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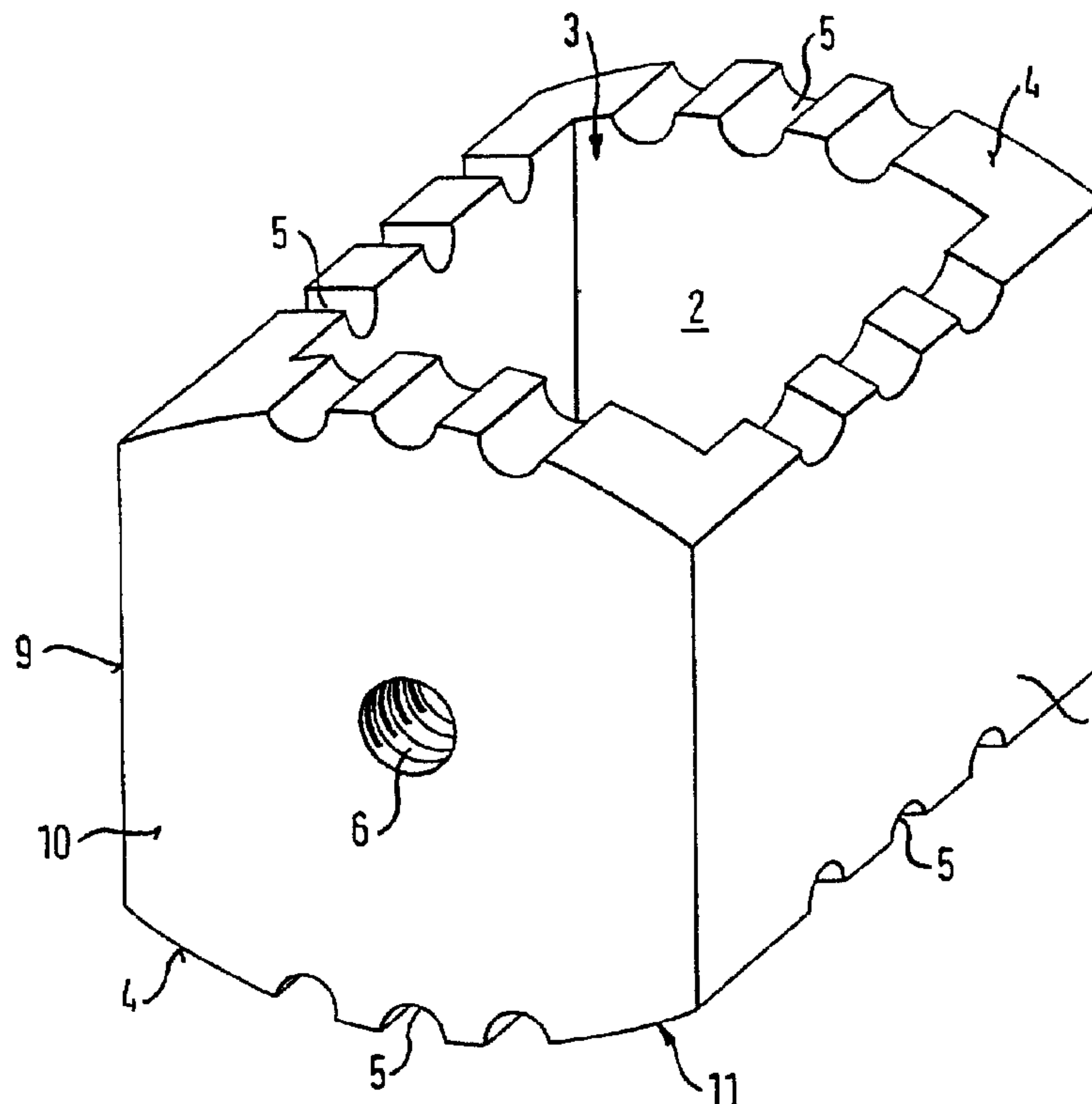
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(54) Titre : IMPLANT EN MATIERE OSSEUSE

(54) Title: IMPLANT OF BONE MATTER



(57) Abrégé/Abstract:

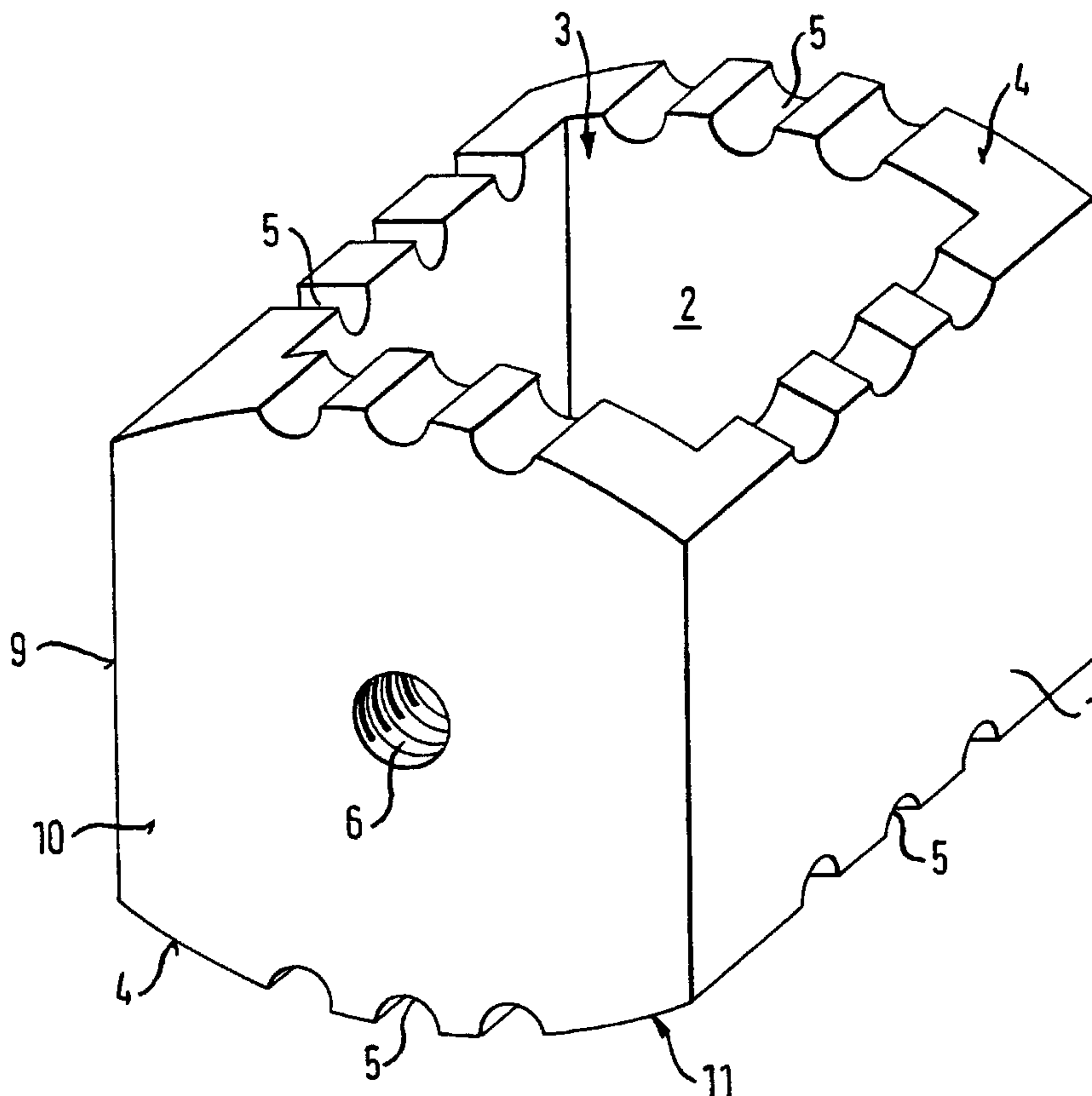
The invention relates to a vertebral implant that consists of a frame (1) from cortical osseous material. Said frame forms at least one continuous cavity (2) that has at least two openings (3, 11) situated opposite one another and that is at least partially filled with spongy and/or osteoinductive osseous material (8). The frame (1) has a substantially cuboid shape and is provided with crowned edge sections (4) at least on one side thereof. The frame (1) is further provided with structures (5) so that the vertebral implant can be fixated between adjacent vertebrae, said frame (1) including at least one opening (6) that receives an application tool.

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[Fortsetzung auf der nächsten Seite](54) Title: **IMPLANT FROM OSSEOUS MATERIAL**(54) Bezeichnung: **IMPLANTAT AUS KNOCHENMATERIAL**

(57) **Abstract:** The invention relates to a vertebral implant that consists of a frame (1) from cortical osseous material. Said frame forms at least one continuous cavity (2) that has at least two openings (3, 11) situated opposite one another and that is at least partially filled with spongiöse and/or osteoinductive osseous material (8). The frame (1) has a substantially cuboid shape and is provided with crowned edge sections (4) at least on one side thereof. The frame (1) is further provided with structures (5) so that the vertebral implant can be fixated between adjacent vertebrae, said frame (1) including at least one opening (6) that receives an application tool.

