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3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD

Frequently Asked Questions (FAQ's)

February 2025

FAQ's

The 1295PCD contains both the 3M™ Attest™ Rapid Readout Biological Indicator 1295 (pink cap, referred to hereinafter as the 1295 BI) and the 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348 (referred to hereinafter as the 1348 CI).

1. **What are the benefits of using the 1295PCD vs. standalone BI or a standalone BI in sterilization pouch?**
   - Reference the Solventum white paper *Why should I use a process challenge device for monitoring vaporized hydrogen peroxide sterilization?*
   - The preassembled 1295PCD can save the time required to assemble a BI, CI, and peel pouch manually
   - Preassembly of 1295PCD can help reduce potential for errors caused by manual assembly of BI and CI into a peel pouch
   - 1295PCD can help streamline inventory management by reducing the need to order VH2O2 BIs, CIs, and peel pouches individually
   - 1295PCD provides a higher level of quality assurance monitoring as compared to standalone BIs or BIs placed inside sterilization pouches
   - The use of the 1295PCD provides a greater confidence in your sterilization assurance program as compared to the use of standalone BIs or BIs placed inside sterilization pouches
   - 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.
   - Using the 1295PCD preassembled test pack allows customers to elevate their current VH2O2 sterilization load monitoring practice to a level that is on par with steam sterilization monitoring best practices/standards
   - The preassembled 1295PCD is designed to more accurately simulate the environment inside of a surgical pack than using just a stand-alone BI (or a BI in a sterilization pouch) for VH2O2 load monitoring. It's the same design principle used in preassembled steam BI test packs.
   - 1295PCD is designed to represent the sterilization process challenge posed by instruments sterilized every day
   - The 1295PCD is placed in a standardized location in the sterilization chamber; top rack towards the front of the chamber. This standardization reduces potential error in the placement of the BI as the ASP® systems and STERIS® systems have different locations for the placement of their BIs in these VH2O2 sterilizer systems.

2. **Do I need a process challenge device (PCD) for monitoring VH2O2 sterilizers in healthcare facilities?**
   Per ANSI/AAMI ST58:2024 *Chemical sterilization and high-level disinfection in health care facilities*
   8.6.5.3 Frequency of use of biological indicators and process challenge devices: *Biological indicators **should be used within PCDs** or an FDA-cleared BI-containing quality monitoring device for routine sterilizer efficacy monitoring for each cycle type every day the sterilizer is in use, but preferably in every load.*

Standards and guidelines in your region of the world may differ. The benefits of using the 1295PCD vs. standalone BI or a standalone BI in sterilization pouch are multifaceted and extensive and are outlined in the beginning of this document.

3. **Can I use the 1295PCD to monitor my VH2O2 sterilizer? The sterilizer manufacturer said that they did not validate the 1295PCD in their sterilizer so the device should not be used in their sterilizer.**
Yes, you can use the 1295PCD as a standard method of routine monitoring and performance qualification (operational and performance) and for process validation of vaporized hydrogen peroxide sterilization processes. In the U.S. if your VH2O2 sterilizer is listed in the indications for use for the 1295PCD, then the 1295PCD can be used a standard method of routine monitoring and performance qualification. The 1295PCD has a comprehensive list of indications for use. Please see the list of VH2O2 sterilizers and cycle types listed in the table below. Per ANSI/AAMI ST58:2024 *Chemical sterilization and high-level disinfection in health care facilities* 8.6.5.2 Using biological indicators and process challenge devices: **BIs used in health care facilities are medical devices that require FDA clearance. Personnel should use BIs cleared by the FDA for use with that sterilization system.**

The 1295PCD has been cleared by the U.S. FDA as safe and effective to monitor and qualify the VH2O2 sterilizers and cycles listed in the indications for use in the instructions for use (IFU). Solventum has completed extensive validation testing on the 1295PCD to meet the stringent requirements of both U.S. FDA and Solventum's own quality system. There is no regulatory requirement for a sterilizer manufacturer to validate or endorse the compatibility of indicators designed to monitor the efficacy of a sterilization cycle in their sterilizers. It is misinformation or disinformation for anyone to express or suggest otherwise. The decision regarding the safety and efficacy of sterilization monitors is addressed by U.S. FDA's review and clearance procedures. There are many examples of monitoring products from multiple manufacturers being used to monitor steam, ethylene oxide, and hydrogen peroxide sterilizers. Solventum strongly objects to statements that may cause confusion for users. Supporting documentation includes the 1295PCD IFU and the U.S. FDA 510(k) Summary for the 1295PCD.

