Evaluation of the 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG to the U.S. Food and Drug Administration (FDA) Performance Requirements for BI PCDs

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Abstract

Background

A "BI PCD" is a process challenge device (PCD) that contains a biological indicator (BI). A BI is the only sterilization process monitoring device that provides a direct measure of lethality of a sterilization process. The new 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG (see **Figure 1**) is specifically designed to qualify and monitor gravity-displacement steam sterilization processes at 121°C (250°F) in healthcare facilities. It consists of a clear plastic shell, and a cavity containing the monitoring products, all covered by a foil lid.

Figure 1. 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG

Method

Three lots of the Attest clear challenge pack 1493PCDG (12 per lot) were tested side-by-side with the AAMI 16-towel reference PCD ("AAMI 16-towel PCD") containing the same three lots of 3M™ Attest™ Super Rapid Readout Biological Indicators 1493 and 3M™ Attest™ Steam Chemical Integrator 1243R to demonstrate that the Attest clear challenge pack 1493PCDG has a resistance that is equivalent to the AAMI 16-towel PCD.

Three lots of the Attest clear challenge pack 1493PCDG (12 per lot), containing three lots of the Attest biological indicator 1493 and three lots of the Attest chemical integrator 1243R, were tested side-by-side with standalone Attest biological indicator 1493 and Attest chemical integrator 1243R to demonstrate that the Attest clear challenge pack 1493PCDG has greater resistance than the standalone indicators.

Results

All three lots of the Attest clear challenge pack 1493PCDG demonstrated equivalent resistance to the AAMI 16-towel PCD and greater resistance than the standalone indicators.

Conclusion

The results demonstrated that the 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG, with an innovative, robust and precisely engineered design and form factor, meets the performance requirements for a BI PCD necessary for 510(k) clearance by the U.S. FDA, as evidenced by the FDA 510(k)(K242538). The results specifically demonstrated that the Attest clear challenge pack 1493PCDG has a resistance that is: (1) equivalent to the AAMI 16-towel PCD, as required by ANSI/AAMI ST79 and other standards, and (2) greater than the standalone indicators. As a result, the Attest clear challenge pack 1493PCDG can be used safely and effectively to qualify and monitor gravity-displacement steam sterilization processes at 121°C/250°F in healthcare facilities.

Background and introduction

What is the purpose of a Biological Indicator (BI) Process Challenge Device (PCD)?

A "BI PCD" is a PCD that contains a biological indicator. A biological indicator (BI) is defined in ISO 11139 as a "*test system containing viable microorganisms providing a specified resistance to a specified sterilization process*".

Standards around the world recognize the BI as *"the only sterilization process monitoring devices that provide a direct measure of lethality of the process"*.[1]

BIs are recognized by most authorities as being closest to the ideal monitors of the sterilization process because they measure the sterilization process directly by using the most resistant microorganisms (i.e., *Bacillus* spores), and not by merely testing the physical and chemical conditions necessary for sterilization. Since the *Bacillus* spores used in biological indicators are more resistant and present in greater numbers than are the common microbial contaminants found on patient-care equipment, the demonstration that the biological indicator has been inactivated strongly implies that other potential pathogens in the load have been killed.[2]

ISO 11139 defines a Process Challenge Device (PCD) as an *"item providing a defined resistance to a cleaning, disinfection, or sterilization process and used to assess performance of the process"*.[3]

PCDs were developed to assess the efficacy of the sterilization process at the end of the cycle, without compromising the sterility of the contents of the load items. A BI is placed inside of a PCD to make it more difficult for the sterilant to reach the BI, and to mimic the BI being placed inside the actual load items. As a result, the BI can be thought to represent the microorganisms on the medical devices, while the PCD can be thought to represent the effect of the packaging (i.e., the sterile barrier system, or SBS).[4]

A BI PCD can be used in routine monitoring to monitor sterilization cycles containing loads, and/or in qualification or validation activities. In the United States, the Indications for Use cleared by the Food and Drug Administration (FDA) for a BI PCD must specifically state whether it is to be used for routine monitoring, qualification/validation, or both.

