



AmSty Medical Application Policy

AmSty produces polystyrene products that are used in a variety of applications including medical. These products are produced under strict quality practices and management of change process. Products used in medical applications are covered under the Notification of Change Policy for Medical Accounts. These products have also been tested against the United States Pharmacopoeia <88> Biological Reactivity Tests *In Vivo* for Class VI Plastics and determined to be compliant with USP Class VI requirements.

AmSty will review, prior to use or sampling, customer requests regarding the use of AmSty products in medical end-uses and determine whether AmSty supports the use of its product(s) in the proposed medical application. The use of AmSty products in medical applications should have written approval from an AmSty representative.

AmSty will not knowingly sell or sample any product or service into any commercial or developmental application that is intended for any of the following unsupported applications:

- a. permanent (long term) contact with internal body fluids or internal body tissues. Long term is a use which exceeds 72 continuous hours;
- b. 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);
- c. use as a critical component in medical devices that support or sustain human life; or
- d. use in applications designed specifically to promote or interfere with human reproduction.

It is the responsibility of customers and distributors or resellers to abide by the above guidelines. AmSty reserves the right to cease sales if use in the above unsupported applications is discovered.

AMERICAS STYRENICS MAKES NO WARRANTIES, EXPRESS OR IMPLIED, CONCERNING THE SUITABILITY OF ANY AMERICAS STYRENICS PRODUCT FOR USE IN MEDICAL APPLICATIONS. AMERICAS STYRENICS DISCLAIMS ANY AND ALL LIABILITY FOR LOSSES OR DAMAGES THAT MAY RESULT FROM THE USE OF AMERICAS STYRENICS PRODUCTS IN MEDICAL APPLICATIONS.