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(54) **BIOCOMPATIBLE AND BIOSTABLE IMPLANTABLE MEDICAL DEVICE**

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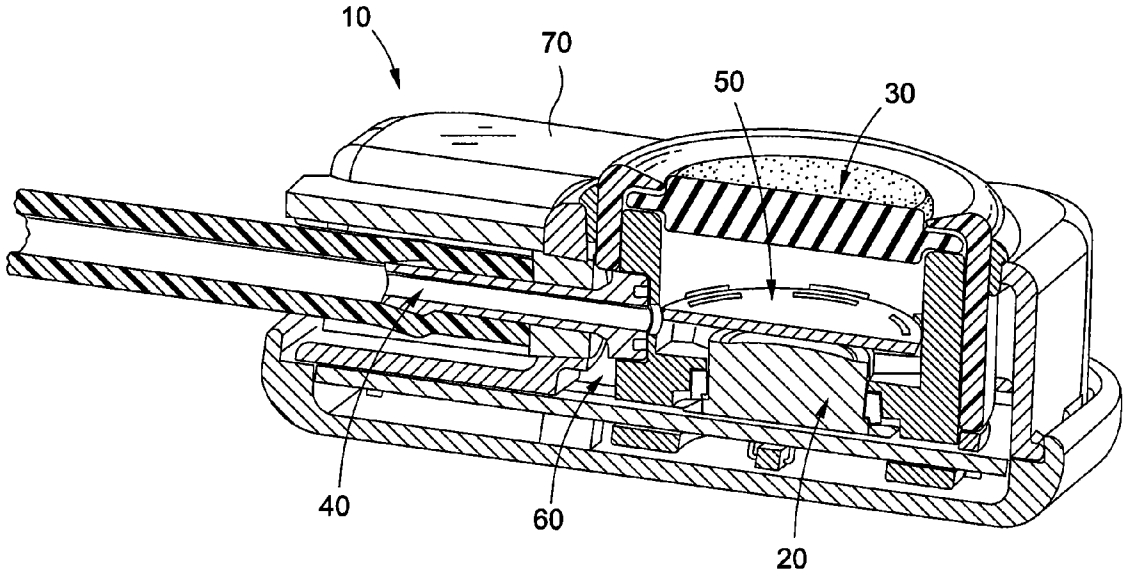
(57) **ABSTRACT**

The present invention is related to a biocompatible and biostable implantable medical device. The present invention can include an implantable medical device including an electro-mechanical component. The electro-mechanical component can be coated with various novel and nonobvious coating combinations designed to promote biocompatibility and biostability. One layer of the coating combinations can be a tie layer. Another layer of the coating combinations can be a layer formed on top of the tie layer, and having biocompatible and biostable properties.



