



(86) Date de dépôt PCT/PCT Filing Date: 2000/10/30
(87) Date publication PCT/PCT Publication Date: 2001/05/10
(45) Date de délivrance/Issue Date: 2009/01/13
(85) Entrée phase nationale/National Entry: 2002/04/30
(86) N° demande PCT/PCT Application No.: EP 2000/010672
(87) N° publication PCT/PCT Publication No.: 2001/032110
(30) Priorité/Priority: 1999/11/03 (DE199 52 939.6)

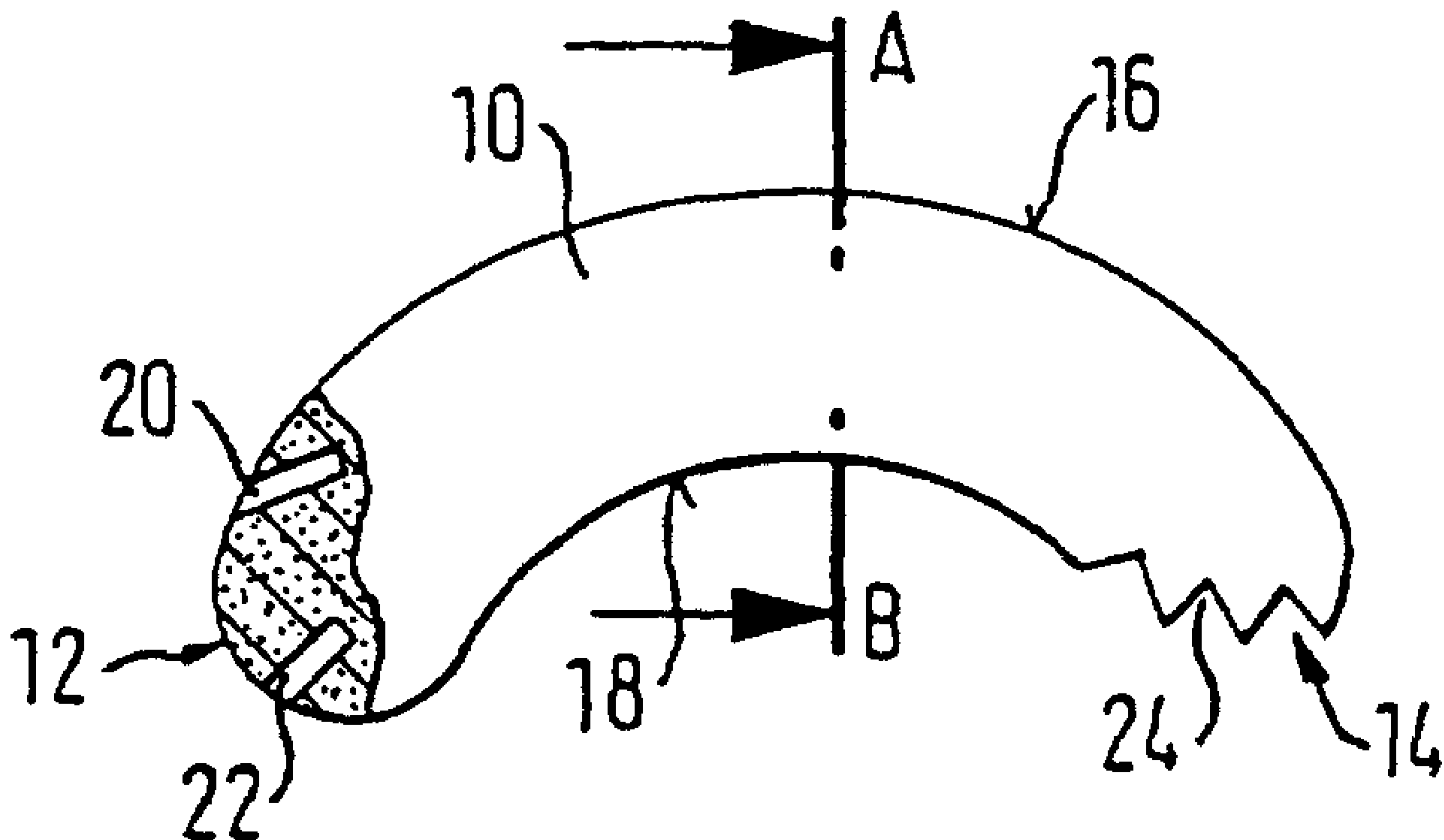
(51) Cl.Int./Int.Cl. *A61F 2/44* (2006.01),
A61L 27/36 (2006.01)

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(54) Titre : IMPLANT EN MATIERE OSSEUSE
(54) Title: IMPLANT CONSISTING OF BONE MATERIAL



(57) Abrégé/Abstract:

The invention relates to a vertebral column implant for intercorporeal fusion on the vertebral column, consisting of a body (10) which consists of bone material and which is curved in the direction in which it extends longitudinally. The size of the implant is adapted to the intermediate vertebral space available between adjacent vertebrae after the intermediate vertebral body has been removed.



