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INSTRUCTIONS FOR USE

Solvent Based Silicone PSA Adhesives

PRODUCT DESCRIPTION:

Solvent Based Silicone Pressure Sensitive (PSA) Adhesives to adhere craniofacial prostheses to skin.

INTENDED USE:

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

INTENDED USERS:

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

INTENDED PATIENT GROUP:

Solvent Based Silicone 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:

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

CONTRAINDICATIONS/LIMITATIONS OF USE:

Solvent Based Silicone PSA Adhesive is suitable to be used with external maxillofacial prostheses on fully healed sites.

Ensure adhesive is fully dry and no solvent is present before applying to skin.

If any irritation occurs stop using immediately.

PRODUCT RANGE:

Material Code	Description	Solvent
G626	Probond Secure Adhesive	Hexamethyldisiloxane
B-400	Secure Adhesive (Medium Tack)	Ethyl Acetate
BT-401	Secure Adhesive-Thick (Medium Tack)	Ethyl Acetate
B-460	Secure Adhesive (High Tack)	Ethyl Acetate
BT-460	Secure Adhesive-Thick (High Tack)	Ethyl Acetate
B-530	Adhere Adhesive	NF Solvent

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 all solvent has flashed off. The prosthesis can now be adhered to the skin by pushing firmly into place with constant pressure.

Removal:

To remove the Solvent Based Silicone Adhesives from skin and the prosthesis use G608 Probond Remover.

STORAGE:

Silicone Solvent Based PSA Adhesives are supplied non-sterile in plastic or glass 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:

- Extremely flammable, do not use near naked flames.
- Use in a well-ventilated area.
- Never paint adhesives directly onto the skin (except G626 Adhesive).
- 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 thoroughly with 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 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



Flammable



Medical Device



Authorised Representative
in the European Community

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