



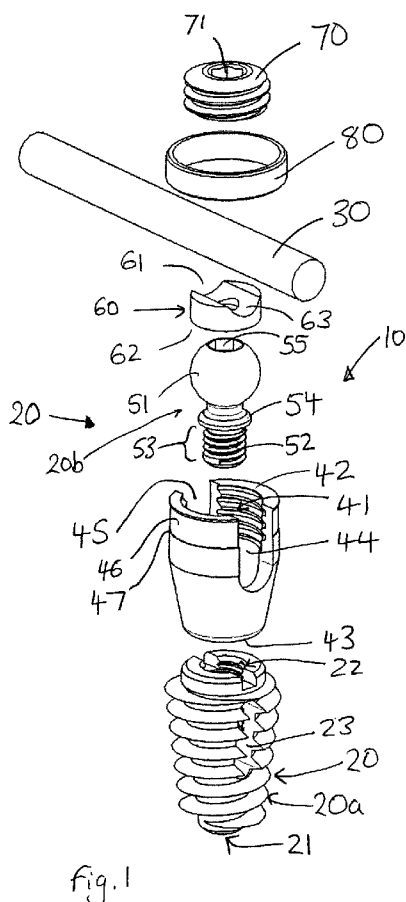
(43) International Publication Date
25 September 2014 (25.09.2014)

- (51) International Patent Classification:
A61B 17/70 (2006.01) *A61B 17/86* (2006.01)
- (21) International Application Number:
PCT/GB2014/050570
- (22) International Filing Date:
26 February 2014 (26.02.2014)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
1304921.8 18 March 2013 (18.03.2013) GB
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- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, 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, IR, IS, JP, KE, KG, 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, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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(54) Title: SPINAL IMPLANT ASSEMBLY



(57) Abstract: A spinal implant assembly (10, 110) comprising an intervertebral device (20) configured to be installed in a spinal disc space, the intervertebral device having a head component (20b) and a body component (20a), the spinal implant assembly further comprising a coupling body (40) for coupling the head component (20b) of the intervertebral device (20) and an elongate member (30), the coupling body (40) and head component (20b) each having a longitudinal axis, wherein the head component (20b) can be received by the coupling body (40) with its longitudinal axis at a selected angle within a predetermined range of angles relative to the longitudinal axis of the coupling body.





(84) **Designated States** (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK,

SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

Spinal Implant Assembly

Field of the Invention

- 5 The invention relates to a spinal implant assembly. More specifically the invention relates to assemblies with parts for implantation into intervertebral space between adjacent vertebrae of the spine.

Background to the Invention

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The spine or vertebral column comprises a plurality of separate vertebrae. The vertebrae are movable relative to one another, and separated from one another by fibrocartilage called inter-vertebral discs.

- 15 In its entirety, the spinal column is highly complex in that it houses and protects critical elements of the nervous system which have innumerable peripheral nerves and arterial and venous bodies in close proximity. In spite of these complexities, the spine is a highly flexible structure, capable of a high degree of curvature and twist through a wide range of motion. The intervertebral discs provide mechanical cushion between
20 adjacent vertebrae. Genetic or developmental irregularities, trauma, chronic stress, tumors, and disease, however, can result in spinal pathologies which either limit this range of motion, or which threaten the critical elements of the nervous system housed within the spinal column. A variety of systems have been disclosed in the art which achieve immobilization by implanting artificial assemblies in or on the spinal column.

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- In order to treat certain injuries or conditions of the spinal column an intervertebral device may be placed in the intervertebral disc space to fuse or promote fusion of adjacent vertebrae. Such fusion devices are often used in combination with stabilisation systems wherein a metal rod that is bendable to match the natural
30 curvature of the spine is mechanically attached at strategically selected vertebrae, allowing the rod to be rigidly fixed to the spine. This provides a rigid support to the spinal column. For this, pedicle screws located in the bone structure are typically fixed to a specially designed clamp to attach to a spinal rod. A problem with these stabilisation systems is that parts of the vertebra cannot stably receive a bone screw,

or can only receive a bone screw screwed in at a certain angle. Also, for spinal fixings for small animals, within the confined spaces allowed therein, conventional rod anchoring methods are not suitable since the placement of the pedicle screw and the direction of the rod cannot be matched adequately. A system that can be used in small animals is needed, wherein confined spaces make conventional rod anchoring systems unsuitable. Furthermore, many devices for providing positioning of bone screws with respect to a stabilising rod loosen over time, providing an unstable joint. There is therefore a need for a solution that overcomes one or more of these problems.

10 Summary of Invention

According to a first aspect of the invention there is provided a spinal implant assembly comprising an intervertebral device configured to be installed in a spinal disc space, the intervertebral device having a head component and a body component, the spinal implant assembly further comprising a coupling body for coupling the head component of the intervertebral device and an elongate member, the coupling body and head component each having a longitudinal axis, wherein the head component can be received by the coupling body with the longitudinal axis of the head component at a selected angle within a predetermined range of angles relative to the longitudinal axis of the coupling body. Suitably the head component can be adjusted polyaxially relative to the coupling body.

The intervertebral device provides a stable anchorage for the spinal stabilisation system provided by the elongate member.

Suitably the spinal implant assembly can be adapted to provide a locked configuration, wherein the head component and/or elongate member are locked in position relative to the coupling body, and an adjustable configuration, wherein the position of the head component and/or elongate member relative to the coupling body can be adjusted.

