

# SURGICAL ILLUMINATOR

Manufactured by Lumitex Medical Devices, Inc.

## Information for Use

For the SURGICAL ILLUMINATOR manufactured by Lumitex Medical Devices, Inc (Lumitex MD™).

## Description

The SURGICAL ILLUMINATOR is a sterile, single use, not made with natural rubber latex, plastic fiber optic device intended to bring cool area lighting into deep surgical sites. The SURGICAL ILLUMINATOR is intended for use with a 300-watt xenon light source, in conjunction with a Fiber Optic Cable with a standard diameter female ACMI connector. For best results use a Fiber Optic Cable by Lumitex MD™.

## Indications for Use

The SURGICAL ILLUMINATOR is intended for the illumination of surgical procedures, particularly where deep cavities or adjacent tissues limit outside light in the surgical field.

## Contraindications

The SURGICAL ILLUMINATOR is not intended for use in intracranial surgery or direct contact with the central nervous system or central circulatory system.

## Warnings

1) **Light Sources & Cables:** The SURGICAL ILLUMINATOR is designed for use with 300-watt xenon light source and the recommended Fiber Optic Cables by Lumitex MD™.

Do not use light sources rated higher than 300 watts. Refer to product labeling for the recommended cable fiber optic bundle diameter. Use of higher watt sources or larger diameter cables could result in overheating; causing product failure and patient injury.

If at any time the SURGICAL ILLUMINATOR dims significantly on its own (without adjusting the light source), turn off the light source immediately, replace the SURGICAL ILLUMINATOR, and use with the light source adjusted to a lower output setting.

2) **Cable Connector & Heat:** As is common with fiber optic equipment, high wattage light sources can generate heat at fiber optic cable connectors, which must be managed by surgical OR staff. Additionally, lamps emit elevated levels of visible light and infrared (heat) during early hours of life (e.g., the first 30 hours of use or after lamp replacement). It is recommended to monitor connector temperature periodically (e.g., every 15 minutes during the first hour) during first time use with a new light source or lamp. If the connector is too hot to hold comfortably, reduce the light source output and continue to monitor the connector temperature.

Never place the connector directly on the patient's skin at any time.

3) **Light Source Variation & Heat:** Light sources vary widely in emission of visible and infrared (heat) energy. The SURGICAL ILLUMINATOR is recommended for use with the Luxtec 9300 and the SunOptics SolarMax 300. Non-recommended light sources (e.g., Welch Allyn, BFW, Stryker, Isolux) can produce increased heating at the connector, requiring OR staff to pay close attention to connector temperature. These light sources should only be used if connector temperature is actively monitored.

4) **Embedding:** Because light energy can be absorbed as heat, the entire lit portion (distal end) of the SURGICAL ILLUMINATOR should not be continuously embedded (i.e. lit surface should not be completely buried) in tissue and held fixed for more than 30 seconds at a time.

5) **Cuts:** Should the SURGICAL ILLUMINATOR become cut, collect fluid inside, appear broken or damaged in any manner, it should be replaced to minimize risk to the patient.

6) **Bare Cables:** Do not operate the light source and cable without the SURGICAL ILLUMINATOR attached. This may cause burns, ignite drapes/gowns, or temporarily blind vision.

7) **Single Use Device:** The SURGICAL ILLUMINATOR is a single use device and cannot be safely reused, regardless of sterilization methods, without significant risk to the health and well-being of the subsequent patient.

After use, this product may be a potential biohazard. Handle and dispose of via incineration by a licensed facility, or other recommended disposal method in accordance with accepted hospital practice and applicable local, state and federal laws and regulations.

8) **Sterilization:** Product is sterilized using Ethylene Oxide (EO). Sterile unless package is opened or damaged. Do not use if package is open or damaged.

If you have questions regarding these warnings, please contact Lumitex MD™.

## Caution

Physicians should consider patient photosensitivity when using any light source.

## Contents

Each SURGICAL ILLUMINATOR package contains one SURGICAL ILLUMINATOR assembly, one Sterilization Indicator strip, optional adhesive strip(s), and may include one or more optical tip covers. Prior to closing the surgical site, all components must be accounted for.

## Directions for Use

The SURGICAL ILLUMINATOR connects to a light source used for head lamps or endoscopes. A fiber optic cable attaches the light source and SURGICAL ILLUMINATOR. Make sure the SURGICAL ILLUMINATOR connector is securely attached to the cable. The cable should be in good repair with clean optics. Dirty optics or cables in need of repair can cause excessive heat at the connectors.

Turning down overhead lighting may improve visualization within the surgical site.

Body fluids or debris collecting on the surface of the SURGICAL ILLUMINATOR may be irrigated or wiped away.

## Notice

Any serious incident that has occurred in relation to the SURGICAL ILLUMINATOR should be reported to the manufacturer and the competent authority of the Member State in which the user/patient is established.

## Limited Warranty

Lumitex warrants the material conformity of the SURGICAL ILLUMINATOR to specifications on the product labeling until the earlier of 12 months from shipment to customer or the expiration date of the product and will repair or replace at Lumitex option and expense any Lumitex product that does not meet specifications in all material respects. LUMITEX LIABILITY TO CUSTOMER, USER, OR PATIENT IS EXPRESSLY LIMITED TO REPAIR OR REPLACEMENT. Lumitex expressly disclaims all other warranties, expressed or implied, including, without limitation, merchantability or fitness for a particular purpose. Please direct any inquires to Lumitex MD™.

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NOT MADE WITH NATURAL RUBBER LATEX

A symbols glossary is provided electronically at:  
<https://www.lumitex.com/packaging-symbols-explained>



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