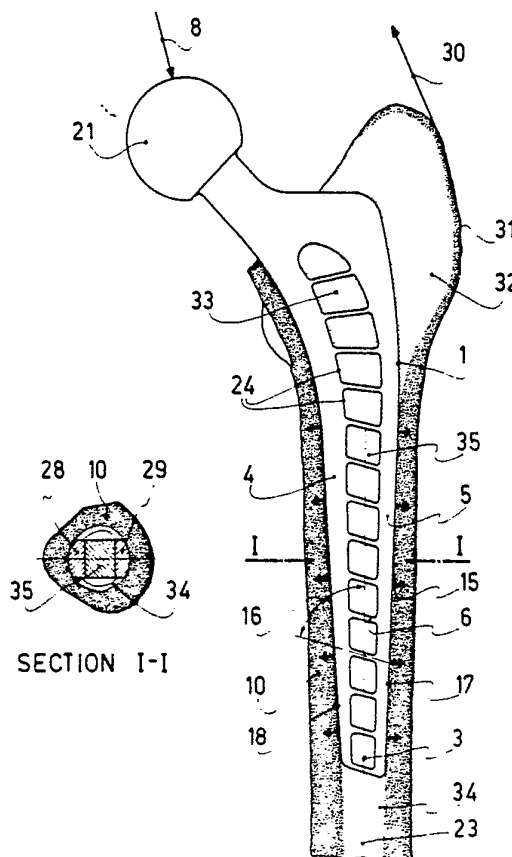


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/EP85/00251 (22) International Filing Date: 23 May 1985 (23.05.85) (71) Applicant (for all designated States except US): LABOR FÜR EXPERIMENTELLE CHIRURGIE SCHWEIZERISCHES FORSCHUNGSINSTITUT [CH/CH]; Obere Strasse 22, CH-7270 Davos (CH). (72) Inventor; and (75) Inventor/Applicant (for US only) : TEPIC, Slobodan [YU/CH]; Oberstrasse 55, CH-7270 Davos Platz (CH). (74) Agent: LUSUARDI, Werther, G.; Lyss-Str. 12, CH-3293 Dotzigen (CH). (81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), US.		Published <i>With international search report.</i>

(54) Title: SELF-LOCKING STEMMED COMPONENT FOR A JOINT ENDO-PROSTHESIS**(57) Abstract**

The self-locking stemmed component (1) for a joint endoprosthesis consists of two lobes (4, 5) of which one (4) is designed for transfer of compression loads and the other (5) for transfer of tension loads. Both lobes (4, 5) are interconnected by a number of connecting structures (6), preferably in the form of struts, which produce an increase of the stem thickness upon loading of the stemmed component (1), thereby pressing the lobes (4, 5) against the inner cortex of the medullary canal (23) of a tubular bone (10).



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SELF-LOCKING STEMMED COMPONENT FOR A JOINT ENDO-PROSTHESIS

This invention relates to a self-locking stemmed component for a joint endo-prosthesis, in particular for the femoral
5 component of a hip joint prosthesis.

Background of the Invention

Twenty-plus years of lively development in hip joint prosthesis design have not produced a fully satisfactory solution to the problem of stem loosening; it still is a major
10 long-term complication. Current trends towards bone integration are addressing only some, perhaps minor problems of prosthesis-bone interaction.

A femoral component for an artificial hip joint is known
15 from the German Offenlegungsschrift no. 31 13 898 in which the stem is formed by several anchoring rods which together with a collar are made from one solid casting. The rods are pressed against the inside of the bone by plugs, thereby producing a locking effect. A fixation system of this kind
20 is not only difficult and time-consuming to insert but produces still an uncontrolled, uneven load transfer from the stemmed component of the joint endo-prosthesis to the bone with high load concentrations at the end of the stem.

Summary of the Invention

The invention as claimed is intended to provide a remedy. It solves the problem of how to design a true self-locking
5 stemmed component that can be easily inserted and removed if necessary and whose load transfer from the stem to the inner cortex of the medullary canal of a tubular bone is evenly distributed in a controlled manner.

In accordance with the invention there is provided a self-
10 locking stemmed component for a joint endo-prosthesis whose stem thickness tends to increase when said stemmed component is loaded by physiological loads.

A self-locking stemmed component in accordance with the invention is distinguished from the known constructions by
15 its optimal adaptability to the medullary canal of the tubular bone, the ability of the stem to transmit independently the specific compressional, respectively tensional forces prevailing at the respective interfaces between stem and cortex in a controlled manner and as gradually and
20 evenly as desired and the ease of its removal.

Bending stiffness of the stem, a major obstacle to controlling the load transfer, is reduced manyfold by the stem geometry according to the invention.

25 The self-locking stemmed component consists preferably of two lobes, one for transfer of compression loads and the other for transfer of tension loads. The two lobes are destined to be pressed against the inner walls of the medullary cavity of a tubular bone by the action of connecting
30 structures interconnecting said two lobes in such a way that relative axial displacement between said two lobes, as produced upon bending of said self locking stemmed component, increases the distance between said two lobes. The pressure for holding the two lobes in place is therefore
35 generated by said connecting structures which are acting as wedges when the stemmed component is loaded and said two lobes are displaced in their relative axial position.

Brief description of the drawing

In the drawing

- 5 Fig. 1 is a schematic view of a stem section according to the state of the art;
- Fig. 2 is a schematic view of a stem according to the invention;
- 10 Fig. 3 is a sectional view of a femoral component for a hip joint prosthesis consisting of a self-locking stemmed component according to the invention and a joint head;
- 15 Fig. 4 is a sectional view of an implanted state-of-the-art femoral component of a hip joint prosthesis;
- 20 Fig. 5 is a sectional view of an implanted femoral component according to the invention and a cross-sectional view of the stem taken along the line I-I;
- 25 Fig. 6 is a magnified sectional view of the femoral component of Fig. 5 showing the effect of insertion;
- Fig. 7 is a sectional view of a femoral component with a curvature greater than that of the natural femur;
- 30 Fig. 8 is a sectional view of the inserted stemmed component according to the invention with a hammering instrument;
- 35 Fig. 9 is a sectional view of the stemmed component according to the invention and explaining the effect of relative axial movement between the medial and lateral lobes; and

Fig. 10 is a perspective view of the means to control relative axial movements between the medial and lateral lobe of the stem. .

- 5 The invention is now described in more detail for the preferred use as a femoral stem component of an artificial hip joint. Of course this embodiment can be easily adapted to stemmed components of other artificial joint prosthesis.

Detailed description:

Figure 1(a) shows a generic stem design setting the requirements for a self-locking stem. Let the stem 1 be fixed to the wall 20 as a cantilever beam and be loaded by, for example, a bending moment 2. To resist the rotation under the bending moment 2, stresses within the stem 1 will develop - tension within the side 5 and compression within the side 4 of the stem 1. There will also be a neutral axis 3 between the sides 4 and 5. The sides 4 and 5 are interconnected by the connecting structure 6. Let points A, B and C lie on a normal to the neutral axis 3 as shown. H is the thickness (in the plane of load 2) of the stem 1.

15

Now consider the shape of the deformed stem shown on the Figure 1(b). The neutral axis 3 defines the so called elastic line. Thickness H1 of the stem under load is measured perpendicularly to the elastic line 3. We will now define the self-locking stem as a stem that under functional load (say the bending moment 2) INCREASES its stem thickness, i.e., H1 is greater than H. This cannot be satisfied by a simple beam. If the stem 1 was a simple beam the points A and B would move to A2 and B2 respectively. Distance (A2,B2) would remain equal to distance (A,B), i.e. the thickness H of the beam would not change under load. But, as will soon be demonstrated, the

25

connecting region 6 may be constructed in such a way as to result in the increase of the stem thickness under functional load. Points A, B and C will move to positions A1, B1 and C1 respectively. The differences between
5 positions A1 and B1 and those that would occur if the stem 1 was a simple beam, i.e. A2 and B2, are utilised to increase the thickness H.

A preferred embodiment of the connecting structure 6 that
10 will satisfy herein established criterium of self-locking is shown on Figure 2(a). The stem 1 is shown inserted into a tubular bone 10. The load-accepting end 7 of the stem 1 is loaded by a force 8. The tension side 5 and the
compression side 4 of the stem 1 are connected by a number
15 of struts 6. These struts are inclined with respect to the neutral axis 3 of the stem 1 by an angle 16 of less than 90 degrees.

Figure 2(b) shows deformations of the stem 1 and the
20 bone 10 under the load 8. Tension side 5 of the stem 1 tends to pull out from the bone 10, as indicated by arrow 13, while the compression side 4 tends to sink into the bone 10, as indicated by arrow 14. This would tend to rotate the struts 6 in the direction indicated by arrows 9
25 producing radial compression on the bone 10, as indicated by arrows 15. These contact stresses 15 between the stem and the bone due to functional load tend to increase

stability of stem anchorage. Loads are transmitted from the stem 1 to the bone 10 by the shear forces at the interfaces - tension from the side 5 of the stem 1 is transferred to the tension side 11 of the bone 10 at the interface 17; compression from the side 4 of the stem 1 to the compression side 12 of the bone 10 at the interface 18. To increase the coefficient of friction at interfaces 17 and 18 the corresponding surfaces of the stem 1 may be specially treated - for example roughened by grit blasting, or plasma sprayed.

Figure 3 shows a functional stem 1 for a femoral side component of the hip joint replacement. Prosthesis head 21 is connected to the proximal, load-accepting section 7 of the stem 1 via prosthesis neck 22. The compression side 4 is connected to the tension side 5 of the stem 1 by a number of struts 6. These struts 6 form an angle 16 with the stem neutral line 3. The angle 16 has less than 90 degrees. It may vary along the stem axis 3 in order to optimise the radial stresses 15, Figure 2(b). The thickness H of the stem 1 also changes along the stem axis in order to fit the natural shape of the femoral bone canal 23, Figure 5. The holes 24 between the struts 6 are cut through the full stem thickness. Some, or all of the holes 24 may be filled by an elastomer such as silicone rubber to prevent bone ingrowth - should that happen, the prosthesis removal in case of necessity would be very

difficult. More proximal holes may be reached by a chisel however, so if desirable, they could be left open for bone to grow in.

5 Figure 4 shows a state-of-the-art femoral component of a hip prosthesis. The stem 25 is of a full cross-section. It may incorporate different surface features such as grooves, or be coated by a porous coat for bone ingrowth. The bending stiffness of these stems is very high compared
10 to that of bone 10 and the load transfer from the prosthesis to the bone is poor - concentrated around the proximal, 26, and distal, 27, parts of the stem 25. High dynamic loads 8 applied to the head 21 of the prosthesis will result in micro-motions between the stem 25 and the
15 bone 10 starting bone resorption within the canal 23 of the bone 10. And further, high bending stiffness of the prosthesis stem will "stress-shield" the bone - this will cause a bone loss and have a detrimental role on the long term prognosis of the joint replacement.

20

Figure 5 shows a femoral component stem 1 according to the invention inserted in the proximal femur 10. Note the correspondence with the situation of Figure 2(a). Bending stiffness of the stem 1 consisting of two lobes - tensile
25 5 and compressive 4, connected by struts 6 is much lower than that of the full stem. Hence this stem will not cause significant stress-shielding of the bone 10. The load

transfer is uniform and can be controlled by the individual cross-sections, 28 and 29, of the lobes 4 and 5, respectively. Load 8 applied to the head 21 is partitioned into compressive and tensile components and each is applied at the appropriate location of the bone. Radial stresses 15 are related to functional load and may be controlled by design (inclination 16 of the struts to the stem axis 3). The muscle force 30 is applied to the greater trochanter 31. This force is the main factor determining the magnitude and direction of the joint force 8. Most of the proximal femur is filled with cancellous bone 32. As suggested earlier, a few, more proximal holes 24 of the stem 1 may be left open to allow for cancellous bone ingrowth, 33. There is also a layer of cancellous bone 34 lining the medullary cavity 23. This should be removed where prosthesis lobes should contact bone 10, i.e. interfaces 17 and 18 should preferably be on the cortical bone. As shown on section I-I, some of the bone 34 may remain, facilitating post operative blood supply to the involved regions of the femur. More distal holes 24 are filled with an elastomer 35 to prevent bone ingrowth.

Figure 6 shows a magnified section of the stem at insertion. The insertion should be performed so as to result in some preload of the interfaces 17 and 18. This is possible by making use of the fact that the stem thickness will decrease when loaded by loads opposite to

- 10 -

physiological. Hence with a bending moment 37 the struts 6 will deform as shown on Figure 6(b). The rotation 19 will result in decreased, H0, thickness of the stem, allowing the stem to move deeper into bone 10 by amount 38 when an axial force 36 is applied. Upon release of the insertion loads 36 and 37 radial preload 15 will be set in at the interfaces 17 and 18.

Figure 7 shows a stem 1 according to the invention which is slightly more curved than the corresponding section of the femur, i.e. the radius of curvature of the stem's neutral line 3 is smaller than that of femur's 39. When the stem is forced into the medullary canal of a tubular bone it will bend in direction opposite to that under physiological load. Insertion will produce preloads as discussed earlier. Note also that the compression lobe 4 will be preloaded by tension and that the tension lobe 5 will be preloaded by compression. This may be of advantage in terms of stem strength. However, the preloads on bone will be of the same sign as the physiological loads, so designing for preload must be exercised with care.

It is sufficient to mismatch the curvatures over only a part of the stem length. In particular, if the curvature of the proximal part of the medial side interface 18a is greater than that of the corresponding bone section 18b, the prosthesis may be inserted as described by Figure 6

and obtain a good fit at all interfaces following insertion. Hammering the prosthesis into prepared cavity by hammer blows applied somewhat laterally as shown on Figure 8 will produce the effects described by Figure 6.

5 An insertion tool 50 may be used to extend and define lateral position, 51, of the hammering force 52. The tool 50 is attached to the conus 53 of the prosthesis which normally receives the prosthesis head 21. The hammering force is transmitted to the prosthesis mainly through the
10 extension 54 of the tool 50, resting against the proximal section 7 of the prosthesis stem.

Figure 9 shows another design feature facilitating insertion and fixation. A slot 40 is made across the
15 section 7 of the stem. It allows relative axial sliding of the lateral lobe 5 with respect to medial lobe 4. At insertion, a displacement in direction of arrow 41 results in the reduced thickness H of the stem 1. Fixation is accomplished by the movement in the direction of arrow 42.

20

Figure 10 shows one possible design for the means to control movements 41 and 42. A bridge 43 is inserted into the receiving hole 47 in the section 7 of the proximal stem. This arrangement allows for parallel movement at the
25 slot 40 while preventing the slot to open. Vertical position of the bridge 43 within the receiving hole 47 is controlled by four set-screws 44 which can be screwed into

threaded portions 48 of the cylindrical sections 49 of the receiving hole 47. Cylindrical sections of the bridge 43 have clearance holes 46 so that a key can be inserted through key holes 45 of all four screws from the top.

- 5 Actually, to effect movements 41 and 42 the key is inserted through both top and bottom set screws on one side, and they are turned together moving the bridge 43 up or down in the hole 47. When desired position is achieved the top screw is tightened against the bridge 43, fixing
- 10 its position.

C l a i m s

1. Self-locking stemmed component (1) for a joint
endo-prosthesis, characterized in that the stem thickness
5 tends to increase when the stemmed component (1) is loaded
by physiological loads.

2. Self-locking stemmed component (1) according to
claim 1, characterized in that the stem has medial and late-
10 ral lobes (4,5) destined to be pressed against the inner cor-
tex of the medullary canal (23) of a tubular bone (10), said
medial and lateral lobes (4,5) being interconnected by
connecting structures (6) in such a way that relative axial
displacement between said two lobes (4,5) as produced upon
15 bending of said stemmed component (1) increases the latero-
medial distance between said two lobes (4,5).

3. Self-locking stemmed component (1) according to
claim 1 or 2, characterized in that the connecting structures
20 (6) are dimensioned in such a way that they are prevented to
buckle when said stemmed component (1) is loaded under phy-
siological conditions.

4. Self-locking stemmed component (1) according to
25 one of the claims 1 to 3, characterized in that the holes (24)
between said connecting structures (6) are filled, at least
partly, with an elastomer (35) to prevent bone ingrowth (33).

5. Self-locking stemmed component (1) according to one of the claims 1 to 4, characterized in that the cross-section of said two lobes (4,5) is diminishing from proximal to distal.

5

6. Self-locking stemmed component (1) according to one of the claims 1 to 5, characterized in that the curvature of the stem is mismatched to that of the receiving tubular bone (10), at least partly, resulting in preloaded interfaces upon
10 insertion of said stemmed component (1) into the medullary canal (23) of said tubular bone (10).

7. Self-locking stemmed component (1) according to claim 6, characterized in that the curvature of said stem
15 is greater than that of the natural medullary canal (23) of said tubular bone (10), preferably only at the proximal part of the medial side interface (18a) of the medial lobe (4).

8. Self-locking stemmed component (1) according to one
20 of the claims 1 to 7, characterized in that it is provided by means (40) of controlled relative axial displacement between the medial and lateral lobes (4,5).

9. Self-locking stemmed component (1) according to one
25 of the claims 1 to 8, characterized in that the bone contacting surfaces of said stemmed component (1) are treated in a way that increases the shear strength of the interface to bone, preferably by grit blasting, coating with a porous layer or plasma spraying.

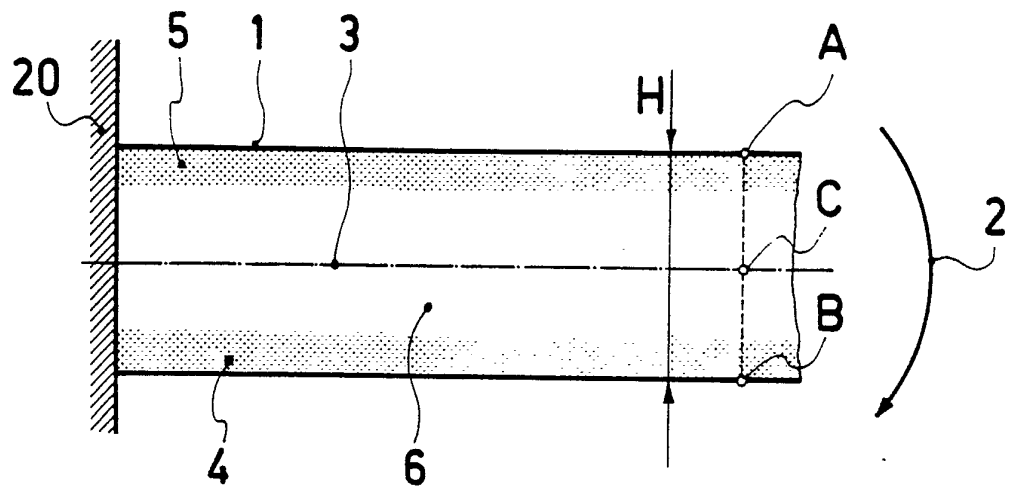
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10. Self-locking stemmed component (1) according to one of the claims 1 to 9, characterized in that the connecting structures (6) are formed by a number of struts including an angle of less than 90°, preferably of approximately 75°, with
35 the neutral axis (3) of the stem and preferably varying along said neutral axis (3) in order to optimize the radial stresses (15).

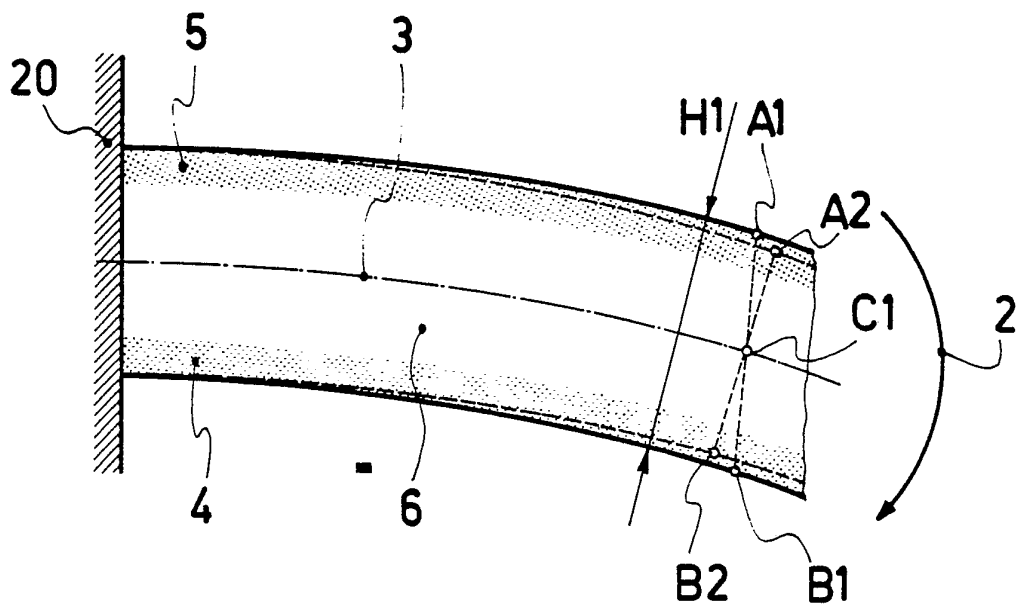
11. Self-locking stemmed component (1) according to one of the claims 1 to 10, characterized in that the stem is bifurcated, whereby one lobe (4) is designed for transferring compression loads and the other lobe (5) is designed for transferring tension loads.

