Spinal Elements, Inc. · 3115 Melrose Dr., Suite 200
Carlsbad, CA 92010 · U.S.A. · 760.607.0121

LUCENT® MIS FIBER OPTIC ASSEMBLY

GENERAL INFORMATION

Spinal Elements' Lucent MIS Fiber Optic Assembly is a light guide that stems from a single cable and can have multiple illumination tips at the distal end. The end existing as a single cable contains a universal light source adapter that can be attached to a multitude of high intensity external light sources (ranging from 150 Watts to 300 Watts). Light provided from the external source is propagated through fiberoptic bundles contained by a jacket made of silicone sheathe. Fiber optic bundles terminate at one or multiple stainless steel illumination tips that deliver light to the surgical site. The energy (Lux) and color temperature (°K) of the light exiting illumination tips will vary, depending upon the wattage intensity of the external light source.

INDICATIONS

The Lucent MIS Fiber Optic Assembly is intended to provide surgical site illumination from a high intensity light source.

WARNINGS

1. Light Guides are provided non-sterile and must be cleaned and sterilized before use. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert.
2. Care should be taken in handling light guides to avoid injury to the user or patient.
3. Appropriate cutoff filters should be used to filter the light source attached to the Lucent MIS Fiber Optic Assembly (i.e. UV Filter, IR Filter).
4. This device is designed for attachment to a tool, instrument, or luminare, and under no circumstances should the light emitting end directly contact tissue or other heat sensitive materials.
5. Carefully read and follow the instructions provided by the manufacturer of the light source to which the Lucent MIS Fiber Optic Assembly is connected, as additional warnings may apply.

PREOPERATIVE MANAGEMENT

1. Device components should be received and accepted only in packages that have not been damaged or tampered with. Damaged implants and/or instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.

CLEANING

Use a mild cleaning solution with a pH range of 5 to 9.
DO NOT use synthetic detergents or oil-based soaps. The petroleum components of these soaps may be absorbed by the silicone rubber components and may leach out during use causing tissue reaction.
Avoid scratching glass fibers at ends or light guide. Damage to fibers may reduce light transmission.

1. Clean thoroughly using a soft-bristled brush in a lukewarm water-soap solution to remove any possible contamination.
2. Rinse thoroughly in lukewarm water.
3. Rinse thoroughly in distilled water.
4. Allow to air dry

STERILIZATION

All instruments are provided non-sterile and must be sterilized before use. Non-sterile instruments should be autoclave sterilized using one of the following validated cycle parameters.

	Method	Cycle Type	Sterilization Temperature	Exposure Time	Dry Time
Wrapped	Steam	Gravity Displacement	270°F (132°C)	15 minutes	45 minutes
	Steam	Pre-vacuum	270°F (132°C)	10 minutes	60 minutes
Rigid Container	Steam	Pre-vacuum	270°F (132°C)	4 minutes	30 minutes

*Note: Rigid containers must have a minimum of 2 filters and require a 30 minute cooldown period post sterilization.

Sterilization parameters were validated per *ANSI/AAMI/ISO 17665-1: 2006. Sterilization of Health Care Products – Moist Heat – Part 1 Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices* and *ANSI-AAMI ST79 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities.* These parameters were validated to a sterility assurance level (SAL) of 10^{-6}. These sterilization cycles are not considered by the Food and Drug Administration to be standard sterilization cycles. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

INFORMATION

REF Catalog Number
LOT Batch Code
Manufacturer
Caution, Consult Accompanying Documents
MAT Material
QTY Packaged Quantity
Date of Manufacture
Do Not Re-Use
NON-STERILE Device Not Sterile
℞ Only Prescription Only
Instruction for Use are provided electronically at ifu.spinalelements.com

Patents: patent.spinalelements.com

For additional information regarding any of Spinal Elements' devices, please contact Spinal Elements, Inc. Customer Service at (760) 607-0121.

CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician