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User Alert

Problems with process monitors for extended steam sterilization cycles

ABSTRACT

Steam sterilization is the backbone of medical device reprocessing in healthcare facilities. Steam sterilization cycle parameters have been validated by the manufacturer to provide appropriate sterility assurance for medical device sterilization. There are only a small number of validated time and temperature settings for these cycles and these are rarely changed. Recently there has been a trend towards medical device manufacturers recommending prolonged steam sterilization cycles for medical devices that are beyond the routine cycle parameters available to healthcare facilities. In some instances the facility ignores these recommendations and processes the medical devices in their routine steam sterilization cycles. In other instances the facility adjusts their steam sterilizer to match the device manufacturer's recommendations, but they use the chemical indicators and biological indicator challenge packs that are used for the routine steam sterilization cycles. The objective of this manuscript is to demonstrate that if the device manufacturer's recommended cycles are not followed there may be inadequate steam penetration. Such failures indicate that the sterility assurance level has not been attained for devices processed in the load. Furthermore, the manuscript outlines actions that users can take in the absence of appropriate biological process challenge devices for extended steam sterilization cycles.

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 there are concerns regarding inactivation of variant Creutzfeld-Jakob disease (vCJD) which is a prion. Many of the medical device manufacturers are recommending cycles in pre-vac steam sterilization at 134°C for 18 minutes. This reflects the current World Health Organization (WHO) recommendations for steam sterilization that is most effective for 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 the packaged device load (e.g. orthopedic case tray set) or the medical device 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 chemical indicator (CI) and biological indicator (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 manuscript is to ensure that users are made aware that use of existing CI and BI challenge packs that are designed for shorter steam cycles (e.g. 3 or 4 minutes in pre-vacuum steam sterilizers at 132°C to 135°C) should not be used to monitor cycles that are longer. The BIs and CIs designed for 3- to 4-minute cycles may not provide an adequate challenge when longer cycle times are used, as they were not

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 minutes PreVac at 132°C	4 minutes PreVac at 134°C If Gripper handle made by Precimed is in set, then 18 minutes at 132°C is needed
Orthopedic set	Dupuy Moreland Revision Instruments	132°C for 40 minutes	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 minutes 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.

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 most acute-care 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 Food and Drug Administration (FDA) in the USA), these instructions must be provided before the company offers

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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 manufacturers to provide validated steam sterilization cycles).

The CIs and BIs 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°C for 30 minutes *should not* be used in a pre-vacuum steam sterilizer cycle at 134°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. 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 two years ago with instructions from the manufacturer that indicated the five-layer set should be steam sterilized at 132°C for 40 minutes. The central processing department followed these guidelines and placed 15 BIs in the set. They used three 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 three 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°C. Retesting of the single layers at this temperature indicated that all BIs passed. The manufacturer still recommends 132°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 even have 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.

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

Item	Gravity Displacement steam sterilizer			Dynamic Air-removal steam sterilizer (e.g. Pre-vacuum steam sterilizer)	
	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 (e.g. 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.

WHAT SHOULD A USER DO?

