Molteno Implants were developed for the treatment of severe and complex cases of glaucoma. The implants consist of a fine bore silicone tube opening onto the upper surface of one or two episcleral plates. The function of the tube is to deliver aqueous from within the eye onto the upper surface of the episcleral plate. The episcleral plate is firmly sutured to the sclera and covered by a thick flap of Tenon’s tissue and conjunctiva. The function of the plate is to initiate the formation of a large bleb which develops a specialised fibrovascular bleb lining and which becomes distended with aqueous. It is this fibrovascular bleb lining that is responsible for regulating the escape of aqueous from the eye and which determines the final level of intraocular pressure (IOP) that is achieved after insertion of the implant.

### Warnings

1. **Complications.**
   - Potential complications accompanying Molteno Implant surgery may in some cases be limited to the following:
     - choroidal detachment
     - retinal detachment
     - pupillary block
     - lenticulociliary block
     - shallowing and flattening of the anterior chamber
     - intraocular infection
     - diplopia
     - loss of central vision
     - hypotony
     - corneal endothelial damage

2. **Adverse reactions.**
   - Molteno Implants are commonly used in patients with pre-existing ocular pathology in many cases associated with general disease eg. diabetes. Adverse reactions have been observed and include:
     - corneal endothelial damage when the tube touches the corneal endothelium
     - breakdown of the tissues overlying the bleb
     - diplopia when the placement of the implant interferes with the action of the extracocular muscles
     - corneal decompensation
     - progression of lens opacities
     - cystoid macular oedema
     - retinal detachment
     - intraocular infection

3. **Postoperative Pharmacology.**
   - Miotics, prostaglandin analogues and other vasodilating agents.

When miotics, prostaglandin analogues and other local vasodilating agents are used after the insertion of a Molteno Implant they may cause elevation of the intraocular pressure. Miotics, prostaglandin analogues and Vasodilating Agents SHOULD BE USED WITH CAUTION after insertion of a Molteno Implant. Steroids or topical steroids.

### Precautions

- Do NOT soak the implant in any solution other than a sterile balanced salt solution or sterile normal saline.
- Avoid chemical contamination.
- Do NOT store the implant at a temperature greater than 77°F (25°C).

**Handle the implant carefully.** Rough or excessive handling may damage the implant.

A high level of surgical skill is necessary for the insertion of Molteno Implants. The surgeon should have observed and/or assisted with several previous implantation procedures and successfully completed one or more courses on Molteno Implant surgery prior to undertaking the treatment of glaucoma with Molteno Implants.

Prior to surgery the surgeon must inform any prospective patient, or their representative, of the possible complications associated with the use of Molteno Implants.

### Sterile Procedure

When properly stored the contents of the pouch are sterile for five years after the sterilization date, unless the package is damaged or opened. Before using the implant, open the box and inspect the implant, checking that it is the correct type and that it is not damaged. Handle the implant carefully. Rough or excessive handling may damage the implant.

### Reporting

Adverse reactions and/or sight threatening complications that may reasonably be regarded as implant related or were unexpected should be reported to your distributor.

Surgeons are encouraged to report such events in order to identify any emerging problems and to document the long-term effects of Molteno Implants. Contact your distributor for the proper forms to report adverse reactions and/or sight threatening complications that may reasonably be regarded as implant related.

### Single Use Only

This device is designated as “single-use” only.

- Do not re-sterilize
- Do not repackage
- Do not use the device if sterile packaging integrity has been compromised
- If the package has been opened and the device is not used it must be destroyed.

Risks involved in reuse of single-use devices include:

- Potential for cross-infection
- Inability to clean and decontaminate
- Patient injury – device failure from reprocessing or reuse
- Residue from chemical decontamination agents
- Material alteration
- Legal implications

Do not re-use – a single use device is used on an individual patient during a single procedure. If the device is not used, it must be discarded. It is not intended to be reprocessed and used again, even on the same patient.

The reuse of single-use devices can affect the safety, performance and effectiveness, exposing patients and staff to unnecessary risk.

### References

Refer to www.molteno.com