

NOTE: Federal law restricts this device to sale by or on the order of a licensed practitioner.



ROVER SLS-S INSTRUCTIONS FOR USE

Description:

Sterile, Single Use, Battery Powered Light Source. This product does not contain any latex.

Intended Use:

The ROVER SLS is intended to provide up to 90 minutes of illumination to a surgical site. The SLS is not intended to be invasive.

Contraindications:

There are no known contraindications.

Intended Users and Patient Target Group:

This device is intended for professional use only. There are no known limitations as far as specific intended patient target group(s).

Lit-231- Sunoptic Technologies - Rover SLS Instructions For Use - Distributed By ASR Systems

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02/25

WARNINGS AND PRECAUTIONS

NOTE: This device is provided sterile using the Ethylene Oxide sterilization method.

The following Warnings and Precautions should be reviewed prior to the use of this device:

Warnings

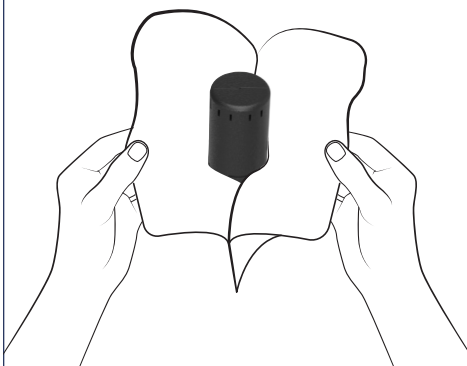
- Inspect the device packaging before use. Do not use if the packaging has been compromised. Inspect packaging for tears or damage that may cause the device to be subject to contamination. Also verify that the Sterilization Expiration Date has not expired and is still valid at time of use.
- Battery powered equipment is considered unsuitable for use in the presence of flammable anesthetics and/or oxygen rich environments.
- Do not modify the device in any manner.
- The device may become warm to the touch and should be monitored during use. DO NOT operate unattended.
- Handle damaged or leaking batteries with care.
- Do not re-sterilize or reuse. The ROVER SLS is provided sterile and is intended for single use only.
- Any serious incident that may have occurred, in relation to this device, should be reported to the manufacturer and the competent authority in which the user and/or patient is established.
- Avoid exposure to liquids. This may cause the device to malfunction.
- Dispose of battery and device according to local regulations.

Precautions

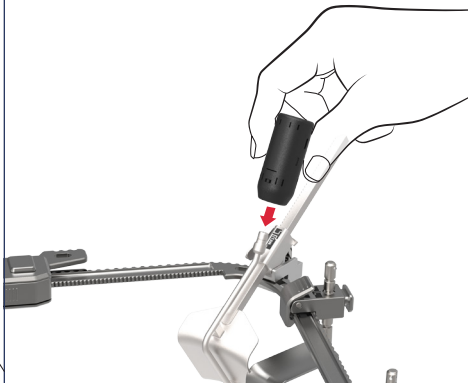
- Avoid looking directly at the LED beam or pointing it directly at anyone's eyes. The LED can momentarily disorient a person and/or can cause lingering ghost images.
- Never dispose of the device while powered on; allow time for device to turn off and cool down before disposal.
- If battery removal is necessary for proper disposal, DO NOT touch the internal circuit board as it may be hot after use.
- Storage Conditions: Storage Temperature: 50°F - 104°F (10° - 40°C) at 0 - 90% Relative Humidity.

DIRECTIONS FOR USE

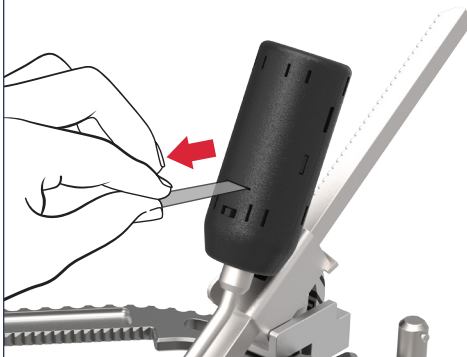
1. Remove SLS from packaging



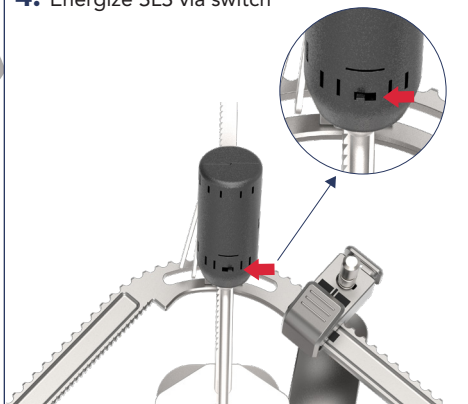
2. Install SLS to Device



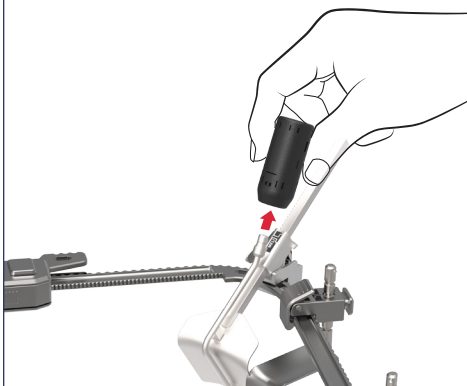
3. Remove TAB and discard



4. Energize SLS via switch























5. Disconnect SLS after use





6. Dispose SLS battery and device according to local regulations



MEDICAL DEVICE LABELING SYMBOLS AND DESCRIPTIONS

	Manufacturer
	Attention: Read all warnings and precautions in instructions for use
	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
	Catalog or Part Number
	Batch / Lot Number
	Quantity
	Medical Device
	Unique Device Identifier
	Sterile Product - Ethylene Oxide
	Warning
	Distributed By
	Date of Manufacture (YYYY-MM-DD)
	Consult Instructions for Use
	Do not use if package is damaged
	Use-By Date
	Do Not Reuse
	Do Not Resterilize
	Keep dry
	Single Barrier
	Precaution

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