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Canadian Intellectual Property Office

CA 2985398 C 2021/08/03

(11)(21) 2 985 398

(12) BREVET CANADIEN
CANADIAN PATENT

(13) C

(86) Date de dépôt PCT/PCT Filing Date: 2016/05/09
(87) Date publication PCT/PCT Publication Date: 2016/11/17
(45) Date de délivrance/Issue Date: 2021/08/03
(85) Entrée phase nationale/National Entry: 2017/11/08
(86) N° demande PCT/PCT Application No.: DE 2016/000207
(87) N° publication PCT/PCT Publication No.: 2016/180397
(30) Priorités/Priorities: 2015/05/08 (DE10 2015 006 154.2); 2016/01/11 (DE10 2016 000 235.2)

(51) Cl.Int./Int.Cl. *A61F 2/28* (2006.01), *A61F 2/30* (2006.01), *A61L 27/02* (2006.01), *A61L 27/14* (2006.01), *A61L 27/58* (2006.01)

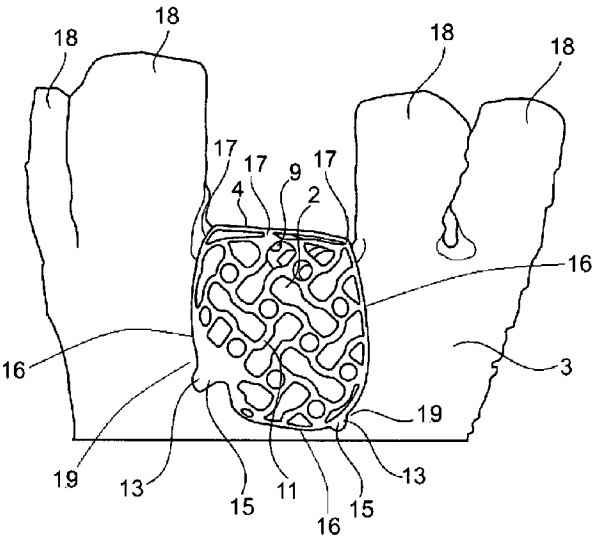
(72) Inventeur/Inventor:
SEILER, MARCUS, DE

(73) Propriétaire/Owner:
REOSS GMBH, DE

(74) Agent: OSLER, HOSKIN & HARCOURT LLP

(54) Titre : DISPOSITIF POUR LE RECOUVREMENT ET/OU LA RECONSTRUCTION D'UN DEFAUT D'UN OS ET PROCEDE DE FABRICATION D'UN COURONNEMENT D'UN DISPOSITIF DE RECOUVREMENT POUR UN DEFAUT D'UN OS

(54) Title: DEVICE FOR COVERING AND/OR RECONSTRUCTING A BONE DEFECT SITE; METHOD FOR PRODUCING A CAP OF A COVERING DEVICE FOR A BONE DEFECT SITE



(57) Abrégé/Abstract:
A device (1) for covering and/or reconstructing a bone defect site (2) and a method for producing a cap (4) of a covering device for a bone defect site (3) are proposed, wherein the device (1) for covering and/or reconstructing a bone defect site (2) consists of a cap (4) (moulded shell, rigid shell, shaped body) having an edge (16) and of at least one fixing means (5) for fixing the cap (4) on a bone, and the cap (4) is characterised by having a dirnensionally stable (rigid) nature, and a wall (9) of the cap (4) directed towards the bone defect or a wall (11) of the cap (4) directed away from the bone defect corresponds to the shape of the regenerated bone, wherein at least one positioning means (13) is arranged at the edge (16) of the cap (4).

Abstract

A device (1) for covering and/or reconstructing a bone defect site (2) and a method for producing a cap (4) of a covering device for a bone defect site (3) are proposed, wherein the device (1) for covering and/or reconstructing a bone defect site (2) consists of a cap (4) (moulded shell, rigid shell, shaped body) having an edge (16) and of at least one fixing means (5) for fixing the cap (4) on a bone, and the cap (4) is characterised by having a dimensionally stable (rigid) nature, and a wall (9) of the cap (4) directed towards the bone defect or a wall (11) of the cap (4) directed away from the bone defect corresponds to the shape of the regenerated bone, wherein at least one positioning means (13) is arranged at the edge (16) of the cap (4).

Device for covering and/or reconstructing a bone defect site; method for producing a cap of a covering device for a bone defect site

Prior art

Bone defect sites in the form of recesses or hollowed-out areas in the body's own bone tissue are often filled with bone augmentation material in bone surgery, for example in the reconstruction of bone in orthopaedic, neurosurgical, or plastic surgery, or in maxillofacial surgery operations. In general, the bone augmentation material consists of a mixture of synthetic bone replacement material (for example hydroxyl apatite granulate) and natural bone particles. In order for osseous growth through the bone augmentation material to take place essentially exclusively from the bone side, the recess is closed off with a covering membrane, as described in the patent document DE 43 02 708 C2. The covering membrane is attached using attachment nails to the body's own healthy bone adjacent to the bone defect site, wherein the attachment process requires a maximum degree of technical skill of the surgeon, because the covering membrane consists of a flexible material.

In order to overcome this disadvantage of a lack of support function of the covering membrane, a covering membrane is described in the patent document US 4 816 339, which consists of multiple layers, wherein these layers do not consist of absorbable membrane material. Here, it might be required that after the bone defect has healed, a second operation is necessary to remove material that is foreign to the body.

In the patent document DE 10 2005 039 382 54, a biodegradable hollow body that particularly has the shape of a hollow cylinder or conical cylinder is proposed. The hollow body has a plurality of openings in its walls, through which take-in of blood and therefore the growth of the body's own bone is possible. It is disadvantageous, in this case, that in order to insert the hollow body, a cylindrical bore must be introduced into the existing bone, by means of a drill.

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In DE 10 2006 047 054 A1, an implant socket is proposed, which is characterised by high fit accuracy and stability, so that the treating physician can handle and implant it in simple manner. The implant socket, which is made from hydroxyl apatite, and has a thin membrane, particularly one consisting of absorbable material, for protection of the mucous membrane from mechanical effects and for protection of the implant socket from tissue growing into it from the mucous membrane, on the side facing the mucous membrane, is produced using an augmenting method of manufacture, so that the material composition forms a "gradient structure" in the sense of a decreasing density, particularly toward the inside. Here, a method of construction with a particularly porous structure is provided on the side facing the bone, and a compact method of construction is provided on the outside of the implant socket, on which a structure for holding a tooth implant and/or a dental prosthesis is situated.

Furthermore, devices for a bone defect site are described in the laid-open (unexamined) patent applications DE 198 30 992 A1, DE 10 2005 060 761 A1, DE 42 26 465 A1, WO 01/91818 A1, DE 10 2005 041 412 A1, DE 10 2006 047 054 A1, US 2011/0151400 A1, WO 00/59409 A1, WO 96/12446 A1, EP 2 737 871 A2 and WO 2006/051401 A2 and in patent document US 7 172 422 B1, wherein all of these solutions have the disadvantage that they affect the healthy bone present next to the bone defect site.

In order to avoid this disadvantage, a covering device with an accurate fit is proposed in the laid-open (unexamined) patent application DE 10 2011 011 191 A1, which covering device, however, has the disadvantage that the positioning of said device at the bone defect site is hindered by the accuracy of fit itself.

