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(54) **SYSTEMS AND METHODS FOR TRANSCUTANEOUSLY IMPLANTING MEDICAL DEVICES**

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(58) **Field of Classification Search**

None

See application file for complete search history.

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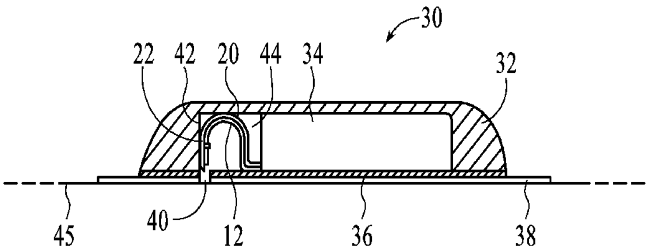
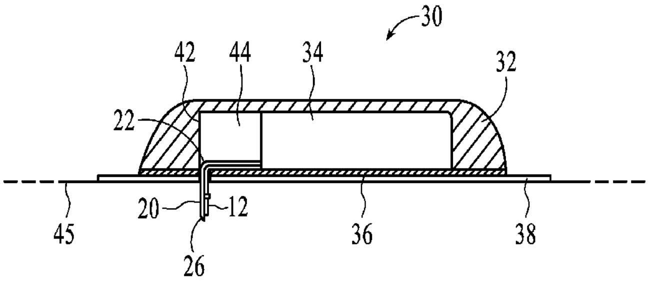
(57) **ABSTRACT**

Systems and methods for transcutaneously implanting medical devices, such as in vivo analyte sensors, are provided. The systems and methods involve the use of introducers or inserters made of shape memory alloy (SMA) materials which are transitionable from one operative state or configuration to another operative state or configuration, wherein the transition from state to state enables the transcutaneous implantation and/or transcutaneous explantation of the medical device.

20 Claims, 4 Drawing Sheets





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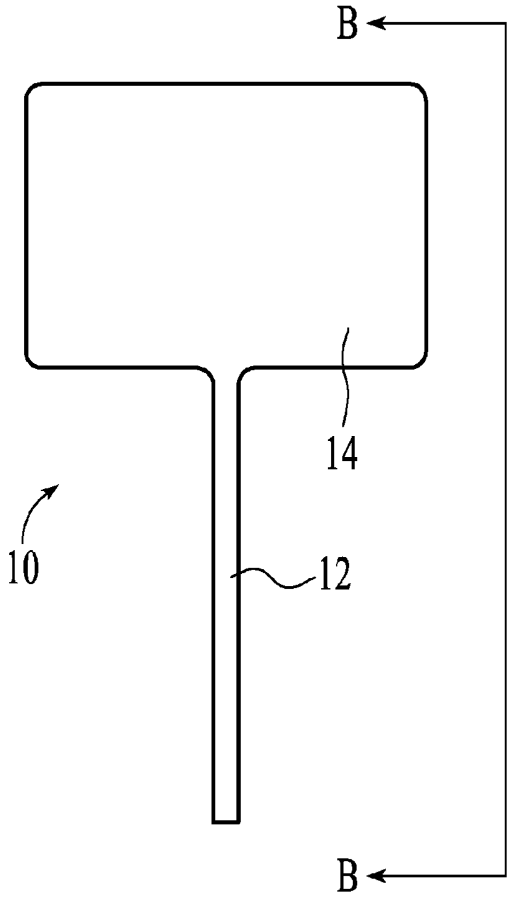

FIG. 1A

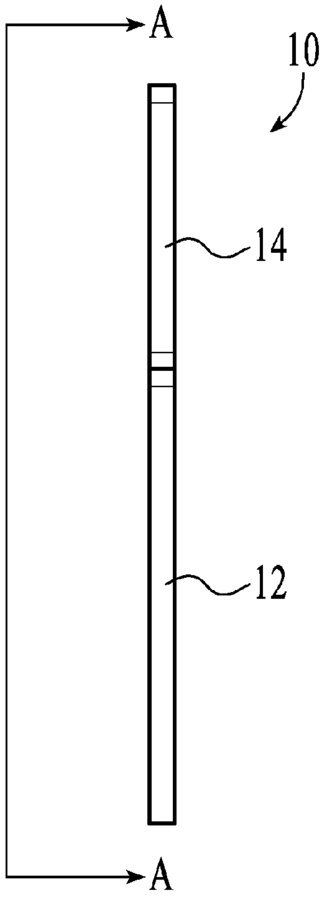

FIG. 1B

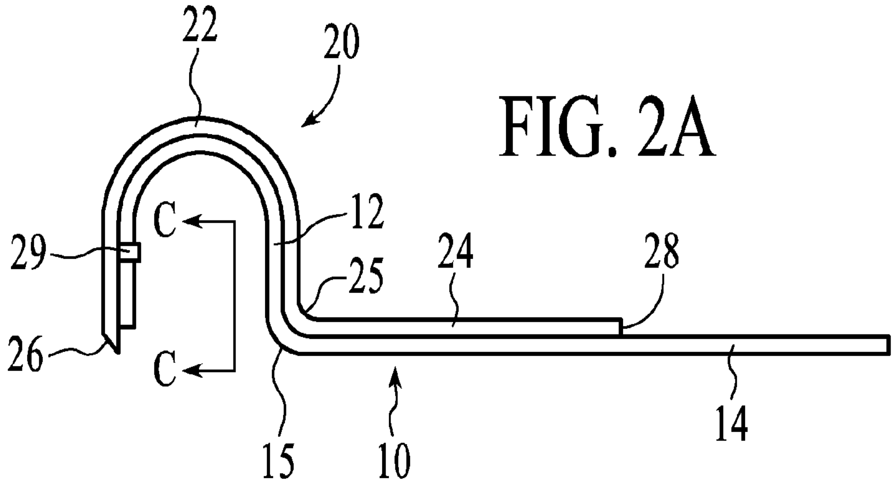

FIG. 2A

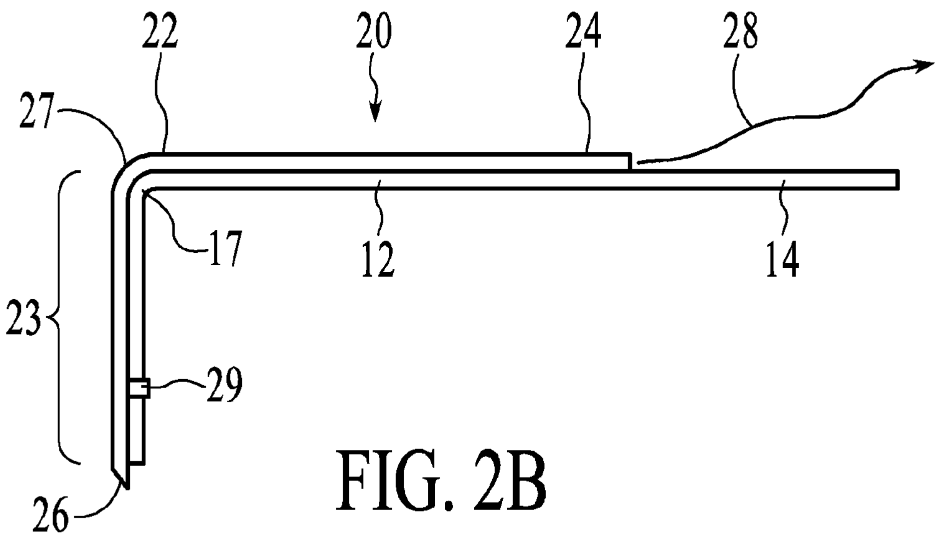

FIG. 2B

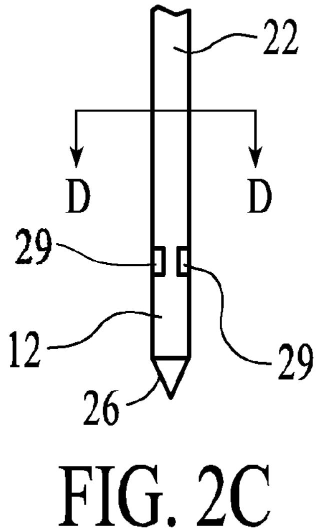

FIG. 2C

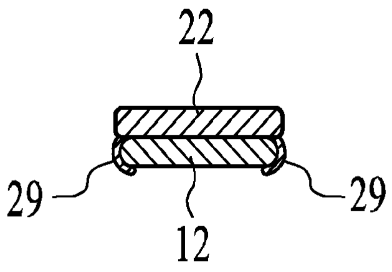

FIG. 2D

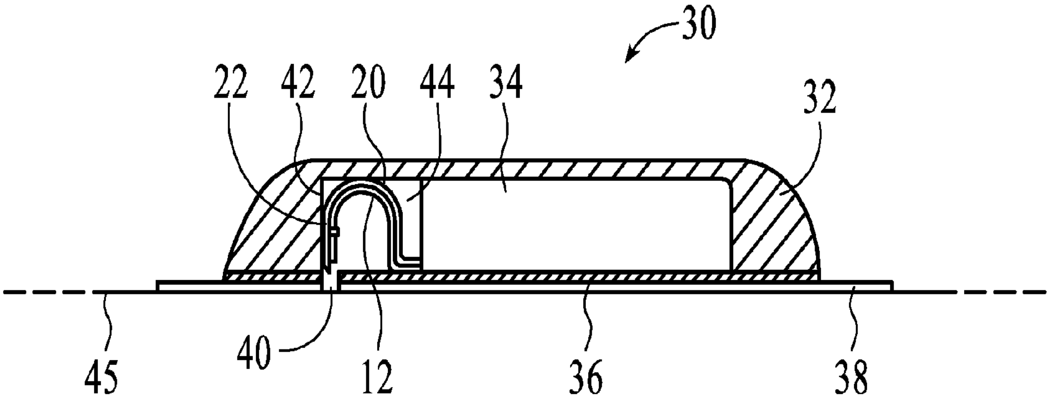

FIG. 3A

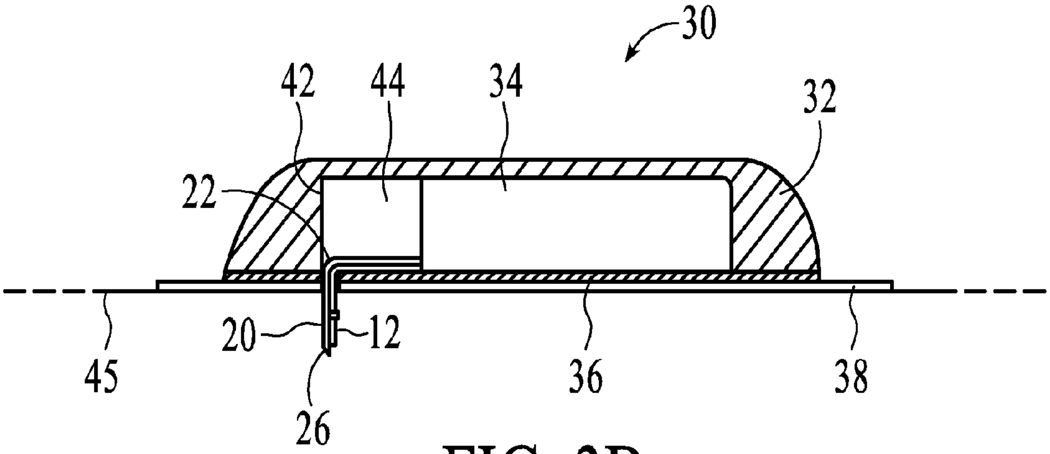

FIG. 3B

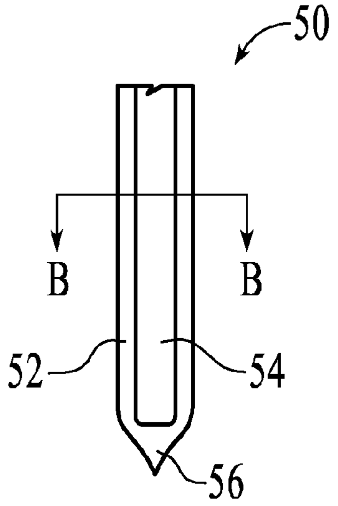

FIG. 4A

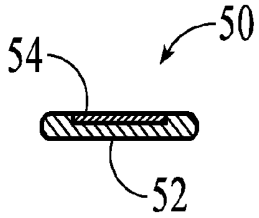

FIG. 4B

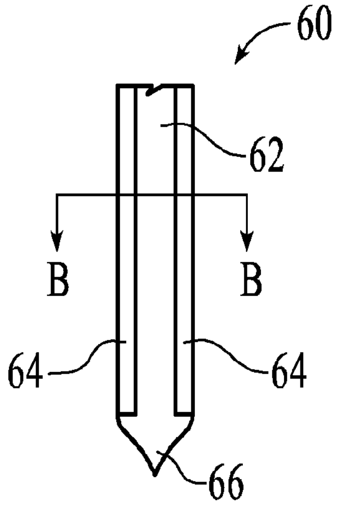

FIG. 5A

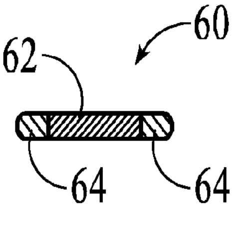

FIG. 5B

SYSTEMS AND METHODS FOR TRANSCUTANEOUSLY IMPLANTING MEDICAL DEVICES

RELATED APPLICATION

The present application claims priority to U.S. provisional patent application No. 61/470,454 filed Mar. 31, 2011, entitled "Systems and Methods for Transcutaneously Implanting Medical Devices", the disclosure of which is incorporated herein by reference for all purposes.

BACKGROUND

The introduction and temporary implantation through the skin, e.g., transcutaneously, percutaneously and/or subcutaneously, of biosensors has become very common in the treatment of patients inflicted with or suffering from any one of many different types of conditions. These implantable sensors include those monitoring a given parameter that indicates a certain bodily condition, e.g., a patient's glucose level, or the actual state of a treatment, e.g., monitoring the concentration of a drug dispensed to the patient or a body substance influenced by the drug.

In recent years, a variety of temporarily implantable sensors have been developed for a range of medical applications for detecting and/or quantifying specific agents, e.g., analytes, in a patient's body fluid such as blood or interstitial fluid. Such analyte sensors may be fully or partially implanted below the epidermis in a blood vessel or in the subcutaneous tissue of a patient for direct contact with blood or other extra-cellular fluid, such as interstitial fluid, wherein such sensors can be used to obtain periodic and/or continuous analyte readings over a period of time.

Certain transcutaneous analyte sensors have an electrochemical configuration in which the implantable portion of these sensors includes exposed electrodes and chemistry that react with a target analyte. At an externally located proximal end of the sensor are exposed conductive contacts for electrical connection with a sensor control unit which is typically mountable on the skin of the patient. One common application of such analyte sensor systems is in the monitoring of glucose levels in diabetic patients. Such readings can be especially useful in monitoring and/or adjusting a treatment regimen which may include the regular and/or emergent administration of insulin to the patient.

A sensor insertion device or kit is typically provided with such analyte monitoring systems for inserting the sensor into a patient. The insertion kit includes an introducer which typically has a sharp, rigid structure adapted to support the sensor during its transcutaneous insertion. Some introducers are in the form of needles having a slotted or hollow configuration in which a distal portion of the sensor is slidably carried to the desired implantation site, e.g., subcutaneous site, after which the insertion needle can be slidably withdrawn from the implanted sensor. Often, the insertion kit also includes an insertion gun for automatically or semi-automatically driving the introducer and attached sensor to within the skin. Implantation of a sensor with such an insertion device typically involves using the insertion gun to drive the introducer and pre-loaded sensor into the skin of the patient. The introducer is retracted into the insertion gun, leaving the sensor implanted within the patient.

While such sensor insertion tools can greatly assist a user in effectively and efficiently implanting transcutaneous sensors, they are not without their drawbacks. As they are designed to be substantially automatic, the insertion guns tend to be mechanically complex, involving numerous static and moving parts. With the added complexity of such tools are significant costs in designing and fabricating them, contributing significantly to the overall cost of the sensor systems. In addition to the financial and manufacturing-related drawbacks, there are significant clinical consequences to using such transcutaneous sensor insertion tools.

The subcutaneous or other placement of such sensors, or any medical device, produces both short-term and longer-term biochemical and cellular responses which may lead to the development of a foreign body capsule around the implant. Consequently, this encapsulation may reduce the flux of an analyte to the sensor, i.e., may reduce the sensitivity or accuracy of the sensor function, often requiring numerous calibrations over the course of the sensor's implantation period. The extent of the immune response presented by implantable sensors, as well as the amount of pain and discomfort felt by the patient, are exacerbated by the size of the sensor introducer and/or the implantable portion of the sensor, often referred to as the sensor tail. With sensor introducers that carry the sensor within an interior or substantially interior space, there is naturally a limit on the extent to which the cross-sectional dimension of the introducer can be reduced.

Accordingly, it would be highly desirable to provide a sensor introducer and associated sensor design, and/or a combined assembly, which do not require a separate insertion tool for their transcutaneous insertion, thereby minimizing the number of components involved, and reducing mechanical complexity and manufacturing costs. It would be additionally advantageous if the respective and combined dimensions and configurations of the introducer and sensor were further reduced to minimize the trauma, pain and immune response to sensor insertion/implantation.

INCORPORATION BY REFERENCE

The following patents, applications and/or publications are incorporated herein by reference for all purposes: U.S. Pat. Nos. 4,545,382; 4,711,245; 5,262,035; 5,262,305; 5,264,104; 5,320,715; 5,509,410; 5,543,326; 5,593,852; 5,601,435; 5,628,890; 5,820,551; 5,822,715; 5,899,855; 5,918,603; 6,071,391; 6,103,033; 6,120,676; 6,121,009; 6,134,461; 6,143,164; 6,144,837; 6,161,095; 6,175,752; 6,270,455; 6,284,478; 6,299,757; 6,338,790; 6,377,894; 6,461,496; 6,503,381; 6,514,460; 6,514,718; 6,540,891; 6,560,471; 6,579,690; 6,591,125; 6,592,745; 6,600,997; 6,605,200; 6,605,201; 6,616,819; 6,618,934; 6,650,471; 6,654,625; 6,676,816; 6,676,819; 6,730,200; 6,736,957; 6,746,582; 6,749,740; 6,764,581; 6,773,671; 6,881,551; 6,893,545; 6,932,892; 6,932,894; 6,942,518; 7,167,818; 7,299,082; 7,381,184; 7,618,369, 7,697,967 and 7,885,698; U.S. Published Application Nos. 2004/0186365; 2005/0182306; 2007/0056858; 2007/0068807; 2007/0227911; 2007/0233013; 2008/0081977; 2008/0161666; 2009/0054748; 2009/0247857; and 2010/0081909; and U.S. patent application Ser. Nos. 11/396,135, 11/537,984, 12/131,012; 12/242,823; 12/363,712; 12/698,124; 12/714,439; 12/807,278; 12/842,013; and 12/848,075.

