Are You Running the Correct Steam Sterilization Cycles for Your Loads?

Understanding the challenges of extended steam sterilization cycles

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Objectives
1. Define extended steam sterilization cycles and explain why they exist.
2. Identify the effect of using extended cycles on the performance of other products such as packaging and other medical devices that do not require processing in extended steam sterilization cycles.
3. Identify by whom and how up-to-date instructions for use on all medical devices will be obtained to ensure that extended steam sterilization cycles are used where required.
4. Develop policies and procedures for product testing and routine sterilizer efficacy testing of extended cycle loads.

Test Questions
True or False. Circle the correct answer.

1. An extended steam sterilization cycle has a longer exposure and/or dry time than those commonly provided by the sterilizer manufacturers.
   A. True   B. False

2. Extended steam sterilization cycles are necessary because the complexity of medical devices (e.g., lumen size, metal mass, container design) require longer times for air removal, steam entry into lumens and materials to reach sterilization temperature.
   A. True   B. False

3. Medical devices can be removed from the original container or organizing case to a rigid container to make it easier to sterilize the instruments.
   A. True   B. False

4. Monitor extended steam sterilization cycles the same way you monitor your commonly used steam cycles.
   A. True   B. False

5. Make sure that the products (e.g., packaging, biological indicators, etc.) used in extended cycles are validated for those types of cycles.
   A. True   B. False

6. Product test the “master product” identified from a family of products that need extended steam sterilization cycles to verify effective sterilization in your facility’s sterilizer using your steam supply, loading technique and the medical device manufacturer’s reprocessing instructions.
   A. True   B. False

7. It is permissible to add other instruments needed for the case to the original container or organizing case.
   A. True   B. False

8. For product testing place multiple chemical and biological indicators inside each layer of the container or organizing case in corners, next to lumens and heat sinks.
   A. True   B. False

9. Reading the physical monitors before removing the load ensures that the correct extended cycle was used for the load contents.
   A. True   B. False

10. Monitor every implant load with a biological indicator (BI) and quarantine until the BI result is negative.
    A. True   B. False
Introduction

Do you know if you are running the correct sterilization cycles for the medical devices you are processing? Do you know what is meant by an extended steam sterilization cycle? Are you running extended steam sterilization cycles? If you have never heard this term before and are not using extended steam sterilization cycles, you may not be correctly processing some of your complex instrument sets. This could have an adverse effect on patient outcomes because these instruments may not be safe to use. The following issues surrounding extended steam sterilization cycle times create new challenges to healthcare facility sterile processing departments.

This in-service will discuss the following topics related to extended steam sterilization cycles that create new challenges to healthcare facility sterile processing departments.

- Definition of an extended steam sterilization cycle;
- Why extended steam sterilization cycles exist;
- Examples of extended steam sterilization cycles;
- How to monitor extended steam sterilization cycles;
- Effects of extended cycles on performance of other products;
- Product testing;
- Routine sterilizer efficacy testing; and
- Hope for the future.

Extended Steam Sterilization Cycles

The Association for the Advancement of Medical Instrumentation’s newly updated, Process challenge devices/test packs for use in health care facilities Technical Information Report (AAMI TIR31:2009) defines an extended steam cycle as:

“A steam sterilization cycle with longer exposure and/or dry times than those commonly provided by the sterilizer manufacturers (e.g. while a normal cycle might be 4 minutes at 270°F, an extended cycle could be 15 minutes at 270°F).”

Medical device manufacturer’s (MDM’s) instructions for use should be followed to ensure that the correct steam sterilization cycles are being used. However, if other medical devices that do not require extended steam sterilization cycles are run in these extended cycles, their functionality or product life maybe affected. “Some of the newer synthetic materials may become warped or brittle.” 1 “Instruments with coating may flake if exposed to the extended cycles.” 1

Why Extended Steam Sterilization Cycles Exist

In 1996, the Food and Drug Administration (FDA) released the document titled, “Labeling reusable medical devices for reprocessing in health care facilities: FDA reviewer guidance,” referred to hearafter as the Labeling Document. 1 This Labeling Document required MDMs to provide written recommendations to hospitals on how to process their medical devices. Through these written recommendations, MDMs informed users if there is a need to run longer sterilization and dry times.

