



Factor II, Incorporated

Inventing and Innovating...

(Information: 1.928.537.8387)

ONLINE ORDERING www.factor2.com

PRODUCT INFORMATION **A-100 Medical Silicone Adhesive**

PRODUCT DESCRIPTION:

Medical Adhesive Silicone, is a one-component, low-slump, translucent silicone used to permanently bond materials. It contains no solvents and cures at room temperature upon exposure to atmospheric moisture. During the curing process, the silicone adhesive releases acetic acid vapor as a by-product. After final cure, the resulting silicone elastomer possesses the appearance, texture and general composition of many conventional silicone elastomers.

Features:

- Cures at room temperature when exposed to atmospheric moisture
- Translucent paste
- Provided in ready-to-use containers
- Available non-sterile
- Easy to apply and use

TYPICAL PROPERTIES AS SUPPLIED:

Property	Unit	Value
Appearance, uncured		Translucent paste
Skin-over time at 55% R.H.	minutes	7-8
Specific gravity at 25°C (77°F)		1.06
Durometer hardness, Shore A3		35
Tensile strength ³	MPa (psi)	3.3 (480)
Elongation at break ³	%	450

How to Use:

Surface Preparation:

Surfaces to be bonded or built-up with silicone adhesive should be cleaned thoroughly with non-oily cleaners or mild soap to remove possible surface contaminants. Rinse copiously with hot water and follow with a thorough rinse using distilled water. Allow surface to dry.

How to Apply:

Apply Medical Adhesive Silicone, to one of the prepared surfaces, and then quickly cover with the other substrate to be bonded. Apply sufficient pressure to ensure full contact, without forcing the silicone out from between the pieces. For best results, maintain a bond thickness of at least 0.25mm.

Under ambient conditions, the adhesive forms a thin, tack-free outer skin for thick-section films within a few minutes after application. Any shaping of the uncured adhesive should be completed before the skin forms.

Cure Time:

Curing or vulcanization time depends on the thickness of the silicone adhesive layer, the relative humidity and the accessibility of atmospheric moisture to the curing adhesive. Cure time is extended at lower humidity levels. Dry heat will not accelerate the cure and should not be used for at least the first 7 hours.



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A 2mm thick sheet of silicone elastomer bonded to stainless steel requires approximately 24 hours for complete vulcanization. Bond strength, however, continues to increase for several days. A 6.4mm thick sheet of silicone elastomer bonded to stainless steel under the same conditions requires 48 to 96 hours for complete vulcanization. If the relative humidity is greater than 60% when curing, a tacky surface may occur -especially with thin films. The tackiness can be removed by exposing the surface to a dry atmosphere.

Dispersion:

Medical Adhesive Silicone, Type A may be dispersed in moisture free aliphatic, aromatic or halogenated hydrocarbon solvents such as hexane or toluene. To disperse, the adhesive is added to the solvent and then agitated until a homogenous dispersion is obtained. A 10% concentration of Medical Adhesive Silicone, by weight will disperse in about 10 minutes when shaken by hand. The dispersion may be applied by brushing, dipping or spraying. A thin coat of cured silicone elastomer will result. Free films and membranes can be formed by coating the dispersion on suitable release sheets, such as polyethylene. If a release agent is needed, a one percent mild, non-oily soap solution may be used. The mild soap release agent may be removed after cure by repeated rinsing with water.

NOTE: When using any solvent, always provide adequate ventilation. When using flammable solvents, take precautions to prevent fire or explosion. Follow precautions on solvent container label.

Important Information:

It is the User's responsibility to ensure the safety and efficacy of this material for all intended uses. While this material has passed screening tests that are applicable to products intended or implantation for up to 29 days, Factor II makes no end use representation based on such testing. Nor does Factor II make any representation concerning the suitability of this product for applications of greater than 29 days of implantation in the human body.

Packaging:

This product is available in 90 gram tubes and 6 ounce Semco cartridges.

The Medical Adhesive Silicone, once opened, sterilization of the tube and its uncured contents is not recommended. The exterior of the tube and cap are non-sterile. They must be sterilized in a secondary packaging operation using either gamma irradiation or ethylene oxide to maintain product sterility during opening the tube. If irradiation is used, it is the user's responsibility to evaluate the effects of sterilization on the physical properties and usable life of the adhesive. If ethylene oxide sterilization is used, the gas will not penetrate the adhesive tube and will have no effect on the contents. It is the user's responsibility to validate either sterilization method to ensure sterility of the exterior and cap. DRY HEAT OR STEAM STERILIZATION MUST NOT BE USED AS THEY WILL MELT THE CAP.

Once sterilized, only the cap supplied with the adhesive should be used to open the blind end tube. Using the piercing pin side of the cap, push the pin straight into the tube. Remove the pin/cap and dispense the amount of adhesive desired. TO AVOID CONTAMINATION, USE ONLY THE CAP PROVIDED WITH THE ADHESIVE AND PUSH THE PIERCING PIN STRAIGHT IN.

WARRANT INFORMATION:



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