SUMMARY

Embodiments of implantable medical devices and of methods, systems and devices for positioning at least a portion of the medical devices beneath the epidermal layer of skin, e.g., transcutaneously, are described. A portion or the entirety of the medical devices may be implanted in a blood vessel, subcutaneous tissue, or other suitable body location. Certain embodiments of the implantable medical devices are in vivo analyte sensors for the continuous and/or automatic detection and measurement of one or more selected analytes.

Certain system embodiments configured for transcutaneously implanting a medical device include an introducer having at least a portion engageable with at least a portion of the medical device, wherein the introducer is at least partially formed from a shape memory material, and an activating component to activate the introducer to transition from a first operative shape memory state to a second operative shape memory state, wherein said transition translates the medical device engaged with the introducer from a position above the skin surface to at least partially through the skin surface. In certain of these embodiments, the first operative shape memory state is a heat-unstable shape and the second operative shape memory state is a heat-stable shape, wherein the activating component may include an electrical current generating component electrically coupled to the introducer.

In certain aspects of these system embodiments, the first operative shape memory state is a physically loaded configuration and the second operative shape memory state is a physically unloaded configuration, wherein the activating component may include a driving mechanism mechanically coupled to the introducer.

In certain embodiments, the subject systems may include a housing configured for placement on a skin surface of a host, wherein the introducer is configured to be at least partially positioned within the housing when in the first operative shape memory state. The housing may include a compartment within which the introducer is configured to be at least partially contained when in the first operative shape memory state.

In certain embodiments, the portion of the introducer engageable with the medical device defines a major axis wherein during the transition from the first operative shape memory state to the second operative shape memory state, the introducer changes shapes along the major axis. Further, in certain embodiments, the subject introducers may have at least one coupling member for securing the medical device to the introducer at least when in the first operative memory state. The shape memory materials suitable for fabricating the subject introducers include, but are not limited to, nickel-titanium, copper-zinc-aluminum-nickel, copper-aluminum-nickel, and alloys of zinc, copper, gold and iron.

In a particular system of the present disclosure adapted for transcutaneously implanting a medical device, the system includes a housing configured for placement on a skin surface of a host, an introducer configured to be at least partially positioned within the housing and having at least a portion engageable with at least a portion of the medical device, wherein the introducer is at least partially formed from a shape memory material, and an electrical current generating component electrically coupled to the introducer for activating the introducer to transition from a heat-unstable shape to a heat-stable shape, wherein said transition translates the medical device engaged with the introducer from a position within the housing to at least partially through the skin surface. The electrical current generating component may include a battery contained within the housing, which battery may also be used to power a control unit for operating the medical device. In other embodiments, the battery may be provided separately, i.e., not contained within the housing.

In other embodiments for transcutaneously implanting a medical device, a system may include a housing configured for placement on a skin surface of a host, an introducer configured to be at least partially positioned within the housing and having at least a portion engageable with at least a portion of the medical device, wherein the introducer is at least partially formed from a shape memory material, and a driving mechanism mechanically coupled to the introducer for moving the introducer relative to the housing in order to transition from a loaded configuration to an unloaded configuration, wherein said transition translates the medical device engaged with the introducer from a position within the housing to at least partially through the skin surface. The system housing may include a compartment configured to physically retain the introducer in the loaded configuration.

The present disclosure is also directed to an in vivo analyte monitoring system including a housing configured for placement on a skin surface of a host, a control unit housed within the housing, an in vivo analyte sensor having a proximal portion and a distal portion, wherein the proximal portion is operatively coupleable to the control unit, a sensor introducer at least partially positioned within the housing, wherein the introducer is at least partially comprised of a shape memory material and wherein a portion of the introducer is engageable with the sensor distal portion, and a transitioning component to transition the introducer from a first operative shape memory state to a second operative shape memory state, wherein said transitioning translates the sensor distal portion from a position within the housing to at least partially through the skin surface.

In certain embodiments, the portion of the introducer engageable with the sensor distal portion may have a crosswise dimension substantially similar to, or alternatively different than, that of the sensor distal portion. For example, the portion of the introducer engageable with the sensor distal portion may have a crosswise dimension smaller than that of the sensor distal portion. In certain aspects, the sensor distal portion and the portion of the introducer engageable with the sensor distal portion may have respective configurations which enable a nesting arrangement between them. This engageable portion of the introducer may have any suitable shape when in the first operative shape memory state including but not limited to a U-shaped configuration.

Other features of the introducer may include a distal tip configured to substantially atraumatically pierce the skin surface, and/or at least one coupling member for securing the medical device, e.g., the sensor distal portion, to the introducer at least when the introducer is in the first operative memory state.

The present disclosure includes embodiments directed to transcutaneously implantable medical devices which are substantially self-implanting without the need for a separate introducer or other instrument to facilitate the device's implantation through the skin. In certain embodiments, these medical devices include a flexible, elongated substrate having a distal tip configured to substantially atraumatically pierce the skin surface, wherein the substrate is formed from a non-conductive material, and at least one spine extending along a length of the substrate, wherein the at least one spine is formed from a shape memory alloy, and wherein the medical device is translatable from a first operative shape memory state to a second operative shape memory state. The shape memory material used to fabricate these medical devices may include, but are not limited to, one or more of nickel-titanium, copper-zinc-aluminum-nickel, copper-aluminum-nickel, and alloys of zinc, copper, gold and iron. Depending, at least in part, on the type of shape memory material employed, the first operative shape memory state of the medical device may be a heat-unstable shape and the second operative shape memory state may be a heat-stable shape. In certain embodiments, the first operative shape memory state is a compressed configuration and the second operative shape memory state is an uncompressed configuration.

The construct of these self-inserting medical devices, in certain embodiments, enable them to function as electrochemical sensors. In certain embodiments, one or more of the spines may also function as an electrode. These electrochemical sensors may include analyte sensors, such as glucose sensors.

The present disclosure is also directed to methods for transcutaneously implanting a medical device. In certain embodiments, at least a portion of the medical device is flexible. Such methods may involve providing an introducer, wherein the introducer is at least partially formed from a shape memory material, engaging at least the flexible portion of the medical device with the introducer, wherein the engaged introducer and medical device are in a nested arrangement, and wherein when the introducer is in a first operative shape memory state, positioning a skin-penetrating end of the introducer adjacent to the skin surface, and transitioning the introducer from the first operative shape memory state to a second operative shape memory state, wherein the introducer penetrates through the skin surface and transcutaneously implants at least a portion of the flexible portion of the medical device beneath the skin surface.

In certain embodiments of the above-described method, transitioning the introducer from the first operative shape memory state to the second operative shape memory state includes applying an electrical current to the introducer. In certain embodiments, the step of engaging the flexible portion of the medical device with the introducer in a nested arrangement includes cooling the introducer to a predefined temperature while the medical device is structurally aligned along a major axis of the introducer.

In certain embodiments of the above-described method, transitioning the introducer from the first operative shape memory state to the second operative shape memory state includes releasing the introducer from a confined space. As such, the step of engaging the flexible portion of the medical device with the introducer in a nested arrangement may include loading the introducer to a reduced profile while the medical device is structurally aligned along a major axis of the introducer and positioning the introducer and nested sensor in the confined space. This confined space may be provided within a housing that is configured for placement on the skin surface.

The subject methods may also include the removal of one or both the introducer and medical device from the skin subsequent to implantation. In certain embodiments, the methods may further include removing the introducer from the skin while leaving the transcutaneously implanted medical device within the patient, or alternatively, maintaining the introducer within the skin along with the transcutaneously implanted medical device for the useful life of the medical device. Such explantation of the introducer and/or introducer and medical device, for example, may be accomplished via manual retraction or by transitioning the introducer from the second operative shape memory state back to the first operative shape memory state.

These and other objects, advantages, and features of the disclosure will become apparent to those persons skilled in the art upon reading the details of the disclosure as more fully described below.

BRIEF DESCRIPTION OF THE DRAWINGS

The disclosure is best understood from the following detailed description when read in conjunction with the accompanying drawings. It is emphasized that, according to common practice, the various features of the drawings are not to scale. On the contrary, the dimensions of the various features are arbitrarily expanded or reduced for clarity. Included in the drawings are the following figures:

FIGS. **1**A and **1**B are front and side views, respectively, of a transcutaneously implantable sensor of the present disclosure, where the views are taken along lines A-A and B-B, respectively, of the other Figure;

FIG. **2**A is a side view of an introducer of the present disclosure with the sensor of FIGS. **1**A and **1**B operatively engaged with the introducer, collectively in a first or pre-insertion state;

FIG. **2**B is a side view of the introducer and sensor of FIG. **2**A, collectively in a second or post-insertion state;

FIG. **2**C is an enlarged view of a distal end portion taken along line C-C of FIG. **2**A;

FIG. **2**D is a cross-sectional view taken along line D-D of FIG. **2**C;

FIGS. **3**A and **3**B are side cross-sectional views of a sensor system of the present disclosure operatively mounted on the skin of a patient, where FIG. **3**A shows the introducer and sensor in operative engagement in a first or pre-insertion state and FIG. **3**B shows the introducer and sensor in operative engagement in a second or post-insertion state;

FIG. **4**A is an enlarged fragmented view of a distal end portion of one embodiment of a sensor of the present disclosure;

FIG. **4**B is a cross-sectional view of the sensor of FIG. **4**A taken along line B-B;

FIG. **5**A is an enlarged fragmented view of a distal end portion of one embodiment of a sensor of the present disclosure; and

FIG. **5**B is a cross-sectional view of the sensor of FIG. **5**A taken along line B-B.

