SELF-STUDY SERIES

The challenges of extended steam sterilization cycles

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Any science fiction fan can tell you that when the fleet flies into a meteor field, the pilots are caught between a rock and a hard place! No matter which way they go, there is a meteorite ready to crash into them. Extended sterilization cycles for medical instruments are a proverbial meteorite field for sterile processing departments because of all the challenges put in their way. Just like the intrepid fleet, sterile processing professionals must be able to navigate around these obstacles to get their job done.

How did we end up in this meteor field?

Extended cycles have been quietly used in sterile processing departments for decades. And steam sterilizers have been programmable for cycle time variations almost since their inception. This allowed healthcare professionals to program the cycle needs of different instruments. When steam sterilizers were designed with pre-programmed cycles, almost everything could be processed with these standardized cycles. But as instrumentation became more complex, packaging configurations became denser, and new health threats emerged (prions for example), the pre-programmed cycles were no longer enough. Requirements for cycles with different exposure times, drying times, or a combination of these became more prevalent. This led to the formal recognition of extended cycles.

Instrument manufacturers led the charge for extended sterilization cycle requirements, but the sterilizer manufacturers, packaging suppliers, sterility assurance suppliers and other sterilization accessory manufacturers did not keep up with the changes. This resulted in instrument instructions for use (IFU) that required extended sterilization parameters, but very few available validated packaging materials, sterilizers or monitoring devices to use for these extended cycles. Sterile processing departments were on their own to figure out how to use what was available to sterilize and monitor them.

Regulatory, material and quality issues

Extended cycles present many challenges for sterile processing departments. One is related to conflicting guidance and instructions. Accreditation and standards organizations stress the importance of following manufacturers’ IFU, but the extended cycles identified in an instrument’s reprocessing instructions are typically not listed or recommended in the sterilizer, packaging or monitoring products’ IFU. Once the department selects and follows extended cycle instructions, they are likely to be using the remaining sterilization products in a manner not listed in their instructions for use. These “off label” uses can lead to audit findings or confusion by staff, and confusion can lead to misuse of products and failure to properly sterilize the instruments.

There are also material issues. Today’s sterilization accessories are designed for standard sterilization exposure and drying times. Putting these products through longer cycle times or dry times can have a negative effect on the products. For example, paper sterilization pouches can become brittle when exposed to extended periods of dry heat. This can change the ability of the pouches to maintain their barrier properties. It can also make the pouch easier to puncture, creating a higher probability of contaminating a device before its next use.

Another important complication can occur with the sterilizer. Extended exposure and dry times can place a strain on steam supplies, steam generators and sterilizers. The longer and higher the steam sterilization temperature is, the harder it is on the steam sterilizer and utilities. Not every sterilizer is designed to maintain these types of conditions in constant use. It may lead to higher incidence of alarms or even cycle aborts.

Quality control issues may be the greatest concern for extended cycles. The instruments processed in extended-exposure cycles require more killing power than the standard cycle can provide. Likewise, the sterility assurance products, such as biological and chemical indicators that have been designed for standard cycles, may not provide the appropriate challenge for extended cycles with longer exposure times. Biological indicator test packs designed for four-minute pre-vacuum steam sterilization cycles have a built-in barrier to air removal and steam...
penetration. The barrier system makes the biological indicator within the test pack hard to kill in a steam sterilizer cycle. The test pack is designed to capture sterilization failures associated with a four-minute exposure time. Using this same test pack in a 10-minute prevacuum cycle provides no assurance that the additional six minutes of lethality has been achieved. The same is true of chemical indicators and other quality control products used to monitor steam sterilization processes.

The concept of designing products for specific cycle parameters is not new. However, in the old days when extended cycles were not part of the conversation, it was generally understood that these products were only for the standard cycles, so the labeling and instructions were often generalized. As extended cycles became more prevalent, manufacturers began to provide ranges of temperatures or times. In some cases, they indicated a minimum exposure time with no maximum exposure time. The Food and Drug Administration (FDA) now is very clear that ranges are no longer acceptable.

Using sterility assurance products, packaging and other steam accessories under conditions for which they are not validated, such as extended cycles, can lead to a false sense of security in sterilization processes. It’s very important to ensure that the right products are used for the right applications.

**FDA labeling guidance**

In March 2015, the FDA addressed the topic of extended sterilization cycles in instrument reprocessing instructions. To help manufacturers navigate the complexity of formulating and validating written reprocessing IFU, the FDA created a guidance document, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling – Guidance for Industry and Food and Drug Administration Staff*. The document provides guidance to reusable medical device manufacturers for the preparation and validation of their device IFU.

