US 20150264816A1

(19) **United States**

(12) **Patent Application Publication**

Askin, III et al.

(10) **Pub. No.: US 2015/0264816 A1**

(43) **Pub. Date: Sep. 17, 2015**

(54) **SYSTEMS AND METHODS FOR FLEXIBLE ELECTRODES**

(71) Applicant: **Ripple LLC**, Salt Lake City, UT (US)

(72) Inventors: **Robert E. Askin, III**, Salt Lake City, UT (US); **Scott D. Hiatt**, Sandy, UT (US); **Kenneth S. Guillory**, Salt Lake City, UT (US); **Daniel McDonnall**, Salt Lake City, UT (US); **Christopher F. Smith**, North Salt Lake, US (US)

(21) Appl. No.: **14/729,027**

(22) Filed: **Jun. 2, 2015**

Related U.S. Application Data

(63) Continuation of application No. 12/889,310, filed on Sep. 23, 2010, now Pat. No. 9,061,134.

(60) Provisional application No. 61/245,276, filed on Sep. 23, 2009, now abandoned.

Publication Classification

(51) **Int. Cl.**

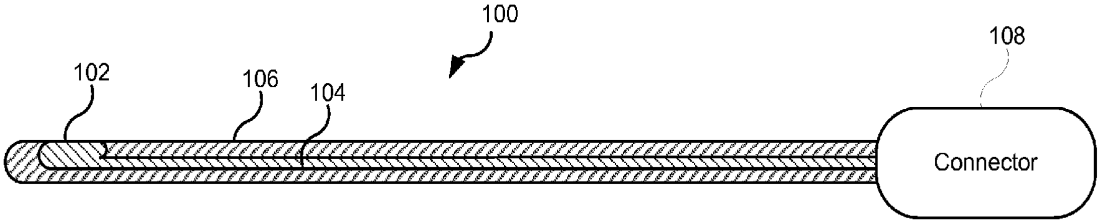
H05K 3/12	(2006.01)
A61N 1/04	(2006.01)
A61B 5/00	(2006.01)
A61B 5/0492	(2006.01)
A61B 5/04	(2006.01)

(52) **U.S. Cl.**

CPC ***H05K 3/125*** (2013.01); ***H05K 3/1216*** (2013.01); ***A61B 5/0492*** (2013.01); ***A61B 5/04001*** (2013.01); ***A61B 5/685*** (2013.01); ***A61N 1/04*** (2013.01); *H05K 2203/0759* (2013.01)

(57) **ABSTRACT**

Disclosed herein are systems and methods for producing and using electrodes, which may be flexible and/or stretchable, and interconnection structures that can be used both externally and/or implanted within the body. Electrodes according to various embodiments disclosed herein may be produced by depositing patterned layers of insulating and conductive polymers to form multi-layer circuits. The conductive materials and layers in the structure can be exposed on the surface of the structures for use as electrodes. A plurality of electrodes may be formed into an electrode array. In various embodiments, electrode arrays may be associated with telemetry modules configured to wirelessly transmit data collected by the electrode array to a receiver module.



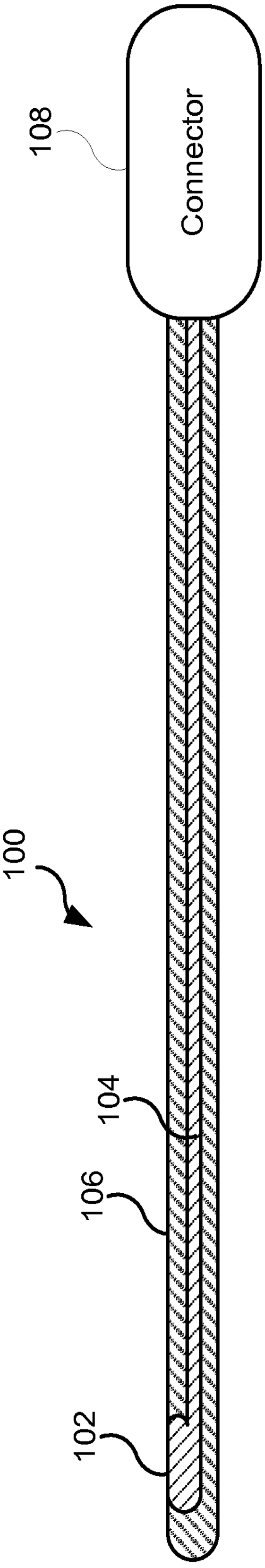

Connector
108
100
104
106
102

FIG. 1

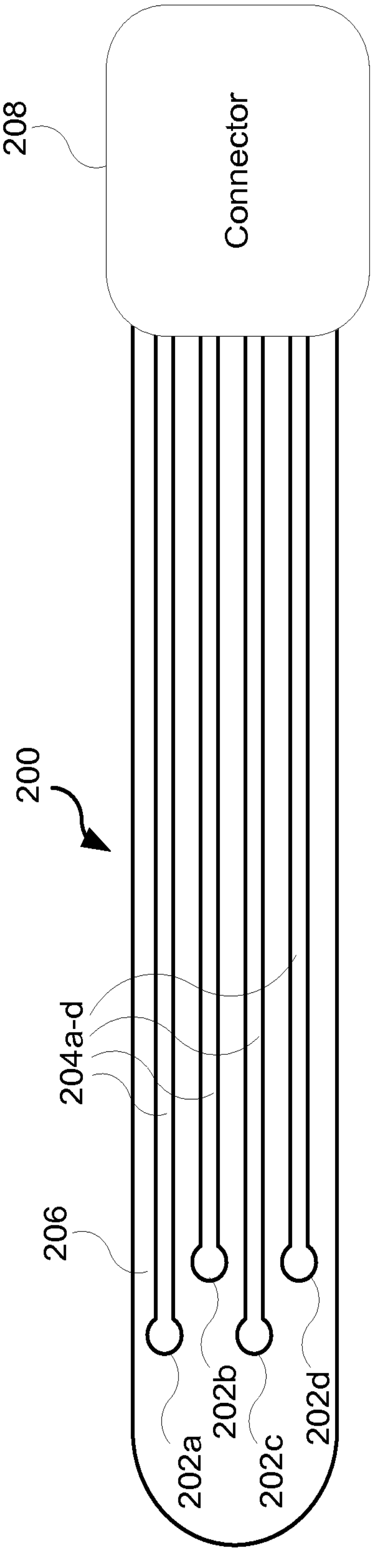

Connector
208
200
204a-d
206
202a
202b
202c
202d

FIG. 2

FIG. 3A

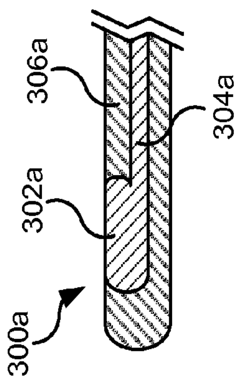


FIG. 3B

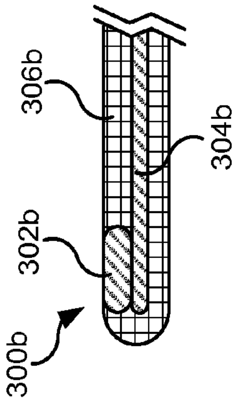


FIG. 3C

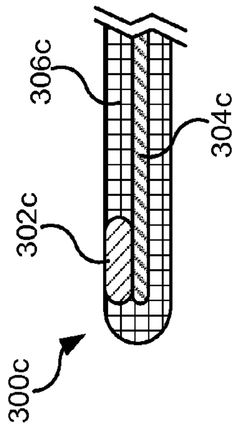


FIG. 4A

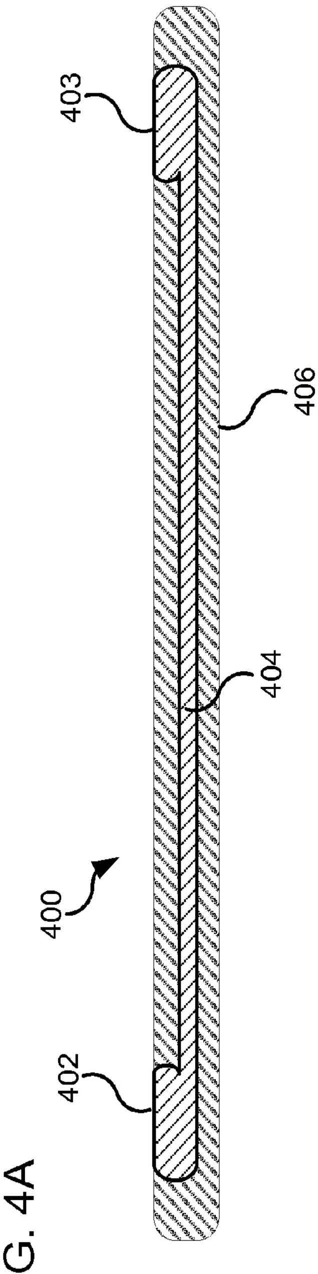
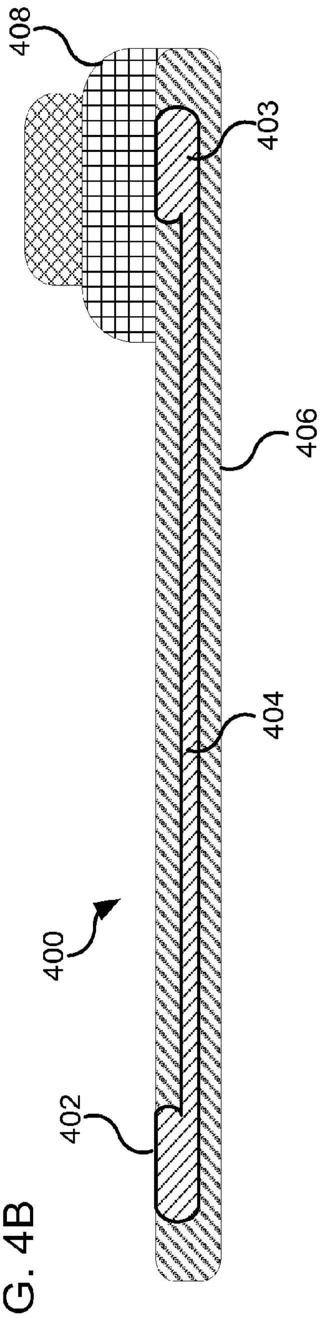


FIG. 4B



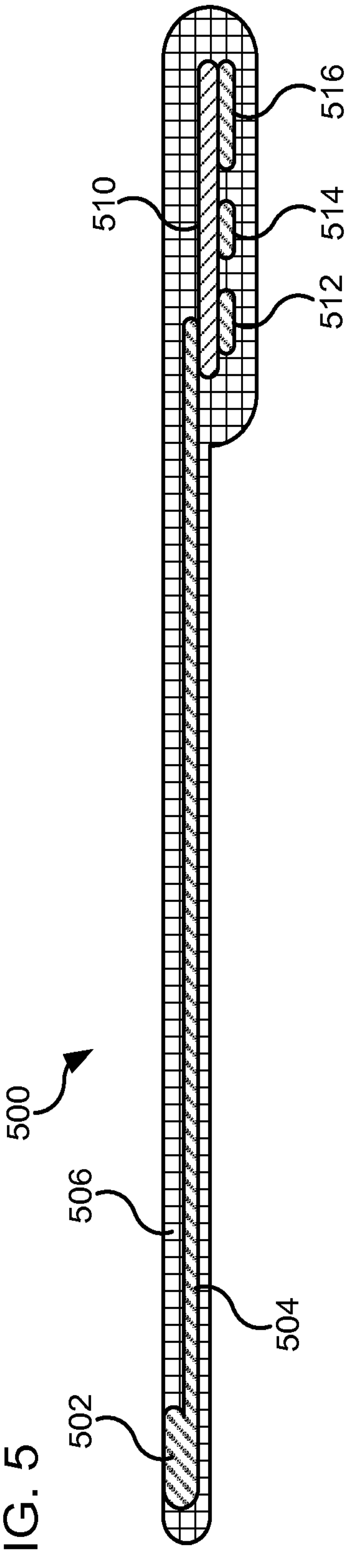


FIG. 5

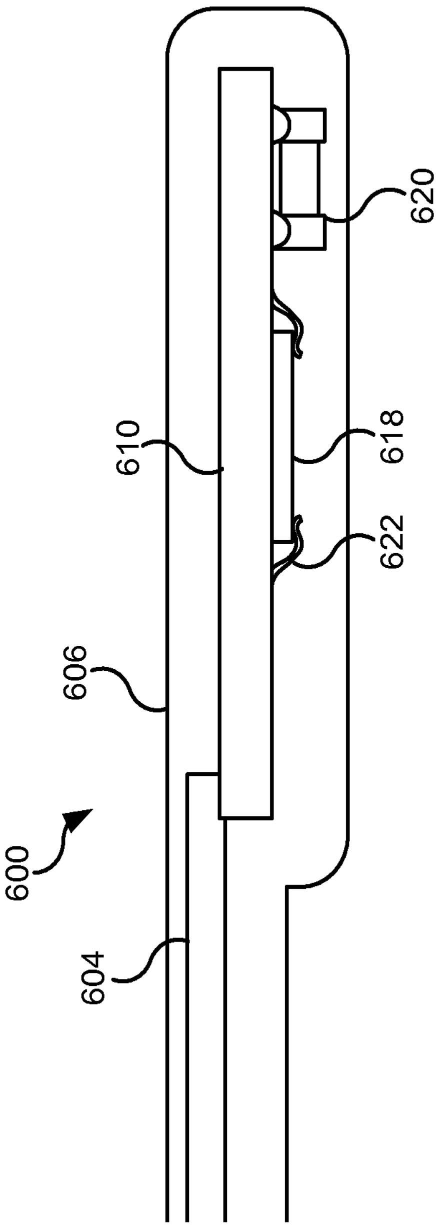


FIG. 6

FIG. 7

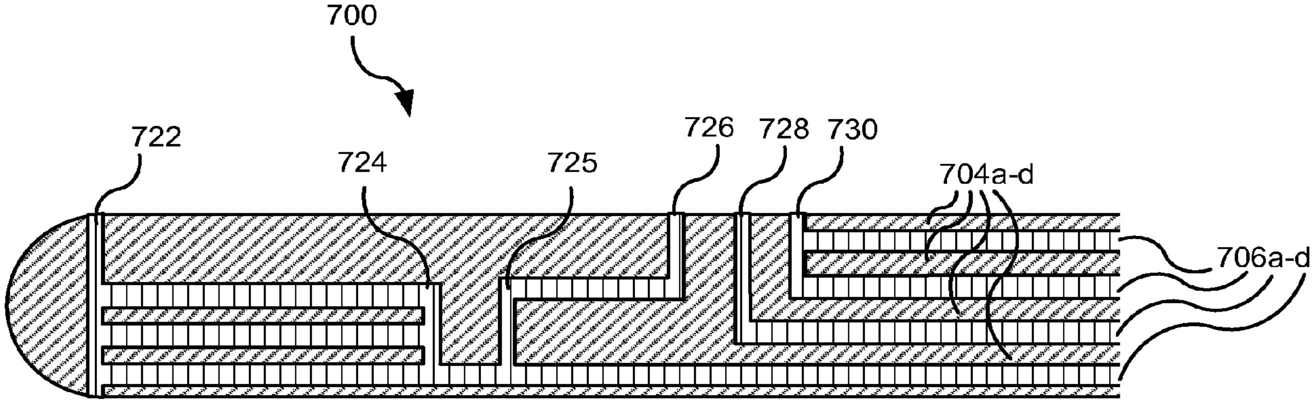

700
722
724
725
726
728
730
704a-d
706a-d

FIG. 8

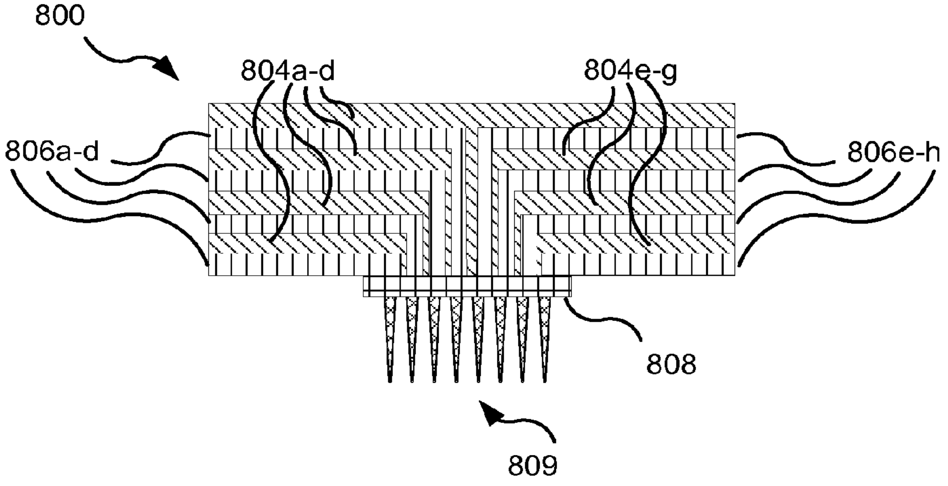

800
804a-d
804e-g
806a-d
806e-h
808
809

FIG. 9

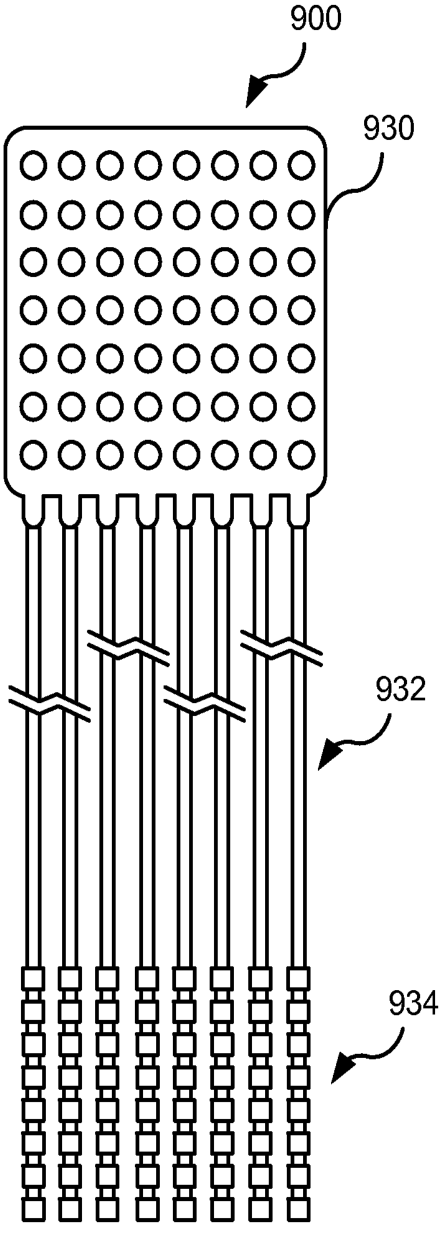


FIG. 10A

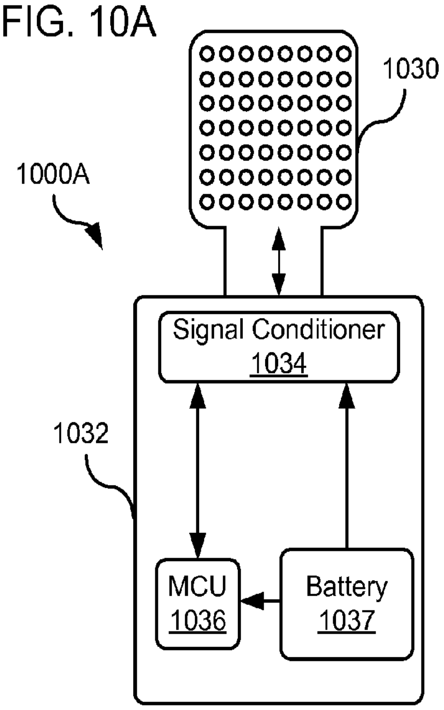
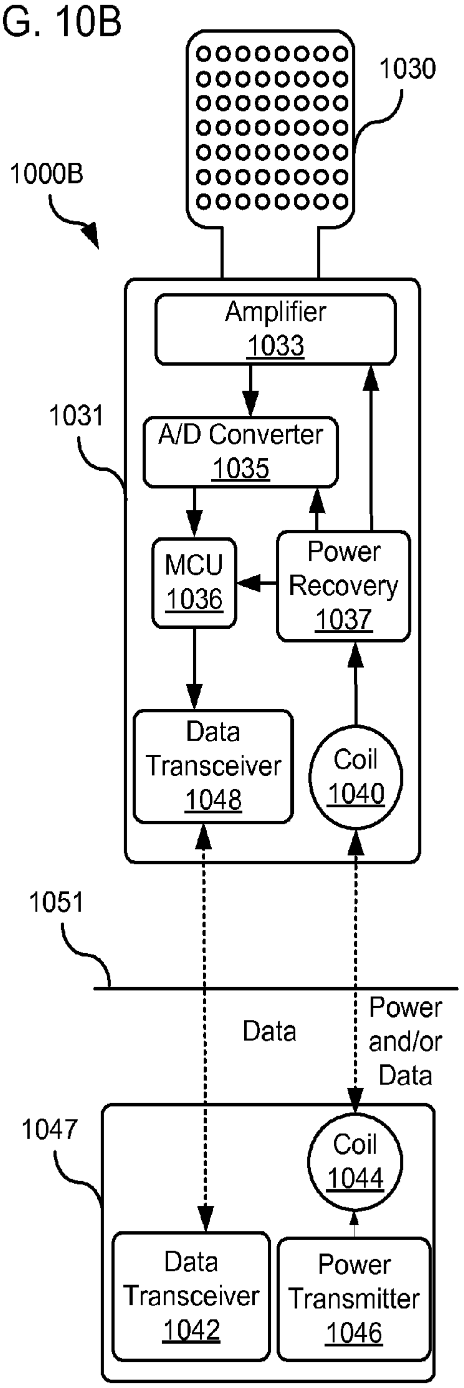


