SION

SION® SURGICAL INSTRUMENT

Instructions for Use

Sight Sciences®

SION

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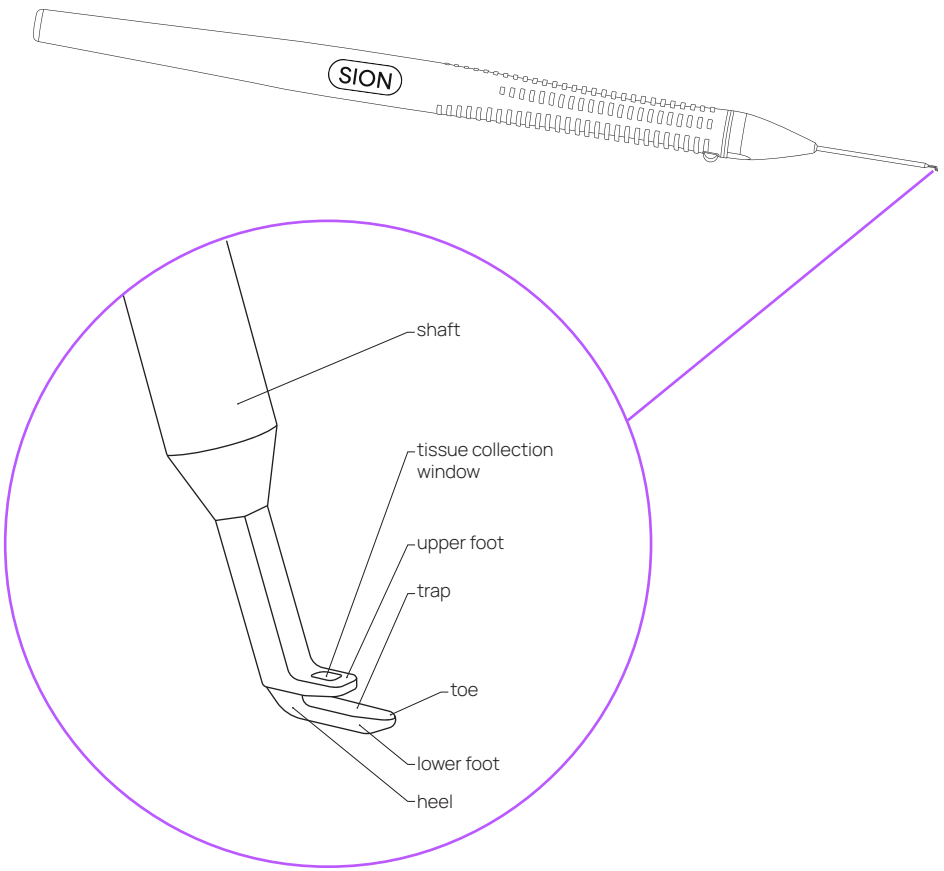
Device Description

The Sight Sciences SION® Surgical Instrument ("SION") is a hand held, single use, sterile, bladeless surgical instrument. The tool utilizes a blunt tip capable of accessing Schlemm's canal via an ab interno approach to bladelessly excise the trabecular meshwork (TM) through grasping and tearing during goniotomy.

Figure 1. SION Surgical Instrument



CAUTIONS

1. Federal (USA) law restricts this device to sale, distribution, or use by or on the order of a physician.
2. Observe the usual precautions undertaken during intraocular surgery.
3. Use aseptic techniques and ensure SION instrument and field sterility as is customary during intraocular surgery.
4. Contents are sterile when the package is sealed and undamaged. Do not use it if the product or seal appears damaged or is past its expiration date.
5. This product is sold in a STERILE condition and is intended for single use. Do not reuse or re-sterilize the product.
6. If the device appears damaged, do not use it.
7. Handle the SION instrument carefully to avoid damaging it.

INDICATIONS FOR USE

The SION Surgical Instrument is a manually operated device used in ophthalmic surgical procedures to excise trabecular meshwork. The SION Surgical Instrument is a sterile, single use device.

CONTRAINDICATIONS

1. Do not use the SION in any situations where the anterior chamber angle has been damaged (i.e., from trauma or surgery) or it may not be possible to pass the device through Schlemm's canal.
2. The SION is contraindicated in patients with angle recession, neovascular glaucoma, chronic angle closure, narrow angle glaucoma, narrow inlets with plateau iris, peripheral anterior synechiae, traumatic, malignant, or uveitic glaucoma.
3. The SION is contraindicated in patients who have had previous argon laser trabeculoplasty, ab interno devices implanted in or through Schlemm's Canal, or prior incisional glaucoma surgery including trabeculotomy, goniotomy.
4. Do not use the SION if there is inadequate corneal clarity, or poor visualization of angle structures.

