement clamping the instrument to a bone, and at the same time aligning the tool guide with the bone.

BACKGROUND

During all types of joint replacement surgery, and in many other surgical procedures, it is necessary to make specific cuts or to drill holes into specific areas of bone. Both the point and angle of entry of the cut or drill hole is important. This is particularly so in the case, for example, of femoral head resurfacing, where it is necessary to drill a pilot hole that passes through the centre of the femoral neck at a specific angle with respect both to the epicondylar axis and the femoral shaft axis. Guide tools exist to aid surgeons in the placement of bone cuts and guide holes. Such tools are often difficult and time consuming to operate, and are inaccurate. Many of the tools of the prior art are also bulky, requiring the removal or displacement of large areas of soft tissue in order to be used.

20

25

5

Use of conventional tool guides generally involves at least the steps of attaching the guide, referencing the position of the guide from an anatomical feature, and adjusting the position of the guide to correspond to the optimal position indicated in the referencing step. Several iterations of referencing and adjustment may be required to achieve the correct position and orientation of the guide.

STATEMENTS OF INVENTION

According to a first aspect of the present invention, there is provided an instrument for aligning a surgical tool, the instrument comprising, a body portion having a tool guide, first and second arms operatively connected to the body portion and adapted to engage a bone, and urging means, acting between the body portion and the first and second arms, for urging the first and second arms into engagement with a predetermined portion of a bone, thereby clamping the arms onto the bone and aligning the tool guide with the bone.

The first and second arms may terminate in first and second jaws. The first jaw may be curved and the second jaw may be bifurcated and may have at least two distinct jaw elements. As the instrument contacts the bone in at least three distinct points or areas, the instrument is held in a very stable manner relative to the bone.

5

The first and second arms may be pivotally connected to the body portion. Alternatively, the first and second arms may be connected to the body portion by means of a linkage which constrains the arms to translate laterally of the body portion towards and away from one another. The linkage may be a quadrilateral linkage. The advantage of constraining the arms to translate laterally is that the angle of the arms relative to a longitudinal axis of the body portion does not change irrespective of the diameter of the bone to be clamped. This enhances the accuracy of referencing and hence the alignment of the tool guide compared to an instrument having pivoting arms, irrespective of the size of the patient.

15

25

35

10

The first and second arms may be disposed on opposite sides of the body portion. Additional arms may also be provided. For example, three arms may be provided spaced equidistantly around the circumference of the body portion.

The urging means may engage the body portion via a threaded connection, and the urging means may be a nut. The nut may comprise a tapering engagement surface, configured to engage the first and second arms directly.

The body portion may comprise a post having projecting tabs that extend from the base of the post. The first and second arms may be mounted in opposed recesses formed in the projecting tabs. Each arm may be pivotably connected to one of the tabs by means of a pinned joint.

Each arm may be connected to the body portion at an intermediate position along its length.

The tool guide may be provided with a plurality of tool guiding openings. At least one of the tool guiding openings may be differently aligned to the or each other tool guiding openings, so that when the first and second arms are clamped to the bone, the said tool guiding opening is aligned with a different part of the bone from the or each other tool guiding opening.

3

The tool guiding openings may comprise bores having longitudinal axes at least some of which converge at a point a predetermined distance proximal of the body portion. The longitudinal axes of some of the bores may converge at a different point from the longitudinal axes of some others of the bores.

5

10

15

35

The provision of a plurality of guide holes or bores enables the surgeon to select an appropriate bore which might compensate for minor misalignment of the instrument. Furthermore, having groups of bores aligned, such that their longitudinal axes intersect at specific points, further increases the options that the surgeon has in selecting an appropriate bore to accommodate minor misalignment or variations in patient anatomy.

According to a second aspect of the present invention, there is provided an instrument for aligning a surgical tool, the instrument comprising a body portion, at least two arms pivotably connected to the body portion and a nut which engages a thread formed on the body portion, the nut engaging the arms as it is threaded onto the body portion in use, thereby forcing the free ends of the arms together to clamp a bone.

According to a third aspect of the present invention, there is provided an instrument for aligning a surgical tool, the instrument comprising a body portion, means for clamping the body portion to a bone, and a tool guide having a plurality of tool guide bores, longitudinal axes of some of the bores converging at a different point from longitudinal axes of others of the bores.

The instrument my be used in a method of aligning a tool guide, the method comprising the steps of:

- a placing the arms of the instrument about a predetermined portion of a bone; and
- 30 b operating the urging means to force the arms to clamp the bone, thereby aligning the tool guide with the bone.

The present invention represents a considerable advance over prior art devices, since simply by operating the urging means to force the arms to clamp a predetermined portion of the bone, the tool guide is automatically aligned with the bone. This is achieved because the arms of the instrument reference on a predetermined portion of

the bone which has a known orientation relative to the part of the bone which is to be drilled, cut of otherwise worked. The automatic alignment provided by the device means that no additional visual checks of the alignment of the device are required, thereby speeding up the surgical procedure. Furthermore, the level of skill and experience required in the surgeon using the instrument is reduced, whilst the accuracy of the surgery is increased. The instrument is also adaptable to different sizes of bone, so that a single instrument can be used on many patients.

BRIEF DESCRIPTION OF THE DRAWINGS

10

5

For a better understanding of the present invention, and to show more clearly how it may be carried into effect, reference will now be made, by way of example, to the accompanying drawings, in which:-

- 15 Figure 1 is an exploded perspective view of a surgical instrument,
 - Figure 2 is a plan view of the instrument of Figure 1,
 - Figure 3 is a side view of the instrument of Figure 1 mounted on a femur, and

20

Figure 4 is an end view of the instrument illustrated in Figure 3.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

- With reference to Figure 1, a surgical instrument 2 comprises a body portion 4, a pair of opposed first and second arms 6, 8 pivotally connected to the body portion 4, and a nut 10 mountable on the body portion 4. The body portion 4 comprises an annular flange 12 and a post 14 that carries an external thread 15.
- In this specification, the terms "distal" and "distally" mean towards the threaded end of the surgical instrument 2, and the terms "proximal" and "proximally" mean towards the opposite end of the surgical instrument 2.
- The post 14 projects substantially perpendicularly from a distal surface 16 of the flange
 12. A first tab 11 projects from a first (or inferior) side of the flange 12 and is
 bifurcated. A recess 22 is defined between substantially parallel forks 18, 20 of the first

WO 2008/040961

15

30

bifurcated tab 11. A second bifurcated tab 30 projects from an opposite (or superior) side of the flange 12. A second recess 24 is defined between substantially parallel forks 26, 28 of the second bifurcated tab 30.

The arms 6, 8 are mounted on the tabs 11 and 30 for pivotal motion relative to the flange 12 and post 14. The arm 6 is mounted between the forks 18, 20 on a pin 32 which extends through the forks 18, 20, and the arm 8 is mounted between the forks 26, 28 on a pin 34 which extends through the forks 26, 28. Each arm 6, 8 includes a cylindrical bore (not shown) extending across the width of the arm 6, 8, at an intermediate position along its length, through which the corresponding pin 32, 34 passes.

Other means of pivotable connections are contemplated, such as replacing the pins 32, 34 with set screws, rivets, or nut and bolt arrangements. In an alternative embodiment, not illustrated, the arms 6, 8 are connected to the body portion 4 by a quadrilateral linkage so that the arms 6, 8 move laterally of the body portion 4, rather than pivoting about the tabs 11, 30.

Each arm 6, 8 extends both proximally and distally of its respective bore such that,
when mounted in the recesses 22, 24, each arm comprises a referencing portion 40,
42, that extends proximally of the flange 12, and an engaging portion 36, 38, that
extends distally of the flange 12. Each arm 6, 8 is substantially "S" shaped, and is
mounted in its corresponding recess 22, 24 such that the engaging portion 36, 38 is
directed away form a central axis 44 of the post 14 and the referencing portion 40, 42 is
directed towards the central axis 44 of the post 14.

The referencing portion 42 of the arm 8 mounted in the second recess 24 (the superior arm) terminates at its free end in a jaw 50. The jaw 50 comprises a single jaw element 52 that extends arcuately so as to define an internal, bone receiving surface 54. The referencing portion 40 of the arm 6 mounted in the first recess 22 (the inferior arm) terminates at its free end in a jaw 60. The jaw 60 is bifurcated, comprising two jaw elements 62, 64 that each extend arcuately so as to define internal, bone receiving surfaces 66, 68.

The engagement portions 36, 38 of the arms 6, 8 define opposed curved cam surfaces 72, 74 that cooperate with an annular engagement surface formed on the nut 10.

The nut 10 comprises a bore 76 having an internal thread 77. The thread 77 cooperates with the external thread 15 formed on the post 4. The nut 10 has a frustoconical engagement surface 78 that tapers outwardly from the rim of the bore 76 to a cylindrical gripping surface 80. Projections 82, 84 are integrally formed with the cylindrical gripping surface 80 to facilitate rotation of the nut 10. Alternatively, the cylindrical gripping surface 80 may be knurled, or otherwise adapted to facilitate turning by hand. In an embodiment not illustrated, the nut may be shaped to facilitate turning using a tool.

