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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.

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.

2. Manufacturing process

The main manufacturing steps

- **Dipping** - the shells/envelopes manufacture; when the 4 layers of MED6 6400 polymer are applied the envelopes are oven cured (140°C for 180 minutes).
- **Texturing** – manufacture of an extra, fifth, textured layer of the silicone polymer (MED6 6400) on the TX models. The oven cured envelopes are immersed in the polymer dispersion, the texturing agent is applied and the whole sysytem is oven cured again (130°C for 120 minutes).
- **Silicone plate manufacturing** – flat sheet of the MED6 6400 polymer used to make finishing or closure patches. Emulsion of the polymer is dispersed over a flat surface and oven cured (140°C for 180 minutes)
- **Marking** – strips of the silicone plate are laser marked with relevant data before the patches are cut.
- **Gluing** – closing the hole in the envelope/shell. Prepared closure patch (made of the MED 2245) and patch cut from the marked strips of MED6 6400 (finishing patch) are assembled with Teflon strip to create a filling hole. The "closure patch – finishing patch" assembly is inserted in the shell/envelope and pressed to perform so-called "cold gluing". The closed shells are again oven cured (160°C for 90 minutes).
- **Filling** – The shells are filled with the row MED 3 6300 according to specification, stored in vacuum to remove babbles of air from the polymer and the filling hole in glued with the NuSil PN 40076 silicone elastomer. The whole implant is again oven cured to cure the filling gel (140°C for 180 minutes).

- **Washing and packaging** – the implants are manually, individually brushed in 10 volume of hydrogen peroxide, soaked in the fresh hydrogen peroxide solution for 15 minutes and wipeed with flush – free duster. Every implant is separately packed in two blisters with individual covers.

All flowcharts for the manufacturing steps contain identification numbers of relevant work instructions.
Provided descriptions, supported by the operations flowcharts, are clear and fully informative.
Every step has defined/described quality inspections of the products to eliminate nonconforming items from further processing.

Curing conditions of various components of the breast implants are in accordance with the supplier recommendations with one exception. The filling gel MED3 6300 according to its supplier (NuSil Silicone Technologies) ought to be cured at 140°C for 5 hours, the Poly Implant Prostheses is curing the filled implants only for 3 hours at the recommended 140°C.

3. Additional information provided on TGA request

Polymerisation/curing/catalysis conditions (temperature and duration of every step) applied during manufacturing process for envelopes, patches, glue and filling gel.

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

Generally information related to row materials used in the manufacturing process is satisfactory (supply documentation, specifications, storing and curing conditions) and provided documentation is well organised.

Manufacturing processes are well defined, provided information clear. Specific work instructions are not included in the provided documents but their identification symbols are included in relevant flowcharts.

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
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