

(21) Application No: 1122013.4  
 (22) Date of Filing: 20.12.2011

(51) INT CL: A61B 17/64 (2006.01) A61B 17/70 (2006.01)  
 (56) Documents Cited: GB 2375051 A  
 (58) Field of Search: INT CL A61B  
 Other: Online: WPI, EPODOC

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(54) Title of the Invention: Bone fixation device  
 Abstract Title: Bone fixation device

(57) A bone fixation device comprises two brackets 6, 8 each defining a bracket surface formed with part-spherical recesses. Part of a ball 12, 14, 16, 18 is mounted in each recess with an exposed face formed with a groove 26, 28 for receiving a fixation rod (2, 4 fig. 1). The brackets are held such that pairs of exposed ball faces are each in juxtaposition to define a sleeve for a fixation rod or bone screw, and means 10 are provided for urging the brackets and the exposed ball faces towards each other to clamp such a rod or screw between each pair of juxtaposed ball faces.

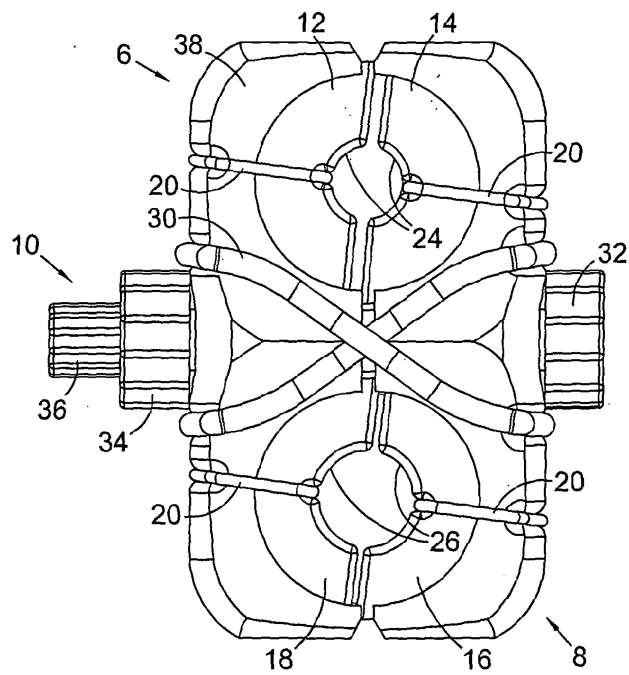


Figure 2

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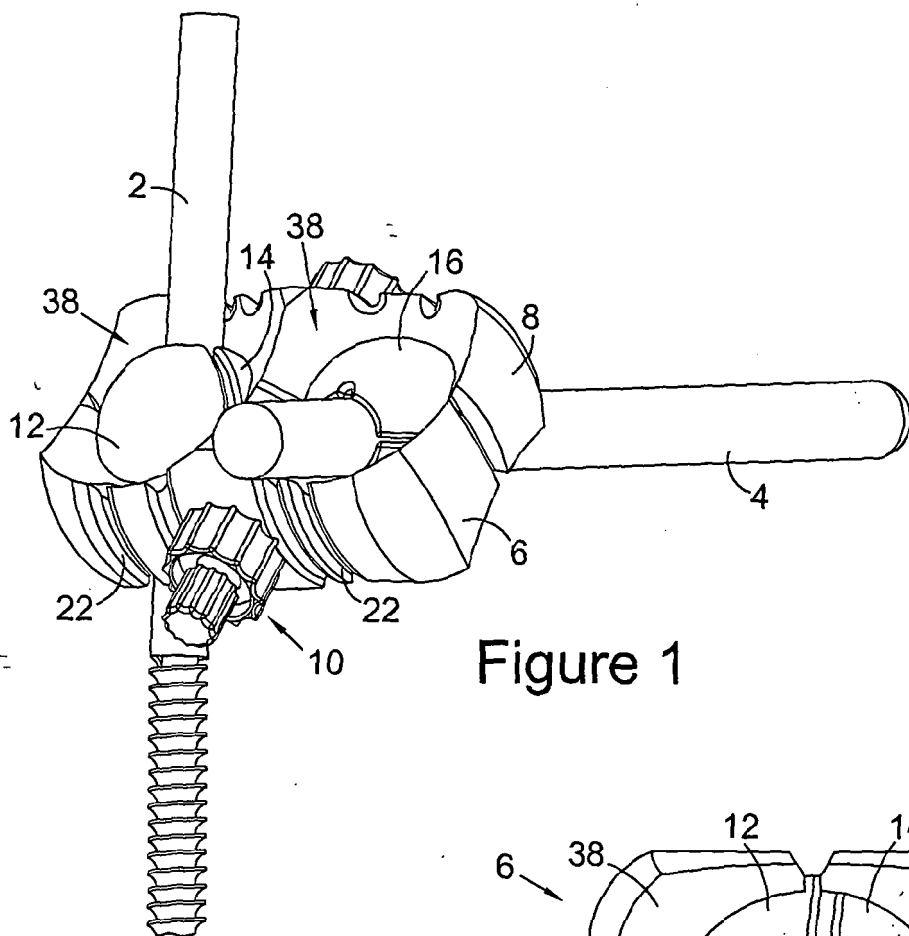


