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(54) **IMPLANTABLE SENSOR**

IMPLANTIERBARER SENSOR

CAPTEUR IMPLANTABLE

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(56) References cited:

US-A- 3 958 558	**US-A- 4 494 411**
US-A- 5 755 743	**US-A- 6 132 384**
US-A1- 2003 078 671	**US-B1- 6 198 969**

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Description

[0001] The present invention relates to an implantable sensor and in particular to a sensor which can be implanted in a bone to be tracked by a tracking system.

[0002] Sensors which can be implanted into a body part of a patient can be used in surgical procedures for many applications. For example, implantable sensors can be used for measuring the temperature of a body part in which the sensor is located, and for measuring the amount of stress a body part is under. In particular, a sensor can be used to provide a registration mark whose location can be determined and tracked by a tracking system. Such a sensor can be implanted in a body part, such as a bone, so that the position of the bone can be tracked, e.g. during a surgical procedure.

[0003] When the sensor is used as a marker, a system in which the sensor is incorporated can be used to track the location of the sensor. This can be achieved using electromagnetic techniques. US-5391199 and US-5443489 provides details of systems which are applicable to the present invention, in which the coordinates of an intrabody probe are determined using one or more field transducers, such as a Hall effect device, coils, or other antennae carried on the probe. Such systems are used for generating location information regarding a medical probe or catheter. A sensor, such as a coil, is placed in the probe and generates signals in response to externally-applied magnetic fields. The magnetic fields are generated by magnetic field transducers, such as radiator coils, fixed to an external reference frame in known, mutually-spaced locations. Systems which are concerned with tracking a sensor in a three-dimensional space are also disclosed in WO-96/05768, US-6690963 and US-A-2002/0065455.

[0004] Implantable sensors are typically implanted immediately prior to a surgical procedure and can subsequently be removed immediately after the completion of the procedure. An implantable sensor of this kind can have a threaded exterior surface, allowing the sensor to be implanted in the bone with a screwing action, and removed from the bone by the reverse unscrewing action.

[0005] It is important that such a sensor is securely held within the body part so as to prevent movement of the sensor once it has been implanted. Any movement of the sensor within the body part can be undesirable, especially when the sensor is used for tracking purposes, because any such movement can lead to inaccuracies in the tracking of the sensor and the body part in which it is implanted. Further, in order to minimise the duration of the medical procedure by which the sensor is implanted, it can be desirable that the sensor can be easily implanted and removed from its site in the body part.

[0006] US-A-6132384 discloses an implantable pressure sensing device. The device includes a mounting element having an outer threaded sleeve and an inner threaded sleeve. The sensing element is positioned in a flexible tube by medical adhesive which fills the cone of the sensing element and covers the outer portions of the sensing element. The sensor assembly is anchored by a suture or bone screw through a hole in a flange portion of the outer threaded sleeve. The sensing device includes a flexible element at the first open end which prevents bone and tissue overgrowth; the flexible element collapses during removal of the assembly.

[0007] US-A-3958558 discloses a wireless, surgically implantable pressure transducer including a housing having a capacitor assembly and an inductor assembly mounted in the housing. Pressure sensitive bellows are secured and sealed to one end of the housing using a conductive epoxy adhesive. A flanged plug is secured to an end of the housing opposite the end on which the housing opposite the end on which the bellows is mounted. The transducer is free of external wired connections.

[0008] US-A-2003/078671 discloses a device suitable for placing in myocardial tissue. The device has a tubular body with at least two expandable anchor features. Anchor features can be formed by cutting several circumferentially spaced lengthwise slots through the wall of the tube along a portion of its length. The anchors can be elastically deflected into a tubular geometry.

[0009] US-B-6198969 discloses a detachable connector device for use with an implantable electrical stimulator. A stiff output bracket forms part of the housing and is made from a hard polymer such as epoxy resin. The output bracket forms part of the case of the implantable device. The bracket has a T-shaped cross section and an array of metal contacts on the base of the 'T'. The electrical circuitry is hermetically sealed within the case. A soft or compliant receiver is adapted to slide over the output bracket. Deformation of the receiver side walls insulates the metal contact connection points.

[0010] The present invention provides an implantable sensor in which the sensor part is enclosed by jacket which can be deformed inwardly.

[0011] Accordingly, the invention provides a sensor which can be implanted in a hole in bone, as defined in claim 1.

[0012] As the cable is not attached directly to the sensor part, the loads experienced by the cable when it is pulled on in use are not transferred to the sensor part. Therefore the likelihood of damage to any delicate parts of the sensor part is reduced.

[0013] The sensor of the invention has the advantage that the ease by which the implantable sensor can be implanted into the bone is significantly increased over existing implantable sensors. The use of a jacket that can be deformed inwardly allows the implantable sensor to be pushed into a previously prepared hole in the bone. This removes the need to apply a torsional force to the sensor during its implantation. This can be particularly advantageous as it can be difficult to impart a rotational force on implantable sensor, particularly because implantable sensors usually have very small dimensions. Further, the implantable sensor has a cable extending from one of its ends, for example, to facilitate extraction of the implantable sensor. During implantation of an existing implantable sensor, the cord can become twisted. The present invention removes the need to rotate the sensor and therefore avoids twisting of the cable which can damage the sensor or cord or both.

[0014] When an implantable sensor according to the present invention is implanted in the bone, the jacket is compressed within the hole. The elastic property of the jacket urges the jacket against the inner walls of the hole, and as a result the implantable sensor is held tight within the hole. Current implantable sensors can become loose from their site in the body part. For example, when the sensor is to be implanted in a bone, the anchorage of the sensor in the bone can be reliant on the thread of the screw thread cutting into the bone. If the bone is brittle, then it can be difficult to obtain a clean cut into the bone and therefore it can be difficult to securely anchor the sensor within the bone. As the present invention relies on compression forces rather than cutting forces, the implantable sensor of the present invention is not as affected by such problems. Accordingly, the use of a jacket that can deform inwardly can decrease the risk of the implantable sensor moving inadvertently relative to the bone during the medical procedure.

[0015] The use of deformable jacket to engage the wall of a hole in a body part such as a bone can help to avoid problems of insecure fixation due to inaccuracies in the preparation of the hole. For example, a hole might be made slightly bigger than is desirable for secure fixation. In the case of a sensor which engages the hole wall by means of a screw thread, the connection that is provided by the screw thread can be less secure than intended. The resilient nature of the jacket of the sensor of the invention can facilitate secure fixation, accommodating variations in the shape and dimensions of the hole.

[0016] Furthermore, it has been found that the use of a jacket that can deform inwardly can increase the ease by which the implantable sensor can be removed from the bone. Implantable sensors that utilise a screw thread require a rotational force to be imparted on the implantable sensor which as described above can be difficult. The sensor of the present invention, can be removed by pulling the sensor out of the hole, along its axis. Little or no rotational force need be imparted on the sensor of the present invention in order to remove it.

[0017] The sensor can be removed by pulling on the cable attached to the end of the sensor with a sufficient force along the axis of the sensor. The use of a jacket can therefore enable the implantable sensor to be removed without the use of a third party instrument. This can greatly simplify the removal of the sensor as the surgeon does not need to locate a third party instrument on the sensor in order to do so. This can be particularly difficult when the dimensions of the sensor are very small.

[0018] It has also been found that the use of a jacket that can deform inwardly can decrease the dimensions of the implantable sensor. The cable means no provision need be made on the implantable sensor which allows it to be attached to a third party implement in order to impart a rotational force on it. This can enable the implantable sensor to be designed so as to be more compact.