WARNINGS

Always maintain direct microscopic and gonioscopic visualization of the instrument tip during the procedure to avoid inadvertently damaging intraocular structures.

Avoid touching the SION tip to any surfaces as this may damage it.

Do not use the SION tip to create a corneal incision.

CONSIDERATIONS

A surgical microscope with appropriate magnification, and gonioprism, are required to visualize the anterior chamber angle and the SION during its use.

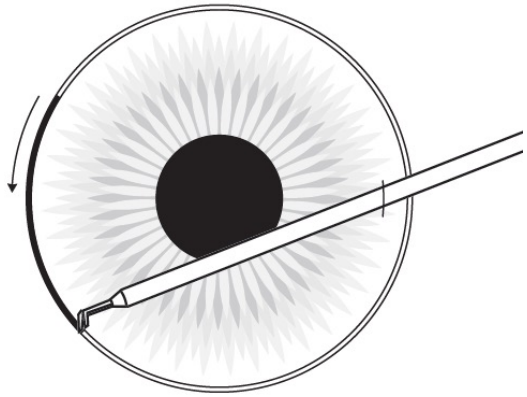
For a proper visualization of the anterior chamber angle, position the patient's head and adjust the microscope's tilt.

The SION is inserted into the eye through a pre-existing clear corneal incision of at least 2mm width. The anterior chamber is maintained with ophthalmic viscosurgical device (OVD). See Figure 2 .

a. The corneal entry incision should be created roughly 180 degrees away from the trabecular meshwork (TM) that is to be bladelessly excised.

b. Do not use the SION tip to make a corneal incision.

Figure 2: Entry and advancement of SION



Directions for Use

REMOVING SION FROM ITS PACKAGING

a. Inspect and ensure the carton packaging is not damaged.

b. Remove the packaged SION tray from the shelf carton and inspect to ensure there is no damage to the sterile barrier.

c. Open the sterile lid barrier from the tray using the exposed edges.

d. First, remove the tray insert (1). Then, remove SION from the packaging tray (2), making sure to hold the textured grip (Figure 3).

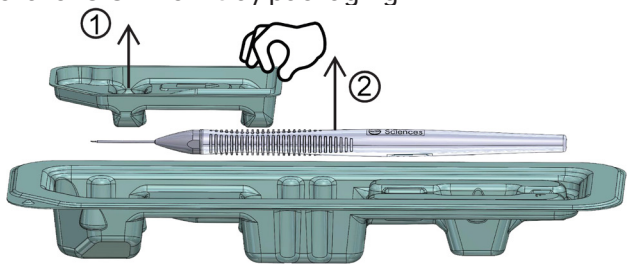
Caution: Handle the SION device carefully to avoid kinking or damaging the tip. Avoid touching the tip to any unintended surfaces as this may damage or compromise cleanliness of the tip.

e. Inspect the SION device for damage.

Caution: If the SION device appears damaged, do not use it.

f. Set SION aside within the sterile field.

Figure 3: Removal of SION from tray packaging



SURGICAL PROCEDURE

The following are the directions for how to use the SION Surgical Instrument:

a. The tip and the shaft of the SION is carefully and slowly advanced into the anterior chamber through the pre-existing corneal incision.

b. Advance the instrument tip into the anterior chamber and towards the angle under direct microscopic visualization.

c. When nearing the angle (and thus the trabecular meshwork), apply a gonioscope or gonioprism to the cornea to visualize the angle. A viscous fluid may be used to couple the gonioscope or gonioprism to the cornea as recommended by the gonioscope manufacturer.

d. Under gonioscopic visualization, identify the anatomic landmarks of the anterior chamber angle: Ciliary body, scleral spur, trabecular meshwork, and Schwalbe's line.

e. With the trabecular meshwork identified, use the toe (Figure 4) of the SION to puncture the trabecular meshwork and advance the lower foot into Schlemm's canal (Figure 5).

Figure 4: Entry with toe of SION

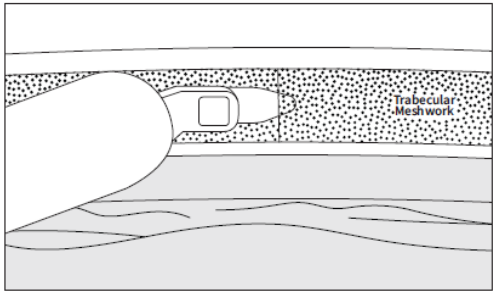
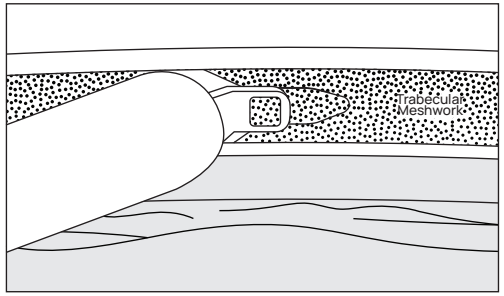


