Aga Khan University Hospital

Title:	CSSD Sterilization Process				
Department / Division	Department of Anesthesiology/CSSD				
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1. Purpose(s):

 \uparrow .1. To ensure the safe cleaning and sterilization of surgical instruments

1.2 To ensure monitoring of all decontamination processes and protocols for the handling and processing of equipment and whether they meet the required standards to prevent cross infection

2. Scope:

To supply a range of sterilized or disinfected items to operating rooms, wards and other units and healthcare establishments such as CHC and clinics etc.

3. Responsibility:

CSSD & all Staff where services are provided

4. Terms & Definition:

4.1. Sterilization

- 4.1.1. The procedure of destroying all microorganisms or on a given environment including killing of their spores such as a surgical instrument, in order
 - to prevent the spread of infection. This is usually done by using heat, radiation, or chemical agents.
- 4.1.2. The basic principle of steam sterilization, as accomplished in an autoclave, is to expose each item to direct steam contact at the required temperature and pressure for the specified time.
- 4.2. Hydrogen Peroxide Gas Plasma

Gas plasmas are generated in an enclosed chamber under deep vacuum using radio frequency or microwave energy to excite the gas molecules and produce charged particles, many of which are in the form of free radicals. The type of seed gas used, and the depth of the vacuum are two important variables that can determine the effectiveness of this process.

5. Process/ Procedure:

5.1. Staffing Considerations

Staff should have documented competencies in all phases and equipment operations of decontamination, packing and sterilization area.

- 5.2. Traffic Control
 - 5.2.1. All CSSD staff are provided authorized access through ID card.
 - 5.2.2. Only authorized personnel in appropriate attire are allowed in CSSD.
- 5.3. CSSD Dress Code

Details are mentioned in Annexure.

5.4. Physical Design

Decontamination /Washing area is physically separate from other areas of CSSD.

- 5.5. Ventilation, Temperature, and Humidity:
 - 5.5.1. Sterilization, preparation, packaging, and sterile storage are considered clean areas and have positive airflow ventilation. Soiled and decontamination areas are under negative pressure. Each area should have a minimum of 6 air exchanges per hour and at least 4 in sterile storage area
 - 5.5.2. Temperature in all work areas should be between 20°C and 24°C.
 - 5.5.3. The relative humidity should be maintained between 30% and 60% in all work areas except sterile storage, where the relative humidity should not exceed 70%).
- 5.6. Instruction to User at Point of Use:
 - 5.6.1. Gross soil is removed from instruments at point of use/ units if immediate transportation is not possible. Soiled items should be kept moist with enzymatic foaming spray product.
 - 5.6.2. Used item must have sent to CSSD with in 24hrs and as early as possible.
- 5.7. Cleaning, disinfection & sterilization:

All the medical/ surgical instrument will be processed (cleaning, disinfection, and sterilization) according to manufacturer recommendations/ guideline.

- 5.8. CSSD Workflow
 - 5.8.1. General workflow for CSSD items is as follows:
 - 5.8.1.1. Receiving, sorting, washing, heat disinfection and drying
 - 5.8.1.2. Inspection, setting trays and assembling packs
 - 5.8.1.3. Sterilization
 - 5.8.1.4. Transfer to sterile area
 - 5.8.1.5. Distribution to wards and other units
- 5.9. Receiving
 - 5.9.1. Used trays and packs are collected from wards and units in covered boxes/ covered trolleys as per agreed time by CSSD staff
 - 5.9.2. Wards and units must remove sharps such as needles and disposable blades from used surgical packs/trays
- 5.10. Cleaning
 - 5.10.1. Items are segregated and cleaned using water with enzymatic cleaners /soap & water as required before processing. Surgical instruments are pre-soaked or prerinsed to prevent drying of blood and tissue. Pre-cleaning in patient-care areas is needed on items that are heavily soiled with feces, sputum, blood, or other material.

Items sent to central processing without removing gross soil may be difficult to clean because of dried secretions and excretions.

