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(54) Title: SYSTEMS AND METHODS FOR MONITORING AND TREATMENT OF AN INJURY

(57) Abstract: Provided herein are systems and methods for monitoring and treatment of an injury. The system includes a control device, an implantable device and/or a wearable device, the implantable device configured to be implanted into a body, the implantable device having a sensing device for sensing a condition of the injury and a treatment device configured to apply a treatment to the injury based on the sensed conditions of the injury. Signals of the sensed condition are sent to the control device, and the control device controls the treatment device of the implantable device to apply treatment for the injury. When a wearable device is included, the wearable device may be configured to sense another condition related to the injury and send signal indicative thereof to the control device.



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SYSTEMS AND METHODS FOR MONITORING AND TREATMENT OF AN INJURY

CROSS-REFERENCE TO RELATED APPLICATIONS

[001] This application claims priority to U.S. Provisional Patent Application Ser. No. 63/088,310, filed October 6, 2020, the disclosure of which is incorporated herein by reference.

BACKGROUND

[002] Few viable treatment options are available for patients who have suffered a traumatic injury, such as a spinal cord injury (SCI), brain injury, burn injury, or another type of serious injury. Spinal cord injury can be a devastating condition with lifelong complications. Spinal cord injury monitoring and interventions remain in their infancy compared with advances made for other types of injuries. For example, monitoring of intracranial pressure and tissue oxygenation are mainstays in the treatment of acute traumatic brain injury (TBI), and information gathered from this monitoring is also helpful in the prevention and mitigation of secondary injury. Similar to TBI, SCI leads to severed axons, glial scarring, and a global lack of innate regenerative capacity at the injury site during the acute phase. Secondary injury is common due to subsequent ischemia and inflammation, and it leads to further tissue destruction, prolonging recovery.

[003] Disruption of the autonomic nervous system after severe SCI, particularly rostral to thoracic level 5, where sympathetic nervous system fibers exit the spinal cord and innervate the immune system, leads to dysregulated local and systemic inflammatory responses, impairment of immune function, and increased infection risk, all of which hinder recovery after SCI. Acute inflammation in the spinal cord exacerbates the primary SCI injury, triggers secondary injury, worsens ischemia and scarring, and inhibits recovery. Chronic SCI results in long-term systemic inflammation, which is clinically exacerbated by a state of chronic immunosuppression.

[004] Spinal cord injury and other types of injury are not totally preventable. Prevention and mitigation of the pathophysiologic sequelae of an SCI devastating injury are critical to preserving spinal cord tissue and improving functional outcome after injury. In acute SCI, multimodal real-time monitoring of biomarkers such as perfusion

(pulsatility of the spinal cord) pressure, oxygenation, intrathecal pressure, temperature, and inflammatory markers does not exist. Interventions such as cerebrospinal fluid (CSF) drainage and maintaining mean arterial pressure (MAP) goals have shown great promise. Electrical stimulation has also been reported to influence inflammatory pathways. However, it is currently impossible to optimally titrate these therapies in real-time because there is no way to directly and continuously assess the spinal cord after SCI.

[005] Loss of motor control is perhaps the most obvious sequela of SCI. However, multiple systems, including the functions of cardiovascular and bladder control, are affected after this injury. Urological complications after SCI require lifelong management. SCI also causes profound disruption of the cardiovascular (CV) system, particularly in motor-complete injuries in the cervical and upper thoracic levels. CV dysregulation leads to persistent hypotension, bradycardia, orthostatic hypotension, and episodes of autonomic dysreflexia, which drastically diminish quality of life by affecting overall health and preventing patients from engaging in activities of daily life. Ultimately, the simultaneous restoration of motor, CV, and urologic systems would allow patients with SCI and certain other injuries to fully participate in daily activities.

[006] Accordingly, there is a need for systems and methods for effective monitoring and treatment of spinal cord and other injuries.

SUMMARY

[007] The present disclosure relates, in certain aspects, to methods, devices, systems, and computer readable media of use in monitoring of and treatment of an injury. In certain applications, for example, the injury may be a spinal cord injury or another type of injury. These and other aspects will be apparent upon a complete review of the present disclosure, including the accompanying figures.

[008] In accordance with some aspects, the present disclosure provides a system, device and/ or corresponding method for treatment of an injury. The system may include an implantable device configured to be implanted into a body, the implantable device having a sensing device and a treatment device, the sensing device configured to sense a first condition of the injury and to generate a signal corresponding

to the sensed condition, the treatment device configured to provide treatment to the injury, a wearable device configured to be wearable on an external portion of the body, the wearable device configured to sense a second condition of the body related to the injury, and a controller connected to the implantable device and to the wearable device, the controller configured to receive signals from the implantable device and from the wearable device and to control the implantable device to selectively cause the treatment device to apply the treatment based on the signal corresponding to the first sensed condition.

[009] In accordance with some aspects, the present invention may include a system or method that includes any combination of: 1) a control device and one implantable device; 2) a control device and a plurality of implantable devices; 3) a control device, an implantable device and a wearable device; 4) a control device and a wearable device; 5) a control device and a plurality of wearable devices; 6) a control device, a plurality of implantable devices; or a control device, an implantable device and a plurality of wearable devices.

[010] In accordance with some aspects, the present disclosure provides a system, the system including a first implantable device configured to be implanted into a body, the first implantable device having a first sensing device and a first treatment device, the first sensing device configured to sense a first condition of the injury and to generate a first signal corresponding to the first sensed condition, the treatment device configured to selectively provide treatment to the injury; a second implantable device configured to be implanted into the body, the second implantable device having a second sensing device and a second treatment device, the second sensing device configured to sense a second condition related to the injury and to generate a second signal corresponding to the first sensed condition, the treatment device configured to selectively provide treatment to the injury; and a control device connected to the first implantable device and connected to the second implantable device, the control device configured to receive the first signal from the first implantable device and the second signal from the second implantable device, and to control the first implantable device and the second implantable device to selectively cause at least one of the first treatment

device and the second treatment device to apply treatment based on the first signal and/or the second signal.

[011] In accordance with some aspects, the present disclosure provides a system, the system including a first implantable device configured to be implantable into a body adjacent the spinal cord injury, the first implantable device including an imaging device configured to create an image of the spinal cord, and including a treatment device configured to selectively treat the injury; a second implantable device configured to be implantable into the body, the second implantable device comprising a catheter device configured to selectively drain spinal fluid from the body and a plurality of sensor devices configured to sense conditions of the body; a wearable device configured to be wearable on or adjacent to an external portion of the body, the wearable device including a sensor configured to sense a condition related to the injury; and a control device connected to the first implantable device, connected to the second implantable device, and connected to the wearable device, the control device configured to receive the image from the first implantable device, to receive a signal from each of the sensor devices of the second implantable device, and to receive a signal corresponding to the sensed condition from the wearable device, and configured to control the first implantable device to cause the treatment device to selectively apply the treatment based on the image of the spinal cord, and to control the second implantable device to selectively cause the catheter device to drain the spinal fluid based on the sensed conditions of the body.

BRIEF DESCRIPTION OF THE DRAWINGS

[012] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate certain embodiments, and together with the written description, serve to explain certain principles of the methods, devices, kits, systems, and related computer readable media disclosed herein. The description provided herein is better understood when read in conjunction with the accompanying drawings which are included by way of example and not by way of limitation. It will be understood that like reference numerals identify like components throughout the drawings, unless the

context indicates otherwise. It will also be understood that some or all of the figures may be schematic representations for purposes of illustration and do not necessarily depict the actual relative sizes or locations of the elements shown.

[013] Figure 1 schematically depicts a system according to an exemplary embodiment.

[014] Figure 2 schematically shows a wearable device according to one exemplary embodiment.

[015] Figure 3 schematically shows an implantable device according to one exemplary embodiment.

[016] Figure 4 schematically shows a control device according to one exemplary embodiment.

[017] Figure 5 is a schematic diagram of an exemplary system suitable for use with certain aspects disclosed herein.

[018] Figure 6A illustrates a perspective view of one of the implantable devices: an acute cerebrospinal fluid management implant (ACMI), and Figure 6B illustrates a cross-sectional view of a portion of the ACMI, according to an embodiment.

[019] Figure 7A-D schematically show a multi-function spinal cord implant (MUSIC) device from various views according to an exemplary embodiment. FIG. 7A shows the MUSIC device from a perspective view. FIG. 7B shows the MUSIC device from a top view. FIG. 7C shows the MUSIC device positioned relative to a spinal cord. FIG. 7D shows the MUSIC device positioned relative to a spinal cord from a sectional view.

[020] Figure 8A schematically shows a MUSIC device from a top view according to an exemplary embodiment. FIG. 8B shows the MUSIC device from FIG. 8A from a partial sectional view.

DETAILED DESCRIPTION

[021] As used in this specification and the appended claims, the singular forms “a,” “an,” and “the” include plural references unless the context clearly dictates otherwise. Thus, for example, a reference to “a method” includes one or more methods, and/or steps of the type described herein and/or which will become apparent to those persons skilled in the art upon reading this disclosure and so forth.

[022] It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting. Further, unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure pertains.

[023] The present disclosure relates, in certain aspects, to systems, devices and methods for the monitoring of and treatment of injuries in humans. In some embodiments, the present disclosure relates, in certain aspects, to systems, devices and methods for the monitoring of and treatment of spinal cord injuries in humans, although the system may be used for other types of injuries such as brain injuries, burn injuries, stroke, etc.

[024] Embodiments disclosed herein provide a system and corresponding methods that can provide monitoring and stimulation of the spinal cord or area of an injury by utilizing an implantable device implantable near the injury. The implantable device may include a sensor to sense/image the injury and a first condition of the human related to the injury. The implantable device may also include a treatment device for treatment of the injury.

[025] The system may also include a wearable device configured to be worn by the human or animals. The wearable device may be configured to sense a second condition of the human related to the injury.

[026] The system may further include a control device separate from the wearable device and the implantable device. The control device may receive signals from the wearable device and from the implantable device based on the sensed first and second conditions. In response to the signals, the control device may be configured to control the treatment device.

