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Inodaya Hospitals

CSSD MANUAL

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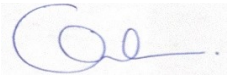
Approved By:	***Designation: MEDICAL DIRECTOR*** **Name** Dr.Gowtham Krihsna **Signature:** 
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AMENDMENT SHEET

S.NO	Section and Page	Date	Amendment	Signature

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1 INTRODUCTION

Sterile supplies continue to be a major support area in the hospital. There is growing knowledge and technique available with regard to sterilisation. While steam sterilisation retains its paramount importance, Ethylene Oxide (ETO, EO) sterilisation is a widely used method for sterilisation. Heat sensititive and fragile items which cannot be sterilised are sterilised by steam. An important area in the support service is that of sterile supplies, the concept of which has also undergone significant transformation in recent times. Newer and better methods of sterilisation, introduction of more and more disposables into hospital practice and the development of quality control systems have all been part of the efforts of the health community in the control of hospital infection.

2 PURPOSE

To establish and maintain standardized procedures for sterilization of different articles used in the hospital.

3 SCOPE

The scope of CSSD services is to provide sterilised instruments and linen to all user departments in time by means of autoclaving, ETO sterilising.

4 RESPONSIBILITY

CSSD In charge shall be responsible for the entire functioning of the CSSD department

Policy

Hospital is committed to ensuring highest standard of sterilization of equipments, instruments and other articles so as to ensure maximum infection control possible.

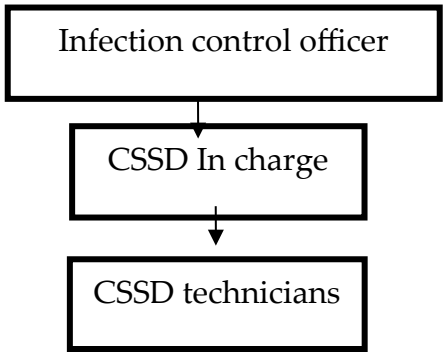
5 EQUIPMENTS USED

- Gauge cutter
- Ultrasonic washer

- Needle flushing device
- Autoclave
- Ethylene Oxide steriliser
- Work benches with marble or stainless-steel top
- Storage cupboards and racks
- Linen folding table
- Soaking sinks
- High pressure water jets
- Punching machine

6 DEPARTMENTAL HIERARCHY

6.1 Hierarchy Chart



7 JOB DESCRIPTION

7.1 CSSD Supervisor

Qualified in CSSD technology with a 3-4 yrs of experience of working in CSSD

- He will be advisor to medical superintendent on all aspect of CSSD functioning.
- He will be responsible for overall functioning of CSSD.
- He will ensure uninterrupted supply of CSSD item to all areas of hospital.
- He will supervise cleaning, checking, assembling and packaging of all articles requiring sterilisation according to set standards
- Will assist the management in planning budget for the department

- Supervise servicing and annual maintenance of the equipments
- Arrange periodic training to the CSSD staff
- Conduct periodic audits to ensure compliance with set standards
- Keep track of recalls and evaluation for the same
- Monitor the calibration, maintenance and AMC of the instruments and equipments used
- Responsible for maintenance of all records in CSSD including receipts and issues.
- Responsible for safe keeping of all stores under his charge.
- Smooth supply of disposables, replacement of broken items, and issue of sterilised items will also be his responsibility.
- Ensure optimum stocking of all stores required for CSSD.
- Responsible for ensuring clean and safe environment within the department
- Monitor the daily activities of the technicians
- Impart training to the staff and judge their competency level
- Ensure highest level of sterilisation of equipments
- Ensure timely supply of items and linen to the user departments
- Ensure proper working conditions for the sterilisers

7.2 CSSD technician

- Receive the materials supplies and equipment for processing.
- Carry out cleaning of equipment material, rubber and plastic goods as per set standards
- Check items for breakages, instruments and needles for sharpness and assembling of the equipment after washing and drying.
- Make sets for various procedures and pack them for sterilisation
- Load and unload sterilizers, and do various other duties like internal housekeeping, under the guidance of CSSD Supervisor
- Store the sterilised items in the storage area and issue thereof under the supervision of the supervisor
- Perform Validation Tests on a daily basis

- Inform any malfunctioning or breakdown of the equipments to the supervisor.

