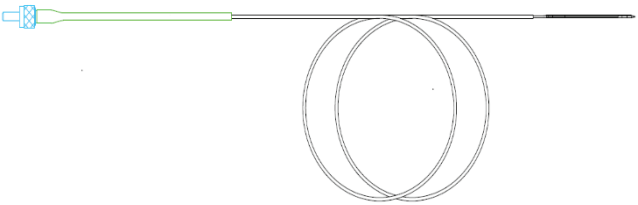
OPTIGUIDE® PB200 Fiber Optic Diffuser Series

REF: **PB210** **PB215** **PB220** **PB225** **PB230** **PB250**

Cylindrical Diffuser

INSTRUCTIONS FOR USE
Single use only - Do not re-sterilize



Model No.	Diffuser Length
PB210	1.0 cm
PB215	1.5 cm
PB220	2.0 cm
PB225	2.5 cm
PB230	3.0 cm
PB250	5.0 cm

CAUTION: US Federal Law restricts this device to sale by or on the order of a physician.

Distributed by Pinnacle Biologics, Inc.

Reorder from CuraScript SD
Tel: 1-866-268-5554 Fax: 1-800-862-6208

PRODUCT DESCRIPTION

The PB series OPTIGUIDE® Fiber Optic Diffuser is a light delivery system consisting of a 400µm coated silica laser fiber, a proximal SMA-type laser connector, and a distal light diffusing tip.

Model No:	Diffuser Length	Type	Power Output	Equivalent Coherent Cat. No	Equivalent Laserscope Cat. No
PB210	1.0 cm	Cylindrical	400 mW	10-9011	10-9001
PB215	1.5 cm	Cylindrical	600 mW	10-9012	10-9002
PB220	2.0 cm	Cylindrical	800 mW	10-9013	10-9003
PB225	2.5 cm	Cylindrical	1000 mW	10-9014	10-9004
PB230	3.0 cm	Cylindrical	1200 mW		
PB250	5.0 cm	Cylindrical	2000 mW	10-9017	10-9007

FOR SINGLE USE ONLY

CAUTION

FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

CONTENTS OF PACKAGE

This package contains one sterile fiber optic diffuser designed to transmit and uniformly distribute light energy radially over the specified length of the diffuser. The OPTIGUIDE® Fiber Optic Diffuser is designed to couple to an approved 630 nm (red light) laser system via an SMA-905 laser connector.

INDICATIONS FOR USE

The OPTIGUIDE® Fiber Optic Diffuser is designed for use in Photodynamic Therapy with PHOTOFRIN® (porfimer sodium) for Injection for:

- palliation of patients with completely obstructing esophageal cancer, or of patients with partially obstructing esophageal cancer who, in the opinion of their physician, cannot be satisfactorily treated with Nd:YAG laser therapy,
- reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial nonsmall cell lung cancer (NSCLC),
- treatment of microinvasive endobronchial NSCLC in patients for whom surgery and radiotherapy are not indicated.
- ablation of high-grade dysplasia (HGD) in Barrett's esophagus (BE) among patients who are not candidates for esophagectomy.

The OPTIGUIDE® Fiber Optic Diffuser is designed for endoscopic positioning for delivery of laser light and should only be used with approved lasers. Refer to the PHOTOFRIN® Package Insert for complete instructions concerning the drug.

WARNINGS

THESE INSTRUCTIONS ARE INTENDED FOR USE BY PHYSICIANS WHO HAVE BEEN TRAINED IN THE USE OF PHOTOFRIN®IN PHOTODYNAMIC THERAPY (PDT).

STERILIZED WITH ETHYLENE OXIDE GAS. STERILE ONLY IF THE PROTECTIVE BAG IS NOT OPENED, DAMAGED OR BROKEN. DO NOT RESTERILIZE.

THESE INSTRUCTIONS ARE APPLICABLE ONLY TO THE OPTIGUIDE® FIBER OPTIC (CYLINDRICAL) DIFFUSER USED IN CONJUNCTION WITH PHOTOFRIN® PORFIMER SODIUM AND APPROVED LASER SYSTEMS IN PDT. INSTRUCTIONS FOR USE OF THE FIBER OPTIC, PHOTOFRIN®, AND THE SELECTED LASER SYSTEM SHOULD BE READ CAREFULLY BEFORE USE.

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

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

Precautions

Fragile: Contains glass fiber that may break if handled roughly or bent sharply. Do not clamp the fiber directly. Store in a cool dry place.

Follow the Laser Operator Manual instructions for setup and operation. Do not exceed maximum laser power setting without investigating the cause for the apparent high energy loss (see PREPARATION FOR USE).

Assure that the laser light is not being transmitted when the diffuser is removed from the power meter.

Avoid inadvertent photoactivation of non-target tissue. Assure that the laser light is not being transmitted when the diffuser is removed from the treatment site.

INSTRUCTIONS FOR USE

APPROVED LASER SYSTEMS:

The following laser systems have been tested in PDT for compatibility with the OPTIGUIDE® Fiber Optic Diffusers and PHOTOFRIN® (porfimer sodium) and are approved for delivery of a stable power output at a wavelength of 630 ± 3 nm.

