HAYDEN MEDICAL

Instructions for Use (IFU) Laser Surgical Instruments

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

1. Device Description

Laser surgical instruments are reusable manual instruments designed for use with medical laser systems.

Some instruments may include matte or coated surfaces designed to reduce laser reflectivity.

2. Intended Use

Laser surgical instruments are intended for use during procedures utilizing medical laser systems.

These instruments assist in tissue manipulation, retraction, and access while minimizing unintended laser reflection and thermal injury.

3. Contraindications

Do not use instruments that are damaged, deformed, or exhibit surface defects.

Refer to the laser system manufacturer's instructions for contraindications related to laser use.

4. Warnings

- Laser energy may be reflected by metallic surfaces and may cause unintended tissue damage.
- Use only instruments designed for compatibility with medical laser systems.
- Avoid direct or reflected laser beam contact with unintended surfaces.
- Inspect instruments before each use for damage, wear, or surface defects.
- Do not use damaged instruments.
- If a device has been used on a patient with known or suspected Creutzfeldt-Jakob Disease (CJD), it must not be reused and must be permanently removed from service.

5. Precautions

- Select instruments appropriate for the surgical procedure and patient anatomy.
- Avoid contact between instruments and sharp objects.
- Inspect instruments regularly throughout their lifecycle.

6. Inspection Before Use

- Inspect instruments for cracks, bends, or surface defects.
- Ensure all components function properly.
- Remove damaged instruments from service.

7. Laser Safety

- Use instruments only with properly calibrated laser systems.
- Avoid direct or reflected laser beam contact with unintended surfaces.
- Ensure proper laser safety protocols are followed, including the use of protective eyewear.
- Damaged surfaces or coatings may increase the risk of laser reflection or thermal injury.

8. Instructions for Use

- Select the appropriate instrument type and size.
- Position the instrument carefully to avoid unintended tissue damage.

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- Use the instrument only for its intended surgical purpose.
- After the procedure, remove the instrument carefully and begin cleaning promptly.

9. Care and Handling

- Handle instruments individually to avoid damage.
- Do not stack instruments during cleaning or transport.
- Protect coated or matte surfaces and instrument tips from sharp objects.
- Keep track of components when disassembling instruments.

10. Pre-Cleaning

- Begin decontamination immediately after use.
- Keep instruments moist and do not allow blood or body fluids to dry.
- Rinse instruments under cool or lukewarm running water to remove gross debris.

11. Cleaning

- Wear protective gloves during cleaning.
- Use a neutral pH enzymatic detergent (pH 6–8).
- Immerse instruments completely during cleaning.
- Clean with a soft bristle brush to remove debris.
- Flush channels or tubing with cleaning solution if applicable.
- Rinse thoroughly with deionized water.
- Repeat cleaning if visible contamination remains.

Cleaning warnings:

- Do not use steel wool, wire brushes, or abrasive detergents.
- Do not soak instruments longer than two hours in any solution.
- Do not use bleach or chlorine-based cleaners.
- Ultrasonic cleaning is not recommended for instruments with coated or matte surfaces, as it may damage the surface.

12. Rinsing and Drying

- Rinse instruments thoroughly with deionized water.
- Dry instruments using a soft lint-free cloth.
- Use compressed air to dry channels or lumens if present.

13. Inspection and Preparation for Sterilization

- Inspect instruments for cleanliness and integrity.
- Verify coated or matte surfaces remain intact.
- Check mechanical function of hinges or joints.
- Remove damaged instruments from service.

14. Packaging for Sterilization

- Wrap instruments individually or place in sterilization trays.
- Protect coated surfaces from contact with other instruments.
- Ensure instruments are positioned to allow sterilant contact.

15. Steam Sterilization Parameters

Sterilization must be performed using validated steam sterilization cycles in accordance with ISO 17665 and applicable national standards.

Method	Temperature	Exposure Time	Dry Time
Gravity Steam Sterilization	121°C (250°F)	30 minutes	30 minutes
Pre-Vacuum Steam Sterilization	132°C (270°F)	4 minutes	30 minutes
Pre-Vacuum Steam Sterilization	134°C (273°F)	3 minutes	30 minutes

The above sterilization parameters are based on recognized steam sterilization practices in accordance with ISO 17665 and are compatible with healthcare facility sterilizers operating under applicable national standards.

16. Storage

- Store sterilized instruments in a clean, dry, dust-free environment.
- Protect instrument surfaces from mechanical damage.
- Verify packaging integrity before use.

17. Limitations on Reprocessing

Repeated reprocessing has minimal effect on stainless steel surgical instruments.

However, coated, insulated, or surface-treated instruments may experience gradual degradation over time due to repeated cleaning, handling, and sterilization cycles.

End of instrument life is determined by wear, damage, coating degradation, or loss of function. Instruments must be inspected prior to each use and removed from service if defects are identified.

18. Disposal

Dispose of damaged instruments according to applicable hospital procedures and national regulations.

19. Warranty

These instruments are manufactured to meet high quality standards. Damage resulting from misuse, improper cleaning, or unauthorized modification may void the warranty.

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