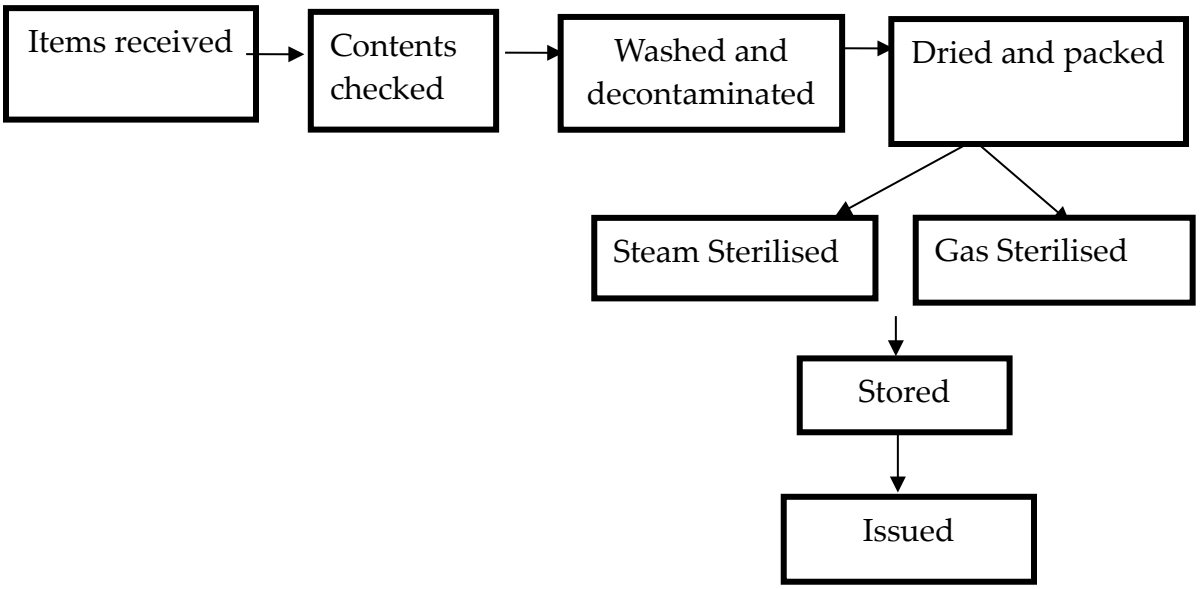
8 QUALITY OBJECTIVES

S. No.	Quality Objectives	Performance Indicators	Measurement Criteria	
			Criteria	Frequency
1	Service Level	Staff availability	Duty Roster / Attendance Record	Monthly
2	Process validation	Manual temperature and digital display checking	Equipment temperature maintenance and Validation register	Daily
		Class V& VI	Autoclave	Every set , Daily
		Bowiedicks test	Equipment temperature maintenance and Validation register	Daily
		Biological Indicator	Equipment temperature maintenance and Validation register	Weekly
		Leak test	Equipment temperature maintenance and Validation register	weekly
		Calibration	Equipment temperature maintenance and Validation register	yearly
		Microbiological cultures	Infection control register	Monthly
3	Internal	Wait time	Feedback / Complaints	Monthly

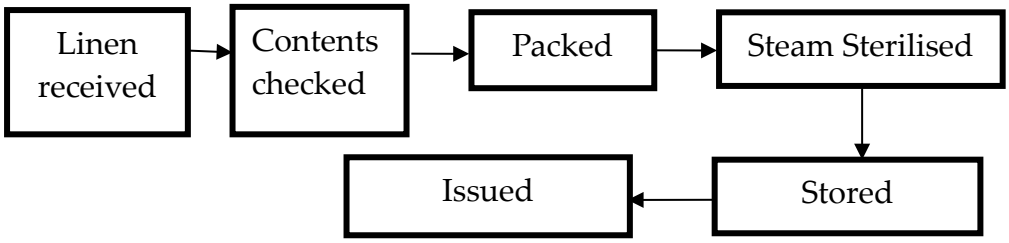
	Customer Satisfaction		to Supervisor -CSSD	

9 ITEM FLOW

9.1 Equipments and Apparatus



9.2 For Linen (from Laundry and OT)



10 AUTOCLAVING

Following are essential pre-requisite that should be observed before attempting to sterilise.

a) All items to be cleaned and dried which will ensure that the minimum number of organisms are present on the item prior to processing.

b) The packaging shall be appropriate for the process and will not obstruct the passage of the steriliant while undergoing the sterilisation process.

c) The machinery will be able to perform its task within well defined parameters and

d) The maintenance and logging of the process and engineering work on the machinery will be strictly monitored

Time and temperature parameters

30 minutes at 30 PSI at 134^{o} C

15 minutes at 15 PSI at 50 ^{o} C

Shelf life of Dressing sets: the shelf life of items autoclaved for SMS sheets is 30 days. , ETO things - 3 months. For cloth wrapper 3 dyas.

Sets for autoclaving will be arranged in accordance to a checklist mentioning the contents of the tray/set

Common sets

- Dressing set
- Lumber Puncture set
- Catheterisation set
- Cut down set

- Chest aspiration set
- Abdominal aspiration set
- LSCS set
- DNC set
- ICD set
- Suturing Tray
- Minor Set

Preparation of Supplies for Autoclaving:

- All articles will be washed and dried before autoclaving.
- Instruments and materials to be wrapped in green sheet or one layer of muslin and one layer of disposable sterilization wrapper
- When articles are placed in glass or metal containers for autoclaving, porous lid to be used to cover the container so the steam penetrates the entire inside of the container.
- Contents of a linen pack to placed in such a way that the articles on top are used first.
- Every item that is packaged to be labelled before sterilization to specify the contents and expiry date.
- Surgical knife blades or suture materials **NOT TO BE** placed inside linen packs or on instrument trays before sterilization.

Instruments:

- Instruments to be cleaned as soon as possible after their use
- Gloves to be worn while handling the instruments to avoid infective material & cuts.
- Each instrument to be washed after use with an antiseptic detergent solution. (multi enzyme)

- When washing by hand, particular attention to be paid hinged parts and serrated surfaces. Rinse all instruments, and dry them thoroughly.
- Separate the sharp instruments from the blunt instruments.
    - The size of instruments pack should allow space for steam penetration in the drum
    - Place the tray inside a bin after spreading the towel inside.

Glassware:

- All reusable glassware to be inspected for cracks or chips.
- All reusable glassware to be washed with soap or detergent and water after use, and rinsed completely.

Rubber Latex Materials:

- Wash rubber tubing in an antiseptic detergent solution.
    - Attention to be paid to the inside of the tubing. Rinse all tubing well and place it flat or loosely coiled in a wrapper or container.
    - When packing latex surgical drains for sterilization, place a piece of gauze in the lumen of the tray.
    - Never re-sterilize surgical drains.
    - Never re-sterilize rubber catheters bearing a disposable label.

(The decision to use reusable or disposable gloves will be taken by the hospital management)

Linen:

- Surgeon's dresses to be washed with detergents and autoclaved.
- Aprons and drape sheets to be washed with detergent, dried in covered area and autoclaved in a loosely packed, separate drum pasted with an indicator strip.

