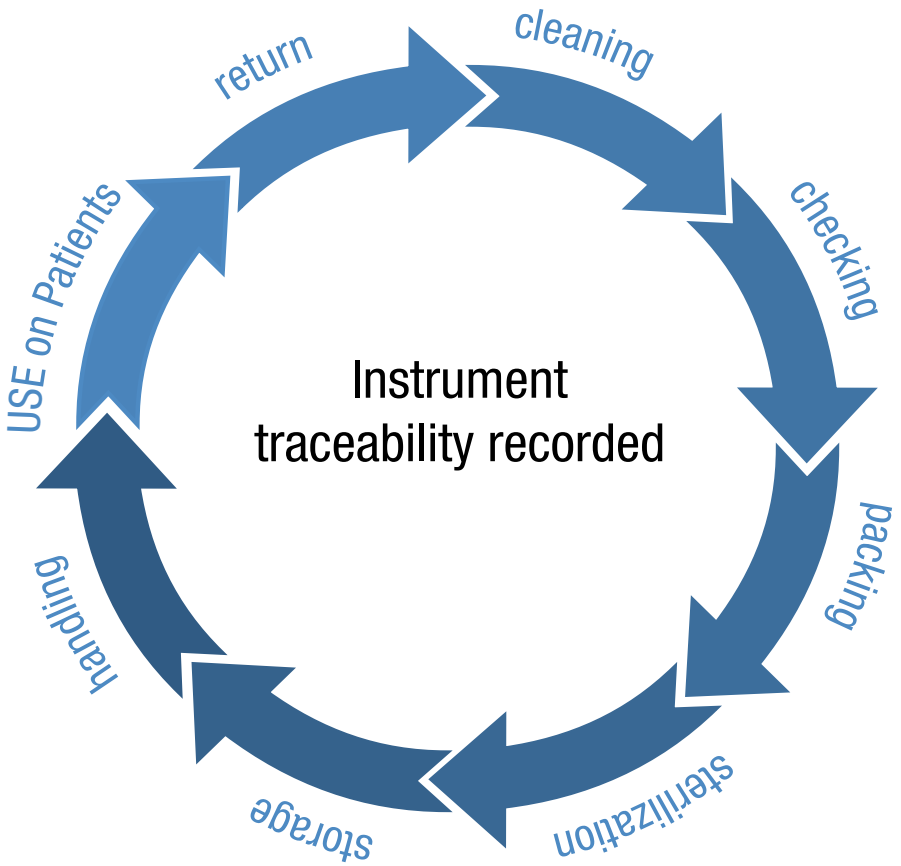
3M™ Sterilisation

Introduction to the Sterilization Process

The Decontamination Cycle in a hospital environment:



Introduction to the Sterilization Process

There are five basic steps in the sterilization process:

- **Clean/Disinfect**
- **Prep/pack**
- **Sterilization**
- **Store**
- **Issue/use**

1. Clean and Disinfect

The first step, cleaning and disinfection, is critical because soil must be removed before instruments are ready for further processing, as the presence of soil or organic material on instruments reduces disinfection or sterilization effectiveness . If the instruments are going to be high level disinfected, a check of the high level disinfectant concentration in the processor/soaking tray is required to ensure its minimum effective concentration level. When time lines are tight and customers are requesting quick turnaround, it's often tempting to cut corners in the cleaning process. Failure to properly prepare items for sterilization can cause a failure of the sterilization process for that item.

1.
X. Chaufour, MD; K. Vickery, Evaluation of disinfection and sterilization of reusable angioscopes with the duck hepatitis B model, J Vasc Surg 1999; 30: 277-282.

