

Eastman **TRITAN™**
copolyester

Solvent bonding capability

Eastman Tritan™ copolyester can be bonded to PVC tubing with popular solvent bonding agents, including cyclohexanone and tetrahydrofuran (solvent bonding Tritan to itself is not recommended).

To learn more about secondary operations with parts made of Tritan and other benefits, visit us at www.eastman.com/Markets/medical_technical_center/Joining_techniques.

The fast, strong solvent bond that is attainable with Tritan copolyester combined with its excellent chemical resistance makes Tritan an ideal candidate for IV component and small bore connector applications.

Tensile force (N) required to delaminate solvent-bonded PVC tubing from female luer as a function of time from bonding

Time from bonding (hr)	Tritan copolyester ^a	IM styrenic ^b (N)	Lipid resistant PC ^b (N)
1	Not measurable (tube failure)	60 ± 6	61 ± 2
2	Not measurable (tube failure)	60 ± 2	63 ± 2
6	Not measurable (tube failure)	53 ± 6	57 ± 2
8	Not measurable (tube failure)	57 ± 3	57 ± 3
24	Not measurable (tube failure)	61 ± 3	65 ± 2
48	Not measurable (tube failure)	59 ± 5	64 ± 3

^aTube failure, bond was stronger than tubing

^bBond failure, tubing was separated from female luer
± indicates 1 standard deviation

Note: Cyclohexanone was used as the bonding solvent for this testing. Also, care should be taken to avoid excessive contact between Tritan and the bonding solvent.

Tritan copolyester



Tubing breaks and remains in luer.

IM styrenic



Tubing delaminates from luer.

Lipid resistant PC





The results of insight™

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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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