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Flexible Iris Retractor Operating Instructions

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Your Iris Retractor is a limited reuse device. No more than then 3 uses per set is recommended. Optimum performance can be achieved by following these directions for cleaning and sterilization.

DESCRIPTION

The Flexible Iris Retractor is made of bright blue polypropylene fiber and an adjustable silicone stopper for temporary iris fixation during surgery.

INTENDED USE

In cases where iris dilatation cannot be achieved pharmacologically, the Flexible Iris Retractor is a simple, fast and safe alternative. The Flexible Iris Retractor gently stretches and retains the iris for maximum visibility during procedures.

PRECAUTIONS

- This device must be used only by physicians who have received appropriate training.
- Do not use any of the components if the sterile package is damaged in any way.
- Iris Retractors have been ETO sterilized and are intended for single use only.
- Use the device prior to the expiry date shown on the package label.

INSTRUCTIONS FOR USE

1. Peel pouch and remove the container which holds the Iris Retractors.
2. The cornea must be clear to control positioning of the Retractors.
3. Make a self-sealing stab incision at the limbus using 0.5mm wide spatula shaped knife.
4. Hold Retractor with needle holders or forceps near the hooked end, introduce the retractor into the eye through the incision.
5. Turn the needle holder so that the retractor can be hooked to the edge of the iris and retract as much as necessary toward the entry site. Adjust the retractor to the appropriate position and tension by moving the silicone stopper towards the cornea.

Removal:

1. Slide the silicone stopper away from the cornea to release the iris.
2. Unhook the retractor from the iris.
3. Slowly withdraw the retractor from the eye. The hooked end will straighten and slip through the self-sealing incision.

CLEANING

1. Cleaning should take place immediately after surgery to prevent intraocular fluid from drying out.
2. Soak retractors in 3% Hydrogen Peroxide solution for 15 minutes (minimum) to dissolve contaminants.
3. Rinse for 10 minutes (minimum) in warm 80°-100°F (27°C-43°C) distilled water in ultrasonic cleaner.
4. Dry completely at room temperature.
5. Prior to sterilization, inspect the retractor under magnification for product integrity / damage.
6. Place Iris Retractors back to storage/sterilization container.

STERILIZATION

Pre-vacuum steam sterilization: 4 minutes at 270° (132°C) with Iris Retractor container double wrapped in peel pouch.

Warning: If this device is/was used in a patient with or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination!