

MED-6311

HIGH PURITY SILICONE GEL

DESCRIPTION

- A high purity, clear silicone gel manufactured under controlled conditions
- Resists fracturing under stress
- Easy mixing, two-component, low viscosity system
- 1:1 Mix Ratio (Part A: Part B)
- Alternate mix ratios may be considered to adjust penetration

APPLICATION

- Ideal for backfilling and dampening
- Suitable for applications requiring a high purity, clear silicone gel that resists fracturing under stressed conditions
- NuSil Technology can formulate custom materials to meet specific penetration requirements

NuSil Technology's MED-6311 may be considered for use in human implantation for a period of greater than 29 days.

PROPERTIES

TYPICAL PROPERTIES	AVERAGE RESULT	STANDARD	NT-TM
Uncured:			
Appearance	Transparent	ASTM D2090	002
Viscosity	500 cP (500 mPas)	ASTM D1084, D2196	001
Volatile Content	0.10%	ASTM D2288	004
Specific Gravity	0.97	ASTM D891/D1475	022

Cured: 3.5 hours at 160°C (320°F)

TYPICAL PROPERTIES	AVERAGE RESULT	STANDARD	NT-TM
Penetration (Lab Line Penetrometer, 12g shaft, 1" diameter foot, 5 seconds)	2.6 mm	-	011
Tissue Culture (Cytotoxicity Testing)	Pass	USP <87> ISO 10993-5	061
Elemental Analysis of Trace Metals	Pass	ASTM E305	131

The above properties are tested on a lot-to-lot basis. Do not use as a basis for preparing specifications. Please [contact](#) NuSil Technology for assistance and recommendations in establishing particular specifications.

INSTRUCTIONS FOR USE

Mixing

Combine Parts A and Part B in a 1:1 mix ratio prior to use. Airless mixing, metering, or dispensing equipment is recommended for production operations. If mixing by hand, take care to minimize air entrapment.

Vacuum Deaeration

Remove air entrapped during mixing by common vacuum deaeration procedure, observing all applicable safety precautions. Slowly apply full vacuum to a suitable container of at least four times the volume of material being de-aired. Hold vacuum until bulk deaeration is complete.

Substrate Considerations

Cures in contact with most materials common to biomedical assemblies. Exceptions include: sulfur-cured organic rubbers, latex, chlorinated rubbers, some RTV silicones and unreacted residues of some curing agents.

Note: Some bonding applications may require the use of a primer. NuSil Technology's MED1-161 is recommended. For more information on primer selection, visit www.nusil.com and review [Choosing a Silicone Primer/Adhesive System](#).

Packaging

2 Pint Kit (0.91 kg)
2 Gallon Kit (7.28 kg)
10 Gallon Kit (26.4 kg)
2 Drum Kit (340 kg)

Warranty

12 Months

FDA MASTER FILE

A Master File for MED-6311 has been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the Master File must [contact](#) NuSil Technology.



REACH COMPLIANCE

MED-6311 is compliant with the Registration, Evaluation, and Authorization of Chemicals (REACH) regulation (European Union 1907/2006). MED-6311 does not contain any of the chemicals or substances identified as Substances of Very High Concern (SVHC) by the European Chemicals Agency (ECHA), which oversees REACH compliance.

Please [contact](#) NuSil Technology's Regulatory Compliance department with any questions or for further assistance.

SPECIFICATIONS

Do not use the properties shown in this technical profile as a basis for preparing specifications. Please [contact](#) NuSil Technology for assistance and recommendations in establishing particular specifications.

WARRANTY INFORMATION

The warranty period provided by NuSil Technology LLC (hereinafter "NuSil Technology") is 12 months from the date of shipment when stored below 40°C in original unopened containers. Unless NuSil Technology provides a specific written warranty of fitness for a particular use, NuSil Technology's sole warranty is that the product will meet NuSil Technology's then current specification. NuSil Technology specifically disclaims all other expressed or implied warranties, including, but not limited to, warranties of merchantability and fitness for use. The exclusive remedy and NuSil Technology's sole liability for breach of warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted. NuSil Technology expressly disclaims any liability for incidental or consequential damages.

WARNINGS ABOUT PRODUCT SAFETY

NuSil Technology believes, to the best of its knowledge, that the information and data contained herein are accurate and reliable. The user is responsible to determine the material's suitability and safety of use. NuSil Technology cannot know each application's specific requirements and hereby notifies the user that it has not tested or determined this material's suitability or safety for use in any application. The user is responsible to adequately test and determine the safety and suitability for their application and NuSil Technology makes no warranty concerning fitness for any use or purpose. NuSil Technology has completed no testing to establish safety of use in any medical application.

NuSil Technology has tested this material only to determine if the product meets the applicable specifications. (Please [contact](#) NuSil Technology for assistance and recommendations when establishing specifications.) When considering the use of NuSil Technology products in a particular application, review the latest Material Safety Data Sheet and [contact](#) NuSil Technology with any questions about product safety information.



Do not use any chemical in a food, drug, cosmetic, or medical application or process until having determined the safety and legality of the use. The user is responsible to meet the requirements of the U.S. Food and Drug Administration (FDA) and any other regulatory agencies. Before handling any other materials mentioned in the text, the user is advised to obtain available product safety information and take the necessary steps to ensure safety of use.

PATENT / INTELLECTUAL PROPERTY WARNING

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