Clinical Audit
Central Sterile Processing

Standard	Y/P/N	Findings
Facility Requirements		
• **Decontamination:** - Negative air flow - 10 air exchanges (minimum) - Air exhausted outdoors - Temperature 60-65° F - Relative humidity 30-60%		
• **Sterilizer equipment access** - Negative air flow - 10 air exchanges (minimum) - Air exhausted outdoors - Temperature 60-65° F - Relative humidity 30-60%		
• **Sterilizer loading/unloading** - Positive air flow - 10 air exchanges (minimum) - Air exhausted outdoors - Temperature 75-85° F or manufacturer recommendation - Relative humidity 30-60%		
• **Prep/packaging, Textile pack room** - Positive air flow - 10 air exchanges, down draft type - Air **not** exhausted outdoors - Temperature 68-73° F - Relative humidity 30-60% • Sorting: by size/type, no dumping/clumping, lay on absorbent surface. • View each instrument: free of soil, function, damage. • Assembly: - Instrument sets in perforated or wire mess bottom tray or specially designed containers. - Use count sheets for accurate assembly, Place: inside under tray liner or edge, or taped on outside, or in pt's record. - If Muslin wrappers used the # of uses must be monitored. (they wear out) - Identification of tray/instrument on indicator tape or plastic side of pouch, not on wrapper.		
• **Clean/sterile storage** - Positive air flow - 4 air exchanges, down draft type - Air **not** exhausted outdoors - Temperature - up to 75° F - Relative humidity – not to exceed 70%		
• **Decontamination area –** separate from other areas with floor, walls, ceilings and work surfaces made of non-porous materials. • Must have eye wash/shower station • Pass thru window to prep area • 2-3 section sink; soaking, washing, rinsing. • Manual Cleaning: wear PPE, wash below water line with brush (reduces aerosols) • Mechanical Cleaning: Ultrasonic cleaner with neutral pH detergent or enzyme solution • Sorting: forceps/delicate items separate, box locks wide open • Cleaning-disassemble, rinse, soak in enzymatic		

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(never saline) wash manually (warm H2O), cleaner, rinse, dry, inspect for debris, flaws or damage.		
• **Sterile storage area** – 1. Adjacent to the sterilization area, a separate, enclosed, controlled access area 2. Rotate products (first in first out) 3. Open shelving 2" from outside wall, 8 – 10" from floor, 18" from ceiling, keep from wet areas		
• **Doors** are kept closed		
• **Eyewash** stations		
• **PPE** Hair covering, face mask with plastic eye shield, water proof disposable gown, gloves, scrubs, shoe covers		
Quality Control		
• Chemical indicators (process vs multi-parameter (MP), Bowie Dick Test) 1. Process Indicators (PI) not sterile indicator o Tapes (steam, EO, Gas Plasma) o Indicators on pouches, o Strips (process or MP.) 2. Multi-parameter reacts to 2 or more of conditions 3. Bowie Dick: Steam vacuum type sterilizers, run daily at the same time. 3.5-4 min, 273° F /132° C; over drain, empty chamber		
• Biological Indicators (spore tests, sterilization has occurred) Designed for specific sterilizers, vary (strip vs vial) time and incubation temperature (+) failed test – investigate (-) passed test (+) control test – separate test, (+) is expected • Log Book: load #, time, temperature, items sterilized, biological test and control test results		
• Recall Process Report to supervisor Immediately Written report includes: date, time, description of load, other info that may help After correction: re-challenged 3 consecutive times with a BI or BI test pack Written P&P's developed by IC & RM		
Processes		
• Single use devices (if using must meet FDA requirements)		
• Event related sterility (sterile unless opened or damaged) In California, must have a program flexibility from the state to use event related sterility.		

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Sterilization		
• Safe operation of equipment - Steam sterilizers Loading: no items touch chamber walls; Lumen instruments irrigated with distilled or de-mineralized water, open hinged/ratchet instruments; Linen packs, basins, & solid trays on their sides; Instrument containers/mesh bottoms flat Container systems can be stacked if documentation is provided by manufacturer; Pouches on edge; If mixture of linen & metal, metal below linen; Do not overcrowd; Biological test pack over drain when run with full load; Unloading: not touched while cooling, not placed on metal/cold surfaces, visual inspect Items must be completely cooled before placing into the plastic dust cover - Ethylene Oxide (EO) sterilizer: (100% or diluted) Located in separate room away from traffic flow; Well designed ventilation system; Procedures for loading/unloading strictly adhered to. Loading: metal basket or mesh tray; Arranged loosely; Pouches on edge; Bio Indicator (BI) test pack in center of load Unloading: if has purge cycle remove and transfer to aerator, no purge phase door cracked 2-8" for 15 minutes, on transfer loads pulled; Aerate BI test pack & small 100% EO canisters (as per manufacturer) & all packaged items (use mechanical aerators) - STERRAD sterilizer (Gas Plasma) - Cycle parameters: 45-74 minutes,104° F (40° C) to 131° F (55° C); must be recorded at end of each cycle; - Specifically designed chemical & biological indicators must be used; - CAN NOT(S): use of paper, linen, towels, cotton, gauze or wood products; Lumens < 8 mm diameter or > 300 cm in length No copper or copper alloys CAN USE: polypropylene wrapper & Tyvek pouches		
• Record keeping		
- QC logs for all sterilizers		

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- QC logs for flash sterilization ▪ Patient name ▪ Date ▪ OR room ▪ Type of instrument/implant ▪ Physical monitors- time/temperature/pressure		
Transporting soiled Items - Use containers that prevent spillage: bins w lids, water proof bags, enclosed or covered carts with a solid bottom shelf, closed sterilization containers - Carts should be decontaminated and dried before reuse		
Regulatory Agencies: Joint Commission, OSHA, AAMI (Association for the Advancement of Medical Instrumentation) and CDC.		