The Design and Performance of Smith & Nephew Orthopaedic Instrument Cases for Reusable Device Sterilization
The Orthopaedic Business of Smith & Nephew, Inc. (Smith & Nephew) manufactures a wide variety of reusable orthopaedic medical devices that are capable of being resterilized by typical hospital steam sterilization cycles. Smith & Nephew recognizes the responsibility as a medical device manufacturer of providing our customers with sterilization information to support the use of our devices. ANSI/AAMI ST77:2006, “Containment Devices for Reusable Medical Device Sterilization,” is a new standard that has been developed to outline manufacturer requirements for the design and performance of containment devices for reusable device sterilization. This white paper will help explain how Smith & Nephew addresses the recommendations given in this standard.

Healthcare personnel bear the ultimate responsibility for using the containment device or the packaging material in the recommended sterilization method, as well as performing tests to ensure that items to be packaged can be sterilized by the specific sterilizers and sterilization methods used within the healthcare facility.

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.

Containment Device  A reusable rigid sterilization container, instrument case/cassette or organizing tray and any reusable accessories for use in healthcare facilities for the purpose of containing reusable medical devices for sterilization.

DataTrace Temperature Logger  A programmable temperature monitoring device that can collect temperature data at specified intervals during a sterilization cycle.

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 (prevacuum 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.

Flash Sterilization  Process designed for the steam sterilization of patient care items for immediate use (reference ANSI/AAMI 79).

F₀  An expression of cycle lethality typically with a temperature at 121°C and a z value of 10°C.

Insert Case  A smaller case that is used to contain instruments within a larger case set.

Instrument Case  Sterilization containment device that consists of a lid and a base with means to allow sterilant penetration and removal and that is enclosed in a sterile barrier system if sterility is to be maintained.

Instrument Caddy  Small flip-up case that is inside a larger containment device that is used to contain and organize small medical devices, i.e., plates, screws.

Lethality  The rate of microbial kill of a population of microorganisms. For steam, lethality is dependent on the exposure time and temperature necessary to accomplish the desired rate of destruction.
Load

Similar items requiring the same sterilization parameters that are sterilized together.

Overkill testing

A steam sterilization test method in which steam resistant BI s 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.

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.

Z value

The number of degrees required to change the D value by a factor of 10.

Materials of Construction (Section 4.2 of ST77)

Smith & Nephew instrument cases are manufactured using various medical grade materials including metals, plastics, coatings, surface treatments and adhesives. The current list of approved materials is controlled in an internal specification. Some Smith & Nephew approved materials are given in Table 1 below.

<table>
<thead>
<tr>
<th>Table 1: Approved Instrument Case Materials</th>
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<td>Approved Materials</td>
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<tr>
<td>---------------------</td>
</tr>
<tr>
<td>Stainless Steels</td>
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<tr>
<td>Aluminum</td>
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<tr>
<td>Titanium</td>
</tr>
<tr>
<td>Thermoformed Plastics</td>
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<tr>
<td>Thermoset Plastics</td>
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<tr>
<td>Coatings</td>
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<tr>
<td>Surface Treatments</td>
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Durability, Corrosion Resistance, Biocompatibility, Compatibility with Reprocessing Procedures

Most of the materials used in Smith & Nephew instrument cases have a proven clinical history of durability, corrosion resistance, biocompatibility, and compatibility with Smith & Nephew recommended cleaning and sterilization procedures given in “Recommendations for Decontamination and Sterilization of Smith & Nephew Inc. Orthopaedic Devices” (Catalog #7198-0826). For new materials, these properties are considered during the design process for new instrument cases. Material properties are obtained from standards organizations like ASTM, AMS, ISO, or DIN. Also, the Smith & Nephew controlled design process for new instrument cases includes a Design and Failure Mode & Effect Analysis (DFMEA) which identifies potential problems associated with new materials. This tool is effective in eliminating any problems associated with material properties during the design phase.

