



In-Service Presentation





Indications

Esophageal Cancer

- Palliation of patients with complete 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

Endobronchial Cancer

- Treatment of microinvasive endobronchial non-small-cell lung cancer (NSCLC) in patients for whom surgery and radiotherapy are not indicated
- Reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial NSCLC

High-Grade Dysplasia in Barrett's Esophagus

- Ablation of high-grade dysplasia (HGD) in Barrett's esophagus (BE) patients who do not undergo esophagectomy



Contraindications

- Porphyria
- Existing tracheoesophageal or bronchoesophageal fistula
- Tumors eroding into a major blood vessel
- Emergency treatment of patients with severe acute respiratory distress caused by an obstructing endobronchial lesion because 40 to 50 hours are required between injection of PHOTOFRIN and laser light treatment
- Esophageal or gastric varices or esophageal ulcers > 1 cm in diameter.

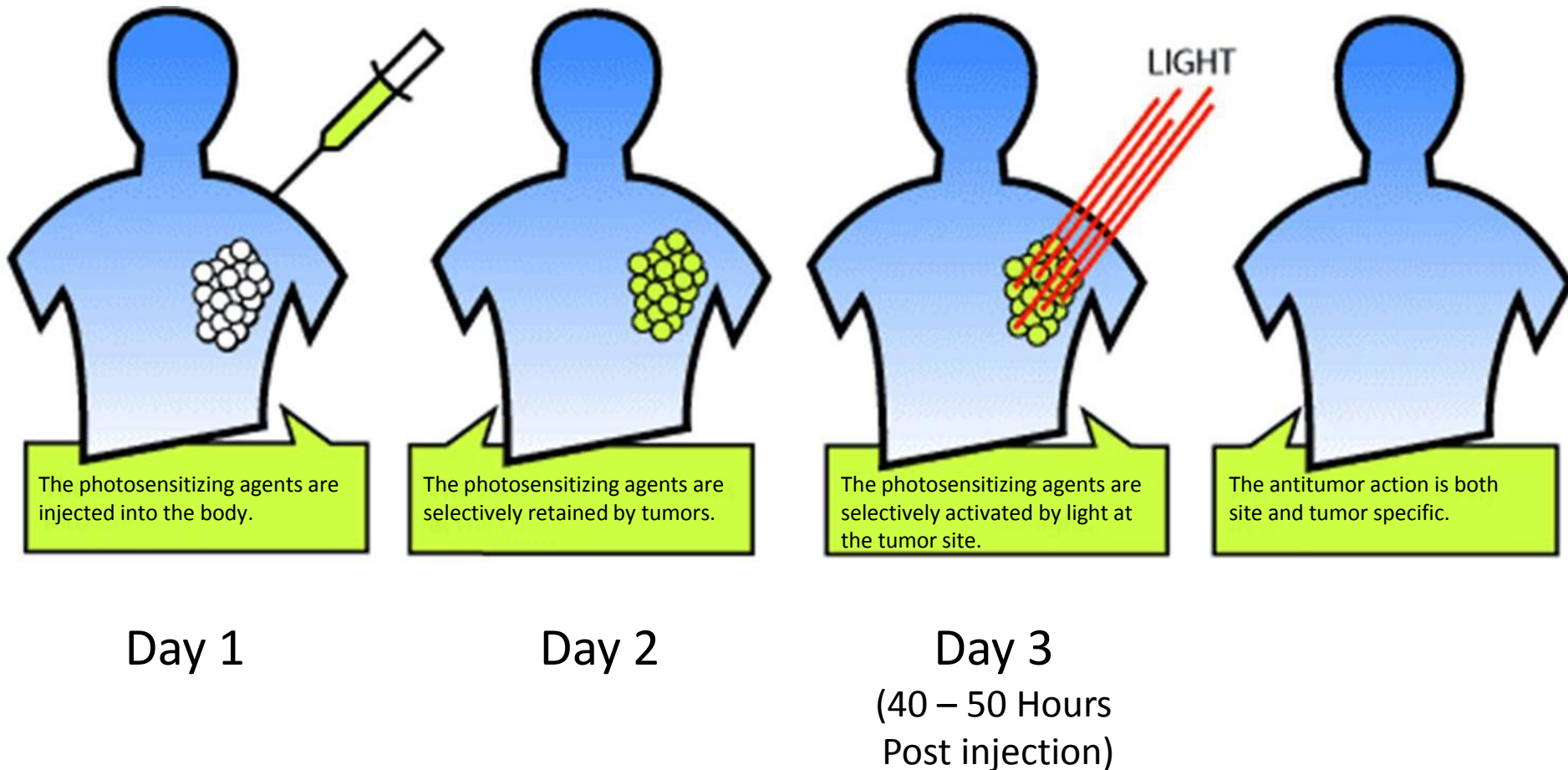


Overview

- What is Photodynamic Therapy?
- Organizing a PDT Procedure
- Administering Photofrin
- Using the Diomed 630 PDT Laser
- Optiguide DCYL Diffusers
- Patient Education
- Important Safety Information

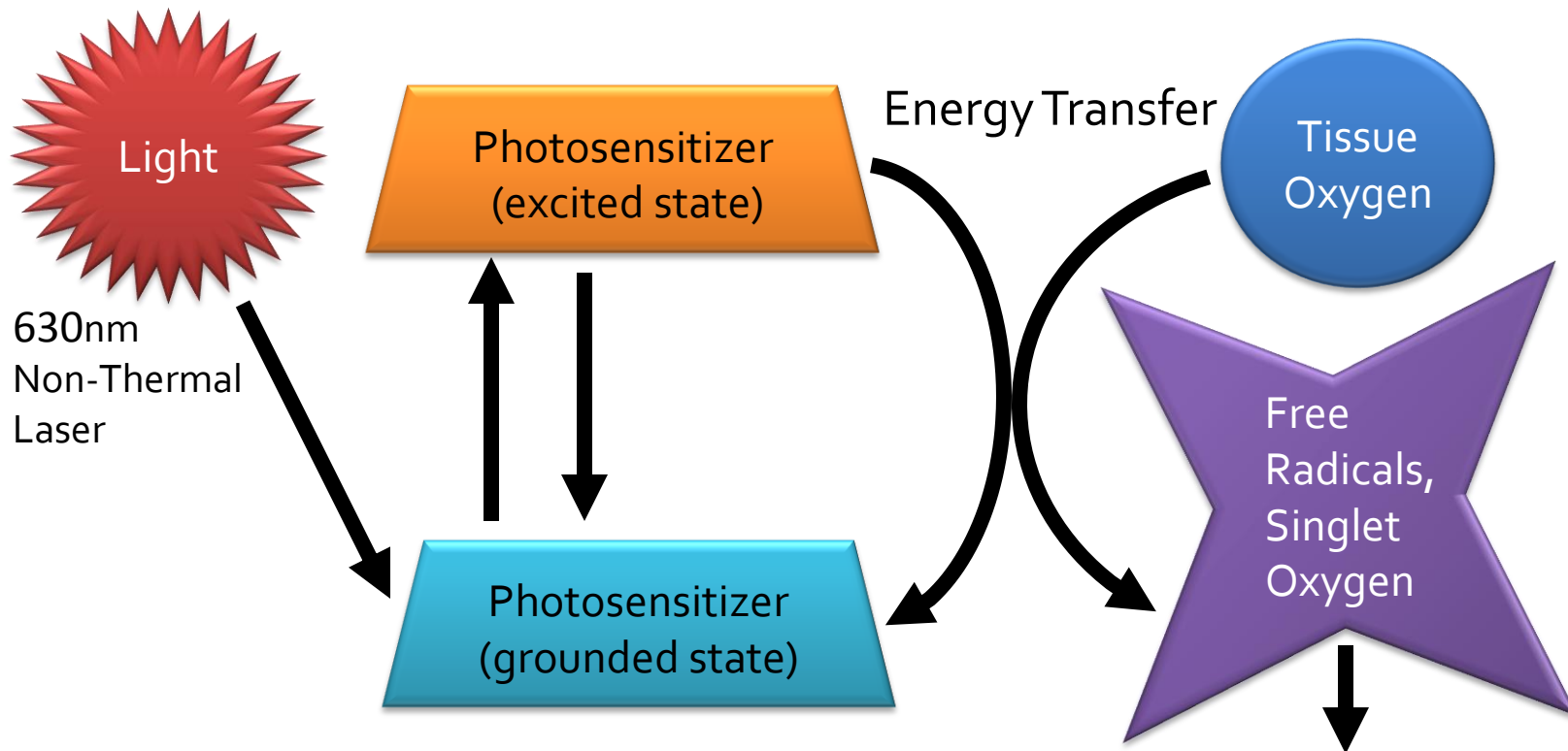


What is Photodynamic Therapy?





