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(71) Applicant: **LUMOPTIK, INC.** [US/US]; 2700 West Park Boulevard, Shaker Heights, OH 44120 (US).

(72) Inventors: **JANICKI, Thomas, I.**; 2700 West Park Boulevard, Shaker Heights, OH 44120 (US). **JANICKI, Arthur, A.**; 10234 Hightower Court, Cincinnati, OH 45249 (US). **JANICKI, Oscar, Thomas**; 28732 Lynhaven Drive, North Olmsted, OH 44070 (US).

(74) Agents: **HANLEY, Elizabeth, A.** et al.; Mccarter & English, LLP, 265 Franklin Street, Boston, MA 02110 (US).

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(54) Title: INSERTION TOOL GUIDANCE SYSTEMS FOR VASCULAR OR JOINT ACCESS

(57) Abstract: Determining the location of a distal end of an insertion tool as it penetrates through biological tissue and into a desired site, such as the lumen of a blood vessel, a joint capsule, or joint space, are described. When the distal tip of an insertion tool traverses the blood vessel wall or penetrates a joint capsule, the reflecting plane of the vessel wall or joint capsule is positioned at or near zero distance relative to the distal tip of the light guide. Once the distal tip enters a less dense blood vessel lumen or joint space, the distance to the reflecting plane becomes greater than zero, thus producing a change or drop in the intensity of the reflected light that is measured by a light sensor and interpreted by a logic unit providing an indication to the operator that the desired site has been reached.

INSERTION TOOL GUIDANCE SYSTEMS FOR VASCULAR OR JOINT ACCESS

Related Applications

This application claims priority under 35 U.S.C. § 119 to U.S. Provisional Application No. 61/783,680, filed March 14, 2013 and U.S. Provisional Application No. 61/783,725, filed March 14, 2013, each of which is incorporated by reference in its entirety.

Background

Establishing vascular access by means of a peripheral intravenous line (PIV), central venous line (CVC) or peripherally-inserted central catheter (PICC) line is associated with almost every hospital admission, outpatient surgery, invasive radiologic procedure and most visits to the emergency room. Conventional techniques of needle insertion into blood vessels are procedures that are limited to visual monitoring and can lead to multiple attempts of insertion, injury to vessels and nerves, hematomas and more serious complications including pneumothorax and internal bleeding. If the needle is not advanced sufficiently through the different solid layers of the blood vessel, the lumen of the vessel is not reached. On the other hand, if the needle is advanced too far, the opposite wall of the vessel may be punctured, resulting in injury to the vessel and leakage of blood. The aging of the population increases the difficulties in inserting needles into the lumen of blood vessels. There is, thus, a need for an improved and effective insertion tool guidance system for access to blood vessels in the body.

Furthermore, acute joint conditions, such as traumatic sport injuries, and chronic joint conditions, such as rheumatoid arthritis and osteoarthritis, affect large population groups worldwide. Conventional systemic delivery of therapeutic agents to a target joint typically requires using large doses of the agent to ensure that a sufficient amount of the agent is delivered to the target. This approach is associated with risks of significant systemic side effects and precludes the use of a number of therapeutic agents because of their toxicity. Thus, systemic treatment of joint conditions is unsatisfactory as it is associated with side effects related to systemic toxicity. Conventional techniques of supplying therapeutic agents into joint spaces are unable to determine in an objective real-time manner whether a joint space has been reached. Due to this high degree of uncertainty in verifying whether a joint space has been reached, it is estimated that there can be a high degree of error in conventional techniques in which a therapeutic agent is not delivered into the joint space as planned.

There is, thus, a need for an improved and effective insertion tool guidance system for local access to joint spaces in the body.

Summary

Exemplary insertion tool guidance systems, devices, kits, and methods described herein provide direct and objective real-time confirmation of entry of a distal tip of an insertion tool (e.g., a needle) into the lumen of a blood vessel in a patient's body. Exemplary embodiments enable medical practitioners and health providers to accurately and efficiently access blood vessels with certainty that the lumen of the vessel has been reached and that the opposite wall of the vessel has not been punctured, thus eliminating the need for multiple attempts and the risk of injury, leakage and associated complications.

In accordance with one exemplary embodiment, a medical penetration detection system is provided to detect insertion of an insertion tool into a lumen of a blood vessel. The system includes a light source, a light sensor, and a light guide configured to fit inside a bore of the insertion tool. A distal end of the light guide is configured to transmit light into biological tissue. A proximal portion of the light guide is in optical communication with the light source to receive light emitted by the light source. The proximal portion of the light guide is also in optical communication with the light sensor to measure light reflected by the biological tissue. The system also includes a computing module coupled with the light sensor and programmed to determine whether the biological tissue is a lumen of a blood vessel based on a decrease in intensity of the light reflected by the biological tissue.

In accordance with another exemplary embodiment, a method is provided for determining a location of a distal end of an insertion tool as it penetrates a patient's body. The method includes disposing a light guide through a bore of the insertion tool, emitting light through a light source, transmitting the emitted light through the light guide and into biological tissue at a distal end of the light guide, detecting light reflected from the biological tissue using a light sensor, and determining whether the biological tissue is a lumen of a blood vessel based on a decrease in intensity of the light reflected by the biological tissue.

In addition, exemplary insertion tool guidance systems, devices, kits, and methods described herein provide direct and objective real-time confirmation of entry of a distal tip of an insertion tool (e.g., a needle) into a joint capsule or a joint space in a patient's body. Exemplary embodiments enable medical practitioners and health providers to accurately and efficiently access joint capsules or joint spaces with certainty that the target location in the

joint has been reached, thus eliminating the need for multiple access attempts and the risk of injury and associated complications.

In accordance with one exemplary embodiment, a medical penetration detection system is provided for detecting insertion of a distal tip of an insertion tool into a joint space or a joint capsule. The system includes a light source, a light sensor, and a light guide configured to fit inside a bore of the insertion tool. A distal end of the light guide is configured to transmit light into biological tissue. A proximal portion of the light guide is in optical communication with the light source to receive light emitted by the light source. The proximal portion of the light guide is also in optical communication with the light sensor to measure light reflected by the biological tissue. The system also includes a computing device coupled with the light sensor and programmed to determine whether the biological tissue is a joint space or a joint capsule based on a change in intensity of the light reflected by the biological tissue.

In accordance with another exemplary embodiment, a method is provided for determining a location of a distal tip of an insertion tool as it penetrates a patient's body. The method includes disposing a light guide through a bore of the insertion tool, emitting light through a light source, transmitting the emitted light through the light guide and into biological tissue at a distal end of the light guide, detecting light reflected from the biological tissue using a light sensor, and determining whether the biological tissue is a joint space or a joint capsule based on a change in intensity of the light reflected by the biological tissue.

Exemplary embodiments also provide computing systems and devices having processing devices or modules programmed or configured to perform any of the methods described herein. An exemplary computing system or device may include, in some embodiments, a visual display device for displaying one or more aspects of the entry of an insertion tool into a blood vessel, a joint capsule, or joint space to enable an operator to monitor the insertion process in real-time. The display device may, for example, display an intensity profile of light reflected from the tissue at the distal end of the insertion tool in real-time as the tool is inserted into the body.

Exemplary embodiments further provide one or more non-transitory computer-readable media having encoded thereon one or more computer-executable instructions that, when executed on a computing system or device, perform any of the methods described herein.

Brief Description of the Drawings

The foregoing and other objects, aspects, features, and advantages of exemplary embodiments will become more apparent and may be better understood by referring to the following description taken in conjunction with the accompanying drawings, in which:

Figure 1 is a block diagram of an exemplary insertion tool guidance system, in which the distal portion of the light guide is in optical communication with a Y-split light guide, one end of the Y-split light guide is in optical communication with a light source, and the other end is in optical communication with a light sensor.

Figure 2 is a partial longitudinal cross-sectional view of the distal portion of an insertion tool and a light guide, in which the light guide is an optical fiber pair.

Figure 3A is a partial longitudinal cross-sectional view of the distal portion of an insertion tool and the distal portion of a light guide, in which the light guide is an annular optical path.

Figure 3B is a magnified longitudinal cross-sectional view of the light guide of Figure 3A.

Figure 4A is a partial longitudinal cross-sectional view of an exemplary insertion tool guidance system.

Figure 4B is a magnified longitudinal cross-sectional view of the distal tip of the insertion tool and light guide of Figure 4A.

Figure 5 is an exploded view of the guidance system illustrated in Figure 4A.

Figure 6 is a block diagram of an exemplary computing module for use in an insertion tool guidance system.

Figure 7 is a side view of an insertion tool and a light transmissive stylet, which fits inside the bore or lumen of the insertion tool, in which the stylet can serve as a light guide for the insertion tool guidance system.

Figure 8A is a partially exploded cross-sectional view of an insertion tool guidance system which includes a light transmissive stylet as the light guide.

Figure 8B is a magnified, cross-sectional view of the distal tip of the insertion tool and light guide of Figure 8A.

Figure 8C is a perspective view of the handpiece for the insertion tool guidance system, which preferably includes a pull tab to activate the device.

Figure 8D is a partial perspective view of the proximal end of a stylet which attaches to the distal end of the handpiece to assemble the insertion tool guidance system.

Figure 9 is a partial circuit drawing of an electronic system for use in an exemplary insertion tool guidance system.

Figure 10 is a schematic illustrating use of an exemplary guidance system in determining when a distal tip of an insertion tool has reached the lumen of a blood vessel.

The accompanying drawings are not intended to be drawn to scale.

Detailed Description

An insertion tool guidance system, device, kit, and method are described herein to assist an operator of an insertion tool, typically, a medical professional, in determining the location of the distal tip of the insertion tool as it penetrates through tissue and into the lumen of a blood vessel, a joint capsule, or a joint space. Exemplary embodiments enable an operator to guide insertion of one or more tools into the lumen of a blood vessel, or a joint capsule or joint space. To this end, exemplary embodiments determine, in real-time and in an objection manner, that the distal tip of the insertion tool has reached the lumen of a blood vessel.

An exemplary insertion tool guidance system includes one or more light sources, one or more light sensors, one or more light guides, and a computing module including a processor programmed or configured to determine in real-time (i.e., concurrently with the insertion process) when the distal end of an insertion tool has reached the lumen of a blood vessel, or a joint capsule or joint space. The light guide is configured such that light emitted by the light source is guided through the insertion tool and transmitted into the body tissue at the distal end of the insertion tool. The same or a separate light guide receives light reflected from the body tissue and transmits it to the light sensor. The computing module of the guidance system determines one or more aspects of the reflected light (e.g., intensity values, absolute and/or relative changes in intensity, combinations thereof) in order to determine, in real-time, whether the distal end of the insertion tool has reached the lumen of a blood vessel, or a joint capsule or joint space. One or more components of the insertion tool guidance system may be provided separately from or may be incorporated with an associated insertion tool, e.g., a needle.

Blood vessels include a central lumen enclosed by a vessel wall. Vascular access for extracting a blood sample or for injecting an agent into the blood involves inserting the distal end of an insertion tool into the lumen. The vessel walls are typically formed of three layers, namely, the tunica intima, the tunica media and the tunica adventitia, and include dense tissues like connective tissue, collagen fibers and elastic fibers. The vessel walls have a

higher density than outside tissues (except bone) and are highly reflective to light. The lumen, being a substantially hollow space filled with blood, is significantly less dense than the vessel walls.

A biological joint typically includes a joint capsule enclosing a joint space. Access to a joint space for aspirating the joint or for injecting an agent into the joint space involves inserting the distal end of an insertion tool into the joint space. The joint capsule includes dense tissues like connective tissue and collagen fibers, has a higher density than outside tissues (except bone and intra-articulate ligaments), and is highly reflective to light. The joint space is significantly less dense than the joint capsule.

The intensity of light reflected from biological tissue at the distal end of an insertion tool depends on the distance of the reflecting plane from the distal end of the light guide, the density of the penetrated tissue and its composition. When the distal end of the insertion tool traverses the relatively dense joint capsule or vessel wall, the reflecting plane of the light reflected from the body tissue is positioned at a zero or near-zero distance relative to the distal end of the light guide. In some embodiments, the insertion tool guidance system may analyze one or more aspects of the reflected light (e.g., intensity values, absolute and/or relative changes in intensity, combinations thereof) in real-time to determine if they are typical of light reflected from vessel walls or a joint capsule. In some embodiments, the guidance system may thereby detect when the distal end of the insertion tool penetrates the vessel wall or joint capsules, and may provide a real-time indication to the operator. For vessel insertion, as illustrated in Figure 10, the indication may include emitting or flashing a color light, e.g., blue, to indicate that the distal end of the insertion tool is penetrating a vessel wall. In response, an operator of the insertion tool may continue to insert the insertion tool to reach the lumen of the blood vessel.

Once the distal end of the insertion tool enters the less-dense blood vessel lumen or joint space, the distance to the light reflecting plane becomes greater than zero, thus producing a drop in the intensity of the reflected light relative to the intensity of the reflected light in the vessel wall or joint capsule. In some cases, the density of the reflecting plane may vary to some extent in the blood vessel lumen. In some embodiments, the insertion tool guidance system may analyze one or more aspects of the reflected light (e.g., intensity values, absolute and/or relative drop in intensity, combinations thereof) in real-time to determine if they are typical of light reflected from the lumen of a vessel or joint space. The guidance system may thereby detect when the distal end of the insertion tool starts to enter the lumen or joint space, and may provide a real-time indication to the operator. As illustrated in Figure

10, the indication may include emitting or flashing a color light, e.g., yellow, to indicate that the distal end of the insertion tool has completed penetrating the vessel wall and has begun to penetrate the lumen of the vessel. In response, an operator of the insertion tool may continue to insert the insertion tool to reach the lumen of the blood vessel. In some cases, the operator may slow down the insertion process to avoid overshooting the lumen of the blood vessel or joint space.

The insertion tool guidance system may continue to analyze one or more aspects of the reflected light (e.g., intensity values, absolute and/or relative drop in intensity, combinations thereof) in real-time to determine if they are typical of light reflected from the lumen of a vessel. The guidance system may thereby detect when the distal end of the insertion tool has entered the lumen of the vessel, and may provide a real-time indication to the operator. As illustrated in Figure 10, the indication may include emitting or flashing a color light, e.g., green, to indicate that the distal end of the insertion tool has completely entered the lumen. In response, an operator of the insertion tool may stop the insertion process as the lumen of the blood vessel has been reached.

If the insertion tool is continued to be inserted beyond the lumen and into the opposite vessel wall, the high-density reflecting plane is again positioned at a zero or near-zero distance relative to the distal end of the light guide. This causes a rise in the intensity of the reflected light relative to the intensity of the reflected light in the lumen of the vessel. In a situation in which the distal tip of the insertion tool encounters atherosclerotic plaque with or without calcium deposits, a partial increase in the intensity of the reflected light may be encountered (relative to the intensity in the lumen of the vessel), followed by a further increase in the intensity of the reflected light when the main portion of the blood vessel wall is encountered. In some embodiments, the insertion tool guidance system may analyze one or more aspects of the reflected light (e.g., intensity values, absolute and/or relative changes in intensity, combinations thereof) in real-time to determine if they are typical of light reflected from the wall of a vessel. The guidance system may thereby detect when the distal end of the insertion tool penetrates the opposite vessel wall, and may provide a real-time indication to the operator. As illustrated in Figure 10, the indication may include emitting or flashing a color light, e.g., red, to indicate that the distal end of the insertion tool has overshot the lumen and has penetrated the opposite vessel wall. In response, an operator of the insertion tool may retrace the insertion path to return the distal tip to the lumen of the blood vessel.

During such a retracing of the distal tip from the opposite vessel wall to the vessel lumen, the insertion tool guidance system may analyze one or more aspects of the reflected

light (e.g., intensity values, absolute and/or relative drop in intensity, combinations thereof) in real-time to determine if they are typical of light reflected from the lumen of a vessel. The guidance system may thereby detect when the distal end of the insertion tool has re-entered the lumen of the vessel, and may provide a real-time indication to the operator. As illustrated in Figure 10, the indication may include emitting or flashing a color light, e.g., green, to indicate that the distal end of the insertion tool has completely re-entered the lumen. In response, an operator of the insertion tool may stop the insertion process as the lumen of the blood vessel has been reached again.

In some embodiments, the guidance system may display, on a visual display device, an intensity profile of the reflected light in real-time during the insertion process.

Exemplary insertion tool guidance systems may be used with insertion tools for extracting a blood sample or for injecting any desired substance into blood. In addition, exemplary insertion tool guidance systems may be used with insertion tools for aspirating the joint or for injecting any desired substance into the joint capsule and/or the joint space, for example, for prolonged release. Exemplary methods may thus replace systemic treatment of the joint, thereby avoiding its attendance complications. Exemplary embodiments thus also enable intra-joint therapies, for example, for osteoarthritis.

Exemplary guidance systems may be used in any suitable setting including, but not limited to, in the home, in medical diagnostic and therapeutic arenas such as hospitals, surgery centers, doctors' offices, invasive radiology, operating rooms, intensive care units, emergency rooms, in first response, and in the military in the battlefield. Exemplary guidance systems may be operated by the patient him/herself or by medical professionals, such as nurses, lab technicians, or physicians.

I. Definitions

Certain terms are defined in this section to facilitate understanding of exemplary embodiments.

The term "insertion tool," as used herein, refers to one or more penetrative devices that can be inserted into a blood vessel, joint capsule, or joint space in an animal body. Exemplary insertion tools may include, but are not limited to, a single needle, multiple needles, a needle coupled to a tubing, catheter or guidewire, multiple needles coupled to one or more tubings, catheters or guidewires, a needle coupled to a therapeutic tool (e.g., an electric lead), one or more catheters, one or more leads, and the like.

The term "patient," as used herein, refers to any type of animal, human or non-human, that may be penetrated with an insertion tool.

The term "body," as used herein, refers to the body of a patient.

The term "blood vessel," as used herein, refers to any artery, vein or capillary in an animal body.

The term "joint," as used herein, refers to any joint in an animal body.

The terms "substance" and "therapeutic agent," as used herein, refer to any type of therapeutic tool, drug, biologically active agent, biological substance, chemical substance or biochemical substance that is capable of being administered to a patient employing an insertion tool. Exemplary substances include, but are not limited to, agents in a liquid state.

The term "optical," as used herein, refers to a material that can be used as a light guide and is capable of transmitting light to the distal end of the light guide with sufficient energy for reflected light to be detected by a light sensor. Suitable optical materials include, but are not limited to, optical quality materials, and also less perfect, but still optically transmissive materials, such as, optically transmissive plastics and similar inert materials.

The term "change in intensity of the light reflected by the biological tissue," as used herein, includes those changes in the intensity of light reflected by biological tissue that are sufficient and/or significant for allowing determination of whether the biological tissue is a blood vessel wall or the lumen of a blood vessel, or a joint capsule or joint space. The change in the intensity can be measured at different wavelengths of light. Examples of ranges for the drop in intensity of reflected light on movement from a blood vessel wall into the lumen of a blood vessel may include, but are not limited to, about 5%-50%, about 5%-40%, about 5%-30%, about 5%-20%, and about 5%-10%, depending on various factors, for example, the type of blood vessel being accessed. Examples of ranges for the rise in intensity of reflected light on movement into a joint capsule may include, but are not limited to, about 5%-50%, about 5%-40%, about 5%-30%, about 5%-20%, and about 5%-10%, depending on various factors, for example, the type of joint being accessed. Examples of ranges for the drop in intensity of reflected light on movement from a joint capsule into a joint space may include, but are not limited to, about 5%-50%, about 5%-40%, about 5%-30%, about 5%-20%, and about 5%-10%, depending on various factors, for example, the type of joint being accessed. All numbers listed above can be the upper or lower limit of ranges for drops in intensity which are intended to be part of this invention. More specific exemplary ranges are set forth in the exemplary embodiments below which are not intended to be limiting.

The term "computer-readable medium," as used herein, refers to a non-transitory storage hardware, non-transitory storage device or non-transitory computer system memory that may be accessed by a controller, a microcontroller, a computational system or a module of a computational system to encode thereon computer-executable instructions or software programs. The "computer-readable medium" may be accessed by a computational system or a module of a computational system to retrieve and/or execute the computer-executable instructions or software programs encoded on the medium. The non-transitory computer-readable media may include, but are not limited to, one or more types of hardware memory, non-transitory tangible media (for example, one or more magnetic storage disks, one or more optical disks, one or more USB flash drives), computer system memory or random access memory (such as, DRAM, SRAM, EDO RAM) and the like.

The term "proximal," as used herein, refers to a portion, end or component of an insertion tool that is farthest from an injection site on a patient's body when the insertion tool is held against the patient for insertion.

The term "distal," as used herein, refers to a portion, end or component of an insertion tool that is closest to an injection site on a patient's body when the insertion tool is held against the patient for insertion.

The term "equal," as used herein, refers, in a broad lay sense, to exact equality or approximate equality within some tolerance.

II. Exemplary Non-Limiting Embodiments of Insertion Tool Guidance Systems

An exemplary insertion tool guidance system includes a light guide, a light source, a light sensor, and a computing module. The light guide has a diameter, shape and length suitable for insertion into and removal from the bore of an insertion tool, for example, a needle. The insertion tool has a path for fluid communication therethrough between a distal sharp end and a proximal end. The path is generally referred to as the lumen or bore of the insertion tool. The devices described herein include an insertion tool (e.g., a needle) with the insertion tool guidance system attached thereto, such that the light guide is positioned in the bore of the insertion tool, preferably with the distal end of the light guide at or near the distal end of the insertion tool.

In a preferred embodiment, the insertion tool guidance system includes a handpiece configured to be held by an operator. In some preferred embodiments, the computing module is housed in the handpiece. Optionally, the system also includes a locking connector which

connects the insertion tool to the guidance system, optionally via the light guide and/or handpiece.

The computing module includes a processing unit programmed or configured to analyze and interpret data provided by the light sensor to determine if the distal end of the insertion tool has entered a dense area such as a joint capsule or a less dense area, such as the lumen of a blood vessel or joint space. Upon making this determination, the computing device triggers one or more indicators, such as a visual, tactile or acoustic signal, to indicate to the operator that the insertion tool has entered into the lumen of a blood vessel or a joint capsule or joint space. In some embodiments, the indicators may be provided on the insertion tool guidance device, such as on a user interface on the device. Alternatively, the indicators and/or data may be transmitted to a remote site, such as a separate computing device, application or user interface. The data may be transmitted wirelessly, such as via Bluetooth, or another transmission system.

Certain exemplary insertion tool guidance systems are described below with reference to Figures 1-9.

Figure 1 illustrates an exemplary insertion tool guidance system 1000 configured for use with an insertion tool (e.g., a needle) 1010. The insertion tool guidance system 1000 includes a light source 1040, a light sensor 1050, a light guide 1020 and a computing device 1060. The light source 1040 and the light sensor 1050 are in optical communication with the light guide 1020. The light source 1040 and the light sensor 1050 are coupled directly or indirectly to the computing device 1060. The insertion tool includes walls 1012 which define a central lumen or bore 1014. (As discussed herein, lumen 1014, 2020, 3020 may be alternatively referred to as a bore 1014, 2020, 3023and lumen will generally refer to a lumen for vascular devices, while bore will refer to a joint access device. One skilled in the art will appreciate that the terms may be interchanged for purposes of the present disclosure). A light guide 1020 of the insertion tool guidance system is configured and sized to fit inside the central lumen or bore 1014, and the distal end 1022 of the light guide 1020 is aligned with the distal tip 1016 of the insertion tool 1010.

In use, the light source 1040 emits light through the light guide 1020 into biological tissue at a tissue plane 1080 at or near the distal end of the insertion tool 1010. Light reflected from the tissue plane 1080 is transmitted from the biological tissue through the light guide 1020 to the light sensor 1050. The output of the light sensor 1050 is used by the computing device 1060 to determine one or more aspects of the reflected light (e.g., intensity values, absolute and/or relative changes in intensity, combinations thereof) in order to detect

if the distal tip 1016 of the insertion tool 1010 has reached the lumen of a blood vessel, or a joint capsule or joint space.

A. Light Guide

A variety of light guides may be included in the insertion tool guidance system, certain non-limiting embodiments of which are described herein. The light guide 1020 may include a single optical fiber, an optical fiber pair (or plurality), an annular optical path, a light transmissive plastic support insert such as a stylet, or a combination thereof. In some exemplary insertion tool guidance systems, the distal tip of the light guide is preferably cut at a 90° angle, a 45° angle, or any other desirable angle, relative to the longitudinal axis of the insertion tool.

In some embodiments, when fully inserted in the insertion tool 1010, the distal end 1022 of the light guide 1020 is flush with the distal tip 1016 of the insertion tool 1010. In other embodiments, the distal end 1022 of the light guide 1020 is disposed inside the lumen or bore 1014 of the insertion tool 1010, in an area proximal to the distal tip 1016 of the insertion tool 1010. In this embodiment, the light guide 1020 typically includes a lens at its distal tip, such that the outer surface of the lens is flush with the distal tip 1016 of the insertion tool 1010.

The distal tip of the light guide, preferably an optical fiber, may be bare or may include a lens, depending on the need. In some embodiments, a lens may be included and associated with a light guide to increase light transmission and to capture reflected light by the light guide. The lens on the distal tip of the light guide may be formed from any suitable material that transmits light, and preferably preserves the evanescent wave at the distal tip of the light guide. In one embodiment, a lens is formed by cutting an optical fiber at a 90° angle, such that the distal tip of the light guide is inside the lumen of the insertion tool, and is short of (and proximal to) the distal tip of the insertion tool, forming a void and then filling the void with a sterile, transparent, biologically inert fluid, such as saline, to form a lens. The fluid fills the beveled portion of the insertion tool, such that the light guide itself does not have direct contact with the reflective plane of the biological tissue. Alternatively, acrylic or another transparent material which improves light transmission and reflection, and preferably also preserves the evanescent wave, can be directly applied to the distal tip of the light guide to form a lens. This is particularly useful for an optical light guide fiber cut at a 45° angle or another angle less than 90° or greater than 90°.

Preferably, as illustrated in Figure 1, the light guide 1020 is in optical communication with a Y-split light guide 1030. One end 1032 of the Y-split light guide 1030 terminates at

and/or is in optical communication with the light source 1040, and another end 1034 of the Y-split light guide 1030 terminates at and/or is in optical communication with the light sensor 1050.

Figure 2 illustrates a distal portion of an exemplary insertion tool guidance system 2000 including a light guide 2030 configured within the lumen or bore 2020 of an insertion tool 2010. The light guide 2030 includes a pair of optical fibers 2032, 2034. The light guide 2030 has a suitable size and shape to fit inside the lumen or bore 2020 of the insertion tool 2010. In the embodiment illustrated in Figure 2, a proximal end (not shown in Figure 2) of the optical transmitting fiber 2032 may be configured for optical communication with a light source for emitting light (not shown in Figure 2), and a proximal end (not shown in Figure 2) of optical receiving fiber 2034 may be configured for optical communication with a light sensor for detecting reflected light (not shown in Figure 2). The fiber pair 2032, 2034 may be advanced through the lumen or bore 2020 of the insertion tool 2010 so that the distal ends 2033, 2035 of the fiber pair 2032, 2034 substantially align with the distal end 2024 of the insertion tool 2010.

Figure 3A illustrates a distal portion of an exemplary insertion tool guidance system 3000 including a light guide 3030 configured within the lumen or bore 3020 of an insertion tool 3010. The light guide 3030 may be advanced through the lumen or bore 3020 of the insertion tool 3010 so that the distal end of the light guide 3030 substantially aligns with the tissue plane at the distal end 3024 of the insertion tool 3010. As illustrated in Figure 3B, the light guide 3030 may include an annular optical path 3034 configured to provide an optical path from the light source to the distal end 3024 of the insertion tool 3010, and from the distal end 3024 of the insertion tool 3010 to the light sensor. In some embodiments, the optical path 3034 may also be configured to provide a path for fluid communication and/or catheter access.

Figures 4A, 4B and 5 illustrate an exemplary insertion tool guidance system 4000/5000 which includes a single optical fiber as the light guide. With respect to Figure 4, in one embodiment, a guidance system 4000 includes or is configured for use with an insertion tool 4010. The guidance system 4000 includes a removable light guide 4020 provided within the lumen of the insertion tool 4010. At the distal end, enlarged in Figure 4B, the light guide 4020 may be appropriately beveled (such as angled at a substantially 45° angle or other suitable angle) in its distal aspect. The proximal end of the light guide 4020 is divided into two light guides, for example via a Y-splitter 4030, although effective splitting may be achieved with a dichroic mirror, beamsplitter, or the like. One end of splitter 4030

terminates at a light source 4040, such as a light emitting diode, and the other end terminates at a light sensor 4050.

In the embodiment of Figures 4A and 4B, the light source 4040 and light sensor 4050 may be disposed in a handpiece 4055 and may be coupled to a computing module 4060, a power supply 4065 and circuitry (not shown) to operably interconnect some or all of the components in the handpiece. For example, the computing module 4060 may be configured or programmed to control the light source 4040 to an illuminating condition. The computing module 4060 may be configured or programmed to detect reflected light from the light sensor 4050, analyze and/or determine one or more aspects of the reflected light, and to provide one or more visual, auditory or other output indicators to the operator of the system.