Figure 1

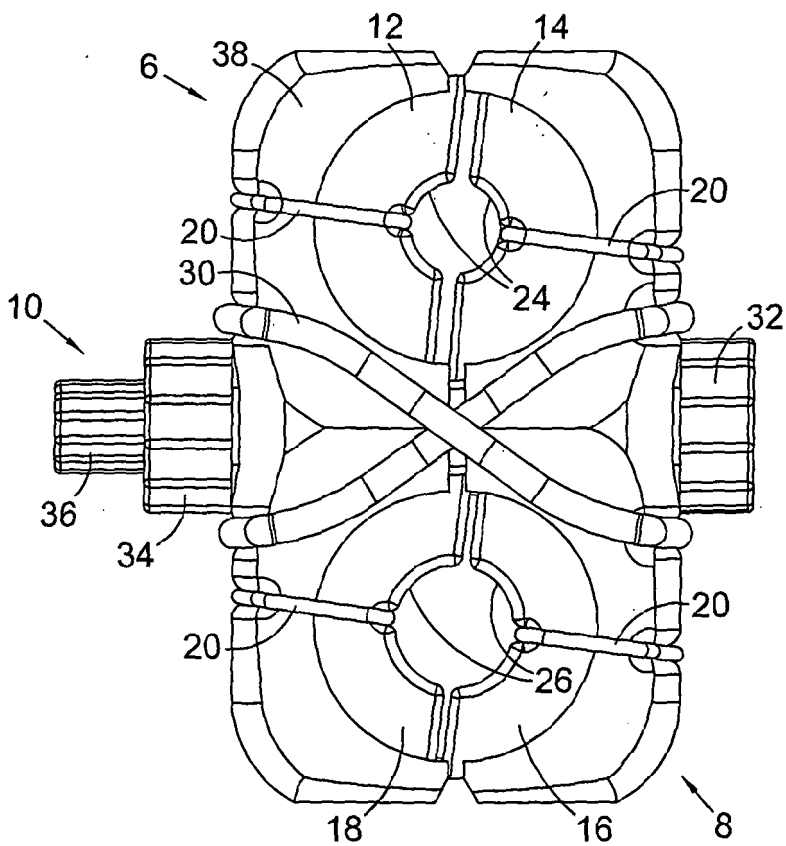


Figure 2



13 2 13

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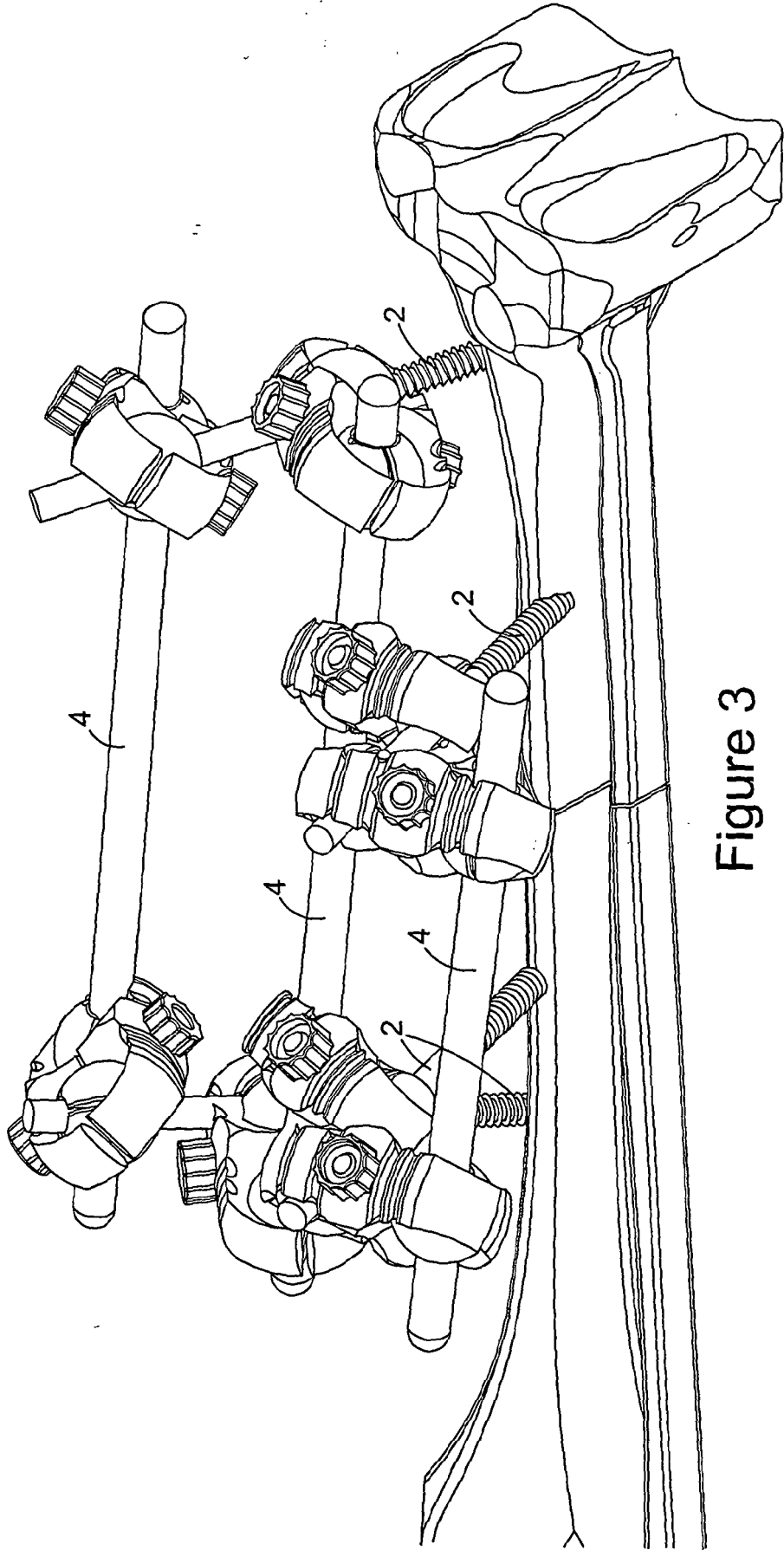


Figure 3

## Bone Fixation Device

5 This invention relates to gripping devices, and has particular use in surgical applications. It is especially useful in applications where bones or bone elements require external fixation. Such devices are commonly known as bone fixation devices, and are used to couple fixation rods to each other and to cortical bone screws secured in a bone or bone part requiring fixation. Such devices are described in European Patent No: 1 309 281, incorporated by reference. Another external fixation system for 10 surgical use is disclosed in US Patent No: 7 048 735, also incorporated by reference.