Preferably the assembly further comprises an elongate member, the coupling body receiving the elongate member and the head component of the intervertebral device when assembled.

The head component and body component can be integral, however preferably are releasably attachable to one another.

Preferably the head component of the intervertebral device is releasably attachable to the body component via a threaded connection.

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Preferably the head component has a head portion and a shank portion, the shank portion being at least partially externally threaded, the body component having a bore with a first open end, the bore being at least partially internally threaded, the internal threads of the bore corresponding with the external threads of the shank portion of the head component such that the head component is releasably attachable to the body component.

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Preferably the head portion of the head component is at least partially spherical.

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Preferably the coupling body comprises a hollow tubular body, the head portion of the head component being receivable in the hollow tubular body.

Preferably the coupling body has a first opening in a first end and a second opening in a second end, the first opening being larger in diameter than that of the head portion and the second opening being smaller in diameter than that of the head portion, a portion of the inner surface of the coupling body having a concavely curved inner surface, the curved inner surface corresponding with the at least partially spherical head portion, such that the head component may be positioned polyaxially relative to the coupling body when assembled.

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Preferably the coupling body has at least a first slot. Suitably the elongate member suitably extends through the first slot when assembled with the coupling body. The slot communicates with the first open end of the coupling body. In some embodiments, when assembled, the elongate member can pivot relative to the coupling body, within the first slot, over a pre-determined range of motion.

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Preferably the coupling body has a second slot. Suitably the elongate member extends through the second slot when assembled with the coupling body. The first and/or second slots preferably are elongate, the or each slot having a longitudinal axis parallel

with the longitudinal axis of a bore of the coupling body. Where the elongate member is a rod, the elongate member will extend through both the first and second slots when assembled, the first and second slots effectively providing a rod receiving channel.

- 5 Preferably the elongate member comprises a rod.

Preferably the elongate member has a first end that is at least partially spherical.
Preferably the elongate member has a second end that is at least partially spherical.

- 10 Preferably the assembly further comprises a washer for location between the head component and the elongate member when assembled.

Preferably the washer has first and second opposing surfaces, the first surface being concavely curved and facing the first end of the elongate member when assembled.

- 15 Such a washer will be used to engage the elongate member when it has a first end that is at least partially spherical.

Preferably the washer has first and second opposing surfaces, the first surface having an elongate groove for receiving the elongate member when assembled. Such

- 20 embodiments are suitable for use with a rod-like elongate member.

Preferably the washer has first and second opposing surfaces, the second surface being concavely curved and facing the head component when assembled.

- 25 Preferably at least part of the body component of the intervertebral device is externally tapered.

Preferably the body component has a proximal end and a distal end and the external taper of the body component tapers towards the proximal end of the bolt. In this
30 context the term proximal used in relation to parts of spinal implants or spinal fixings means located nearer or towards the centre of the subject's body or spine when the implant part or fixing part is installed and distal means located away from the centre of the body or spine when the implant part or fixing part is installed. The term subject as used herein can be a human or animal subject.

The maximum diameter of the body component at any point along its longitudinal axis is greater than the opening in the second open end of the coupling body. In this way, the coupling body can be compact whilst the body component can be large in diameter, suitable for vertebral distraction and stable anchoring in the disc space.

Preferably at least part of the body component is externally threaded.

Preferably the body component has a hollow bore.

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Preferably the head component has a shank portion insertable within the hollow bore of the body component, the shank portion of the head component being shorter in length than the hollow bore of the body component such that with the shank portion fully inserted in the body component, at least some hollow space in the hollow bore remains unoccupied by the shank portion. This allows for bone ingrowth into the body component when installed, thus improving the stability of the anchorage.

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Preferably the body component has at least one aperture, the aperture communicating with the hollow bore. Suitably said at least one aperture is not obscured, or is only partially obscured, by the shank portion of the head component when assembled, such that the aperture communicates with the hollow bore when the spinal implant assembly is assembled.

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Preferably at least part of the body component is hydroxyapatite coated.

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Preferably the assembly further comprises a compression member for compressing the elongate member and the head component in locking engagement within the coupling body.

Preferably the compression member is a locking screw. The locking screw may be externally threaded, the coupling body having a bore with first and second open ends, at least part of the bore being internally threaded, the internal threads of the bore corresponding with the external threads of the locking screw. Preferably the assembly further comprises a ring, configured to be received around the coupling body when

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assembled.

There is also provided a spinal implant system comprising two or more spinal implant assemblies according to any previous aspect of the invention and an elongate member, wherein the assemblies are configured to be coupled together using the elongate member. This provides a system wherein a first implant assembly can be installed in a first disc space and a second implant assembly can be installed in a second, adjacent disc space, and the spine can be stabilised by the coupling of the implant assemblies using the elongate member. Further implant assemblies installed in further disc spaces can be assembled, all being coupled by a single elongate member. Alternatively a first implant assembly can be installed in a disc space and a second implant assembly can be installed in the same disc space.

The assembly can also be used as part of a spinal implant system comprising a spinal implant assembly according to any preceding claim and an elongate member, wherein the system further comprises a spinal fixing comprising a bone fastener configured to be installed into bone and a coupling body for receiving the bone fastener and said elongate member such that the elongate member couples the spinal implant assembly and spinal fixing when the system is assembled. The bone fastener may be a pedicle screw for example, suitable for installation into a vertebra.