Section 13.5.4, "Process challenge devices" of ANSI/AAMI ST79 requires that commercially-available BI PCDs be cleared by the FDA for their intended use and demonstrate a resistance equivalent to the AAMI 16-towel reference PCD ("AAMI 16-towel PCD" or "AAMI 16-towel test pack"):

> *"A PCD may be a user-assembled challenge test pack or test tray or a commercially available, disposable, preassembled challenge test pack. The premarket [510(k)] notification submitted by the manufacturer to FDA should include* ***scientific evidence demonstrating that the commercial PCD is comparable in performance to the user-assembled challenge test pack defined in 13.7.2.2****. Health care personnel should use commercially available PCDs only if they have been cleared by FDA for their intended use. Any manufacturer-supplied scientific data on equivalence should be reviewed".*[1] Emphasis added.

Section 13.7.2 of ANSI/AAMI ST79 further states:

> *"For routine sterilizer efficacy monitoring (see 13.5.4), the AAMI 16-towel test pack is considered the representative standard for the appropriate worst-case challenge to steam sterilization cycles.* ***... Alternatively, a pre-assembled, commercially available PCD that has demonstrated equivalence to the 16-towel PCD and is cleared by the FDA may be used.****"*
>
> *A BI PCD should be used for routine monitoring of sterilizers larger than 2 cubic feet.* ***Commercially available PCDs are recommended****; however, a facility-assembled PCD may be used (see 13.7.2.2).*
>
> Rationale: *Commercially available disposable PCDs (BI challenge test packs) provide standardization and reduce variability and potential for error.*[1] Emphasis added.

What is required to obtain U.S. FDA 510(k) Clearance of a BI PCD?

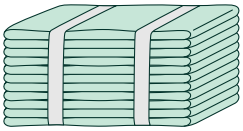
The United States FDA *Guidance for Industry and FDA Staff — Biological Indicator (BI) Premarket Notification [510(k)] Submissions*[5] sets forth the guidance for manufacturers on BI PCDs. Section 10 of this Guidance states:

> *"BIs may be used in test packs to simulate products being sterilized.*[9] *Test packs are intended to simulate products and constitute a defined challenge to the sterilization process that is equal to or greater than the most difficult item routinely processed. For BIs indicated for use in specific test packs, you should demonstrate that the performance of the BI in that test pack is equivalent to the performance of the AAMI reference BI in the same test pack in their respective sterilization processes. You should also demonstrate that the BI test pack provides a greater challenge to the process than the BI itself".*

Based on this, in order to obtain U.S. FDA clearance, BI PCD manufacturers need to demonstrate the following performance criteria[5] (see **Figure 2**):

1. Equivalent resistance as the AAMI 16-towel PCD[1] at a given exposure time and temperature.
2. Greater resistance than standalone BIs.

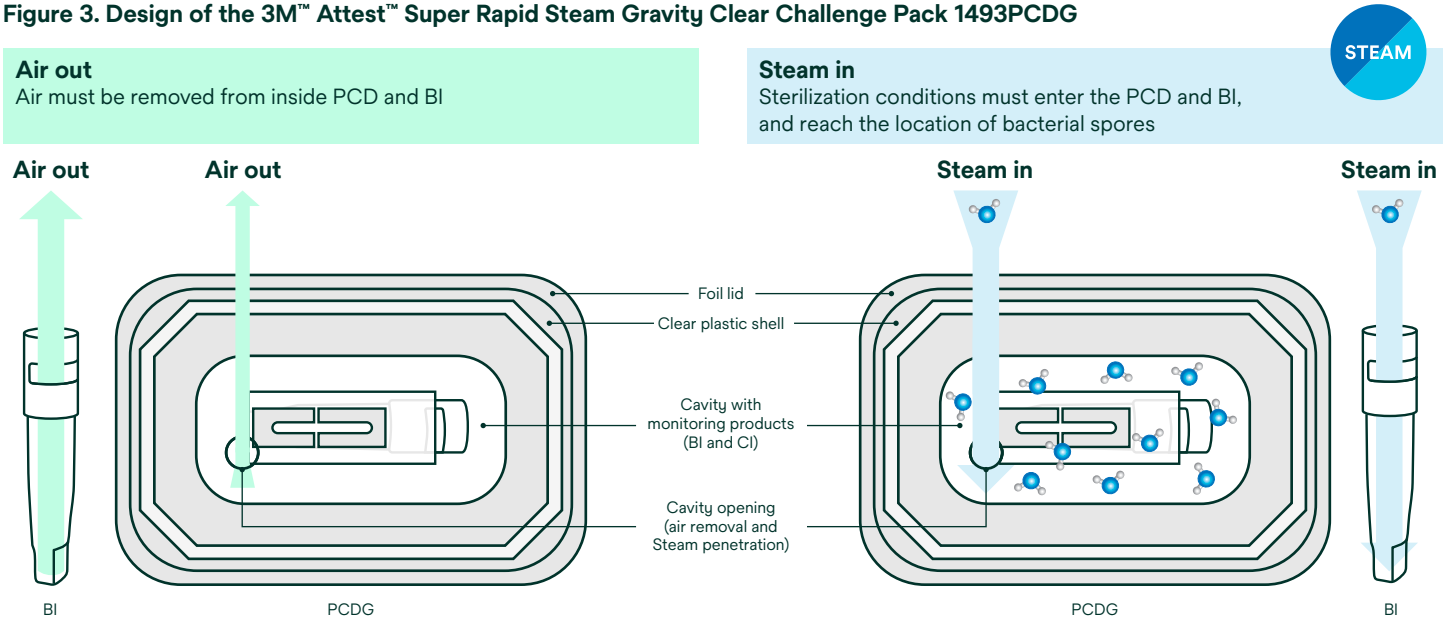
Figure 2. Requirements for BI PCD U.S. FDA clearance

