STERILIZATION

Review

Process challenge devices in medical device sterilization – the standards and guidelines explained

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Summary

Process challenge devices (PCDs) are used to design, validate, and routinely test medical device sterilization processes. They are also used in the qualification of sterilizers. PCDs are used in both medical device manufacturing settings as well as in health care facilities. The design of a process challenge device will depend on the mode of sterilization that it is intended to test (e.g., steam, vaporized hydrogen peroxide, ethylene oxide) and may also depend on the specific cycle to be tested or the load items to be sterilized.

Recommendations and requirements regarding process challenge devices are provided in a number of national and international sterilization standards and guidelines. However, there has been confusion, especially in health care facilities, about the PCD information contained in these standards, especially differentiating requirements related to PCD performance versus requirements related to the use and application of PCDs.

This paper will review the process challenge device information provided in these documents, summarizing and comparing actual performance requirements for PCDs to requirements related to the use of PCDs.

Keywords

- process challenge device
- sterilization
- standards
- guidelines

Introduction to process challenge devices

Process challenge devices have a formal definition in international standards. A PCD is an "item providing a defined resistance to a cleaning, disinfection, or sterilization process and used to assess performance of the process".[1] Process challenge devices contain an indicator or sensor that provides information about the quality of the sterilization process. The most common indicators found in PCDs are biological indicators or chemical indicators (and occasionally both), although some specialized PCDs may contain an electronic sensor such as a thermocouple. The PCD itself is intended to create a physical barrier that restricts the access of the sterilization process to the indicator during routine processing. It is intended to mimic the effect of placement of the indicator inside one of the sterilization load's packages or medical devices, where the load and packaging would also restrict access of the sterilization process to the indicator. The PCD is easily retrieved from the sterilizer after the cycle is completed, and the indicator can be removed and evaluated without compromising any of the load contents.

Process challenge device designs will vary but all will have two main elements – the indicator and a barrier system. The biological or chemical indicators should be appropriate for testing the specific sterilization process that will be monitored. The PCD's barrier design can have a wide range of acceptable forms and will depend on the type of process to be monitored and the level of challenge to the process that is required. Barrier designs fall into two main categories. The first type are barriers that require the sterilant to penetrate a material or layers of material before reaching the indicator. For example, layers of surgical towels or paperboard material are a common design used for PCDs that are used to monitor steam sterilization processes (see Figure 1). The second type are barriers that require the sterilant to pass through a narrow channel or lumen before reaching the indicator (see Figure 2). The overall challenge of the PCD will depend on the sterilization process and the level of challenge required. In the first type, the level of challenge to a given sterilization

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process is determined by the material properties of the barrier material, the cross-sectional area of each layer, and the total thickness or number of layers. In the second type, the resistance is determined by the dimensions of the opening and length of the lumen and may also depend on the material composition of the lumen (e.g., metal vs flexible plastic lumens for VH2O2) .

PCDs are sometimes used in sterilization process development and validation. They are also sometimes used for sterilizer qualification or re-qualification. However, they are more commonly placed inside the sterilizer with the medical device load and used as part of the load release decision process.

Specialized PCDs called reference PCDs are designed to provide a reference or standardized challenge to a sterilization process but are often not designed for everyday use. Reference PCDs can be assembled from the design information provided in a standard but are not user friendly or cost-effective and are typically not used on a routine basis in sterilization processing. Reference PCDs can be used as the baseline for comparative laboratory testing in the development of commercial PCDs that are designed to be economical and practical for everyday use. The most well-known reference PCD is the AAMI 16 towel challenge pack [2], for large steam sterilizers.

Bowie-Dick test packs are specialized process challenge devices for testing the air removal system of pre-vacuum steam sterilizers. They operate under the same general principle as load PCDs, but they have specialized requirements in the standards. They are used only with special test cycles, only in empty chambers, and only to evaluate the air removal or steam penetration process. Bowie-Dick test packs are out of the scope of this paper. This paper will focus on PCDs used to assess the quality of sterilization cycles containing medical device loads.

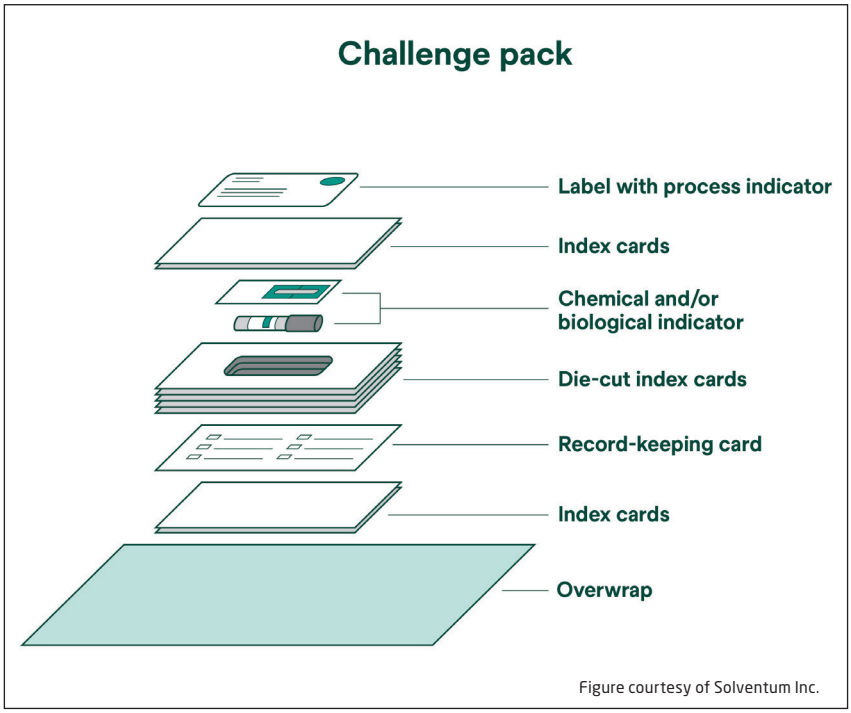

Fig. 1: Multi-layer barrier

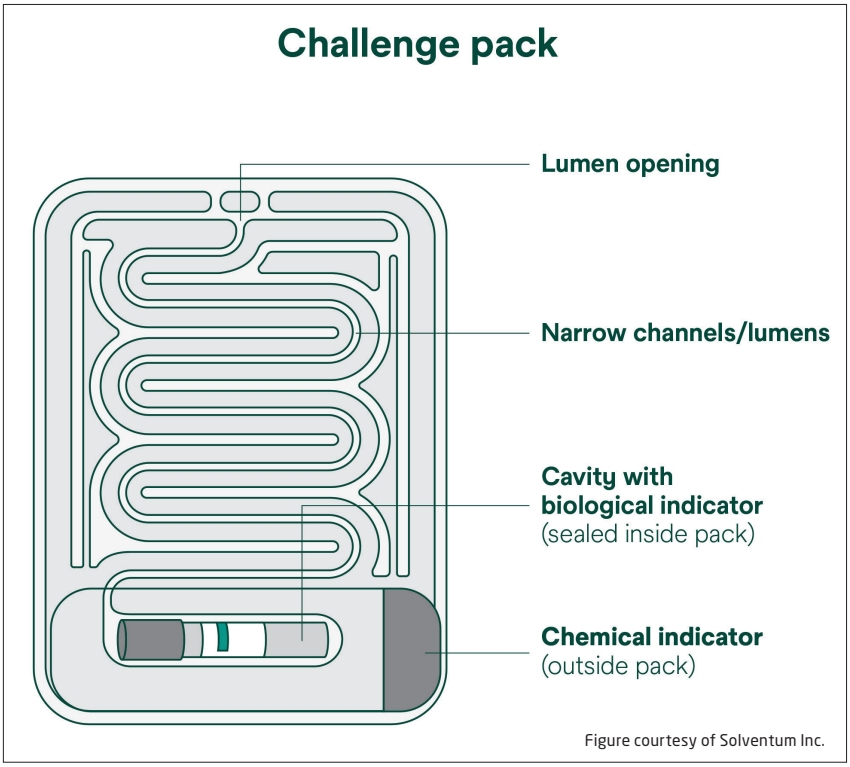

Fig. 2: Lumen barrier

Introduction to standards and guidelines

Standards and guidelines provide recommendations and requirements that address the processes, supplies, equipment, and procedures used in medical device sterilization in manufacturing and healthcare settings. They help establish and maintain the high levels of quality and consistency that are critical for patient safety. Sterilization consensus standards are written and published by standards setting organizations through committees comprised of experts representing manufacturers, regulators, and end users that follow a process of discussion and consensus agreement within the committee. Industry guidelines are written by experts working within a guideline organization, and draft guidelines are generally made available for public comment before publication. Specific standards or guidelines may apply to a single country or may be international (regional or

Table 1: PCD Performance Requirements

Standard Number	Standard Title	Category of Standard	Geographical Application	Key Points
EN 285 [3]	Steam sterilizers – Large sterilizers	Equipment and Supplies	Regional (Europe)	Specifies requirements for large steam sterilizers ≥60L. References hollow load test for empty chamber equipment qualification, not routine PCD load monitoring[a]
EN 13060 [4]	Small steam sterilizers	Equipment and Supplies	Regional (Europe)	Applies only to small steam sterilizers <60L. Describes reference PCDs for empty chamber operational qualification, not routine load monitoring[b]
ISO 11140-6 [5]	Chemical indicators – Type 2 indicators for use in PCDs	Equipment and Supplies	International	Defines reference PCDs (e.g., porous and lumen barriers) to test small steam sterilizers <60L[c]
ISO 17665 [6]	Moist heat sterilization – Process development and validation	Sterilization Process Standard	International	For development and validation of steam sterilization processes. Requires validation of PCD design and use when applied. States there are no international standards for design or requirements for PCDs[d]
ISO 22441 [7]	Vaporized hydrogen peroxide sterilization – Development and validation	Sterilization Process Standard	International	For development and validation of vaporized hydrogen peroxide processes. States PCDs shall simulate worst-case sterilization conditions. Use must be validated; no design specifications are provided[e]
AAMI TIR 31 [8]	Technical Information Report: Design and use of PCDs	Informative document	National (U.S.)	Informative report only. Describes reference PCDs per sterilization method. No test methods or required performance criteria are defined[f]

Notes:

a. The standard references a hollow load test, and this test is sometimes confused with routine monitoring with a PCD. The hollow load test device is placed in an empty chamber and used to test the air removal and steam penetration capabilities of the sterilizer. Thus, this test is more closely related to the Bowie-Dick test and is not related to the use of a PCD in routine efficacy monitoring for medical device sterilization.

b. Section 8 of EN13060 describes test equipment and reference challenge devices to be used for qualifying small steam sterilizers, including representation of narrow lumens and simple hollow items. However, the test equipment described in this section is intended for use in the operational qualification (OQ) of the small steam sterilizer. Also, OQ testing is typically done in an empty chamber, so the PCDs described here are not intended for routine use with fully loaded sterilizers.

c. ISO 11140-6 addresses both barrier types – a stacked sheet barrier (called a reference porous barrier) and a lumen barrier (called a reference hollow barrier).

d. ISO 17665 Clause 8.10 states that "if a PCD is to be used to assess the efficacy of the specified characteristics of a sterilization process, the validity of the PCD, test methodology(ies) and acceptance criteria shall be established and documented."

e. ISO 22441 clause 8.8 states that: "PCDs shall present a challenge to the specified characteristics of the sterilization process that is equivalent to or greater than that at the position in product where it has been determined that sterilizing conditions are most difficult to achieve. The demonstration of the appropriateness of a PCD may be performed through comparative resistance studies utilizing tests of sterility in accordance with ISO 11737-2."

f. Reference PCDs designs described in AAMI TIR 31are most commonly used for comparative testing and are not designed to be user friendly or cost-effective.

global). Some standards are intended for use in health care facilities, others are intended for medical device manufacturers, and some may be applicable to both. Guidelines are typically intended for healthcare facilities.

Sterilization standards and guidelines can be grouped into three categories:

Standards for sterilization equipment and supplies

These standards are typically used by manufacturers of sterilization-related equipment (e.g., sterilizers) and supplies (e.g., packaging products, biological indicators, chemical indicators). These standards are international and are often adopted as national standards by a country's national standards setting organization. These standards will specify performance (often with test methods) and labeling requirements for the subject products. Standards preferably do not specify materials or product designs, as this would restrict innovation and commerce.

Sterilization process standards

These international standards provide the requirements for developing sterilization processes, including defining both the product to be sterilized and the process itself. They also provide the requirements for validating the sterilization process, and for routine monitoring and control of that process to enable the release of goods. These standards typically apply to a medical device manufacturing environment where sophisticated measuring equipment will be used to complete detailed process definition and process validation work and thus are primarily used by medical device manufacturers to produce sterile medical device products. However, elements of these standards are referenced by some health care facilities in a few countries in the world. This category of standards covers all the common industrial sterilization processes, including moist heat, vaporized hydrogen peroxide, ethylene oxide, radiation, and dry heat. These international standards can be often adopted by national standards organizations to become the national standard for that country.

Guidelines and recommended practice standards for sterilization

These documents are typically country specific and provide recommendations on sterilization related activities and procedures for health care facilities. The scope of these documents generally covers all aspects of a particular sterilization process in the health care facility, including transport of instruments, cleaning, packaging, sterilization, storage, and quality control.

Process challenge devices in standards and guidelines

Conformance to standards

The information provided in standards and guidelines is utilized by medical device manufacturers and health care facilities to improve the quality and consistency of medical device products and the delivery of related health care processes. Conformance to the requirements and recommendations provided in standards and guidelines is generally voluntary and will be driven by organizational philosophy or financial considerations such as reimbursements or commercial interests. If local regulators or legislative bodies elevate a standard to a legal or regulatory requirement, then compliance with that standard may be mandatory. In some circumstances conformance to a standard may be verified by a third party, but often conformance is self-determined by the manufacturer.

A product such as a PCD may conform to a standard by meeting the specific performance requirements provided in the standard. Establishing this conformance will generally require testing the PCD against the performance specifications provided in the standard, using test methods provided or referenced in the standard. Standards will not provide product specific design requirements because this would be considered restrictive and would limit product innovation. However, design requirements for reference PCDs may be provided, as the reference PCD is most often used for comparative lab testing so design information is needed to correctly assemble the reference PCD for testing.

Conformance to standards for sterilization equipment and supplies can be evaluated because these standards generally provide performance requirements and test methods. This type of conformance is generally not possible with process standards or sterilization guidelines as these documents provide more general process-related requirements and typically do not provide specific product performance requirements. However, a process standard or guideline may provide recommendations or requirements regarding the use of a product such as a PCD. In this case, the health care facility could conform to the standard by using the PCD in the manner and frequency prescribed in the standard or guideline.

The following sections will examine how PCDs are addressed in standards. Part I will review standards with PCD product performance related requirements, and Part II will examine recommendations for the use of PCDs.

Part I: Process challenge device performance requirements in standards and guidelines

Table 1 provides a high-level summary of information related to PCD performance requirements prescribed in key sterilization standards. The standards selected represent national, regional, and international standards that are commonly referenced in the sterilization industry. The key points were selected to summarize the information related to PCD performance requirements in each document.

Summary – Performance requirements for PCDs

Performance requirements with appropriate test methods for PCDs are not provided in sterilization standards. The exception is the PCD related information in EN 13060 and ISO 11140-6, however, this information is specific to small steam sterilizers and does not relate to PCDs used to release sterile medical device loads (e.g. routine load monitoring) from standard large health care sterilizers. So, statements of conformance to these standards for specific PCDs for large sterilizers will not be possible as the standards do not provide performance requirements with test methods.

Part II: Recommended use of process challenge devices in standards and guidelines

PCDs containing biological and/or chemical indicators are often used to monitor healthcare sterilizer loads and play a role in both qualification and requalification of sterilization equipment. Table 2 provides a high-level summary of the recommended use of PCDs provided by a selection of national and international standards and guidelines. Again, the standards and guidelines

Table 2: Recommended Use of PCDs

Standard Number	Standard Title	Category of Standard	Geographical Application	Key Reference/Points
ISO 11138-7 [9]	Sterilization of health care products – Biological indicators – Part 7: Guidance for the selection, use and interpretation of results	Equipment and Supplies	International	Offers general information on using BIs in PCDs for routine monitoring and validation. Emphasizes proper placement and correlation with validation locations[a]
ISO 17665 [6]	Sterilization of health care products – Moist heat – Requirements for the development, validation, and routine control of a sterilization process for medical devices	Process	International	Describes use of PCDs in monitoring and validation. Annex F provides interpretation and guidance on how the standard's requirements apply to health care facilities[b]
AAMI TIR 31 [8]	Technical Information Report: Guidance on selection and use of PCDs	Guidelines and Recommended Practice	United States (National)	Provides comprehensive guidance for selecting and using PCDs across multiple sterilization modalities. Focuses on assisting healthcare personnel in evaluating PCD suitability.
AAMI ST79 [2]	Comprehensive guide to steam sterilization and sterility assurance in health care facilities	Guidelines and Recommended Practice	United States (National)	Recommends specific placement and frequency of use for PCDs in steam sterilization. Identifies "cold point" placement in the chamber and provides recommended testing frequency[c]
AAMI ST58 [10]	Chemical sterilization and high-level disinfection in health care facilities	Guidelines and Recommended Practice	United States (National)	Provides placement and frequency guidance for PCDs in vaporized hydrogen peroxide sterilization. Includes requirements for implant loads and BI orientation[d]
APSIC Guideline [11]	APSIC Guidelines for Disinfection and Sterilization of Instruments in Health Care Facilities	Guidelines and Recommended Practice	International (Asia Pacific)	Recommends PCD placement at the cold point and outlines required indicators (BI + Type 5 CI) for implant loads.[e]
CSA Z314:23 [12]	Canadian standard for medical device reprocessing	Guidelines and Recommended Practice	Canada (National)	Requires validated PCDs for each cycle type and outlines routine BI testing procedures based on manufacturer's IFUs.

Notes:

a. ISO 11138-7 clause 9.2.1 states that "During routine monitoring, it could be desirable to place the biological indicators in more accessible locations using a PCD. (see 9.3). In these situations, the placement of the biological indicators should be correlated with the locations employed during cycle development or validation to ensure that the integrity of the sterilization process is not compromised… ". Clause 9.3.1 goes on to state that "A PCD in combination with biological indicators can be used both for validation and routine monitoring of sterilization cycles. PCDs are designed so that the placement of the biological indicator within the PCD constitutes a location that is deemed to represent a suitably stringent challenge to the process."

b. ISO 17665 Clause 10.1 states: "Delivery of an effective sterilization process shall be verified by confirming that recorded data from routine monitoring are within specified tolerances measured by physical sensors together with the results from chemical indicators and/or biological indicators and/or PCDs, if used."

c. AAMI ST79 Clause 13.6.1 states: "Every sterilization load may be monitored with a PCD containing a) a BI; b) a BI and a Type 5 CI (integrating indicator); c) a BI and a Type 6 CI (emulating indicator); d) a Type 5 CI (integrating indicator); or e) a Type 6 CI (emulating indicator). A BI PCD should be used at least weekly and preferably daily."

d. AAMI ST58 Clause 8.6.5.3 states (frequency of use): "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 … Additionally, BIs within PCDs or an FDA-cleared BI-containing quality monitoring device should be used to monitor every load containing implants that have been cleared for low temperature sterilization".

e. APSIC Guideline Clause 4 states: "The PCD should be placed in the area representing the greatest challenge, normally the identified cold point in the chamber. The sterilizer manufacturer should advise on the cold point. This does vary but is normally in the front near the door and bottom section of the chamber near the drain. The commercially prepared PCD should be positioned as guided by the PCD manufacturer's instructions for use." Routine monitoring section: "For loads containing an implant, a PCD containing a biological indicator and a Type 5 chemical indicator must be included in each load."

selected represent national, regional, and international standards that are commonly referenced in the sterilization industry, and the key points were selected to summarize the information related to recommended use of PCDs in each document.

Summary - Recommended Use of PCDs

Several international, regional, and national standards and guidelines provide specific recommendations on the use of process challenge devices. These include guidance on placement in the sterilizer chamber and the frequency of use (e.g., daily, weekly, or per load), and the use of appropriate indicators within the PCD (e.g., BI, CI, or both). Adherence to these recommendations is essential for claims of standard conformance in healthcare sterilization practices.

Discussion

The intention of this paper is to provide an overview of PCD related information in different types of standards, but not to give an assessment of the reliability or suitability of PCDs for any application including process validation and routine sterilization control. Assessment of suitability of a specific PCD for a specific application would best be accomplished by practical studies accomplished by validation studies conducted either by the manufacturer of commercially available PCDs or by the user.

Process challenge devices play a key role in medical device sterilization. They provide a defined challenge to the sterilization process and contain sensors that respond to the sterilization process variables. The sensors (electronic, biological, chemical) provide valuable information about the quality of the process.

Process challenge devices are used in different applications. Specialized Bowie-Dick PCDs are used to test air removal and steam penetration in pre-vacuum steam sterilizers. PCDs are also used in medical device manufacturing settings to help develop and validate sterilization processes and may also be used for routine load release. In healthcare, PCDs may be used to qualify or requalify sterilizers, but are primarily used for routine load release.

Process challenge devices are discussed in many national and international sterilization related standards and guidelines. Standards do not specify PCD performance requirements with accompanying test methods to evaluate conformance with the requirement. (The one exception – ISO 11140-6, is only applicable to small steam sterilizers). There are standards that specify performance requirements and test methods for the biological or chemical indicators used inside a PCD, so conformance claims can be made for the sensors used in a PCD. But PCDs themselves, and particularly those used to assess sterilization cycles containing medical device loads, will not conform with a standard.

PCDs, however, can facilitate a user's conformance with a standard. Standards and guidelines do provide recommendations and requirements related to placement of PCDs in the chamber as well as the frequency of use of PCDs. Standards conformance for these aspects are the responsibility of the facility. In this case, the use of PCDs can facilitate conformance to these standards.

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