

**WESTERN CAPE 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 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. Packing of Loaner Sets
- 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. Monitoring
- SOP No 20. Monitoring autoclaves
- SOP No 21. Traceability & Recall Procedures
- SOP No 22. Validation of Equipment
- SOP No 23. Monitoring ETO Steriliser
- 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. Quality Management
- SOP No 29. Decontamination of Textiles/Linen for sterilization
- SOP No 30. Inspection, Repair and Replacement of instruments
- SOP No. 31 Checking, Assembling and Packing (Wrapping) an Instrument Set
- SOP No. 32 Prepare, Load and Operate Ultrasonic Cleaner
- SOP No. 33 Low Temperature Sterilization (Hydrogen Peroxide Plasma /  
Vapourized Hydrogen Peroxide)
- SOP No. 34 Decontamination and Management of Laryngoscopes
- SOP No. 35 Daily Heat Sealer Checks

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

### SOP No. 1

#### Title

Safety Awareness in Sterile Service Department

#### Date of preparation

July 2008

#### Review date (Usually one year unless a change occur)

July 2009

#### Prepared by

Cape Town CSSD Forum

#### 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 so they can easily find the information needed.
- All employees must wear 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 to S. O. P. no:
- 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-obstructive entrances and exits.
- Visitors are prohibited from entering CPD spaces. If visitors must enter restricted space, appropriate attire is required and they will be escorted by CPD staff.

##### Patient Safety

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

## **WESTERN CAPE 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 by working heat resistant gloves.
- Employees must use proper body mechanics when carrying or handling heavy items.
- Use care and caution when handling sharps.
- Maintain “line of light “when reading into any container.
- In 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 used to contaminated items, always wear the proper PPE for the task.

#### **Note**

- Use of electrical extension cards are prohibited in sterile service areas.
- Use of any type of forms prohibited in work spaces.
- All employees must be aware of fire and safety regulations.
- Refer to MSDS before handling chemical specific to the area of work.
- If spills occur, refer to policy management of body fluids spillages or consult safety representative.

#### **Expected Outcome**

Reduced medical legal hazards  
Safe working environment

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

**SOP No. 2**

### **Title**

**Department Cleaning Procedure**

### **Date of preparation**

1 August 2009

### **Review date** (Usually 1 year later unless a change occurs)

1 August 2010

### **Prepared by**

Cape Town CSSD Forum

### **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 facility.

### **Relevant/Related Documents**

Procedure Manual

Standard Precautions

### **Equipment/Supplies**

All surfaces and equipment in CSSD.

All new equipment prior to introduction for use.

### **Procedure**

- The CSSD will be cleaned in accordance with the cleaning schedule
- All cleaning procedures and cleaning agents in the department will be in line with Departmental recommendations
- 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
- Cleaning equipment will be stored in a designated area for that area's use only.
- Cleaning work will be undertaken by Staff in that area
- CSSD staff are responsible for making sure that all surfaces are cleaned in accordance with the room cleaning schedule
- Only those cleaning agents purchased for use in the preparation room will be used (alcohol spray, Cloths-non linting, Stainless steel spray)
- Cleaning will be undertaken between times to be agreed that will enable any aerosol particles to settle prior to commencement of work.

### **Expected outcome**

Quality controlled safe, clean and functional department.

**WESTERN CAPE CSSD FORUM**  
**STANDARD OPERATING PROCEDURE**

**STERILE SERVICES DEPARTMENT CLEANING SCHEDULE**

**List of Inspection Points**

Area	Yes
1. Wet mops floors (vacuum first if necessary).	
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, 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 frontage of Autoclaves with Stainless Steel cleaner.	
11. Cream clean sinks, taps and surrounds. Remove debris from waste outlet.	
12. Damp wipe pipe works, doors, doorframes and door handles.	
13. Polish washer's exterior with stainless steel cleaner.	

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

### SOP No. 3

**Title**

Departmental Dress Code

**Date of preparation**

1 August 2009

**Review date** (Usually 1 year later unless a change occurs)

1 August 2010

**Prepared by**

Cape Town CSSD Forum

**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**

N/A

**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
- 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

# WESTERN CAPE CSSD FORUM

## STANDARD OPERATING PROCEDURE

### STERILE SERVICE DEPARTMENT

#### SOP No. 4

**Title**

Collection of soiled/contaminated equipment

**Date of preparation**

20 June 2008

**Review date**

20 June 2009

**Prepared by**

Cape Town CSSD Forum

**Area of application**

Theatres/wards/clinics

**Staff involved**

Trained SSD personnel and Nursing

**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

OHSACT , 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 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 to hospital.
- 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 Hospital Policy.
- Collect used items in puncture resistant containers; do not overload.
- Do not 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 cleaning area.
- Clean and disinfect collection trolleys and bins and store appropriately.
- Remove gloves and wash hands according to Policy.

## WESTERN CAPE 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

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

### SOP No. 5

#### Title

**Manual Decontamination of Medical Devices**

#### Date of preparation

1 August 2009

#### Review date (Usually 1 year later unless a change occurs)

1 August 2010

#### Prepared by

Cape Town CSSD Forum

#### 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

Cleaning Area of Theatre/CSSD/Loaner Companies

#### Staff Involved

Only staff trained in decontamination process

#### Relevant/Related Documents

Procedure Manual

Standard Precautions

#### Equipment

- Mid–arm to elbow gloves, Full plastic apron, mask, eye protection, hair/head protection
- Double sinks
- Hot and Cold water
- Elbow taps
- Selection of cleaning Brushes
- Detergent
- Soap and paper towel dispensers
- Non-linting Drying clothes

#### 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
- 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

## WESTERN CAPE CSSD FORUM

### STANDARD OPERATING PROCEDURE

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 using all appliances and processing of medical devices.
- Handle contaminated devices as little as possible.
- All equipment is transferred from the trolley to the work surface.
- Each instrument will be prepared for decontamination
- Remove the protective outer wraps
- 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.
- 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).
- Follow the Hospital Policy Incidents
- Sort cannulated and solid devices.
- 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 being used should be hand hot. Or warm. And have the correct chemical mixture.
- Use enzymatic cleaners / detergents according to manufacturer's instructions.
- Use the correct detergent. Follow manufacturer's instructions.
- The dedicated sink that is used only for washing instruments, not for hand washing or anything else, should have water measurement marks, to assist with the detergent concentration.
- If the water, is visibly stained at any stage it must be replaced
- Handle contaminated devices as little as possible.
- 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.
- Separate baskets, container and instruments.
- Open all instruments fully. Open hinged items.
- All handling and processing of devices is to be undertaken 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.
- Check degree of soil, sort and discard any disposable material.
- Separate cannulated and solid devices.

## **WESTERN CAPE CSSD FORUM**

### **STANDARD OPERATING PROCEDURE**

- Flush all cannulated instruments with the pressure jet gun / syringe before and after brushing
- Pressure sprays can be used according to manufacturer's guidelines.
- 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

#### **Expected outcome**

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

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

### SOP No. 6

#### Title

Prepare, Load and Operate Decontamination Equipment

#### Date of preparation

1 July 2009

#### Review date (Usually 1 year later unless a change occurs)

1 July 2010

#### Prepared by

Cape Town CSSD Forum

#### 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

Procedure Manual

Standard Precautions

Equipment guidelines

#### Equipment/Supplies

Personal Protective Equipment

Washing Machine

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
- 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 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.

## WESTERN CAPE CSSD FORUM

### STANDARD OPERATING PROCEDURE

- 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.
- Handle contaminated devices as little as possible.
- Separate baskets and containers
- Washer disinfectors will be prepared for use as described in the Working Instructions Manual.
- All equipment is transferred from the trolley to the work surface.
- Each instrument will be prepared for decontamination
- Remove the protective outer wraps
- 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.
- 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).
- Follow the Hospital Policy Incidents
- Sort cannulated and solid devices.
- Open hinged medical devices
- Open all instruments fully and place caps etc into the nik nak basket
- Be aware that small items may become lodged in drainage system
- Place instruments into a wash basket after the manual cleaning aspects have been fully and thoroughly carried out and check is made to ensure all items and parts are present.
- 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.
- Wash Baskets must not be overloaded
- Layer heavy items at the bottom making sure that all surfaces can be reached by the spray jets
- Do not pack too densely
- Do not over-pack trays, note manufacturers maximum prescribed weight
- Make sure that instruments do not stick out of baskets as they may affect the washer operation
- Flush all cannulated instruments with the pressure jet gun / syringe before and after brushing. prior to placing in the tray
- Choose the relevant washer rack
- Connect all tubes to the appropriate connector on the basket union if option is available
- Position tray into the chamber according to manufacturer instructions
- Enzymatic cleaners are recommended bearing in mind manufacturers instructions
- Only prescribed automatic cleaning agents should be used
- Check that connection is made with the machine union before closing the door.
- A full-automated process should be used including pre rinsing, washing at 60°C minimum (if recommended by manufacturer), rinsing and drying.
- Chamber self-disinfection should be carried out each week as per manufacturer's recommendations and documented.
- 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.

## **WESTERN CAPE CSSD FORUM**

### **STANDARD OPERATING PROCEDURE**

- 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 disinfectors (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
- Identify the correct process for the medical devices to be decontaminated
- Identify items requiring special attention and handle in accordance with documented manufacturers instructions
- 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
- 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
- Follow manufacturer's instructions when working with detergents
- Where more than one chemical is used in the automated washer disinfectant, the tubing will be marked to indicate which chemical it carries. The containers should not be able to be incorrectly connected
- Follow manufacturer's instructions and departmental policies and procedures for the use of any equipment used for cleaning purposes.
- 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
- 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
- Dismantle items to be processed where this is required and appropriate
- Open all instruments fully and place caps etc into the nik nak basket ensure all items and parts are present. All handling and processing is to be undertaken in accordance with the manufacturers instructions
- Flush all cannulated instruments with the pressure jet gun / syringe before and after brushing, prior to placing in the washer basket.
- 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
- Check that connection is made with the machine union before closing the door.
- Manually clean items that are too large or unsuitable for mechanical washer/disinfectant in accordance with the protocol displayed, making use of the drying cabinet where appropriate
- Chamber self-disinfection should be carried out each week 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.

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

### SOP No. 7

#### Title

Decontamination and Inspection of Loaner Medical Devices

#### Date of preparation

1 November 2009

#### Review date (Usually 1 year later unless a change occurs)

1 November 2010

#### Prepared by

Cape Town CSSD Forum

#### Area of application

Cleaning Area of Theatre/CSSD/Loaner Companies

#### Staff involved

Only staff trained in decontamination process

#### Objective/Purpose

To ensure that all loaner sets are decontaminated, functional and ready for packaging using quality safety controls