DETAILED DESCRIPTION

Before the subject devices, systems and methods are described, it is to be understood that this disclosure is not limited to particular embodiments described, as such may, of course, vary. 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, since the scope of the present disclosure will be limited only by the appended claims.

Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limits of that range is also specifically disclosed. Each smaller range between any stated value or intervening value in a stated range and any other stated or intervening value in that stated range is encompassed within the disclosure. The upper and lower limits of these smaller ranges may independently be included or excluded in the range, and each range where either, neither or both limits are included in the smaller ranges is also encompassed within the disclosure, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the disclosure.

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 belongs. As used herein, the terms transcutaneous, subcutaneous and percutaneous and forms thereof may be used interchangeably.

All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited. It is understood that the present disclosure supersedes any disclosure of an incorporated publication to the extent there is a contradiction. The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present disclosure is not entitled to antedate such publication by virtue of prior disclosure. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

It must be noted that as used herein and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise.

As will be apparent to those of skill in the art upon reading this disclosure, each of the individual embodiments described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other several embodiments without departing from the scope or spirit of the present disclosure.

Generally, the present disclosure is directed to transcutaneously implantable or partially implantable medical devices and to devices, systems and methods for transcutaneously implanting such implantable devices. In certain embodiments, the present disclosure is directed to implantable medical devices which are configured to be substantially self-implanting without the need for a separate skin-penetrating structure. While embodiments of the subject disclosure are primarily described below with respect to analyte sensors and analyte monitoring devices, systems and methods, such as for glucose monitoring, such description is in no way intended to limit the scope of the disclosure. It is understood that the subject disclosure is applicable to any medical device in which at least a portion of the device is intended to be implanted within the body of a patient.

Referring now to the drawings and to FIGS. **1**A and **1**B in particular, there is shown an embodiment of a partially implantable sensor **10** of the present disclosure. Embodiments of sensor **10** are for the in vivo monitoring or measurement of a physiological condition or state or of a value of a naturally-occurring or unnaturally-occurring substance or agent within the body. As such, sensor **10** may be an analyte sensor (electrochemical, optical, etc.) wherein at least a portion of the sensor is positionable beneath the skin of the user or host for the in vivo determination of a concentration of an analyte in a body fluid, e.g., interstitial fluid, blood, urine, etc. Alternatively or additionally, sensor **10** may be positionable in a body vessel such as a vein, artery, or other portion of the body. Sensor **10** may also have an ex vivo portion which is positionable outside the body, i.e., above the skin surface, and configured to be coupled to a component of a medical device system such as to a control unit **34** mounted on the skin of a patient (see FIGS. **3**A and **3**B). The intended site and depth of implantation may affect the particular shape, components and configuration of sensor **10** and its in vivo and ex vivo portions, respectively. Examples of such sensors and associated analyte monitoring systems can be found in U.S. Pat. Nos. 6,134,461; 6,175,752; 6,284,478; 6,560,471; 6,579,690; 6,746,582; 6,932,892; 7,299,082; 7,381,184; 7,618,369, 7,697,967 and 7,885,698; and U.S. Patent Application Publication Nos. 2008/0161666, 2009/0247857 and 2010/0081909, the disclosures of each of which are incorporated herein by reference.

Although the subject sensors in at least some embodiments have uniform dimensions along the entire length of the sensor, in the illustrated embodiment, sensor **10** has a distal portion **12** and a proximal portion **14** with different widths. Distal portion **12**, also referred to as the tail portion of the sensor, has a relatively narrow width to facilitate subcutaneous implantation of at least a portion of its length, while proximal portion **14** has a relatively wider width to facilitate coupling with an external control unit **34** (see FIGS. **3**A and **3**B). In certain embodiments, distal portion **12** is substantially narrower than proximal portion **14**, having a strip-like or wire-like configuration, while proximal portion **14** has a substantially flat, planar configuration. The cross-wise dimension, i.e., the thickness of flat or strip configurations and the diameter of wire-like configurations, of at least distal portion **12** is relatively thin, having a cross-wise dimension in the range from about 0.02 mm (20 μm) to about 1.2 mm (1,200 μm), and more typically from about 0.2 mm (200 μm) to about 0.6 mm (600 μm).

Where sensor **10** is an electrochemical sensor, the sensor includes at least one working electrode formed on a substrate. The sensor may also include at least one counter electrode and/or at least one reference electrode and/or at least one counter/reference electrode. The sensor substrate may be formed using a variety of non-conducting materials, including, for example, polymeric or plastic materials and ceramic materials; however, at least the implantable portion of sensor **10**, i.e., at least a portion of distal portion **12**, is made of a flexible, bendable and/or deformable material. Suitable materials for a flexible substrate include, for example, thermoplastics such as polycarbonates, polyesters (e.g., Mylar™ and polyethylene terephthalate (PET)), polyvinyl chloride (PVC), polyurethanes, polyethers, polyamides, polyimides, or copolymers of these thermoplastics, such as PETG (glycol-modified polyethylene terephthalate).

Analytes measurable by the subject sensors may include but are not limited to glucose, lactate, acetyl choline, amylase, bilirubin, cholesterol, chorionic gonadotropin, creatine kinase (e.g., CK-MB), creatine, DNA, fructosamine, glucose, glutamine, growth hormones, hormones, ketones, lactate, peroxide, prostate-specific antigen, prothrombin, RNA, thyroid stimulating hormone, and troponin. Other of the subject sensors may be configured to detect and measure drugs, such as, for example, antibiotics (e.g., gentamicin, vancomycin, and the like), digitoxin, digoxin, drugs of abuse, theophylline, and warfarin. Two or more analytes and/or drugs may be monitored at the same or different times, with the same or different analyte sensor(s).

Sensors described herein may be configured for monitoring the level of an analyte over a time period which may range from minutes, hours, days, weeks, one month or longer. Of interest are analyte sensors, such as glucose sensors, that have an in vivo operational life of about one hour or more, e.g., about a few hours or more, e.g., about a few days of more, e.g., about three days or more, e.g., about five days or more, e.g., about seven days or more, e.g., about several weeks or months.

As mentioned previously, eliminating the need for a separate sensor insertion tool, e.g., an insertion gun, for transcutaneously implanting the subject sensors would provide the benefits of fewer components, reduced costs, and increased ease of use for a user of such sensors. The present disclosure provides an introducer or inserter (both terms are used interchangeably herein) for transcutaneously implanting a medical device, such as sensor **10**, without the need for a separate tool or instrument for driving and/or retracting the introducer through the skin. Instead, the introducer or inserter is driven or translated solely by its shape-shifting material characteristics. More particularly, the subject introducers or inserters are made, at least in part, of a shape memory alloy (SMA) having memory characteristics which function to define one operative configuration which is transitionable or convertible to another operative configuration.

In certain embodiments, the state transition is a reversion from a heat-unstable configuration to an original, heat-stable configuration upon the application of heat to the SMA structure. In the manufacturing process, the original, heat-stable or "austenitic" state of the SMA structure is deformed to a new, heat-unstable or "martensitic" state when cooled below the temperature at which the SMA is transformed from the austenitic state to the martensitic state. The temperature at which this martensitic transformation begins is usually referred to as M_s and the temperature at which it finishes is referred to as M_f. When an article thus deformed is heated to the temperature at which the alloy starts to revert back to austenite, referred to as A_s (A_f being the temperature at which the reversion is complete), the deformed object will begin to return to its original, heat-stable configuration. The martensitic and austenitic temperatures of a particular SMA structure are predefined based on the type of SMA material from which the structure is formed.

In other embodiments, the transition of the SMA structure from one operative configuration to another is the reversion of the structure from a physically stressed or confined state to an unstressed, unconfined original state upon the removal of an externally applied force. During the manufacturing process, the SMA structure is formed to a selected unloaded or unstressed shape. When the structure is loaded or stressed, typically by positioning it in a confined space, typically to a lower-profile state, a bias toward the original, unstressed state is created. When the structure is released or the confinement removed, the biased SMA structure returns to its original, unloaded, unstressed condition. This type of memory characteristic is sometimes referred to as superelasticity or pseudoelasticity.

Suitable shape memory alloys for use in the introducers of the present disclosure include but are not limited to nickel-titanium (NiTi), copper-zinc-aluminum-nickel, copper-aluminum-nickel, and other alloys of zinc, copper, gold, and iron.

The subject introducers are structurally configured to accommodate the shape and size of the medical device, such as a sensor, to be transcutaneously positioned. As many medical devices configured for transcutaneous implantation, such as the in vivo analyte sensors discussed herein, are designed to minimize pain and trauma to the patient, their implantable portions are very narrow and elongated. Accordingly, in many embodiments, the subject introducers have a shape and cross-sectional dimension to substantially match those of the medical device, e.g., very narrow and elongated needle-type structure, so as to minimize pain and trauma. However, in certain embodiments, the introducer may have a shape and/or size which are dissimilar to those of the medical device to be implanted. Because minimizing pain and trauma is an important objective in treating patients, in some embodiments, the smaller the introducer, the better. In some cases, the introducer may have a cross-wise dimension that is smaller than that of the medical device as long as the introducer is able to retain the medical device in a compressed condition prior to transcutaneous insertion and to effectively advance it through the skin when activated.

