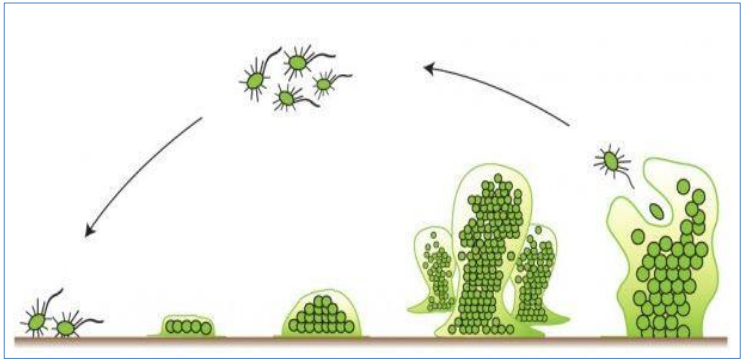
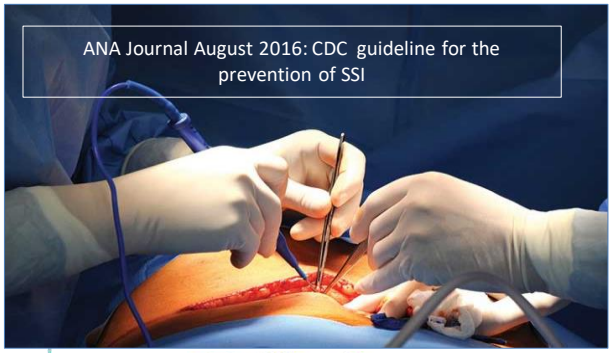
Complex design of surgical instruments as barrier for cleaning effectiveness, favouring biofilm formation

L.K.O. Lopes et al. 2018. Roel Beltran Castillo - Presenting Author

Introduction: Reprocessing, biofilm, surgery and SSI



Ana Sayfa et al. DiaTech: Biyofilm Nedir?



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***Aim*:**

Determine the cumulative effect on high-complex-design reusable surgical instruments (RSI) used for orthopaedic surgery after 20 cycles of:

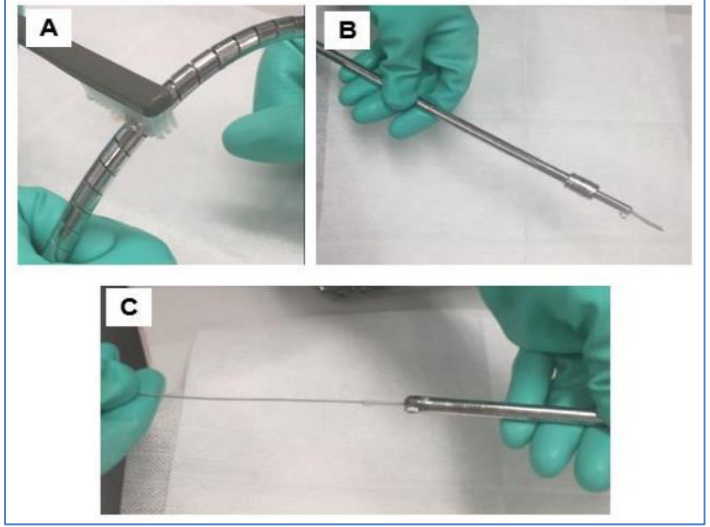
Contamination – TSB +S. aureus + sheep blood

