

Manufacturer:
 TECHNOVENT LIMITED
 Unit 5, York Park, Bridgend Industrial Estate
 Bridgend, CF31 3TB, UK
 Tel: +44 (0) 1656 768566
 www.technovent.com



INSTRUCTIONS FOR USE

Ocular Prosthesis Components

PRODUCT DESCRIPTION:

Materials for the construction of Ocular/Orbital Prostheses.

INTENDED USE:

The Ocular Prosthesis Components are used to construct ocular units for orbital prostheses for patients who have lost their eye and surrounding tissues through disease or trauma.

INTENDED USERS:

The Ocular Prosthesis Components are intended for professional use only, in particular maxillofacial prosthetists and Ocularists who have experience and training in the use of acrylics for the construction of external prostheses.

Proper procedures and techniques are the responsibility of the medical professional. They must evaluate the appropriateness of the procedure based on personal training and experience as applied to the patient at hand.

INTENDED PATIENT GROUP:

The Ocular Prosthesis Components are intended to be used on patients who need an Orbital or Ocular prosthesis due to the loss of facial parts including the eye due to congenital malformation, tumour surgery or trauma of the craniofacial region.

INDICATIONS OF USE:

The Ocular Prosthesis Components are useable in most situations – see Intended Use (above) for conditions indicating the use of the device.

CONTRAINDICATIONS/LIMITATIONS OF USE:

If any skin irritation occurs stop using immediately.

PRODUCT RANGE:

CU11515	Cornea Unit 11.5mm dia 1.5mm pupil
CU11520	Cornea Unit 11.5mm dia 2.0mm pupil
CU11525	Cornea Unit 11.5mm dia 2.5mm pupil
CU11530	Cornea Unit 11.5mm dia 3.0mm pupil
CU11535	Cornea Unit 11.5mm dia 3.5mm pupil
CU11540	Cornea Unit 11.5mm dia 4.0mm pupil
CU11545	Cornea Unit 11.5mm dia 4.5mm pupil
CU11550	Cornea Unit 11.5mm dia 5.0mm pupil
CU12015	Cornea Unit 12.0mm dia 1.5mm pupil
CU12020	Cornea Unit 12.0mm dia 2.0mm pupil
CU12025	Cornea Unit 12.0mm dia 2.5mm pupil
CU12030	Cornea Unit 12.0mm dia 3.0mm pupil
CU12035	Cornea Unit 12.0mm dia 3.5mm pupil
CU12040	Cornea Unit 12.0mm dia 4.0mm pupil
CU12045	Cornea Unit 12.0mm dia 4.5mm pupil
CU12050	Cornea Unit 12.0mm dia 5.0mm pupil
CU12515	Cornea Unit 12.5mm dia 1.5mm pupil
CU12520	Cornea Unit 12.5mm dia 2.0mm pupil
CU12525	Cornea Unit 12.5mm dia 2.5mm pupil
CU12530	Cornea Unit 12.5mm dia 3.0mm pupil
CU12535	Cornea Unit 12.5mm dia 3.5mm pupil
CU12540	Cornea Unit 12.5mm dia 4.0mm pupil
CU12545	Cornea Unit 12.5mm dia 4.5mm pupil
CU12550	Cornea Unit 12.5mm dia 5.0mm pupil
CU13015	Cornea Unit 13.0mm dia 1.5mm pupil

CU13020	Cornea Unit 13.0mm dia 2.0mm pupil
CU13025	Cornea Unit 13.0mm dia 2.5mm pupil
CU13030	Cornea Unit 13.0mm dia 3.0mm pupil
CU13035	Cornea Unit 13.0mm dia 3.5mm pupil
CU13040	Cornea Unit 13.0mm dia 4.0mm pupil
CU13045	Cornea Unit 13.0mm dia 4.5mm pupil
CU13050	Cornea Unit 13.0mm dia 5.0mm pupil

STORAGE:

The Ocular Prosthesis Components are supplied in plastic bags and it is recommended that they are stored in their original containers. It is recommended that they are stored at ambient temperature (between 15 and 30 degrees Celsius) and out of direct sunlight. Do not use if the packaging is open or has been damaged and do not use after the labelled expiry date.

PRECAUTIONS / RESIDUAL RISKS / SIDE EFFECTS:

-The materials designed for external use only on unbroken healed skin.

-In the unlikely event of a localized allergic reaction to the material, stop using immediately and seek advice from Technovent.

DISPOSAL:

Disposal of the materials should follow local regulations and environmental requirements taking different contamination levels into account.

IMPORTANT INFORMATION:

It is the User's responsibility to ensure the safety and efficacy of these materials for all intended uses. While the materials have been deemed safe for use as external prostheses on unbroken healed skin, Technovent makes no end use representation based on such testing. It must be understood that because conditions and methods of use of our products is beyond our control, the information in this document should not be used in substitution for customer's tests to ensure the product is safe, effective and fully satisfactory for the intended end use.

Designed for external use only. Avoid use on broken skin.

HARMONISED SYMBOLS:



Consult Instructions for Use



Lot Number



Manufacturer



Product Code/Ref



Manufacturing Date



Do Not Store in Direct Sunlight



Expiry Date



Do Not Use if Packaging is Open/Damaged



Store Between 15-30 Degrees Celsius