HAYDEN MEDICAL **Instructions for Use (IFU) Fiber Optic Light Cables**

The reprocessing instructions provided in this document were developed in accordance with ISO 17664 and are consistent with healthcare facility practices described in ISO 15883 (washer-disinfectors) and ISO 17665 (moist heat sterilization).

1. Device Description

Fiber optic light guides illuminate surgical sites by transmitting light from a compatible fiber optic light source to surgical instruments, endoscopes, microscopes, or surgical headlights. Compatible with halogen, metal halide, xenon, or LED light sources.

2. Intended Use

Fiber optic light guides deliver light from a medical light source to illuminate surgical or examination sites during procedures.

3. Contraindications

No known contraindications when used as intended.

4. Warnings

- Light emitted from the light guide may cause burns or fire hazards if improperly used.
- End fittings may exceed 50°C (122°F) during operation.
- Never operate the light source unless the light guide is attached to an instrument.
- Do not place exposed light guide ends near drapes or combustible materials.
- Device is supplied non-sterile and must be sterilized prior to use.
- Devices used on patients with known or suspected Creutzfeldt-Jakob Disease (CJD) must be removed from service and destroyed.

5. Precautions

- Inspect the light guide prior to each use.
- Ensure correct size matching between light guide and instrument port.
- Do not force connections.
- Verify all connections are secure before activating light source.

6. Inspection Before Use

- Inspect cable sheath for tears, kinks, or crushed areas.
- Inspect polished fiber faces for cracks.
- Check fittings are securely attached.
- Remove damaged devices from service.

7. Care and Handling

- Do not cut, stretch, kink, or puncture the cable.
- Avoid dropping end fittings.
- Store cables loosely coiled (>12 inch diameter).
- Disconnect by grasping connector handle, not the jacket.

8. Preventative Maintenance

- Clean fiber faces with alcohol swab prior to use.
- Check that cable sheath and fittings remain secure.
- Ensure lens components remain clear if present.

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9. Cleaning

- Clean using soft-bristled brush and lukewarm water with mild detergent (pH 5–9).
- Rinse thoroughly with lukewarm water.
- Perform final rinse with distilled water.
- Allow device to air dry completely.
- Do not use abrasive cleaners or synthetic detergents.

10. Packaging for Sterilization

- Package cables in sterilization wrap or trays compatible with steam sterilization.
- Ensure cable is loosely coiled during packaging.
- Do not place heavy instruments on top of cables.

11. Steam Sterilization Parameters

Parameters consistent with ISO 17665 and AAMI ST79.

Method	Temperature	Exposure Time	Dry Time
Gravity Displacement	121°C (250°F)	30 minutes	20 minutes
Pre-Vacuum	132°C (270°F)	4 minutes	Per facility protocol

12. Alternative Sterilization Methods

- Follow manufacturer instructions for Sterrad® systems.
- Ethylene Oxide sterilization may be used according to hospital protocols.
- Flash sterilization should only be used for urgent situations.

13. Storage

- Store in clean, dry, dust-free environment.
- Avoid tight coils or compression.
- Protect packaging from moisture or damage.

14. Instrument Life

With proper care, fiber optic cables may withstand approximately 200 autoclave cycles. End of life is determined by wear, damage, or reduced light transmission.

15. Limited Warranty

The device is warranted to be free from defects in materials and workmanship for twelve months from purchase. Warranty covers repair or replacement only. Damage caused by misuse or improper processing is not covered.

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