Use the 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater or a 3M™ Attest™ Mini Auto-reader 490M or a 3M™ Attest™ Auto-reader 490H as a standard method of routine monitoring and performance qualification of vaporized hydrogen peroxide sterilization processes in the following systems:

STERRAD 100S® Sterilization System
STERRAD NX® Sterilization System (Standard and Advanced cycles)
STERRAD 100NX® Sterilization System (Standard, Flex, Express, and Duo cycles)
STERRAD NX® with ALLClear® Technology Sterilization System (Standard and Advanced cycles)
STERRAD 100NX® with ALLClear® Technology Sterilization System (Standard, Flex, Express, and Duo cycles)
V-PRO® 1 Low Temperature Sterilization System (Lumen cycle)
V-PRO® 1 Plus Low Temperature Sterilization System (Lumen and Non Lumen cycles)
V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles)
V-PRO® 60 Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles)
V-PRO® maX 2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast Non Lumen cycles)
V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles)
SteroScope® Sterilization System

4. **Will my facility observe false positives if we use the 1295PCD? I was told by the sterilizer manufacturer the 1295PCD is too challenging for my VH2O2 sterilizers.**
   1295PCD has undergone years of development work that includes extensive design iterations and evaluations, bench testing, clinical field testing, design verification and design validation. In addition, 1295PCD has been tested successfully in clinical field testing for the cycles listed in the indications for use.

   Our successful field testing in a clinical setting for the indicated sterilizers demonstrates that the user will be successful with 1295PCD if their practices follow the details of instructions for use (IFU) for the sterilizer, the packaging, the medical device and the 1295PCD. Our data indicates that the legacy ASP® STERRAD® 100NX EXPRESS cycle will be the most challenging. Prewarming or preheating the load may be required per 1295PCD IFU for the legacy EXPRESS cycle.

5. **What should I do if the sterilizer manufacturer said they will not service my sterilizer if we are using the 1295PCD?**
   We acknowledge your frustration with this communication from your sterilizer manufacturer, and we hope to provide some additional insights.

   “Service” could mean different activities. “Service” could mean preventative maintenance or physical repair of the sterilizer machine. “Service” could also mean the sterilizer manufacturer will not assist in troubleshooting any failed cycles because of the monitoring product. Solventum has the expertise and knowledge to troubleshoot failed monitoring products and Solventum will assist if your facility observes failures of any sterilization monitoring products.

