Glaukos® iAccess® Precision Blade
INSTRUCTIONS FOR USE

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DEVICE DESCRIPTION

The Glaukos® iAccess® Precision Blade is a sterile, single-use, disposable ophthalmic instrument.

Catalogue #	Description
AX1	Glaukos® iAccess Precision Blade

INDICATIONS FOR USE

The Glaukos® iAccess Precision Blade is intended for use in ophthalmic surgical procedures to manually cut trabecular meshwork (TM) in pediatric and adult patients.

INSTRUCTIONS FOR USE

A. Inspect the device for damage and use care when removing from packaging and handling device. Cutting edge must remain sharp and can be damaged if contacted. Tip protector should remain in place if the instrument is placed onto the sterile tray.
B. Place a gonioprism onto the cornea and adjust the angle of the patient's head and surgical microscope as needed to visualize the TM.
C. The anterior chamber should be inflated with viscoelastic when using the iAccess Precision Blade.
D. Insert the iAccess Precision Blade into the eye through a temporal, clear corneal incision (≥ 1.5 mm) opposite the desired site of tissue perforation. Take care not to damage the corneal endothelium or iris, and prop open the incision as needed in order to safely pass the blade into the eye.
E. Advance the blade tip to penetrate the TM at a location opposite the corneal incision. With the tip of the instrument contacting the TM directly over the Canal of Schlemm, perform one of the following techniques:
    - Apply forward pressure with slight rotation (if necessary) to cut the tissue. Cutting depth is limited by shoulder of support tube to prevent over insertion. Multiple incisions are performed opening the TM over an area of ≥ 90 degrees.
    - Apply forward pressure, press and slide the tip of the blade against the TM to create a contiguous incision for at least 3 clock hours.
F. Upon exposure of Schlemm's Canal, and depending on the pressure in the eye, blood may reflux into the anterior chamber from the collector channels. Viscoelastic or balanced salt solution (BSS) can be used to tamponade or clear blood to improve visualization.
G. A unlimited number or size of incisions of the TM may be achieved without removing the device from the eye.
H. Irrigate the anterior chamber with (BSS) through the corneal wound to remove all viscoelastic. Press down on the posterior edge of the incision as needed to facilitate complete removal of viscoelastic.
I. Inflate the anterior chamber with saline solution as needed to achieve normal physiologic pressure.
J. Ensure that the corneal incision is sealed.
K. Dispose of the device after use in accordance with facility standard operating procedures for sharps and medical waste.

WARNINGS / PRECAUTIONS

- For prescription use only.
- Physician training is required prior to use of the iAccess Precision Blade, including intraoperative gonioscopy.
- Do not use the Glaukos iAccess Precision Blade if there is poor visualization of angle structures. Improper visualization could result in damage to adjacent eye structures.
- Do not use the device if the Tyvek lid has been opened or the packaging appears damaged. In such cases, the sterility of the device may be compromised.
- Do not re-sterilize or reuse the device as this may result in infection and/or intraocular inflammation, as well as occurrence of potential postoperative adverse events.
- Used or unused product and packaging may be disposed of in accordance with facility procedures for handling Sharps and medical waste.

CONTRAINDICATIONS

The Glaukos iAccess Precision Blade is contraindicated under the following circumstances or conditions:

- In eyes where there is poor visualization of angle structures.

HOW SUPPLIED

The Glaukos iAccess Precision Blade is supplied sterile and in a Tyvek-sealed blister tray with removable Sharps protector attached. The device has been sterilized by gamma radiation. One device is supplied in each unit carton. Each unit is labeled with a lot number that is provided on both the tray lid and unit carton.

EXPIRATION DATE

The expiration date on the device package (tray lid) is the sterility expiration date. In addition, there is a sterility expiration date that is clearly indicated on the outside of the unit carton. Sterility is assured if the tray seal is not punctured or damaged until the expiration date. This device should not be used past the indicated sterility expiration date.

STORAGE REQUIREMENTS

The device should be stored at room temperature (15°-30°C).

LABELING

The following symbols are used on the device packaging.

Symbol	*Definition*	*Symbol*	*Definition*
REF	Catalogue/Model Number		Do not use if package is damaged
LOT	Lot Number	STERILE R	Sterilized by Gamma Irradiation
	Do not re-use	RxOnly	For prescription use only
yyyy-mm-dd	Use By (year-month-day)		Consult Instructions For Use.
15°C 30 °C	Temperature Storage Requirements		

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CAUTION: Federal law restricts this device to sale by, or on the order of a physician.

Patent Pending