

## Body Art Facility Autoclave/Sterilization Requirements

Clean instruments to be sterilized shall first be sealed in sterilization packaging that contain either a sterilizer indicator or process indicator, unless instruments are being processed for immediate use. The outside of the pack shall be labeled with the name of the instrument if not immediately identifiable, the date sterilized, and the initials of the person operating the sterilizing equipment unless instruments are being sterilized for immediate use.

The autoclave must be loaded, operated, decontaminated, and maintained according to the manufacture's direction and shall meet the following requirements.

1. The autoclave must be manufactured for the sterilization of medical instruments.
2. The autoclave must be Tested after initial installation, after any major repairs, and a least once per month using a commercial biological indicator (spore test). Results must be kept for at least 3 years
3. Each Sterilization load shall be monitored with mechanical indicators for time, temperature, and pressure. Each sterilization load shall include, at a minimum, a Class V Integrator.
4. Maintain a log of each sterilization cycle available on site for at least 3 years. The log must include:
  - A. The date of the load
  - B. A list of the Contents of the load
  - C. The exposure time and temperature
  - D. The results of the Class V Integrator
  - E. For cycles where the results of the biological indicator monitoring test are positive, how the items were cleaned, and proof of a negative test before reuse.

Clean instruments and sterilized instrument packs shall be placed in clean dry, labeled containers, or stored in a labeled cabinet that is protected from dust and moisture.

Sterilized instruments shall be stored in the intact sterilization packaging or in the sterilization equipment cartridge until time of use

Sterile instrument packs shall be evaluated at the time of storage and before use. If the integrity of the pack is compromised, including, but not limited to, cases where the pack is torn, punctured, wet, or displaying any evidence of moisture contamination, the pack shall be discarded or reprocessed before use.