[0019] The cable can include a reinforcing member to strengthen the cable. The reinforcing member can be provided as a core of the cable. This helps to increase the strength of the cable and reduces the likelihood of the wire or wires in the cable being damaged when the cable is pulled on in use.

[0020] The sensor part can comprise at least one sensor coil. The sensor coil can be electrically connected to the wire or wires in the cable to allow signals generated by the sensor coil to pass from the sensor along the wire. Hence electrical signals from the sensor part can be supplied to other electrical equipment outside the sensor. For example the other electrical equipment can be a tracking system.

[0021] The sensor can collect data relating to the body part. For example, the sensors can be used for measuring the temperature of a body part in which the sensor is located. Optionally, the sensor can be used to measure the amount of stress a body part is under.

[0022] Preferably, the sensor part can be adapted to be tracked by a tracking system. Preferably, the sensor part can be trackable by an electromagnetic tracking system. Preferably, the sensor part includes at least one sensing coil which can generate a signal in response to an electromagnetic field generated by a generator coil or coils of a tracking system. Preferably, the sensor part is able to provide position information in multiple degrees of freedom, including up to six degrees of freedom. It can be preferred for the sensor of the present invention to provide position information in three degrees of freedom and/or orientation information in three degrees of freedom. Less detailed information can be appropriate for some applications, for example at least three degrees of freedom, preferably at least four degrees of freedom, more preferably at least five degrees of freedom.

[0023] Preferably, the sensor part comprises three mutually perpendicular coils which can generate electrical signals via induction owing to the location of the sensor in a time varying magnetic field. Preferably, the signals generated by the coils are proportional to the strength of three perpendicular components of the magnetic field, from which the position of the sensor part in the magnetic field and the orientation of the sensor part can be determined.

[0024] The cable includes a wire or wires for carrying an electrical signal or signals which can be connected to, and allow communication between, the sensor part and an external device. The cable can carry power to the sensor where this is required in order for the sensor to produce a signal.

[0025] A wire which extends from the sensor can carry a signal from the sensor to an external component. For example, the signal can be carried to a system controller, in particular which is able to analyse the signal. The wire can extend from the sensor to an external pad which can be fastened to the patient's skin or to another convenient surface, for example on the operating table. Preferably, the sensor generates a field when it is within a magnetic field which is generated by a local magnetic field generator provided on a pad which is adapted to be affixed to a surface of the body of the patient. The pad can include a plurality of concentric orthogonal magnetic field generating coils. A driving antenna can be provided to radiate a radio frequency (RF) electromagnetic field. The pad can include a power coil which is coupled to receive the RF electromagnetic field and thereby to provide power for generating the magnetic field. Alternatively, the pad can include an internal power source to provide power for generating the magnetic field. It can however be particularly preferred for the pad to be connected by means of conductors to a source of electrical power.

[0026] A local magnetic field generator which is provided on a pad can be used in conjunction with the sensor of the invention, when implanted in a patient's body, to provide information about the patient, in particular as to the location and orientation of the part of the body in which the sensor is implanted.

[0027] Tracking systems which comprise a pad by which a magnetic field can be generated and at least one position transducer or sensor are disclosed in US patent application no. 11/062,258 filed on 22 February 2005 and published under publication number US 2005/0245821.

[0028] The cross-sectional shape of the sensor along its length will generally be uniform. The cross-sectional shape of the sensor will generally be circular. It will be understood that the cross-sectional shape can be any other regular or irregular shape, for example square or triangular.

[0029] The cross-sectional size of the sensor will be generally uniform along at least part of its length. However, it can be preferable for the cross-sectional size to decrease towards its ends. This can aid insertion and removal of the sensor from the body part. For example, the ends of the sensor can be tapered towards a point. For example, when the cross-sectional shape of the sensor is generally circular, the end sections of the sensor can be generally conical. A taper at one end of the sensor can also allow attachment of a cord without affecting the ability of the sensor to fit into a hole in the bone or other body part.

[0030] Preferably, the cross-sectional shape of the jacket along at least part of its length is circular. The cross-sectional shape of the jacket will generally be the same as that of the sensor part. For example, when the cross-sectional shape of the sensor part is circular, the cross-sectional shape of the jacket can also be circular. However, it will be appreciated that this need not be the case and the jacket and sensor can have different cross-sectional shapes.

[0031] Preferably, the jacket has at least one compression line that extends generally between the first and second ends which facilitates inward deformation of the jacket. A compression line can be any formation in the jacket which extends along the length of the jacket which facilitates inward deformation of the jacket. The provision of at least one compression line can help ensure that the jacket is able to compress sufficiently for it to be fitted within a prepared hole in a bone or other body part. It can also ensure that the jacket compresses in a controlled manner. It has been found that the provision of a compression line can allow the inward deformation of the jacket (with any associated creasing) to be controlled and as a result can help prevent the jacket from creasing undesirably. The proper deformation of the jacket can help to make the anchorage of the sensor within the bone more secure. It can also increase the reusability of the sensor.

[0032] Preferably, the compression line extends along at least 60% of the length of the jacket, more preferably at least 70% of the length of the jacket, especially preferably at least 80% of the length of the jacket, for example at least 90% of the length of the jacket. The greater the proportion of jacket along which the compression line extends, the greater proportion of the jacket that facilitates inward deformation.

[0033] Preferably, the jacket has at least two compression lines spaced around the jacket. The provision of two compression lines can increase the amount by which the jacket can be inwardly deformed. More preferably, the jacket has at least three compression lines, especially preferably at least four compression lines. Preferably the compression lines are spaced apart around the jacket approximately equally. This can help to ensure that the jacket deforms evenly.

[0034] As will be understood, a compression line can reduce the structural integrity of the jacket. Preferably, the jacket has not more than eight compression lines. More preferably the jacket has not more than six compression lines, especially preferably not more than five compression lines.

[0035] The compression line can be a longitudinally extending crease which facilitates folding of the jacket along the crease. The use of a crease can be advantageous as the crease can be formed so that when the jacket folds along the crease, the jacket along the fold protrudes radially outward relative to the sensor. This can increase the amount by which the jacket is compressed in the hole, and therefore can increase the force by which the jacket is urged against the walls of the hole in which the sensor is implanted. Therefore, the use of a crease can increase anchorage of the sensor in the body part.

[0036] Preferably the compression line is in the form of a longitudinally extending slit formed in the jacket. This can be advantageous as it can allow the jacket to deform inwardly without restriction. Also, as the jacket is urged radially outward once compressed in a hole, the edges of the slits can tend to catch against the walls of the hole. This has been found to enhance the stability and anchorage of the sensor in the hole. Furthermore, a jacket in which the compression line is a slit can also be manufactured easily by simply cutting a section of the jacket.

[0037] Preferably, the jacket and slit are configured so that when the sensor is implanted in the body part, the opposing longitudinal edges of the slit come close to abutting.

[0038] The greater the width of the slit between its opposing longitudinal edges, the greater the inward deformation of the jacket facilitated by the slit. Preferably, the ratio of the circumference of the jacket to the width of the slit is not more than about 10, more preferably not more than about 5, especially preferably no more than about 2. Preferably, the width of the slit, between opposing longitudinal edges, is at least about 0.1 mm, more preferably at least about 0.2 mm.

[0039] The greater the width of the slit between its opposing longitudinal edges, the greater the reduction in structural integrity. Also, the greater the width of the slit between its opposing longitudinal edges, the more easily the jacket will compress, therefore the less the jacket will resist being compressed, and hence the smaller the retaining force provided by the jacket. Preferably, the width of the slit is not more than about 2.0 mm, more preferably not more than about 1.0 mm, especially preferably no more than about 0.4 mm.