With reference to Figure 5, the insertion tool guidance system 5000 includes or is configured for use with an insertion tool 5010 that is connected to the insertion tool guidance system 5000 with a locking connector 5020, such as a Luer lock. The light guide 5030 is inserted into the bore or lumen of the insertion tool 5010 such that the distal ends of the light guide and that of the insertion tool are aligned. The light guide 5030 connects on the proximal side to a computing module 5040 that may include an indicator, such as an indicator 5050 (e.g., one or more LEDs having the same or different colors, an audio emitter, etc.), that is operable to indicate unit readiness, penetration or other desirable alerts. In one example, the indicator 5050 includes at least two different colored LEDs, such as a red LED indicator and a green LED indicator. The computing device 5040 may be configured to fit within a handpiece 5060. The distal end 5062 of the handpiece 5060 may be configured to accept the locking connector 5020. The handpiece 5060 may also be configured to expose the indicator 5050 to the operator and to protect the computing module 5040.

Figures 7 and 8A-8D illustrate exemplary insertion tool guidance systems in which a light guide is an optically transmissive stylet. With reference to Figure 7 and 8A-8D, in one embodiment, an optically transmissive stylet 7020/8020, such as a Tuohy Needle Plastic Stylet, may be used as the light guide within an insertion tool 7010/8010, and may be configured to establish an optical path from the computing module 8040 in the handpiece 8060 to a proximal end of the stylet held in place with the insertion tool 8010 by a connector 8020. The distal end of the handpiece 8060 is configured to connect with and attach to, such as with a notch or snap-fit, and align with the proximal end of the stylet 8034 in the desired orientation. The connector 8020 is configured to fit over the distal end of the stylet and attach it to the proximal end 8062 of the handpiece 8060. In a preferred embodiment, the handpiece 8060 is configured to reduce or prevent slippage when the operator's hand grips

the system. For example, the handpiece 8060 may have a surface provide with a gripping texture (*e.g.,* ribbed or raised surfaces), for example, on opposite sides of the handpiece. In a preferred embodiment, the handpiece 8060 includes a removable tab configured to activate the system (e.g., by turning on the light source, the light sensor, and the computing module) after the insertion tool guidance system is connected to and assembled with the insertion tool.

One of ordinary skill in the art will recognize that the size and configuration of the light guide(s) and/or the insertion tool may be selected based on the type of blood vessel (e.g., artery, vein, capillary) and the size of the blood vessel to be penetrated, or the type and/or size of joint to be penetrated.

B. Light Source

The light source in an insertion tool guidance system may be any collimated or non-collimated light source, such as a light emitting diode (LED), an incandescent light source, and the like. The light source provides light of any desired wavelength, or multiple desired wavelengths. In some embodiments, the light is preferably a non-collimated light from an LED or other non-collimated light producing device. Such a non-collimated source is less expensive to implement than a collimated light source, such as a laser.

Preferably, the light source is a compact electrically-driven light source emitting adequate radiant flux to allow measurements by the light sensor. One embodiment of the light source is a low-power white-light broadband visible spectrum LED with a molded plastic lens. However, the light source may be chosen to enhance measurement of particular tissues to be penetrated by the insertion tool. Possible light source optical parameters include narrow or broadband spectral content from the UV to infrared region, linear or circular polarization, incoherent light, and intensity pulsing or modulation. These characteristics are readily available with off-the-shelf light sources, such as LEDs, laser diodes, incandescent bulbs, and discharge lamps, combined with the use of optional wavelength converting phosphors and optical filters.

In some embodiments, a light source may include or be associated with a lens for efficient optical coupling between the light source and the optical fiber. In some embodiments, light pulsing may be used to reduce power consumption, and light modulation may be used to reduce ambient light interference. Preferably, the light provided by the light source is modulated at a suitable frequency. This allows for elimination of background ambient light and increases the dynamic range of the useful light. Suitable frequencies include, but are not limited to, 1 kHz, 2 kHz, and the like.

In one embodiment, in order to eliminate the impact of ambient light on the measurement of reflected light intensity, two measurements are performed during each measurement cycle. First, the returned light is measured with the light source off (*i.e.*, only ambient light is measured). Then the returned light is measured with the light source on (*i.e.*, a sum of ambient light and the true return light is measured). Subsequently, the former result is subtracted from the latter result, such as by the computing module, yielding the intensity value of a true and robust return light.

The measurements by the light sensor and/or the computing module may be performed continuously. By way of example, light measurements may be taken every 500 μs, i.e., true return light measurements are obtained every 1 ms (i.e., 1 kHz frequency). The results are accumulated, and preferably the result is averaged at regular intervals (e.g., every 50 ms or other suitable interval). Averaging is implemented to reduce the level of noise in the measurement.

In some embodiments, the light source may be pulsed or modulated by a digital or analog control signal from a microcontroller provided in the computing module. The light source may use power from the computing device or a power source.

C. Light Sensor

In an insertion tool guidance system, the light sensor is configured to receive reflected light from the light guide and to convert the reflected light to an electrical signal. The light sensor may be spectrally matched to the light source and may be sensitive to one or more optical wavelengths of interest. The response time is selected to be adequate to detect light intensity variations during penetration of different tissues or spaces in a patient's body by the distal end of the insertion tool to determine when the distal tip of the insertion tool reaches a desired site or tissue.

An example of a suitable light sensor is a photodiode with a molded plastic lens. Other suitable light sensors may be selected based on cost, sensitivity, and response time. Alternative suitable light sensors may include, but are not limited to, a light dependent resistor, photovoltaic cell, phototransistor, CCD, microbolometer, photomultiplier tube, or other electro-optical sensor matched to the light source.

In some embodiments, optical filters may be applied to the light sensor to restrict the measurement spectrum or polarization, to reduce interference, or increase measurement sensitivity. The light sensor may, in some embodiments, a lens for efficient optical coupling between the optical fiber and light sensor. The light sensor may use power from the computing device or a power source.

D. Computing Module

As generally used herein, the term "computing module" refers to hardware, software, firmware, or combinations thereof that are configured or programmed to perform an operation, action or function and/or to cause an operation, action or function from another component. For example, depending on the application or needs of the guidance system, the computing module may include a software controlled microprocessor, discrete logic such as an application specific integrated circuit (ASIC), a programmed logic device, memory device containing instructions, or the like. The computing module may include and may execute one or more computer-readable and/or computer-executable instructions that are configured or programmed to perform one or more desired operations, actions or functions described herein. The computer readable and/or executable instructions may cause a computer or other electronic device to perform operations, functions, actions, and/or behave in a desired manner. The instructions may be embodied in various forms such as routines, algorithms, modules, or programs including separated applications or code from dynamically linked libraries. The instructions may also be implemented in various forms such as a stand-alone program, a function call, a servlet, an applet, instructions stored in a memory, part of an operating system or other type of executable instructions. As is appreciated by one of ordinary skill in the art, the form of the instructions is dependent on, for example, requirements of a desired application, the environment it runs on, and/or the desires of a designer/programmer or the like.

Figure 6 is a block diagram of certain components of an exemplary insertion tool guidance system 6000. The system 6000 includes one or more light sources 6201, one or more light sensors 6202, and a computing module. In some embodiments, the computing module may include a controller and/or processor module 6204 (e.g., a microcontroller and/or microprocessor) that is programmed or configured to analyze the data provided by the light sensor 6202, and to provide outputs regarding system status information when the appropriate conditions are reached. The controller/processor module 6204 may also participate in operating the light source 6201.

The computing module may include memory 6208 that includes one or more non-transitory computer-readable media for storing one or more computer-executable instructions or software for implementing any of the methods disclosed herein. The non-transitory computer-readable media may include, but are not limited to, one or more types of hardware memory, non-transitory tangible media, and the like. Memory 6208 may include a computer

system memory or random access memory, such as DRAM, SRAM, EDO RAM, and the like. Memory 6208 may include other types of memory as well, or combinations thereof.

The computing module may include a data storage device 6210 for storing raw or processed data obtained from the light sensor 6202 and/or the microcontroller/microprocessor 6204. The data may be communicated to a different module in the guidance system or to an external device or application.

In some embodiments, a signal conditioning circuitry 6203 is provided in electrical communication with the light sensor 6202 and the controller 6204 to convert the light sensor output to a suitable input for the control logic.

In some embodiments, one or more indicators 6205a, 6205b are provided in or outside the computing module to communicate information about the insertion process and/or the system state to the operator. A power supply 6206 provides power to operate the light source 6201, the light sensor 6202, the controller module 6204, and the signal conditioning circuitry 6203.

The computing module of the guidance system may also include one or more network adapters 6212 for connecting with a network media that is interconnected with a computer network to communicate data or indicators to an external device or application. The network adapter 6212 may be a network interface card suitable to the particular network media. For example, exemplary network adapters 6212 may include, but are not limited to, a built-in network adapter, network interface card, PCMCIA network card, card bus network adapter, wireless network adapter, USB network adapter, modem or any other device. The network media may be any type of wired or wireless network media including, but not limited to, Ethernet, firewire, radio frequency, television cable, Local Area Network (LAN), Wide Area Network (WAN) or the Internet through a variety of connections including, but not limited to, standard telephone lines, LAN or WAN links (for example, 802.26, T1, T3, 56kb, X.25), broadband connections (for example, ISDN, Frame Relay, ATM), wireless connections, controller area network (CAN), or some combination of any or all of the above.

Figure 9 is a block diagram of certain electronic components that can be used in the insertion tool guidance system. The system contains a microprocessor, such as a digital signal processor (DSP) processor 9204. The input data for the processor 9204 may be provided by a signal conditioning unit, such as a photo amplifier 9203, which receives the light signal from the light sensor 9202. The microprocessor 9204 sends output data to an indicator, such as the LED driver produces a light signal, and to a wireless communication module 9207, such as a Bluetooth module, which transmits data to an external computer. An

exemplary guidance system is powered from a power module 9206, which may be a wall wart.

a. Control Logic

Control logic is configured and embodied on any suitable microcontroller or microprocessor 6204. In one embodiment, the control logic is configured and embodied on a single-chip microcontroller/microprocessor 6204 with integrated program memory, RAM, timers, and an analog-to-digital converter to control the system. The microcontroller 6204 may sample the signal-conditioned or raw signal from the light sensor 6202, execute an algorithm to analyze the output from the light sensor 6202, and output system status information to one or more indicator 6205. The microcontroller/microprocessor 6204 may send a digital or analog control signal to the light source 6201 to modulate or pulse the light intensity. In the case of an analog control signal, the microcontroller/microprocessor 6204 includes a digital-to-analog converter. The microcontroller/microprocessor 6204 receives power from the power source 6206 and may control power functions including power-saving mode and energy storage (e.g., battery charging). The microcontroller/microprocessor 6204 may be integrated to include some or all of the logical assembly components, or may use external components for individual features.

The control logic embodied on the microcontroller/microprocessor 6204 analyzes the light sensor data for changes in the intensity of the reflected light. The intensity of the reflected light depends on the tissues or spaces encountered by the distal tip of the insertion tool. For example, upon reaching the lumen of a blood vessel, a measurable reduction in reflected light may be sensed by the light sensor. Upon detecting that an absolute and/or relative level of change in the intensity of reflected light falls within a range typical of movement from a vessel wall to a vessel lumen, the control logic provides a user feedback indicator in any suitable form, such as a visual, acoustic, or kinetic signal, or a combination thereof.

For joints, upon reaching a joint capsule from surrounding less-dense tissue, a measurable increase in the intensity of the reflected light may be sensed by the light sensor. Upon detecting that an absolute and/or relative increase in the intensity of reflected light falls within a range typical of movement into a joint capsule from surrounding tissue, the control logic provides a user feedback indicator in any suitable form, such as a visual, acoustic, or kinetic signal, or a combination thereof, to indicate that a joint capsule has been reached. Upon reaching a joint space from a joint capsule, a measurable reduction in the intensity of the reflected light may be sensed by the light sensor. Upon detecting that an absolute and/or

relative reduction in the intensity of reflected light falls within a range typical of movement from a joint capsule to a joint space, the control logic provides a user feedback indicator in any suitable form, such as a visual, acoustic, or kinetic signal, or a combination thereof, to indicate that a joint space has been reached.

b. Signal Conditioning Circuitry

Signal conditioning circuitry 6203 converts the light sensor electrical output to a suitable voltage range for sampling by the control logic in the microcontroller/microprocessor 6204, such as in analog–to-digital converter circuitry. The signal conditioning circuitry 6203 may include passive or active circuitry. Additionally, frequency selective filtering may be applied to reduce unwanted noise and perform anti-aliasing before analog-to-digital conversion.

The preferred embodiment for the signal conditioning circuitry 6203 of a photodiode light sensor 6202 is a transimpedance amplifier circuit with a low-pass filter characteristic for anti-aliasing. Other light sensors 6202 have well known application circuits that may be implemented at low cost. System performance may allow a simple and lowest cost resistor-capacitor (RC) signal conditioning circuitry 6203.

The signal conditioning circuitry may use power from power source 6206.

c. Indicator

The system includes one or more indicator generators to communicate to the operator one or more of the conditions including, but not limited to, (1) state of the system (e.g., power on/off), (2) penetration of the distal tip of the device (e.g., penetration of vessel wall or joint capsule, start of penetration of lumen or joint space, penetration of lumen or joint space, or penetration of opposite vessel wall, as illustrated in Figure 10), (3) values of the reflected light intensities during the insertion process and/or absolute and/or relative changes in intensity values encountered during the insertion process, (4) a visual (e.g., graphic) representation of values of the reflected light intensities during the insertion process and/or absolute and/or relative changes in intensity values encountered during the insertion process, and (5) communication ability (e.g., wireless communication enabled).

The indicator 6205 displays the system state to the operator. System states may include indication of power on/off, system ready, and level of penetration of the distal end of the system. The indicator provides a signal, such as a visual, tactile or acoustic signal.

In one embodiment, the system includes two indicator LEDs 6205a and 6205b to visually alert the operator. One 6205a of the LEDs may indicate system power or readiness, and the other 6205b may indicate level of penetration, in some embodiments.

Alternatively, or additionally, an indicator may provide an audible signal such as a beep, tone, speech, or some other audible signaling method, or a visual signal that varies intensity, color, shape, text, or symbols to indicate the system state. Further, alternatively or additionally, an indicator may provide a tactile signal, such as vibration or a variety of vibrational patterns.

