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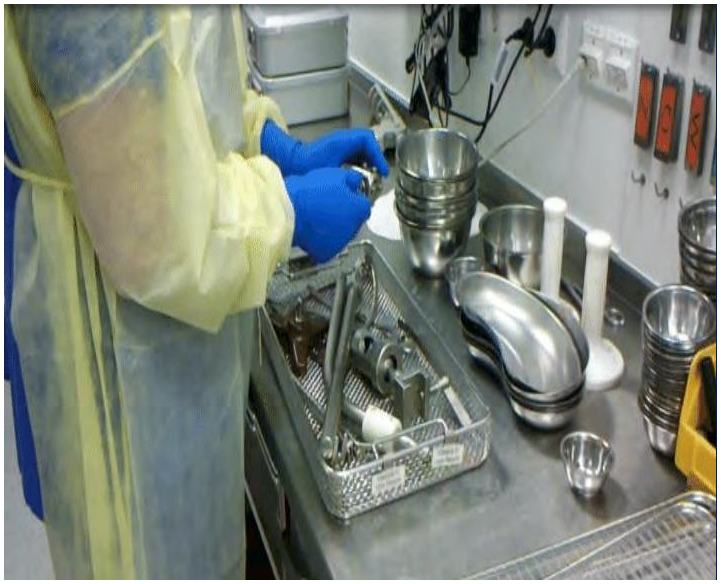
HEALTHCARE & RESEARCH PVT. LTD.



CENTRAL STERILIZATION SERVICES DEPARTMENT (CSSD) MANUAL

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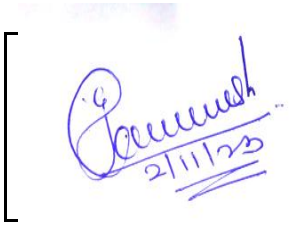
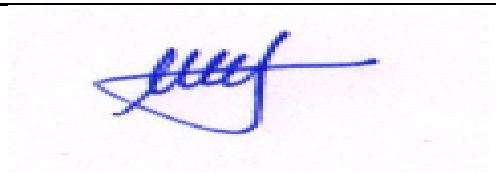
Annual Documents adequacy & Change Requirements Review

Sr.No	SOP /Doc No	Documents Name	Issue. No	Rev.No	Review Date	Change	Rev No	Revision Date	Reason for Change	Amendment
1	SDH/CSSD /01	Contents	1	1	20-Nov-22	No Any Change Review Completed	1	20-Nov-23	No Any Change Review Completed	No Any Amendment History
2		department Organizational Chart	1	1	20-Nov-22		1	20-Nov-23		
3		Roles & Responsibilities	1	1	20-Nov-22		1	20-Nov-23		
4		Services Standards	1	1	20-Nov-22		1	20-Nov-23		
5		Standard Operating Procedures	1	1	20-Nov-22		1	20-Nov-23		
6		Receipt Of items	1	1	20-Nov-22		1	20-Nov-23		
7		Decontamination Activities	1	1	20-Nov-22		1	20-Nov-23		
8		Assembling & Packing Activities	1	1	20-Nov-22		1	20-Nov-23		
9		Labeling	1	1	20-Nov-22		1	20-Nov-23		
10		Steam Sterilization	1	1	20-Nov-22		1	20-Nov-23		
11		ETO Sterilization	1	1	20-Nov-22		1	20-Nov-23		
12		Storage and Issues of item	1	1	20-Nov-22		1	20-Nov-23		
13		Quality Control	1	1	20-Nov-22		1	20-Nov-23		
14		Recall of Items	1	1	20-Nov-22		1	20-Nov-23		
15		Environment Cleaning & Disinfection Practices	1	1	20-Nov-22		1	20-Nov-23		
16		Reuse Policy	1	1	20-Nov-22		1	20-Nov-23		
17		CSSD PCD Protocol	1	1	20-Nov-22		1	20-Nov-23	New Policy Added	Processing of chemical & Biological Device
		Records								

	Original Date	Effective Date	Next Date Of Revision	Issue NO		
	01 November 2021	**20 November 2023**	**20 November 2024**	1		

Reviewed & Prepared By		Recommended By	Approved By
Mr.Ganesh Thorat	Mrs.Shraddha suryavanshi	Dr.H.Kalgaonkar	Dr.S.S.Deepak
CSSD HOD	Quality Co-ordinator	Chief Medical Administartor	Chairman & Managing Director
			

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	Original Date	Effective Date	Next Date Of Revision	Issue NO
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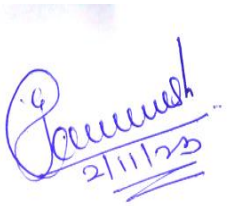
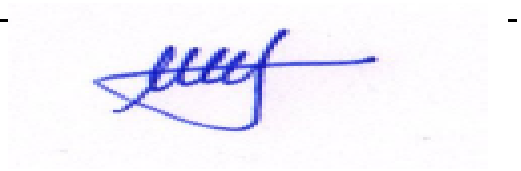
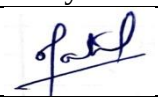
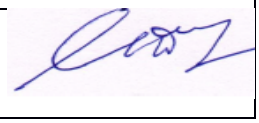
Reviewed & Prepared By		Recommended By	Approved By
Mr.Ganesh Thorat	Mrs.Shraddha suryavanshi	Dr.H.Kalgaonkar	Dr.S.S.Deepak

CSSD HOD	Quality Co-ordinator	Chief Medical Administartor	Chairman & Managing Director
			

	SAIDEEP HOSPITAL CSSD MANUAL	Doc No	SDH/CSSD/01
		Issue No	01
		Rev No.	01
		Date	1 NOV 21
		Page	1
	Amendment Sheet		