[0040] Preferably, the proportion of the of the jacket that is open in a band that extends around the circumference of the jacket and which is arranged such that its plane is perpendicular to the axis of the jacket, is not more than 50%, more preferably not more than 25%, especially preferably no more than 10%.

[0041] The cable can include a signal carrying wire which can be connected to, and facilitate communication between, the sensor part and an external device.

[0042] Preferably, the cable comprises a load bearing core for transferring force to the jacket, and at least one signal carrying wire for carrying electronic signals to and/or from the sensor part. It can be preferable to provide a load bearing core in order to help prevent any load being borne by the signal carrying wire, in particular during extraction of the sensor. This is because, the signal carrying wire, and/or the connection between the signal carrying wire and the sensor part, can be structurally weak and not able to withstand forces required to extract the sensor from the body part.

[0043] Preferably, the force transfer member is a bar that extends across the jacket between opposite side walls, and the cable is connected to the bar. Preferably, it is the core of the cable that is attached to the bar, for example by means of a knot or of a crimped ferrule.

[0044] The core of the cable can be made of any material which can withstand forces exerted upon the core during removal of the sensor in the body part. For example, preferably the core can withstand forces of at least 98 N (10 kg), more preferably at least 147 N (15 kg), especially preferably at least 196 N (20 kg), for example 255 N (25 kg). The core can be made of fishing wire. The core can be made of extruded polyethylene wire. The core can be made of an aramid fibre.

[0045] Preferably, the signal carrying wire is a twisted pair of insulated copper wire. Preferably, the signal carrying wire is coated in an insulating material. For example, the signal carrying wire can be coated with a low friction polymer such as a polytetrafluoroethylene. Preferably, there are at least two signal carrying wires, more preferably at least three signal carrying wires.

[0046] Preferably, the cable includes an insulating member so as to shield the sensor carrying wire from electrical noise created by external devices. Preferably, the insulating member is an inner coating formed on the inside of the cable.

[0047] Preferably, the sensor part is connected to the force transfer member.

[0048] Preferably, the connection between the sensor part and the force transfer member is embedded in a body of a resin material. Preferably, the connection between the sensor part and the bar is encapsulated by a resin material. Preferably, the sensor part and the bar are encapsulated by a resin material. Preferably, the jacket encloses the resin material. It can be preferable to encapsulate the sensor part within a resin material as this can help prevent the ingress of moisture during use of the sensor. It can also help to provide some structural rigidity and stability to the sensor part. This can be useful when the sensor part contains delicate electronics. Preferably, the resin material is an epoxy resin. Preferably, the resin material is moulded around the sensor part and the bar.

[0049] Preferably, the bar is in the form of a generally cylindrical bar extending between opposing sides of the jacket. Preferably, the length of the bar is greater than the width of the sensor part so as to allow the jacket to be attached to the ends of the bar. Preferably, the bar is made of a sufficiently strong and rigid material so as to withstand forces exerted upon it by the cable during removal of the sensor. The connection between the sensor part and the bar should be sufficiently strong so as to withstand compression and tension forces exerted on the bar during insertion and removal of the sensor. When the sensor part and the bar are encapsulated by a mould of epoxy resin, this can increase the strength of the connection between the bar and the sensor part. The sensor can include a wireless transmitter, receiver or transceiver for sending and/or receiving signals to an external device. Further, the sensor need not necessarily send signals to an external device during the medical procedure. For example, the sensor could include memory which can store data which can be transferred to an external device subsequent to the medical procedure.

[0050] Preferably, the jacket is tapered inwardly at at least one of the first and second ends. This can aid implantation and extraction of the sensor. In particular, when the end of the jacket which is to be inserted into the hole first is tapered, this can increase the ease by which the sensor can be located in the hole and hence implanted into the body part.

[0051] Preferably, the jacket comprises a first portion at the first end, a second portion at the second end, and a third portion between the first and second ends. The provision of different portions can allow the different portions to have different characteristics. For example, preferably the first and second portions are tapered towards their free ends, and the width and shape of the third portion is substantially uniform along at least part, preferably all, of its length.

[0052] This is particularly true when the width of the third portion is significantly greater than the width of the sensor part which it encapsulates. This is because the jacket can be compressed and deform to allow the sensor to be implanted into a hole which has a width less than the width of the jacket, but greater than the sensor. Preferably, the average transverse dimension (which will be the diameter when the jacket has a circular cross-section) of the third portion is at least 5% greater than the width of the sensor part which is surrounded by the third portion, more preferably at least 10%, especially preferably at least 20%, for example, at least 40%.

[0053] Preferably, the width of the third portion is substantially uniform along its length. Preferably, the cross-sectional shape of the jacket along taken in a direction perpendicular to the axis of the third portion is approximately constant along its length. Therefore, when the cross sectional shape of the jacket is generally circular, the third portion is generally cylindrical.

[0054] Preferably, the ratio of the length of the third portion (measured along the jacket) to the length of the first portion is at least about two, more preferably at least about three, especially preferably at least about four, for example at least about five. Preferably, the ratio of the length for the third portion to the length of the second portion is at least about two, more preferably at least three, especially preferably at least four, for example five. Therefore, the length of the third portion is preferably longer than the length of the first and second portions. This is especially preferable when the first and second portions taper inwardly as towards the ends of jacket, because it will generally be the third portion that provides a significant proportion of the retaining force which helps to hold the sensor in place in the body part.

[0055] Preferably, the compression line extends along the entire length of the third portion. Preferably, the compression line extends into the first portion. Preferably, the compression line extends into the second portion.

[0056] Preferably, the compression line extends along at least 25% of the length of the first portion (measured in a direction parallel to the axis of the first portion), more preferably at least 35%, especially preferably at least 40%, for example at least 45%. Preferably, the compression line extends along not more than 90% of the length of the first portion, more preferably not more than 70%, especially preferably not more than 60%, for example not more than 50%.

[0057] Preferably, the compression line extends along at least 25% of the length of the second portion taken in a direction parallel to the axis of the second portion, more preferably at least 35%, especially preferably at least 40%, for example at least 45%. Preferably, the compression line extends along not more than 90% of the length of the second portion, more preferably not more than 70%, especially preferably not more than 60%, for example not more than 50%.

[0058] The three portions of the jacket can be formed from separate pieces of material, joined together at their ends. Preferably, the three portions of jacket are formed from material having the same material properties. More preferably, the three portions of the jacket are formed from separate pieces of the same material.

[0059] It is however particularly preferred that the jacket is formed from a single piece of material, for example from a sheet of material that is welded or otherwise bonded along a seam, or by an extrusion technique, possibly in combination with cutting and bonding steps. This can be simpler to manufacture than a jacket which is formed in three portions joined together at their ends.

[0060] Preferably, the side wall of the jacket is sufficiently resilient so that it returns substantially back to its original shape upon removal of an external force after it has been deformed. The side wall of the jacket is sufficiently resilient so that once it has been deformed by placing the sensor in a hole in a body part, the jacket is urged against the inner walls of the hole so as to provide a retaining force which is sufficient to hold the sensor in place. Preferably, the side wall of the jacket is sufficiently resilient so that, when the sensor is implanted in a hole in a bone, a force of at least 29.4 N (3 kgf) in an outward direction parallel to the axis of the sensor is required to pull the sensor out of the bone, more preferably at least 39.2 N (4 kgf), especially preferably at least 49.0 N (5 kgf). Preferably, the force required to pull the sensor out of the bone is less than 78.5 N (8 kgf), more preferably less than 68.6 N (7 kgf), especially preferably less than 49 N (5 kgf).

