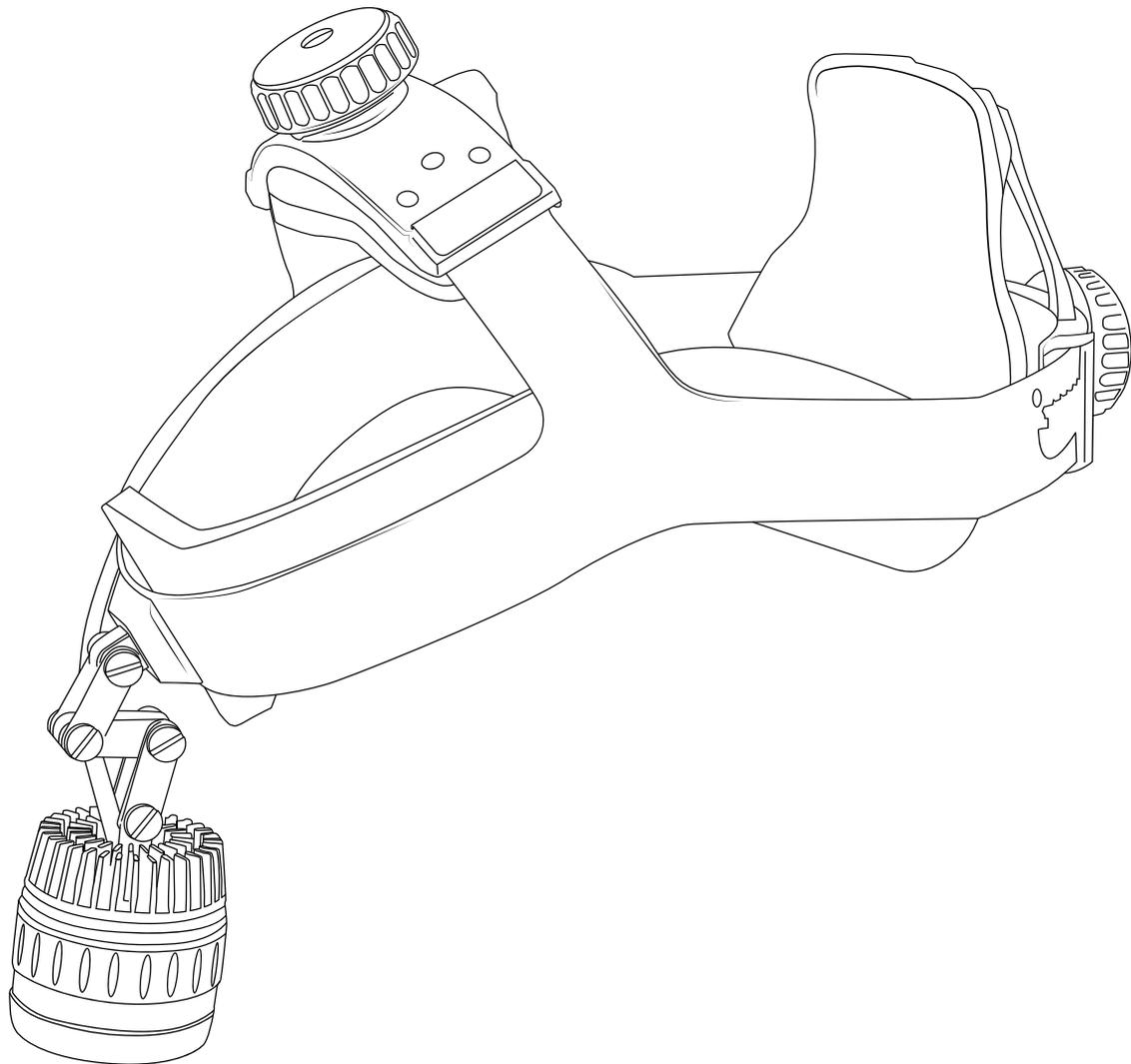


Quantum™ LED Surgical Headlights

Quantum™ Cool LED Surgical Headlight

Quantum™ Warm LED Surgical Headlight

Instructions For Use



Introduction

This *Instructions For Use* manual is the most comprehensive source of information for the safe and effective use of your product. This manual may be used by surgeons, dentists, veterinarians, or other healthcare professionals.

