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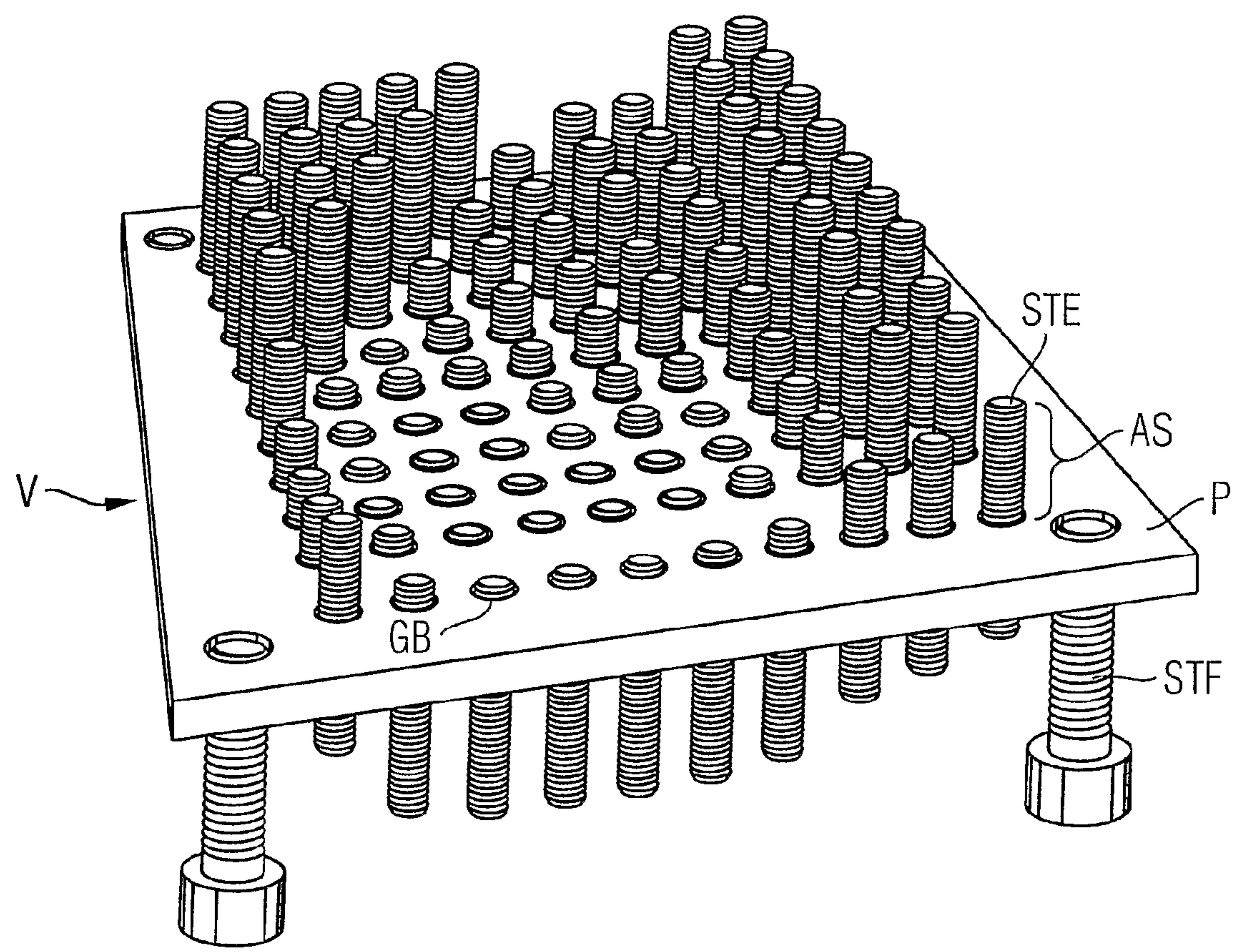
(54) Titre : PROCEDE ET DISPOSITIF DE FABRICATION D'UN IMPLANT PLAT PREFORME EN CORRESPONDANCE A UNE FORME ANATOMIQUE DE CONSIGNE POUR LE CORPS HUMAIN OU LE CORPS D'UN ANIMAL

(54) Title: METHOD AND DEVICE FOR PRODUCING A FLAT IMPLANT FOR A HUMAN OR ANIMAL BODY, WHICH FLAT IMPLANT IS PREFORMED CORRESPONDING TO A DESIRED ANATOMICAL SHAPE



(57) Abrégé/Abstract:
The present invention relates to a method and a device for producing a planar implant (I) for a human or animal body, which planar implant (I) is preformed corresponding to a desired anatomical shape. The method comprises the following steps: making available

(57) Abrégé(suite)/Abstract(continued):

a blank of the planar implant; making available a preforming device (V) that comprises a plurality of discrete adjustable support elements (STE) for adjusting an associated plurality of support points in accordance with the desired anatomical shape; defining the desired anatomical shape and determining corresponding settings for the support elements; adjusting the support elements in accordance with the settings determined for the desired anatomical shape; and producing the preformed implant by bending the blank onto the adjusted support elements.

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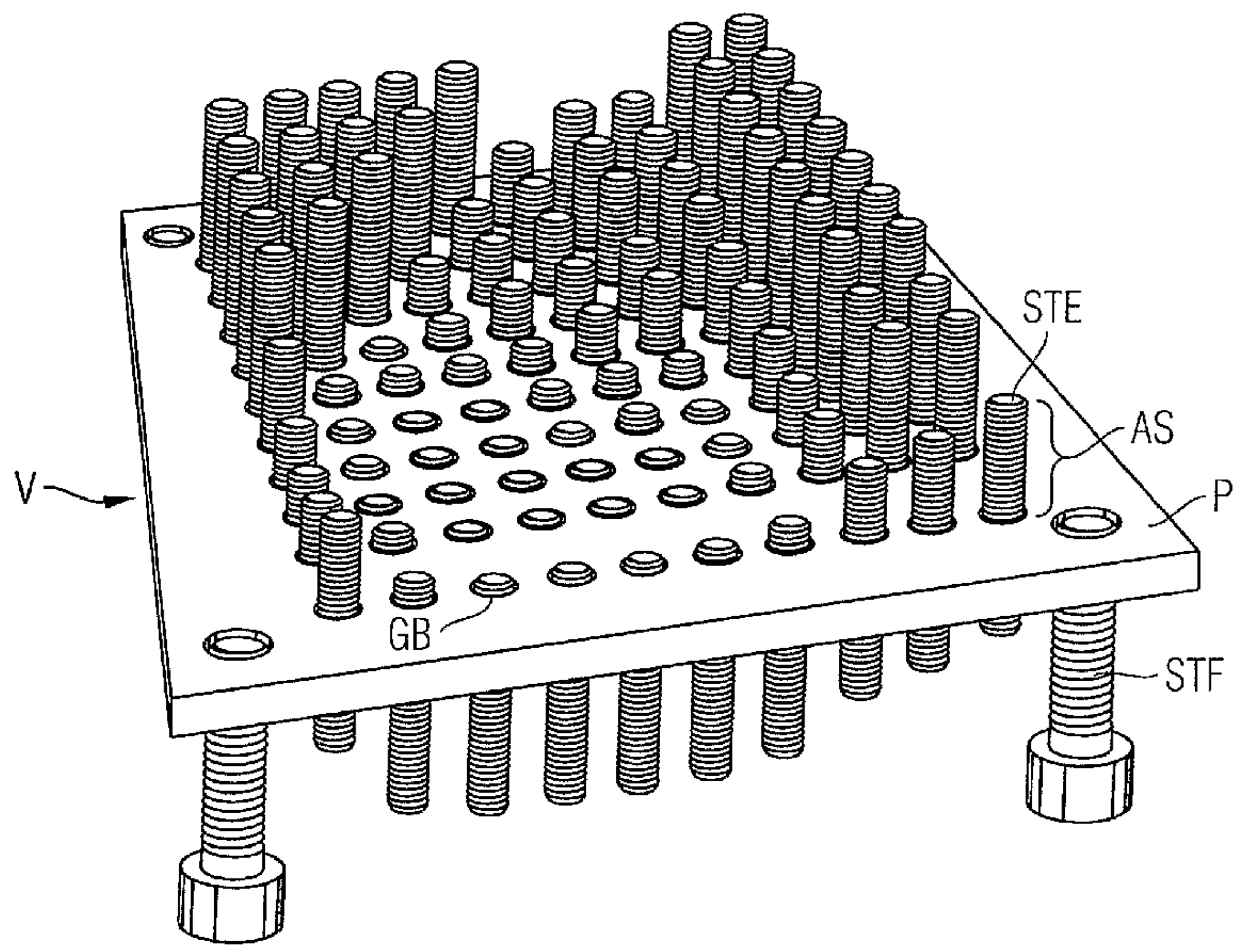
[Fortsetzung auf der nächsten Seite]

(54) **Title:** METHOD AND DEVICE FOR PRODUCING A PLANAR IMPLANT FOR A HUMAN OR ANIMAL BODY, WHICH PLANAR IMPLANT IS PREFORMED CORRESPONDING TO A DESIRED ANATOMICAL SHAPE

(54) **Bezeichnung:** VERFAHREN UND VORRICHTUNG ZUR HERSTELLUNG EINES ENTSPRECHEND EINER ANATOMISCHEN SOLLFORM VORGEFORMTEN FLÄCHIGEN IMPLANTATS FÜR EINEN MENSCHLICHEN ODER TIERISCHEN KÖRPER



(57) **Abstract:** The present invention relates to a method and a device for producing a planar implant (I) for a human or animal body, which planar implant (I) is preformed corresponding to a desired anatomical shape. The method comprises the following steps: making available a blank of the planar implant; making available a preforming device (V) that comprises a plurality of discrete adjustable support elements (STE) for adjusting an associated plurality of support points in accordance with the desired anatomical shape; defining the desired anatomical shape and determining corresponding settings for the support elements; adjusting the support elements in accordance with the settings determined for the desired anatomical shape; and producing the preformed implant by bending the blank onto the adjusted support elements.

