



LED ROVER IV+

Instructions for Use



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1. INTRODUCTION



The LED Rover IV+ is a Light Emitting Diode (LED) and battery unit designed to couple onto the light post of commercially available endoscopes having an ACMI or Wolf light post. The LED Rover IV+ is made to take the place of conventional light cables and remote light sources. It couples to the endoscope in the same fashion as a conventional light cable by press fitting onto the endoscope's light post. The LED Rover IV+ is powered by a single "18650" size lithium-ion 3.7V rechargeable battery.

The battery powers an LED via a current converter that supplies a constant current to the LED. The light is directed into the light post of the scope. The light is then carried by internal fiber optics to the scope to illuminate the target. The amount of light emitted from the Rover IV+ can be adjusted by pressing the switch at the rear of the body.

2. INTENDED USE / INDICATIONS FOR USE

The LED Rover IV+ is used to illuminate the site of surgery during minimally invasive surgical procedures in arthroscopy (orthopedic surgery), laparoscopy (general and gynecological surgery) and in Endoscopy (general, gastroenterological and ENT surgery). The light is transmitted from the light source through a scope.

3. WARNINGS / LABELING

3.1 WARNINGS

CAUTION

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

CAUTION

Battery powered equipment is considered unsuitable for use in the presence of flammable anesthetics.

CAUTION

The LED Rover IV+ is provided **non-sterile**. If used for sterile procedures, the unit must be sterilized or draped with commercially available surgical drapes.

 **CAUTION**

The LED Rover IV+ will become warm to the touch; however, it has been shown that prolonged contact during use will not cause injury.

 **CAUTION**

Avoid looking directly at the LED inside the port or pointing it directly at anyone's eyes. The LED is painfully bright, can momentarily blind a person and/or can cause lingering ghost images. Due to the microprocessor controls of the Rover IV+ the light might momentarily energize when changing batteries.

 **CAUTION**

Handle damaged or leaking batteries with care. Should you come in contact with the electrolyte, wash the exposed area with soap and water. Should the eye come in contact with the electrolyte, flush the eye with water for 15 minutes and seek medical attention. Do not incinerate discarded batteries. Follow local EPA requirements for proper disposal.

 **CAUTION**

Only operate the Rover IV+ with batteries approved by Sunoptic Technologies®.

The device has no known contraindications.

4. SPECIFICATIONS

Item	Specification
Lamp Type	LED
Color temperature	5000 K (nominal)
Battery	Lithium Ion 18650 3.7V
Current converter output	800 milliamps (nominal)
Endurance time	2.5 hours High 4.5 hours Medium 19 hours Low (typical, actual endurance may vary)
Model	LED Rover IV+
Dimensions	4.78 inches long X 1.12 inches diameter at LED housing
Weight	5.1 oz.
Electrical Protection	Class I, Type BF
Medical Classification	FDA Class II Europe Class I
Port	ACMI
Operating Environment Temperature Relative Humidity Air Pressure	+0° to +30° C (32° to 86° F) 0 to 85%rh, non condensing 700 to 1060 hPa
Storage Environment Temperature Relative Humidity Air Pressure	-20° to +60° C (-4° to 140° F) 30 to 95%rh, non condensing 700 to 1060 hPa

5. OPERATION

The LED Rover IV+ is operated by a normally closed momentary pushbutton. When the pushbutton is pressed and released (starting from the off state), the device provides maximum power to the LED. Pressing and releasing the pushbutton again will change the power output to the LED to 66% of the maximum. Pressing and releasing the pushbutton a third time will change the output to the LED to 33% of the maximum. Pressing and releasing the pushbutton a fourth time will return the device to the OFF state.

6. BATTERY INFORMATION

6.1 RECHARGEABLE BATTERY

The rechargeable batteries provided are high capacity 18650 3.7 volt Lithium-ion battery. The battery charger provided is compatible only with the 3.7 volt high capacity rechargeable Lithium-ion batteries that are supplied. The 3.7 volt high capacity batteries provided are compatible *only* with chargers specifically designed for them. Do not put attempt to charge the batteries with another type of charger.

A fully-discharged battery may require approximately eight hours to reach a full charge. The three indicator lights on the charging cradle will be blank when there is no battery in the cradle. The charger will flash one LED while determining what configuration of battery is in the charger and this LED will remain solid once the configuration is determined. The second and third LEDs will flash while it is charging, and there will be three solid lights when the battery is fully charged. Batteries may be “topped off” to full charge even if they are not fully discharged. Batteries may be left in the charging cradle when charged. Avoid directly short circuiting a battery. The power converter operates on 100~240 VAC, 50~60Hz @ 0.25A. With fully charged batteries the light source is approximately 2.5 hours with the strongest brightness, followed by approximately ½ hour of usable light.

Consult the charger's individual instructions for further operational details, additional warnings, and safety data.

6.2 BATTERY REPLACEMENT

Unscrew the headpiece that houses the LED. (Do not remove the switch; the battery cannot fit through the switch end.) Remove the discharged battery and insert a fully charged battery. Observe correct polarity. The positive (+) end of the battery must point toward the headpiece. The positive end of the battery has a protruding nipple; the negative (-) end is flat.

7. CLEANING / STERILIZATION

7.1 CLEANING

The LED Rover is a high quality optical device. Care for it appropriately.

A soft brush with mild detergent may be used to clean the device. The lens of the LED inside the optic port may be wiped with a swab. Avoid harsh or abrasive material that could scratch or in any way damage the optical surface.

7.3 HIGH LEVEL DISINFECTION (IMMERSION)



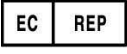



The LED Rover may be immersed in high level disinfectant solution no deeper than six (6) inches (15cm) for as long as one (1) hour. Process according to the disinfectant manufacturer's instructions or your institution's established protocol. We make no claims other than the Rover's immersibility as stated.

8. LIMITED WARRANTY

Your LED Rover carries a 1-year warranty from the date of shipment on workmanship and all defects of material except batteries. Should your product prove to have such defects within one year from the date of shipment, **Sunoptic Technologies®** will repair or replace the product or component part without charge. Should your LED Rover need servicing under this warranty, please contact **Sunoptic Technologies®** for return authorization documentation. You should carefully pack product in a sturdy carton and ship it to the factory. Please include a note describing the defects, your name, telephone number and a return address. Warranty does not cover equipment subject to misuse, accidental damage, and normal wear and tear. This warranty gives you specific legal rights and you may also have other rights that vary from state to state.

- In the U.S call: 877 677-2832 (toll free)
- FAX number: 904 733-4832
- Customer Service 904 737-7611

9. CHART OF MEDICAL DEVICE SYMBOLS USED

	Manufacturer
	Date of manufacture (YYYY-MM-DD)
	"Authorized Representative" in the European Community
	Caution, consult accompanying documents
	Consult Instructions for Use
	CE mark