# Reprocessing of surgical instrument sets

Process Definition Document (PDD): template and worked example

*Example company (fictional): Hôpital Universitaire Saint-Aurélien, a university hospital in Lyon, France (900 beds), and its central sterile services department (CSSD).*

## Document control

| Field | Value |
|---|---|
| Process name | Reprocessing of surgical instrument sets |
| Process owner | [Name, role] |
| Prepared by | [Name] |
| Reviewed by | [Names of the people who do the work] |
| Approved by | [Name, date] |
| Version | 1.0 (as-is) |
| Status | Draft |

## How to use this template

This is a complete process definition document (PDD) for the reprocessing of reusable surgical instrument sets, also called the CSSD process, the sterile processing workflow or instrument decontamination and sterilisation. It describes how a used set travels from theatre through washing, inspection, packing and steam sterilisation back to sterile storage, with the roles, systems, decisions and controls you would expect in a hospital sterile services department.

Use it as a starting point. Replace the hospital details, keep the sections, and walk through each step with the operators and technicians on the floor. Most departments change the cycle parameters, the release rule and the way defects are logged. The structure stays the same. Endoscopes, single-use devices and repair contracts need their own documents.

- Replace the hospital, the tracking system and the quality system with yours. If you use paper records, say so in the systems list and in steps 2, 12 and 15.
- Set your own cycle parameters and times. Washer programmes, the 134 degree cycle and the drying time differ by device and by validation.
- Decide who may release a load. A single releaser causes waiting during absences, so many departments name a deputy.
- Check the percentages with a month of tracking data. Missing instruments and damaged instruments are usually easy to count from the records.
- Add the endoscope and single-use device flows as separate documents if they sit in the same department.
- Keep the as-is version after you redesign the process. It is your baseline for measuring the change.

## 1. Purpose and scope

This procedure describes how the sterile services department at Hôpital Universitaire Saint-Aurélien reprocesses reusable surgical instrument sets, from the moment a used set reaches the dirty receiving area to the moment the sterile set is released and stored or returned to theatre. It gives the department and the operating theatres one shared description of who does what, so that every set that leaves the CSSD is complete, clean, sterile and traceable.

### In scope

- Reusable surgical instrument sets from all operating theatres

- Receiving, composition check and manual pre-cleaning
- Washer-disinfector cycles and steam sterilisation in autoclaves
- Inspection, packing, labelling and load release
- Traceability of set, load and cycle
- Handling of failed cycles and non-conformities

### Out of scope

- Endoscopes
- Single-use devices
- Repair contracts and vendor management
- Patient data, which this process does not handle

## 2. Process at a glance

| Item | Description |
|---|---|
| Trigger | A used instrument set is sent from theatre in a closed container. |
| Starts when | The Receiving Operator scans the set barcode in the tracking system. |
| Ends when | The sterile set is released, stored or returned to theatre and the handover is recorded. |
| Inputs | Used instrument set, Set composition list, Spare instruments, Packing material and chemical indicators |
| Outputs | Sterile packed set with label and expiry date, Washer and autoclave printouts, Cycle and load records, Non-conformity report when a cycle fails |
| Volume | About 46,000 sets a year, around 180 per working day |
| Working hours | Monday to Friday 06:00 to 22:00, Saturday 07:00 to 15:00, with night on-call for emergencies |

## 3. Roles and responsibilities

| Role | Responsibilities |
|---|---|
| Theatre Assistant | Sends used sets to the CSSD in closed containers and collects sterile sets, or receives them when the CSSD delivers. |
| Receiving Operator | Registers used sets, checks them against the composition list, pre-cleans them by hand when needed and loads the washer trays. |
| Sterilisation Operator | Runs the washers and the autoclaves, checks the printouts, builds the loads and moves released packs to storage. |
| Packing Technician | Inspects every instrument, swaps in spares for damaged ones, assembles the set, packs it and prints the label. |
| Quality Officer | Reviews records and releases loads, blocks failed loads, raises and closes non-conformities and sends defective instruments for repair. |
| Instrument Repair Vendor (external) | Repairs or replaces damaged instruments sent by the CSSD. |

## 4. Systems

- Instrument tracking system: set lists, cycle records and traceability
- Washer and autoclave control software with printouts
- Veeva Vault QMS: non-conformity reports
- Excel: tracker for instruments out for repair
- Hospital email and telephone

## 5. Process map

**Process diagram goes here**

Draw one lane per role from section 3, the steps from section 6 in order, and a diamond for each decision in section 7.

