

Instructions for Use (IFU)

Device Name: HErD Star Accessory

Manufacturer: del Sol Designs, LLC

1. Device Description

HErD Star accessories are reusable, medical-grade silicone grip enhancements designed to fit a variety of dental hand instruments, including scalers, curettes, and other clinical tools. They improve ergonomics and help reduce hand fatigue during clinical procedures. HErD Star accessories do not contact the patient and serve only as instrument handle enhancements.

2. Indications for Use

HErD Star accessories are intended to enhance comfort and efficiency when used with compatible handheld instruments in clinical and dental environments. They are fully reusable and must be cleaned and sterilized before each use in sterile or aseptic settings.

With proper care and maintenance, HErD Star accessories have an expected useful life of at least one year.

3. Contraindications

None known.

4. Warnings & Precautions

- Accessories are shipped non-sterile; sterilization is required before first and subsequent uses.
- Do not exceed 275°F (135°C) during sterilization to avoid material degradation.

- Avoid direct contact with metal during sterilization; use pouches if accessories do not fit standard cassettes.
- Inspect before each use. Do not use if cracked, deformed, sticky, swollen, or showing any signs of wear.
- Ensure the accessory is fully seated and secure on the instrument before clinical use.
- Avoid contact with abrasive cleaning tools such as steel wool or metal brushes.
- Do not expose to petroleum-based products, iodine-based disinfectants, or phenol-containing solutions.
- Avoid prolonged exposure to direct sunlight or UV sources.

5. Cleaning Instructions

1. Remove HErD Star accessories from instruments before cleaning.
2. Rinse thoroughly under cool running water to remove gross debris.
3. Clean using one of the following approved methods:
 - Ultrasonic cleaning using detergent manufacturer instructions.
 - Enzymatic cleaning solutions.
 - Commonly used healthcare disinfectants (non-abrasive).
4. Use a soft nylon brush as needed. Do not use abrasive materials.
5. Rinse thoroughly and dry completely before sterilization.

Avoid exposing the accessories to the following chemicals:

- Organic solvents (aromatic or chlorinated hydrocarbons)
- Ketones (e.g., methyl ethyl ketone)
- Esters
- Halogenated organic solvents

6. Sterilization Instructions

Use standard steam sterilization cycles consistent with typical dental hand instruments. Follow sterilizer manufacturer guidance for loading, cycle selection, and drying.

Steam Sterilization Parameters:

- Pre-vacuum: 270–275°F (132–135°C) for 3–4 minutes
- Gravity: 270–275°F (132–135°C) for 15 minutes

After sterilization, allow accessories to dry completely. Store in a clean, dry, dust-free environment. Use only FDA-cleared pouches or wraps for steam sterilization.

7. Storage

Store accessories between 5–40°C (41–104°F) in a dry area away from direct sunlight. Keep accessories in their packaging or sterilization pouches to maintain cleanliness.

8. Disposal

Dispose of worn or damaged accessories as non-hazardous waste in accordance with local regulations.

9. Material Specification

The product is manufactured from medical-grade silicone. The material is latex-free and BPA-free.

10. Replacement Criteria

Replace the accessory immediately if it exhibits any of the following:

- Cracks or tears

- Permanent deformation or swelling
- Sticky, brittle, or excessively soft texture
- Discoloration
- Increased slippage on the instrument

12. Contact Information

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