



CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

### Contents

- SOP No 1. Safety Awareness in Sterile Service Department
- SOP No 2. Department Cleaning Procedure
- SOP No 3. Departmental Dress Code
- SOP No 4. Collection of Soiled/Contaminated Equipment
- SOP No 5. Manual Decontamination of Medical Devices
- SOP No 6. Prepare, Load and Operate Automated Decontamination Equipment
- SOP No 7. Decontamination and Inspection of Loaner Medical Devices
- SOP NO 8. Cleaning and Maintenance of Rigid Containers
- SOP No 9. Missing Instruments
- SOP No 10. Control of Packing Area
- SOP No 11. Packing Area Operation
- SOP No 12. To describe the operation and procedure controls for tracking instruments
- SOP No 13. Cleaning of Autoclaves
- SOP No 14. Steam Sterilization Procedure
- SOP No 15. Ethylene Oxide Sterilisation
- SOP No 16. Loading and unloading items from the autoclave
- SOP No 17. Sterile Pack Storage
- SOP No 18. The Delivery and Distribution of Processed items
- SOP No 19. Quality Control
- SOP No 20. Monitoring autoclaves
- SOP No 21. Recall Procedures
- SOP No 22. Validation of Equipment
- SOP No 23. Monitoring ETO Sterilizer
- SOP No 24. Malfunction of Ethylene Oxide Steriliser
- SOP No 25. Planned Maintenance Schedule of Equipment
- SOP No 26. Action for Breakdown of Equipment
- SOP No 27. Sterile Packaging
- SOP No 28. Management of Loan sets
- SOP No 29. Decontamination of Textiles/Linen for sterilization
- SOP No 30. Inspection, Repair and Replacement of instruments
- SOP No. 31. Checking and Assembling Instrument Sets
- SOP No. 32. Prepare, Load and Operate Ultrasonic Cleaner
- SOP No. 33. Validating an Ultrasonic Cleaner
- SOP No .34. Low Temperature Sterilization (Hydrogen Peroxide Plasma / Vaporized Hydrogen Peroxide)
- SOP No. 35. Decontamination and Management of Laryngoscopes
- SOP No. 36. Daily Heat Sealer Checks
- SOP No. 37. Decontamination and Disinfection of Babies Bottles
- SOP No. 38. Decontamination and Sterilisation of reusable LMA's
- SOP No. 39. Wrapping Medical Devices ready for sterilisation



CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

SOP No. 1

### Title

**Safety Awareness in Sterile Service Department**

### Review Date

July 2019

### Prepared by

**CSSD Forums of South Africa (CFSA)**

### Area of application

Sterile Service Department

### Staff involved

All personnel that are assigned or engaged in Sterile service operation.

### Objective / Purpose

To establish an overview of guidelines and safety awareness procedures in the Sterile service department.

### Relevant / Related documents

Occupational Health and Safety Act and Regulation 85 of 1993  
Standard Precaution Guidelines  
Infection Control Policy

### Equipment/Supplies

PPE

### Procedure

#### General Guidelines

- All personnel must follow established work and traffic flow patterns.
- Material Safety Data Sheets (MSDS) for all chemicals used in the sterile service department must be available in a binder index.
- Employee must be trained in a safe work procedure and be aware of any relevant procedures, policies.
- All employees must be trained in appropriate personnel protective equipment designated for each area.
- Employees must adhere to dress code and policies before entering and when leaving the area.
- Employees must follow and practice hand washing guidelines (before and after each tasks) in accordance with WHO guidelines.
- Eating and drinking is prohibited in all workspaces including supply storage, processing and decontamination sections.
- Work spaces must be free from clutter and have un-obstructed entrances and exits.
- Visitors are prohibited from entering CPD spaces without permission.
- If visitors must enter restricted areas, appropriate attire is required and they should be escorted by CSSD staff.

#### Patient Safety

- Ensure that all items are processed according to established guidelines (manufacturer's instructions).
- All CSSD personnel should be trained in Decontamination and Sterilization Practices.



## CSSD FORUM STANDARD OPERATING PROCEDURE

- Safe keeping of all items by ensuring that storage areas are kept clean, storage cupboards are locked, equipment is covered and preventive maintenance is performed on all equipment.
- Assure there is no contamination of patient care areas during collection and transportation of contaminated items.

### **Employee Safety**

- Prevent burn injuries when loading or unloading steam sterilizers and washer disinfectors by following procedure and wearing appropriate PPE.
- Employees must use proper body mechanics when carrying or handling heavy items.
- Use care and caution when handling sharps.
- Maintain “line of light “when handling medical devices.
- In the decontamination area, employees must wear proper personal protective equipment (PPE) to prevent direct exposure from contaminants and injury that could result when handling contaminated and sharp instruments.
- Appropriate PPE must be worn when handling chemicals used for cleaning and decontamination.
- When receiving or handling contaminated items, always wear the correct PPE for the task.

### **Note**

- Use of electrical extension cords is prohibited in sterile service areas.
- All employees must be aware of fire and safety regulations.
- Refer to MSDS before handling chemicals.
- If spills occur, refer to policy management of body fluids spillages or consult safety representative.

### **Expected Outcome**

Reduced medical legal hazards  
Safe working environment



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No. 2**

**Title**

**Department Cleaning Procedure**

**Review Date**

July 2019

**Prepared by**

CSSD Forums of South Africa

**Area of Application**

All areas of the facility

**Staff Involved**

Only staff trained in decontamination process

**Objective/Purpose**

To ensure an acceptable level of hygiene and cleanliness throughout the CSSD area

**Relevant/Related Documents**

Procedure Manual

Standard Precautions

**Equipment/Supplies**

All surfaces and equipment in CSSD

All new equipment prior to introduction for use

Cleaning materials

**Procedure**

- The CSSD will be cleaned in accordance with the cleaning schedule
- Cleaning will be undertaken between times to be agreed that will enable any aerosol particles to settle prior to commencement of work.
- Cleaning will take place before work commences or after work is completed, in the case of a 24hour facility cleaning will be rotated through areas when work is not in progress
- The cleaning schedule will specify frequency of cleaning
- A departmental cleaning inspection report will be prepared each month (at random times) by the Sterile Services Manager or Senior Staff
- Designated cleaning equipment will be stored in a designated area for that area's use only.
- Cleaning work will only be undertaken by Staff trained to work in that area
- CSSD staff are responsible for making sure that all surfaces are clean
- All cleaning procedures and cleaning chemicals used in the department will be in line with Departmental recommendations
- The use of brooms is discouraged

**Expected outcome**

Quality controlled safe, clean and functional department.



CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICES DEPARTMENT CLEANING SCHEDULE

### List of Inspection Points

Area	Yes
1. Wet mops floors (vacuum first if necessary, do not sweep)	
2. Damp wipe all low-level ledges, shelves, and skirting and window ledges.	
3. Remove splash stains and finger marks from walls and paintwork using damp cloth.	
4. Empty waste bins, replace waste bags, and wash bins if necessary.	
5. Clean all internal glass surfaces.	
6. Wet wipe walls, wall fittings and ceilings. Clean light fittings.	
7. Clean all ceiling air vents.	
8. Check and clean as necessary around sinks, doors, etc.	
9. Empty waste bins and wash inside.	
10. Clean and polish all frontages of Autoclaves with Stainless Steel cleaner.	
11. Cream clean sinks taps and surrounds. Remove debris from waste outlet.	
12. Clean inside washer disinfectors according to manufacturers' instructions	
13. Clean inside washer sterilisers according to manufacturers' instructions	
14. Damp wipe pipe works, doors, doorframes and door handles.	
15. Polish washer's exterior with stainless steel cleaner.	



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No. 3**

**Title**

**Departmental Dress Code**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of Application**

All areas of the facility

**Staff Involved**

All

**Objective/Purpose**

To ensure that staff are properly attired according to the requirements of their work area

**Relevant/Related Documents**

Procedure Manual

Standard Precautions

**Equipment/Supplies**

PPE

**Procedure**

- On entering the Sterile Service Department, all staff will change into departmental uniform provided in the changing area
- Staff moving into the wash area, who will be engaged in the handling and processing of incoming equipment, will put on an extra protection gown, gloves and protective goggles (when splashing is anticipated) in addition to the departmental uniform
- When leaving the wash area staff will remove and discard the gown and gloves and wash their hands
- Prior to entering the preparation area all staff and visitors will wash and dry their hands and put on the relevant PPE
- Staff visiting from other areas will wear the departmental uniform and must comply with the dress code when moving to other areas of the department.

**Expected Outcome**

All staff are properly attired according to the requirements of their work area



## CSSD FORUM STANDARD OPERATING PROCEDURE

### STERILE SERVICE DEPARTMENT

**SOP No. 4**

**Title**

**Collection of soiled/contaminated equipment**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of application**

Theatres/wards/clinics

**Staff involved**

Trained CSSD personnel

**Objective/ Purpose**

To ensure the safe collection, handling and transportation of contaminated equipment from the clinical setting to the Central Service Facility in a safe manner.

**Relevant / Related Documents**

Standard Precaution Guidelines

OHSA, 85 of 1993

Managing of Heavy Equipment

Infection Prevention Control Policy

**Equipment/Supplies**

Puncture proof and leak resistant trolleys with removable bins, dedicated instrument trolleys.

Protective attire: i.e. clothing, masks, gloves, eye protection, safety footwear.

**Procedure**

- Non-sterile gauntlet gloves must be worn for the collection of instruments and be discarded into the medical waste container at each collection point.
- Wash hands in accordance with departmental procedures.
- Wear protective clothing / attire in compliance with standard precaution guidelines.
- Use allocated trolleys.
- Follow designated collection routine and time table in accordance with department guidelines.
- Linen and waste must be separated from reusable medical devices at the point of use.
- Gross contaminants such as large amount of blood, faeces, urine, etc. must be removed at the point of use, in accordance with safety procedures.
- Collect used items in puncture resistant containers; do not overload.
- Place heavy instrument containers at the bottom of trolleys.
- Secure contaminated items and cover prior to transportation.
- Do not leave contaminated goods unattended during transportation.
- Transport / Deliver used items and equipment to the cleaning area
- Unload and sort items in the receiving area.
- Clean and disinfect collection trolleys and bins and store appropriately.
- Remove gloves and wash hands according to Policy.



CSSD FORUM STANDARD OPERATING PROCEDURE

All effort must be made to facilitate transport of contaminated equipment to decontamination area as soon as possible to facilitate cleaning. Prompt processing of items will likely decrease potential hazards associated with contamination.

**Expected Outcome**

Safe handling, collection and transportation of contaminated equipment, ready for further processing





**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No. 5**

**Title**

**Manual Decontamination of Medical Devices**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Purpose**

To ensure that all soiled equipment returned to the CSSD is cleaned to an acceptable standard.

**Scope**

All instruments and equipment returned to CSSD.  
All new equipment prior to introduction for use  
All damaged equipment prior to sending for repair.

**Area of Application**

Decontamination Area of CSSD/Loaner Companies

**Staff Involved**

Only staff trained in the decontamination process

**Relevant/Related Documents**

Procedure Manual  
Standard Precautions  
Manufacturers' Instructions

**Equipment**

- Gauntlet gloves, Full plastic apron, face mask, eye protection, hair protection
- Double sinks with plugs
- Marked sinks or measuring jugs
- Hot and Cold running water
- Elbow taps
- High pressure cleaner
- Selection of cleaning Brushes
- Drying area
- Non-linting Drying clothes
- Hand cleaning facilities

**Procedure**

- When washing Instruments manually standard/universal precaution must be applied at all times
- Only staff trained in decontamination should manually clean medical devices
- Maintain segregation of designated clean and other areas within the department
- Identify the correct process for the items to be decontaminated according to manufacturers instructions
- Staff working in this area will wear protective clothing at all times in compliance with the standard precautions dress. PPE is additional to the uniform code for your specific working environment and may include:



## CSSD FORUM STANDARD OPERATING PROCEDURE

- a) Gloves
  - b) Aprons, gowns, overalls (single-use, fluid- repellent, disposable)
  - c) Masks
  - d) Face and eye protection
  - e) Footwear
- Apply standard precautions for infection control and other relevant health and safety measures
  - Use and store all equipment chemicals and materials in accordance with manufacturer's instructions and organisational policies and procedures.
  - Ensure that stock of chemicals and materials that are being accommodated is rotated so that oldest is used first.
  - Keep work areas safe and free from hazards during work activities and report any situations where risks arise that prevent work going ahead or continuing, restricting access to risk area until the area has been assessed as safe by a line manager
  - Place waste containers in positions that will minimise hazards to staff and visitors and dispose of full waste containers promptly and in accordance with departmental procedures
  - Comply with manufacturers' and organisation specifications when processing of medical devices.
  - Handle contaminated devices as little as possible.
  - All equipment is transferred from the trolley to the work surface.
  - Check instruments off against the checklist returned with the set and take notice of any comments made on the check list by the theatre team/user
  - Identify if the medical devices can be decontaminated in the washer
  - Identify items requiring special attention and handle in accordance with documented manufacturers' instructions
  - Each instrument will be prepared for decontamination as follows
    - Remove the protective outer wraps
    - Wearing gloves and using a Cheatle Forcep discard any disposable materials into the appropriate containers. Clinical waste in red plastic bags, domestic waste into black bags, sharps into sharps container taking special care to dispose of sharp objects safely.
    - Avoid contaminating hands with soilage.
    - Separate baskets, container and instruments.
    - Check degree of soil, sort and discard any disposable material.
    - If needles/blades are found, the instrument set should be set aside and the end-user contacted to come and remove the sharps (if this is possible).
    - Sort Cannulated and solid devices.
    - Open all hinged instruments
    - Flush all Cannulated instruments with the pressure jet gun / syringe before and after brushing
    - Pressure sprays can be used according to manufacturer's guidelines.
    - Loosen all instrument pins and separate instruments
    - Disassemble all multi part instruments
    - Handle and process all devices in accordance with the manufacturers' instructions.
    - If an instrument is broken, any broken piece is located immediately, or a report made following the missing instrument procedure. It is vital to identify any missing screws or broken part as a matter of urgency, as the sooner it is identified the better chance there is of locating it.
    - Set the tray aside until the instrument is replaced or repaired
    - Follow manufacturer's instructions and departmental policies and procedures for the use of any equipment used for cleaning purposes.



#### CSSD FORUM STANDARD OPERATING PROCEDURE

- Keep sets of items being processed together where possible
- Two dedicated deep sinks must be available with a dedicated drying surface
- Sinks and accessories must be cleaned at each water change
- When cleaning manually, a pre-rinse, wash, rinse and drying process must be followed.
- The water temperature should be according to detergent manufacturers' instructions.
- Water and detergent should be measured according to manufacturers' instructions and have the correct chemical mixture.
- The dedicated sinks should only be used for washing instruments, not for hand washing or anything else
- The sink should have water measurement marks, to assist with the detergent concentration.
- Use the cleaning equipment, materials and agents in a manner that minimises risk to yourself and others taking appropriate action when problems arise during cleaning
- If the water, is visibly stained at any stage it must be replaced
- All devices being manually cleaned must be fully immersed in the washing water while being scrubbed. This is to ensure that any aerosols being generated are in the main, contained.
- Special attention must be paid to the joints of any jointed instrument and meticulous attention paid to the tips or crevices.
- A clean soft brush or soft cloth /Sponge is required to clean the surfaces.
  - If the water, is visibly stained during the rinsing stage. The cleaning stage should be repeated. It is important that all soil and chemical is removed prior to, or during the rinsing stage. Instruments.
  - After decontamination, all devices must be visually inspected for soil, damage and functionality.
  - Place clean, functioning items on a drainage area
  - Keep drainage area dry
  - Dry items using a non linting cloth
  - Clean items should be stored and transported in such a manner that cross contamination is avoided
  - Ensure that cleaning equipment is cleaned disinfected and dried before being stored.
  - Return cleaning equipment and cleaning materials in good working order and condition to the appropriate place after use

#### **Expected outcome**

Quality controlled safe, clean and functional medical devices ready for packing.



