





Maintaining the Integrity of the Assembly Area

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LEARNING OBJECTIVES

1. Discuss the importance of a clean and controlled assembly area
2. Explain the technician's role in maintaining the physical environment of the clean assembly area
3. Outline the requirements for individuals entering the clean assembly area

Each day in healthcare facilities across the world, instruments are used in surgery and then returned to the Sterile Processing (SP) area for reprocessing. Simply stated, instruments are cleaned, made safe for handling, inspected, packaged, sterilized and stored until they are needed again. The goal of this multistep process is to take a contaminated instrument and make it safe for use in a future procedure.

Many precautions must be taken when preparing patient-ready medical devices. After an instrument has been decontaminated, special care is required to help ensure that the instrument is not recontaminated before it is sterilized. To prevent instruments from coming into contact with possible contaminants, SP professionals must maintain the clean assembly area and adhere to strict requirements for attire, hygiene and behaviors. This lesson examines the technician's role in providing a clean and controlled environment during instrument assembly.

Objective 1: Discuss the importance of a clean and controlled assembly area

The clean assembly area—the workspace where medical devices are handled during inspection, testing, assembly and packaging—must be designed to prevent the recontamination of the instruments. Creating an area that is easy to keep clean is the first step in maintaining its integrity. The assembly area should be constructed of materials that can be cleaned and disinfected, and regular cleaning must be scheduled for all surfaces. The environment requires specific air exchange, temperature and humidity controls, and the space must be restricted to limit traffic flow.

Instruments in the assembly area have been cleaned and made safe for technicians to handle. Every effort, however, must be made to help ensure that the instruments will not become recontaminated. The cleaner an item is when it undergoes sterilization, the better chance the sterilization process will be successful. SP professionals must consistently maintain a work area that



shields instruments from contaminants such as microorganisms, dust and lint—all of which can jeopardize patient safety. If the sterilization process fails and an unsterile instrument reaches a procedure, the patient's risk of infection increases.

Objective 2: Explain the technician's role in maintaining the physical environment of the clean assembly area

Specific standards and guidelines set the parameters for temperature, humidity, air exchanges and other physical requirements of the clean assembly area. Similar to most aspects of reprocessing, however, success depends on the people who work within the area.

Technicians play an important role in maintaining the physical workspace. They are the guardians of the clean assembly area. SP staff must ensure that contaminants are not introduced to the area and that it is kept clean to reduce the number of microorganisms. Doing so helps increase the likelihood that items will remain clean before sterilization, thereby increasing the chance of successful sterilization.

In most facilities, the Environmental Services department (EVS) provides general daily cleaning services, including trash collection, floor cleaning and fixture cleaning. EVS staff may also be responsible for regularly scheduled cleaning of air vents, walls, ceilings, etc. Even so, SP staff are responsible for cleaning their work areas and ensuring that high-touch areas—such as door handles, light switches, computer keyboards and scanners—are routinely cleaned to keep microbial contamination to a minimum. SP professionals are also responsible for keeping inspection and testing equipment clean. By maintaining a clean work area, contaminants can be minimized, along with the risk of recontaminating instruments.

Technicians must also prevent contaminants from being brought into the work area. They must wash their hands thoroughly before entering the area to minimize the microorganisms introduced. They should also keep their hands clean while in the area by handwashing with soap and water or using an approved hand sanitizer.

SP professionals must also guard against items entering the work area that have a potential to negatively impact future sterilization processes. Personal items known to carry large amounts of microorganisms—such as electronic devices, backpacks, bags or purses—should be kept out of the work area. These items carry contaminants from various sources that can pose a threat of contamination to the environment. If electronic devices are brought into the work area, they must first be decontaminated.

Bringing food and drink into the department's work areas also goes against standards, guidelines and best practices. For example, if a snack (like chips or chocolate) was brought into the area and consumed by staff, the oils in those foods could be transferred from the technician's hands to the item being sterilized. Those oils could create a barrier that would impede the sterilant's contact with the instrument and result in an unsterile instrument. Food items can also invite insects and rodents. SP technicians assigned to the clean assembly area must always protect that area from microorganisms and contaminants that may pose a risk to their processes and patients.