How does PDT work?



Photodynamic Reaction:

Tumor Death: Cellular Necrosis

Tumor Micro-environment Toxicity: Vascular-bed Shutdown, Ischemic Necrosis



Preparing for a PDT Procedure

- Patient Education
- Infusion Location
- Operating Room or Endoscopy Suite booked
 - Appropriate number of endoscopies scheduled to include follow-up and debridement if necessary.
- Equipment Ordered
 - Diomed 630 PDT Laser
 - Photofrin Vials
 - Optiguide DCYL fibers

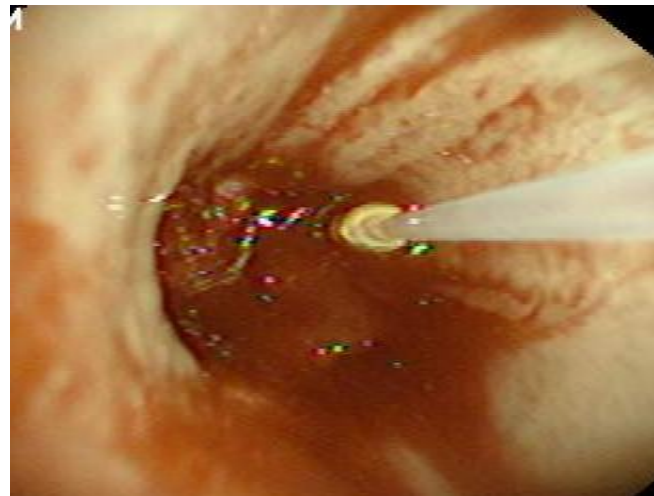


Photodynamic Therapy Case

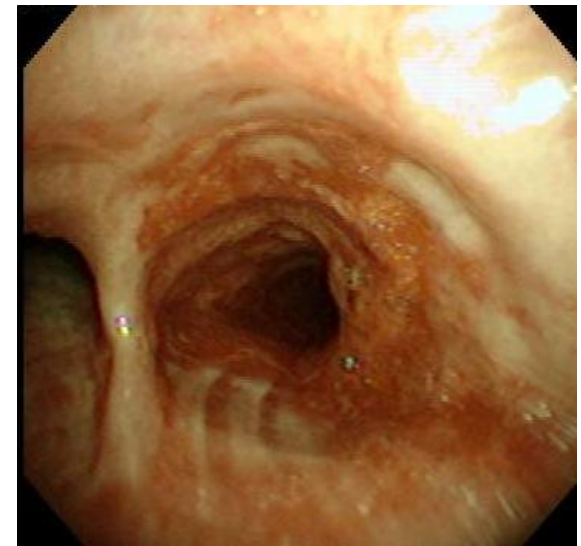
- Illustration of Photodynamic Therapy with Photofrin in non-small-cell lung cancer.



Day 3
1st Light Infusion



Day 5
2nd Light Infusion
following debridement



Day 7
Follow-up Bronchoscopy



Administering Photofrin

- Photofrin Dosage

- 2 mg / kg

Weight (lbs)	< 82.5	83 – 165	> 166
Vials of Photofrin needed	1	2	3

- Reconstitution

- Mix with 31.8mL of either 5% Dextrose Injection (USP) or a 0.9% Sodium Chloride Injection (USP).
 - Protect from bright light and use immediately.

- Administration

- Single slow IV injection over 3 to 5 minutes.

- Review patient education materials with the patient.



