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INSTRUCTIONS FOR USE

Edge Adhesive

PRODUCT DESCRIPTION:

Silicone Based Adhesive to adhere the thin edges of a prosthesis to skin.

INTENDED USE:

Edge Adhesive is designed to be used to adhere thin edges of external craniofacial prostheses to healed skin, when the main retention is given via attachment to implants.

INTENDED USERS:

Edge Adhesive is intended to be used by the prosthesis wearer.

INTENDED PATIENT GROUP:

Edge Adhesive is 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:

Edge Adhesive is useable in most situations – see Intended Use (above) for conditions indicating the use of the device.

CONTRAINDICATIONS/LIMITATIONS OF USE:

Edge Adhesive is suitable for use with external maxillofacial prostheses on fully healed sites.

If any irritation occurs stop using immediately.

PRODUCT RANGE:

Material Code	Description
G604	Edge Adhesive

APPLICATION INSTRUCTIONS:

Apply a very thin layer of the adhesive to the skin where the feathery edge is to be adhered. Firmly press the edge into place and wipe away excess material with a tissue. When removing the prosthesis, simply wipe away adhesive with a tissue.

STORAGE:

The Edge Adhesive are supplied non-sterile in aluminium tubes 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:

- Only use pH neutral soaps/cleansers to clean prosthesis/skin - avoid using aggressive chloride-based cleaning solutions.

-This 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.

-- It is essential that all excess adhesive is removed from the silicone daily so as to ensure cleanliness and an accurate fit.

-Extreme care is needed when detaching adhesive retained prostheses especially in regard to the very thin edges that blend into the skin. Tearing of these thin edges will often necessitate the remaking of the prosthesis.

FIRST AID MEASURES:

If swallowed may result in gastric disturbances. Seek medical attention.

Remove excess and wash with soap and water.

May cause temporary irritation and redness. Irrigate with water for 15 minutes, holding eyelid open.

DISPOSAL:

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

HARMONISED SYMBOLS:



Consult Instructions for Use



Manufacturer



Manufacturing Date



Expiry Date



Store Between 15-30 Degrees Celsius



Medical Device



Lot Number



Product Code/Ref



Do Not Store in Direct Sunlight



Do Not Use if Packaging is Open/Damaged



Authorised Representative in the European Community

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



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