- 5.10.2. Enzymatic Foaming spray should be used on all the instruments except for Ophthalmology instruments.
- 5.10.3. Surgical instruments are sorted & classified for cleaning as follows
 - 5.10.3.1. Stainless General Instruments
 - 5.10.3.2. Micro and Delicate Instruments
 - 5.10.3.3. Power Drill Saw
 - 5.10.3.4. Electrical Lead & Fiber Optic
- 5.11. Disinfection
 - 5.11.1. Item that requires disinfection will be cleaned with soap & water, then will be immersed in detergent solution/ moped with alcohol disinfectant wipes as required.
 - 5.11.2. Alkaline-based cleaning agents are used for processing medical devices because they efficiently dissolve protein and fat residues, with that a neutral pH detergent solution is used because such solutions generally provide the best material compatibility profile and good soil removal.
 - 5.11.3. Daily washer chemical indicator is run in every cycle.
- 5.12. Washer
 - 5.12.1. Washing is performed in washer disinfector that performs thermal disinfection of instrument at 93°C
 - 5.12.2. Washer-disinfectors are automated and closed equipment that clean and disinfect surgical instruments.
 - 5.12.3. Distill water and RO water quality control must be checked by MEP.
- 5.13. Dilution of Detergents / Enzymatic Solution
 - 5.13.1. All instruments should be soaked in enzymatic solution. It will be changed in every shift and as frequently based on the presence of dirt.
 - 5.13.2. Following process will be followed to prepare enzymatic solution
 - 5.13.2.1. 30ml of enzymatic solution will be mixed in 970 milliliter clean water to prepare 1-liter and soaked for 3 to 5 minutes
 - 5.13.3. Detergent is used to clean glass distil water bottles & face mask & ambo bag. It will be changed in every shift and as frequently based on the presence of frequency of dirt
 - 5.13.4. Following process will be followed to prepare detergent
 - 5.13.4.1. 30ml of detergent will be mixed in 970 milliliter clean water to prepare 1liter and soaked for 3 to 5 minutes
- 5.14. Assembly and Packing
 - 5.14.1. All surgical instruments will be dried either manually or with dryer
 - 5.14.2. CSSD staff will check instruments for any wear & tear. If any wear & tear is observed, the shift in-charge will be informed.
 - 5.14.3. Any foreign body/organic material will be found in item; it will send back to washing area.
 - 5.14.4. CSSD staff will lubricate all instruments according to company instructions
 - 5.14.5. CSSD staff will verify the entire set of instruments with surgical checklist/photo gallery
 - 5.14.6. If any instruments mismatch, the shift in-charge will be informed. Shift in-charge will take steps to find out about the mismatch
 - 5.14.7. All instruments that are presented with open ratchets will be kept in proper position
 - 5.14.8. Before completing the set, it will be counter checked by the charge hand /shift in-

charge or supervisor who countersigns to endorse by mentioning his/her name and initials on the checklist

- 5.14.9. Sets will be packed according to the checklist
- 5.14.10. After the final wrap label of the tray will be pasted on the final wrapper contain the following information: Pack ID, date of packaging, staff initials, expiry date and a disclaimer "Until packaging is damage"
- 5.14.11. Container clip and autoclave tape will be placed on each tray
- 5.14.12. Trays will be placed on holding trolley
- 5.15. Load Configuration

Items should be placed correctly and loosely into the basket, shelf or cart of the sterilizer so as not to block the penetration of the sterilant

