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NOTICE OF ENTITLEMENT

We, **BRISTOL-MYERS SQUIBB COMPANY** of 345 Park Avenue, New York, New York 10154, United States of America state the following in connection with Australian Application No. 27552/92:

1. We are the nominated person.

2. The nominated person is the assignee of the actual inventor.

3. The nominated person is the applicant of the basic application listed in the declaration under Article 8 of the PCT.

4. The basic application is the application first made in a Convention country in respect of the invention.

Dated: 26 May, 1993

By **PHILLIPS ORMONDE & FITZPATRICK**
Patent Attorneys for the Applicant
By:

David B Fitzpatrick

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To: The Commissioner of Patents

PHILLIPS ORMONDE & FITZPATRICK
367 Collins Street
Melbourne, Australia, 3000

Our Ref: 329582

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PROCESS FOR PRODUCING A BONE IMPLANT AND BONE IMPLANT THUS PRODUCED

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(71) Applicant(s)
BRISTOL-MYERS SQUIBB COMPANY

(72) Inventor(s)
MARTIN SCHUG

(74) Attorney or Agent
PHILLIPS ORMONDE & FITZPATRICK , 367 Collins Street, MELBOURNE VIC 3000

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(57) Claim

1. A process for the production of a bone implant made from metal or plastic, in which a positive moulding is produced, which at least in sections possesses an open-pore or open-cell structure on the surface, including the steps of:

(i) producing the positive moulding from a base member of moulding material, which at least in sections is covered with a porous structural covering, including a predetermined porous structure made from moulding material,

(ii) embedding the positive moulding into a ceramic embedding compound to fill the pores of the open-pore structure,

(iii) removing the moulding material by the application of heat to form a core,

(iv) filling the spaces produced in the core, which were previously occupied by the moulding material, by casting or centrifuging with the metal or plastic, and

(v) removing the core material to form the implant. which at least in sections possesses an open-pore or open-cell structure on the surface.

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(71) Anmelder *(für alle Bestimmungsstaaten ausser US)*: BRISTOL-MYERS SQUIBB COMPANY [US/US]; 345 Park Avenue, New York, NY 10154 (US).

(72) Erfinder; und
(75) Erfinder/Anmelder *(nur für US)* : SCHUG, Martin [DE/DE]; Schulweg 12, D-2406 Stockelsdorf (DE).

(74) Anwalt: RABUS, Werner, W.; Eisenführ, Speiser & Partner, Martinistrasse 24, D-2800 Bremen 1 (DE).

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(54) Title: PROCESS FOR PRODUCING A BONE IMPLANT AND BONE IMPLANT THUS PRODUCED

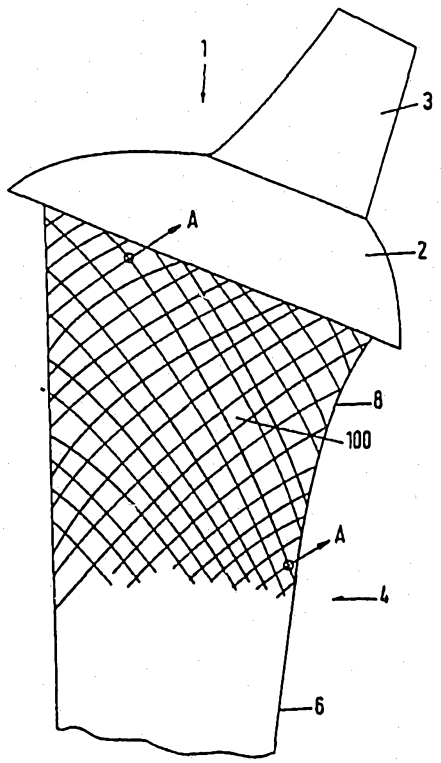
(54) Bezeichnung: VERFAHREN ZUR HERSTELLUNG EINES KNOCHENIMPLANTATES SOWIE KNOCHENIMPLANTAT

(57) Abstract

A process is disclosed for producing a bone implant which has at least in sections a surface structure with open pores. The positive model for the implant is moulded from a base body made of a modelling material coated at least in sections with a porous coating having a predetermined pore structure. Also disclosed is a bone implant made of metal or plastics with a local distribution of pore sizes and/or densities at the surface of the implant that corresponds to the trabecular structure of the osseous environment in which the implant is implanted.

(57) Zusammenfassung

Es wird ein Verfahren zur Herstellung eines Knochenimplantates angegeben, welches mindestens abschnittsweise eine offenporige Struktur an der Oberfläche besitzt. Das Positivmodell für das Implantat wird aus einem Grundkörper aus Modellmaterial geformt, der mindestens abschnittsweise mit einem porenhaltigen Strukturbelag mit einer vorgegebenen Porenstruktur belegt wird. Es wird ferner ein Knochenimplantat aus Metall oder Kunststoff angegeben, bei dem die Porengröße und/oder Porendichte an der Oberfläche des Implantates eine örtliche Verteilung aufweist, welche der Trabekel-Struktur der Knochenumgebung entspricht, in die das Implantat implantiert wird.



A PROCESS FOR THE PRODUCTION OF A BONE IMPLANT AND A BONE IMPLANT PRODUCED THEREBY

Description

The invention relates to a process for the production of a bone implant made from metal or plastic, in which a positive moulding is produced, which at least in sections possesses an open-pore or open-cell structure on the surface, the positive moulding is embedded into a ceramic embedding compound filling the pores of the open-pore structure, the moulding material is removed by the use of heat, the spaces produced in the remaining core, which were previously occupied by the moulding material are filled by casting or centrifuging with the metal or plastic, and subsequently the core material is removed, whereby the positive cast is moulded from a base member of moulded material, which at least in sections is covered with a porous structural covering made from moulding material.

The invention also relates to a bone implant.

Such a process is known for example from German Patent Specification 31 06 917 or from German Patent Specification 32 24 265, in which an open-pore plastic moulding member, for example an open-pore or open-cell natural or synthetic sponge, is used as the positive moulding. The open-pore surface of the positive moulding results in the production of an implant having an open-pore surface structure, whereby the open pores of the cells in each case should be the same size or larger than the spongy trabeculae of a natural bone, so that the ingrowth of the osseous tissue with subsequent bone formation begins immediately after implantation. However as the pore size occurs

statistically distributed within predetermined limits in the plastic member used as the positive cast, and as the pores are also at random, an implant surface is produced in which the pores are locally distributed at random. The ingrowth of spongiosa trabeculae, which in the adjacent osseous tissue possess a natural order structure, is impeded by the arbitrary distribution of the pores on the implant surface.

The object of the invention is therefore to provide a process for the production of a bone implant possessing an open-pore surface structure covering comprises a predetermined pore structure.

A further object of the invention is also to provide a bone implant having an open-pore surface structure which facilitates the ingrowth of the adjacent osseous tissue in comparison ~~which~~ to known structures.

The object is achieved in accordance with the invention by an implant which made of metal or plastic, possesses an open-pore surface structure and which is characterised in that the pore size and/or pore density on the surface of the implant has a local distribution which corresponds to the trabecula structure of the bone environment in which the implant is attached.

The advantages of the invention lie particularly in the fact that implants having an open-pore surface structure can be produced which, with respect to their local distribution of the pore size and density, correspond to the spongiosa trabecula structures present at the implant site to an extent hitherto not achieved. This adaption of the pore distribution with respect to size, density and depth is possible according to the invention on the surface of an implant and allows the pore and cell sizes to be adapted to the spongiosa trabecula structure of the

surrounding osseous tissue so that many spongiosa trabeculae also encounter a correspondingly large number of pores arranged according to the natural conditions. As the distribution of the spongiosa trabeculae in the bone are ordered with respect to their size, density and with respect to their local position, a corresponding arrangement of the surface pores of the implant produced in accordance with the invention can improve the anchoring quality.

In the process according to the invention the local distribution of the pore size and/or pore density of the structural covering applied to the positive moulding is reproduced on the surface of the bone implant produced. Therefore a distribution of the pore sizes and/or density is particularly preferably chosen so that this distribution roughly corresponds to the structure of the spongy tissue, which is present in the vicinity in which the implant is to be placed.

According to a particularly preferred embodiment of the invention, the structural covering has a regular, uniform structure consisting of threads and/or webs and spaces located therebetween, which form the pores. A knitted, woven or braided fabric, which has a periodic structure, the periodicity of which can constantly change as a function of the site, is preferably used as the structural covering. The alteration in this periodicity of the structural covering can either be achieved by a local alteration of the threads or webs forming the structural covering, or alternatively this alteration can be also achieved by a locally variable elongation or extension of a per se uniform structural covering.

In a particularly preferred manner, the pore depth and/or the thickness of the structural covering on the base member alters in a locally predetermined manner. A particularly

preferred local distribution of the pores of the structural covering on the base member corresponds to the trabecula structure of the bone bed, into which the implant is to be subsequently inserted. In this way a fine structure of the open pores on the implant surface is achieved, which enables a particularly fast and adapted ingrowth of the adjacent spongy tissue into the pores, and as a result a particularly secure fit between the bone and implant.