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No. 6**

**Title**

**Prepare, Load and Operate Automated Decontamination Equipment**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of application**

Cleaning Area of Theatre/CSSD/Loaner Companies

**Staff involved**

Only staff trained in decontamination process

**Objective/Purpose**

To ensure that medical devices/equipment are correctly prepared and loaded for decontamination

**Relevant/Related Documents**

ISO 15883:2006

Procedure Manual

Standard Precautions

Equipment guidelines

Manufacturers' guidelines

**Equipment/Supplies**

Personal Protective Equipment

Washer Disinfector

Ultrasonic Cleaner

Detergent

Stain Remover

**Procedure**

- Maintain segregation of designated clean and other areas within the department
- Identify the correct process for the items to be decontaminated following manufacturer's instructions
- Staff working in this area will wear protective clothing at all times in compliance with the standard precautions dress. PPE is additional to the uniform code for your specific working environment and may include:
  - a) gloves
  - b) aprons, gowns, overalls (single-use, fluid-repellent, disposable)
  - c) masks
  - d) face and eye protection
  - e) footwear
- Apply standard precautions for infection control and other relevant health and safety measures
- Use and store all equipment chemicals and materials in accordance with manufacturer's instructions and organisational policies and procedures.
- Ensure that stock of chemicals and materials that are rotated so that oldest is used first.



## CSSD FORUM STANDARD OPERATING PROCEDURE

- Keep work areas safe and free from hazards during work activities and report any situations where risks arise that prevent work going ahead or continuing, restricting access to risk area until the area has been assessed as safe by a line manager.
- Place waste containers in positions that will minimise hazards to staff and visitors and dispose of full waste containers promptly and in accordance with departmental procedures
- Comply with manufacturers' and organisation specifications when using all appliances and processing of medical devices. Follow manufacturers' instructions
- Handle contaminated devices as little as possible.
- Washer disinfectors will be prepared for use as described in the Working Instructions Manual. Follow manufacturers' instructions
- All equipment is transferred from the trolley to the work surface.
- Identify if the medical devices can be decontaminated in the washer
- Identify items requiring special attention and handle in accordance with documented manufacturers' instructions
- Each instrument will be prepared for decontamination as follows
  - Remove the protective outer wraps
  - Wearing gloves and using a Cheatle Forcep discard any disposable materials into the appropriate containers. Clinical waste in red plastic bags, domestic waste into black bags, sharps into sharps container taking special care to dispose of sharp objects safely.
  - Avoid contaminating hands with soilage.
  - Separate baskets, container and instruments.
  - Check degree of soil, sort and discard any disposable material.
  - If needles/blades are found, the instrument set should be set aside and the end-user contacted to come and remove the sharps (if this is possible).
  - Sort Cannulated and solid devices.
  - Open all hinged instruments
  - Flush all Cannulated instruments with the pressure jet gun / syringe before placing in the tray
  - Pressure sprays can be used according to manufacturer's guidelines.
  - Loosen all instrument pins and separate instruments
  - Disassemble all multi part instruments
  - Handle and process all devices in accordance with the manufacturers' instructions.
  - If an instrument is broken, any broken piece is located immediately, or a report made following the missing instrument procedure. It is vital to identify any missing screws or broken part as a matter of urgency, as the sooner it is identified the better chance there is of locating it.
  - Set the tray aside until the instrument is replaced or repaired
  - Be aware that small items may become lodged in the drainage system
  - Check instruments off against the checklist returned with the set and take notice of any comments made on the check list by the theatre team/user
  - Keep sets of items being processed together where possible
  - Manually clean items that are too large or unsuitable for mechanical washer/disinfector in accordance with the manual cleaning protocol
- All handling and processing is to be undertaken in accordance with the manufacturers instructions
- Note manufacturers instructions if items can be cleaned in washer
- Standardised washing and disinfecting processes should be used and validated.
- Choose the relevant washer rack
- Place instruments into a wash basket and check to ensure all items and parts are present.
- Load items to be decontaminated in the correct position in baskets so that maximum exposure to the decontamination process is achieved on all surfaces of the instrument



#### CSSD FORUM STANDARD OPERATING PROCEDURE

- Connect all tubes to the appropriate connector on the basket union. And position tray into the chamber. (All staff working in this area must be qualified and have received training from the manufacturers on which tubing to fit to which channel. A certificate of competence will be held on file for each member of staff who is competent)
- Place heavier items at the bottom making sure that all surfaces can be reached by the spray jets
- Do not pack too densely or over-pack trays, all surfaces must be reached by the spray jets
- Make sure that instruments do not stick out of baskets as they may affect the washer operation
- Connect all tubes to the appropriate connector on the basket union if option is available
- Position tray into the chamber according to manufacturer instructions
- Use detergents according to washer manufacturers' instructions
- Only prescribed automatic cleaning agents should be used
- A full-automated process should be used including pre rinsing, washing at 60°C minimum (if recommended by manufacturer), rinsing and drying.
- Where more than one chemical is used in the automated washer disinfectant, the tubing should be marked to indicate which chemical it carries.
- The containers should not be able to be incorrectly connected
- The containers must be checked regularly and not allowed to run out
- All staff working in this area must be qualified and have received training from the manufacturers on how to operate the machinery.
- A certificate of competence will be held on file for each member of staff who is trained and competent
- Identify and follow operating instructions for washer disinfectants (W/D's) accurately
- Check that all daily tests are completed satisfactorily and results recorded in appropriate log books accurately and legibly before using cleaning equipment, reporting any abnormal performance of the cleaning equipment promptly to the appropriate member of staff
- Chamber self-disinfection should be carried out each week as per manufacturer's recommendations and documented.
- Maintain records of all items received and prepared for processing
- Comply with manufacturers' and organisation specifications when using all appliances and processing
- Record data correctly as per departmental procedure using log books

#### **Expected outcome**

Quality controlled safe, clean and functional medical devices ready for packing.



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No. 7**

**Title**

**Decontamination and Inspection of Loaner Medical Devices**

**Review Date**

July 2019

**Prepared By**

**CSSD Forums of South Africa**

**Objective/Purpose**

To ensure that all loaner instrumentation is effectively and safely managed and controlled

**Relevant/Related Documents**

SABS 1541:2013

Procedure Manual

Standard Precautions

Manufacturers Instructions

**Equipment/Supplies**

Personal Protective Equipment

Automated Machines – washing/Ultrasonic

Double Sinks

Brushes

Detergent

**Procedure**

- SABS 1541:2013 provides requirements for loan set management principles between
- Manufacturers', suppliers and health care facilities, to guide all steps involved in ordering, transporting, receiving, on-site processing, use, and return of these items, clearly identifying individual responsibilities.
- To ensure accountability, a written agreement between the facility and the lender should also be in place.
- Staff involved in any aspect of the process must be aware of SABS 1541 requirements, trained and knowledgeable.
- Loan sets must be ordered timeously in accordance with the loan agreement and delivered to the facility at an agreed time
- The CSSD must be notified of the date of the booked surgery, doctor, procedure, and the type of loan equipment ordered at least a day prior to delivery quantities, with estimated time of loan set delivery and estimated time of use and return.
- Loan sets should be delivered to the decontamination area at a very minimum 4 hours before use leaving sufficient time for disassembly, cleaning, packaging, and sterilization of the instruments before the scheduled surgery. If a large number of trays need decontaminating the minimum time needed for decontamination must be requested from the CSSD
- For transportation the loan sets should be packed in secure/ impenetrable, sealed containers to help reduce the possibility of contamination and damage during transport
- On receipt of the loan set the trays must be checked
- It is the loan set suppliers responsibility to provide training on disassembly and decontamination of item
- It is the loan set companies responsibility to provide the following information:



## CSSD FORUM STANDARD OPERATING PROCEDURE

- number of trays
- details of all prostheses supplied
- name of the surgeon
- name of patient (if known)
- date of use for the instrumentation.
- cleaning and sterilising instructions.
- specialised equipment required to clean the instrumentation.
- tray checklists configured so that the items on each tray can be easily and efficiently verified by staff that are unfamiliar with the contents.
- photographs and checklists to identify items and assist with checking
- identification numbers on the tray list should correspond with those on the instrumentation.
- Decontamination certificate declaring that items are clean and safe to handle, NB this does not verify that instruments have been adequately decontaminated merely that they are safe to handle.
- The check list should signed by the person who was responsible for packing the instrumentation
- A tracking and traceability system should be in place.
- Written instructions on the disassembly, assembly, cleaning and processing of complex instruments and training should be provided on request.
- Each loan set must pass through a full validated decontamination process before being delivered to the theatre, it is the responsibility of the CSSD to render all items safe for use

### **CSSD Responsibility Pre-Operative**

- Check loaner instruments for accuracy and completeness against the inventory sheet
- Missing instruments should be reported to the loan company
- Verify types of instruments and implants
- Verify quantities of instruments and implants
- Visually inspect instruments and implants for damage.
- Manufacturer's written instructions for disassembly, cleaning, packaging, and sterilization of instruments should be available
- Process according to manufacturers' guidelines and hospital policy and procedure for disassembly, cleaning, packaging, and sterilization of the instruments.
- If written instructions are not available contact the manufacturer
- Check functionality
- Damaged instruments should be logged and reported to the loan company
- Notify theatre immediately of any problems that may delay or compromise the surgical procedure
- Package and sterilise according to hospital procedure
- On completion of the process the loan set may be sent to theatre

### **Post Operative**

- After the surgical procedure is completed, return the instrumentation to the decontamination area
- Verify that all loaner instruments are accounted for
- Handle contaminated devices as little as possible.
- Sort and discard any disposable material. Avoid contaminating hands with soilage
- Disassemble all of the instruments according to training
- Sort cannulated and solid devices.
- Cannulated devices can be cleaned in an ultrasonic cleaner or using brushes/high pressure sprays, according to manufacturers guidelines
- Open hinged medical devices
- If using an automated process layer heavy items at the bottom.





#### CSSD FORUM STANDARD OPERATING PROCEDURE

- Do not pack too densely
- Standardised washing and disinfecting processes should be used and validated.
- Enzymatic cleaners are recommended bearing in mind manufacturers instructions.
- Containers should be washed with a neutral detergent
- A full-automated process should be used including pre rinsing, washing at 60C minimum (if recommended by manufacturer), rinsing and drying.
- If cleaning manually a pre rinse, wash, rinse and drying process should be followed
- Once decontaminated all devices should be visually inspected for soil, damage and functionality.
- Check instruments are clean and functioning
- Clean functioning items should be placed in a tray.
- The tray should be placed in a metal/plastic transport container.
- The packer should seal the transport container with a tamper proof seal.
  - Return loaner instruments to the loan company according to contract include the following information
    - Date
    - Time
    - Signature of processing individual
  - Maintain complete records
  - A signed cleaning declaration stating the following should be placed on the outside of the transport container together with the signed Checklist
    - That the Cleaning SOP was followed
    - Date and Time
    - Name of packer that did the inspection
    - Hospital/Trade
- Clean items should be stored and transported in such a manner that cross contamination is avoided.
- For transportation the loan sets should be packed in secure/ impenetrable, sealed containers to help reduce the possibility of contamination and damage during transport
- Loan sets must be cleaned by the User before transportation it is illegal to transport contaminated items without a special licence

#### **Expected outcome**

Quality controlled safe, clean and functional loan sets ready for transport and reprocessing



CSSD FORUM STANDARD OPERATING PROCEDURE

**STERILE SERVICE DEPARTMENT**

**SOP No. 8**

**Title**

**Cleaning and maintenance of Rigid Containers**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of application**

Decontamination Area

**Staff involved**

Only CSSD and Theatre Staff working in the cleaning area

**Objective/ Purpose**

To ensure that all rigid containers are correctly cleaned and maintained

**Relevant / Related Documents**

Manufacturer's information  
Sterilization policy and process  
Quality Manual

**Equipment/Supplies**

Cleaning equipment  
Rigid Containers

**Procedure**

- Disassemble container
- Remove all accessories
- Remove reusable filters
- Remove interior basket(s)
- Remove disposable filters, locks, bands etc.
- Pay particular attention to the type of detergent recommended for use by the manufacturer
- A neutral pH detergent should be used for anodized containers
- Fully submerge the container if cleaning manually
- Wash in automated washer, Use a good loading techniques to allow for drainage

Prior to each use, inspect for:

- Dents, chips, warping
- Filter retention mechanism function
- Fasteners, rivets, and screws
- Latches
- Filters – single use/ reusable
- Replace single use filters
- Track number of filter reuses, see manufacturers guidelines for reusable filters
- Check reusable filters for cracks and chips
- Reusable filters must be cleaned every use
- Very Important to ensure that the lid seals



#### CSSD FORUM STANDARD OPERATING PROCEDURE

- If seal is not airtight sterility will not be maintained
- Check gasket for fraying, cuts, missing pieces, bubbling, compression
- Some containers can be stacked, check documentation with the manufacturer
- Check Health and Safety re weight

#### **Expected Outcome**

Rigid containers are correctly cleaned and maintained



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No. 9**

**Title**

**Missing Instruments / Items**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of Application**

Theatre/CSSD

**Staff Involved**

Only staff trained in decontamination process

**Objective/Purpose**

To locate instruments missing from a set or parts of instruments / scopes.

**Relevant/Related Documents**

Procedure Manual

Standard Precautions

**Equipment/supplies**

N/A.

**Procedure**

- When wash or preparation room staff identify a missing instrument or part of an instrument the Operator will immediately isolate the tray and contact theatre.
- The Operator will ensure that:
  - All wash baskets are checked.
  - The washer disinfectors are checked
  - All transport trolleys are checked.
  - The floor areas are checked
  - Linen and rubbish sacks are checked
- If located, the missing item will be returned to circulation. If the item is not located, the set will be held out of circulation until it is found or, authority from senior theatre staff for it to be replaced, if possible, the tray put back into circulation or, quarantined.
- If the set is required to be put into use without replacing the instrument, a note must be completed and the sister concerned sign as authority to proceed.
- The incident must be fully recorded

**Expected Outcome**

All sets in circulation are complete



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No. 10**

**Title**

**Control of Packing Area**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of Application**

Packing Area

**Staff Involved**

All

**Objective/Purpose**

To ensure everybody entering the preparation area is correctly dressed and conforms to policy

**Relevant/Related Documents**

Procedure Manual  
Standard Precautions

**Equipment/Supplies**

Relevant PPE

**Procedure**

- All staff visitors and other personnel wishing to enter the preparation room will change into the uniform provided.
- No personal possessions other than locker keys are allowed to be taken into the preparation area.
- No facial jewellery is allowed, other than stud type earrings, and these must be covered completely by the headwear
- No food or confectionery of any kind may be taken into any area of the department.
- Before entry to the preparation room area, all personnel will put on suitable head covering and a clean room gown. The gowns are to be placed in the wash basket at the end of each shift.
- Personnel will wash and dry their hands before entering area
- Head covering must be worn at all times and only discarded at the end of the shift
- Clean Room coat to be placed on packing room exit rack, unless it is the end of a shift, when it is disposed of.