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(57) Zusammenfassung: Die vorliegenden Erfindung schafft ein Verfahren und eine Vorrichtung zur Herstellung eines entsprechend einer anatomischen Sollform vorgeformten flächigen Implantats (I) für einen menschlichen oder tierischen Körper. Das Verfahren umfasst folgenden Schritte: Bereitstellen eines Rohlings des flächigen Implantats, Bereitstellen einer Vorformeinrichtung (V) , wekche eine Mehrzahl diskreter einstellbarer Stützeinrichtung (STE) zum Einstellen einer zugehörigen Mehrzahl von Stützpunkten entsprechend der anatomischen Sollform aufweist; Vergeben der anatomischen Sollform und Ermitteln entsprechender Einstellungen für die Stützeinrichtungen; Einstellen der Stützeinrichtungen entsprechend der für die anatomischen Sollform ermittelten Einstellungen; und Bilden des vorgeformten Implantats durch Anbiegen des Rohlings an die eingestellten Stützeinrichtungen .

METHOD AND DEVICE FOR PRODUCING A FLAT IMPLANT FOR A HUMAN OR ANIMAL BODY, WHICH FLAT IMPLANT IS PREFORMED CORRESPONDING TO A DESIRED ANATOMICAL SHAPE

Prior Art

The present invention relates to a method and a device for producing a flat implant for a human or animal body, which flat implant corresponds to a desired anatomical shape.

Although, in principle, they can be used for any pre-shaped, flat implant for a human or animal body, the devices of the present invention and the problems, on which they are based, are explained in relation to preformed osteosyntheses for the orbits.

Mesh or plates of titanium or other materials, for instance, are used for the surgical care of fractures in the orbit. These are available in different prototypes and thicknesses and usually are formed planar when sold.

During the operation, therefore, the surgeon must cut these meshes to size and fold and bend them, in order to imitate the desired anatomical structures. In so doing, it is not always possible to reach, clearly define and reconstruct the lower anatomical structures of the orbital apex. Moreover, the result is highly dependent on the experience of the surgeon.

If the defect in the lower part of the orbit is not bridged, the consequences are double vision (diplopia), recession of the eyeballs (enophthalmus) and mobility disorders. In the worst case, excessive manipulations at the eye or at the visual nerve during the operation can lead to blindness (amaurosis), so that meshes should not be fitted too frequently into the orbit.

The problems, on which the present invention is based, therefore generally consist of providing a method and a device for producing a flat implant, preformed to correspond to a desired anatomical shape, for a human or animal body. The implant is to have an improved replication of the structure and to represent a simplification for the surgeon.

Advantages of the Invention

The inventive method for producing a flat implant, preformed to correspond to a desired anatomical shape, for a human or animal body with the distinguishing features of claim 1, and the corresponding device of claim 12, and the corresponding method of claims 20 and 24, have the advantage over the known solutions that they make an anatomically preformed implant possible, which replaces or reconstructs the anatomical structure ideally.

With the present invention, it is achieved that the surgical reconstruction of body tissue takes place anatomically more individually, more accurately, less dangerously for the patient, time wise more efficiently, in a more standardized fashion and independently of the experience of the surgeon.

The idea, on which the present invention is based, consists therein that a preforming device is made available, which has a plurality of discrete, adjustable supporting devices for adjusting an associated plurality of associated supporting points corresponding to the desired anatomical shape and at which preforming device the pre-formed implant is formed by bending the blank into contact with the adjusted supporting devices.

For example, individual or clustered anatomical structures are reproduced by means of CT data records for the production of the preformed implant over the correspondingly adjusted supporting point surface of the preforming device.

Advantageous further developments and improvements of the respective subject matter of the invention are found in the dependent claims.

According to a preferred further development, the preform has a two-dimensional mesh structure, which is transformed by bending into a three-dimensional mesh structure.

According to a further preferred development, the adjustments for the supporting devices are determined by the following steps:

imaging a region of the body corresponding to the desired anatomical shape in a supporting point mesh;

determining the distances between a reference surface corresponding to a specified reference setting of the supporting points of the preforming device and the supporting point mesh at the supporting points in the reference surface for a specified orientation of the supporting point mesh; and

setting the distances determined at the supporting devices.

According to a further, preferred development, the desired anatomical shape corresponding region of the body is imaged in a supporting point mesh by the following steps:

imaging a region of the body corresponding to a desired anatomical shape corresponding to a mathematical image in an image supporting point mesh and transforming the image supporting point mesh into the supporting point mesh corresponding to the mathematical image.

According to a further preferred development, the imaging is carried out by means of a computer tomography device.

According to a further preferred development, the preformed implant is a preformed osteosynthesis for the orbit.

According to a further preferred development, the supporting devices have cylindrical pin devices, the height of which can be adjusted and which are mounted at a planar plate device.

According to a further preferred development, the supporting devices are adjusted by an automatic adjusting device.

According to a further preferred development, before the bending procedure, a thin deformable sheet device or an integrally molded casing device is mounted on the adjusted supporting devices of the preforming device.

According to a further preferred development, the desired anatomical shape is specified and the corresponding adjustments for the supporting devices are determined by the following steps:

standard, desired shapes and corresponding adjustment data is entered into a database;

a standard, desired shape is selected from the database by means of one or more of the following diameters: sex, age, race, height, side of body; and the corresponding adjustments for the supporting devices are determined by means of the adjustment data record belonging to the standard desired shapes selected.

According to a further preferred development, the implant consists of titanium. Other materials or the combination of titanium with different coatings and coverings is possible. The lining of the mesh with other material compositions, such as plastic or other bio-absorbable materials is also conceivable.

Drawings

Examples of the invention are shown in the drawings and explained in greater detail in the description that follows. In the drawings,

Figures 1a - d show layers of an orbit, recorded by computer tomography, to illustrate an embodiment of the inventive method;

Figures 2a - c different representations of the supporting point mesh, determined for the embodiment of the inventive method for the desired anatomical shape of the implant;

Figure 3 shows a set preforming device for the embodiment of the inventive method;

shows a preformed implant for the embodiment of the inventive method and

Figure 5 shows a set preforming device for a further embodiment of the inventive method

Description of the Examples

In the Figures, identical reference numbers refer to elements having the same function.

Figures 1a-d show layers of an orbit, recorded by computer tomography, for explaining an embodiment of the inventive method.

In a first step of this embodiment, a desired anatomical shape for a flat implant, which is to be preformed in the form of an osteosynthesis for the orbit, is to be established.

For this purpose, computer tomography recordings of different planes of the orbit are recorded in different views, as shown in Figures 1 a-d. As will be explained later, a supporting point mesh, with the help of which the settings for a preforming device for preforming the implant can be determined, will be formed from these recordings.

DICOM data, which is visualized three-dimensionally with the help of appropriate software, is used for the present embodiment. The software, for example, permits the following views:

- a three-dimensional view of the whole skull
- coronal view (sections from front)
- sagittal view (sections from the side).
- axial view (sections in the axis)

In order to determine the bottom structure of the orbit for the present example, the healthy side of the skull is measured by computer tomography and subsequently reflected at the middle of the skull. Accurately defined points, which have a grid for which the distances between the measurement points is defined accurately, are required for the later formation of the supporting point mesh. For this purpose, the coronal and sagittal views are used in order to mark layers at a defined distance. The marking can be made by means of Houndsfield units, which reproduced the different gray values of the computer tomogram automatically by gray value definition or manually by means of a brush tool.

When layers are marked in the coronal view, the area of the front edge of the orbit of the orbit is available as the starting layer. For example, each layer has a thickness of 0.5 mm. A resolution can be specified by selecting or skipping certain layers. In that case of the example, the highest resolution is an interval of 0.5 mm between layers and the least resolution can be defined individually by a multiple of the interval of 0.5 mm between layers.

When layers are marked in the sagittal view, the region of the side edge of the orbit is available as starting layer. Preferably, the same interval between layers is used as for the coronal view.

