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(54) **Title:** PERCUTANEOUS DEPLOYABLE ELECTRODE ARRAY

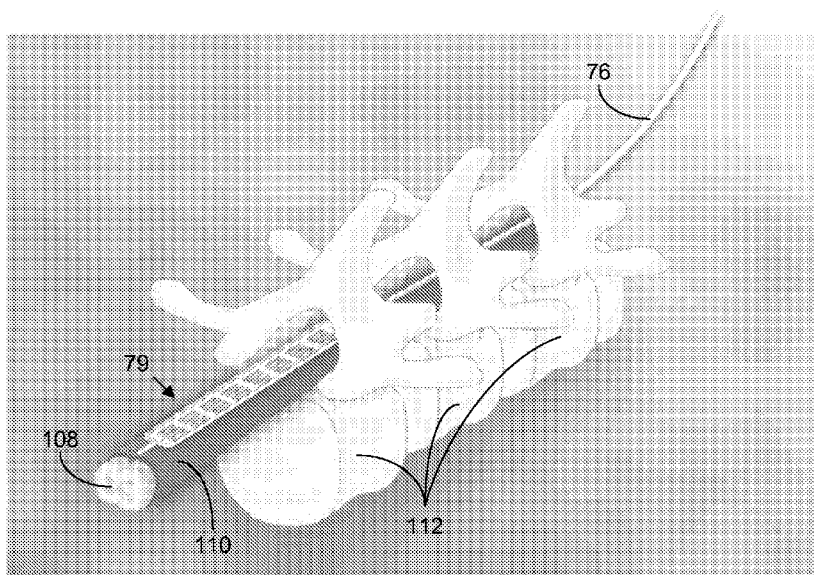


FIG. 37

(57) **Abstract:** A percutaneous stimulation device includes (a) a plurality of electrode panels joined via hinges, wherein each electrode panel includes a substrate and an electrode mounted on the substrate, and wherein the substrate is a laminate comprising a flexible layer joined with a rigid layer on each side of the flexible layer; (b) an elongate insertion shaft to or within which the plurality of electrode panels are mounted; (c) electrically conductive wiring coupled with each electrode and extending along the insertion shaft; and (d) an actuation mechanism coupled with electrode panels and configured to extend and retract the electrode panels when actuated.





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PERCUTANEOUS DEPLOYABLE ELECTRODE ARRAY

BACKGROUND

Micron-scale device fabrication is dominated by micro-electro-mechanical structures (MEMS) technology, which typically involves a single planar substrate and serial processes. Meanwhile, centimeter-scale manufacturing is covered by a multitude of conventional machining processes. Manufacturing at the millimeter scale, however, is plagued with fabrication and assembly issues that greatly impact the cost and performance of micro-robots and other functional mechanical devices at this scale.

Various pop-up laminate structures are described in priority US Application No. 61/862,066, filed 4 August 2013, which is incorporated by reference herein in its entirety.

SUMMARY

Percutaneous stimulation devices including deployable electrode arrays and methods for their fabrication are described herein. Various embodiments of the structures and methods may include some or all of the elements, features and steps described below.

A percutaneous stimulation device includes the following: (a) a plurality of electrode panels joined via hinges, wherein each electrode panel includes a substrate and an electrode mounted on the substrate, and wherein the substrate is a laminate comprising a flexible layer joined with a rigid layer on each side of the flexible layer; (b) an elongate insertion shaft to or within which the plurality of electrode panels are mounted; (c) electrically conductive wiring coupled with each electrode and extending along the insertion shaft; and (d) an actuation mechanism coupled with electrode panels and configured to extend and retract the electrode panels when actuated.

In additional embodiments, the electrically conductive wiring, through which electrical current is delivered to the electrodes, can be incorporated as a flexible circuit extending through the hinges, which flex when the electrode panels extend and collapse. The actuation device can include a push rod that serves as the elongate insertion shaft and a pull wire extendably and retractably mounted within the push rod. The pull wire, push rod, and electrode panels can also be coupled with the

electrode panels and configured such that retraction of the pull wire into the push rod extends the electrode panels in a deployed configuration and extension of the pull wire out of the push rod re-collapses the electrode panels. In other embodiments, the panels are collapsed using another type of actuator or via a drag force applied to the panels by the elongate insertion member, the tissue of the organism, and/or an introducer needle through which the panels entered the organism.

The hinges can be incorporated into an extendable and collapsible frame to which the electrode panels are mounted. In additional embodiments, a strain gauge can be included in the array and configured to measure external force acting against the electrode array.

The stimulation device can also include a steering finger extending from a distal end of the electrode panels and configured to bend in opposite directions to steer the stimulation device when inserted into a human body. In particular embodiments, at least one steering wire is coupled with the steering finger to bend the steering finger when pulled or released. In additional embodiments, the steering device comprises a magnetic material that can be positioned or moved outside the body to steer the stimulation device into position. In additional embodiments, the stimulation device can also include springs incorporated into the structure of the electrode panels to allow the electrode panels to flex during insertion and extension. In still more embodiments, the steering mechanism includes (a) a pre-curved stylet insertable through or into a distal end of the shaft or electrode panels or (b) a hinged wrist mechanism in the shaft configured with an actuator to bend or pivot the hinged wrist.

A method for performing neurostimulation inside a body of an organism can be carried out using a stimulation device that comprises an elongate insertion shaft and a plurality of electrode panels, wherein each electrode panel includes a laminate comprising a flexible layer joined on each side to a rigid layer and electrode panels mounted to the laminate and is mounted to or within the elongate insertion shaft. The method includes the following: (a) inserting the collapsed electrode panels and the elongate insertion shaft through the tissue of the organism; then (b) actuating electrode panels inside the body of the organism to extend the electrode panels into an extended paddle array; (c) establishing contact between the extended paddle array and nerve cells inside the body of the organism; (d) delivering electric current or

voltage to the electrodes in the paddle array to stimulate the nerve cells; then, if desired, (e) actuating the electrode panels to collapse the panels into a compact form (and optionally reposition the panels inside the body); and then (f) sliding the collapsed electrode panels back through the skin and out of the body, which can be performed percutaneously.

The stimulation device can also include a magnetic material, and the stimulation device can be steered through the body by moving a steering magnet outside the body. In additional embodiments, contact between the electrode array and organs or tissues in the body can be sensed via a strain gauge incorporated into the electrode array. In further embodiments, the electrodes stimulate nerve cells in the spinal cord, brain, or other portion of the nervous system; and the electrode panels can be extended and collapsed multiple times after insertion of the stimulation device into the organism.

These apparatus and methods can be fabricated using three-dimensional laminate construction techniques, wherein three-dimensional structure can be formed by stacking a plurality of patterned layers and bonding the plurality of patterned layers (*i.e.*, layers having a patterned shape/features formed, *e.g.*, by machining) at selected locations to form a laminate structure with inter-layer bonds. The laminate structure can then be expanded into an expanded three-dimensional configuration by selectively distorting at least one of the layers to produce gaps between layers while maintaining at least some of the inter-layer bonds.

The layers in the structure can include at least one rigid layer and at least one flexible layer, wherein the rigid layer includes a plurality of rigid segments, and the flexible layer can extend between the rigid segments to serve as a joint. The flexible layers are substantially less rigid than the rigid layers, wherein the rigid layer can have a rigidity that is at least twice as great as or an order of magnitude greater than (*e.g.*, greater than 10x or greater than 100x) the rigidity of the flexible layer; likewise, the flexible layer can have at least 10 times or at least 100 times the flexibility of the rigid layers. The layers can then be stacked and bonded at selected locations to form a laminate structure with inter-layer bonds, and the laminate structure can be distorted or flexed to produce an expanded three-dimensional structure, wherein the layers are joined at the selected bonding locations and separated at other locations.

Methods and structures described herein can be used, for example, across and beyond the entire millimeter-scale manufacturing process (*e.g.*, for apparatus with dimensions from 100 μm to 100 mm), and they enable mass production of precisely fabricated mechanisms, machines, and autonomous robots at this scale. When compared to traditional MEMS, the methods described herein are extremely versatile with respect to the materials that can be used. In addition, traditional MEMS are largely limited to bulk addition of materials, whereas the methods described herein can be used not only to add precisely patterned layers, but also full sub-components, such as integrated circuits, flex circuits, actuators, batteries, *etc.* The thermal requirements of the multi-layer, super-planar structures described herein can also be much lower, and the fabrication-equipment costs can be much lower, as well. Further still, processing steps in these methods on the various layers can be performed simultaneously in parallel, while much of MEMS processing takes place sequentially in series, resulting in a faster process compared to traditional MEMS.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1a-d illustrate formation of folding joints.

FIG. 2 is a schematic illustration of a discrete strain gauge element in a complicated pattern.

FIGS. 3 and 4 illustrate a pop-up deployable electrode array emerging from a needle (FIG. 3) and fully deployed (FIG. 4).

FIGS. 5-8 are photographic images of custom flex-circuits used as a compliant flexure hinge layer to allow for internal wiring for electrical components; the etched flex circuit layer with LED's attached is shown in FIG. 5; the finished (laminated and released) devices with internal traces and rigid mechanical structure are shown in FIG. 6, while the device with an LED activated is shown in FIGS. 7 and 8.

FIGS. 9-14 show a deployable electrode array with a decoupled diamond-shaped unfolding mechanism.

FIGS. 15-19 show a deployable electrode array with a 2-x-2 sliding four-bar unfolding mechanism.

FIGS. 20-24 show a deployable electrode array with an accordion unfolding mechanism.

FIGS. 25-28 show the unfolding of an electrode array via activation of a push rod and pull wire.

FIG. 29 shows a sequence of added layers to form an embodiment of an electrode panel.

FIG. 30 shows an embodiment of an entire pop-up spinal cord stimulator (SCS) system, including the electrode array, the shaft and sheath, the handle interface, and electrical wiring.

FIGS. 31 and 32 show an embodiment of the shaft and sheath assembly with the electrode array extending from the shaft and retractable into the sheath.

FIG. 33 shows an embodiment of a sectional view of a multi-lumen shaft extrusion design.

FIGS. 34 and 35 respectively show an embodiment of the electrode array in collapsed and expanded configurations with the areas marked where adhesives and biocompatible coatings can be applied.

FIGS. 36 and 37 provide conceptual images of an embodiment of the deployable electrode array opening over a spinal cord.

FIGS. 38-40 show three designs for the deployable electrode array structure.

FIGS. 41 and 42 show an embodiment of the electrode array collapsed inside a tube; the appendage at the front of the device is a steering figure used to navigate up the spinal canal epidural space.

FIGS. 43 and 44 show embedded springs distributed throughout the structure of the deployable array, allowing the array to be flexible and to move inside of the body during and after implantation.

FIGS. 45 and 46 are images of flexible electrical wiring and traces embedded in the deployable electrode structure across hinges and through mechanical components to allow the electrodes to receive signals without the need for external electrical wiring.

FIG. 47 is a photographic image of a flex circuit layer upon which the electrodes will be mounted to form an electrode panel (top) and a magnified view of the encircled section, provided below, showing the electrical traces in greater detail.

In the accompanying drawings, like reference characters refer to the same or similar parts throughout the different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating particular principles, discussed below.

DETAILED DESCRIPTION

The foregoing and other features and advantages of various aspects of the invention(s) will be apparent from the following, more-particular description of various concepts and specific embodiments within the broader bounds of the

invention(s). Various aspects of the subject matter introduced above and discussed in greater detail below may be implemented in any of numerous ways, as the subject matter is not limited to any particular manner of implementation. Examples of specific implementations and applications are provided primarily for illustrative purposes.

Unless otherwise defined, used or characterized herein, terms that are used herein (including technical and scientific terms) are to be interpreted as having a meaning that is consistent with their accepted meaning in the context of the relevant art and are not to be interpreted in an idealized or overly formal sense unless expressly so defined herein. For example, if a particular composition is referenced, the composition may be substantially, though not perfectly pure, as practical and imperfect realities may apply; *e.g.*, the potential presence of at least trace impurities (*e.g.*, at less than 1 or 2%) can be understood as being within the scope of the description; likewise, if a particular shape is referenced, the shape is intended to include imperfect variations from ideal shapes, *e.g.*, due to manufacturing tolerances.

Percentages or concentrations expressed herein can represent either by weight or by volume.

Although the terms, first, second, third, *etc.*, may be used herein to describe various elements, these elements are not to be limited by these terms. These terms are simply used to distinguish one element from another. Thus, a first element, discussed below, could be termed a second element without departing from the teachings of the exemplary embodiments.

Spatially relative terms, such as “above,” “below,” “left,” “right,” “in front,” “behind,” and the like, may be used herein for ease of description to describe the relationship of one element to another element, as illustrated in the figures. It will be understood that the spatially relative terms, as well as the illustrated configurations, are intended to encompass different orientations of the apparatus in use or operation in addition to the orientations described herein and depicted in the figures. For example, if the apparatus in the figures is turned over, elements described as “below”

or “beneath” other elements or features would then be oriented “above” the other elements or features. Thus, the exemplary term, “above,” may encompass both an orientation of above and below. The apparatus may be otherwise oriented (*e.g.*, rotated 90 degrees or at other orientations) and the spatially relative descriptors used
5 herein interpreted accordingly.

Further still, in this disclosure, when an element is referred to as being “on,” “connected to,” “coupled to,” “in contact with,” *etc.*, another element, it may be directly on, connected to, coupled to, or in contact with the other element or intervening elements may be present unless otherwise specified.

10 The terminology used herein is for the purpose of describing particular embodiments and is not intended to be limiting of exemplary embodiments. As used herein, singular forms, such as “a” and “an,” are intended to include the plural forms as well, unless the context indicates otherwise. Additionally, the terms, “includes,” “including,” “comprises” and “comprising,” specify the presence of the stated
15 elements or steps but do not preclude the presence or addition of one or more other elements or steps.

The apparatus can be a multi-layer, super-planar structure. The planar structure includes a layer or plane that can be distorted, flexed or folded (these terms may be used interchangeably herein). An embodiment of this structure can be
20 achieved, for example, by forming a five-layer composite with the following sequence of joined layers: rigid layer, adhesive layer, flexible layer, adhesive layer, and rigid layer. Alternatively, a thinner composite can be formed from a stacking of just a rigid layer, an adhesive layer, and a flexible layer, though this structure is not symmetric. The rigid layers are machined to have gaps that correspond to fold lines, while the
25 flexible layer is continuous, thereby providing a joint where the flexible layer extends across the gaps machined from the rigid layers. The dimensions and feature sizes of the various apparatus described herein can be, *e.g.*, 0.1 mm to 5 cm or, in more particular embodiments, 0.5 mm to 2 cm. Moreover, the devices described, below, can be mass-fabricated by forming a plurality of the laminate structures across a
30 large-area multi-layer laminate from which the individual devices can then be popped by, *e.g.*, severing sacrificial bridges that joint the devices to the rest of the large-area laminate.

Characterization of the structure as being “super-planar” means taking multiple planar layers and selectively connecting them. An analogy here can be drawn to circuit boards, where electrical vias connect circuits on different layers. Here, in contrast, the structure is made with “mechanical vias.” By stacking multiple
5 planar layers, the range of achievable devices is greatly expanded. The super-planar structure also enables features and components to be packed into the structure that would not fit if the device could only be made out of one planar sheet.

Advantageously, super-planar structures with mechanisms that operate normal to the plane can now be made with these techniques. In practice, forming Sarrus linkages
10 between planar layers is an advantageous strategy for designing an assembly mechanism/scaffold. Other mechanisms can attach to the Sarrus links to effect component rotations.

The fabrication of a multi-layer expandable structure is shown in FIG. 1 and can include the formation of folding joints 21, wherein (a) features are first micro-
15 machined 101 in individual material layers, and the resulting chips 13 are removed; (b) during lamination, dowel pins 20 align material layers while heat and pressure are applied; here, two rigid carbon-fiber layers 12 bonded to a flexible polyimide-film layer 16 with adhesive 14 form a five-layer laminate 15 referred to as a “linkage sub-laminate”; (c) micro-machining cuts mechanical bridges 17 that constrain individual
20 elements, allowing the creation of articulated structures; and (d) a completed folding joint 21 is formed and removed from the surrounding scaffold 19. The castellated pattern allows this flexure joint 21 to approximate an ideal revolute joint. Polyimide can have a flexural modulus of about 20 GPa; other materials (*e.g.*, polymers) with a flexural modulus with a flexibility within about, *e.g.*, 25%, 50% or 75% of this value
25 (higher or lower) can alternatively be used for the flexible layer. The rigid layers can be, *e.g.*, less than half as flexible (*i.e.*, more than twice as stiff as the flexible layer).

Machining of Layers

In one embodiment, the multi-layer structure is formed from a multitude of thin (1.5- μm to about 150- μm thick) layers of various materials. The layers can be
30 laser micro-machined (*e.g.*, by a diode-pumped solid-state pulsed laser) with desired features, usually cutting all the way through the layer to create individual planar structures. Each layer is micro-machined so as to leave a unified (contiguous) part with robust connections to surrounding alignment holes. The micro-machining can

produce complex in-plane features with dimensions as small as 10 μm . In particular embodiments, many copies of the devices are formed on a laminate panel, and the machining process removes sufficient material to form each part and part feature, while leaving thin tabs to connect each device to the surrounding laminate; in this regard, the arrangement of devices in a laminate panel can be similar to that of a batch of circuit boards attached to a surrounding laminate structure by thin, easily breakable tabs.

In this case, the tabs (bridges) 17 (shown in stages a-c of FIG. 1) connecting the devices to the surrounding laminate will be removed after lamination or assembly.

Layers of metal, composite, polymer, *etc.*, are machined or formed by virtually any method; and virtually any material may be used. Exemplary machining methods include laser cutting from sheet material, photo-chemical etching, punching, electroforming, electric discharge machining, *etc.*--basically any method that has appropriate resolution and compatibility with the desired material. Machined layers may then be subjected to additional processes, such as cleaning/etching to remove machining debris, plating (*e.g.*, plating fluxed copper on a layer to facilitate adhesion of solder thereto), preparation for bonding, annealing, *etc.* The unified nature of each layer makes handling and post-processing easy. Advantageously, each layer can be a different material and can be machined and treated differently from each of the other layers.

Each layer can also advantageously be formed of a material that is sufficiently rigid, strong, and tough to allow holes 22 for alignment pins 20 and other features to be machined into the layer, to facilitate easy handling, and to not distort when placed into the layup and when restrained by alignment pins 30. In other embodiments, layers that do not have the structural stability to support alignment features can nevertheless be used by attaching such layers, in bulk form, to a rigid frame that meets these objectives without introducing enough additional thickness to disturb the other layers or parts in the laminate.

In particular examples, a very thin polymer film (*e.g.*, 2-10 micrometers thick) is included among the layers. Due to its thinness and insulating qualities, the thin polymer film is prone to wrinkling and electrostatic handling issues. To address this tendency, the thin polymer film can be lightly stretched, in bulk form, to a flat and controlled state and then bonded to a thin frame that is made, for example, of thin

metal or fiberglass composite. Next, the thin polymer layer can be machined with the fine part features (*e.g.*, tiny holes in the polymer at precise locations), and the alignment hole features can be machined into the frame material.

In additional embodiments, the device can be designed to mitigate thin-layer handling issues. For example, a part within the device can be designed such that all machining pertinent to a fragile layer is performed post-lamination; thus, this layer will not require precision alignment when put into the laminate, though the material is advantageously capable of being placed into the laminate sufficiently flat and extending over a sufficient area to cover the desired parts of the device.

In exemplary embodiments, the various layers can be laser machined before lamination to form the multi-layer structure. Examples of compositions that can be laser machined to form these layers include the following: bulk polymer films (formed, *e.g.*, of polyester, polyimide, *etc.*); metal sheets and foils [formed, *e.g.*, of stainless steel, spring steel, titanium, copper, invar (FeNi36), nickel-titanium alloy (nitinol), aluminum, *etc.*]; copper-clad laminates; carbon fiber and glass fiber composites; thermoplastic or thermoset adhesive films; ceramic sheets; *etc.*. The laser machining can be performed, *e.g.*, with a 355-nm laser (from DPSS Lasers Inc. of Santa Clara, California) with a spot size of about 7 microns on materials with typical thicknesses of 1-150- μ m, although thicker layers can be machined with such a laser as well. Accordingly, this type of laser allows for very high resolution and an ability to machine almost any type of material.