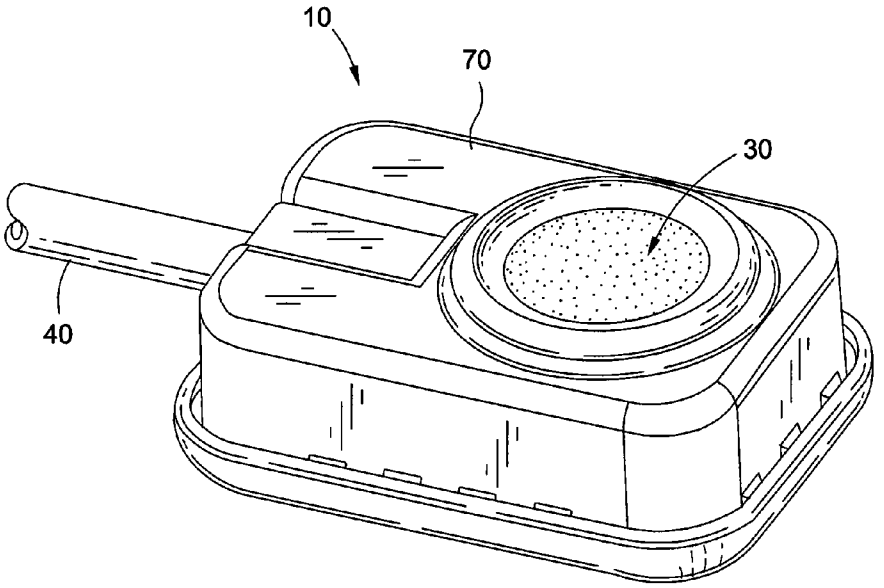


FIG. 1A

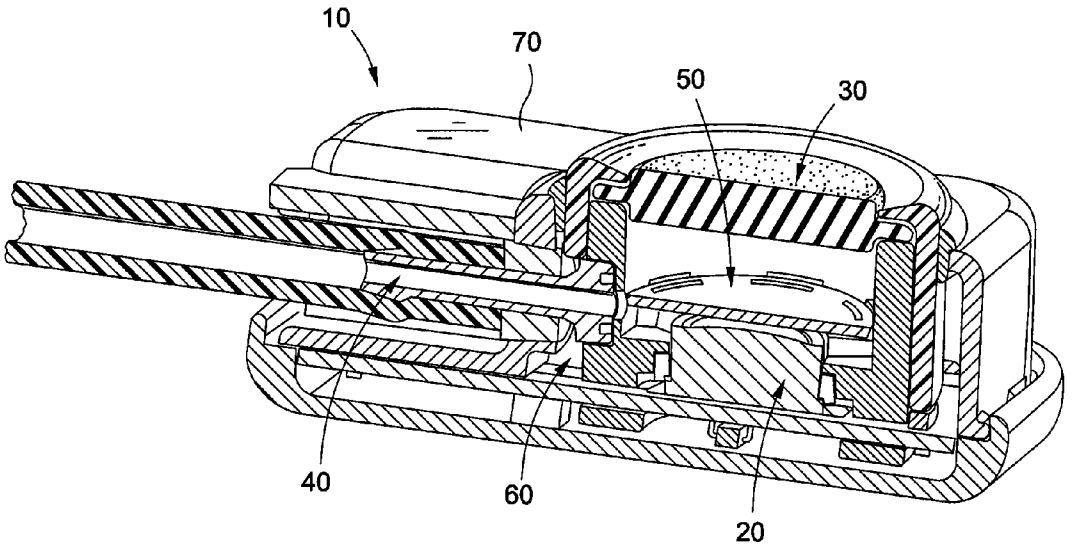


FIG. 1B

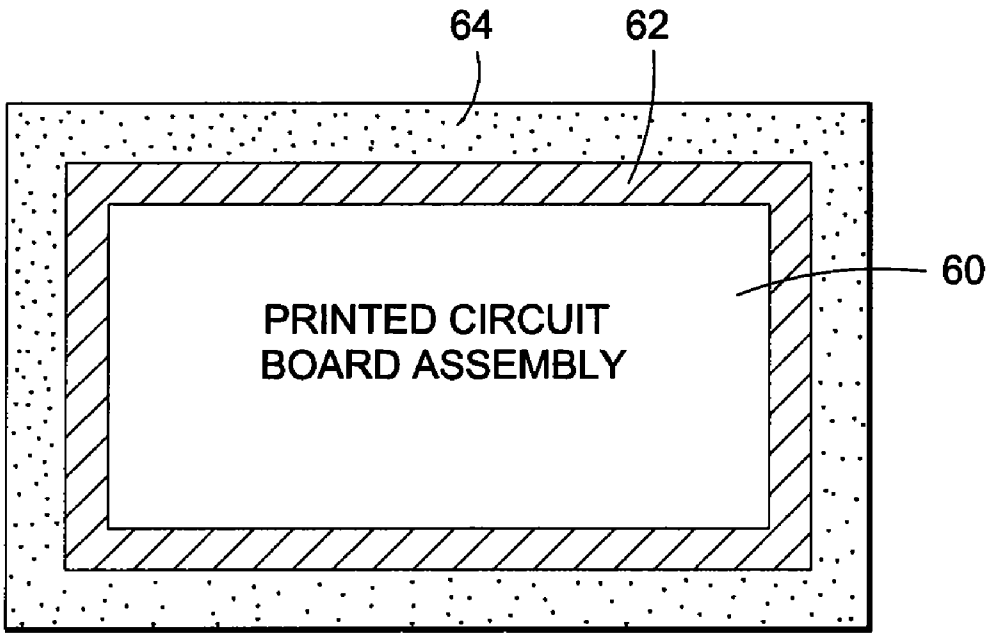


FIG. 2

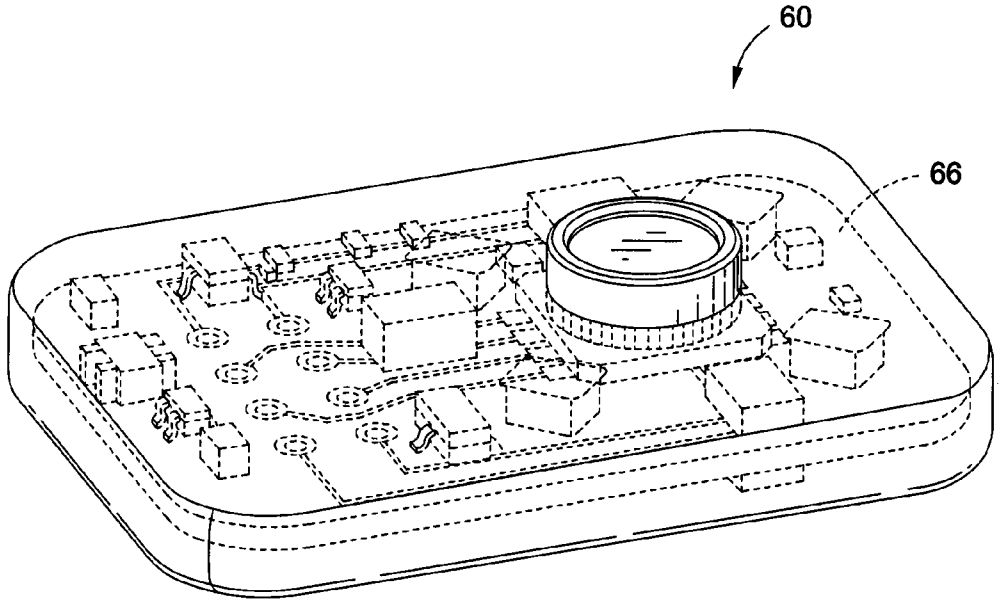


FIG. 3

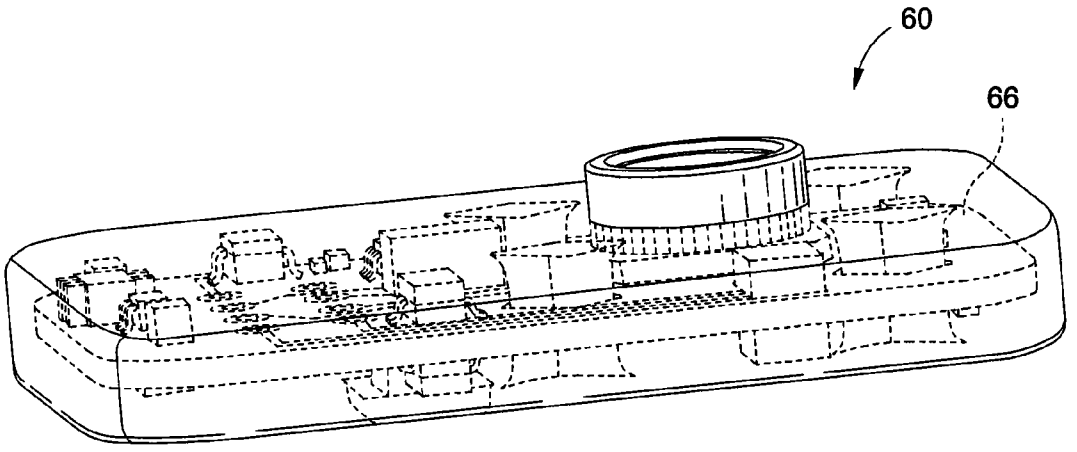


FIG. 4

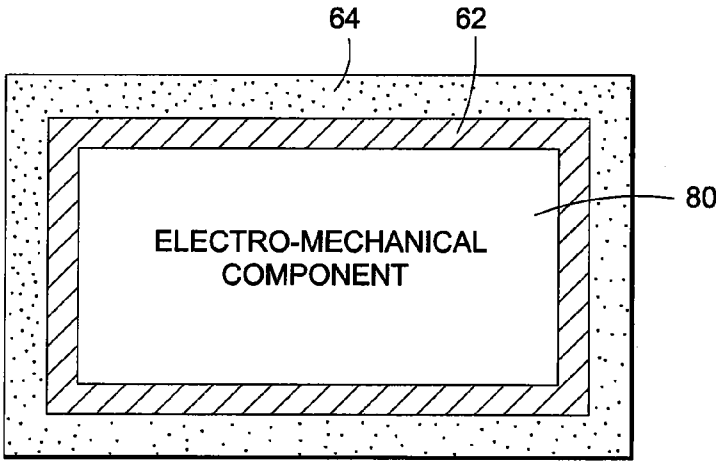

64
62
80
ELECTRO-MECHANICAL COMPONENT

FIG. 5

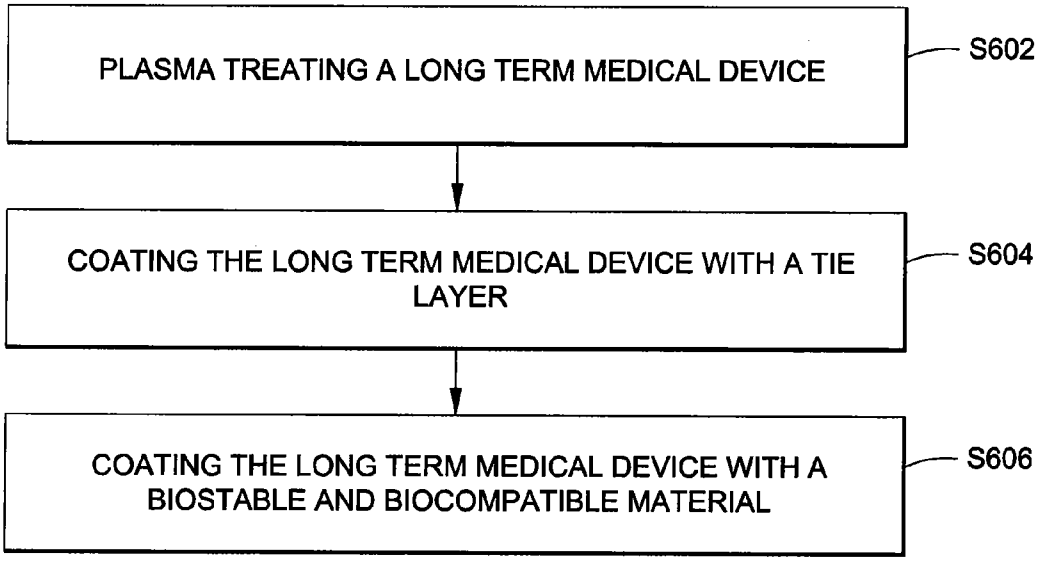

PLASMA TREATING A LONG TERM MEDICAL DEVICE
S602
COATING THE LONG TERM MEDICAL DEVICE WITH A TIE LAYER
S604
COATING THE LONG TERM MEDICAL DEVICE WITH A BIOSTABLE AND BIOCOMPATIBLE MATERIAL
S606

FIG. 6

BIOCOMPATIBLE AND BIOSTABLE IMPLANTABLE MEDICAL DEVICE

RELATED APPLICATIONS

[0001] This application claims priority to and the benefit of U.S. Provisional Patent Application No. 61/330,266, entitled "BIOCOMPATIBLE AND BIODURABLE, ELECTRONICALLY ENHANCED ACCESS PORT FOR A FLUID FILLED IMPLANT" filed on Apr. 30, 2010, the entire disclosure of which is incorporated herein by reference.

FIELD

[0002] The present invention broadly relates to medical devices and more specifically, to a biocompatible and biostable implantable medical device.

BACKGROUND

[0003] There are numerous varieties of implantable medical devices, such as fluid filled surgical implants presently comprising, or which may in the future comprise, access ports, for hydraulically adjustable gastric bands.

[0004] An exemplary hydraulic adjustable gastric band comprises a saline solution inside of one or more inflatable portions (e.g., silicone shells) positioned on the stomach surface of the ring of the gastric band to adjust the gastric band through a variety of diameters. As the inflatable portion is inflated it reduces the stoma of the gastric band and when the inflatable portion is deflated it increases the stoma of the gastric band. The saline solution is added to or removed from the inflatable portion via an access port fixed beneath the skin of the patient in the abdomen on the rectus muscle sheath using a fine needle to find the right level of restriction.

[0005] An exemplary gastric band (hydraulic, hydraulic-mechanical hybrid, or otherwise) may additionally, or alternatively, comprise an access port coupled with an override mechanism to rapidly remove fluid or gel from the implant in the event of an emergency.

[0006] Each of the foregoing implants, as well as others, comprise access ports that may be candidates for various electronics based enhancements, e.g., an access port fitted with a pressure sensor and/or an access port that transmits a signal for easier detection of its location within the body of the patient.

[0007] Furthermore, incorporation of electronic components into such access ports has not been workable at least in part because of bioincompatibility. More specifically, these enhancements and the associated electronics have heretofore caused cytotoxicity and/or been compromised by the body's interstitial fluids over time.

