

light jacket[®]

Attachable Light for Electrosurgical Pencil

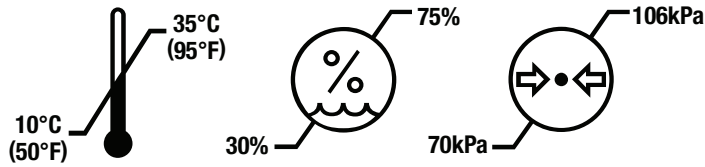
INSTRUCTIONS FOR USE



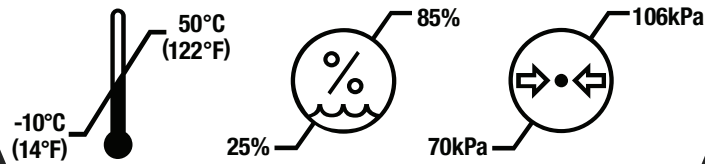
STERILE CD

Rx ONLY

OPERATING CONDITIONS



STORAGE CONDITIONS



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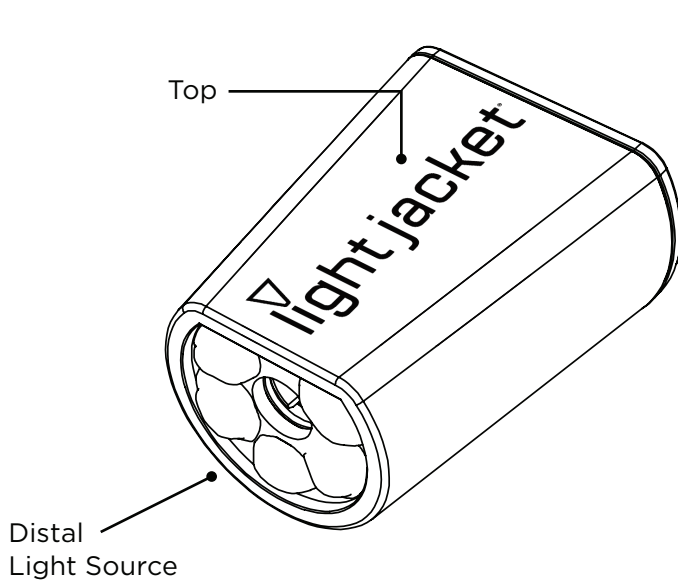


LIGHT JACKET® DESCRIPTION

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.

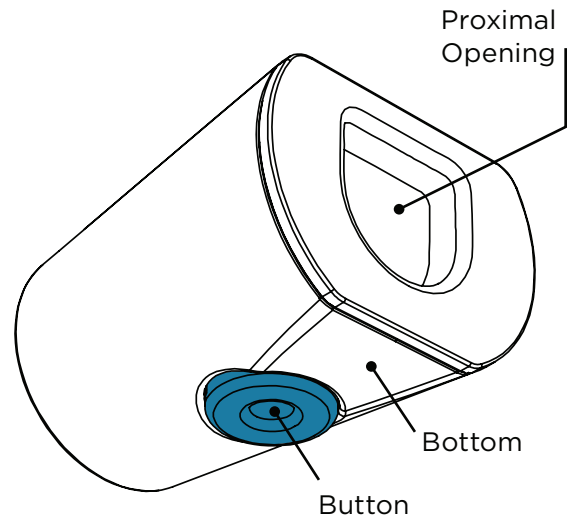


INDICATIONS FOR USE

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.