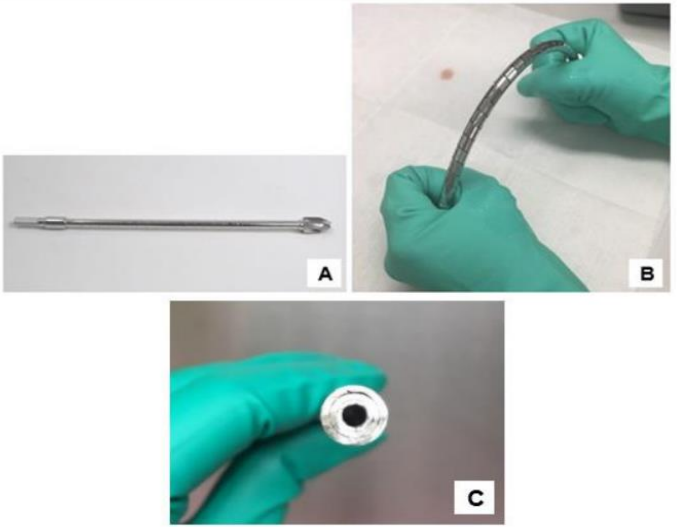
Cleaning – via 3 group methods

1. Rinse only
2. Manual
3. Manual + Automated

Steam Sterilisation -

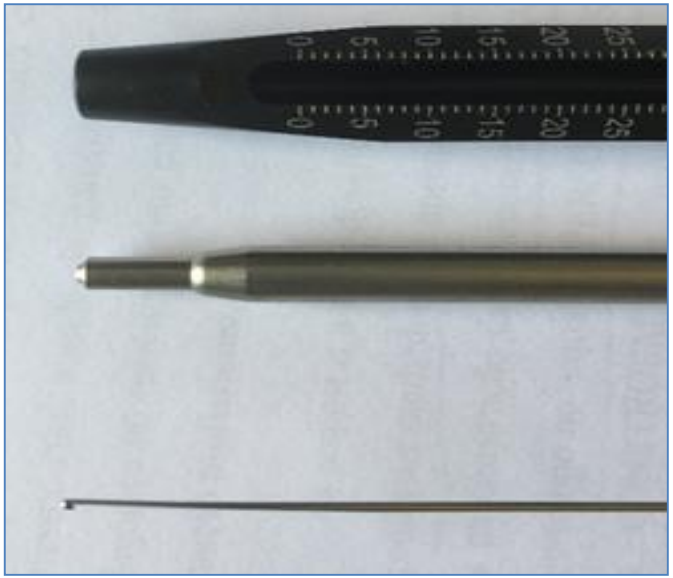
Materials :

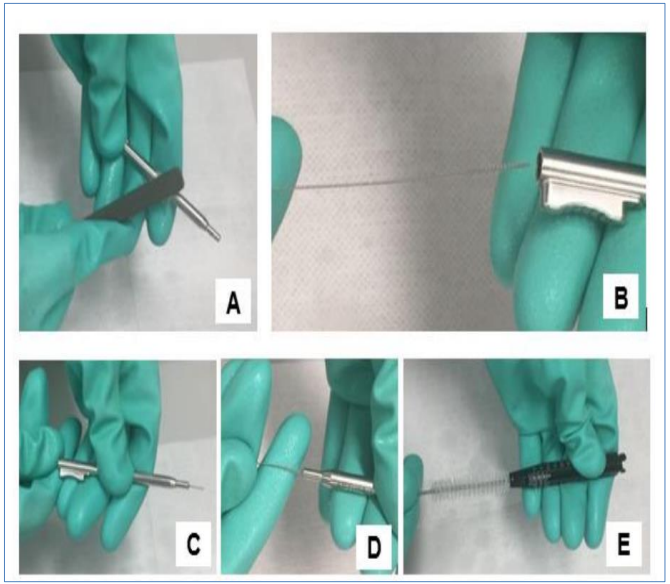




Flexible medullary reamer (FMR) - Implantec®, Implantes Materiais Médicos & Hospitalares Ltda, Belo Horizonte, Brasil.

Materials :





Depth Gauge (DG) - APTUS® - Medartis, Basel, Switzerland.

Methods:

Surgical instrument contamination- for each group of test RSI

- Contamination by immersion for 5 minutes

- Contaminant = 250 mL of TSB,
  - Staphylococcus aureus 109 CFU/ml
  - 5% sheep blood

- Dried at room temperature for 7 hours

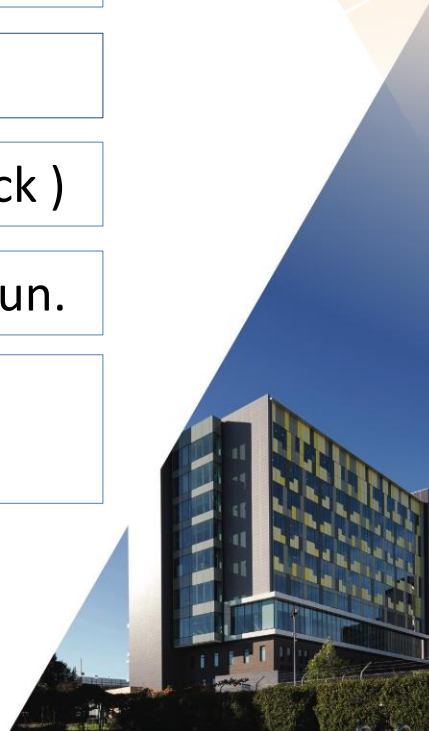
Methods: After contamination – proceed to each 3 cleaning groups:

Surgical instrument reprocessing: **Group 1 - Rinsing Only**

- RSI were rinsed with distilled water for 30 seconds
- Dried with a sterile non-woven fabric.

Methods: Surgical instrument reprocessing: **Group 2 - Manual cleaning**

- Rinsed in distilled water - 30 seconds
- Soaked in enzymatic detergent - 5 minutes
- Surface brushed - 5 repetitions
- Soft bristle brush on lumens - 5 repetitions (through and back)
- Surface rinsed - filtered tap water/Lumen rinsed - tap water gun.
- External surface – dried sterile non-woven fabric
- Lumen – dried using medical air



Methods : Group 3 Manual plus automated cleaning:

- RSI - rinsed and manually cleaned as described in group 2 protocol
    - Rinse – filtered water
    - Soak – enzymatic detergent
    - Scrub – surface and lumen
    - Rinse – filtered/tap water
- The lumened section of the DG and the FMR were subjected to ultrasonic cleaning
- Instruments were placed in a washer disinfector cycle

Methods: Following cleaning

- Three RSI/group randomized - tested ATP contamination
  1DG/1FMR from each cleaning Group

- All instruments - packed into medical surgical grade peel pouches

- Sterilized at 134 C for 3 minutes and 30 seconds.

