

# Loan Sets and the Traceability Gap

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Image-based verification.

## Abstract

Loan and consignment reusable medical devices (RMDs) present a distinctive traceability challenge for sterilising services because the receiving facility is accountable for safe reprocessing and traceability while having limited control over device identification, tray configuration and supplier documentation. This educational paper reviews relevant requirements of AS/NZS 5369:2023, Australian and international evidence on loan-set reprocessing, and a single-site operational example of image-based tray verification at Clinique Rhéna, Strasbourg. The evidence indicates that loan instrumentation is associated with workflow variability, unfamiliar devices, incomplete information and instrument errors, while conventional identification controls may not provide a durable instrument-level record. Operational data reported by ATH Medical suggest that image-based verification can reduce tray-control and reception times and detect non-conformities; however, these results derive from one European site and should not be generalised without local validation. The practical implication for central sterile services department (CSSD) leaders is that technology should supplement, not replace, validated reprocessing, competent inspection, the manufacturer's instructions for use, documented release criteria and established tracking systems.

## Introduction

Loan and consignment instrumentation is integral to contemporary surgical services, particularly orthopaedics and other implant-intensive specialties. For CSSDs, these sets can be among the most complex and least familiar RMDs entering the reprocessing pathway. They may arrive from multiple suppliers, at variable times, with manufacturer-specific nomenclature, tray configurations and documentation. The operational task is therefore not simply to sterilise a borrowed tray: it is to receive, identify, clean, inspect, assemble, package, sterilise, release and document an externally owned RMD within the facility's validated reprocessing system.<sup>1,2</sup>

This paper examines the traceability gap that can arise when the sterilising service must account for a critical RMD that it does not own and may not be authorised to permanently mark. It combines standards-based analysis, published evidence and a measured operational example to identify implications for Australian CSSD governance and practice.<sup>3</sup>

### Loan sets under AS/NZS 5369:2023

A key principle in AS/NZS 5369:2023 is that loan and trial devices are not treated as a separate or lower-risk category of reusable medical devices (RMDs). The definition of an RMD specifically notes that the term includes both loan and trial RMDs (Clause 1.5.76). A loan or trial RMD is further defined as a device that is not owned by the facility and is supplied by a commercial supplier, another facility or an individual clinician (Clause 1.5.43).<sup>3</sup>

The practical implication is that the reprocessing and traceability obligations follow the device while it is within the healthcare facility, irrespective of ownership. Several clauses are particularly relevant to CSSD governance and loan-set management:

- Clause 2.5.3.1 requires documented procedures for the identification and tracking or traceability of critical RMDs, expressly including trial and loan devices, through reprocessing and subsequent use on patients.<sup>3</sup>
- Clause 2.5.2 requires competent personnel from the reprocessing facility to be involved in device selection before purchase, loan or trial, and requires appropriate validated manufacturer-provided reprocessing instructions for loan and trial devices, consistent with ISO 17664.<sup>3</sup>
- Clause 2.3.2(h) requires documented procedures for the handling of instruments supplied on loan or trial.<sup>3</sup>
- Clause 5.1.3 addresses the processing of loan devices entering circulation, including the use of validated cleaning methods and further validated cleaning and high-level disinfection before release off site.<sup>3</sup>
- Clause 5.6.1 explicitly extends applicable reprocessing-environment requirements to loan and trial devices.<sup>3</sup>
- Clause 9.4 links release documentation back to the traceability requirements in Clause 2.5.3 and notes that facilities should be progressing towards electronic tracking and process-record systems.<sup>3</sup>

Read together, these provisions offer no reduced obligation simply because an RMD is borrowed rather than owned. The device is in your facility, so it is yours to account for.

## Where the traceability gaps arises

Traceability depends on reliable identification. AS/NZS 5369:2023 provides guidance on methods for uniquely identifying RMDs where identification is necessary for reprocessing, including high-quality etching, and cautions against methods such as engraving and some colour-coded identification systems because of device-integrity and reprocessing concerns. Loan instruments create a practical constraint: the receiving facility may not have authority to permanently mark a device it does not own.<sup>3</sup>

In practice, many services manage this limitation using supplier tray lists, photographs, graphic layouts, tracking records and the knowledge of competent technicians. These are legitimate controls, but their effectiveness depends on the accuracy and currency of the source information and may not create an enduring device-level record independent of the individual technician. This is the traceability gap considered in this paper.<sup>4</sup>