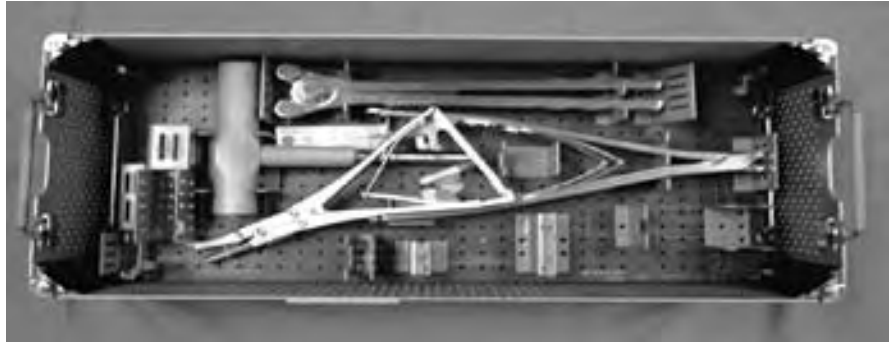
1) **Prior to the purchase/trial of any new equipment** users should require from the medical device manufacturer detailed information on the cleaning procedures and steam sterilization cycles appropriate for use with the device. If the cycle recommended is an 18-minute pre-vac cycle, the manufacturer should be asked to provide a statement in writing regarding whether or not a pre-vac four-minute cycle is adequate. If the manufacturer indicates that a pre-vac four-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 BIs 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 BIs are removed (and incubated as appropriate for that type of BI) and the tray is reprocessed. If any BIs fail (exhibit growth of the test organism), this means there is a high probability of inadequate steam penetration or poor heating since these BIs should be completely killed within 3-4 minutes of exposure. If possible, breaking down the tray to smaller tray sets and

Figure 1: Placement of BIs within containers to evaluate steam and heat penetration

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

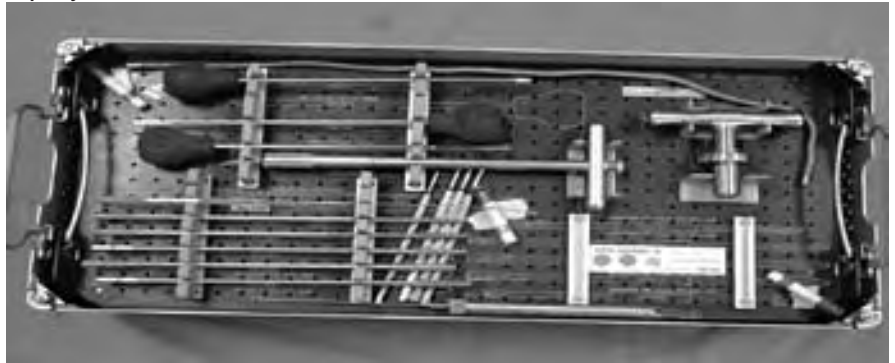
A) Wrapped container – Bottom layer



Middle layer



Top layer



Final wrapped package of three layers



B) Unwrapped container – Container shell



Tray with instruments



Fully assembled spine tray pan



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.

For a rigid container system designed to be sterilized without wrapping, a BI should be positioned on the underside of the lid away from the filters as well as in diagonally opposite corners (one in a lower corner, and the other in the upper corner diagonally opposite). For a rigid sterilization container designed to be wrapped, the BIs should be positioned in the same locations as indicated above. Regardless of the container design, the testing should include three BIs placed in each layer of the set (Figure 1 A and B).

Once the cycle has been completed, the tray/container should be dismantled and the BIs 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 (e.g. orthopedic devices or electrical equipment).

Even if the regular paper strip or self-contained ampule BIs are killed, this may not be a valid indication that the device has been adequately sterilized. Most BIs are typically inactivated within 3-4 minutes of steam exposure at 132°C-135°C (indeed in most pre-vac sterilizers, the spores are killed within the first 1-2 minutes of exposure). Another issue is that the growth media inside self-contained BIs may not function properly after processing through very long steam sterilization cycles. If the growth media is part of the challenge pack (e.g. as is the case for the self-contained BI) and if the growth-promoting ability of this media is detrimentally affected by the long exposure of the media to heat, then this too could negatively affect the ability of such a BI to perform properly. This again emphasizes why the BI manufacturer must provide validated data to confirm that the BI functions appropriately and can be used in extended cycles. 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.

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 indicator device received clearance from either Health

Canada or the FDA (Food and Drug Administration of the USA) for use in extended cycles? If so, ask for a copy to verify claim. If there is no clearance for the indicator device it should not be used.

- 2) Which cycle parameter does the CI or BI monitor and which 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 four minutes at 132°C-134°C or three minutes at 135°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. This is critical to ensure adequate patient safety. ●

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