The markings M1, M2 in Figures 1a and 1c show the coronal as well as the sagittal marking of the bottom of the orbit as it extends in the selected layers. The layers, marked correspondingly M1' and M2', are shown in Figures 1b and 1d at a viewing angle, which is rotated exactly by 90°. By putting together the markings of Figures 1a and 1b, a three-dimensional supporting point mesh is obtained, as is explained in connection with Figures 2a-c.

Figures 2a-c show different representations of the supporting point mesh, as determined for the embodiment of the inventive method, for the desired anatomical shape of the implant.

As shown in Figure 2a, the aforementioned mirroring results in a supporting point mesh SG by viewing the coronal and sagittal layers in the three-dimensional mode. This supporting point mesh SG reflects the three-dimensional mesh profile of the desired anatomical shape of the implant, which, in this case, is the height profile of the bottom of the orbit.

Further, with regard to Figure 2b, the ascertained supporting point mesh SG is then brought spatially into a specified orientation to a reference surface R, which corresponds to a specified reference setting of the supporting points of the preforming device. In the present case, the reference surface R is a rectangular, planar surface.

Further, with regard to Figure 2c, the distances between the reference surface R and B. supporting point mesh at the supporting points in the reference surface is then determined for a specified orientation of the supporting point mesh.

For this purpose, perpendicular lines are simply drawn from the reference surface R to the corresponding points of the supporting point mesh, that is, there, where the supporting devices of the preforming device, which will still be explained in the following, are to rest later on.

The distances AS determined (or their relative relationships) are then identical with the settings of the supporting devices STE of the preforming device V, which is illustrated in Figure 3.

For the present example, the preforming device V consists of a rectangular plate arrangement P, which has a rectangular matrix of threaded boreholes GB, through which the screwed-in cylinders STE, the heights of which can be adjusted, are passed. The plate device P rests on supporting feet STF, which ensure that the bottom is free for the screwed-in cylinders STE, which have been screwed in.

Once all of the distance values AS, determined according to Figure 2c, have been converted into screw heights of the screwed-in cylinders STE, the adjustment of the preforming device V is concluded and a supporting point model of the desired anatomical structure of the implant is available.

After the adjustment of the preforming device V, the bending of the implant I takes place. To improve the configuration, a thin deformable film device or an integrally molded casing device, for example, of aluminum foil or of a rubber film or a plastic casing, may be placed on the adjusted supporting devices in the form of screwed-in cylinders STE of the preforming device V. As a result, the transitions between the supporting points are fitted better and do not have any undesirable bulges due to the contacting pressure.

After or before the implant I is bent, the edge of the implant I can be cut to size, in order to ensure that it fits exactly into the anatomical structure, which is to be operated on.

The alignment of the implant I during surgery takes place by means of the anatomical edge boundary, especially, in the present case, the front and lateral edge of the orbit, which also can be found once again easily intraoperatively.

Figure 5 shows a further embodiment of the preforming device V', which enables the supporting devices S1-S10, which here are thin cylindrical pins without a thread, to be adjusted automatically.

P1 and P2 in the present example refer to an upper plate device and a lower plate device. Height adjustment devices H1 - H10, which set the distances AS of the supporting devices S1 - S10 from the upper plate device P1, are provided between the upper plate device P1 and the lower plate device P2. In the present case, the height adjusting devices H1-H10 are electromagnetic solenoids. However, they may also be pneumatic or other mechanical height adjusting devices.

Although the present invention was described above by means of a preferred example, it is not limited to this and can be modified in various ways.

The present invention is not limited to the particular configuration of the preforming device. In particular, it is not absolutely necessary that the supporting devices all start out from a planar reference surface; instead, they may also start out from a three-dimensional reference surface if, for example, the preforming device is to be used for a highly curved, desired anatomical shape.

It is also not absolutely necessary to fix the desirable anatomic shape for each operation exactly by means of computer tomography or a similar method. Instead, once a statistically significant number of data records for the settings have been obtained, these can be stored in a database and standardized templates of the desired anatomical structure can be created. Sex, age, race, height, side of body, etc. can be provided as selection parameters.

It should also be mentioned that implants may consist of different materials, such as titanium or titanium with a coating of an absorbable, soft material, such as PDS film. In principle in any case, the present invention is not limited to the special material of the implant, as long as the material can be shaped by a bending process.

Finally, it should be mentioned that the setting of the supporting devices for the preforming device do not have to be mechanically reversible or changeable and instead, in the case of a large scale industrial production of large numbers of the same standard implant, may also be irreversible. In this case, the supporting devices can be adjusted, for example, by modeling a plastic or the like.

This is particularly the case if, before the bending, a permanently integrally molded casing device is mounted on the set supporting devices of the preforming device.

Data records, made available, can also be used with the steps for configuring the preforming device for producing a flat implant, preformed to correspond to a desired anatomical shape, for a human or animal body for the purpose of shaping continuously, for example, by milling or casting.

METHOD AND DEVICE FOR PRODUCING A FLAT IMPLANT FOR A HUMAN OR ANIMAL BODY, WHICH FLAT IMPLANT IS PREFORMED CORRESPONDING TO A DESIRED ANATOMICAL SHAPE

Claims

1. A method for producing a flat implant for a human or animal body, which is preformed corresponding to a desired anatomical shape, with the steps of:

making available a blank of the flat implant;

making available a preforming device, which has a plurality of discrete, adjustable supporting devices for adjusting an associated plurality of supporting points corresponding to the desired anatomical shape;

specifying the desired anatomical shape and determining corresponding settings for the supporting devices;

setting the supporting devices to correspond to the settings determined for the desired anatomical shape; and

forming the preformed implant by bending the blank against the set supporting devices.

2. The method of claim 1, characterized in that the blank has a two-dimensional mesh structure, which is converted by bending into a three-dimensional mesh structure.

3. The method of claims 1 or 2, characterized in that the settings for the supporting devices are determined by the following steps:

imaging a region of the body corresponding to the desired anatomical shape in a supporting point mesh;

determining the distances between a reference surface corresponding to a specified reference setting of the supporting points of the preforming device and the supporting mesh at the supporting points in the reference surface for a specified orientation of the supporting point mesh; and

setting the distances determined at the supporting devices.

4. The method of claim 1, 2 or 3, characterized in that the imaging of the region of the body into a supporting point mesh, which corresponds to the desired anatomical shape, takes place in the following steps:

imaging a region of the body corresponding to a mathematical image in an image supporting point mesh and

transforming the image supporting point mesh into the supporting point mesh corresponding to the mathematical image.

5. The method of claims 3 or 4, characterized in that the imaging is carried out by means of a computer tomography device.

6. The method of one of the preceding claims, characterized in that the preformed implant is a preformed osteosynthesis for the orbit.

7. The method of one of the preceding claims, characterized in that the supporting devices have cylindrical pin devices, the height of which can be adjusted and which are mounted in a planar plate device.

8. The method of one of the preceding claims, characterized in that the setting of the supporting devices is accomplished by and automatic setting device.

9. The method of one of the preceding claims, characterized in that, before the bending procedure, a thin, deformable film device or an integrally molded casing device is mounted on the set supporting devices of the preforming device.

10. The method of one of the preceding claims, characterized in that the desired anatomical shape is specified and the corresponding settings for the supporting devices are determined by the following steps:

standard, desired shapes and corresponding adjustment data records are entered into a database;

standard, desirable shape is selected from the database by means of one or more of the following parameters: sex, age, race, height, side of body; and

the corresponding adjustments for the supporting devices are determined by means of the adjustment data record belonging to the desired standard shapes selected.

11. The method of one of the preceding claims, characterized in that the implant consists of titanium.

12. A device for producing a flat implant for a human or animal body, which is preformed corresponding to a desired anatomical shape, with:

a preforming device, which has a plurality of discrete, adjustable supporting devices for adjusting an associated plurality of supporting points corresponding to the desired anatomical shape;

and the set supporting devices enable a preformed implant to be formed by bending a blank against the set supporting devices.

13. The device of claim 12, characterized in that the supporting devices have cylindrical pin devices, which are mounted adjustability at a planar plate device.

14. The device of claim 13, characterized in that the pin devices are screw-in cylinders, the height of which can be adjusted and which are guided by associated threaded boreholes of the plate device.

15. The device of one of the claims 12 to 14, characterized by a setting device for automatically setting the supporting devices by means of settings supplied.

16. The device of one of the claims 12 to 15, characterized by a setting-determining device.

for imaging a region of the body, corresponding to a desired anatomical shape, in a supporting point mesh and

for determining the distances between a reference surface corresponding to a specified reference setting of the supporting points of the preforming device and the supporting point mesh at the supporting points in the reference surface for a specified orientation of the supporting point mesh as the settings.

17. The device of claim 16, characterized in that the setting-determining device for imaging the region of the body, corresponding to the desired anatomical shape, in a supporting point mesh, automatically carries out the following steps:

imaging a region of the body, corresponding to the desired anatomical shape, in accordance with a mathematical image, in a supporting point mesh image and

transforming the supporting point mesh image into the supporting point mesh in accordance with the mathematical image.

18. The device of claim 16 or 17, characterized in that the setting-determining device carries out the imaging by means of a computer tomography device.

