

# SOP: Documentation and Labeling of Instrument Sets

This SOP details the **documentation and labeling of instrument sets**, encompassing the proper identification, organization, and tracking of surgical instruments. It ensures accurate recording of instrument contents, sterilization status, and procedural usage to maintain safety, efficiency, and compliance with healthcare standards. This process supports effective inventory management and prevents errors during surgical procedures.

## 1. Purpose

To standardize the documentation and labeling of instrument sets to ensure traceability, safety, and compliance with regulatory requirements.

## 2. Scope

This procedure applies to all staff responsible for handling, assembling, sterilizing, distributing, and tracking surgical instrument sets in the healthcare facility.

## 3. Responsibilities

- **Sterile Processing Personnel:** Assembly, labeling, and documentation of instrument sets.
- **Nursing Staff:** Verification of instrument set contents and labels before and after use.
- **Quality/Compliance Team:** Auditing documentation and labeling processes.

## 4. Procedure

1. **Instrument Set Assembly**
  - Assemble instruments according to the standard set list.
  - Visually inspect instruments for function and cleanliness.
2. **Documentation**
  - Complete the Instrument Set Checklist, recording the following:
    - Set name and unique identification number
    - Date and time of assembly
    - Initials of assembler
    - Sterilization batch/lot number
  - Update inventory management system, if electronic tracking is utilized.
3. **Labeling**
  - Affix an identification label to each set, clearly showing:
    - Set name
    - Unique ID or barcode
    - Sterilization status (e.g., indicator tape, tag, or color coding)
    - Date of sterilization
    - Expiry date, if applicable
  - Ensure labels are durable and legible after sterilization.
4. **Storage and Tracking**
  - Store labeled sets in designated sterile storage areas.
  - Record location and status in tracking logs or systems.
5. **Pre- and Post-use Accountability**
  - Verify set contents and labels before issuing to surgical suites.
  - Document any missing or damaged items after use, report to supervisor, and update records as necessary.

## 5. Records

- Instrument Set Checklists
- Sterilization logs/batch records
- Tracking/inventory system entries
- Audit reports

## 6. References

- Facility policies and procedures
- Regulatory standards (e.g., AAMI, CDC, Joint Commission)

- Equipment manufacturer instructions

## Appendix: Sample Instrument Set Label

Set Name	Major Orthopedic Set
Unique ID	MO-2024-0011
Sterilization Date	2024-06-25
Expiry Date	2024-07-25
Sterilization Status	Sterile
Assembled By	JD

Version: 1.0 | Effective Date: 2024-06-25