Some examples of the ways in which Smith & Nephew evaluates and/or addresses the material properties of new instrument cases are:

- Physical testing like controlled shipment, manual shaking and vibration testing evaluates the durability of new materials.
- Repetitive reprocessing using Smith & Nephew recommended procedures is carried out to evaluate new material compatibility with Smith & Nephew reprocessing procedures.
- The corrosion resistance of metals is improved by treating the surfaces of the metals. This is accomplished by covering the surface with a plastic coating, passivation of the surface or anodizing the surface.
- The biocompatibility of instrument cases that are used to hold or support Smith & Nephew medical devices is addressed by using materials subjected to USP Class VI or ISO Class 10993 biocompatibility testing. These tests demonstrate that the materials are safe for healthcare use.

Design (Section 4.3 of ST77)

Smith & Nephew instrument cases are designed for safe and effective use in healthcare facilities. Safe and effective use includes the ability for proper handling, organization and storage of instruments, and also the ability of the case to allow for adequate cleaning and sterilization.

Organization, Storage and Handling

Smith & Nephew instrument cases are designed to have designated locations for the instruments, internal cases, caddies and trays in the cases. The layout has predetermined brackets and artwork descriptions, which help to organize the instruments in the set for easier identification, storage and use. The contents of the instrument cases are oriented by surgical technique, weight distribution and density, and are distributed evenly within the case to allow for ergonomic handling.

Figure 1: Example of Instrument Case Artwork in a Smith & Nephew Instrument Case
Decontamination and Sterilization

Decontamination of the instrument cases is essential for sterilization. Without proper decontamination, adequate sterilization may not be achieved. Smith & Nephew instrument cases are designed and tested to ensure that they can be adequately cleaned and sterilized following Smith & Nephew recommended procedures given in “Recommendations for Decontamination and Sterilization of Smith & Nephew, Inc. Orthopaedic Devices,” Item #7198-0826. Smith & Nephew recommended cleaning procedures include manual and automatic washer procedures, and are based on the use of typical hospital cleaners, equipment and tools. Smith & Nephew recommended sterilization procedures are based on typical hospital steam sterilization cycles. The ability to clean and sterilize Smith & Nephew instrument cases is considered during the design phase. Design considerations for cleaning and sterilizing instrument cases are detailed in internal specifications. Also, cleaning and sterilization testing is a part of the Design Review procedure for new instrument cases. The test procedures to qualify new instrument cases for cleaning and sterilization following Smith & Nephew recommended procedures are given in internal specifications.

The Smith & Nephew design control procedure requires that instrument cases are redesigned during the design phase if they cannot be adequately cleaned and sterilized by Smith & Nephew recommended procedures. All instrument case designs must be able to be cleaned and sterilized following Smith & Nephew recommended procedures which are based on commonly available hospital equipment, tools and cleaners, and sterilization. This is a great benefit for the hospitals because it eliminates the need for extending sterilization cycle times, as well as for purchasing additional equipment or tools to reprocess Smith & Nephew cases.

Perforations

The size and number of perforations is a critical design feature for cleaning and sterilization of Smith & Nephew instrument cases because it allows for efficient air removal, sterilant penetration/evacuation and drying. Design considerations for cleaning and sterilization are detailed in an internal specification and include adding perforations to the case design. Validation testing is carried out to confirm that new case designs can be adequately cleaned, sterilized and dried in Smith & Nephew recommended procedures.

Internal and External Stacking

Some Smith & Nephew instrument case designs have two (2) internal layers with multiple insert cases, instrument caddies or trays. Internal stacking in the cases is considered and tested in the design process. Smith & Nephew instrument cases are designed with designated locations for each internal insert case, caddy and tray. For testing, the fully assembled cases are tested following the guidance given in ANSI/AAMI ST77 to ensure that the trays and caddies, along with their contents, are stable for transport and handling in a hospital. Fully assembled cases are also tested to ensure that they can be adequately sterilized and dried in Smith & Nephew recommended cycles.

Smith & Nephew does not recommend external stacking of instrument cases during sterilization.

Weight

Smith & Nephew has been aware of the case weight and ergonomic concerns facing our customers for several years. In response to this, Smith & Nephew began changing the instrument case designs. New case designs can be easily separated into smaller ones to achieve a case weight that is less than 25 pounds. Although there are still some older models that cannot be separated to achieve a weight below 25 pounds, Smith & Nephew is rapidly moving forward to address the weight issue for all of its cases. All current Smith & Nephew instrument cases in their fully assembled forms, as well as those that are separated into smaller cases (to achieve <25 lb weight), can be adequately sterilized following our recommended procedures. Furthermore, all of the cases are designed for ergonomic handling due to the designated content locations that allow for even weight distribution.
Performance (Section 4.4 of ST77)

Performance testing is carried out on new Smith & Nephew instrument cases to validate them for reprocessing by Smith & Nephew recommended cleaning and sterilization procedures which are given in “Recommendations for Decontamination and Sterilization of Smith & Nephew, Inc. Orthopaedic Devices,” Item #7198-0826. Smith & Nephew cleaning and sterilization validation test procedures are given in internal specifications that are based on current standards for reusable medical devices.

Performance testing consists of cleaning, sterilization and dryness. All three (3) must be achieved to ensure that the instruments will reach the Operating Room (OR) in a sterile condition.

- Proper cleaning is critical because adequate sterilization cannot be guaranteed without it.
- Adequate sterilization is currently recognized as a $10^{-6}$ Sterility Assurance Level (SAL) or the probability that there is one (1) non-sterile item in 1,000,000 cases tested.
- Dryness of the instrument case following sterilization must be achieved to maintain the sterility of the instrument cases.

Instrument Case Families

Smith & Nephew instrument cases were grouped into families based on critical design features which included the materials of construction, flow area/mass ratio, weight, density, number of drain holes and the number and types of inner trays. Worst case designs from each family were validated to a $10^{-6}$ Sterility Assurance Level (SAL). All new instrument case designs are evaluated against the current list of case families to determine if they might challenge the recommended reprocessing methods. Testing of challenging designs is carried out following an internal specification that is based on recognized standards for reusable medical devices.

Validation of Cleaning

Cleaning is considered to be the first and most critical step in the reprocessing of reusable medical devices. Without proper cleaning, adequate sterilization may not be achieved. Smith & Nephew carries out testing of new instrument case designs to ensure that they can be adequately cleaned following the recommended procedures.

In general, testing is carried out by simulating worst case clinical soiling of the case followed by cleaning using Smith & Nephew recommended procedures and then inspecting the case for removal of the challenge soil. Smith & Nephew recommended cleaning procedures require that the case base and the case lid are cleaned separately. Also, all internal caddies and trays are treated as separate cases for cleaning. For testing, the lid is disassembled from the base of each case.

For validation testing of Smith & Nephew instrument cases, the representative instrument case was soiled with a mixture of egg yolk, defibrinated blood and hog mucin. After soiling, the case was allowed to sit at room temperature for 30 minutes. The case was then cleaned following Smith & Nephew recommended procedures. Both manual and automatic washing procedures were tested. After cleaning, the case was inspected to determine if the soil was removed by the cleaning operation. Difficult-to-see locations were inspected using 3% hydrogen peroxide, which bubbles upon contact with blood. The cases were determined to be cleaned if there was no visible soil or bubbling of the hydrogen peroxide at any location of the instrument case following the cleaning procedure.
Figure 2: An example of a soiled case that was used for cleanability testing.

Table 2 gives the recommended cleaning procedures that were used for testing.

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<thead>
<tr>
<th>Manual Cleaning Procedure</th>
<th>Automatic Cleaning Procedure</th>
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<tr>
<td>1. Remove lid and clean the case and lid separately.</td>
<td>1. Disassemble the case and lid and load them separately in the washer.</td>
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<tr>
<td>2. Soak for one (1) minute in enzymatic detergent.</td>
<td>2. Automatic wash cycle - Minimum cycle parameters:</td>
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<tr>
<td>3. Remove visible soil with a cleaning brush and/or cloth.</td>
<td>• 5-minute Cold Prewash</td>
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<tr>
<td>4. Rinse thoroughly with warm water.</td>
<td>• 5-minute Enzyme Wash at 43°C minimum temperature</td>
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<td></td>
<td>• 5-minute Detergent Wash at 55°C minimum temperature</td>
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<td></td>
<td>• 1-minute Rinse at 45°C minimum temperature</td>
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</table>

