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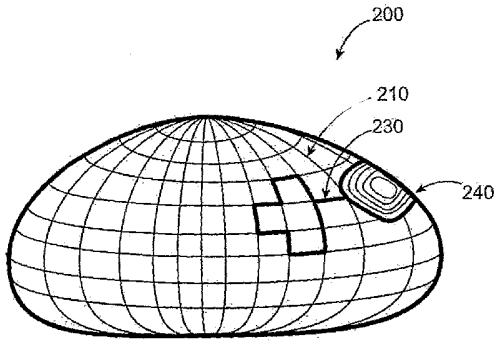
(54) Title: WIRELESS BREACH DETECTION



(57) Abstract: Methods and systems for detecting wall breach in inflatable prostheses rely on intrusion of a body fluid or inflation medium to electrically alter a signaling circuit. In one embodiment, an open portion of a circuit is closed to enable or modify a transmitted signal. In another embodiment, electrical current is generated to power an electrical transmission.

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WIRELESS BREACH DETECTION

BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention. The present invention relates generally to medical apparatus and methods. More particularly, the present invention relates to implantable devices and methods and systems for detecting their malfunction or failure or impending malfunction or failure.

[0002] All implants of devices, especially those indicated for long term use, in the human body are highly regulated and must meet certain safety requirements. One such requirement is biocompatibility of the materials used in the construction of the device in the event they come into direct contact with body tissues and fluids. Even if the material is biocompatible, the contact with body tissues and fluid could result in diminished performance or malfunction esp. in devices with electronic components. It is known that when a device is implanted in the body, the materials forming the cover and structural elements of the device degrade and fatigue over time. It is also well known that excessive handling during implantation or even normal, repetitive movements could stress the structural integrity of the device. Failure of the structural integrity of the device or its covering, which eventually happens, causes the contents of the device, which heretofore were confined in the interior of the device, to be in contact with the surrounding tissues and their secretions. Therefore, it would be desirable to detect or to predict such an event before any potentially harmful contents come in contact with the surrounding tissues, before tissue secretions leak into the interior of the device resulting in malfunction, or before the content itself suffers a malfunction.

[0003] Prosthetic devices implanted in numerous locations in the body are prevalent in medical practice. Many of these prostheses are designed to assume the structural shape of the body part yet are soft and have similar flexibility to approximate the look and feel of normal human tissue. A common use has been for reconstructing the normal contour, improving the shape, and/or enlarging the size of the human breast. The most common breast prosthesis is a soft elastomeric container made of silicone rubber which is filled or "inflated" with a liquid or gel, typically a saline solution or a silicone gel, or a combination of such filling materials. Typically such prostheses are surgically implanted to fit underneath the skin of the body either between the chest wall and the mammary gland or in place of the mammary gland following a mastectomy. The ideal result after implantation is to achieve the contours and

tissue characteristics of a natural breast, and prosthetic devices filled with silicone gel have been found to produce the best cosmetic result. Hence, silicone gel breast implants are the devices of choice in locations where they are approved.

[0004] Degradation and fatigue of the silicone rubber container of such breast implants, however, can lead to perforations, tears, ruptures, and seam separations, resulting in the leakage of filling materials to the surrounding tissues. Leakage from a saline filled device is usually harmless as the solution, if uncontaminated, is absorbed. Leakage from the preferred silicone gel filled device is much more problematic. Bleeding of gel at the surface is believed to contribute to the development of capsular contracture, a scarring condition that compresses the implanted device from a soft, natural profile into a rigid, spherical shape. More serious is the migration of leaked silicone gel to other parts of the body such as the lymph nodes and major organs where it becomes unremovable. Consequently, silicone gel has been implicated in many health problems including connective tissue diseases. This risk increases with the length of time the device is implanted.

[0005] The problem is exacerbated by the fact that leakage of silicone gel is not easily detected and the rupture of the device cannot be predicted. Unlike saline filled devices where rupture and leakage results in deflation over a short period of time and readily discovered by the patient, silicone gel tends to leak slowly and can go unnoticed for years. Often the rupture is discovered only upon removal of the device for another reason. The only noninvasive method currently sensitive enough to detect such an event reliably is an MRI scan. To monitor the integrity of a silicone gel device by regularly scheduled MRI scans is cost prohibitive. Consequently, the use of silicone gel filled breast prostheses is now highly restricted by regulatory authorities.

[0006] Gastric balloons are another type of implantable, inflatable prosthesis which is subject to failure from breach of the wall. Gastric balloons are typically introduced through the esophagus and inflated *in situ* in order to occupy a significant volume within the stomach. While gastric balloons are typically inflated with saline or other non-toxic materials which are benign if released into the stomach, the balloon structure itself is hazardous if accidentally deflated since it can pass and cause obstruction of the pyloric valve or the intestines distal to the pyloric valve. Any such obstruction is a medical emergency.

[0007] The problem is not limited to inflatable devices. Many implanted devices, e.g., cardiac pacemakers, contain electronic circuits and have insulated wires or leads that sense or

deliver signals at certain points in the body. For example, the covering or insulation could deteriorate over time or tear in response to normal body movements. Body fluids from the surrounding could then leak into the circuitry, either as a liquid or vapor, causing disruption of signals. Or the lead could break at any point or detach from the connector to the device. Another class of implanted devices involves a closed vessel system conveying fluids leading from a part of the device or a part of the body to another part of the body, such as a shunt conveying blood or cerebrospinal fluid. The catheter or reservoir in the system could tear or break leading to the leakage of material out of the catheter to an unintended part of the body or leakage of body fluids into the catheter causing contamination. Yet another class of devices, which depend on solid objects for function or structural support, could fail from fracture or dislocation. These fractures can start as a hairline from repeated mechanical stress from use and progress to a complete fracture. Dislocations start with a loosening of the structure(s) holding an object in place and progress to a complete dislocation.