(12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES
PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG(19) Weltorganisation für geistiges Eigentum
Internationales Büro(43) Internationales Veröffentlichungsdatum
10. Mai 2001 (10.05.2001)

PCT

(10) Internationale Veröffentlichungsnummer
WO 01/32110 A3(51) Internationale Patentklassifikation⁷: A61F 2/44, 2/46, A61L 27/36

(21) Internationales Aktenzeichen: PCT/EP00/10672

(22) Internationales Anmeldedatum:
30. Oktober 2000 (30.10.2000)

(25) Einreichungssprache: Deutsch

(26) Veröffentlichungssprache: Deutsch

(30) Angaben zur Priorität:
199 52 939.6 3. November 1999 (03.11.1999) DE

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(81) Bestimmungsstaaten (national): AE, AG, AL, AM, AT, AT (Gebrauchsmuster), AU (petty patent), AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, CZ (Gebrauchsmuster), DE, DE (Gebrauchsmuster), DK, DK (Gebrauchsmuster), DM, DZ, EE, EE (Gebrauchsmuster), ES, FI, FI (Gebrauchsmuster), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Gebrauchsmuster), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Bestimmungsstaaten (regional): ARIPO-Patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), eurasisches Patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), europäisches Patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI-Patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Veröffentlicht:

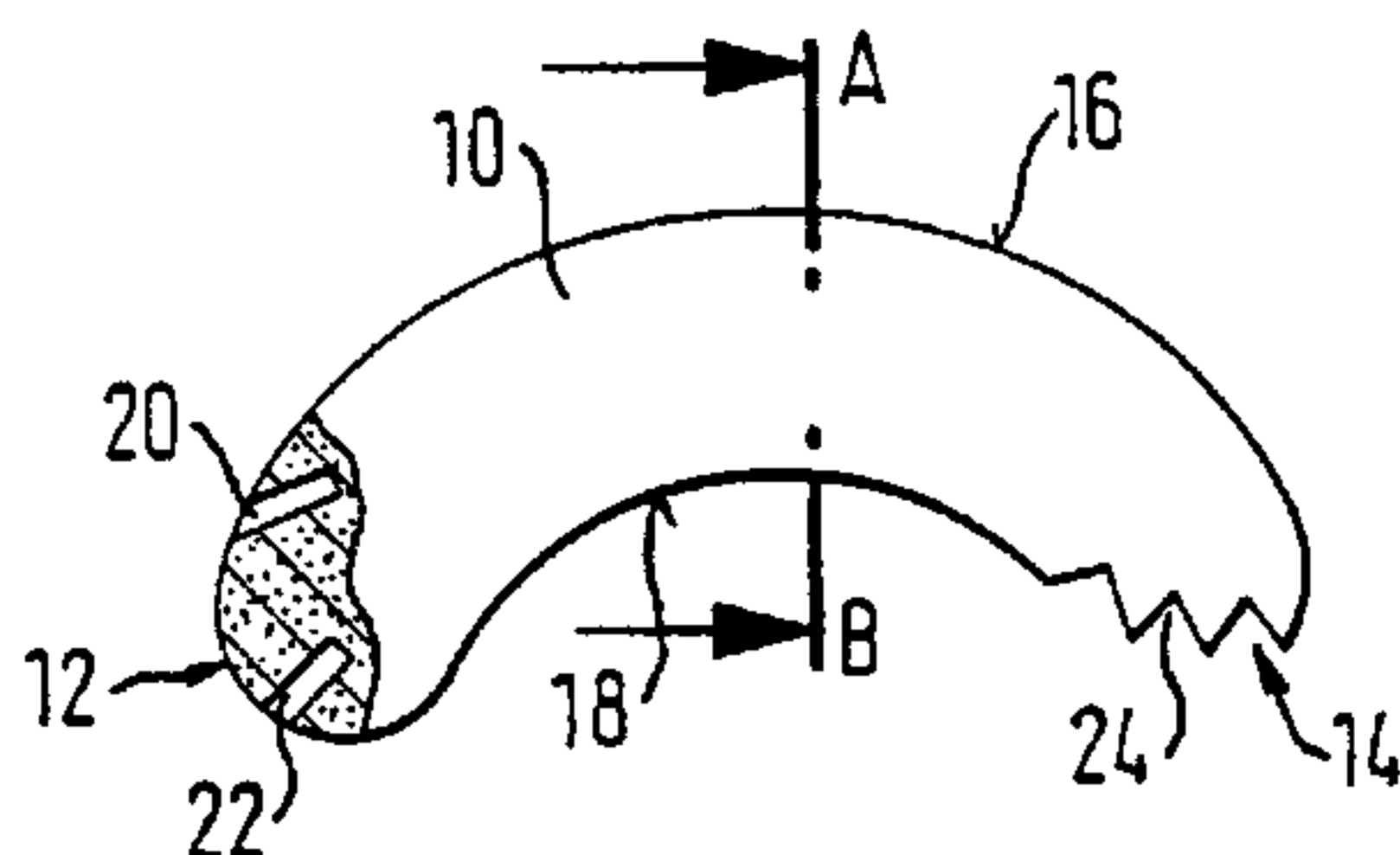
— mit internationalem Recherchenbericht

(88) Veröffentlichungsdatum des internationalen
Recherchenberichts: 4. April 2002

Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

(54) Title: IMPLANT CONSISTING OF BONE MATERIAL

(54) Bezeichnung: IMPLANTAT AUS KNOCHENMATERIAL



(57) Abstract: The invention relates to a vertebral column implant for intercoral fusion on the vertebral column, consisting of a body (10) which consists of bone material and which is curved in the direction in which it extends longitudinally. The size of the implant is adapted to the intermediate vertebral space available between adjacent vertebrae after the intermediate vertebral body has been removed.

