



Axis™ Elite

LED Light System

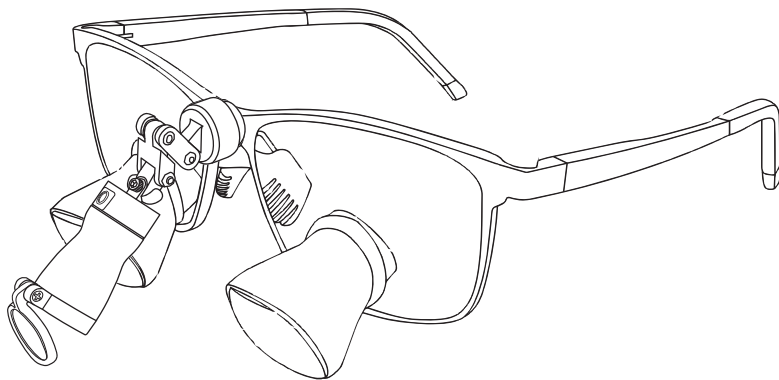
Activ Elite Neck Battery Package

PP1.5 Elite Hip Battery Package

Hybrid Package



Instructions For Use



Note: The image shown above is for illustration purposes only. Actual product may vary depending on model purchased.

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 injury to patient, user, medical personnel, and/or other persons and animals.
- 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 sales representative or Enova Customer Care Team at support@goenova.com

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Indications for Use

Axis Elite light is a loupe light system designed to provide illumination during dental or minor surgical procedures. Axis Elite light is part of the Enova Illumination product family.

Contraindications

None known.

Limitations of Use

None known.

For Use With

Approved batteries, charging cables, Axis Elite battery cables and Enova loupes.
See [Accessories] section.

Safety & Care Instructions



WARNING:

- Please read the instruction manual carefully before using your Enova light. Damages due to disregard of the instructions within this manual are not covered under the warranty policy of Enova Illumination.

- Do not look directly into the light when illuminated. Do not shine the light directly into the patient's eyes or face. Due to the intensity of light, eye injury may result. Patient's eyes should be appropriately protected in procedures involving the face or head.
- After a few minutes of operation, the light housing may become warm to the touch. This is normal and functions to dissipate heat from the LED chip. Always use a surgical glove or sterile cloth to adjust the angle of the lens when in use.
- Do not use the light while batteries are charging.
- Do not use any third-party chargers with Activ Elite neck battery or PP1.5 Elite hip battery, even if they look identical. Third-party chargers are not compatible with the batteries and could damage them.
- Avoid direct sunlight or heated surfaces to prevent batteries from overheating.
- Do not use close to explosive or highly flammable materials like alcohol, methanol, acetone, etc.
- Avoid shock to product by keeping product in approved composite carrying case when not in use.
- Do not use the light, batteries or charging cables in explosive gas environments.
- Do not autoclave, immerse or submerge in liquid, spray with liquids or leave the light "on" when transporting as it will cause damage to the light or may cause a fire.
- Please consult local regulations for the disposal of electronic products.

Accessories

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



WARNING:

- Use only Enova-approved components and accessories, including batteries, unless otherwise specified.
- Do not modify any component or accessory, unless otherwise specified.

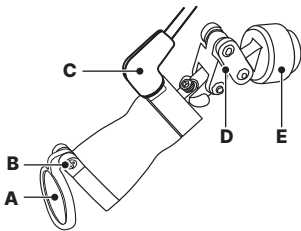
The following Enova approved accessories can be sold in conjunction with the Axis Elite LED Light System.

