



# PhotonBlade®

REF PB1

## Instructions for Use



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			Consult Instructions for Use and Symbols Glossary on this website: <a href="http://www.invuity.com/documentlibrary">www.invuity.com/documentlibrary</a>		

# PhotonBlade - Instructions for Use (IFU)

## Description

The Invuity PhotonBlade is a single-use, RF device with integrated LED-based illumination that is powered by a replaceable battery. The PhotonBlade consists of a single blade with a rotatable and adjustable length shaft. It is designed to be used with an approved electrosurgical unit (ESU). The PhotonBlade is operated by use of an integrated hand switch or ESU footswitch similar to an electrosurgical pencil.

## Indications for Use

The PhotonBlade is a monopolar RF device coupled with illumination that is indicated for cutting and coagulation of soft tissue during general surgical procedures.

## Contraindications

There are no known contraindications.

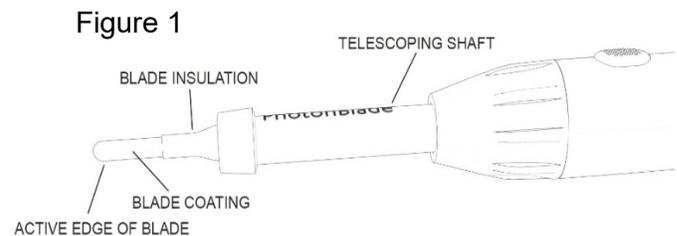
## Warnings

- Based on the desired tissue effect, the lowest energy settings should be used. It is not recommended to use CUT or COAG settings over 50 watts or any power setting and mode that results in an output voltage greater than 3000V. Consult the user manual of the electrosurgical unit (ESU) to determine the voltage output characteristics for different power settings and modes. Refer to Table 1 in Step 5 of the Set Up section for additional information.
- Operate the device using the lowest power settings and the shortest tissue-contact time required for the desired effect, as electrosurgery may cause unintended damage to surrounding tissue.
- During use, do not allow the illumination output surface of the PhotonBlade to be obstructed or rest on tissue. 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.
- When in use, keep the device in motion to prevent tissue build up on the electrode. However, the blade may be held stationary to spot coagulate. The blade should be carefully cleaned as tissue build-up occurs.
- While activating energy, be aware of critical anatomy that is in contact with the blade, waveguide and telescoping shaft. The waveguide and telescoping shaft should not be touching or retracting tissue while activating energy.
- Only contact the patient with the blade of the device. Do not insert the device into tissue beyond the blade, as unintended injury or damage to the device may occur.
- Do not use in patients that have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g. cardiologist). Possible hazards exist because interference with the action of the electronic implant may occur, the implant or implantable leads may be damaged.
- Do not place active accessories near or in contact with flammable materials, flammable gases, or high levels of oxygen. Electrosurgical accessories that are activated or hot from use can cause a fire.
- Do not contact metal objects or instruments with the PhotonBlade while the Cut or Coag function is activated, including sutures, staples or clips, as this may cause patient or user injury, tissue damage, or damage to the device.

- DO NOT activate energy unless the active edge of the blade is in direct contact with tissue. Failure to ensure the active edge of the blade is in direct contact with target tissue while activating energy could result in patient injury, including burns.
- Do not touch the blade or telescoping shaft assembly while the Cut or Coag function is activated, as this may result in injury.
- Do not use the PhotonBlade on small appendages, as monopolar electrosurgery may cause thrombosis or unintended tissue injury.
- Do not use electrosurgery in the presence of flammable anesthetics.
- Turn off the Illumination when the device is not in use to prevent the battery life from declining.
- Stop using the device if energy discharge is observed from any other areas besides the active edge of the blade.
- If tissue builds up on the blade of the device, use soft wet gauze or the provided slot in the holster to clean the device electrode during the procedure. Do not use sharp or abrasive objects, such as a scratch pad, on the PhotonBlade, as it may damage the device.

