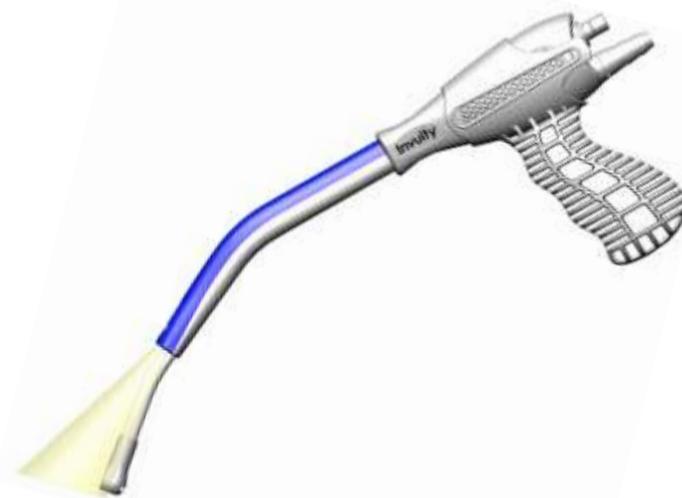




PhotonSaber® Y

REF ES1Y / ES3Y / ES4Y

Instructions for Use



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

PhotonSaber Y – Instructions for Use (IFU)

Description

The PhotonSaber Y Handheld Illuminator with Aspiration is a handheld instrument that provides illumination to the surgical field using a high intensity light source and provides aspiration from the surgical field using a vacuum source. The PhotonSaber Y is available in multiple tip configurations. It is a single-use device and is provided sterile, pyrogen free and not made with natural rubber latex. The PhotonSaber Y is compatible with the Invuity Single Fiber Optic Cable, with commercially available 300-watt surgical light sources (with infrared filter), and with commercially available medical suction tubing. The device is packaged with an optional pistol grip handle to provide improved ergonomics and a stylet which can be used to clear the device lumen during use.

Indications for Use

The PhotonSaber Y is intended to deliver illumination from a high intensity light source and to aspirate from the surgical site.

Contraindications

There are no known contraindications.

For Use With

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 and Precautions

Cleaning and Sterilization:

- The PhotonSaber Y is provided sterile and intended for single-use only. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulation. **DO NOT REPROCESS.**

Product Use:

- The PhotonSaber Y should be handled and operated by trained personnel.
- Inspect device and packaging before use. Do not use if the device or packaging is opened or damaged.
- Use the PhotonSaber Y only with an Invuity Fiber Optic Cable and with a surgical light source that has an ACMI output jack to connect to the Invuity Fiber Optic Cable. Use of other fiber optic cables may generate excessive heat at the connector and cause patient or user injury.
- **DO NOT USE** with a surgical light source greater than 300 watts. Using the PhotonSaber Y with a surgical light source with output greater than 300 watts or a surgical light source without an infrared (IR) filter may cause thermal injury to the patient or user or may cause damage to equipment. When using high-powered surgical light sources, reduce the power output to avoid thermal damage to the PhotonSaber Y.
- **DO NOT USE** with the BFW ChromaLUME turbo plasma surgical light source. This light source is not compatible with the PhotonSaber Y.
- When an illuminated PhotonSaber Y is out of the surgical field, it is recommended to place the device in a holster, reduce the intensity, or ensure that there is no material in close proximity that can obstruct the output surface. High intensity illumination has the potential to cause thermal damage or injury. Do not place on top of drape.

- When using PhotonSaber Y for aspiration of smoke, note that smoke evacuation systems produce a strong vacuum. Adjust the airflow and the position of the inlet end of the PhotonSaber Y to prevent patient injury and to prevent suction of surgical materials and surgical specimens. If the smoke evacuator is activated while the airflow is set to a high speed, it may produce a sudden, strong suction action. Check the airflow setting before activating the smoke evacuator to prevent patient injury and to prevent suction of surgical materials and surgical specimens.
- During use, do not allow the illumination output surface of the PhotonSaber Y to be obstructed. The high intensity illumination has the potential to cause thermal damage or injury if the output surface is obstructed by tissue, gloves, or other material.
- Use caution to prevent damage to the PhotonSaber Y during surgery. If the device is damaged during surgery, irrigate the surgical site to remove debris, dispose of the device in accordance with accepted medical practice, and use a new device. The application of excessive force may cause damage to the instrument and should be avoided.

