

(12) STANDARD PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. **AU 2006244673 B2**

(54) Title
Light coupling adapter device for photodynamic or photothermal therapy or photodynamic diagnosis, corresponding system and method

(51) International Patent Classification(s)
A61B 18/24 (2006.01) **A61M 25/18** (2006.01)
A61M 25/01 (2006.01) **A61N 5/06** (2006.01)
A61M 25/06 (2006.01) **A61N 1/30** (2006.01)

(21) Application No: **2006244673** (22) Date of Filing: **2006.05.12**

(87) WIPO No: **WO06/121407**

(30) Priority Data

(31) Number	(32) Date	(33) Country
60/680,779	2005.05.13	US
0501077-2	2005.05.12	SE

(43) Publication Date: **2006.11.16**

(44) Accepted Journal Date: **2011.07.28**

(71) Applicant(s)
SpectraCure AB

(72) Inventor(s)
Svanberg, Sune

(74) Agent / Attorney
Freehills Patent & Trade Mark Attorneys, Level 38 MLC Centre Martin Place, Sydney, NSW, 2000

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
16 November 2006 (16.11.2006)

PCT

(10) International Publication Number
WO 2006/121407 A1

(51) International Patent Classification:

A61B 18/24 (2006.01) A61M 25/18 (2006.01)
A61M 25/01 (2006.01) A61N 5/06 (2006.01)
A61M 25/06 (2006.01) A61N 1/30 (2006.01)

(21) International Application Number:

PCT/SE2006/050120

(22) International Filing Date: 12 May 2006 (12.05.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

0501077-2 12 May 2005 (12.05.2005) SE
60/680,779 13 May 2005 (13.05.2005) US

(71) Applicant (for all designated States except US): SPEC-TRACURE AB [SE/SE]; Ole Römers Väg 16, S-223 70 Lund (SE).

(72) Inventor; and

(75) Inventor/Applicant (for US only): SVANBERG, Sune [SE/SE]; Nicolovius Väg 2, S-224 65 Lund (SE).

(74) Agent: KRAHBICHLER, Erik; Ström & Gulliksson AB, Järnvägsgatan 3, S-252 24 Helsingborg (SE).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

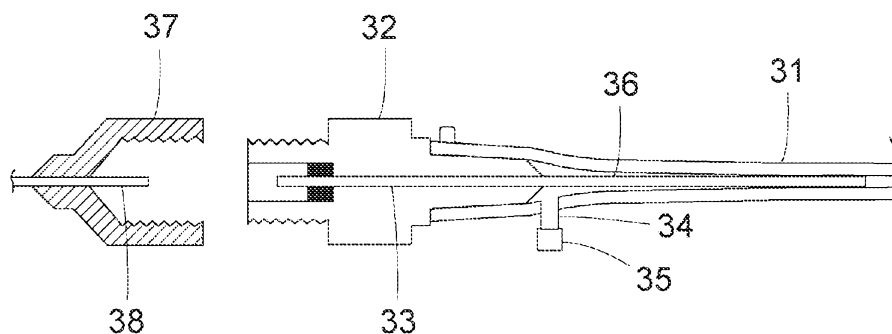
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: LIGHT COUPLING ADAPTER DEVICE FOR PHOTODYNAMIC OR PHOTOTHERMAL THERAPY OR PHOTODYNAMIC DIAGNOSIS, CORRESPONDING SYSTEM AND METHOD



(57) Abstract: A system configured for photodynamic or photothermal therapy and photodynamic diagnosis of a tissue is disclosed. The system comprises in combination an assembly of: a proximal end adapter for a catheter comprising an adapter body (32), having proximal and distal ends, defining an axial lumen extending between the proximal and distal ends, a catheter mounting element at the distal end of the adapter body (32) for sealingly mounting a catheter to the adapter body, and a hollow catheter (31), wherein the catheter mounting element connects a catheter body to the hollow catheter so that the hollow catheter extends from the distal end of the catheter body; a first light guide (36) having proximal and distal ends, wherein said first light guide is sealingly contained in said axial lumen defining an axial optical path extending between the proximal and distal ends of the adapter body (32) towards said tissue (8) and into close proximity thereof or 20 interstitially into said tissue; an optical connector mounting element at the proximal end having mounted an optical connector (37) to the adapter body, and wherein said optical connector (37) is coupled to a light source via a second light guide (38), such that light from said light source is transmittable from said light source via said second light guide (38) and further via said optical connector (37) to said first light guide (36) via said proximal end adapter towards said tissue (8) through said catheter (31).



WO 2006/121407 A1

**LIGHT COUPLING ADAPTER DEVICE FOR PHOTODYNAMIC OR
PHOTOTHERMAL THERAPY OR PHOTODYNAMIC DIAGNOSIS,
CORRESPONDING SYSTEM AND METHOD**

5 **FIELD OF THE INVENTION**

The present invention relates to a system for interactive interstitial photodynamic or photothermal therapy and/or diagnosis of a tissue by an apparatus having at least one source of therapeutic or diagnostic light, such as a source of laser radiation, and at least one radiation conductor, such as a light guide in the form of an optical fibre, for transmitting light between said tissue and said apparatus, for instance the laser radiation to said tissue, and a light coupling adapter mechanism for conveniently connecting an optical path, including said optical fibre, between the tissue and the apparatus, for instance to said laser source.

BACKGROUND OF THE INVENTION

20 A system and method for therapy and diagnosis using interactive interstitial photodynamic tumour therapy (PDT) and/or photothermal tumour therapy (PTT) and photodynamic diagnosis (PDD) is disclosed in WO 03/041575. The system comprises a plurality of optical fibres directly inserted at selected interstitial positions in tissue to be treated and/or diagnosed, such as cancer tissue.

In WO 03/041575 it is disclosed that for diagnosis, a source of diagnostic laser light is connected to one of the fibres, operating as a diagnostic transmission fibre for transmitting the diagnostic laser light towards the tissue. The remaining fibres are operating as receivers for light passing from the distal end of the diagnostic transmission fibre through the tissue to the distal ends of the remaining fibres and further on to detectors. Each fibre is used in sequence for being a transmitter and the other fibres being receivers. By calculations, a tomographic image of certain properties of the tissue may be obtained,

such as fluorescence properties arising from certain sensitizers.

Further, WO 03/041575 discloses that, for therapy, the same system is used, whereby light is transmitted
5 through the all fibres simultaneously to the tissue for activation of agents, such as sensitizers, which are localized to the tumour cells. Through the therapy, the cells are eradicated and the tissue goes into necrosis. Moreover, it is disclosed that the system may be used for
10 photo-thermal therapy comprising transmitting radiation through the fibres, which heats the tissue sufficiently for killing the tumour cells. It may be noted that tumour cells may be more sensitive to heat than other cells.

In the diagnosis and therapeutic system of WO
15 03/041575, optical fibres are used, which are directly interstitially inserted into the tissue at places to be treated. The agent to be activated or sensitized may be brought to the tissue by systemic administration, intravenously or orally and accumulated in the relevant
20 tissue by any mechanism. The surplus agent is normally removed by the body action, such as the liver or kidney, which may place a considerable burden on these organs or systems.

A further method of supplying the agent to a tissue
25 would be the direct injection of the substance with a needle and syringe if the position of the tissue to be treated is well defined and known.

The agent may also be applied topically on the skin whereupon an iontophoretic technique could be used for
30 improved transportation into the relevant tissue. Here, an electric current is generated by means of electrodes arranged in a suitable arrangement and the agent is transported with the current in dependence of the ionic properties of the agent.

35 In PDT/PTT and PDD, as mentioned above, light fibres are directly interstitially inserted in the tissue to be

diagnosed/treated, i.e. the distal ends of the fibres, which proximally are connected to a distributor for radiation, are stuck into the tissue for interstitial arrangement therein. However, this has a number of
5 drawbacks. For instance the fibres, or at least the distal ends thereof, have to be sterilized between subsequent treatments or patients. However, sterilization methods often deteriorate the optical qualities of the fibres, e.g. aggressive solvents when using plastic fibres or residues
10 may be left on the surface of the fibres after sterilization or disinfection. Alternatively, the patient contaminated fibres have to be discarded, which is costly. When the distal fibre ends are inserted through the lumen of a cannula, which is stuck into the tissue to be
15 treated/diagnosed, leaking is a concern that has to be dealt with. Furthermore, in case a drug has to be delivered to the tissue during treatment, e.g. in order to increase the amount of sensitizer in the tissue, it would be convenient, if the same access to the tissue, as used for
20 the fibre, could be used. Today, the tissue is punctured with additional syringes, which may cause inconvenience or harm to the patient, e.g. due to an increased risk of infection and bleeding. Therefore, there is a need to provide a convenient way of interstitially accessing a
25 tissue in a body for PDT/PTT and PDD, having a minimal number of access points by providing easy external access to the tissue when performing the treatment/diagnosis or between occasions of the same treatment/diagnosis. Moreover, a more cost-effective way of providing sterility
30 between treatments or patients is desired.

Some attempts have been made to deal with these issues, which will be described below. However, hitherto none of these attempts has been successful.

EP 523417 discloses a system in which sleeves are
35 arranged so that a radiating body may be inserted so that

adjacent tissue is radiated and a sensor can be introduced in another sleeve to determine the effect of the radiation.

US 5,454,794 discloses a steerable light diffusion catheter. More specifically, a steerable catheter is disclosed which can treat luminal surfaces such as those occurring in the vascular tree, pulmonary tree, gastrointestinal tract, urological organs, etc. with Photodynamic Therapy (PDT) or other optical diffusing treatments. The catheter has a light-diffusing tip, which can be deflected allowing the catheter to be steered precisely. The light-diffusing tip on the steerable catheter is able to gain access to and enter the luminal system being treated. The catheter does not require a guidewire lumen for insertion, and thus the profile is reduced. A low profile device allows treatment light to be delivered to the walls of the most distal, small diameter lumen. However, US 5,454,794 is not suited for photodynamic diagnosis. Furthermore, the catheter of US 5,454,794 does not allow interstitial insertion thereof, only transluminal delivery. Transdermal insertion directly into a tumour, e.g. close to the skin, is not possible with this catheter. It is not suited for this purpose, partly due to its flexible design.

US 5,304,171 also discloses catheter devices and methods for delivering laser energy to a body. An apparatus for delivering laser energy to a site is disclosed that includes a flexible tube, a liquid, the tube having an opening in a first end through which the liquid can pass, means for providing a flow of the liquid into the tube, and a source of laser energy operationally associated with a second end of the tube, wherein the tube and the liquid are adapted to cooperate, when the tube contains the liquid, to conduct laser energy from the source and to emit a portion of the laser energy from the first end of the liquid-containing tube. According to a disclosed method, laser energy is conducted to the site by bringing the proximal

end of the flexible tube near the site, filling at least a proximal portion of the tube with a liquid by introducing the liquid into the tube, allowing a portion of the liquid to flow out from the proximal end of the tube toward the site, and directing laser energy from a laser energy source into the distal end of the tube, whereby a portion of the laser energy emerges from the proximal end of the tube at the site. The liquid is for instance a radiographic contrast medium. The method is for instance used for removing an obstruction from a blood vessel in an animal.

The device of US 5,304,171 is neither suited for photodynamic diagnosis nor for photodynamic therapy. Furthermore, the catheter of US 5,304,171 does also not allow interstitial insertion thereof. Moreover, transdermal insertion directly into a tumour, e.g. close to the skin, is not possible with this catheter.

EP 1334748 discloses an apparatus for photodynamic therapy. Light generated by an implantable probe is used to illuminate a treatment site that has been perfused with a photoreactive agent. A number of different embodiments of implantable probes are disclosed. Preferably, an array of light emitting diodes (LEDs) or solid-state laser diodes (LDs) are mounted on a light bar inside the implantable probe and are energized either using a storage battery power source, an inductively coupled external transformer, or with current provided in leads running through a flexible catheter that extends outside the patient's body to an external source. The implantable probe is normally intended to be disposed inside a patient's body during a surgical procedure, at a treatment site, and left in place for several days (or longer) after an incision is closed, while light produced by the array of LEDs or solid-state LDs irradiates the treatment site. The apparatus of EP 1334748 is not configured for photodynamic diagnosis. Furthermore, interstitial insertion as well as removal of a probe has to be performed by a surgical procedure. Easy

delivery of light to a tumour during short-term diagnosis and treatment is not provided.

WO2004/012589 discloses a catheter and method for diagnosis and treatment of diseased vessels. A catheter for
5 detecting and treating diseased tissue in a blood vessel or other hollow body organ is provided. The catheter comprises an elongated tubular catheter shaft having a distal end comprising a light transmission zone. A first fiber lumen in the catheter shaft contains a diagnostic optical fiber
10 having a distal end terminating within the light transmission zone for emitting and receiving light through the light transmission zone. A diagnostic subassembly at the proximal end and in communication with the diagnostic optical fiber processes diagnostic light for use in
15 connection with a diagnostic method for detecting diseased tissue. A second fiber lumen can be provided in the catheter shaft for containing a treatment optical fiber for delivering treatment light from a light source at the proximal end of the catheter shaft to the light
20 transmission zone. The treatment optical fiber has a distal end terminating within the light transmission zone for emitting light for treatment of the diseased tissue. An occlusion balloon is positioned on the distal end of the catheter shaft adjacent to the light transmission zone and
25 in fluid communication with an inflation lumen. One or more infusion ports formed on or near the light transmission zone and in fluid communication with an infusion lumen deliver infusion fluid to the hollow body organ.

The catheter of WO2004/012589 does not allow
30 interstitial insertion thereof. Moreover, transdermal insertion directly into a tumour, e.g. close to the skin, is not possible with this catheter.

The above described catheter devices are definitively not suited for a system involving a plurality of light
35 guides inserted into a tissue, such as the system disclosed in WO03/041575 of same applicant, already mentioned above.

2006244673 01 Jul 2011

WO03/041575 discloses a system and method for interactive, interstitial photodynamic and/or photothermal tumour therapy. The system comprises a distributor for distribution of radiation from at least one radiation source to a reaction site, or from the reaction site to at least one radiation sensor. A plurality of first radiation conductors are arranged for conduction of radiation to and from the reaction site and a plurality of second radiation conductors are arranged for emitting radiation from the radiation source and/or conduction of radiation to the radiation sensor. The distributor comprises two plane discs mounted abutting each other, one being fixed and the other turnable relative the first, each disc having holes arranged equally separated on a circle line the number of holes in the turnable disc being a multiple of the number of holes in the fixed disc. One end of the first radiation conductors are fixed in the holes of the fixed disc and one end of the second radiation conductors are fixed in the holes of the turnable disc. Hence, there is a need for an improved device and method that provides a more advantageous way of accessing a tissue for interactive interstitial photodynamic or photothermal therapy and/or diagnosis of the tissue, and in particular allowing for increased flexibility, cost-effectiveness, or user friendliness.

It will be understood that any reference herein to prior art is not to be taken as an admission as to the common general knowledge of a person skilled in the art.

SUMMARY OF THE INVENTION

As used herein, except where the context requires otherwise, the term "comprise" and variations of the term, such as "comprising", "comprises" and "comprised", are not intended to exclude further additives, components, integers or steps.

The present invention seeks to mitigate, alleviate or eliminate one or more of the above-identified deficiencies in the

2006244673 01 Jul 2011

art and disadvantages singly or in any combination and solves, among others, at least partly the above-mentioned issues by providing a device, system, method and use, according to the appended patent claims . Described herein is a system for
5 conveniently arranging at least one radiation conductor for photodynamic or photothermal therapy and/or diagnosis.

An exemplary system for photodynamic or photothermal therapy and/or diagnosis of a tissue by an apparatus comprises at least one source of laser radiation, at least one radiation conductor
10 for transmitting the laser radiation to said tissue, and a mechanism for connecting said radiation conductor to said laser source. The system comprises: an arranging device for arranging said radiation conductor from said tissue to said mechanism, said
15 arranging device enclosing at least a portion of said radiation conductor. The arranging device may comprise a sleeve arranged from the tissue to said mechanism whereby said radiation conductor is insertable in said sleeve after arranging said sleeve in said
20 tissue. The system may further comprise a supply device for supplying an agent via said arranging device to said tissue. The sleeve may be provided with a port for supply of said agent. The supply device may be a syringe. A first sleeve may be arranged from the tissue to a distribution disk of said mechanism, and a
25 second sleeve may be arranged from said distribution disk to said laser source, said second sleeve being provided with a port for the supply of said agent. The system may further comprise a pad including said agent and arranged at the skin adjacent said tissue and forming a first electrode connected to a first electric
30 potential, whereby a second electric potential is connected to an electrically conductive lining arranged on at least one radiation conductor, to form a current for introduction of said agent into said tissue by iontophoresis. The conductive lining may be of a metal, such as silver.

8A

An exemplary method in photodynamic or photothermal therapy and/or photodynamic diagnosis of a tissue by an apparatus having: at least one source of laser radiation, at least one radiation conductor for transmitting the laser

5

2006244673 01 Jul 2011

radiation to said tissue, and a mechanism for connecting said radiation conductor to said laser source. The method may comprise: placing an arranging device in the tissue with a distal end in or close to a tissue to be treated; inserting a radiation conductor in the arranging device; and connecting the radiation conductor with said apparatus. The method may further comprise supplying an agent to said tissue to be treated via said arranging device.

According to a first aspect of the invention, a proximal end adapter for a catheter is provided. The adapter comprises: an adapter body, having proximal and distal ends, defining an axial lumen extending between the proximal and distal ends, a catheter mounting element at the distal end of the adapter body for sealingly mounting a catheter to the body; an optical connector mounting element at the proximal end for mounting an optical connector to the adapter body; and a light guide having proximal and distal ends, wherein said light guide is sealingly contained in said axial lumen defining an axial optical path extending between the proximal and distal ends of the adapter body. The proximal end adapter is configured for use in a system for interactive interstitial photodynamic or photothermal therapy and/or diagnosis of a tissue.

The optical connector mounting element at the proximal end for mounting an optical connector to the adapter body may be configured to directly mount to said adapter body.

The catheter mounting element at the distal end of the adapter body may comprise a mounting surface to sealingly engage said optical connector. The mounting surface may be an internal tapered surface sized to matingly and sealingly engage an external tapered surface of a Luer lock connector comprised in said optical connector. The mounting surface may be threaded for matingly and sealingly engage a threaded surface comprised in said optical connector.

The proximal end adapter according may comprise a radially compressible seal having a central bore receiving the light guide therein, positioned within the adapter body along the axial lumen at a distance from the proximal end, 5 wherein the seal is radially outward compressed by said light guide to provide said sealing.

The light guide may be sealingly attached in said axial lumen by a fastening means, such as glue.

According to an embodiment, the catheter is a 10 transcutaneous intravenous catheter device. The catheter may have a relatively short length of approximately less than 10 cm.

The adapter, when mounted to said catheter, seals said lumen against fluid connection from said proximal side 15 of said adapter and provides light connection from said proximal side of said adapter to said lumen via said light guide.

According to a further aspect of the invention, a combination of the above-mentioned adapter and a hollow 20 catheter is provided. The catheter mounting element is adapted to connect the adapter body to the hollow catheter so that the hollow catheter extends from the distal end of the adapter body.

The proximal end of the light guide may be positioned 25 within the adapter body at a distance from the proximal end of the adapter body, and wherein the distal end of the light guide extends from the distal end of said adapter body into the hollow catheter.

The hollow catheter may define an axially extending 30 catheter lumen, wherein the light guide is radially in contact with the interior wall of the axially extending catheter lumen.

The hollow catheter may define an axially extending catheter lumen, wherein the light guide has a diameter less 35 than the interior diameter of the catheter lumen, so that a

coaxial, radially offset, channel is formed in the catheter lumen.

The secondary lumen may include an entrance port opening into a portion of the axial lumen of the catheter body.

The combination may further comprise a needle that is insertable and retractable in the hollow catheter for arranging said catheter to said tissue when said adapter is disconnected from said catheter, such that said radiation fibre is insertable through the catheter or the needle towards said tissue.

According to yet a further aspect of the invention, a system configured for photodynamic or photothermal therapy and/or photodynamic diagnosis of a tissue is provided. The system comprises in combination an assembly of: a proximal end adapter for a catheter comprising an adapter body, having proximal and distal ends, defining an axial lumen extending between the proximal and distal ends, a catheter mounting element at the distal end of the adapter body for sealingly mounting a catheter to the adapter body, and a hollow catheter, wherein the catheter mounting element connects a catheter body to the hollow catheter so that the hollow catheter extends from the distal end of the catheter body; a first light guide having proximal and distal ends, wherein said first light guide is sealingly contained in said axial lumen defining an axial optical path extending between the proximal and distal ends of the adapter body towards said tissue and into close proximity thereof or interstitially into said tissue; an optical connector mounting element at the proximal end having mounted an optical connector to the adapter body, and wherein said optical connector is coupled to a light source via a second light guide, such that light from said light source is transmittable from said light source via said second light guide and further via said optical connector to said first

light guide via said proximal end adapter towards said tissue through said catheter.

The first light guide may be insertable into said catheter after arranging said sleeve in said tissue.

5 The system may further comprise a supply device for supplying an agent via said catheter to said tissue.

The catheter may be provided with a port for supply of said agent.

10 The system may further comprise a pad including said agent and arranged at the skin adjacent said tissue and forming a first electrode connected to a first electric potential, whereby a second electric potential is connected to an electrically conductive lining arranged on at least one of said radiation fibres, to form a current for
15 introduction of said agent into said tissue by iontophoresis. The conductive lining may be of a metal, such as silver.

The system may further comprise a second adapter for releasably connecting the proximal end of said adapter body
20 to a further optical connector proximally arranged at said optical connector, in order to ensure patient safety and to avoid contamination of re-usable articles of said system.

According to another aspect of the invention, a method for use of a proximal end adapter of a catheter is
25 provided. The adapter has an adapter body, having proximal and distal ends, defining an axial lumen extending between the proximal and distal ends, and a catheter mounting element at the distal end of the adapter body for sealingly mounting a catheter to the body; an optical connector
30 mounting element at the proximal end for mounting an optical connector to the adapter body; and a light guide having proximal and distal ends, wherein said light guide is sealingly contained in said axial lumen defining an axial optical path extending between the proximal and
35 distal ends of the adapter body. The method comprises: mounting the adapter to a catheter housing by said catheter

mounting element, to provide the light guide in a lumen of the catheter; mounting an optical connector to said optical connector mounting element of said adapter, thus providing an optical path via said adapter.

5 The mounting of the adapter and the mounting of the optical connector may comprise threadably mounting thereof.

 According to a further aspect of the invention, a method for photodynamic or photothermal therapy and/or diagnosis of a tissue is provided. The method comprises
10 providing at least one source of laser radiation, and providing at least one radiation fibre for transmitting the laser radiation to said tissue, arranging a catheter interstitially in said tissue; mounting a proximal end adapter to the proximal end of the catheter, said adapter
15 having a radiation fibre thus mounted in a lumen of the catheter to said tissue, connecting said adapter to a distal radiation fibre via an optical connector coupled to said at least one source of laser radiation, such that when said adapter is connected to said connector laser radiation
20 from said at least one source of laser radiation is transmitted via said distal optical fibre to said at least one radiation fibre and said tissue.

 The method may, prior to mounting the adapter to the catheter, comprise inserting a needle into the tissue, said
25 needle having a catheter sleeve arranged over said needle, removing said needle, and inserting at least one radiation fibre in said sleeve.

 The method may comprise retracting of said a proximal end adapter from said lumen, draining said tissue from
30 liquid through said lumen, and re-mounting the proximal end adapter to the proximal end of the catheter.

 According to a further aspect of the invention, a use of an intravenous access device for interstitially coupling light to a tissue is provided.

35 The present invention thus provides an advantageous device, system, use and method.

BRIEF DESCRIPTION OF DRAWINGS

Further objects, features and advantages of the invention will appear from the following detailed description of several embodiments of the invention with
5 reference to the drawings, in which:

Fig. 1 is a schematic view of a previously known system in which the invention may be used;

Fig. 2 is a schematic view of the system of Fig. 1 adapted for diagnosis;

10 Fig. 3 is a cross-sectional view of a sleeve for an optical fibre;

Fig. 4 is a schematic view of an embodiment of the invention;

15 Fig. 5 is a schematic view of another embodiment of the invention;

Fig. 6 is an enlarged view of a portion of Fig. 5;

Fig. 7 is a schematic plane view of a conventional transcutaneous intravenous catheter device,

20 Fig. 8a is a cross sectional view of a proximal end adapter for a catheter;

Fig. 8b is a cross sectional view of another proximal end adapter; and

25 Figs. 9a, 9b, 10a, 10b and 11-16 are cross-sectional views of various proximal end adapter and catheter assemblies.

DETAILED DESCRIPTION OF EMBODIMENTS

Fig 1 is a schematic view of a device for interactive interstitial photodynamic light therapy (PDT) or photo-
30 thermal therapy (PTT) and photodynamic diagnosis (PDD) of a site on and/or in a human being or an animal. A plurality of, or at least two, radiation conductors, such as light guides or optical fibres 6 are directly inserted in a
tissue 8, which may be an organ, a tumour or any other
35 tissue. The fibres 6 may be inserted with their distal ends, respectively, in the tissue 8 in a geometric pattern

and interstitially. Thus fibres 6 are patient fibres. As shown in Fig. 1, the distal ends of the patient fibres 6 are arranged in a geometric pattern covering a certain area to be investigated and/or treated. The proximal ends of the patient fibres 6 arranged at a distance from the tissue are inserted and attached to a flat disc 3 of a switching means 1, as shown in Fig 1. The flat disc 3 is arranged adjacent a second flat disc 4 and the flat discs are rotatable in relation to each other around a shaft 2.

10 A plurality of, or at least two, optical fibres 7 are connected to the second flat disc 4 in openings 5 as shown in Fig 1. A first diagnostic fibre 7a, see Fig. 2, is connected to a source of diagnostic light 9a at its proximal end arranged at a distance from plate 4. The diagnostic source may be a laser emitting light at a specific wavelength. Diagnostic light is passed from diagnostic light source 9a via diagnostic fibre 7a to patient fibre 6a via the two flat discs, suitably adjusted in relation to each other for good light transmission, and further to the tissue 8 via patient fibre 6a.

15 The diagnostic light is emitted through the distal end of patient fibre 6a into the tissue 8 and is scattered inside the tissue. The scattered diagnostic light is picked up by the distal ends of the remaining patient fibres 6b and passed therefrom to diagnostic sensors arranged in a diagnostic sensor unit 12. As is illustrated in Fig. 2, the diagnostic sensor unit 12 is connected to the second flat disc 4 via fibres 7b. The scattered light collected by the distal ends of patient fibres 6a is passed via patient fibres 6b and diagnostic fibres 7b, via the two flat discs 3, 4, respectively, to the diagnostic sensors in unit 12.

25 By rotating the second plate 4, the set of diagnostic fibres 7 are placed opposite the fibres 6 in a different order, whereupon another patient fibre 6 acts as transmitting fibre 6a and the remaining fibres act as receiving fibres, respectively.

The combined reply of the diagnostic sensors in unit 12 may be evaluated and a diagnostic image of the tissue 8 is thus obtained. Such diagnostic images may include information about the light flow through the tissue, auto-
5 fluorescence of the tissue, or a fluorescence signal, which is obtained from a tumour sensitizer when the tissue is excited with visible or ultraviolet radiation. The last-mentioned fluorescence signal is shifted towards longer wavelength and clearly appears in contrast to the endogen
10 fluorescence of the tissue. This information is used for localising tumours and for quantifying the size of the uptake of the sensitizer in the tissue. In this way, the correct light dose may be calculated or measured. Microthermistors may be arranged in connection with fibres
15 6 to measure temperature of the tissue, or temperature may be measured optically through specially prepared fibres.

The device in Figs. 1 and 2 may also be adjusted to a therapy position. In the therapy position, the proximal ends of all fibres may be connected to one or several laser
20 sources, in order to obtain an efficient light radiation of the tissue to be treated. In this case therapeutic light sources may conveniently be fixed into the holes of flat disc 4, shown in Fig. 2, as illustrated in Fig. 1, and remote from disc 4 be connected to therapeutic light
25 sources. Therapeutic light may thus be transmitted to the tissue 8 via a set of therapeutic fibres (a subset of fibres 7) to patient fibres 6 via the flat discs 4 and 3, respectively, and into tissue 8.

The light radiation may be infrared light, near-
30 infrared light (NIR), visible light or ultraviolet (UV) light both in the therapy mode and the diagnostic mode.

The optical fibres, i.e. patient fibres 6, may be arranged directly into the tissue 8, or by means of insertion needles, usually in the form of a hollow cannula
35 of metal with a sharp tip. Such a metal needle may be

arranged in the correct position, for example by the aid of X-ray, ultrasound or visually.

An optical patient fibre 6 may be inserted distally through the lumen of the metal needle so that the tip of the optical fibre, at its distal end thereof, is arranged in the correct position towards tissue 8. The needle may be left in place or removed during PDT, PTT and PDD or interactive variants thereof. The optical fibre is normally covered by a lining or cladding, so that it is not exposed to body tissue and body fluids, and without leaking light radially, i.e. light is only transmitted or collected from the tip of the fibre. The proximal end at a distance from the tissue 8 of the optical patient fibre 6 is arranged in holes of the flat disc 3.

Since the needle for inserting the fibre is passed into the tissue 8, the needle may be used for adding an agent, which is usable for the subsequent diagnosis and/or therapy.

Another way to arrange the optical fibre in place may be to insert the needle as mentioned above, whereupon a plastic sleeve may be inserted over the needle, whereupon the needle is retracted and the optical fibre is subsequently inserted in the plastic sleeve. The optical fibre may then be permanently arranged in the sleeve. In this way, the plastic sleeve protects the optical fibre.

During medical treatment, patients often require medication, blood, or fluids. The most efficient way of administering these substances is by depositing them directly into the patient's blood stream where the circulatory system quickly directs the substance to the target tissue or organ. Administering a substance directly into a patient's blood stream is most commonly accomplished by injection with a conventional needle and syringe. During the course of treatment, however, a patient will often require repeated or continuous doses of medications.

Repeated injections with conventional syringes damage blood vessels and cause significant discomfort to the patient.

Therefore, when a patient requires repeated doses of medication or other substances, catheters are commonly used
5 in the health care profession. However, catheters are up to now not known for interstitial delivery of light to a tissue within systems for interactive interstitial photodynamic diagnosis and therapy of a tissue.

Hence, an alternative system to the system described
10 above, is disclosed in Fig. 3, which comprises a sleeve of the Venflon® type intravenous access device; however, for a different use than conventionally known.

Generally, a Venflon® device, as shown in Fig. 7, may be classified as a ported intravenous (IV) catheter when it
15 is in place in the patient. An IV catheter includes a catheter having a wall 110 defining a lumen, a proximal end, and a distal end, as well as a catheter adapter body that is in fluid communication with the catheter lumen. Initially a Venflon® device comprises furthermore an
20 extremely thin needle 111 for inserting the catheter into a blood vessel. More precisely, "intravenous" means that a known Venflon® is configured for accessing the interior of a vein from outside the body, by means of the sharp needle that is put into a vein. Usually this is done for getting
25 blood samples or for delivering drugs to the circulatory system via the veins. The needle is put into a vein close to the surface of the skin in either the arm or the back of a patients hand. This needle 111 is wrapped up with a soft plastic tube, arranged as a sleeve 110 around the needle.
30 The needle makes the entry into the vein, and then is slid out leaving the soft plastic tube in place in communication with the vein. The drugs are put in through that tube 110, which then correctly is referred to as an "intraluminal indwelling catheter", but more commonly known by the
35 tradename of Venflon®. The tube usually stays in place for

a longer time, for instance throughout a surgical procedure.

