

VASCULAR ACCESS DEVICE WITH INTEGRATED LIGHT GUIDE

[0001] This application claims priority to U.S. provisional application 61/887,670 filed October 7, 2013, U.S. provisional application 61/957,464, filed July 3, 2013, and U.S. provisional application 61/957,465, filed July 3, 2013. This application also claims priority to U.S. provisional applications 61/957,463 (filed July 3, 2013), 61/957,513 (filed July 5, 2013), 61/887,845 (filed October 7, 2013), and 61/887,800 (filed October 7, 2013). U.S. provisional applications 61/887,670, 61/957,464, 61/957,465, 61/957,463, 61/957,513, 61/887,845 and 61/887,800, as well as all other referenced extrinsic materials are incorporated herein by reference in their entirety. Where a definition or use of a term in a reference that is incorporated by reference is inconsistent or contrary to the definition of that term provided herein, the definition of that term provided herein is deemed to be controlling.

[0002] This application is related to co-pending U.S. patent application number ____, titled “Sheathed Optical Fiber”, co-pending international patent application number ____, titled “Sheathed Optical Fiber”, co-pending U.S. patent application number ____, titled “Systems and Methods for In Vivo Irradiation of Blood”, and co-pending international patent application number ____, titled “Systems and Methods for In Vivo Irradiation of Blood”. All of these co-pending U.S. and international patent applications are incorporated by reference herein in their entirety.

Field of the Invention

[0003] The present invention generally relates to systems, devices and methods for treatment of human blood. More particularly, the present invention relates to systems, devices and methods for irradiating human blood *in vivo*.

Background

[0004] It has long been accepted that certain wavelengths of electromagnetic radiation, such as ultraviolet light, have the ability to affect biological and chemical structures. For example, the formation of thymine dimers under the influence of ultraviolet light is well known and has been utilized to sterilize surfaces by killing or inactivating a variety of pathogens. In the early 1900's efforts were made to incorporate exposure to ultraviolet light as a treatment modality for various

diseases, including bacterial and viral infections. Procedures were typically extracorporeal; a volume of blood would be removed from a patient, irradiated to modify a patient's immune response and/or inactivate pathogens, and returned to the patient. Such efforts were hindered, however, by the sources of ultraviolet light available at the time. UV lamps of the time period did not operate reliably, produced inconsistent illumination, and generated large amounts of heat. The development of effective and reliable antibiotics that were easily administered resulted in a loss of interest in this therapeutic approach.

[0005] The increasing prevalence of antibiotic-resistant pathogens and the recognition of potential effectiveness for the treatment of noninfectious medical conditions have led to an increasing interest in the use of blood irradiation as a treatment modality. A variety of devices for improved extracorporeal irradiation of blood have been proposed.

[0006] For example, United States Patent Application No. 2004/0116912 to Appling and United States Patent Application No. 2004/0010248 to Appling, et al, both discuss endovascular laser treatment devices used with an optical fiber running from a laser source to the patient's body. However, the length of the singular fibers in these approaches present installation challenges to the administering personnel. Additionally, if the optical fiber has to be replaced at any time after introduction into the patient, the entire fiber must be withdrawn from the patient's body and a new one installed.

[0007] Other approaches have included devices whereby the fiber is divided. For example, United States Patent Application No. 2008/0249517 to Svanberg discusses connecting a light guide within an adapter body to a light guide of a light source via an optical connector using a threaded connection. However, the coupling and uncoupling of adapter body and optical connector require the rotation of the adapter body and/or optical connector, which risks injury to the patient if the coupling or uncoupling occurs while the adapter body is connected to an inserted catheter or needle.

[0008] This and all other extrinsic materials discussed herein are incorporated by reference in their entirety. Where a definition or use of a term in an incorporated reference is inconsistent or contrary to the definition of that term provided herein, the definition of that term provided herein applies and the definition of that term in the reference does not apply.

[0009] Unless the context dictates the contrary, all ranges set forth herein should be interpreted as being inclusive of their endpoints and open-ended ranges should be interpreted to include only commercially practical values. Similarly, all lists of values should be considered as inclusive of intermediate values unless the context indicates the contrary.

[0010] While certain devices and methods are known in the art to irradiate blood, all or almost all of them suffer from one or more disadvantages. Thus, there is still a need for simple system for the effective *in vivo* irradiation of blood.

Summary of The Invention

[0011] The inventive subject matter discloses systems and devices that provide a waveguide, safe and convenient vascular and/or lymphatic access for the waveguide, and an effective and efficient optical coupling between the waveguide and one or more sources of electromagnetic radiation. When the system is in place at least a portion of the waveguide is in optical communication with the vasculature and/or lymphatic system of an individual undergoing treatment. Electromagnetic radiation, for example ultraviolet and/or visible light, can be transferred from the light source to the waveguide, and from the waveguide to the vasculature and/or lymphatic system of the individual undergoing treatment, thereby providing *in vivo* irradiation of blood and/or other body fluids.

[0012] The system can include an adapter device and an optical interface that can be coupled together to align a waveguide within the adapter with a waveguide (*e.g.*, a light delivery cable) of a light source such that the radiation from the source can be administered to a patient's body *in vivo*. The adapter device can include a fluid port that permits exogenous fluids to be administered during this irradiation. The optical interface between the waveguide and the light delivery cable can be isolated from body fluids, exogenous fluids, and/or both body fluids and exogenous fluids. In embodiments of the inventive concept the optical interface does not include active optics, and most preferably a dry optic coupling between a light delivery cable and the waveguide (*i.e.*, light does not travel through any liquid at the interface between the light delivery cable and the waveguide).

[0013] In embodiments, the adapter device can be coupled to the optical interface via a tapered end of the adapter device and a corresponding cavity in the optical interface, such that the waveguide of the adapter device and the waveguide of the radiation source are brought into alignment within required angular and distance tolerances. The adapter device can further include protrusions such as tabs or threads that engage with a slip lock ring on the optical interface.

[0014] In embodiments of the inventive concept the optical interface can be configured to accept industry standard optical coupling, for example a SMA-905 optical fiber connector. In other embodiments of the inventive concept an optical adapter may be interposed between a waveguide of the adapter device and an optical fiber connector that is in optical communication with a source of electromagnetic radiation.

[0015] In some embodiments of the inventive concept the adapter device can include machine readable indicia (for example, a one dimensional barcode, a two dimensional barcode, an RFID device, and/or an optical RFID or OPID device). Such machine readable indicia can be utilized to associate a specific device with a specific individual undergoing treatment, permitting device tracking, prevention of cross contamination between individuals, and/or prevention of re-use of a disposable implementation of a device of the inventive concepts.

