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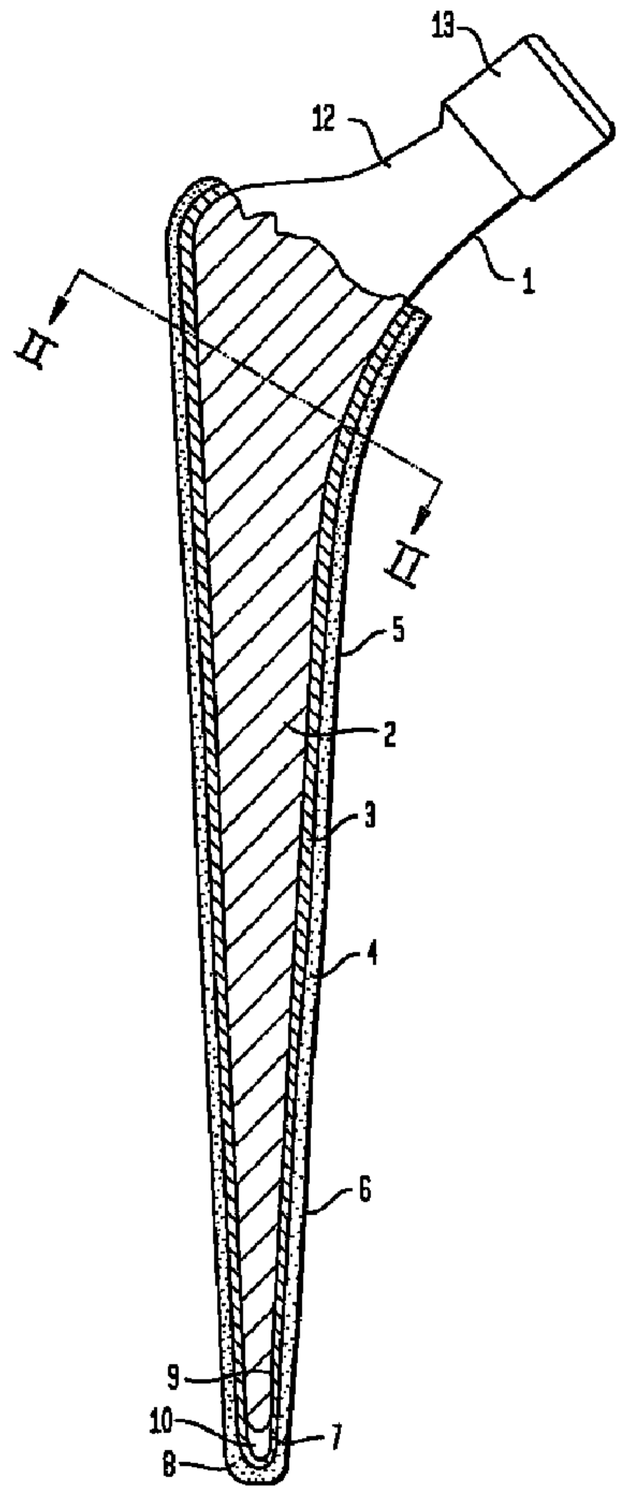
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(54) **Titre : IMPLANT PROTHETIQUE POUR UTILISATION SANS CIMENT OSSEUX**
(54) **Title: PROSTHETIC IMPLANT FOR USE WITHOUT BONE CEMENT**



(57) **Abrégé/Abstract:**
A prosthetic implant which has an attachment portion for insertion into or attachment to a patient's bone without bone cement and in which the outer surface of the attachment portion which is to be attached to said bone has a first layer made of synthetic resin

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(57) **Abrégé(suite)/Abstract(continued):**
material over which is secured a second layer made of a metallic material, a first and proximal portion of said second layer being porous or roughened to encourage bone ingrowth or ongrowth and a second and distal portion of said second layer being less porous, substantially non-porous or less roughened in relation to the first portion, or smooth.

Abstract

A prosthetic implant which has an attachment portion for insertion into or attachment to a patient's bone without bone cement and in which the outer surface of the attachment portion which is to be attached to said bone has a first layer made of synthetic resin material over which is secured a second layer made of a metallic material, a first and proximal portion of said second layer being porous or roughened to encourage bone ingrowth or ongrowth and a second and distal portion of said second layer being less porous, substantially non-porous or less roughened in relation to the first portion, or smooth.