(57) **Zusammenfassung:**

Die Erfindung betrifft Wirbelsäulenimplantat bestehend aus einem Rahmen (1) aus kortikalem Knochenmaterial, der mindestens einen durchgehenden Hohlraum (2) bildet, der mindestens zwei gegenüberliegende Öffnungen

(3, 11) aufweist und zumindest teilweise mit spongiösem und/oder osteoinduktivem Knochenmaterial (8) gefüllt

[Fortsetzung auf der nächsten Seite]**WO 01/08611 A1**

Implant of bone matter

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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 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 operative 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 known possibility of fusing two vertebrae accordingly consists in the insertion of a suitably shaped cylinder or dowel into a prepared cavity which reaches the two vertebrae to be fused. The matter which is required for this is removed beforehand from the patient for example

from the pelvic ridge. From the thus won autogenic bone matter, that is, bone matter stemming from the same patient, an implant is produced and then inserted into the intervertebral space of the patient between the two vertebrae to be fused (auto-grafting). Alternatively, fusion
5 dowels can be used whose matter is won from allogeneic, cortical or cortico-spongy bone matter of a donor (allografting) or which is made from cortico-spongy, bovine matter (xenografting).

The first-named method has the disadvantage that it produces a high
10 rate of collapsing bones with insufficient bio-mechanical stability and that the secondary operation required to win additional bone matter causes pain to the patient which can be greater than the pain which is to be eliminated by surgery.

15 It is furthermore known to provide the fusion dowel used for the relevant treatment method with an outer thread in order to obtain a better fit between the vertebrae to be fused. During the implantation, a naturally present opening in the dowel, such as a medullary passage, vertically to the direction of insertion of the implant into the vertebrae
20 or a drilled opening in the bone dowel can be used such that this opening is filled with spongy bone that can stem from the patient himself or also from donors. A united, osseous connection of the vertebrae to be fused is achieved with the incorporation due to the fast remodeling behavior of the spongy bone filled in.

25

The known fusion dowels, however, have the disadvantage that the end-plates of the vertebrae to be fused have to be drilled out for the secure

fit of the dowels. The risk is thereby created that the dowel sinks into the vertebra, which can result in a loss of height and thus to fresh damage to the nerve roots.

- 5 The failure is due to the large diameter of the inserted fusion dowels, which usually amounts to 12 to 16 mm, on the one hand, and to the size of the drilling required for the implant, on the other hand, with the side displacement of the spinal cord required for the setting of the drilling and the insertion of the implant triggering substantial tensile
10 forces onto the nerve roots. Furthermore, the introduction of the required drilling, and the enlarging of the space between the spinal processes this requires, is unfavorable for the healing process, since in this respect healthy bone is removed from the vertebrae and a weakening of the vertebrae is induced. A further disadvantage is that
15 the cylindrical fusion bodies do not allow any forward curvature of the spinal column (lordosis).

Another known possibility for the fusion of two vertebrae consists of the insertion of implants with cages made of metal or plastic. These cages
20 have a cavity which can be filled with spongy, autogenic bone matter or also with allogeneic bone matter. The cages usually have a cylindrical shape so that they can be inserted into a drilling prepared in the spinal column. In addition, cages with flat shapes, similar to a briquette, are known which are inserted into the intervertebral space without a
25 drilling having to be prepared in the spinal column for this purpose. With these cages of a flat shape, the space between the vertebrae to be fused which is produced by removing the intervertebral bodies (vertebral

discs) is used for the insertion.

- With the known cages for implants, however, the use of metals or plastics has a disadvantageous effect, since these non-biological materials remain in the body of the patient as foreign bodies and can thus cause rejection reactions of the body against the implant. Due to the fact that an incorporation of these implants into the bone is not possible with such non-biological materials, there is a permanent weakening in the fusion region between the affected vertebrae.
- Furthermore, the rigidity of the metal cages has a disadvantageous effect, since it is higher than that of the vertebra and thus causes a constant mechanical strain of the spinal column which can result in the cage sinking in to the vertebral end-plates.
- The object of the present invention therefore lies in providing an implant for the fusion of bones which eliminates the aforesaid disadvantages. The object of the invention lies in particular in providing a stable implant for the fusion of two vertebrae which restores the correct distance between the vertebrae and the stability of the spinal column, ensures the correct statics of the spinal column, provides the correct course of the nerves in the spinal column and does not thereby cause any body defense reactions.

