EASTMAN

BPA free and biocompatible

MEDICA S.p.A. selects Eastman Tritan™ copolyester for manufacturing dialysis treatment devices.

A global producer of renal filtration equipment, MEDICA S.p.A. has switched from polycarbonate to Eastman Tritan™ copolyester to produce filter housings and caps for its SMARTFLUX dialyzers and neonatal blood filters. To better meet the biocompatibility needs of health care providers, MEDICA selected Tritan because it is a BPA-free material with excellent post-sterilization clarity and color stability. Eastman provided technical assistance for the transition from polycarbonate; and since Tritan does not require a separate annealing process due to lower residual stress of molded parts, MEDICA expects to see an added benefit of energy savings in manufacturing.

For more information on Eastman Tritan™ copolyester, visit www.eastman.com/medical.

MEDICA addresses the need for clear, biocompatible renal filtration devices by using Eastman Tritan™ copolyester for the filter housings and caps.

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The results of **insight**™

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Safety Data Sheets providing safety precautions that should be observed when handling and storing Eastman products are available online or by request. You should obtain and review the available material safety information before handling any of these products. If any materials mentioned are not Eastman products, appropriate industrial hygiene and other safety precautions recommended by their manufacturers should be observed.

It is the responsibility of the medical device manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including any Eastman product, used in its final product to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies.

Eastman products have not been designed for nor are they promoted for end uses that would be categorized either by the United States FDA or by the International Standards Organization (ISO) as implant devices. Eastman products are not intended for use in the following applications: (1) in any bodily implant applications for greater than 30 days, based on FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" tests (including any cosmetic, reconstructive, or reproductive implant applications); (2) in any cardiac prosthetic device application, regardless of the length of time involved, including, without limitation, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass assisted devices; or (3) as any critical component in any medical device that supports or sustains human life.

For manufacturers of medical devices, biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The ranges of tests under FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (subacute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available on request. The Manufacturer of the medical device is responsible for the biological evaluation of the finished medical device.

The suitability of an Eastman product in a given end-use environment is dependent on various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.

SP-MBS-1417 6/15