EASTMAN

Disinfect **with confidence.**

Test housing material performance using this simple 4-step test.

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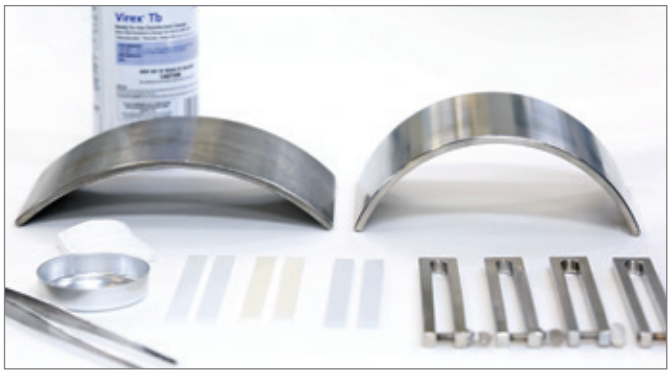
Choosing plastics for medical device housings and hardware can be challenging. Many commonly used materials can crack, craze, discolor, and become sticky after being exposed to aggressive disinfectants and drugs in clinical settings. That's why knowing how a plastic performs before exposing it to heavy use in a harsh environment is key to end-market success.

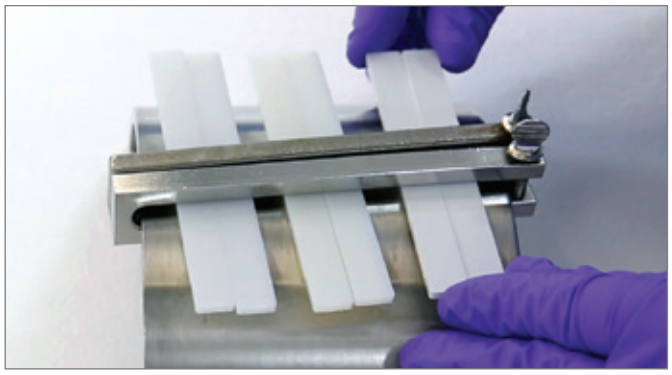
To answer the question of why plastics fail and better understand how different plastics perform, Dr. Yubiao Liu, Eastman medical application development scientist, developed the following 4-step testing protocol. Not only is this test easily repeatable, but it takes only 24 hours to complete.

1. Select the appropriate jig.



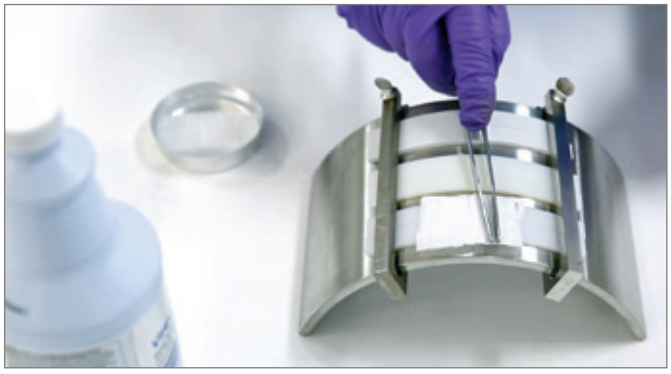
Step 1: Simply select a jig with the appropriate strain level.

2. Load flex bars onto jig.



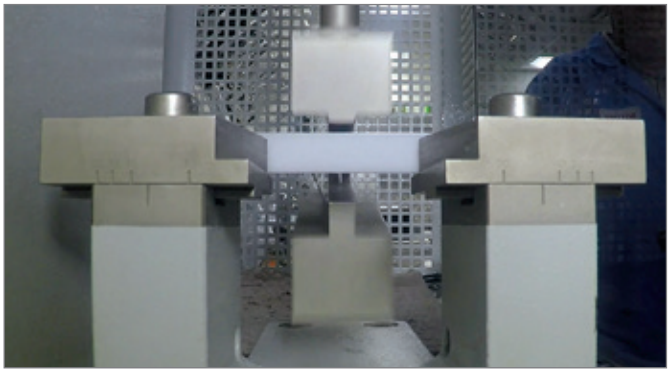
Step 2: Load plastic flex bars onto the jig. Remember to load some control samples that will not be exposed to chemicals.

3. Apply chemicals to the flex bars.



Step 3: Apply chemicals such as commonly used hospital disinfectants, lipids, drugs, or drug carrier solvents to the flex bars using a presoaked piece of cotton. Enclose the entire sample jig in a plastic bag to prevent evaporation and leave at room temperature for 24 hours.

4. Perform reverse side impact test.
This is the differentiating step.



Step 4: Unload the samples, and run a reverse side impact test on the exposed and control samples.

To best interpret the results, record the impact strength of exposed and control samples to calculate the percentage of impact strength retention. Higher retention translates to better reliability after exposure.

4-step test results

Materials	Control (joules)	DISINFECTANTS						
		Diversey Virex® TB (ether, benzyl quat)	Clorox Healthcare® Bleach Germicidal Wipes (germicidal hypochlorite)	Clorox Healthcare® Multi-Surface (IPA quat)	Clorox Healthcare® Hydrogen Peroxide (H_2O_2 cleaner)	PDI Sani-Cloth® AFIII (benzyl quat, DPG ether)	PDI Super Sani-Cloth® (IPA quat)	PDI Sani-Cloth® Plus (IPA benzyl quat)
		% RETENTION OF IMPACT ENERGY TO BREAK						
Eastman Tritan™ MX711 copolyester	4.3	75 ± 26	89 ± 1	92 ± 4	95 ± 5	109 ± 3	101 ± 3	114 ± 1
Eastman Tritan™ MX731 copolyester	4.3	65 ± 24	96 ± 5	98 ± 5	99 ± 5	104 ± 2	100 ± 2	116 ± 1
Eastman MXF221 copolyester	5.2	94 ± 2	95 ± 2	92 ± 3	98 ± 1	93 ± 4	83 ± 1	96 ± 3
PC/PBT	5.3	8 ± 3	98 ± 2	57 ± 45	94 ± 2	9 ± 2	91 ± 8	16 ± 2
PC/polyester	5.5	6 ± 1	6 ± 2	91 ± 12	23 ± 1	5 ± 0	75 ± 28	8 ± 2
PC/ABS 1	6.8	15 ± 1	70 ± 21	84 ± 13	97 ± 2	20 ± 3	16 ± 1	71 ± 22
PC/ABS 2	6.6	Break on jig	102 ± 1	64 ± 21	69 ± 32	6 ± 1	42 ± 37	5 ± 0
PVC	4.5	19 ± 2	19 ± 0	45 ± 36	56 ± 32	46 ± 36	18 ± 2	100 ± 0

% Retention

≥ 80% ≥ 60% < 60%

Tell a more complete story.

Step 4 is the differentiating step in this protocol. Visual inspection after step 3 may reveal changes in some plastics. However, there may be cracks or crazes that are not visible to the naked eye or identified by weight or dimensional changes. By performing Step 4, the reverse side impact test, a more complete story is told in predicting the reliability of a device after exposure.

Ultimately, this test should help you confidently choose the best material for your next project.

To learn more about Eastman MXF221 copolyester in medical device housings and hardware, visit Eastman.com/medicalhousings.

EASTMAN

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.

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