Evaluation of the 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD 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 sterilisation process monitoring device that provides a direct measure of lethality of a sterilisation process. The new 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD ('1492PCD,' see **Figure 1**) is specifically designed to qualify and monitor dynamic-air-removal steam sterilisation processes at 132°C, 134°C, and 135°C in healthcare facilities. The 1492PCD consists of a clear plastic shell, with a tortuous channel designed to mimic the challenge to air removal and steam penetration posed by individual devices and device loads, and a cavity containing the monitoring products, all covered by a foil lid.

Figure 1. 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD

Method

Three lots of 1492PCDs (12 1492PCDs 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 1492V (1492V BIs) and 3M™ Attest™ Steam Chemical Integrator 1243R ('1243R CIs') to demonstrate that the 1492PCD has a resistance that is equivalent to the AAMI 16-towel PCD.

Three lots of 1492PCDs (12 1492PCDs per lot), containing three lots of 1492V BIs and three lots of 1243R CIs, were also tested side-by-side with standalone 1492V BIs and 1243R CIs to demonstrate that the 1492PCD has greater resistance than the standalone indicators.

Results

All three lots of 1492PCDs 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 Clear Challenge Pack 1492PCD, 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. the Food and Drug Administration (FDA), as evidenced by the FDA 510(k) (K241959). The results specifically demonstrated that the 1492PCD 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 1492PCD can be used safely and effectively to qualify and monitor dynamic-air-removal steam sterilisation processes at 132°C, 134°C and 135°C) 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 sterilisation process"*.

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

BIs are recognised by most authorities as being closest to the ideal monitors of the sterilisation process because they measure the sterilisation process directly by using the most resistant microorganisms (i.e., *Bacillus* spores), and not by merely testing the physical and chemical conditions necessary for sterilisation. 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 sterilisation process and used to assess performance of the process"*.[3]

PCDs were developed to assess the efficacy of the sterilisation 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 sterilisation 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 steriliser 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 sterilisation 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 sterilisers 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 standardisation 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?

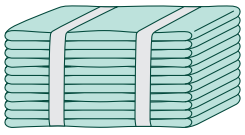
The United States FDA Guidance for Industry and FDA Staff — Biological Indicator (BI) Premarket Notification [510(k)] Submissions[5] sets forth the guidance for manufacturers on BI PCDs. Section 10 of this Guidance states:

> *"BIs may be used in test packs to simulate products being sterilised.*[9] *Test packs are intended to simulate products and constitute a defined challenge to the sterilisation 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 sterilisation 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 PCD1 at a given exposure time and temperature.
2. Greater resistance than standalone BIs.

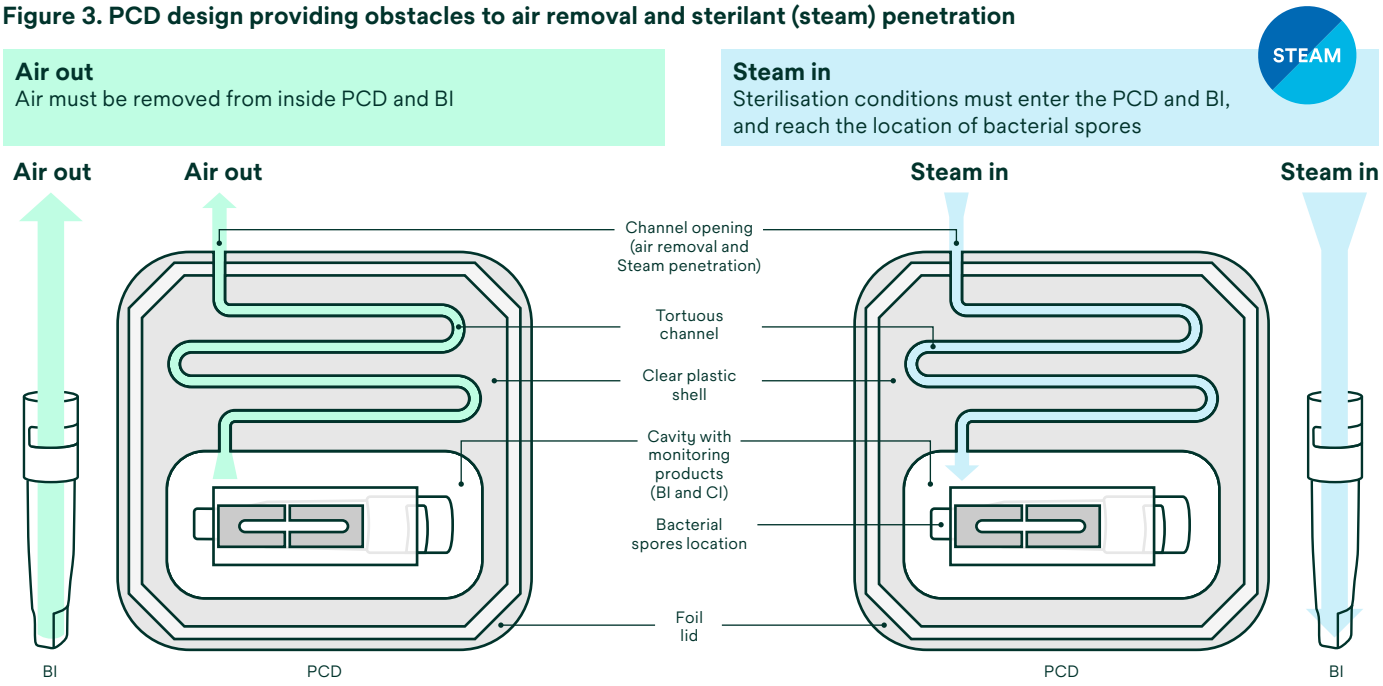
Figure 2. Requirements for BI PCD U.S. FDA clearance

