Abstract: A bone cement restrictor (10) includes a solid cylindrical body (12), a trailing end of which defines an exterior zone to be gripped by an insertion device (30) to facilitate insertion of the body 12 into a medullary canal of a femur. At least one flange (20, 22) is arranged about the body (12) to bear against a wall of the medullary canal to inhibit cement flow past the flange (20, 22), in use. A restrictor insertion device (30) suitable for use in inserting the restrictor 10 into a medullary canal of a femur includes a holder (32). A collet (36) having jaws (40) is displaceably arranged relative to the holder 32 for releasably gripping the exterior zone of the body (12) of the restrictor (10). A manipulating element (46) is displaceably arranged relative to the holder (32) and cooperates with the collet (36) for effecting releasable gripping of the body (12) of the restrictor (10).
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

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

Field of the Invention

This invention relates to equipment for use in joint replacement surgery. More particularly, the invention relates to a bone cement restrictor for insertion into a patient's bone and to an insertion device for inserting the restrictor into the bone.

Background to the Invention

Joint replacement surgery such as hip replacement surgery is done regularly to replace damaged or diseased joints. Using hip replacement surgery as an example, the surgery involves removal of a head of the femur which is replaced by a prosthetic femoral implant. The femoral implant comprises a ball mounted on a stem. The stem of the femoral implant is typically of a cobalt or titanium alloy. A metal (typically cobalt alloy) or ceramic ball is mounted on a taper above the stem. The ball articulates against an insert of a high density polyethylene, cobalt alloy or ceramic bearing that is fixed within the acetabulum of the patient's pelvis.

To affix the prosthetic femoral implant in position, the stem of the prosthetic implant is inserted into the medullary canal of the femur and is commonly anchored in position by means of an acrylic bone cement. The cement, a methyl methacrylate cement, is inserted under pressure into the medullary canal. It is necessary to confine the cement to the part of the shaft of the bone surrounding the stem of the implant. This confinement also urges the cement under pressure into interstices within the bone of the femur surrounding the medullary canal to enhance bonding.

Cement restrictors of which the Applicant is aware make use of an internal, threaded socket which is engaged by a threaded end of an applicator. These restrictors are made of a synthetic plastics material. It is difficult to fabricate an internal thread accurately in the plastics material. Also, a boss defining the socket needs to be of a predetermined thickness so that rupturing of a wall surrounding the socket does not occur, in use. Radially outwardly extending flanges surround the boss and are used to inhibit passage of the cement past the restrictor when inserted into the medullary canal. However, due to the cross-sectional dimension of the boss, which is necessitated by the internal, threaded socket, the active length of the flanges is limited. This also limits their flexibility.

Summary of the Invention

According to a first aspect of the invention, there is provided a bone cement restrictor which includes:
a solid cylindrical body, a trailing end of which defines an exterior zone to be
gripped by an insertion device to facilitate insertion of the body into a medullary canal
of a femur; and

at least one flange arranged about the body for bearing against a wall of the
medullary canal to inhibit cement flow past the flange, in use.

A leading end of the body may be shaped to facilitate insertion of the body into
the medullary canal. Typically, the leading end of the body may be rounded or tapered
to facilitate insertion into the medullary canal.

Preferably, the restrictor includes a plurality of flanges axially spaced along the
body. At least two such flanges may be provided.

A major cross-sectional dimension of the, or each, flange may be at least three
times a major cross-sectional dimension of the body.

In a preferred embodiment of the invention, the body is a right circular
cylindrical body. Then, the major cross-sectional dimension of the body, being the
diameter of the body, may be, at most, one-third the diameter of the, or each, flange.
While the restrictor may be provided in a range of sizes, a typical restrictor would have
a body having a diameter of approximately 6mm with the flanges ranging from at least
18mm to about 26mm in diameter.

The restrictor may be formed of a biocompatible material. Preferably, the
biocompatible material is a polyethylene incorporating biocompatible plasticisers.

According to a second aspect of the invention, there is provided a restrictor
insertion device suitable for use in inserting a restrictor, as described above, into a
medullary canal of a femur, the device including:

a holder;

a gripping means displaceably arranged relative to the holder for releaseably
gripping the exterior zone of the body of the restrictor; and

a manipulating means displaceably arranged relative to the holder and which
cooperates with the gripping means for effecting releasable gripping of the body of the
restrictor.

The holder may comprise a sleeve defining an open passage.

The gripping means may comprise an elongate element in the form of a shaft
having a plurality of opposed jaws at a first, operatively distal end. If desired, an
internal surface of the jaws may be roughened to enhance gripping of the exterior zone
of the body of the restrictor. For example, each jaw may have a radially inwardly
projecting lip or rib.
Each jaw may include a flared outer surface which bears against a correspondingly flared, operatively distal end of the passage of the sleeve, when the jaws are drawn into the passage under the action of the manipulating means, for effecting gripping of the body of the restrictor.

