

# MOLTENO® *M-Sphere*® Orbital Implant and *MoaBone*® Surgical Implant Reconstruction Pack

## PRODUCT INFORMATION

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

### DESCRIPTION

#### *M-Sphere* Orbital Implants

MOLTENO *M-Sphere* Orbital Implants have been developed for use in cases where reconstruction is required following enucleation or evisceration of the eye. The *M-Sphere* implant consists of a white, very light framework of natural hydroxyapatite, formed from the mineral portion of mammalian bone which has been treated to remove the organic components. The function of the implant is to impart movement to an artificial eye (prosthesis) after enucleation, while eliminating dead space in the socket. The implant promotes rapid ingrowth of fibrovascular tissue and provides a stable base for an artificial eye.

#### *MoaBone* Natural Hydroxyapatite Surgical Implant Reconstruction pack

The *MoaBone* Reconstruction pack consists of a selection of 4 segments (*M-Sphere* Orbital Implants quartered). These are designed to correct cosmetic defects due to post traumatic atrophy of the orbital fat. When packed posteriorly, between the periosteum and the adjacent bone of the lateral and inferior portions of the orbit, they reduce the volume of the bony orbit and displace the remaining orbital fat forward. This corrects the sunken appearance and fills the hollow beneath the brow.

#### Selecting the correct size of MOLTENO *M-Sphere* Orbital Implant

Using the correct size of *M-Sphere* implant minimises the risk of dead space, exposure and internal/external pressures on the surrounding tissues. The correct size of *M-Sphere* implant is usually between 3/4ths and 7/8ths of the diameter of the eye that has been removed. The *M-Sphere* implant is available in 16mm, 18mm, 20mm, and 22mm sizes. When soaked in sterile antibiotic or saline solutions the implant can be easily shaped to accommodate special circumstances.

### INDICATIONS

MOLTENO *M-Sphere* Orbital Implants are used to reconstruct the orbit to support and impart movement to an artificial eye after enucleation. The surgeon must weigh up the risks and benefits in each case. Indications include:

- The need for a cosmetically pleasing result following enucleation.
- The need to minimise the risk of migration and extrusion.
- The need to maximise motility of an artificial eye.

*MoaBone* Surgical Implant Reconstruction Pack is used to correct cosmetic defects due to atrophy of the orbital fat. The surgeon must weigh up the risks and benefits in each case. Indications include:

- The need for a cosmetically pleasing result following atrophy of the orbital fat.

### CONTRAINDICATIONS

- 1.) *M-Sphere* and *MoaBone* Implants should not be used in the presence of infection of the orbital tissues.
- 2.) *M-Sphere* and *MoaBone* Implants should not be used when the general state of the patient or the local condition of the orbit is so poor that healing and tissue ingrowth into the implant will be seriously impaired.

### CAUTIONS

Complications that may occur after inserting an orbital implant are most often due to internal or external pressure. Internal pressure from the swelling of traumatised tissues or the selection of too large an implant may result in exposure of the implant. External pressure applied to the eye after surgery, such as the use of a conformer or overfirm bandaging, may cause ischaemic necrosis of the tissues covering the implant and should be avoided.

### WARNINGS

#### Complications:

As with any surgical procedure there are risks involved. Potential complications associated with MOLTENO *M-Sphere* or *MoaBone* Implant surgery include, but are not limited to the following:

- Breakdown of the tissues overlying the implant with exposure of the implant.
- Infection of the exposed implant.
- Resorption of the implant resulting in volume loss

Several cases of reduced implant volume requiring revision surgery have been reported some years after implantation of the *M-Sphere* orbital implant. Affected individuals had enucleations after trauma and were in the fourth and fifth decades at the time of implantation. The surgeon must consider the possibility of implant resorption and volume loss requiring revision when selecting an orbital implant to best suit the individual case.

### PRECAUTIONS

DO NOT soak the implant in any solution other than a sterile balanced salt solution, sterile normal saline or an appropriate sterile antibiotic solution.

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.

Prior to surgery the surgeon must inform any prospective patients, or their representative, of the possible complications associated with the use of MOLTENO *M-Sphere* or *MoaBone* Implants.

### DIRECTION 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. The implant should be rinsed in a sterile balanced salt solution or sterile antibiotic solution prior to insertion.

A variety of surgical techniques may be employed during the placement of MOLTENO *M-Sphere* or *MoaBone* Implants. The surgeon is best advised to use the methods that his or her 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 device tracking card.

### REPORTING

Adverse reactions and/or complications that may reasonably be regarded as implant related and 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 *M-Sphere* and *MoaBone* Implants.

Contact your distributor for the proper forms to report adverse reactions and/or complications that may reasonably be regarded as implant related.

### HOW SUPPLIED

MOLTENO *M-Sphere* Orbital Implant and the *MoaBone* Surgical Implant Reconstruction Pack are supplied STERILE in a dry heat sealed package. The inner package is sterilised with saturated steam under pressure and should be opened under sterile conditions only. (See DIRECTIONS FOR USE).

### SINGLE USE ONLY

This device is designated as 'single-use' only

- Do not reuse
- Do not re-sterilise
- 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
- Residues from chemical decontamination agents
- Material alteration
- Legal implications

Do not reuse – 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](http://www.molteno.com)

SYMBOL			REF	
MEANING	Sterilized by Steam	DO NOT RESTERILIZE	CATALOGUE NUMBER	ATTENTION, SEE INSTRUCTIONS FOR USE

SYMBOL			LOT	
MEANING	USE BY (YYYY-MM-DD) year-month-day	Single use only DO NOT REUSE	BATCH CODE	STORAGE TEMPERATURE 25°C



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