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(54) DEVICE FOR COUPLING A BONE CONDUCTION VIBRATOR

(57) The present invention relates to a device for cou-

pling a bone conduction device, comprising a plate arranged for osseointegration and a coupling for attaching an acoustic bone conduction device to said plate.



Fig.3a

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<u>Fig. 3b</u>

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Description

Field of the invention

[0001] The present invention is generally related to the field of hearing aid devices based on bone conduction.

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Background of the invention

[0002] For most patients conductive hearing loss can be treated with classical hearing aids or by performing middle ear surgery. There are however patients for whom surgical intervention is impossible or no classical hearing aid can be applied. One such example relates to children born with major aural atresia who present with malformed middle ears, have no external ear canal and no auricle allowing for placement of a classical air-conduction hearing aid.

[0003] For these patients the only functional solution is a hearing aid that operates via bone conduction. A bone conduction device (BCD) comprises a BCD transducer and a mechanical coupling to the human body. A BCD transducer is provided with a microphone (Mic), an amplification processor (Amp), a battery (Bat) and an actuator (Act) (Fig.1.). The microphone captures an acoustic input signal and converts it into an electrical signal, the amplification circuit processes the received electrical signals and generates control signals to cause the actuator to vibrate. The actuator of a BCD is an electromagnetic or piezoelectric vibrator that transmits vibrations in the audible range to a recipient's inner ear. These vibrations stimulate the sensory cells located at the basilar membrane of the cochlea and evoke hearing sensations. There are different implementations of BCDs available, from non-implantable external BCDs to (semi-)implantable BCDs. Depending on the type of the BCD, the mechanical vibration is transferred to the inner ear by coupling vibrations of the transducer to the skin covering the skull, directly to the skull bones, to the middle ear ossicles or to the bony or membranous parts of the inner ear.

[0004] Conventionally, an external non-implantable BCD is connected to a metallic diadem or an elastic head band that is worn on the head. The function of this diadem (see Fig.2a) or the head band (Fig.2b) is to press the BCD against the skin ensuring coupling of the vibrations to the skull bone. These solutions have however, several disadvantages. First of all, patients, even little children, are forced to wear an aesthetically compromising bulky metallic diadem or an elastic head band with a BCD vibrator fixed to it. Also, the pressure exerted by the metallic diadem or the elastic head band often causes pain reactions. Last but not least, problem with the coupling of the vibrations to the skull by pressing the BCD against the skull skin is the damping of the vibrations through the skin. The damping can amount up to 20dB for the speech frequencies above 1kHz. The recent trials of replacing the coupling through the metallic diadem by using the adhesive tape glued to the skin covering the mastoid

process of the temporal bone, as described e.g. in JP2001087142 A, are cosmetically more acceptable, but still show the disadvantage of vibration damping by the skin.

[0005] Since the 1980s implantable screw fixtures made of titanium of tantalum have been introduced, based on the phenomenon of osseointegration. These screw fixtures are surgically placed directly into the skull bone and allow for coupling of the BCD transducers directly to the skull through a BCD attachment piece, called a percutaneous coupling abutment, that penetrates the skin (Fig.1). Examples can be found amongst others in US2010/112519 A1, US2004/234091 Α1 US2006/093175 A1. Osseointegration is the formation of a direct interface between an implant and bone, without intervening soft tissue. The direct structural and functional connection between living bone and the surface of a load-bearing artificial implant ensures increased mechanical stability of the implant.

[0006] The main advantage of direct contact of the osseointegrating screw fixture with the skull bone is that one gets rid of the damping of the vibrations through the skin. This solution has, however, also an important disadvantage. The percutaneous coupling abutment penetrating through the skin causes very frequent infections and inflammatory reactions around the osseointegrating fixture screw and the percutaneous coupling abutment that require medical intervention and sometimes lead even to the loss of the osseointegrating fixture screw.

[0007] This problem has recently been solved by coupling BCD transducers directly to the osseointegrating fixture screw without percutaneous abutment. In this way the BCD vibrating transducer remains under the skin and is powered by an external (transcutaneous) BCD processor sending the power and the microphone signal to the implanted vibrating transducer by a radiofrequency link. The external (transcutaneous) BCD processor is held in place by magnets contained in the implanted vibrating transducer and in the external BCD processor. An illustration can be found in US2004/032962 A1.

[0008] However, solutions wherein a BCD is coupled to an osseointegrating fixture screw, either in a percutaneous or a transcutaneous implementation, can only be considered in patients older than 4 year, as the bone needs to be thick enough (more than 3-4mm) to allow reliable placement and fixation of the osseointegrating titanium or tantalum fixture screw. This means that it is impossible to apply this solution in children under 4 years old.

[0009] Therefore children with congenital aural atresia have to use the vibrators attached to metallic head diadems, elastic head bands or glued to the skin. All these solutions are not comfortable and not optimal from the audiological point of view, because of the above-mentioned acoustic damping through the skin.

[0010] Consequently, there is a need for improvement, so that also children younger than four years can benefit from bone conduction devices with osseointegrated cou-

pling.

Summary of the invention

[0011] It is an object of embodiments of the present invention to provide for a device that allows for coupling of a bone conduction device (BCD) to the skull bone, wherein the above-mentioned drawbacks are avoided or overcome, and in particular the limitation that such coupling of a bone conduction device by means of an osseointegrating screw cannot be applied in the case of very young children.

[0012] The above objective is accomplished by the solution according to the present invention.

[0013] In a first aspect the invention relates to a device for coupling a bone conduction device, comprising a plate arranged for osseointegration and a coupling abutment for attaching an acoustic BCD to the plate.

[0014] The proposed solution indeed allows for coupling a BCD. The device of the invention comprises a plate, preferably a metallic plate, arranged for allowing and stimulating the adhesion and proliferation of osteoinducible cells on its surfaces and the acoustic bone conduction device can be fixed to that plate via the coupling abutment. The proposed solution can be used for any person in which general anaesthesia can be applied. This means in practice that even children of only 6 months of age can receive the proposed device. There is no need any more to wait until the bone has reached a certain thickness as is the case in the prior art solutions.

[0015] In a preferred embodiment the device of the invention is made of titanium or tantalum. These materials have the advantageous property of easy osseointegration with the bone. Alternatively, the plate can be made of another metal or of another material allowing for osseointegration with living bone.

[0016] In embodiments of the invention the plate comprises a plurality of screw holes, which can be used for primary fixing the plate by means of screws, for example bioresorbable screws, before the osseointegration process ensures the final fixation of the plate to the bone.

[0017] In advantageous embodiments the device for coupling according to this invention comprises at least one cut-out. By providing at least one cut-out additional area is created for bone growth.

[0018] In preferred embodiments the plate, e.g. metallic plate, comprises a transversal connection whereon said coupling is provided.

[0019] In embodiments of the invention the plate is ring shaped. In some embodiments the plate is elliptic.

[0020] Advantageously, a surface of the plate has a lattice or mesh structure arranged for inducing bone formation and osseointegration.

[0021] In one embodiment the surface of the plate that faces the skull of the patient is customized to the 3D anatomy of a patient's skull. That surface may be provided with a lattice or mesh structure.

[0022] In a preferred embodiment the plate comprises

at least one position marker. This may facilitate the correct positioning of the plate on the bone surface.

[0023] In another embodiment the part of the coupling abutment closest to the plate is polished.

[0024] In one embodiment a part of said coupling closest to said plate is covered by hydroxyapatite. This offers the advantage of an improved healing of the skin and infection prevention. Alternatively, another healing coating can be used, for example antibacterial or steroid releasing coatings.

[0025] In another embodiment the plate comprises one or more extensions. These extensions further increase the contact surface with the bone.

[0026] In another aspect the invention relates to a kit of parts comprising a device for coupling as previously described and fixation means for fixating an acoustic bone conduction device to the plate of the device.

