KLARO™
IN VIVO SURGICAL LIGHTING

vivo Surgical
Beyond Surgery

IN VIVO SURGICAL LIGHTING
INSTRUCTIONS FOR USE

MANUFACTURER

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Box Content: 5 KLARO™	REF 555-01-01	LOT YYMMXX		
CE 0197				YYYY-MM
IPX4	15°C 30°C	40% 70%	STERILE EO	

Product Description

KLARO™ is a deep-cavity surgical LED lighting device for open surgery use. It is discreet, easy to use and provides bright, uniform and localized "flood-lighting" from within the surgical site. KLARO™ maintains a safe and cool working temperature suited for use inside the human body regardless of the luminous intensity selected.

Key Features

- Sterile, single-use disposable
- Discreet form factor in a small, battery-powered device
- Maintains a safe working temp. (<38°C) throughout 4-hour lifespan
- Wide and variable illumination "flood" angle (over 180°)
- Adjustable luminous intensity
- Self-retaining – the user is not required to hold onto the device during surgery

Intended Use and Users

KLARO™ In Vivo Surgical Lighting is intended to provide direct localized "flood-lighting" from within the open surgical site. Intended users of KLARO™ are medical doctors.

Warnings and Precautions

Read Instructions prior to use.

Sterilization and Disposal:

- KLARO™ has been sterilized in its packaging by Ethylene Oxide (EO) and is a single-use product.
- Do not re-use or re-sterilize KLARO™. User may be at risk of infection and device may malfunction if it is re-used or re-sterilized.
- After use, discard KLARO™ according to national biohazard waste disposal laws.

Product Use and Safety:

- Do not use for purposes other than intended. Do not put the product in direct contact with the heart, the central circulatory system or the central nervous system.
- Before opening the package containing KLARO™, check the package for puncture, tear or integrity of seal. Do not use the product if the package has been damaged or opened.
- Handle the product with care. Do not drop or throw the device. Do not use excessive force when using KLARO™ as this may damage the device. If damaged, do not continue using. Replace with a new KLARO™.
- Do not shine the light directly into the eyes.
- Do not allow KLARO™ to be near conductive instruments or in contact with active energy devices as they may damage KLARO™ and render it not usable.
- KLARO™ contains a non-rechargeable Manganese Dioxide-Lithium battery. Do not recharge, disassemble, heat above 100ºC, incinerate, or expose the battery directly to water. Do not immerse the battery pack in liquids as this may damage the device.
- KLARO™ has been tested and conforms to electrical safety and EMC standards according to EN 60601-1:2006+A1:2013+A11:2011+A12:2014 and IEC 60601-1:2005+AMD1:2012, EN 60601-1-2:2015 and IEC 60601-1-2:2014.
- KLARO™ can be used for up to 4 hours continuously. When KLARO™ reaches 3 hours and 45 minutes of usage, a red LED will light up next to the Black Boundary Line on the light tip indicative of 15 minutes left of usage.

KLARO™ is to be used in conjunction with existing surgical luminaire systems in operating room.

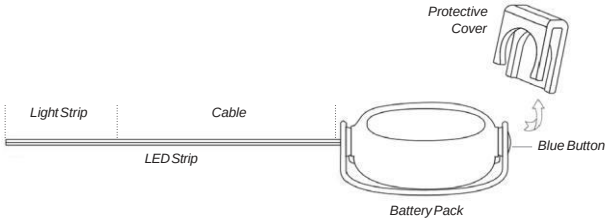
Storage:

- KLARO™ should be stored in a clean and dry place with room temperature between 15˚C-30˚C and between 40-70% RH.
- Do not use KLARO™ beyond the "Use-by" date on the packaging.

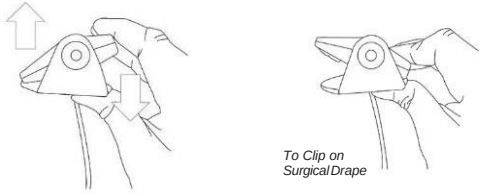
Directions for Use

The following directions serve as instructions for the user to have the most optimal experience when using KLARO™:

1. Peel open the package and place KLARO™ onto the sterile field.
2. Discard the Protective Cover. Inspect the product for any damage. Do not use if the product is damaged.

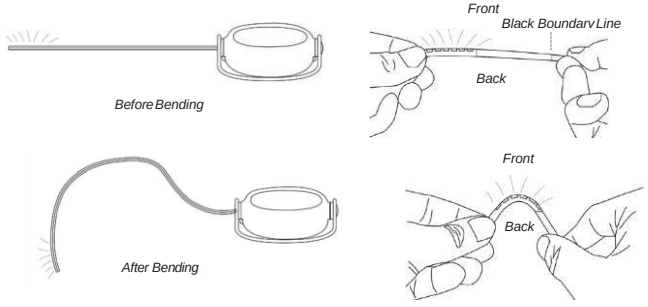


3. Attach the battery pack onto the surgical drape using the built-in clip.



Note: The clip can be repositioned to any desired area of the surgical drape throughout the course of surgery (Maximum number of repositioning: 100 times).

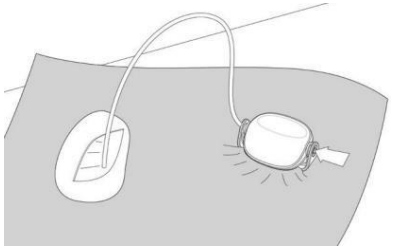
4. Hold the light strip and press the blue button with ⊙/◌ symbol on the battery pack ONCE to activate the light strip to the "LOW intensity" setting.
5. The lighted LEDs are located at the FRONT of the light strip. The light strip can be bent from the FRONT to the BACK and vice versa in a reverse direction.