10

15

20

5

With reference to Figure 2, the post 14 comprises a series of guide bores 90 extending from a distal surface of the post 14. The bores 90 are open, allowing communication from a distal to a proximal end of the body portion 4. The post 14 may be hollow, in which case the flange 12 includes a corresponding opening and the bores 90 extend through the distal end wall of the post 14. Alternatively, the post 14 may be solid, in which case the bores 90 extend through the length of the post 14 and the thickness of the flange 12. At least one bore 90 is positioned such that the axis of the bore 90 coincides with the longitudinal axis 44 of the post 14. The bores 90 are orientated such that the longitudinal axes of the bores 90 converge on predetermined points which are predetermined distances proximal of the body portion 4.

The instrument 2 is particularly suited for use in surgical procedures involving the hip and shoulder.

With reference to Figures 3 and 4, the instrument 2 may be used to guide a femoral alignment pin during a femoral resurfacing procedure. Prior to use, the instrument 2 is prepared by unscrewing the nut 10, so as to allow free pivoting motion of the arms 6, 8. The instrument is then placed over the femoral head with the inferior arm 6 on the inferior side of the femoral neck and the superior arm 8 on the superior side of the femoral neck. The nut 10 is then screwed onto the post 14. As the nut 10 progresses proximally down the post 14, the engagement surface 78 of the nut 10 contacts the cam surfaces 72, 74 of the engagement portions 36, 38 of the arms 6, 8. Further proximal motion of the nut 10 forces the engagement portions 36, 38 of the arms 6, 8 apart, thus bringing the jaws 50, 60 of the arms 6, 8 into contact with the femoral neck.

The nut 10 is screwed onto the post 14 until the jaws 50, 60 are firmly clamped around

7

the femoral neck. The regions or points of contact provided by the three jaw elements 52, 64, 66 ensure a stable connection between the instrument and the bone.

5

10

15

With the instrument correctly mounted on the bone, the inferior, bifurcated jaw 60 provides a three dimensional reference of the calcar surface of the femoral neck. The superior jaw 50 provides a two dimensional reference of the superior surface of the femoral neck. The position at which the instrument centres itself on the femoral neck is thus determined by the inferior angle of the femoral neck (the calcar angle) and by the diameter of the femoral neck. The curvature of the arms 6, 8, the curvatures of the cam surfaces and engagement surface 72, 74, 78, and the orientation of the bores 90 are selected such that, with the instrument clamped in the manner described above, the axes of the bores 90 converge towards the centre of the femoral neck and are aligned at an optimal collodiaphyseal angle (the angle between the femoral neck and shaft) and optimal anteversion to guide the insertion of a femoral alignment pin. The provision of several bores 90, each having a slightly different orientation, allows a surgeon a certain flexibility, enabling the most appropriate orientation for a particular patient to be selected.

CLAIMS

5

15

25

- An instrument for aligning a surgical tool, the instrument comprising, a body portion having a tool guide, first and second arms operatively connected to the body portion and adapted to engage a bone, and urging means, acting between the body portion and the first and second arms, for urging the first and second arms into engagement with a predetermined portion of a bone, thereby clamping the arms onto the bone and aligning the tool guide with the bone.
- 10 2 An instrument for aligning a surgical tool as claimed in claim 1, wherein the first and second arms terminate in first and second jaws.
 - 3 An instrument for aligning a surgical tool as claimed in claim 2, wherein the first jaw is curved.
 - 4 An instrument for aligning a surgical tool as claimed in claim 1 or 2, wherein the second law is bifurcated and has at least two distinct jaw elements.
- 5 An instrument for aligning a surgical tool as claimed in any one of the preceding claims, wherein the first and second arms are pivotally connected to the body portion.
 - An instrument for aligning a surgical tool as claimed in any one of the preceding claims, wherein the arms are connected to the body portion by means of a linkage which constrains the arms to translate laterally of the body portion, towards and away from one another.
 - 7 An instrument for aligning a surgical tool as claimed in claim 6, wherein the linkage in a quadrilateral linkage.
- 30 8 An instrument for aligning a surgical tool as claimed in any one of the preceding claims, wherein the first and second arms are disposed on opposed sides of the body portion.
- 9 An instrument for aligning a surgical tool as claimed in any one of the preceding claims, wherein the urging means engages the body portion via a threaded connection.

