

00612

FORM 1

SPRUSON & FERGUSON

COMMONWEALTH OF AUSTRALIA

PATENTS ACT 1952

APPLICATION FOR A STANDARD PATENT
APPLICATION ACCEPTED AND AMENDMENTS

ALLOWED 28.5.90

Philip Christopher Noble, of 2147 Swift Boulevard, Houston, Texas, UNITED STATES OF AMERICA, hereby apply for the grant of a standard patent for an invention entitled:

Sealing Device for Introducing Cement into a Bone Canal

which is described in the accompanying complete specification.

Details of basic application(s):-

<u>Basic Applic. No:</u>	<u>Country:</u>	<u>Application Date:</u>
126,451	US	30 November 1987

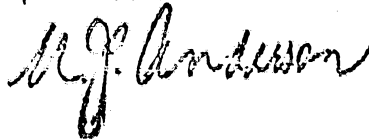
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DATED this TWENTY EIGHTH day of NOVEMBER 1988

Philip Christopher Noble

By:



Registered Patent Attorney

TO: THE COMMISSIONER OF PATENTS
OUR REF: 78882
S&F CODE: 60030

500371B 29/11/88

5845/2

DECLARATION IN SUPPORT OF A
CONVENTION APPLICATION FOR A PATENT

In support of the Convention Application made for a patent for an invention entitled:

ALL INFORMATION CONTAINED HEREIN IS UNCLASSIFIED
DATE 01-11-2001 BY 60322 UCBAW

~~PC 7302~~

Title of Invention

SEALING DEVICE FOR INTRODUCING CEMENT INTO A BONE CANAL

1/XX Philip Christopher Noble

Full name(s) and
address(es) of
Declarant(s)

of 2147 Swift Boulevard, Houston, State of Texas,
United States of America

do solemnly and sincerely declare as follows:--

Full name(s) of Applicant(s)

1. I am/~~XX/XX~~ the applicant(X) for the patent
(or, in the case of an application by a body corporate)
X. ~~XXXXXX XXXXXXXXXX XXXXXXXXXX~~

the applicant(s) for the patent to make this declaration on
its/their behalf.

2. The basic application(s) as defined by Section 141 of the Act was/were made

Basic Country(les)

in United States of America

Priority Date(s)

on November 30, 1987

Basic Applicant(s)

by Philip Christopher Noble

Full name(s) and
address(es) of
inventor(s)

3. I am/~~XX XX~~ the actual inventor(~~s~~) of the invention referred to in the basic application(~~s~~)
(or where a person other than the inventor is the applicant)

3. Philip Christopher Noble

of 2147 Swift Boulevard, Houston, State of Texas,
United States of America;(Citizen: Australia;
Occupation: Engineer)

(respectively)-
is/are the actual inventor(s) of the invention, and the facts upon
which the applicant(s) is/are entitled to make the application are
as follows:

Set out how Applicant(s) derive title from actual inventor(s) e.g. The Applicant(s) is/are the assignee(s) of the invention from the inventor(s)

4. The basic application(s) referred to in paragraph 2 of this Declaration was/were the first application(s) made in a Convention country in respect of the invention(s) the subject of the application.

Declared at Houston this 9th day of November 1988

Signature of Declarant(s)

Philip Christopher Noble

1/81

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SPRUSON & FERGUSON
- (56) Prior Art Documents
US 4338925
EP 0093560
US 4627434
- (57) Claim

1. A sealing device for introducing bone cement into a bone canal through an opening in the bone, characterized in that said sealing device has:

(a) body member having a passageway of predetermined cross-section extending therethrough for passage of cement;

(b) generally annular wall member extending from said body member and defining an outer surface at least a portion of which is elastically expandable and is configured and dimensioned so as to be capable of extending into the bone canal said outer surface adapted to provide a contacting seal along a length of the inner walls of the bone canal; and

(c) chamber defined by said annular wall member, said chamber having a cross-section greater than said predetermined cross-section of said passageway and communicating with said passageway and relatively stationary with said bone canal such that cement, upon its introduction into said bone canal, will also fill said chamber and cause said elastically expandable portion of said annular wall to expand so as to aid in maintaining said seal.

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FORM 10

COMMONWEALTH OF AUSTRALIA

PATENTS ACT 1952

COMPLETE SPECIFICATION

(ORIGINAL)

FOR OFFICE USE:

Class Int Class

Complete Specification Lodged:
Accepted:
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Related Art:

This document contains the
amendments made under
Section 49.

and is correct for printing.

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Complete Specification for the invention entitled:

Sealing Device for Introducing Cement into a Bone Canal

The following statement is a full description of this invention, including the
best method of performing it known to me/us

SEALING DEVICE FOR INTRODUCING
CEMENT INTO A BONE CANAL

ABSTRACT

5 A proximal femoral sealing device 10 is disclosed
for use in the application of bone cement under
pressure to a surgically prepared medullary canal 15 of
a femur prior to the implantation of a hip prosthesis.
The proximal femoral sealing device 10 is formed of a
10 generally solid body member 12 with a passageway 26 and
a flexible annular wall member 14 extending from the
body member 12. The sealing device 10 has an
anatomically shaped outer surface 13, corresponding to
the exposed endosteal surface 11 of a prepared
15 medullary canal 15. A chamber 16 defined by a flexible
annular wall 14 and the body member 12 opens into the
medullary canal 15. In turn, the passageway 26
communicates with the chamber 16 and permits insertion
of a cement nozzle 27 therethrough into the chamber.
20 In operation, the proximal femoral sealing device 10 is
placed within the proximal end of a surgically prepared
medullary canal 15. The canal 15 and chamber 16 of the
sealing device are filled with cement resulting in the
expansion of the flexible annular wall member 14
25 against the exposed endosteal walls 11 of the medullary
canal 15 by cement pressure within the chamber thereby
forming a pressure seal. The escape of cement through
the open end of the excavated medullary canal 15 is
prevented via this pressure seal insuring that the
30 applied cement is properly pressurized and that the
medullary canal 15 is prepared for ^{implantation} ~~implementation~~ of
the prosthetic device 10. A method of providing cement
under pressure to the exposed endosteal surface 11 of a
medullary canal 15 is also disclosed using this
35 proximal femoral sealing device 10.



