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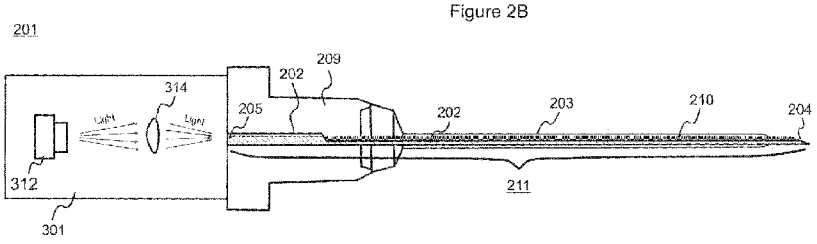
(54) Title: SOLID INTRODUCER NEEDLE FOR CATHETER

Figure 2B



(57) Abstract: A solid introducer needle with a light guide unit (211) for catheter assemblies is provided, which comprises a sharp rigid needle-like member (202) and a light guide (210), forming a substantially monolithic structure. The monolithic structure is thus non-transparent for optical radiation over its entire length, allowing optical radiation to be emitted solely at the distal end thereof. Unit (211) is preferably provided with an adapter (209), via which adapter unit (211) may be connected to an electronic module (301), thus forming a catheter assembly (201). The light guide (210) is configured to receive by its proximal end at least one light beam from at least one light source of the electronic module device, to further conduct said optical radiation beam throughout intern - al space thereof and to emit optical radiation beam at a distal end thereof. Optical radiation, thus emitted at the distal end of the unit (211), is preferably of such a wavelength, to be strongly absorbed by blood and walls of the blood vessels.

SOLID INTRODUCER NEEDLE FOR CATHETER

FIELD OF THE INVENTION

The present invention relates to medical intravascular catheter systems and, in particular, to modified intravascular introducer needle for catheter assembly incorporating a light guide.

BACKGROUND

Modern medical practice cannot be imagined without peripheral intravascular catheter systems. Conventional catheter systems commonly employ common medical needles comprising a lumen, although catheterization does not involve blood sample collection step. The introducer needle is intended basically for skin and/or blood vessel puncture; being withdrawn from the blood vessel after catheter itself is secured on patient's skin. Conventional method of placing the peripheral intravascular catheter into a blood vessel thus comprises skin puncture with an introducer needle, moving said needle in surrounding tissues forward towards target blood vessel, puncturing the wall of a target blood vessel and pushing a cannula of the catheter assembly inside target blood vessel while removing an introducer needle. A successful puncture of a blood vessel is confirmed by visual observation of blood flow into a flashback chamber of a catheter assembly. However, venipuncture has been traditionally associated with a number of common problems. One of those problems is difficulty in determination of the exact position of a needle tip inside the skin relatively to a blood vessel, especially on a dark skin. Another problem concerns the fact, that an observation of blood flow into a flashback chamber may not always serve a reliable indicator of penetration through a blood vessel wall. In case introducer needle penetrates blood vessel through and hits surrounding soft tissues, some blood would appear in the flashback chamber, thus giving a clinician a wrong indication of successful blood vessel entrance. Abovesaid problems become particularly important when placing a catheter system on any patient with small, deep, faulty or damaged veins, and/or in cases of emergency, ambulance and in children's hospitals.

From the construction point of view, the closest prior art for the present disclosure may be represented by trocars for preforming biopsy and/or for removing fluids from the abdomen, as well as by Central Venous Catheters (CVC), inserted into a large vein in the neck, and/or Peripherally Inserted Central Catheters (PICC), inserted into a vein in the arm, rather than in the neck. However, said introducer needles are commonly provided with the bore for fluids to pass. In addition, both biopsy procedures and insertion of CVC are commonly performed while observing the needle advancing into body by ultrasound visualization

means. Additional confirmation of CVC needle entrance into vein is received by observing (by eye) blood in syringe barrel.

For peripheral intravascular catheters system various means are developed in order to localize blood vessels, including those light guides/illumination means.

Thus, prior art catheter systems commonly employ an introducer needle, comprising a sharp, tubular, hollow from inside metallic member, further provided with a void chamber, wherein blood flow occurs upon successful vein penetration. However, in order to puncture skin and blood vessel one may not necessarily need the needle provided with a bore therein. Confirmation of the successful blood penetration whether that is the case, is to be performed by other means, than visual observation of blood flow inside the void chamber.

SUMMARY OF THE INVENTION

The objective of the invention is to provide a novel concept for medical introducer needles, by implementing a solid introducer needle for the intravascular catheter assembly which major purpose is piercing, wherein said needle is constructed as a substantially solid member provided with a light guide integrated therein so, that a substantially monolithic structure is created. Introducer needle in accordance with some embodiments thus does not comprise inner space for blood to flow in. Monitoring of blood vessel penetration events is implemented by optical means. Introducer needle may thus be utilized for fast and accurate localization of blood vessels and for detection of an exact moment of intravascular penetration, in accordance with certain embodiments.

The objective is attained by various embodiments of solid introducer needle in accordance with the present invention.

In one aspect of the present invention, a solid introducer needle with a light guide unit for intravascular catheter assembly is provided, comprising a rigid needle-like member with an integrated light guide, in accordance with the embodiments of the invention.

In one embodiment a solid introducer needle with a light guide unit is provided, said unit comprising a sharp, rigid, substantially tubular metallic member cut from its distal end longitudinally along certain length, thus forming along that length a duct-like structure, into which duct a light guide is positioned. The light guide is thus arranged to fill the rest of the tubular metallic member (non-cut) from inside. Plastic cannula is positioned over a duct-like needle structure with a light guide so, that above mentioned elements are being wrapped into the cannula tubing element. For clarity purposes, the solid introducer needle

of the catheter assembly in accordance with present embodiment will be referred in this disclosure as "semilunar".

In another embodiment a solid introducer needle with a light guide unit is provided, said unit comprising a sharp, rigid metallic bradawl blade-like member, enclosed into a light guide element, further provided with a cannula. For clarity purposes, the solid introducer needle of this embodiment will be referred as "bradawl-needle" in this disclosure.

In further embodiment of the invention a solid introducer needle with a light guide unit is provided, wherein a light guide is arranged to form a non-withdrawable piece with the introducer needle, wherein the lightguide element is preferably manufactured by filling a hollow needle piece by plastic material, thus sealing the needle over its whole length.

In further, substantially additional embodiment, an introducer needle unit is provided sealed from distal and proximal ends thereof by abovementioned light guide element.

In further embodiment a solid introducer needle with a light guide unit is provided, said introducer needle unit is coupled to an adapter member, further connected to the electronic module, wherein an introducer needle unit is adapted to receive a plastic cannula in a common way.

In further embodiment a solid introducer needle with a light guide unit is provided, comprising a light guide configured to receive by its proximal end at least one optical radiation beam of at least one wavelength from at least one optical radiation source, to further conduct said optical radiation beam throughout internal space thereof and to emit said optical radiation beam at its distal end, wherein the light guide is configured to receive, conduct and emit an optical radiation beam of such a wavelength, that is strongly absorbed by blood and/or walls of the blood vessels.

In another aspect of the invention, a method for detection of an exact moment of the intravascular penetration and for safeguarding the blood vessel from being damaged from inside is provided.

In further aspect of the invention a method for confirming an intravascular penetration of cannula tubing into the blood vessel is provided.

In still another aspect of the invention, a method for placing a peripheral intravascular catheter into a blood vessel is provided.

The term "solid" refers is this disclosure to an introducer needle unit and/or introducer needle assembly provided as a substantially monolithic structure with a light guide integrated therein. Hollow interiors are thus absent from the solid introducer needle and/or introducer needle assembly providing no or negligible opportunity for fluids to flow in.

The term "peripheral intravascular catheter" refers in this disclosure to a catheter assembly placed into a peripheral blood vessel, i.e. blood vessel located not in the chest or abdomen and thus being most commonly accessed by intravascular methods.

The term "blood vessel" may in this disclosure be vastly equivalent to the term "vein", since peripheral veins are the most common access point for intravascular methods. To those skilled in art, however, it must be clear, that the term "blood vessel" may also relate to arteries.

The term "optical radiation" refers in this disclosure to radiation comprising a part of the electromagnetic spectrum and including ultraviolet, visible and infrared light ranges. The term may be used within this disclosure as an equivalent to the term "light".

The term "introducer needle assembly" refers in this disclosure to an entity comprising a metallic needle, often referred to an "introducer needle", with a flashback chamber typically being provided as an internal space of the introducer needle connection hub.

The term "introducer needle" refers in this disclosure to a needle for catheter systems, i.e. intended only for placing a catheter into blood vessel. Medical needles, intended for supplying/withdrawal fluids into the body, are not covered by this term within this disclosure.

The term "cannula" refers is this disclosure to a plastic part of the catheter assembly comprising flexible cannula tubing and cannula connection hub. Cannula is normally advanced into blood vessel and secured therein for further medicinal proceedings. The term "cannula" may substantially equal with the term "catheter" within said disclosure.

Different embodiments of the present invention will become apparent by consideration of the detailed description and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A illustrates a conventional peripheral intravascular catheter assembly.

Fig. 1B illustrates an introducer needle assembly of a conventional peripheral intravascular catheter assembly.

Fig. 1C illustrates a cannula of a conventional peripheral intravascular catheter assembly.

Fig. 1D illustrates a distal end of the conventional introducer needle provided with cannula tubing.

Fig. 1E illustrates a conventional process for the introduction of peripheral intravascular catheter assembly into blood vessel.

Fig. 2A illustrates a solid introducer needle with a light guide unit, in accordance with some embodiment.

Fig. 2B illustrates a solid introducer needle with a light guide unit in accordance with some embodiment, said unit provided with the adapter and connected to electronic module.

Fig.3 is an enlarged view of a solid introducer needle with a light guide unit in accordance with some embodiment, provided with the adapter and connected to electronic module.

Fig. 4A schematically illustrates a side view of a solid introducer needle with a light guide, referred in present disclosure as a "semilunar needle", in accordance with some embodiment.

Fig. 4B schematically illustrates a crosscut section of a solid introducer needle with a light guide, referred in present disclosure as a "semilunar needle".

Fig.4C schematically illustrates a sectional crosscut of a solid introducer needle with a light guide, referred in present disclosure as a "semilunar needle" in slightly different configuration.

Fig. 5A-B illustrate benefits of semilunar introducer needle application in comparison to conventional introducer needles, in particular, concerning size of light guide to be integrated within the introducer needle.

Fig. 6A schematically illustrates a side view of a solid introducer needle with a light guide, referred in present disclosure as a "bradawl needle", in accordance with some embodiment.

Fig. 6B schematically illustrates a sectional crosscut of a solid introducer needle with a light guide, referred in present disclosure as a "bradawl needle".

Fig. 7A schematically illustrates a side view of a solid introducer needle with a light guide arranged to form a non-withdrawable piece with the introducer needle by filling a hollow needle piece by plastic material, for example.