- 5.16. Sterilization
 - 5.16.1. Steam Sterilization Process
 - 5.16.1.1. The two-following steam-sterilizing temperatures are used for sterilization: 5.16.1.1.1. 121°C
 - 5.16.1.1.2. 134°C
 - 5.16.1.2. Recognized minimum exposure periods for sterilization of wrapped healthcare supplies are
 - 5.16.1.2.1. 30 minutes at 121°C in a gravity displacement sterilizer
 - 5.16.1.2.2. 4 minutes at 134°C in a prevaccum Sterilizer
 - 5.16.1.3. In some circumstances sterilization time varies depending on the type of items being sterilized e.g., metal versus rubber, plastic, items with lumens, whether the item is wrapped or unwrapped and the sterilizer type
 - 5.16.2. Hydrogen Peroxide Gas Plasma
 - 5.16.2.1. The plasma sterilizing temperature is 50°C and has following two cycle types:
 - 5.16.2.1.1. Express Cycle sterilization time is 30 to 35 minutes (Sterrad NX100)
 - 5.16.2.1.2. Standard Cycle sterilization time is 45 to 55 minutes (Sterrad NX100)
 - 5.16.2.1.3. Hydrogen Peroxide Gas Plasma (V-PRO maX 2)
 - 5.16.2.1.4. The Plasma sterilizing temperature is 50 C and has following 4 cycle types:
 - 5.16.2.1.5. Fast Non-Luman Cycle time is 16 minutes
 - 5.16.2.1.6. Non-Luman Cycle time is 28 minutes
 - 5.16.2.1.7. Flexible Cycle time is 35 minutes
 - 5.16.2.1.8. Luman Cycle time is 55 minutes
- 5.17. Quality control check and validation
 - 5.17.1. Mechanical indicator
 - 5.17.1.1. Each autoclave cycle is mechanically monitor for steam sterilization by assessment of each cycle time and temperature
 - 5.17.1.2. After cycle completion machine will give indicate of completion of cycle based on the fixed parameters
 - 5.17.2. Chemical indicator
 - 5.17.2.1. Daily Bowie Dick test is performed through chemical Indicator run before starting steam sterilization process. Log will be maintained for 1 year
 - 5.17.2.2. Every surgical instrument set contains chemical indicator which ensures proper sterilization of the set. The scrub person in operating room verifies it before surgery

- 5.17.3. Biological indicators
 - 5.17.3.1. Ultra-Rapid Biological Indicator for Steam sterilization is run twice a week in all the sterilizers and incubates for 20 minutes as per the manufacturer recommendation. Supervisor will read the results and maintain log for a year.
 - 5.17.3.2. Super Rapid Biological Indicator for Plasma sterilization is run twice a week and incubates for 30 minutes as per the manufacturer recommendation. Supervisor will read the results and maintain log for a year.
 - 5.17.3.3. In case of an unsatisfactory result in any of the quality indicators sterilizer will be hold until satisfactory results are obtained, and infection control representative is contacted for further guidance
- 5.18. Documentation
 - 5.18.1. The following information should be recorded for each sterilization cycle in CICS
 - 5.18.1.1. Sterilizer identification
 - 5.18.1.2. Type of sterilizer and cycle used
 - 5.18.1.3. Sterilization Cycle ID
 - 5.18.1.4. Load contents
 - 5.18.1.5. Expiry date
 - 5.18.1.6. Operator's name
 - 5.18.2. Sterilization records should be maintained for a time specified In case of an unsatisfactory result in any of the quality indicators sterilizer will be hold until satisfactory results are obtained and infection control representative is contacted for further guidance
- 5.19. Sterile Storage
 - 5.19.1. Sterile storage area is a well-ventilated area that provides protection against dust, moisture, insects and temperature and humidity extremes
 - 5.19.2. Sterile supplies should be stored at least 18 inches far from ceiling and 8 to 10 inches far enough from the floor
 - 5.19.3. Sterile storage area requires positive pressure with 4 air cycles changes per hour in the sterilizer equipment room
 - 5.19.4. Sterile items should be store in a way, so the packaging is not compromised (e.g., punctured, bent).
 - 5.19.5. Evaluate packages before use for loss of integrity (e.g. torn, wet, and punctured). The pack can be used unless the integrity of the packaging is compromised
 - 5.19.6. If the integrity of the packaging is compromised (e.g. torn, wet, or punctured), the pack need to repack and reprocessed before use
 - 5.19.7. Shelf life of sterile items is 2 years, once this date passes, pack needs to reprocess
 - 5.19.8. On Sterile distilled water, one-month expiry will be printed. It can be used within 24 hours once opened.
 - 5.19.9. On sterile tap water, one-month expiry will be printed. It can be used within 24 hours once opened.
 - 5.19.10. All malfunction/out of order instruments will be sent to disposal department for dispose quarterly.

