EASTMAN

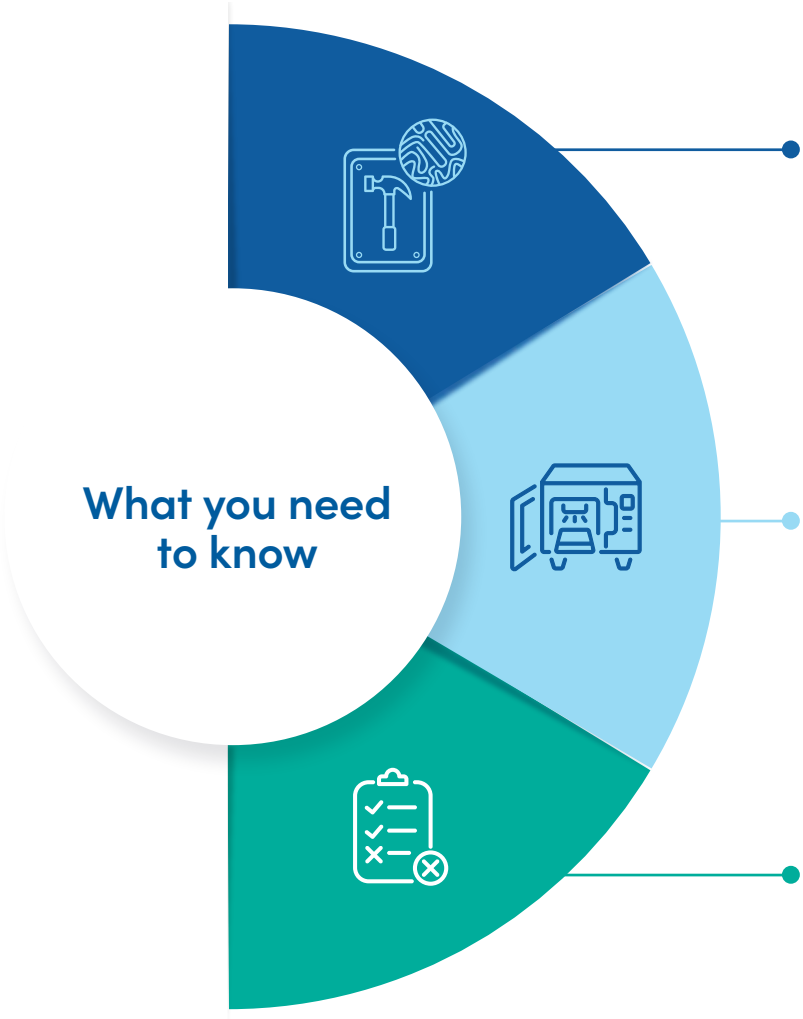
Hammertime study

Evaluating APET and PETG performance

Our goal as leaders in the healthcare packaging industry is to help make sure medical devices are kept sterile and effective when they reach a healthcare professional's hands.

The Eastman Hammertime Study examines the key differences between types of commercially available modified APET and PETG. It explores how the materials perform in thermoformed, sterilized trays during real-life use scenarios, including transportation and aging.

Our scientists know that different sterilization methods impact resins differently, so it was important to stress test all materials.



Not all materials are created equal.

- Different materials respond uniquely to different sterilization methods, impacting the performance outcomes.
- Modified APET readily crystallizes, increasing tray failure rate.

Keep real-world conditions in mind.

- Hammertime trays were designed to incorporate realistic design requirements and were sterilized just like a real-life device.
- Materials were run at their optimal conditions to prevent processing bias.
- Testing protocols replicated actual use conditions to ensure meaningful, applicable performance data.