#### Relevant/Related Documents

Procedure Manual

Standard Precautions

#### Equipment/Supplies

Personal Protective Equipment

Automated Machines – washing/Ultrasonic

Double Sinks

Brushes

Detergent

#### Procedure

- Standard safety precautions must be adhered to when working with medical devices that may be contaminated with secretions from patients
- Staff working in this area will wear protective clothing at all times in compliance with the standard precautions dress code
- CSSD personnel must follow infection control principles when handling contaminated devices, by donning personal protective equipment (PPE) including gloves and gowns that provide adequate barrier properties.
- Staff working in the cleaning area must be provided with water resistant gloves and plastic aprons or water resistant gowns for protection. Hand washing facilities, including a hygienic sink, soap dispensers and paper towels, must be provided in the soiled-linen processing facility.
- Handle contaminated devices as little as possible.
- Separate baskets and containers
- Remove reusable filters from rigid container to wash
- When receiving contaminated trays and check for soil.
- Sort and discard any disposable material. Avoid contaminating hands with soilage.
- Sort cannulated and solid devices.
- Cannulated devices can be cleaned in an ultrasonic cleaner or using brushes/high pressure sprays, according to manufacturers guidelines

## **WESTERN CAPE CSSD FORUM**

### **STANDARD OPERATING PROCEDURE**

- Open hinged medical devices
- If using an automated process layer heavy items at the bottom.
- 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.
- Remove and replace single use filters in rigid containers
- Check rigid container for dents
- Check gasket in rigid containers for tears and wear
- 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.
- A signed cleaning declaration stating the following should be placed on the outside of the transport container together with the signed Checklist
  1. That the Cleaning SOP was followed
  2. Date and Time
  3. Name of packer that did the inspection
  4. Hospital/Trade
  5. Clean items should be stored and transported in such a manner that cross contamination is avoided.

#### **Expected outcome**

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

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

### SOP No. 8

**Title**

Cleaning and maintenance of Rigid Containers

**Date of preparation**

1 November 2009

**Review date**

1 November 2010

**Prepared by**

Cape Town CSSD Forum

**Area of application**

Packing 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 used follow manufacturers instructions
- 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 lid seals

## **WESTERN CAPE 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

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

### SOP No. 9

#### Title

Missing Instruments / Items

#### Date of preparation

1 August 2009

#### Review date (Usually 1 year later unless a change occurs)

1 August 2010

#### Prepared by

Cape Town CSSD Forum

#### 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

All instruments and equipment returned to CSSD.

All new equipment prior to introduction for use.

All damaged equipment prior to sending for repair.

#### Procedure

- When wash or preparation room staff identify a missing instrument, or part of an instrument 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

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

**SOP No. 10**

### **Title**

**Control of Packing Area**

### **Date of preparation**

1 August 2009

### **Review date** (Usually 1 year later unless a change occurs)

1 August 2010

### **Prepared by**

Cape Town CSSD Forum

### **Area of Application**

Sterile Storage Area

### **Staff Involved**

All

### **Objective/Purpose**

To ensure everybody entering the preparation area is correctly dressed and conform 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

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

**SOP No. 11**

**Title**

**Packing Area Operation**

**Date of preparation**

1 November 2009

**Review date** (Usually 1 year later unless a change occurs)

1 November 2010

**Prepared by**

Cape Town CSSD Forum

**Area of application**

All wash, decontamination process, packaging, sterilisation, storage and dispatch processes

**Staff involved**

Only staff trained in CSSD/Theatre

**Objective/Purpose**

To describe the operation and procedure controls in the Preparation Room

**Relevant/Related Documents**

Quality Manual

Working Instructions Manual

Reject Form

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 processed items are received into the preparation room
- 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

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

### SOP No. 12

#### Title

Packing of Loaner Sets

#### Date of preparation

8 April 2009

#### Review date (Usually 1 year later unless a change occurs)

8 April 2010

#### Prepared by

Cape Town CSSD Forum

#### Area of application

Cleaning Area of Theatre/CSSD/Loaner Companies

#### Staff involved

Only staff trained in decontamination process

#### Objective/Purpose

To ensure that all loaner sets are correctly packed and ready for sterilization

#### Relevant/Related Documents

Procedure Manual

Standard Precautions

#### Equipment/Supplies

Packing materials

#### Procedure

- Staff working in this area will wear protective clothing at all times in compliance with the standard precautions dress code
- Loan set transport containers must be received sealed with a tamper proof seal /unopened in the packing area.
- A signed cleaning declaration stating the following must be on the outside of the transport container together with the signed Checklist.
  - That the Cleaning SOP was followed
  - 1. Date and Time
  - 2. Name of packer that did the inspection
  - 3. Hospital/Trade
- The person receiving the container must sign that the container was sealed and that a signed instrument checklist was present when received
- Wipe the transport container down before it is taken into the packing area.
- Unseal the container and remove the tray
- Wrap according to departmental policy

#### Expected outcome

Loan sets are correctly packed, sealed and ready for sterilization

# WESTERN CAPE CSSD FORUM

## STANDARD OPERATING PROCEDURE

**SOP No. 13**

### **Title**

**Cleaning of Sterilizers (Autoclaves)**

### **Date of preparation**

26 March 2009

### **Review date** (Usually 1 year later unless a change occurs)

26 March 2010

### **Prepared by**

Cape Town CSSD Forum

### **Area of application**

Autoclaving area

### **Staff involved**

Personnel involved in sterilization

### **Objective/ Purpose**

To maintain the 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
- Remove the drain screen and clean out any debris that may be trapped.
- Wipe outside stainless steel paneling with lint-free cloth.
- Daily damp dust loading trolleys carriages, racks, baskets or trays that hold items in the sterilizer.
- The autoclave must be turned off and allowed to cool
- Thoroughly clean the entire inside surface including the walls, rear panel, floor and inside the door, according to manufacturer's recommendations
- A non – abrasive cleaning product be used to clean stubborn stains or marks on stainless steel.
- Rinse thoroughly with tap water or wipe with clean lint-free cloth moistened with tap water.

