Best Practices for Reprocessing Robotic Instruments

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Agenda

1. Background on robotic instruments
2. Reprocessing procedure for robotic instruments
3. Demonstration of effective reprocessing
Robotic instruments – Background
Background - Instruments
Perceived to be difficult to clean

- Intricate components
- Look different
Designed for reprocessing

The Primary Flush Port is connected to the Flush Tube, which is a long plastic tube that carries fluid down the shaft to the tip of the instrument. The fluid flows back up and out of the housing.

The Secondary Flush Port cleans the plastic housing of the instrument and its internal components (NOT the shaft).
Designed for reprocessing

**Position of the Flush Ports on Instruments with Shaft Flush Port:**

- Primary Flush Port
- Secondary Flush Port

**Position of the Flush Ports on Instruments without shaft flush port:**

- Primary Flush Port (#1)
- Secondary Flush Port (#2)
Designed for reprocessing
Designed for reprocessing
Agenda

1. Background on robotic instruments
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3. Demonstration of effective reprocessing
Reprocessing Flow

1. Storage
2. Sterilize
3. Dry and Package
4. Disinfect
5. Prep at point of use
6. Pre-clean
7. Manual / Automated Process
8. Use
9. Storage
Cleaning Steps

Pre-Clean
1. Soak in enzymatic detergent
2. Flush, Spray, Brush
3. Rinse and Inspect

Manual
Ultrasonic bath

Automated
Washer-Disinfector
## Cleaning Steps: Pre-Clean

<table>
<thead>
<tr>
<th>Preparation in OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prime/Soak in water or cleaner</td>
</tr>
<tr>
<td>Transport to SPD or CSSD</td>
</tr>
</tbody>
</table>

- **Prime Instruments with cold water or instrument cleaner**
- **Soak instruments in cold water or cleaner**
# Cleaning Steps: Pre-Clean

<table>
<thead>
<tr>
<th>Step</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleaner Prime and Soak</td>
<td>30 min</td>
</tr>
<tr>
<td>Flush</td>
<td>20 sec</td>
</tr>
<tr>
<td>Spray Tip</td>
<td>30 sec</td>
</tr>
<tr>
<td>Brush</td>
<td>60 sec</td>
</tr>
<tr>
<td>Rinse</td>
<td>60 sec</td>
</tr>
</tbody>
</table>

Flush each Flush Port with cold water using the *Intuitive Surgical* provided Luer fitting.
## Cleaning Steps: Pre-Clean

<table>
<thead>
<tr>
<th>Task</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleaner Prime and Soak</td>
<td>30 min</td>
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<tr>
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<td>Brush</td>
<td>60 sec</td>
</tr>
<tr>
<td>Rinse</td>
<td>60 sec</td>
</tr>
<tr>
<td>Inspect</td>
<td></td>
</tr>
</tbody>
</table>

Spray tip with *Intuitive Surgical* provided Luer fitting
Cleaning Steps: Pre-Clean

Brush the outside of the entire instrument and move the instrument wrist through its full range of motion.

Inspect with 4X magnification. Repeat brushing until there is no visible soil remaining.
Cleaning Steps: Pre-Clean

Rinse the outside of the instrument with cold water until no visible soil is observed. Specifically rinse the tip and where the instrument shaft enters the housing.
Cleaning Steps

Pre-Clean

Manual Process

Flush and Rinse

Automated Process

Inspect
Washer-Disinfector

- Type Testing according to ISO 15883-1
  - Belimed WD 290
  - Getinge T88
  - Medisafe SI PCF
  - Medisafe SI PCF Niagara
  - Miele 8528
  - Steelco DS1000
  - Steelco DS610

- Specialized load carriers and cycles
- Refer to Appendices of user manuals
Cleaning Steps

- Pre-Clean
  - Manual Process
  - Automated Process
    - Flush and Rinse
    - Inspect
### Cleaning Steps: Manual Process

<table>
<thead>
<tr>
<th>Ultrasonic Cleaning</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Prime and Ultrasonically clean</td>
<td>15 min</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Post-Ultrasonic Cleaning</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Flush (high purity water)</td>
<td>20 sec</td>
</tr>
<tr>
<td>Rinse (high purity water)</td>
<td>60 sec</td>
</tr>
</tbody>
</table>

*Soak and Prime in bath with cleaner*
Flush each Flush Port with cold water using the *Intuitive Surgical* provided Luer fitting.

