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External Transport of Medical Devices

BY SUSAN KLACIK

Learning Objectives

1. **Describe the concerns related to shock and vibration during transport.**
2. **Examine methods to maintain the integrity of sterile packages.**
3. **Describe how to safely transport contaminated items.**

In recent years, there has been a shift in sterile processing. Previously, nearly all processing was performed in the same healthcare facility where the instrumentation was used. Recently, this trend is changing. For a variety of reasons, instrumentation used at a facility may be processed at an off-site location that is across campus, across town, or elsewhere. In the past, sterile processing departments were located near surgery departments. However, this space is valuable and often needed for other important uses, such as patient care procedures near surgery or to expand the surgical department.

Semi-critical devices that were previously high-level disinfected (HLD) are transitioning to low temperature sterilization methods. This sterilization process can be expensive due to equipment and operational costs. To reduce costs, low-temperature sterilization is centralized in one facility. Many new medical devices are complex and may require specialized training and equipment. Processing these types of devices is also centralized to one facility to keep costs down.

Processing medical devices off-site has solved many of these problems. However, the external transport of medical devices has resulted in new concerns. When medical devices are moved within a healthcare facility, they are transported on smooth floors in a controlled environment, temperature and humidity are monitored, and transport is completed within minutes. In contrast, when medical

devices are transported over roadways, they are exposed to new risks that can harm the integrity of the device and its packaging. The environment is not controlled, and temperature and humidity may not be monitored during transport. Roadways are uneven, which expose devices to shock and vibration. Additionally, if contaminated devices are not transported correctly, they can pose safety and regulatory risks. The transport time is extended from minutes to hours, or even days in some cases. This lesson plan discusses these risks and how they are addressed in the new *AAMI TIR 109:202*, which focuses on the external transport of reusable medical devices for processing.[1]

Objective 1: Describe the concerns related to shock and vibration during transport.

New equipment received at a healthcare facility is delivered in a box that is specially packaged to reduce shock and vibration experienced over roadways. For example, scopes are packaged in foam with cutouts specifically designed for each scope, which reduces its movement during transport. The scope fits snugly in the foam, which is placed in a protective case. Medical device manufacturers design their packages to prevent damage during transport. The manufacturer performs specific testing of the package to demonstrate it can safely transport items over roadways and deliver them to healthcare facilities without damage.

Typically, when a healthcare facility transports an item over public roadways, it is in a sterilization package or biohazard container that was not intended for transportation over public roadways. This can result in damage to the item. Shock and vibration can occur due to improper handling, speed, maneuvers, road conditions, sudden stops, or similar factors. Some damage may be visual and easily detected during inspection. However, some damage may not be noticed immediately as failure can occur slowly over time, causing parts to become loose, displaced, or misaligned.

Monitors are available to measure shock and vibration, helping to accurately determine if conditions are serious enough to cause damage. This information could be used to prevent damage during transport. Using the right monitoring devices can provide a traceable record that can improve transport by changing the route,

Electronic Monitor	Description
Single-use chemical indicato referred to as critica temperature indicators)	The result is based on a phase change or chemical reaction that occurs as a function of temperature.
Electronic temperature indicator	A compact, portable monitor that measures temperature over time by means of a built-in sensor.
Electronic data logging monitor	A small portable monitor that measures and stores temperature at pre-determinded time intervales by means of an electronic sensor
Electronic data integrator	A monitor that combines features of an electronic temperature indicator with the report/data producing capabilities of an electronic data logging monitor that combines the features and functions of a Go/No-Go device with the record retention and data.

Table 1: Electronic monitors for tracking temperature during transport

Lesson:

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Ocotober 2025

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Quiz Answers:
Answers: 1. C, 2. C, 3. A, 4. D, 5. A, 6. C, 7. C, 8. B, 9. C, 10. B, 11. D, 12. D, 13. A, 14. A, 15. D

time of day, or by identifying poor driving habits. Real-time shock and vibration monitoring devices can show unacceptable shock and vibration levels and can alert the receiver of a potential problem. This allows the item to be inspected or rejected before use.

When medical devices are transported over roadways, they should be assembled in a manner that prevents shock and vibration. When possible, instrument trays with specific instrument holders that secure instruments to a tray should be used. These trays should be placed into a transport carrier in a way that helps prevent damage. Using packing materials such as bubble cushioning (a plastic material with small air-filled bubbles), packing foam, or packing paper should be considered. For sterile items, protective packaging should also be considered.

Objective 2: Examine methods to maintain the integrity of sterile packages.

