the medical device and a method of characterizing a healing with the medical device, and other aspects as disclosed herein. The medical device generally has a structure configured to extend at least partially into boney tissue. For example, the structure may be a screw, a pin, a rod, a nail, a part of a joint replacement implant (e.g., hip, shoulder, knee, etc.), a part of a spinal fixation device, or a part of other orthopedic devices. In one embodiment, the medical device is a screw. The implantable smart medical device includes a sensor for obtaining one or more measurements indicative, e.g., of the healing state of fractured boney tissue within which the device is implanted, and communication circuitry for communicating such measurements to an external device.

[0006] Disclosed herein is a smart medical device that includes a structure configured to be at least partially implanted in a body, and an electronics cartridge that is configured to be inserted into the structure after the structure is implanted in the body. The structure may be a cannulated screw for use in treating bone fractures. The medical device includes an impedance sensor for monitoring and reporting on the healing state of bone fractures. The sensor includes components of the electronics cartridge and electrodes that are either associated with the cannulated screw or with the insertable electronics cartridge.

[0007] Disclosed herein is a medical device that includes a structure having a lumen extending at least partially therethrough and an insertable electronics cartridge including electronics. The structure is configured to be at least partially implanted in a body, and the electronics cartridge is configured to be inserted into the lumen after implant of the structure.

[0008] According to a first aspect of the present disclosure, there is provided a medical device that includes a cannulated structure having a plurality of electrodes at an outer surface of the structure, and an insertable electronics cartridge. The cannulated structure has a lumen extending therethrough and is configured to be at least partially implanted in a body. The electronics cartridge includes electronics and is configured to be inserted into the lumen of the cannulated structure such that one or more electrical couplings between the electronics and the plurality of electrodes are established upon such insertion.

[0009] Disclosed herein is a medical device that includes a cannulated structure having least one aperture through a sidewall of the structure, and an insertable electronics cartridge. The cannulated structure has a lumen extending therethrough and is configured to be at least partially implanted in a body. The electronics cartridge includes a plurality of electrodes and electronics electrically coupled to the electrodes. The electronics cartridge is configured to be inserted into the lumen, and to provide alignment between the plurality of electrodes and the at least one aperture upon such insertion.

[0010] Disclosed herein is a medical device that includes a cannulated structure having a distal end opening and a proximal end opening, and an insertable electronics cartridge. The cannulated structure has a lumen extending therethrough and is configured to be at least partially implanted in a body. The electronics cartridge includes a plurality of electrodes and electronics electrically coupled to the electrodes. The electronics cartridge is configured to be inserted into the lumen, and to position a first electrode of the plurality of electrodes at the distal end opening of the cannulated structure and a second electrode of the plurality of electrodes at the proximal end opening upon such insertion.

[0011] Disclosed herein is a medical device that includes a short, cannulated structure having a distal end opening and a proximal end opening, and an insertable electronics cartridge. The cannulated structure has a lumen extending therethrough and is configured to be at least partially implanted in a body. The electronics cartridge includes a plurality of electrodes and electronics electrically coupled to the electrodes. The electronics cartridge is configured to be inserted into the lumen, and to position the plurality of electrodes beyond the distal end opening of the cannulated structure upon such insertion.

[0012] Disclosed herein is a medical device that is preloaded with electronics. The medical device is configured to be at least partially implanted in a body, and includes a structure having a head and a shaft, each respectively defining a head cavity and a shaft cavity. The preloaded medical device also includes electronics located in one or more of the head cavity and the shaft cavity, and at least one electrode that is associated with the shaft and is electrically coupled to the electronics.

[0013] Disclosed herein is a medical device that includes a cannulated structure preloaded with an electronics cartridge. The cannulated structure is configured to be implanted in a body and includes a lumen extending at least partially therethrough. The electronics cartridge is at least partially within the lumen and is permanently secured therein. The cannulated structure has a plurality of apertures through a sidewall, and a plurality of electrodes each associated with one of the plurality of apertures. The electronics cartridge includes electronics, and a plurality of electrical contacts each aligned with one of the apertures to establish an electrical coupling between the electronics and each of the plurality of electrodes.

[0014] In one embodiment, the medical device of the present disclosure may be used to assist in treating a fracture in boney tissue. For example, the medical device may be in the form of a screw that is placed across a fracture in boney tissue, where the screw aids in holding together the bone tissue adjacent to the boney fraction and thus provides a stability function for the healing bone. Optionally, the medical device has little or no stability function but instead is implanted in fractured boney tissue, optionally across a fracture in boney tissue, primarily or solely in order to characterize the bone fracture during the healing process, and thus provides a characterization function. Optionally, the implanted medical device provides both stability function and characterization function. Particularly in the case where the medical device of the present disclosure provides little or no stability function, the medical device of the present disclosure may be utilized in association with other medical devices, e.g., standard orthopedic screws which do not contain a sensor, which primarily provide a stability function. Thus, in one aspect, the present disclosure provides a set of medical devices, where at least one member of the set is a smart medical device of the present disclosure which provides characterization function (and optionally some stability function), and at least one member of the set is utilized to provide primarily or exclusively stability function. In use, the smart medical device of the present disclosure may be placed in boney tissue at a location where stability function is not necessary, i.e., at a non-loaded location. The medical devices that are utilized to provide primarily or exclusively stability function, may be placed at loaded locations in the boney tissue.

