Smith & Nephew switches to STERIS VHP® MD System and stays with DuPont™ Tyvek® for medical packaging

Smith & Nephew Orthopaedics, a global provider of leading-edge joint replacement systems, has a reputation for innovative products that offer clear clinical and cost benefits, supported by first-class service. Located in Memphis, Tenn., this medical device manufacturer (MDM) provides an industry-leading range of implants for hips and knees, developing tougher materials that extend the life of the implant and make them suitable for younger patients.

Since launching its line of joint replacement systems in the early 1980s, Smith & Nephew Orthopaedics had always packaged them using a PETG tray and a lid of coated DuPont™ Tyvek® 1073B. Sterilization was done by a contract sterilizer using ethylene oxide (EtO). But that all changed in 2002.

Relying on a contract sterilizer meant long turnaround times. Typically, 12 days were required before product could be released. This was becoming a major issue for a company so focused on first-class service, especially when custom orders were requested.

“We wanted to take back control over turnaround time to better meet our customers’ needs,” said David Vogel, Director of Validation and Microbiological Control at Smith & Nephew. “So, we looked at bringing EtO sterilization in-house. But there are many safety and environmental concerns when processing in-house with EtO. The decision was made to find a process that didn’t require a large investment just to address environmental issues.”

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ISO EN 11607-1 and ISO EN 11607-2 Published


The standard has also been adopted as an American national standard and is designated AAMI/ANSI/ISO 11607-1 and -2. The document can be obtained as hard copy or PDF at www.AAMI.org.

The AAMI/ANSI/ISO version is identical to the ISO printing and the printings of the various European standards bodies. The only difference is that the European versions have an extra annex that outlines specific clauses that support the medical device directives. This is a European Committee for Standardization (CEN) requirement and doesn’t change the requirements of the standard in any way.

Since April, I have received many questions about the standard. In this issue of Tyvek® Rx, I will highlight areas where guidance is sought on a regular basis. In future issues, I will address specific questions in detail.

Definitions

There are four new critical definitions that I have previously written about in this column. We must all get used to the new terminology of sterile barrier systems, preformed sterile barrier systems, protective packaging and packaging systems. Also, it is important to pay attention to the term “product” as defined in the standard.

Compliance

To comply with the standard, you must have documented evidence that demonstrates compliance with each of the “shall statements” in the standards. Part 1 has 82 shall statements and part 2 has 48. Because 11 of these are identical in the two documents, you must comply with a total of 119 unique shall statements.

European compliance

As Europe transitions from EN868-1 to ISO 11607, there is a one-year period (which started in April 2006 when the standard was published by ISO) during which you can demonstrate compliance to either standard. If you already have demonstrated conformity to EN868 on existing products, there is no requirement to go back and demonstrate conformity to ISO EN 11607. However, after April 2007, only conformity to ISO EN 11607 will be acceptable for new products.

In addition, the rest of the EN868 series (parts 2 through 10) remain as guidance and can be used to demonstrate compliance with relevant clauses in ISO EN 11607. CEN/TC205/WG4 on medical packaging retains responsibility for these standards and is currently revising them to be in line with ISO EN 11607 as the horizontal standard instead of EN868-1.

Test method validation

This requirement has been in every edition of ISO EN 11607, but it seems to have created some confusion since the inclusion of Annex B, which lists test methods. The requirement is that all test methods must be validated. Annex B is an informative annex that lists test methods that users may choose to validate in their laboratory. Test methods do not have to come from this list. Any test method validated in the test laboratory is acceptable.

In addition, just because a particular test method is a standardized test method with a statement...
of repeatability and reproducibility developed as a result of an inter-laboratory study does not mean it is validated in a particular lab. Additional work must be done to demonstrate the method performs in a given lab with results that are comparable to the inter-laboratory study results.

**Product family and worst-case configuration**

This edition of ISO EN 11607 introduces the concepts of product families and worst-case configurations. Although not specifically mentioned, they were applicable to previous editions. The concept of a product family is when a similar collection of medical devices is packaged in the same sterile barrier system. IV tubing sets are a good example. A single manufacturer may have multiple configurations of IV tubing sets that have differences in the length of tubing and the number of ports or valves (e.g., three feet of tubing with two ports vs. 10 feet of tubing with three ports and two valves). These are all packaged in identical header bags and the devices are made of the same materials. One approach to compliance is to document a rationale for a family of products and establish the worst-case configuration (in this case, probably the set with the most of everything). The requirements for the family can be met by demonstrating that the worst-case configuration complies.

This concept can also be applied to preformed barrier systems where multiple size pouches or header bags of identical materials can be formally grouped into a family for demonstrating compliance using the worst-case configuration.

**Performance testing and stability studies**

The standard requires real-time stability studies but allows for concomitant accelerated aging studies. It also urges the user to perform stability studies using only elevated temperature because other factors, such as freeze/thaw cycles, are not part of the mathematical equation. These challenges to environmental stresses should be performed based upon knowledge of the distribution chain and conducted as part of performance qualification.

**Looking back**

The development of a harmonized global standard began for me in 1992 when I attended my first meeting of ISO TC198/WG7 “Medical Packaging” in Hamburg as a member of the U.S. delegation. In my naivety, I thought this would be quick and easy.

My hair is now gray, one of my children is married, the other is in college and I have a new bride of two years. I look back without regret because I always knew this was the right approach.

As the working group finishes this chapter of its evolution, I would like to thank all of my colleagues around the world for their hard work and dedication, and thank their companies for supporting this effort. Many of these committee members will be retired before the working group starts work again and they will be missed. But I know in five years there will be new representatives who will approach the issues with the same optimism that I had in 1992. I hope I am able to be there to greet them.

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**People on the move**

**Eric Schmohl** joined the DuPont Medical Packaging Team in Luxembourg earlier this year as a Key Account Manager for northern European countries. During his nine-year career with DuPont, Eric has worked as a Technical Marketing Manager and Sales Manager in both the nylon and nonwovens business units. His educational and work experiences give him a unique combination of technical expertise in synthetic textile products and thermally bonded nonwovens, as well as strong skills in international sales and marketing. Eric, who is fluent in German and English, has a degree in engineering.
After investigating other available sterilization methods, Vogel and his team decided that the STERIS VHP® MD sterilization system would best meet their needs. This rapid, just-in-time vaporized hydrogen peroxide (VHP) sterilization process allows MDMs to integrate sterilization with assembly and packaging operations, supporting lean manufacturing.

“The STERIS VHP® MD sterilization system means quicker sterilization turnaround time and reduced finished goods inventory,” said Larry Lachowski, Sales & Marketing Manager, STERIS Corporation. “This gives medical device manufacturers more flexibility in product scheduling and helps them to ship finished product sooner into their supply chain, reducing costs, increasing profits and enhancing customer satisfaction.”

According to Lachowski, there are many advantages to VHP sterilization, including:

- Low operating temperature (86°F to 104°F [30°C to 40°C])
- Proven sterilization efficacy
- Rapid sterilization cycle time, leading to quicker turnaround time
- Environmentally friendly by-products—water vapor and oxygen
- Broad material compatibility
- Low operating costs
- No gas plasma phase required
- No long post-sterilization aeration phase required

“We were impressed with the STERIS VHP® MD system and, based on published data, we knew that DuPont™ Tyvek®—unlike medical-grade paper—was compatible with this sterilization method,” noted Vogel. “This was a key factor in our decision because we have always been very happy with the performance of Tyvek® and we did not want to change this important component of our packaging.”

Before validation began, Smith & Nephew Orthopaedics conducted extensive testing to determine the effects of VHP sterilization on the ultra-high molecular weight plastics used in its hip and knee replacement implants. The tests demonstrated that there is no difference between non-sterilized cross-linked polyethylene (XLPE) and XLPE sterilized with EtO or with VHP. The effects of aging were also investigated and it was found that material sterilized with VHP did not change after the aging process.

The VHP sterilization process that Smith & Nephew validated has been cleared by the U.S. Food and Drug Administration (FDA) and by its counterparts in Canada, Australia and the European Union. The process has been validated to ensure that the product achieves the acceptable Sterility Assurance Level (SAL) of 10⁻⁶, which is the international standard for sterile products.

Although Smith & Nephew Orthopaedics did not want to consider any changes to the Tyvek® portion of its packaging, it did look at alternatives to the PETG tray to reduce package size in the VHP chamber and facilitate the VHP process. “We decided to use a PET/PE pouch with a lid of Tyvek® instead of the PETG tray,” said Randall Troutman, Project Manager, Global Packaging Development, Smith & Nephew Orthopaedics. “Tyvek® provides the performance we need in terms of strength, exceptional puncture resistance, outstanding microbial barrier and permeability for the hydrogen peroxide vapor. The change to a pouch allowed us to process a larger quantity in each VHP cycle.”

Vogel noted that educating surgeons about why Smith & Nephew Orthopaedics decided to switch from EtO to VHP sterilization, and reassuring them that the VHP process does not change the mechanical properties of the XLPE in any way, was an important issue. So, he teamed up with M. Scott McCaig, Ph.D, Project Manager at Smith & Nephew, and

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wrote a white paper that included detailed information about the STERIS VHP® process, compatibility testing data and a comparison of common sterilization processes.

