



A.I.M. Clear Flush® Kerrison

Cleaning Validation Test

Conducted By:

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At Midbrook BioMedical On:

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Introduction

Midbrook BioMedical received a request from Mr. James Schneiter of AIM to perform decontamination and cleaning validation testing on AIM's patented Clear Flush® Kerrisons (<http://www.aimclearflush.com/>) with the Midbrook Tempest Washer. The test was designed to see if the Tempest Washer could thoroughly decontaminate and clean the Clear Flush® Kerrisons after they had been completely contaminated with Artificial Test Soil (ATS) and allowed to sit for twenty-four (24) hours without manual pre-flushing, pre-soaking, or manual pre-washing.

Procedure

Midbrook BioMedical received six (6) Clear Flush® Kerrisons (ranging in size from 1mm to 6mm) from AIM for cleaning validation and verification in Midbrook Medical's Tempest Washer. AIM shipped the instruments with the top bar removed to provide easy access to the internal surfaces for inoculation and testing. AIM Clear Flush® Kerrisons are not designed to be disassembled (i.e., they are not a 'take-apart' style Kerrison) and disassembly during normal use is discouraged in the Instructions For Use (IFUs). After receiving the instruments, pictures were taken of each one prior to any inoculation or cleaning in order to establish a baseline for post-testing comparison.

All instruments were then seeded both inside and out with Healthmark's Artificial Test Soil (ATS) containing hemoglobin, protein and carbohydrate to simulate the types of bioburden most frequently encountered in surgical cases. Following the guidelines outlined in AAMI TIR#12, the ATS serves as the inorganic/organic challenge for this test protocol. The instruments were then left for twenty-four (24) hours to allow the Test Soil to dry and harden on the outsides and insides of the instruments to simulate a 'worst case' reprocessing scenario. After the twenty-four (24) hour mark, more pictures were taken of the instruments in order to show that the Test Soil was present and had thoroughly dried and hardened on the instruments.

After the Clear Flush® Kerrisons were photographed with the dried and hardened Test Soil, they were reassembled for decontamination and cleaning (again, these instruments are not 'take-apart' style instruments and they were only disassembled for the purpose of this test). The instruments were then put into the Tempest Washer and were connected to the Tempest Washer's pressure infusion hoses using Midbrook's exclusive infusion fixation devices.

Once all of the Clear Flush® Kerrison infusion ports were connected to the pressure infusion hoses, the Tempest Washer was run through the standard, automatic cannulated cycle (please see the 'Additional Information, Pictures and Test Results' section for a full cycle breakdown). The jaws of the flushable Kerrisons were in the open, normal position during the entire cleaning cycle. Upon completion of the standard cleaning cycle inside the Tempest, the instruments were air-dried, inspected, and post-cleaning pictures were taken to document the results.

Equipment

- 6 Clear Flush® Kerrison Rongeurs 8" length, 40 degree up, coated:
 - A70-0162FP (1mm)
 - A70-0330FP (2mm)
 - A70-0332FP (3mm)
 - A70-0334FP (4mm)
 - A70-0336FP (5mm)

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- A70-0338FP (6mm)
- Tempest Washer
- Healthmark Artificial Test Soil (ATS), containing hemoglobin, protein, and carbohydrate
- Sterile Water
- Syringe
- Camera

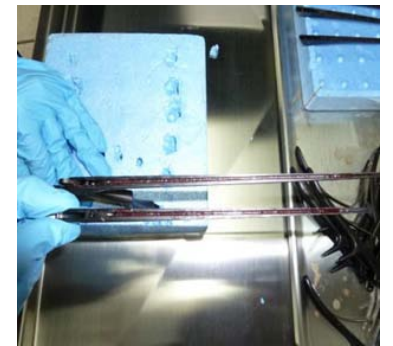
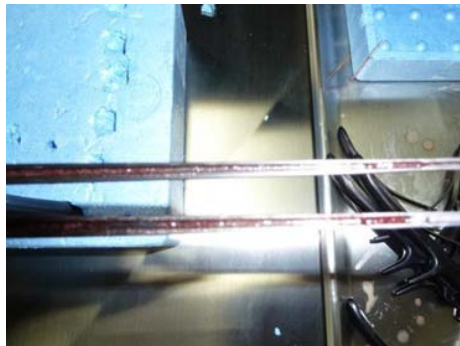
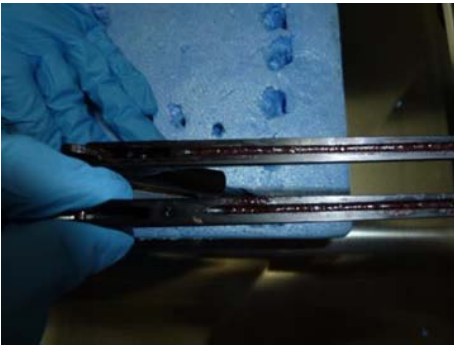
Results