19. The device of one of the preceding claims, characterized in that the setting-determining device for imaging the region of the body, corresponding to the desired anatomical shape, in a supporting point mesh, carries out the following steps automatically:

specifying desired standard shapes and corresponding adjustment data records in a database;

selecting a desired standard shape from the data base by means of one or more of the following parameters, received by an input device: sex, age, race, height, side of body; and

determining the corresponding adjustments for the supporting devices by means of the adjustment data record belonging to the desired standard shapes selected.

20. A method for making available a data record for configuring a preforming device for producing a flat implant, preformed in accordance with a desired anatomical shape, for a human or animal body with the steps of:

imaging a region of the body, corresponding to the desired anatomical shape, in a supporting point mesh;

determining the distances between a specified reference surface of the preforming device and the supporting point mesh at the supporting points in the reference surface for a given orientation of the supporting point mesh.

21. The method of claim 20, characterized in that the imaging of the region of the body, corresponding to the desired anatomical shape, in a supporting point mesh is accomplished by the following steps:

imaging a region of the body, corresponding to the desired anatomical shape according to a mathematical image, in a supporting point mesh image and

transforming the supporting point mesh copy into the supporting point mesh in accordance with the mathematical image.

22. The method of claims 20 or 21, characterized in that the imaging is carried out by means of a computer tomography device.

23. The method of claim 20, characterized in that the imaging of the region of the body, corresponding to the desired anatomical shape, in a supporting point mesh, is accomplished by the following steps:

specifying desired standard shapes and corresponding setting data records in a database;

selecting a desired standard shape from the database by means of one or more of the following parameters: sex, age, race, height, side of the body; and establishing the supporting point mesh by the setting data record belonging to the selected desired standard shapes.

24. Method for configuring a preformed device for producing a flat implant for a human or animal body, corresponding to a desired anatomical shape, with a data record according to one of the claims 20 to 23, a surface topology for the preforming device being formed from the data record and, correspondingly, the preforming device being produced preferably by milling or casting.

25. The method of claim 24, characterized in that the preforming device has a plurality of discrete adjustable supporting devices for adjusting an associated plurality of supporting points corresponding to the desired anatomical shape, the following steps being carried out:

determining corresponding settings for the supporting devices from the data record and

setting the supporting devices in accordance with the settings determined for the desired anatomical shape.

26. The method of claim 25, characterized in that a thin, deformable film device or an integrally molded casing device is mounted on the set supporting devices of the preforming device.