The need for extended cycle instructions for use are a result of the MDM’s testing to determining the steam sterilization cycle required to produce a sterile device (called validation testing). During this testing, Geobacillus stearothermophilus spores are typically placed inside of areas that create challenges to air removal such as lumens, crevices and other small interior features of instruments that could harbor residual infectious material that could be transmitted to a patient. MDM’s seed spores or place spore strips and/or self-contained biological indicators in various areas of the sterilization container such as next to the largest heat sink (largest metal mass) that may take longer to reach the sterilization temperature. Once all the spores are killed, the cycle time is doubled to meet the safety factor required to ensure that there is sufficient lethality to produce the desired sterility assurance level (SAL) for the device (typically 10^-6). The resulting cycles are then listed in the MDM’s Instructions for Use.

The fear of prion contamination is also a cause for extended steam sterilization cycles. Many countries in Europe recommend using an 18-minute prevacuum cycle at 274°F/134°C to inactivate prions associated with Creutzfeldt-Jakobs Disease (CJD). Some MDM’s instructions reflect the need for this kind of cycle. 2

Practical Application

- Extended cycles are the result of the need to sterilize complex medical devices and the containers provided with those devices and the need to inactivate prions.
- Follow the MDM’s instructions for use to ensure medical devices are being processed for sufficient time to kill spores.

Examples of Extended Steam Sterilization Cycles

Tables 1-4 list some examples of extended steam sterilization cycles. The information includes the type of...
sterilization cycle required (e.g., gravity, dynamic-air-removal [pre-vacuum, steam-flush pressure pulse]), the minimum numbers of vacuum pulses required during the come-up-time (e.g., three or four), the minimum temperature and sterilization time and often a dry time. If the information supplied does not match your sterilization process, you should contact the MDM and sterilizer manufacturer to determine an acceptable solution. For example, if the validation testing was performed in a four pulse prevacuum sterilizer can you use the same cycle parameters if you have a three pulse prevacuum sterilizer? Also, you should read the other information supplied with the instructions that describe the cleaning, disassembly, packaging and whether or not the devices can be processed unwrapped.

Table 1. DePuy recommendations for processing instruments used to implant orthopaedic prostheses

Instructions for use:
- Validated in a wrapped, multiple insert instrument case.

Table 2. Synthes recommendations for reprocessing specific complex graphic cases and their accessories (lids/trays/modules/racks)

Instructions for use:
- Use in a legally marketed sterile barrier system, i.e. wrap and/or pouch.
- Do not use rigid sterilization container system unless user validates that process.

Table 3. Synthes recommendations for processing a power drive set

Instructions for use:
- Steam sterilize in the graphic case.

As of February 2, 2009 other complex graphic cases not listed in Table 2, standard graphic cases, implants, and instruments can be processed in standard hospital steam sterilization processes as shown in Table 3. Synthes was able to reduce the sterilization times as a result of re-qualification of the medical devices by improving their previously established sterilization test protocols. The February 2, 2009 Synthes letter states:

“Retesting has provided data which supports a sterility assurance level (SAL) of 10^-6 using a standard hospital Pre-vacuum cycle, e.g. 4 minutes @ 132°C. New test protocols were established utilizing the “overkill method” and sterilization performance criteria outlined in AAMI TIR12:2004 and AAMI ST77:2006. The new test protocols included worst-case devices for sterilization with respect to the device design, device material, case ventilation, and weight.”

Table 4. Synthes recommendations for processing a power drive set

Instructions for use:
- Obtain and follow the medical device manufacturer’s instructions to ensure the correct extended steam sterilization cycle is used.
How Do You Monitor Extended Steam Sterilization Cycles

Dr. Michele Alfa stated in the Canadian Journal of Infection Control in the fall of 2006:

"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."

The AAMI Process Challenge Working Group is currently discussing and working to identify the appropriate process challenge devices (PCDs) for extended cycles. It is most likely that the chemical indicators (CIs) and biological indicators (BIs) themselves will remain unchanged but the process challenge devices into which they will be placed will be modified. "The BI PCD should provide a challenge to the sterilization process that is equal to or greater than the challenge posed by the most difficult item to be processed."1

This yet to-be-developed PCD must create a challenge more appropriate for monitoring lumens which require a longer time for complete air removal and the metal mass of orthopedic sets which require a longer time to heat the materials during the steam sterilization process.1 These may even require different PCDs to create the appropriate challenge. The AAMI TIR31:2009 introduced the terms Hollow Challenge PCD and Solid Load PCD for these potentially different PCDs. The PCD(s) would replace or augment the AAMI 16 towel pack or disposable pack of equivalent challenge (e.g., both are considered Porous Load PCD) for both routine sterilizer efficacy monitoring and for sterilizer qualification testing of extended steam sterilization cycles. Until the new PCDs are developed, however, existing PCDs should be used. Monitoring of these extended steam sterilization cycles will be discussed under Routine Sterilizer Efficacy Monitoring.