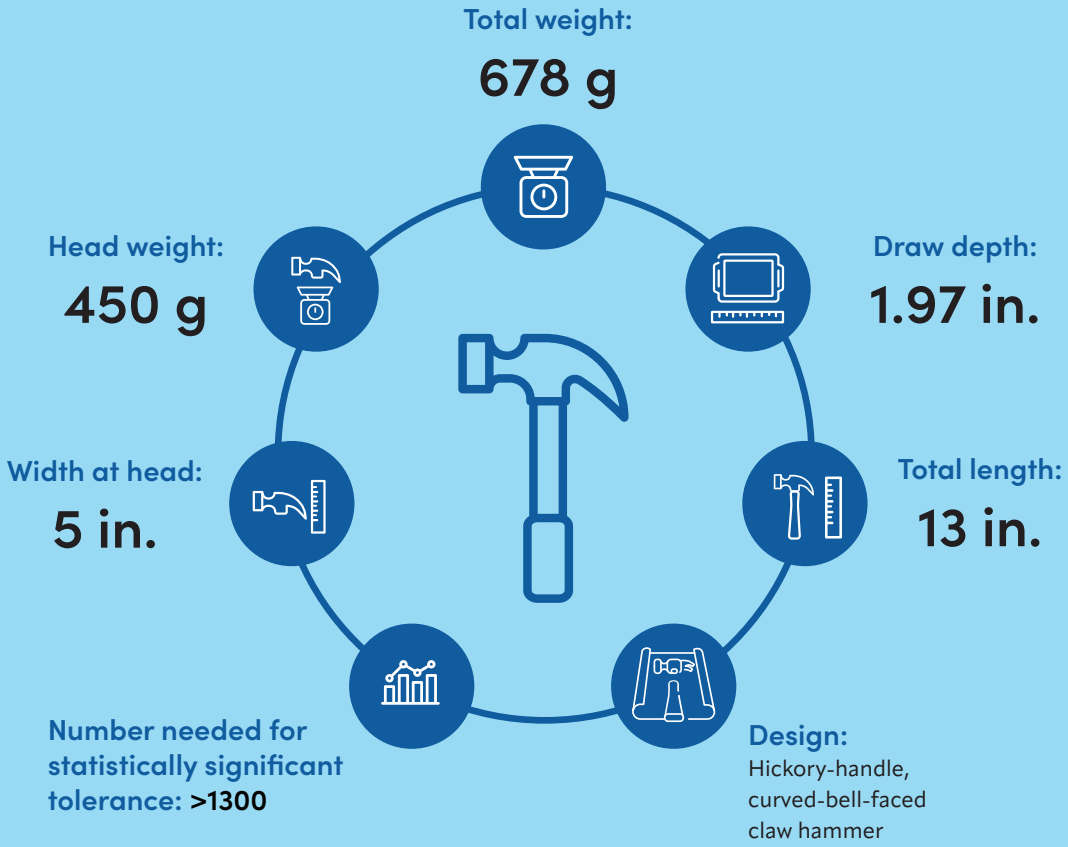
Modified materials are not a miracle.

- Increased modifications of APETs did not guarantee improved pass rates.
- The specific type of modification matters.

Putting materials to the test

Using industry-standard sterilization modalities and tray integrity testing, the Hammertime Study reviewed how packing tray materials held up. To test durability, a third-party, independent testing facility stress tested 11 APET and PETG materials, including Eastman Eastar™ 6763 copolyester (a PETG) and Eastman Tritan™ copolyester.

A hammer was chosen for the study because its shape, size and uneven weight distribution resemble the complexity of many medical devices.



We took special note of ISO standards and worked to make sure all tests examined "functionally equivalent performance" after sterilization.

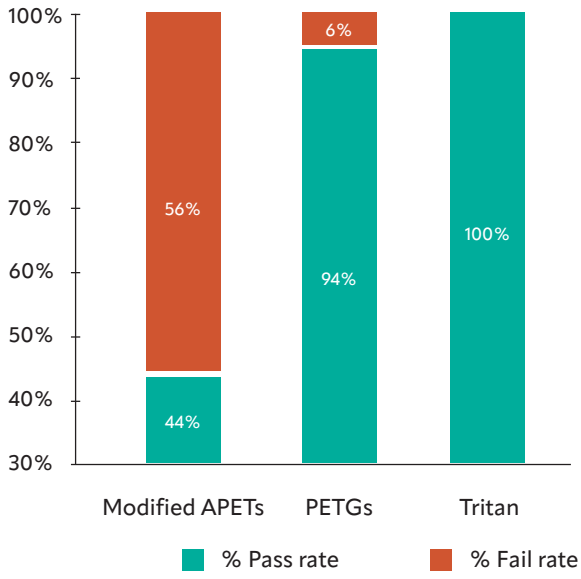
The 3P testing lab is ISO 17025 accredited, ISTA certified, ISO 13485:2016 certified and U.S. FDA registered (PCM) and regularly works with medical device manufacturing industry leaders on packaging design, testing and validation.

The testing protocol we followed:

1. Climatic conditioning per ASTM D4332-22
2. Transit simulation to ASTM D4169 distribution cycle 13 AL1
3. Sterile barrier integrity testing via Gross Visual
4. Sterile barrier integrity testing via Bubble Leak ASTM F2069
5. Seal strength via ASTM F88

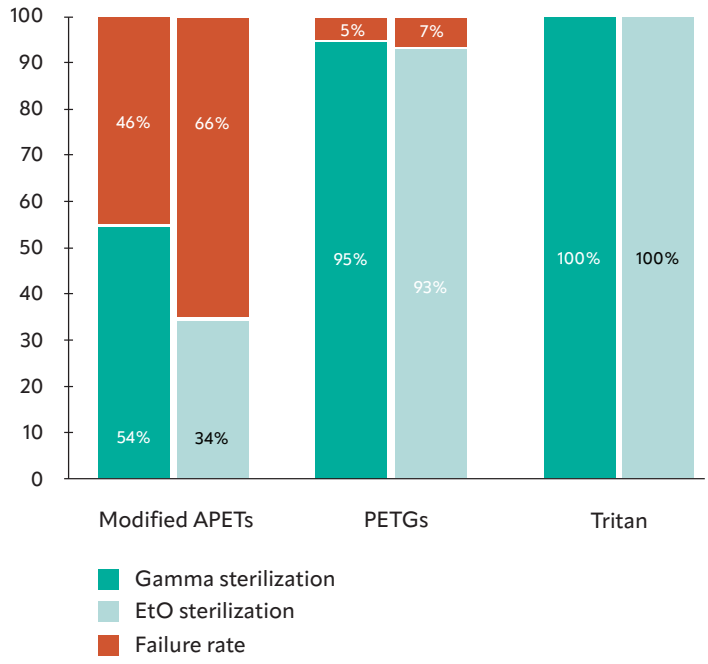
Clear differences between materials

Bubble leak test



PETGs notably outperformed modified APETs, which failed over nine times more than PETGs.

Performance after sterilization

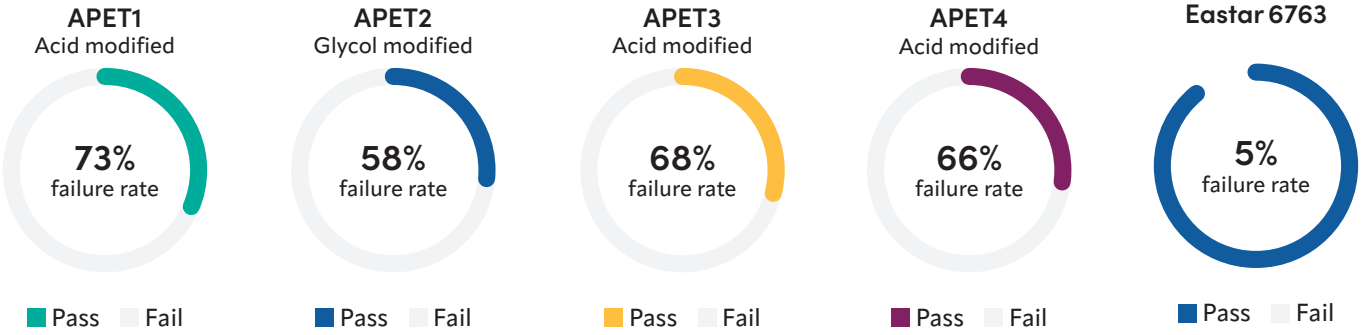


Ethylene oxide (EtO) sterilization resulted in a more significant drop for modified APETs than PETGs.
APET failed 44% more after EtO, which is crucial when:

- 110,880 surgical site infections (SSI) are associated with inpatient surgeries in the U.S.
- Up to 11% of surgeries in low- and middle-income countries result in SSIs.