To prevent damage to packages or medical devices that are externally transported, they should be prepared to provide additional protection. The risks to sterile packages from exposure to the external environment include contamination from moisture, excessive humidity, condensation caused by exposure to temperature extremes, and microorganisms. When preparing sterile items for external transport, protective packaging can be used to provide better safety. Protective packaging can be both internal and external. Internal protective packaging is used inside the package to protect it from breaches. For example, a corner guard helps protect the package from tears.

External protective packaging is used outside of the sterile barrier system and is not a replacement for it but rather is used in conjunction with it. External protective packaging is referred to as sterility maintenance covers in *ANSI/AAMI ST 79:2017 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*.[2] According to this sterilization standard, they are designed to provide protection against environmental contaminants such as dust, and not to provide a microbial barrier. They consist of a plastic material that provides a barrier to moisture and dust. This additional barrier may help maintain the sterile integrity of the package when exposed to uncontrolled environments such as external transport.

Sterility maintenance covers are designed to protect the integrity of the sterile barrier system. Only protective packaging that has been designed and validated by the manufacturer and intended for this purpose should be used. Sterility maintenance covers should be applied as soon as possible after sterilization when the packages are cooled and dry. Applying a sterility maintenance cover on a package that is not cool and dry could result in condensation, rendering it contaminated and not sterile. They should be sealed following the manufacturer's instructions for use (IFU) and the package content label should be visible through the protective packaging. If needed, a duplicate label should be placed on the protective packaging.

To further protect processed items during external transportation, they should be carefully placed in transport carriers that protect package integrity. A transport carrier is a portable, closeable, rigid, and leak-proof enclosure specifically designated to temporarily contain medical devices during transit from one facility to another facility. Safety issues of ergonomics and weight should also be considered. To prevent shock and vibration, packing material may be used to further safeguard the items. Staff transporting tote boxes and carts should be able to transport them safely.

Sterility maintenance covers are designed to protect the integrity of the sterile barrier system.

Reusable transport carriers such as tote bins or carts should be clean. Carrier construction should have surfaces that tolerate thorough cleaning and disinfection. Prior to use, transport carriers should be inspected for visible soils or debris. Tamper evident locks on transport carriers may be used to identify if they were opened. The transport carrier should be labeled with a description of the contents, date and time, package origin and destination, if hazardous medication is included and its processed status noting clean, disinfected and/or sterile. The items should be recorded either manually or electronically for both the sending and receiving facility and the records should be maintained.

Objective 3: Describe how to safely transport contaminated items.

Contaminated items that are transported internally and externally must follow the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard [29 CFR 1910.1030] requiring that the container be puncture-resistant, leak-proof on the sides and bottom, closeable, and labeled with the biohazard label, a red bag, or other means of identifying contaminated contents. Additionally, when items are transported on public roadways, they must also meet the requirements of the Department of Transportation (DOT), and the Environmental Protection Agency (EPA). The DOT requires hazardous communication labeling for infectious materials. It is important to note that state and local governments may have their own requirements.

Once soils dry on instrumentation, they are difficult to clean. Keeping soiled instruments moist reduces the risk of corrosion and biofilm formation and facilitates

the decontamination process. Recent research has shown the effects of time, temperature, and humidity on soiled devices.[3] This research supports concerns about transporting soiled medical devices in uncontrolled environments. Soils that were allowed to dry on medical devices at approximately 71 F became less soluble the longer they were allowed to dry. There was no statistical difference in the change of solubility between one and eight hours of dry time. A statistical difference was observed between 8 and 15 hours, with the most soil retention at 72 hours. The temperature research demonstrated that as temperature rises after 22 C/71.2 F the solubility decreases, and the soils dry onto the device. Humidity research demonstrated that at less than 50% relative humidity (RH) the soil retention was higher than at higher levels of humidity. At 100% humidity the soil did not dry. This research shows the importance of maintaining moisture content for soiled instruments.

Contaminated items should be prepared in a manner that prevents debris from drying. Methods to prevent the drying of soils on medical devices include using a towel moistened with water (not saline), a point-of-use treatment product specifically intended for this use, or by placing items inside a package that maintains moist conditions. The IFU for medical devices and the product used to prevent drying should be reviewed and followed.

Contaminated instruments should be carefully placed into a clean, biohazard-labeled transport carrier, such as a tote bin or cart. Care should be taken to prevent shock and vibration during transport. Safety considerations of ergonomics and weight should be addressed. The transport carrier should also be labeled with a description of contents, date and time, package origin and destination. The items should be recorded either manually or electronically for both the sending and receiving facility, and the records should be maintained.