Machining or Patterning Adhesives

Adhesion between layers is achieved by patterning adhesive onto one or both sides of a non-adhesive layer or by using free-standing adhesive layers ("bondplies")

14. In the latter case, an intrinsically adhesive layer 14, *e.g.*, in the form of a sheet of thermoplastic or thermoset film adhesive, or an adhesive laminate, such as a structural material layer with adhesive pre-bonded to one or both sides, is used. The adhesive layer 14 is machined like the other layers. Specific examples of sheets that can be used as the adhesive layer 14 include sheet adhesives used in making flex circuits (*e.g.*, DuPont FR1500 adhesive sheet) or polyimide film 16 coated with FEP thermoplastic adhesive 14 on one or both sides. Free-standing sheet adhesives can be acrylic-based for thermosets; alternatively, the adhesive can be thermoplastic, wherein the thermoplastic film can be formed of polyester, fluorinated ethylene

propylene (or other fluoropolymer), polyamide, polyetheretherketone, liquid crystal polymer, thermoplastic polyimide, *etc.* Any of these adhesives can also be applied on one or both sides to a non-adhesive carrier. In additional embodiments, a layer may serve both as a structural layer 12 and as a thermoset adhesive 14—for example, liquid crystal polymer or thermoplastic polyimide. Furthermore, for special types of structural layers, a variety of wafer bonding techniques that do not require an adhesive may be employed, such as fusion bonding.

In another technique for achieving adhesion between layers, adhesive 14 is applied and patterned directly on a non-adhesive layer 12. This technique can be used where, for example, the type of adhesive desired may not be amenable to being in a free-standing form. Examples of such an adhesive 14 include solders, which are inherently inclined to form a very thin layer, or adhesives that are applied in liquid form (by spraying, stenciling, dipping, spin coating, *etc.*) and then b-stage cured and patterned. B-staged epoxy films are commonly available, but they usually cannot support themselves unless they are quite thick or reinforced with scrim.

The resulting bond can be a “tack bond,” wherein the adhesive 14 is lightly cross-linked to an adjacent layer before laser micromachining with sufficient tack to hold it in place for subsequent machining and with sufficient strength to allow removal of the adhesive backing layer. The tack bonding allows for creation of an “island” of adhesive 14 in a press layup that is not part of a contiguous piece, which offers a significant increase in capability. Another reason for tacking the adhesive 14 to an adjacent structural layer is to allow for unsupported “islands” of adhesive 14 to be attached to another layer without having to establish a physical link from that desired adhesive patch to the surrounding “frame” of material containing the alignment features. In one embodiment, a photoimagable liquid adhesive, such as benzocyclobutene, can be applied in a thin layer, soft baked, and then patterned using lithography, leaving a selective pattern of adhesive. Other photoimagable adhesives used in wafer bonding can also be used.

The adhesive 14 is patterned while initially tacked to its carrier film, aligned to the structural layer 12 using pins 20, and then tacked to at least one adjoining layer in the layup 29 with heat and pressure (*e.g.*, at 200°C and 340 kPa for one hour). Alternatively, the adhesive layer can be patterned by micro-machining the adhesive layer as a free sheet. Tack bonding can involve application of heat and pressure at a

lower intensity and for less time than is required for a complete bond of the adhesive. In yet another embodiment, the adhesive film 14 can be tack bonded in bulk, and then machined using, for example, laser skiving/etching. Advantageously, use of this variation can be limited to contexts where the machining process does not damage the host layer. Both of these variations were tried using DuPont FR1500 adhesive sheet and laser skiving.

Stacking and Laminating the Layers

To form the multi-layer laminate structure, a multitude of these layers are ultrasonically cleaned and exposed to an oxygen plasma to promote bonding and aligned in a stack by passing several vertically oriented precision dowel pins 20 respectively through several alignment apertures 22 in each of the layers and by using a set of flat tooling plates with matching relief holes for the alignment pins 20. In other embodiments, other alignment techniques (*e.g.*, optical alignment) can be used. All layers can be aligned and laminated together.

Linkages in the laminated layers can be planar (where all joint axes are parallel); or the joint axes can be non-parallel, allowing for non-planar linkages, such as spherical joints.

Where the flexible layers 16 are bonded to rigid segments 12 and extend across the gaps between the rigid segments 12, they enable flexure of the rigid segments 12 relative to one another at the flexible layer 16 in the gaps between the rigid segments 12. Accordingly, the exposed sections of the flexible layer 16 effectively serve as joints. In particular embodiments, the “rigid” layers 12 comprise carbon and “flexible” layers 16 are formed of polyimide.

The choice of the flexible layers 16, which can be formed of a polymer—polyimide in this example—is based upon compatibility with the matrix resin in the carbon fiber. The cure cycle can reach a maximum temperature of 177°C using a curing profile of four hours. Polyimide film (available, *e.g.*, as KAPTON film from E.I. du Pont de Nemours and Company), for example, has a sufficiently high service temperature (up to 400°C) to survive the curing step. The polyimide film can have a thickness of, *e.g.*, 7.5 μm .

The rigid layers 12 in this embodiment are standard cured carbon fiber sheets (*e.g.*, with three layers of unidirectional fibers, wherein the fiber layers are oriented at 0°, 90°, and 0° to provide thickness in two orthogonal directions) having a thickness

of, *e.g.*, 100 μm . After the layers are stacked to form the layup, pressure and heat are applied, typically in a heated platen press to cure/crosslink the adhesive layers.

Specifically, the layup can be cured in a heated press, autoclave, or other device that provides the atmosphere (or lack thereof), temperature, and pressure to achieve the

5 bonding conditions required by the adhesive. One embodiment of the curing process uses 50-200 pounds-per-square-inch (psi) clamping pressure, 350°F (177°C) temperature, and two-hours cure time (optionally with temperature ramping control) to cure DuPont PYRALUX FR1500 acrylic sheets in a heated press with temperature, pressure, and atmosphere control.

10 Post-Lamination Machining

The laminate 31 is then machined (*e.g.*, by severing tabs with a laser) to release the device(s) from a surrounding frame structure in the laminate 31. In some embodiments, additional machining that is not involved with freeing the device from the external frame (circumscribing the device in the laminate 31) is reserved for after

15 lamination (*e.g.*, post-lamination machining of a layer that is structurally weak or that, for some other reason, cannot be precisely aligned since the weak layer is better supported after lamination).

Post-Lamination Treatment

A post-lamination treatment can include plating or coating on an exposed

20 layer. Additional components may be attached to the laminate 31 using a pick-and-place methodology. Pick-and-place operations can be used to insert discrete components into layups before press lamination.

For example, a stimulus responsive material, such as an electroactive material, can be inserted among the layers to serve as an actuator, as described in US

25 2014/0202628 A1. In one embodiment, a lead zirconate titanate piezoelectric plate is mounted on a spring clip in the carbon layer and has been demonstrated to create a functional bimorph cantilever actuator within a device. A broad range of discrete components can be inserted this way, such as mirrors or other optical components, micro-electro-mechanical systems (MEMS), discrete sensors, *etc.* These components

30 may alternatively be added earlier—*e.g.*, before lamination at some point in the stack-up process—or they can be added after the subsequent assembly of the device.

In other embodiments, actuators can be built into the laminate to effect assembly. For example, a piezoelectric bending actuator, shape memory layer, or other type of actuator can be laminated into the structure as a pick-and-place component or inserted as an integral part of a layer in the layup; and the actuator can be actuated, *e.g.*, by supplying electrical current or by changing temperature, to expand the structure of the device. In one embodiment, the actuator is a bimorph cantilever including two 127- μm nickel-plated lead zirconate titanate (PZT) piezoelectric plates (PSI-5H4E, Piezo Systems, Inc.) coated with chromium to provide protection during the downstream locking process and bonded to a central carbon-fiber layer. Quasi-kinematic mating features and planar spring clips in the carbon-fiber layer or titanium layer can hold each plate in alignment during lamination.

Separating Parts from the Scrap Frame

When mass-manufactured in parallel from continuous sheets, the devices can be separated from the scrap frame (*e.g.*, an outer frame to which the parts are connected by bridges of material) of the scaffold 19 by laser machining 101, punching, *etc.*

Specific advantages that can be provided by embodiments of the deployable electrode array include the following. First, electronics (*e.g.*, sensors, actuators) can be integrated directly or in parallel into the manufacturing, allowing for fabrication of customized sensors and actuators based on functional requirements with negligible additional manufacturing overhead. Second, for monolithic manufacturing, all components can be manufactured and assembled using the same process. No additional assembly, especially the type that requires precise alignment of sensors with mechanical part features, is required. Third, for flexural-enabled motion, no pins or sliding joints are required for articulation, which minimizes or completely eliminates friction and wear. Fourth, laser machining allows for smaller features than those achievable via conventional machining processes (*e.g.*, down to 20 microns with the current system). Fifth, traditional structural materials (*e.g.*, plastics, metals, carbon fiber) can be used to make meso- and micro-scale devices. Multiple materials can be integrated and laminated into a single, monolithic structure using this method. Sixth, sensing, on-board actuation, and articulated components can be integrated into micromanipulation tools. Seventh, the collapsible geometry of the device allows for insertion through smaller incisions or access ports.

Strain Gauge Design and Characterization

The device can also include one or more strain gauges, as shown in FIG. 2, printed on its surface. The strain gauge can be coupled via electrically conductive wiring (*e.g.*, having an electrical conductivity that is at least half as high as the conductivity of copper) to a voltage detector that detects current generated by deformation of the strain gauge.

The strain gauge can be formed, *e.g.*, of Constantan (with a thickness of 5 μm) adhered to the device via an additional adhesive layer and can be designed to detect loads applied to the distal end of the device so that force magnitude can be accurately sensed given gauge calibration data and a linear elastic assumption. Given the design requirements set forth in the previous section, the geometry of the gauge pattern can be designed with several considerations in mind. A particular design challenge is to maximize the gauge factor, S_e , while minimizing the overall footprint, where:

$$S_e = \frac{\Delta R_s / R_s}{\varepsilon}, \quad (3)$$

where R_s is the nominal gauge resistance, ΔR_s is the resistance change induced by mechanical deformation, and ε is the material strain. Assuming a linear elastic, isotropic gauge material, for a given gauge configuration, we can express the resistance equation, $R = \rho l / A$, as a function of applied strain, ε , to obtain an analytical model for the change in resistance assuming uniaxial loading, as follows:

$$\Delta R_s(\varepsilon) = \rho \sum_{i=1}^N \frac{l_i}{w_i t_i} \left(\frac{(1+\varepsilon)}{\left[(1-\nu\varepsilon)^2 \right]} - 1 \right), \quad (4)$$

where ρ is the resistivity of the gauge material, and ν is the Poisson ratio. Assuming a complex geometry, we have summed resistance contributions from each discrete feature (length, l_i ; width, w_i ; and thickness, t_i) of the gauge pattern. FIG. 2 demonstrates the geometry of a discrete element in a more complicated gauge pattern.

From Equation (4), the sensitivity of the gauge is directly proportional to length, l_i , and inversely proportional to cross-sectional area, $A_{c,i} = w_i t_i$. Serpentine gauge patterns typical of commercial off-the-shelf (COTS) metal foil gauges are designed to optimize this relationship. For this reason, a serpentine gauge pattern

was implemented to fit the form factor of the grasper jaw. Other gauge patterns that are sensitive in multiple other directions could also be implemented for sensing other motions besides bending of the jaws.

Practical machining considerations, such as the DPSS laser tolerance, thermal conductivity of the gauge material, and potential inclusion of foreign particulates, limit the smallest achievable feature size to around 50 μm . As such, gauge factors (Equation 3) using this process are limited to 1-2 according to Equations (3) and (4).

Formation of the strain gauge can be integrated directly into the manufacturing of the mechanical grasper structure using pop-up book MEMS fabrication. Constantan foil (5 μm thick, 45% Cu, 55% Ni) can be chosen as the sensing layer due to its high resistivity ($\sim 520 \times 10^{-9} \Omega/\text{m}$), versatility, biocompatibility, and comparable thermal expansion (15.0 ppm/ $^{\circ}\text{C}$) with 304 stainless steel (17.2 ppm/ $^{\circ}\text{C}$). The Constantan foil 72 can be laminated to the top structural layer of the grasper. KAPTON Polyimide 16 can provide an extra layer of insulation between the gauge 72 and the steel substrate 12.

The delicate nature of the thin Constantan film yields special processing considerations. The strain gauge is machined and laminated in parallel with the mechanical structure, and as a result, the gauge material experiences significant thermal gradients ($\sim 200^{\circ}\text{C}$) during lamination. The residual stress, σ_{therm} , induced on the gauge material during the lamination process can be calculated using a thin-film approximation by assuming the thermal behavior is dominated by the steel substrate:

$$\sigma_{therm} = \frac{E_{const}}{(1-\nu_{const})} (\alpha_{T,const} - \alpha_{T,s}) \Delta T, \quad (5)$$

where E_{const} is the Young's Modulus of Constantan (169 GPa), ν_{const} is the Poisson ratio (0.33), $\alpha_{T,const}$ is the thermal expansion coefficient for Constantan (15 ppm/ $^{\circ}\text{C}$), $\alpha_{T,s}$ is the thermal expansion coefficient for 304 SS (17.2 ppm/ $^{\circ}\text{C}$), and ΔT is the process temperature gradient. Based on these parameters, the thermal stresses, σ_{therm} , induced via lamination are on the order of 166 MPa, resulting in a safety factor of about 3 (given $\sigma_y = 500 \text{ MPa}$ for Constantan) demonstrating that thermal stress induced during the manufacturing process will not result in failure.

After the gauge material is laminated directly onto the layout, the serpentine gauge pattern can be machined into the Constantan foil during the release step following the full cure. At this point, the foil is already fully bonded to the polyimide

insulating layer, so the depth of cut is closely controlled such that the insulating layer is not ablated by the laser, providing a conductive path to the steel substrate.

Following successful manufacture of the gauge material integrated to the structural substrate, the gauge forms one leg of a Wheatstone bridge with tunable balance to account for gauge manufacturing variations. The output of the bridge is amplified via a differential operational amplifier (LM741CN) with a gain of 500. Data is then acquired via an Analog-to-Digital Converter (ADC) and passed to the host PC through a serial interface at a sampling rate of 500 Hz. Assuming a perfectly balanced bridge, the relationship between gauge resistance change and output voltage is given by Equation (6).

$$\Delta V_{out} = G V_{cc} \left[\frac{R_s}{2R_s + \Delta R_s} - \frac{1}{2} \right]. \quad (6)$$

This amplification circuit boosts fractional gauge resistance changes to measurable voltages such that strains are resolved with much higher resolution.

A final 35µm thick coating of parylene or other biocompatible coating is coated on the structure to promote the biocompatibility of the device.

Detailed Exemplification of Percutaneous Deployable Electrode Array

The neurological system of humans (or other organisms) can be modified and altered for therapeutic purposes by the application of electrical energy. This process is known as neuromodulation. The electrical signals are applied directly or indirectly to the nerves via electrodes and electrode arrays. These electrodes come in different shapes and sizes, including fine wires, cylindrical conduits, and larger flat two-dimensional (2D) arrays known as paddles. The electrodes (*e.g.*, when incorporated into a paddle) can be provided in the form of an array (*e.g.*, a 4 x 10 array of 40 electrodes).

Existing paddles are manufactured by St. Jude Medical, Inc. (St. Paul, Minnesota, US) (see, *e.g.*, US Patent No. 8,099,172 B2) and by Boston Scientific Corporation (Marlborough, Massachusetts, US) (see, *e.g.*, US Patent App. Pub. No. 2012/0143296 A1).

Paddles have the advantage of allowing a larger area to be covered and treated because they cover a 2D surface, as opposed to the single point or linear coverage of the other electrode options. Paddles, however, heretofore, could typically only be

implanted via an open surgery, while cylindrical leads can be implanted via a needle inserted through the skin (*i.e.*, percutaneously). Percutaneous implantation does not require significant incisions through tissue (or “open” surgery) or any bone cutting for implantation, only a needle puncture, and is therefore a minimally invasive
5 implantation option.

The device can include layers of precision-machined (through laser machining, die stamping, or any other method) metal and plastic. The top panel 82 of an embodiment of a pop-up deployable electrode array is shown emerging from a needle 76 in a collapsed configuration in FIG. 3 and fully deployed in FIG. 4, where
10 the expanded array 79 includes a 4 x 6 array of electrodes 80 on two panels 82 extending from an elongate insertion shaft 78.

In one embodiment, the electrodes have an exposed surface area of 1 mm x 3 mm and are spaced 1 mm apart; accordingly, the deployed electrode array, in this embodiment, is about 24 mm long and about 8 mm across.

The number of layers can vary depending on the amount of manual assembly required for the final product. A basic version of the design, shown in FIGS. 5-8 includes the following seven layers: steel – adhesive – polyimide (KAPTON) – metal circuits – adhesive – polyimide – adhesive – steel. In these embodiments, custom flex-circuits are used as a compliant flexure hinge layer to allow for internal wiring for
20 electrical components, such as surface-mount electronics. The etched flex circuit layer with LED’s attached is shown in FIG. 5. The finished (laminated and released) devices with internal traces and rigid mechanical structure are shown in FIG. 6 adjacent a US nickel (0.835 inches or 2.1 cm diameter), while the device with an LED activated is shown in FIGS. 7 and 8. The electrical traces 81, electrodes 80, wiring
25 from a voltage source 83, and hinges 84 can be seen in this design. To reduce the amount of assembly, the device can be partly or completely assembled by fabricating more layers to reduce the amount of manual folding and connecting/welding. In one embodiment, this device includes 53 layers (8 layers x 6 + 5 additional adhesive layers).

Wiring can be achieved by integrating a flexible circuit into the flexure hinge components, thus removing the need for external wiring or further manual assembly. One way to achieve creation of a flex circuit is by etching a copper-clad polyimide sheet and insulating it with another thin layer of polyimide. Another method for
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integrating wiring into the device is by depositing electrical traces onto the polyimide hinge components. Wiring can also be coated on or incorporated into the rigid layer(s). Electrical components, such as electrodes, on the surface of the device are attached to the internal wiring using vias, electrical conduits aligned perpendicular to the plane of the surface of electrodes and device.

Assembly for these devices can be achieved via any of multiple ways. For example, the device can be cut and laminated in its final, functional form with no assembly required. Alternatively, it can be fabricated in partly assembled form and then additional folding and welding, gluing, or connecting operations can be performed to complete the assembly, optionally with the assistance of a jig to aid in alignment and ease manipulation.

The device, mounted in an elongate shaft (*e.g.*, a push rod) can enter the body percutaneously, through, *e.g.*, a needle or cannula without the need for open surgery. In other embodiments, the needle or cannula can also function as the elongate insertion shaft. Once inside, the device can deploy or unfold from a compact geometry into a more open geometry with larger area. In particular embodiments, the device can be popped open and closed multiple times if necessary to aid placement in contrast with previously methods that passively pop open just once without means for recollapsing and reopening. Possible methods of deployment include unfolding, unrolling, expanding outwards, fanning open, or sliding open.

In particular embodiments, the panels can be collapsed from their extended array configuration (a) by pushing the push rod back over the electrode panels (or by drawing the panels into the push rod , (b) via embedded actuators (*e.g.*, electrically powered motors or other displacement mechanisms), (c) using the passive motion of pulling of the device via the shaft connected to the device to collapse it through interaction with the tissue or through the introducer needle, and (d) using internal mechanical energy storage elements (*e.g.*, springs, shape memory elements) to fold the device when a trigger/lock is released or the tension on the deployment pull wires is removed.

To aid in placement in the body, the device can be instrumented with the additional capability of steering once it is inserted into the body. Embodiments of the steering include pre-curved wires, pulled wires, active wrists, crawling mechanisms, pressurization, or forces provided by ejecting saline for locomotion. An alternative

guidance approach is the use of externally applied magnetic fields or adjusted permanent magnets (acting on magnetic materials, such as iron, in the device) to guide the device into the targeted location. Guidance of the device can also be achieved using fluoroscopic imaging, which is able to see metal objects through soft tissue and bone.

