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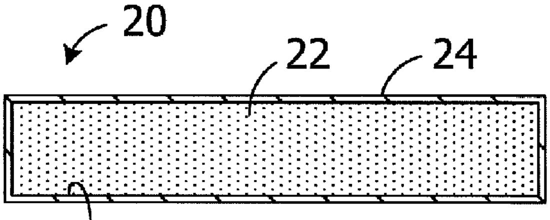

FIG. 2B

(57) Abstract: A cochlear implant is disclosed, including a cochlear lead, an antenna, a stimulation processor, a magnet apparatus, associated with the antenna, including a case and a plurality of magnetic material particles within the case that are movable relative to one another.

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COCHLEAR IMPLANTS HAVING MRI-COMPATIBLE MAGNET APPARATUS AND ASSOCIATED METHODS

BACKGROUND

1. **Field**

The present disclosure relates generally to the implantable portion of implantable cochlear stimulation (or “ICS”) systems.

2. **Description of the Related Art**

ICS systems are used to help the profoundly deaf perceive a sensation of sound by directly exciting the intact auditory nerve with controlled impulses of electrical current. Ambient sound pressure waves are picked up by an externally worn microphone and converted to electrical signals. The electrical signals, in turn, are processed by a sound processor, converted to a pulse sequence having varying pulse widths and/or amplitudes, and transmitted to an implanted receiver circuit of the ICS system. The implanted receiver circuit is connected to an implantable electrode array that has been inserted into the cochlea of the inner ear, and electrical stimulation current is applied to varying electrode combinations to create a perception of sound. The electrode array may, alternatively, be directly inserted into the cochlear nerve without residing in the cochlea. A representative ICS system is disclosed in U.S. Patent No. 5,824,022, which is entitled “Cochlear Stimulation System Employing Behind-The-Ear Sound processor With Remote Control” and incorporated herein by reference in its entirety. Examples of commercially available ICS sound processors include, but are not limited to, the Advanced Bionics^{TM} Harmony^{TM} BTE sound processor, the Advanced Bionics^{TM} Naida^{TM} BTE sound processor and the Advanced Bionics^{TM} Neptune^{TM} body worn sound processor.

As alluded to above, some ICS systems include an implantable cochlear stimulator (or “cochlear implant”), a sound processor unit (e.g., a body worn processor or behind-the-ear processor), and a microphone that is part of, or is in communication with, the sound processor unit. The cochlear implant communicates with the sound processor unit and, some ICS systems include a headpiece that is in communication with both the sound processor unit and the cochlear implant. The headpiece communicates with the cochlear implant by way of a transmitter (e.g., an antenna) on the headpiece and a receiver (e.g., an antenna) on the implant. Optimum communication is achieved when the transmitter and the receiver are aligned with one another. To that end, the headpiece and the cochlear implant may include respective positioning magnets that are attracted to one another, and that maintain the position of the headpiece transmitter over the implant receiver. The implant magnet may, for example, be located within a pocket in the cochlear implant housing.

The present inventors have determined that conventional cochlear implants are susceptible to improvement. For example, the magnets in many conventional cochlear implants are disk-shaped and have north and south magnetic dipoles that are aligned in the axial direction of the disk. Such magnets are not compatible with magnetic resonance imaging ("MRI") systems. In particular, the cochlear implant 10 illustrated in FIG. 1 includes, among other things, a housing 12 and a disk-shaped solid block magnet 14. The implant magnet produces a magnetic field M in a direction that is perpendicular to the patient's skin and parallel to the axis A, and this magnetic field direction is not aligned with, and may be perpendicular to (as shown), the direction of the MRI magnetic field B. The misalignment of the interacting magnetic fields M and B is problematic for a number of reasons. The dominant MRI magnetic field B (typically 1.5 Tesla or more) may demagnetize the implant magnet 14 or generate a significant amount of torque T on the implant magnet 14. The torque T may dislodge the implant magnet 14 from the pocket within the housing 12, reverse the magnet 14 and/or dislocate the cochlear implant 10, all of which may also induce tissue damage. One proposed solution involves surgically removing the implant magnet 14 prior to the MRI procedure and then surgically replacing the implant magnet thereafter. The present inventors have determined that a solution which does not involve surgery would be desirable.

SUMMARY

A cochlear implant in accordance with one of the present inventions includes a cochlear lead, an antenna, a stimulation processor, a magnet apparatus, associated with the antenna, including a case and a plurality of magnetic material particles within the case that in contact with one another and are movable relative to one another.

A method in accordance with one of the present inventions may be practice in conjunction with an implantable cochlear stimulator including an antenna and a magnet apparatus, associated with the antenna, having a case and a plurality of magnetic material particles within the case that are in contact with one another. In response to the application of a magnetic field defining a magnetic field direction to the implantable cochlear stimulator, the magnetic field is allowed to rotate the magnetic material particles in any direction, relative to the case, into magnetic alignment with the magnetic field.

A system in accordance with one of the present inventions includes cochlear implant, with a cochlear lead, an antenna, a stimulation processor, a magnet apparatus, associated with the antenna, including a case and a plurality of magnetic material particles within the case that are in contact with one another and movable relative to one another, and headpiece.

There are a number of advantages associated with such apparatus and methods. For example, a strong magnetic field, such as an MRI magnetic field, will not demagnetize the magnet apparatus. Nor will it generate a significant amount of torque on the magnet apparatus and associated cochlear implant. As a result, surgical removal of the cochlear implant magnet prior to an MRI procedure, and then surgically replacement thereafter, is not required.

The above described and many other features of the present inventions will become apparent as the inventions become better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Detailed descriptions of the exemplary embodiments will be made with reference to the accompanying drawings.

FIG. 1 is a plan view showing a conventional cochlear implant in an MRI magnetic field.

FIG. 2A is a perspective view of an implant magnet apparatus in accordance with one embodiment of a present invention.

FIG. 2B is a section view taken along line 2B-2B in FIG. 2A.

FIG. 2C is a section view of an implant magnet apparatus in accordance with one embodiment of a present invention.

FIG. 3A is a section view of an implant magnet apparatus in accordance with one embodiment of a present invention.

FIG. 3B is a section view of an implant magnet apparatus in accordance with one embodiment of a present invention.

FIG. 3C is a perspective view showing the interior of a portion of an implant magnet apparatus in accordance with one embodiment of a present invention.

FIG. 4A is a magnified view of exemplary magnetic particles.

FIG. 4B is a magnified view of exemplary magnetic particles in a loosely packed state

FIG. 5A is a perspective view of a plurality of magnetic particles a loosely packed state prior to being exposed to a magnetic field.

FIG. 5B is a perspective view of a plurality of magnetic particles a loosely packed state after being exposed to a magnetic field.

FIG. 6A is a section view of the implant magnet apparatus illustrated in FIG. 2 prior to being exposed to a magnetic field.

FIG. 6B is a section view of the implant magnet apparatus illustrated in FIG. 2 being exposed to a magnetic field.

FIG. 7 is a plan, cutaway view showing a cochlear implant in accordance with one embodiment of a present invention being used in conjunction with a cochlear implant headpiece.

FIG. 8 is a plan, cutaway view showing a cochlear implant in accordance with one embodiment of a present invention being exposed to an MRI magnetic field.

FIG. 9 is a plan, cutaway view showing a cochlear implant in accordance with one embodiment of a present invention being exposed to an MRI magnetic field.

FIG. 10 is a plan view of a cochlear implant in accordance with one embodiment of a present invention.

FIG. 11 is a block diagram of a cochlear implant system in accordance with one embodiment of a present invention.

FIG. 12 is a section view showing portions of a system in accordance with one embodiment of a present invention.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

The following is a detailed description of the best presently known modes of carrying out the inventions. This description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles of the inventions.