Keep and consult this reference manual during the life of the product.

The following conventions are used in this manual:

- A **WARNING** highlights a safety-related issue. ALWAYS comply with this information to prevent patient and/or healthcare staff injury.
- A **CAUTION** highlights a product reliability issue. ALWAYS comply with this information to prevent product damage.
- A **NOTE** supplements and/or clarifies procedural information.

If additional information, especially safety information, or in-service training is required, contact your Enova sales representative or call Enova customer service.

NOTE: The user and/or patient should report any serious product-related incident to both the manufacturer and the Competent Authority of the European Member State where the user and/or patient is established.

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Indications for Use

LED Surgical Headlight Systems are adjunct light sources used for illumination during clinical or surgical procedures in a medical setting.

Contraindications

None known.

Limitations of Use

None known.

For Use With

Rechargeable PP4 Power Pack and the Quantum Twist Cable.
See *Accessories* section.

User / Patient Safety



WARNINGS:

- Prior to operation, users of Enova LED Surgical Headlight Systems should read and understand the operation manual for all equipment used in conjunction with the LED surgical headlight. Contact your local distributor for service and warranty information.
- DO NOT look directly into the LED surgical headlight when illuminated. DO NOT shine the light directly into the patient eyes or face. Due to the intensity of light, eye injury may result. Patient's eyes should be appropriately protected in surgeries involving the face or head.
- After a few minutes of operation, the headlamp housing may become warm to the touch. This is normal and functions to dissipate heat from the LED. Always use a surgical glove, or sterile cloth to adjust the angle of the lens when in use.
- Use only Enova's SUPPLIED BASE STATION AND POWER PACKS. The use of other base stations or power packs may result in fire, explosion, or damage to the power packs or LED surgical headlight and will void warranty. The power pack must be powered off when charging. DO NOT USE OR STORE BASE STATION IN OPERATING ROOM OR SURGERY SUITE.
- All Enova's LED surgical headlights are designed to be wireless. DO NOT USE THE LED SURGICAL HEADLIGHT WHILE POWER PACKS ARE CHARGING.
- DO NOT use the LED surgical headlight, power packs or base station in explosive gas environments.
- DO NOT autoclave, immerse or submerge in liquid, spray with liquids or leave the LED surgical headlight "on" when inside the composite carrying case as it will cause damage to the LED surgical headlight or may cause a fire.
- Please consult local regulations for the disposal of electronic products.
- DO NOT INTERCHANGE TWIST CABLES. Use specified twist cable for correct LED surgical headlight otherwise, the LED surgical headlight will function abnormally and may damage the circuitry causing the light to fail.

NOTE: The expected service life of the headlight is 5 years.

Accessories

This section describes components that may be ordered to replace original equipment that is damaged, worn, or must be replaced.



WARNINGS:

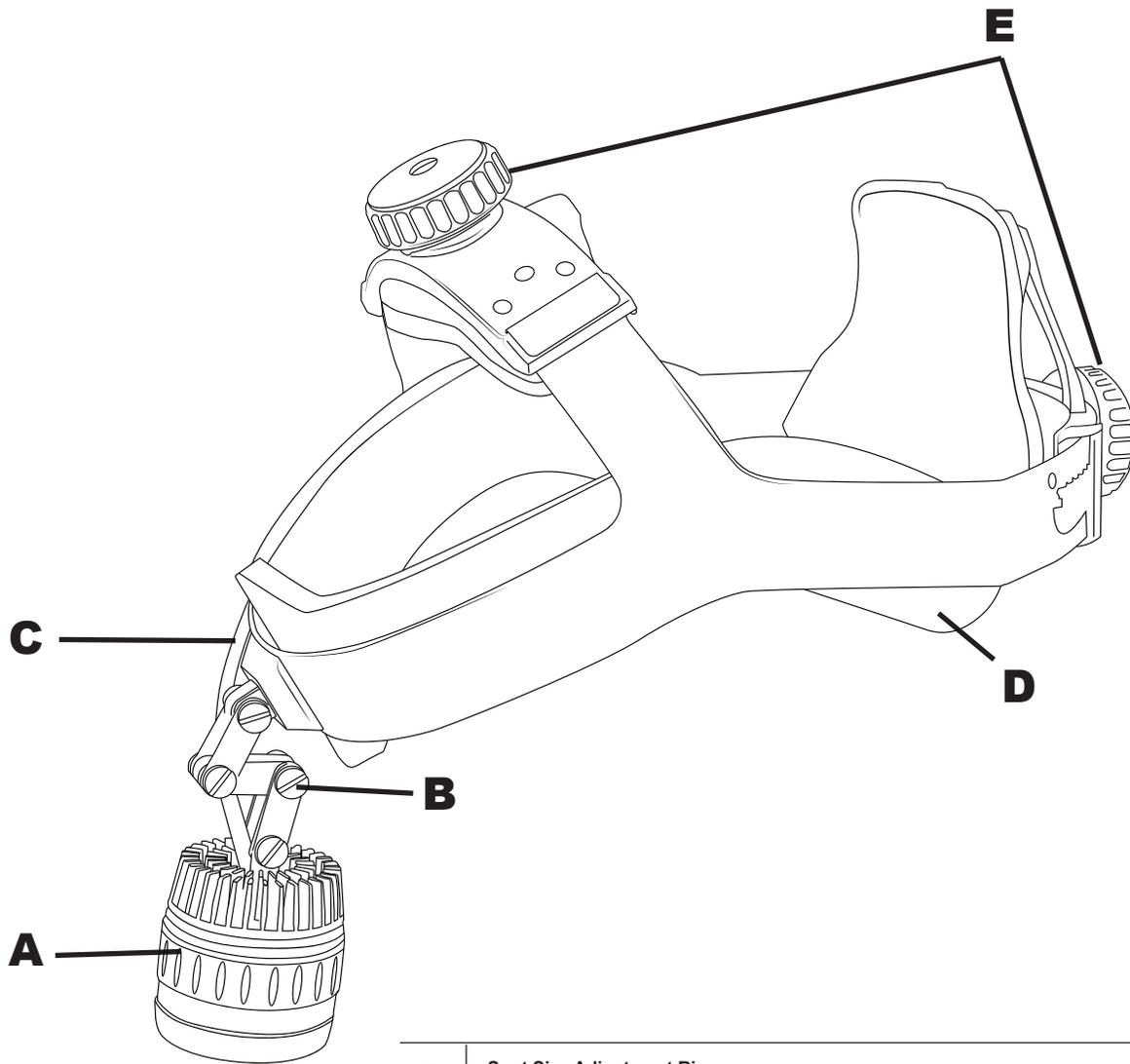
- Use only Enova-approved components and accessories, including power packs, unless otherwise specified.
- DO NOT modify any component or accessory, unless otherwise specified.

The following Enova-approved accessories are sold separately:

DESCRIPTION	REF
PP4 Power Pack	80201-001
PP4 Power Pack Charging Base Station	80100-001
NA C-13 Power Cord	80150-001
Gray Twist Cable	80302-001
Battery Belt	80500-001
Deluxe Comfort Pad Set	80403-001
Composite Carrying Case	80034-001

NOTE: For a complete list of accessories, contact your Enova's sales representative or call Enova's customer service.

Features



A	Spot Size Adjustment Ring: This ring is used to make the spot size smaller (2") and bigger (5").
B	Headlight Adjustment Bracket: This bracket is used to adjust the light beam to fit coaxially to the line of sight.
C	Quantum Twist Cable: This cable routes light from the power pack to the LED surgical headlight.
D	Comfort Pads: These removable pads provide a comfortable fit.
E	Headband Adjustment Knobs: Customize the fit by turning the knob clockwise to tighten and counterclockwise to loosen the headband.

Instructions



WARNINGS:

- Perform recommended inspection and testing as indicated in the Inspection and Testing section.
- ALWAYS operate the equipment within the specified environmental condition values. See the Specifications section.
- This equipment is suitable to use in a professional healthcare facility environment.
- DO NOT cut or puncture the twist cable.
- ALWAYS turn the light source power off before connecting or disconnecting the twist cable to or from the LED surgical headlight.
- ALWAYS hold the strain relief near the end of the twist cable when connecting or disconnecting the twist cable from the light source.