If, for example, a thigh part of a hip joint prosthesis is used as the implant, according to the invention the structural covering or respectively the knitted/woven or braided fabric can be applied to the positive moulding in such a manner that the webs or threads, and therefore the pores, are disposed on the positive moulding in curves, which correspond to the trajectories of the spongy tissue present in the upper femur, so that the spongiosa trabeculae, which are disposed along these trajectories, can grow into the pores of the implant according to their natural growth inclination.

In accordance with the invention the pore size and/or pore depth - in a thigh part to be used - on the positive moulding is particularly preferably specified so that the pore size and/or depth decreases towards the distal end of the prosthesis shaft and in the proximal shaft region corresponds to the relatively large spongiosa trabeculae there. Alternatively only a proximal section of the base member is provided with structural covering, but the adjacent distal section on the other hand is free from structural material so as to produce a smooth surface.

A base member made of wax or a heat-volatile plastic is preferably produced as the positive cast, whereby the base member can be made from solid material or also from an open-pore material. Subsequently the knitted, braided or woven fabric made from plastic material is applied, which

evaporates with the action of heat and is therefore suitable as the moulding material and which has the desired pore distribution. If necessary, the positive moulding may be immersed in liquified wax or a wax-water emulsion or be sprayed with wax or a wax-water emulsion before being embedded in the embedding ceramic in order to bring the webs of the knitted or braided fabric located between the pores to a desired thickness.

When embedding the positive moulding in the ceramic embedding compound, the pores are filled with embedding compound and then the core is compacted by the action of heat, as a result of which the moulding material evaporates. With the subsequent pouring in of metal the negatively imitated pores - now in the core material - remain free from metal. If the core material is subsequently removed, for example by acid solutions, such as for example hydrofluoric acid, an implant made of metal is produced, which on its surface possesses the pore structure originally produced on the positive cast.

According to a particularly preferred embodiment of the invention, the knitted, woven or braided fabric contains longitudinal webs, which intersect the longitudinal webs at predetermined angles, because with such a web structure the trabecula structure of the natural flat tissue can be imitated particularly well.

If a femur prosthesis is to be produced, then the positive moulding has a corresponding oblong shaft. In accordance with the invention the knitted, woven or braided fabric made of moulding material is applied to the base member of the positive moulding in such a manner that the longitudinal and transverse webs extend in preferred directions on the base member. The longitudinal webs posses a distinctive directional component in the longitudinal direction of the shaft, and the transverse

webs have a corresponding directional component in the circumferential direction.

The longitudinal webs and the transverse webs are preferably formed by an accumulation and/or a thickening of threads extending in the web direction.

The knitted, woven or braided fabric can be placed as a mat on the base member of the positive moulding and be attached there. Alternatively the knitted, woven or braided fabric can be constructed as a hose, which is pulled on the base member. If the knitted, woven or braided fabric is made from elastic moulding material, then when the hose is pulled on to the base member an automatic expansion and adjustment of the shape of the tissue structure occurs, which, with the greater expansion of the tissue, for example at the proximal section of the shaft of a femur prosthesis, results in an enlargement of the pores or cells.

The longitudinal threads and transverse threads of the knitted, woven or braided fabric are particularly preferably constructed in one layer. However alternatively multi-layer knitted or woven fabrics are possible, which result in a complexity of the pore formation and in an enlargement of the pore depth. The longitudinal threads and/or transverse threads may be wave-shaped within their layer and be connected to one another by means of loops or by gluing or bonding.

In accordance with the invention the open-pore structure is achieved in that on the surface of the implant is tip-stretched a uniform hollow lattice structure, which consists of wire-shaped lattice webs or filaments and between and beneath the lattice webs produces spaces which form pores which are open to the outside. In order to structure the pores, i.e. the spaces between and beneath

the lattice webs, in the desired manner corresponding to the trabecula structure of the bone environment, the lattice webs along the trajectories of the spongy tissue must correspond to the natural bone adjacent implant site. Woven, knitted or braided structures, the filaments of which are formed as wire-shaped lattice webs, are suitable as the hollow lattice structure.

The hollow lattice structure on the surface of the implant is particularly preferably integrally tip-stretched from implant material. Alternatively the hollow lattice structure may however be produced as a separate covering from the implant material, which is welded onto a base member of the implant or connected in another suitable way.

The hollow lattice structure on the surface of the implant can be disposed in locally variable lattice depths from single-layer or multi-layer lattice webs.

In order to produce a porous structure in which an adequate positive locking is achieved between the implant and the ingrowing spongiosa material, at least some of the wire-shaped lattice webs preferably extend in waves on the implant core and are only connected by predetermined longitudinal sections with the implant core, while the transverse webs extend over the intermediate sections at a distance from the solid implant core. The lattice webs are then surrounded on all sides by the spongy tissue growing back in intermediate sections spaced from the implant core.

Advantageous refinements of the invention are characterised by the features of the subordinate claims.

Exemplified embodiments of the invention are explained in further detail below by means of the drawings.

Fig. 1 shows a thigh part of a hip joint endoprosthesis

produced by the process in accordance with the invention;

Fig. 2 shows a positive moulding for a thigh part of a hip joint endoprosthesis;

Fig. 3 shows a cross section along line A-A of Fig. 2;

Fig. 4 shows a cross section along line B-B of Fig. 2;

Fig. 5 shows a detailed view X from Fig. 3;

Fig. 6 shows a detailed view Y from Fig. 4;

Fig. 7 shows a further positive moulding of a thigh part of a hip joint endoprosthesis;

Fig. 8 shows a cross section along line A-A from Fig. 7

Fig. 9 shows a detail from Fig. 8;

Fig. 10 shows a plan view of the structure of a knitted fabric, which is suitable for covering a base member;

Fig. 11 shows a cross section along line A-A through Fig. 10;

Fig. 12 shows a plan view of a further knitted structure;

Fig. 13 shows a further plan view of a woven or braided structure;

Fig. 14 shows a section through the upper region of a femur bone;

Fig. 15 shows a section as in Fig. 14 but with a hip

joint prosthesis according to the invention;

Fig. 16 shows a lateral elevation of the proximal region of a hip shaft prosthesis according to the invention;

Fig. 17 shows a section along line A-A of Fig. 16; and

Fig. 18 shows a plan view of the structure shown in Fig. 17.

Fig. 1 shows, as a special case of a bone implant, the thigh part of a hip joint endoprosthesis. A shaft 4 has a distal section 6, which comprises a closed or smooth surface, and a proximal section 8, which supports an open-pore structure on the surface. The proximal section 8 ends at the collar 2, which is adjacent to a conical neck section 3, onto which a prosthetic articulated spherical part can be placed.

The proximal section 8 of the implant is provided with an open-pore or open-cell surface structure. To produce the open-pore or open-cell surface structure, a uniform hollow lattice structure made from implant material is integrally tip-stretched on the solid shaft core. The hollow lattice structure 10 consists of wire-shaped lattice webs 11, which are orientated in predetermined directions on the implant core. Between and beneath the lattice webs 11 lie spaces 11a, which form the pores open to the outside. As can be seen from Fig. 1, the pore size or pore density of the surface structure 10 in the proximal section is locally structured so that the pores have a distribution which corresponds to the trabecula structure of the spongiosa tissue of the femur, in which the implant is anchored, cf. Figures 14 to 17.

Fig. 2 to 6 show a positive moulding for a thigh part of a

hip joint endoprosthesis in lateral elevation and in different detailed elevations. The positive moulding 12 possesses a shaft 16 having a distal free end 17. At the proximal end the shaft 16 is surrounded by a collar having a conical neck projection 14. Alternatively the neck may be provided in one piece with a spherical prosthesis head.

The positive moulding 12 is composed of a single-piece base member 15 made from wax or a heat-volatile plastic comprising a shaft core having a tip-stretched neck projection 14. The shaft core - in the embodiment shown - is covered with a porous structural covering, for example a knitted, woven or braided material 18 made from heat-volatile moulding material, for example an elastic plastic material and on the shaft core produces a predetermined porous structure. The knitted, woven or braided fabric 18 is, for example, prefabricated as a homogenous expandable hose having a constant structure over the entire length and is then applied to the shaft core. As the hose made from moulding material at the widening of the shaft core which increases to the neck projection 14 stretches in a corresponding manner, in the upper region of the shaft larger spaces are produced between the threads or webs 24, 26 and as a result a porous structure is produced which has been stretched more and has larger pores than at the distal shaft end 17.

The structural covering 18 applied to the shaft core as shown in Fig. 2 is constructed in several layers, it consists of a three-layer woven or braided fabric having longitudinal threads 24 of the different layers, cf. Fig. 3 to 6. The circles represented in Fig. 2 and 3 mark a basic period or a basic cell having a predetermined thread structure, to which the next basic period or basic cell is attached on all sides, in which the thread structure of the basic cell is identically repeated. As can be seen in Fig. 2 to 4, the basic period is at its largest in the proximal

region of the shaft 16 and gradually and constantly decreases towards the distal shaft end 17. In Fig. 5 and 6, which are detailed representations X and Y respectively of Fig. 3 and 4, is represented a cross-section through a basic cell 19 of the structural covering 18.

