

Light Diffusing Devices for Use in Photoimmunotherapy

CLAIM OF BENEFIT OF FILING DATE

[0001] This application is a continuation-in-part of U.S. Patent Application
5 Serial No. 15/790,110 titled: "Frontal Light Diffusing Device for Use in
Photoimmunotherapy" and U.S. Patent Application Serial No. 15/790,113
titled: "Cylindrical Light Diffusing Device for Use in Photoimmunotherapy" and
International Patent Application No. PCT/UC2017/057787 titled: "Light
Diffusing Devices for Use in Photoimmunotherapy", all filed on October 23,
10 2017 and claim the benefit of the filing date of U.S. Provisional Application
Serial No. 62/412,606 titled: "Light Diffusing Device for Use in
Photoimmunotherapy" filed on October 25, 2016 and U.S. Provisional
Application Serial No. 62/529,507 titled: "Frontal Light Diffusing Device for
Use in Photoimmunotherapy" filed on July 7, 2017, which are incorporated
15 herein by reference for all purposes.

FIELD OF INVENTION

[0002] The present invention relates to a medical device for performing
photoimmunotherapy ("PIT"), photodynamic therapy ("PDT") or other light
20 activated treatments upon tissue of an organism, cellular or acellular
organisms and methods of using such medical device in PIT, PDT or other
light activated therapies. More particularly, the invention is a fiber optic
diffuser device to deliver light in a desired illumination pattern and wavelength
for PIT, PDT or other light therapies to an area under treatment.

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BACKGROUND OF THE INVENTION

[0003] PIT, PDT and other light activated therapies have been used to
treat various maladies and diseases. PIT and PDT and other light activated
therapies often involve the use of an exogenous or endogenous
30 photosensitizing agent or substance that is activated by electromagnetic
radiation (e.g., light such as laser light, LED light, etc.). PIT is based on a new
drug system that consists of a cancer targeting monoclonal antibody

conjugated to a photoactivatable molecule. The targeting agent can include other moieties such as ligands, viral capsid, peptides, liposomes, nanoparticles, etc. This drug conjugate is not pharmacologically active until the conjugate is bound to the cancer cells and gains anticancer activity upon light-mediated activation at the tumor site. Tumor targeting and context precision activation of the drug provides exquisite cancer specificity and permits rapid cancer cell killing without damage to the surrounding healthy tissues. Anticancer activity of PIT is highly effective and it works with multiple types of monoclonal antibodies and other targeting moieties, thus the platform enables the targeting of a broad range of cancer antigens and tumor types. It should be noted that the present invention is not limited to targeting tumor sites. Instead, the present invention can also be used to target other cellular and acellular organisms including bacteria, fungi, viruses, prions, etc. in order to treat or prevent disease(s).

[0004] The basic requirements for PIT and/or PDT light sources are to match the activation spectrum of the exogenous or endogenous photosensitizer (usually the wavelength of peak absorbance) and to generate adequate power at this wavelength, deliverable to the target tissue ergonomically and with high efficiency. Typically, 1–5 W of usable power are required in the 630–850 nm range at irradiances of up to several hundred mW cm⁻² in order to deliver treatments in tens of minutes. In addition, the sources must be reliable in the clinical environment and be cost-effective.

[0005] For illumination of the area to be treated (“treatment area”), usually cylindrical and frontal (superficial) diffusers, sometimes also called “micro lens diffusers”, are generally used. The fiber optic cylindrical (side firing) and superficial (front firing) diffusers consist of multimode fiber assemblies with a round core/cladding structure from 50-1000um core diameter with attached diffusing section that can be connected directly to a light source, for instance by means of an optical connector.

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I. Conventional Cylindrical Light Diffusers

[0006] FIG. 1 shows an example of a typical commercially available cylindrical light diffusing device 100 comprising an optical connector 10 connecting to a light source (not shown) on one end, an optical fiber 12 and a cylindrical diffuser 16 on the other end. During operation, the optical fiber 12 is in light communication with the cylindrical diffuser 16 causing the cylindrical diffuser 16 to out-couple light in a longitudinally radial-symmetric irradiance distribution 18 across the longitudinal length 19 of the cylindrical diffuser 16.

[0007] A map of the irradiance at a vertical (i.e., latitudinal) cross-section (shown as "11" in FIG. 1) through the core of the optical fiber 12 taken just before the optical fiber 12 enters the cylindrical diffuser 16 is shown in FIG. 2. In this exemplary embodiment, the light source used is a 690 nm laser with 1 Watt launch power and this power was adjusted until the irradiance 18 measured at the center 17 of the longitudinal length of the diffuser 16 was 150 mW/cm². This measurement is taken 0.75 mm from the central axis of the stated location of the diffuser 16. The optical fiber 12 from the light source leading up to the cylindrical diffuser 16 ("lead fiber") is 2 meters long. The optical fiber 12 has a 700 µm outer diameter ("OD") glass core and a 740 µm OD cladding. During operation, the optical fiber 12 is filled with laser light having an angular distribution of a numerical aperture ("NA") of 0.22. The cross-section 11 was taken after 2 meter lead fiber (12). The associated irradiance distribution graphs of FIG. 2 taken from vertical and horizontal cross sections through the center of the map of the irradiance show that there is poor spatial uniformity of the irradiance distribution in the core of the optical fiber 12 ("core irradiance distribution"). The large values in the center of the graphs show that there is significantly higher irradiance in the center of the fiber core than near its edges. The graph on the top of FIG. 2 shows the irradiance distribution of the horizontal cross section while the graph on the right side of FIG. 2 shows the irradiance distribution of the vertical cross section. As shown in FIG. 2, both graphs have two axes: one axis shows width (e.g., diameter) in mm and the other axis shows irradiance in Watt/cm².

[0008] Not only does the core irradiance distribution of the optical fiber 12 have poor spatial uniformity, the out-coupled longitudinally radially-symmetric irradiance distribution along the outer surface of irradiance emitting section of the cylindrical diffuser 16 ("diffusing irradiance distribution") also demonstrates
5 poor spatial uniformity leading to a non-ideal irradiance distribution as shown in FIG. 3. This uneven irradiance distribution is undesirable because the irradiance uniformity would not satisfy the needs of a proper "dosimetry", meaning the correct irradiance in light power/surface area for an optimal medical treatment efficacy. In FIG. 3, the horizontal axis shows the
10 longitudinal length (in mm) used to measure the length 19 of the cylindrical diffuser 16 and the vertical axis shows the out-coupled irradiance at the surface of the cylindrical diffuser 16 measured in Watts/cm² at a distance 0.75 mm from the central axis.

[0009] FIG. 4 is an example for a typical commercially available cylindrical
15 light diffusing device 200 comprising an optical connector 20 connecting to a light source (not shown) on one end, an optical fiber 22 and a cylindrical diffuser 26 on the other end. During operation, the optical fiber 22 is in light communication with a mode mixer 24 and the cylindrical diffuser 26 causing the cylindrical diffuser 26 to out-couple light in a longitudinally radial-
20 symmetric irradiance distribution 28 across the longitudinal length 29 of the cylindrical diffuser 26.

[0010] FIG. 5 shows a map of the irradiance at a vertical cross-section (shown as "21" in FIG. 4) through the core of the optical fiber 22 taken just before the optical fiber 22 enters the cylindrical diffuser 26. In this exemplary
25 embodiment, the light source used is a 690 nm laser with 1 Watt launch power and this power was adjusted until the irradiance 28 measured at the center 27 of the longitudinal length of the diffuser 26 was 150 mW/cm². This measurement is taken 0.75 mm from the central axis of the stated location of the diffuser 26. The optical fiber 22 from the light source leading up to the
30 cylindrical diffuser 26 ("lead fiber") is 2 meters long. The optical fiber 22 has a 700 µm OD glass core and a 740 µm OD cladding. During operation, the optical fiber 22 is filled with laser light having an angular distribution of a

numerical aperture ("NA") of 0.22. The cross-section 21 was taken after 2 meter lead fiber (22). Unlike FIG. 2, the associated irradiance distribution graphs shown in FIG. 5 taken from vertical and horizontal cross sections through the center of the map of the irradiance show that when a mode mixer (24) is used with the optical fiber 22, a "top hat" irradiance distribution profile is achieved (i.e., variation of the irradiance distribution of the entire cross-section is less than +/- 20% of the average irradiance), indicating a high degree of uniformity of the irradiance distribution in the core of the fiber 22 (e.g. optimal core irradiance distribution). Similar to FIG. 2, the graph on the top of FIG. 5 shows the irradiance distribution of the horizontal cross section while the graph on the right side of FIG. 5 shows the irradiance distribution of the vertical cross section. As shown in FIG. 5, both graphs have two axes: one axis shows width (e.g., diameter) in mm and the other axis shows irradiance in Watt/cm².

[0011] In contrast to the graph shown in FIG. 3, the out-coupled longitudinally radially-symmetric irradiance distribution along the outer surface of irradiance emitting section of the cylindrical diffuser 26 (e.g., the diffusing irradiance distribution) shows spatial uniformity leading to an optimal "top hat" diffusing irradiance distribution as shown in FIG. 6. FIG. 6 shows that the variation of the out-coupled irradiance distribution should be a "top hat" with less than +/- 20% of the average (" I_0 ") optical irradiance for a cylindrical diffuser in terms of the radially emitted irradiance distribution (e.g., optimal diffusing irradiance distribution). The horizontal axis of FIG. 6 shows longitudinal length in mm and the horizontal arrow indicates the length 29 of the cylindrical diffuser 26. The vertical axis of FIG. 6 shows the out-coupled irradiance at the surface of the cylindrical diffuser 26 measured in Watts/cm² at a distance 0.75 mm from the central axis.

[0012] As shown above, in order to achieve the "top hat" diffusing irradiance distribution for a conventional cylindrical diffuser, optimal mode mixing (e.g., with an effective mode mixer) in the optical fiber is required. The mode mixer 24 shown in FIG. 4 is created in the optical fiber 22 by a series of five consecutive alternating tight radius bends. Another conventional mode

mixing method (not shown) is to wrap the optical fiber 22 tightly multiple times around an object (e.g. a mandrel). These popular forms of mode mixing create spatial uniformity at the expense of increased transmission losses, often resulting in the losses of 50% or more. Additionally, these techniques
5 also create stress points within the optical fiber 22. Applying stress to an optical fiber is problematic because it can lead to irreversible damage to such optical fiber, as the micro-bending pushes the optical fiber bending force to the maximum fatigue limit of the glass fiber. Furthermore, these cylindrical
diffuser fiber assemblies are sometimes used with optical power that can
10 exceed 1 Watt, which lowers the maximum fatigue limits even more due to thermal heating from the light lost from the fiber core. This thermal heating issue can adversely impact both glass and polymer materials. Thermally destroyed mode mixers have occurred in practice, which represents one major driver to substitute these conventional mode mixers with an alternative
15 according to the described invention.

[0013] Please note that an effective mode mixer *by itself* is insufficient to achieve the “top hat” diffusing irradiance distribution. An effective light diffuser or diffusing section is also required. For cylindrical diffusers, the diffuser section commonly uses additional elements and/or processing of the
20 diffuser section in order to achieve the “top hat” diffusing irradiance distribution. As shown in FIG. 7, one conventional method is removing the cladding of the fiber tip 30 (the diffusing section) and etching the exposed fiber core with hydrofluoric acid or grinding it on a polishing apparatus. The resulting conical tip with its frosted appearance is then covered with a
25 protective transparent envelope 32. Referring to FIG. 8, another conventional method is manufacturing a separate diffuser 34 containing scattering medium 36 that is composed of micron-sized titanium oxide (TiO₂) particles embedded in clear epoxy or silicone elastomer, which is encased in a protective Teflon sheath 38. A reflector 40 attached to a plastic plug 42 is then inserted into the
30 open distal end of the sheath 38. The purpose of the coated plug 42 is to reflect any light that survives forward propagation back through the scattering medium 36 where it can be re-distributed, thus improving the uniformity of the

emission profile. Yet another method of construction can be described as a hybrid of the two previous methods wherein the cladding of an optical fiber is removed mechanically leaving the surface of the core roughened. This surface is then coated with a silicone elastomer on to which a second layer of elastomer impregnated with titanium oxide particles is deposited. Finally, the entire diffusing tip is encased in an outer PTFE tube which in turn is terminated with a reflective end cap in a manner similar to the above-described method and shown in FIG. 8. These described techniques are costly, labor intensive and time consuming. Hence, these light diffusers are very expensive.