(57) Zusammenfassung: Ein Wirbelsäulenimplantat zur interkorporellen Fusion an der Wirbelsäule besteht aus einem Körper (10) aus Knochenmaterial, der in Richtung seiner Längserstreckung gekrümmt ausgebildet ist. Das Implantat ist in seiner Größe an den nach Ausräumung des Wirbelzwischenkörpers vorhandenen Wirbelzwischenraum zwischen benachbarten Wirbeln angepaßt.

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Implant consisting of bone material

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The present invention relates to an implant for the connection of bones and in particular to a spinal column implant for the intercorporal fusion of vertebrae which is inserted between two vertebrae to be fused.

10 Through the degeneration of the vertebral disc, in particular of the vertebral disc nucleus (nucleus pulposus) a loss of height in the affected vertebral disc space often comes about which is connected with a loosening of the vertebral disc annulus (annulus fibrosus) and of the ligaments. Through this, the spinal column becomes instable at this
15 location. The result is a horizontal displaceability of the vertebral bodies relative to one another (spondylolisthesis), which leads to impairments of the nerve roots in this region and/or of the spinal cord together with the pain resulting from this. Similar symptoms can arise after a chemo-enzymatic or physical (laser) disintegration of the vertebral disc nucleus
20 (nucleolysis) for the treatment of a herniated disc (post-nucleolysis syndrome).

The principle for treating these symptoms consists in the surgical removal of the vertebral disc nucleus and the laying in or insertion
25 respectively of one – in the region of the cervical vertebral column – or of two – in the region of the lumbar vertebral column – sufficiently stable bodies in order to restore the normal height of the vertebral disc space.

At the same time the horizontal displaceability must be prevented. This takes place either through the implant itself or through additional metal implants (instrumented fusion). These implants are subject in particular in the lumbar vertebral column to considerable forces, which can lead to the breakage of the metal implant. Therefore an attempt is made to have the intermediate vertebral insert grow together or fuse respectively as rapidly and as solidly as possible with the adjacent vertebral bodies.

Essentially two techniques are used for the treatment of patients with spinal trauma or degenerative disease of the spinal column.

1. Removal of the vertebral disc nucleus and of the cartilage at the end-plates, expansion of the intervertebral space to a normal width and insertion of a plano-parallel or horizontally slightly wedge-shaped block (Smith-Robinson technique).
2. Expansion of the vertebral disc space to normal height, drilling of a cylindrical opening which covers both vertebrae and insertion of a cylindrical dowel (Cloward technique). The dowel can in this connection either be a smooth cylinder or have the shape of a machine bolt.

A relatively new method for the intercorporeal fusion at the lumbar vertebral column is the posterior lumbar intercorporeal fusion in a unilateral transforaminal technique. In this connection, the foramen intervertebrale of the affected segment is opened unilaterally, the vertebral disc space is removed and, for the ventral support, two

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titanium lattice baskets are introduced which are cut to the matching height and which are filled with bone chips. This tissue-saving method
5 does, however, have different disadvantages. On the one hand, the sharp edges of the titanium baskets can damage the nerve roots during introduction. Furthermore, no lordosiation is possible as the baskets are practically introduced blind. Finally, only the rims of the basket are available to absorb the pressure present. The titanium makes the fusion
10 control more difficult due to artifacts and in computer tomography. Furthermore, the implant removal in revision operations is extremely difficult.

A two-part spinal column implant is known from US 5,861,041 which
15 has a substantially elliptical configuration in the bonded state.

The object of the present invention therefore lies in providing an implant for the fusion of bones which eliminates the aforesaid disadvantages.

20 This object is satisfied by the features of claim 1 and in particular by a spinal column implant for intercorporal fusion at the spinal column consisting of a body of bone material which has a substantially rectangular or trapezoidal cross-section with sides extending obliquely in cross-section and which is made curved in a banana shape in the
25 direction of its longitudinal extent, whereby one convexly curved side and one concavely curved side is formed, and wherein the implant is matched in size to the intervertebral space between adjacent vertebrae

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after the removal of the intervertebral body, with at least one end of the body being rounded in plan view, and the sides extending obliquely in cross-section are inclined in the direction of the concave outer surface.

A special advantage of the spinal column implant in accordance with the invention is given by the material used which does not represent a foreign body due to its biological origin and to a special preservation.

Furthermore, due to the curved design of the implant, the advantage results that it is matched to the shape of the front edge of the lumbar vertebrae and thus automatically comes into the right position on insertion.

Further advantageous embodiments of the spinal column implant in accordance with the present invention are specified in the description, the drawing and the dependent claims.

In accordance with the invention, the body can consist of processed, preserved and sterile bone material of human origin, a so-called allograft, or of processed, preserved and sterile bone material of animal origin, a so-called xenograft. The body can be made of solid cortical bone material or also of spongy bone material, for example of the humerus, femur, tibia or of other bones either of deceased humans or of animals, in particular of bovine bone material, or also as a hollow body which is then filled with spongy bone material.

