INSTRUCTIONS FOR USE

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE

INDICATIONS FOR USE

The Alite™ Device is indicated to interface with a compatible commercially available needle to illuminate the subcutaneous space as a visual aid in the delivery of solutions through the needle.

DEVICE DESCRIPTION

Alite™ is a single-use disposable fiber-optic surgical lamp intended to provide visible illumination of the patient's subcutaneous space as a visual aid in the delivery of solutions. Alite™ is only compatible with the 3.5-inch, 18 gauge needles specified in Table 1 (purchased separately). The device consists of a Handle that houses the light delivery system and fluid pathway, the Light Fiber, male and female luer connectors, and a Pull Tab.

Figure 1 - The Alite™ Device

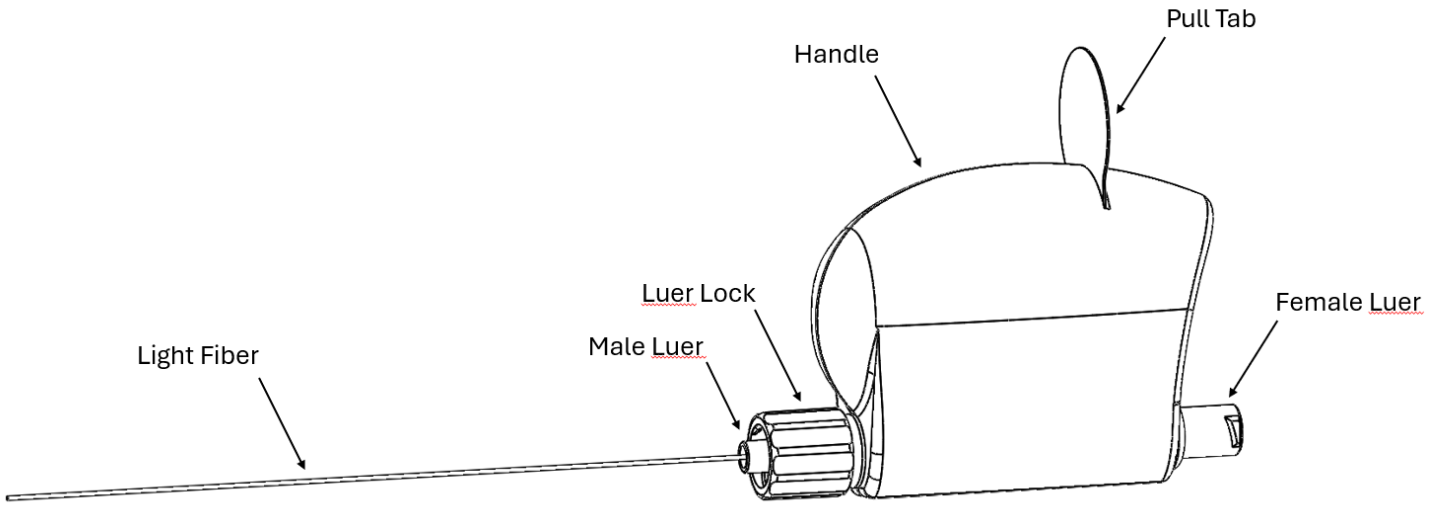


Table 1: COMPATIBLE NEEDLES

Supplier	Part Number
Myco Medical	RELI® SN18G351
McKesson	4628V2

CONTRAINDICATIONS

Alite™ is not intended to be used with any needle other than needles specified in Table 1.

WARNINGS

- Failure to carefully follow all applicable instructions may result in injury to the patient, user, or attendants and may have an adverse effect on procedural outcomes.
- Alite™ is for single use only. Do NOT re-use or re-sterilize. Re-sterilization of the device or components may result in a risk of device malfunction and/or contamination due to residual fluids/tissue in the device.
- Prior to use, inspect device and packaging for damage or breach of sterile packaging seals. Do NOT use product if there is any evidence of damage or breach.
- No modification of Alite™ is permitted.

