

EASTMAN

Connecting with confidence and safety

Elcam Medical chose Eastman Tritan™ copolyester for its stopcocks, resulting in a lasting partnership.

Elcam Medical is a world-class manufacturer of disposable medical devices for the OEM market. They strive to provide equipment for safer and more effective fluid management in medical settings. The company is a supplier to the medical industry's leading companies and has particular expertise in the areas of fluid management and intravenous therapy, vital-sign monitoring, interventional cardiology, radiology and dialysis.

When Elcam wanted to further improve its offering of safe and effective fluid management devices by developing a **drug- and lipid-resistant, BPA-free stopcock**, they turned to the technical experts at Eastman. **The experts recommended Eastman Tritan™ copolyester.**

Drug- and lipid-resistant polymers are playing an increasingly important role in enhancing patient safety. Tritan is resistant to a large spectrum of medical fluids, such as oncology drugs, drug carrier solvents and lipids that can cause cracking, crazing and hazing in other plastics. It is also known for its toughness, low residual stress and color stability post-sterilization

Tritan offers a clear advantage.

When devices lose their clarity and transparency, potential problems such as air bubbles are more difficult to detect. Meanwhile, stringent sterilization techniques can have a yellowing effect on certain polymers, which can impact color-coding systems in connector applications.

"To help offer safer patient treatment through the use of our products, we were interested in Tritan because of its BPA-free manufacture, drug and lipid resistance, and polymer performance when sterilizing," said Eldad Ohayon, Elcam Medical stopcock product manager. "But it also allows us to develop materials with improved thermal and mechanical properties compared to other polymers."

Elcam Medical designed its Tritan integrated four-way standard stopcock with T-handle to meet the ISO 80369-7 standard for intravascular and hypodermic applications. The goal of the standard is to improve patient safety by encouraging worldwide consistency in small-bore connectors for liquids and gases in healthcare applications. This consistency can help reduce the risk of misconnections between medical devices and accessories.

For more information about Elcam Medical and their Elcam Tritan integrated stopcock, visit www.elcam-medical.com.

To learn how Eastman Tritan copolyester can help you stay ahead of industry changes and meet new ISO 80369 standards for small-bore connectors, contact your Eastman representative or scan the QR code.



Made with Eastman Tritan copolyester, Elcam Medical designed its Tritan integrated stopcock to meet ISO 80369 standard for intravascular and hypodermic applications.

tritan™
from Eastman

EASTMAN

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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.

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