Fig. 7B and 7C schematically illustrate a side view of a solid introducer needle with the hollow needle unit, provided sealed from distal and proximal ends thereof by a light guide element.

Fig. 8A and 8B illustrate a process of blood vessel puncturing by means an intravascular catheter assembly comprising a solid introducer needle with a light guide.

DETAILED DESCRIPTION OF THE EMBODIMENTS

Detailed embodiments of the present invention are disclosed herein with the reference to accompanying drawings. The same reference characters are used throughout the drawings to refer the same members. Following citations are used for the members:

Prior art:

101 – intravascular catheter assembly;

111 – introducer needle assembly;

121 – cannula;

102 – metallic introducer needle of the introducer needle assembly;

103 – flexible cannula tubing;

104 – insertion (distal) end of the introducer needle;

105 – chamber (proximal) end of the introducer needle;

106 – introducer needle hub;

107 – flashback chamber of the introducer needle assembly formed by a needle hub

108 – blood;

109 – connection hub of the cannula.

Present disclosure:

201 – intravascular catheter assembly provided with an electronic module;

211 – introducer needle with a light guide;

202 – rigid needle-like member of introducer needle assembly;

202D – distal section of rigid needle-like member;

202P – proximal section of rigid needle-like member;

203 – cannula tubing;

204 – distal end (tip) of the introducer needle;

205 – proximal end of the introducer needle;

209 – adapter;

210 – light guide;

212 –introducer needle bore;

213 – protective layer;

214 – empty space created between inner walls of cannula tubing, introducer needle and light guide;

301 – electronic module;

312 – optical radiation source;

314 – optical radiation converging device;

501 – light spot.

A conventional peripheral intravascular catheter assembly is illustrated by Figure 1A (prior art). A catheter assembly **101** is shown (Fig. 1A), comprising an introducer needle assembly **111** (Fig. 1B) and a plastic cannula (Fig. 1C). The term "introducer needle assembly" refers herein to the metallic introducer needle **102** with a connection hub **106**. A hollow interior of the connection hub **106** forms a flashback chamber **107**. Onto a metallic introducer needle **102** an over-the-needle flexible plastic cannula **121** is mounted. Cannula **121** (Fig. 1C) thus comprises a cannula connection hub **109** and flexible cannula tubing **103**. Cannula is a part of a catheter assembly that normally stays within blood vessel. Introducer needle **102** is provided with a sharp insertion end **104**, referred herein as a distal end or the tip of the needle, and with a chamber end **105**, referred herein as a proximal end.

Introducer needles for conventional catheter assemblies (like the one mentioned above) are normally provided as metallic, rigid, tubular and hollow from inside members, into the bore thereof blood flow occurs. Blood flows through the bore of the introducer needle **102**, and via the chamber end **105** enters a flashback chamber **107**. Visual monitoring of blood appearance in a flashback chamber **106** is a routine method to establish the fact of blood vessel penetration.

A solid introducer needle with a light guide, referred herein as unit **211**, is thus provided (Fig. 2A), in accordance to some embodiment. Unit **211** is configured as a rigid needle-like member **202**, supplied with a light guide **210**, wherein light guide is preferably arranged to form a non-withdrawable (solid) structure with needle-like member **202**. Needle-like member **202** may be metallic, as a conventional needle, however, any material of sufficient hardness and/or rigidity may be utilized for manufacturing said member, so far as the material is technically suitable for the purposes of the invention. Light guide **210** is preferably produced by the material with good light conducting properties and may be represented by an optical fiber permanently fixed inside the member **202**, for example. Solid introducer needle with a light guide unit **211** may be releasably or permanently connected to the electronic module **301** by means of an adapter **209**, thus forming an assembly structure **201**. Such exemplary assembly structure **201** is represented on Fig. 2B. Assembly **201**, however, may comprise unit **211**, configured in accordance with any embodiment of present invention. Assembly structure may comprise, in addition, a cannula with tubing **203** with a connection means, realized as a connection hub, for example (not on the figure).

Fig. 3 is an enlarged view of the introducer needle assembly **201** of Fig. 2B. Introducer needle with a light guide unit **211** preferably integrated within the adapter 209; however 211 may be implemented as a withdrawable unit. Adapter **209** on the proximal side thereof comprises connection means, such as connection hub, for example, to be coupled to the electronic module **301**. Electronic module **301** thus comprises at least one light source **312**, light converging means **314**, power source(s), such as battery(s) or the like, other electronic components and switches. Those are part of known prior art and are not described further in this document. Light source, however, may be arranged also inside the adapter **209**, whether required for some particular applications.

Fig. 4A and 4B schematically illustrate a solid introducer needle with a light guide unit **211**, referred herein as "semilunar", in accordance with some embodiment. Fig.4A provides a side view of the semilunar introducer needle unit **211** and Fig. 4B is a crosscut section. In accordance with the embodiment, unit **211** comprises a sharp, rigid, substantially tubular member **202**, cut from its distal end longitudinally along certain

length, thus providing a structure substantially comprised of two sections, distal **202D** and proximal **202P** (Fig. 4A). The proximal section **202P** is provided as an elongated substantially tubular structure that may be best described as a pipe. The distal section **202D** is provided in the form of a duct-like structure and may be best described as an above mentioned pipe, but horizontally severed. The distal end **204** (tip) of said distal section **202D** is obliquely severed to form a sharp surface, suitable for puncturing skin, tissue and blood vessel. Member **202** is preferably metallic; however use of other material of sufficient hardness may not be ruled out. Preferably, the introducer needle with a light guide **211** is further surrounded by thin non-transparent protective film **213** (Fig. 4A). It is important to note, that light is intended to be emitted precisely at the distal end opening of the introducer needle with a light guide. Protective film **213** is thus intended to cover the introducer needle with a light guide unit **211** over its length in order to prevent light "leak" elsewhere than at the distal end **204.**

By the proximal end **205** thereof introducer needle **201** may be connected to an electronic module **301** via an adapter **209**. The adapter is positioned so, that an introducer needle proximal section **202P** is completely hidden within the adapter, so as a part of a distal section **202D**. The light guide **210** is integrated within needle-like member **202**, being positioned along proximal and distal sections **202D** and **202P** to fill an entire proximal section from inside and to substantially fill the duct created by the distal section. Considering the fact, that proximal section **202P** is hidden inside the adapter **209**, the user may observe only horizontally cut duct-like distal section **202D** with a light guide integrated therein. The cannula tubing **203** is positioned around the introducer needle with a light guide unit **211**, 'wrapping' a part of the distal section **202D**.

Fig. 4B illustrates a crosscut of the distal section **202D** of the introducer needle with a light guide unit **201** of Fig.4A with cannula tubing **203** wrapped over said unit. Fig. 4B shows a distinctive "semilunar" shape of the needle-like member **202**, in accordance with some embodiment. Fig.4B also schematically illustrates a light guide **210** position within distal section **202D** of introducer needle unit **211**. Light guide **210** is tightly positioned within the duct, provided by distal section **202D** of unit **211**, and fills up most of the space within tubular proximal section **202P**. However, there may be still some empty space **214** left between light guide **210** and the walls of the tubular proximal section **202P** of the unit **211**, as well as between the light guide **210**, inner walls of the duct-like distal section **202D** of the unit **211** and inner surface of the cannula tubing **203** (Fig. 4B). However, those empty spaces (gaps) **214** are of such negligible size that no essential amount of fluid may flow in, therefore gaps **214** are not intended for receiving blood flow for further visual observations.

Fig. 4C illustrates a crosscut of the distal section **202D** of the semilunar introducer needle with a light guide **211** in slightly different configuration. While a crosscut shape of the needle-like member **202** of Fig.4B is literally "semilunar", i.e. most closely reminds of a half-moon, the needle-like member **202** of Fig. 4C in crosscut thereof may be closer to a horizontally severed pipe, which severed walls in a crosscut are leveled to small plateaus and not sharpened, like in Fig. 4B.

Fig.5A and 5B schematically illustrate the benefits of utilization of the introducer needle with a light guide **211** in substantially semilunar configuration, in accordance with above disclosed embodiments. As may be noticed from Fig.5A, representing a conventional needle **202** with a light guide **210** within a bore **212** thereof, a diameter of the light guide (d1) that may be inserted into said needle is limited by the diameter of needle inner walls (d2). Taking into consideration the fact that needle **202** is supposed to provide space for fluid to flow in, the diameter of the light guide must be very small (Fig. 5A). However, utilization of semilunar configuration (Fig. 5B) provides an opportunity to utilize a light guide with wider diameter (d2), occupying practically a whole interior of the needle-like member **202** (Fig.5B). The diameter of the light guide for semilunar configuration (Fig. 5B) may be 1.5 times wider than that for conventional configuration (Fig. 5A). Since ultrathin optical fibers may require a more powerful optical radiation source to emit same amount of optical radiation at distant end thereof as compared to wider optical fibers, the "semilunar" solution may be less expensive to manufacture.

Fig. 6A and 6B schematically illustrate another embodiment of solid introducer needle with a light guide unit **211**, wherein the introducer needle is provided in so called "bradawl" configuration. Fig.6A is a side view of the bradawl introducer needle with a light guide unit **211**, and Fig. 6B is a crosscut section thereof. In accordance with this embodiment, a solid introducer needle is provided as a sharp, rigid, rod-like member **202** that may be best described as a bradawl blade-like member. Rod **202** may be metallic; however it may be manufactured from any other material of sufficient hardness, suitable for the purposes of the invention, such as hard transparent or non-transparent plastic or similar. Bradawl solid introducer needle **202** is enclosed into a light guide member **210** in a rod wire manner. The introducer needle of present embodiment may be best described as a common graphite pencil, said "pencil" comprises e.g. metallic rod in the middle, surrounded by the light-conductive layer. The tip **204** of the introducer needle with a light guide **211**, in accordance with this embodiment, is sharpened in a bradawl blade-like manner (Fig. 6A). Bradawl solid introducer needle **202** rod may be provided retractable. Preferably, the light guide **210** is further surrounded by thin non-transparent protective film **213** (Fig. 6A). Fig.6A also shows cannula tubing **203**, placed over the introducer needle with a light guide **211**. By the proximal end **205** thereof a bradawl introducer needle with a

light guide may be connected to the adapter **209** and via an adapter – to the electronic module **301**, like shown on Fig.2B.

Fig. 4B illustrates a cross-cut of the bradawl introducer needle with a light guide unit **211** of Fig.4A with cannula tubing **203** wrapped over it. The protective film **213** is not shown.

Returning further to Fig.2B, both introducer needle with a light guide in bot semilunar and bradawl configurations, in accordance with above disclosed embodiments, may be connected to the electronic module **301**. The connection is implemented via an adapter **209**, which partly encloses an introducer needle with a light guide at proximal section thereof. Preferably, the introducer needle with a light guide unit **211** is manufactured as an assembly with the adapter **209**, which further may be mounted onto an electronic module **301**, or connected thereto by other suitable means. Said connection may be either releasable or permanent. Correspondingly, the manufacture of disposable, vacuum-packed assemblies **211+209** or **211+209+301** is possible; however the latter may be more cost-expensive.

