User Alert

Problems with process monitors for extended steam sterilization cycles

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Introduction:

Some manufacturers of medical devices are providing instructions for new medical devices that require steam sterilization cycle times that are outside the currently utilized healthcare steam sterilization cycles. This is being done for two basic reasons:

1) The device was manufactured in a European country where vCJD (prion) inactivation is a concern. Many of the medical device manufacturers are recommending cycles in pre-vac steam sterilization at 134^{o} C for 18 minutes. This reflects the current WHO recommendations for steam sterilization that is most effective in inactivation of prion agents.

2) Orthopedic or other medical device manufacturers are recommending prolonged pre-vac steam sterilization cycles of 8, 10 or 20 minutes or longer. These recommendations are based on the manufacturer's testing that has demonstrated that the packaged device load (eg orthopedic case trays) or medical devices has poor steam penetration or heating characteristics. In order to ensure sterilization of the device, longer cycle times are needed.

Despite the requirement by the medical device manufacturer for longer cycles, there has not been the concurrent development of the appropriate CI's and BI challenge packs to adequately monitor these extended steam sterilization cycles. Examples of medical devices requiring extended steam sterilization times are given in Table 1. A primary objective of this article is to ensure that users are aware of this problem and furthermore that they are made aware that use of existing CI and BI challenge packs that are designed for shorter steam cycles (eg 3, 4 minute pre-vac at 132^{o}C – 135^{o}C) should not be used to monitor cycles that are longer as the BIs and CIs may not provide an adequate challenge as they were not designed to monitor such extended cycles. This lack of appropriately qualified challenge packs presents a potentially significant patient risk, especially if some of the devices are implantable and the facility cannot be assured that the packaged medical device reached conditions adequate to provide reliable assurance of sterility. It should be noted that there are CIs that have been validated for 18 minute pre-vac cycles.

Background:

Steam sterilization of reprocessed medical devices is an established practice that is performed in almost all health care facilities. Normally, the medical device manufacturer is expected to provide the user with instructions regarding the appropriate steam sterilization cycle that can be used to sterilize the device safely. In order to obtain approval from the Medical Devices Division of Health Canada (or clearance from the FDA in the USA), these instructions must be provided before the company offers to sell these devices in Canada unless the device is deemed equivalent to an existing marketed medical device (some of these pre-date the requirement for manufacturer's to provide validated steam sterilization cycles).

The CI's and BI's and the CI and BI challenge packs used in healthcare reprocessing facilities are designed, tested and qualified for use as process monitors with specific steam sterilization cycles such as those illustrated in Table 2. For instance, a BI qualified for use in a gravity displacement sterilizer at 121^{o}C for 30 minutes should not be used in a pre-vacuum steam sterilizer cycle at 134^{o}C for 4 minutes unless the BI manufacturer has validated its use and provides label claims for that cycle. There are a

finite set of steam cycles that are routinely used in healthcare facilities. Indeed the sterilizers are validated by the sterilizer manufacturer to provide adequate steam sterilization conditions for these specific cycles and users do not usually alter these once the sterilizer has been installed. Examples of these cycles are given in Table 2 (AAMI). The users should follow the medical device manufacturer's recommendations, as well as the instructions of the sterilizer manufacturer, for sterilization to ensure the device is safe to use on the next patient. However, the problem is that the medical device manufacturer's recommendations may call for extended cycle times that are not normally used in health care.

Example of the Problem:

A set of orthopedic instruments was received by a site approximately 2 years ago with instructions from the manufacturer that indicated the five-layer set should be steam sterilized at 132^{o}C for 40 minutes. The central processing department followed these guidelines and placed 15 BIs in the set. They used 3 BIs per layer, with a BI positioned in the right, left and middle, for each of the five layers. Of the 15 BIs tested, there were 3 BI failures. One of three BIs in each of the three middle trays failed. When the five layer set was broken down into single layers and re-tested, all BIs passed. Subsequently the site has converted their steam sterilizers to 134^{o}C. Retesting of the single layers at this temperature indicated that all BIs passed. The manufacturer still recommends 132^{o}C for 40 minutes.

One might ask "How can a device be sold/marketed in Canada if no process monitors exist for the cycles recommended?" One of the problems is that these devices may not have even been reviewed by Health Canada. Some of the orthopedic instrument sets are provided free of charge by the implantable device manufacturer. The surgical equipment used to do the surgery for the implant is provided as an "accessory" to the implantable device and therefore is not reviewed by Health Canada because it is not sold, it is provided free.