As illustrated for example in FIGS. 2A and 2B, an exemplary magnet apparatus 20 includes magnetic material particles (or “particles”) 22 within the internal volume of a case 24. The particles 22, which are discussed in greater detail below with reference to FIGS. 4A-6B, are in contact with one another and are independently and freely rotatable and otherwise movable relative to one another and to the case. The particles 22 are free to move from one X-Y-Z coordinate to another and/or rotate in any direction. For example, some particles 22 may move linearly and/or rotate relative to other particles and relative to the case 24, while the orientation of the case remains the same, when the magnet apparatus 20 is exposed to an external magnetic field. The magnet apparatus 20 may be incorporated into a cochlear implant in the manner described in greater detail below with reference to FIGS. 7-11.

The case 24 is not limited to any particular configuration, size or shape. In the illustrated implementation, the case 24 includes a base 26 and a cover 28 that may be secured to base after the magnetic material particles 22 have been dispensed into the base. The cover 28 may be secured to the base 26 in such a manner that a hermetic seal is formed between the cover and the base. Suitable techniques for securing the cover 28 to the base 26 include, for example, seam welding with a laser welder. With respect to materials, the case 24 may be formed from biocompatible paramagnetic metals, such as titanium or titanium alloys, and/or biocompatible non-magnetic plastics such as polyether ether ketone (PEEK), low-density polyethylene (LDPE), high-density polyethylene (HDPE) and polyamide. In particular, exemplary metals include commercially pure titanium (e.g., Grade 2) and the titanium alloy Ti-6Al-4V (Grade 5), while exemplary metal thicknesses may range from 0.20 mm to 0.25 mm. With respect to size and shape, the case 24 may have an overall size and shape similar to that of conventional cochlear implant magnets so that the magnet apparatus 20 can be substituted for a conventional magnet in an otherwise conventional cochlear implant. The exemplary case 24 is disk-shaped and defines a central axis A. In some implementations, the diameter that may range from 9 mm to 16 mm and the thickness may range from 1.5 mm to 3.0 mm. The diameter of the case 24 is 12.9 mm, and the thickness is 2.4 mm, in the illustrated embodiment.

The magnet apparatus 20 includes an inner surface 30 which, in this embodiment, is formed by the inner surface of the case 24, i.e., the inner surfaces of the base 26 and cover 28. A lubricious layer may be added to the inner surface to improve the movement of the particles 22 that are adjacent to the inner surface 30. To that end, and referring to the magnet apparatus 20a illustrated in FIG. 2C, which is otherwise identical to the magnet apparatus 20, a lubricious layer 32 covers the inner surface 30 of the case 24. The lubricious layer 32 may be in the form of a specific finish of the inner surface that reduces friction, as compared to an unfinished surface, or may be a coating of a lubricious material such as polytetrafluoroethylene (PTFE), Parylene, or fluorinated ethylene propylene (FEP). In those instances where the base 26 is formed by stamping, the finishing process may occur prior to stamping.

The exemplary magnet apparatus 20b illustrated in FIG. 3A is substantially similar to magnet apparatus 20 and similar elements are represented by similar reference numerals. Here, however, a shim 34 may be inserted into the case 24 to focus the magnetic field created by the magnetic material particles 22. More specifically, when the associated cochlear implant is implanted, the shim 34 (sometimes referred to as a “flux guide”) will increase the flux density and focus the magnetic field toward the patient’s skin and an externally worn headpiece. Although the present shims are not so limited, the exemplary shim 34 is cup-shaped and may be about 0.25 mm thick and formed from iron or from a nickel–iron alloy, referred to as mu-metal, that is composed of approximately 77% nickel, 16% iron, 5% copper and 2% chromium or molybdenum. In other implementations, a flat disk positioned at the bottom of the base 26 may be employed.

Referring to FIG. 3B, the exemplary magnet apparatus 20c is substantially similar to magnet apparatus 20b in FIG. 3A and similar elements are represented by similar reference numerals. Here, however, a lubricious layer 32 covers the inner surface 30b of the magnet apparatus 20c. The inner surface 30b is formed by the inner surfaces of the cover 28 and the shim 34. The lubricious layer 32 may be formed in the manner discussed above with reference to FIG. 2C. In those instances where the shim 34 is formed by stamping, the finishing process may occur prior to stamping.

The exemplary magnet apparatus 20d illustrated in FIG. 3C is substantially similar to magnet apparatus 20 in FIG. 2A and similar elements are represented by similar reference numerals. Here, however, a divider 36 is located within the internal volume of case 24 (shown with the cover 28 removed). The divider 36, which may include one or more walls 38 that extend from the bottom of the case 24 to the top, separates the internal volume into a plurality of sub-volumes 40 and facilitates an even distribution of the magnetic material particles 22 within case 24 by limiting particle migration. The even distribution of the magnetic material particles 22 provided by the divider 36 results in proper alignment of the magnet apparatus 20 with the associated headpiece magnet or magnet apparatus, which in turn results in proper alignment of the implant antenna with the headpiece antenna. Although the exemplary divider 36 is X-shaped and divides the volume into four sub-volumes 40, any suitable configuration and number of sub-volumes may be employed. Other exemplary divider shapes include, but are not limited to, an asterisk shape and a honey-comb shape. Suitable divider materials include, but are not limited to, plastics such as PEEK and PTFE and metals such as iron, titanium and mu-metal. A divider, such as exemplary divider 36, may also be positioned within the other magnet apparatus described herein, including magnet apparatus 20b and magnet apparatus 20c.

Turning to FIGS. 4A and 4B, and although the present magnetic material particles are not limited to any particular shape unless so specified in a particular claim, the exemplary magnetic material particles 22 are non-spherical, polyhedral shapes or at least substantially polyhedral shapes, i.e., multi-sided shapes that are regular or irregular, symmetric or asymmetric, with or without smooth side surfaces, and with or without straight edges, that will permit the particles to rotate relative to one another when loosely packed. Any three-dimensional shapes that permit the movement described herein may also be employed. The magnetic material particles 22 may be formed from any suitable magnetic material. Such materials include, but are not limited to, neodymium-iron-boron ("$Nd_2Fe_{14}B$") magnetic material, isotropic neodymium, anisotropic neodymium, samarium-cobalt ("Sm_2Co_{17}"). The at least substantially polyhedral shapes illustrated in FIGS. 4A and 4B are the fractured pieces of a larger magnet that are created by a magnet crushing process. The present particles may have a mesh size that ranges from 50 μm to 500 μm, or from 100 μm to 300 μm, or from 300 μm to 500 μm, and the shape and size may vary from particle to particle. The particles 22, which are not suspended in liquid or any other carrier, may be packed loosely and pressed with a slight force of, for example, 100kPa (0.14 psi) in order to insure that adjacent particles will be in contact with one another (FIG. 4B), yet will also be independently movable and movable relative to one another. To that end, and referring to FIGS. 5A and 5B, three exemplary particles 22-1, 22-2 and 22-3 are shown in both arbitrary orientations prior to being exposed to a magnetic field (FIG. 5A) and after they have been aligned with a magnetic field (FIG. 5B). The reorientation-related movement of the particles 22-1, 22-2 and 22-3, which varies from one particle to another, may entail rotation about, and/or movement in the direction of, the X-axis, the Y-axis, and/or the Z-axis, and any and all combinations thereof.

The magnetic material density ratio within the case 24, i.e. the ratio of the total volume of magnetic material particles to the total volume within the case 24, may be at least 70%, i.e., there is no more than 30% free space within the case. This ratio allows the present magnet apparatuses 20-20d to be essentially the same size and shape as a conventional disk-shaped permanent magnet in a cochlear implant when combined with an appropriate headpiece. With respect to the density of the magnetic material particles, the density may range, in the exemplary context of neodymium-iron-boron, from 2.75 g/cm^3 (30% free space) to 3.94 g/cm^3 (fully packed and pressed with a force of 100kPa). Free space percentages that are larger than 30% may be employed in those instances where the magnet apparatus is larger. The magnetic strength of the of the exemplary magnet apparatus 20b, which includes the particles 22 within the case 24 and a shim 34, is about 60-70 gauss measured at a distance of 1 mm from the case on the axis A. The pull force between a cochlear implant including the magnet apparatus 20 and a cochlear implant headpiece (e.g., headpiece 300 in FIG. 11), including headpieces that have one or more magnets therein, at a distance of 3 mm may be about 2.2±0.1 N. The 3 mm distance corresponds to the distance (or “air gap”) between the implant magnet apparatus and the headpiece magnet (or magnet apparatus) during pull force testing, and the pull force will be different at other testing distances. Various headpiece magnet apparatus configurations which, when combined with an implant magnet apparatus in a system that includes both a cochlear implant and a cochlear implant headpiece, and where the pull force between the headpiece magnet apparatus and the implant magnet apparatus is about 2.2±0.1 N, are discussed below with reference to FIG. 12.