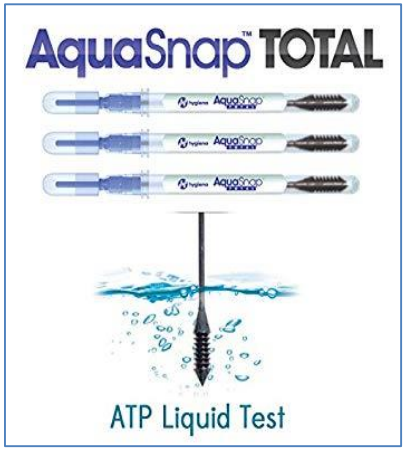
All test instruments:

- **Re - contaminated with the same contamination method**
- **Subjected to reprocessing = 20 times**

Methods: Detection of Residual Soil following cleaning:

Adenosine Triphosphate (ATP) detection:

Lumen - AquaSnap total™ ATP Detection Device for Water



25 RLU benchmark

External ATP - ATP LuciPan Pen™

115 RLU benchmark

Methods: Detection of Residual Soil following reprocessing:

Protein contamination: 10th and 20th reprocessing cycle

Randomised from each cleaning group

3 x DG per group

3 x FMR per group

Methods: Detection of Residual Soil following reprocessing:

Microbial Load determination:

- After the 10th and 20th sterilisation

- Immersion
- Sonication – 42-47 khz
- Dilution
- Incubation

Methods: Detection of Residual Soil following reprocessing:

Scanning Electron Microscopy (SEM):

- Aseptically sectioned
- Performed in a biological safety cabinet
- Sterile blade/sterile non woven fabrics

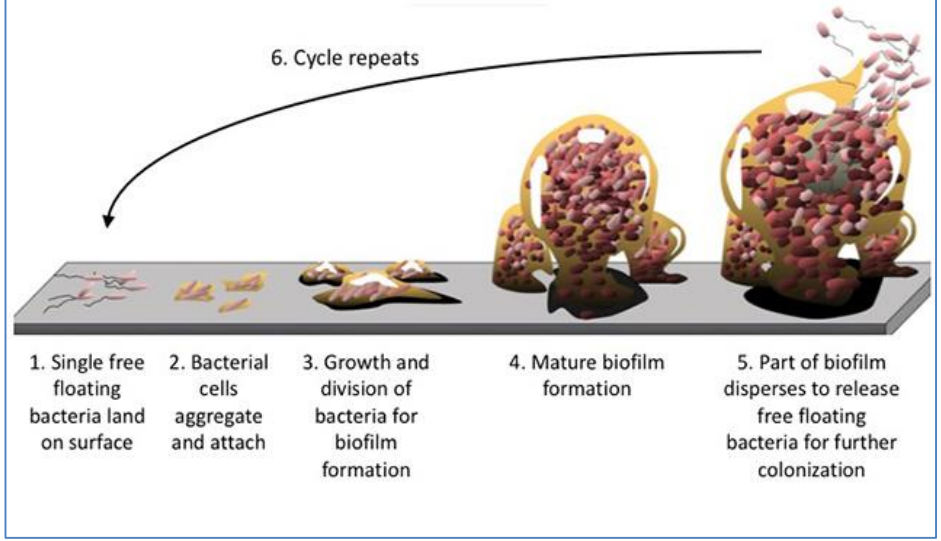
- FMR, inner layer analysed.
- DG hook and lumen cross sectioned.

Methods : Further Scanning Electron Microscopy (SEM):

The following surgical instruments were analysed:

- One new FMR subjected to reprocessing (manual plus automated cleaning and steam sterilisation - negative control)
- 1 FMR & 1 DG - contaminated with TSB and 5% sheep blood
- One FMR and one DG from each reprocessing protocols:
  - Group 1 – rinsed only
  - Group 2 – manual cleaning
  - Group 3 – manual cleaning and automated cleaning

Methods : Scanning electron microscopy (SEM): Biofilm



The life cycle of a biofilm. Credit: Bay Area Lyme Foundation.

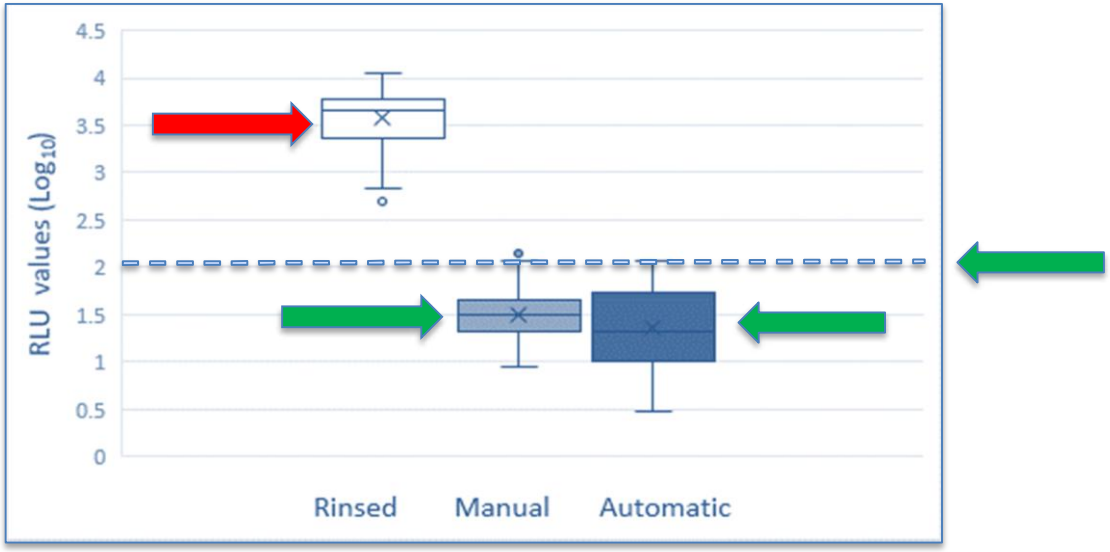
Biofilms are defined as "a community of bacteria attached to a surface and each other and surrounded by extracellular polymeric substances (EPS) that is produced by themselves". - Deva et al. The role of bacterial biofilms in device-associated infection. Plast Reconstr Surg 2013

