In 2015, AORN published an updated recommended practice for the Cleaning and Care of Surgical Instruments.[1] In this edition, there is a requirement to monitor the efficacy of manual cleaning and cites the use of ATP bioluminescence assays (e.g., Clean-Trace ATP Monitoring System) as a valid approach. They further state that quantitative testing data will allow tracking and trending of performance as part of a quality program.[1] The Association for Advancement of Medical Instruments (AAMI) also recommends cleaning monitoring for automated cleaning equipment and offers testing individual instruments as an option.[2]

How to go from Standards and Guidelines to Implementation of a Routine Quality Control Program

There are five key components that go into the successful design and implementation of a routine Clean-Trace ATP cleaning monitoring program for surgical instruments:

1. Design a test plan and determine test points.

2. Identify pass/fail thresholds.

3. Determine frequency of testing.

4. Establish meaningful metrics.

5. Track, trend, and regularly review test result data.

1. Design a Test Plan and Determine Test Points

The surgical instruments chosen for audit should represent the most difficult-to-clean instruments in order to provide a robust measure of cleaning effectiveness.[1]

Surgical instruments should be monitored after they are removed from the automated washer-disinfector and before they are packed and prepped for terminal sterilization.

Clean-Trace ATP Tests should never be used to monitor the sterilization process.

Warning

To reduce the risks associated with injury or inflammation due to the potential for residual trace amounts of swab solution on the instrument:

- Do not use Clean-Trace ATP Surface Test for ophthalmic instruments used in intraocular procedures due to concerns with Toxic Anterior Segment Syndrome (TASS).
- Do not use Clean-Trace ATP Surface Test for instruments used in the middle or inner ear due to concerns with neurotoxic effects.

Routine Monitoring

Instruments will vary widely between healthcare facilities as not all locations will perform the same procedures. It is recommended that each facility identify the instruments that are most difficult to clean based on their unique instrument sets. Neogen recommends testing the following instruments, recognizing that this list may not be representative for all healthcare facilities.

- Bone impactor
- Curettes
- Kerrison forceps
- Reamer
- Sagittal saw
- Bone mill
- Dermatome
- Mosquito clamp
- Rongeur
- Scissors

Surgical Instrument Implementation Guide for Routine Cleaning Monitoring

Neogen® Clean-Trace® ATP Monitoring System

High-risk Instruments

High risk instruments are defined by the facility but could include the following:

- Instruments that cannot be washed in automatic washer disinfector (e.g. batteries, drills)
- Lumened instruments (e.g. arthroscopic shaver)
  Note: lumened instrument requires use of Clean-Trace ATP Water Test H20
- Robotics (e.g. Intuitive Surgical® da Vinci Surgical System®)

2. Pass/Fail Threshold

The pass/fail threshold for instruments cleaned by an automated washer-disinfector is as follows:

Pass ≤150 RLU
Fail ≥151 RLU

For those facilities wishing to monitor the hand wash and sonication steps, contact Neogen for assistance with determining a valid pass/fail threshold.

3. Frequency of Testing

In order to obtain statistically valid feedback, sufficient data must be collected on a routine basis. Neogen recommends that 10 hard-to-clean surgical instruments be monitored every shift, every day. Every high-risk instrument **should be monitored after every use.**

Refer to guidelines for additional guidance and rationale to determine the frequency of testing.

4. Establishing Metrics

The target metrics for the facility should reflect the cleaning monitoring program objectives and may evolve and change over time.

- % Pass/Fail of combined data for an overall view of cleaning effectiveness.
- % Pass/Fail by instrument type provides a means to target problem areas and surfaces.
- % Pass/Fail of high-risk instruments allows early identification of developing problems.
- % Pass/Fail by reprocessing staff highlights training successes as well as identifies those needing to increase competency levels.

5. Track and Trend Test Result Data

In order to obtain actionable feedback, sufficient data sets must be collected if a true understanding of cleaning efficacy is to be achieved. The Neogen® Quality Control Data Manager provides a dashboard for quick, visual snapshots of cleaning performance and powerful reporting options to manage and communicate results.

Surgical instruments should be monitored at the recommended frequency of testing so that any adverse trends can be detected in a timely manner. Neogen recommends that data be reviewed, at a minimum, once per week and preferably each day the system in used.

Using Monitoring Data to Improve Surgical Instrument Reprocessing

Monitoring data is typically used in two ways:

Quality Control: Monitoring results provide real-time feedback on cleaning efficacy. Neogen recommends routine monitoring in which 100% of the instruments show passing results. Failing instruments should be re-cleaned and re-tested. If greater than 2 out of 10 instruments fail, then the entire surgical instrument set should be re-cleaned and re-tested. For high-risk instruments, all failing instruments should be re-cleaned and re-tested until passing values are achieved.

Process Improvement: The collection of monitoring results over-time offers the opportunity to gather statistically valid data sets that can be used to improve surgical instrument cleaning efficacy.

- Identify aging and damaged surfaces or equipment that are difficult or impossible to clean.
- Identify when cleaning processes are not being performed according to established procedures.
- Assess effectiveness of training and competency protocols by highlighting both successes and improvement opportunities.

References

1. AORN Guidelines on Cleaning and Care of Surgical Instruments. 2015. Sec tion XVII.a.4.
2. NSI/AAMI (R) 2022. ANSI/AAMI ST79:2017/(R)2022; Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities. Section 10.2.

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