EtO sterilization results

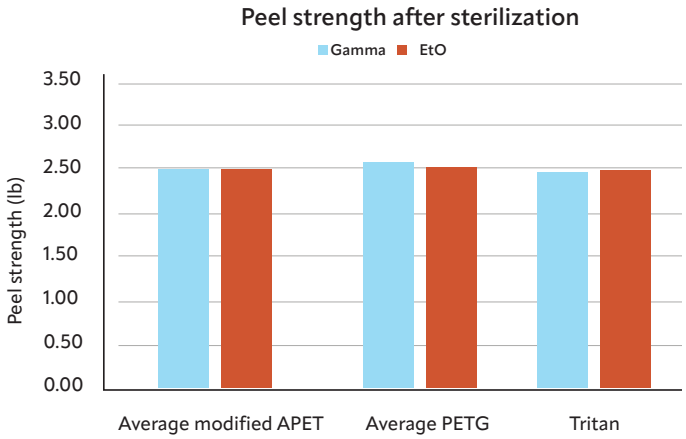
Modified APETs



We tested APET materials that would be used in various medical packaging applications, and materials varied in performance based on their specific chemistries. Though there are subtle differences in modified APET performance based on modifications, **none had a pass rate of more than 50%.**

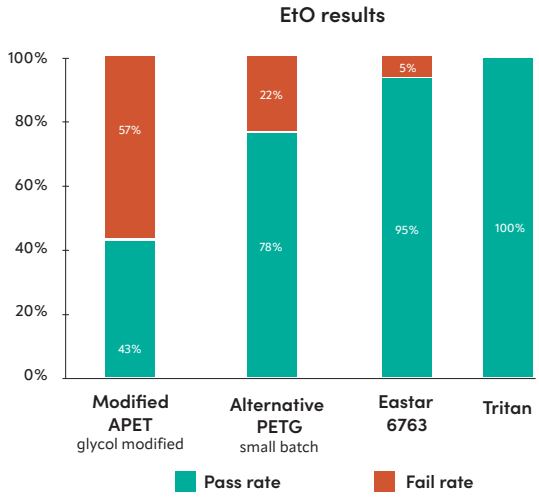
Peel strength results

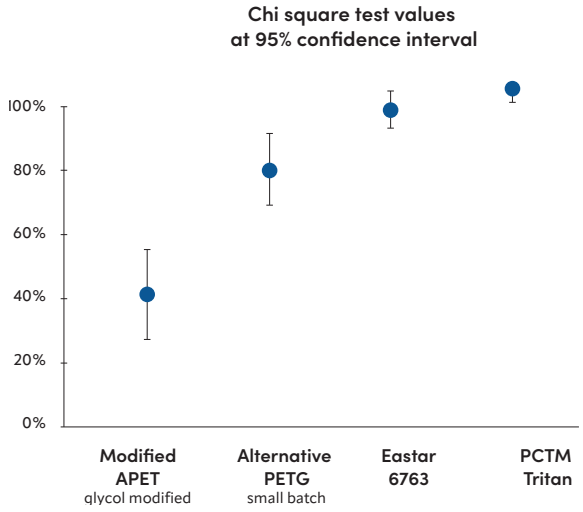
Although we saw clear differences in packaging performance, the root cause was due to failure of the tray itself, mostly through brittle fracture. Peel strength performance was consistent across all the materials tested, indicating robust lidding application and system design.



Ensuring accuracy

Performance repeatability is key to manage quality risk.





Eastar 6763 and Tritan are not statistically different from each other. However, both are statistically different in performance than the highest-performing modified APET and the lowest-performing alternative PETG. We can know this because of the sample size of materials. Testing small amounts of materials does not differentiate between materials. **Sample sizing is critical for statistical power of results.**

Want to see more?

Learn more about the Hammertime Study in a webinar presented by Jeremy Williams, advanced technical service representative for Eastman medical applications.
Partner with Eastman to find a protective and durable medical packaging solution.

EASTMAN

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

eastman.com/locations

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