[0027] Preferably the fixing means comprises metallic screws or bioresorbable screws or bone cement.

[0028] For purposes of summarizing the invention and the advantages achieved over the prior art, certain objects and advantages of the invention have been described herein above. Of course, it is to be understood that not necessarily all such objects or advantages may be achieved in accordance with any particular embodiment of the invention. Thus, for example, those skilled in the art will recognize that the invention may be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other objects or advantages as may be taught or suggested herein.

[0029] The above and other aspects of the invention will be apparent from and elucidated with reference to the embodiment(s) described hereinafter.

Brief description of the drawings

[0030] The invention will now be described further, by way of example, with reference to the accompanying drawings, wherein like reference numerals refer to like elements in the various figures.

Fig.1 illustrates a prior art solution with a percutaneous osseointegrating screw fixture.

Fig.2a and 2b illustrate a metallic diadem and a head band as used in prior art solutions.

Fig.3a illustrates an above view of the ring shaped osseointegration-enabled scaffold plate with integrated coupling abutment according to the present invention. Fig.3b shows the undersurface of the plate

Fig.4 illustrates an embodiment where the osseointegration-enabled scaffold plate and the coupling abutment are produced as two separate pieces that can be connected together with e.g. a screw.

Fig.5 illustrates a lattice structure as found at the undersurface of the scaffold plate in certain embodiments.

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Fig.6 illustrates the use of an (arrow) marker on the scaffold plate to ease a correct positioning.

Fig.7 illustrates an osseointegration-enabled scaffold plate provided with cut-outs (shown as crosshatched areas) in an embodiment with a separate coupling abutment fixed to the osseointegration-enabled scaffold plate by a screw.

Fig.8 illustrates a scaffold plate provided with one or more extensions. The undersurface with the mesh structure is being shown.

Fig.9 illustrates the connecting parts being undercut to facilitate removal of the coupling abutment.

Detailed description of illustrative embodiments

[0031] The present invention will be described with respect to particular embodiments and with reference to certain drawings but the invention is not limited thereto but only by the claims.

[0032] Furthermore, the terms first, second and the like in the description and in the claims, are used for distinguishing between similar elements and not necessarily for describing a sequence, either temporally, spatially, in ranking or in any other manner. It is to be understood that the terms so used are interchangeable under appropriate circumstances and that the embodiments of the invention described herein are capable of operation in other sequences than described or illustrated herein.

[0033] It is to be noticed that the term "comprising", used in the claims, should not be interpreted as being restricted to the means listed thereafter; it does not exclude other elements or steps. It is thus to be interpreted as specifying the presence of the stated features, integers, steps or components as referred to, but does not preclude the presence or addition of one or more other features, integers, steps or components, or groups there-of. Thus, the scope of the expression "a device comprising means A and B" should not be limited to devices consisting only of components A and B. It means that with respect to the present invention, the only relevant components of the device are A and B.

[0034] Reference throughout this specification to "one embodiment" or "an embodiment" means that a particular feature, structure or characteristic described in connection with the embodiment is included in at least one embodiment of the present invention. Thus, appearances of the phrases "in one embodiment" or "in an embodiment" in various places throughout this specification are not necessarily all referring to the same embodiment, but may. Furthermore, the particular features, structures or characteristics may be combined in any suitable manner, as would be apparent to one of ordinary skill in the art from this disclosure, in one or more embodiments.

[0035] Similarly it should be appreciated that in the description of exemplary embodiments of the invention, various features of the invention are sometimes grouped together in a single embodiment, figure, or description thereof for the purpose of streamlining the disclosure and

aiding in the understanding of one or more of the various inventive aspects. This method of disclosure, however, is not to be interpreted as reflecting an intention that the claimed invention requires more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive aspects lie in less than all features of a single foregoing disclosed embodiment. Thus, the claims following the detailed description are hereby expressly incorporated into this detailed description, with each claim standing on its own as a separate embodiment of this invention.

