Glaukos® iAccess® Precision Blade
INSTRUCTIONS FOR USE

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

Catalogue #	Description
AX1	Glaukos iAccess Precision Blade

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

INTENDED USE
The Glaukos iAccess Precision Blade is an ophthalmic surgical tool intended to manually cut trabecular meshwork (TM) in pediatric and adult patients.

INDICATIONS FOR USE
The Glaukos iAccess Precision Blade is a surgical tool used to manually cut the trabecular meshwork (TM).

INTENDED PATIENT POPULATION
The target patient population is pediatric and adult patients who require cutting of the TM.

CONTRAINDICATIONS
The Glaukos iAccess Precision Blade is contraindicated under the following circumstances or conditions:
- In eyes where there is inadequate visualization of angle structures.
- In eyes with angle closure glaucoma where angle has not been surgically opened
- In eyes with acute traumatic, malignant, or active neovascular glaucoma
- In patients with retrobulbar tumor, thyroid eye disease, Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure

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 device into the eye.
E. Advance the blade tip to penetrate the TM at a location opposite the corneal incision. With the tip of the blade 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 the shoulder of the 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. An 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.
- The following conditions may prohibit sufficient visualization required for safe and successful use: corneal edema, corneal haze, corneal opacity, hyphema, excessive patient movement or any other conditions that may inhibit surgeon view. 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.

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

LABELING
The following symbols are used on the device packaging.

Glaukos® iAccess® Precision Blade
INSTRUCTIONS FOR USE

Symbol	*Definition*
REF	Catalogue/Model Number
LOT	Lot Number
	Do not re-use
yyyy-mm-dd	Use By (year-month-day)
	Do not use if package is damaged
STERILE R	Sterilized by Gamma Irradiation
Rx Only	For prescription use only
	Consult Instructions For Use.
	Temperature Limit
QTY	Quantity
	Single *sterile* barrier system with protective packaging outside
	Importer
EC REP	Authorized representative in the European Community
CE	CE Marking
MD	Medical Device
UDI	Unique Device Identifier
	Manufacturer
	Date of Manufacture

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Report all product complaints and incidents immediately to Glaukos at MedicalSafety@glaukos.com. Upon receipt, Glaukos will assess the event for reportability and report the event to the national Competent Authority as required.

Patent Pending