It should also be noted that the use of significantly larger magnetic elements within the case in place of the magnetic material particles will decrease the magnetic material density (due to air gaps between the magnetic elements) and prevent magnet apparatus which have cases of the sizes and shapes disclosed herein from achieving the desired level of magnetic strength. Similarly, the use of ferrofluids, which include nano-sized particles dispersed and suspended within a fluid, in place of the magnetic material particles would also necessitate the use of a case that is larger than a conventional cochlear implant magnet to achieve the desired level of magnetic strength.

For ease of illustration purposes on only, the non-spherical particles may be represented in the manner shown in FIGS. 6A and 6B. The north pole N of each particle 22 is black (or grey) and the south pole S is white. The respective N-S orientations of the particles 22 will vary from one particle to the next, with the particles being magnetically attracted to one other in arbitrary directions, after the particles have been dispensed into the case 24. The particles 22 will remain in their random angular orientations until they are reoriented by a magnetic field in the manner described below. Such reorientation is possible because the particles 22 are independently movable relative to one another in any and all directions. Relative movement of the particles 22 may entail rotation about the X-axis, or rotation about the Y-axis, or rotation about the Z-axis, and/or any and all combinations thereof, and/or non-rotational movement in the X-direction, or the Y-direction, or the Z-direction, and/or any and all combinations thereof.

An external magnetic field may be used to reorient the magnetic material particles 22 within the case 24 to establish the desired N-S orientation of magnet apparatuses 20-20d. Such reorientation may be performed before or after the magnet apparatuses 20-20d are incorporated into a cochlear implant. To that end, and referring to FIG. 6B, the magnet apparatus may be exposed to the magnetic field M of the magnet 32. With the exception of those particles 22 that were by chance already aligned with the magnetic field M, the particles 22 will rotate into alignment with the magnetic field M (e.g., from the orientation illustrated in FIG. 6A to the orientation illustrated in FIG. 6B), thereby establishing the intended N-S orientation of the magnet apparatus 20. Here, the intended N-S orientation is parallel to the central axis A of the disk-shaped magnet apparatus 20.

The magnet apparatus 20 (or 20a-20d) may form part of a cochlear implant in a cochlear implant system that also includes a sound processor and a headpiece. One example of such a cochlear implant system is the system 50, which is described in greater detail below with reference to FIGS. 10 and 11, and which includes a cochlear implant 100 and a headpiece 300. As illustrated for example in FIG. 7, the implanted headpiece 100 includes the magnet apparatus 20. The N-S orientation of the magnet apparatus 20 is the same as the orientation illustrated in FIG. 6. The headpiece 300, which includes a magnet apparatus 310 with the same N-S orientation, may be held in place by virtue of the attraction between the magnet apparatus 20 and the magnet apparatus 310. The central axis A of the magnet apparatus 20 is perpendicular to the patient's skin and parallel to the magnetic field M. Communication between the headpiece 300 and cochlear implant 100 may then occur in conventional fashion.

FIG. 8 shows the implanted cochlear implant 100 being exposed to an MRI magnetic field B. The orientation of the cochlear implant 100 is such that the central axis A of the magnet apparatus 20 is perpendicular to the MRI magnetic field B. In contrast to the conventional magnet 14 illustrated in FIG. 1, however, the magnetic field M of the magnet apparatus 20 is not perpendicular to the MRI magnetic field B. Instead, the dominant MRI magnetic field B reorients magnetic material particles 22 relative to the case 24 and to the associated cochlear implant, from the orientation illustrated in FIG. 7 to the orientation illustrated in FIG. 8, such that the N-S orientation of the magnet apparatus 20 is perpendicular to the central axis A and the magnetic field M is parallel to the MRI magnetic field B.

There are a variety of advantages associated with such magnetic field reorientation. For example, the MRI magnetic field B (typically 1.5 Tesla or more) will not demagnetize the magnet apparatus 20 or generate a significant amount of torque T on the magnet apparatus and associated cochlear implant. As a result, surgical removal of the cochlear implant magnet prior to an MRI procedure, and then surgically replacement thereafter, is not required.

It should also be noted that movement of the patient relative to the MRI magnetic field B while in the MRI magnetic field B will also result in reorientation of the magnetic material particles 22 within the case 24, as is illustrated in FIG. 9. Here, the N-S orientation of the magnet apparatus 20 neither perpendicular, nor parallel, to the central axis A and the magnetic field M remains parallel to the MRI magnetic field B. The ability of the particles 22 to rotate and move relative to the case 24 about and along the X, Y and Z-axes, as well as any and all combinations of such rotation and movement (i.e., in any direction, and any rotational direction, relative to the case and relative to the remainder of the associated cochlear implant), allows the N-S orientation of the each particle 22 (and the magnet apparatus 20) to align itself with an MRI magnetic field B regardless of the relative orientations of the MRI magnetic field and the magnet apparatus. As the orientation of one or both of the MRI magnetic field B and the magnet apparatus 20 changes, the N-S orientation of the magnet apparatus 20 relative to the case 24 and central axis A will change so as to maintain the alignment of the N-S orientation of the magnetic material particles 22 (as well as the magnet apparatus itself) with the MRI magnetic field.

After the MRI procedure has been completed, the implanted magnet apparatus may be exposed to a magnetic field (e.g., with the magnet 32) to return the particles 22 to their intended N-S orientation.

One example of a cochlear implant (or “implantable cochlear stimulator”) including the present magnet apparatus 20 is the cochlear implant 100 illustrated in FIG. 10. The cochlear implant 100 includes a flexible housing 102 formed from a silicone elastomer or other suitable material, a processor assembly 104, a cochlear lead 106, and an antenna 108 that may be used to receive data and power by way of an external antenna that is associated with, for example, a sound processor unit. The cochlear lead 106 may include a flexible body 110, an electrode array 112 at one end of the flexible body, and a plurality of wires (not shown) that extend through the flexible body from the electrodes 112a (e.g., platinum electrodes) in the array 112 to the other end of the flexible body. The magnet apparatus 20 is located within a region encircled by the antenna 108 (e.g., within an internal pocket 102a defined by the housing 102) and insures that an external antenna (discussed below) will be properly positioned relative to the antenna 108. The exemplary processor assembly 104, which is connected to the electrode array 112 and antenna 108, includes a printed circuit board 114 with a stimulation processor 114a that is located within a hermetically sealed case 116. The stimulation processor 114a converts the stimulation data into stimulation signals that stimulate the electrodes 112a of the electrode array 112.

Turning to FIG. 11, the exemplary cochlear implant system 50 includes the cochlear implant 100, a sound processor, such as the illustrated body worn sound processor 200 or a behind-the-ear sound processor, and a headpiece 300.

The exemplary body worn sound processor 200 in the exemplary ICS system 50 includes a housing 202 in which and/or on which various components are supported. Such components may include, but are not limited to, sound processor circuitry 204, a headpiece port 206, an auxiliary device port 208 for an auxiliary device such as a mobile phone or a music player, a control panel 210, one or microphones 212, and a power supply receptacle 214 for a removable battery or other removable power supply 216 (e.g., rechargeable and disposable batteries or other electrochemical cells). The sound processor circuitry 204 converts electrical signals from the microphone 212 into stimulation data. The exemplary headpiece 300 includes a housing 302 and various components, e.g., a RF connector 304, a microphone 306, an antenna (or other transmitter) 308 and a positioning magnet apparatus 310, that are carried by the housing. The magnet apparatus 310 may consist of a single magnet or, as is discussed below with reference to FIG. 12, may consist of one or more magnets and a shim. The headpiece 300 may be connected to the sound processor headpiece port 206 by a cable 312. The positioning magnet apparatus 310 is attracted to the magnet apparatus 20 of the cochlear stimulator 100, thereby aligning the antenna 308 with the antenna 108. The stimulation data and, in many instances power, is supplied to the headpiece 300. The headpiece 300 transcutaneously transmits the stimulation data, and in many instances power, to the cochlear implant 100 by way of a wireless link between the antennae. The stimulation processor 114a converts the stimulation data into stimulation signals that stimulate the electrodes 112a of the electrode array 112.