Biological Indicator	Meets requirement	Performance criteria	
 **3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD**	✓	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 Clear Challenge Pack 1492PCD

The new 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD ('1492PCD') is specifically designed to qualify and monitor dynamic-air-removal steam sterilisation processes at 132°C, 134°C and 135°C in healthcare facilities. The 1492PCD consists of a clear plastic shell, with a tortuous channel designed to mimic the challenge to air removal and steam penetration posed by individual devices and device loads, and a cavity containing the monitoring products (see **Figures 1** and **3**), all covered by a foil lid (**Figure 3**).

Figure 3. PCD design providing obstacles to air removal and sterilant (steam) penetration



This convenient disposable challenge pack presents a challenge to the sterilisation 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 1492PCD is a single-use device.

Each 1492PCD contains a 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V (brown cap, '1492V BI') and a 3M™ Attest™ Steam Chemical Integrator ('1243R CI,' see **Figure 4**). 1492V 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 categorised by ISO 11140-1:2014.

ANSI/AAMI ST79 recommends that steam sterilisation 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 Clear Challenge Pack 1492PCD

3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD

3M™ Attest™ Super Rapid Readout Biological Indicator 1492V

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:

1492PCD versus AAMI 16-towel PCD
Compare the resistance of the 1492PCD to the AAMI 16-towel PCD in dynamic-air-removal steam sterilisation processes at 132°C, 134°C and 135°C.

1492PCD versus standalone BIs and CIs
Compare the resistance of the 1492PCD to standalone 1492V BIs and standalone 1243R CIs in dynamic-air-removal steam sterilisation processes at 132°C, 134°C and 135°C.

Materials and equipment

1492PCDs

Three lots of 1492PCDs were manufactured using three lots of 1492V BIs and three lots of 1243R Type 5 CIs. **Table 1** details the specific indicator lots used in each respective 1492PCD lot. All 1492PCD 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 1492PCD lot

1492PCD lot code	1492V BI lot	1243R CI 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 9 inches wide x 9 inches long x 6 inches high.

Each AAMI 16-towel PCD constructed with 1492V BIs and 1243R CIs 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) and a relative humidity of approximately 50% RH for at least two hours. Next, each AAMI 16-towel PCD was loaded with three 1492V BIs and three CIs (from the same lots used in each of the 1492PCDs) placed between the eighth and ninth towels with 1492 BI spore chambers and CI pellets located in the approximate geometric center 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 1492V BIs and three 1243R CIs were loaded into a small metal basket. The same three lots of 1492V BIs and the same three lots of 1243R CIs as those used in the 1492PCDs and the AAMI 16-towel PCDs were used as standalone indicators.

Equipment

Comparison to AAMI 16-towel PCD
1492PCDs were evaluated in 132°C and 134°C dynamic-air-removal sterilisation test cycles using the AMSCO Lab 110 steam steriliser, chamber size: 406 x 406 x 660 mm.