The invention and its advantages

The invention proceeds from a device for covering and/or reconstructing a bone defect site, a device for covering, reconstructing, or covering and reconstructing a bone defect site, with a cap, which has an edge and a wall directed away from the bone defect and a wall directed towards the bone defect, wherein the cap consists of a dimensionally stable material and the wall directed towards the bone defect of the

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cap directed towards the bone defect or the wall directed away from the bone defect of the cap directed away from the bone defect corresponds to the shape of the regenerated bone, characterized in that at least one opening-free positioning means is arranged at the edge of the cap, which positioning means has a wall which is directed towards a healthy bone adjacent to the bone defect, or in that the device has at least one fixing means for fixing the cap to a bone within the bone defect site, and at least one positioning means, which has a wall which is directed towards a healthy bone adjacent to the bone defect, is arranged at the edge of the cap, and a method for producing a cap of a covering device for a bone defect site, a method for producing a cap of a covering device for a bone defect site, consisting of the following method steps: recording a first data record, which represents the affected bone defect site in its actual state, comparing the first data record with a second data record, which represents the target state of a bone regenerated at the bone defect site, wherein the second data record is produced by calculation or was recorded at a moment in time at which the bone at the position now to be regenerated was still a healthy bone, using the first data record and the second data record to plan the cap, which has an edge and a wall directed away from the bone defect and a wall directed towards the bone defect, whereby the cap can be arranged exclusively in the region of the bone defect site, and which can be fixed to the bone with at least one fixing means, as appropriate, implementing the planning of the cap in the form of a planning data record, and providing the planning data record to a manufacturing method, in particular to a computer-controlled manufacturing method, in which the cap is formed from a dimensionally stable material and the wall thereof directed towards the bone defect or the wall thereof directed away from the bone defect corresponds to the shape of the regenerated bone in the target state, wherein, during the manufacture of the cap, at least one positioning means is arranged at the edge of the cap, which positioning means is used to position the cap on a healthy bone adjacent to the bone defect site, wherein a positioning means has a wall directed away from the healthy bone and a wall directed towards the healthy bone and corresponding at least in part thereto.

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The device according to the invention for covering and/or reconstructing a bone defect site, wherein the term "bone defect site" refers to a site of a bone (for example hip, spine, head, jaw, or the like) of a human or animal (said bone being diseased, deformed, injured, modified by ageing processes, modified by degeneration (for example following tooth extraction, tumour, etc.) and/or modified in volume), that deviates from the shape and/or volume of a healthy bone, having the features of a device for a bone defect site, the device comprising: a cap comprising a rim and a first side configured to face away from the bone defect and a second side configured to face toward the bone defect, wherein the cap comprises a dimensionally stable material, and the second side of the cap or the first side of the cap is configured to correspond to the shape of a regenerated bone, wherein the device has at least one positioning portion having a continuous wall configured to face a healthy bone that borders on the bone defect, the at least one positioning portion being disposed at the rim of the cap, or the device has at least one connector for fixation of the cap within the region of the bone defect, and the device has at least one positioning portion having a wall configured to face a healthy bone that borders on the bone defect, the at least one positioning portion being disposed at the rim of the cap, and the method according to the invention for producing a cap of a covering device for a bone defect site, having the features of a method for production of a cap of a covering device for a bone defect site, comprising the following method steps: recording of a first data set that represents the affected bone defect site in the actual state, comparison of the first data set with a second data set, which represents the reference state of a bone regenerated at the bone defect site, wherein the second data set is produced via calculation or was recorded at a time when the bone at the site now to be regenerated was still a healthy bone, use of the first data set and of the second data set for planning of the cap, which has a rim and a first side configured to face away from the bone defect and a second side configured to face the bone defect, thereby making it possible for the cap to be disposed exclusively in the region of the bone defect site, and to be fixed in place on a bone, conversion of the planning of the cap to a planning data set, and provision of the planning data set to a manufacturing method, in which the cap is formed from a dimensionally stable material, and the first side or the second side corresponds to the shape of the regenerated bone in the reference state, wherein during manufacturing of the cap, at least one positioning portion is

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disposed at the rim of the cap, and serves for positioning of the cap on a healthy bone that borders on the bone defect site, wherein the at least one positioning portion has a positioning device first wall that is configured to face away from the healthy bone and a positioning device second wall that is configured to face the healthy bone and to correspond to the healthy bone, at least in part, by contrast have the advantage that the device for covering and/or reconstructing a bone defect site consists of a cap (for example moulded shell, rigid shell, shaped body) having an edge, which cap can be formed in one or more layers, and, as appropriate, of at least one fixing means, which can be arranged within the bone defect site, for fixing the cap on a bone, wherein, at the edge of the cap, which is characterised by having a dimensionally stable (rigid) nature and being in contact with the bone at least in part (at the edge) in the boundary region between the bone defect site and the adjacent healthy bone, there is arranged at least one positioning means, wherein a wall (in the sense of a surface or side) of the cap directed towards the bone defect or a wall (in the sense of a surface or side) of the cap directed away from the bone defect corresponds to the shape of the bone regenerated within the bone defect site, said bone regaining the shape of a healthy bone on account of its regeneration. Due to the at least one positioning means, it is possible to position the cap at a healthy bone adjacent to the bone defect site, since the positioning means has a wall (in the sense of a surface or side) directed away from the healthy bone and a wall (in the sense of a surface or side) directed towards the healthy bone and corresponding at least in part thereto. The cap is arranged and/or fixed exclusively in the region of the bone defect site covered fully or at least in part by the cap, so that the cap does not affect the healthy bone adjacent to the bone defect site, where no regeneration of the bone takes place anyway on account of the healthy nature of said healthy bone. Instead of the merely partial covering of the bone defect site by the cap, the cap is thus adapted to the bone defect site, preferably with an accurate fit, and preferably ends flush with the healthy bone. The bone defect site is hereby fully covered by the cap, which does not protrude beyond the bone defect site.

According to an advantageous embodiment of the device according to the invention, the cap and/or at least one fixing means and/or at least one positioning means consist at least in part of a biocompatible material.

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According to an additional advantageous embodiment of the device according to the invention, the material is of organic and/or inorganic origin. The material can also be an autogenic, syngenic, allogenic, xenogenic, synthetic, or alloplastic material.

According to an additional advantageous embodiment of the device according to the invention, the cap and/or at least one fixing means and/or at least one positioning means consist at least in part of a biodegradable material.

According to an additional advantageous embodiment of the device according to the invention, the cap and/or at least one fixing means and/or at least one positioning means consist at least in part of an absorbable material. Advantageously, the absorption time of the rigid shell can be controlled by means of its absorption gradients and/or the absorption time can also amount to less than six months, so that the implant can be placed in a timely manner. Absorbable metals or alloys, in particular magnesium or magnesium alloys, are preferably used. The 3D models (for example the cap and/or the fixing means) are preferably constructed by means of a laser melting method under vacuum, wherein a 3D printer is preferably used.

According to an additional advantageous embodiment of the device according to the invention, the cap and/or at least one fixing means and/or at least one positioning means consist at least in part of a polymer or a polymer compound.

According to an additional advantageous embodiment of the device according to the invention, the cap and/or at least one fixing means and/or at least one positioning means consist at least in part of polylactide. Polylactides are composed of many lactic acid molecules chemically bound to one another, and belong to the polymers. The advantage of polylactide plastics, which are also referred to as polylactic acids (PLAs), is that they are plastics that are deformable by supplying heat, and are biocompatible.

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According to an additional advantageous embodiment of the device according to the invention, the cap and/or at least one positioning means has a constant or varying wall thickness.

According to an embodiment of the device according to the invention that is advantageous in this regard, the wall thickness should amount to at least 0.2 mm, preferably 0.5 mm, but at least to such an amount that the moulded shell or a positioning means is dimensionally stable.

According to an additional advantageous embodiment of the device according to the invention, the fixing means is a pin, a screw, a nail and/or a bone adhesive. In order to protect the healthy bone, the fixing means is/are preferably arranged in the region of the bone defect site.

According to an additional advantageous embodiment of the device according to the invention, the cap has at least one milled region (bore for the fixing means).

According to an embodiment of the device according to the invention that is advantageous in this regard, the milled region corresponds to the fixing means.

According to an additional advantageous embodiment of the device according to the invention, the wall directed towards the bone defect has a surface conditioning.

According to an embodiment of the device according to the invention that is advantageous in this regard, the surface can have a microstructuring, pores, osteoblast attraction substances, means for promoting bone growth, and/or bone replacement material that contains bone morphogenetic protein (BMP).

According to an additional advantageous embodiment of the device according to the invention, the cap has at least one opening. This means that the cap does not have to have a closed wall. The cap can have a mesh structure, at least at individual points, on account of a multiplicity of openings, wherein the wall of the mesh struc-

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ture directed away from the bone defect or the wall of the mesh structure directed towards the bone defect corresponds to the shape of the regenerated bone.

According to an additional advantageous embodiment of the device according to the invention, the cap has at least one predetermined breaking point. The predetermined breaking point brings the advantage that, provided the cap is to be removed following successful bone regeneration, this removal can be performed in a minimally invasive manner, without "having to open everything up", since the cap can be divided into at least two parts on account of the predetermined breaking point. The cap can therefore be removed (for example following bone regeneration) very easily. Furthermore, the predetermined breaking point can be used to separate parts of the cap not required from the rest of the cap.