In orthopaedic surgery where bone fixation is required, devices for securing fixation rods must be fitted and manipulated in awkward locations and with great care. The aim of the present invention is to provide a device which can be easily installed, adjusted and secured, with an installed rod having the widest possible range of 15 orientations relative to another rod or bone screw fitted to the device. According to the invention, a bone fixation device comprises two brackets, each defining a bracket surface formed with part-spherical recesses. Part of a ball is mounted in each recess with an exposed face formed with a groove for receiving a fixation rod. The brackets are held such that pairs of exposed ball faces are each in juxtaposition to define a 20 sleeve for a fixation rod or bone screw, and means are provided for urging the brackets and the exposed ball faces towards each other to clamp such a rod or screw between each pair of juxtaposed ball faces. Typically a device according to the invention will be designed to couple two fixation rods or one fixation rod to a bone screw. In other words, the brackets will define two pairs of recesses, housing four part-balls and 25 between them, two grooves in each of which a fixation rod or bone screw is clamped.

The recesses for the ball parts can conveniently be provided in the form of arcuate channels. On either side of each channel the respective bracket can be shaped to form lateral recesses having the shape of shallow frusto-cones. This ensures that a rod or screw received in the respective part balls can be directed in the 30 widest possible range of orientations.

A device according to the invention is in modular form, and ultimately held assembled by the means urging the brackets and exposed ball faces towards each other. Prior thereto, the part balls can be held in their respective recesses by resilient ties, typically in the form of elastic O-rings. The brackets themselves can also be held 35 together by resilient ties, again in the form of elastic O-rings. This allows the brackets

to be separated with the part-balls attached, to allow for insertion of a fixation rod or bone screw in one of the defined grooves, or for mounting the device on a rod or bone screw if the latter is already in place. It will be appreciated that the brackets can be pivoted relative to one another to allow separate installation in one or other of the grooves. Normally, a device according to the invention will be adapted to couple two elements, but it will be appreciated that if a circumstance requires the device may be adapted to define three or more grooves. This might be required for example, if two rods are required to be mounted on the same bone screw although generally, separate fixation devices would be used.

The part-balls used in devices according to the invention will each have outlines defining substantially an hemisphere. However, it is not essential that they are identical, provided they provide for easy receipt of a fixation rod or bone screw when the brackets are separated. Typically then, the part of each part-ball face on the side of the groove past which a fixation rod or a bone screw will be installed, will be aligned with or close to the bracket edge. It is though, preferred that this part of the part-ball face is not aligned exactly with the bracket edge. In particular embodiments of the invention the space between these part-ball faces is closed by a section of the respective recess, adjacent the space between the brackets. This reduces the likelihood of a fixation rod being unintentionally withdrawn from the device during its assembly. Typically, these part-ball faces are substantially planar, and are in planes other than perpendicular to the axis along which the brackets are urged together during installation. It is preferred that each pair of juxtaposed ball faces defines a plane, and that this plane traverses the planes of the bracket surfaces when a fixation rod or bone screw is clamped between the ball faces.

As noted above, in its modular form the ball parts can be held temporarily in their respective recesses in the brackets, and the brackets themselves are also held together relatively loosely until the installed device is secured. Once the device is secured, these temporary ties can be superfluous, and may be biodegradable. If this feature is adopted, particular care must be taken when the devices are eventually removed and for this reason, there can be merit in at least the ties holding the balls in place remaining.

When a device according to the invention is installed, the brackets can be urged together by means of a locking screw. This can be a single screw extending through an opening in one of the brackets for engagement in a threaded section in the other bracket, or for extending through openings in both brackets for engagement with a

threaded locknut on the other side. In other variations the locking screw can comprise male and female threaded parts extending respectively in aligned openings in both brackets for engagement within the assembled device. Whatever mechanism is employed, it is important to ensure that any locking screw is tightened to the right degree. According to one aspect of the invention, this is accomplished by including on the locking device a torque limiting element specifically for tightening. The element is adapted to break off when the torque applied exceeds a pre-set limit. In order to minimise the risk of such an element being dropped, tightening should be completed using a wrench or other unit to which the element is or becomes attached.

