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# White Paper Report

***Study #01-08-07***

## *Sterilization of Dental & Medical Instrument in the Statim 7000*

Conducted by Chris H. Miller Ph.D., Professor of Oral Microbiology at Indiana University and completed in July 2007.

Chris H. Miller was a Professor of Oral Microbiology and Director, Infection Control Research and Services of Indiana University School of Dentistry, USA, prior to his retirement in August 2007. His research interests were focused on infection control, primarily in the development and validation of procedures and chemicals that are designed to control the spread of infection agents. His efforts concentrated on the development of special methodologies that measured microbial killing when performing a particular infection control procedure.

## Executive Summary

In the Indiana University study, the STAT*IM* 7000 cassette autoclaves were tested to determine if the kill of high levels of Geobacillus stearothermophilus (a bacteria most resistant to sterilisation by steam) spores placed inside various dental and medical instruments is achieved when the instruments are processed in the STAT*IM* 7000.

Results demonstrated that standard sterilization half-cycles in the STAT*IM* 7000 cassette autoclaves killed the high levels of Geobacillus stearothermophilus spores placed in the instruments tested.

The various instruments were inoculated at internal sites and processed using STAT*IM* 7000 both wrapped and unwrapped conditions.

### Methods:

Dental and medical instruments were inoculated at internal or external sites with at least one million spores of *Geobacillus stearothermophilus* in 10% sheep blood per instrument and then dried at room temperature overnight. They were wrapped individually in paper/plastic peel pouches (or left unwrapped) and distributed within a full load (3.4 kg) of filler hand items in the sterilizing cassette of the STATIM 7000.

The loads were processed through Hollow Unwrapped and through Wrapped sterilization ½-cycles at 134$^{o}$C for 105 seconds (1/2 of the regular 3.5 minute cycles). The test instruments were then completely submerged in a validated growth medium and incubated at 56$^{o}$C to recover any remaining live spores. Each test instrument was tested in triplicate in 3 runs for a total of 9 tests per instrument. Positive and negative controls were used, and the level of spores in the inoculum was confirmed to assure that at least one million spores were placed on each instrument tested.

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**Results:**

No live spores were recovered from any of the tested instruments that were processed through the STAT*IM* 7000 unit in wrapped or unwrapped half-cycles.

Live spores were recovered from all the positive control instruments and no contaminants were detected from culturing the negative control instruments. Since each test and positive control instrument was inoculated with 10 microliters of the spores-blood suspension, it was confirmed that each instrument was challenged with at least one million spores.

**Instruments Tested:**

**Dental**

- SciCan SL100.1
- SciCan ML 200.1
- Satelec scaler F12200
- KaVo scaler 2003L
- KaVo handpiece 647B
- KaVo handpiece 635B
- KaVo handpiece 6500B
- KaVo 25LPA contra angle
- Bien-Air 1600386-001 contra-angle
- Bien-Air 1600424-001contra-angle
- NSK Ti-Max handpieceX600KL
- NSK Ti-Max handpieceAK700L
- NSK Pana Max handpiece
- NSK PA-SU M4 Pana Air handpiece
- Midwest Tradition handpiece
- Midwest 780014 Quiet-Air L
- Sirona SIROPure P Control
- Sirona SIROPure P 200 IL
- Star 430SWL handpiece
- W&H TA-98Lw handpiece
- W&H WA-99 LT contra angle
- W&H WS-75 contra angle

**Medical**

- Alcon 8065750120 handpiece
- Alcon 8065750121 handpiece
- Alcon 8065750469 handpiece
- Alcon 8065750193 handpiece
- AMO SOV680290 handpiece
- B&L Irrigating cannula E4894
- B&L Phaco handpiece CX7000
- B&L Lasik cannula E4989
- Hockeystick forceps mw-1925
- Trocar sleeve 104 mm 10-000800
- Trocar sleeve 143 mm
- Trocar sleeve 302 mm
- Beckton Dickinson needles 30G½
- Miltex Frazier needles 26-778
- Miltex Frazier-Ferguson 19-570
- Miltex Menghini biopsy needle13-150
- Kerrison Rongeur 18-1994