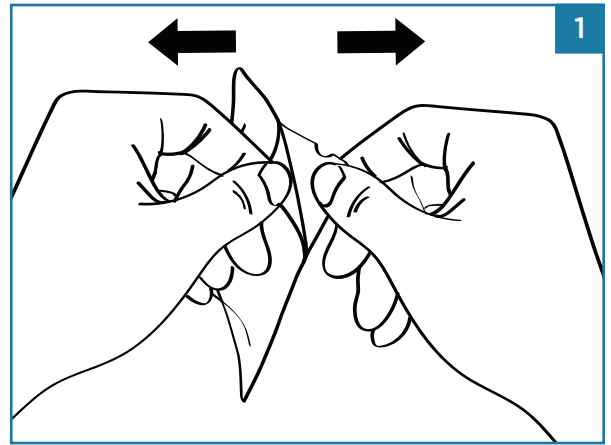


SYMBOL GUIDE

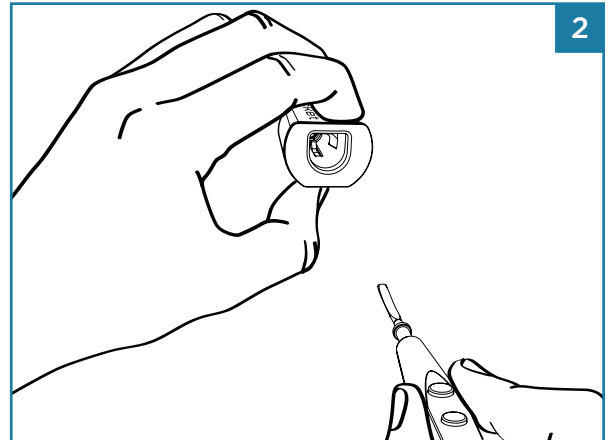
Do Not Re-Sterilize		Caution		STERILE CD Sterilized using chlorine dioxide	Catalog Number	REF	
Do Not Use If Package Is Damaged		Humidity Limitation		Batch Code	LOT	Legal Manufacturer	
Do Not Re-Use		Temperature Limitation		Expiration Date		Authorized Representative in the European Community	EC REP
Do Not Recharge		Atmospheric Pressure Limitation		Date of Manufacture			Rx ONLY
WEEE Directive Dispose per Local Regulations		eIFU Indicator		Quantity	QTY	Medical Device. Prescription Use Only. US Federal Law restricts this device to sale by or on the order of a physician	

LIGHT JACKET® DIRECTIONS FOR USE

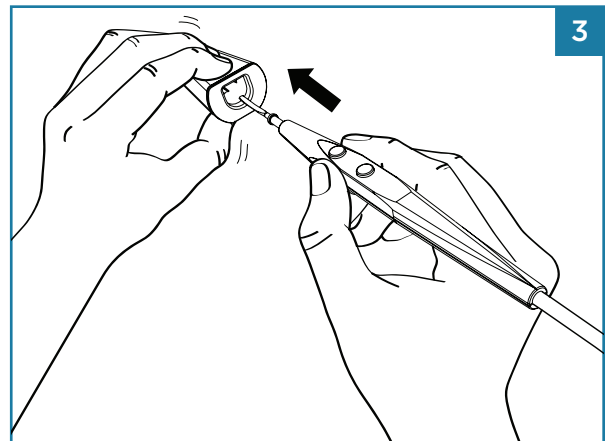
1. Using aseptic technique, open sterile package and transfer the Light Jacket® onto sterile field.



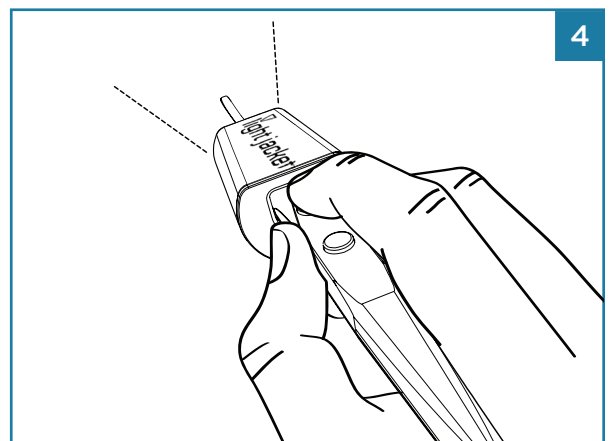
2. Hold the Light Jacket® so light source is positioned distally. Align Buttons/Rocker Switch of electro-surgical pencil with the Light Jacket® logo (top).

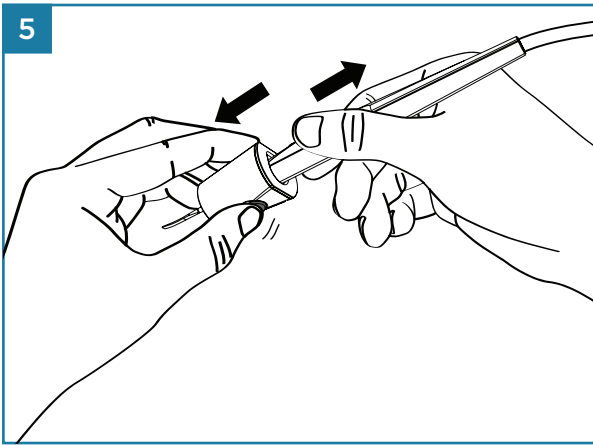


3. With thumb on button (bottom), squeeze until button is fully depressed. Insert electro-surgical pencil into proximal opening of the Light Jacket® until it stops. The Light Jacket® will illuminate.



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





5. To remove the Light Jacket® from electrocautery pencil, squeeze button with thumb until fully depressed. Remove electrocautery pencil. Light will deactivate.
6. 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.
7. 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 electrocautery 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.

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 electrocautery 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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