For certain of the introducer embodiments of the present disclosure, the subject sensors, such as sensor **10** of FIGS. **1**A and **1**B, are operatively coupled with the subject introducers prior to implantation of the sensor, wherein the respective major axes of the insertion portion of introducer and the sensor distal or tail portion, i.e., their longitudinal axes, are substantially parallel and in substantial physical contact with each other. The flexibility of the sensor substrate allows it to be engaged with and deformable or bendable in tandem with the introducer as the latter transitions between its heat-unstable and heat-stable states. One such operative engagement between a shape memory introducer **20** of the present disclosure and a medical device, such as sensor **10**, is illustrated in FIGS. **2**A-**2**D. In particular, FIG. **2**A shows the introducer-sensor assembly in a pre-implantation or pre-insertion state in which at least a distal portion of sensor **10** has been deformed from its naturally flat straight condition, as illustrated in FIGS. **1**A and **1**B, to a shape in which it nests with inserter **20** when the inserter is in its heat-unstable, martensitic state (in the case of heat-transitionable memory embodiments of the introducer) or in its stressed, loaded or confined state (in the case of the elastic memory embodiments of the introducer). FIG. **2**B, on the other hand, shows the inserter-sensor assembly in a post-implantation or post-insertion state in which inserter **20** has been transitioned to its heat-stable, austensitic state (in the case of heat-transitionable memory embodiments of the introducer) or to its unstressed, unloaded or unconfined state (in the case of elastic memory embodiments of the introducer). For purposes of this description, the pre-implantation/pre-insertion state of FIG. **2**A may be referred to as a first operative shape memory configuration or shape, and the post-implantation/post-insertion state of FIG. **2**B may be referred to as a second operative shape memory configuration or shape.

With reference to FIG. **2**A, the first operative shape of inserter **20** includes a U-shaped distal portion **22** transitioning at a bend **25** to a straight proximal portion **24** where the transition bend has an angle of about 90°. The corresponding first operative shape of sensor **10** substantially conforms to that of inserter **20**, i.e., sensor distal portion **12** has taken on the U-shape of introducer distal portion **22** and sensor proximal portion **14** has aligned with introducer proximal portion **24** with a transition bend **15** therebetween. Introducer **20** may be configured to have any suitable heat-unstable or elastically-deformable shape or configuration, provided the resulting profile of the introducer-sensor assembly allows it to be positionable within the structure or housing used for delivering or carrying the assembly prior to transcutaneous implantation, as discussed in greater detail below. Accordingly, the pre-implantation introducer-sensor assembly may have any suitable first operative configuration including, but not limited to V-shaped, C-shaped, coiled, looped, sinusoidal, etc.

With reference to FIG. **2**B, the second operative shape of introducer **20** includes a length **23** of distal portion **22** which is shaped for transcutaneous implantation, which length portion **23** is typically substantially straight and substantially corresponds to the length of sensor distal portion **12** which is intended for transcutaneous implantation. As the entire distal portion **12** of sensor **10** is not intended to be implanted, introducer **20**, in its second operative state, includes a transition bend **27** within or about distal portion **22** wherein the remaining proximal end portion of introducer

20 has a substantially straight configuration, providing a cooperative L-shaped configuration when in the second operative state. As with the first operative shape of sensor **10**, the corresponding second operative shape of sensor **10** is substantially conforming to that of introducer **20**, i.e., having a transition bend **17** between distally and proximally extending straight portions. Transition bends **17** and **27** within the sensor and introducer, respectively, may have any suitable angle, wherein the transition angle may be selected to provide a skin penetration path that is substantially transverse to the skin surface, i.e., at about a 90° angle. Alternatively, the transition angle may be in the range from less than 90° degrees to about 135°, but may be more or less, to provide a skin penetration path that is angled with respect to the skin surface.

It is noted that the respective first and second operative configurations of introducer **20** may have any suitable shape for the given application, insertion site, etc., with the respective transition bends **25** and **27** of introducer **20** in the first and second operative configurations provided at any suitable location along the length of the introducer, including within the distal portion **22**, as illustrated, or substantially between the distal and proximal portions. Further, bends **25** and **27** may have any suitable angle including angles greater or less than the illustrated 90°. Further, the respective locations of bends **25** and **27** along the length of introducer **20** may differ from each other, as illustrated, or introducer **20** may be configured such that the bends in the first and second operative configurations coincide at the same location along the introducer's length. For example, in the illustrated embodiment, bend **27** in FIG. **2**B (when introducer **20** is in the second operative state) is located substantially closer to the distal tip **26** of the introducer than bend **25** in FIG. **2**A (when introducer **20** is in the first operative state). In any embodiment, when in the second operative configuration, the length or portion **23** of introducer **20**, as well as the corresponding length/portion of sensor **10** extending distally of transition bend **27**, are typically those length portions which are positioned beneath the skin surface upon transcutaneous implantation.

As best illustrated in FIGS. **2**C and **2**D, introducer **20** may include one or more coupling members **29** for securing sensor **10** to introducer **20** or for guiding sensor **10** along the transcutaneous insertion path enabled by introducer **20** upon implantation. In the illustrated embodiment, the coupling member **29** includes tabs or protrusions positioned on opposing sides of introducer **20** which engage sensor **10** about its width. Coupling member **29** may be positioned at any suitable location along the length of introducer **20**, such as about distal portion **22**, as illustrated. The securement provided by coupling member **29** may be releasable or permanent. In certain embodiments, introducer **20** is configured and intended to be withdrawn from the skin after transcutaneous insertion of sensor **10**. As such, coupling member **29** is configured to enable introducer **20** to be slidably removable from implanted sensor **10**. To this end, coupling member **29** may extend laterally from introducer **20** only to the extent necessary to maintain sensor **10** in longitudinal alignment with introducer **20** and function as guides during the pre- and post-implantation states, while allowing introducer **20** to be slidably removed from the skin in a retrograde direction after transcutaneous implantation of sensor **10**. In embodiments where introducer **20** is to remain coupled and implanted with sensor **10** after transcutaneous implantation, coupling member **29** may be configured to completely engage sensor **20**, and may even fully crosswise encircle the sensor.

It is noted that while a coupling member **29** is provided in the illustrated embodiment, no such member may be needed in certain embodiments where the spring bias placed on flexed sensor **10** via the physical confinement by introducer **20** in the first (and sometimes the second) operative state is sufficient to maintain the sensor's engagement and alignment with the introducer prior to and during its transcutaneous implantation. To provide such sufficient spring-biased engagement between the sensor and the introducer, the sensor may need to be nested within or constrained in a somewhat confined space or plane defined by the introducer, at least when in the first operative state, as illustrated in FIG. **2**A. More specifically, sensor **10** is nested within the concave side of introducer **20**, where such "nesting" may place a sufficient spring bias along the longitudinal axis of sensor **10** to maintain its static position against the introducer prior to and during transcutaneous insertion.

In certain embodiments, the size of an SMA introducer is comparable to the size of the device to be transcutaneously implanted, i.e., the larger the sensor, the larger the introducer. The introducer should not be any larger than necessary as the larger the introducer, the more energy (i.e., electrical current or physical force) required to activate the shape transition of the introducer. However, the introducer should be large enough to enable the sensor to penetrate the skin without bearing much frictional resistance. Accordingly, introducers for use with the sensors having the dimensions described previously herein will have comparable cross-sectional dimensions (i.e., thicknesses or diameters). For example an SMA introducer with the same or substantially similar cross-sectional area as the previously described sensors can exhibit a one-time force of over 6 kg. That much force applied to an introducer having a pointed or sharpened tip **26**, as shown in FIGS. **2**A and **2**B, would be more than sufficient to penetrate skin.

In addition to comparable sizes, the crosswise shape of introducer **20** may be identical or similar to that of sensor **10**, such as illustrated in FIG. **2**D, where both the introducer and sensor have a strip or flat rectangular configuration. Alternatively, the two components may each have a crescent or C-shape to facilitate their "nesting" engagement. In other embodiments, the sensor and introducer may have different cross-sectional shapes, where the shapes have respective mating configurations to also facilitate "nesting" of the sensor with the introducer. For example, the introducer may have a concave surface which engages with a corresponding convex surface of the sensor. Their respective outer or non-contacting surfaces may both be convex to facilitate penetration into the skin. Still yet, in certain embodiments, the crosswise configuration and size of introducer **20** may be substantially different from that of sensor **10**. For example, the introducer may have a wire configuration with a relatively small cross-sectional surface area as compared to that of the sensor, provided the mass of the wire introducer is sufficient to conform the sensor into the predefined operative states.

It is noted that due to the metallic and, thus, conductive nature of introducer **20**, care should be taken to ensure that the electrodes of sensor **10** (in electrochemical embodiments) are insulated from introducer **20**. This may be accomplished by providing an insulative coating around either or both sensor **10** and introducer **20**, while ensuring that such a coating does not in any way obstruct exposure of the sensing portion of the sensor electrodes to the subcutaneous environment.

In certain embodiments, introducer **20** is configured at its proximal end **24** to couple, mate or engage with an activation mechanism or component **28** (illustrated schematically) for activating a transition from the first operative state of FIG. **2**A to the second operative state of FIG. **2**B. The construct and the type of energy/force imparted by activation component **28** is dependent upon the type of memory function employed by introducer **20**. For introducers **20** having a heat-transitionable memory, activation component **28** may be an electrical coupling to a source of electrical power for conducting an electrical current to introducer **20** which heats the introducer SMA material to a temperature sufficient to transition the introducer from its heat-unstable martensitic state (i.e., the first operative state of FIG. **2**A) to its heat-stable austensitic state (i.e., the second operative state of FIG. **2**B). For introducers **20** having an elastic memory, activation component **28** may include a mechanical coupling between introducer **20** and a driving mechanism for imparting a physical force on introducer **20** sufficient to translate it out from a physically confining space, such as within a housing of an on-skin unit as illustrated in FIGS. **3**A and **3**B, in order to transition the introducer from its loaded, stressed configuration (i.e., the first operative state of FIG. **3**A) to its unloaded, unstressed configuration (i.e., the second operative state of FIG. **3**B).