This object is satisfied by a spinal column implant consisting of a frame of cortical bone matter, which forms at least one through-going cavity, which has at least two oppositely disposed openings and is at least partly filled with spongy and/or osteoinductive bone matter, with

the frame substantially having the shape of a rectangular parallelepiped and having convex edge sections at least at one side, with shaped features being provided at the frame in order to fix the spinal column implant between adjacent vertebrae, and with the frame having at least
5 one reception opening for an application tool.

A particular advantage of the spinal column implant in accordance with the invention is given through the material used, which, as a result of its biological origin and of a special preservation, does not represent a
10 foreign body. Through this the implant, which is produced of bone matter, contributes in its entirety, that is both the frame of cortical bone matter and the filling of spongy bone matter, to the fusion of the vertebral bodies in that it converts into the body's own tissue during the incorporation. Alternatively, osteoinductive bone matter can also be
15 introduced into the cavity of the implant instead of spongy bone matter, said osteoinductive bone matter being able to accelerate bone fusion via its osteoinductive potential.

The fusion effect of the implant in accordance with the invention is
20 aided in particular by the design of the frame which has at least one opening at the sides which are disposed opposite the vertebral bodies to be fused in the applied state. In this way, the spongy bone matter comes into direct contact with the bone surfaces of the vertebral bodies in the cavity of the frame in order to form an osseous connection with
25 these and to thereby connect them or fuse them to one another. Due to the special design of the frame of the spinal column implant in accordance with the invention, its use is possible both in the lumbar

and in the cervical intervertebral space without a drilling having to be prepared in the vertebrae to be fused and without a significant weakening of the healthy vertebra which has to be maintained.

- 5 A further advantage results from the fact that the frame has convex edge sections at least at one side. As a result of this shape, the spinal column implant in accordance with the invention admittedly has a higher traction, but achieves, due to the convexity, a better areal contact with the lightly invaginated, distal end-plate of the vertebra. If
10 this side with the convex edge section confronts a bone surface to be fused, a forward curvature of the spinal column (lordosis) can also be achieved.

In accordance with a further aspect of the present invention, one or
15 more reception openings for a tool can be provided at at least one side of the frame, said tool being formed, for example, as a fork, with whose aid the spinal column implant can be introduced into the intervertebral space between the vertebrae to be fused. The application of the spinal column implant is thereby facilitated.

20

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.

- 25 In accordance with the invention, the material of the frame consists of processed, preserved and sterile bone matter of human origin, a so-called allograft, or of processed, preserved and sterile bone matter of

animal origin, a so-called xenograft. The frame can be made of cortical bone material, for example of the humerus, femur, tibia or another bone either of deceased humans or of animals, in particular of bovine bone matter.

5

In a particularly advantageous embodiment of the spinal column implant of the invention, the substantially rectangular parallelepiped frame has rounded edges. Such a design of the frame facilitates the application of the spinal column implant between the vertebral bodies to
10 be fused in that the roundings avoid a canting of the implant during application.

The frame of the spinal column implant in accordance with the invention preferably has, at least at both sides which are disposed
15 opposite the vertebrae to be fused in the applied state, a peripheral edge region which surrounds the respective opening of the through-going cavity. It is thereby ensured that the cavity is easily accessible for it to be filled with spongy bone matter and that the spongy filling comes into direct and areal contact with the vertebrae to be fused both
20 upwardly (cranially) and downwardly (caudally).

In accordance with a preferred embodiment of the present invention, the frame of the spinal column implant is designed such that the given shape of the vertebral bodies above or below the inserted spinal column
25 implant are taken into account in dependence on the application site, for example for a lumbar or cervical application. This means that the frame of the spinal column implant is shaped such that it is matched to

the given shape of the vertebral bodies by a corresponding curvature of the convex edge sections. In this way, an areal contact is achieved which promotes the incorporation of the implant and improves the stability of the treated spinal column.

5

In a further preferred embodiment of the spinal column implant of the invention, the frame has convex edge sections at two oppositely disposed sides in order to match the implant to the given natural curvature of the vertebral end-plates with which the implant comes into contact. The oppositely disposed convex edge sections can furthermore be provided both in the edge region around the upper opening and in the edge region around the lower opening of the frame. Moreover, the filling of spongy bone matter can also be curved or formed in a convex manner in order to match it to the given shape of the vertebral end-plates.

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It is particularly advantageous for the edge regions of the spinal column implant in accordance with the invention to have shaped features on each of two oppositely disposed sides of the frame which are made in the form of notches, corrugates or crenellations. The application of such shaped features to the contact sides of the frame with the bone have the advantageous effect of improving the seat and anchoring of the spinal column implant at the vertebral bodies.