In accordance with an additional advantageous embodiment of the device according to the invention, the cap has at least one fastening device (for example a recess) for at least one implant to be fitted.

According to an embodiment of the device according to the invention that is advantageous in this regard, at least one fastening device (for example a recess) is covered at least in part by a part of the cap which is connected by means of at least one predetermined breaking point to the rest of the cap.

According to an embodiment of the device according to the invention that is advantageous in this regard, at least one predetermined breaking point is arranged between the cap and a positioning means. A positioning means resting on the healthy bone and thus possibly causing discomfort can thus be removed from the part of the cap possibly remaining, for example once the cap has been fixed or following the regeneration of the bone at the bone defect site.

According to an advantageous embodiment of the method according to the invention for producing a cap of a covering device for a bone defect site, in which the computer-assisted design (CAD) of the cap is combined with computer-assisted manufacturing (CAM), as CAD/CAM, so that a design model of the cap developed on the com-

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puter is transmitted directly electronically to the manufacture, consisting of the following method steps:

- recording a data record, which represents the affected bone defect site in its three-dimensionality, by means of tomography or similar imaging methods
- using the data record for planning of the cap, which has a wall directed away from the bone defect and a wall directed towards the bone defect, and can be fixed in place on a bone with at least one fixing means
- implementing the planning of the cap in a planning data record, and
- providing the planning data record to a computer-controlled manufacturing method,

wherein the cap is formed from a dimensionally stable material and its wall (in the sense of a surface or side) directed towards the bone defect or its wall (in the sense of a surface or side) directed away from the bone defect corresponds to the shape of the regenerated bone, and the data record representing the affected bone defect site in its three-dimensionality is recorded by means of tomography, computed tomography, digital volume tomography, sonography, or the like, wherein at least one positioning means is arranged at the edge of the cap during and/or after the manufacture of the cap, which positioning means is used to position the cap at a healthy bone adjacent to the bone defect site and has a wall (in the sense of a surface or side) directed away from the healthy bone and a wall (in the sense of a surface or side) directed towards the healthy bone and corresponding at least in part thereto, the recording of the first data record represents the affected bone defect site in its three-dimensionality and/or the recording of the second data record represents the shape of the still healthy bone in its three-dimensionality.

According to an additional advantageous embodiment of the method according to the invention for producing a cap of a covering device for a bone defect site, the first data record, which represents the actual state, and/or the second data record, which represents the target state, are/is recorded by at least one imaging method.

According to an additional advantageous embodiment of the method according to the invention for producing a cap of a covering device for a bone defect site, the first data record and/or the second data record are/is recorded by means of at least one

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method which enables a three-dimensional representation of a bone. In particular, the first data record and/or the second data record are/is recorded by means of tomography, computer tomography, digital volume tomography, sonography, or the like.

According to an additional advantageous embodiment of the method according to the invention for producing a cap of a covering device for a bone defect site, the data record of the healthy bone is recorded once the healthy bone is mature. it is thus possible that the ideal state (target state) of the bone might be documented, so that it is known how a bone potentially requiring regeneration later should look. In humans, the data record of the healthy bone should preferably be recorded between the ages of 18 and 25 years. Of course, it is also conceivable for a plurality of healthy bones or the entire skeleton of a human or animal to be recorded, documented and/or stored once a mature state of the bones has been reached. It is also conceivable to manufacture a cap at least in part already at the time at which the healthy bone is recorded.

According to an embodiment of the method according to the invention for producing a cap of a covering device for a bone defect site that is advantageous in this regard, the data record of the healthy bone is stored (preserved) for its later use, on a storage medium.

According to an additional advantageous embodiment of the method according to the invention for producing a cap of a covering device for a bone defect site, the cap is formed by means of milling, in the manufacturing process.

According to an additional advantageous embodiment of the method according to the invention for producing a cap of a covering device for a bone defect site, at least one fastening device for at least one implant to be fitted is arranged on the cap during the manufacture of the cap. The fastening device, for example, can be formed as a recess.

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According to an embodiment of the method according to the invention for producing a cap of a covering device for a bone defect site that is advantageous in this regard, at least one fastening device (for example recess) is exposed by removing part of the cap connected by means of at least one predetermined breaking point to the rest of the cap prior to the removal. The moment in time at which the fastening device is exposed can be before or after the moment in time at which the covering device is arranged at the bone defect site.

According to an additional advantageous embodiment of the method according to the invention for producing a cap of a covering device for a bone defect site, at least one predetermined breaking point is arranged on the cap during the manufacture of the cap.

According to an additional advantageous embodiment of the method according to the invention for producing a cap of a covering device for a bone defect site, at least one predetermined breaking point is arranged between the cap and a positioning means.

According to an additional advantageous embodiment of the method according to the invention for producing a cap of a covering device for a bone defect site, a cleaning and/or sterilisation process is performed during the manufacture of the cap.

According to an additional advantageous embodiment of the method according to the invention for producing a cap of a covering device for a bone defect site, the cap can be used in a device for covering and/or reconstructing a bone defect site according to the presently claimed invention. In this way, a device for covering and/or reconstructing a bone defect site can be created, the cap and/or fixing means of which, for example made of an artificial material and/or of a material of autogenic, syngenic, allogenic or xenogenic origin from human and/or animal bone or the human, animal or a synthetic matrix, has a shape by means of which the region situated between the bone and the desired shape of the regenerated bone is completely or almost completely filled. To this end, a bone block is removed from the donor, for example, and subsequently modelled by means of CAD/CAM, as appropriate.

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By means of the method according to the invention, a device according to the invention for covering and/or reconstructing a bone defect site can be created, the cap and/or fixing means of which for example originates from a material of organic and/or inorganic origin. This can also be a synthetic material and/or a material of autogenic, syngenic, allogenic or xenogeneic, alloplastic, human and/or animal origin. Here, the human, animal or synthetic matrix can also have a shape by means of which the region situated between the bone and the desired shape of the regenerated bone is completely or almost completely filled. For this purpose, a bone block is removed from the donor (same patient or third-party donor), for example, and subsequently modelled by means of CAD/CAM, as appropriate.

Further features and advantageous embodiments of the invention can be derived from the following description and drawings.

Drawing

Exemplary embodiments of the subject matter of the invention are shown in the drawing and will be explained in greater detail in the following. The figures show:

Fig. 1 a representation of a device according to the invention for covering and/or reconstructing a bone defect site,

Fig. 2 a representation of a differently shaped device according to the invention for covering and/or reconstructing a bone defect site,

Fig. 3 a representation of a differently shaped device according to the invention for covering and/or reconstructing a bone defect point,

Fig. 4 a representation of a differently shaped device according to the invention for covering and/or reconstructing a bone defect site,

Fig. 5 a detail of a cap,

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Fig. 6 to 8 various representations of a cap with positioning means, and

Fig. 9 a cap arranged at a bone defect site.

Description of the exemplary embodiments

Fig. 1 shows a representation of a device 1 according to the invention, for covering and/or reconstructing a bone defect site 2 (bone defect) of a bone, particularly of a jaw bone 3. The device 1 consists of a cap 4, which is formed in a single layer, and of a fixing means 5, which is shown as a pin in Fig. 1 and which is arranged in the bone defect site 2 so as not to injure the healthy bone adjacent to the bone defect site 2. Of course, it is also conceivable for a plurality of fixing means 5 to be used to fix the cap 4, wherein these fixing means would likewise be arranged in the bone defect site 2. The cap 4 is made of a dimensionally stable material, so that it supports itself and no additional support is required. For fixing of the cap 4 (moulded shell, rigid shell), the fixing means 5 is pushed through a bore 6, into the cap 4, and subsequently introduced into the bore 7 arranged in the jaw bone 3. The cap 4 is subsequently fixed preferably by means of ultrasonic welding. During ultrasonic welding, an ultrasound generator preferably generates a precisely defined frequency that is bundled by way of a sonotrode. Once the absorbable fixing means 5 (pin) has been fitted onto a bore hole (bore 7) pre-drilled in the bone, a vibration that is produced ensures liquefaction of the pin surface at its edges, thereby bringing about the result that the pin slides into the bore hole. By means of a change in the state of aggregation, the pin also penetrates into the osseous cavities that cannot be reached by a conventional bone screw, so that great initial strength is achieved. Furthermore, the pin head connects to the cap 4 and ensures a stable three-dimensional construct with an interlocking mechanism. During ultrasonic welding, the fixing means 5 is therefore softened, so that it connects to the jaw bone 3 and the cap 4. By means of the cap 4, which has been fixed in place, a sealed interior space 8 is formed between the jaw bone 3 and the cap 4, which space is filled by means of the regeneration of the bone and/or by means of the introduction of a material of organic and/or

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inorganic origin, which material can also be an autogenic, syngenic, allogenic, xenogenic, synthetic and/or alloplastic material, so that the regenerated bone or the introduced material corresponds to the shape of the wall 9 (in the sense of a surface or side) of the single-layer cap 4 directed towards the bone defect site 2. In order to accelerate the regeneration process of the jaw bone 3, the wall 9 of the cap 4 directed towards the bone defect can have a surface conditioning (for example a microstructuring, pores, osteoblast attraction substances, means for promoting bone growth, and/or bone replacement material that contains BMP).

Fig. 2 shows a representation of a differently shaped device 1 according to the invention for covering and/or reconstructing a bone defect site 2 (bone defect) of a bone, particularly of a jaw bone 3. In this figure, the gum 10 is additionally shown.

Fig. 3 shows a representation of a differently shaped device 1 according to the invention for covering and/or reconstructing a bone defect site 2 (bone defect) of a bone, in particular a jaw bone 3. In this figure, the cap 4 is formed as a moulded body, for example made of human or animal bone, and has a wall 9 (in the sense of a surface or side) directed towards the bone defect, which wall is adapted to the relief of the bone defect site 2, and a wall 11 (in the sense of a surface or side) directed away from the bone defect, which wall corresponds to the shape of the regenerated bone.

Fig. 4 shows a representation of a differently shaped device 1 according to the invention for covering and/or reconstructing a bone defect site 2 (bone defect) of a bone, in particular a jaw bone 3. In this figure, the cap 4 is formed as a moulded body, for example made of human or animal bone, and has a wall 9 directed towards the bone defect and a wall 11 directed away from the bone defect, which corresponds to the shape of the regenerated bone. An interior space 8 is situated between the wall 9 and the bone defect site 2, which space is filled by means of the regeneration of the bone and/or by means of the introduction of autogenic, syngenic, allogenic, xenogeneic, synthetic and/or alloplastic material.

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Fig. 5 shows a detail of a cap 4, the wall 9 of which directed towards the bone defect has openings 12, thus resulting in a mesh-like structure.

Fig. 6 to 8 show various representations of a cap 4, which has a wall 9 directed towards a bone defect site and a wall 11 directed away from the bone defect site, with positioning means 13 arranged at the edge 16 of the cap 4, which positioning means have a wall 14 directed towards a healthy bone and a wall 15 directed away from the healthy bone. When the cap 4 is arranged correctly at the bone defect site, this being assisted by the positioning means 13, the walls 14 directed towards a healthy bone contact the healthy bone, whereby the positioning means 13 ensure that the cap 4 sits in a perfect position, even without arrangement of at least one fixing means (not shown in Fig. 6 to 8) or at least until at least one fixing means is arranged in the bone defect site, as appropriate. So as to be able to easily remove the cap 4 following the bone regeneration, said cap has predetermined breaking points 17, whereby it can be divided into two parts for its removal once these predetermined breaking points have been severed.

Fig. 9 shows a cap 4 arranged at a bone defect site 2 of a jaw bone 3 (shown in part), which has teeth 18. It can thus be seen that the cap 4 is arranged preferably only in the region of the bone defect site 2 of the jaw bone 3, so that it neither spans nor contacts a healthy bone 19. Thus, only the positioning means 13 arranged on the cap 4 are in contact with the healthy bone 19.

In Fig. 6 to 9 a cap 4 is shown, the wall 9 of which directed towards the bone defect corresponds to the shape of the regenerated bone. It is also conceivable for the positioning means 13 to be arranged on the cap 4 in such a way that the wall 11 thereof directed away from the bone defect corresponds to the shape of the regenerated bone. This could also be achieved for example by arranging the positioning means 13 on the wall 11 of the cap 4 directed away from the bone defect.

All of the features presented here can be essential to the invention individually and in any combination with one another.

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List of reference signs

1	device
2	bone defect site
3	jaw bone
4	cap
5	fixing means
6	bore
7	bore
8	interior space
9	wall
10	gum
11	wall
12	opening
13	positioning means
14	wall
15	wall
16	edge
17	predetermined breaking point
18	tooth
19	healthy bone

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The embodiments of the present invention for which an exclusive property or privilege is claimed are defined as follows:

1. A device for a bone defect site, the device comprising:

a cap comprising a rim and a first side configured to face away from the bone defect and a second side configured to face toward the bone defect,

wherein the cap comprises a dimensionally stable material, and the second side of the cap or the first side of the cap is configured to correspond to the shape of a regenerated bone,

wherein

the device has at least one positioning portion having a continuous wall configured to face a healthy bone that borders on the bone defect, the at least one positioning portion being disposed at the rim of the cap, or

the device has at least one connector for fixation of the cap within the region of the bone defect, and the device has at least one positioning portion having a wall configured to face a healthy bone that borders on the bone defect, the at least one positioning portion being disposed at the rim of the cap.

2. The device according to claim 1, wherein at least one member selected from the group consisting of the cap, the at least one connector, and the at least one positioning portion comprises, at least in part, a biocompatible material.

3. The device according to claim 2, wherein the material of the at least one member selected from the group consisting of the cap, the connector, and the at least one positioning portion is of organic or inorganic origin.

4. The device according to claim 1, wherein at least one member selected from the group consisting of the cap, the at least one connector, and the at least one positioning portion comprises, at least in part, a biodegradable material.

5. The device according to claim 1, wherein at least one member selected

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from the group consisting of the cap, the at least one connector, and the at least one positioning portion comprises, at least in part, a resorbable material.

6. The device according to claim 1, wherein at least one member selected from the group consisting of the cap, the at least one connector, and the at least one positioning portion comprises, at least in part, a polymer or a polymer compound.

7. The device according to claim 1, wherein at least one member selected from the group consisting of the cap, the at least one connector, and the at least one positioning portion comprises, at least in part, polylactide.

8. The device according to claim 1, wherein at least one member selected from the group consisting of the cap and the at least one positioning portion has a varying wall thickness.

9. The device according to claim 8, wherein the wall thickness amounts to at least 0.2 mm.

10. The device according to claim 1, wherein the connector comprises at least one member selected from the group consisting of a pin, a screw, a nail, and a bone adhesive.

11. The device according to claim 1, wherein the cap has at least one milling.

12. The device according to claim 11, wherein the milling corresponds with the connector.

13. The device according to claim 1, wherein the second side has a surface conditioning.

14. The device according to claim 13, wherein the surface conditioning has at least one member selected from the group consisting of a micro-structuring, pores, osteoblast attractants, a bone growth promoter, and bone replacement material that

contains BMP.

15. The device according to claim 1, wherein the cap has at least one opening.

16. The device according to claim 1, wherein the cap has at least one breaking point.

17. The device according to claim 1, wherein the cap has at least one attachment device for at least one implant to be set.

18. The device according to claim 17, wherein the at least one attachment device is covered, at least in part, by a part of the cap that is connected with the remaining part of the cap via at least one breaking point.

19. The device according to claim 1, wherein a breaking point is disposed between the cap and the at least one positioning portion.

20. A method for production of a cap of a covering device for a bone defect site, comprising the following method steps:

recording of a first data set that represents the affected bone defect site in the actual state,

comparison of the first data set with a second data set, which represents the reference state of a bone regenerated at the bone defect site, wherein the second data set is produced via calculation or was recorded at a time when the bone at the site now to be regenerated was still a healthy bone,

use of the first data set and of the second data set for planning of the cap, which has a rim and a first side configured to face away from the bone defect and a second side configured to face the bone defect, thereby making it possible for the cap to be disposed exclusively in the region of the bone defect site, and to be fixed in place on a bone,

conversion of the planning of the cap to a planning data set, and

provision of the planning data set to a manufacturing method, in which

the cap is formed from a dimensionally stable material, and the first side or the second side corresponds to the shape of the regenerated bone in the reference state, wherein during manufacturing of the cap, at least one positioning portion is disposed at the rim of the cap, and serves for positioning of the cap on a healthy bone that borders on the bone defect site, wherein the at least one positioning portion has a positioning device first wall that is configured to face away from the healthy bone and a positioning device second wall that is configured to face the healthy bone and to correspond to the healthy bone, at least in part.

