

MED5-6381

FIRM RTV SILICONE GEL

DESCRIPTION

- Pourable, three-component silicone gel
- 97 : 2.50 : 0.50 Mix Ratio (Base:Crosslinker:Catalyst)

APPLICATION

- Suitable for applications requiring a pourable, unfilled RTV material.

NuSil Technology's MED5-6381 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	Translucent	ASTM D2090	002
Viscosity	10,000 cP (10,000 mPas)	ASTM D1084, D2196	001
Cured: 24 hours at ambient temperature and humidity			
Specific Gravity	0.98	ASTM D792	003
Durometer, Type 00	75	ASTM D2240	006
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

Add 2.50% crosslinker and 0.50% catalyst by weight to the base material and mix thoroughly for two minutes. If an air-free mixture is desired, then vacuum de-air the mixture to minimize trapped air bubbles.

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 MED-160 is recommended. For more information on primer selection, visit www.nusil.com and review [Choosing a Silicone Primer/Adhesive System](#).

Packaging

1 Pint Kit (471 g)

Warranty

12 Months

FDA MASTER FILE

A Master File for MED5-6381 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

MED5-6381 is compliant with the Registration, Evaluation, and Authorization of Chemicals (REACH) regulation (European Union 1907/2006). MED5-6381 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.

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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.

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