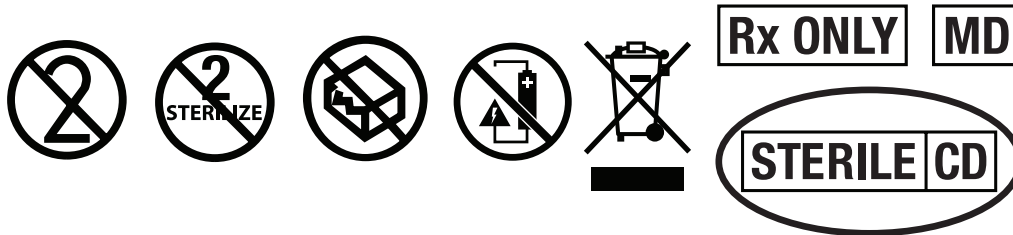


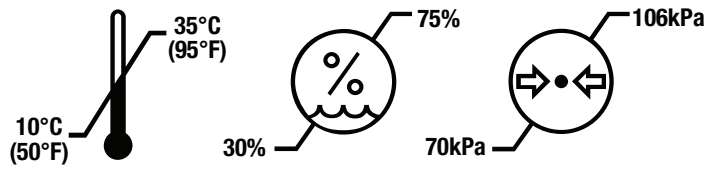
light jacket®

Attachable Light for Electrosurgical Pencil

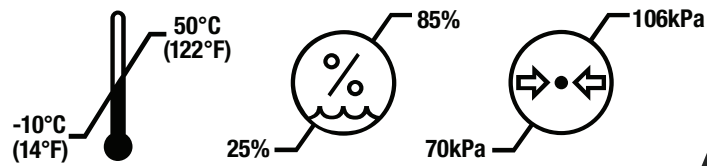
INSTRUCTIONS FOR USE



OPERATING CONDITIONS



STORAGE CONDITIONS



EN



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LIGHT JACKET® DESCRIPTION

The Light Jacket® Attachable Light for Electrosurgical Pencil is offered as a sterile, one-time use disposable medical device for providing enhanced illumination of the surgical site when attached to an electrosurgical pencil.

INTENDED USE

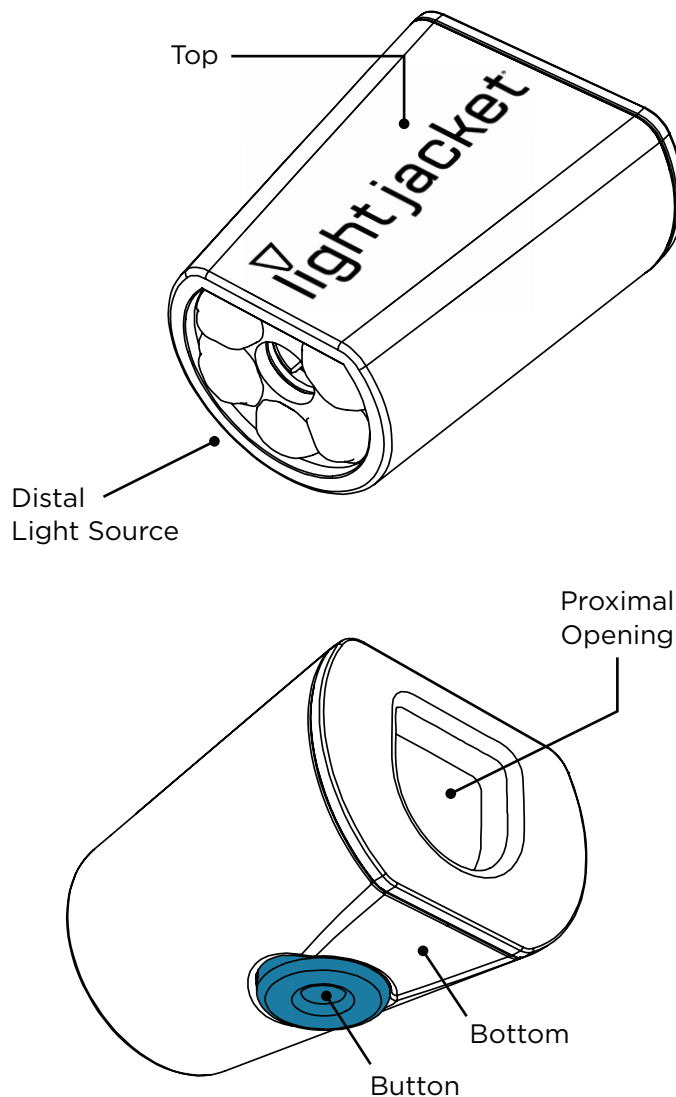
The device is a self-powered light source attachment to electrosurgical pencils and is intended to provide visible illumination of the surgical field from outside the surface of the body.