Sr.No	Page No	Clause No	Date of Amendment	Amendment Made	Reasons	Signature of Approval Authority
01.	5.12	HIC 7.B	20-Nov-22	CSSD PCD Protocol	As per NABH NC	

Recommended By	Signature	Approved By	Signature
Dr. HrishikeshKalgaonkar		Dr. S. S. Deepak	
Chief Medical Administrator		Chairman & Managing Director	

Recommended By	Signature	Approved By	Signature
Dr. HrishikeshKalgaonkar		Dr. S. S. Deepak	
Chief Medical Administrator		Chairman & Managing Director	

CSSD In-Charge

- Oversee unit administration and report to CMA
- Plan manpower deployment and duty rosters and monitor the same
- Ensure orientation and training of staff
- Coordinate with HR on staff management
- Oversee equipment management
- Ensure process compliance in CSSD
- Establish and ensure quality management of CSSD process
- Oversee material management and stock keeping of department consumables

CSSD Technicians

- Oversee decontamination activities
- Perform instrument checking, tray assembling and packing
- Proper labelling of items
- Sterilizer operation and documentation of load as per procedures
- Perform, monitor and document quality control protocols as required
- Manage issue of items from sterile stores

CSSD Helpers

- Manage collection of materials at CSSD
- Perform deliveries and issues to wards if required
- De-contamination of unsterile items as per protocols
- Assisting technician in their tasks
- Assist in cleaning and decontamination activities of the CSSD work areas, furniture and equipment

Service Objectives

- To provide inventoried sterile supplies, instruments and equipment to service areas.
- To maintain an accurate record of the effectiveness of the cleaning, disinfecting, and sterilizing processes.
- To strive for uniformity and simplicity in the trays and sets that the department provides.
- To maintain an adequate inventory of sterile supplies, instruments and equipment.
- To monitor and enforce controls necessary to prevent cross infection according to infection control policies.
- To establish and maintain sterile processing, issue and transportation standards.
- Ensure long life and functioning of surgical instruments
- To support hospital in safe reprocessing of Single Use Devices where applicable and approved for reprocessing and reuse
- To operate efficiently and use sterilization and reprocessing technology to reduce overhead expenses of the hospital.

Measurable Service Standards

Service Parameters	**Measurable Outcomes / Outputs**
Minimise rejection and return of instruments pack from OT and service areas due to defects in CSSD processes	Less that 0.5 percent of CSSD issue volumes

Objective

- Proper receiving of items at CSSD from OT and other client department of the hospital

Scope

- Improve coordination between OT and CSSD
- Improve coordination between other client department and CSSD
- Not Applicable for Cold Sterilization Process which is mostly performed at Point of Care

Expected Outcomes

- Reduce the loss of instrument while returning
- Ensure proper documentation of items received to ensure proper tracking of received items

No	Process Step / Activity	Responsibility	Outputs/ Records / Connections
1	The user department shall intimate that the items/instruments/ equipment are ready to be transferred to the CSSD after use.	OT In-charge/Floor Supervisor	
2	Appropriate entries in the register need to be made at the time of collection of non-sterile material after counting the type/number of items collected. A countersign by the user department shall be taken in the register as per Un-sterile Items Collection Register.	CSSD Technician / CSSD Helpers	Collection / Receiving Register
3	Instruments shall be received and transported in covered bins / trolleys. The same shall ne marked red (indicating non-sterile) and shall have bio-hazard warning symbols	CSSD Technician / CSSD Helpers	
4	A trolley would be maintained at Dirty Utility room of the OT with trays with water with enzymatic detergents for collection of used instruments in between surgery. The water with enzymes cleaners	OT Nurses	

	is to ensure that the blood and other tissue debris do not dry on the instruments.		
5	The same method shall be followed by the Cath Lab also for their reusable items. The same shall be stored in the pre-wash area provided near the Cath Lab. The Cath Lab technicians shall check the reusable items prior to sending them to Cath Lab to ensure their working condition and reusability. If any reused items do not have markings indicating no of reuse, the same shall be disposed.	Cath Lab Technicians	
6	No units are allowed to undertake washing or any other type of decontamination of instruments / materials in their work areas. All such activities will be centrailsed at CSSD which is provided with appropriate tools for the same. The same is not applicable in cases of cold sterilisation process followed in departments like endoscopy and sterilization process for dental department.	All Staff	

Records

Record ID	Name	Type	Responsible Person	Retention Period
	CSSD Collection / Receiving Register	Register	CSSD Helpers / Technicians	2 Years

Objective

- Ensuring proper cleaning and decontamination of instruments and equipment's received by CSSD to reduce infection and ensure proper life of instruments / equipment

Scope

- Cleaning of equipment
- Removal of tissue debris / bio burden from instruments / equipment
- Cleaning of carts / transport containers

Expected Outcomes

- Removal of contaminants and bio-burden from equipment / instrument
- Prevention of possible cross contamination
- Prevention of damage to equipment during decontamination process