21. The method according to claim 20, wherein recording of the first data set represents the affected bone defect site in its three-dimensionality, or recording of the second data set represents the shape of the bone that is still healthy in its three-dimensionality, or recording of the first data set represents the affected bone defect site in its three-dimensionality and recording of the second data set represents the shape of the bone that is still healthy in its three-dimensionality.

22. The method according to claim 20, wherein recording of at least one of the first data set and the second data set takes place via at least one imaging method.

23. The method according to claim 20, wherein recording of at least one of the first data set and the second data set take(s) place using at least one method that allows three-dimensional representation of a bone.

24. The method for production of a cap according to claim 20, wherein recording of the data set of the healthy bone takes place after the healthy bone has grown out.

25. The method for production of a cap according to claim 24, wherein the data set of the healthy bone is stored on a memory medium for later use.

26. The method for production of a cap according to claim 20, wherein during the manufacturing process, the cap is formed via milling.

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27. The method for production of a cap according to claim 20, wherein during manufacturing of the cap, at least one attachment device for at least one implant to be set is disposed on the cap.

28. The method for production of a cap according to claim 27, wherein at least one attachment device is exposed by removal of a part of the cap, which is connected with the remaining part of the cap via at least one breaking point before removal.

29. The method for production of a cap according to claim 20, wherein during manufacturing of the cap, at least one breaking point is disposed on the cap.

30. The method for production of a cap according to claim 20, wherein at least one breaking point is disposed between the cap and the at least one positioning portion.

31. The method for production of a cap according to claim 20, wherein at least one of a cleaning process and a sterilization process is carried out during manufacturing of the cap.

32. The method for production of a cap according to claim 20, wherein the cap is used in at least one member selected from the group consisting of a device for covering of a bone defect site, a device for reconstruction of a bone defect site, and a device for covering and reconstruction of a bone defect site.