All Staff are responsible for keeping the preparation room entry / exit neat and tidy.

**Expected Outcome**

Everybody entering the preparation area is correctly dressed and conforms to policy



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No. 11**

**Title**

**Packing Area Operation**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of application**

Packing Area

**Staff involved**

Only staff trained in CSSD/Theatre

**Objective/Purpose**

To describe the operation and procedure controls in the Packing Room

**Relevant/Related Documents**

Quality Manual

Working Instructions Manual

Missing Instrument Form

**Equipment/Supplies**

N/A

**Procedure**

- Senior Staff will ensure the order of production meets immediate customer priority where appropriate.
- After decontamination, all clean items are received into the packing area
- Any item that is rejected due to evidence of residual blood, body fluid, stains or water are placed in a plastic bag and identified before being returned for washroom staff to action
- Any item that is damaged or broken is sent for repair
- Bio burden tests will be performed on the washer disinfectors regularly, according to policy, ensure that items being processed are safely disinfected.

**Expected Outcome**

The Packing Area is operating effectively



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No. 12**

**Title**

**Tracking Instruments**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of application**

All Areas of the CSSD

**Staff involved**

Only staff trained in CSSD/Theatre

**Objective/Purpose**

To ensure that surgical instruments can be tracked through decontamination processes in order to ensure that the processes have been carried out effectively.

To ensure that a process is in place to track any product suspected of being substandard, contaminated or infected is identified, quarantined, collected, investigated and the findings recorded

**Relevant / Related Documents**

Sterilization policy and process

Quality Manual

Working Instructions Manual

National Core Standards - 3.5 Sterilisation Services

**Equipment/Supplies**

Tracking System – manual or automated

**Procedure**

It is good practice that reprocessing facilities implement appropriate systems to allow for the tracking of reusable devices throughout the decontamination process and from patient to patient. Systems should enable the identification of patients on whom instrument sets have been used.

- Manual methods include the use of checklists and appropriate labelling of packaged devices/device set.
- Labels are applied to the external packaging, prior to sterilization to allow ease of identification of the contents of a package and the process
- Packaging should be labelled prior to sterilisation in a way that does not compromise the integrity of the pack.
- Labels must be able to withstand exposure to the sterilization process, storage and transport. Labelling must not:
  - Affect the sterility or integrity of the pack;
  - Become illegible;
  - Transfer to pack contents;
  - React with packaging;
  - Interfere with the decontamination process;



#### CSSD FORUM STANDARD OPERATING PROCEDURE

- Become detached such sterilization or subsequent storage
- Labelling should not damage the packaging material; never use a ballpoint pen on any packaging material as it can create holes in the material.
- Recommended labelling methods include the use of:
  - pre-printed tapes
  - pre-printed bags
  - stamping systems
  - pre-printed labels
  - automated labelling systems
- Manual system labels should identify the operator, the cycle printout and any other monitoring devices linked to the load
- An electronic system allows the items to be scanned by a hand held scanner with the information downloaded to produce a batch report.
- Labels may be pre-printed directly onto packaging materials, or packaging materials can be printed in-line.
- A common method involves the use of bar codes that are used to identify packs and device locations by a scanning process
- Packaging systems should be labelled with;
  - a description of the package contents
  - identification (e.g., initials) of the person receiving, cleaning, checking, assembling, sterilising, storing, dispatching the package
  - a lot control number
  - date of automated cleaning and sterilisation
  - washer and cycle number
  - sterilizer and cycle number
  - any expiration date/shelf life statement applicable to the facility
  - dispatch information
- In the event of sterilization failure, such as positive biological indicators/Failed Load Controls or sterilizer malfunction, items from that test and previous loads after the last known good test must immediately be recalled.
- All affected trays can be recalled in the event of failed quality management or in the event of a contagious disease or infection, if an effective tracking system is in place
- A written Recall Procedure must be followed in the event of a sterilization failure

#### **Expected Outcome**

A quality management system is in place enabling any product that is substandard or infected to be tracked back through the process and recalled





CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT

**SOP No. 13**

**Title**

**Cleaning of Steam Sterilizers (Autoclaves)**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of application**

Autoclaving area

**Staff involved**

Personnel involved in sterilization

**Objective/ Purpose**

To maintain the steam sterilizer in a good working order and, to prevent the contamination of items due to deposits from walls of the sterilizer, leaking gasket or plugged drain.

**Relevant/Related documents**

Procedure Manual

Manufacturer's Instructions

**Equipment / Material**

Lint – free clothes

Mild detergent

Bucket / basins

Dedicated long – handle mop

Lubrication oil for wheels of trolleys

**Procedure**

- Follow the manufacture's guidelines for the cleaning of all autoclaves
- On a daily basis, inspect the door gaskets for cracks and clean with a lint-free cloth, according to manufacturer's recommendations
- The autoclave must be turned off and allowed to cool
- Wipe outside stainless steel panelling with lint-free cloth.
- Daily damp dust loading trolleys carriages, racks, baskets or trays that hold items in the sterilizer.
- Remove drain plug from bottom of the chamber and remove lint and sediment from strainer.
- Replace drain plug in bottom of chamber.
- Thoroughly clean the entire inside surface including the walls, rear panel, floor and inside the door, according to manufacturer's recommendations
- Use a soft mop or lint free cloth and water to clean
- Be aware that detergents can stain the walls of the autoclave if not thoroughly rinsed off

**Expected Outcome**

Autoclaves maintained in a good condition in accordance with manufacturer's guidelines.



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No. 14**

**Title**

**Steam Sterilization Procedure**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of application**

Autoclave area/ specialized area in theatre

**Staff involved**

Only trained personnel allocated to area and engineering/maintenance staff

**Objective/ Purpose**

To ensure consistent sterilisation of items through quality control checks of the autoclave  
To ensure that all reprocessed medical devices are sterilized to an acceptable standard and ready for use.

**Safety Warning**

**Protective Equipment: heat resistant leather gloves and appropriate footwear.  
Sterilizer is hot, burns may occur!**

**Relevant / Related Documents**

Manufacturer's Manual  
Occupational Health and Safety Act, 85 of 1993  
Standard Precautions

**Equipment/Supplies**

Steam Sterilizer (Autoclave), Loading Trolleys, Log books  
Testing products: Bowie & Dick test pack, Microbiology test vials

**Procedure**

The steam sterilizer must be operated accordance with the manufacturer's instructions.

**Daily Preparation of the autoclave**

- For an autoclave with a manual recording chart, replace chart identifying autoclave, date and initial in place provided
- For autoclaves with a computerised recording, check paper
- Check to ensure printer, recorder is working properly
- The first cycle will be a "warm up" cycle.
- On the second cycle place a Bowie & Dick Test Pack, in the warm empty chamber above the drain, on a pre-vacuum cycle, (first or second of the day depend on whether the sterilizer was shutdown). Run the test according to manufacturers' instructions
- Once the cycle has run record the Bowie & Dick according to procedure
- If the Bowie Dick result is a fail repeat the test with a new Bowie Dick Test pack.
- If the Bowie Dick is still a fail shut down the autoclave for repair and recall all sterile packs after the last Positive Bowie Dick Test result
- Run a daily Biological, according to manufacturers' instructions, in the first full load of the day as well as any load containing implants.



#### CSSD FORUM STANDARD OPERATING PROCEDURE

- Record the result according to procedure
- Complete test and record biological indicator ( BI ) Test according to procedure

#### **Operational Guidelines**

- Record contents of load, information must be detailed enough to allow for tracking and recall if necessary.
- Label Package according to policy
- Make sure each pack has a tracking label affixed
- Packaging manufacturers must validate that the product contained can be satisfactorily sterilized within the wrap, pouch, container etc.
- Ensure that items being loaded are compatible with High Temperatures
- Process full loads – not overloaded- to limit the number of cycles you need to run
- Load the autoclave according to manufacturers' instructions, make sure the door to the chamber is locked, and the appropriate cycle is selected based on the types of devices being processed
- Load items in a loose fashion to facilitate air removal, and steam penetration of all surfaces – do not stack items one on top of the other.
- Packages must not be in contact with walls or ceiling of chamber, package damage from heat or moisture may occur
- Load baskets and carts so hands won't touch packs when removing the hot trolley
- For approved rigid containers, follow manufacturer's validated loading instructions.
- Close and secure lock the autoclave door.
- On completion of cycle, cycle complete indicator will appear, visually check the graph / printer to determine that all parameters have been met.
- Follow manufacturer's directions for door opening and load transfer
- In the event of a cycle failure / cycle aborted, the entire load will need to go through the full reprocessing cycle
- The person responsible for checking the load should sign their name on the printout before opening the sterilizer door or scan in their data for tracking
- Before opening the door, thoroughly wash hands according to Hospital Policy
- Open the door while standing towards the side to avoid burns.
- Put on heat resistant gloves and remove carrier from Autoclave.
- Allow to cool for 10 – 20 minutes before storage or dispensing.
- Do not touch hot packs
- Inspect packages to ensure integrity and external chemical indicators have changed.
- Record results in log book and file for each autoclave according to Procedure no:

#### **Expected Outcome**

Consistent sterilisation of items through quality control checks of the autoclave  
All packs are sterile and safe to use



CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT

**SOP No. 15**

**Title**

**Ethylene Oxide Sterilisation**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of application**

ETO area

**Staff involved**

Only trained personnel allocated to area and engineering staff.

Pregnant women should not be allocated to this area

**Objective/ Purpose**

To ensure that all ETO sterilisers are functional and operated according to departmental policy.

To ensure that all reprocessed medical devices are sterilized to an acceptable standard and ready for use.

To ensure that the work environment is safe for employees

**Safety Warning:**

**ETO is an odourless gas**

**Skin contact** with liquid EO - immediately wash affected area

**Eye contact** with liquid EO - flush eyes with copious amounts of water for at least 15 minutes

Ensure staff have been educated regarding safety precautions when working with ETO

**Relevant / Related Documents**

Manufacturer's Manual

Occupational Health and Safety Act, 85 of 1993

Standard Precautions

Sterilization policy and process

Environment requirements

Safe work practices

Emergency procedures

Logbooks

**Equipment/Supplies**

ETO Sterilizer

ETO Cartridges

Aeration Cabinet

Monitoring equipment

Emergency equipment

Personal Protective equipment

**Procedure**

**Daily Preparation of ETO Sterilizer**

- Ensure the work environment is safe for employees
- Replace Load Control Slips Daily or computer printout paper
- Identifying sterilizer, date and initial on load control slip



## CSSD FORUM STANDARD OPERATING PROCEDURE

- Check to ensure printer is working where applicable
- Complete test and record biological indicator (BI) Test according to manufacturers instructions
- It is important that all staff members are aware of the policy and procedures that relate to EtO sterilization
- Operators must know how to operate the ETO sterilizer safely as well as the importance of adequate aeration
- Operators need to understand the environment requirements and safe work practices
- Operators must know what the emergency procedures are in case of a leak or accident
- Operators must understand that regulations have to be followed
- The ETO sterilizer must be operated accordance with the manufacturer's instructions
- The ETO sterilizer must be used in a well ventilated controlled room with dedicated exhausts, emission control, enclosed ETO sterilizer/aerator room, ventilation, air exchanges and environmental monitoring provided
- Single-use cartridge delivers the appropriate volume/concentration of ETO
- Check with gas manufacturer/supplier for storage recommendations and MSDS sheet.
- ETO gas must be stored at the prescribed temperature in a well ventilated area in a cupboard marked with Hazardous materials label
- The cycle must be long enough to allow thorough ETO penetration to kill microorganisms
- The sterilizer operating temperature is usually preset by the sterilizer manufacturer; there are usually two options: 100F (cold cycle) 130F (warm cycle)
- The manufacturer of a device is responsible for providing validated information regarding proper sterilization and aeration of their products, usually between 1 to 6 hours, depending on the concentration, humidity, temperature parameters, and the type of sterilizer
- The ETO cartridge must be discarded in a safe manner according gas manufacturer/supplier and hospital policies
- Personnel exposure must be measured as a Time Weighted Average based on environmental exposure. Average personnel exposure concentration should be measured over a specific period of time, usually 8 hours
- Employer must ensure that no employee is exposed to airborne concentrations of ETO in excess of the concentration recommended by suppliers (<1 ppm)
- ETO won't penetrate soil so proper cleaning and decontamination must be done for the items that will be processed (See Cleaning SOP)
- Soil and Liquids hinder sterilization efficacy and may result in harmful residuals being formed: Water + EO = Ethylene Glycol (Antifreeze); Saline + EO = Ethylene Chlorohydrins (Possible carcinogen)
- Material compatibility with EtO must be validated by the device manufacturer
- Aeration Cabinets are required to remove residual ETO before patient contact with the device
- If plastic instrument containers/trays are used, make sure they can be sterilized with ETO and aerated
- It is important that the ETO is aerated from the device within and from the plastic container itself with no cumulative ETO absorption/residual into the plastic that cannot be satisfactorily removed by each aeration cycle
- Plastic, rubber or silicone mats must have been validated by the manufacturer for suitability in ETO processing
- Make sure that instrument tip protector manufacturers have validated their recommendations for the application and use of ETO
- Verify with the manufacturer if colour code tape can be used with ETO
- Packaging manufacturers must validate that the product contained can be satisfactorily sterilized within the wrap, pouch, container etc. and can release EO upon aeration in a reasonable amount of time; not only from the device but the packaging material too



## CSSD FORUM STANDARD OPERATING PROCEDURE

- Do not use plastic coated baskets unless designed and validated for ETO sterilization and aeration
- Label Package according to policy
- Load items in a loose fashion to facilitate air removal, humidification, ETO circulation and penetration of all surfaces, and ETO removal during aeration
- Packages must not contact walls or ceiling of chamber, package damage from heat or moisture may occur
- Process full loads to limit the number of cycles you need to run
- Load the sterilizer according to manufacturers instructions, make sure the door to the chamber is locked, and the appropriate cycle is selected based on the types of devices being processed
- Group like products that need same aeration times to avoid exposure when opening the sterilizer/aerator to retrieve items during the aeration process
- Load baskets and carts so hands won't touch packs if you need to transfer them to an aeration cabinet.
- For approved rigid containers, follow manufacturer's validated loading instructions.
- Follow manufacturer's directions for door opening and load transfer
- When unloading some sterilizer manufacturers recommend immediate removal if transferring items to a freestanding aerator
- Opening the door 2 inches for 15 minutes is recommended... obviously you would not remain in the area
- **Load is transferred to separate aeration unit/area**
- Rolling carts should be PULLED (NOT pushed) to minimize Operator exposure to off-gassing ETO vapors
- Butyl rubber or Neoprene gloves should be worn if Operator will be in possible contact with ETO residuals, touching wrappers before aeration
- Aeration in the sterilizer doesn't require transfer
- **Aerate** until potentially toxic ETO residues are removed before storage and use of medical devices
- Length of aeration depends on Composition/materials, thickness, design and weight of the device and it's wrapping, sterilization and aeration system used, temperature, ETO, concentration, duration of gas exposure, rate of air exchange, and air flow pattern
- Size and arrangement of packages in the sterilizer/aerator or aeration cabinet and the number of ETO absorbent materials being aerated
- Device manufacturer's recommendations must be **VALIDATED aeration parameters** (time/temperature)
- Manufacturer recommended aeration times **MUST BE FOLLOWED!!!**
- Preset temperature selections per the aerator manufacturer
- The aeration time must be uninterrupted
- 8 hours at 140° F (60°C)
- 10 hours at 130° F (54°C)
- 12 hours at 120°F (49°C)
- 20 hours at 100° F (38°C)
- **DO NOT** remove prematurely, with premature removal, personnel and patients may be adversely affected
- **Signing a waiver sheet DOES NOT relieve any liability for anyone**
- "Ambient air" aeration is not recommended as it greatly increases the risk of worker exposure to EO and is not necessarily a reliable means of removing ETO from the items

### **Expected Outcome**

ETO sterilizers are operated according to manufacturers instructions.

