



## **DuPont POLICY Regarding Medical Applications of DuPont Materials** **(January 1, 2011)**

DuPont is continuing its Policy regarding medical applications of DuPont materials and the following clarifies the Policy language based on more than a decade of experience. This Policy does not affect customers who use DuPont 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 DuPont approach 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 positive relationships with FDA and other regulatory agencies.
- We continually seek to identify areas where our businesses can contribute to the health care industry.

### **CATEGORIES:**

DuPont categorizes 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 may supply materials for a Category A application where DuPont is the owner, designer or manufacturer of the medical device, or there is an approved DuPont 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 the sole discretion of DuPont, on a case by case basis, and shall not be made at the business unit level.

DuPont 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 business units shall discourage their use of DuPont 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 strategic business units may decide to supply materials to customers. DuPont 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 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 packaging, including bags and tubing for holding, storing or administering drugs.

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

#### **TRADE NAMES, MASTER FILES AND STANDARD CAUTION STATEMENT:**

Unless DuPont expressly agrees by written contract, DuPont product names, trademarks and the DuPont name shall not be used in conjunction with either permanent or temporary implantable devices, and customers should not represent to others that DuPont 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's Standard Policy and Caution Statement regarding use of Company materials in implantable medical devices.

Copyright © 2008-2011 DuPont. The DuPont Oval Logo is a registered trademark of E.I. du Pont de Nemours and Company or its affiliates. All rights reserved.

H-50103-4