[0008] Spehr (U.S. Pat. No. 6,240,320) discloses that biocompatible material such as diamond-like carbon, sapphire, parylene compounds, diamond, or like materials may be used to coat an exterior of the electrode member. However, Spehr suffers from the drawback that it does not use, for example, a tie layer to enhance adhesion of the biocompatible material. Furthermore, Spehr does not disclose that several types of coatings can be used in conjunction with each other to address all of the essential requirements for a successful long-term function. Such requirements can include, for example, long-term biocompatibility (10+ years), ability to coat relatively uniformly and thoroughly over an abrupt topology in a conformal manner, provide a significant barrier against water molecule penetration or transmission, utilize a deposition temperature and other processing parameters which are not too harsh for the substrate material and the electromechanical device being coated, non-conductivity of the portion of the coating that directly contacts an electrical equipment, and ability to stay attached to the substrate materials and retain its moisture barrier properties despite (i) abrasion caused by handling during assembly; (ii) thermal expansion and contraction during shipping and handling and then due to operation of the device after implantation; (iii) material aging; (iv) chemical interaction between adjacent materials; and (v) exposure to sterilization, such as heat, chemicals or radiation.

[0009] Adamis (U.S. Pat. No. 7,563,255) discloses coating devices contacting tissue or bio fluid with biocompatible material, such as, polyethyleneglycol, polyvinylchloride, polycarbonate, polysulfone, polytetrafluoroethylene, parylene, titanium or the like, prior to implantation. However, Adamis suffers from the drawback that it does not use, for example, a tie layer to enhance adhesion of the biocompatible material. Furthermore, Adamis does not disclose that several types of coatings can be used as a multilayered combination to address all of the requirements listed above.

SUMMARY

[0010] In accordance with exemplary embodiments, the present invention provides for a biocompatible and biostable medical device that addresses the needs in the prior art.

[0011] In accordance with exemplary embodiments, the present invention provides for a medical device, such as an access port configured to detect the pressure of a fluid within the implant. In accordance with other exemplary embodiments, the present invention provides for various novel and nonobvious coating combinations designed to promote biostability and biocompatibility of electro-mechanical components in the medical devices, including, but not limited to, those disclosed herein.

[0012] In one embodiment, the present invention is an access port for a gastric band including a housing, and an electro-mechanical component located within the housing, wherein the electro-mechanical component is coated with a coating combination.