CAUTIONS:

- DO NOT scratch the LED surgical headlight lens.
- DO NOT stretch or kink the twist cable. Failure to comply will damage the twist cable and reduce the light output permanently.

NOTE: Headband position will vary from person to person depending on head size and personal comfort preferences.

Inspection and Testing



WARNINGS:

- Only individuals trained and experienced in the maintenance of reusable medical devices should inspect and test this equipment.
- DO NOT use any equipment if damage is apparent or the inspection criteria are not met.
- DO NOT disassemble or service this equipment, unless otherwise specified.

NOTE: For service, contact your Enova's sales representative or call Enova's customer service.

INTERVAL	INSPECTION CRITERIA	ACTION
Before Use	Inspect equipment for damage, wear, or missing components.	If damage is apparent, replace the equipment.
	Inspect power cord and twist cable for cuts or punctures.	
	Inspect headlight lens for scratches.	
	Inspect the power pack housing for cracks.	

NOTE: If any component must be discarded, see the *Disposal / Recycle* section.

To Don a LED Surgical Headlight

DO NOT connect the twist cable to the power pack before donning the LED surgical headlight.

1. Connect the LED surgical headlight power cable to the appropriate twist cable (figure 2). See the Accessories section.

NOTE: To disconnect the power cable, twist the connector sleeve back before separating the connector plug and receptacle (figure 2).

2. Loosen the headband adjustment knob on the top and back of the LED surgical headlight (figure 3).

3. Put the LED surgical headlight on your head and turn the headband knob on the top and back to secure the LED surgical headlight (figure 4). When using loupes, put them on after this step.

NOTE: Make sure the LED surgical headlight fits securely on top of your head and that the light is coaxial to your line of sight (figure 5).

