White Paper Report 01/03/07

# Sterilisation of Medical Endoscopes in the Statim 5000 and 5000S Cassette Autoclaves

Conducted by Chris H. Miller Ph.D., Professor of Oral Microbiology at Indiana University
and completed in October, November and December 2006 and January 2007

SciCan
A HIGHER STANDARD

**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 in the development and validation of procedures and chemicals that are designed to control the spread of infection agents. His efforts are concentrated 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 study, the Statim 5000 and 5000S cassette autoclaves, each fitted with Statim extended length cassettes, were tested to determine if the kill of high levels of Geobacillus stearothermophilus (a bacteria most resistant to sterilisation by steam) spores placed inside medical endoscopes is achieved when the endoscopes are processed in these units.

Results demonstrated that standard sterilization half-cycles in both the Statim 5000 and 5000S cassette autoclaves killed the high levels of Geobacillus stearothermophilus spores placed in the medical endoscopes (ureterscopes) tested.

The two test instruments, a semi-rigid Karl Storz ureterscope and a fiberoptic Schölly uretero-renoscope, were inoculated at internal sites and processed using Statim extended length cassettes in both wrapped and unwrapped conditions.

### Methods:

Internal sites on the two different models and makes of endoscopes were inoculated with at least one million spores of Geobacillus stearothermophilus in 10% sheep's blood per test endoscope. The sites of inoculation, namely, the eyepiece window, main body and channel, were determined as most difficult to sterilize. The endoscopes were then left to dry at room temperature overnight, and the next day, they were wrapped individually in paper/plastic peel pouches or left unwrapped. Loads consisted of one to three endoscopes (depending on how many fit into the extended cassette) with enough uninoculated filler instruments added to achieve the maximum load of 1.5kg for each run.

The endoscopes were processed in triplicate runs. The Statim 5000S processed loads through hollow wrapped and unwrapped sterilisation half-cycles of 134°C for 1 minute 45 seconds (half the regular 3.5-minute cycle) preceded by 3 pre-sterilisation cycle purges. The Statim 5000, processed loads through heavy duty and wrapped sterilisation half-cycles of 132°C for 3 minutes (half the regular 6-minute cycle) preceded by 6 pre-sterilisation cycle purges.

Each run contained a spore strip of Geobacillus stearothermophilus containing at least one million spores. The test endoscopes and the spore strips were then incubated in a Tryptic-soy broth at 56°C for seven days to recover any live spores. Positive and negative cultures were confirmed. Spore concentrations used were confirmed and the growth media used were validated.

### Results:

No live spores were recovered from either the Storz or Schölly endoscopes processed through the Statim 5000 and 5000S units in wrapped or unwrapped half-cycles, and using the extended cassette.

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

**Endoscopes tested:**

- Karl Storz Semi-Rigid Ureterscope / Model 27001 KA
- Schölly Fiberoptic, Uretero-renoscope / Model 41.0612a

Please visit our website at **www.scican.com**