High-Barrier Lidstock Maximizes Seal Strength and Maintains Peelability

Service Life of Implantable Plastic Components is Improved

When Howmedica (Rutherford, NJ), a leading manufacturer of orthopedic implants for total joint replacements, developed a new process to improve the wear resistance of implants over time, the demands placed on the products' package became extreme. The company searched for a high barrier lidding material that could withstand their high temperature processing while maintaining seal strength and remaining peelable. Howmedica turned to Rollprint Packaging Products Inc. (Addison, IL) and found two different polyester foil sealant laminations that offered these often-mutually-exclusive characteristics.

"With most of the films we tested, if the seals were strong enough to withstand our processing , we ended up with welded seals that couldn't be peeled open. The Rollprint films were the only two we found that met all our criteria," noted Larry Van House, Director of Packaging Operations at Howmedica. "Thanks to Rollprint, we now have a package that maintains an inert environment, withstands the rigors of our stabilization process and the shipping environment, and remains peelable."

Now used in Howmedica's blisters to contain implants, the 26-1093 laminate from Rollprint offers the highest oxygen barrier protection available. The material is sealed to Howmedica's PETG trays and subjected to processes that sustain 50º C for 144 hours. Rollprint's 26-1093 laminate continues to offer seal strength of six pounds per inch after processing, and can easily be peeled open. It is Rollprint's proprietary sealant layers which are credited for simultaneously maintaining seal integrity and easy peelability after the punishing heat stabilization process.

Longer Service Life

The need for the demanding properties offered by the Rollprint film followed the development of Howmedica's patented Duration® stabilization process that improves the wear resistance, or service life, of implantable plastic components used for total joint replacement. The process increases 3-D crosslinking by eliminating oxygen during gamma irradiation and post-irradiation stabilization step, producing Duration stabilized ultra-high molecular weight polyethylene (UHMWPE) components.

At Howmedica, total joint replacement components made of UHMWPE are packed in a double sterile package. The inner blister holds the product and a second blister protects the sterility of the inner package, allowing a circulating nurse to easily pass the sterile product to a scrub nurse working within the sterile field of an operating room. Both blisters contribute to the package's total oxygen barrier property.

Howmedica first places the implantable plastic product and an insert to help secure the product in a medical grade PETG tray. Using MultiVac semi-automated technology, Howmedica draws a vacuum, flushes the package with nitrogen, and seals Rollprint's 26-1093 laminate to the inner tray. This combination of vacuum, nitrogen, and the barrier property of the packaging material eliminates oxygen within the inner tray. Howmedica then places the inner tray in a second PETG tray, flushes the second package with nitrogen, and seals Rollprint's 26-1010 laminate to the outer tray.

The two Rollprint materials used to lid Howmedica's trays are similar in composition but feature different sealants that result in different seal strengths. The 26-1093 lidding material used on the inner blister is a three-layer laminate made of a 72 gauge polyester adhesive, 1 mil foil, and 1.5 mil polyester sealant. The 26-1010 used on the outer blister is a coated three-layer laminate made of a 48 gauge polyester, 1 mil foil, and a 2 mil polyethylene layer that has a proprietary heat seal coating.

"There is some pressure build-up inside the package during gamma sterilization but a lot more pressure is created during our Duration stabilization process. The greater the surface area of the UHMWPE component, the greater the pressure build-up during the process," explained John Prizzi, Jr., Senior Package Development Engineer. "The inner package is our first line of defense and needs the strongest seal." Since Rollprint's 26-1093 material features a polyester sealant, the laminate is less sensitive to long periods of high temperatures and maintains the stronger seal strength of six pounds per inch, even after Howmedica's rigorous stabilization process.

Maintaining a strong seal after the stabilization is important to Howmedica because the package then meets another significant challenge: shipping. "Going up to 10,000 feet in a non-pressurized cabin isn't an issue for medical device manufacturers who package with Tyvek®, because the material breathes and pressure build-up is never a factor," says Bruce Corini, Senior Manager of Package Engineering at Howmedica. "But with a package like ours that doesn't transmit oxygen, the pressure inside the package that is generated at high altitudes puts a lot of stress on the seals."

"We're walking a fine line between seal strength and consistently peelable seals," added Jon Klippel, Director of Market Development at Howmedica. "It would be easy to achieve the oxygen barrier, and withstand the process and the transportation environment…that would be so simple. But the end-user of this package, the nurse in the OR, is used to peeling Tyvek lids with only one pound seals. The lidding material from Rollprint gives us the best of both worlds."

Material Stabilization

"In the late 1980's, the industry became concerned about material property changes in the weight bearing polyethylene components. We found that 'traditional' gamma irradiation sterilization of polyethylene causes the formation of free radicals, which subsequently react with oxygen, resulting in the oxidation of the polyethylene component," Klippel explained. In response to these concerns, Howmedica developed a patented proprietary process that improves the wear resistance of polyethylene. "We discovered that eliminating the oxygen in the package, and then subjecting the packaged product to gamma irradiation sterilization, followed by a 'stabilization' process, combine the free radicals to form cross-links. This 'stabilized' material is now resistant to oxidation."

Howmedica's approach to maximizing product quality by improving the wear resistance of implants helps the company succeed in today's changing medical environment. Klippel noted that "In today's medical care environment, Howmedica must demonstrate that its products offer superior long-term value. Tied into this is an ever-increasing focus on outcomes; getting patients back into their active routines; and providing long-term pain-free

mobility." Howmedica's unique approach to improving the durability of polyethylene implants has contributed to their growing market share.

Minimizing blister designs also helps Howmedica reduce packaging changeovers even though manufacturing lot sizes are typically less than 50 pieces. Each inner blister has the same footprint and each outer blister has the same footprint. With only the depth of the tray varying, there is no changeover needed to prepare the MultiVac packaging equipment for another product.

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