WO 2008/040961

5

10

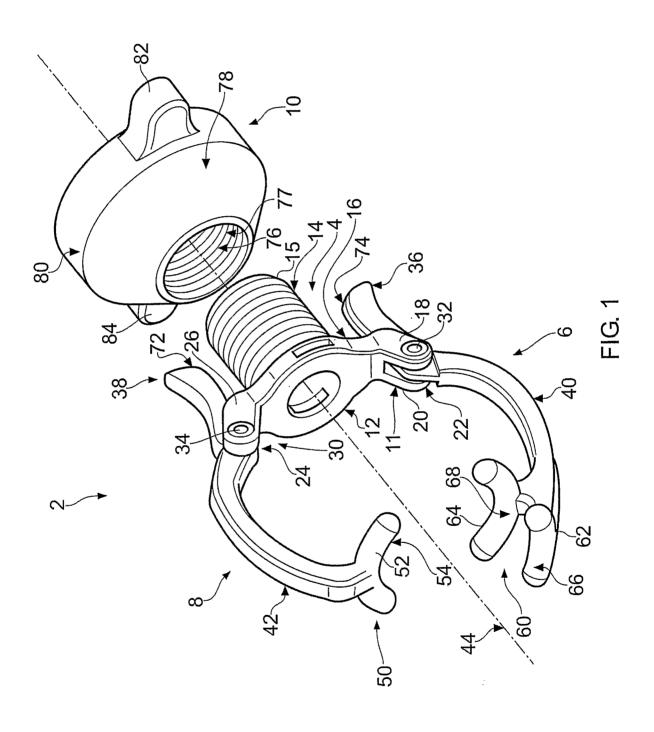
20

9

PCT/GB2007/003737

10 An instrument for aligning a surgical tool as claimed in claim 9, wherein the urging means is a nut.

- 11 An instrument for aligning a surgical tool as claimed claim 10, wherein the nut comprises a tapering engagement surface, configured to engage the first and second arms directly.
- An instrument for aligning a surgical tool as claimed in any one of the preceding claims, wherein the body portion comprises a post having projecting tabs that extend from the post.
- An instrument for aligning a surgical tool as claimed in claim 12, wherein the first and second arms are mounted in opposed recesses formed in the projecting tabs.
- 15 14 An instrument for aligning a surgical tool as claimed in claim 12 or 13, wherein each arm is pivotably connected to one of the tabs by means of a pinned joint.
 - An instrument for aligning a surgical tool as claimed in any one of the preceding claims, wherein each arm is connected to the body portion at an intermediate position along its length.
 - An instrument for aligning a surgical tool as claimed in anyone of the preceding claims, wherein the tool guide is provided with a plurality of tool guiding openings.
- 25 17 An instrument for aligning a surgical tool as claimed in claim 14, wherein at least one of the tool guiding openings is differently aligned, so that when the first and second arms are clamped on the bone, the said tool guiding opening is aligned with a different part of the bone from the or each other tool guiding opening.
- 30 18 An instrument for aligning a surgical tool, as claimed in claims 16 or 17, wherein the tool guiding openings comprise bores having longitudinal axes, at least some of which converge at a point a predetermined distance proximal of the body portion.
- 19 An instrument as claimed in claim 16, wherein the longitudinal axes of some of the bores converge at a different point from the longitudinal axes of some others of the bores.



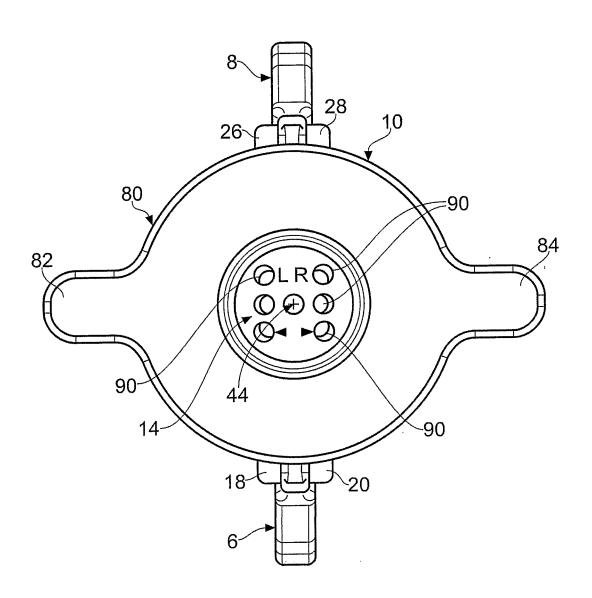
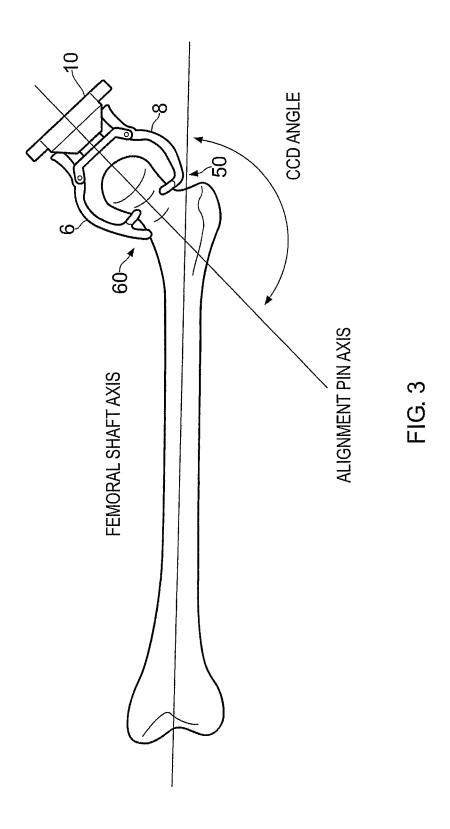