20

25 The implant is preferably matched in size to the intervertebral space present between adjacent vertebrae after the removal of the intermediate vertebral body. The application of the spinal column

- 10 -

implant in accordance with the invention is carried out after removal of the vertebral disc with a subsequent uncovering of the vertebral bodies disposed below and above it without healthy bone matter having to be damaged in so doing. This provides the advantages that the existing
5 intervertebral space is not enlarged and the bearing structures are maintained.

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

15 In accordance with the invention a suitable allogenic or xenogenic bone matter is processed in such a manner that it is preserved, is capable of storage and can be used in accordance with its purpose. The preservation of the bone matter can for example take place by means of freeze drying. The spongy bone matter is preferably produced
20 through solvent dehydration of native bone matter by means of an organic solvent which is miscible with water, e.g. methanol, ethanol, propanol, isopropanol, acetone, methyl ethyl ketone or mixtures of these solvents. The preservation and sterilization of the bone matter in accordance with this method is also a subject matter of the patent DE
25 29 06 650.

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 matter, so that the processed bone matter has a morphological structure in a histological view which is very similar to
5 that of the natural bone, and thus the desired properties of the bone matter are retained. This method of solvent dehydration also has the advantage that a substantially lower apparative cost and complexity is required in comparison with freeze drying.

10 Furthermore, the spongy bone matter can also be produced through solvent dehydration of bone matter with the subsequent terminal sterilization, in particular through irradiation with gamma rays. Alternatively, the spongy bone matter can be produced through aseptic processing of bone matter without terminal sterilization.

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 in each case a perspective view of an embodiment of a spinal column implant in accordance with the present invention; and

25 Fig. 2 a perspective view of a further embodiment of a spinal column implant in accordance with the present invention.

In the figures the same reference symbols designate in each case the same components of the illustrated embodiments. The illustrated exemplary embodiments are suitable both for the cervical and for the lumbar fusion of vertebral bones.

5

The embodiment of a spinal column implant in accordance with the invention illustrated in Fig. 1 comprises a frame 1, which consists, for example, of cortical, diaphyseal bone matter, e.g. of human origin. This frame forms a through-going cavity 2 which is open to the top and the bottom via respective openings 3 and 11, with the lower opening 11 only being indirectly recognizable in the drawing. The frame 1 substantially has the form of a rectangular parallelepiped and has a peripheral edge region 7 at its upper periphery which comes into contact with the bone surface of the vertebral body (not shown) to be fused in the applied state. In the illustrated case, the edge region 7 fully surrounds the opening 3 of the through-going cavity 2 and has convex edge sections 4 at both oppositely disposed broad sides of the frame 1. The lower opening 11 of the frame 1 is likewise surrounded by a periphery whose edge region has convex edge sections formed in the same way.

20

Generally, the frame 1 of the spinal column implant is matched in size to the given space at which the implant should be inserted. The outer dimensions of such a spinal column implant can, for example, be as follows depending on the application site for a cervical or lumbar application: length 15 to 32 mm, width 8 to 13 mm, height 5 to 13 mm. The inner dimensions of the frame 1 and thus the dimensions of the cavity 2 can, for example, be as follows: length 11 to 19 mm, width 4 to

25

9 mm, height 5 to 13 mm. The convex edge sections 4 at the broad side of the frame 1 are matched, depending on the application site, to the vertebral end-plates not shown in the drawing having a central maximum height of approximately 1.0 to 1.5 mm.

5

Since the frame 1 substantially has the shape of a rectangular parallelepiped, it has edges 9. The edges 9 which extend vertically in the Figures, but also the other edges, can be rounded in order to facilitate the introduction of the implant. The frame 1 furthermore has a
10 reception opening 6 which is preferably arranged centrally in the side surface 10 and into which an application tool can be inserted.

In Fig. 2, the spinal column implant of Fig. 1 is illustrated, with the through-going cavity 2 formed by the frame 1 being filled with
15 spongy bone matter 8. The spongy bone matter 8 can be of human or animal, in particular bovine, origin and preferably has osteoinductive properties in order to promote the incorporation process. The filling of the cavity 2 with spongy and/or osteoinductive bone matter is preferably carried out such that with a smooth, non-
20 structured design of the edge region 7 of the frame 1, the filling 8 projects beyond this over the whole edge region 7, also into the convex edge sections 4, preferably by 0.5 mm. With a structured design of the edge region 7, the filling 8 preferably projects beyond the whole edge region 7 up to the height of the free ends of the shaped features 5. As a
25 result of the bone matter of the edge region 7, which is harder in comparison with the filling material 8, and of the shaped features formed therein, a good contact of the spongiosa 8 of the spinal column

implant to the bone surface of the vertebral bodies to be fused is in this way ensured in the applied state

