

HOSPITAL PHARMACY

**CENTRAL STERILE
SUPPLY SERVICES-
ROLE OF PHARMACIST**

RESEARCH DOCTOR PHARMA

Central Sterile Supply Department (CSSD)

The Sterile Processing Department (Central Supply, or Sterile Supply as it is also known), comprises that service within the hospital in which medical/surgical supplies and equipment, both sterile and nonsterile, are cleaned, prepared, processed, stored, and issued for patient care.

Until the 1940s, medical/surgical supplies were, for the most part, processed and maintained in the departments and patient care areas in which they were to be used. Under this system, there was considerable duplication of effort and equipment, and it was difficult to maintain consistently high standards for sterilization technique and product quality throughout the health care facility.

As the number and variety of surgical procedures grew and the types of medical devices, equipment, and supplies proliferated, it became apparent that a centralized processing was needed for efficiency, economy, and patient safety. The work of scientists W.B. Underwood and J.J. Perkins (3) was instrumental in encouraging health care facilities to establish a separate and distinct department, the Sterile Processing Department, with specialized expertise and direct responsibility for providing clean and sterile medical/surgical supplies and equipment to patient care areas.

Functions

Sterile Processing Departments are typically divided into four major areas to accomplish the functions of decontamination, assembly and sterile processing, sterile storage, and distribution.

In the decontamination area, reusable equipment, instruments, and supplies are cleaned and decontaminated by means of manual or mechanical cleaning processes and chemical disinfection.

Clean items are received in the assembly and packaging area from the decontamination area and are then assembled and prepared for issue, storage, or further processing (like sterilization).

After assembly or sterilization, items are transferred to the sterile storage area until its time for them to be issued.

Several major functions are carried out in the distribution area: case cart preparation and delivery; exchange cart inventory, replenishment and delivery;

telephone-order and requisition-order filling; and, sometimes, patient care equipment delivery.

Decontamination Process

Decontamination is the physical or chemical process that renders an inanimate object that may be contaminated with harmful microbial life safe for further handling. The objective of decontamination is to protect the preparation and package workers who come in contact with medical devices after the decontamination process from contracting diseases caused by microorganisms on those devices.

Steps in the Decontamination Process

Transport – Used supplies and equipment should be collected and taken to the Decontamination Area in the Sterile Processing Department in a way that avoids contamination of personnel or any area of the hospital. Equipment should be covered and supplies should be moved in covered carts, closed totes or containers, or closed plastic bags.

Attire – Personnel working in the decontamination area should wear protective clothing, which includes a scrub uniform covered by a moisture-resistant barrier, shoe covers, rubber or plastic gloves, and a hair covering. During manual cleaning processes, when splashing can occur, safety goggles and a face mask should be worn.

Sorting – sorting begins at the point of use. Handling of contaminated items should be minimized unless the user of the device is already wearing full personal protective attire, such as following care in the operating room. In areas where workers are wearing no or minimal protective attire, sorting should consist only of removing disposable sharps and discarding other single-use items.

Soaking – this is necessary only if you have lumens or other complex designs that are filled with debris or if the devices are very bloody and cannot be rinsed or wiped at the point of use.

Washing

- Detergent** – should be compatible with the materials in the device and suited for the type of soil. Consult the recommendations from the device manufacturer.
- Equipment** – many types of cleaning equipment are available, the most commonly used are:

Washer/decontaminator – the washer/decontaminator is used to clean heat-tolerant items. The cycle consists of several washes and rinses, followed by a steam sterilization cycle appropriate for the types of items contained in the load. Although subjected to a cycle designed to sterilize clean items, items processed in a washer/decontaminator should not be assumed to be sterile at the end of the process. The reason for this is that items enter the washer/decontaminator with an unknown, but probably very high, level of microbial contamination, which the sterilization cycle may not be able to completely destroy.

