



PhotonGuide® Adapt Illuminator

REF PGA1

Instructions for Use



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				STERILE E0	R_x Only
			Consult Instructions for Use and Symbols Glossary on this website: www.invuity.com/documentlibrary		

PhotonGuide Adapt Illuminator - Instructions for Use (IFU)

Description

The Invuity PhotonGuide Adapt Illuminator provides illumination in a surgical field for a wide variety of surgical procedures. The PhotonGuide Adapt 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 Adapt compatible surgical retractors, and Invuity Fiber Optic Cables.

Indications for Use

The Invuity PhotonGuide Adapt 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 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 Adapt with an LED light source.** Since the PhotonGuide Adapt can be positioned more distally on the Invuity retractor, 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 Adapt. LED light sources are available from Invuity, Stryker, and Sunoptics.
- **Maintain a minimum distance of 2 cm** (approximately the width of two fingers) between the distal face of the PhotonGuide Adapt waveguide 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 Adapt 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 Adapt 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 Adapt.
- **PhotonGuide Adapt 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 Adapt to the Fiber Optic Cable before turning on the light source.
- **Do not obstruct the output surface of the PhotonGuide Adapt.** 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 Adapt clean throughout the procedure.** If the output surface of a PhotonGuide Adapt 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 Adapt 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 Adapt, or dried blood or debris on the output surface, can cause thermal damage to the device or injury to the patient.

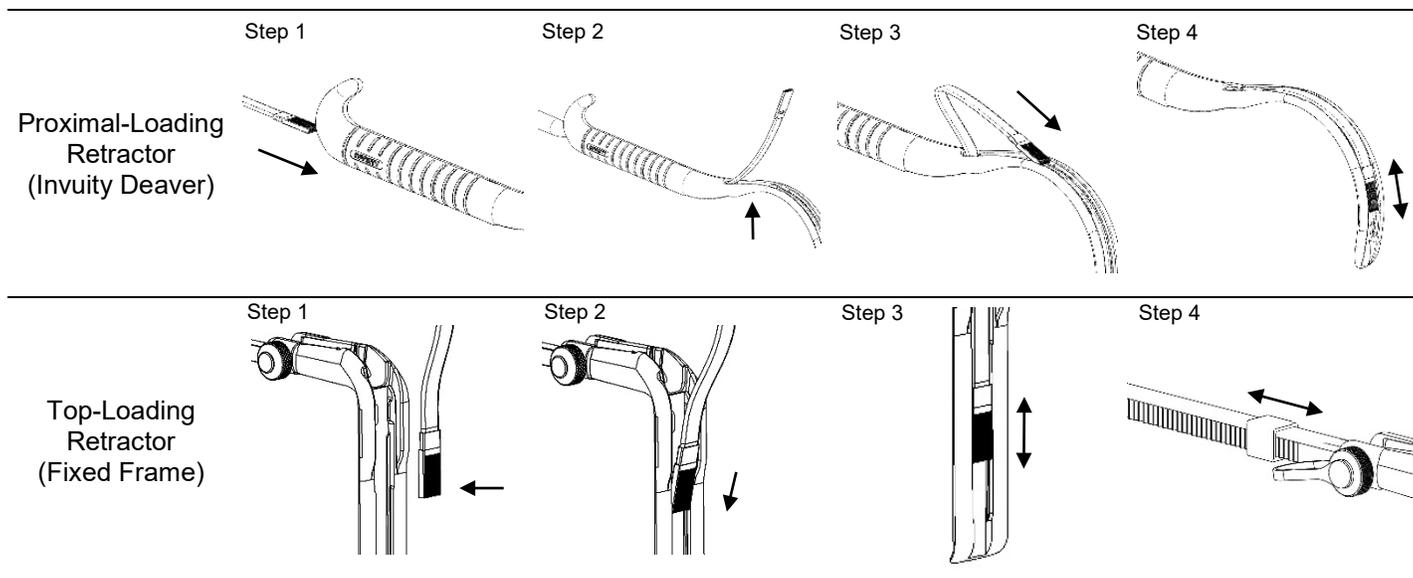
Precautions

- The PhotonGuide Adapt 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.

