

Instructions for Affidavit

In order to purchase Medical Grade Products, the end user must have on file at the headquarters of Factor II, Inc., an affidavit of intended use. The purpose of this document is to formally proclaim that Factor II, Inc. does not sell any products that may be implanted into the human body, for any use of 29 days and above. Factor II, Inc. does not allow for sale silicone elastomer for the use to place uncured elastomer against living tissue for any prolonged use or exposure. We do not carry or sell any implantable products for any use within the body for any period beyond 29 days!

In an effort to comply with GMP Good Manufacturing Practices and all government regulatory affairs the sale of the certain products is limited to only those companies, institutions, or individuals who have submitted a sworn affidavit to the effect that this aforementioned product will only be used for acceptable purposes, that being external use for orthotic, prosthetic, and/or three dimensional devices or studies/research with approved animal protocol. The required affidavit and any supporting documentation noted are only for the reasons stated above and will be maintained in strictest confidence.

This document is only meant to serve as a vehicle to fully understand the END USE of this Silicone Product (Silicone Elastomer, Fluid or Adhesive.) If you the end user are in any way opposed to the wording used in this document, simply explain your intended use of the product on your company letterhead and submit this explanation to the Management of Factor II, Inc. signed and notarized. Full confidentiality of your usage will be retained within Factor II, Incorporated's records.

Distribution Policy for Medical Grade Products

The purpose of this document is to formally proclaim that Factor II, Inc. does not sell any products that may be implanted into the human body, or cured against living tissue. We do not carry or sell any implantable products. The required affidavit and any supporting documentation noted are only for the reasons stated above and will be maintained in strictest confidence.

This document is only meant to serve as a vehicle to fully understand the END USE of this Silicone Product. If you, the end user is in any way opposed to the wording used in this document, simply explain your intended use of the product on company letterhead and return, signed by end user.

PLEASE RETURN THE SECOND PAGE BY MAIL TO:

Factor II, Inc. • Attn: Affidavit. P.O. Box 1339 . Lakeside, AZ 85929 USA

Email: info@factor2.com

Web: www.factor2.com

If you have questions or concerns regarding this process please contact us and we will be happy to assist you, our goal is to educate the end user in the choice of product, limiting the risk of any misunderstanding as to the products intended end use. This process will not only protect you the provider of a product or device but the patients Factor II, Inc serves.

Important Note

It is insufficient to have the name of an Institution on the affidavit. The Individual who is the actual end user MUST be on the affidavit. If the affidavit is returned without the name of the responsible party this product will not be shipped until this document with signature is on file. To speed the approval of this process we will ship with a faxed or emailed copy and the original can be mailed at your convenience.

Please Indicate the Product(s) that you are intending to purchase from Factor II, Inc.

Product(s): _____

From this point on, the product(s) listed above shall be referred to as the "aforementioned product(s)".
This form should NOT BE ALTERED IN ANY MANNER.

Name of INDIVIDUAL using the product	_____
Federal ID or Social Security Number	_____
Company or Organization	_____
Address1	_____
Address2	_____
City	_____
State	_____
Postal Code	_____
Country	_____
Phone	_____
Fax	_____
E-Mail	_____

I, _____ being duly sworn, depose and say as follows:
I certify that I will not knowingly use, in either its pure state or as a component of some other material, any of the aforementioned product(s) hereafter received by me from Factor II, Inc. into humans for injection into any areas of the body, or onto any areas of the body in an uncured state, nor will I supply the aforementioned product(s) to others for such purposes.

Is the product to be implanted? YES / NO .

If YES, is the product to be implanted into: HUMANS / ANIMALS

Duration of implantation (months/days/hours/minutes)

Is the product to be in contact with tissue externally? YES / NO

How and in what form _____

Please describe briefly below (or on separate page if need be) the protocol for your application of the aforementioned product(s). I certify that a current study protocol or detailed protocol summary (on letterhead stationery) is attached to this affidavit or explanation thereof:

Signature: _____

Notary Public/Witness: _____

Date _____