Practical Application

• Until new PCDs are developed that reflect the same challenge as the devices processed in extended cycles, existing PCDs should be used.

Effect of Extended Cycles on Performance of Other Products

Another concern with extended cycles is the effect on the other products used in these cycles. Because of the limited products and information on extended cycle times, the Specialty Assembly of AORN for Sterile Processing/Materials Management in August 2007 released this statement to inform users about the concern over extended cycles:

"Many medical facilities are faced with the issue of extended steam sterilization cycles for their surgical instruments (a cycle time longer than the traditional 4 minutes). Each medical facility needs to make sure that all of their products used for sterilization (peel pouches, wrap, …) can withstand these longer steam sterilization cycles. Each medical facility needs to make sure that the products used in extended cycles are validated for these types of cycles. Many manufacturers have tested their products for these longer cycles’ times. The manufacturer of the products should supply information to the user for their records."8

There are two manufacturers of sterilization packaging products that have documentation posted on AORN’s SP/MM SA Web portal at http://communities.aorn.org/COP/SPMatMngmt/ FileSharing/index.fusion.8 These documents can also be obtained from the manufacturers. The posted statements are:

Wipack Medical Steriking® Sterilization Packaging Products (peel pouches & paper bags) Distributed by Healthmark Industries.

"Steriking® Sterilization Packaging products (peel pouches and paper bags) have demonstrated that they will withstand extended steam sterilization process with 134°C (273°F) for 30 minutes (steam pre-vacuum)."8

"The sterilization parameters assume that all instruments or other items placed within the Steriking® Sterilization Packaging products have been cleaned prior to packaging and the process verified. User must consult with sterilizer manufacturer and follow instructions for proper use, cycle parameters, appropriate applications, load capacity, configuration and performance monitoring."8

Kimberly-Clark Corporation

"Kimguard One-Step Sterilization Wrap has been tested following steam sterilization cycles with extended exposure times up to 30 minutes. These cycles were conducted in a pre-vacuum sterilizer operating at 275°F. Strength, barrier, lint and repellency were tested and compared to the same properties after the commonly used three minute exposure time recognized by AAMI†. No statistically significant negative performance differences were found in the compared data."8

"Please note that this is not a guarantee of package sterility. Validation of sterilization efficacy must be sought from the sterilizer manufacturer and appropriate
device manufacturers. Drying time used in this study was 20 minutes.\textsuperscript{8}

\textsuperscript{8} ANSI/ANSI/AAMI ST79:2006

One-Step Sterilization Wrap is a Registered Trademark of Kimberly-Clark Worldwide Inc.

Not published on the AORN Web site but published in Managing Infection Control\textsuperscript{9} and Infection Control Today\textsuperscript{10} and in a white paper available from 3M is information about the performance of 3M\textsuperscript{TM} Attest\textsuperscript{TM} Rapid Readout Biological Indicators in extended cycles.

"The 3M Attest Rapid Readout Biological Indicators with the 3 hour enzymatic readout were not affected by exposure of the ampouled media to extended cycle conditions (134°C for 20 minutes and 20 minute dry time). There was no statistically significant difference between the BIs assembled with “exposed” and “unexposed” ampouled media in the survival, kill and fractional cycles. This study demonstrates the ampouled media in the 3M Attest Rapid Readout Biological Indicator functions properly after exposure to extended cycle conditions."\textsuperscript{11}

### Practical Application

- Each medical facility needs to make sure that the products used in extended cycles are validated for these types of cycles.

### Product Testing

Since MDMs generally only provide steam sterilization parameters for complex instrument sets run in otherwise empty sterilizers, it is necessary for a hospital to perform product testing to see if they can effectively process these medical devices using the recommended extended steam sterilization cycles in their sterilizers with their load configuration and steam quality. “Therefore, product testing is recommended as part of a complete quality assurance program to ensure the effectiveness of the sterilization process and to avoid wet packs.”\textsuperscript{12}

To effectively process instruments in extended cycles it is necessary to obtain the most up-to-date instructions for use and follow them. They might be obtained from the company by accessing their Web site and certainly by calling the company’s regulatory department. When talking to the regulatory department, ask if you can be placed on a list to automatically receive updates or changes to the package insert. If this is not possible then every six to 12 months check back with the MDM to see if any updates or changes have been made.