However, it is pointed out that Venflon® devices are not supposed to be inserted interstitially into tissue. On the contrary, this has to be avoided, as for instance punctured veins leaking blood into the body are a serious threat to patient health. Catheters of this type, namely intravascular (IV) catheters, are conventionally used for infusing fluid, such as normal saline solution, various medicaments and total parenteral nutrition, into a patient, withdrawing blood from a patient or monitoring various parameters of the patient's vascular system, but not for inserting a light guide there through into a tissue. Peripheral IV catheters tend to be relatively short, and typically are on the order of about 5 cm or less in length.

In more detail, an IV catheter generally comprises a housing 102, an introducer needle 111, and a catheter 110, see Fig. 7. The housing is used to grip the vascular access device, e.g. at an gripping area 104, during catheter insertion. The introducer needle is attached to the proximal end of the catheter housing, e.g. by means of an intermediate catheter needle adaptor 103, and used to pierce the patient's skin and access the blood vessel. The catheter fits concentrically over the introducer needle and is held in place by friction engagement between the catheter needle adaptor 103 and the catheter housing 102. The relative lengths of the introducer needle and the catheter cannula are such that the tip of the introducer needle extends beyond the end of the catheter cannula when the introducer needle is attached to the housing. In use, a clinician pierces the patient's skin with the introducer needle and locates the patient's blood vessel. With the introducer needle in the patient's blood vessel, the clinician detaches the catheter needle adaptor 103 from the housing. The clinician then withdraws the introducer needle 111, leaving the catheter in place, and attaches an

appropriate device to the catheter. The catheter is usually provided with a lock 101 to seal off the proximal end of the catheter device when needed during the procedure. Different lock mechanisms are available, usually in the form of a slide lock lid, e.g. a Luer lock mechanism. Lock 101 has a gripping area 105, an intermediate portion 106 and an insertion portion to fit into the proximal portion 108 of the catheter housing 102 or the catheter needle adaptor 103. Engagement of lock 101 with the catheter is provided by mating elements 109, 106 on the lock 101 and catheter housing 102 or catheter needle adaptor 103, respectively, e.g. a bayonet closing or mating threads.

According to an embodiment of the invention, a proximal end adapter for an IV catheter is provided. With reference to Figs. 3 and 8a, among others, the adapter has an adapter body 32, having proximal and distal ends, defining an axial lumen 33 extending between the proximal and distal ends. A catheter mounting element is provided at the distal end of the adapter body 32 for sealingly mounting a catheter to the body. An optical connector mounting element is provided at the proximal end of the adapter for mounting an optical connector 37 directly to the adapter body. Furthermore, the adapter has a light guide 36 that has proximal and distal ends. The light guide 36 is sealingly contained in said axial lumen defining an axial optical path extending between the proximal and distal ends of the adapter body 32.

In order to ensure that the light guide 38 transmitting light between the adapters 32 and 37, below also called main fibre, does not get contaminated during use, a further proximal, second adapter may be used to increase patient safety and ease of use. In this case, e.g. a SMA connector (SMA is an acronym for SubMiniature version A) (not shown in the Figs.) may be provided to connect proximally to fibre 38, which then distally is connected to fibre 36 by threading part 37 on part 32. Thus it is

ensured that a fibre leading to an apparatus for providing or receiving light to or from fibre 36 is a true multiple use fibre. Fibre 36, and eventually the proximal thread of the adapter may be contaminated by body fluids during use.

5 Hence the first adapter comprising parts 32, 36 may be a single use consumable device and be discarded after use. The first adapter may be made of a plastic material at low cost. The second adapter may be made have a metal housing and a glass light guide therein, and thus it may easily be

10 sterilized. Hence the second adapter may be an adapter intended for multiple use. Instead of SMA type connectors also other commercially available optical connector types may be used, e.g. ST, FC or SC connector types. Optical connectors are used to mate a fiber to another fiber or to

15 equipment.

Good coupling efficiency is to be provided by all connectors described herein, which requires precise positioning of the fibers in relation to each other. Connectors are used to provide a convenient system as the

20 connection from an apparatus for photodynamic or photothermal therapy and/or diagnosis occasionally must be broken, for instance between patients or during therapy, e.g. to drain a tissue from fluid. The optical connectors described herein center fibers to each other so that their

25 light transmitting part lies directly over the connector and in line.

According to an embodiment, this adapter is combined with a catheter that comprises a plastic and flexible sleeve 31 attached to the body portion 32 of the adapter.

30 Instead of the body portion an insertion needle may be arranged in the catheter lumen. The needle is long enough to extend out of the plastic sleeve. The needle with the plastic sleeve is operated to pass into the skin and into the tissue. The plastic sleeve is of such a diameter that

35 it fits tightly around the needle and is sufficiently rigid to follow the needle into the skin and tissue. When the

plastic sleeve 31 has been placed in the desired position, the needle may be retracted leaving the catheter in place. Normally, the catheter is fixed to the skin by tape, so that it will not accidentally be removed. The catheter may
5 comprise a port 34 that is normally closed by a lid 35. Agents or medicaments may be added to the plastic sleeve through said port, such as via a syringe. Such addition may be a bolus before the start of the diagnosis or therapy, intermittent addition or continuous addition of said agent.
10 Moreover, excessive fluid may be drained from the tissue through the port. However, the port is optional according to some embodiments.

When the needle has been retracted, an optical fibre 36 may be inserted in place of the needle as shown in Fig.
15 3. Such insertion may take place after addition of a bolus, or take place before any addition of the agent. According to the present embodiment, the optical fibre attached to the adapter body 32, wherein this assembly is attached to the catheter. In this manner the optical fibre 36 is
20 conveniently inserted into the catheter and towards the tissue to be diagnosed and treated. According to a specific embodiment, the distal end of the adapter body is attached to the proximal end of the catheter housing. The attachment may be done by means of mating Luer lock connectors, e.g. a
25 male Luer connector on the proximal catheter housing and a female Luer connector on the distal adapter body 32, or vice versa. An example of an adapter having a Luer lock connection 141 is given in Fig. 8b, parts 145, 146, 147 correspond to parts 105, 106, 107, (Fig. 7) respectively.
30 However, Luer lock coupling 141 is rotatably attached to adapter housing 132 for connecting to a catheter, as shown in Figs. 9a, 9b, 10a, 10b and 11-16 that are cross-sectional views of various proximal end adapter and catheter assemblies.

35 Finally, a connector 37 having an optical connector 38 may be attached to the proximal end of the adapter body

26-07-2007

32, and thus to the catheter, in order to couple laser radiation or light into the optical fibre 36. The optical connector 37 has an optical fibre 38 centrally arranged, and it is at its other end connected to the flat disk 3, as shown in Fig. 1. Thus an optical path is ensured between the disk 3 and the tissue 8 via fibre 38, adapter 32 and fibre 36. The connection may conveniently be released and reattached by detaching adapter body 32 and thus fibre 36 from the catheter 31, e.g. for intermittent addition of new sensitizer to tissue 8. At the end of treatment, adapter 32 and catheter 31 may be discarded. Thus, contamination may be avoided by the adapter device when used for single treatment disposable use.

According to an embodiment, the catheter mounting element of the proximal end adapter at the distal end of the adapter body 32 comprises an internal tapered surface sized to matingly and sealingly engage an external tapered surface of a Luer lock connector.

According to another embodiment, the proximal end adapter has a radially compressible seal with a central bore receiving the light guide 36 therein. The seal is positioned within the adapter body along the axial lumen at a distance from the proximal end of the adapter, wherein the seal is radially outward compressed by said light guide to provide a sealing effect preventing leakage from the catheter through the adapter when mounted thereto.

According to an embodiment of the proximal end adapter, said light guide is sealingly attached in said axial lumen by a fastening means, such as glue, a clamp or local melting the adapter housing around the fibre 36.

According to an embodiment, a combination of the adapter and a hollow catheter is provided. The catheter mounting element is adapted to connect the adapter body to the hollow catheter so the hollow catheter extends from the distal end of the adapter body. The proximal end of the light guide may be positioned within the adapter body at a

distance from the proximal end of the adapter body, and the distal end of the light guide may extend from the distal end of the adapter body into the hollow catheter. The hollow catheter defines an axially extending catheter lumen, wherein the light guide may be radially in contact with the interior wall of the axially extending catheter lumen in order to provide a tight fitting therein.

5
10
15
Alternatively, the light guide has a diameter less than the interior diameter of the catheter lumen, so that a coaxial, radially offset, channel is formed in the catheter lumen, when the light guide is inserted therein. The coaxial lumen may include an entrance port opening 34 into the portion of the axial lumen of the catheter body, e.g. for delivery of drugs.

15
20
The optical fibre 36 may end a few millimeters before the end of the sleeve 31, as shown in Fig. 3. In this way, light is emitted from the optical fibre and is spread by the sleeve before reaching the tissue.

20
25
In another embodiment, the optical fibre extends out of the end of the sleeve, whereby the optical fibre may be provided with a spreading device, such as a lens or a cone at the end of the optical fibre. Alternatively, the surface of the outer sector of the fibre may be ground to diffuse the light.

25
30
35
Fig. 9a shows the proximal end adapter 132 connected to a catheter body 102. In this embodiment the optical fibre 136 is arranged in the lumen 110 of catheter 102 and further inside the hollow needle 111. Fig. 9b illustrates how the optical connector 137 is threadably mounted on the proximal end of the adapter 132. In Fig. 9b and 16, the end of the optical fibre 136 or 236, respectively appears to converge into the tip of needle 111. However, in practice the needle is slightly wider than the optical fiber, in order to house the fibre therein; in contrast to the illustration of Fig. 9b and 16, where the tip of the needle

due to the mentioned illustrative purposes appears to be part of the fibre 136 or 236, respectively.

In Figs. 10a and 10b the fibre 136 is directly arranged in the lumen 110 of catheter 102, and the needle
5 is omitted. Fig. 11 illustrates an end adapter 230 that is insertable into a hollow needle 111, see Fig. 12, or a catheter, see Figs. 13-16. Here, a Luer lock connector 237 comprises an optical fibre arranged therein for coupling to the fibre 236 of the adapter 230. Adapter 230 is inserted
10 into needle 111 (Fig. 12) or lumen 110 (Fig. 14). Alternatively needle 111 with adapter 230 inside is arranged in catheter 102, see Fig. 16.

All embodiments of the adapter described herein may advantageously be used in systems as described above with
15 reference to Figs. 1 and 2.

