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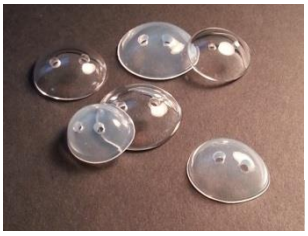
Symblepharon Rings and Ophthalmic Conformers Instruction Sheet.

IMPORTANT: Only suitably trained and qualified personnel should carry out this procedure under normal operating room conditions.

CE 1639

Assorted Conformers



Silicone - Soft / Cloudy Finish
PMMA - Hard / Clear Finish

Above: Contoured Symblepharon Ring
Below: Classic Symblepharon Ring

The Altomed Conformers and Symblepharon Rings are used to help retain the socket and keep the fornices formed after enucleation, evisceration or socket reconstruction.

They are fitted with holes to allow easy insertion and removal, to provide drainage of mucoid discharge and also to provide access for any postoperative medication. Tarsorrhaphy procedures may be needed after insertion if deemed necessary by the Surgeon.

The Symblepharon Rings are used if there is excessive swelling or if the patient lacks volume in the socket post enucleation or evisceration. The **Classic Style** has been on the market for many years, has a tight dimensional range and is more circular in design whereas the **NEW Contoured** ones are an improved ergonomic design and are shaped more to fit the eye.

The PMMA Conformers and Symblepharon Rings are hard and inflexible; by contrast the Silicone Conformers are soft and flexible. The Surgeon will select the best device for each patient depending upon their individual needs. The device selected should follow the contour of the socket and be big enough to maintain the fornices but not so large as to apply tension on wound closure or exert pressure on, or otherwise affecting the suture line. The use of an inappropriate device may lead to tissue erosion or pressure necrosis, especially in the paediatric population.

Children and patients with special needs should be evaluated before using the device to determine their suitability. All patients should be told not to touch the device or rub or otherwise apply pressure to the device once in place.

Once in position the eyelids should easily close over the conformer. As the swelling subsides, it may be necessary to change the conformer to a smaller size. The devices can be used in conjunction with a suitable antibiotic ointment if deemed necessary by the Surgeon.

It is important that a temporary prosthesis is used after enucleation to prevent contracture of the socket. It may be necessary to apply a pressure patch if there is difficulty in retaining the conformer. If deemed necessary by the surgeon, the lids can be sutured (e.g. 4-0 or 5-0 nylon intermarginal mattress sutures) together until edema has subsided.

Conformers and Rings can be kept in place for 6 to 8 weeks; however the length of time should be determined by the Surgeon. The surgeon should monitor the patient after insertion on a regular basis for any procedural or device problems.

To insert - Use a suitable antibiotic or ophthalmic lubricant within the lid and surfaces.
Very carefully pull the upper eye lid up, gently place the conformer in the socket and then pull the lower lid over the device.

To remove - Very carefully pull the lower lid out and gently slide the conformer out.

If the patient feels the conformer has become contaminated and it is not as comfortable as normal, eg it feels gritty etc, it is recommended to replace the device with a new one.

Product Range:

Size = Approximate outside dimensions

A7122 PMMA (Lucite) Conformer Small 20 x 23mm
A7124 PMMA (Lucite) Conformer Medium 21 x 25mm
A7126 PMMA (Lucite) Conformer Large 25 x 28mm

A7130 Silicone Conformer Small 20 x 23mm
A7132 Silicone Conformer Medium 21 x 25mm
A7134 Silicone Conformer Large 25 x 28mm

A3710 PMMA Symblepharon Ring Small 21.0mm
A3712 PMMA Symblepharon Ring Medium 21.5mm
A3714 PMMA Symblepharon Ring Large 22.0mm

A3716 PMMA Contoured Symblepharon Ring Small 20.5 x 22mm
A3718 PMMA Contoured Symblepharon Ring Medium 22.5 x 24mm
A3720 PMMA Contoured Symblepharon Ring Large 24.5 x 26mm

Reprocessing

The sterile devices are supplied sterile and single use and are not designed to be reprocessed or reused. Reprocessing may alter the structure and surface of the device and affect the performance and safety in use causing possible harm to the patient. Incorrect handling and reprocessing will also increase the risk of cross contamination and infection.

Non-sterile devices should be washed in an ultrasonic bath first using a pH neutral Endozyme detergent following your validated procedures and the Ultrasonic Bath and Detergent manufacturer's instructions, eg Ruhof LiquicleanH diluted as per manufacturer's instructions at 20°C-35°C for 6 minutes with a final rinse in RO water. Silicone devices should be by autoclaved using a standard 134°C-137°C cycle with a 3 to 3½ minute holding time. PMMA devices should be sterilized by Ethylene Oxide using hospital validated cycles. Contact Altomed for details of the validated processing parameters for Ethylene Oxide

PMMA devices will melt if they are autoclaved, do not expose to temperatures over 40°C or to isopropyl alcohol!

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