

Product Stewardship

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- use in cardiac prosthetic devices regardless of the length of time involved ("cardiac prosthetic devices" include, but are not limited to, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass-assisted devices);
- use as a critical component in medical devices that support or sustain human life; or
- use specifically by pregnant women or in applications designed specifically to promote or interfere with human reproduction.

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Additional Information

North America		Europe/Middle East	+800-3694-6367
U.S. & Canada:	1-800-441-4369		+31-11567-2626
	1-989-832-1426	Italy:	+800-783-825
Mexico:	+1-800-441-4369		
Latin America		South Africa	+800-99-5078
Argentina:	+54-11-4319-0100		
Brazil:	+55-11-5188-9000		
Colombia:	+57-1-219-6000	Asia Pacific	+800-7776-7776
Mexico:	+52-55-5201-4700		+603-7965-5392

www.dowplastics.com

This document is intended for use within Asia Pacific, Europe

Published: 2003-10-30

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