Electronic module **301** may be therefore provided preferably as a multi-use unit, which comprises at least one optical radiation source, such as a light source **312**, for example, and light converging means, such as lens **314**, optical fiber or similar. Light source **312** is preferably laser source; however, any other suitable light source may be implemented herein. Electronic module **301** may be preferably equipped with an on-off switch, implemented, for example, as a manually operated pushbutton switch, a lever-actuated switch, a rotational switch, a slide switch with a seesaw action or any other suitable type of an on-off mechanism capable of providing a control over an on-off state of the electronic module. Electronic module may be equipped with a mechanism to control an amount of emitted light and/or color thereof. Electronic module **301** preferably comprises a power source, such as a battery, generator or the like. Electronic module **301** may comprise additional electronic components.

Figures 7A-C illustrates another embodiment of solid introducer needle with a light guide. The introducer needle with a light guide is shown on Fig.7A-C coupled to the adapter **209**. In accordance to this embodiment, light guide **210** (shown in dark) is arranged to form a non-withdrawable piece with an introducer needle **202** thus forming a monolithic structure with the introducer needle **202**. Configuration of Fig.7A is obtained by filling a bore of common tubular hollow metallic introducer needle **202** by light transmitting plastic material, serving herein as a light guide **210**. The bore of the needle **202** thus becomes completely sealed over its whole length so, that no fluid may enter. Figures 7B and 7C illustrate a cost-effective version of same embodiment, wherein the introducer needle **202**

is sealed only by its distal and proximal ends, while the bore **212** thereof remains empty. Polished inner surface of an introducer needle **202**, however, may in this case operate as a light transmitting surface. Light beam is represented by a dashed line inside an introducer needle **202**. Proximal end of the light guide, corresponding in Fig. 7B-C to a proximal end **205** of an introducer needle **202,** may be simply cut (Fig.7B), or be adapted to take a substantially spherical form (Fig.7C) by mounting e.g. lens into proximal end of the needle, in order to enhance optical radiation input. Distal end 'seal' may be arranged into a very close proximity to a needle tip opening or alternatively at some distance from a needle tip opening (dashed box, Fig.7C.

Light guide **210**, in accordance to all embodiments, is therefore adapted to receive light originating from at least light source **312**, to transmit light throughout its internal space and to emit at a distal end thereof. Light source may thus be arranged inside an electronic module **301**, or inside an adapter **209**. Whether light source is arranged within the adapter **209**, electronic module may comprise a power source, such as battery.

The process of entering a blood vessel by means of a catheter assembly **201** provided with the introducer needle with a light guide in accordance to above said embodiments, is illustrated by Fig. 8A and 8B, wherein said needle is coupled to the electronic module **301** via an adapter **209**. A light source is activated. Whether light of predetermined wavelength travels along light guide, a spot of light appears at a distal end **204** of the introducer needle unit **211**. Preferably, at least one light source is adjusted to emit light of such wavelength, that is strongly absorbed by blood, in particular by red blood cells, and/or by the walls of blood vessels (such as veins and arteries), but is relatively weakly absorbed by skin, fat and other surrounding tissues. In order to enter a blood vessel an introducer needle with a light guide unit **211** has to penetrate tissues with different light scattering properties, such as skin, soft tissues and a wall of a blood vessel. When the distal end **204** of the introducer needle with a light guide unit **211** has already penetrated skin and tissues but has not yet entered a blood vessel, light illuminates surrounding tissues, being partly reflected and scattered therefrom, thus generating an illuminated spot on skin surface, that may be observed by eye. As soon as the introducer needle with a light guide unit **211** had entered blood vessel, light becomes absorbed by blood and/or the walls of a blood vessel, therefore causing the light spot to disappear from the skin surface. Since the penetration of a blood vessel wall by the needle tip is a very rapid process, optical properties of needle tip surrounding environment change momentarily from relatively low light absorption level to very high light absorption level. As a result, an outside observer (eye pictogram, Fig. 8A,B)may easily visually detect the moment when light, otherwise visible on skin, disappears; which event is indicative of a successful venipuncture. Since catheterization procedure does not require blood sample collection, and the necessity of observing blood

appearing in the flashback chamber is now eliminated, solid introducer needle with an integrated light guide unit **211** in accordance with the embodiments of the invention may be successfully utilized for fast and accurate intravascular catheter placement.

Above described phenomenon may be observed upon selecting light of a specific wavelength, such as green, for example. However, light of other wavelengths of visible spectra, such as white, yellow and red, for example, may be utilized. In addition, IR radiation may be utilized as well.

The electronic module **301** may be, in addition, adapted to generate optical radiation, herein light, of at least two wavelengths at the same time by means of separate optical radiation sources. At least one optical radiation source is therefore configured to emit light of such a wavelength that is strongly absorbed by blood and the walls of blood vessels, in accordance with above disclosed.

It is to be understood, that abovesaid optical radiation color spectra examples are not intended to limit the purposes of the invention, and the light source(s) provided with the electronic module **301** may be set up to generate optical radiation of any other suitable wavelength as far as the aforementioned effect from utilizing of the intravascular catheter assembly of the invention is achieved.

In another aspect of the invention, a method for detection of an exact moment of the intravascular penetration and for safeguarding blood vessel from being damaged from inside is provided, wherein said method is performed by means of the introducer needle with a light guide unit **211** in accordance with abovesaid embodiments, and wherein said method comprises at least several of the following steps:

a. obtaining a catheter assembly **201** provided with solid introducer needle with a light guide unit **211**, a cannula and an electronic module **301**;
b. activating optical radiation source(s), said optical radiation source(s) implemented preferably in the form of laser source(s), for optical radiation to be observed on the distal end **204** of the introducer needle with a light guide unit **211**;
c. puncturing the skin with by means of the introducer needle with a light guide unit **211**;
d. localizing a blood vessel position intracutaneously by monitoring illumination events at the distal end **204** of unit **211**;
e. detecting the moment when distal end of unit **211** penetrates the wall of a blood vessel and enters a lumen thereof by observing at least one of the following illumination events at the introducer needle distal end **204**: instant disappearance of

illumination, rapid illumination fading, rapid change in light color and/or rapid illumination fading along with rapid change in light color, wherein said events are dependent on the optical radiation wavelength utilized;

f. ensuring a correct position of the introducer needle with a light guide unit **211** within a lumen of a blood vessel by monitoring illumination events at the distal end **204** thereof;

g. advancing the cannula inside a lumen of a blood vessel.

In accordance with aforesaid aspect of the invention, said method may be applied equally efficiently to patients of any age group, independent of size, diameter and depth of blood vessels thereof.

In further aspect of the invention a method for confirming an intravascular penetration of cannula tubing into the blood vessel is provided, which method comprises at least several of the following steps:

a. obtaining a catheter assembly **201** provided with the introducer needle in accordance to some embodiments, and with the electronic module **301**;

b. switching on the optical radiation source(s), said optical radiation source(s) implemented preferably in the form of laser source(s), of the electronic module **301** for optical radiation to be observed on the distal end **204** of the introducer needle **211**;

c. puncturing the skin with the introducer needle **211**;

d. localizing a blood vessel position intracutaneously by monitoring illumination events at the distal end **204** of the introducer needle **211**;

e. detecting the moment when the introducer needle **211** penetrates the wall of a blood vessel and enters the lumen of a blood vessel by observing at least one of the following illumination events at the introducer needle distal end **204**, said illumination events comprising disappearance of visible light and/or the instant change in visible light color;

f. ensuring a correct position of the introducer needle **211** inside the lumen of a blood vessel by monitoring illumination events at the introducer needle distal end **204**;

g. observing blood flow inside the cannula tubing **203** from the distal end of the catheter assembly towards a proximal end thereof via space **214**;

h. extending the cannula tubing **203** inside a lumen of a blood vessel.

In still another aspect of the invention, a method for placing a peripheral intravascular catheter into a blood vessel is provided in accordance with aforesaid embodiments, wherein said method comprises at least several of the following steps:

a. determination of a patient condition (child, adult, emergency, hospital etc) and determination of a blood vessel to be punctured condition (wide, thin, deep, damaged);
b. obtaining a catheter assembly **201** provided with solid introducer needle with a light guide unit **211**, a cannula and an electronic module **301**;
c. activating optical radiation source(s), said optical radiation source(s) implemented preferably in the form of laser source(s), for optical radiation to be observed on the distal end **204** of the introducer needle with a light guide unit **211**;
d. puncturing the skin with by means of the introducer needle with a light guide unit **211**;
e. localizing a blood vessel position intracutaneously by monitoring illumination events at the distal end **204** of unit **211**;
f. detecting the moment when distal end of unit **211** penetrates the wall of a blood vessel and enters a lumen thereof by observing at least one of the following illumination events at the introducer needle distal end **204**: instant disappearance of illumination, rapid illumination fading, rapid change in light color and/or rapid illumination fading along with rapid change in light color, wherein said events are dependent on the optical radiation wavelength utilized;
g. ensuring a correct position of the introducer needle with a light guide unit **211** within a lumen of a blood vessel by monitoring illumination events at the distal end **204** thereof;
h. advancing the cannula inside a lumen of a blood vessel;
i. withdrawing the introducer needle with a light guide unit **211** from a blood vessel, leaving the cannula inside a blood vessel;
j. securing the cannula over the skin of a patient and connecting an appropriate system thereto.

Important aspects of the invention are summarized in the following sentences:

1. An introducer needle **211** comprising a sharp rigid metallic member **202** provided with at least one light guide **210**; wherein said introducer needle **211** is solid structure; wherein a light guide **210** is configured to receive by its proximal end at least one optical radiation beam of at least one wavelength from at least one optical radiation source of the electronic module device **301**, to further conduct said optical radiation beam throughout internal space thereof and to emit said optical radiation beam at its distal end; and wherein a light guide **210** is configured to receive, conduct and emit an

optical radiation beam of such a wavelength, that is strongly absorbed by blood and walls of the blood vessels and is reflected and/or scattered from blood vessel surrounding tissues.

2. The solid introducer needle **211** of sentence 1, wherein the needle member **202** is provided as a sharp, rigid, substantially tubular metallic member cut from its distal end longitudinally along certain length, providing a structure substantially comprised of two sections; wherein the distal section **202D** is provided in the form of a duct-like structure, and the proximal section **202P** is provided as an elongated substantially tubular structure; and wherein the light guide **210** is positioned along both proximal and distal sections, said light guide is arranged to fill an interior of a tubular proximal section **202P** and further to be tightly positioned within the duct created by the distal section **202D**.

3. The solid introducer needle **211** of sentences 1 and 2 arranged into a catheter assembly **201**, said assembly comprising:
    a. the solid introducer needle **211** with a light guide **210**, in accordance with sentences 1 and 2;
    b. a cannula provided with a tubing **203** and connection means;
    c. an adapter **209** and
    d. an electronic module **301**,

    wherein the cannula tubing **203** is arranged to surround the structure formed by distal and proximal sections of the introducer needle with a light guide unit **211**.

