PhotonGuide® Illuminator

REF 104008 / 104015

Instructions for Use

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				STERILE EO	Rx Only
		Consult Instructions for Use and Symbols Glossary on this website: www.invuity.com/documentlibrary			

PhotonGuide Illuminator - Instructions for Use (IFU)

Description
The Invuity PhotonGuide Illuminator provides illumination in a surgical field for a wide variety of surgical procedures. The PhotonGuide is sterile, single-use, pyrogen free, and not made with natural rubber latex. It is compatible with LED, infrared radiation-filtered 300-watt xenon or metal halide high intensity surgical light sources, Invuity surgical retractors, and Invuity Fiber Optic Cables.

Indications for Use
The Invuity PhotonGuide is intended to provide surgical site illumination from a high intensity light source.

Contraindications
There are no known contraindications.

For Use With
Can be used with any Invuity retractors except Adapt retractors.

Description	REF
Single Fiber Optic Cable, 10 ft [3.05 m], ACMI	FC1S
Single Fiber Optic Cable, Pink, 10 ft [3.05 m], ACMI	FC1SP
Bifurcated Fiber Optic Cable, 11.5 ft [3.50 m], ACMI	FC1B

Warnings
- **It is recommended to use PhotonGuide with an LED light source**. When using shorter retractor lengths, the need for higher light output from a Xenon light source is reduced. The lower intensity light output from an LED light source reduces the risk of thermal injury to patient or user or damage to the PhotonGuide. LED light sources are available from Invuity, Stryker, and Sunoptic.
- **Maintain a minimum distance of 2 cm** (approximately the width of two fingers) between the distal face of the PhotonGuide and the surrounding tissue when using a Xenon light source. If the 2 cm distance cannot be maintained, use an LED light source.
- **Do not use with a xenon light source greater than 300 watts.** Using the PhotonGuide with a xenon light source with output greater than 300 watts or without an infrared (IR) filter may cause thermal injury to the patient or user, or may cause damage to equipment.
- **Do not use with the BFW ChromaLUME turbo plasma surgical light source.** This light source is not compatible with the PhotonGuide Illuminator(s).
- **Do not use with a xenon light source output setting above 60%** The light intensity of a Xenon light source varies greatly during the life of the bulb, therefore it is necessary to use the lowest power output necessary up to a maximum of 60% in order to avoid potential thermal injury to the patient or user or thermal damage to the PhotonGuide.
- **PhotonGuide must be attached to the Invuity Fiber Optic Cable prior to turning on the light source.** The output of the Fiber Optic Cable is extremely intense and may cause burns, ignite drapes/gowns, or temporarily blind vision. Therefore, it is important to attach PhotonGuide to the Fiber Optic Cable before turning on the light source.
- **Do not obstruct the output surface of the PhotonGuide**. The high intensity illumination has the potential to cause thermal damage or injury if the surface is obstructed by dried blood, tissue, gloves, or other material.
- **Keep the PhotonGuide clean throughout the procedure.** If the output surface of a PhotonGuide is obstructed with debris or blood, immediately clean the surface with a sponge or gauze dampened with sterile water or saline. Blood or debris that becomes lodged underneath the PhotonGuide should be flushed with sterile water or saline. After flushing, blot or wipe with a dry gauze to remove excess fluid. Absorption of light energy by fluid under the PhotonGuide, or dried blood or debris on the output surface, can cause thermal damage to the device or injury to the patient.

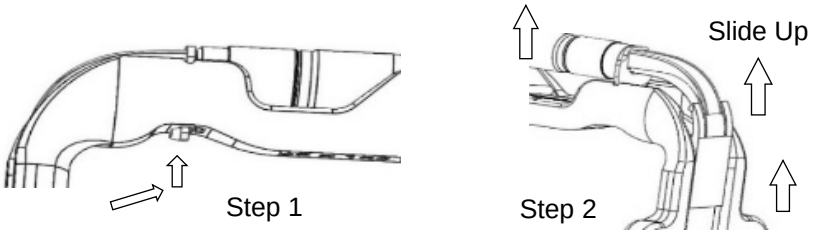
Precautions
- The PhotonGuide should be handled and operated by hospital personnel familiar with and trained in its use, assembly, and disassembly.
- Inspect the device packaging before use. Do not use if the packaging is opened or if the device has passed the labeled expiration date.
- Do not use the instruments for any purpose or in any manner other than described in this Instructions for Use. Such use may cause device damage or failure, which could result in patient or user injury.
- Do not use PhotonGuide without an Invuity compatible retractor.
- Use the PhotonGuide only with the appropriate Invuity Fiber Optic Cable and with a surgical light source that has an ACMI connector. Using non-Invuity fiber optic cables may generate excessive heat at the connector and cause thermal injury to the patient or user.

- When attached to the surgical light source, the Bifurcated Fiber Optic Cable requires two Invuity devices to be used simultaneously. Never leave one branch (or both branches) of the Single or Bifurcated Fiber Optic Cable unused. The output of the Fiber Optic Cable is extremely intense and may cause burns, ignite drapes/gowns, or temporarily blind vision.
- Handle all instruments with care. Use caution to prevent damage to the PhotonGuide during surgery. If damaged, remove and dispose. Replace with a new PhotonGuide. Irrigate surgical site and remove any debris prior to continuing procedure.
- Inspect all reusable retractors for damage before and during a procedure. If reusable retractor is damaged, follow hospital standards for disposal.
- Do not leave illuminated device unattended.
- To avoid damage to the PhotonGuide, do not pry the device out of the Retractor by pulling out from the bottom of the PhotonGuide.
- When removing the Fiber Optic Cable from the light source, grasp the connector, not the black insulation, as pulling on the insulation with excess force can cause product damage.
- DO NOT RESTERILIZE OR REUSE. The PhotonGuide is provided sterile and is intended for single use only.
- After use, handle and dispose of the PhotonGuide according to hospital procedures and in accordance with local, state and federal laws and regulations.
- Refer to the Instructions for Use for the Invuity Fiber Optic Cables, Sterilization Trays and Retractors for additional information.