FIG. 2



4/4

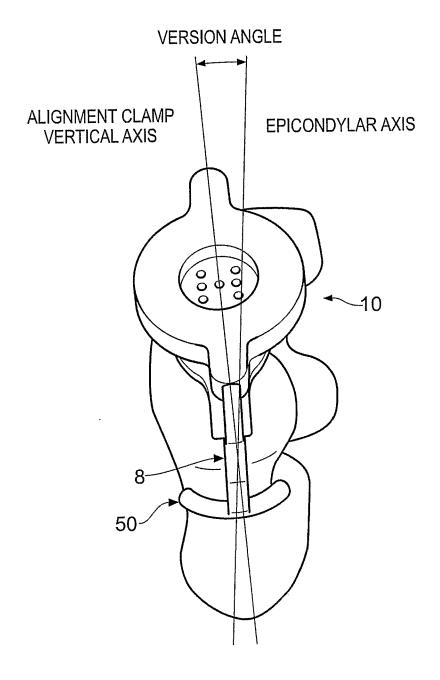


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No PCT/GB2007/003737

	ISIO A TION OF OUR LEAT							
A. CLASSI INV.	FICATION OF SUBJECT MATTER A61B17/17							
According to	o International Patent Classification (IPC) or to both national classifica	ation and IPC						
B. FIELDS SEARCHED								
Minimum do	ocumentation searched (classification system followed by classification	on symbols)	-					
Documenta	tion searched other than minimum documentation to the extent that s	uch documents are included in the fields se	earched					
Electronic d	ata base consulted during the international search (name of data base	se and, where practical, search terms used)					
EPO-In	ternal							
C. DOCUM	ENTS CONSIDERED TO BE RELEVANT							
Category*	Citation of document, with indication, where appropriate, of the rele	evant passages	Relevant to claim No.					
X	US 6 156 069 A (AMSTUTZ H.C.) 5 December 2000 (2000-12-05) page 9, line 45 - line 56; figure	· 9	1-15					
X	WO 2005/051209 A (WRIGHT MEDICAL TECHNOLOGY) 9 June 2005 (2005-06-	-09)	1-8, 12-14, 16-18					
	page 5, line 19 - page 6, line 9 page 6, line 23 - page 7, line 2 page 8, line 5 - line 8 page 8, line 15 - page 9, line 3 page 10, line 20 - page 11, line figures 1,2,14,15	17						
		-/						
Further documents are listed in the continuation of Box C. X See patent family annex.								
"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 						
	actual completion of the international search 7 January 2008	Date of mailing of the international sea 25/01/2008	arch report					
ļ	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	Nice, Philip						

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2007/003737

C(Continua	tion). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	<u> </u>	Relevant to claim No.
X	US 4 896 663 A (VANDEWALLS M.V.) 30 January 1990 (1990-01-30) column 1, line 40 - line 58 column 4, line 41 - line 66 figures 3,8		1-15
X	EP 1 588 669 A (FINSBURY (DEVELOPMENT)) 26 October 2005 (2005-10-26) paragraphs [0022], [0023], [0025], [0049], [0053]; figures 1,2		1-8

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2007/003737

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 6156069	Α	05-12-2000	NONE	
WO 2005051209	Α	09-06-2005	AU 2004292996 A1 BR PI0416213 A CN 1882285 A JP 2007512097 T US 2005113841 A1	09-06-2005 26-12-2006 20-12-2006 17-05-2007 26-05-2005
US 4896663	Α	30-01-1990	NONE	
EP 1588669	Α	26-10-2005	AT 371410 T US 2005245936 A1	15-09-2007 03-11-2005