### **Expected Outcome**

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

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

### SOP No. 14

#### Title

Steam Sterilization Procedure

#### Date of preparation

26 March 2009

#### Review date (Usually 1 year later unless a change occurs)

26 March 2010

#### Prepared by

Cape Town CSSD Forum

#### Area of application

Autoclave area in Sterile store/ Specialized area in theatre

#### Staff involved

Only trained personnel allocated to area and engineering staff

#### Objective/ Purpose

To ensure that all steam sterilizers are operated according departmental policy, and procedures.  
To ensure that all soiled returned equipment is sterilized to an acceptable standard and ready to 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 steam sterilizers

- For sterilizers with recording chart, replace chart,
- Identifying sterilizer, date and initial in place provided
- Check to ensure printer, recorder is working properly
- Remove drain plug from bottom of the chamber and remove lint and sediment from strainer.
- Replace drain plug in bottom of chamber.
- The first cycle will be a "warm up" cycle.
- Prepare Bowie & Dick test in a warm empty chamber on a pre-vacuum cycle, ( first or second of the day depend on whether the sterilizer was shut )
- Complete test and record the Bowie & Dick according to procedure No:
- Run a daily Biological test in the first load of the day as well as any loading containing implants.
- Complete test and record biological indicator ( BI ) Test according to procedure no:

# **WESTERN CAPE CSSD FORUM**

## **STANDARD OPERATING PROCEDURE**

### **Operational Guidelines**

- Record contents of load checklist no: information must be detailed
- Enough to allow for tracking and recall if necessary.
- Place load in sterilizer according to loading instructions.
- Close, secure lock door.
- Choose cycle and run load.
- On completion of cycle, cycle complete indicator will appear, visually check the graph / printer to determine that all parameters have been met.
- In the event of a cycle failure / cycle aborted, discard the load.
- The person responsible for checking the load should sign their name on the printout before opening the sterilizer door.
- Before opening the door, thoroughly wash the 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.
- Inspect packages to ensure integrity and external indicators have changed.
- Record results in log book and file for each autoclave according to Procedure no:
- Maintain in Archives for seven years in accordance with Hospital Policy and Procedure.

### **Expected Outcome**

Steam autoclaves are operated according to departmental policy and procedures.  
All equipment is sterilized to an acceptable standard.

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

### SOP No. 15

#### Title

Ethylene Oxide Sterilisation

#### Date of preparation

1 August 2009

#### Review date (Usually one year unless a change occur)

1 August 2010

#### Prepared by

Cape Town CSSD Forum

#### Area of application

ETO area

#### Staff involved

Only trained personnel allocated to area and engineering staff.

#### Objective/ Purpose

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

To ensure that all soiled returned equipment is sterilized to an acceptable standard and ready to 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

#### 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
- Identifying sterilizer, date and initial on load control slip
- Check to ensure printer is working where applicable

## WESTERN CAPE CSSD FORUM

### STANDARD OPERATING PROCEDURE

- 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 EO 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
- 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 Chlorohydrine (Possible carcinogen)
- Material compatibility with EO 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
- Do not use plastic coated baskets unless designed and validated for ETO sterilization and aeration
- Label Package according to policy

## WESTERN CAPE CSSD FORUM

### STANDARD OPERATING PROCEDURE

- 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

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

**SOP No. 16**

### **Title**

**Loading and unloading items from the autoclave**

### **Date of preparation**

1 November 2009

### **Review date**

1 November 2010

### **Prepared by**

Cape Town CSSD Forum

### **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

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

**SOP No. 17**

**Title**

Sterile Pack Storage

**Date of preparation**

1 August 2009

**Review date** (Usually 1 year later unless a change occurs)

1 August 2010

**Prepared by**

Cape Town CSSD Forum

**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**

N/A

**Procedure**

- This area will be kept clean and tidy at all times
- The autoclave operator will ensure that stock is rotated and will monitor stock levels
- Any member of staff may issue out packs to customers, provided that **ALL** the checks have been carried out by the person releasing the goods

**Shelf life internal**

- All finished products manufactured by CSSD will have a shelf life of 1-3months, depending on packaging, handling and storage conditions.
- Commercially produced sterile packs will have a shelf life as described by the manufacturer
- Storage conditions will be such that product integrity is not compromised by moisture or any other means which breach the wrapping materials

**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.**

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

**SOP No. 18**

### **Title**

**The Delivery and Distribution of Processed Items**

### **Date of preparation**

1 November 2009

### **Review date** (Usually 1 year later unless a change occurs)

1 November 2010

### **Prepared by**

Cape Town CSSD Forum

### **Area of application**

All wash, decontamination process, packaging, sterilisation, storage and dispatch processes

### **Staff involved**

Only staff trained in CSSD/Theatre

### **Objective/Purpose**

To ensure customers receive re-processed items in a safe condition

### **Relevant/Related Documents**

Quality Manual

Working Instructions Manual

Dispatch Log

Tray lists

### **Equipment/Supplies**

Clean Trolleys

### **Procedure**

- All items will be checked for sterility before they are released
- All damage items are returned to the decontamination area
- All items issued will be recorded so that a tracking system is effected
- Items will be placed onto a clean trolley that can be covered
- Items will not be stacked
- Trolleys will not be overloaded
- Soiled items will NOT be loaded onto the same trolley
- Loaded trolleys will not be left to stand

