FRONTAL LIGHT DISTRIBUTOR, FD1
Instructions for Use

PRODUCT DESCRIPTION
The FD1 frontal light distributor is a light delivery device consisting of a fused silica laser fiber, a proximal standard laser connector and a distal microlens tip.
This device is intended to transmit light from a laser source to the device tip and to obtain a uniform circular illumination spot in front of the end surface of the tip thanks to the distal microlens.
The small diameter of the 1,4 m long distal catheter (Ø 1.8 mm, tip Ø 2.1 mm) allows endoscopic use through the working channel of standard flexible endoscopes.

INTENDED USE
The FD1 frontal light distributor is intended for use in photodynamic therapy (PDT) with an approved PDT protocol.
This device is used in conjunction with laser light during PDT and should only be used with compatible lasers.
This device is supplied sterile and for single use only.

CAUTION: The device is not designed for re-use. The cleaning with standard clinical cleaning procedure by untrained personnel can damage the device. The damage cannot be detected without specific equipment and can reduce the efficacity of the treatment.

CAUTION: The device cannot be re-sterilized with standard EtO sterilization procedure. Medlight S.A. sterilizes the device with a validated specific EtO sterilization procedure.

CAUTION: Do not use this device for any purpose other than the stated intended use. The device should not be used in contact with central circulatory system and with central nervous system.

CONTENTS OF PACKAGE AND STORAGE CONDITIONS
The package contains one FD1 frontal light distributor intended for use in photodynamic therapy.
Store the device in its Med*light* S.A. original box, in a cool dark dry location.

EQUIPMENT REQUIRED
FD1 frontal light distributor.
Laser with calibration unit and protective eyewear (not included).
Photodynamic therapy drug with protocol (not included).

WARNINGS
THESE INSTRUCTIONS ARE INTENDED FOR USE BY PHYSICIANS WHO HAVE BEEN TRAINED IN THE USE OF PHOTODYNAMIC THERAPY (PDT) WITH AN APPROVED PDT DRUG AND APPROPRIATE LASER SYSTEM.

THESE INSTRUCTIONS ARE APPLICABLE ONLY TO THE THE FD1 FRONTAL LIGHT DISTRIBUTOR USED IN CONJUNCTION WITH AN APPROVED PDT DRUG AND APPROPRIATE LASER SYSTEM FOR PDT. INSTRUCTIONS FOR USE OF THE FIBER OPTIC, THE PHOTOSENSITIZING PDT DRUG AND THE SELECTED LASER SYSTEM SHOULD BE READ CAREFULLY BEFORE USE.

FOLLOW THE LASER MANUFACTURER OPERATING MANUAL FOR LASER INSTALLATION AND OPERATION.

USE OF INCOMPATIBLE LASERS THAT ALTER THE REQUIRED LIGHT OUTPUT CHARACTERISTICS FOR THE PHOTOACTIVATION OF THE PDT DRUG COULD RESULT IN INCOMPLETE TREATMENT DUE TO PARTIAL PHOTOACTIVATION OF THE PDT DRUG, OVERTREATMENT DUE TO OVERACTIVATION OF THE PDT DRUG, DAMAGE TO SURROUNDING NORMAL TISSUE AND/OR DAMAGE TO THE FIBER OPTIC WHICH COULD ADDITIONALLY CREATE AN OPTICAL HAZARD FOR MEDICAL PERSONNEL AND/OR THE PATIENT.

COMPLY WITH FACILITY LASER SAFETY REQUIREMENTS.

ENSURE THAT ALL PERSONNEL ARE AWARE OF FIBER OPTIC HANDLING IN CONJUNCTION WITH THE LASER AND ARE TAKING PROPER PRECAUTIONS.

ALWAYS WEAR PROTECTIVE EYEWEAR DURING LASER LIGHT DELIVERY. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION. DO NOT VIEW THE LASER BEAM DIRECTLY, EVEN WHILE WEARING PROTECTIVE EYEWEAR. PROVIDE EYE PROTECTION FOR PATIENT IN ADDITION TO ALL OPERATING ROOM STAFF.

DO NOT EXCEED MAXIMUM FIBER OUTPUT POWER SPECIFICATION.

PREPARATION FOR USE
1. Prepare the laser system for delivery of light of the specified wavelength for photoactivation of the PDT drug as indicated in the appropriate laser system operating manual.
   CAUTION: Verify that the output characteristics of the laser match the input characteristics of the fiber, to assure uniform light distribution from the microlens as required for the photoactivation of the PDT drug.
2. Remove the frontal light distributor from its package, after verification of the shelf-life of the device. Uncoil slowly and carefully the catheter. Inspect the fiber for visible signs of damage. Securely attach the optical connector to the laser fiber port.
   CAUTION: Fragile device, contains optical fiber that may break if handled roughly or bent sharply.
   CAUTION: Keep the optical connector clean. Avoid touching the optical connector surface, as this may stain or scratch the optical surface of the laser connector.
3. Calibrate the fiber output using the laser calibration unit (integrating sphere), according to the procedure described in the laser system operating manual, or a suitable external calibration unit.
   CAUTION: If the calibration procedure gives unexpected results (for example, fiber transmission lower than specified), do not continue without investigating the cause for the apparent high energy loss. Possible causes may include inappropriate laser source, laser out of alignment, dirty cuvette into calibration unit, incorrect setting or malfunction of the calibration unit, defect or break in the fiber optic, dirty optical connector, stained or damaged microlens.
   CAUTION: Where applicable, be sure to perform calibration procedure in sterile condition. Use of a sterile cuvette is necessary to assure fiber sterility.
4. Set the laser to emit low power (aiming beam) and check the output uniformity of the fiber by directing the tip towards a white, flat surface. If the illumination spot does not appear to be homogeneous with sharp edges, switch off the laser and inspect the microlens for dirt or damage. Do not use the fiber if the output uniformity pattern is not acceptable or if damage is evident.
   CAUTION: Never look directly into laser beam even with protective eyewear. This may cause permanent eye damage
5. Follow the PDT drug protocol to determine the required light dose needed for the expected PDT outcome. Adjust the power output of the laser to that required for the treatment.
   CAUTION: Do not exceed maximum fiber power specification when adjusting laser power. Setting the laser power beyond specified levels may result in overtreatment or damage the fiber optic.
   Do not use the device into Intralipid or similar medium with high scattering and low absorption properties.

PROCEDURE

1. Position the FD1 frontal light distributor and direct the fiber tip towards the treatment area. Adjust the distance between tissue and fiber tip so that the beam fills the entire treatment area. If needed, set the laser to emit low power (aiming beam) to help in positioning the fiber.

   CAUTION: Do not position distal tip of the device in contact with tissue. This may cause excessive light absorption and thus damage the optical tip of the device. A minimum distance to tissue of 10 mm shall be observed. For same reason avoid tissue residue, blood and/or expectoration to stain the microlens.

2. Begin light treatment by depressing the laser footswitch / handswitch. To assure correct dosimetry, the fiber must be maintained perpendicular to tissue surface, so that the spot is perfectly round. Release the laser footswitch / handswitch when the treatment is complete.

   CAUTION: Avoid inadvertent photoactivation of non-target tissue. Ensure that surrounding areas are shielded from laser light.

3. If a treatment area requires more than one illumination, reposition the frontal light distributor over the next treatment area. Avoid overdosing with laser light by minimizing overlapping of treatment areas.
4. Discard the device after use and / or when shelf-life is expired, see use-by date on Med*light* S.A. original box labeling.
5. Dispose of as medical waste.

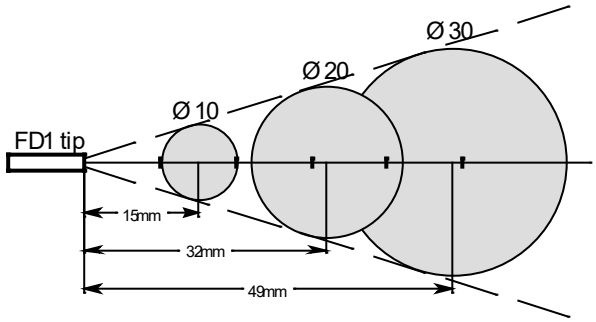
   CAUTION: Do not clean the device for re-use or re-sterilization. The device is not designed for reprocessing.

DEVICE CHARACTERISTICS:
FD1 FRONTAL LIGHT DISTRIBUTOR

MECHANICAL	FD1
OVERALL LENGTH	4 m ± 5 cm
DISTAL LENGTH	1.4 m ± 3 cm
DISTAL DIAMETER (EXCLUDING TIP)	1.8 ± 0.15 mm
TIP DIAMETER	2.1 ± 0.1 mm
OPTICAL	
TYPICAL TRANSMISSION (*)	85 %
FULL ANGLE OF DIVERGENCE	34.7°
UNIFORMITY	+/- 15%
LASER	
MAXIMUM POWER (Calibrated power output)	2.0 W (cw)
WAVELENGTH RANGE	480-800 nm
OPTICAL FIBER	
FIBER MATERIAL	SILICA, low OH^-
CORE DIAMETER	600 µm
NUMERICAL APERTURE (NA)	0.37
MINIMUM BENDING RADIUS (long term)	94 mm
OPTICAL CONNECTOR	SMA-905
CONDITIONING	
PACKAGING	SINGLE POUCH INDIVIDUAL BOX
STERILIZATION	STERILE / EtO
USEFUL LIFE	
RE-USE	DISPOSABLE
SHELF LIFE	2 YEARS

(*) Transmission is defined in comparison with a 4 m / 600µm / NA0.37 silica bare fiber.

SPOT SIZE VS DISTANCE TO TISSUE:



SYMBOLS

LEGAL MANUFACTURER

COUNTRY OF MANUFACTURE

SERIAL NUMBER

DATE OF MANUFACTURE

USE-BY-DATE

UNIQUE DEVICE IDENTIFIER

MEDICAL DEVICE

CONSULT INSTRUCTION FOR USE

LASER RADIATION. AVOID DIRECT EYE EXPOSURE

DO NOT USE IF PACKAGE IS DAMAGED

DO NOT RE-USE

SINGLE STERILE BARRIER SYSTEM

STERILIZED USING ETHYLENE OXIDE

DISCLAIMER OF WARRANTIES

Med*light* S.A. product warranties and liability are limited in accordance with the Med*light* S.A. Terms and Conditions of Sale which states, among other things, that the warranties are not effective if the user misuses the product in any manner, has failed to use the product in accordance with industry standards and practices, or has failed to use the product in accordance with its instructions for use.
In no case can Med*light* S.A. be held responsible for an incorrect light dose applied during a PDT treatment.

VIGILANCE

In case of any serious incident that has occurred in relation to the device, it should be reported without any delay to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

LEGAL MANUFACTURER

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