FIG 1A

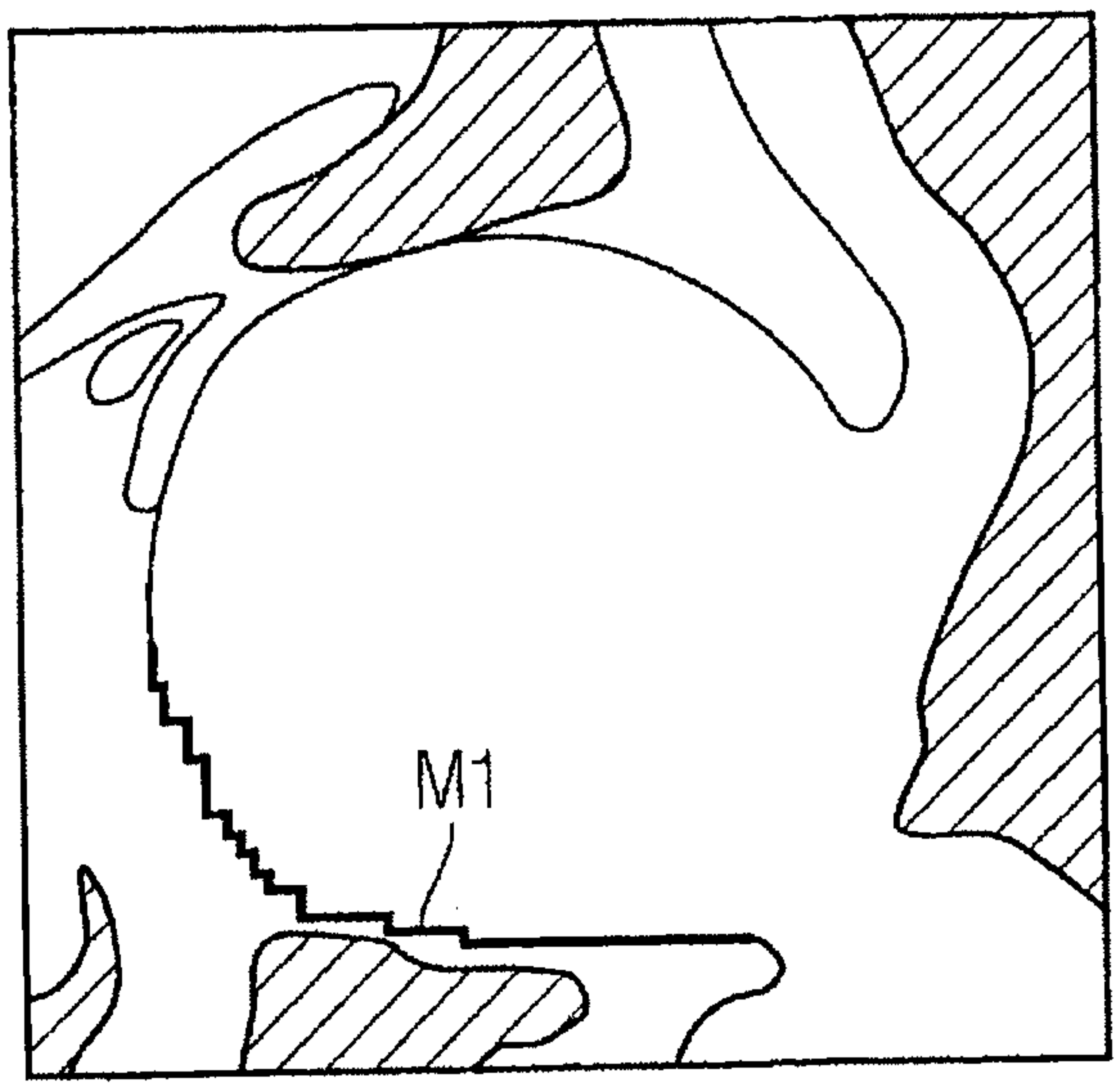


FIG 1B

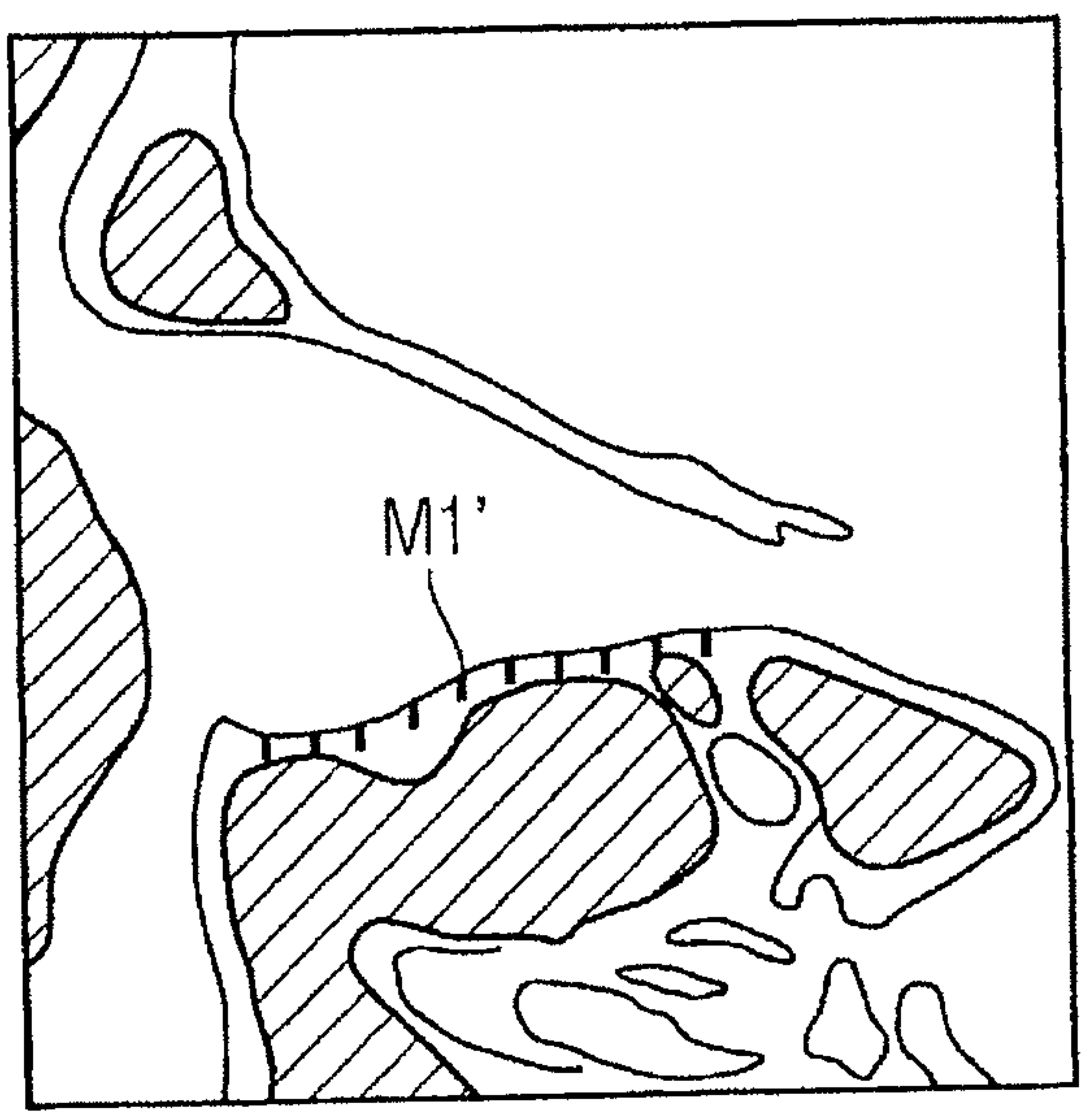


FIG 1C

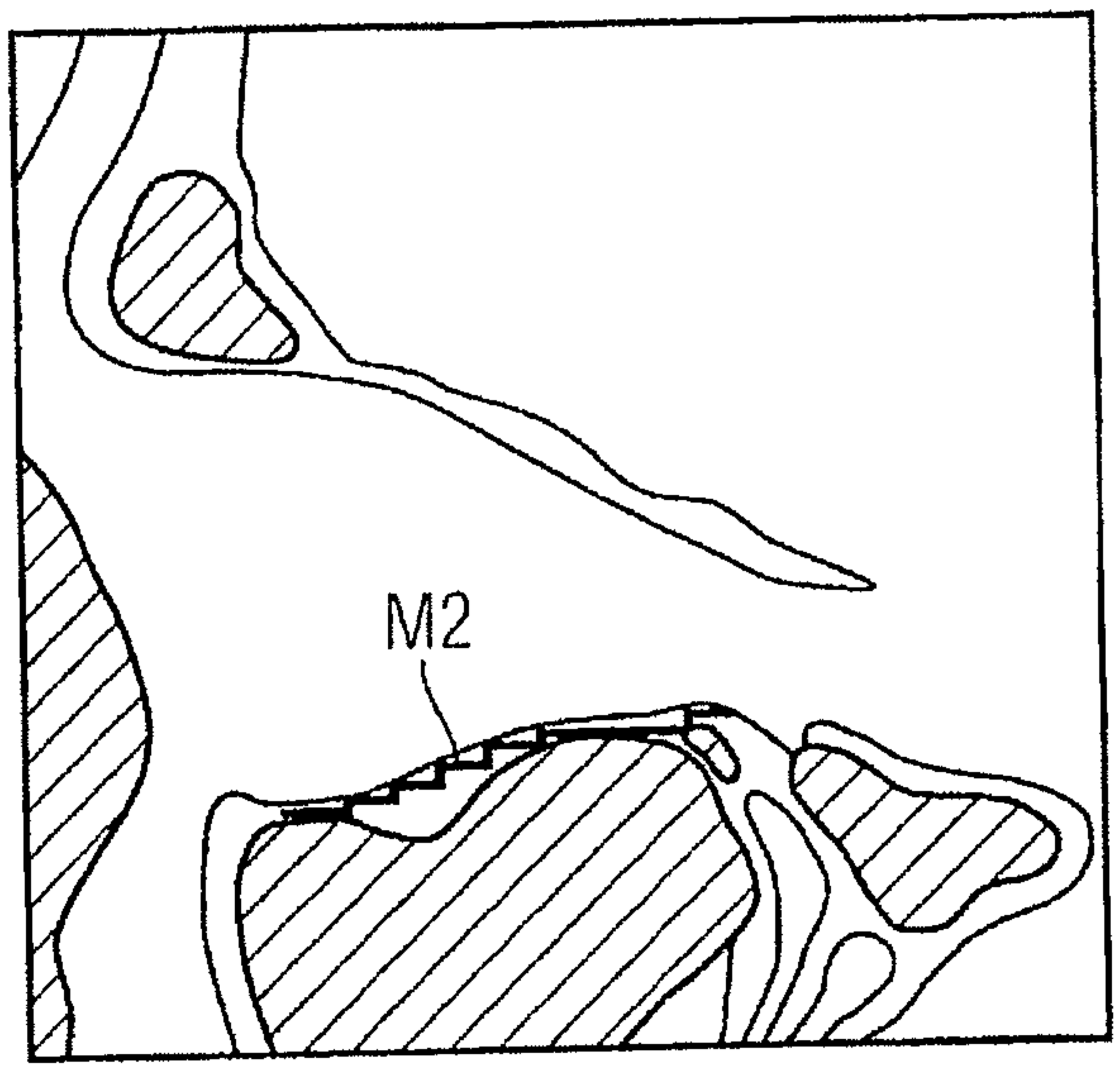