[027] In some embodiments, the system is configured to monitor and treat spinal cord injuries (SCI), although other types of injuries could be monitored and treated, such as traumatic brain injury, burn injury, stroke, etc. The implantable device may be configured to be implanted near the spinal cord injury or other type of injury to sense conditions of and treat the spinal cord injury or other injury.

[028] As shown in FIG. 1, a system 100 is configured for monitoring and treatment of injuries to a human body. The system may include a control device 102, a wearable device 104 and an implantable device 106. The control device 102 may be configured to control the system 100. The control device 102 is connected to the wearable device 104 and to an implantable device 106. The control device 102 may be connected to the wearable device 104 and to the implantable device 106 by a wired connection, such as by cables, or in certain preferred embodiments the control device 102 may be connected to the wearable device 104 and to the implantable device 106 by a wireless connection, such as Wi-Fi, Bluetooth, etc. The system 100 may include a plurality of implantable devices 106 and/or a plurality of wearable devices 104. In some examples, the system 100 may omit the wearable device 104 and include one or more implantable device 106 and the control device 102, or the system 100 may omit the implantable device 106 and include one or more wearable device 104 and the control device 102.

[029] The wearable device 104 may be one wearable device or a plurality of wearable devices. The wearable device 104 is configured to be wearable on or in proximity to the human body. For example, the wearable device 104 may be attached by a strap or other means to a portion of the human body such as to an arm, a leg, a waist, a neck, etc. In some examples, the wearable device 104 can be held in place using a negative pressure (i.e., instead of a push on the skin or target tissue). Wearable device 104 can be placed on a sticky gel that due its stickiness, allows proper contact between the tissue/skin and wearable device 104. In some examples, the gel is made out of both biocompatible and sonolucent materials. The materials can be chosen in a manner that its acoustic properties (e.g., speed of sound and attenuation) allows for passage of ultrasonic waves without production of non-desirable echoes. In some examples, the gel can be a hydrogel, e.g., a photo-crosslinkable gel (i.e., where

wearable device 104 is positioned on the patient and a light, such as UV light, is used to make sure the gel gets solidified and sticky enough for proper contact with the body). In other examples, the gel can be a shear-thinning material (STM), such as materials that respond to pressure and make a solid paste become more liquified and easy to move. In other examples, the gel can be shear-thinning biomaterials (STB) that are used for proper contact with the body, as well as to facilitate better ultrasound energy transfer from wearable device 104 to the body. The STM/STB can be placed on the skin and when wearable device 104 is pressed on it, it liquifies just enough to accommodate wearable device 104 and establish appropriate contact with the body. After which point, the gel solidifies and hence keeps wearable device 600 on its intended placement.

[030] In alternative embodiments, the wearable device may be configured to be attached in proximity to a particular portion of the human body. For example, the wearable device 104 may be configured to be attached to clothes worn by a person. The wearable device 104 may also be integrated into or attached to another device worn by a person. For example, the wearable device 104 could be configured to attach to a watch, to a belt, to jewelry, etc.

[031] The system 100 may additionally include a software application running on a device such as an Android tablet with an SCI-specific interface for both a physician and a patient that includes an API, allowing peripherals to use the application to change device settings to support closed-loop control of the therapy.

[032] Fig. 2 illustrates further details of the wearable device 104. In certain embodiments, the wearable device may include a sensing device 108 configured to sense conditions of a human related to an injury. The sensing device 108 may be a sensor, imaging device or other type of sensing device configured to sense a condition of the human body related to an injury. For example, the sensing device 108, in some embodiments, may be configured to sense blood pressure, temperature, conditions related to a bladder such as pressure and volume, motion of human limbs such as an arm or a leg, etc.

[033] The sensing device 108 may be any type of sensing device configured to sense a condition of the human body related to the injury. In some embodiments, the

sensing device may be an imaging device, an ultrasound device, a temperature sensing device, an electromyography (EMG) sensor with accelerometers, a flow sensing device, a tissue perfusion or autoregulation sensing device, an elasticity measurement sensing device, a thermometry device, etc.

[034] The wearable device 104 in some embodiments may include a treatment device 112, although other wearable devices 104 may omit the treatment device. The treatment device 112 may be configured to apply a treatment related to the injury, or other areas in the body, such as peripheral nerves. In some embodiments described herein the treatment device may be configured to apply an electrical stimulation or some other type of treatment, as further described herein.

[035] The wearable device 104 may include a communications interface 110 for sending signals to the control device 102 and for receiving signals from the control device 102. The communications interface in some embodiments may be a wireless interface configured to send and receive signals to and from the control device 102. The signals may be indicative of the sensed conditions of the body related to the injury. The control device 102 is configured to send and receive signals to the communications interface to control the sensing device 108 of the wearable device 104 and/or to control the treatment device 112. For example, the control device can be configured to cause the sensing device 108 to be activated to sense conditions and to cause the treatment device 112 to apply treatment to the human body.

[036] Fig. 3 illustrates the implantable device 106. The system 100 may include one implantable device or a plurality of implantable devices 106. The implantable device 106 is configured to be implanted within the human body. In some embodiments, the implantable device 106 may include a sensing device 116, a treatment device 118 and a communications interface 120. The implantable device 106 may include means to affix to the body, such as a sticky surface, a strap, an inflatable member to allow for a release of moisture, moist, oil or gel, to the treatment site and/or the measurement site, etc.

[037] The sensing device 112 may be configured to sense conditions of or related to an injury to a human. For example, the sensing device 112 may be an

imaging device, a sensor or another type of sensing device. In some embodiments the sensing device may be an imaging device such as an ultrasound imaging device or other type of imaging device. In some embodiments, the sensing device 112 may be a sensor configured to sense conditions of a body related to an injury, such as a flow sensor, a pressure sensor, a temperature sensor, an oxygenation sensor, a biomarker sensor, an EMG sensor, etc.

[038] Figure 4 illustrates the control device 400 which may be equivalent to the control device 102 of Fig. 1. The control device 400 may be a computerized device such as a desktop or laptop computer, a server computer, a mobile platform (such as a mobile phone with a processor, etc. The control device 400 includes a processor 402, a memory, storage device, or memory component 404, and a communications interface 408. The memory 404 optionally includes volatile and/or nonvolatile memory including, for example, RAM, ROM, and magnetic or optical disks, among others. The control device 400 may also include a display and a user interface (not shown). In certain aspects, the communications interface allows the control device 400 to send a receive signals to and from the implantable device 106 and the wearable device 104. The control device 400 also includes program product 406 stored in the memory 404.

[039] Exemplary program product or machine readable medium 406 is optionally in the form of microcode, programs, cloud computing format, routines, and/or symbolic languages that provide one or more sets of ordered operations that control the functioning of the hardware and direct its operation. Program product 406, according to an exemplary aspect, also need not reside in its entirety in volatile memory, but can be selectively loaded, as necessary, according to various methodologies.

[040] The term "computer-readable medium" or "machine-readable medium" refers to any medium that participates in providing instructions to a processor for execution. To illustrate, the term "computer-readable medium" or "machine-readable medium" encompasses distribution media, cloud computing formats, intermediate storage media, execution memory of a computer, and any other medium or device capable of storing program product 508 implementing the functionality or processes of various aspects of the present disclosure, for example, for reading by a computer. A

"computer-readable medium" or "machine-readable medium" may take many forms, including but not limited to, non-volatile media, volatile media, and transmission media. Non-volatile media includes, for example, optical or magnetic disks. Volatile media includes dynamic memory, such as the main memory of a given system. Transmission media includes coaxial cables, copper wire and fiber optics, including the wires that comprise a bus. Transmission media can also take the form of acoustic or light waves, such as those generated during radio wave and infrared data communications, among others. Exemplary forms of computer-readable media include a floppy disk, a flexible disk, hard disk, magnetic tape, a flash drive, or any other magnetic medium, a CD-ROM, any other optical medium, punch cards, paper tape, any other physical medium with patterns of holes, a RAM, a PROM, and EPROM, a FLASH-EPROM, any other memory chip or cartridge, a carrier wave, or any other medium from which a computer can read.

[041] In some aspects, program product 406 includes non-transitory computer-executable instructions which, when executed by electronic processor 402 perform at least: monitoring and treatment of injuries in a human by controlling the implantable device 106 and/or the wearable device 104. The systems and methods disclosed herein may include machine learning such that the systems can adapt by learning. For example, the system 100 can monitor how a human reacts to various treatments applied by the implantable device 106 and/or the wearable device 104 and learn how to better apply the treatments to various sensed conditions.

[042] Figure 5 illustrates a system 500 according to a particular embodiment. The system 500 may be configured for monitoring and treatment of a spinal cord injury of a human, although the system 500 could be used for other types of injuries, such as a brain injury, etc. The system 500 includes a control device 502, a plurality of implantable devices 504 and 506, and a plurality of wearable devices 508, 510 and 512. One or more of the implantable devices 504 and 506 and the plurality of wearable devices 508, 510 and 512 could be omitted from the system 500. The control device 502 may be configured in a same manner as the control device 400.

[043] The wearable device 508 may be a wearable device configured to sense

a blood pressure of a human wearing the wearable device. In some embodiments, the wearable device may be configured to sense a tissue perfusion or autoregulation of a spinal cord. In Fig. 5, the wearable device is shown wearable over an arm of a human, although the wearable device 508 could be positioned in a different location, such as on a torso, a leg, etc. The wearable device 508 may include a sensing device to sense a blood pressure. The wearable device 508 may be configured to generate signals indicative of the sensed conditions, and to send the signals to the control device 102. The wearable device 508 may include means to affix to the body, such as a sticky surface, a strap, an inflatable member to allow for a release of moisture, moist, oil or gel, to the treatment site and/or the measurement site, etc.

[044] The wearable device 510 may be a wearable device configured to sense a bladder volume and or bladder pressure of a human wearing the wearable device. In Fig. 5, the wearable device is shown. The wearable device 510 may include a sensing device to sense a bladder pressure and/or volume. The wearable device 510 may be configured to generate signals indicative of the sensed conditions, and to send the signals to the control device 102. The wearable device 510 may include means to affix to the body, such as a sticky surface, a strap, an inflatable member to allow for a release of moisture, moist, oil or gel, to the treatment site and/or the measurement site, etc.