FIG. 10B



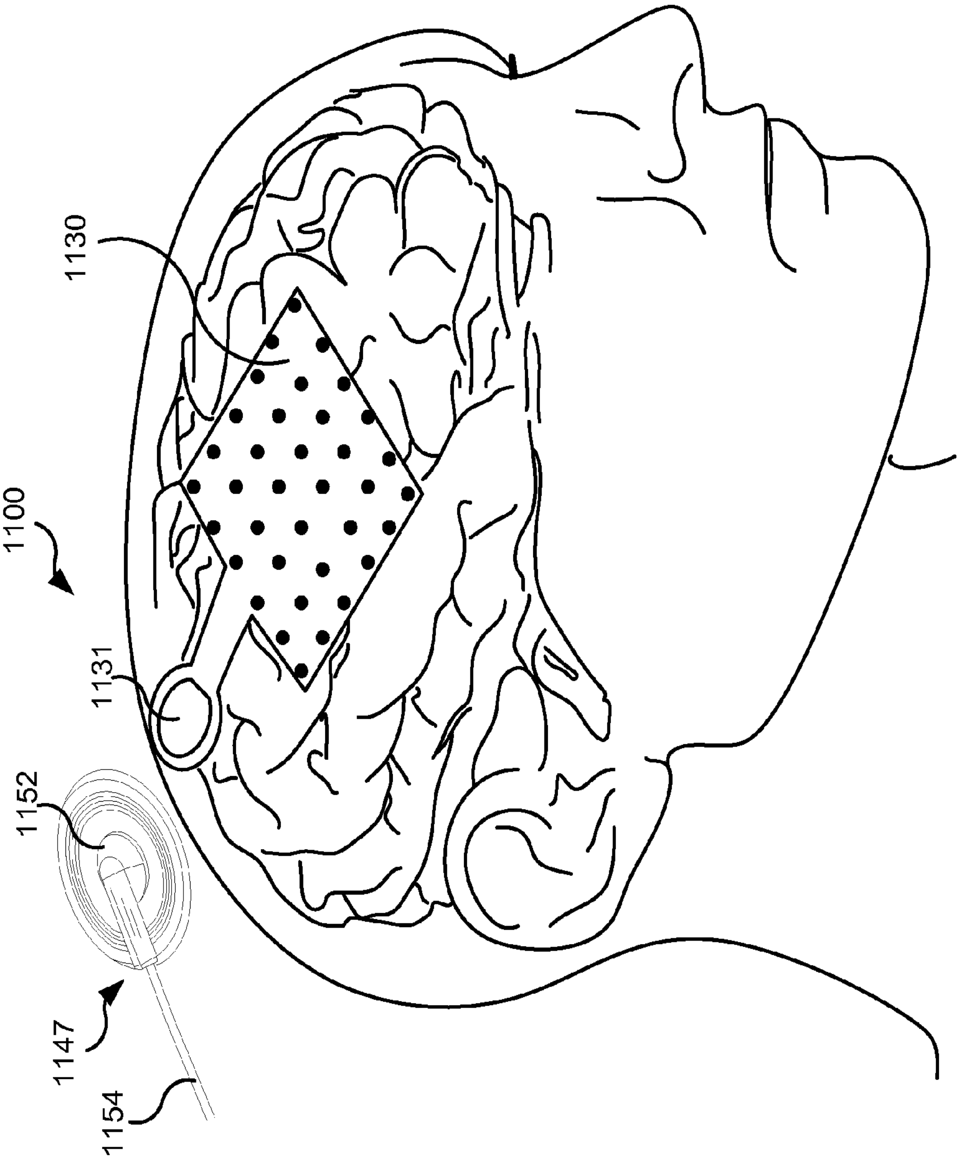


FIG. 11

FIG. 12

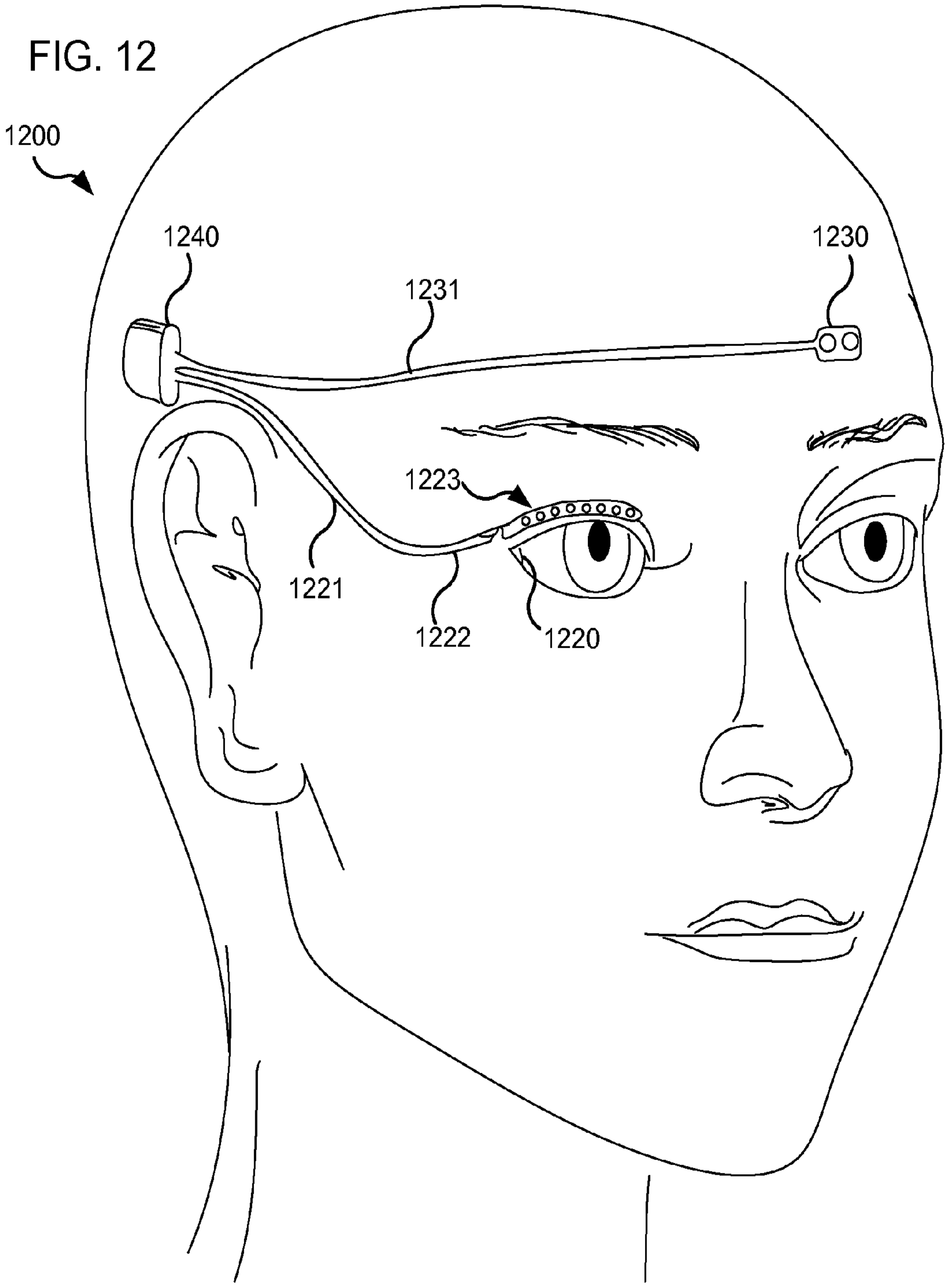
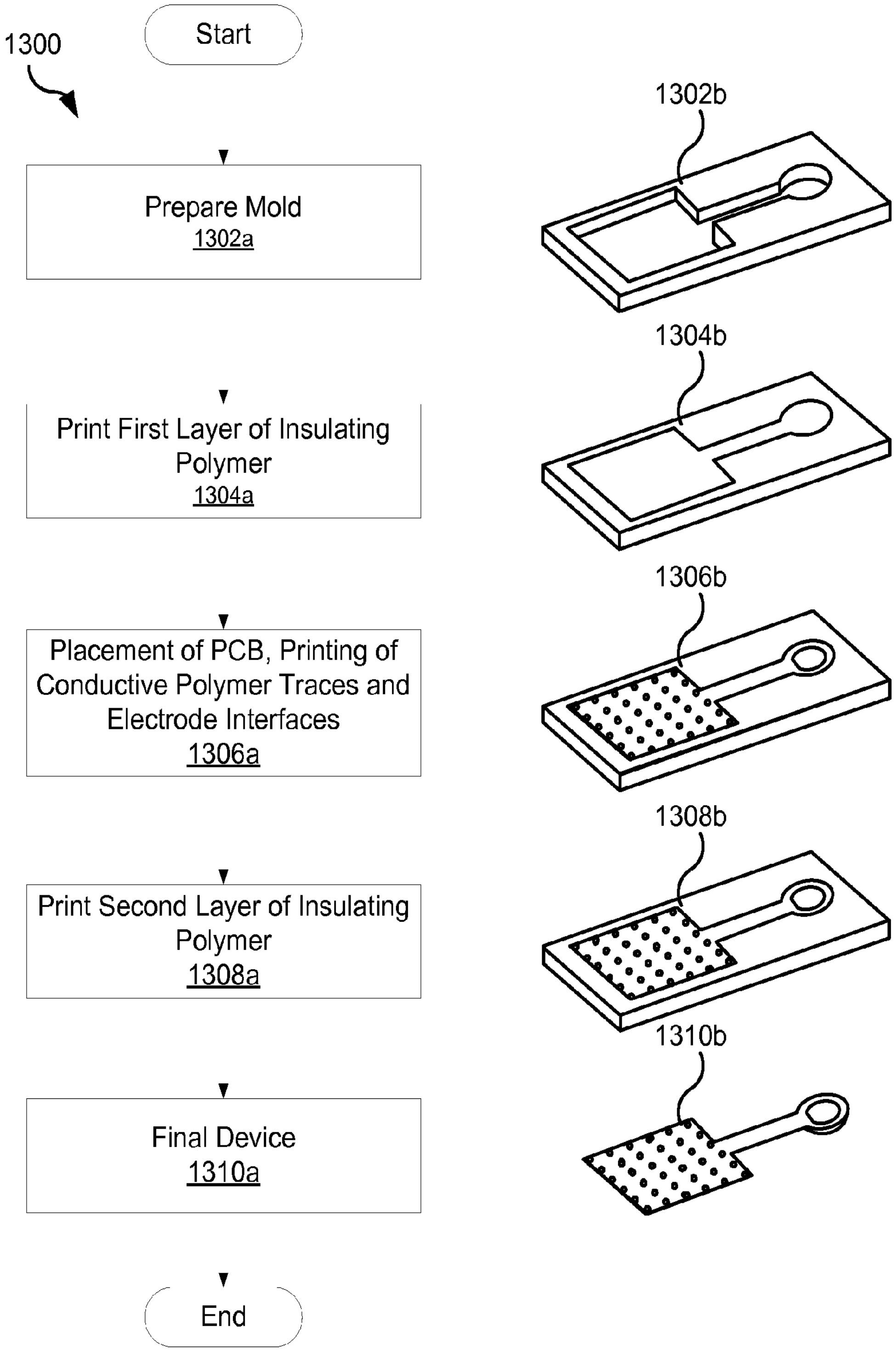


FIG. 13


1300
Start
Prepare Mold
1302a
Print First Layer of Insulating Polymer
1304a
Placement of PCB, Printing of Conductive Polymer Traces and Electrode Interfaces
1306a
Print Second Layer of Insulating Polymer
1308a
Final Device
1310a
End
1302b
1304b
1306b
1308b
1310b

SYSTEMS AND METHODS FOR FLEXIBLE ELECTRODES

RELATED APPLICATIONS

[0001] This application is a continuation of patent application Ser. No. 12/889,310, filed on Sep. 23, 2010 and titled "SYSTEMS AND METHODS FOR FLEXIBLE ELECTRODES," which application claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Patent Application No. 61/245,276, filed Sep. 23, 2009, titled "Thin Film Electrode and Interconnect Technology with Optional Integrated Electronics." The entire contents of both of the foregoing applications are incorporated herein by reference.

FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] This invention was made with U.S. Government support under contract no.: R44NS061604 awarded by National Institutes of Health. The U.S. Government has certain rights in this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0003] FIG. **1** illustrates a cross-sectional view of one embodiment of an electrode.

[0004] FIG. **2** illustrates a top view of one embodiment of an electrode.

[0005] FIGS. **3**A, **3**B, and **3**C are cross sectional views that illustrate three embodiments of electrodes.

[0006] FIG. **4**A illustrates a cross sectional view of one embodiment of an electrode comprising two electrode interfaces.

[0007] FIG. **4**B illustrates a cross sectional view of an electrode that includes a connector in electrical communication with an electrode interface.

[0008] FIG. **5** illustrates a cross sectional view of one embodiment of an electrode that includes an electronic package.

[0009] FIG. **6** illustrates a side view of one embodiment of an electrode that includes a printed circuit board, which is coupled to an optical transceiver and an application specific integrated circuit.

[0010] FIG. **7** illustrates a cross sectional view of one embodiment of a multi-layer electrode.

[0011] FIG. **8** illustrates a cross-sectional view of one embodiment of a multi-layer electrode and a connector.

[0012] FIG. **9** illustrates one embodiment of an electrode array.

[0013] FIG. **10**A illustrates a block diagram of one embodiment of an implantable system that includes an electrode grid and a signal processing unit.

[0014] FIG. **10**B illustrates a block diagram of one embodiment of a wireless system that includes an electrode grid, a telemetry module, and a receiver module.

[0015] FIG. **11** illustrates one embodiment of a system that comprises an electrode grid, a telemetry module, and a receiver module.

[0016] FIG. **12** illustrates one embodiment which includes components for electrical stimulation and/or recording as part of a biocompatible system.

