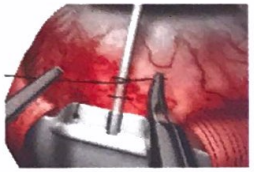
Step 4:

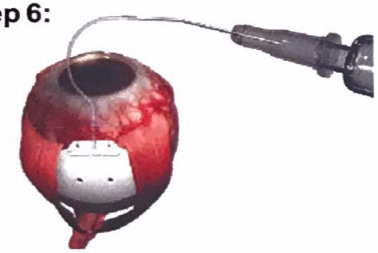


A non compressing mattress suture stabilizing the tube to the sclera is placed

Step 5:

Temporary tube occlusion is accomplished by ligating it with 6-0 Polycryl (Absorbable) suture.

Step 6:

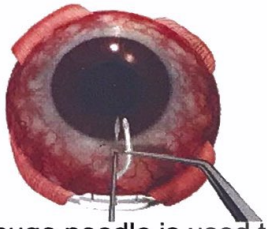


Complete closure is confirmed by attempting to irrigate balanced salt solution through the tube. The absorbable suture reliably lyses 5 to 6 weeks post operatively causing spontaneous opening of the tube.

Step 7:

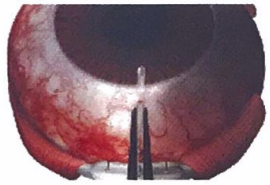
The tube is draped across the cornea and cut with an anterior bevel so that a 2 to 3 mm segment of the tube extends into the anterior chamber from the site of limbal entry.

Step 8:



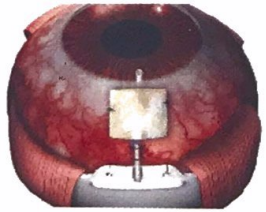
A 23 gauge needle is used to make an entry incision into the anterior chamber at the posterior limbus parallel to the iris plane.

Step 9:



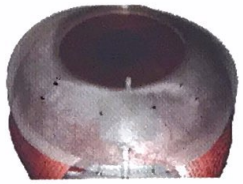
The tube is inserted through the needle track, proper positioning of the tube anterior to the iris and posterior to the cornea should be confirmed

Step 10:



The limbal portion of the tube is covered with a donor scleral/corneal patch graft. The graft is sutured in place with interrupted sutures.

Step 11:



The conjunctiva is closed by reapproximating it to the limbus with mattress sutures and a running closure for radial relaxing incisions.

Symbols used on labeling

	Do not reuse
	Do not resterilize
	Manufacturing Date
	Should not use after the specified month and year
	Consult Instructions For Use
LOT	Lot Number
STERILE EO	Method of sterilization using ethylene oxide
	Attention, see Instructions For Use
	Do not use if package is damaged
	Manufacturer Symbol
45°C	Upper limit of temperature
CE 0197	CE-mark and identification number of notified body. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC.
EC REP	Authorized Representative in the European Community

Manufacturer :
Aurolab,
I, Sivagangai Main Road,
Veerapanjan,
Madurai - 625 020, India.
Tel : 91 452 309 6100
Fax : 91 452 244 6200
E.mail : sales@aurolab.com
Web : www.aurolab.com

EC REP
mdi Europa GmbH
Langenhagener Straße 71,
D-30855 Langenhagen, Germany
Phone:+49 511 39089530 .
Fax: +49 511 39089539
E-mail: info@mdi-europa.com

Issue - 04 TSSNPM - 63 04/16

aurolab CE 0197

aurolab aqueous drainage implant

aadi

aadi Description:

The **aadi** is a non valved aqueous drainage sterile implant that shunts aqueous via a tube to an episcleral plate centered over the equatorial region of the globe. It is made of permanent Implant medical grade silicone elastomer that has passed tissue culture cytotoxicity test. The surface area of the **aadi** end - plate is 350 mm^2 and molded to conform to the curvature of the globe with a 13mm convex radius and the silicone tube length is 35mm. The proximal portion of the plate has two fixation holes for scleral attachment. The end- plate of the **aadi** has fenestration that allow growth of fibrous bands reducing the profile of the bleb.

The silicone plate is barium impregnated to increase ultrasound resolution and identification with the CT Scan, MRI, and plain skull films.

Model	**aadi** - 350
Surface Area	350 mm^2
Plate Length	31 mm
Tube Length	35 mm
Insertion	Anterior Chamber
Style	Straight Tube

Indications:

The **aadi** is used to manage medically uncontrolled glaucoma when trabeculectomy has failed or is unlikely to succeed such as, but not limited to primary open angle glaucoma, primary angle closure glaucoma,pseudophakic/aphakic glaucomas,neovascular glaucoma, congenital/developmental glaucomas, uveitic glaucoma, sturge - weber glaucoma.