Fig. 7 to 9 show a further positive moulding for a thigh part of a hip joint endoprosthesis in a further embodiment. The base member 15 made from moulding material itself consists of a shaft core 15 with neck projection 14 tip-stretched at the proximal end. To produce the desired porous structure, the shaft core is covered with a knitted, woven or braided fabric 18 made from moulding material, for example heat-volatile plastic. The structure of the coating 18 is selected so that longitudinal webs 20 and transverse webs 22 crossing the longitudinal webs 20 and transverse webs 22 intersect almost at right angles, the longitudinal webs 20 extend in the shaft direction, and the transverse webs 22 extend in the circumferential direction of the shaft 16. As can be seen in particular from Fig 8 and 9, the longitudinal webs are produced from individual, spaced, undulating longitudinal threads, and the transverse webs 22 are formed from correspondingly spaced transverse threads 26, which connect the longitudinal threads 24 to one another in a wave shape.

Fig. 10 and 11 show a plan view of a knitted fabric 18, which is also suitable for covering a base member 15. Transverse threads 32 are shown, which are meshed and cross-linked to one another.

In Fig. 12 is represented a further knitted structure 18, in which spaced longitudinal threads 24 are connected to undulating transverse threads 26. To improve the strength of the woven, braided or knitted fabric are also provided mesh threads 44 extending in the longitudinal direction.

Fig. 13 shows an enlarged plan view of a knitted, braided or woven fabric 18, in which longitudinal webs 20 and transverse webs 22 intersect at right angles to one another, whereby the webs 20, 22 are formed by an accumulation of threads 24, 26. Longitudinal threads and transverse threads can be bonded to one another at the intersection points or can be connected in another suitable manner, for example by cross-linking.

Fig. 14 and 15 represent a cross section through the upper region of a femur bone without or with an inserted hip shaft prosthesis. The trabecula structure of the spongy tissue is clearly visible. The trajectories 46 of the spongy tissue start at the cortical substance 44 of the bone and extend upwards curved substantially in a circle either into the neck region 42 or the region of the greater trochanter 42. An implanted hip shaft endoprosthesis 1 is diagrammatically shown, which beneath its collar 2 in its proximal shaft section comprises an open-pore surface structure in the form of a hollow lattice structure 100. The hollow lattice structure 100 is formed by wire-shaped lattice webs, which between and beneath them produce spaces which form the pores of the structure which are open to the outside. As can be clearly seen in Fig. 14 and 15, the wire-shaped lattice webs of the prosthesis 1 extend along the trajectories 46 of the spongy tissue of the adjacent natural implant site.

Fig. 16 shows an enlarged lateral elevation of the hip shaft prosthesis 1 diagrammatically represented in Fig. 15, whereby the lower part of the prosthesis is broken away to enlarge the representation. The hip shaft prosthesis 1 diagrammatically represented in Fig. 15, whereby the lower part of the prosthesis is broken away to enlarge the representation. The hip shaft prosthesis 1 contains a shaft 4, at the proximal section 8 of which a collar 2 laterally protruding over the shaft with a conical neck

section 3 is tip-stretched. The proximal section 8 of the shaft 4 passes - towards its free end - into a distal section 6, which is partially broken away. The proximal shaft section 8 possesses an open-pore surface structure, which is integrally tip-stretched at the shaft core as a hollow lattice structure 100 and consists of several intersecting, wire-shaped lattice webs 102 to 112, the height of the hollow lattice structure 100 continuously decreased towards the distal section 6, so that the distal section 6 - in the exemplified embodiment represented - possesses a smooth, structure-free surface.

Fig. 17 represents a section along line A-A of Fig. 16 on an enlarged scale, and Fig. 18 is a plan view of the structure of Fig. 17.

The hollow lattice structure 100 is integrally tip-stretched on the implant core 130 made from metal or plastic. In the intersection plane extend two wire-shaped lattice webs 101, 102 as mirror images of one another and form loops 118 and burls 120, whereby the lattice web 102 close to the implant core is connected to the implant core 130 at the loops, and the lattice webs 101, 102 are connected to one another at the burls 120. In the embodiment represents a further rectilinear lattice web 104 extends through the burls in the intersection plane.

Further lattice webs 101, 102 and 104, which have the same path as the lattice webs 101, 102 and 104, which are represented cut-off, and also the same, relatively thick cross section, extend - in the direction of the trajectories of the adjacent osseous tissue - at a predetermined distance, roughly parallel to the lattice webs 101, 102 and 104, which are represented but-off. Between the groups of lattice webs 101, 102 and 104 extend, roughly parallel to these lattice webs 101, 102 and 104, but with a smaller cross section, further groups of lattice

webs 106, 108, the burls of which lie in the plane fixed by the burls 120, which however have a smaller amplitude than lattice webs 101 and 102 and therefore do not touch the implant core 130 in the loop sections. The loops and burls of the lattice webs 106, 108 are offset with respect to the loops and burls 118, 120 of the lattice webs 101 and 102 by half a wavelength.

At right angles to the lattice webs 101 to 108 extend - in the burls 118 of the lattice webs 101 and 102 - further lattice webs 110 formed in waves, the amplitude of which is the same as the entire loop amplitude of the lattice webs 101 and 102. Over the loops of the lattice webs 106 and 108 also extend wave-shaped lattice webs 112 having a smaller cross section, the amplitude of which is roughly the loop amplitude of the lattice webs 101 and 102. Lattice webs 112 are integrally connected in predetermined sections to the implant core 130.

The lattice webs 101 to 108 extend over the implant core, as shown in Fig. 14 and 15, along the trajectories of the adjacent spongy tissue, i.e. from the ventral side curved roughly in circle upwards to the collar 2 or to the lateral boundary line of the shaft. The lattice webs 110, 112 also extend along the trajectories of the adjacent spongy tissue, beginning at the lateral boundary contours of the prosthesis curved roughly as a circle upwards to the collar 2 and to the ventral contours respectively.

Apart from the hollow lattice structure 100 shown, in accordance with the invention any modifications and variations in the hollow lattice structures are possible and are within the scope of the present disclosure.

The claims defining the invention are as follows:

1. A process for the production of a bone implant made from metal or plastic, in which a positive moulding is produced, which at least in sections possesses an open-pore or open-cell structure on the surface, including the steps of:

(i) producing the positive moulding from a base member of moulding material, which at least in sections is covered with a porous structural covering, including a predetermined porous structure made from moulding material,

(ii) embedding the positive moulding into a ceramic embedding compound to fill the pores of the open-pore structure,

(iii) removing the moulding material by the application of heat to form a core,

(iv) filling the spaces produced in the core, which were previously occupied by the moulding material, by casting or centrifuging with the metal or plastic, and

(v) removing the core material to form the implant. which at least in sections possesses an open-pore or open-cell structure on the surface.

2. A process according to Claim 1, wherein the structural covering includes a regular structure consisting of threads and/or webs and spaces therebetween, which form the pores.

3. A process according to Claim 2, wherein the structural covering is a knitted, woven or braided fabric.

4. A process according to Claim 3, wherein the knitted, woven or braided fabric contains longitudinal threads and/or transverse threads in one or more layers.

5. A process according to any one of the preceding Claims, wherein the pore size of the structural covering constantly changes as a function of the location.

6. A process according to any one of the preceding Claims, wherein the pore depth of the structural covering on the base member possesses a predetermined local distribution.

7. A process according to any one of the preceding Claims, wherein the thickness of the structural covering placed on the base member comprises a predetermined local distribution.

8. A process according to any one of the preceding Claims, wherein the local distribution of the pores of the structural covering on the base member corresponds to the trabecula structure of the bone environment into which the implant is inserted.

9. A process according to Claim 8, whereby the implant is a thigh part of a hip joint endoprosthesis, wherein the pores of the structural covering on the base member of the positive mouldng are disposed in the proximal section of the prosthesis stem along predetermined curves corresponding to the trajectories of the spongy tissue of the natural implant site in the femur.

10. A process according to Claim 2, wherein the threads and/or webs of the structural covering on the base member are disposed along predetermined curves corresponding to the trajectories of the spongy tissue of the natural implant site.

11. A process according to any one of the preceding Claims, wherein the pore size of the structural covering decreases towards the distal end of the prosthesis stem.

12. A process according to any one of Claims 6, 7 or 8, wherein the structural covering is applied only to the proximal section of the base member, but the distal section of the base member connected thereto on the contrary has a smooth surface.

13. A process according to any one of the preceding claims, wherein wax or heat-volatile plastic is used as the moulding material.

14. A process according to any one of the preceding Claims, wherein the structural covering includes longitudinal webs and transverse webs crossing said longitudinal webs.

15. A process according to Claim 14, wherein the longitudinal webs and the transverse webs intersect by predetermined angles which correspond to the cutting angles of the trajectories of the spongy tissue of the natural implant site.

16. A process according to any one of the preceding Claims, wherein the longitudinal webs and/or the transverse webs of the structural covering extend in preferred directions on the base member.

17. A process according to any one of Claims 14 to 16, wherein the longitudinal webs and the transverse webs are formed by an accumulation and/or a thickening of threads extending in the web direction.

18. A process according to any one of Claims 1 to 15, wherein the structural covering is constructed as a hose, which is pulled onto the base member of the positive moulding.

19. A process according to Claim 18, wherein the hose has a constant diameter over its length.

20. A process according to any one of the preceding Claims, wherein the structural covering is made from an elastic moulding material and is applied to the base member with locally varying expansion.