Devices of the invention and their components can be made of any material suitable for the environments in which the devices are to be used. For surgical applications the selection of the materials is of course important, with stainless steel often being preferred. However, we have found that carbon fibre materials are particularly suitable for devices of the invention. Moulded carbon nanotubes materials are particularly preferred.

The invention will now be described by way of example and with reference to the accompanying drawings wherein:

Figure 1 is a perspective view of a device according to the invention mounted on a bone screw, and supporting a fixation rod;

Figure 2 is a side view of a device according to the invention assembled prior to installation; and

Figure 3 illustrates how devices according to the invention can be used in a surgical application to fixate a bone fracture.

Figure 1 shows a device according to the invention mounted on a bone screw 2, and supporting a fixation rod 4. The fixation device itself comprises two brackets 6,8 held together by a locking screw 10. The bone screw 2 is clamped between two ball parts 12,14 which are themselves held between juxtaposed recesses formed in the brackets 6 and 8. The fixation rod 4 is held in the same way between ball parts 16 and 18 received in similar recesses.

Figure 1 shows a device of invention installed and secured. Figure 2 shows the device in the form in which it would normally be supplied, with the locking screw installed but not tightened, with the other elements of the device held in place by resilient ties. The part-balls 12 and 14, and 16 and 18, are respectively held in place

by elastic O-rings 20 which fit into channels 22 formed on the outer surfaces of the brackets 6 and 8. Grooves 24 and 26 are formed in the part-balls 12,14,16,18 to define sleeves for receiving fixation rods or bone screws, and at the base of each groove is formed a channel for receiving the respective O-ring 20.

5 In the form in which the device is supplied, the brackets 6 and 8 are themselves held together by two elastic O-rings 30. With these in place, the locking screw 10 can be removed, without disrupting the assembly. The brackets can be pivoted relative to each other against the resilient force of the O-rings 30, to admit a bone screw for example into the channel formed by grooves 26, and then in the opposite sense to admit a fixation rod into the channel formed by grooves 24. The device can then be  
10 manoeuvred into the desired position on an installed bone screw with the fixation rod in the desired orientation, and the locking screw can then be installed.

As can be seen from Figure 2, the part-balls 12,14 and 16,18 have a substantially hemispherical outline, with bases defining a plane of juxtaposition. The  
15 brackets 6 and 8 also define a plane of juxtaposition between surfaces in which recesses are formed to receive the part-balls, but as can be seen the planes of juxtaposition of the part-balls are inclined to that of the brackets, the former traversing the latter. This inclination is small; typically in the range  $5^{\circ}$  to  $10^{\circ}$  and preferably  $7^{\circ}$ , and does not interfere with the installation of a fixation rod or bone screw, as described  
20 above. It does though, reduce the risk of a fixation rod or bone screw becoming inadvertently dislodged during installation. It will be noted that the plane of the O-rings 20 securing the part-balls on the brackets is similarly inclined.

In the embodiment illustrated, the locking screw 10 comprises a bolt extending through openings in the brackets 6,8 to a nut 32 mounted on the opposite side. The  
25 bolt has a head formed in two parts 34 and 36. Either part can be manipulated by hand during initial installation of the device, but when the device is to be secured only the part 36 is turned. Part 36 is a torque limiting element, and attached to the part 34 in such a manner that the attachment breaks once the torque applied exceeds a pre-set limit. This ensures that when the device is installed, the part-balls engage the fixation  
30 rod and bone screw with the right pressure. It will be noted in this respect that neither the brackets nor the ball parts should themselves be in engagement. They will be held apart by the fixation rod and bone screw.

Once the device is installed and in place, the O-rings 20 and 30 can be left in place or removed, as most appropriate to the particular circumstance.