Methods: Data analysis:

- ATP readings between multiple treatments a Kruskal- Wallis One Way ANOVA combined with the Tukey all pairwise multiple comparison was used.

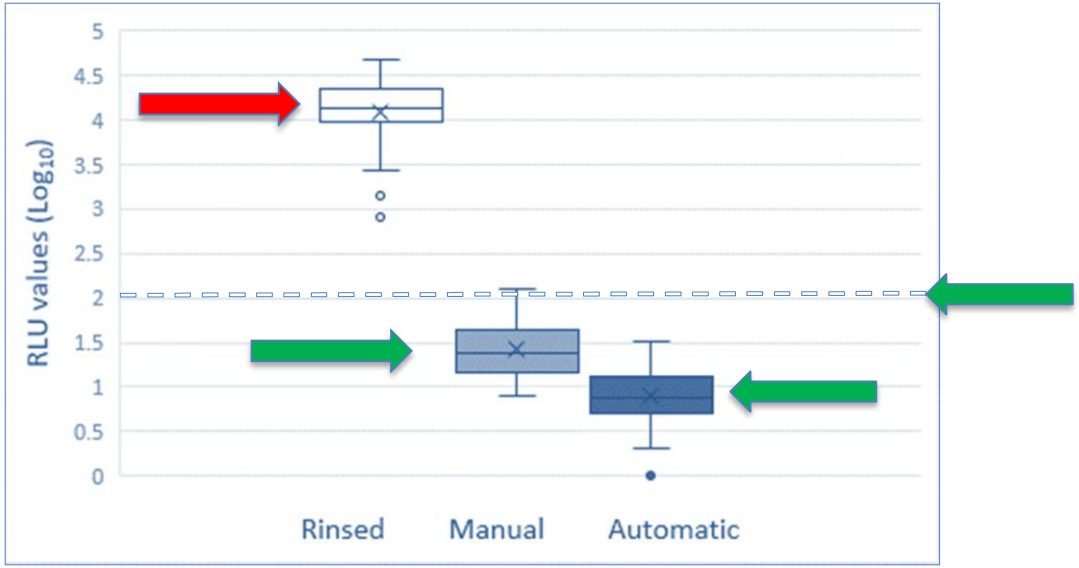
- Protein contamination between treatments, a Student's t-test was used. SigmaPlot and *IBM SPSS Statistic View* version 21