21. A bone implant made from metal or plastic, including a solid implant core and having an open-pore surface structure, wherein the pore size and/or pore density on the surface has a local distribution corresponding to the trabecula structure of the bone environment in which the implant is to be anchored.

22. A bone implant according to claim 21, wherein at least in sections of the surface there is provided a uniform hollow lattice structure formed by wire-shaped lattice webs, which beneath them produce spaces which form the pores of the structure which are open to the outside.

23. A bone implant according to Claim 22, wherein the lattice webs extend on the surface of the implant along predetermined curves, which correspond to the trajectories of the spongy tissue of the natural implant site.

24. A bone implant according to Claim 22 or 23, wherein the hollow lattice structure has the form of a knitted or woven or braided fabric.

25. A bone implant according to any one of Claims 22 to 24, wherein the depth of the hollow lattice structure has a predetermined local distribution.

26. A bone implant according to any one of Claims 22 to 25, wherein the hollow lattice structure is integrally tip-stretched from the material of the implant on the surface.

27. A bone implant according to any one of Claims 22 to 26, wherein the wire-shaped lattice webs are disposed in a single layer or multiple layers or multiple layers on the surface and are connected to one another at intersection points.

28. A bone implant according to any one of claims 22 to 27, wherein at least some of the wire-shaped lattice webs are connected via predetermined longitudinal sections with the solid implant core and extend at spaced intervals in intermediate sections from the solid implant core.

29. A process according to claim 1 substantially as hereinbefore described with reference to any one of the drawings.

30. A bone implant according to claim 21 substantially as hereinbefore descibed with reference to any one of the drawings.

DATED: 14th July 1994
PHILLIPS ORMONDE & FITZPATRICK
Attorneys for:
BRISTOL-MYERS SQUIBB COMPANY

David P Fitzpatrick

Abstract

A PROCESS FOR THE PRODUCTION OF A BONE IMPLANT AND A BONE IMPLANT PRODUCED THEREBY

A process is given for the production of a bone implant which possesses an open-pore structure on the surface at least in sections. The positive moulding for the implant is moulded from a base member made of moulding material, which at least in sections is covered with a porous structural covering having a predetermined pore structure. Furthermore a bone implant made from metal or plastic is disclosed, in which the pore size and/or pore density on the surface of the implant comprises a local distribution corresponding to the trabecula structure of the bone environment into which the implant is implanted.

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Fig.1

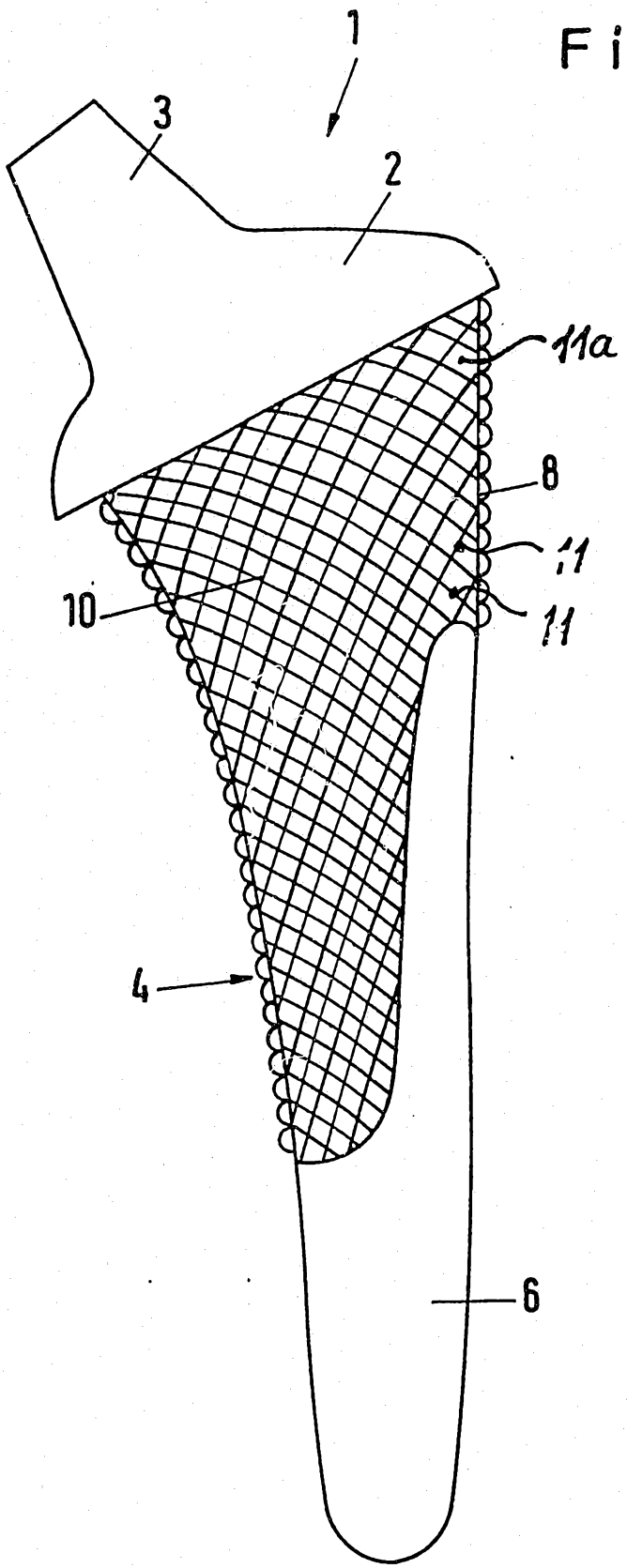

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Fig.2

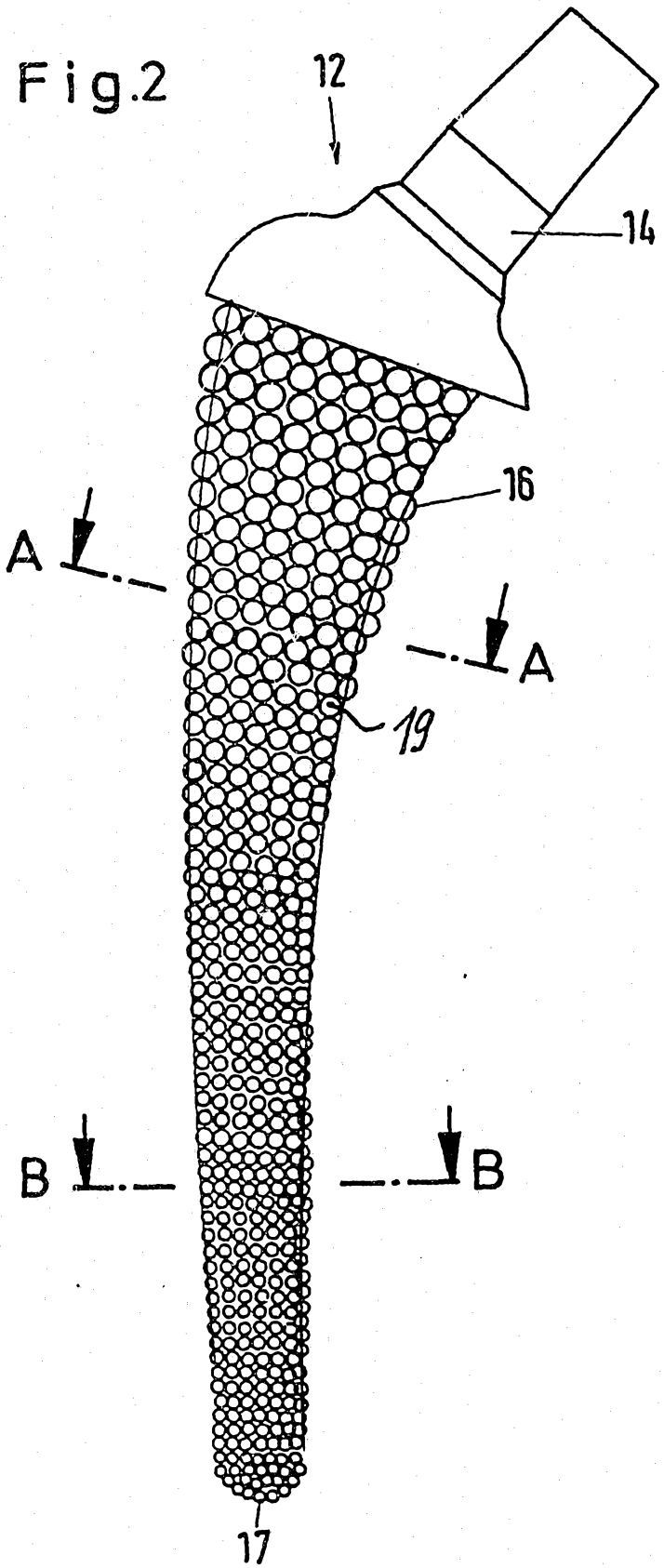

Fig.3
(A-A)