The conclusion in the white paper says it best: “The VHP sterilization process from STERIS provides a significant improvement in the way we manufacture and sterilize polyethylene liners. It will allow Smith & Nephew to dramatically reduce turnaround time and continue to be good environmental stewards. The VHP process is safe and effective and will not change the properties of our polyethylene in any way. This change should be seen as an improvement in the speed of doing business without compromising our standards.”

Founded in 1856, Smith & Nephew is a global medical device company developing innovative products that help people regain their lives. The company has three global business units—Orthopaedics, Endoscopy and Acute Wound Management. It operates in 33 countries.

STERIS Corporation is a leading provider of infection prevention, contamination prevention, microbial reduction and therapy support systems, products, services and technologies to healthcare, scientific, research, food and industrial customers throughout the world.
Experts gather in Italy to help MDMs

Representatives from Encaplast, a sterile packaging manufacturer headquartered in Mirandola, Italy, were also present to answer specific questions concerning their broad range of medical packaging products, which are produced in a certified cleanroom environment.

Looking to the future

DuPont Medical Packaging will continue to organize special seminars, such as this event in Italy, as part of its commitment to providing information and sharing expertise to help MDMs protect the health of patients around the world.

In addition, the DuPont Medical Packaging Seminar Series, which consists of six modules, is available for presentation at individual MDM locations. Open-session seminars are also held in major U.S. cities throughout the year. For more information, visit the website at www.MedicalPackaging.DuPont.com.

Featured speakers

Mariangela Dondi, Ph.D., Technical Leader, Italian Consobiomed Industry Association. Dondi provided guidelines about managing the production environment to achieve effective sterilization. In her presentation, the clear message was that reduction of risks starts before sterilization—with design and procedures that take into account every step and material in the production process before packaging. Dondi also talked about cleanroom and surface contamination classification being main inputs to the probability of sterility at the end of the process.

Paul Fielding, Consultant, DuPont Medical Packaging, and senior UK representative for the European Committee for Standardization (CEN) and International Organization for Standardization (ISO) Medical Packaging Committees. Fielding explained the requirements of the new ISO 11607 norm about packaging. A highlight of his presentation was information about the additional steps required for validation of the installation, process and operation of medical device packaging equipment.

Marcelo Milani, Engineer, Regional Business Manager for Europe and Middle East/Africa Regions, DuPont Medical Packaging. Milani spoke about DuPont™ Tyvek® medical packaging, discussing the inherent advantages it has over other materials.
Seminar attendees listened to presentations by national and international experts.

**Vincenzo Silvestri, Ph.D.** Lead Auditor for Quality Systems and Notified Body Auditor for TÜV. Silvestri spoke about packaging as a requirement for conformity with the European Medical Device Directive and risk management. He also presented a new holistic approach to risk management.

**Renzo Coronati, Ph.D.**, Technical Director, Coronati Consulting, a company that specializes in helping MDMs to achieve validation. According to Coronati, “Packaging of medical devices is a critical process and is regarded as such by European Notified Bodies and competent authorities in all countries.”

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**Alcan receives special citation for innovative packaging**

Alcan Packaging – Medical Flexibles Americas was awarded a Special Citation in the 19th DuPont Awards Competition. Alcan earned this award for its innovative high-barrier terminal steam sterilization package. Last year, Alcan earned awards in both the Gold and Silver categories.

Sponsored by DuPont Packaging, this prestigious international competition honors innovation in food and non-food packaging. Since its inception in 1986, the competition has received more than 900 entries from more than 40 countries. Over the years, more than 185 innovations have been honored.

Entries are judged by an international panel of qualified experts representing industry, equipment suppliers, academia, the trade press and governmental, environmental and trade organizations. Judging criteria include: material specification of the package structure; marketplace acceptance; impact on consumers; function; improvement from current packaging; and the degree of design, engineering or technical innovation.

To read about this year’s award winners and see photos of the winning entries, visit http://www2.dupont.com/Packaging/en_US/.

Entry forms for next year’s competition will be available in mid-January 2007 at www.packaging.dupont.com. We encourage you to submit your latest innovation in medical or pharmaceutical packaging.
Calendar of events

MD&M West*
February 13–15, 2007
Anaheim Convention Center
Anaheim, CA
DuPont Booth #TBD

Medtec*
February 27–March 1, 2007
Messe Stuttgart, Germany

MD&M East*
June 12–14, 2007
Jacob K. Javits Convention Center
New York, NY
DuPont Booth #TBD

*For more information, contact Canon Communications at (310) 445-4200 or visit www.devicelink.com/expo.