Results: Depth Gauge over 20 Cycles



Amount of residual soil (ATP) - Figure 1. A

Results: Surface of Flexible Medullary Reamer over 20 cycles



Amount of residual soil (ATP) - Figure 1. B

Results: Detection of ATP in Lumens

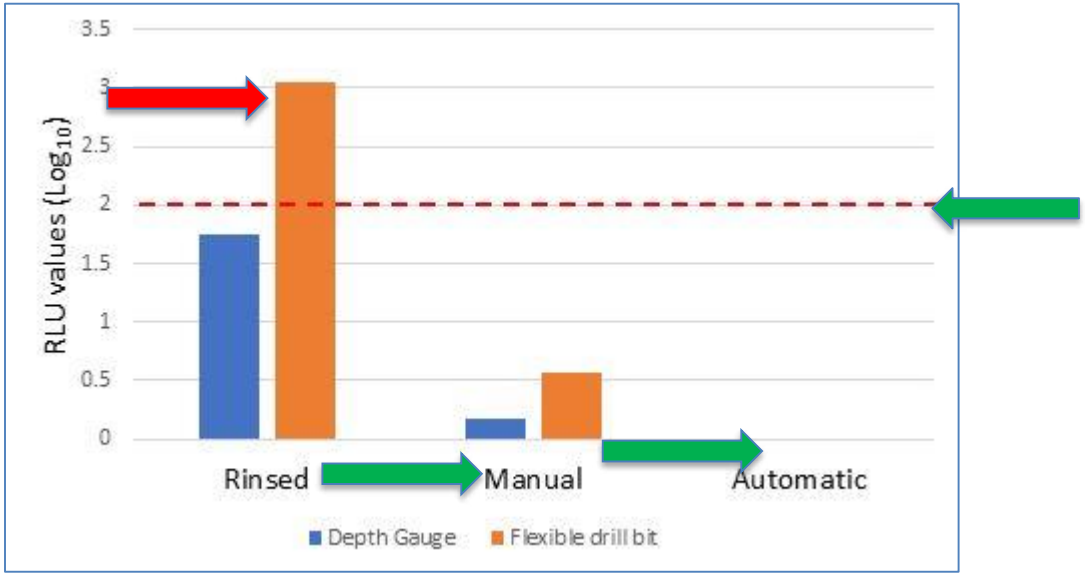


Figure 2 - Lumens

Results: Protein Contamination Group 1 rinse only

After 10th Reprocessing in µg/mL	After 20th Reprocessing in µg/mL
Depth Gauge – • Mean = 1,380 • Range = 420 – 2,341	Depth Gauge – • Mean = 1,212 • Range = 685- 1,739
Flexible Medullary Reamer – • Mean = 2,191 • Range = 1,576 – 2,876	Flexible Medullary Reamer – • Mean = 3,891 • Range = 2,645 - 5,137

