HONG KONG ASIAWORLD-EXPO 亞洲國際博覽館

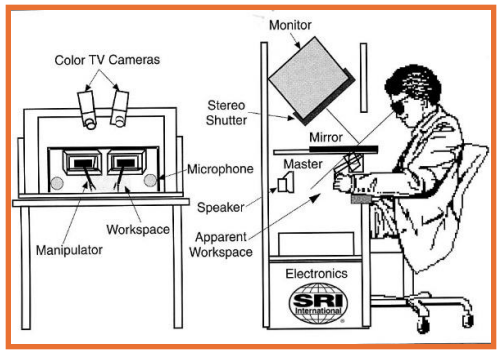
3RD TO 6TH DECEMBER 2025

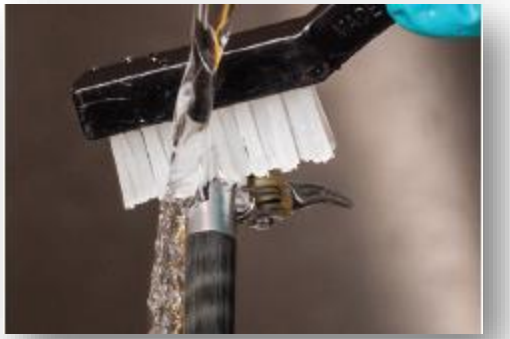
World Federation for Hospital Sterilisation Sciences

Innovation in Reprocessing Robotic Surgical Instruments

Name: Nick Dassatti
Affiliation: Intuitive

Evolution of Robotic Surgery and Reprocessing





Manual cleaning

Automated cleaning for robotic instruments

Pre-cleaning devices

Robotic Surgical Innovation Drives Reprocessing Innovation

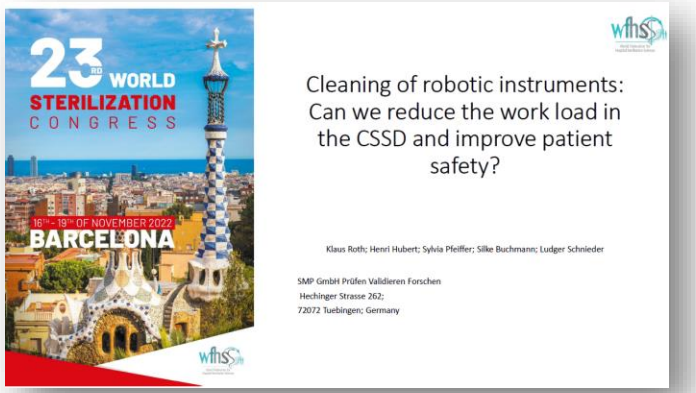
Development of **new solutions** to **improve** robotic reprocessing and sterile processing workflows.

- Automated ultrasonics with flushing and articulation
- Pre-cleaning pumps
- Drying cabinets
- Protection and storage

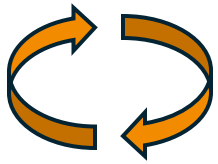
Reprocessing Innovations and Patient Safety

- Validation of state-of-the-art reprocessing solutions **demonstrates high level of patient safety**.
- 10 years of PQ data on robotic instruments **resulted in an average of 34µg total protein per device** using validated washer-disinfectors.
- New manual pre-cleaning technologies **show improvement of reprocessing workflow** with reduced cleaning steps.

