**Immediate-Use Steam Sterilization (IUSS): Sample Policy and Procedure**

**Purpose**

To ensure appropriate steam sterilization guidelines and evidence-based practices are adhered to in the perioperative setting.

**Policy**

The use of immediate-use steam sterilization shall be kept to a minimum. It shall be utilized only when there is insufficient time to process by the preferred wrapped or container method. Immediate-use steam sterilization shall not be used as a substitute for insufficient instrument inventory. Use of IUSS must be in compliance with specific manufacturer’s and, if applicable, container manufacturer’s validated written instructions for use. IUSS should not be used as a substitute for sufficient instrument inventory.

Immediate-use sterilization shall not be performed on the following devices or in the following situations:

* Implants, except in a documented emergency situation when no other option is available.
* Post-procedure decontamination of instruments used on patients who may have Creutzfeldt-Jacob disease (CJD) or similar disorders.
* Devices or loads that have not been validated with the specific cycle employed.
* Devices that are sold sterile and intended for single-use only.

**Definition**

“Immediate-use” is broadly defined as the shortest possible time between a sterilized item’s removal from the sterilizer and its specific transfer to the sterile field. A sterilized item intended for immediate use is not stored for future use, nor held from one case to another.

**Procedure**

1. Immediate-use steam sterilization may be performed only if the following conditions are met:

* The device manufacturer’s written instructions on cycle type, exposure times, temperature settings, and drying times (if recommended) are available and followed.
* Items are disassembled and thoroughly cleaned with detergent and water to remove soil, blood, body fats, and other substances.
* Lumens are brushed and flushed under water with a cleaning solution and rinsed thoroughly.
* Items are placed in a closed sterilization container or tray, validated for immediate-use sterilization, in a manner that allows steam to contact all instrument surfaces.
* Measures are taken to prevent contamination during transfer to the sterile field.
* All items to be processed must be able to withstand steam under pressure, without being damaged.

2. Packaging and wrapping:

Textiles, paper/plastic pouches, and non-woven wrappers shall not be used in immediate-use sterilization cycles unless the sterilizer is specifically designed and labeled for such use. Sterilizer manufacturer’s written directions should be followed and reconciled with the packaging manufacturer’s instructions for sterilization.

* Device manufacturers' instructions may not always be compatible with the sterilizer or container/wrapper instructions.
* When there is a conflict in instructions or instructions are insufficient, the device manufacturer should be contacted for more information and guidance.
* Instruments must be used immediately and not stored for future use.

3. Process Challenge Devices (PCDs):

Process challenge and process monitoring devices provide information to demonstrate that conditions for sterilization have been met.

* PCDs shall be used with routine process monitoring devices (i.e. chemical indicators, biological indicators, and physical monitoring devices)
* Each sterilization cycle shall be monitored to verify parameters required for sterilization have been met.
* Biological (BI) and chemical indicators shall be used to monitor sterilizer efficacy and assess compliance of monitoring standards established for gravity displacement and dynamic air removal sterilizers.
* On a daily basis, a biological indicator test (ATTEST) must be run in a flash cycle and the results recorded. Any potential sterilizer failure will be reported to the nurse leader.
* Class 5 chemical integrating indicators shall be used within each sterilizer container or tray.
* Each IUSS cycle must use the following chemical indicators:
	+ A Class 1 chemical indicator is used outside each sterilization container/package unless the internal Class 4,5 or 6 CI which must be used inside each package is visible.
	+ The Class 6 CI must be used in the cycle for which it is labeled.
* A biological indicator (BI) must be used at least weekly for the cycle used for IUSS.
* If more than one exposure time is used at a single temperature, then only the shortest exposure needs to be tested.
* All testing and documentation will be kept with each sterilizer for the cycle used for IUSS.

4. Transport:

The user shall adhere to aseptic technique for immediate use steam sterilized items during transport to the point of use. The user shall ensure that the transfer is performed in a manner that prevents contamination.

5. Sterilization containers:

Rigid sterilization containers designed and intended for immediate-use steam sterilization cycles shall be used for the following reasons:

* Reduce the risk of contamination during transport,
* Facilitate ease of presentation to the sterile field, and
* Protect sterilized items during transport.

The containers shall be used, cleaned, and maintained according to manufacturer’s written instructions. The containers shall be opened, used immediately, and not stored for later use.

The containers shall be differentiated from other types of containers. [*List how you will differentiate.]*

6. Implantable devices:

Immediate-use steam sterilization shall not be used for implantable devices except in cases of emergency when no other option is available. In an emergency when immediate-use sterilization of an implant is unavoidable, a rapid-action BI with Class 5 chemical integrating indicator (or enzyme only indicator) shall be run with the load. The implant shall be quarantined on the back table and shall not be released until the rapid-action BI provides a negative result.

If the implant is not used, it may not be saved as sterile for future use. Re-sterilization of the device is required if the implant is to be used at a later date.

7. Documentation:

Documentation of cycle information and monitoring results shall be maintained in a log to provide tracking of the immediate-use item(s) to the individual patient. The following shall be documented:

* Medical record number and patient name for traceability purposes
* Date and time of the cycle
* Autoclave ID
* Duration of cycle used
* Temperature of the cycle
* Item(s) sterilized
* Reason for immediate-use steam sterilization
* Name of the staff member processing the item(s)

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| **EXAMPLES OF TYPICAL IMMEDIATE-USE STEAM STERILIZATION PARAMETERS** |
| **Type of sterilizer** | **Load configuration** | **Time** | **Exposure Temp** | **Drying Times** |
| Gravity Displacement | Metal or nonporous items only (i.e. no lumensMetal items with lumens and porous items (e.g. rubber, plastic) sterilized together. Complex devices (e.g. powered instruments requiring extended exposure times). Manufacturer instructions should be consulted | 3 minutes10 minutes | 270o F – 275o F (1320 C – 1350 C)270o F – 275o F (1320 C – 1350 C) | 0 - 1 minute0 - 1 minute |
| Dynamic air-removal (pre-vacuum) | Metal or nonporous items only (i.e. no lumensMetal items with lumens and porous items sterilized together | 3 minutes4 minutes3 minutes | 270o F – 275o F (1320 C – 1350 C) 270°F (132°C) 275°F (135°C) |  N/A N/A N/A |
| The sterilizer manufacturer’s instructions for use of express cycles should be followed. One sterilizer manufacturer provides an express flash cycle that permits flash sterilization with a single-ply wrapper to help contain the device to the point of use. This cycle is not recommended for devices and lumens. Express cycles should only be used if the sterilizer is designed with this feature.Steam flush pressure-pulse: See manufacturer’s written instructions for time and temperature.This table does not include specific instructions for rigid flash sterilization containers. The container manufacturer’s instructions should be followed.**Reference**: Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79:2006 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. Arlington VA. Association for the Advancement of Medical Instrumentation |

All perioperative personnel are responsible for understanding the principles of immediate-use steam sterilization and the correct method for operating the autoclaves. Documentation of each load shall be done by the person actually running the load (include initials, patient’s name, record number and items flashed). The record will be retained indefinitely in a permanent logbook.

The Infection Control Professional must verify that all personnel understand the proper method of immediate-use steam sterilization. All new personnel must be educated on the proper procedure prior to using the autoclaves.

**References**

Association of PeriOperative Registered Nurses (AORN), Perioperative Standards and Recommended Practices, 2009 Edition Position Paper, Association for the Advancement of Medical Instrumentation.

ANSI/AAMI ST79:2010 & A1:2010 – Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical, 2010