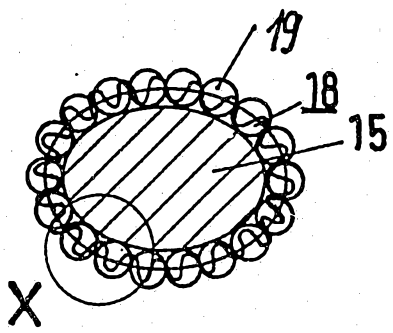

Fig.4
(B-B)

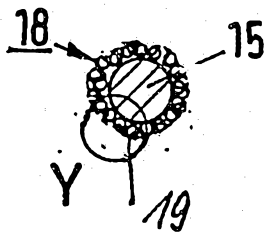

Fig.5
(X)

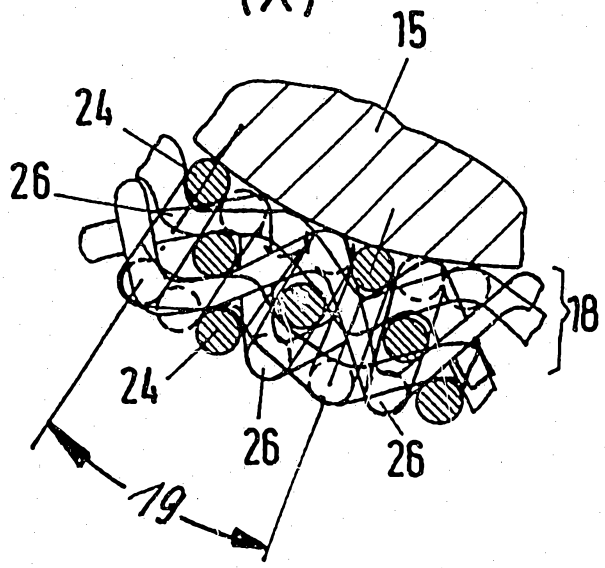

Fig.6
(Y)

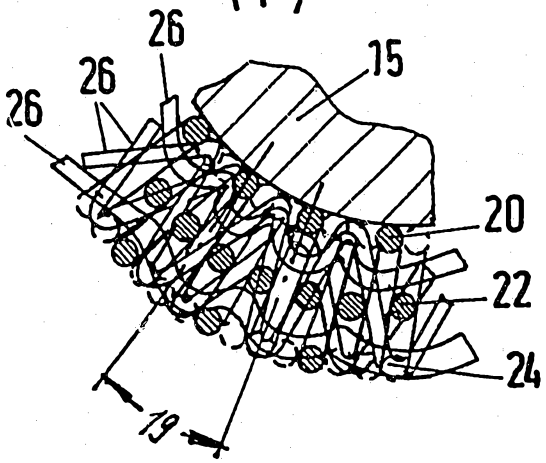

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Fig.7

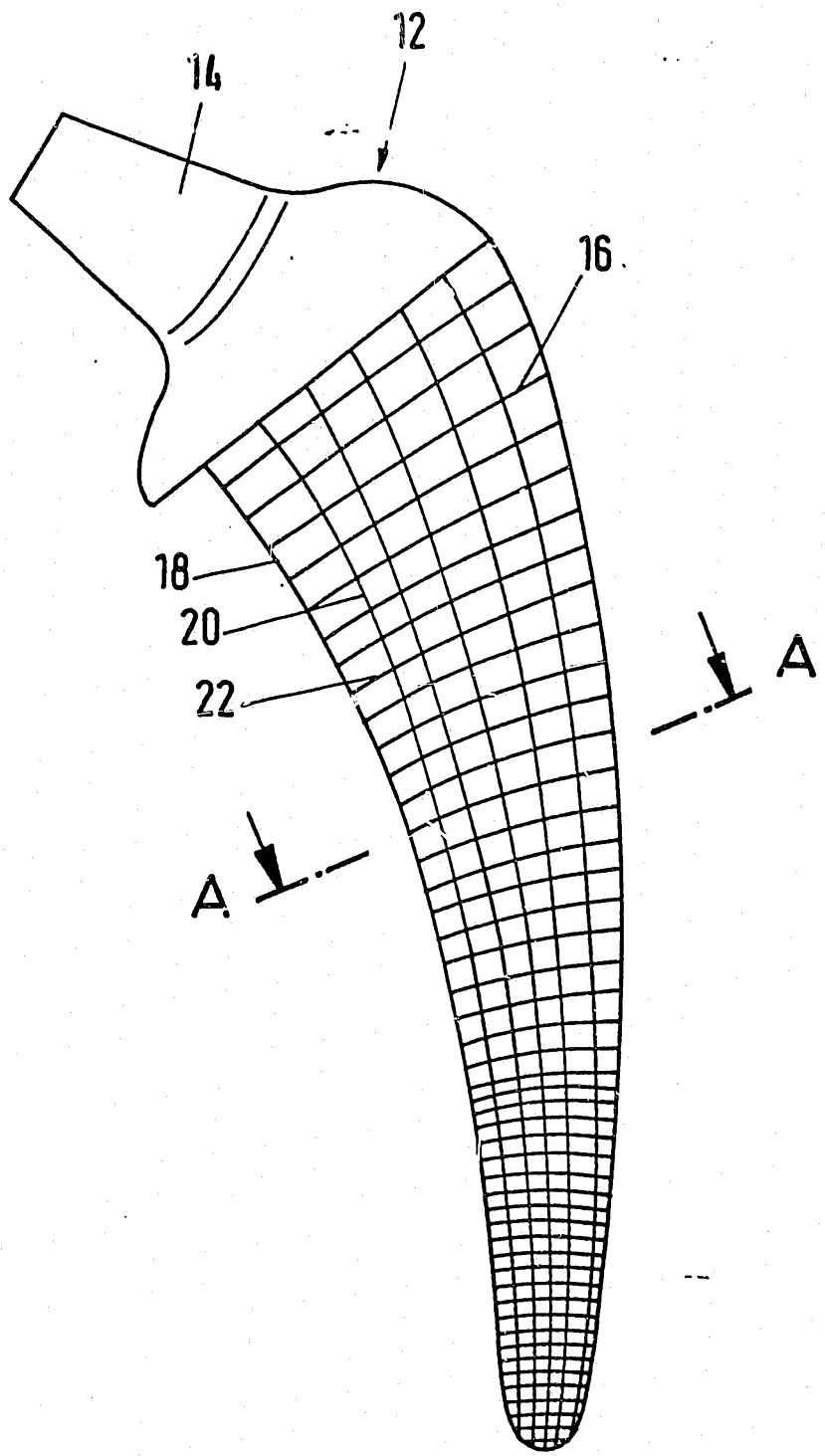

Fig.8
(A-A)