[0013] In another embodiment, the present invention is an access port for a gastric band including a penetrable septum defining an outer wall of a housing, a conduit configured to provide fluid communication between the penetrable septum and the gastric band, a pressure sensor in fluid communication with a fluid within the gastric band, and a printed circuit board assembly connected to the pressure sensor, wherein the printed circuit board assembly is coated with a coating combination.

[0014] In yet another embodiment, the present invention is an access port for a gastric band including a penetrable septum defining an outer wall of a housing, a conduit configured to provide fluid communication between the penetrable septum and the gastric band, and a pressure sensor in fluid communication with a fluid within the gastric band, wherein the pressure sensor is coated with a coating combination.

[0015] In still another embodiment, the present invention is a method for protectively coating a long term medical device including coating the long term medical device with a tie layer, and coating the long term medical device with a biostable and biocompatible material.

[0016] In one embodiment, the present invention is an implantable medical device including an electro-mechanical component coated with a coating combination including a tie layer.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The exemplary embodiments of the present invention will be described in conjunction with the accompanying drawing FIGS. in which like numerals denote like elements and:

[0018] FIG. **1**A illustrates an access port comprising a pressure sensor according to an embodiment of the present invention;

[0019] FIG. **1**B illustrates a cross sectional view of an access port comprising a pressure sensor according to an embodiment of the present invention;

[0020] FIG. **2** illustrates a printed circuit board assembly coated with various layers according to an embodiment of the present invention;

[0021] FIG. **3** illustrates a printed circuit board assembly coated with various layers according to an embodiment of the present invention;

[0022] FIG. **4** illustrates a printed circuit board assembly coated with various layers according to an embodiment of the present invention;

[0023] FIG. **5** illustrates an electro-mechanical component for a medical device coated with various layers according to an embodiment of the present invention; and

[0024] FIG. **6** depicts a process according to an embodiment of the present invention.

DETAILED DESCRIPTION

[0025] In accordance with exemplary embodiments, the present invention comprises a biocompatible and biostable medical device, such as an access port for a gastric band. Persons skilled in the art will readily appreciate that various aspects of the invention may be realized by any number of methods and devices configured to perform the intended functions. Stated differently, other methods and devices may be incorporated herein to perform the intended functions. It should also be noted that the drawing FIGS. referred to herein are not all drawn to scale, but may be exaggerated to illustrate various aspects of the invention, and in that regard, the drawing FIGS. should not be construed as limiting. Finally, although the present invention may be described in connection with various medical principles and beliefs, the present invention should not be bound by theory.

[0026] By way of example, the present invention will be described primarily with reference to hydraulically adjustable gastric bands. Nevertheless, persons skilled in the art will readily appreciate that the present invention advantageously may be applied to and one of the numerous varieties of fluid filled surgical implants presently comprising, or which may in the future comprise, access ports. Similarly, while the present invention will be described primarily with reference to fluid filled surgical implants, persons skilled in the art will readily appreciate that the present invention advantageously may be applied to other medical devices, whether fluid or gel filled.

[0027] In accordance with exemplary embodiments, the present invention provides for an access port configured to detect the pressure of a fluid within the implant.

[0028] At the outset, it should be noted that while the present invention will be described primarily with reference to an access port, persons skilled in the art will readily appreciate that an access port is not necessary for detection of the pressure of a fluid within an implant. Stated differently, the diagnostic and therapeutic advantages associated with knowing the pressure of a fluid within an implant, as provided for by the present invention, may be realized without fluid access to the implant via an access port.

[0029] As seen in FIGS. **1**A and **1**B, a medical device, such as an access port **10** including a pressure sensor **20**, and a penetrable septum **30** is depicted. The penetrable septum **30** can be penetrated by a needle to allow fluid or gel to be added or removed from the access port **10**. A conduit **40** provides access to a fluid filled implant such that the addition or removal of fluid to the access port **10** thereby adds or removes fluid from the fluid filled implant. The needle can be, for example, a fine needle, a hypodermic needle, a Huber needle, or any other type of needle which can supply fluid or gel to the access port **10**. In addition, a tube, instead of a needle can be used. The access port **10** can be connected, for example, to the fluid filled implant(not shown) and can be used to supply or remove fluid or gel from the fluid filled implant. The fluid filled implant can be, for example, a gastric band, and/or a breast implant (not shown).

[0030] The access port can also optionally include a plate element **50** which is positioned between the penetrable septum **30** and the pressure sensor **20**. The positioning of the plate element **50** serves to prevent the needle from damaging the pressure sensor **20**. The plate element **50** can be formed, for example, from titanium, stainless steel, or any other type of material that can protect the pressure sensor **20** from damage.

[0031] A printed circuit board assembly (PCBA) **60** can be connected, for example, to the pressure sensor **20**. The PCBA **60** is configured to telemetrically relay a pressure value obtained from the pressure sensor **20** to an external control unit. The pressure value can indicate, for example, a pressure of the access port **10** and/or the fluid filled implant. The pressure sensor **20** can also detect, for example, a fill volume, a strain, and/or a linear measurement of the access port **10**. The access port **10** can also include, for example, a housing **70** which can, for example, define a cavity containing the pressure sensor **20**, a portion of the conduit **40**, the plate element **50**, and/or the PCBA **60**. The penetrable septum **30** can define, for example, an outer wall of the housing **70**.

[0032] The present invention provides for various novel and nonobvious coating combinations designed to promote biostability and/or biocompatibility of electro-mechanical components of the access port or other medical devices, including, but not limited to, those disclosed herein.

[0033] The term biostable or biostability can mean, for example, that an implantable device or object is capable of being in contact with living tissues or organisms and still function within the expected performance parameters. In one embodiment, a biostable object or implanted device can still function within the expected performance parameters, for example, for 10 years or more while being in contact with the living tissues or organisms.

[0034] The term biocompatible or biocompantibility can mean, for example, that the implantable device or object is capable of being in contact with living tissues or organisms without causing harm to the living tissue or the organism. In one embodiment, a biocompatible object can be, for example,

an object which meets the U.S. Pharmacopoeia ("USP") Class VI requirements. For example, the coating combination may be biocompatible over an extended period of time, such as for 1, 2, 5, 10, 15, 20, or more years.

[0035] In accordance with exemplary embodiments, the present invention provides for coating combinations that isolate electro-mechanical components, including, but not limited to, printed circuit board assemblies, sensors, motors and other components typical to implantable medical devices, and/or components forming those objects listed above. The electro-mechanical components can be purely electrical components, purely mechanical components, or a hybrid of electrical and mechanical components.

[0036] In one embodiment, the coating combinations can be, for example, a multilayer coating.

