

599849

FORM 1

SPRUSON & FERGUSON

COMMONWEALTH OF AUSTRALIA

PATENTS ACT 1952

APPLICATION FOR A STANDARD PATENT

Pfizer Hospital Products Group, Inc., incorporated in Delaware, of 235 East 42nd Street, New York, New York, 10017, UNITED STATES OF AMERICA, hereby apply for the grant of a standard patent for an invention entitled:

Long Stem Hip Implant

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>
124134	US	23 November 1987

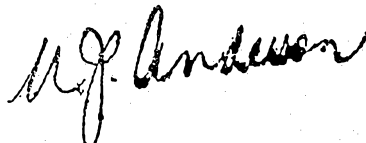
The address for service is:-

Spruson & Ferguson
Patent Attorneys
Level 33 St Martins Tower
31 Market Street
Sydney New South Wales Australia

DATED this TWENTY FIRST day of NOVEMBER 1988

Pfizer Hospital Products Group, Inc.

By:



Registered Patent Attorney

TO: THE COMMISSIONER OF PATENTS
OUR REF: 78203
S&F CODE: 60030

APPLICATION ACCEPTED AND AMENDMENTS

5003790 22/11/88

REGISTERED 16.5.90

5845/5

COMMONWEALTH OF AUSTRALIA
THE PATENT ACT 1952
DECLARATION IN SUPPORT OF A
CONVENTION APPLICATION FOR A PATENT

AUSTRALIA
CONVENTION
STANDARD
& PETTY PATENT
DECLARATION

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

PC-7294

Title of Invention

LONG STEM HIP IMPLANT

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

I/~~We~~ Allen J. Spiegel on behalf of Pfizer Hospital Products
Group, Inc.
of 235 East 42nd Street, New York, State of New York,
United States of America

do solemnly and sincerely declare as follows:-

Full name(s) of
Applicant(s)

- X. ~~I am/we are the applicant(s) for the patent~~
(or, in the case of an application by a body corporate)
- 1. I am/~~We are~~ authorised by
Pfizer Hospital Products Group, Inc.
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(ies)

in United States of America

Priority Date(s)

on November 23, 1987

Basic Applicant(s)

by Charles John Muller

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

- X. ~~I am/we are 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. Charles John Muller

of 33 Sunrise Drive, Gillette, State of New Jersey, United
States of America; Citizen: United States of America;
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)

The Applicant Company is the Assignee of the said
invention from the actual inventors by virtue of an
Assignment dated November 20, 1987.

- 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 New York, this 27th day of September 1988
New York Pfizer Hospital Products Group, Inc.

Signature of Declarant(s)

(12) PATENT ABRIDGMENT (11) Document No. AU-B-25794/88
(19) AUSTRALIAN PATENT OFFICE (10) Acceptance No. 599849

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LONG STEM HIP IMPLANT
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- (71) Applicant(s)
PFIZER HOSPITAL PRODUCTS GROUP, INC.
- (72) Inventor(s)
CHARLES JOHN MULLER
- (74) Attorney or Agent
SPRUSON & FERGUSON
- (57) Claim

1. A long stem hip joint prosthetic device for implantation into the reamed or broached out medullary canal of the femur comprising:
a femoral component having an intramedullary stem having a proximal and a distal portion the combined length of which, when implanted, is longer than the distance in the intramedullary canal from the femur lesser trochanter to the isthmus, said proximal portion of said intramedullary stem being substantially straight over its major extent, said distal portion made up of a first component and a second component, wherein (a) said first component is the projection of said distal curve on the A-P plane and is a simple curve having its center of curvature (when positioned in the body upon implantation) lying posteriorly with respect to the axis of the femur; and (b) said second component is the projection of said distal curve on the M-L plane and is a simple curve having its center of curvature (when positioned in the body upon implantation) lying laterally with respect to the axis of the femur, said curvature of said second component beginning at a point closer to a tip of said distal portion than the curvature of said first component.