The results of testing demonstrated that all instrument case families can be cleaned following Smith & Nephew recommended cleaning procedures. There was no visible soil or bubbling of the hydrogen peroxide at any location in the cases.
Validation of Sterilization

Sterilization validation is carried out using the “overkill” approach and temperature monitoring to demonstrate a Sterility Assurance Level (SAL) of $10^{-6}$. For terminal sterilization processes, $10^{-6}$ (or the probability that less than one (1) item out of 1,000,000 might be non-sterile) is the recommended probability of survival for bioburden on medical devices. Testing is carried out on fully loaded (all contents, i.e., instruments, caddies, insert cases [internal trays] and assembled Smith & Nephew instrument cases. The instruments are placed and positioned in the instrument case based on the predetermined design locations (see Design-Organization, Storage and Handling).

For validation testing, steam-resistant BIs and temperature-monitoring devices are placed throughout the case at challenging locations in order to demonstrate that design features and devices inside the case can be sterilized. The challenging locations are those that are the hardest to access by steam due to design features like density, material, lumens etc. 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 to demonstrate a 12 log reduction of spores or a $10^{-6}$ SAL for a full cycle. The temperature monitoring data must show a minimum lethality that is equal to a $10^{-6}$ SAL in a full exposure cycle.

For validation of Smith & Nephew instrument case families, BIs of $10^6$ *Geobacillus stearothermophilus* spores and programmed Data Trace temperature loggers were placed at challenging locations throughout the representative instrument case. The temperature loggers were programmed to calculate $F_0$ lethality based on a reference temperature of $121^\circ$C. (Note: $F_0$ is the time in minutes required to kill all the spores at a temperature of $121^\circ$C and a z value of 10 minutes.) The case was wrapped with Kimberly Clark KC 600 One Step wrap following standard hospital wrapping procedures. The autoclave used for testing was an AMSCO Century Sterilizer, Model #SV-120 that was calibrated to NIST traceable standards. The autoclave was fully loaded for testing with one (1) case on the top shelf and one (1) case on the bottom shelf. The test case was placed on the top shelf because temperature profile testing had shown this to be the coldest location in the chamber. A dunnage case full of instruments was placed on the bottom shelf. The instrument case was not preheated for testing. The half exposure sterilization cycle was started within two (2) minutes of closing the door. Three (3) repeat cycles were carried out to show reproducibility of the results.

Table 3 gives the half exposure steam sterilization cycles that were used for validation testing:

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<th>Table 3</th>
<th>Half Exposure Cycles Used for Instrument Case Sterilization Validation</th>
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<tr>
<td>Cycle ID</td>
<td>Half Exposure Cycle Parameters</td>
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</table>
| Dynamic Air Removal (4 pulse Prevacuum) | • Purge Time: 1 minute  
  • 4 pulses (Maximum - 26.0 psig [2.8 bars], Minimum - 10.0 inHg [339 mbars]) or  
  • Exposure Temperature: 132°C  
  • Half Cycle Exposure Time: 1.5 minutes |
| Dynamic Air Removal (3 pulse Prevacuum) | • Purge Time: 2 minutes  
  • 3 pulses (Maximum 17.3 psig, Minimum 9.7 inHg)  
  • Exposure Temperature: 135°C  
  • Half Cycle Exposure Time: 1.5 minutes |
| Gravity Displacement (Wrapped) | • Exposure Temperature: 132°C  
  • Half Cycle Exposure Time: 15 minutes  
  • One (1)-minute purge |
| Flash (Gravity Displacement) | • 1 minute purge (min 10inHg, max 26 psig)  
  • Exposure Temperature: 132°C  
  • Half Cycle Exposure Time: 5 minutes  
  • Dry Time: 1 minute |
Following the half cycle, the BIs were removed and tested. The BIs were aseptically transferred to 10 ml of Soybean Casein Digest Media and incubated for seven (7) days at 55-60°C. Growth of the indicator organism was indicative of a non-sterile result. The Data Trace temperature loggers were removed and the temperature profile data was downloaded to calculate the lethality of the cycle.