Fig. 4 discloses a system in addition adding a substance to a tissue at photodynamic diagnosis or therapy or photo-thermal therapy. Several optical fibres 41 have been arranged with a distal tip portion ending in a tissue
20 8 to be treated and extending through sleeves 42, which may be flexible or more or less rigid. The end of each optical fibre being distal from the tissue 8 and the corresponding end of the sleeve is attached to a plate 43 which may be similar to plate 3 shown in Fig. 1. While only two have
25 been shown in Fig. 4, any number of fibres may be used. The sleeve may be of a plastic material or a metal.

Another plate 44 is arranged adjacent to plate 43. Plate 44 may be similar to plate 4 in Fig. 1. A sleeve 45 including an optical fibre 46 is connected to plate 44.
30 Optical fibre 46 may be similar to optical fibre 7a shown in Fig. 2.

Sleeve 45 is provided with a port 47 which may be normally closed by a lid (not shown) and a syringe 48 may be attached to the port. The syringe may deliver a
35 substance or an agent to the tissue 8 through the port 47 and the sleeves 45 and 42. The supply may be a bolus, or

intermittent or continuous supply. The supply may take place before or during the diagnosis or during the therapy.

In Fig. 4, only one sleeve is shown provided with a port 47. Such sleeve may be connected to each sleeve 42 during the diagnosis step as described above.
5 Alternatively, several or all sleeves 45 are provided with ports.

Fig. 5 discloses a further method for supplying a substance to the tissue. The optical fibre may be covered
10 by a lining having the property to conduct electric current. This property may be used for electrophoretic supply of a substance to the tissue. The ends of the optical fibres are arranged in the tissue as described above with reference to Fig. 3.

15 The optical fibre is in an embodiment covered by a lining of a suitable metal, such as silver (Ag). The metal lining serves multiple purposes.

1) The metal lining operates as a total reflection medium, which means that the optical fibre may be arranged
20 directly in the tissue, without a protecting sleeve. The optical fibre may be arranged in direct contact with any fluid present around the tissue.

2) The metal is a conductor for electricity, which means that the optical fibre can be used as an electrode,
25 for example for iontophoretic introduction of a substance in the tissue.

Fig. 5 is a schematic diagram of a system for introduction of an agent to a tissue by iontophoresis. A tumour 81 has been identified below the skin 82 of a
30 patient. The tumour may be positioned close to the skin or at a substantial depth. The effect of iontophoretic introduction of a substance may be larger if the tumour to be treated is located close to the skin.

A pad 83 comprising the agent to be introduced is
35 arranged on the skin surface above the tumour to be treated. The pad may at the same time act as an electrode

as indicated by a connector 84 to a positive contact of an electric current.

Two optical fibres 85, 86 covered with a metal layer are shown in Fig. 5 and are arranged in plastic sleeves 87, 88. However, any number of optical fibres and sleeves may be used, such as three, four, five or six fibres and sleeves. The fibres 86, 87 may be arranged in the tissue 81 by means of the above described adapter 32 and catheter 31. Each sleeve is at one end connected to a plate, similar to the plate 43 in Fig. 4, and at the other end terminated at a position in the tissue of tumour 81. The optical fibres 85,86 extend through the sleeves 87,88. At the end distal from the tumour, each optical fibre is electrically connected to a ground potential. Thus, the distal end extends out of the sleeve into contact with the tissue. An electric current is generated between the pad 83 and each end of the fibres. The current carries the agent through the skin and into the tumour. The agent may be ALA-solution, phtalocyanines, chlorines etc. For certain agents the polarity may be reversed.

These agents act in the following manner for therapy of the tumour.

ALA or aminolevulinic acid is a precursor photosensitizer. When applied, ALA is gathered in the tumour cells, due to their high activity, and is converted into protoporphyrin IX (PPIX), which is a photosensitizer. By applying a laser beam, at a wavelength of approximately 635nm, on the tumour, the PPIX is excited contributing to excite the oxygen, in the cells, to its singlet state. The singlet state oxygen will fatally damage the cells and within a few days the cells in the affected area are dead.

Phtalocyanines are a second generation of photosensitizers with improved pharmaceutical profiles. They have a strong absorption in the red region in which tissue is rather transparent making them suitable for PDT.

Chlorines are also a second generation photosensitizer suitable for PDT.

Other sensitizers are Foscan and Tookad.

The metal layers, notably silver, in contact with the tissue or tumour may act as a bacteriostatic matter preventing infections.

As shown in Figs. 5 and 6, the distal end of the fibre extends out of the plastic sleeve into contact with the tissue. This distal end 93 may also be free from the lining of metal, at least over the end portion thereof. Fig. 6 shows an optical fibre 91 covered by a metal lining 92, which is able to reflect the light passing inside the fibre and act as an electric current conducting layer. The fibre is arranged inside a plastic sleeve 94, which protects the fibre and forms an insulation in relation to the body portion surrounding the sleeve. Because the end 93 is not covered by silver coating and is in contact with a fluid in the tissue, the light in the fibre will partially pass out through the side walls of the fibre. Thus, the end 93 will diffuse the light. This is an advantage in PDT and PDD.

When the optical fibre is used for optical diagnosis or therapy, the light passing through the fibre is spread in the area surrounding the end or collected therefrom, which is an advantage. The same is true at light therapy.

The methods of supplying the agent as described above may be used as alternatives or in combination.

The sleeves 87 and 88 may be a plastic sleeve or a tube of a material that is compatible with the human being. It may be more or less flexible or elastic.

The sleeve 87,88 may be a needle of steel attached to a plate, similar to the plate 43 in Fig. 4, in a suitable configuration. There may be 6 needles arranged in a geometric configuration. The needles are pushed through the skin and into the tumour.

The sleeves may be made from polyurethane or polyvinyl chloride with a suitable softener. The sleeves may incorporate barium, so that the positioning of the sleeves may be monitored by X-ray.

5 In a further embodiment, each sleeve is a so called Venflon® device, which is of the intravenous catheter type described above.

In cases, where no administration of agent needs to take place through a sleeve, the sleeve may be dispensed
10 with and the fibre may pass directly to the tissue. In this case it may be advantageous that the metal lining is covered by an electrically insulating layer leaving only a small exposed area of the silver lining at the end, so that iontophoretic administration of substance may be possible.

15 As used herein, the term "proximal" refers to a location on the catheter that, during normal use, is closest to the clinician using the device and farthest from the patient in connection with whom the device is used. Conversely, the term "distal" refers to a location on the
20 catheter that, during normal use, is farthest from the clinician using the device and closest to the patient in connection with whom the device is used.

Reference has been made to threads and tapered surfaces suitable for use with Luer lock type connectors.
25 Generally, Luer locks have a 6° included angle taper as fully characterized in publication ISO 594/1, First Edition, 1986-06-15 and made part of this application by reference. Luer lock connectors have a double start, right-hand thread described in publication ISO 594-2, First
30 Edition, 1991-05-01 made part of this application by reference.

Herein above, a specific embodiment of the invention has been described with reference to the drawings. However, the invention can be varied within the embodiments shown.
35 The different separate features may be combined in other

combinations than specifically disclosed. The invention is only limited by the appended patent claims.

CLAIMS

1. A proximal end adapter for a catheter comprising

an adapter body, having proximal and distal ends, defining
5 an axial lumen extending between the proximal and distal ends,
wherein

a catheter mounting element arranged at the distal end of
the adapter body for mounting, such as sealingly mounting, a
catheter to the distal end of the adapter body;

10 an optical connector mounting element arranged at the
proximal end of the adapter body (for mounting an optical
connector to the proximal end of the adapter body; and

15 a light guide having proximal and distal ends, wherein
said light guide is sealingly contained in said axial lumen
defining an axial optical path extending between the proximal
and distal ends of the adapter body, wherein the proximal end
of the light guide is configured to be positioned within the
adapter body,

20 whereby said proximal end adapter is configured for use,
such as single treatment disposable use, in a system for
interactive interstitial photodynamic or photothermal therapy
and/or diagnosis of a tissue.

25 2. The proximal end adapter according to claim 1, wherein
said optical connector mounting element at the proximal end
for mounting an optical connector to the adapter body is
configured to directly mount to said adapter body; and/or

2006244673 01 Jul 2011

wherein said optical connector mounting element at the proximal end of the adapter body comprises a mounting surface to sealingly engage said optical connector.

5 3. The proximal end adapter according to claim 2, wherein said mounting surface is an internal tapered surface sized to matingly and sealingly engage an external tapered surface of a Luer lock connector comprised in said optical connector; or

10 wherein said mounting surface is threaded for matingly and sealingly engaging a threaded surface comprised in said optical connector.

15 4. The proximal end adapter according to any of claims 1 to 3, comprising a radially compressible seal having a central bore receiving the light guide therein, positioned within the adapter body along the axial lumen at a distance from the proximal end, wherein the seal is radially outwardly compressed by said light guide to provide said sealing; and/or

20 wherein said light guide is sealingly attached in said axial lumen by a fastening means, such as glue.

5. The proximal end adapter according to any of the preceding claims, wherein said catheter is a transcutaneous intravenous catheter device; or

25 wherein said catheter is a transcutaneous intravenous catheter device wherein said catheter has a length of approximately less than 10 cm; and/or

01 Jul 2011

2006244673

wherein said adapter when mounted to said catheter seals said lumen against fluid connection from said proximal side of said adapter and provides light connection from said proximal end of said adapter to said lumen via said light guide.

5

6. A combination of the adapter of any of claims 1 to 5 and a hollow catheter, wherein the catheter mounting element is adapted to connect the adapter body to the hollow catheter so that the hollow catheter extends from the distal end of the adapter body.

10

7. The combination of claim 6, wherein the proximal end of the light guide is positioned within the adapter body at a distance from the proximal end of the adapter body, and wherein the distal end of the light guide extends from the distal end of said adapter body into the hollow catheter.

15

8. The combination of claim 7, wherein the hollow catheter defines an axially extending catheter lumen, wherein the light guide is radially in contact with the interior wall of the axially extending catheter lumen.

20

9. The combination of claim 7, wherein the hollow catheter defines an axially extending catheter lumen, wherein the light guide has a diameter less than the interior diameter of the catheter lumen, so that a coaxial, radially offset, channel is formed in the catheter lumen.

25

10. The combination of claim 9, wherein the catheter lumen includes an entrance port opening into a portion of the axial lumen of the catheter body.

5 11. The combination of claim 6, further comprising a
needle that is insertable and retractable in the hollow
catheter for arranging said catheter to said tissue when said
adapter is disconnected from said catheter, such that said
radiation fibre is insertable through the catheter or the
10 needle towards said tissue.

12. A system configured for photodynamic or photothermal
therapy and/or photodynamic diagnosis of a tissue, said system
in combination comprising an assembly of:

15 a proximal end adapter for a catheter comprising

an adapter body), having proximal and distal ends,
defining an axial lumen extending between the proximal and
distal ends, wherein said proximal end adapter is a single use
consumable device,

20 a catheter mounting element at the distal end of the
adapter body for sealingly mounting a catheter to the adapter
body,

and a hollow catheter, wherein the catheter mounting
element connects a catheter body to the hollow catheter so
25 that the hollow catheter extends from the distal end of the
catheter body,

a first light guide having proximal and distal ends,
wherein said first light guide is sealingly contained in said
axial lumen defining an axial optical path extending between

01 Jul 2011

2006244673

the proximal and distal ends of the adapter body towards said tissue and into close proximity thereof or interstitially into said tissue, wherein the proximal end of said first light guide is configured to be positioned within the adapter body,

5 an optical connector mounting element at the proximal end having mounted an optical connector to the adapter body, and

wherein said optical connector is coupled to a light source via a second light guide located at a proximal end side thereof,

10 such that light from said light source is transmittable from said light source via said second light guide to the distal end thereof and further via said optical connector to the proximal end of said first light guide within the adapter body and via said proximal end adapter towards said tissue through said catheter for said therapy and/or diagnosis of said tissue.

15

13. The system according to claim 12,

wherein said first light guide is insertable into said catheter after arranging said sleeve in said tissue; and/or

20 wherein said second light guide is a true multiple use fibre; or

wherein said system further comprises a supply device for supplying an agent via said catheter to said tissue; or

25 wherein said system further comprises a supply device for supplying an agent via said catheter to said tissue and wherein said catheter is provided with a port for supply of said agent; or

30 wherein said system further comprises a pad including said agent and arranged at the skin adjacent said tissue and forming a first electrode connected to a first electric potential, whereby a second electric potential is connected to an electrically conductive lining arranged on at least one of said

2006244673 01 Jul 2011

radiation fibres, to form a current for introduction of said agent into said tissue by iontophoresis; or

wherein said system further comprises a pad including said agent and arranged at the skin adjacent said tissue and forming
5 a first electrode connected to a first electric potential, whereby a second electric potential is connected to an electrically conductive lining arranged on at least one of said radiation fibres, to form a current for introduction of said agent into said tissue by iontophoresis and wherein said
10 conductive lining is of a metal, such as silver; and/or

wherein said system comprises a second adapter for releasably connecting the proximal end of said adapter body to a further optical connector proximally arranged at said optical connector on a proximal end of said second light guide.

15

14. A method for use of a proximal end adapter of a catheter, the proximal end adapter having an adapter body, having proximal and distal ends, defining an axial lumen extending between the proximal and distal ends, and a catheter
20 mounting element at the distal end of the adapter body for mounting a catheter to the body; an optical connector mounting element at the proximal end for mounting an optical connector to the adapter body; and a first light guide having proximal and distal ends, wherein said first light guide is sealingly
25 contained in said axial lumen defining an axial optical path extending between the proximal and distal ends of the adapter body, said method comprising:

30

mounting the proximal end adapter to a catheter housing by said catheter mounting element, to provide the light guide in a lumen of the catheter;

mounting said first light guide with the proximal end thereof within the adapter body,

2006244673 01 Jul 2011

mounting an optical connector to said optical connector mounting element of said adapter body, thereby coupling a distal end of a second optical light guide comprised in said optical connector to the proximal end of said first light guide, thus

providing an optical path via said adapter.

15. The method according to claim 14, wherein said mounting the proximal end adapter and said mounting of the optical connector comprise threadably mounting.

16. A method for photodynamic or photothermal therapy and/or photodynamic diagnosis of a tissue, comprising

providing at least one source of laser radiation,

providing at least one radiation fibre for transmitting the laser radiation to said tissue;

arranging a catheter interstitially in said tissue;

mounting a proximal end adapter to the proximal end of the catheter, said proximal end adapter having a radiation fibre thus mounted in a lumen of the catheter to said tissue, and

connecting said adapter to a distal end of a second radiation fibre via an optical connector coupled to said at least one source of laser radiation,

such that laser radiation from said at least one source of laser radiation is transmitted via said distal optical fibre to said at least one radiation fibre and said tissue, when said proximal end adapter in use is connected to said optical connector.

17. The method according to claim 16, prior to mounting the adapter to the catheter comprises

inserting a needle into the tissue, said needle having a catheter sleeve arranged over said needle,

5 removing said needle, and inserting at least one radiation fibre in said sleeve; and/or

wherein said method further comprises

retracting of said proximal end adapter from said lumen, and

draining liquid through said lumen, and re-mounting the
10 proximal end adapter to the proximal end of the catheter.

18. Use of an intravenous access device for interstitially coupling light to a tissue.

15 19. Use according to claim 18 comprising photodynamic or photothermal therapy and/or photodynamic diagnosis of said tissue.

20 20. A proximal end adapter for a catheter substantially as described herein with reference to any one of the embodiments as illustrated in the Figures.

2006244673 01 Jul 2011

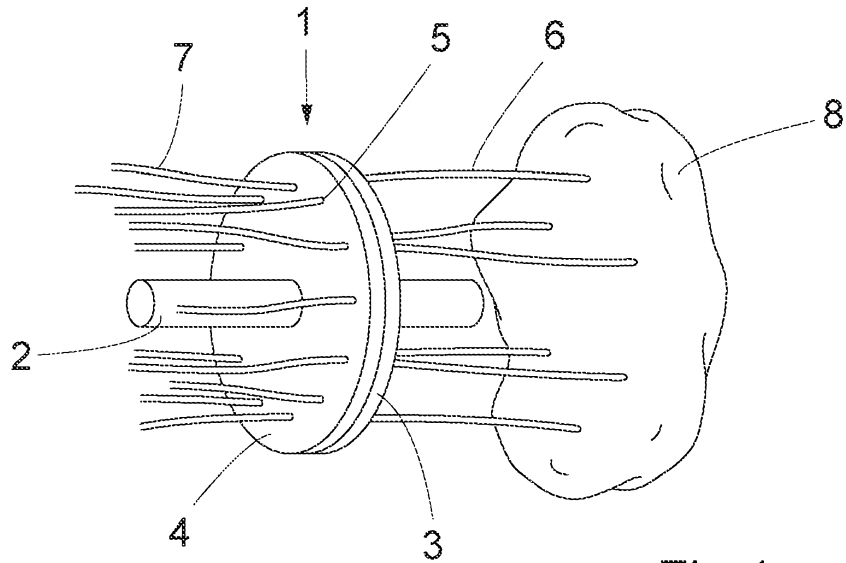


Fig.1

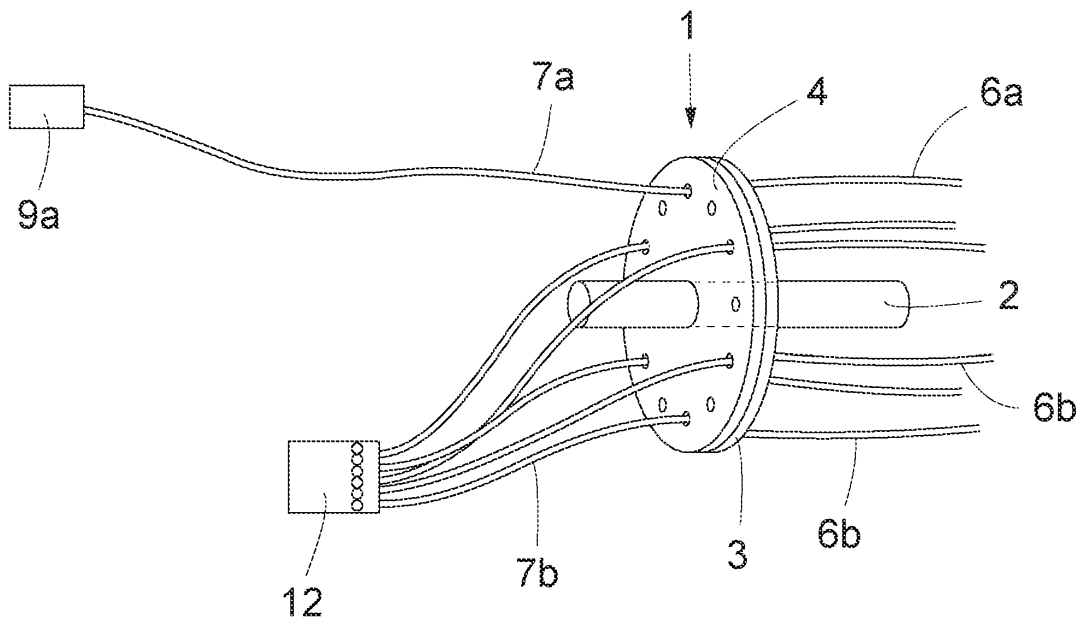


Fig.2

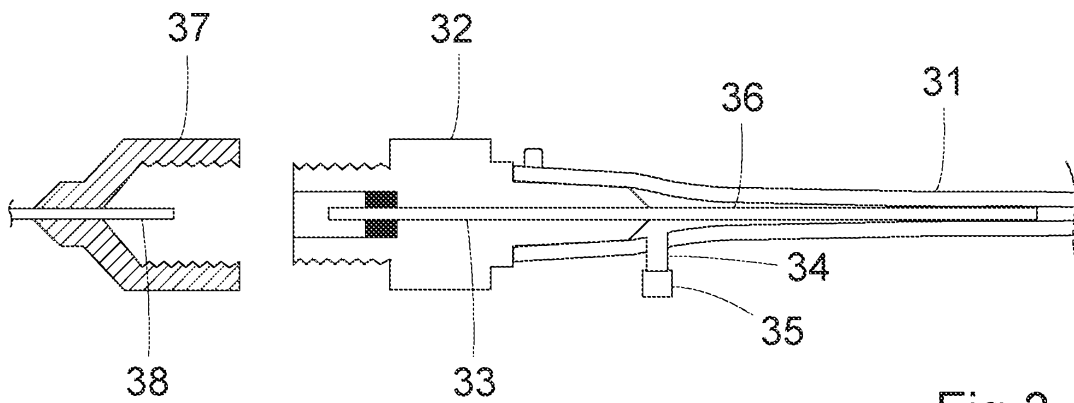


Fig.3

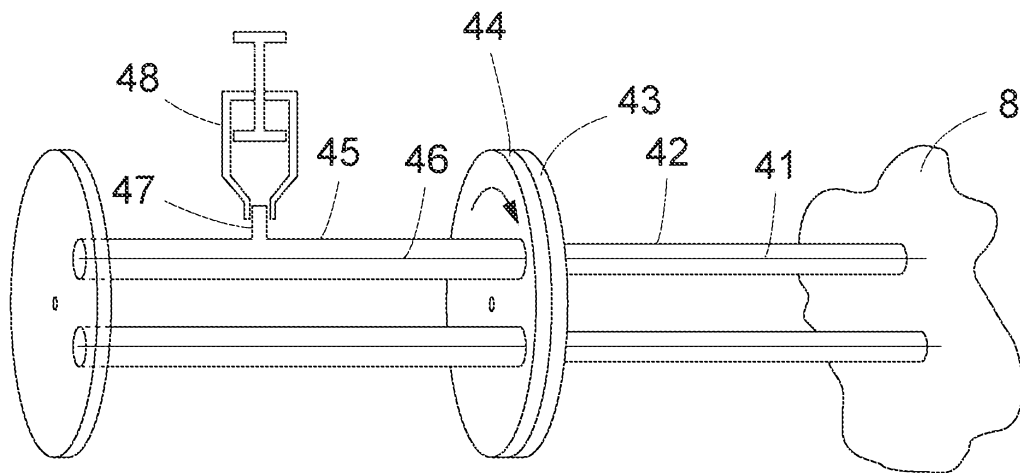


Fig.4

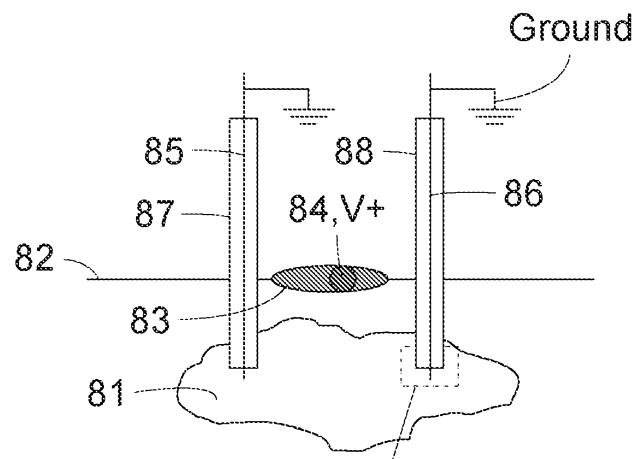


Fig. 5

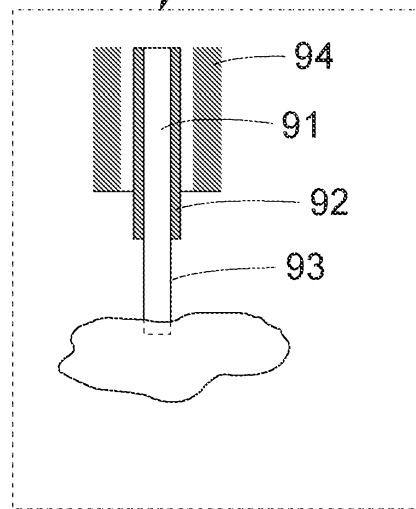


Fig. 6

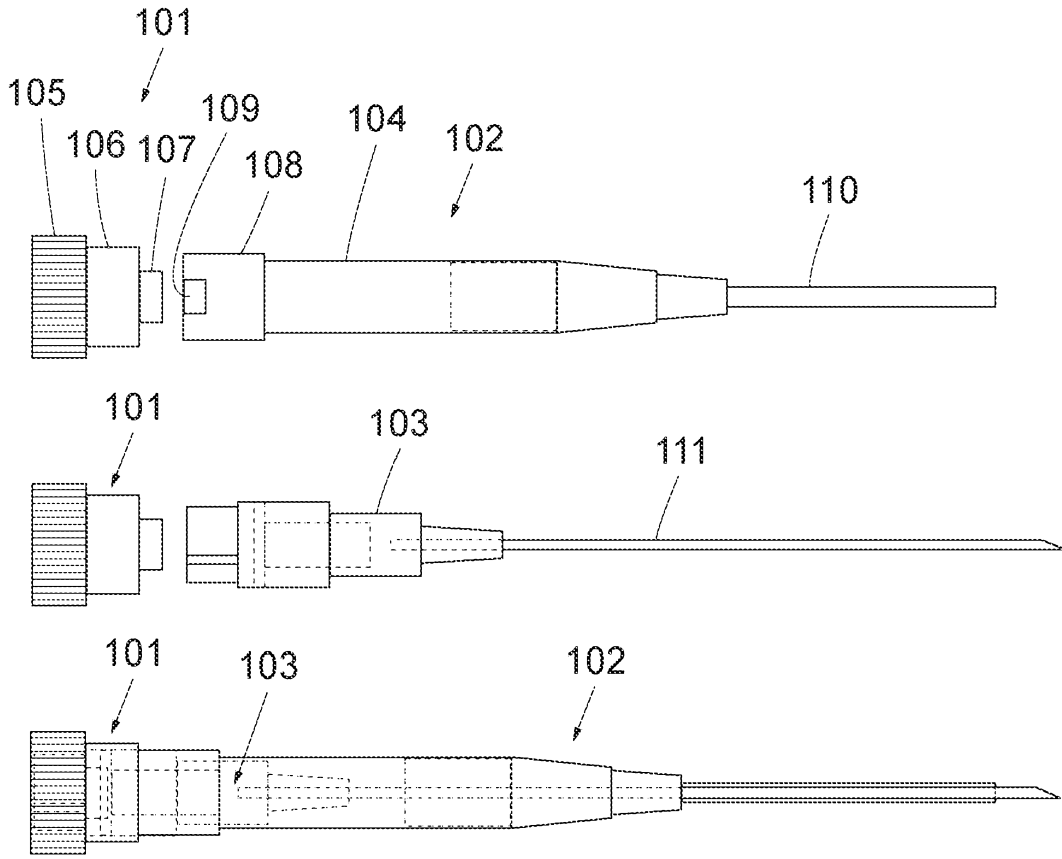


Fig.7

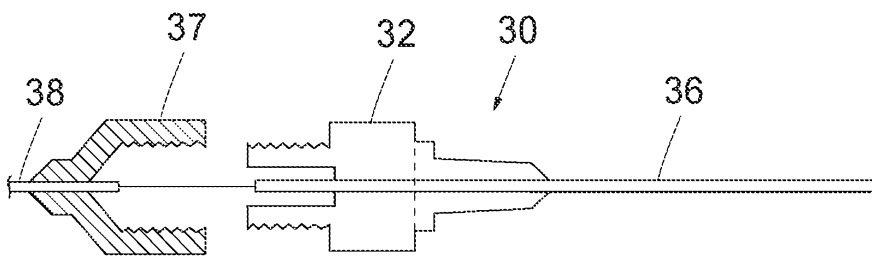


Fig.8a

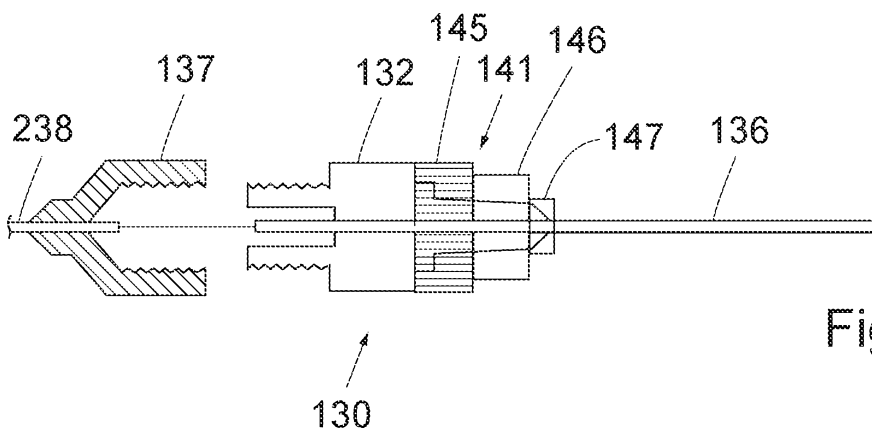


Fig.8b

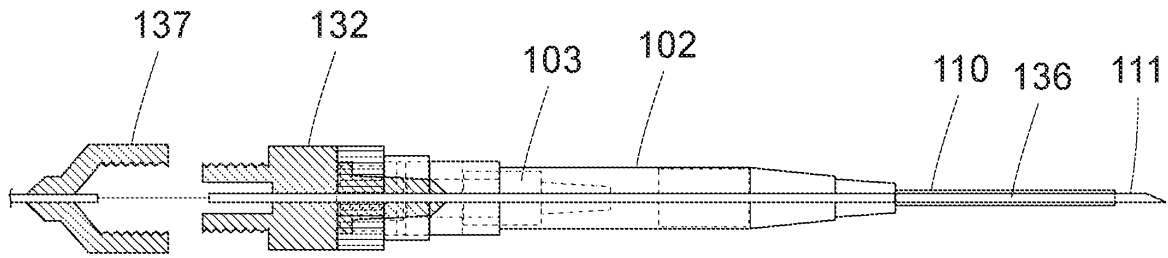


Fig.9a

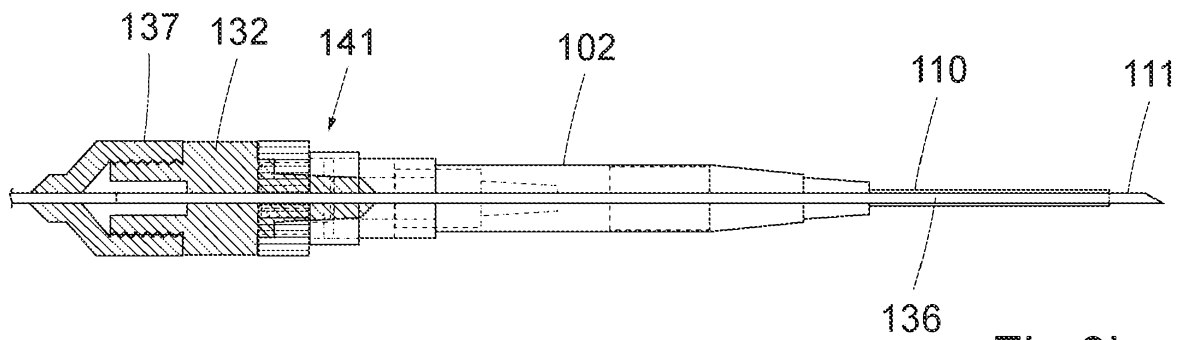


Fig.9b

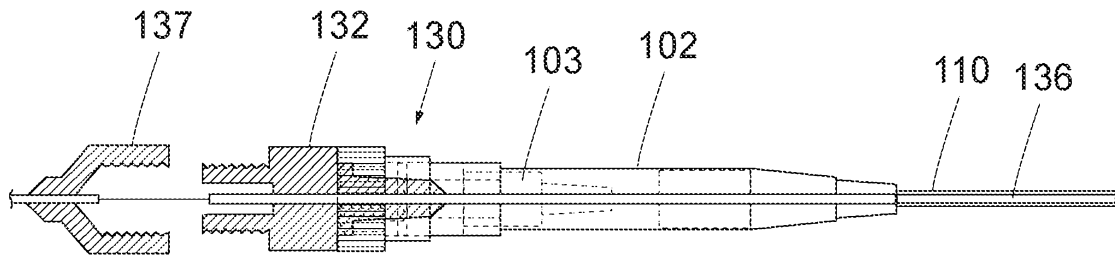


Fig.10a

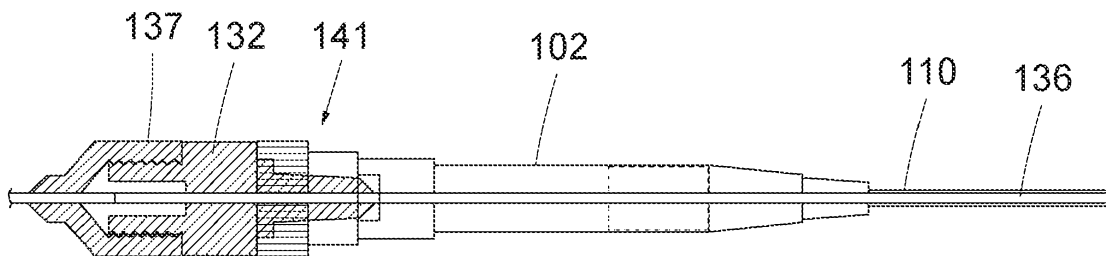


Fig.10b

7/9

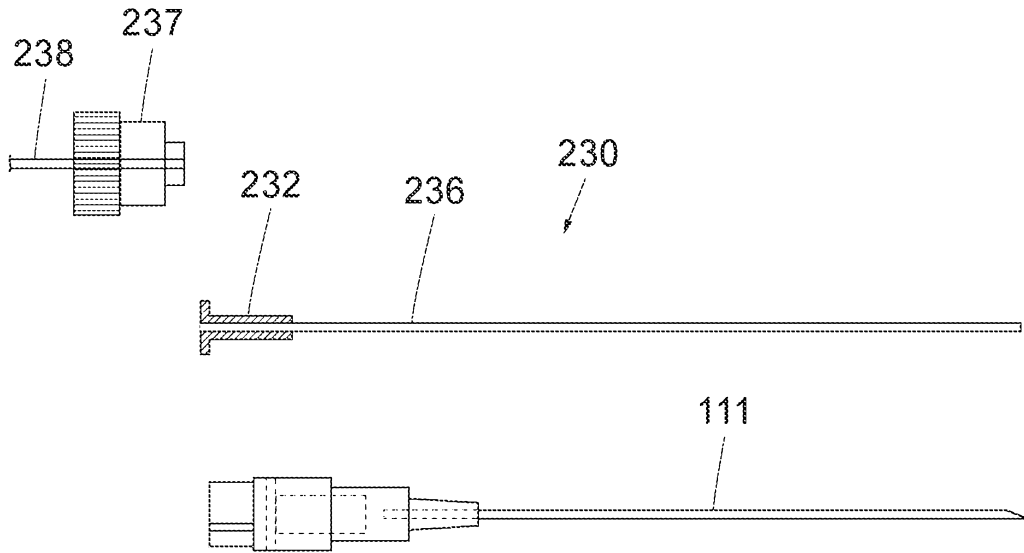


Fig.11

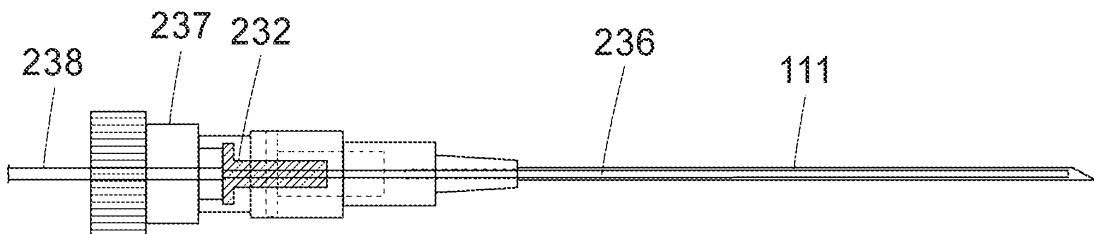


Fig.12

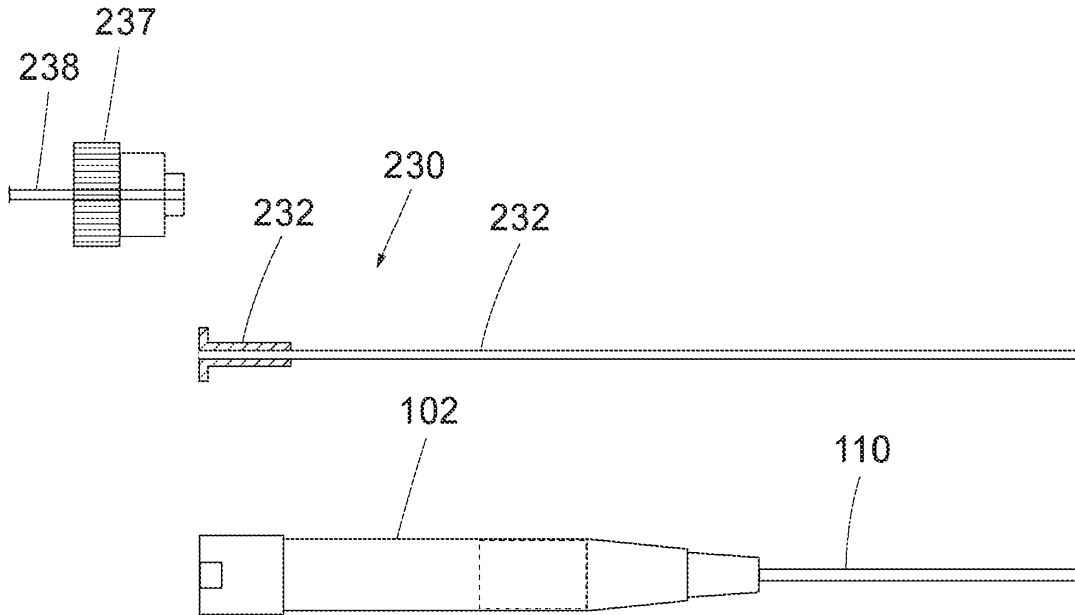


Fig.13

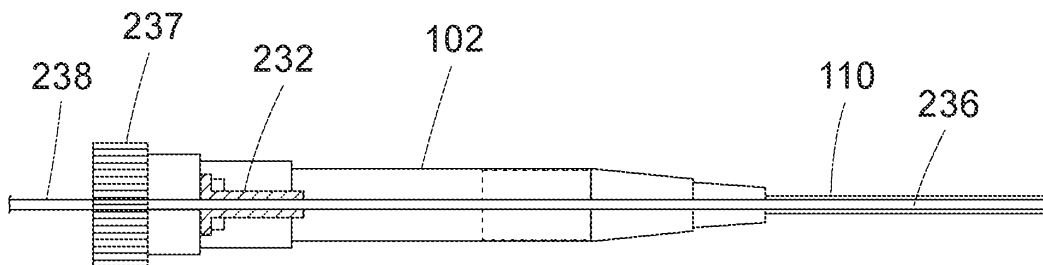


Fig.14

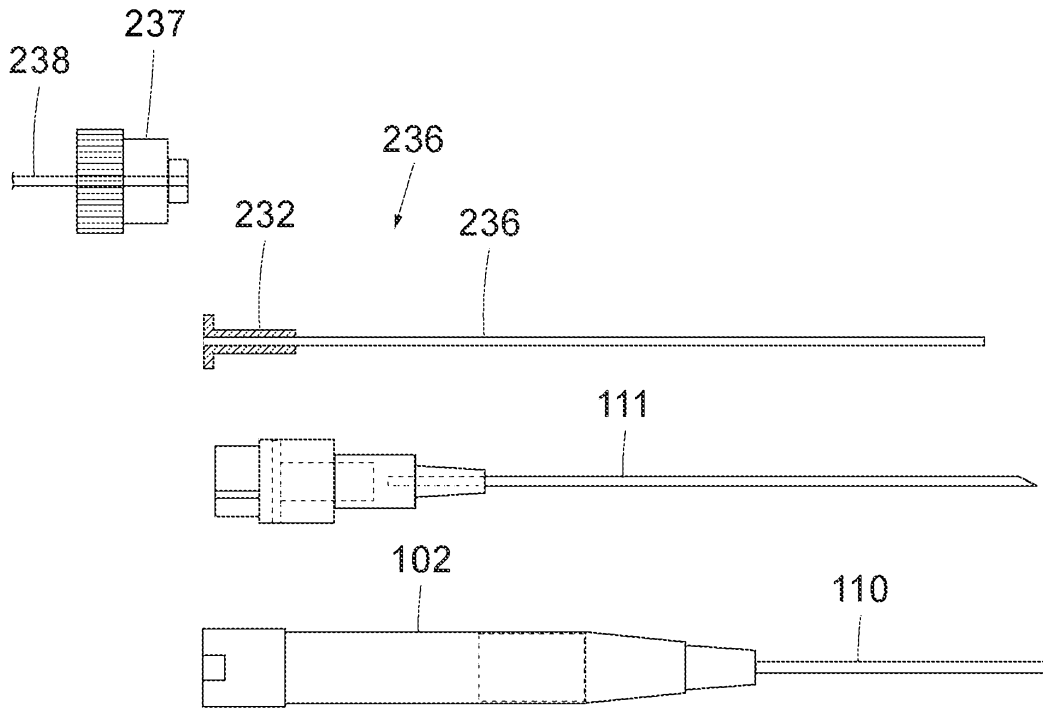


Fig.15

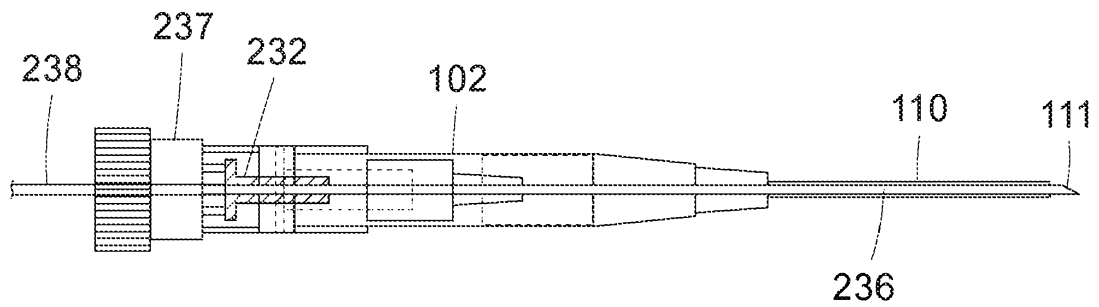


Fig.16