[0008] For these reasons, it would be desirable to provide apparatus and methods to detect or predict an actual or potential wall breach which can lead to leakage of the filling contents of breast implants, gastric balloons, catheters, reservoirs, and the like or an actual or potential disruption of an electronic circuit in cardiac pacemakers or neurostimulators or the like or an actual or potential stress fracture or dislocation in the case of solid components in prosthetic devices or the like. It would desirable further to monitor remotely the structural integrity and presumed functional status of a device without activating the function after device implantation in the case of cardiac defibrillators or without directly applying stress to the monitored part in the case of solid components. Prompt removal of such devices upon breach or imminent breach would avert most, if not all, of the ensuing problems including catastrophes. The methods and apparatus will preferably be adaptable for use in any structural design of the device without adversely affecting its structure or, in the case of breast implants, the final cosmetic result, and further be applicable to solid and rigid body implants containing electronic components such as pacemaker and defibrillator canisters and leads and to solid body implants such as prosthetic heart valves or orthopedic devices. It would be further desirable if the breach or imminent breach of the device were detectable to the patient in an easy, rapid, and reliable fashion outside of a medical facility or at home. Additionally, it would be beneficial if the system were able to monitor the device non-invasively on a frequent basis over the life of the device without incurring significant

additional cost for each diagnostic event. At least some of these objectives will be met by the inventions described hereinafter.

[0009] 2. Description of the Background Art. Leakage detection is described in U.S. Patent No. 6,826,948 and published applications US 2004/0122526 and US 2004/0122527. Breast implants and methods for their use are described in U.S. Patent Nos. 6,755,861; 5,383,929; 4,790,848; 4,773,909; 4,651,717; 4,472,226; and 3,934,274; and in U.S. Publ. Appln. 2003/163197. Gastric balloons and methods for their use in treating obesity are described in U.S. Patent Nos. 6,746,460; 6,736,793; 6,733,512; 6,656,194; 6,579,301; 6,454,785; 5,993,473; 5,259,399; 5,234,454; 5,084,061; 4,908,011; 4,899,747; 4,739,758; 4,723,893; 4,694,827; 4,648,383; 4,607,618; 4,501,264; 4,485,805; 4,416,267; 4,246,893; 4,133,315; 3,055,371; and 3,046,988 and in the following publications: US 2005/0137636; US 2004/0215300; US 2004/0186503; US 2004/0186502; US 2004/0162593; US 2004/0106899; US 2004/0059289; US 2003/0171768; US 2002/0099430; US 2002/0055757; WO 03/095015; WO88/00027; WO87/00034; WO83/02888; EP 0103481; EP0246999; GB2090747; and GB2139902.

BRIEF SUMMARY OF THE INVENTION

[0010] The present invention provides systems and methods for detecting partial or complete breach in the exterior wall of an implantable device, such as an inflatable, implantable prosthesis of the type where a wall at least partially surrounds a fluid medium, liquid or air, in one or more inflatable compartments. The walls of inflatable devices will usually be non-rigid, either elastic or non-elastic. Other implantable devices subject to exterior structure breach include metal and plastic (polymer) devices which may comprise rigid-walled casings or housings, such as pacemakers, implantable defibrillators, neurostimulators, insulin pumps, reservoirs, devices having flexible housings such as elastomeric reservoirs containing with naturally collected or pre-filled fluids or insulation or other coverings formed over the electrically conductive core of electrical leads, electrical connectors (e.g., plugs), and the like. Implantable devices subject to stress fracture in solid functional components include artificial joints, prosthetic heart valves, and the like. These and other devices may contain potentially bioincompatible materials, such as batteries, circuitry, synthetic chemicals, and the like. While the implementation of these systems and methods will be described in detail in connection with inflatable devices such as breast implants and gastric balloons and with solid core devices such as electrical leads, it will be

appreciated that the principles may be applied to other inflatable prostheses, such as penile implants, to vessel systems containing or conveying fluids, to electronic and other devices having solid internal structural or functional components. The systems of the present invention are incorporated into at least a portion of the wall of the wall or covering of the inflatable prosthesis or other device or coupled to the electronic circuitry or embedded in the solid component itself and provide for or enable the emission or transmission of a detectable radio-frequency or other electronic signal upon breach or partial breach of the wall or the structural integrity of the component. As used hereinafter, the term "breach" will refer to any partial or full penetration of the structure of the wall or covering as well as to other mechanical disruption of a solid part of the device which could initiate or lead to the contact of materials inside the wall or covering or the solid component itself with tissues or body fluids outside the device. Such breach signifies a compromise or a threatening compromise to the integrity of the device.

[0011] The signal emission system of the present invention preferably comprises a signaling circuit having one or more components which become exposed to an exterior or interior environment surrounding or within the prosthesis or other implantable device upon breach or partial breach of the wall or covering, wherein such exposure enables, disables, energizes, and/or changes a signal which is emitted by the system. In particular, the breach may act like a switch to close or open a region within the signaling circuit to cause, enable, disable, or alter the signal emission. Alternatively, the exposure of the circuit and/or internal structure to the interior or exterior environment may result in a change in impedance, capacitance, inductance or other detectable circuit characteristics that can trigger or modify the signal emitted.

[0012] In a first embodiment, the component of the signaling circuit will generate electrical current when exposed to a body fluid and/or an interior medium within the device upon breach or failure of the exterior structure. Body fluids such as blood, cerebrospinal fluid, lymph fluid, and the like, are naturally conductive, i.e., contain electrolytes. The interior medium, such as an inflation medium, can be selected to be electrically conductive, e.g., comprise or consist of saline or other biologically compatible electrolytes and salt solutions.. In such cases, the generated electrical current can power an unpowered transmission component to emit the signal. Alternatively, the power can alter a signal which has already been continuously or periodically emitted by the signaling circuit. In the latter case, the signaling circuit may require a separate source of energy, such as a battery or circuit

components which are placed on the exterior or interior of the wall so that they are always exposed to fluids to provide for current generation.

[0013] Alternatively, the circuit components may include spaced-apart conductors which are electrically coupled to the signaling circuit to "close" the signaling circuit to permit current flow when exposed to a body fluid and/or device contents by a wall breach. Alternatively, the circuit may be altered, enabled or otherwise modified by a sufficient flow of electrolytes to enable, interpret, disrupt, or modify a signal emission. The circuit components may include spaced apart conductors which are coupled to the signaling circuit to detect a change in resistance, capacitance, impedance, or voltage. Since the breach could be small and intermittent as it starts, it can be difficult to detect as a flow but the cumulative gain or loss of the electrolytes from the contents or surrounding body fluids could cause a change in the resistance, capacitance, or impedance across the conductors. Alternatively, the detection circuit is closed and the contact of the contents or the body fluids with the conductors could cause a break, disruption, or change in the functioning of the circuit. In the exemplary embodiments described below, the conductors may comprise meshes, films, or other relatively large surface areas covering most or all of the wall so that breach at any point in the wall will provide the intended electrically conductive bridging between the conductors. The coupling of the conductors may also cause, alter, or enable a signal emission to alert the patient of the breach or potential breach. The spaced-apart conductors can have any one of a variety of shapes or configurations, continuous configurations, such as plates and films, or discontinuous configurations, such as lattices, meshes, and the like, can be placed in various locations, preferably near interior portions of the device where body fluids will pool to enhance sensitivity and reliability of the detection.

