

MED2-4213

Fast-cure silicone adhesives

DESCRIPTION

- Two-part, low-slump, solvent-free
- Cures rapidly 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® MED2-4213 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:			
Viscosity, Part A	80,000 cP (80,000 mPas)	ASTM D1084, D2196	001
Appearance	Translucent	ASTM D2090	002
Work Time	72 hours minimum	-	008
Cured: 15 minutes at 150°C			
Specific Gravity	1.11	ASTM D792	003
Durometer, Type A	14	ASTM D2240	006
Tensile Strength	845 psi (5.8 MPa)	ASTM D412	007
Elongation	800%	ASTM D412	007
Tear Strength	130 ppi (22.8 kN/m)	ASTM D624	009
Peel Strength	25 ppi (4.4 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 Consideration

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. Clean units being encapsulated or potted to ensure they are free of surface contaminates. Also, clean and dry containers and dispensers being used. Prevent cure inhibition by washing all containers with clean solvent or volatilizing the contaminants by heating.

Adjustable Cure Schedule

Products cure at a wide range of cure times and temperatures to accommodate different production needs. <u>Contact</u> NuSil for details.

FDA MASTER FILE

A Master File for MED2-4213 has been filed with the U.S. Food and Drug Administration (FDA). Customers interested in authorization to reference the Master File must contact NuSil.

REACH COMPLIANCE

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

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

SPECIFICATIONS

Do not use the typical properties shown in this technical profile as a basis for preparing specifications. Please <u>contact</u> 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 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

BIOMATERIALS IMPLANT LINE



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.

PATENT / INTELLECTUAL PROPERTY WARNING

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