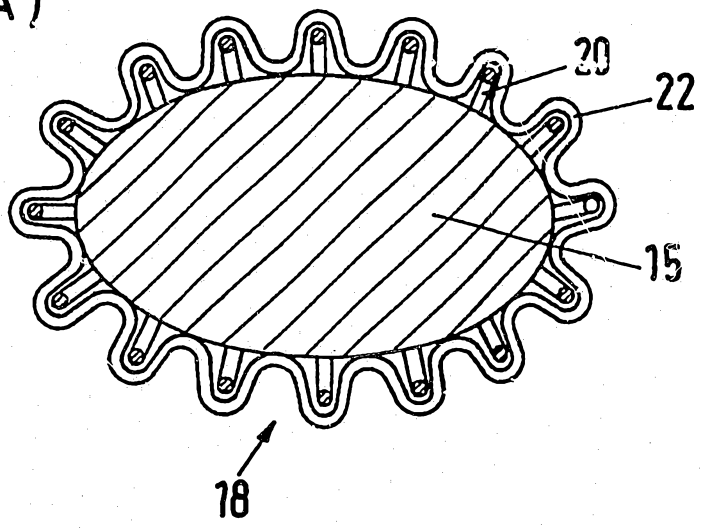

Fig.9

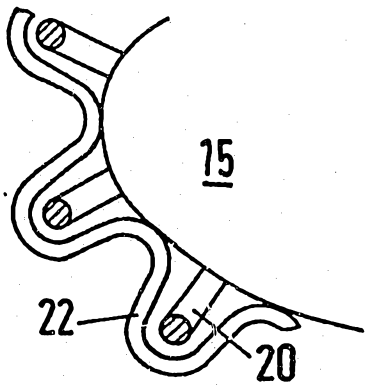

Fig.10

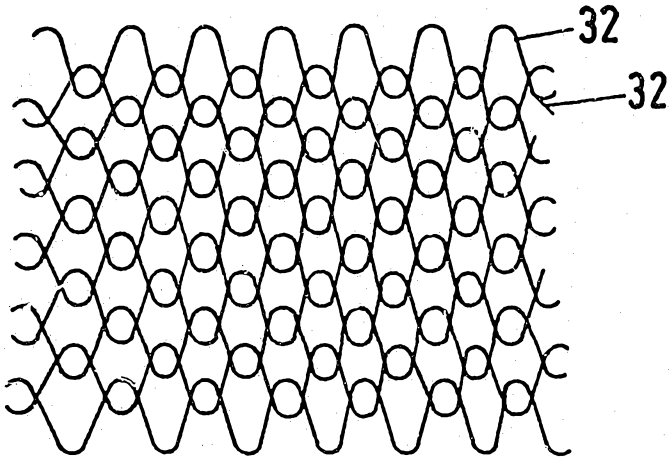

Fig.11

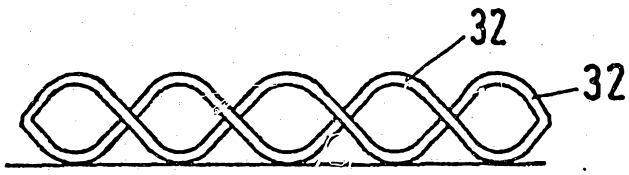

Fig.12

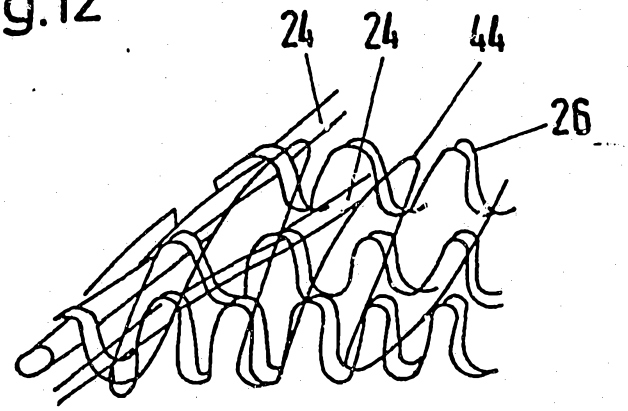

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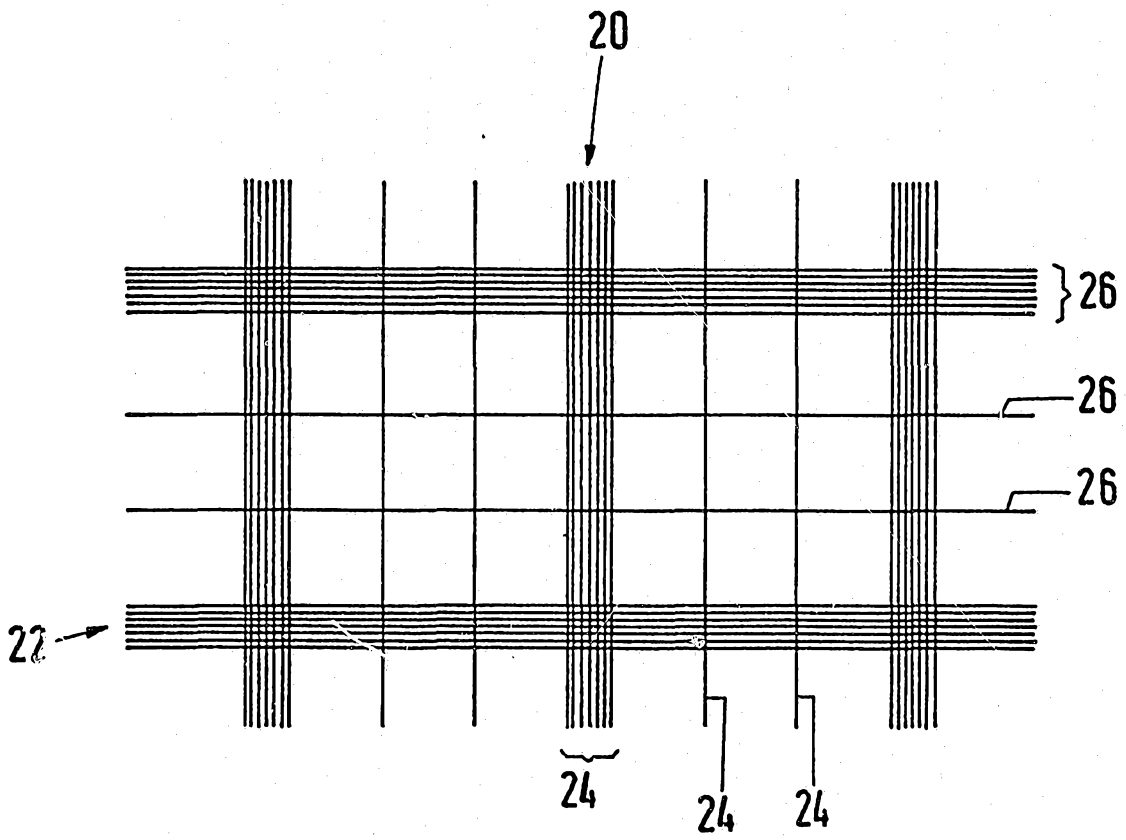
Fig.13



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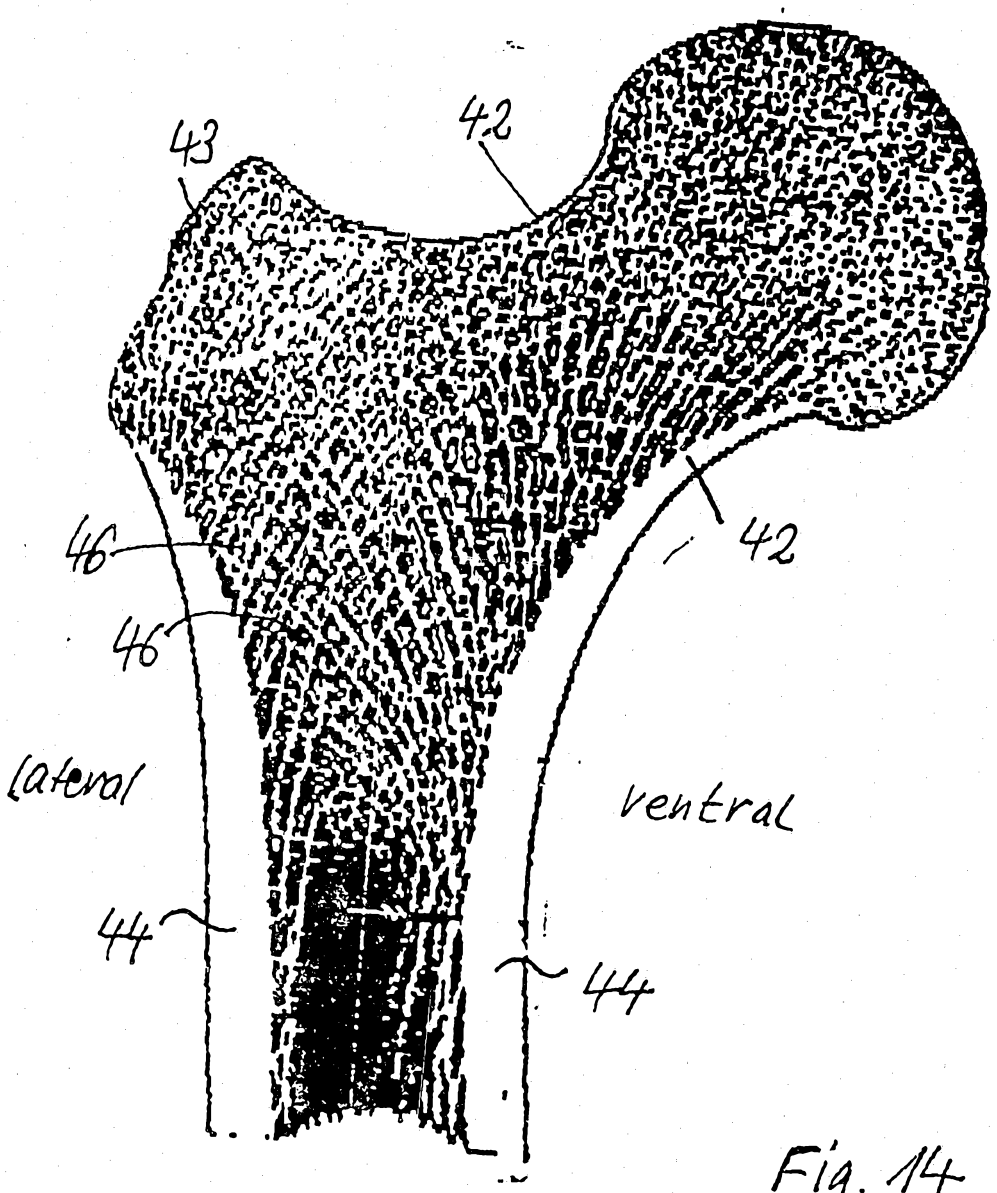