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FORM 10

COMMONWEALTH OF AUSTRALIA

PATENTS ACT 1952

COMPLETE SPECIFICATION

(ORIGINAL)

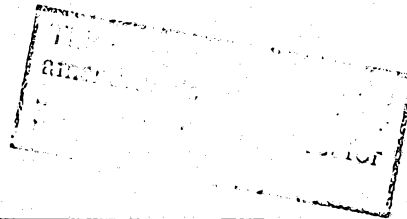
FOR OFFICE USE:

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Complete Specification Lodged:
Accepted:
Published:

Priority:

Related Art:



Name and Address
of Applicant:

Pfizer Hospital Products Group, Inc.
235 East 42nd Street
New York New York 10017
UNITED STATES OF AMERICA

Address for Service:

Spruson & Ferguson, Patent Attorneys
Level 33 St Martins Tower, 31 Market Street
Sydney, New South Wales, 2000, Australia

Complete Specification for the invention entitled:

Long Stem Hip Implant

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

ABSTRACT

A long stem hip joint prosthetic device for implantation into the reamed or broached out medullary canal of the femur comprising:

5 a femoral component having an intramedullary stem having a proximal and a distal portion the combined length of which, when implanted, is longer than the distance in the intramedullary canal from the femur lesser trochanter to the isthmus, said proximal portion of said intramedullary stem being substantially straight over its major extent, said distal portion made up of a first component and a second component, 10 wherein (a) said first component is the projection of said distal curve on the A-P plane and is a simple curve having its center of curvature (when positioned in the body upon implantation) lying posteriorly with respect to the axis of the femur; and (b) said second component is the projection of said distal curve on the M-L plane and is a simple curve having its center of curvature (when positioned in the body upon implantation) lying 15 laterally with respect to the axis of the femur, said curvature of said second component beginning at a point closer to a tip of said distal portion than the curvature of said first component.



PC 7294

LONG STEM HIP IMPLANT

For operations involving patients who require multiple hip surgeries, it is often necessary to replace a femoral hip implant with a long stem hip
5 implant. That is, a short stem hip implant is not generally used for revisions. Long stem hip implants can also be used in other situations. For example, they can be used in patients undergoing revision surgery or requiring an implant with a long stem
10 because of a fracture in the femur or a bone defect (for example as a result of tumor removal).

However, when such a long stem hip implant is fully implanted, it is very important that its distal end be centered in the medullary canal. If the distal
15 end is not centered, a non-uniform cement mantle will result as the implant is inserted into the canal containing cement. Then, unequal stresses on the cement mantle may result in failure of the cement mantle. Such failure can eventually result in
20 loosening of the implant.

Additionally, because long stem hip prostheses generally extend in the femur beyond the region referred to as the isthmus of the femur (where the cortical bone thickens and the opening in the
25 intramedullary canal decreases), correct placement of a long stem prosthesis presents a special challenge to the physician.

Broaches are often used to prepare the medullary canal. These broaches can be designed to rotate
30 slightly into anteversion (i.e., the neck of the broach rotates forward as the broach is driven into the bone). The final orientation mimics the natural anatomic orientation of the femoral neck. This rotation (which

is approximately 10°) presents no problem in the alignment of a short prosthesis, wherein the stem is not long enough to impinge on the curved section of the femur, particularly in the region of the isthmus. However, when a long, bowed stem is used as a prosthesis, the rotation will often result in poor placement of the distal tip of the implant.

It is known in the prior art to have "anatomically" shaped prostheses which have been made with simple distal bows and/or distal and proximal curvatures. However, the distal tip of the implant must still be correctly positioned, as described above. The problem of positioning an implant within the isthmus of the bone has not previously been adequately addressed in the prior art.

Additionally, for economic purposes, it is desirable to have a limited number of ready-made long stem hip implants for use by the population requiring such implants.

An object of this invention is to provide a femoral component suitable for use in patients having hip surgery requiring a long stem prosthesis.

Another object of this invention is a long stem hip implant which is suitable for a large segment of the population requiring revision surgery.

Yet another object of this invention is a modular long stem hip implant.

These and other objects are satisfied by the invention described and claimed herein.

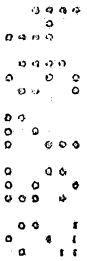
According to the invention there is provided a long stem hip joint prosthetic device for implantation into the reamed or broached out medullary canal of the femur comprising:

a femoral component having an intramedullary stem having a proximal and a distal portion the combined length of which, when implanted, is longer than the distance in the intramedullary canal from the femur lesser trochanter to the isthmus, said proximal portion of said intramedullary stem being substantially straight over its major extent, said distal portion made up of a first component and a second component, wherein (a) said first component is the projection of said distal curve on the A-P plane and is a simple curve having its center of curvature (when positioned in the body upon implantation) lying posteriorly with respect to the axis of the femur; and (b) said second component is the projection of



said distal curve on the M-L plane and is a simple curve having its center of curvature (when positioned in the body upon implantation) lying laterally with respect to the axis of the femur, said curvature of said second component beginning at a point closer to a tip of said distal
5 portion than the curvature of said first component.

According to the invention a hip joint prosthetic device (which is suitable for use a in large segment of the population requiring revision surgery, without modification of that device) comprises a femoral component having a long stem which is sufficiently long



when implanted so that it extends beyond the isthmus in the femur, which is substantially straight over its major extent, but which is curved in a very particular way, described below, in the distal section of the stem. That curve in the distal section of the stem is formed generally from two components.

The stem of the invention can be viewed as having a single curve, which has a component in the A-P (anterior/posterior) plane and another component in the M-L (medial-lateral) plane. That is, the projection of this single curve on the A-P plane and the projection of the single curve on the M-L plane can be discussed as two curves, even though the femoral component stem actually includes only one curve in three-dimensional space in its distal section.

The components of the curve will be discussed separately herein. The first and the second of these components are two curves located in perpendicular planes. One of these components is a curve lying in the A-P plane and is the projection of the single curve on the A-P plane. The A-P component is a simple curve having its center of curvature (when positioned in the body) posterior to the axis of the femur. The second component of the single curve is the projection of the single curve on the M-L plane, which also is a simple curve but its center of curvature is lateral to the axis of the femur. The stem of the resulting device avoids impingement on the wall of the medullary canal, even in the region of the isthmus.

Also, according to the invention, the distal portion of the long stem femoral hip implant may be used as a component of a modular device.

Fig. 1 is a plan view of an embodiment of the device of the invention, for use in a right femur as viewed in the A-P plane from the lateral direction. A portion of a right femur is shown with cross-hatching.

5 Fig. 2 is a plan view of the device of Fig. 1 as viewed in the M-L plane from the dorsal direction. A portion of a right femur is shown with cross-hatching.

10 Fig. 3 is a cross-sectional view of the device of Fig. 1, as viewed near its distal end, taken along line 3-3 in Fig. 1, and located within the medullary canal, showing cement surrounding the device.

Fig. 4 is a schematic illustration of a right human leg, showing the device of Fig. 1 in dotted lines, located within a right femur.

15 Fig. 5 is a pictorial representation of the device of Fig. 1, showing its relationship with respect to the M-L plane and the A-P plane at a time when the device has just been inserted into the body and prior to its being rotated about 10° by the physician.

20 As shown in Figures 1 and 2, each of the components of the curve in the stem of the hip implant 12 of the invention is a simple curve having one center of curvature. (This is in contradistinction to a compound curve.)

25 The curve component lying in the A-P plane shown in Figure 1 has a center of curvature C which is posterior to the axis of the femur and to the axis of the stem when the device is positioned in the body.