SEALING DEVICE FOR INTRODUCING
CEMENT INTO A BONE CANAL

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This invention generally relates to an apparatus and method for injecting bone cement under pressure into a bone canal. The cement allows for implantation of a prosthetic device.

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There are from 80,000 to 150,000 total hip arthroplasty (THA) procedures completed each year in the United States. Worldwide, there are over 300,000 to 400,000 THA procedures performed each year. This procedure, whether unilateral or bilateral, is performed to relieve a variety of objective signs of disability, such as to relieve pain and to increase or preserve mobility. A diagnosis which suggests THA for treatment may include, for instance, primary or secondary osteoarthritis, congenital dysplasia, polyarthrititis, including rheumatoid arthritis, and ankylosing spondylitis, previous unsuccessful joint surgery and Paget's Disease of the bone. The indications for bilateral THA include primary idiopathic bilateral monoarticular osteoarthritis, primary generalized osteoarthritis, ischemic necrosis of the femoral head with secondary acetabular failure, and secondary degenerative osteoarthritis resulting from congenital dysplasia.

30 Additional factors such as flexion deformity of more than 30°, one hip fixed in adduction, the other fixed in abduction (causing the patient to fall from lack of

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balance), leg shortening, acetabular protrusion, age and other factors should be considered prior to considering a bilateral procedure.

5 Generally stated, THA is an operation where the ball and socket joint which forms the natural hip is replaced by artificial materials. The development of THA components has occurred over the last three decades. The THA procedure and related components are described in the
10 publication entitled The Howmedica Precision Hip System, Copyrighted 1986 by Howmedica, Inc., which publication is hereby incorporated by reference in its entirety. In the procedure carried out today, the spherical end of the femur is removed and replaced with an artificial metallic implant.
15 The stem to which the ball is attached (via a "neck") fits down the middle of the femur in the surgically prepared medullary canal and is located in place by bone cement. The spherical head of the femoral component is placed into the socket of the acetabular component forming a total
20 replacement of the hip joint (both components are commercially available as the A.T.S.* Total Hip System and the P.C.A.* Total Hip System from Howmedica, Inc.).

25 In preparing the femoral medullary canal for implantation, the steps after resection (removal) of the head of the femur include reaming, broaching and cleaning out (lavage and brush) the medullary canal. This area of the bone contains the bone marrow which also fills spaces in cancellous bone.

30 The femoral canal typically is prepared from its distal portion to the proximal portion, i.e., in a retrograde manner. The femoral canal may be opened with any standard blunt surgical awl or manual reamer. The surgeon,

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in cleaning the medullary canal, will progressively use larger reamers until the reamer contacts the harder bone at the cortex of the isthmus. Broaches or rasps are utilized in order to accommodate the appropriate implant with

5 neutral, posterior and anterior implants. At the proximal end (with reference to the surgeon) of the medullary canal, the proximal broach is used. This broach has a smooth tip and middle portion with its cutting surface being proximal. This instrument has five functions: it provides the precise
10 canal size for the cement mantle; it is used to position the calcar reamer; the flat plane can be used to provide the final osteotomy level and it is used in trial reduction to assure proper fit and as a trial since it is sized to correspond to the correct femoral component plus cement
15 mantle. The prepared (reamed and broached) medullary canal is then cleaned and dried.

Prior to introducing cement into the intramedullary plug is typically utilized to effectively
20 create a block at the isthmus (a lower portion of the medullary canal at which it has a narrow diameter) to make the upper femur a closed system. The plug reduces the amount of debris forced up the canal when cement is
25 introduced and it insures pressurization thus helping to provide stem fixation.

The actual bone cement is not a glue but is a filler and enables the mechanical interlock of bone on one side to a prosthesis on the other. The material used in
30 creating the bone/prosthesis interface which is presently preferred is polymethylmethacrylate (also known as PMMA), one of a family of the polymers known as acrylics and is familiar commercially as Plexiglass® and Lucite®. This material is "cold-curing" or "self-polymerizing" thus

enabling its use in the THA procedure. A preferred cement utilized today is Surgical Simplex® P Bone Cement (commercially available from Howmedica, Inc.), which is a co-polymer of polymethylmethacrylate and styrene. This material has a compressive strength ranging from 9,000 to about 13,800 pounds per square inch, a tensile strength ranging from about 3,600 to 6,800 psi; a shear strength ranging from 5,700 to 7,000 psi and a modulus of elasticity ranging from 2.3 to 3.8 X 10⁵ psi.

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A variety of factors and variables will influence the effectiveness of the cement used in the THA procedure, such as: the rate of mixing; the porosity of the cement formed during mixing; the additives utilized in conjunction with the bone cement such as the addition of antibiotics to the cement mix; polymer shrinkage; the THA procedure itself; the set time; the powder to liquid ratio; preparation of the bone surface including the presentation of debris such as blood, bone chips or powder and other tissue; the delay in applying the cement; the pressure at which the cement is applied into the medullary canal and the cement thickness. The pressure at which the cement is supplied to the medullary canal is one of the most significant factors in the success of the implant.

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In the early days of prosthetic surgery, the mixed cement was placed into the femur and simply manually pressed into place. No matter how much pressure is manually applied sufficient pressure to insure a good interface between cement and bone could not be assured. Furthermore, use of this technique in the past often resulted in a femoral canal that was incompletely filled with cement.

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The cement is now typically provided to the interior exposed endosteal surface of the medullary canal with a bone cement gun (commercially available, for example, as the Exeter® Cement Gun & Syringe from Howmedica, Inc.).

5 In the commercially available cement guns, a nozzle is fitted to the gun and delivers the cement under pressure to the canal. The liquid and powder which comprises the cement may be mixed prior to placement in the cement gun with commercially available systems (i.e., the Mix-Kit® Systems
10 or in the Simplex Enhancement Mixer® commercially available from Howmedica, Inc.) so that it may be applied in a viscous or liquid state.