No	Process Step / Activity	Responsibility	Outputs/ Records / Connections
1	The person working in the decontamination area must follow universal precautions. He must wear gloves, a plastic apron and a cap while working here.	CSSD Helpers / CSSD Technician	
2	CSSD Helpers must be trained in proper methods of cleaning and decontamination of all types of instruments and equipment handled by the CSSD and proper usage of cleaning equipment	Chief / Senior CSSD Technician	Training Records / Register
2	Handle delicate, precision items with care to avoid damage.	CSSD Helpers / CSSD Technician	
3	Notify CSSD In-charge and user department of any missing parts or instruments.	CSSD Technician	Damage Items Register
4	Though items received are initially rinsed at user level, once again look for any visible soil such as blood/tissue. Rinse such items in cold water to remove debris before	Chief / Senior CSSD Technician	

	placing them in ultrasonic cleaner / washer decontaminator for a normal washing cycle. The Ultrasonic Washer shall be operated as per *Operating Instructions for Ultrasonic Washer*. The same shall be displayed near the equipment		
5	Open all locked instruments and disassemble parts prior to cleaning.	Chief / Senior CSSD Technician	
6	Special attention to be paid to items with lumens. Air jets and Water jets along with long fine brushes are used to clean the narrow lumens.	Chief / Senior CSSD Technician	
7	Thoroughly clean all surfaces of equipment and cables (which are not to be soaked in water) with hospital-approved disinfectant (Rapid Multi-Enzymatic Cleaning Solution), let air dry and return to appropriate clean area.	Chief / Senior CSSD Technician	
8	Any sterile disposable item that is returned to this area should be considered contaminated and thus cleaned and sterilized.	Chief / Senior CSSD Technician	
9	Linen from OT will be washed first and then packed Inspection should be done prior to packing	Chief / Senior CSSD Technician	

Records

Record ID	Name	Type	Responsible Person	Retention Period
NA	Damaged Items Register	Register	CSSD Helpers / Technicians	2 Years
NA	CSSD Staff Training Records	Forms / File	Chief / Senior CSSD Technician	NA

Annexures

SDH/CSS/WI/01 – Operating Instructions for Ultrasound Washer

Recommended By	Signature	Approved By	Signature
Dr. HrishikeshKalgaonkar Chief Medical Administrator		Dr. S.S. Deepak Chairman & Managing Director	

	SAIDEEP HOSPITAL CSSD MANUAL	Doc No	SDH/CSS/SOP/3
		Issue No	01
		Rev No.	01
		Date	1 Nov 21
		Pages	1
	SOP – Packing and Assembling		

Objective

- Ensure proper assembling and packing of various surgery / procedure packs and other sterile supply products prior to their sterilization

Scope

- Checking of instrument condition and functionality
- Ensuring appropriate assembly of surgical packs as per specified content lists for various packs

Expected Outcomes

- Proper arrangement and contents for various types of surgery packs and prevention of missing items

No	Process Step / Activity	Responsibility	Outputs/ Records / Connections
1	Inspect instruments for cleanliness: Dirty instruments are sent back for repeat cleaning	CSSD Technicians	
2	Instruments and checked for proper functioning especially hinges etc. Magnifying glasses are used for proper visual inspections of tiny instruments. Instruments are lubricated where necessary to ensure proper functioning	CSSD Technicians	
2	Use a mesh-bottomed or perforated tray or equivalent. Instrument trays shall be designed for effective sterilization, drying and orderly arrangement of instruments. .	CSSD Technicians	
3	The instruments are packed in a definite and orderly manner as per the list to facilitate their use in OT and wards. For reference Master File For Instrument Sets is available	CSSD Technicians	Master File for Instrument Check Lists
4	A checklist with signature of person responsible for packing, to be signed by person using the set and later by person receiving the used set is added in the large sets	CSSD Technicians	Checklist File

Recommended By	Signature	Approved By	Signature
Dr. Hrishikesh Kalgaonkar Chief Medical Administrator		Dr. S.S. Deepak Chairman & Managing Director	

5	The contents of the pack are changed only through amendment duly authorized by CSSD In-Charge based upon either verbal or written requests from the concerned users.	Chief / Senior CSSD Technician	
6	Place a fully opened (single layer) green towel in bottom of tray to assist in drying. Use a towel that covers the bottom of the tray with minimum excess overhang.	CSSD Technicians	
7	Trays are wrapped in single thickness of muslin cloth for use in wards and double thickness of muslin cloth for sets to be used in O.T.	CSSD Technicians	
8	The linen wrappers must be checked for cleanliness and absence of holes or tears. Defective linen to be separated for mending or condemnation depending on extent of defects observed.	CSSD Technicians	
9	The assembled instrument sets are packed in appropriate wrappers and sealed with sticking tape and labeled with the name of the set, expiration date and a process indicator	CSSD Technicians	

Records

Record ID	Name	Type	Responsible Person	Retention Period
NA	Pack Items Checklists	Checklist / File	CSSD Technicians	1 Years

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		Issue No	01
		Rev No.	01
		Date	1 Nov 21
		Pages	1
	SOP – Labelling Process		

Objective

- Ensure proper labeling of CSSD processed items to ensure validity of sterilization process, proper identification, expiry tracking and recall

Scope

- Labelling of items

Expected Outcomes

- Proper labelled items

No	Process Step / Activity	Responsibility	Outputs/ Records / Connections
1	One each on the outer surface of the pack/pouch and on the outer surface of the item inside the pack/pouch: Label with details of Item Name, Batch no., Date of Packing, Date of Expiry duly entered	CSSD Technicians	
2	On the outer surface of the item inside the pack: Autoclave indicator tape sticker. Autoclave indicator tape is not used in case paper pouches are used for packing	CSSD Technicians	
3	Expiry for steam-sterilized linen packed items is 7 days and for crape paper & paper pouches is one month from the date of sterilization.	CSSD Technicians	
4	For ETO On the outer surface of the pack/pouch: Label with details of Batch no., Item Name, Date of Packing, Date of Expiry duly entered. - Every pack/ pouch which shall be E.T.O. sterilized subsequently, in case the date has expired, is affixed with updated labels:	CSSD Technicians	

Records
Nil

Recommended By	Signature	Approved By	Signature
Dr. HrishikeshKalgaonkar Chief Medical Administrator		Dr. S.S. Deepak Chairman & Managing Director	