[0014] It should be noted there exist other conventional techniques to provide a light diffuser that can produce the “top hat” diffusing irradiance distribution such as having light scattering features on the outside of the optical fiber surface (e.g., divots, threads, notches, general roughening, or the like). These techniques are labor intensive and the resulting homogeneity of the light output pattern relies strongly on a constant fiber diameter, which can vary by up to +/-5%, making it cumbersome to achieve constant and repeatable results in the manufacturing process. Furthermore, light scattering features on the smooth outside surface of the fiber often affect the mechanical strength of the fiber so that for instance the tensile strength drops substantially.

II. Conventional Frontal Light Diffusers

[0015] Referring to FIG. 37A, an exemplary embodiment of a typical frontal (superficial) diffuser 500 is provided with 690 nm light introduced onto an optical fiber 506 (e.g., a cylindrical optical fiber) with a 550 um diameter core via a fiber optic connector 503. A ¼ pitch, 1 mm diameter graded index (“GRIN”) lens component 504 located at the distal end output face 510 of the optical fiber 506 generates the outcoupled light 502. Since the desired treatment area (i.e., target) 508 has a much larger diameter (e.g. 42 mm) than the diameter of the optical fiber 506 (e.g. 550 um), the effect of the lens component 504, to a first approximation, is to form an image of the output

face 510 of the optical fiber 506 onto the target 508 where the target 508 is located at some standoff distance 512 (e.g., 64 mm) away from the lens component 504. In this fashion, the spatial irradiance distribution of a cross section along the target 508, as shown in FIG. 37C, is closely related to the spatial irradiance distribution along a cross section of 510, as shown in FIG. 37B. Note that this exemplary embodiment exhibits low loss (e.g., -0.25 dB), where 1.0 Watt input power is enough to generate the irradiance distribution in FIG. 37C. The fiber spatial irradiance distribution at 510 of a cylindrical fiber 506 is typically non-uniform, resulting on a non-uniform target spatial irradiance distribution at the target 508. This is not ideal for PIT and PDT application where a constant, uniform spatial irradiance distribution is required over the whole treatment area target 508.

[0016] Referring to FIG. 38A, the typical prior art addresses the issue of the non-uniform target spatial irradiance distribution at the target 508 as shown in FIG. 37C by including a mode mixing section 520 in the fiber 506 at a predetermined distanced location prior to the lens component 504. The effect of the mode mixing section 520 is to convert the non-uniform cross sectional spatial irradiance distribution at 510, as shown in FIG. 38B, to the significantly more uniform cross sectional spatial irradiance distribution at 514, as shown in FIG. 38C. Therefore, as shown in FIG. 38D, the target spatial irradiance distribution created by the lens component 504 at the target 508 will have a spatial irradiance distribution that is also more uniform.

[0017] The typical prior art mode mixing section 520 not only produces a more uniform fiber spatial irradiance distribution but it also creates a more uniform angular intensity distribution at the output of the fiber 506. However, when using a projection lens 504 to illuminate a target 508 as shown in FIG. 38A, the angular intensity distribution is not as important as the spatial irradiance distribution. This because the image formed by the projection lens 504 is essentially mapping all the light from one location in the fiber 506 to a location on the target 508, regardless of emission angle.

[0018] As discussed above, the mode mixing section 520 found in the prior art can be constructed of a serpentine section of one or more tight radius

bends as shown in FIGS. 39A-39B, a coiled section of tight radius loops as shown in FIG. 39C, or a section with multiple turns of a tight radius helix as shown in FIG. 39D. Other art-disclosed embodiments of the mode mixing section 520 may also be used (e.g., alternating sections of graded and step index fibers, etc.). However, all these techniques suffer from a significant drawback, they create good mode mixing at the expense of creating high losses in the mode mixing section 520. In one exemplary prior art embodiment, the configuration in FIG. 38A is identical to the configuration in FIG. 37A with the addition of a mode mixing section 520 formed as shown in FIG. 39A with 7.5 mm radius bends. This embodiment exhibits a loss of -2.32 dB, requiring 3.25 Watts of input power to generate the irradiance distribution at the target shown in FIG. 38D.

[0019] At worst, these losses mean enough power leaks out of the fiber 506 to heat up the mode mixing section 520, resulting in catastrophic failure of the diffuser 500 and even presenting a safety concern to the operator and the patient. More subtle drawbacks are that the losses incurred by these types of mode mixer sections 520 tend to vary from device to device, making it hard to produce a consistent product and making it hard to calibrate the output from the pairing of a single device with a different light source.

[0020] Note that the lens component 504 may be comprised of a combination of one or more of optical elements including spherical, aspherical, graded index and diffractive elements. In the typical prior art, the fiber 506 and lens 504 are often part of a disposable assembly and the lens component 504 tends to have a small diameter.

[0021] Referring to FIG. 40A, this creates a condition where the beam of light 502 emerging from the lens component 504 is diverging. The diverging nature of the typical projection lens 504 results in different beam sizes at target position locations 516, 508 and 518 located at stand-off distance 520, 512 and 522 respectively in FIG. 40A. As the target is moved from position 516, past 508, ending at 518, the total power in the resulting beam is the same. However, as shown in the target spatial irradiance distributions in FIG. 40B, the size of the irradiance distribution on the target locations gets larger

with distance while the value of the irradiance drops. This is not ideal, as the magnitude of irradiance of the beam (power/area) drops as a function of distance from the output face of the lens component 504 while the area illuminated increases, resulting in only a narrow range of standoff values
5 where the irradiance meets the desired treatment values.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] The features and inventive aspects of the present invention will become more apparent upon reading the following detailed description,
10 claims, and drawings, of which the following is a brief description:

FIG. 1 is a graphical depiction of a prior art exemplary cylindrical light diffusing device;

FIG. 2 is a map of the irradiance at a vertical cross-section of the optical fiber of the cylindrical light diffusing device of FIG. 1 and its associated irradiance
15 distribution graphs;

FIG. 3 is a graph of the out-coupled longitudinally radially-symmetric irradiance distribution of the cylindrical light diffusing device of FIG. 1;

FIG. 4 is a graphical depiction of a prior art exemplary cylindrical light diffusing device that utilizes a mode mixer;

20 FIG. 5 is a map of the irradiance at a vertical cross-section of the optical fiber of the cylindrical light diffusing device of FIG. 3 and its associated irradiance distribution graphs;

FIG. 6 is a graph of the out-coupled longitudinally radially-symmetric irradiance distribution of the cylindrical light diffusing device of FIG. 3;

25 FIG. 7 is a graphical depiction of a prior art exemplary cylindrical light diffuser;

FIG. 8 is a graphical depiction of another prior art exemplary cylindrical light diffuser;

FIG. 9 is a graphical depiction of a cylindrical light diffusing device according to the present invention;

30 FIG. 10 is a vertical cross-sectional view of a non-circular core fiber exemplary embodiment accordingly to the present invention at a location right before the diffusing proximal end of the light diffusing section;

FIG. 11 is a graphical depiction of another embodiment of a cylindrical light diffusing device according to the present invention;

FIG. 12 is a vertical cross-sectional view of a non-circular core fiber exemplary embodiment accordingly to the present invention at a location right
5 before the diffusing proximal end of the light diffusing section;

FIG. 13 is a vertical cross-sectional view of a non-circular core fiber exemplary embodiment accordingly to the present invention at a location right before the diffusing proximal end of the light diffusing section;

FIG. 14 is a vertical cross-sectional view of a non-circular core fiber
10 exemplary embodiment accordingly to the present invention at a location right before the diffusing proximal end of the light diffusing section;

FIG. 15 is a vertical cross-sectional view of a non-circular core fiber exemplary embodiment accordingly to the present invention at a location right before the diffusing proximal end of the light diffusing section;

FIG. 16 is a vertical cross-sectional view of a non-circular core fiber
15 exemplary embodiment accordingly to the present invention at a location right before the diffusing proximal end of the light diffusing section;

FIG. 17 is a vertical cross-sectional view of a non-circular core fiber
20 exemplary embodiment accordingly to the present invention at a location right before the diffusing proximal end of the light diffusing section;

FIG. 18 is a vertical cross-sectional view of a non-circular core fiber exemplary embodiment accordingly to the present invention at a location right before the diffusing proximal end of the light diffusing section;

FIG. 19 is a vertical cross-sectional view of a non-circular core fiber
25 exemplary embodiment accordingly to the present invention at a location with an internal scattering feature of the light diffusing section;

FIG. 20 is a vertical cross-sectional view of a non-circular core fiber exemplary embodiment accordingly to the present invention at a location with an internal scattering feature of the light diffusing section;

FIG. 21 is a vertical cross-sectional view of a non-circular core fiber
30 exemplary embodiment accordingly to the present invention at a location with an internal scattering feature of the light diffusing section;

FIG. 22 is a vertical cross-sectional view of a non-circular core fiber exemplary embodiment accordingly to the present invention at a location with internal scattering features of the light diffusing section with another set of internal scattering feature superimposed.

5 FIG. 23 is a longitudinal cross-sectional view of the light diffusing section of a non-circular core fiber exemplary embodiment accordingly to the present invention;

FIG. 24 is a longitudinal cross-sectional view of the light diffusing section of a non-circular core fiber exemplary embodiment accordingly to the present
10 invention;

FIG. 25 is a longitudinal cross-sectional view of the light diffusing section of a non-circular core fiber exemplary embodiment accordingly to the present invention;

FIG. 26 is a longitudinal cross-sectional view of the light diffusing section of a
15 non-circular core fiber exemplary embodiment accordingly to the present invention;

FIG. 27 is a map of the irradiance at a vertical cross-section of the optical fiber of the cylindrical light diffusing device of FIGS. 9 and 14 and its associated irradiance distribution graphs;

20 FIG. 28 is a graph of the out-coupled longitudinally radially-symmetric irradiance distribution of the cylindrical light diffusing device of FIGS. 9, 10, and 14;

FIG. 29 is a vertical cross-sectional view of a square shaped core fiber exemplary embodiment with the projected paths of its skew and meridional
25 rays;

FIG. 30 is a vertical cross-sectional view of a circular shaped core fiber exemplary embodiment with the projected paths of its skew and meridional rays;

FIG. 31 is a graphical depiction of an exemplary cylindrical light diffusing
30 device according to the present invention;

FIG. 32 is a map of the irradiance at a vertical cross-section of the optical fiber of the cylindrical light diffusing device of FIG. 31 and its associated irradiance distribution graphs;

FIG. 33 is a vertical cross-section view of a circular shaped core fiber exemplary embodiment at a location with internal scattering features;

FIG. 34 is a graph of the out-coupled longitudinally radially-symmetric irradiance distribution of the cylindrical light diffusing device of EXAMPLE II;

5 FIG. 35 is a map of the irradiance at a vertical cross-section of the optical fiber of the cylindrical light diffusing device of FIGS. 11 and 12 and its associated irradiance distribution graphs;

FIG. 36 is a graph of the out-coupled longitudinally radially-symmetric irradiance distribution of the cylindrical light diffusing device of FIGS. 11 and
10 12;

FIG. 37A is a graphical depiction of a prior art exemplary frontal light diffusing device;

FIG. 37B is a graph of the spatial irradiance distribution along a vertical cross section (510) of the optical fiber of the frontal light diffusing device in FIG. 37A; FIG. 37C is a graph of the spatial irradiance distribution along a vertical
15 cross section (508) of the target by the frontal light diffusing device in FIG. 37A;