There is also provided a kit for assembly into a spinal implant assembly or system, wherein the kit comprises the parts of the assembly according to any previous aspect of the invention. A modular kit can be provided wherein intervertebral devices of differing dimensions are provided, for example.

There is also provided a computer program embodied on a computer readable medium for manufacturing a spinal implant assembly or system to any previous aspect of the invention.

There is also provided a method of installing a spinal implant assembly, the method comprising the steps of providing a spinal implant assembly, the spinal implant assembly comprising an intervertebral device configured to be installed in a spinal disc space, the intervertebral device having a head component and a body component, the

spinal implant assembly further comprising a coupling body for coupling the head component of the intervertebral device and an elongate member, the coupling body and head component each having a longitudinal axis, wherein the head component can be received by the coupling body with its longitudinal axis at a selected angle within a predetermined range of angles relative to the longitudinal axis of the coupling body, the method further comprising

implanting the body component of the intervertebral device between adjacent vertebrae or between a vertebra and the sacrum;

coupling the intervertebral device with the coupling body, before or after implanting the body component, wherein the head component can be received by the coupling body such that its longitudinal axis is at a selected angle within a predetermined range of angles relative to the longitudinal axis of the coupling body.

Brief Description of the Drawings

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A preferred embodiment of the present invention will now be more particularly described by way of example only with reference to the accompanying drawings, wherein:

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Figure 1 is an exploded view of a spinal implant assembly;

Figure 2 is a perspective view of the assembly of Figure 1, assembled together;

Figure 3 is a side view of the assembly of Figure 2, but with the longitudinal axis of the intervertebral device shown non-parallel with that of the coupling body;

Figure 4 is a cross-sectional view of the assembly of Figure 2;

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Figures 5 to 7 show another embodiment, similar to that of Figures 1 to 4, but wherein the elongate member is a dumbbell rather than a rod;

Figure 5 is an exploded view of a spinal implant assembly;

Figure 6 is a perspective view of the assembly of Figure 4, assembled together;

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Figure 7 is a cross-sectional view of the assembly of Figure 6.

Description of the Preferred Embodiments

The present embodiments represent currently the best ways known to the applicant of

putting the invention into practice. But they are not the only ways in which this can be achieved. They are illustrated, and they will now be described, by way of example only.

5 Referring to Figure 1, this shows a spinal implant assembly 10 according to a first embodiment. The assembly can be used to fuse two or more vertebra together, in order and to provide stabilisation of the spine. The assembly 10 comprises an intervertebral device 20, an elongate member 30 and a coupling body 40. The assembly is designed such that the intervertebral device 20 can be coupled for
10 multiaxial positioning relative to the coupling body 40 and elongate rod 30.

The intervertebral device 20 comprises a body component 20a and a head component 20b. The body component 20a of the intervertebral device is configured for installation in a spinal disc space between any two vertebrae of a subject, including the space
15 between the sacrum and the adjacent vertebra. The body component 20a of the intervertebral device is a tapered bolt that can be used to induce fusion and distraction when implanted. The bolt 20a has a proximal end 21 and a distal end 22, and is tapered towards the proximal end 21. The external surface of the bolt 20a is threaded with deep threads for cutting into vertebral bone on either side of the spinal disc space.
20 The threads are thin in section and very pronounced, to cut into the bone and aid the insertion process.

The bolt 20a has a hollow bore. The proximal end 21 is closed and the distal 22 end is open. Alternatively, the proximal end 21 may be open. The hollow bore is internally
25 threaded, at least partially, at or near the distal end 22 of the bolt.

The bolt has a first elongate slot 23, having a longitudinal axis running parallel with the longitudinal axis of the bolt 20. The bolt has a second elongate slot opposite the first elongate slot (not visible in the figures). The bolt may have more than two elongate
30 slots. The outer surface of the bolt 20 may have a hydroxyapatite coating to stimulate bone ingrowth.

The head component 20b of the intervertebral device has a head portion 51 and a shank portion 52. The shank portion 52 has an externally threaded portion 53 and an

enlarged shoulder 54. The externally threaded shank portion 52 is receivable within the hollow bore of the bolt 20a, the external threads of the shank portion 52 corresponding with the internal threads of the hollow bore of the bolt 20a, such that the head component 20b is releasably attachable to the bolt 20a. The enlarged shoulder
5 54 butts up against the distal end 22 of the bolt 20a when the shank portion 52 is fully inserted in the bolt 20a.

The head portion 51 and shank portion 52 of the head component 20b are preferably integral with one another. The head portion 51 comprises a substantially spherical
10 head with a female recess 55 at its distal end. The recess is hexagonal in shape. The recess 55 can receive a wrench or other torque-transferring tool, for transferring torque to the head component 20b during assembly, to assemble it to the bolt 20a. Alternatively, the recess 55 may be a shape other than hexagonal, the shape being suitable for receiving torque transfer from a suitable tool. In an alternative embodiment
15 the head portion 51 can comprise a part-spherical portion and removable rocker, to form a substantially complete ball end. The term part-spherical as used herein refers to a surface that comprises a portion of a sphere.

The coupling body 40 comprises a tubular, hollow body. The coupling body 40 has a
20 bore 41 having first and second open ends. The first and second open ends each have an opening that is circular in shape 42,43, the first opening communicating with first and second elongate slots 44, 45, disposed in opposite sides of the coupling body 40. The elongate slots 44,45 extend from the first opening 42, part of the way down the side of the coupling body 40. The elongate slots 44, 45 form a channel for receiving
25 the elongate member 30 when assembled. The second opening 43, in the proximal end, is smaller in diameter than the first opening 42. The first opening 42 is large enough to receive the head portion 51 of the head component 20b therethrough. The second opening 43 is surrounded by a curved inner surface, internally to the coupling body 40. The curvature of the curved inner surface corresponds to the curvature of the
30 head portion 51, such that the head portion 51 can pivot smoothly in the coupling body 40 within a pre-determined range of angles relative to the coupling body 40 when the head component 20b is received within the coupling body 40.

The assembly further comprises a washer 60, located between the head component

20b and the elongate member 30 when assembled. The washer 60 is circular in shape, having first and second opposing surfaces 61, 62 (top and bottom surfaces, or distal and proximal surfaces). The first surface 61 has an elongate groove 63 for receiving the elongate member 30 when assembled. The second surface 62 is concavely curved (not visible in the figures). The groove 63 in the first surface and concavely curved second surface form sockets for receiving the elongate member 30 and head portion 51 respectively. The intermediate conforming washer 60 increases the surface contact area that would exist between the head portion 51 and the elongate member 30, if the washer were not present. The washer allows the distribution of loads evenly between the head portion 51 and the elongate member 30.

In some embodiments the sockets in the washer conform in shape with the corresponding piece of the assembly to be received therein. In alternative embodiments, the first and second surfaces of the washer may include one or more points or edges that, when the assembly is subjected to compressive force by a locking member 70 (described below), bite into the respective members the washer engages with. The axial mouth of the groove 63 may have a transverse diameter that is smaller than the radius of the elongate member. Similarly the radius of curvature of the second surface 62 may be slightly less than the radius of curvature of the head portion 51. This non-conformance between the sockets in the first and second surfaces of the washer and the corresponding head portion and elongate member provides an edge contact between the socket and the member to be received therein, which enhances the locking mechanism provided by the washer.

The elongate extension 30 is a rod. The rod may of course be long or short, and may be fixed to the subject using another fixing device at its end or at one or more points along the length of the rod. The rod may be longer than as shown in Figures 1 to 3. The rod may be straight or curved. The rod may be flexible, such that it can be curved into a desired shape by the surgeon during installation.

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The assembly further comprises a locking screw 70, which acts as a compression member in use, to compress the elongate member 30, washer 60, and head component 20b together, against the inside of the coupling body 40, and therefore to lock the head component 20b at a selected angular orientation relative to the coupling

body 40. The locking screw 70 has a circular cross-section, and has externally threaded sides. The coupling body 40 has internal threading on at least part of its internal surface, near to the first opening 42. The internal threads of the coupling body 40 correspond with the external threads of the locking screw 70. The locking screw 70 can be screwed into the first opening 42 of the coupling body, thus providing a compressive force on the elongate member 30, washer 60 and head component 20b. The locking screw 70 has a hexagonal shaped recess 71 in its top surface (distal surface), which can receive a hexagonal shaped torque-transferring tool for tightening the locking screw 70 in threaded engagement in bore 41. Alternatively the recess 71 may be a shape other than hexagonal, the shape being suitable for receiving torque transfer from a suitable tool.

The Figure 1 embodiment also includes a further optional feature, ring 80. The ring 80 is a circular piece which is shaped and dimensioned to sit in a recessed region 46 in the outer wall of the distal end of the coupling body 40, as shown assembled in Figure 2. The ring 80 is placed in the recessed region 46, the ring 80 butting up against a shoulder on the outer wall of the coupling body 40. The ring 80 is usually placed around the coupling body 40 before the locking screw 70 is tightened. The ring 80 captivates the distal end of the coupling body 40, preventing the split distal end of the coupling body from springing apart as the locking screw 70 is tightened. The ring is shown in the embodiment of Figures 1 to 4, but it is an optional part of the assembly.

In operation, in order to assemble the spinal implant assembly and install it in a subject, the shank portion 52 of the head component 20b is inserted, through the first opening 42, then through the second opening 43 of the bore 41 of the coupling body 40, until the head portion 51 butts up against the internal edges of the second opening 43. A torque-transferring tool, such as a wrench, is received in recess 55 to threadedly secure the head component 20b to the bolt 20a. The bolt 20a may already be installed in a subject's disc space or may be installed in a subject's disc space after the head component 20b with coupling body 40 assembled thereto is secured to the bolt 20a.

When installing the bolt 20a in the subject it is inserted in the disc space between adjacent vertebrae or at the lumbo-sacral joint. The threads on the external surface of the bolt 20a cut into the bone during insertion. The hollow bore of the bolt 20a can be

impregnated with bone graft before insertion of the bolt 20a in the subject. The subject's bone will ingrow, through the elongate slots 23, and attach with the bone graft inside the hollow section of the bolt 20a. This further anchors the bolt 20a in the subject. Even if no bone graft is inserted in the hollow of the bolt 20a before
5 implantation of the bolt 20a into the subject, cutting of the subject's bone by the bolt threads as the bolt is inserted will create bone debris that will accumulate, via the elongate slots 23, in the hollow bore of the bolt 20a. The subject's bone will ingrow, through the elongate slots 23, and attach with the accumulated bone debris, further anchoring the bolt 20a against rotation.

