Materials & Manufacturing

Component Evaluation Report for Design Examination

Product:	**Breast implants** **Smooth IMGHC – LS types** **Textured IMGHC –TX types**
Submission No:	**2003/098**
File No:	**2003/003664**
Sponsor:	**Medical Visions Australia**
Sponsor ID:	**29703**
Manufacturer:	**Poly Implants Prostheses**

RECOMMENDATION

Materials applied in the gel filled breast implants are appropriate and provided documentation is satisfactory. Manufacturing conditions are established in accordance with the chosen polymers processing parameters. Manufacturing processes are adequately described and documented.

EVALUATION

1. Description of evaluated materials

The following materials are used in the manufacture process:

- **Nusil MED6 6400**(polydimethyldiphenylsiloxane) for all layers of envelopes (smooth – 4, textured –5) and closure/finishing patch.
  The supplier's curing conditions: 45 ± 5 minutes @ 75 ± 5°C plus 135 ± 15 minutes @ 150 ± 5°C.
- **Nusil MED 6640** (polydimethylmethylvinylsiloxane) for the very first glue layer inside the envelope (applied on the mould before dipping) facilitating connection during patching process.
  ~~**Nusil MED 2245** (polydimethylmethylvinylsiloxane), so called glue,~~ its solution in Heptane is used to form a closure patch.

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The supplier's curing conditions: 10 ± 0.5 minutes @ 171 ± 5°C, post cure 120 ± 5 minutes @ 148 ± 5°C.

- **Nusil MED3 6300** (polydimethylmethylvinylsiloxane) highly cohesive gel/filling material. The supplier's curing conditions: 5 hours @ 140 ± 2°C.
- **Applied Silicone PN 40076** (medical grade silicone elastomer) polymer solution used to close filling holes before the final, gel curing step.
- **Additives:**
  Xylene (solvent in the Nusil silicone dispersions and purchased by PIP from another supplier to adjust the dispersions viscosity),
  Heptane (for viscosity adjustment and as a solvent for the glue),
  Ethanol (envelopes cleaning),
  Isopropanol (stamp patches cleaning),
  Texturing agent (calibrated saccharose/purified cane sugar No 1),
  3% Hydrogen peroxide (finished product washing).
- **Teflon film** – little strips used to create a filling hole during the closure patch assembly.
- **Packaging**: internal and external blisters are formed in PETG, lids are made of Tyvek.

Specifications are provided for all of the above listed materials. The specified mechanical and chemical properties are for polymers cured according to conditions specified by their supplier.

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4. **Noticed irregularities in documentation**

- "Nusil MED26 6400 for last layer of textured envelope" (page 30), nowhere else this material is mentioned, in Technical File in the analogical information related to envelopes NuSil MED 6 6400 is specified;
- No information about solvent and curing conditions for the NuSil PN 40076, this polymer is used for closure of the filling hole therefore its small amount is in immediate contact with tissues – more data could be necessary if this material is not included in biocompatibility testing.
- Discrepancy in provided information; on page 1845 closure patch is made of MED 2245, in the provided response to TGA Section 41JA request (table specifying curing conditions) closure patch is specified as made of MED6 6400.

5. **Justification for the recommendation**

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All materials are processed according to suppliers' recommendations with only one exception. The filling gel MED3 6300 is cured in the breast implants for much shorter time that recommended. NuSil Silicone Technology recommends 5 hours at 140°C, in the breast implants this polymer was exposed to the recommended curing temperature only for 3 hours. As every batch of the filling gel is tested for penetrability and level of the implants so-called gel bleeding is lower then in the classic shells, the change of the recommended curing time is documented as acceptable.

The polydimethyldiphenylsiloxane (MED6 6400) is commonly used in other manufacturers breast implants as a barrier layer, in the implants under evaluation all four or five layers are made of this material which is recognised as possessing better barrier properties.

Prepared by:

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Device Registration and Assessment Section
16 October 2003