[0037] Another exemplary coating combination may be able to coat relatively uniformly and/or thoroughly, over electro-mechanical components with an abrupt topology. Such electro-mechanical components can be objects with various abrupt geometries and/or various surface chemistries and thermal expansion properties such as a PCBA. Stated differently, an exemplary coating combination is capable of conformal coating.

[0038] Yet another exemplary coating combination may be a barrier against water molecule and other moisture penetration and/or transmission. Qualitatively, an exemplary coating combination may have a moisture vapor transmission rate (MVTR) roughly equivalent to that of titanium at approximately 25 μm (0.001 inches) thickness. Or, stated in terms of water vapor transmission rate (WVTR), an exemplary coating combination may allow less than 0.001 g/m^2/day. MVTR and WVTR are measures of the passage of water vapor through a substance.

[0039] Exemplary coating combinations may remain attached to the substrate material and/or the electro-mechanical component being coated and retain its moisture barrier properties despite: (i) abrasion caused by handling during assembly; (ii) thermal expansion and contraction during shipping, handling, and operation of the electro-mechanical component after implantation; (iii) material aging; (iv) chemical interaction between adjacent materials; and (v) exposure to sterilization such as heat, chemicals or radiation.

[0040] The deposition temperature and other processing parameters of other exemplary coating combinations should not be too harsh for the substrate material and the electro-mechanical component being coated.

[0041] Depending on the electro-mechanical component being coated, yet other exemplary coating combinations may be non-conductive or conductive. For example, where the electro-mechanical components transmit or receive RF signals, the coating combinations should not be an RF shield. However, the coating combinations may provide RF interference protection where appropriate.

[0042] In one embodiment, the coating combination, along with its coating process, may be reasonable in terms of cost, e.g., no more than the cost of the underlying electro-mechanical component being coated.

[0043] In accordance with exemplary embodiments of the present invention, an exemplary coating combination may comprise one or more of the following layers depending on the desired coating combination characteristics: (i) parylene (e.g., Parylene P, or Parylene M); (ii) diamond like carbon (DLC); (iii) titanium nitride (TiN); (iv) titanium carbide or silicon nitride; (v) cyclo olefin copolymer (COC) or cyclo olefin polymer (COP); (vi) epoxy; (vii) silicone polymer (e.g., primarily resin based (Q or T functional), linear polymer based, or a hybrid of both); (viii) glass; (ix) chloro-trifluoro-ethylene (CTFE) or poly-chloro-tri-fluoro-ethylene (PCTFE); (x) poly-ether-ether-ketone or polysulfone; (xi) acetal or polyoxymethylene (POM); (xii) polypropylene; (xiii) liquid crystal polymer (LCP); (xiv) ultra high molecular weight polyethylene (UHMWPE); and (xv) fluoropolymer acrylate; and (xvi) synthetic diamond.

[0044] Exemplary methods of applying an exemplary coating combination comprises one or more of the following steps: (i) testing the electro-mechanical component for functionality; (ii) plasma treating the external surfaces of the electro-mechanical component, e.g., to remove small contaminants and/or enhance surface adhesion; (iii) packaging the electro-mechanical component in a particle free environment and package meeting the ISO class 6, or better, ISO 14644-1 clean room standard (class 1000 under the FED-STD-209E clean room standard); (iv) opening and handling the package under clean room conditions; (v) placing the electro-mechanical component in a coating chamber; and (vi) applying the coating(s).

[0045] In accordance with exemplary embodiments of the present invention, an exemplary coating combination may comprise one or more layers applied with chemical vapor deposition (CVD), physical vapor deposition (PVD), plasma enhanced chemical vapor deposition (PECVD), injection molding, compression molding, transfer molding, film forming, thermoforming, vacuum forming, or dipping. In addition, other types of layer applications are possible, which can be used to deposit layers which have conformal properties, adhesive properties, biocompatible properties, and/or biostable properties.

[0046] What follows now are several materials used for coating combinations in accordance with the present invention.

[0047] Parylene P is a Parylene variation with high penetration properties. However, Parylene P may not necessarily be optimized for moisture barrier properties. In one embodiment, Parylene P can be, for example, Parylene HT produced by Specialty Coating Systems or Parylene diX N produced by Kisco Conformal Coating. Parylene M is a variation of Parylene with good moisture barrier properties. However, Parylene M may not have the penetrative properties of Parylene P. In one embodiment, Parylene M can be, for example, Parylene C produced by Specialty Coating Systems or Parylene diX D produced by Kisco Conformal Coating.

[0048] DLC can be a hard coating that can be applied with either a chemical vapor deposition (CVD) or a physical vapor deposition (PVD) process. In one embodiment, the CVD version of the DLC including the Plasma Enhanced CVD (PECVD) can be used due to its improved conformal characteristics. The CVD version of the DLC can require a lower process temperature, reducing a likelihood of damage to the electro-mechanical component being coated. Generally, DLC can be applied as a first layer to medical devices, or electro-mechanical components of medical devices that do not have abrupt topographies. In electro-mechanical components of medical devices that do have abrupt topographies, the abrupt topographies can be smoothed out by over-molding (COC/Epoxy, etc.) or undercoating with some other more conformal coatings (Parylene), before the DLC is applied. Alternatively, a DLC with improved conformal characteristics can be used, such as the PECVD.

[0049] TiN can be deposited using CVD or variations of the CVD, and is generally biocompatible and a good moisture barrier. Some versions of TiN can be deposited in a CVD process with temperatures below 60° C., which makes it safe for most electro-mechanical components. TiN can be somewhat conductive, and may be beneficial for electrostatic discharge (ESD) protection and electromagnetic interference (EMI) protection.

[0050] Titanium carbide, silicon nitride, and a number of metallic thin coatings can be used as moisture barriers due to their low processing temperatures. Any biocompatibility issues can be addressed by over-coating. Their conductive properties may also be beneficial in certain applications, such as for electrostatic discharge (ESD) protection and electromagnetic interference (EMI) protection.

[0051] COC, COP, or epoxy may not be as thin as Parylene or DLC, but they can provide good barriers against moisture migration. In addition, this over-mold or coverage can also allow a flat surface to be formed over the electro-mechanical component, even when the electro-mechanical component has an abrupt topography. The flat surfaces increases the likelihood that a uniform DLC or Parylene overcoat can be formed. The epoxy can be applied by a casting or pouring process, while the COC can be applied using injection molding.

[0052] Silicone polymer materials may be primarily resin based (Q or T functional), linear polymer based, or any combination of the two. The silicone polymer materials may be long term-term biocompatible and can smooth out any abrupt topography in the electro-mechanical component. In addition, the silicone polymer materials can provide good adhesion to the subsequent coating options such as Parylene and DLC.