Rinse the outside of the instrument with cold water until no visible soil is observed. Specifically rinse the tip and where the instrument shaft enters the housing.
Advantages of Reprocessing procedure

- One process for all robotic instruments
- Straightforward and models best practices from standards
- Multiple washer-disinfectors are validated
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1. Background on robotic instruments
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Cleaning validation

• Intuitive Surgical follows international standards:
  • ISO 15883-1
  • ISO 15883-5
  • AAMI TIR 12
  • AAMI TIR 30
  • ISO 17664

• If instructions are not followed, Central Processing Department is responsible for validating cleaning steps that are performed.
Cleaning Validation

• Perform testing for reprocessing under worst case conditions:

  - Use of positive controls and negative control
  - Acceptance criteria applied to visual inspection and protein analysis to determine if process renders the product clean
• Worst case clinical use determines:
  • Type of Test Soil
  • Location of Test Soil
  • Amount of Test Soil

• As a worst case, tips are completely immersed in Test Soil
• As a worst case, a safety factor is applied to the inner shaft volume.

<table>
<thead>
<tr>
<th>Product Family</th>
<th>Amount of Test Soil in Shaft (µL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8mm</td>
<td>600</td>
</tr>
<tr>
<td>Single Site</td>
<td>270</td>
</tr>
<tr>
<td>Stapler</td>
<td>50</td>
</tr>
</tbody>
</table>
Soiling
• Cleaning is performed under worst case parameters:
  • Test Soil is allowed to dry
  • Time, pressure, concentration of detergent
  • Visual inspection is not performed during cleaning but as an acceptance criterion at the end of the process
  • During Washer-Disinfector validation, thermal disinfection is not performed
• Extraction method is validated by performing a recovery efficiency calculation.

<table>
<thead>
<tr>
<th>Product Family</th>
<th>Tips Recovery Efficiency</th>
<th>Inner Shaft Recovery Efficiency</th>
</tr>
</thead>
<tbody>
<tr>
<td>8mm</td>
<td>94%</td>
<td>82%</td>
</tr>
<tr>
<td>Single Site</td>
<td>99%</td>
<td>87%</td>
</tr>
<tr>
<td>Stapler</td>
<td>95%</td>
<td>85%</td>
</tr>
</tbody>
</table>
• Quantitative protein analysis is performed using the modified OPA method using a spectrophotometer
• Modified OPA method was validated method:
  • Correlation coefficient $> 0.999$
• **Acceptance criteria**
  • Total residual protein < 200µg
    • Local guidelines: e.g. KRINKO: < 100µg
  • Total residual protein corrected for surface area < 6.4 µg/cm²

<table>
<thead>
<tr>
<th>Product Family</th>
<th>Surface Area (cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8mm</td>
<td>280</td>
</tr>
<tr>
<td>Single Site</td>
<td>237</td>
</tr>
<tr>
<td>Stapler</td>
<td>320</td>
</tr>
</tbody>
</table>

• **Visual Inspection** – no visible soil (magnification: 4x)
Results

Total Protein Residual after Manual and Automated Cleaning

Acceptance criteria per ISO 15883

Acceptance criteria: KRINKO guidelines

Total Protein Residual (μg)

8mm  Single Site  Stapler
n=18  n=96  n=15  n=99  n=15  n=63
Results

Total Residual Protein from mildly alkaline detergents and pH-neutral detergent

Test Sample - Mildly Alkaline Detergent
Negative Control - Mildly Alkaline Detergent
Test Sample - Neutral Detergent
Negative Control - Neutral Detergent

8mm | Single Site | Stapler
Results from Clinical Use

- All hospitals had total protein residuals of below 200ug.
- Hospital A-05: cleaning process was not followed and after corrections to the process validation, results are below 100ug.
- Data from hospital is consistent with validation data.
Results – Visual Inspection

- Post disassembly visual examination
- 40 8mm *da Vinci®* instruments from 11 hospitals
Results – Visual Inspection
Summary

- Reprocessing method for robotic instruments:
  - Straightforward
  - Effective
  - One process for all instruments
  - Multiple WDs validated
- Robotic instruments can be reproducibly and effectively reprocessed
  - Supported by laboratory validation data
  - Clinical data consistent with laboratory validation data
THANK YOU