Biological Indicator	Meets requirement	Performance criteria
 **3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG**	✓	Equivalent resistance as AAMI 16-towel PCD at a given exposure time and temperature
		 **AAMI 16-towel PCD**
	✓	Greater resistance than standalone BIs
		 **Standalone BI**

3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG

The new Attest clear challenge pack 1493PCDG is specifically designed to monitor gravity displacement steam sterilization processes at 121°C/250°F in healthcare facilities. It consists of a clear plastic shell, and a cavity containing the monitoring products (see **Figures 1 and 3**), all covered by a foil lid (see **Figures 3 and 4**). The clear plastic shell includes a cavity opening designed to mimic the challenge to air removal and steam penetration posed by individual devices and device loads, and particularly in gravity-displacement steam sterilization.

Figure 3. Design of the 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG



This convenient disposable 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) — the AAMI 16-towel PCD. The 1493PCG is a single-use device.

Each Attest clear challenge pack 1493PCDG contains a 3M™ Attest™ Super Rapid Readout Biological Indicator 1493 (light blue cap) and a 3M™ Attest™ Steam Chemical Integrator (see **Figure 4**). 1493 BIs meet the performance specifications of ISO 11138-1:2017, ISO 11138-3:2017 and ISO 11138-8:2021. 1243R CIs are Type 5 (Category i5) Integrating Indicators as categorized by ISO 11140-1:2014.

ANSI/AAMI ST79 recommends that steam sterilization loads containing an implant be monitored with a process challenge device (PCD) containing a biological indicator and a Type 5 integrating chemical indicator (CI).[1]

Figure 4. Components of the 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG

3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG

3M™ Attest™ Super Rapid Readout Biological Indicator 1493 BI

3M™ Attest™ Steam Chemical Integrator 1243R Type 5 CI

Purpose

The purpose of this study was to demonstrate the performance criteria necessary for U.S. FDA clearance of a BI PCD by comparing:

Attest clear challenge pack 1493PCDG versus AAMI 16-towel PCD:
Compare the resistance of the Attest clear challenge pack 1493PCDG to the AAMI 16-towel PCD in gravity displacement steam sterilization processes at 121°C (250°F).

Attest clear challenge pack 1493PCDG versus standalone BIs and CIs:
Compare the resistance of the Attest clear challenge pack 1493PCDG to standalone Attest biological indicator 1493 and standalone Attest chemical integrator 1243R in gravity displacement steam sterilization processes at 121°C (250°F)

Materials and equipment

Attest Clear Challenge Pack 1493PCDG

Three lots of the Attest clear challenge pack 1493PCDG were manufactured using three lots of 1493 BIs and three lots of 1243R CIs. **Table 1** details the specific indicator lots used in each respective Attest clear challenge pack 1493PCDG lot. All lots were made with the same resin lot for the clear plastic shell and the same laminate foil lot for the foil lid.