[045] The wearable device 512 may be an EMG wearable device configured to sense/detect motor functions of a human wearing the wearable device. In Fig. 5, the wearable device 512 is shown wearable in a leg area of a human, although the wearable device 512 could be positioned in a different location. The wearable device 512 may include a sensing device or devices to sense a motor functions. The wearable device 512 may be configured to generate signals indicative of the sensed conditions, and to send the signals to the control device 102. The wearable device 512 may include means to affix to the body, such as a sticky surface, a strap, an inflatable member to allow for a release of moisture, moist, oil or gel, to the treatment site and/or the measurement site, etc.

[046] In some examples, the wearable device 512 can further comprise a

photoacoustic transceiver that provides light pulses to the monitoring site and/or the treatment site and receives ultrasound energy from the monitoring site and/or the treatment site, such as by using a transducer array (one or more transducers). In some examples, the wearable device 512 can further comprise a photothermal transmitter and a thermal camera, such as by the transducer array (one or more transducers), wherein the photothermal transmitter provides light pulses to the monitoring site and/or the treatment site and the thermal camera detects thermal changes at the monitoring site and/or the treatment site.

[047] In some embodiments, a plurality of the wearable devices 512 may be utilized. For example, in some embodiments, a wearable device could be wearable on each arm and each leg, so that the system could monitor motor function of each arm and leg.

[048] In some embodiments, the wearable device may include one or a plurality of accelerometers. In some embodiments, the accelerometers may be configured to generate signals indicative of a limb's motion in real time. The wearable device may be configured to send such signals to the control device 102.

[049] The implantable device 504 may be a multi-function spinal cord implant (MUSIC). The multi-function spinal cord implant 504 may include one or more imaging or sensing devices and one or more treatment devices. In a preferred embodiment, the imaging devices may include an ultrasound imaging array or arrays to generate three-or four-dimensional images of the spinal cord at an injury location and an electrical array or arrays for electrical recording, although other types of imaging or sensing devices could be used. The treatment devices may include an electrical stimulation device or devices for applying electrical stimulation and a focused ultra-sound (FUS) device or devices for applying focused ultra-sound treatment, although other types of treatment devices may be used.

[050] In some embodiments, the implantable device 504 may comprise a photoacoustic transceiver that provides light pulses to a target location (e.g., a monitoring site and/or treatment site) and receives ultrasound energy from the target location. In some embodiments, the implantable device 504 may comprise a

photothermal transmitter and a thermal camera in which the photothermal transmitter provides light pulses to the target location (e.g., a monitoring site and/or treatment site) and the thermal camera detects thermal changes at the target location. In some of these embodiments, for example, the implantable device 504 may be configured to perform deep-tissue temperature sensing.

[051] The multi-function spinal cord implant 504 may be a multimodal, conformal, wireless epidural implant device for use in patients with acute or chronic SCI. The multi-function spinal cord implant 504 may be configured to: a) produce three-dimensional, real-time, high-resolution imaging at the injury site to monitor and prevent secondary injury; b) evaluate and assess the reestablishment of autoregulation to optimize acute intervention; (c) measure biomarkers using aptamers; (d) enhance blood flow and potential neural regeneration as a result of acoustic neuromodulation/focused ultrasound (FUS) at the site of injury; (e) actuate release of encapsulated pharmacotherapeutic agents; (f) measure temperature of spinal cord, using ultrasound thermometry; (g) measure electrical conductivity above and below the site of injury; and (h) stimulate and record neurophysiological data with electrodes. In some embodiments, the multi-function spinal cord implant 504 may conform to the dorsal spinal cord while displacing a volume of only about 50 mm³.

[052] In some embodiments, the multi-function spinal cord implant 504 may be wirelessly powered from an external “relay station” attached outside the body at the implant site. This facilitates higher power levels without bulky battery implants. In some embodiments, the multi-function spinal cord implant 504 may communicate with the relay station via a custom ultra-wide-band networking protocol that may support 200 Mbps uplink and 100 Mbps downlink. The relay station may be an 802.11 device that communicates wirelessly with the control device 102.

[053] In some embodiments, the multi-function spinal cord implant (MUSIC) 504 may be configured to interface with custom-designed encapsulating hydrogel scaffolds that can be stimulated with focused ultrasound (FUS) to deliver pharmacotherapeutic agents. FUS may also be used to enhance blood flow at the site of the injury. In some embodiments, the multi-function spinal cord implant 504 may be a

biocompatible, permanently implantable wireless device. In some embodiments, the multi-function spinal cord implant 504 may be a biodegradable or bioresorbable implant.

[054] The implantable device 506 may be a cerebrospinal fluid (CSF) management implant, also referred to as an acute CSF management implant (ACMI), 506, although other type of implantable devices could be used. In some embodiments, the ACMI 506 may be a smart spinal fluid drainage catheter. In some embodiments, the ACMI 506 may be configured to drain CSF while simultaneously using fiber optics technology to sense biomarkers such as intrathecal pressure, oxygenation, lactate, and temperature.

[055] In some embodiments, ACMI 506 may include one or a plurality of sensors. The sensors may be configured to sense/detect temperature, pressure and biomarkers. In some embodiments, the ACMI 506 may be configured to include optical sensors for measuring intrathecal pressure and temperature. In some embodiments, ACMI 506 may include sensors such as a fiber-optic, spectroscopy system that monitors spinal cord oxygenation by providing nearly continuous CSF concentration measurements of oxygenation indicators, such as lactate, glutamate, cytochrome C, L-citrulline, S100b, IL-6, GFAP, bilirubin, ascorbate, or a combination thereof.

[056] In some embodiments, ACMI 506 may include a drainage catheter to remove spinal fluid to adjust intraspinal pressure. In some embodiments, ACMI 506 measuring and managing CSF pressure throughout the acute phase of neurological injury.

[057] As mentioned above, the system 100, 500 may include six devices. Three of the devices may be remote wireless wearable devices, and three of the devices may be implantable devices. One of the implantable devices may be an acute cerebrospinal fluid management implant (ACMI), such as ACMI 506. The ACMI may be configured to be implanted at least partially into a subarachnoid space in a spine in a body. The ACMI may serve as a smart multi-luminal spinal fluid drainage catheter. The ACMI may be capable of simultaneously draining cerebrospinal fluid (CSF) and sensing parameters such as intrathecal pressure, temperature, lactate, and oxygenation. Modulating the CSF in the subarachnoid space may adjust intraspinal pressure, which

may enhance cerebral blood flow. In one embodiment, a cardiac-gated oscillatory balloon may be implanted at least partially within the ACMI to enhance spinal cord perfusion (pulsatility of the spinal cord) at the site of the injury and the penumbral zone. The ACMI may be biocompatible, flexible, and small enough in diameter to be inserted with minimal flow disruption into a spinal drainage catheter.

[058] Figure 6A illustrates a perspective view of the ACMI 600, according to an embodiment. The ACMI 600 may be the same as or different from the ACMI 506 described above. The ACMI 600 may include a cannula 610. The cannula 610 may be or include a thin tube that is configured to be inserted into a vein or body cavity to administer medicine, drain off fluid, or insert a surgical instrument. In one embodiment, the cannula 610 may have a cross-sectional width (e.g., diameter) from about 1 mm to about 3 mm, about 1.5 mm to about 2.5 mm, or about 1.75 mm to about 2.25 mm. The cannula 610 may define drainage bore 612. The cannula 610 may include a plurality of openings (also referred to as a fenestrated tip) 620 that provide a path of fluid communication between the exterior of the cannula 610 and the interior of the cannula 610 (e.g., the drainage bore 612). The openings 620 may extend in a substantially radial direction with respect to a central longitudinal axis 611 through the cannula 610. The openings 620 may be located proximate to an end portion of the cannula 610. The fluid may flow into the bore 612 via the openings 620. In one example, the openings 620 may serve to drain CSF from the spine (e.g., from the subarachnoid space).

[059] Figure 6B illustrates a cross-sectional view of a portion of the ACMI 600 in Figure 6A, according to an embodiment. In addition to the drainage bore 612, the ACMI 600 may also define one or more sensor bores (three are shown: 614, 616, 618). The sensor bores 614, 616, 618 may be positioned radially-outward from the drainage bore 612. The sensor bores 614, 616, 618 may be circumferentially offset from one another around the central longitudinal axis 611 and/or the drainage bore 612. The sensor bores 614, 616, 618 may each have a smaller diameter than the drainage bore 612. For example, one or more of the sensor bores 614, 616, 618 may have a diameter from about 0.2 mm to about 0.6 mm, about 0.3 mm to about 0.5 mm, or about 0.4 mm, and the drainage bore 612 may have a diameter from about 0.5 mm to about 1 mm, about 0.6 mm to about 0.8 mm, or about 0.7 mm.

[060] The ACMI 600 may also include one or more sensors. In the embodiment shown, there are three sensors 630, 640, 650, which may be positioned at least partially in the sensor bores 614, 616, 618. One or more of the sensors 630, 640, 650 may be or include fiber optic sensors, although other types of sensors could be utilized.

[061] The first sensor 630 may be or include a biomarker sensor that is configured to sense one or more biomarkers (e.g., in the fluid in the subarachnoid space in the spine in the body). The biomarker(s) may be or include lactate, glutamate, cytochrome C, L-citrulline, S100b, IL-6, GFAP, bilirubin, ascorbate, or a combination thereof. As described below, the biomarker(s) may be used to determine a concentration of oxygenation in the CSF.

[062] In one embodiment, the first sensor 630 may be or include an evanescent wave spectrophotometer. Thus, the first sensor 630 may include a light source 632 that is configured to transmit light. The light may have a wavelength that substantially matches (e.g., +/- 20 nm) a peak wavelength of an intrathecal optical absorption of the biomarker (e.g., lactate). The first sensor 630 may also include a beam splitter 634 that is configured to separate the transmitted light from received light. In one embodiment, a directional coupler may be used instead of, or in addition to, the beam splitter. Absorbed light is equal to the transmitted light minus the received light. The first sensor 630 may also include a first fiber optic sensor 636 that is configured to measure the absorbed light. The absorbed light may then be used to determine a chemical concentration of the CSF without altering the chemical concentration of the CSF. The chemical concentration of the CSF may then be used to determine the intrathecal optical absorption of the biomarker (e.g., lactate). As mentioned above, the intrathecal optical absorption of the biomarker may then be used to determine the concentration of oxygenation in the CSF.