Warnings:

Do not use the device if sterile package integrity has been compromised. Do not resterilize the implant by any method. Do not reuse the implant. Do not store at temperature above 45°C (113° F). Store aadi away from strong acids and oxides.

Contraindications:

Bacterial conjunctivitis, bacterial corneal ulcers, endophthalmitis, orbital cellulitis, bacteremia or septicemia, active scleritis and/or no light perception.

Complications/Adverse Events:

The complications during and after surgery include, but are not limited to:

chorodial hemorrhage, hyphema, serous choroidal effusion, hypotony, flat anterior chamber, phthisis bulbi, retinal detachment, endophthalmitis, tube erosion, tube touch to cornea, tube block by iris or vitreous, bullous keratopathy, uveitis and diplopia. There is no undesirable side effects are foreseen after surgery.

Directions for use:

A high level of surgical skill is required for the implantation of artificial drainage devices. Correct patient selection, meticulous surgery and post operative care are required.

Implant preparation:

The implant should be grossly examined and the patency of the tube is confirmed by injecting balanced salt solution through the tube using a 27 gauge cannula.

How supplied :

The **aadi** is supplied sterile in sealed pouches and available in a pack of one implant per box. To ensure reliable safety package, the inner tyvek pouch is covered with an outer tyvek pouch. Product information and general surgical procedures are also enclosed with the sterile package. The tyvek pouches does not contain any radioactive substances.

Precautions for Use :

The **aadi** must be removed from tyvek pouches and handled in aseptic conditions. The implant must not be used after the expiration date shown on the package. Disposal of product is not mentioned, as full product is being used during surgery.

Additional information to the patient:

The patient can enter the potentially adverse environments as it could not affect the performance of the implant. The patient can interact with MR imaging after surgery

Actions to be avoided after surgery:

- Do not wear contact lenses until we advise you that it is safe to do so.
- Do not wear eye makeup for four weeks after surgery. You may also want to avoid face cream or lotion.
- You can shower or wash your hair the day after surgery, but keep water, soap, shampoo, hair spray, and shaving lotion out of your eye, especially for the first four weeks. Make sure to not get a stream of fluid in the eye directly if you shower.
- Do not get your hair colored or treated for seven days after surgery and after that take care to have your eye covered or closed during hair appointments. We recommend that you schedule hair treatments before your surgery.
- Do not swim, sit in hot tubs or saunas, garden, or do house cleaning tasks, such as dusting, for four weeks.
- Do not lift weights, do yoga, jump, run or participate in other strenuous activities; do not strain, do not bend

Precautions during normal activities:

- The patient may resume normal activity gradually, but do not bend, strain, or lift for four weeks or longer.
- A good rule of thumb to know if you are bending too much is to keep your head above your heart level. You may have to squat to do so and to prevent problems after your surgery.
- The patient may not know if any change in implant performance since it can be identified only by the Glaucoma surgeon. So, after implantation, the patient will have to meet the surgeon regularly.
- Do not rub or touch your eye unless we tell you to do so. You may be able to return to desk work or your non-physical routine one to two weeks after surgery.

General surgical procedure:

Step : 1

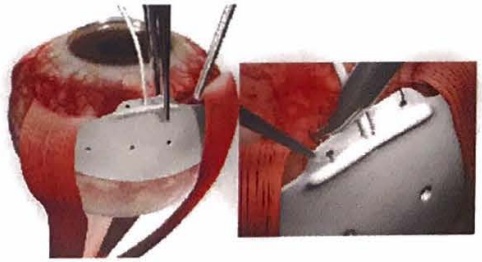
The **aadi** is commonly implanted in the supero temporal or the infero nasal quadrant. A fornix based conjunctival flap is used to dissect the conjunctiva and tenon's capsule from the sclera.

The **aadi** may be inserted through a 100° incision. A relaxing incision on either side of the conjunctival flap will improve exposure.

Step 2 :

Adjacent rectus muscles are identified and isolated with muscle hooks. Muscle hooks are used to create space for the implant.

Step 3 :



The lateral wings of the **aadi** are designed for positioning under the rectus muscles. The end plate is positioned between the rectus muscles and is attached to the sclera about 10mm posterior to the limbus with 8-0 or 9-0 nylon sutures through the fixation holes of the implant. The knots are rotated into the fixation holes to prevent erosion through the conjunctiva.