Figure 5: Advancing the foot in Schlemm's Canal



Advance the instrument in the direction of the TM that you intend to excise through grasping and tearing by keeping the toe in Schlemm's canal, and the lower foot resting against the outer wall of Schlemm's canal. The TM behind the bladeless instrument is pulled from its attachments at or near the scleral spur and Schwalbe's line.

f. TM will accumulate in the trap and tissue collection window of the device. (Figure 6,7)

Note: Do not angle the heel away from the back wall such that the lower foot would engage the TM of the Schlemm's canal as this will prevent smooth advancement.

Figure 6: Proper placement of SION

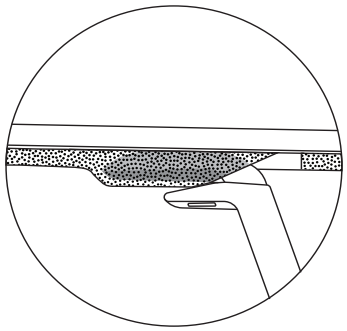
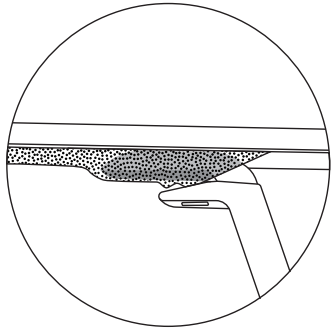


Figure 7: Tissue accumulation and advancement



g. Blood reflux can be experienced during this step. OVD can be used to improve visualization of the area that you want to treat.

h. Advance the SION several clock hours until you reach the desirable size of goniotomy.

i. Once goniotomy is complete, the SION can be removed from the eye. Residual tags of trabecular meshwork may be removed with micro-forceps or aspiration.

Postoperative Instructions:
Patients should be observed postoperatively for intraocular pressure increases.

Potential Adverse Events

ADVERSE EVENTS

Adverse events that may be reasonably associated with the use of the instrument include but are not limited to the following: anterior chamber shallowing, prolonged, or persistent intraocular inflammation, aqueous misdirection, choroidal effusion, suprachoroidal hemorrhage, Descemet's membrane tear or detachment, corneal decompensation, corneal injury, corneal edema or opacification, intracorneal hematoma, cyclodialysis cleft, damage to posterior wall of Schlemm's canal, hyphema, hypopyon, hypotony, hypotonic maculopathy, IOL dislocation, iris injury, tear, or iridodialysis, loss of vitreous, perforation of sclera, posterior capsular bag rupture, posterior capsule opacification, proliferative vitreoretinopathy, pupillary block, pupillary membrane formation, retinal detachment, retinal dialysis, retinal tears, vitreous hemorrhage, elevated IOP requiring treatment and endophthalmitis.

ADVERSE EVENT REPORTING

Adverse Events and/or potentially sight-threatening complications that are reasonably associated with the use of the SION Surgical Instrument must be reported to Sight Sciences, Inc.

Manufactured by: SIGHT SCIENCES, Inc.
4040 Campbell Ave Ste 100
Menlo Park, CA 94025
Customer Service: 1-877-266-1144

How Supplied

Catalog Number	Description
1-107	SION Surgical Instrument

STORAGE REQUIREMENTS

-18°C to +60°C temperature & 15% to 90% non-condensing humidity

EXPIRATION DATE

The expiration date on the SION package is the sterility expiration date. Sterility is assured if the packaging is not punctured or damaged until the expiration date.

DEVICE DISPOSAL

Dispose of the SION Surgical Instrument following your facility's procedures for sharps and hazardous waste.

RETURNED GOODS POLICY

Please contact Sight Sciences, Inc.

LABELING

The following symbols are used on the SION packaging

Symbol	Title of Symbol	ISO 7000 Reg. no	Definition
	Catalog Number	2493	Indicates the manufacturer's catalogue number so that the device can be identified.
	Batch Code	2492	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Do not re-use	1051	Indicates a device that is intended for one use.
	Use by Date	2607	Indicates the date after which the device is not to be used.
	Manufacturer	3082	Indicates the device manufacturer
	Sterilized using irradiation	2502	Indicates a device that has been sterilized using irradiation.
	N/A	N/A	For prescription use only
	Keep dry	0626	Indicates a device that needs to be protected from moisture
	Consult instructions for use	1641	Indicates the need for the user to consult the instructions for use.
	Do not use if package is damaged and consult instructions for use	2606	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	Temperature limit	0632	Indicates the temperature limits to which the device can be safely exposed.

MANUFACTURER

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Menlo Park, CA 94025

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