[0036] Furthermore, while some embodiments described herein include some but not other features included in other embodiments, combinations of features of different embodiments are meant to be within the scope of the invention, and form different embodiments, as would be understood by those in the art. For example, in the following claims, any of the claimed embodiments can be used in any combination.

[0037] It should be noted that the use of particular terminology when describing certain features or aspects of the invention should not be taken to imply that the terminology is being redefined herein to be restricted to include any specific characteristics of the features or aspects of the invention with which that terminology is associated. [0038] In the description provided herein, numerous specific details are set forth. However, it is understood that embodiments of the invention may be practiced without these specific details. In other instances, well-known methods, structures and techniques have not been shown in detail in order not to obscure an understanding of this description.

[0039] The invention presents a device that facilitates the osseointegrated coupling of a bone conduction device (BCD) to the skull of a patient. It is a major advantage of the proposed device that it can be used even for children as young as 6 months of age, i.e. as soon as a general anaesthesia can be applied. This is in great contrast to the prior art solutions as indicated in the background section.

[0040] The device according to the invention comprises an osseointegration-enabled scaffold plate, hereafter sometimes also referred to as 'scaffold plate' or just 'plate', provided with a coupling abutment (further in this description also shortened to 'abutment') for attaching a BCD (Fig.3a and 3b). A scaffold plate is a 3D matrix, for example a metallic 3D lattice or mesh, that allows and stimulates the adhesion and proliferation of osteoinducible cells on its surfaces.

[0041] The osseointegration-enabled scaffold plate and the abutment can in some embodiments be manufactured as one integrated piece. In alternative embodiments they can be produced as two or more pieces to be connected together with e.g. one or more screws or other fixation means (Fig.4.).

[0042] The scaffold plate can have different shapes in different embodiments of the invention, ranging for example from regular circular to oval or irregular, without

however being limited thereto. In advantageous embodiments the plate, preferably a metallic plate, of the scaffold is ring shaped, for example as a circular or an elliptic ring. Such embodiments were already illustrated in Fig.3. Such a ring provides the main stability, strength, and fixation to the device.

[0043] The coupling abutment for attachment of a BCD is for example cylindrically or conically shaped. Preferably the coupling abutment is positioned centrally on the scaffold plate. However, excentric positions are also possible in other embodiments.

[0044] In some embodiments the coupling abutment will pierce the skin once placed, so allowing for fixation of a BCD, for example a commercially available percutaneous BCD. In other embodiments the abutment does not pierce the skin and allows for connecting an implantable BCD with the vibrating part remaining under the skin. [0045] The coupling abutment is in some embodiments so oriented that, when the device is applied to a patient, the abutment is perpendicular to the skin surface. In that way the abutment is also positioned perpendicular to the underlying bone so that collision is avoided between the BCD and the patient's skull. However, in some patients it may be more advantageous to deviate from a 90-degree angle between the osseointegration-enabled scaffold plate and the axis of the coupling abutment. An inclination relative to the X, Y or Z axis may then be applied. [0046] The coupling abutment can in preferred embodiments have different lengths and shapes making it suitable for connecting different percutaneous BCDs with the vibrating element placed above the skin surface as well as implantable BCDs wherein the vibrating part remains under the skin. The abutment is advantageously so shaped that the connecting parts of commercially available bone conduction devices fit inside or around the coupling abutment by means of fit geometry or threads. The abutment may have a length between for example 1 and 15 millimetres. The abutment may be cylindrically or conically shaped. In order to optimize the piercing through the skin and to minimize the risk of local infections, a part of the abutment penetrating through the skin may be polished or covered with other biocompatible materials, for example hydroxyapatite or other coatings improving healing of the skin or preventing infection around the coupling abutment, for example antibacterial or steroid releasing coatings.

