Steam sterilization validation of Smith & Nephew orthopaedic instrument sets in reusable rigid container systems

Introduction

This white paper summarizes the testing that was carried out on Smith & Nephew orthopaedic instrument sets in Aesculap and Case Medical perforated bottom rigid container systems. A rigid container is a reusable case system that is used as an alternative to the traditional woven or nonwoven wrapping materials that are used to sterilize medical devices and containment devices.

Sterilization validation was carried out using the 'overkill' approach. Biological indicators, temperature profiles and dryness testing were used to show that Smith & Nephew instrument sets could be adequately sterilized in the rigid container systems by a typical hospital steam sterilization cycle.

Definitions

Biological Indicator (BI)	A measured number of microorganisms in a test system (i.e., a strip) that provides a defined resistance to the specified sterilization process.
Caddy	Small containment device or flip-up case that is used to contain and organize small medical devices, i.e., plates, screws.
Containment Device	Containment devices are any reusable container (i.e. instrument case, caddy or tray) that is designed for use in healthcare facilities for the purpose of containing reusable medical devices for sterilization. In this white paper the containment devices inside the instrument sets are caddies and instrument trays.
DataTrace Temperature Logger	A programmable temperature monitoring device that can collect temperature data at specified intervals during a sterilization cycle.
D value	Time or dose required to achieve inactivation of 90% of a population of a test microorganism under stated conditions.
Drying Time	Time required to dry steam sterilized items inside the sterilizer.
Exposure Time	Period for which the process parameters are maintained within their specified tolerances.
Instrument Tray	A containment device that has a bottom but no lid and that is used to organize reusable medical devices for sterilization. The instrument tray is designed to go inside of a larger containment device as a part of an instrument set.
Overkill testing	A steam sterilization test method in which steam resistant BIs are exposed to a half exposure cycle to demonstrate the inactivation of at least 12 logarithms of bacterial spores with a D value of one (1) minute at a temperature of 121°C and a z value of approximately 10°C for a full cycle.
Pre-vacuum Steam Sterilization	Also known as dynamic air removal steam sterilization. One of two types of sterilization cycles in which air is removed from the chamber and the load by means of a series of pressure and vacuum excursions (pre-vacuum cycle).
Steam sterilizer	Sterilizer that uses saturated steam under pressure as the sterilizing agent.
Sterilization	A process used to render a product free of microorganisms.
Sterility Assurance Level (SAL)	Probability of a single viable microorganism occurring on product after sterilization.
Validation	Documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

Procedure

Test Materials

Aesculap SterilContainer™ System Containers JN440, JN442, JN444, JN446 and Case Medical SteriTite® SC06FG

Disposable sterile filter paper

DataTrace temperature monitoring loggers and computer interface system

AMSCO Century Sterilizer, Model #SV 120

Ethox Geobacillus stearothermophilus paper biological indicators (BIs) – population -10^6, D value -2 minutes

SCDM (Soybean Casein Digest Media)

Incubator capable of 55-60°C

ID of Smith & Nephew instrument set representatives used for testing

Three Smith & Nephew instrument sets were determined to be worst case and to represent all Smith & Nephew case families. The criteria used to determine the worst case instrument sets were the materials of construction, types and numbers of internal containment devices, density, flow area/mass ratio (which is based on the number of flow holes in the case) and weight. **Table 1** identifies the representative instrument sets that were used for testing.

Table 1

Instrument set representative	Challenging case features
PROFIX° Revision System	Represents upper end of weight for cases with plastic trays; contains three plastic trays: a top, middle and bottom tray.
TC-100° Small Fragment Case	Represents worst case for cases that contain multiple caddies; contains four metal and plastic caddies.
GENESIS° II Revision Tibial	Represents upper end of weight for cases with metal trays, contains two metal trays: an upper and lower tray.

Aesculap rigid containers used for testing

Two rigid container systems have been validated by Smith & Nephew for use with Smith & Nephew instrument sets: 1) Aesculap SterilContainer with perforated bottom and 2) Case Medical SteriTite™ rigid container with perforated bottom. These rigid containers are made of aluminum and have filter retention plates on the lid and case bottom for placement of disposable filters. Figure 1 shows the design of the rigid cases that were tested.

Figure 1: Rigid containers

Aesculap SterilContainer™

Case Medical SteriTite™

Placement of Smith & Nephew representative instrument sets in rigid container

For each Smith & Nephew representative set, all of the internal containment devices (CDs) were removed from the outer case of the set and placed inside the rigid container(s) in a manner that met the acceptable weight limit of 25 lbs. In most cases, the instrument CDs were stacked inside the rigid container(s).

The weight of each representative instrument set in each of the Aesculap and Case medical rigid containers was measured to determine if the acceptable 25 lb weight limit was met. All of the instrument sets with rigid containers were within the 25 lb weight limit. The upper and lower trays of the GENESIS® II Revision Tibial Set had to be processed in separate rigid containers in order to meet the 25 lb weight limit.

BI and temperature monitor placement

BIs and DataTrace temperature loggers were placed at locations inside the instrument set containment devices that were determined to be the most difficult to sterilize. A DataTrace temperature logger was also placed at the center of the case and at the drain of the autoclave.

Overkill testing and temperature monitoring

Sterilization validation testing was carried out using the 'overkill' approach and temperature monitoring to demonstrate a Sterility Assurance Level (SAL) of 10^{-6}. For overkill testing, steam-resistant BIs with a population of 10^6 spores and a minimum D value of one (1) minute must be sterile following a half exposure cycle. For temperature monitoring, the temperature inside the cases must reach the exposure temperature during the sterilize phase.

