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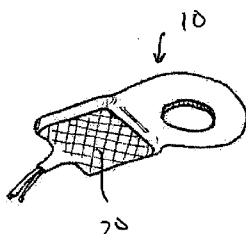


Figure 2

(57) Abstract: Disclosed is a medical device and a method of attaching the medical device to a user or another medical device. The medical device comprises an attachment region comprising a plurality of hair-like members. In one example, at least some of the hair-like members may be coated in an adhesive to enhance attachment. The attachment region may be provided integrally with the device or may be applied as a pad. The medical devices may be medical implants such as cochlear implants.



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MEDICAL DEVICE AND FIXATION

FIELD

The present invention relates to the fastening or securing of a, or a part of a, medical device to a part of a user's body or another part of the medical device.

PRIORITY

The present application claims priority from Australian Provisional Patent Application No. 2009900212 entitled "Fixation of a Medical Device", filed on 20 January 2009.

The entire content of this document is hereby incorporated by reference.

INCORPORATION BY REFERENCE

The following documents are referred to in the following description:

- "Nanomolding Based Fabrication of Synthetic Gecko Foot-Hairs"; Metin Sitti and Ronald S. Fearing; IEEE-NANO 2002; pp.137-140;
- "A Biodegradable and Biocompatible Gecko-inspired Tissue Adhesive"; Madhavi et al; Proceedings of the National Academy of Sciences February 19, 2008 vol. 105 no. 7 2307-2312;
- "A reversible Wet/Dry Adhesive Inspired by Mussels and Geckos"; Lee et al; Nature 448, 338-341 (19 July 2007) | doi:10.1038/nature05968;
- US Patent No. 6,872,439 entitled "Adhesive Microstructure and Method of Forming Same".

The entire content of each of these documents is hereby incorporated by reference.

BACKGROUND

In many applications of medical implants or devices, it is necessary to attach a medical implant or device to a portion of a user's body, either internally or externally. In some cases, a part of a medical implant or device also needs to be attached to another part of the medical implant or device. In some cases, this attachment is temporary.

SUMMARY

According to one aspect, there is provided a medical device for attachment to a part of a user of the medical device, the medical device having an attachment region wherein the attachment region comprises a plurality of hair-like members.

In one form, the plurality of hair-like members are formed from silicone.

In one form, the attachment region is provided by a pad attached to the medical device.

5 In another form, the attachment region is integral to the medical device.

In one form, the medical device is a stimulator of a cochlear implant.

In one form, there are provided at least two attachment regions.

10

In one form, one of the at least two attachment regions is a receiving region for a magnet.

In one form, at least some of the hair-like members are coated with an adhesive.

15 According to a second aspect, there is provided a method of forming an attachment region on a part of a medical device, the method comprising providing a plurality of hair-like members on the part of the medical device.

20 In one form, the step of providing the plurality of hair-like members comprises moulding a plurality of silicone cylinders on the part of the medical device.

In another form, the step of providing the plurality of hair-like members comprises attaching a pad comprising the plurality of hair-like members to the part of the medical device.

25 In one form, the method further comprises coating at least some of the hair-like members with an adhesive.

30 According to another aspect, there is provided a sheet of material having two sides, for application to a portion of a medical device, each side of the sheet of material having an attachment region, and wherein the attachment region of at least one of the two sides is formed from a plurality of hair-like members.

In one form, the sheet of material is bio-resorbable.

35 In one form, at least some of the hair-like members are coated with an adhesive.

According to another aspect, there is provided a method of implanting a medical device in a user, the method comprising:

exposing a portion of bone of the user;

attaching the medical device to the exposed portion of bone without forming a seat in the

5 exposed portion of bone; and

covering the attached medical device and the exposed portion of bone.

In one form, the medical device is a stimulator of a cochlear implant.

10 According to another aspect, there is provided a medical device having a magnet receiving region for receiving a magnet, wherein the magnet receiving region is open.

In one form, the magnet receiving region comprises an attachment region comprising a plurality of hair-like members.

15

In one form, the medical device is a stimulator of a cochlear implant.

DRAWINGS

Various aspects of the present invention will be described in detail with reference to the following
20 drawings in which:

Figure 1 – shows a cochlear implant including a fixation region according to one aspect of the present invention;

25 Figure 2 – shows a cochlear implant showing a different fixation region according to one aspect of the present invention;

Figure 3 – shows a traditional method of implanting a cochlear implant;

Figure 4 – shows a modified method of implanting a cochlear implant according to an aspect of the present invention;

Figure 5 – shows a “Behind the Ear (BTE) arrangement of a medical hearing device;

30 Figure 6 – shows an external coil housing of a cochlear implant system according to one aspect of the present invention;

Figure 7 – shows an internal stimulator housing of a cochlear implant according to an aspect of the present invention;

Figure 8 – shows a side view of the housing of Figure 7;

35 Figure 9 – shows the housing of Figure 7 without the magnet in place;

Figure 10 – shows an external sound processor of a cochlear implant system according to one aspect of the present invention; and

Figure 11 – shows a representation of the hair-like members forming the attachment region.

5 DETAILED DESCRIPTION

It has been discovered that a region comprising a plurality of thin, hair-like members, such as small cylinders, can provide an attractive force when applied to a surface. Due to their small size, the hairs will make intimate contact with the surface and stick to it via many weak bonds. As each individual hair is small, any bond it makes with the surface will be quite weak, however, with a plurality of
10 hairs, the overall strength is quite high and so provides an attachment force between the hairs and the surface to which they are applied.

According to one aspect of the present invention, there is provided a medical device having an attachment region which is made up of a plurality of hair-like members.

15 A medical device, such as a cochlear implant system, has several parts which in use, are required to be attached to a part of the user's body, either internally or externally. In some cases, a part of the medical device is required to be attached to another part of the medical device. Sometimes, this attachment is only required to be temporary.

20 There are a number of interfaces where this technology may be applied:

1. The fixation of the implant to the temporal bone and/or periosteum to prevent translation (both the stimulator and/or the electrode could have these features to prevent movement)
- 25 2. The fixation of the implant coil magnet to the implant (eliminating the need for a silicone pocket)
3. The fixation of the external RF coil to the scalp of the recipient (at least partially eliminating the need for a magnet for coil retention)
4. The fixation of the BTE (or other external component of a CI or hearing aid system) to the
30 recipient (eliminating the need for an earhook)

This aspect of the invention provides an attachment region in the form of a surface area or series of surface areas that have the hair-like members, facilitating adherence to a corresponding mating surface, to which the device is to be attached. Such an arrangement provides for strong resistance to
35 sliding (translational movement) but less resistance to removal upon applying force normal to the surface to which they are attached. Therefore, in the case of an explant procedure of an implanted

medical device, repositioning or explant is relatively easy, but when under a skin flap or periosteum, translational movement is strongly resisted.

In a further embodiment, the hair-like members may be impregnated or coated with a substance such as an adhesive to further assist in the attachment. In particular, in the case of use in a wet environment, such as within the body of a user, certain adhesives may be used to enhance the attachment force in the wet environment.

In one example, a sugar-based adhesive, such as dextran, a branched glucan, may be used to coat the ends of at least some of the hair-like members to enhance the adhesive action of the attachment region. An example of such an adhesive is described in the paper "A Biodegradable and Biocompatible Gecko-inspired Tissue Adhesive" previously incorporated by reference.

Another example is described in the paper entitled "A reversible Wet/Dry Adhesive Inspired by Mussels and Geckos", also previously incorporated by reference.

In another embodiment, these features may be formed on a strip of bio-resorbable material which is used as a tape or strip to hold the device down until the device is stabilised by fibrous tissue formation. These features may be formed on one side only of the strip, or on both sides. If not formed on one side, more conventional adhering substances may be provided on that one side, such as an appropriate glue.

In one form, the attachment region may be made by forming a plurality of hair-like members. In one example, these may be made by moulding small cylinders (e.g. diameters of about 0.01mm and height of about 0.05mm) from silicone onto, or as part of, the region. Various methods of fabricating these hair-like members may be used. Two examples of methods of fabrication are described in the IEEE publication "Nanomolding Based Fabrication of Synthetic Gecko Foot-Hairs" previously incorporated by reference. Other examples are described in US Patent No. 6,872,439 previously incorporated by reference.

In one embodiment, a pad or attachment region, fabricated as described above may be attached to the cochlear implant on the surface which interfaces with the bone or periosteum of the recipient.

Possible pad or attachment region patterns are shown in Figure 1 and Figure 2, which show a medical device such as a cochlear implant stimulator 10 with attachment regions or pads 20 (20').

