MIST AB INTERNO

Hexiris

REF *020-1200*

DIRECTIONS FOR USE

Investigational Device / Instrument de recherche

To be Used by Qualified Investigators Only / Réservé uniquement à l'usage de chercheurs compétents

Investigator shall refer to 020-0026 for device clinical use technique

DEVICE DESCRIPTION:

The Hexiris MIST (microinvasive scleral trephine) injector is a manual, non-powered instrument intended for use by qualified physicians to create a channel through the sclera allowing flow of aqueous humor from the anterior chamber into the subconjunctival space.

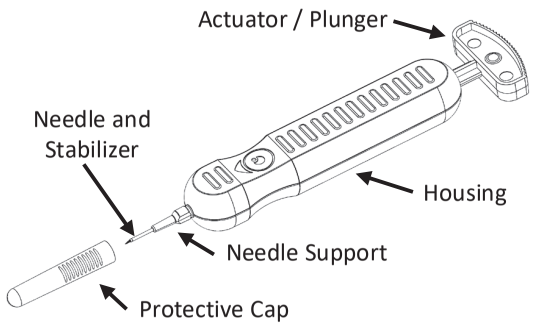
The Hexiris MIST device is indicated for use in adult patients with moderate to advanced glaucoma that is unresponsive to maximum tolerated medical therapy and/or has a rapid rate of progression with risk of symptomatic disability.

The Hexiris MIST device is intended to be used in ophthalmic procedures, including those for glaucoma treatment and/or cataract treatment. In this use, the devices contact the internal and external structures of the eye including the conjunctiva, sclera, tenon, trabecular meshwork, aqueous humour and cornea.

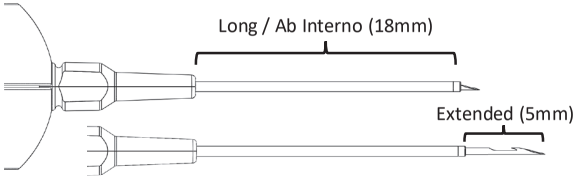
The MIST device is intended to be used by qualified, trained physicians including glaucoma specialists and comprehensive ophthalmologists.

The MIST device is intended for use in a clinical setting. The ab interno device is intended for use in a traditional ophthalmological operating room.

The MIST device features a single-use sterile injector assembly. Components of the device are shown below:



The device features short and long configurations allowing either ab externo or ab interno approaches. The diagram below shows the long / ab interno configuration in both retracted (rest) and extended positions:



020-0027-01

Product REF	Product Configuration	
	Description	Needle Gauge
020-1200	MIST Injector Ab Interno	27

INDICATIONS FOR USE:

The Hexiris MIST device is intended for reduction of intraocular pressure in eyes of patients with primary open angle glaucoma where IOP remains uncontrollable while on maximum tolerated medical therapy, where previous surgical treatment has failed, or where glaucoma progression warrants intervention.

CONTRAINDICATIONS:

Use of the MIST Injector is contraindicated under the following circumstances or conditions:

- *Angle-closure glaucoma*
- *Previous glaucoma shunt or valve in the treatment quadrant*
- *Eyes with conjunctival scarring, prior conjunctival surgery or other pathologies in the treatment quadrant*
- *Eyes with scleral thinning, staphyloma, or structural abnormalities in the treatment quadrant*
- *Active inflammation (e.g. blepharitis, conjunctivitis, keratitis, uveitis)*
- *Active or recent (within 6 months) iris neovascularization in the treatment quadrant*
- *Impaired episcleral venous drainage*
- *Anterior chamber intraocular lens*
- *Patients with uncontrolled bleeding disorders or those receiving anticoagulation therapy without appropriate perioperative management*
- *Patients unable to comply with postoperative follow-up or treatment instructions*

POTENTIAL ADVERSE EVENTS:

The complications that may occur in conjunction with the use of the MIST Injector includes, but are not limited to, *eye injury, choroidal effusion, hyphema, hypotony, hemorrhage, conjunctival complications (tear, ulcer, bleb leak, blebitis, fibrosis), iridodialysis, corneal complications (abrasion, edema, ulceration, endothelial cell loss), infections or inflammatory conditions (endophthalmitis, uveitis, conjunctivitis, keratitis, toxic anterior segment syndrome TASS), flat/shallow chamber, elevated IOP, and the need for secondary surgical intervention. Adverse events and/or potentially sight-threatening complications that are reasonably associated with the use of the MIST device must be reported to Hexiris, Inc.*

WARNINGS AND PRECAUTIONS:

- Device is for single-use only. Do not reuse the device. Do not re-sterilize the device.
- Store device at controlled room temperature, within the temperature and humidity limits specified in labeling. Avoid direct sunlight and water contact. If the device is stored in conditions that exceed these limits, do not use the device.
- Do not use the device beyond the expiration date month-year specified in labeling. Device may be safely used during the labeled month of expiration, if desired.
- Confirm package is intact and not damaged. Do not use the device if the package is damaged, opened, or contaminated.
- Carefully inspect the device prior to use. Do not use the device if damage or contamination is suspected.
- Upon cap removal, avoid contact with sharp tip. Injury may result.
- Do not press the actuator to extend the needle while the cap is in-place. This will damage the needle and create potential for eye injury.

DEVICE WARNINGS AND PRECAUTIONS (CONT):

- Confirm needle travel prior to use. Press actuator and confirm acceptable extension and full retraction.
- Confirm understanding of the device technique, required hand orientation and capabilities / limitations of the vision system before starting procedure.
- Confirm adequate anesthesia and patient positioning to prevent uncontrolled movement during the procedure.
- Carefully inspect the device following use. Confirm that no damage has been sustained and no device fragments have been created.
- The patient's IOP should be monitored post-procedure. If IOP is not adequately maintained, appropriate additional therapy to maintain IOP should be considered.
- Dispose according to local regulations and facility requirements for biohazards and sharps.

MATERIALS COMPLIANCE:

- This device does not contain latex, restricted substances in accordance with ROHS directive 2002/95/EC, or animal derivatives.
- The device needle contacting aqueous humor has been confirmed to have < 0.2 EU (endotoxin unit) level as required for ophthalmic medical devices per ANSI/AAMI ST72.

SYMBOLS GLOSSARY:

Symbol	Reference	Symbol Title	Description
LOT	ISO 15223-1, 5.1.5	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
QTY	N/A	Quantity	Package or Box Quantity
REF	ISO 15223-1, 5.1.5	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	ISO 15223-1, 5.3.4	Keep dry	Indicates a medical device that needs to be protected from moisture.
	ISO 15223-1, 5.4.4	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot be presented on the medical device itself.
STERILE R	ISO 15223-1, 5.2.4	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation
	ISO 7000-3709	N/A	Single barrier with protective outer packaging
Rx only	21 CRF 801.109	Prescription only	Use only by trained medical personnel. Requires prescription in the United States.
	ISO 15223-1, 5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC AND 98/79/EC.
	ISO 15223-1, 5.1.3	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1, 5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1, 5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1, 5.3.8	Humidity Limit	Indicates the humidity limits to which the medical device can be safely exposed.
	ISO 15223-1, 5.3.7	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1, 5.4.2	Do not re-use	Indicates a device that is intended for one use or for use on a single patient during a single procedure.
	ISO 15223-1, 5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use.

MANUFACTURER CONTACT

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