INDICATIONS FOR USE

This single-use device is indicated for use by healthcare professionals on patients undergoing surgery where the use of an electrosurgical pencil is required.

PERFORMANCE CHARACTERISTICS

A single-use, sterile, active medical device containing battery-powered LED lights that activate when attached to an electrosurgical pencil for up to 60 minutes of continuous illumination or up to 2 hours of intermittent illumination.

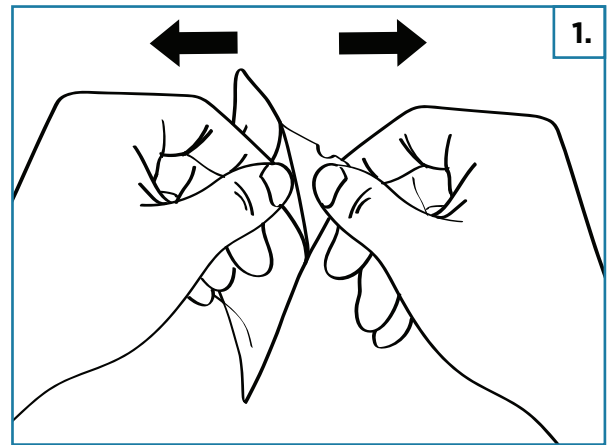


SYMBOL GUIDE

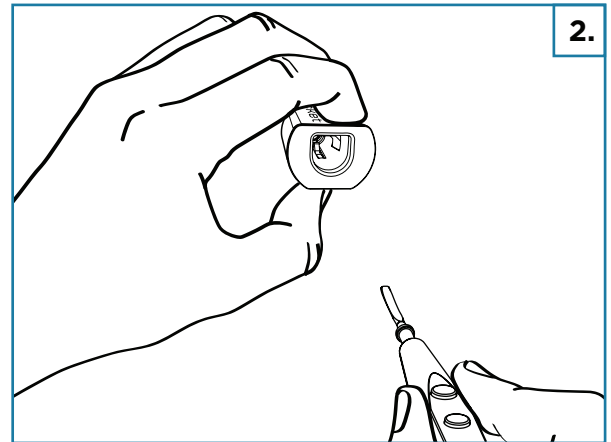
Do Not Re-Sterilize		Caution		STERILE CD	Sterilized using chlorine dioxide
Do Not Use If Package Is Damaged		Humidity Limitation		Batch Code	LOT
Do Not Re-Use		Temperature Limitation		Expiration Date	
Do Not Recharge		Atmospheric Pressure Limitation		Date and Country of Manufacture	
WEEE Directive Dispose per Local Regulations		Consult Instructions for Use		Quantity	QTY
Catalog Number	REF	Legal Manufacturer		Rx ONLY	Medical Device. Prescription Use Only. US Federal Law restricts this device to sale by or on the order of a physician
Authorized Representative in the European Community	EC REP	Importer			
Distributor		Unique Device Identifier	UDI	Single Sterile Barrier System	
Translation		Medical Device	MD	CE Marking of Conformity	CE

LIGHT JACKET® DIRECTIONS FOR USE

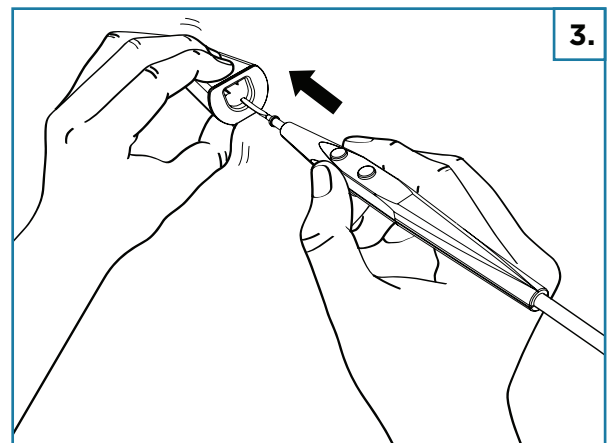
1. Using aseptic technique, open sterile package and transfer the Light Jacket® onto sterile field.