[0061] The material of the jacket may deform plastically on insertion into the hole in the body part.

[0062] A jacket can be made of any material having the aforesaid properties. A jacket can be made from a metallic material (including an alloy) having the aforesaid properties. For example, the jacket could be made from a shape-memory alloy, stainless steel or titanium. A jacket can be made from a polymeric material having the aforesaid properties.

[0063] The sensor of the invention can be implanted using an exemplary instrument comprising: a guide sheath for defining a path to the surface of the body part through overlaying soft tissue, the sheath having a bore extending along its length between first and second open ends through which the tool can pass and a slot that extends along its length between its first and second open ends; and a delivery sheath for inserting the sensor in the hole, the delivery sheath having a bore extending along its length between a first open end at which the sensor can be mounted and a second end, with the wire extending from the sensor along the bore, in which the sheath has a slot that extends along its length between its first and second end, and wherein the delivery sheath can be received within the guide sheath by sliding the delivery sheath within the bore of the guide sheath; wherein the slots of the guide and delivery sheaths can be aligned to allow the wire to be removed from the bores other than at the ends of the bores.

[0064] Such an exemplary instrument is disclosed in the co-pending PCT application filed with the present application which claims priority from European Patent Application no. 05250996.5 and published under publication no. WO 2006/090139. Details of such a sensor are also disclosed in US patent application no. 11/063,018 filed on 22 February 2005 and published under publication no. US 2006-0190009.

[0065] An embodiment of the invention will now be described in detail, by way of example only, and with reference to the accompanying drawing, in which:

Figure 1 shows a schematic longitudinal cross section through a sensor according to the invention;

Figure 2 shows a transverse cross section through a cable part of the sensor;

Figure 3 shows a schematic illustration of the sensor shown in Figure 1;

Figure 4 shows a schematic illustration of the sensor shown in Figure 1 located in a bone; and

Figure 5 shows a flow chart illustrating an exemplary method of making the sensor shown in Figures 1 to 4.

[0066] Referring to the drawings, Figure 3 shows a schematic illustration of an implantable sensor 100 according to the invention. For illustrative purposes only, the sensor described hereinafter is a sensor that can be tracked by a tracking system in order to track the location of the body part in which the sensor is implanted. Also as described hereinafter, the sensor is implanted in a bone.

[0067] The sensor includes an external jacket 102 which encloses a sensor part 110, as illustrated in Figure 1. Figure 1 shows a view of the sensor 100 with external jacket 102 removed. Sensor part 110 includes a body or bobbin around which three mutually perpendicular coils of 10 μm diameter wire are wound. In use, the three mutually perpendicular coils generate electrical signals via induction owing to the location of the sensor part in a time varying magnetic field. The signals generated by the coils are proportional to the strength of three perpendicular components of the magnetic field, from which the position of the sensor part in the magnetic field and the orientation of the sensor part can be determined. The two ends of each coil are soldered to a contact pad toward the distal or free end of the sensor. The sensor part may be a Hall effect device, coils, or other antennae which can be contained in the shaft. An example of a suitable coil sensor part is disclosed in US-A-2003/0120150 (Govari). The disclosed sensor part, includes at least one sensing coil which can generate a signal when it moves within an electromagnetic field transmitted by a local transmitter. The disclosed coil sensor part is able to provide position information in multiple degrees of freedom, including up to six degrees of freedom. It can be preferred for the sensor part to provide position information in six degrees of freedom, although less detailed information can be appropriate for some applications, for example at least three degrees of freedom, preferably at least four degrees of freedom, more preferably at least five degrees of freedom.

[0068] Sensor 100 also includes a cord 104. Figure 2 shows a transverse cross section through cord 104. The cord 104 includes a central load bearing core 106 having a diameter of approximately 0.3 mm. The cord 104 has an outer diameter of approximately 2.8 mm. The core 106 can be made of any suitable material which can handle forces up to approximately 20 kg, such as an aramid fibre (especially that sold under the trade mark Kevlar), or extruded polyolefin (especially polyethylene) wire or fishing wire. Arranged around core 106 are three twisted pairs of insulated copper wire, each having a diameter of approximately 40 microns. The wire may be a low friction polymer such as a polytetrafluoroethylene (PTFE) (such as that sold under the trademark Teflon) coated or have some other insulating coating. Each twisted pair 108 carries an electrical signal from a respective one of the coils of the sensor part 110. The cord 104 also includes an inner coating 107 providing electrical insulation and also to shield electrical noise, such as white noise and electrical cross talk. Finally, an outer coating 105 is provided. The outer coating 105 can be of PTFE, polyethylene or any other similar bio-compatible material, and provides an interface between the cord and soft tissue of a patient in use.

[0069] Each wire of the twisted pair 108 of cord 104 is attached to respective contact pads for respective coils to provide electrical communication between the signals generated by the sensor coils and the cord.

[0070] The sensor also includes a circular bar 112 extending transversely across the sensor. The internal core 106 of cord 104 is tied around bar 112 using a hitch knot, or similar, non-slipping knot, so that loads on cord 104 are transferred to bar 112 which acts as a force transfer member.

[0071] The sensor part 110, bar 112 and cord 104 are held together by a moulded epoxy resin 114 which provides some structural rigidity to the sensor and encapsulates the sensor part and electronics so as to hermetically seal the sensor part and electronics. The epoxy resin material also acts to attach the sensor part to the bar 112 and also to stabilise the cord 104 toward the proximal end of the sensor. The epoxy resin toward the proximal end of the sensor has a shoulder structure 116.

[0072] Jacket 102 is made of a metal or alloy, such as

316 stainless steel or titanium. The jacket can be assembled from a piece of sheet metal bent into the appropriate profile and laser welded along a longitudinal seam. Alternatively, the jacket can be manufactured from three tubular sections which are joined together by circumferential laser welding. The jacket has a thickness of approximately 0.1 mm and has a plurality of gaps or cut outs 118 therein. The jacket has a tapered leading free end 120 which acts to automatically locate the free end of the sensor in a hole in use. A central body section 122 of the jacket has a diameter of approximately 2.8 mm and is slightly larger than the diameter of a hole into which the sensor is to be press fitted. An upper or neck portion 124 of the jacket has a diameter substantially matching that of the hole into which the sensor is to be press fitted and provides continuous smooth fit with the shoulder portion 116 of the epoxy resin encapsulate. The jacket 102 is attached to the remainder of the sensor by laser welding to the free ends of bar 112. Hence the jacket 102 encloses sensor part 110 and loads impinging on jacket 102 are transferred to force transfer member 112 rather than to the sensor part which is isolated from forces applied to the jacket.

[0073] The body portion 122 of the jacket acts similarly to a leaf spring so that the jacket is resiliently deformable to secure locate the sensor in a patient's bone in use. Figure 4 shows a schematic illustration of the sensor 100 located in use in a drilled hole 130 in a bone 132 of a patient. The hole 130 has been pre-drilled in the patient's bone using a drill having a drill bit with a diameter of approximately 2.6 or 2.7 mm. As illustrated in Figure 4, a hole drilled in bone typically does not have a smooth well defined surface but rather the shape of the hole varies with depth. The sensor 100 is press fitted in hole 130. Initially the leading distal end 120 helps to guide the sensor into the aperture of hole 130. As the sensor is pushed into hole 130 the jacket deforms as the jacket has a diameter greater than that of the hole. As illustrated in Figure 4, the slits 118 of the jacket are sized or otherwise configured such that when the jacket is fully deformed in the hole, the edges of the slits, 134, 136, abut, or come close to abutting, so as to close the slits. The slits are also required in order to allow the diameter of the jacket to reduce as the sensor is pushed into the hole 130. When the sensor is implanted in the hole, the elastic property of the material of the jacket urges the walls of the body of the jacket against the inner walls of the hole so as to provide a retaining force helping to hold the sensor in place. In particular, the material of the jacket may plastically deform slightly.