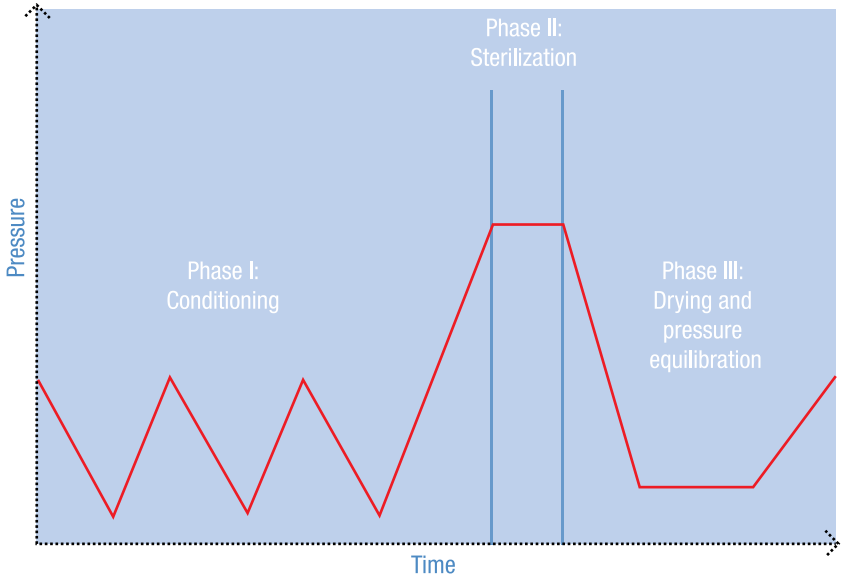
2. Prep and Pack

Prep and pack is next in the sterilization process.

Packaging materials should be equilibrated for a minimum of two hours at room temperature (e.g. 20°C to 23°C) and at a relative humidity between 30 to 60% before use. Before packing, instruments should be dry and inspected for cleanliness and flaws or damage. Multipart instruments should be disassembled for sterilization. Instruments should be held open and unlocked during sterilization. For successful surface sterilization all surfaces must be exposed to the sterilization conditions for a predetermined time. Generally, the sterilant must be in contact with all the surfaces (e.g. saturated steam, ethylene oxide) for a defined time. When packing items for steam sterilization, whether in soft wrappers, paper-plastic pouches or in rigid container systems, it's important to consider air removal and steam penetration. With the use of internal and external indicators in the packages the effectiveness of the sterilization process can be monitored.

3. Sterilize

In step 3, instruments are exposed to the actual sterilization conditions (saturated steam, ethylene oxide, etc.). Every sterilization process consists out of three phases. Phase I the conditioning phase, phase II the actual sterilization phase and phase III: bringing the sterilizer in a safe state to open. Or in other words: bringing the sterilizing agent to all surfaces (phase I), the actual sterilization phase (phase II) and removal of the sterilizing agent from all surfaces (phase III).



A sterilization process is a combination of the sterilizer (including the sterilizer agent), the process, the load, the loading pattern and the wrapping (system). The results of a sterilization process can be determined after the sterilization cycle. If a fail is recognized at the end of the process often it is initiated in phase I or before. The most important phase in steam sterilization is phase I, or even the preparations before phase I. The air removal or steam penetration should be checked before use of the sterilizer. Routine monitoring of the sterilization process is needed to ensure effective sterilization (see ISO 17665). This is done through the use of equipment displays and printouts and proper selection and use of Bowie-Dick type tests (ISO 11140-3 and -4) and indicators.

4. Store

In the fourth step, instruments are removed from the sterilizer/processor and quality system documentation is completed. Then, appropriate storage is required to maintain the integrity of the packaging and the sterility of the instrument(s) prior to use. Documentation for each individual pack is recommended by quality systems (e.g. ISO 9000 and ISO 13485).

5. Issue and Use

Finally, when items are requested for use, they are retrieved from storage and checked to ensure the external chemical indicator has reached its endpoint and then issued for use. Prior to use, the internal chemical indicators are checked to ensure that the surfaces are exposed to the sterilization condition for the predetermined time.

Points of attention

Sterilization process monitoring impacts just two of these steps, Sterilize and Issue/Use. Your instruments may have been through the sterilizer, but that does not mean they are sterile. Many things can adversely affect the sterilization process.

- **The sterilizer can malfunction.**
- **Time or temperature can be incorrect.**
- **Air may not be removed.**
- **Sterilization conditions may not reach the center of the pack.**
- **Improper loading or packaging.**

Monitoring tools verify the outcome of “Sterilize” and supply safeguards to “Issue/Use” and contribute that no non-sterile medical devices are released for use on patients. The threat of postoperative infections caused by non-sterile medical devices makes sterilization process monitoring extremely important.

For further information see our 3M Sterilization Assurance Program.

The transportation and logistics within a hospital is not addressed in this tutorial.