In at least some implementations, the cable 312 will be configured for forward telemetry and power signals at 49 MHz and back telemetry signals at 10.7 MHz. It should be noted that, in other implementations, communication between a sound processor and a headpiece and/or auxiliary device may be accomplished through wireless communication techniques. Additionally, given the presence of the microphone(s) 212 on the sound processor 200, the microphone 306 may be also be omitted in some instances. The functionality of the sound processor 200 and headpiece 300 may also be combined into a single head wearable sound processor. Examples of head wearable sound processors are illustrated and described in U.S. Patent Nos. 8,811,643 and 8,983,102, which are incorporated herein by reference in their entirety.

Turning to FIG. 12, and as noted above, the respective configurations of the magnet apparatus 20c (or 20-20b, 20d) in the cochlear implant 100 and the magnet apparatus 308 in the headpiece 300 create a pull force there between that is about 2.2±0.1 N with a 3 mm air gap. The magnetic field generated by the magnet apparatuses 20-20d is weaker than a similarly sized conventional magnet apparatus that includes a solid block magnet in place of the magnetic particles 22. The exemplary headpiece 300, on the other hand, has a magnet apparatus 308 that is configured to generate a stronger magnetic field than that associated with a conventional headpiece having a similar configuration. As a result, the present implant/headpiece system is able to provide the above-described benefits associated with the movable magnetic particles without increasing the thickness of the implant magnet and, accordingly, the thickness of the implant itself, as compared of conventional implants. The elements of the implant 100 and the headpiece 300 that are not discussed in the context of FIG. 12 have been omitted from FIG. 12 for the sake of simplicity.

The exemplary magnet apparatus 308 illustrated in FIG. 12 includes a plurality of solid block magnets 309 and a shim 311. The strength of the magnetic field associated with the headpiece may be adjusted by replacing one or two of the magnets with a similarly sized plastic spacer. In other implementations, a single, thick magnet may be employed. The magnets 309 are disk-shaped in the illustrated embodiment, but other shapes may be employed. The shim 311 increases the flux density and focus the magnetic field associated with the magnets 309 toward the patient’s skin and the internal magnet apparatus 20c. Although the present shims are not so limited, the exemplary shim 311 is cup-shaped and may be about 1.5 mm thick and formed from iron or mu-metal. In other implementations, a flat disk positioned above the magnets 309 may be employed.

By way of example, but not limitation, the following are specific examples of the magnet apparatus 308 that will, in combination with an implant 100 having the internal magnet apparatus 20c and isotropic neodymium particles 22 with a mesh size that ranges from 300 μm to 500 μm, provide a pull force of about 2.2±0.1 N when there is a spacing of about 3 mm between the external magnet apparatus 308 and the internal magnet apparatus 20c. A magnet apparatus 308 with the shim 311 and three N52 magnets that are 12.7 mm in diameter and 1.5 mm thick is one example. Another example is a magnet apparatus 308 with the shim 311 and a single N52 magnet that is 10.0 mm in diameter and 5.0 mm thick. In those instances where even more pull force is required, e.g., where a patient has a relatively thick skin flap, a magnet apparatus 308 with the shim 311 and a single N52 magnet that is 12.7 mm in diameter and 5.0 mm thick may be employed. It should also be noted that particles 22 having a mesh size that ranges from 100 µm to 300 µm may be used when the headpiece includes such a magnet apparatus. In another otherwise identical example, which instead employs anisotropic neodymium particles 22 with a mesh size that ranges from 50 µm to 200 µm, the pull force is about 2.4±0.1 N when there is a spacing of about 3 mm and the magnet apparatus 308 includes two N52 magnets that are 12.7 mm in diameter and 1.5 mm thick. The pull force at about 3 mm increases to about 3.0±0.1 N when a third N52 magnet (12.7 mm in diameter and 1.5 mm thick) is added to the magnet apparatus 308.

Although the inventions disclosed herein have been described in terms of the preferred embodiments above, numerous modifications and/or additions to the above-described preferred embodiments would be readily apparent to one skilled in the art. By way of example, but not limitation, the inventions include any combination of the elements from the various species and embodiments disclosed in the specification that are not already described. In some instances, a lubricant such as vegetable oil may be applied to the particles 22 to reduce friction and improvement movement of the particles relative to one another. It is intended that the scope of the present inventions extend to all such modifications and/or additions and that the scope of the present inventions is limited solely by the claims set forth below.

We claim:

1. A cochlear implant, comprising:

a cochlear lead including a plurality of electrodes;

an antenna;

a stimulation processor operably connected to the antenna and to the cochlear lead; and

a magnet apparatus, associated with the antenna, including a case and a plurality of magnetic material particles packed within the case in such a manner that adjacent magnetic material particles are in contact with one another and are also movable relative to one another.

2. A cochlear implant as claimed in claim 1, wherein

the magnetic material particles are rotatable relative to one another.

3. A cochlear implant as claimed in claim 1, wherein

the magnetic material particles are each are free to move from one X-Y-Z coordinate to another and to rotate in any direction.

4. A cochlear implant as claimed in claim 1, wherein

the magnetic material particles are at least substantially polyhedral in shape.

5. A cochlear implant as claimed in claim 1, wherein

the magnetic material particles define mesh sizes that range from 50 μm to 500 μm, or from 100 μm to 300 μm, or from 300 μm to 500 μm.

6. A cochlear implant as claimed in claim 1, wherein

the magnetic material particles are formed from a material selected from the group consisting of neodymium-iron-boron, magnetic material, isotropic neodymium, anisotropic neodymium, samarium-cobalt.

7. A cochlear implant as claimed in claim 1, wherein the case comprises a disk-shaped case.

8. A cochlear implant as claimed in claim 1, wherein the case is formed from a material selected from the group consisting of paramagnetic metal and plastic.

9. A cochlear implant as claimed in claim 1, further comprising: a magnetic field focusing shim located within the case.

10. A cochlear implant as claimed in claim 1, wherein the antenna, the stimulation processor and the magnet apparatus are located within a flexible housing.

11. A cochlear implant as claimed in claim 1, wherein the magnet apparatus defines a strength of at least 60-70 gauss measured at a distance of 1 mm from the case.

12. A cochlear implant as claimed in claim 1, wherein the case has an internal volume and includes a divider that separates the internal volume into a plurality of sub-volumes.

13. A method, comprising the step of: in response to the application of a magnetic field defining a magnetic field direction to an implantable cochlear stimulator including an antenna and a magnet apparatus, associated with the antenna, having a case and a plurality of magnetic material particles packed within the case in the absence of a carrier and with adjacent magnetic material particles in contact with one another, allowing the magnetic field to rotate the magnetic material particles in any direction, relative to the case, into magnetic alignment with the magnetic field.

14. A method as claimed in claim 13, wherein

the magnetic field has a magnetic flux density of at least 1.5 Tesla.

15. A method as claimed in claim 13, wherein
the magnetic field comprises a MRI magnetic field.

16. A method as claimed in claim 13, wherein
the step of allowing the magnetic field to rotate the magnetic material particles comprises allowing the magnetic field to rotate the magnetic material particles in any direction, relative to the case and relative to one another, into magnetic alignment with the magnetic field.

17. A method as claimed in claim 13, wherein
the step of allowing the magnetic field to rotate the magnetic material particles comprises allowing the magnetic field to move from one X-Y-Z coordinate to another and to rotate in any direction relative to the case and relative to one another into magnetic alignment with the magnetic field.

18. A method as claimed in claim 13, wherein
the magnetic material particles are at least substantially polyhedral in shape.

19. A method as claimed in claim 13, wherein
the magnetic material particles define mesh sizes that range from 50 μm to 500 μm, or from 100 μm to 300 μm, or from 300 μm to 500 μm.

20. A method as claimed in claim 13, further comprising the step of:
in response to movement of the implantable cochlear stimulator within the magnetic field subsequent to the magnetic material particles having been rotated into alignment with the magnetic field, allowing the magnetic field to further rotate the magnetic material particles in any direction, relative to the case, back into magnetic alignment with the magnetic field.

21. A method as claimed in claim 13, wherein

the magnet apparatus defines a strength of at least 60-70 gauss measured at a distance of 1 mm from the case.

22. A system, comprising

a cochlear implant as claimed in any one of claims 1-12; and

a headpiece including

an antenna, and

a headpiece magnet apparatus associated with the antenna;

wherein the cochlear implant magnet apparatus and the headpiece magnet apparatus are respectively configured such that a pull force is defined there between that is equal to about 2.2±0.1 N when the cochlear implant magnet apparatus and the headpiece magnet apparatus are separated by a distance of 3 mm.

23. A system as claimed in claim 22, wherein

the headpiece magnet apparatus includes a magnetic field focusing shim.

24. A system as claimed in claim 22, wherein

the headpiece magnet apparatus includes a plurality of magnets.

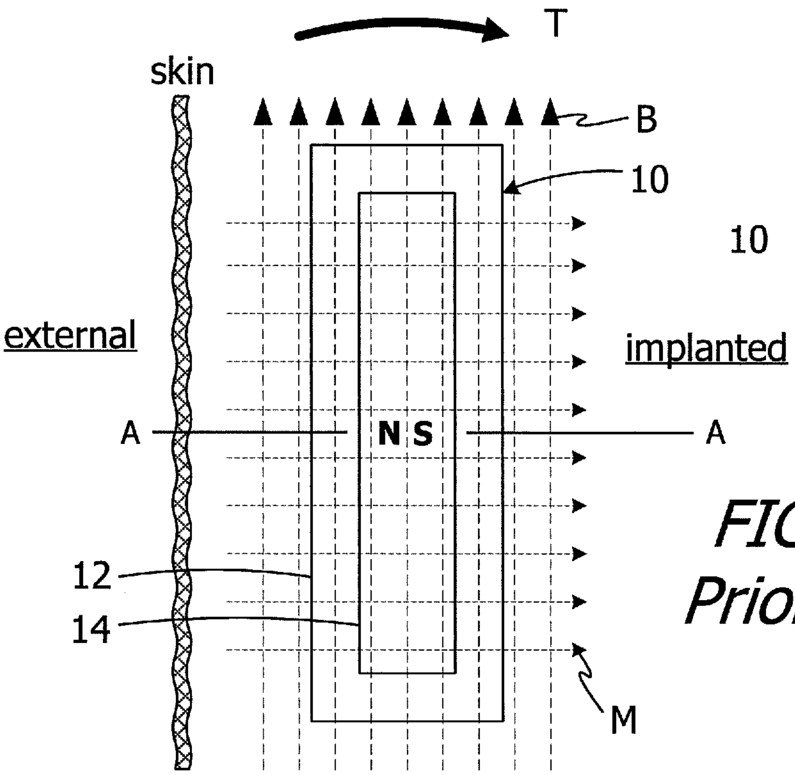


FIG. 1
Prior Art

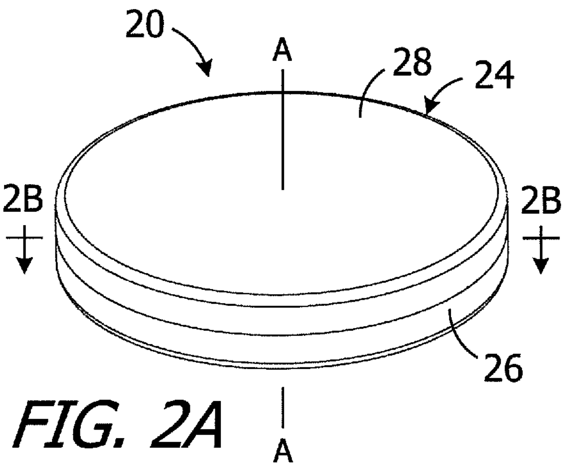


FIG. 2A

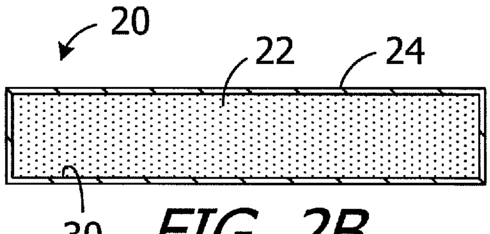


FIG. 2B

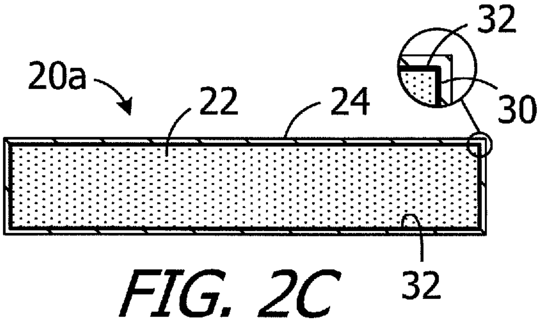


FIG. 2C

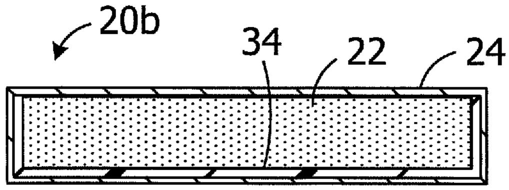


FIG. 3A

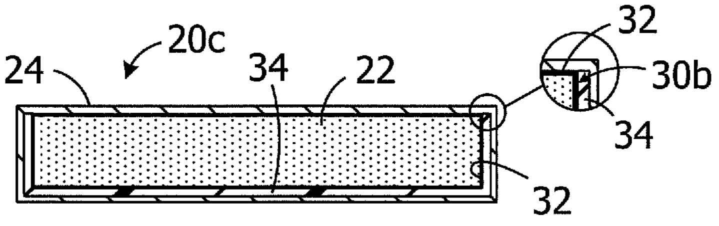


FIG. 3B

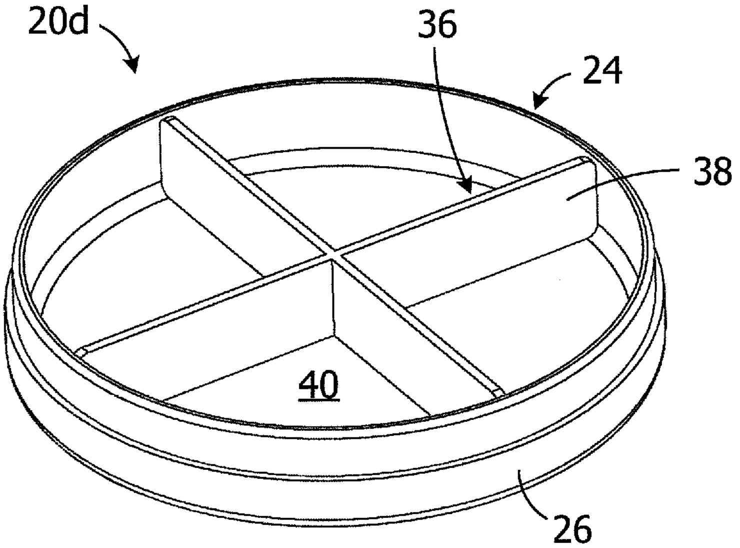


FIG. 3C

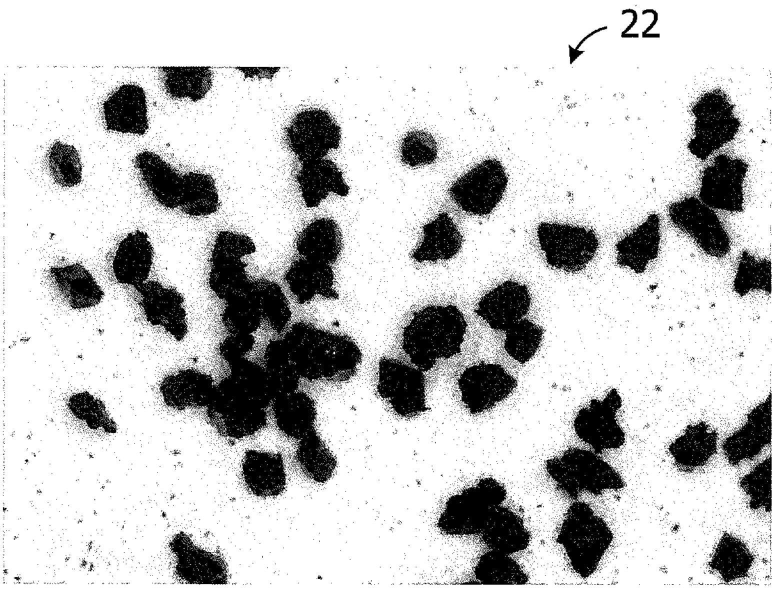


FIG. 4A

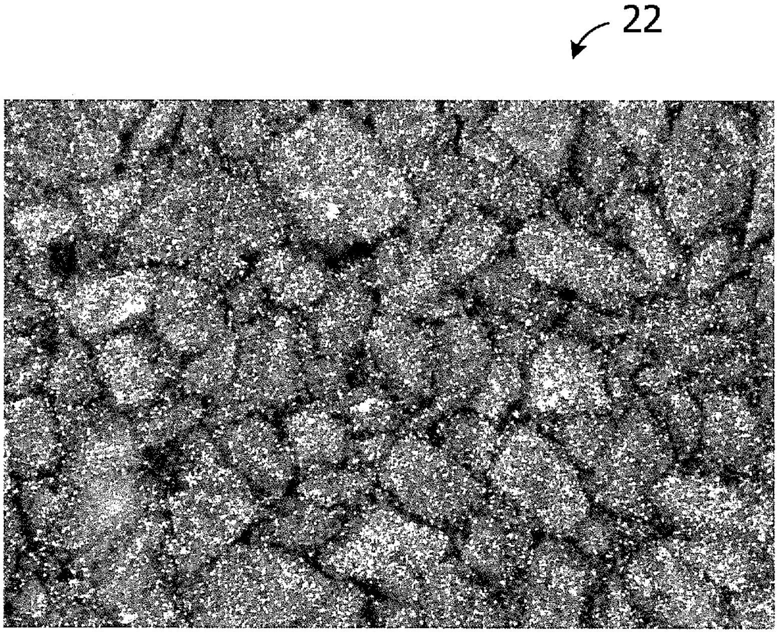


FIG. 4B

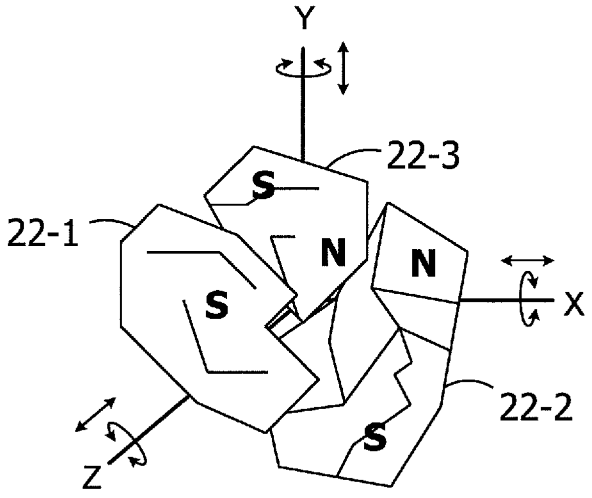


FIG. 5A

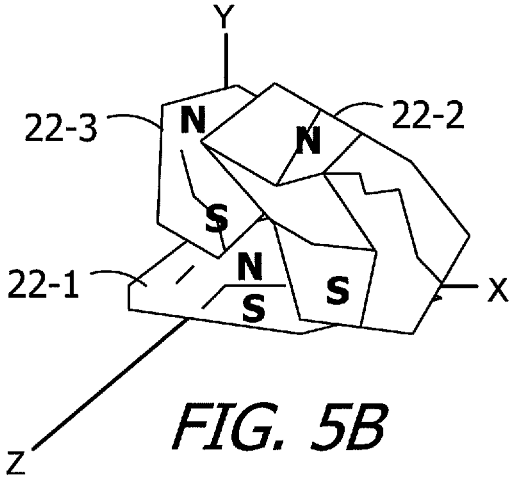


FIG. 5B

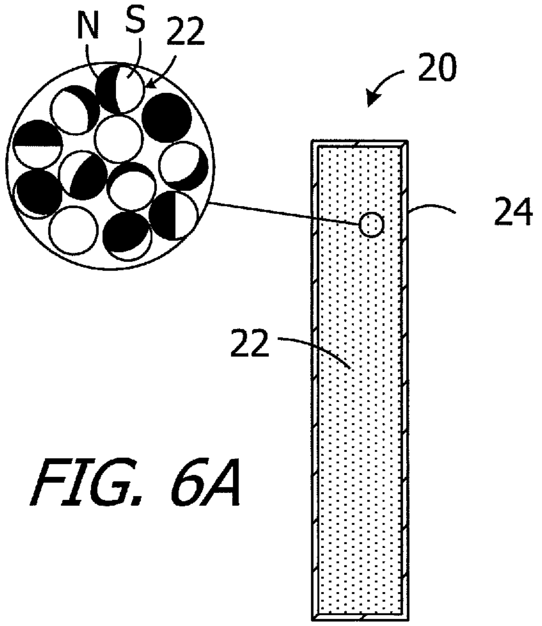
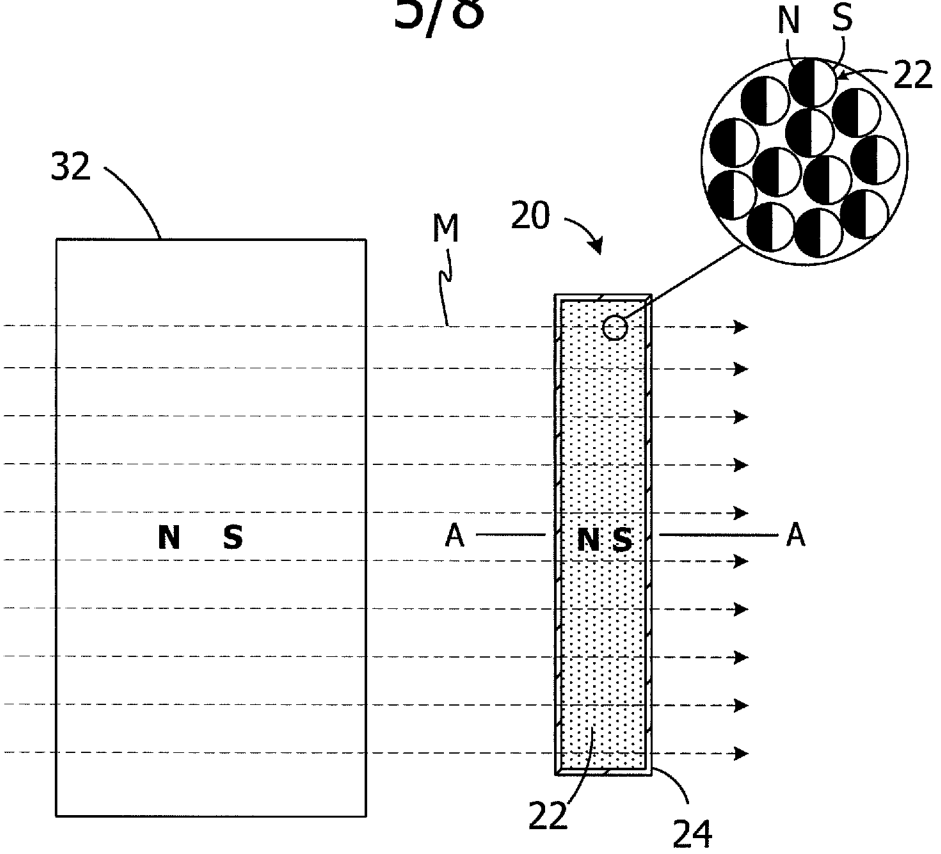


FIG. 6A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22
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M
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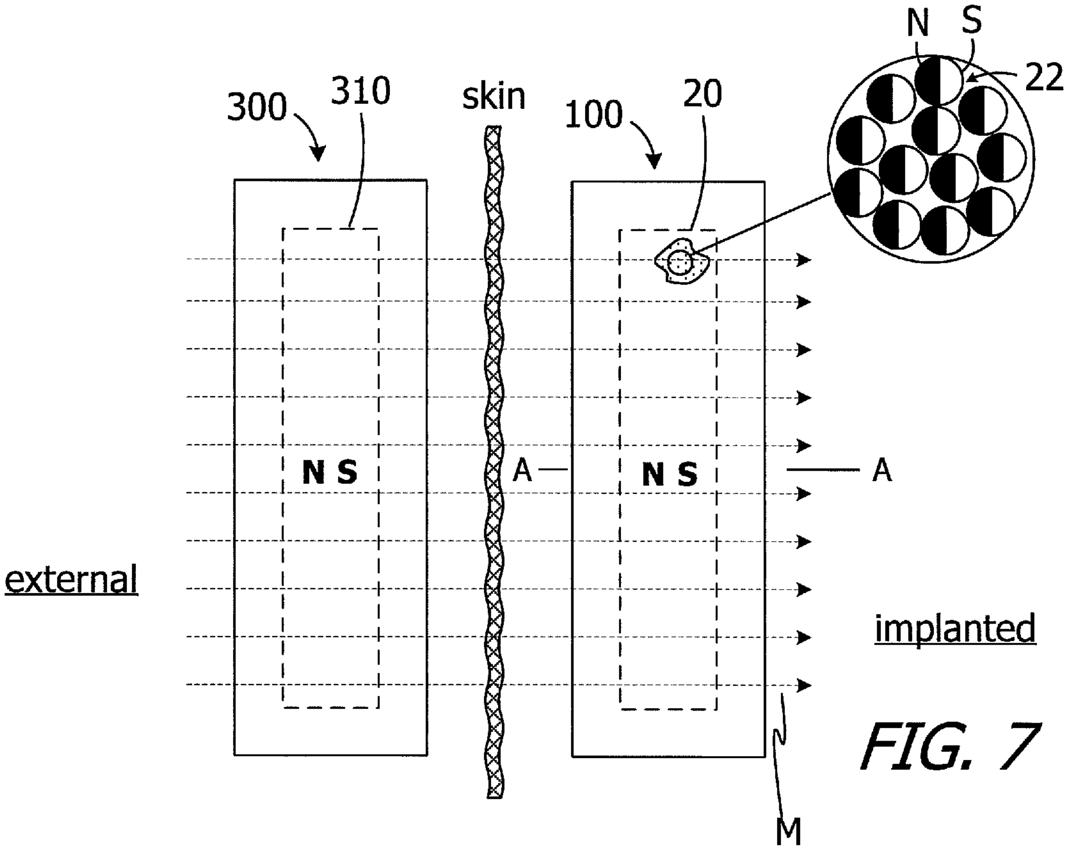
N S
A
N S
A
22
24

FIG. 6B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300
310
skin
100
20
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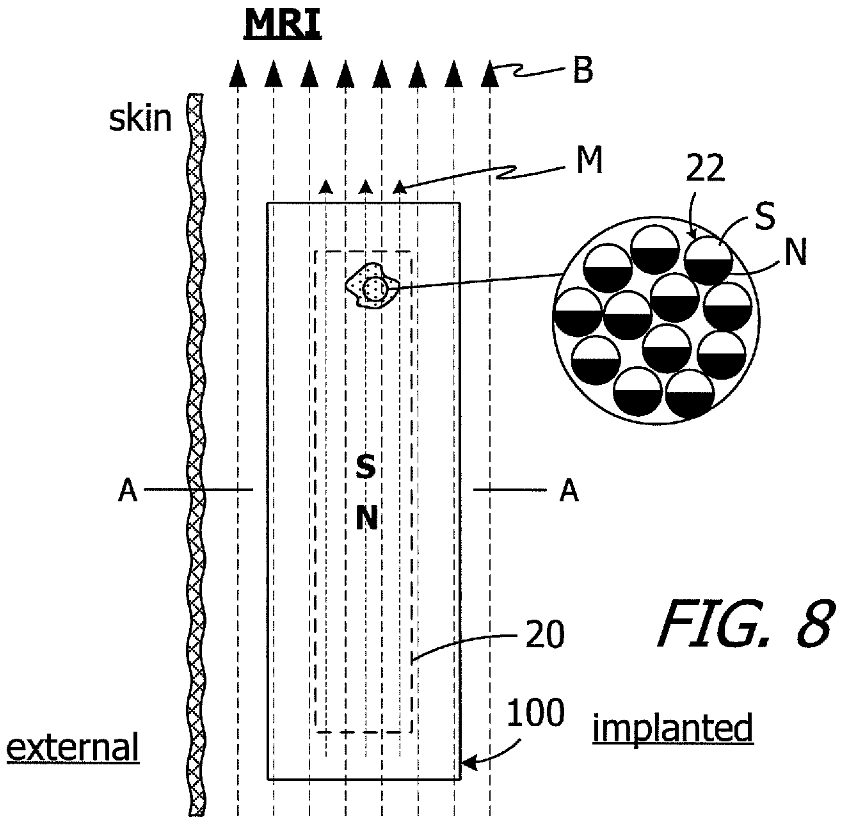
A
N S
A
external
implanted
M

FIG. 7


MRI
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22
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S
N
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20
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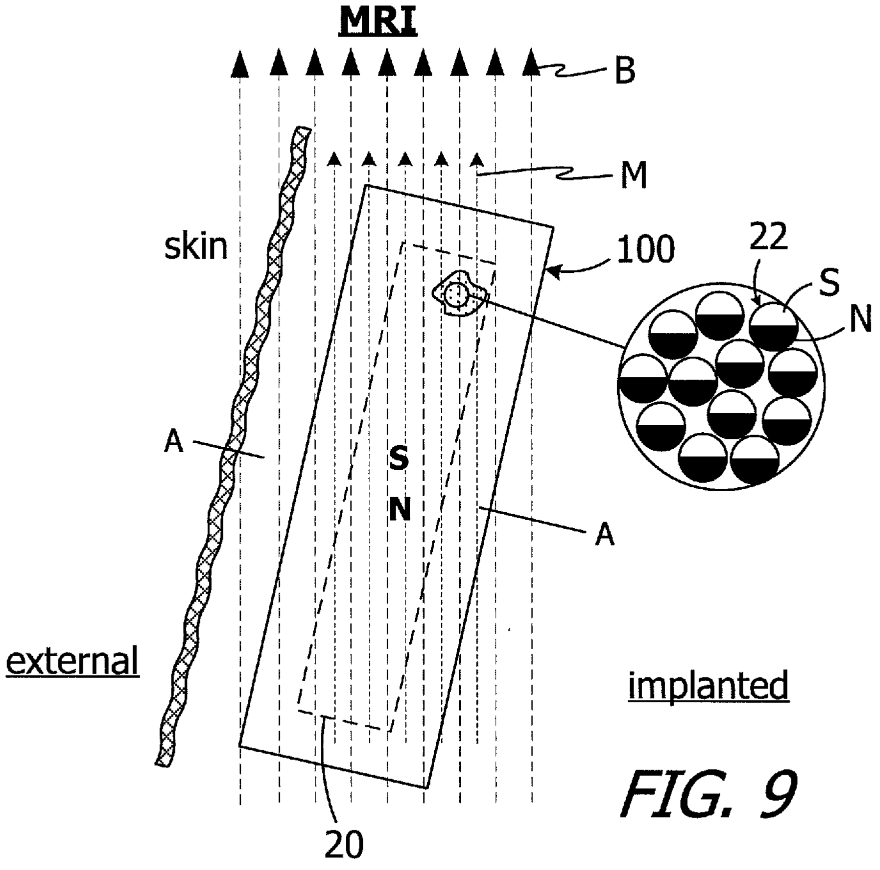
implanted
external

