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INSTRUCTIONS FOR USE

Thixotropic/Anti Slump Agents

PRODUCT DESCRIPTION:

Silicone polymer-based additives designed to thicken uncured prosthetic silicones.

INTENDED USE:

The Thixotropic/Anti-Slump Agents are used to thicken silicone materials prior to being placed in a processing mould.

INTENDED USERS:

The Thixotropic/Anti-Slump Agents 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:

Thixotropic/Anti-Slump Agents 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:

Thixotropic/Anti-Slump Agents are useable in most situations – see Intended Use (above) for conditions indicating the use of the device.

CONTRAINDICATIONS/LIMITATIONS OF USE:

Thixotropic/Anti-Slump Agents are suitable to be used in the construction of external maxillofacial prostheses on fully healed sites. The materials are fully encapsulated in the

silicone rubber material and there should not be any full contact with external healed skin.

PRODUCT RANGE:

The Thixotropic/Anti-Slump Agents are specialized polymers designed to thicken filled silicone elastomer bases (see Table 1 below)

Table 1 – Thixotropic/Anti-Slump Agents

A-300-1	Thixotropic Agent (30g)
A-300-8	Thixotropic Agent (30g)
M514	Anti-Slump Agent (20g)

APPLICATION INSTRUCTIONS:

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

The Thixotropic/Anti-Slump Agents are designed to be added to silicone material while they are still un-crosslinked and in a 'wet' viscous state.

Add approximately one drop per 10g of thixotropic agent to the silicone after mixing A and B together prior to placing in the mould.

STORAGE:

The Thixotropic/Anti-Slump agents 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:

- This material is designed for external use only on unbroken healed skin.
- Using excess thixotropic agent can affect the mechanical properties of the silicone.

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 in the construction of external prostheses for use 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



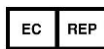
Expiry Date



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.