The attachment regions or pads 20, 20' may be held in place by adhesive (such as silicone adhesive or cyanoacrylate) or may be held by the silicone overmould. In this example, the silicone is

prevented from coating the active surfaces of the pads 20, 20'. In other embodiments, the pads may be formed with these features on both sides to facilitate attachment to the implant surface.

In other embodiments, the surface of the medical device or cochlear implant stimulator 10 itself may be so formed to provide the attachment region 20, without the use of a separate pad or strip. In other embodiments, a combination of directly-formed attachment regions and added pads or strips in the form of one or more sheets comprising the hair-like members providing the attachment regions may be used.

Thus, in another aspect, there is provided a sheet of material having two sides, for application to a portion of a medical device, each side of the sheet of material having an attachment region, and wherein the attachment region of at least one of the two sides is formed from a plurality of hair-like members. In some examples, the sheet of material is bio-resorbable. In some examples, at least some of the hair-like members are coated with an adhesive as described previously.

This arrangement could eliminate the need for drilling a seat 51 in the bone or skull 50 (as shown in Figure 3), which is a time-consuming part of the surgical procedure. In children, where the bone is often less than 2mm thick, drilling to the dural membrane is required. The seat 51 (Figure 3) is normally necessary to locate and stabilise the medical device 10 particularly in the immediate post operative period while the medical device 10 is encapsulated in fibrous tissue. The attachment region 20 has the property that it is strong in shear but weaker in direct pull and peel tests. Therefore, removal of the medical device 10 to reposition or replace it is readily achieved. This also means that if the medical device is peeled off the skull 50, only a few hairs at a time will be exposed to force, and so will therefore debond from the skull. This means that the medical device, such as the cochlear implant stimulator can be easily removed (as opposed to adhering the entire bottom surface of the stimulator to the skull). Alternatively, poking a thin scraper under the stimulator can be similarly be used to break only a few bonds at a time.

Additional attachment regions 20 could be incorporated in the electrode arrays to assist the surgeon in "tacking" these into position in the mastoid cavity and through the facial recess.

Figure 4 shows an example of an implantation method possible by the use of this aspect of the present invention. In this method, it is not required to form a seat in the bone 50, and the medical device, in this case, a cochlear implant stimulator 10 may lie directly onto the bone 50 and be retained thereto by the use of the attachment region (not visible in this view) which would be between the stimulator 10 and the bone 50. This arrangement would allow a new method of

implanting a medical device, namely, exposing a portion of bone of the user; attaching the medical device to the exposed portion of bone without forming a seat in the exposed portion of bone; and covering the exposed portion of bone. As will be understood, the step of exposing the portion of bone will involve lifting a flap of tissue such as a portion of the scalp, from the skull and then the step of covering the exposed portion of the bone would involve replacing the scalp portion in its original position covering the bone and the attached medical device.

A further application of this technology to a cochlear implant system is associated with the external subsystems. Usually, a recipient wears a sound processor 11 as shown in Figure 5, behind the ear (BTE). An RF coil 12 is connected to the BTE by a cable 13. The RF coil 12 transmits information transcutaneously to the implant, being the stimulator (Figure 2 for example), which has its own RF coil. The relative position of the two coils is important to its reliable operation and so magnets at the centre of both the internal and external coils provide this alignment. However, the magnet in the implant affects the compatibility with MRI scanners. MRI is an important diagnostic tool which scans the reflected magnetic impulse of tissue in a high magnetic field. The presence of the implant magnet can be hazardous to the recipient at higher field strengths and can distort the image obtained, particularly in the region around the magnet. Elimination or temporary removal of the magnet may therefore be achieved or facilitated in some applications if so desired.

In Figure 6, the face of the external RF coil 12 moulding includes features according to one aspect of the invention (i.e. an attachment region 20), as previously described, to enable attachment to the head of the recipient. Attachment region 20 may be provided by one or more pads or strips and/or may be incorporated directly onto or integrally with, the surface.