Ultrasonic – the ultrasonic washer is used to remove fine soil from surgical instruments after manual cleaning and before sterilization. The equipment works by converting high-frequency sound waves into mechanical vibrations that free soil from the surface of instruments. The high-frequency energy causes microscopic bubbles to form on the surface of the instruments and as the bubbles implode, minute vacuum areas are created, drawing out the tiniest particles of debris from the crevices of the instruments. This process is called cavitation.

Inspection – after cleaning, all instruments should undergo inspection before being packaged for reuse or storage. Box locks, serrations, and crevices should be critically inspected for cleanliness. Instruments with cutting edges such as scissors, rongeurs, chisels, curettes, etc., should be checked for sharpness. There should be no dull spots, chips, or dents. Hinged instruments such as clamps and forceps should be checked for stiffness and alignment of jaws and teeth. Tips should be properly aligned, jaws should meet perfectly, and joints should move easily. Ratchets should close easily and hold firmly. Any instruments with pins or screws should be inspected to make sure they are intact. Plated instruments should be checked to make sure there are no chips, worn spots, or sharp edges. Worn spots can rust during autoclaving. Chipped plating can harbor soil and damage tissue and rubber gloves. If any problems are noticed during the inspection process, these instruments should be either cleaned again, or sent for repair depending on the problem observed.

RESEARCH DOCTOR PHARMA

Assembly & Packaging Process

After the instruments have been cleaned and inspected, they are typically assembled into sets or trays according to recipe cards that detail instructions for assembling each set or tray.

Assembly 1

Assembly 2

Instruments and other items that are prepared for sterilization must be packaged so that their sterility can be maintained to the point of use. The materials and techniques used for packaging must allow the sterilant to contact the device during the sterilization process as well as to protect the device from contamination during storage and handling before it is used. The time between sterilization and use may range from a few minutes to several weeks to many months. The packaging material selected must also permit the device to be removed aseptically.

Types of Packaging

- Textiles
- Nonwovens
- Pouch packaging
- Rigid container systems

Sterilization Process

Bacterial spores are the most resistant of all living organisms because of their capacity to withstand external destructive agents. Although the physical or chemical process by which all pathogenic and nonpathogenic microorganisms, including spores, are destroyed is not absolute, supplies and equipment are considered sterile when necessary conditions have been met during a sterilization process.

Methods

Reliable sterilization depends on contact of the sterilizing agent with all surfaces of the item to be sterilized. Selection of the agent to achieve sterility depends primarily upon the nature of the item to be sterilized. Time required to kill spores in the equipment available for the process then becomes critical.

Steam

- Heat destroys microorganisms, but this process is hastened by the addition of moisture. Steam in itself is inadequate for sterilization. Pressure, greater than atmospheric, is necessary to increase the temperature of steam for thermal destruction of microbial life. Death by moist heat in the form of steam under pressure is caused by the denaturation and coagulation of protein or the enzyme-protein system within the cells. These reactions are catalyzed by the presence of water. Steam is water vapor; it is saturated when it contains a maximum amount of water vapor.
- Direct saturated steam contact is the basis of the steam process. Steam, for a specified time at required temperature, must penetrate every fiber and reach every surface of items to be sterilized. When steam enters the sterilizer chamber under pressure, it condenses upon contact with cold items. This condensation liberates heat, simultaneously heating and wetting all items in the load, thereby providing the two requisites: moisture and heat.
- No living thing can survive direct exposure to saturated steam at 250 F (120 C) longer than 15 minutes. And 134c longer than 4 to 7 mint As temperature is increased, time may be decreased. A minimum temperature-time relationship must be maintained throughout all portions of load to accomplish effective sterilization. Exposure time depends upon size and contents of load, and temperature within the sterilizer. At the end of the cycle, re-evaporation of water condensate must effectively dry contents of the load to maintain sterility.