Referring now to FIGS. **3**A and **3**B, there is shown an analyte monitoring system **30** in which operatively assembled sensor **10** (see FIG. **2**A) and introducer **20** are shown operatively coupled to a sensor control unit **34** contained within an on-skin/on-body housing **32**. Control unit **34** may provide most or all of the electronic components of an analyte monitoring system including, but not limited to, data processing and communication electronics, the latter of which may include a transmitter for relaying or providing data obtained using the sensor to a remotely located device. The control unit **34** may also include a variety of optional components, such as, for example, a receiver, a power supply (e.g., a battery), an alarm system, a display, a user input mechanism, a data storage unit, a watchdog circuit, a clock, a calibration circuit, etc. A remote unit (not shown), if employed with the on-skin control unit **34**, may include one or more of the same components and/or additional components such as an analyte measurement circuit for use with a test strip sensor, a pager, a telephone interface, a computer interface, etc. Examples of such are provided in the patents and patent applications incorporated by reference above.

Housing **32** preferably has a low-profile configuration to provide comfort to the patient or user and enable easy concealment. Housing **32** may include a base or mounting structure **36** which is configured for releasable engagement with the skin surface **45**, such as by an adhesive layer, patch or strip **38**, or by strapping it to the body. Housing **32** is further configured to provide or facilitate physical and/or electrical coupling between the proximal portion of sensor **10** (not shown in FIGS. **3**A and **3**B) and control unit **34**, as well as to electrically and/or mechanically couple proximal portion of introducer **20** to an activation component **28** (see FIGS. **2**A and **2**B; not shown in FIGS. **3**A and **3**B). The respective distal portions **12**, **22** of sensor **10** and introducer **20** extend from control unit **34** to within a chamber or compartment **44** within housing **32**. An aperture **40** is provided within mounting structure **36** and adhesive layer **38** to allow for the extension therethrough of engaged and nested sensor and introducer distal portions **12**, **22** when introducer **20** is caused to transition from the first operative or contained state of FIG. **3**A to the second operative or extended or implanted state of FIG. **3**B by the introducer's SMA memory function.

The introducer transition activation component **28**, as discussed above, may be an electrical and/or mechanical component depending on the type of memory function employed by the particular introducer **20**, and may be physically housed within or coupled to or associated with housing **32** and/or control unit **34**.

For introducer embodiments having heat-transitionable memory capabilities, the proximal end **24** of introducer **20** is coupled to an electrical activation component. In certain of these embodiments, the activation component is an electrical power source, e.g., a battery or power circuit, and/or the associated electrical coupling housed within housing **32** and/or control unit **34**. System **30** may be configured such that when control unit **34** is turned on, subsequent to operative mounting of the on-skin unit, an electrical current is provided from the battery or power circuit to introducer **20** by electrical coupling between the two. Such electrical coupling may be a wire or an electrical contact extending between the proximal portion **24** of introducer **20** and the power source, or proximal portion **24** may be directly electrically coupled to the power source. The amount of current supplied to introducer **20** is sufficient to result in a temperature rise sufficient to trigger the martensitic-to-austensitic shape change, which physical change in introducer **20** causes it, along with nested/coupled sensor **10**, to be forced downward through housing aperture **40** and through the adjacent skin surface **45** (see FIG. **3**B). The activation/transition temperature should have a minimum value sufficiently greater than the range of possible ambient temperatures to avoid unintentional activation of the introducer's shape change, but otherwise should have a maximum value as low as possible to minimize the amount of energy required to activate it. In certain embodiments, the activation temperature of SMA introducer **20** is just below body temperature (37° C.) so that activation and transcutaneous insertion occurs automatically very shortly after the on-body control unit housing **32** is attached to the skin. The maximum heat generated in the introducer should not exceed a temperature which may feel uncomfortable to the user, cause burning of or damage to the user's skin or tissue, or cause damage to the medical device, such as sensor **10**, to which the introducer is engaged.

The electrical current necessary to activate a heat-transitional SMA introducer of the present disclosure will vary depending on the size, i.e., cross-sectional dimension, of the introducer. More specifically, the minimum required current (I_{M-A}) to produce or activate the requisite temperature to initiate the martensitic-to-austenitic transition of SMA structures is generally represented by the linear equation

$$I_{M-A}\ (\text{amps})=0.25\times10^{-4}\ (\text{amps}/\mu\text{m}^2)\times A\ (\mu\text{m}^2),$$

where A is the average cross-sectional area of the SMA structure. Accordingly, for introducers having sizes suitable for implantation of the sensors described above, i.e., having cross-sectional areas in the range from about 400 μm^2 to about 1,440$\times10^3$ μm^2, and more typically from about 40$\times10^3$ μm^2 to about 360$\times10^3$ μm^2, the activation current will range from about 0.01 amps to about 36 amps, and more typically from about 1 amp to about 9 amps, but may be higher or lower depending on the size of the introducer. In one particular embodiment in which a the sensor distal section has a rectangular cross-section with a thickness of about 200 μm, a width of about 600 μm, and a resulting cross-sectional area of about 120$\times10^3$ μm^2, and the corresponding SMA introducer has substantially similar dimensions, the activation current range is about 3 amps.

Typically, the activation current need only be supplied to the introducer for less than a second (i.e., milliseconds) to create the shape transition in the introducer and to drive the sensor into the skin. When the temperature of the SMA introducer reaches a temperature above ambient temperature, it begins to cool spontaneously through free convection. For efficiency and power conservation reasons, then, it is advantageous to heat the introducer to its transition temperature as quickly as possible. The larger the control unit battery, the greater the possible output current and the faster the introducer is heated. However, to avoid adding unwanted weight and mass to the on-body control unit with a larger battery, a super capacitor may be placed in a parallel circuit with a smaller battery to insulate the battery from the high power draw of the SMA introducer. Alternatively, a separate hand-held battery pack may be provided which is used only initially upon operative placement of the on-body control unit to activate the SMA introducer. After transcutaneous insertion of the sensor, the battery pack may be unplugged from the control unit and the on-board, internally housed smaller battery employed to operate the device.

In certain embodiments, introducer **20** may include an insulative layer to protect the patent or user and/or the medical device, such as sensor **10**, from heat or electrical damage due to the current and subsequent temperature increase provided to introducer **20** to transition from the first operative state to the second operative state.

Pursuant to certain introducer embodiments providing an elastic memory function, proximal end **24** of introducer **20** is coupled to a mechanical activation component (not illustrated). When activated, the mechanism axially drives or moves introducer **20** such that it is caused to forcibly abut the side and/or overhead interior walls **42** of compartment **44** (see FIG. **3**A) which, in turn, forces at least distal portion **22** of introducer **20** and nested sensor **10** through housing aperture **40**. Alternatively, compartment **44** may have a construct different than the one illustrated, and a mechanical driving force other than an axial force may be placed upon introducer **20** in order to initiate the displacement of it through aperture **40**. In either case, the mechanical activation component may be activated automatically upon turning on control unit **34** or may be triggered manually by a switch or button (not shown) provided on the outer surface of housing **32**. Upon release from the confinement of compartment **44**, the loaded introducer structure **20** reverts to its unstressed, unconfined original state which drives it into the skin surface **45** (see FIG. **3**B).

With any of the above described embodiments, system **30** may be configured such that introducer **20** is automatically retracted or removed from the skin **45** immediately upon transcutaneous placement of sensor **10** while leaving sensor **10** transcutaneously implanted. In the heat-transitionable memory embodiments of introducer **20**, cessation of the current supply to introducer **20** initiates a cooling of introducer **20** to a temperature which commences the shape conversion from the second operative state, i.e., the heat-stable austensitic state, to the first operative state, i.e., the heat-unstable martensitic state, thereby removing itself from the skin and back into compartment **44**. In certain embodiments, the cooling process may be expedited to transition introducer **20** from the second operative state back to the first operative state. Because the transcutaneous application and the subcutaneous environment in which introducer **20** is employed, the temperature ranges in which the introducer changes shape, in certain embodiments, will be relatively narrow, e.g., from about 45° C. (for introducer removal) to about 65° C. (for introducer insertion), but may have a narrow or wider temperature range. In the elastic memory introducer embodiments, removal of the introducer may be effected mechanically (not shown), e.g., by utilizing an extension spring or the like, which pulls or lifts introducer **20** in a retrograde direction, i.e., in a direction opposite to its entry into the skin, thereby retrieving the distal portion **22** extending from aperture **40** back into compartment **44**. Such a mechanical removal approach may also be used for heat-transitionable introducer embodiments in lieu of having to electrically reactivate the introducer and, in certain embodiments, reconnect the ancillary battery pack.

Alternatively, with introducers of either type of memory function, system **30** may be configured such that introducer **20** remains implanted with sensor **10** for the useful life of the sensor, and is removed along with the sensor upon sensor expiration. While a heat-transitionable SMA introducer may be configured to remove itself as well as the sensor from the implant site, i.e., to transition it from the second operative or austensitic shape back to the first operative or martensitic shape, it may be more efficient and less complicated and costly to simply employ a mechanical retraction component to retract the coupled introducer and sensor back into compartment **44** of housing **32**. The same mechanical activation component used for transitioning an elastic memory introducer to a transcutaneously implanted condition may be used to reversibly transition the introducer whereby it is retracted from the skin back into compartment **44**. Still yet, systems employing either type of SMA introducer may be configured such that the coupled introducer and sensor are merely pulled out of the skin insertion site along with manual removal of housing **32** from the skin.

Referring now to FIGS. **4**A and **4**B and FIGS. **5**A and **5**B, two other sensors **50** and **60** of the present disclosure are provided which are configured to include a feature or structure which enables the respective sensor to be completely self-implanting, i.e., advanced from an on-skin housing/unit to a desired transcutaneous position without the use of a separate introducer, such as introducer **20**. Referring to the Figures, in certain embodiments, a member **54** or members **64** made of a shape-shifting material, such as nitinol (NiTi) or another SMA, are provided along at least a portion of the length of the respective sensor substrates **52** and **62**, the latter being made of one or more flexible materials discussed above with respect to sensor **10**. As such, the respective members **54**, **64** function as "spines" to facilitate translation or movement of sensors **50**, **60** and, along with pointed substrate tips **56**, **66**, facilitate penetration of sensors **50**, **60** through the skin surface. With sensor **50**, for example, a single SMA spine **54** extends substantially along the central axis on one side of sensor **50**. With sensor **60**, two parallel, spaced apart spines **64** extend along opposing sides of sensor **60**. However, any suitable number and location of the spines may be employed on a particular sensor.

The SMA spine(s) may have the heat-transitionable and/or elastic memory characteristics discussed above with respect to introducer **20** and, as such, enable sensors **50**, **60** to itself take on the first and second operative states discussed above with respect to introducer **20** but without the assistance of an introducer. In heat-transitionable memory sensor embodiments, spines **54**, **64** are electrically coupled to a source of electrical power in a manner similar to that described above with respect to introducer **20**, with the coupling to the power source being, in certain embodiments, for example, directly through the control unit of the system. However, the temperature for converting sensors **50**, **60** back to the first operative state in order to effect retraction from skin, is likely to be below body temperature, otherwise, the sensors will not remain implanted, but immediately or imminently retract themselves upon cessation of current to their respective spines **54**, **64**. In elastic memory sensor embodiments, spines **54**, **64** are coupled to a mechanical driving mechanism at proximal ends in a manner similar to that described above with respect to introducer **20**, with transcutaneous implantation and retraction of sensor **50** being similar as well.

Because of the metallic nature of SMA materials, spines **54**, **64** may double as functional electrodes of their respective sensors **50**, **60** in the electrochemical sensing of an analyte. In heat-transitional embodiments of such aspects of the present disclosure, spines **54**, **64** would function to first translate or drive sensors **50**, **60** transcutaneously into the skin and, upon cessation of the driving electrical current through it, would function as analyte sensing electrodes, e.g., as either a working, reference and/or counter electrode.

As shown in the cross-sectional view of FIG. **4**B, spine **54** may be embedded within a surface of substrate **52** so as to provide sensor **50** with a flush exterior. Alternatively, spine **54** may lie on a surface of substrate **52** or, as shown in FIG. **5**B, spine **64** may form one or more portions or sides of the overall sensor construct. The substrate surface on which or within which the spines is/are provided may be a major surface, as in FIG. **4**B, i.e., extending the width side of the sensor substrate, or may be a minor surface, as in FIG. **5**B, i.e., extending across the thickness of the sensor substrate. The respective spines **54**, **64** extend from a proximal end of sensor **50**, **60** (not shown) to a distal portion to the extent necessary to provide the necessary leverage (by mass and/or force) to operatively translate sensors **50**, **60**.

Sensors **50** and **60** may be fabricated by one or more extrusion methods. For example, the sensor substrate material **52**, **62** may be made of a polymer material which may be formed in the desired shape by an extrusion process, in which case, the sensing components, including the conductive materials, as well as the SMA spines **54**, **56** are formed or provided on the substrate material after extrusion. In still other embodiments, the subject sensors may be fabricated by an extrusion process in which the SMA spines and the non-conductive materials, e.g., dielectric material forming the substrate, are co-extruded. The substrate-spine structures may then be treated to provide the desired memory characteristics, either temperature-based or elastic types, to the SMA material of the spines. Subsequently, the remaining conductive materials, e.g., metal material forming the electrode and traces, are then formed thereon. Still yet, all of the conductive and non-conductive materials and components may be formed in a single extrusion process. Examples of sensors fabricated by extrusion methods are disclosed in U.S. Patent Application Publication Nos. 2010/0331728; 2010/0331771; 2010/0326842; 2010/0326843; and 2010/0331643; all of which are assigned to the assignee of the present disclosure and are incorporated herein by reference in their entireties.

Certain embodiments of the present disclosure may include system for transcutaneously implanting a medical device, the system comprising an introducer having at least a portion engageable with at least a portion of a medical device, wherein the introducer is at least partially formed from a shape memory material, and an activating component to activate the introducer to transition from a first operative shape memory state to a second operative shape memory state, wherein said transition translates the medical device engaged with the introducer from a position above the skin surface to at least partially through the skin surface.

In certain aspects, the first operative shape memory state may comprise a heat-unstable shape and the second operative shape memory state comprises a heat-stable shape.

In further aspects, the activating component may comprise an electrical current generating component electrically coupled to the introducer.

In certain aspects, the first operative shape memory state may comprise a loaded configuration and the second operative shape memory state comprises an unloaded configuration.

In certain aspects, the activating component may comprise a driving mechanism mechanically coupled to the introducer.

Certain aspects may further comprise a housing configured for placement on a skin surface of a host, wherein the introducer is configured to be at least partially positioned within the housing when in the first operative shape memory state.

In certain aspects, the housing may comprise a compartment within which the introducer is configured to be at least partially contained when in the first operative shape memory state.

In certain aspects, the shape memory material may comprise one or more of nickel-titanium, copper-zinc-aluminum-nickel, copper-aluminum-nickel, and alloys of zinc, copper, gold and iron.

In certain aspects, the portion of the introducer engageable with the medical device may define a major axis wherein, during the transition from the first operative shape memory state to the second operative shape memory state, the introducer changes shapes along the major axis.

In certain aspects, the medical device may comprise an in vivo sensor.

In certain aspects, the introducer may comprise at least one coupling member for securing the medical device to the introducer at least when in the first operative memory state.

Certain embodiments of the present disclosure may include a system for transcutaneously implanting a medical device, the system comprising a housing configured for placement on a skin surface of a host, an introducer configured to be at least partially positioned within the housing and having at least a portion engageable with at least a portion of a medical device, wherein the introducer is at least partially formed from a shape memory material, and an electrical current generating component electrically coupled to the introducer for activating the introducer to transition from a heat-unstable shape to a heat-stable shape, wherein said transition translates the medical device engaged with the introducer from a position within the housing to at least partially through the skin surface.

In certain aspects, the electrical current generating component may comprise a battery contained within the housing.

In certain aspects, the battery may be further configured to power a control unit for operating the medical device.

In certain aspects, the electrical current generating component may comprise a battery not contained within the housing.

Certain embodiments of the present disclosure may include a system for transcutaneously implanting a medical device, the system comprising a housing configured for placement on a skin surface of a host, an introducer configured to be at least partially positioned within the housing and having at least a portion engageable with at least a portion of a medical device, wherein the introducer is at least partially formed from a shape memory material, and a driving mechanism mechanically coupled to the introducer for moving the introducer relative to the housing to transition the introducer from a loaded configuration to an unloaded configuration, wherein said transition translates the medical device engaged with the introducer from a position within the housing to at least partially through the skin surface.

In certain aspects, the housing may comprise a compartment configured to physically retain the introducer in the loaded configuration.

Certain embodiments of the present disclosure may include an in vivo analyte monitoring system comprising a housing configured for placement on a skin surface of a host, a control unit housed within the housing, an in vivo analyte sensor having a proximal portion and a distal portion, wherein the proximal portion is operatively coupleable to the control unit, a sensor introducer at least partially positioned within the housing, wherein the introducer is at least partially comprised of a shape memory material and wherein a portion of the introducer is engageable with the sensor distal portion, and a transitioning component to transition the introducer from a first operative shape memory state to a second operative shape memory state, wherein said transitioning translates the sensor distal portion from a position within the housing to at least partially through the skin surface.

In certain aspects, the portion of the introducer engageable with the sensor distal portion may have a crosswise dimension substantially similar to that of the sensor distal portion.

In certain aspects, the portion of the introducer engageable with the sensor distal portion may have a crosswise dimension smaller than that of the sensor distal portion.

In certain aspects, the sensor distal portion and the portion of the introducer engageable with the sensor distal portion may have respective configurations which enable a nesting arrangement between them.

In certain aspects, the portion of the introducer engageable with the sensor distal portion may comprise a U-shaped configuration when in the first operative shape memory state.

In certain aspects, the introducer may comprise a distal tip configured to substantially atraumatically pierce the skin surface.

In certain aspects, the introducer may comprise at least one coupling member for securing the sensor distal portion to the introducer at least when the introducer is in the first operative memory state.

Certain embodiments of the present disclosure may include a transcutaneously implantable medical device comprising a flexible, elongated substrate having a distal tip configured to substantially atraumatically pierce the skin surface, wherein the substrate is formed from a non-conductive material, and at least one spine extending along a length of the substrate, wherein the at least one spine is formed from a shape memory material, and wherein the medical device is translatable from a first operative shape memory state to a second operative shape memory state.

In certain aspects, the first operative shape memory state may comprise a heat-unstable shape and the second operative shape memory state comprises a heat-stable shape.

In certain aspects, the first operative shape memory state may comprise a compressed configuration and the second operative shape memory state comprises an uncompressed configuration.

