Policy Information

Rev. 2, January 2006

DuPont Performance Elastomers

DuPont Performance Elastomers Policy Regarding Medical Applications

DuPont Performance Elastomers is continuing its Policy regarding medical applications of its products and the following clarifies the Policy language based on more than a decade of experience. This Policy does not affect customers who use DuPont Performance Elastomers materials in medical articles unless the application involves implantation in the human body or contact with internal body fluids or tissues (Categories A and B below).

PRINCIPLES:

Several principles guide the approach used by DuPont Performance Elastomers to this area:

- We encourage business relationships within the health care industry that result in delivery of high value medical products.
- We seek to maintain safety where we are involved in the health care industry.
- We seek to maintain a positive relationship with the FDA and other regulatory agencies.
- We continually seek to identify areas where our businesses can contribute to the health care industry.

CATEGORIES:

DuPont Performance Elastomers classifies Medical Applications into the following three (3) categories:

Category A: Medical Applications involving permanent implantation (more than 30 days) in the human body or permanent contact with internal human body fluids or tissues;

DuPont Performance Elastomers may supply materials for a Category A application where DuPont Performance Elastomers is the owner, designer or manufacturer of the medical device, or there is an approved DuPont Performance Elastomers development program, or where the structure of the business relationship, or other business risk management strategies are determined to adequately manage the business risks. The decision whether particular business risk management strategies are adequate shall be made at the corporate level, at DuPont Performance Elastomers sole discretion, on a case by case basis, and shall not be made at the business unit level.

DuPont Performance Elastomers business units will not supply standard materials under ordinary terms to firms using such materials for medical applications involving permanent implantation in the human body. If customers, distributors or resellers fail to comply with this Policy, then DuPont Performance Elastomers business units shall discourage their use of DuPont Performance Elastomers materials.

Category B: Medical Applications involving brief or temporary implantation (30 days or less) in the human body and more than transient or minimal contact with internal human body fluids or tissues;

DuPont Performance Elastomers may decide to supply materials to customers. DuPont Performance Elastomers will not supply materials to customers with Category B applications unless the material is provided under the corporate risk management contract and other specific corporate risk management conditions are met. Permission to refer to material Master Files is restricted.

Category C: All other Medical Applications, including transient or minimal contact with internal human body fluids or tissues (where “transient” means less than 24 hours). Some examples of transient or minimal contact are drapes and gowns, clamps, needles, suction devices, bandages, sponges and bags and tubing for holding, storing or administering drugs.

DuPont Performance Elastomers will use normal good business judgment in forming supplier/customer relationships.

TRADE NAMES, MASTER FILES AND STANDARD CAUTION STATEMENT:

Unless DuPont Performance Elastomers expressly agrees by written contract, DuPont Performance Elastomers product names, trademarks and the DuPont Performance Elastomers name shall not be used in conjunction with either permanent or temporary implantable devices, and customers should not represent to others that DuPont Performance Elastomers permits, recommends, or endorses the use of our materials in implantable medical devices. Permission to

refer to material Master Files will be restricted, and given only to direct customers who are purchasing material under contract. Direct customers for Category A and B applications shall receive DuPont Performance Elastomers Standard Caution Statement regarding use of Company materials in implantable medical devices.

CAUTION:

DO NOT USE DUPONT PERFORMANCE ELASTOMERS MATERIALS IN MEDICAL APPLICATIONS INVOLVING **IMPLANTATION** IN THE HUMAN BODY OR CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES UNLESS THE MATERIAL HAS BEEN PROVIDED FROM DUPONT PERFORMANCE ELASTOMERS UNDER A WRITTEN CONTRACT THAT IS CONSISTENT WITH THE DUPONT PERFORMANCE ELASTOMERS POLICY REGARDING MEDICAL APPLICATIONS AND EXPRESSLY ACKNOWLEDGES THE CONTEMPLATED USE.

DUPONT PERFORMANCE ELASTOMERS MAKES NO REPRESENTATION, PROMISE, EXPRESS WARRANTY OR IMPLIED WARRANTY CONCERNING THE SUITABILITY OF THESE MATERIALS FOR USE IN **IMPLANTATION** IN THE HUMAN BODY OR IN CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES.

THE CONTENT OF **DUPONT PERFORMANCE ELASTOMERS** MATERIAL IS NOT CERTIFIED FOR IMPLANTS.

DuPont Performance Elastomers materials are not designed or manufactured for use in implantation in the human body or in contact with internal body fluids or tissues. DuPont Performance Elastomers has not performed clinical testing of these materials for implantation. DuPont Performance Elastomers will not provide to customers making implantable devices any notice concerning its materials, as specified under United States Code of Federal Regulations 21 CFR Section 820.50, or any other information necessary for medical device use of the materials under any other statute or FDA regulation. DuPont Performance Elastomers has neither sought, nor received, approval from the FDA for the use of these materials in implantation in the human body or in contact with internal body fluids or tissues.

DO NOT MAKE REFERENCE TO THE DUPONT PERFORMANCE ELASTOMERS NAME OR ANY DUPONT PERFORMANCE ELASTOMERS TRADEMARK IN ASSOCIATION WITH AN IMPLANTABLE MEDICAL DEVICE.

Do not use a DuPont Performance Elastomers trademark as the descriptive name of an implantable medical device.

ALL IMPLANTABLE MEDICAL DEVICES CARRY A RISK OF FAILURE AND ADVERSE CONSEQUENCES.

Regarding implantation of materials, you should rely upon the medical judgment of the physician, the medical device seller and the FDA. Do not rely upon DuPont Performance Elastomers. Examples of both harmful consequences and life-saving benefits from the implantation of various materials can be found in published medical articles. DuPont Performance Elastomers does not perform clinical medical studies of an implantable medical device. DuPont Performance Elastomers cannot weigh the benefits against the risks of a device and cannot offer a medical judgment on the safety or efficacy of the use of our material in a medical device.

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