[0053] Glass can be applied in a casting or over-mold process when the high temperature of the molten glass does not damage the substrate or the electro-mechanical component that it is coating. However, if temperatures typically over 260° C. are not acceptable, a glass encapsulation process can be used. The glass encapsulation process can include, for example, shrinking a thin glass layer over the electro-mechanical component, or making a two-part glass housing in a casting process, fitting them over the electro-mechanical component, and then sealing the seams with a glass-to-glass sealing. Glass can provide a good moisture barrier, and many grades of glass are biocompatible. In addition, glass can offer a relatively flat surface for further coating layers if necessary.

[0054] CTFE or PCTFE can have low friction, inertness, and improved moisture barrier properties. In one embodiment, Aclar® RX by Honeywell® can be used. Although it may be difficult to injection mold the CTFE or PCTFE, the CTFE or PCTFE material can be applied as a film over the electro-mechanical component such as through thermoforming. In thermoforming, the film of the CTFE or PCTFE can be heated and pressure sealed, or adhesively bonded.

[0055] Poly-ether-ether-ketone (PEEK) and polysulfone film or resin can possess desirable biocompatibility properties due to its long-term implantable grades. Due to their high temperature requirements, PEEK and polysulfone film or resin may be suitable for high temperature electro-mechanical components, or electro-mechanical components which do not require the PEEK and polysulfone film or resin to be over-molded over the electro-mechanical component. Although the PEEK and polysulfone film or resin may have reduced moisture barrier properties, they can be thermoformed over the electro-mechanical component, for example, to smooth out the abrupt topography in preparation for a Parylene or DLC layer.

[0056] Although POM has reduced moisture barrier properties, it can have biocompatible grades and can be injection molded, making it a good choice for reducing the abrupt topography in an over-mold.

[0057] Polypropylene can provide a good moisture barrier and can be injection molded at relatively low temperatures. Thus, polypropylene can be beneficial for reducing the abrupt topography in an over-mold for the electro-mechanical component while avoiding heat damage to the electro-mechanical component. In addition it can be relatively low cost for any cost-sensitive applications. Any biocompatibility issues can be addressed by over-coating the polypropylene layer with DLC or Parylene layers.

[0058] LCP can be injection moldable and can penetrate tight areas. It can also be molded in thin sections over the electro-mechanical component due to its desirable rheological behavior during injection molding. Thus, although it may have reduced moisture barrier properties and reduced long-term implantable qualities, the liquid crystal polymer may be effective in reducing abrupt geometries in the electro-mechanical component.

[0059] Ultra high molecular weight polyethylene has good abrasion resistance and relatively good moisture barrier properties. It can also be long-term biocompatible. The ultra high molecular weight polyethylene can be compression molded instead of injection molded, and also applied as a thin film similar to PCTFE, PEEK, or polysulfone, but does not require as high as a temperature as such materials for thermoforming.

[0060] Fluoropolymer acrylate coating is applied as a coating in a dipping process, where the electro-mechanical component is dipped into an organic solvent containing fluoropolymer acrylate. This coating is typically used as protective barrier layer on the electro-mechanical component, such as when the electro-mechanical component is an electrical component. Fluoropolymer acrylate can have relatively good moisture barrier properties.

[0061] In the coating combinations, a tie layer can also be used. The tie layer can be formed, for example, from a material which is conformal and has good adhesive properties. In one embodiment, the tie layer can be, for example, AdPro Plus produced by Specialty Coating Systems.

[0062] In one embodiment, the coating combinations can include a first layer formed on top of an electro-mechanical component and which has conformal and/or adhesive properties. The first layer can be, for example, a tie layer. A second layer can be formed on top of the first layer. The second layer can have biocompatible and biostable properties. The second layer can be, for example, the outermost layer which contacts the body of a patient. If the second layer does not have moisture barrier properties, additional layers can be formed between the first layer and the second layer with moisture barrier properties. In addition, additional layers can be formed between the first layer and the second layer with additional desirable properties.

[0063] What follows are coating combinations which use some of the materials listed above, according to various embodiments of the present invention:

[0064] Coating Combination 1

[0065] Layer 1—Tie layer which enhances adhesion of Parylene.

