

SOP Template: Verification of Surgical Instrument Sterilization and Availability

This SOP details the process for **verification of surgical instrument sterilization and availability**, encompassing the inspection of sterilization indicators, documentation of sterilization cycles, ensuring the integrity of packaging, and confirming the timely availability of sterilized instruments for surgical procedures. The goal is to maintain patient safety by preventing infections through strict adherence to sterilization protocols and ensuring that all required instruments are ready and properly sterilized before use.

1. Purpose

To define the standardized process for verifying the sterilization and availability of surgical instruments prior to surgical procedures.

2. Scope

This procedure applies to all healthcare personnel responsible for handling, processing, and preparing surgical instruments in the sterile processing department (SPD) and the operating room (OR).

3. Responsibilities

- **Sterile Processing Personnel:** Responsible for sterilizing, inspecting, and documenting surgical instrument sets.
- **Operating Room Staff:** Responsible for receiving, verifying, and confirming the readiness of instrument trays before any surgical procedure.
- **Supervisors/Managers:** Ensure compliance with protocols and oversee documentation.

4. Procedure

1. **Preparation and Sterilization**
 - Clean and prepare all instruments according to manufacturer and institutional guidelines.
 - Assemble instruments into designated trays/sets and apply appropriate sterilization indicators (chemical/biological).
 - Load trays into sterilizer, ensuring correct cycle selection and loading patterns.
2. **Verification of Sterilization**
 - Upon cycle completion, verify and interpret all sterilization indicators (chemical strips, color change tapes, biological spore tests as applicable).
 - Check for proper documentation of sterilizer cycle parameters (time, temperature, pressure, load ID).
3. **Inspection of Packaging Integrity**
 - Visually inspect instrument packaging (wrappers, pouches, containers) for any damage, tears, moisture, or signs of compromise.
 - Label each set with sterilization date, load/cycle number, and expiration (if applicable).
4. **Storage and Inventory Management**
 - Store sterilized instruments in designated sterile storage areas, ensuring separation from non-sterile items.
 - Maintain proper inventory controls to track set availability and expiration dates.
5. **Availability and Preoperative Verification**
 - Before scheduled surgeries, OR staff must confirm the availability and readiness of all required instrument sets.
 - Re-check packaging integrity and sterilization indicator results before opening.
 - Document the verification check on the surgical safety checklist or log sheet.
6. **Non-conformity Handling**
 - Report, quarantine, and reprocess any instrument tray that shows compromised sterilization, damaged packaging, or failed indicator results.

5. Documentation

- Sterilization cycle records/logs (cycle printouts, indicator results, date/time, operator signature).
- Instrument set/tray log (ID, contents, sterilization date, expiration, verification signatures).
- Incident/Non-conformance reports when applicable.

6. References

- Institutional Infection Prevention and Control Policy
- Manufacturer's Instructions for Use (IFU) for instruments and sterilizers
- Applicable regulatory guidelines (e.g., CDC, AAMI, OSHA, Joint Commission)

7. Revision History

| Version | Date | Changes | Approved by |
|---------|------------|--------------------------|-----------------|
| 1.0 | 2024-06-20 | Initial template release | Department Head |