[0015] Disclosed herein is an implantable medical device for characterizing a bone fracture in a bone. The medical device includes an implant configured to be at least partially implanted in the

bone and across the bone fracture. The implant includes an impedance sensor that includes a first electrode and a second electrode, and a sensing module configured to obtain impedance measurements between the first electrode and the second electrode. The implant also includes a controller and memory that are configured to process and store the impedance measurements, and communication circuitry that is configured to transmit the impedance measurements to an external device.

[0016] Disclosed herein is an implantable medical device for characterizing a bone fracture in a bone. The medical device includes a first implant and a second implant, each configured to be at least partially implanted in the bone, and a third implant configured to be placed adjacent the bone across the bone fracture and secured in place by the first implant and the second implant. The first implant has a first electrode, and the second implant has a second electrode. The medical device also has an impedance sensor that includes the first electrode and the second electrode and a sensing module. The sensing module is included in one or more of the first, second, or third implants and is configured to obtain impedance measurements between the first electrode and the second electrode. The medical device also includes a controller and memory that is configured to process and store the impedance measurements, and communication circuitry that is configured to transmit the impedance measurements to an external device. The controller, memory, and communication circuitry may be included in one or more of the first, second, or third implants.

[0017] Disclosed herein is a method of characterizing a bone fracture through electrodes on opposite sides of the bone fracture. The method includes obtaining a plurality of measures of an electrical property of tissue overtime through a plurality of electrodes associated with a single implant and located in a boney tissue and across the bone fracture. The plurality of electrodes include a first electrode and a second electrode on opposite sides of the bone fracture. The method also includes processing the measures to determine a characterization of the bone fracture, the characterization corresponding to a healing state of the bone fracture.

[0018] Disclosed herein is a method of characterizing a bone fracture through electrodes within a gap of the bone fracture. The method includes obtaining a plurality of measures of an electrical property of tissue overtime through a plurality of electrodes associated with a single implant and located in a boney tissue at the bone fracture. The plurality of electrodes include a first electrode and a second electrode, each within a gap of the bone fracture. The method also includes processing the measures to determine a characterization of the bone fracture, the characterization corresponding to a healing state of the bone fracture.

[0019] Disclosed herein is a method of characterizing a bone fracture through electrodes that span a gap of the bone fracture. The method includes obtaining a plurality of measures of an electrical property of tissue overtime through a plurality of electrodes located in a boney tissue at the bone fracture. The plurality of electrodes including a first electrode and a second electrode, each spanning a gap of the bone fracture. The method also includes processing the measures to determine a characterization of the bone fracture, the characterization corresponding to a healing state of the bone fracture.

[0020] Disclosed herein is a method of manufacturing an implantable medical device. The method includes creating a plurality of apertures through a sidewall of a cannulated structure

configured to be at least partially implanted in a body and having a lumen extending therethrough. The method also includes associating an electrode with each of the plurality of apertures, and associating an electronics cartridge with the lumen of the cannulated structure. The electronics cartridge includes electronics and a plurality of electrical contacts, wherein the association aligns each of the plurality of electrical contacts with one of the apertures to establish an electrical coupling between the electronics and each electrode.

[0021] Disclosed herein is a method of implanting a medical device. The method includes implanting an implant structure at least partially in a body. The structure has a lumen extending at least partially therethrough. The method also includes inserting an electronics cartridge into the lumen after implanting the implant structure.

[0022] Disclosed herein is a tool for implanting an implant structure having a proximal end having a head, a shaft extending from the head to a distal end of the implant structure, and a lumen extending through the shaft. The tool includes a drill bit, and a mechanism for applying rotational torque to the drill bit. The drill bit includes a first portion configured to directly couple to the head of the implant structure, and a second portion extending from the first portion. The second portion is configured to extend at least partially into the lumen of the implant structure.

[0023] Disclosed herein is a coupling device for implanting an implant structure having a proximal end having a head, and a shaft extending from the head to a distal end of the implant structure. The coupling device includes a body having a proximal end region and a distal end region. The distal end region is configured to establish a mechanical coupling to a distal end portion of the implant structure. The coupling device may also include a cap configured to the couple to the proximal end region of the body without directly coupling to the implant structure.

[0023a] According to a second aspect of the present disclosure, there is provided a method of characterizing a fracture in boney tissue, the method including identifying a fracture in boney tissue, inserting a medical device according to the first aspect into the bony tissue, where the medical device is inserted across the fracture; and characterizing the fracture with a sensor located in the medical device

[0023b] According to a third aspect of the present disclosure, there is provided a set of medical devices, the set including at least one first medical device according to the first aspect, the set further including at least one second medical device configured for insertion into boney tissue, where the second medical device does not contain a sensor.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] Exemplary features of the present disclosure, its nature and various advantages will be apparent from the accompanying drawings and the following detailed description of various