12. Hammering instrument (50) for inserting the self-locking stemmed component (1) according to one of the claims 1 to 11 into the medullary canal (23) of a tubular bone (10), characterized in that it extends and defines the lateral position (51) of the hammering force (52).

13. Use of the self-locking stemmed component (1) according to one of the claims 1 to 11 for the femoral component of a hip joint prosthesis.

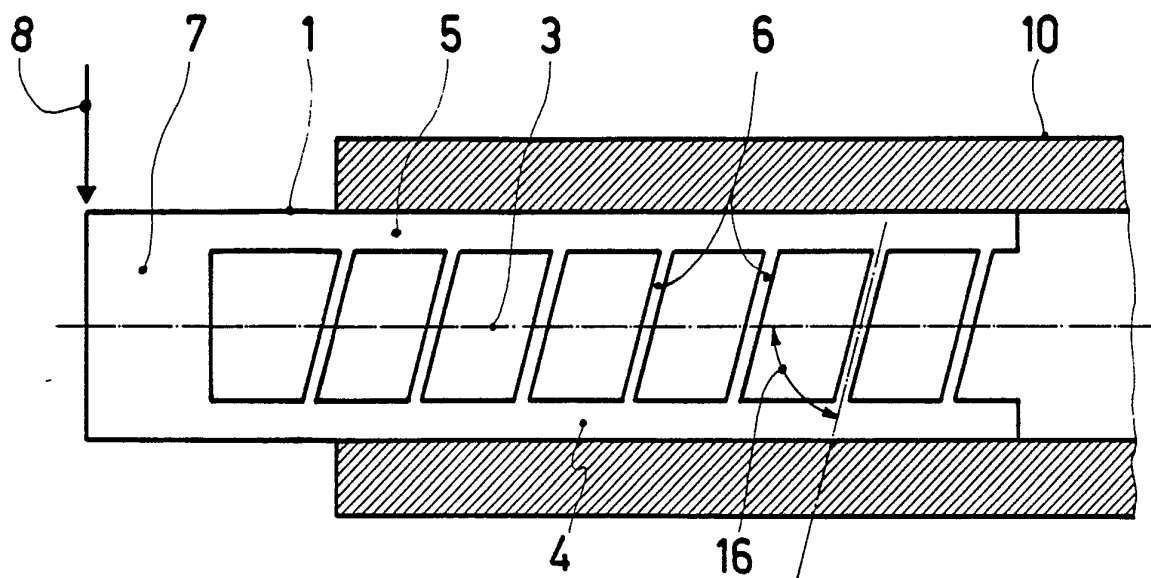


(a)

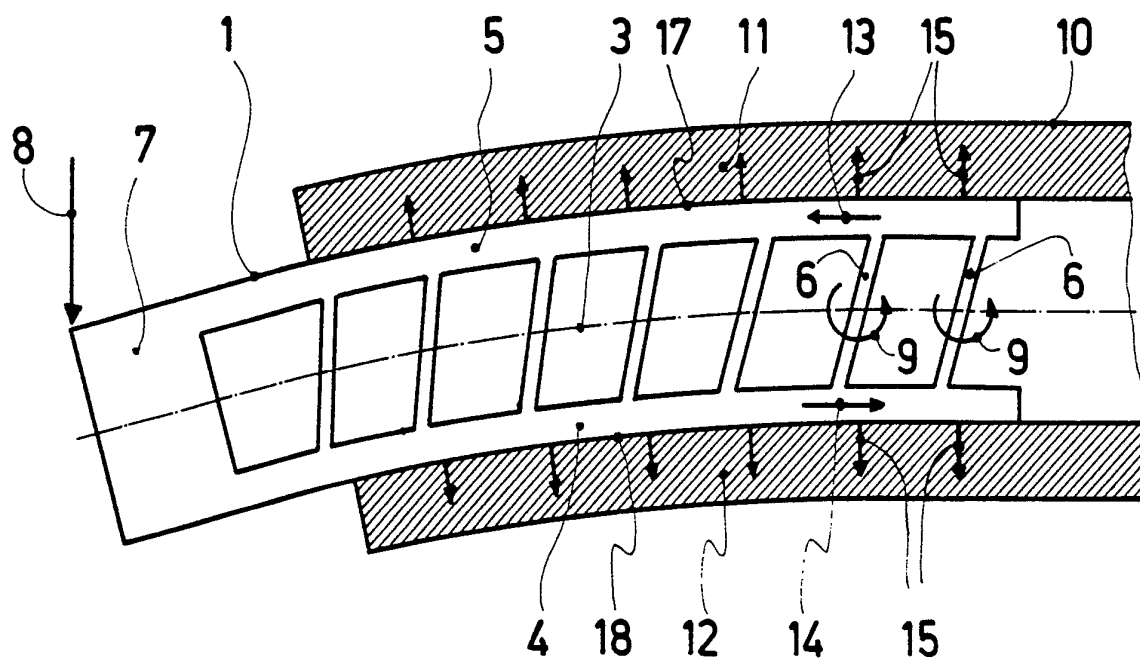


(b)

FIGURE 1



(a)



(b)