After the bone cement is applied to the exposed
15 endosteal surface of the prepared medullary canal, the implant is inserted into the canal. The cement, which polymerizes and hardens in the space between the bone and the implant, functions as a luting agent. The quality of the fixation is greatly enhanced by the mechanical
20 interlocking of the cement with the porous trabecular structure of the cancellous bone of the wall of the intramedullary canal and with any pores, dimples, elevations, keys, etc. provided on the surface of the
implant.

25 Fixation of surgical implants with polymethylmethacrylate bone cements within intramedullary canals has been practiced with great success for many years. On occasion, however, problems associated with the premature
30 loosening of the implant in use have been observed. One explanation for these loosening problems is an inadequate penetration of the bone cement into the cancellous bone of the intramedullary canal wall. It is known that this penetration can be improved by pressurizing the viscous or

liquid bone cement within the intramedullary canal so as to work the cement deeply into the cancellous bone of the canal wall before it hardens. Thus, it is well known to utilize an intramedullary plug as described above to prevent passage 5 of cement distally (with reference to the surgeon) of its desired location within the intramedullary canal (see, for example, U.S. Patent Nos. 4,245,359; 4,276,659 and 4,293,962 and European Patent No. 6408).

Pressurization can be further improved to some but, as noted above, a limited extent by finger packing by the surgeon. Compactors have also been used to compress and pressurize bone cement applied to an intramedullary canal. However, the use of a compactor requires the addition of a distinct, time-consuming step to the surgical procedure, with the results being operator intensive, i.e., the extent of pressurization achieved depends upon the axial force exerted by the surgeon.

20 Additionally, it is known to equip the nozzle of
 25 a bone cement extruder with a restricter (e.g., the Miller
 Bone Cement Injector Restrictor Set; Zimmer, USA; Warsaw,
 Ind.) made of a solid resilient material to block the flow
 of cement between the nozzle and the bone through the open
 end of the prepared intramedullary canal. However, the
 quality of the seal obtained is limited because the fit of
 such a restricter against the prepared bone is more in the
 nature of a line contact at the open end than a surface-to-
 surface contact and, furthermore, the quality of the seal
 30 will be reduced when the restricter is unable to completely
 fill any irregularities in the bone against which it fits.
 Again, the extent of pressurization achieved depends upon
 the axial force exerted by the surgeon.

Devices similar to the Miller device have been utilized wherein the upper or proximal portion of the seal is more flexible than on the Miller seal in order to accommodate a wider variety of openings in the medullary canal. This type of seal remains within the medullary canal by virtue of axial pressure from the surgeon holding it in place or alternatively by its fit within the prepared medullary canal. The pressure of the cement added to the bone would oppose, however, the fit of this type of plug pushing it in a direction out of the proximal end of the medullary canal.

In addition, U.S. Patent No. 4,462,394 discloses an intramedullary canal seal which comprises a hollow tube adapted to slidably receive the nozzle of a bone cement extruder and an inflatable cuff surrounding the tube and a means to inflate the cuff. The inflated cuff is said to form a seal against the wall of the intramedullary canal, thereby preventing escape of cement through the open end of the prepared canal. In European Patent Application No. 82304353.4, a device is disclosed which is designed to fit over and seal the opening of a cavity in a bone to allow pressurization of cement in the cavity. This device is described as having an aperture for sealingly receiving a cement delivery nozzle and the seal member itself may be a balloon seal, which is inflatable and expandable, or a solid material, either of which embodiments is urged or pressed against the opening of the bone by force of the barrel of the cement delivery gun or an additional abutment means. This device does not fit within the intramedullary canal but instead seats on top of the proximal end of the canal. The cement sealing effect is achieved by the force of holding this seal against the opening of the bone and not by any force exhibited from the cement against the seal.

Cement restrictors have also been disclosed for use in conjunction with fixing the acetabular portion of the hip prosthesis as in U.S. Patent Nos. 3,889,665 and 3,866,248. These restrictors do not provide for the use of the cement pressure itself to hold the seal in place during application of the bone cement.

I have invented a sealing device which avoids the aforementioned problems and provides for much greater penetration of cement into the bone.

The present invention is directed to an apparatus for introducing cement into a bone canal through an opening in the bone, comprising body member having a passageway therethrough for passage of cement; generally annular wall member extending from the body member and defining an outer surface at least a portion of which is configured and dimensioned so as to be capable of extending into the bone canal and generally seal the bone opening; and chamber defined by the annular wall member, the chamber communicating with the passageway and with the bone canal such that cement, upon its introduction into the bone canal, will also fill the chamber so as to aid in maintaining the seal.

Preferably the apparatus is suitable for injecting cement into the bone canal and the generally annular wall member is flexible and together with the body member defines a generally continuous outer surface which is configured and dimensioned such that at least a portion of the outer surface corresponds anatomically to a portion of the bone canal adjacent the opening so as to be capable of extending into the bone canal and sealing the bone opening. The chamber defined

by the annular wall member and the body member communicates with the passageway and with the bone canal such that cement upon its injection into the bone canal will also fill the chamber so as to expand the flexible annular wall member and thus maintain the seal and aid in the penetration of cement into the bone within the canal.

In a preferred embodiment, the present invention relates to a proximal femoral sealing device for seating within the medullary canal of a prepared proximal end of a femur and for injecting cement under pressure into the medullary canal, comprising body member having a passageway therethrough for passage of cement; generally flexible annular wall member extending from the body member and defining with the body member an outer surface which is anatomically shaped and conforms generally along the vertical and horizontal axes of the body member to the exposed internal endosteal surface shape of the proximal end of the medullary canal of the femur; and chamber defined by the flexible wall member and the body member, the chamber opening onto and communicating at one end with the proximal end of the medullary canal, the other, opposite end opening onto and communicating with the distal end of the passageway, the chamber further having a generally rounded-trapazoidal cross-sectional configuration defined by the flexible wall member which is capable of expanding under pressure of cement within the chamber against the exposed internal endosteal surface of the medullary canal so as to form a pressurization cement seal.

The anatomically shaped outer surface can generally correspond to the outer surface shape of a broach utilized to expose the endosteal surface of the medullary canal or to the natural internal surface shape of the medullary canal. In an alternative embodiment, the

anatomically shaped outer surface further comprises a plurality of ridges which are dimensioned and configured so that leading edges thereof contact the exposed internal endosteal surface.