FIG. 38A is a graphical depiction of a prior art exemplary frontal light diffusing device with a mode mixing section;

20 FIG. 38B is a graph of the spatial irradiance distribution along a vertical cross section (510) of the optical fiber of the frontal light diffusing device in FIG. 38A;

FIG. 38C is a graph of the spatial irradiance distribution along a vertical cross section (514) of the optical fiber of the frontal light diffusing device in FIG.
25 38A;

FIG. 38D is a graph of the spatial irradiance distribution along a vertical cross section (508) of the target by the frontal light diffusing device in FIG. 38A;

FIG. 39A is a graphical depiction of a prior art fiber optic mode mixing section with four quarter turns with small radii;

30 FIG. 39B is a graphical depiction of a prior art fiber optic mode mixing section with twelve quarter turns with small radii;

FIG. 39C is a graphical depiction of a prior art fiber optic mode mixing section with three small radius loops formed around an axis perpendicular to the axis

of the fiber;

FIG. 39D is a graphical depiction of a prior art fiber optic mode mixing section with two helical loops formed around an axis parallel to the axis of the fiber;

FIG. 40A is a graphical depiction of a prior art frontal light diffusing device
5 shown with the targeted treatment area at various standoff distances (520, 512, 522);

FIG. 40B is a graph of the spatial irradiance distributions along vertical cross sections (516, 508, 518) of the targeted treatment area at various standoff distances (520, 512, 522) by the frontal light diffusing device in FIG. 40A;

10 FIG. 41A is a graphical depiction of an exemplary embodiment of a frontal light diffusing device according to the present invention;

FIG. 41B is a graph of the spatial irradiance distribution along a vertical cross section (608) of the optical fiber of the frontal light diffusing device in FIG. 41A;

15 FIG. 41C is a graph of the spatial irradiance distribution along a vertical cross section (610) of the optical fiber of the frontal light diffusing device in FIG. 41A;

FIG. 41D is a graph of the spatial irradiance distribution along a vertical cross section (614) of the target by the frontal light diffusing device in FIG. 41A;

20 FIG. 42A is a graphical depiction of another exemplary embodiment of a frontal light diffusing device according to the present invention;

FIG. 42B is a graph of the spatial irradiance distributions along a vertical cross section (718) of the frontal light diffusing device of FIG. 42A and along vertical cross sections (720, 722) of the targeted treatment area at two standoff
25 distances (724, 726) by the frontal light diffusing device in FIG. 42A; and

FIG. 43 is a vertical cross-sectional view of a non-circular core fiber exemplary embodiment accordingly to the present invention at a location right before the diffusing proximal end of the light diffusing section;

FIG. 44 is a graphical depiction of a distal portion of a diffuser having a non-
30 uniform light emissions caused by a facet in the diffuser;

FIG. 45 is a graphical depiction of a distal portion of a diffuser having a non-uniform light emissions caused by a facet in the diffuser;

FIG. 46 is a graphical depiction of a distal portion of a diffuser having a non-

uniform light emissions caused by a back scatter off the diffuser's end treatment;

FIG. 47 is a graphical depiction of a distal portion of diffuser and the geometry of the light rays that can escape the diffuser and generate non-uniform light emissions.

FIG. 48 is a longitudinally cross-sectional view of a distal portion of a diffuser capped with one embodiment of a diffuser light blocking device according to the present invention;

FIG. 49 is a longitudinally cross-section view of the diffuser light blocking device shown in FIG. 48;

FIG. 50 is a longitudinally cross-sectional view of a distal portion of a diffuser capped with another embodiment of a diffuser light blocking device according to the present invention; and

FIG. 51 is a longitudinally cross-section view of the diffuser light blocking device shown in FIG. 50.

DESCRIPTION OF THE PREFERRED EMBODIMENT

I. A Light Diffusing Device Providing a "Top Hat" core irradiance distribution Without a Conventional Mode Mixer

[0023] Referring to FIGS. 9-26, the present invention provides a light diffusing device 300 having a non-circular core fiber 302 that provides a "top hat" core irradiance distribution (i.e., optimal core irradiance distribution) without the necessity of using a mode mixer (e.g., 24 shown in FIG. 4). The light diffusing device 300 of the present invention emits irradiance in a radially symmetric longitudinally "top hat" diffusing irradiance distribution (i.e., optimal diffusing irradiance distribution) without the necessity of using the above-described known light diffusers and/or diffusing sections.

[0024] Referring to FIGS. 9 and 11, the device 300 further includes a lead-in optical fiber 304 and at least one optical connector 306. During operation, one end of the lead-in optical fiber 304 is in light communication to a light source (not shown) while the other end of the lead-in optical fiber 304 is in light communication with the proximal end of the non-circular core fiber 302

through the at least one optical connector 306 as shown in FIGS. 9 and 11. The non-circular core fiber 302 further includes a light diffusing section 308 having a diffusing proximal end 310 and a diffusing distal end 312.

[0025] In the exemplary embodiments shown in FIG. 9 and 11, the light
5 diffusing section 308 is located near the distal end of the non-circular core fiber 302. Furthermore, the non-circular core fiber 302 may optionally include a light blocking means 314 (e.g., physical cap, coating such as aluminum deposition, or the like) preventing superficial or frontal light emission from the distal end of the non-circular core fiber 302. In one embodiment, the light
10 blocking means 314 is a mirror that turns light around and reuses it while avoiding over illuminating the treatment area. It provides a highly efficient light diffusing device because only about 6% of the launched light couples back into the lead-in optical fiber 304.

[0026] In one embodiment, the lead-in optical fiber 304 is connected to the
15 light source via an additional optical connector 306. The lead-in optical fiber 304 can be any conventional optical fiber including but not limited to the optical fiber (12, 22) described above. The at least one optical connector 306 connects and allows the lead-in optical fiber 304 to be in light communication with the non-circular core fiber 302 during operation. An alternative to the at
20 least one optical connector 306 is a conventional glue joint or fusion joint between the lead-in optical fiber 304 and the non-circular core fiber 302. Furthermore and in an alternative exemplary embodiment, the non-circular core fiber 302 actually also serves as the lead-in optical fiber 304 (resulting in a single optical fiber) and is connected to a light source via the at least one
25 optical connector 306, a glue/fusion joint, or other conventional connection means. The at least one optical connector 306 can be any art-disclosed optical connector (e.g., SMA connectors or the like).

[0027] FIGS. 13-18 each shows a vertical (i.e., latitudinal) cross-sectional
30 view of the non-circular core fiber 302 at location 316, which is right before the diffusing proximal end 310 of the light diffusing section 308 (see FIGS. 9 and 11). FIGS. 10, 12 and 19-22 each shows a vertical cross-sectional view of the diffusing distal end 312 of the light diffusing section 308 as shown in FIGS. 9

and 11. The non-circular core fiber 302 includes a fiber core 350. The non-circular core fiber 302 may optionally include a cladding 352 as shown in FIGS. 10, 12-14 and 16-18. The fiber core 350 has a non-circular geometry such as hexagon (as shown in FIGS. 10 and 12-15), square (as shown in
5 FIGS. 16-18), rectangle, triangle, octagon, other regular polygons and non-regular polygons. Accordingly, there is a wide range of potential non-circular core shapes that can achieve homogeneous irradiance inside the core. Some shape characteristics make a shape particularly well suited for the present invention. Although radial symmetry is not required, it does provide the
10 benefits of ease of manufacture and promoting radially symmetric output irradiance pattern. The inclusion of inflection points in the cross section profile where the tangent of the shape changes rapidly encourages better mixing by sending adjacent rays in different directions. The inclusion of facets also promotes better mixing by avoiding self-focusing behavior. Avoiding re-
15 entrant geometry aides in manufacture and avoids physically weak structures. These shape characteristics combined tend to encourage the use of regular polygon shapes as the basis for the non-circular core geometry. It should also be noted that a core with a helical or twisted shape could also be of interest for generating spatially homogeneous irradiance in the core.

20 [0028] The cladding 352 may have the same non-circular vertical (i.e., latitudinal) cross sectional geometry as the fiber core 350 (see e.g., FIGS. 12, 13, and 16). Alternatively, the cladding 352 may have a circular exterior surface geometry 354 with an interior surface geometry 356 that has the same general shape as the fiber core 350 (see e.g., FIGS. 10, 14, 17 and
25 18).

[0029] Referring to FIGS. 15, 19-22, in some exemplary embodiments of the present invention, the cladding 352 does not exist but is replaced with an enclosed open cavity or environment (e.g., air) 358 between the fiber core 350 and a covering 360 that is concentric with the fiber core 350 and radially
30 envelopes (but does not tightly cladded) the fiber core 350. The covering 360 can be any suitable art-disclosed polymeric material (e.g., Pebax®) and is generally circular in shape as shown in FIGS. 11, 12, 15, 18-22. The covering

360 offers additional protection for the non-circular core fiber 302. The covering 360 can be clear or translucent. If clear, the covering 360 does not provide any light scattering thus no extra losses of light. If translucent, internal scattering by the covering 360 can assist in improving the uniformity of the diffusing irradiance distribution. However, too much internal scattering by the covering 360 can cause excess losses of light due to absorption.

[0030] As shown in FIG. 12 and 18, it is possible to mix and match the fiber core 350 and the cladding 352 in different vertical cross sectional geometries and combined them with either the enclosed open cavity 358 and/or the covering 360. For example and referring to FIG. 18, a vertical cross sectional view of the non-circular core fiber 302 shows its fiber core 350 has a square geometry. The interior surface geometry 356 of its cladding 352 matched this square geometry while the exterior surface geometry 354 of its cladding 352 is circular in shape. The non-circular core fiber 302 further includes the enclosed open cavity 358, which is sandwiched between the cladding 352 and the covering 360. The covering 360 has a circular geometry.

[0031] In one exemplary embodiment of the device 300 and referring to FIGS. 9 and 14, the fiber core 350 of the non-circular core fiber 302 is constructed out of poly (methyl methacrylate) ("PMMA") with a hexagonal geometry in a circumscribed $\phi 660 \mu\text{m}$ diameter circle. The fiber core 350 is clad by the cladding 352 with an interior surface geometry 356 that has the same hexagonal geometry as the fiber core 350. However, the exterior surface geometry 354 of the cladding 352 is circular. The cladding 352 is constructed of a silicone with an $\phi 740 \mu\text{m}$ OD. The lead-in fiber 304 of the device 300 has a $200 \mu\text{m}$ OD glass core and a $230 \mu\text{m}$ OD cladding. The length of the non-circular core fiber 302 is 30 cm. During operation, the core optical fiber 302 is filled with laser light having an angular distribution of a NA of 0.22. It should be noted that other embodiments could include different materials for both the core and cladding, including utilizing various transparent or translucent glasses and polymers. If the total length of the diffuser is short, then absorbance is not of primary concern, but the materials should not be opaque at the wavelengths of interest. For example, if the diffuser is to be

used to provide UV illumination then a silica core light guide is appropriate, whereas use of mid wave IR light would encourage the use of a fluorite or silver halide glass. A wide range of injection moldable polymer materials are appropriate for visible and near IR applications, including but not limited to PMMA, poly carbonate (PC) and polystyrene (PS). Various castable materials including epoxies and silicones are also of interest. In all cases, care should be utilized to ensure the materials could handle the required amount of optical power without ill effects, such as melting or crazing.

