Finally, ‘Validated Clean’ Kerrison Rongeurs For Every Patient, Every Time.

Surgeons, O.R. nurses, reprocessing personnel, and instrument manufacturers have long known that conventional Kerrison Rongeurs are the dirtiest, most difficult instrument to decontaminate and clean in a neuro-surgical case. Now, with the introduction of the world’s only ‘flushable’ Kerrison Rongeur, and the use of the innovative Tempest Washer, there is no need to disassemble, manually clean, and reassemble the Kerrison for effective reprocessing.

Jackson, MI (PRWEB) July 10, 2014 -- Introduction:
With the average cost to treat a surgical infection now at $20,785.00 [i] and with over 16,500 patient deaths annually from surgical infections, [ii] the pressure is on hospitals to reduce their patients’ risk. Inadequate cleaning of difficult-to-clean surgical instruments has resulted in cross-contamination and surgical site infections.[iii]

Conventional Kerrison Rongeurs are examples of difficult -- or even impossible -- to clean surgical instruments. These instruments are especially challenging to reprocess. Surgeons, O.R. nurses, reprocessing personnel, and instrument manufacturers have long known that conventional Kerrison Rongeurs are the dirtiest, most difficult instrument to decontaminate and clean in a neuro-surgical case.

Midbrook BioMedical received a request from Advanced Instrumentation for Medicine (AIM) to design and conduct a ‘worst case’ scenario decontamination and cleaning validation test on AIM’s unique, flushable Clear Flush® Kerrisons utilizing the patented Tempest Washer. The test was designed specifically to see if the Clear Flush® Kerrisons could be completely decontaminated and cleaned with the Tempest Washer after the Kerrisons had been thoroughly 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.

Background:
In today’s ever-tightening reimbursement environment, the pressure on hospitals to cut reprocessing costs while at the same time reducing surgical infections intensifies daily. Advances in infection control practices include improved operating room ventilation, sterilization methods, barriers, improved surgical technique, and availability of antimicrobial prophylaxis. Despite all of these activities, surgical infections remain a substantial cause of morbidity and mortality among hospitalized patients.[iv]

Microorganisms that remain in Kerrison Rongeurs after reprocessing may contain or produce toxins and other substances that increase their ability to invade a host, produce damage within the host, or survive on or in host tissue. For example, many gram-negative bacteria produce endotoxins, which stimulate cytokine production. In turn, cytokines can trigger the systemic inflammatory response syndrome that sometimes leads to multiple system organ failure. [v]

An early attempt by manufacturers to solve the cleanability and infection issues associated with Kerrison Rongeurs was to introduce ‘take-apart’ style Kerrisons and later on ‘convertible’ style Kerrisons. These Kerrisons could be disassembled (the ‘take-apart’ style) or opened up (the ‘convertible’ style) for easier decontamination and cleaning. According to the manufacturers of these Kerrisons, their major benefit is that once they have been disassembled or opened up, reprocessing personnel can ‘visualize’ the bioburden inside of the instrument and manually remove it. Regrettably, the human eye is not capable of seeing microscopic bacteria and biofilm on the surface of a surgical instrument.
Being able to 'visualize' the inside of a Kerrison Rongeurs does not ensure a clean instrument (and this is assuming that reprocessing personnel know how to, much less remember or have the time to disassemble, manually clean, and then correctly reassemble the instrument). According to the CDC, the FDA and AAMI, the only way to ensure clean surgical instruments on every reprocessing cycle is only to use instruments whose cleaning instructions (Instructions for Use, or IFUs) have been validated using AAMI and FDA recommended ‘worst case’ decontamination and cleaning validation protocols.

A more recent solution to the cleanability and infection issues with Kerrison Rongeurs was the introduction of the world’s only ‘flushable’ Kerrison Rongeurs. The patented Clear Flush® Kerrison Rongeurs (http://www.aimclearflush.com/) were designed so they do not have to be disassembled or opened up to be thoroughly decontaminated and cleaned on every reprocessing cycle. The unique design incorporates a flush port and an internal channel to provide a fluid pathway to flush out infectious bioburden from the fixed shank, the moveable crossbar, and the internal ‘I’ beam inside the fixed shank.