Objective

- Ensure proper techniques and process of steam sterilization as per recommended operations methods of autoclaves

Scope

- Steam sterilization process

Expected Outcomes

- Proper sterilization of items

No	Process Step / Activity	Responsibility	Outputs/ Records / Connections
	Loading the sterilizer - All items for steam sterilization shall be properly wrapped or packaged with the appropriate indicators. - A detail list of load in each sterilizer is maintained along with its indicator chart. - Load the transfer basket or cart into the sterilizer chamber. - Align trolley in front of sterilizer. - Push trolley forward until latching mechanism engages the latching stud in the chamber. - To push the carriage from the trolley, press the carriage release handle to unlock it and push the carriage forward. - To unlock the trolley from the sterilizer, pull back on the trolley release handle to disengage the latching device and pull trolley away from the sterilizer. - Close Door - Select appropriate cycle and Start it. **Precautions that must be taken during Loading Of**		Steam Sterilization Record

	Sterilizer. - Place all packs and sets on edge and arrange the load in chamber to allow minimal resistance to steam passage through the load. - Items shall not be horizontally stacked and shall not protrude outside of the carriage frame or exceed height limits. Arrange all bundles on side to allow free flow of steam through all layers of the wrap. - All non-perforated trays and basins shall be placed vertically on edge, tipped slightly forward so they will be sterilized and dried properly. - In mixed loads, combining fabrics and hard goods, place the hard goods on lower shelves. This prevents wetting of fabrics from condensate dripping from the hard goods. - Do not overload shelves or compress packages. Do not allow wrapped packages to contact the sterilizer chamber wall. Provide at least three (3) inches between the sterilizer chamber ceiling and the topmost package of the load. Never place packages on the chamber floor. - Place paper/plastic peel pouch type packages in a wire mesh basket on edge with plastic side of one package facing paper side of next package; paper side facing slightly downward to prevent entrapment of moisture. - Report any suspected malfunctions to the CSSD Team Leader immediately		
	Unloading of sterilizer - After completion of cycle check graph/chart, open door, pull basket or carriage out. - Visually check outside wrappers for dryness. A wrapped tray of instruments is considered unacceptable if there are water droplets or visible moisture on the exterior of the package or on the tape used to secure it. - Sterilized items shall remain on the loading basket or carriage and not be handled until contents have reached ambient room temperature. - When all items have cooled, remove from the loading carriage carefully, being sure not to damage		

	wrappers. As each item is unloaded check to see that identification tape has changed colors. - Person removing the load initials printed read-out and every load is identified with a single number on a day-to-day basis.		
	Care And Maintenance Of Autoclaves a) Daily Care of the Sterilizer: - Remove plug screen strainer and remove lint and sediment from the pores with a brush. It is through this screen that air and condensate particles are removed from the chamber. If this detail is neglected, the sterilizer cannot be depended on to provide proper sterilization. - All accessible surfaces of the carriage shall be washed with a mild detergent solution. Use a damp cloth, begin at the top and work downwards. Castors shall be cleaned last. B0In case of a minor error refer to Equipment Manual File. If problem persists in the functioning of the sterilizer, shut down sterilizer. Cycle printout and report of Biological Indicator is filed for analysis and further reference. C0 Notify Biomedical Engineer. The status of the sterilizer to be informed to CSSD In-Charge and other departmental members. Communicate for other shifts. If you are unable to sterilize any particular requirement due to a major failure then inform user department. d)Details regarding equipment failure, repair and downtime are recorded. e)After any major repair of the sterilizer, three negative biological cultures shall be obtained on three consecutive days before the sterilizer is returned to service. f)A preventative maintenance contract with the supplier is maintained for all sterilizing equipment. They are responsible for all repairs and bi-yearly checks. g) Minor repairs, adjustments and changing of paper roll		

	for recorder is the responsibility of CSSD technicians.. h) Cleaning and monitoring of the sterilizers is the responsibility of CSSD technician. i) Never attempt to open the door during the autoclave cycle. Time and temperature are not to be changed unless a manufacturer of an article recommends different parameters and this should be done only after approval from CSSD Team Leader.		

Records

Record ID	Name	Type	Responsible Person	Retention Period
NA	Steam Sterilization Record	Form / File	CSSD Technicians	2 Years

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Objective

- Ensure proper techniques and process of Ethylene Oxide(ETO) sterilization as per recommended operations methods of autoclaves

Scope

- ETO sterilization process

Expected Outcomes

- Proper sterilization of items

No	Process Step / Activity	Responsibility	Outputs/ Records / Connections
	4.1. Daily Care of the Sterilizer: - All accessible surfaces of the chamber shall be cleaned with a mild detergent solution. Use a damp cloth, begin at the top and work downwards. 4.2. An item is sterilized by E.T.O. only if it cannot withstand high temperatures and pressure. 4.3. All items to be gas sterilized will be packaged in appropriate size of polypropylene packaging 4.4. The package must have the E.T.O. specific indicator on it. 4.5. Any details on item being packed such as size or catalogue number should be visible through the transparent side of packaging material. 4.6. Place all items in the basket and place wrapped items on edge. Paper/plastic pouches must also be placed on edge with plastic side of one package facing the paper side of the one next to it. If pouches must be placed flat, the paper side shall face down. Expiration	CSSD Technicians	ETO Sterilization Record