## Precautions

- The PhotonBlade should be handled and operated by hospital personnel familiar with and trained in its use. Handle all instruments with care.
- Do not use this instrument for any purpose or in any manner other than described in this Instructions for Use. Such use may cause instrument damage or failure, which could result in patient or user injury.
- Completely inspect package prior to use. Do not use if the sterile packaging has been opened or damaged.
- Before use, inspect the device and DO NOT USE the device if there are breaks, chips, cracks, scratches, tears or missing insulation on the blade or telescoping shaft of the device. See Figure 1
- Only use CR123A 3V batteries for the illumination function.
- Activation of the device when not in contact with tissue, but close to a conductive object, may cause capacitive coupling.
- Confirm proper electrosurgical generator power settings before proceeding with surgery.
- Do not look directly at the LED light source while illumination is active. The light source is extremely intense and may temporarily impair vision.
- Position the cable to the side of the operating table to avoid contact with the patient or a potential tripping hazard.
- Avoid fluid contact with the device hand switch, as this may cause damage to the device.
- When not in use, keep the device in the provided holster, with the holster securely attached to the surgical drape, or a dry, non-conductive area away from the patient to prevent unintended contact with patient or user.
- Do not activate the device near electrocardiograph electrodes, as the electrical current may cause interference.
- Both oxygen and nitrous oxide support combustion. Avoid enriched atmospheres, which may result in fires and burns to patients or surgical personnel.

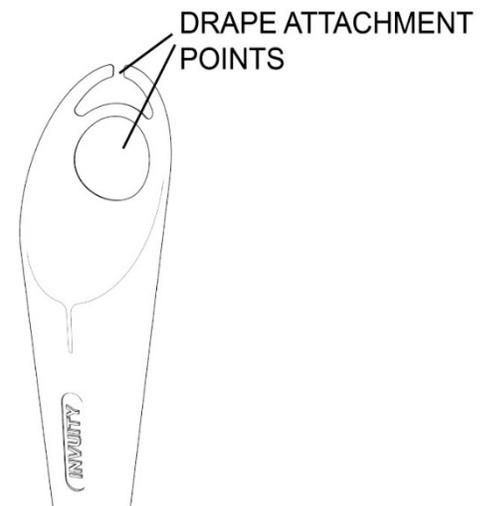


- The following substances contribute to increased fire and explosion hazards in the operating room:
  - Flammable substances (such as alcohol-based skin prepping agents and tinctures)
  - Naturally occurring flammable gases which may accumulate in body cavities such as the bowel
  - The sparking and heating associated with electrosurgery can provide an ignition source. Observe fire precautions at all times. When using electrosurgery in the same room with any of these substances or gases, prevent their accumulation or pooling under surgical drapes, or within the area where electrosurgery is performed.
- Follow all surgical fire precautions and hospital safety procedures. Do not use the device in the presence of flammable gases such as nitrous oxide and oxygen. Do not activate the device until vapors from alcohol-based skin prepping agents have dissipated. (combine with above)
- Verify that all oxygen circuit connections are leak free before and during the use of electrosurgery. Verify that endotracheal tubes are leak free, and the cuff is properly sealed to prevent oxygen leaks.
- Proper patient return electrode application is very important. Refer to the ESU and patient return electrode Instructions for Use for guidance regarding the patient return electrode selection, placement and application procedures. Do not rely entirely on the ESU impedance sensing feature as it can be affected by a damaged (shorted) patient return electrode. It is recommended that the operator verify appropriate placement and contact of the patient return electrode. Improper placement or application of patient return electrode may cause patient injury.
- Position the patient return electrode cable to avoid contact with the patient or other cables.
- Before installing or removing the patient return electrode, ensure that the handset is not connected to the electrosurgical generator, or the generator is OFF or in Standby mode, if available.
- **DO NOT RESTERILIZE OR REUSE.** The PhotonBlade is provided sterile and intended for single use only.
- After use, discard of the PhotonBlade and the battery in accordance to hospital procedures and in accordance with local, state and federal laws and regulations related to clinical waste.

