HAYDEN MEDICAL **Instructions for Use (IFU)**

Reusable Liposuction Cannulas and Cannula Accessories

Reprocessing instructions were developed in accordance with ISO 17664. Cleaning and disinfection processes are compatible with ISO 15883. Steam sterilization parameters are provided in accordance with ISO 17665. Healthcare facilities are responsible for validating their reprocessing equipment and procedures in accordance with applicable standards.

1. Device Description

Reusable liposuction cannulas and cannula accessories are manual surgical instruments intended for use in procedures involving the infiltration and aspiration of fluids from targeted areas of the body.

These devices are available in a range of sizes, lengths, diameters, and configurations to support various clinical applications. They are manufactured from medical-grade materials, including stainless steel, aluminum, and polymer components such as acetal (Delrin).

Metal components may be susceptible to corrosion if improperly handled or processed. Polymer components may degrade over time when exposed to repeated mechanical, chemical, or thermal stress.

2. Intended Use

These devices are intended for use by qualified healthcare professionals during surgical procedures requiring the introduction (instillation) or aspiration of fluids.

3. User Qualifications

This device is intended for use by trained and qualified healthcare professionals, including licensed physicians, surgeons, and operating room personnel familiar with surgical instrumentation and sterile processing procedures.

4. Device Condition Upon Delivery

These devices are supplied non-sterile.

They must be cleaned, inspected, and sterilized prior to initial use and before each subsequent use.

5. Warnings and Precautions

- Do not use the device if it is bent, cracked, corroded, or otherwise damaged.
- Do not use the device if it does not function as intended.
- Do not allow blood, tissue, or debris to dry on the device.
- Do not use metal brushes, abrasive materials, or harsh cleaning agents.
- Do not expose the device to corrosive chemicals, including strong acids, alkaline solutions, or oxidizing agents.
- Do not apply excessive force, bending, or torque to the cannula shaft.
- Do not drop the device onto hard surfaces.
- Do not force the device into cleaning equipment, sterilizers, or storage areas.
- Ensure all components are thoroughly cleaned and dried prior to sterilization.

Failure to follow these instructions may result in device damage, reduced performance, or patient risk.

6. Limitations on Reuse

These devices are reusable; however, repeated use and reprocessing may result in material fatigue, wear, or degradation.

All devices must be inspected prior to each use. Devices showing signs of damage, wear, or compromised integrity must be removed from service and disposed of in accordance with facility policy.

19425 Soledad Canyon Rd Suite 411, Santa Clarita, CA 91351
661-296-7200 info@haydenmedical.com www.haydenmedical.com

7. Reprocessing Instructions

7.1 Point-of-Use Pre-Cleaning

Immediately after use:

- Remove gross debris using a disposable, non-shedding cloth.
- Rinse with lukewarm water (not exceeding forty degrees Celsius).
- Do not allow soil or biological material to dry on the device.
- If immediate cleaning is not possible, cover with a cloth moistened with distilled or deionized water.

7.2 Manual Cleaning

- Immerse the device in a neutral pH enzymatic cleaning solution.
- Soak for a minimum of ten minutes.
- Clean all external surfaces using a soft-bristled brush.
- Clean all internal lumens using a non-metal, flexible cleaning brush.
- Pay particular attention to lumens, ports, openings, and connection points.
- Flush lumens with distilled or deionized water using a syringe.
- Repeat flushing a minimum of three times.

7.3 Ultrasonic Cleaning

- Fully submerge the device in an ultrasonic cleaner containing enzymatic solution.
- Ensure all surfaces are exposed and not in contact with the bottom of the tank.
- Process for a minimum of ten minutes.
- Rinse thoroughly with distilled or deionized water following ultrasonic cleaning.

7.4 Rinsing

- Rinse all components thoroughly with distilled or deionized water.
- Ensure all cleaning agents and visible debris are removed.

7.5 Drying

- Dry using a clean, non-shedding cloth.
- Allow to air dry completely.
- Filtered compressed air may be used to dry internal lumens.
- Ensure the device is completely dry prior to sterilization.

7.6 Inspection

Inspect all devices prior to sterilization:

- Check for bending, cracks, fractures, corrosion, or surface damage.
- Verify secure attachment between shaft and hub or handle.
- Perform a gentle pull test to confirm structural integrity.
- Inspect critical areas visually and, where appropriate, using magnification.

Devices that show any signs of damage or irregularity must not be used.

7.7 Packaging

- Ensure devices are clean and completely dry prior to packaging.
- Disassemble components as applicable.
- Package individually or in trays using approved sterilization wraps or pouches.
- Protect devices from mechanical damage during sterilization.

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8. Sterilization

The following steam sterilization parameters are recommended for reprocessing this device:

Pre-Vacuum Steam Sterilization:

- **Temperature: 132 degrees Celsius (270 degrees Fahrenheit)**
- **Exposure Time: 4 minutes**
- **Dry Time: Minimum 30 minutes**

Devices must be thoroughly cleaned, rinsed, and completely dried prior to sterilization.

Healthcare facilities are responsible for ensuring that sterilization methods are appropriate, effective, and performed in accordance with their validated procedures, institutional protocols, and applicable standards.

Failure to properly clean and sterilize the device may result in contamination, device damage, or compromised performance.

9. Storage

- Store in a clean, dry, and controlled environment.
- Protect from dust, moisture, and temperature fluctuations.
- Maintain sterility of packaged devices until point of use.

10. Handling and Care

- Handle devices with care to prevent bending or impact damage.
- Do not stack or overcrowd instruments.
- Avoid contact with dissimilar metals during cleaning to reduce risk of corrosion.
- Use only compatible cleaning agents and sterilization processes.

11. Disposal

Devices that are damaged, worn, or no longer functional must be disposed of in accordance with facility policies and applicable regulations for medical waste.

12. Responsibility

It is the responsibility of the healthcare facility and reprocessing personnel to ensure that all instructions are followed and that devices are safe, clean, and functional prior to use.

13. Standards and Guidance

Reprocessing, cleaning, disinfection, and sterilization shall be performed in accordance with the instructions provided in this document.

Healthcare facilities are responsible for ensuring that their equipment and procedures are validated and operated in accordance with applicable standards and institutional policies.

The following standards may be used as guidance:
• ISO 17664 – Processing of health care products
• ISO 17665 – Moist heat sterilization
• AAMI ST79 – Steam sterilization guidance

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