

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

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

***ALL QUESTIONS MUST BE ANSWERED ***

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

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

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

*Will the final product to be implanted?

If YES, please attach additional information/protocol, along with this document.
We may contact you for further information.

*How long will the product be implanted? _____ Days

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

*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. **Factor II cannot advise if the product you are using will be suitable for your
application. All companies and/or individuals are responsible for final testing of their products
to determine their safety and use.**

*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 understand the END USE of 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

Factor II cannot advise if the product you are using will be suitable for your application. All companies and/or individuals are responsible for final testing of their products to determine its safety and use.

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.