# PhotonBlade: Directions for Use

## Set-Up:

1. BEFORE USE, OPEN THE BATTERY DOOR TO REMOVE THE BATTERY PROTECTION.
  - The Invuity PhotonBlade is provided with a CR123A 3V battery for the illumination function.
  - The battery is located in the connector.
  - There is a battery protection tab (clear tab protruding from battery compartment door) in place for protection during shipment and storage. (See Battery Replacement section below).
2. If replacement is necessary, only use a CR123A 3V battery for replacement
3. Place the patient return electrode on the patient. Connect the patient return electrode to the ESU.
4. Inspect the device package before use. Do not use if the device or packaging has been opened or damaged. Remove the PhotonBlade from the package and inspect the tip of the device for damage. Do not use if damaged.
5. Attach the provided holster to the surgical drape. Place the cable of the device through the cutout in the side of the holster.



6. Turn on the ESU. Follow the manufacturer's manual for setup instructions. Plug the PhotonBlade monopolar connector into the monopolar port of the ESU.



7. Based on the desired tissue effect the lowest energy settings should be used. It is not recommended to use CUT or COAG settings over 50 watts or any power setting and mode that results in an output voltage greater than 3000V. Consult the user manual of the electrosurgical unit (ESU) to determine the voltage output characteristics for different power settings and modes.

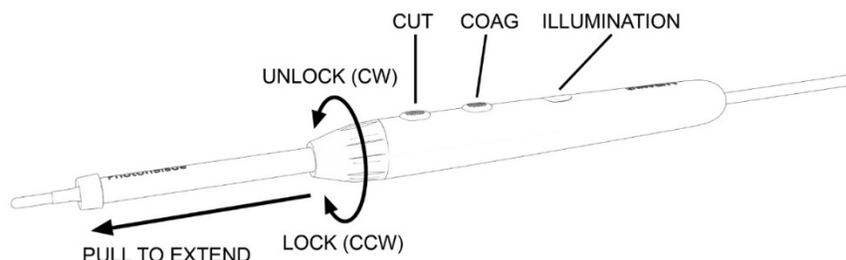
Table 1 lists CUT and COAG power settings and modes used with the PhotonBlade device in combination with the ConMed System 5000 and Valleylab FX-C ESUs to conduct in-vitro testing that confirmed device performance in the specified tissue types.

	ConMed System 5000 ESU (muscle)			Valleylab FX-C ESU (muscle, liver, kidney)		
	Power (Watts)	Mode	Approximate Open Circuit Max. Voltage (Volts)	Power (Watts)	Mode	Approximate Open Circuit Max. Voltage (Volts)
<b>CUT</b>	20	Pure	400	20	Low	380
	35	Pure	450	35	Low	560
	50	Pure	500	50	Low	560
<b>COAG</b>	20	Pinpoint	700	20	Desiccate	900
	35	Standard	1800	35	Fulgurate	2500
	50	Standard	2500	50	Fulgurate	3000

**Table 1**

Comparable output voltage characteristics to those shown in Table 1 can be obtained with other approved electro-surgical units by using similar power settings and modes. Consult the user manual of the electro-surgical unit to determine the voltage output characteristics for different power settings and modes.

### Using the PhotonBlade:



- Set the desired length and rotation of the device shaft:
  - To extend the shaft, unlock the handle nose cone by rotating it 90° clockwise.
  - Pull the shaft distally to the desired length and rotate the shaft to the desired position.
  - Lock the nose cone by rotating it 90° counterclockwise. Confirm that shaft is secured in the desired position before proceeding.
- To collapse the shaft of the device, loosen the nose cone, push on the shaft to the desired length, then tighten the nose cone.
- Adjust the length and rotation of the PhotonBlade shaft as needed throughout the procedure.
- To cut, press and hold the yellow button continuously on the handswitch. The Cut button is the most distal on the hand-piece.
- To coagulate, press and hold the blue button continuously on the handswitch. The Coag button is the middle button on the hand-piece.



6. To turn the illumination on, first ensure the device is not contacting tissue, then press the **white** button on the handswitch once. The illumination button is the most proximal on the hand-piece.
7. To turn the illumination off, first ensure the device is not contacting tissue, then press and hold the white button on the hand switch for 2 seconds.