Ethylene Oxide

Ethylene oxide is used to sterilize items that are heat or moisture sensitive. Ethylene oxide (EO) is a chemical agent that kills microorganisms, including spores, by interfering with the normal metabolism of protein and reproductive, processes, (alkylation) resulting in death of cells. Used in the gaseous state, EO

gas must have direct contact with microorganisms on or in items to be sterilized. Because EO is highly flammable and explosive in air, it must be used in an explosion-proof sterilizing chamber in a controlled environment. When handled properly, EO is a reliable and safe agent for sterilization, but toxic emissions and residues of EO present hazards to personnel and patients. Also, it takes longer than steam sterilization, typically, 16-18 hrs. for a complete cycle.

EO gas sterilization is dependent upon four parameters: EO gas concentration, temperature, humidity, and exposure time. Each parameter may be varied. Consequently, EO sterilization is a complex multi-parameter process. Each parameter affects the other dependent parameters.

Others

Dry heat: Dry heat in the form of hot air is used primarily to sterilize anhydrous oils, petroleum products, and bulk powders that steam and ethylene oxide gas cannot penetrate. Death of microbial life by dry heat is a physical oxidation or slow burning process of coagulating the protein in cells. In the absence of moisture, higher temperatures are required than when moisture is present because microorganisms are destroyed through a very slow process of heat absorption by conduction.

Quality Assurance

To ensure that instruments and supplies are sterile when used, monitoring of the sterilization process is essential.

Administrative Monitoring

Work practices must be supervised. Written policies and procedures must be strictly followed by all personnel responsible and accountable for sterilizing and disinfecting items, and for handling sterile supplies. If sterility cannot be achieved or maintained, the system has failed. Policies and procedures pertain to:

- Decontaminating, terminally sterilizing, and cleaning all reusable items; disposing of disposable items.
- Packaging and labeling of items.
- Loading and unloading the sterilizer.
- Operating the sterilizer.
- Monitoring and maintaining records of each cycle.
- Adhering to safety precautions and preventive maintenance protocol.

- Storing of sterile items.
- Handling sterile items ready for use.
- Making sterile transfer to a sterile field.

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Mechanical Indicators

Sterilizers have gauges, thermometers, timers, recorders, and/or other devices that monitor their functions. Most sterilizers have automatic controls and locking devices. Some have alarm systems that are activated if the sterilizer fails to operate correctly. Records are maintained and review for each cycle. Test packs (Bowie-Dick test) are run at least daily to monitor functions of each sterilizer, as appropriate. These can identify process errors in packing or loading.

Chemical Indicators

A chemical indicator on a package verifies exposure to a sterilization process. An indicator should be clearly visible on the outside of every on-site sterilized package. This helps differentiate sterilized from unsterilized items. More importantly, it helps monitor physical conditions within the sterilizer to alert personnel if the process has been inadequate. An indicator may be placed inside a package in a position most likely to be difficult for the sterility to penetrate. A chemical indicator can detect sterilizer malfunction or human error in packaging or loading the sterilizer. If a chemical reaction on the indicator does not show expected results, the item should not be used. Several types of chemical indicators are available:

- Tape, labels, and paper strips printed with an ink that changes color when exposed to one or more process parameters.
- Glass tube with pellets that melts when a specific temperature is attained in sterilizer.
- Integrating or wicking paper with an ink or chemical tablet at one end that melts and wicks along paper over time under desired process parameters. The color bar reaches the “accept” area if parameters are met.

Biological Indicators

Positive assurance that sterilization conditions have been achieved can be obtained only through a biologic control test. The biologic indicator detects nonsterilizing conditions in the sterilizer. A biologic indicator is a preparation of living spores resistant to the sterilizing agent. These may be supplied in a self-contained system, in dry spore strips or discs in envelopes, or sealed vials or ampoules of spores to be sterilized and a control that is not sterilized. Some incorporate a chemical indicator also. The sterilized units and the control are incubated for 24 hours for *Bacillus stearothermophilis* at 131 to 141°F (55 to 66°C) to test steam under pressure, for 48 hours for *Bacillus subtilis* at 95 to 98.6°F (35 to 37°C) to test ethylene oxide.