Operating the Diomed 630 Laser

- Introducing the Diomed 630 PDT Laser



Touch Screen

Emergency Switch

Delivery Fiber Port

Key Switch



Operating the Diomed 630 Laser

- Introducing the Diomed 630 PDT Laser

Rear Panel



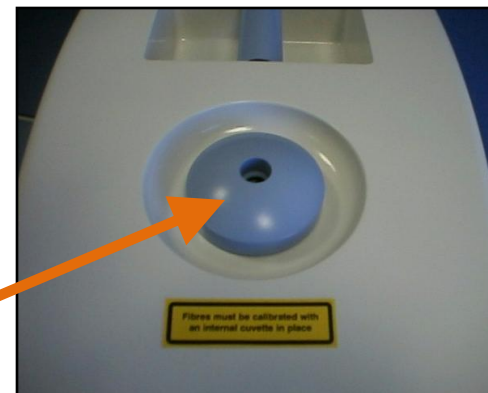
Hand Switch Connection

Remote Interlock Connection

Power Plug, Switch, Voltage Selection

Cuvette Calibration Port

Top of Unit

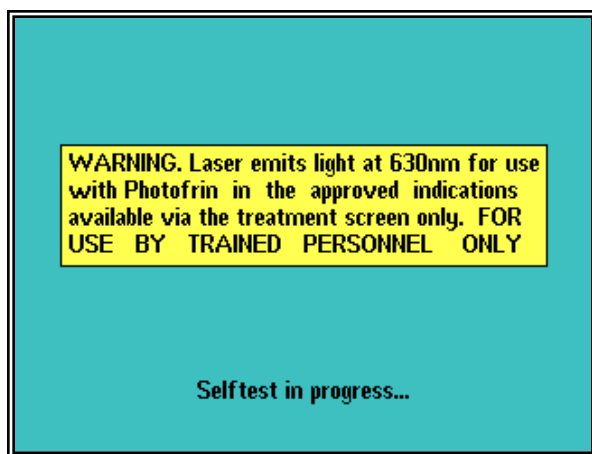




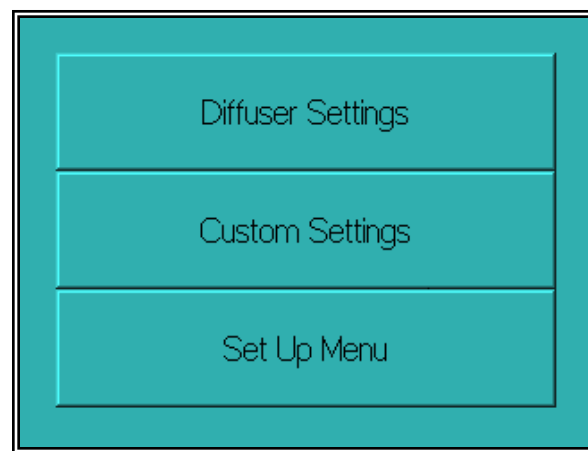
Operating the Diomed 630 Laser

- Turning on the Diomed 630 PDT Laser

1. Self Test



2. Main Menu

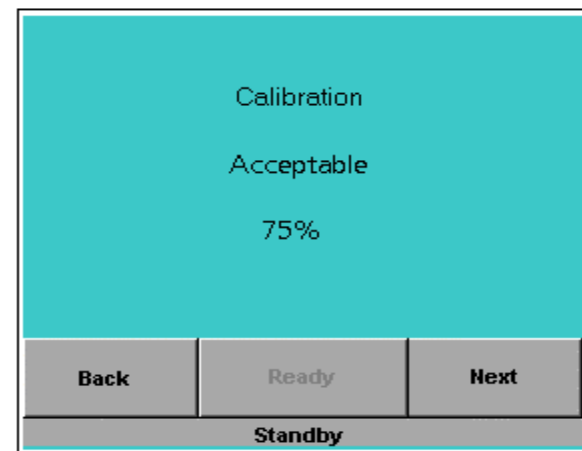
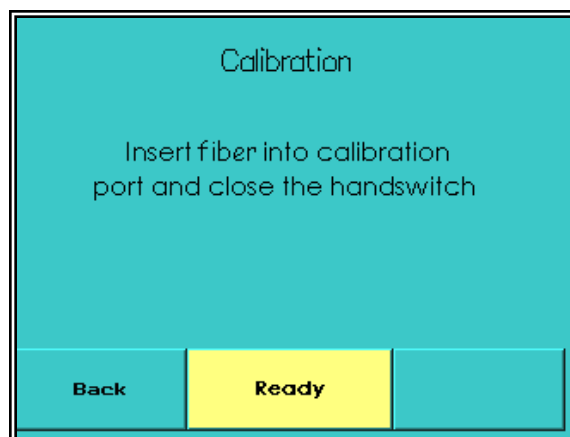
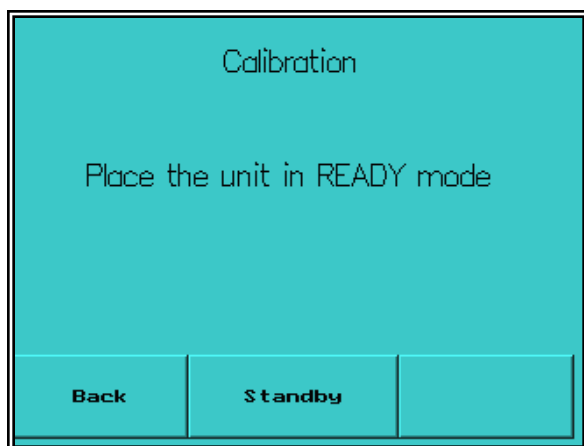


After selecting the desired treatment mode, the laser will enter Calibration Mode.