[0014] Alternatively, the detection and signaling circuit may comprise at least two conductors coupled to a third conductor which is part of the functional circuitry or is embedded in the solid component of the device or is the solid component itself. In the event any of the conductors, and the third, functional conductor in particular, is fractured, even intermittently, a circuit is broken thereby causing a signal alteration by the signaling circuit to alert the patient of the breach or potential breach. The detecting conductors can have any one of a variety of shapes or configurations, including continuous configurations, such as plates and films, or discontinuous configurations, such as lattices, meshes, braids, fabrics, and the like, and can be placed in various locations, preferably spanning parts of the device where fractures are prone in order to enhance sensitivity and reliability of the detection. More than

one of these couplings could be made in any configuration or location on a device to determine the site of the breach.

[0015] The signaling circuit can be active or passive. In a preferred embodiment, the signaling circuit will comprise a passive transponder and antenna which are adapted to be powered and interrogated by an external reader. Such transponder circuitry may conveniently be provided by using common radiofrequency identification (RFID) circuitry where the transponder and tuned antenna are disposed on or within a protected area in the prosthesis and connected to remaining portions of the signaling circuit. Passively powered circuitry is particularly preferred in devices with on board batteries where the amount of energy stored in the battery generally determines the functional product life. The antenna and transponder could be located in close proximity to the detection circuitry or placed elsewhere in the device or another part of the body. For example, by connecting the transponder circuitry to "open" conductors which is closed in the presence of body fluids and/or inflation medium, the signal emitted by the transponder upon interrogation by an external reader may be altered. Thus, the patient or medical professional may interrogate the prosthesis and determine whether or not the prosthesis remains intact or the threat of an impending breach exists. This is a particularly preferred approach since it allows the user to determine that the transponder circuitry is functional even when a breach has not occurred.

[0016] The present invention further provides methods for signaling breach of a wall or covering of an inflatable prosthesis, electronic prosthesis, solid prosthesis, electrical cable, or the like. Usually, signaling comprises generating an emission by closing a signaling circuit when the wall or part of the device is at least partially breached. Usually a flow of electrolytes occurs when the wall or part of the device is at least partially breached, thereby closing the signaling circuit. To detect a near complete or complete fracture in solid components, generating an emission may comprise opening a signaling circuit when the wall, covering, or other part is substantially breached or generating an electrical current when the part is substantially breached. The particular signaling circuits and transmission modes have been described above in connection with the methods of the present invention.

[0017] The signaling system of the present invention can be designed to function using any one of a variety of algorithms to notify the patient in a simple, unequivocal fashion. For example, in a toggle algorithm, the transmitter is either on in the static state or preferably off in order to reduce the need for power. Upon direct contact between the conductors and the

body fluids and or device contents, the now closed circuit cause the transmitter to turn the signal off or preferably on to be able to send a wireless signal on a continuous basis. The wireless signal or lack thereof depending on the algorithm is recognized by the detector to notify the patient that the integrity of the device is compromised.

[0018] Alternatively, the algorithm could be based on time, amplitude, frequency, or some other parameter. For example, the transmitter may send a wireless signal at a predetermined time interval in its static state. The detector recognizes the length of the interval as normal and the existence of the signal as the system in working order. Upon direct contact with the body fluids or device contents by the probes, the transmitter is enabled to send the same signal at different time intervals or a different signal, which is recognized by the detector to notify the patient that the integrity of the device is compromised. The lack of a signal is recognized by the detector to notify the patient of a detection system malfunction and potential compromise of the integrity of the device.

[0019] Optionally, more than one probe or more than one type of probe may be placed internally in different parts or components in the device so that the particular part or component which failed may be identified based on which probe was activated. The transmitter would send different signals for the receiver to display the source of the failure.

[0020] The internal probe could be of any shape and is disposed in the interior or preferably in the wall or covering of the device. The preferred configuration is a fine lattice or continuous film of the detection material embedded in the wall or in between layers of the wall covering the entire device, thereby conforming to the shape of the device. Such a configuration optimizes the performance of the system in detecting failures early. As the site of the tear or rupture cannot be predicted, the probe would be unlikely to miss detecting the breach by covering the entire device.

[0021] Compromise of the device typically starts with a somewhat linear split or tear in surface of the device wall or covering from mechanical fatigue or handling damage. As the split propagates, it will expose more and more lines of the lattice or area of the film to the body fluids and or device contents. Consequently, as the size and seriousness of the breach increases, the probability of detection increases. Embedding the detection material in the covering such as the wall of the balloon further enables detection before a full breach of the entire thickness of the device wall.

[0022] The detection material could be any metal, polymer, fiber, ingredient, or combination thereof, with or without any coating that can generate an electrical charge or enable flow of electric current when in contact with the body fluids or device contents. For example, an electrical charge could be generated from a non-toxic chemical reaction when the lattice exposed underneath a tear comes in contact with the body secretions. Flow of electric current could be enabled when two ends of an electric circuit hitherto physically separated by electrically non-conductive material in the covering or a structural element of the device are in contact with electrolytes in the body secretions when the electrically non-conductive material is compromised. For example, a charged lattice is embedded in the wall separated by silicone rubber from the ground probe on the external surface of the device. When the lattice is exposed to the electrolytes in the body fluids in the event of a tear, the circuit is closed. Alternatively, the lattice and ground could be separate from each other but interlaced in the wall of the device. Preferred materials include non-corrosive, biocompatible metals and elastomers, inks, or the like which contain electrically conductive particles.

[0023] The transmitter can be a simple wireless signal generator triggered by an electric current or preferably a transponder using the well-established RFID technology, i.e., produces a wireless signal when triggered by an interrogating signal. The electric charge generated or the electric current enabled by the probe in contact with the body fluids or device contents changes the logic state thereby enabling the transmitter to emit or causes it to emit a wireless signal. Typically, the transponder is powered by the interrogating radio frequency signal so that no power source of its own is required. Alternatively, the transmitter could be powered by a micro battery or by the electrical power generated by a chemical reaction. For protection from degradation by an acidic and electrolyte solution and become potentially toxic, the transmitter or transponder circuit is encased in a highly resistant material, such as silicone rubber or stainless steel. The transmitter or transponder circuit can be placed on the exterior, embedded in the wall, or preferably in the interior of the device for shielding from chemical degradation and mechanical stress. It can be placed in any orientation, preferably in the plane where the antenna is most sensitive and the transmitter is most effective in sending and receiving signals through body tissue overlying the device.