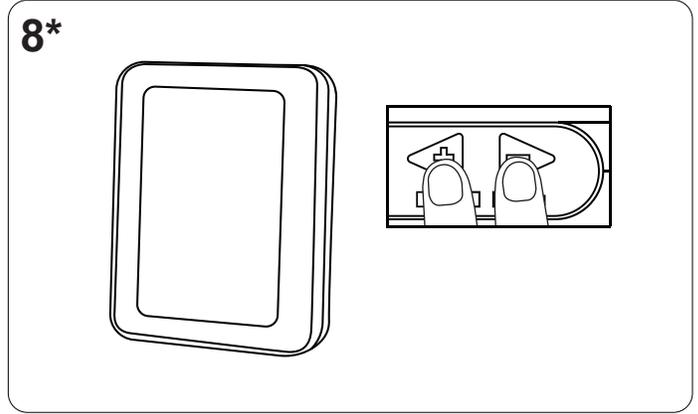
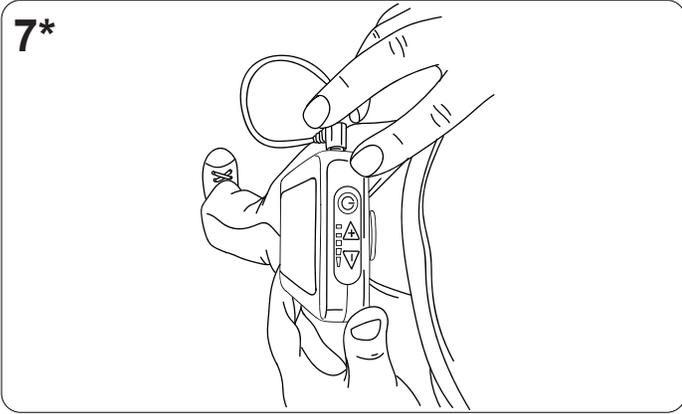
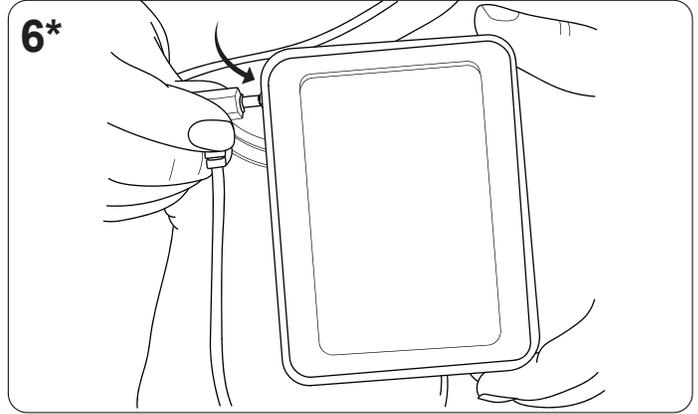
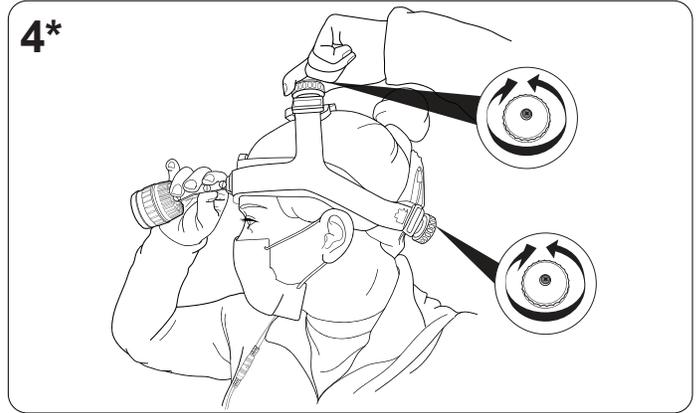
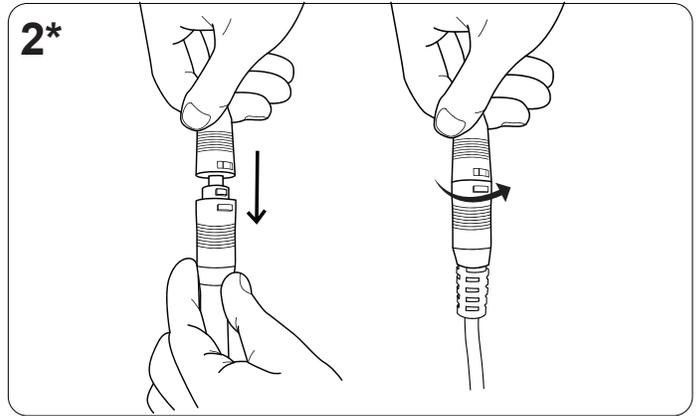
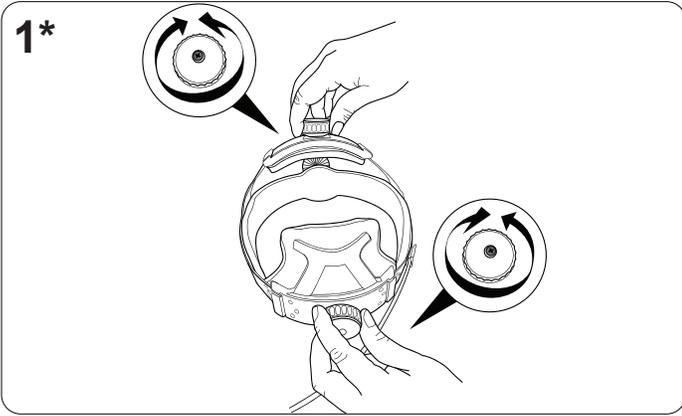
To Use a LED Surgical Headlight

1. Plug the twist cable connector into the jack on the power pack (figure 6).
2. Press the power button on top of the power pack (figure 7).
3. Press the variable control buttons ("+" and "-") to adjust the light intensity. See the *Troubleshooting* section if required (figure 8).

To Doff a LED Surgical Headlight

1. Turn the power pack off.
2. Loosen the headband knobs on the top and back of the LED surgical headlight and remove the LED surgical headlight from your head.
3. Clean the LED surgical headlight and cord. See the *Cleaning* section. To clean the PP4 Power Pack, see the instructions for use supplied with the PP4 Charging Base Station.

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*** NOTE:** It is recommended the operator wears gloves while performing these steps.