Testing was carried out on worst case representative cases from each of the product families. For all instrument case representatives, all of the BIs were sterile following processing in three (3) repeat half cycles of each cycle type (see Table above). Also, for all test cycles, the temperature data at all monitored locations showed that the lethality of the cycle results in a $10^{-6}$ SAL at all locations. The results showed that all of the instrument case families can be processed to a $10^{-6}$ Sterility Assurance Level (SAL) following our recommended sterilization cycles.

The full steam sterilization cycles that have been validated for Smith & Nephew instrument cases are given in Table 4.

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<tr>
<td>Full Steam Sterilization Cycle Parameters for Smith &amp; Nephew Instrument Cases</td>
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<tr>
<td>Cycle ID</td>
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<td>Flash (Gravity Displacement)</td>
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<td>Gravity Displacement (Wrapped)</td>
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<tr>
<td>Dynamic Air Removal (4 pulse Prevacuum)</td>
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<td>Dynamic Air Removal (3 pulse Prevacuum)</td>
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**Dryness Testing**

The dryness of Smith & Nephew instrument cases following sterilization is included in the validation process because dryness following sterilization is critical in maintaining the sterility of the instruments. In general, the test procedure consists of subjecting a fully loaded instrument case to Smith & Nephew recommended sterilization and drying parameters and then evaluating it for the presence of moisture.

Testing of representative cases was carried out by first wrapping a fully loaded case with Kimguard KC600 One-Step wrap. Kimguard KC600 One-Step wrap is the most challenging wrap for dryness due to its density. No additional internal absorbent materials were used for testing. The chamber was fully loaded with two (2) instrument sets, one (1) on each shelf (no stacking). The case was not preheated prior to testing. Sterilization following Smith & Nephew recommended procedures (see Table 4) was carried out. The sterilization cycle was started immediately upon closing the door of the autoclave. After the cycle, the autoclave door was opened 4-6” for about 15-20 minutes to allow the case to cool and to prevent removal of the case and contact with a cool surface that may cause condensation. The instrument case was removed from the chamber and placed on a wire rack that was covered with a sheet of sterilization wrap to cool for 30 minutes. The wrap was removed from the case and immediately examined for moisture. Also, the outside
of the case, the inner trays and the lid were examined for moisture. Three (3) test cycles were carried out to show repeatability. For validation of drying, no moisture could be observed at any location of the wrap or instrument case in three (3) repeatable cycles.

The dryness test results for Smith & Nephew Instrument Case Families showed that all instrument case families can be dried in the current validated sterilization cycles with a 30-minute drying time. There was no evidence of moisture at any of the locations in the sterilization wrap or instrument cases for all representative cases that were tested.

Sterility Maintenance

Smith & Nephew instrument cases were designed to maintain sterility with the use of an FDA-cleared sterilization wrap. With the proper use of a sterilization wrap, the sterility of Smith & Nephew instrument cases can be maintained until the case is opened and the sterile contents are used. Validation testing of the sterility maintenance of Smith & Nephew instrument cases was carried out by simulating clinical usage of representative wrapped and processed instrument cases and then performing physical integrity testing on the wrap to show that the wrap had not been compromised.

For testing, worst case representative instrument cases were wrapped in Kimguard KC600 One-Step wrap and then sterilized following Smith & Nephew recommended procedures. The cases were then exposed to the expected stresses of storage, transport and handling conditions in the hospital. For evaluation of the wrap, the wrap was carefully removed and inspected for tears and/or holes. Since there were no signs of tears or holes, the most challenging areas of the case wrap were physically tested using hydrostatic pressure testing following method AATCC 127. Testing concluded that the physical integrity of the wrap had not been compromised. The test results showed that all Smith & Nephew case families can maintain sterility with the use of an approved FDA cleared sterilization wrap.

References