Fig. 14

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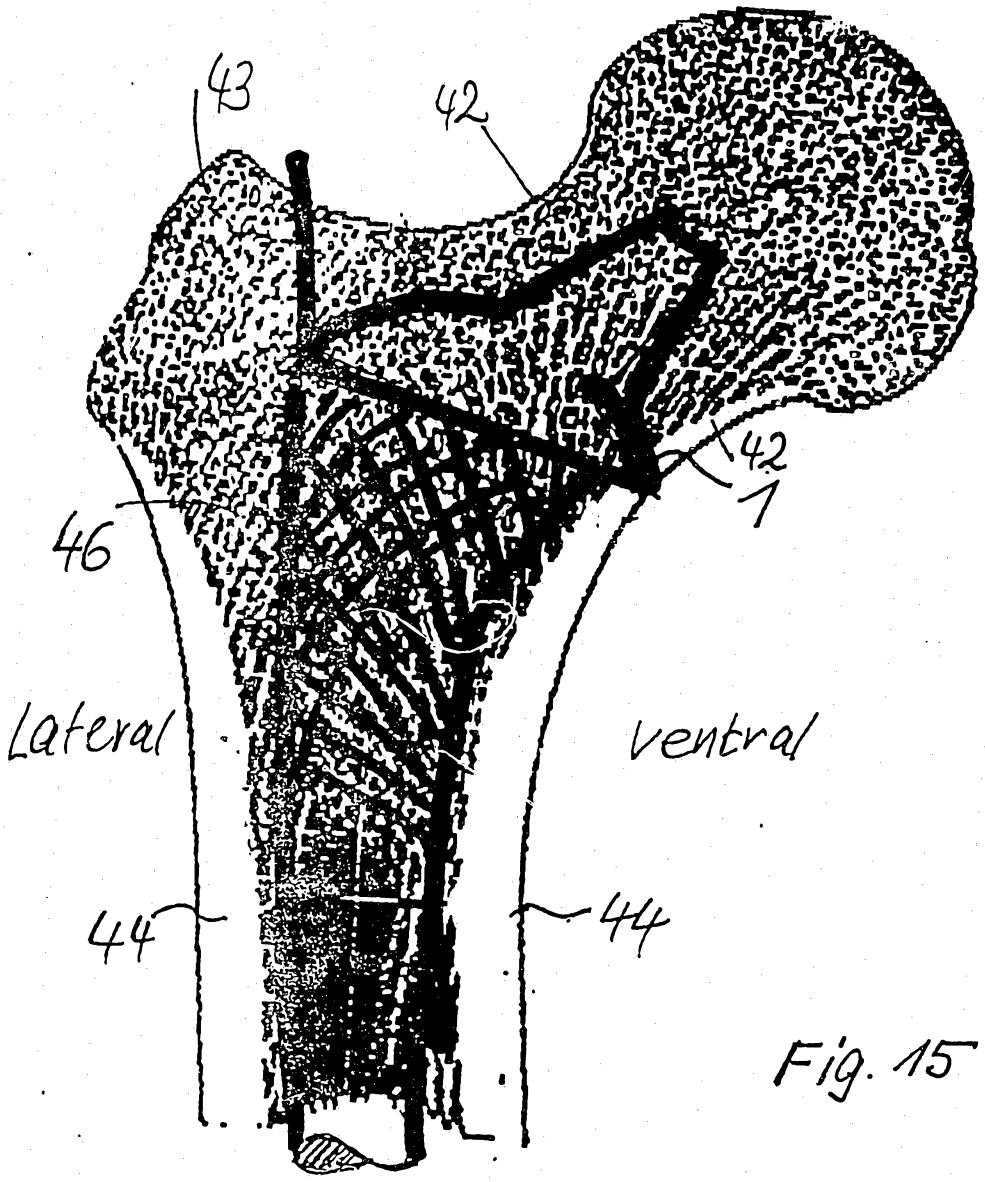