4. The solid introducer needle **211** of sentence 1, wherein the needle member **202** is provided as a sharp, rigid, rod-like member, substantially enclosed into a light guide element **210**, which is further surrounded by a thin protective film **213**, and wherein the tip **204** of the introducer needle **211** is sharpened in a bradawl blade-like manner.

5. The solid introducer needle **211** of sentences 1 and 4 arranged into a catheter assembly **201**, said assembly comprising:
    e. an introducer needle **211** with a light guide **210**, in accordance with sentences 1 and 4;
    f. a cannula provided with a tubing **203** and connection means;
    g. an adapter **209** and
    h. an electronic module **301**,

    wherein the cannula tubing **203** is arranged to surround the structure formed by the introducer needle with a light guide unit **211** of sentence 4.

6. The solid introducer needle **211** of sentence 1 provided as a rigid tubular hollow member **202**, which interior is filled by a light transmitting plastic material serving as a light guide **210**, wherein the light guide **210** is arranged to form a non-withdrawable piece with member **202**.

7. The solid introducer needle **211** of sentences 1 and 6, wherein said unit is provided as a rigid tubular hollow member **202** sealed by a light transmitting material solely at distal and proximal ends thereof.

8. The solid introducer needle **211** of sentences 1, 6 and 7, arranged into a catheter assembly **201**, said assembly comprising:
   a. a rigid tubular hollow needle-like member **202** with a light guide **210** provided as a substantially monolithic structure therewith, in accordance with sentences 1, 6 and 7;
   b. a cannula provided with a tubing **203** and connection means;
   c. an adapter **209** and
   d. an electronic module **301**,

   wherein the cannula tubing **203** is arranged to surround the structure formed by the member **202** with an integrated light guide **210** of sentence 6 and 7

9. The solid introducer needle **211** of sentences 2 and 4, which is permanently coupled to the adapter **209**.

10. The solid introducer needle **211** of sentences 2 and 4, which is releasably coupled to an adapter **209**.

11. The solid introducer needle **211** of sentences 3 and 5, wherein connection of **211** to the electronic module **301** via the adapter **209** is permanent.

12. The solid introducer needle **211** of sentences 3 and 5, wherein connection of **211** to the electronic module **301** via the adapter **209** is releasable.

13. The solid introducer needle **211** of sentences 3 and 5 provided with the electronic module **301**, wherein the electronic module **301** comprises at least one optical radiation source, optical radiation converging means and at least one power source, and wherein said optical radiation source is configured to generate an optical radiation beam of such a wavelength, that is strongly absorbed by blood and walls of the blood vessels, but is reflected and/or scattered from surrounding tissues.

14. The solid introducer needle **211** of any of the preceding sentences, wherein the light guide **210** is manufactured from a substantially optical radiation conductive material, preferably optical fiber.

15. The solid introducer needle **211** of any of the preceding sentences, wherein the light guide **210** is configured to receive an optical radiation from a light source.

16. The solid introducer needle **211** of any of the preceding sentences, wherein the light guide **210** is configured to receive an optical radiation from a laser source.

17. The solid introducer needle **211** of any of the preceding sentences, wherein the light guide is configured to receive an optical radiation from a light diode.

18. The solid introducer needle **211** of any of the preceding sentences, wherein the light guide **210** is arranged to receive at least two optical radiation beams of different wavelengths from at least two optical radiation sources at the same time, one of which optical radiation beams is of a wavelength, that is strongly absorbed by blood and walls of the blood vessels, but is reflected and/or scattered from the surrounding tissue.

19. The solid introducer needle **211** of any of the preceding sentences, wherein the light source **312** is arranged within the electronic module **301**.

20. The solid introducer needle **211** of any of the preceding sentences, wherein the light source **312** is arranged within the adapter **209**.

21. The introducer needle **211** of any of the preceding sentences, wherein the adapter **209** is manufactured from a material, substantially non-transparent for optical radiation.

22. A method for detection of an exact moment of the intravascular penetration and for safeguarding blood vessel from being damaged from inside is provided, said method comprises:

a. obtaining a catheter assembly **201** provided with solid introducer needle **211**, with a cannula and with an electronic module **301**;
b. activating optical radiation source(s), for optical radiation to be observed on the distal end **204** of the introducer needle **211**;
c. puncturing the skin by means of the introducer needle **211**;
d. localizing a blood vessel position intracutaneously by monitoring illumination events at the distal end **204** of the unit **211**;
e. detecting the moment when distal end of the unit **211** penetrates the wall of a blood vessel and enters a lumen thereof by observing at least one of the

following illumination events at the introducer needle distal end **204**: instant disappearance of illumination, rapid illumination fading, rapid change in light color and/or rapid illumination fading along with rapid change in light color, wherein said events are dependent on the optical radiation wavelength utilized;

f. ensuring a correct position of the introducer needle with a light guide unit **211** within a lumen of a blood vessel by monitoring illumination events at the distal end **204** thereof;

g. advancing the cannula inside a lumen of a blood vessel.

23. A method for placing a peripheral intravascular catheter into a blood vessel, said method comprises:

a. visual or by palpation determination of the condition of a blood vessel to be punctured;

b. obtaining a catheter assembly **201** provided with solid introducer needle with a light guide unit **211**, a cannula and an electronic module **301**;

c. activating optical radiation source(s), for optical radiation to be observed on the distal end **204** of the introducer needle with a light guide unit **211**;

d. puncturing the skin with by means of the introducer needle with a light guide unit **211**;

e. localizing a blood vessel position intracutaneously by monitoring illumination events at the distal end **204** of the unit **211**;

f. detecting the moment when distal end of the unit **211** penetrates the wall of a blood vessel and enters a lumen thereof by observing at least one of the following illumination events at the introducer needle distal end **204**: instant disappearance of illumination, rapid illumination fading, rapid change in light color and/or rapid illumination fading along with rapid change in light color, wherein said events are dependent on the optical radiation wavelength utilized;

g. ensuring a correct position of the introducer needle with a light guide unit **211** within a lumen of a blood vessel by monitoring illumination events at the distal end **204** thereof;

h. advancing the cannula inside a lumen of a blood vessel.

i. withdrawing the he introducer needle with a light guide unit **211** from a blood vessel, leaving the cannula inside a blood vessel;

j. securing the cannula over the skin of a patient and connecting an appropriate system thereto.

24. An intravascular catheter needle **211** comprising:

a. a needle member **202** having a proximal end and a distal end,

b. a light guide **210** extending along at least a portion of the needle member **202** and terminating at the distal end of the needle member,

wherein the catheter needle is devoid of a lumen forming a channel that would be suitable for guiding blood from the distal end to the proximal end of the needle member.

25. The catheter needle of sentence 24, wherein the distal end of the needle member is sharpened.

26. The catheter needle of sentences 24 and 25, wherein the needle member is a rigid metallic one-piece structure.

27. The catheter needle of any of the preceding sentences 24-26, wherein the light guide **210** is an optical fiber.

28. The catheter needle of any of the preceding sentences 24-27, wherein the needle member **202** comprises a tubular portion, in which it contacts completely a circumferential surface of the light guide, and a non-tubular portion, in which the needle member contacts only a portion of the circumferential surface of the light guide.

29. The catheter needle of sentence 28, wherein the non-tubular portion has a cross-section that has a semi-lunar shape.

30. The catheter needle of sentence 28, wherein the light guide **210** has the shape of a cylinder, and wherein the non-tubular portion has a cross-section that has the shape of a ring segment, and wherein an inner diameter of the ring is at least substantially equal to an outer diameter of the cylinder.

31. The catheter needle of any of sentences 28 to 30, wherein the tubular portion adjoins the proximal end of the needle member and the non-tubular portions adjoins the distal end of the needle member.

32. The catheter needle of any of sentences 24 to 27, wherein the needle member **202** has along its entire length a tubular shape such that it contacts completely a circumferential surface of the light guide accommodated therein.

33. The catheter needle of any of the sentences 24 to 31, wherein at least a portion of the light guide **210** has a tubular shape such that it contacts completely a circumferential surface of the needle member accommodated therein.

34. An intravascular catheter assembly **201**, comprising an intravascular catheter needle **211** of any of the preceding sentences 24-33 and a cannula tubing **203** that is configured to be slid over a proximal end of the catheter needle **211** so as to surround at least a portion thereof.

35. The catheter assembly of sentence 34, comprising a light source **312**, which is configured to emit light that is coupled into the light guide **210**, and an electronic module **301** that is configured to power the light source.

36. The catheter assembly of sentence 35, wherein at least 40% of light that is emitted by the light source has a wavelength between 500 nm and 580 nm.

37. The catheter assembly of any of the sentences 34 to 36, comprising an adapter **209** to which a proximal end of the light guide **210** is fixed, wherein the adapter is releasably connected to the electronic module **301**.

38. The catheter assembly of any of the sentences 34 to 37, comprising a first light source that is configured to emit light having a first color and a second light source that is configured to emit light having a second color that differs from the first color.

39. The catheter assembly of sentence 38, wherein the light having the first color is more strongly absorbed by blood and walls of the blood vessels than light having the second color.

40. A method for the detection of an exact moment of the intravascular penetration and for safeguarding the blood vessel from being damaged from inside is provided, said method comprises:

a. obtaining the intravascular catheter needle **211**, provided with the electronic module **301**;

b. switching on the optical radiation source(s), said optical radiation source(s) implemented preferably in the form of laser source(s), of the electronic module **301** for optical radiation to be observed on the distal end **204** of the catheter needle **211**;

c. puncturing the skin with the catheter needle **211**;

d. localizing a blood vessel position intracutaneously by monitoring illumination events at the distal end **204** of the catheter needle **211**;

e. detecting the moment when the catheter needle **211** penetrates the wall of a blood vessel and enters the lumen of a blood vessel by observing one of the following illumination events at the catheter needle distal end **204**, said illumination events comprising disappearance of visible light and the instant change in visible light color;

f. ensuring a correct position of the catheter needle **211** inside the lumen of a blood vessel by monitoring illumination events at the catheter needle distal end **204**;

g. extending the cannula tubing **203** inside the lumen of a blood vessel.

41. A method for placing a peripheral intravascular catheter into a blood vessel, said method comprises:

a. visual or by palpation determination of the condition of a blood vessel to be punctured;

b. obtaining the intravascular catheter needle **211**, provided with the electronic module **301**;

c. switching on the optical radiation source(s), said optical radiation source(s) implemented preferably in the form of laser source(s), of the electronic module **301** for optical radiation to be observed on the distal end **204** of the catheter needle **211**;

d. puncturing the skin with the catheter needle **211**;

e. localizing a blood vessel position intracutaneously by monitoring illumination events at the distal end **204** of the catheter needle **211**;

f. detecting the moment when the catheter needle **211** penetrates the wall of a blood vessel and enters the lumen of a blood vessel by observing one of the following illumination events at the catheter needle distal end **204**, said illumination events comprising disappearance of visible light and the instant change in visible light color;

g. ensuring a correct position of the catheter needle **211** inside the lumen of a blood vessel by monitoring illumination events at the catheter needle distal end **204**;

h. extending the cannula tubing **203** inside the lumen of a blood vessel.

i. withdrawing the catheter needle **211** from a blood vessel, leaving the cannula tubing **203** inside a blood vessel;

j. securing the cannula tubing **203** over the skin of a patient and connecting an appropriate system thereto.