1492PCDs were also evaluated in 132°C, 134°C and 135°C dynamic-air-removal sterilisation test cycles using the Getinge Model 666 AC1 steam steriliser, chamber size: 660 x 672 x 660 mm.

Comparison to standalone indicators
1492PCDs (see Figures 1 and 3–4) were evaluated in 132°C and 134°C dynamic-air-removal sterilisation test cycles using the AMSCO Lab 110 steam steriliser, chamber size: 406 x 406 x 660 mm.

1492PCDs were evaluated in 135°C dynamic-air-removal sterilisation test cycles using the Getinge Model 666 AC1 steam steriliser, chamber size: 660 x 672 x 660 mm.

The delivered lethality of FDA-cleared cycles does not readily allow for characterisation of the resistance of various indicators (which are normally tested in resistometers capable of precision performance and lower levels of lethality). To clearly characterise the resistance of the indicators both within a 1492PCD 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 1492PCDs and 16-towel PCDs).

Methods

Three lots of 1492PCDs (12 1492PCDs per lot), containing three lots of 1492V BIs and three lots of 1243R CIs (as detailed in **Table 1**), were tested side-by-side with the AAMI 16-towel PCD containing the same three lots of 1492V BIs and 1243R 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 1492PCDs (12 1492PCDs per lot), containing three lots of 1492V BIs and three lots of 1243R CIs (as detailed in **Table 1**), were tested side-by-side with the same three lots of standalone indicators 1492V BIs and 1243R 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 summarises 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 sterilisation test cycle contained three 1492PCDs from a single lot and one AAMI 16-towel PCD containing three 1492V BIs and three 1243R CIs from corresponding lots.

For all cycles using the Amsco Lab 110, the 1492PCDs 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 5** shows an example of the 1492PCD and AAMI 16-towel PCD placement in the Lab 110 chamber.

For all cycles using the Getinge Model 666 AC1, the 1492PCDs and AAMI 16-towel PCD were centered over the drain. **Figure 6** shows an example of the 1492PCDs and AAMI 16-towel PCD placement in the Getinge Model 666 AC1 chamber.

Methods for demonstrating greater resistance than standalone BIs

For standalone testing, each sterilisation test cycle contained three 1492PCDs from a single lot, and a metal basket loaded with three standalone 1492V BIs and three standalone 1243R CIs from corresponding lots. **Figures 5** and **6** also show an example of 1492PCD and standalone indicator placement in the Lab 110 chamber and Getinge Model 666 AC1 chamber, respectively.

Figure 5. Diagram of 1492PCD and AAMI 16-towel PCD or standalone placement within Lab 110

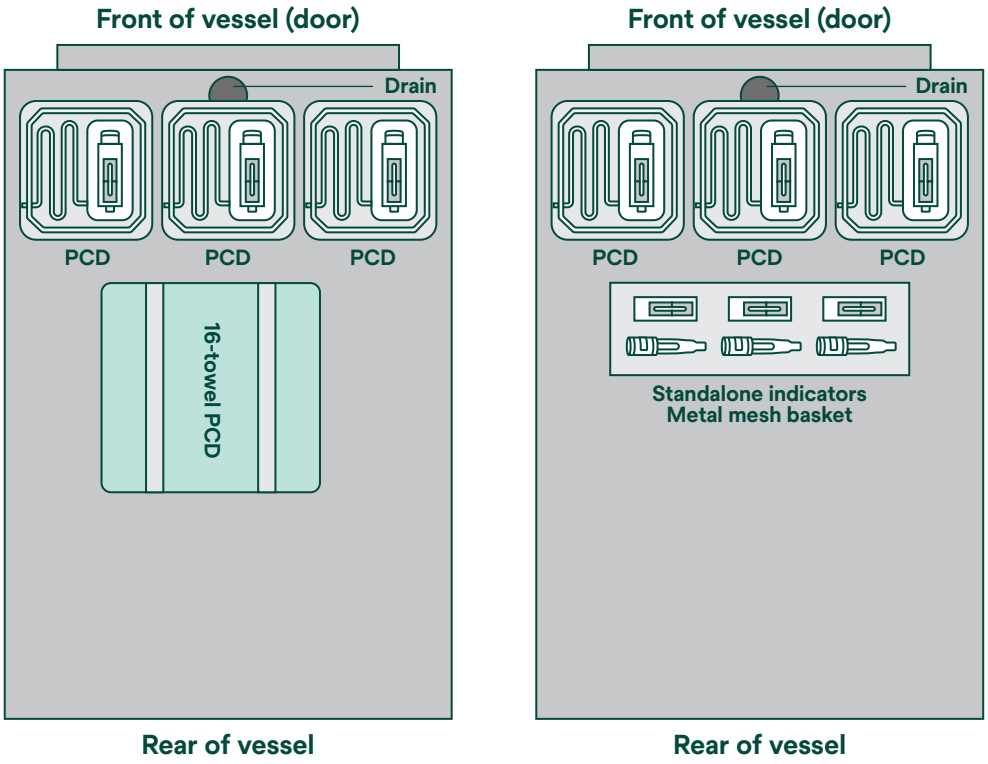
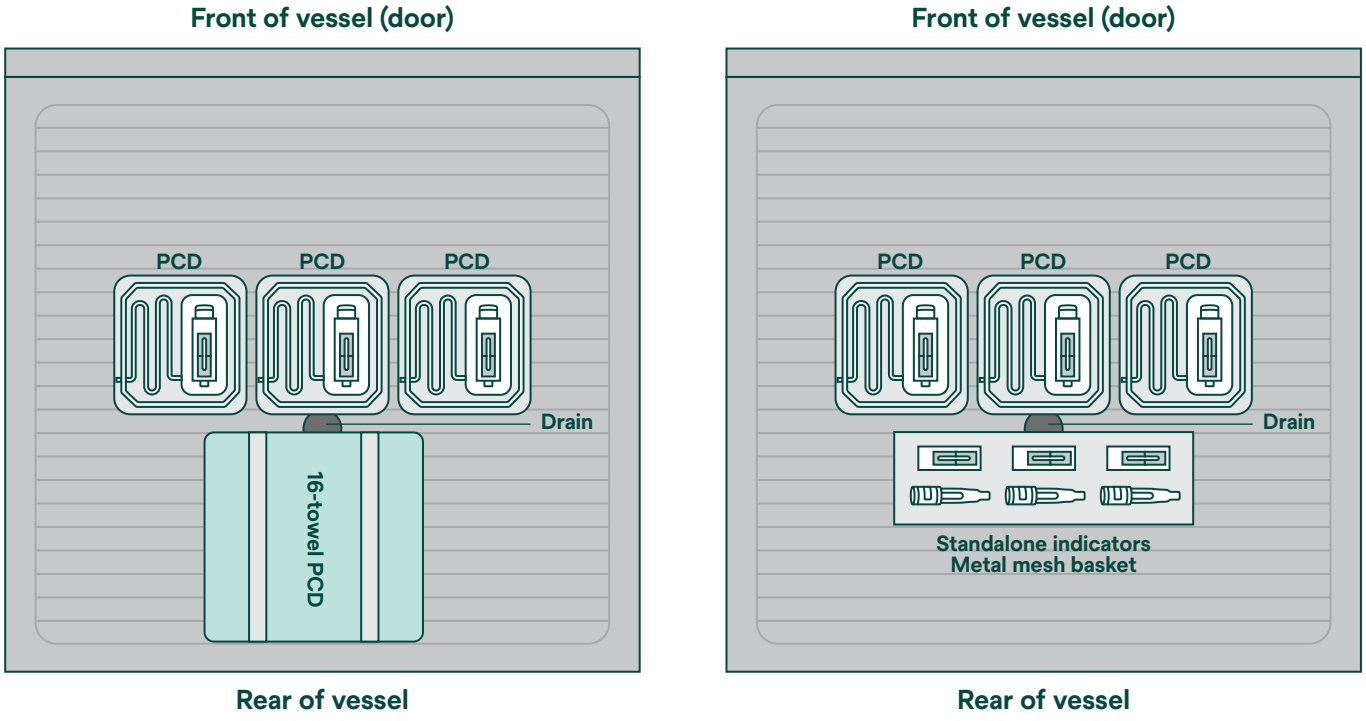


Figure 6. Diagram of 1492PCD and AAMI 16-towel PCD or standalone placement within Getinge 666 AC1



After the sterilisation test cycle, the 1492V BIs and 1243R CIs were removed from the 1492PCDs and AAMI 16-towel PCDs. 1492V BIs were activated and read for 24 minute fluorescence using the 3M™ Attest™ Auto-reader 490. They were further incubated in the Attest Auto-reader 490 at 60°C ± 2°C and read for visual pH color change after 48 hours of incubation. Additionally, the 1492V BI cap process indicators were visually read for colour change and the 1243R CIs were visually read for accept or reject (see **Figure 4**).