	dates of sterilization are required on all gas-sterilized items. 4.7. Arrange load in the basket so that the gas can circulate freely. Do not overload shelves. Do not compress packages, since air and gas must be able to circulate during the cycle. 4.8. Do not allow load components to contact the sterilizer chamber wall. 4.9. Provide at least 3 inches between the sterilizer chamber ceiling and the topmost package of the load. 4.10. Check cartridge before using it in chamber. 4.11. Check recorder chart for correct time and water level for humidity. 4.12. Open door by turning handle counter clockwise until it stops and pull the door open. 4.13. Place basket into sterilizer chamber following above loading guidelines. 4.14. Close door securely. Select appropriate cycle. Start the sterilizer 4.15. After sterilization cycle is completed, the aeration cycle begins. 4.16. Unload after cycle has completed. 4.17. File the cycle printout. 4.18. In case of a minor error in sterilizer refer to Equipment Manual File. If problem persists in the functioning of the sterilizer, shut down sterilizer. 4.19. Notify Biomedical Engineer. The status of the sterilizer to be informed to CSSD In-Charge and other departmental members. Communicate for other shifts. If you are unable to sterilize any particular requirement due to a major failure, then inform user department 4.20. Record of servicing done is maintained. Details regarding equipment failure, repair and downtime are recorded.		
	If personnel exposure is suspected, give FIRST AID and send for further medical treatment		

Recommended By	Signature	Approved By	Signature
Dr. HrishikeshKalgaonkar Chief Medical Administrator		Dr. S.S. Deepak Chairman & Managing Director	

Records

Record ID	Name	Type	Responsible Person	Retention Period
NA	ETO Sterilization Record	Form / File	CSSD Technicians	2 Years

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Recommended By	Signature	Approved By	Signature
Dr. HrishikeshKalgaonkar Chief Medical Administrator		Dr. S.S. Deepak Chairman & Managing Director	

	SAIDEEP HOSPITAL CSSD MANUAL	Doc No	SDH/CSS/SOP/07
		Issue No	01
		Rev No.	01
		Date	1 Nov 21
		Pages	1
	SOP – Storage and Issue of CSSD Items		

Objective

- Ensure sterile storage of sterilized items and their proper issue to OT and other client departments in the hospital

Scope

- Sterile storage of items
- Issue of Items to OT
- Issue of Items to various units / departments

Expected Outcomes

No	Process Step / Activity	Responsibility	Outputs/ Records / Connections
1	All sterilized materials will be removed from the sterile side only post autoclaving and stored in the sterile store	CSSD Technician	
2	ETO sterilized items will be unloaded and immediately transferred through the pass box to sterile storage	CSSD Technician	
3	While unloading the batch passing indicator will be checked to validate the load / batch parameters. In case of failure the batch will not be accepted and unloaded from clean side.	CSSD Technician	
4	While unloading each pack would be checked for appropriate color change of chemical integrator pasted on each pack. Units which do not indicate color change will not be unloaded to sterile side. The packs would be checked to integrity of packing also.	CSSD Technician	
6	The sterile store shelves will be properly labelled to indicate which types of packs / materials to be kept at each shelves	CSSD Technician	
7	The staff entering sterile storage side for unloading and issue of items would go through full dress and scrub protocol of the OT.	CSSD Technician	
8	Any OT staff entering sterile storage should inform the CSSD prior toe entering storage and should perform	CSSD Technician	

Recommended By	Signature	Approved By	Signature
Dr. Hrishikesh Kalgaonkar Chief Medical Administrator		Dr. S.S. Deepak Chairman & Managing Director	

	surgical hand wash and proper drying; prior toe entering sterile storage		
9	CSSD will maintain a weekly and daily time schedule for issue of Items from sterile storage and communicate the same to all user departments. This would reduce the number of entry to sterile storage room and there by chances of contamination	CSSD Technician	
10	All issues done from CSSD will be recorded in the CSSD Issue register	CSSD Technicians	Issue Register
11	The OT In-charge will share a copy of the posting list and requirements one day prior for preparation of the issues	CSSD Technician	
12	Emergency pack will be kept at stock for emergency issues	CSSD Technician	
13	The Sterile Storage area will be cleaned daily using a separate set of mops by the cleaning staff assigned to OT in the presence of CSSD staff only. A checklist of cleaning will be maintained. The cleaning and disinfectant agents used would be same as that used in OR cleaning	CSSD Technician	
14	Deep Cleaning would be done on a monthly basis or in cases where environment surveillance swabs failure is reported and corrective action is needed. A deep cleaning checklist will be used to record the same.	CSSD Technician	

Records

Record ID	Name	Type	Responsible Person	Retention Period
NA	CSSD Collection / Receiving Register	Register	CSSD Helpers / Technicians	2 Years
NA	Sterile Storage Area Daily Cleaning and Disinfection Check List	Form / File	CSSD Helpers / Technicians	1 Year
NA	Sterile Storage Area Deep Cleaning Check List	Form / File	CSSD Helpers / Technicians	1 Year

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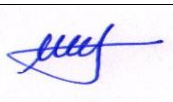
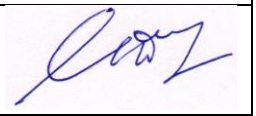
Recommended By	Signature	Approved By	Signature
Dr. Hrishikesh Kalgaonkar Chief Medical Administrator		Dr. S.S. Deepak Chairman & Managing Director	

Objective

- Ensure quality control of steam and ETO sterilization process to ensure effectiveness of the sterilization

Scope

- Verification and validation of steam sterilization process
- Verification and validation of ETO sterilization process