10.1 Loading

- Remember: If an item goes in wet, it will come out wet. All items (instruments, basins and glassware) must be dry before loading into the sterilizer. This helps prevent "wet packs." The sterilizer is capable of drying items that have become moist during a properly loaded and operated sterilization process, but it cannot remove excess moisture.
- When loading, leave sufficient space for steam to circulate freely. **Do not overload.**
- Place all packs (linen, gloves) on edge and place canisters, utensils and treatment trays on their sides.
- Place instrument sets in trays having mesh or perforated bottoms flat on the shelves.
- In combination loads of cloth (or paper) packs and instruments trays, place linens on top shelves and trays on lower shelves. This prevents any condensation (moisture), which forms on cool metal when steam initially contacts the item, from dripping onto linen packs
- Surgical gloves will be sterilized by themselves or placed on the top shelves.
- Nested packs will be positioned in the same direction to help prevent air pockets, so

condensation can drain and steam can circulate freely.

- Shelves (metal wire) or a loading cart must be used to ensure proper loading. It is preferable to use the cart that comes with the sterilizer.
- Metals and Glassware
    i. Instrument sets should not exceed 13 kg (28 lbs). Basin sets should not exceed 20 kg (44 lbs). This is to limit the amount of condensation which forms when steam contacts cool metal. Using these limits ensures that the items will dry during the sterilization cycle.
    ii. Solid containers will be placed on their sides to allow airflow out of hem. If air is trapped in a solid container, it will prevent the steam from contacting the inner surface and prevent sterilization.
    iii. Linen packs should not be too large and weigh no more that 10 kg (22 pounds) in order to assure steam penetration of the pack in 30 minutes (the time allowed for sterilizing wrapped items).
    iv. Packs containing sheets, table covers and towels are the most difficult for steam to penetrate and contact each fibre. Such packs must be placed on edge on the shelf to insure steam penetration.

Loading the Steam Sterilizer Using Loading Carts or Shelves

- Place all items on a shelf. Use either a loading cart or shelves in the sterilizer. Never place items (wrapped or unwrapped) on the floor of the sterilizer. Items

placed on the floor could block discharge of air from the sterilizer, or allow air and moisture to be trapped in pockets, resulting in sterilization failure and "wet packs."

- Items must not touch chamber walls. Packs touching the chamber walls can be scorched or contents damaged due to excessive heat of the metal walls.
- Always allow 7–8 cm (3 inches) of space between top-most package and top of chamber. This allows displacement of air and free flow of steam
- Place all fabric packs on the edge (folds perpendicular to shelf); and when loading two layers on one shelf, place the upper layer crosswise to the bottom layer. It is easier for steam to flow down through the folds to penetrate each fibre than through flat, compressed surfaces.
- Cloth items, such as surgical drape packs, must be placed on the cart so that the folds on the items inside the packs are arranged vertically.
- Loads containing both metal and cloth items must have the metal items placed on the bottom shelf.
- Items that could trap water must be placed on edge to allow water to drain out.
- Place all bottles, solid metal and glass containers of dry materials on their sides with lids held loosely in place. Air will drain out and steam will take its place.
- Place treatment trays and utensils on the edge, tipped slightly forward. This prevents pooling of condensation and facilitates drying.
- Place instrument trays (mesh or perforated bottom only) flat on shelves. If instruments have been placed in a solid tray or on a Mayo tray, the tray must be

placed on the edge and tipped slightly forward. This helps maintain an orderly arrangement of contents and reduces damage caused by "Dumping" all the instruments into bottom of tray if instrument tray is placed on its side. This also facilitates drying.

- Solutions must be sterilized by themselves, and placed on the shelves not touching each other. There is always a possibility that solutions will explode. If instruments and other items are in the steam sterilizer, they will be contaminated and they may be damaged.
- Use only the upper shelves for gloves. Place glove packages loosely on edge with thumbs up, well away from the walls of the chamber. Never place them on the bottom shelf of the chamber. Residual air gravitates to the lower part of the chamber and will increase the rate of deterioration of the rubber.
- Do not compress packages or overload the chamber. When placing packages on shelves, put hand between them to be sure packages are not compressed and give least possible resistance to steam throughout the load.

- Combination Loads
  - In loads which combine linens (fabrics) and metal items, place linens on top shelves and metal items below. This prevents condensation from dripping onto the linen packs, causing them to absorb the excess moisture.
  - When a load is made up of wrapped and unwrapped items requiring different times to ensure sterilization, the longest required time (i.e., 60 minutes) must be used.

- Remember: The sterilizer is unable to remove excess moisture. The fundamental rule in loading the sterilizer is to prepare all items and to arrange the load in such a manner as to present the least possible resistance to the passage of steam through the load (i.e., from the top of the chamber toward the bottom).

10.2 Unloading

- After the sterilizing cycle has been completed and the chamber pressure gauge reaches "0," open the door 12–14 cm (5–6 inches). Always keep the door between you and the sterilizer when opening the door.
- Wait 30 minutes before unloading the sterilizer. This allows residual moisture to dry and the load to cool.
- Allow instrument packs to dry completely before removal (takes 30 minutes).
- Place sterile trays and packs on surfaces padded with paper or fabric.
- (Do not place warm packs on cold metal surfaces, as condensation will occur.)
- Store when packs reach room temperature (usually takes about an hour).
- Sterilized packs and articles will be handled gently and as little as possible.
- **Note**: If a pack is dropped, tears or comes in contact with moisture, it must be considered contaminated
- After sterilizing, objects wrapped in cloth or paper are considered sterile if kept dry and the package intact. Sealing packs in plastic bags can help to prevent damage to the packs and permits a longer shelf life. Unwrapped objects must be used immediately or placed in a sterile, covered container.