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PROSTHETIC IMPLANT FOR USE WITHOUT BONE CEMENT

This invention relates to a prosthetic implant, of any kind, which has any attachment portion for insertion into or attachment to a patient's bone without bone cement. Thus the invention can be applied, for example, to a femoral prosthesis, a tibial component of a total knee prosthesis or a hip cup.

The term 'bone ongrowth' will be used herein to indicate a surface onto which bone can grow, for example a roughened surface. The term 'bone ingrowth' will be used herein to indicate a surface in which bone can grow inwardly, for example a porous surface.

It is known from, for example, US 5,665,121 to use a sheath made from a synthetic plastics material which could have a roughened outer surface to promote bone ongrowth over the stem of a femoral prosthesis for use without bone cement. It is also known from US 4,650,489 to provide a femoral prosthesis with an outer sheath made of stainless steel or titanium steel which encloses the stem but is separated from it by a layer of elastomeric material such as silicon or a butyl rubber. The inner surface of the metallic sheath and the outer surface of the stem are indented to retain the elastomeric material in place and prevent movement between the stem and the outer metallic sheath. The distal end of the stem is located in a closed cavity filled with an air/gas below the elastomeric material to allow the stem to displace slightly under shock due to the resilience of the elastomeric material but there is no provision to allow the stem to subside downwardly within the sheath after insertion.

Some embodiments of the present invention are intended to provide a construction which has the advantage over those referred to in the earlier documents in that it allows a sheath to be proximally loaded by arranging the outer surface to be metallic and encourage bone ingrowth, and for the distal part of the sheath to encourage bone ongrowth or only a very minor ingrowth or none at all. With this arrangement the loading on the

distal end of the sleeve is reduced in relation to the proximal loading, which has been found to be desirable.

According to some embodiments of the present invention a prosthetic implant has an attachment portion for insertion into or attachment to a patient's bone without bone cement and the outer surface of the attachment portion which is to be attached to said bone has a first layer made of synthetic resin material over which is secured a second layer made of a metallic material, the proximal portion of said second layer being porous or roughened to encourage bone ingrowth or ongrowth and a distal portion thereof being less porous, substantially non-porous or less roughened in relation to the first portion, or smooth.

This type of construction allows for the desirable proximal loading capability.

Thus, the outer surface of the metallic layer can, for example, have an interconnected porosity where bone ingrowth is required on the proximal portion and a roughened surface where bone ongrowth is required on the outer distal surface of the metallic layer or this portion maybe relatively smooth.

In some constructions the required proximal locking can be achieved by a roughened surface on the proximal portion and smooth or less roughened on the distal portion.

The first and second layers can be applied in situ to the attachment portion, for example the plastic sheath is preferably cast into position on the attachment portion with which it is to be used and this can be temporarily fitted with a mechanism to create the distal void.

Alternatively the first and second layers can be preformed as a separate sheath for attachment to the attachment portion. Again, the plastic inner layer can

be cast on the intended femoral implant or, alternatively, the inner layer can be moulded into the outer metallic layer.

A sheath can also be made which is not preferentially matched with the intended femoral implant, for example, the sheath could be of a standard dimension which could be used with existing implants.

The second metallic material layer can be made from titanium, titanium alloy or any other suitably bio-compatible metal which contacts directly with the bone.

The metal can be in the form of a preformed shape or can be formed by metallic sputtering or, for example, forming by a laser melting process.

The layer melting process can, for example, be as set forth in US Patent Application Publication Nos. 20040191106 entitled, “Laser-Produced Porous Surface”; 20060147332 entitled, “Gradient Porous Implant”; and 20070142914 entitled, “Laser-Produced Porous Surface”. As discussed in US Patent Application Publication No. 20040191106, the metal structure may be constructed using a selective laser melting or sintering process, which hereby grows the structure in a layer by layer process. In the alternative, the metal structure may be built using an alternate process described in US Patent Application Publication No. 2004019116 wherein the intermediate portion acts as a base or substrate on which the polymer engaging portion and bone ingrowth portion are built thereon, also in a layer-by-layer fashion. Additional techniques for constructing the metal lattice may also be employed such as that disclosed in US Patent Application Publication No. 20030153981 entitled, “Porous Metallic Scaffold for Tissue”, as well as additional methods known to those in the art such as that disclosed in Patent Application Publication Nos. 20060228247 and 20060002810.