The manipulating means may comprise a handle carried at a second, operatively proximal end of the elongate element for facilitating axial displacement of the elongate element relative to the sleeve.

Preferably, the device is demountable for cleaning or sterilisation purposes. For this purpose, the handle may be removably attached to the elongate element. For example, the handle may be secured to the proximal end of the elongate element by means of a retaining member, such as a grub screw. In addition, or instead, the elongate element and the sleeve may have complementary retaining formations for removably retaining the elongate element in the passage of the sleeve. For example, the elongate element may have a radially outwardly projecting pin on its surface which engages a U-shaped slot in the wall of the sleeve. One end of the slot may be a closed end and the other end may open into the proximal end of the sleeve. By appropriately manipulating the elongate element, it can be removed from the sleeve for cleaning purposes.

The parts of the device may be of a material capable of being sterilised. For example, the parts of the device may be of a surgical steel.

**Brief Description of the Drawings**

The invention is now described by way of example with reference to the accompanying drawings in which:

Figure 1 shows a side view of a bone cement restrictor, in accordance with a first aspect of the invention;

Figure 2 shows a bottom view of the restrictor;

Figure 3 shows a three-dimensional, exploded view of a first embodiment of an insertion device, in accordance with a second aspect of the invention, together with the restrictor of Figure 1;

Figure 4 shows a three-dimensional view of the insertion device together with the restrictor;

Figure 5 shows a three-dimensional view of an accessory for use with the device of Figures 3 and 4;

Figure 6 shows a sectional side view of part of the device;
Figure 7 shows a three-dimensional view of a second embodiment of an insertion device in accordance with the second aspect of the invention;

Figure 8 shows a three-dimensional view of a part of the device of Figure 7;

Figure 9 shows a side view of a further a part of the device of Figure 7; and

Figure 10 shows a three-dimensional view of a third embodiment of the device in accordance with the second aspect of the invention.

**Detailed Description of the Drawings**

Referring initially to Figures 1 and 2 of the drawings, a bone cement restrictor, in accordance with a first aspect of the invention is, illustrated and is designated generally by the reference numeral 10. The restrictor 10 comprises a solid right circular cylindrical body 12. A trailing end 14 of the body defines an exterior zone or external surface 16 to be gripped by an insertion device, as will be described in greater detail below, to facilitate insertion of the body 12 into a medullary canal (not shown) of a femur of a patient undergoing hip replacement surgery.

A leading end 18 of the body 12 is tapered to facilitate insertion of the body into the medullary canal.

A pair of flanges 20, 22, which are axially spaced with respect to each other, is arranged on the body 12.

The flanges 20, 22 have an outer diameter which is at least three times the outer diameter of the trailing end 14 of the body 12. Typically, the trailing end 14 of the body 12 has a diameter of approximately 6mm while the flanges 20, 22 have an outer diameter ranging from approximately 18mm to 24mm. It will, however, be appreciated that the restrictors 10, in use, are provided in various sizes to cater for various sizes of medullary canals of patient's femurs.

The restrictor 10 is formed as a one-piece integral unit by machining, more particularly, turning, or by a suitable moulding process such as injection moulding.

In Figures 3 to 6 of the drawings, a restrictor insertion device, in accordance with a first embodiment of a second aspect of the invention is illustrated and is designated generally by the reference numeral 30. The device 30 includes a holder in the form of a sleeve 32. The sleeve 32 has an open passage 34 defined through it. A gripping means in the form of a collet 36 is carried on a distal end of an elongate element in the form of a shaft 38. The shaft 38 is received through the passage 34 of the sleeve 32. The collet 36 defines two or more opposed jaws 40 which are flexibly spaced from each other by slots 42.
A proximal end of the shaft 38 has an external screw thread 44. When the shaft 38 is received through the passage 34, the threaded end 44 projects through the proximal end of the sleeve 32.

The device 30 includes a manipulating means in the form of a knurled wheel or handle 46 which engages the threaded end 44 of the shaft 38. For this purpose, the wheel 46 has an internal threaded bore 48 in which the end 44 of the shaft 38 is received. The wheel 46 bears against a bearing surface 54 (Figure 4) at the proximal end of the sleeve 32.

An operatively upper end of each jaw 40 tapers inwardly to the shaft 38. A distal end 52 of the passage 34 is correspondingly flared outwardly to define a bearing surface against which the tapered parts 50 of the jaws 40 bear, in use.