[0017] FIG. **13** illustrates one embodiment of a method for manufacturing an electrode array and an associated telemetry module.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0018] Disclosed herein are systems and methods for producing and using electrodes, which may be flexible and/or stretchable, and interconnection structures that can be used both externally and/or implanted within the body. Electrodes according to various embodiments disclosed herein may be produced by depositing patterned layers of insulating and conductive polymers to form multi-layer circuits. The conductive materials and layers in the structure can be exposed on the surface of the structures for use as electrodes. A plurality of electrodes may be formed into an electrode array. In various embodiments, electrode arrays may be associated with telemetry modules configured to wirelessly exchange data between an implantable component and an external module.

[0019] Certain embodiments may be suited for short-term implantation, while other embodiments may be suited for long-term implantation. Still other embodiments may be used for in vitro applications. Some applications of the systems and methods disclosed herein may include recording from and stimulation of neural tissue, stimulation of muscles, sub- and epi-dural monitoring, use in connection with a blink prosthesis, use in treating incontinence via posterior tibial nerve stimulation, use in restoring sexual function via stimulation of the spinal cord, use in recording implanted EMG and neural signals for use in prosthesis control, use in the stimulation of the recurrent laryngeal nerve for treatment of dystonia, use in stimulation of peripheral nerves for nerve block, and use in connection with neuroprosthetic and neural interface applications (e.g., a pacemaker device).

[0020] Multiple types of conductive polymers can be used within the same structure depending on factors, such as cost, conductivity, biocompatibility, and manufacturability for different feature sizes. For example, exposed electrode areas can also be formed from a conductive polymer that is different from conductive polymers used within the structures.

[0021] According to various embodiments, electrodes on the surface of the structure can also be formed by embedding metal or other electrode materials into the structures, and connecting to them with conductive polymers. These electrodes may also include geometrical and structural features for penetrating into tissues, hooking or providing mechanical fixation, mitigating stress around flexion points, or increasing the surface area of the electrode. In some embodiments, conducting traces can also be brought to the surface of the structure to create contact pads for bonding to other devices, including sensors, actuators, or other devices or assemblies. Bonding can be performed by applying pressure to hold the conductive areas in contact with bond pads on the devices, or by applying conductive adhesives or joining materials. These joints can also be further encapsulated with insulating polymers, such as silicones to seal and/or structurally reinforce them.

[0022] In various embodiments, electrodes may include embedded electronics. Such electronics may include, but are not limited to, any combination of silicon integrated circuits ("ICs"), circuit boards with electronic components, hermetic enclosures with contacts and feed-throughs to internal electronics, and the like. These electronics may include amplifiers, filters, analog to digital conversion, digital signal processing, stimulators, control circuits, fail-safe monitoring, data error checking, batteries, and connections for data and power telemetry with external devices.

[0023] Flexible electrodes, according to the present disclosure, may be manufactured by any method for controlled dispensing and/or forming of insulating and conductive polymers into patterns, including: spraying polymer layers onto a surface; depositing polymer layers through needles and narrow dispensing nozzles, including those that use gas pressure and positive displacement for flow control; depositing polymer layers through an ink jet dispenser (such as picodot systems); depositing polymer layers by screen printing and printing through masks; using optical, plasma, or chemical methods to selectively activate areas of a substrate to facilitate selective coating of areas with patterns of polymers; using laser ablation, or plasma or chemical etching (including use of photolithography or overlay masks) to selectively remove and form patterns in layers of deposited polymers; and depositing polymer layers onto both 2D surfaces and 3D molds.

[0024] Applications for electrodes, as disclosed herein, may include any application for which electrodes are currently utilized. Certain embodiments may be employed for sensing of electrophysiological signals from cells, tissues, organs, and body parts, including signals from nerves and muscles, EEG, EMG, ECG, EOG, ERG, ENG, ECoG, EGG, LFP, single and multiunit action potentials, and evoked potentials. Sensing and recording can be performed at the cell, tissue, organ, and body part scales, and used for diagnostic purposes, construction of neuroprosthetic systems for functional restoration, and brain machine interfaces to control external devices based on neural and/or muscle signals. These devices can be used for implanted and external body surface applications, as well as for temporary insertion into and/or application to tissues and organs during surgery and diagnostic procedures, for both short- and long-term sensing purposes.

[0025] In addition, various embodiments disclosed herein may be utilized for electrical stimulation of cells, tissues, organs, and body parts, including stimulation of nerves and muscles, for diagnostic purposes, enhancing trophic effects, functional restoration or rehabilitation in Functional Electrical Stimulation (FES) and other neuroprosthesis systems, and neuromodulation applications including Deep Brain Stimulation (DBS) targets, the cerebral cortex, sympathetic and parasympathetic nerves, peripheral nerves, and the spinal cord. These devices can be used for implanted and external body surface applications, as well as for temporary insertion into and/or application to tissues and organs during surgery and diagnostic procedures, for both short- and long-term stimulation purposes.

[0026] Still other embodiments may be utilized for sensing potentials and currents related to chemical reactions associated with the electrodes, including reactions for oxygen sensing, pH sensing, protein-specific binding of materials to the electrodes, and other chemical sensors based on electrodes. These may also include chemical modification and/or coating of the electrodes, or use of the electrodes with other application-specific materials necessary to sense these reactions.

[0027] Flexible electrodes, as disclosed herein, may be also utilized for control or forcing chemical reactions associated with the electrodes, including release of chemicals or drugs, modification of the local chemical environment, and forcing of chemical reactions. These may also include chemical modification and/or coating of the electrodes, or use of the electrodes with other application-specific materials necessary to create or control these reactions. Various embodiments may also be utilized to control chemical reactions, such as gas evolution or pH changes to effect structural changes in materials, including inflation of balloons and changing the shape, rigidity and forces within the device.

[0028] Various embodiments disclosed herein may be utilized to generate and sense electrical currents in the body for device operation, implant integrity, and diagnostic and therapeutic use, including imaging and facilitation of trophic effects and promoting recovery and healing of tissues in the body, including nerves or bone, and restoring function to paralytic and paretic body parts. Measurements of electrode and biological material impedances may be collected, including fixed frequency impedance and multi-frequency impedance spectroscopy methods to characterize electrode interfaces and characteristics of cells, tissues, organs, and body parts of humans and animals, including nerve, muscle and dental tissues. Such measurements may include frequency, phase, and all other measures used to characterize impedances.

[0029] Still other uses of flexible electrodes, as disclosed herein, may include measurements of biological material impedances, which may used to compute impedance tomography images at the cell, tissue, organ, and body scale; application of potentials for electrophoresis, microelectrode array dish, and other in vitro applications; application of potentials for electroporation and other electrical modifications of tissues; and creation of voltage gradients to accelerate the delivery or migration of drugs.

[0030] Various techniques may be utilized in order to facilitate bonding and/or integration of a flexible electrode into a body. For example, adhesives may be applied to the structures to bond them to the body; coatings, such as hydrogels, PEG structures, or other biomaterials, may be used to modulate the tissue response to the structure, including coatings that release drugs for this purpose; coatings may be applied to the electrode to change the adhesion of body tissues to the structures; drugs may be embedded within the non-conducting or insulating material that are released over time to affect the biocompatibility and local tissue response to the implanted structures; chemical surface modification (e.g., hydrophobic, hydrophilic, or non-stick materials) may be utilized to affect the interaction of the surfaces with materials in the environment or biocompatibility in the body; nanomaterials or coatings (e.g., iridium, conductive polymers, or carbon nanotubes) may be applied to electrodes to affect their biocompatibility and impedance; radio-opaque alignment markings, identification information, and/or serial numbers may be embedded into the structures for visualization under x-ray; shapes such as protuberances, pits, holes, or other features may be used to increase the surface area of the electrodes; barbs or hooking features may be included to fix the device within the body; flat tabs, strings, loops or other features may be used to grip, glue, and/or suture the electrode for fixation within the body; or a fabric mesh (such as Dacron) may be used for suturing and/or forming strong tissue adhesions to portions of the structure;

[0031] Flexible electrodes disclosed herein may be implanted into the body with a variety of methods, including: insertion into epidural and subdural spaces through openings in the cranium; folding/unfolding and/or rolling/unrolling to deploy the structure once inside the body; use of saline and/or air balloons within the structure to affect mechanical changes inside the body for fixation, application of pressure, guidance, manipulation of placement, or other purpose; use of guide needles and other surgical instruments to create pilot holes and channels for insertion of the structures into the tissue; and use of needles or other surgical instruments to push or pull the structures into the tissue, then removing the instruments while leaving the structures in place.

[0032] According to various embodiments, insulated conductors may be disposed within a flexible electrode. Providing insulated conductors within the flexible electrode may also allow for the connection of embedded electrodes; the connection of probes and sensors (e.g., accelerometers, pressure sensors, optical and IR sensors, contact switches, magnetic field sensors, capacitive sensors, inductive coils, thermal flux sensors, temperature sensors, proximity sensors, piezo sensors, ultrasound transducers, sound sensors, etc.); the connection of actuators or devices (e.g., force generators, motors, piezo actuators, electromagnets, coils, inductors, ultrasound transducers, stimulators, light emitting diodes etc.); the formation of flexible elastic resistor and capacitor elements that can stretch around tissues and detect structural changes in the sensor by changes in electrical impedance in the sensor elements; the formation of capacitive shields and guard traces for protection of other traces within the structure from interference and electrostatic discharge (ESD); and the measurement of conductivity within the electrode and electrode structures to diagnose problems within the device structure.