[0047] The device according to the present invention is preferably made in titanium or tantalum. Titanium and tantalum are preferred materials because of their strength and hardness. Further they are easily osseointegrated with the bone in the form of a direct structural and functional connection between living bone and the surface of a load-bearing artificial implant that ensures increased mechanical stability of the implant. However, also other metals or biocompatible materials can be applied.

[0048] In advantageous embodiments the plate of the device can be primarily attached to the skull of the patient

by means of screws, for example metallic or bioresorbable screws. The osseointegration-enabled scaffold plate is then provided with a plurality of screw holes, for example two or three or more screw holes. The screws hold the device in place during the period of osseointegration. The screw holes may be counterbore structures in certain embodiments. In other embodiments also other methods for fixation to the patient's skull can be envisaged, for example by means of bone cement. The screws can be positioned perpendicular to the bone structure or with an inclination increasing the mechanical stability of the device.

[0049] Eventually the scaffold plate gets itself osseointegrated in the bone. In this way the scaffold replaces the osseointegrating fixture applied in the prior art solutions as discussed in the background section.

[0050] In order to obtain good osseointegration of the scaffold it is important to ensure that the undersurface of the scaffold plate (i.e. the surface of the plate that faces the skull of the patient), makes good and tight contact with the bone. In order to achieve this the scaffold plate can in some embodiments of the device according to the invention be custom made following the three-dimensional (3D) structure of the skull bone. This can be achieved by means of a customised manufacturing, for example based on a computer tomography (CT) scan or a cone-beam computer tomography (CBCT) scan of the patient's skull with subsequent 3D reconstruction of the bone surface. The CT or CBCT images of the patient, including the temporal and parietal region, are collected to obtain a DICOM (Digital Imaging and Communications in Medicine) format image data set. Using three-dimensional reconstruction software for 3D design, a 3D-model of the patient is acquired from the DICOM format image data.

[0051] The data, e.g. the image data, concerning the design of the device may next be transformed into 3D printable and machinable data.

[0052] The post-processing of the appliance may be performed by using a computer numerical control centre or a numerically controlled milling machine, and manually drilling, grinding and polishing. Additional surface treatments can be applied to the device, to optimize for example the osseointegration, the soft tissue integration, sound conduction and healing. This can contain, but is not limited to, an acid etching process, a specialized coating, anodization or any other chemical/mechanical treatment.

[0053] In order to facilitate and shorten the process of osseointegration, the surface of osseointegration-enabled scaffold plate having contact with the bone can be provided with a lattice or mesh structure capable of inducing bone formation. Fig.5 provides an example of such a mesh structure.

[0054] In advantageous embodiments the plate, e.g. metallic plate, comprises, for example on its outer ring, one or more markings that facilitate the correct positioning of the scaffold plate on the bone surface. The mark-

ers, for example arrows, can define e.g. the top-down direction or point at the predefined landmarks (Fig.6). **[0055]** In an embodiment of the device of the invention, the osseointegration-enabled scaffold plate has a form of a disc, e.g. a circular or elliptic disc, with a flat, noncustomized undersurface. In order to obtain good and tight contact of the flat undersurface of such scaffold plate with the bone, the bone has to be first flattened with a burr in such embodiments. An advantage of this solution is that this type of scaffold is suitable for different patients and avoids the necessity for customized 3D prints. Additionally, due to its axial symmetry, such a 'ready-for-all' embodiment can be positioned at all axial angles and does not require markers defining the directions or pointing at the predefined landmarks.

[0056] In some embodiments the scaffold plate comprises two or more cut-outs with a connecting part in between the cut-outs, as shown in Fig.7. In some embodiments the connecting parts between the cut-outs may form the shape of a cross. Providing these cut-outs is advantageous in that in such a way additional area for bone growth is created, which may reduce the period of time required for the osseointegration. In Fig.7 an embodiment with a separate coupling abutment is shown. Such abutment is fixed to the osseointegration-enabled scaffold plate by a screw. As mentioned above the BCD can fit inside or around the coupling abutment by means of fit geometry or threads.

