



IR-2006 Reusable Flexible Iris Retractors DIRECTIONS FOR USE



Description

Reusable Iris Retractor is a limited reuse device. Iris Retractor made of bright blue polypropylene fiber and adjustable silicone stopper for temporary iris fixation. Each package contains six (6) hooks.

Intended Use

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

Precautions

- This device must be used only by physicians who have received appropriate training.
- Iris Retractors have been ETO sterilized.
- It is recommended no more than three (3) uses.
- Do not use any of the components if the sterile package is damaged.
- Use the device prior to the expiry date shown on the package label.

Instructions for Use

Insertion:

1. Peel pouch and remove storage/sterilization container that holds 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 the Retractor with a small needle holder 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 & Sterilization

Cleaning:

1. Cleaning should take place immediately after surgery is finished.
2. Soak retractors in 3% Hydrogen Peroxide solution for a minimum 15 minutes to dissolve contaminations.
3. Rinse for a minimum 10 minutes in warm 80°F-100°F (27°C-43°C) distilled water in ultrasonic cleaner.
4. Dry completely at room temperature.
5. Carefully inspect Iris Retractors under magnification for product integrity.
(Discard damaged devices)
6. Place Iris Retractors back to storage/sterilization container for sterilization.

Sterilization

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