

To Protect an Innovative Product, Lifecore Biomedical Relies on DuPont Tyvek®

Faced with the challenge of packaging a unique product, Lifecore Biomedical turned to a trusted product, Tyvek® brand protective material. "Most of our products are packaged in Tyvek®," says Lifecore Biomedical President and CEO James Bracke. "We need its porosity for sterilization processes, and the product is well known, reliable and has well-understood properties."

Pairing an innovative product with outer and inner packaging that balances ease of use and the ability to maintain sterile integrity won Lifecore Biomedical a Silver Award in the Surgical Equipment, Instruments and Supplies category during the 2000 Medical Design Excellence Awards (MDEA) competition. Created to recognize innovation and excellence in the design of medical devices, the 2000 MDEA competition was sponsored by DuPont Medical Packaging (Wilmington, Del.), Eastman Chemical Products (Kingsport, Tenn.) and Medsource Technologies (Minneapolis, Minn.).

GYNECARE INTERGEL Adhesion Prevention Solution, Lifecore's award-winning product, provides surgeons with a product that has been shown in clinical trials to reduce postsurgical adhesions resulting from peritoneal cavity surgery. The product is co-marketed by Lifecore Biomedical and GYNECARE, the women's health care division of ETHICON, a Johnson & Johnson Company. It is a manufactured form of hyaluronic acid (HA), a substance that also occurs naturally in the body.

"From our standpoint, the packaging for this product had to be unique," says Julie Kaiser-Braden, Product Manager, Lifecore Biomedical. "We needed to design the package for GYNECARE INTERGEL Solution for a very specific reason: to minimize the fill volume into the bellows and yet deliver the clinical dose (300 mL) needed to coat the peritoneal cavity after surgery, quickly and easily." To achieve this goal, packaging engineers created a delivery system that incorporated a bellows design. To deliver the product, the surgeon places his thumbs at the base of the bellows and directs the GYNECARE INTERGEL Solution toward the desired site(s). The surgeon squeezes the base and top together like an accordion. The GYNECARE INTERGEL Solution packaging consists of four parts: a bellows that maintains the sterile product, an optional extension tube that attaches to the bellows enabling the surgeon a more direct product delivery, a PETG tray and a lid made of Tyvek®.

In addition to providing ease of use, the outer packaging for GYNECARE INTERGEL Solution needed to maintain the sterility of the product. For lidding material that meets these demands, Lifecore relied on the proven

performance of Tyvek®, supplied by Turso Companies, Inc., a second-tier medical/pharmaceutical converter located in St. Paul, Minn.

"We've partnered with Lifecore for over 10 years," says Brian Lokrantz, Account Executive for Turso. "It's been great working with them as they've expanded their operations from a small company to a business selling to the global market. Because GYNECARE INTERGEL Solution is marketed with GYNECARE, there were very specific requirements for the outer product packaging. Each element of the outer packaging was prequalified by GYNECARE, and they specified the use of Tyvek® because it met all of their requirements."



Significant effort went into the design of the bellows container. Balancing the need to maintain sterile integrity with the demand that the product be easy to use was challenging for other aspects of the packaging design as well. The bellows design required that the wall thickness withstand secondary sterilization yet have sufficient flexibility, such that the surgeons could easily deliver the product. The tear-twist cap for the bellows had to be easy to twist but strong enough to maintain the integrity of the seal. An additional need was identified for the extension tube, which was required to remain stable during product application. Engineers addressed this by adding threads to the tube, allowing it to screw onto the bellows. Throughout the design process, GYNECARE INTERGEL Solution was "road-tested" by surgeons to ensure that it met their needs.

The company's high-quality product design and packaging have paid off in other ways as well. Driven by the need for the product and the marketing efforts of ETHICON in Europe, GYNECARE INTERGEL Solution has been well received and has experienced steady growth.

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Improving Quality Using Risk Management Tools

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important to conduct a formal analysis to identify and eliminate unnecessary risk; to select high-quality packaging materials such as Tyvek®; and to use a scientific physical inspection process, such as the PacGuard® 450, to detect defects in trays before use, or the PacGuard® 460 to verify the integrity of the finished package. By doing so, companies can reduce the potential of a defective product being used and can substantially reduce the total risk associated with sterile packaging for medical devices.

PacGuard® is a registered trademark of MOCON Corporation.

Figure 1
Potential Contributors to Package Integrity Failure

Raw materials variation	Improper handling
Operator error	Variations in sterilizer process
Shims under mat of sealer	Sealer bearing failure
Sealing Process: time ■ temperature ■ pressure	Imperfection of sealing die
Mismatch of lids and trays	Lack of operator training
Improper insertion of device or inner tray	Misalignment of lids and trays

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The product is currently available in 25 countries outside the United States. Lifecore Biomedical also has submitted GYNECARE INTERGEL Solution for U.S. Food and Drug Administration approval, for use in reducing postsurgical adhesions after gynecological surgery procedures. As a supplier of high-quality packaging materials, DuPont Medical Packaging is proud to support innovative products in the medical device industry, such as those developed by Lifecore.

Capitalized product names are trademarks of ETHICON, INC.

Editor's Note:

DuPont Medical Packaging is proud to sponsor the 2001 MDEA competition. Created to recognize innovation and excellence in the design of medical devices, the MDEA program is organized by Canon Communications, publisher and trade show producer for the medical device industry. The competition is open to companies and individuals involved in the design, engineering, manufacture or distribution of finished medical devices or medical packaging. Awards were presented in June 2001 at MD&M East, the conference for medical manufacturing and design professionals.

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