Preferably, the synthetic resin material is polymethylmethacrylate (PMMA).

Preferably there is engagement or interlock between the first and second layers, for example by providing a roughened surface on inner surface of the second layer.

The distal end of the first and second layers can be formed as a cup, the inner surface of which is spaced away from the distal end of the attachment portion to provide a distal void when initially located in position to accept subsequent movement between the first layer and the attachment portion after fitting. This movement allows the stem to subside to its natural position after initial weight bearing of the implanted device.

The thickness of the wall formed by the two layers can be between 1 mm and 3 mm and is preferably between 1.8 mm and 2.5 mm.

If desired, the inner surface of the metal second layer can be roughened to enhance the bonding to the outer surface of the synthetic resin first layer. Preferably this bonding can take place with the addition of a PMMA bone cement.

Some embodiments of the invention also include a method of forming the prosthetic implant which has an attachment portion as set forth above, the method includes attaching the first layer of a synthetic resin material by dipping the stem portion into a liquid bath of material or by spraying the material onto the outer surface of the attachment portion, then applying the metal second layer by either buttering a metal onto the synthetic resin material layer or by using a selective laser sintering process.

In an alternative method the first and second layers are provided as a sheath which is formed separately and slid onto the attachment portion in a distal to proximal direction.

This can be performed by preforming and bonding the two layers together by using additional PMMA bone cement.

According to one aspect of the present invention, there is provided a femoral prosthesis which has an attachment portion in the form of a stem for insertion into our attachment to a patient's bone without bone cement, in which the outer surface of the stem is smooth and tapered on moving proximal to distal on the stem, the stem has a first layer made of synthetic resin material applied thereto, in which the stem has a smooth surface suitable to allow the stem to move downwardly in relation to said first layer after fitting, in which a second layer is secured to said first layer and is made of metallic material, a first and proximal portion of said second layer being porous or roughened to encourage bone ingrowth or ongrowth and a second and distal portion of said second layer being less porous, substantially non-porous or less roughened in relation to the first portion, or smooth.

According to another aspect of the present invention, there is provided a method of forming the femoral prosthesis as described herein which includes attaching the first layer of a synthetic resin material by dipping the stem portion into a liquid bath of material or by spraying the material onto the outer surface of the attachment portion, then applying the metal second layer by either buttering a metal onto the synthetic resin material layer or by using a selective laser sintering process.

According to yet another aspect of the present invention, there is provided a method of forming the femoral prosthesis as described herein which includes providing the first and second layers as a sheath which is formed separately and slid onto the attachment portion in a distal to proximal direction.

The invention can be performed in various ways but one embodiment will now be described by way of example and with reference to the accompanying drawings in which –

Figure 1 is a part-cross-sectional side elevation of a femoral prosthesis embodying the invention; and,

Figure 2 is a cross-sectional plan view on the line II-II shown in Figure 1.

As shown in the drawings, the invention is applied to a prosthetic implant in the form of a femoral prosthesis 1 which has an attachment portion for insertion into or attachment to a patient's bone without bone cement in the form of a stem 2. The outer surface of the stem 2 is smooth and may be polished and tapered on moving proximal to distal on the stem. The outer surface of the stem 2 is smooth and has a first layer 3 made of a synthetic resin material which in this example is polymethlymethacrylate.

A second layer made of a metallic material 4 is applied over the first layer 3 and the proximal part 5 of the second layer 4 is porous. The distal portion 6 (in the diaphysis of the femur) of the second metallic layer 4 is less porous or substantially non-porous in relation to the proximal part (in the epiphysis and metaphysic of the femur) 5.

With this construction the proximal part 5 of the second layer 4 which is porous provides for bone ingrowth and the distal portion 6 can either be less porous

or substantially non-porous by providing it as a roughened surface to allow for bone ongrowth. Thus the maximum bone attachment is provided at the proximal end where the stem is proximally loaded. In the area where no distal locking is required the outer surface of the distal portion 6 could be relatively smooth.

