It is important to read the Instructions for Use in its entirety
Prior to using the APX 200

℞ Only

Do not reuse

Made in Israel

APX Ophthalmology LTD
25 Yefe-Nof St.
Haifa 3437113 , ISRAEL
TEL: (972)-(4)-8337250
FAX: (972)-(4)-8334213

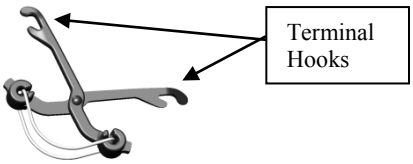
EC REP **CEPartner4U BV**
Esdoornlaan 13,
3951 DB Maarn,
The Netherlands
Tel: (31)-(0)343-442-524
Fax: (31)-(0)343-442-162

CE 0483

Description:

The APX 200 is a Single Patient Single Use device, supplied Sterile, intended for mechanical pupil expansion in intraocular surgery.
The APX 200 kit consists of two Iris Expanders positioned in a designated base and two specialized forceps:

Expander



Specialized Forceps

Base

Intended Use:

The APX 200 is intended to provide expansion of the pupillary aperture in cases of constricted pupil or intraoperative floppy iris syndrome (IFIS) to allow comfortable visualization and facilitate intraocular surgery.

Contraindications:

The device is contraindicated for use in cases of:

- Obscured visualization of the pupillary aperture
- Severe damage to the iris

Warnings:

- DO NOT RESTERILIZE. Reusing the device may result in biocontamination, degraded performance, mechanical/material failure, or loss of functionality. This product is not designed or validated to be cleaned, disinfected, or sterilized by the user.
- For single patient single use only.
- Prior to use, inspect the device package and the product itself for signs of damage or tampering. If tampering or damage exists, do not use. If the sterile package is not sealed, do not use.
- Do not use the kit after the expiration date.
- It is imperative that the surgeon and operating room staff be fully conversant with the appropriate surgical technique prior to using this device.

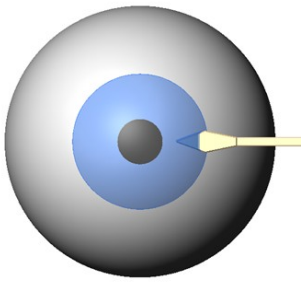
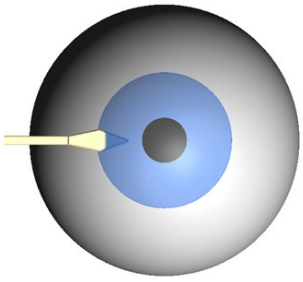
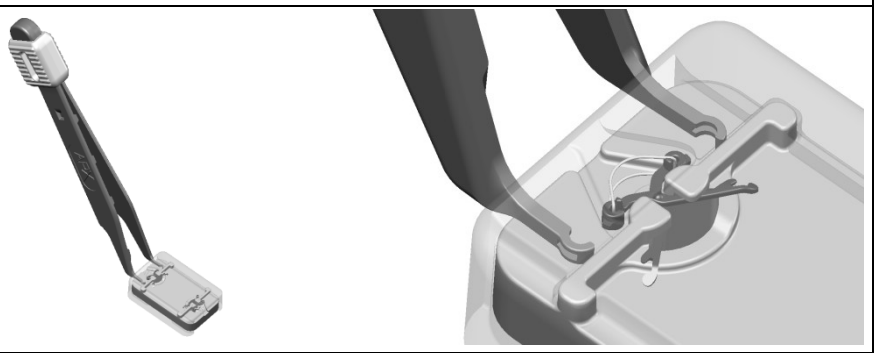
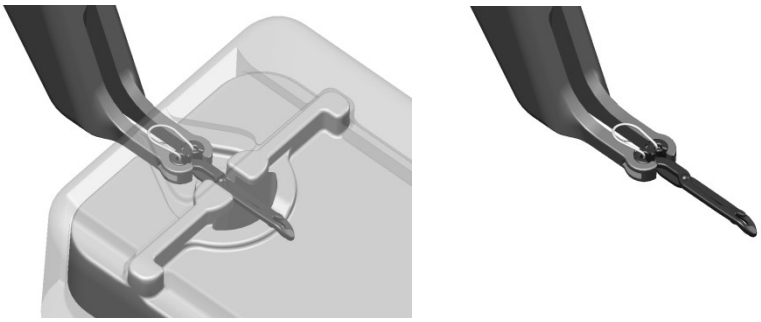
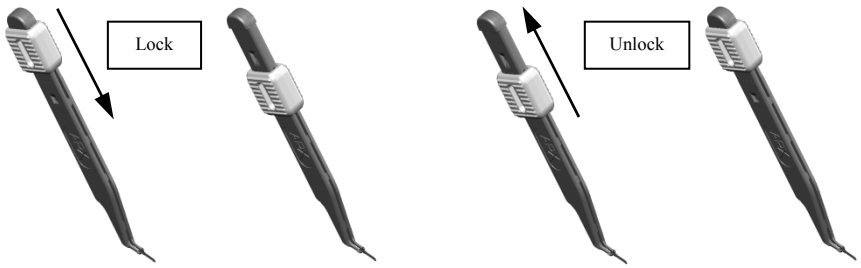
Precautions:

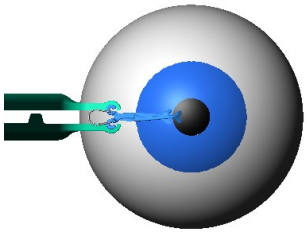
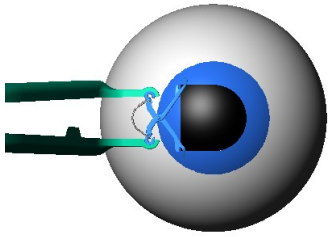
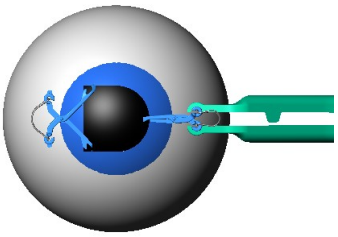
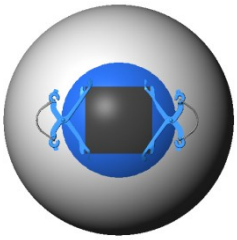
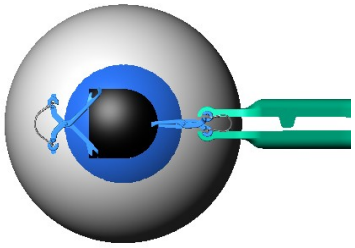
- The two arms of the device should be fully closed during insertion to prevent damage to the cornea such as endothelial touch or descemet's membrane detachment.
- The anterior chamber should preferably be filled with Ophthalmic Viscosurgical Devices (OVDs) to allow smooth insertion and positioning of the terminal hooks.
- The arms of the APX should be opened slowly, under direct and clear visualization to prevent damage to adjacent tissues such as the corneal endothelium or the lens capsule.
- Removal of the APX should be done only after the device is fully closed and stabilized and the anterior chamber is filled with OVDs.

Adverse Effects:

- If not closed properly, the terminal hooks of the APX 200 may cause damage to the ocular tissues during insertion and removal.
- Over stretching of the pupil may cause permanent damage to the sphincter resulting in a fixed and irregular pupil postoperatively.
- Stretching of the pupil may cause bleeding from iridal vessels.
- The terminal hooks may rub against the anterior capsule and cause capsular breaks and rupture.
- Fluid may leak through the corneal incisions through which the device is inserted and anchored.
- Iris manipulation may increase intraocular inflammation.

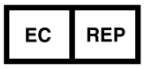
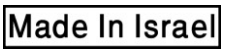
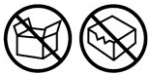
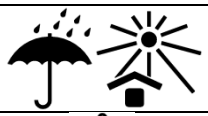
Instructions for use:

Perform a standard corneal incision parallel to iris plain at the corneal limbus using a 19G blade. Fill the anterior chamber with a cohesive Ophthalmic Viscosurgical Devices (OVDs). Inject some OVDs between the iris and the anterior capsule to create space for the APX 200 terminal hooks.	
Perform another incision on the opposite side.	
Use the designated forceps to manipulate the Expanders. Make sure the Expander is fully closed to enable disengagement from the base. Make sure that during engagement the tips of the forceps are properly positioned in relation to the Expander and the Expander is fixed and stable.	
Close the arms of the Expander fully before detachment from the Base.	
The specialized forceps are equipped with a locking mechanism, to enable locking preloaded forceps either by the physician or the assistant in advance. The locking mechanism is operated by sliding the Slider lock when the forceps are fully closed, down to lock, up to unlock.	

Close the arms of the Expander fully, insert the Expander through the paracenthesis under direct visualization. Push the expander all the way, until the pivot pin is located within the corneal tunnel.	
Slowly release the forceps grip and open the Expander. It is advisable to partially open the Expander, place the terminal hooks through the pupil under the iris and then open the Expander as shown below. Try to avoid contact or pressure on the anterior lens capsule. Do not completely release the Expander until the device is properly positioned.	
Perform the same procedure on the opposite side.	
Make sure that the devices are properly positioned and stable and that the terminal hooks are located behind the iris. Check for capsular damage, iris defects and wound leak.	
Removal of the Expander at the end of intraocular surgery is done using the same designated forceps. Make sure that the forceps are properly positioned and fixated, slowly close the Expander arms until they are firmly closed and pull out the device under direct visualization.	

Storage conditions
The APX 200 should be stored at 10 - 30°C.

Symbols on Labeling:

	**Single use only / Re-use is not allowed**
	**See Instructions for Use**
	**Manufacturer**
	**Authorized Representative in the European Community**
	**Made In Israel**
	**Caution: Federal (USA) law restricts this device to sale by or on the order of a physician**
	**Use by (Expiration date)**
	**Catalogue number**
	**Lot Number - Manufacture date: YYMMAA (AA=The number of the lot in this month)**
	**Do not use if package is damaged or open**
	**Keep away from sunlight** **Keep dry**
	**Temperature limit (see storage conditions)**
	**Sterilization using Ethylene Oxide**
	**CE Mark**
	**Do not re-sterilized**