The above description of various embodiments of the introducer needle with a light guide unit is given by way of example, and not limitation. Configurations of said unit, in accordance with the embodiments disclosed herein, are illustrative and are intended to provide a representative basis for teaching one skilled in art to employ the present invention in various configurations in regards to its aspects within the scope of the protective claims.

Patent claims

1. An introducer needle (211) comprising:
    a. a needle member (202) having a proximal end and a distal end,

    b. a light guide (210) extending along at least a portion of the needle member (202) and terminating at the distal end of the needle member,

wherein the introducer needle is devoid of a lumen forming a channel that would be suitable for guiding blood from the distal end to the proximal end of the needle member.

2. The introducer needle of claim 1, wherein the distal end of the needle member is sharpened.

3. The introducer needle of claim 1 or 2, wherein the needle member is a rigid one-piece structure.

4. The introducer needle of claim 3, wherein the needle member is manufactured from metal.

5. The introducer needle of any of the preceding claims, wherein the light guide is an optical fiber.

6. The introducer needle of any of the preceding claims, wherein the needle member comprises a tubular portion, which surrounds a circumferential surface of the light guide, and a non-tubular portion, in which the needle member contacts only a portion of the circumferential surface of the light guide.

7. The introducer needle of any of the claims 1 to 5, wherein the needle member comprises only a non-tubular portion, in which the needle member contacts only a portion of the circumferential surface of the light guide.

8. The introducer needle of any of the preceding claims, wherein the non-tubular portion has a cross-section that has a substantially semi-lunar shape.

9. The introducer needle of any of the preceding claims, wherein an empty space created between inner walls of cannula tubing, introducer needle and

the light guide (214) is provided as an additional volume to enable blood flow.

10. The introducer needle of any of the preceding claims, wherein the light guide has the shape of a cylinder, and wherein the non-tubular portion has a cross-section that has the shape of a ring segment, and wherein an inner diameter of the ring is at least substantially equal to an outer diameter of the cylinder.

11. The introducer needle of any of claims 1-6 and 8 to 9, wherein the tubular portion adjoins the proximal end of the needle member and the non-tubular portion adjoins the distal end of the needle member.

12. The introducer needle of any of claims 1 to 5, wherein the needle member has along its entire length a tubular shape that liquid-tightly surrounds a light guide accommodated therein.

13. The introducer needle of any of claims 1 to 5, wherein at least a portion of the light guide has a tubular shape such that it contacts completely a circumferential surface of the needle member accommodated therein.

14. An intravascular catheter assembly (201), comprising an introducer needle (211) of any of the preceding claims and a cannula tubing (203) that is configured to be slid over a proximal end of the introducer needle (211) so as to surround at least a portion thereof.

15. The catheter assembly of claim 14, comprising a light source (312), which is configured to emit light that is coupled into the light guide (210), and an electronic module (301) that is configured to power the light source.

16. The catheter assembly of any of the claims 14 and 15, wherein at least 40% of light that is emitted by the light source has a wavelength between 510 nm and 600 nm.

17. The catheter assembly of any of claims 14 to 16, comprising an adapter (209) to which a proximal end of the light guide (210) is fixed, wherein the adapter is releasably connected to the electronic module (301).

18. The catheter assembly of any of claims 14 to 17, comprising a first light source that is configured to emit light having a first color and a second light source that is configured to emit light having a second color that differs from the first color.

19. The catheter assembly of claim 18, wherein the light having the first color is more strongly absorbed by blood and walls of the blood vessels than light having the second color.

20. A method for the detection of an exact moment of the intravascular penetration and for safeguarding the blood vessel from being damaged from inside is provided, said method comprises:

a. obtaining the catheter assembly of claim 14 provided with the electronic module (301);

b. switching on the optical radiation source(s), said optical radiation source(s) implemented preferably in the form of laser source(s), of the electronic module (301) for optical radiation to be observed on the distal end (204) of the introducer needle (211);

c. puncturing the skin with the introducer needle (211);

d. localizing a blood vessel position intracutaneously by monitoring illumination events at the distal end (204) of the introducer needle (211);

e. detecting the moment when the introducer needle (211) penetrates the wall of a blood vessel and enters the lumen of a blood vessel by observing at least one of the following illumination events at the introducer needle distal end (204), said illumination events comprising disappearance of visible light and/or the instant change in visible light color;

f. ensuring a correct position of the introducer needle (211) inside the lumen of a blood vessel by monitoring illumination events at the introducer needle distal end (204);

g. extending the cannula tubing (203) inside a lumen of a blood vessel.

21. A method for confirming an intravascular penetration of cannula tubing into the blood vessel, said method comprises:

a. obtaining the catheter assembly provided with the introducer needle (211) of claims 6 to 9 and with the electronic module (301)

b. switching on the optical radiation source(s), said optical radiation source(s) implemented preferably in the form of laser source(s), of the electronic

module (301) for optical radiation to be observed on the distal end (204) of the introducer needle (211);

c. puncturing the skin with the introducer needle (211);

d. localizing a blood vessel position intracutaneously by monitoring illumination events at the distal end (204) of the introducer needle (211);

e. detecting the moment when the introducer needle (211) penetrates the wall of a blood vessel and enters the lumen of a blood vessel by observing at least one of the following illumination events at the introducer needle distal end (204), said illumination events comprising disappearance of visible light and/or the instant change in visible light color;

f. ensuring a correct position of the introducer needle (211) inside the lumen of a blood vessel by monitoring illumination events at the introducer needle distal end (204);

g. observing blood flow inside the cannula tubing (203) from the distal end of the catheter assembly towards a proximal end thereof via space (214);

h. extending the cannula tubing (203) inside a lumen of a blood vessel.

22. A method for placing a peripheral intravascular catheter into a blood vessel, said method comprises:

a. visual or by palpation determination of the condition of a blood vessel to be punctured;

b. obtaining the catheter assembly of claim 14, provided with the electronic module (301);

c. switching on the optical radiation source(s), said optical radiation source(s) implemented preferably in the form of laser source(s), of the electronic module (301) for optical radiation to be observed on the distal end (204) of the introducer needle (211);

d. puncturing the skin with the introducer needle (211);

e. localizing a blood vessel position intracutaneously by monitoring illumination events at the distal end (204) of the introducer needle (211);

f. detecting the moment when the introducer needle (211) penetrates the wall of a blood vessel and enters the lumen of a blood vessel by observing at least

one of the following illumination events at the introducer needle distal end (204), said illumination events comprising disappearance of visible light and/or the instant change in visible light color;

g. ensuring a correct position of the introducer needle (211) inside the lumen of a blood vessel by monitoring illumination events at the introducer needle distal end (204);

h. extending the cannula tubing (203) inside the lumen of a blood vessel.

i. withdrawing the introducer needle (211) from a blood vessel, leaving the cannula tubing (203) inside a blood vessel;

j. securing the cannula tubing (203) over the skin of a patient and connecting an appropriate system thereto.