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The washer is then inserted in the coupling body, with the second surface 62 facing the head component 20b, then the elongate member 30 is inserted in the slots 44, 45 of the coupling body 40.

15 With the assembly assembled as described above, the coupling body 40 can pivot relative to the anchored intervertebral device 20 (comprising the bolt 20a and head component 20b), giving rise to polyaxial positioning within a predetermined angle range. Therefore, the assembly is in this adjustable configuration, it provides a polyaxial or universal joint between the bolt 20a and the coupling body 40 and also
20 between the bolt 20a and the elongate member 30. The elongate extension can slide within the slots 44, 45, relative to the coupling body 40. The locking screw 70 can be tightened within the threaded bore 41, with the ring 80 in place around the coupling body 40, to compress the head component 20b, washer 60 and elongate member 30 together, against the inside of the coupling body 40, until the elongate member 30 and
25 intervertebral device 20 are locked, relative to the coupling body, such that they can no longer be positionally adjusted. An assembled device is shown in Figure 2. A further assembled device in which the longitudinal axis of the intervertebral device 20 is non-parallel with that of the coupling body 40 is shown in Figure 3.

30 The spinal implant assembly can be provided as part of a system in which two or more spinal implant assemblies, as described above, are coupled by a single elongate member 30. A first implant assembly can be installed in a first disc space and a second implant assembly can be installed in a second, adjacent disc space, and the spine can be stabilised by the coupling of the implant assemblies using the elongate

member. Alternatively a first implant assembly can be installed in a disc space and a second implant assembly can be installed in the same disc space.

Instead of a bolt, the body component 20a may be an interbody cage.

5

The spinal implant assembly can also be provided as part of a system in which one or more spinal implant assemblies, as described above, are coupled to at least one spinal fixing having a simple pedicle screw or other bone fixing means, which is coupleable to the elongate member 30 via a suitable coupling body.

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Figures 5 to 7 show an alternative embodiment for a spinal implant assembly 110 similar to that of Figures 1 to 4. The same reference numerals have been used in Figures 5 to 7 to refer to components which are substantially the same as those in the previous embodiment. The implant assembly 110 differs from that of Figures 1 to 4 in that the elongate member 130 in the Figure 5 embodiment has first and second ball ends 131, 132 joined by a rod portion 134. Each ball end 131, 132 is substantially spherical, such that the elongate member 130 is like a dumbbell. Each ball end 131, 132 can have a diameter that is substantially the same as that of the head portion 51 of head component 20b.

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For the embodiment of Figure 5, both the first and second surfaces 161 of the washer 160 will be concavely curved. The washer 161 has a notch 164 extending between the first surface 161 and the side of the washer. When assembled, the notch 164 faces toward the rod portion 134 of the elongate member 130.

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The coupling body 141 only has one slot 144 (although it can have a second slot on the opposing side).

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The underside 171 of the locking screw 170 has a concavely curved surface corresponding with the curvature of the first ball end 131 of the elongate member 130. The elongate member can pivot relative to the coupling body 140, along the axis of slot 144, when the locking screw 170 is not fully tightened. The notch 164 in the washer 160 allows for a greater range of movement when the elongate member 130 pivots within slot 144.

The second ball end 132 can be received within the coupling body 40 of a second spinal implant assembly like that of Figure 5, or some other spinal implant assembly (such as an assembly including a pedicle screw rather than an intervertebral device
5 with detachable head component).

In alternative embodiments, the elongate member 130 may have only a first ball end 130 which is received by the coupling body 40, the elongate member forming a simple rod extending from the first ball end 130.

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Like the embodiment of Figures 1 to 4, the assembly of Figures 5 to 7 allows polyaxial positioning of the bolt 20a relative to the coupling body 140 when the assembly is in an adjustable configuration (when the locking member 170 is not tightly compressing the assembly components) but not when the assembly is in a locked configuration (when
15 the locking member not tightly compressing the assembly components).

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The embodiment of Figures 5 to 7 is installed in a very similar manner to that of Figures 1 to 4.

Claims

1. A spinal implant assembly comprising
an intervertebral device configured to be installed in a spinal disc space, the
5 intervertebral device having a head component and a body component,
the spinal implant assembly further comprising a coupling body for coupling the
head component of the intervertebral device and an elongate member, the coupling
body and head component each having a longitudinal axis,
wherein the head component can be received by the coupling body with the
10 longitudinal axis of the head component at a selected angle within a predetermined
range of angles relative to the longitudinal axis of the coupling body.
2. A spinal implant assembly according to claim 1, wherein the assembly further
comprises an elongate member, the coupling body receiving the elongate member and
15 the head component of the intervertebral device when assembled.
3. A spinal implant assembly according to any preceding claim, wherein the head
component of the intervertebral device is releasably attachable to the body component.
- 20 4. A spinal implant assembly according to any preceding claim, wherein the head
component of the intervertebral device is releasably attachable to the body component
via a threaded connection.
5. A spinal implant assembly according to any preceding claim, wherein the head
25 component has a head portion and a shank portion, the shank portion being at least
partially externally threaded,
the body component having a bore with a first open end, the bore being at least
partially internally threaded, the internal threads of the bore corresponding with the
external threads of the shank portion of the head component such that the head
30 component is releasably attachable to the body component.
6. A spinal implant assembly according to any preceding claim, wherein the head
portion of the head component is at least partially spherical.