Alternatively, the proximal part 5 of the second layer 4 can be roughened rather than being porous to allow for bone ongrowth and the distal portion 6 can be less roughened or substantially smooth to provide the same effect.

The second layer 4 can be made from titanium, titanium alloy or any other bio-compatible metal which contacts directly with the bone.

The distal end 7 of the first layer 3 and second layer 4 are formed as a cup 8, the inner surface of which is spaced away from the distal end 9 of the stem 2 to provide a void 10 when initially located in position. This void 10 can accept subsequent movement between the first layer 3 and the stem after fitting.

The thickness of the wall formed by the layer 3 and 4 can be between 1 mm and 3 mm and is preferably between 1.8 mm and 2.5 mm.

The first and second layers 3 and 4 can be applied in situ to the stem 2, for example, the plastic first layer can be cast into position on the stem with which it is to be used and this can then be temporarily fitted with a mechanism to create the distal void.

Alternatively, the first and second layers can he preformed as a separate sheath for attachment to the stem. Again, the plastic inner layer 3 can be cast on the stem or, alternatively, this inner layer can be moulded into the outer metallic second layer 4.

A sheath of this type can be made which is not preferentially matched with the intended femoral implant, for example, a sheath could be of a standard dimension which could be used with the existing implants.

During construction a first layer 3 can be applied to a stem 2 by dipping or a spraying process and the second metallic layer 4 can be applied, for example, by sputtering or any other layering process or it can be made by a laser melting process. Such as that disclosed in US Publications Nos. 20040191106 and 20060147332.

This will still allow the stem to move downwardly after fitting provided the surface of the stem has a suitable smooth surface.

Alternatively the first and second layers 3 and 4 can be preformed as a sheath by forming on a suitable former, for example, the stem with which it is intended to be matched.

If the proximal portion of the metallic layer 4 is porous it allows for boney ingrowth and firm fixation of the assembly into the bone and the solid or less porous distal portion 6 allows for bone ongrowth, this portion being fitted as an interference fit between the sheath and the surrounding bone when installed.

If desired the inner surface of the metal second layer 4 can be roughened to enhance the bonding to the outer surface of the synthetic first layer 3. Preferably this bonding can take place with the addition of a PMMA bone cement (not shown).

In the construction shown the femoral prosthesis has a neck 12 and a tapered spigot 13 to receive a prosthetic head bearing ball (not shown) of well-known type.

In the example described above the invention is applied to a femoral prosthesis but it can be equally well applied to any other prosthesis which has an attachment portion which is for insertion into or attachment to a patient's bone without bone cement.

If desired a layer of bio-active material, such as hydroxyapatite (not shown) can be applied to the outer surface of the second metallic material layer 4 to encourage bone ingrowth or ongrowth.

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CLAIMS:

1. A femoral prosthesis which has an attachment portion in the form of a stem for insertion into or attachment to a patient's bone without bone cement, in which the outer surface of the stem is smooth and tapered on moving proximal to distal on the stem, in which the stem has a first layer made of synthetic resin material applied thereto, in which the stem has a smooth surface suitable to allow the stem to move downwardly in relation to said first layer after fitting, in which a second layer is secured to said first layer and is made of metallic material, a first and proximal portion of said second layer being porous or roughened to encourage bone ingrowth or ongrowth and a second and distal portion of said second layer being less porous, substantially non-porous or less roughened in relation to the first portion, or smooth.

2. A femoral prosthesis as claimed in claim 1 in which the first and second layers are preformed as a separate sheath for attachment to said attachment portion.

3. A femoral prosthesis as claimed in any one of claims 1 to 2 in which the metal layer is titanium, titanium alloy or any other suitably compatible bio-compatible metal.

4. A femoral prosthesis as claimed in any one of claims 1 to 3 in which the metal layer is in the form of a preformed shape.

5. A femoral prosthesis as claimed in any one of claims 1 to 3 in which the metal layer is formed by metallic sputtering.

6. A femoral prosthesis as claimed in claim 5 in which the metal layer is formed by a laser melting process.

7. A femoral prosthesis as claimed in any one of claims 1 to 6 in which the synthetic resin material is polymethylmethacrylate.