[063] The second sensor 640 may be located at least partially in the second sensor bore 616. The second sensor 640 may be or include a pressure sensor that is configured to measure a pressure of the fluid (e.g., in the subarachnoid space in the spine in the body). For example, the second sensor 640 may be or include an extrinsic

interferometer. The second sensor 640 may be or include a drum-like structure 642 and a flexible membrane (e.g., a diaphragm) 644 that define a cavity (e.g., a Fabry-Perot cavity) 646 therebetween. The second sensor 640 may also include a second fiber optic sensor 648 into which the light is reflected back to the signal conditioner. The second sensor 640 may be configured to measure a phase shift of the transmitted light (e.g., light transmitted from the first sensor 630 and/or the second sensor 640) due to deflection of the diaphragm 644 located at a tip of the second sensor 640. The phase shift may then be used to determine the intrathecal pressure of the fluid in the subarachnoid space in the spine in the body.

[064] The third sensor 650 may be located at least partially in the third sensor bore 618. The third sensor 650 may be or include a temperature sensor that is configured to measure a temperature of the fluid (e.g., in the subarachnoid space in the spine in the body). The third sensor 650 may be or include a third fiber optic sensor. For example, the third sensor 650 may be or include an internal Bragg grating that is configured to measure an intrathecal temperature of the fluid in the subarachnoid space in the spine in the body.

[065] Referring again to Figure 6A, while the ACMI 600 is implanted in the body, the ACMI 600 (e.g., the sensors 630, 640, 650) may be configured to communicate with a control device (also referred to as a computing system) 660 that is located outside of the body. The control device 660 may be or include one or more of the control devices (e.g., 102, 400, and/or 502) described above. The communication may be wirelessly or via one or more wires.

[066] Another implantable device may be utilized with the system 500, an epidural spinal stimulator (ESS) device. In some embodiments, the ESS device may be a biocompatible epidural implant. Like the other implantable devices, the ESS device may be biodegradable or bioresorbable as well. The ESS implantable device may be placed at the lumbosacral level (L1-S2), such as in the post-acute period of injury.

[067] In some embodiments, the ESS device may be configured with electrodes configured to selectively apply electrical stimulation of the spinal cord, particularly of the dorsal lumbosacral spinal cord. Dorsal epidural electrical stimulation

does not induce movement by directly activating motor pools. Instead, it enables motor function by (1) stimulating medium- and large-diameter afferent fibers in lumbar and upper sacral posterior roots that transmit proprioceptive information from muscle spindle primary endings in the legs to the spinal cord and trans-synaptically engaging interneurons that integrate the proprioceptive inputs and central pattern generator networks. Epidural electrical stimulation modulates spinal circuits into a physiological state that allows for task-specific sensory input derived from movements to serve as a source of motor control.

[068] In certain embodiments, motor outputs of the stimulation provided by the ESS device can be monitored and characterized by an accelerometer as well as by EMG potentials in target muscles. The EMG wearable device 512 may be used in conjunction with the ESS device in a manner that when the ESS device applies electrical stimulation, the EMG device monitors and generates signals indicative of the movement of the limbs of a human (or an animal).

[069] In some embodiments, properties of the signals generated by the EMG wearable device, such as latencies and peak-to-peak amplitudes, will be fed back to the epidural stimulation console to provide real-time information on locomotor output that are used to dynamically modulate and optimize stimulation parameters.

[070] The ESS device may be configured to provide extremely fine temporal resolution (i.e., time resolution of 10 μ s), increased independent rate options for programs providing therapy simultaneously, and independent amplitude control on each active electrode. The control device 102 may be configured with an ESS application programming interface (API), may be configured to wirelessly adjust the stimulation provided by the ESS device, at a rate of, for example, up to six times per second. In conjunction with intent information decoded from the individual's neural activity (the MUSIC device), posture and muscle-firing information (wearable EMG and accelerometer), bladder and cardiovascular (CV) parameters (wearable sensors), and machine learning algorithms for closed-loop neuromodulation, the ESS device is configured to be used to restore complex motor, bladder, and CV control.

[071] In some embodiments, the ESS device is configured to be used along

with the other elements of the system 100 to restore complex motor, bladder, and CV control to an individual with a SCI. For example, when electrical stimulation is provided by the ESS device, the control device can receive signals from the sensor devices to monitor motor, bladder and CV control in response thereto.

[072] In some embodiments, the ESS device can use a MICS band/Bluetooth relay, with USB or Bluetooth connection to the control device 102. MICS band communication will allow the control device to be several feet away from the patient while still providing therapy in a closed-loop manner through distance telemetry.

[073] In some embodiments, the ESS device is configured to be implanted subcutaneously in the abdomen, flank, or upper buttock area, but could be implanted elsewhere. consists of a hermetic titanium enclosure housing stimulation and telemetry electronics with a battery. In some embodiments, the ESS device is configured to be used to stimulate the lumbar area of the spinal cord to provide SCI therapy.

[074] In some embodiments, the system 100, 500 may be used to treat and monitor an individual with a SCI. For example, an individual with a SCI, such as a severe thoracic SCI, can have the ACMI device 506 implanted at subarachnoid space, and the MUSIC device 504 implanted epidurally at the site of the injury.

[075] The ACMI device 506 is used for selectively draining CSF based on sensed feedback from its sensors. For example, the sensors the ACMI device may be configured to sense intrathecal pressure, oxygenation, lactate, and temperature, and feed signals indicative of the sensed conditions to the control device 102. The control device can control the ACMI device 506 to then selectively draining CSF based on analyzing the signals.

[076] The MUSIC device 504 utilizes its ultrasound and/or electrical imaging sensors to generate planar (two-) three- or four-dimensional, real-time, high-resolution imaging at the injury site to monitor and prevent secondary injury, and to selectively provide acoustic neuromodulation and/or focused ultrasound (FUS) at the site of injury. The MUSIC device 504 may be configured to generate signals/images based on conditions sensed by its sensors, and to send those signals to the control device 102.

The control device 102 may be configured to selectively provide acoustic neuromodulation and/or focused ultrasound based on analyzing the received signals.

[077] In a post-acute period, the ESS device may be implanted, and the wearable devices 104 may be worn and utilized with the system 100, 500. The ESS device may be configured to selectively apply electrical stimulation of the dorsal lumbosacral spinal cord based on sensed conditions from any of the wearable devices 104 or the implantable devices 106.

[078] The system 100, 500 includes software programs (algorithms) as program product 406 that include a machine-learning modelling framework. All sensed data may be loaded to a persistent datastore. The data in the datastore is used with a real-time implementation of a multimodal time-series classification network built on efficient implementations of deep convolutional neural networks for processing multi-scale spatiotemporal representations. The networks are trained to predict optimal interventions (e.g., stimulation with electrodes, ultrasound, and drug delivery) based on simultaneous analysis of the MUSIC implant's electrode array, ultrasound measurements, and ACMI biomarker inputs, for example. Regression models based on deep features extracted from ultrasound using convolutional neural networks, can be used to estimate bladder state and blood pressure. As the amount of chronic data in the datastore increases and more functionality is demanded from the system, the algorithms are trained and deployed to predict improved stimulation patterns from multimodal inputs.

[079] The present disclosure also provides various systems and computer program products or machine readable media. In some aspects, for example, the methods described herein are optionally performed or facilitated at least in part using systems, distributed computing hardware and applications (e.g., cloud computing services), electronic communication networks, communication interfaces, computer program products, machine readable media, electronic storage media, software (e.g., machine-executable code or logic instructions) and/or the like.

[080] As understood by those of ordinary skill in the art, memory 404 of the control device 400 optionally includes volatile and/or nonvolatile memory including, for

example, RAM, ROM, and magnetic or optical disks, among others. It is also understood by those of ordinary skill in the art that although illustrated as a control device, the illustrated configuration of control device 400 is given only by way of example and that other types of servers or computers configured according to various other methodologies or architectures can also be used. As also understood by those of ordinary skill in the art, the control device 400, for example, can be a laptop, desktop, tablet, personal digital assistant (PDA), cell phone, server, or other types of computers.

[081] As further understood by those of ordinary skill in the art, exemplary program product or machine readable medium 406 is optionally in the form of microcode, programs, cloud computing format, routines, and/or symbolic languages that provide one or more sets of ordered operations that control the functioning of the hardware and direct its operation. Program product 406, according to an exemplary aspect, also need not reside in its entirety in volatile memory, but can be selectively loaded, as necessary, according to various methodologies as known and understood by those of ordinary skill in the art.

[082] As further understood by those of ordinary skill in the art, the term "computer-readable medium" or "machine-readable medium" refers to any medium that participates in providing instructions to a processor for execution. To illustrate, the term "computer-readable medium" or "machine-readable medium" encompasses distribution media, cloud computing formats, intermediate storage media, execution memory of a computer, and any other medium or device capable of storing program product 508 implementing the functionality or processes of various aspects of the present disclosure, for example, for reading by a computer. A "computer-readable medium" or "machine-readable medium" may take many forms, including but not limited to, non-volatile media, volatile media, and transmission media. Non-volatile media includes, for example, optical or magnetic disks. Volatile media includes dynamic memory, such as the main memory of a given system. Transmission media includes coaxial cables, copper wire and fiber optics, including the wires that comprise a bus. Transmission media can also take the form of acoustic or light waves, such as those generated during radio wave and infrared data communications, among others. Exemplary forms of computer-readable media include a floppy disk, a flexible disk, hard disk, magnetic tape, a flash drive, or

any other magnetic medium, a CD-ROM, any other optical medium, punch cards, paper tape, any other physical medium with patterns of holes, a RAM, a PROM, and EPROM, a FLASH-EPROM, any other memory chip or cartridge, a carrier wave, or any other medium from which a computer can read.

[083] Program product 406 is optionally copied from the computer-readable medium to a hard disk or a similar intermediate storage medium. When program product 406, or portions thereof, are to be run, it is optionally loaded from their distribution medium, their intermediate storage medium, or the like into the execution memory of one or more computers, configuring the computer(s) to act in accordance with the functionality or method of various aspects. All such operations are well known to those of ordinary skill in the art of, for example, computer systems.