Coherent, Inc., Santa Clara, CA- PDL1 Lambda Plus™ Laser System

Coherent, Inc., Santa Clara, CA- PDL2 Lambda Plus™ Laser System

Pinnacle Biologics, Inc., Bannockburn, IL - DIOMED 630 PDT Laser

Pinnacle Biologics, Inc., Bannockburn, IL - Photofrin® 630 PDT Laser

Angiodynamics, Queensbury NY - 630 PDT Laser.

Laserscope, San Jose, CA - KTP/532® Surgical Laser System (Series 800) in combination with Laserscope Model 630 or Model 630 XP Dye Modules

Laserscope, San Jose, CA - KTP/YAG® Surgical Laser System (Series 800) in combination with Laserscope Model 630 or Model 630 XP Dye Modules

NOTE

- THE INPUT OF CHARACTERISTICS OF THE FIBER AND THE OUTPUT CHARACTERISTICS OF THE LASER HAVE BEEN TESTED TO ASSURE THAT THEY ARE OPTICALLY MATCHED TO PRODUCE UNIFORM LIGHT DISTRIBUTION FROM THE DIFFUSER AS REQUIRED FOR THE PHOTO-ACTIVATION OF PHOTOFRIN®.
- THE USE OF THE OPTIGUIDE® FIBER OPTIC DIFFUSER WITH UNAPPROVED LASERS COULD ALTER THE OUTPUT CHARACTERISTICS OF THE FIBER (SEE WARNINGS).
- CERTAIN PULSED LASERS WITH HIGH PEAK POWERS ARE NOT COMPATIBLE WITH THE OPTIGUIDE® FIBER OPTIC DIFFUSER.

Laser Safety

Use protective eyewear specifically rated for lasers operating over the range of 630 ± 3 nm. Provide approved eye protection for patient in addition to all operating room staff (see WARNINGS). Comply with facility laser safety requirements.

Follow the laser manufacturer's operator manual instructions for setup and operation. Do not exceed maximum laser power setting without investigating the cause for the apparent high energy loss (see PREPARATION FOR USE).

Table 1. Examples of use of Optiguide® Cylindrical Diffusers

Tumor Length	Diffuser Model	Diffuser Length	Segment Number	Fiber Optic Power Output (mW)
1.0cm	PB 210	1.0cm	1	400
2.0cm	PB 220	2.0cm	1	800
3.0cm	PB 215	1.5cm	1	600
	PB 215	1.5cm	2	600
3.0cm	PB230	3.0cm	1	1200
5.0 cm	PB250	5.0cm	1	2000
7.0cm	PB 250	5.0cm	1	2000
	PB 220	2.0cm	2	800

Dosimetry

Photoactivation of PHOTOFRIN® is controlled by the total light dose delivered. In the treatment of esophageal cancer, a light dose of 300 J/cm of diffuser length should be delivered. In the treatment of endobronchial cancer, 200 J/cm of diffuser length should be delivered for superficial or obstructing tumors. In the pre-treatment of nodules or for the treatment of a "skip" area in HGD in BE, 50 J/cm of diffuser length should be delivered. For this PB series of OPTIGUIDE® Fiber Optic (Cylindrical) Diffusers, the following specific light dosimetry equation applies:

$$\text{Treatment Time (Seconds)} = \frac{\text{Tissue Dose (J/cm)}}{\text{Power (W/cm)}}$$

eg. (esophageal cancer)

$$\text{Treatment Time} = \frac{300 \text{ J/cm}}{0.4 \text{ W/cm}}$$

= 750 seconds (12 minutes, 30 seconds)

Fiber Optic Diffuser Selection

OPTIGUIDE® cylindrical diffusers are available in several lengths. The choice of diffuser length depends on the length of the tumor. Select an appropriate diffuser length to avoid exposure of nonmalignant tissue to light and to minimize overlapping of previously treated malignant tissue. Overlapping could result in unintended light overdose.

Increased symptoms and damage to normal tissue might be expected following an overdose of light. Light doses of two to three times the recommended dose have been administered to a few patients with superficial endobronchial tumors. One patient experienced life-threatening dyspnea and the others had no notable complications.

Tumors with lengths that differ from available diffuser lengths may require multiple use of a single OPTIGUIDE® Fiber Optic Diffuser or the use of two or more OPTIGUIDE® Fiber Optic Diffusers of differing lengths. The total power output from the diffuser, as measured by a suitable integrating sphere power meter, is set to: 400 mW x cm diffuser length. Diffusers or combinations of diffusers should be selected to minimize patient treatment time. Table 1 provides examples for various tumor sizes and diffuser lengths.

Esophageal Cancer (300 J/cm		Endobronchial Cancer (200 J/cm)[a]	
Min Sec Per Segment	Total Time (min sec)	Min Sec Per Segment	Total Time (min sec)
12.30	12.30	8.20	8.20
12.30	12.30	8.20	8.20
12.30 12.30	25.00	8.20 8.20	16.40
12.30	12.30	8.20	8.20
12.30	12.30	8.20	8.20
12.30 12.30	12.30	8.20 8.20	16.40

[a] For superficial or obstructing tumors.