FIG. 8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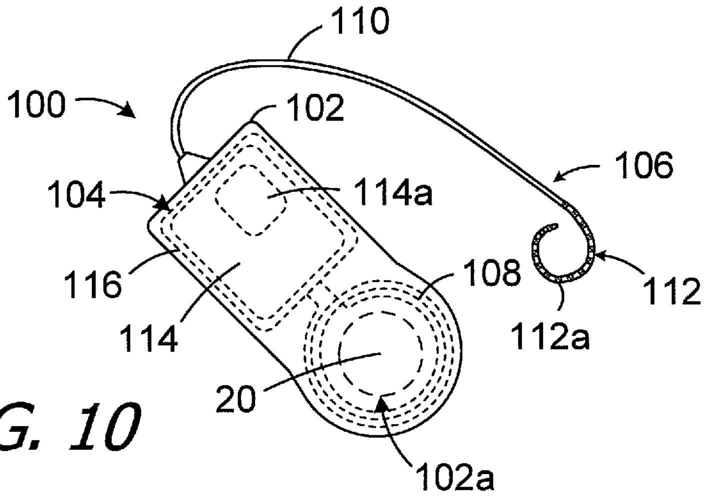
external
implanted
20

FIG. 9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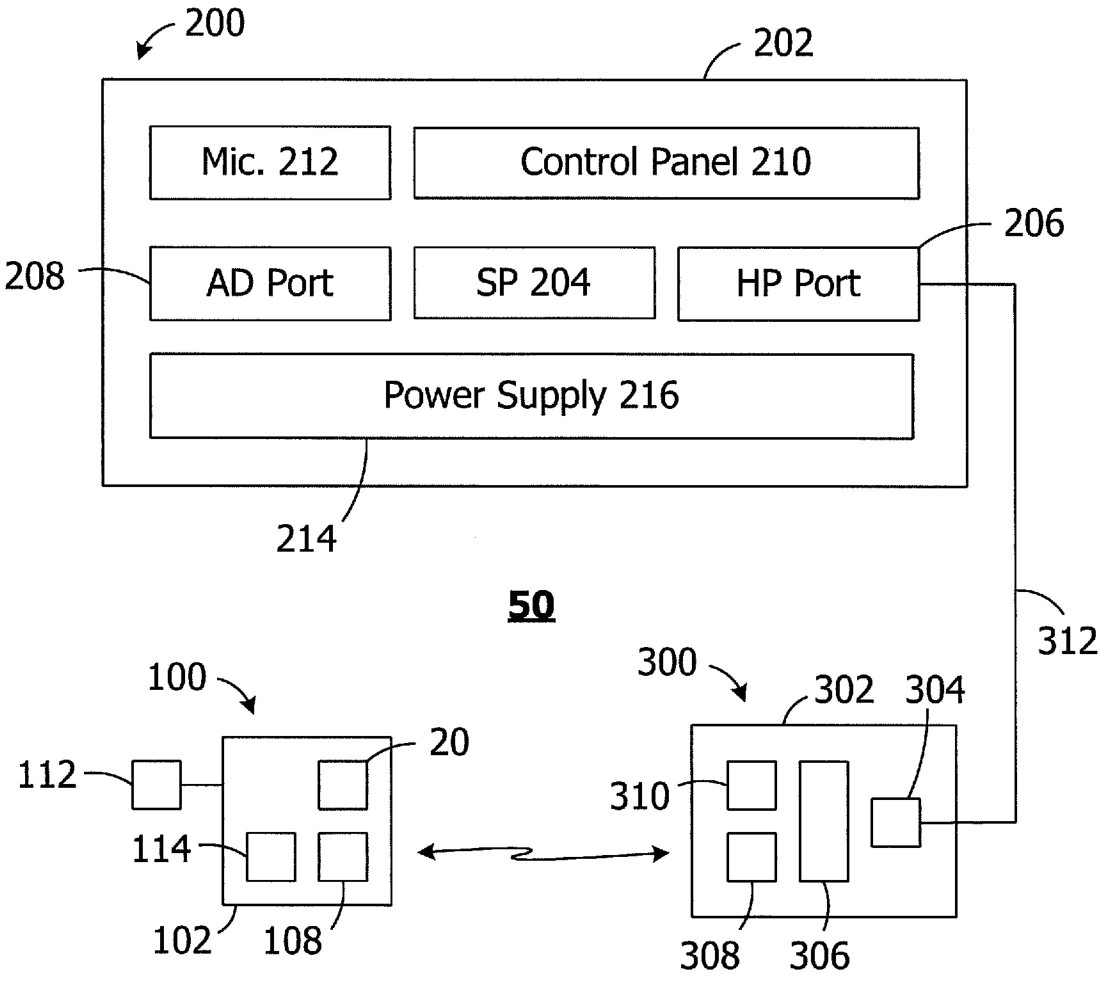
102a

FIG. 10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306

FIG. 11

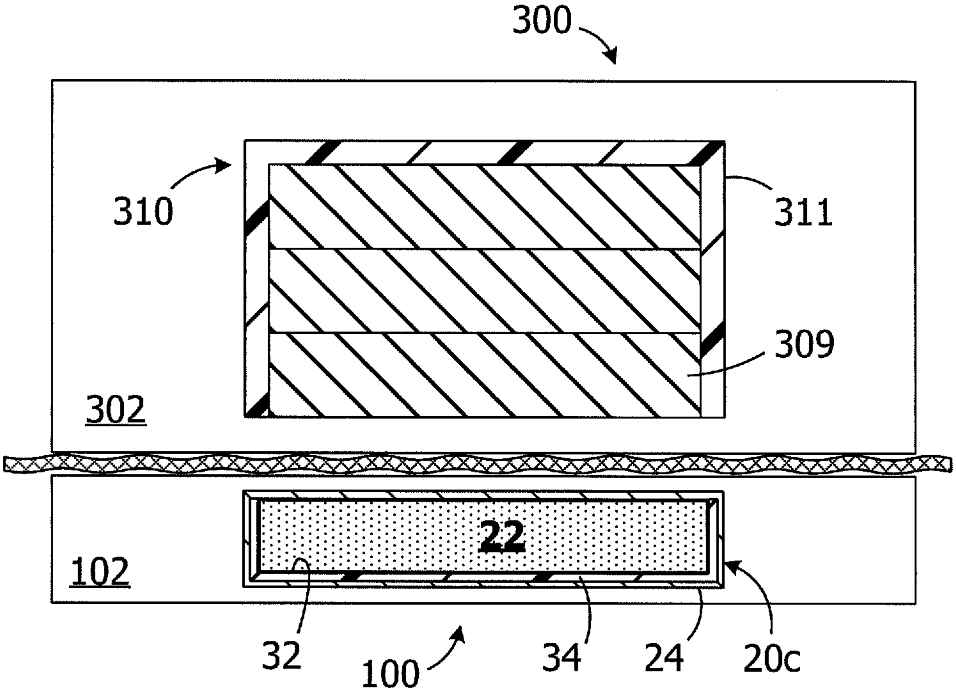

FIG. 12

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2015/033040

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/36 A61N1/08
ADD.

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)
A61N

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)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2014/012349 A1 (ZIMMERLING MARTIN [AT]) 9 January 2014 (2014-01-09) the whole document -----	1-24
A	WO 2014/011582 A2 (VIBRANT MED EL HEARING TECH [US]) 16 January 2014 (2014-01-16) the whole document -----	1-24
A	US 2014/012070 A1 (NAGL MARKUS [AT] ET AL) 9 January 2014 (2014-01-09) the whole document -----	1-24
A	US 2011/264172 A1 (ZIMMERLING MARTIN [AT] ET AL) 27 October 2011 (2011-10-27) the whole document -----	1-24

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"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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"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

"&" document member of the same patent family

Date of the actual completion of the international search 15 January 2016	Date of mailing of the international search report 01/02/2016
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Smit, Jos

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2015/033040

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