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INSTRUCTIONS FOR USE

HCR PROSTHETIC SILICONES (1:1)

PRODUCT DESCRIPTION:

The High Consistency Rubber (HCR) Prosthetic Silicones (1:1) are a range of 2 parts (A and B) silicone rubber materials for prosthetic use which are mixed 1:1 by weight ratio A:B.

INTENDED USE:

The HCR Prosthetic Silicones (1:1) are general-purpose Liquid Silicone Rubber (LSR) materials which are safe to be used as an external prosthetic material. The materials are supplied in two-part kits which are designed to be mixed in equal quantities and thoroughly milled before use.

The HCR Prosthetic Silicones (1:1) can be used as a material to construct external craniofacial prostheses in the auricular, nasal and orbital areas where anatomical structures have been lost due to trauma (including burns), tumour surgery or congenital malformations. They also can be used to construct larger body prostheses such as finger, hands, arm and leg covers.

INTENDED USERS:

The HCR Prosthetic Silicones (1:1) are intended for professional use only, in particular maxillofacial and orthopaedic 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:

The HCR Prosthetic Silicones (1:1) are intended to be used on patients who need a maxillofacial and body prosthesis due to the loss of body parts due to congenital malformation, tumour surgery or trauma.

INDICATIONS OF USE:

The HCR Prosthetic Silicones (1:1) are useable in most situations – see Intended Use (above) for conditions indicating the use of the device.

CONTRAINDICATIONS/LIMITATIONS OF USE:

The HCR Prosthetic Silicones (1:1) are suitable to be used for making external maxillofacial prostheses on fully healed sites. Silicone rubber is an extremely durable and biocompatible material when fully cured. The cured HCR Prosthetic Silicones (1:1) will not show any degradation of mechanical properties in use unless exposed to extreme temperature. The material has a shelf life of 6 months from date of shipment when stored in original containers at room-temperature.

PRODUCT RANGE:

Teksil 20 -	Standard High Consistency 1:1 Silicone Rubber
Teksil 35 -	Standard High Consistency 1:1 Silicone Rubber
Teksil 65 -	Standard High Consistency 1:1 Silicone Rubber
Alsil 10 -	Standard High Consistency 1:1 Silicone Rubber
Alsil 20 -	Standard High Consistency 1:1 Silicone Rubber
Alsil 35 -	Standard High Consistency 1:1 Silicone Rubber
Alsil 65 -	Standard High Consistency 1:1 Silicone Rubber
Alsil 80 -	Standard High Consistency 1:1 Silicone Rubber

APPLICATION INSTRUCTIONS:

For full details refer to Technovent User Guides at www.Technovent.com

The elastomers are supplied in two-component kits (Parts A & B) that must be thoroughly mixed in equal portions, by weight, prior to use. Typically, a two-roll mill is used for the blending process.

When weighing out Part A and B of the material ensure you use a calibrated scale with accuracy to 100th of a gram (i.e 2 x decimal point)

- Use 1-part A by weight to 1 part of B by weight e.g., 100g part A to 100g part B = 200g
- Ensure that both parts are uniformly and evenly blended in the mill.
- Cure for a minimum of 1 hour at 100°C. For curing without a mould a prolonged cure at lower temperature (50°C) is recommended to avoid air blows in the silicone.
- Work time at 21°C is 5-6 hours.

Please note: Work times will decrease at higher temperature and increase at lower temperature. To prolong work time the material can be stored in the fridge or freezer after blending.

Table 1 – Average Mechanical Properties of The HCR Prosthetic Silicones (1:1)

Material	Hardness (Shore A)	Tensile Strength (N/mm ²)	Percentage Elongation	Tear Strength (N/mm)
Teksil-20	22	9.83	1283	35.22
Teksil-35	36	8.28	1117	32.22
Teksil-65	61	8.05	939	42.21
Alsil-10	10	9.83	1283	35.22
Alsil-20	20	8.28	1117	32.22
Alsil-35	35	8.05	939	42.21
Alsil-65	65	9.02	879	45.31
Alsil-80	80	10.65	500	48.91

STORAGE:

The HCR Prosthetic Silicones (1:1) are supplied non-sterile in plastic packaging 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:












- Ensure care is taken to weigh out accurately and fully cure the material. Failure to do so will result in inferior mechanical properties and potentially early failure of the prosthesis.
- 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.
- Addition cure silicone rubber materials are low surface energy biologically inert materials. In the unlikely event of a localized allergic reaction to the material, stop using immediately and seek advice from Technovent.
- If adhesives are used to retain the prostheses 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.
- All Technovent silicones are platinum catalyzed addition curing materials. Avoid the use of latex gloves which can poison the silicone and stop the full curing of the material in the mould.

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 as 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. Avoid use on broken skin.