Monitoring devices are available to track temperature and humidity during transport (Table 1). They can be used to determine if an item was exposed to environmental conditions outside of the acceptable range, as a post-use analytical tool for identifying weaknesses in the transport system, conducting a trend analysis, or collecting performance data.

Conclusion

The external transportation of medical devices comes with new challenges that need attention. Exposing medical devices to uncontrolled environments increases the risk of damage and contamination. In 2025, AAMI released a new guidance document to address these concerns, the Technical Information Report AAMI *TIR109:2025 External transport of reusable medical devices for processing*. **HPN**

REFERENCES:

1. AAMI TIR109:2025 External transport of reusable medical devices for processing
2. ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*
3. Kremer TA, Carfaro C, Klacik S. Effects of time, temperature, and humidity on soil drying on medical devices. BI&T. 2023, pp 58-66 https://doi.org/10.2345/0899-8205-57.2.58 Accessed 15 August 2023.

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External Transport of Medical Devices - Practice Quiz

1. **Which reason below is not a reason to relocate sterile processing to an off-site facility?**
   A. The space is needed for other necessities, typically for patient care procedures closer to surgery.
   B. Semi-critical devices that were previously high-level disinfected (HLD) are being transitioned to sterilization using a low temperature sterilization modality. To reduce costs low temperature sterilization is centralized to one facility.
   C. The union contract mandates only one processing center.
   D. New specialized medical devices are complex to process; this specialized processing is centralized at one center.

2. **What has been identified as a concern for external transportation of medical devices?**
   A. Smooth floors
   B. Regulated environment
   C. Shock and vibration
   D. Quick turn-around

3. **Which of the following variables can be controlled when performing external medical device transportation?**
   A. Transport route
   B. Temperature
   C. Humidity
   D. Shock and vibration

4. **Equipment received at a healthcare facility from a manufacturer is packaged in a manner that:**
   A. Provides promotional material.
   B. Shows the route taken to the facility.
   C. Shows the temperature it was exposed to.
   D. Is packaged in a manner that greatly reduces the shock and vibration experienced over the roadways.

5. **Which of the following actions below do not result in shock and vibration damage?**
   A. Transport over smooth floors
   B. Improper handling
   C. Sudden stops on the roadway
   D. Poor road conditions

6. **Which of the following items could be considered as an external transport carrier?**
   A. A corrugated box
   B. A cardboard box
   C. A closable plastic tote bin
   D. A shopping bag

7. **Which of the following material can be used as packing materials to reduce shock and vibration?**
   A. Newspaper
   B. Cotton balls
   C. Packing foam
   D. Packing gauze

8. **What is considered as an internal protective packaging?**
   A. Packing gauze
   B. Corner protectors
   C. Packing foam
   D. Cotton balls

9. **When should a sterility maintenance cover be placed on a sterile instrument set?**
   A. Before it is placed into a transport carrier
   B. Prior to sterilization
   C. As soon as possible after sterilization when the packages are cooled and dry
   D. When the sterile package has a hole in it

10. **What could occur if a package is placed into a sterility maintenance cover immediately after sterilization before it is allowed to cool and dry?**
    A. Dust and debris build up would be prevented.
    B. Condensation could form inside the sterility maintenance cover rendering it contaminated.
    C. It could be safely transported outside of the building without another covering.
    D. The inner package could deteriorate.

11. **The use of tamper-evident locks on transport carriers indicates:**
    A. It passed inspection.
    B. It has been received.
    C. It was subjected to shock and vibration.
    D. Identifies the carrier was opened.

12. **What does not need to be included in the labeling of a transport carrier?**
    A. Description of contents
    B. Date and Time
    C. Package destination
    D. When it will be used

13. **To prevent the risk of corrosion and biofilm formation and facilitate the decontamination process, contaminated (soiled) instruments should be kept**
    A. Moist
    B. In a dark area
    C. At a high temperature
    D. In a cool room before transport

14. **Which of the following is not an acceptable method of keeping contaminated instruments moist?**
    A. Use of towel moistened with saline
    B. Use of a towel moistened with water
    C. A point of use treatment product specifically intended for this use
    D. Placing contaminated instruments inside a package that will maintain moist conditions

15. **Which of the following documents provides information on the proper external transportation of medical devices?**
    A. FDA Guidance on Medical Device Patient Labeling; Final Guidance
    B. U.S. Department of Transportation (DOT) Hazardous Materials Regulations (HMR), 49 CFR
    C. Centers for Disease Control and Prevention (CDC). Guidelines Environmental Infection Control in Healthcare Facilities
    D. AAMI TIR109:2025 External transport of reusable medical devices for processing