

Sioux Falls Operating Room Instrumentation Vendor Requirements:

Objective:

- Sanford Health has committed to eliminating flash sterilization. The procedures in this document are intended to be clear on actions needed to achieve this goal.

Orientation:

- Vendors new to Sanford must complete a Central Processing orientation program prior to working in the Operating Room.
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Case Confirmation:

- Vendors are responsible to confirm surgical procedures case times/ changes with the Clinical Care Coordinators and Sterilization Techs.
- Case confirmation on weekends should be handled through Central Processing by calling 605-328-4252 and asking for a Central Processing orthopedic call person.
- In order to protect our patient's confidentiality, vendor representatives are not to view the grease boards or schedules posted in the Operating Room. Please seek assistance from the OR desk for your room assignment.

Acquisition of New Instrument/ Implant Sets into Sanford:

- All instrument/ implant sets that are new to Sanford must be approved through Supply Chain Management for pricing and contract agreement verification prior to scheduled cases.
- Vendors must provide manufacturer's written instructions for disassembly, cleaning, packaging, and sterilization of instruments to the Sterilization Tech supervisors in Central Processing PRIOR to use in the Operating Room.
- When containment devices, including their contents and any accessories or wrappers, are too heavy, sterilization and/ or drying time may be compromised. Additionally, there may be ergonomic issues associated with heavy containerized instruments sets. A maximum weight of 25 pounds for containerized instrument sets is required in Central Processing. It is the vendor's responsibility to ensure that instrument and implant sets meet this 25 pound or less weight requirement and are packaged accordingly.

In-servicing of Instrument/ Implant Sets:

- Vendors are responsible to contact the Clinical Care Coordinators in the Operating Room and the Central Processing supervisors as soon as a case is scheduled to set up individual department in-services. In-servicing must be provided by vendor prior to scheduled case.
 - o In-services should include preparation, inspection, assembly and proper sterilization methods of surgical instrumentation.

Drop off of Instrument/ Implant Sets in Central Processing:

- All instrument / implant sets will be delivered to the Vendor staging area (L715) located in MB4 Surgical Tower Lower Level. All instruments and implants sets must be dropped off or shipped so they arrive 24 hours prior to the scheduled case. Instruments for cases scheduled on Mondays will need to be dropped off the Friday before the case. Drop off time is from 7AM-3:30PM Monday- Friday.
 - o This will provide sufficient time to permit in-house disassembly, cleaning, packaging, and sterilization of the instruments before the scheduled surgery.
 - o All loaned instrument and implant sets will be considered complete PRIOR to the start of the OR case. Vendors are responsible for the completeness of all loaned instrument sets.
- Vendors will log the receipt of loaner instrumentation and implants into log in book:
 - o Date
 - o Time in/ out
 - o Company name/ vendor name
 - o Instrument description
 - o Case Number
 - o Number of instrument pans
 - o Doctor's name
- Vendors will fill out a label for each pan using Tyvek tags. The information listed will include
 - o Surgery Date
 - o Case Number
 - o Doctor name
 - o Company name and number of pans
 - o Type of Procedure

Pick up of Instrumentation/ Implant Sets in Central Processing:

- Upon completion of the surgical procedure, all instrumentation will be returned to the decontamination area in Central Processing.
 - o Vendors are responsible to inventory their instrument/ implant sets upon completion of scheduled cases.
 - Sanford will not be held responsible for instruments or implants that are missing from sets as it is the vendor's responsibility to follow the set through from acquisition to disposition.
 - Vendors must physically present any broken instruments with a completed form upon completion of a case to the Advanced Sterilization Tech.
 - Forms can be obtained in the vendor staging area or from an Instrument Assistant.
- Vendors are responsible for disposition of instruments out of Central Processing. Instrument/ Implant set pick-up must be completed within 48 hours of scheduled case. Instrument pick-up is located in the Vendor staging area (L715) located in MB4 Surgical Tower Lower Level.
 - o Vendors must log out instrument/ implants sets prior to removing from Sanford.
 - o Failure to pick-up instrument/ implant sets in within the time guidelines will result in a pick-up storage fee.

Sterilization of Instrument/ Implant Sets:

- Flash sterilization is a sub-standard process for sterilization of instruments. Vendors are not allowed under any circumstance to operate flash autoclaves or STERIS units for the purpose of sterilization. Flash sterilization in the Operating Room is reserved for emergent/immediate use of instruments.

Instrument Storage Space Allocation:

- Vendors are assigned shelving space in room L-700 for the purpose of storing loaned instrumentation/ implants. This space is delineated among vendors based off volume of cases serviced. Sanford reserves the right to reallocate space based on volumes and needs.
 - o No storage totes on floor at any time.
 - o Sterile wrapped items can not be stacked without exception or stored next to un-sterile pans or totes.
 - o Transport trays are Sanford property and must not be removed from Sanford at any time.
 - o Transport carts are for transportation only. Items stored on a transport cart must be used within 24 hours or put back on to storage shelf or removed from the hospital.
- Level 2000 Vendor Room: This space is designed as a 24 hour holding area for implants.
 - o No totes on the floor
 - o No cardboard
 - o No sterile instruments
 - o Remove items within 24 hours of scheduled case.
 - Failure to pick-up instrument/ implant sets in within the time guidelines will result in a pickup storage fee.

Noncompliance Notification and Corrective Action:

In order of occurrences, all actions will be conducted in writing:

Improper inventory resulting in case delay:

- 1st Vendor notification
- 2nd Vendor's supervisor notification/ Sanford surgeon notification
- 3rd Vendor Action plan development- submitted to Sanford surgeon/ OR team/ CP team
- 4th Temporary loss of privileges/ suspension from Sanford Health facilities
- 5th Permanent suspension from Sanford Health facilities

Improper inventory resulting in flash sterilization:

- 1st Vendor notification/ Immediate Surgeon Notification/Vendor Action Plan Development- submitted to Surgeon/Performance Improvement Committee/ OR Team and Central Processing Team
- 2nd Vendor supervisor notification (plus same as 1st occurrence)
- 3rd Temporary loss of privileges/ suspension from Sanford Health facilities (plus same as 1st occurrence)
- 4th Permanent suspension from Sanford Health Facilities

Failure to properly manage space or pick-up instruments within guideline parameters:

Each Occurrence - Storage fee per established contract terms

Sanford Health reserves the ability to modify the above corrective action steps based on severity of incident or management review.