[0057] In another embodiment the osseointegration-enabled scaffold plate is provided with one or more extensions, as depicted in Fig.8. This increases the surface of the contact with the bone, facilitates osseointegration and ensures increased strength of the coupling to the bone. These extensions can be provided with additional screw holes for the primary fixation. The different extensions do not necessarily have all the same shape or size. The number and the size of these extensions can be defined on basis of the preoperative CT or CBCT scans in such a way that optimal fixation points relative to the patient's anatomy can be obtained.

[0058] An abutment for coupling a BCD can be attached to the scaffold plate or to the connecting part between the cut-outs. As already mentioned above in certain embodiments this abutment may be integrated with the connecting part of the plate or fixed to it with for example a screw. In preferred embodiments the abutment is centrally positioned on the connecting part. However, as mentioned above, excentric positions are also possible in some embodiments.

[0059] In yet another embodiment, illustrated in Fig.9, the connecting parts in between the cut-outs, lateral relating to the abutment, can be recessed or undercut in order to facilitate the removal of the part of the device comprising the coupling abutment in case a problem occurs. In this case there is no need for extensive drill-out of the bone and removal of the whole already osseointegrated scaffold plate.

[0060] In another aspect the invention relates to kit of

parts comprising a device for coupling a bone conduction device as described above and fixation means for fixing of the osseointegration-enabled scaffold plate to the bone as well as screw(s) for connecting of the coupling abutment to the osseointegration-enabled scaffold plate. [0061] While the invention has been illustrated and described in detail in the drawings and foregoing description, such illustration and description are to be considered illustrative or exemplary and not restrictive. The foregoing description details certain embodiments of the invention. It will be appreciated, however, that no matter how detailed the foregoing appears in text, the invention may be practiced in many ways. The invention is not limited to the disclosed embodiments.

[0062] Other variations to the disclosed embodiments can be understood and effected by those skilled in the art in practicing the claimed invention, from a study of the drawings, the disclosure and the appended claims. In the claims, the word "comprising" does not exclude other elements or steps, and the indefinite article "a" or "an" does not exclude a plurality. A single processor or other unit may fulfil the functions of several items recited in the claims. The mere fact that certain measures are recited in mutually different dependent claims does not indicate that a combination of these measures cannot be used to advantage. A computer program may be stored/distributed on a suitable medium, such as an optical storage medium or a solid-state medium supplied together with or as part of other hardware, but may also be distributed in other forms, such as via the Internet or other wired or wireless telecommunication systems. Any reference signs in the claims should not be construed as limiting the scope.

Claims

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- Device for coupling a bone conduction device, comprising a plate arranged for osseointegration and a coupling abutment for attaching an acoustic bone conduction device to said plate.
- 2. Device for coupling as in claim 1, implemented in titanium or tantalum or in another biocompatible material.
- Device for coupling as in any of the previous claims, wherein said plate comprises a plurality of screw holes for fixing said metallic plate.
- **4.** Device for coupling as in any of the previous claims, wherein said plate comprises at least one cut-out.
- **5.** Device for coupling as in any of the previous claims, wherein said plate is ring shaped.
- Device for coupling as in claim 5, wherein said plate is elliptic.

- **7.** Device for coupling as in claim 5 or 6, wherein said plate comprises a transversal connection whereon said coupling is provided.
- **8.** Device for coupling as in any of the previous claims, wherein a surface of said plate has a structure arranged for inducing bone formation and osseointegration.
- **9.** Device for coupling as in claim 8, wherein said surface provided with said structure is customized to the 3D anatomy of a patient's skull.
- Device for coupling as in any of the previous claims, wherein said plate comprises at least one position marker.
- **11.** Device for coupling as in any of the previous claims, wherein a part of said coupling abutment closest to said plate is polished.
- **12.** Device for coupling as in any of the previous claims, wherein a part of said coupling abutment closest to said plate is covered by hydroxyapatite.
- 13. Device for coupling as in any of the previous claims, wherein said plate comprises one or more extensions.
- **14.** Kit of parts comprising a device for coupling as in any of the previous claims and fixing means for fixating an acoustic bone conduction device to said plate of said device.
- **15.** Kit of parts as in claim 14, wherein said fixing means comprises metallic screws or bioresorbable screws or bone cement.