[0074] As well as the resilience of the jacket holding the sensor in place, over time, bone material toward the outer of the bone 132 tends to move over the shoulder portion 116 of the sensor with a further action to retain the sensor in place. Hence, during insertion, the jacket of the sensor absorbs the forces applied to the sensor thereby tending to isolate the sensor part from those forces.

[0075] In order to remove the sensor, a force is applied to the cord 104 in a direction substantially parallel to the longitudinal axis of the sensor and hole 130. If the force is applied at an angle to that direction, then the sensor tends to be retained within the bone so that the sensor tends not to be removed unless the cord is pulled on the correct direction. This helps to prevent the sensor from becoming dislodged during a medical procedure.

[0076] The properties of the metal jacket are selected so as to optimise the balance of the insertion force required, the holding or retaining force when in place and the extraction force required to remove the sensor.

[0077] In practice, the sensor can be implanted in various different bones or body parts. With regard to bones, in general, the diameter of the hole 130 into which the sensor is implanted should not be greater than approximately 10% of the diameter of the bone at the location implantation. It has been found that holes with a greater diameter are not reliable. Therefore, for a typical bone diameter of approximately 30 cm, an upper limit on the diameter of the bone hole would be approximately 3 mm and so the diameter of the sensor should similarly be approximately 3 mm or slightly greater.

[0078] As well as helping to retain sensor 100 in place in the bone, shoulders 116 also help to facilitate removal of the sensor by enabling a smooth release of the sensor through soft tissue. In practice, owing to the small diameter of the sensor, the sensor can be implanted without requiring an incision. A local anaesthetic can be used and then a guide tube, having a drill with a drill bit extending at the free end of the guide tube is used as a trocar to puncture the skin of the patient. The drill bit is then operated to drill the hole in the bone, before being withdrawn from the guide tube. The sensor is then introduced via the guide tube into the pre-drilled hole 130 and can be press fitted therein. Removal is as described above, in which a practitioner simply pulls on the cord 104, in a direction along the longitudinal axis of the hole 130 so as to release the sensor from the bone. As the central reinforcing cord 106 of the cord 104 is secured to the bar 112, on extraction, the pulling force is transmitted to the bar 112 rather than to the sensor electronics. Therefore, on removal, the forces applied to the sensor are isolated from the sensor components.

[0079] With reference to Figure 5 there is shown a flowchart illustrating a method 150 for making the sensor shown in Figures 1 to 4. The method begins at step 152 at which the three mutually perpendicular coils are wound on the body or former. Then at step 154 the two free ends of each coil are each contacted to a respective contact pad by soldering. Then at step 156 the two wires of each twisted pair 108, 108', 108", are each electrically connected to a respective wire of the induction coils by soldering so as to provide an electrical connection from the coils out of the sensor. Then at step 158, the reinforcing core 106 of the cord 104 is fastened around bar 112 for example using a knot so as to anchor the cord to the force transfer member. Then at step 160, a mould is used to encapsulate the sensor electronics and cord within an epoxy resin. After the epoxy resin has set, the encapsulated sensor part is removed from the mould and at step 162 the jacket is attached around the encapsulated sensor part and secured to the sensor by laser welding to the exposed free ends of the bar 112.

[0080] The epoxy resin both encapsulates the sensor part to prevent the ingress of moisture during use and also helps provide some structural rigidity and stability to the delicate sensor part electronics. Further, the attachment of the cord to the bar and the connection of the jacket to the bar 112 causes forces experienced by the sensor during insertion and extraction not to be passed to the sensor part components, thereby protecting the delicate sensor part electronics. Hence, the present invention provides a sensor which can easily be implanted in and extracted from a patient's bone and also protecting the delicate sensor part electronics.

Claims

1. A sensor (100) which can be implanted in a hole (130) in bone (132), the sensor comprising:

   a jacket (102) which has a resilient side wall which can be deformed inwardly such that, when the sensor is placed in the hole, the jacket is compressed and urged against the inner side walls of the hole so as to provide a retaining force sufficient to hold the sensor in place, and the jacket having a longitudinal axis,
   a sensor (110) part which is contained within the jacket (102),
   a force transfer member (112) to which the jacket is attached, and
   a cable (104) including a wire (108, 108', 108") for carrying electrical signals to or from the sensor part, wherein the cable is attached to the force transfer member so that the sensor part is at least partially isolated from forces resulting from pulling on the cable in the direction of the longitudinal axis of the jacket.

2. A sensor (100) as claimed in claim 1, wherein the cable (104) includes a reinforcing member (106) to strengthen the cable.

3. A sensor (100) as claimed in claim 2, wherein the cable (104) is attached to the force transfer member (112) by the reinforcing member (106).

4. A sensor (100) as claimed in any of claims 1 to 3, wherein the sensor part comprises at least one sensor coil and wherein the sensor coil is electrically connected to the wire to allow signals generated by the sensor coil to pass from the sensor along the wire.

5. A sensor (100) as claimed in claim 1, wherein the jacket has first and second ends, and wherein the sensor part is fastened to the jacket at or towards the first end of the jacket.

6. A sensor (100) as claimed in claim 1, in which the sensor is configured to collect data relating to the body part.

7. A sensor (100) as claimed in claim 1, in which the sensor is trackable by a tracking system.

8. A sensor (100) as claimed in claim 5, in which the jacket has at least one longitudinally extending slit (118) or longitudinally extending crease, which facilitates folding of the jacket along the crease, that extends generally between the first and second ends which facilitates inward deformation of the jacket (102).

9. A sensor (100) as claimed in claim 8, in which the longitudinally extending slit (118) or longitudinally extending crease extends along at least 60% of the length of the jacket.

10. A sensor (100) as claimed in claim 8, in which the jacket has at least two spaced apart longitudinally extending slits or longitudinally extending creases.

11. A sensor (100) as claimed in claim 1, in which the force transfer member is a bar (112) which extends across the jacket (102) between opposite side walls.

12. A sensor (100) as claimed in claim 11, in which the sensor part (110) is connected to the bar (112).

13. A sensor (100) as claimed in claim 12, in which the connection between the sensor part (110) and the bar (112) is embedded in a body of a resin material (114).

14. A sensor as claimed in claim 5, in which the jacket (102) is tapered inwardly at at least one of the first and second ends (120).

15. A sensor (100) as claimed in claim 5, in which the jacket (102) comprises a first portion at the first end (124), a second portion (120) at the second end, and a third portion (122) between the first and second ends.

16. A sensor (100) as claimed in claim 15, in which the first, second and third portions of the jacket are formed from separate pieces of material.

17. A sensor as claimed in claim 15, in which the cross-sectional shape of the jacket is approximately constant along the third portion (122) of the jacket.

18. A sensor as claimed in claim 5, in which the jacket (102) comprises a single sheet of material, welded along a longitudinal seam.