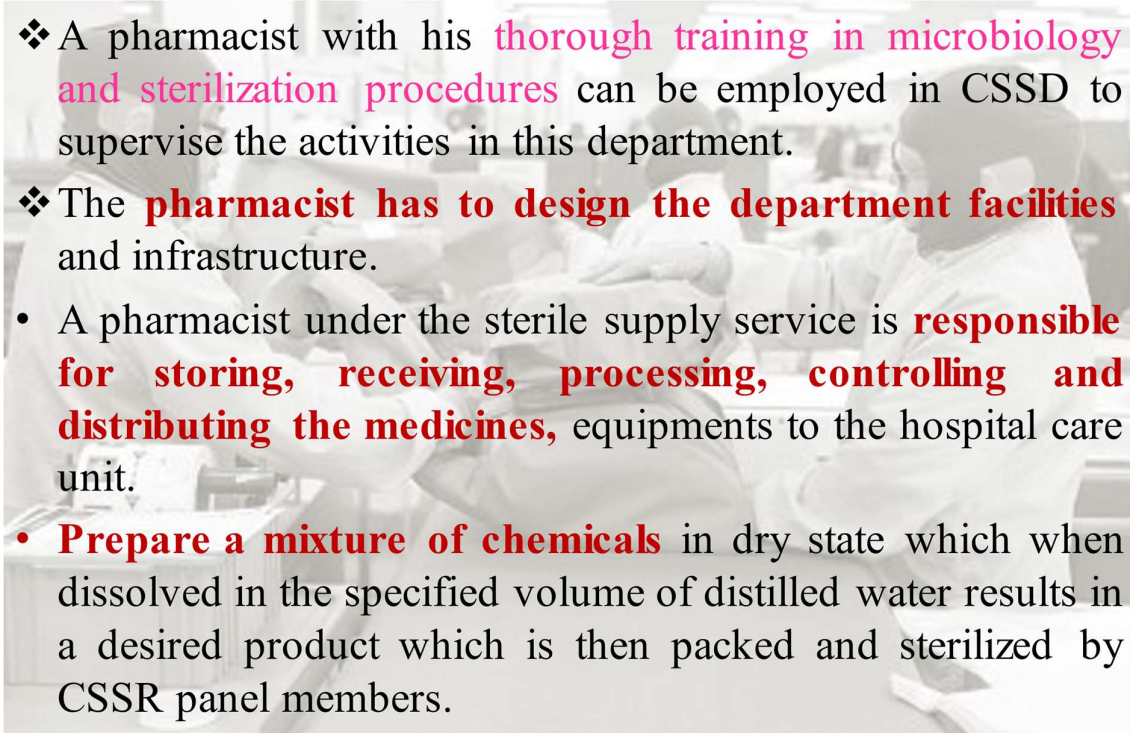
A biologic indicator must conform with USP testing standards. A control test must be performed at least weekly in each sterilizer. Many hospitals monitor on a daily basis; others test each cycle. Very load of implantable devices must be monitored and the implant should not be used until negative test results are known. Biological indicators also are used as a challenge test before introducing new products or packaging materials, after major repairs on the sterilizer, or after a sterilization failure. All test results are filled as a permanent record for each sterilizer.

ADDITIONAL REQUIREMENT OF CENTRAL STERILE SERVICE DEPARTMENT [CSSD]