7. A spinal implant assembly according to any preceding claim, wherein the coupling body comprises a hollow tubular body, the head portion of the head component being receivable in the hollow tubular body.
- 5 8. A spinal implant assembly according to claim 7, wherein the coupling body has a first opening in a first end and a second opening in a second end, the first opening being larger in diameter than that of the head portion and the second opening being smaller in diameter than that of the head portion, a portion of the inner surface of the coupling body having a concavely curved inner surface, the curved inner surface
10 corresponding with the at least partially spherical head portion, such that the head component may be positioned polyaxially relative to the coupling body when assembled.
9. A spinal implant assembly according to any preceding claim, wherein the
15 coupling body has at least a first slot.
10. A spinal implant assembly according to claim 9, wherein the coupling body has a second slot.
- 20 11. A spinal implant assembly according to any preceding claim, wherein the elongate member comprises a rod.
12. A spinal implant assembly according to any preceding claim, wherein the elongate member has a first end that is at least partially spherical.
25
13. A spinal implant assembly according to claim 12, wherein the elongate member has a second end that is at least partially spherical.
14. A spinal implant assembly according to any preceding claim, wherein the
30 assembly further comprises a washer for location between the head component and the elongate member when assembled.
15. A spinal implant assembly according to claim 14, wherein the washer has first and second opposing surfaces, the first surface being concavely curved and facing the

first end of the elongate member when assembled.

16. A spinal implant assembly according to claim 14, wherein the washer has first and second opposing surfaces, the first surface having an elongate groove for receiving the elongate member when assembled.

17. A spinal implant assembly according to any of claims 13 to 15, wherein the washer has first and second opposing surfaces, the second surface being concavely curved and facing the head component when assembled.

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18. A spinal implant assembly according to any preceding claim, wherein at least part of the body component of the intervertebral device is externally tapered.

19. A spinal implant assembly according to claim 18, wherein the body component has a proximal end and a distal end and the external taper of the body component tapers towards the proximal end of the bolt.

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20. A spinal implant assembly according to any preceding claim, wherein at least part of the body component is externally threaded.

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21. A spinal implant assembly according to any preceding claim, wherein the body component has a hollow bore.

22. A spinal implant assembly according to claim 21, wherein the head component has a shank portion insertable within the hollow bore of the body component, the shank portion of the head component being shorter in length than the hollow bore of the body component such that with the shank portion fully inserted in the body component, at least some hollow space in the hollow bore remains unoccupied by the shank portion.

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23. A spinal implant assembly according to claim 21 or 22, wherein the body component has at least one aperture, the aperture communicating with the hollow bore.

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24. A spinal implant assembly according to any preceding claim, wherein at least part of the body component is hydroxyapatite coated.

25. A spinal implant assembly according to any preceding claim, wherein the assembly further comprises a compression member for compressing the elongate member and the head component in locking engagement within the coupling body.

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26. A spinal implant assembly according to any claim 25, wherein the compression member is a locking screw.

27. A spinal implant assembly according to any preceding claim, wherein the assembly further comprises a ring, configured to be received around the coupling body when assembled.

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28. A spinal implant system comprising two or more spinal implant assemblies according to any preceding claim and an elongate member, wherein the assemblies are configured to be coupled together using the elongate member.

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29. A kit for assembly into a spinal implant assembly or system according to any preceding claim, wherein the kit comprises the parts of the assembly according to any preceding claim.

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30. A computer program embodied on a computer readable medium for manufacturing a spinal implant assembly or system to any preceding claim.

31. A method of installing a spinal implant assembly according to any of claims 1 to 27, the method comprising the steps of

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providing a spinal implant assembly according to any of claims 1 to 27;

implanting the body component of the intervertebral device between adjacent vertebrae or between a vertebra and the sacrum;

coupling the intervertebral device with the coupling body, before or after implanting the body component, wherein the head component can be received by the coupling body such that its longitudinal axis is at a selected angle within a predetermined range of angles relative to the longitudinal axis of the coupling body.

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32. A spinal implant assembly, spinal implant system, a kit, and/or a method of

installing a spinal implant assembly substantially as hereinbefore described with reference to any suitable combination of the accompanying drawings.

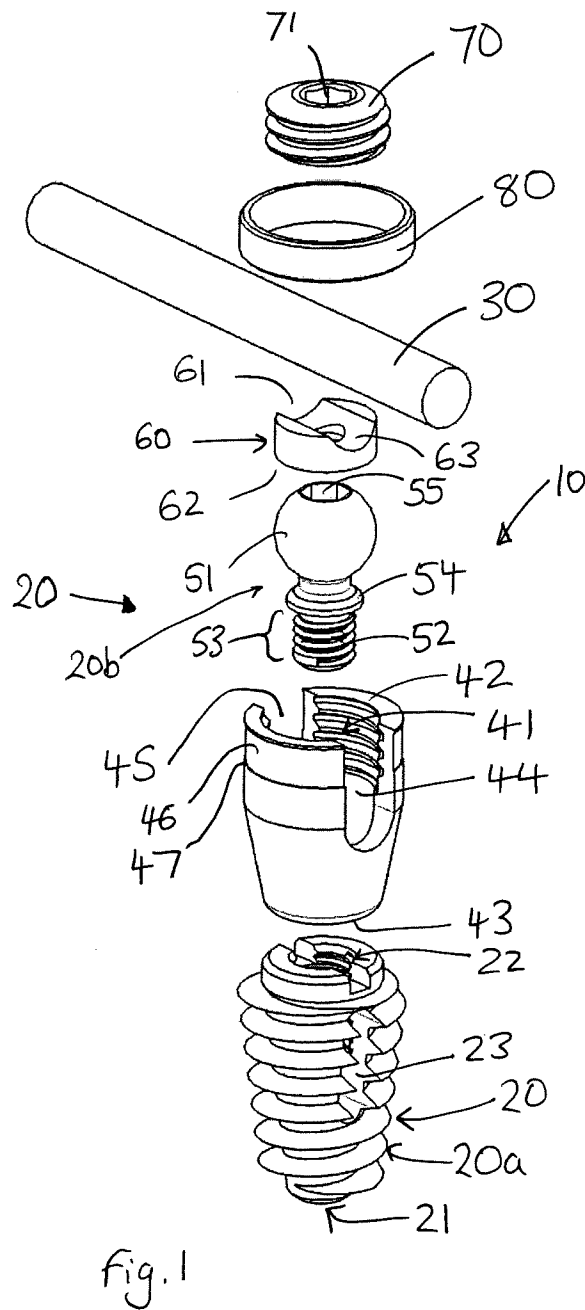


Fig. 1

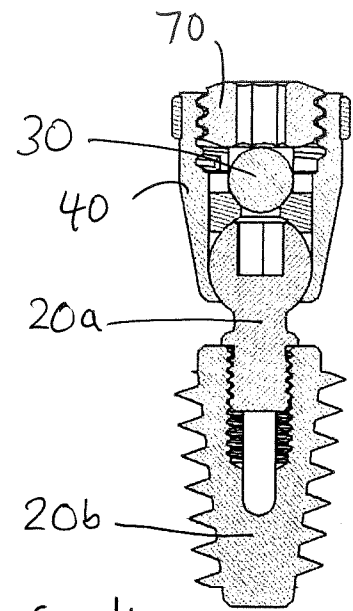


Fig. 4

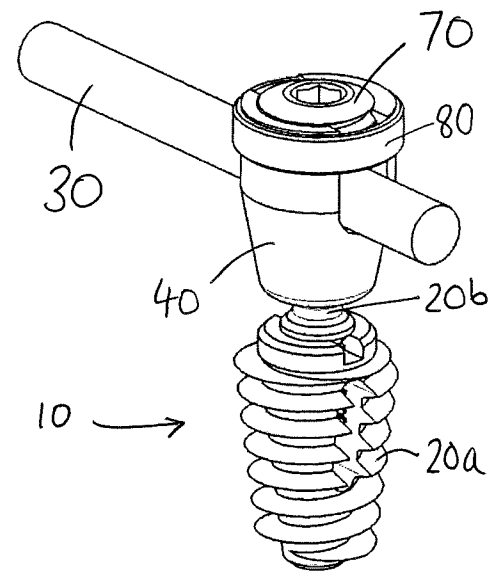


Fig. 2

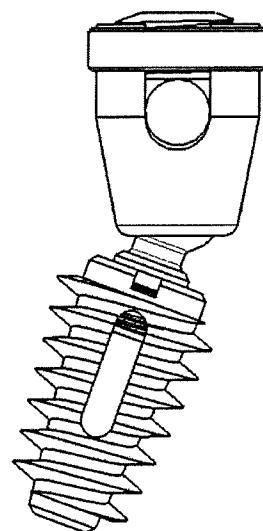


Fig. 3

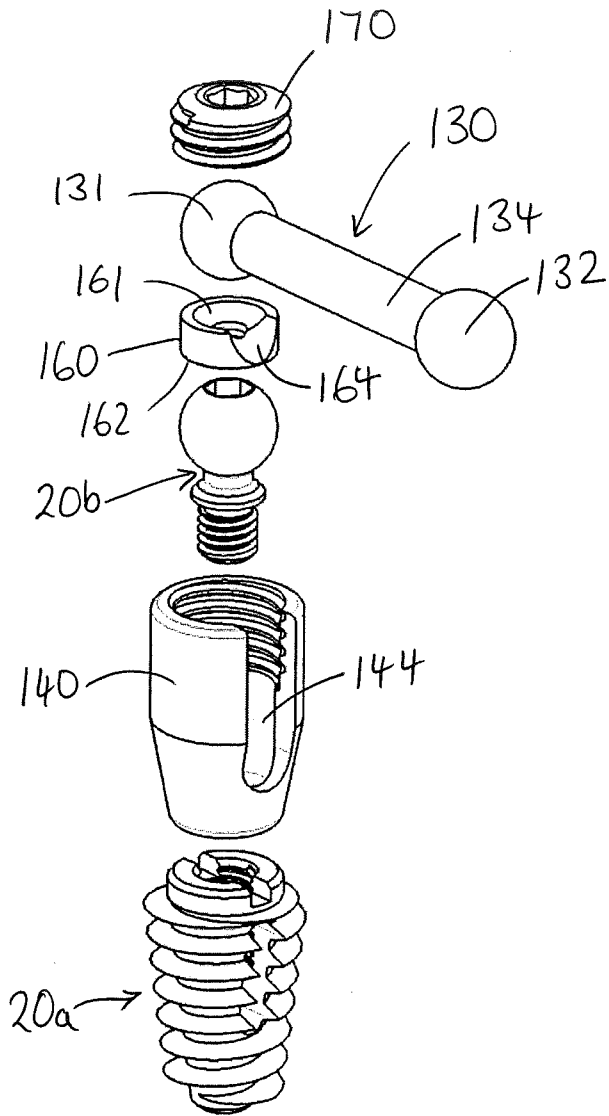


Fig. 5

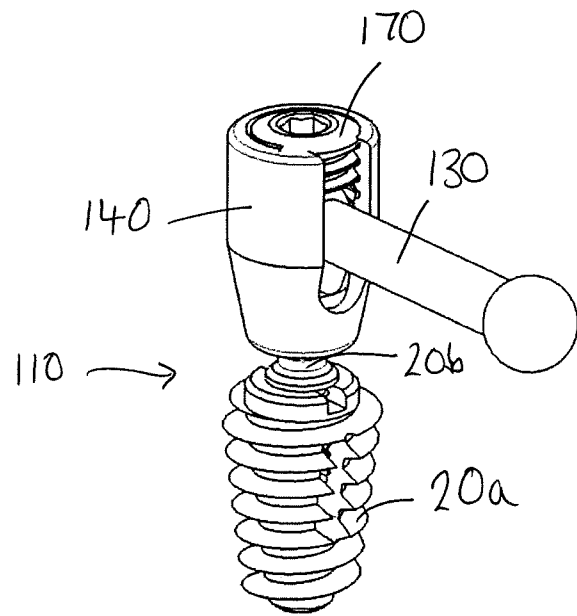


Fig. 6

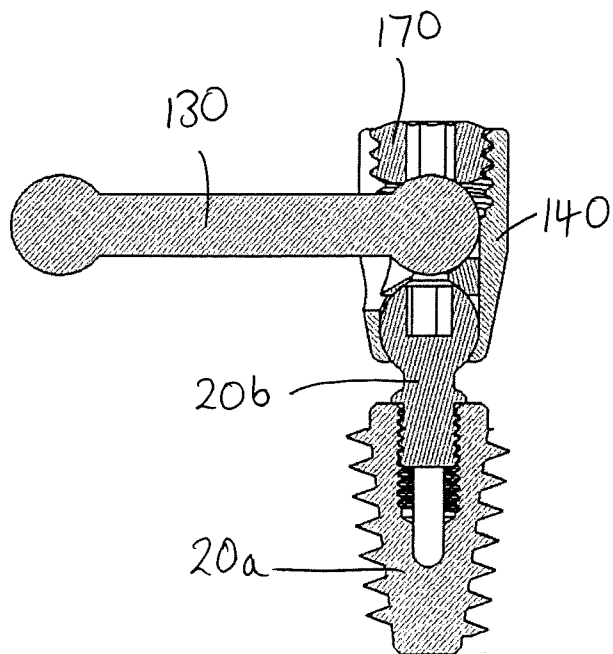


Fig. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2014/050570

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/70 A61B17/86
ADD.

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)
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 practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/015596 A1 (WHIPPLE DALE E [US]) 17 January 2008 (2008-01-17)	1-8,11, 14-21, 25,26, 28,29
Y	paragraph [0027] - paragraph [0032]; figures	9,10,12, 13, 22-24,27
Y	----- WO 2008/024373 A2 (ABDOU M SAMY [US]) 28 February 2008 (2008-02-28) figures 5,16A,16B	9,10
Y	----- GB 2 479 829 A (ORTHOFITZ IMPLANTS LTD [GB] FITZBIONICS LTD [GB]) 26 October 2011 (2011-10-26) page 17, line 29 - page 18, line 6; figures 19A,30 ----- -/-	12,13, 22-24

☒ Further documents are listed in the continuation of Box C.

☒ See patent family 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 application or patent 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

8 May 2014

Date of mailing of the international search report

19/05/2014

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Authorized officer

Kempen, Peter

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2014/050570

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 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. ☒ Claims Nos.: 31, 32
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.: 30