A70-0162FP (1mm)

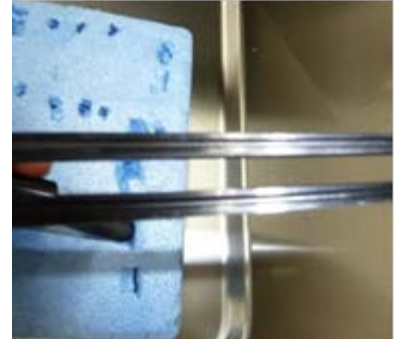
Pre-Inoculation



Post-Inoculation



Post-Wash

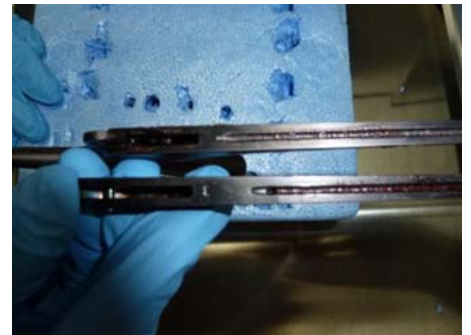
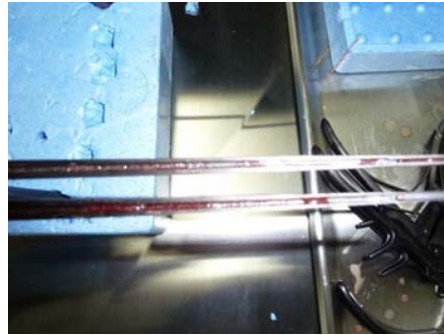
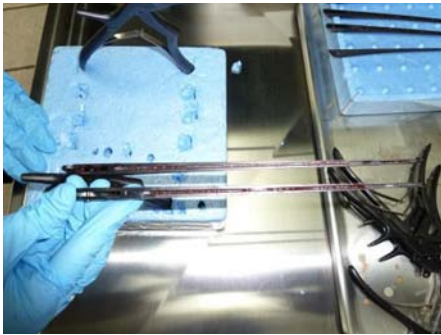


A70-0330FP (2mm)

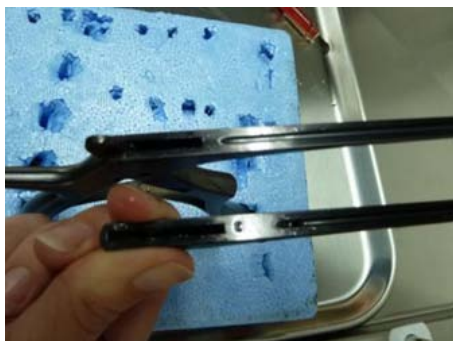
Pre-Inoculation



Post-Inoculation



Post-Wash

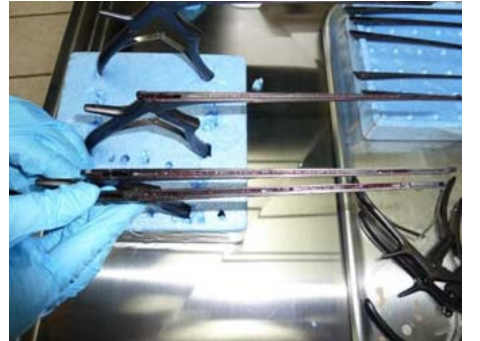
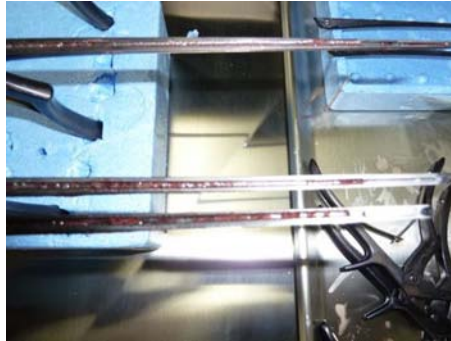


A70-0332FP (3mm)

Pre-Inoculation



Post-Inoculation



Post-Wash

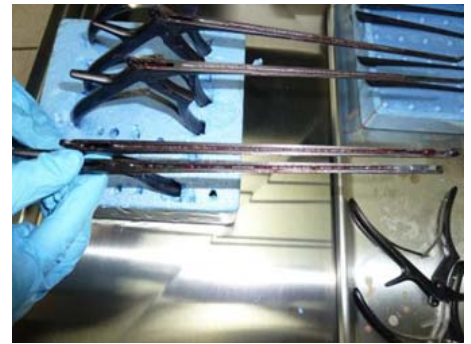
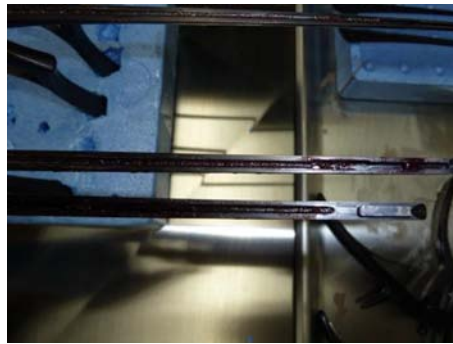
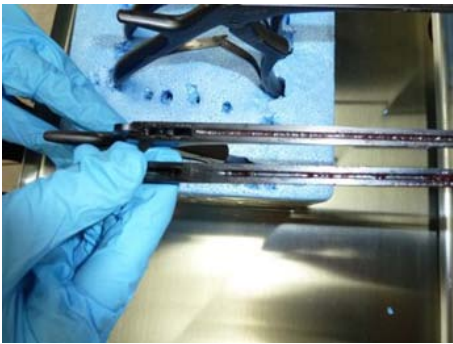


A70-0334 (4mm)

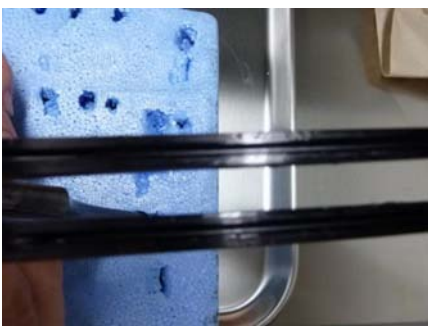
Pre-Inoculation



Post-Inoculation



Post-Wash

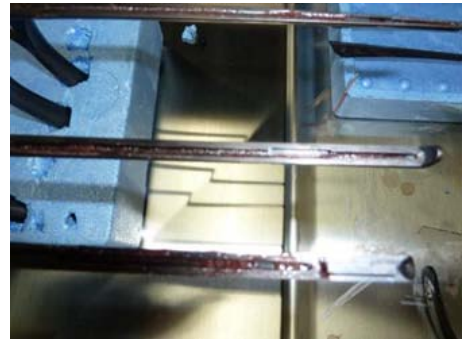


A70-0336FP (5mm)

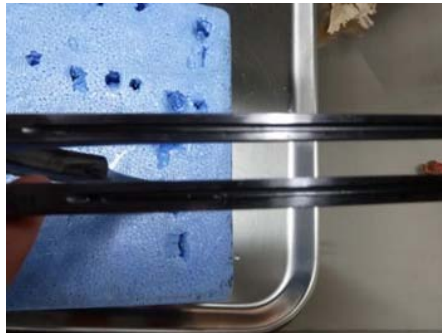
Pre-Inoculation



Post-Inoculation



Post-Wash

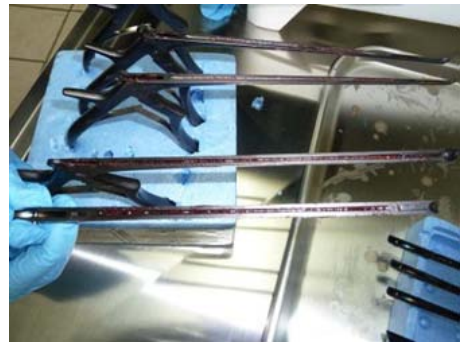
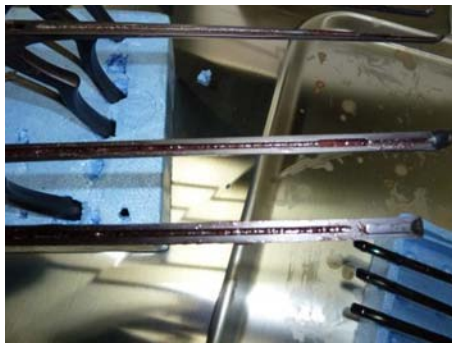
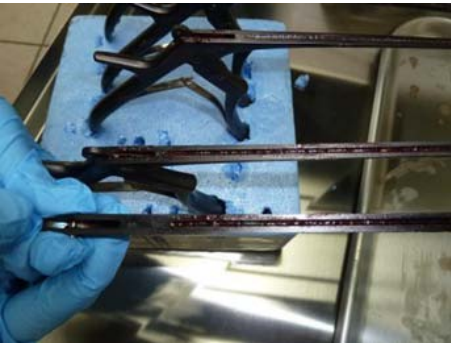


