How important is the Cleaning Process for Laparoscopic Equipment?

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Current Challenges:
Reprocessing Medical Instruments

- Device Design & Manufacturer’s Validated Cleaning Instructions
- Reprocessing Personnel Competency
- Adequacy of reprocessing protocols
When you Look Closely
What do you see????

....I can’t believe my eyes!!!!
Narrow Lumen Cleaning:

What you don’t know can hurt you!!
Laparoscopic Accessory Devices

- Ported
- Non-ported
- Disassemble?
- Sonicate?
Laparoscopic Accessory Devices: Non-ported

Non-ported need Retro-flushing
Protein removal; Laparoscopic devices

A) Non-ported

I: Uncleaned-positive control
II: Manual cleaning
III: SI-Auto (ported device connected, non-ported device not connected)
IV: SI-Auto (Retro-flushed)
V: Negative control

B) Ported

I: Uncleaned-positive control
II: Manual cleaning
III: SI-Auto (ported device connected, non-ported device not connected)
IV: SI-Auto (Retro-flushed)
V: Negative control
Medical device specific instructions for Reprocessing

Cysto-ureteroscope
Cleaning Agents:

- Chemical detergents:
  - Alkaline, Acid, Neutral
- Enzymatic detergents:
  - single or multi-enzyme
  - contact time
  - protein solution (rinsing important)
- Accelerated Hydrogen Peroxide agents

The **specific formulation** determines efficacy; cannot compare across class of agents (e.g. not all enzymatic detergents are equally effective)
Survival of bacteria in enzymatic detergent

**Enterococcus faecalis**

![Graph showing the survival of Enterococcus faecalis in PBS and Pentazyme (1:128) over time.](image)

**Pseudomonas aeruginosa**

![Graph showing the survival of Pseudomonas aeruginosa in PBS and Pentazyme (1:128) over time.](image)
Soaking overnight at room temperature in enzymatic detergent will lead to biofilm formation!!
Cleaning of Medical Devices: Who is responsible for What??

- Manufacturer’s *validate* that instrument can be reliably cleaned and sterilized/disinfected and is therefore re-usable.

- Users *verify* that cleaning equipment is working and that in-hospital cleaning methods are consistently performed.
Cleaning Mechanics: 
Automated versus Manual

**Automated preferred**
(equipment must be maintained properly)

- Narrow lumen cleaners
  - immersion in wash liquid
  - ultrasonic, detergent, and fluid flow
  - self-decontamination (thermal or other)**

- Washer/Disinfectors
  - Spray for exterior, and lumen attachments
Final Rinse Water

- Tap water
- Treated water (e.g. Reverse osmosis, deionized water)
Water-associated Microorganisms

- Coliforms e.g., *E. coli*
- *Cryptosporidium, Giardia*
- Enteric viruses
- *Pseudomonas and other pseudomonads*
- *Legionella*
- *Mycobacterium*

Pictures from: Google Images
FDA Alert: “Use sterile water for rinsing or removing residual germicides from devices which have been processed using liquid chemical germicides. Do not rinse reprocessed device with tap water, which may recontaminate the device.”

http://www.fda.gov/cdrh/safety/061906-ultrasoundtransducers.html
Non-infectious Residuals on Medical Devices

Sterilized but organic material is still present (Sterile Crud)
- Endotoxin (LPS) from dead bacteria
- blood and organic debris from previous patient
- residuals from cleaning process
  (e.g. enzymatic detergent, water organisms etc).

- Contact with mucosal surfaces;
  e.g. flexible endoscopes
- Contact with sterile body site;
  e.g. MIS accessory devices
- Contact with ocular tissues;
  e.g. cataract surgery instruments
“Show Me the MONEY”!!

- STERILE Crud (organic residues)!!!
- No “infection” risk so what is the issue?
- Water quality... least of our worries!
- Cost/Benefit: What is realistic???
What evidence exists that sterile crud is problematic?

LPS adsorbed on surface of particulate wear debris contributes to inflammatory reactions that lead to aseptic loosening of implants.

[Xing et al. *Accumulation of LPS by polyethylene particles decreases bone attachment to implants*. J Orthopaedic Res 2006;24:959-966]
Toxic Anterior Segment Syndrome (TASS)

- Cataract surgery (large outbreak in USA; 2008)
- Early onset (12-24 hrs post-surgery) inflammation pain, blurred vision (limbus-to-limbus corneal edema)
- Non-infectious toxic agent enters anterior segment of eye during surgery and causes inflammatory reaction.

TASS: What causes it?

- Residual LPS (from tap water rinse) or residual organic material (e.g. enzymatic detergent) in cataract surgery instruments (e.g. Phaco tips)
- Cleaning and rinsing with sterile distilled water critical for ophthalmic surgery instruments.

Laparoscopic Instruments:

Current Approach:

.......Respond to problems when they occur!
Reprocessing of Medical Instruments is NOT a Race!

„Doc, you are showing us right now, how you clean, control, pack and sterilize your Scope in 30 minutes“!
SUMMARY:

Laparoscopic instrument Cleaning: Current Issues & Advances
- Manufacturer validated protocols
- Cleaning mechanics
- Cleaning agents

Investigate before problems occur:
- Washer efficacy
- Training/Compliance of Staff
- Adequate cleaning protocols**
Laparoscopic Instruments:

*Jump in to see the issues ......*

*But be sure to wear your goggles!*