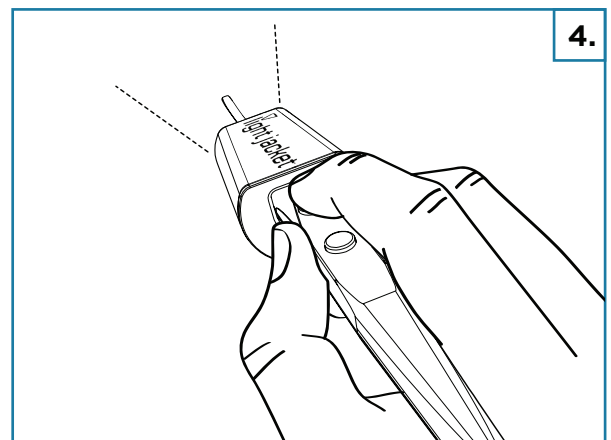
2. Hold the Light Jacket® so light source is positioned distally. Align Buttons/Rocker Switch of electrocautery pencil with the Light Jacket® logo (top).



3. With thumb on button (bottom), squeeze until button is fully depressed. Insert electrocautery pencil into proximal opening of the Light Jacket® until it stops. The Light Jacket® will illuminate.



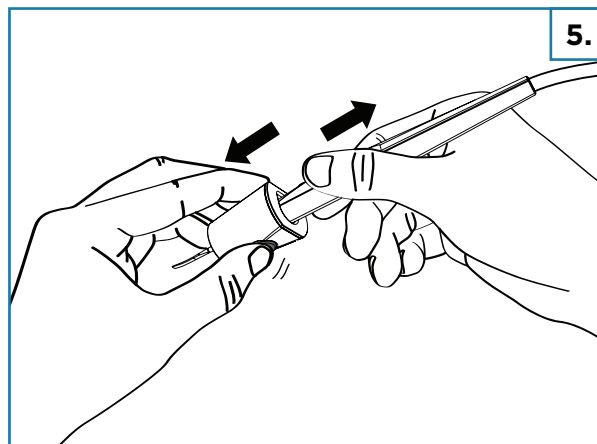
4. Release button to secure the Light Jacket® onto electrocautery pencil. The Light Jacket® will remain illuminated for up to 2 hours of intermittent use.



5. To remove the Light Jacket® from electro-surgical pencil, squeeze button with thumb until fully depressed. Remove electro-surgical pencil. Light will deactivate.

When the battery is low, the Light Jacket® will flash and remain illuminated for 30 seconds. If continued illumination is required, replace the Light Jacket® immediately.

Dispose of used Light Jacket® in proper manner for surgical waste and in accordance with local laws.



WARNINGS

- Do not shine Light Jacket® into eyes. May cause temporary blindness.
- Do not install or remove Light Jacket® while over an open surgical cavity.
- Do not leave Light Jacket® in a patient cavity.
- Do not insert finger(s) into Light Jacket®.
- Fire / Explosion / Burn Hazard. Do not crush, disassemble, incinerate, or heat batteries above 100°C/212°F.
- The Light Jacket® contains non-rechargeable batteries. Do not recharge batteries. Dispose of batteries in accordance with local laws.
- Use with untested electro-surgical pencils may result in improper attachment, improper light activation/deactivation, and/or damage to the device or pencil.
- Do not reuse. Reuse can lead to infection, contamination, or battery failure.
- Should the user or patient experience any serious incident that has occurred in relation to the Light Jacket®, report it to Pathy Medical® and the authority having jurisdiction in your locale.

RECOMMENDATIONS

- Users should add Light Jacket® to the surgical count.
- Light Jacket® should be attached and removed no more than ten times.
- Light Jacket® should be used to enhance lighting and not as only source of light.
- Light Jacket® is tested for compatibility with the following electro-surgical pencils*:

Covidien™* Edge™*/Valleylab™* Button Switch Pencil

Covidien™* Edge™*/Valleylab™* Rocker Switch Pencil

Megadyne™* Button Switch Pencil

Megadyne™* Rocker Switch Pencil

ConMed®* GoldLine®* Push Button Pencil

ConMed®* GoldLine®* Rocker Switch Pencil

Medline®* Vega Series Cautery Pencil, Push-Button

Medline®* Vega Series Cautery Pencil, Rocker



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The Light Jacket® is not compatible with the Covidien™ Force TriVerse™* and PlasmaBlade®*.

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*All other trademarks are the property of their respective owners.

Protected by US and Int'l patents. See www.pathymedical.com/patents



Pathy Medical