



# INSTRUCTIONS FOR USE

## Sterile Conformers

**Professional Use Only:**

**To be used by an Ophthalmic Surgeon or other suitably trained professional.**

### Intended Use and Indications for OCULAR CONFORMERS

- **USE:** Conformers are used to help retain the socket and keep the fornices formed after enucleation, evisceration or socket reconstruction. Non-vented conformers provide a smooth surface for the eyelid to blink over. Vented conformers contain holes to provide drainage of mucoid discharge and as well as provide access for any postoperative medication.
- **INDICATIONS:** To be used on patients having an 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
  - Evisceration: Endophthalmitis, ocular trauma, blind painful eye, microphthalmos

### Sterility

- Sterile devices are supplied sterile and single use only
- 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



sterilized using  
ethylene oxide



single use

### Clinical Benefits

- Biocompatible
- Protect Orbital tissue from damage
- Suitable for clinically effective treatment in human patients

### Storage and Handling

- Store package/pouch in a cool (59 - 85°F temperature) and dry (40% - 70% humidity) environment.
- Keep away from direct sunlight and water.
- Conformers 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 pressure necrosis of the conjunctival tissue.



do not use if  
package is damaged

### Warnings and Precautions

- This device is only to be used by a suitably trained or qualified healthcare professional.
- It is important that the correct size of conformer is selected taking into account orbital tissue contraction and the risk of dehiscence; too small of a conformer will not provide enough volume and too large may increase the risk of extrusion.
- **UNDESIRABLE SIDE EFFECTS:** The use of an inappropriate device may lead to tissue erosion or pressure necrosis, especially in the pediatric 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, rub or otherwise apply pressure to the device once in place.
- It is important that a temporary conformer 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 together until edema has subsided.



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