

	POLICY Number: 7311-20-015 Title: EMERGENCY (FLASH) STERILIZATION
Authorization <input type="checkbox"/> President and CEO <input checked="" type="checkbox"/> Vice President, Finance and Administration	Source: Director, Materials Management Cross Index: Date Approved: May 25, 2009 Date Revised: Date Reaffirmed: Date Effective: June 26, 2009 Scope: SHR

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DEFINITIONS

Closed Flash Sterilization Container's (CFSC) means specially designed containers validated for flash sterilization which are stored in the operating room core and are designed to facilitate aseptic transport to the sterile field.

Emergency (Flash) Sterilization means the process by which medical devices are sterilized for immediate use, should an emergency situation arise during surgery. Herein also referred to as 'emergency sterilization'.

Implant means any item that remains in the body for at least 30 days.

1. PURPOSE

The purpose of this policy is to establish appropriate use of Emergency (Flash) Sterilization at the Saskatoon Health Region (SHR).

2. PRINCIPLES

2.1 Reprocessing of medical devices is a process that involves multiple steps; only one of those steps is the actual sterilization cycle.

2.2 Effective sterilization is impaired if all the necessary parameters of sterilization are not met.

3. POLICY

- 3.1 SHR acknowledges emergency sterilization of medical devices as a safe method of sterilization under certain circumstances.
- 3.2 Emergency sterilization may only be used in the following circumstances:
 - 3.2.1 An urgent need/emergency does not allow for sterilization in the Sterile Processing department.
 - 3.2.2 The medical device can **only** be sterilized with a flash cycle and the process has been validated by the device manufacturer.
 - Vendor supplied loaner instruments must be cleaned, processed and sterilized in the Sterile Processing Department with regular sterilization cycles as per manufacturers' guidelines for cleaning and sterilization.
- 3.3 Items should only be emergency (flash) sterilized in CFSCs which have been validated for emergency sterilization.

Exceptions

- 3.2.1 The medical device does not fit into a CFSC.
- 3.2.3 The medical device is not approved for sterilization in a CFSC.
- 3.4 Emergency sterilization shall not be used as a substitute for insufficient instrument inventory.
- 3.5 Medical devices that have been emergency flash sterilized shall not be stored for later use.
- 3.6 Emergency flash sterilization shall not be used for implantable items except in cases of emergency when no other options are available.
- 3.7 Implants that have been emergency flash sterilized must be reported as an adverse event (see SHR Policy Adverse Events).
- 3.8 All instances of emergency flash sterilization shall be documented and be available for review for a period of two years.

4. ROLES AND RESPONSIBILITIES

4.1 Operating Room Nursing and Support staff

- 4.1.1 Determines where medical devices will be decontaminated (SPD or OR).
- 4.1.2 Documents all incidents of flash sterilization in the Emergency Flash Sterilization Log Book.

4.2 Operating Room (O.R.) Educator

4.2.1 Provides training regarding SHR decontamination and emergency sterilization procedures to all healthcare providers that will be flash sterilizing.

4.3 O.R. Manager

4.3.1 Reviews and forwards all Adverse Event Reports to Risk Management.

4.4 SPD Decontamination area

4.4.1 Responsible for quick turnaround of items being sent from the O.R. for decontamination.

4.5 Physician

4.5.1 In the case of emergency flash sterilized implants, informs the patient that a flashed implant was used during the surgery.

5. POLICY MANAGEMENT

The management of this policy including policy monitoring, implementation and amendment is the responsibility of the Director, Materials Management.

6. NON-COMPLIANCE/ BREACH

Performing emergency sterilization outside the parameters of this policy poses a risk to the patient. Non-compliance of this policy will result in at a minimum, a review of the situation. An education/training session must be repeated on the appropriate use of emergency sterilization will be required.

PROCEDURE

Number: 7311-20-015

Title: Emergency (Flash) Sterilization

Authorization

President and CEO

Vice President, Finance and Administration

Source: Director, Materials Management

Cross Index:

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1. PURPOSE

The purpose of this procedure is to establish the required steps for the use of emergency sterilization.

2. PROCEDURE

2.1 A member of the OR team determines timelines required for the medical device.

2.2 A member of the OR team contacts SPD to determine if medical device can be decontaminated in SPD within the required timelines.

2.2.1 Whenever possible, items should be sent to SPD for decontamination as this area is better suited for this purpose.

2.2.2 If SPD cannot provide the required turnaround time, decontamination may be performed in the OR.

2.3 Transport to Decontamination Area (SPD or OR).

- Gloves shall be worn when handling medical devices
- Soiled items should be contained during transport from the point of use to the decontamination area and then cleaned immediately.
- Containment devices include, but are not limited to, bins with lids, impermeable bags and covered carts. Reusable containers and carts must be cleaned and decontaminated after each use.
- Containment may be accomplished by any means that adequately prevents exposure to the soiled items during the transfer.

2.4 Preparation (SPD and OR)

2.4.1 Wear personal protective equipment that is appropriate for the task. This includes gloves, mask, eye shield and apron.

2.4.2 Clean the medical devices

- Items must be clean and free of bioburden (microbial contamination); hinges and stopcocks must be open; and lumens must be brushed and flushed with enzymatic detergent and rinsed with water.
- Position items with concave surfaces to facilitate drainage of water.
- Disassemble items with removable parts unless otherwise directed by the device manufacturer.
- Inspect the CFSC for cracks or chips. Ensure there are no cuts or tears in the gasket or silicone
- Put the medical device in the CFSC

2.5 Emergency Sterilization (OR)

2.5.1 Place in the emergency flash sterilizer and process on a ten minute cycle.

2.6 Monitoring of Process Parameters

2.6.1 Non-implants

All items to be emergency sterilized must be monitored in 2 ways:

1. Monitor mechanical indicators; readout from the sterilizer describing time and temperature results from the cycle.
2. Monitor Class 5 Chemical Integrator

2.6.3 Implants

Items to be emergency sterilized must be monitored in 3 ways:

1. Monitor mechanical indicators; Readout from the sterilizer describing time and temperature results from the cycle.
2. Monitor Class 5 Chemical Integrator
3. Monitor Biological Indicator (3M Rapid Read 1291). The results of these tests shall be included in the Flash Sterilization Log Book.

NOTE: Implants should be quarantined and not released until the rapid action BI provides negative results.

2.7 Aseptic Transfer to Sterile Field

Return medical device to the sterile field in a direct manner without opening the CFSC until arriving.

2.8 Documentation

2.8.1 All medical devices:

- Record in the Emergency Flash Sterilization Log Book a description of the device being flashed, date, time, signature of qualified person operating the sterilizer and addressograph (or two patient identifiers).

2.8.2 Implantable Devices:

- Record in the Emergency Flash Sterilization Log Book a description of the device being flashed, date, time, signature of qualified person operating the sterilizer and addressograph (or two patient identifiers).
- A member of the surgical team must also complete an Acute Care Safety Report and forwarded to the O.R. Manager.

2.8.3 The Emergency Flash Sterilization Log Book is reviewed on a monthly basis by the O.R. Manager or Educator and forwarded to SPD for storage.

3. PROCEDURE MANAGEMENT

The management of this procedure including procedure education, monitoring, implementation and amendment is the responsibility of the Director, Materials Management.