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Three Barriers

Protect Orthopedic Implants

Osteonics' blister-in-a-blister-in-a-pouch safeguards implants from the potential of detrimental oxidation.

Osteonics Corp., Allendale, NJ, redesigned the packaging for orthopedic implants made with polyethylene to minimize the risk of oxidation during gamma sterilization. Osteonics replaced a single tray with a package that has three layers of barrier protection.

Michael O'Brien, packaging team leader, says the package has built-in redundancy to keep oxygen away from implants.

"It's a real belt and suspenders project," he says. "We used three barriers to try to keep as much oxygen out of the package as possible. Our theoretical models show that leakage is very low, which is a function of each layer having extremely low oxygen transmission rates."

Two trays, both flushed with nitrogen gas, prevent oxygen from reaching plastic orthopedic implants.
Photo courtesy—Plastofilm Industries.

The package consists of a tray-within-a-tray-within-a-pouch. Barrier layer one is a thermoformed Barex® blister with a laminated foil lid. Layer two is another thermoformed Barex blister into which the first tray is sealed. Layer three is a flexible pouch made from Clearfoil®, a silica oxide film with a high oxygen barrier. The finished package is placed into a paperboard carton for shipping.

The package is about as expensive as the standard tray used for orthopedic implants with metal parts, but the effort is worth the extra protection, according to Osteonics. The company used a thermoformed tray made from Eastar™ PETG from Eastman Chemical Company, Kingsport, TN.

NITROGEN PURGE

The package is thermoformed by Plastofilm Industries, a division of IVEX Packaging, Wheaton, IL. The Barex is provided by BP Chemical, Cleveland, OH. The Clearfoil film is supplied by Rollprint Corp., Addison, IL. All three companies worked closely with Osteonics to develop the package.

Because oxygen barrier was crucial, the team decided to flush both trays with nitrogen to eliminate as much entrained oxygen as possible. During packaging, the implant is placed into the primary or inner tray. The tray is purged with nitrogen and after flushing, a vacuum step is performed as the packaged is being sealed. Next, the inner tray is placed into the outer Barex tray and the process is repeated.

The final step is sealing the two trays into a Clearfoil pouch. The material is oriented polyester film (OPET) coated with a thin layer (100 to 2000 angstroms) of silicon oxide. The coating imparts excellent moisture, oxygen and chemical barriers that are unaffected by gamma sterilization. The coating is deposited on the OPET base film by either evaporation or gas plasma. The pouch is filled with nitrogen which serves as a final barrier.

The Barex trays are thermoformed with interchangeable molds, according to Plastofilm. The molds can run either Barex or PETG depending on Osteonics' production schedule. The Barex trays are run with full plug assists. Osteonics' existing packaging line was retrofitted to accommodate the nitrogen flush vacuum seal system.

The geometry of the inner tray allows the implant to rest securely and be suspended in the outer tray for added protection. The two trays feature easy-to-peel lids for fast, dust-free opening by user. PMP News