8. A femoral prosthesis as claimed in any one of claims 1 to 7 in which the distal end of the first and second layers is formed as a cup, the inner surface of which is spaced away from the distal end of the attachment portion to provide a distal void when initially located in position to accept subsequent movement between the first layer and the attachment portion after fitting.

9. A femoral prosthesis as claimed in any one of claims 1 to 8 in which the thickness of the wall formed by the two layers is between 1 mm and 3 mm.

10. A femoral prosthesis as claimed in claim 9 in which the thickness of the wall formed between the two layers is between 1.8 mm and 2.5 mm.

11. A femoral prosthesis as claimed in any one of claims 1 to 10 in which the inner surface of the metal second layer is roughened to enhance the bonding to the outer surface of the synthetic resin first layer.

12. A femoral prosthesis as claimed in claim 11 in which the bonding takes place with the addition of a PMMA bone cement.

13. A method of forming the femoral prosthesis set forth in claim 1 which includes attaching the first layer of a synthetic resin material by dipping the stem portion into a liquid bath of material or by spraying the material onto the outer surface of the attachment portion, then applying the metal second layer by either buttering a metal onto the synthetic resin material layer or by using a selective laser sintering process.

14. A method of forming the femoral prosthesis set forth in claim 1 which includes providing the first and second layers as a sheath which is formed separately and slid onto the attachment portion in a distal to proximal direction.

