



Current Status: Active

PolicyStat ID: 7427624



Origination: 11/2011
Effective: 01/2020
Last Approved: 01/2020
Last Revised: 01/2020
Next Review: 01/2023
Owner: Roshelle Satterthwait: Dir
 Perioperative Svcs
Policy Area: Sterile Processing
References:
Applicability: WA - Kadlec Regional Medical Center

(IUSS) Sterilization and/or Early Release of Implants in Perioperative Services, 49.03.09

Document Type: Policy

SUPERSEDES: 11/11

PURPOSE:

Defines the standard by which implants are to be IUSS sterilized or released prior to the biological passing. *Implantable devices should only be IUSS sterilized when there is no alternative. (i.e. in case of emergency)*

Approval to IUSS an implant comes from a Core Leader in both Sterile Processing and the Operating Room.

IUSS / Early Release Form will be provided to the OR room by SPD. The doctor and SPD Tech are responsible for filling out the form once the case is complete. The SPD Core Leader is responsible for scanning the document into the hospital reporting system.

Standard Sterilization Setting:

4 minutes at 270° F, 1 minute Dry Time or per manufacturer's recommendations.

Safety Concerns: The biological indicator has a definitive 24 minute read time. Early detection of a positive result may assist in preventing the release of a non-sterile load. The final negative indicator reading for a fluorescence change is made at 24 minutes.

GENERAL:

1. All implants must be properly decontaminated per IFU.
2. Sterilize implant in validated pan/container on IUSS sterilization setting (see above). Include an external indicator, integrator, and biological challenge pack in load.
3. A SPD Tech shall complete the IUSS process immediately upon cycle end.
4. A SPD Tech shall return the IUSS implant to the OR flowing sterilization and collect the class 5 integrator from inside pan.
5. A SPD Tech will document required information on paper IUSS Sterilization Log and electronically in computer tracking system. Include patient information sticker, doctor, item, etc.
6. Validate the parameters of the cycle have been met by circling the time and temperature on autoclave

printout.

7. The SPD Tech will incubate and log biological.
8. When appropriate time and/or temperature have not been achieved, the SPD Tech shall notify the SPD Core Leader and Lead. IUSS Sterilizer and printout shall be marked as "Out of Order" with time and date.
 1. If the implant is used, and the biological does not pass, both Core Leaders must be notified. (For following procedures, refer to the Core Leaders in Periop services)

Attachments

No Attachments

Approval Signatures

Approver	Date
Kirk Harper: CNO	01/2020
Heather Shipman: Executive Assistant	01/2020
Roshelle Satterthwait: Dir Perioperative Svcs	01/2020

Applicability

WA - Kadlec Regional Medical Center