FIGURE 2

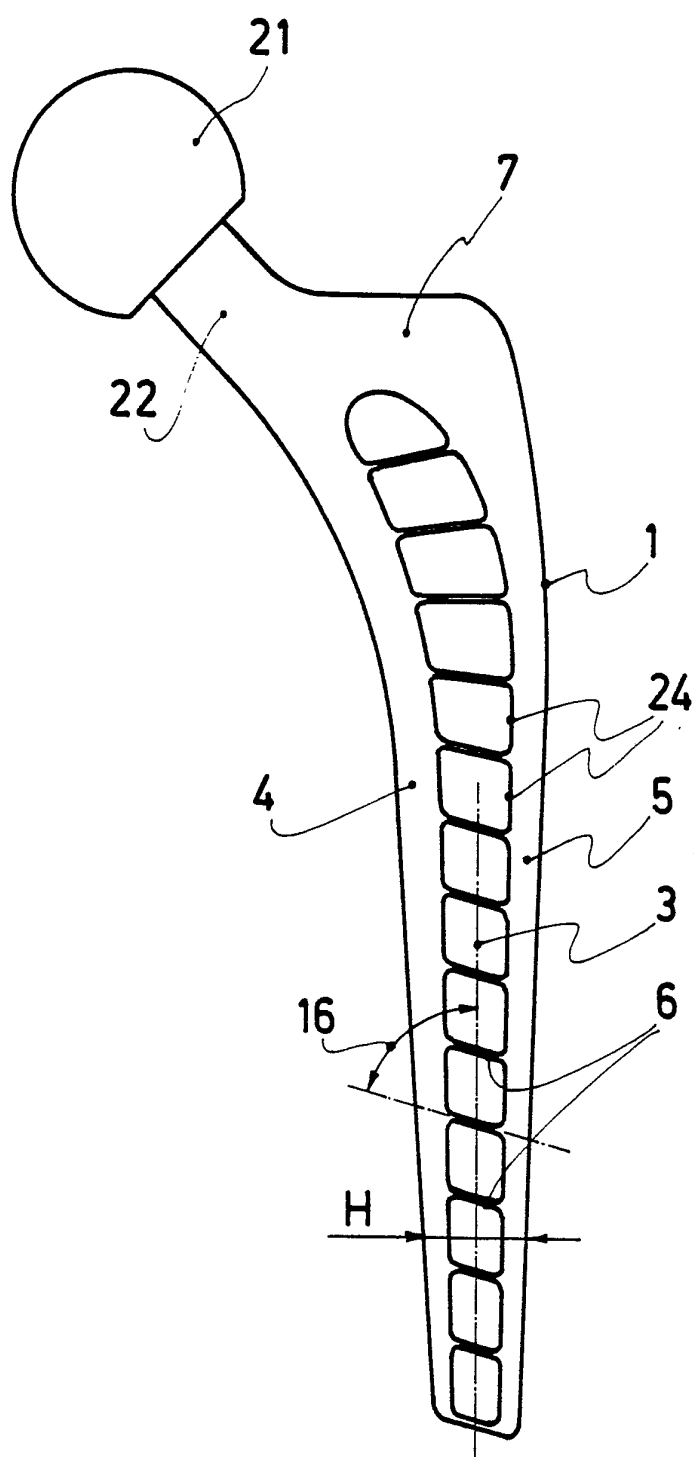


FIGURE 3

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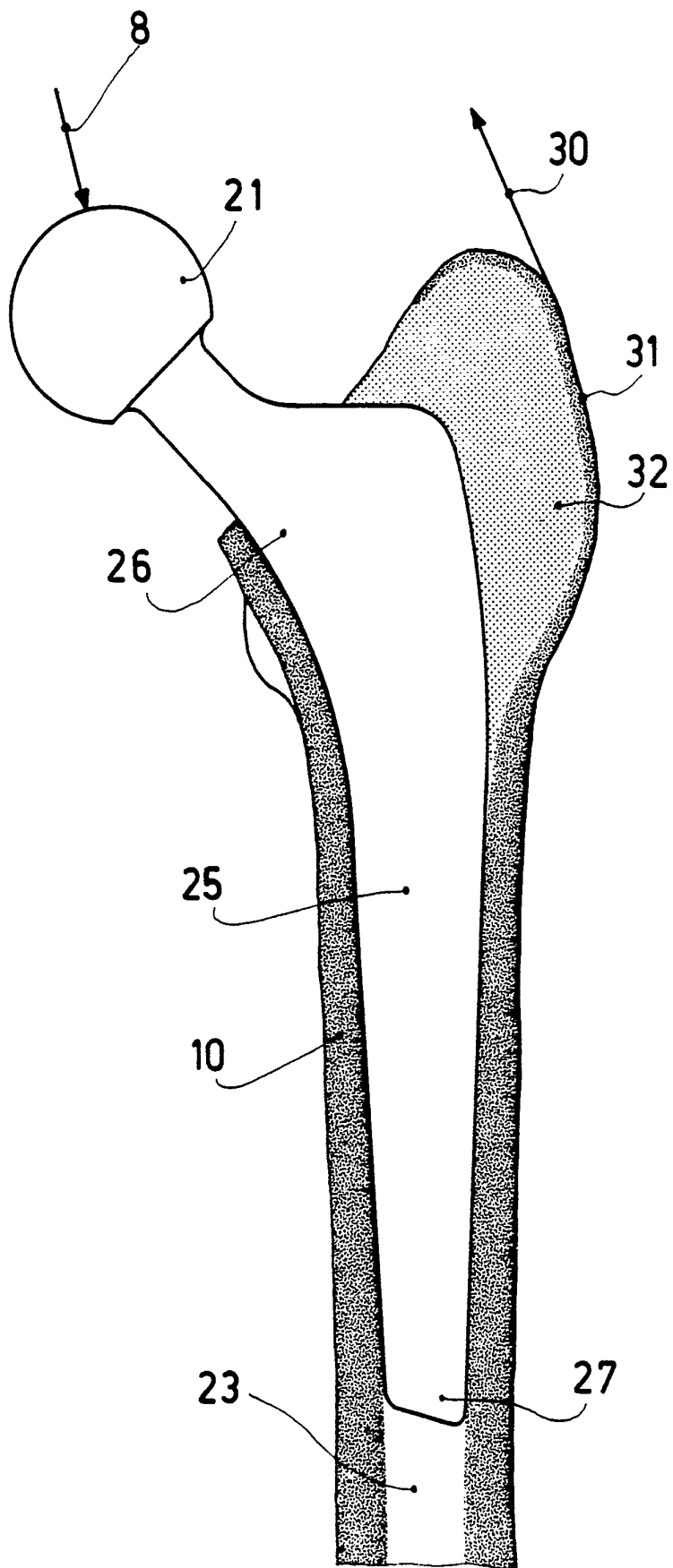


FIGURE 4

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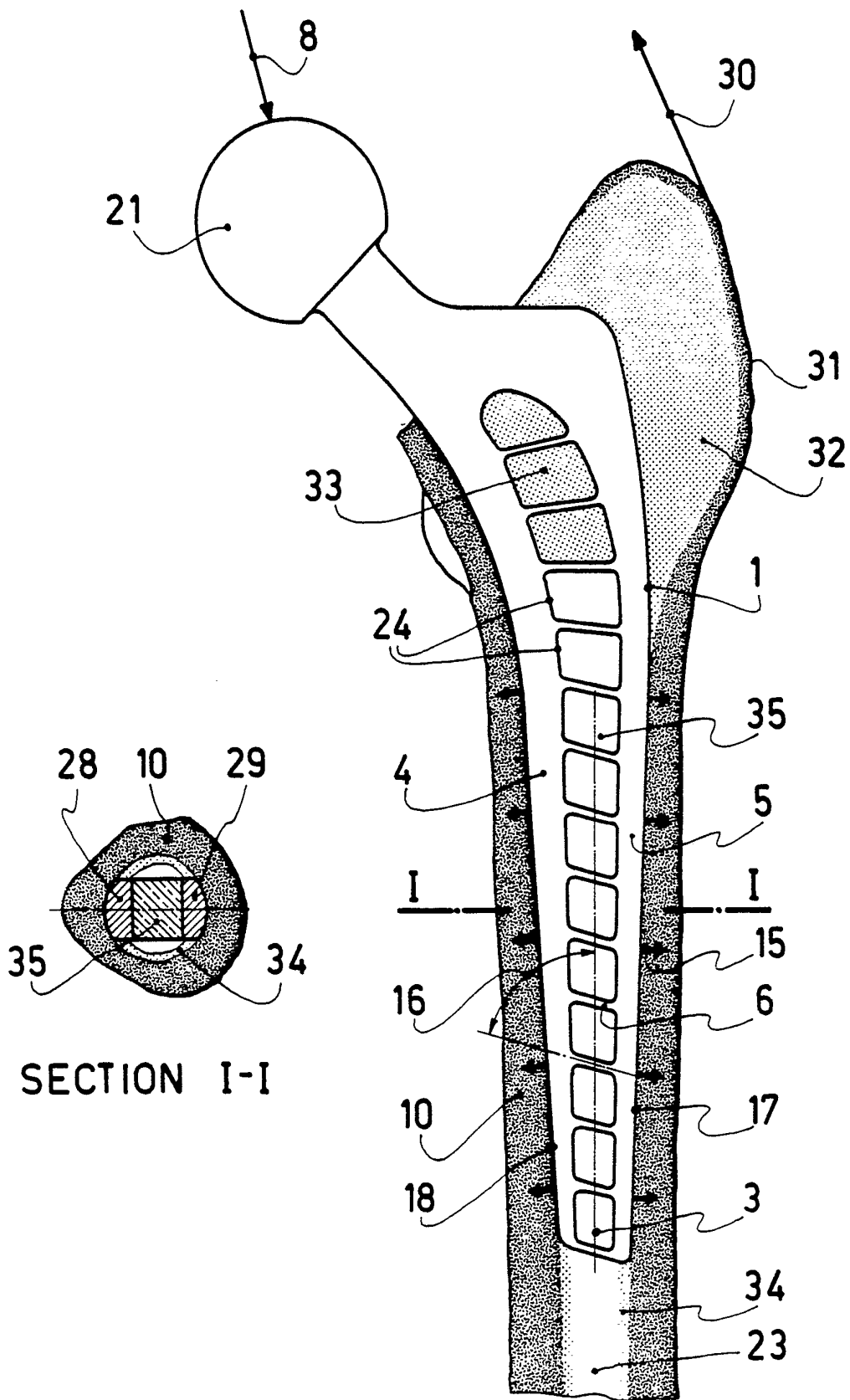