FIG 1D

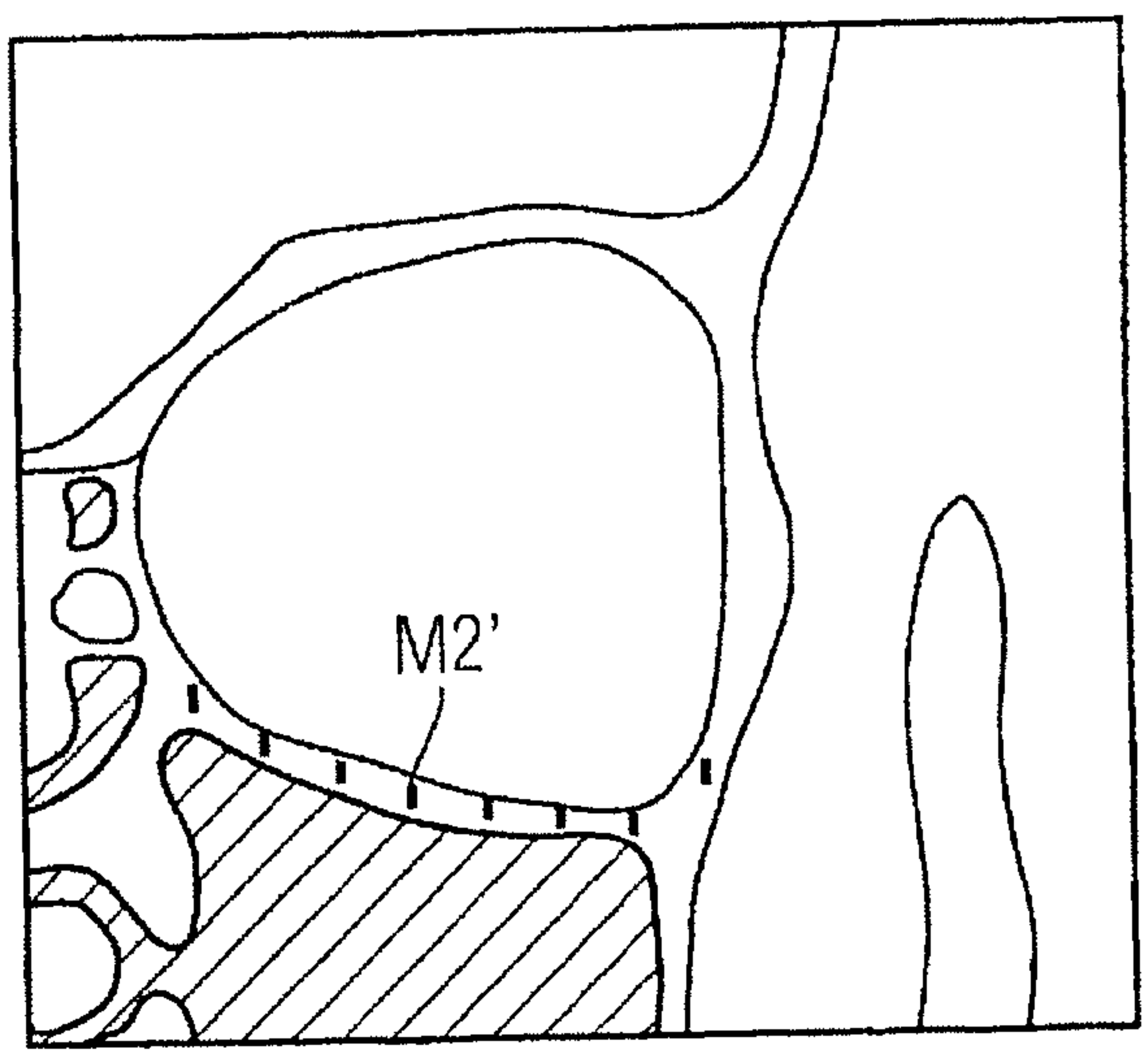


FIG 2A

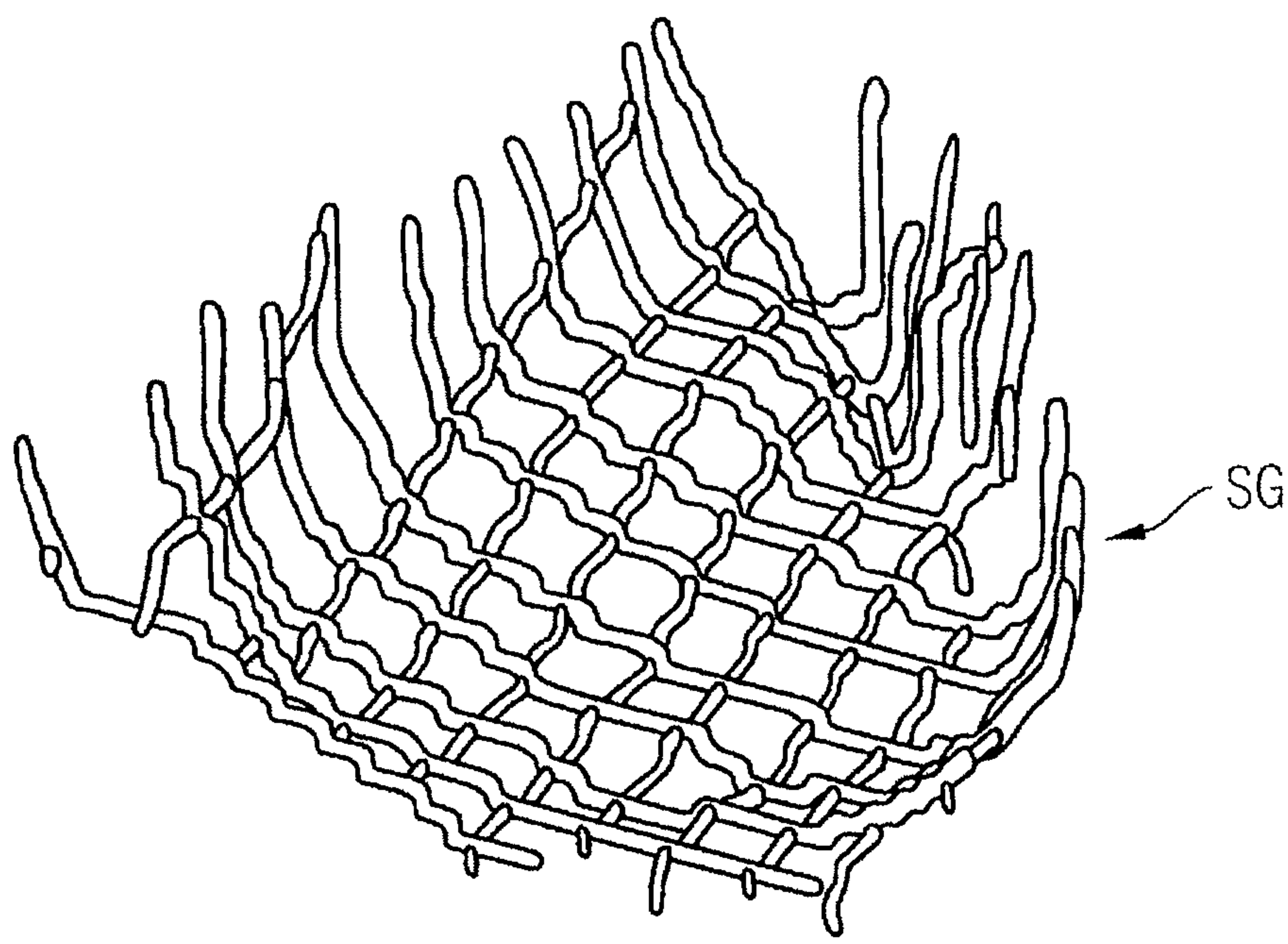


FIG 2B

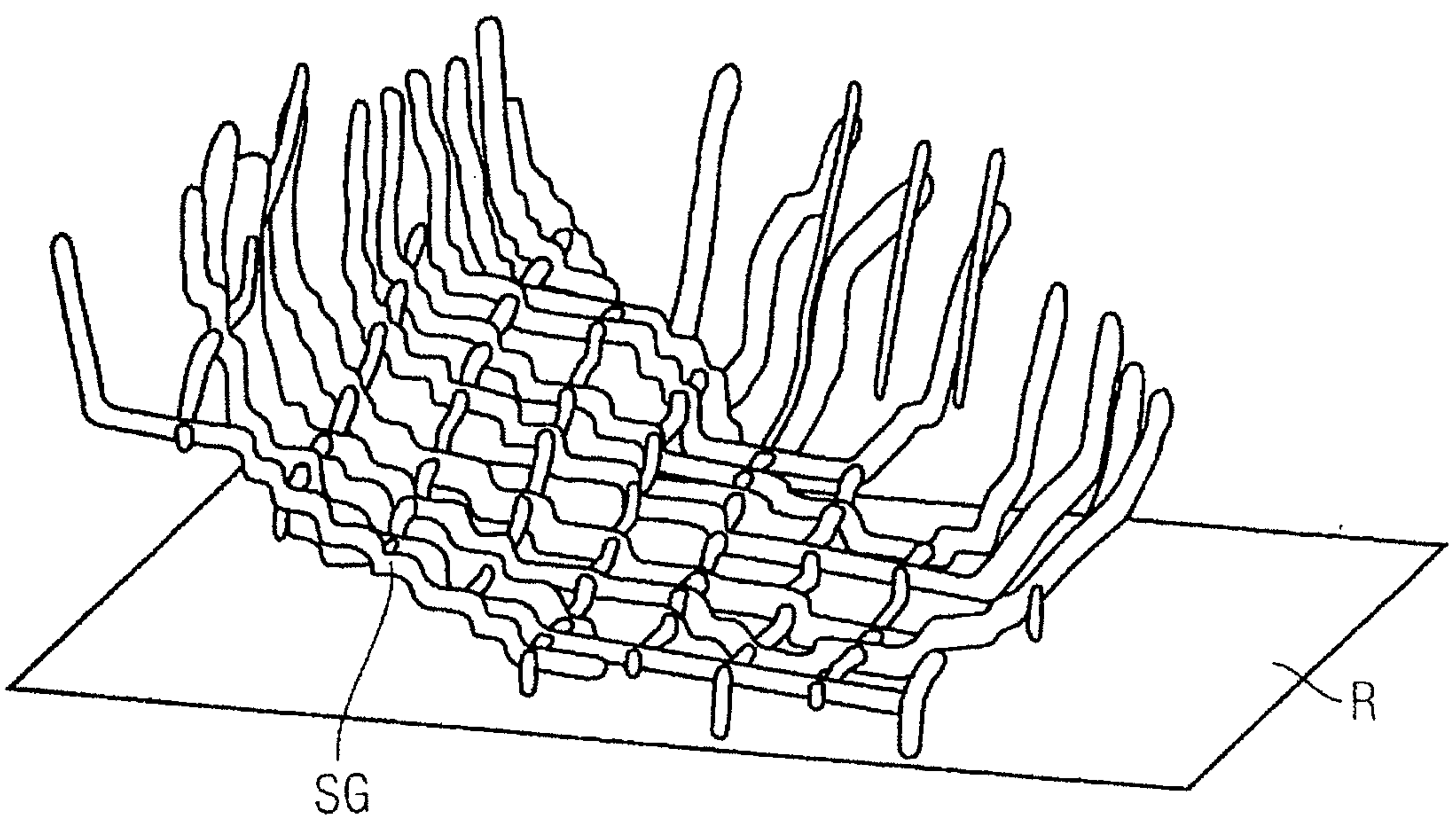