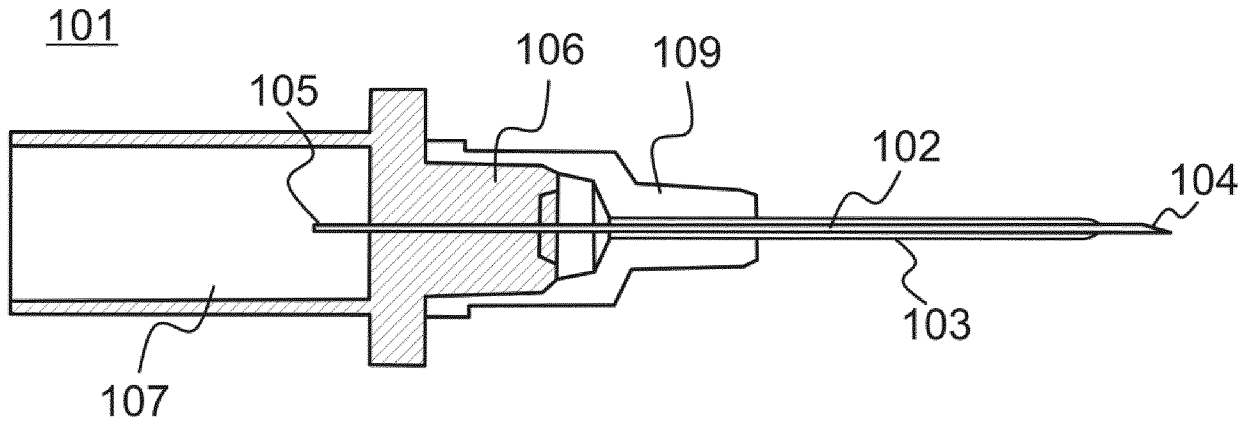


Figure 1A
Prior Art

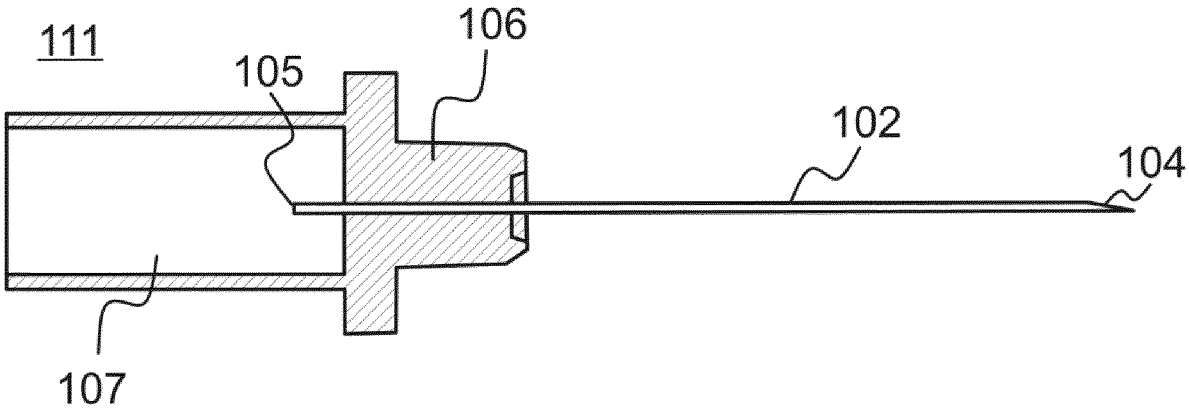


Figure 1B
Prior Art

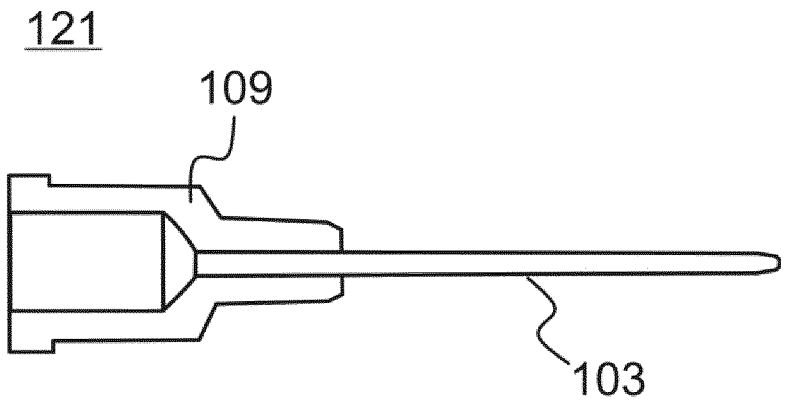


Figure 1C
Prior Art

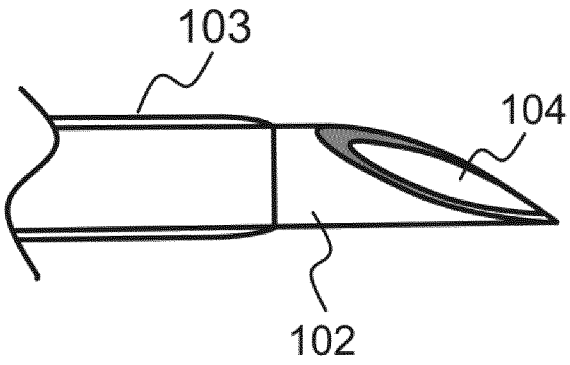


Figure 1D
Prior Art

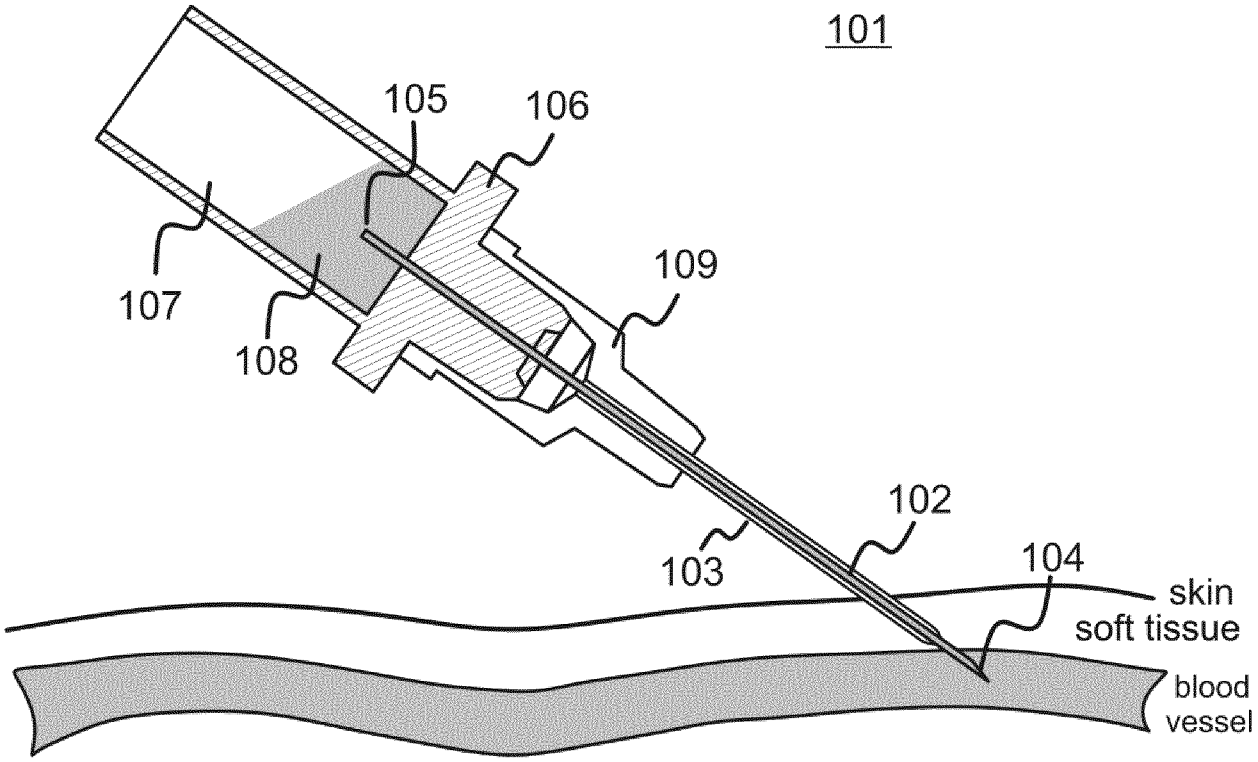


Figure 1E
Prior Art

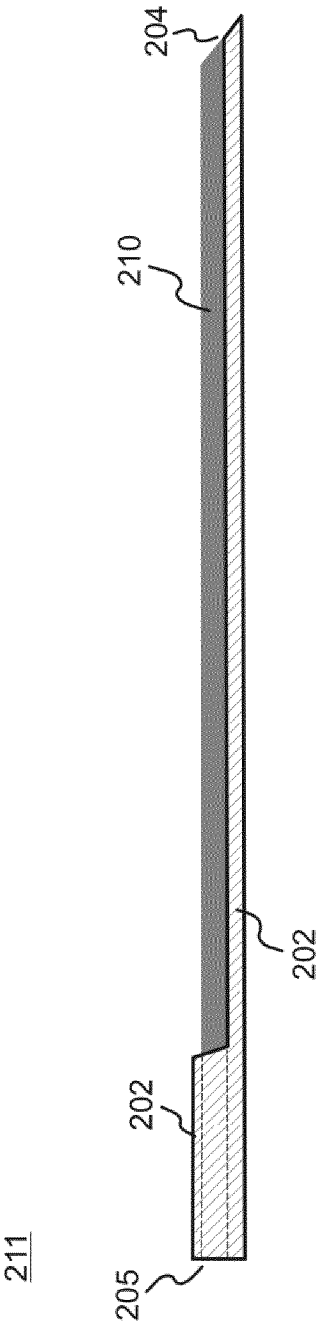


Figure 2A

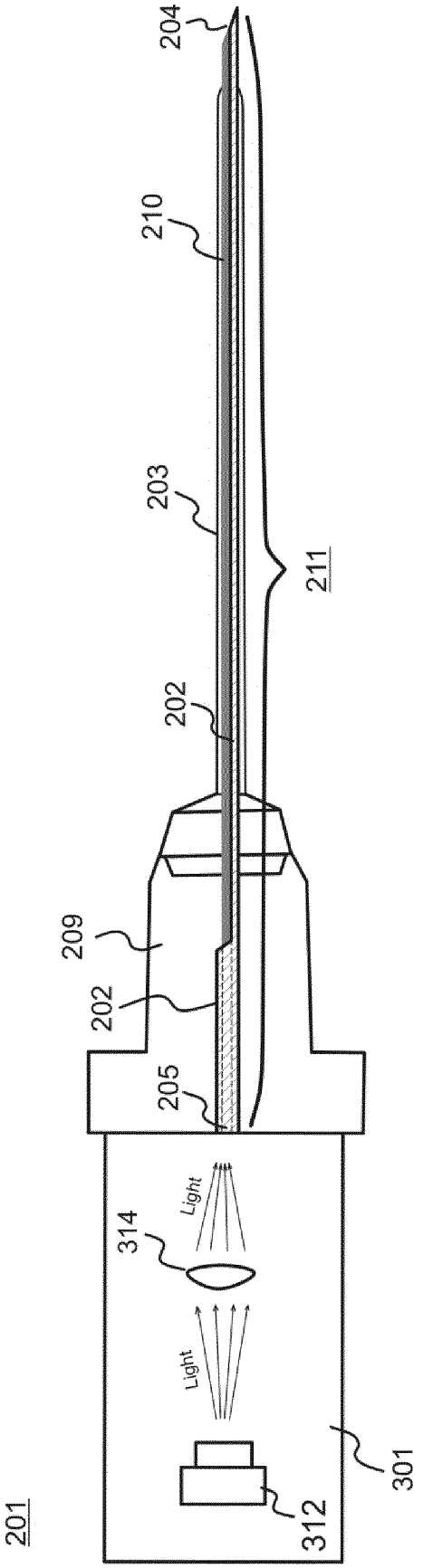


Figure 2B

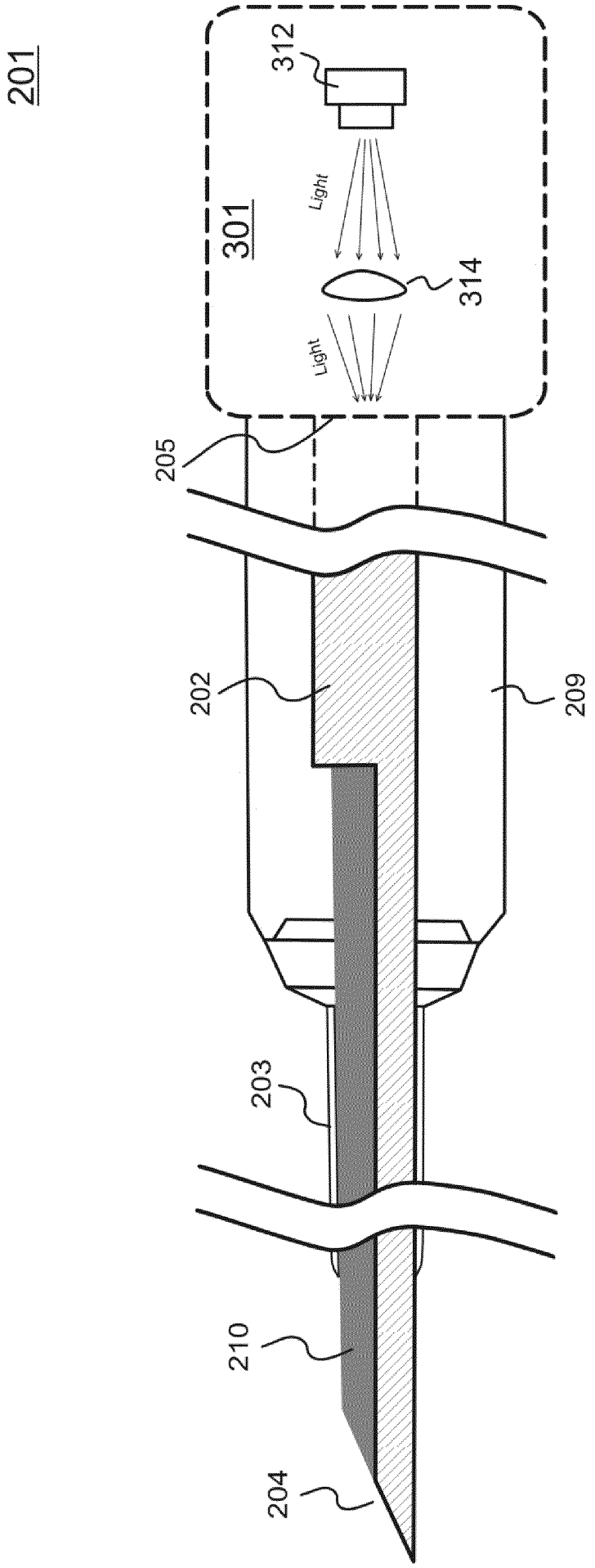


Figure 3

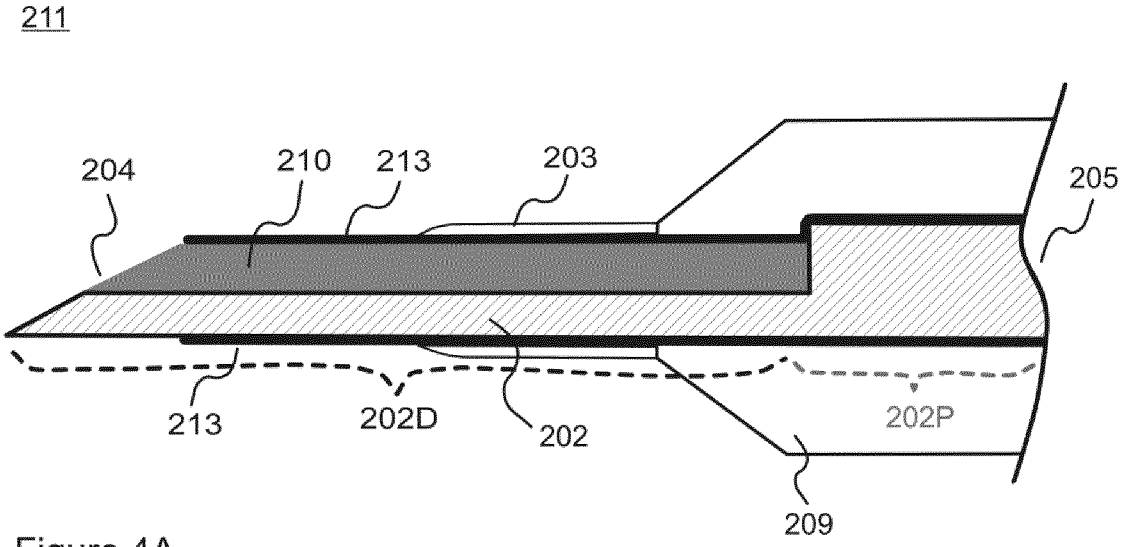


Figure 4A

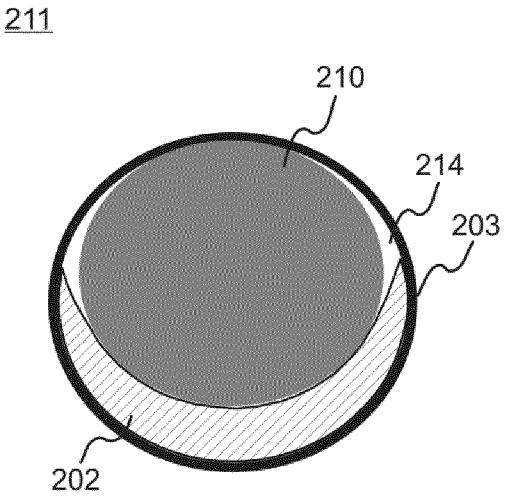


Figure 4B

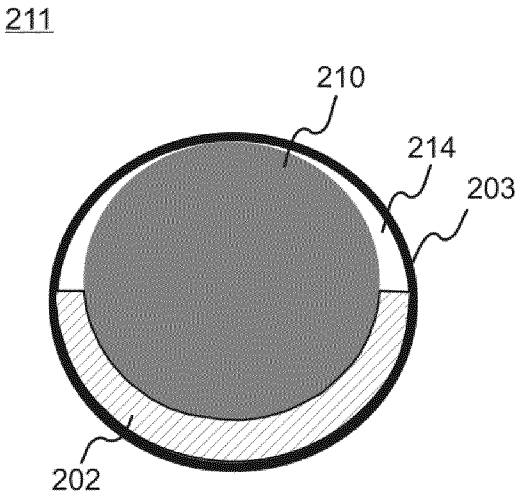


Figure 4C

Prior art

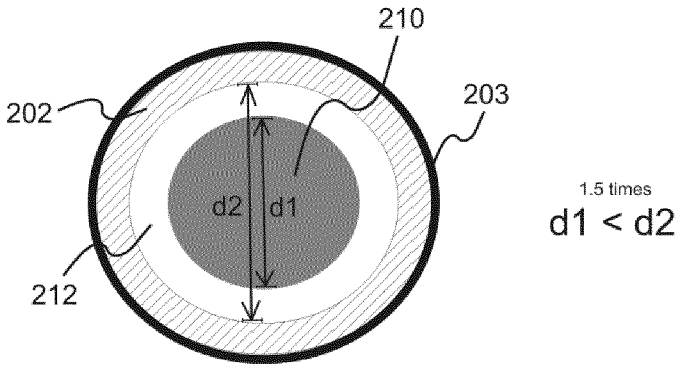


Figure 5A

211

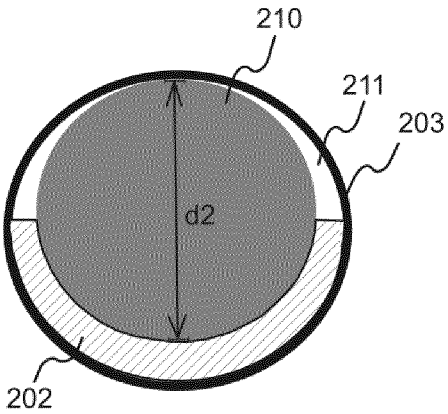


Figure 5B

211

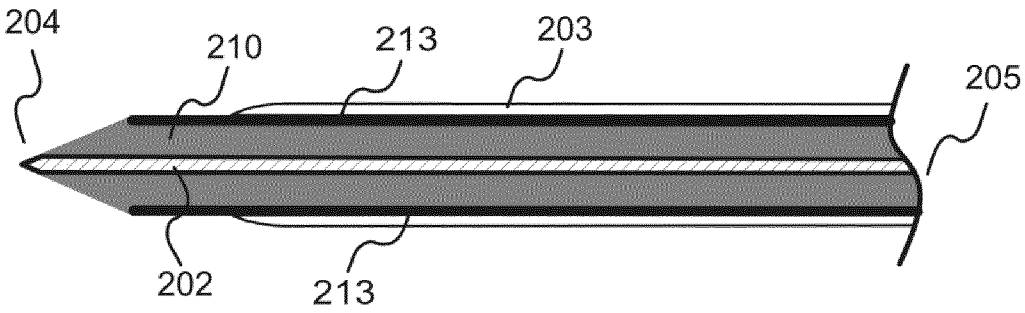


Figure 6A

211

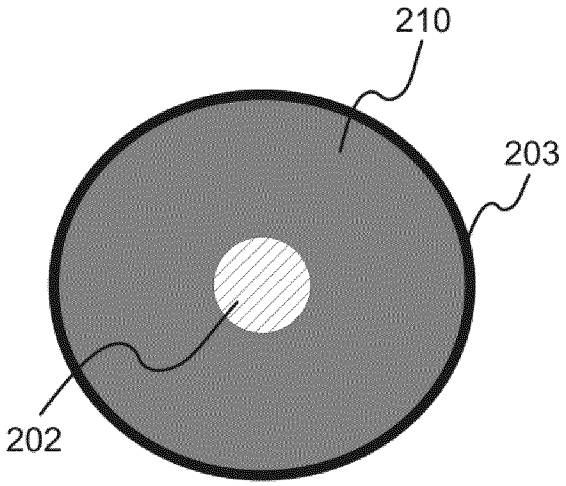


Figure 6B

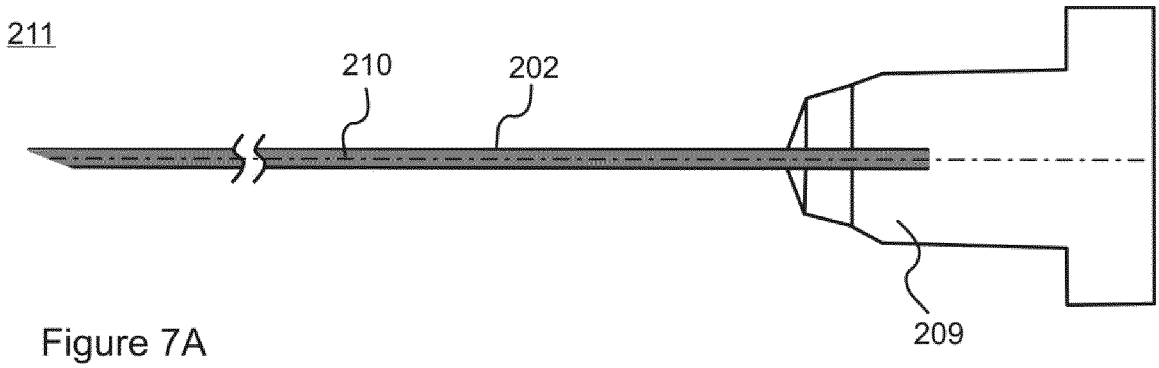


