

**1. Indications for Use**

Fiber optic retractors and instruments illuminate surgical sites by transmitting light from a compatible fiber optic light source.

**2. Device Description**

Reusable surgical devices designed to transmit light to illuminate deep surgical fields.

**3. How Supplied**

Devices are supplied non-sterile and must be cleaned, disinfected and sterilized prior to use.

**4. Contraindications**

No known contraindications.

**5. Warnings**

- Failure to follow instructions may result in injury or device damage.
- Devices must be reprocessed prior to use.

**6. Heat / Burn Warnings**

- Light sources use high intensity lamps that generate heat and bright light.
- Do not place illuminated instruments on patient drapes or the patient.
- Turn off the light source before disconnecting cables.
- Never look into the optical end while connected to a light source.
- The distal end of the light carrier may become hot and could cause burns.

**7. Care and Handling**

- Coil fiber optic cables with a minimum diameter of 6 inches (15 cm).
- Do not kink, twist, pull or stretch the cable.
- Avoid contact with sharp edges or pointed instruments.
- Do not modify or remove end fittings.
- Keep optical surfaces clean and free of debris.

**8. Inspection**

- Inspect devices before each use for cracks, corrosion or damage.
- Inspect optical surfaces for scratches or discoloration.
- Check for reduced light transmission.
- Remove damaged devices from service.

**9. Pre-Processing Instructions**

- Begin cleaning as soon as possible after use, ideally within 2 hours.
- Remove gross contamination by rinsing or wiping the device.
- Transport devices according to institutional procedures.
- Ensure instruments are fully open to allow cleaning solution contact with all surfaces.

### 10. Cleaning and Disinfection

- Clean instruments immediately after use.
- Do not allow blood or tissue to dry on instruments.
- Use soft brushes only.
- Use neutral pH cleaning solutions (pH 6–8).
- Follow cleaning solution manufacturer instructions.
- Rinse thoroughly with distilled or deionized water.
- Dry using lint-free cloth or sterile compressed air.

### 11. Ultrasonic Cleaning

- **ULTRASONIC CLEANING IS NOT RECOMMENDED.**

### 12. Automatic Cleaning Parameters

Phase	Minimum Time	Temperature	Detergent
Pre-Wash	15 sec	1–16°C	None
Enzyme Wash	1 min	43–82°C	Enzymatic
Wash	2 min	43–82°C	Neutral
Rinse	15 sec	43–82°C	None
Final Rinse	10 sec	Purified Water	None

### 13. Packaging

Package instruments using sterilization wrap approved for steam sterilization. Packaging materials should comply with ISO 11607 requirements.

### 14. Steam Sterilization Parameters

Sterilization must be performed using a steam sterilization cycle (moist heat) in accordance with applicable national guidelines and institutional procedures.

Method	Temperature	Exposure Time	Dry Time	Configuration
Pre-vacuum Steam Sterilization	132°C (270°F)	4 minutes	30 minutes	Wrapped (2-layer 1-ply or 1-layer 2-ply wrap)
Gravity Steam Sterilization	132°C (270°F)	15 minutes	30 minutes	Wrapped (2-layer 1-ply or 1-layer 2-ply wrap)

### 15. Adverse Events

No adverse events are currently known when the device is used as intended. Improper use may result in thermal injury or device malfunction.

### 16. Creutzfeldt-Jakob Disease (CJD) Warning

Devices used on patients with known or suspected CJD must not be reused and must be disposed of according to applicable regulations.

### 17. Disposal

Dispose of devices in accordance with applicable local, state and national regulations governing medical devices.