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TECHNOVENT

INSTRUCTIONS FOR USE

Prosthetic Silicones (10:1 mixing ratio)

PRODUCT DESCRIPTION:

The Prosthetic Silicones (10:1) are a range of 2 parts (A and B) silicone rubber materials for prosthetic use which are mixed 10:1 by weight ratio A:B.

INTENDED USE:

Prosthetic Silicone Rubbers (10:1 ratio) are designed to 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.

INTENDED USERS:

Prosthetic Silicone Rubbers (10:1 ratio) are intended for professional use only, in particular maxillofacial 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:

Prosthetic Silicone Rubbers (10:1 ratio) 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:

Prosthetic Silicone Rubbers (10:1 ratio) are useable in most situations – see Intended Use (above) for conditions indicating the use of the device.

CONTRAINDICATIONS/LIMITATIONS OF USE:

Prosthetic Silicone Rubbers (10:1 ratio) 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 Prosthetic Silicone Rubber (10:1 ratio) materials will not show any degradation of mechanical properties in use unless exposed to extreme temperature. If, however the uncured materials are stored without use for long periods of time hydrogen bonding between filler particles (structuring) can occur which will increase the viscosity of the material making it more difficult to mix. Although this hydrogen bonding doesn't affect the curing or mechanical properties of the cured material, it is recommended that on long term storage the material is opened and mixed every week to reduce the thickening effect.

PRODUCT RANGE:

M511 - Standard Liquid 10:1 Silicone Maxillofacial Prosthetic Rubber

Teksil-25 - Standard Liquid 10:1 Silicone Maxillofacial Prosthetic Rubber

A588-1 - Standard Liquid 10:1 Silicone Maxillofacial Prosthetic Rubber

A588-2 - Standard Liquid 10:1 Silicone Maxillofacial Prosthetic Rubber

A-2186 - Standard Liquid 10:1 Silicone Maxillofacial Prosthetic Rubber

VST-30 - Standard Liquid 10:1 Silicone Maxillofacial Prosthetic Rubber

VST-50 - Standard Liquid 10:1 Silicone Maxillofacial Prosthetic Rubber

VST-50F - Standard Liquid 10:1 Silicone Maxillofacial Prosthetic Rubber

VST-50HD - Standard Liquid 10:1 Silicone Maxillofacial Prosthetic Rubber

APPLICATION INSTRUCTIONS:

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

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 10-parts A by weight to 1 part of B by weight e.g. 10g part A to 1g part B = 11g
- Ensure that both parts are uniformly and evenly mixed.

Please note: Work times will decrease at higher temperature and increase at lower temperature.

Table 1 – Average Mechanical Properties of Prosthetic Silicone Rubbers (10:1 ratio)

Material	Work Time at 21°C (mins)	Cure Time at 100°C (Hours)	Hardness (Shore A)	Tensile Strength (N/mm^2)	Percentage Elongation	Tear Strength (N/mm)
M-511	90	1	24	2.94	1514	23.21
Teksil-25	20	1	27	3.48	551	24.10
A-588-1	60	1	12	4.13	425	7.88
A-588-2	60	1	30	4.83	600	11.38
A-2186	120	1	30	6.20	650	15.76
VST-30	10	1	23	4.79	525	17.51
VST-50	90	3	30	5.17	480	19.61
VST-50F	30	1	28	4.99	500	18.56
VST-50HD	120	3	38	5.17	480	19.61

STORAGE:

The Prosthetic Silicones (10:1 ratio) 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:

- 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 Lot Number

 Manufacturer

REF 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

EC REP Authorised Representative in the European Community

MD Medical Device

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