Another application is shown in Figure 7, Figure 8 and Figure 9, relating to the application of a magnet 30 to the medical device or cochlear implant stimulator 10. Here the magnet 30 is attached to the silicone substrate of the implant 10 over moulding using mating surfaces as previously described. This eliminates the magnet pocket design used in conventional devices. The magnet pocket or magnet receiving region 14 (see Figure 9) is provided so that the magnet 30 can be removed using an outpatient procedure prior to an MRI scan. Removal and replacement of the magnet 30 in conventional devices is not always straightforward and damage to the thin silicone flange of the magnet pocket frequently occurs. Furthermore, the pocket can be a site where infection takes hold. As can be seen in Figure 8 and Figure 9, the silicone around the magnet 30 has been trimmed back and retention of the magnet 30 is achieved by the attachment regions 20 according to the various aspects of the present invention, on the mating surfaces. In one example, the magnet

pocket or magnet receiving region 14 is open, i.e. there is little or no material covering the magnet receiving region 14, thus allowing easy placement and removal of the magnet 30.

In one example, the magnet receiving region 14 may have the attachment region 20. In another example, the magnet receiving region may not have the attachment region 20, but the attachment region 20 is associated with the magnet, still allowing the magnet receiving region to be formed open.

A further application is to apply an attachment region 20 to the external medical device being a sound processor itself (Figure 10). Conventionally, the behind-the-ear sound processor is retained to the head of the recipient using an ear hook 15 (see Figure 5) (this is also the most common method of retention for hearing aids) as previously described with reference to Figure 5. The ear hook 15 increases the visibility of the aid, which is undesirable due to the stigma of hearing loss. Furthermore, the ear hook 15 can be a source of irritation to the recipient (due to the combination of sweat, natural body oils and relative movement between the pinna, ear hook and scalp).

In this embodiment, a pad or pads, or general attachment region 20 of the present invention, may be added to the surface of the sound processor 11, or the surface of the sound processor moulding itself could be so treated, to enable attachment directly to the head of the recipient. This would minimise the contact area with the recipient and would also provide much greater design freedom in the size and shape of the sound processor 11 (currently the size is limited by the force due to mass which can be applied to the ear hook and the shape is limited by the contour of the pinna, as the device sits so closely behind it).

Figure 11 shows a representation of the hair-like members forming the attachment region 20.

The various aspects of the present invention provide a number of advantages as follows:

1. The fixation of the implant to the temporal bone and/or periosteum to prevent translation. This eliminates or reduces the need to suture the device in place. Suturing takes some time to prepare the holes in the bone to which the suture is attached; furthermore access for suturing is limited, particularly when minimally invasive techniques are employed. Sometimes other means are used for fixation – these include titanium brackets and bone screws. This invention enables the implant to be placed without additional fixation and have the assurance that it will not migrate over time.

2. The fixation of the implant coil magnet to the implant (eliminating the need for a conventional silicone magnet pocket). Currently a silicone pocket is formed in the implant to retain the magnet. However the pocket is open so that the magnet can be easily removed in case the recipient needs an MRI scan. This pocket can be an area where biofilms attach leading the chronic bacterial infection. There are advantages where the magnet can be retained to the implant silicone without needing to be almost fully encapsulated.
3. The fixation of the external RF coil to the scalp of the recipient (at least partially eliminating the need for a magnet for coil retention).
4. The fixation of the BTE (or other external component of a CI or hearing aid system) to the recipient (eliminating the need for an earhook).

While the various aspects of the present invention have been described with specific reference to a cochlear implant, it will be understood that the principles of the various aspects of the present invention may be applied to other types of medical implants. For example:

ABI (Auditory Brainstem Implant, electrode for hearing, placed in the brainstem) such as Cochlear Corporation's Nucleus 24 [R] Multichannel Auditory Brainstem Implant (Multichannel ABI).

The auditory brainstem implant consists of a small electrode that is applied to the brainstem where it stimulates acoustic nerves by means of electrical signals. The stimulating electrical signals are provided by a signal processor processing input sounds from a microphone located externally to the user. This allows the user to hear a certain degree of sound.

FES (Functional Electrical Stimulation)

FES is a technique that uses electrical currents to activate muscles and/or nerves, restoring function in people with paralysis-related disabilities.

Injuries to the spinal cord interfere with electrical signals between the brain and the muscles, which can result in paralysis.

SCS (Spinal Cord Stimulator)

This system delivers pulses of electrical energy via an electrode in the spinal area and may be used for pain management. An example of a commercially available system is the RESTOREPRIME system by Medtronic, Inc, USA.

Throughout the specification and the claims that follow, unless the context requires otherwise, the words “comprise” and “include” and variations such as “comprising” and “including” will be understood to imply the inclusion of a stated integer or group of integers, but not the exclusion of any other integer or group of integers.