The autoclave was fully loaded for each test cycle with one case on the top shelf and one on the bottom shelf. The half exposure cycle parameters were: Prevacuum Steam Sterilization Cycle, Exposure Temperature - 132°C, Exposure Time - 1.5 minutes. After the cycle, the BIs and DataTrace temperature loggers were removed. The BIs were aseptically transferred to 10ml of Soybean Casein Digest Media and incubated for seven (7) days at 55-60°C. Growth of the indicator organism is indicative of a non-sterile result. The temperature data from the DataTrace loggers was downloaded using the DataTrace computer interface system. For each representative set pre-vacuum half exposure steam sterilization cycle tests were carried out.

Procedure *continued*

Dryness testing

The dryness of Smith & Nephew instrument sets following sterilization is included in the validation process because dryness following sterilization is critical in maintaining the sterility of the instruments. For this testing, a full cycle is run at a specified dry time. The case and its contents are then inspected for the presence of moisture.

For testing of each representative instrument set inside the rigid container, the CDs in the instrument set were removed and placed in the rigid container. The autoclave was fully loaded with one case on the top shelf and one on the bottom shelf. A full pre-vacuum steam sterilization cycle with a 30-minute dry time was conducted. The full cycle parameters were: pre-vacuum, 4 pulses, 132°C exposure temperature, 3-minute exposure time, 30-minute dry time.

After the cycle, the rigid containers were removed from the chamber and placed on a wire rack that was covered with a sheet of sterilization wrap. The set was allowed to cool for 30 minutes at room temperature. The rigid containers were then inspected for the presence of moisture by removing the lid and inspecting the rigid container base and lid, instrument set CDs and instruments.

Results and analysis

Overkill testing/BI results

The BI results from overkill half cycle exposure testing for the Aesculap Sterilcontainer (Aes) and the Case Medical Steritite® (C Med) rigid containers are given in **Table 2**.

Table 2

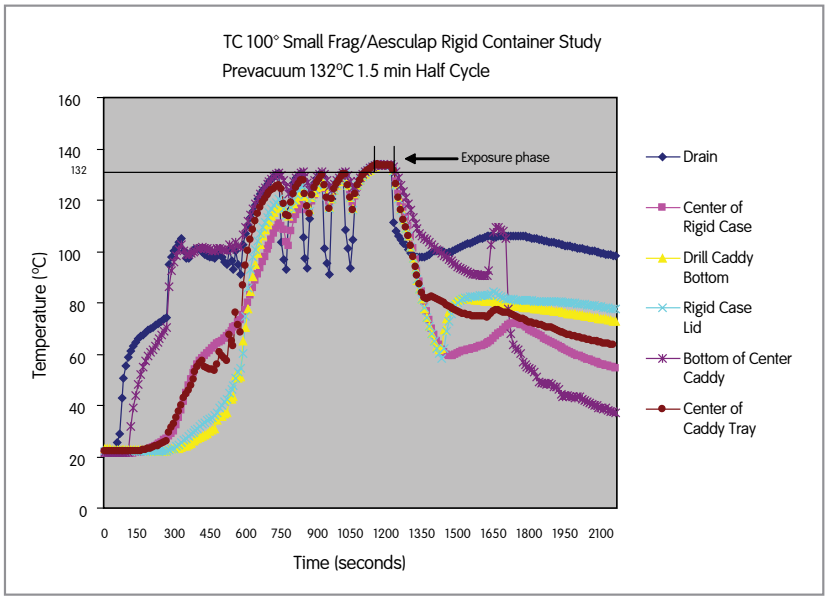
Instrument Set Representative	Sterility Results (# of positive BIs/total # of BIs)					
	Cycle 1		Cycle 2		Cycle 3	
	Aes	C Med	Aes	C Med	Aes	C Med
TC-100° Small Fragment	0/18	0/18	0/18	0/18	0/18	0/18
PROFIX° Tibial Revision	0/12	0/12	0/12	0/12	0/12	0/12
GENESIS° II Tibial Upper Tray	0/7	0/7	0/7	0/7	0/7	0/7
GENESIS II Tibial Lower Tray	0/7	0/7	0/7	0/7	0/7	0/7

For all Smith & Nephew instrument sets, there were no positive BIs in any of the three overkill half exposure test cycles for both rigid container systems.

Temperature monitoring

The temperature monitoring results showed that the set exposure temperature of 132°C was achieved during the exposure phase for all three validation test cycles. All of the temperature profiles for both rigid container systems followed the same temperature profile pattern. A graph of one of the temperature profiles from the rigid container studies is shown in **Figure 2**.

Figure 2: Rigid Container Temperature Profile



Dryness testing results

Moisture was not observed in the rigid containers, instruments or CDs following the pre-vacuum steam sterilization cycles for all rigid container systems.

Summary

The results showed that Smith & Nephew instrument sets processed in Aesculap Sterilcontainer™ systems JN440, JN442, JN444, JN446 and Case Medical SteriTite® SC06FG rigid containers can be sterilized to a 10^{-6} sterility assurance level (SAL) in a Dynamic Air Removal (pre-vacuum) Steam Sterilization Cycle: **Exposure temperature:** 132°C (270°F), **Exposure time:** 4 minutes OR, **Exposure temperature:** 135°C (275°F), **Exposure time:** 3 minutes.

Smith & Nephew does not recommend the use of Gravity Displacement steam cycles for sterilization of Smith & Nephew instrument sets in Aesculap rigid container systems.

References

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5. Aesculap Instructions for Use for STERILCONTAINER SYSTEMTM, 405-03-1007, AIC-5000238.
6. "Recommendations for Decontamination and Sterilization of Smith and Nephew Inc. Orthopaedic Medical Devices", Smith & Nephew Item # 7198-0826, Rev 8/08.
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8. Case Medical SteriTite® Instructions for Use, 2009.

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