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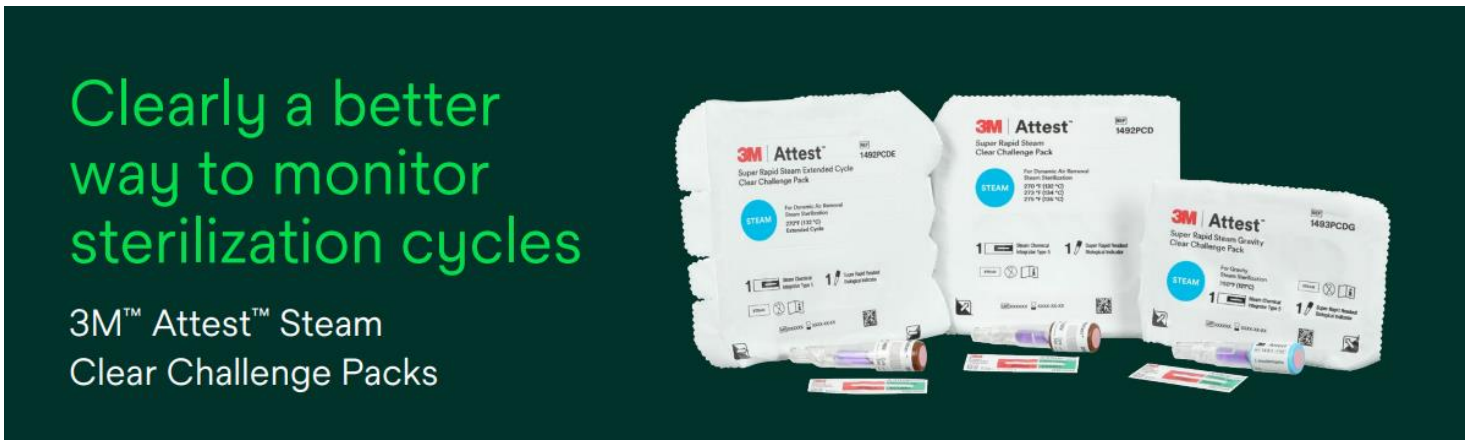
3M™ Attest™ Steam Clear Challenge Pack FAQ

3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD
3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG
3M™ Attest™ Super Rapid Steam Extended Cycle Clear Challenge Pack 1492PCDE

October, 2025



Frequently Asked Questions (FAQ)

1. **The Attest steam clear challenge pack complies with the definition of a PCD (also known as test pack) and may be used to facilitate compliance to the following standards:**

   - AAMI and FDA guidance
   - Biological Indicator meets ISO 11138-1, 3 & 8 requirements
   - Chemical Indicator meets ISO 11140-1 Type 5 requirements and in compliance with FDA

2. **What AAMI/ANSI requirements do the devices meet?**

   The Attest steam clear challenge pack presents a challenge to the sterilization process equivalent to the user-assembled biological indicator (BI) challenge test pack (towel PCD) recommended by the Association for the Advancement of Medical Instrumentation (AAMI).

3. **Can I use the devices in a tabletop sterilizer?**

   We do not recommend using the Attest steam clear challenge packs in tabletop sterilizers. For tabletop monitoring, we recommend purchasing a standalone BI and assembling a representative PCD according to Section 13.7.3 in AAMI ST79.

4. **Can this be used for both routine monitoring and qualification testing?**

   Yes. The Attest steam clear challenge packs are designed as a standard method of rapid and reliable routine monitoring and performance qualification of steam sterilization processes per the cycles indicated in IFUs.

5. **Can I reuse the device?**

   No. The Attest steam clear challenge packs are one-time use only. DO NOT reuse challenge pack, even if only exposed to a partial (canceled or aborted) cycle.

6. **Does the biological indicator (BI) need to cool outside of the device after sterilization?**

   The BIs in the Attest steam clear challenge packs can cool inside **or** outside the PCD for 10 minutes prior to activation.

7. **Where and/or how do I place the device in the sterilizer?**

   Place the PCD in the sterilizer chamber, with the foil side facing up or down, in the most challenging area for the sterilant to reach. Typically on the bottom shelf, over the drain. There are no restrictions on orientation.
   DO NOT place objects (e.g. another pack) directly on top of the challenge pack. This will create too great a challenge for air removal and steam penetration.

8. **What is the shelf life?**

   All 1492 SKUs are 21 months and both 1493 SKUs are 24 months.
   - 1493 = 24 months
   - 1493PCD = 24 months
   - 1492V = 21 months
   - 1492PCD = 21 months
   - 1492PCDE = 21 months

9. **How do I store the devices?**

   Remove only the number of PCDs needed and leave any remaining PCDs in the foil pouch to prevent long-term exposure to environmental conditions.

   The remaining PCDs should be used within 8 weeks of opening the foil pouch.

10. **Is the device recyclable?**

    The challenge pack plastic shell is made from polypropylene and is recyclable. However, recycling programs for this product may not exist in your area.

    The foil lid must be completely removed to recycle the polypropylene plastic shell.

11. **Is the design and challenge of the Attest™ steam clear challenge packs equivalent to any packaging type, load type or instrumentation or device type?**

    The performance of the Attest steam clear challenge packs has not been comparison tested against any specific medical device. The Attest steam clear challenge packs present a challenge to the sterilization process equivalent to the user-assembled biological indicator (BI) challenge test pack (towel PCD) recommended by the Association for the Advancement of Medical Instrumentation (AAMI). The physics of air removal embodied by the channel challenge of the Attest steam clear challenge packs is very similar to the challenge of air removal from a lumened instrument. For example, rigid endoscopes and laparoscopic instruments have narrow internal channels requiring air removal to ensure that adequate steam sterilization can occur. Any air remaining in the lumens of these instruments may compromise the sterilization of those internal surfaces

12. **Is a channel-based process challenge pack better than a porous-based paper process challenge device?**

    The challenge to air removal and steam penetration in a steam sterilization cycle, whether using a porous media or an engineered channel, can be made to be equivalent in performance to each other. Yet, the physics describing the nature of these challenges is different.

    A paper test pack is designed to provide a challenge to air removal and steam penetration by stacking cards of a given property until an adequate challenge is achieved. This challenge can be variable in nature because it is

based in part on a property of the paper (the permeability constant) which results from the manufacturing process for making the paper.

In the Attest steam clear challenge pack, every dimension of the channel is engineered (i.e., predetermined) and can be replicated with high precision from challenge pack to challenge pack.

13. What are the benefits of using the 1492PCD vs. standalone BI?

- To comply with globally recognized standards and guidelines.
- Using 1492PCD can save the time required to assemble a 16 towel pack PCD manually
- 1492PCD can help reduce potential for errors caused by manual assembly of a test pack.
- 1492PCD provides a higher level of quality assurance monitoring as compared to standalone Bis
- The use of the 1492PCD provides a greater confidence in your sterilization assurance program as compared to the use of standalone Bis
- By subjecting the sterilization process to a greater challenge during routine monitoring, healthcare facilities can better assess the effectiveness and reliability of their sterilization methods
- It enhances confidence that the sterilization process used is effective and reliable helping to support patient safety.
- 1492PCD is designed to more accurately simulate the environment inside of a surgical pack than using just a stand-alone BI for steam load monitoring.
- 1492PCD is designed to represent the sterilization process challenge posed by instruments sterilized every day

15. Do I need a process challenge device (PCD) for monitoring steam sterilizers in healthcare facilities?

Per ANSI/AAMI ST79:2017/(R)2022 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

13.5.3.2 Using biological indicators
Biological indicators should be used within PCDs (see 13.5.4, 13.7.2.1, 13.7.3.1, and 13.7.4.1) for routine sterilizer efficacy monitoring at least weekly, but preferably every day that the sterilizer is in use (see 13.7). Biological indicators within a PCD may be used as part of the criteria for release of loads. Additionally, BIs with Type 5 integrating indicators within PCDs should be used to monitor every load containing implants; implants should be quarantined until the results of the BI testing are available. (CDC, 2008).

Standards and guidelines in your region of the world may differ. The benefits of using the 1492PCD vs. standalone BI or a standalone BI in a 16 towel pack are multifaceted and extensive and are outlined in this document.

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Solventum Corporation
3M Center, Building 275
2510 Conway Avenue East
Maplewood, MN 55144

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