Protein was not detected in Groups 2 & 3

Flexible Medullary Reamer by SEM: Clean (new) V. Contaminated

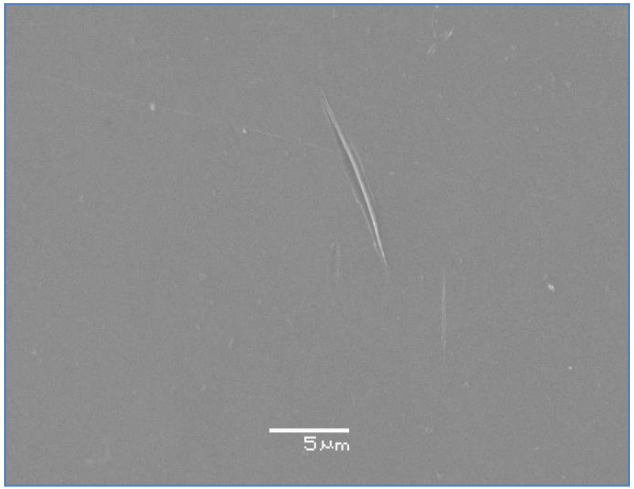


Fig. 3A. Without contamination

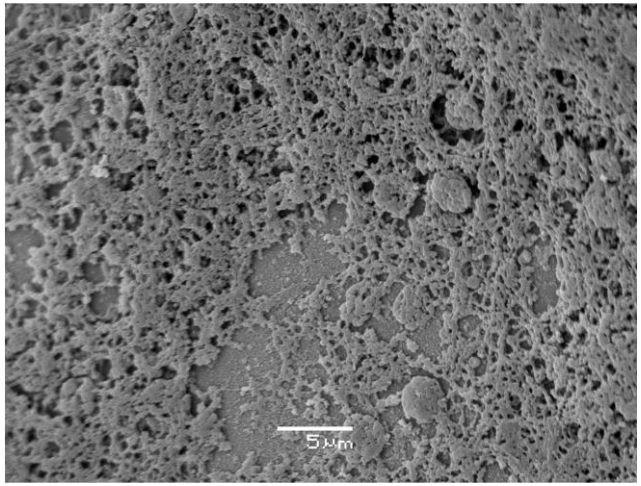


Fig 3B. TSB contaminated

Results: SEM - Depth Gauge after 20 cycles

Group 1 – Rinse Only + Sterilisation = biofilm formation

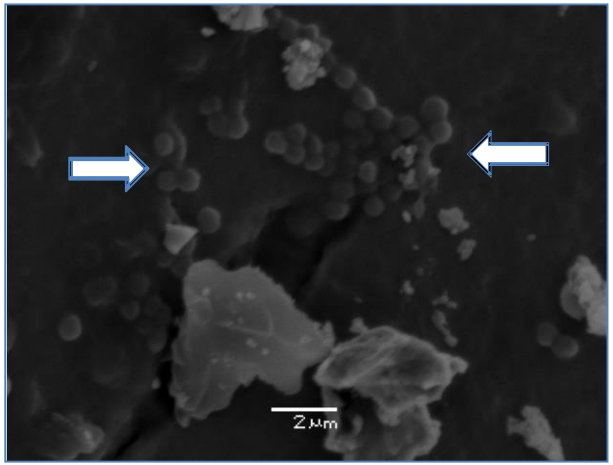


Fig. 4A – Lumen

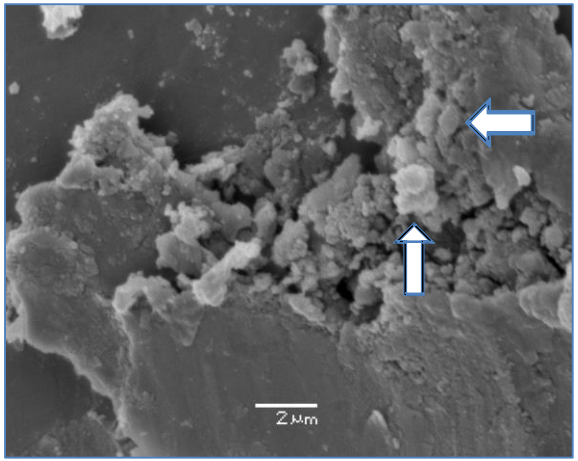


Fig. 4B – Hook

Results: SEM - Depth Gauge after 20 cycles

Group 2 – Manual Cleaning + Sterilisation = biofilm formation

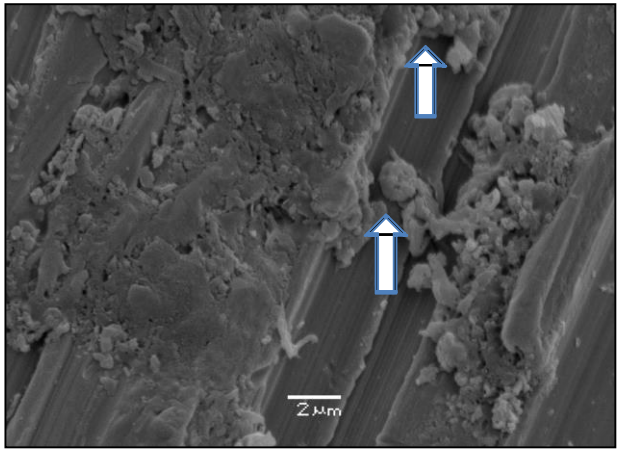


Fig. 4 C – Lumen

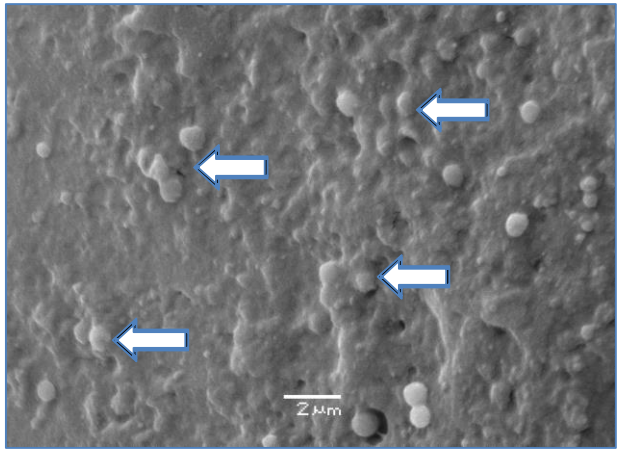


Fig. 4 D - Slim part

Results: SEM - Depth Gauge after 20 cycles

Group 3 – Manual + Automated Cleaning + Sterilisation = biological deposits

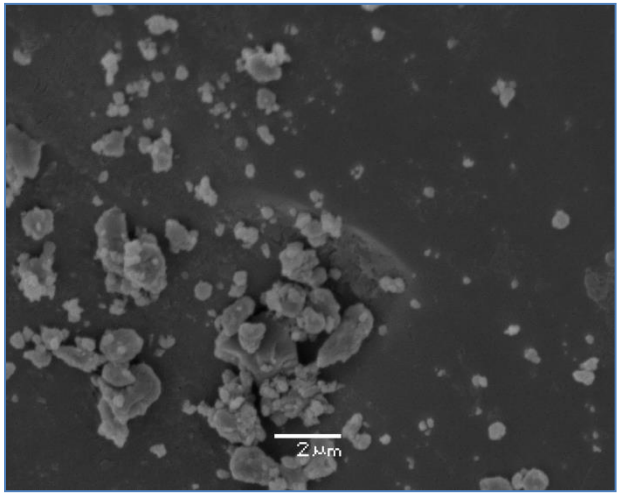


Fig. 4 E – Lumen

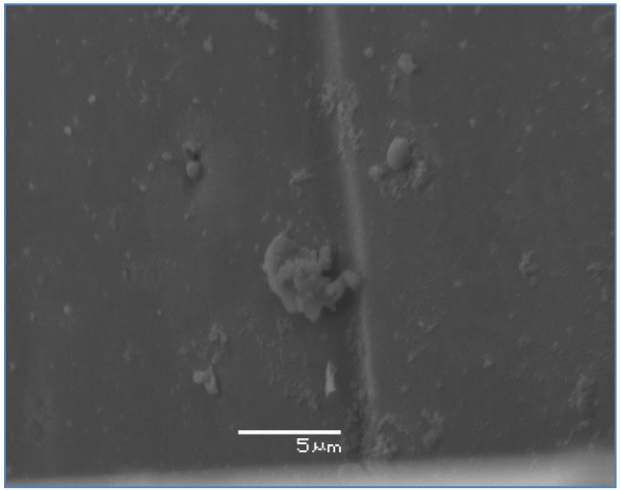
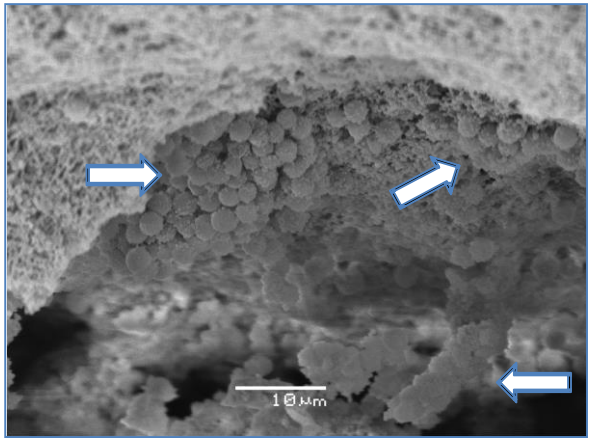


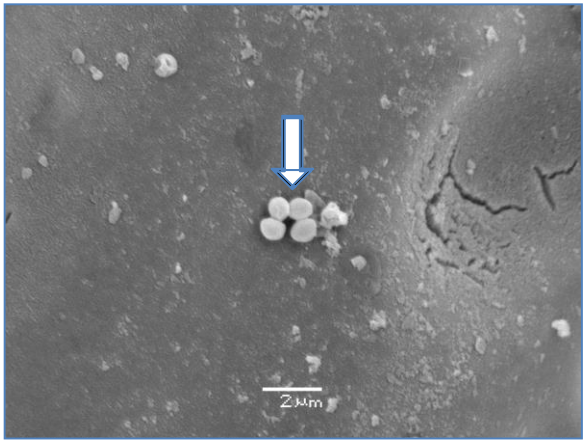
Fig. 4 F – Slim part

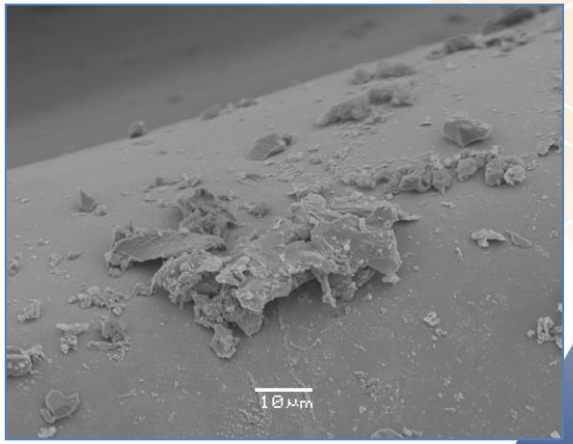
Results: SEM – FMR inner layer : 20 X contamination + cleaning + sterilisation



5 A. Rinse only

5 B. Manual Cleaning





5 C. Manual + US + WD

Other clinical publications supporting these findings:

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- Costa DM, Lopes LKO, Tipple AFV, Johani K, Hu H, Deva AK, et al. Evaluation of stainless steel surgical instruments subjected to multiple use/processing. Infection, Disease & Health. 2018

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Results: Manual Cleaning after 20 cycles = biofilm formation