19. A sensor as claimed in claim 5, in which the jacket (102) is formed from a metallic material.

Patentansprüche

1. Sensor (100), der in ein Loch (130) in einem Knochen (132) implantiert werden kann, wobei der Sensor umfasst:

einen Mantel bzw. eine Ummantelung (102), der bzw. die eine rückstellfähige bzw. elastische Seitenwand ist, die nach innen verformt werden kann, so dass, wenn der Sensor in dem Loch platziert ist, der Mantel komprimiert wird und gegen die inneren Seitenwände des Lochs gedrängt wird, um eine Rückhaltekraft bereitzustellen, die ausreichend ist, den Sensor in Position zu halten, und wobei der Mantel eine Längsachse aufweist,
einen Sensorteil (110), der innerhalb des Mantels (102) enthalten ist,
ein Kraftübertragungsglied (112), an dem der Mantel angebracht ist, und
ein Kabel (104) mit einem Draht (108, 108', 108") zum Führen von elektrischen Signalen zu oder von dem Sensorteil, wobei das Kabel an dem Kraftübertragungsglied angebracht ist, so dass der Sensorteil zumindest teilweise von Kräften isoliert wird, die aus dem Ziehen des Kabels in der Richtung der Längsachse des Mantels resultieren.

2. Sensor (100) nach Anspruch 1, wobei das Kabel (104) ein Verstärkungsglied (106) enthält, um das Kabel zu verstärken.

3. Sensor (100) nach Anspruch 2, wobei das Kabel (104) an dem Kraftübertragungsglied (112) durch das Verstärkungsglied (106) angebracht ist.

4. Sensor (100) nach einem der Ansprüche 1 bis 3, wobei der Sensorteil zumindest eine Sensorspule umfasst und wobei die Sensorspule elektrisch mit dem Draht verbunden ist, um zu erlauben, dass Signale, die von der Sensorspule erzeugt werden, von dem Sensor entlang des Drahts verlaufen.

5. Sensor (100) nach Anspruch 1, wobei der Mantel ein erstes und ein zweites Ende aufweist und wobei der Sensorteil an dem Mantel an dem oder zu dem ersten Ende des Mantels hin befestigt ist.

6. Sensor (100) nach Anspruch 1, wobei der Sensor konfiguriert ist, Daten zu erfassen, die sich auf das Körperteil beziehen.

7. Sensor (100) nach Anspruch 1, wobei der Sensor durch ein Tracking-System verfolgbar ist.

8. Sensor (100) nach Anspruch 5, wobei der Mantel zumindest einen sich längs erstreckenden Schlitz (118) oder eine sich längs erstreckende Falte aufweist, der bzw. die das Falten des Mantels entlang der Falte vereinfacht, der bzw. die sich im Allgemeinen zwischen dem ersten und dem zweiten Ende erstreckt, was eine Einwärtsverformung des Mantels (102) vereinfacht.

9. Sensor (100) nach Anspruch 8, wobei sich der längs erstreckende Schlitz (118) oder die sich längs erstreckende Falte entlang zumindest 60% der Länge des Mantels erstreckt.

10. Sensor (100) nach Anspruch 8, wobei der Mantel zumindest zwei beabstandete sich längs erstreckende Schlitze oder sich längs erstreckende Falten aufweist.

11. Sensor (100) nach Anspruch 1, wobei das Kraftübertragungsglied eine Stange (112) ist, die sich über den Mantel (102) zwischen gegenüberliegenden bzw. entgegengesetzten Seitenwänden erstreckt.

12. Sensor (100) nach Anspruch 11, wobei der Sensorteil (110) mit der Stange (112) verbunden ist.

13. Sensor (100) nach Anspruch 12, wobei die Verbindung zwischen dem Sensorteil (110) und der Stange (112) in einen Körper aus einem Harzmaterial (114) eingebettet ist.

14. Sensor nach 5, wobei der Mantel (102) nach innen an zumindest einem des ersten und des zweiten Endes verjüngt ist.

15. Sensor (100) nach Anspruch 5, wobei der Mantel (102) einen ersten Abschnitt an dem ersten Ende (124), einen zweiten Abschnitt (120) an dem zweiten Ende und einen dritten Abschnitt (122) zwischen dem ersten und dem zweiten Ende umfasst.

16. Sensor (100) nach Anspruch 15, wobei der erste, zweite und dritte Abschnitt des Mantels aus separaten Materialstücken gebildet sind.

17. Sensor nach Anspruch 15, wobei die Querschnittsform des Mantels entlang des dritten Abschnitts (122) des Mantels in etwa konstant ist.

18. Sensor nach Anspruch 5, wobei der Mantel (102) eine einzige Materialplatte bzw. -lage bzw. -bogen umfasst, die bzw. der entlang einer Längsnaht verschweißt ist.

19. Sensor nach Anspruch 5, wobei der Mantel (102) aus einem metallischen Material gebildet ist.

Revendications

1. Capteur (100) qui peut être implanté dans un trou (130) dans l'os (132), le capteur comprenant :

une gaine (102) qui a une paroi latérale résiliente qui peut être déformée vers l'intérieur de sorte que, lorsque le capteur est placé dans le trou, la gaine est comprimée et poussée contre les parois latérales internes du trou afin de fournir une force de retenue suffisante pour maintenir le capteur en place, et la gaine ayant un axe longitudinal,
une partie de capteur (110) qui est contenue à l'intérieur de la gaine (102),
un élément de transfert de force (112) auquel la gaine est fixée, et
un câble (104) comprenant un fil (108, 108', 108'') pour transporter des signaux électriques vers ou de la partie de capteur, dans lequel le câble est fixé à l'élément de transfert de force de sorte que la partie de capteur est au moins partiellement isolée des forces résultant de la traction sur le câble dans la direction de l'axe longitudinal de la gaine.

2. Capteur (100) selon la revendication 1, dans lequel le câble (104) comprend un élément de renforcement (106) pour renforcer le câble.

3. Capteur (100) selon la revendication 2, dans lequel le câble (104) est fixé sur l'élément de transfert de force (112) par l'élément de renforcement (106).

4. Capteur (100) selon l'une quelconque des revendications 1 à 3, dans lequel la partie de capteur comprend au moins une bobine de capteur et dans lequel la bobine de capteur est électriquement raccordée au fil pour permettre aux signaux générés par la bobine de capteur de passer par le capteur le long du fil.

5. Capteur (100) selon la revendication 1, dans lequel la gaine a des première et seconde extrémités, et dans lequel la partie de capteur est fixée à la gaine au niveau de ou vers la première extrémité de la gaine.

6. Capteur (100) selon la revendication 1, dans lequel le capteur est configuré pour collecter des données relatives à la partie de corps.

7. Capteur (100) selon la revendication 1, dans lequel le capteur est traçable par un système de traçage.

8. Capteur (100) selon la revendication 5, dans lequel la gaine a au moins une fente (118) s'étendant de manière longitudinale ou un pli s'étendant de manière longitudinale, qui facilite le pliage de la gaine le long du pli, qui s'étend généralement entre les première et seconde extrémités, ce qui facilite la déformation vers l'intérieur de la gaine (102).

9. Capteur (100) selon la revendication 8, dans lequel la fente (118) s'étendant de manière longitudinale ou le pli s'étendant de manière longitudinale s'étend le long d'au moins 60 % de la longueur de la gaine.

10. Capteur (100) selon la revendication 8, dans lequel la gaine a au moins deux fentes espacées s'étendant longitudinalement ou des plis s'étendant longitudinalement.

11. Capteur (100) selon la revendication 1, dans lequel l'élément de transfert de force est une barre (112) qui s'étend d'un côté à l'autre de la gaine (102) entre des parois latérales opposées.

12. Capteur (100) selon la revendication 11, dans lequel la partie de capteur (110) est raccordée à la barre (112).

13. Capteur (100) selon la revendication 12, dans lequel le raccordement entre la partie de capteur (110) et la barre (112) est mis en oeuvre dans un corps d'un matériau en résine (114).