Medical devices should only be processed in the original container or organizing case unless the MDM has supplied validation information for other sterilization options. Synthes states in their instructions for use:

“If Synthes devices are sterilized using a rigid sterilization container system, the recommended parameters may not be valid and new cycle parameters may need to be established by the user. Our current validations have been established with the use of legally marketed sterilization wraps. Terminal sterilization through use of a rigid sterilization container system cannot, presently, be recommended for use with Synthes products. It will be the user’s responsibility to assure validation with these devices.”\textsuperscript{4}

In addition the MDMs validate the instrument set only in the configuration as it comes directly from them. If you, the delivery person or the sales representative place any additional instruments into the set when it reaches your department, the set is no longer validated. Extra instruments for the case should be placed into another tray, rigid container, or peel pouches. Do not change the composition of the original MDM’s instrument set.

The next step is to perform product testing according to the ANSI/AAMI ST79 protocol (Section 10.9) using the CIs, BIs and BI PCD routinely used.\textsuperscript{12} Not every instrument tray supplied by the manufacturer needs to be tested. MDMs divide instrument sets into families of products based on similarities such as mass, material, construction, shapes, lumens and packaging systems.

Other MDMs also address the sterilization of families of products in their instructions for use. Choose the most difficult-to-sterilize tray from each family of instruments to test. This is called the “master product.” The MDM can assist in family and “master product” identification.

Multiple BIs and CIs (Class 3, Class 4 or Class 5) should be placed within the product to be tested. MDMs provide product testing information for other sterilization options. Synthes states in their instructions for use:

“If Synthes devices are sterilized using a rigid sterilization container system, the recommended parameters may not be valid and new cycle parameters may need to be established by the user. Our current validations have been established with the use of legally marketed sterilization wraps. Terminal sterilization through use of a rigid sterilization container system cannot, presently, be recommended for use with Synthes products. It will be the user’s responsibility to assure validation with these devices.”\textsuperscript{4}

Multiple BIs and CIs (Class 3, Class 4 or Class 5) should be placed within the product to be tested.\textsuperscript{12} Check with the MDM to see which areas are suggested as a result of thermocouple (temperature probe) testing results performed during their validation study.

The number of BIs and CIs used will depend on the size and configuration of the pack being tested. See Figure 1 for an example of placement of BIs and CIs inside a multi-level instrument container processed in an extended cycle. BIs and CIs are placed inside each layer in multiple locations such as corners, next to lumens and heat sinks (large metal mass instruments). The product test samples should be labeled and placed among other products in a full load. Also place your BI PCD in the same load. After the sterilization process, BIs should be retrieved and incubated along with a positive control BI. The physical monitoring
results and CI results should be recorded, followed by the BI results when available.

Figure 1. Placement of Biological and Chemical Indicators for Product Testing

A photo of the placement of the BIs and CIs for your records would assist in recording the results according to location of the BIs and CIs. If any CIs do not reach their endpoint or the BIs are positive (including the BI PCD), investigate to determine the cause, correct the problem and retest. Contact the MDM for assistance if needed. Reasons for failures could include:

- Type or adequacy of air removal used in your sterilizer (e.g., vacuum depth, number of vacuum pulses, steam charge rate between pulses, etc.);
- Sterilizer not reaching the appropriate time at temperature;
- Loading technique;
- Too much metal mass in load;
- Additional instruments or peel pouches with instruments were incorrectly added to the original tray;
- Original validated tray or containment system not used.

The packages should also be inspected for evidence of moisture. “If moisture is observed, steps should be taken to remedy the problem.” These include:

- Changing the packaging;
- Adjusting the loading;
- Decreasing the amount of metal in the load;
- Selecting a longer sterilization and/or drying time;
- Adjusting the unloading and cooling procedure.

Do not place the instrument trays into routine use until the monitoring results indicate a successful sterilization process.

**Practical Application**

- Obtain and follow the medical device manufacturer’s instructions to ensure that the correct extended steam sterilization cycle is used.
- Do not remove the medical devices that require extended cycle testing from the original container or organizing case for processing unless the MDM has validated the packaging you are going to use.
- Do not add extra instruments to the original container or organizing case unless your hospital has completed a validation study to determine the extended cycle needed.
- Perform product testing on the “master product” identified for each family of identified products.

**Routine Sterilizer Efficacy Monitoring**

Routine sterilizer efficacy monitoring includes both the use of physical monitors, chemical and biological indicators and the documentation of the results. This type of monitoring does not change when testing extended steam sterilization cycles.

**PHYSICAL MONITORS (EQUIPMENT CONTROL)**

Be sure to correctly set the cycle parameters on the sterilizer for the load to be run. Consider an internal system that codes the packages so that packages requiring the same extended cycle are placed on the same loading cart and processed at the correct cycle parameters. See Figures 2-5. Many electronic record keeping systems will alert you when packages are not placed in the correct load with the correct sterilization cycle parameters. If an identification system is not in place, the wrong cycle might be run and the process could be ineffective.

For recording charts, mark the date, sterilizer number, and your initials on the printout at the beginning of the cycle. For sterilizers with printouts, check to make sure the cycle identification number has been recorded and the pen or printer is functioning properly. Ensure that the person opening the sterilizer reads the printout to verify the correct extended cycle was run for the load. Initial after verifying the correct results. Sterilizers without recording devices should not be used.

If the physical monitors indicate a malfunction, consider the load nonsterile and do not distribute it. Do not put the sterilizer back into routine use until the problem has been identified, corrected and the sterilizer is retested with biological and chemical indicators that show the correct results. This is called qualification testing and more information can be obtained by reading “The Day in The Life of a Dynamic-Air-Removal Steam Sterilizer” in the December 2007 issue of *Managing Infection Control* and ANSI/AAMI ST79.
CHEMICAL INDICATORS

Bowie-Dick Test (Equipment Control)

The ANSI/AAMI ST79 recommended practice states that for 270-275°F (132-135°C) dynamic-air-removal steam sterilizer the first step of the day is to run a Bowie-Dick (BD) type test. The Bowie-Dick type test checks for:
- air leaks;
- inadequate air removal;
- inadequate steam penetration;
- presence of noncondensable gases (i.e., air or gases from boiler additives).12

Always check with the manufacturer of the Bowie-Dick test pack and sterilizer for their specific instructions. This test must be run correctly for the results to be valid. The sterilizer cannot be put into routine use until the Bowie-Dick test sheet shows a uniform color change. In addition to daily testing the Bowie-Dick test should be run during sterilizer qualification testing.12,13

External Chemical Indicators (Exposure Control)

The ANSI/AAMI ST79 recommended practice states that a Class 1 Process Indicator (external chemical indicator) should be used on the outside of each hospital-assembled package, tray or containment device intended for sterilization unless the internal chemical indicator is visible.12 The Association of periOperative Registered Nurses (AORN) Recommended Practices for Sterilization in Perioperative Practice Settings, 2009 also has this recommendation.14

This allows you to tell as soon as a package comes out of the load that it has been processed. After unloading the sterilizer, check the external indicator for each package. Do not release the tray or package for use if the chemical indicator has not reached an acceptable endpoint.

Internal Chemical Indicators
(Pack Control)

The ANSI/AAMI ST79 recommended practice says to place an internal chemical indicator (CI) (Class 3 single-variable, Class 4 multi-variable indicator or a Class 5 integrating indicator) inside each package, peel pouch, tray or containment device in the area determined to be the least accessible to steam penetration.12

The recommended practices state that Class 4 Multi-variable and Class 5 Integrating Indicators provide more information than Class 3 Single-variable Indicators.12

The AORN Recommended Practices for Selection and Use of Packaging Systems for Sterilization, 2009 suggests the following placement of internal CIs.15

Place:
- A CI in the geometric center but not on the top of a wrapped pack or tray;
- Two CIs inside rigid containers: one in each of two opposite corners of the inside basket,
- Multi-level rigid containers should have a CI placed in two opposite corners (e.g., one in each of two corners) of each level;
- A CI on each level of multi-level wrapped sets.

The ANSI/AAMI ST79 recommended practice states, “If the interpretation of the CI suggests inadequate steam processing, the contents of the package should not be used.”12
The complete unused package, including the load identification and the CI should be returned to the processing department. The decision to recall the entire load should be based on the results of physical monitoring, CI results from other packs in the load, and the results of BIs if available. If BI results will be available, quarantine the load until that time. Internal CIs are designed to detect errors in packaging, loading, incorrect choice of sterilization cycle for a particular load, and equipment malfunctions.

**Class 5 Integrating Indicators (Load Control)**

*To release nonimplant loads*

In addition to using a Class 5 Integrating Indicator as an internal CI, the ANSI/AAMI ST79 recommended practice states that a Class 5 Integrating Indicator:

- May be used in a process challenge device (PCD) that is representative of the load to monitor loads not containing implants to supplement the results of physical monitors and Class 1 Process Indicators.