### **Expected Outcome**

Customers receive re-processed items in a safe condition

**WESTERN CAPE CSSD FORUM**  
**STANDARD OPERATING PROCEDURE**

**STERILE SERVICE DEPARTMENT**

**SOP No. 19**

**Title**

**Monitoring**

**Date of preparation**

1 August 2009

**Review date**

1 August 2010

**Prepared by**

Cape Town CSSD Forum

**Area of application**

Any area where items are reprocessed

**Staff involved**

All SSD, Clinic and Theatre Personnel

**Objective/ Purpose**

To ensure that the SSD provides a quality service

**Relevant / Related Documents**

Manufacturer Guidelines

Sterilization policy and process

**Equipment/Supplies:**

N/A

**WESTERN CAPE 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 the washers/automatic control test, check spray arms and jets</li> <li>2. Check Detergents</li> <li>3. Sign the daily washer log sheet/ checklist</li> <li>4. All instrument sets to be checked against packing slip to identify missing items</li> <li>5. Soil Tests according to policy</li> </ol>
<b>Packing Area</b>	<ol style="list-style-type: none"> <li>1. All instruments to be visually checked for cleanliness. Any rejected items are to be dealt with in accordance with hospital policy</li> <li>2. NB Signing a check sheet indicates that this activity has been undertaken by the signatory</li> <li>3. Check that all instrument sets have a packing list enclosed and are packed correctly</li> <li>4. Check that all trays have a chemical in-pack indicator</li> <li>5. Check the function of heat sealers daily</li> </ol>
<b>Autoclave Area</b>	<ol style="list-style-type: none"> <li>1. Inspect the porous load autoclaves, sign daily test sheet in log book</li> <li>2. Check ETO sterilisers, sign daily check sheets</li> <li>3. Perform daily Vacuum Tests on all steam autoclaves (BD)</li> <li>4. Perform daily Biological Tests on all autoclaves</li> <li>5. Check that all packs have external chemical indicators before loading into a autoclave</li> <li>6. Check the TST indicator strip to ensure parameters have been met. Before load is released to store room</li> <li>7. Check that all packs removed from the autoclave have a clear indication of a positive colour change on the indicator used</li> <li>8. Check the autoclave printout for a pass and sign the printout</li> <li>9. Complete log sheets</li> <li>10. Check that all items removed from the autoclave are intact, dry and undamaged.</li> <li>11. All items that have residual moisture, tears or from a failed cycle are to be dealt with in accordance with policy</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. Before issuing out, check all produced items to ensure that the expiry date has not been exceeded</li> </ol>

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

**SOP No: 20**

**Title**

**Monitoring Steam Autoclaves**

**Date of preparation**

1 November 2009

**Review date**

1 November 2010

**Prepared by**

Cape Town CSSD Forum

**Area of application**

Autoclave Area

**Staff involved**

Trained CSSD Staff

**Objective/ Purpose**

To monitor that all steam autoclaves are functioning

**Relevant / Related Documents**

Manufacturer's information  
Sterilization policy and process  
Quality Manual

**Equipment/Supplies**

Autoclave  
Monitoring Supplies

**Procedure**

**7 Physical Monitors**

- Measures that autoclave is functioning effectively
- Monitoring includes all autoclave 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

**Bowie Dick Test (BD)**

- 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 storage, handling, use
- 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 colour change
- The Bowie Dick manufacturer must be consulted for recommendations regarding how to use their specific product
- Test cards and results must be recorded and stored according to Hospital policy

# WESTERN CAPE CSSD FORUM

## STANDARD OPERATING PROCEDURE

### Test Results of Bowie Dick

Complete uniform colour change - PASS

- Sterilization process was effective since it indicates no air was present

Incomplete colour change - FAIL

- Indicates air was present and sterilization was not achieved
- Repeat the test
- If results still show a FAIL do not use autoclave

### 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
- 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.

### Test Results of External Chemical Indicators

Colour change according to the manufacturer's reference – Pass

- Medical Device can be moved to the Sterile Storage Area for use

Colour change not according to the manufacturer's reference – Fail

- Medical Device should be reprocessed

### Internal Indicators

- Placed inside the pack
- Measure if sterilizing parameters have been met inside the pack
- Place an indicator in the densest part of each pack
- This is a patient record and must be kept

### Test Results of Internal Chemical Indicators

Colour change even and according to the manufacturer's reference – Pass

- Medical Device can be used

Colour 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

### Biological Indicators (BI)

- 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
- BI is placed into the center of a **FULL** loadThe BI manufacturer **must be consulted** for recommendations regarding how to use their specific product

### Incubation

- Follow BI manufacturer's instructions for activation and incubation
- 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.

## **WESTERN CAPE CSSD FORUM**

### **STANDARD OPERATING PROCEDURE**

- Results must be recorded and stored according to Hospital policy
- Do not release products until the BI has been read and is positive

#### **Test Results of Biological Tests**

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 autoclaved should not be released until the BI results are known

#### **Load Check**

- This indicates to CSSD staff that the sterilization parameters have been met in the load and that it can be released
- Load Check devices are designed to act as a challenge to the steam penetration capability of the autoclave and are made up of a barrier system, inside of which is a chemical 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
- The Load Check is placed at the centre of every load to be sterilized
- Test results must be recorded and stored according to hospital policy

#### **Test Results of Load Check**

Complete uniform colour change - Pass

- Sterilization process was effective and autoclave load can be released  
Incomplete colour change – Fail
- 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

#### **Recall Procedures**

- Must be written and followed in the event of a fail
- Follow recall policy for issuing the recall order
- Designates the person(s) authorized to issue the recall order
- Recall order must be written and followed
- Write a recall report

#### **Expected Outcome**

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

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

**SOP No. 21**

### **Title**

**Traceability & Recall Procedures**

### **Date of preparation**

1 August 2009

### **Review date**

1 August 2010

### **Prepared by**

Cape Town CSSD Forum

### **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**

***Trays will be recalled in the event of failed quality management tests i.e. Biological***

### **Traceability**

- Traceability can only be achieved if the trays are recorded.
- The record of all trays that have been decontaminated will contain details of batch number, date, and washer cycle numbers.
- When trays are unloaded after processing, a record is kept of the batch number in the relevant washer log.
- Traceability of batches can therefore be achieved by referral to records.

