

# INSTRUCTIONS FOR USE

## for symblepharon shells acc. Dr. Illig

CE 0481

A product made from PMMA by the Institut für Kunstaugen und ophthalmologische Hilfsmittel (Institute for Ocular Prosthetics and Ophthalmological Aids) • Friedrichstrasse 55 • D-65185 Wiesbaden

### Application

The symblepharon shells are used as placeholders or interim prostheses. These are required amongst other things after conjunctival surgery, plastic surgery to the eyelids which involves the conjunctiva, and in case of chemical burns and burns to the outer eye. However, the shells may also be used after enucleation.

They serve to prevent and delay shrinkage and/or scarring of the conjunctival sac. The shape and size must be decided individually by the doctor. The prosthesis must not be too large (due to the risk of excess pressure on the surrounding tissue), but also not too small (the prosthesis does not have an effect).

### Material information

The shells are produced from Plexiglas 6N S000, a polymethylmethacrylate (PMMA).

There are no known indications for toxic effects, irritation or sensitization through the application of PMMA in contact with skin or bodily fluids, for example as intraocular lenses, dental prosthetics or artificial hip joints.

The shells are reusable following suitable preparation.



Clean symblepharon shells **prior** to every application, observing the following recommendations, and disinfect and/or sterilize them depending on the medical requirements.

### Cleaning and disinfecting the shells

Rinse the shells under running water.

Put shells in an ultrasonic bath with the addition of an enzymatic cleaner (eg Medizym by Dr. Weigert)

Clean for 5 minutes at 40 ° C. For disinfection, a 10-minute bath in a 3% hydrogen peroxide solution is recommended

Alternatively, the disinfection can also be done with a disinfectant from the list of VAH / DKKH for medical devices made of PMMA according to manufacturer's instructions. Then rinse with demineralized water or NaCl.

### Sterilization

As a validated procedure, we recommend a low-temperature gas plasma sterilization process for this material.

We advise against using **other sterilization procedures**, in particular disinfection/sterilization using ethylene oxide or gamma radiation!



#### WARNING

Symblepharon shells are produced from heat-sensitive PMMA and therefore must not be heated above 60°C, and should not be boiled or treated with hot air over 60 °C.

### Product liability

In case of non-compliance with the abovementioned information or incorrect handling of the symblepharon shells, any product liability shall lapse and with this any warranty and/or guarantee claims.

### Application period

The prostheses should not be used uninterrupted for longer than 14 days.



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