SPHERICAL DIFFUSER
Model SD200
Instructions for Use

PRODUCT DESCRIPTION

SD200 spherical light diffuser is a catheter type device based on an optical glass fiber. A standard optical connector is assembled at the proximal end of the fiber and a light scattering sphere at the other extremity (distal end). A flexible plastic tube protects the proximal part of the fiber.
Connected to a laser source, the SD200 spherical light diffuser guides the light from the laser to its distal end, where the light is uniformly distributed around the spherical tip.

INTENDED USE

SD200 spherical light diffuser is suitable for controlled illumination of biological tissues with low intensity. It is intended for use in photodynamic therapy (PDT) with approved PDT photosensitizing drug and protocol.
This device is used in conjunction with laser light during PDT and should only be used with compatible lasers.
SD200 spherical light diffuser can only be used in organs where the PDT photosensitizing drug and protocol are approved and should never be used in contact with central circulatory system and with central nervous system. The device should not be used in liquid medium with very high scattering and low absorption properties, such as Intralipid
This device is supplied sterile and is intended 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 SD200 spherical light diffuser 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

SD200 spherical light diffuser.
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 SD200 SPHERICAL LIGHT DIFFUSER 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 isotropic light distribution from the spherical lightl diffuser as required for the photoactivation of the PDT drug.

2. Remove the spherical light diffuser 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 optical spherical tip.

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 light uniformity around the diffusing spherical tip. If the illumination does not appear uniform, switch off the laser and inspect the optical tip for dirt or damage. Do not use the fiber

if the output uniformity pattern is not acceptable or if damage is evident.

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 SD200 spherical light diffuser in the organ to be treated following the instructions of the approved PDT protocol.

CAUTION: Avoid tissue residue, blood and/or expectoration to stain the optical tip. This may cause excessive light absorption and thus damage the optical tip of the device.

2. Begin light treatment by depressing the laser footswitch / handswitch. 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. Discard the device after use.

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

DEVICE CHARACTERISTICS:
SD200 SPHERICAL LIGHT DIFFUSER

MECHANICAL (APPROXIMATE)	
TIP DIAMETER	2.0 mm
OVERALL CATHETER LENGTH	3.0 m
OPTICAL	
TRANSMISSION (*)	80%
ISOTROPY IN AIR (standard deviation from 40° to 320°)	max 10%
MAXIMUM POWER (calibrated fiber output)	
IN AIR	1 W (cw)
IN WATER	3 W (cw)
WAVELENGTH RANGE	480-800 nm
FIBER OPTIC	
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 3m / 600µm / NA0.37 silica bare fiber

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

Medlight S.A. product warranties and liability are limited in accordance with the Medlight 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 Medlight 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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