In a particularly advantageous embodiment of the spinal column

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implant in accordance with the invention, the body has a banana-like curvature. In a particularly advantageous embodiment, the body has rounded edges. Such a design of the body facilitates the application of the spinal column implant between the vertebral bodies to be fused in that the roundings avoid a canting of the implant during application. The implant is matched particularly well to the natural shape of the end plates of the vertebral bodies by the special banana shape and so offers the largest possible contact surface for the end plates. In this way, a more physiological distribution

vertebral bodies due to this are avoided. Since a correct positioning takes place automatically due to the curvature of the implant, the restoration of the physiological curvature of the spinal column – lordosis – is also possible by a trapezoidal cross-section.

5

It is particularly advantageous when notches or recesses are provided at the body which make possible the taking along of loosely introduced bone powder into the intervertebral space. In this way, bone powder can automatically be introduced into the concavely shaped region of the
10 implant during insertion of the implant into the intervertebral space.

In accordance with a further aspect of the present invention, reception openings are designed at one or more sides of the body as drillings with a thread of a depth of preferably 3 mm. Application tools provided with
15 a matching thread can then be screwed into these tapped drillings in order to insert the implant in an accurate position between the vertebrae to be fused.

As the material for the spinal column implant in accordance with the
20 present invention, a suitable allogenic or xenogenic bone material is processed in such a manner that it is preserved, is capable of storage, is sterile and can be used in accordance with its purpose. The preservation of the bone material can for example take place by means of freeze drying. Another preferred method for the production of the
25 bone material is a processing through preferably solvent dehydration of native bone material by means of an organic solvent which is miscible with water, e.g. methanol, ethanol, propanol, isopropanol, acetone,

methylethyl ketone or mixtures of these solvents. The preservation and sterilization of the bone material in accordance with this method is also a subject matter of the patent DE 29 06 650, the contents of which are taken up into the disclosure of the present application through this
5 reference.

This method serves for the production of transplant preserves and enables a dehydration and exposure right into the fine structure of the fibrils of the bone material, so that the processed bone material has a
10 morphological structure in a histological view which is very similar to that of the natural bone, and thus the desired properties of the bone material are retained. This method of solvent dehydration also has the advantage that a substantially lower apparatus cost and complexity is required in comparison with freeze drying.

15 Furthermore, the bone material can also be produced through solvent dehydration of bone material with subsequent terminal sterilization, in particular through irradiation with gamma rays. Alternatively, the spongy bone material can be produced through aseptic processing of
20 bone material without terminal sterilization. The starting material of the bone implant in accordance with the invention is human or animal bone of sufficient size.

To remove the antigenicity, the bone is subjected to an osmotic
25 treatment. Furthermore, an oxidizing treatment is carried out for denaturation of soluble proteins. To optimize virus deactivation, a reduction of pH to pH 3, or a treatment with caustic soda or another

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an oxidizing treatment is carried out for denaturation of soluble proteins. To optimize virus deactivation, a reduction of pH to pH 3, or a treatment with caustic soda or another substance which destroys DNA/RNA, can take place. The dehydration takes place through organic solvents, preferably acetone. The concluding sterilization takes place through high-energy radiation, preferably γ rays with a maximum dose of 25 kGy.

10

A bone treated in this manner maintains its natural mineral collagen bond and properties. Furthermore, a bone treated in this manner can be reworked.

15 The present invention will be described in the following in a purely exemplary manner with reference to embodiments of a spinal column implant in accordance with the invention and with reference to the accompanying drawings. There are shown:

- 20 Fig. 1 a plan view of an embodiment of a spinal column implant in accordance with the present invention;
- Fig. 2 a known cross-sectional shape of a spinal column implant;
- Fig. 3 a possible cross-sectional shape of the spinal column implants in accordance with the invention;
- 25 Fig. 4 a plan view of a further embodiment of a spinal column implant in accordance with the present invention; and

invention.

In the figures the same reference symbols designate in each case the same components of the illustrated embodiments.

5

The embodiment of a spinal column implant in accordance with the invention illustrated in Fig. 1 comprises a body 10, which consists, for example, of cortical, diaphyseal bone material, e.g. of human origin.

10 This body 10 is, in a plan view, substantially elongate and made curved in the direction of its longitudinal extent.

The two opposite ends 12 and 14 of the body 10 are made rounded such that overall a banana-like or also kidney-like design of the base body 10 results. The body 10 has a convexly curved surface 16 and a concavely
15 curved surface 18 between the two ends 12 and 14.

As Fig. 1 shows, the base body has two reception openings 20, 22 for application tools in the regions of its one end 12. The reception openings 20, 22 are made as drillings whose longitudinal axes do not
20 extend parallel to one another.

In the region of the oppositely disposed end 14, a structured design of the surface of the base body is provided in the region of the concave surface 18, preferably by notches or recesses 24 which allow the taking
25 along of loosely added bone powder into the intervertebral space. The taking along and compacting of the bone powder during the insertion of the bone implant into the intervertebral space is ensured by the

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powder into the intervertebral space. The taking along and compacting of the bone powder during the insertion of the bone implant into the intervertebral space is ensured by the structured design of the surface provided (three notches are provided in the example shown).

Fig 3 shows a possible cross-sectional shape of the body 10 along the intersection line A-B of Fig. 1.

10

Fig. 2 shows a known cross-sectional shape in the form of a rectangle with rounded edges. Fig. 3 shows a trapezoidal cross-sectional shape, with the obliquely extending sides of the trapezoid deviating from the rectangular shape by an angle α of approximately 3° to 6° .

15

As in particular Fig. 3 shows, with a trapezoidal cross-section of the implant, the obliquely extending outer sides 17, 19 can be inclined in the direction of the convex outer surface 18, i.e. in the direction of the ring center of the implant formed in the shape of a ring segment.

20

Figure 1 shows a substantially symmetrical embodiment of a spinal column implant. In contrast to this, an asymmetrical shape is selected in the further embodiment shown in Fig. 4, in which the shape of the body 10' in a plan view tapers from the one end 12 in the direction of the other end 14. In other respects, the same reference numerals designate the same elements. At the same time, the cross-sectional shapes shown in Figs. 2 and 3 can also be used in the embodiment shown in Fig. 4.

25

being selected. Furthermore, it can be recognized in the embodiment of Fig. 4 that the one end 12 of the body 10' is wider than the oppositely disposed end 14 in order to facilitate an insertion of the implant into the foramen intervertebrale.

5

Generally, the body 1 of the spinal column implant is matched in size to the pre-determined space at which the implant should be inserted. The outer dimensions of such a spinal column implant can, for example, be
10 as follows for a lumbar application: length approximately 30 to 60 mm, width approximately 8 to 20 mm, height approximately 6 to 18 mm.

Generally, the possibility exists of forming the spinal column implant as a solid implant, for example of cortical or of spongy bone. An
15 alternative embodiment of the invention provides that the spinal column implant – likewise made of cortical or spongy bone – is designed as a hollow body.

Fig. 5 shows such an embodiment in which the body 10" has a cavity 26
20 which is filled with spongy bone 28. The cavity 26 extends substantially from the end of the reception openings 20, 22 up to and into the region of the recesses 24. In this connection, the cavity 26 is matched to the outer contour of the body 10".

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The invention further provides a spinal column implant for intercorporal fusion at the spinal column comprising a body (10, 10', 10'') of bone material having a first end and an opposing second end, the body having a trapezoidal cross-section and which is made curved in the direction of its longitudinal extension, whereby one convexly curved side (16) and one concavely curved side (18) is formed, and wherein the implant is matched in size to an intervertebral space present between adjacent vertebrae after removal of the intervertebral body, wherein a first and a second outer side (17, 19) connecting the one convexly curved side and the one concavely curved side are inclined in the direction of the one concavely curved side so as to form a cross-section tapering towards the concavely curved side, and wherein at least one end of the body is rounded in plan view into a semi-circular shape, wherein the first end has at least one reception opening for an application tool and the opposing second end has a plurality of notches formed across a transition between the concavely curved side and a curved surface of the second end, which allows the taking along of loosely introduced bone powder into the intervertebral space.

The invention further provides a spinal column implant for intercorporal fusion at the spinal column comprising a body of bone material having a first end and an opposing second end, the body having a trapezoidal cross-section and which is made curved in the direction of its longitudinal extension, whereby one convexly curved side and one concavely curved side is formed, and wherein the implant is matched in size to an intervertebral space present between adjacent vertebrae after removal of the intervertebral body, wherein a first and a second outer side connecting the one convexly curved side and the one concavely curved side are inclined in the direction of the one concavely curved side

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so as to form a cross-section tapering towards the concavely curved side, and wherein at least one end of the body is rounded in plan view into a semi-circular shape, wherein the body is smooth except for holes consisting of an application tool reception opening in the first end and a plurality of notches which are formed across a transition between the concavely curved side and a curved surface of the second end.

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Reference numeral list

	10, 10', 10"	body
	12, 14	end
10	16	convex outer side
	17	outer side
	18	concave outer side
	19	outer side
	20, 22	reception opening
15	24	recesses
	26	cavity
	28	spongy bone
	α	inclination angle

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WE CLAIM:

1. A spinal column implant for intercorporal fusion at the spinal column comprising a body (10, 10', 10'') of bone material having a first end and an opposing second end, the body having a trapezoidal cross-section and which is made curved in the direction of its longitudinal extension, whereby one convexly curved side (16) and one concavely curved side (18) is formed, and wherein the implant is matched in size to an intervertebral space present between adjacent vertebrae after removal of the intervertebral body, wherein a first and a second outer side (17, 19) connecting the one convexly curved side and the one concavely curved side are inclined in the direction of the one concavely curved side so as to form a cross-section tapering towards the concavely curved side, and wherein at least one end of the body is rounded in plan view into a semi-circular shape, wherein the first end has at least one reception opening for an application tool and the opposing second end has a plurality of notches formed across a transition between the concavely curved side and a curved surface of the second end, which allows the taking along of loosely introduced bone powder into the intervertebral space.

2. A spinal column implant in accordance with claim 1 characterized in that the body (10, 10', 10'') is formed of preserved and sterile bone material of human or animal origin.

3. A spinal column implant in accordance with claim 1, characterized in that the first end and the second opposing end of the body (10, 10', 10'') are rounded in plan view in a semi-circular shape.

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4. A spinal column implant in accordance with claim 1, characterized in that the body (10, 10', 10'') has rounded edges.

5. A spinal column implant in accordance with claim 1, characterized in that the body has the form of a ring segment.

6. A spinal column implant in accordance with claim 1, characterized in that the second end (14) of the body (10') is narrower than the first end (12).