Example of PQ testing

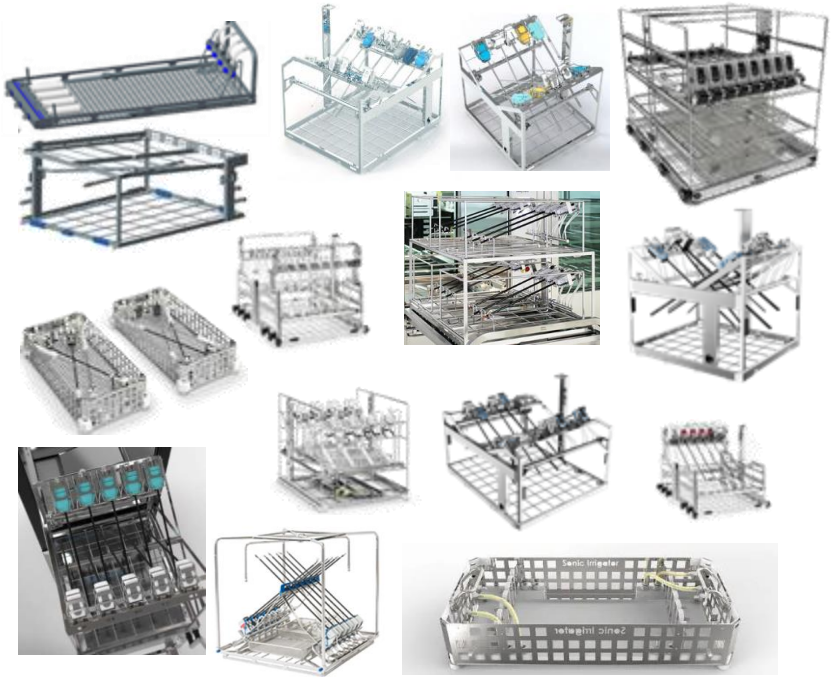


Historical Approach to Development



Early design iterations

Instrument manufacturer design freeze



Reprocessing solutions

Limitations

- Requires years of development and validation.
- Limited by timing of final device design.
- Dedicated robotic racks and washer-disinfectors.
- Specialized cleaning cycles.

Development of a New Approach to Automated Cleaning

Can we improve on existing solutions and the current development process?

Goals

- Maintain or improve on the high level of patient safety previously established.
- Improve workflow and equipment compatibility for users.
- Faster time-to-market of reprocessing solutions to support site case load.

How do we get there?

Key Questions

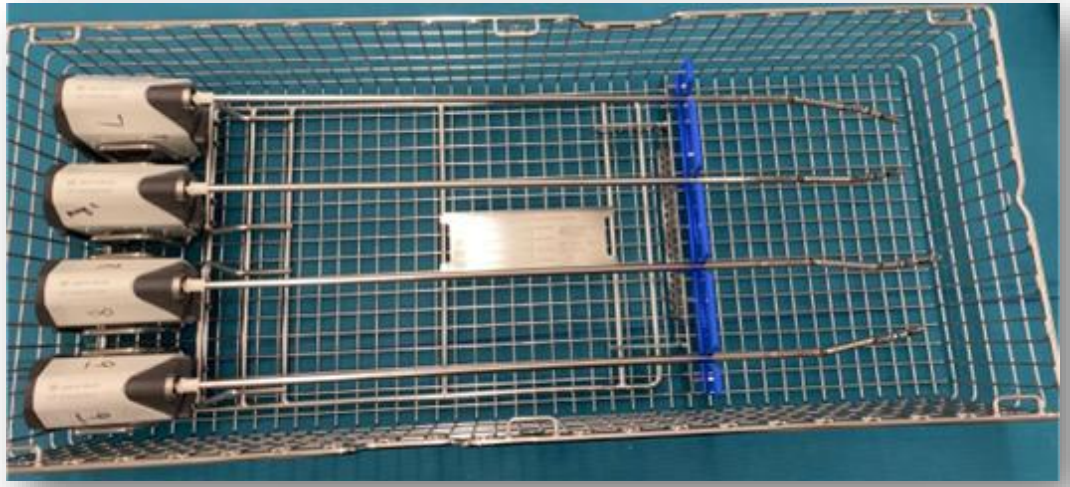
- Can we achieve the high bar set by existing reprocessing solutions?
- What equipment do global users have?
- How do we accommodate for the diversity of washer-disinfectors early into the design process?

Development of a New Approach to Automated Cleaning

How do we get there?

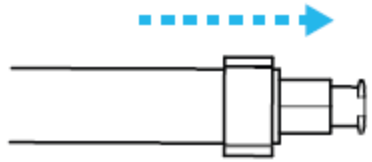
Key Questions		Approach
• Can we achieve the high bar set by existing reprocessing solutions?	→	• Comprehensive feasibility testing and formal validation to international standards.
• What equipment do global users have?	→	• In depth review of equipment common among users and sites with robotics.
• How do we accommodate for the diversity of washer-disinfectors early into the design process?	→	• Compliance to ISO standards.