The FDA document lists six criteria for reprocessing instructions (See Table 1, right). The fourth criterion dictates that reprocessing instructions must be “technically feasible and include devices and accessories that are legally marketed.” This means that the sterilization parameters specified by the instrument manufacturers must use a steam sterilizer with the desired FDA-cleared cycle parameters. Additionally, the instrument manufacturer must ensure that packaging, sterility monitoring devices and any other necessary steam sterilization accessories be validated and cleared for that same cycle.

The guidance document expresses FDA concern that “extended cycles pose serious technical challenges in healthcare settings for which there are currently limited or no FDA-cleared sterilization accessories, such as biological indicators, chemical indicators and sterilization packaging, for use in extended cycles.”

**Navigating the extended cycle ‘meteors’**

As any ship captain will tell you, the best way to plan an important journey is to follow three simple steps:

1. Determine where you want to go; your goal.
2. Assess where you are now.
3. Map a path to get from here to there.

**Set the goals**

All sterile processing departments work to provide their reusable medical devices on time, in complete sets, and sterile. However, extended cycles lengthen reprocessing time and have the potential to slow sterile processing workflow. To avoid these issues, the goals should be to reduce the total number of extended cycles being used, streamline the reprocessing process through standardization, and use appropriate steam sterilization accessories for the required sterilization parameters.

**Assess current reprocessing needs**

The first step to any process improvement is to understand and map current practices and needs.

- Identify all manufacturers whose products are used within your facility. This includes medical devices, sterilizers, sterilization packaging and monitoring products.
- Identify all the sterilization parameters currently being used in the department.
- Obtain and review the most updated IFU from those manufacturers. Many manufacturers have updated their reprocessing instructions for their most common instruments. Their goal should be your goal; to standardize on commonly used, standard sterilization cycles.

- Contact device manufacturers and ask whether a pre-vacuum four-minute cycle (or another preprogrammed cycle) will achieve the desired sterile results. If so, obtain this confirmation in writing from the manufacturer.
- Identify and group instruments according to their sterilization requirements.

**Map the path**

Once all needs have been identified, it’s time to organize and standardize.

- Group instrumentation into the appropriate approved standardized cycles.
  - A variety of exposure times and temperatures exist. It is common for IFU to identify 270°F/132°C pre-vacuum cycles with four-minute, five-minute, eight-minute or 10-minute exposure times. Some IFU may provide a temperature range with a single exposure time, 270-273°F/132-134°C for four minutes. By grouping instruments into two or three standard cycles, the workflow can be simplified.
  - Instruments may be placed in a group with a longer exposure time but can never be placed in a group with a shorter exposure time than that listed in its IFU. For example, the instruments requiring five- and eight-minute exposure times may go in a 10-minute cycle, but could not go in a four-minute cycle.
- Once you have grouped your instruments, confirm with your manufacturers in writing that the longer exposure times can be used to sterilize them. As previously mentioned, exposing items to longer exposure times may damage them. It may seem like an additional six minutes of exposure in a 45-minute cycle is a small difference, but this can’t be assumed.

**Table 1:**

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• Develop a means to segregate and identify the cycle needs of the instruments. There are many ways that this can be done. Some departments include specific instructions on the pick lists. Others provide guidance near the sterilizers, on a wall poster. And others use instrument management systems to identify and control the sterilization cycles to be used.
• Determine the packaging materials to be used for the identified sterilization cycles. Wherever possible, standardize packaging products to prevent errors.
• Identify the appropriate validated chemical and biological indicator products to be used for each cycle.

No cleared products? What to do

Clearly, it’s optimal to use validated and FDA-cleared products for each cycle whenever possible. When one does not exist, it becomes the facility’s responsibility to determine the best practice to follow. A clinical review of available options should be completed with documented justification for the choices made. The clinical review should evaluate all available options, even if they aren’t currently used at the facility. If a sterilization wrap is validated for the cycle but the container systems at the facility are not, the wrap should be used instead of the container, for example.

When no option is available, the clinical evaluation should include supportive test data to justify the final practice, and products selected for sterilizing and monitoring instruments processed in extended cycles.

Sterile packaging

The instrument manufacturer should identify the packaging materials that should be used to validate the reprocessing instructions. If the facility chooses to use a different method, or the original method recommended by the instrument manufacturer is no longer available, test data from the proposed packaging material should demonstrate that the material does not change its physical properties and that the instrument within is still able to be sterilized with the chosen sterilization cycle.

Biological indicator test packs

As previously mentioned, biological indicator test packs are designed for specific sterilization cycles. A biological indicator test pack does exist for one extended cycle, the 10-minute pre-vacuum steam cycle, but not for all.

