Increased Sales for The West Company Are in the Bag — A Bag That Includes Tyvek®, That Is

Parenteral pharmaceutical products (drugs that are injected via syringe) must meet stringent U.S. Food and Drug Administration (FDA) inspection standards and regulations. Many components must be washed, rinsed and siliconized prior to sterilization. The processes are time-, energy- and labor-intensive — if pharmaceutical suppliers perform all these functions themselves. Or, they can rely on The West Company to do the work for them.

A leader in innovative packaging for the healthcare industry for the past 70 years, The West Company offers ready-to-sterilize closures to pharmaceutical companies worldwide. Packaged under the Westar® RS name, the company’s line of stoppers and syringe components are washed and rinsed in water for injection, and pre-siliconized according to customers’ specifications.

For added convenience and extra protection against contaminants, the components are packaged in a STERILIZABLEBAG™ made of Tyvek® spunbonded olefin and high density polyethylene (HDPE). The STERILIZABLEBAG™ is an improvement over packaging The West Company had previously used.

“Our first sterilizable bags were made with paper,” said Dietmar Döelcher, The West Company’s vice president of quality assurance for Europe and Asia. “But we had problems with fiber contamination. Plus, if the products in the bags weren’t thoroughly dried after sterilization, the bags could break at our customers’ facilities.”

The company decided it needed to find alternate packaging. The search lasted almost a year and a half. “We tried a bag with polyamide [nylon], but it had a long drying time, and the bags could burst during sterilization,” Döelcher said.

Then, the development team tried an HDPE bag with one complete side of Tyvek® 1073B. The advantages were apparent right away. “Our particulate situation was solved with Tyvek®,” Döelcher said. “And, its drying time is less than nylon’s. If the right temperature and drying process are utilized, Tyvek® dries as quickly as paper.”

What’s more, Tyvek® provides the strength paper was lacking. “One of the biggest advantages of Tyvek® is its tear strength,” said Val Romberg, global director of medical packaging.

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On June 13, 1998, Directive 93/42 CEE becomes obligatory for all member countries of the European Community. Also known as the Medical Device Directive, 93/42 CEE provides the criteria for packaging used to keep medical products sterile. All medical devices sold on the European free market after June 13, 1998, must meet the specifics of this directive, which overrides all national regulations.

To help evaluate packaging materials and systems that will be covered by 93/42 CEE, representatives of European Community member countries developed standard EN-868 Part 1.

The first part of this standard, which was finalized in May 1997, contains specific performance requirements similar to those of the Medical Device Directive. Therefore, compliance with EN-868 Part 1 implies compliance with 93/42 CEE.

As with 93/42 CEE, EN-868 Part 1 cancels pre-existing national standards and cannot be modified during implementation. However, unlike 93/42 CEE, compliance with EN-868 Part 1 is not compulsory. EN-868 Parts 2-10 are in various stages of the approval process and have not been finalized to date. Viewed as an attempt to reconcile the national standards of European Community countries, EN-868 Parts 2-10 will include elements of standards from different member nations.

More explicit than Part 1, the latter parts of EN-868 will contain physical values, as well as provide examples of packaging that has proven effective in the marketplace. EN-868 Parts 2-10 are considered horizontal standards that will be adopted on a voluntary basis.
and punctures...highest water resistance...lowest particulate generation...and lowest weight. The data from standardized tests — and the real-life experiences of medical packagers that use Tyvek® every day — prove that Tyvek® is the material of choice for sterile packaging applications.

Here’s what Doug Uelmen, director of quality assurance, Bard Radiology Division, had to say about Tyvek® vs. paper: “Tyvek® has all the qualities we were looking for when we set out to correct the paper tear problem [at Bard]. It doesn’t tear or shred, and customers always get a clean, easy peel. Customer satisfaction was the driving force behind our decision to get out of paper, and we couldn’t be happier with the result of this switch to Tyvek®.”

The folks at Maxxim Medical also found distinct advantages in switching from paper to Tyvek®. “As we’ve changed more kits over to packaging of Tyvek®, we’ve seen a dramatic reduction in complaints,” said John Winslow, Maxxim’s vice president of marketing. “On the surface, it may appear cheaper to use paper, but when you consider returns, Tyvek® is probably as inexpensive as, or even less expensive than, paper.”