In particular embodiments, steering can be achieved with a pre-curved stylet by introducing the stylet either through the device where it protrudes from the front of the device in a similar configuration to the steering finger or into the distal end of the sheath where it can contort and alter the curvature of the complaint sheath material. The introduction of this component introduces an adjustable curvature for to the device that allows the user to change the trajectory of the front of the device as it is advanced in the epidural space of the spine.

In additional embodiments, a hinged wrist mechanism, located either at the point where the electrode array attaches to the shaft or in the body of the device, allows the entire device to act as a steering mechanism. By actuating the device using pull wires or other similar mechanisms to pivot or bend the hinged wrist, the device can be adjusted to curve or tilt in the lateral direction (left or right) to adjust the trajectory of the electrode array during insertion.

In addition to positioning guidance, sensing can also be included to improve positioning and adjust the distance relative to the spinal cord or other nervous system structures. Possible sensing methods include E/M, IR/optical, or pressure/force sensing. In exemplary embodiments, the device can include strain gauges laminated to a surface of the device to detect force, as described in the previous section. Particular embodiments employ a sensor (*e.g.*, a strain gauge or force sensor) to detect whether the device has fully deployed (popped up). In one embodiment, a strain gauge can be mounted at or across the hinge to detect increased or decreased strain corresponding with extension or contraction of the strain gauge that correlates with the open or closed position of a hinge. In another embodiment, contact between members is sensed by a contact sensor (*e.g.*, via conduction) when the device is in a fully expanded or collapsed position; in other embodiments, the absence of contact (as detected by the sensor) between members can indicate that the device is fully expanded or collapsed. In still another

embodiment, a force sensor is incorporated into the device to detect force acting thereon by surrounding structures when the device is fully expanded or collapsed.

Once the device is guided to the targeted location (*e.g.*, the correct vertebrae level or a location in the skull), it will be deployed into an open configuration.

- 5 Deployment can be achieved using a number of mechanisms, including a scissor mechanism (FIGS. 9-14), a four-bar unfolding mechanism (FIGS. 15-19), or an unfolding accordion-like mechanism (FIGS. 5-8 and 20-28).

10 An electrode array 79 is shown in its collapsed form (for insertion into the body) in FIGS. 9 and 10. Lateral expansion of the array 79 into paddle form is shown in FIG. 11, where the electrode panels 82 (each with a plurality of electrodes 80) fan out beyond an elongate insertion shaft 78, as hinges 84 in the extendable and collapsible frame pivot while the distance between the distal ends 86 of the array 79 are drawn together. One diamond section of the array 79 is shown in FIGS. 12 and 13 to illustrate deployment and collapse of the panel configuration. The arrows in FIG.
15 12 show the panel array in its collapsed configuration and the direction of the actuation force on the hinges 84 used to deploy the panels 82 in a laterally outward expansion of the array 79. When the array 79 is at an intermediate stage of deployment, as shown in FIG. 13, pulling the top and bottom hinges 84 apart will collapse the array 79, while pushing the top and bottom hinges 84 toward each other
20 will deploy the panels outward. The array 79 is shown in an expanded, deployed configuration in FIG. 14, and the arrows show the direction of the actuation force applied to the middle hinges 84 to re-collapse the array 79.

A single row of a four-bar unfolding mechanism is shown in its collapsed state in FIG. 15 (with the direction of the actuation force for deployment shown with the
25 arrows), at an intermediate state of deployment/collapse in FIG. 16, and in a deployed (expanded) state in FIG. 17 (with the direction of the actuation force for collapsing the panels 82 shown with the arrows). A full array 79 of unfolding four-bar panel configurations is shown in its collapsed state in FIG. 18 and in its
30 deployed/expanded state in FIG. 19.

An accordion mechanism for collapsing and expanding the electrode panel array 79 is shown in FIGS. 20-22. A single row of the array 79 (with four electrode panels 82 aligned in series and sandwiched between two end plates 88) are shown in FIGS. 20-22. Again, arrows show the direction of the actuation force for deployment

in FIG. 20 and the direction of the actuation force for panel collapse in FIG. 22, with an intermediate deployment stage shown in FIG. 21.

The actuation of the deployment and expansion can be achieved in multiple ways, including using a pull wire and/or push rod/tube mounted to the device and configured to provide, *e.g.*, a compressive force when remotely actuated (*e.g.*, pushed or pulled from a position outside the body) by an operator (or via automation) to cause the mechanism to open up or unfold. An illustration of the deployment of an accordion panel configuration is shown in FIGS. 25 (bottom perspective view) and 26 (top perspective view), where the end plates 88 are coupled via hinges 84 to side plates 90. In its fully collapsed configuration, that may be, *e.g.*, only 1.4 mm thick, which is less than the space budget for insertion through a 12-gauge needle. A pull wire 92 extends through a push rod (tube) 94, which can be subcutaneously inserted into a patient. The pull wire 92 is mounted to the hinge 84 joining the side plates 90 remote from the push rod 94; so when the terminal section of the pull wire 92 is withdrawn into the push rod 94, it opens the hinge 84 joining the remote side plates 90 to thereby force apart the end plates 88 and, consequently, unfold the electrode panels 82 that were folded between the end plates 88 when the array 79 was collapsed.

Collapsing or re-folding of the device can also be achieved in multiple ways, including pushing on deployment linkages with rigid or flexible rods/tubes to reverse their motion, releasing tension on the pull wires to reverse the force on components used to expand the device, or sliding tubes or other structures over the device to force them to close and fold down into a smaller size.

Top and bottom perspective views of this electrode array 79 in its fully deployed state (with the pull wire 92 at its peak retraction into the push rod 94) are respectively shown in FIGS. 27 and 28. The terminal section of the pull wire 92 is sufficiently stiff so that the pull wire 92 can be released back out of the push rod 94 to re-collapse the electrode array 79. Meanwhile, the pull wire 92 and push rod 94 can be made with sufficient flexibility (*e.g.*, by controlling its composition or by manufacturing hinges into their structure) to enable the device to be steered through the body.

Three layers that are laminated to form an embodiment of an electrode panel are shown in FIG. 29, alongside a ruler with numbered centimeter designations for scale. The first layer 100 is a copper layer that provides electrical circuit connections

with the electrodes 80 that will subsequently be laminated thereto. The first layer is here shown with laser-machined electrodes 80, which are applied with the third layer 96, discussed below. The second layer 98 is a KAPTON polyimide layer that serves as a mask with small apertures through which conductive epoxy is flowed to provide a
5 conductive link between the underlying copper layer 100 and the electrodes 80. The third layer 96 is a stainless steel electrode layer with adhesive tape (*e.g.*, Gel-Pak adhesive tape from Gel-Pak of Hayward, California) on its back side. The surrounding scaffold of the third layer 96 is removed, leaving behind the electrodes 80 on copper layer 100. Alternatively, the electrodes 80 can be deposited onto the
10 underlying layers by electroplating or other type of deposition.

A photographic image of a flex circuit layer upon which the electrodes will be mounted to form an electrode panel is provided at the top of FIG. 47. A magnified view of the encircled section is provided at the bottom of FIG. 47, showing the electrical traces 81 printed on the KAPTON polyimide layer 98 in greater detail. The
15 KAPTON polyimide layer 98 is part of a laminate structure with an underlying copper layer and an adhesive layer between the copper layer and the polyimide layer 98. Also illustrated are a plurality of apertures 22 through which dowel pins 20 are passed for alignment during lamination. The electrical traces 81 lead from a voltage source to electrode pads 118 to which the electrodes are electrically coupled.

20 An embodiment of an entire pop-up spinal cord stimulator (SCS) system is shown in FIG. 30. The SCS system includes an electrode array 79, a shaft and sheath 76, a controller interface 91, and electrical wiring.

An embodiment of the shaft and sheath assembly with the electrode array 79 extending from the shaft and retractable into the sheath 76 is shown in FIGS. 31 and
25 32. In FIG. 31, the electrode array 79 is retracted into the sheath 76 with the flexible steering finger 93 extending therefrom for steering through the human body (*e.g.*, inside the spinal canal) and, *e.g.*, along the spinal column during insertion. In FIG. 32, the electrode array 79 is passed out of the sheath 76 for deployment when the electrode array 79 is positioned at the location in the body where electro-stimulation
30 is needed.

A sectional view of a multi-lumen shaft extrusion design is provided in FIG. 33. Contained within the sheath 76 is the shaft 95. The shaft 95 includes a plurality of lumens 102 for electrical wiring to deliver electrical current from a voltage source to

the electrodes 80. Closer to the center of the shaft 95 are four lumens 104—(a) two lumens for steering wires for steering the steering finger 93 (*e.g.*, pushing/pulling the far tip of the steering 93 in either direction) to direct the device along a chosen path and (b) two lumens for pull wires 92 for deployment of the device.

5 An embodiment of the electrode array 79 is shown in a collapsed configuration in FIG. 34 and in an expanded configuration in FIG. 35. The electrode array 79 can be expanded merely by retracting the sheath 76 so that the sheath 76 no longer constrains the array 79 in its collapsed configuration. The electrode array 79 can similarly be re-collapsed by pulling the shaft 95 to withdraw the electrode array back
10 into the sheath 76 or by advancing the sheath 76 over the array 79. In addition to being easily expandable inside the body, the device is also easily collapsible and removable. This allows for the device to be collapsed and repositioned during implantation, removed immediately after implantation, and removed a period of time after the implantation once the device has healed in place and become
15 encapsulated in scar. The collapsing process, which can involve advancing the sheath over the deployment linkages to squeeze the device, will cause the implant to collapse inside of the sheath, thus pulling away from any scar on the surface of the device and into the sheath. In other embodiments, the electrode array 79 can be expanded and/or collapsed via wires coupled with the electrode panels 82 (*e.g.*, by
20 tensioning/torsioning or releasing the tension to the wires) or via actuators embedded in or coupled with the panels 82 at their junctions.

A biocompatible coating (formed, *e.g.*, of parylene) 106 can be applied to the exposed surfaces of the steering finger 93 and the electrode array 79 to promote the biocompatibility of the device and reduce the risk of triggering an immunological
25 response.

Conceptual images of an embodiment of the deployable electrode array 79 opening over a spinal cord 108 are provided in FIGS. 36 and 37. As shown in FIG. 36, the device is passed through vertebrae 112 and positioned along the dura 110 surrounding the spinal cord 108 and then expanded, as shown in FIG. 37 to place the
30 electrodes in contact with the dura 110; although the electrodes may appear to be facing up FIG. 37, the electrodes face downward in the orientation of this embodiment—toward the spinal cord).

Three designs for the deployable electrode array structure are shown in FIGS. 38-40. The embodiment of FIG. 38 utilizes a single pull wire and no pull wires for steering. In the embodiment of FIG. 39, two pull wires and two steering wires 99 extend from the panel array 79 and steering finger 93, respectively, through the shaft to the controller interface 91 (see FIG. 30). The controller interface 91 releases or retracts the steering wires 99 (*e.g.*, by rotating a knob to which the wires 99 are joined in either direction). Likewise, the controller interface 91 releases or retracts the pull wires to expand or collapse the electrode panel array 79. Hinges 114 in the panel array 79 provide the array 79 with flexibility in both collapsed and deployed forms, which is advantageous when inserting and steering the array 79. In additional embodiments, the steering finger 93 can include a magnetic material (*e.g.*, iron) to enable steering of the steering finger 93 by placement/movement of a magnet outside the body (to attract or repel the steering finger 93 to/from the magnet).

One embodiment of the controller interface 91 includes three control mechanisms—a slide lever for pulling the wire(s) to deploy and expand the device, a slider lever for extending and retracting the shaft 95 within the sheath 76 and a knob for pulling the wire(s) coupled with ends of the steering column 93 on either side to bend the steering column 93 in the direction toward which the steering wire is pulled.

An embodiment of the electrode array collapsed inside a tube serving as the sheath 76 is shown in FIGS. 41 and 42. As shown here, tensioning the near-side steering wire 99 bends the steering finger 93 to navigate the device up the spinal canal epidural space.

Embedded springs 114 are distributed throughout the structure of the deployable electrode array 79 in the embodiment of FIGS. 43 and 44. These embedded springs 114 (where the metal is cut to provide a tortuous, meandering path) allow the electrode array 79 to flex and to move inside of the body during and after implantation. Flexing of the array 79 with an external force applied is especially evident in FIG. 44.

Images of flexible electrical wiring and traces embedded in the deployable electrode structure are shown in FIGS. 45 and 46. As shown therein, beneath a stainless steel layer 96 with flexible hinges 114, electrical traces 81 (formed, *e.g.* of copper) and an underlying conductive copper layer 100 traverse across hinges 84 and through mechanical components to allow the electrodes 80 to receive signals without

the need for external electrical wiring. The widths of the gaps in the stainless steel layer 96 through which the electrical traces 81, polyimide layer 98, and conductive copper layer 100 can be seen can be about 100 micrometers.

In other embodiments, a voice coil actuator (VCA) fabricated via pop-up MEMS techniques, as described in US Application No. 61/862,066, can be incorporated into the device and coupled with the remote electrode sections to unfold and fold the sections with the displacement generated by the VCA.

Deployment can also be achieved by embedding springs or shape memory materials and releasing their stored energy (*e.g.*, by delivering electric current thereto via a conductive pathway) to produce an expansion, contraction or other displacement to deploy the device. Expansion of the device can also be achieved by an embedded electromechanical, hydraulic, or pneumatic actuator (in communication with a voltage or actuating-fluid source), where the actuator applies a sufficient force or displacement to cause the device to open up.

Once the device is open and deployed, it can be locked in the open position by the passive mechanical resistance of the mechanism or the surrounding tissue, a bistable locking joint in the mechanism, or an active locking component such as a pin, button, or ratchet, in the deployment mechanism.

Once opened, the device can be permanently locked open and fixated in place. Stimulation electrodes cover one side and maintain contact with the underlying tissue to allow for the stimulation. For additional fixation to prevent the device from sliding out of place, anchoring mechanisms can be included to attach the implant to tissues in the area for better stabilizations. Options for fixation include barbs, adhesives, applied forces, suction, or tissue in-growth. The device can later be collapsed and the anchoring mechanisms disengaged for readjustment or removal.

Additionally, the device can be encapsulated in a compliant, biocompatible polymer coating formed, *e.g.*, of silicone, parylene or SILASTIC silicone elastomer from Dow Corning Corp., to prevent ingrowth of scar tissue into the device so that the device can be readily re-collapsed.

The electrodes, deployment devices, and steering mechanism can be designed and fabricated in part by using pop-up MEMS. Wiring and circuitry for the electrodes can be integrated directly into the pop-up structure, including the articulated or folding components of the structure; and the electrode plates can be fabricated and

assembled as part of the pop-up lamination process. Further still, the paddle electrode array, including all of the complex wiring, can be auto-assembled without any manual processing steps. The wiring, in turn, can be coupled with a voltage source to deliver electric current from the voltage source to the electrodes.

Specific features for improving clinical care provided by this device include the following: allowance for the introduction of a large electrode array into the body through a small needle puncture hole; inclusion of integrated steering, guidance, and sensing to allow for better placement of the device; and delivery of an implant with the efficacy of the more invasive open surgery through a simple needle stick.

Exemplary applications for these electrodes include the following: spinal cord stimulation (insertion of the electrodes into the epidural space percutaneously to replace a conventional paddle electrode); intracranial electrode array for epilepsy diagnosis, testing, and treatment; and other neurostimulation or neuromodulation treatments for, *e.g.*, peripheral nerve pain or damage, angina/cardiac pain, obesity, incontinence, deep brain stimulation to treat a range of movement and psychological disorders, peripheral nerve stimulation to treat pain and other issues.

Integration of Electronic Components

Pop-up MEMS allow for the fabrication of mechanical and electromechanical devices with dimensions and features in the sub-mm through mm range (*e.g.*, with dimensions in the range from 0.1 mm to 2 cm). One feature of pop-up MEMS is the ability to integrate electronics and discrete electrical components directly into the structure. This section is directed toward how to best accomplish the integration and wiring of electronics in pop-up structures.

Multiple options are available to fabricate and integrate electronics into pop-up devices, including the following: (a) direct fabrication of electrical components into pop-ups and from pop-up materials (*e.g.*, laser ablating force and strain sensors into a pop-up structure—*e.g.*, by applying a layer of a composition that generates a voltage under stress and shaping it by removing portions with a laser); (b) use of electrical components as mechanical components (*e.g.*, use of flex circuits as hinges) and the use of mechanical components as electrical conduits (*e.g.*, use of structural linkages as electrical vias and connectors); (c) embedding electrical components (*e.g.*, electrodes, LEDs, *etc.*) into the mechanical structure and mechanical operation of the

pop-up mechanism; and (d) the development of electromagnets and wrapped circuits using pop-ups.

In other embodiments, a strain gauge of FIG. 2 can be directly manufactured into the pop-up structure. In additional embodiments, as shown in FIGS. 5-8, flex-
5 circuits are used as the compliant flexure hinge layer to allow for internal wiring for electrical components--in this case, surface mount electronics. The integration of electronics (*e.g.*, sensors and actuators) directly or in parallel into the manufacturing of pop-up structures allows for fabrication of customized sensors and actuators based on functional requirements with negligible additional manufacturing overhead.

10 Additionally, one can integrate sensing, on-board actuation, and other commercial off-the-shelf electronic components into the pop-up structure without additional wiring, separate assembly, or manufacturing steps.

The particular example of employing the electrode array 79 for spinal cord stimulation is described above. In this example, the electrode array 79 can enter the
15 body (*e.g.*, a human body) via an epidural needle inserted into the spine; and the electrode array opens inside the epidural space to provide wider coverage over the spinal cord. Therapeutic targets for this approach can include back and limb pain, chest pain, neuropathic pain, and/or cardiac conditions. Use of the array in this context offers a strong value proposition in that the unfolded array can provide the
20 coverage and fixation of an open surgery paddle with minimally invasive implantation, while allowing for easier removal of the electrode array when treatment is complete.

Another application for employing the electrode array 79 is for vagus nerve stimulation. In this embodiment, the electrode array 79 can enter the body via an
25 ultrasound-guided injection into the neck of a human. The electrode array 79 can then passively encircle and anchor around the vagus nerve in the neck region. Therapeutic targets with this approach can include epilepsy, migraines, depression, and/or other neurological and psychological disorders. Use of the array in this context offers a strong value proposition in that it enables quick and simple
30 minimally invasive implantation of a subcutaneous vagus nerve stimulator without any incisions or dissection of the major vessels in the neck.

Another application for employing the electrode array 79 is for sacral nerve stimulation. In this application, the electrode array 79 is inserted in collapsed form

into the body through the sacral hiatus or foramina into the sacrum. The electrode array 79 is expanded inside the sacrum to make contact with multiple sacral nerves with a single device. Therapeutic targets via this application can include urinary and fecal incontinence, sexual disorders, genital and/or rectal pain. Use of the array in this context offers a strong value proposition in that it provides a percutaneous and minimally invasive method for stimulating multiple or all sacral nerves and treating a range of serious conditions with a single implant.

Another application for employing the electrode array 79 is for gastric nerve stimulation. The electrode array 79 is inserted into the abdominal cavity under ultrasound or CT image guidance. The electrode array then opens inside the abdominal cavity or inside of tissue that surrounds the nerves. Therapeutic targets via this application can include digestive issues, such as motility, stimulating abdominal organs, such as the pancreas or liver, or addressing more complex systemic nervous system issues. Use of the array in this context offers a strong value proposition in that it provides a minimally invasive way to sense and stimulate the network of organs and nerves associated with the gastric system. The deployable electrode array allows for a sophisticated and flexible structure that can surround and accurately anchor to gastric nerves without causing any unintentional tissue damage or requiring an open surgery.

In describing embodiments of the invention, specific terminology is used for the sake of clarity. For the purpose of description, specific terms are intended to at least include technical and functional equivalents that operate in a similar manner to accomplish a similar result. Additionally, in some instances where a particular embodiment of the invention includes a plurality of system elements or method steps, those elements or steps may be replaced with a single element or step; likewise, a single element or step may be replaced with a plurality of elements or steps that serve the same purpose. Further, where parameters for various properties or other values are specified herein for embodiments of the invention, those parameters or values can be adjusted up or down by $1/100^{\text{th}}$, $1/50^{\text{th}}$, $1/20^{\text{th}}$, $1/10^{\text{th}}$, $1/5^{\text{th}}$, $1/3^{\text{rd}}$, $1/2$, $2/3^{\text{rd}}$, $3/4^{\text{th}}$, $4/5^{\text{th}}$, $9/10^{\text{th}}$, $19/20^{\text{th}}$, $49/50^{\text{th}}$, $99/100^{\text{th}}$, *etc.* (or up by a factor of 1, 2, 3, 4, 5, 6, 8, 10, 20, 50, 100, *etc.*), or by rounded-off approximations thereof, unless otherwise specified. Moreover, while this invention has been shown and described with references to particular embodiments thereof, those skilled in the art will understand

that various substitutions and alterations in form and details may be made therein without departing from the scope of the invention. Further still, other aspects, functions and advantages are also within the scope of the invention; and all embodiments of the invention need not necessarily achieve all of the advantages or possess all of the characteristics described above. Additionally, steps, elements and features discussed herein in connection with one embodiment can likewise be used in conjunction with other embodiments. The contents of references, including reference texts, journal articles, patents, patent applications, *etc.*, cited throughout the text are hereby incorporated by reference in their entirety; and appropriate components, steps, and characterizations from these references may or may not be included in embodiments of this invention. Still further, the components and steps identified in the Background section are integral to this disclosure and can be used in conjunction with or substituted for components and steps described elsewhere in the disclosure within the scope of the invention. In method claims, where stages are recited in a particular order—with or without sequenced prefacing characters added for ease of reference—the stages are not to be interpreted as being temporally limited to the order in which they are recited unless otherwise specified or implied by the terms and phrasing.

CLAIMS

What is claimed is:

1. A stimulation device including a percutaneous deployable electrode array, wherein the stimulation device comprises:
 - 5 a plurality of electrode panels joined via hinges, wherein each electrode panel includes a substrate and an electrode mounted on the substrate, and wherein the substrate is a laminate comprising a flexible layer joined with a rigid layer on each side of the flexible layer;
an elongate insertion shaft to or within which the plurality of electrode
10 panels are mounted;
electrically conductive wiring coupled with each electrode and extending along the insertion shaft; and
an actuation mechanism coupled with the electrode panels and configured to extend and retract the electrode panels when actuated.
- 15 2. The stimulation device of claim 1, wherein the electrically conductive wiring is incorporated as a flexible circuit extending through the hinges.
3. The stimulation device of claim 1, wherein the actuation device includes a push rod that serves as the elongate insertion shaft and a pull wire extendably and retractably mounted within the push rod.
- 20 4. The stimulation device of claim 3, wherein the pull wire, push rod, and electrode panels are configured such that retraction of the pull wire into the push rod extends the electrode panels in a deployed configuration and release of the pull wire out of the push rod re-collapses the electrode panels.
- 25 5. The stimulation device of claim 1, wherein the hinges are incorporated into an extendable and collapsible frame to which the electrode panels are mounted.
6. The stimulation device of claim 1, further comprising a strain gauge configured to measure external force acting against the electrode array.

7. The stimulation device of claim 1, further comprising a steering finger extending from a distal end of the electrode panels and configured to bend in opposite directions to steer the stimulation device when inserted into a human body.
- 5 8. The stimulation device of claim 7, further comprising at least one steering wire coupled with the steering finger to bend the steering finger.
9. The stimulation device of claim 7, wherein the steering finger comprises a magnetic material.
- 10 10. The stimulation device of claim 1, further comprising at least one of the following steering mechanisms: (a) a pre-curved stylet insertable through or into a distal end of the shaft or electrode panels and (b) a hinged wrist mechanism in the shaft configured with an actuator to bend or pivot the hinged wrist.
- 15 11. The stimulation device of claim 1, further comprising springs incorporated into the structure of the electrode panels to allow the electrode panels to flex during insertion and extension.
- 20 12. A method for performing neurostimulation inside a body of an organism using a stimulation device that comprises an elongate insertion shaft and a plurality of electrode panels, wherein each electrode panel includes a laminate comprising a flexible layer joined on each side to a rigid layer and electrode panels mounted to the laminate and is mounted to or within the elongate insertion shaft, the method comprising:
- 25 inserting the electrode panels, in a collapsed state, and the elongate insertion shaft through tissue of the organism; then
- extending the electrode panels inside the body of the organism into an extended paddle array;
- establishing contact between the extended paddle array and nerve cells inside the body of the organism;

delivering electric current or to the voltage electrodes in the paddle array to stimulate the nerve cells; then

collapsing the electrode panels into a compact form; and then

sliding the collapsed electrode panels back through the skin and out of the body.

13. The method of claim 12, wherein the stimulation device includes a steering finger configured to extend from a distal end of the shaft or electrode panels, the method further comprising using the steering finger to steer the device into position inside the body.

10 14. The method of claim 13, further comprising steering the stimulation device by pulling or releasing at least one steering wire attached to the steering finger.

15. The method of claim 12, wherein the stimulation device includes a magnetic material, the method further comprising steering the stimulation device through the body by moving a steering magnet outside the body.

15 16. The method of claim 12, further comprising steering the stimulation device by pivoting or bending a hinged wrist or by inserting a pre-curved stylet into or through the device.

17. The method of claim 12, further comprising sensing contact between the electrode array and organs or tissues in the body via a strain gauge
20 incorporated into the electrode array.

18. The method of claim 12, wherein the electrodes stimulate nerve cells in the spinal cord, brain, or other portion of the nervous system.

19. The method of claim 12, further comprising hinges that join the electrode panels and that pivot when the electrode panels are extended and collapsed.

25 20. The method of claim 19, further comprising delivering electricity to the electrodes through electrical wiring incorporated as flexible wiring through the hinges.

21. The method of claim 12, wherein the electrode panels are extended to form the paddle array using an actuator.
22. The method of claim 21, wherein the actuator includes at least one pull wire and a push rod serving as the elongate insertion member, wherein the pull
5 wire and push rod extend and collapse the electrode panels.
23. The method of claim 12, wherein the electrode panels are collapsed via a drag force applied to the panels by at least one of the elongate insertion member, the tissue of the organism, and an introducer needle through which the panels entered the organism.
- 10 24. The method of claim 12, further comprising extending and collapsing the electrode panels and repositioning the electrode panels multiple times after insertion of the stimulation device into the organism.
25. The method of claim 12, further comprising removing the stimulation device percutaneously from the organism.

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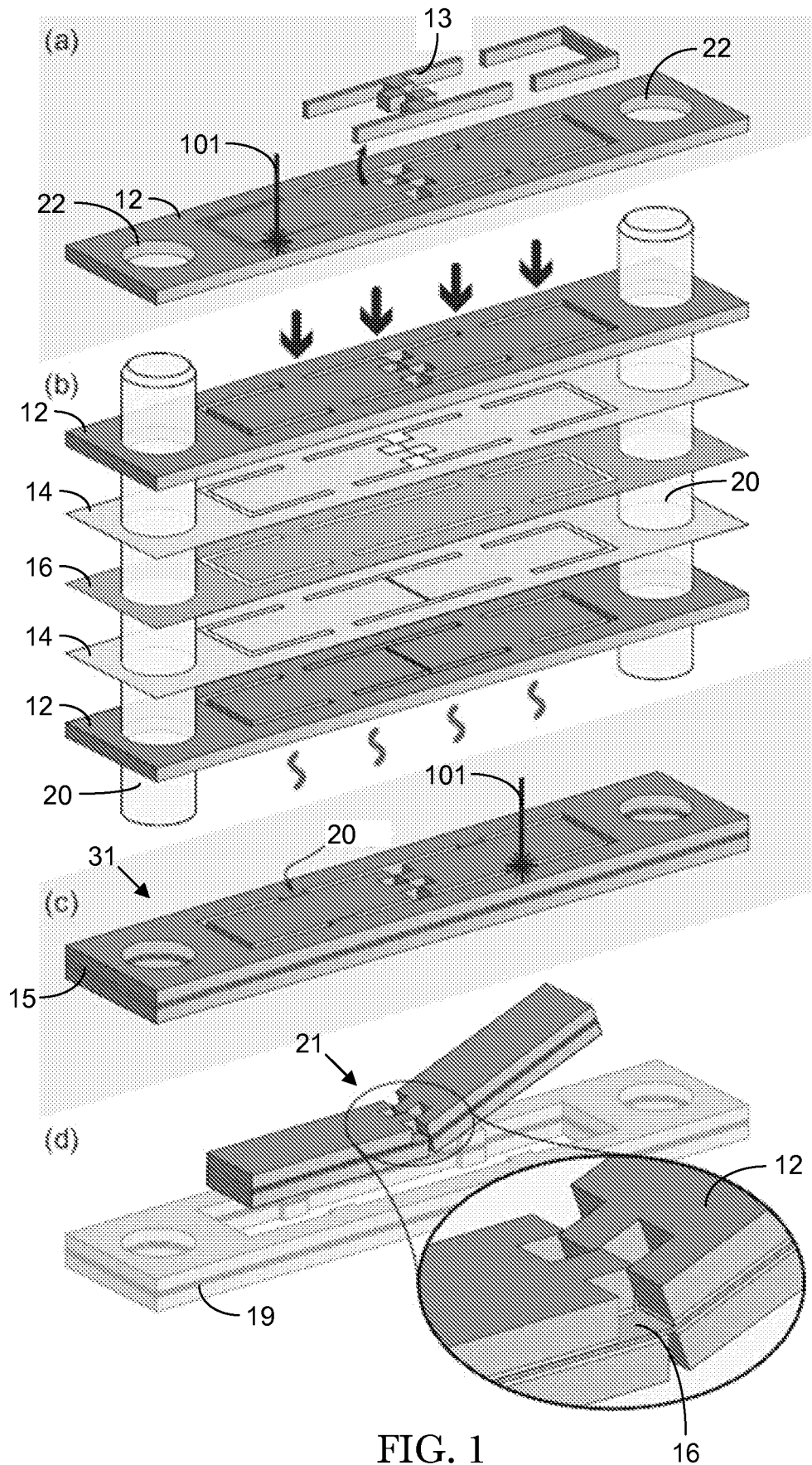


FIG. 1

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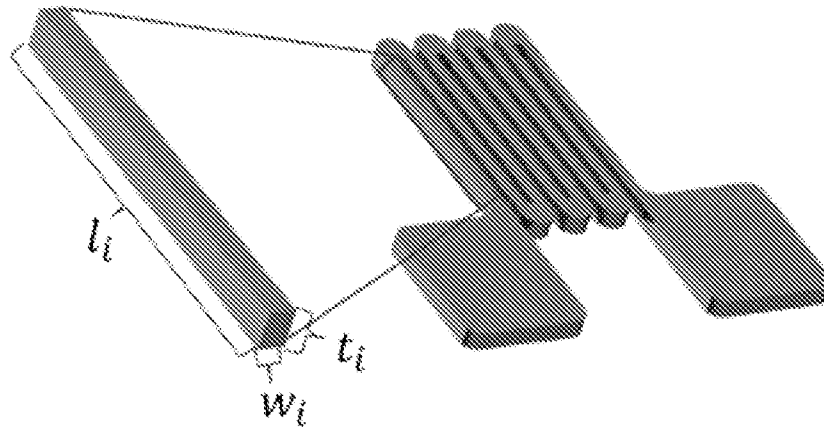


FIG. 2

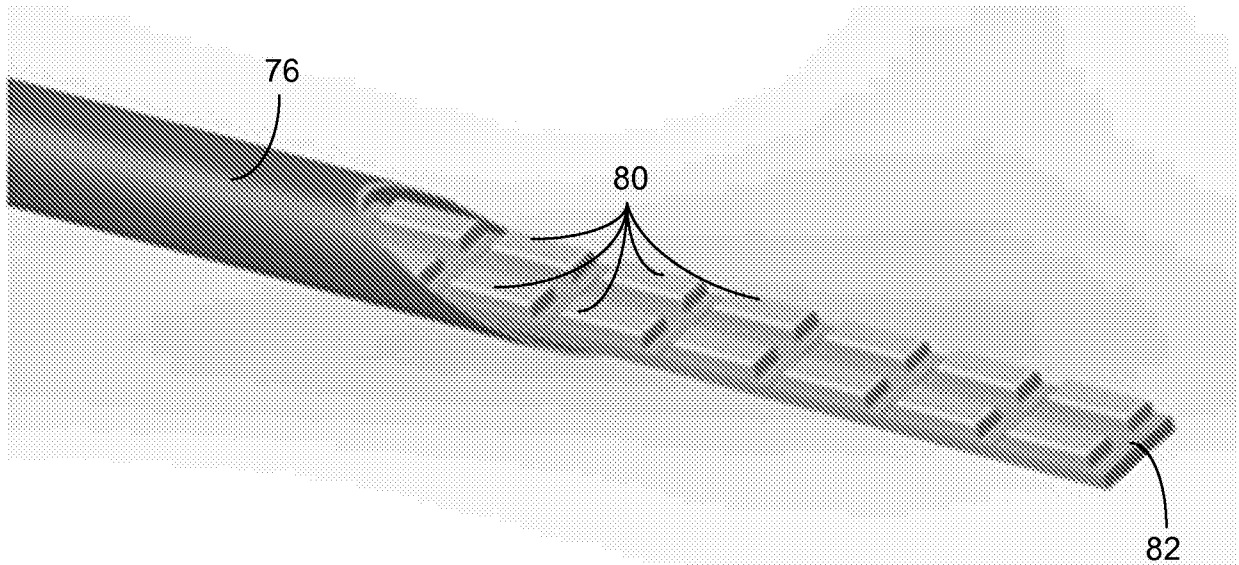


FIG. 3

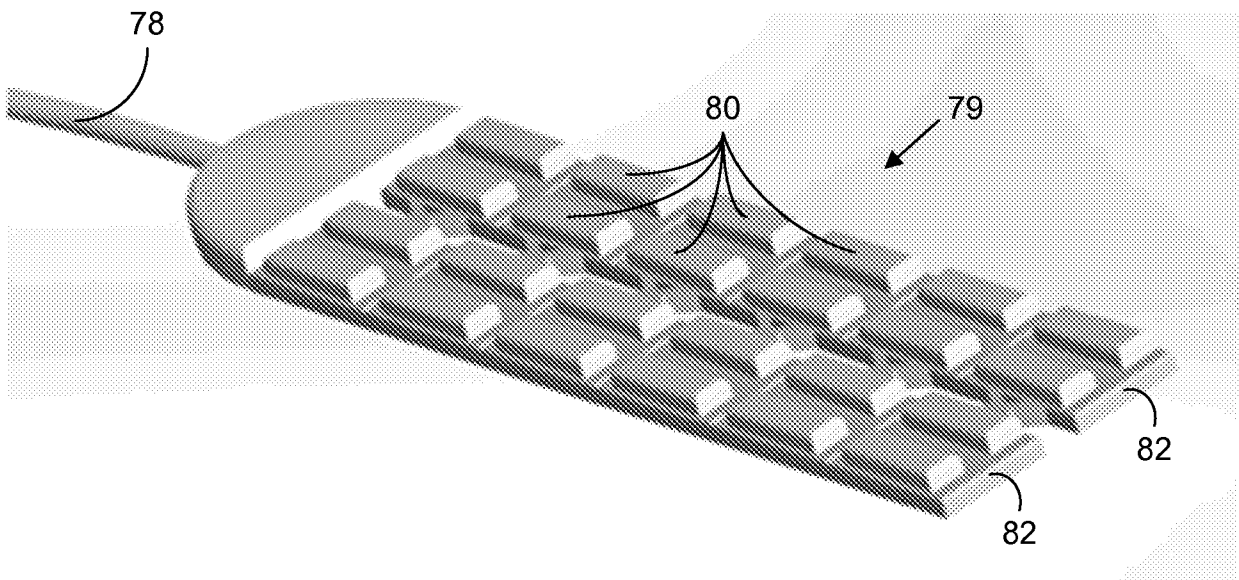


FIG. 4

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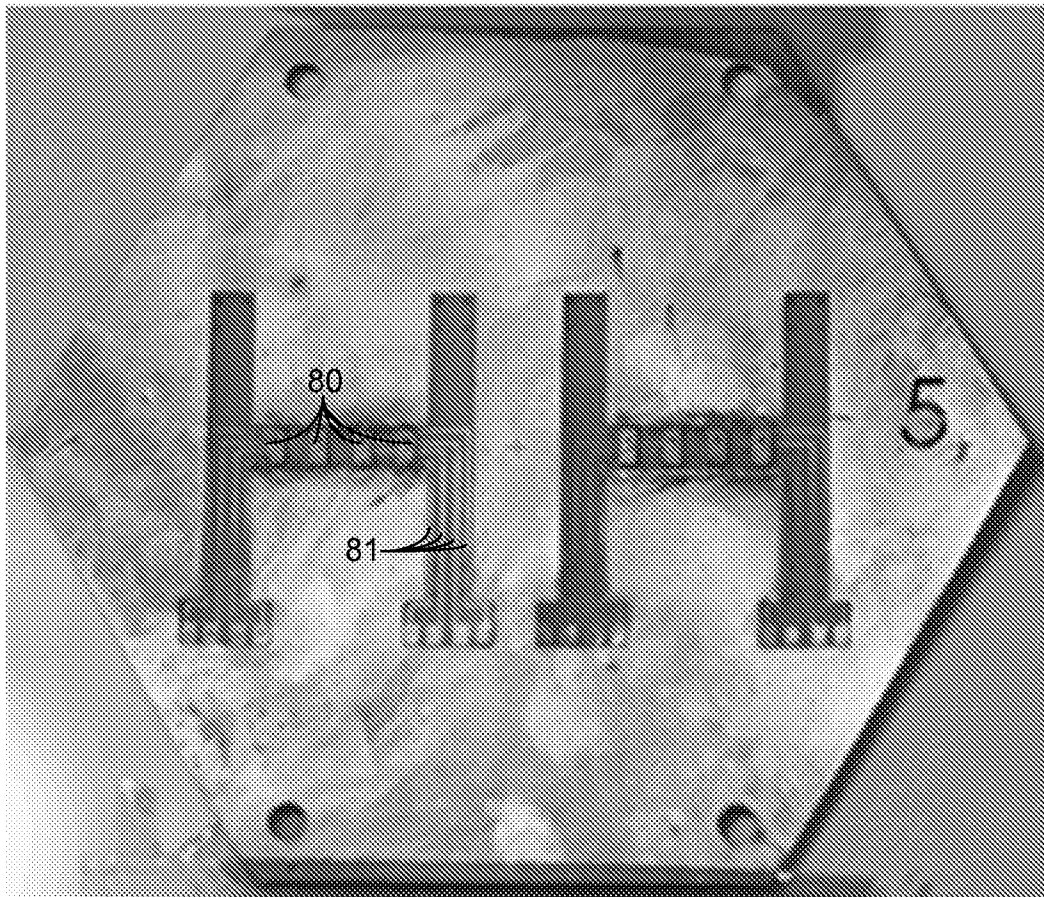


FIG. 5

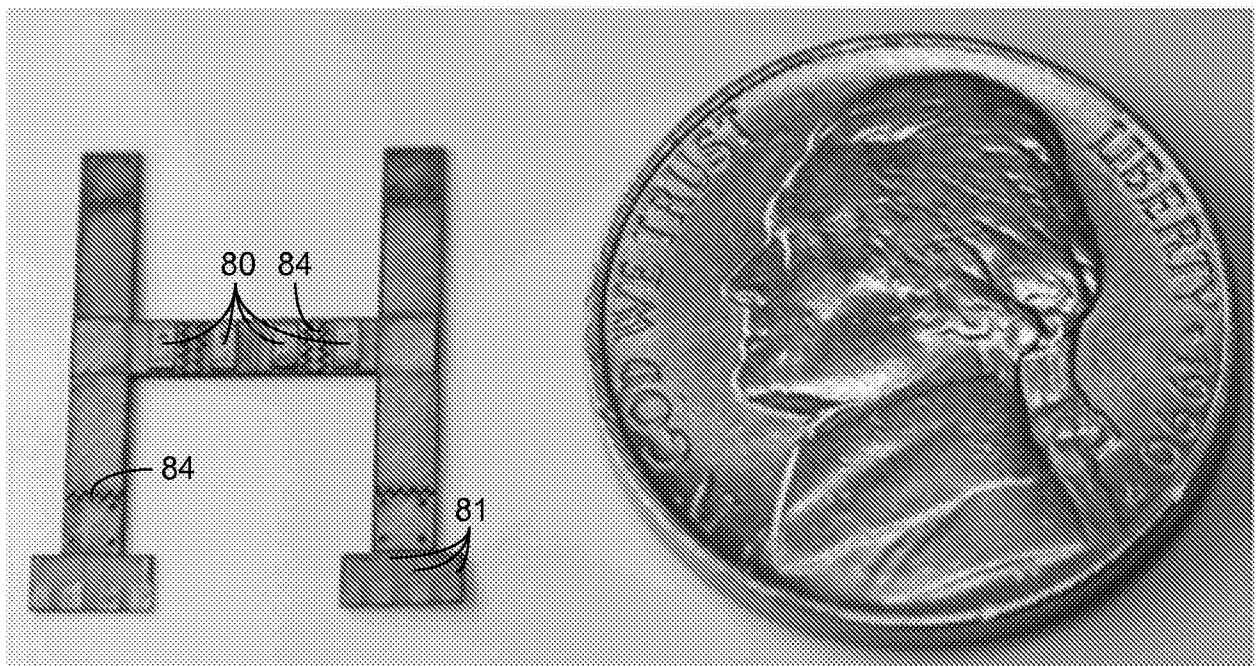


FIG. 6

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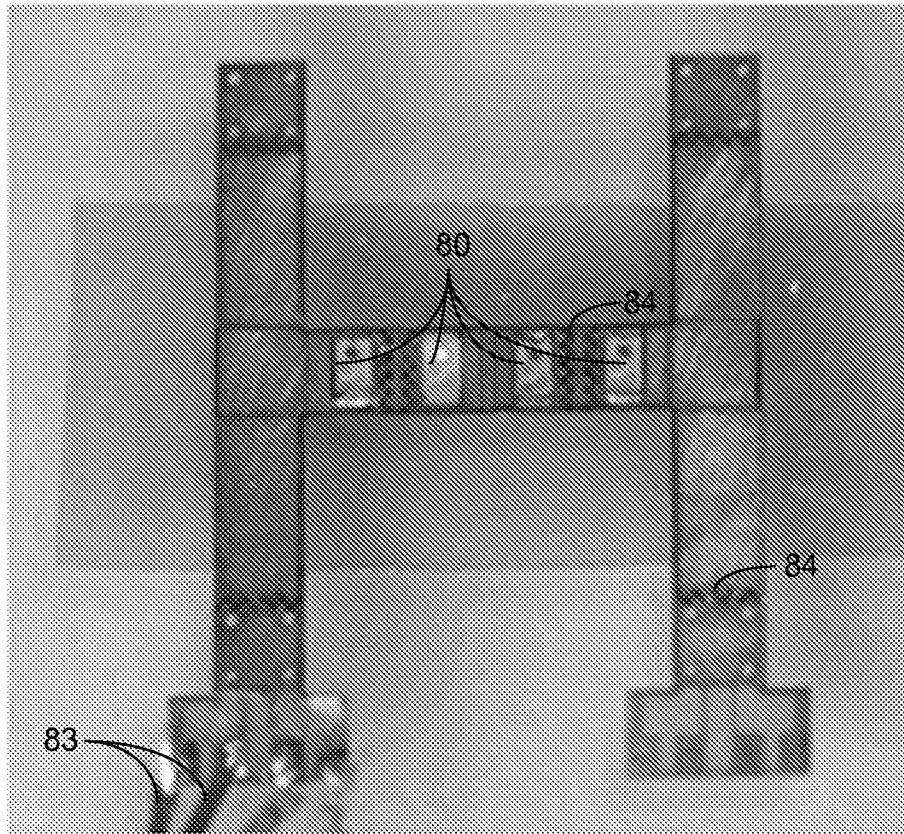


FIG. 7

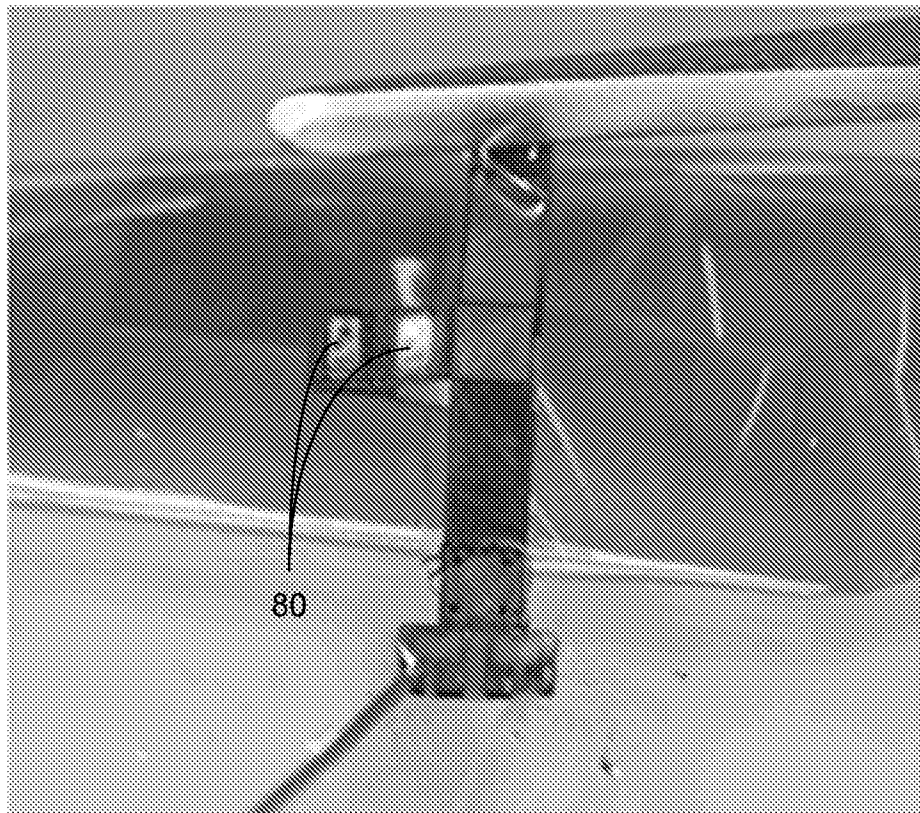


FIG. 8

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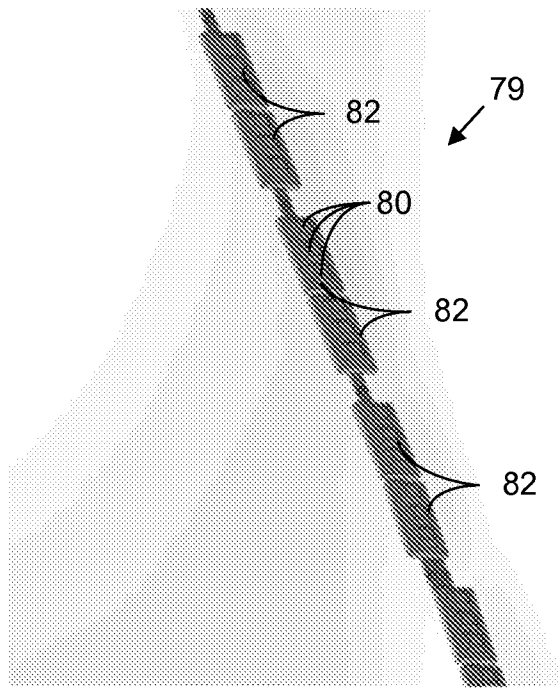


FIG. 9

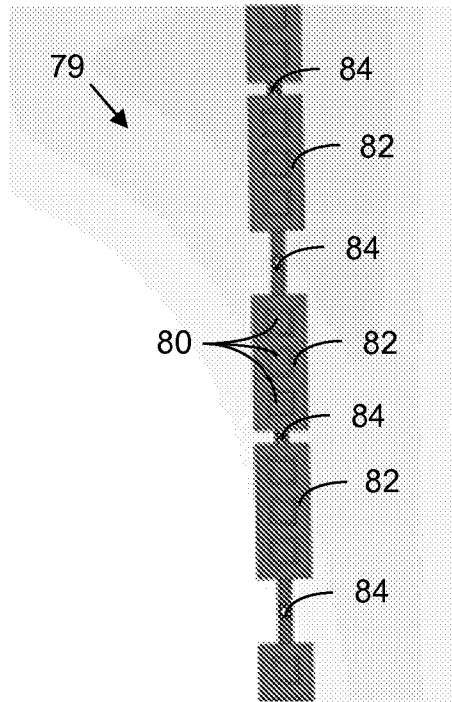


FIG. 10

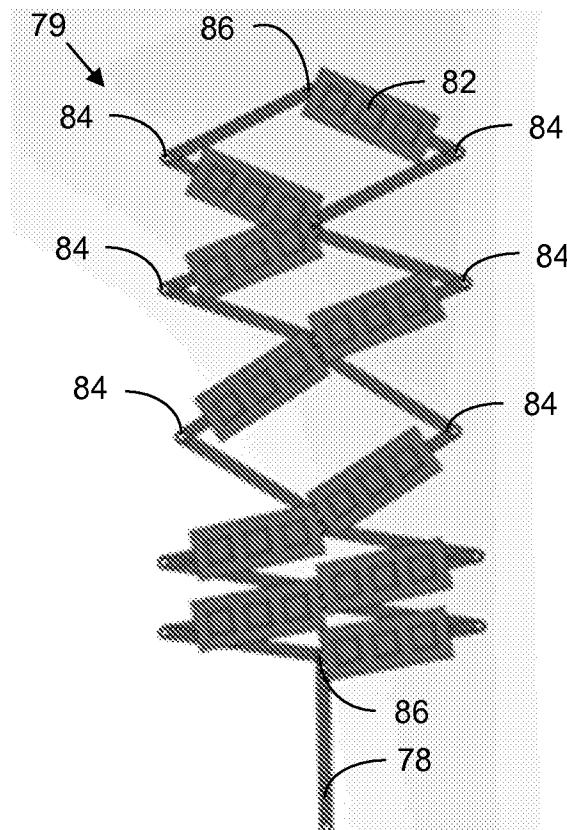


FIG. 11

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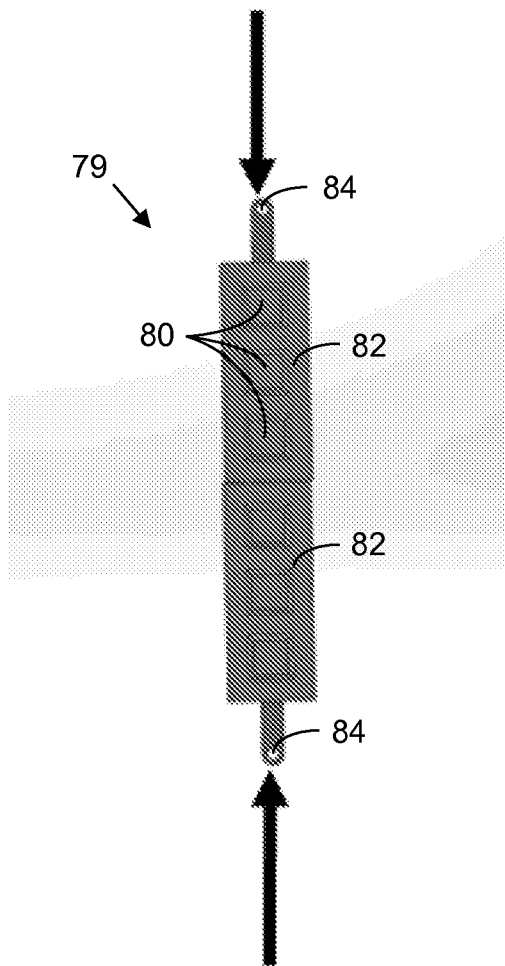


FIG. 12

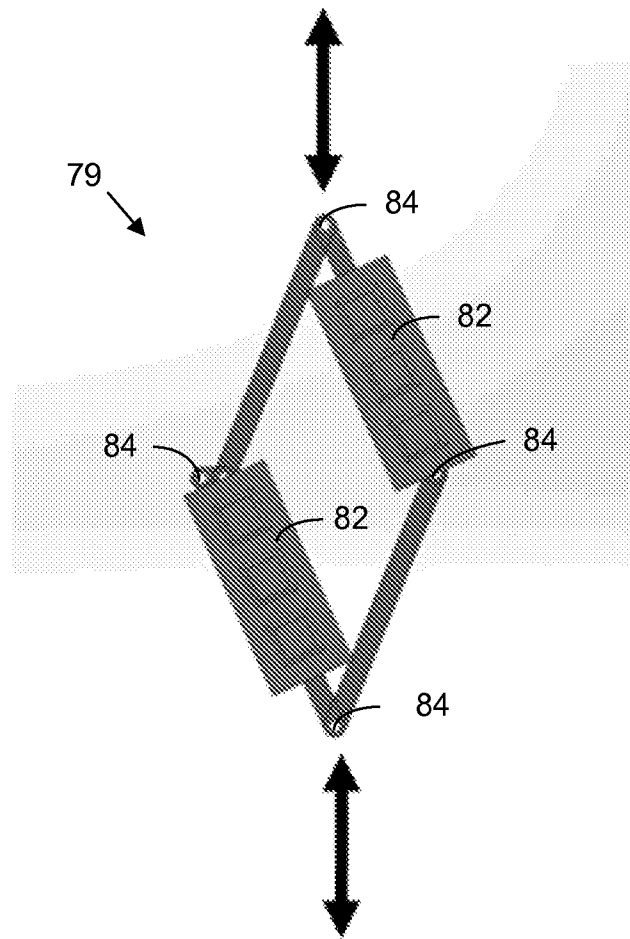


FIG. 13

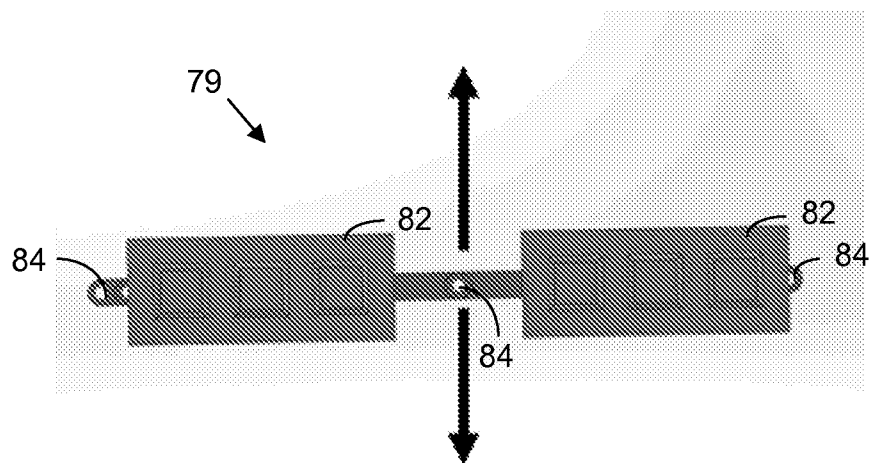


FIG. 14

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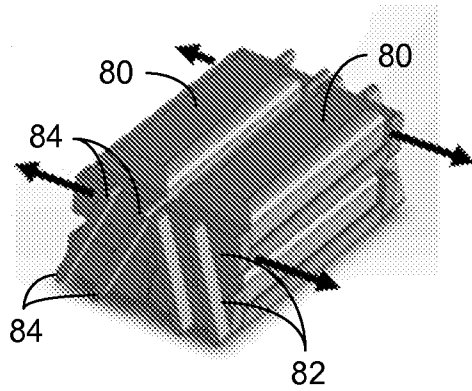


FIG. 15

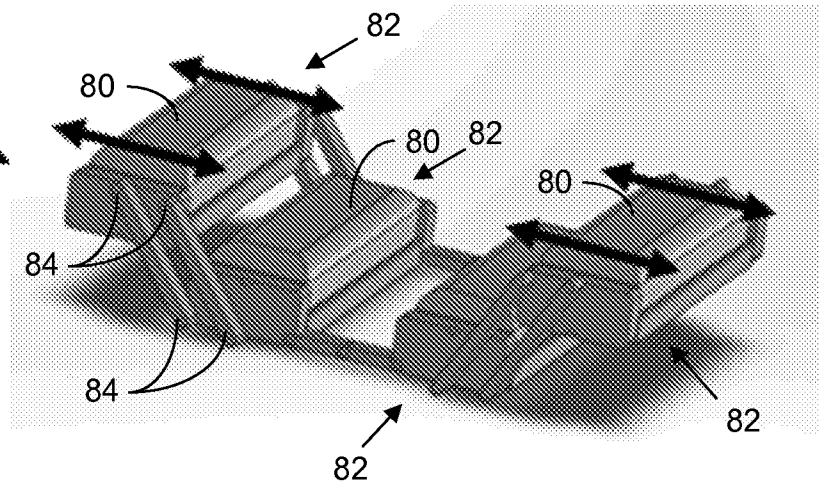


FIG. 16

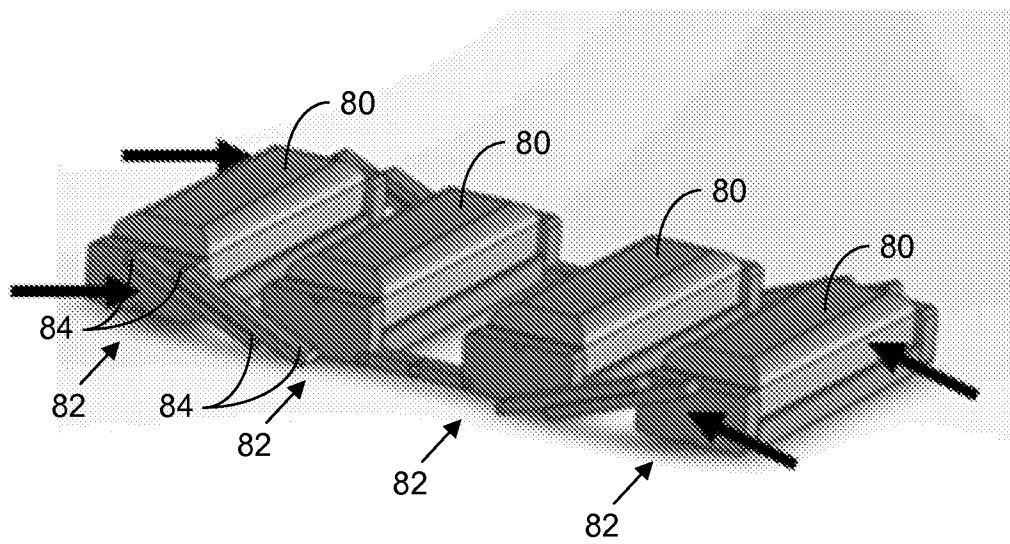


FIG. 17

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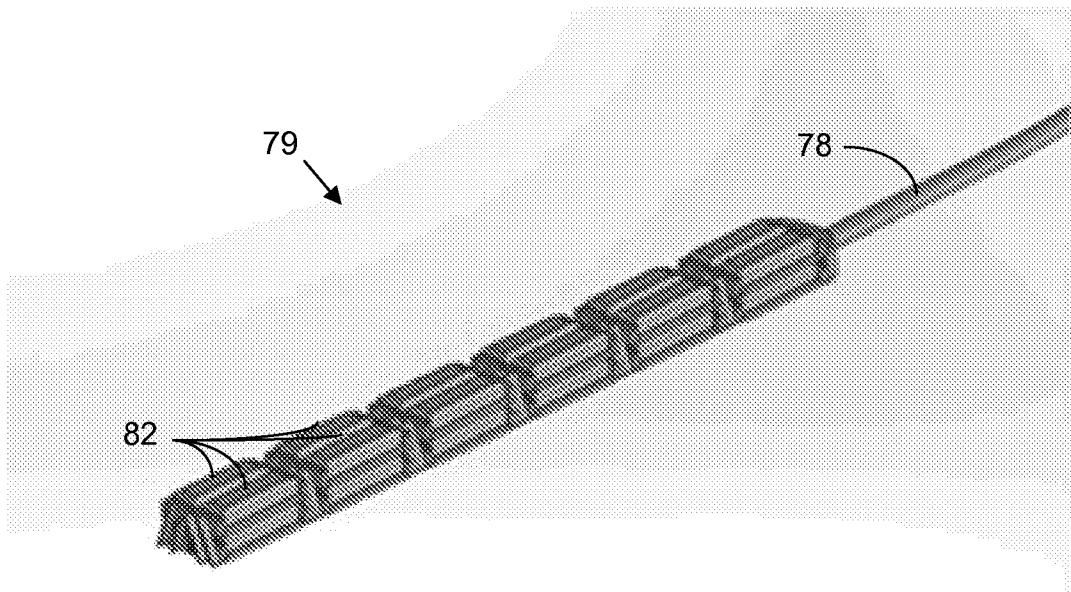


FIG. 18

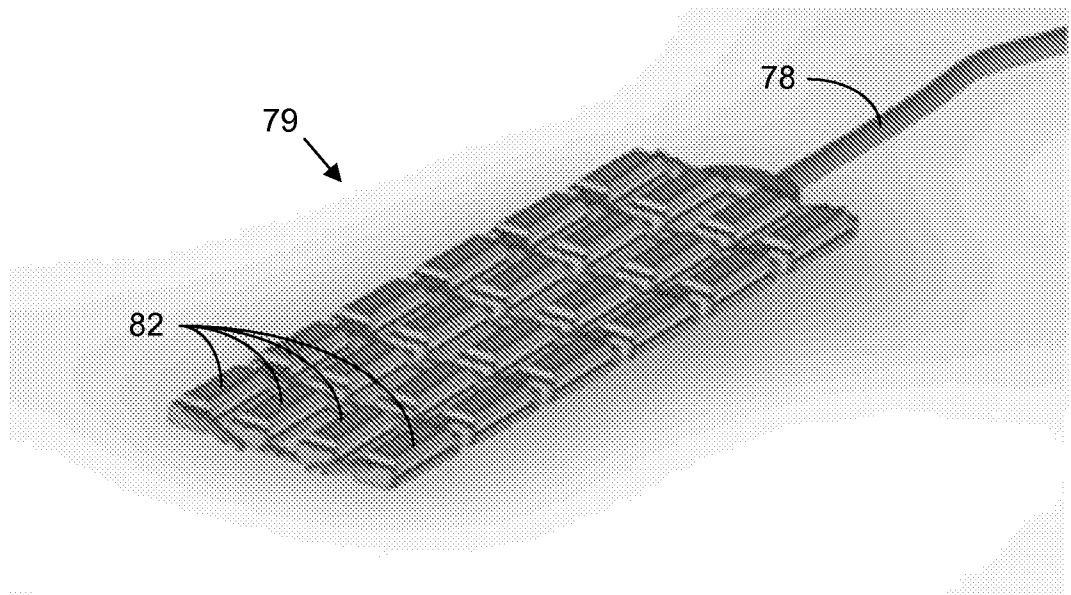


FIG. 19

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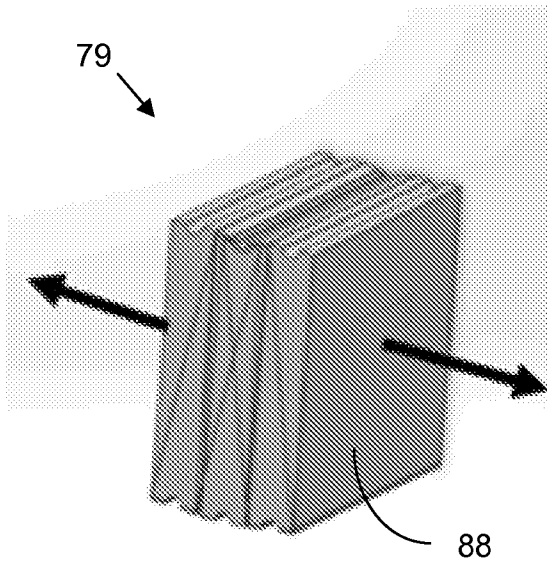


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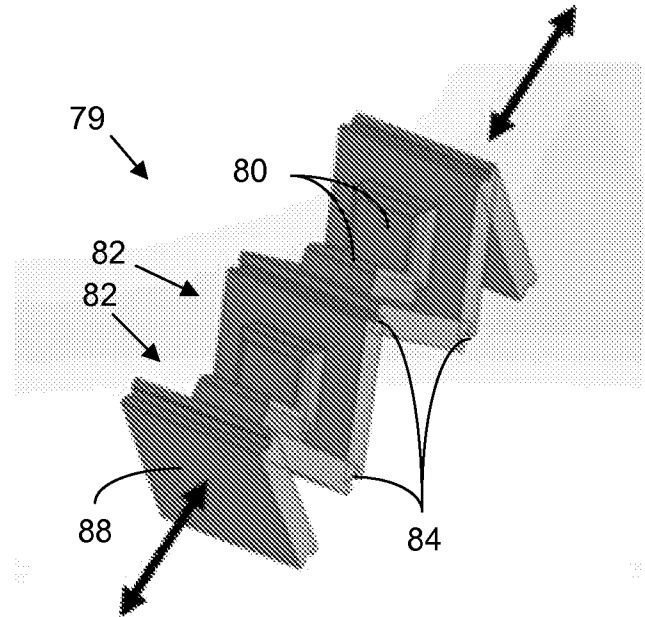


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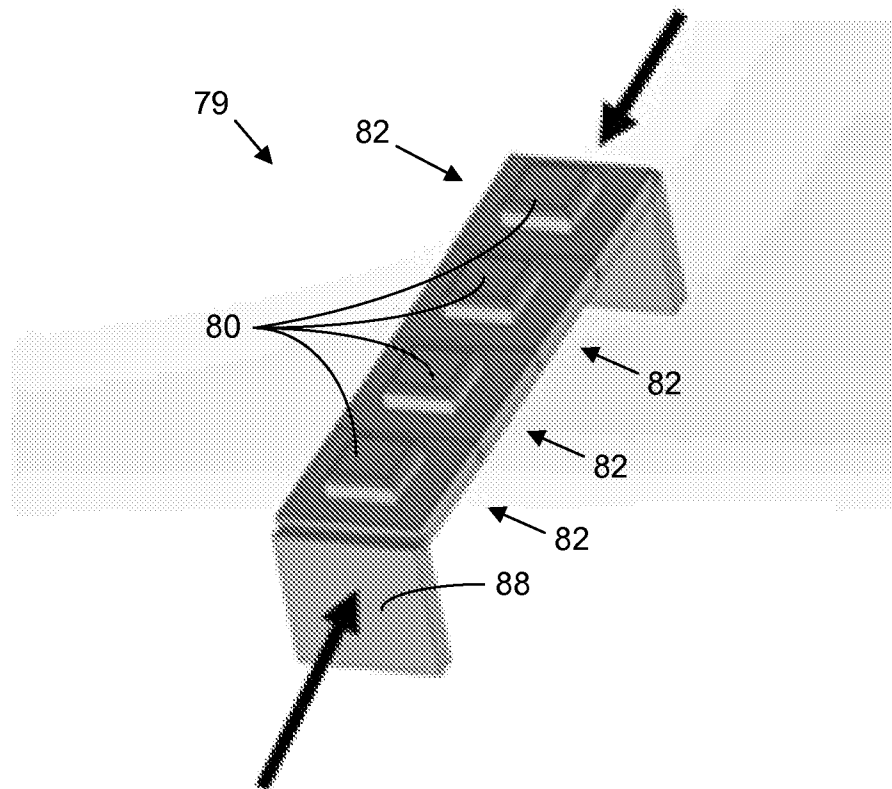


FIG. 22

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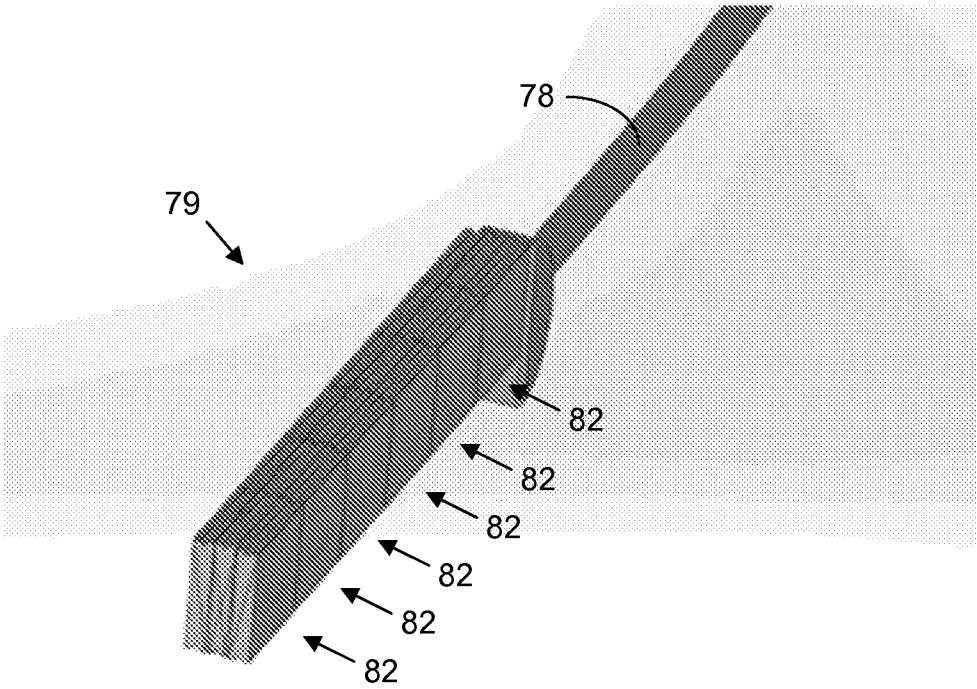


FIG. 23

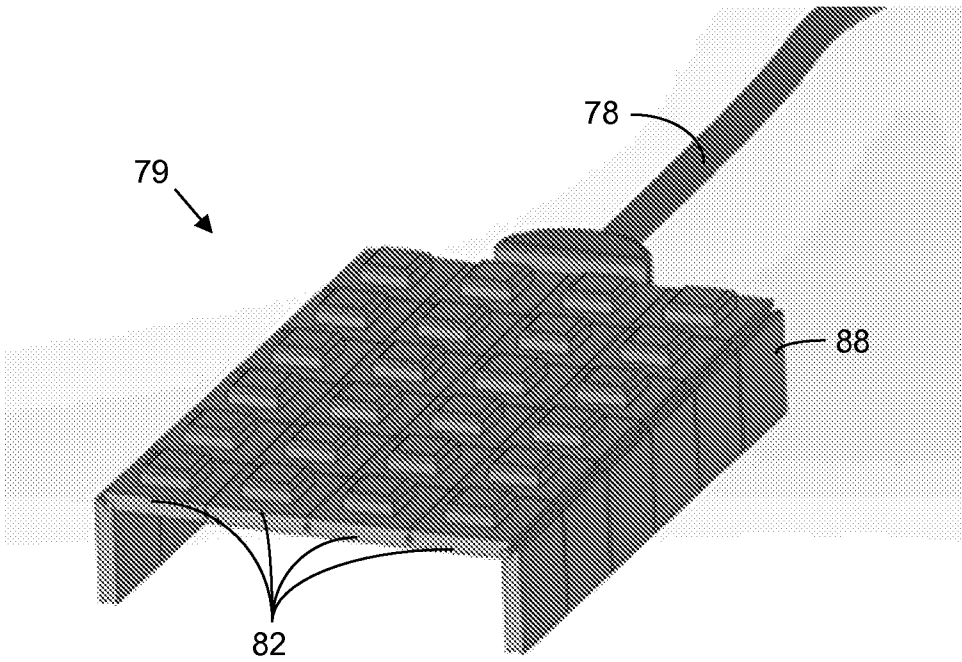


FIG. 24

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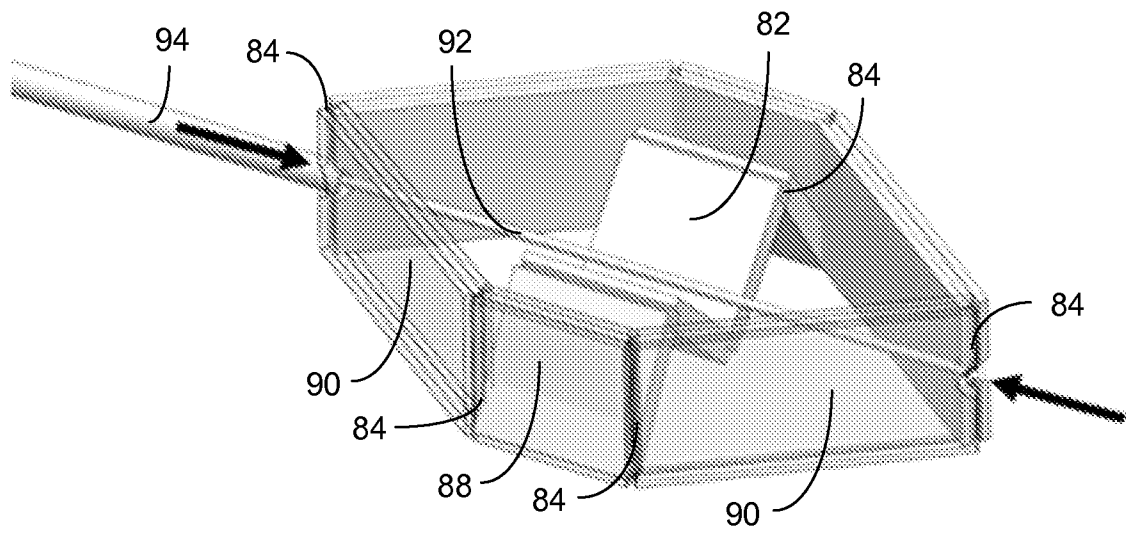


FIG. 25

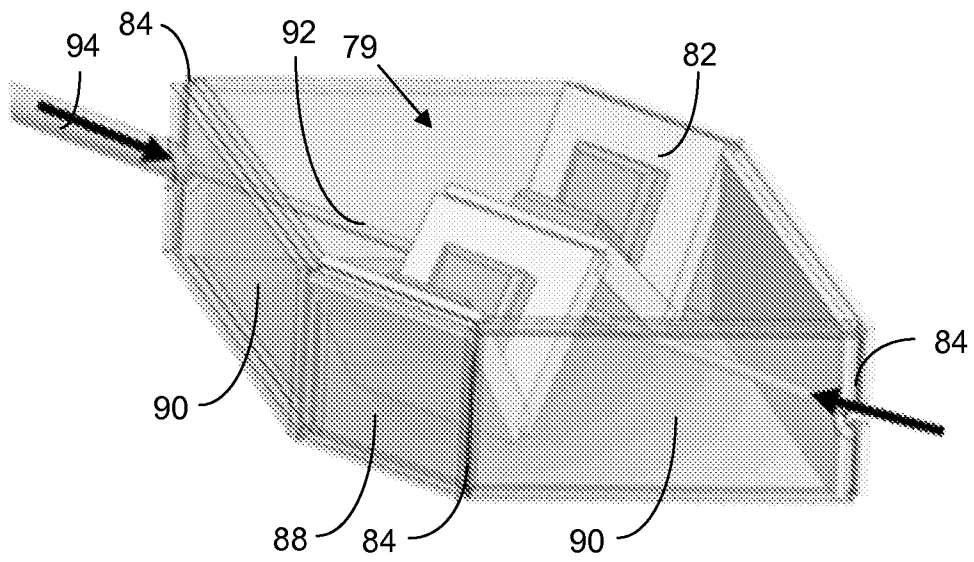


FIG. 26

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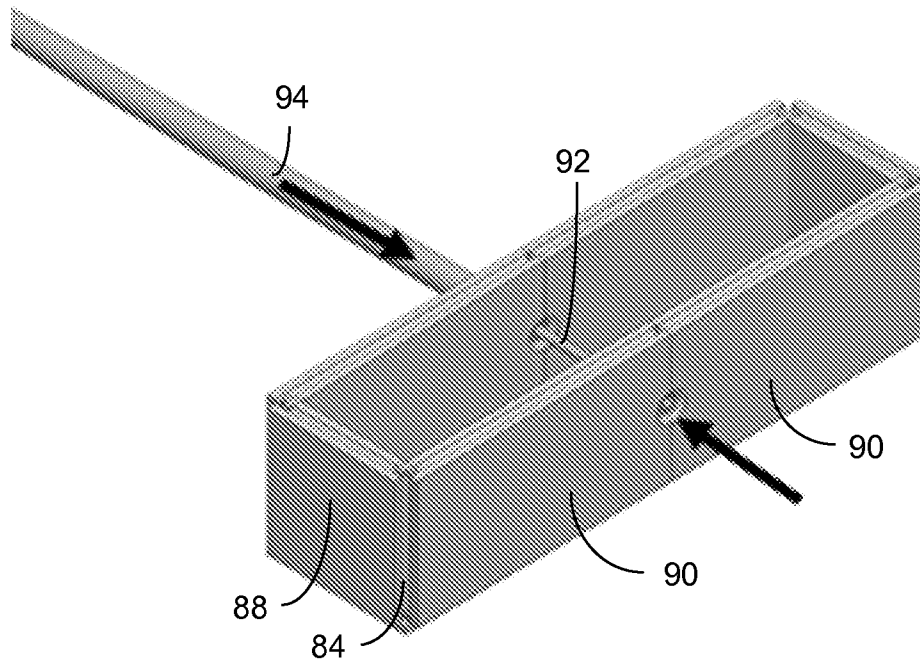


FIG. 27

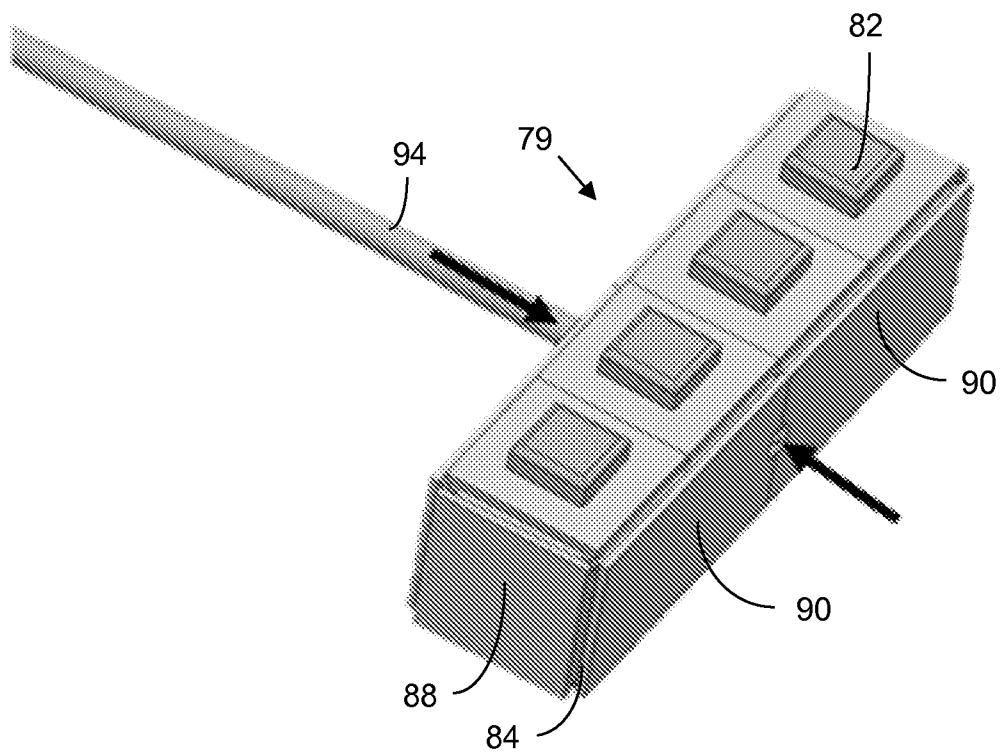


FIG. 28

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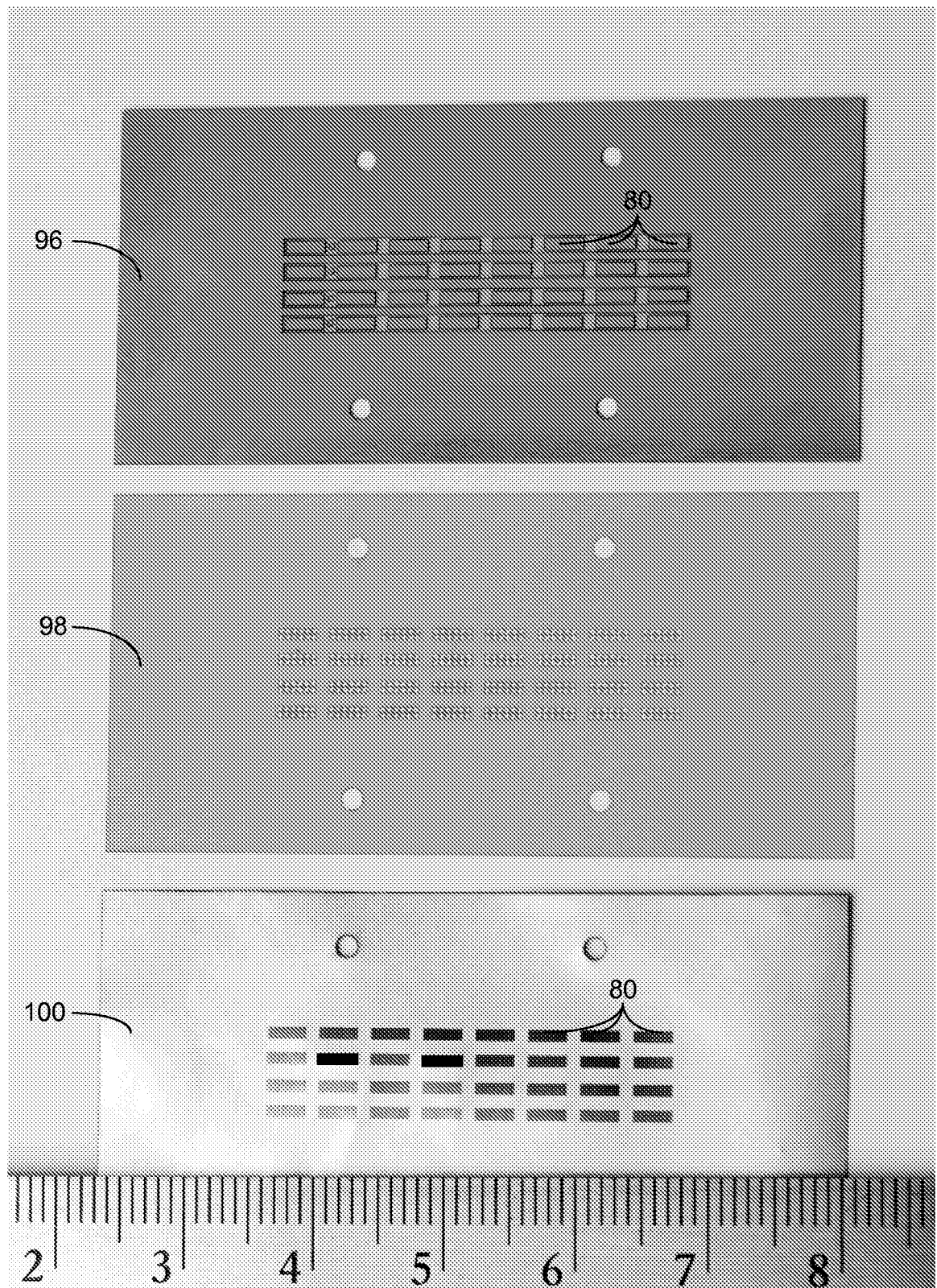


FIG. 29

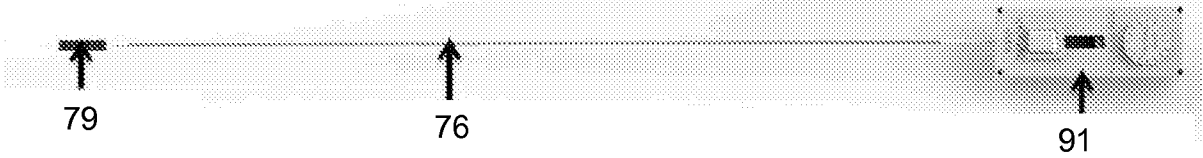


FIG. 30

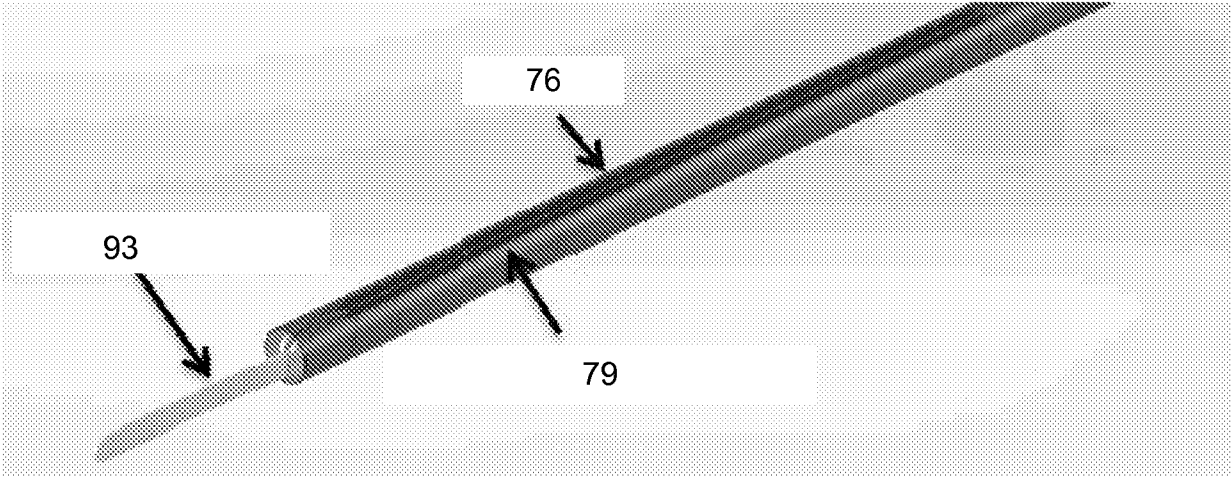


FIG. 31

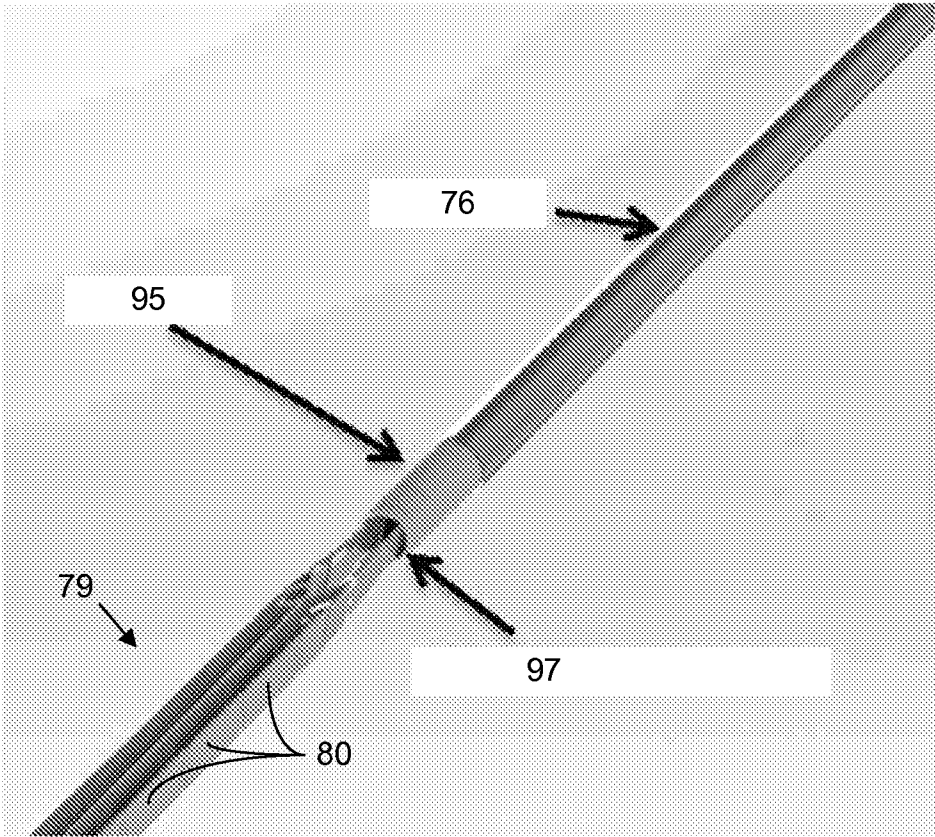


FIG. 32

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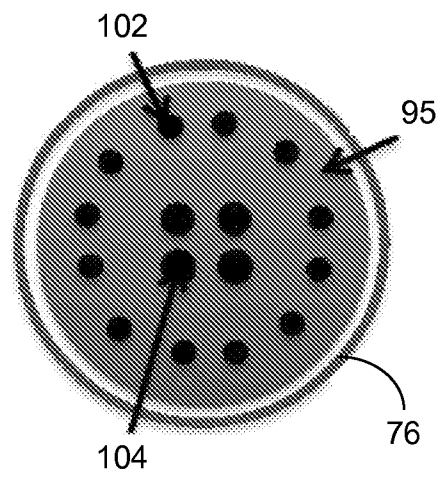


FIG. 33

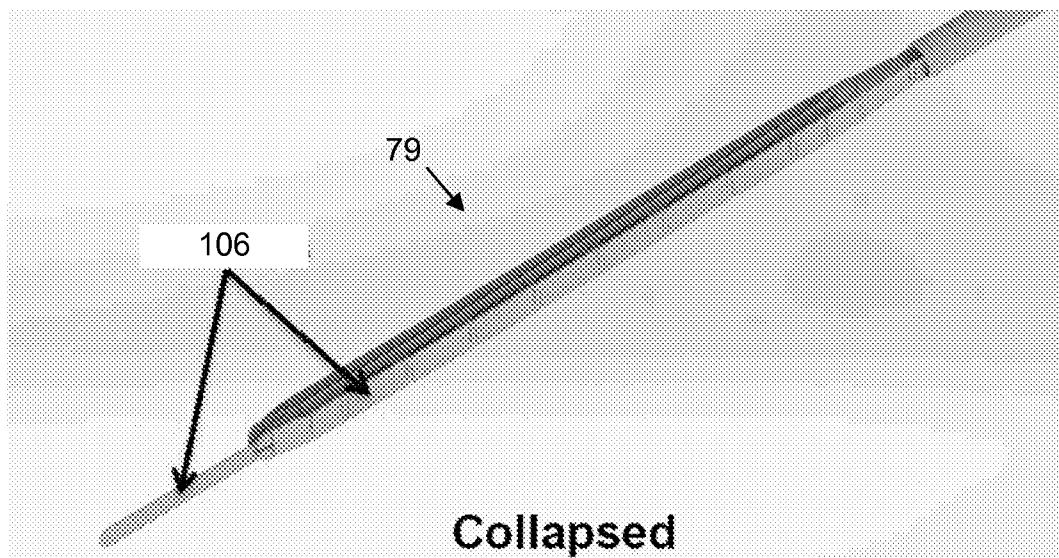


FIG. 34

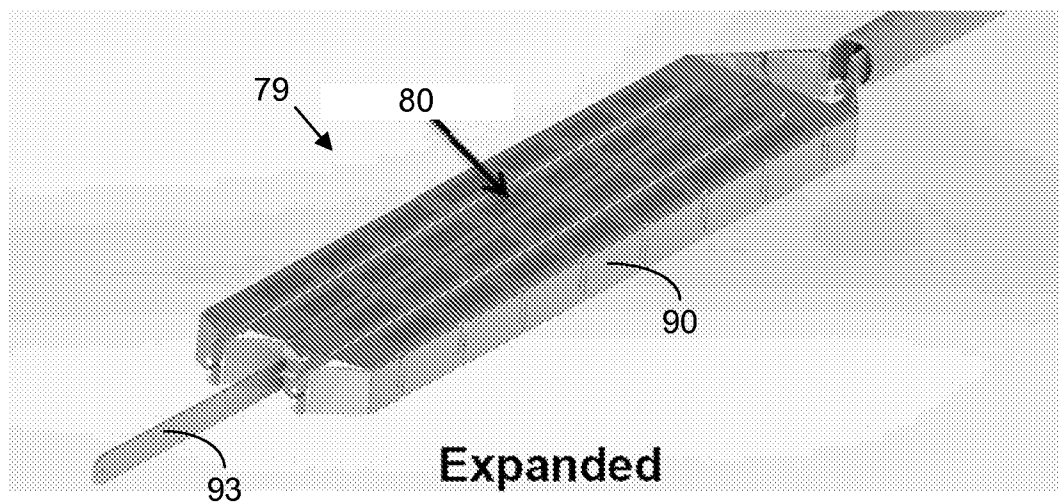


FIG. 35

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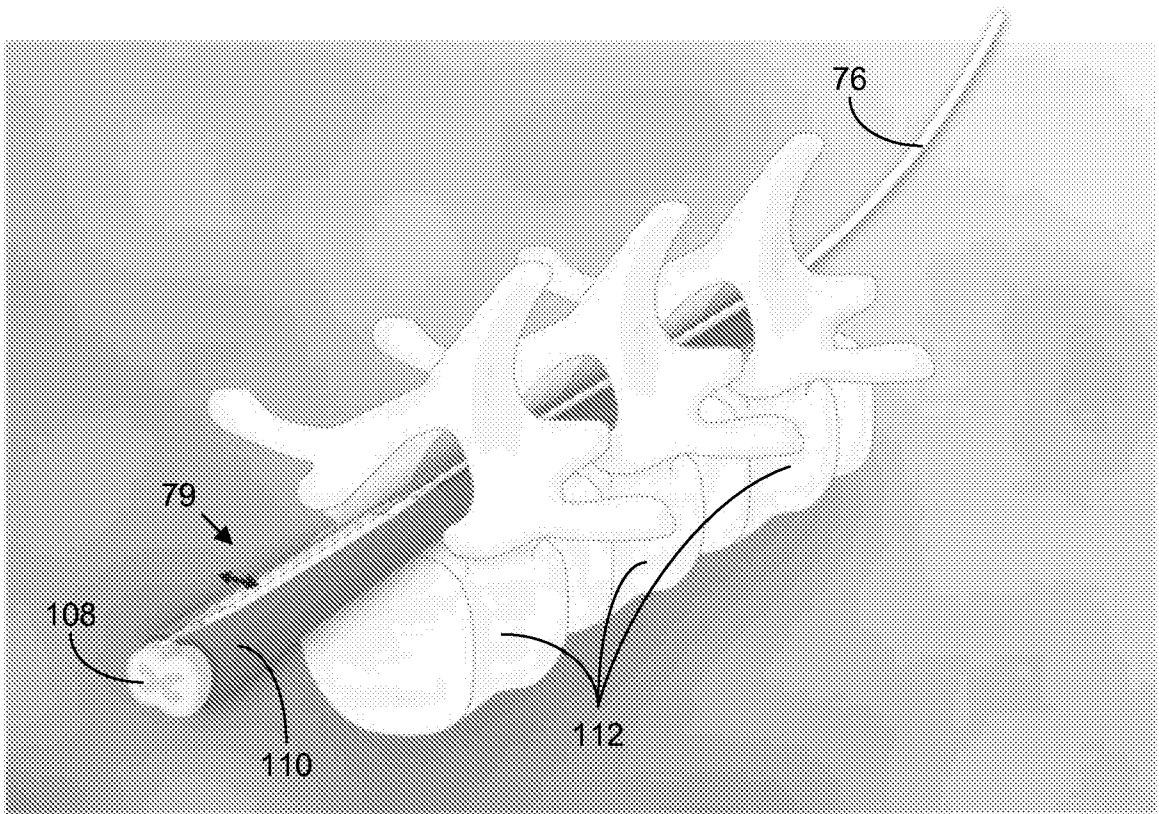


FIG. 36

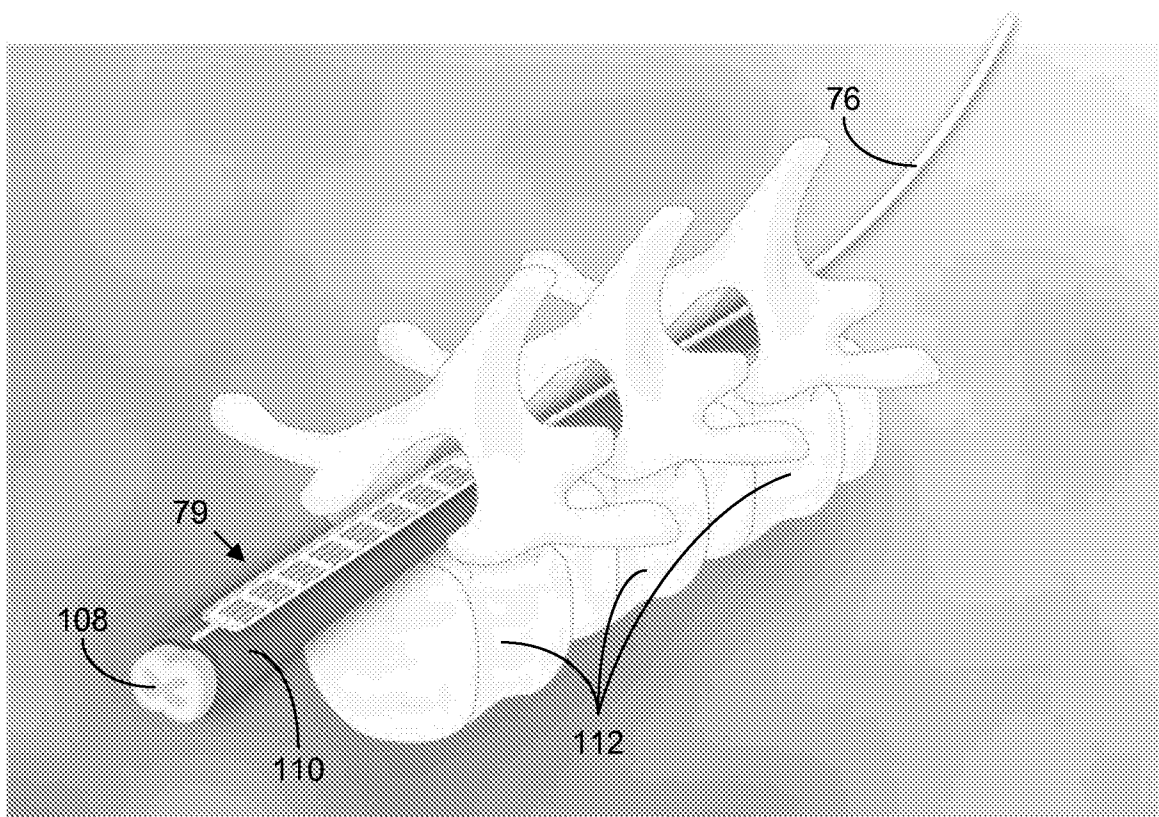


FIG. 37

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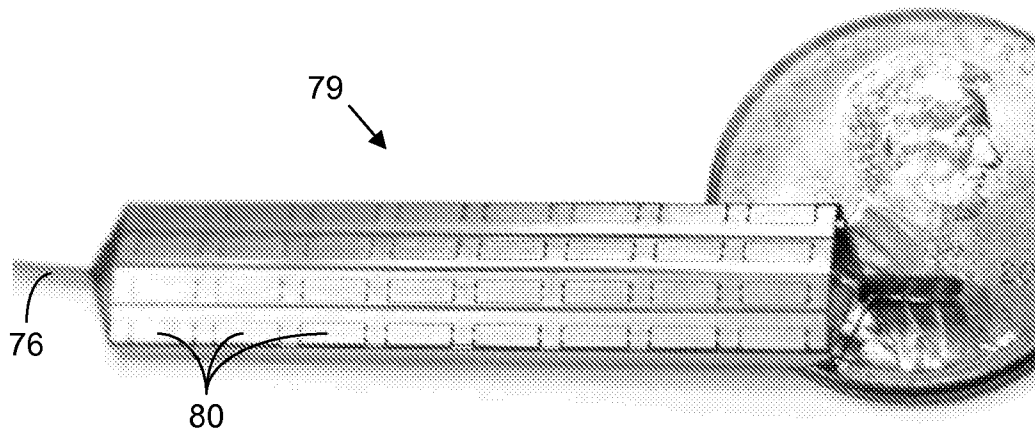


FIG. 38

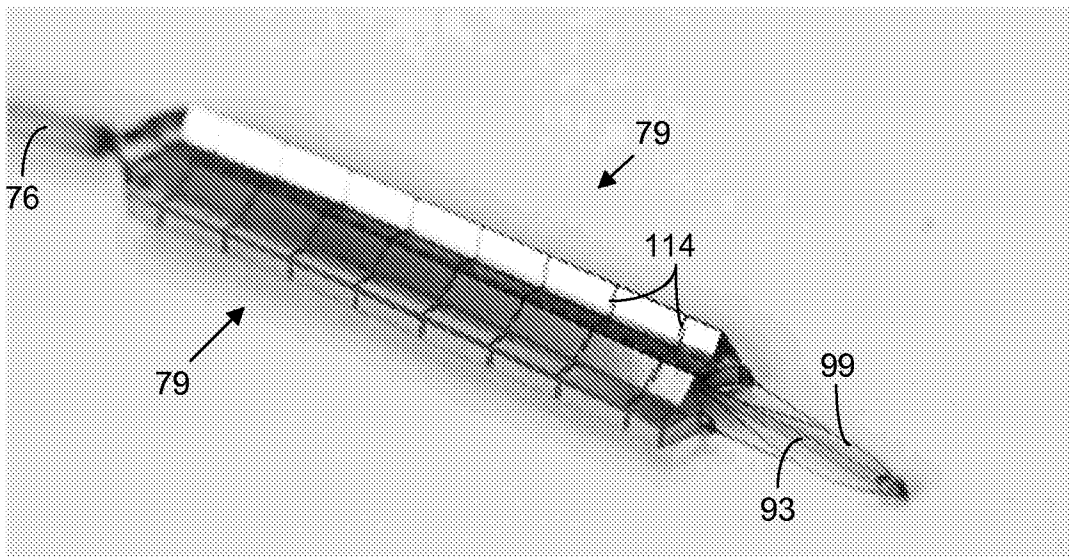


FIG. 39

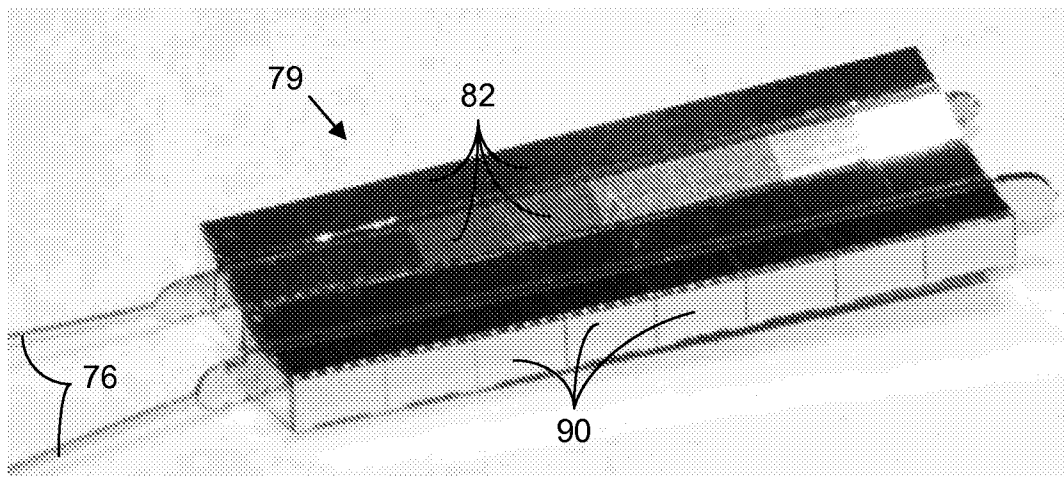


FIG. 40

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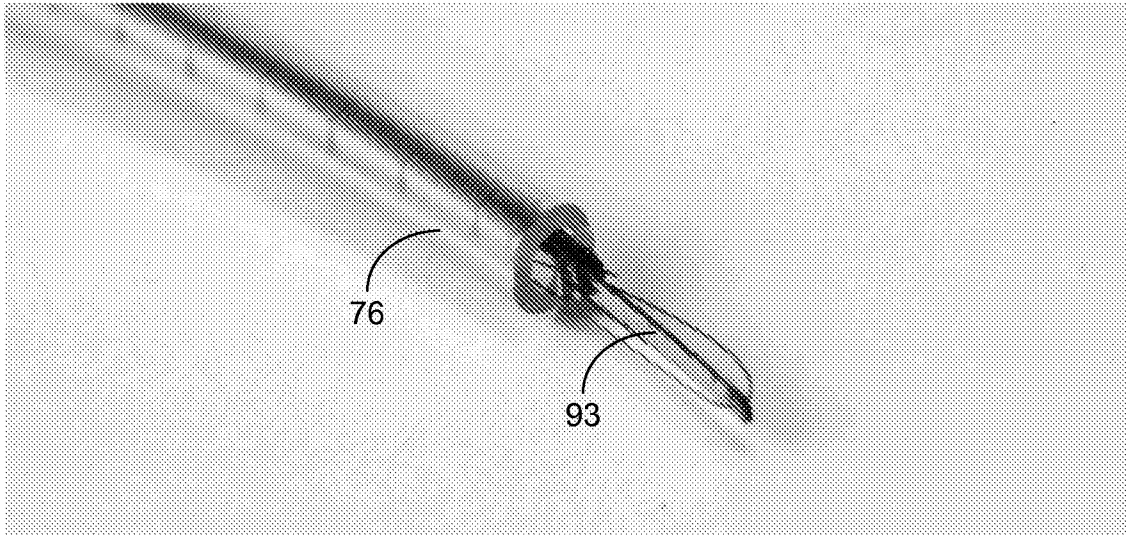


FIG. 41

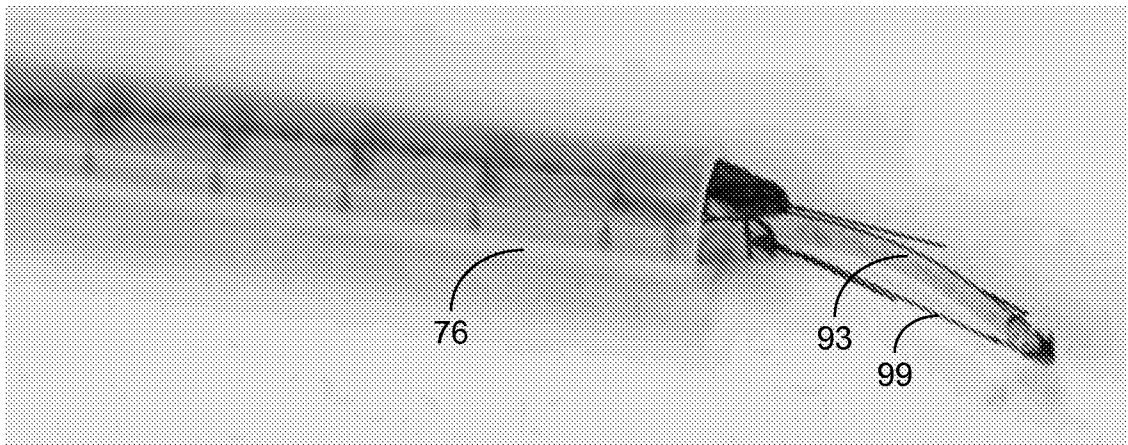


FIG. 42

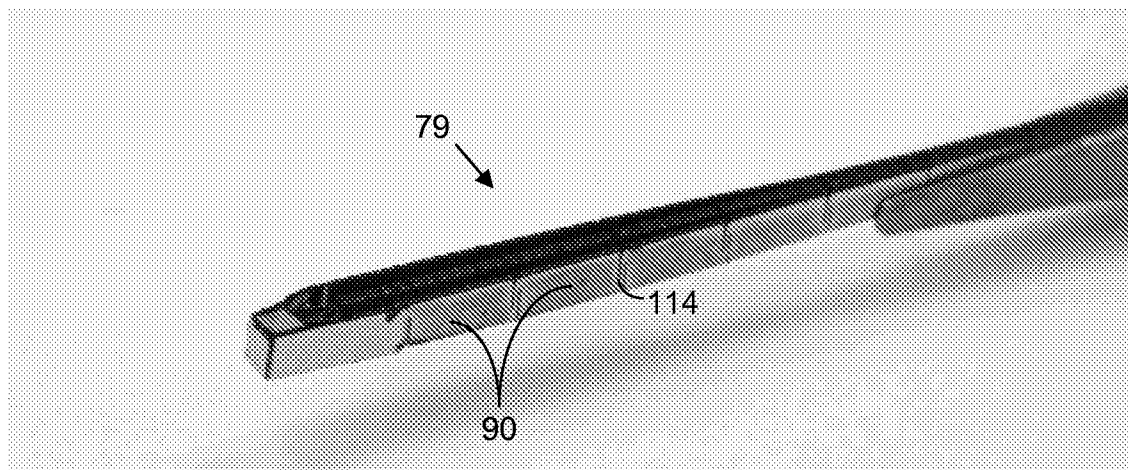


FIG. 43

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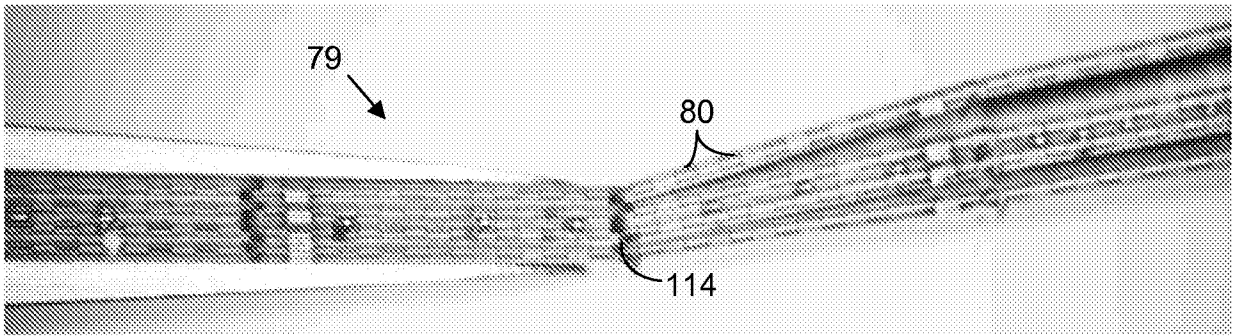


FIG. 44

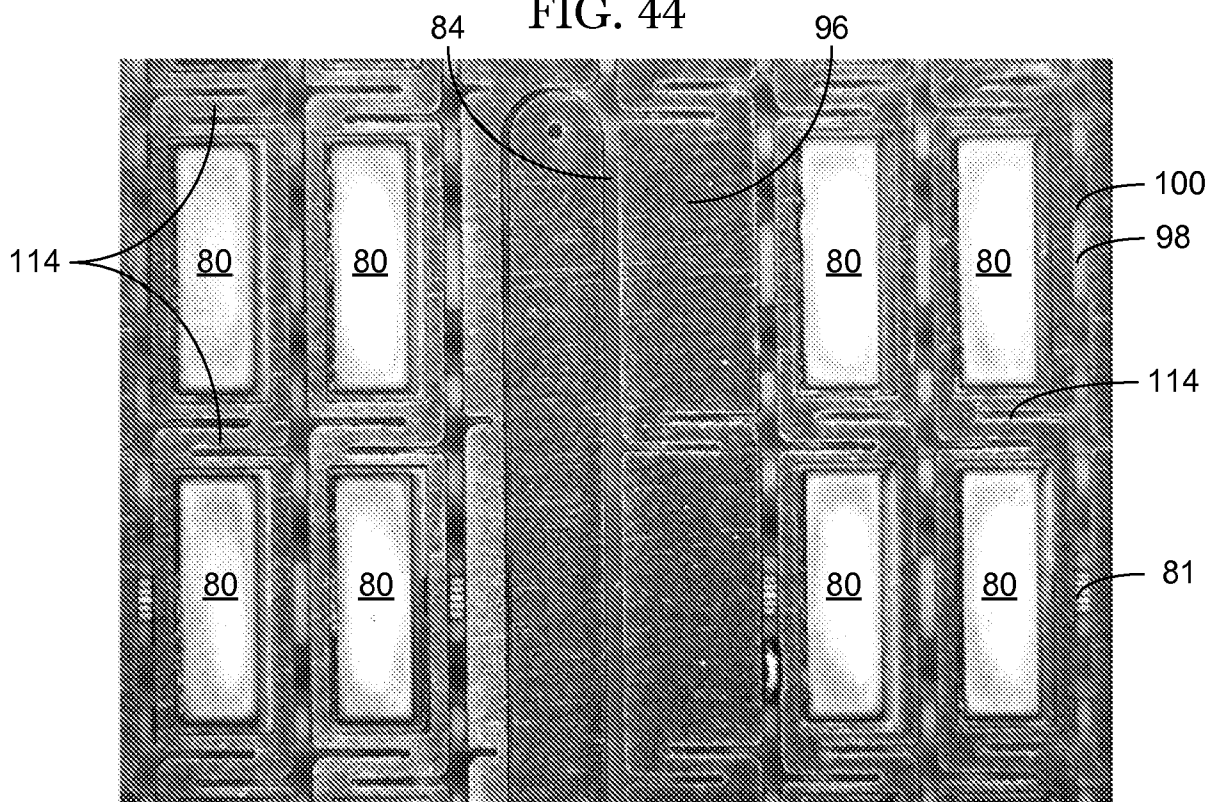


FIG. 45

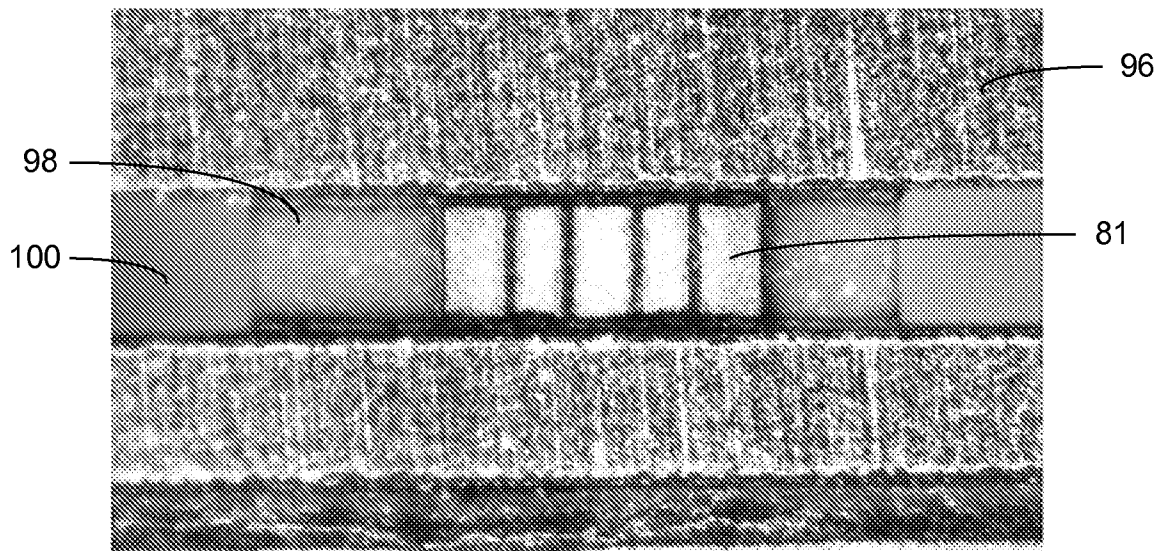


FIG. 46

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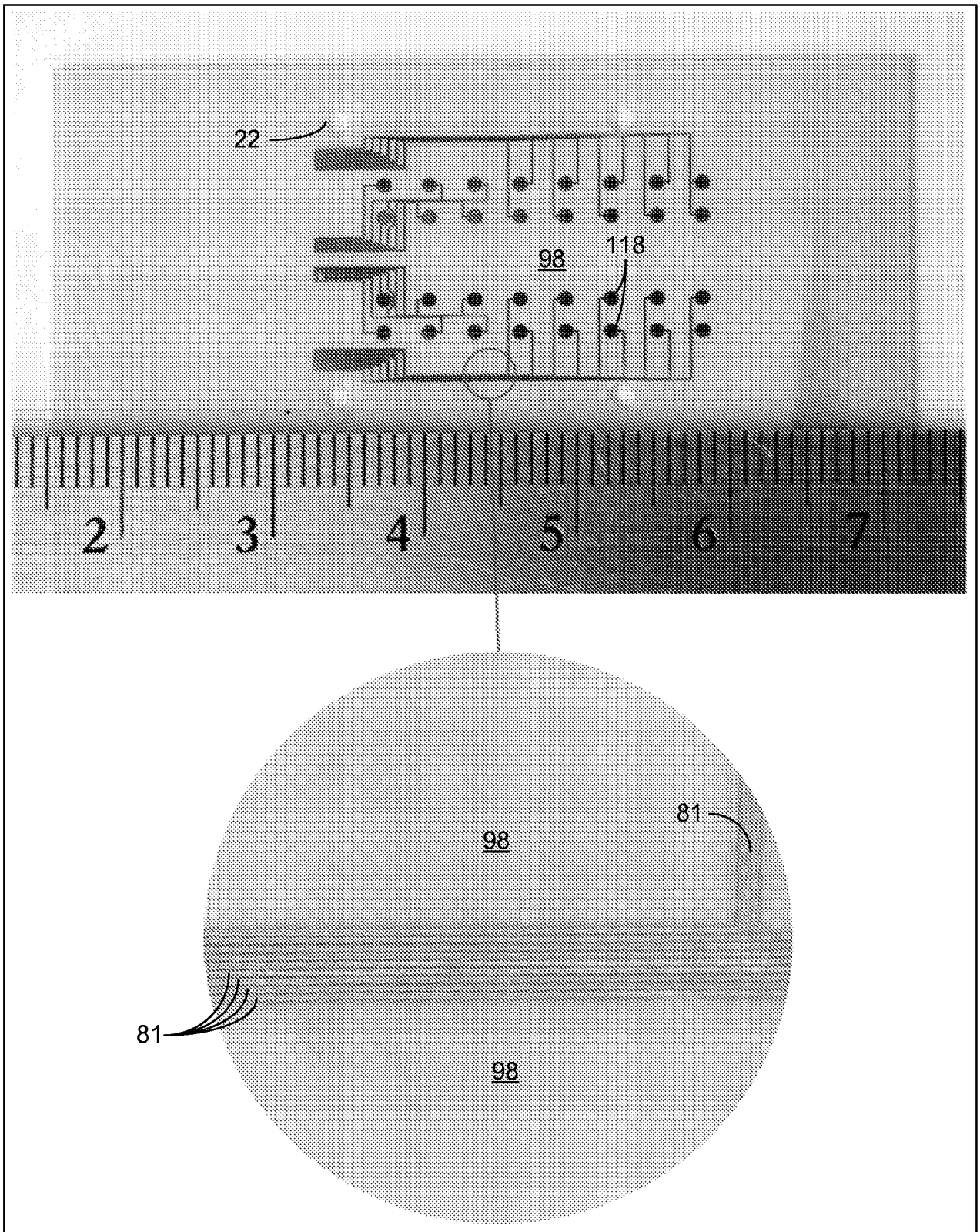


FIG. 47