For example, an indicator may include one or more LED indicators, such as one or more colored lights; an audible sound; or tactile signal, such as vibration or different vibrational patterns; or a combination thereof.

d. Power Source

The power source 6206 in the guidance system 6000 may include an internal battery or an external power source. Preferably, the guidance system 6000 uses an internal battery, although power may be provided through an external power jack that overrides internal battery power, on-board energy storage in the form of a rechargeable or non-rechargeable battery or other energy storage device, with control of energy management may be performed by the microcontroller/microprocessor 6204. In some embodiments, the power source 6206 may be a wall source generating DC voltage, which can be converted into two voltages to power the subsystems, for example, 5 V and 3.3 V. The power may be supplied to components using electrically conductive wires, wireless power transfer using inductive, RF, or optical power transfer, or other methods.

III. Methods of Using Exemplary Insertion Tool Guidance Systems for Blood Vessels

An exemplary guidance system 1000 uses differences in the density of a blood vessel wall and the lumen of the blood vessel and the behavior of those structures around the distal tip of the insertion tool during its insertion in the patient to determine the location of the distal tip of the insertion tool. The position of the distal tip of the insertion tool may be determined or confirmed from the absolute and/or relative change in the intensity of the light from the reflecting plane at the biological tissue at the distal tip of the insertion tool as the tip moves from a vessel wall into the lumen of a blood vessel.

A general method for determining the position of the distal tip of the insertion tool can be understood with reference to the figures, particularly Figure 1 and Figure 6. The light receiving interface, i.e., the reflecting plane, is the distal tip 1022 of the light guide 1020 within the insertion tool 1010. The system operates in zero or near zero distance from the reflecting plane.

In use, as illustrated in Figures 1 and 6, the light source 1040, 6201 is powered by a suitable power source 6206, and light is carried through the Y-split light guide 1030 or other suitable light guide, down the length of the light guide 1020 to a tissue plane 1080. Certain amounts of the light are reflected off the tissue plane 1080 and travel back along the light guide 1020, through the Y-split 1030 and are detected by the light sensor 1050, 6202. The intensity of the reflected light is then measured and interpreted by the computing module 1060, 6204. Optionally, the electrical output from the light sensor is converted to a suitable voltage range by signal conditioning circuitry 6203 prior to analysis by the microcontroller 6204. The intensity of the reflected light changes depends on the tissues or spaces encountered. Upon detecting that the absolute and/or relative change in the intensity of the reflected light falls within a range typical of movement from a vessel wall to a vessel lumen, the computing module may determine that the lumen of the vessel has been reached. The indicator(s) 6205 may provide a suitable indication to the operator.

In use, the system detects the intensity of the reflected light returned by a penetrated barrier. The reflecting plane is at a zero or near-zero distance from the distal tip of the light guide when the distal tip of the insertion tool penetrates a dense tissue, such as the wall of a blood vessel. At the moment of piercing of the outer shell of the tissue and progression into a less dense environment, the distance from the distal tip of the light guide to the reflecting plane becomes greater than zero. Any change in near-zero distance environments produces much greater changes in intensity than those measured from reflections in the 1 mm or 2 mm range. According to the light intensity formula ($I = 1/r^2$), the intensity of the reflected light is inversely proportional to the square of the distance. Indeed, reflections in the zero or near-zero distance environments for non-collimated light approach reflection percentages of collimated light due to the reduced opportunity of light to scatter in the zero or near zero distance environments.

When used in the vascular environment, an insertion tool 1010 is inserted through a blood vessel wall toward the lumen of the blood vessel. The high density of collagen fibers in the vessel wall being perforated produces a tight apposition against the distal tip of the insertion tool. As a result, the distance between the distal tip of the light guide and the reflective plane of the vessel wall approaches zero mm during penetration. Upon entering the vessel lumen, which is a structure of much lower density, the distance between the light guide within the insertion tool and the reflecting plane of the vessel lumen becomes non-zero, that is, greater than zero mm. The reflected light conveyed by the light guide 1020, through the Y-split 1030 to the light sensor 1050, decreases significantly upon entering the vessel lumen,

causing the computing module 1060 to detect the decreased intensity of the reflected light which is indicative of the distal tip of the insertion tool entering the lumen of a blood vessel. The computing module 1060 may provide the operator with an appropriate indication, such as a warning or notice. The indication can be in any suitable manner to indicate that the distal end of the insertion tool has reached the lumen of a blood vessel, including visual, tactile or acoustic signals.

In some embodiments, an indication may be provided to an operator at one or more stages of the insertion process including, but not limited to, penetration of a blood vessel wall, start of penetration of a blood vessel lumen, penetration of a blood vessel lumen, and penetration of the opposite blood vessel wall, as illustrated in Figure 10. Different indications may be provided for the different stages of the insertion process, for example, using light of different colors.

Different light guides, such as those illustrated in Figures 2 and 3, may be used in place of the Y-split light guide. Regardless of the implementation of the light guide, the insertion tool and light guide assembly may be advanced to an appropriate depth or tissue penetration as assisted by the light sending and sensing logic. Once the distal end of the insertion tool is placed in the desired location in the patient's body (e.g., in the lumen of a blood vessel), the optical components may be removed as needed and appropriate medical care provided through the bore in the insertion tool or fluid path.

In typical use, a medical practitioner prepares the patient for the insertion of the insertion tool as usual. The insertion tool guidance system is removed from the sterile package and either fitted into the well of the transparent plastic stylet, or the usual stylet is removed from the insertion tool and a replacement light transmissive stylet (e.g., a transparent plastic stylet, such as that illustrated in Figure 7) or light guide with attached handpiece and/or logical components, such as those illustrated in Figures 1, 2, 3, 4, and 5, is inserted into the standard insertion tool. Preferably, an activation tab (see, e.g., Figure 8C) is pulled out of the device, thereby activating the electronic circuit. In a preferred embodiment, when the electronic circuit is activated, an indicator provides a signal to the user, such as by illuminating a light, e.g., a LED light.

After inserting the light guide into the lumen of the insertion tool and attaching the insertion tool guidance system to the insertion tool, the distal tip of the insertion tool is then slowly advanced by the medical professional through the skin, subcutaneous fat and blood vessel wall toward the lumen of a blood vessel.

In one preferred embodiment, an indicator, e.g., LED light, stays on indicating proper functioning of the system, and a second indicator is provided when the entry into the lumen is detected by the system, such as due to a decrease in the intensity of reflected light. The second indicator can be any suitable indicator, such as a second LED or other warning or notice signal, e.g., tactile or audible.

The medical professional then disengages the insertion tool guidance system and removes the stylet or light guide from the insertion tool, if necessary. The medical practitioner may then proceed conventionally with the insertion tool in the lumen, for example, to extract a blood sample or to inject a substance into the blood. The components of the insertion tool guidance system may then be disposed.

In the vascular environment, the exemplary guidance system provides medical practitioners with immediate, real-time and objective confirmation of entry into the lumen of a blood vessel, avoiding the risk of stopping the insertion before the lumen is reached and the

risk of advancing the insertion tool too far and producing undesired perforation of the opposite wall of the blood vessel with its potential for all associated complications.

IV. Methods of Using Exemplary Insertion Tool Guidance Systems for Joints

An exemplary guidance system 1000 uses differences in the density of a joint capsule and a joint space and the behavior of those structures around the distal tip of the insertion tool during its insertion in the patient to determine the location of the distal tip of the insertion tool. The position of the distal tip of the insertion tool may be determined or confirmed from the absolute and/or relative change in the intensity of the light from the reflecting plane at the biological tissue at the distal tip of the insertion tool as the tip moves from surrounding tissue to a joint capsule and subsequently into a joint space.

A general method for determining the position of the distal tip of the insertion tool can be understood with reference to the figures, particularly Figure 1 and Figure 6. The light receiving interface, i.e., the reflecting plane, is the distal tip 1022 of the light guide 1020 within the insertion tool 1010. The system operates in zero or near zero distance from the reflecting plane.

In use, as illustrated in Figures 1 and 6, the light source 1040, 6201 is powered by a suitable power source 6206, and light is carried through the Y-split light guide 1030 or other suitable light guide, down the length of the light guide 1020 to a tissue plane 1080. Certain amounts of the light are reflected off the tissue plane 1080 and travel back along the light

guide 1020, through the Y-split 1030 and are detected by the light sensor 1050, 6202. The intensity of the reflected light is then measured and interpreted by the computing module 1060, 6204. Optionally, the electrical output from the light sensor is converted to a suitable voltage range by signal conditioning circuitry 6203 prior to analysis by the microcontroller 6204. The intensity of the reflected light changes depends on the tissues or spaces encountered. Upon detecting that the absolute and/or relative increase in the intensity of the reflected light falls within a range characteristic of moving from surrounding less-dense tissue to a joint capsule, the computing module may determine that a joint capsule has been reached. Upon detecting that the absolute and/or relative decrease in the intensity of the reflected light falls within a range characteristic of moving from a joint capsule to a joint space, the computing module may determine that a joint space has been reached. The indicator(s) 6205 may provide a suitable indication to the operator.

In use, the system detects the intensity of the reflected light returned by a penetrated barrier. When the distal tip of the insertion tool is in less-dense tissue surrounding a joint (e.g., subcutaneous fat), the distance between the reflecting plane at the tissue and the distal tip of the light guide is greater than zero. The reflecting plane is at a zero or near-zero distance from the distal tip of the light guide when the distal tip of the insertion tool penetrates the dense joint capsule. At the moment of piercing of the outer shell of the tissue and progression into the less-dense joint space, the distance from the distal tip of the light guide to the reflecting plane becomes greater than zero. Any change in near-zero distance environments produces much greater changes in intensity than those measured from reflections in the 1 mm or 2 mm range. According to the light intensity formula ($I = 1/r^2$), the intensity of the reflected light is inversely proportional to the square of the distance. Indeed, reflections in the zero or near-zero distance environments for non-collimated light approach reflection percentages of collimated light due to the reduced opportunity of light to scatter in the zero or near zero distance environments.

When used in a biological joint environment, an insertion tool 1010 is inserted through less-dense tissue surrounding a joint into a joint capsule and subsequently into a joint space. During penetration of the less-dense surrounding tissue, the distance between the light guide within the insertion tool and the reflecting plane of the joint space becomes non-zero, that is, greater than zero mm. In contrast, the high density of collagen fibers in the joint capsule being perforated produces a tight apposition against the distal tip of the insertion tool. As a result, the distance between distal tip of the light guide and the reflective plane of the joint capsule approaches zero mm during penetration of the joint capsule, and causes a

significant rise in the intensity in the reflected light during penetration of the joint capsule. The computing module 1060 may provide the operator with an appropriate indication, such as a warning or notice. The indication can be in any suitable manner to indicate that the distal end of the insertion tool has reached a joint capsule, including visual, tactile or acoustic signals.

Upon entering the joint space, which is a structure of much lower density, the distance between the light guide within the insertion tool and the reflecting plane of the joint space becomes non-zero, that is, greater than zero mm. The reflected light conveyed by the light guide 1020, through the Y-split 1030 to the light sensor 1050, decreases significantly upon entering the joint space, causing the computing module 1060 to detect the decreased intensity of the reflected light which is indicative of the distal tip of the insertion tool entering a joint space. The computing module 1060 may provide the operator with an appropriate indication, such as a warning or notice. The indication can be in any suitable manner to indicate that the distal end of the insertion tool has reached a joint space, including visual, tactile or acoustic signals.

In some embodiments, an indication may be provided to an operator at one or more stages of the insertion process including, but not limited to, penetration of a joint capsule, start of penetration of a joint space, and penetration of a joint space. Different indications may be provided for the different stages of the insertion process, for example, using light of different colors.

Different light guides, such as those illustrated in Figures 2 and 3, may be used in place of the Y-split light guide. Regardless of the implementation of the light guide, the insertion tool and light guide assembly may be advanced to an appropriate depth or tissue penetration as assisted by the light sending and sensing logic. Once the distal end of the insertion tool is placed in the desired location in the patient's body (e.g., in a joint capsule or a joint space), the optical components may be removed as needed and appropriate medical care provided through the bore in the insertion tool or fluid path.

In typical use, a medical practitioner prepares the patient for the insertion of the insertion tool as usual. The insertion tool guidance system is removed from the sterile package and either fitted into the well of the transparent plastic stylet, or the usual stylet is removed from the insertion tool and a replacement light transmissive stylet (*e.g.* a transparent plastic stylet, such as that illustrated in Figure 7) or light guide with attached handpiece and/or logical components, such as those illustrated in Figures 1, 2, 3, 4, and 5, is inserted into the standard insertion tool. Preferably, an activation tab (*see, e.g.* Figure 8C) is pulled

out of the device, thereby activating the electronic circuit. In a preferred embodiment, when the electronic circuit is activated, an indicator provides a signal to the user, such as by illuminating a light, *e.g.*, a LED light.

After inserting the light guide into the bore of the insertion tool and attaching the insertion tool guidance system to the insertion tool, the distal tip of the insertion tool is then slowly advanced by the medical professional through the skin, subcutaneous fat and into a joint capsule and/or a joint space.

In one preferred embodiment, an indicator, *e.g.* LED light, stays on indicating proper functioning of the system, a second indicator is provided when the entry into the joint capsule is detected by the system (such as based on an increase in the intensity of reflected light), and a third indicator is provided when the entry into the joint space is detected by the system (such as based on a decrease in the intensity of reflected light). The second and third indicators can be any suitable indicator, such as a second LED or other warning or notice signal, *e.g.* tactile or audible.

The medical professional then disengages the insertion tool guidance system and removes the stylet or light guide from the insertion tool, if necessary. The medical practitioner may then proceed conventionally with the insertion tool in the joint capsule or joint space, for example, to aspirate the joint or to inject a substance into the joint capsule or space. The components of the insertion tool guidance system may then be disposed.

In the joint environment, the exemplary guidance system provides medical practitioners with immediate, real-time and objective confirmation of entry into a joint capsule or joint space, thereby avoiding the risk of stopping the insertion before the joint capsule or joint space is reached.

V. Exemplary Kits

Exemplary guidance systems may be provided in a sterile packaging or kit that is self-contained and disposable.

In one embodiment, the kit includes a single guidance system with the system preassembled (i.e., light guide connected to the handpiece) and ready for insertion into and assembly to an insertion tool. The insertion tool guidance system may include any suitable light guide of a length and diameter suitable to fit within the central lumens of standard vascular access needles. Preferably, the light guide may be a Y-split light guide. In other embodiments, the light guide may be retracted, cut or otherwise modified to length. In still other embodiments, a light guide may have a suitable diameter and length to fit within

orthopedic, neurosurgical and/or surgical piercing instruments, or within non-medical piercing or perforating equipment. In some embodiments, the kit includes an optically transmissive stylet as the light guide. In other embodiments the kit includes an optical fiber as the light guide.

In another embodiment, the kit includes a plurality of light guides, optionally of different lengths and diameters, to enable an operator to select the appropriate light guide for the insertion tool to be guided. After selecting the appropriate light guide, the operator attaches it at its proximal end to the handpiece such that it is in optical communication with the light sensor and light source, places the light guide through the insertion tool, and attaches the insertion tool to the guidance system.

In some embodiments, a kit includes instructions to guide the operator in proper assembly, use and disposal of the guidance system. Based on the instructions, in use, the insertion tool guidance system is removed from the sterile package and either fitted into the well of the transparent plastic stylet, or the usual stylet is removed from the insertion tool and a replacement light transmissive stylet (e.g., a transparent plastic stylet, such as that illustrated in Figure 7) or light guide with attached handpiece and/or logical components, such as those illustrated in Figures 1, 2, 3, 4, and 5, is inserted into the standard insertion tool. Preferably, an activation tab (see, e.g., Figure 8C) is pulled out of the device activating the electronic circuit. In a preferred embodiment, when the electronic circuit is activated an indicator provides a signal to the user, such as by illuminating a light, e.g., a LED light.

VI. Exemplification of Blood Vessel Insertion Tools

Certain exemplary techniques of detecting that a distal tip of an insertion tool has reached the lumen of a blood vessel, are described herein. Light of any wavelength or plurality of wavelengths may be used in exemplary techniques.

An exemplary technique may use a percentage drop (or a range thereof) in the intensity of the reflected light that is characteristic of the distal tip moving from the wall of a blood vessel into the lumen of the blood vessel. Upon detecting a percentage drop in the reflected light intensity that exactly or approximately matches this characteristic percentage drop, the guidance system may determine that the lumen of the blood vessel has been reached. One of ordinary skill in the art will recognize that this characteristic percentage drop may be determined based on one or more factors including, but not limited to, patient age, patient gender, patient weight, type of the blood vessel penetrated, size of the blood

vessel penetrated, wavelength(s) of the light used, design of the distal end of the light guide, and the like.

Another exemplary technique may use a percentage drop (or a range thereof) in the intensity of the reflected light that is characteristic of the distal tip moving from the wall of a blood vessel into the lumen of the blood vessel, and may also use one or more insertion distances characteristic of complete penetration of a vessel wall. Blood vessels have varying thicknesses. A blood vessel having a thicker wall may exhibit a relatively high reflected light intensity (characteristic of the vessel wall) over a longer insertion distance than that exhibited by a blood vessel having a thinner wall. An exemplary guidance system may account for these variations based on the thickness of the blood vessel to be penetrated. For example, for a vessel with a thinner wall, the guidance system may expect a sharper spike in the light intensity characteristic of the vessel wall (i.e., over a shorter insertion distance) before the light intensity falls in the lumen of the blood vessel. Subsequently, upon detecting a percentage drop in the reflected light intensity that exactly or approximately matches the percentage drop characteristic of a lumen, the guidance system may determine that the lumen of the blood vessel has been reached.

Another exemplary technique may use an absolute drop (or a range thereof) in the intensity of the reflected light that is characteristic of the distal tip moving from the wall of a blood vessel into the lumen of the blood vessel. Upon detecting a drop in the reflected light intensity that exactly or approximately matches this characteristic drop, the guidance system may determine that the lumen of the blood vessel has been reached. One of ordinary skill in the art will recognize that this characteristic drop may be determined based on one or more factors including, but not limited to, patient age, patient gender, patient weight, type of the blood vessel penetrated, size of the blood vessel penetrated, wavelength(s) of the light used, design of the distal end of the light guide, and the like.

Another exemplary technique may use an absolute drop (or a range thereof) in the intensity of the reflected light that is characteristic of the distal tip moving from the wall of a blood vessel into the lumen of the blood vessel, and may also use one or more insertion distances characteristic of complete penetration of a vessel wall.

Another exemplary technique may use absolute intensity values of the reflected light that are characteristic of the distal tip being in the wall of a blood vessel and in the lumen of the blood vessel.

Experiments were performed to insert an insertion tool into the vein of a pig and into human blood. In the experiments, non-collimated light at wavelength of about 600 nm to

about 670 nm with a dominant wavelength of about 630 nm, was used. The light was continuously calibrated to eliminate ambient light effects. Nonetheless, light of any suitable wavelength may be used in performing exemplary methods. One of ordinary skill in the art will recognize that exemplary methods may be performed on other types of blood vessels, animals, and the like.

Exemplary non-limiting intensity values of reflected light characteristic of the distal tip of an insertion tool being in the wall of a blood vessel may range from about 1200 lumens to about 1400 lumens, although one of ordinary skill in the art will recognize that other suitable values may be used based on the particular set of parameters.

Exemplary non-limiting intensity values of reflected light characteristic of the distal tip of an insertion tool being in the lumen of a blood vessel may range from about 760 lumens to about 770 lumens, although one of ordinary skill in the art will recognize that other suitable values may be used based on the particular set of parameters.

Exemplary non-limiting values of the absolute drop in the intensity of reflected light characteristic of the distal tip of an insertion tool moving from a vessel wall to a lumen may range from about 430 lumens to about 640 lumens.

Exemplary non-limiting values of the percentage drop in the intensity of reflected light characteristic of the distal tip of an insertion tool moving from a vessel wall to a lumen may range from about 35% to about 46%.

One of ordinary skill in the art will recognize that characteristic reflected light intensity values and/or changes may depend on one or more factors including, but not limited to, patient age, patient gender, patient weight, type of the blood vessel penetrated, size of the blood vessel penetrated, wavelength(s) of the light used, design of the distal end of the light guide, and the like. For each set of parameters used, exemplary embodiments may be configured with intensity values and/or changes that are typical of that set of parameters for entry into the lumen of a blood vessel.

In describing exemplary embodiments, specific terminology is used for the sake of clarity. For purposes of description, each specific term is intended to, at least, include all technical and functional equivalents that operate in a similar manner to accomplish a similar purpose. Additionally, in some instances where a particular exemplary embodiment includes a plurality of system elements or method steps, those elements or steps may be replaced with a single element or step. Likewise, a single element or step may be replaced with a plurality of elements or steps that serve the same purpose. Further, where parameters for various properties are specified herein for exemplary embodiments, those parameters may be adjusted

up or down by 1/20th, 1/10th, 1/5th, 1/3rd, 1/2nd, and the like, or by rounded-off approximations thereof, unless otherwise specified. Moreover, while exemplary embodiments have been shown and described with references to particular embodiments thereof, those of ordinary skill in the art will understand that various substitutions and alterations in form and details may be made therein without departing from the scope of the invention. Further still, other aspects, functions and advantages are also within the scope of the invention.

Exemplary flowcharts are provided herein for illustrative purposes and are non-limiting examples of methods. One of ordinary skill in the art will recognize that exemplary methods may include more or fewer steps than those illustrated in the exemplary flowcharts, and that the steps in the exemplary flowcharts may be performed in a different order than shown.

VII. Exemplification of Joint Access Tools

Certain exemplary techniques of detecting that a distal tip of an insertion tool has reached a joint capsule or a joint space, are described herein. Light of any wavelength or plurality of wavelengths may be used in exemplary techniques.

An exemplary technique may use (i) a percentage increase (or a range thereof) in the intensity of the reflected light that is characteristic of the distal tip moving from surrounding tissue into a joint capsule, and/or (ii) a percentage decrease (or a range thereof) in the intensity of the reflected light that is characteristic of the distal tip moving from a joint capsule into a joint space. With respect to characteristic increase (i), upon detecting a percentage increase in the reflected light intensity that exactly or approximately matches this characteristic percentage increase, the guidance system may determine that a joint capsule has been reached. With respect to characteristic decrease (ii), upon detecting a percentage decrease in the reflected light intensity that exactly or approximately matches this characteristic percentage decrease, the guidance system may determine that a joint space has been reached. One of ordinary skill in the art will recognize that the characteristic percentage changes may be determined based on one or more factors including, but not limited to, patient age, patient gender, patient weight, type of the joint penetrated, size of the joint penetrated, wavelength(s) of the light used, design of the distal end of the light guide, and the like.

Another exemplary technique may use a percentage change (or a range thereof) in the intensity of the reflected light that is characteristic of the distal tip moving from a joint

capsule into a joint space, and may also use one or more insertion distances characteristic of complete penetration of a joint capsule. Joint capsules have varying thicknesses. A thicker joint capsule may exhibit a relatively high reflected light intensity (characteristic of the joint capsule) over a longer insertion distance than that exhibited by a thinner joint capsule. An exemplary guidance system may account for these variations based on the thickness of the joint capsule to be penetrated. For example, for a thinner joint capsule, the guidance system may expect a sharper spike in the light intensity characteristic of the joint capsule (i.e., over a shorter insertion distance) before the light intensity falls in the joint space. Subsequently, upon detecting a percentage drop in the reflected light intensity that exactly or approximately matches the percentage drop characteristic of a joint space, the guidance system may determine that the joint space has been reached.

Another exemplary technique may use (i) an absolute increase (or a range thereof) in the intensity of the reflected light that is characteristic of the distal tip moving from surrounding tissue into a joint capsule, and/or (ii) an absolute decrease (or a range thereof) in the intensity of the reflected light that is characteristic of the distal tip moving from a joint capsule into a joint space. With respect to characteristic increase (i), upon detecting an increase in the reflected light intensity that exactly or approximately matches this characteristic increase, the guidance system may determine that a joint capsule has been reached. With respect to characteristic decrease (ii), upon detecting a decrease in the reflected light intensity that exactly or approximately matches this characteristic decrease, the guidance system may determine that a joint space has been reached. One of ordinary skill in the art will recognize that the characteristic changes may be determined based on one or more factors including, but not limited to, patient age, patient gender, patient weight, type of the joint penetrated, size of the joint penetrated, wavelength(s) of the light used, design of the distal end of the light guide, and the like.

Another exemplary technique may use an absolute change (or a range thereof) in the intensity of the reflected light that is characteristic of the distal tip moving from a joint capsule into a joint space, and may also use one or more insertion distances characteristic of complete penetration of a joint capsule.

Another exemplary technique may use absolute intensity values of the reflected light that are characteristic of the distal tip being in a joint capsule and in a joint space.

Experiments were performed to insert an insertion tool into a medium-sized leg joint of a sheep. The joint had a diameter of about 5 cm and a joint space dimension of about 5 mm. In the experiments, non-collimated light at wavelength of about 600 nm to about 670

nm with a dominant wavelength of about 630 nm, was used. The light was continuously calibrated to eliminate ambient light effects. Nonetheless, light of any suitable wavelength may be used in performing exemplary methods. One of ordinary skill in the art will recognize that exemplary methods may be performed on other types of joints, animals, differently sized joints, and the like.

Based on these experiments, exemplary non-limiting intensity values of reflected light characteristic of the distal tip of an insertion tool being in a joint capsule may range from about 1320 lumens to about 1400 lumens, although one of ordinary skill in the art will recognize that other suitable values may be used based on the particular set of parameters.

Exemplary non-limiting intensity values of reflected light characteristic of the distal tip of an insertion tool being in a joint space may range from about 900 lumens to about 960 lumens, although one of ordinary skill in the art will recognize that other suitable values may be used based on the particular set of parameters.

Exemplary non-limiting values of the absolute drop in the intensity of reflected light characteristic of the distal tip of an insertion tool moving from a joint capsule to a joint space may range from about 360 lumens to about 500 lumens.

Exemplary non-limiting values of the percentage drop in the intensity of reflected light characteristic of the distal tip of an insertion tool moving from a joint capsule to a joint space may range from about 27% to about 35%.

One of ordinary skill in the art will recognize that characteristic reflected light intensity values and/or changes may depend on one or more factors including, but not limited to, patient age, patient gender, patient weight, type of the joint penetrated, size of the joint penetrated, wavelength(s) of the light used, design of the distal end of the light guide, and the like.

In describing exemplary embodiments, specific terminology is used for the sake of clarity. For purposes of description, each specific term is intended to, at least, include all technical and functional equivalents that operate in a similar manner to accomplish a similar purpose. Additionally, in some instances where a particular exemplary embodiment includes a plurality of system elements or method steps, those elements or steps may be replaced with a single element or step. Likewise, a single element or step may be replaced with a plurality of elements or steps that serve the same purpose. Further, where parameters for various properties are specified herein for exemplary embodiments, those parameters may be adjusted up or down by 1/20th, 1/10th, 1/5th, 1/3rd, 1/2nd, and the like, or by rounded-off approximations thereof, unless otherwise specified. Moreover, while exemplary

embodiments have been shown and described with references to particular embodiments thereof, those of ordinary skill in the art will understand that various substitutions and alterations in form and details may be made therein without departing from the scope of the invention. Further still, other aspects, functions and advantages are also within the scope of the invention.

Exemplary flowcharts are provided herein for illustrative purposes and are non-limiting examples of methods. One of ordinary skill in the art will recognize that exemplary methods may include more or fewer steps than those illustrated in the exemplary flowcharts, and that the steps in the exemplary flowcharts may be performed in a different order than shown.

Claims

What is claimed is:

1. A medical penetration detection system for detecting insertion of an insertion tool into a lumen of a blood vessel, the system comprising:

a light source;

a light sensor;

a light guide configured to fit inside a bore of an insertion tool, a distal end of the light guide configured to transmit light into biological tissue, a proximal portion of the light guide being in optical communication with the light source to receive light emitted by the light source, the proximal portion of the light guide also being in optical communication with the light sensor to detect light reflected by the biological tissue; and

a computing device coupled with the light sensor and programmed to determine whether the biological tissue is a lumen of a blood vessel based on a decrease in intensity of the light reflected by the biological tissue.

2. The medical penetration detection system of claim 1, wherein the light source emits non-collimated light.

3. The medical penetration detection system of claim 1, wherein the light guide comprises a plurality of discrete fiber optic paths and at least a proximal side of one of the plurality of discrete fiber optic paths is in optical communication with the light source and at least a proximal side of another of the plurality of discrete fiber optic paths is in optical communication with the light sensor.

4. The medical penetration detection system of claim 1, wherein the light guide comprises an optically transmissive stylet, the stylet comprising a proximal side in optical communication with a splitter, wherein the splitter is in temporally-controlled optical communication with the light source and the light sensor.

5. The medical penetration detection system of claim 1, further comprising:

a splitter, wherein the light guide comprises an optical fiber, wherein a proximal side of the light guide is in optical communication with the splitter, and wherein the splitter is in temporally controlled optical communication with the light source and the light sensor.

6. The medical penetration detection system of any one of claims 1 to 5, wherein the light guide comprises a lens at its distal tip.

7. The medical penetration detection system of any one of claims 1 to 6, wherein the computing device comprises a microprocessor.

8. The medical penetration detection system of claim 7, wherein the microprocessor is programmed to receive and analyze data from the light sensor.

9. The medical penetration detection system of claim 7, further comprising:

one or more indication modules in electrical communication with the microprocessor, and wherein one of the indication modules is configured to provide an indicator to alert an operator when the microprocessor detects that the biological tissue is a lumen of a blood vessel.