PRECAUTIONS

- Federal law restricts this device to sale by or on the order of a physician or other licensed practitioner.
- Alite™ is intended for use by medical professionals.
- Prior to using the device, the user must thoroughly read and understand the Instructions for Use.
- Inspect device prior to use for damage. If damage is found, set device aside and use another.
- Do not drop Alite™. If dropped it should be inspected for damage and its function checked. If dropped and any part of the device leaves the sterile field, the device should be considered non-sterile and removed from use.
- The Handle contains electrical components. Do NOT expose the Handle directly to fluids.

ADDITIONAL WARNINGS AND PRECAUTIONS

Additional warnings and precautions are provided within the **Instructions for Use** section for specific procedural steps.

RISKS

Potential adverse events related to the Alite™ device or procedures for delivering solutions, such as anesthesia, include the following:

- Abnormal or burning sensation
- Bleeding
- Ecchymosis / bruising
- Fainting
- Fluid collection
- Fluid discharge
- Hyper/hypo pigmentation
- Infection
- Inflammation / swelling
- Irritation, itch
- Laceration
- Pain / Stinging / Tenderness / Discomfort
- Scar
- Skin discoloration
- Toxic, allergic, or other reaction from the anesthetic

PROCEDURE OVERVIEW

Alite™ is a sterile, single-use device that provides visible illumination of a patient's subcutaneous space as a visual aid in estimating needle tip position and depth in the delivery of solutions through a compatible needle. The user threads the Light Fiber into a compatible needle and connects the needle to the Male Luer using the Luer Lock. The Female Luer is connected to the source of solution, such as an infusion pump or syringe. The user removes the Pull Tab to illuminate the Light Fiber. The compatible needle is used to puncture the skin and is advanced into subcutaneous tissue to a procedure location. The end of the Light Fiber is situated at the tip of the needle and provides illumination allowing the user to track and advance the needle tip to the procedure location. The user advances and retracts the device in the subcutaneous space using the Handle and delivers solution to the treatment area by controlling the output from the source of solution.

PACKAGING

Alite™ is provided sterile and has a limited shelf life. The device must be used on or before the "Use by Date" provided on the package.

INSTRUCTIONS FOR USE

Device Set Up

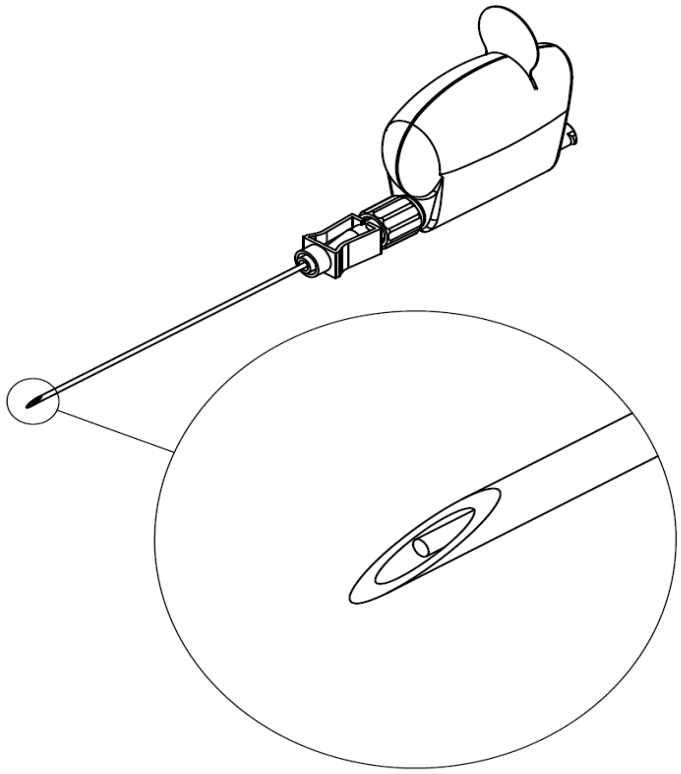
Connect the Female Luer at the proximal end of the device to the solution source, such as an infusion pump or syringe. Ensure the connection is fully tightened and secure.