[0016] Various objects, features, aspects and advantages of the inventive subject matter will become more apparent from the following detailed description of preferred embodiments, along with the accompanying drawing figures in which like numerals represent like components.

Brief Description of the Drawings

[0017] Figure 1 provides an overview of an adapter device, according to embodiments of the inventive subject matter.

[0018] Figure 2 provides an isometric view of the adapter device of Fig. 1 and the assembly of a waveguide and sheath.

[0019] Figure 3 provides a cross-section view of the assembled adapter device, waveguide and sheath.

[0020] Figure 4 provides a view of a slip lock ring, optical connector adapter and optical cable separately, aligned for assembly.

[0021] Figure 5 provides an assembled view of the components of Fig. 4 as a patient cable.

[0022] Figure 6 illustrates the patient cable of Fig. 5 with an overmold.

[0023] Figure 7 provides an overview of an adapter device and patient cable aligned for coupling.

[0024] Figure 8 provides a cross-section view of the aligned adapter device and patient cable of Fig. 7.

[0025] Figure 9 provides a cross-section view of the coupled adapter device and patient cable of Fig. 8.

[0026] Figure 10 provides an overview of a catheter/cannula aligned for attachment to the assembly of Fig. 9.

[0027] Figure 11 provides examples of calculations for waveguides for use in catheters of various catheter sizes.

[0028] Figure 12 is an overview of a variation of the adapter device of Fig. 1, including a segmented lumen.

[0029] Figure 13 is a close-up view of the tapered terminus of the adapter device of Fig. 12, illustrating the channels used to form the segmented lumen.

[0030] Figure 14 is an end view of the tapered terminus of Figs. 12-13.

[0031] Figure 15 is an overview of the components used to assemble an optical adapter for use in adapter device, according to alternative embodiments of the inventive subject matter.

[0032] Figure 16 provides an isometric view of the optical adapter components of Fig. 15, with the assembled sheathed waveguide.

[0033] Figure 17 provides an isometric view of the optical adapter components of Fig. 16, with the o-ring fitted over the assembled sheathed waveguide.

[0034] Figure 18 provides an isometric view of the assembled optical adapter.

[0035] Figure 19 shows the optical adapter of Fig. 18 aligned for assembly with an adapter device, according to the alternative embodiments of the inventive subject matter.

[0036] Figure 20 illustrates the assembled dry light adapter.

[0037] Figure 21 illustrates the assembled dry light adapter of Fig. 20, with a slip lock ring.

[0038] Figure 22 provides an overview of the light and fluid paths through the dry light adapter.

[0039] Figure 23 shows an optical cable aligned for coupling with a bulkhead adapter.

[0040] Figure 24 shows the coupled optical cable and bulkhead adapter of Fig. 23 as an assembled patient cable.

[0041] Figure 25 illustrates the patient cable of Fig. 24 with an overmold.

[0042] Figure 26 shows the dry light adapter of Fig. 20 aligned for coupling with the patient cable of Fig. 24.

[0043] Figure 27 is an illustration of the coupled dry light adapter and patient cable.

[0044] Figure 28 is a cross-section view of the assembly of Fig. 27.

[0045] Figure 29 shows a catheter/cannula aligned for coupling with the assembly of Fig. 27.

[0046] Figure 30 is a cross-section view of the radiation and fluid flows through the coupled catheter/cannula coupled and dry light adapter/patient cable assembly.

[0047] Figure 31 is an isometric view of the assembly of Fig. 30, with the overmold illustrated in Fig. 25.

Detailed Description

[0048] Throughout the following discussion, numerous references will be made regarding sources of electromagnetic radiation. It should be appreciated that the use of such terms is deemed to represent one or more sources configured to produce electromagnetic energy, particularly ultraviolet, visible, and/or infrared light. Such light may be coherent or incoherent. For example, a source of electromagnetic energy can include one or more of an incandescent light, a metal vapor lamp, an HID lamp, a fluorescent lamp, a laser, a gas laser, an LED laser, a light emitting diode, and/or any suitable light source. Such sources of electromagnetic energy can be configured to produce a plurality of different wavelengths, and can also include devices for distribution of electromagnetic energy (for example, fiber optic cables and their associated connectors). It should also be appreciated that such sources may utilize a variety of optical connectors, for example an SMA-905 optical fiber connector. A device of the inventive concept can be compatible with any suitable optical connector.

[0049] One should appreciate that the devices described herein provide a simple and direct means of irradiating blood and other body fluids, without the hazards associated with removal and return of fluid volumes and without the possibility of accidental transfer of potentially contaminated fluids between individuals. In addition, isolation of the optical interface from such fluids insures optimal and consistent transmission of light from the light source to the waveguide within the individual undergoing treatment, thereby providing consistent and reproducible irradiation. One should appreciate that the disclosed techniques provide many advantageous technical effects including providing an optical interface between a light/radiation source and an adapter device such that the light/radiation and an exogenous fluid can be simultaneously provided to a patient through the adapter device via a catheter while maintaining the optical interface isolated from the exogenous fluid flow, such that the light source can be simply and easily coupled and decoupled from the adapter device without requiring twisting of the adapter device or the light source fiber.

[0050] The following discussion provides many example embodiments of the inventive subject matter. Although each embodiment represents a single combination of inventive elements, the inventive subject matter is considered to include all possible combinations of the disclosed

elements. Thus if one embodiment comprises elements A, B, and C, and a second embodiment comprises elements B and D, then the inventive subject matter is also considered to include other remaining combinations of A, B, C, or D, even if not explicitly disclosed.

[0051] As used herein, and unless the context dictates otherwise, the term "coupled to" is intended to include both direct coupling (in which two elements that are coupled to each other contact each other) and indirect coupling (in which at least one additional element is located between the two elements). Therefore, the terms "coupled to" and "coupled with" are used synonymously.

