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B-HEX[®] Pupil Expander

Preloaded Iris Retractor Ring

Directions for Use



*Pupil Expansion
Redefined*

Description:

The **B-HEX[®] Pupil Expander** is a thin flexible hexagonal plastic ring with notches, flanges and positioning holes disposed in a single plane.

Each disposable B-HEX ring is preloaded in a housing which presents the sterile device at the incision. The transparent lid allows constant visibility of the device during its travel.

Pupil expansion is achieved when alternate flanges are tucked under the pupil margin and notches at the corners engage the pupil margin.

Intended Use:

The B-HEX Pupil Expander is used to expand the pupil of the eye during cataract or vitreo retinal surgery.

A B-HEX 23 gauge Micro-forceps (not provided) is used for insertion, engagement and removal of the ring.

The 6.5 mm B-HEX ring provides a 5.5 mm expanded pupil.

Caution:

1. Do not use if package or device appears damaged.
2. Do not remove the device from the housing. This may damage it or render it unsterile.
3. The B-HEX is intended for single use and is sold sterile. Do not attempt to sterilize, reprocess or reuse the device.
4. The B-HEX is not an implantable device and has not been tested for implantation. Remove the ring from the eye after its use.

Instructions:

Preparation

1. The B-HEX can be inserted through a 1.5 mm or larger incision and can be removed through a 1.0 mm or larger incision.
2. Rigid Pupils smaller than 4.0 mm are preferably bimanually stretched to about 5.5 mm before placement of the B-HEX.
3. Viscoelastic is injected into the B-HEX housing.
4. Viscoelastic is injected under and over the pupil margin keeping the anterior chamber under-filled. Over-filling pushes the iris against the lens decreasing the space required to tuck the flanges.

Introducing the B-HEX into the Eye

1. The housing is positioned at the main phaco incision.
2. The leading flange of the B-HEX ring is held with the B-HEX 23 gauge Micro-forceps to slide the device through the incision.
3. The ring is completely inserted into the anterior chamber and placed on the Iris.

Engaging the B-HEX® to the Pupil margin

1. Alternate flanges are tucked under the Iris with the Micro-forceps using the main and side-port incisions.
2. Visualization of a flange obscured by corneal periphery can be enhanced by nudging the partially engaged ring centrally.
3. Rarely, a second instrument or a Kuglen hook may be required for bimanual tucking like a 'tire-iron'.
4. Two Sinsky hooks may be used bimanually to push adjacent notches apart to achieve a regular hexagon shaped expanded pupil.

Removing the B-HEX® from the Eye

1. After IOL implantation, with the anterior chamber still filled with viscoelastic, the Micro-forceps is passed through a main or side-port incision to hold the flanges anterior to the iris and untuck the tucked flanges so as to disengage the ring completely and bring it anterior to the iris.
2. The flange closest to the main incision is held and the device is drawn out of the eye.

Symbols used on packaging:



Sterilized using EO Gas



Do not reuse or resterilize this product



Attention, see instructions for use



Do not use if package is open or damaged