Fig. 3 shows a further embodiment of the present invention in which
5 shaped features 5 are provided at the frame 1 of the spinal column
implant to fix the spinal column implant between adjacent vertebrae.
These shaped features 5 are preferably provided in the edge sections 4
of the edge regions 7 which surround the openings 3 and 11 and which
are in contact with the bone surface of a vertebral body to be fused in
10 the applied state of the implant. A particularly good fixing of the spinal
column implant can be achieved if the shaped features 5 are distributed
over the whole peripheral edge region 7 – both around the upper
opening 3 and around the lower opening 11 of the frame 1 of
substantially rectangular parallelepiped shape. Furthermore, all contact
15 areas of the frame 1 coming into contact with the vertebral body end-
plates can have a structured design.

The shaped features can, for example, be made in the form of notches,
corrugations or crenellations. The shaped features 5 are preferably
20 provided, as in the embodiment illustrated in Fig. 3, at each side of the
edge region 7 of the frame 1 and given a crenellated design. For this
purpose, three cut-outs each with interposed crenellations are formed
in the center of each side of the edge region 7 and are oriented such
that they mesh with one another in the adjacent bone surface when the
25 implant is inserted between the vertebrae to be fused for its intended
purpose.

In the embodiment illustrated in Fig. 3, it can be recognized that the reception opening 6 can be designed as a drilling in the frame 1 having a thread of preferably 3 mm depth into which an application tool provided with a suitable thread can be screwed. As in the illustrated
5 embodiment, the reception opening 6 is preferably arranged in the center of the side surface 10 of the frame 1. The application of the spinal column implant in accordance with the invention can be additionally facilitated if reception openings 6 for an application tool are provided at opposite sides 10 of the frame 1 to be able to grasp the
10 implant, for example, with plier-like tools.

Reference numeral list

- | | | |
|----|----|-------------------------------------|
| | 1 | frame |
| 5 | 2 | cavity |
| | 3 | upper opening of the cavity |
| | 4 | convex edge section of the frame |
| | 5 | shaped features |
| | 6 | reception opening |
| 10 | 7 | peripheral edge region of the frame |
| | 8 | filling |
| | 9 | edges of the frame |
| | 10 | side surface of the frame |
| | 11 | lower opening of the cavity |

CLAIMS:

1. Spinal column implant consisting of a frame of cortical bone matter, which forms at least one through-going cavity which has at least two oppositely disposed openings and is at least partly filled with a filling of bone matter, with the frame substantially having the shape of a rectangular parallelepiped and having convex edge sections at least at one side, with shaped features being provided at the frame in order to fix the spinal column implant between adjacent vertebrae, and with the frame having at least one reception opening for an application tool.
2. Spinal column implant in accordance with claim 1, characterized in that the material of the frame consists of preserved and sterile bone matter of human or animal origin.
3. Spinal column implant in accordance with claims 1 or 2, characterized in that the frame, which substantially has the shape of a rectangular parallelepiped, has rounded off edges.
4. Spinal column implant in accordance with any one of claims 1 to 3, characterized in that the frame has peripheral edge regions which in each case surround the openings of the through-going cavity.
5. Spinal column implant in accordance with any one of claims 1 to 4, characterized in that the frame has in each case convex edge sections at two oppositely disposed sides.
6. Spinal column implant in accordance with any one of claims 1 to 5, characterized in that the filling projects at least partly beyond the edge region of the frame.

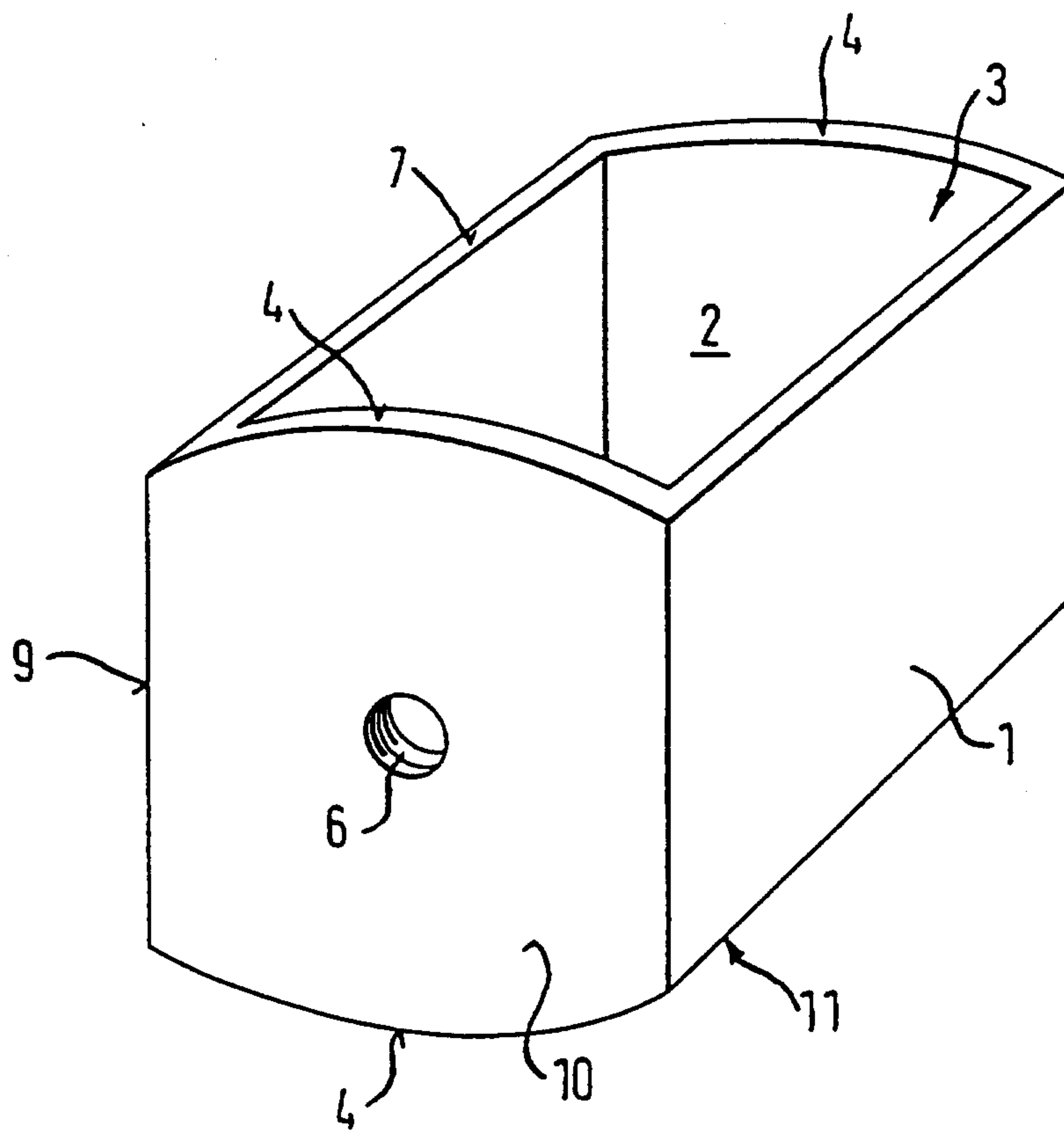
7. Spinal column implant in accordance with any one of claims 1 to 6, characterized in that the edge sections have shaped features on two oppositely disposed sides of the frame which are executed in the form of notches, corrugations or crenellations.
8. Spinal column implant in accordance with claim 7, characterized in that the filling projects at least partly beyond the edge region.
9. Spinal column implant in accordance with any one of claims 1 to 8, characterized in that the implant is matched in its size to the intervertebral space between adjacent vertebrae which is present after the removal of the intervertebral body.
10. Spinal column implant in accordance with any one of claims 1 to 9, characterized in that the reception opening is executed on one or more sides of the frame as a drilling with a thread having a predetermined depth.
11. Spinal column implant in accordance with any one of claims 1 to 10, characterized in that the filling of bone matter is spongy and produced through solvent dehydration of bone matter by means of an organic solvent which is miscible with water.
12. Spinal column implant in accordance with any one of claims 1 to 11, characterized in that the filling of bone matter is produced through solvent dehydration of bone matter with subsequent terminal sterilization.
13. Spinal column implant in accordance with any one of claims 1 to 12, characterized in that the filling of bone matter is spongy and produced through aseptic processing of bone matter without terminal sterilization.