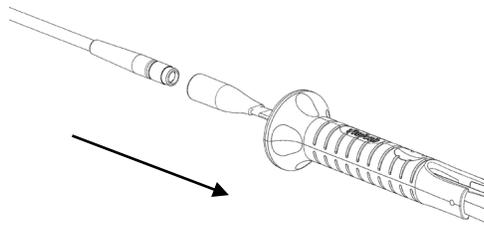
- Use the PhotonGuide Adapt only with the appropriate Invuity Fiber Optic Cable and with a surgical light source that has an ACMI connector. Using non-Invuity fiber optic cables may generate excessive heat at the connector and cause thermal injury to the patient or user.
- When attached to the surgical 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 Adapt during surgery. If damaged, remove and dispose. Replace with a new PhotonGuide Adapt. 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.
- Do not use excessive force when installing and removing the PhotonGuide Adapt.
- When removing the Fiber Optic Cable from the light source, grasp the widest area of the black strain relief closest to the ACMI connection on the light source. Pulling on the insulation with excess force can cause product damage.
- **DO NOT RESTERILIZE OR REUSE.** The PhotonGuide Adapt is provided sterile and is intended for single use only.
- After use, handle and dispose of the PhotonGuide Adapt 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 Lighted Retractors for additional information.

Directions for Use

1. Identify the appropriate Invuity Fiber Optic Cable for the PhotonGuide Adapt.
2. Inspect the PhotonGuide Adapt for damage prior to assembling. If damaged, discard and replace with a new PhotonGuide Adapt.
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 2cm (approximately 2 finger widths) between the distal face of the PhotonGuide Adapt waveguide and the surrounding tissue.
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 Adapt into the appropriate Invuity Adapt compatible retractor. If the retractor has a handle, route the PhotonGuide Adapt through the handle. Adjust output surface along the blade to the desired location. All compatible retractors are either proximal-loading, top-loading as shown below. If needed, secure the PhotonGuide Adapt with the provided VELCRO® straps.



6. Attach the Fiber Optic Cable to the PhotonGuide Adapt fiber optic connector.



Note: Use the Single Fiber Optic Cable when one PhotonGuide Adapt 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 Adapt. 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 Adapt 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 Adapt 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 Adapt, or dried blood or debris on the output surface, can cause thermal damage to the PhotonGuide Adapt or injury to the patient.
Note: If the surface of the PhotonGuide Adapt is contaminated, the high intensity illumination has the potential to cause thermal damage to the device.
11. During the procedure, the PhotonGuide Adapt, and Fiber Optic Cable may be transferred to another Invuity retractor. To transfer the PhotonGuide Adapt to another retractor:
 - i. First, fully reduce power. Remove Velcro strips if necessary.
 - ii. Flush, wipe and blot dry the PhotonGuide Adapt prior to transferring it. Reapply Velcro strips as needed.
12. Upon completion of the procedure, turn the surgical light source off, disconnect the Fiber Optic Cable from the PhotonGuide Adapt. Remove the PhotonGuide Adapt from the retractor.
13. Disconnect the Fiber Optic Cable from the surgical light source. When removing the Fiber Optic Cable from the light source, grasp the widest area of the black strain relief closest to the ACMI connection on the light source. Pulling on the insulation with excess force can cause product damage.
14. Discard the PhotonGuide Adapt in accordance with 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 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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PRINTING INSTRUCTIONS

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

Do not print Revision History and Printing Instructions Page (page 6 & 7)

Print in black ink on white paper.

Print subsequent pages double sided, booklet style.

Fold into booklet then fold vertically with front page showing (folded size is 8.5in x 2.75in)