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INSTRUCTIONS FOR USE

Intrinsic Colours

PRODUCT DESCRIPTION:

A range of colours in silicone oil, dry pigment and flockings for colouring prosthetic silicone materials prior to curing.

INTENDED USE:

The Technovent intrinsic colours are used to colour silicone materials prior to being placed in a processing mould. They are then encapsulated in the final prosthesis creating a matching colour to the surrounding tissues.

INTENDED USERS:

The Technovent Intrinsic colours 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 intrinsic colours 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 Intrinsic colours are useable in most situations – see Intended Use (above) for conditions indicating the use of the device.

CONTRAINDICATIONS/LIMITATIONS OF USE:

Technovent Intrinsic colours are suitable to be used in the construction of external maxillofacial prostheses on fully healed sites. The colours are fully encapsulated in the silicone rubber material and there should not be any full contact with external healed skin.

PRODUCT RANGE:

The Technovent intrinsic colours comprise of pigments suspended in silicone polymer, dry earth powered pigments and flockings (see Table 1 below)

Table 1 – Technovent Intrinsic Colours

Item Code	Item Name
P101 - P199	Technovent Master Colours
P201 – P299	Technovent Dry Pigments
P301 – P399	Technovent Flocking
P401 – P499	Technovent Skin Shades
FI-201 - FI-299	Factor 2 Master Colours
FI-SK01 - FI-SK99	Factor 2 Skin Shades
I100A – I100Z	Factor 2 Paste Colours
H101 – H199	Factor 2 Flocking

STORAGE:

The intrinsic colours are supplied in plastic dropping bottles or plastic jars 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:

-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 within 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
 Medical Device	

Designed for external use only.