FIGURE 5

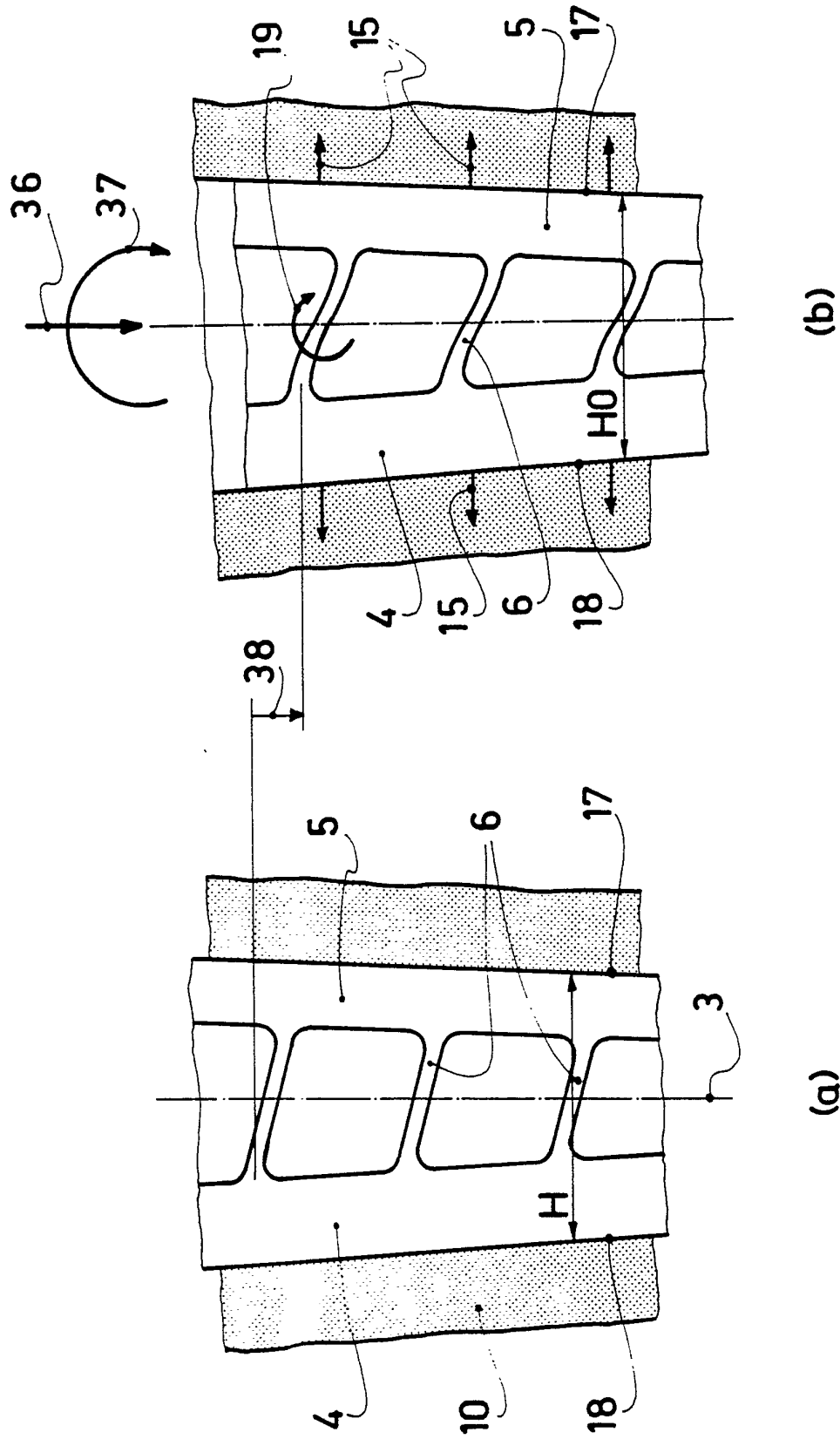


FIGURE 6

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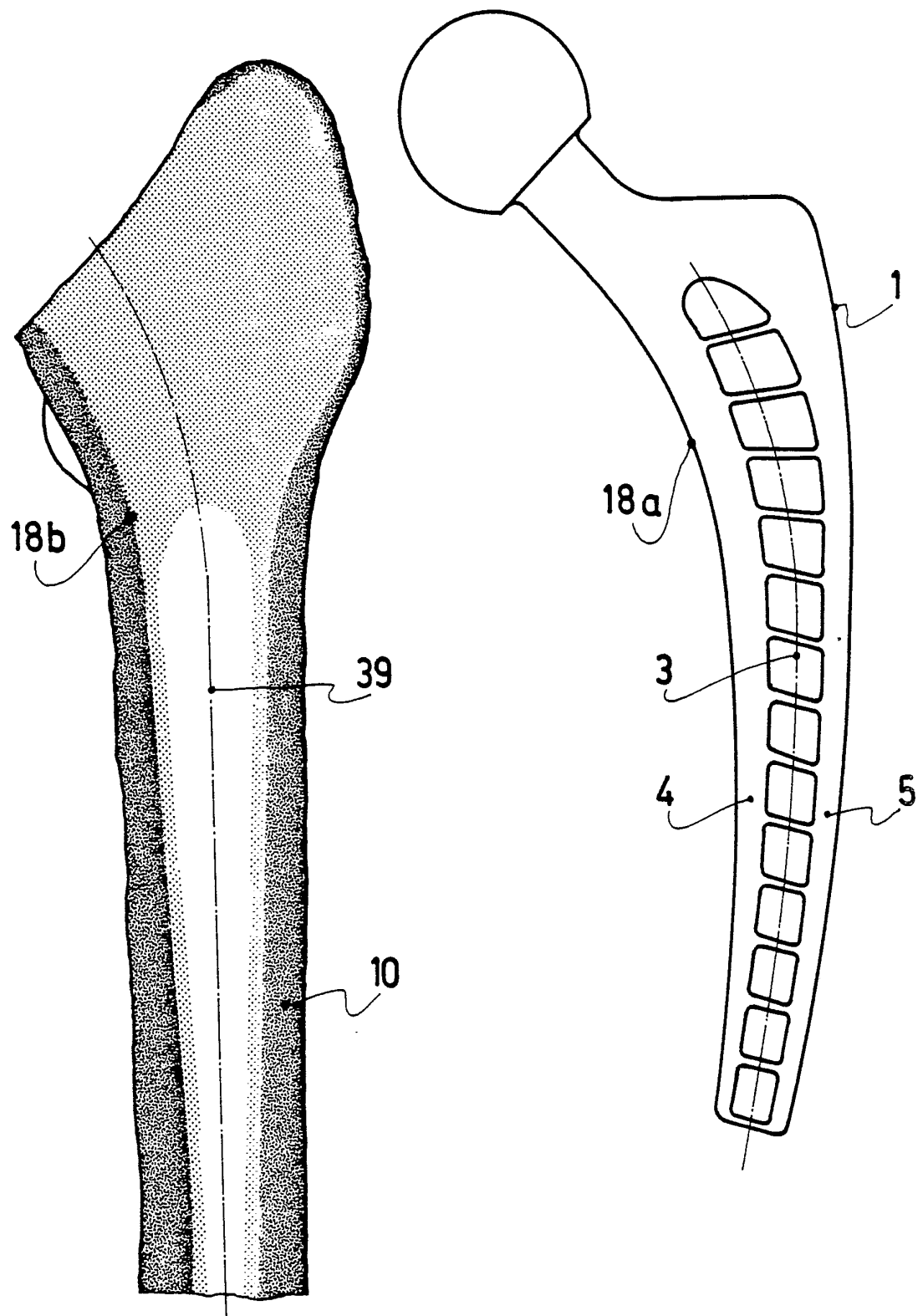