Instrument manufacturers will not typically provide guidance on an appropriate biological indicator test pack. The clinical review will be dependent on test data provided by the biological indicator manufacturers. It is not enough to provide studies showing that the vial does not melt or that the media does not degrade after exposure to extended cycle conditions. Unless specifically designed for the sterilization cycle, the biological indicator test pack will not provide an appropriate resistance. However, not all biological indicator test packs are made the same. The clinical review should include test data that demonstrates the product of choice is providing the best challenge available.

Chemical indicator strips and test packs

As with the biological indicator test packs, a limited number of chemical indicator strips and test packs have been validated and cleared for extended cycles. Like biological indicator test packs, the clinical review should include test data that demonstrates the product of choice is providing the best challenge available.

Complying with ANSI/AAMI ST79

ST79 is the comprehensive reprocessing guide for steam sterilization. It includes recommendations for packaging, sterilization and quality assurance. The number one rule in this document is to always follow the manufacturer’s instructions for use. Yet as we’ve discussed, non-compliance with this portion of the guidance is unavoidable.

It may be necessary to use several products to ensure compliance and maintain an appropriate challenge for the extended sterilization cycle. For example, ST79 indicates that a biological indicator test pack is required in every steam sterilization cycle that contains an implantable device. For a 20-minute pre-vacuum steam cycle, there is currently no cleared and marketed biological indicator test pack, so using any test pack would be an off-label use. However, there is a chemical indicator test pack that is designed and cleared specifically for this cycle. By using both the biological indicator test pack and the chemical indicator test pack, the facility can comply with ST79 requirements for a biological indicator and still use a chemical indicator test pack that is an appropriate challenge for the extended cycle.

Assess, organize and document for best results

Extended cycles are clearly here to stay because they’re necessary for specific reusable medical devices. But they add time, confusion and other obstacles to the sterilization process that can seem impossible to navigate in today’s highly regulated healthcare environment. By following a thoughtful plan of action, organizing and clinically evaluating sterilization processes and tools, and documenting all justifications, sterile processing departments can clear a path to a better workflow and to the best available reprocessing practices.
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Circle the one correct answer:

1. Which item is not an IFU criterion required by the FDA Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling – Guidance for Industry and Food and Drug Administration Staff?
   a. Labeling should reflect the intended use of the device.
   b. Reprocessing instructions should be technically feasible and include only devices and accessories that are legally marketed.
   c. Reprocessing instructions should only include sterilization instructions.
   d. Reprocessing instructions for reusable devices should advise users to thoroughly clean the device.

2. The FDA stated that extended cycles pose a serious technical challenge in healthcare facilities.
   a. True
   b. False

3. Which are examples of technical challenges associated with extended cycles?
   a. Extended exposure times and/or dry times may negatively impact sterilization pouches
   b. Instrument manufacturers can validate more than one sterilization process
   c. Biological indicator test packs are not designed to provide an appropriate challenge for extended cycles with longer exposure times
   d. A and C only

4. The goal of the sterile processing department is to
   a. Provide instrumentation that looks like new to the OR
   b. Provide instrumentation on time, complete and sterile
   c. Provide instrumentation that is on time and sterile with as few containers as possible
   d. None of the above

5. Because there is so much overkill in the steam sterilizer cycle, it is okay to group instruments requiring a five-minute exposure time in a cycle with a four-minute exposure time.
   a. True
   b. False

6. Which of these tasks can help reduce the number of sterilization cycles needed?
   a. Obtain the most current reprocessing instructions for instrumentation
   b. Contact instrument manufacturers to see if an instrument can be processed in a cycle with a longer exposure time
   c. Ask the instrument manufacturer if they have revalidated the instrument in a standard sterilization cycle
   d. All the above

7. What is not included in a clinical evaluation of packaging for off-label use in extended cycles?
   a. A biological indicator can be sterilized in the packaging when processed in an extended cycle
   b. Determination if the packaging was used in the instrument manufacturer’s validation
   c. Test data demonstrating that the physical properties of the packaging is not changed following the sterilization cycle.
   d. None of the above

8. Instrument manufacturers are not likely to provide guidance on which biological indicator test pack to use.
   a. True
   b. False

9. Which items are considered when performing a clinical evaluation for biological indicator off-label use in extended cycles?
   a. Test data demonstrating the compatibility of the materials of construction
   b. The comparative challenge to other commercially available biological indicator test packs in the extended cycle
   c. Test data provided by the biological indicator manufacturer
   d. A and C only

10. What benefits can be obtained by using two load monitoring products in an extended cycle?
    a. Provide two checks for the extended sterilization cycle
    b. The sterilization cycle can be released if one shows passing results even if the other shows failing results.
    c. One can ensure compliance to recommended practices while the other provides the necessary challenge for the extended cycle
    d. None of the above.

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