SPSmedical Sterilization Audit
CHECKLIST

Date: _____ *Auditor:* _____

Facility: _____ *Location:* _____

*Contacts:*_____

POINT OF USE – Instrument Preparation & Transport

	Yes	No	Y/N
1. Are instruments wiped of gross soil with sterile surgical sponges and sterile water?	☐	☐	☐
2. Are lumens irrigated with sterile water throughout the procedure to remove gross soil?	☐	☐	☐
3. Are sharps separated from other instruments and placed into a puncture proof container?	☐	☐	☐
4. Are multi-part instruments opened, disassembled and arranged within their original set?	☐	☐	☐
5. Are hinged instruments kept fully open using stringers, racks and/or instrument pegs?	☐	☐	☐
6. Are light instruments placed on top of heavy instruments or placed in separate containers?	☐	☐	☐
7. Is pre-soak solution or wet towels being used to keep instruments moist?	☐	☐	☐
8. Are instruments contained properly during transport to Decontamination area?	☐	☐	☐
9. Are transport containers (e.g. bags, carts and/or containers) labeled biohazard?	☐	☐	☐
10. Are instruments being transported as soon as possible to prevent blood from drying?	☐	☐	☐

Decontamination – Facility Design, PPE & Procedures

	Yes	No	Y/N
1. Is the area separate from clean activities and accessible by a door and pass through window?	☐	☐	☐
2. Is floor, walls, ceiling and work surfaces made of proper materials to withstand frequent cleaning?	☐	☐	☐
3. Is there negative pressure and a minimum of 10 air exchanges to the outside w/o recirculation?	☐	☐	☐
4. Is temperature (60-65°F) and humidity (30-60% RH) controlled and recorded daily?	☐	☐	☐
5. Is there an appropriate eye wash station (e.g. hands free and able to flush both eyes)?	☐	☐	☐
6. Are the manual cleaning sinks 3 section to allow for soaking, washing and rinsing?	☐	☐	☐
7. Do all personnel wear appropriate PPE and remove PPE properly?	☐	☐	☐
8. Is there a proper hand wash station and do personnel wash hands when leaving the area?	☐	☐	☐
9. Are instruments sorted upon arrival by their different cleaning instructions for use (IFU)?	☐	☐	☐
10. Is detergent type, dilution, water quality/ temperature and brushes per the instrument MFG's IFUs?	☐	☐	☐
11. Are sterilization containers cleaned between use and with proper detergent per the MFG's IFU?	☐	☐	☐
12. Are ultrasonic cleaners used and for proper time according to the instrument MFG's IFUs?	☐	☐	☐
13. Are all mechanical cleaners being tested, i.e. at least weekly, preferably daily?	☐	☐	☐
14. Are mechanical cleaners loaded properly to allow for effective cleaning?	☐	☐	☐
15. If the mechanical cleaners have a printout, is it located on the clean side?	☐	☐	☐

Prep & Pack – Inspection, Assembly & Packaging

	Yes	No	Y/N
1. Is every instrument visually inspected for cleanliness and function?	☐	☐	☐
2. Are dirty instruments returned to decontamination for re-cleaning?	☐	☐	☐
3. Are cleaning brushes only being used in decontamination area and not the clean assembly area?	☐	☐	☐
4. Is compressed, medical grade air available and used to dry instruments, i.e. lumens?	☐	☐	☐
5. Are instruments sets being assembled correctly and in appropriate trays?	☐	☐	☐
6. Are misc. items (e.g. towels, count sheets, tray liners, tape) being used properly?	☐	☐	☐
7. Are paper plastic pouches, wraps and/or containers being used correctly?	☐	☐	☐
8. Are packaging materials and container accessories being inspected prior to use?	☐	☐	☐
9. Are all instrument sets (including loaners) at or below the maximum weight of 25 lbs.?	☐	☐	☐
10. Is there a lot control label placed properly on all packages prior to sterilization?	☐	☐	☐

Sterilization – Steam, Low Temperature & QA

	Yes	No	Y/N
1. Are steam sterilizers being loaded properly, i.e. light items on top, heavy items on bottom?	☐	☐	☐
2. Are steam sterilizer cycles selected in accordance with instrument MFG's IFUs?	☐	☐	☐
3. Are MFG's IFUs readily accessible for personnel who are processing instruments?	☐	☐	☐
4. When IUSS occurs, is it performed correctly, i.e. approved container, cycle, indicators?	☐	☐	☐
5. Are all instruments and packaging systems used in low temperature processes validated?	☐	☐	☐
6. Are terminally processed loads allowed to cool to room temperature before handling?	☐	☐	☐
7. Is each sterilizer cycle printout reviewed and initialed before load removal?	☐	☐	☐
8. Does each sterilization package have an external and internal chemical indicator?	☐	☐	☐
9. Are internal CIs located properly, i.e. each level of multiple trays, corners of rigid containers?	☐	☐	☐
10. Are biological indicators (BIs) used daily and with every load containing an implant?	☐	☐	☐
11. Do personnel activate and incubate BIs properly, i.e. MFG's IFU and to national standards?	☐	☐	☐
12. Is an unprocessed BI from the same lot being incubated daily in each incubator?	☐	☐	☐
13. Are pre-vacuum steam sterilizers tested daily for air removal using a Bowie-Dick type test pack?	☐	☐	☐
14. Are positive BIs sent to microbiology laboratory for gram staining to protect against false +?	☐	☐	☐
15. Are all sterilization records complete, accurate and presentable?	☐	☐	☐

Sterile Storage & House Keeping

	Yes	No	Y/N
1. Are sterile items located in a clean, separate and enclosed storage area?	☐	☐	☐
2. Is temperature (75°F max) and humidity (30-70% RH) controlled and recorded daily?	☐	☐	☐
3. Is storage shelving appropriate, i.e. bottom shelves covered, all smooth surfaces, clean?	☐	☐	☐
4. Is ceiling or ceiling tiles made of an appropriate construction (e.g. not particulate-fiber shedding)?	☐	☐	☐
5. Are sterile wrapped packages placed flat on storage shelves and not stacked?	☐	☐	☐
6. Does each sterile package have a load label with sterilizer no., load no. and date of processing?	☐	☐	☐
7. Is an "event-related" sterility assurance policy being used along with FIFO?	☐	☐	☐
8. Are floors cleaned and disinfected at least daily for all instrument reprocessing areas?	☐	☐	☐
9. Do work surfaces and frequently touch items receive daily for all instrument reprocessing areas?	☐	☐	☐
10. Are walls, equipment, ducts, light fixtures and storage shelves on a routine cleaning schedule?	☐	☐	☐

Management & SPD Training

	Yes	No	Y/N
1. Are Policies & Procedures updated to best practices, i.e. loaners, hand hygiene, product recall?	☐	☐	☐
2. Is there a Soiled Instrument Transport Checklist in place at point of use?	☐	☐	☐
3. Is there an Instrument Tray Audit program in place to inspect instrument sets for accuracy?	☐	☐	☐
4. Are reusable instrument MFG's required to provide a validated IFU before purchase, loan or trial?	☐	☐	☐
5. Have all sterile processing personnel certified and are CE training records up to date?	☐	☐	☐

IUSS = Immediate Use Steam Sterilization (aka Flash sterilization)

Comments

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