Expected Outcomes

-

No	Process Step / Activity	Responsibility	Outputs/ Records / Connections
1	**Bowie Dick Test** Each steam sterilizer on the day of their intended use runs Bowie Dick Test. The test sheet is filed in the Bowie Dicks Test File with date and details of sterilizers marked on them with indelible ink. Any deviation from the accepted shall be immediately informed to the Infection Control Officer. A re-run of the test would be done in the presence of ICO. In case of repeated failure; appropriate corrective actions would be ensured in coordination with Biomedical Engineering and authorized AMC/CMC provider The Bowie Dick Tsing would be conducted as per " Work Instructions for Performing Bowie Dick Test"	CSSD Technicians	Bowie Dick Test File Work Instructions For Performing Bowie Dick Test
2.	**Load / Batch Quality Testing for Steam Sterilization:** **A. Multi-parameter Integrator Based Dummy packs**	CSSD Technicians	Steam Sterilization Record

	- The CSSD technician shall incorporate an integrator (Class IV to VI) in a dummy load in the same cycle as the surgical sets. An integrator strips that changes color only multiple parameters – temperature, Steam exposure time and pressure match with prescribed values is used as a check for every load. This strip is placed near the drain. The load is considered sterile and issued to the concerned department only if there is an appropriate color change. The accepted integrator is pasted in the appropriate location filed in the Steam Sterilization Record. B**. Verification and Recording of Steam Sterilizer Cycle Parameters** - All steam sterilisers are equipped with sensors and record the various physical parameters related to sterilization process. The machine printout describes the sterilizer cycle accurately as a plot of these parameters against timeline of each process of the sterilizer cycle. It gives information regarding heat-up time, holding time, exhaust creation time, etc. CSSD technicians shall check the achievement of parameters of sterilization against the printout and based on same the load is accepted as passed. A copy of the print out is attached to the Steam Sterilization Record (photocopy of print out is suggested in case of thermal paper printouts) **C. Pack / Item Level verification Using Chemical Indicators** - Chemical Indicators strips impregnated with certain dyes, which change color when the required temperatures are reached. Hence chemical indicators reach their end point in the form of a chemical (color) change. Every pack must have an indicator affixed on the label. After sterilization, these packs are issued for		Steam Sterilization BI Test Reports File Work Instructions For Performing Bowie Dick Test

	use only if the indicator shows the prescribed color change. **D. Biological Indicators** - Daily a Biological Indicator is included in a bio-challenge load being put for steam sterilization. (Ref. Steam Sterilization Biological Test Record.) and sent to the Clinical Lab for processing. (Biological Indicator Register) On failure of a BI the entire batches affected shall be recalled from user departments		
	E.T.O. Sterilization A. Use of Biological Indicator - For ethylene oxide sterilization, place the biological indicator capsule inside of a disposable 20 cc syringe with the cap towards the needle end of the syringe. Remove the needle if necessary and put the plunger in place. Place this syringe in a sterilization pouch, seal and place in the center of the sterilization load. Process as usual. Aeration of the test pack is not necessary when following this method - Every cycle a biological indicator is included in any regular load being put for E.T.O sterilization. (Ref. ETO Sterilization Biological Test Record.) and sent the Clinical Lab for processing. Analysis of reading Biological Indicator Results - After the completion of the sterilization cycle, the test package is removed and the biological indicator capsule is removed. - The test capsule is placed in the proper area of the incubator and crushed, allowing release of the	CSSD Technicians	ETO Sterilization BI Test Reports File

	culture medium. A biological indicator capsule not exposed to the sterilant (control) is also marked and placed in the incubator. - The first reading is done in 24 hours. Compare the test capsule and control capsule. The control capsule shall show a colour change, as per the manufacturer's instructions. The test capsule shall remain the same color, as when sterilized. Any change in color indicates a potential sterilizer failure. The recall procedure shall be initiated at this time . - If no color change occurs, the capsules are allowed to incubate for another 24 hours. The procedure described above is again followed. - Control capsules shall be subjected to sterilization prior to their disposal. - Any positive biological indicator shall be considered evidence of inadequate sterilization. This evidence shall not be ignored; nor shall it be regarded as a "false" positive test. The biological indicator should continue to be cultured to make sure that what is growing is the same substance as was in the capsule. Immediately the recall procedure shall be initiated		

Records

Nil

Work Instructions

SDH/CSS/4.8/ WI -01 - Work Instructions For Performing Bowie Dick Test

Objective

- Establish a system for recall of CSSD supplied items from client departments / units in case of sterilization process quality control process failures or other situation requiring recall

Scope

- Recall of CSSD packs / items

Expected Outcomes

- Effective removal of items of specified batch numbers from all locations of hospital and their return to CSSD

No	Process Step / Activity	Responsibility	Outputs/ Records / Connections
1	A decision for the recall of CSSD item would be based on recommendation of the Infection Control Officer based on events like BI test failures or reported HAI; and shall need approval from Medical Superintendent	Chief / Senior CSSD Technician ICO MS	
2	In preparation of recall CSSD will prepare a list of items pertaining to affected batch numbers based on the CSSD Issue registers	CSSD Technicians	
3	Existing stocks in sterile storage will be removed and sent to CSSD processing area	CSSD Technicians	
4	All units / department would be informed by CSSD on the details of affected batch numbers and requested to immediately remove the affected items and separated store them till their collections from unit by CSSD staff	Hospital Staff	
5	CSSD staff will collect the recalled items from each department and tally them against the recall list.	CSSD Technicians	
6	A review of the recall process will be conducted by the ICO, CSSD team and other key stakeholders. The review		CSSD Recall Review

	will assess the extent of potential use of items belonging to recalled batch based on data collected from sterilization records, issue records, recall record, OT and other department process records. Details of potentially affected patients also shall be included in the review report		Report/File
7	ICO along with ICN will review potential infections arising out of use of affected materials / instruments	ICO/ICN	
8	The recall review report and possible impact of the process failure shall be discussed as an agenda item by the next Infection Control Committee meeting	ICO HIC Committee	HIC Minutes