Results

The test results are shown in **Table 2**. Table 2 shows that for each type of sterilisation 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)	Testing purpose	Acceptance criteria	Results
1492PCD versus 16-towel PCD comparison testing				
Kill (full exposure time)	132/270 134/273 135/275	Demonstrate indicators in the 1492PCDs are a pass or accept Demonstrate indicators in the AAMI 16-towel PCD are a pass or accept	**All kill/accept** **1492V BI:** 100% negative fluorescent and pH color change **1243R CI:** 100% accept **Process indicator:** Light brown or darker color change	**Pass**
Survive (shortened exposure time)	132/270 134/273 135/275	Demonstrate indicators in the 1492PCDs are a fail or reject Demonstrate indicators in the AAMI 16-towel PCD are a fail or reject	**All survive/reject** **1492V BI:** 100% positive fluorescent and pH color change **1243R CI:** 100% reject	**Pass**
Fractional (shortened exposure time)	132/270 134/273 135/275	Demonstrate a mixed response in the 1492V BIs for 1492PCDs and equivalent resistance versus the AAMI 16-towel PCD Demonstrate a mixed response in the 1243R CIs for 1492PCDs and equivalent resistance versus the AAMI 16-towel PCD	**Mixed BI & CI results** **1492V BI:** Mixed negative/positive fluorescence and pH color response in 1492PCD with equivalent resistance versus the AAMI 16-towel PCD **1243R CI:** Mixed accpet/reject response in 1492PCD with equivalent resistance versus the AAMI 16-towel PCD	**Pass**
1492PCD versus standalone indicator comparison testing				
Fractional (shortened exposure time)	132/270 134/273 135/275	Demonstrate indicators in the 1492PCD are a fail or reject Demonstrate standalone indicators are a pass or accept	**Indicators in 1492PCD** **1492V BI:** 100% positive fluorescent and pH color change **1243R CI:** 100% reject **Standalone indicators** **1492V BI:** 100% negative fluorescent and pH color change **1243R CI:** 100% accept	**Pass**

Discussion

The 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD was cleared by the U.S. FDA on 18 October 2024 (K2419596), demonstrating that the 1492PCD has met the requirements of FDA Guidance[5] and applicable sections of ANSI/AAMI ST79:2017.[1]

Performance of the 1492PCD was verified,[7] as detailed in **Table 3**.

Table 3. Performance data summary of 1492PCD

Test performed	Device description	Applicable standards	Purpose	Acceptance criteria	Results
Resistance of 1492PCD compared to AAMI 16-towel PCD	1492PCD 3 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 1492PCD is equivalent to the performance of the AAMI 16-towel PCD	Indicators contained in the 1492PCD must demonstrate equivalent resistance as compared to the indicators contained in the AAMI 16-towel PCD	**Pass**
Resistance of 1492PCD compared to standalone indicators	1492PCD 3 lots	U.S. FDA Guidance[5]	Demonstrate the 1492PCD provides a greater challenge than the standalone indicators	Indicators contained in the 1492PCD must demonstrate greater resistance compared to the standalone indicators in the claimed cycles	**Pass**

Particularly, the following performance criteria were demonstrated by the test results reported in **Table 2** and **Table 3**, and further evidenced by the U.S. FDA clearance (K2419596).

1. Equivalent resistance as the AAMI ST79 16-towel PCD1 at a given exposure time and temperature.
2. Greater resistance than standalone BIs (and CIs).

The results presented above validate that the 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD meets the requirements for a BI PCD. In addition, based on the FDA clearance (K2419596), the 1492PCD can be used safely and effectively to qualify and monitor dynamic-air-removal steam sterilisation processes at 132°C, 134°C and 135°C in healthcare facilities.