### **Recall**

- A recall is authorised by the Senior CSSD Staff
- Affected departments will be advised verbally, with confirmation advisory notices in writing, that trays from a particular batch are suspect and should not be used.
- 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
  - Departments are requested to check their stock held in theatre for any trays from the suspect batch.

## **WESTERN CAPE CSSD FORUM**

### **STANDARD OPERATING PROCEDURE**

- 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 product will be labelled '**IN QUARANTINE**' whilst in transit
- Returned trays will be reprocessed as if they had been used and returned for reprocessing.
- The cause of the recall will 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

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

**SOP No. 22**

**Title**

**Validation of Equipment**

**Date of preparation**

1 August 2009

**Review date**

1 August 2010

**Prepared by**

Cape Town CSSD Forum

**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

**Equipment/Supplies**

N/A

**Procedure**

- All orders for new CSSD as appropriate and safe to use
- Copies of any relevant documentation relating to the product 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
- This approval will be in writing and signed before use. This certificate is to be maintained with the log book for the equipment
- Equipment will only be used after the necessary staff training
- No new or replacement equipment will be used without the appropriate approval and training

**Expected Outcome**

Quality and safety is maintained

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

**SOP No. 23**

**Title**

**Monitoring ETO Sterilisation**

**Date of preparation**

1 August 2009

**Review date**

1 August 2010

**Prepared by**

Cape Town CSSD Forum

**Area of application**

ETO area

**Staff involved**

All SSD and Theatre Personnel

**Objective/ Purpose**

To ensure that the SSD provides a quality service

**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.

# WESTERN CAPE 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 **Aeration of Test**
- 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, **EO (*Bacillus atrophaeus*) is incubated at 37° C for 48 hours. Steam (*Goebacillus 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 EO sterilized must not be released until the BI results are known

### Recall Procedures

- Must be written
- Collaborate with Infection Control and Risk Management committees
- Follow recall policy for issuing the recall order
- Designates the person(s) authorized to issue the recall order
- Recall order must be written and followed
- Write a recall report

### Environmental Monitors

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

## **WESTERN CAPE CSSD FORUM**

### **STANDARD OPERATING PROCEDURE**

#### **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
- Check with state and local agencies for how long sterilization records must be kept.

#### **Expected Outcome**

The ETO machine and loads are validated

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

**SOP No. 24**

**Title**

**Malfunction of Ethylene Oxide Steriliser**

**Date of preparation**

1 August 2009

**Review date**

1 August 2010

**Prepared by**

Cape Town CSSD Forum

**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 operating 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 then repackaged 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

**WESTERN CAPE 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

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

**SOP No. 25**

### **Title**

**Planned Maintenance Schedule of Equipment**

### **Date of preparation**

1 August 2009

### **Review date** (Usually 1 year later unless a change occurs)

1 August 2010

### **Prepared by**

Cape Town CSSD Forum

### **Area of Application**

Sterile Service Department

### **Staff Involved**

Senior Staff

Maintenance Department

### **Objective/Purpose**

To ensure all plant and equipment is checked and maintained according to manufacturers guidelines

### **Relevant/Related Documents**

Quality manual

Working Instructions Manual

Planned Preventative Maintenance Schedules

Machine Log

### **Equipment/Supplies**

All equipment listed

### **Procedure**

- Equipment to be checked under this procedure is listed in the Machinery Log.
- The schedule of checks on plant and equipment is documented.
- The work to be carried out at each check is documented.
- 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 dockets are completed by the maintenance person responsible and a copy issued to the SSD manager for filing in the appropriate log after the service schedule has been updated

### **Expected Outcome**

All equipment is checked on a regular planned basis

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

**SOP No. 26**

### **Title**

**Action for Breakdown of Equipment**

### **Date of preparation**

1 August 2009

### **Review date** (Usually 1 year later unless a change occurs)

1 August 2010

### **Prepared by**

Cape Town CSSD Forum

### **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

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

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

**SOP No. 27**

**Title**

**Sterile Packaging**

**Date of preparation**

1 November 2009

**Review date**

1 November 2010

**Prepared by**

Cape Town CSSD Forum

**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**

Instruments and other items that are prepared for sterilization must be packaged so that their sterility can be maintained to the point of use.

Use only medical grade SABS approved packaging that:

- Allows sterilization agents to penetrate and then provide a barrier, which will maintain the sterility of the wrapped devices
- Allows aeration post sterilization
- Is an effective barrier
- Is easy to use
- Is puncture resistant
- Is liquid resistant
- Is resistant to tearing
- Is non-Linting
- Is non reactive
- Is heat compatible
- Is non-toxic
- Is non Odorous
- Has flexible sizing

## **WESTERN CAPE CSSD FORUM** **STANDARD OPERATING PROCEDURE**

Use a wrapping technique compatible with the materials being used  
Always follow manufacturer and hospital guidelines

Do not re-use single use packaging  
Use a hospital grade masking tape when using wrap  
Use all packaging according to manufacturer's guidelines

### **Expected Outcome**

Pack integrity is maintained through correct use of packaging

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

**SOP No. 28**

### **Title**

**Quality Management**

### **Date of preparation**

1 November 2009-

### **Review date** (Usually 1 year later unless a change occurs)

1 November 2010

### **Prepared by**

Cape Town CSSD Forum

### **Area of application**

All wash, decontamination process, packaging, sterilisation, storage and dispatch processes

### **Staff involved**

Only staff trained in CSSD/Theatre

### **Objective/Purpose:**

To establish standards for quality which can be used at appropriate points within the CSSD

### **Relevant/Related Documents**

Procedure Manual

Working Instructions Manual

Service reports

Daily checklists

### **Maintenance Logs**

Washer Disinfector Log Books

Autoclave

BD Records

Biological Records

### **Equipment/Supplies**

N/A

### **Procedure**

- 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.
- The Service Engineer must sign the report.

### **Expected Outcome**

The checking and control of activities within the preparation area is ongoing and all processes are validated

# WESTERN CAPE CSSD FORUM

## STANDARD OPERATING PROCEDURE

### STERILE SERVICE DEPARTMENT

**SOP No: 29**

**Title**

**Decontamination of Textiles/Linen for sterilization**

**Date of preparation**

1 April 2010

**Review date**

1 April 2011

**Prepared by**

Cape Town CSSD Forum

**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 working in this area will wear protective clothing at all times in compliance with the standard precautions dress code
- Healthcare workers and laundry personnel must follow infection control principles when handling contaminated linen, including donning personal protective equipment (PPE) including gloves and gowns that provide adequate barrier properties. Laundry sorters must be provided with water resistant gloves and plastic aprons or water resistant gowns for protection. Hand washing facilities, including a hygienic sink, soap dispensers and paper towels, must be provided in the soiled-linen processing facility.
- Handle contaminated linen as little as possible.
- Soiled linen should be contained when transporting from Theatre
- Sort and discard any disposable material Avoid contaminating hands with soilage.
- Clinical waste in yellow plastic bags, domestic waste into black bags, sharps into sharps container taking special care to dispose of sharp objects safely. If instruments are found these should be set aside and the end user contacted

## **WESTERN CAPE CSSD FORUM**

### **STANDARD OPERATING PROCEDURE**

- Bags of soiled linen should be taken to an area dedicated for pre-wash sorting i.e. a dirty area.
- If linen is not washed immediately any stains should be moistened
- Soiled linen should be sorted before being loaded into washing machine units. Sorting before washing protects both machinery and linen from the effects of objects in the linen and reduces the potential for recontamination of clean linen that sorting after washing requires.
- Standardized washing and disinfecting processes should be used and validated
- Hot air drying or drying on a clothesline in sunlight will reduce the numbers of bacteria present, as will ironing with a hot iron
- Clean linen must be stored and transported in such a manner that cross contamination is avoided. Clean and dirty linen must not be mixed.
- 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.

All linen must be opened and inspected for holes, stains, wear before being used in sterile packages

A validated process must be used to determine when reusable textiles have to be withdrawn from use.

#### **Expected outcome**

Clean undamaged linen when inspected visually

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

**SOP No: 30**

### **Title**

**Inspection, Repair and Replacement of instruments**

### **Date of preparation**

1 April 2010

### **Review date**

1 April 2011

### **Prepared by**

Cape Town CSSD Forum

### **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.
- Instruments must be allowed to cool first if passing through an automated washer\.
- All instruments should be visually inspected following the cleaning and drying process.
- Only once instruments have been inspected can they be reassembled.
- Every instrument should be inspected for residual soil or any damage that may prevent it from functioning properly.
- 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
- Broken or damaged instruments will be decontaminated prior to sending for repair and a decontamination certificate sent with the consignment.
- 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.
- All parts of the instrument should be inspected for visible soil:
  - blood
  - protein and other residue

## WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

- 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
- 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

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 trace ability.
- 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

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

### SOP No. 31

#### Title

Checking, Assembling and Packing (Wrapping) an Instrument Set

#### Date of preparation

1 June 2010

#### Review date

1 June 2011

#### Prepared by

Cape Town CSSD Forum

#### Area of application

Packing Area

#### Staff involved

Personnel involved in packing

#### Objective/ Purpose

To ensure that all instrument sets are 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

Magnifying Glass

Packing materials

Autoclave and Masking tape

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.
- 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.
- Select 2 pieces of the appropriate, correct sized (new/unused) wrapping material and place on packing table, making sure that the wrapping material does not touch the floor.
- **Note** *Wrap is single use and cannot be re-used*
- Place the correct wrap onto the packing table so that the longest side of the wrap is parallel with the packing table.
- Place the instrument tray in the centre of the wrapping material
- 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.

## WESTERN CAPE CSSD FORUM

### STANDARD OPERATING PROCEDURE

- Instruments must be laid out according to the order on the check list.
- 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.
- Examine and count dressings as per tray list, place on tray (if included in set).
- **Note:** *Do not over pack trays; steam must be able to touch all surfaces.*
- Overloaded trays will result in wet packs.
- Examine hollow ware for cleanliness, place open side down; do not nest bowls and receivers (if included in set).
- 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.
- Preferably place the list on top of the 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.
- 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 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.

#### **Expected outcome**

Sets are correctly wrapped and sealed and ready for sterilization

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

**SOP No. 32**

### **Title**

**Prepare, Load and Operate Ultrasonic Cleaner**

### **Date of preparation**

1 September 2010

### **Review date (Usually 1 year later unless a change occurs)**

1 September 2011

### **Prepared by**

Cape Town CSSD Forum

### **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

## WESTERN CAPE CSSD FORUM

### STANDARD OPERATING PROCEDURE

- All handling and processing is to be undertaken in accordance with the manufacturers instructions
- 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 manufacturers 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

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

**SOP No. 33**

### **Title**

**Validating an Ultrasonic Cleaner**

### **Date of preparation**

1 September 2010

### **Review date (Usually 1 year later unless a change occurs)**

1 September 2011

### **Prepared by**

Cape Town CSSD Forum

### **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 center 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.