[0033] FIG. **1** illustrates a cross-sectional view of one embodiment of an electrode **100**, according to the present disclosure. Electrode **100** includes an internal conductive polymer trace **104** that is disposed within an insulating polymer **106**. An electrode interface **102** may be in electrical communication with internal conductive polymer trace **104**. Internal conductive polymer trace **104** may also be in electrical communication with a connector **108**. According to various embodiments, connector **108** may comprise a percutaneous or transcutaneous connector.

[0034] Insulating polymer **106** may comprise any flexible and/or elastomeric material that provides electrical insulation. According to various embodiments, insulating polymer **106** may comprise any combination of silicones, siloxanes, polydimethylsiloxane (PDMS), rubber materials, latex materials, polyesters, polypropylenes, polytetrafluoroethylenes (PTFE), Parylenes, liquid crystal polymers, polyimides, polyesterimides, polyamides, polybutyldienes (PBD), flexible copolymers, or any other polymer used for medical applications.

[0035] Internal conductive polymer trace **104** may comprise polymers that are intrinsically conductive (including polypyrrole, polyacetylene, polyaniline or poly[dioctylbithiophene] (PDOT)), or polymers that are doped with conductive particles. Any type of conductive particle may be utilized in connection with internal conductive polymer trace **104**, including any combination of: conductive forms of carbon (including graphite, carbon black, vitreous carbon, acetyl carbon, and carbon nantotubes); metal particles (e.g., particles of silver, gold, platinum, iridium, platinum-iridium alloys, titanium, tungsten, stainless steel); particles of other materials (e.g., nickel, ceramics, or carbon) that are coated with metals with higher contact conductivity (e.g., silver, gold, iridium, and platinum). Further, according to various embodiments, particles of shapes and morphologies may be utilized to better facilitate electrical contact between conductive particles in the polymer. According to various embodiments utilizing polymers doped with conductive particles, conductive particles may be pre-mixed into the polymer that is subsequently formed into an electrode, may be simultaneously mixed with a polymer and dispensed to form an electrode, or may be injected into a previously dispensed polymer layer with a carrier material (e.g., toluene or alcohol).

[0036] According to various embodiments, the design and manufacturing of the flexible devices may also include: use of polymers that are made conductive by filling with conductive particles, and in which the polymer shrinks to keep conductive particles in compression; polymers that shrink, expand, and/or soften after curing or when exposed to the body, to introduce stresses and/or shape changes into the material and/or other changes in mechanical compliance; substrate layers that are stretched during application of other layers, to keep the secondary layers in compression when the substrate is relaxed; other materials and fibers (including carbon or glass fibers) embedded into the structures to provide mechanical strain reinforcement and/or affect the mechanical properties of the structure in homogeneous and complex heterogeneous arrangements; coatings (such as polyethylene glycol) that stiffen the structure to aid insertion into tissues, that soften or dissolve away over time; formation of twisted-pair cables and/or cable ground planes within the structure; use of magnetic fields to manipulate conductive polymers with particles that respond to magnetic fields; plasma cleaning or other types of surface activation and adhesion promotion methods (such as silanes or other compounds) applied to polymer layers to enhance their bonding and reduce the chances of delamination.

[0037] FIG. **2** illustrates a top view of one embodiment of an electrode **200** according to the present disclosure. Electrode **200** includes a plurality of internal conductive polymer traces **204***a-d* surrounded by an insulating polymer **206**. A plurality of electrode interfaces **202***a-d* power in electrical communication with internal conductive polymer traces **204***a-d*, respectively. Although FIG. **2** illustrates an embodiment including four electrode interfaces **202***a-d* associated with four internal conductive polymer traces **204***a-d*, according to various embodiments, any number of electrode interfaces **202** may be utilized in connection with any number of internal conductive polymer traces **204**. Internal conductive polymer traces **204***a-d* are also in electrical communication with connector **208**.

[0038] Multiple types of conductive polymers can be used within the same structure, depending on factors such as cost, conductivity, biocompatibility, and manufacturability for different feature sizes. FIGS. **3**A-**3**C are cross sectional views that illustrate three embodiments of electrodes **300***a-c*, which may be utilized in various embodiments. FIG. **3**A illustrates electrode **300***a*, in which the same material forms both an internal conductive polymer trace **304***a* and an electrode interface **302***a*. An insulating polymer **306***a* is disposed around electrode interface **302***a* and internal conductive polymer trace **304***a*. FIG. **3**B illustrates electrode **300***b*, in which an internal conductive polymer trace **304***b* comprises one polymer, and an electrode interface **302***b* comprises a second polymer. An insulating polymer **306***b* is disposed around electrode interface **302***b* and internal conductive polymer trace **304***b*. FIG. **3**C illustrates electrode **300***c*, in which an electrode interface **302***c* is comprised of metal. Electrode interface **302***c* is in electrical communication with an internal conductive polymer trace **304***c*. An insulating polymer **306***c* is disposed around electrode interface **302***c* and internal conductive polymer trace **304***c*.

[0039] Electrode interfaces **302***a-c* may, in various embodiments, include geometrical and structural features for penetrating into tissues, hooking or providing mechanical fixation, or increasing the surface area of the electrode. Bonding between electrode interfaces **302***b-c* and internal conductive polymer traces **304***b-c* can be performed by the application of pressure to hold the conductive areas in contact, or by applying conductive adhesives or joining materials. These joints can also be further encapsulated with insulating polymers such as silicones to seal and/or structurally reinforce them.

[0040] FIG. **4**A illustrates a cross sectional view of one embodiment of an electrode **400** comprising two electrode interfaces **402** and **403**. Electrode interfaces **402** and **403** are in electrical communication by way of internal conductive polymer trace **404**. Electrode interfaces **402** and **403** and internal conductive polymer trace **404** are surrounded by insulating polymer **406**. Embodiments including multiple electrode interfaces, such as electrode **400**, may allow for the connection of other devices, including sensors, actuators, or other devices or assemblies to electrode **400**.

[0041] FIG. **4**B illustrates a cross sectional view of electrode **400** that also includes a connector **408** in electrical communication with electrode interface **403**. Various embodiments may also include connectors, including percutaneous connectors that pass out of the body. Such connectors may, in various embodiments, be encased in titanium, sintered titanium, stainless steel, polymer fabrics, or other materials to facilitate better biocompatibility and infection resistance for percutaneous applications. These connectors may also include screw holes, mounting flanges, rings, loops, fasteners, fabrics, or other structures for fixing the connector to tissue, skin, and/or bone.

[0042] FIG. **5** illustrates a cross sectional view of one embodiment of an electrode **500** that includes a printed circuit board **510** and various electronic components **512**, **514**, and **516**. Electrode **500** also includes an electrode interface **502** in electrical communication with an internal conductive polymer trace **504**. An insulating polymer **506** may be disposed around internal conductive polymer trace **504**, printed circuit board **510**, and various electronic components **512**, **514**, and **516**. According to various embodiments, a variety of electronic components may be integrated with a printed circuit board **510**. For example, such electronic components may include amplifiers, stimulators, data transmission circuitry, light emitting diodes and/or photo sensing diodes, data processing circuitry, batteries, and/or circuitry for receiving power from an external power source.

[0043] FIG. **6** illustrates a side view of an electrode **600** that includes a printed circuit board **610**, which is coupled to a transceiver **620**, and an application specific integrated circuit **618**. An insulating polymer **606** may be disposed around an internal conductive polymer trace **604**, printed circuit board **610**, application specific integrated circuit **618**, and transceiver **620**. Wire leads **622** may electrically connect a printed circuit board **610** to application specific integrated circuit **618**.

[0044] Certain embodiments may utilize infrared data transmission in order to transmit data collected by electrode **600** to an external data receiver (not shown). Such embodiments may comprise materials with optical properties selected for selective transparency to certain optical or infrared signals so that the device can use these wavelengths for telemetry. For example, insulating polymer **606** may be selected so as to provide minimal attenuation to an infrared data signal generated by transceiver **620**.

[0045] FIG. **7** illustrates a cross sectional view of one embodiment of a multi-layer electrode **700**. Electrode **700** comprises a plurality of internal conductive polymer traces **706***a-d* separated by a plurality of insulating layers **704***a-d*. Electrode **700** includes conductive vias **722**, **724**, **726**, **728**, and **730** that connect between internal conductive polymer traces **706***a-d* and/or the surface of electrode **700**. Electrode **700** includes through via **722**, which passes through all conductive layers to the surface of electrode **700**; blind vias **726**, **728**, and **730**, which pass from the surface of electrode **700** to some conductive layers; and buried vias **724** and **725**, which are completely embedded within electrode **700**.

