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INSTRUCTIONS FOR USE

Softening Agent and Gel Part B (M511 System)

PRODUCT DESCRIPTION:

The softening agent is an additive to reduce the hardness of cured M511 silicone rubber. The Gel Part B is an alternative cross-linker for M511 which creates a gel material, rather than a rubber.

INTENDED USE:

Both materials are designed to be used as additives for M511 a silicone rubber 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:

Softening agent and Gel Part B 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:

Softening Agent and Gel Part B are intended to be used for the construction of prostheses for 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:

Softening Agent and Gel Part B are useable in most situations – see Intended Use (above) for conditions indicating the use of the device.

CONTRAINDICATIONS/LIMITATIONS OF USE:

Only to be used within the M511 maxillofacial silicone rubber system.

PRODUCT RANGE:

M510 - M511 Gel Part B
M513 - M511 Softening Agent

APPLICATION INSTRUCTIONS:

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

Softening Agent

The softener should be added at the same time as part B of the M511 maxillofacial silicone rubber and mixed thoroughly.

The maximum amount of softener added should never exceed the amount of part B added: e.g. if 10g of part A is weighed out 1g of part B should be added and a maximum of 1g of softener can also be added.

Table 1 – Average Mechanical Properties of M511 with Maximum Softening Agent

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	15	2.38	1544	13.55

Gel Part B

Mix 10:1 with standard M511, e.g. if 10g of part A is weighed out 1g of Gel part B should be added.

STORAGE:

The Softening Agent and Gel Part B are supplied in plastic dropper bottles 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.












- 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 within 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.