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INSTRUCTIONS FOR USE

Coform Hard and Soft

PRODUCT DESCRIPTION:

Cartridge based silicone materials for taking external impressions to aid the construction of prostheses.

INTENDED USE:

The Coform impression materials are designed as an external impression material for use within maxillofacial technology. The materials are thixotropic so they do not run or slump when injected on a vertical surface. Coform-Soft is designed as a high detail impression which is designed to be backed with Coform-Hard impression material.

The materials are 2-part 1:1 room temperature [RT] platinum addition cure system.

The materials are supplied in dual cartridge dispensing system for use with the supplied mixing nozzles and dispensing gun.

INTENDED USERS:

Coform Hard and Soft 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:

Coform Hard and Soft silicones 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:

Coform Hard and Soft silicones are useable in most situations – see Intended Use (above) for conditions indicating the use of the device.

CONTRAINDICATIONS/LIMITATIONS OF USE:

Coform Hard and Soft silicone is suitable to be used for taking external impression on fully healed sites. Silicone rubber is an extremely durable and biocompatible material when fully cured. The cured Coform Hard and Soft material will not show any degradation of mechanical properties in use unless exposed to extreme temperature. The material has a shelf life of 3 years from point of manufacture.

PRODUCT RANGE:

M517 - Coform Soft 1:1 Silicone Impression Rubber
M518 - Coform Hard 1:1 Silicone Impression Rubber

APPLICATION INSTRUCTIONS:

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

Fit new mixing nozzle by locating onto end of cartridge and twisting to lock. Pump gun several times to advance the plunger until a little of the mixed material is ejected through the end of the nozzle.

Table1: Work and Cure Time for Coform Materials

<u>MATERIAL</u>	<u>Work Time</u>	<u>Cure Time</u>
COFORM-SOFT	40 seconds	3-4 minutes
COFORM-HARD	20 seconds	3-4 minutes

All cure times and work times were measured at 21°C, times will reduce with increased room temperature and decrease with lower temperature. To increase work times the materials should be stored in a refrigerator.

STORAGE:

The Coform impression materials are supplied non-sterile in dual dispensing cartridges 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.
- 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 as external impression 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.