7. A spinal column implant in accordance with claim 1, characterized in that the body (10, 10', 10'') is trapezoidal in cross-section having obliquely extending sides deviating from a cross-section in the form of a rectangle with rounded edges by an angle (α) from approximately 3° to 6°.

8. A spinal column implant in accordance with claim 2, wherein said preserved and sterile bone material is bovine bone material.

9. A spinal column implant in accordance with claim 5 wherein said ring segment forms one-third to one-half a complete ring.

10. A spinal column implant in accordance with claim 1 further comprising bone powder in the at least one notch or recess.

11. A spinal column implant for intercorporal fusion at the spinal column comprising a body of bone material having a first end and an opposing second end, the body having a trapezoidal cross-section and which is made curved in the direction of its longitudinal extension, whereby one convexly curved side and one concavely curved side is

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formed, and wherein the implant is matched in size to an intervertebral space present between adjacent vertebrae after removal of the intervertebral body, wherein a first and a second outer side connecting the one convexly curved side and the one concavely curved side are inclined in the direction of the one concavely curved side so as to form a cross-section tapering towards the concavely curved side, and wherein at least one end of the body is rounded in plan view into a semi-circular shape, wherein the body is smooth except for holes consisting of an application tool reception opening in the first end and a plurality of notches which are formed across a transition between the concavely curved side and a curved surface of the second end.

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FIG. 1

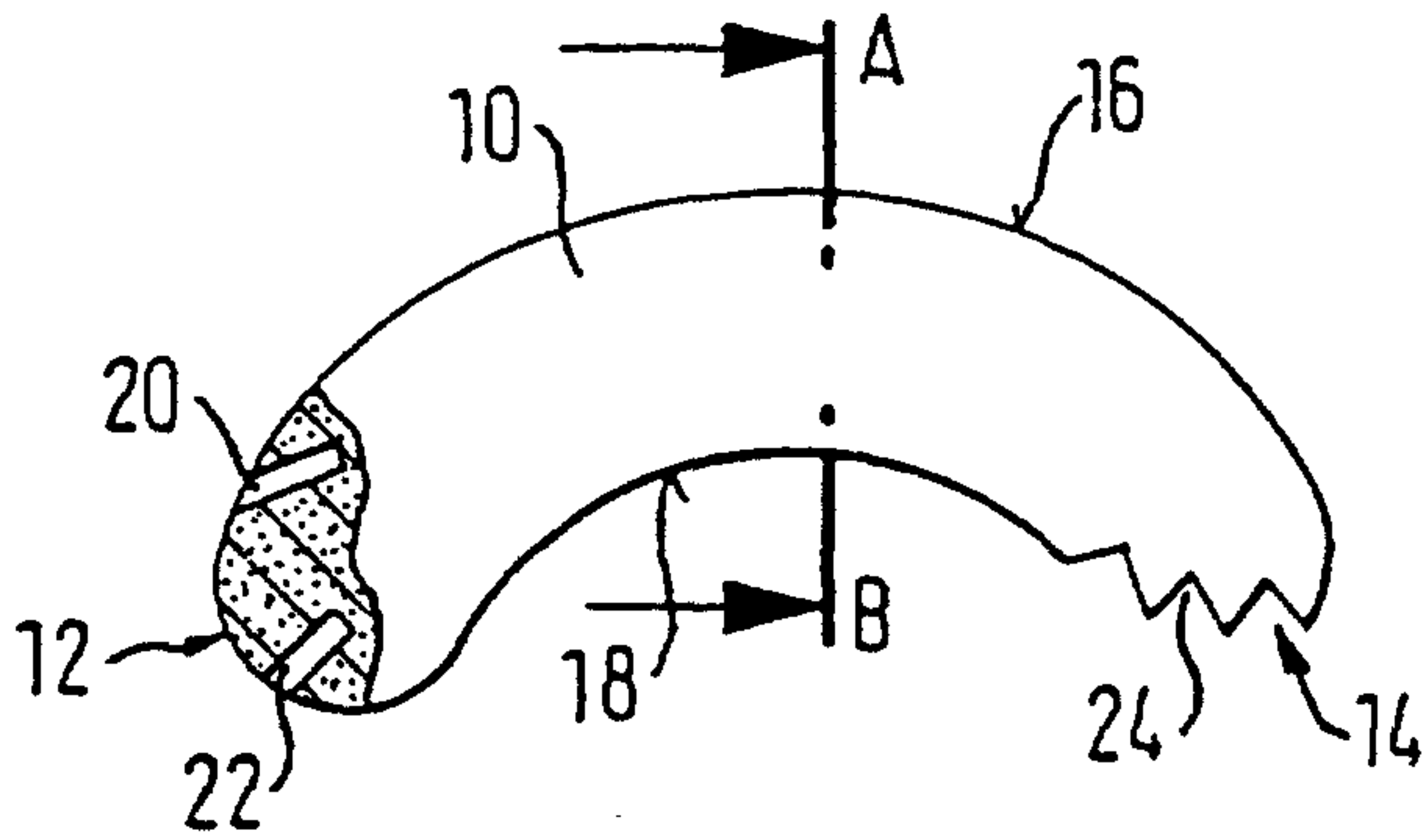


FIG. 2

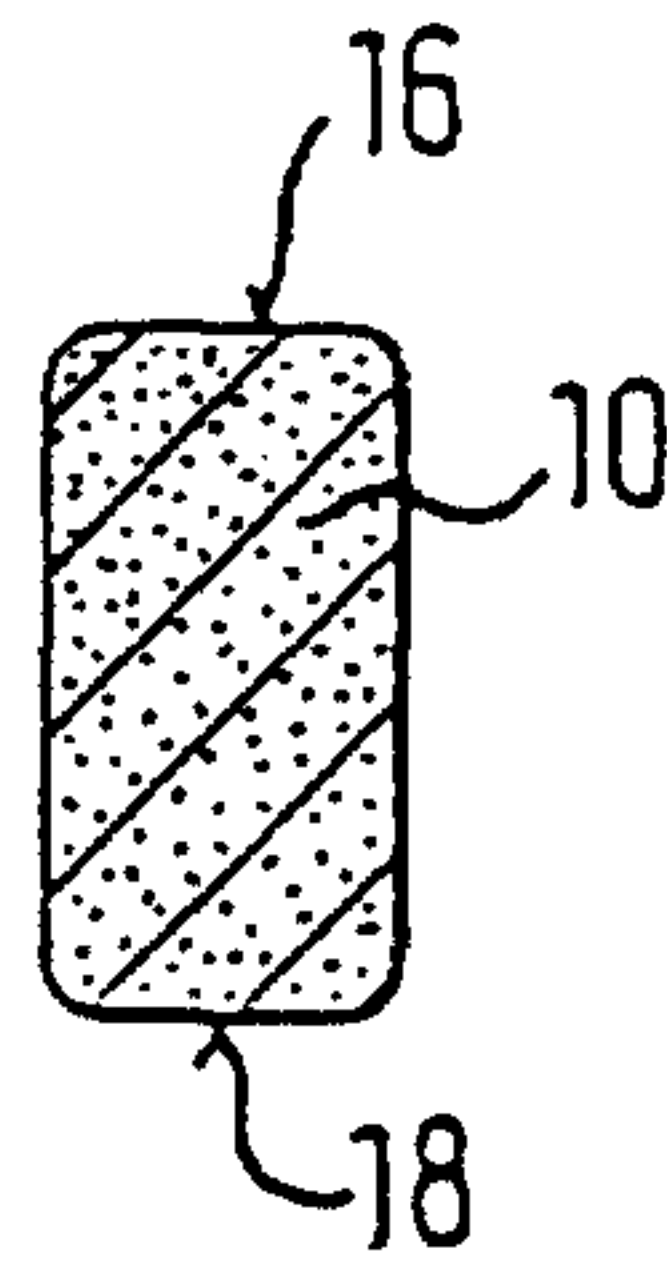


FIG. 3

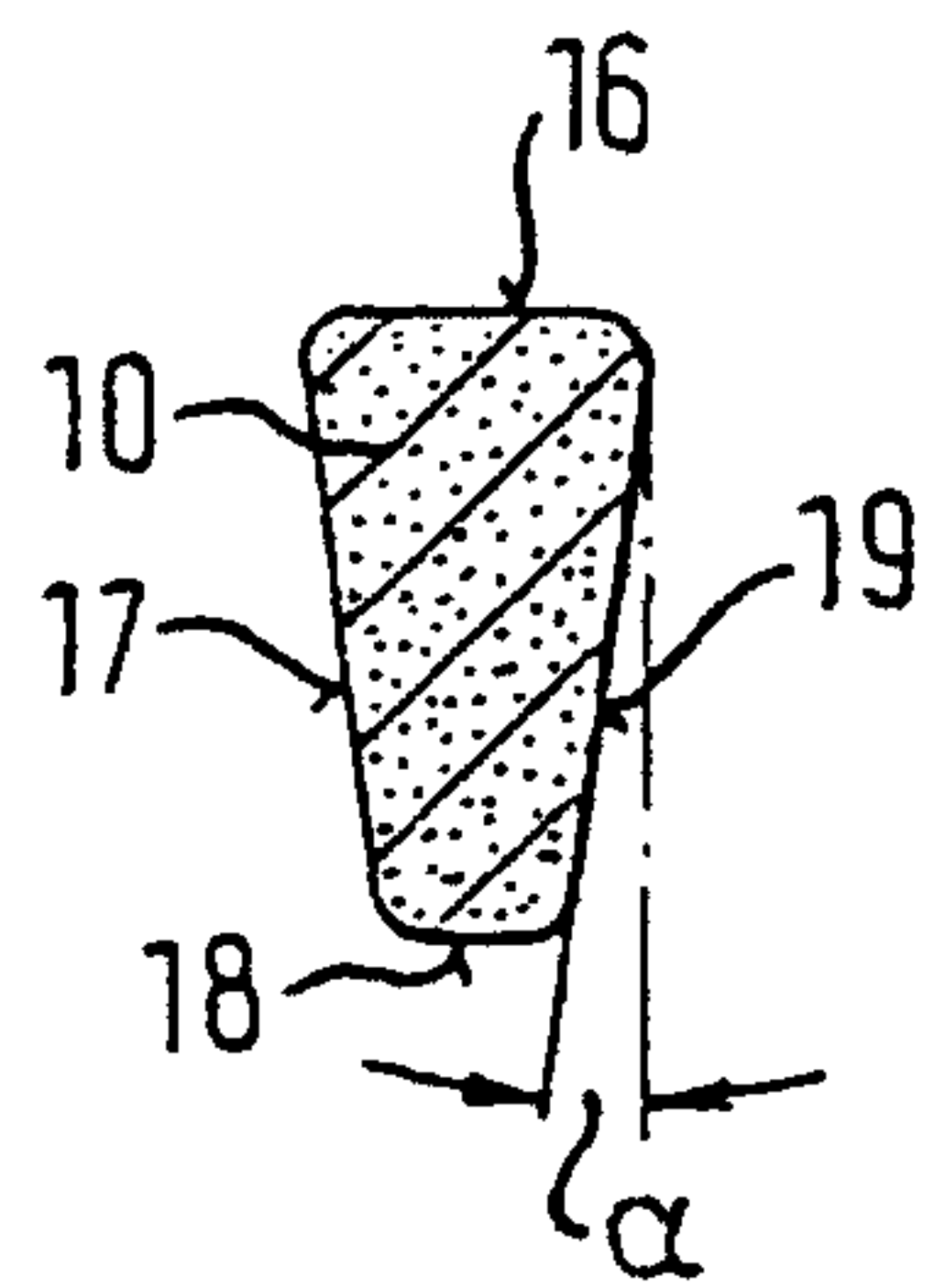


FIG. 4

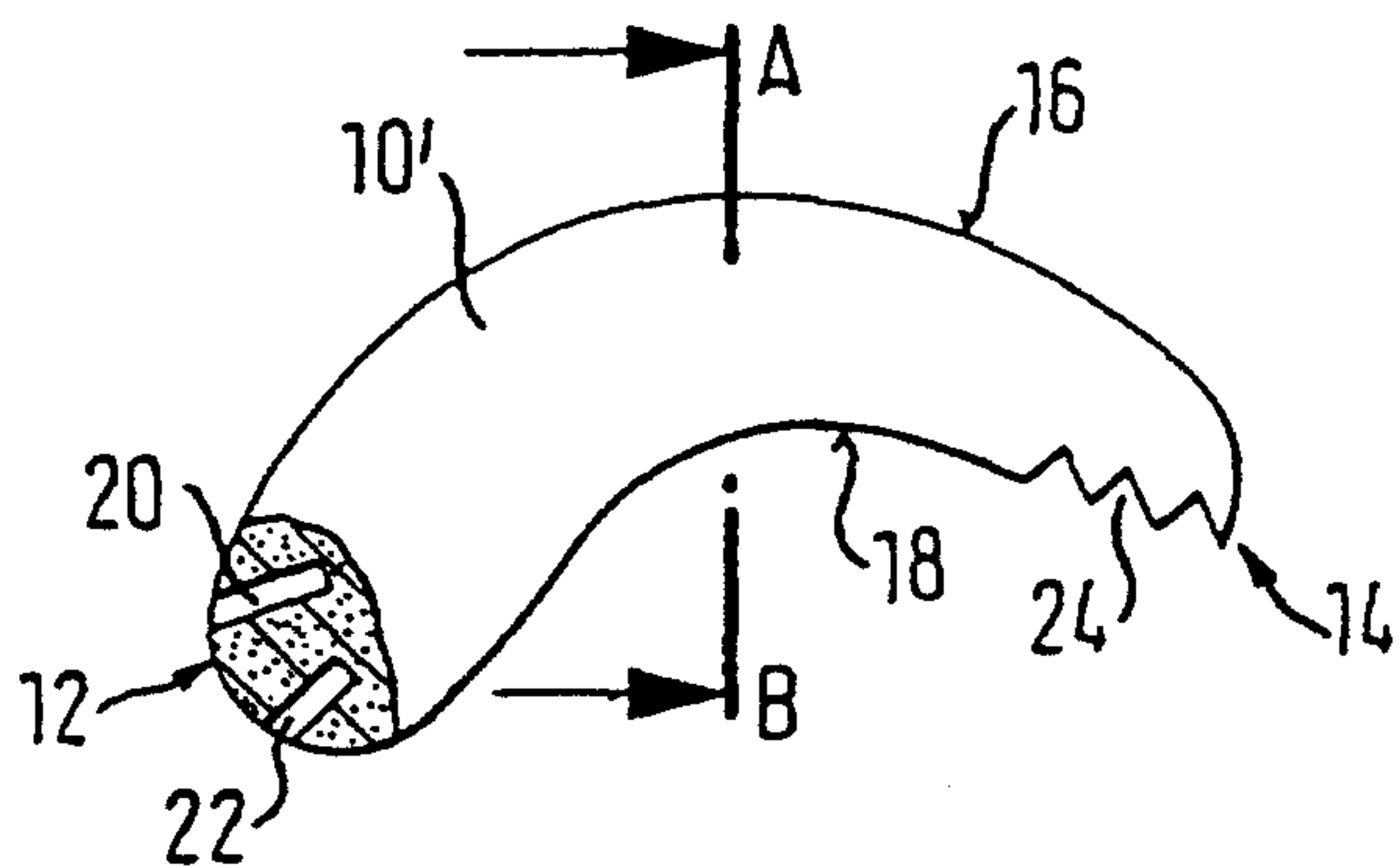


FIG. 5