If the Class 5 Integrating Indicator used for load control has not reached its acceptable endpoint, do not use the load, but reprocess.

*To release implant loads*

In addition, ANSI/AAMI ST79 recommended practice states that a Class 5 Integrating Indicator:

- Should be used in a PCD containing a BI to monitor implant loads.
  - The CI results may be used as a basis for early load release in documented emergency situations only.
  - “Loads containing implants should always be biologically monitored and, whenever possible, implants should be quarantined until the BI results (early readout or spore growth) are available.”

**Biological Indicators (Load Control)**

*Biological Indicators are used within a PCD:*

- to routinely monitor sterilizers at least weekly, but preferably every day that the sterilizer is in use in each type of cycle for which a sterilizer is designed to be used:
  - gravity-displacement at 132°C to 135°C [270°F to 275°F];
  - gravity-displacement at 121°C [250°F];
  - dynamic-air-removal at 132°C to 135°C [270°F to 275°F];
  - flash at 132°C to 135°C [270°F to 275°F];
  - flash with single wrapper or other packaging.

ST79 clarifies in NOTE-2 that: “If a sterilizer will run the same type of cycle (e.g., dynamic-air-removal at 132°C to 135°C [270°F to 275°F]) for different exposure times (e.g., 4 minutes and 10 minutes), then only the shortest cycle time needs to be tested.”

For flash sterilization each type of tray configuration in routine use should be tested separately.

- to monitor every load containing implants; these loads should be quarantined until the BI is negative

Biological indicators are also used for sterilizer qualification testing.

The main advantage of running a BI PCD in each load is to ensure all implants are monitored and quarantined until the BI is negative, thus avoiding recalls. The other advantage is to ensure that all sterilization modes used for all sterilizers and all types of packaging used in flash sterilizers are routinely tested.

### Practical Application

- Check the physical monitors for each load to ensure the correct extended cycle was used.
- Run a Bowie-Dick test pack every day before the prevacuum sterilizer is placed into routine use and for qualification testing.
- Place a Class 1 process indicator on the outside of each package, tray or containment device unless the internal CI is visible, to distinguish processed from unprocessed items.
- Place a Class 4 Multi-variable or Class 5 Integrating Indicator inside each package, peel pouch, tray or containment device in the area determined to be the least accessible to steam penetration.
- Do not release or use the package, tray or containment device for use if the external or internal chemical indicator has not reached an acceptable endpoint.
- Class 5 Integrating Indicators in an appropriate PCD may be used to monitor non-implant loads.
- The BI PCD used to monitor each implant load should contain a Class 5 Integrating Indicator and the implant should be quarantined until the BI is negative unless it is a documented emergency.
- Run a BI weekly, preferably daily in the shortest cycles run for each type of sterilization cycle used.
- Run a BI in each load containing an implant and quarantine until the BI is negative.
Future

The Canadian Standards Association and the AAMI Process Challenge Device working group, based on analysis of existing extended steam sterilization cycle recommendations and discussions with the MDMs, recommend that the following extended steam sterilization cycles “be adopted as standard extended cycles, and that new and existing devices be qualified in at least one of these cycles.”

- 270-275°F (132-135°C), 10 minutes in dynamic-air-removal steam sterilizers;
- 270-275°F (132-135°C), 20 minutes in dynamic-air-removal steam sterilizers;
- 250°F (121°C), 40 minutes in gravity steam sterilizer;
- 250°F (121°C), 60 minutes in gravity steam sterilizers.

All involved parties are interested in standardization of these extended steam sterilization cycles. Stay tuned.

Practical Application

- Standardized steam sterilization cycle times would reduce the number of extended cycles used in Sterile Processing Departments, improving the workflow and efficiency of the SPD department and reducing the likelihood of using the wrong extended cycle.

Summary

Using extended steam sterilization cycles, when required, ensures that those medical devices are effectively sterilized and safe for patient use. A top priority is to obtain the most up-to-date instructions for use from your medical device manufacturers to ensure you are running the correct sterilization cycle for the load contents. Do not add other instruments needed for the case to the original container or organizing case and do not transfer those instruments to a rigid container unless the MDM has validated that usage. With a complete quality assurance program you can have confidence in the medical devices being processed in an extended steam sterilization cycle in your facility.

Ordering Information

AAMI


Available in an attractive binder featuring sturdy metal rings, ledger-weight pages, and a laminated tab for each section for easy navigation. AAMI will issue revised pages that can be substituted into the binder when changes are made. Also available in PDF format and as part of AAMI’s electronic CD and subscription products.

