

MED1-4013

Fast-cure silicone adhesive

DESCRIPTION

- Two-part, low-slump, solvent-free
- Cures rapidly at room temperature or with the application of heat
- Does not require atmospheric moisture to cure
- No curing byproducts such as acetic acid or methyl alcohol
- Cures via platinum catalyzed, addition-cure chemistry

APPLICATION

- Supplied in ready-to-use, airless cartridges
- For applications requiring the bonding of silicone to silicone, metals, urethanes and various other substrates

NuSil® MED1-4013 shall not be considered for use in human implantation for a period of greater than 29 days.

PROPERTIES

Typical Properties	Average Result	Standard	NT-TM
Uncured:			
Viscosity, Part A	80,000 cP (80,000 mPas)	ASTM D1084, D2196	001
Appearance	Translucent	ASTM D2090	002
Work Time	20 minutes	-	008
Cured: 24 hours minimum at ambient temp	perature and humidity		
Specific Gravity	1.12	ASTM D792	003
Durometer, Type A	20	ASTM D2240	006
Tensile Strength	1,000 psi (6.9 MPa)	ASTM D412	007
Elongation	760%	ASTM D412	007
Tear Strength	120 ppi (21.0 kN/m)	ASTM D624	009
Peel Strength	20 ppi (3.5 kN/m)	ASTM D1876	087
Tissue Culture (Cytotoxicity Testing)	Pass	USP <87>	061
		ISO 10993-5	





Typical Properties	Average Result	Standard	NT-TM
Elemental Analysis of Trace Metals	Pass	ASTM E305	131

The test data shown for this material is the average value for typical properties. All of these properties may not be tested on a lot to lot basis and cannot be used to draft specifications. Please contact NuSil for assistance and recommendations in establishing limits for product specifications.

INSTRUCTIONS FOR USE

Mixing

Combine Part 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. When using the airless dispensing cartridges, attach the disposable static mix tip and extrude the product directly onto the substrate.

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.

Surface Preparation

Thoroughly clean the surfaces being bonded with a non-oily cleaner or mild soap to remove any surface contaminants. Do not use synthetic detergents or oil-based soaps, as they may be absorbed and subsequently leach out. Rinse first with hot water, followed by a thorough rinse using distilled water. Use compatible degreasers to clean metal surfaces.

Bonding Applications

Spread a layer of silicone adhesive on one of the surfaces. Squeeze both surfaces together to bond. Apply sufficient pressure to ensure full contact without forcing the silicone adhesive from between the pieces.

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

Packaging

50 mL SxS Kit (0.054 kg) 200 mL SxS Kit (0.210 kg) 400 mL SxS Kit (0.420 kg) 2 Pint Kit (0.910 kg) 2 Gallon Kit (7.28 kg) 10 Gallon Kit (36.4 kg) **Case Packaging Available**

Warranty 12 Months

FDA MASTER FILE

A Master File for MED1-4013 has been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the Master File must contact NuSil.

REACH COMPLIANCE

Please contact NuSil's Regulatory Compliance department with any questions or for further assistance.

SPECIFICATIONS

Do not use the typical properties shown in this technical profile as a basis for preparing specifications. Please contact NuSil for assistance and recommendations in establishing limits for product specifications.

WARRANTY INFORMATION

The warranty period provided by NuSil Technology LLC is 12 months from the date of shipment when stored below 40°C in original unopened containers. Unless NuSil provides a specific written warranty of fitness for a particular use, NuSil's sole warranty is that the product will meet NuSil's then current specification. NuSil specifically disclaims all other expressed or implied warranties, including, but not limited to, warranties of

BIOMATERIALS PREMIUM CARE LINE





merchantability and fitness for use. The exclusive remedy and NuSil'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 expressly disclaims any liability for incidental or consequential damages.

WARNINGS ABOUT PRODUCT SAFETY

NuSil 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 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 makes no warranty concerning fitness for any use or purpose. NuSil has completed no testing to establish safety of use in any medical application.

NuSil has tested this material only to determine if the product meets the applicable specifications. (Please <u>contact</u> NuSil for assistance and recommendations when establishing specifications.) When considering the use of NuSil products in a particular application, review the latest Material Safety Data Sheet and <u>contact</u> NuSil 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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