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:
see FURTHER INFORMATION sheet PCT/ISA/210
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 No. III Observations where unity of invention is lacking (Continuation of item 3 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 fees, this Authority did not invite payment of additional fees.
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 and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 31, 32

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

Continuation of Box II.2

Claims Nos.: 30

It is not clear what technical features are meant by defining a "computer program for manufacturing...". Indeed a computer program can cause a computer to execute specific steps, but not to manufacture. Furthermore it appears that support in the description entirely missing. Therefore, the description cannot be used to interpret claim 30; the claim is so unclear that no meaningful search is possible.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2014/050570

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2008/119857 A1 (POTASH ROBERT [US] ET AL) 22 May 2008 (2008-05-22) paragraph [0048] - paragraph [0050]; figures 8a-8f -----	27

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2014/050570

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2008015596	A1	17-01-2008	NONE

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			WO 2008024373 A2 28-02-2008

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			GB 2479829 A 26-10-2011
			US 2013035724 A1 07-02-2013
			WO 2011131994 A1 27-10-2011

US 2008119857	A1	22-05-2008	US 2008119857 A1 22-05-2008
			US 2008119858 A1 22-05-2008
			US 2012226317 A1 06-09-2012
			US 2013289623 A1 31-10-2013
			WO 2008088611 A1 24-07-2008