In other instances, the prolonged cycle requirements may be overlooked as the device by the implant manufacturer is claimed to be equivalent to a device already being sold in Canada, so it is approved because the reviewers may not realize that the new device has different sterilization cycle requirements that are not standard hospital cycles.

What Should a User Do?

1) **Prior to the purchase/trial of any new equipment** users should require from the medical device manufacturer detailed information on the cleaning procedures and steam sterilization cycles appropriate for use with the device. If the cycle recommended is an 18 minute pre-vac cycle, the manufacturer should be asked to provide a statement in writing regarding whether or not a pre-vac 4 minute cycle is adequate. If the manufacturer indicates that a pre-vac 4 minute cycle is not adequate and extended processing is necessary, the user should request information from the manufacturer as to the means whereby the extended processing cycle should be monitored in order to ensure that effective sterilization of the device is assured. ***This process should be implemented for all medical devices, regardless of whether the device is purchased, leased or loaned.***

2) **For existing sets:** In the absence of appropriate BI and CI challenge packs that have been validated for use with these prolonged sterilization cycles, users can do some limited testing to ensure that steam penetration is achieved by placing regular BI's in various locations inside the case set (Fig. 1). This is done before the case tray set is used for the first time. Once the case set has been wrapped and sterilized in the appropriate prolonged steam sterilization cycle, the BI's

are removed (and incubated as appropriate for that type of BI) and the tray is reprocessed. If any BI's fail (exhibit growth of the test organism), this means there is a high probability of inadequate steam penetration or poor heating since these BI's should be completely killed within 3-4 minutes of exposure. If possible, breaking down the tray to smaller tray sets and then retesting can be done. If this is not possible or if BI failure still occurs then this would warrant immediate removal of this device from use and an incident report to both the device manufacturer and Health Canada.

Even if the regular paper strip or self-contained ampule BI's are killed, this may not be a valid indication that the device has been adequately sterilized. Most BI's are typically inactivated within 3-4 minutes of steam exposure at 132^{o}C – 135^{o}C (indeed in most pre-vac sterilizers, the spores are killed within the first 1-2 minutes of exposure). What is needed is a challenge pack that provides a challenge to the sterilization process equivalent to that presented by the actual device or load. This could be provided either by the BI manufacturer or the manufacturer of the device.

For a rigid container system designed to be sterilized without wrapping, place a BI suspended from a lower corner and the upper corner diagonally opposite as well as the under side of the lid away from the filters. For rigid sterilization container designed to be wrapped, place BIs in the same locations indicated above. Testing should include placement of BIs in each layer in the set.

Once the cycle has been completed, the tray/container should be dismantled and the BI's tested. The loaded tray is serving as the test pack. Although user testing can be done for surgical sets, it is not possible to do this for individual devices where steam penetration is questionable (eg orthopedic devices or electrical equipment).

Prion Cycle Monitors:

Users need to be aware that manufacturers may claim their indicators can be used for "prion cycles" but users need to be cautious. Questions users should ask include:

1) Has the device received clearance from either the FDA or Health Canada for extended cycles? If so, ask for a copy to verify claim.

2) What cycle parameter does the CI or BI monitor and what label claims does it have?

Conclusion:

Users need to ensure that the medical device manufacturer's instructions are followed for extended cycle times unless the manufacturer provides written documentation that the device can be properly sterilized for 4 minutes at 132^{o}C - 134^{o}C or 3 minutes at 135^{o}C. This will occur most frequently for the 18 minute prion cycle for medical devices manufactured in Europe. If no appropriate BI or challenge pack exists for the extended cycle, users need to require the device manufacturers to provide advice as to the appropriate BI or challenge pack to use or perform testing themselves to ensure adequate sterilization conditions are realized.

References:

1. Association for the Advancement of Medical Instrumentation. AAMI DS2/ST79/2005-02-07. Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities (Draft 2005).
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Source:

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Table 1. Examples of Medical devices where the manufacturer recommends extended steam sterilization cycle times.

Device Name	Manufacturer	Cycle time recommended by manufacturer	Alternative cycle times also approved by manufacturer
Acetabular reamer system	Zimmer	18 mins PreVac at 132°C	4 mins PreVac at 134°C If Gripper handle made by Precimed is in set, the 18 min at 132°C is needed
Orthopedic set	Dupuy Moreland Revision Instruments	132°C for 40 mins	None
OsteoMed Osteopower system	OsteoMed	5 minutes in PreVac at 132°C, 0 minutes dry minimum wrapped	15 minutes PreVac at 135°C, 25 minute dry time
Trigen Nail System Tray 1 and 2	Smith & Nephew	4 minute in PreVac at 132°C, 15 minute dry time	18 minutes PreVac at 135°C, 25 minute dry time

Note: This table provides a few examples and is by no means exhaustive.

