Medical Product Manufacturing News

ENGINEERING SOLUTIONS

Custom Desiccant Minimizes Moisture in Bioabsorbable Staple Packaging

A custom-developed desiccant protected surgical staples from degradation by managing free moisture and ensuring product stability

A desiccant removes moisture from a foil package's headspace as well as from a surgical stapler's molded components.

When it comes to wound closure, methods such as sutures and staples help to minimize scar tissue and instances of surgical-site infection (SSI). But along with the benefits of these commonly used techniques are several drawbacks. Although they produce a cosmetically appealing result, traditional sutures, for example, can be time-consuming to place. Metal staples, in contrast, can save time but may leave a more-prominent scar.

Combining the benefits of these conventional wound-closure techniques while eliminating some of the drawbacks are bioabsorbable surgical staples. Developed by **Incisive Surgical Inc.** (Plymouth, MN; www.insorb.com), the Insorb single-use stapler inserts bioabsorbable PLA/PGA staples below the epidermis, where they are absorbed and metabolized over the course of several months. The staples are easy to use, can be administered rapidly, and produce a good cosmetic closure, according to Incisive. They also eliminate the need for postoperative staple removal and reduce the risk of SSI and needlesticks.

While the bioabsorbable nature of the staples is among their most-desirable characteristics, it also presents a significant packaging challenge in the form of moisture sensitivity. To avoid the negative effects of high summer humidity, Incisive Surgical dedicated a specialized cleanroom for product assembly at its Minnesota manufacturing plant. There, workers sealed the Insorb staplers within a foil pouch to isolate them from the outside environment before shipping them to undergo sterilization. However, early testing showed that moisture trapped within the sealed pouch could be detrimental to the product's properties and stability.

"Proactively finding a solution to our packaging challenge was key to us," says David Stoen, vice president of operations at Incisive Surgical. "We knew that moisture was the enemy and wanted to take the necessary steps to remove it from the final packaging."

The first step proved to be contacting **Multisorb Technologies** (Buffalo, NY; www.multisorb.com), which customizes desiccants to meet the chemical and physical stability needs of a given product. "We know from our years of analysis and development that the source of the 'free moisture' emanates from two areas," says Virginia Cullison, business development leader, healthcare packaging at Multisorb Technologies. "The headspace within the foil pouch in which the stapler was packaged is a primary consideration, but the injection-molded components that make up the staple-gun housing can be an important and unexpected secondary source."

The Multisorb team performed the initial calculations to ensure sufficient desiccant capacity and to both stabilize the product and manage any additional free moisture that may have been present in the packaging materials. An additional safety measure was applied to account for any potential edge-seal diffusion over the validated shelf life of the device.

A number of desiccant options were then presented to Incisive Surgical, which ran its own quality control tests, shipping simulation, and moisture experiments on packaged assemblies. Based on these qualification results, the companies identified the MiniPax molecular sieve packet solution—with 2% moisture content—as the sorbent technology needed to safeguard against potential moisture degradation.

In the current design, Incisive Surgical integrates Multisorb's Drop-In desiccant into a molded protective retainer, which positions the desiccant in proximity to the staples to create a dry and stable environment. When the sterilized pouch is opened in the OR, the retainer is removed and discarded. This single step of device preparation clears the MiniPax desiccant from the sterile field over the patient, removes the protective features from the stapler, and engages the spring-loaded device for use.

MULTISORB Technologies