Cleaning of Reusable Medical Devices
Dr. Michelle Alfa
A Webber Training Teleclass

Slide 1
CLEANING OF REUSABLE MEDICAL DEVICES
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Hosted by Paul Webber  paul@webbertraining.com

Overview:
- Basic Cleaning Concepts
- Overview of medical device issues
- Impact of suboptimal cleaning

Slide 3
What is Proper Reprocessing?
1. Cleaning:
   - Physical removal
   - Detergent effect
   - Temperature
   - Rinsing
2. Disinfection/Sterilization:
   - Killing of organisms
   - SAFE to use; no risk of disease transmission

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**Cleaning Process:**

- **Pre-rinse:** remove gross debris (soil)
- **Detergent (chemical or enzymatic):** improves ability to remove soil
- **Sonication:** physically "knocks” soil off device surface
- **Rinsing:** removes loosened soil & detergent
- **NOTE: Lubrication:** (after cleaning, before sterilization; where needed)

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**Step 1:**

**Cleaning Instructions**

- Obtain VALIDATED cleaning instructions from Manufacturer

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**Step 2:**

**CRITIQUE device**

- ? Can patient secretions enter areas of device you can’t visually inspect?
- ? Does cleaning process get fluid into ALL areas of device?

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Slide 7

<table>
<thead>
<tr>
<th>Device Constraints that Prevent Cleaning:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access of Fluid to ALL areas of device</td>
</tr>
</tbody>
</table>

Slide 8

<table>
<thead>
<tr>
<th>Step 3: Select Detergent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical (washer/disinfector) vs Enzymatic (sonicator, manual)</td>
</tr>
<tr>
<td>Tap water quality will affect choice (treated water source?)</td>
</tr>
<tr>
<td>Ensure Contact time is adequate (e.g. Enzymatic; 3-5 min, RT, minimum contact time)</td>
</tr>
</tbody>
</table>

Slide 9

<table>
<thead>
<tr>
<th>Step 4: Rinse Water</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOTS OF IT!!!</td>
</tr>
<tr>
<td>Tap water is O.K.</td>
</tr>
<tr>
<td>Rust/mineral deposits</td>
</tr>
<tr>
<td>Final rinse (e.g. Reverse osmosis water if possible)</td>
</tr>
</tbody>
</table>

NOTE: Lubrication: after cleaning but before sterilization (when recommended)
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Automated Vs Manual
- Automated is preferred:
  - consistency,
  - large volumes of fluid
  - temperature control
- Machines are only as good as their DRIVERS!!!

Slide 11
Manual Versus Automated Cleaning of Ported Laparoscopic devices

Slide 12
Cleaning Machine Test Methods; Available for in-hospital use
- TOSI:
  Protein/fibrin
  QA device for washers; visual inspection post-cleaning.

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Issues:

- Complex Device Design:
  - High Level Disinfection
    (Low margin of safety)
  - Steam sterilization
    (False sense of security)

Current Guidelines: "Visibly Clean"

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Repeated Use Build-up
(Device reused thousands of times/year)

- Want build-up kinetics as close to ideal as possible

How can this "Cleanliness level" be assessed??

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Sphinctertomes:

Rate of build-up dependent on:
device complexity & ease of cleaning
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Current Cleaning Benchmarks:

- Guidelines: "Visibly Clean"
- What is realistic??

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General Surgery:

- Surgical instruments:
- Hinges, serrated edges

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Orthopaedic Surgery:

- Bone Reamers:
  - device design
  - options exist

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Cardiovascular Surgery:

Balloon Catheters

Flexible Endoscopy:

“Critical” Devices pose highest risk of infection transmission

ENDOSCOPES ARE PROBLEMATIC!
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Laparoscopic Surgery
Ported or Not???

Slide 23

Laparoscopic Device Cleaning: Cleaning Validation

Is manual cleaning as effective as automated cleaning??

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Effect of Sonication on Cleaning of Protein in Laparoscopic devices

A) Non-ported; no fluid flow  B) Ported; fluid flow

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**So what if Cleaning is suboptimal??**

- Endoscopes: infection transmission
- Arthroscopes: increased infection rates
- Brain surgery: CJD transmission

### Slide 26

**Value of Cleaning**

Verification tests for users

- Washing Machine tests:
  - confirm proper function (QA)
- Medical device tests:
  - confirm that cleaning protocol used in-hospital is effective
  - confirm staff training and document competency over time

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**Guidelines:**

- CEN/ISO: working toward standardizing tests for users
- AAMI: guideline for manufacturer’s
  - recommending manufacturers provide rapid tests for users

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Summary:
- Device Complexity: Cleaning Issues
- Ensure Proper PROCESS in place
- Equipment
  - optimal cleaning capacity
  - monitor for functionality
  - sonication needs FLUID FLOW
- MANUFACTURER’S responsibilities
- FLUID FLOW>>>FLUID FLOW!!

Drowning in Cleaning Issues!!??

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