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Turning up the Heat on Heat Sealer Quality

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LEARNING OBJECTIVES

1. Review requirements for sterile packaging used in heat sealers
2. Discuss sterilization pouches designed for heat sealers
3. Review heat sealer basics
4. Discuss quality assurance testing for heat sealers

Heat sealers are a fast, efficient method of creating tamper-evident seals for sterile packages. Heat sealers have been a part of Sterile Processing departments (SPDs) for years and, unfortunately, are sometimes taken for granted. In some cases, heat sealers receive little more than a yearly safety check and are used until they malfunction or stop working altogether. Because they appear simple, SP professionals are trained to use them, but are rarely taught more about them. This lesson will examine considerations and good work practices for working with heat sealers.

Objective 1: Review requirements for sterile packaging used in heat sealers

Sterile packaging is designed to protect medical devices from contamination between the time they are sterilized and when they are used in patient treatment and care. The packaging must be designed to allow for air removal and sterilant penetration and, at the same time, protect contents from contamination by not allowing microorganisms to enter the sterile

package during handling, storage and transport. To accomplish that goal, packaging must be applied correctly. This can be challenging because medical devices vary in size and shape – and complex shapes can make the packaging process more difficult. Sterile packaging must also be able to be opened aseptically. If a package cannot be opened aseptically, it is of no use to procedural staff.

Sterile packaging must also have tamper-evident seals to ensure that once the seal is broken, the package cannot be resealed; this eliminates the risk of opened and contaminated packages being mistaken for sterile ones. One type of tamper-evident seal is applied to pouches and sterile packaging tubing using a heat sealer. Heat sealers are designed to unite surfaces by heat and pressure to make a closure. That closure creates a tamper-evident seal for the package.

Objective 2: Discuss sterilization pouches designed for heat sealers

SP professionals most commonly use heat sealers to seal sterilization pouches. These pouches may be open-ended and



Only pouches and tubing that are designed for sterilization and cleared by the US Food and Drug Administration (FDA) should be used in SPDs. When selecting a heat seal packaging system, the heat sealer and the type of packaging used must be compatible. Pouches that can be heat sealed will indicate the sealing temperature and method in the manufacturer's instructions for use (IFU).

of a prescribed size, or they may come as tubing on a roll that allows the user to cut it to the desired length for the item being packaged.

Only pouches and tubing that are designed for sterilization and cleared by the US Food and Drug Administration (FDA) should be used in SPDs. When selecting a heat seal packaging system, the heat sealer and the type of packaging used must be compatible. Pouches that can be heat sealed will indicate the sealing temperature and method in the manufacturer's instructions for use (IFU). Some pouches require a lower temperature than others. For example, pouches used in steam sterilization have a higher sealing temperature requirement than pouches designed for some low-temperature sterilization processes. If two separate temperature requirements are needed, it is best to use two separate heat sealers to avoid delays and errors.

Objective 3: Review heat sealer basics

Like all equipment, heat sealers must be used properly, checked for functionality and receive specific maintenance to ensure proper operation. Like all equipment used in the SPD, heat sealers must be operated exactly as outlined in their IFU. Operators can reduce the risk of failure by performing the following:

Ensuring the packaging and heat sealer are compatible. The manufacturer of the sealer and/or pouch material must verify that the two are compatible. If they are not, the seal may not bond, or there may be "burn through"; both situations will compromise the seal and render the package unusable.

Following the IFU. The heat sealer's operating instructions should be carefully followed. The manufacturer's instructions for temperature settings, applied pressure during the sealing

process, and contact times should be written into procedures and consistently followed.

Selecting the correct pouch for the temperature setting. Not all pouches require the same sealing temperature. As previously stated, pouches made of materials for low-temperature sterilization may need a lower seal temperature than pouches designed for steam sterilization.

Reducing the risk of incomplete seals. Multiple-band or wide-band heat sealers should be used to reduce the possibility of an incomplete seal. It is important to ensure that the sides of the pouch are flat together, with no creases that may impede the sealing process. Pouches that have defective seals must be repackaged. Proper seals will not have folds, bubbles or wrinkles.

Ensuring that all heat sealer operators are properly trained. Any piece of equipment is only as good as its operator. Training should include familiarity with the heat sealer's IFU and the IFU of the packaging to be used. Training should also address processes to prepare packages for heat sealing, how to heat seal properly, and processes for checking the integrity of heat seals. All training should conclude with competency testing.


Reporting any issues with sealing. Failure of the sealing process may indicate that the heat sealer is in need of adjustment or repair. Technicians should know basic troubleshooting steps and if they do not indicate the source of the problem, a process should be in place to notify designated maintenance personnel.

Ensuring that regular maintenance is performed. Heat sealers require specific maintenance to ensure that sealing



For many SPDs, heat sealers are workhorses that generally are given little thought and attention; however, like all equipment used in the department, requirements must be met to help ensure that each heat sealer provides a proper seal on every package. The first necessary requirement is ensuring technicians have the knowledge and skills to use the device properly and safety.