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Fig. 1

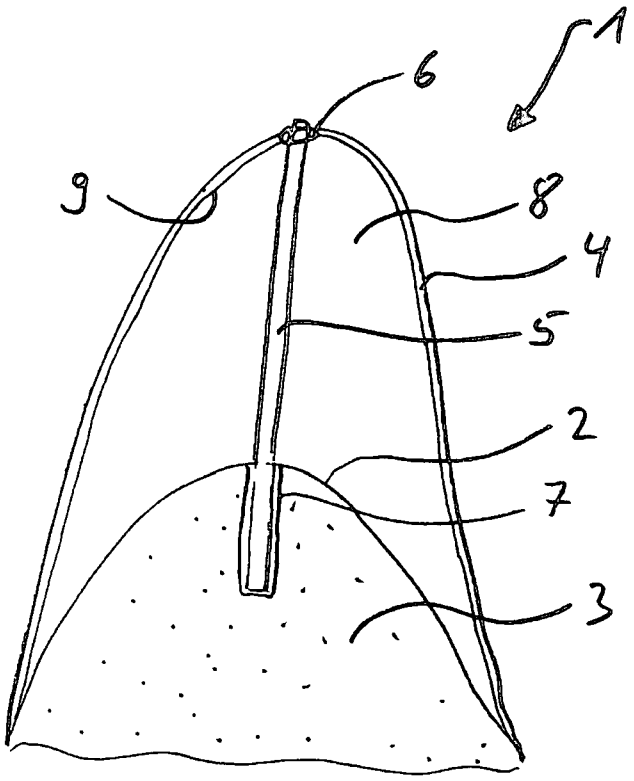


Fig. 2

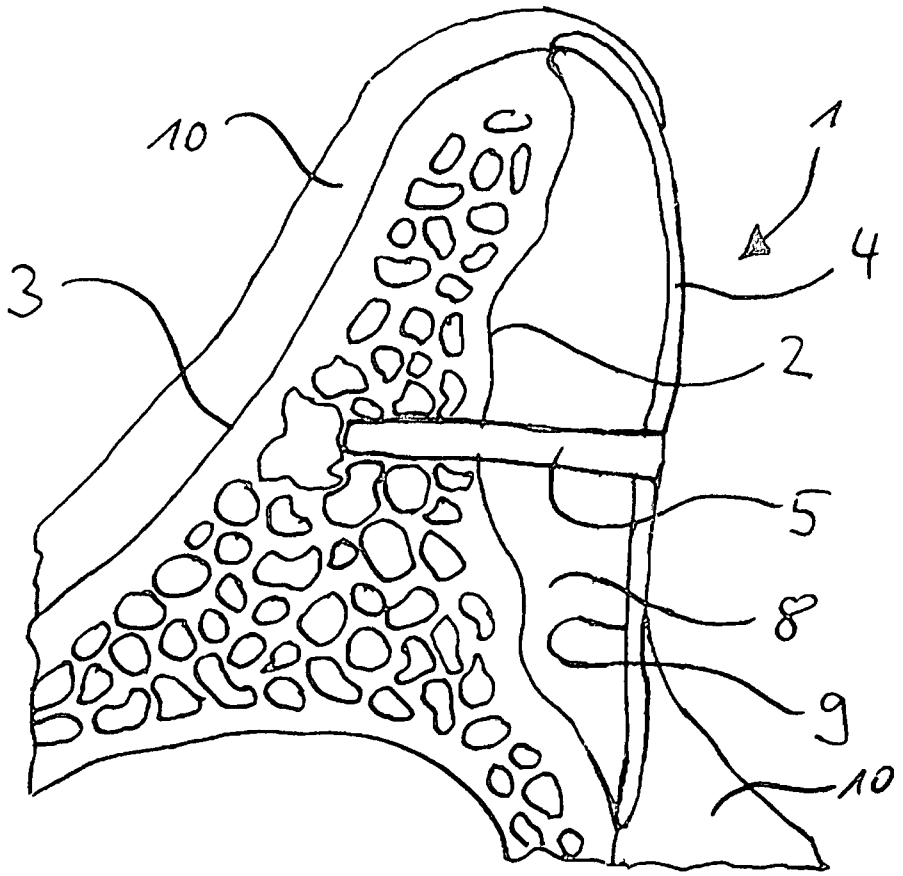


Fig. 3

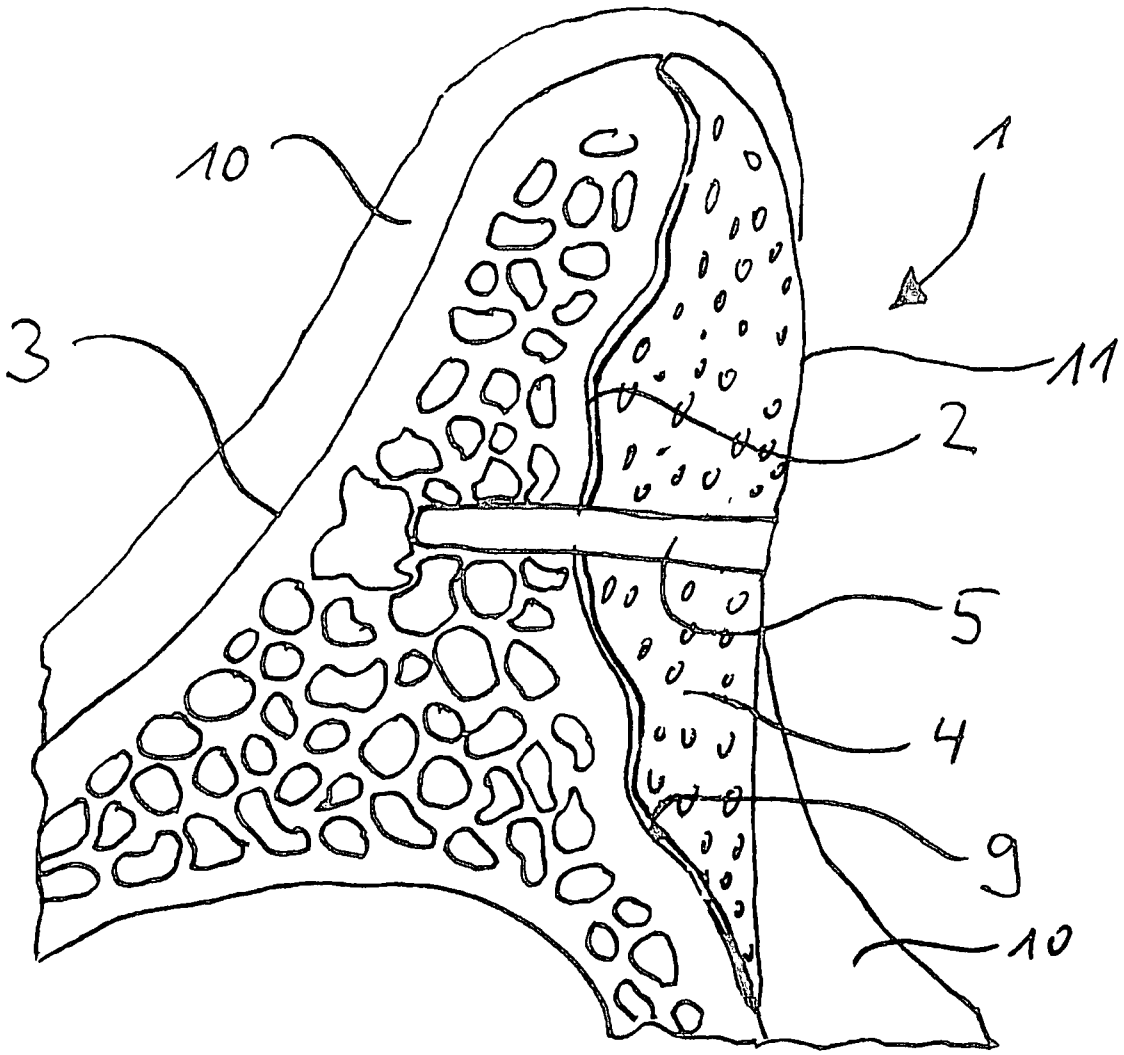


Fig. 4

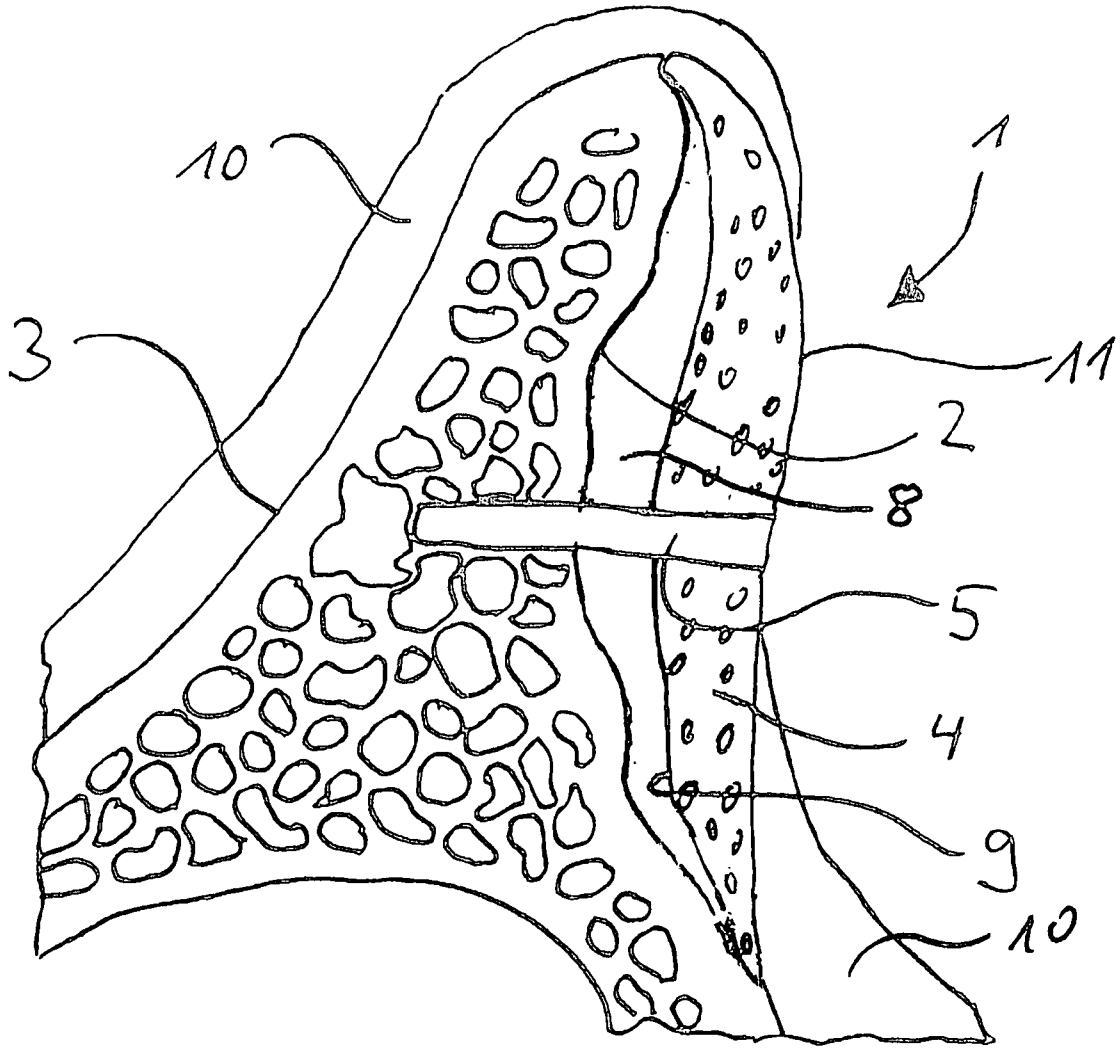


Fig. 5

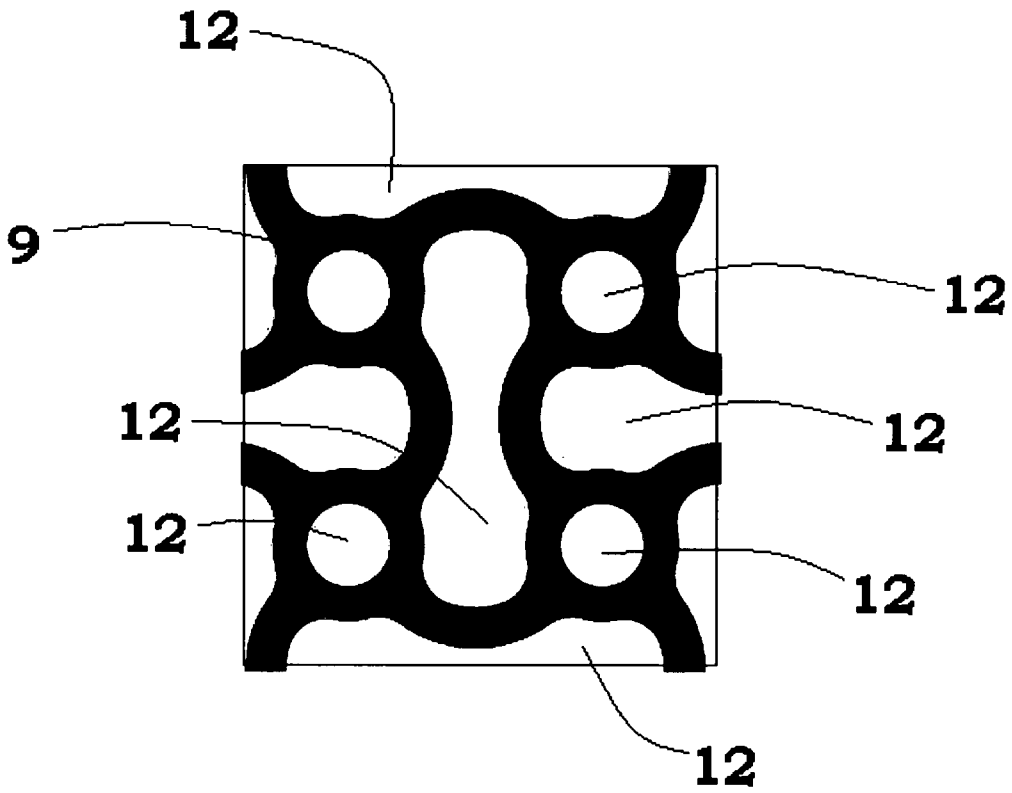


Fig. 6

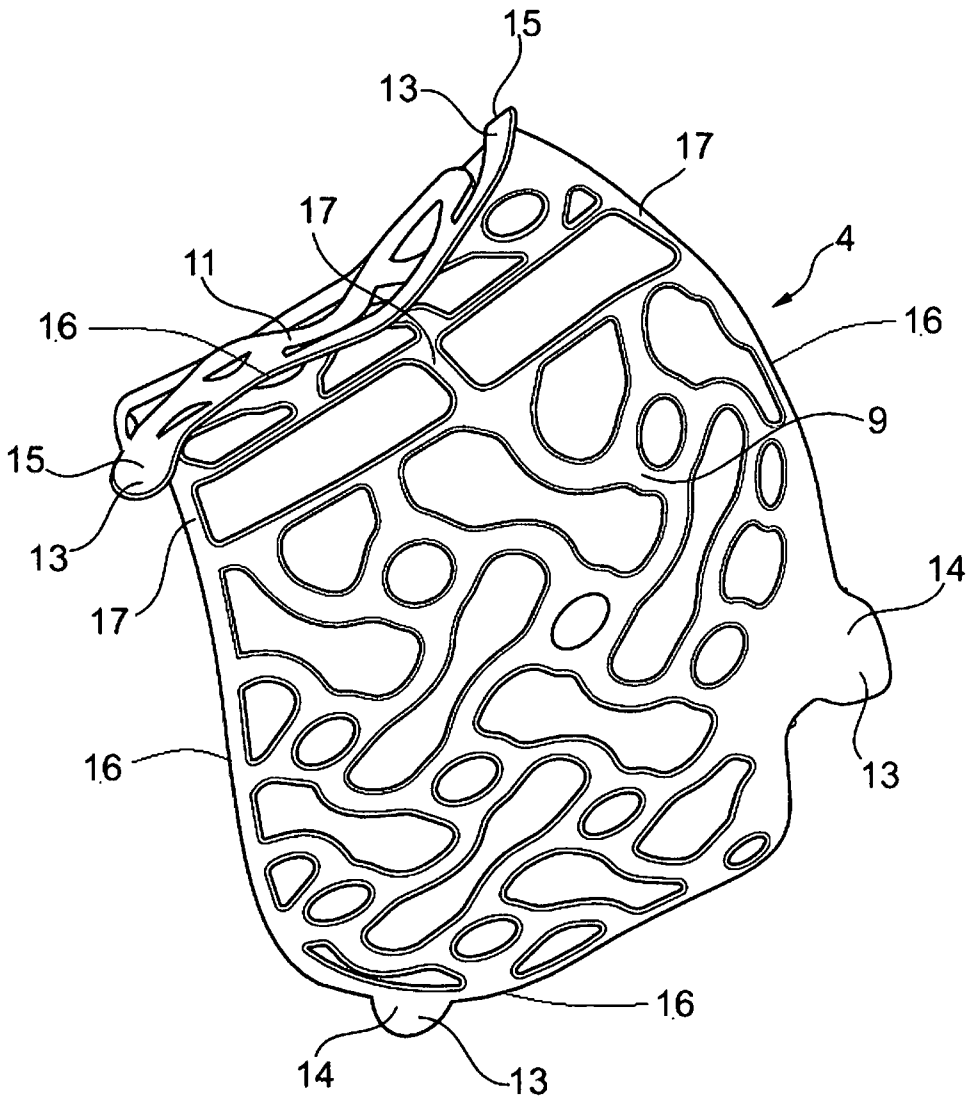


Fig. 7

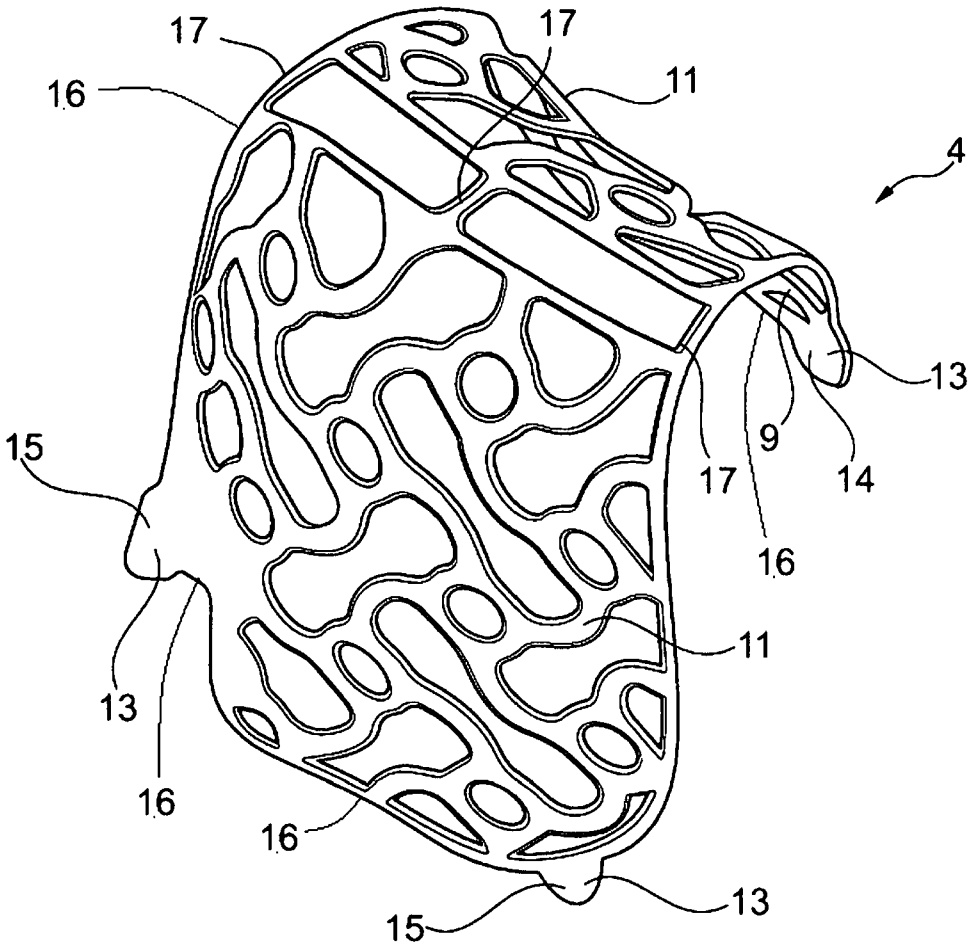