To insert the restrictor 10 into the medullary canal of the patient's femur, the trailing end 14 of the body 12 of the restrictor 10 is inserted in place between the jaws 40 of the collet 36. The knurled wheel 46 is rotated in the direction of arrows 56 (Figure 4) drawing the tapered parts 50 of the jaws 40 against the flared end 52 of the passage 34 of the sleeve 32.

The shaft 38 has a longitudinally extending slot 58 defined along it. A radially inwardly projecting pin 60 engages the slot 38 to inhibit rotation of the shaft 38 relative to the sleeve 32.

As the wheel 46 is rotated in the direction of the arrows 56 the tapered parts 50 of the jaws 40 of the collet 36 are drawn into, and bear against, the flared end 52 of the passage 34 forcing the jaws 40 towards each other to grip the external surface 16 of the body 12 of the restrictor 10 to inhibit slippage of the restrictor 10 relative to the device 30.

To enhance gripping of the external surface 16 of the restrictor 10, an internal surface of each jaw 40 is roughened by means of a radially inwardly projecting rib 62 (Figure 6).

As shown in Figure 4 of the drawings, an external surface of the sleeve 32 carries graduations 64, for example, at 10cm intervals. This enables the surgeon easily to measure the depth of insertion of the restrictor 10 into the medullary canal.

It may happen in practice that the restrictor gets lodged in the medullary canal 10 in an undesired position. To facilitate the removal of the restrictor 10 from that undesired position, the device 30 includes an accessory 70 shown in Figure 5 of the drawings. The accessory 70 is fixed to the end of the sleeve 32 by a grub screw, interference fit, or other suitable means. For this purpose, the accessory 70 includes a
collar 72 which is placed about the proximal end of the sleeve 32. The collar depends from an underside 74 of a bar 76.

Once the accessory 70 has been placed over the sleeve 32 the knurled wheel 46 is replaced on top of the bar 76. By applying a force to the underside 74 of the bar 76, the accessory 70 assists in removing the restrictor from the undesired location.

Referring now to Figures 7 to 9 of the drawings, a second embodiment of the device 30 of the second aspect of the invention is described. With reference to Figures 3 to 6 of the drawings, like reference numerals refer to like parts, unless otherwise specified.

In this embodiment of the invention, the device 30 includes the sleeve 32 and the shaft 38 projecting through the passage 34 of the sleeve 32. The collet 36 of the device 30 includes three or more jaws 40 (three of which are shown in Figure 9 of the drawings). Once again, the jaws 40 include tapered upper regions or parts 50 which bear against the distal end 52 of the passage 34 of the sleeve 32. The jaws 40 are flexibly arranged relative to each other by the slots 42 being defined between the jaws 40.

In this embodiment, the manipulating means is in the form of a handle 80 instead of the knurled wheel 46. The handle 80 is secured to the proximal end 44 of the shaft 38 by a retaining means in the form of a grub screw 82. This is shown in greater detail in Figure 8 of the drawings. The grub screw 82 facilitates removal of the handle 80 from the end 44 of the shaft 38 allowing the device 30 to be disassembled for sterilisation purposes.

In use, with this embodiment of the device 30, the body 12 of the restrictor 10 is inserted between the jaws 40 so that the jaws 40 lightly grip the external surface 16 of the body 12 of the restrictor 10.

The sleeve 32 is slid downwardly in the direction of arrow 84 relative to the shaft 38 so that, when the distal end 52 of the passage 34 bears against the tapered parts 50 of the jaws 40, the jaws 40 are urged towards each other and, in so doing, grip the external surface of the body 12 of the restrictor 10.

It is to be noted that a distal end 40 of each jaw includes a lip 86 which projects slightly inwardly as well as outwardly to enhance gripping of the exterior surface 16 of the body 12 of the restrictor 10. When the sleeve 34 is displaced in the direction of arrow 84, when it is fully in its gripping position, the distal end of the sleeve 32 bears against the ribs 86 of the jaws 40 or as close to the ribs 86 as required to receive a tight interlock.
The Applicant believes that hand pressure will be sufficient to lock the collet 36 to the body 12 of the restrictor 10. The surgeon inserts the restrictor 10 into the desired position in the medullary canal by pressing down on the handle 80. The restrictor 10 can also be removed by applying force to an underside of the handle 80 should the restrictor 10 be lodged in an undesirable position and need to be dislodged from that position.

In Figure 10 of the drawings, yet a further embodiment of the insertion device 30 is illustrated. Once again, with reference to the previous drawings, like reference numerals refer to like parts, unless otherwise specified.