FIGURE 7

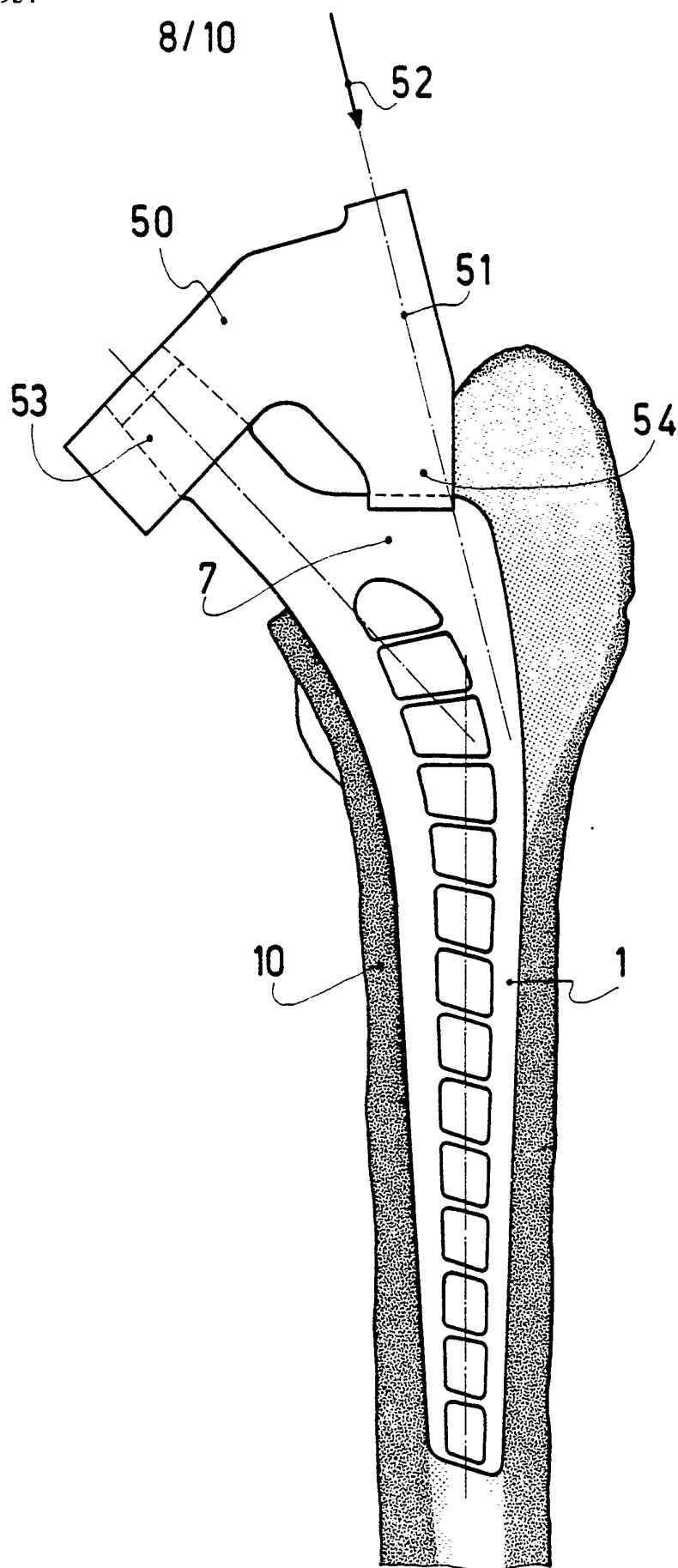


FIGURE 8

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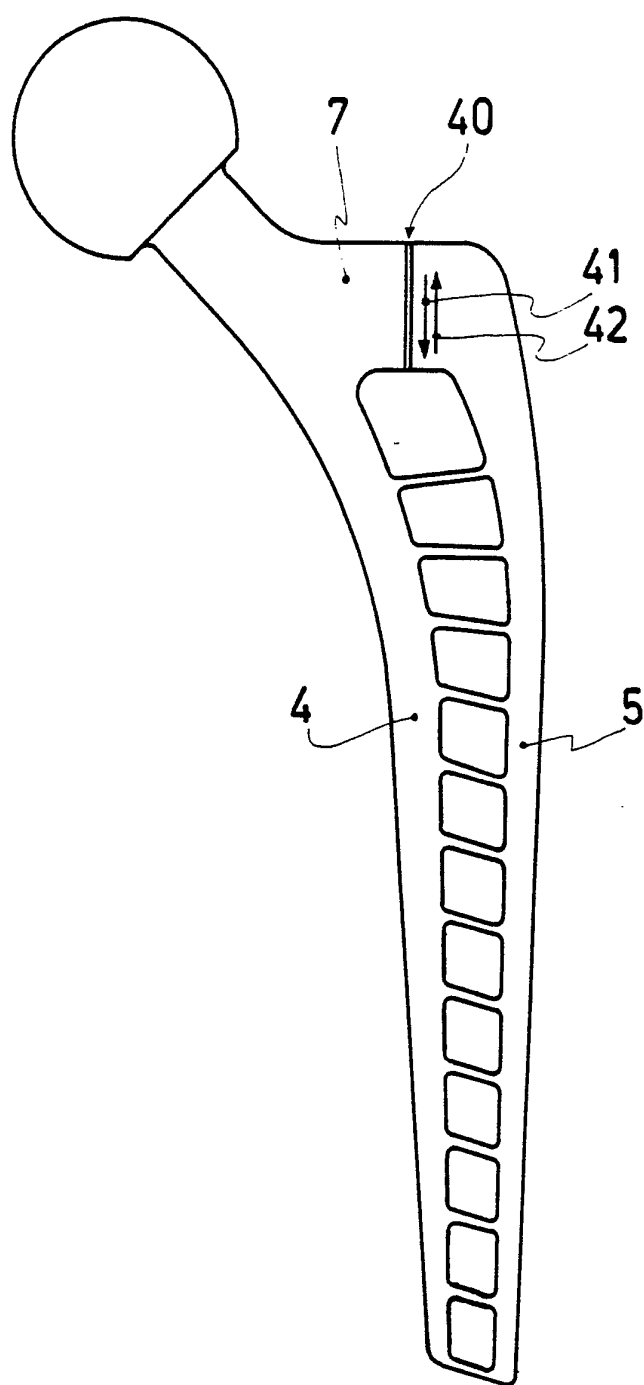


FIGURE 9

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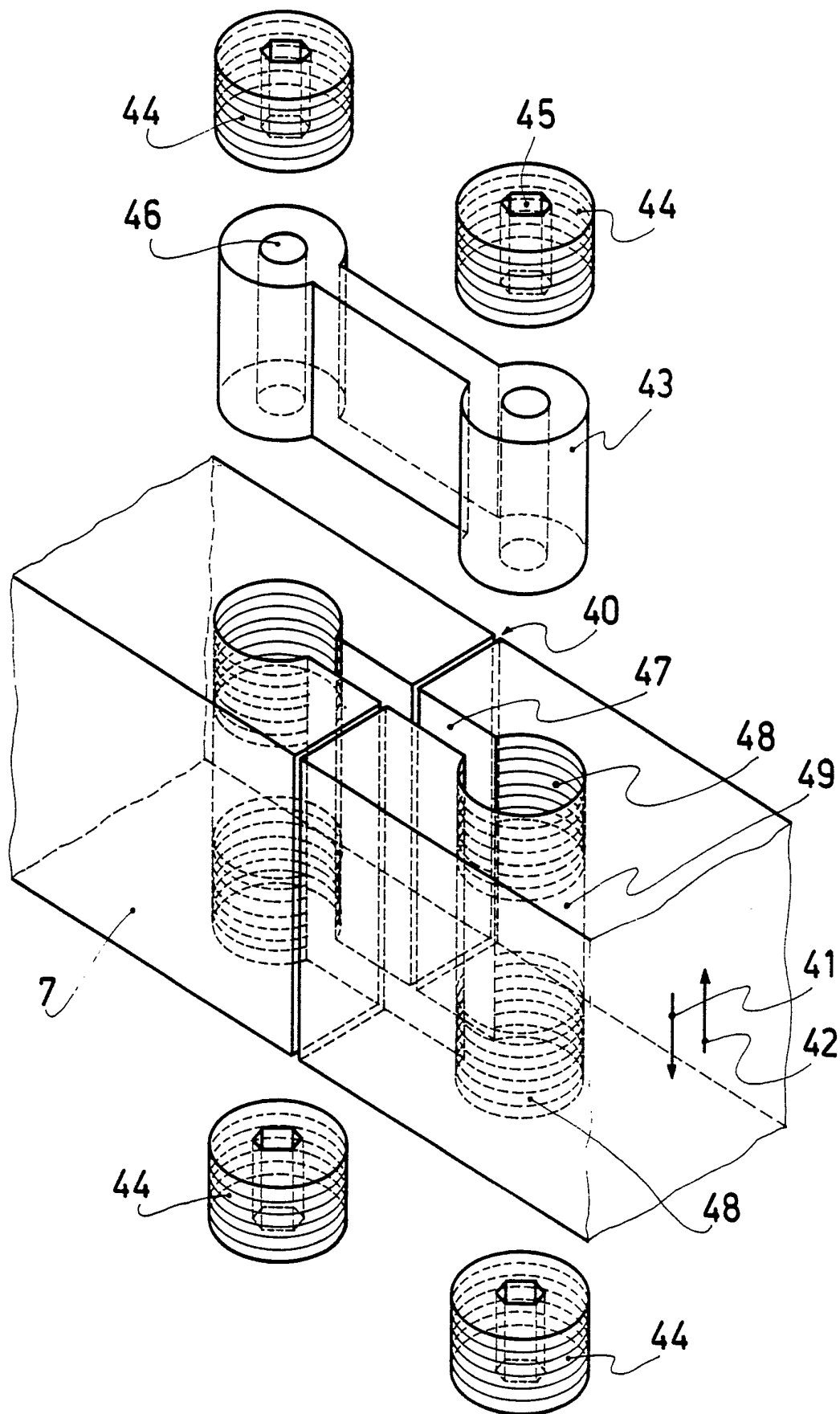


FIGURE 10

INTERNATIONAL SEARCH REPORT

International Application No PCT/EP 85/00251

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC ⁴ : A 61 F 2/30; A 61 F 2/36; A 61 F 2/46		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
IPC ⁴	A 61 F A 61 B	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹		
Category ⁹	Citation of Document, ¹¹ with Indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	GB, A, 2078523 (LORD) 13 January 1982, see page 2, line 105 - page 3, line 105; figures 1-4 --	1-11,13
X	US, A, 4292695 (J.B. KOENEMAN) 6 October 1981, see the whole document --	1,3,4,9,13 2,8,10,11
A		
X	DE, A, 3028393 (E. KOUTROLIKOS) 11 February 1982, see page 9-14; figures 4-9 --	1-3,5-9,11, 13
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X	EP, A, 0085147 (SULZER & PROTEK) 10 August 1983, see figures 1-5 --	1-3,5,6,8, 9,11,13 12
Y		
Y	FR, A, 1158993 (DRAPIER) 20 June 1958, see figures 3-5 --	12 ./.
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IV. CERTIFICATION		
Date of the Actual Completion of the International Search		Date of Mailing of this International Search Report
23rd January 1986		14 FEB 1986
International Searching Authority		Signature of Authorized Officer
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III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
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X A	DE, A, 2305441 (ROSENTHAL) 8 February 1974, see figures 1,2 --	1,3,8,9,13 2,4
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A	US, A, 4306550 (M.R. FORTE) 22 December 1981, see figures 1-5 --	12
X	FR, A, 2502939 (M.W. HAPPEL) 8 October 1982, see figures 4-6 & DE, A, 3113898 (cited in the application)	1-3,5,9-11, 13

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON

INTERNATIONAL APPLICATION NO. PCT/EP 85/00251 (SA 9786)

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 08/02/86

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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