RVO®
REVISION OPTICS

INLAY INSERTER CHUCK HANDLE
INSTRUCTIONS FOR USE
DEVICE: INSERTER HANDLE
REF **607-0002**

CAUTION
Federal law restricts this device to sale by or on the order of a physician. Refer to Professional Use Information for additional discussions on risks, benefits, alternatives, and results of the study conducted to support FDA approval.

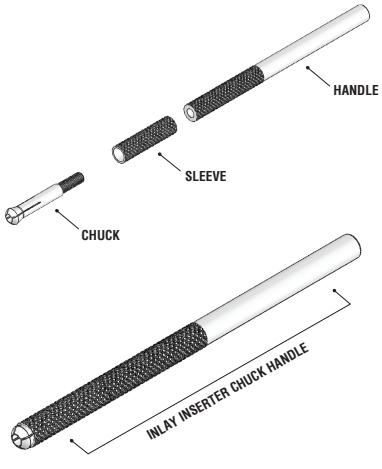
CAUTION
Federal law restricts this device to practitioners who have been trained and have experience in the surgical management and treatment of refractive errors.

INSTRUCTIONS FOR USE
Intended Use
The Inlay Inserter Chuck Handle is used in conjunction with the Inlay Inserter to extend the length of the device for ease of use while delivering the Raindrop® Near Vision Inlay.

PLEASE READ BEFORE USE
Warnings
- The Inserter Handle is distributed NON-STERILE. Prior to use, it is the responsibility of the user to thoroughly clean and sterilize the instrument according to the recommendation of this document.
- The Inserter Handle is intended to be used only for the purpose for which it was designed, and it is the responsibility of the physician to become familiar with the proper use of this instrument.
- Wear appropriate protective equipment (gloves, eye protection, etc.) when reprocessing any medical device.
- Do not use corrosive cleaning agents with low pH (below 5) or high pH (above 10), which will damage the instrument's metal surface.

Limitations on Reprocessing
Proper repeated processing has a minimal effect on the instrument. End of life is normally determined by wear and damage due to use (see Inspection and Testing section).

Directions for Use
- The Inserter Handle has three components: the handle, the sleeve, and the chuck.



- The Inserter Handle should be thoroughly cleaned and sterilized while disassembled before use.
- To assemble the Inserter Handle, the surgical assistant should first insert the chuck's screw end through the sleeve via the ring end of the sleeve. Then screw the handle into the chuck sleeve assembly holding the chuck round open end and sleeve together.

To attach the Inserter Handle to the Inlay Inserter:
1. First, slightly loosen the chuck from the handle by holding the chuck's round opening end and the sleeve together.
2. Twist the handle counterclockwise a few times, so that the jaws of the chuck open enough for the shaft of the Inlay Inserter to fit in.
3. Gently slide the shaft of the Inlay Inserter into the opening of the chuck.
4. While holding onto the Inlay Inserter, the chuck and the sleeve all together, twist the handle clockwise to secure the Inlay Inserter in place.
5. Verify Inlay Inserter and Inlay Inserter Handle are securely attached prior to use.

CLEANING INSTRUCTIONS FOR FIRST USE AND REPROCESSING
Preparation for Decontamination for First Use
- Carefully remove the Inserter Handle from its packaging.
- Visually inspect the instrument to ensure there is no visible damage. Do not use the instrument if it is damaged.
- Proceed to thoroughly clean and sterilize the instrument as described in this document.

Preparation at Point of Use
- Reprocess the instrument as soon as reasonably practical following use – up to 24 hours.
- As soon as possible, rinse the assembled instrument under cold running tap water (<27°C; <80°F) for at least one (1) minute to remove any gross debris.

Preparation for Decontamination
Disassemble (unscrew) the instrument into the individual components: chuck, sleeve, and handle.

Cleaning: Manual with Ultrasonic Bath
- The individual components of the instrument should be thoroughly cleaned by the following manual cleaning procedure.
- Ensure that the ultrasonic bath is clean before use. Fill the bath to operation level with deionized or distilled water.
- Use a solid tray or tote to contain the components and cleaning solution. Do not place the components directly into the ultrasonic bath.
- Rinse each individual component under cold running tap water (<27°C; <80°F) for at least one (1) minute each to remove major debris. Hold the sleeve vertically and rotate all components to expose all surfaces and cavities to flowing water.
- Pat the components' surfaces with a soft, low lint cloth to remove excess moisture and debris.
- Place all individual components in the solid tray or tote and add freshly prepared Proklenz® NpH High Performance Neutral Detergent cleaning solution, prepared according to the directions of the solution manufacturer, ensuring that all components are totally submerged in the solution.
- Place the tray or tote in the ultrasonic bath, remove some water in the bath, if necessary, to avoid overflow and turn it on for a minimum of 5-minute cycle.
- Thoroughly rinse all components under warm (27°C - 44°C; 80°F - 100°F) running tap water for at least one (1) minute each. Hold the sleeve vertically and rotate all components to expose all surfaces and cavity to flowing water.
- Final rinse individual components by pouring deionized water on them for a minimum of 30 seconds each.

Drying
Pat-dry all components with a soft, low lint cloth.

Inspection and Testing:
- Under magnification in a well-lit area, visually verify that all the components are clean and dry. If soil is still visible, repeat cleaning. If moisture is still visible, repeat drying with the low lint cloth.
- Assemble the instrument's components by first inserting the chuck's screw end through the sleeve via the ring end of the sleeve and then screw the chuck into the handle. If the components do not fit smoothly together, it is possible that the components are still soiled. Repeat cleaning.
- If after repeat cleanings, the components show rust, cracks, bends, or still do not fit smoothly together, it is an indication that the handle is damaged and cannot be used. Discard inserter handle.
- If the components fit smoothly together, repeat tightening and loosening the handle and chuck and observe to ensure that the chuck's jaws slightly open and close uniformly. If the jaws do not open when loosened, then the handle is damaged and cannot be used.
- If any of the defects listed in the labeling are observed during inspection, discard the inserter handle.
- If the instrument can be assembled properly and has no visible damage, disassemble (unscrew) it into individual components and move to the next step.

Packaging
For steam sterilization: package the individual components of the Inserter Handle together in double pouches of a legally marketed sterilization pouch that is approved for the steam sterilization process.[1]

Sterilization: Moist Heat
- Cycle Type: Dynamic air-removal (Prevacuum)
- Temperature Set-point: 132°C (270°F)
- Exposure Time: 4 minutes
- Drying Time: 20 minutes

Storage
In between use, store the packaged instrument in a dry and clean environment.

Additional Information
- When sterilizing multiple instruments in one cycle, ensure that the sterilizer's maximum load is not exceeded.
- The instructions provided above have been validated by the manufacturer of the medical device as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials, and personnel in the reprocessing facility achieve the desired results. This normally requires validation and routine monitoring of the process.

1. Crosstex® SPSmedical Cat. No. SSP-381-1 and SSP-383-1, or equivalent.

SYMBOLS ON PACKAGING

SYMBOLS	EXPLANATION (English)
	Manufacturer
LOT	Lot Number
	Date of Manufacture (YYYY-MM-DD: Year-Month-Day)
REF	Catalog Number
	Consult instructions for use
NON STERILE	Non Sterile

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