[0032] FIG. 27 shows a map of the irradiance at the vertical cross-section (shown as "316" in FIG. 9) through the fiber core 350 taken just before the diffusing proximal end 310. The light source used is a 690 nm laser with 0.125 Watt launch power and this power was adjusted until the irradiance measured at the center 307 of the longitudinally length of the light diffusing section 308 was 150 mW/cm². This measurement is taken 0.75 mm from the central axis of the stated location of the light diffusing section 308. The total length of optical fiber (combination of the lead-in fiber 304 and the non-circular core fiber 302) from the light source leading up to this location 316 is 2 meter long. The associated irradiance distribution graphs shown in FIG. 27 taken from vertical and horizontal cross sections through the center of the map of the irradiance show the same "top hat" core irradiance distribution as the above-discussed conventional cylindrical light diffusing device 200 (shown in FIG. 5), which requires a mode mixer (24). This "top hat" core irradiance distribution indicates a high degree of uniformity of the irradiance distribution in the fiber core 350 (i.e., optimal core irradiance distribution). "Top hat" core irradiance distribution and/or optimal core irradiance distribution shall be defined hereinafter in this Specification as having all irradiance of a cross-section of the fiber core 350 to be within at least +/- 20% of the average irradiance of the cross-section of the fiber core 350, indicating a high degree of uniformity of the irradiance distribution in the core of the fiber 22. In some exemplary embodiments, the at least +/- 20% value can be further reduced to +/- 15% range, or even +/- 10% range.

[0033] The examination of two types of rays that can propagate in a perfectly symmetrical cylindrical light guide may assist in understanding how the non-circular core fiber 302 of the present invention can provide a “top hat” core irradiance distribution in the fiber core 350. It is possible for light to propagate forward as “skew rays” that spiral around the outer edge of the fiber core 350 without ever crossing through the center portion of the fiber core 350. This is depicted in FIG. 30 which shows a vertical cross-sectional view of a circular shaped core fiber 301 where the projected path of a propagating skew ray 366 that always stays near the edge of the fiber core 351. It is also possible to have meridional rays 368 with paths that lie on a plane so that rays that start on the central axis of the light guide always cross back through the central axis of the fiber core 351. In comparison and referring to FIG. 29, which shows a vertical cross-sectional view of a square shaped non-circular core fiber 302 with the projected path of similar propagating rays. The skew ray 370 still propagates without crossing the central axis of the fiber core 350, but now its path is such that its energy can at some locations be found near the edges of the fiber core 350 while in other locations it can be found closer the center of the fiber core 350. A meridional ray 372 that starts on the central axis of the fiber core 350 can have a path that samples much of the area of the fiber core 350 without ever crossing the axis again. These two examples demonstrate how introducing a large set of rays with a range of different launch angles into a non-circular core fiber 302 can yield a “top hat” core irradiance distribution after a short propagation length that corresponds to only a few internal reflections.

[0034] Our study indicates that replacing the non-circular core fiber 302 shown in FIG. 14 with any of the above-discussed different embodiments of the non-circular core fiber 302 would still allow the device 300 to provide the desired “top hat” core irradiance distribution (e.g., FIGS. 13-18). For example, the fiber core 350 of FIG. 13 is same as the fiber core 350 shown in FIG. 14. They both are constructed out of PMMA with a hexagonal geometry in a circumscribed $\varnothing 660\text{ }\mu\text{m}$ diameter circle.

The non-circular core fiber 302 of FIG. 13 differs from the core fiber of FIG. 14

because the cladding 352 of FIG. 13 has a hexagonal geometry. The cladding 352 of FIG. 13 is constructed of a fluorinated polymer in a circumscribed $\varnothing 740$ μm diameter circle.

[0035] In another exemplary embodiment and referring to FIG. 15, the fiber core 350 has the same geometry and dimensions as the fiber core of FIG. 14 except that it is constructed out of polystyrene instead of PMMA. However, the non-circular core fiber 302 of FIG. 15 does not have the cladding 352. Instead, it (302) further includes the enclosed open cavity 358 and the covering 360. The covering 360 is constructed of a translucent Pebax® resin with an $\varnothing 1000$ μm OD and an $\varnothing 900$ μm inner diameter ("ID"). In this exemplary embodiment, the trapped air contained in open cavity 358 acts as a cladding to ensure the light is contained within the fiber core 350.

[0036] The exemplary embodiments shown in FIGS. 16-17 use the same fiber core 350 constructed out of PMMA with a $500\text{ }\mu\text{m} \times 500\text{ }\mu\text{m}$ square geometry. The non-circular core fiber 302 of FIG. 16 has a cladding 352 constructed out of fluorinated polymer with a $540\text{ }\mu\text{m} \times 540\text{ }\mu\text{m}$ square geometry. The non-circular core fiber 302 of FIG. 17 has a different cladding 352 as it has a square interior surface geometry 356 and a circular exterior surface geometry 354. The cladding 352 is constructed of a silicone with an $\varnothing 740\text{ }\mu\text{m}$ diameter OD.

[0037] In another exemplary embodiment and referring to FIG. 18, the fiber core 350 has the same geometry and dimensions as the fiber core 350 of FIG. 17 except that it is constructed out of polystyrene instead of PMMA. Both have the same cladding 352. However, the non-circular core fiber 302 of FIG. 18 further includes the enclosed open cavity 358 and the covering 360. The covering 360 is constructed of a translucent Pebax® resin with an $\varnothing 1000$ μm OD and an $\varnothing 900$ μm ID.

[0038] In yet another exemplary embodiment and referring to FIG. 12, the non-circular core fiber 302 is a combination of the core fiber shown in FIG. 13 plus the enclosed open cavity 358 and the covering 360. The covering 360 is constructed of a translucent Pebax® resin with an $\varnothing 1000$ μm OD and an $\varnothing 900$

μm ID.

[0039] As discussed above, the non-circular core fiber 302 of the present invention with its variety of shapes, materials, cladding (352), and covering (360) can provide “top hat” core irradiance distribution without needing a mode mixer thus providing a less expensive and sturdier light diffusing device (300). The non-circular core fiber 302 of the present invention can be used in conjunction with one of the above-described conventional lighting diffusers or diffusing sections to provide “top hat” diffusing irradiance distribution.

10 II. Cylindrical Light Diffusing Device Providing a “Top Hat” Diffusing Irradiance Distribution

[0040] In order for the device 300 to provide a “top hat” diffusing irradiance distribution without using such a conventional light diffuser or diffusing section, the device 300 must include internal (i.e., not reaching the exterior surface of the fiber core 350) scattering features 362, preferably inscribed or written by laser, within the light diffusing section 308 as shown in FIGS. 9 and 11.

[0041] The “top hat” diffusing irradiance distribution is defined in this Specification as having a longitudinal variation of the out-coupled irradiance to be less than +/- 20% of the average (I_0) optical irradiance for a cylindrical diffuser in terms of the radially emitted irradiance distribution (see e.g., FIG. 6), indicating a high degree of uniformity. In some exemplary embodiments, the at least +/- 20% value can be further reduced to +/- 15% range, or even +/- 10% range.

[0042] The internal scattering features 362 generally begin at the diffusing proximal end 310 and end at the diffusing distal end 312. The features 362 can be in a variety of shapes and patterns as shown in FIGS. 10, 12, 19-22. FIGS. 10, 12, 19-22 show a vertical (i.e., latitudinal) cross-sectional view of the diffusing distal end 312 of the light diffusing section 308. For example, the features 362 can be (i) three cylinders oriented around the central axis of the fiber core 350 at 60° increments as shown in FIGS. 10, 12 and 19 (ii) a single line of spheres concentric to the central axis of the fiber core 350 as shown in FIG. 20; (iii) a symmetrical array of elliptical features (e.g., features that are

elliptical or spherical) centered on radius around the central axis of the fiber core 350 at 60° increments as shown in FIG. 21 and distributed down a predetermined longitudinal length of the fiber core 350 in linear, nonlinear, spiral pattern, or pseudo random pattern; and (iv) a pair of parallel cylinders
5 361 where each cylinder of a pair are located at a predetermined distance from the central axis of the fiber core 350, with subsequent pairs of cylinders that are located at different longitudinal locations along the length of the light diffusing section 308 are oriented at different angles around the central axis of the fiber core 350, (e.g. the pair of parallel cylinders 363 are located at a
10 different cross section of the fiber and are clocked at 60° relative to the pair 361). Please note that while the embodiments discussed herein use 60° increments, other predetermined patterns such may also be suitable such as, without limitations, 45°, 72°, 90°, 120°, 180° increments.

[0043] Each scattering feature 362 can be created by a suitable art-disclosed laser. For example, a focused, mode-locked 532 nm 10 pico-second laser pulse at 1.5 Watts average power can create the features 362 shown in FIG. 10, which is comprised of three cylinders, each approximately 27 μm in diameter and 270 μm in length oriented around the central axis of the fiber core 350 at 60° increments. In another example, a series of 520 nm
20 400 femto-second laser pulses at 2.0 Watts average power focused through an objective lens with a numerical aperture of 0.4 can create the features 362 shown in FIG. 43 (discussed in more details below), each feature a sphere approximately 40 μm in diameter centered around the central axis of the fiber core 350 at increments of 60°. Please note that while the embodiments
25 discussed herein use 60° increments, other degree increments are also suitable such as 45°, 72°, 90°, 120°, 180°, etc.

[0044] The scattering characteristics of each of the features 362 are varied by material, geometry and processing. The proportion of light scattered per
30 length or per feature 362 must increase as the density of light per length in the light diffusing section 308 decreases due to light being scattered out of the non-circular core fiber 302. This can be achieved by changing the number of

features 362 per unit length or the size of the features 362 as a function of length. Depending on the amount of return light acceptable, linear increase in size may suffice but a non-linear increase in size vs length may be preferred. In another exemplary embodiment, the number of features 362 per unit length
5 may increase while the size of the features 362 as a function of length may decrease. It should be noted that it is also possible for one skilled in the art to change the processing parameters in order to change the amount of scattering per feature 362.

[0045] When the internal scattering features 362 are distributed in the light
10 diffusing section 308 along the central axis 364 of the non-circular fiber core 350 as shown in FIGS. 9 and 11, the light propagates down the light diffusing section 308 and there is constant mixing occurring in the light diffusing section 308 itself. As the light in the center of the fiber core 350 encounters the internal scattering features 362 and is scattered out of the light diffusing
15 section 308, the light redistribution ensures the irradiance in the center of the fiber core 350 is replenished. This simplifies the challenge of finding a pattern of scattering features 362 to achieve a uniform emission pattern while allowing the scattering features 362 to be kept smaller and located towards the center of the light diffusing section 308, resulting in a potentially more
20 physically robust device with better emission characteristics.

[0046] Referring to FIGS. 23-26, the feature 362 can also be longitudinally spaced in a variety of patterns. For example, the features 362 can be arranged longitudinally in a uniform linear manner concentric with the central axis 364 of the fiber core 350 as shown in FIG. 23. The features 362 can be
25 arranged longitudinally in a non-uniform linear manner by changing the number of the features 362 per unit length as shown in FIG. 24. In FIG. 24, the number of features 362 per unit length increases going from the diffusing proximal end 310 to the diffusing distal end 312 of the light diffusing section 308. As discussed above and in the alternative, the number of features 362
30 per unit length may decrease going from the diffusing proximal end 310 to the diffusing distal end 312 of the light diffusing section 308 but size of the features 362 may increase going from the diffusing proximal end 310 to the

diffusing distal end 312 of the light diffusing section 308.

[0047] Furthermore, the features 362 can be arranged longitudinally in a uniform linear manner with a linear increase in size as shown in FIG. 25. Finally, the features 362 can be arranged longitudinally in a uniform manner
5 with a non-linear increase in size as shown in FIG. 26.

III. Frontal Light Diffusing Device Providing a "Top Hat" Spatial Irradiance Distribution

[0048] Referring to FIG. 41A, the present invention provides a frontal light
10 diffusing device 600 including a fiber optic connector 603, a cylindrical optical fiber section 602, a non-circular core fiber section 604, a fiber splice 605 joining the two fiber sections, and a lens component 606. During the operation of the device 600, the cylindrical optical fiber section 602 is in light communication with the non-circular core fiber section 604, and the non-
15 circular core fiber section 604 is also in light communication with the lens component 606. The non-circular core fiber section 604 can have the same characteristics as the above-discussed non-circular core fiber 302 which provides a "top hat" core irradiance distribution (without the necessity of using a mode mixer) except that it does not include the optional light blocking
20 means 314 discussed above. Please note the cross section can also vary down the longitudinal length of the non-circular core fiber section 604 to assist in creating a better mixing effect, e.g. there can be one or more regions of 604 where the outer dimension of the core increases and then decreases, or the core of 604 can have varying amounts of twist (i.e., rotation around the
25 longitudinal axis of the fiber section 604) instead of a straight extrusion, or the non-circular profile of 604 can vary from one shape to another (e.g. hexagonal to square). The non-circular core fiber section 604 acts as a spatial mode mixer to cause several internal bounces of the propagating light so that there is little to no loss of propagating light.