With all the extras Tyvek® has to offer — at a real-use cost similar to paper — it really makes you wonder: Why would anyone ever settle for anything but Tyvek®? Editor’s Note: For additional data comparing Tyvek® vs. medical-grade papers, call 1-800-44-TYVEK and request technical bulletin H-64643 or reference our web site at www.dupont.com/Tyvek/sterilepkg.

**Tyvek® Proven to Be Number One**

Testing the properties and performance of competitive materials provides invaluable data for material selection. However, to be useful, the data must provide meaningful measurements that are verifiable.

Therefore, it is important to rely on data generated from industry recognized and accepted testing procedures when making material selections. And when it comes to ISO and ASTM recognized testing procedures for porous packaging materials, Tyvek® spunbonded olefin takes first place for the highest barrier...highest strength against tears and punctures...highest water resistance...lowest particulate generation...and lowest weight. The data from standardized tests — and the real-life experiences of medical packagers that use Tyvek® every day — prove that Tyvek® is the material of choice for sterile packaging applications.

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of Westar®. "Tyvek® doesn’t tear during shipping to our customers — or after sterilization. Our customers can use the same STERILIZABLEBAG™ for steam sterilizing the parenteral components and as a transport bag to another sterilizable area instead of using a separate container. Our customers really like the bag’s seam strength and particle control. The bags also offer a high inherent resistance to penetration by microorganisms and comply with FDA food packaging requirements.

In the past five years, since adopting the STERILIZABLEBAG™ for its parenteral pharmaceutical products, annual Westar® RS sales have grown from 100,000 bags to 1 million bags. In fact, the packaging has proved so popular, The West Company has begun selling the STERILIZABLEBAG™ alone. So, its customers have a safe, convenient way of sterilizing a wide variety of pharmaceutical products via steam or ethylene oxide (EtO).

The West Company has also begun using the STERILIZABLEBAG™ in Europe to package rubber-lined aluminum caps generically used for pharmaceutical packaging. And, the company is continuing to develop other packaging with Tyvek®.

“We’ve had a growing demand for the STERILIZABLEBAG™ with Tyvek® ever since its introduction,” Romberg said. “Our customers simply say it’s a better bag.”

*Tyvek® is compatible with steam sterilization under controlled conditions at temperatures up to 260° F (127° C).

Westar® is a registered trademark of The West Company, Incorporated.

STERILIZABLEBAG™ is a trademark of The West Company, Incorporated.

Congratulations, Perfecseal!

Perfecseal, Inc., one of the largest manufacturers and marketers of packaging materials for the healthcare industry, recently received the 1997 Shingo Prize for Excellence in Manufacturing at an awards ceremony in Detroit, Mich. The company was recognized for achieving true excellence in all phases of its Philadelphia site’s manufacturing process, including the significant reduction of both lead and overall set-up times, as well as the improvement of on-time order fulfillment, productivity, safety and quality.

“Receiving the Shingo Prize confirms that our focus on customer service, quality, speed and the removal of non-value-added activity is right on target,” said Perfecseal Materials Business Unit Leader, John Marits. “It is a testament to our people and their commitment to building a world-class company in every respect.”

The Shingo Prize, considered to be one of the most prestigious honors in manufacturing management, is awarded to companies in the United States, Mexico and Canada that excel in productivity and process improvement, quality enhancement and customer satisfaction. It is named for Shigeo Shingo, the manufacturing expert who developed the revolutionary Toyota Production System.

Perfecseal is a division of the Curwood Group, a wholly owned subsidiary of the Bemis Company, Inc., a $1.7 billion corporation.
As the medical device industry is well aware, DuPont Nonwovens is upgrading the manufacturing process for Tyvek® spunbonded olefin for product improvements and corporate product stewardship. To minimize the systems costs associated with this transition for the medical packaging industry, DuPont developed an extensive, two-stage test protocol in conjunction with the U.S. Food and Drug Administration (FDA), sterile packaging manufacturers (SPMs), medical device manufacturers (MDMs) and HIMA.

