Eastman **TRITAN**™
copolyester

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

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 commonly used or aggressive disinfectants and drugs.

To better understand why plastics fail and how different plastics perform in the real world, Dr. Yubiao Liu, Eastman medical application development scientist, developed a simple 4-step testing protocol based on modified ASTM D543 and ASTM D4812 standards (step 4 only).

This test was developed from publicly available literature on standards to provide a repeatable, uniform testing tool. This quick, simple screening test is the most effective way to mimic failures from typical hospital usage conditions.

Our 4-step test method uses a 1.5% constant strain jig together with wet patches for applying chemical reagents.

All sample bars used in this test were molded according to the raw material manufacturers' specifications. Improper molding could result in early failure and inaccurate results. Using a minimum of 4 replicates is recommended to substantiate your data. More replicates may be needed depending on the standard deviation of observed results.

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

Tell a more complete story.

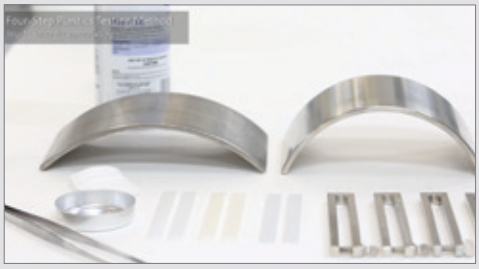
Step 4 is the differentiating step in this testing protocol. Visual inspection after step 3 may reveal changes in some plastics. However, there may be cracks or crazes that are not visible to the naked eye or identified by weight or dimensional changes. By performing Step 4, the reverse side impact test, you are better able to predict 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 Tritan™ copolyester in medical device housings and hardware, visit Eastman.com/medicalhousings.

EASTMAN

1
Select the appropriate jig.

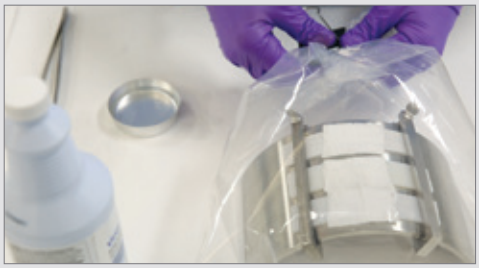


Choose the strain level that most appropriately reflects environmental stress cracking.

2
Load the flex bars onto the job.

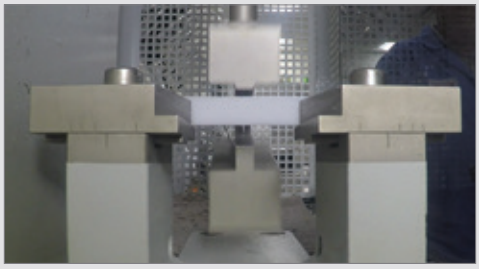
Remember to load some control samples that will not be exposed to chemicals.

3
Apply chemicals to the flex bars using presoaked pieces of cotton.



Chemicals such as commonly used hospital disinfectants, lipids, drugs, or drug carrier solvents can be used. 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.



Unload the samples and run a reverse side impact test on the exposed and control samples

EASTMAN

The results of **insight**™

Eastman Corporate Headquarters
P.O. Box 431
Kingsport, TN 37662-5280 U.S.A.

U.S.A. and Canada, 800-EASTMAN (800-327-8626)
Other Locations, +(1) 423-229-2000

www.eastman.com/locations

Safety Data Sheets providing safety precautions that should be observed when handling and storing Eastman Chemical Company ("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-4327 5/17