FIG 2C

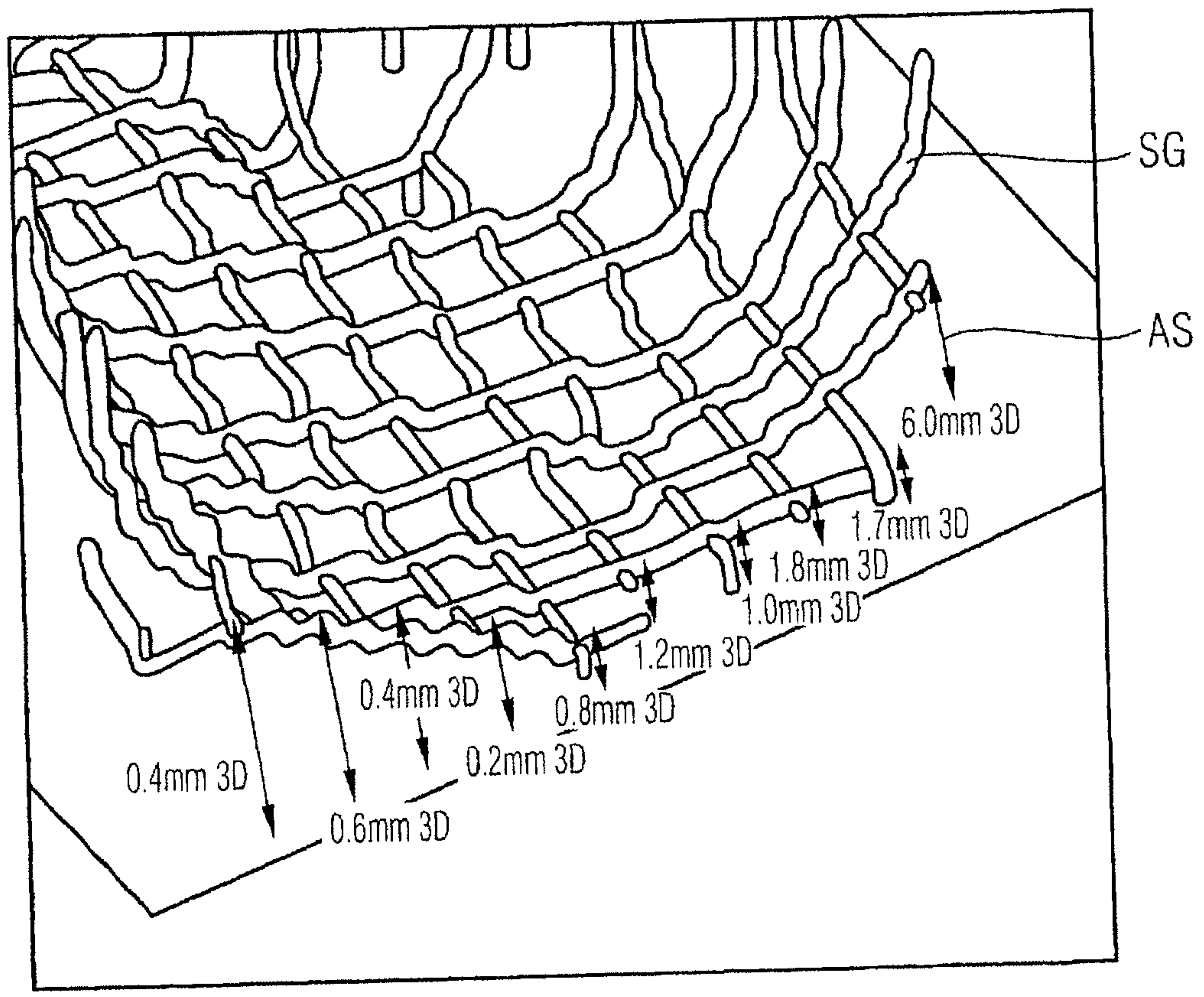

SG
AS
6.0mm 3D
1.7mm 3D
1.8mm 3D
1.0mm 3D
1.2mm 3D
0.8mm 3D
0.4mm 3D
0.2mm 3D
0.4mm 3D
0.6mm 3D