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Also the proximal end of the anatomically shaped outer surface preferably is wider than the distal end along a cross-section of the vertical axis of the seal. The portion of the anatomically shaped outer surface adjacent the lateral side of the medullary canal can be aligned at an angle from about 1° to about 4° in from the vertical axis of the seal towards the wall on the medial side of the medullary canal. The portion of the substantially anatomically shaped outer surface on the medial side of the medullary canal can be straight to curved, for example, with a radius of from about 3-10 inches from the proximal to distal end of the substantially anatomically shaped outer surface.

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In a preferred embodiment, the wall member is thicker at the proximal end of the chamber than at the distal end of the chamber. In addition, the wall member tapers to reduce in thickness from the proximal end to the distal end.

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The substantially anatomically shaped outer surface which ends at the distal end of the seal can be aligned at an angle of about 0° to about 20° away from the horizontal axis of the seal toward the proximal end of the seal with the shorter wall length being angled towards the proximal end. The lateral portion of the wall member and medial portion of the wall member can be aligned at about 10° from the vertical axis of the seal, with the lateral and medial portions being aligned parallel to each other and with the end of the medial portion of the wall being more

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proximally located to the vertical axis than the lateral portion of the wall. The anterior and posterior portions of the wall member between the medial and lateral portions can be aligned on the horizontal axis at an angle from about 10° to about 12° away from the transverse axis, with the anterior and posterior portions being closer together at the medial portion than at the lateral portion.

The passageway is preferably centrally disposed in the body member and is dimensioned and configured to receive a nozzle for injection of cement. The passageway preferably is cylindrical in shape. The passageway narrows to form a gasket-seal so as to restrain a cement nozzle inserted through the passageway. This gasket-seal is disposed adjacent the proximal end of the chamber or can be disposed between the proximal and distal ends of the passageway. Also a medial portion of the body member can be inset from the medial portion of the anatomically shaped outer surface.

It is preferred that the body member and flexible annular wall member are formed of a medical grade elastomer and, in particular, they can be integrally formed of silicone.

The present invention is also directed to a method for introducing cement into a bone canal comprising: preparing an opening in the bone; positioning a sealing device according to the present invention into the bone canal through the opening; inserting a cement nozzle through the passageway and into the chamber of the sealing device; and providing cement under pressure to the bone canal and to the chamber of the sealing device whereby the walls of the chamber, being under pressure, expand against the exposed

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surface of the bone canal thereby forming a pressure seal against the exposed surface enabling the cement to completely fill the medullary canal under pressure.

5 In accordance with a preferred embodiment, the present invention is also related to a method for providing cement under pressure to the exposed endosteal surface of a medullary canal of a femur, comprising exposing the
10 a proximal femoral sealing device according to the present invention into the proximal portion of the medullary canal; inserting a cement nozzle through the passageway and into the chamber of the sealing device; and injecting cement
15 through the cement nozzle under pressure into the medullary canal and into the chamber of the sealing device such that the flexible annular wall member, being under pressure, expands against the exposed endosteal surface so as to form a pressure seal against the exposed surface enabling the cement to completely fill the medullary canal under
20 pressure.

The cement is provided under pressures ranging from at least about 30 to about 100 psi and preferably the cement has an average pressure of about 50 psi while filling
25 the medullary canal. The pressure is sufficient to permit permeation of the cement into the exposed endosteal surface to a depth of at least about 5 millimeters. After the sealing device is removed from the proximal end of the medullary canal of the femur upon filling of the medullary
30 canal under pressure, a femoral stem is implanted therein. In an alternative embodiment, a bone plug is inserted into the distal portion of the medullary canal prior to inserting said sealing device. Also if desired, the medullary canal can be filled with some cement prior to inserting the
35 proximal femoral sealing device.

According to the method of this invention, the increased cement pressure on the seal's flexible walls relieves the surgeon from having to use as much force as is required with other seals to maintain the seal in position
5 within the medullary canal. This further permits increased pressurization of the cement application within the medullary canal. Increased pressure of cement within the medullary canal helps to insure better and more secure prosthetic implant anchoring. In addition, the flexibility
10 of the walls of the seal permit a better and more uniform seal against the endosteal surface of the medullary canal without regard to minor irregularities in shape which may be present in different patients. This invention also provides for a novel method for delivering cement under pressure to
15 the exposed endosteal surface of a medullary canal in such a manner that the depth of cement penetration is significant and assists in generating excellent prosthesis anchoring.

It is also within the scope of this invention
20 that some cement can be introduced into the canal prior to positioning the sealing device into the medullary canal and thereafter the procedure described above can be followed. If desired, the seal can additionally be secured in place with external axial pressure (i.e., by hand or mechanical
25 means) so as to provide additional assurance of the positioning of the seal when providing the cement under high pressure.

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The present invention is described in detail below with reference to the drawings wherein:

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FIG. 1 is a perspective view of a proximal femoral sealing device according to the present invention.

FIG. 2 is a cross-sectional view of the proximal femoral sealing device taken along the lines 2-2, ^{the transverse axis of the device,} of FIG. 1.

FIG. 3 is a cross-sectional view of the proximal femoral sealing device as shown in FIG. 1 taken along the lines 3-3, ^{the vertical axis of the device,} of FIG. 2.

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FIG. 4 is a cross-sectional view of the proximal femoral sealing device as shown in FIG. 1 taken along the lines 4-4, ^{the horizontal axis of the device,} of FIG. 2.

FIG. 5 is a bottom view of the proximal femoral sealing device of FIG. 1.

FIG. 6 is a side elevational view partially in cross-section illustrating the positioning of the proximal femoral sealing device of FIG. 1 within the proximal end of the femoral intramedullary canal.

FIG. 7 is a perspective view of an alternative embodiment of a proximal femoral sealing device according to the present invention.

FIG. 8 is a cross-sectional view of the proximal femoral sealing device taken along the lines 8-8 of FIG. 7.

FIG. 9 is a cross-sectional view of the proximal femoral sealing device as shown in FIG. 1 taken along the lines 9-9 of FIG. 8.

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FIG. 10 is a cross-sectional view of a second alternative embodiment of the proximal femoral sealing device according to the present invention.