14. Capteur selon la revendication 5, dans lequel la gaine (102) est progressivement rétrécie vers l'intérieur au niveau d'au moins l'une des première et seconde extrémités (120).

15. Capteur (100) selon la revendication 5, dans lequel la gaine (102) comprend une première partie au niveau de la première extrémité (124), une deuxième partie (120) au niveau de la seconde extrémité, et une troisième partie (122) entre les première et seconde extrémités.

16. Capteur (100) selon la revendication 15, dans lequel les première, deuxième et troisième parties de la gaine sont formées à partir de pièces séparées de matériau.

17. Capteur selon la revendication 15, dans lequel la forme transversale de la gaine est approximativement constante le long de la troisième partie (122) de la gaine.

18. Capteur selon la revendication 5, dans lequel la gaine (102) comprend une seule feuille de matériau, soudée le long d'une soudure longitudinale.

19. Capteur selon la revendication 5, dans lequel la gaine (102) est formée à partir d'un matériau métallique.

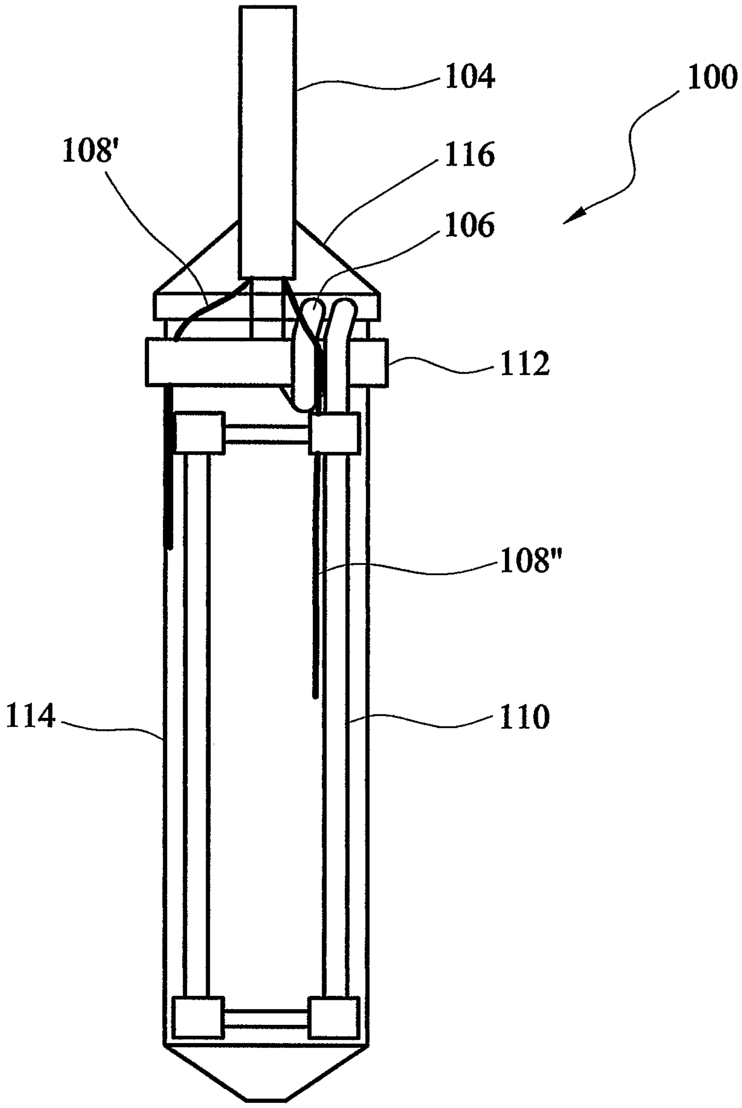

FIG. 1

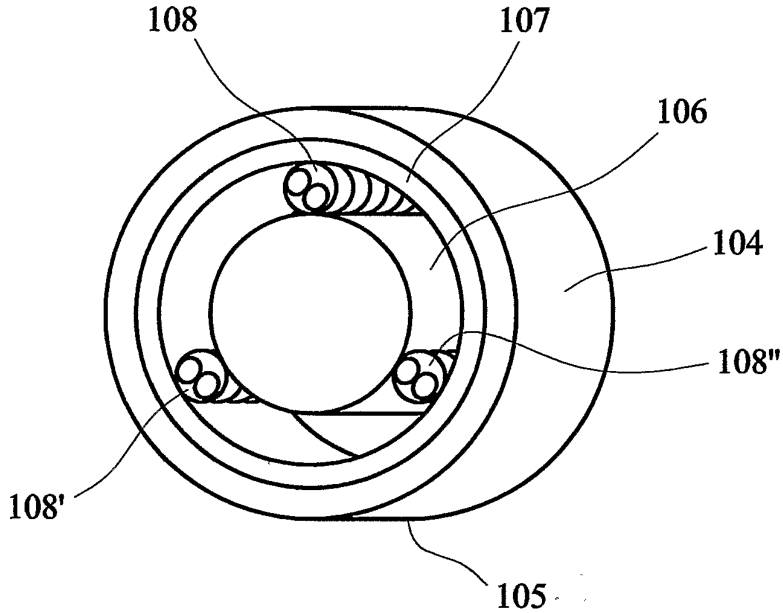

FIG. 2

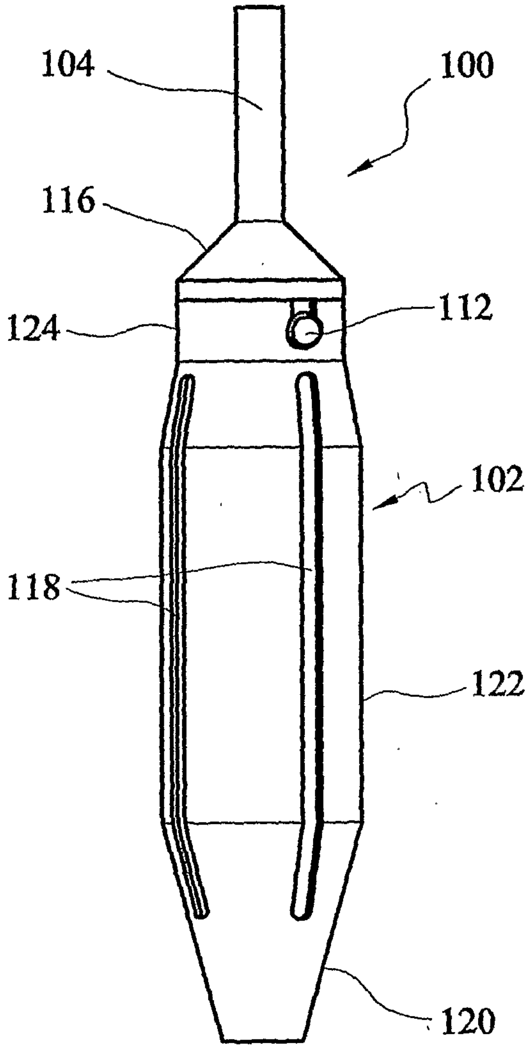