Safety:

- Use of this instrument for any purpose or in any manner other than described in this **Instructions for Use** may cause instrument damage or failure, which could result in patient or user injury. Do not use instruments that appear broken, cracked, deformed, or chipped.

Directions for Use

1. Prior to use, verify that the PhotonSaber Y is not damaged. If damaged, discard and replace with a new device.
2. Verify the surgical light source is 300 watts or less and equipped with an IR blocker.
3. To attach the optional pistol grip, slide the pistol grip over the distal tip and slide it proximally over the handle as shown until it clicks into place. (Fig 1)
4. The PhotonSaber Y has two proximal connectors, an ACMI connector and a barbed connector. Attach the ACMI connector to the Invuity Single Fiber Optic Cable. Attach the barbed connector to the suction tubing. Verify that both connectors are securely attached.
5. Turn the vacuum source on and verify that the device distal tip is drawing a vacuum.
6. Reduce the intensity setting of the light source to the minimum level before turning on the power.
7. Turn the light source on and verify that the device has light output.
8. Increase the intensity setting of the light source to approximately 50% and assess the illumination transmitted by the PhotonSaber Y. It is recommended to avoid increasing the intensity setting of the light source beyond the level of illumination required to perform the procedure to minimize any thermal hazard.
9. Direct the active light output and suction toward the surgical field **ONLY**. If the device is oriented away from the surgical field, it may cause temporary glare or blindness. When the device is not being used in the surgical field, either reduce the intensity setting of the light source, place in a holster or ensure that there is no material in close proximity that can obstruct the output surface. Do **not** place on top of drape.
10. If the illumination output surface of the PhotonSaber Y is obstructed with blood or debris, rinse with saline to clean the surface. Absorption of intense light energy by blood or debris on the output surface can cause thermal damage to the waveguide.
11. If the lumen becomes obstructed during use, insert and gently advance the Stylet through the device to clear the lumen.

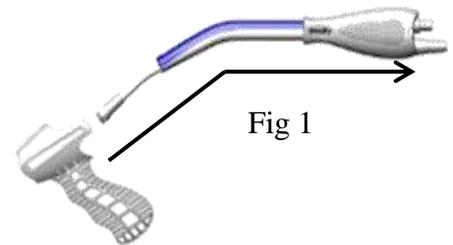


Fig 1

12. To remove the pistol grip, spread the tabs on the proximal (1) end of the pistol grip to release and slide the pistol grip distally (2) down the device to remove. (Fig 2).
13. After the procedure, power off the light source and vacuum source. Disconnect the Invuity Single Fiber Optic Cable and suction tubing.
14. Discard the PhotonSaber Y in accordance to hospital procedures and in accordance with local, state and federal laws and regulations related to clinical waste.

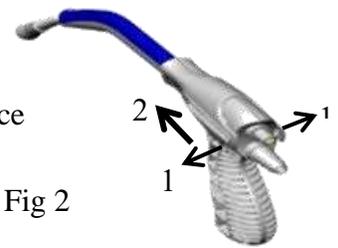


Fig 2

Warranty

INVUITY warrants, for the earlier of (i) the expiration date, if applicable, or (ii) one (1) year from 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 within the warranty period stated above, 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 the medical device is used for any purpose other than its intended purpose.

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Customer must obtain and comply with a Return Material Authorization to return product to Invuity.

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Revision History

Rev	CO #	Description	Approved Date	Effective Date	Originator
A	19-0045	Initial Release for UK Launch	04/04/2019	04/09/2019	J. Wentz

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PRINTING INSTRUCTIONS

Print at an approved supplier and route to receiving.

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

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

Fold in quarters (folded size is 4.25 in x 5.5 in).