Table 2. Minimum cycle times for gravity-displacement and dynamic air-removal steam sterilization cycles*

	Gravity Displacement steam sterilizer			Dynamic Air-removal steam sterilizer (e.g. Pre-vacuum steam sterilizer)	
Item	**Exposure time at 250°F (121°C)**	**Exposure time at 270°F (132°C)**	**Exposure time at 275°F (135°C)**	**Exposure time at 270°F (132°C)**	**Exposure time at 275°F (135°C)**
Wrapped instruments	30 minutes	15 minutes		4 minutes	
			10 minutes		3 minutes
Textile packs	30 minutes	25 minutes		4 minutes	
			10 minutes		3 minutes
Wrapped utensils	30 minutes	15 minutes		4 minutes	
			10 minutes		3 minutes
Unwrapped nonporous items (eg instruments)		3 minutes	3 minutes	3 minutes	3 minutes
Unwrapped nonporous and porous items in mixed load		10 minutes	10 minutes	4 minutes	3 minutes

*This table represents the variation in sterilizer manufacturers' recommendations for exposure at different temperatures. For a specific sterilizer, consult only that manufacturer's recommendations. Dry times have not been indicated as this varies substantially depending upon the sterilizer manufacturer, season and/or other site specific issues.
Note: Extracted from AAMI DS2/ST79/2005-02-07.

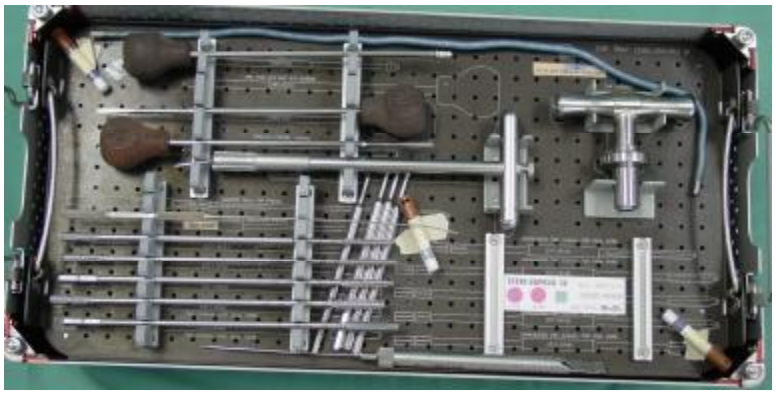
Figure 1. Placement of BI's within containers to evaluate steam and heat penetration

For wrapped containers (A), three BI's were included per layer; one in each opposing corner and one in the middle of the tray (eg for 3 layers, this would involve 9 BI's in total). For unwrapped containers (B), the same positioning of BI's would be used and, in addition, BI's should be placed on the underside of the lid away from the filter.

A) Wrapped container

Bottom Layer

Middle Layer

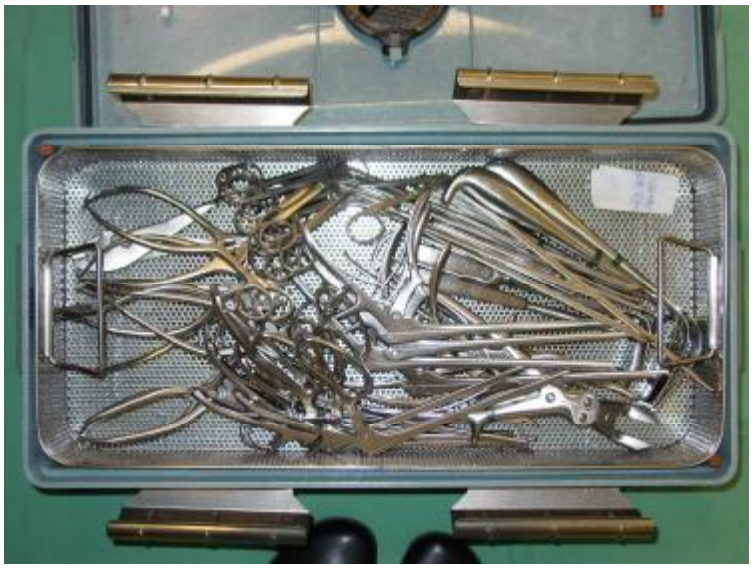


Top Layer

Final Wrapped Package of three layers

B) Unwrapped container

Container shell



Tray with instruments

Fully assembled spine tray pan