Hexiris

REF 020-2600 020-2610 020-2700 020-2710

SAFE

SCLERAL **A**CCESS **F**ILTRATION FOR **E**YE PRESSURE

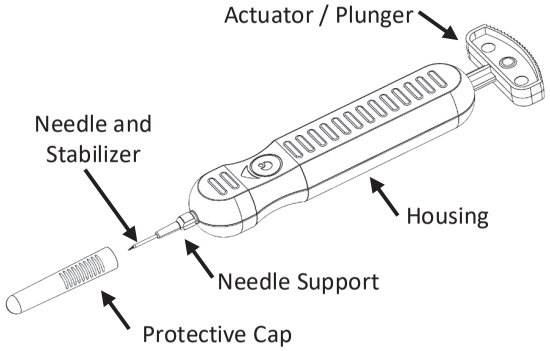
DIRECTIONS FOR USE

INDICATIONS FOR USE:

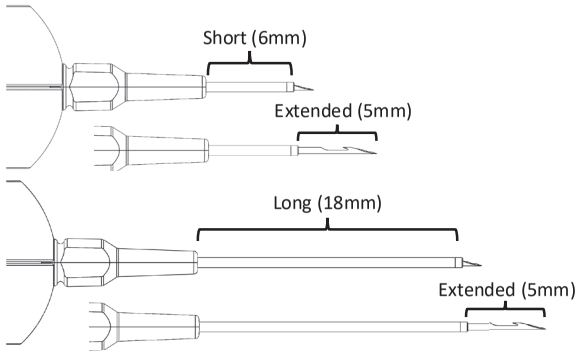
The Hexiris SAFE device is indicated for use in ophthalmic procedures where a sclerostomy may be required as part of the treatment protocol.

DEVICE DESCRIPTION:

The Hexiris SAFE device is a manual, non-powered instrument that may be used to create a channel through the sclera allowing flow of aqueous humor from the anterior chamber into the subconjunctival space. The SAFE device features a single-use sterile device assembly. Components of the device are shown below:



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



The device features multiple gauge configurations to allow the user to optimize the sclerostomy to the needs of the procedure. **Note that not all configurations are available in all markets.**

Product REF	Product Configuration		Ostomy Size (Approx)
	Description	Needle Gauge	
020-2600	SAFE 26ga – 6mm	26	150µm x 300µm
020-2610	SAFE 26ga – 18mm	26	
020-2700	SAFE 27ga – 6mm	27	100µm x 250µm
020-2710	SAFE 27ga – 18mm	27	

DIRECTIONS FOR USE:

A. Inspect the device for damage and use care when removing from packaging and handling the device. Needle cutting edge must remain sharp and can be damaged if contacted. Retain protective cap in place until use.
B. Remove cap and confirm needle travel prior to use. Press actuator and confirm acceptable extension and full retraction.
C. A gentle air or viscoelastic pre-dissection and elevation may be performed beneath the conjunctiva in the target bleb region prior to use.
D. EXTERNO: Insert the needle beneath the conjunctiva approximately 5-6mm posterior to the limbus. Advance the needle until the tip is positioned 1-1.5mm posterior to the limbus.
E. INTERNO: Insert the needle into the corneal incision and advance into the trabecular meshwork of the eye at the desired location.
F. Adjust the angle of approach so that the needle trajectory is parallel to the iris plane. With the stabilizer end fixed against the sclera (Externo) or trabecular meshwork (interno), depress the actuator slowly, advancing the needle through the sclera.
G. With the stabilizer still fixed, release the actuator slowly, allowing full needle retraction.
H. Slowly pull on the device to remove from the eye. **If resistance is felt, stabilize the device against the eye with one hand and use a second hand to gently pull the actuator back manually to shear any residual tissue.**
I. Complete procedure per physician discretion. Monitor eye intraocular pressure (IOP) post-procedure; consider additional therapy as required.
J. Dispose according to local regulations and facility requirements for biohazards and sharps.

WARNINGS:

- For prescription use only by licensed healthcare professionals. Physician training is required prior to use of the device.
- Device is supplied sterile for single-use only. Do not reuse the device. Do not re-sterilize the device.
- 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.
- **Do not use the device if there is poor visualization of the angle structures.**
- **Ensure that the trajectory angle and insertion location of the needle are appropriate prior to actuation. Avoid iris or corneal contact—if noticed, reposition the entry point more anteriorly or posteriorly as appropriate.**
- **Do not force the stabilizer into the sclera. Keep the marked end of the stabilizer gently fixed against the surface during the entire coring stroke.**
- **Do not modify device angle at any point after actuation. Moving the device may result in an oversized ostomy.**
- **Do not withdraw the device until the needle has fully retracted to avoid tissue damage. Refer to direction 'H' above.**

PRECAUTIONS:

- Store device at controlled room temperature, within the temperature and humidity limits specified in labeling. Avoid direct sunlight and water contact.
- 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.
- 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. Upon cap removal, avoid contact with sharp tip - injury may result.

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.

All adverse events that may be device related, regardless of the severity, must be reported to Hexiris.

MANUFACTURER CONTACT

Hexiris

5085 Principale-Est Ave, Dieppe, New Brunswick, E1A 9T8, Canada

www.hexiris.ca info@hexiris.ca