Conclusion

For many SPDs, heat sealers are workhorses that generally are given little thought and attention; however, like all equipment used in the department, requirements must be met to help ensure that each heat sealer provides a proper seal on every package. The first necessary requirement is ensuring technicians have the knowledge and skills to use the device properly and safety. Ensuring proper function of the heat sealer is another essential requirement. SP professionals should always ask the question, “How do we know the heat sealer is working?” 

temperatures are calibrated, worn parts are replaced and the machine is in good working order. This work should be performed by qualified Biomedical or Facility Engineering technicians.

Objective 4: Discuss quality assurance testing for heat sealers

Quality assurance (QA) products are available to help determine if a heat sealer is functioning as designed. These tests often detect issues before they become obvious to the operator and include the following:

Heat Seal Testing - This heat seal test uses material like a sterilization pouch to help operators identify issues in seal integrity. The test is sealed and inspected. Sections of the test provide areas for documentation of the test results. The test can be filed or scanned for a paperless record system.

Pouch Seal Testing - This type of test uses ink to identify possible breaches in the seal of a heat-sealed or self-sealed pack. A pouch is sealed with an ink packet inside. Once sealed, the ink packet is broken and the ink runs to the seal. The ink will contact the seal and run into small crevices or other breaches in the seal. If the test fails or other performance issues

are identified, work processes should be reviewed; if work processes are deemed appropriate, the heat sealer should be checked before continued use.

Documentation

Every QA process performed in SP should be documented. That documentation provides evidence that the SPD has performed tests to measure the device’s ability to perform as designed. Documentation forms may be available with some testing products. If such forms are not available, the technician performing the testing should document the following:

- Unique identifier of the heat sealer (serial number or unique facility identification number);
- Type of test;
- Date of testing;
- Name of the technician performing the test;
- Lot number of testing product; and
- Test results.

Testing is designed to measure the seal of a pouch, but it may also serve as an effective training tool to help staff understand the importance of small imperfections in seals and the danger they pose to package integrity.

RESOURCES

ANSI/AAMI ST79: 2017, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*.

International Association of Healthcare Central Service Materiel Management. 2016. *Central Service Technical Manual*, 8th Ed.



CRCST Self-Study Lesson Plan Quiz - Turning Up the Heat on Heat Sealer Quality

Lesson No. CRCST 171 (Technical Continuing Education - TCE) • Lesson expires March 2023

1. Heat sealers are often overlooked/taken for granted because:
 - a. They are so difficult to operate
 - b. They rarely malfunction
 - c. They are rarely used
 - d. They appear simple
2. Sterile packaging is designed to protect medical devices:
 - a. During cooling
 - b. In-between sterilization and use
 - c. In-between cleaning and sterilization
 - d. During opening
3. Tamper-evident seals provide evidence that a package:
 - a. Has been sterilized
 - b. Is ready for use
 - c. Has been opened
 - d. Is ready for sterilization
4. Heat sealers function by:
 - a. Melting adhesive that technicians apply to package seams
 - b. Fusing paper sheets together to create a sterile bond
 - c. Using extremely high temperatures to form seams in packaging
 - d. Using heat and pressure to seal pouches and tubes
5. Sterilization pouches and tubing designed to be heat sealed must be:
 - a. Industrial strength
 - b. Waterproof
 - c. Cleared for use by the US Food and Drug Administration
 - d. All the above
6. Heat sealers must be:
 - a. Set to the temperature indicated on the sterilization pouch or tube instructions for use
 - b. Set to their highest temperature to be effective
 - c. Shut off in-between uses
 - d. Cleaned daily using a germicide
7. Heat sealer training for Sterile Processing technicians must include:
 - a. Maintenance checks
 - b. Safety checks
 - c. Competencies
 - d. Self-sealing techniques
8. Creases in seals:
 - a. Can allow microorganisms to enter packages
 - b. Are acceptable if they do not run the length of the seal
 - c. Can be sealed after sterilization using autoclave tape
 - d. Do not impact package sterility
9. To ensure proper function, heat sealers must receive:
 - a. Safety checks
 - b. Function checks and replacement of worn parts
 - c. Temperature calibration
 - d. All the above
10. Heat seal testing:
 - a. Provides verification that the heat sealer is functioning
 - b. Increases the likelihood that seals will provide protection for package contents
 - c. May be an effective training tool
 - d. All the above
11. Pouch seal testing:
 - a. Must be performed monthly
 - b. Should be performed after sterilization
 - c. Uses ink to identify seal defects
 - d. All the above
12. If a failure is identified during pouch seal testing:
 - a. Work practices and the heat sealer should be checked
 - b. The test should be repeated two more times to determine if an issue really exists
 - c. The heat sealer temperature should be increased
 - d. The heat sealer should be restarted to calibrate
13. Quality assurance tests for heat seals:
 - a. Are required by law in most states
 - b. Can help identify seal issues before they become obvious to the operator
 - c. Can identify seals that require resealing
 - d. Can serve as tests for items before they are placed in the sterilizer
14. In addition to verifying seal integrity, heat seal testing:
 - a. Can be used to provide evidence of the sterility of peel pouches
 - b. Can be used to extend shelf life of peel packs
 - c. Provides evidence of heat sealer temperatures
 - d. Can be used as a training tool for employees
15. Heat sealer quality testing must be documented because it:
 - a. Is required by law
 - b. Is required in the device's instructions for use
 - c. Provides evidence that testing took place
 - d. Provides assurance that items are sterile

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