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INSTRUCTIONS FOR USE

Ocular Impression Trays

PRODUCT DESCRIPTION:

Impression Trays to assist in taking ocular impressions.

INTENDED USE:

The Ocular Impression Trays are used in the taking of impressions of the defect area for ocular prostheses.

INTENDED USERS:

The Ocular Impression Trays 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 Impression Trays 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 Impression Trays 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:

| | |
|------|---------------------------------------|
| SI04 | Non Sterile Ocular Impression Tray 04 |
| SI07 | Non Sterile Ocular Impression Tray 07 |
| SI16 | Non Sterile Ocular Impression Tray 16 |
| SI17 | Non Sterile Ocular Impression Tray 17 |
| SI18 | Non Sterile Ocular Impression Tray 18 |
| SI19 | Non Sterile Ocular Impression Tray 19 |
| SI20 | Non Sterile Ocular Impression Tray 20 |
| SI21 | Non Sterile Ocular Impression Tray 21 |
| SI22 | Non Sterile Ocular Impression Tray 22 |
| SI23 | Non Sterile Ocular Impression Tray 23 |

DETAILED DESCRIPTION:

The impression Trays are designed to aid the in the impression taking for an ocular prosthesis. They come in 10 different sizes to accommodate different orbital sizes and are to be used in conjunction with a suitable cartridge-based silicone impression material.

STORAGE:

The Ocular Impression Trays are supplied in plastic bags and it is recommended that they are stored in their original packaging. 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 are 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.

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. Avoid use on broken skin.