[0024] The wireless signal from the transmitter is recognized by a separate detector, typically external to the body. The detector could be simply a receiver tuned to the transmitter's signal or, preferably, a combination of both a transmitter of a signal to interrogate the transponder and a receiver to distinguish the different signals from the

transponder. The detector is preferably powered by batteries and portable enough to be worn on a wristband, necklace, or belt or can be placed conveniently near a place where the patient spends most of his time. Upon receiving a signal that a breach has occurred, the detector will alert the patient to seek medical assistance or alert medical professionals directly through other devices, such as Bluetooth linked to an autodial telephone. The alarm could be auditory, such as beeping sounds, visual, such as flashing LED's or a LCD display, sensory, such as vibrations, or preferably a combination of any or all of the above.

[0025] Optionally, the detector could have different auditory, visual, sensory, or different combinations to identify the source of the detected breach, especially with more than one probe or more than one type of probe. For example, LED's of different colors or different sounds could be used. The alarm could further indicate the seriousness of the breach. For example, when multiple probes detect a breach, the volume of the alarm would increase to a higher level.

[0026] In the case of electronic implantable devices, such as pacemakers and defibrillators, the devices will be subject to failure due to intrusion of body fluids through breaches, particularly at the seams and lead connections. Thus, the detector circuit components described above could be located within the device canister near those seams and connectors at risk of failure so that initial penetration of fluids could be detected before sufficient amount of fluids, liquid or vapor, has entered to cause failure of the device.

[0027] In the case of electrical leads used in electronic stimulation devices, a breach in the insulation and a breach in the conductor can both be detected. The embodiments described above are particularly suitable for detecting a breach in the covering insulation from wear and tear. Usually this breach will precede and can serve as a sentry for a breach in the conductor. A breach in the conductor without a breach in the insulation can be detected by a closed circuit formed by two conducting probes, one coupled to the conductor near its proximal end and the other at its distal end. Any fracture or disruption of the current flow in the conductor, whether made of a metal, elastomer, or gel, between the two points will result in "opening" the circuit. An opening will change the logic state of the detection circuit and enable the transmitter to emit or causes it to emit a wireless signal. The detection and transmitting circuitry could be attached to any part of the lead or is in its own separate housing connected to the lead by the conducting probes. Thus, the detection and transmitting circuitry could be

placed in a preferred orientation where normal body movements would not cause any sharp angles in the conductors and an area away from sites where wear and tear are more prone.

[0028] In the case where electrical leads are coupled to another conductor such as the connector outside the canister containing the functioning hardware and software, the principles and methods can detect detachment of the lead. In this embodiment, one probe is electrically coupled to the male and another probe to the female side of the connection. When the lead is detached from the connector, the circuit is thereby "opened" and detected as a breach.

[0029] In the case of solid devices, such as artificial joints or heart valves, the conductors are embedded in the device components prone to failure. The detection and transmitting circuitry could also be embedded in the device or placed in an area away from sites where wear and tear are more prone or signal transmission could be adversely affected.

BRIEF DESCRIPTION OF THE DRAWINGS

[0030] Fig. 1 illustrates a gastric balloon having the wall breach detections system of the present invention incorporated therein.

[0031] Fig. 2 illustrates a breast implant having the wall breach detection system of the present invention incorporated therein.

[0032] Fig. 3 illustrates a multi-layer wall structure useful for the prostheses of the present invention.

[0033] Fig. 4 illustrates a passive transponder system which may be utilized in the wall breach detection systems of the present invention.

[0034] Fig. 5 illustrates a hand-held interrogation unit useful with the systems of the present invention.

[0035] Figs. 6 illustrate leads and connectors used in electronic stimulators having the covering breach detection system of the present invention incorporated therein.

[0036] Figs. 7 illustrate solid device components having the wall breach detection system of the present invention incorporated therein.

DETAILED DESCRIPTION OF THE INVENTION

[0037] Referring now to Fig. 1, the gastric balloon 100 includes two electric probes. Probe 130 is on the external surface in contact with the surrounding tissues, body fluids, and contents of the stomach. Probes 130 and 110 can have any of a variety of shapes or configurations, including circular plates, lattices, films, and the like, cover all or a portion of the balloon or other device. Probe 110, shown here in a lattice configuration, provides the second probe incorporated in the wall of the balloon. The probe material could be any metal, polymer, fiber, or combination thereof, with or without any coating that can generate an electrical charge or enable flow of electric current when in contact with the stomach contents. The probes are connected electronically to the wireless transmitter 140, but are separated from each other by at least one layer of non-conductive material in the balloon wall. The transmitter can be a simple wireless signal generator triggered by an electric current or preferably is an unpowered transponder using well-established RFID technology which produces a wireless signal in response to an interrogating signal. In the intact state when the wall is not breached, components 130, 110, and 140 comprise an open electrical circuit and the transmitter is inactive, disabled, or enabled to transmit a base signal.

[0038] Referring now to Fig. 2, a breast implant 200 may be similarly formed with a lattice 210 formed within the breast wall, an external electrically conductive probe 230 formed on or over the exterior surface of the implant, and a transmitter 240 connected to both the lattice and exterior probe. In the case of breast implants filled with low conductivity materials, such as silicone gel, it may be desirable to provide conductive materials to enhance conductivity upon leakage.

[0039] As magnified in Fig. 3, the second internal probe comprises both a fine lattice 110 and a thin film configuration 112 in the wall of the balloon in between, at the minimum two layers, an outermost layer 102 and innermost layer 104. The second internal probe can be also disposed in any enclosed space in the device (not shown). In the configuration described in Fig. 1, probes 130 and 110 and transponder 140 represent one open circuit and probes 130 and 112 and transponder 140 represent a second open circuit. Each open circuit is available to power or enable the transmitter or may enable the transponder to alter a base signal.

[0040] After the balloon is deployed in the stomach, the external probe 130 is in contact with the surrounding tissue and body fluids and stomach contents. Upon a breach in the integrity of the wall, such as a tear in the outermost layer 102, the leakage of physiologic

fluid or stomach contents with electrolytes into the tear forms a salt bridge that closes the circuit formed probes 130 and 112 and transponder 140. Once the circuit is closed, a toggle is switched in the transponder, which will be enabled to transmit a "layer 102 breach" signal. Tears through layer 106 in the balloon wall will allow leakage of physiologic fluid or stomach contents with electrolytes into the tear forming a salt bridge that closes the circuit formed probes 130 and 110 and transmitter 140. Closing this circuit switches another toggle in the transponder, which will be enabled to transmit a "layer 106 breach" signal.

[0041] The preferred radiofrequency identification circuit is shown schematically in Fig. 4. The circuit comprises a transmitter component 300 which includes transponder circuitry 302, typically formed as an integrated circuit, and a tuned antenna-capacitor circuit 304. An interrogator reader 310 comprises circuitry 312 including the power supply (typically a battery) demodulator circuitry, decoder circuitry, and the like. An antenna 314 is tuned so that it can communicate wirelessly with the antenna 304 of the transponder 300. Operation of this circuitry is generally conventional and provides for energizing, demodulating, and decoding signals between the external and implanted components. The transponder circuitry, however, will be modified so that the conductive elements implanted in the wall, such as film 320 and lattice 330 may enable or alter the signal emitted by the transponder when the conductive elements are bridged by body fluids or inflation medium. In the preferred embodiments described above, electrical coupling of the conductors 320 and 330 will alter the signal that is produced by the transponder 302. In that way, the patient or other user will be able to interrogate the transponder and receive a base or "normal" response signal when no wall breach has occurred. In the event of a wall breach, the signal emitted by the transponder will be altered so that the breach will be made evident.

[0042] An exemplary reader module 120 is shown in Fig. 5 and includes LEDs to indicate normal or "on" function, failure, and emergency failure. An audible the alarm 126 could also be provided to alert with beeping sounds, or sensory, such as vibrations, or preferably a combination of any or all of the above. Optionally, the detector could have different auditory, visual, sensory, or different combinations to identify the source of the detected breach, especially with more than one chemical substance used. The alarm could further indicate the seriousness of the breach. For example, when breaches are detected, the volume of the alarm would increase to a higher level.

[0043] Referring now to Fig. 6A, an electrical lead 600 with a functional conductor 650 which is useful for cardiac or neuro stimulators may be similarly formed with an electrically conductive lattice 610 embedded within an insulating covering 605, an external electrically conductive cable coil 630 attached to the exterior surface of the implant, and a transmitter 640 connected to both the lattice 610 and external coil 630. As shown in the cross section Fig. 6B, the lattice 610 is preferably formed coaxial to the conductor 650 and separated from the conductor and the surrounding environment by inner and outer annular portions of the cover 605. The cross section of Fig. 6C shows conductive probes 610 and 620 in lattice form both embedded in the covering. The cross section of Fig. 6D shows a plurality of conducting probes 610 and 620 which are embedded coaxially in the insulating covering 605. In this embodiment, a current flow enabled by electrolytes between external probe 630 and 610 or 620 or the functional conductor 650 could indicate the extent of the breach. An alternative configuration is shown as lead 601 in Fig. 6E and Fig. 6F with two functional conductors 650a and 650b connected at their ends but electrically isolated from each other along their length so that each can serve as a backup for the other. In this configuration, the probes 610 and 620 do not have to be separated from but are in contact with the functional conductors.

[0044] In the case of detecting a breach of the functional conductor, a lead 602 is shown with two electrically conductive probes 660 and 670 coupled to two ends of the functional conductor 650, as shown in Fig. 6G.

[0045] In the case where the functional conductor 650 is connected to another functional electrical conductor 680, as shown in Fig. 6H, a lead 603 is shown with a transmitter 640 with two probes, 660 and 670. Probe 660 is coupled to the functional conductor 650 and 670 to the other functional conductor 680, in this embodiment an electrical connector. One or both of the probes 660 and 670 are attached after the connection is made. Both probes 660 and 670 can be embedded in the functional conductor connection housing in either the male or female side, as shown in Fig. 6I. In this embodiment of a female connector 604, functional conductor 650 passes through and is electrically coupled to functional conductor 680. In this embodiment as electrically isolated rings inside the female connector 604, probe 670 is coupled to 680 and probes 660a and 660b coupled to 650. Such a configuration would enable detection of a partial detachment of the male member 649 when the circuit between 670 and 660b is closed but that between 660a and 660b is open and a possible complete lead detachment when all the detection circuits are open. The placement and physical length of

the probes 660a and 660b would determine the amount of detachment necessary to open the circuit and enable the system to signal a breach.

[0046] While the leads and connectors incorporating the detection system are illustrated independently above, they may be configured independent to each other in a device system or together in any combination using one or more common detecting or signaling circuits.

[0047] Referring now to Fig. 7, two solid prosthetic device forms are shown. Cylindrical shaped 701 and a flat triangular shaped 702 are shown with a transmitter 740, an electrically conductive lattice 710, and an external electrically conductive probe 730. 701a and 702a are cross sections of each respectively. Any wear and tear or fracture deep to the lattice 710 is detected as a breach. It can be appreciated that the principle can be applied to a solid object of any shape. In the case of an object holding other parts of the device in place or within a range of motion (not shown), such as functioning like a ligamentous or cartilagecartilaginous structure in the body, respectively, detecting a breach of the object would indicate a potential dislocation of the other parts.

[0048] While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

WHAT IS CLAIMED IS:

1. An improved implantable device having an exterior structure, wherein the improvement comprises a system incorporated into said exterior structure, which system emits a detectable wireless signal upon breach of said exterior structure.

2. An improved implantable device as in claim 1, wherein the exterior structure comprises a wall which at least partially surrounds a compartment which is fillable with a fluid medium.

3. An improved device as in claim 2, wherein the exterior structure is inflatable and the liquid medium is an inflation medium.

4. An improved device as in claim 3, wherein the exterior structure is non-rigid.

5. An improved device as in claim 4, which comprises a breast implant, a gastric balloon, or a penile implant, or a reservoir.

6. An improved implantable device as in claim 1, wherein the exterior structure comprises a rigid housing.

7. An improved implantable device as in claim 6, wherein the device comprises a pacemaker, a defibrillator, a neurostimulator, or an insulin a biochemical delivery pump, or a reservoir.

8. An improved implantable device as in claim 1, wherein the exterior structure comprises a covering formed over an electrically conductive core.

9. An improved implantable device as in claim 8, wherein the device comprises an electrical cable or an electrical connector.

10. An improved device as in claim 1, wherein the signal emission system comprises a signaling circuit having one or more components which are exposed to an exterior or interior environment upon breach of the exterior structure, wherein exposure of the component energizes the circuit, closes the circuit or opens the circuit to cause, alter, disable, or enable signal emission.

11. An improved device as in claim 10, wherein the component generates electrical current when exposed to body fluid and/or an interior medium by a wall breach.

12. An improved device as in claim 10, wherein the component includes spaced-apart conductors which are electrically coupled to close and/or alter a capacitance or inductance of the signaling circuit when exposed to a body fluid and/or the fillable medium by a wall breach.

13. An improved device as in claim 10, wherein the signaling circuit comprises a transponder and an antenna, wherein the transponder is powered by an external reader which is tuned to the antenna of the transponder, wherein the transponder and antenna are inactive or operational in a first mode until a wall breach closes the control or signaling circuit, wherein closing of the control or signaling circuit activates or alters the transponder emission.

14. A method for signaling breach of an external structure of an implantable device, said method comprising emitting an externally detectable wireless signal when the external structure has been at least partially breached.

15. A method as in claim 14, wherein the exterior structure is inflatable and the liquid medium is an inflation medium.

16. A method as in claim 15, wherein the exterior structure is non-rigid.

17. A method as in claim 16, a breast implant, a gastric balloon, or a penile implant, or a reservoir.

18. A method as in claim 14, wherein the exterior structure comprises a rigid housing.

19. A method as in claim 18, wherein the device comprises a pacemaker, a defibrillator, a neurostimulator, a biochemical deliveryan insulin pump, or a reservoir.

20. A method as in claim 14, wherein the exterior structure comprises a covering formed over an electrically conductive core.

21. A method as in claim 20, wherein the device comprises an electrical cable or an electrical connector.

22. A method as in claim 14, wherein emitting comprises closing or opening or signaling circuit when the exterior structure is at least partially breached.

23. A method as in claim 22, wherein the signaling circuit is unpowered and comprises an antenna and a transponder, further comprising directing an interrogation signal to the antenna and detecting a return signal from the transponder, wherein the returned signal is altered, present or ceases only when the control or signaling circuit has been closed or opened by a breach of the exterior structure.

24. A method as in claim 22, wherein the signaling circuit is powered and emitting comprises exposing a component of a signaling circuit to an internal or external environment when the exterior structure is at least partially breached wherein the control or signaling circuit is closed and transmits a signal.

25. A method as in claim 14, wherein emitting comprises exposing a component of a signaling circuit to an internal or external environmental when the exterior structure is at least partially breached, wherein the control or signaling circuit generates energy and transmits a signal.