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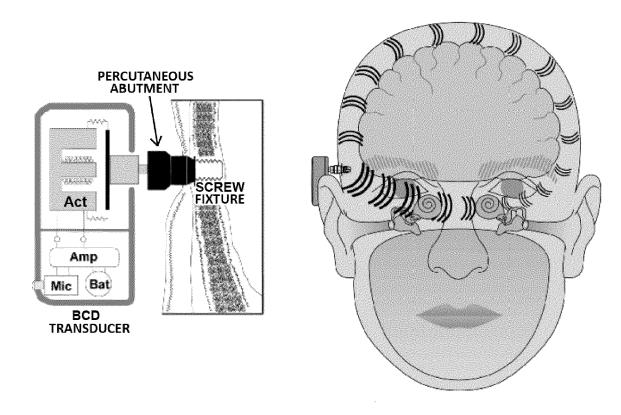


Fig.1

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Fig.2a

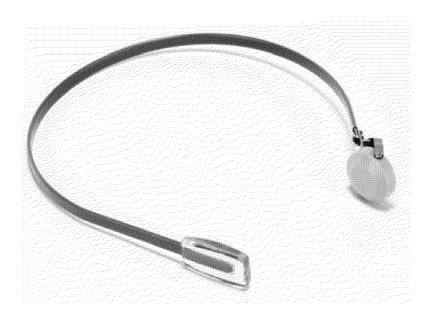


Fig.2b





Fig. 3b

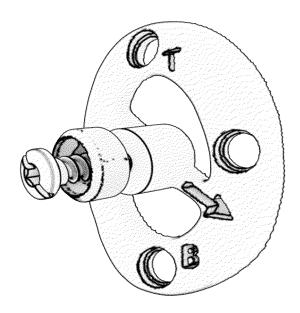
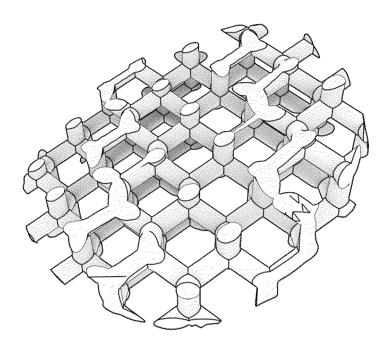
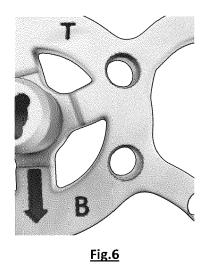
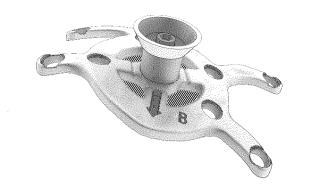


Fig.4



<u>Fig.5</u>





<u>Fig.7</u>



Fig.8

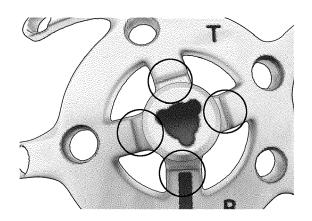


Fig.9



EUROPEAN SEARCH REPORT

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	DOCUMENTS CONSID	ERED TO BE R	ELEVANT		
Category	Citation of document with in of relevant passa		priate,	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
Х	WO 2018/024275 A1 (8 February 2018 (20		[DE])	1-4, 8-11, 13-15	INV. H04R25/00
	* page 1 * * page 22 - page 25 * page 23; figures	; figures 4-9) *		
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	The present search report has b	peen drawn up for all d	plaims		
	Place of search	Date of comp	letion of the search		Examiner
	The Hague	19 Apr	ril 2021	Bet	gen, Benjamin
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