## 6. Procedure, step by step

| # | Step | Who | What happens | System | Output |
|---|---|---|---|---|---|
| 1 | Send the used set | Theatre Assistant | Sends the used set in a closed container to the dirty receiving area by lift. This takes about 5 minutes. | Lift | Used set at CSSD |
| 2 | Scan the set | Receiving Operator | Scans the set barcode in the tracking system. This takes 3 to 5 minutes. | Tracking system | Set registered |
| 3 | Check against the composition list | Receiving Operator | Checks the set against its composition list. If instruments are missing (about 7% of sets), records it and calls the theatre. Otherwise the set moves on. | Tracking system | Verified set, or missing instrument recorded |
| 4 | Pre-clean by hand | Receiving Operator | If the set has dried debris (about 25% of sets), pre-cleans it manually. This takes 10 to 20 minutes. Otherwise it goes straight to washing. | Manual | Set ready for the washer |
| 5 | Load washer trays | Receiving Operator | Loads the washer trays and selects the programme. This takes 5 to 8 minutes, after a wait of 30 to 120 minutes before washing. | Washer | Loaded washer |
| 6 | Run the washer cycle | Sterilisation Operator | Starts the washer cycle, which runs 50 to 70 minutes. The software records the temperature and the A0 value. | Washer software | Washed load and cycle record |
| 7 | Check the washer printout | Sterilisation Operator | At unloading, checks the printout. If parameters are out of limits (about 3% of loads), the load is rewashed from step 5. Otherwise the trays go to the clean side. | Washer printout | Accepted trays, or rewash |
| 8 | Inspect each instrument | Packing Technician | Inspects each instrument for residue, corrosion and damaged joints. This takes 15 to 30 minutes per set. | Manual | Inspected set |
| 9 | Swap damaged instruments | Packing Technician | If an instrument is damaged or stained (about 10% of sets), swaps in a spare and records the defect. Otherwise the set is assembled complete. | Tracking system | Complete set, defect recorded |
| 10 | Send defects for repair | Quality Officer | Once a week, sends logged defective instruments to the repair vendor and updates the Excel tracker. | Excel, email | Instruments at the vendor, updated tracker |
| 11 | Assemble and pack | Packing Technician | Assembles the set, adds a chemical indicator and packs it in a container or double wrap. This takes 10 to 15 minutes. | Manual | Packed set |
| 12 | Label the pack | Packing Technician | Prints and attaches a label with the set ID and the expiry date. | Tracking system, label printer | Labelled pack |

| # | Step | Who | What happens | System | Output |
|---|---|---|---|---|---|
| 13 | Build the autoclave load | Sterilisation Operator | Builds the load, scanning each pack so that load and set are linked. The wait for a free autoclave is typically 20 to 60 minutes. | Tracking system | Load linked to sets |
| 14 | Run steam sterilisation | Sterilisation Operator | Starts steam sterilisation at 134 degrees C. The cycle takes 60 to 90 minutes including drying. | Autoclave software | Sterilised load and cycle record |
| 15 | Check and sign the batch record | Sterilisation Operator | Checks the printout and the indicators and signs the batch record. | Autoclave printout | Signed batch record |
| 16 | Review and release the load | Quality Officer | Reviews the record and releases the load. The release check takes about 5 minutes per load. On Mondays the biological indicator load waits 24 hours for a negative result. | Tracking system | Released load |
| 17 | Block a failed load | Quality Officer | If a cycle fails or an indicator did not change (about 1% of loads), blocks the load and raises a non-conformity. Otherwise the load is released. | Veeva Vault QMS | Blocked load and non-conformity, or released load |
| 18 | Reprocess and close the non-conformity | Quality Officer | All packs of a failed load are reprocessed from step 5. The non-conformity is closed after the root cause is entered, within about 3 working days. | Veeva Vault QMS | Reprocessed packs, closed non-conformity |
| 19 | Move to sterile storage | Sterilisation Operator | Moves released packs to sterile storage and updates the location. This takes about 5 minutes. | Tracking system | Stored packs with location |
| 20 | Collect or deliver | Theatre Assistant | Collects the set, or the CSSD delivers it. The handover is recorded. | Tracking system | Set back in theatre, handover recorded |

## 7. Decision points and business rules

- Are instruments missing from the set? Yes (about 7% of sets): record it and call the theatre (step 3).
- Does the set have dried debris? Yes (about 25% of sets): pre-clean it manually before washing (step 4).
- Are the washer parameters within limits? No (about 3% of loads): rewash the load from step 5 (step 7).
- Is an instrument damaged or stained? Yes (about 10% of sets): swap in a spare and record the defect (step 9).
- Did the cycle pass and did the indicator change? No (about 1% of loads): block the load and raise a non-conformity (step 17).
- Is it Monday? Yes: the biological indicator load waits 24 hours for a negative result before release (step 16).

## 8. Exceptions

- Urgent flash sterilisation request (about 3% of sets): a short cycle runs with the Quality Officer's verbal approval, documented afterwards.
- Wet packs after the autoclave (about 2% of loads): the packs are unpacked and rewashed.
- Tracking system down (a few hours per year): paper forms are used and entered later.
- Set arrives after 20:00 (about 6% of sets): it waits for the morning shift unless on-call is activated.

## 9. Controls

- Every cycle is documented by printout and system record, linking set, load and cycle.
- The Quality Officer releases loads, not the operator who ran them (segregation of duties).
- Steam sterilisation follows ISO 17665 and washers follow ISO 15883, both validated yearly.
- A weekly biological indicator test runs on a dedicated load.
- Non-conformities are recorded in the quality system with root cause and corrective action.

- Each pack carries a label with set ID and expiry date.

## 10. Known issues today

- Missing instruments are found only at receiving, hours after the operation.
- Defects are logged on paper first and copied into Excel, so repair status is often out of date.
- The washers are the bottleneck from 14:00 to 18:00.
- Only the Quality Officer can release loads, so loads wait during absences.
- Composition lists do not always match what the theatres actually use.

## 11. RACI matrix

R = responsible (does the work), A = accountable (owns the outcome), C = consulted, I = informed.

| Activity | Theatre | Receiving | Sterilisation Op. | Packing | Quality Officer |
|---|---|---|---|---|---|
| Send and receive used sets | R | A | | | |
| Check composition and pre-clean | I | A/R | | | |
| Wash and check the printout | | C | A/R | | I |
| Inspect, repair log and pack | | | | R | A |
| Run the autoclave and sign the record | | | A/R | | I |
| Release the load | | | C | | A/R |
| Handle failed cycles | | | R | I | A |
| Store and hand back | R | | A | | I |

## 12. KPIs

| KPI | Definition | Target |
|---|---|---|
| Turnaround to sterile release | Hours between a set arriving at the CSSD and its release as sterile. The target is under 8 hours. | [set] |
| Loads rewashed or failed | Share of washer and autoclave loads that were rewashed or failed in the period. | [set] |
| Sets with missing or damaged instruments | Share of sets with at least one missing or damaged instrument recorded at receiving or inspection. | [set] |
| Washer and autoclave utilisation by hour | Share of each hour that each machine is running, used to see the afternoon bottleneck. | [set] |
| Open non-conformities older than 5 working days | Number of non-conformities still open after 5 working days, counted weekly. | [set] |

## 13. Revision history

| Version | Date | Author | Change |
|---|---|---|---|
| 1.0 | [date] | [name] | First as-is version |
| | | | |

*Free template from processfix.ai. You may copy and adapt it. The company in the example is fictional.*