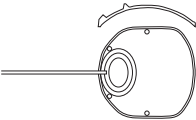


# Molteno3® Technical Specifications & Product Information

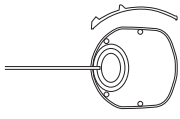
## Technical Specifications:

GL - Single Plate 230mm<sup>2</sup>

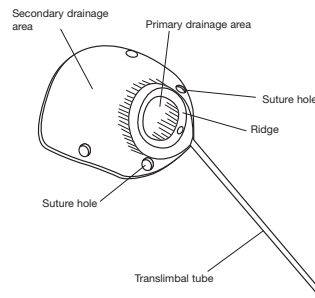


Surface Area of Plate	=	230 mm <sup>2</sup>
Plate Thickness	=	0.4 mm
Maximum Height of Ridge	=	1.5 mm
Maximum Length	=	16 mm
Maximum Width	=	15 mm
Tube Internal Diameter	=	0.34 mm
Tube External Diameter	=	0.64 mm
Translimbal Tube Length	=	17 mm

GS - Single Plate 175mm<sup>2</sup>



Surface Area of Plate	=	175 mm <sup>2</sup>
Plate Thickness	=	0.4 mm
Maximum Height of Ridge	=	1.5 mm
Maximum Length	=	13.6 mm
Maximum Width	=	14.2 mm
Tube Internal Diameter	=	0.34 mm
Tube External Diameter	=	0.64 mm
Translimbal Tube Length	=	19 mm



Molteno3® glaucoma drainage device.

# MOLTENO® IMPLANTS *Glaucoma Drainage Devices*

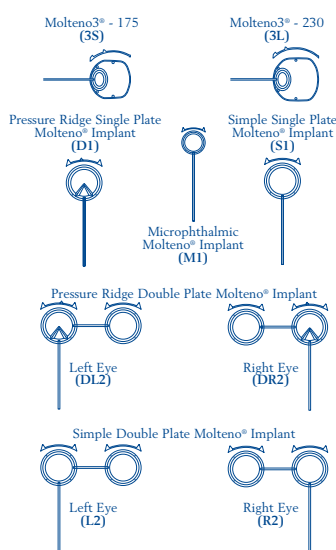
## PRODUCT INFORMATION

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

### DESCRIPTION

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 more 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.

### STYLES OF MOLTENO® IMPLANTS



### INDICATIONS

Molteno® Implants are used to reduce the intraocular pressure in severe and complex cases of glaucoma where conventional drainage procedures have failed or offer little prospect of success. The surgeon must weigh up the risks and benefits in each case.

Indications include:

- failure of previous drainage operations
- glaucoma associated with aphakia, trauma and uveitis
- neovascular glaucoma
- infantile and juvenile glaucoma including cases associated with Sturge-Weber syndrome and neurofibromatosis
- adrenal primary glaucoma

### CAUTIONS

Molteno® Implants are frequently used as a last resort in cases where other procedures have failed or offer little prospect of success. Additionally these cases often have complicating conditions that must be taken into account. Patients with the following conditions may not be suitable candidates for a Molteno® Implant:

- **Intraocular infection.** Molteno® Implants SHOULD NOT BE USED in patients with an intraocular infection.
- **Rheumatoid arthritis, scleritis and immune corneal melt syndromes.** In these conditions there is a strong tendency for the tissues in the vicinity of the implant to erode. This may result in extrusion of the implant and loss of the eye.
- **Scleral Buckle.** The placement of a Molteno® Implant may interfere with the subsequent surgical treatment of detachment of the retina.

### WARNINGS

#### 1. Complications.

As with any surgical procedure there are risks involved. Potential complications accompanying Molteno® Implant surgery may include, but are not limited to the following:

- choroidal detachment
- retinal detachment
- expulsive haemorrhage
- pupillary block
- lenticulo-ciliary 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 extraocular muscles
- corneal decompensation
- progression of lens opacities
- cystoid macula 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.**

The administration of steroids, particularly topical steroids, is indicated in the early post-operative period after insertion of a Molteno® Implant. In certain cases these may later cause an elevation of the intraocular pressure.

**THE INTRAOCULAR PRESSURE OF PATIENTS RECEIVING STEROIDS OR TOPICAL STEROIDS SHOULD BE CAREFULLY MONITORED POSTOPERATIVELY.**

### 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 110 F (44°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 of Molteno® Implant surgery prior to undertaking the treatment of glaucoma with Molteno® Implants.

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

### DIRECTIONS FOR USE

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 of the correct type and that it is not damaged. Handle the implant carefully. Rough or excessive handling may damage the implant.

A variety of surgical techniques may be employed during the placement of a Molteno® Implant. The surgeon is best advised to use the methods that his training and judgement dictate to be best for the patient.

The implant package contains peelable labels that display the implant type and serial number, etc. These labels are for convenience in maintaining records and reporting results. They are designed to be affixed to the patient's hospital chart, the physician's card and the return card.

### 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.

### HOW SUPPLIED

The Molteno® Ophthalmic Ltd, Molteno® Implant is supplied STERILE in a dry heat sealed package. The inner package is sterilised with moist heat and should be opened under sterile conditions only. (See DIRECTIONS FOR USE).

REFERENCES Refer to [www.molteno.com](http://www.molteno.com)

SYMBOL		REF	
MEANING	Sterilized by Steam	CATALOGUE NUMBER	ATTENTION SEE INSTRUCTIONS FOR USE

SYMBOL			
MEANING	USE BY (YYYY-MM) year-month	Single use only DO NOT REUSE	BATCH CODE

0705-GPI



**MOLTENO®**  
OPHTHALMIC LIMITED

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U.S. Patent Nos. 4,457,757 4,750,901