Removal of infectious bioburden prior to sterilization dramatically reduces the risk of microbial endotoxins that are heat-stable surviving the sterilization cycle, thus allowing a contaminated Kerrison Rongeurs to be returned to surgery and potentially causing an infection. Healthcare staff members often mistakenly believe that sterilization alone adequately prepares instruments for reuse; this is simply not true.[vi]

Testing 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 IFUs.

After receiving the instruments, pictures were taken of each instrument 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) [vii] 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, [viii] 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 ATS 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...
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 and inspected. 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)
  - A70-0338FP (6mm)
- Tempest Washer
- Healthmark Artificial Test Soil (ATS), containing hemoglobin, protein, and carbohydrate
- Sterile Water
- Syringe
- Camera

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 designed to replicate a ‘worst case’ scenario from the start of a surgical procedure, the duration of a procedure (which can be up to 14 hours for a liver transplant), transport to decontamination, and the eventual start of the cleaning process.

The Tempest Washer’s three-cycle, hydro-jet flushing coupled with the patented internal venturi design of the Clear Flush® Kerrison flushed 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 provided for the removal of all of the dried, encrusted test soil on every instrument.

For a cleaning test to be clinically valid, it must be repeatable by anyone at any time. With the automated Tempest Washer and the flushable Clear Flush® Kerrisons, these extraordinary test results can be repeated in any hospital, by any reprocessing personnel, at any time.

Unlike ‘take-apart’ or ‘convertible’ Kerrisons that require special training and two to three minutes per instrument to reprocess (assuming people actually remember or have time to disassemble it, manually clean it and then properly reassemble it), it takes just five seconds to attach a Clear Flush® Kerrison to a Tempest Washer. By utilizing this unique, validated technology, hospitals can eliminate the ‘human variable’ in instrument reprocessing and have the guaranteed assurance of thoroughly decontaminated, surgically clean Kerrisons with a minimum of effort for every patient, every time.

Conclusion:
This ‘worst case’ validation testing* confirms that a Midbrook Tempest Washer combined with Clear Flush® Kerrisons is the new standard for instrument reprocessing. More importantly, this combination virtually eliminates a patient’s risk of contracting a surgical infection from a contaminated instrument.

With this readily available solution to the costly and dangerous problem of surgical infections caused by contaminated Kerrison Rongeurs, you have to ask yourself, why is your hospital still using the dirtiest instrument in the O.R. on your patients? The validated solution to reducing your patients’ risk of contracting a surgical infection caused by difficult, if not impossible to clean Kerrison Rongeurs lies within your hands.

Validation testing & article provided by: Jahan Azizi, BS, CBET, Amanda Simonsen, BA - April 22, 2014

*To see the complete validation test with before & after photos click here http://www.aimclearflush.com or see the attached file.

For more information on these validated, innovative products, go to Midbrook BioMedical’s web site at http://www.midbrookmedical.com/ or the AIM Clear Flush® Kerrison web site at http://www.aimclearflush.com/.

About Midbrook BioMedical:
Midbrook BioMedical is the world-leader in custom-designed, process-specific cleaning and decontamination equipment. Midbrook has applied technology and expertise gained from other industries to solve some of the most pressing issues facing healthcare facilities. Visit our website for details on all Midbrook BioMedical Infection Prevention products.


ii http://www.cdc.gov/media/releases/2014/p0326-hospital-patients.html; Centers for Disease Control; March 2014

iii Today Show Investigates; http://www.today.com/health/today-investigates-dirty-surgical-instruments-problem-or-1C9382187; February 2012

iv CDC’s “Guideline for the Prevention of Surgical Site Infection.”; April 1999

v Ibid.

vi “Inadequately Reprocessed Instruments: If It’s Dirty, How Can It Be Clean?” ECRI's Patient Safety Organization Brief (PSO), April 2013.

vii Healthmark Industries, Fraser, MI. http://artificialtestsoil.com/, 2010

viii Association for the Advancement of Medical Instrumentation, Technical Information Report #12, [http://marketplace.aami.org/eries/scriptcontent/docs/Preview%20Files/tir121009_preview.pdf __title__], September 2010
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