[0046] FIG. **8** illustrates a cross-sectional view of one embodiment of a multi-layer electrode **800** and a connector **808**. Connector **808** may comprise a plurality of penetrating electrodes **809**, which although not shown in a grid configuration in FIG. **8**, may be arranged in a grid configuration. A plurality of internal conductive polymer traces **806***a-h* may be in electrical communication with the plurality of penetrating electrodes **809**. A plurality of insulating polymer layers **804***a-g* may be disposed between the plurality of internal conductive polymer traces **806***a-h*. Accordingly, electrical signals may be confined to internal conductive polymer traces **806**, which may in turn be transmitted to an external connector.

[0047] FIG. **9** illustrates one embodiment of an electrode array **900**. Electrode array **900** may include an electrode grid **930** that includes a plurality of individual electrodes. Although FIG. **9** illustrates a square electrode array **900**, having eight electrodes on each side, any number of configurations may also be utilized in alternative embodiments. Each electrode in electrode grid **930** may be in electrical communication with an internal conductive polymer trace (not shown). A plurality of internal conductive polymer traces may be grouped in one of a plurality of lead wires **932**. Lead wires **932** may also be an electrical communication with the plurality of leads **934**. Electrical signals received by each of the plurality of electrodes in electrode grid **930** may be conducted to one of the plurality of leads **934**.

[0048] In one embodiment, electrode array **900** may be utilized for intracranial epilepsy monitoring. Some of the patients suffering from epilepsy that do not respond adequately to drug therapies are candidates for surgical treatment to resect or disrupt seizure foci. In preparation for such a surgery, an electrode array, such as electrode array **900**, may be implanted over the focal areas for up to 30 days to accurately localize the seizure foci and minimize damage to surrounding cortical areas. According to various embodiments, electrode arrays may range in size from large grids (e.g., 9 cm×9 cm) to small strips of electrodes (e.g., 1 cm×6 cm). Additional embodiments include high density microECoG electrodes which may be present in conjunction with larger conventional cortical mapping electrodes. After implantation, lead wires **932** may connect the implanted electrode array to a neural instrumentation system (not shown), which records information regarding electrical conditions detected by the plurality of electrodes in electrode grid **930**. Lead wires **932** may pass through the scalp of the patient. The use of percutaneous lead wires **932** may expose patients to a risk of infection.

[0049] FIG. **10**A illustrates a block diagram on one embodiment of an implantable system **1000**A that includes an electrode grid **1030** and a signal processing unit **1034**. According to various embodiments, system **1000**A may be utilized in a variety of applications, including deep brain stimulation and intracranial monitoring. Electrode grid **1030** is in electrical communication with signal processing unit **1034** and may exchange data with signal processing unit **1034**. Data may be received by signal processing unit **1034** and recorded and/or data may be transmitted from signal processing unit **1032** to electrode grid **1030** in order to provide electrical stimulation. Data sent to or received from electrode grid **1034** may be conditioned by signal conditioner **1034**. Such conditioning may include, in various embodiments, amplification, analog to digital conversion (e.g., conversion of analog data recorded by electrode grid **1030** to digital data), and digital to analog conversion (e.g., conversion of digital data from signal processing unit **1032** to analog data). A microprocessor unit ("MCU") **1036** may be in electrical communication with signal conditioner **1034**, and may record, analyze, and/or generate data signals received from work to be sent to electrode grid **1030**. A battery **1037** may provide power to MCU **1036** and signal conditioner **1034**.

[0050] FIG. **10**B illustrates a block diagram of one embodiment of a wireless system **1000**B that includes an electrode grid **1030**, a telemetry module **1031**, and a receiver module **1047**. In various embodiments, system **1000** may be utilized for intracranial epilepsy monitoring. Telemetry module **1031** and receiver module **1047** may be configured to exchange data and power wirelessly across the patient's skin **1051**. In contrast to the embodiment illustrated in FIG. **9**, system **1000** does not include percutaneous lead wires, and accordingly, use of system **1000** may reduce the risk of infection to a patient associated with percutaneous lead wires.

[0051] The electrode grid **1030** is in electrical communication with a telemetry module **1031**. Telemetry module **1031** includes an amplifier **1033**, which receives and amplifies signals collected by each of the plurality of individual electrodes. Amplifier **1033**, in one particular embodiment, may comprise analog amplifier components, such as those available from Intan, Technologies, LLC of Salt Lake City, Utah. Amplified signals generated by amplifier **1033** may be converted to digital signals by ND converter **1035**. According to various embodiments, A/D converter **1035** may also comprise a multiplexer configured to generate a digital output from a plurality of analog inputs.

[0052] A microprocessor unit (MCU) **1036** may receive and process the output of A/D converter **1035**. According to various embodiments, MCU **1036** may comprise a commercially available microcontroller, or may comprise an application specific integrated circuit. In one particular embodiment, MCU **1036** may be embodied as a microprocessor in the TI MSP430 product family available from Texas Instruments of Dallas, Tex. In various embodiments, MCU **1036** may comprise both one-time programmable memory for core software storage and EEPROM memory for device serialization information and special feature programming.

[0053] MCU **1036** may prepare data to be transmitted by a data transceiver **1048**. In one embodiment data transceiver **1048** may comprise an infrared transceiver, and infrared data may be transmitted via a Return to Zero (RZ) scheme with adaptive thresholding. If further DC balance is needed, 86106 or Manchester codes may be utilized. All data may include error-checking codes. In an alternative embodiment, data transceiver **1048** may comprise a radio frequency data transmission system.

[0054] System **1000** may also include a receiver module **1047**, which may be separated from telemetry module **1031** by the skin **1051** of the patient. Receiver module **1047** may comprise a data transceiver **1042**. Receiver module **1047** and telemetry module **1031** may exchange data across the patient's skin using a bidirectional communications channel. Data received from telemetry module **1031** may include recorded data from electrode grid **1030**, while data transmitted to telemetry module **1031** may comprise data to provide stimulation using electrode grid **1030**.

[0055] Receiver module **1042** may further comprise a power transmitter **1046**, which is coupled to a coil **1044**. Coil **1044** may be inductively coupled to coil **1040**. Power transferred to coil **1040** may be provided to a circuit for power recovery **1037**, which may in turn provide power to A/D converter **1035** and amplifier **1033**. According to various embodiments, inductive coupling between coil **1044** and coil **1040** may also be used to transmit data. Circuitry for power recovery circuit **1037** may comprise a resonant full-wave rectifier (not shown) and filter with a low drop-out linear regulator (not shown). Circuitry for power recovery **1037** may also include the ability to measure the over-voltage of the rectifier and pass the signal to MCU **1036** for sampling. This signal passed from circuitry for power recovery **1037** to MCU **1036** may be transmitted to receiver module **1047**, and may allow receiver module **1047** to optimize transmitted power to minimize thermal dissipation in circuitry for power recovery **1037**. This signal may also be used by the receiver module **1047** to sense coupling strength and alignment of receiver module **1047** relative to telemetry module **1031**.

[0056] FIG. **11** illustrates one embodiment of a system **1100** that comprises an electrode grid **1130**, a telemetry module **1131**, and a receiver module **1147**. In the illustrated embodiment, electrode grid **1130** and telemetry module **1131** are implanted in a patient. Electrode grid **1130** may be in electrical communication with telemetry module **1131**, which may include wireless data and power transmission systems.

[0057] Receiver module **1147** may inductively provide power via a coil and may receive a data signal transmitted by telemetry module **1131**. The inductive power transfer between receiver module **1147** and telemetry module **1131** may be accomplished using Class E architecture. In various embodiments, system **1100** allows for the adjustment of the carrier used by the inductive power transfer system and for the adjustment of the transmitted power. In one embodiment, an infrared detector (not shown) may be located in the center of receiver module **1147**. An infrared-transparent window may be aligned over the infrared detector to provide a light path from an infrared transmitter (not shown) emitter in telemetry module **1131**. In various embodiments, a coil for inductive power transfer may be constructed by winding Litz wire around a soft substructure, or the RF coil may be integrated into a flexible receiver printed circuit board. Receiver module **1147** may be fixed to the body by adhesives, compression bands, bandages, or any other methods.

[0058] In certain embodiments, an alignment indicator **1152** may be disposed on the receiver module **1147**. Alignment indicator **1152** may provide an indication of the relative strength of the telemetry coupling between receiver module **1147** and telemetry module **1131**. Alignment indicator **1152** may allow a clinician to find the optimal placement for the receiver module **1147**. Certain embodiments may be able to tolerate alignment errors up to 1 cm from center.

[0059] Receiver module **1147** may be coupled to a power source and a neural instrumentation system by way of wire **1154**. Certain embodiments may feature an interface adapter for connecting the External Transceiver to the Grapevine™ neural instrumentation system, which is available from Ripple, LLC of Salt Lake City, Utah. The Grapevine™ neural instrumentation system is available in both bedside and wearable configurations. The neural instrumentation system may provide for recording of data received by receiver module **1147**.