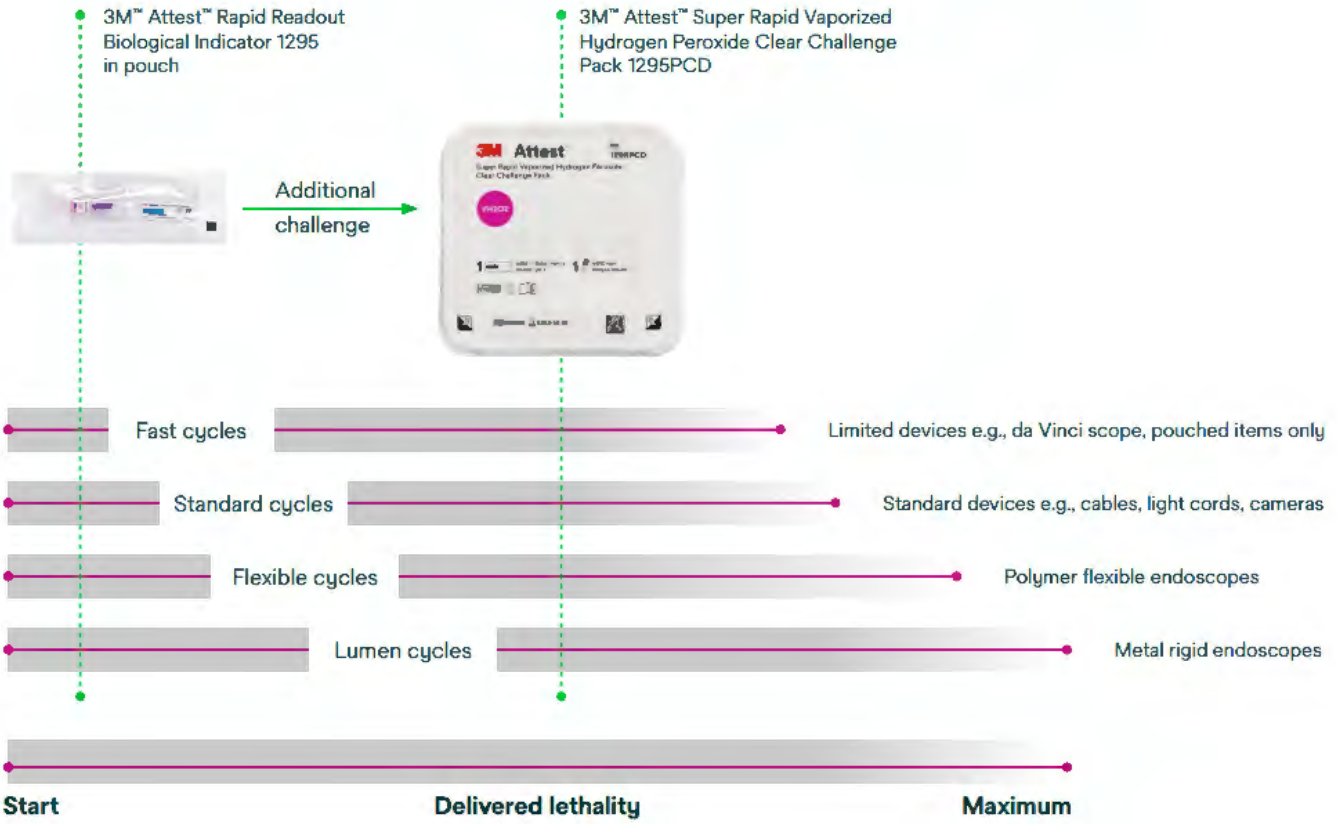
   We encourage you to reach out to your cross functional departments and administrators at your facility (Infection Prevention, Operating Room Management, Purchasing, Sourcing, Supply Chain, Facilities Management etc) to help your department navigate the matter with your sterilizer vendor should the matter persist.

   Solventum sterilization monitoring products (including 3M™ Attest™ Rapid Readout Biological Indicator 1295, 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E, 3M™ Comply™ Chemical Indicator Strip 1248 and 3M™ Comply™ Indicator Tape 1228) are currently used in a variety of manufacturers’ sterilizers, including thousands of STERRAD® and V-PRO® sterilizers globally. We've successfully monitored millions of cycles with these sterilizers and continue to support your colleagues world-wide.

6. **Why does the 1295PCD have two channels vs one channel in and out of the monitoring products cavity?**
   Standards and guidelines lack applicable performance requirements for PCDs used in monitoring VH2O2 sterilization in healthcare. 1295PCD is first of its kind in healthcare. Early in the 1295PCD design iteration process, Solventum established and investigated a single-channel design of the 1295PCD and found that the two-channel design was a more appropriate challenge for compatibility in the use of the wide range of sterilization conditions presented in the number of global VH2O2 sterilization cycles.

7. **How can the same PCD be used to monitor and challenge so many different cycles that have different sterilization conditions?**
   Standards and guidelines lack applicable performance requirements for PCDs used in monitoring VH2O2 sterilization in healthcare. 1295PCD is first of its kind in healthcare. The 1295PCD provides the same consistent and defined challenge to each cycle type that is monitored. For all the cycles, the 1295PCD provides a greater challenge to the vaporized hydrogen peroxide sterilization process as compared to standalone BIs or BIs placed inside sterilization pouches. See the list of advantages for the use of the 1295PCD that provides a greater challenge to the sterilization cycle. The diagram below helps illustrate the concept of a greater challenge for different cycle types and conditions.

Delivered cycle lethality and defined challenge of the 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD



8. **How much more resistant is the 1295PCD as compared to the 1295 BI in a pouch?**
Standards and guidelines lack applicable performance requirements for PCDs used in monitoring VH2O2 sterilization in healthcare. 1295PCD is first of its kind in healthcare. The 1295PCD is more resistant than the 1295 BI in a pouch.

   It has undergone years of development work that includes extensive design iterations and evaluations, bench testing, clinical field testing, design verification and design validation. In addition, 1295PCD has been tested successfully in clinical field testing for the cycles listed in the indications for use.

   An actual challenge or resistance value cannot be used as a factor to determine future success with 1295PCD. There are too many variables to consider. Our successful field testing in a clinical setting for the indicated sterilizers demonstrates that the user will be successful with 1295PCD if their practices follow the details of instructions for use (IFU) for the sterilizer, the packaging, the medical device and the 1295PCD. Our data indicates that the legacy ASP® STERRAD® 100NX EXPRESS cycle will be the most challenging. Prewarming or preheating the load may be required per 1295PCD IFU for the legacy EXPRESS cycle.

9. **How was the challenge of the 1295PCD determined?**
Standards and guidelines lack applicable performance requirements for PCDs used in monitoring VH2O2 sterilization in healthcare. 1295PCD is first of its kind in healthcare. The challenge of the 1295PCD evolved during years of development work. The evolution of the design of the 1295PCD began with assessing the performance of 30 vaporized hydrogen peroxide sterilization cycle types to understand the vaporized hydrogen peroxide conditions to obtain sterilization. After understanding the many vaporized hydrogen peroxide sterilization conditions used in clinical settings, iterations of the 1295PCD design evolved through several concepts (e.g. one channel vs two channels) and versions during bench testing and clinical evaluation activities to establish the challenge of the 1295PCD. After the final PCD design was verified, clinical field testing was performed to confirm compatibility of

the 1295PCD in 31 vaporized hydrogen peroxide sterilization cycle types across 11 models and two different sterilizer manufacturers. Finally, the 1295PCD design was validated to demonstrate the consistent and defined challenge of the 1295PCD.

10. **Is the 1295PCD safe to handle after processing?**
    Yes! The 1295PCD has been U.S. FDA cleared as safe and effective when used per the instructions for use. The materials of the 1295PCD (e.g. polypropylene plastic shell and aluminum foil lid etc..) are safe for use and compatible in VH2O2 sterilization processes. The 1295PCD is safe to handle as are other packages and devices (e.g. endoscopes, batteries, cables) that are sterilized using VH2O2 processes.
    Also, our studies indicated there was negligible VH2O2 remaining in the 1295PCD after routine processing. Per the instructions for use after completion of the cycle, don safety glasses and gloves and remove the 1295PCD from the sterilizer chamber. Continue to wear safety glasses and gloves until the 1295 BI is placed in a 3M Attest Auto-reader.
    Don safety glasses and gloves and avoid direct contact with the 1295PCD or 1295 BI if the sterilization cycle automatically cancels or is cancelled by the user before completion. Residual hydrogen peroxide may be trapped within the 1295PCD or 1295 BI and may result in hydrogen peroxide burns. Follow the disposal instructions provided at the end of the instructions for use.

11. **Why is there an option to prewarm or preheat the load prior to processing?**
    Warming or preheating the load prior to starting the cycle may reduce the amount of typical degradation of vaporized hydrogen peroxide during the sterilant exposure phase. This additional step may provide a significant advantage for commonly used rapid or fast vaporized hydrogen peroxide cycles. The critical process variables for VH2O2 sterilization are exposure time, temperature and VH2O2 concentration. If the critical process variables change, the effectiveness of the process changes. Warming or preheating the load prior to starting the cycle can change the critical process variable of exposure temperature and change the effectiveness of the process.

12. **What is the shelf-life for the 1295PCD?**
    The 1295PCD has an 18-month shelf-life from the date of manufacture at the time the 1295PCD was launched / available for sale in the U.S.. Aging studies are currently ongoing and the 1295PCD will eventually have a 2-year shelf life when aging and testing is complete.

13. **Can the 1295PCD be placed in the same location in the chamber as the 1295 BI in the pouch?**
    No, the 1295PCD should not be placed in the same chamber location as the 1295 BI in the pouch. Place the 1295PCD on the top rack or shelf in the sterilizer chamber, towards the front of the chamber door. Process the load according to established procedures.