[0052] Fundamentally, embodiments of the inventive concept can be systems and devices that support optical communication or insertion of a waveguide into a vascular and/or lymphatic of an individual and connection of the waveguide to a source of electromagnetic radiation (for example, ultraviolet or visible light) via an optical interface. In such embodiments, an adapter device such as a "T adapter" can serve to support a waveguide, a connector that supports a device for accessing a venous or lymphatic space (for example a needle, cannula, or catheter), and provide a connection that supports optical interfacing with a light source. An example of an adapter device **100** according to embodiments of the inventive subject matter is shown in **Figure 1**. The adapter device **100** can include a rotatable slip lock ring **110** that is compatible with commercially available Luer lock devices that are commonly utilized for venous access. The adapter device **100** can also include an exogenous fluid inlet **120**, which can permit administration of fluids (e.g., pharmaceutically acceptable fluids) to an individual during irradiation. Fluids (such as saline) can be used to prevent the formation of clots during treatment. Alternatively, therapeutic fluids (for example, vitamins, cofactors, and pharmaceuticals) may be administered during irradiation via the exogenous fluid inlet **120**. As shown in Fig. 1, embodiments of the adapter device **100** can include a modified tapered male terminus **130** and protrusions **140** configured to capture a rotatable locking ring, forming a "reverse" Luer lock or connector. As illustrated in Fig. 1, the protrusions **140** can be "wings" or "tabs". In other embodiments, the protrusions **140** can include threads that match with the threaded interior of a locking ring. The adapter device **100** can be made of medical grade polymers providing a suitable rigidity of construction. Examples of suitable medical grade polymers can include polyacrylates, polyamides, polycarbonates, and combinations thereof.

[0053] In embodiments, the taper angle α of tapered terminus **130** can be between 1 and 10 degrees from horizontal. In preferred embodiments, the taper angle α of tapered terminus **130** is between 2 and 6 degrees. In still more preferred embodiments, the taper angle α of the tapered terminus **130** is 3 degrees from horizontal.

[0054] For the purposes of reference, the section of the adapter device **100** having the slip lock ring **110** and opening to connect to a catheter can be generally referred to as the vascular access section **150**, and the section of the adapter device **100** between the vascular access section **150** and the tapered terminus **130** can be generally referred to as the central section **160**. In the embodiment illustrated in Fig 1, the protrusions **140** and the fluid inlet **120** are considered to be part of the central section **160**.

[0055] As shown in Fig. 1, the adapter device **100** includes lumens **170-173**. Lumens **170-172** are in fluid communication with one another. In embodiments, lumens **170** and **171** are the same lumen extending through the central section **160** and vascular access section **150**. The diameter of lumens **170-172** can be standard sizes, configured to fit exogenous fluid sources and/or the largest lumen diameters of attached catheters/cannula. Lumen **173** is aligned axially with, but fluidly isolated from, lumens **170, 171**.

[0056] In embodiments of the inventive concept the tapered male terminus **130** may be essentially solid or filled with solid material at final assembly. As will be described below, this “reverse Luer” connector can be utilized to connect with a light source. Use of a solid tapered male terminus **130** can advantageously isolate an optical interface of a device of the inventive concept from fluids, reducing light losses due to scattering and providing a consistent light intensity during use. Of course, it should be recognized that all medically acceptable couplings are also expressly contemplated for use herein. While it is generally preferred that the fluid (and other connectors) are Luer-type connectors, it should be appreciated that all other types of medically acceptable connectors, and particularly tapered connectors are also deemed suitable for use herein. Thus, the term “Luer” should not be understood to be limited to a specific type of connector, but as an example of medically-acceptable connectors (most typically tapered connector with retention and/or locking element).

[0057] As shown in **Figure 2**, the adapter device **100** of the inventive concept can include a waveguide **210** (for example, an optical fiber) and a sheath **220**. The waveguide **210** can be placed within the sheath **220**, and can be held in place using a biocompatible adhesive or filler, shown collectively as sheathed waveguide **300** in **Figure 3**. In such an embodiment the sheath **220** can serve to guide and protect the waveguide **210**. The sheath **220** can be constructed of any suitable material that provides the requisite strength and biocompatibility, for example heat shrink tubing or stainless steel.

[0058] In further contemplated aspects of the inventive subject matter, the waveguide **210** may be purpose-built to accommodate one or more additional functions, including resiliency and shatter proofing. For example, the waveguide **210** may be coated or otherwise at least partially coupled (*e.g.*, adhesively coupled) to a polymer sheath that helps retain potential fragments where the waveguide is exposed to undue forces. Alternatively, or additionally, the waveguide **210** may be further encased in a secondary sheath that is mechanically more resilient (*e.g.*, has higher modulus or hardness) than the polymer sheath. For example, a waveguide (with or without polymer sheath) may be at least partially encased in a metal tube to further protect the waveguide from mechanical impact. Thus, especially preferred exemplary waveguides may have a multi-layer configuration in which the waveguide **210** is surrounded by/bonded to a polymer sheath that is in turn disposed in a metal (*e.g.*, stainless steel) sheath. In alternative embodiments, it is contemplated that waveguide **210** can be incorporated into adapter device **100** without a sheath.

[0059] With respect to the waveguide fiber **210**, it should further be appreciated that in at least some preferred embodiments the ends of the waveguide **210** are sculpted for reduction of angular content of light, preferably to limit angular content to equal or less than 10%, more preferably to limit angular content to equal or less than 5%, and most preferably to limit angular content to equal or less than 2%.

[0060] Fig. 3 shows the positioning of the waveguide **210**, and sheath **220** (as sheathed waveguide **300**) within adapter device **100** according to embodiments of the inventive concept. As shown, the sheathed waveguide **300** can extend through a solid filler of the tapered male terminus **130** of the reverse Luer connector, protecting the optical interface at the end of the

waveguide **210** from fluid contact while providing a fixed and reproducible alignment with a connector from a light source. This can be accomplished for example, via injection molding of the waveguide/sheath combination **300** into the adapter device **100** or by insertion of the waveguide/sheath combination **300** through a through-hole provided in the tapered male terminus **130** followed by the application of an adhesive. The sheathed waveguide **300** may be polished at each end to facilitate light transmission and reception. For convenience, the assembly of the waveguide **210**, sheath **220**, and adapter device **100** can be referred to as a dry light adapter (“DLA”). In some embodiments of the inventive concept the dry light adapter **100** is a disposable, single use item.

[0061] As illustrated in Fig. 3, the sheathed waveguide **300** is disposed within lumen **173** and passes across the length of adapter device **100**, via lumens **171** and **170**, extending beyond the adapter device **100**. In embodiments, lumen **173** can be a “through hole” formed during the manufacturing of the adapter device **100**, to which the sheathed waveguide **300** is introduced. The sheathed waveguide **300** is adhered within the lumen **173** using suitable adhesives. Suitable methods of adapter device **100** having lumen **173** within are discussed in additional detail below.

[0062] In embodiments, the interface end of the waveguide **300** (i.e., the end of the waveguide **300** on the terminus side of the adapter device **100** and opposite the end extending beyond the vascular access side of the adapter device **100**) is flush or approximately flush with the end of the tapered terminus **173**. In embodiments, “approximately flush” refers to the end of waveguide **300** being within .010 inches (0.254 millimeters) of being completely flush with the end of tapered terminus **173**. In other embodiments, “approximately flush” refers to the end of waveguide **300** being within .005 inches (0.127 millimeters) of being completely flush with the end of tapered terminus **173**. In still other embodiments, “approximately flush” refers to the end of waveguide **300** being within .002 inches (.0508 millimeters) of being completely flush with the end of tapered terminus **173**.

[0063] To ensure that the sheathed waveguide **300** remains aligned within the adapter device **100**, the diameter of lumen **173** is preferably within .005 inches (0.127 millimeters) of the outer diameter of the sheathed waveguide **300**. Even more preferably, the difference between the diameter of lumen **173** and the outer diameter of sheathed waveguide **300** is less than or equal to

.003 inches (.0762 millimeters). For example, for a sheathed waveguide **300** having an outer diameter of .025 inches (.635 millimeters), lumen **173** preferably has a diameter of .028 inches (.7112 millimeters).

[0064] In alternative embodiments, the sheathed waveguide **300** can be injection molded into the tapered terminus **130**.

[0065] In embodiments of the inventive subject matter, adapter device **100** can include machine-readable indicia such as RFID tags, 2-dimensional barcodes, one-dimensional barcodes, etc. For example, the adapter device **100** illustrated in Fig. 3 includes an RFID tag **310**. The machine-readable indicia can include information about the adapter device **100**, which can include a unique adapter device identifier (e.g., for that specific adapter device **100**), a part number associated with the adapter device, a lot number associated with the adapter device, an expiration date of the adapter device, adapter device specifications (e.g., size, flow capacity, compatible catheters, etc.). The machine-readable indicia can be read by corresponding devices (e.g., RFID readers, scanners, NFC interfaces, etc.), and the information provided to a system at the health care provider site (or accessible to the health care provider site). The information can be used to track the adapter device **100** via a corresponding record that can indicate to the user (e.g., administering health care professional) whether the device has been previously used, whether it has expired, and/or provide any additional warnings or instructions regarding the device. The system can provide the information via a computer terminal accessible by the user, a mobile computing device, or any other output device enabling the output of visual and/or audio information to a user. The system can include one or more computing devices that include one or more processors, non-transitory computer-readable media storing system instructions, databases storing device data, and communication interfaces enabling the exchange of data between the various components (e.g., Internet, Ethernet, cellular, WiFi, USB, HDMI, wired communications, wireless communications, etc.). In embodiments, a first scan of the machine-readable indicia on an adapter device **100** can trigger the system to create a record entry of the adapter device **100**, which can include the unique identifier of the device. This record entry can be performed, for example, following a comparison of the adapter device **100**'s unique identifier against all present unique identifiers in the database, whereby the entry is created if no matching identifiers are found. Thereafter, a second scan of the same adapter device **100** triggers a similar

comparison. Because the unique identifier for the scanned adapter device **100** exists in the database, the match can trigger the system to return a result of “previously used” for the adapter device **100** or other indication that the adapter device **100** is not fit for use and that another adapter device **100** must be retrieved for use.

[0066] The reverse Luer connector of the adapter device **100** can permit attachment to and optical communication with a light source, for example via an optical cable fitted with a suitable optical connector. Such an optical cable can be reusable. Suitable optical connections include the commonly used SMA-905 connector, however it should be understood that an adapter device **100** can be configured to interface with a wide variety of suitable optical connectors. In some embodiments of the inventive concept a reverse female Luer to optical connector adapter may be interposed between an adapter device **100** and an optical connector, permitting a single type of adapter device **100** to connect with a variety of different light sources via the use of different adapters.

[0067] **Figure 4** shows an example of an optical connector adapter **400**. The optical connector adapter **400** illustrated in Fig. 4 is a reverse female Luer to optical connector, in this instance configured for an SMA-905 optical connector, along with a typical SMA-905 terminated optical cable **420** from a light source (not shown). The optical cable **420** can include a waveguide (e.g. optical fiber) of its own used to propagate the light or other radiation from the light source to the end of the optical cable **420** and, to the waveguide **210** of the adapter device **100** when aligned via the optical connector adapter **400**. Such an adapter **400** can include a slip lock ring **410**, such as a Luer locking ring, that permits it to be attached securely to the protrusions **140** of the adapter device **100**, such as the wings **140** of a reverse Luer connector of a dry light adapter **100** such as that shown in Figs. 1 and 3.

[0068] **Figure 5** illustrates how the slip lock ring **410**, the optical connector adapter **400** and the SMA-905 terminated optic cable **420** from a light source can be assembled. It should be appreciated that the use of an alternative optical connector adapters **400** (e.g., alternative reverse-female Luer adapters) readily permits a single type of adapter device **100** with a differently terminated optical cable **420**. Such an assembly of slip lock ring **410** (of the optical connector adapter **400**), optical connector adapter **400**, and source optical cable **420** can be referred to as a

patient cable **500**. Since patient cable **500** is not in contact with a patient or patient-associated fluids it may be re-used. Such a patient cable **500** may also include power sources and/or readers for machine readable indicia (such as RFID **310**) that may be incorporated into an adapter device **100**. In embodiments of the inventive concept, a portion of the terminus of the patient cable can be covered with an overmold **600**, as shown in **Figure 6**. As illustrated in Fig. 6, the slip lock ring **410** remains external to the overmold **600**. In these embodiments, it is contemplated that the overmold **600** can include a device (e.g., a battery or other power source) for energizing and/or obtaining data from machine readable indicia (such as RFID **310** illustrated in Fig. 3) included in an adapter device **100**. For example, in some embodiments of the inventive concept such an overmold **600** may include a device (e.g. battery or other power source) for energizing RFID **310**.

[0069] **Figure 7** shows an external view the alignment and orientation for coupling of an adapter device **100** to a patient cable **500**. The tapered terminus **130** of the adapter device **100** provides alignment of the polished end of the waveguide **210** (of sheathed waveguide **300**) with the optical fiber(s) of the patient cable **500**. A detailed illustration of this alignment is shown in **Figure 8**. Fig. 8 shows a cross section of adapter device **100** and patient cable **500** (i.e., the optical connector adapter **400** and its slip ring lock **410**, and the source optical cable **420**), aligned and oriented for coupling. As shown in Fig. 8, the source optical cable **420** includes an internal source waveguide **830** (e.g., an optical fiber), which is connected to a light source and/or radiation source (not shown).

[0070] The cross section of optical connector adapter **400** illustrated in Fig. 8 shows the internal threading of slip ring lock **410** that couples to the protrusions **140** of adapter device **100**. Fig 8 also shows a tapered internal cavity **810** that receives the tapered end **130** of the adapter device **100** and an internal interface cavity **820** that receives the male member of the source optical cable **420** (shown as already inserted in Fig. 8).

[0071] The taper of internal cavity **810** follows the taper of tapered end **130** such that the tapered end **130** fits into the cavity **810** securely without lateral movement. In embodiments, the fit of the tapered end **130** within the cavity **810** is such that the tapered end **130** is held in place via a friction fit. While it is contemplated that, in alternative embodiments of the adapter device **100**,

the tapered end **130** and cavity **810** can include corresponding threaded protrusions to enable a screw fit, preferred embodiments of the inventive subject matter do not include the threaded coupling between the tapered end **130** and cavity **810**. Thus, the tapered end **130** and cavity **810** can be coupled and decoupled without requiring a torsion or rotational force to be applied to one or more of the adapter device **100** and the patient cable **500**.

[0072] The internal interface cavity **820** can be shaped to fit standard optical cable fittings. In the example illustrated in Fig. 8, the interface cavity **820** is configured to fit the male member of the optical cable **420** according to the SMA-905 standard. The internal cavity **810** and the internal interface cavity **820** are shaped and aligned such that the end of waveguide **210** is optically aligned with the source waveguide **830** when the adapter device **100** is coupled with the patient cable **500**, as shown in **Figure 9**. For the purposes of clarity, the combined adapter device **100** and patient cable **500** are referred to collectively as assembly **900**.

[0073] Fig. 9 illustrates the adapter device **100** coupled with the patient cable **500** such that tapered terminus **130** is introduced within cavity **810**, and protrusions **140** are engaged with the threads of slip ring lock **410**. As shown in Fig. 9, the end of the waveguide **210** is brought into optical alignment with the end of the source waveguide **830** at optical interface point **900**. The optical interface point **910** can be at the shared boundary of the cavities **810** and **820**. Optical alignment can be considered generally to be a distance, angle difference, or combination of distance and angle difference between the waveguide **210** and the source waveguide **830** such that light loss remains acceptable during the transfer between source waveguide **830** and waveguide **210**. In embodiments, the cavities **810,820** of optical connector adapter **400** are configured to receive the tapered end **130** and source cable **420**, respectively, such that the ends of waveguide **210** and source waveguide **830** are brought within .003 inches (.0762 millimeters) of one another, and preferably between .001 to .003 inches (.0254 to .0762 millimeters) of one another. Additionally and/or alternatively, the cavities **810,820** of optical connector adapter **400** are configured to receive the tapered end **130** and source cable **420**, respectively, such that the ends of waveguide **210** and source waveguide **830** are brought within (i.e. less than or equal to) 10 degrees of parallel to one another. In other words, the long axis of the waveguide **210** and long axis of the source waveguide **830** are not offset from each other by more than 10 degrees. In embodiments, the ends of waveguide **210** and source waveguide **830** are brought within (i.e.

less than or equal to) 5 degrees of parallel to one another. In still other embodiments, the ends of waveguide **210** and source waveguide **830** are brought within (i.e. less than or equal to) 2 degrees of parallel to one another.

[0074] It should be appreciated that, in embodiments of the inventive concept the optical interface (at optical interface point **910**) between the waveguide **210** of the adapter device **100** and the optical fiber(s) of the patient cable **500** is isolated from patient associated fluids and does not require the use of intervening active optics (for example, a lens) for efficient light transfer. This lack of active optics simplifies design and manufacturing in addition to reducing loss of light via diffraction and scatter.

[0075] As described above, an adapter device **100** can include a slip lock ring **110** (e.g., a Luer locking ring) for attachment of a device that permits access to venous and/or lymphatic spaces. An example of this is shown in **Figure 10**, which illustrates how a catheter or cannula **1000** with wings **1100** for coupling to Luer lock devices may be added to assembly **900**.

[0076] It should be appreciated that, when intended for use in applications involving insertion into a catheter or cannula, the dimensions of the lumen of the cannula within which the sheathed waveguide is located drives the selection of the sheath and waveguide components of the sheathed waveguide to be used. As noted above, in embodiments it can be desirable to provide a flow of a pharmacologically acceptable fluid through a lumen of a catheter or cannula that is also occupied by the sheathed waveguide of the inventive concept. The dimensions of such catheters and cannulas is dependent on their intended use and the dimensions of the vascular space into which they are inserted. For example, a catheter intended for pediatric use in a peripheral vein can be a 22 gauge catheter, wherein a catheter used in veterinary practice or in emergency situations can be as large as 18 gauge. The waveguides and sheaths for use in such catheters can be selected so as to permit sufficient residual volume between the sheath of the waveguide and the inner wall of the lumen of the catheter or cannula to permit fluid flow. For example, the minimum flow rate through a 24 gauge catheter can be selected as a minimum desirable flow rate through a catheter or cannula with a lumen occupied by a sheathed waveguide. This flow rate can be used in combination with the size of the catheter or cannula to be used to determine the maximum acceptable diameter of the sheathed waveguide (and hence the sheath), which in turn

can be used to determine the maximum acceptable diameter of the optical fiber. Examples of such calculations performed for waveguides for use in 18, 20, and 22 gauge intravenous catheters are provided in **Figure 11**.

[0077] In embodiments, it is contemplated that the maximum diameter body of adapter device **100** (excluding slip lock ring **110**) is less than or equal to the maximum diameter of the particular catheter to be used. Thus, in these embodiments, the diameter of the slip lock ring **110** is the largest diameter of the adapter device **100** as a whole.

[0078] It should be appreciated that lumen **173** of the inventive concept can be continuous or discontinuous (i.e. segmented). **Figure 12** shows an adapter device **100a**, which is a variation of the adapter device **100** of Fig. 1. It should be noted that the labeled features of adapter device **100a** having the “-a” suffix correspond to those same features in adapter device **100** of Fig. 1. For example, lumens **170a-173a** of Fig. 12 correspond to lumens **170-173** of Fig. 1, and so on. Device adapter **100a** is shown in Fig. 12 as having tab **140a** for engagement with slip lock ring **410** of the patient cable **500**. While only one tab **140a** is visible in Fig. 12, it should be noted that adapter device **100a** has a mirroring tab **140a** on the opposite side of the device body.

[0079] As shown in Fig. 12, adapter device **100a** includes a segmented lumen **173a**. For the purposes of illustrating the segmenting nature of lumen **173a**, the lumen is shown separated into three sections whose alignment is skewed to exaggerate the segmentation. However, it is understood that the segmented sections of lumen **173a** line up to form a uniform lumen **173a** through which a sheathed waveguide **300** is introduced. Additionally, while not shown in Fig. 12, the adapter device **100a** also includes a slip lock ring used to secure a catheter or cannula, in the same manner of the slip lock ring **110** of adapter device **100** shown in Fig. 1.

[0080] The segmented lumen **173a** of the inventive concept can include a set of contiguous “shutoffs” or channels **1201,1202,1203** arranged in a linear series. As shown generally in Fig. 12 and in greater in **Figure 13**, at least a portion of these channels can be exposed. Such channels **1201,1202,1203** can be in rotated radially relative to one another, so that at the intersection of such rotated channels a complete encirclement occurs around the passageway (i.e. lumen **173a**) thus defined. In embodiments of the inventive concept, lumen **173a** can comprise a primary channel **1301** having an at least partially semicircular cross section arranged in a linear

fashion with a secondary channel **1302** that has an at least partially semicircular cross section and is radially rotated by about 180 degrees relative to the primary channel, such that the region of the intersection between the primary and secondary channels **1301,1302** is circular or approximately circular. In embodiments, the lumen **173a** can include additional channels offset from one another such that the region of intersection of all of the channels is circular or approximately circular. For example, three channels offset by approximately 120 degrees, four channels offset by approximately 90 degrees, etc.

[0081] It is contemplated that exposed regions of such segmented channels can be filled or partially filled during the manufacturing process. In embodiments, the sheathed waveguide **300** can be inserted into the formed lumen **173a**, and the channels filled or partially filled with the waveguide **300** in place.

[0082] **Figure 14** provides a detailed view of the adapter device **100a**, as viewed from the vascular access end. As shown in Fig. 14, the lumen **173a** is formed by the intersection of channels **1201,1202,1203**. As channel **1203** is aligned with channel **1201**, channel **1203** would be “behind” channel **1201** from the perspective of Fig. 14.

[0083] Returning to Fig. 12, the adapter device **100a** is shown having an upper wing **1210** and lower wing **1220**, each extending from opposite sides of the central section of device **100a**.

[0084] The wings **1210,1220** are arranged on adapter device **100a** such that, when the tapered end **130a** is inserted into the space **810**, and the slip lock ring **410** is fully secured onto the adapter **100a** without interference from the wings **1210,1220**. Also, the purpose of the wings **1210** and **1220** are three-fold: they provide the healthcare provider with surfaces by which the healthcare provider can hold steady the adapter device **100a** when inserting into the catheter and spinning the slip lock ring to lock the catheter **1000** and adapter device **100a** in place; they likewise provide the gripping surface necessary to hold adapter device **100a** steady and in place, and to prevent the adapter device **100a** from spinning or pushing/torquing the catheter when attaching the patient cable **500** and locking it to the patient cable **500** with the patient cable’s slip lock ring **410**; and wings **1210,1220** provide a surface for securing the adapter device **100a** to the patient’s arm (via taping or other adhesive strip), once the whole assembly has placed together and within the patient’s vein, providing strain relief. In embodiments, wings **1210,1220** are a

part of the single injection mold, and are of the same material as the rest of the body of the adapter device **100a**, which is typically a medical grade polymer that is suitably stiff or rigid. Suitably stiff or rigid medical grade polymers allow the wings **1210,1200** and adapter device **100a** generally to maintain the optical alignment of the waveguide **300** with the source waveguide **830** within the combined assembly for optimum optical coupling. In another embodiment, the wings **1210** and **1220** are overmolded onto the adapter device body, wherein the material of the wings **1210,1220** is a semi-rigid or flexible material. Examples of suitable semi-rigid or flexible materials can include silicon rubber, polyurethane, latex, nitrile, etc. In these embodiments, semi-rigid or flexible wings **1210,1220** providing the holding/grasping support required, but are able to conform to the shape of the patient's arm when the assembly is in place, increasing comfort and providing strain relief. In other embodiments, wings **1210,1220** can be added to adapter device **100a** via a sleeve that is slipped over the body of the device adapter **100a**, whereby the sleeve seats in place in the middle of the device adapter body at the corresponding location. In still other embodiments, the wings **1210,1220** can each comprise as two halves of a sleeve that can be assembled around the body of the adapter device **100a**, and then glued together to capture the adapter device body. It is contemplated that the material, regardless of the method used to apply the wings **1210,1220** would be silicon rubber...in all cases, the wings could be secured using a close-fit, adhesive, ultrasonic weld, RF weld, etc, as is common in the art. In embodiments where the wings **1210,1220** are not part of the single injection mold, the wings **1210,1220** can be secured to adapter body **100a** via methods and techniques such as close-fit, adhesive, ultrasonic welding, RF welding, etc.

[0085] In alternative embodiments of the inventive concept, an adapter device can receive a standard or conventional optical adapter. An example of such an embodiment is shown in **Figure 15**. In these embodiments of the inventive concept, waveguide **210** for use in irradiation of blood may be adapted for use in a standard optical connector **1500** (for example, a standard SMA-905 connector) through the use of a sheath **220** and an O-ring **1530**. Such a standard optical connector **1500** can include a mating end **1510** and a ferrule **1520** that provide connection with a suitably terminated optical cable from a light source. It should be appreciated that any suitable standard optical connector **1500** may be utilized.

[0086] As shown in **Figure 16** (and as illustrated in Fig. 3), the waveguide **210** can be secured within a sheath **220** to form sheathed waveguide **300**. As described above, this can provide both protection for the waveguide **210** and the rigidity necessary for safe handling and accurate alignment. The waveguide **210** may be secured within the sheath **220** via an adhesive or simply held in place by close mechanical tolerances. The sheath **220** may be of any material with suitable mechanical properties and biocompatibility, for example stainless steel or heat shrink tubing.

[0087] As shown in **Figure 17**, the O-ring **1530** can be slipped over the sheath **220** during assembly, positioning the O-ring **1530** to act as a seal against the mating end of a standard optical connector **1500**. The O-ring **1530** may be constructed of any suitably pliant and biocompatible material, such as silicon rubber.

[0088] **Figure 18** shows a waveguide/sheath assembly **300** inserted into a standard optical connector **1500**, with the O-ring **1530** positioned against the mating end of the optical connector **1500**. The outer diameter of the sheath **220** of sheathed waveguide **300** and the inner diameter of the O-ring **1530** can be selected to provide a fluid-tight seal between the outer surface of the sheath **220**, the mating surface of a standard optical connector **1500**, and the surface of the O-ring **1530**. This advantageously prevents fluids from reaching the optical interface between the waveguide and the light source. In embodiments of the inventive concept this assembly of a SMA-905 connector **1500**, sheathed waveguide **300**, and O-ring **1530** is referred to as a SWO assembly **1800**.

[0089] As shown in **Figure 19**, in some embodiments of the inventive concept a SWO **1800** (or analogous assembly incorporating other standard optical connectors) can be coupled to an adapter device **1900**. As with adapter device **100** described above, such adapter device **1900** can include an exogenous fluid inlet **1910**. Such an adapter device **1900** can also include features that permit seating of the O-ring **1530** of a SWO assembly **1800**. In the example shown in Fig. 19, adapter device **1900** includes initial recess **1920** and secondary recess **1940** portions, connected by an interposing recess transition **1930**. The secondary recess **1940** can have a smaller internal diameter than the initial recess **1920**, and in such embodiments the recess

transition **1930** can be tapered or approximately conical. This produces a seating surface for the O-ring **1530** of the SWO **1800** upon assembly.

[0090] As shown in **Figure 20**, a SWO **1800** and adapter device **1900** can be coupled to form a “dry light adapter” **2000** with functions similar to the dry light adapter described above. It should be noted that the O-ring **1530** can form a fluid-tight seal with the interior walls of the recess transition **1930**, providing further protection of the optical interface from fluids. In some embodiments of the inventive concept the SWO **1800** (or analogous device) can be secured to an adapter device **1900** using a medical grade adhesive. As shown in **Figure 21**, dry light adapter **2000** can include a slip lock ring **2100** (e.g., a Luer locking ring), which permits attachment to a wide variety of medical devices used to access the venous and/or lymphatic system. Such a dry light adapter **2000** can also include machine readable indicia, as described above. As with the adapter device **100** described above, in some embodiments of the inventive concept dry light adapter **2000** can be a disposable and/or single use device.

[0091] Light and fluid paths through dry light adapter **2000** are shown in **Figure 22**.

Electromagnetic (EM) radiation from an EM or light source enters at the waveguide **300** at the interface with an optical connector. Fluids (such as saline, vitamins, cofactors, dyes, and/or pharmaceuticals) can enter through an exogenous fluid inlet. EM radiation exits from the waveguide **300** at the terminus opposing the optical connector, while exogenous fluids flow along the outside of the waveguide/sheath assembly, advantageously reducing clotting and preventing debris from entering the dry light adapter **2000**. It should be noted that, despite their active introduction into the dry light adapter **2000**, the optical interface is not exposed to fluids. In the illustrated example of Fig. 22, the dry light adapter **2000** is shown including RFID tag **2200**.

[0092] The use of a standard optical connector in dry light adapter **2000** permits the use of conventional fiber optic cables without the need for specialized adapters. An example of this is shown in **Figure 23**, which depicts a typical optical cable **2300** of the art that includes a fiber optic cable from a source that terminates in a standard SMA-905 connector that can be combined with a standard SMA-905 bulkhead adapter **2310**. The combination of these off the shelf components is shown in **Figure 24**, and can constitute patient cable **2400** of the inventive

concept. As with patient cable **500** described above, such a patient cable **2400** can be a reusable component.

[0093] As shown in **Figure 25**, a terminus of patient cable **2400** (including the optical connector and at least part of the bulkhead adapter) can be enclosed in an overmold **2500**. As noted for patient cable **500** above, such an overmold can incorporate an energizer and/or reader for machine readable indicia that can be incorporated into a dry light adapter **2000**.

[0094] **Figure 26** depicts how a dry light adapter **2000** can be aligned for assembly with a patient cable **2400** in some embodiments of the inventive concept. Such an embodiment permits mating of a standard optical connector incorporated into dry light adapter **2000** with a standard optical connector that forms part of the terminus of a fiber optic cable from a light source via an off the shelf bulkhead connector, without the need for intervening active optics (for example, a lens). This provides an inexpensive, reliable, and efficient connection that is not subject to light loss due to diffraction and scatter. The ferrules of such optical connectors can provide optical losses of 2dB of attenuation or less if an overmold is present. In addition, the optical interface is isolated from fluids that may be involved in a treatment process. **Figure 27** depicts an assembled exemplary dry light adapter **2000** and exemplary patient cable **2400**, collectively referred to as assembly **2700**.

[0095] Alignment of components and flow of electromagnetic energy through assembly **2700** is depicted in **Figure 28**, which shows a cross-section view of such an assembly **2700**.

[0096] Electromagnetic radiation (for example, UV and/or visible light) is supplied by the source optic cable **2810** (within optical cable **2300**) and exits from the waveguide **300**. The optical interface **2800** between the waveguide **300** and the optical fiber(s) **2810** of the source fiber optic **2300** is within the bulkhead adapter **2310**, which provides precise alignment. Use of an O-ring **1530** that seats tightly against an interior surface of the adapter device **1900** and an exterior surface of a SMA connector **1800** associated with the dry light adapter **2000** prevents fluids from reaching the optical interface **2800**, preventing contamination of patient cable **2400** and keeping optical performance consistent during use.

[0097] As noted above, dry light adapter **2000** can incorporate features that permit attachment of a variety of Luer lock compatible devices for access to venous and/or lymphatic spaces. As shown in **Figure 29**, a catheter or cannula **2900** with wings **2910** (such as those described above associated with Figs. 10-11) suitable for interfacing with a Luer lock ring can be aligned for attachment.

[0098] **Figure 30** shows a cross section of assembly **2700** with an attached catheter or cannula **2900** that permits access of the waveguide **300** to a venous and/or lymphatic space.

Electromagnetic energy from the source is transmitted through the waveguide **300**, which can extend partially into the catheter/cannula **2900**, and can then exit the waveguide **300** and enter a venous or lymphatic space of an individual undergoing treatment. Exogenous fluid (such as saline) can be supplied through the exogenous fluid inlet **1910**, where it can exit through the catheter/cannula **2900** and keep the device free of clots and debris. As noted above, such exogenous fluids may also be selected for therapeutic effect. Similarly, **Figure 31** shows an embodiment of the inventive concept that includes assembly **2900** with an overmold **2500**. Such an overmold may be used to house an energizer or reader for machine readable indicia (for example, an RFID tag) that is incorporated into disposable or single-use portions of the device.

[0099] It should be apparent to those skilled in the art that many more modifications besides those already described are possible without departing from the inventive concepts herein. The inventive subject matter, therefore, is not to be restricted except in the spirit of the appended claims. Moreover, in interpreting both the specification and the claims, all terms should be interpreted in the broadest possible manner consistent with the context. In particular, the terms “comprises” and “comprising” should be interpreted as referring to elements, components, or steps in a non-exclusive manner, indicating that the referenced elements, components, or steps may be present, or utilized, or combined with other elements, components, or steps that are not expressly referenced. Where the specification claims refers to at least one of something selected from the group consisting of A, B, C and N, the text should be interpreted as requiring only one element from the group, not A plus N, or B plus N, etc.

01.05.2015

CLAIMS

What is claimed is:

1. A system for irradiation of a vascular space and its contents, comprising:
 - an adapter device (100) comprising:
 - a central section (160) having a first end and second end, the central section (160) comprising:
 - a central lumen (171) extending from the first end to the second end;
 - an engaging protrusion (140) at the second end; and
 - a fluid port (120) configured to introduce an exogenous fluid into the central lumen (171);
 - a vascular access portion (150) extending from the first end of the central section (160), comprising an access lumen (170) in fluid communication with the central lumen (171);
 - a tapered end (130) extending from the second end of the central section (160), the tapered end (130) including a waveguide lumen (173) aligned with the central lumen (171) and the access lumen (170) and wherein the waveguide lumen (173) is fluidly isolated from the central lumen (171); and
 - a waveguide (210) housed within the waveguide lumen (173), wherein the waveguide (210) includes a first end having a first face that is approximately flush with the tapered end (130) and extends through the central lumen (171) and the access lumen (170); and
 - an optical connector adapter (400) having an adapter end and an interface end comprising:
 - a tapered cavity (810) extending inwardly from the adapter end, the tapered cavity configured to receive the tapered end (130) of the adapter device (100),
 - an interface cavity (820) extending inwardly from the interface end, the interface cavity (820) configured to receive a source interface (420) including a source waveguide (830) having an engagement end comprising a second face, wherein the interface cavity (820) is aligned with the tapered cavity (810), and wherein the tapered end (130) is configured to provide alignment of the first end of the waveguide (210) relative to the tapered cavity (810) such that the first end of the waveguide (210) of an inserted tapered end (130) is optically aligned with the engagement end of the source waveguide (830) of an

01.05.2015

- inserted source interface (420) such that the first face of the waveguide (210) is within 0.0762 mm of the second face of the engagement end of the source waveguide (830) and the first face of the waveguide (210) and the second face of the engagement end of the source waveguide (830) are within 10° of parallel to one another when the tapered cavity (810) is engaged with the tapered end (130) of the adapter device (100); and
- a slip lock ring (410) rotatably coupled to the adapter end, the slip lock ring (410) including internal threading configured to engage with the engaging protrusion (140) of the second end of the central section (160).
2. The system of claim 1, wherein the waveguide (210) comprises an optical fiber.
 3. The system of claims 1 or 2, wherein the exogenous fluid comprises a pharmaceutically acceptable fluid.
 4. The system of any of claims 1 through 3, wherein the internal threading of the slip lock ring (410) and the engaging protrusion (140) of the central section comprise a Luer lock fitting arrangement.
 5. The system of any of claims 1 through 4, wherein the source waveguide (830) comprises a second optical fiber connected to a radiation source.
 6. The system of any of claims 1 through 5, wherein the interface end further comprises a standardized female interface configured to receive a standardized male fiber-optic cable interface
 7. The system of claim 6, wherein the standardized male fiber-optic cable interface comprises an SMA-905 connector interface.
 8. The system of any of claims 1 through 7, wherein the engaging protrusion (140) comprises at least one of threading or an engagement tab.
 9. The system of any of claims 1 through 8, wherein the vascular access portion (150) is configured connect with a catheter (1000).
 10. The system of claim 9, wherein the waveguide (300) extends at least partially into the catheter (1000).

01.05.2015

11. The system of any of claims 1 through 10, wherein the adapter device (100) further includes machine readable indicia.
12. The system of claim 11, wherein the machine readable indicia includes at least one of a unique identifier of the adapter device, a part number of the adapter device, a lot number of the adapter device, and an expiration date of the adapter device.
13. The system of claims 11 or 12, wherein the machine readable indicia comprises at least one of a one dimensional barcode, a two dimensional barcode, an RFID device (310), and an optical RFID or OPID device.
14. The system of any of claims 1 through 13, wherein the first end of the waveguide (300) of an inserted tapered end (130) optically aligned with the engagement end of the source waveguide (830) of an inserted source interface (420) further comprises the first end of the waveguide (300) aligned at an angle less than or equal to 10 degrees relative to the engagement end of the source waveguide (830).
15. The system of any of claims 1 through 14, wherein the first end of the waveguide (300) of an inserted tapered end (130) optically aligned with the engagement end of the source waveguide (830) of an inserted source interface (420) further comprises the first end of the waveguide (300) aligned at an angle less than or equal to 5 degrees relative to the engagement end of the source waveguide (830).
16. The system of any of claims 1 through 15, wherein the first end of the waveguide (300) of an inserted tapered end (130) optically aligned with the engagement end of the source waveguide (830) of an inserted source interface (420) further comprises the first end of the waveguide (300) aligned at an angle less than or equal to 2 degrees relative to the engagement end of the source waveguide (830).
17. The system of any of claims 1 through 16, wherein the first end of the waveguide (300) of an inserted tapered end (130) optically aligned with the engagement end of the source waveguide (830) of an inserted source interface (420) further comprises the first end of the waveguide (300) aligned at a distance of less than or equal to .003 inches (.0762 millimeters) from the engagement end of the source waveguide (830).

18. The system of any of claims 1 through 17, wherein the first end of the waveguide (300) of an inserted tapered end (130) optically aligned with the engagement end of the source waveguide (830) of an inserted source interface (420) further comprises the first end of the waveguide (300) aligned at a distance of less than or equal to .003 inches (.0762 millimeters) and greater than or equal to .001 inches (.0254 millimeters) from the engagement end of the source waveguide (830).

19. The system of any of claims 1 through 18, wherein the waveguide lumen (173) comprises a segmented lumen (173a).