- If steam escapes from the safety valve instead of the pressure valve, **the pressure valve must be cleaned and inspected**.
- If steam escapes from under the lid, **the gasket (rubber ring) must be cleaned and dried or replaced**.
- At the end of the sterilizer cycle, open the door of the sterilizer and remove the basket or cart. Use long cuffed terry cloth gloves or thick towels to protect yourself from the hot items.
- Carefully lift the items off the shelf. Dragging the items across the shelf can cause cuts or tears in the wrappers.
- Do not place warm items on a cold surface since condensation may occur resulting in contamination of the items.
- Carefully inspect each item being removed for any of the following problems:
    i. Broken or burst seals
    ii. Cuts in the wrappers
    iii. Water drops on the packages
    iv. Indicator tape that has not changed to show the item has been sterilized. Missing load labels

Unloading Using a Loading Cart

- Remove the loading cart from the sterilizer and place it where there is no open window or fan in close proximity. Do not place freshly sterilized packages, especially those not completely cooled, in front of an open window or a fan because there may be residual humidity in the packages, and dust and dirt could be forced through the wrappers, contaminating the

contents. If there are water droplets or visible moisture on the outside of the wrapper or package, or on the tape used to secure it, the package is contaminated. It must be reprocessed before use. Look at, but do not handle, the outside of the package to test for dryness. When the packs reach room temperature, remove packs from the loading cart and place on storage shelves. They may be dispensed or placed in sterile storage. It may take 1 hour or longer for packs to reach room temperature. Avoid unnecessary handling.

Unloading Using Shelves

- Remove packages from the sterilizer shelves. Avoid unnecessary handling.
    - Look at outside of the wrappers for dryness. If there are water droplets or visible moisture (water stains) on the outside surfaces of packages, or on the tape used to secure it, the package is contaminated. It must be reprocessed before use.
    - Place packs on a surface well padded with paper or fabric, away from open windows or the front of a fan. In order to prevent condensation from forming, do not place on a cool or cold surface. Do not place freshly sterilized packages, especially those not completely cooled, in front of an open window or a fan because there may be residual humidity in the packages, and dust and dirt could be forced through the wrappers, contaminating the contents. If there are water droplets or visible moisture on the outside of the wrapper or package, or on the tape used to secure it, the package is contaminated. It must be reprocessed before use.

- When packages have cooled to room temperature, they may be dispensed or placed in sterile storage. It may take 1 hour or longer for packs to reach room temperature. Avoid unnecessary handling.

12.CLEANING

- Cleaning area shall be separated and not shared with other facilities.
- Personal protective equipments shall be worn while in CSSD
- A dedicated sink (not hand wash basin), to contain water/detergent mixture for cleaning instruments;
- A second dedicated sink (not hand wash basin) for rinsing items;
- A supply of cleaning implements and accessories i.e. brushes/cloths etc (as recommended by the instrument manufacturers) which are themselves routinely decontaminated after each use or disposed of after each single use if so marked by the manufacturer.
  - Brush, wipe, agitate, irrigate, jet wash or hand spray the item to dislodge and remove all visible soil, taking care to ensure the item remains under the surface of the water at all times to prevent the creation of aerosols.
  - Item to be removed from the sink and excess detergent drained prior to placing in the second sink to rinse in clean water.
- Ultrasonic Cleaning
  - Dismantle or open the instruments/ items to be cleaned and fully immerse in the solution in order to displace trapped air and to ensure penetration of the lumen if hollow instruments are being cleaned. Consideration shall be given to the use of a protein-

enzyme dissolving solution (3M RAPID ENZYMATIC SOLUION) when cleaning medical devices with lumens or complex parts. Manufacturer's guidelines for use of Machine shall be followed

- Item will be removed and drained before drying using the preferred method.

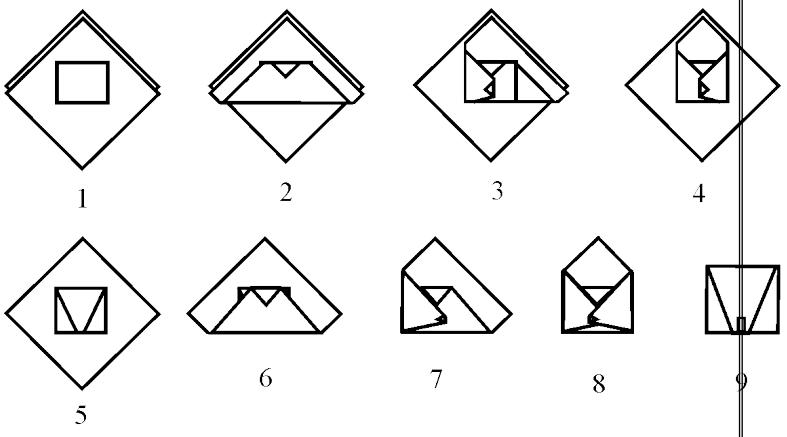
13.PACKING AND WRAPPING

- All packed instruments will be sterilized on the same day.
- Packed items (not yet sterilized can be stored in separate cupboard)
- Types of materials that can be used as wrappers include:
  - **Paper**: Double wrapping (two layers) recommended. Use for steam sterilization only and **do not reuse**.
  - **Do not** wrap items in any waterproof material, such as plastic or canvas, for steam sterilization, as steam will not penetrate the material and the item will not be sterile.
  - Wrappers should not be reused if they are torn, stained with oils or if they have hard or gummy deposits. Linen wrappers will be laundered between sterilizations, **even if unused**; in order to restore moisture to them (dried out fibres decrease the ability of the cloth to form a barrier to micro-organisms). Dust covers (sealed plastic bags 2–3 mils thick) can protect the integrity of sterile packs during storage. Packs will be placed in plastic bags or other dust covers after cooling.