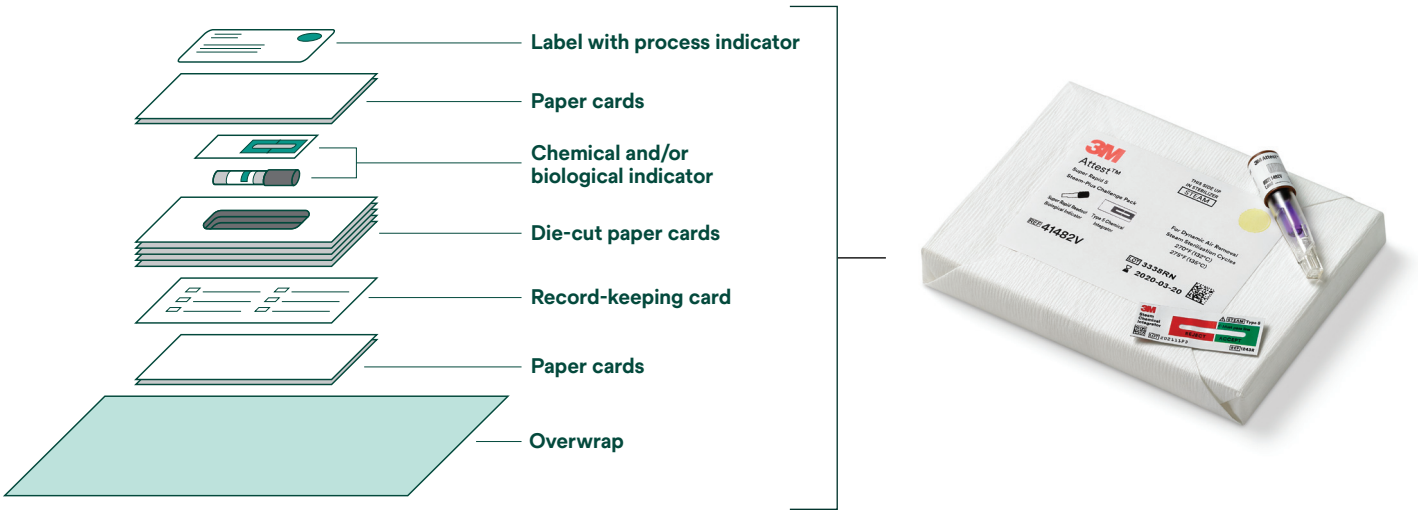
Comparison of a channel-based challenge and a porous paper-based challenge in process challenge devices

Although the challenge to air removal and steam penetration in a steam sterilisation 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.

An example of a porous-based challenge pack, or test pack, is shown in **Figure 7**. The permeability of the paper allows air removal 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 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD (see **Figure 1** and **Figure 3**), the challenge to air removal and steam penetration is provided by an engineered channel. Air removal in this channel is inversely dependent on the length of the channel and directly dependent on its cross section. Every dimension of the channel used in 1492PCD is engineered (i.e., predetermined) and can be replicated with high precision from challenge pack to challenge pack. The physics of air removal embodied by the channel challenge of the 1492PCD 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 sterilisation can occur. Any air remaining in the lumens of these instruments may compromise the sterilisation of those internal surfaces.

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 Clear Challenge Pack 1492PCD 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 1492PCD – the 1492V BIs and 1243R CIs. As a result, the 1492PCD can be used safely and effectively to qualify and monitor dynamic-air-removal steam sterilisation processes at 132°C, 134°C and 135°C in healthcare facilities.

The innovative design and form factor of the 1492PCD also affords a robust, repeatable and reliable challenge to every cycle for which it is indicated to monitor.

References

1. ANSI/AAMI ST79:2017(R)2022+A1,A2,A3,A4:2020(R)2022. *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.*
2. Center for Disease Control (CDC). *Guideline for Disinfection and Sterilization in Healthcare Facilities*. Published online (R)2019 2008.
3. ISO 11139:2018. *Sterilization of health care products – Vocabulary of terms used in sterilization and related equipment and process standards.*
4. Kirckof S. Process Challenge Devices: Validating Sterilization. *Biomed Instrum Technol*. 2008;42(4):309–311.
5. U.S. Department of Health and Human Services. Food and Drug Administration – Center for Devices and Radiological Health. *FDA Guidance for Industry and FDA Staff - Biological Indicator (BI) Premarket Notification [510(k)]* Submissions. 2007. https://www.fda.gov/media/71134/download.
6. U.S. FDA 510(k) Summary for K241959 for 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K241959.
7. Data on file (EM-05-999927 and EM-05-1086317).

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