

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, for any use of 29 days and beyond. 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 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 fluid. If the end user is in any way opposed to the wording used in this document, simply explain your intended use of the product on your company letterhead, sign and submit the explanation to management of Factor II, Inc. Full confidentiality of your usage will be retained within Factor II, Inc.'s records.

PLEASE COMPLETE AND RETURN THE FOLLOWING PAGE TO FACTOR II, INC.:

Email: sales@factor2.com

OR

Fax: 928-537-0893

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, 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, this product will not be shipped until a fully completed document with signature is on file.