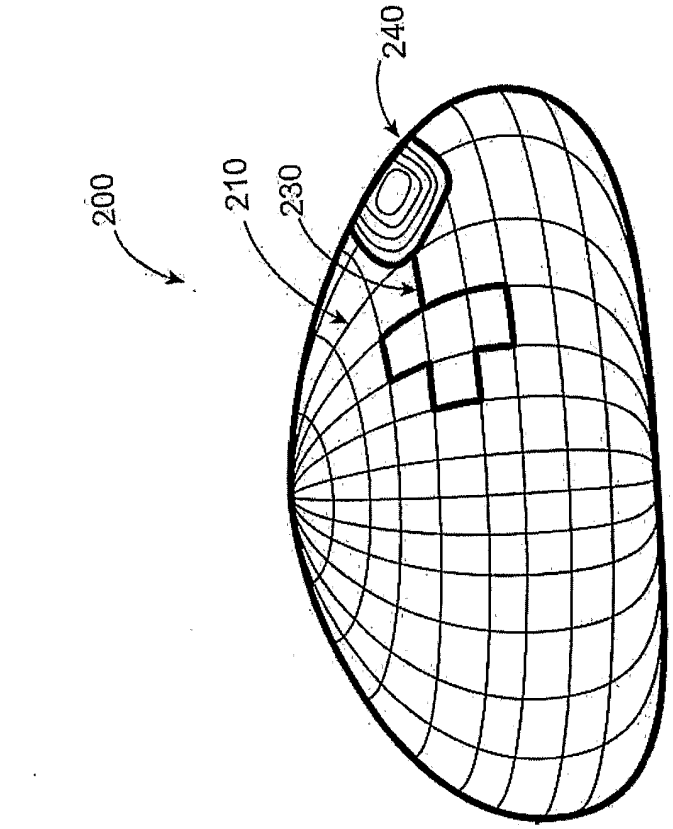


FIG. 2

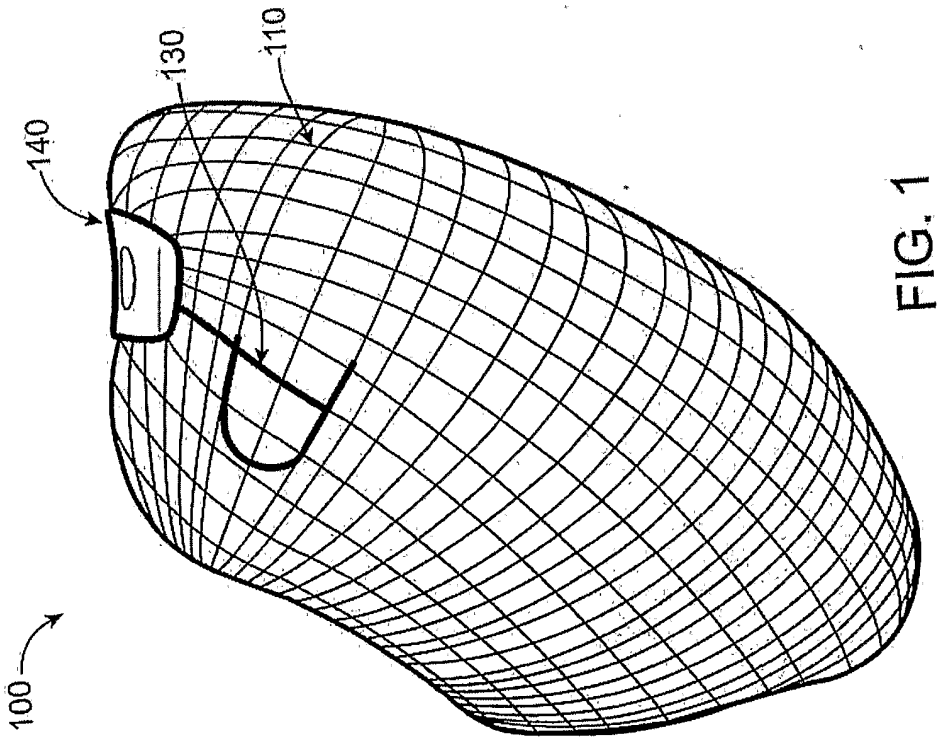


FIG. 1

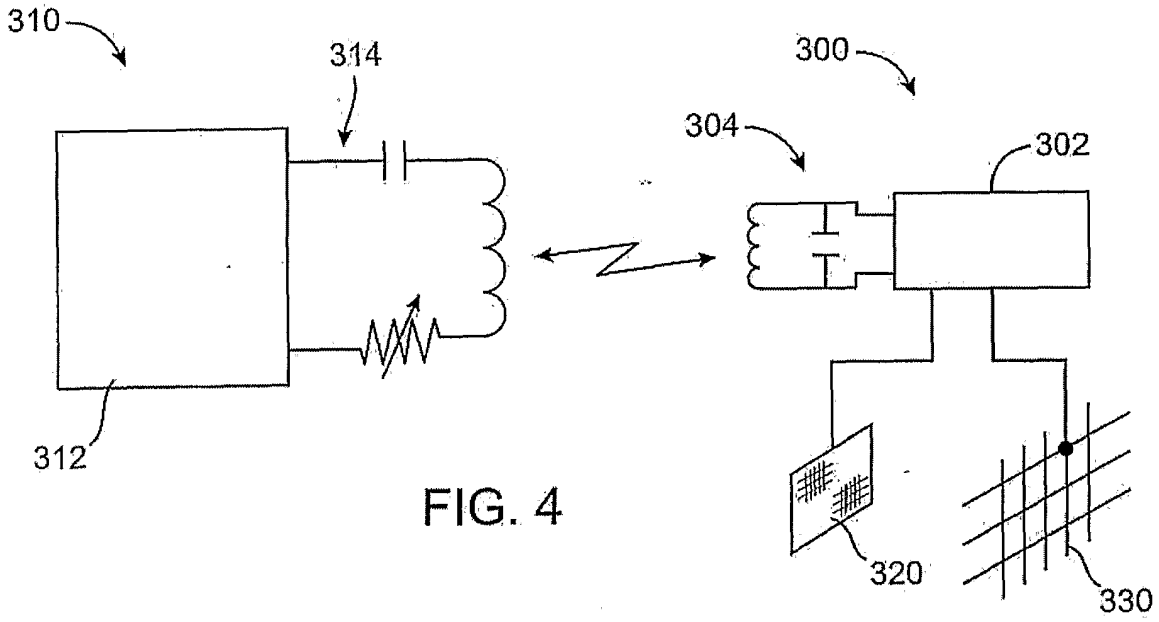


FIG. 4

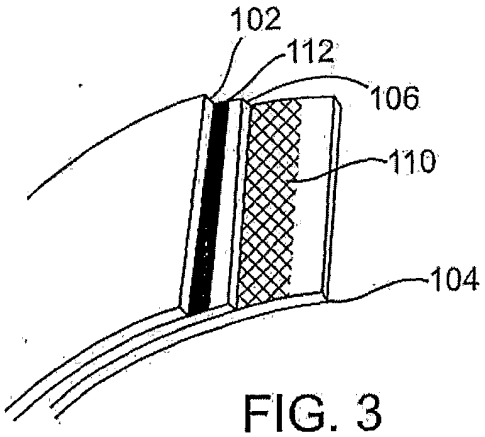


FIG. 3

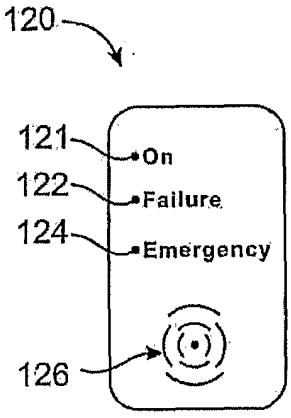
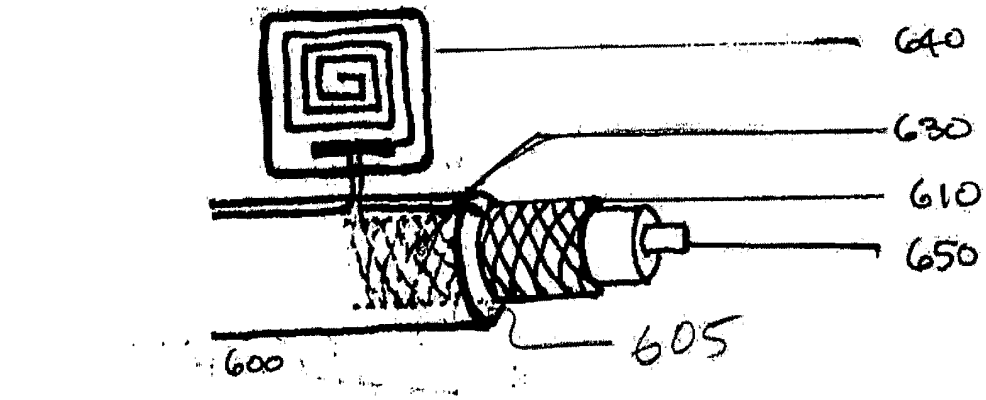