Figure 7A

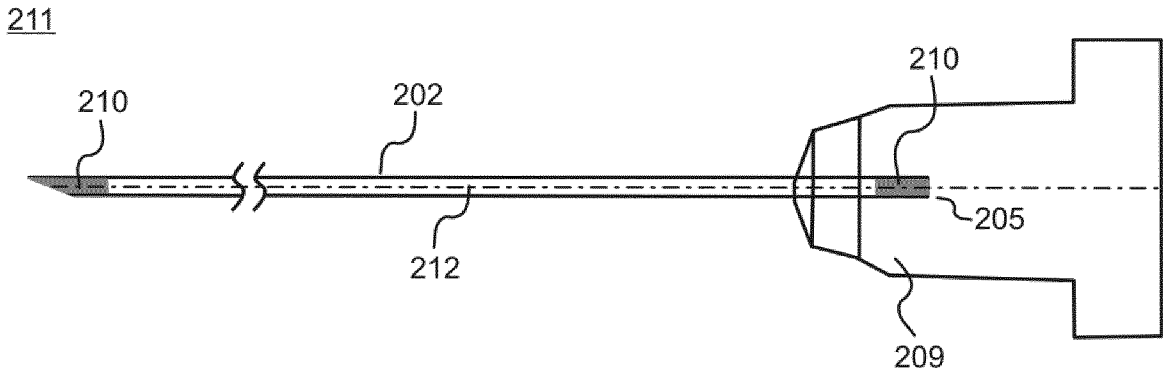


Figure 7B

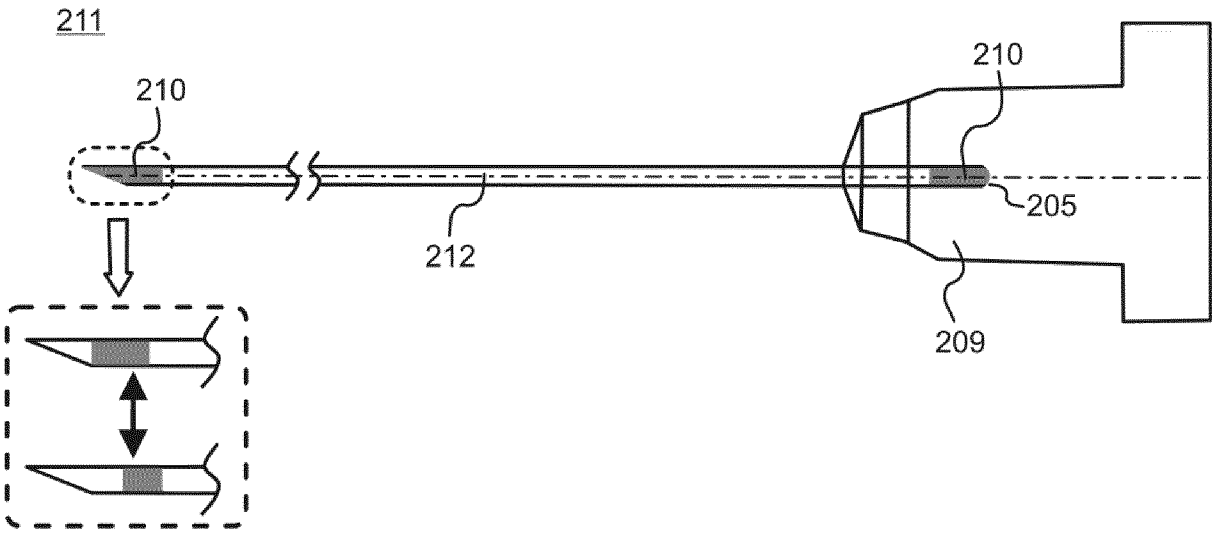


Figure 7C

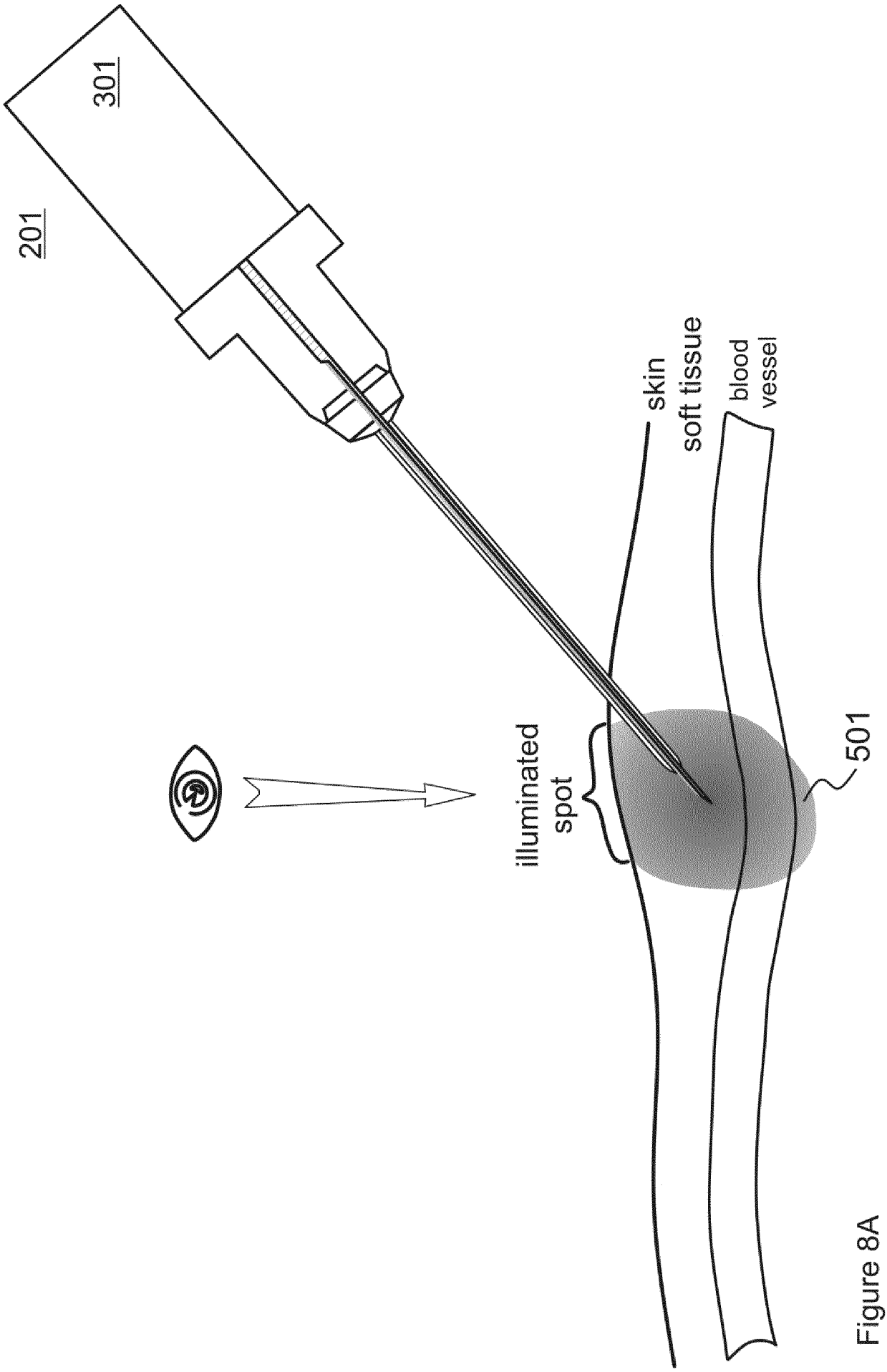


Figure 8A

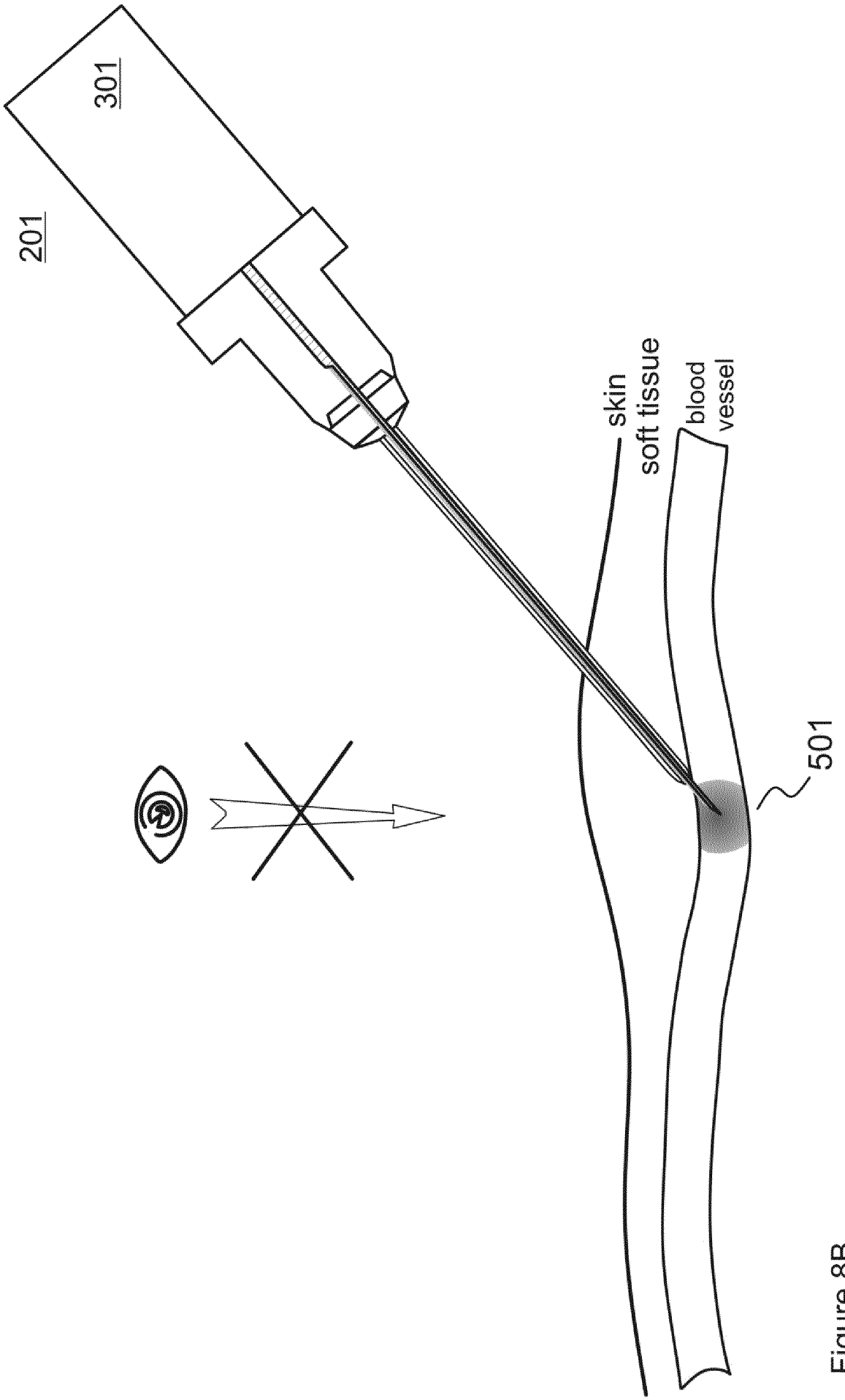


Figure 8B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2012/066251

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. [X] Claims Nos.: 20-22
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 20-22 relate to subject-matter concerning methods for treatment of the human by surgery, Rule 67.1(iv) PCT. The step of puncturing the skin is considered to be surgery.

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.:
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 an 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.

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2012/066251

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/34 A61M25/06
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 884 211 A2 (ZUCKERMAN STEPHEN D) 6 February 2008 (2008-02-06)	1-3
Y	paragraphs [0028] - [0031]; figure 2	4-19
Y	US 5 460 182 A (SEXTANT MEDICAL CORP) 24 October 1995 (1995-10-24) column 10, lines 55-64; figure 3I	4
Y	US 2011/288405 A1 (RAZAVI MEHDI ET AL) 24 November 2011 (2011-11-24) paragraph [0016]; figure 2	5-19

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

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"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
22 March 2013	03/04/2013

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Segerberg, Tomas

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2012/066251

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 1884211 A2	06-02-2008	EP 1884211 A2	06-02-2008
		US 2008097378 A1	24-04-2008
		WO 2008016959 A2	07-02-2008
US 5460182 A	24-10-1995	NONE	
US 2011288405 A1	24-11-2011	NONE	