[0066] Layer 2—Parylene P with crevice penetration properties at a thickness of approximately 10 μm to 100 μm.
[0067] Layer 3—Parylene M at a thickness of approximately 10 μm to 100 μm.
[0068] Coating Combination 2
[0069] Layers 1 through 3—same as coating combination 1.
[0070] Layer 4—DLC at a thickness of approximately 0.02 μm to 0.2 μm.
[0071] Coating Combination 3
[0072] Layer 1—Tie layer which enhances adhesion of Parylene.
[0073] Layer 2—Parylene P with crevice penetration properties at a thickness of approximately 10 μm to 100 μm.
[0074] Layer 3—Epoxy (cast as thin as possible to smooth out abrupt topographies).
[0075] Layer 4—Parylene M at a thickness of 10 μm to 100 μm.
[0076] Coating Combination 4
[0077] Layers 1 through 4—Same as coating combination 3.
[0078] Layer 5—DLC at a thickness of approximately 0.02 μm to 0.2 μm or more.
[0079] Coating Combination 5
[0080] Same as coating combination 3 but replace Epoxy with COC, applied in an injection molding tool.
[0081] Coating Combination 6
[0082] Same as coating combination 4 but replace Epoxy with COC, applied in an injection molding tool.
[0083] Coating Combination 7
[0084] Same as coating combination 5, but instead of COC, use any of glass, chloro-tri-fluoro-ethylene or poly-chloro-tri-fluoro-ethylene, poly-ether-ether-ketone or polysulfone, polyoxymethylene, polypropylene, liquid crystal polymer, ultra high molecular weight polyethylene, and fluoropolymer acrylate.
[0085] Coating Combination 8
[0086] Same as coating combination 6, but instead of COC, use any of glass, chloro-tri-fluoro-ethylene or poly-chloro-tri-fluoro-ethylene, poly-ether-ether-ketone or polysulfone, polyoxymethylene, polypropylene, liquid crystal polymer, ultra high molecular weight polyethylene, and fluoropolymer acrylate.
[0087] What follows now are several embodiments of coating combinations comprising silicone polymer in accordance with the present invention. In exemplary embodiments, silicone polymer is formulated to cure from a specified uncured state to a specified cured state. The uncured state would range from low to moderate viscosity (1-1000 cp), used to control the coating process, and the cured state would be in a range of hardness (Shore A 20-100). An exemplary cure mechanism is a platinum system, but other systems may be suitable as well, for example, a condensation or peroxide cure system.
[0088] Coating Combination 9
[0089] Layer 1—A low durometer (softer) silicone applied directly to the substrate in a relatively thicker (higher viscosity) coating.
[0090] Layer 2—Parylene, DLC, TiN, PCTFE film, and/or combinations of the materials listed.
[0091] Coating Combination 10
[0092] Layer 1—A high durometer (firmer) silicone applied directly to the substrate in a relatively thinner (lower viscosity) coating.
[0093] Layer 2—Same as coating combination 9.
[0094] Coating Combination 11
[0095] Layer 1—A low durometer (softer) silicone applied directly to the substrate in a relatively thicker (higher viscosity) coating.
[0096] Layer 2—A high durometer (firmer) silicone applied directly to the substrate in a relatively thinner (lower viscosity) coating.
[0097] Layer 3—Same as coating combination 9.
[0098] Coating Combination 12
[0099] Layer 1—A primer or tie layer which may be composed of silicone prime (resin), or any other material designed to increase adhesion.
[0100] Layer 2—A low durometer (softer) silicone applied directly to the substrate in a relatively thicker (higher viscosity) coating.
[0101] Layer 3—A high durometer (firmer) silicone applied directly to the substrate in a relatively thinner (lower viscosity) coating.
[0102] Layer 4—Same as coating combination 9.
[0103] Coating Combination 13
[0104] Layer 1—Same as coating combination 1.
[0105] Layer 2—A low durometer (softer) silicone applied directly to the substrate in a relatively thicker (higher viscosity) coating.
[0106] Layer 3—A high durometer (firmer) silicone applied directly to the substrate in a relatively thinner (lower viscosity) coating.
[0107] Layer 4—Same as coating combination 9.
[0108] Coating Combination 14
[0109] Layer 1—A primer or tie layer which may be composed of silicone prime (resin), or any other material designed to increase adhesion.
[0110] Layer 2—A single layer of silicone formulated to provide necessary, mechanical, thermal, and chemical properties.
[0111] Layer 3—Same as coating combination 9.
[0112] Coating Combination 15
[0113] Layer 1—Same as coating combination 1.
[0114] Layer 2—A single layer of silicone formulated to provide necessary, mechanical, thermal, and chemical properties.
[0115] Layer 3—Same as coating combination 9.
[0116] Coating Combination 16
[0117] Layer 1—A layer of silicone with conformal and adhesive properties.
[0118] Layer 2—A layer including materials which have moisture barrier properties, such as DLC, Parylene M, TiN, or PCTFE.
[0119] Layer 3—A layer of silicone with biocompatible and biostable properties.
[0120] For example, in one embodiment as seen in FIG. **2**, a PCBA **60** can be coated by a layer **62** and/or a layer **64**. The layer **62** and/or the layer **64** can form, for example, the coating combinations 1-15. The layer **62** can be, for example, the Layer 1 in the coating combinations 1-15. The layer **64** can be, for example, the other layers, in the coating combinations 1-15. The PCBA **60**, which is coated, can also be seen in FIGS. **3** and **4**. In FIGS. **3** and **4**, all sensitive electro-mechanical components in the PCBA **60** are coated by a coating combination **66** except for the sensing element which is already biocompatible and/or biostable by choice of its construction material or by a thin layer of coating including but not limited to DLC or TiN. The sensing element can be, for example, a pressure sensing element.

[0121] In addition, although a PCBA **60** is depicted in FIGS. **2**, **3** and **4**, any medical device can be coated. The medical device can be, for example, an access port fitted with a pressure sensor which measures the pressure in the saline solution, an access port that transmits a signal for easier detection of its location in the body, a pump that controls an amount of fluid in the gastric band, any long term medical device such as a device which is implanted for a long term (e.g. 10 years or more) within a body, and/or any electro-mechanical components of the objects listed above. In one embodiment, the medical device can also include electro-mechanical components and/or software for detecting breaches to the coating combinations. The medical device can include, for example, an onboard diagnostic tool to detect such breaches to the coating combinations.

[0122] In one embodiment, electro-mechanical components of a medical device, such as a long term medical device, can be coated. For example, an electro-mechanical component **80** of a long term medical device can be coated as seen in FIG. **5**. The electro-mechanical component **80** can be coated with the layer **62** and/or the layer **64**.

[0123] In one embodiment, the one or more coatings or layers may be applied to various implantable medical devices such as an access port, a breast implant, a cardiac rhythm management device, a pacemaker, a cardioverter, a defibrillator, a neurostimulator, an activity sensor, a pressure sensor, a multi-sensor device, a drug delivery pump or device, a heart monitor, a respiratory monitor, an artificial kidney or other artificial organs aside from the heart, orthopedic implants with electronics incorporating stress, pressure or force sensors. In one embodiment, the various implantable medical devices are medical devices which may come in contact with interstitial body fluids, but do not come in contact with blood.

[0124] The foregoing disclosure is illustrative of the present invention and is not to be construed as limiting the invention. Although one or more embodiments of the invention have been described, persons skilled in the art will readily appreciate that numerous modifications could be made without departing from the spirit and scope of the present invention. By way of mere example, persons skilled in the art will readily appreciate that the novel and nonobvious coating combinations designed to promote biostability described herein advantageously may be applied not just to surgical implants, but to any device or device component having biostability as a design requirement. In sum, it should be understood that all such modifications are intended to be included within the scope of the invention.

[0125] The terms "a," "an," "the," and similar referents used in the context of describing the present invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. Recitation of ranges of values herein is merely intended to serve as a shorthand method of referring individually to each separate value falling within the range. Unless otherwise indicated herein, each individual value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., "such as") provided herein is intended merely to better illuminate the present invention and does not pose a limitation on the scope of the present invention otherwise claimed. No language in the specification should be construed as indicating any non-claimed element essential to the practice of the present invention.

[0126] Groupings of alternative elements or embodiments of the invention disclosed herein are not to be construed as limitations. Each group member may be referred to and claimed individually or in any combination with other members of the group or other elements found herein. It is anticipated that one or more members of a group may be included in, or deleted from, a group for reasons of convenience and/or patentability. When any such inclusion or deletion occurs, the specification is deemed to contain the group as modified thus fulfilling the written description of all Markush groups used in the appended claims.

[0127] Certain embodiments of this invention are described herein, including the best mode known to the inventors for carrying out the invention. Of course, variations on these described embodiments will become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventor expects skilled artisans to employ such variations as appropriate, and the inventors intend for the invention to be practiced otherwise than specifically described herein. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

[0128] Furthermore, certain references have been made to patents and printed publications throughout this specification. Each of the above-cited references and printed publications are individually incorporated herein by reference in their entirety.