Cleaning



WARNINGS:

CAUTION: DO NOT use solvents, lubricants, or other chemicals, unless otherwise specified.

To Clean the Surgical Headlight

1. Exterior surfaces of LED surgical headlight, headband, and comfort pads can be cleaned using a gauze pad or cotton swab moistened with 70% isopropyl alcohol or mild soap. After cleaning, wipe the area with a lint-free cloth moistened with water to remove any residue from cleaning products.

DO NOT immerse or spray the LED surgical headlight, power pack or base

2. station with disinfecting liquids or sterilizers, nor should any liquids be poured on the lens, lens housing or cable connections. Make sure no liquid comes in contact with the LED surgical headlight, electrical connectors, base station or power packs.

To ensure a long life of the LED surgical headlight, power packs, and base

3. station, Enova recommends storing them in the Carrying Case

For proper hygiene, it is recommended to replace the comfort pads every 3-6 months. Users may order additional comfort pads from Enova or your local

4. distributor.

Lens - Avoid scratching or striking the front lens as a reduction in light transmission may occur.

- 5.

Storage and Handling

CAUTION: ALWAYS store the equipment within the specified environmental condition values throughout its useful life. See the *Specifications* section.

To ensure the longevity, performance and safety of this equipment, use of the original packaging material is recommended when storing or transporting this equipment.

Disposal / Recycle



WARNINGS: ALWAYS follow the current local recommendations and/or regulations governing environmental protection and risks associated with recycling or disposing of the equipment at the end of its useful life.

Troubleshooting



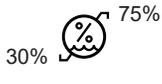
WARNINGS: DO NOT service this equipment, unless otherwise specified. If you require service, contact your Enova's sales representative or call Enova's customer service.

PROBLEM	CAUSE	ACTION
The LED surgical headlight is flickering	Twist cable may be damaged.	Try another twist cable. If it works, then replace the other twist cable.
	Cable attached to LED surgical headlight is damaged.	If the other twist cable does not work. Send the LED surgical headlight in for repair.
	The LED surgical headlight is damaged	Replace the LED surgical headlight.
The LED surgical headlight does not turn on.	The power pack is not charged.	Replace the power pack with a fully charged one. Put the power pack on the base station.
	The twist cable is damaged.	If the other power pack does not work, try another twist cable. If it works, then replace the twist cable.
	The LED surgical headlight is damaged.	Replace the LED surgical headlight.
The LED surgical headlight is shorting out.	The twist cable is damaged.	Try another twist cable. If it works, then replace the other twist cable.
	The LED surgical headlight is damaged.	Replace the LED surgical headlight.

NOTE: If any component must be discarded, see the *Disposal/Recycle* section.

Specifications

Model:	Quantum Cool XLT-250A	Quantum Warm PLT-175A
Description:	Quantum Cool LED Surgical Headlight	Quantum Warm LED Surgical Headlight
Lamp Illumination:	250,000 - 500,000 Lux	175,000 - 480,000 Lux
Color Temperature:	6100K	4500K
Light Source:	LED Refractive Technology	
Illumination Spot Size:	2" to 5" adjustable (5.08 cm to 12.7 cm)	
Headlight Weight:	12 oz (340 g)	
Headlight Construction:	Aluminum	

Environmental Conditions:	Operation	Storage and Transportation
Temperature Limitation:	 10°C 30°C	 5°C 50°C
Humidity Limitation:	 30% 75%	 10% 75%
Atmospheric Pressure Limitation:	 70 kPa 106 kPa	 50 kPa 106 kPa

Symbol Definition

Symbol	Definition (Indication Color)
	General Warning Sign (Yellow)
	Refer to Instruction Manual / Booklet (Blue)
	Catalog number
QTY	Quantity
	Lot number
	Storage: Temperature Limitation
	Transportation: Temperature Limitation
	Operation: Temperature Limitation
	Storage, Transportation, and Operation: Humidity Limitation
	Storage, Transportation, and Operation: Atmospheric Pressure Limitation
	Medical Device
	Recycle (in Accordance with Local Laws) of Li-Ion Battery
	Power On/Off
	Light Intensity Adjustment and Indicator

