



White Paper Report 01/11/05

Sterilisation of Medical Instruments in the Statim 2000S and 5000S Cassette Autoclaves

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Chris H Miller is Professor of Oral Microbiology and Director, Infection Control Research and Services of Indiana University School of Dentistry, USA. His research interests are focused on infection control. Primarily development and validation of procedures, chemicals, are designed to control the spread of infection agents. Efforts concentrate on the development of special methodologies that can measure microbial killing that occurs when performing a particular infection control procedure.

Executive Summary

In the Indiana University studies, the Statim 2000S and Statim 5000S cassette autoclaves were modified to incorporate an embedded thermocouple boiler configuration and special development software (PCD-1.7A). The units were tested to validate pre-sterilisation cycle steam purges, which are needed to kill high levels of *Geobacillus stearothermophilus* spores (a bacteria most resistant to sterilisation by steam). Various dental, medical and ophthalmic handpieces were inoculated with the test spores.

Using the standard 134°C half-cycle in both the Statim 2000S and Statim 5000S cassette autoclaves, results demonstrated that the three pre-sterilisation purges (unwrapped hollow cycle) killed the high levels of *Geobacillus stearothermophilus* spores placed in the instruments tested.

Methods:

Internal sites on several medical instruments were inoculated with at least one million spores of *Geobacillus stearothermophilus* in 10% sheep's blood per test instrument and then left to dry at room temperature overnight. The next day, instruments were wrapped individually in paper/plastic peel pouches and or left unwrapped. Three of each type of instrument was then distributed within a full load of "filler" hand instruments to achieve maximum loads in the sterilising cassette of a Statim 2000S and a Statim 5000S cassette autoclave.

The instruments were processed in triplicate runs through a sterilisation half-cycle of 134°C for 1 minute 45 seconds (half the regular 3.5-minute cycle) preceded by 3, 4 or 6 pre-sterilisation cycle purges (wrapped and unwrapped hollow cycle). Each run contained a spore strip of *Geobacillus stearothermophilus* containing at least one million spores. The test instruments and the spore strips were then incubated in a Tryptic-soy broth at 56°C for three weeks to recover any live spores. Positive and negative cultures were confirmed.

Results:

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.

No live spores were detected from any of the wrapped or unwrapped test instruments in either the Statim 2000S or the Statim 5000S cassette autoclaves when using half-cycles with three and six pre-sterilisation purges for the instruments listed below.

Thus the data indicated that three and six pre-sterilisation purges killed high levels of *Geobacillus stearothermophilus* spores placed in the medical instruments processed in the Statim 2000S and Statim 5000S's sterilisation half-cycle of 134°C.

B&L Ophthalmology instruments (3 Purge Unwrapped Hollow Cycle)

- | | |
|--|-----------|
| • Gillis irrigating-aspirating cannula | E4932 |
| • Gimble irrigating cannula 30g | E4894 |
| • Irrigating-aspirating handpiece | MVS 1063C |
| • Lasik cannula | E4989 |
| • Nichamin hydrossection cannula 26g | E4421 H |

Rudolf Medizintechnik GmbH Endoscope accessories (3 Purge Unwrapped Hollow Cycle)

- Trocar sleeve, arthroscopy, 2 rotating stopcocks (1.7mm dia x 104mm length – 10-0008-00)
- Trocar sleeve, hysteroscopy diagnostic sheath, 1 fixed stopcock (2.7 mm dia x 302 mm length – 10-0049-00)

Alcon Ophthalmic handpiece

- NeoSonix Phaco handpiece

Miltex Medical Instruments

- | | |
|---|---------|
| • Frazier-Ferguson tube | 19-570 |
| • Frazier needle | 26-778 |
| • Kerrison rongeur | 18-1994 |
| • Menghini biopsy needle | 12-150 |
| • Yankauer suction tube | 2-104SS |
| • Yeoman biopsy forceps with rotating shaft | 28-304 |

Becton Dickinson

- Needle, 30G1

Medical Workshop

- Hockeystick forceps, membrane peeling mw-1925

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