30 [0049] As discussed below and in one exemplary embodiment, during operation, the cylindrical optical fiber section 602 has the non-uniform fiber spatial irradiance distribution of light shown in FIG. 41B as measured at cross

section 608. The non-circular core fiber section 604 outputs the significantly more uniform mixed fiber spatial irradiance distribution shown FIG. 41C as measured at cross section 610. The target spatial irradiance distribution shown in FIG. 41D created by lens component 606 at the target cross section 614 is also more uniform. Accordingly, both the mixed spatial irradiance distribution measured at 610 and the target spatial irradiance distribution measured at 614 have the desired "top hat" spatial irradiance distribution. The "top hat" spatial irradiance distribution and/or optimal spatial irradiance distribution shall hereinafter be defined as having variation of the out-coupled spatial irradiance distribution be less than $\pm 20\%$ of the average (I_0) optical irradiance for a frontal diffuser in terms of the emitted irradiance distribution, indicating a high degree of uniformity of the spatial irradiance distribution at the relevant location (e.g., at 610 and/or at target 614). In some exemplary embodiments, the at least $\pm 20\%$ value can be further reduced to $\pm 15\%$ range, or even $\pm 10\%$ range.

[0050] In the prior art, the mixing of propagation angles means that some rays of light that did propagate down the fiber core get perturbed into angles that exceed the critical angle of the fiber and are emitted, resulting in transmission loss and other unwanted effects like local heating of the surrounding materials. The non-circular core fiber section 604 does not change the angles such that they cannot propagate, they only re-arrange the paths of the rays while preserving the angle of each ray to the optical axis of the non-circular core fiber section 604. As discussed above, it is possible to create variations in the shape or size of the non-circular core fiber section 604 down the length of the mixing section so that controlled amounts of angular mixing can be included in the effect of the non-circular core fiber section 604, noting that any increased angular mixing will also be accompanied by incurring corresponding transmission losses.

[0051] In one alternative embodiment of the present invention, the non-circular core fiber section 604 can extend from the light source to the projection lens (e.g., 606) or, as shown in FIG. 41A, a short section 604 can be utilized after a cylindrical fiber section 602 and prior to the lens component

606. Note that if a section of cylindrical fiber 602 is used between the non-circular core fiber section 604 and the lens component 606, care should be utilized that it not be too long (e.g., less than 0.25 meters or the like) or the mixed spatial irradiance distribution measured prior to 606 can become non-uniform again.

[0052] As discussed above for the non-circular core fiber 302, the non-circular core fiber section 604 can be a separate piece of material that is connected using standard fiber optic connectors 605 or can be permanently affixed to one end of the cylindrical fiber section 602 by glue or even melted into place by a fusion bonding technique (e.g., welding or the like). It is also possible to mold or emboss a non-cylindrical section 604 into an otherwise cylindrical section of fiber 602. Care should be taken to engineer the junction between the cylindrical fiber section 602 and the non-circular core fiber section 604 to minimized losses, e.g., matching sizes and maximum propagation angles.

[0053] Referring to FIG. 41A and in one exemplary embodiment of device 600, the cylindrical optical fiber section 602 is comprised of a core fiber constructed out of glass with a 600 μm OD core covered by a 630 μm OD cladding. It has numerical aperture (NA) = between 0.22 and 0.26. The non-circular fiber core section 604 is at least 50 mm in length and constructed out of glass with a hexagonal geometry of 600 μm ID, with a 680 μm OD cladding. The lens component 606 is comprised of a $\frac{1}{4}$ pitch, 1 mm diameter GRIN lens.

[0054] In one exemplary embodiment, the light source used is a 690 nm laser with 2.4 Watt launch power and this power was adjusted until the irradiance measured at the target 614 was 150 mW/cm^2 with a top hat distribution with a 42 mm internal diameter when measured with the stand-off (e.g. 616) = 64 mm. This embodiment demonstrates low transmission losses of -0.36 dB. The total length of optical fiber (combination of the cylindrical optical fiber section 602 and the non-circular core fiber section 604) from the light source to the projection lens 606 is 2 meter long.

[0055] During operation, the cylindrical optical fiber section 602 has the

non-uniform fiber spatial irradiance distribution of light shown in FIG. 41B as measured at cross section 608. The non-circular core fiber section 604 outputs the significantly more uniform mixed fiber spatial irradiance distribution shown FIG. 41C as measured at cross section 610. The target spatial irradiance distribution shown in FIG. 41D created by lens component 606 at the target cross section 614 is also more uniform. Accordingly, both the mixed spatial irradiance distribution measured at 610 and the target spatial irradiance distribution measured at 614 have the desired "top hat" spatial irradiance distribution.

10 [0056] As shown in FIG. 40A and FIG. 40B, the prior art frontal illuminators have diverging beams. This forces the operator to hold the illuminator at a very specific standoff from the target zone for the duration of the treatment in order to achieve the desired irradiance levels. An ideal frontal illuminator would have the same irradiance on the target regardless of the standoff distance. Additionally, the ideal frontal illuminator would also allow the size and shape of the illumination pattern on the target to easily be adjusted.

[0057] Referring to FIG. 42A, the present invention provides a frontal light diffusing device 700 that satisfies these goals comprising an optical fiber 702 with a proximal connector 703, a distal termination 705, and a collimation lens assembly 704. The optical fiber 702 can be a cylindrical fiber, a non-circular core fiber (e.g., 302, 604), or a combination thereof discussed above. The collimation lens assembly 704 includes a collimation lens 706, which can be constructed of a transparent optical material, i.e. glass, crystal, a transparent polymer, or a reflective material. The collimation lens 706 can be comprised of a single optical element or a combination of optical elements. The collimation lens 706 can have any combination of spherical, aspherical, refractive, diffractive or reflective surfaces and the materials can have a graded index profile. The naturally divergent light output 708 of the fiber 702 is allowed to expand until it encounters the collimation lens 706. The fiber 702 is located so its output face 710 is approximately at the back focal length 712 of the collimation lens 706. A variable aperture 714 is located near or at the output of the collimation lens 704 where it can block portions of the light

output 708, producing a light output beam 716 with extent that corresponds to the opening in 714. As shown in FIG. 42A, only the central portion of the light output 708 from the fiber 702 is allowed through the aperture 714 (i.e., collimated light output 716). This resulting collimated light output 716 has a
5 "top hat" irradiance distribution as shown in FIG. 42B that is essentially the same magnitude (e.g., less +/- 20% difference in values, less than +/- 15% difference in values, or even +/- 10% difference in values) in (i) the near field (e.g. cross section 720 at a standoff distance of 724), (ii) the far field (e.g. cross section 722 at a standoff distance of 726), and the distance in between
10 the near field and the far field, hereinafter defined as "flat irradiance distribution".

[0058] The expanding cone of rays out of the fiber 702 is deliberately allowed to overfill the collimating lens 706. The solid line in the plot in FIG. 42B is the irradiance distribution measured at location 718 shown in FIG. 42A.
15 The portions of the distribution with high variation are allowed to land on the structure of the collimation lens 704 and are blocked, reflected or absorbed. Only the uniform central portion of the irradiance distribution passes through both the collimation lens 706 and the variable aperture 714 to generate output beam 716, resulting in the flat irradiance distribution 720, shown as a dashed
20 line in FIG. 42B.

[0059] The aperture 714, located on the output side of the collimation lens 704 blocks portions of the light output 708 that are not desired. In a preferred embodiment, the aperture 714 is an iris that allows the beam size to be varied from 1 mm to 12 mm in diameter. Alternatively, the aperture 714 could be
25 configured to produce a square, rectangular, or even a non-symmetric light output.

[0060] The collimated light output 716 after the aperture 714 has very low divergence, so that the light output 718 is approximately the same size in the near field, at location 720 in FIG. 42A as it is in the far field, at location 722 in
30 FIG. 42A. Referring to FIG. 42B, this resulting flat irradiance distributions at cross section 720 (shown as a dashed line) and cross section 722 (shown as a dash-dot line) have very close to flat top irradiance distribution and the

beam size does not change significantly with distance (hereinafter defined as “flat irradiance distribution”).

[0061] In one exemplary embodiment of the frontal light diffusing device 700, the input fiber has a core diameter of 400 μm and a clad diameter of 430 μm and is filled with 1.01 Watts of 690 nm light having a numerical aperture of 0.29. The collimation lens 706 is comprised of a plano-convex lens with a 25 mm diameter and a focal length of 75 mm. In this embodiment, the amount of excess optical power absorbed by the hand piece when generating a 12 mm diameter beam of 150 mWatt/cm² at 720 is less than 0.85 Watts, which is easily dissipated by the body of the hand piece. Referring to FIGS. 41A-42B, the flat irradiance distribution at cross section 720 is measured at the standoff distance 724 of 100 mm from the aperture 714 and the flat irradiance distribution at cross section 722 is measured at the standoff distance 726 of 200 mm from the aperture 714.

[0062] The performance of this embodiment 700 presents several advantageous characteristics. First, the size and geometry of the light output can be adjusted over a wide range without variation to the irradiance (mWatt/cm²) at the target. Secondly, the irradiance created on the target has very little dependence on the standoff distance between the projector and the target. These features make it easy to calibrate the output of the light source to generate the desired levels of treatment light and make it easier for the operator to position the illuminator to achieve the desired exposure levels. Please note that the light output of an unmodified cylindrical optical fiber 702 was used in FIGS. 42A. If an angular mode mixing section or a non-circular core fiber section (e.g., 302, 606) was used that created a more uniform, flat top angular distribution than 718 in FIG. 42B, then a wider output beam could be obtained. Additionally, a non-circular core input fiber could be used.

IV. Diffuser Light Blocking Device

[0063] When a diffuser is used in a PIT/PDT application, it is important that the diffuser not generate any thermal conditions where the surrounding tissues exceeds 42° C, which can cause cellular damage to the surrounding

tissue and reduce the effectiveness of the treatment. For instance, if there is 100 mW of forward propagating light remaining at the distal end of a diffuser that has a 500 um diameter core, then the transmitted irradiance at the very distal surface could be 50 Watts/cm², which is more than enough to cause thermal damage to the surrounding tissue. If a light blocking means is utilized at the distal end of the diffuser to reduce the transmitted light, it is important that it doesn't absorb enough light energy to experience a thermal rise and cause the diffuser surface temperature to exceed 42° C.

[0064] It is also important that a diffuser not generate or create (hereinafter collectively referred to as "create") any "irradiance hot spots" that are localized regions where the light output exceeds the specified treatment levels (hereinafter defined as "diffuser irradiance hot spot(s)"). For instance, when the treatment protocol specifies 150 mW/cm², a local irradiance that is greater than 20% over that level can prematurely bleach the PIT/PDT compounds in that localized region, deactivating them before the end of the treatment and thereby reducing its overall effectiveness.

[0065] There are characteristics at the distal end of a diffuser that can interact with light propagating through the diffuser to create diffuser irradiance hot spots. Referring to the distal end 851 of a diffuser 850 shown in FIG. 44, a small facet 852 is shown on the distal face 853 of the diffuser 850, similar to the chips, bevels or other deviations from a perfect perpendicular plane that might be unintentionally created as manufacturing variations during a typical manufacturing process. A mirror 854 is shown applied to distal surface 853 as a light blocking means. Since the mirror 854 was applied after the distal end 851 was created, the facet 852 is also mirrored. The rays 856 that interact with the facet 852 are not directed back into the diffuser 850, but instead are reflected out the side 855 of the diffuser 850 up as localized non-uniform irradiance output 858. This reflected irradiance is not isotopically scattered as in the rest of the diffuser 850 but is somewhat directional, creating a localized region of non-uniform irradiance output. For example, if there is 100 mW of forward propagating light remaining at the distal end 851 of the diffuser 850, the facet 852 represents 5% of the cross sectional area of the diffuser 850,

80% of the incident light onto the facet 852 is reflected off the mirrored surface 857, and the power directed out through the side 855 irradiates a 1 mm² region near the surface of the diffuser 850, then the localized irradiance created by the facet 852 could be 400 mW/cm². This irradiance might also be
5 combined with the irradiance output from the rest of the diffuser 850, creating an unacceptable diffuser irradiance hot spot condition.

[0066] FIG. 45 shows a similar distal end 861 of a diffuser 860 with an unwanted facet 862 where a separate mirror component 864 is provided as a light blocking means. Some of the forward propagating light 868 in the diffuser
10 860 will transmit through the facet 862, bypass the mirror 864 and end up as localized non-uniform output 869. Some of the forward propagating light 866 will undergo total internal reflection off the facet 862 and end up being directed out the side 863 of the diffuser 860, creating a different region of localized non-uniform irradiance output 867. Some of the light will interact with
15 the facet 862 but be properly directed by the mirror 864 and returned into the core 865 of the diffuser 860. For example, if there is 100 mW of forward propagating light remaining at the distal end 861 of the diffuser 860, the facet 862 represents 5% of the cross sectional area of the diffuser 860, 30% of the incident light onto the facet 862 is transmitted out the side 863 into a 1 mm²
20 region, 30% is total internally reflected out the side 863 into a 1 mm² region, and the remained is properly reflected and recaptured, then the localized irradiance from both the transmitted and reflected beams could be 150 mW/cm². If these localized irradiances are combined with light from the rest of the diffuser 860, multiple unacceptable diffuser irradiance hot spot
25 conditions can be caused by the same manufacturing defect.

[0067] FIG. 46 shows the distal end 871 of another diffuser 870 where a scattering compound 872 is provide as a light blocking means. Forward propagating light 874 will back scatter off of 872, where some of the backscattered light will escape from the side 873 of the diffuser 870 as rays
30 876. Whereas light scattered from the body of the diffuser 870 might scatter isotopically into 4p steradians, all the light energy back scattered off 872 will be into 2p steradians. This means the rays 876 might create a localized

irradiance that is as much as double the irradiance produced by the body of the diffuser 870, creating an unacceptable diffuser irradiance hot spot. This is an example of a design choice that can contribute to unintended performance issues.

5 [0068] Another potential root cause of non-uniform irradiance output can be related to the uniformity of the end treatment. For example, if the distal end of the diffuser has a reflector formed by a metallic deposition but the reflector has voids, a non-uniform emission pattern may result. This is another example of a manufacturing variation that can contribute to unintended
10 performance issues. Combinations of design issues and manufacturing variations can result diffuser irradiance hot spots observed near the distal end of a diffuser that exceed the treatment specifications and reduces treatment efficacy. Processes to solve or screen for these manufacturing variations can cause increased manufacturing complexity, reduced component yield, and
15 increased costs in production.

[0069] Accordingly, there is a need to provide an end treatment for a diffuser that can simultaneously block transmitted light, block the creation of diffuser irradiance hot spots, and avoid creating unacceptable thermal conditions in the surrounding tissues. Ideally, this solution should also help
20 protect the end of the diffuser and would not be complicated or expensive to manufacture or install. It would be especially beneficial if the solution could correct for minor manufacturing variations and some design issues thereby simplifying the manufacturing process, increasing yield and lowering costs.

[0070] In order to block the light from the distal end of the diffuser that can
25 create the diffuser irradiance hot spots, it is useful to understand the physics of total internal reflection that dominates the containment of backwards propagating light as depicted in FIG. 47. FIG. 47 shows distal end 881 of a diffuser 880. For diffusers made from materials with a refractive index above 1.42, Snell's Law indicates that rays 886 that are internally incident on the
30 inside of the diffuser 880 at angles from the normal θ that that are greater than 45° will be totally internally reflected (TIR) and contained inside the diffuser 880. Rays 885 that are below this critical angle can escape the side

883 of the diffuser 880 and contribute to the creation of diffuser irradiance hot spots. Therefore, an end treatment for the diffuser 880 that can block, absorb, reflect, or backscatter rays 885 can significantly reduce the creation of diffuser irradiance hot spots. The worst case ray that needs to be contained
5 is shown by incident ray 884 that is scattered or otherwise redirected from the extreme corner of diffuser 880 as ray 886. Assuming a 45° angle from the lower corner of the diffuser 880 with the diameter shown as 888, then a blocking region 889 that has the same dimension as the diameter 888 will suffice to block rays escaping rays 885. Therefore, an end treatment with a
10 blocking dimension of at least the diameter of diffuser 880 is desired.

[0071] If the light blocking means comprises a perfect mirror, then all the incident light will be turned around and the light blocking means will not absorb light energy and convert it to heat. Accordingly, an end treatment with a highly reflective back reflector with low absorbance is desired. Further, if the
15 light blocking means were to absorb light energy but were to have very small surface area, the thermal energy per surface area could be high, resulting in an unacceptable temperature rise. For instance, if 100 mW of light energy were incident on a thin 500 μm diameter mirror coating that absorbed a mere 1% of the incident power, the mirror layer would have a total external surface
20 area of less than 0.2 mm^2 to emit or conduct away from the diffuser body the 1 mW of thermal power absorbed. In contrast, an end treatment that has the same sized mirror that is in thermal contact with a heat spreading component that has, for example, dimensions of at least 1 mm long x 0.7 mm diameter, would have an external surface area that is greater than 13 times the external
25 surface area of mirror on its own. This increased surface area to dissipate the same 1 mW of light energy absorption would result in a significantly lower thermal rise. Therefore, an end treatment comprised of a material with good thermal conductance with an external surface area that is at least 10 times (i.e., 1,000%) the surface area of the diffuser end face is desired.

30 [0072] Referring to FIGS. 48-51, the present invention provides a diffuser light blocking device that simultaneously meets all the previously desired characteristics of an ideal end treatment for a diffuser. The diffuser light

blocking device can serve as the light block means 314 discussed above in this specification.

[0073] As shown in FIGS. 48-51, the diffuser light blocking device includes an end cap member 820 having a pocketing feature 821 designed to accept and enclose a distal portion 830 of a diffuser 800 having a distal end surface 801. The pocketing feature 821 includes a side wall 822 and an end reflective surface 810. The shape of the pocketing feature 804 generally corresponds to exterior shape of the distal portion 830 of the diffuser 800 allowing the distal portion 830 to engage and to fit within the pocketing feature 821. The side wall 822 has an overlapping section 815 that encloses (e.g., overlaps) the side wall 802 of the distal portion 830 of the diffuser 800 with a length 830. The side wall 822 simultaneously provides a mechanical means to attach the diffuser light blocking device including the end cap member 820 to the diffuser 800 while also blocking high angle non-uniform light from creating a diffuser irradiance hot spot. The overlapping section 815 of the side wall 822 is designed to surround side wall 803 of the distal portion 830 of the diffuser 800 and allows the diffuser light blocking device to prevent at least 95% (preferred at least 97% and more preferred at least 98%) of the light output of the distal portion 830 from escaping out of the side wall 803 of the distal portion 830. The reflective end surface 810 returns, reflects, or back scatters (hereinafter collectively referred to as "returns") the light emitted from the distal end surface 801 of the diffuser 800 back towards the diffuser 800 while blocking any forward propagating light output from the distal end surface 801. The reflective end surface 810 returns at least 80% of light output from the distal end surface 801 back towards the diffuser 800.

[0074] The end cap member 820 is thermally conductive allowing heat generated by absorption of the light output from the distal portion 830 of the diffuser 800 to be dispersed throughout the end cap member 820. The diffuser light blocking device including the end cap member 820 may be composed of any opaque material that absorbs, reflects, or back scatters incident light. It is useful if they are formed from a thermally conductive

metallic material, such as aluminum, that can disperse and dissipate any thermal energy created by the absorption of blocked light.

[0075] Referring to FIGS. 50-51 and in an alternative embodiment, the end cap member 820 is comprised of a sleeve 835 and a rod 840 inserted into the sleeve 835. The sleeve 835 provides the overlapping section 815 with length 830 that blocks non uniform light emissions while providing mechanical means to attach both the diffuser 800 and the rod 840. The rod 840 provides the end reflective surface 810 that returns the light emitted from the distal end surface 801 of the diffuser 800 back towards the diffuser 800 while blocking any forward propagating light.

[0076] As noted above, it is advantageous for the sleeve 835 and the rod 840 to be thermally conductive. It is also advantageous for the rod 840 to be constructed out of a thermally conductive metallic material such as aluminum, gold, silver, copper, stainless steel, nickel, any suitable metal alloy, or any suitable ceramic with high thermal conductivity, to further aid in blocking transmitted light and dispersing any thermal energy generated.

[0077] The end reflective surface 810 can be formed by techniques such as, but not limited to, machining, mechanical polishing, electro polishing, chemical deposition, vacuum deposition, or application of a paint like compound. Ideally, the reflective surface 810 should return at least 80% of the incident light from the distal end surface 801 and preferably greater than 90% and even more preferably greater than 98%. In general, the more light reflected back towards the diffuser 800, the less light absorbed by the end cap member 820 and the less thermal rise in the components and surrounding tissue that is observed. Accordingly, the end cap member 820 should return at least 80% (preferred at least 90%, and more preferably at least 98%) of the light output from the distal portion 830.

[0078] It is important to avoid the exterior surfaces of the end cap member 820 exceeding 42° C and causing cellular damage to the surrounding tissue. The length 831 and a diameter 832 create an external surface area of the end cap member 820 of the diffuser light blocking device that is larger than the surface area of the distal end surface 801 of the diffuser 800, aiding in the

dispersal and dissipation of any thermal energy created by the absorption of incident light. It is desirable for the length 831 and the diameter 832 of the end cap member 820 to provide an exterior surface area that is at least 1,000% (preferred ranges from 1,000% to 2,000%, more preferred from 1,500% to 2,000%, even more preferred from 1,700% to 1,900%, and most preferred at 1,800%) of the surface area of the distal end surface 801 of the diffuser 800.

[0079] Referring to FIGS. 48 and 50, when the end cap member 820 is engaged with the distal portion 830, a cavity or void (hereinafter collectively referred to as "void") 825 is likely to exist between the distal end face 801 of the diffuser 800 and the end reflective surfaces (810, 845) of the end cap member 820. The void section 825 may be filled with a compound that matches the refractive index of the diffuser 800 material, further reducing non-uniform irradiance by reducing TIR from the light interacting with any imperfections in the distal end surface 801 of the diffuser 800. The compound in the void 825 may have adhesive characteristics that serve to help hold the entire assembly together. Additionally, the void 825 maybe filled with a scattering material, such as titanium oxide filled epoxy, that aids in back scattering transmitted light back into the fiber.

[0080] As noted above, the diffuser light blocking device of the present invention including its end cap member 820 can serve as the light blocking means 314 discussed above for the cylindrical light diffusing device (e.g., 300) described above in the specification. In one example, the cylindrical light diffusing device is comprised of an optical fiber with a non-circular fiber core such as a hexagon core fiber with 480 um cladding OD. The non-circular fiber core includes a light diffusing section and internal scattering features distributed within the fiber core of the light diffusing section along central axis of the fiber core, wherein the light diffusion section provides a "top hat" diffusing irradiance distribution, thereby limiting the variation of radially emitted irradiance longitudinally from the light diffusing section to be within +/- 15% of the average (" I_0 ") optical irradiance. The light diffusing section of this exemplary embodiment may have a length that is 10 mm, 20 mm, 30 mm or

40mm. Alternatively, such length can ranges anywhere from 10 mm to 40 mm. The cylindrical light diffusing device further includes the diffuser light blocking device of the present invention including the end cap member 820. In this exemplary embodiment, the end cap member is constructed out of
5 aluminum with 0.7mm OD and 1.5 mm length with a 1.0 mm deep pocketing feature 821.

EXAMPLE I

[0081] In one embodiment and referring to FIG. 31, a cylindrical light
10 diffusing device 400 is provided wherein it (400) is exactly the same as the cylindrical light diffusing device 100 discussed above except that it (400) has the non-circular core fiber 302 instead of the conventional circular optical fiber 12 of the device 100. The vertical (i.e., latitudinal) cross-sectional view of the non-circular core fiber 302 is the same as the embodiment shown on FIG. 14.
15 Using a 690 nm laser with 1 Watt launch power as the light source and adjusting the power until the irradiance measured at the center 17 of the longitudinal length of the diffuser 16 was 150 mW/cm² resulted in the “top hat” core irradiance distribution shown in FIG. 32. The irradiance measurement value of 150 mW/cm² is measured 0.75 mm from the central axis of the stated
20 location of the diffuser 16. FIG. 32 shows the core irradiance distribution at the vertical cross-section (e.g., shown as “11” in FIG. 31) through the non-circular core fiber 302 taken just before the cylindrical diffuser 16. The associated irradiance distribution graphs shown in FIG. 32 taken from vertical and horizontal cross sections through the center of the map of the irradiance
25 show the same “top hat” core irradiance distribution as the above-discussed conventional cylindrical light diffusing device 200, which requires a mode mixer (24). This “top hat” core irradiance distribution indicates a high degree of uniformity of the irradiance distribution in the fiber core 350. This demonstrates that including a non-circular core fiber 302 prior to a cylindrical
30 diffuser 16 can improve the irradiance or light output characteristic of the device 400. However, please note that the device 400 cannot achieve the “top hat” diffusing irradiance distribution as shown in FIGS. 6, 28 and 35 unless

the construction of the cylindrical diffuser 16 is optimized to account for the launch conditions. The present invention includes the device 400 with such optimized cylindrical diffuser 16 in order to deliver the “top hat” diffusing irradiance distribution as shown in FIGS. 6, 28 and 36.

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EXAMPLE II

[0082] In another embodiment of the present invention, a cylindrical light diffusing device is provided. This device has the same components as the device 400 discussed above in EXAMPLE I and shown in FIG. 31 except that the cylindrical diffuser 16 is now a conventional circular core optical fiber having a light emitting section containing internal scattering features 362 as shown in FIG. 33. FIG. 33 shows a vertical cross sectional view of this circular core fiber's 301 light emitting section having its cladding 352 and its circular fiber core 351, which contains internal scattering features 362. Using a 690 nm laser with 0.2 Watt launch power as the light source and adjusting the power until the irradiance measured at the center 17 of the longitudinal length of the circular core fiber's light diffusing section was 150 mW/cm^2 , this device resulted in the diffusing irradiance distribution shown in FIG. 34 which provides a generally “top hat” diffusing irradiance distribution. The irradiance measurement of 150 mW/cm^2 is measured 0.75 mm from the central axis of the stated location of the light diffusing section. The diffusing irradiance distribution shown in FIG. 34 is closer to the optimal “top hat” diffusing irradiance distribution shown in FIG. 6, 28, and 36 especially when compared to the diffusing irradiance distribution of the device 100 shown in FIG. 3. For the purpose of this specification, the term “top hat” diffusing irradiance distribution shall include both the generally “top hat” diffusing irradiance distribution shown in FIG. 34 and the optimal “top hat” diffusing irradiance distribution shown in FIGS. 6, 28, and 36.

[0083] FIG. 34 shows that there is a potential for sub-optimal efficiency and efficacy when using internal scattering features 362 in a circular core optical fiber to create a light diffusing section intended to emit the desired “top hat” diffusing irradiance distribution because as the light propagates forward

in the light emitting section, the irradiance in the optical axis of the optical fiber will gradually be depleted as the light encounters subsequent scattering features and leaves the light diffusing section. Since there is no mode mixing within this circular core light diffusing section, the vertical cross-sectional irradiance pattern will be less uniform, with the irradiance higher near the edges of the fiber core and depleted near the center where the scattering features are located.

[0084] This demonstrates that it is more desirable to use a non-circular fiber core 350 than a circular fiber core for the light emission section containing the internal scattering features 362. Nevertheless, the present invention includes the cylindrical light diffusing device presented in this example and its generally “top hat” diffusing irradiance distribution because it is possible this device and its generally “top hat” diffusing irradiance distribution are sufficient for certain applications.

15

EXAMPLE III

[0085] In one exemplary embodiment of the device 300 and referring to FIGS. 9, 10, and 14, the device 300 includes the non-circular core fiber 302, the lead-in optical fiber 304, the at least one optical connector 306. During operation, the lead-in optical fiber 304 is in light communication to (i) a light source (not shown) and (ii) the non-circular core fiber 302 via the at least one optical connector 306. The lead-in fiber 304 has a 200 μm OD glass core and a 230 μm OD cladding. The length of the non-circular core fiber 302 is 30 cm, which distally terminates into the light blocking means 314 made out of a reflecting coating of aluminum deposition. During operation, the non-circular core fiber 302 is filled with laser light having an angular distribution of a NA of 0.22.

[0086] Referring FIGS. 10 and 14, the fiber core 350 of the non-circular core fiber 302 is constructed out of PMMA with a hexagonal geometry in a circumscribed $\varnothing 660 \mu\text{m}$ diameter circle. The fiber core 350 is cladded by the cladding 352 with an interior surface geometry 356 that has the same hexagonal geometry as the fiber core 350. However, the exterior surface

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geometry 354 of the cladding 352 is circular. The cladding 352 is constructed of a silicone with a $\varnothing 740$ μm OD.

[0087] The non-circular core fiber 302 further includes the light diffusing section 308 having the diffusing proximal end 310 and the diffusing distal end 312. The light diffusing section 308 is 10.8 mm in longitudinal length and the internal scattering features 362 begin at the diffusing proximal end 310 and ends at the diffusing distal end 312. The features 362 are comprised of 27 sets of three cylinders. Each cylinder is approximately 27 μm in diameter and 270 μm in length oriented around the central axis 364 at 60° increments as shown in FIGS. 9 and 10. The 27 sets of the features 362 are arranged based upon the following formula in a non-linear fashion: $z_i = 0.5i + 0.0045i^2 - 0.0003i^3$ where the index i is an integer with values from 0 to 26 and z_i is the relative z location of the i^{th} feature 362 along the axis 364. Please note that the present invention is not limited to this formula, the size of the features 362, the number of features 362 per unit length of the diffusing section 308, or the amount of scattering per feature 362. Instead, the present invention includes other suitable spacing's, sizes, numbers of features 362 per unit length, and amounts of scattering per feature 362.

[0088] Furthermore, the following characteristics of the device 300 may be adjusted in order to further optimize its diffusing irradiance distribution: the longitudinal length and diameter of the diffusing section 308, the size and geometry of the fiber core 350 and any cladding 352, the scattering characteristics of the features 362, the maximum angle coming out the of the light source and/or the lead-in fiber 304, and the inclusion of the light blocking means 314 at the distal end of the non-circular core fiber 302. This optimization can be performed experimentally or using a ray tracing CAD program. The common factor in determining an optimal diffusing irradiance distribution is to engineer a linear increase in the effective scattering per incremental volume, as there is a linear decrease in the light density per incremental volume in the fiber core 350.

[0089] As discussed above, FIG. 27 shows a map of the irradiance at the vertical cross-section (shown as "316" in FIG. 9) through the fiber core 350

taken just before the diffusing proximal end 310 for this exemplary embodiment of the device 300. The light source used is a 690 nm laser with 0.125 Watt launch power and this power was adjusted until the irradiance measured at the center 307 of the longitudinal length of the light diffusing section 308 was 150 mW/cm². This measurement is taken 0.75 mm from the central axis of the stated location of the light diffusing section 308. The total length of optical fiber (combination of the lead-in fiber 304 and the non-circular core fiber 302) from the light source leading up to this location 316 is 2 meters long. During operation, the non-circular core fiber 302 is filled with laser light having an angular distribution of a NA of 0.22.

[0090] The associated irradiance distribution graphs shown in FIG. 27 taken from vertical and horizontal cross sections through the center of the map of the irradiance show the same “top hat” core irradiance distribution as the above-discussed conventional cylindrical light diffusing device 200 containing a mode mixer 24. This “top hat” core irradiance distribution indicates a high degree of uniformity of the irradiance distribution in the fiber core 350 (e.g. optimal core irradiance distribution).

[0091] FIG. 28 shows the out-coupled longitudinally radially-symmetric irradiance distribution along the outer surface of the light diffusing section 308 (e.g., the diffusing irradiance distribution) of this exemplary embodiment of the device 300. The diffusing irradiance distribution shows the optimal “top hat” irradiance distribution indicating spatial uniformity of the out-coupled longitudinally radially-symmetric irradiance along the outer surface of the light diffusing section 308. The horizontal axis of FIG. 28 shows longitudinal length in mm and the horizontal arrow indicates the longitudinal length of the light diffusing section 308. The vertical axis of FIG. 28 shows the out-coupled irradiance at the surface of the light diffusing section 308 measured in Watts/cm² at a distance 0.75 mm from the central axis.

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EXAMPLE IV

[0092] In an exemplary embodiment and referring to FIGS. 11 and 12, the device 300 includes the non-circular core fiber 302, the lead-in optical fiber

304, the at least one optical connector 306. During operation, the lead-in optical fiber 304 is in light communication to (i) a light source (not shown) and (ii) the non-circular core fiber 302 via the at least one optical connector 306. The lead-in fiber 304 has a 200 μm OD glass core and a 230 μm OD cladding.

5 The length of the non-circular core fiber 302 is 30 cm, which distally terminates into the light blocking means 314 made out of a reflecting coating of aluminum deposition.

[0093] Referring to FIG. 12, the non-circular core fiber 302 includes the fiber core 350 constructed out of PMMA with a hexagonal geometry in a
10 circumscribed $\varnothing 660$ μm diameter circle. The fiber core 350 is clad by the cladding 352 with an interior surface geometry 356 that is same hexagonal geometry as the fiber core 350. However, the exterior surface geometry 354 of the cladding 352 is circular. The cladding 352 is constructed of a polymer with a $\varnothing 740$ μm OD. The non-circular core fiber 302 further includes the
15 enclosed open cavity 358 and the covering 360. The covering 360 is constructed of a translucent Pebax® resin with a $\varnothing 1000$ μm OD and a $\varnothing 900$ μm ID. The covering is heat sealed at one or both of its ends.

[0094] The non-circular core fiber 302 further includes the light diffusing section 308 having the diffusing proximal end 310 and the diffusing distal end
20 312. The light diffusing section 308 is exactly the same as the light diffusing section 308 of the embodiment described above in Example III including its internal scattering features 362.

[0095] FIG. 35 shows a map of the irradiance at the vertical cross-section (shown as "316" in FIG. 11) through the fiber core 350 taken just before the
25 diffusing proximal end 310 for this exemplary embodiment of the device 300. The light source used is a 690 nm laser with 0.125 Watt launch power and this power was adjusted until the irradiance measured until the irradiance measured at the center 307 of the longitudinal length of the light diffusing section 308 was 150 mW/cm^2 . This measurement is taken 0.75 mm from the
30 central axis of the stated location of the light diffusion section 308. The total length of optical fiber (combination of the lead-in fiber 304 and the non-circular core fiber 302) from the light source leading up to this location 316 is 2 meters

long. During operation, the non-circular core fiber 302 is filled with laser light having an angular distribution of a NA of 0.22.

[0096] The associated irradiance distribution graphs shown in FIG. 35 taken from vertical and horizontal cross sections through the center of the map of the irradiance show the same “top hat” core irradiance distribution as the above-discussed conventional cylindrical light diffusing device 200 with a mode mixer (24). This “top hat” core irradiance distribution indicates a high degree of uniformity of the irradiance distribution in the fiber core 350.

[0097] FIG. 36 shows the out-coupled longitudinally radially-symmetric irradiance distribution along the outer surface of the light diffusing section 308 (e.g., the diffusing irradiance distribution) of this exemplary embodiment of the device 300. The diffusing irradiance distribution shows the optimal “top hat” irradiance distribution indicating spatial uniformity of the out-coupled longitudinally radially-symmetric irradiance along the outer surface of the light diffusing section 308. The horizontal axis of FIG. 36 shows longitudinal length in mm and the horizontal arrow indicates the longitudinal length of the light diffusing section 308. The vertical axis of FIG. 36 shows the out-coupled irradiance at the surface of the light diffusing section 308 measured in Watts/cm² at a distance 0.75 mm from the central axis.

EXAMPLE V

[0098] In an exemplary embodiment and referring to FIGS. 11 and 43, the device 300 includes the non-circular core fiber 302, the lead-in optical fiber 304, the at least one optical connector 306. During operation, the lead-in optical fiber 304 is in light communication to (i) a light source (not shown) and (ii) the non-circular core fiber 302 via the at least one optical connector 306. The lead-in fiber 304 has a 200 μm OD glass core and a 230 μm OD cladding. The length of the non-circular core fiber 302 is 30 cm, which distally terminates into the light blocking means 314 made out of a reflecting coating of aluminum deposition.

[0099] Referring to FIG. 43, the non-circular core fiber 302 includes the fiber core 350 constructed out of glass with a hexagonal geometry in a

circumscribed $\varnothing 460$ μm diameter circle. The fiber core 350 is cladded by the cladding 352 with an interior surface geometry 356 that is same hexagonal geometry as the fiber core 350. However, the exterior surface geometry 354 of the cladding 352 is circular. The cladding 352 is constructed of a glass with a $\varnothing 480$ μm OD. The non-circular core fiber 302 further includes the enclosed open cavity 358 and the covering 360. The covering 360 is constructed of a translucent Pebax® resin with a $\varnothing 1000$ μm OD and a $\varnothing 800$ μm ID. The covering is heat sealed at one or both of its ends.

[00100] The non-circular core fiber 302 further includes the light diffusing section 308 having the diffusing proximal end 310 and the diffusing distal end 312. The light diffusing section 308 is 11.3 mm in longitudinal length and the internal scattering features 362 begin at the diffusing proximal end 310 and ends at the diffusing distal end 312. The features 362 are comprised of 37 sets of 6 ellipses. Each ellipse is approximately spherical with a 40 μm diameter and is located 100 μm from the central axis of the fiber core 350 and distributed at 60° increments as shown in FIG. 43. The 37 sets of the features 362 are arranged based upon the following formula in a non-linear fashion: $z_i = 0.35i + 0.00015i^2 - 0.000032i^3$ where the index i is an integer with values from 0 to 36 and z_i is the relative z location of the i^{th} feature 362 along the axis 364. Please note that the present invention is not limited to this formula, the size of the features 362, the number of features 362 per unit length of the diffusing section 308, or the amount of scattering per feature 362. Instead, the present invention includes other suitable spacing's, sizes, numbers of features 362 per unit length, and amounts of scattering per feature 362.

[00101] The light source and the total length are exactly the same as the embodiment described above in Example IV and the map of the irradiance at the vertical cross-section 316 has values that are within +/- 10% to that shown in FIG. 35. When the source is adjusted in the same fashion as in Example IV, the diffusing irradiance distribution shows an optimal "top hat" irradiance distribution that has values that are within +/- 20% as shown in FIG. 36.

EXAMPLE VI

[00102] In an exemplary embodiment and referring to FIG. 41A, the present invention provides a frontal light diffusing device 600 includes a fiber optic connector 603, a cylindrical fiber section 602, a non-circular core fiber 604, a pair of optical connectors 605, and a lens component 606. During operation, the cylindrical fiber section 602 is in light communication to (i) a light source (not shown) via fiber optic connector 603 and (ii) the non-circular core fiber section 604 is also in light communication with the lens component 606.

[00103] The fiber optic connector 603 is SMA style and the cylindrical fiber section 602 has a 200 μm OD glass core and a 220 μm OD cladding and a 700 μm OD Tefzel jacket. The pair of fiber optical connectors 605 are SMA style and the non-circular core fiber 604 has a hexagonal glass core with a circumscribed 460 μm diameter and a cylindrical glass core with a 480 μm external diameter and is covered by a 1.05 mm diameter Tefzel jacket. The lens component 606 is a 0.5 NA, $\frac{1}{4}$ pitch GRIN lens with a 0.8 mm OD that is affixed to the distal end of the non-circular core fiber 604 with an optical epoxy. The length of the non-circular core fiber is 30 cm and the combined length of the frontal light diffusing device 600 is 2 meters.

[00104] The light source used is a 690 nm laser that couples 2.2 Watts of 0.22 NA launch power into the lead in fiber 602 and this power is adjusted until the irradiance measured at the target 614 with a stand-off 616 of 80 mm is 150 mW/cm^2 with a top hat distribution with a 40 mm internal diameter that has values that are within $\pm 10\%$ of the FIG 41D.

[00105] Please note that unless otherwise expressly stated, all diffusing irradiance distribution data presented in this specification and drawings (e.g., FIGS. 2-3, 5-6, 27-28, 34-36) are taken 0.75 mm from the central axis of the applicable location of either the fiber core or the diffuser.

[00106] The method of the present invention further includes applying a photosensitive drug composition to desired treatment site; placing the device (300, 400) described interstitially inside the desired treatment site and applying light delivered by the device 300 to the treatment site at a

wavelength absorbed by the photosensitive drug composition so as to inhibit targeted cells located within the treatment site.

[00107] Although there has been hereinabove described a fiber optic light diffusing device and method for PIT, PDT and other light activated therapies
5 in accordance with the present invention, for purposes of illustrating the manner in which the invention may be used to advantage, it will be appreciated that the invention is not limited thereto. Accordingly, any and all modifications, variations, or equivalent arrangements which may occur to those skilled in the art should be considered to be within the scope of the
10 present invention as defined in the appended claims.

CLAIMS

1. A diffuser light blocking device comprising an end cap member having a length, a diameter, and a pocketing feature wherein:
 - a. the diffuser light block device is designed to engage with a light diffuser having a distal portion having an exterior shape and a distal end surface;
 - b. the pocketing feature includes a side wall and an end reflective surface;
 - c. shape of the pocketing feature corresponds to the exterior shape of the distal portion of the diffuser;
 - d. the pocketing features engages the distal portion;
 - e. an overlapping section of the side wall of the pocketing feature surrounds side wall of the distal portion and prevents at least 95% of light output from the distal portion from escaping out of the side wall of the distal portion;
 - f. the end reflective surface blocks any forward propagating light output from the distal end surface and returns at least 80% of light coming out of the distal end surface back towards the diffuser;
 - g. the end cap member is thermally conductive allowing heat generated by absorption of the light output from the distal portion to be dispersed throughout the end cap member;
 - h. the length and the diameter of the end cap member provide an exterior surface area that is at least 1,000% of surface area of distal end surface; and
 - i. the diffuser light blocking device reduces creation of a diffuser irradiance hot spot.
2. The device of claim 1 wherein a void exists between the distal end surface and the end reflective surface.
3. The device of claim 2 wherein the void is filled with a compound that matches

refractive index of the diffuser material.

4. The device of claim 2 wherein the void is filled with titanium oxide filled epoxy.
5. The device of claim 2 wherein a compound is used to fill the void and the compound has a characteristic selected from the group consisting of adhesiveness, light scattering, and a combination thereof.
6. The device of claim 1 wherein the overlapping section of the side wall of the pocketing feature prevents at least 98% of the light output from the distal portion from escaping out of the side wall of the distal portion.
7. The device of claim 1 wherein the end cap member is constructed out of aluminum.
8. The device of claim 1 wherein the end cap member is biocompatible.
9. The device of claim 1 wherein the end cap member is comprised of a sleeve and a rod wherein: (i) the rod is inserted into the sleeve; (ii) the sleeve provides the side wall of the pocketing feature including the overlapping section and the rod provides the end reflective surface of the pocketing feature.
10. The device of claim 1 wherein the end reflective surface return at least 98% of the light coming out of the distal end surface back towards the diffuser.
11. The device of claim 1 wherein the end cap member returns at least 80% of light output from the distal portion.
12. The device of claim 1 wherein the end cap member returns at least 90% of light output from the distal portion.

13. The device of claim 1 wherein the end cap member returns at least 98% of the light output from the distal portion.
14. The device of claim 1 wherein the exterior surface area of the end cap member ranges from 1,000% to 2,000% of the surface area of the distal end surface.
15. The device of claim 1 wherein the exterior surface area of the end cap member ranges from 1,500% to 2,000% of the surface area of the distal end surface.
16. The device of claim 1 wherein the exterior surface area of the end cap member ranges from 1,700% to 1,900% of the surface area of the distal end surface.
17. A diffuser light blocking device comprising an end cap member having a length, a diameter, and a pocketing feature wherein:
- a. the diffuser light block device is designed to engage with a light diffuser having a distal portion having an exterior shape and a distal end surface;
 - b. the pocketing feature includes a side wall and an end reflective surface;
 - c. shape of the pocketing feature corresponds to the exterior shape of the distal portion of the diffuser;
 - d. the pocketing features engages the distal portion;
 - e. an overlapping section of the side wall of the pocketing feature surrounds side wall of the distal portion and prevents at least 95% of light output from the distal portion from escaping out of the side wall of the distal portion;
 - f. the end reflective surface blocks any forward propagating light output from the distal end surface and returns at least 90% of light coming out of the distal end surface back towards the diffuser;
 - g. the end cap member is thermally conductive allowing heat generated by absorption of the light output from the distal portion to be dispersed

- throughout the end cap member;
- h. the length and the diameter of the end cap member provide an exterior surface area is from 1,700% to 1,900% of surface area of distal end surface;
 - i. the diffuser light blocking device reduces creation of a diffuser irradiance hot spot; and
 - j. a void exists between the distal end surface and the end reflective surface.
18. A cylindrical light diffusing device comprising: a fiber having a non-circular fiber core and a diffuser light blocking device wherein:
- a. the non-circular fiber core provides a “top hat” core irradiance distribution and has a latitudinal cross-sectional shape of a regular polygon;
 - b. a light diffusing section having a diffusing proximal end surface, a diffusing distal end surface, and internal scattering features distributed within the fiber core of the light diffusing section along central axis of the fiber core, wherein the light diffusion section provides a “top hat” diffusing irradiance distribution, thereby limiting the variation of radially emitted irradiance longitudinally from the light diffusing section to be within +/- 15% of the average (“ I_0 ”) optical irradiance;
 - c. the light diffusing section further includes a distal portion having an exterior shape and the distal portion includes the diffusing distal end surface;
 - d. the diffuser light blocking device is comprised of an end cap member having a length, a diameter, and a pocketing feature wherein:
 - i) the pocketing feature includes a side wall and an end reflective surface;
 - ii) shape of the pocketing feature corresponds to the exterior shape of the distal portion of the light diffusing section;
 - iii) the pocketing features engages the distal portion;

- iv) an overlapping section of the side wall of the pocketing feature surrounds side wall of the distal portion and prevents at least 95% of light output from the distal portion from escaping out of the side wall of the distal portion;
- v) the end reflective surface blocks any forward propagating light output from the diffusing distal end surface and returns at least 80% of light coming out of the diffusing distal end surface back towards the diffusing section;
- vi) the end cap member is thermally conductive allowing heat generated by absorption of the light output from the distal portion to be dispersed throughout the end cap member;
- vii) the length and the diameter of the end cap member provide an exterior surface area that is at least 1,000% of surface area of diffusing distal end surface; and
- viii) the diffuser light blocking device reduces creation of a diffuser irradiance hot spot.

19. The device of Claim 18 wherein the regular polygon is a hexagon.

20. The device of Claim 18 wherein the light diffusing section ranges from 10 mm to 40 mm.