[0060] FIG. **12** illustrates an embodiment of a system **1200** that comprises a stimulating electrode array **1220**, stimulation leads **1221**, a recording electrode array **1230**, recording leads **1231**, and an electronics module **1240**. In the illustrated embodiment, all components are implanted subcutaneously in a patient. The stimulation electrode array **1220** and stimulation leads **1221** may consist of a contiguous structure of layered conductive polymer and insulating substrate materials. Similarly the recording electrode array **1230** and recording leads **1231** may also consist of a contiguous structure of layered conductive polymer and insulating substrate materials. The stimulation **1220** and recording **1230** arrays are electrically connected to the electronics module **1240** via their respective leads **1221** and **1231**. The electronics module **1240** communicates with an external module (not shown) in a manner similar to the telemetry protocol outlined between components **1131** and **1147** shown in FIG. **11**. The stimulation lead **1221** may also include a mechanical feature **1222** designed to provide additional stress relief around the lateral canthus area to mitigate flexion forces. The stimulation electrode array **1220** may also have a plurality of electrodes **1223** designed to permit the efficient conduction of exogenous charge to paretic and paralytic facial musculature.

[0061] This embodiment may be used as a blink prosthesis to restore eyelid function to patients with unilateral facial paralysis. The exogenous electrical charge it injects may functionally activate paretic or paralytic muscles to effect closure of the lid margin. The prosthesis records EMG with an array **1230** implanted in the contralateral neurologically intact hemiface to detect the onset of blink, and uses this detected signal to time stimulation via the implanted electrode array **1220** in the nonfunctioning eyelid to create a synchronous bilateral blink. Stimulation may also provide a trophic effect to permit more complete and more rapid recovery in facial paralysis patients.

[0062] FIG. **13** illustrates one embodiment of a method **1300** for manufacturing an electrode array and an associated telemetry module. Also shown in FIG. **13** is an illustration of each step of method **1300**. In the illustrated embodiment, the electrode array comprises medical grade polymers, with insulating polymer forming the main body and a conductive, particle-filled polymer of similar formulation providing the conductive traces and active electrode sites. According to various embodiments, the electrode array may be formed with blunt and/or soft edges that allow pushing into spaces while minimizing the changes of cutting and/or rupturing vasculature and other sensitive tissues (for example, minimizing chances of cutting blood vessels within subdural and epidural spaces in the head). The electrode array and associated telemetry module may be created in a layer-by-layer buildup of materials, with the conductive traces disposed between insulating layers. Each layer of the device may be deposited in a variety of ways, such as by a programmable XYZ robotic dispensing system.

[0063] At **1302**, a mold may be prepared. The mold may take on a variety of shapes, as dictated by the particular application for which the device is to be utilized. The mold may be fabricated from a variety of materials, such as fluoropolymers. Alternatively, a flat plate may be used instead of a mold. The base layer of insulating polymer may be dispensed in the desired pattern and each subsequent layer following a similar pattern. Surface tension of the dispensed material may be sufficient to produce a fabricated device in a desired shape. Further, the shape of an electrode array may be adjusted at the time of implantation. For example, a surgeon may trim the electrode array in order to suit a particular application.

[0064] A base layer of insulating polymer (e.g., silicone) may be dispensed into the prepared mold, at **1304**. A printed circuit board (PCB) with electronic components may be pressed into a well in the mold using an alignment fixture, level with the surrounding substrate layer at **1306**. Further, at **1306**, conductive polymer traces and electrode interfaces may be printed. At **1308**, a second layer of insulating polymer may be printed. The second layer of insulating polymer may be applied over the signal traces and around the electrode interfaces. Partial curing and plasma surface treatments may be used between deposition steps to enhance bonding.

[0065] The following criteria may be utilized in evaluating suitable materials for use in connection with method **1300**: pre-cure viscosity; surface tension for dispensing without the aid of a mold; curing properties; post-cure rigidity; adhesion between layers; ability to act as a carrier for the conductive particles.

[0066] Commercially available medical grade conductive silicones may be utilized in connection with 1300, and are available from NuSil in Carpinteria, Calif., and Creative Materials in Tyngsboro, Mass.

[0067] It will be obvious to those having skill in the art that many changes may be made to the details of the above-described embodiments without departing from the underlying principles of the invention. The scope of the present invention should, therefore, be determined only by the following claims.

1. A method of forming a flexible electrode, comprising:

depositing a first layer along a length of the flexible electrode, the first layer comprising a first polymer, the first polymer comprising an insulating polymer;

depositing a second layer on the first layer and along at least a portion of the length of the flexible electrode, the second layer comprising a second polymer and a conductive trace, the conductive trace comprising a plurality of distinct conductive particles, at least a plurality of the distinct conductive particles being separated by the second polymer;

forming an electrode interface in electrical communication with the conductive polymer trace; and

depositing a third layer, the third layer comprising the insulating polymer, such that the first layer and the third layer encompass the conductive trace along at least a portion of the length.

2. The method of claim **1**, wherein each of the first layer, the second layer, and the third layer are directly deposited.

3. The method of claim **1**, wherein each of the first layer, the second layer, and the third layer are deposited using an ink jet process.

4. The method of claim **1**, wherein each of the first layer, the second layer, and the third layer are deposited using a screen printing process.

5. The method of claim **1**, wherein each of the first layer, the second layer, and the third layer comprise a bio stable polymer.

6. The method of claim **1**, wherein the plurality of distinct conductive particles comprises at least one of: conductive forms of carbon, metal particles, and composite materials comprising an interior particle coated with metal.

7. The method of claim **1**, wherein the conductive trace comprises a plurality of distinct conductive micro-particles.

8. The method of claim **1**, wherein the second layer exhibits a compressive force upon the plurality of distinct conductive particles.

9. The method of claim **1**, wherein the second polymer comprises an intrinsically conductive polymer.

10. The method of claim **9**, wherein the intrinsically conductive polymer comprises one of polypyrrole, polyacetylene, polyaniline, and polydioctyl-bithiophene.

11. The method of claim **1**, further comprising associating a plurality of electrical components with the conductive trace.

12. The method of claim **11**, further comprising:

providing a printed circuit board to interconnect the plurality of electrical components and the conductive trace; and

depositing the first layer and the third layer encompass the printed circuit board.

13. The method of claim **1**, further comprising:

depositing a fourth layer, the fourth layer comprising a conductive trace, wherein the third layer at least partially insulates the third layer from the fourth layer along at least a portion of the length.

14. The method of claim **1**, further comprising depositing at least one of the first layer, the second layer, and the third layer in a mold.

15. The method of claim **1**, further comprising curing at least one of the first layer, the second layer, and the third layer.

16. The method of claim **1**, further comprising:

generating an electrical signal using a stimulator in electrical communication with the conductive trace to be transmitted to the electrode interface.

17. A method of forming a flexible electrode, comprising:

depositing a first layer comprising an insulating polymer along a length of the flexible electrode;

depositing at least a second layer on the insulating polymer, the second layer comprising a second polymer, the second layer forming a plurality of conductive traces, each of the plurality of conductive traces comprising a plurality of distinct conductive particles, and each of the conductive traces being insulated from each of the other conductive traces by the insulating polymer;

forming a plurality of electrode interfaces, each of the plurality of electrode interfaces being in electrical communication with at least one of the plurality of conductive traces; and

depositing a third layer comprising the insulating polymer over the second layer, the third layer comprising the insulating polymer, such that the first layer and the third layer encompass the plurality of conductive traces along at least a portion of the length.

18. The method of claim **17**, wherein at least one of the first layer, the second layer, and the third layer are formed using one of a direct deposition process, an ink jet process, a screen printing process.

19. The method of claim **17**, further comprising depositing at least one of the first layer, the second layer, and the third layer in a mold.

20. The method of claim **17**, wherein the plurality of electrode interfaces are disposed in a grid pattern.

* * * * *

专利名称(译)	用于柔性电极的系统和方法		
公开(公告)号	US20150264816A1	公开(公告)日	2015-09-17
申请号	US14/729027	申请日	2015-06-02
[标]申请(专利权)人(译)	波纹		
申请(专利权)人(译)	纹波LLC		
当前申请(专利权)人(译)	纹波LLC		
[标]发明人	ASKIN III ROBERT E HIATT SCOTT D GUILLORY KENNETH S MCDONNALL DANIEL SMITH CHRISTOPHER F		
发明人	ASKIN, III, ROBERT E. HIATT, SCOTT D. GUILLORY, KENNETH S. MCDONNALL, DANIEL SMITH, CHRISTOPHER F.		
IPC分类号	H05K3/12 A61N1/04 A61B5/00 A61B5/0492 A61B5/04		
CPC分类号	H05K3/125 H05K3/1216 A61B5/0492 H05K2203/0759 A61B5/685 A61N1/04 A61B5/04001 A61B5/0408 A61B5/0478 A61N1/05		
优先权	61/245276 2009-09-23 US		
外部链接	Espacenet USPTO		

摘要(译)

本文公开了用于制造和使用可以是柔性和/或可拉伸的电极的系统和方法，以及可以在体外和/或植入体内使用的互连结构。根据本文公开的各种实施方案的电极可以通过沉积图案化的绝缘和导电聚合物层来制备，以形成多层电路。结构中的导电材料和层可以暴露在结构的表面上以用作电极。多个电极可以形成为电极阵列。在各种实施例中，电极阵列可以与遥测模块相关联，遥测模块被配置为将由电极阵列收集的数据无线传输到接收器模块。