FIG. 3

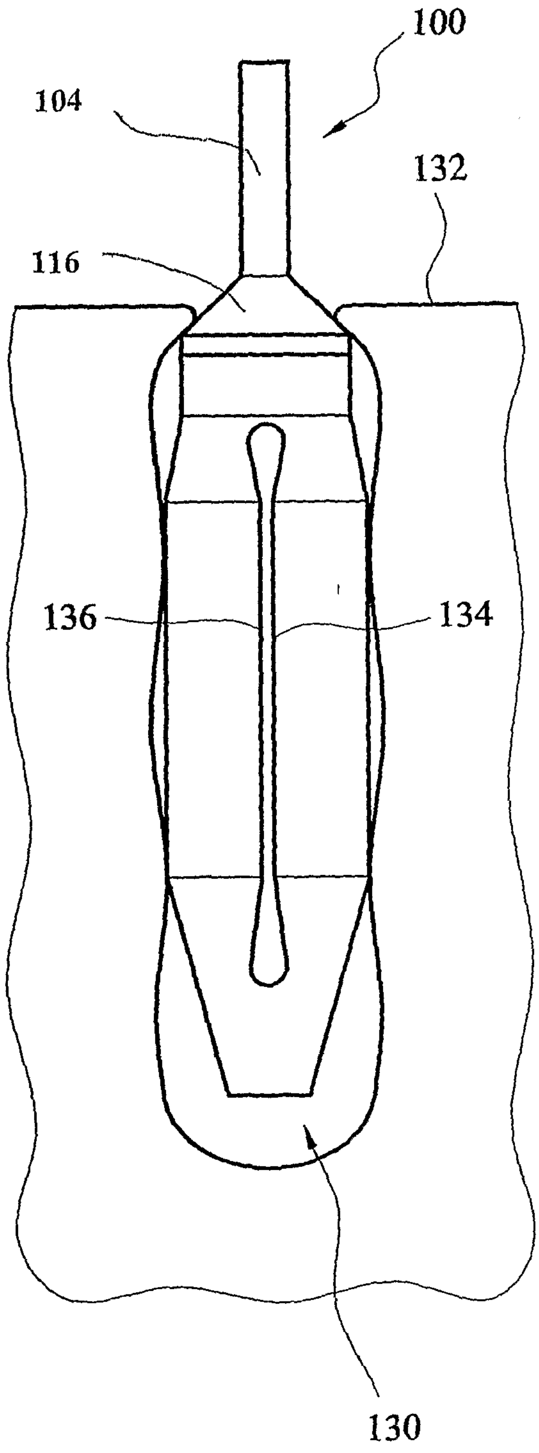

FIG. 4

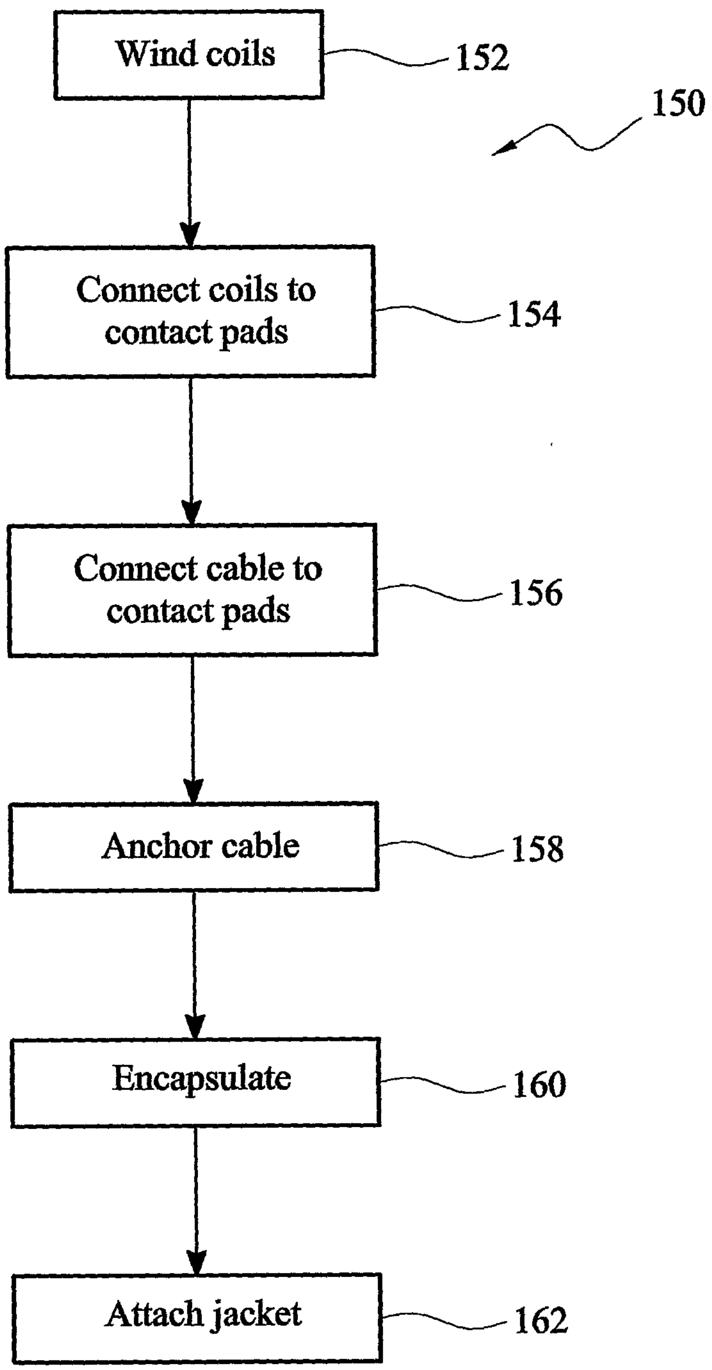
Wind coils
152
150
Connect coils to contact pads
154
Connect cable to contact pads
156
Anchor cable
158
Encapsulate
160
Attach jacket
162

FIG. 5

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 5391199 A **[0003]**
- US 5443489 A **[0003]**
- WO 9605768 A **[0003]**
- US 6690963 B **[0003]**
- US 20020065455 A **[0003]**
- US 6132384 A **[0006]**
- US 3958558 A **[0007]**
- US 2003078671 A **[0008]**
- US 6198969 B **[0009]**
- US 11062258 B **[0027]**
- US 20050245821 A **[0027]**
- EP 05250996 PCT **[0064]**
- WO 2006090139 A **[0064]**
- US 11063018 B **[0064]**
- US 20060190009 A **[0064]**
- US 20030120150 A, Govari **[0067]**

专利名称(译)	植入式传感器		
公开(公告)号	EP1859232B1	公开(公告)日	2018-04-25
申请号	EP2006709836	申请日	2006-02-21
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优先权	2005003618 2005-02-22 GB		
其他公开文献	EP1859232A2		
外部链接	Espacenet		

摘要(译)

一种传感器，其可以植入身体部分以收集与身体部位有关的数据，该传感器包括具有可以向内变形的侧壁的护套，以及第一和第二端。传感器部件包含在护套内，并且在护套的第一端处或朝向护套的第一端紧固到护套。传感器部分至少部分地与施加到传感器的压缩力隔离，该压缩力使得护套的侧壁向内变形。

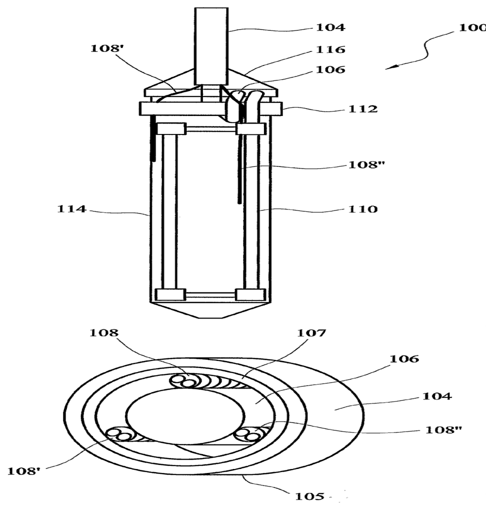

FIG. 1

FIG. 2