**Notes:**

- a. **Do not contact tissue when turning the illumination on or off.**
  - b. **Turn off the illumination when the device is not in use to preserve the battery.**
8. Illumination has no effect on the CUT and COAG functions.
  9. Keep the electrode clean throughout the procedure. Remove tissue build-up with wet gauze pads or by sliding the blade through the provided slot on the holster.
  10. Keep the waveguide clean throughout the procedure. Remove fluid or debris with a tapered swab.



**Battery Replacement:**

1. The PhotonBlade will provide approximately 2 hours of illumination. If the battery needs to be replaced:
  - a. Turn OFF the ESU and unplug the device from the ESU.
  - b. Then, press firmly inward and up on the battery compartment door tab, located on the side of the monopolar connector.
  - c. Replace the battery with a new CR123A 3V battery. The positive end of the battery should be oriented toward the connector pins.
  - d. Dispose of the used battery according to hospital procedures and in accordance with local, state and federal laws and regulations.
  - e. Close the battery door and plug the connector back into the ESU.



**Note: The Cut and Coag functions of the device operate independently of the illumination. If the illumination decreases or stops, there is no effect on the Cut and Coag functions.**

**After Surgery:**

1. Turn off the ESU.
2. Disconnect the PhotonBlade connector and the patient return electrode from the ESU.
3. Remove the battery from the battery compartment on the connector.
4. Discard the PhotonBlade and battery in accordance to hospital procedures and in accordance with local, state and federal laws and regulations related to clinical waste. Do not re-use the device.

## ELECTROMAGNETIC COMPATIBILITY (IEC 60601-1-2)

The Invuity PB1 PhotonBlade complies with the appropriate IEC 60601-1-2 specifications regarding electromagnetic compatibility.

<b>Guidance and Manufacturer's Declaration – Electromagnetic Emissions</b>		
The Invuity PB1 PhotonBlade is intended for use in the electromagnetic environment specified below. The customer or user of the Invuity PB1 PhotonBlade should ensure that it is used in such an environment.		
<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic Environment – Guidance</b>
RF Emissions CISPR 11	Group 1	The Invuity PB1 PhotonBlade must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected when RF is energized. As per IEC 60601-1-2, 4 <sup>th</sup> Edition, Clause 7.1, the test performed was CISPR 11 test: Limits for radiated disturbance 30MHz-1Ghz. The EUT (Equipment Under Test, PB1) was tested in two configurations: 1) EUT standalone with illuminator turned on. 2) EUT connected to HF surgical generator. The HF surgical generator was switched on and left in standby mode; the illuminator function of the surgical pen was turned on.
RF Emissions CISPR 11	Complies	The Invuity PB1 PhotonBlade is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics EN 61000-3-2	Not Applicable <sup>1</sup>	
Flicker EN 61000-3-3	Not Applicable <sup>1</sup>	

<sup>1</sup>The Invuity PB1 PhotonBlade does not contain AC power ports. The Invuity PB1 PhotonBlade is battery powered.

<b>Recommended separation distances between portable and mobile RF communications equipment and the Invuity PB1 PhotonBlade</b>			
The Invuity PB1 PhotonBlade is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Invuity PB1 PhotonBlade can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Invuity PB1 PhotonBlade as recommended below, according to the maximum output power of the communications equipment.			
<b>Rated maximum output power of transmitter (W)</b>	<b>Separation distance according to frequency of transmitter (m)</b>		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

## 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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**REVISION HISTORY**

<b>Rev</b>	<b>CO #</b>	<b>Description</b>	<b>Approved Date</b>	<b>Effective Date</b>	<b>Originator</b>
A	20-0113	Initial Release	20MAY2020	02JUN2020	C. Hewitt

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## **PRINTING INSTRUCTIONS**

Print in-house or at an approved supplier.

Do not print Revision History or Printing Instructions pages (page 10 & 11).

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

Fold in booklet and staple fold.

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