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INSTRUCTIONS FOR USE

Water Based PSA Adhesives

PRODUCT DESCRIPTION:

Water Based Pressure Sensitive (PSA) Adhesives to adhere prostheses to skin.

INTENDED USE:

Water Based PSA Adhesives are designed to be used to adhere external craniofacial prostheses to healed skin.

INTENDED USERS:

Water Based PSA Adhesives are intended to be used by the prosthesis wearer.

INTENDED PATIENT GROUP:

Water Based PSA Adhesives 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:

Water Based PSA Adhesives are useable in most situations – see Intended Use (above) for conditions indicating the use of the device.

CONTRAINDICATIONS/LIMITATIONS OF USE:

Water Based PSA Adhesives are suitable to be used with external maxillofacial prostheses on fully healed sites.

Ensure adhesive is fully dry and colourless before applying to skin.

If any irritation occurs stop using immediately.

PRODUCT RANGE:

G609	- Probond Adhesive
B200-R	- Daro Regular
B200-ES	- Daro Extra Strength
B230	- Daro Hydrobond

APPLICATION INSTRUCTIONS:

Ensure surfaces to be bonded are clean and free from grease/loose particles (make up etc). Apply a thin coating of the adhesive to the back of the prosthesis and allow 2-3 minutes until the adhesive appears clear in colour. The prosthesis can now be adhered to the skin by pushing firmly into place with constant pressure.

Removal:

The Water Based PSA adhesives can be removed using soap and water, ensuring any residue of the adhesive is removed from the prosthesis. If there is difficulty in removing residue use G608 Probond Remover.

STORAGE:

The Water Based PSA adhesives are supplied non-sterile in 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:

- 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 localised 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:

Ingestion:	If swallowed do not induce vomiting, rinse mouth. Drink 1-2 glasses of water. Seek medical attention.
Skin Contact:	In the event of the undried adhesive coming into contact with skin, rinse with running water and soap.
Eye Contact:	Flush eyes with water for 10 minutes and seek medical attention if irritation develops and persists.
Inhalation of Vapour:	Move to fresh air, get medical attention if complaint persists.

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



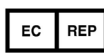
Expiry Date



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.