Solution – Instrument Reprocessing Trays



Reprocessing Tray Approach for Robotic Instruments

Early design iterations



Automated cleaning parameters per ISO 17664-1 with connection method

Benefits

- More solutions available sooner to the user.
  - Washer-disinfector flexibility based on connection design.
  - Enables routine cycle parameters.
- Less dedicated space to robotic reprocessing.
- Improved efficiency with washer-disinfectors being used for both robotics and non-robotics.
- Multi-purpose with sterilization compatibility.

Validations of Cleaning Efficacy

Surgical Simulated Use and Drying → **Manual Pre-Cleaning** → **Automated Cleaning** → **Extraction** → **Analysis**

Residuals analysis in accordance with ISO 15883-5: 2021.

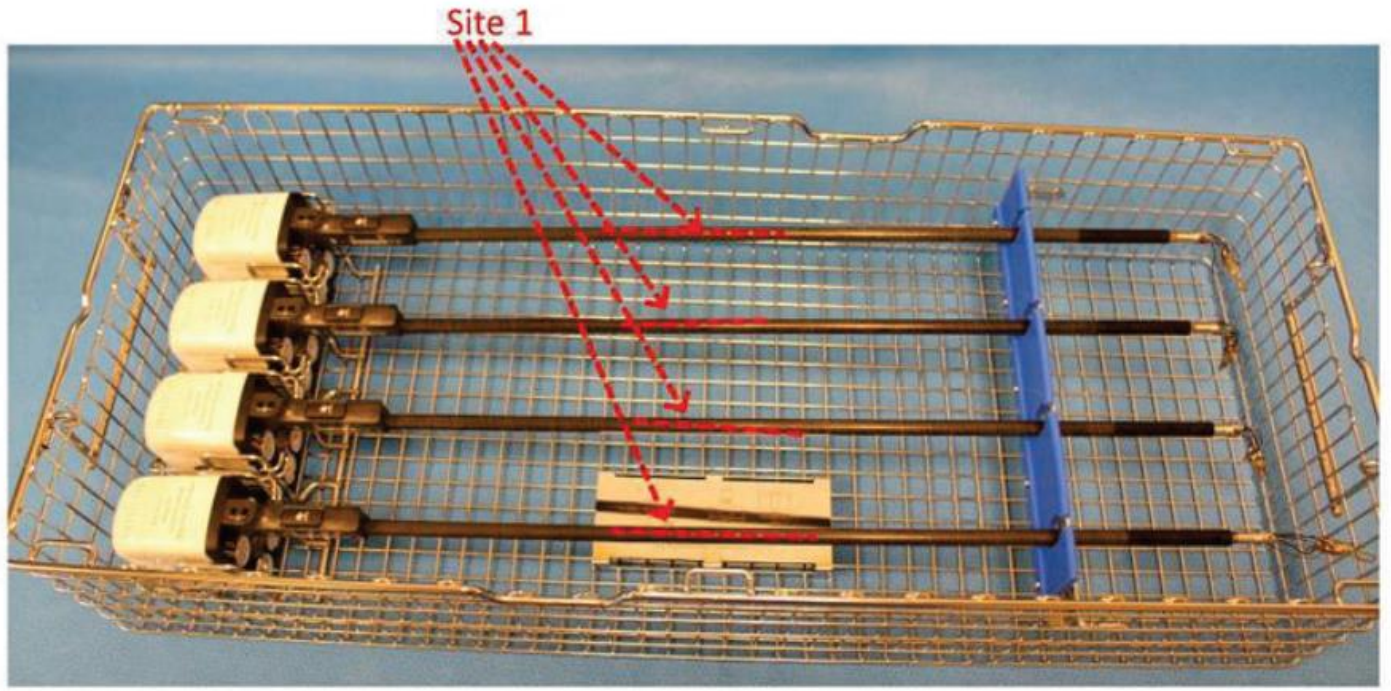
Protein:
- < 6.4 µg/cm^2
- < 200 µg/device

Hemoglobin:
- < 2.2 µg/cm^2

Validations of Steam Sterilization Efficacy

Test Method and Results

- Three cycles with fully loaded trays.
- Worst-case biological indicator placement.
- Overkill method for a 6-log reduction in a half-cycle.
- No growth after incubation period.



