# Polymer Systems Technology Limited

UK & Ireland Distributor

NuSil SILICONE TECHNOLOGY®
Creative Partners in a Material World


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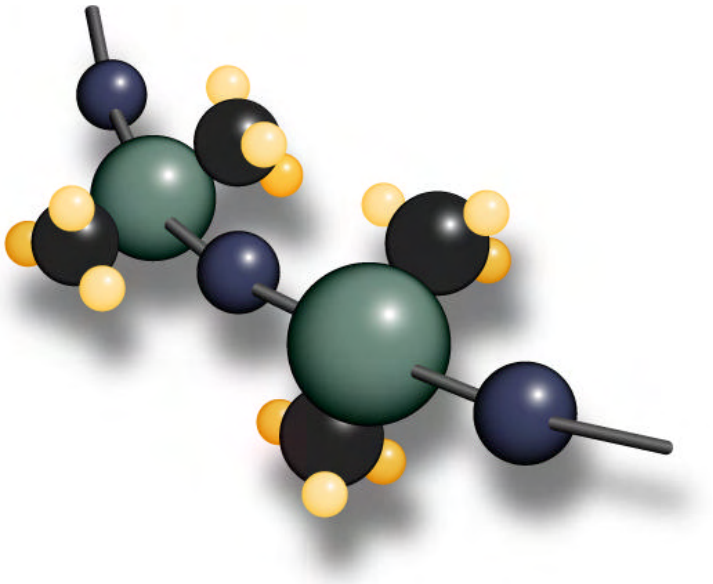

NuSil SILICONE TECHNOLOGY

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# Low Durometer Silicones Designed for Soft Tissue Implant Applications

Silicone materials, in various forms, have a long history of use in healthcare applications. The wide range of silicone types combined with silicone's good physical properties, excellent stability, and established biocompatibility make silicone the ideal material for many healthcare applications. Silicone gels and elastomers have been used in soft tissue implant applications for decades because gels offer softness and silicone elastomers offer increased cohesive strength. However, they both offer these unique benefits independent of the other.

NuSil's MED-4801, MED-4805, and MED-4286 silicone elastomers bridge the gap between silicone gels and elastomers. When cured with heat, they yield low or ultra low durometers and subsequently provide softness near to that of many gel products, but with the increased cohesive strength of an elastomer. A chart comparing their physical properties is listed below.

| NuSil Product Number | Cure | Work Time | Durometer | Rheology | Elongation | Tear Strength | Comments |
|---|---|---|---|---|---|---|---|
| MED-4286 | 45 minutes @ 150°C | 14 hours | 55 "000" | 6500 cP | 475% | - | Low modulus, easily moldable |
| MED-4801 | 5 minutes @ 150°C | 6 hours min. | 40 "00" | 160 g/min | 1075% | 60 ppi 10.6 kN/m | Low modulus, long work time |
| MED-4805 | 5 minutes @ 150°C | 24 hours | 7 "A" | 67 g/min | 1100% | 60 ppi 10.6 kN/m | LSR with high tear strength |

These materials are designated as Unrestricted and may be considered for use in long-term implant applications (29 days or longer). They may also be considered for use in soft tissue implant devices such as:

- Maxiofacial
- Pectoral
- Testicular
- Calf
- Malar
- Gluteal

These materials are offered in a variety of packaging which will accommodate most processing requirements. Standard packaging configurations include:

50 ml SxS Kit
400 ml SxS Kit
2 Pint Kit (910 g)
2 Gallon Kit (7.28 kg)
10 Gallon Kit (36.4 kg)
2 Drum Kit (360.0 kg)

## About NuSil Technology

NuSil Technology is a cutting edge global formulator and manufacturer of silicone compounds for the healthcare industries with over 30 years of experience. Developing novel silicone systems, NuSil offers a complete line of customizable adhesives, elastomers, fluids, and gels. We meet the demands of new and innovative technologies by building on our experience and expanding our products and services to offer exclusive silicone solutions specifically designed for drug delivery and combination medical device products.

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## Regulatory Support

MED-4286, MED-4801 and MED-4805 are supported by US FDA Masterfiles, including extensive biological testing. Customer interested in authorization to reference Masterfiles or requiring assistance with submissions to other regulatory agencies must contact NuSil Technology.

| Test | Standard/Method | Test Results |
|---|---|---|
| Cytotoxicity Study Using The ISO Elution Method (1X MEM Extract) | ISO 10993-5 USSP<87> | A-Noncytotoxic<br>B-Noncytotoxic<br>C-Noncytotoxic |
| ***In Vitro*** Hemolysis Study (Modified ASTM-Extraction Method) | ISO 10993-4 | A-Nonhemolytic |
| USP and ISO Systemic Toxicity Study Extract* | ISO 10993-11 USP <88> | A-Nontoxic |
| ISO Intracutaneous Study Extract* | ISO 10993-10 USP <88> | A-Nonirritant |
| ISO Muscle Implantation Study 1 Week*<br>ISO Muscle Implantation Study 12 Week | ISO 10993-6 USP <88> | A-Nonirritant<br>A-Nonirritant |
| Genotoxicity: Bacterial Reverse Mutation Study (DMSO and Saline Extracts) | ISO 10993-3 | A-Nonmutagenic |
| USP Pyrogen Study Material Mediated | ISO 10993-11 USP <151> | A-Nonpyrogenic |
| ISO Maximization Sensitization Study | ISO 10993-10 | A-Nonsensitization |
| Mammalian Mutagenesis<br>Schultz, "Scientific Justification For The Deletion Of Certain Biological Test From The Testing Scheme Proposed In The FDA's 'Guidance for Manufacturers Of Silicone Devices Affected By The Withdrawal Of Dow Corning Silastic Materials.' " | ------- | ---------- |
| Cytogenic Damage<br>Schultz, "Scientific Justification For The Deletion Of Certain Biological Test From The Testing Scheme Proposed In The FDA's 'Guidance for Manufacturers Of Silicone Devices Affected By The Withdrawal Of Dow Corning Silastic Materials.' " | ------- | ---------- |

NOTE: Some applications may require that devices made from these materials be encapsulated. For those purposes MED-6400, MED-6600 and MED-6655 are suggested. Contact NuSil Technology for more information.

Restricted (may be considered or use in short-term implant applications (29 days or less) or for external applications) versions of these materials are also available, please contact NuSil Technology for additional information.

For more information, please visit:
**www.nusil.com**

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