[084] To further illustrate, in certain aspects, this application provides systems that include one or more processors, and one or more memory components in communication with the processor. The memory component typically includes one or more instructions that, when executed, cause the processor to provide information that causes at least one result, data, and/or the like to be displayed or otherwise indicated (e.g., via a result indicator of control device 400) and/or receive information from other system components and/or from a system user (e.g., via communication interface 408 or the like).

[085] In some aspects, program product 406 includes non-transitory computer-executable instructions which, when executed by electronic processor 402 perform at least execution of algorithms contained in the computer program product 406 configured to perform the functionality described herein.

[086] FIGS. 7A-D show a MUSIC device from various views according to an exemplary embodiment. As shown, the MUSIC device 700 includes a body structure 701, which includes imaging array 702 and stimulation array 704. FIGS. 7C and 7D show the MUSIC device 700 positioned relative to a spinal cord 710 as well as an imaging plane 706 and a therapy area 708. The body structure 701 also includes substantially rigid sections and substantially flexible sections. As shown, subassemblies (i.e., imaging array 702 and stimulation array 704) are disposed in a substantially rigid

section. In some embodiments, the body structure 701 comprises a length of less than about 100 millimeters (e.g., about 75 mm, about 50 mm, about 25 mm, or less), a width of less than about 10 millimeters (e.g., about 9 mm, about 8 mm, about 7 mm, about 6 mm, about 5 mm, or less), and a depth of less than about 5 millimeters (e.g., about 4 mm, about 3 mm, about 2 mm, about 1 mm, or less). In some embodiments, for example, the MUSIC device body structure comprises a form-factor about the size of a BAND-AID®. In one embodiment, for example, the overall dimensions of the MUSIC device are 39 mm length, 9.7 mm width, and 2.4 mm height.

[087] FIG. 8A shows a MUSIC device 800 from a top view according to an exemplary embodiment. FIG. 8B shows the MUSIC device 800 from FIG. 8A from a partial sectional side view. As shown, the MUSIC device 800 includes a body structure 802, which includes healthy site imaging array or transducer 804, injured site imaging arrays or transducers 806, stimulation arrays 808 (e.g., an ultrasonic stimulation array), and electrode arrays 810 disposed in rigid sections of the body structure 802. In some embodiments, these subassemblies are disposed in flexible sections of device body structures. In these embodiments, MUSIC devices are typically operably connected to a position tracking system that tracks angular and torsional deflection to accurately control, for example, the ultrasonic stimulation. In some embodiments, subassemblies of MUSIC devices are operably connected to power sources via flexible and/or rigid circuits.

[088] In some embodiments, the stimulation arrays 808 have a spatial frequency of half lambda. This allows the beam to radiate with very little directivity within the sagittal plane, which allows for the focus to move throughout a large volume in front of the arrays through applying time delay or phasing to the signals. In some embodiments, there is effectively a 1 to 1 relationship from the radiating surface to the focal zone of the device. In some embodiments, the beam can then be swept around to cover the volume in front of the arrays with a collimating beam if subsequent focal positions are time averaged. Typically, the stimulation arrays 808 provide coverage from about 4 mm to about 12 mm in depth.

[089] In some embodiments, the MUSIC device is inserted through the skin of

a patient and is positioned alongside the spine. In these embodiments, the implanted end of the device is typically encapsulated, providing a smooth gap free surface to minimize tissue response of the device. In some embodiments, an over-mold extends outside of the surgical incision before transitioning to a bare flex circuit. The flex circuit is typically a multi-layer assembly. In some embodiments, the entire length of flex circuit is over-molded, whereas a disposable sleeve is used in other embodiments. In some embodiments, one or more components of the MUSIC device are fabricated from, for example, a conformal coating (e.g., parylene), an elastic epoxy, a rigid epoxy/urethane, silicone (e.g., stimulation lens), ULTEM® 1000 resin (e.g., imaging lens), polyimide (PI), and the like.

[090] While the foregoing disclosure has been described in some detail by way of illustration and example for purposes of clarity and understanding, it will be clear to one of ordinary skill in the art from a reading of this disclosure that various changes in form and detail can be made without departing from the true scope of the disclosure and may be practiced within the scope of the appended claims. For example, all the methods, devices, systems, computer readable media, and/or component parts or other aspects thereof can be used in various combinations. All patents, patent applications, websites, other publications or documents, and the like cited herein are incorporated by reference in their entirety for all purposes to the same extent as if each individual item were specifically and individually indicated to be so incorporated by reference.

WHAT IS CLAIMED IS:

1. A system for treatment of an injury, the system comprising:
an implantable device configured to be implanted into a body, the implantable device having a first sensing device and a treatment device, the first sensing device configured to sense a first condition of the injury and to generate a signal corresponding to the first sensed condition, the treatment device configured to selectively provide treatment to the injury;
a wearable device configured to be wearable on or adjacent to an external portion of the body, the wearable device having a second sensing device configured to sense a second condition of the body related to the injury; and
a control device connected to the implantable device and connected to the wearable device, the control device configured to receive a first signal from the implantable device and a second signal from the wearable device, and to control the implantable device to selectively cause the treatment device to apply the treatment based on the first signal and/or the second signal.
2. The system according to claim 1, wherein the implantable device comprises a first implantable device and a second implantable device.
3. The system according to claim 2, wherein the first implantable device comprises an ultrasound imaging device configured to generate a signal corresponding to the injury after the implantable device is implanted into the body, and the treatment device of the first implantable device comprises an ultrasound treatment device and/or an electrical stimulation treatment device configured to apply treatment to the injury.
4. The system according to claim 3, wherein the ultrasound imaging device is configured to send the first signal to the control device, and the control device is configured to control the ultrasound treatment device and/or the electrical stimulation treatment device to selectively apply the treatment to the injury.

5. The system according to claim 2, wherein the second implantable device comprises a plurality of sensor devices and a catheter device configured to selectively drain spinal fluid from the body.

6. The system according to claim 5, wherein the plurality of sensor devices comprise a temperature sensor, a pressure sensor and a biomarker sensor configured to sense conditions including temperature, pressure and biomarker conditions, and the sensor devices are configured to generate signals indicative of the sensed conditions and to send the signals to the control device.

7. The system according to claim 6, wherein the control device is configured to control the catheter device to selectively drain spinal fluid from the body based on the signals received from the temperature sensor, the pressure sensor and/or the biomarker sensor.

8. The system according to claim 2, further comprising a third implantable device, the third implantable device comprising an epidural spinal stimulator device configured to selectively apply electrical stimulation to a spinal cord.

9. The system of claim 1, wherein the wearable device comprises a first wearable device, a second wearable device and a third wearable device.

10. The system of claim 9, wherein the first wearable device comprises a blood pressure sensor configured to measure a blood pressure, the second wearable device comprises a bladder sensor device configured to sense a volume of a bladder, and the third wearable device comprises an electromyograph (EMG) sensor configured to monitor motion of a limb.

11. The system of claim 10, wherein the EMG sensor includes a plurality of accelerometers configured to sense a motion of a limb of the human and to generate a

signal corresponding to the sensed motion, and to send the signal corresponding to the sensed motion to the control device.

12. A system for monitoring and treatment of a spinal cord injury, comprising:
a first implantable device configured to be implantable into a body adjacent the spinal cord injury, the first implantable device including an imaging device configured to create an image of the spinal cord, and including a treatment device configured to selectively treat the injury;

a second implantable device configured to be implantable into the body, the second implantable device comprising a catheter device configured to selectively drain spinal fluid from the body and a plurality of sensor devices configured to sense conditions of the body;

a wearable device configured to be wearable on or adjacent to an external portion of the body, the wearable device including a sensor configured to sense a condition related to the injury; and

a control device connected to the first implantable device, connected to the second implantable device, and connected to the wearable device, the control device configured to receive the image from the first implantable device, to receive a signal from each of the sensor devices of the second implantable device, and to receive a signal corresponding to the sensed condition from the wearable device, and configured to control the first implantable device to cause the treatment device to selectively apply the treatment based on the image of the spinal cord, and to control the second implantable device to selectively cause the catheter device to drain the spinal fluid based on the sensed conditions of the body.

14. The system of claim 13, wherein the imaging device is an ultrasound imaging device and the treatment device is an ultrasound treatment device and/or an electrical stimulation treatment device configured to apply treatment to the injury.

15. The system of claim 13 wherein the plurality of sensor devices comprise a temperature sensor, a pressure sensor and a biomarker sensor configured to sense

conditions including temperature, pressure and biomarker conditions, and the sensor devices are configured to generate signals indicative of the sensed conditions and to send the signals to the control device.

16. The system of claim 13, wherein the wearable device comprises a first wearable device, a second wearable device and a third wearable device.

17. The system of claim 16, wherein the first wearable device comprises a blood pressure sensor configured to measure a blood pressure, the second wearable device comprises a bladder sensor device configured to sense a volume of a bladder, and the third wearable device comprises an electromyograph (EMG) sensor configured to monitor motion of a limb.

18. A method for monitoring and treating an injury, the method comprising:
implanting a first implantable device into a body, the implantable device having a sensor and a treatment device, the sensor configured to sense a first condition of the injury and to generate a signal corresponding to the first sensed condition, the treatment device configured to selectively provide treatment to the injury;
attaching a first wearable device on an external portion of the body, the first wearable device having a first sensing device configured to sense a second condition of the body related to the injury;
receiving signals from the first implantable device and from the wearable device at a control device outside the body; and
controlling the first implantable device with the control device based on the signals received from the implantable device and/or from the first wearable device to selectively cause the treatment device to apply the treatment.

19. The method of claim 18, wherein the injury is a spinal cord injury, and the first sensing device is an ultrasound imaging device configured to generate an image of the injury.

20. The method of claim 19, wherein the treatment device of the first implantable device comprises an ultrasound treatment device and/or an electrical stimulation treatment device configured to apply treatment to the injury.

21. The method of claim 19, further comprising:
implanting a second implantable device into the body, the second implantable device comprising a plurality of sensor devices and a catheter device configured to selectively drain spinal fluid from the body;
receiving signals at the control device from the plurality of sensor devices; and
controlling the catheter device with the control device to selectively drain spinal fluid from the body based on the signals from the plurality of sensor devices.

22. The method of claim 21, further comprising:
attaching a second wearable device on an external portion of the body, the second wearable device having a second sensing device configured to sense a second condition of the body related to the injury;
attaching a third wearable device on an external portion of the body, the wearable device having a third sensing device configured to sense a second condition of the body related to the injury; and
receiving signals from the second wearable device and from the third wearable device at the control device.

23. A system for treatment of an injury, the system comprising:
a first implantable device configured to be implanted into a body, the first implantable device having a first sensing device and a first treatment device, the first sensing device configured to sense a first condition of the injury and to generate a first signal corresponding to the first sensed condition, the treatment device configured to selectively provide treatment to the injury;
a second implantable device configured to be implanted into the body, the second implantable device having a second sensing device and a second treatment device, the second sensing device configured to sense a second condition related to the

injury and to generate a second signal corresponding to the first sensed condition, the treatment device configured to selectively provide treatment to the injury; and

a control device connected to the first implantable device and connected to the second implantable device, the control device configured to receive the first signal from the first implantable device and the second signal from the second implantable device, and to control the first implantable device and the second implantable device to selectively cause at least one of the first treatment device and the second treatment device to apply treatment based on the first signal and/or the second signal.

24. The system of claim 23, wherein the first implantable device comprises an ultrasound imaging device configured to generate a signal corresponding to the injury after the first implantable device and the second implantable device are implanted into the body.

25. The system of claim 24, wherein the first treatment device of the first implantable device comprises an ultrasound treatment device and/or an electrical stimulation treatment device configured to apply treatment to the injury and the second treatment device comprises a catheter device configured to selectively drain spinal fluid from the body.

26. The system of claim 25, wherein the ultrasound imaging device is configured to send the first signal to the control device, and the control device is configured to control the ultrasound treatment device and/or the electrical stimulation treatment device to selectively apply the treatment to the injury.

27. The system of claim 26, wherein the second implantable device comprises a plurality of sensor devices, and wherein the plurality of sensor devices comprise a temperature sensor, a pressure sensor and a biomarker sensor configured to sense conditions including temperature, pressure and biomarker conditions, and the sensor devices are configured to generate signals indicative of the sensed conditions and to send the signals to the control device.

28. The system according to claim 27, wherein the control device is configured to control the catheter device to selectively drain spinal fluid from the body based on the signals received from the temperature sensor, the pressure sensor and/or the biomarker sensor.

29. The system according to claim 27, further comprising a wearable device configured to be wearable on or adjacent to an external portion of the body, the wearable device having a third sensing device configured to sense a third condition of the body related to the injury.

30. The system according to claim 23, wherein the first wearable device comprises a blood pressure sensor configured to measure a blood pressure, the second wearable device comprises a bladder sensor device configured to sense a volume of a bladder, and the third wearable device comprises an electromyograph (EMG) sensor configured to monitor motion of a limb.

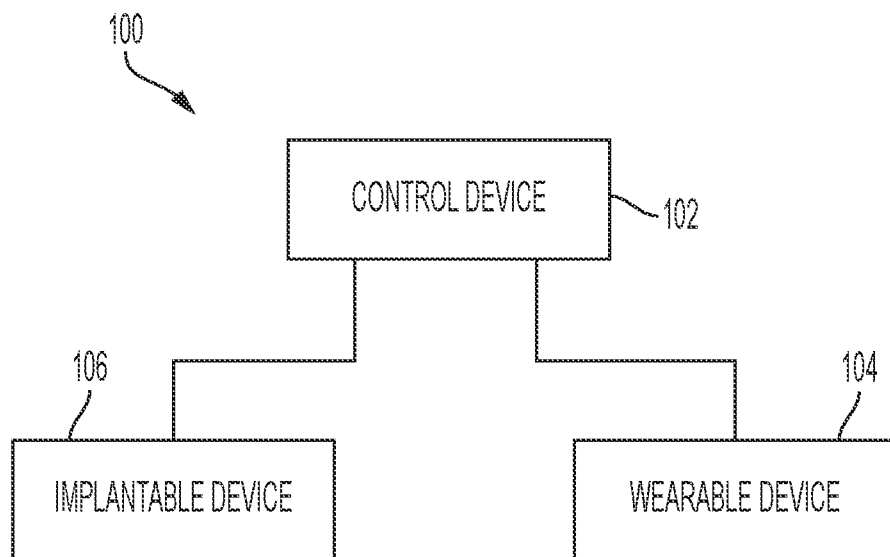


FIG. 1

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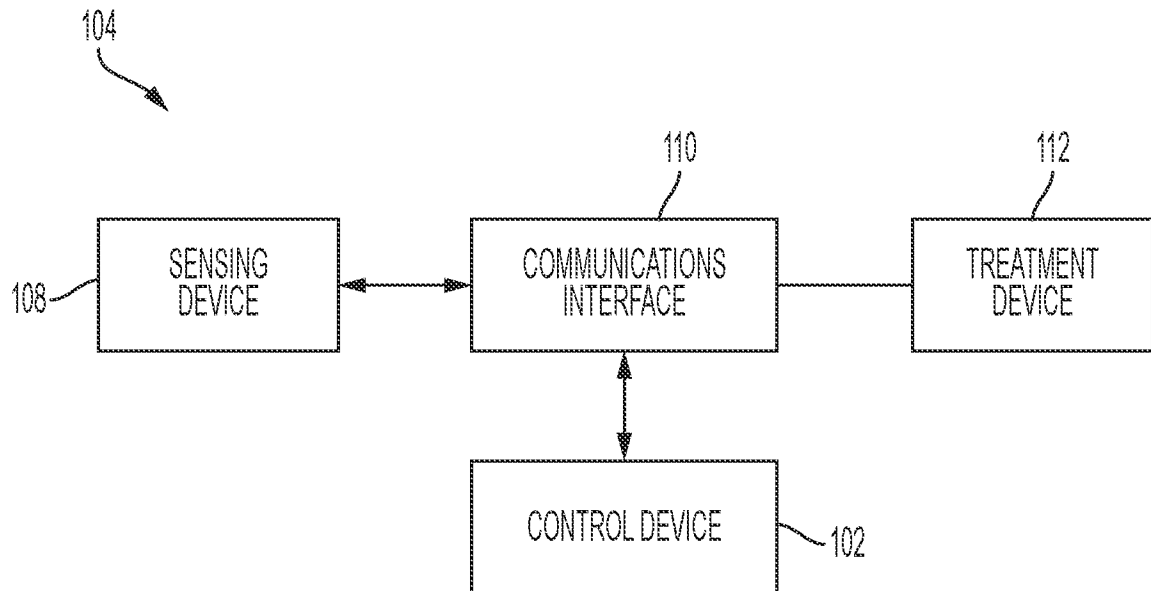


FIG. 2

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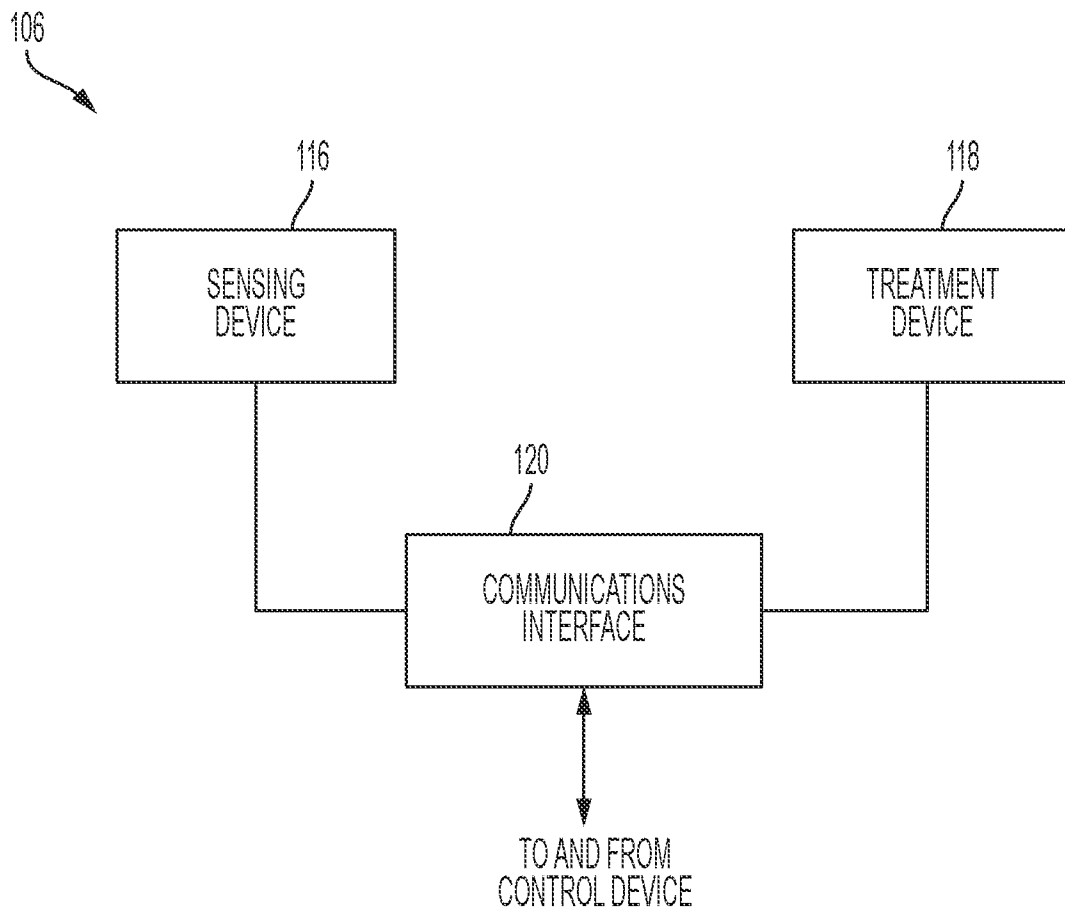


FIG. 3

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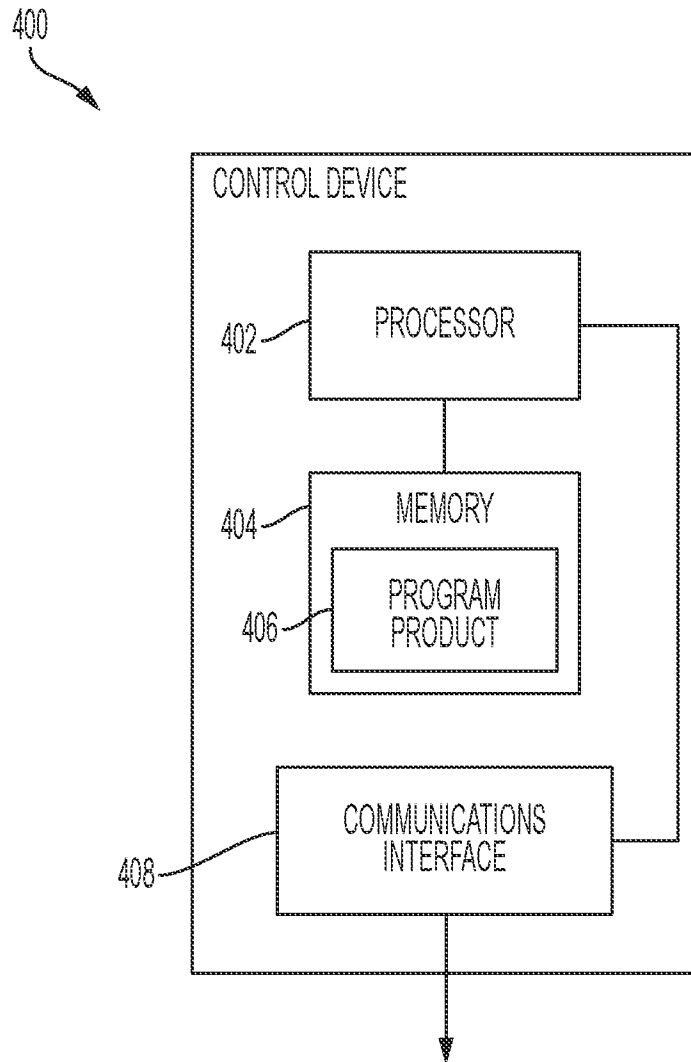


FIG. 4

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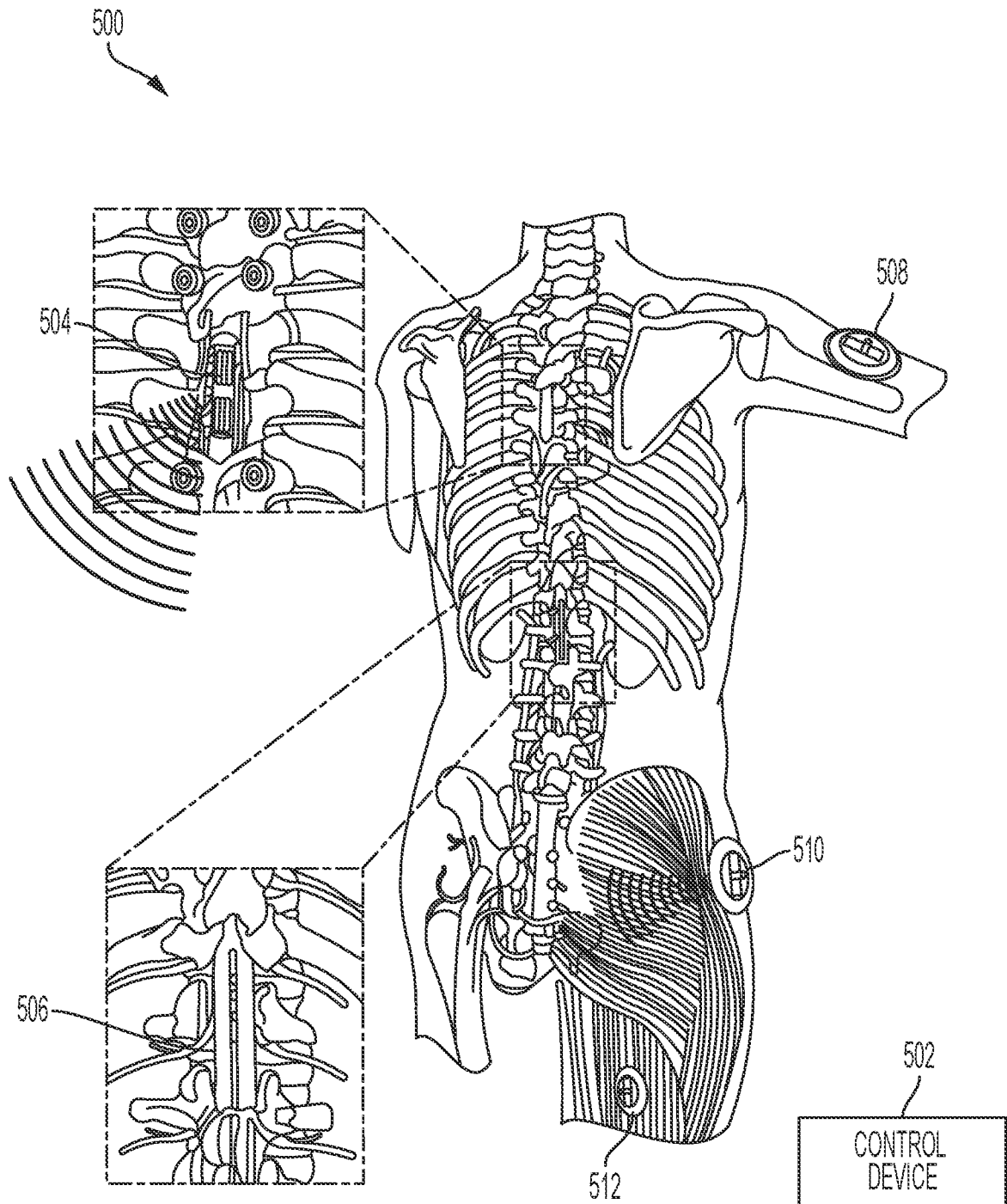


FIG. 5

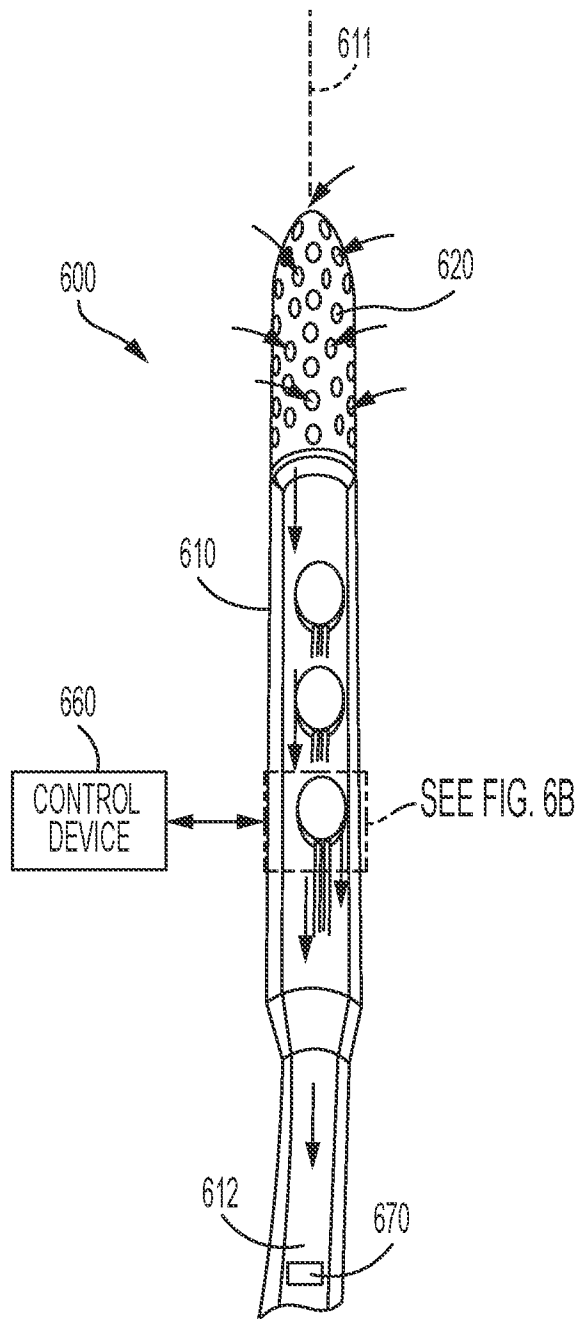


FIG. 6A

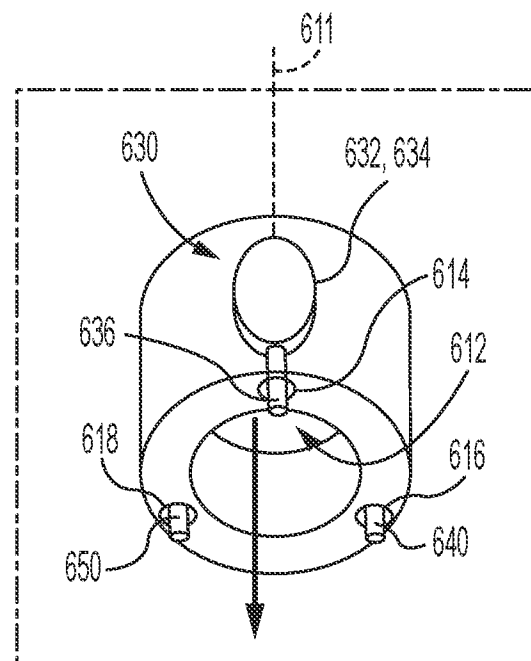


FIG. 6B

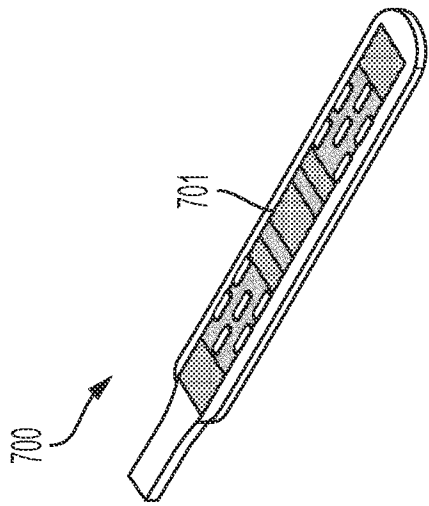


FIG. 7A

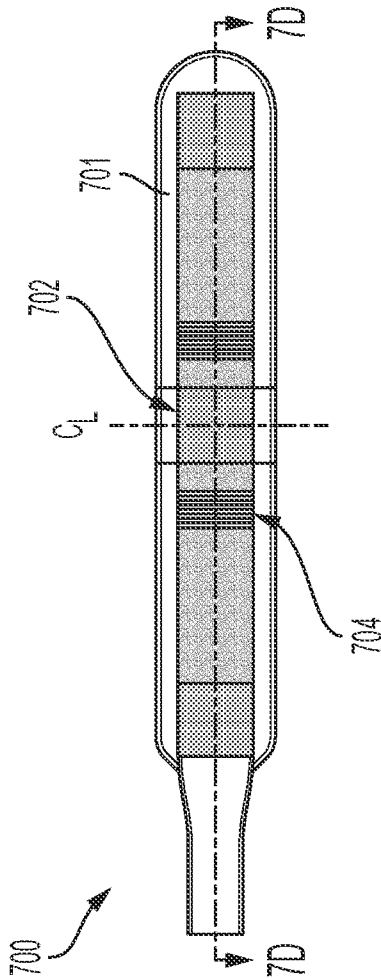


FIG. 7B

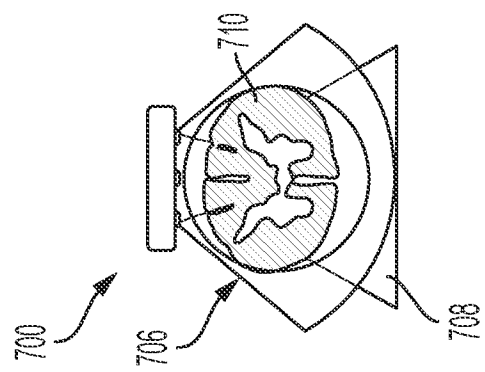


FIG. 7C

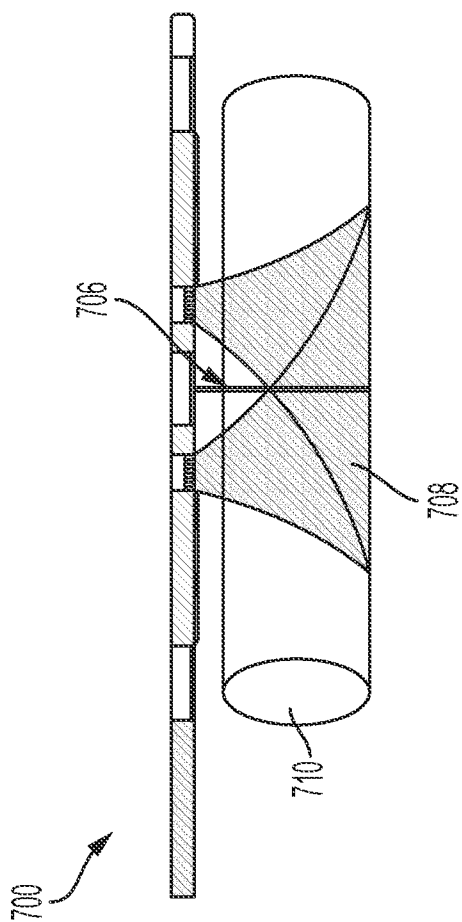
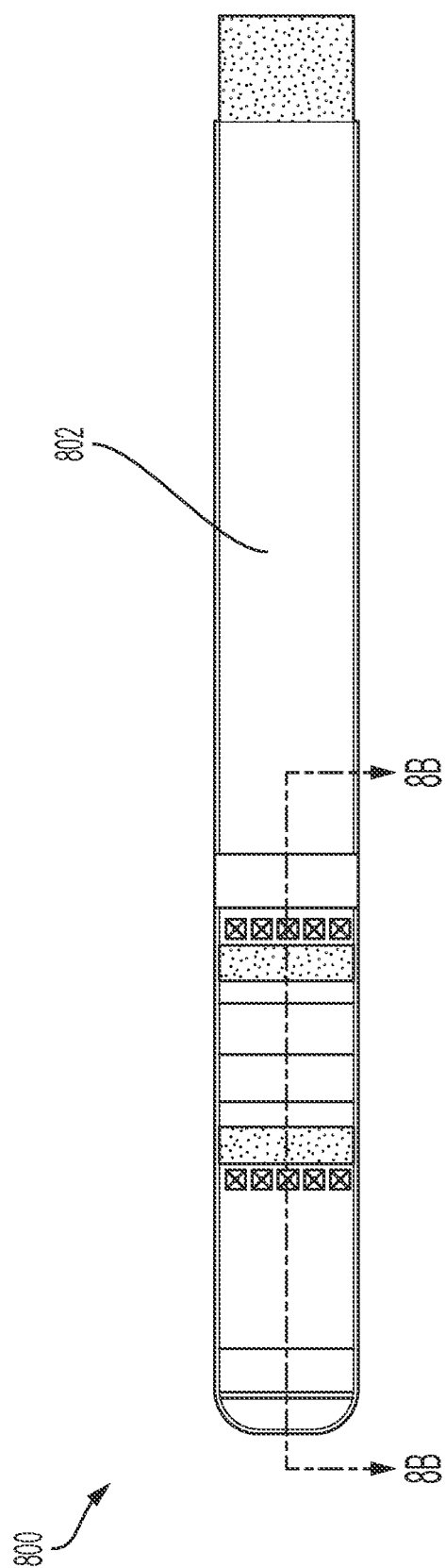
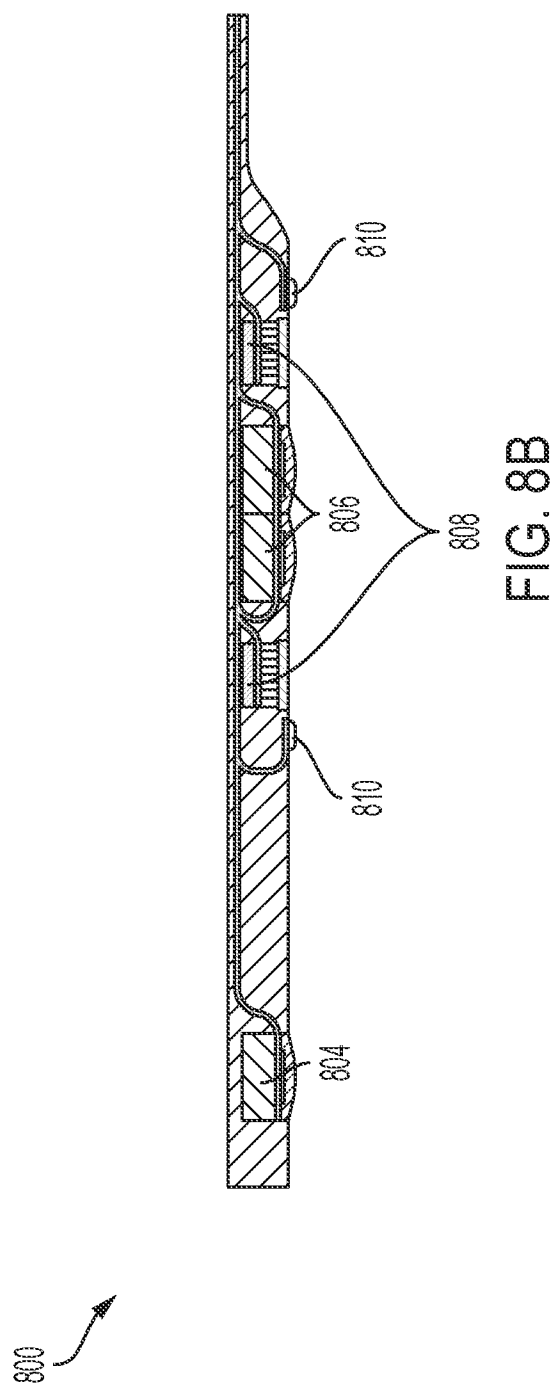


FIG. 7D



8A
GLE



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 2021/053738

A. CLASSIFICATION OF SUBJECT MATTER		<i>A61B 8/08 (2006.01)</i> <i>A61N 1/36 (2006.01)</i> <i>A61N 7/00 (2006.01)</i> <i>A61B 5/00 (2006.01)</i> <i>A61M 1/00 (2006.01)</i>
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
A61B 8/00, 8/08, 5/00, A61N 1/00, 1/36, 7/00, A61M 1/00		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
PatSearch (RUPTO Internal), USPTO, PAJ, Espacenet, Information Retrieval System of FIPS		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2018/0056079 A1 (CARDIAC PACEMAKERS INC) 01.03.2018, figures 1, paragraphs [0061]-[0069], [0078]-[0080]	1-11, 18-22
Y	US 2015/0321010 A1 (BOSTON SCIENTIFIC NEUROMODULATION CORPORATION) 12.11.2015, paragraphs [0004]-[0008], [0034]-[0036]	1-11, 18-22, 30
X	US 2007/0043591 A1 (MERETEI ATTILA et al.) 22.02.2007, paragraphs [0010]-[0013], [0030]	23
Y		24-30
A		12, 14-17
Y	US 2020/0114174 A1 (THE HONG KONG POLYTECHNIC UNIVERSITY) 16.04.2020, paragraphs [0004], [0005], [0007]	3, 4, 8, 19-22, 24-29
☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "D" document cited by the applicant in the international application "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search		Date of mailing of the international search report
10 December 2021 (10.12.2021)		16 December 2021 (16.12.2021)
Name and mailing address of the ISA/RU: Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37		Authorized officer S. Bykovskaya Telephone No. 8(495)531-64-81

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 2021/053738

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2013/0023814 A1 (MEDTRONIC, INC et al.) 24.01.2013, paragraphs [0007], [0008], [0053]	5-7, 21, 22, 24-29