FIG. 1

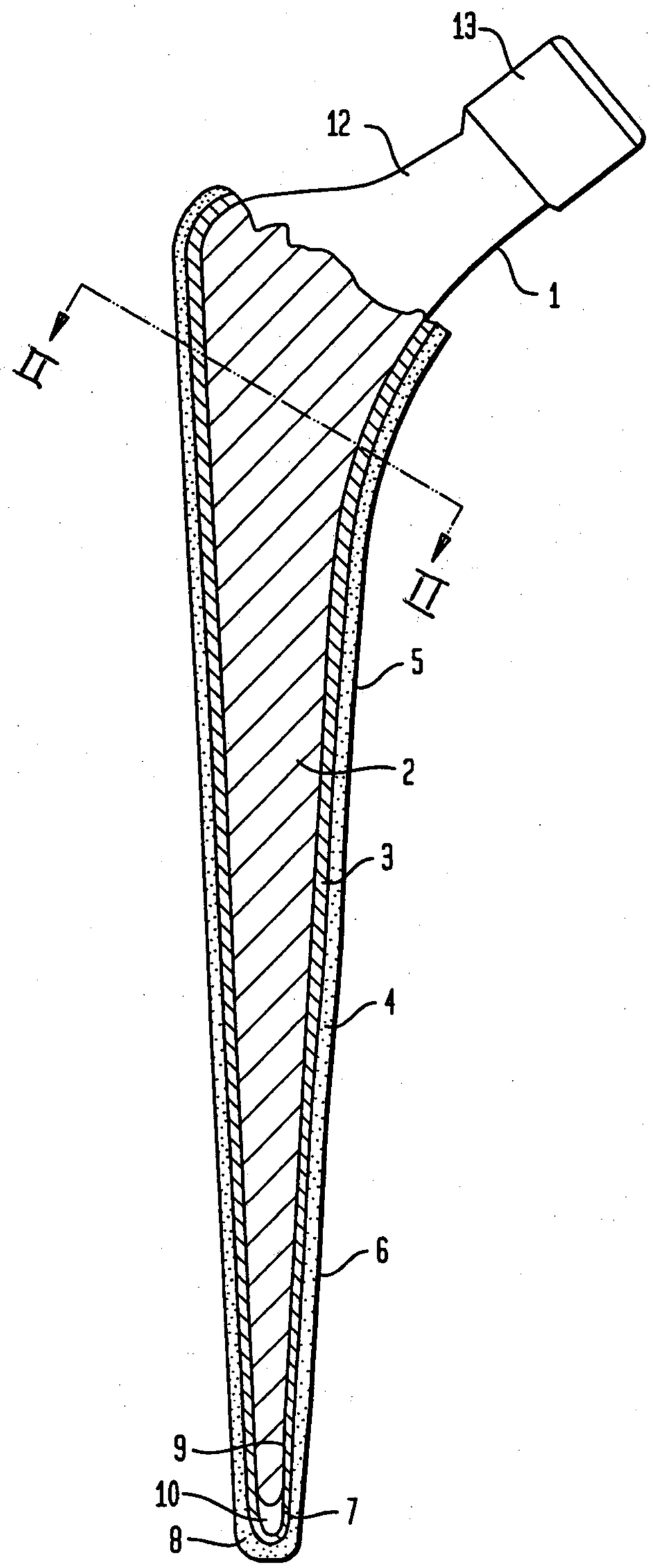
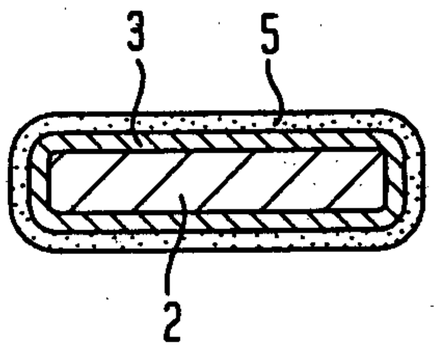
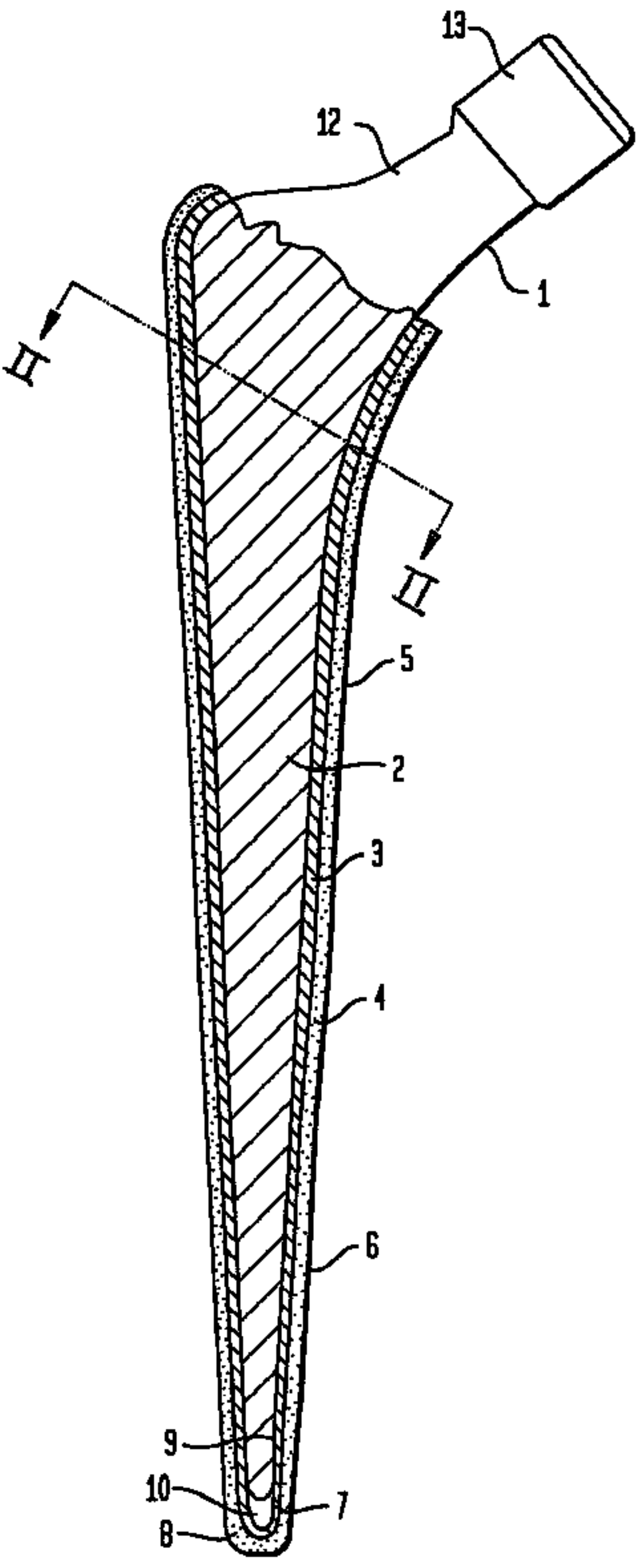


FIG. 2




13
12
1
II
II
5
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4
6
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8