Table 1. Indicator contents of each 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1493PCDG lot

Attest clear challenge pack 1493PCDG lot code	3M™ Attest™ Super Rapid Readout Biological Indicator 1493 lot	3M™ Attest™ Steam Chemical Integrator 1243R lot
Lot 1	Lot A	Lot X
Lot 2	Lot B	Lot Y
Lot 3	Lot C	Lot Z

AAMI 16-towel PCDs

AAMI 16-towel PCDs were constructed per ANSI/AAMI ST79:2017[1] with clean, reusable absorbent surgical towels of approximately 16 inches by 26 inches folded lengthwise into thirds and then folded widthwise in the middle. Towels were placed one on top of another, with folds opposite each other, to form a stack that was approximately 228 mm wide x 228 mm long x 152 mm high (9 inches wide x 9 inches long x 6 inches high).

Each AAMI 16-towel PCD constructed with Attest biological indicator 1493 and Attest chemical integrator 1243R were conformed to the ANSI/AAMI ST79:2017 recommendation of an approximately 3-pound weight and 11 pounds per cubic foot density.

After folding, the AAMI 16-towel PCDs were preconditioned at room temperature (18°C–24°C or 65°F–75°F) and a relative humidity of approximately 50% RH for at least two hours. Next, each AAMI 16-towel PCD was loaded with three Attest biological indicator 1493 and three CIs (from the same lots used in each of the Attest clear challenge pack 1493PCDG) placed between the eighth and ninth towels with Attest biological indicator 1493 spore chambers and CI pellets located in the approximate geometric centre of the towel pack, respectively. The stack of 16 towels was then reassembled and taped as described in ANSI/AAMI ST79:2017.[1] Finally, the weight of the AAMI 16-towel PCD (including contained BIs and CIs) was measured using a balance (in grams).

Standalone Indicators

For standalone indicators, three Attest biological indicator 1493 and three Attest chemical integrator 1243R were loaded into a small metal basket. The same three lots of BIs and the same three lots of CIs as those used in the Attest clear challenge pack 1493PCDG and the AAMI 16-towel PCDs were used as standalone indicators.

Equipment

Comparison to AAMI 16-towel PCD
Attest clear challenge pack 1493PCDGs were evaluated in 121°C/250°F gravity displacement sterilization cycles using an AMSCO EAGLE® 3013-C steam sterilizer, chamber size 406 x 406 x 660 mm (16 x 16 x 26 inches).

Comparison to standalone indicators
Attest clear challenge pack 1493PCDGs (see **Figures 1 and 3–4**) were evaluated in 121°C/250°F gravity displacement sterilization cycles using an AMSCO EAGLE® 3013-C steam sterilizer. **Figure 6** shows the placement of the standalone indicators in the AMSCO EAGLE® 3013-C steam sterilizer.

The delivered lethality of FDA-cleared cycles does not readily allow for characterization of resistance of various indicators (which are normally tested in resistometers capable of precision performance and lower level of lethality). To more clearly characterize the resistance of the indicators both within an Attest clear challenge pack 1493PCDG and in an AAMI 16-towel PCD, a series of cycles were developed to show their effect on indicators in the tested formats (i.e., in Attest clear challenge pack 1493PCDGs and 16-towel PCDs).

Methods

Three lots of Attest clear challenge pack 1493PCDG (12 per lot), containing three lots of the Attest biological indicator 1493 and three lots of the Attest chemical integrator 1243R (as detailed in **Table 1**), were tested side-by-side with the AAMI 16-towel PCD containing the same three lots of BIs and CIs. Testing was completed per the *Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions*, October 4, 2007[5], and ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*.[1]

Three lots of Attest clear challenge pack 1493PCDG (12 per lot), containing three lots of the Attest biological indicator 1493 and three lots of the Attest chemical integrator 1243R (as detailed in **Table 1**), were tested side-by-side with the same three lots of standalone indicators BIs and CIs. Testing was completed per the *Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions*, October 4, 2007.[5]

Table 2 summarizes additional details of the testing methodology.

The sample size for this performance testing (12 PCDs per lot and three distinct lots), is adequate and meets conventional industry standards when assessing an attribute-based response with the following quality levels: AQL = 0.4%, Alpha and Beta = 5%, and RQL = 8%.

Methods for demonstrating a resistance equivalent to the AAMI ST79 16-towel PCD

For 16-towel PCD comparison testing, each sterilization cycle contained three Attest clear challenge pack 1493PCDGs from a single lot, and one AAMI 16-towel PCD containing three Attest biological indicator 1493 and three Attest chemical integrator 1243R from corresponding lots.

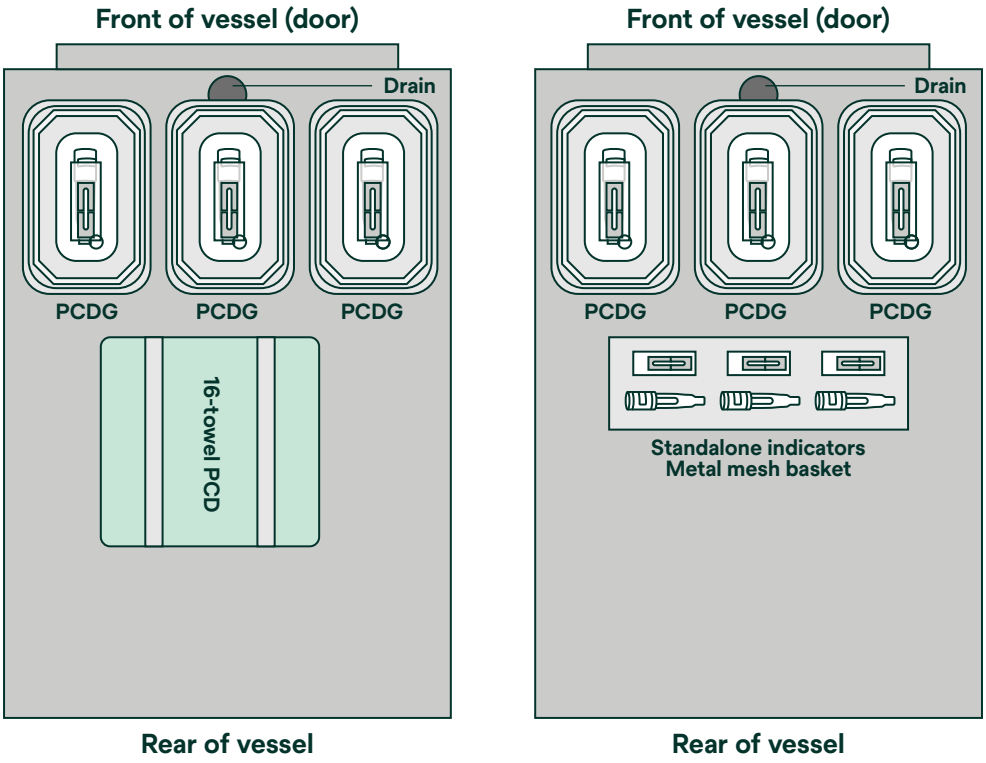
For all cycles using the Amsco EAGLE® 3013-C steam sterilizer, the 1493PCDGs were placed in a row in the front of the chamber (over the drain), with the AAMI 16-Towel PCD directly behind (also near the drain). **Figure 6** shows an example of the Attest clear challenge pack 1493PCDG and AAMI 16-Towel PCD placement in the Amsco EAGLE® 3013-C steam sterilizer.

Methods for demonstrating greater resistance than standalone BIs

For standalone testing, each sterilization cycle contained three Attest clear challenge pack 1493PCDGs from a single lot, and a metal basket loaded with three standalone Attest biological indicator 1493 and three standalone Attest chemical integrator 1243R from corresponding lots. **Figure 6** also shows an example of the standalone indicator placement in the Amsco EAGLE® 3013-C.

After the sterilization test cycle, the Attest biological indicator 1493 and Attest chemical integrator 1243R were removed from the Attest clear challenge pack 1493PCDGs and AAMI 16-towel PCDs. BIs were activated and read for 24-minute fluorescence using the 3M™ Attest™ Auto-reader 490. They were then further incubated in the Attest Auto-reader 490 at 60°C ± 2°C and read for visual pH colour change from purple to yellow after 48 hours of incubation. Additionally, the BI cap process indicators were visually read for colour change and the CIs were visually read for run region (accept or, reject see **Figure 5**).

Figure 5. Diagram of Attest clear challenge pack 1493PCDG and AAMI 16-towel PCD and standalone placement within Amsco EAGLE® 3103-C



Results

The test results are shown in **Table 2**. Table 2 shows that for each type of sterilization cycle tested (kill, survive, fractional and standalone), the acceptance criteria were met.

