SPSmedical Sterilization Audit
CHECKLIST

Date: ___________________________ Auditor: ________________________________
Facility: ______________________ Location: ________________________________
Contacts: _______________________________________________________________

**POINT OF USE – Instrument Preparation & Transport**

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 sharp instruments 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**

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**

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**

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**

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**

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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