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In the description which follows, any reference to either direction or orientation is intended primarily and solely for purposes of illustration and is not intended in any way as a limitation of the scope of the present invention. Also, the particular embodiments described herein, although being preferred, are not to be considered as limiting of the present invention. Furthermore, like parts or elements in the various drawings hereto are identified by like numerals for ease of reference.

A proximal femoral sealing device 10 of the present invention is shown in FIGS. 1-5. Sealing device or seal 10 is formed of a body member 12 and an annular wall member 14 that extends from the body member as shown more clearly in FIG. 2. The seal 10 has an outer substantially anatomically shaped surface 13 which conforms, along the vertical and horizontal axis of the seal 10, to the internal exposed endosteal surface 11 shape of the proximal end of the surgically prepared medullary canal of the femur as shown in FIG. 6. The anatomically shaped surface 13 is defined by wall portions 14 which are flexible and are capable of expanding under pressure against the internal exposed endosteal surface of the medullary canal so as to form a pressurization seal. The seal 10 can be formed of various sizes to permit insertion within the proximal end of the medullary canal so as to engage the exposed endosteal

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surface which would surround the anatomically shaped surface upon its insertion into the proximal end of the medullary canal.

5 The proximal femoral seal 10 of the present invention also has an internal chamber 16 defined by the inner surfaces 18 of flexible portions of the annular wall member 14 (which defines the anatomically shaped outer surface 13) and inner surface 20 of body member 12. At one
10 end, the internal chamber 16 opens onto and communicates with a proximal end of the medullary canal as shown in FIG. 6. At the other opposite end, the internal chamber opens
15 onto and communicates with the distal end 22 of a cement nozzle entry port or passageway 26 in body member 12. The internal chamber 16 has a generally rounded-trapazoidal cross-sectional configuration which is defined by the
flexible portions of the wall as shown in FIG. 3.

 The body member 12 of proximal femoral seal 10
20 also preferably has an upper portion 24 which is located on the vertical axis of the seal 10 above the anatomically shaped surface 13. The upper portion 24 is contiguous with
the anatomically shaped surface and also has a generally
rounded-trapazoidal cross-sectional configuration along the
25 horizontal axis of the seal 10 as shown in FIG. 5. The upper portion 24 also includes the cement nozzle entry port
26 which has a smaller distal end 22. The cement nozzle entry port traverses the upper portion along the vertical axis of the proximal femoral seal 10 with the distal end 22
30 of the cement nozzle entry port 26 communicating with the internal chamber 16. The proximal femoral seal 10 preferably is formed integrally as a single unit, i.e., by known molding techniques, from a medical grade elastomer such as silicone rubber.

It is also preferred that the substantially anatomically shaped surface 13 generally corresponds to the outer surface shape of a broach utilized to prepare the medullary canal and expose the endosteal surface 11. It is 5 within the scope of this invention that a variety of sizes of broaches may be used and that the proximal femoral seal preferred embodiment shown in FIGS. 1-6 and 10 will preferably accommodate a larger size broach whereas the proximal femoral seal preferred embodiment shown in FIGS. 7, 10 8 and 9 would preferably accommodate smaller size broaches utilized typically where the femur or medullary canal is of a smaller size.

15 In both operation and principle, however, both of these designs are equal. The two embodiments as shown in FIGS. 1 through 10 would, by virtue of their anatomic shapes, accommodate most, if not all, prepared medullary canals. FIG. 6 shows a cross-sectional view of the seal in place within a medullary canal with a cement gun nozzle 27 20 located through the passageway 26 and into the interior chamber 16. It is clear from this view that the seal could also be accommodated within a larger opening of the proximal end merely by fitting it down further into the medullary canal 15 or alternatively fitting it within a smaller 25 opening by placing it higher up the canal where the opening is smaller. It is also within the scope of this invention that the substantially anatomically shaped surface 13 generally corresponds to the natural internal endosteal surface shape 11 of the medullary canal 15. In this manner, 30 it is clearly within the scope of this invention that this seal would be utilizable in a medullary canal which is prepared without the use of a broach.

As shown in FIG. 10, another alternative preferred embodiment 50 of this invention, the substantially anatomically shaped surface 13 is not smooth as in the embodiment FIGS. 1-9 but rather comprises concentric ridges 51 along the horizontal axis of the outer surface. In the operation of a seal having this ridged surface, the crest of the ridges are the portions of the sealing device which come in contact with the exposed endosteal surface 11 of the proximal end of the medullary canal 15. It is these crests which are forced against the exposed endosteal surface to provide a gripping effect upon an increase in cement pressure from within the internal chamber 16 of the sealing device 50 during the cement filling operation. In both this and the embodiments of the proximal femoral seal described above, the proximal end on the vertical axis of the substantially anatomically shaped ridged surface 51 is wider than the distal end when viewed along a cross-section of the vertical axis of the seal (from the medial to the lateral edges).

In all of the embodiments, 10, 30 and 50 the general relationships of the wall and internal chamber to each other are generally the same. However, they may be modified by one of ordinary skill in the art to accommodate a variety of circumstances and surgical situations so long as the sealing device has a substantially anatomical shape and an internal chamber with annular wall member that will flex outwardly under increased cement pressure. In the preferred embodiments, however, various angles and relationships are described for the purpose of illustration.

In the preferred proximal femoral sealing devices 10, 30 and 50 of FIGS. 1-10 the annular wall member 14 defining of the substantially anatomically shaped surface

ranges from a straight surface to one which is curved (angle A), for example, with a radius of from about 3-10 inches from the proximal to the distal end of the substantially anatomically shaped surface 13.

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In addition, the wall defining the substantially anatomically shaped surface 13 is thicker at the proximal end of the internal chamber 16 than at the distal end of the internal cavity. The distal end of the internal chamber 16 communicates with the medullary canal. It is seen in FIGS. 1-10 that this wall tapers to reduce in thickness from the proximal end to the distal end of the sealing device 10, 30 and 50. It is also seen in FIGS. 1 - 10 that the wall of the substantially anatomically shaped surface 13 which ends at the distal end of the seal is aligned at an angle of about 20° from the horizontal axis of the seal towards the proximal end of the seal (angle B). The shorter portion of the annular wall length is angled towards the proximal end. It is also within the scope of this invention that the sealing device 10, 30 and 50 would be perfectly operable with the walls being aligned parallel to each other on the horizontal axis at the distal end of the sealing device 10, 30 and 50. However, while not losing any strength inherent in the sealing device by canting the annular wall member up at a 20° angle, it is possible to expose a greater amount of the exposed endosteal surface 11 to cement during the procedure by which the cement is applied to the medullary canal 15.