DESCRIPTION	REF
PP1.5 Elite (Hip) Battery	80206-001
Activ Elite (Neck) Battery	80207-XXX
PP Mobile Battery Charger	80102-001
Axis Elite Light Cable	800071-001
Axis Extension Battery Cable	80304-004
Enova Light Case (Hip/Hybrid package)	80034-006
Enova Light Case (Neck package)	80034-008

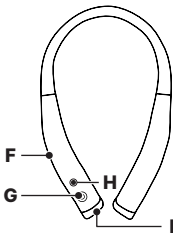
Note: For a complete list of accessories, contact sales representative or Enova Customer Care Team at support@goenova.com

Features

Axis Elite LED Light



Activ Elite Neck Battery



PP1.5 Elite Hip Battery



- A. Optional HD Glass Composite Filter:**
Removes the light wavelength that speeds up the curing of composite materials.
- B. Filter Screw**
Tightening screw for optional filter.
- C. Axis Elite Light Cable:**
Connects the light source to the battery connection.
- D. Light Adjustment Bracket:**
This bracket is used to adjust the light beam to fit coaxially to the line of sight.
- E. Magnetic Loupe Adapter:**
This adapter attaches the light to the frames or loupes with pivot arm for custom alignment.
- F. Output Port for Axis Elite Light Cable:**
Connection port to attach light source cable.

- G. Power/Brightness Button (Activ Elite):**
Touch capacitive turn light On/Off and adjust brightness.
- H. Indicator Light (Activ Elite):**
Indicate charging status and in use.
(Green - Fully charged, Red - Charging)
- I. Charging Port (Activ Elite):**
Port to connect mobile charging cable.
- J. Power Button (PP1.5 Elite):**
Turn light On/Off.
- K. Variable Control Buttons (PP1.5 Elite):**
Adjust three brightness levels.
- L. Output Port for Extension Battery Cable:**
Connection port to attach light source cable.
- M. Charging Port (PP1.5 Elite):**
Port to connect mobile charging cable.

Instructions

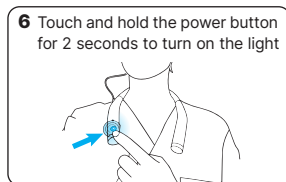
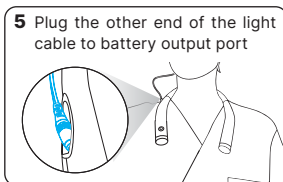
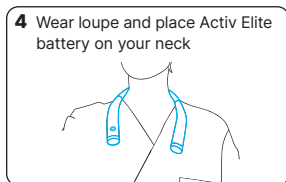
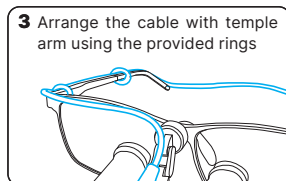
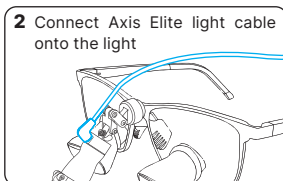
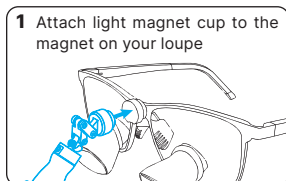


WARNING: Perform recommended inspection and testing as indicated in the [Prior To Use] section.

- Always operate the equipment within the specified environmental conditions.
- Do not cut or puncture the cables.
- Always remove cable from battery after each use.

- CAUTIONS:**
- Do not scratch the light lens.
 - Do not stretch or kink the cables. Failure to comply will damage the cable and reduce the light output permanently.

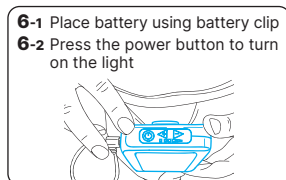
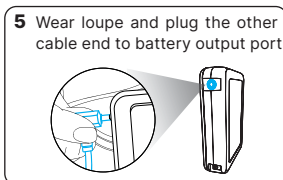
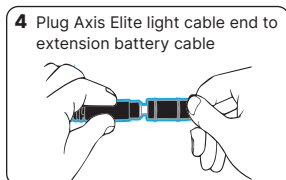
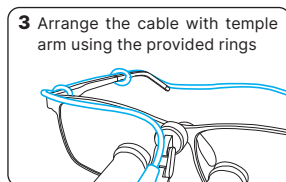
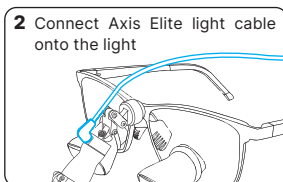
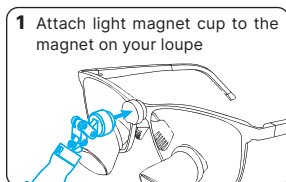
Instructions with Activ Elite Neck Battery:



Instructions with PP1.5 Elite Hip Battery:



WARNING: Do not plug Axis Elite light cable directly to PP1.5 Elite battery. It can cause burning. Always connect Axis Elite light cable with extension battery cable to source power to the light.



Charging Battery:

1. Turn off the light and remove from battery. Detach all cables from their ports.
2. Plug mobile charger into outlet with appropriate electrical voltage. Refer to specification label or charger.
3. Connect mobile charger to battery's charging port.

To Connect Axis Elite Light to Loupes



WARNING: Do not over-loosen filter. Small internal components may be lost.

Connect to Enova Loupes:

1. Ensure that loupe has a magnetic secured to frame with notch of magnet pointing down.
2. Connect Axis Elite light cable onto the light and ensure the light cable is at the top and gently secure the magnetic loupe adapter to magnet on brim of the loupe frame. Do not pull tight as it may cause damage to the cord connection.
3. Adjust angle of the light source to be coaxial with eyes and illuminate the entire field of view through the loupe telescopes.
4. Secure the cable to the fasteners on the temple arm of the frame.
5. If necessary, tighten hinge on filter using provided screwdriver. Be gentle as the components are very small. Tighten as you would normally a screw until filter moves up and down at your desired resistance.

Connect to non-Enova Loupes using Universal Clip (sold separately):

1. Clip securely to frame by pinching and then releasing the clip.
2. Each frame is different and you may need to adjust a few times to find the right fit.
3. Follow steps above ("Connect to Enova Loupes") to connect the light to the magnet on the adapter.

Note: The attach the light on a non-Enova loupe, please contact sales representative for an approved adapter or universal clip. Adapters and universal clips are sold separately.

Battery Information

Axis Elite light is compatible with two Enova manufactured batteries and offers various levels of light intensity. Activ Elite battery is a neck-worn, capacitive touch battery designed to be easily activated and adjusted through gowns and without removing gloves. PP1.5 Elite is a standard hip battery.

The battery will not be fully charged when it arrives. Batteries will be shipped at less than or equal to 30% charge in accordance with the International Air Transport Association. It is highly recommended to charge the battery fully before use. The LED indicator shows status of charge.

Activ Elite Neck Battery:

As battery life decreases, the LED will go through the following sequence:

1. The LED flashes red while charging.
2. The LED turns solid green when fully charged.
3. The LED is solid green when powered on.
4. The LED light flashes red and the light flashes when the battery has approximately 5 minutes of power remaining.

PP1.5 Elite Hip Battery:

As battery life decreases, the LED will go through the following sequence:

1. The green LED lights decrease from 5 to 1 and then increase as flashing red LED lights from 1 to 5 as the power is depleted. The battery sounds a beep when each LED turns red.
2. With 5 flashing red LED lights, the battery has about 5 minutes of power left.
3. When charging, the LED lights will flash green and increase from 1 to 5 lights.
4. When fully charged, the middle LED light will be solid green.

To Use Axis Elite Light

With Activ Elite Neck Battery:

1. Plug Axis Elite light cable to the light and connect the light cable to the Activ Elite battery output port.
2. Turn the light on by touching and holding the power button for 2 seconds.
3. Adjust brightness level by touching the same power button. (3 brightness levels)
4. Adjust angle of the light so light beam is visible through loupes or frame and coaxial to line of sight.
5. Turn the light off by touching and holding the power button until the light turns off.