The first stage, known as the Preliminary Study, compared Tyvek® 1073B produced using the current process in Richmond, Va., to Tyvek® 1073B produced in Luxembourg. The purpose of this study was to validate the test protocol.

Following the FDA's review and acceptance of the Preliminary Study results, the agency issued a guidance letter on October 14, 1997, to the industry stating that the manufacturing process does not result in a significant change to the functional performance of Tyvek® during medical device sterilization and the maintenance of package integrity over time.

As a result, the FDA recommends that it is not necessary for MDMs to file amended 510kS or amended PMAs when Tyvek® produced in one location is substituted for Tyvek® produced in another location during the manufacture of approved medical devices. However, the FDA notes that the change in the source of Tyvek® should be documented in each applicable device record. This recommendation applies to both coated and uncoated Tyvek®.

The Tyvek® Sterile Packaging team would once again like to thank all of the SPMs and MDMs who participated in the Preliminary Study. The FDA's acceptance marks the completion of the first stage of the transition plan. The final stage will be a Full Study comparing Tyvek® 1073B produced using the current process to Tyvek® 1073B produced using the upgraded process.

Our original plans called for the Full Study to begin in late 1997. Since the initiation of the transition plan, however, polymer technology has advanced rapidly and we want to take full advantage of these developments in the next generation of Tyvek® for the medical packaging industry. Therefore, we have decided to delay the Full Study so that we can ensure that our process is at a “steady state” with the new polymer technology with no further enhancements planned.

By delaying the start of the Full Study until we have solidified the polymer package for the third-generation process, we can transition once to the upgraded process. We currently anticipate that we will begin the Full Study by the year 2000.

In the meantime, we will continue to supply the medical device industry with Tyvek® from the current process – without interruption – until the protocol is complete.

To obtain a copy of the summary of the Preliminary Study, please call 1-800-44-TYVEK. More details about the transition plan, as well as additional information about the Preliminary Study results, are contained in a videotape and handout sheet, which are available upon request.
Bar Coding on Tyvek®: Where Cost Savings and Quality Meet

There’s no doubt about it. The use of bar coding on medical packages is only going to increase in the future. That’s because more and more purchasers are demanding bar coding to obtain cost savings in distribution and inventory control. A good example is the U.S. military, which recently instituted a requirement that all products be bar coded.

Some people believe that the only way to print variable information, such as bar codes, on Tyvek® spunbonded olefin is via labels. But that’s not the case. Printing on the narrowest bar or space in the code — of 0.0075”. These can be obtained through the use of a thin (0.067” or less), low Durometer photopolymer plate with a shore A range of 45 to 60. Commercial printers should be provided with camera-ready artwork. Prior to printing, the film master of the bar code symbol should be reduced from designated dimensions to compensate for the print gain resulting from the use of many types of press. We recommend a medium density code with an element width of 0.0115” and a bar width reduction of 0.003”. This process prints constant information bar codes.

Thermal transfer can also be used to provide acceptable bar codes on Tyvek®. However, because medical-grade Tyvek® — 1059B and 1073B — is not corona treated, ribbons with a high wax-to-resin content should be used for better performance. All major machine and ribbon manufacturers stock these ribbons and will be able to recommend those compatible with Tyvek®.

When using an ink jet process, solvent or oil-based inks should be used. A carbon black ink provides the best contrast and decodability. But, regardless of the ink color used, it’s important to remember that using a 203 DPI (dots per inch) ink jet printer limits the X dimension to between 0.012” and 0.014”. Consequently, more space is needed for each bar code. Variable information can be printed via thermal transfer or ink jet. Due to the fibrous nature of Tyvek®, printing methods may need to be adjusted somewhat to obtain good ANSI quality grade bar codes. But with minor alterations, medical device packagers can produce bar codes on Tyvek® that hospitals and clinics can easily scan. And they can provide the quality of Tyvek® plus the convenience and cost savings of bar coding for their customers.

For more information on printing on Tyvek®, watch for future issues of Tyvek® Rx. Or call 1-800-44-TYVEK for information on printing, printers, inks and ribbons.

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