Central Sterile Supply Manual

GEISINGER	*Section*	*Title*
	1.0 Administrative	**Guidelines for Prevention of Bioburden**

This policy applies to:			
X	***Geisinger Medical Center***		*Geisinger Health*
X	***Geisinger Wyoming Valley Medical Center***	X	***Geisinger Lewistown Hospital***
X	***Geisinger Shamokin Area Community Hospital***		*Geisinger Holy Spirit*
X	***GMC Outpatient Surgery-Woodbine***		*Geisinger Holy Spirit Medical Group*
			Holy Spirit Corporation
	Community Practice Service Line		*Holy Spirit Ventures, Inc.*
	Geisinger Community Health Services		
	Marworth		*Holy Spirit Health System*
	Geisinger Medical Laboratories		
	Geisinger Clinic		
	Geisinger System Services		*GNJ Physicians Group*
	Geisinger Gray's Woods Outpatient Surgery & Endoscopy Center		*Geisinger Commonwealth School of Medicine*
	Geisinger Health Plan		*Geisinger Endoscopy – Montoursville*
	Family Health Associates of Geisinger Lewistown Hospital	X	***Geisinger Jersey Shore Hospital***
	ISS Solutions, Inc.		*Geisinger Jersey Shore Hospital Foundation*
	Geisinger Gastroenterology and Endoscopy Center - Lewistown		
X	***Geisinger Community Medical Center***		
X	***Geisinger Bloomsburg Hospital***		

Eliminating bioburden will increase patient/staff safety, quality of care, and improve financial performance. In addition, removing unnecessary work and reducing delays in surgical cases will improve patient/staff satisfaction.

Purpose:

To provide effective management of and ensure standardization of processing for all reusable surgical instruments that are owned, consigned in a GHS facility, or loaned to effectively facilitate the prevention of bioburden leaving the CSR department.

Processes:

All instruments (owned, loaned or consigned) must be received, inspected, recorded, decontaminated, assembled/packaged, and sterilized in CSS.

Owned or Consigned:

All instruments must be inspected for the presence of bioburden in decontamination and assembly. If bioburden is discovered, the CSS team member will start the decontamination process again and inform CSS leadership.

Consigned or owned instruments will not be processed without the manufacturer's tray content lists and the manufacturer's written instructions for use (IFU). Pictures must be provided and on file within the department for each tray/set.

Loaned:

Loaned instruments will not be accepted by CSS without the manufacturer's tray content lists and the manufacturer's written instructions for use (IFU). Pictures must be provided and on file within the department for each tray/set. If the IFUs, content list and pictures are not present, CSS will follow the below stated escalation process:

- First Occurrence-Communicate with vendor that the loaners did not contain IFUs, pictures on file and/or tray lists > Make all attempts obtain the above document > every effort will be made to reschedule surgery on the same day.
- Second Occurrence-Vendor is informed that he/she is on their second Occurrence and a meeting is requested with the vendor to review the guidelines and expectations > every effort will be made to reschedule surgery on the same day > Inform surgeon of vendor noncompliance.
- Third Occurrence- Vendor is informed that he/she is on their third Occurrence, CSS informs OR leadership who informs surgeon of continued vendor noncompliance with loaner policy> every effort will be made to reschedule surgery on the same day. Executive leadership will be informed of continued vendor noncompliance with process.

Vendor Requirements:

Vendors must inform CSS via email to csrloaners@geisinger.edu, GCMCloaners@geisinger.edu, GWVloaners@geisinger.edu with information about the names and quantity of trays, surgeon/case, and method of shipment before the instruments are received and delivered.

- Vendors must provide the Manufacturer's Instructions for Use (IFU).
- An in-service is required for all first-time vendor-loaned sets. In-servicing will include disassembly/reassembly, decontamination, inspection, packaging, sterilization,

handling, and any other information that is needed for proper processing of the instrumentation.

* If above requirements are not met, CSS cannot proceed with processing the tray(s). CSS staff will call vendor immediately to inform them of noncompliance. All attempts will be made to ensure requirements are met. Failure to meet the above requirements will require OR leadership to inform surgeon and executive leadership of vendor noncompliance. Every effort will be made to reschedule surgery on the same day.

- Geisinger Health System requires receipt of loaner instrumentation at least 48 hours prior to the scheduled case. Instrumentation that arrives in less than 48 hours prior to a scheduled case, CSS will follow the below stated escalation process:

    - First Occurrence-Reinforce with vendor that the loaners must arrive in less than 48 hours prior to a scheduled case CSS>Proceed with sterilization.
    - Second Occurrence-Vendor is informed that he/she is on their second Occurrence and a meeting is requested with the vendor to review policy and expectations>Proceed with sterilization and inform surgeon/institute of vendor noncompliance.
    - Third Occurrence-CSS rejects instruments, vendor is informed that he/she is on their third Occurrence, > every effort will be made to reschedule surgery on the same day. CSS informs OR leadership who informs surgeon and executive leadership of continued vendor noncompliance with process.

- Geisinger Health System requires receipt of instrumentation that is patient-specific, not on contract, at least 72 hours prior to the scheduled case. Instrumentation that arrives in less than 72 hours prior to a scheduled case, CSS will follow the below stated escalation process:

    - First Occurrence-Reinforce with vendor that the loaners must arrive in less than 72 hours prior to a scheduled case CSS>Proceed with sterilization.
    - Second Occurrence-Vendor is informed that he/she is on their second Occurrence and a meeting is requested with the vendor to review policy and expectations>Proceed with sterilization and inform surgeon/institute of vendor noncompliance.
    - Third Occurrence-CSS rejects instruments, vendor is informed that he/she is on their third Occurrence, > every effort will be made to reschedule surgery on the same day. CSS informs OR leadership who informs surgeon and executive leadership of continued vendor noncompliance with process.

- Provide written inventory of all items and verify the inventory of any missing stock (to be noted with a CSS staff member upon receipt of the instrumentation).
- All incoming instrument trays should be considered contaminated.

- The instrumentation must be inspected for the presence of bioburden before the set is put through the decontamination process.
- All instrumentation must be inspected for the presence of bioburden by CSS staff and vendor prior to the set leaving a GHS CSS department.
- If a case has been rescheduled to a date within 72 hours of the original case date, the vendor must email the corresponding csrloaners@geisinger.edu.

Instrument trays that are loaned from one GHS platform to another will:

- Sending CSS will inspect instruments prior to the trays being transferred to another platform to ensure they are free from bioburden, functioning properly, contain IFUs, pictures and tray lists.
- Receiving CSS will inspect instruments prior to decontamination to ensure they are free from bioburden.
- Receiving CSS will inspect instruments prior to the trays being returned to ensure they are free from bioburden, functioning properly and complete.
- Sending CSS will inspect instruments upon return and prior to decontamination to ensure they are free from bioburden.
- If bioburden is found on a receiving set the follow escalation process will be followed:
    - First Occurrence-Inform CSR leadership, on both campuses, of the presence of bioburden.
    - Second Occurrence-Inform OR campus leadership, on both campuses, of the presence of bioburden.
    - Third Occurrence-Inform regional AVPs, on both campuses, of the presence of bioburden.

- *All attempts will be made to follow the guidelines for emergent and late add on cases.

Developed	*Revised/Reviewed**	*Guideline Owner*	*Approved by*	*Date*
10/2/19	9/21/2020	System CSR Managers	AVP, Surgical Services	9/21/2020