30

It is also seen in FIGS. 2, 8 and 10 that the lateral wall portion and medial wall portion of the internal chamber are aligned at about 10° from the vertical axis of the seal (see angle C). These portions of the wall member 14 are also aligned parallel to each other with the end of

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the medial portion of the wall member 14 being more proximally located to the vertical axis than the lateral portion of the wall. In this manner, the wall thickness is essentially the same on either the medial or lateral side of the interior chamber 16 thereby allowing an equal tapering of the wall to be achieved from the proximal to the distal end of the seal. This in turn permits equal expansion of the wall member 14 upon pressurization.

10 In order to accommodate for the natural anatomical shape of the excavated medullary canal 15, it can also be seen in FIGS. 1, 3 and 5 that the anterior and posterior wall of the internal cavity between the medial and lateral portions of the wall are aligned on the horizontal axis at an angle ranging from about 10° to about 12° away from the transverse axis (angle D), with their walls being closer together at the medial portion of the wall than at the lateral portion of the wall. It can also be seen from FIGS. 3, 5 and 6 that the internal chamber 16 opening onto the medullary canal 15 is defined solely by the annular wall member 14 of the internal chamber 16. In this embodiment, the cement can easily enter and fill the internal chamber and thereby exert pressure to push out the annular wall member 14 of the internal chamber 16 against the exposed endosteal surface 11 forming the desired pressure seal.

FIG. 1 also shows that the cement nozzle port 26 is centrally disposed in the proximal end of the sealing device 10 and substantially centrally disposed on the proximal end of the chamber 16. However, it is also within the scope of this invention that the cement nozzle entry port 26 could be disposed at any location on the top of the internal chamber 16 so long as adequate support is provided for the cement nozzle 27 on the seal. It can be seen in

FIG. 1 that the medial portion of the body member 12 of the upper portion of the seal is inset from the medial wall of the anatomically shaped surface 13. In this fashion, the weight of the seal 10 can be reduced and the inset portion 5 24 also provides a stepped area upon which additional axial external force can be applied manually or mechanically so as to retain the seal within the medullary canal 15. It can also be seen that in FIG. 7 the medial portion of the body member 12 of the sealing device 10 may alternatively be 10 formed contiguous with the medial portion of the substantially anatomically shaped surface 13.

FIGS. 1-10 show that the inner surface 20 of the body member 12 also defines the proximal end of the internal 15 chamber 16 having the distal end 22 of passageway 26. In this embodiment, the body member 12 provides additional support for the pressure encountered in the internal chamber thereby insuring that the maximal expansion is encountered in the annular wall 14 of the interior chamber 16 as opposed 20 to the inner surface 20 of the chamber 16 so as to enhance the sealing effect.

In order to accommodate the standard cement 25 nozzles or syringes, the cement gun nozzle entry port 26 of the proximal femoral sealing device 10 is preferably cylindrical in shape. As can be seen in FIG. 2, the cement gun nozzle entry port may also comprise a gasket-seal 28 which also provides an additional means to restrain the 30 cement gun nozzle when it is inserted into and through the cement nozzle entry port 26. This gasket expands when the cement gun nozzle is forced through it, thereby expanding and tightly fitting around the cement nozzle itself. This gasket-seal 28 helps prevent leakage of cement under

pressure through the cement gun nozzle port 26 and also assists in securing the cement gun nozzle itself when exposed to the pressurized cement within the internal cavity. The gasket-seal 28 can be located adjacent to the
5 internal chamber 16, i.e., directly at the opening to the internal chamber 16, or inset a short distance from the internal chamber 16 as in FIG. 6. The gasket-seal 28 may also preferably be located at any point between the interior chamber 16 and the opening of the cement nozzle entry port
10 26 at the top, proximal end of the sealing device 10.

The present invention is also directed to use of the sealing device for injecting cement into a bone canal prior to implantation of a femoral prosthesis. After the
15 medullary canal of the femur has been surgically prepared (and preferably reamed with an appropriate broach), the cleaned cancellous bone is essentially ready to be exposed to the bone cement. If desired, an intermedullary plug such as the Seidel plug can be preferably inserted into the
20 canal to prevent passage of cement distally of the plug. The bone cement is then mixed and loaded into a cement gun according to the manufacturer's instructions. The cement gun nozzle is then inserted through the open proximal end of
the prepared medullary canal until its distal tip is
25 generally approximate to the plug.

The bone cement is then applied through the cement gun nozzle and as the application continues it proceeds to fill the canal to a desired level. The nozzle
30 is then removed at a point where the cement has filled the canal up to about the proximal opening of the medullary canal. At this point the nozzle is placed into the passageway 26 on the proximal femoral seal 10. The proximal

femoral seal 10 is then placed in the proximal end of the prepared medullary canal and additional cement is then injected into the canal under pressure. Sufficient cement is also added so as to fill the interior chamber 16 of the

5 proximal femoral seal 10 thereby expanding its flexible annular wall 14 outwardly forming a tight pressure seal against the exposed endosteal walls 11 of the proximal end of the medullary canal. The formation of a tight and secure seal by the expanded walls 14 of the proximal femoral seal

10 10 against the exposed endosteal walls 11 insures that cement is prevented from escaping through the open proximal end and thus insures that a high degree of pressurization is achieved. After sufficient pressurization is achieved, the nozzle and proximal seal 10 can be removed from the canal.

.....
.....15 It is also within the scope of this invention that the cement nozzle can be placed through the passageway 26 on the proximal femoral seal 10 prior to the cement level reaching the proximal end of the medullary canal. Alternatively, all of the cement needed can be injected into the canal after
.....
20 the cement nozzle is positioned through the passageway 26 and the sealing device 10 is inserted into the proximal open end of the medullary canal.

