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INSTRUCTIONS FOR USE

Technovent Extrinsic Colours and Sealant

PRODUCT DESCRIPTION:

Technovent Extrinsic Colours and Sealant are products to extrinsically colour and seal colours onto processed prostheses.

INTENDED USE:

The Technovent Extrinsic Colours are used to colour silicone rubber prostheses on their external surface after they have been processed, creating a matching colour to the surrounding tissues. The Sealant is used to seal the extrinsic colours on the external surface.

INTENDED USERS:

The Technovent Extrinsic Colours and Sealant are intended for professional use only, in particular maxillofacial prosthetists who have experience and training in the use of silicone rubber systems for 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:

Technovent Extrinsic Colours and Sealant are intended to be used on patients who need a maxillofacial prosthesis due to the loss of facial parts due to congenital malformation, tumour surgery or trauma of the craniofacial region.

INDICATIONS OF USE:

Technovent Extrinsic Colours are useable in most situations – see Intended Use (above) for conditions indicating the use of the device.

CONTRAINDICATIONS/LIMITATIONS OF USE:

Technovent Extrinsic Colours and Sealant are suitable to be used in the construction of external maxillofacial prostheses on fully healed sites. The colours are fully sealed by an extrinsic silicone sealant and shouldn't come into contact with healed skin.

PRODUCT RANGE:

The Technovent Extrinsic Colours comprise of pigments suspended in ethanol and the sealant is a two-part addition cured silicone diluted in a silicone solvent (see Table 1 below)

Table 1 – Technovent Extrinsic Colours and sealant

P702	Extrinsic Colouring Kit
P799	Extrinsic Sealant

APPLICATION INSTRUCTIONS:

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

The Technovent Extrinsic Colours are designed to be painted onto the external surface of the final cured silicone prosthesis

Until the colours are sealed, they can be wiped off the prosthesis if mistakes are made. The sealant should be mixed 1:1 by weight and lightly painted over the extrinsically coloured parts of the prosthesis.

The sealant can be cured in the oven at 50°C for 10 minutes or at room temperature for 2 hours.

STORAGE:

The extrinsic colours and sealant are supplied non-sterile in plastic bottles 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 extrinsic sealant is flammable, do not use near naked flames.
- This material is designed for external use only on unbroken healed skin.

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.

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	 Authorised Representative in the European Community
 Flammable	 Medical Device

Designed for external use only.