14. **What are the associated and applicable standards for the 1295PCD?**
    Standards and guidelines lack applicable performance requirements for PCDs used in monitoring VH2O2 sterilization in healthcare. 1295PCD is the first of its kind in healthcare. The 1295PCD complies with the definition of a PCD (also known as test pack) and may be used to facilitate compliance to the standards listed in the 1295PCD Technical Information Sheet.

15. **Why don't we need to follow the sterilizer manufacturer's worst-case location for placement of the 1295PCD in the chamber?**
    Standards and guidelines lack applicable performance requirements for PCDs used in monitoring VH2O2 sterilization in healthcare. 1295PCD is first of its kind in healthcare. Solventum strives to simplify and standardize practices in the Sterile Processing Department. To that end, we designed the 1295PCD to be placed in a standardized chamber location and become the last item placed in the load.

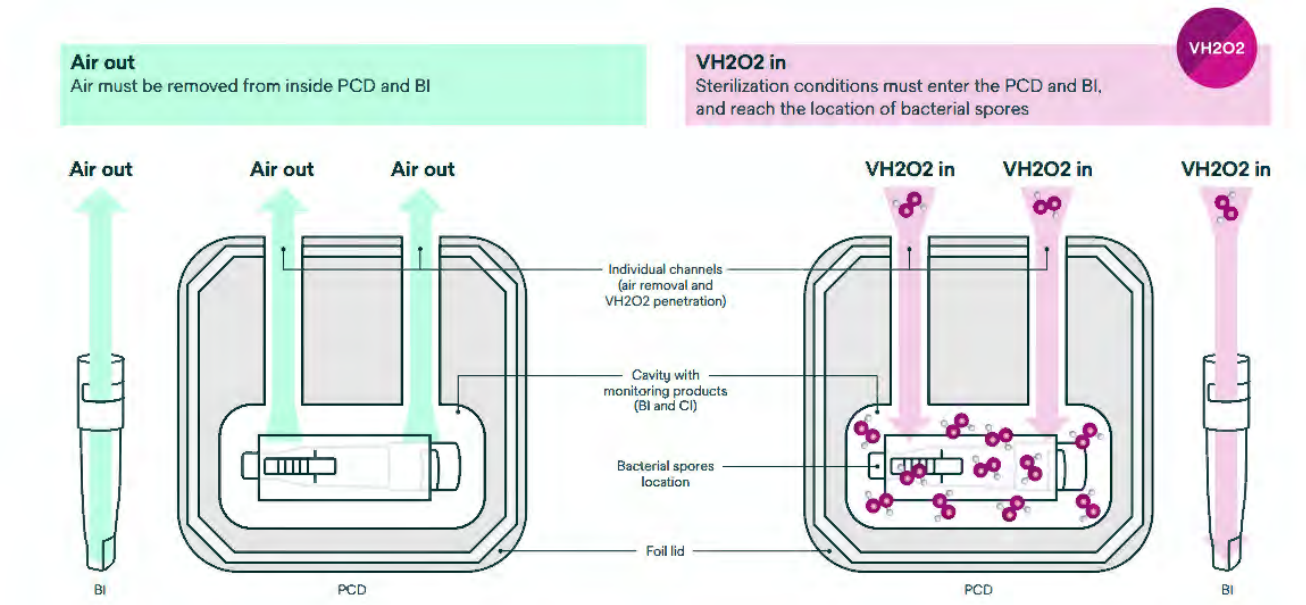
    The sterilizer manufacturer's worst-case location in the chamber adds an 'additional challenge' to the monitoring biological indicator. The 1295PCD was specially designed to include that 'additional challenge'. Therefore, the U.S. FDA cleared 1295PCD as safe and effective to be placed in the top rack or shelf in the sterilizer chamber, towards

the front of the chamber door and not in the sterilizer manufacturer's worst-case location. 1295PCD is shifting paradigms in Sterile Processing Departments.

16. **When placing the 1295PCD in the sterilization chamber, should the 1295PCD be placed labelled side up cavity side up on the rack?**
    There is no restriction on the orientation of the 1295PCD when placing the PCD directly on the sterilizer chamber rack. The user will probably prefer to place the PCD label side down as the PCD will lay flat and stable on the rack and the 1348 CI is clearly visible to the user before and after processing.