.....
.....25 At the completion of the cement deposit procedure, the nozzle and proximal femoral seal can be removed simultaneously or separately, i.e., the nozzle may be removed prior to removal of the seal. Because of the excellent pressurization of cement resulting from the use of the femoral seal 10 of the present invention, the cement
.....
30 penetrates deeply into the cancellous bone of the medullary canal wall and provides a very strong and stable fixation of the prosthesis. The depth of capillary penetration is, for instance, shown in the respective figure illustrated in the

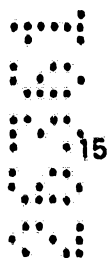
publication entitled "Innovations In Cementing Techniques In Total Hip Replacement" presented as a Scientific Exhibit at the American Academy of Orthopedic Surgeons 54th Annual Meeting, San Francisco, held on January 22-27, 1987. This

5 figure clearly demonstrates that utilization of the present invention provides a much greater cement penetration depth than other methods utilizing manual pressurization or the solid seal type (Miller) of device. This publication in another figure shows the increased pressure capable with the
10 proximal femoral seal 10 of the present invention as compared to manual techniques and the use of solid seals. Pressures of up to 60 pounds per square inch are shown in this figure. However, pressures of up to 100 pounds per
15 square inch have been achieved with the proximal femoral seal 10 described herein. While this publication in another figure demonstrates average pressure of about 30 psi, this seal 10 is also capable of maintaining an average cement pressure of at least about 50 pounds psi. Finally, another
20 figure in this publication shows that a peak intramedullary pressure of about 60 psi is possible using the proximal femoral seal 10 as compared to the manual technique and use of a solid seal. Yet, peak pressures of up to 100 psi have been achieved using the proximal femoral seal 10 described
25 herein.

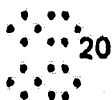
Variations of the above described method which
30 involve minor changes in the sequencing of steps are clearly contemplated to be within the scope of the present invention. In addition, minor variations in the design, angles or materials of the proximal femoral seal of the present invention are also contemplated to be within the scope of the present invention. These modifications and variations of the above invention may be made without

departing from it spirit and scope, as will become apparent to those skilled in the art. The specific embodiments described herein are offered by way of example only, and the invention is limited only by the terms of the appended
5 claims.

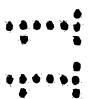
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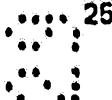
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The claims defining the invention are as follows:

1. A sealing device for introducing bone cement into a bone canal through an opening in the bone, characterized in that said sealing device has:

(a) body member having a passageway of predetermined cross-section extending therethrough for passage of cement;

(b) generally annular wall member extending from said body member and defining an outer surface at least a portion of which is elastically expandable and is configured and dimensioned so as to be capable of extending into the bone canal said outer surface adapted to provide a contacting seal along a length of the inner walls of the bone canal; and

(c) chamber defined by said annular wall member, said chamber having a cross-section greater than said predetermined cross-section of said passageway and communicating with said passageway and relatively stationary with said bone canal such that cement, upon its introduction into said bone canal, will also fill said chamber and cause said elastically expandable portion of said annular wall to expand so as to aid in maintaining said seal.

2. A sealing device for injecting bone cement into the bone canal through an opening in the bone, characterized in that said sealing device has:

(a) body member having a passageway of predetermined cross-section extending therethrough for passage of cement;

(b) generally elastically expandable annular wall member extending from said body member and defining with said body member a generally continuous outer surface which is configured and dimensioned such that at least a portion of said outer surface corresponds anatomically to a portion of the bone canal adjacent the opening so as to be capable of extending into the bone canal said outer surface adapted to provide a contacting seal along a length of the inner walls of the bone canal; and

(c) chamber defined by said annular wall member and said body member, said chamber having a cross-section greater than said predetermined cross-section of said passageway and communicating with said passageway and relatively stationary with said bone canal such that cement upon its



injection into said bone canal will also fill said chamber so as to expand said elastically expandable annular wall member and thus maintain said seal and aid in the penetration of cement into the bone within the canal.

3. A sealing device for seating within the medullary canal of a prepared proximal end of a femur and for injecting bone cement under pressure into the medullary canal, characterized in that said sealing device has:

(a) body member having a passageway of predetermined cross-section extending therethrough for passage of cement;

(b) generally elastically expandable annular wall member extending from said body member and defining with said body member an outer surface which is anatomically shaped and conforms generally along the vertical and horizontal axes of the body member to the exposed internal endosteal surface shape of the proximal end of the medullary canal of the femur; and

(c) chamber defined by said elastically expandable wall member and said body member, said chamber having a cross-section greater than said predetermined cross-section of said passageway and opening onto and communicating at one end with said proximal end of said medullary canal, the other, opposite end opening onto and communicating with the distal end of said passageway, said chamber further having a generally rounded-trapazoidal cross-sectional configuration defined by said elastically expandable wall member which is capable of expanding under pressure of cement within said chamber against the exposed internal endosteal surface of the medullary canal so as to form a pressurization cement seal.

4. The sealing device of claim 3 characterized in that said anatomically shaped outer surface generally corresponds to the outer surface shape of a broach utilized to expose the endosteal surface of the medullary canal.

5. The sealing device of claim 3 characterized in that said anatomically shaped outer surface generally corresponds to the natural internal surface shape of the medullary canal.

6. The sealing device of claim 3 characterized in that said anatomically shaped outer surface further comprises a plurality of ridges.



7. The sealing device of claim 6 characterized in that said plurality of ridges are dimensioned and configured so that leading edges thereof contact the exposed internal endosteal surface.

8. The sealing device of claim 3 characterized in that the proximal end of said anatomically shaped outer surface is wider than the distal end along a cross-section of the vertical axis of the seal.

9. The sealing device of claim 3 characterized in that the portion of said substantially anatomically shaped outer surface on the medial side of said medullary canal ranges from a straight surface to one which is curved from the proximal to distal end of said substantially anatomically shaped outer surface.

10. The sealing device of claim 3 characterized in that said wall member is thicker at the proximal end of said chamber than at the distal end of said chamber.

11. The sealing device of claim 10 characterized in that said wall member tapers to reduce in thickness from said proximal end to said distal end.

