

## Nelson Laboratories Cleaning Validation Report Summary

Nelson Laboratories is a leading independent provider of full, life-cycle microbiology testing services for the medical device, pharmaceutical, and natural product industries. Nelson Labs employs simulated use testing practices that simulate actual surgical procedures rather than direct inoculation methods. This test complies with AAMI TIR 12:2004 and AAMI TIR 30:2003 guidance documents.

The Cleaning Validation Report describes the laboratory evaluation of the Instructions for Use (IFUs) for the Clear Flush® Kerrison Rongeurs. The testing was conducted utilizing AAMI Cleaning Validation protocols designed to replicate a 'worst case' contamination and transport/handling scenario.

Three Rongeurs were completely contaminated with defibrinated blood soil (DBLSO) containing *Geobacillus stearothermophilus*, ATCC #7953. The Rongeurs were then allowed to remain in complete contact with the contaminated bioburden for fifteen (15) minutes to ensure total saturation of the bioburden and to simulate the wait time between an instrument's use in the O.R. and the start of the decontamination/cleaning process.

The thoroughly contaminated Rongeurs were then removed from the bioburden and placed into a clean pan. The pan was covered with a towel dampened with purified water and allowed to sit for thirty (30) minutes to simulate the wait/transportation time between contamination and cleaning.

The contaminated Rongeurs were cleaned following the manufacturer's IFUs and bioburden assays were performed to determine the bioload reduction in each Rongeur. The test assays documented a 99.9998% reduction in bioburden in all three Clear Flush® Rongeurs (see Table 1, Cleaning Results).