

# Support for molding precision medical devices

*World-class capabilities for small-bore connectors and other complicated parts*

The growing need for precision molding of complicated medical components has created an unmet need for advanced medical polymers. Many companies have found solutions in medical grades of Eastman Tritan™ copolyester—and the support provided by Eastman.

The success of Tritan is built on its unique combination of properties that includes:

- Biocompatibility—meets ISO 10993 and/or USP Class VI requirements
- Excellent chemical resistance against lipids, medical disinfectants, powerful drugs and their carrier solvents, and solvents used in secondary applications
- High impact strength—excellent durability
- Outstanding clarity and functional integrity after sterilization (EtO and gamma irradiation)
- Made without bisphenol A (BPA), halogens, or ortho-phthalate plasticizers
- Compliance with ISO 80369 standards ([http://www.eastman.com/Pages/Small\\_bore\\_connectors.aspx](http://www.eastman.com/Pages/Small_bore_connectors.aspx))

Eastman provides the region's highest level of technical support for those who design and mold complicated medical components. Two excellent examples of this support are demonstrated in a three-way stopcock that was designed and molded in Eastman's China Technology Center (CTC) in Shanghai and the development of a 32-cavity demonstration R&D mold.



*Three-way stopcock produced at our China Technology Center, drawing on in-house testing, molding, and application development capabilities*

## Expertise in multicavity processing of small medical parts

Eastman has made a commitment to working with customers to find precision multicavity molding solutions using Eastman Tritan™ copolyester in small, complicated medical parts. While Tritan was still relatively new to the medical device market, Eastman designed its own demonstration R&D mold and collaborated with a leading mold maker. The mold is a 32-cavity hot runner/valve gate system that shows the efficiencies possible when using Tritan to produce parts with outstanding clarity, toughness, chemical resistance, and sterilization stability—without BPA, BPS, or other chemicals of concern.

Watch a short video about this showcase mold (<http://www.tritanmoldit.com/medical/video-library#32-Cavity-Mold>), or read an in-depth blog (<https://www.tritanmoldit.com/blog/efficient-multicavity-processing-small-medical-parts>) at TritanMoldIt.com, Eastman's online technical information center.

The table shows how Eastman added value at three key phases in the commercialization of the three-way stopcock.

### Examples of Eastman capabilities and applied support

Phase	Eastman capabilities	Three-way stopcock application
Product development	<ul style="list-style-type: none"> <li>• Technical guidance for part design; mold flow analysis to improve molding success rate</li> <li>• Recommend best raw material and grade</li> <li>• Provide comprehensive data for chemical resistance</li> </ul>	<ul style="list-style-type: none"> <li>• Mold flow analysis                             <ul style="list-style-type: none"> <li>– Determine how product will fill the mold</li> <li>– Optimize position of weld line</li> </ul> </li> <li>• Finite-element analysis helped determine shrinkage</li> <li>• Use design of experiment (DOE) to improve product design; optimize outside and inside diameters, thickness, and joint surface; and determine optimal design combination</li> </ul>
Mold development	<ul style="list-style-type: none"> <li>• Optimize the structural design of the mold</li> <li>• Recommend water channel design for optimum mold cooling</li> <li>• Provide technical recommendations for secondary processing</li> </ul>	<ul style="list-style-type: none"> <li>• Use mold flow analysis to help:                             <ul style="list-style-type: none"> <li>– Determine position and size of runner</li> <li>– Avoid shrinkage</li> <li>– Determine position of venting</li> </ul> </li> <li>• Improve success rate of trial</li> </ul>
Product testing and improvement	<ul style="list-style-type: none"> <li>• CTC (China Technology Center, Shanghai) has first-class equipment and technical capability to conduct:                             <ul style="list-style-type: none"> <li>– Mechanical property testing</li> <li>– Chemical resistance testing</li> <li>– Intrinsic viscosity (IV) testing</li> <li>– Chemical analyses</li> <li>– Testing for other physical properties</li> </ul> </li> <li>• Molding lab (Shanghai)                             <ul style="list-style-type: none"> <li>– Conduct research for typical applications</li> <li>– Help clients mold samples</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Use DOE for the following tests to improve product performance:                             <ul style="list-style-type: none"> <li>– Twist tests</li> <li>– Leaking tests</li> <li>– Simulated sterilization tests</li> <li>– Aging tests</li> </ul> </li> <li>• Determine optimal pretreatment technology</li> </ul>



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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.*

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