Operating the Diomed 630 Laser

- Calibrating the Diomed 630 Laser
 - Follow the On-screen prompts



- The laser will calibrate the fiber at 75% transmittance or higher. A rating of 75% or higher indicates sufficient light power is available in order to conduct photodynamic therapy.



Operating the Diomed 630 Laser

- Common errors that prevent calibration:
 - Forgetting to attach the “Interlock Key”
 - Having the handswitch in the active position rather than on standby
 - Forgetting the PDT Laser Key Switch
 - Cuvettes have to be cleaned and sterilized





Operating the Diomed 630 Laser

- Two Operational Modes

Diffuser Settings Mode

- Allows for preset Joules per indication and fiber length

Diffuser Settings

length 2.5cm

Back Standby Next

Treatment site

Esophageal cancer

Back Standby Next

Custom Settings Mode

- Allows for customization of power and treatment time.

Custom Settings

Power 100mW

Duration 490s

Back Standby Next

Custom Settings

100mW 8m 10s

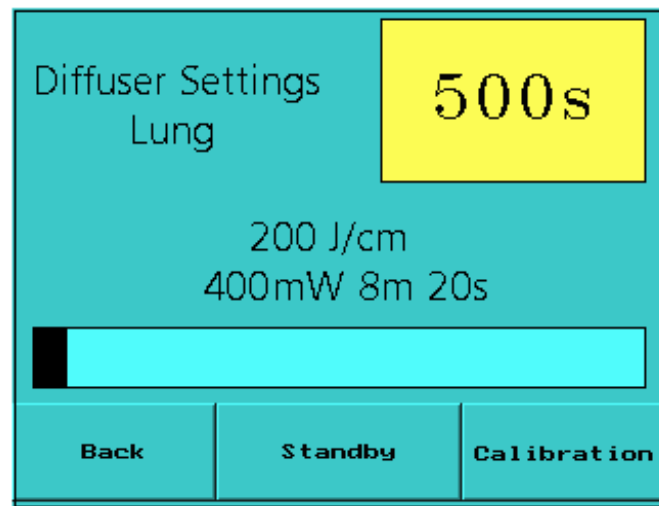
Press NEXT to confirm

Back Standby Next



Operating the Diomed 630 Laser

- Laser Activation Screen
 - Will track the time left in the procedure





Operating the Diomed 630 Laser

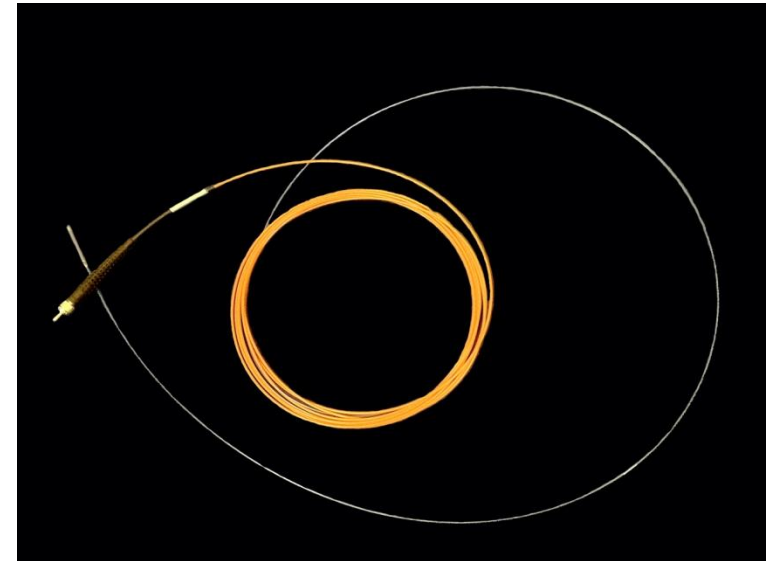
- Recommended Light Dosimetry

Indication	Drug Dose	Light Dose
Lung Cancer	2 mg / kg	200 J / cm ²
Esophageal Cancer	2 mg / kg	300 J / cm ²
Barrett's Esophagus with High Grade Dysplasia	2 mg / kg	150 J / cm ²



Optiguide DCYL Diffusers

- Disposable
 - Approved for single use only
- Repeat use can degrade the fiber's surface, impeding its ability to transmit light properly
 - A factor in fibers failing the initial calibration test





Patient Education

- Photosensitivity and Ocular Sensitivity
 - All patients who receive PHOTOFRIN will be photosensitive.
 - The photosensitivity is due to residual drug, which will be present in all parts of the skin.
 - Ocular discomfort, can occur in patients who receive PHOTOFRIN
- Photosensitivity and Ocular Sensitivity can be avoided by proper patient education



Patient Education

- Photosensitivity and Ocular Sensitivity



- Avoid exposure of eyes and skin to direct sunlight and very bright indoor lights for at least 30 days.

- Operating Room Lights, Dental Examination Lights

- Some patients may remain photosensitive for 90 days or more.

- Sunscreen does not help as it does not block the proper wavelength of light.



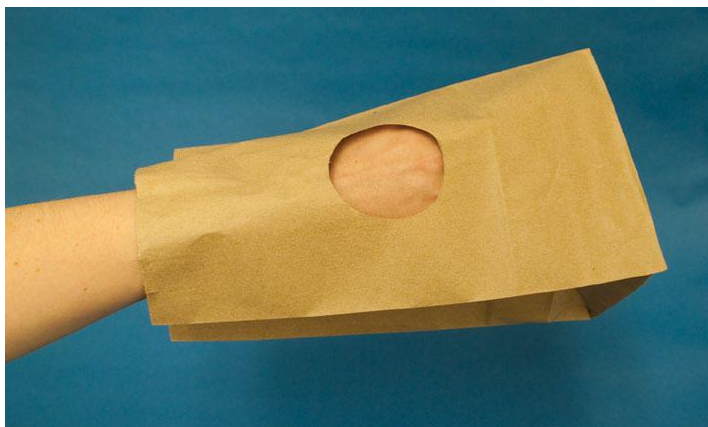
Patient Education

- Photobleaching is an important aspect of limiting the duration of photosensitivity
 - Exposing the skin to ambient indoor lighting assists in safely and gradually clearing the remaining drug from the skin.
 - Keeping patients in the dark prolongs their photosensitivity.



Patient Education

- When can the patient stop avoiding bright direct lighting?
 - After 30 days expose a small area of the skin for 10 minutes.
 - If no reaction occurs within 24 hours, the patient can slowly resume normal outdoor activities





Patient Education

- Patient Kits consisting of important safety articles will be given to the patient on the day of the injection.



Patient Education

- Patient kit contents:
 - Wide-brim hat to shade the face and eyes
 - Dark sunglasses to protect the eyes
 - Gloves to protect the hands
 - Pocket card and bracelet to identify the person with photosensitivity
 - Patient education booklet



Patient Education

- The patient will need a few things from home
 - Light colored scarf to cover their neck
 - Light colored, long-sleeve top to protect their arms
 - Light colored, long pants to protect their legs
 - Socks and shoes to make sure no part of their feet are exposed



Patient Education

- In order to mitigate the patient's concerns over photosensitivity and of inadvertently having a phototoxic reaction, there are several opportunities to discuss patient safety, specifically:
 - Initial consultation
 - During Infusion
 - Following the first treatment session
 - Following the treatment follow-up session



Patient Education

- What happens if a patient has a phototoxic reaction?



Separate Case Study to follow. Images not related to the same incident.