5.20. Distribution

All sterilized surgical instruments packs & trays are distributed to wards & units as per specific time

6. Reference:

CDC Guideline for Disinfection and Sterilization in Healthcare Facilities https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines.pdf. Last

update: May 2019

APSIC- Asia Pacific Society of Infection Control (guidelines for disinfection & Sterilization of Instruments in Health Care Facilities.

http://apsic-apac.org/wp-content/uploads/2017/01/APSIC-Sterilization-guidelines-2017.pdf Reprocessing of Instruments to retain Value

(frankshospitalworkshop.com)

7. Annexure 1:

Dress Code in CSSD:

- 7.1. Packing and Assembling Area
 - 7.1.1. Staff: On entering the Sterile Service Department, all CSSD staff will wear CSSD uniform or blue scrub suits, cap and beard mask (if applicable).
 - 7.1.2. Visitors: Visitors will wear gown to ensure the street clothes are completely covered with the gown. Further they will need to wear cap and beard mask (if applicable).
 - 7.1.3. All staff and visitors entering packing and assembling area must need to sanitizehands before entering.

7.2. Washing Area

- 7.2.1. Staff working in washing (decontamination) area, will be required to wear liquidresistant gown, apron, general-purpose heavy duty utility gloves, cap, shoe covers, mask and protective goggles over the CSSD uniform or blue scrub suits.
- 7.2.2. Per shift PPE will be issued to staff and will be utilized.
- 7.2.3. When leaving the washing area CSSD staff will remove the gown and gloves and wash their hands.
- 7.2.4. The assigned staff must be immunized with Hepatitis B.
- 7.2.5. All unprotected exposures, sharp injuries / NSI needs to be reported immediately to unit supervisor/ Infection control department.
- 7.2.6. Visitors entering into the washing area needs to wear liquid-resistant gown, cap, shoe covers and masks.

7.3. Sterile Area

Restricted entry, only CSSD uniform or blue scrub suits will be allowed along with cap and beard mask (if applicable).

Annexure 2:

Recommended Cleaning/washing process of different instrument types

Stainless General Instruments	Micro and Delicate Instruments
 All the ratchets & joints must be opened & put into the washing rack. A Spray water washing Gun is used to remove contamination. 	 Instruments must be thoroughly cleaned with enzymatic cleaner/soap & water. Instruments must be thoroughly rinsed in running water. Instrument washing racks are fed into the washer disinfector.

•	Any instrument not cleaned properly by the washing gun, will require manual washing.	 Ir d S 	nstruments are kept for drying in the rying cabinet. taff will pick trays /packs according to
•	Instruments need to be scrubbed with a washing brush in running water (if deemed necessary).	S	pecialty.
•	Instruments should be rinsed in running water.		
•	Galipots and Kidney dishes will be washed with soap & water.		
•	Hollow and tunnel instruments e.g. suction nozzle cannula, must be internally cleaned with a spray gun.		
•	Surgical Instruments will be immersed in Enzymatic cleaner for 3 to 5 minutes.		
•	Instrument washing racks are fed into the washer disinfector and particular cycle will be initiated.		
•	Instrument rack will be placed in a drying cabinet for 20 to 30 minutes.		
•	Instruments will be placed for assembly and packing on the holding trolley.		
•	Staff will pick trays /packs according to specialty.		

Power Drill Saw	Electrical Lead & Fiber Optic
 Attach the hose pipe to hand pieces during cleaning. Mop all the attachments & hand pieces with enzymatic cleaner/soap & wipe with water. Thoroughly scrub the hand pieces & attachments with a soft brush. Keep the nose of the hand piece pointed downward while rinsing under running water. Do not immerse the hand pieces & attachments into water or detergent. To dry-wipe the surfaces with a clean towel. Detach all hoses from the hand pieces. Complete Drill set / Saw will be forwarded to assembly area Staff will pick trays /packs according to specialty. 	 Thoroughly scrub the Electrical wires with enzymatic cleaner/soap and water. Ensure the soap solution or rinsing water should not enter the hand pieces Blood stains or soap on the instruments must be cleaned under running water. Do not immerse wires and attachments in water or Detergent. Wipe the surface with a clean towel. Staff will pick trays /packs according to specialty

8. Document Change Record Form:

Review #	Review Date (dd-mm-yyyy)	Description Of Change	Identification of Change
01	20-May-2016	Formatting as per service line. Change in document no.	
02	20-Aug-2018	Entire Document Reviewed and updated	Whole document changed
03	02-Aug-2021	Changes in document	