Innovation Outcomes – PQ Testing

Cleaning Performance Qualification (PQ) Testing

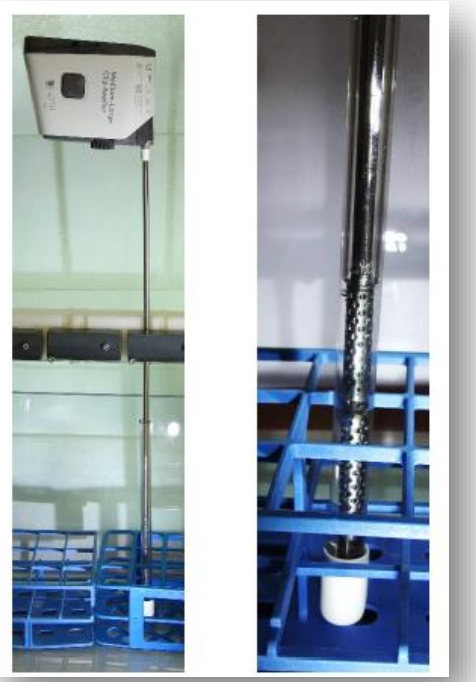
In accordance with:

- HTM 01-01Part D
- ISO 15883-1: 2025 / ISO 15883-5: 2021

Collected data in clinical settings to <100ug levels as seen with historical data for innovative approaches to robotic reprocessing.

UK Quarterly Periodic Testing - Before

UK Quarterly Periodic Testing - After



EU PQ Testing - Extraction

Innovation Outcomes - Implementation

SteriLog – Lucerne, Switzerland

Challenged with limited time to start reprocessing of new robotic instruments.

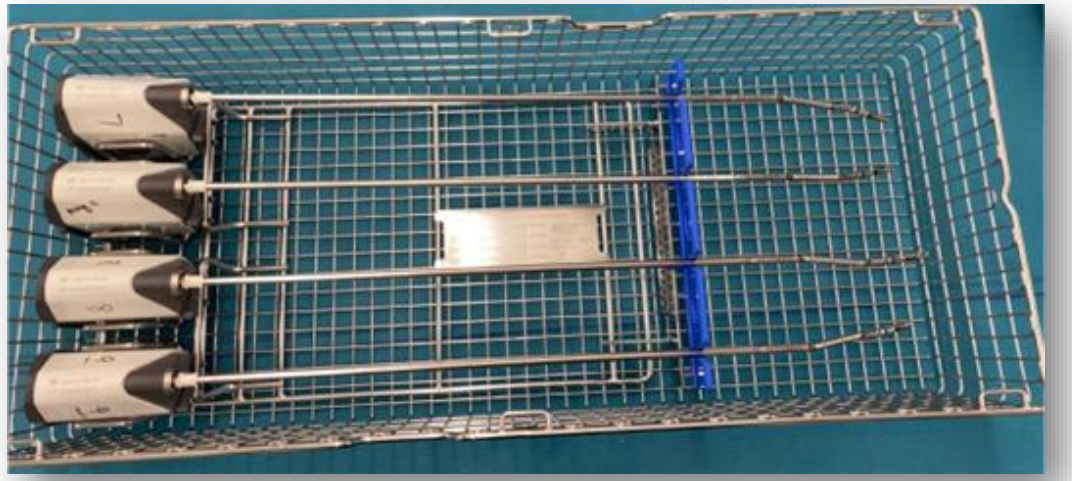
- Tray approach allowed for fast implementation.
- Simple integration into existing workflow.
- Minimal adjustment to existing wash rack.
- Quick turnaround of successful performance qualification (PQ) testing.

Markus Seichter
Managing Director of SteriLog
Sterile Goods Supply Lucerne AG

Innovation Outcomes – Handling

London, UK

- Trays provide security of instruments throughout cleaning and sterilization.
- Reduction in manual handling of products.
- Alleviates space constraints in a small, busy sterile processing department.



Future Opportunities

- Continued collaboration for collection of PQ data.
- Cross collaboration across companies:
  - Further optimization of cycle parameters.
  - Combination of tray with other pre-cleaning technologies.
- Design to fit future device designs.

Questions?

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Refer to the manufacturer's reprocessing instructions for full details regarding cleaning and disinfection of the items listed above. It is the responsibility of the owner of the da Vinci surgical system to properly train and supervise its personnel to ensure that the da Vinci instruments, accessories, endoscopes, and cameras are properly cleaned, disinfected, and sterilized as required by the reprocessing instructions. The da Vinci products should not be used in a clinical setting unless the institution has verified that these devices are properly reprocessed in accordance with the da Vinci system reprocessing instructions.

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