## WESTERN CAPE 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 a 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.

#### Notes

#### Ultrasonic cleaning equipment

Ultrasonic cleaners are available as smaller table top units, large integrated basins, integrated into a washer/disinfecter or a stand alone machine.



Stand alone Ultrasonic cleaner



Desktop ultrasonic cleaners



Desktop ultrasonic cleaners



# WESTERN CAPE CSSD FORUM

## STANDARD OPERATING PROCEDURE

### Components of an Ultrasonic cleaner

#### Ultrasonic generator

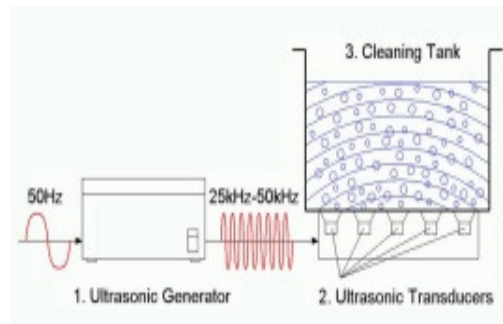
Through the mains electricity supply the electric waves at ultrasonic frequencies are created. (depending on the application 25kHz-50kHz).

#### Transducers

One or more transducers (speakers) transform the electric waves into ultrasonic sound waves.

#### Cleaning tank

The cleaning tank contains the cleaning fluid (usually water with an enzymatic detergent). At the bottom of the cleaning bath the transducers are attached.



#### Cleaning Process

An ultrasonic washer is used to remove fine soil and hardened debris from surgical instruments before sterilization. Ultrasonic cleaning is by far the better cleaning process because it has the ability to clean on a microscopic level.

The ultrasonic washer works by converting high-frequency sound waves into mechanical vibrations that free soil from the surface of instruments.

Ultrasonic cleaners work on the principle of sound waves moving through a liquid. Ultrasound is a cyclic sound pressure with a frequency greater than the upper limit of human hearing usually about 20 kHz. Ultra-sonic energy of high intensity can be transmitted through liquids. Ultrasonic cleaners use high frequency sound waves to agitate in a solution or organic compound, the sound waves move in a circular movement agitating the water and forming a ripple effect.

The ultrasonic cleaner vibrates water at ultrasonic frequencies forming ultrasonic waves which cause very fast pressure decreases and increases in the fluid. The high-frequency energy causes microscopic bubbles to form on the surface of the instruments and as the bubbles implode, minute vacuum areas are created, drawing out the tiniest particles of debris from the crevices of the instruments. The sudden decrease causes gas bubbles to form, with the subsequent increase of pressure causing the bubbles to collapse. This process is known as cavitation. Ultrasonic cleaning depends upon this process of cavitation, the rapid formation and violent collapse of minute bubbles or cavities in a cleaning liquid. This agitation by countless small and intense imploding bubbles creates a highly effective scrubbing of both exposed and hidden surfaces of parts immersed in the cleaning solution. As the frequency increases, the number of these cavities also increases but the energy released by each cavity decreases making higher frequencies ideal for small particle removal without damage of the items to be cleaned. An ultrasonic cleaner works by dislodging dirt with the energy released from cavitation.

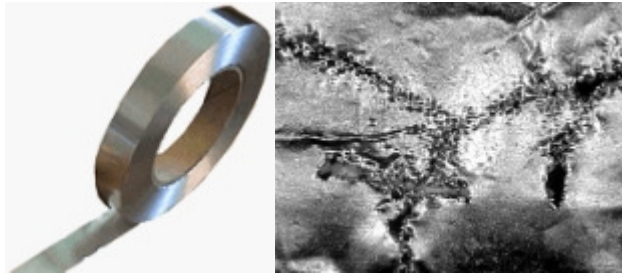
***NB!!!Do NOT use ultrasonic cleaning for Flexible endoscopes and Elastic materials***

# WESTERN CAPE CSSD FORUM

## STANDARD OPERATING PROCEDURE

Ultrasonic Testing Equipment

Foil Test



Chemical indicators



# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

### SOP No. 33

**Title:**

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

**Date of preparation**

September 2010

**Review date**

September 2011

**Prepared by**

Pretoria CSSD Forum

**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

## WESTERN CAPE 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.

# WESTERN CAPE CSSD FORUM

## STANDARD OPERATING PROCEDURE

### STERILE SERVICE DEPARTMENT

**SOP No. 34**

#### **Title**

**Decontamination and Management of Laryngoscopes**

#### **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.
- 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 in soapy water, with a soft brush, to provide a thorough cleaning.
- Either clean manually or in an automated cleaner according to manufacturers instructions
- After cleaning, rinse blades thoroughly, and dry prior to disinfection/sterilization.

## WESTERN CAPE CSSD FORUM

### STANDARD OPERATING PROCEDURE

- 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 usually 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

# WESTERN CAPE CSSD FORUM STANDARD OPERATING PROCEDURE

## STERILE SERVICE DEPARTMENT

**SOP No. 35**

### **Title**

**Daily Heat Sealer Checks**

### **Date of Preparation**

September 2010

### **Review Date**

September 2011

### **Prepared**

CSSD Forum

### **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

**WESTERN CAPE CSSD FORUM**  
**STANDARD OPERATING PROCEDURE**

Seal strength

- The pouch should be such that when peeling it open, neither the paper nor the laminate will tear.
- 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:** \_\_\_\_\_