Table 2. Cycle type, cycle temperature, purpose, acceptance criteria, and results

Cycle type	Cycle temp (°C/°F)	Testing purpose	Acceptance criteria	Results
Attest clear challenge pack 1493PCDG versus 16-towel PCD comparison testing				
Kill (full exposure time)	121/250	Demonstrate Indicators in the Attest clear challenge pack 1493PCDGs are a pass or accept Demonstrate Indicators in the AAMI 16-towel PCD are a pass or accept	**All kill/accept** **Attest biological indicator 1493**: 100% negative fluorescent and pH colour change **Attest chemical integrator 1243R**: 100% accept **Process Indicator**: Light brown or darker colour change	**Pass**
Survive (shortened exposure time)	121/250	Demonstrate Indicators in the Attest clear challenge pack 1493PCDGs are a fail or reject Demonstrate Indicators in the AAMI 16-towel PCD are a fail or reject	**All survive/reject** **Attest biological indicator 1493**: 100% positive fluorescent and pH colour change **Attest chemical integrator 1243R**: 100% reject	**Pass**
Fractional (shortened exposure time)	121/250	Demonstrate a mixed response in the Attest biological indicator 1493 for Attest clear challenge pack 1493PCDGs and equivalent resistance versus the AAMI 16-towel PCD Demonstrate a mixed response in the Attest chemical integrator 1243R for Attest clear challenge pack 1493PCDGs and equivalent resistance versus the AAMI 16-towel PCD	**Mixed BI & CI results** **Attest biological indicator 1493**: Negative/positive fluorescence and pH colour change response in Attest clear challenge pack 1493PCDG with equivalent resistance versus the AAMI 16-towel PCD **Attest chemical integrator 1243R**: Accept/reject response in Attest clear challenge pack 1493PCDG with equivalent resistance versus the AAMI 16-towel PCD	**Pass**
Attest clear challenge pack 1493PCDG versus standalone indicator comparison testing				
Fractional (shortened exposure time)	121/250	Demonstrate indicators in the Attest clear challenge pack 1493PCDG are a fail or reject Demonstrate standalone indicators are a pass or accept	**Indicators in 1493PCDG** **Attest biological indicator 1493:** 100% positive fluorescent and pH colour change **Attest chemical integrator 1243R:** 100% reject **Standalone indicators** **Attest biological indicator 1493:** 100% negative fluorescent and pH colour change **Attest chemical integrator 1243R:** 100% accept	**Pass**

Discussion

The 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG was cleared by the U.S. FDA on October 18, 2024 (K242538[6]), demonstrating that the Attest clear challenge pack 1493PCDG has met the requirements of FDA Guidance[5] and ANSI/AAMI ST79:2017.[1]

Performance of the Attest clear challenge pack 1493PCDG was verified,[7] as detailed in **Table 3**.

Table 3. Performance data summary of 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1493PCDG

Test performed	Device description	Applicable standards	Purpose	Acceptance criteria	Results
Resistance of Attest clear challenge pack 1493PCDG compared to AAMI 16-towel PCD	Attest clear challenge pack 1493PCDG three lots	U.S. FDA Guidance[1] and ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*	Demonstrate the performance of the Attest clear challenge pack 1493PCDG is equivalent to the performance of the AAMI 16-towel PCD	Indicators contained in the Attest clear challenge pack 1493PCDG must demonstrate equivalent resistance as compared to the indicators contained in the AAMI 16-towel PCD	**Pass**
Resistance of Attest clear challenge pack 1493PCDG compared to standalone indicators	Attest clear challenge pack 1493PCDG three lots	U.S. FDA Guidance[5]	Demonstrate the Attest clear challenge pack 1493PCDG provides a greater challenge than the standalone indicators	Indicators contained in the Attest clear challenge pack 1493PCDG must demonstrate greater resistance compared to the standalone indicators	**Pass**

Particularly, the following performance criteria were demonstrated by the test results reported in **Tables 2 and 3**, and further evidenced by the U.S. FDA clearance (K242538[6]).

1. Equivalent resistance as the AAMI ST79 16-towel PCD[1] at a given exposure time and temperature.
2. Greater resistance than standalone BIs (and CIs).

The results presented above validate that the Attest clear challenge pack 1493PCDG meets the requirements for a BI PCD. In addition, based on the FDA clearance (K242538[6]), the Attest clear challenge pack 1493PCDG can be used safely and effectively to qualify and monitor gravity displacement steam sterilization processes at 121°C (250°F) in healthcare facilities.

