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COLLEGE OF PHYSICIANS & SURGEONS OF ALBERTA

Making Process Challenge Devices that Contain Biological Indicators or "BI Test Packs"

IPAC Program Guidance

Infection Prevention and Control (IPAC) Program
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Introduction

Adequately challenging a biological indicator during sterilization is an important step in ensuring reusable medical devices are sterile. The College of Physicians & Surgeons of Alberta (CPSA)'s Reusable & Single-Use Medical Device Requirements for Medical Clinics requires that a process challenge device containing a biological indicator is used as part of daily biological monitoring (Section 8.10.4) and during operational qualification and requalification (Section 8.4).

CPSA's Infection Prevention and Control (IPAC) Program has identified that physicians and clinic staff could benefit from additional information about how to properly build these process challenge devices.

Purpose

This guidance is intended to assist physicians and medical clinic staff in understanding how to build and use process challenge devices containing biological indicators to confirm the effective operation of table-top steam sterilizers.

For assistance or more information, contact the CPSA IPAC Program at ipac@cpsa.ab.ca or 780-969-5001.

Purpose of a process challenge device

The purpose of a process challenge device (PCD) is to provide measurable resistance to the sterilization process. Successfully passing this "challenge" helps confirm that the table-top steam sterilizer has met critical parameters for effective operation in clinic settings.

What does CPSA require?

CPSA requires that a PCD containing a biological indicator (BI) be used as part of daily biological monitoring and during operational qualification and requalification.

What's in a name?

There are many names for a PCD containing a biological indicator. They may also be known as a biological indicator process challenge device (BI PCD) or a "BI test pack."

Building your BI test pack

BI test packs are easy to make within your clinic. The test pack should be assembled the same way you routinely assemble your medical instrument packs for sterilization. The test pack should also include a biological indicator (BI) and a chemical indicator (CI). If the packages are released for use based on monitoring physical parameters and CI results, the internal CI must be a Type 5 or 6. Your test pack will be placed inside the sterilizer's chamber and evaluated after the sterilization process has been completed. To be effective, the test pack's "challenge" must be equal to, or greater than, the challenge posed by your most difficult-to-sterilize (e.g., bulkiest, largest) set. The instrument(s) chosen for your BI test pack will vary depending on the instruments and sets typically used at the clinic.

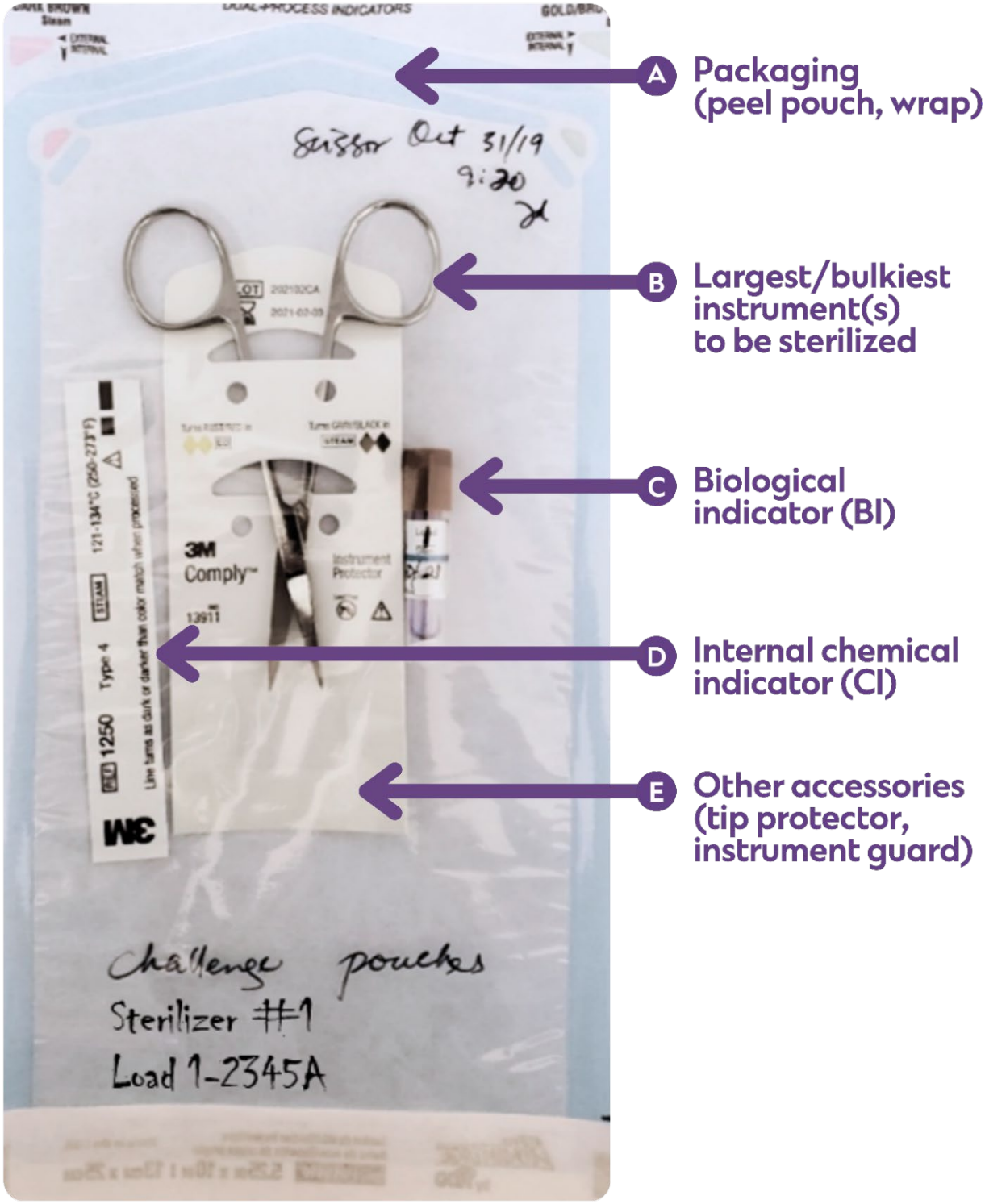
BI test pack components

A test pack is composed of:

A. The same packaging (e.g., peel pouch, wrap) that you routinely sterilize
B. Your largest/bulkiest instrument(s) that are routinely sterilized
C. A biological indicator
D. An internal chemical indicator
E. Other accessories typically used, like tip protectors or instrument guards

Example of a BI test pack

Your test pack may look slightly different from the example, depending on the packaging and instruments you use in your clinic.



Utilizing your BI test pack

1. Seal the components into the BI test pack.
2. Place the test pack in the coldest area of the sterilizer chamber, typically near the drain. Refer to the sterilizer's Manufacturer's Instructions for Use (MIFU) for proper placement. The sterilizer chamber should also be loaded with other packaged instruments (not empty). This will present the necessary sterilization challenge to the BI test pack.
3. Run the applicable sterilization cycle.
4. After the sterilization cycle is complete, retrieve the test pack first. Check that the internal and external chemical indicators have successfully passed (i.e., colour change).
5. Open the test pack and activate/incubate the BI.

Reading test results

After the necessary incubation period, if the BI from the BI test pack shows a "no growth" result, then record the test as "successful." If the BI from the test pack shows growth, then record the test as "unsuccessful" and initiate recall procedures.

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References and resources

1. CPSA guidance for clinics: Qualification of Table-Top Steam Sterilizers
2. CPSA requirements for clinics: Reusable and Single-Use Medical Device Requirements for Medical Clinics
3. Quality Control of Table-top Steam Sterilizers Update. Martha Young. January 2010. https://multimedia.3m.com/mws/media/635341O/quality-control-of-table-top-steam-sterilizers-mic-jan10.pdf
4. Downloadable BI test pack example