



DuPont Teijin Films CAUTION Regarding Medical Applications of
DuPont Teijin Films Materials
(January 1, 2011)

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

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

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 Teijin Films. Examples of both harmful consequences and life-saving benefits from the implantation of various materials can be found in published medical articles. DuPont Teijin Films does not perform clinical medical studies of an implantable medical device. DuPont Teijin Films 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.

Copyright © 2008-2011 DuPont Teijin Films. Mylar® is a registered trademark of DuPont Teijin Films. All rights reserved.