ISOTROPIC PROBE
Model IP85
Instructions for Use

PRODUCT DESCRIPTION

IP85 isotropic probe 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.
The IP85 isotropic probe is designed to collect light at its distal extremity, in a large solid angle with an identical efficiency and to guide the collected light to its proximal end where the light can be coupled to an optical detector.

INTENDED USE

IP85 isotropic probe is intended for measuring diffused light intensity in human body organs.
The device is not intended for use in contact with central circulatory system and with central nervous system.
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 IP85 isotropic probe.
Store the device in its Med*light* S.A. original box, in a cool dark dry location.

EQUIPMENT REQUIRED

IP85 isotropic probe
Optical detector (not included)

WARNINGS

THE IP ISOTROPIC PROBE HAS BEEN TESTED AS A PROBE AND MUST NOT BE USED AS SPHERICAL LIGHT DIFFUSER.

PREPARATION FOR USE

1. Remove the isotropic probe 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. Verify that the spherical tip is properly attached at the fiber optic extremity.

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.

2. Securely attach the optical connector to the optical detector.

PROCEDURE

1. Position the IP85 isotropic probe in the organ to be investigated following the usual safety procedures.

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

2. After use, withdraw with care the probe from the organ or from the protective catheter. The high profile of the optical spherical tip can constrict the move back. The spherical tip could even be detached from the catheter.
3. Discard the device after use. Inspect the fiber for visible signs of damage. Verify that the spherical tip is properly attached at the fiber optic extremity.

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

DEVICE CHARACTERISTICS: IP85 ISOTROPIC PROBE

MECHANICAL (APPROXIMATE)	
TIP DIAMETER	0.85 mm
OVERALL LENGTH	3.0 m
OPTICAL	
ISOTROPY (standard deviation from 40° to 320°, in air)	max 10%
WAVELENGTH RANGE	480 – 800 nm
OPTICAL FIBER	
FIBER MATERIAL	SILICA, low OH^-
CORE DIAMETER	400 µm
NUMERICAL APERTURE (NA)	0.37
MINIMUM BENDING RADIUS (long term)	47 mm
OPTICAL CONNECTOR	SMA-905
CONDITIONING	
PACKAGING	DOUBLE POUCH INDIVIDUAL BOX
STERILIZATION	STERILE / EtO
USEFUL LIFE	
RE-USE	DISPOSABLE
SHELF LIFE	2 YEARS

SYMBOLS


LEGAL MANUFACTURER

COUNTRY OF MANUFACTURE

SERIAL NUMBER


DATE OF MANUFACTURE


USE-BY-DATE

UNIQUE DEVICE IDENTIFIER

MEDICAL DEVICE


CONSULT INSTRUCTION FOR USE


DO NOT USE IF PACKAGE IS DAMAGED


DO NOT RE-USE


DOUBLE STERILE BARRIER SYSTEM

STERILE EO 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.

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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