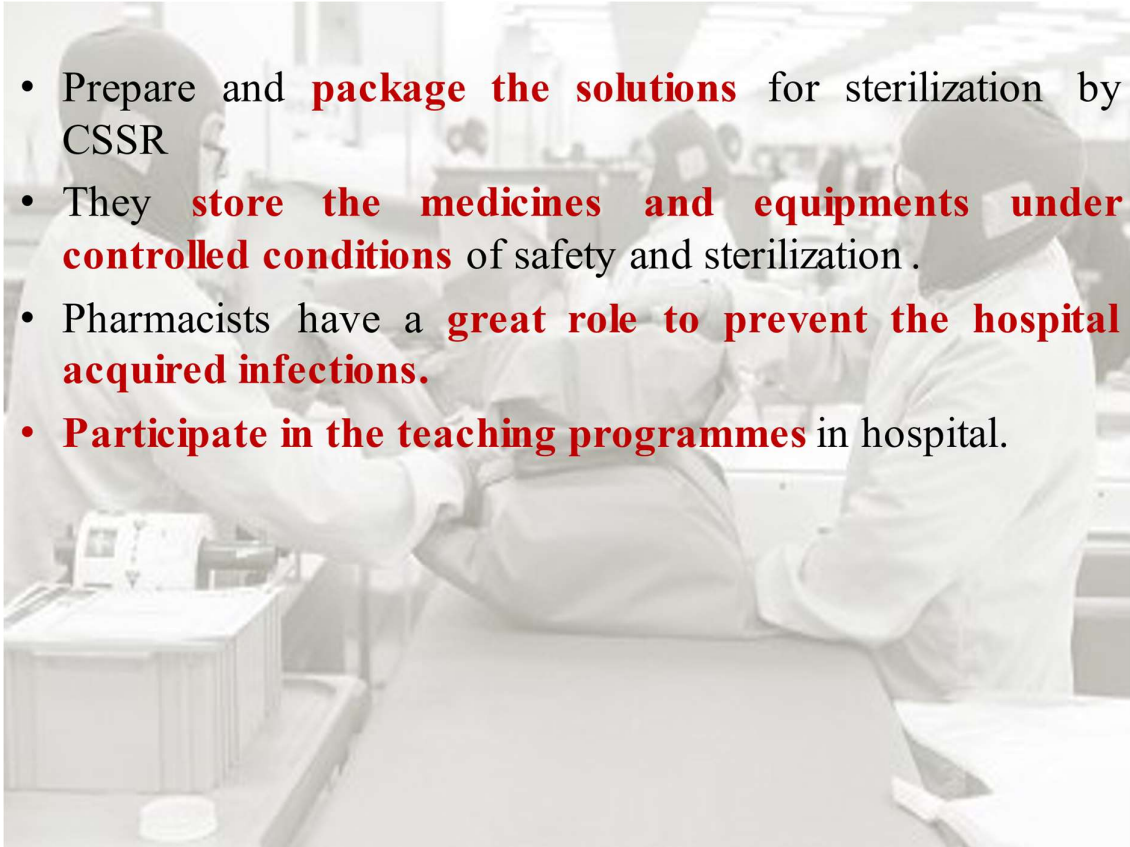
HYDROGEN PEROXIDE PLASMA STERILIZER:

Hydrogen peroxide is activated to create a reactive plasma or vapor. Plasma is a state of matter distinguishable from solid, liquid, or gas. It can be produced through the action of either a strong electric or magnetic field, somewhat like a neon light. The cloud of plasma created consists of ions, electrons, and neutral atomic particles that produce a visible glow. Free radicals of the hydrogen peroxide in the cloud interact with the cell membranes, enzymes, or nucleic acids to disrupt life functions of microorganisms. The plasma and vapor phases of hydrogen peroxide are highly sporicidal even at low concentrations and temperature.

PHARMACISTS ROLE IN CSSD

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- ❖ A pharmacist with his **thorough training in microbiology and sterilization procedures** can be employed in CSSD to supervise the activities in this department.
 - ❖ The **pharmacist has to design the department facilities** and infrastructure.
 - A pharmacist under the sterile supply service is **responsible for storing, receiving, processing, controlling and distributing the medicines**, equipments to the hospital care unit.
 - **Prepare a mixture of chemicals** in dry state which when dissolved in the specified volume of distilled water results in a desired product which is then packed and sterilized by CSSR panel members.

- Prepare and **package the solutions** for sterilization by CSSR
- They **store the medicines and equipments under controlled conditions** of safety and sterilization .
- Pharmacists have a **great role to prevent the hospital acquired infections.**
- **Participate in the teaching programmes** in hospital.



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