Fig. 8

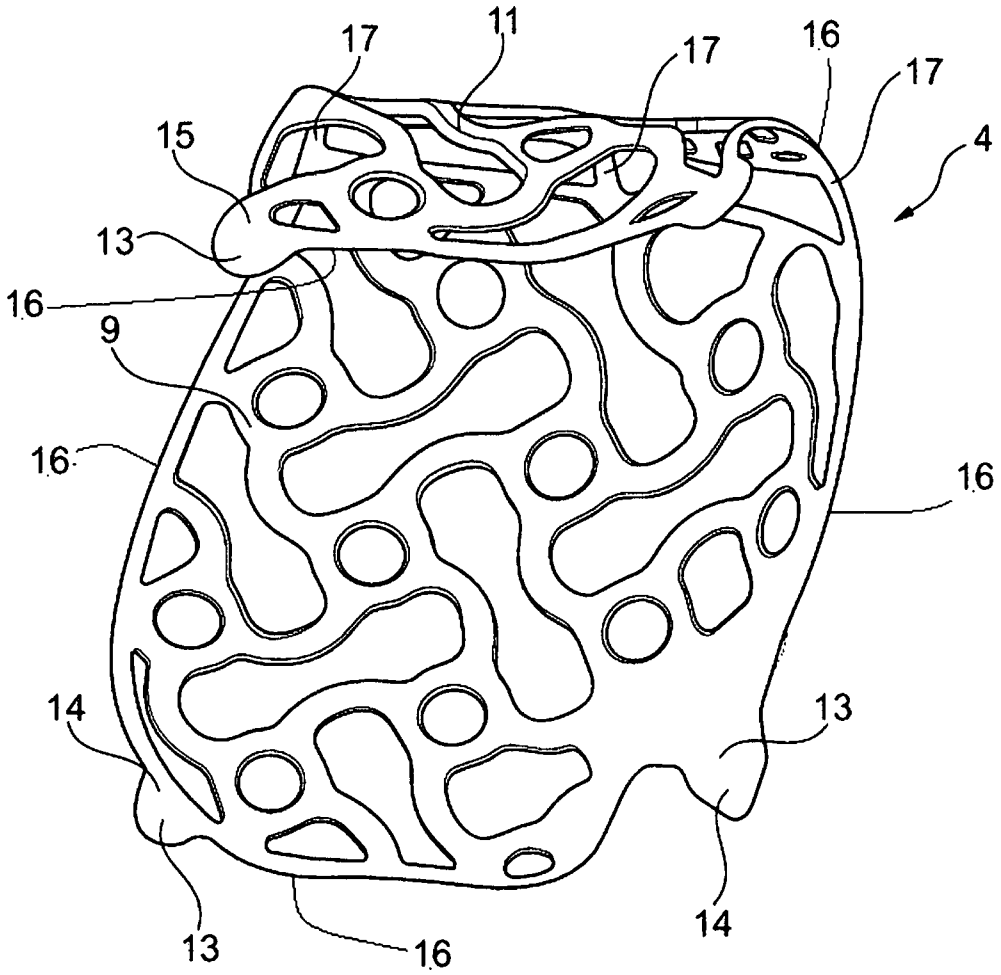
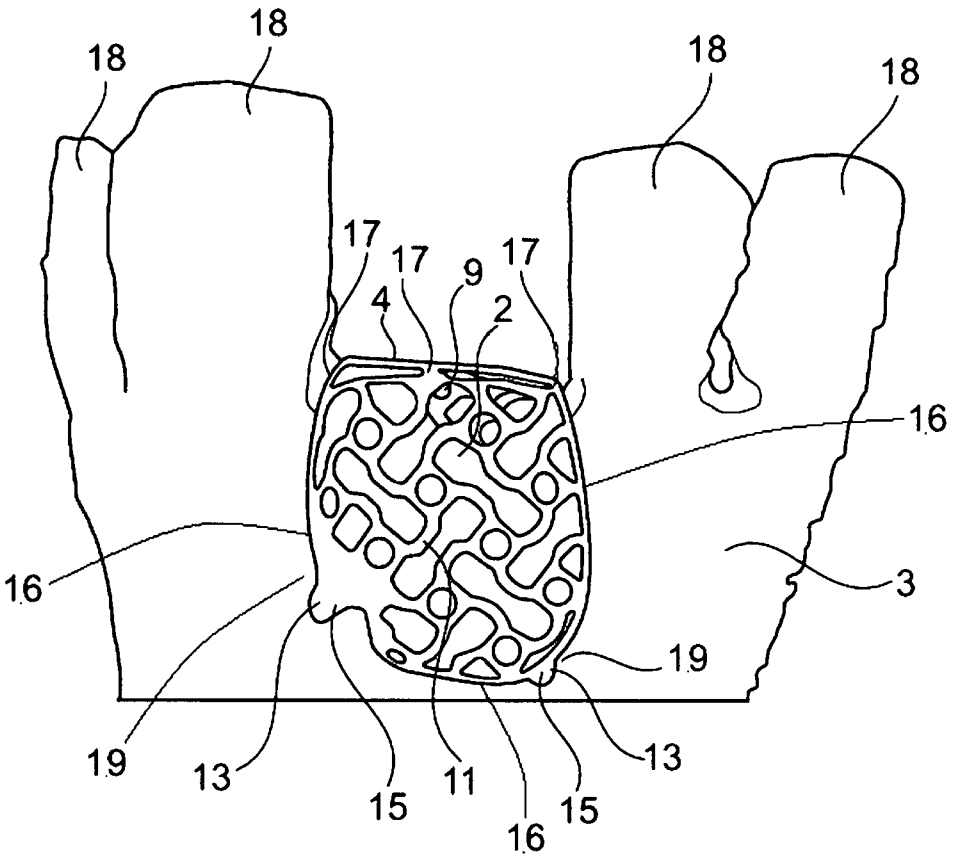
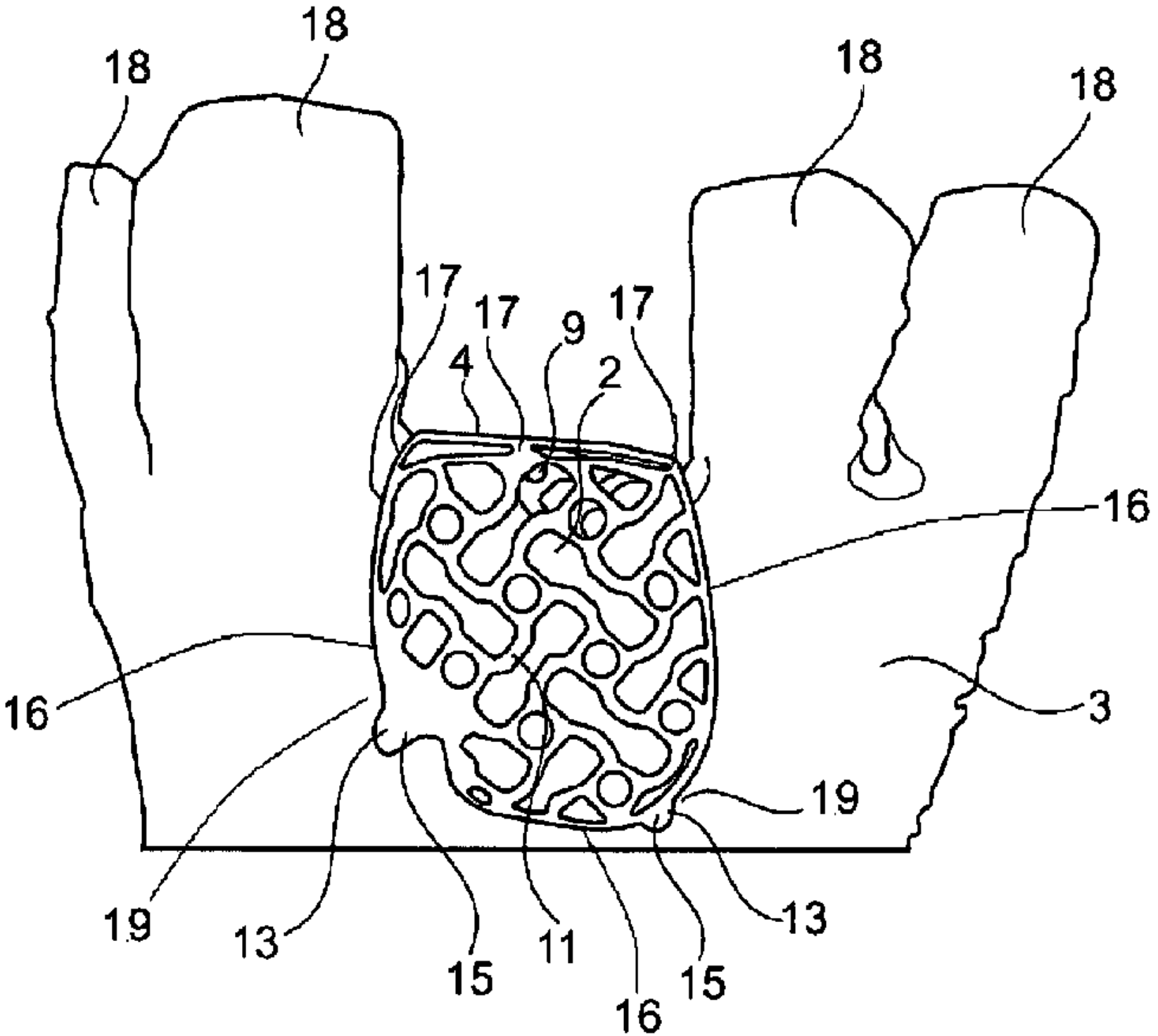


Fig. 9

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