In certain aspects, the shape memory material may comprise one or more of nickel-titanium, copper-zinc-aluminum-nickel, copper-aluminum-nickel, and alloys of zinc, copper, gold and iron.

In certain aspects, the medical device may be an electrochemical sensor.

In certain aspects, the electrochemical sensor may comprise at least one electrode.

In certain aspects, at least one spine may function as the at least one electrode.

In certain aspects, the electrochemical sensor may be an analyte sensor.

In certain aspects, the analyte sensor may be a glucose sensor.

Certain embodiments of the present disclosure may include a method for transcutaneously implanting a medical device, at least a portion of which is flexible, the method comprising providing an introducer, wherein the introducer is at least partially formed from a shape memory material, engaging at least the flexible portion of the medical device with the introducer, wherein the engaged introducer and medical device are in a nested arrangement, and wherein the introducer is in a first operative shape memory state, positioning a skin-penetrating end of the introducer adjacent the skin surface, and transitioning the introducer from the first operative shape memory state to a second operative shape memory state, wherein the introducer penetrates through the skin surface and transcutaneously implants the flexible portion of the medical device.

In certain aspects, engaging the flexible portion of the medical device with the introducer in a nested arrangement may comprise cooling the introducer to a predefined temperature while the medical device is structurally aligned along a major axis of the introducer.

In certain aspects, transitioning the introducer from the first operative shape memory state to the second operative shape memory state may comprise applying a selected amount of electrical current to the introducer.

In certain aspects, engaging the flexible portion of the medical device with the introducer in a nested arrangement may comprise loading the introducer to a reduced profile while the medical device is structurally aligned along a major axis of the introducer and positioning the introducer and nested sensor in a confined space.

In certain aspects, transitioning the introducer from the first operative shape memory state to the second operative shape memory state may comprise releasing the introducer from the confined space.

In certain aspects, the confined space may be provided within a housing that is configured for placement on the skin surface.

Certain aspects may further comprise removing the introducer from the skin while leaving the medical device transcutaneously implanted.

In certain aspects, the removing the introducer from the skin while leaving the medical device transcutaneously implanted may comprise manually retracting the introducer from within the skin.

Certain aspects may further comprise maintaining the introducer within the skin along with the transcutaneously implanted medical device for the useful life of the medical device.

Certain aspects may further comprise simultaneously removing the introducer and the medical device from the skin subsequent to the expiration of the useful life of the medical device.

In certain aspects, the simultaneous removal of the introducer and the medical device from the skin may comprise manually retracting the introducer and the medical device.

In certain aspects, the simultaneous removal of the introducer and the medical device from the skin may comprise transitioning the introducer from the second operative shape memory state to the first operative shape memory state.

In certain aspects, the medical device may comprise an analyte sensor.

The preceding merely illustrates the principles of the disclosure. It will be appreciated that those skilled in the art will be able to devise various arrangements which, although not explicitly described or shown herein, embody the principles of the disclosure and are included within its spirit and scope. Furthermore, all examples and conditional language recited herein are principally intended to aid the reader in understanding the principles of the disclosure and the concepts contributed by the inventors to furthering the art, and are to be construed as being without limitation to such specifically recited examples and conditions. Moreover, all statements herein reciting principles, aspects, and embodiments of the disclosure as well as specific examples thereof, are intended to encompass both structural and functional equivalents thereof. Additionally, it is intended that such equivalents include both currently known equivalents and equivalents developed in the future, i.e., any elements developed that perform the same function, regardless of structure. The scope of the present disclosure, therefore, is not intended to be limited to the exemplary embodiments shown and described herein. Rather, the scope and spirit of present disclosure is embodied by the appended claims.

What is claimed is:

1. A system for transcutaneously implanting a medical device, the system comprising:

an introducer having at least a portion engageable with at least a portion of a medical device, wherein the introducer comprises a shape memory alloy having a predetermined activation temperature range,

wherein the introducer, at a temperature below the predetermined activation temperature range, is in a first shape memory state configuration in which the introducer includes a first transition bend adjacent to a straight proximal portion of the introducer, and

wherein the introducer, at a temperature above the predetermined activation temperature range, is in a second shape memory state configuration in which the introducer includes a second transition bend adjacent to a straight distal portion of the introducer; and

an activating component to change the temperature of the introducer to transition the introducer from the first shape memory state configuration to the second shape memory state configuration, wherein said transition changes the shape of the introducer and translates the medical device engaged with the introducer from a position above the skin surface to a position at least partially through the skin surface;

wherein said transition is driven by a martensitic-to-austenitic change of the shape memory alloy.

2. The system of claim **1** wherein the activating component comprises an electrical current generating component electrically coupled to the introducer to heat the introducer above the predetermined activation temperature range to cause the transition of the introducer from the first shape memory state configuration to the second shape memory state configuration.

3. The system of claim **1** further comprising a housing configured for releasable placement on a skin surface of a host using an adhesive, wherein the introducer is configured to be at least partially positioned within the housing when in the first shape memory state configuration.

4. The system of claim **3** wherein the housing comprises a compartment within which the introducer is configured to be at least partially contained when in the first shape memory state configuration.

5. The system of claim **1** wherein the shape memory alloy comprises one or more of nickel-titanium, copper-zinc-aluminum-nickel, copper-aluminum-nickel, and alloys of zinc, copper, gold and iron.

6. The system of claim **1** wherein the medical device is an analyte sensor and further wherein the portion of the introducer engageable with the medical device defines a major axis wherein, during the transition from the first shape memory state configuration to the second shape memory state configuration, a distal portion of the introducer changes shape along the major axis, while a proximal portion of the introducer remains fixed relative to the activating component.

7. The system of claim **1** wherein the introducer comprises at least one coupling member for securing the medical device to the introducer at least when in the first shape memory state configuration.

8. The system of claim **1** wherein the introducer, in the first shape memory state configuration, comprises a U-shaped distal portion that transitions at a bend to a straight proximal portion, and wherein the introducer, in the second shape memory state configuration, is L-shaped.

9. The system of claim **1**, wherein the introducer includes an insulative layer to protect the user or medical device from heat or electrical damage.

10. The system of claim **1**, wherein the location of the first transition bend along the length of the introducer differs from the location of the second transition bend.

11. The system of claim **1**, wherein the location of the first transition bend along the length of the introducer coincides with the location of the second transition bend.

12. A method for transcutaneously implanting a medical device, at least a portion of which is flexible, the method comprising:

engaging at least the flexible portion of the medical device with an introducer, wherein the engaged introducer and medical device are in a nested arrangement, and wherein the introducer comprises a shape memory alloy having a predetermined activation temperature range,

wherein the introducer, at a temperature below the predetermined activation temperature range is in a first shape memory state configuration in which the introducer includes a first transition bend adjacent to a straight proximal portion of the introducer, and

wherein the introducer, at a temperature above the predetermined activation temperature range is in a second shape memory state configuration in which the introducer includes a second transition bend adjacent to a straight distal portion of the introducer; and

positioning a skin-penetrating end of the introducer adjacent the skin surface; and

changing the temperature of the introducer to transition the introducer from the first shape memory state configuration to the second shape memory state configuration such that the introducer penetrates through the skin surface and transcutaneously implants the flexible portion of the medical device, and further wherein said transition changes the shape of the introducer, and is driven by a martensitic-to-austenitic change of the shape memory alloy.

13. The method of claim **12** wherein engaging the flexible portion of the medical device with the introducer in a nested arrangement comprises cooling the introducer below the predetermined activation temperature range while the medical device is structurally aligned along a major axis of the introducer, and wherein a distal portion of the introducer changes shape along the major axis, while a proximal portion of the introducer remains fixed relative to the activating component.

14. The method of claim **13** wherein transitioning the introducer from the first shape memory state configuration to the second shape memory state configuration comprises applying a selected amount of electrical current from an electrical current generating component electrically coupled to the introducer to heat the introducer above the predetermined activation temperature range.

15. The method of claim **12** further comprising removing the introducer from the skin while leaving the medical device transcutaneously implanted.

16. The method of claim **12** further comprising maintaining the introducer within the skin along with the transcutaneously implanted medical device for the useful life of the medical device.

17. The method of claim **16** further comprising simultaneously removing the introducer and the medical device from the skin subsequent to the expiration of the useful life of the medical device.

18. The method of claim **17** wherein the simultaneous removal of the introducer and the medical device from the skin comprises transitioning the introducer from the second shape memory state configuration to the first shape memory state configuration.

19. The method of claim **12** wherein the introducer, in the first shape memory state configuration, comprises a U-shaped distal portion that transitions at a bend to a straight proximal portion, and wherein the introducer, in the second shape memory state configuration, is L-shaped.

20. The method of claim **12**, wherein the introducer includes an insulative layer to protect the user or medical device from heat or electrical damage.

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专利名称(译)	用于经皮植入医疗装置的系统和方法		
公开(公告)号	US9743862	公开(公告)日	2017-08-29
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[标]申请(专利权)人(译)	雅培糖尿病护理公司		
申请(专利权)人(译)	雅培糖尿病INC.		
当前申请(专利权)人(译)	雅培糖尿病INC.		
[标]发明人	STAFFORD GARY ASHLEY RUSH BENJAMIN MARK		
发明人	STAFFORD, GARY ASHLEY RUSH, BENJAMIN MARK		
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摘要(译)

提供了用于经皮植入医疗装置的系统和方法，例如体内分析物传感器。该系统和方法涉及使用由形状记忆合金（SMA）材料制成的引入器或插入器，其可从一个操作状态或配置转换到另一个操作状态或配置，其中从状态到状态的转换使得经皮植入和/或经皮外植医疗器械。