Group 2 – Manual Cleaning + Sterilisation

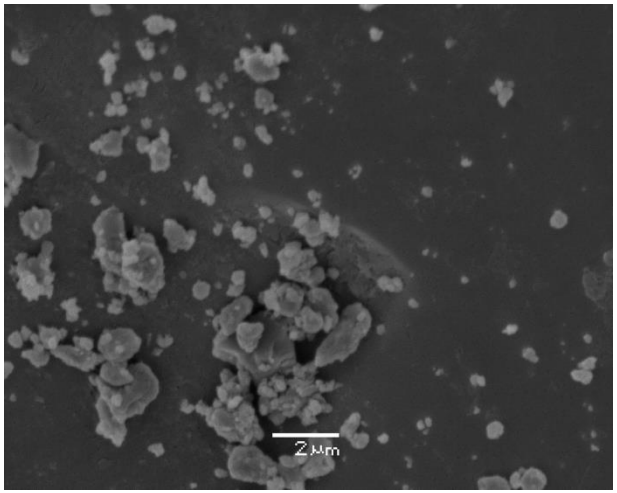

Fig. 4 E – Lumen

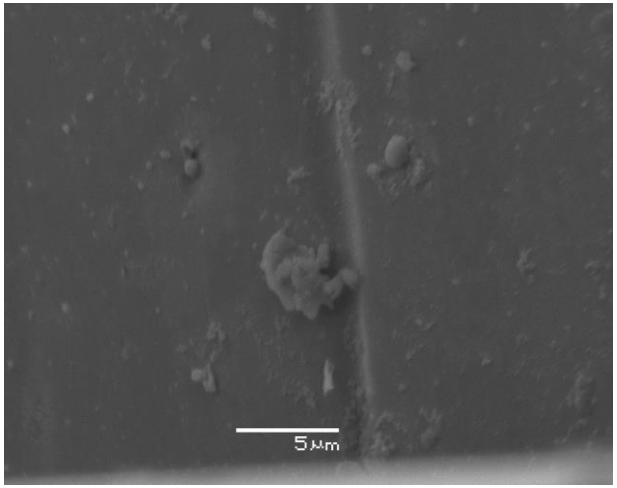

Fig. 4 F – Slim part

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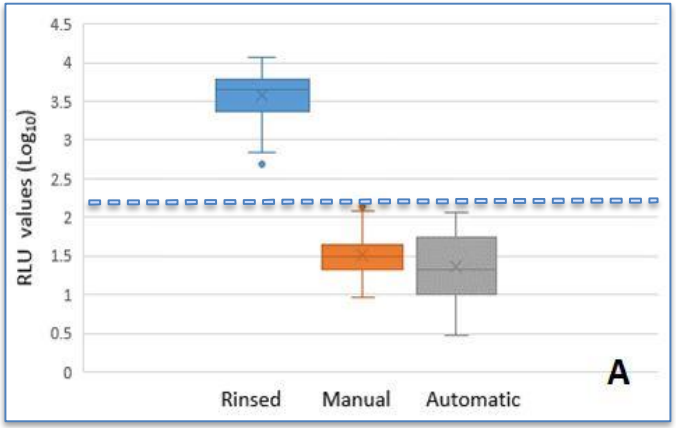
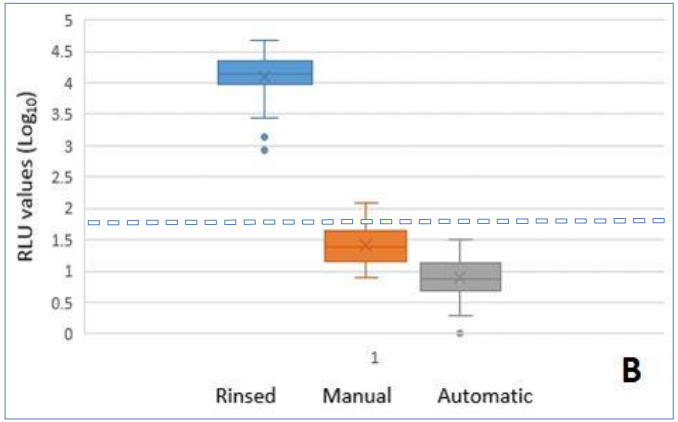
Results: Residual Soil – presence of ATP



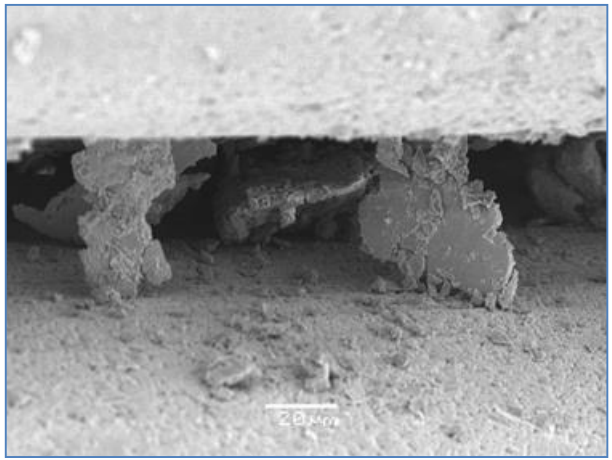


Depth gauge

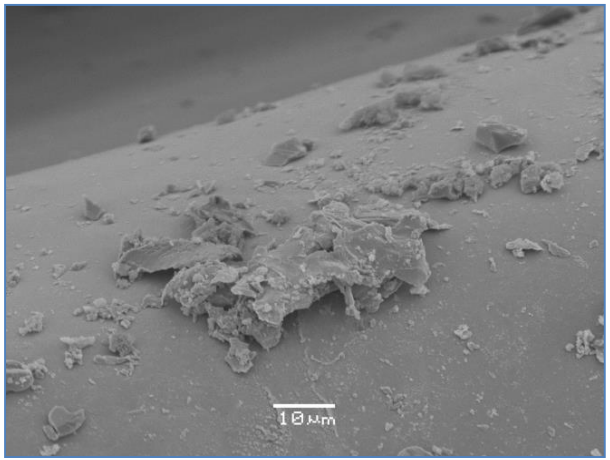
F M R

Methods: After 20 cycles of recontamination + reprocessing = Soil Presence

Group 3 – Manual + Automated Cleaning + Sterilisation



FMR - Figure 5 E



FMR - Figure 5 F

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Conclusion:

- Soil and/or biofilms were evident on complex-design RSI following 20 cycles of contamination and reprocessing, even using stringent method of cleaning.

- Although the depth gauges are disassembled during cleaning, biological residues and biofilm accumulated in its lumen.

- The current design of these RSI prevents removal of all biological soil and this may have an adverse effect on patient outcome.

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Take home:

- The critical importance for medical device manufacturers provide a validated instructions for reprocessing (IFU) to CSSD/SP
- Vigilance in following correct instructions for reprocessing and associated training and competency of CSSD/SP
- This outcome lobbies for more stringent requirement that regulatory bodies

The team makes it happen and do their best to save patients















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Thank you all for your time

https://researchers.mq.edu.au/en/publications/complex-design-of-surgical-instruments-as-barrier-for-cleaning-ef

Special thanks to:
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and Karen Vickery
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Macquarie University Hospital CSSD
AHCL – Sydney Adventist Hospital Perioperative Leadership Team
Karen Reimer, David Billings
Sydney Adventist Hospital Sterile Processing Team

My family:
Cathy
Chakri, Miguel, Paulo, Noah and Gabriel

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