



DuPont CAUTION Regarding Medical Applications of DuPont Materials

(January 1, 2011)

DO NOT USE DUPONT 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 UNDER A WRITTEN CONTRACT THAT IS CONSISTENT WITH THE DUPONT POLICY REGARDING MEDICAL APPLICATIONS AND EXPRESSLY ACKNOWLEDGES THE CONTEMPLATED USE.

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THE CONTENT OF DUPONT MATERIAL IS NOT CERTIFIED FOR IMPLANTS.
DuPont materials are not designed or manufactured for use in implantation in the human body or in contact with internal body fluids or tissues. DuPont has not performed clinical testing of these materials for implantation. DuPont 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 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 NAME OR ANY DUPONT TRADEMARK IN ASSOCIATION WITH AN IMPLANTABLE MEDICAL DEVICE.
Do not use a DuPont trademark as the descriptive name of an implantable medical device (e.g. do not call it the “Teflon® prosthesis” or “prosthesis made with Teflon®”).

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. Examples of both harmful consequences and life-saving benefits from the implantation of various materials can be found in published medical articles. DuPont does not perform clinical medical studies of an implantable medical device. DuPont cannot weigh the benefits against the risks of a device and cannot offer a medical judgment on safety or efficacy of use of our material in a medical device.

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