Records

Nil

Objective

- Define process for cleaning and disinfection of CSSD environment to prevent cross contamination

Scope

- Cleaning of CSSD areas
- Disinfection of CSSD Surfaces
- Cleaning and Disinfection of CSSD Carts
- Environment Surveillance of Sterile Storage Units

Expected Outcomes

- Prevention of potential growth of organisms in critical areas and equipment used in CSSD

No	Process Step / Activity	Responsibility	Outputs/ Records / Connections
1	Establishing a clean work and storage environment is a constant aim. Cleaning procedures shall be considered among vital tasks and each technician is responsible for getting the area cleaned. In addition, those areas that are not used exclusively to store or handle direct patient contact items; but are a part of the department such as storage area, office area, etc. are to be kept clean and in order	CSSD Technicians / CSSD Helpers	
2	Storage racks and carts shall be cleaned on a weekly basis.	CSSD Technicians / CSSD Helpers	
3	Tabletops, counters, sinks and cupboard doors require daily cleaning.	CSSD Technicians / CSSD Helpers	
4	Housekeeping shall clean all walls and ceilings after an interval of one day.	CSSD Technicians / CSSD Helpers	
5	The floors are wet mopped twice a day.	CSSD Technicians / CSSD Helpers	
6	Sterile trolley shall be wet dusted and cleaned with	CSSD Technicians	

	Bacilocid. (Low Level Disinfectant may suffice)	/ CSSD Helpers	
7	Wet dusting of the walls, steam sterilizers, ETO sterilizer and Flash Sterilizer, all shelves, table, movable furniture, all other hard surfaces and floor shall be done and cleaned with Bacilocid solution. RO water shall be used	CSSD Technicians / CSSD Helpers	
8	Washing: All shelves, table, movable furniture, all other hard surfaces and floor shall be done on every Wednesday with Bacilocid solution	CSSD Technicians / CSSD Helpers	

1. PURPOSE

Ensure proper reprocessing of single use devices approved by hospital Infection Control Policy and approval of Hospital Infection Control Committee

2. SCOPE

- Reprocessing of SUDs

3. Expected Outcomes

- Reduction of risks associated with reprocessing of Single Use Devices

No	Process Step / Activity	Responsibility	Outputs/ Records / Connections
1	The end-user submits a written request for re-sterilization, reprocessing or re-use of a single use device to the chairperson of the Hospital Infection Committee. A completed proposal form must accompany the request.	Clinical Departments / HIC	Request for SUD Reprocessing Approval
2	The HIC reviews the requests or identifies areas thatrequires further investigation. The HIC may form a technical team to evaluate the request and form guideline for reprocessing of said SUD based on manufacturer recommendations and / or published resources on the same	HIC	
3	The Committee uses an established review process, which includes consideration of: • the categorization of the device • the safety and efficacy of re-sterilization or reprocessing • the likelihood the device will work properly after re-sterilization or	HIC	

	• reprocessing • the cost effectiveness of re-sterilization or reprocessing for re-use • the ability of the organization to measure any of these considerations through • objective, quantifiable means • the manufacturers' willingness to collaborate in the re-use program by • providing pertinent information e.g. product specifications, sterilization • parameters		
4.	The Committee will approve or reject requests for re-use. This decision will beforwarded in writing to the applicant.	ICO	
5.	In case of approval the List of SUDs approved for reprocessing is updated and updated copy circulated to all departments concerned. The CSSD shall display the latest version of the list in decontamination and processing zones always for reference	Chief / Senior CSSD Technicians	
6.	The Hospital Infection Control team shall coordinate with respective clinical departments and track the status of hospital acquired infection for all patents who has used the reprocessed items of the category approved recently. This surveillance will be done for for all patients using reprocessed device for each newly approved category / device for a period of three months from date of first approval. The finding shall be reported as a part of HIC surveillance data. In case of reported potential infections the decision for approval will be reviewed by the committee	Hospital Infection Control Committee / Hospital Infection Control Team	
7.	Reprocessing and Labeling of SUDs will be done as per " General Instructions for Reprocessing of SUDs".	CSSD Technicians / CSSD helpers	General Instructions for Reprocessing of

			SUDs
8.	Separate detailed work instructions would be developed and training for CSSD staff conducted on same for each Critical / High Risk SUD approved for reprocessing. Chief / CSSD technician shall maintain a list of technicians / helpers with competency to reprocess each approved SUD of Critical / High Risk category. No SUD shall be handled for reprocessing by a CSSD Technicians / Helper with out approved competency for reprocessing the same These instructions shall be available for reference / displayed in an appropriate manner at decontamination and processing zones of CSSD	Chief / Senior CSSD Technicians	Work Instruction – Separate for Each High Risk / Critical SUD
9	A separate register will be maintained by CSSD to track the reprocessing of SUDs	CSSD Technicians	SUD Reprocessing Register

Records

Record ID	Name	Type	Responsible Person	Retention Period
	SUD Reprocessing Record	Form / File	CSSD Technicians	2 Years

Work Instructions

SDH/CSS/4.7/WI – 01 - General Instructions for Reprocessing of SUDs
SDH/CSS/4.7/ WI – 02.01 onward – Specific Wis

Recommended By	Signature	Approved By	Signature
Dr. Hrishikesh Kalgaonkar Chief Medical Administrator		Dr. S.S. Deepak Chairman & Managing Director	

PROCESS CHALLENGE DEVICE – AUTOCLAVE

1.Take 16 clean absorbable towels.