FIG 3

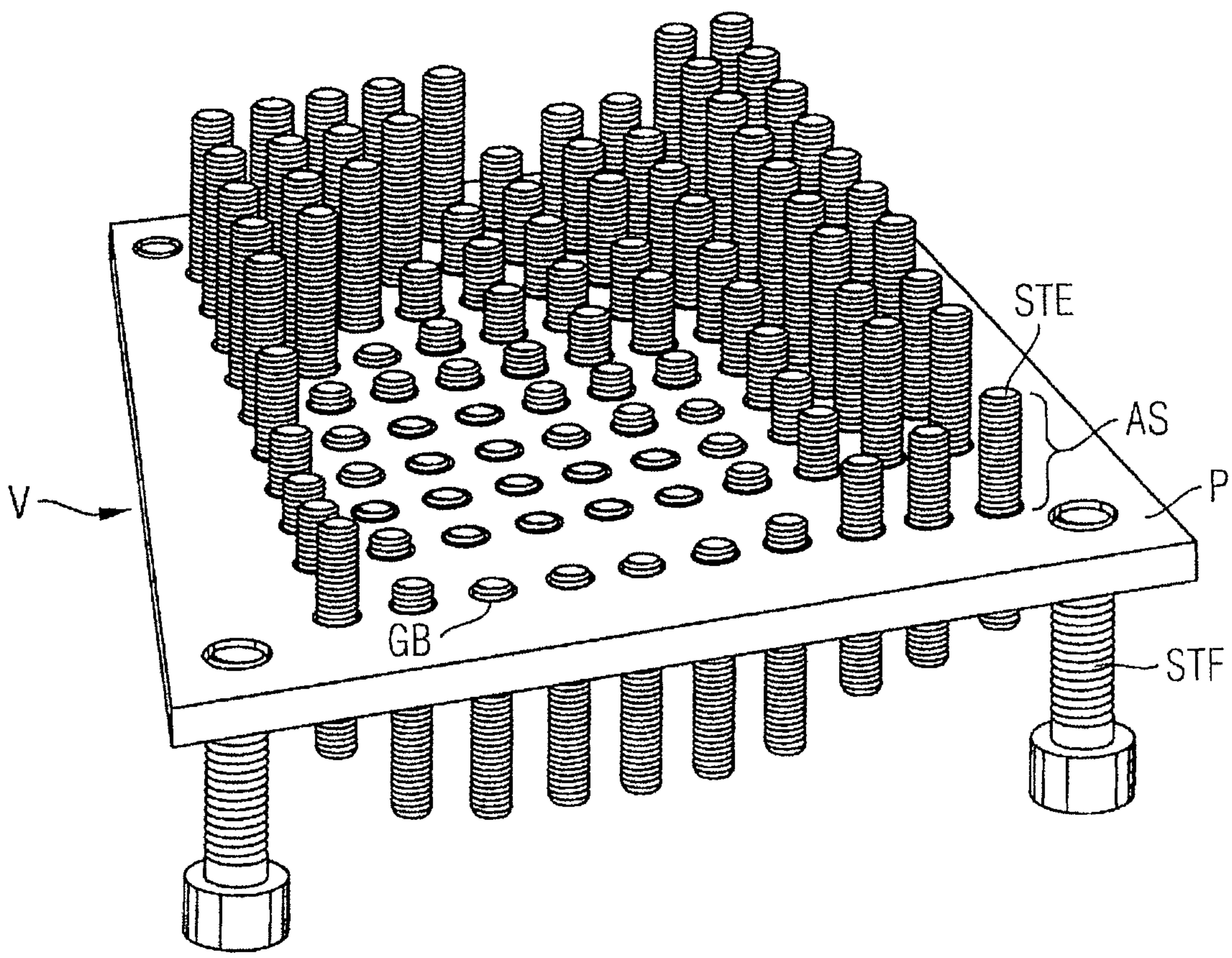


FIG 4

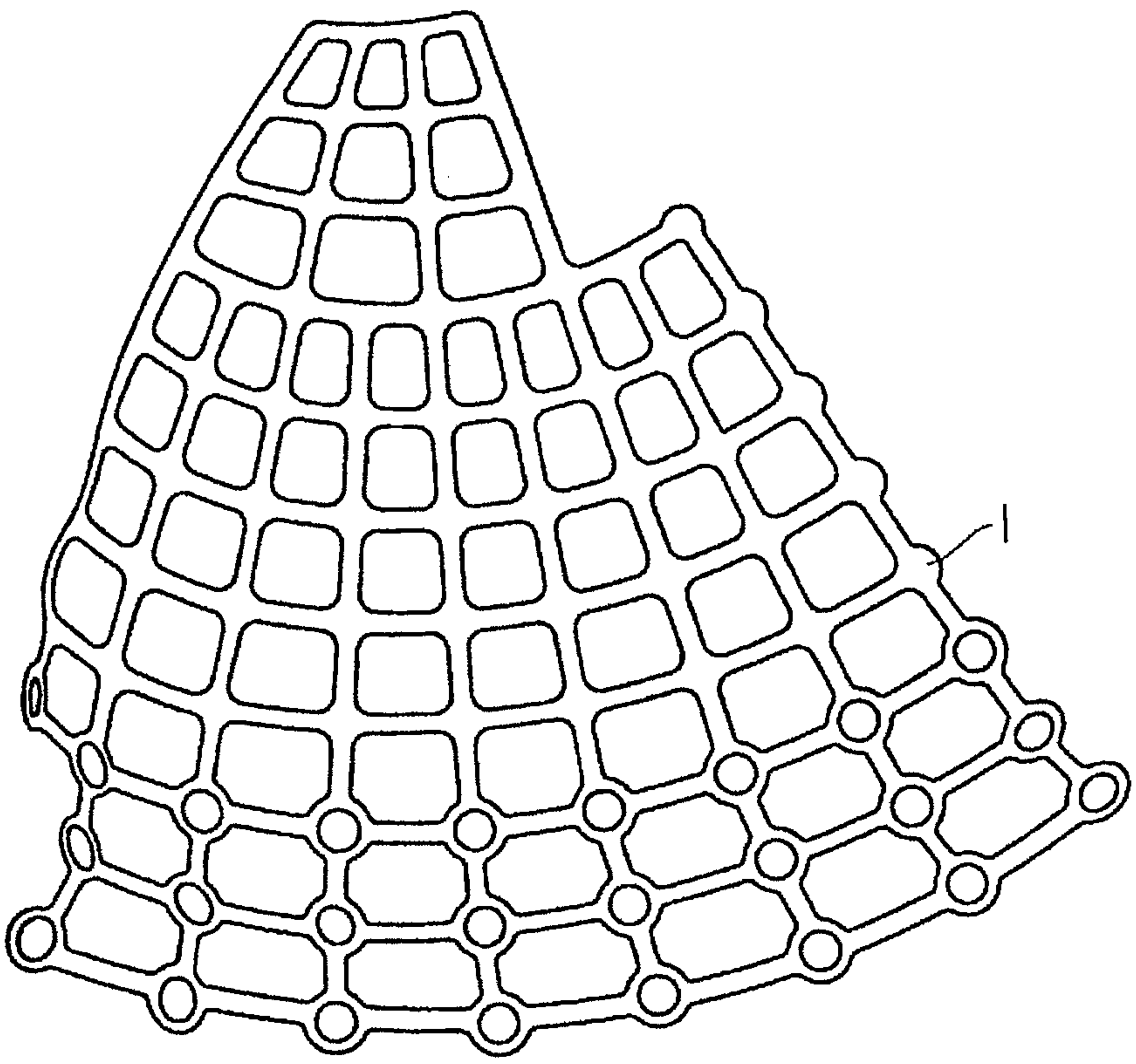
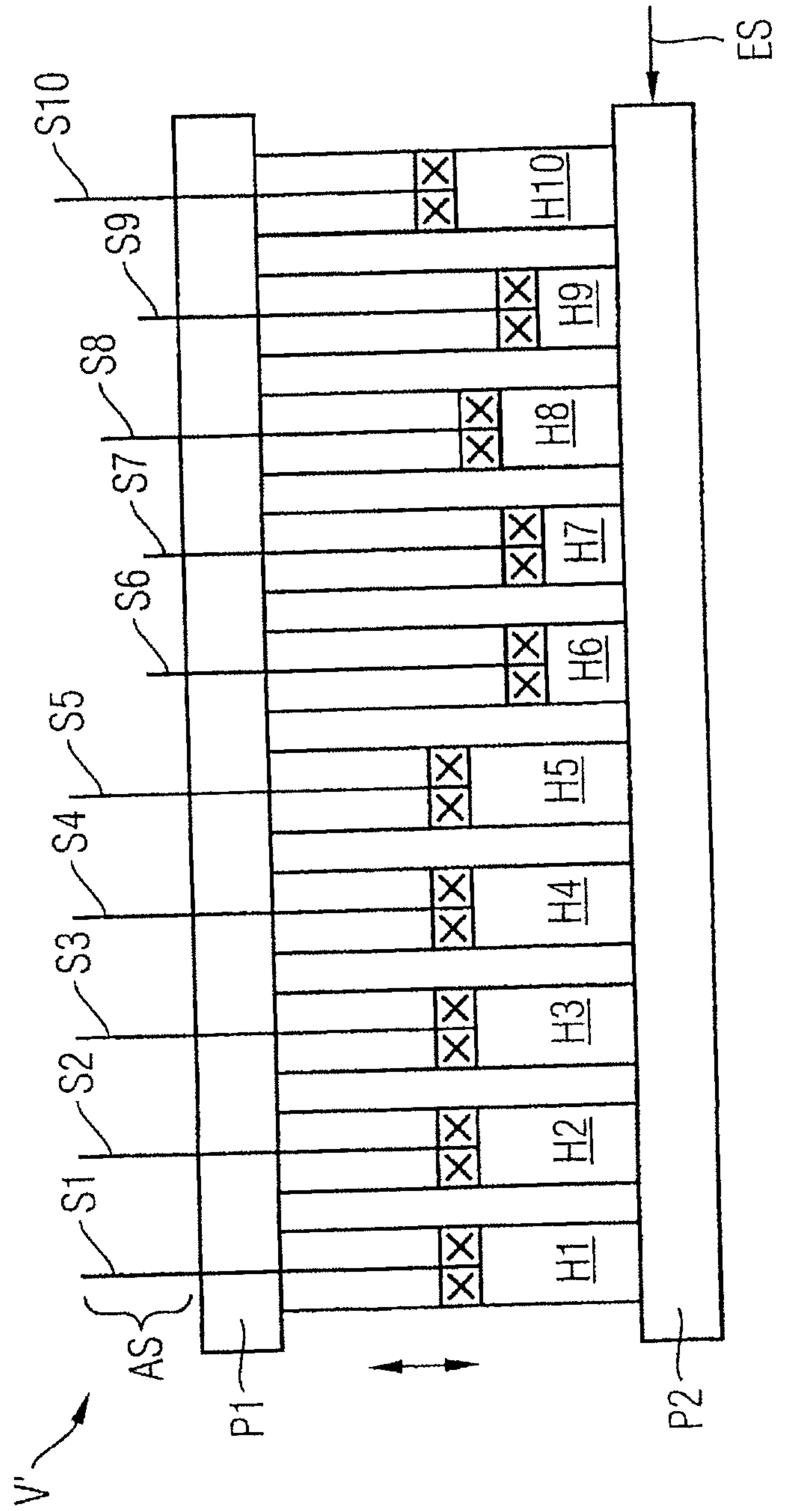
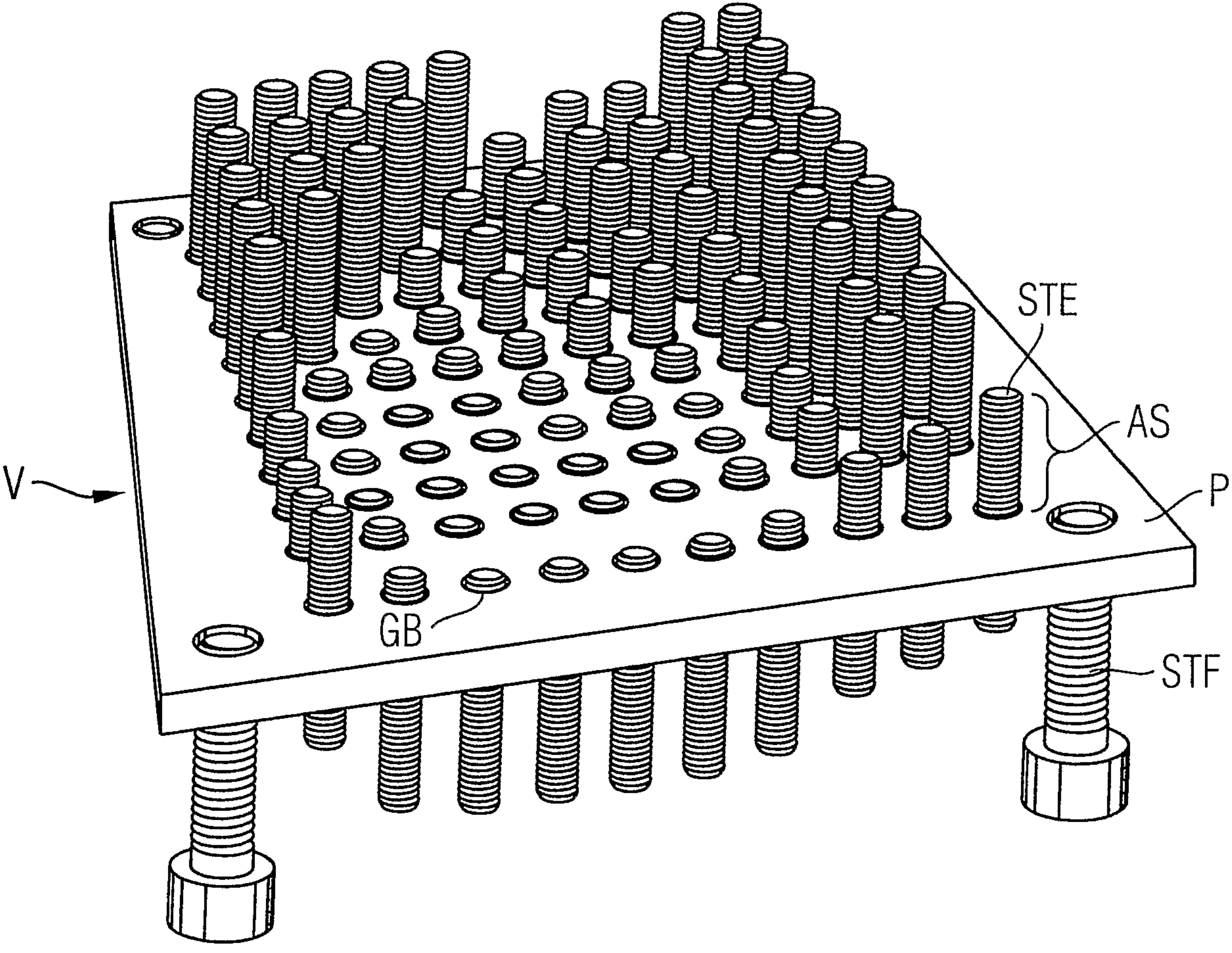


FIG 5


ES
S10
S9
S8
S7
S6
S5
S4
S3
S2
S1
H10
H9
H8
H7
H6
H5
H4
H3
H2
H1
AS
P1
P2
V'


STE
AS
V
P
GB
STF