30 The curve component lying in the M-L plane shown in Figure 2 has a center of curvature C' lateral to the axis of the femur and to the axis of the stem when the device is positioned in the body.

As shown in Figures 1 and 2, the component of curvature lying in the A-P plane is the larger and more visually obvious of the two curve components. That is, distance B in Figure 1 is substantially larger than distance X in Figure 2, which reflects a substantially smaller average radius of curvature in the A-P plane than in the M-L plane. The bend positions the distal tip 10 of the prosthesis posteriorly with respect to the body, thus accommodating the natural curve of the mid-shaft of the femur and avoiding impingement of the prosthesis on the canal even in the region of the isthmus.

The curve component in the M-L plane is less pronounced, begins more distally on the stem (as compared with the curve in the A-P plane, described above), and positions the tip 10 of the prosthesis laterally with respect to the body (see Figure 2).

As shown in Figure 3, this curve in the stem of the prosthesis 12 of the invention helps to keep the distal section 14 of the stem centered in the cement 16 in the medullary canal of the femur 18.

Also shown in Figures 1 and 2 are other features and parts of the device of the invention. These include the trunion 20, onto which a head component (not shown) can be attached. The neck 22 connects the trunion 20 to the collar 24 (shown only in Figures 2 and 4). The lateral aspect 26 of the proximal portion of the stem is shown. The centerline 28 of the proximal portion of stem 12 in the A-P plane is shown in Figure 1 to be coplanar with the centerline of the neck 22, and no anteversion of the neck with respect to the proximal stem is present.

The centerline 30 in the A-P plane and the centerline 31 in the M-L plane of the distal portion of the stem are curved.

B is the perpendicular distance in the A-P plane between the centerline 30 at the distal tip 10 of the implant and the extension in space of the centerline 28 in the A-P plane of the proximal portion of stem 12. X is the perpendicular distance in the M-L plane between the centerline 31 at the distal tip 10 of the implant and the extension in space of the centerline 29 in the M-L plane of the proximal portion of stem 12. Suitable values for X and B (defined above) are shown in the table below for the stem lengths provided. For the primary (i.e., the more prominent) curve in every case, the radius of curvature for C is 1140 mm. For the secondary (i.e., the less prominent) curve, the radius of curvature for C' varies, as shown in the table under the heading r(mm).

In Figure 2, one can see the textured surface 32 which improves cement adhesion to the device. The lateral flare 34 improves the stress distribution in the bone cement mantle. The thickness of bone 36 is cross-hatched in the Figures 1, 2, and 3. The cement 16 is shown with a dotted area in the figures.

Regions of bone 36 are indicated, including the lesser trochanter 38 and the region of the isthmus 40 of the femur.

The stem length of the long stem hip implant of this invention will be sufficiently long for a given patient so that the distal tip of the implant extends beyond the isthmus in the intramedullary canal of the patient's femur. The length of the stem D will therefore generally be at least about 200 mm.

It has been found that four sizes of the proximal section of the femoral component of the long stem prosthesis of the invention with two lengths of each size will fit most femora encountered in patients requiring hip surgery. For these, the distance D in

Fig. 1 and Fig. 2 will be within the range from about 21 to about 35 cm in length.

The stem lengths of these four sizes of long stem hip implants are given in the following table, with two stem lengths for each size. Also given is a range of suitable associated neck lengths for these four sizes. It is noted that the use of different heads will provide different effective neck lengths contributing to the total length of the implant.

Table

Size	Stem length D' (mm)	Neck length (mm)	B (mm)	X (mm)	r (mm)
1	175/225	36	9.0	0,20	1900
2	200/250	41	9.0	1.6	2600
3	225/275	44	11.9	2.0	3300
4	225/300	46	15.0	4.0	2700

In prior art long stem bowed prostheses, the plane of the bow is perpendicular to the plane of the proximal stem. Anteversion, if present at all, is accomplished by a rotation of the neck of the device itself with respect to the long axis of the stem. That is, the centerline of the neck is not coplanar with the centerline of the proximal stem.

