Information for Use
For the Aesculap Surgical Illuminator (PN: ME423SU)

Description
The Aesculap Surgical Illuminator is a sterile, single use, latex free, plastic fiber optic device intended to bring cool area lighting into deep surgical sites. The Aesculap Surgical Illuminator is intended for use with a 300 watt xenon illuminator and a 2.5mm fiber optic cable.

Indications for Use
The Aesculap Surgical Illuminator is intended for the illumination of surgical procedures, particularly where deep cavities or adjacent tissues limit outside light in the surgical field. It is designed for use in surgical specialties of gynecology, general surgery, colon-rectal surgery, urology, ENT, Maxillo-Facial, and oral surgery. It is not intended for use in intracranial surgery.

Contraindications
The Aesculap Surgical Illuminator presents no contraindication. However, the user should be familiar with the use of light sources and cables and should take precautions accordingly.

Warnings
The Aesculap Surgical Illuminator is designed for use with 300 watt xenon illuminators, using a 2.5mm fiber optic cable.

Do not use light sources rated higher than 300 watts, or cables with fiber optic bundles of more than 2.5mm diameter. Use of higher watt light sources or larger diameter cables could result in overheating; causing product failure and patient injury.

Precautions
Light sources vary widely in emission of visible and infrared energy. As a precautionary measure, we recommend occasionally monitoring connector temperature during first time use with a new light source or lamp; thereafter if needed. As is common with fiber optic equipment, metal portion of connector can become hot to the touch. Use plastic grip as handle. Do not place the metal ring portion of connector directly on the patient’s skin. (See Figure 1)

Because light energy can be absorbed as heat, the entire lit portion (distal end) of the Aesculap Surgical Illuminator should not be continuously embedded (i.e. lit surface should not be buried) in tissue and held fixed for more than a few minutes at a time.

Each Aesculap Surgical Illuminator package contains one Aesculap Surgical Illuminator assembly, and three (3) adhesive strips. Each adhesive strip includes paper release liners. Prior to closing the surgical site, all components must be accounted for.

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Directions for Use
The Aesculap Surgical Illuminator may be used as a retractor or may be attached to other surgical instruments. If attaching the Aesculap Surgical Illuminator to other instruments, use the adhesive strips provided. Both a wrap-around adhesive strip (blue) and double-sided adhesive strip (green) are included. The instrument and the Aesculap Surgical Illuminator must be clean and dry before applying the adhesive strips.

The Aesculap Surgical Illuminator connects to a light source used for head lamps or endoscopes. A fiber optic cable connects the light source and the Aesculap Surgical Illuminator. Make sure the Aesculap 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.

Bodily fluids or debris collecting on the surface of the Aesculap Surgical Illuminator may be irrigated or wiped away.

Sterile unless package is opened or damaged. Do not use if package is opened or damaged.

Limited Warranty
LumitexMD warrants the material conformity of the Aesculap Surgical Illuminator to specifications in the product labeling until the earlier of twelve (12) months from shipment to customer or the expiration date of the product, and will repair or replace at LumitexMD option and expense any Aesculap product that does not meet specifications in all material respects. LUMITEXMD LIABILITY TO CUSTOMER, USER, OR PATIENT IS EXPRESSLY LIMITED TO REPAIR OR REPLACEMENT. LumitexMD expressly disclaims all other warranties, express or implied, including, without limitation, merchantability, or fitness for a particular purpose. LumitexMD is registered trademark of Lumitex, Inc. Lumitex products are protected by U.S. and foreign patents and patents pending. Please direct any inquiries to Aesculap Implant Systems.

© Copyright 2010 Lumitex Medical Devices, Inc. All Rights Reserved. All trademarks acknowledged.

Distributed in USA by:
Aesculap Implant Systems
3773 Corporate Parkway
Center Valley, PA 18034
USA

Distributed in EU by:
Aesculap AG
Am Aesculap Platz
Tuttlingen
Germany

LumitexMD, Inc.
8443 Dow Circle
Strongsville, OH 44136
USA
800-969-5483
www.lumitexmd.com
info@lumitexmd.com

Authorized EC Representative:
Medical Device Safety Service GmbH
Schieffgraben 41
D-30175 Hanover
Germany