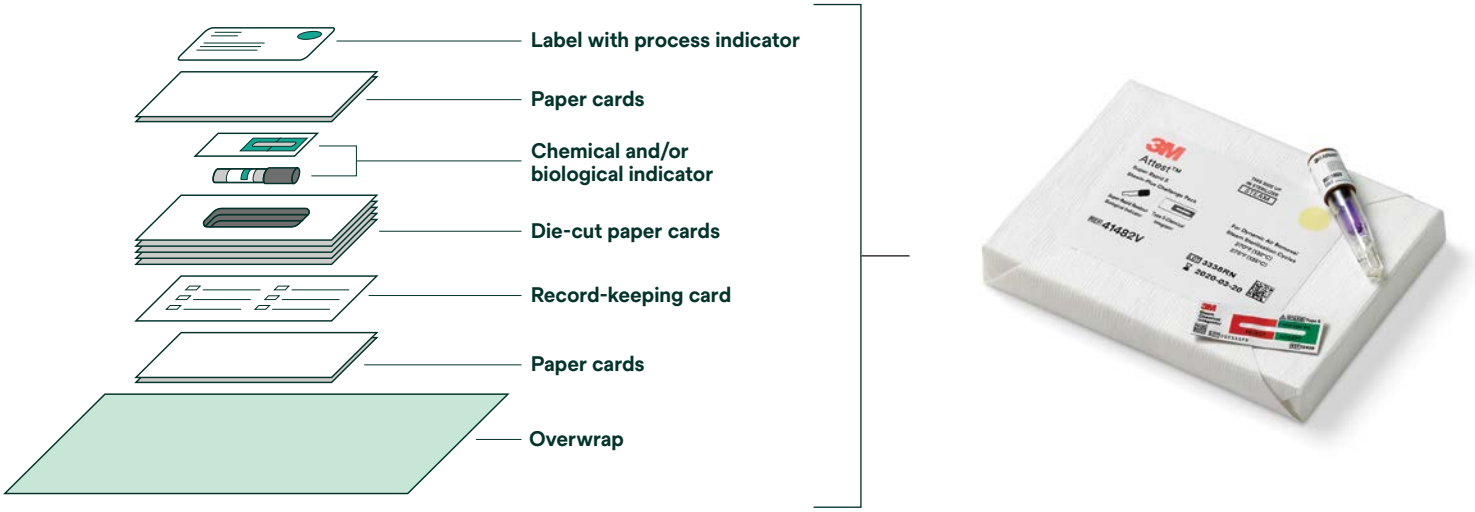
Comparison of an aperture-based challenge and a porous paper-based challenge in process challenge devices

Although the challenge to air removal and steam penetration in a steam sterilization cycle, whether using a porous media or an aperture-based challenge, can be made to be equivalent in performance to each other yet the physics describing the nature of these challenges is different.

An example of a porous-based challenge pack, or test pack, is shown in **Figure 7**. The permeability of the paper allows air to flow through it under a pressure difference across the sheet. The air permeability through an individual paper card making up the construction of a paper-based test pack indirectly depends on the thickness of the paper card, and is directly dependent on the area, and the permeability constant of the paper card. 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 clear challenge pack 1493PCDG (see **Figures 1, 3 and 4**), the challenge to air removal and steam penetration is provided by an engineered orifice. Air removal and steam penetration through an orifice is proportional to the area of the orifice. The dimensions of the orifice and indicator cavity used in the clear challenge pack are engineered (i.e., predetermined) and can be replicated with high precision from challenge pack to challenge pack. In contrast to a channel-based challenge, an orifice-based challenge to steam penetration provides a better representation of the instrument load in a gravity cycle, as non-lumened instruments are typically the instruments appropriate for sterilization in a gravity cycle.

Figure 7. Exploded view of an example porous-based challenge pack — 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V



Conclusion

As evidenced by the U.S. FDA clearance, and as presented above, the 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG meets the requirements for a BI PCD outlined by the U.S. FDA, demonstrating a resistance equivalent to the AAMI 16-towel PCD, as well as greater resistance than the standalone indicators contained with the Attest clear challenge pack 1493PCDG — the Attest biological indicator 1493 and Attest chemical integrator 1243R. As a result, the Attest clear challenge pack 1493PCDG can be used safely and effectively to qualify and monitor gravity displacement steam sterilization processes at 121°C (250°F) in healthcare facilities.

The innovative design and form factor of the Attest clear challenge pack 1493PCDG also affords a robust, repeatable, and reliable challenge to every cycle for which it is indicated to monitor.

References

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