2. Each towel is approximately 16 inches × 26 inches.

3. Each towel is folded lengthwise into third and then folded widthwise in the middle.

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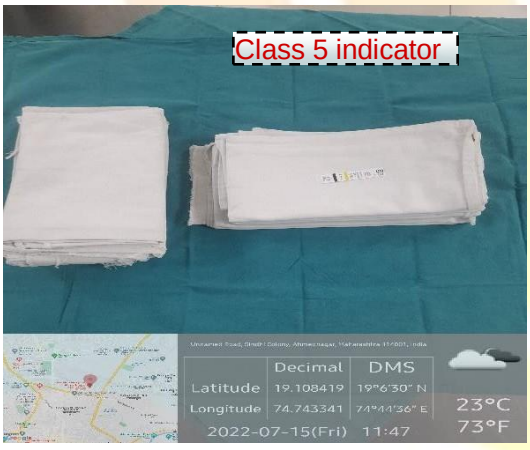
Dr. Hrishikesh Kalgaonkar Chief Medical Administrator		Dr. S.S. Deepak Chairman & Managing Director	

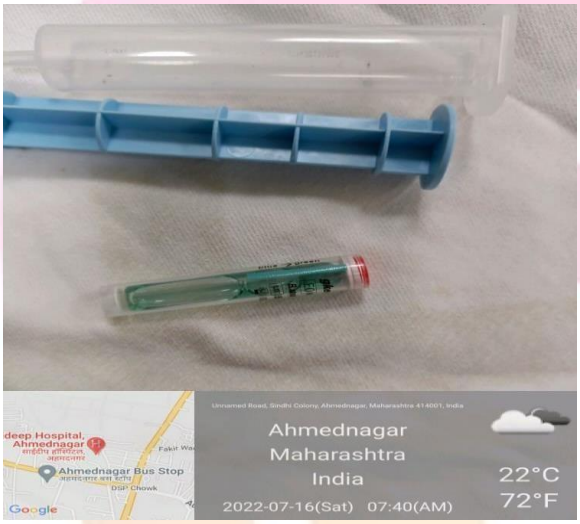
4. The folded towels are kept one on top of another to form a stack of approximately 6 inchesin height and weight 1.4 Kg in weight.



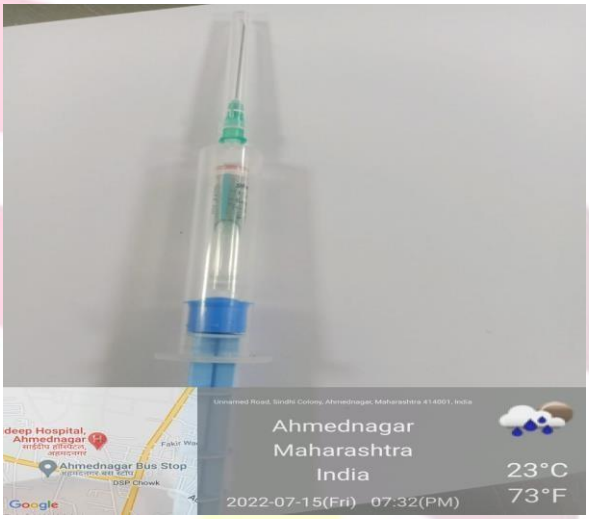
5. This PCD should be used for testing class 5 integrator and biological indicator.

6. Indicators are kept in between towel no 8 & 9, and placed near drain of autoclave.

PROCESS CHALLENGE DEVICED FOR ETO

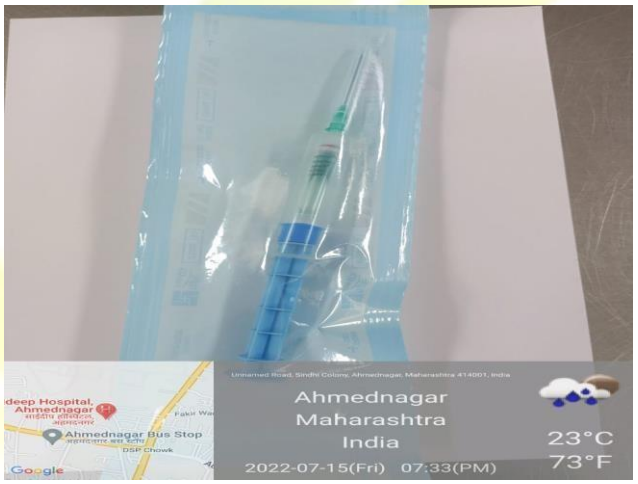


1. 10cc syringe to be used with capped needle in place.



2. Plunger is removed and biological indicator kept inside.

3. Plunger re-insert only up to the top section.



4. This syringe packed with regular packing for ETO.

Recommended By	Signature	Approved By	Signature
Dr. Hrishikesh Kalgaonkar Chief Medical Administrator		Dr. S.S. Deepak Chairman & Managing Director	

5. Then it is placed in the folds of clean surgical towel and wrapped.

6. It is then processed in the regular ETO Cycle along with the load

PROCESS CHALLENGE DEVICE – AUTOCLAVE

1. Take 16 clean absorbable towels.
2. Each towel is approximately 16 inches × 26 inches.
3. Each towel is folded lengthwise into third and then folded widthwise in the middle.
4. The folded towels are kept one on top of another to form a stack of approximately 6 inches in height and weight 1.4 Kg in weight.
5. This PCD should be used for testing class 5 integrator and biological indicator.
6. Indicators are kept in between towel no 8 & 9, and placed near drain of autoclave.

PROCESS CHALLENGE DEVICED FOR ETO

1. 10cc syringe to be used with capped needle in place.
2. Plunger is removed and biological indicator kept inside.
3. Plunger re-insert only up to the top section.
4. This syringe packed with regular packing for ETO.
5. Then it is placed in the folds of clean surgical towel and wrapped.
6. It is then processed in the regular ETO cycle along with the load.