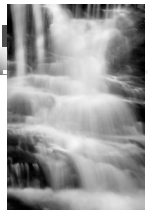
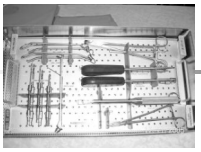
Water for Reprocessing of Medical Devices

Dr. Michelle Alfa, St. Boniface Hospital

A Webber Training Teleclass

Water for Reprocessing of Medical Devices:
My cup runneth over … but is it enough?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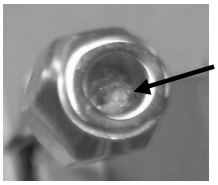
Cleaning Medical Devices

What you don't know can hurt you!!




Medical Procedures: Device Reprocessing

- **First: Do no Harm**
- **60's – 70's:**
  Age of Aquarius and Free Love???
- **New Millenium:**
  Age of the Internet and Litigation!!
  (The Public are informed and demanding more of HealthCare)

Current Challenges:

- Device Design & Manufacturer's Validated Cleaning Instructions
- Reprocessing Personnel Competency
- Water Quality…. is it really an issue???

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.

Water Quality Impacts:

- **Impact on Medical Devices:**
  - Damage: pitting, corrosion,→ loss of function
  - Reduction in cleaning efficacy
  - Interference with disinfection/sterilization efficacy
- **Impact on patient:**
  - Infection transmission
  - Adverse reaction; inflammation, fever

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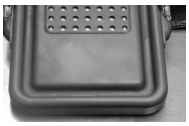
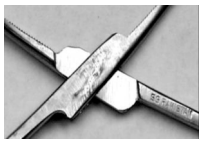
Impact on Medical Devices: Discoloration





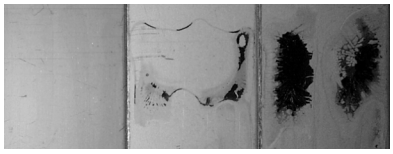
Impact on Medical Devices: Corrosion





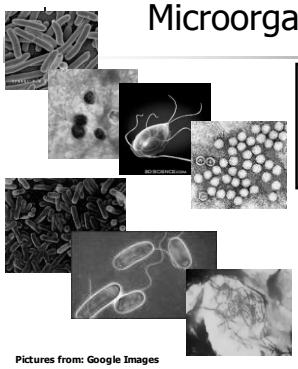
Impact on Device: Inefficient Device Reprocessing

- Same cleaning process, different quality of water



- Washer-disinfectors
  - increased foaming
  - blocking of spray jets

Water-associated Microorganisms



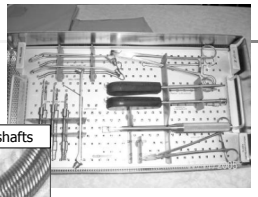
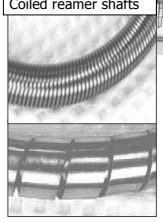
- **Coliforms**
  - **e.g., *E. coli***
- ***Cryptosporidium, Giardia***
- **Enteric viruses**
- ***Pseudomonas* and other pseudomonads**
- ***Legionella***
- ***Mycobacterium***

Pictures from: Google Images

Residuals on Medical Devices

- 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

Orthopaedic Instruments



Coiled reamer shafts

Crud from between coils

Alternative: solid shaft

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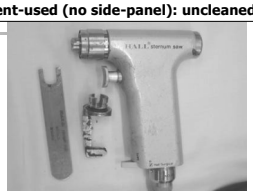
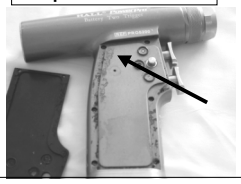
Hand pieces: residual crud

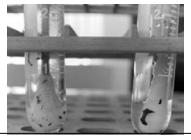
- Under side-panel
- Inside connector ring

Patient-used (no side-panel): uncleaned



Patient-used repeatedly; side-panel removed





Patient-impact of Water Quality: What can I do to address this??

1. What are the adverse patient-impacts ?
2. What steps are needed to ensure adequate water quality for medical device reprocessing?

New Developments: Manufacturer's Instructions:

- AAMI ST81, EN ISO 17664, (CSA 17664) Guidance documents now require medical device manufacturers provide at least one manual and one automated validated cleaning protocol
- USERS: refuse to order/pay for medical device until validated cleaning protocol provided by manufacturer

"Show Me the MONEY"!!

