Symblepharon Rings and Ophthalmic Conformers

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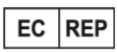

Advena Ltd. Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013, Malta.

Intended Use	Conformers and Symblepharon Rings are used to help retain the socket and keep the fornices formed after enucleation, evisceration or socket reconstruction. They contain 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 a tight dimensional range and is more circular in design whereas the 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.
Indication(s)	Patients who are having an old implant removed or an eye enucleated or eviscerated. Enucleation: Intraocular malignancy or high suspicion for intraocular malignancy (most commonly uveal melanoma and retinoblastoma), blind painful eye, trauma, Sympathetic ophthalmia, microphthalmos, panophthalmitis. Evisceration: Endophthalmitis, ocular trauma, blind painful eye, microphthalmos.
Sterility	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.
Intended Patient Group(s)	Patients who are having an old implant removed or an eye enucleated or eviscerated, typical causes include eye trauma, eye cancer, painful blind eye and other congenital disorders (e.g., microphthalmia). The conformers can also be used to treat patients with poor orbital volume or patients with microphthalmos or anophthalmos and cyst.
Intended User(s) & Facilities	Professional use only, Consultant Ophthalmic Surgeon or other suitably trained personnel.
Clinical Benefits & Performance Characteristics	Biocompatible. Protect orbital tissue from damage. Shall be suitable for clinically effective treatment in human patients.
Storage, Handling, Preparation & Use Considerations	Store at room temperature and humidity away from direct sunlight and water. 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 since rubbing can cause corneal abrasions. Furthermore, there is a possibility that there may be adhesions of the upper lid to the cornea.
Contraindications	Enucleation: Consideration should be given to the risk of potential spread of infection with CSF space exposed, and the increased risk of haemorrhage.

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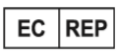

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	Evisceration: Where an intra-orbital neoplasm is suspected, where trauma may prevent the complete removal of uveal tissue or where a complete histological exam is required.
Warnings and Precautions	This device is only to be used by a suitably trained or qualified healthcare professional. The device should be implanted in accordance with the surgeon's standard procedures and training. It is important that the correct size of conformer is selected taking into account orbital tissue contraction and the risk of dehiscence; too small a conformer will not provide enough volume and too large may increase the risk of extrusion.
Residual Risks & Undesirable Side-Effects	The use of an inappropriate device may lead to tissue erosion or pressure necrosis, especially in the paediatric population.
Additional Safety Information	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. 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.
Disposal Considerations	If removed after use, the implants must be disposed of in accordance with hospital approved procedures for contaminated waste.
In the event of an incident or defective device	If any serious incident has occurred in relation to the device, the user and/or patient should be report it to the manufacturer at the contact details below, and the competent authority of the Member State in which the user and/or patient is established (refer to https://ec.europa.eu/health/md_sector/contact_en)

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