SOP: Documentation, Traceability, and Storage of Sterilized Medical Equipment

This SOP details the **documentation, traceability, and storage of sterilized medical equipment**, encompassing procedures for accurate record-keeping of sterilization cycles, labeling protocols for identification, chain of custody maintenance, tracking systems to ensure equipment traceability, and proper storage conditions to maintain sterility. The goal is to ensure patient safety, compliance with regulatory standards, and efficient management of sterilized instruments within healthcare facilities.

1. Purpose

To provide standardized procedures for documenting, ensuring traceability, and storing sterilized medical equipment, so as to enhance patient safety and regulatory compliance.

2. Scope

This SOP applies to all staff involved in handling, documenting, and storing sterilized medical equipment within the facility.

3. Responsibilities

- **Sterilization Personnel:** Operate equipment, document cycles, perform labeling.
- **Supervisors:** Verify records and labels, monitor storage conditions.
- **Inventory/Distribution Staff:** Maintain traceability through tracking systems.

4. Procedure

4.1 Documentation of Sterilization Cycles

- Record cycle date, time, equipment ID, operator name, and load contents in the sterilization log (manual or electronic).
- Document type of sterilization process, parameters (temperature, pressure, duration), and results of biological/chemical indicators.
- Retain logs for a minimum period as defined by regulatory requirements (e.g., 3-5 years).

4.2 Labeling Protocols

- Label each sterilized package/container with:
  - Sterilization date
  - Batch or lot number
  - Expiry/reprocessing date
  - Operator initials
- Use tamper-evident, sterile-compatible labels.

4.3 Chain of Custody Maintenance

- Track custody from sterilization area to storage and clinical area using a log or digital tracking system.
- Document all hand-offs and transfers, noting date, time, and responsible personnel.

4.4 Traceability Systems

- Unique batch or lot numbers must be assigned to each load for end-to-end traceability.
- Link batch/lot numbers to documentation, storage location, and usage/distribution records.
- Implement barcode or RFID tracking if available.

4.5 Storage of Sterilized Equipment

- Store in designated clean, dry, temperature- and humidity-controlled areas.
- Prevent crushing, puncturing, or contamination of packages.
- Observe First-In, First-Out (FIFO) principle for distribution/use of sterilized items.
- Regularly inspect stock for package integrity and expiration dates.

5. Documentation and Records

Record Type	Responsibility	Retention Period
Sterilization Log (manual/electronic)	Sterilization Personnel	3-5 years or as required
Label Verification Sheets	Supervisors	1 year
Storage Condition Logs	Supervisors	1 year
Chain of Custody/Distribution Logs	Inventory/Distribution Staff	3 years

6. References

- Relevant national and international sterilization standards (e.g., AAMI, CDC, WHO)
- Facility Infection Prevention and Control Policy

7. Revision History

Version	Date	Summary of Change	Approved By
1.0	2024-06-01	Initial release	Committee Chair