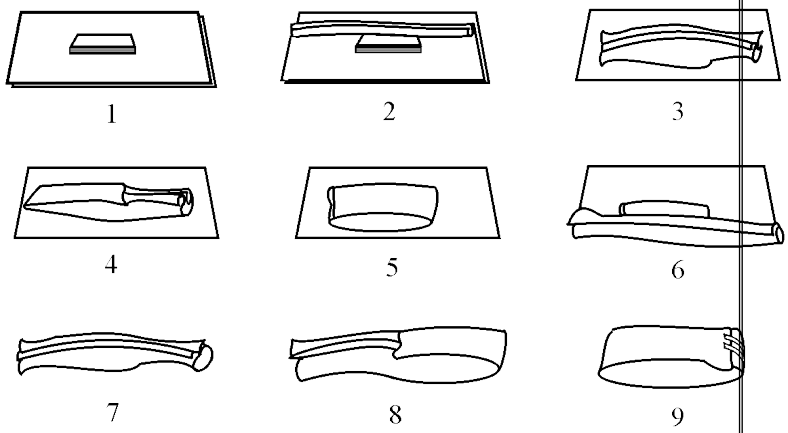
- Cover all sharp pointed items with plastic tubing or gauze to prevent tips from puncturing the package.
- Place item(s) in package with the "handle end" of the instrument toward the end of the package that will be opened by the user.

- Following Figures shows method for Packaging

Envelope Wrap



Square Wrap



- Peel Pouches, medical grade Paper, Polyethylene plastic

bags, Non-woven polypropylene

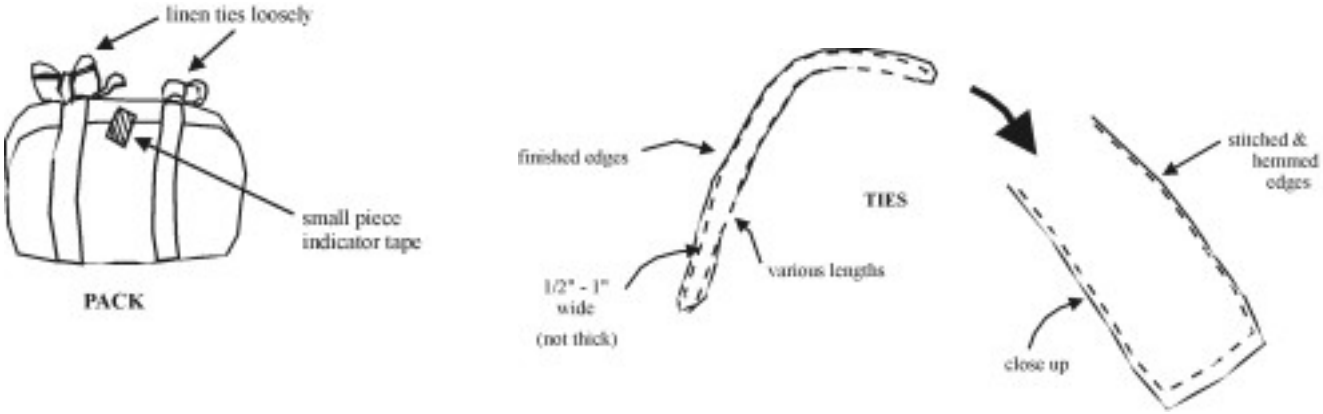
- All items for ETO sterilizer will be packed with Medical Grade paper. Allow enough room for securely sealing the package.
- When Medical Grade packaging; select a larger size outer package to allow the inner package to remain unfolded. Folding the inner package may hinder the sterilant from penetrating the packaging.
- Peel pouches may be sealed by a heat seal or by folding over the end twice and sealing it with tape. Self-sealing peel pouches are also acceptable. All seals on peel pouches must be carefully inspected for wrinkles or "tunnels" that could allow the contents to become contaminated.
- Place a piece of sterilizing indicator tape on the transparent side of the package, then write the description of the contents and your initials on the tape.

14. TIPS FOR WRAPPING

- Wrapping Surgical gowns
  - Hold the gown so that the outside is facing away from you. Place the outside right and left ties into the white tab
- At least two layers of wrapping should always be used to reduce the possibility of contaminating the contents during unwrapping.
- Do **not** wrap packages too tightly. If wrapped too tightly, air can become trapped at the centre of packages, preventing the temperature from getting high enough to kill all the micro-organisms. Also, wrapping

with strings or rubber bands or **tying linen ties too tightly** can prevent steam from reaching all surfaces.

- The outer wrapper of the pack can be loosely secured using linen **ties** (as described below) or masking tape. (The use of indicator tape for holding packs together will be minimized, as it is expensive and very hard to remove from linen. It is best used in the centre of the pack to verify steam penetration.)
- Packs can be secured with linen **ties** made from the same cloth. Hemmed strips about ½ inch wide, in various lengths, can be used one or two to a package and eliminate the need for a lot of expensive and hard-to-remove indicator tape. They can be used to secure almost any size package



14.1.Non Sterile Packaging

- Prior to packaging any item, carefully inspect the item for cleanliness and proper function.
- Types of non-sterile packaging that is acceptable, depending on the intended use of the item(s) being packaged, is:
  - Plastic bags (1-2 mil thick)- Many items and kits

can be packaged using plastic bags and closed with either tape, a twist-tie, or by heat sealing.

- Paper bags- Items that do not require water repellence can be packaged in a paper bag and closed by stapling.
- As with any method of packaging, the initials of the person packaging the item must be written on the outside of the package.

14.2.Labeling

- After packaging, all trays or sets will be labelled with a description of contents and with the technician's initials.
- Date of Sterilization
- The expiration date (where applicable) for the tray or set will be indicated on the outside of the packaging, or the "event related" label will be attached to the wrapped item.
- All trays and sets will have an external chemical sterilization indicator (sterilizer tape).
- Initials of the technician

14.3. Storage, Handling and Transport

- The environmental conditions of the areas designated for storage and distribution should ensure the integrity of all materials and products ie clean, well ventilated and secure.
- The accommodation should afford adequate protection to prevent contamination or deterioration of the product. Stock rotation will be used for storage i.e., FIFO (First in, first out). Expiry time and date will be marked on the sterile pack. If unused within the expiry date, the pack will be sent for re-sterilization. The item will be stored in closed cupboards in sterile zone.
- The integrity of the packaging material (Wrap, peel pouch, container) must be verified prior to the release and prior to

the use of sterile items. Any sterile package that shows evidence of breach of integrity will be considered unsterile. It must be returned to the Sterile Processing department.