Objective 3: Outline requirements for individuals entering the clean assembly area

People entering the clean assembly area are the biggest threat to instrument recontamination. For that reason, strict

requirements apply to anyone who enters the area. Those requirements begin with personal hygiene.

Personal cleanliness is a must. Hair, body and fingernails should be clean, and hand hygiene should be performed several times per shift (or more, as needed). Fingernails should not extend beyond the fingertips because long nails can harbor soil and bacteria. Artificial nails and nail polish should not be worn. The same is true of jewelry, including rings and watches, which can harbor microorganisms and damage gloves and other personal protective equipment (PPE).

All SP technicians should monitor their personal health and should not report to work if they are sick. Not only could an illness endanger the integrity of the work area, germs could be passed to co-workers and others within the facility.

It is important to remember that the clean assembly area is a semi-restricted area. SP technicians assigned to the area are responsible for monitoring traffic in it. Unauthorized personnel should not be allowed, and traffic flow should be kept to a minimum. Access should be limited to authorized personnel who are properly attired. Anyone entering the semi-restricted area should wear clean surgical scrubs provided and laundered by the facility. Surgical scrubs should be donned (put on) clean and laundered between uses. Street clothes should never be worn in the semi-restricted area.

Employees should not wear scrubs outside the building and should change into street clothes before leaving the facility for the day or when traveling between facilities. Attire approved for the clean assembly area is designed to protect the area from contaminants that could be brought in on clothing. Hair coverings are designed to reduce the risk of hair falling into a tray or wrap.



All hair, except eyebrows and eyelashes, should be completely covered. Beards, regardless of length, should be covered using a beard cover. To be effective, attire in semi-restricted areas must be worn properly. Scrub attire should be changed if it becomes contaminated or soiled, and shoes should be clean and designed to protect the wearer from injury.

Although the dress code may seem straightforward, basic requirements are often ignored. When attire is worn inappropriately, for example, caps that do not cover all hair, the purpose of the requirement is defeated. Choosing to follow only parts of the dress code (such as wearing appropriate attire but also wearing jewelry) does not meet the intent of the requirements. SP technicians assigned to the clean assembly area must strive to ensure that all parts of the dress code are followed to protect the integrity of the work area.

Personal items (including decorative items) should not be kept in the clean assembly area. They can harbor microorganisms and trap dust or lint, which can become airborne and settle on instruments before they are packaged. When lint or dust particles enter a wound, they can carry microorganisms that can cause infection. These particles may also become irritants within the wound and impede the patient's healing process.

Electronic devices and backpacks are also not permitted in the clean assembly area. Even items inadvertently kept in pockets can jeopardize the integrity of the area. For example, if an SP professional has money or tissues in their scrub pocket, they may reach into that pocket and accidentally contaminate their hand. Those contaminants/microorganisms can then be transferred to the work area or onto instruments being prepared for sterilization.

Contamination can also occur when soiled instruments are found in the clean assembly area. Technicians must inspect every instrument for cleanliness. If remaining soil is found on an instrument, the device should be sent back to the decontamination area for recleaning. The work area must then be cleaned and disinfected before work is resumed. Technicians should never attempt to reclean an instrument in the clean assembly area.

Conclusion

Keeping the assembly area clean begins with ensuring that the physical area meets requirements and is properly and consistently maintained. Technicians assigned to the clean assembly area must remember that they are guardians of the area, and it is their duty to maintain its integrity. Doing so protects their patients.

Note: To review specific standards for clean area integrity, please refer to the Association for the Advancement of Medical Instrumentation, ANSI/AAMI ST79:2017 & 2020 Amendments A1, A2, A3, A4, Comprehensive guide to steam sterilization and sterility assurance in health care facilities, and the Association of periOperative Registered Nurses (AORN) Guidelines for Perioperative Practice (2020): Surgical Attire.