10. The medical penetration detection system of any one of claims 1 to 9, further comprising:

a handpiece, wherein the computing device is housed inside the handpiece, and wherein the handpiece is configured to attach to the proximal end of the insertion tool.

11. A device comprising an insertion tool for insertion in a patient and the medical penetration detection system of any one of the claims 1 to 10.

12. The device of claim 11, wherein the insertion tool is a needle.

13. A kit comprising the medical penetration detection system of any one of claims 1 to 10 in sterile packaging.

14. The kit of claims 13, comprising a plurality of light guides.

15. A method for determining a location of a distal tip of an insertion tool as it penetrates a patient's body, the method comprising:

disposing a light guide through a bore of the insertion tool;

emitting light through a light source;

transmitting the emitted light through the light guide and into biological tissue at a distal end of the light guide;

detecting light reflected from the biological tissue using a light sensor; and

determining whether the biological tissue is a lumen of a blood vessel based on a decrease in intensity of the light reflected by the biological tissue.

16. The method of claim 15, further comprising:

upon determining that the biological tissue is a lumen of a blood vessel, providing an indication to an operator indicating penetration of the lumen of the blood vessel.

17. The method of claim 15, further comprising:

determining whether the biological tissue is an opposite wall of a blood vessel based on an increase in intensity of the light reflected by the biological tissue; and

upon determining that the biological tissue is an opposite wall of a blood vessel, providing an indication to an operator indicating penetration of the opposite wall of the blood vessel.

18. The method of any one of claims 15-17, further comprising:

removing the light guide from the bore of the insertion tool upon detection of the decrease in the intensity of the reflected light.

19. The method of claims 18, further comprising:

extracting a blood sample or injecting a substance into the blood using the insertion tool after removal of the light guide from the insertion tool.

20. A medical penetration detection system for detecting insertion of a distal tip of an insertion tool into a biological joint space or a biological joint capsule, the system comprising:

a light source;

a light sensor;

a light guide configured to fit inside a bore of the insertion tool, a distal end of the light guide configured to transmit light into biological tissue, a proximal portion of the light guide being in optical communication with the light source to receive light emitted by the light source, the proximal portion of the light guide also being in optical communication with the light sensor to detect light reflected by the biological tissue; and

a computing device coupled with the light sensor and programmed to determine whether the biological tissue is a joint space or a joint capsule based on a change in intensity of the light reflected by the biological tissue.

21. The medical penetration detection system of claim 20, wherein the light source emits non-collimated light.

22. The medical penetration detection system of claim 20 wherein the light guide comprises a plurality of discrete fiber optic paths and at least a proximal side of one of the plurality of discrete fiber optic paths is in optical communication with the light source and at least a proximal side of another of the plurality of discrete fiber optic paths is in optical communication with the light sensor.

23. The medical penetration detection system of claim 20, wherein the light guide comprises an optically transmissive stylet, the stylet comprising a proximal side in optical communication with a splitter, wherein the splitter is in temporally-controlled optical communication with the light source and the light sensor.

24. The medical penetration detection system of claim 20, further comprising:

a splitter, wherein the light guide comprises an optical fiber, wherein a proximal side of the light guide is in optical communication with the splitter, and wherein the splitter is in temporally controlled optical communication with the light source and the light sensor.

25. The medical penetration detection system of any one of claims 20 to 24, wherein the light guide comprises a lens at its distal tip.

26. The medical penetration detection system of any one of claims 20 to 25, wherein the computing device comprises a microprocessor.

27. The medical penetration detection system of claim 26, wherein the microprocessor is programmed to receive and analyze data from the light sensor.

28. The medical penetration detection system of claim 26, further comprising:

one or more indication modules in electrical communication with the microprocessor, and wherein one of the indication modules is configured to provide an indicator to alert an operator when the microprocessor detects that the biological tissue is a joint space or a joint capsule.

29. The medical penetration detection system of any one of claims 20 to 28, further comprising:

a handpiece, wherein the computing device is housed inside the handpiece, and wherein the handpiece is configured to attach to the proximal end of the insertion tool.

30. A device comprising an insertion tool for insertion in a patient and the medical penetration detection system of any one of the claims 20 to 29.

31. The device of claim 30, wherein the insertion tool is a needle.

32. A kit comprising the medical penetration detection system of any one of claims 20 to 31 in sterile packaging.

33. The kit of claims 32, comprising a plurality of light guides.

34. A method for determining a location of a distal tip of an insertion tool as it penetrates a patient's body, the method comprising:

disposing a light guide through a bore of the insertion tool;

emitting light through a light source;

transmitting the emitted light through the light guide and into biological tissue at a distal end of the light guide;

detecting light reflected from the biological tissue using a light sensor; and

determining whether the biological tissue is a joint space or a joint capsule based on a change in intensity of the light reflected by the biological tissue.

35. The method of claim 34, further comprising:

upon determining that the biological tissue is a joint space or a joint capsule, providing an indication to an operator indicating penetration of the joint space or a joint capsule, respectively.

36. The method of any one of claims 34 or 35, further comprising:

removing the light guide from the bore of the insertion tool upon detection of the change in the intensity of the reflected light.

37. The method of claims 36, further comprising:

injecting a substance into the joint space or the joint capsule using the insertion tool after removal of the light guide from the insertion tool.

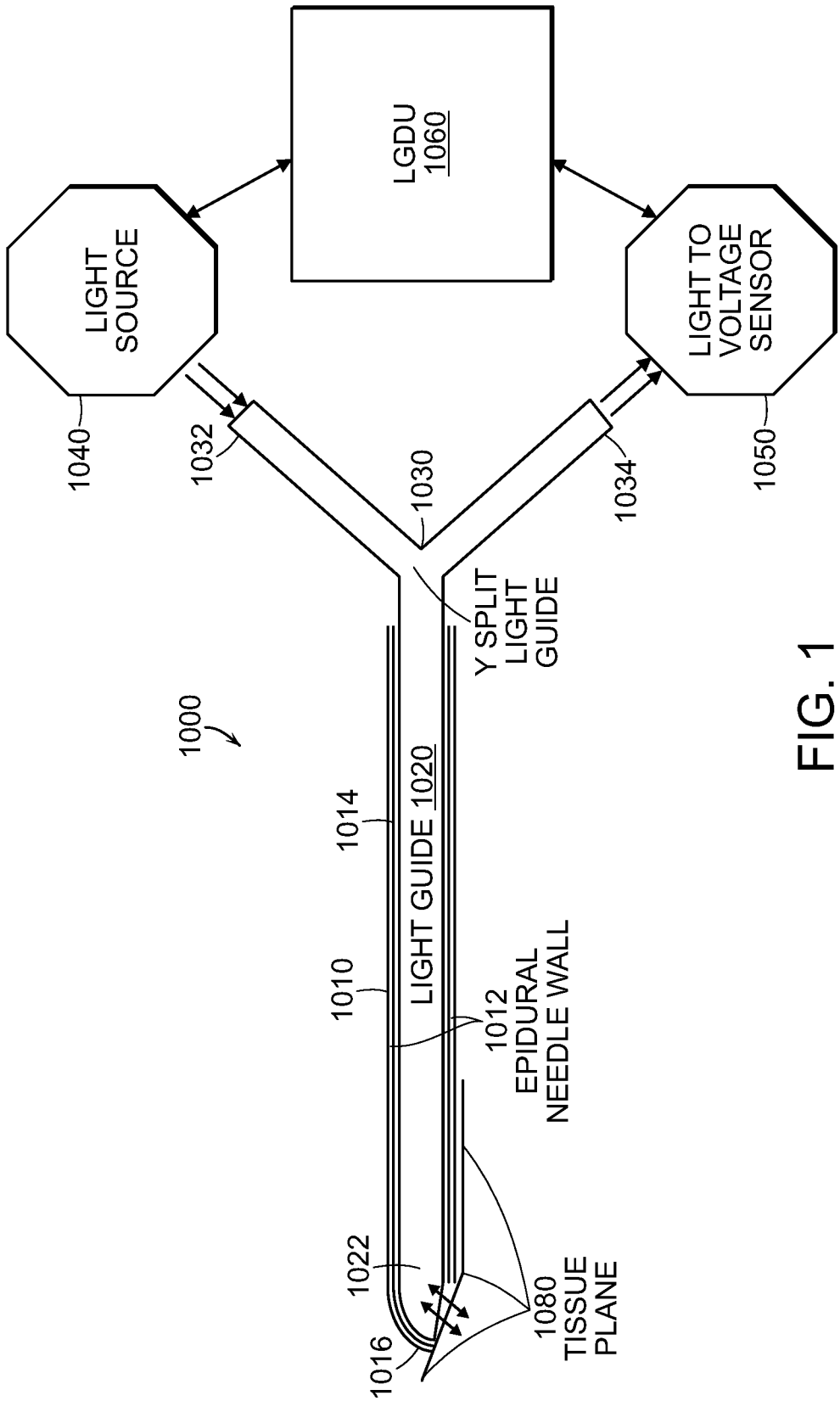

LGDU
1060
LIGHT
SOURCE
LIGHT TO
VOLTAGE
SENSOR
1040
1032
1030
1034
1050
Y SPLIT
LIGHT
GUIDE
1000
1014
LIGHT GUIDE 1020
1010
1012
EPIDURAL
NEEDLE WALL
1022
1016
1080
TISSUE
PLANE

FIG. 1

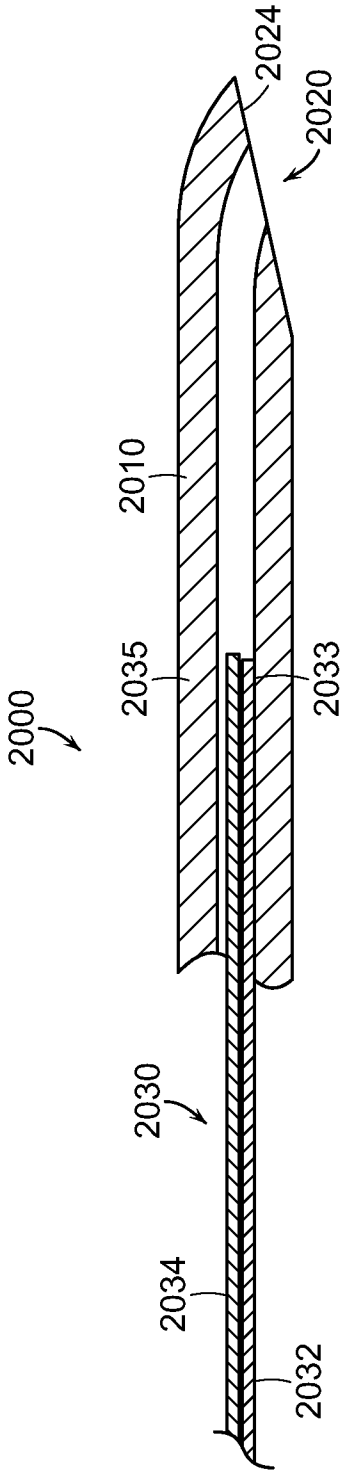


FIG. 2

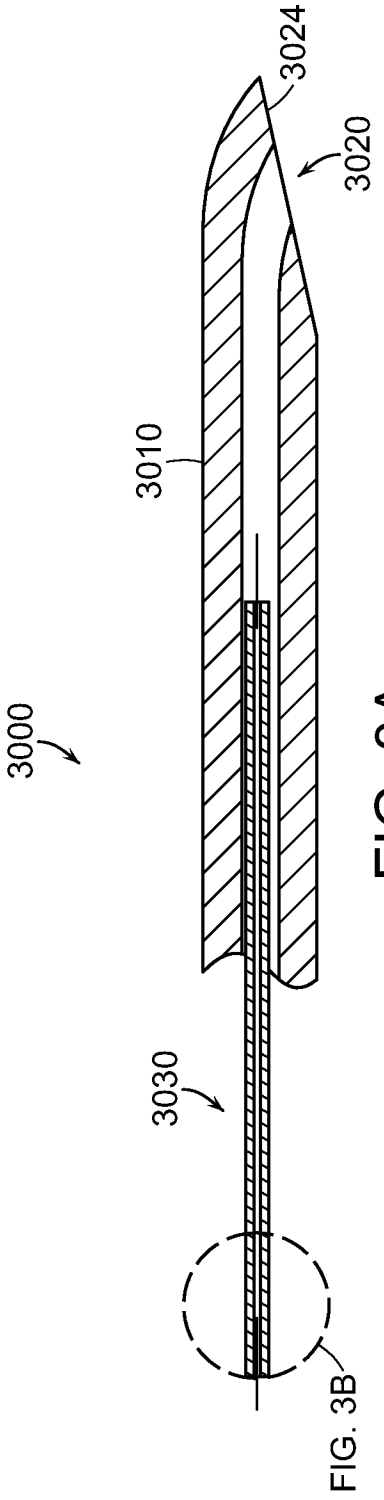


FIG. 3A

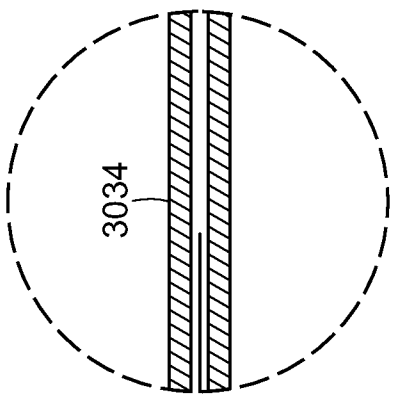


FIG. 3B

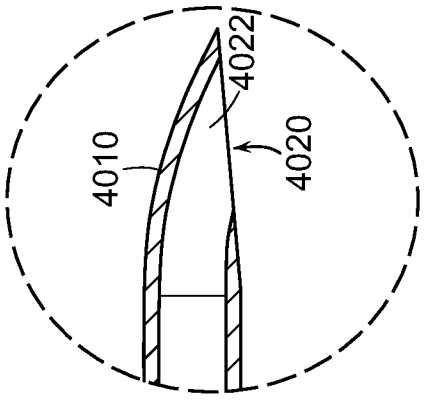

4022
4010
4020

FIG. 4B

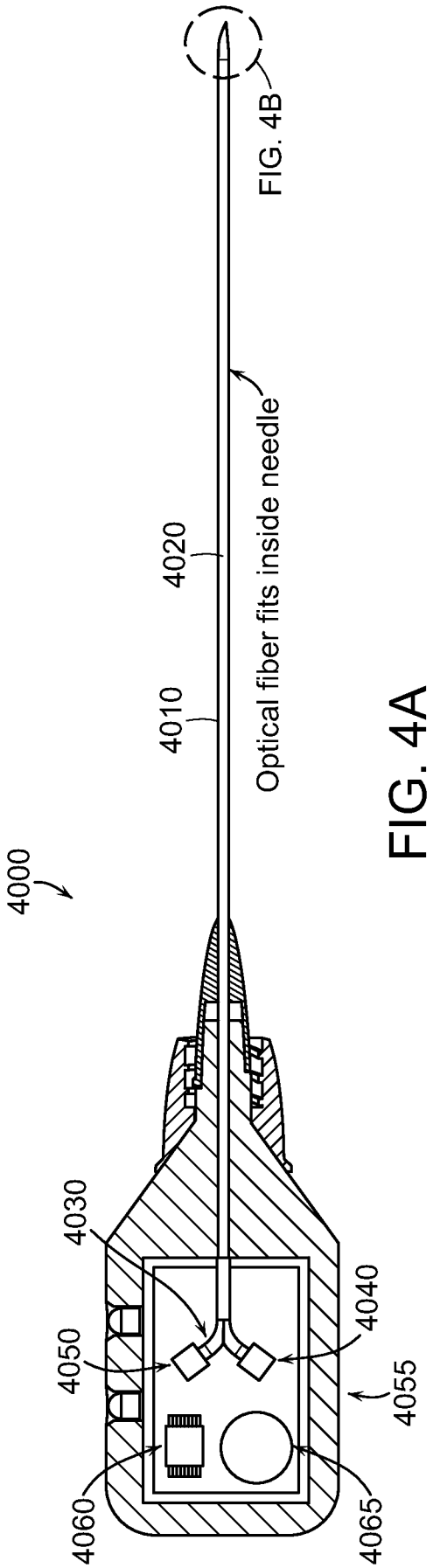


FIG. 4B
Optical fiber fits inside needle
4020
4010
4000
4030
4040
4050
4055
4060
4065

FIG. 4A

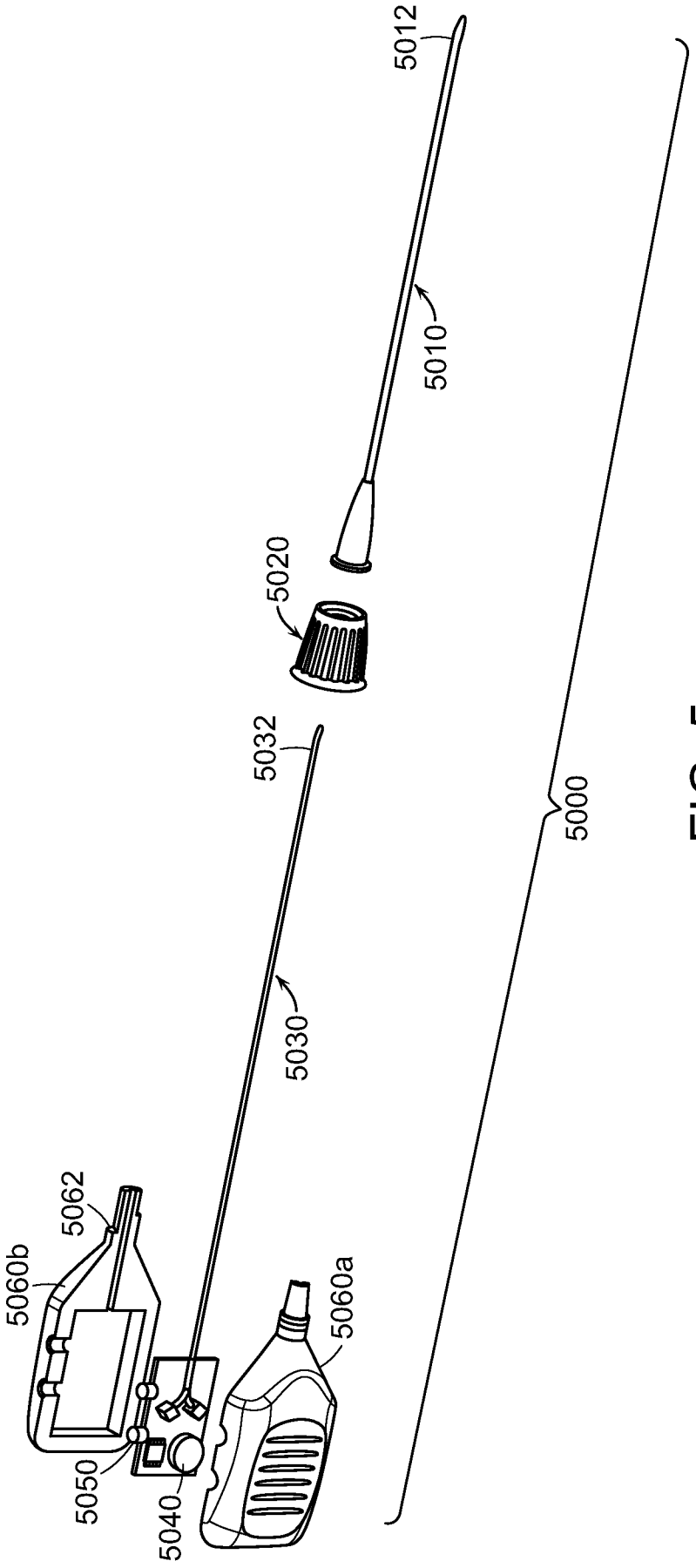
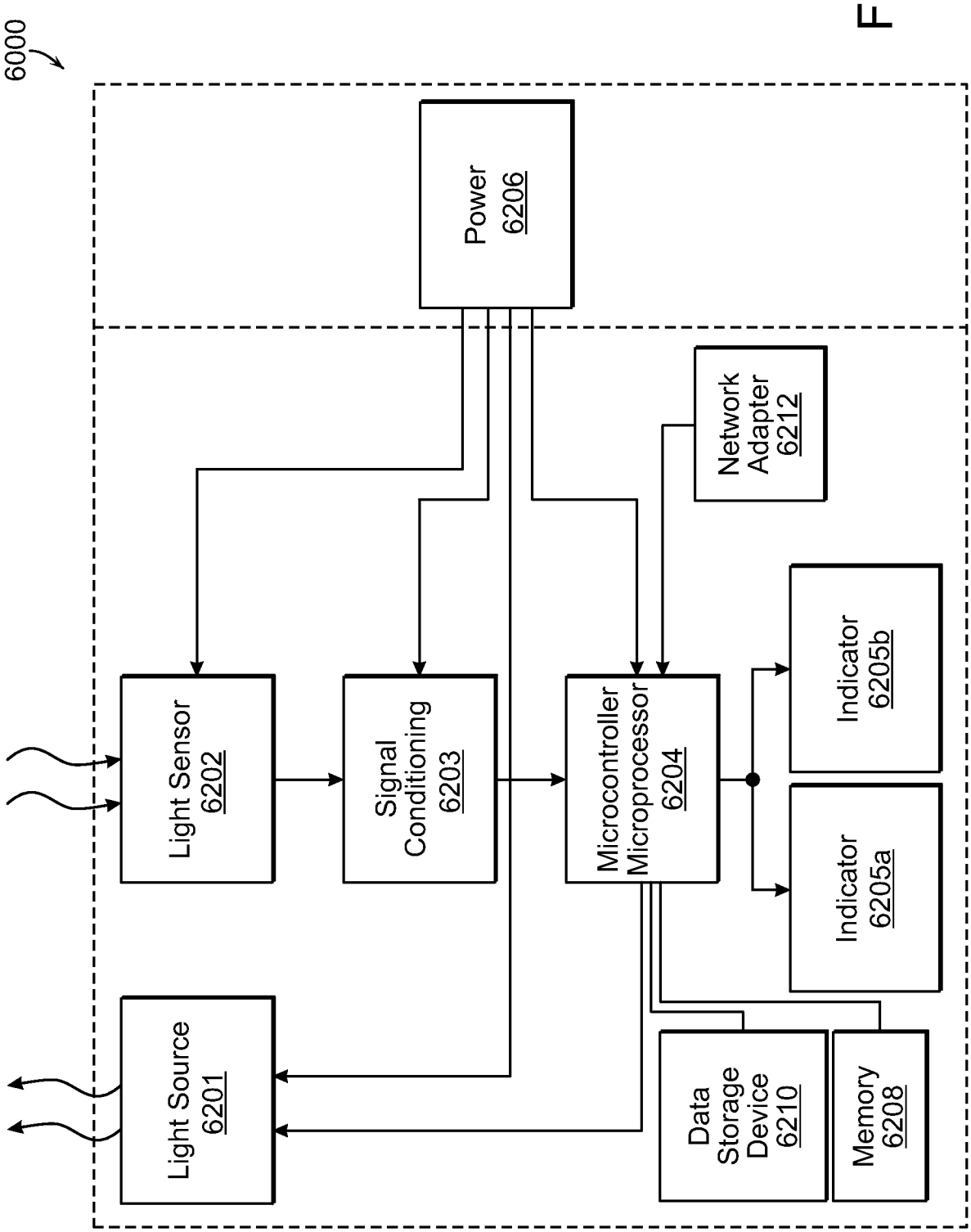


FIG. 5

FIG. 6


6000
Power 6206
Network Adapter 6212
Light Sensor 6202
Signal Conditioning 6203
Microcontroller Microprocessor 6204
Indicator 6205b
Indicator 6205a
Light Source 6201
Data Storage Device 6210
Memory 6208

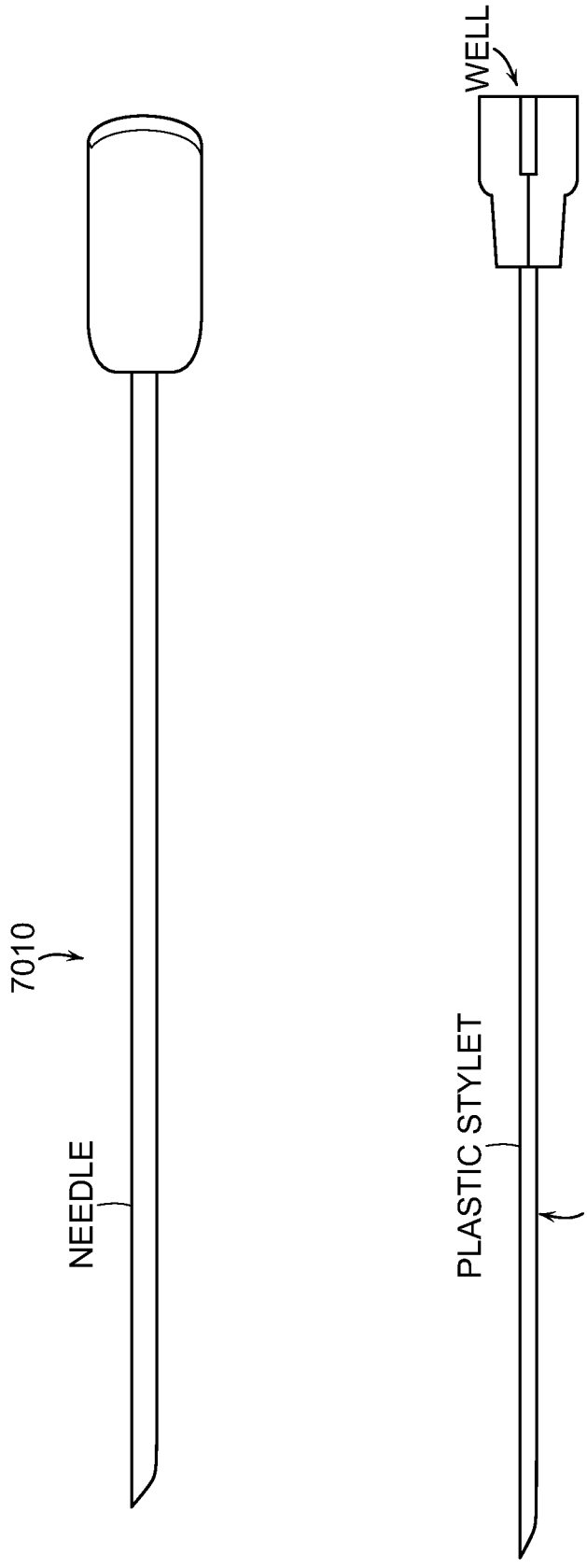


FIG. 7

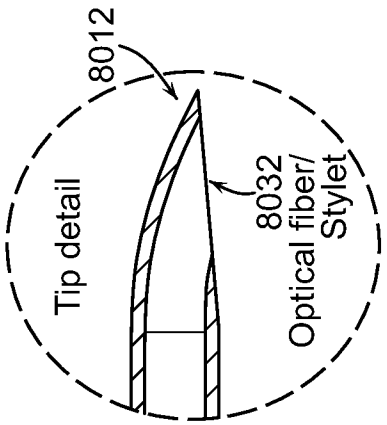

8012
Tip detail
8032
Optical fiber/
Stylet

FIG. 8B

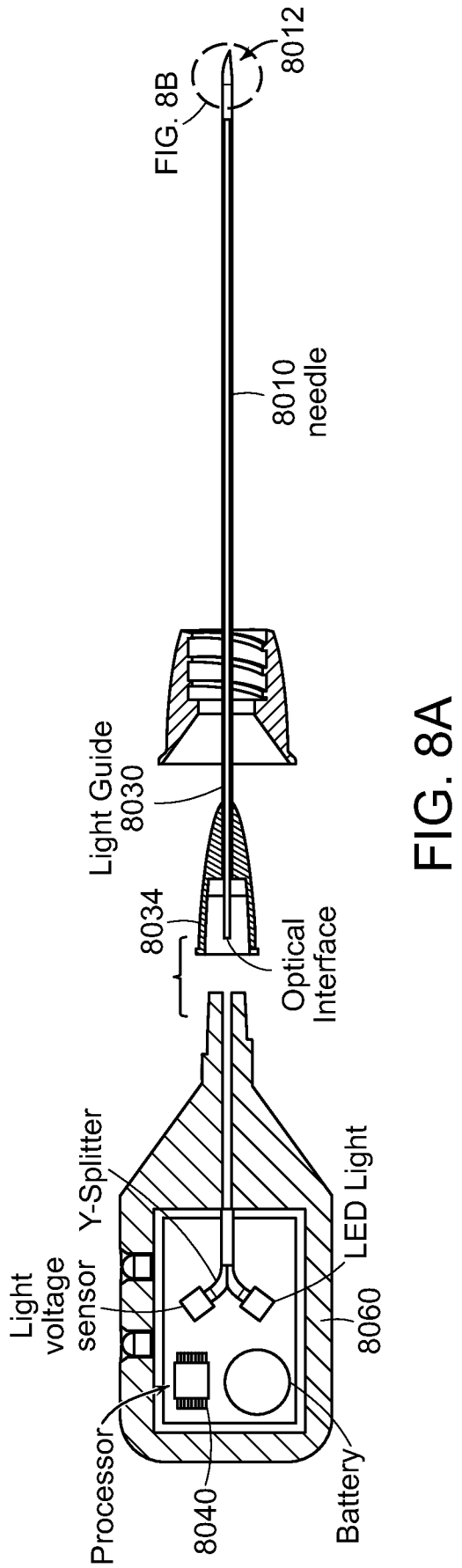


FIG. 8B
8012
8010
needle
Light Guide
8030
8034
Optical
Interface
Y-Splitter
Light
voltage
sensor
LED Light
8060
Processor
8040
Battery

FIG. 8A

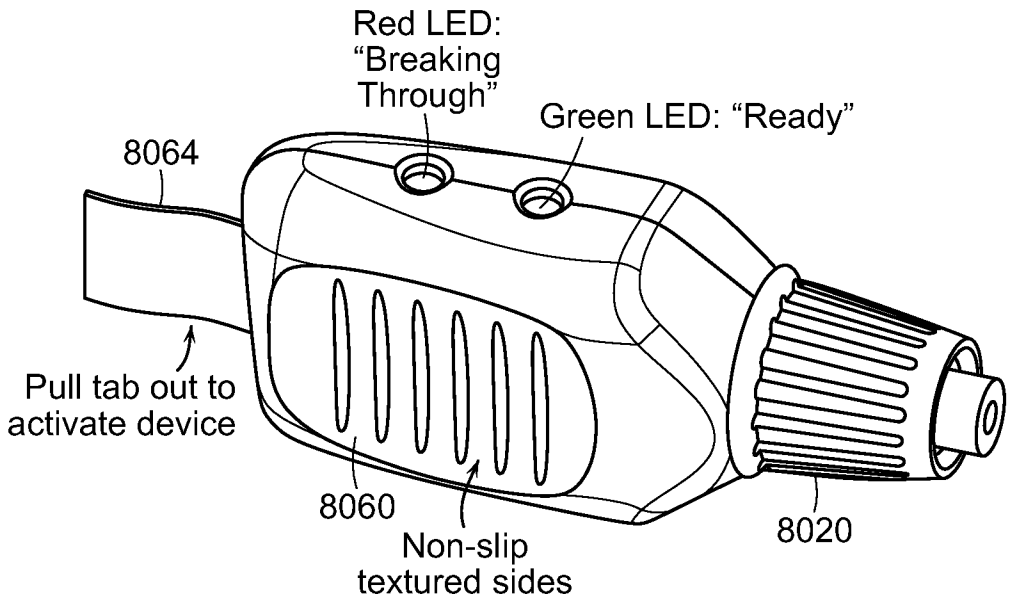

Red LED:
"Breaking
Through"
Green LED: "Ready"
8064
Pull tab out to
activate device
8060
Non-slip
textured sides
8020

FIG. 8C

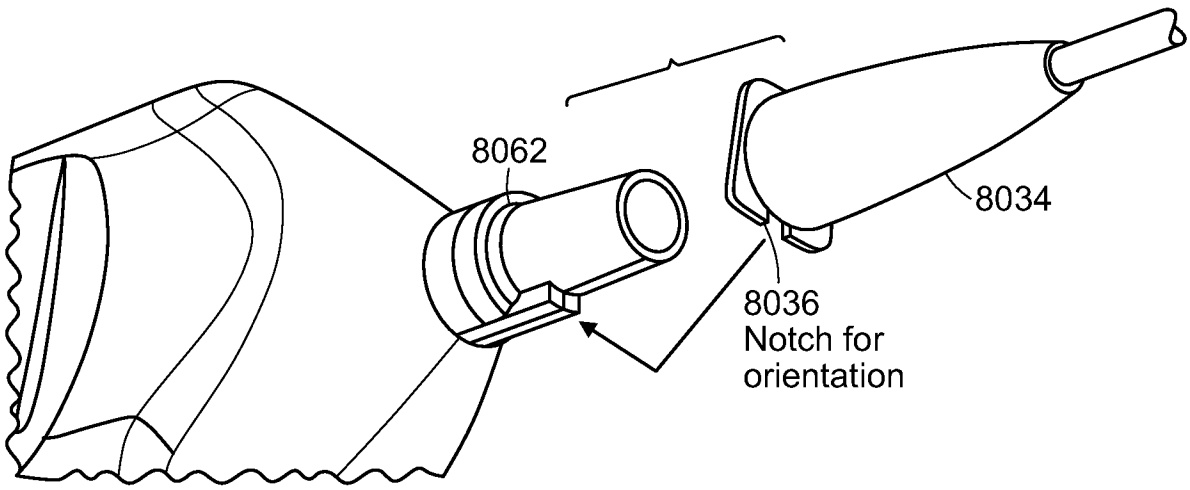

8062
8034
8036
Notch for
orientation

FIG. 8D

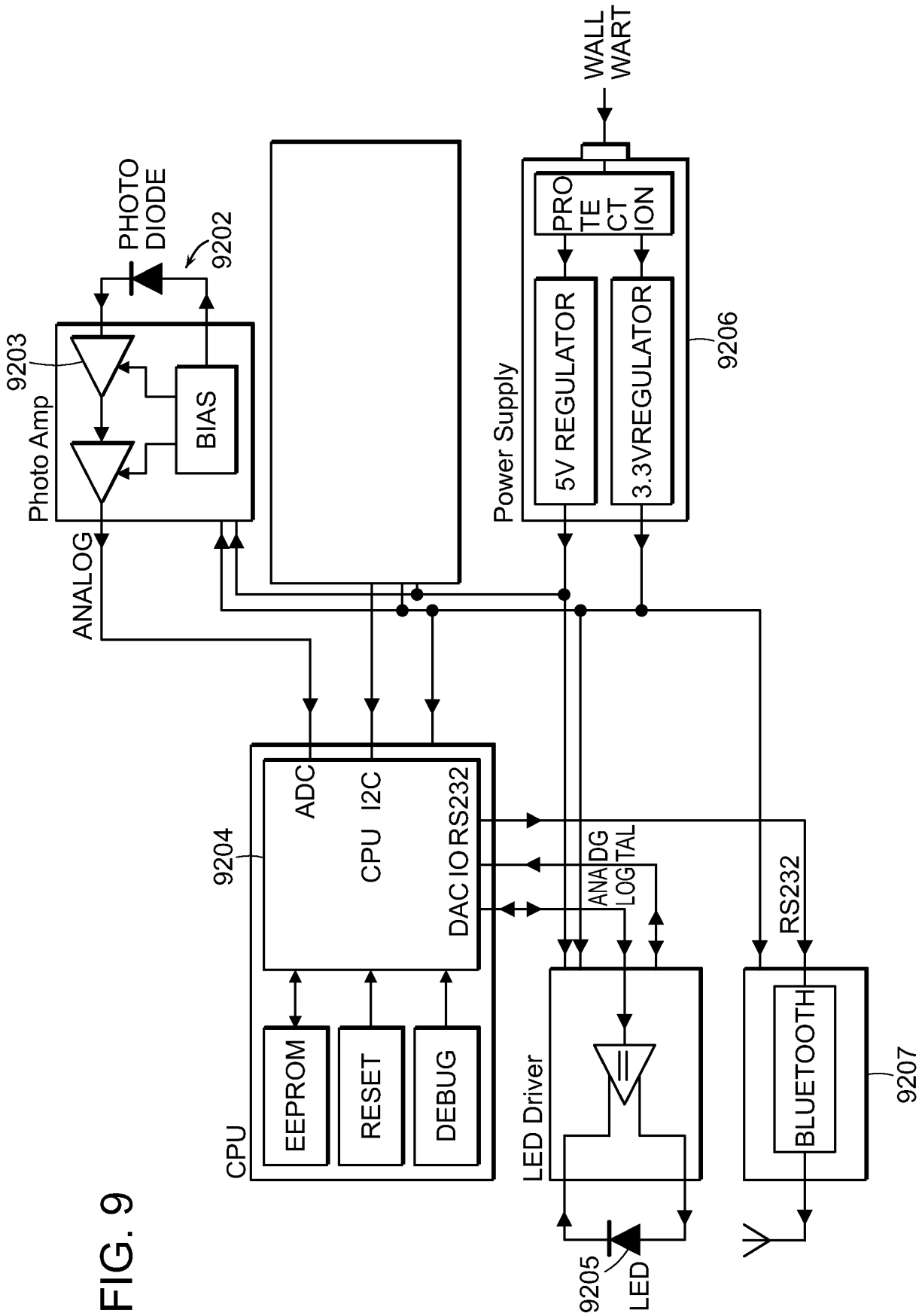
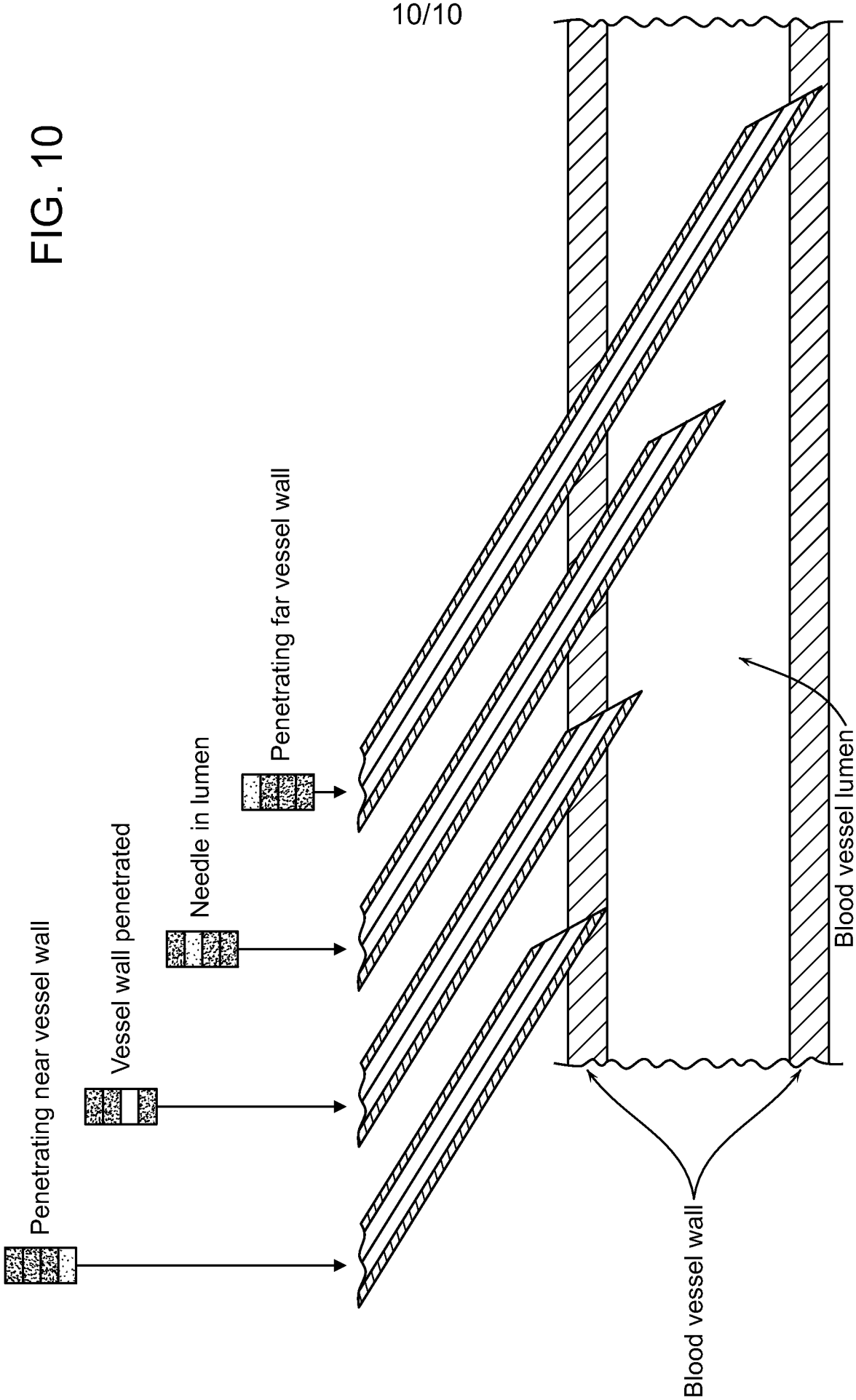

WALL WART
PHOTO DIODE
9202
9203
Photo Amp
BIAS
ANALOG
PRO TE CT ION
5V REGULATOR
3.3VREGULATOR
Power Supply
9206
9204
ADC
CPU I2C
DAC IO RS232
ANA DG LOG TAL
RS232
CPU
EEPROM
RESET
DEBUG
LED Driver
BLUETOOTH
9207
9205
LED

FIG. 9

FIG. 10


Penetrating near vessel wall
Vessel wall penetrated
Needle in lumen
Penetrating far vessel wall
Blood vessel lumen
Blood vessel wall

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 14/25400

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 1/07(2014.01)
USPC - 600/114
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC: 600/114

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 600/114,118,122,120,101,109 (keyword limited; terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Patbase; Google Scholar; Google Patents
Keywords: light guide, blood vessel, insertion tool, lumen, fiber optic, non-collimated, splitter, lens, joint capsule

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/0099501 A1 (CHANG et al.) 16 April 2009 (16.04.2009), entire document, especially; para [0017], [0019], [0021], [0023]-[0025]	20, 22-24, 25/(20, 22-24), 34-37
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Y		1-5, 6/(1-5), 15-19, 21, 25/(21)
Y	US 2008/0287742 A1 (ST. GEORGE et al.) 20 November 2008 (20.11.2008), entire document, especially; para [0035], [0036], [0038], [0039]	1-5, 6/(1-5), 15-19
Y	US 2003/0208154 A1 (CLOSE et al.) 06 November 2003 (06.11.2003), entire document, especially; para [0026], [0031], [0070], [0071]	2, 2/(6), 21, 25/(21)
Y	US 2010/0253949 A1 (ADLER et al.) 07 October 2010 (07.10.2010), entire document	1-5, 6/(1-5), 15-19
A	TUCHIN, V. V. "Optical immersion as a new tool for controlling the optical properties of tissues and blood." LASER PHYSICS-LAWRENCE- 15.8 (2005): 1109. Retrieved online on 13 June 2014 at <http://www.maik.ru/full/lasphys_archive/05/8/lasphys8_05p1109full.pdf>	1-5, 6/(1-5), 15-24 25/(20-24), 34-37
A	US 2011/0307061 A1 (ASSELL et al.) 15 December 2011 (15.12.2011), entire document, especially; para [0149]	1-5, 6/(1-5), 15-24 25/(20-24), 34-37

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 June 2014 (13.06.2014)	21 JUL 2014
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 14/25400

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 7 - 14, 26 - 33
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.