- The persons responsible for handling, storage, cleaning and inspecting of sterile supplies should receive training including the following; (Time related vs event related shelf life, inspecting the condition of sterile packages, handling transportation and storage of sterile supplies, consequences of using unsterile supplies, stock rotation, and consequences of excessive dust on outside wrapping).
- Users of sterile supplies should also be educated to inspect all products prior to use.
- All sterile patient items require storage in the following manner:
    - 10" away from the foor
    - At least 18" from the ceiling
    - At least 2" from the outside walls
    - Away from potential moisture contamination (sinks, steam pipes etc)
    - Packages will be positioned in a way that avoids crushing, bending or compression.
    - It is recommended that sterile items be stored in cabinets or closed containers.
- All sterile supplies will be carefully checked before delivery to the clinical area to make certain the package is not damaged or has an expired expiration date. (for items that are not part of the “Event related Shelf Life”)
- Periodic inspections of the sterile stock must be conducted to make certain no outdated or damaged items remain in stock.

- Outdated supplies will be removed from stock and removed from their package, inspected, then repackaged and resterilised or discarded, as necessary.
- Good personal hygiene, especially good hand washing, is required when handling sterile items.
- Sterile items must never be allowed to come in contact with water, unsanitary surfaces or other sources of contamination.
- Shelves containing sterile supplies will be maintained in an orderly manner and will be cleaned on a routine basis.
- Any sterile item that is dropped onto the floor must be carefully and thoroughly inspected. If it is found to be undamaged; then it may be returned to the shelf. If there is any damage or contamination to the packaging or contents, the item must be repackaged and resterilised or discarded.
- Food and beverages are not allowed in areas where sterile supplies are stored.
- The temperature shall be controlled between 65°and 72° F. and the relative humidity between 40% and 70% at all times.
- The Sterile Storage area will have good ventilation, with at least 10 air changes per hour, and be balanced with a positive air pressure.
- Sterile supplies will be transported to of-site buildings in covered carts, while items transported within the facility will be transported in trolley meant for such transports only preferably in plastic bags
- Inspections: All departments or clinics storing sterile patient items must inspect their stock for evidence of tampering, punctures, moisture or other signs of compromised packaging. Such inspections will be scheduled at **three-month intervals.** Documentation of

such inspections will be maintained by the departments and must also be forwarded to the In charge CSSD.

- Exceptions: In accordance with the manufacturer's recommendations, patient items sterilized in rigid sterilization containers expire one year after the sterilization date. Implant items will be reprocessed after one year.
- Sterile items must be transported in clean containers or on clean carts whenever possible. If hand carrying sterile items is necessary, the item will be placed in a clean bag. Sterile items must never be carried under the arm or cradled in the arms.
- The final user is responsible for carefully inspecting all sterile packages for signs of contamination, damage, or for expired shelf life.

14.4. Requisition and distribution

- **Requisition system**- Request for operating instruments shall be forwarded to the CSSD in a written format a day ahead in accordance with the surgeries planned. The CSSD supervisor shall ensure the timely supply of the required items to the OT through dumbwaiter
- **Daily quota system**- Items and instruments required in the different OPD and wards including ICU will be fixed as per predetermined schedule and supplied in the early hours of the day
- The emergency department shall be supplied with all instruments as predetermined. However special attention will be paid to the CSSD needs of this department as this area is prone to unfore casted requirements

15. RECALL PROCEDURE

- All Load and items sterilized in the load are numbered with batch no.
- In case any of the Indicators mentioned above shows results not acceptable then
    i. The sterilizer in question shall be stopped and not used
    ii. Biomedical Engineer will be notified
    iii. The sterilization log will be reviewed and any items that have left the department as per the load and batch no. will be tracked
    iv. Nursing staff of the concerned unit where the batch has been issued will be contacted
    v. The supplied items will be collected back
    vi. After problem is corrected and a negative biological spore test is obtained, the CSSD In charge, after consultation with Infection Control, can allow the sterilizer be returned to operation.

16. QUALITY AND MONITORING SYSTEM

- Chemical indicators are designed to show a defined colour change when specified conditions have been attained. Colour change to black on chemical indicators indicates that the sterilient has penetrated the wrapper/container. A failed operating cycle must always be regarded as unsatisfactory, irrespective of the results obtained from any chemical indicators. All items sterilized will have a chemical indicator that is sensitive to the appropriate sterilization cycle conditions attached to the outside of the package. The

external chemical indicator can be **chemically sensitive tape (sterlometer), a paper strip, or a pre-printed indicator** that is visible on the outside of the package. To prevent items that have not been sterilized from being issued, the external indicator must be inspected each time a sterile device is handled (while unloading the sterilizer, when placing the item on the storage shelf, when dispensing the item).

- Tests (bowiedicks test and leak tests) will be conducted to verify efficiency o equipments and packing procedure
- Label every item that is packaged for sterilization to specify the contents and expiry date.
- Metallic Indicator: Metallic indicators are used for steam sterilizers. These are kept inside one pack selected randomly per day. If the Color falls in the acceptable range then steam has passed through the pack. A Logbook is maintained to track the dispatch of the pack and load no. he uses opening the pack in the user's department will inform the CSSD regarding eth status of the color. If the color doesn't fall under acceptance zone, all the packs in that particular load is recalled. Internal chemical indicators will be used in all instrument sets or trays whether wrapped or in rigid containers. Internal chemical indicators will be placed in an area that is most difficult for the sterilient to reach. The internal chemical indicators will be readily visible to the user. This allows the user to remove the indicator for inspection prior to using the item in patient care.
    - Once a week an autoclaved set will be sent to the microbiology department for culture and sensitivity check. Records of the same shall be maintained in the department
    - **Microbiological test-** Autoclaves will be monitored for quality control with **Bacillus Stearothermophilus**

- The equipments used in the CSSD are checked on a daily basis. If equipment undergoes dysfunction the biomedical engineering dept. is immediately informed
- The CSSD department shall have a **positive air pressure** in the clean and sterile zone and an **air change of 10 per hour** will be ensured

MONITORING REPORTS –

Maintain an Autoclave Record of all loads sterilized. Include on this record the date, load number, contents, time in, time out, temperature, indicator change, and operator. If the autoclave has printouts, initial, date, and affix the printout to the record book.

Monitoring reports will be periodically submitted to the Infection Control Committee.

Sterilization Date - Every wrapped item sterilized will be labelled with the date of sterilization and the sterilizer number, if needed.

17. INDICATORS:

1. Chemical indicators:

- *Indicator strips show that the intended combination of temperature, time, and pressure has been achieved and are effective.*
- *Chemical indicators are used for testing steam processes.*
- *These indicators are used internally, placed where steam or temperature is tough to reach, or are put on the outside of the wrapped packs to distinguish processed from non-processed packages.*

2. Biological indicators

- *Biological indicators are used during initial installation testing of steam sterilizers and after any major repairs of the sterilizer.*

- *Each load containing implantable devices shall be biologically monitored and, whenever possible, the implantable device quarantined until the results of the biological indicator test are available.*

3. The Bowie-Dick test

- *The Bowie-Dick test shall be carried out each day the high vacuum steam sterilizer is used before the first processed load.*
- *Schedule For Monitoring of Sterilization*
- *If the autoclave has recording chart, review it after each load. If not, record the temperature, time and pressure information in a log book that is reviewed after each load.*
- *Place steam-sensitive chemical indicators, on the outside of each pack.*
- *Perform testing with biological indicators weekly and preferred to be daily.*
- *The Bowie -Dick test or a commercially available equivalent shall be carried out everyday*
- *Pack monitoring Indicators should be in the middle of the item reprocessed (the most difficult part of the load).*

4. Physical Indicators:

- **Indicator tapes:**
  - *Are only process indicators.*
  - *Does not indicate for sensitivity for sterilization but only suggests the process completion.*
- **Batch Labels/Validity Labels:**
  - *These labels indicate the lot in which the specific instrument has been sterilized with.*
  - *A validity label indicates the validity up-to which the sterilization will be valid for.*

18. PREVENTIVE AND ROUTINE MAINTENANCE

- On a scheduled day each month, at the end of the business day, the sterilizers will be turned off and allowed to cool in preparation for cleaning the following morning.
- Obtain the cleaning supplies necessary. This may include clean rags, a mild detergent solution, a non-abrasive stainless-steel paste, buckets or basins, and any cleaning tools (scrubbing pad and handle) as needed. Do **not** use abrasives or steel wool because they may scratch the stainless steel surface and increase the occurrence of corrosion.
- The **outlet screen** (or **pin-trap**) will be removed daily and cleaned using a mild soap and brush under running water.
- The chamber will be cleaned daily using a soft cloth, or for large sterilizers, a long-handled mop which is used only for this purpose.
- All door gaskets will be cleaned daily with a lint-free cloth and checked for defects. Defective rubber gaskets will be replaced. Also scrub the door gasket and the sealing surface on the chamber with a mild detergent solution.
- Thoroughly scrub the entire inside surface (walls, the rear panel, the floor and the inside the door) with a mild detergent solution. Stubborn stains or marks on stainless steel can be cleaned using a non-abrasive cleaning paste.
- Rinse thoroughly with tap water or wipe with a clean cloth moistened with tap water.
- Remove the drain screen and clean out any debris that may be trapped.

- On the Steris sterilizer, remove the inner tray and clean out any residual water in the chamber.
- Any carts, carriages, baskets or trays used to hold items in the sterilizer will be cleaned as well. If no damage will result, they can be placed in an automatic washer for cleaning.
- After cleaning, the sterilizer can be placed back into service.
- A log documenting all the cleaning activities shall be maintained.
- The carriage (loading cart used to hold the packs placed in a sterilizer) will be cleaned daily using a mild soap and lint-free cloth. (The wheels of the loading cart also will be cleaned at this time, removing any string or other debris.
- The **exhaust line** (or chamber drain) will be flushed weekly. This will keep the drain free of substances that might hinder air or steam removal from the chamber. Before flushing the **exhaust line**. This can be prepared by adding 1-ounce trisodium phosphate to 1 litter (1 quart) hot water.
- If this chemical is not available, the exhaust **line** can be flushed with hot water containing a mild soap solution. To do this, first remove the screen. Then pour 1 litter (1 quart) of the solution down the drain using a funnel. Complete the process by pouring a litter of hot water to rinse out the soap and replace the screen. Because the specific operating instructions for a high-pressure steam sterilizer (autoclave) usually also contain instructions for routine maintenance, managers should make copies of these instructions available for staff to use. If replacement copies are

needed, they can be obtained by writing to the individual manufacturer (normally the address can be found on the autoclave) or from the donor agency providing the equipment.

- Qualified repair personnel must perform preventive maintenance.
- Equipment will be maintained according to manufacturer's specifications.
- After any major repairs or modifications are made to sterilizing equipment, a Chart Graph result must be obtained before the equipment is placed back into service.
- If there are any concerns about the sterility of items run in any sterilizer, the Infection Control department must be notified.
- Case carts will be maintained by the engineering department in order to avoid back injuries.

19. INFECTION CONTROL PRACTICES

- **Cleaning of Department**
  - Personnel are expected to maintain their assigned workstation in an orderly fashion.
  - All counter surfaces are to be disinfected at least daily, using a 0.5% Sodium Hypo chlorite.
  - Daily cleaning of the area includes damp mopping floors and emptying trash and linen containers. High cleaning is performed on a less frequent schedule.
  - Vacuuming the air vents and cleaning out the light fixtures is recommended at least 3 months to prevent the build up of dust and lint.
  - Regular schedule will be established for clean the walls, storage shelves, floors and other surfaces as

needed. Care must be taken in this process to avoid compromising the integrity of packaging. Attention must be paid to the sequence of cleaning, to avoid transferring contaminants from "dirty" to "clean" areas.