Case Study of a Phototoxic Reaction

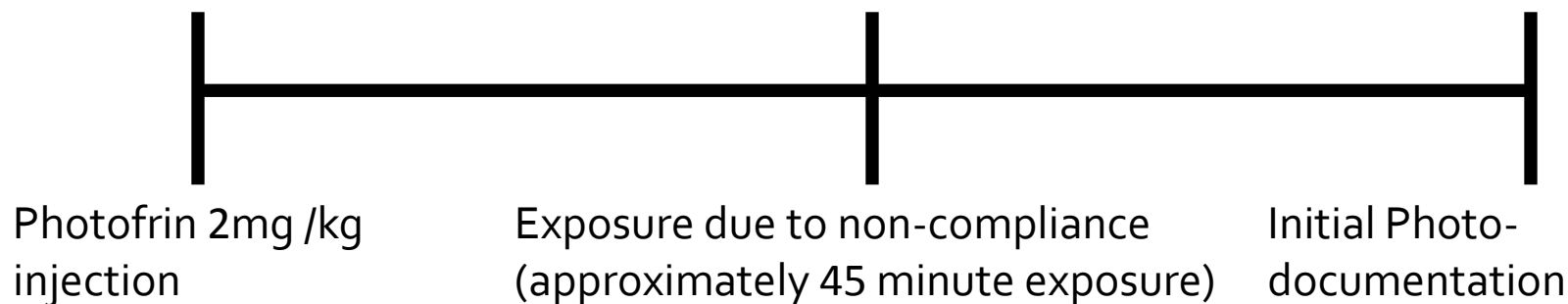


Photos taken on August 5th, 2 days after exposure

July 31

August 3

August 5





Case Study of a Phototoxic Reaction



Photos taken on August 5th, 2 days after exposure

Patient instructed to keep hands elevated.

Precautions regarding sun and exposure were reinforced for the patient and family.



Case Study of a Phototoxic Reaction



August 17th, 14 days after exposure



September 5th, 32 days after exposure

Patient recommended to apply
Silvadene daily by the attending nurse.



Important Safety Information

Contraindications

- PHOTOFRIN® is contraindicated in patients with porphyria
- PDT is contraindicated in patients with an existing tracheoesophageal or bronchoesophageal fistula
- PDT is contraindicated in patients with tumors eroding into a major blood vessel
- PDT is not suitable for emergency treatment of patients with severe acute respiratory distress caused
- by an obstructing endobronchial lesion because 40 to 50 hours are required between injection with
- PHOTOFRIN and laser light treatment
- PDT is not suitable for patients with esophageal or gastric varices, or patients with esophageal ulcers >1 cm in diameter



Important Safety Information

Warnings and Precautions

- Tracheoesophageal or bronchoesophageal fistula can occur if esophageal tumor is eroding into trachea or bronchial tree
- Gastrointestinal perforation can occur
- High risk of bleeding in patients with esophageal varices
- High risk for fatal massive hemoptysis with endobronchial tumors that are: large, centrally located; cavitating; extensive, extrinsic to the bronchus
- After treatment of HGD in BE, monitor endoscopic biopsy every three months, until four consecutive negative evaluations for HGD have been recorded
- Photosensitivity can be expected; ocular sensitivity is possible
- Allow 2-4 weeks between PDT and subsequent radiotherapy
- Substernal chest pain may occur after treatment
- Treatment induced inflammation can cause airway obstruction. Administer with caution to patients with tumors in locations where treatment-induced inflammation can obstruct the main airway
- Esophageal stenosis occurs frequently after treatment of HGD in BE
- Patients with hepatic or renal impairment may need longer precautionary measures for photosensitivity
- Thromboembolic events can occur following photodynamic therapy with PHOTOFRIN



Important Safety Information

Adverse Reactions

Most common adverse reactions reported during clinical trials (>10% of patients) are:

- **Esophageal Cancer:**
 - Anemia, Atrial Fibrillation, Constipation, Nausea, Abdominal pain, Vomiting, Dysphagia, Pyrexia, Chest Pain, Pain, Back Pain, Insomnia, Pleural Effusion, Dyspnea, Pneumonia, Pharyngitis, Respiratory Insufficiency, Photosensitivity Reaction.
- **Obstructing Endobronchial Cancer:**
 - Pyrexia, Dyspnea, Cough, Hemoptysis, Pneumonia, Bronchitis, Photosensitivity Reaction.
- **Superficial Endobronchial Tumors:**
 - Exudate, Bronchial Mucus Plug or Bronchial Obstruction, Edema, Bronchostenosis, Photosensitivity Reaction.
- **High-Grade Dysplasia in Barrett's Esophagus:**
 - Nausea, Vomiting, Esophageal Stricture, Esophageal Narrowing, Dysphagia, Constipation, Chest Pain, Pyrexia, Dehydration, Pleural Effusion, Photosensitivity Reaction.