[0129] Specific embodiments disclosed herein may be further limited in the claims using consisting of or consisting essentially of language. When used in the claims, whether as filed or added per amendment, the transition term "consisting of" excludes any element, step, or ingredient not specified in the claims. The transition term "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic(s). Embodiments of the invention so claimed are inherently or expressly described and enabled herein.

[0130] In closing, it is to be understood that the embodiments of the present invention disclosed herein are illustrative of the principles of the present invention. Other modifications that may be employed are within the scope of the present invention. Thus, by way of example, but not of limitation, alternative configurations of the present invention may be utilized in accordance with the teachings herein. Accordingly, the present invention is not limited to that precisely as shown and described.

What is claimed is:

1. An access port for use in conjunction with a gastric band, the access port comprising:

a housing; and

an electro-mechanical component located within the housing, wherein the electro-mechanical component is coated with a coating combination.

2. The access port of claim **1**, wherein the gastric band is a hydraulically adjustable gastric band.

3. The access port of claim **1** further comprising:

a penetrable septum formed on the housing; and

a conduit configured to carry fluid between the penetrable septum and an inflatable portion of the gastric band.

4. The access port of claim **3**, wherein the electro-mechanical component is a pressure sensor in communication with a fluid within the gastric band and configured to monitor a parameter of the fluid, generate a pressure value signal based on the parameter, and communicate the pressure value signal to an external control unit via RF telemetry.

5. The access port of claim **4**, further comprising a plate element positioned between the penetrable septum and the pressure sensor to guard the pressure sensor against a needle damaging it.

6. The access port of claim **1**, wherein the electro-mechanical component is a printed circuit board assembly.

7. The access port of claim **1**, wherein the electro-mechanical component is a motor.

8. The access port of claim **1** wherein the coating combination includes a tie layer.

9. The access port of claim **1**, wherein the coating combination comprises at least two different layers selected from the group consisting of parylene, diamond like carbon, titanium nitride, titanium carbide, silicon nitride, cyclo olefin copolymer, cyclo olefin polymer, epoxy, silicone polymer, glass, chloro-tri-fluoro-ethylene, poly-chloro-tri-fluoro-ethylene, poly-ether-ether-ketone, polysulfone, polyoxymethylene, polypropylene, liquid crystal polymer, ultra high molecular weight polyethylene, fluoropolymer acrylate, and synthetic diamond.

10. The access port of claim **9**, wherein the at least two different layers are applied by one or more of chemical vapor deposition, physical vapor deposition, plasma enhanced chemical vapor deposition, injection molding, compression molding, transfer molding, film forming, thermoforming, vacuum forming, or dipping.

11. The access port of claim **1**, wherein the coating combination is biocompatible for at least 10 years.

12. The access port of claim **1** wherein the coating combination includes a first layer having conformal and adhesive properties, and a second layer on top of the first layer having biocompatible and biostable properties.

13. An access port for a gastric band comprising:
a penetrable septum defining an outer wall of a housing;
a conduit configured to provide fluid communication between the penetrable septum and the gastric band;
a pressure sensor in fluid communication with a fluid within the gastric band; and
a printed circuit board assembly connected to the pressure sensor, wherein the printed circuit board assembly is coated with a coating combination.

14. The access port of claim **13**, wherein the coating combination comprises at least two different layers selected from the group consisting of parylene, diamond like carbon, titanium nitride, titanium carbide or silicon nitride, cyclo olefin copolymer, cyclo olefin polymer, epoxy, silicone polymer, glass, chloro-tri-fluoro-ethylene, poly-chloro-tri-fluoro-ethylene, poly-ether-ether-ketone, polysulfone, polyoxymethylene, polypropylene, liquid crystal polymer, ultra high molecular weight polyethylene, fluoropolymer acrylate, and synthetic diamond.

15. The access port of claim **13** wherein the coating combination includes a tie layer.

16. The access port of claim **15** wherein the coating combination includes a layer formed on top of the tie layer, and which has biocompatible and biostable properties.

17. The access port of claim **13** wherein the pressure sensor is coated with the coating combination.

18. An access port for a gastric band comprising:
a penetrable septum defining an outer wall of a housing;
a conduit configured to provide fluid communication between the penetrable septum and the gastric band; and
a pressure sensor in fluid communication with a fluid within the gastric band, wherein the pressure sensor is coated with a coating combination.

19. The access port of claim **18**, wherein the coating combination comprises at least two different layers selected from the group consisting of parylene, diamond like carbon, titanium nitride, titanium carbide, silicon nitride, cyclo olefin copolymer, cyclo olefin polymer, epoxy, silicone polymer, glass, chloro-tri-fluoro-ethylene, poly-chloro-tri-fluoro-ethylene, poly-ether-ether-ketone, polysulfone, polyoxymethylene, polypropylene, liquid crystal polymer, ultra high molecular weight polyethylene, fluoropolymer acrylate, and synthetic diamond.

20. The access port of claim **18** wherein the coating combination includes a tie layer.

21. The access port of claim **20** wherein the coating combination includes a layer formed on top of the tie layer, and which has biocompatible and biostable properties.

22. An implantable medical device comprising:
an electro-mechanical component coated with a coating combination including a tie layer.

23. The implantable medical device of claim **22**, wherein the coating combination comprises at least two different layers selected from the group consisting of parylene, diamond like carbon, titanium nitride, titanium carbide, silicon nitride, cyclo olefin copolymer, cyclo olefin polymer, epoxy, silicone polymer, glass, chloro-tri-fluoro-ethylene, poly-chloro-tri-fluoro-ethylene, poly-ether-ether-ketone, polysulfone, polyoxymethylene, polypropylene, liquid crystal polymer, ultra high molecular weight polyethylene, fluoropolymer acrylate, and synthetic diamond.

24. The implantable medical device of claim **22** wherein the coating combination includes a layer formed on top of the tie layer, and which has biocompatible and biostable properties.

25. A method for protectively coating a long term medical device comprising:
coating the long term medical device with a tie layer; and
coating the long term medical device with a biostable and biocompatible material.

26. The method of claim **25**, wherein the biostable and biocompatible material is selected from a group consisting of parylene, diamond like carbon, titanium nitride, titanium carbide, silicon nitride, cyclo olefin copolymer, cyclo olefin polymer, epoxy, silicone polymer, glass, chloro-tri-fluoro-ethylene, poly-chloro-tri-fluoro-ethylene, poly-ether-ether-ketone, polysulfone, polyoxymethylene, polypropylene, liquid crystal polymer, ultra high molecular weight polyethylene, fluoropolymer acrylate, and synthetic diamond.

27. The method of claim **25** further comprising plasma treating the long term medical device.

28. The method of claim **25** further comprising coating the long term medical device in a clean room meeting the ISO class 6 ISO 14644-1 clean room standard.

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