With PP1.5 Elite Hip Battery:

1. Plug Axis Elite light cable to the light and connect the light cable to the extension battery cable.
2. Connect the extension battery cable to the PP1.5 Elite battery output port.
3. Turn the light on by pressing the power button.
4. Press the “+” and/or “-” buttons on the battery to adjust the light intensity.
5. Turn the light off by pressing the power button.

Note: The +/- buttons can be used to increase or decrease the intensity of the light, but the LED lights on the battery do not reflect the current output/light intensity.

To Disconnect Axis Elite Light

1. Turn off the light and disconnect from power source.
2. The light is held in place by a strong magnetic connection. Grip the frame and body of the light firmly and pull apart with enough force to detach the light from the magnetic loupe adapter.
3. Clean after each use. See [Cleaning] section.

Note: The strong magnetic connection ensures light will remain in place and will not fall off during procedures or exams.

Prior To Use



WARNING:

- Only individuals trained and experienced in the maintenance of medical devices should inspect this equipment.
- Do not use any equipment if damage is apparent or the inspection criteria are not met.

Interval	Inspection Criteria	Action
Before each use	Inspect equipment for damage, wear, or missing components.	If damage is apparent, replace the equipment.
	Inspect cables. Twist cable for cuts, punctures, or kinks.	
	Inspect light lens for scratches.	
	Inspect batteries housing for cracks.	

Note: For service, contact sales representative or Enova Customer Care Team at support@goenova.com

Note: If any component must be discarded, see [Disposal/Recycle] section.

Cleaning

CAUTIONS: Do not use solvents, lubricants, or other chemicals, unless otherwise specified.

To clean the light:

1. Exterior surfaces of the light can be cleaned using a gauze pad or cotton swab moistened with 70% isopropyl alcohol. After cleaning, wipe the area with a lint-free soft cloth moistened with water to remove any residue.
2. Do not immerse or spray the light, batteries or charging cables with any liquids. Make sure no liquid comes in contact with the light, electrical connectors, charging cables or batteries.
3. To ensure a long life of the light, batteries and charging cables, Enova recommends storing them in the supplied case when not in use.

Storage and Handling

CAUTIONS: Always store the equipment within the specified environmental conditions throughout its useful life. To ensure the longevity, performance and safety of this equipment, use of the case supplied by Enova or water tight packaging is recommended when storing or transporting this equipment.

Disposal / Recycle



WARNING:

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

Specifications

Model Name	Axis Elite LED Light System
Part Number	90901-XXX
Lamp Illumination	42,000 Lux @ 10"
Color Temperature	5,700K
Light Spot Size	3.25" @ 12"
Light Source	High Performance LED
Housing Material	Plastic
Weight	7.8g / 0.28oz (w/o filter)

Symbol Definition

Symbol	Definition (Indication Color)
	General Warning Sign (Yellow) BS EN ISO 7010 Ref. W001
	Catalog Number BS EN ISO 15223-1 Ref 5.1.6
	Quantity
	Batch Code BS EN ISO 15223-1 Ref 5.1.5
	Recycle: Electronic Equipment
	Light Intensity

Symbol	Definition (Indication Color)
	Authorized Representative in the EU Community BS EN ISO 15223-1 Ref 5.1.2
	Manufacturer BS EN ISO 15223-1 Ref 5.1.1
	Medical Device BS EN ISO 15223-1 Ref 5.7.7
	CE Mark indicating that the device complies with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
	This product complies with relevant UK legislation and safety standards and has met the requirements for sale in Great Britain

Troubleshooting

Issue	Troubleshooting
The light does not work steadily due to discharged battery.	Replace battery. Charge the discharged battery.
Battery does not function.	Discontinue use and contact sales representative or Enova Customer Care Team at support@goenova.com
LED failure.	
Battery overheats or produces fire during charge.	
Battery leakage.	
Battery swelling.	

Warranty

Your Enova product is backed by an industry-leading warranty.
To review your product warranty, visit: www.goenova.com/product-support

Keep this warranty in your records.

ORDER No.			
	Model	Serial Number	Year of Manufacture
LOUPE	Axis Elite Light		
OTHER			

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