The recesses in the brackets 6 and 8 in which the ball parts are received are defined by relatively narrow arcuate channels within the outline of each bracket. This allows for the creation of lateral recesses 38 on either side of the assembled device permitting a wide range of orientations for the fixation rod and bone screw. This versatility is illustrated in Figure 3 which shows two bone screws 2 in each of two parts of a fractured bone, interconnected by three fixation rods 4. Multiple devices are used, and the bone screws are installed at different angles, to ensure that the fixation accomplished by the rods 4 holds the fractured bone parts in their proper orientation.



## CLAIMS

- 5 1. A bone fixation device for mounting a fixation rod on a bone screw, comprising two brackets, each defining a surface formed with recesses; part of a ball mounted in each recess with an exposed face formed with a groove for receiving a said rod or screw, the brackets being held such that pairs of exposed ball faces are in juxtaposition to define sleeves for receiving a said rod or screw; and means for urging the brackets and the exposed ball faces towards each other to clamp a said rod or screw between  
10 pairs of juxtaposed ball faces.
2. A device according to Claim 1 wherein the urging means acts along an axis and the juxtaposed ball faces are in planes other than perpendicular to said axis.
3. A device according to Claim 2 wherein said bracket surfaces are planar and parallel, and wherein the plane of each pair of juxtaposed ball faces traverses the  
15 planes of said bracket surfaces when a fixation rod is clamped between the ball faces.
4. A device according to any preceding Claim wherein the outline of each ball part is substantially an hemisphere.
5. A device according to any of Claims 1 to 3 wherein the outline of each ball part is non-hemispherical, but complementary to its pair.
- 20 6. A device according to any preceding Claim wherein each ball part is held in its respective recess by a resilient ball tie.
7. A device according to Claim 6 wherein the ball tie is an elastic O-ring.
8. A device according to any preceding Claim wherein the two brackets are provisionally held against each other by a resilient bracket tie.
- 25 9. A device according to Claim 8 wherein the bracket tie comprises two elastic O-rings.
10. A device according to any of Claims 6 to 9 wherein the ties are self-degrading in water.
11. A device according to any preceding Claim wherein the urging means  
30 comprises a locking screw for coupling the brackets.
12. A device according to Claim 11 wherein the locking screw extends through an opening in one of the brackets for engagement in a threaded section in the other bracket.
13. A device according to Claim 11 wherein the locking screw extends through  
35 openings in both brackets for engagement with a threaded lock nut.

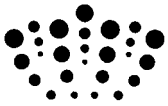
14. A device according to Claim 11 wherein the locking screw comprises male and female threaded parts extending respective in aligned openings in both brackets for engagement between the distal ends of said aligned openings.

5 15. A device according to any of Claims 11 to 14 wherein the locking screw has a torque-limiting element for tightening, which element breaks off when the torque applied thereto exceeds a pre-set limit.

16. A device according to any preceding Claim wherein the recesses for the ball parts are defined by arcuate channels within the outline of each bracket.

10 17. A device according to any preceding Claim wherein the Brackets define lateral recesses on either side of the device for universal orientation of a said rod or screw held therein.

18. A device according to any preceding Claim wherein the brackets, the ball parts, and the urging means are made of carbon fibre.



**Application No:** GB1122013.4

**Examiner:** Paul Jenkins

**Claims searched:** 1-18

**Date of search:** 22 March 2012

**Patents Act 1977: Search Report under Section 17**

**Documents considered to be relevant:**

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1-5, 11-12, 16-17 at least	GB 2375051 A (BIOMET) whole document relevant see especially ball-like couplings 24 & 70 in figure 2.

**Categories:**

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

**Field of Search:**

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC<sup>X</sup> :

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Worldwide search of patent documents classified in the following areas of the IPC

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The following online and other databases have been used in the preparation of this search report

WPI, EPODOC
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**International Classification:**

Subclass	Subgroup	Valid From
A61B	0017/64	01/01/2006
A61B	0017/70	01/01/2006