FIG. 5

Fig. 6A



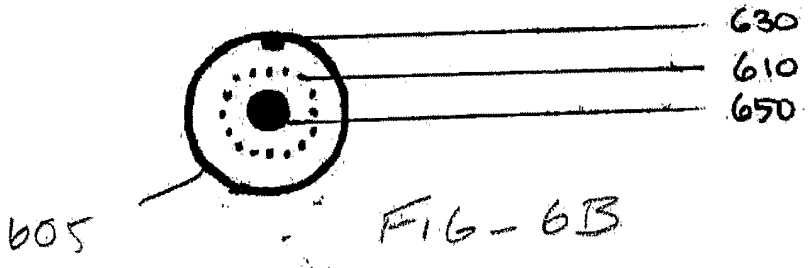


FIG-6B

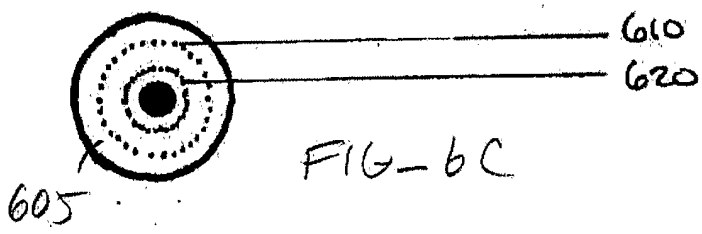


FIG-6C

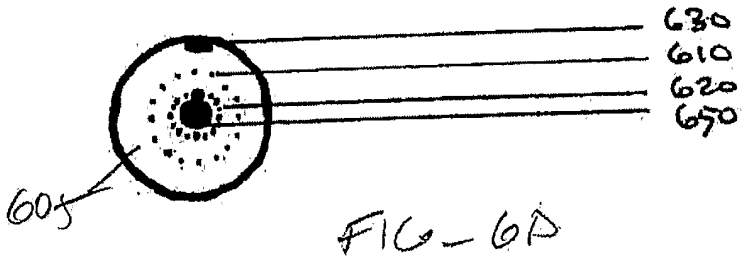


FIG-6D

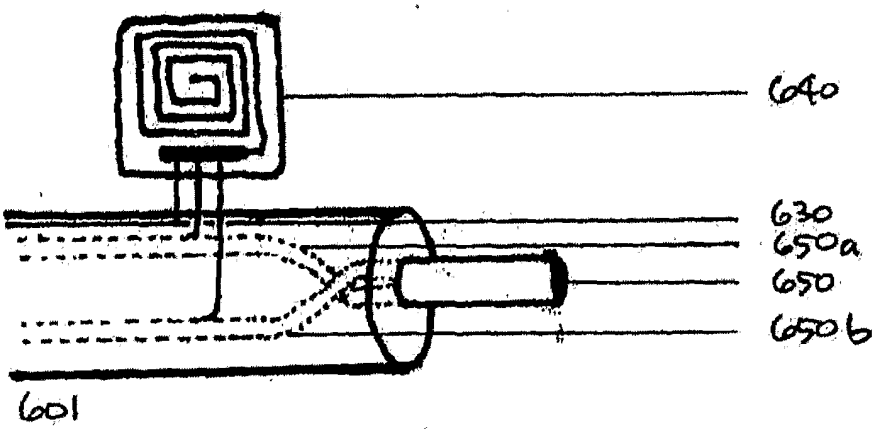


FIG_6E

FIG_6F

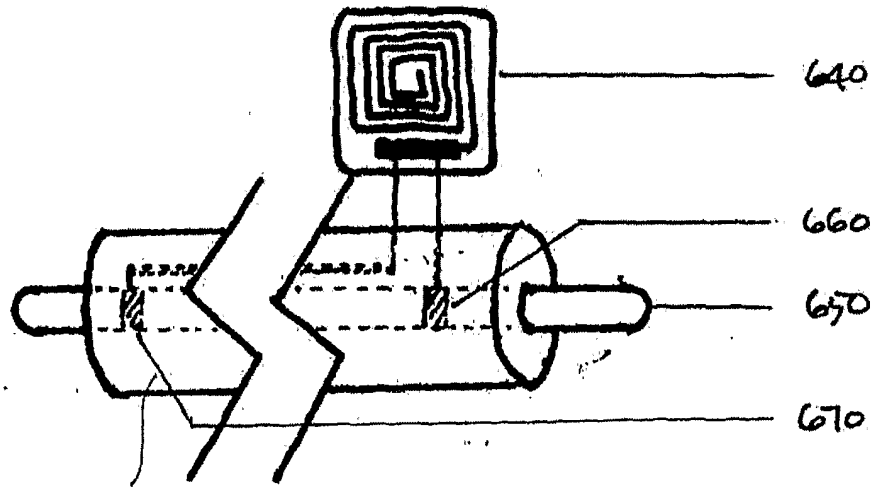


FIG_6G

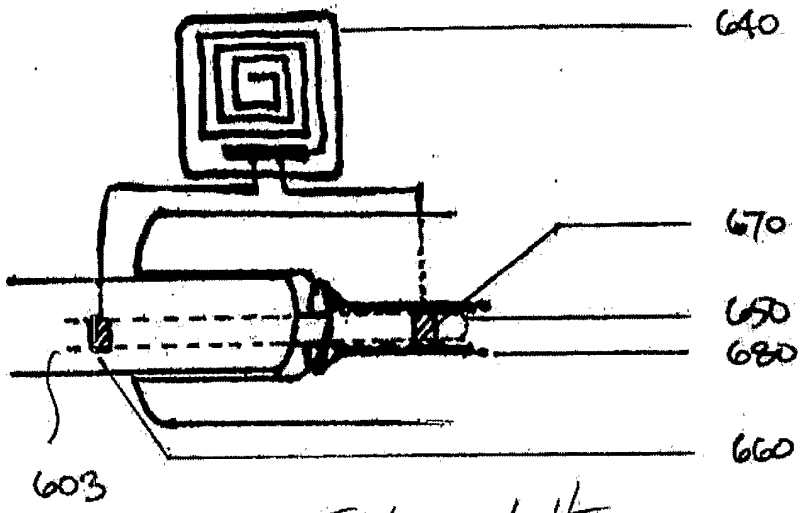


FIG- 6H

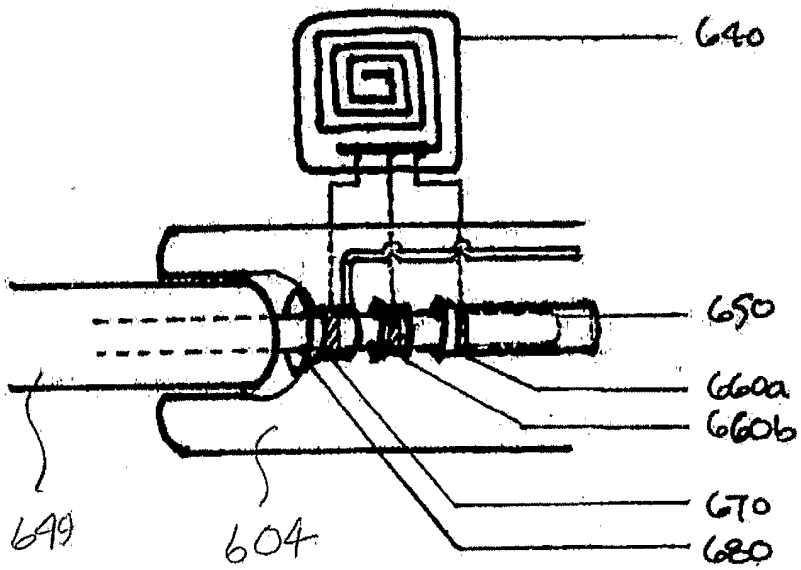


FIG- 6I

Fig. 7