In this embodiment of the invention, to facilitate removal of the shaft 38 from the sleeve 32, the sleeve 32 and the shaft 38 include complementary retaining formation being a U-shaped slot 88 in a wall 90 of the sleeve 32 and a retaining pin 92 projecting radially outwardly from the sleeve 38. The slot 88 has a first limb 94 which is closed in that it does not extend to the proximal end of the sleeve 32. The other limb 96 of the slot 88 opens out into the proximal end of the sleeve 32.

To remove the sleeve 32 from the shaft 38, the pin 92 is slid downwardly to the base of the limb 94 of the slot 88. The handle 80 is rotated through a quarter turn so that the pin 92 is aligned with the limb 96. The shaft 38 can then be withdrawn from the sleeve 32. In this embodiment, the bottom end of each jaw 40 does not include the outwardly extending lip 86.

It is a particular advantage of the invention that a restrictor is provided which, rather than being engaged by an applicator in an internal location of the restrictor, is gripped on an external surface of the restrictor. This allows a body of smaller diameter to be used than other restrictors of which the Applicant is aware resulting in greater flexibility being imparted to the flanges 20, 22 of the restrictor. The use of a solid body 12 for the restrictor 10 also enhances gripping thereof by the device 30 and improves the flexibility of the flanges 20, 22 relative to the body 12. The Applicant believes that the increased flexibility of the flanges 20, 22 will result in improved sealing in the medullary canal inhibiting flow of cement past the restrictor, in use. Greater flange flexibility may also be beneficial in reducing the occurrence of fat embolisms.

The use of a collet rather than threads also facilitates easier placement and re-positioning of the restrictor 10 should the restrictor 10 be lodged in an undesirable location in the medullary canal.

Still further, the absence of an internal thread in the restrictor 10 facilitates manufacture thereof and reduces manufacturing costs associated with the restrictor 10.
It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.
CLAIMS:

1. A bone cement restrictor which includes:
   a solid cylindrical body, a trailing end of which defines an exterior zone to be
   gripped by an insertion device to facilitate insertion of the body into a medullary canal
   of a femur; and
   at least one flange arranged about the body for bearing against a wall of the
   medullary canal to inhibit cement flow past the flange, in use.

2. The restrictor of claim 1 in which a leading end of the body is shaped to
   facilitate insertion of the body into the medullary canal.

3. The restrictor of claim 1 or claim 2 which includes a plurality of flanges axially
   spaced along the body.

4. The restrictor of any one of the preceding claims in which a major cross-
   sectional dimension of the flange is at least three times a major cross-sectional
   dimension of the body.

5. The restrictor of any one of the preceding claims in which the body is right
   circular cylindrical.

6. The restrictor of any one of the preceding claims which is formed of a
   biocompatible material.

7. A restrictor insertion device suitable for use in inserting a restrictor as claimed
   in any one of claims 1 to 6 into a medullary canal of a femur, the device including:
   a holder;
   a gripping means displaceably arranged relative to the holder for releasably
   gripping the exterior zone of the body of the restrictor; and
   a manipulating means displaceably arranged relative to the holder and which
   cooperates with the gripping means for effecting releasable gripping of the body of the
   restrictor.

8. The device of claim 7 in which the holder comprises a sleeve defining an open
   passage.
9. The device of claim 8 in which the gripping means comprises an elongate element having a plurality of opposed jaws at a first, operatively distal end.

10. The device of claim 9 in which each jaw includes a flared outer surface which bears, against a correspondingly flared, operatively distal end of the passage of the sleeve, when the jaws are drawn into the passage, of the manipulating means for effecting gripping of the body of the restrictor.

11. The device of claim 9 or claim 10 in which the manipulating means comprises a handle carried at a second, operatively proximal end of the elongate element for facilitating axial displacement of the elongate element relative to the sleeve.

12. The device of any one of claims 7 to 11 which is demountable for cleaning purposes.

13. In combination
   at least one bone cement restrictor as claimed in any one of claims 1 to 6; and
   an insertion device as claimed in any one of claims 7 to 12.
FIG. 8

FIG. 9

SUBSTITUTE SHEET (Rule 26)
INTERNATIONAL SEARCH REPORT

International application No. PCT/NZ03/00013

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. 7: A61F 2/46 2/28

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)

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)

DWPI and keywords: bone and cement and restrict and similar terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<th>Relevant to claim No.</th>
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<td>US 4344190 A (LEE et al.) 17 August 1982 Column 2 lines 8 to 19</td>
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<td>US 6179842 B1 (SPOTORNO et al.) 30 January 2001 Column 4 lines 3 to 16</td>
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<td>A</td>
<td>US 4697584 A (HAYNES) 6 October 1987 Figures 1 and 2</td>
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X Further documents are listed in the continuation of Box C  X 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

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Date of the actual completion of the international search 30 April 2003

Date of mailing of the international search report 5 MAY 2003

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This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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END OF ANNEX