Thread the Light Fiber into a compatible needle and connect the needle to the Male Luer at the distal end of the device but do not tighten the Luer Lock. Orient the needle so that the bevel is facing upward (as shown) and twist the luer lock to secure the needle in this orientation. Be sure the connection is fully tightened and secure.

Activate the light by removing the Pull Tab. Confirm the Light Fiber is illuminating from the tip of the needle.

If during use the illumination dims or turns off, remove device safely and complete procedure with a new device.

CAUTION: DO NOT stare directly at the Light after the Pull Tab has been removed.



Device Use

With the device illuminated, puncture the skin with the needle and advance it through the subcutaneous space in the procedure area with the light facing up. Using the light, track the device as it advances through the treatment area. The light size and brightness can aid in ensuring the tip is at the appropriate depth.

Deliver solution to the treatment area by controlling the output of the source of solution while advancing the device through the subcutaneous space.

CAUTION: DO NOT use excessive force to advance device.

CAUTION: DO NOT press on patient's skin near the light to avoid laceration.

Once solution is delivered throughout the entire treatment area, withdraw the device from the subcutaneous space.

CAUTION: DO NOT withdraw the device before stopping the flow of solution from the source.

DEVICE DISPOSAL

Dispose of device according to Federal, state, and local regulations, and appropriate environmental health safety guidelines. Device contains lithium battery. Do NOT incinerate except for disposal in a controlled incinerator.

Graphic Symbols Contained on Device Labeling

	Consult Instructions for Use
	Lot Number
	Model Number
	Sterilization with Ethylene Oxide Single Sterile Barrier System with Protective Packaging Inside
	Do Not Reuse
	Manufacturer
	Manufacture Date
	Use By
	Type BF Applied Parts
	Temperature Range
	Humidity Symbol
	Do Not Use if Package is Damaged and Consult Instructions for Use
	Unique Device Identifier
	Do Not Re-Sterilize

SPECIFICATIONS

Model Number	AVE003
Weight	29 Grams
Light Source	620 - 630 nm
Activation Time	60 Minutes
Battery Type	Lithium Manganese Dioxide, CR2, 3V
Power Source	Internally Powered
LED Output	65000 mcd, typ.
Mode of Operation	Continuous
Operating Temperature Range	15° to 31° C (59° to 88° F)
Operating Humidity Range	30%-75% RH Non-Condensing
Transport Temperature Range	-30° to 60° C (-22° to 140° F)
Storage Temperature	0° to 40° C (32° to 104° F)
Storage and Transport Humidity Range	15% to 90% RH Non-Condensing
Altitude (Operating)	<3000 m (9800 ft.)
Complies with medical safety standards	AAMI/IEC 60601-1, IEC60601-1-6/62366

ELECTROMAGNETIC COMPATIBILITY (EMC)

Alite™ complies with the requirements of IEC 60601-1-2:2020. The system was tested to the following standards.

Emissions (Class A, Group 1)	CISPR 11: 2015 (Radiated Emissions)
Immunity	IEC 61000-4-2:2008 – ESD
	IEC 61000-4-3:2006 +A1+A2 – Radiated
	IEC 61000-4-8: 2009 – Magnetic

The limits are designed to provide reasonable protection against harmful interference in a typical hospital/medical installation. This equipment generates, uses, and can radiate radio frequency energy, and if not used in accordance with the manufacturer's instructions may cause harmful interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular circumstance.

To maintain proper functioning of Alite™ as it pertains to EMC, all the instructions in this manual should be followed throughout the useful life of the product.

Interference from electronic sources may result in loss of illumination.

The operator should be aware of the following; however, they do not pose hazards to the patient or operator.

If this equipment causes interference with other devices or if other equipment is causing interference with this equipment, which may be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the device receiving the interference.
- Increase the separation between the equipment (minimum 30cm is recommended)
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Replace un-shielded cables with shielded ones.
- Consult the manufacturer or field service technician for help.

alite™
light-guided injection

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