Fig. 15

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Fig.16

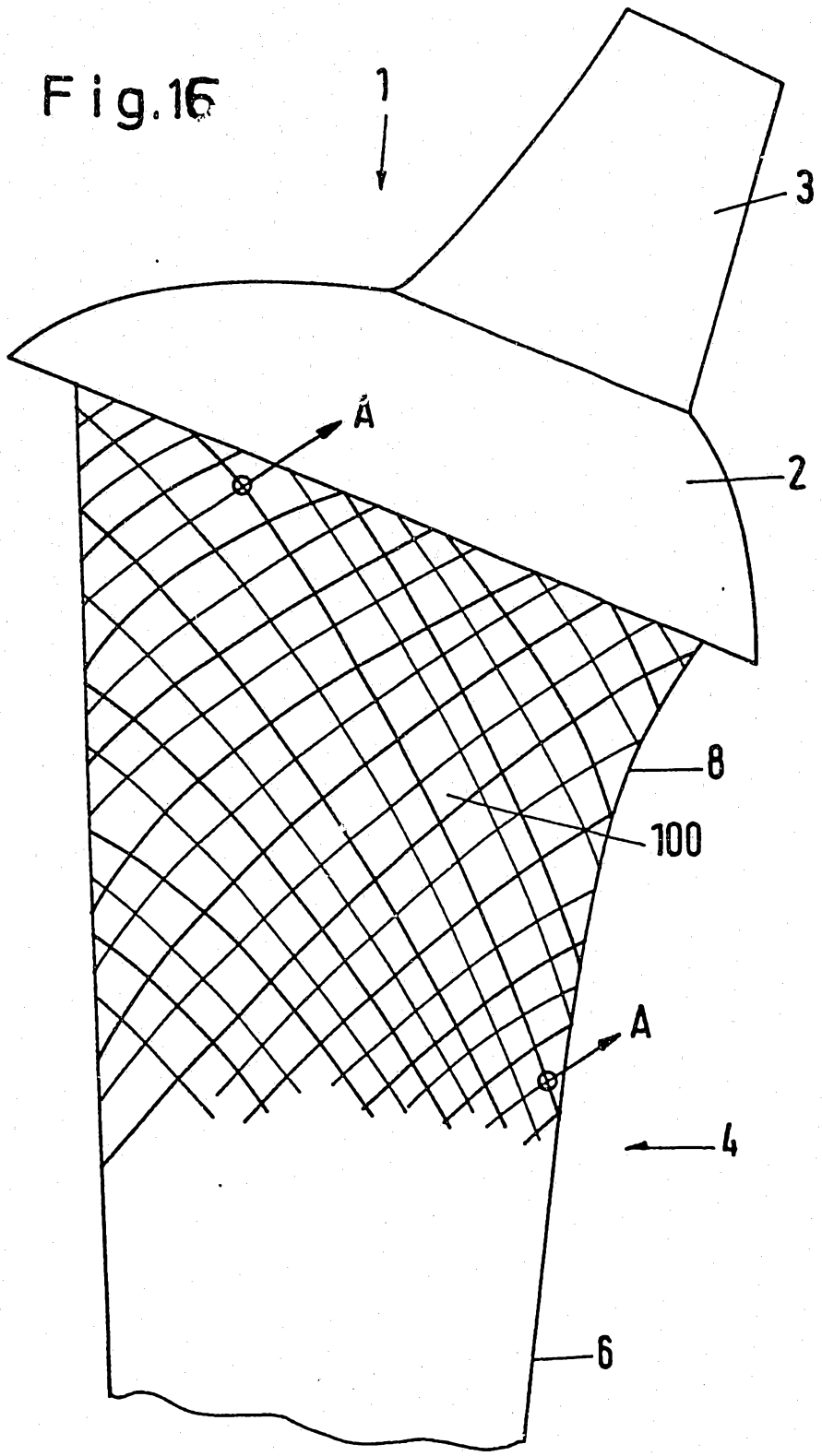

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Fig.17

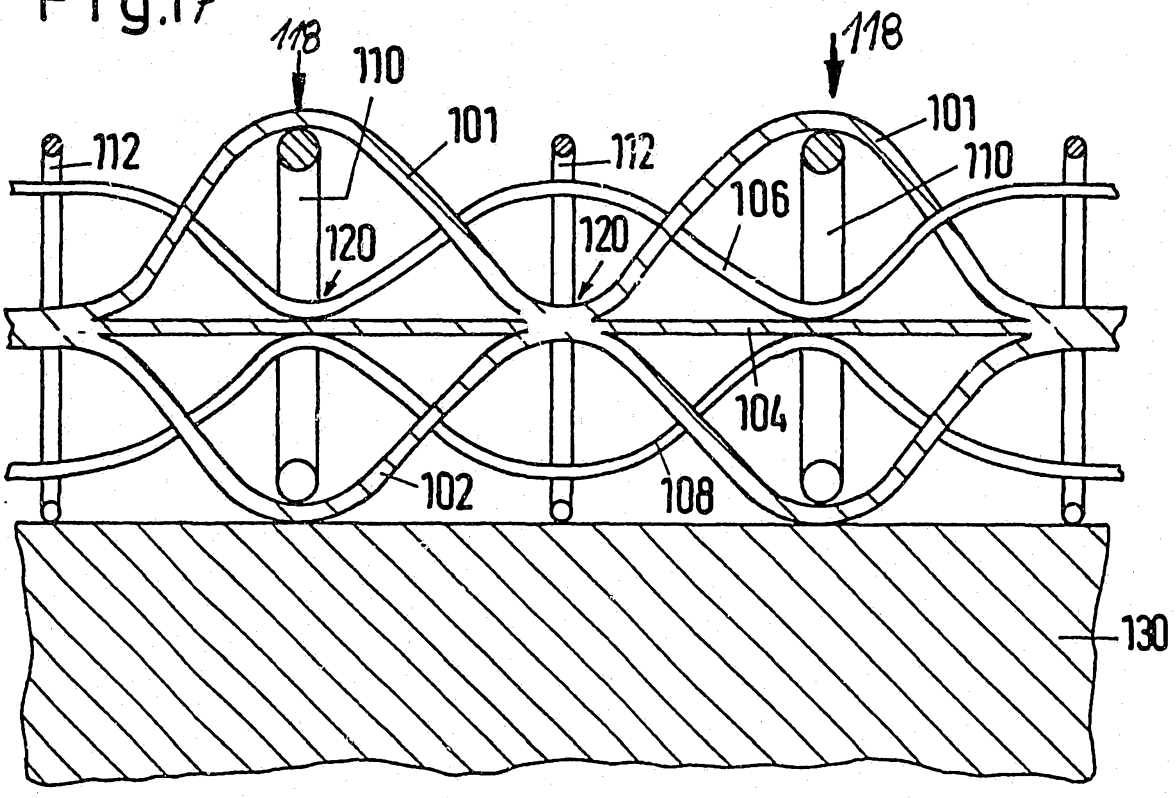
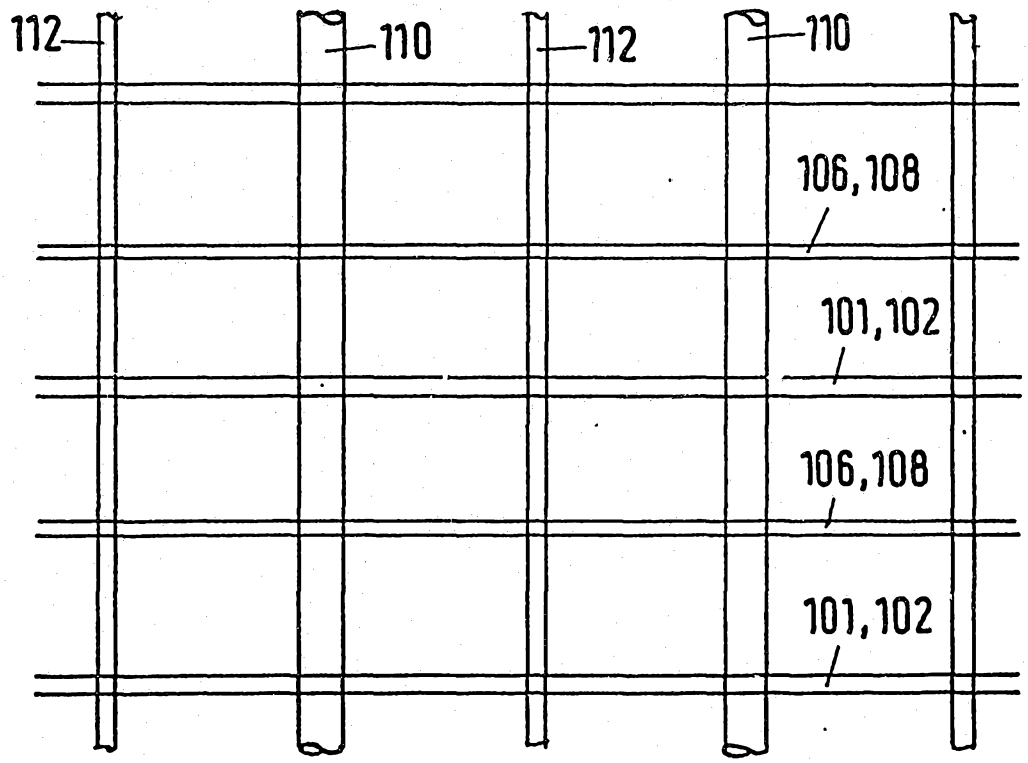


Fig.18



INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP92/02335

A. CLASSIFICATION OF SUBJECT MATTER
Int. Cl.^{5} : A61F 2/30; A61F 2/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
Int.Cl.^{5} : A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4 492 577 (FARRIS ET AL.) 8 January 1985, see the whole document	1-28
Y	EP, A, 0 399 163 (ESKA MEDICAL) 28 November 1990, see column 4, line 43 - column 5, line 27; figures	1-20
Y	FR, A, 2 412 304 (THE SAMPSON CO.) 20 July 1979, see page 5, line 14 - page 8 , line 26; claim 14; figures	21-28
A	EP, A, 0 197 441 (MAN TECHNOLOGIE) 15 October 1986, see abstract; figures	1,21
A	US, A, 4 976 738 (FREY ET AL.) 11 December 1990,	
A	US, A, 4 737 411 (GRAVES JR. ET AL.) 12 April 1988,	
A	EP, A, 0 420 542 (PFIZER HOSPITAL) 3 April 1991,	

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 February 1993 (15.02.93)	24 February 1993 (24.02.93)
Name and mailing address of the ISA/ European Patent Office Facsimile No.	Authorized officer Telephone No.

Form PCT/ISA/210 (second sheet) (July 1992)

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

EP 9202335
SA 66190

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
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-4492577	08-01-85	None	
EP-A-0399163	28-11-90	DE-C- 3917033	02-08-90
		JP-A- 3029649	07-02-91
		US-A- 5042560	27-08-91
FR-A-2412304	20-07-79	None	
EP-A-0197441	15-10-86	DE-A- 3524020	02-10-86
		CA-A- 1253306	02-05-89
		JP-A- 61226038	07-10-86
		US-A- 4714467	22-12-87
US-A-4976738	11-12-90	None	
US-A-4737411	12-04-88	CA-A- 1266685	13-03-90
		EP-A- 0271236	15-06-88
EP-A-0420542	03-04-91	CA-A- 2026301	29-03-91
		DE-U- 9011363	15-11-90
		JP-A- 3123546	27-05-91
		US-A- 5108435	28-04-92

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen PCT/EP 92/02335

I. KLASSIFIKATION DES ANMELDUNGSGEGENSTANDS (bei mehreren Klassifikationssymbolen sind alle anzugeben)[6]

Nach der Internationalen Patentklassifikation (IPC) oder nach der nationalen Klassifikation und der IPC

Int.Kl. 5 A61F2/30; A61F2/36

II. RECHERCHIERTE SACHGEBIETE

Recherchierter Mindestprüfstoff [7]

Klassifikationssytem	Klassifikationssymbole
Int.Kl. 5	A61F

Recherchierte nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Sachgebiete fallen [8]

III. EINSCHLAGIGE VEROFFENTLICHUNGEN [9]

Art.°	Kennzeichnung der Veröffentlichung[11], soweit erforderlich unter Angabe der maßgeblichen Teile[12]	Betr. Anspruch Nr.[13]
Y	US,A,4 492 577 (FARRIS ET AL.) 8. Januar 1985 siehe das ganze Dokument	1-28
Y	EP,A,0 399 163 (ESKA MEDICAL) 28. November 1990 siehe Spalte 4, Zeile 43 - Spalte 5, Zeile 27; Abbildungen	1-20
Y	FR,A,2 412 304 (THE SAMPSON CO.) 20. Juli 1979 siehe Seite 5, Zeile 14 - Seite 8, Zeile 26; Anspruch 14; Abbildungen	21-28
A	EP,A,0 187 441 (MAN TECHNOLOGIE) 15. Oktober 1986 siehe Zusammenfassung; Abbildungen	1,21

-/--

° Besondere Kategorien von angegebenen Veröffentlichungen [10]:

"A" Veröffentlichung, die den allgemeinen Stand der Technik definiert, aber nicht als besonders bedeutsam anzusehen ist

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"X" Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann nicht als neu oder auf erfinderischer Tätigkeit beruhend betrachtet werden

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"&" Veröffentlichung, die Mitglied derselben Patentfamilie ist

IV. BESCHEINIGUNG

1

Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
15.FEBRUAR 1993	24. 02. 93
Internationale Recherchenbehörde	**Unterschrift des bevollmächtigten Bediensteten**
EUROPAISCHES PATENTAMT	SANCHEZ Y SANCHEZ J.

III. EINSCHLAGIGE VEROFFENTLICHUNGEN (Fortsetzung von Blatt 2)

Art °	Kennzeichnung der Veröffentlichung, soweit erforderlich unter Angabe der maßgeblichen Teile	Betr. Anspruch Nr.
A	US,A,4 976 738 (FREY ET AL.) 11. Dezember 1990 ---	
A	US,A,4 737 411 (GRAVES JR. ET AL.) 12. April 1988 ---	
A	EP,A,0 420 542 (PFIZER HOSPITAL) 3. April 1991 -----	

ANHANG ZUM INTERNATIONALEN RECHERCHENBERICHT ÜBER DIE INTERNATIONALE PATENTANMELDUNG NR.

EP 9202335
SA 66190

In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten internationalen Recherchenbericht angeführten Patentdokumente angegeben.
Die Angaben über die Familienmitglieder entsprechen dem Stand der Datei des Europäischen Patentamts am 15/02/93
Diese Angaben dienen nur zur Unterrichtung und erfolgen ohne Gewähr.

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie		Datum der Veröffentlichung
US-A-4492577	08-01-85	Keine		
EP-A-0399163	28-11-90	DE-C-	3917033	02-08-90
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		US-A-	5042560	27-08-91
FR-A-2412304	20-07-79	Keine		
EP-A-0197441	15-10-86	DE-A-	3524020	02-10-86
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US-A-4976738	11-12-90	Keine		
US-A-4737411	12-04-88	CA-A-	1266685	13-03-90
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EP-A-0420542	03-04-91	CA-A-	2026301	29-03-91
		DE-U-	9011363	15-11-90
		JP-A-	3123546	27-05-91
		US-A-	5108435	28-04-92

EPO FORM P0473