The work environment is safe for employees

All equipment is sterilized to an acceptable standard



CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT

**SOP No. 16**

**Title**

**Loading and unloading items from the autoclave**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of application**

Autoclave area

**Staff involved**

Only CSSD and Theatre Staff trained in the task

**Objective/ Purpose**

To ensure that items are correctly loaded and unloaded from autoclaves in order to maintain sterility

**Relevant / Related Documents**

Manufacturers Instructions  
Sterilization policy and process  
Quality Manual

**Equipment/Supplies**

Autoclave  
Loading/unloading carts  
PPE  
Slatted stainless steel airing shelves

**Procedure**

- Load according to manufacturers instructions
- Wear relevant protective clothing
- Load instrument sets flat in single layer
- Load soft packages on their sides with a hand's width between items
- Load soft packs on top shelf and large instrument trays on lower shelf
- Load containers according to manufacturers instructions some may be stacked
- Do not allow packs to touch top, bottom or sides of autoclave
- Do not compress packs
- Position peel packs on sides
- Do not overload
- On completion of cycle record according to policy
- Allow autoclave and packs to cool before handling
- Do not touch packs until completely cooled
- DO NOT TOUCH HOT RACKS WITHOUT HEAT RESISTANT GLOVES
- Once cooled check for wet packs, tears, indicator changes etc.
- Store according to policy

**Expected Outcome**

Sterility of packs is not compromised through incorrect loading and unloading



CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT

**SOP No. 17**

**Title**

**Sterile Pack Storage**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of Application**

Sterile Storage Area

**Staff Involved**

All

**Objective/Purpose**

To ensure the safe storage of all sterile packs up to release to other departments

**Relevant/Related Documents**

Procedure Manual

Standard Precautions

**Equipment/Supplies**

Stainless Steel slatted Shelving

**Procedure**

- This is a clean area and should be kept clean and tidy at all times with limited access
- Ensure that stock is rotated and monitor stock levels
- Any member of the CSSD staff may issue out packs to customers, provided that **ALL** the checks have been carried out by the person releasing the goods
- Only CSSD staff should be allowed access to the storage area
- Doors and windows must be kept closed
- Temperature should be controlled
- The Sterile Storage area should be arranged to make it easy to identify packs and be well lit and easy to clean.
- There should be enough shelves and cupboards available to store all sterile goods without having to stack them tightly or on top of one another.
- Products should be stored away from outside walls.
- There should be space between shelving and floor and ceiling to allow air to circulate and to allow cleaning of the floor area.
- Surgical and medical supplies should be stored at least 25cms from the floor, 45cms from the ceiling and 5cms from outside walls to allow for air circulation in the room and to prevent contamination during cleaning.
- Items should not be stored next to or under sinks, on the floor or windowsills where they are likely to get wet or damaged.
- You need enough space to store all the medical devices your department is using.
- Do not bend or fold large packs.
- Storage components should be designed so that you can easily see the number of products in storage.





## CSSD FORUM STANDARD OPERATING PROCEDURE

- Follow a system of use the First in First out (FIFO) system. Rotate stock so that oldest items are used first.
- Shelving should be easily cleaned and allow air to circulate around stored products.
- Products should be stored away from direct sunlight and water.
- Do not squeeze packs into tight spaces as this can tear the packaging
- Closed or covered cabinets are preferred for seldom-used items. If items are stored on open (wire) shelving, the bottom shelf (only) needs a physical barrier between the shelf and traffic or housekeeping activities.
- Cupboards can be used to store small, delicate or expensive items. All cupboards must have doors, preferably with a lock. Open shelves (wire-mesh or bars) allow dust to pass through making them easier to clean than solid shelves.
- Cardboard boxes should not be used as storage containers because they release fibres, cannot be easily cleaned and sometimes have rough edges which can make holes in packaging.
- Shipping cartons should not be brought into the Sterile Storage area because they can collect microorganism during transport, which can increase the risk of infection. Insects and rats, which spread microorganism, should not be allowed to enter either.
- Surfaces in contact with sterile goods should be as clean as possible to prevent microorganism penetrating the packaging of these items. Trolleys should be cleaned and dried after each use, because even though they are used with sterile items, contamination can be picked up during transport outside the CSSD.

### Shelf life

- The shelf life of a pack is dependent on packaging, handling and storage conditions.
- The shelf life of a CSSD processed sterile item is based on events rather than time.
- This also applies to all commercially prepared items which are labelled as “Sterile unless opened or damaged”.
- The date on a sterile package indicates the date the item was sterilized or manufactured. Sterility is maintained as long as the integrity of all barrier properties and seals are maintained
- Expiration date is a reminder “Use Before” /”Use First”
- Storage conditions will be such that product integrity is not compromised by moisture or any other means which breach the wrapping materials
- The probability of a contaminating event happening increases over time. You can maintain a product’s shelf life by:
  - reducing its exposure to direct sunlight, excessive temperatures and humidity
  - reducing handling and transportation as much as possible
- Events that can compromise the sterility of a sterile item include:
  - Holes or torn wrappers
  - Securing tapes or locks that have been tampered with or removed
  - Broken or incomplete seals on laminated pouches
  - Items that have been dropped on a dirty surface
  - Exposure to blood, body fluids or any type of moisture.
  - Cardboard boxes are not to be used except where supplied by the manufacturer for dispensing (i.e. gloves or sutures). Do not top up or reuse cardboard dispenser boxes.
  - Items should be decanted from large outer (shipping) boxes prior to being brought into the sterile storage area.
  - Elastic bands or tapes should not be used to bundle items



## CSSD FORUM STANDARD OPERATING PROCEDURE

### **Expected Outcome**

Sterility of all packs is maintained whilst in the CSSD

**NB The expiry date is only a guide. Events related to the storage of products are critical for the ability of materials used to maintain integrity. Any event which could deteriorate the wrapping material must be managed so that wraps are not damaged in any way and sterility of contents compromised.**



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No. 18**

**Title**

**The Delivery and Distribution of Processed Items**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of application**

All sterile storage and dispatch areas

**Staff involved**

Only staff trained in CSSD/Theatre

**Objective/Purpose**

To ensure customers receive sterile items in a safe condition and ready to use

**Relevant/Related Documents**

Quality Manual

Dispatch Log

**Equipment/Supplies**

Clean Trolleys

**Procedure**

- All items will be checked for sterility before they are released
- The following should be checked when deciding if the pack is still sterile: -
  - Holes or tears
  - Wetness or stains
  - Broken seals
  - Dust
  - Evidence of crushing
- All damage items are returned to the decontamination area
- All items issued will be recorded so that a tracking system is effected
- Various methods can be used in the transport of sterile packaged items to their point of use.
- This can range from hand carriage (in particular where a decontamination area is located close or adjacent to a point of use), to the use of trolley's and other such transport systems for taking items to a remote location (within a facility or at a different facility).
- Sterile supplies should be transported in covered or enclosed trolleys with a solid bottom shelf. The solid bottom shelf prevents microorganism on the floor being picked up by the wheels of the trolley and then spun upwards onto the sterile packs.
- If items are placed inside plastic or paper bags, they should be arranged to prevent them from being crushed or damaged during transport. They all protect medical devices from damage
- Items must be placed onto a clean trolley that can be covered
- Trolleys must not be overloaded
- Soiled items must NOT be loaded onto the same trolley
- Loaded trolleys must not be left to stand

**Expected Outcome**

Customers receive sterile items safe to use



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No. 19**

**Title**  
**Quality Control**

**Review Date**  
July 2019

**Prepared by**  
**CSSD Forums of South Africa (CFSA)**

**Area of application**  
Any area where items are reprocessed

**Staff involved**  
All CSSD, Clinic and Theatre Personnel

**Objective/ Purpose**  
To ensure that the CSSD provides a quality service

**Relevant / Related Documents**  
Manufacturer Guidelines  
Sterilization policy and process  
Relevant Legislation

**Equipment/Supplies:**  
Relevant Consumables  
Equipment



CSSD FORUM STANDARD OPERATING PROCEDURE

Procedure

Area Where Test Is To Be Performed	Details of Test
<b>Washing Area</b>	<ol style="list-style-type: none"><li>1. Check that complete sets have been received from user</li><li>2. Check spray arms and jets of washers</li><li>3. Check Detergent levels on washers</li><li>4. Soil Tests according to policy</li><li>5. Check tracking system is in place - record</li></ol>
<b>Packing Area</b>	<ol style="list-style-type: none"><li>1. All instruments to be visually inspected for cleanliness/functionality – deal with rejected items according to policy</li><li>2. Check all instrument are present and packed correctly</li><li>3. Place a chemical in-pack indicator</li><li>4. External chemical indicators-auto - record</li><li>5. Check the functioning of heat sealers daily</li></ol>
<b>Autoclave Area</b>	<ol style="list-style-type: none"><li>1. Mechanical monitoring of all sterilisers</li><li>2. Perform daily Vacuum Tests on all steam autoclaves (BD)</li><li>3. Perform daily Biological Tests on all sterilisers</li><li>4. Check that all packs have external chemical indicators before loading into steriliser</li><li>5. Check load control test has passed before load is released - ensure a positive colour change - record</li><li>6. Check that all parameters have been met on autoclave printout - record</li><li>7. Complete any log sheets</li><li>8. Check that all items removed from the autoclave are intact, dry and undamaged.</li><li>9. All items that have residual moisture, tears or from a failed cycle are to be dealt with in accordance with policy</li><li>10. Check tracking system is in place - record</li></ol>
<b>Sterile Goods Storage Area</b>	<ol style="list-style-type: none"><li>1. Before releasing goods for delivery, check the packaging for damage.</li><li>2. Reject any suspect packs and unpack before sending to the wash area for reprocessing</li><li>3. Check the external chemical indicator to ensure that the pack has been through a steriliser</li><li>4. Check tracking system is in place - record</li></ol>



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No: 20**

**Title**

**Monitoring Steam Autoclaves**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of application**

Steriliser Area

**Staff involved**

Trained CSSD Staff

**Objective/ Purpose**

To monitor that all steam autoclaves are functioning optimally

**Relevant / Related Documents**

Manufacturer's information  
Sterilization policy and process  
Quality Manual

**Equipment/Supplies**

Autoclave  
Monitoring Supplies

**Procedure**

- Monitoring includes all sterilizer components that track and record time, temperature and pressure during each cycle, Printouts, gauges, round charts, etc.
- Documentation of critical cycle parameters permits the earliest detection of equipment malfunctions since they can be evaluated when the cycle is in progress

Sterilization failure can be identified at a number of stages:

- Autoclave parameters are not met
- Biological Test shows growth
- Bowie Dick Test Failure
- Process Challenge Device or Load Control Failure
- External Process Indicator Failure
- Internal Chemical Test Failure
- Wet Packs

**Chemical Indicators**

Chemical Indicators are used in combination with physical parameter to monitor the effectiveness of the sterilizer. They monitor conditions in the sterilizer chamber or from within the load as part of a total system of sterilization monitoring. The following main types of chemical indicators are available:

- Process indicators
- In-Pack indicators
- Load controls or Process Challenge Devices



## CSSD FORUM STANDARD OPERATING PROCEDURE

The ISO 11140-1 standard classifies indicators according to intended use or performance criteria as follows:

Class 1: Process indicators/external indicators

Class 2: Indicators for use in specific tests/Bowie Dick

Class 3: Single parameter indicators/respond to one parameter

Class 4: Multi-parameter indicators/respond to 2 or more parameters

Class 5: Integrating indicators/react to all parameters/ mirror the performance of Biological indicators

Class 6: Emulating indicators/react to all parameters/ verify specific cycle parameters

### **Bowie Dick Test (BD)**

- Bowie-Dick test should be run and documented at least daily before the first process load and after any steam autoclave shut-down.
- This indicates if air is being removed completely from the autoclave
- Manufacturer's of the Bowie Dick should provide data on the reliability, safety and performance characteristics of their product, as well as instructions for use storage, handling
- The Bowie Dick is placed on a rack above the drain of the autoclave in an **EMPTY** load
- This test should be done daily in each machine, the machine must be warm
- There must be a complete, uniform color change which indicates a PASS
- A PASS indicates that the sterilization process was effective since it indicates no air was present
- An incomplete or no color change - FAIL
- A FAIL indicates air was present and sterilization was not achieved
- Repeat the test
- If results still show a FAIL do not use the autoclave
- The Autoclave number and test result must all be recorded in the record book provided.
- Test cards and results must be recorded and stored according to Hospital policy

### **External Chemical Indicators (CI)**

- A Process indicator is placed on the outside of each individual package to verify that the package has been exposed to a sterilization process.
- Indicator should be clearly visible on the outside of the sterilized package. This helps differentiate sterilized from unsterilized items.
- Fix the Process indicator tape or label on the outside of the package or rigid container, once it has been assembled for sterilization.
- This is not necessary in the case of packaging with pre-printed Process indicators on them.
- Readily visible and color change provides a quick indication that the load has or has not been exposed to the sterilization process
- Check that the Process indicator has changed colour according to the manufacturer's instruction after the sterilization cycle has been completed, prior to placing the package in sterile storage.
- If the process indicators have not changed, the packages should NOT be released.
- Process indicators provide an indication that the load has been exposed to the conditions necessary to achieve sterilization
- Helps detect failures in packaging, loading, and sterilizer malfunction.
- Color change according to the manufacturer's reference – Pass - Medical Device can be moved to the Sterile Storage Area for use
- Color change not according to the manufacturer's reference – Fail - Medical Device should be reprocessed



## CSSD FORUM STANDARD OPERATING PROCEDURE

### Internal Chemical Indicators

- In-pack chemical indicator can detect sterilizer malfunction or human error in packaging or loading of the sterilizer.
- Place the CI in an area of the package, instrument tray or rigid container in an area that is determined to be the densest part of each pack
- Measure if sterilizing parameters have been met inside the pack
- A member of the surgical team should retrieve the CI at the time of use and interpret its reaction to the sterilization process.
- This is a patient record and must be kept
- Color change even and according to the manufacturer's reference – Pass - Medical Device can be used
- Color change uneven and/or not according to the manufacturer's reference – FAIL - Medical Device should not be used
- Send back to Sterilization Department for reprocessing