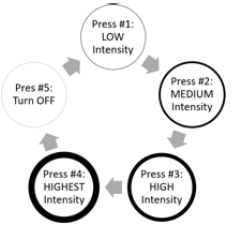
Note:

- **When using KLARO™, the light strip can be bent at various angles.**
- **Do not bend the light strip beyond 120° from the neutral position.**
- **The user is recommended to bend the light strip between the Black Boundary Line and the tip of the light strip.**
- **Not recommended to bend the light strip at a fixed point for more than 10 times.**

6. Once the light strip has been bent to the desired angle, place it within the cavity of the surgical incision. Clip the battery pack onto the surgical drapes.



7. The lighting intensity can be adjusted at any point during the surgery by pressing the blue button with ⊙/◌ symbol as follows:



Note: During the surgery, bodily fluid or debris may stick to the light strip and may affect the intensity of the emitted light. The user may use a sponge, wipe or gauze with sterile water to wipe the surface of the light strip.

8. After the surgical procedure is completed, if required by national laws governing disposal of Lithium ion batteries, drain the battery before discarding KLARO™. Otherwise, directly discard KLARO™ according to national biohazard waste disposal laws.

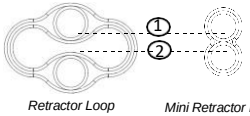
Retractor Loop

KLARO™ is provided with 4 Retractor Loops (RL) and 2 Mini Retractor Loops (MRL). The RL/MRL enable the user to easily and quickly fasten the KLARO™ LED Strip onto most surgical retractors in the market. The following directions serve as instructions for the user to have the most optimal experience when using KLARO™ in combination with the RL/MRL:

1. Insert the surgical retractor blade through loop ② of the RL/MRL.
2. Place the first RL/MRL along the retractor blade (e.g. at position ⓐ as shown).
3. For added stability, use a second RL/MRL (e.g. at position ⓑ as shown).
4. Once the RL/MRL are in place on the retractor, insert the KLARO™ LED Strip through loop ① of the RL/MRL as shown.
5. The KLARO™ LED Strip can be bent by the user so that it conforms to the shape of the retractor blade to provide optimum stability during the procedure.
6. At the end of the surgical procedure, discard the RL/MRL following the same disposal instructions as KLARO™.

Note:

- The RL/MRL are provided sterile in the same packaging as KLARO™.
- The RL/MRL are single-use disposables. Do not re-use or re-sterilize them.
- Do not use excessive force when using the RL/MRL.



EMC Notes

- The purchaser or user of KLARO™ should use the device under a specified electromagnetic environment. Otherwise, it may cause KLARO™ to not work properly.
- Portable and mobile RF communication equipment may affect the normal use of KLARO™. Please use KLARO™ in the recommended electromagnetic environment.
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

EMC Warning

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of KLARO™, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guide and manufacturer's statement – Electromagnetic emission		
KLARO™ is intended to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment:		
Emission test	Compliance	Electromagnetic environment
RF emission CISPR 11	Group 1	KLARO™ uses RF energy only for its internal function. Therefore, its RF emissions are low and there is little possibility of producing interference to nearby electronic equipment.
RF emission CISPR 11	Class A	KLARO™ is suitable for use in professional healthcare facilities.
Harmonic distortion IEC 61000-3-2	N/A	
Voltage fluctuations and flicker IEC 61000-3-3	N/A	

Guide and manufacturer's statement – Electromagnetic immunity			
KLARO™ is intended to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment:			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guide
Conducted disturbances induced by RF fields IEC 61000-4-6	3V 0.15 MHz～80 MHz 6V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1kHz	N/A	N/A
Radiated RF EM fields IEC 61000-4-3	3 V/m 80 MHz～2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz～2.7 GHz 80%AM at 1 kHz	CISPR11 class A

Guide and manufacturer's statement – Electromagnetic immunity			
KLARO™ is intended to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment:			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guide
Electrostatic discharge IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15kV air	The floor should be wood, concrete or ceramic. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients/ bursts IEC 61000-4-4	±2 kV 100 kHz repetition frequency	N/A	Battery powered and no signal line >3m
Surges IEC 61000-4-5	±1 kV line-to-line ±2 kV line-to-ground	N/A	Battery powered and no signal line >30m or going out to outdoor
Voltage dips IEC 61000-4-11	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315°	N/A	Battery powered
	70% U_T; 25 cycles at 0°		
Voltage interruptions IEC 61000-4-11	0% U_T; 250 cycle		
Rated power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz	30 A/m 50Hz	The power frequency magnetic field should have the characteristics for use in a typical place in a typical commercial or hospital environment.
Note: U_T refers to the AC voltage of the power supply before the test voltage is applied.			

Guide and manufacturer's statement – Electromagnetic immunity						
KLARO™ is intended to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment:						
Immunity to RF wireless communications equipment（IEC 61000-4-3）						
Test frequency (MHz)	Band (MHz)	Service	Modulation	Max. power (W)	Distance (m)	Immunity test level (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM ±5kHz deviation 1kHz sine	2	0.3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800 — 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700 — 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25, UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400 — 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100 — 5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

Symbols Glossary

	Consult Instructions For use		Use By Date (YYYY-MM)
	Catalog Number	IPX4	Ingress Protection
	Lot Number		Acceptable Temperature
	Do Not Reuse		Acceptable Relative Humidity
STERILE EO	Method of sterilization using EO		Device Manufacturer
	Content is sterile unless inner package has been opened or damaged	EC REP	Authorized EC Representative
	Keep Dry		Caution
	Type BF Applied Part (light strip)		