5

The reference to any prior art in this specification is not, and should not be taken as, an acknowledgement of any form of suggestion that such prior art forms part of the common general knowledge.

CLAIMS

1. A medical device for attachment to a part of a user of the medical device, the medical device having an attachment region wherein the attachment region comprises a plurality of hair-like members.
5
2. A medical device as claimed in claim 1 wherein the plurality of hair-like members are formed from silicone.
- 10 3. A medical device as claimed in claim 1 or claim 2 wherein the attachment region is provided by a pad attached to the medical device.
4. A medical device as claimed in claim 1 or claim 2 wherein the attachment region is integral to the medical device.
15
5. A medical device as claimed in claim 1 or claim 2 wherein the medical device is a stimulator of a cochlear implant.
6. A medical device as claimed in claim 1 wherein there are provided at least two attachment regions.
20
7. A medical device as claimed in claim 6 wherein one of the at least two attachment regions is a receiving region for a magnet.
- 25 8. A medical device as claimed in claim 1 wherein at least some of the hair-like members are coated with an adhesive.
9. A method of forming an attachment region on a part of a medical device, the method comprising providing a plurality of hair-like members on the part of the medical device.
30
10. A method as claimed in claim 9 wherein the step of providing the plurality of hair-like members comprises moulding a plurality of silicone cylinders on the part of the medical device.
11. A method as claimed in claim 9 wherein the step of providing the plurality of hair-like members comprises attaching a pad comprising the plurality of hair-like members to the part of the medical device.
35

12. A method as claimed in claim 9 further comprising coating at least some of the hair-like members with an adhesive.

5 13. A sheet of material having two sides, for application to a portion of a medical device, each side of the sheet of material having an attachment region, and wherein the attachment region of at least one of the two sides is formed from a plurality of hair-like members.

14. A sheet as claimed in claim 13 wherein the sheet of material is bio-resorbable.

10 15. A sheet as claimed in claim 13 wherein at least some of the hair-like members are coated with an adhesive.

16. A method of implanting a medical device in a user, the method comprising:

exposing a portion of bone of the user;

15 attaching the medical device to the exposed portion of bone without forming a seat in the exposed portion of bone; and

covering the attached medical device and the exposed portion of bone.

20 17. A method as claimed in claim 16 wherein the medical device is a stimulator of a cochlear implant.

18. A medical device having a magnet receiving region for receiving a magnet, wherein the magnet receiving region is open.

25 19. A medical device as claimed in claim 18 wherein the magnet receiving region comprises an attachment region comprising a plurality of hair-like members.

20. A medical device as claimed in claim 18 wherein the medical device is a stimulator of a cochlear implant.

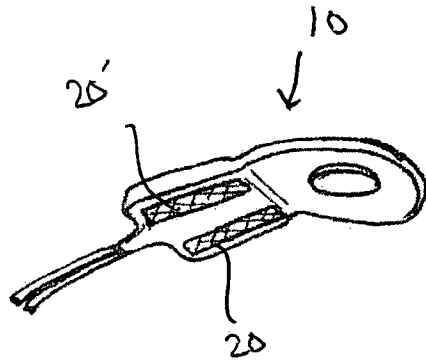


Figure 1

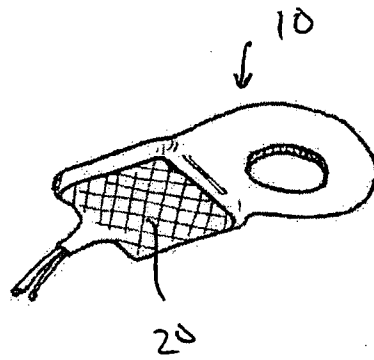


Figure 2

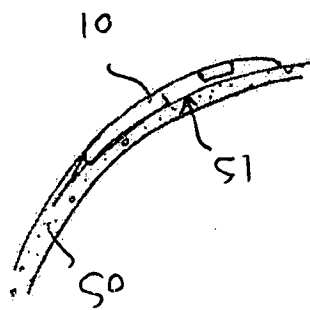


Figure 3

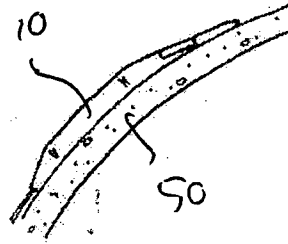


Figure 4

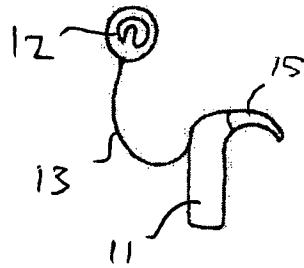


Figure 5

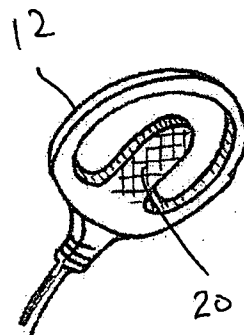


Figure 6

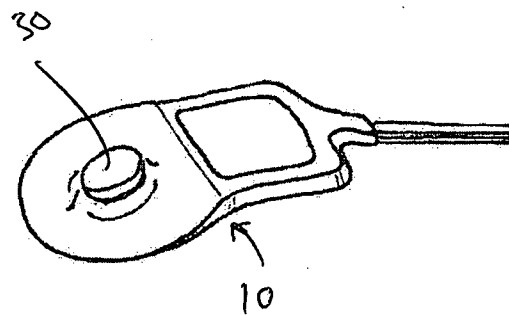


Figure 7

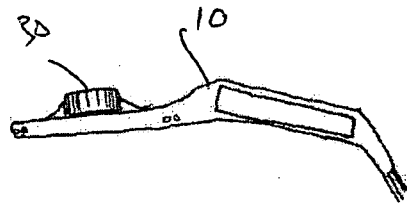


Figure 8

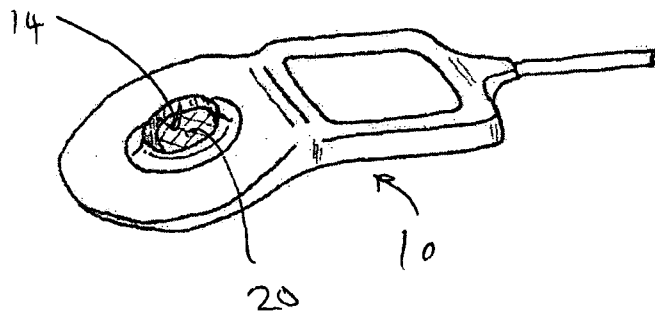


Figure 9

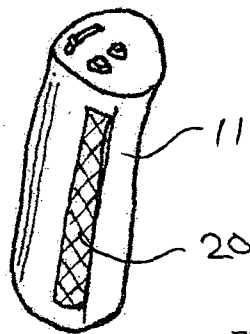


Figure 10

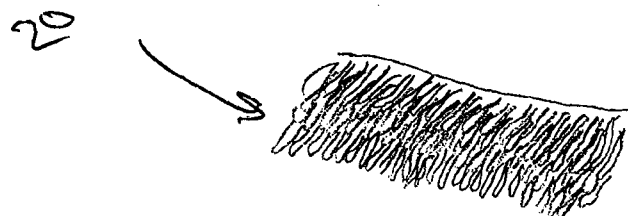


Figure 11

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2010/000043

A. CLASSIFICATION OF SUBJECT MATTER												
Int. Cl.												
<i>A61F 2/02</i> (2006.01) <i>B32B 5/10</i> (2006.01) <i>H04R 25/00</i> (2006.01)												
According to International Patent Classification (IPC) or to both national classification and IPC												
B. FIELDS SEARCHED												
Minimum documentation searched (classification system followed by classification symbols)												
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched												
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) WPI and EPODOC and keywords such as: medical device; medical apparatus, hair-like, seta, microstructure, attach, adhere, adhesive, fix, stick, Van der Waals, hair like, arrays, protrusion, surface, implant, adhere to bone, magnet, silicone and the like..												
C. DOCUMENTS CONSIDERED TO BE RELEVANT												
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.										
X	US 2003/0124312 A1 (AUTUMN) 03 July 2003 Abstract, para[0113], para[0007], para[0009], para[0021], para[0106]-[0108], all figures.	1-4, 6, 8-12										
X	US 6737160 B1 (FULL ET AL.) 18 May 2004 Abstract, Figures 1C-I elements (24)-(30), Figure 7; column 10, lines 13-17, column 9, lines 9-15; column 10, line 30-34.	1-4, 6, 8-12										
X	US 6872439 B2 (FEARING ET AL.) 29 March 2005 Abstract, Figures 1A,B; Figure 2, Figures 9, 11, 12, 13A-13C and Figure 17, see elements (10)-(56) and related text; column 12, lines 48-column 13, line 6.	1-4, 6, 8-12										
X	US 2006/0204738 A1 (DUBROW ET AL.) 14 September 2006 Abstract, Figure 1, Figures 4D-F, Figures 6A,B; Figure 14A and related text, para[0078]-[0081]; para[0084], para[0208], para[0059], [0123] - [0194]; para[0229].	1-4, 6, 8-15										
☒ Further documents are listed in the continuation of Box C ☒ See patent family annex												
* Special categories of cited documents: <table border="0"> <tr> <td>"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"E" earlier application or patent but published on or after the international filing date</td> <td>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td>"&" document member of the same patent family</td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> </tr> </table>			"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family	"P" document published prior to the international filing date but later than the priority date claimed	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention											
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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art											
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family											
"P" document published prior to the international filing date but later than the priority date claimed												
Date of the actual completion of the international search 30 March 2010		Date of mailing of the international search report - 7 APR 2010										
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. +61 2 6283 7999		Authorized officer VIARA VAN RAAD AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No : +61 2 6222 3643										

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

As reasoned on extra sheet.

Text continues in Supplemental Box (A)

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: **1-15 and 18-20**

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

Supplemental Box (A)

(To be used when the space in any of Boxes I to IV is not sufficient)

Continuation of Box No: III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claims 1-15 directed to an attachment means used in medical devices and implants. It is considered that the hair-like attachment means used for attachment in implants and medical devices comprises a first distinguishing feature.
- Claims 16-17 directed to a method of implanting a medical device which is attached to a bone or a hearing implant that is attached to a bone. It is considered that the method of implanting a medical device wherein the implant is attached to the bone comprises a second distinguishing feature.
- Claims 18-20 directed to a medical device having a magnet receiving region for receiving a magnet wherein the magnet receiving region is open. It is considered that the medical device having a magnet receiving region for receiving a magnet represents a third distinguishing feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

Each of the abovementioned groups of claims has a different distinguishing feature and they do not share any feature which could satisfy the requirement for being a special technical feature. Because there is no common special technical feature it follows that there is no technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a priori*.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2010/000043

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/0033383 A1 (IBRAHIM ET AL.) 10 February 2005 Abstract, Figures 1A,B, elements (110), (164), Figures 3B, 4A-4F and para [0023]-[0044].	18, 20
X	US 6648914 B2 (BERRANG ET AL.) 18 November 2003 Abstract, column 7, Figure 14 column 15, lines 65-column 16, line 5.	18, 20
A	Yao, H. et al, 'Adhesion and sliding response of a biologically inspired fibrillar surface: Experimental observations,' <i>J. R. Soc. Interface</i> 2008, Vol. 5, pages 723-733. Entire document	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2010/000043

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
US	2003124312	AU	2003226433	US	7335271	WO	03097702
US	6737160	AU	55150/01	AU	2006252338	CA	2609545
		EP	1241930	EP	1896254	US	2004005454
		US	7011723	US	2005072509	US	7229685
		US	2006078725	US	2008073323	WO	0149776
		WO	2006130864				
US	6872439	AU	2003230396	CA	2485717	EP	1511618
		US	2003208888	US	2005181170	WO	03095190
US	2006204738	AU	2004233002	AU	2004236260	AU	2004256392
		AU	2005218592	CA	2522678	CA	2522866
		CA	2522872	CA	2557757	EP	1617769
		EP	1618223	EP	1620256	EP	1725189
		EP	1869237	EP	2114299	US	2004206448
		US	7056409	US	2004250950	US	7074294
		US	2006165952	US	7344617	US	2006159916
		US	7579077	US	2007275232	US	7651769
		US	2005038498	US	2005181195	US	2005221072
		US	2005289084	US	2006031492	US	2006122596
		US	2006161644	US	2006168116	US	2006168161
		US	2007282247	US	2009162643	WO	2004094303
		WO	2004099068	WO	2005005679	WO	2005084582
		WO	2007078304	WO	2008103464		
US	2005033383	NONE					
US	6648914	AU	18459/01	CA	2384248	EP	1233812
		US	6358281	US	2002019669	WO	0139830

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX