



## **DuPont POLICY Regarding Medical Applications of DuPont Materials** **(April 14, 2014)**

DuPont is continuing its Policy regarding medical applications of DuPont standard materials. DuPont standard materials are generally designed for industrial applications and are NOT a medical grade of material. DuPont standard materials are merely subject to fixed release specification. The following clarifies the Policy language based on more than two decades of experience. This Policy does not affect customers who use DuPont standard materials in medical applications 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 are committed to safety in our business and in the health care industry.
- We encourage business relationships within the health care industry that result in delivery of high value medical products.
- 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 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 level.

DuPont Businesses 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. Permission to refer to FDA material Master Files is restricted.

**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 Businesses may decide to supply standard materials to customers with Category B applications at their discretion if the material is provided under the Approved Terms and Conditions Contract and other specific corporate risk management conditions are met. Permission to refer to FDA 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 Businesses will use normal sound 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 for any customer to refer to an FDA material Master File must be obtained in writing for each individual application. Direct customers for Category A and B applications shall receive a copy of DuPont Standard Policy (this document) and its Caution Statement regarding use of Company materials in implantable medical devices (“DuPont Caution Regarding Medical Applications of DuPont Materials”).

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