Directions for Use

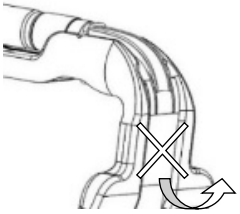
1. Identify the appropriate Invuity Fiber Optic Cable for the PhotonGuide.
2. Inspect the PhotonGuide(s) for damage prior to assembling. If damaged, discard and replace with a new PhotonGuide.
3. Verify the surgical light source is LED or 300 watts or less and is equipped with an infrared (IR) blocking filter. Reduce the intensity setting of the light source to the minimum level before turning on the power.
   Note: Maintain a minimum distance of 2 cm (approximately the width of two fingers) between the distal face of the PhotonGuide and the surrounding tissue when using a Xenon light source. If the 2 cm distance cannot be maintained, use an LED light source.
4. Inspect all reusable retractors for damage before and during a procedure. If reusable retractor is damaged, follow hospital standards for disposal.
5. Insert the PhotonGuide into the appropriate Invuity retractor.
6. Attach the Fiber Optic Cable to the PhotonGuide fiber optic connector.
   Note: Use the Single Fiber Optic Cable when one PhotonGuide is needed. Use the Bifurcated Fiber Optic Cable when two Invuity devices are needed.
7. Connect the Fiber Optic Cable to the ACMI port on the surgical light source.
8. Reduce the intensity setting of the light source to the minimum level before turning on the power. Then, turn the surgical light source on.
9. Increase the intensity setting of the light source to 60% and assess the illumination transmitted by the PhotonGuide. Avoid increasing the intensity setting of the light source beyond the level of illumination required to perform the procedure. **If using a xenon light source, DO NOT increase the light intensity above 60%.**
10. If the output surface of a PhotonGuide is obstructed with debris or blood, immediately clean the surface with a sponge, wipe, or gauze dampened with sterile water or saline. Blood or debris that becomes lodged underneath the PhotonGuide should be flushed with sterile water or saline. After flushing, blot dry with a dry gauze or wipe to remove excess fluid. Absorption of light energy by fluid under the PhotonGuide, or dried blood or debris on the output surface, can cause thermal damage to the PhotonGuide or injury to the patient.
    Note: If the surface of the PhotonGuide is contaminated, the high intensity illumination has the potential to cause thermal damage to the device.
11. During the procedure, the PhotonGuide and Fiber Optic Cable may be transferred to another Invuity retractor. To transfer the PhotonGuide to another retractor:
    i. First, fully reduce power
    ii. Flush, wipe and blot dry the PhotonGuide prior to transferring it.
12. Remove the PhotonGuide by pressing in and up on the retention clip, then lifting the device up and out of the Retractor (Figure 1).

Figure 1: Removing the PhotonGuide from the Retractor



13. Do not pry the PhotonGuide from the Retractor to remove. Prying or pulling from the bottom of the PhotonGuide can cause damage to the device (Figure 2).

Figure 2: Do not pry the PhotonGuide from the Retractor



14. Upon completion of the procedure, turn the surgical light source off, disconnect the Fiber Optic Cable from the PhotonGuide. Remove the PhotonGuide from the retractor.
15. Disconnect the Fiber Optic Cable from the surgical light source. When removing the Fiber Optic Cable from the light source, grasp the connector, not the black insulation, as pulling on the insulation with excess force can cause product damage.
16. Discard the PhotonGuide(s) according to hospital procedures and in accordance with local, state and federal laws and regulations related to clinical waste.
    Note: Refer to the Instructions for Use for the Invuity Fiber Optic Cables, Sterilization Trays and Retractors and Accessories for additional information.

Warranty

INVUITY warrants, for the earlier of (i) the expiration date, if applicable, or (ii) one (1) year from the date of purchase, that this medical device is free from defects in both material and workmanship when used normally for its intended purposes. Suitability of the medical device for any surgical procedure shall be determined by the user alone (in light of relevant instructions for use) and not by INVUITY, and such user shall be responsible for understanding how to use the device for its intended purpose. In the event that purchaser believes that any INVUITY medical device is defective, purchaser will promptly notify INVUITY. Any INVUITY brand named instrument delivered from INVUITY proving to be defective will, as purchaser's sole and exclusive remedy, be replaced at no charge or the amount paid refunded, at INVUITY's discretion, so long as the defect is discovered and reported to INVUITY within the earlier of thirty (30) days of discovery or one (1) year of purchase, and INVUITY determines that the product is defective and is covered by the warranty. Notwithstanding, INVUITY shall not be responsible for normal wear and tear, including minor cosmetic damage compromise or defect caused by re-sterilization. INVUITY does not repair, sharpen, recoat or otherwise refurbish any used product. The foregoing limited warranty and limited obligation of replacement is void and of no effect in the event that there is any modification made to the medical device or the medical device is used for any purpose other than its intended purpose.

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Customer must obtain a Return Material Authorization (RMA) to return product to Invuity.

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A	19-0045	Initial release OUS	04/04/2019	04/09/2019	J. Wentz

PRINTING INSTRUCTIONS

Print in house or at an approved supplier and route to receiving.

Do not print Revision History and Printing Instructions Page (page 5 & 6).

Print double sided, booklet style in black ink on white paper.

Fold in eighths (folded size is 4.25in x 2.75in).