

ALL FIELDS WITH * MUST BE FILLED OUT!!!
THIS FORM SHOULD NOT BE ALTERED IN ANY MANNER.

*Factor II Product Code(s): _____
(Aforementioned product)

*Name: INDIVIDUAL Responsible for product	
*Company or Organization	
*Address 1	
*Address 2	
*City	
*State	
*Postal Code	
*Country	
*Telephone	
*Fax	
*Email	

*****PLEASE ANSWER ALL QUESTIONS BELOW INCLUDING THE BRIEF DISCRPTION*****

*Is the product to be in contact with tissue externally?

*How and in what form(Cured or Uncured)?

*Please briefly describe below (or on separate page if necessary) the protocol for your application of the aforementioned product(s).

*Is the product to be implanted?

If YES, attach additional information/protocol, along with this document.

*How long will the product be implanted? _____ Days

*Print Name: _____, being duly sworn, depose and say as follows:

I certify that I will not use, either in 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. for injection or implantation into any areas of the human body in a cured or uncured state, or onto any areas of the human body in a cured or uncured state for an un-approved application, nor will I supply the aforementioned product(s) to others for such purposes.

*Signature: _____

*Title: _____

*Date: _____

AFFIDAVIT INFORMATION

Overview

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 or come in contact with human tissue in an uncured form. **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 Good Manufacturing Practices (GMP) and all government regulations, the sale of certain products is limited to only those companies, institutions or individuals who have submitted a sworn affidavit to the effect that the 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 protocol. The required affidavit and any supporting documentation noted are only for the reasons stated above and will be maintained in strict confidence.

This document is required for silicone purchases to fully understand the END USE of the silicone products. Full confidentiality of your usage will be retained within Factor II, Inc.'s records.

PLEASE COMPLETE AND RETURN THE PREVIOUS PAGE TO:

Email: sales@factor2.com

OR

Fax: 928-537-0893

Our goal is to educate the end user in the choice of product, thus limiting the risk of any misunderstanding as to the product's intended end use. This process will not only protect you, the provider of a product or device, but also the patients Factor II, Inc. serves.

Important Note

It is insufficient to have only the name of an institution or company 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 or without all questions answered, this product will not be shipped until a fully completed document with signature is approved and on file.