The device of this invention having the centerline of its neck preferably coplanar with the centerline of the proximal stem allows anteversion of the proximal stem by the physician without risking impingement of the distal stem on the intramedullary canal.

The devices of the invention are implanted into the body by the following general procedure. A soft tissue dissection is made to expose the joint capsule. The femoral head is then dislocated from the acetabulum

and the femoral head is removed (or the old prosthesis is removed if revision surgery is being done). The medullary canal is either reamed and broached (or the old cement is removed if revision surgery is being done). Then cement is injected into the canal and the prosthesis is inserted. The entire implant is then rotated forward preferably about 10° to 12° with respect to the M-L plane during the implanting procedure. This rotation accomplishes the anteversion, and there is preferably no anteversion of the neck of the prosthesis with respect to its shank.

It is noted that in the device of the invention, the curved portion is preferably located only in the distal section 14 of the stem. However, minor, insignificant curves in other sections of the device could also be present, and such a device would fall within the scope of this invention, provided that the curves in the distal segment (described above) are present.

When made of metal, the devices of the invention can be produced so that initially they have no curvature. The two components of the curves can be made in two separate bending operations. Alternatively, the stem can be forged in a single operation to its final configuration.

Preferably, the long stem femoral components are forged to the final configuration. The trunion for the head is machined and ground, and the forging flash is removed by hand-finishing operations.

Although it is expected that the devices of the invention will usually be made of metal, any biocompatible material can be used, so long as the final product has the configuration described above and has sufficient strength and other required properties for a prosthetic hip implant.

A long stem femoral component of the invention can be used as part of a modular system if desired.

The claims defining the invention are as follows:

1. A long stem hip joint prosthetic device for implantation into the reamed or broached out medullary canal of the femur comprising:

a femoral component having an intramedullary stem having a proximal and a distal portion the combined length of which, when implanted, is longer than the distance in the intramedullary canal from the femur lesser trochanter to the isthmus, said proximal portion of said intramedullary stem being substantially straight over its major extent, said distal portion made up of a first component and a second component, wherein (a) said first component is the projection of said distal curve on the A-P plane and is a simple curve having its center of curvature (when positioned in the body upon implantation) lying posteriorly with respect to the axis of the femur; and (b) said second component is the projection of said distal curve on the M-L plane and is a simple curve having its center of curvature (when positioned in the body upon implantation) lying laterally with respect to the axis of the femur, said curvature of said second component beginning at a point closer to a tip of said distal portion than the curvature of said first component.

2. A device according to claim 1, wherein said first component lying in the A-P plane has a smaller radius of curvature than the curve component lying in the M-L plane.

3. A device according to claim 1 or claim 2, wherein said femoral component includes a neck having a centerline coplanar with a centerline of said proximal portion.

4. A device according to claim 3 wherein the length of said stem is at least about 200 mm.

5. A device according to any one of claims 1 to 4, wherein, the curvature of said second curve component and the curvature of said first curve component have predetermined radii resulting in a stem which avoids impingement on the wall of the medullary canal when the prosthetic device is inserted and rotated therein at an angle from about 10° to about 12° anteriorly with respect to the M-L plane.

6. A device according to any one of claims 1 to 5 wherein the distal section and the proximal section of said device are separable from each other.

7. A device according to any one of claims 1 to 6 wherein said intramedullary stem has a cross-section relative to the cross-section of the reamed out or broached out medullary canal producing a predetermined concentric gap therebetween such that the device is spaced from the wall of said medullary canal.

8. A device according to one any of claims 1 to 7 wherein said femoral component includes a neck having a centerline in a plane parallel to a plane containing the centerline of said proximal portion so that all anteversion is accomplished by the procedure of rotating said prosthesis with respect to the M-L plane during its insertion into the medullary canal of the patient.

9. A long stem hip joint prosthetic device for implantation substantially as hereinbefore described with reference to the accompanying drawings.

DATED this TWENTY-SIXTH day of APRIL 1990
Pfizer Hospital Products

Patent Attorneys for the Applicant
SPRUSON & FERGUSON



Fig. 1.

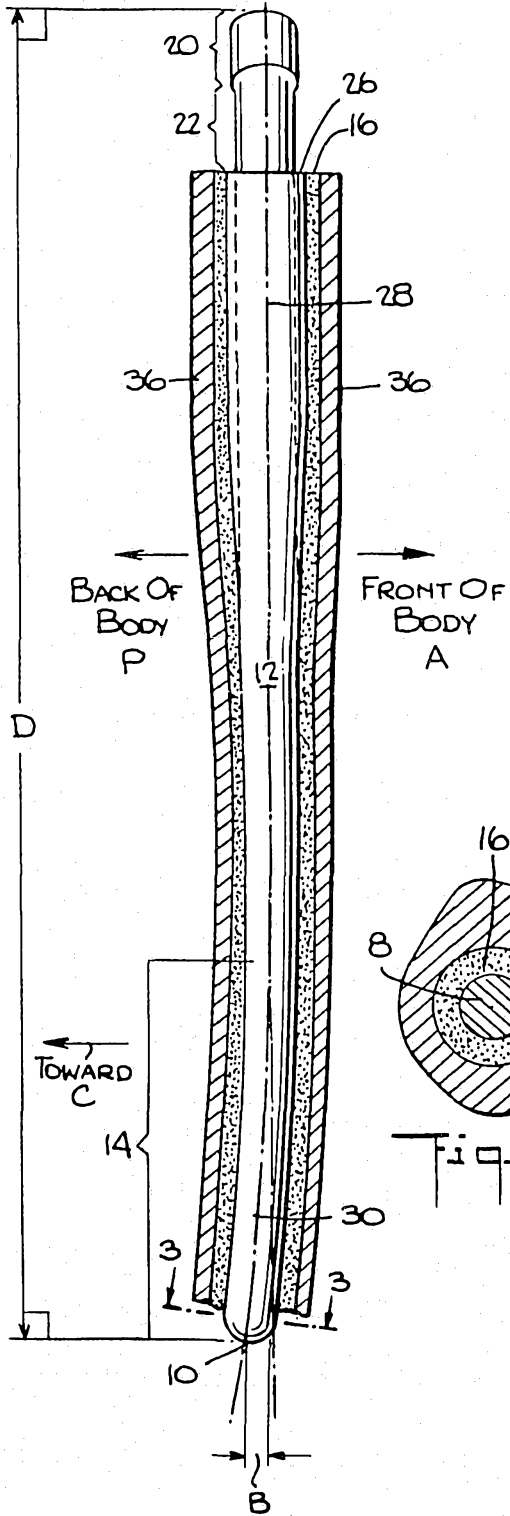
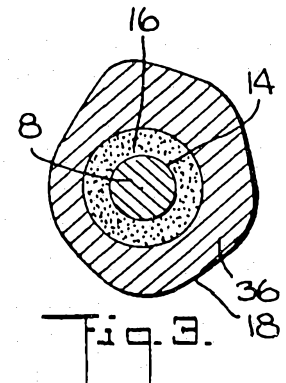
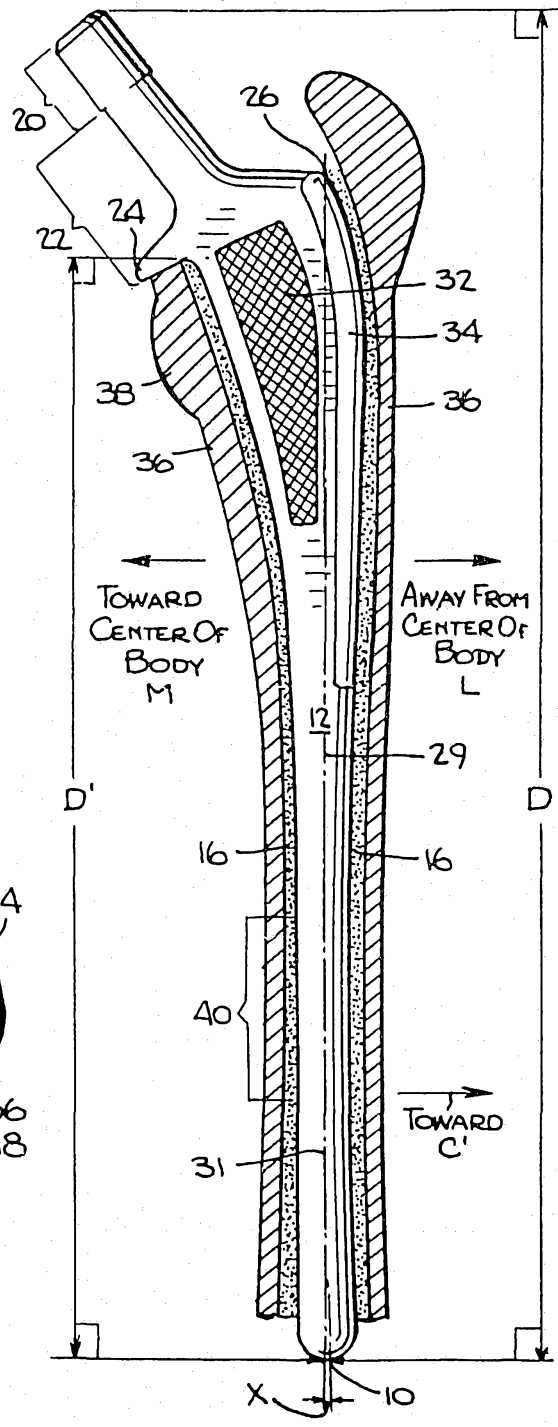


Fig. 2.



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Fig. 4.

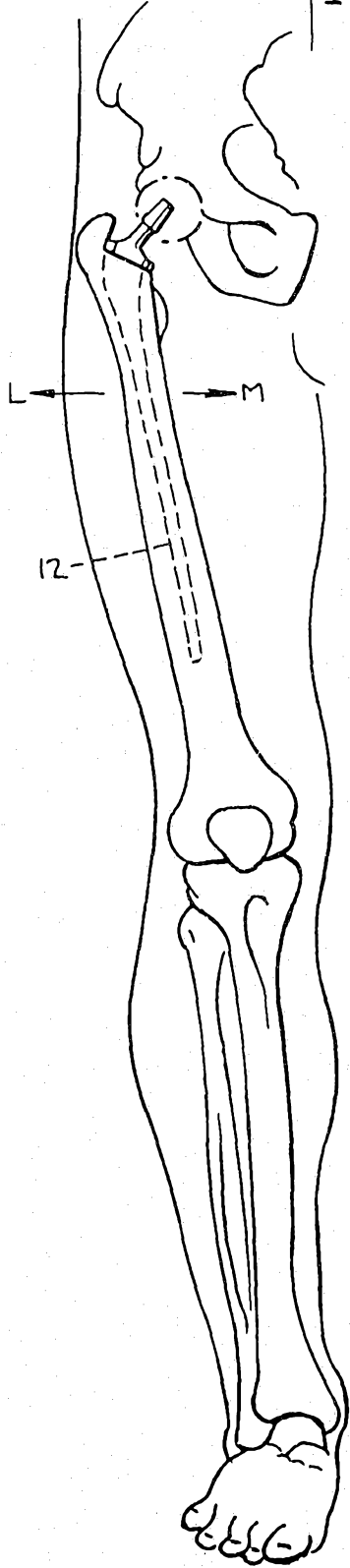


Fig. 5.