### Process Challenge Devices/ Load Controls (PCD)

- This indicates to CSSD staff that the sterilization parameters have been met in the load and that it can be released
- Process Challenge Devices/Load controls are devices designed to act as a challenge to the steam penetration capability of a sterilizer and is made up of a barrier system, inside of which a chemical or biological indicator is.
- The intention of a PCD is to challenge the sterilization process, by either using a Biological or Class 5 integrating indicator, or an enzyme-only indicator.
- Load Checks are reusable devices; therefore a new indicator has to be loaded into it before use. Follow the manufacturer's instructions in this regard
- Load the Process Challenge device with an unused chemical indicator, following the manufacturer's instructions. Place it in a peel-open sterilization pouch and seal.
- Place the PCD, in every full sterilizer load at a point where steam penetration will be most difficult.
- Process the load as usual.
- After sterilization, retrieve the PCD and interpret the result of the chemical indicator against its colour standard.
- The test result PASS/FAIL should be recorded in the sterilizer log book.
- Complete uniform color change – PASS
- If the PCD shows a PASS it can be assumed that the entire load has met the necessary conditions required for that particular sterilization process
- Sterilization process was effective and autoclave load can be released
- Incomplete color change – FAIL
- If the test result is a FAIL, the load should be quarantined and not used until the reason for the fail can be determined and rectified.
- Sterilization process was ineffective – Do not release the load
- Repackage all sets with new indicators and re-autoclave
- If results still show a fail, do not use the autoclave

### Biological Indicators (BI)

- A biological indicator is a preparation of living spores which provide a defined resistance to a specified sterilization process.
- A PASS Indicates if sterilizing conditions are adequate to kill micro-organisms
- Non-pathogenic micro-organisms are used
- Manufacturer's of the BI should provide data on the reliability, safety and performance characteristics of their product, as well as instructions for storage, handling, use





## CSSD FORUM STANDARD OPERATING PROCEDURE

- A test must be performed at least daily in each sterilizer.
- Place the BI in a test pack, into the center of a **FULL** load.
- The BI manufacturer **must be consulted** for recommendations regarding how to use their specific product
  - Process the load as usual.
  - After sterilization, retrieve the BI Test out of the pack.
  - Allow the BI to cool for 10 minutes after sterilization. (Note the BI contains a glass ampoule, which needs to cool prior to crushing and incubating)
  - Check the chemical indicator strip on the BI has changed appropriately according to the manufacturers' instructions.
  - Record the sterilizer, load and date on the BI label.
  - Crush the vial inside of the self-contained BI, and start incubation.
  - Follow BI manufacturer's instructions for activation and incubation
  - Now take an unprocessed BI from the same box/batch, and write a 'C' (control) on the side of it.
  - Write the date on the vial.
  - This control vial does not go through the sterilization cycle, and validates that the spores and media solution are viable, the incubator is operating at the correct temperature, and that the BI's have been stored correctly.
  - Incubate the Test BI and the Control BI for 24 to 48 hours according to the manufacturer's instructions
  - Run Control BI every time a BI is incubated
  - If the spores are alive, they give off an acid, which changes the colour of the solution in the vial.
  - Check for any signs of colour change
  - Document the visual result at 24 or 48 hours in the Log Book, dependent on the type of spore being used.
  - **Negative '-'** means no colour change/no growth
  - Sterilization process was effective since it indicates no growth.
  - **Positive '+'** means colour change/growth of microorganisms.
  - Indicates microorganism growth and sterilization was not achieved
  - The Test BI (that has been processed) should always remain the same colour before and after incubation, as the sterilization process should have killed the live bacteria.
  - The Control BI (which has not been processed) should always change color after incubation, as the live bacteria would have been cultivated.
  - If there is a BI failure on any load, the whole load must be recalled, repackaged and re-sterilized.
  - Refer to the individual manufacturers guidelines to activate and incubate the Control.
  - Results must be recorded and stored according to Hospital policy
  - Do not release products until the BI has been read and is positive

### Maintenance

The following information should be recorded in the maintenance logbook for each autoclave:

- Date of servicing or repair work
- Description of work performed
- Name of service engineer
- Signature of service engineer

### Expected Outcome

The steam autoclave is working effectively and if all re-processing standards have been met, products should be sterile



CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT

SOP No. 21

**Title**  
Recall Procedure

**Review Date**  
July 2019

**Prepared by**  
CSSD Forums of South Africa (CFSA)

**Area of application**  
CSSD, Wards, Clinics and Theatre

**Staff involved**  
All CSSD, Clinic, Ward and Theatre Personnel

**Objective/ Purpose**  
To ensure that any product suspected of being substandard is identified, quarantined, collected, investigated and the findings recorded

**Relevant / Related Documents**  
Sterilization policy and process  
Quality Manual  
Working Instructions Manual  
Daily, Weekly Quarterly and Annual Test record

**Equipment/Supplies**  
N/A

**Procedure**

- In the event of sterilization failure, such as positive biological indicators/Failed Load Controls or sterilizer malfunction, items from that test and previous loads after the last known good test must immediately be recalled.
- **All affected trays must be recalled in the event of failed quality management tests i.e. Biological, Load Control**
- A written Recall Procedure must be followed in the event of a sterilization failure
  - The sterilizer must be shut down and all staff must be made aware that it is out of operation.
  - The sterilization record sheets should be checked for a list of “sterilized” items that need to be recalled.
  - The recall procedure should be documented on the sterilization record sheets listing what items have been retrieved and reprocessed and which items had already be used and on whom. Note items that may have already been used on the list.
  - As it becomes apparent that items need to be recalled reprocessing personnel will immediately notify users and retrieve the supplies from storage and from user as soon as possible.
  - A recall is usually authorised by the most senior staff member on the shift.
  - Other responsible persons i.e. Infection Control should be advised of the recall according to hospital policy.



#### CSSD FORUM STANDARD OPERATING PROCEDURE

- Affected departments should be advised verbally as soon as possible, with a follow up written confirmation advisory stipulating which items, trays from a particular batch are suspect and should be returned.
- Departments should be requested to check their sterile stock as well as used stock for the suspect batch.
- The following details will be given:
  - The name of the sets to be recalled
  - The sterilising date
  - Details of the action to be taken
  - Reasons for the recommended actions and any likely associated hazards
- Sterile services staff will attempt to confirm that the check has been carried out
- Any decontaminated in the CSSD will be checked by the Sterile Services Staff and any identified suspect batch removed
- Sterile Services Staff will arrange collection of any identified suspect stock on the customer's premises.
- Recalled items should be labelled '**Under Quarantine**' whilst in transit to the cleaning area of the reprocessing area where it will be reprocessed or be put into quarantine.
- All items retrieved from a Recall must be completely reprocessed.
- All items must be disassembled, processed with fresh linen, assembled, rewrapped and sterilized.
- Once the sterilizer has been repaired all monitoring results must be checked before the sterilizer is used.
- The cause of the recall should be investigated and a report written

#### **Expected Outcome**

A quality management system is in place confirming that all products leaving the CSSD are sterile and safe to use



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No. 22**

**Title**

**Validation of Equipment**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of application**

All equipment (new or used).

**Staff involved**

All CSSD, Clinic, Ward and Theatre Personnel

**Objective/ Purpose**

To ensure that all equipment which can influence quality or safety is not used for processing until its performance has been approved.

**Relevant / Related Documents**

Manufacturers Instructions  
Sterilization policy and process  
Quality Manual  
Relevant ISO Standards

**Equipment/Supplies**

N/A

**Procedure**

- Ensure all new equipment ordered for CSSD is appropriate and safe to use
- Copies of any relevant documentation relating to the equipment must be given to the manager
- Equipment will not be used until it has been validated and an assurance is given that the equipment will give an acceptable quality of product and is safe to operate
- The installer / manufacturer should verify in writing that all is in order by way of a certificate.
- This certificate is to be maintained with the log book for the equipment
- Equipment will only be used after the necessary training is given to the staff
- No new or replacement equipment will be used without the appropriate approval and training

**Expected Outcome**

Quality and safety is maintained



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No. 23**

**Title**

**Monitoring ETO Sterilisation**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of application**

ETO area

**Staff involved**

All CSSD and Theatre Personnel

**Objective/ Purpose**

To ensure that all ETO sterilisers are functioning optimally

**Relevant / Related Documents**

Manufacturer's Manual  
Sterilization policy and process  
Environment requirements  
Safe work practices

**Equipment/Supplies**

Physical monitors  
Chemical indicators  
Biological indicators  
Environmental monitors

**Procedure**

**Physical Monitors**

- Measures that ETO machine is functioning effectively
- Monitoring includes all sterilizer components that track and record time, temperature and pressure during each cycle, Printouts, gauges, round charts, etc.
- Documentation of critical cycle parameters permits the earliest detection of equipment malfunctions since they can be evaluated when the cycle is in progress

**Chemical Indicators (CI)**

Indicator of conditions present:

- Provide an indication that the load has been exposed to the conditions necessary to achieve sterilization
- Helps detect failures in packaging, loading, and sterilizer malfunction.

**External Indicators**

- Placed on the outside of each pack to be sterilized
- Often included on load record cards
- Readily visible and color change provides a quick indication that the load has or has not been exposed to the sterilization process
- If the process indicators have not changed, the packages should NOT be released.



## CSSD FORUM STANDARD OPERATING PROCEDURE

### **Biological Indicators (BI)**

- Indicates if sterilizing conditions are adequate to achieve sterilization
- *Bacillus atrophaeus*: Microorganism of choice for monitoring EO sterilization as it offers the best test challenge since it is most resistant to kill
- Non-pathogenic
- Manufacturer's of the BI should provide data on the reliability, safety and performance characteristics of their product, as well as instructions for storage, handling, use
- **IMPORTANT** to note that equipment sets/trays prepared with surgical towels may absorb so much of the humidification available to the ETO process that the biological indicator may show Positive results because not enough humidity was available to kill the test spore. Limit the use of absorbent surgical towels in these setups
- BI is placed into the center of a full load Consider placing the test pack into a small metal basket or instrument tray for easy retrieval if it must be removed before a load is transferred to a separate aerator
- The BI manufacturer **must be consulted** for recommendations regarding how to handle their BI
- If the BI test is removed before aeration, do it in a well ventilated room, protect yourself from EO residue on the package by wearing butyl rubber gloves to disassemble the pack and retrieve the BI for incubation and then aerate the test packaging material before discarding
- Worker safety must be given primary consideration.

### **Incubation**

- Follow BI manufacturer's instructions for activation and incubation
- Be careful with dual temperature incubators, be certain you put the ETO BI in the appropriate place
- For example, **ETO (*Bacillus atrophaeus*) is incubated at 37° C for 48 hours. Steam (*Geobacillus stearothermophilus*) is incubated at 55° C for 24 hours**
- *Bacillus atrophaeus* will not grow at higher temperatures
- Incubate an activated but not sterilized biological to verify that the test microorganisms are alive and ready for use in testing
- Run Control BI every time a new package of BI's is opened and everyday.
- If there is a BI failure on any load, the whole load must be recalled, repackaged and re-sterilized.
- Refer to the individual manufacturers guidelines to activate and incubate the Control.

### **Test Results**

#### Negative "Test"

- Sterilization process was effective since it indicates no growth.

#### Positive "Test"

- Indicates microorganism growth and sterilization was not achieved
- Implants that have been EtO sterilized must not be released until the BI results are known

### **Environmental Monitors**

- Area monitoring – Required!
- Personnel monitoring advisable – not required
- These must be monitored according to manufacturer agreement

### **Record-Keeping**

- Load record card (LRC)
- Packages must be properly identified and recorded on the LRC
- Expiration date or statement, load contents, sterilization date, load number, sterilizer number and name of the sterilizer operator must be on the card. Examples of the package load stickers should also be affixed to the card. All of this helps with package retrieval in case of a recall
- The load record card is run with the load
- The LRC has an ETO chemical indicator



**CSSD FORUM STANDARD OPERATING PROCEDURE**

- Check with state and local agencies for how long sterilization records must be kept which must be in line with Hospital Policy

**Expected Outcome**

The ETO machine and loads are validated



CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT

**SOP No. 24**

**Title**

**Malfunction of Ethylene Oxide Steriliser**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of application**

ETO area

**Staff involved**

Trained service personnel needed to identify and correct the cause of the malfunction

**Objective/ Purpose**

To ensure that all ETO sterilisers are monitored and operated according to departmental policy, and procedures.

To ensure a safe work environment

**Safety Warning:**

**ETO is an odourless gas**

**Skin contact** with liquid EO - immediately wash affected area

**Eye contact** with liquid EO - flush eyes with copious amounts of water for at least 15 minutes

**Relevant / Related Documents**

Manufacturer's Manual

Occupational Health and Safety Act, 85 of 1993

Standard Precautions

Sterilization policy and process

Environment requirements

Safe work practices

Emergency procedures

**Equipment/Supplies**

ETO Sterilizer

Aeration Cabinet

Monitoring equipment

Emergency equipment

Personal Protective equipment

**Procedure**

- Notify department head or designated supervisor
- Remove sterilizer from service
- If the malfunction compromised the sterility of the load, the load is aerated adequately and reprocessed
- If the system has a diagnostic capability, run the system
- Microprocessor controlled ETO sterilizer are designed to provide indication of "error" conditions that may lead to malfunction
- Messages are provided to alert the Operator and are part of the cycle record





**CSSD FORUM STANDARD OPERATING PROCEDURE**

- Do not use until an Engineers has signed that the machine is safe to use
- Do not use after repair until a ROUTINE biological test is done

**Expected Outcome**

The ETO steriliser is monitored and operating according to departmental policy, and procedures.  
A safe work environment



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No. 25**

**Title**

**Planned Maintenance Schedule of Equipment**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of Application**

Sterile Service Department

**Staff Involved**

Senior Staff

Maintenance Department

**Objective/Purpose**

To ensure all plant and equipment is checked and maintained in good working order according to manufacturer's guidelines and departmental maintenance schedule

**Relevant/Related Documents**

Quality manual

Working Instructions Manual

Planned Preventative Maintenance Schedules

Machine Log

**Equipment/Supplies**

All machinery and equipment used in the Decontamination Department

**Procedure**

- A schedule of planned maintenance of all machinery and equipment used in the Decontamination Department is documented.
- Shutdown of equipment is planned according to schedule
- The work to be carried out at each check is documented.
- All maintenance carried out is recorded
- Log Books will be examined at least on a monthly basis or as appropriate, and signed by the test person, designated for all equipment, for completion and accuracy.
- Task sheets for weekly and quarterly Planned Maintenance detail the work to be undertaken and work order docketts are completed by the maintenance person responsible and a copy issued to the CSSD manager for filing in the appropriate log after the service schedule has been updated
- Senior staff will carry out daily checks on equipment in all Areas according to policy and as detailed in the Working Instructions Manual
- Testing will be carried out at prescribed frequencies (Daily, Weekly, Quarterly and Annually).
- Results will be recorded on the Daily Test / Check Forms in the respective log books
- Service Engineers will carry out inspections under the planned preventative maintenance programme according to the agreed schedule.
- At the end of the visit the Service Engineer will complete a Preventative Maintenance Plan (PMP) form for the equipment checked.



#### CSSD FORUM STANDARD OPERATING PROCEDURE

- The Service Engineer must sign the report.

#### **Expected Outcome**

All equipment is checked and maintained on a regular planned basis



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No. 26**

**Title**

**Action for Breakdown of Equipment**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of Application**

Sterile Service Department

**Staff Involved**

Senior Staff

Maintenance Department

**Objective/Purpose**

To record all breakdowns of machinery

To record reasons for breakdowns

To record action taken to remedy breakdown.

**Relevant/Related Documents**

Quality manual

Working Instructions Manual

Planned Preventative Maintenance Schedules

Machine Log

**Equipment/Supplies**

All machinery and equipment used in the Decontamination Department

**Procedure**

- All equipment breakdowns will be reported to the Supervisor
- The Supervisor will remove the equipment from further use by switching off (if appropriate), implementing the defect reporting procedure and attaching a clear label showing:- **“OUT OF ACTION - DO NOT USE”**
- The Supervisor will hand over the equipment to the designated engineer.
- This must be documented in all cases.
- All breakdowns or repairs will be phoned into the relevant manufacturer if still under guarantee
- If equipment is still under guarantee **NO-ONE** must attempt to repair the equipment without the manufacturers permission
- Equipment on loan or used under service exchange must be returned to the relevant company for repair or replacement
- All breakdowns are recorded in the relevant logbook and the engineer will enter the job number and repairs completed and signed before the equipment is put back into use.

**Expected Outcome**

All breakdowns of machinery are reported and recorded with complete details



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No. 27**

**Title**

**Sterile Packaging**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of application**

Packing area

**Staff involved**

Only CSSD and Theatre Staff trained in the task

**Objective/ Purpose**

To ensure that the correct materials are used and that items are correctly packaged in order to maintain sterility

**Relevant / Related Documents**

Manufacturer's information  
Sterilization policy and process  
Quality Manual

**Equipment/Supplies**

Stainless steel packing tables  
Packaging materials  
Packaging Accessories e.g. Tape, sealers

**Procedure**

- Sterile packaging must provide protection against contamination during handling as well as providing an effective barrier against microbial penetration.
- Items classified as critical devices should be packaged for sterilization (with the exception of flash sterilization methods)
- An ideal packaging should have the ability to allow sterilization agents to penetrate and then provide a barrier, which will maintain the sterility of the wrapped devices.
- Use only medical grade SABS approved packaging
- The type of packaging and the way you package the devices will determine if aseptic opening is possible in the operating theatre or the ward.
- The packaging should allow air that is in the pack to be driven out and the sterilizing agent to reach all surfaces of its content.
- The packaging should protect the contents against damage during handling and transport.
- The packaging should be able to withstand the conditions during the sterilization process such as pressure changes, high temperature and humidity
- It is important that the following points are taken into consideration when choosing a tray/set and packaging method:
  - The type of pack
  - The size and weight of items to be packed
  - The number of times the pack will be handled before use
  - The number and training of personnel who may handle the pack



#### CSSD FORUM STANDARD OPERATING PROCEDURE

- The distances that packs will be transported
  - Whether the storage system is open or closed
  - The condition of the storage area (cleanliness, temperature, humidity)
  - If secondary packaging (e.g., asepto bags or dust covers) will be used or are necessary
  - The method of sealing packs
- The packaging should bear a clearly visible marking indicating whether or not the product has been through a sterilization process.
  - There are many different types of packaging that can be used for different items
  - Packaging material used in steam sterilization must be able to withstand high temperatures, allow for adequate air removal, be flexible considering changes in pressure during the process, permit steam penetration to the pack's contents and allow for adequate drying.
  - Packaging materials used with low temperature sterilization processes (e.g., ethylene oxide and gaseous hydrogen peroxide processes) must have similar properties, particularly being compatible with the sterilization chemicals, moisture, pressure changes and temperature ranges.
  - The packaging system chosen should be appropriate for the items being sterilized and compatible with the specific methods of sterilization being used.
  - Choose packaging to suit the dimensions of the instruments/tray and type of sterilization technique to be used.
  - In addition to containers, individual devices and sets can be packaged with sterilization pouches or wraps
  - The choice of packaging will generally depend on the sterilization method being used.
  - Packaging materials should only be used that have been tested to be compatible and safe for each sterilization purpose.
  - Always follow manufacturer and hospital guidelines

#### **Medical Grade single Use Disposable Sterilization Wrap**

- Double wrapping creates a package within a package.
- Two sheets of wraps are used providing multiple layers of protection of surgical instruments from contamination. Double wrap = wrap and wrap
- The use of two layers of wraps reinforces the strength of the packaging.
- Folding the two wraps separately, one after the other makes the pack more secure, as the greater the number of folds the more tortuous the path becomes for micro-organisms to penetrate into the packaging.
- The double wrap with two sequential folds also affords a two-step unwrapping process which assists in aseptic presentation and creation of a sterile field for users in the operating theatre; the outer wrap is removed before entering the operating room or by an assistant.
- Do not re-use single use packaging
- Use a hospital grade masking tape and autoclave tape when using wrap
- Do not write on packaging

#### **Disposable Peel-open Pouches and Reels**

- Paper/Plastic peel-open packaging materials are suitable for steam, steam formaldehyde and low temperature sterilization processes such as ethylene oxide. It is not suitable for use in hydrogen peroxide gas and ozone sterilizers, again due to the paper (cellulose) content. Disposable peel-open pouches and reels are designed to contain lightweight or small items and are available in various sizes, for single use only.
- Peel-open packaging should not be used for heavy or bulky items because the seals can become stressed and rupture.
- Pouches are available in many sizes.



#### CSSD FORUM STANDARD OPERATING PROCEDURE

- The open end of the pouch is closed with a sealing device. It is essential that the heat sealer is functioning effectively in order to get an adequate seal.
- Both ready-made pouches and reels are available flat or with side gussets for packing bulkier objects.
- The user can cut reels to any size needed, in which case both sides of the pack will need to be sealed by the user.
- Peel-open packaging is useful when visibility of the contents is important.
- When packaging items, care must be taken to leave a minimum of 1 inch (2.5cm) of space between the end of the item and the seal of the pouch or reel in order to facilitate aseptic opening.
- When double pouching, the inner pouch should be at least a size smaller than the outer pouch to prevent folding which may entrap air and inhibit the sterilization process. They must be packaged paper against paper, plastic against plastic in order to enable sterilant penetration.
- A felt-tip, indelible, non-toxic ink marker can be used on clear plastic side of the pouch to label.

#### **Reusable rigid container systems**

- Sterilization containers are a durable sterilization packaging system constructed of a rigid material such as metal, or plastic.
- A variety of sizes can accommodate a wide range of instrument sets.
- Containers need to be disassembled and cleaned after each use, following the reprocessing instructions supplied by the container manufacturer. Remember! Containers are classified as devices themselves and as such should be reprocessed after each use, not just wiped down. Containers must be cleaned in the same way as any other reusable device.
- Following reprocessing they should be checked to include:
  - Checks of gaskets for fraying, cuts, missing pieces, bubbling or compression
  - Cleaning reusable filters and inspecting them for cracks or chips. The number of uses also needs to be logged and the manufacturer's recommendations not exceeded.

#### **Expected Outcome**

Pack integrity is maintained through correct use of packaging



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No. 28**

**Title**

**Management of Loan sets**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of application**

CSSD/Theatre

**Staff involved**

Only CSSD and Theatre Staff trained in the task

**Objective/ Purpose**

To ensure that loan sets are ordered and delivered in time to undergo a full decontamination and sterilisation process

**Relevant / Related Documents**

**SANS 1541:2013**

Manufacturer's information  
Sterilization policy and process  
Quality Manual

**Equipment/Supplies**

Loan sets

**Procedure**

- Loan sets must be ordered and delivered timeously
- An individual loan set must be ordered for each new patient/individual operation
- Loan sets should be delivered to the health care facility to the health care facility, ensuring within the agreed period of time allowing enough time for CSSD staff to check, clean, pack and sterilise the instrumentation before the planned surgery.
- This period of time should be negotiated with a nominated representative of the health care facility and the supplier and should be acceptable to the Supplier/Theatre/User and CSSD.
- Loan Sets required by a surgeon should be requested when drawing up the surgery Schedule and notify CSSD immediately.
- The responsible person, in theatre, should order the loan set according to their agreement with the loan set company, then inform the person responsible for decontamination and sterilisation as soon as
- The relevant form, preferably the form provided in SAN 1541, should contains the following information
  - Date of procedure.
  - Estimated time of procedure
  - Patient identification Gender of the patient.
  - Procedure to be done including reaffirmation of side i.e. left or right.
  - Surgeons name.





#### CSSD FORUM STANDARD OPERATING PROCEDURE

- The responsible person, in theatre, should confirm the availability of the loaner instruments and request written IFUs, (Instructions for Use).
- When booking a surgical case that requires a loan set, the responsible person, in theatre, should inform CSSD immediately of what sets have been ordered, when they will be needed and how much time CSSD needs to process the sets
- Enough loan sets must be ordered for each individual patient, Loan sets cannot be shared between patients.
- It is **NOT** acceptable to decontaminate only soiled items and re-use a loan set on another patient without reprocessing all opened used and unused trays.
- Loan sets may only be reprocessed in CSSD they may **NOT** be reprocessed and flash sterilised in theatre
- The responsible person, in theatre, must check with the CSSD that they have been trained on the sets, and have the necessary equipment to process them.
- All loan sets should be delivered the designated receiving area in CSSD where they must be checked by the CSSD staff in the presence of the company representative
- The following should be provided to the health care facility with the loan set:
- A check list stating the number of trays
  - The details of all implants supplied with the instrumentation.
  - The name of the surgeon, patient (if known) and proposed date of use for the instrumentation.
  - Decontamination declaration certificate
- Incomplete sets should be marked as such by both the company and the receiver on receipt.
- Instrument trays sets should not weigh no more than 10kg each (including sterilization containers). If weight exceeds 10 kg it should be noted
- Tray lists must easily identify instruments which require special attention e.g. complex instruments and number of parts for disassembles instruments as well as graphic photos that are accurate and correspond with trays provided
- Prior to use the full loan set should pass through a validated decontamination and sterilisation process.
- Once the loan set has passed through a full validated decontamination process it should be delivered to User.
- If loan sets are delivered late it is **NOT** acceptable to use immediate use steam sterilisation (flash) as a substitute for a full validated decontamination process.
- Immediately post procedure all loan sets should be returned to the decontamination area where the full set will be cleaned according to hospital protocol and manufacturer's written guidelines, irrespective of whether it was used or not.
- If loan set are to be used on another patient this must be done with the permission of the loan set company and the complete loan set of all opened and unopened trays must go through a fully validated decontamination process.
- It is the responsibility of the decontamination area to ensure that all items are clean, safe to handle and ready in time for the return shipment and that the loan set is accompanied by a completed declaration of decontamination.
- Contaminated items that have not been cleaned should **NOT** leave the facility without a hazardous label.
- Clean and contaminated loan sets should be transported in separate sealed containers to prevent cross contamination

#### Expected Outcome

Loan sets are controlled and managed according to **SANS 1541:2013**



CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT

**SOP No:** 29

**Title**

**Decontamination of Textiles/Linen for sterilization**

**Review Date**

July 2019

**Prepared by**

CSSD Forums of South Africa (CFSA)

**Area of application**

Laundry

Linen room, packing area

**Staff involved**

Trained CSSD Staff

**Objective/ Purpose**

To ensure that all contaminated textiles are cleaned, disinfected and inspected to an acceptable standard.

**Relevant / Related Documents**

Sterilization policy and process

Quality Manual

**Equipment/Supplies**

Washing Machine

Drier

Ironing

Detergent

Stain Remover

Container bags

**Procedure**

- Standard precautions for linen and laundry must be adhered to when working with linen that may be contaminated with secretions from patients
- Staff should wear full PPE when dealing with contaminated textiles to protect themselves and to avoid injuring or contaminating their hands with sharps and soilage. They should handle contaminated linen as little as possible
- Bags of soiled textiles should be taken to a dedicated soiled linen area i.e. a dirty area
- All masking/autoclave tape must be removed from the textiles prior to returning them to the laundry.
- Standardized validated washing and disinfecting processes should be used.
- Moisten soiled textiles to prevent staining. Treat stains to prevent them setting.
- Stains must be removed if possible, holes must be repaired with heat patches, foreign debris (hair, lint) must be removed, labels etc. removed and tapes on gowns repaired.
- Soiled textiles should be sorted before being loaded into washer, to prevent damage to machines from sharps and instruments.
- A validated written process must be used to determine when textiles, used in packing, need to be withdrawn from use. (condemned)
- A cold prewash rinse cycle will remove gross soilage preventing it from baking onto the fabric.



#### CSSD FORUM STANDARD OPERATING PROCEDURE

- A hot detergent cycle of at least 91 degrees C will destroy microorganisms.
- A minimum wash time of 25 minutes is commonly recommended. Soaps or detergents loosen soil and also have some microbicidal properties, so it is crucial to use only recommended detergents that will also not cause irritation to skin.
- The addition of a mild acid to neutralize any alkalinity in the water supply, soap, or detergent decreases skin irritation and further reduces the number of bacteria present
- Clean textiles must be stored in a clean storage area with slatted shelving and transported in a closed container to prevent cross contamination.
- Textiles that are to be returned to the Reprocessing Area for sterilization must pass through a validated process and be appropriately transported to the sterile processing department
- Textiles should be visually inspected between drying and packing, with the assistance of a light table, for stains, physical defects, foreign debris, labels/tape, against written quality standards. The critical zones of gowns, drapes, table covers, and sterilization wraps, as defined by ISO 13995, should be visually inspected to determine if they meet the criteria.
- If textiles are being processed and used as a 'sterile items' they become an integral part of the Reprocessing Facility quality assurance program and need to have a system in place that enables complete traceability.
- Quality assurance measures need to be in place to ensure that every step in the process i.e. collecting, cleaning, disinfecting, drying, function checks, storage and transporting of textiles meet validated process specifications. Acceptable standards can be met if reusable textiles are treated as medical devices and are professionally processed accordingly.
- The drying cycle is an important part of the cleaning process as it assists in killing any remaining microorganisms that may be left after the laundry machine has done its work. Drying in a dryer is recommended, as the heat can be very efficient in killing microorganisms, air drying in direct sun-light is also an option.
- Linen to be sterilized must be appropriately wrapped before being sent to the sterile processing department. Linen must not be placed or stored on the floor.
- Linen must be stored in a dedicated clean storage area.

#### **Expected outcome**

Clean undamaged linen when inspected visually



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No: 30**

**Title**

**Inspection, Repair and Replacement of instruments**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of application**

Sterile Service Department

**Staff involved**

Trained CSSD Staff

**Objective/ Purpose**

To ensure that all instruments are inspected and to effect repairs to or the replacement of broken or damaged instruments.

**Relevant / Related Documents**

Quality Manual

Relevant Repair/Condemning documents

**Equipment/Supplies**

Instruments

Lubricant

Good lighting

Magnifying glass preferably lighted

**Procedure**

- It is advisable to use magnifying lights when inspecting instruments.
- Theatres when returning any damaged item must ensure that it will be readily identified in the wash reception area.
- Feedback from theatres re damaged instruments is vital. This information must be marked on the checklist
- Broken or damaged instruments will be decontaminated prior to sending for repair and a decontamination certificate sent with the consignment.
- All instruments should be visually inspected following the cleaning and drying process.
- All parts of the instrument should be inspected for visible soil:
  - blood
  - protein and other residue
- Pay particular attention to:
  - Cannulas and recessed areas
  - Hinges, joints
  - Serrations, shafts
- All instruments must be checked for visible damage:
  - Breaks and cracks
  - Deformed
  - Signs of wear
  - Discolouration, rust, corrosion



#### CSSD FORUM STANDARD OPERATING PROCEDURE

- All instruments with lumens must be checked for blockages.
- All dirty or clogged instruments must be returned to the cleaning area for reprocessing.
- Functional Checks should be performed on all instruments if possible:
  - Always apply lubricants to the instruments before checking function, repeated opening and closing of the instrument will spread lubricant.
  - Lubricate joints, threads and gliding surfaces prior to any function tests
  - Instruments must operate smoothly
  - Check that points touch, jaw tips must not open or shift laterally when the forceps are closed
  - Check for bent or broken tips or guide pins or broken springs
  - Check for bent jaws, ratchets and shanks
  - Grasping surfaces must be in firm contact with each other.
  - Serrations/grooves slot into each other when the instrument is closed
  - Operate and lubricate moving parts
- Only once instruments have been inspected can they be reassembled.
- All defective instruments should be reported and sent for repair.
- Instruments identified as needing repair are placed in a dedicated tray in the preparation room after following the wash/decontamination procedure
- The records will be maintained by the technician in the area and any repair received back will be issued to the technician who will complete the documentation.
- CSSD staff will enter all damaged or broken instruments into the relevant documentation.
- Maintenance and care should be routinely performed. This includes targeted application of lubricants and stain removers.

**Note:** *Tracking of instruments is a main consideration and it is paramount that consideration is given;*

- To processing the set with an instrument missing until the repair has been completed.
- Whether it is viable to repair or replace and dispose of the item requiring repair. To facilitate full traceability.
- Advice from the manager must be obtained if temporary replacement is considered.

#### **Expected outcome**

Instruments must be free of visible soil

Instruments are suitable for their intended use

Instrument trays are complete



CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT

**SOP No. 31**

**Title**

Checking and Assembling Instrument Trays

**Review Date**

July 2019

**Prepared by**

CSSD Forums of South Africa (CFSA)

**Area of application**

Packing Area

**Staff involved**

Personnel involved in packing

**Objective/ Purpose**

To ensure that all instrument sets are complete and safely packed before sterilization.

**Relevant/Related documents**

Procedure Manual

Instrument Checklist

Manufacturer's Instructions

**Equipment / Material**

All instrument sets for use in theatres and ward procedure packs.

Checklist

Packing materials

In pack indicators

Labels/Labeling Gun

• **Procedure**

- Staff working in this area will wear protective clothing at all times in compliance with the standard precautions dress code
- Make sure that all work surfaces are clean. Clean work surfaces according to department procedure.
- It is critical that staff understand what the instruments are used for, that they are functioning correctly and that each set is assembled in the proper manner for any given procedure.
- When choosing trays make allowance for extra length, ungainly, heavy or delicate design, all of which are more susceptible to damage than 'regular' shaped instruments.
- Trays should be perforated to allow penetration of the sterilizing agent and efficient drying.
- The person checking should indicate and sign that the quantities are correct and that nothing is missing.
- Instruments must be laid out according to the order on the check list.
- Trays are usually packed in the order that instruments are used.
- The contents of instrument sets are usually decided by the surgical team.
- Depending on the types of surgery the following are most commonly used first: BP handle and scalpel blade (for cutting), diathermy (bleeding control), scissors (cutting/dissecting), retractor / dilators and forceps



#### CSSD FORUM STANDARD OPERATING PROCEDURE

- The assembly of a tray should be agreed by both the reprocessing area and theatre managers
- The weight of packs must be taken into consideration when assembling trays.
- Overloaded and heavy trays/sets may some cases remain wet
- Instrument trays must be assembled to maximize instrument exposure to the sterilant, as well as, sterilant (e.g., water) removal
- Choose the relevant tray checklist for the instrument set
- Place a small strip of autoclave tape in the margin on the front of the tray list, making sure that no information is covered.
  - Place a tray liner (where indicated) on the bottom of the tray.
- Check that all instruments are present against the checklist, check instruments one by one.
- Check instruments visually for cleanliness and missing parts (tips, screws, free movement, sharpness and overall condition).
- Do functionality tests on all instruments to check that they are working effectively.
- Instruments with ratchets or hinges should be held in an open and unlocked position; sliding/extended/complex multiple-part instruments should be disassembled or sufficiently loosened to permit the sterilizing agent to come into contact with all parts of the instrument.
- Instrument should be left slightly open to allow for sterilant penetration, rings should be slightly separated.
- Tips of instruments should all be facing the same direction the use of tip protectors is often advised by the manufacturer.
- Always make sure that all parts of the instruments are present
- Items (bowl/basins/receivers) that could hold water during steam sterilization must be placed in a way that allows easy drainage.
- Examine hollow ware for cleanliness, place open side down; do not nest bowls and receivers (if included in set).
- Heavy instruments should be placed at the bottom of the tray as the weight of heavy instruments or retractors lying on top or over other instruments can cause the instruments at the bottom to bend and become misaligned.
- Placing the instruments in a single layer will provide more protection to the instruments.
- Examine and count linen (if included on set) as per tray list, place on top of tray to prevent them getting soaked during sterilisation. (This not a recommended practice)
- Place an in-pack chemical indicator into the densest most challenging part of the tray. This indicator will only change colour if the in pack sterilization parameters have been reached, i.e. depending on class of indicator used, steam, time and temperature.
  - **NB:** *These indicators act as a final confirmation to the scrub nurse that the set has been through the sterilization process.*
- Ensure that the tray checklist is dated and signed by the packer and checked.
- Place the completed checked trays into the packing of choice

#### **Expected outcome**

Sets are correctly assembled ready for packaging and sterilization



CSSD FORUM STANDARD OPERATING PROCEDURE

**SOP No. 32**

**Title**

**Prepare, Load and Operate Ultrasonic Cleaner**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of application**

Cleaning Area of Theatre/CSSD/Loaner Companies

**Staff involved**

Only staff trained in the use of the equipment

**Objective/Purpose**

To ensure that medical devices/equipment are correctly prepared and loaded for decontamination

**Relevant/Related Documents**

Procedure Manual

Standard Precautions

Equipment guidelines

**Equipment/Supplies**

Personal Protective Equipment

Ultrasonic Cleaner/Washer

Detergent

**Procedure**

- Maintain segregation of designated clean and other areas within the department
- Identify the correct process for the items to be decontaminated
- Staff working in this area will wear protective clothing at all times in compliance with the standard precautions dress. PPE is additional to the uniform code for your specific working environment and may include:
  - gloves
  - aprons, gowns, overalls (single-use, fluid- repellent, disposable)
  - masks
  - face and eye protection
  - footwear
- Apply standard precautions for infection control and other relevant health and safety measures
- Use and store all equipment chemicals and materials in accordance with manufacturer's instructions and organisational policies and procedures.
- Comply with manufacturers' and organisation specifications when using all appliances and processing of medical devices.
- Handle contaminated devices as little as possible.
- Equipment will be prepared for use as described in the Manufacturers Guidelines
- All handling and processing is to be undertaken in accordance with the manufacturers instructions





## CSSD FORUM STANDARD OPERATING PROCEDURE

- Note item manufacturers instructions if it is safe to process in the ultrasonic cleaner
- Highly contaminated instruments should always be pre-cleaned in the ultrasonic bath as otherwise they cannot be properly cleaned in the washer-disinfector.
- It is recommended that sensitive instruments that can only be cleaned manually should first be cleaned in the ultrasonic washer. (First check manufacturer's guidelines).
- It is also recommended that all trays with instruments should be put through the ultrasonic washer at least once a week in order to give them a microscopic clean.
- In the case of table top cleaners;
- Fill the tank with potable water (drinking quality) to the manufacturer's designated level.
- De-gas the water as recommended by the machine manufacturer.
- Add detergent, ensuring the manufacturer's recommendations are followed. It is advisable to use a suitable enzymatic detergent that is effective at low temperatures.
- If the tank has a heater, set the temperature control to be comparable with the detergent manufacturer's recommendations...
- Sort cannulated and solid devices. Avoid contaminating hands with soilage.
- Open hinged items
- Place the basket of instruments into the tank. Never put instruments directly onto the base of an ultrasonic washer. (if instruments are placed directly onto
- Make sure that instruments do not stick out of baskets as they may affect the washer operation
- Connect all cannulated instruments to the appropriate connector on the basket union if option is available
- Position the basket into the chamber according to manufacturer instructions
- Only prescribed automatic cleaning agents should be used, Enzymatic cleaners are recommended bearing in mind manufacturers instructions
- Check that connection is made with the machine union before closing the door.
- Select a program or set the timer control to the time specified by the machine manufacturer.
- After the cycle has been completed, remove the basket from the tank and rinse the items with clean, potable water – unless the machine has an automatic rinse stage, or the load is to be transferred directly into a washer/disinfector for further processing.
- Drain and dry the items using a non-linting cloth or mechanical drying system.
- If the ultrasonic cleaner does not automatically drain after use, the ultrasonic washer should be drained, cleaned, dried, covered and left dry and empty until
- Required for further use, as per the manufacturer's instructions. The frequency of water renewal depends very much on how often the machine is used and on the degree of contamination. Ultrasonic Baths with visible contamination should be renewed frequently, possibly several times each day. Otherwise, daily renewal is recommended.

### **Expected outcome**

Quality controlled safe, clean and functional medical devices ready for packing



CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT

**SOP No. 33**

**Title**

**Validating an Ultrasonic Cleaner**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of application**

Areas with Ultrasonic Cleaners

**Staff involved**

Only staff trained in the use of the equipment

**Objective/Purpose**

To ensure that the ultrasonic cleaner is working efficiently and is able to perform the assigned task.

**Relevant/Related Documents**

Procedure Manual  
Standard Precautions  
Equipment guidelines

**Equipment/Supplies**

Personal Protective Equipment

**Procedure**

There are two simple tests for checking the performance of your ultrasonic cleaner:

**Glass slide test**

- Wet the frosted portion of a glass slide with tap water and draw an "X" with a No. 2 pencil from corner to corner of the frosted area.
- Making sure that the tank is filled to the fill line; immerse the frosted end of the slide into fresh cleaning solution.
- Turn the Machine on.
- The lead "X" will begin to be removed almost immediately, and all lead should be removed within ten seconds.

**Aluminium foil test**

Use the prescribed roll of aluminium foil or cut three small pieces of aluminium foil about 10cm x 20cm each.

- Fold each piece over a rod or length of string which will allow the foil to be suspended in the tank.
- Making sure that the tank is filled to the fill line; immerse the foil strips into fresh cleaning solution.
- Suspend the first strip in the centre of the tank and the other two a couple of inches from each end of the tank.
- Make sure that the tank is filled to the fill line, and turn the machine on.



#### CSSD FORUM STANDARD OPERATING PROCEDURE

- Remove the foil and inspect: All three pieces of aluminium foil should be perforated and wrinkled to about the same degree.

#### **Chemical indicators**

- Place the vial with the cavitation indicators i.e. glass beads and a chemical, which initially is green into the basket.
- The cavitation triggers a chemical reaction in the test fluid, causing a clear colour change.
- When an effective cavitation is reached, the colour of the fluid in the vial changes from green to yellow. Advantage of this system is that it can be used together with the load to be cleaned.

#### **Expected Outcome**

The ultrasonic cleaner is working efficiently and is able to perform the assigned task.



CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT

SOP No. 34

**Title:**

**Low Temperature Sterilization  
(Hydrogen Peroxide Plasma / Vapourized Hydrogen Peroxide)**

**Review Date**

July 2019

**Prepared by**

**CSSD Forums of South Africa (CFSA)**

**Area of application**

Low Temperature Sterilizer Area

**Staff involved**

Trained personnel allocated to Low Temperature Sterilizing

**Objective/ Purpose**

To ensure that Low Temperature Sterilizer's are operated according to department policy.  
To ensure that all soiled returned equipment is sterilized according to an acceptable standard and ready to use.  
To ensure the work environment is safe for all employees.

**Safety Warning**

Always wear gloves recommended by manufacturer when handling Hydrogen Peroxide cassettes or cartridges, and when removing items from the sterilizer if the cycle has been aborted.

**Relevant/Related documents**

Procedure Manual  
Manufacturer's Instructions

**Equipment / Material**

- Sterilizer
- Cassettes / cartridges
- Tyvek
- Wrap recommended by manufacturer
- Cassette collection boxes
- Printer paper
- Instrument sterilization containers recommended by manufacturer
- PPE

**Procedure**

Items that can not be processed in a Hydrogen Peroxide Plasma / Vapourized Hydrogen Peroxide

- Any item that is not completely dry
- Items or materials that absorb liquids
- Items made from materials containing cellulose e.g., cotton, paper, cardboard, linens, gauze or items that contain wood pulp
- Consult manufacturer for a complete list of what can and can not be processed in sterilizer



## CSSD FORUM STANDARD OPERATING PROCEDURE

### Inserting and removing cassettes / cartridge

- Wear appropriate PPE as described by manufacturer
- Check item for damage
- Do not remove cassette from plastic wrapper if indicator strip is red (Sterrad) this indicates that the cassette might have been damaged
- Check expiry date

### Biological Monitoring

- Use manufacturer approved biological indicators
- Daily biological monitoring is recommended (as per hospital policy)
- Place biological monitor into a Tyvek pouch
- Place biological monitor in a load in the sterilizer
- Place the biological monitor in the sterilizer as per manufacturers recommendation (Sterrad= back of the chamber on the bottom shelf with the opening toward the back of the chamber)
- Process Biological indicator
- Incubate Biological indicator at temperature as recommended by manufacturer.

### Preparing Items for loading

- All items must be thoroughly cleaned and dried before packaging
- Use packaging and containers recommended by the manufacture
- Place chemical indicator in each packaged item

### Loading sterilizer

- Arrange items in such a way as to ensure sterilant will come into contact with all surfaces
- Do not allow any items to touch the walls or the door
- Do not stack containers
- Place items packed in Tyvek on their sides

### **Expected outcome**

Sterilizer is operated as per manufacturer's instructions  
All equipment is sterilized to an acceptable level.



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No. 35**

**Title**

**Decontamination and Management of Laryngoscopes**

**Review Date**

July 2019

**Prepared**

**CSSD Forums of South Africa (CFSA)**

**Purpose**

To ensure that all laryngoscopes are decontaminated and fit for purpose.

**Scope**

All laryngoscopes returned to CSSD.

**Area of Application**

CSSD

Wards

Theatre

**Staff Involved**

Only staff trained in decontamination of laryngoscopes

**Relevant/Related Documents:**

Procedure Manual

Standard Precautions

**Equipment**

- PPE
- Cleaning materials
- Disinfectant

**Procedure**

- When washing Instruments manually standard/universal precaution must be applied at all times.
- Only staff trained in decontamination should manually clean medical devices
- Identify the correct process for the items to be decontaminated following manufacturers instructions.
- Check laryngoscope for functionality.
- Any laryngoscope found to be non-functional should be taken out of service and replaced or repaired as soon as possible.
- All instruments should be cleaned and sterilised according to department policy.
- If the blade is disposable, dispose of it according to hospital policy
- At point of use, immediately after use, the laryngoscope blade should have been rinsed in clean tap water or wiped down to remove any residue.
- Before cleaning check that the bulb in the laryngoscope is working.
- Disconnect the blade from the handle.
- Prior to removal of light carrier, allow the lamp to cool.
- Prior to cleaning, remove any debris trapped between the carrier and the blade. Reassemble the light carrier and blade.



## CSSD FORUM STANDARD OPERATING PROCEDURE

- Check that the lamp is sufficiently tightened before submerging in water.
- NOTE: Submerging in water with lamp removed will result in damage to the electrical circuit.
- Unscrew bottom cap of handle and remove batteries.
- NOTE: Batteries will be damaged if submerged in water
- External surfaces should then be gently scrubbed with a soft brush, to provide a thorough cleaning. (using a medical grade detergent prepared as per the manufacturers instructions)
- Either clean manually or in an automated cleaner according to manufacturers instructions
- After cleaning, rinse blades thoroughly, and dry prior to disinfection/sterilization.
- Inspect physical condition for: Foreign Substances, Damage or cracks, broken, loose or wear

**WARNING:** ultrasonic cleaning is not recommended

- A minimum of High Level Disinfection is required.
- If recommended by manufacture blades may be steam autoclaved

**NOTE:** Autoclaving with lamp removed will result in damage to the electrical circuit.

- Standard battery handles are usually not compatible with steam autoclave sterilization
- Autoclaveable handles can often be identified by the term 'AUTOCLAVE' written on the handle. If they do not have the marking they ARE NOT autoclavable.

**NOTE: ALWAYS FOLLOW MANUFACTURERS GUIDELINES**

- Always wrap laryngoscope blades and handles unattached if autoclaving.

**NOTE:** Do not exceed temperature of 134°C

- Flash and Hot air sterilisation is not recommended
- If disinfecting refer to solution manufacturer's instructions for recommended exposure times and solution concentrations,

**NOTE:** Disinfecting with lamp removed will result in damage to the electrical circuit.

- Prior to immersion, ensure that the lamp is secure.
- Rinse thoroughly in sterile water.
- Dry with a non linting cloth

### Test Procedure

- **Once Disinfected/Autoclaved** (unwrap pack) replace appropriate size batteries (as per manufacturers instructions) into Laryngoscope handle and replace bottom cap. Stubby handle: insert battery pack with tab side down.
- Laryngoscope blades and handles should always be tested after cleaning/disinfection/sterilization and prior to use.
- To check, connect the laryngoscope blade to the handle and pull open to the "on" position. If the unit fails to light or flickers, check the lamp/ batteries.
- Be sure adequate supplies of spare lamps, batteries, and replacement parts are readily available.
- Be sure the lamp's glass envelope is clean and free of any fingerprints after assembly. If necessary, the glass may be cleaned with a soft cloth or cotton ball moistened in alcohol.
- Wrapping the reassembled laryngoscope should protect it from contamination until the item is to be used the.
- A re-sealable plastic bag or other impermeable wrap may be used as the covering because the laryngoscope is clean not sterile. Wrapping the blades in sterilization wrap or a sterilization peel pack is not recommended because this may lead the user to think that the blade is sterile.
- Contamination may result from a clean blade coming into contact with a contaminated laryngoscope handle.
- The item should be clearly labelled as being high-level disinfected and not sterile. Labelling should also contain some method to indicate the date when the high-level disinfection occurred and the person responsible for completing the process.

### Expected Outcome

Laryngoscope is clean and fit for purpose



CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT

**SOP No. 36**

**Title**

**Daily Heat Sealer Checks**

**Review Date**

July 2019

**Prepared**

**CSSD Forums of South Africa (CFSA)**

**Purpose**

To ensure accurate, safe use of heat sealer, and implement quality control

**Scope**

All areas with heat sealers

**Area of Application**

CSSD

Theatre TSSU

**Staff Involved**

Only staff trained in use of heat sealers

**Relevant/Related Documents**

Procedure Manual

Standard Precautions

**Equipment**

PPE

Heat sealer

See through Packaging

Scissors

**Procedure**

Apply a neat seal to a piece of see through packaging daily and check the following: (Use the maximum width reel in your facility)

Check that the heat sealer is set to the manufacturer's specifications i.e. the correct:

- Temperature
- Temperature 150 –200C as per manufacturers recommendations
- Uniform pressure - The heat sealer must give an adequate consistent pressure.
- A clean, uniform seal pattern
- Sealing dwell time as per manufacturers guidelines
  - Seal Integrity
  - No gaps in seal
  - No creasing or scorching
  - Uniform pattern
  - Seal strength
- The pouch should be such that when peeling it open, neither the paper nor the laminate will tear.





CSSD FORUM STANDARD OPERATING PROCEDURE

- It should open neatly along the seals.

Check if heat sealer's edge is in good condition

- The edges should be perfectly flush or parallel to the sealing fixture to allow uniform pressure to be exerted.
- The gasket material should be in good condition.

Complete the attached check list. File the check list for quality control purposes. If any problems are found please contact the supplier.

**Expected Outcome**

Adequately Sealed packages

**DAILY HEAT SEALER CHECKLIST**

**Date:** \_\_\_\_\_

Procedure	Yes	No
Temperature uniformity Temperature set between 150 –200°C		
Is the heat sealer sealing edge perfectly flush or parallel to the sealing fixture		
Seal Integrity No gaps in seal		
No creasing or Scorching		
Pressure Uniformity Is the pattern uniform		
Strength of Seal Pouch opens without tearing		

**Signature:** \_\_\_\_\_

**Sample attached Yes/No:** \_\_\_\_\_



**CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT**

**SOP No. 37**

**Decontamination and Disinfection of Babies Bottles**

**Review Date**

July 2019

**Prepared**

**CSSD Forums of South Africa (CFSA)**

**Purpose**

To ensure that all soiled/used babies milk bottles returned to the Milk Kitchen are cleaned to an acceptable standard.

To minimize pathogenic contamination

**Scope**

All bottles returned to the milk kitchen.

All new bottles prior to introduction for use.

**Area of Application**

Cleaning Area of the Milk Kitchen

**Staff Involved**

Only staff trained in decontamination process

**Relevant/Related Documents**

Procedure Manual

Standard Precautions

**Equipment**

- Personal Protective Equipment
- Washer/Disinfector Machine
- Doubler sink
- Detergent

**Procedure**

- When washing bottles standard/universal precaution must be applied at all times
- Only staff trained in decontamination should clean babies bottles
- Staff working in this area will wear protective clothing at all times in compliance with the standard precautions dress. PPE is additional to the uniform code for your specific working environment and may include:
  - a) Gloves
  - b) Aprons, gowns, overalls (single-use, fluid- repellent, disposable)
- Comply with manufacturers' and organisation specifications when using all appliances and processing of medical devices.
- Transfer all bottles to the work surface.
- Each bottle will be prepared for decontamination
- Remove the protective bottle cap
- Remove the teat from the bottle cap
- Prepare Sink and add detergent according to manufacturers guidelines
- Washer disinfectors will be prepared for use according to manufacturers guidelines
- Standardised washing and disinfecting processes should be used and validated.



#### CSSD FORUM STANDARD OPERATING PROCEDURE

- Choose the relevant washer rack
- Identify the correct process for the bottles to be decontaminated
- Place bottle in washer disinfectant, Be aware that teats may become lodged in drainage system
- Pack bottles ensuring that all surfaces can be reached by the spray jets
- Bottles must be packed upright
- Place teats and bottle caps in a covered basket
- Do not pack too densely
- Do not over-pack trays, note manufacturers maximum prescribed weight
- Position tray into the chamber according to manufacturer instructions
- Only prescribed automatic cleaning agents should be used
- A full-automated process should be used including pre rinsing, washing at 60°C minimum (if recommended by manufacturer), rinsing at 90°C if manufacturers instructions allow and drying.
- Ensure bottle dry in washer
- Place bottle into holder and wrap in sterile towel till needed
- Bottle must be used within 24hrs

#### **Expected outcome**

Quality controlled safe, clean bottles ready for use



CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT

SOP No. 38

**Title**

**Decontamination and Sterilization of reusable LMA's**

**Review date**

July 2014

**Prepared by**

CSSD Forums of South Africa

**Area of application**

Sterile Service Department

**Staff involved**

All personnel that are assigned or engaged in Sterile service operation.

**Objective / Purpose**

To ensure that all soiled LMA's are cleaned to an acceptable standard.

To ensure that all LMA's are sterile and ready for use

**Relevant / Related documents**

Occupational Health and Safety Act and Regulation 85 of 1993.

Standard Precaution Guidelines

Infection Control Policy.

**Equipment/Supplies**

PPE

Mild detergent or enzymatic cleaner in accordance with manufacturer's recommendations.

Small 12.5mm diameter soft bristle brush.

20ml syringe.

**Procedure**

- Wipe the LMA cuff and airway tube using a lint free cloth and gloved hands to remove any lubricant and any secretions.
- Wash the LMA in a prepared detergent and warm water solution (as per manufacturer's instructions).
- Detergents used must not contain skin or mucous membrane irritants.
- Do not use the following: disinfectants or chemical agents such as Gluteraldehyde,
- Ethylene Oxide, Phenol-based cleaners or iodine containing cleaners to clean or sterilise LMA's.
- These substances may be absorbed by the LMA airway materials, resulting in exposure of the patient to potentially severe tissue burns and possible deterioration of the LMA airway.
- Always adhere to manufacturers' instructions.
- *Do not expose the valve to any cleaning solution.*
- Before cleaning ensure that the balloon valve is closed so that water or cleaning solution does not enter the valve line.
- Inflate the cuff slightly to act as a seal during cleaning.
- Flush tube channel with warm water.
- Manual clean or clean in automated washer disinfectant (as per manufacturer's instructions).
- Using appropriate soft bristle LMA cleaning brush (12.5mm diameter), insert brush between middle aperture bars and proceed to clean the airway channel.



## CSSD FORUM STANDARD OPERATING PROCEDURE

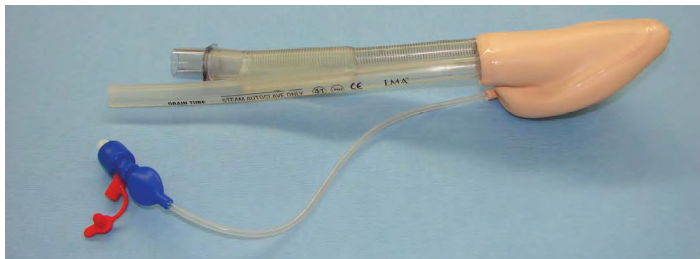
- Gently clean the side aperture bars with the cleaning brush tip. Be careful not to break or damage the aperture bars.
  - Gently insert the brush through the aperture bars into the airway tube taking care not to damage the bars of the mask.
  - *Clean the inside of the airway tube with a soft bristle brush, taking care not to damage the bars at the front of the mask.*
  - Rinse the LMA cuff and airway tube under running warm water to remove cleaning residues.
  - Remove excess water from the valve and dry using A Lint free cloth
  - Use an air gun to blow any moisture from channel/s following decontamination, and ensure there is no water in the valve tip.
  - Carefully inspect the LMA to ensure that all visible foreign matter is removed.
  - Ensure LMA is completely cleaned and that all lubricant and secretions are removed
  - Look through the air channel and/or suction channel to ensure no debris are present and that the channel is patent.
  - Flex the tube to no more than 180°.
  - If the tube kinks, the LMA is to be discarded.
  - Check to see that there is no damage from inadequate bite block protection following use.
- Steam autoclaving is the only recommended method of sterilisation for the LMA airway.**
- Deflate the cuff using a syringe (as per manufacturer's instructions) (deflation of the cuff may require a deflation tool since residual air can accumulate in the dorsal cuff)
  - The cuff should be fully deflated and dry before autoclaving
  - Autoclave according to manufacturers' guidelines usually at 134°C for 3-4 minutes (pre-vacuum and wrapped).

### Note

**Reusable LMA's have a limited use (e.g. 40 uses or a period of one (1) year, so a record must be kept each time the LMA is used)), Please read the manufacturers instruction manual and guidelines.**

### Expected Outcome

Quality controlled safe, clean and functional LMA's ready for use.





CSSD FORUM STANDARD OPERATING PROCEDURE  
STERILE SERVICE DEPARTMENT

**SOP No. 39**

**Title**

Wrapping Medical Devices ready for sterilisation

**Review Date**

July 2019

**Prepared by**

CSSD Forums of South Africa (CFSA)

**Area of application**

Packing Area

**Staff involved**

Personnel involved in packing

**Objective/ Purpose**

To ensure that all instrument sets are complete and safely packed before sterilization.

**Relevant/Related documents**

Procedure Manual

Instrument Checklist

Manufacturer's Instructions

**Equipment / Material**

All instrument sets for use in theatres and ward procedure packs.

Checklist

Packing materials

In pack indicators

Labels/ Labelling Gun

Tracking devices

• **Procedure**

- Staff working in this area will wear protective clothing at all times in compliance with the standard precautions dress code
- Make sure that all work surfaces are clean. Clean work surfaces according to department procedure.
- Trays should be perforated to allow penetration of the sterilizing agent and efficient drying.
- The person checking should indicate and sign that the quantities are correct and that nothing is missing.
- Instruments must be laid out according to the order on the check list.
- The weight of packs must be taken into consideration when assembling trays.
- Overloaded and heavy trays/sets may some cases remain wet.
- Preferably place the list on top of the tray folded inner wrap, between the two layers?
- Close the inner wrap by taking the wrap on the side nearest to you and folding it towards the middle of the pack.
- Fold the edge back towards you, according to the size of the pack, creating a cuff.
- Repeat this procedure with the opposite side.
- Paper must be large enough to ensure that both sides meet and overlap in the centre.



## CSSD FORUM STANDARD OPERATING PROCEDURE

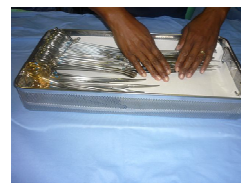
- Fold both ends of the wrap to produce a V shape.
- Fold both V's towards the centre.
- Both V's must meet in the centre and overlap.
- Repeat the folding with a second piece of wrap.
- Seal the pack with 2 pieces of masking tape +- 10cm and a small piece of autoclave tape +- 5cm.
- Label the pack either using a labelling gun or a strip of masking tape or whatever tracking system is being used, with the pack details written on it. (according to hospital policy) Do not write directly on the wrapping.
- If the pack is to be transported to the wards or clinics it should be placed into the appropriate sized aseptic bag to protect it.
- The aseptic bag must be 'marked' prior to inserting the pack. Do not write directly on the bag; write on a strip of masking tape.
- Place the completed set on the autoclave trolley ready for autoclaving.



**1. Select the appropriate tray**



**2. Place tray liner in the bottom of the tray**



**3. Inspect and pack instruments according to tray layout**



**4. Complete packing instrument set**



**5. Check the type and quantity of instruments against a check list**

### Expected outcome

Sets are correctly wrapped and ready for sterilization