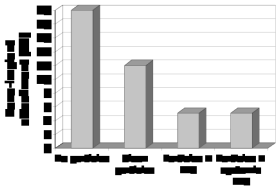
- STERILE Crud!!!
  - Acetabular reamers
  - Electronic drill handpieces
- No "infection" risk → so what is the issue?
- Water quality… least of our worries!
- Cost/Benefit: What is realistic???

Residuals: Ineffective cleaning/rinsing

- Foreign organic material
  - Endotoxin (LPS) from dead bacteria
  - blood and other organic debris from previous patient or from cleaning process (e.g. enzymatic detergent residuals, water organisms etc).
- Can it get "Out/Off" of device into patient??

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



Orthopedic Implanted Screws

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

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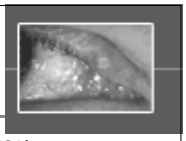
Toxic Anterior Segment Syndrome



- Cataract surgery (current outbreak in USA)
- 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.
- 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.

Recommended practices for cleaning and sterilizing intraocular surgical instruments. J Cataract Refract Surg 2007;33:1095-1100.

Ultrasound Transducer Assemblies; Biopsies

- 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

What to do….What to do????

….Just when you thought the water was safe!!!!

AAMI TIR34:

Water for the reprocessing of medical devices

Association for the Advancement of Medical Instrumentation

Abstract: This Technical Information Report (TIR) covers the selection and maintenance of effective water quality suitable for reprocessing medical devices. It provides guidelines for selecting the water quality necessary for the reprocessing of categories of medical devices and addresses water treatment equipment, water distribution and storage, quality control procedures for monitoring water quality, strategies for bacterial control, and environmental and personnel considerations.

Four Essential Steps

Step	Procedure
1	**Assessment of water quality**
2	**Implementation of water treatment process**
3	**Assurance of proper water quality for the various stages in medical device reprocessing**
4	**Ongoing monitoring of water quality**

Water Quality Document: AAMI

- **Big picture issues:**
  - water assessment
  - tap water: ?needs treatment or not
- **Water quality for various stages/types of medical device reprocessing**
  - tap water
  - softened water
  - Deionized, or Highly treated water (e.g. treated with deionization, carbon filter, reverse osmosis & sub-micron filtration)

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AAMI FDS/TIR34

	Potable water	Softened water	Deionized water	High-purity water (RO or distilled)
Primary uses for medical devices				
Critical	Precleaning, cleaning	Precleaning, cleaning	Precleaning, cleaning, rinsing	Rinsing
Semicritical	Precleaning, cleaning, rinsing	Precleaning, cleaning, rinsing	Precleaning, cleaning, rinsing	Rinsing
Noncritical	Precleaning, cleaning, rinsing	Precleaning, cleaning, rinsing	Precleaning, cleaning, rinsing	
Primary uses for reprocessing methods	Pasteurization (if recommended by the device manufacturer) Input water for some types of washer-disinfectors	Pasteurization Input water for some types of washer-disinfectors	Pasteurization Input water for some types of washer-disinfectors Input water for steam, ethylene oxide, and ozone sterilizers	Input water for some types of washer-disinfectors

If Treatment of Potable Water is Needed

Ongoing Monitoring of Water: Impact on Device Reprocessing Personnel??

Characteristic	Category of water	Type of testing	Sample site	Samples taken and analyzed	Suggested frequency of testing
Bacteria	High-purity	Heterotrophic plate count[2] (see Annex D)	Reprocessing area, storage tanks (if used), immediately downstream of water treatment process	Maintenance personnel	Monthly
Endotoxin	High-purity	LAL test	Reprocessing area, storage tanks (if used), immediately downstream of water treatment process	Maintenance personnel	On installation, modification, or repair of the high-purity water treatment system or when persistent increased microbial levels are detected by heterotrophic plate count, ATP, or TOC
Total organic	High-purity	TOC test	Reprocessing area	Maintenance personnel	Monthly or quarterly
pH	Potable, softened	pH meter Colorimetric dipsticks	Reprocessing area Reprocessing area	Maintenance personnel Reprocessing personnel	Monthly Monthly

Conclusions

- What is "Water Quality"?
  - Chemical content
  - Microbial content
  - Organic content
- Adverse Effects:
  - Devices: Do you see problems (e.g., rusting, spotting)?
  - Patients: infections, inflammatory response
- Basic 4 steps
  - Assess, Treat (if necessary), Assure, Maintain
- Common water qualities used
  - Potable, Softened, Deionized, Highly Treated (e.g. RO, distilled)
- Monitoring Water Quality

Water Issues aren't all BAD!

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