- The ST79 Amendments, ANSI/AAMI ST79:2006 and A1:2008 can be purchased separately on 3 hole punched paper or the PDF can be downloaded for free at www.aami.org. To download the complimentary PDF copy, click on ANSI/AAMI ST79:2006 and A1:2008 under “Marketplace News.” Scroll down to ST79 Amendment 1-PDF and click on the shopping cart to launch the complimentary PDF.

- The Process challenge devices/test packs for use in health care facilities, AAMI/FDT1 TIR31:2009 and other AAMI documents can also be purchased through AAMI by credit card using the following four options:
  1. Internet: http://marketplace.aami.org
  2. Call: 1-877-249-8226
  3. Fax: 301-206-9789
  4. Mail: AAMI Publications, P.O. Box 0211, Annapolis Junction, MD 20701-0211

Glossary of Terms

- Extended cycle: “A steam sterilization cycle with longer exposure and/or dry times than those commonly provided by the sterilizer manufacturers (e.g. while a normal cycle might be 4 minutes at 270°F, an extended cycle could be 15 minutes at 270°F.)”

- Medical device: “Instrument, apparatus, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of
  - diagnosis, prevention, monitoring, treatment, or alleviation of disease;
  - diagnosis, monitoring treatment, alleviation of, or compensation for an injury or handicap;
  - investigation, replacement, or modification of the anatomy or of a physiological process; or
  - control of conception.”

- Validation: “Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.
  NOTE 1-Validation covers three activities; installation qualification, operational qualification, and performance qualification.
  NOTE 2-Validation is performed by the device manufacturer.”

- Sterility Assurance Level (SAL): Probability of a single viable microorganism occurring on product after sterilization.
Prions: “Transmissible pathogenic agents that cause a variety of neurodegenerative diseases of humans and animals, including scrapie in sheep and goats, bovine spongiform encephalopathy (BSE) in cattle, and Creutzfeldt-Jacob disease (CJD) in humans. They are unlike any other infectious pathogens, including viruses, because they are composed of an abnormal conformational isoform of a normal cellular protein, the prion protein (prP). Prion diseases are disorders of protein configuration involving template-assisted replication and resulting in abnormal protein accumulation in the brain, which causes neuronal dysfunction, degeneration, and death. Prions are extremely resistant to inactivation by heat and disinfecting agents. [Baron et al., 2001]”

Process challenge device (PCD): “Item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process.”

Routine sterilizer efficacy monitoring: Testing all steam sterilizers and all sterilization cycles used with a biological indicator process challenge device (BI PCD) weekly, preferably daily.

Product testing: Part of a complete quality assurance program to ensure effective processing of all items routinely processed and to avoid wet packs.

Dynamic-air-removal steam sterilizers: “Type of sterilization cycle in which air is removed from the chamber and the load by means of a series of pressure and vacuum excursions (prevacuum cycle) or by means of a series of steam flushes and pressure pulses above atmospheric pressure (steam-flush pressure- pulse [SFPP] cycle).

NOTE 1-The dynamic-air-removal cycle is generally preferred to a gravity-displacement cycle because of more efficient air removal, a shorter exposure time at higher temperatures, and a vacuum drying phase, resulting in an overall reduction in cycle time.

NOTE 2-Typical operating temperatures are 132°C to 135°C (270°F to 275°F)”

Gravity-displacement steam sterilizers: “Type of sterilization cycle in which incoming steam displaces residual air through a port or drain in or near the bottom (usually) of the sterilizer chamber.

NOTE-Typical operating temperatures are 121°C to 123°C (250°F-254°F) and 132°C to 135°C (270°F to 275°F)”

Steam Quality: “Steam characteristic reflecting the dryness fraction (weight of dry steam present in a mixture of dry saturated steam and entrained water) and the level of noncondensable gas (air or other gas that will not condense under the conditions of temperature and pressure used during the sterilization process).

NOTE-The dryness fraction (i.e., the proportion of completely dry steam in the steam being considered) should not fall below 97%.”

Physical monitors: Time, temperature, and pressure recorders; displays; digital printouts; and gauges that provide real-time assessment of the sterilization cycle conditions and permanent records.

Equipment control: Monitoring the sterilizer prior to, and during daily use to determine if the sterilizer is operating to the set conditions of time, temperature, pressure, air removal, moisture conditioning, and sterilant exposure. Includes physical monitors and Bowie-Dick tests.

Bowie-Dick test: “Diagnostic test of a dynamic-air-removal steam sterilizer’s ability to remove air from the chamber and prevent air re-entrainment.”

Chemical indicator (CI): “Device used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or used in specific tests of sterilization equipment.”

External chemical indicator: Chemical indicator used outside of packages to distinguish processed from unprocessed items.

Exposure control: Identifies processed medical devices from unprocessed medical devices at a glance. External chemical indicators are used for exposure control.

Internal chemical indicator: Chemical indicator used on the inside of packages to determine that the sterilant has penetrated inside the packaging.

Pack control: Use of internal chemical indicators to monitor the conditions inside individual packs to determine that the sterilant has penetrated to the location of the medical devices.

Biological indicator (BI): “Test system containing viable microorganisms providing a defined resistance to a specified sterilization process.”

Load control: The process by which a load is monitored and released based on the result of a BI and/or a Class 5 CI indicator in a process challenge device.

Sterilizer qualification testing: Testing the sterilizer with a biological indicator process challenge device and Bowie-Dick test after events (e.g., sterilizer relocation, malfunction, major repair, and sterilization process failure) which could affect the ability of the sterilizer to perform.

References

3. DePuy Instructions for Use for instruments used to implant orthopaedic prostheses. DePuy Orthopedics, Inc. IFU-0902-00-721, Rev. E.

Steven Kirckof, BSCE (Chemical Engineering) is an advanced product development specialist in 3M Infection Prevention Division's Sterilization Assurance group in St. Paul, Minn. He has more than 25 years of experience in sterilization assurance practice. Mr. Kirckof holds many patents and records of invention related to sterilization monitoring products. He participates in several AAMI Sterilization Standards Working Group committees and is the co-chair of the AAMI Chemical Indicator and Process Challenge Device Working Groups. Because of his position as co-chair, he is a United States delegate to the ISO (International Standards Organization) Chemical Indicator and Moist Heat Working Groups developing international sterilization standards.

Susan Flynn, BESc, CSPDT is a technical service specialist with 3M Infection Prevention Division's Sterilization Assurance group in St. Paul, Minn. She is routinely involved in troubleshooting and addressing sterilization questions. Ms. Flynn's role at 3M includes providing education for customers and sales personnel on improving the performance of the sterilization process and implementing best practices. She is a certified central sterile processing and distribution technician and a member of IAHCSMM. In addition, she is a member of several AAMI working group committees that are developing recommended practices and a published author of sterilization-related self-study articles.

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Sterile Process and Distribution CEU Information
CEU Applicant Name ________________________________
Address __________________________________________
City __________________ State ________ Zip Code _________

The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this inservice for one and one-half (1.5) contact hours for a period of five (5) years from the date of publication. Successful completion of the lesson and post test must be documented by facility management and those records maintained by the individuals until recertification is required. DO NOT SEND LESSON OR TEST TO CBSPD.

For additional information regarding Certification contact: CBSPD, 121 State Hwy 31N, Suite 500, Flemington, NJ 08822 or call 908-788-3847 or visit the Web site at www.sterileprocessing.org.

IAHCSMM has awarded one and one-half (1.5) Contact Points for completion of this continuing education lesson toward IAHCSMM recertification.

Nursing CE Application Form
This inservice is approved by the California Board of Registered Nurses, CEP 5770 for one (1) contact hour. This form is valid up to five years from the date of publication.
1. Make a photocopy of this form.
2. Print your name, address and daytime phone number and position/title.
3. Add the last 4 digits of your social security number or your nursing license number.
4. Date the application and sign.
5. Answer the true/false CE questions. KEEP A COPY FOR YOUR RECORDS.
6. Submit this form and the answer sheet to:
   3M Sterilization Assurance, Attn HC4160
   RR Donnelly Fulfillment Services
   585 Hale Ave N., Oakdale, MN  55128-9935
7. For questions or follow-up, contact craig@manageinfection.com.
8. Participants who score at least 70% will receive a certificate of completion within 30 days of Managing Infection Control’s receipt of the application.

Application
Please print or type.
Name ________________________________________________
Mailing Address ________________________________________
City, State, Country, Zip ________________________________
Daytime phone ( )______________________________________
Position/Title _________________________________________
Social Security or Nursing License Number __________________
Date application submitted ______________________________
Signature ______________________________________________

On a scale of 1-5, 5 being Excellent and 1 being Poor, please rate this program for the following:
1) Overall content ____________________
2) Met written objectives ______________
3) Usability of content ________________

ANSWERS
1. A  6. A
2. A  7. B
3. B  8. A
4. A  9. A
5. A  10. A

Offer expires March 2014