POSEIDON LENS CLEANING SHEATH—Instructions For Use

Read all Instructions prior to use

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Sterility: Provided Sterile, Ethylene Oxide (EO) Sterilization

Single Use: Disposable, For Single Patient Use Only, Do Not Re-sterilize and/or Reuse

Storage: Store in a cool, dry place.

Indication for Use

Intended to clear the end of a rigid rod endoscope in order to maintain clear visualization of endoscopic procedures without having to remove the scope from the surgical site. The device is indicated for use during routine diagnostic procedures and during endoscopic sinus surgery.

Description

The Poseidon Lens Cleaning Sheath is a disposable medical device that allows a user to clear the end of a rigid rod endoscope utilizing irrigation and suction. The Poseidon Lens Cleaning Sheaths include the WaveGrip, 275mm (108”) extension tubing and valve cartridge.

The Poseidon Lens Cleaning Sheath includes an atraumatic distal tip on a nonmalleable hypotube, WaveGrip handle and field irrigation connection. Irrigation and suction is performed by connecting the valve cartridge to the controller then engaging individual foot switches which independently control the opening of either the irrigation or suction valve of the valve cartridge.

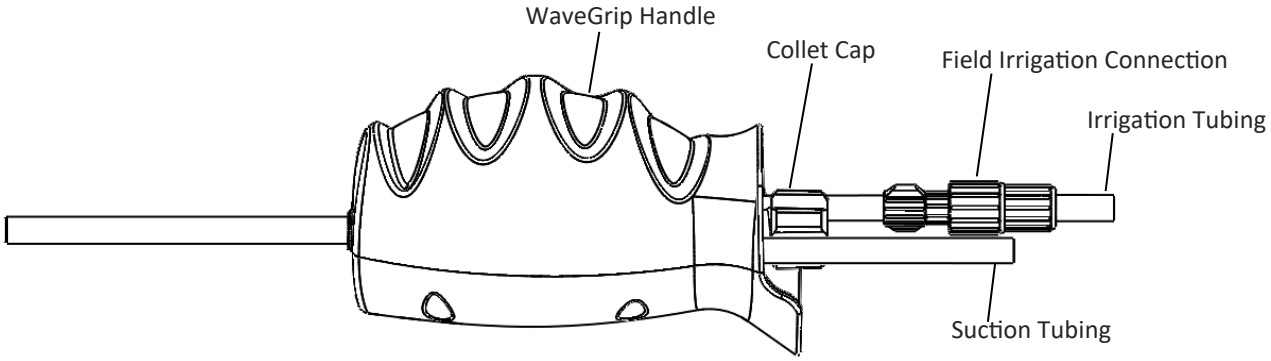

Figure 1: Poseidon Lens Cleaning Sheath

Contraindications

None known.

Warnings

- Do not use breached or damaged packages, since the sterility and functionality of the device may be compromised.
- Single Use Only. Do not re-sterilize or reuse, as doing so may result in compromised device performance and risk improper sterilization and cross contamination.
- Never advance or withdraw the device against unknown resistances as this can cause tissue trauma or device damage.

Precautions

- Due to the variability of sinonasal anatomy, review radiographic imaging (e.g. a CT scan) prior to the procedure.

Adverse Effects

Possible adverse effects include, but are not limited to, the following:

- Damage of the orbital wall or other structures of the eye
- Tissue inflammation, swelling or trauma
- Loss of vision or diplopia (double vision)

Supplies

The following supplies are not provided with the Poseidon Lens Cleaning Sheath or Poseidon Lens Cleaning System and should be available for the procedure:

- Appropriate endoscope and compatible camera system
- Sterile Saline Solution
- Standard suction tubing and suction systems/vacuum pumps.

Compatibility

The device is compatible with endoscopes with an outer diameter of 4mm and 170mm to 185mm in length.

Instructions for Use

1. Remove the Poseidon Lens Cleaning Sheath, WaveGrip, and valve cartridge from the protective packaging.
2. Orientate valve cartridge following diagram on top of Controller and insert valve cartridge into valve cartridge bracket.

NOTE: An audible click will be heard when the valve cartridge is fully seated into the valve cartridge bracket. Valve cartridge can only be fully inserted into bracket when correctly orientated.

3. Connect female connector of suction tubing attached to the valve cartridge to the patient port of suction canister.
4. Remove cap of IV spike attached to the valve cartridge and insert IV spike into IV fluid bag.
5. Remove hypotube protective cover from distal end of Poseidon Lens Cleaning Sheath.
6. Remove collet cap from the WaveGrip, insert endoscope through opening of collet cap then insert endoscope into collet valve located in the WaveGrip.
7. Position and orientate endoscope as desired then tighten collet cap onto collet valve until endoscope is secured.

Refer to Installation, Operation and Maintenance Guide for instruction on Control Tower Preparation and Operation.

8. If field irrigation is desired, remove the twist lock on the irrigation tubing and attach to desired irrigation device and operate engage irrigation utilizing foot switch.
9. After the procedure, dispose of device according to appropriate environmental health and safety guidelines.

Limited Warranty

Refer to Huck Medical Technologies Standard Terms and Conditions.

Not made with dry, natural rubber.

Symbols

Consult Instructions for Use

Lot Number

Reference Number

Use by Date

Do not use if package is damaged

Do not re-use

Prescription Use Only

Manufacturer

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