Short fiber optic diffusers (≤ 2.5 cm) are used to pre-treat nodules or for the re-treatment of "skip" areas after the first light session. For this treatment a light intensity of 400 mW/cm is used. Table 2 lists appropriate fiber optic power outputs and treatment times using a light intensity of 400 mW/cm.

Table 2. Short Fiber Optic Diffusers Used to Deliver 50 J/cm of Diffuser Length at Light Intensity of 400 mW/cm

Diffuser Length (cm)	Required Power Output from Diffuser[A]	Treatment Time (sec)	Treatment Time (min sec)
1.0cm	0.4	125	2:05
1.5cm	0.6	125	2:05
2.0cm	0.8	125	2:05
2.5cm	1.0	125	2:05

[A] As measured by immersing the diffuser into the cuvet in the power meter and slowly increasing the laser power.

PREPARATION FOR USE

1. Prepare the laser system for delivery of 630 ± 3 nm light as indicated in the appropriate laser system operator manual. Select minimal power settings.

2. Aseptically remove the OPTIGUIDE® Fiber Optic Diffuser from the sterile bag. Do not use if there are visible signs of damage or breakage. Hang or secure the fiber spool in the sterile field.

3. Remove the SMA connector from the spool and pull out enough fiber to reach the laser system optical coupler.

4. Hold the SMA connector without touching the polished end. Seat the connector into the optical coupler and secure by turning the SMA nut until it is finger tight. Do not over tighten.

5. Gently pull the diffuser and fiber from the opposite side of the spool. Avoid touching the diffuser.

6. The power output from the OPTIGUIDE® Fiber Optic Diffuser should be measured using a suitable integrating sphere power meter. The power meter should be able to measure laser power up to 3.0 W at 630 ± 3 nm. Adjust the laser power setting to obtain the specified power output for the specific diffuser model.

Model No:	Maximin Fiber Power Output
PB210	400 mW
PB215	600 mW
PB220	800 mW
PB225	1000 mW
PB230	1200 mW
PB250	2000 mW

NOTE

- DO NOT EXCEED MAXIMUM LASER POWER SETTING WITHOUT INVESTIGATING THE CAUSE FOR THE APPARENT HIGH ENERGY LOSS. EXCESS POWER BEYOND LEVELS SPECIFIED MAY DAMAGE THE FIBER OPTIC DIFFUSER. POSSIBLE CAUSES MAY INCLUDE THE WRONG LASER SOURCE, LASER OUT OF ALIGNMENT, DEFECT OR BREAK IN THE FIBER OPTIC, INCORRECT SETTING ON THE POWER METER, OR THE MALFUNCTION OF THE POWER METER.
- ASSURE THAT THE LASER LIGHT IS NOT BEING TRANSMITTED WHEN THE DIFFUSER IS REMOVED FROM THE POWER METER (SEE PRECAUTIONS).

7. The fiber optic power output is now adjusted. Do not adjust laser power settings. The OPTIGUIDE® Fiber Optic Diffuser is now ready for use. Repeat PREPARATION Steps 1 through 7 if a different diffuser is used.

PROCEDURE

1. Thread the OPTIGUIDE® Fiber Optic Diffuser into the working channel of the selected endoscope or bronchoscope.

2. Position the diffuser as required to treat the tumor.

3. Begin delivery of the laser light and expose the treatment site for the appropriate time for each treated segment. Do not move the diffuser during the exposure period.

4. Stop laser light delivery.

NOTE

- AVOID INADVERTENT PHOTOACTIVATION OF NON-TARGET TISSUE, ASSURE THAT THE LASER LIGHT IS NOT BEING TRANSMITTED WHEN THE DIFFUSER IS REMOVED FROM THE TREATMENT SITE (SEE PRECAUTIONS).

5. If multiple segments are to be treated, reposition the fiber optic diffuser in the next treatment position. Avoid over-dosing with laser light by minimizing overlapping of treatment areas.

6. Readjust and/or confirm the power level each time a different fiber optic diffuser is used or if the fiber optic in use is disconnected and reconnected to the laser.

Disclaimer of Warranties

Pinnacle Biologics, Inc. warrants that reasonable care has been used in the manufacture of this device. The warranty printed above is the only warranty applicable to this purchase. All other warranties, express or implied, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose are disclaimed.

It is understood and agreed that seller's liability whether in contract, in tort, under any warranty, in negligence, or otherwise shall not exceed the return of the amount of the purchase price paid by purchaser. Under no circumstances shall seller be liable for special, indirect, or consequential damages. The price stated for the equipment is a consideration in limiting seller's liability. No action, regardless of form, arising out of the transactions under this agreement may be brought by purchaser more than one year after the cause of action has accrued.

No representative of Pinnacle Biologics, Inc. may change any of the foregoing or assume any additional liability or responsibility in connection with this device.

Distributed by Pinnacle Biologics, Inc., Bannoclburn, IL
60015 Tel: 1-773-312-3723
www.pinnaclebiologics.com

PINN-201v1