- **General**
  - Surgical scrub attire, cover gowns or lab coats will be worn in the processing area of the department.
  - Hair must be covered in the processing areas of the department.
  - When handling contaminated items, wearing personal protective equipment (PPE) is required. PPE's include: eye protection, gloves, surgical mask, moisture resistant gown, shoe covers and hair covering. After task is completed, remove and discard all PPE's and thoroughly wash hands.
  - All surgical scrub uniforms/cover gowns must be laundered by the laundry facility and must not be taken home.
  - Utilize the space allocated to assure a division between clean, dirty, and sterile areas.

20.SAFETY PROCEDURES

- All staff must receive training covering safety procedures at least annually.
- **Decontamination Area :**
  - Standard precaution including the following recommendations will be observed:
    - Caution will be taken while handling sharps.
    - Contaminated needles should not be recapped.

- Needles should not be bent, broken or manipulated by hand.
- Sharps must be placed in puncture resistant containers.
- Hands and other skin surfaces that are contaminated with potentially infectious fluids will be immediately and thoroughly washed.
- Eating and drinking is prohibited in the work areas.

- Proper body mechanics must be employed while moving carts and lifting equipment to avoid back injuries.
- To protect staff members against biological and chemical hazards, the following personal protection equipment must used when working in the decontamination area:
- Eye protection
- Water resistant gown
- Gloves
- Hair covering
- Mask
- Shoe Covers
- Sharps Containers

- Frequent hand washing is required, even though gloves are worn.
- Tray Assembly Area - “Clean Area."
  - Frequent hand washing is recommended.
  - Proper body mechanics must be used to avoid injury.
  - Caution will be used when handling sharp instruments.
  - Handle any chemicals in accordance with

manufacturers recommendations;

- Be familiar with the ETO alarm and response procedure

21. TIPS FOR PREVENT FAILURES IN STERILIZATIONS

- **Failure to clean the object being sterilized adequately**. Any coating of soil can protect the micro-organisms from direct steam contact. In addition, the effectiveness of sterilization is dependent on the "bioload" (number of micro-organisms) present prior to the sterilization cycle.
- **Instruments closed, locked or stacked**. All instruments must be packed in an open and unlocked position, or disassembled, so that steam can reach all surfaces (e.g., Place gauze or linen in between bowls so that steam can reach all surfaces of each bowl).
- **Packages wrapped too tightly**. Air and steam do not mix readily. Air, being heavier than steam, normally is displaced to the bottom of the sterilizer and is then forced out through the drain. If the packs are wrapped too tightly, however, air is trapped and cannot escape. It forms cool air pockets at the centre of the packages, preventing the items from reaching temperatures sufficient to kill all micro-organisms.
- **Packs too crowded**. It is essential that the packs be arranged loosely on the cart or the same type of problem as that in the above example will occur. Packs will be placed on the edge because it is easier for air to be displaced downward between the packs than to go through the many layers of fabric of horizontally placed packs.

- **Wrong position of container**. If pans, bottles or other airtight containers are to be sterilized, including containers with instruments inside, it is essential that the tops be removed (or held loosely in place) and that the containers be placed on their sides. (If the containers are placed upright, the air cannot be displaced and will be trapped in them.)
- **Clogged strainer**. At the bottom of most sterilizers is a small drain strainer used to keep lint, pins and other small objects from entering the exhaust line. It is essential that these screens be cleaned daily, or they will become clogged and trap air in the sterilizer.
- **Other mechanical problems**. Several other problems can occur, such as a defective steam trap and clogged exhaust lines. Often, the sterilizer operator cannot repair such problems. In some cases, however, a weekly flush of hot liquid soap through the exhaust line will keep it cleaned out. If the sterilizer manual calls for this weekly flush, it must be performed or sterilization failure may occur.

22. RECORDS AND REGISTERS

- Receiving and issue Register
- CSSD stock register
- Autoclave register
- Inventory Register of Unsterile and sterile items
- Complete the check-off list for positive cultures and maintain record in area/clinic
- Re call register
- ETO register
- Re used items register

23. ANNEXURE

23.1. Forms / Documents

1.1. Autoclave record book
1.2. CSSD/ OT receiving book or CSSD dept receiving book
1.3. CSSD checklist
1.4. Bowie Dick test file
1.5. Vacuum leak test record
1.6. CSSD instruments inventory book
1.7. CSSD daily stock maintenance book,
1.8. CSSD ward stock inventory book
1.9. CSSD store inventory book, CSSD pharmacy inventory book
1.10. Biological indicator file
1.11. CSSD equipment checklist
1.12. CSSD load record checklist
1.13. Surveillance reports file

23.2. CSSD Duty Roster

Sl. no	Name	Area / activity / Ward	Shift	Off Day

23.3. CSSD stock register

Name of Article …… Material Code ……..

Reservation if any …… Min Stock Required ……..

Date	Particulars	Bill #	Receipt	Issue	Balance	Remarks

23.4. CSSD Condemnation Register

Sl.	Date	Item name with full description/specification	Quantity/Number	Reason of Condemnation	Approving Authority	Remarks

23.5. CSSD Issue & Receipt register

Date	Ward / Area	Item Description	Quantity Received	Quantity Issued back	Balance if any	Remarks

23.6. CSSD Maintenance & Calibration Records

S. N	Location /	Instrument	Make / Identifica	Range Or	Control # .	Date Of	Due Date	Frequency	Remark &

o.	Departm ent		tion	G/L		Cal/ Mai nt.	Of Cal/ Mai nt.	Of Cal.	Status. (Histo ry)