



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 Acrylic Materials

PRODUCT DESCRIPTION:

Materials for the construction of Ocular/Orbital Prostheses.

INTENDED USE:

The Ocular Acrylic Materials are used to construct ocular units for orbital prostheses for patients who have lost the orbit and surrounding tissues through disease or trauma.

INTENDED USERS:

The Ocular Acrylic Materials 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 Acrylic Materials 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 Acrylic Materials 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:

Material Code	Description
J-570	Acrylic Monomer
J-600	Clear Acrylic Polymer
J-510	Scleral Acrylic Polymer
J-305	Monopoly Syrup

APPLICATION INSTRUCTIONS:

For full details refer to Technovent User Guides at www.Technovent.com

To construct an orbital prosthesis acrylic polymer and monomers are needed in addition to pre-made units (see Ocular

Components). Monopoly Syrup is also used for painting and sealing of the acrylic eyes.

Proportions:

Measure 4:1 by volume polymer powder to monomer liquid (e.g., 40 cc, powder to 10 cc liquid). The powder and liquid must be measured accurately for the best results. Do not add extra liquid to the mix. This will cause porosity in the finished prosthesis.

Monopoly Syrup:

Monopoly syrup is used for painting and sealing of the acrylic eyes.

STORAGE:

Ocular acrylic materials are supplied in glass and plastic containers 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:

- Extremely flammable do not use near naked flames.
- Use in a well-ventilated area.
- The fully cured material is 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



Manufacturer



Manufacturing Date



Expiry Date



Store Between 15-30 Degrees Celsius



Lot Number



Product Code/Ref



Do Not Store in Direct Sunlight



Do Not Use if Packaging is Open/Damaged



Flammable