- 19 -

14. The spinal column implant recited in claim 1, wherein the filling of bone matter is spongy.
15. The spinal column implant recited in claim 1, or claim 14, wherein the filling of bone matter is osteoinductive.
16. The spinal column implant recited in claim 2, wherein the cortical bone matter consists of preserved and sterile bovine bone matter.
17. The spinal column implant recited in claim 12, wherein the filling of bone matter is produced through irradiation with gamma rays.
18. The spinal column implant recited in claim 6, wherein the filling projects beyond the edge region of the frame by 0.5 mm.
19. The spinal column implant recited in claim 8, wherein the filling projects beyond the edge region of the frame up to the level of the free ends of the shaped features.
20. The spinal column implant recited in claim 10, wherein the depth is 3 mm.
21. The spinal column implant recited in claim 11, wherein the organic solvent is selected from a group consisting of:
methanol, ethanol, propanol, isopropanol acetone, methyl ethyl ketone or mixtures of these solvents.

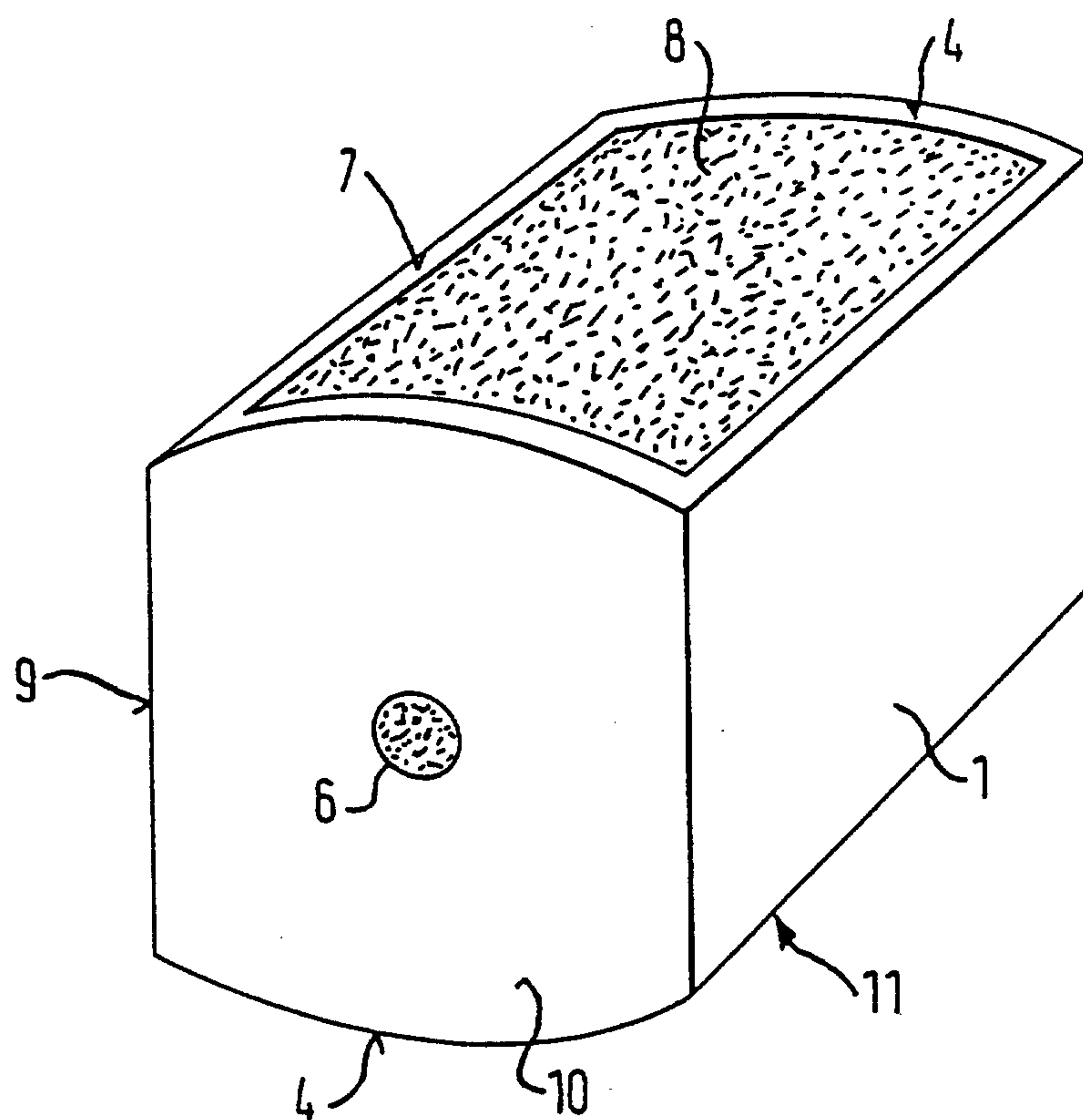
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FIG. 1



2/3

FIG. 2



3 / 3

FIG. 3