17. **Could the 1295PCD fall off the sterilizer chamber top shelf if it is leaned against a package per the IFU?**
    Yes it could be possible the 1295PCD that is leaned against a package could fall off the top shelf during processing. When there is adequate space in the loaded sterilizer chamber, place the 1295PCD directly on the sterilizer chamber rack or shelf. Only lean the package if necessary.

18. **Is the design and challenge of 1295PCD equivalent to any packaging type, load type or instrumentation or device type, for example an endoscope?**
    Standards and guidelines lack applicable performance requirements for PCDs used in monitoring VH2O2 sterilization in healthcare. 1295PCD is first of its kind in healthcare. The performance of the 1295PCD has not currently been comparison tested against any specific medical device. The preassembled 1295PCD is designed to more accurately simulate the environment inside of a surgical pack than using just a standalone BI (or a BI in a sterilization pouch) for VH2O2 load monitoring. The 1295PCD is designed to represent the sterilization process challenge posed by instruments sterilized every day. The design mimics the challenge of air removal and vaporized hydrogen peroxide penetration posed by individual devices and device loads. It consists of a clear plastic shell, with two individual channels. Those two individual channels connect to a cavity containing the monitoring products and all are covered by a foil lid (see image).



19. **While using the 1295PCD is it possible that the 1348 CI will indicate an ACCEPT and the 1295 BI indicates a FAIL result?**
    Our data indicates this scenario has a very low risk of occurrence based on historical data.

    The 1295PCD has undergone years of development work that includes extensive design iterations and evaluations, bench testing, design verification, clinical field testing and design validation. This extensive amount of development work did not reveal any concerns that this event could happen at any discernable level. The user should respond to this event per their facility policy for a failed biological indicator result.

20. **While using the 1295PCD is it possible that the 1348 CI will indicate a REJECT and the 1295 BI indicates a PASS result?**
Our data indicates this scenario has a very low risk of occurrence based on historical data.

The 1295PCD has undergone years of development work that includes extensive design iterations and evaluations, bench testing, design verification, clinical field testing and design validation. This extensive amount of development work did not reveal any concerns that this event could happen at any level discernable level.

The user should respond to this event per their facility policy for a CI that has not been exposed to sufficient vaporized hydrogen peroxide sterilization conditions that was located inside a test pack.

21. **If the 1295PCD is not opened immediately after the sterilization cycle is complete could the 1348 CI result change from a REJECT to ACCEPT?**
Per the instructions for use for the 1295PCD, always activate and incubate the 1295 BI within one hour of the completion of the sterilization cycle. Our testing of the 1295PCD after the completion of the sterilization cycle indicates the 1348 CI result will not change from REJECT to ACCEPT when the 1295 BI is activated and incubated within one hour of the completion of the sterilization cycle.

22. **The 1295 BI Quality Certificate indicates the performance of 1295 BI is tested at 10 mg/L of VH2O2 and the performance of the 1348 CI has a stated value tested at 5.1 mg/L of VH2O2. How do these devices consistently provide the same end result when they are located next to each other inside the 1295PCD?**
There are significant design differences between the 1295 BI and the 1348 CI. The 1295 BI provides a result based on biological activity and the 1348 CI provides a result based on a chemical reaction. Furthermore, the spores of the 1295 BI are contained on a special carrier located at the bottom of the sleeve/plastic vial of the 1295 BI. Within this plastic vial there are obstacles for air removal and sterilant penetration to the spores (e.g. label filter, media ampoule, nonwoven material).

The 1295PCD has undergone years of development work that includes extensive design iterations and evaluations, bench testing, design verification, clinical field testing and design validation. This extensive amount of development work revealed the performance of the 1295 BI and the 1348 CI were comparable inside the 1295PCD design.

23. **I thought the 1295 BI in the pouch was a PCD, why do I want to use the 1295PCD?**
The 1295 BI in a pouch has not been U.S. FDA cleared nor validated as a PCD. The 1295PCD is the FIRST preassembled VH2O2 test pack that is U.S. FDA-cleared for routine monitoring across multiple sterilizer brands, models, and cycle types. See the list of advantages in the beginning of this document for the use of the 1295PCD that provides a greater challenge to the sterilization cycle.

24. **How is the design of the 1295PCD more consistent vs the use of a standalone BI in a sterilization pouch?**
Sterilization pouches that are compatible with VH2O2 sterilization processes can have more innate variation in their design and construction than one might think at first glance. A common sterilization pouch is composed of four primary components; the clear plastic side, the white opaque printed side, the adhesive that keeps these components together and the process indicator that changes color with the exposure to the sterilization process. The physical composition of each component can be different between manufacturers, catalogue numbers and can have variation within each specific lot. Between manufacturers globally the plastic side can be made of different materials, can have different thickness, density and performance (e.g. vapor transmission rate) and the plastic could have a coating or no coating. The white opaque printed side can also be made of different types of materials, can also have different thickness, density and performance (e.g. vapor transmission rate), and can have different types of coatings. There are many types of possible adhesives that can be significantly different in physical properties and compositions. The process indicators are also made from a wide assortment of different compositions of chemistries.

On the contrary, the 1295PCD is a precision engineered device made of two primary materials. The plastic shell is a precision injected molded part made of virgin pellets of polypropylene resin with detailed dimensional

specifications. The aluminum foil lid is an engineered multilayered precision film made with raw material specifications. There is no adhesive used in the design of the 1295PCD. The multilayered precision film lid is heat sealed to the polypropylene shell to create a closure that maintains integrity through the sterilization process.

The characteristics of the 1295PCD outlined above confirm that it offers a more consistent challenge to the VH2O2 sterilization process compared to using a standalone BI in a sterilization pouch.

25. **Can we use the 1295PCD to monitor the new ASP STERRAD® 100NX ULTRA GI Cycle (for duodenoscopes)?**
The ULTRA GI cycle is a new VH2O2 sterilization cycle (July 2024) that can be found or installed on the ASP STERRAD 100NX® with ALLClear® Technology Sterilization System. The cycle was designed for sterilization of hydrogen peroxide compatible flexible multi-channel duodenoscopes, one flexible duodenoscope per tray, and no more than two flexible duodenoscope per cycle.

In the U.S. the 1295PCD is currently not U.S. FDA cleared for use in this new cycle. Solventum will welcome the opportunity to validate the 1295PCD at a customer's facility using their ASP STERRAD 100NX® with ALLClear® Technology Sterilization System to allow them to use the 1295PCD in the future to monitor this new cycle.

Outside the U.S. (OUS) the 1295PCD can be used as a standard method of routine monitoring and performance qualification (operational and performance) and for process validation of vaporized hydrogen peroxide sterilization processes. We would recommend performing an evaluation on the performance of the 1295PCD in the ULTRA GI cycle on the ASP STERRAD 100NX® with ALLClear® Technology Sterilization System before routine use of the 1295PCD in this new cycle type. We would also recommend a discussion amongst the regional Solventum product team and the user to understand the risks and benefits of using the 1295PCD in this new cycle.

26. **Can we use the 1295PCD to monitor the new STERIS V-PRO® maX 2 Low Temperature Sterilization System Specialty Cycle (for 3D printed items)?**
The Specialty Cycle is a new VH2O2 sterilization cycle (August 2023) that can be found or installed on the STERIS V-PRO® maX 2 Low Temperature Sterilization System. The cycle was designed for sterilization of patient-specific surgical guides (e.g. osteotomy, shoulder, hip, knee, spine) or anatomical models fabricated via additive manufacturing (3D printing) processes and intended for single-use during operative procedures.

In the U.S. the 1295PCD is currently not U.S. FDA cleared for use in this new cycle. Solventum will welcome the invitation to validate the 1295PCD at customer facilities using a STERIS V-PRO® maX 2 Low Temperature Sterilization System installed with the new Specialty Cycle.

Outside the U.S. (OUS) the 1295PCD can be used as a standard method of routine monitoring and performance qualification (operational and performance) and for process validation of vaporized hydrogen peroxide sterilization processes. Solventum would recommend performing an evaluation on the performance of the 1295PCD in the Specialty Cycle on the STERIS V-PRO® maX 2 Low Temperature Sterilization System before routine use of the 1295PCD in this new cycle type. Solventum would also recommend a discussion amongst the regional Solventum product team and the user to understand the risks and benefits of using the 1295PCD in this new cycle.

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3M Health Care is now Solventum