12. The sealing device of claim 3 characterized in that said passageway is centrally disposed in the body member.

13. The sealing device of claim 3 characterized in that said passageway is dimensioned and configured to receive a nozzle for injection of cement.

14. The sealing device of claim 3 characterized in that a medial portion of said body member is inset from the medial portion of said anatomically shaped outer surface.

15. The sealing device of claim 3 characterized in that said passageway is cylindrical in shape.

16. The sealing device of claim 3 characterized in that said passageway narrows to form a gasket-seal so as to restrain a cement nozzle inserted through said passageway.

17. The sealing device of claim 3 characterized in that said body member and flexible annular wall member are formed to a medical grade elastomer.

18. A sealing device for introducing cement into a bone canal substantially as hereinbefore described with reference to the accompanying drawings.



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19. A sealing device for injecting cement into a bone canal substantially as hereinbefore described with reference to the accompanying drawings.

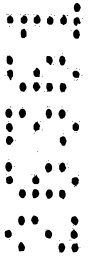
20. A femoral sealing device substantially as hereinbefore described with reference to the accompanying drawings.

DATED this THIRD day of MAY 1990

Philip Christopher Noble

Patent Attorneys for the Applicant

SPRUSON & FERGUSON



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A detailed cross-sectional view of a mechanical component. The main body is a tapered cylinder labeled 12. Inside it, there's a smaller tapered part labeled 22, which has vertical ridges or grooves labeled 20 and 28. At the top of this inner part is a flange-like feature labeled 30. Below the main body 12 is a base or support structure labeled 14. A horizontal dashed line indicates a section plane. Arrows labeled 3 point horizontally towards the center from both sides. Arrows labeled 4 point vertically downwards from above. A curved arrow labeled 13 indicates a rotational movement around a central axis. A dimension line labeled B shows a vertical distance. A label A points to the outer surface of the tapered member 12. At the bottom, another horizontal dashed line is shown with arrows labeled 3 pointing horizontally.

FIG. 3

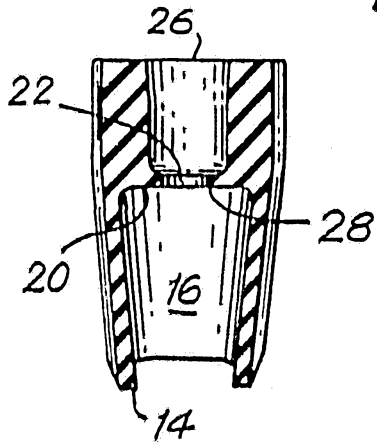


FIG. 4

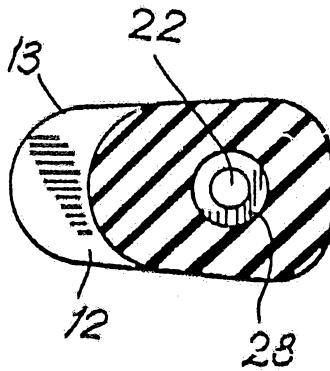
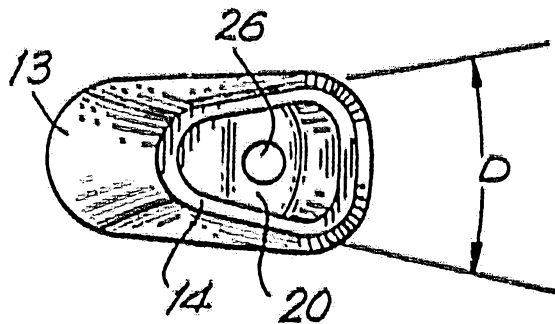


FIG. 5



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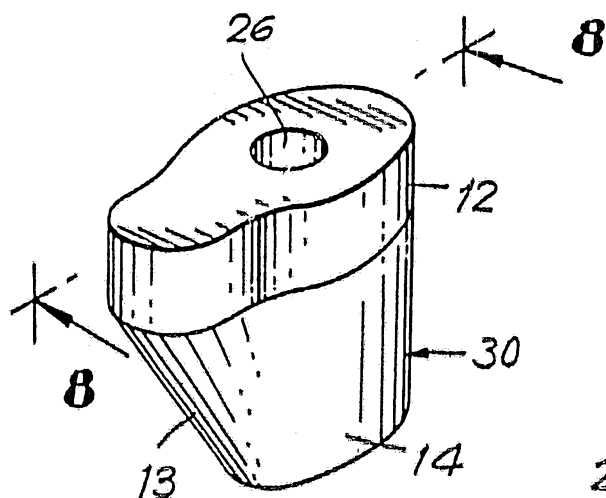


FIG. 7

FIG. 8

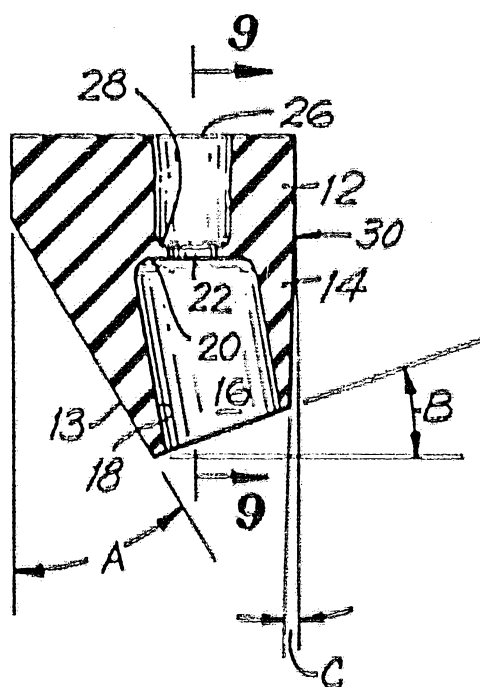


FIG. 9

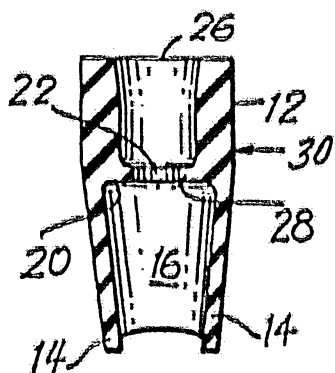


FIG. 10