## Evidence relevant to CSSD practice

Nichol and colleagues directly observed 147 surgical cases and identified 236 instrument errors. Visualisation-related failures, including inspection, identification and function, accounted for 88.6% of observed errors; missing, wrong or extra instruments accounted for 67.8%. Orthopaedic cases had a 40.0% error rate, and delays averaged 10.16 minutes in affected cases for which delay data were available. Importantly, the observed error rate substantially exceeded staff-reported events, demonstrating the limitations of incident reporting as the sole measure of instrument-process reliability.<sup>5</sup>

Australian evidence also identifies persistent challenges. A 2022 cross-sectional survey of sterilising service personnel included 65 Australian and 168 Brazilian responses. Although Australian structure and process indicators were generally stronger, failures were reported in both countries, including delivery delays and non-recommended point-of-use practices.<sup>6</sup> More recent AORN literature describes recurring loan-set problems including inconsistent arrival times, incomplete manufacturer instructions for use, complex or unfamiliar instruments, inventory and scheduling conflicts, communication gaps and difficulties coordinating return of sets.<sup>1</sup>

Together, these findings support a systems approach: loan-set risk is not attributable to a single processing step. It arises through supplier coordination, receipt, device identification, access to current instructions for use, decontamination, inspection and assembly, release, theatre use, return logistics and documentation.<sup>1,5,6</sup>

## Good practice for loan and consignment RMDs

The NSW Clinical Excellence Commission procedure for consignment and loan RMDs requires supplier information that includes accurate, legible tray lists and photographs or graphic outlines identifying instrument placement. For CSSD managers, the practical question is not whether such controls are desirable, but whether

they are consistently available, current and verified for every relevant set and supplier.<sup>4</sup> A robust local control framework should therefore address:

- defined acceptance and arrival-time requirements for loan sets;
- current manufacturer instructions for use and validated cleaning and sterilisation processes<sup>3</sup>;
- accurate tray lists and positional reference information<sup>4</sup>;
- clear responsibility for receipt, discrepancy escalation and release;
- competency requirements for personnel inspecting and assembling complex loan instrumentation;
- traceability records linking reprocessing and release to subsequent patient use<sup>3</sup>; and
- management of non-conforming, incomplete or unidentifiable instrumentation

## Image-based verification as an additional control

Where permanent device marking is unavailable or inappropriate, image-based verification offers an alternative method of recognising the physical instrument. Such systems can compare a tray and its contents with a reference database, identify expected instrument positions, flag discrepancies and retain a photographic record. This approach should be understood as an adjunct to the CSSD quality system rather than a substitute for validated reprocessing or technician judgement.<sup>5,7</sup>

One example is AnciTrak<sup>2</sup>, a standalone image-based workstation developed by ATH Medical. According to the manufacturer, the system identifies instruments by appearance, records tray configuration and flags missing or non-conforming items. Because recognition does not depend on a permanent physical identifier applied by the receiving hospital, the approach is potentially relevant to loan instrumentation.<sup>7</sup>



Figure 1. Image-based verification workstation

Operational case example: Cliniqu Rhéna, Strasbourg

Clinique Rhéna is a private hospital in Strasbourg, France. Based on information presented by ATH Medical, the hospital opened in 2017, operates 35 operating rooms and performed approximately 46,000 procedures in 2025, of which approximately 70% were ambulatory. Its sterilising service employs approximately 25 staff and manages approximately 800 loan-set kits. These figures provide context for a high-volume surgical and sterilising environment; they are vendor-provided case information rather than independently audited study data.<sup>8</sup>

The reported loan-instrument mix includes at least five implant manufacturers. The largest supplier represents 47% of activity and the three largest collectively 89%. Despite this concentration, manufacturer-specific variation remains in tray configuration, nomenclature, set composition and instrument positioning. For CSSD personnel, this variability affects receipt, identification, inspection, assembly, verification and discrepancy management.<sup>8</sup>

ATH Medical presented 12 months of operational data from Clinique Rhéna at the IPS Conference in Dilbeek in March 2026. The results are reproduced with permission in Table 1.<sup>8</sup>

should model local tray complexity, volumes, staffing, wage rates, existing tracking capability, implementation workload and the cost of maintaining reference data.<sup>8</sup>

Implications for Australian CSSD Managers

The central question for CSSD leaders is not whether image recognition is technologically impressive, but whether an additional verification control improves the reliability of the local reprocessing system. Evaluation should consider:

- Whether the system supports, rather than bypasses, AS/NZS 5369:2023 traceability and release requirements<sup>3</sup>;
- How reference images and instrument master data are created, validated, approved and maintained;
- How the system manages visually similar instruments, configuration changes and unrecognised devices;
- Whether the photographic record can be linked to existing RMD tracking and patient-use records<sup>3</sup>;
- How discrepancies are escalated and documented;
- System availability, cybersecurity, downtime and business-continuity arrangements;
- Staff training, competency assessment and human

| PERFORMANCE MEASURE                                                                                                                       | REPORTED RESULTS                 |
|-------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| Tray control time for a 287-instrument revision knee kit (10 boxes, 15 trays): manual versus AnciTrak <sup>2</sup> -assisted verification | 77.0 to 30.0 min (61% reduction) |
| Loan-set reception time: first to fourth reception of the same kit                                                                        | 28.5 to 15.3 min (46% reduction) |
| Average verification time across all trays                                                                                                | 1.5 min per tray                 |
| Incomplete trays: February 2025 versus February 2026                                                                                      | 78 to 30 (62% reduction)         |
| Set conformity rate                                                                                                                       | 69%                              |
| Missing-instrument rate                                                                                                                   | 4%                               |

Table 1. Loan-set and tray-verification outcomes reported before and after AnciTrak<sup>2</sup> implementation at Clinique Rhéna. Source: ATH Medical presentation, IPS Conference, Dilbeek, March 2026; reproduced with permission.<sup>8</sup>

Interpretation of the operational findings

The case data suggest three operational considerations. First, the reduction in reception time developed across repeated receptions of the same kit rather than appearing immediately. This is consistent with a reference-building and familiarisation effect and means that implementation should be evaluated over a sufficient period rather than on initial throughput alone.<sup>8</sup>

Second, non-conformity is broader than instrument loss. In the source data, instrument mix-ups accounted for 16% of trays and assembly errors for a further 12%, whereas a genuinely missing instrument was reported in 4%. For CSSD risk management, the relevant outcome is therefore set correctness and conformity, not simply prevention of loss.<sup>8</sup>

Third, the reported results are single-site operational data from a European private hospital with a dedicated loan-set workflow. They are not a controlled comparative trial and do not establish that equivalent reductions will occur in an Australian service. Any business case



Figure 2. Workstation in use during tray assembly in the clean area

- Locally measured outcomes such as verification time, incomplete-set rate, non-conformity detection, rework and theatre delay.

Technology does not remove the requirement for competent inspection. A system may assist with identity and configuration, but CSSD personnel must still assess cleanliness, condition, function, assembly, packaging and compliance with the manufacturer's instructions for use and validated local processes. The appropriate model is technology-assisted practice within a controlled quality system.<sup>3</sup>

### Questions for local governance review

Question 1: For a loan set processed six months ago, can the service retrieve evidence of the tray contents at assembly and link that record to reprocessing and patient use?

Question 2: Do suppliers consistently provide current tray lists, positional images and applicable manufacturer instructions for use before processing commences?<sup>4</sup>

Question 3: What proportion of loan-set discrepancies is captured by the incident or quality system, and how is under-reporting assessed?

Question 4: How dependent are complex loan-set builds on a small number of experienced technicians?

Question 5: Does the local loan-set procedure explicitly map its controls to the relevant requirements of AS/NZS 5369:2023?<sup>3</sup>

### Conclusion

Loan sets are not exempt from the traceability, validated reprocessing and release obligations applied to othercritical RMDs. Their external ownership, variable presentation and limited opportunities for permanent identification can, however, make those obligations more difficult to demonstrate consistently. Published evidence confirms that instrument identification, assembly and loan-set coordination remain vulnerable points in the perioperative pathway.<sup>1,3,5,6</sup>

Image-based verification is one potential additional control for this gap, particularly where instrument-levelidentification cannot rely on a mark applied by the receiving facility. The Clinique Rhéna case demonstrates reported improvements in verification and reception time and reductions in incomplete trays, but the findings should be treated as single-site operational evidence and validated against local Australian workflows before investment decisions are made.<sup>7,8</sup>

For CSSD managers, the objective is not automation for its own sake. The objective is a more reproducible, auditable and resilient reprocessing system in which the correct RMD can be identified, processed, assembled, released and traced with confidence.

### Disclosure

Josephine Maprock and Mai Nguyen are with HealthKare Intelligence, the authorised Australia and New Zealand distributor for ATH Medical. This paper is offered for

educational purposes. Clinique Rhéna operational data are reproduced with permission from ATH Medical. The standards, peer-reviewed literature and jurisdictional guidance discussed in this paper are independent of that commercial relationship. Readers are encouraged to evaluate available systems against local clinical, technical, quality and governance requirements.

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