A70-0338 (6mm)

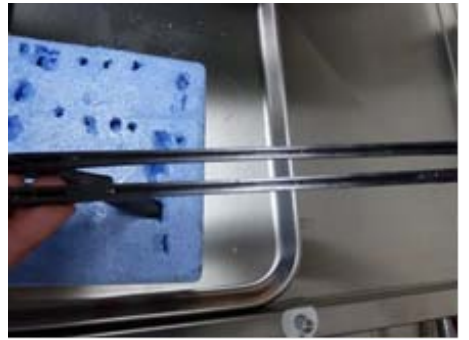
Pre-Inoculation



Post-Inoculation



Post-Wash



Additional Information, Pictures, and Test Results

The Tempest's three cycle hydro jet flushing coupled with the patented internal venturi design of the flushable Clear Flush® Kerrison forces all of the test soil, water and enzymatic cleaner out of the open distal tip of the instrument. The varying sonication and agitation action of the Tempest coupled with the exclusive internal fluid dynamics of the Clear Flush® Kerrison removed one-hundred percent (100%) of the dried, encrusted test soil on every instrument.

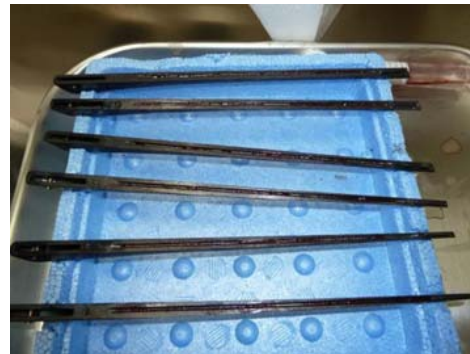


Arrangement and connections of the Clear Flush Kerrisons® inside the Tempest Washer

As can be seen in the photos below, all of the Clear Flush® Kerrisons are connected to the pressure infusion hoses using Midbrook's exclusive infusion fixation devices.



After Inoculation



Standard Tempest Cannulated Cleaning Cycle (Approximately 32 minutes):

- Bath fills with enzymatic cleaner and 120°F tap water
- Instrument lumens are infused with enzymatic cleaner to soak
- First hydro jet flushing (scrubbing bubbles) for the internal lumen of the instruments
- Concurrent ultrasonic cleaning for the outside of the instruments
- Second hydro jet flushing of the internal lumen of the instruments
- Concurrent ultrasonic cleaning for the outside of the instruments
- Third hydro jet flushing of the internal lumen of the instruments
- Bath is drained of all residual fluids
- Instruments rinsed with 190°F tap water both outside and inside
- Exterior cool down rinse with ozonated water to supplement previous thermal disinfection
- Fluid stream ceases and remaining water is drained from the tank hood

Test Results

The Tempest Washer removed one-hundred percent (100%) of the inoculated Artificial Test Soil (ATS) containing hemoglobin, protein, and carbohydrate after drying for twenty-four (24) hours from all six Clear Flush® Kerrisons.

The twenty-four (24) hour inoculation period was design to replicate a ‘worst case’ scenario from the start of a surgical procedure, the duration of a procedure (up to 14 hours for a liver transplant), transport to decontamination and the eventual start of the cleaning process.

Conclusion

This validation testing confirms that a Midbrook Tempest Washer combined with the flushable Clear Flush® Kerrisons is the new standard for instrument reprocessing and reduced patient risk from a contaminated instrument.

For more information on these innovative products, go to Midbrook’s web site at <http://www.midbrookmedical.com/> or AIM’s web site at <http://www.aimclearflush.com/>