

Tyvek® Rx

Tyvek® Protects New Stryker® Howmedica Osteonics Implant that Could Revolutionize Lower Back Surgery

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Lower back pain — a chronic, often debilitating condition — is a major health problem both in the United States and in the rest of the world. Traditional treatment options have included non-surgical approaches, such as medicine and exercise, and surgical options of either a discectomy (removal of the nucleus of the afflicted intervertebral disc) or fusion of the two vertebrae adjacent to the afflicted disc. Success rates vary with non-surgical approaches, and surgical options don't always provide the hoped-for results. What's more, the most aggressive current treatment option — fusion — requires a long recovery period and results in a permanent reduction in mobility of that part of the spine.

A multi-disciplinary product development team at Stryker® Howmedica Osteonics & Stryker® Spine wanted to give patients another option — one that would provide the same pain relief as that achieved with fusion, but without the need for the invasive surgery, long recovery time and reduction in spine mobility associated with fusion. The result of their years of hard work is known as the Aquarelle™ Hydrogel Disc Nucleus, a unique artificial disc nucleus implant that could revolutionize the way lower back pain is treated.

The Aquarelle™ Hydrogel Disc Nucleus is an implant made of



a polyvinyl alcohol hydrogel (similar to the material used for soft contact lenses). Unlike total artificial discs that have been used in Europe on a limited basis during the last decade, in addition to allowing mobility, Aquarelle™ is designed to provide important shock-absorbing benefits that replicate those of the natural disc nucleus. What's more, because Aquarelle™ relies on the patient's own annulus for containment rather than requiring metal end plates with a polyethylene core, it requires less invasive surgery.

"Aquarelle™ is a truly unique product that has the potential to improve the quality of life for tens of thousands of people who currently suffer from chronic lower back pain," said Phillip Williams, Ph.D., Manager - Artificial Nucleus

Project at Stryker® Howmedica Osteonics. "We faced many challenges during the development of this product, not the least of which was determining the most appropriate packaging configuration. To help us do that, we called in Donald Barcan, president and CEO of Donbar Industries, Inc., a package engineering consulting firm for the health care industry," noted Williams.

"The first step was to develop a list of specific packaging requirements based on the unique nature of this product," said Donald Barcan. "The Aquarelle™ implant has 75% water content when it is fully hydrated, but must be supplied to surgeons at approximately 50% water content due to the

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intra-discal pressure associated with the position of the patient during surgery.

“So, in addition to protecting the product from physical damage and ensuring sterility maintenance, the packaging had to be breathable to allow it to be partially dehydrated after sterilization without compromising the sterile barrier. What’s more, the package had to be capable of preventing the product from losing additional moisture after it had reached the desired water content, and to maintain that water content during its shelf life,” explained Barcan.

The Aquarelle™ Hydrogel Disc Nucleus is susceptible to denting or “taking a set,” so a rigid tray and lid was the obvious choice to prevent physical damage. But, the need to gamma sterilize the product at 75% water content and then reduce the water content to 50% through dehydration without sterilizing the product twice, added a new challenge. In addition, because the product is 50% water when shipped, the final package must prevent moisture loss before use.

Barcan carefully examined the manufacturing/processing steps, reviewed the package requirements, evaluated various materials and then designed a unique, multi-component package that offered the best protection for this implant. The final package consists of an inner tray and lid that snaps into an outer tray and lid that is placed inside a foil pouch that is put into a box.

“I knew that a rigid tray fabricated from PETG with a lid of Tyvek® 1073B was the ideal starting point for this product,” said Barcan. “Tyvek® brand protective material is tear and puncture resistant; offers superior microbial barrier properties; is low linting and clean peeling; and can be sterilized using gamma radiation. PETG offers the visibility required by surgeons and has a proven performance record. Working with Tolas Health Care Packaging, we determined the best zone coating for the lid to enhance dehydration speed and restrict the implant from contacting the adhesive.”

Because the implant is free floating in the inner package, it can come into contact with the lid. To eliminate the possibility of biologic recontamination, the lid of the outer tray is raised approximately ¼-in. higher than the lid of

the inner tray, and both lids have zone-coated adhesive. The zone coating on the inner lid serves two purposes: it ensures that the implant will not come into contact with the adhesive and it maximizes the moisture vapor permeability during the dehydration processing phase. This double package is then vacuum packed in a foil pouch with multiple inert dry nitrogen gas flushing. It is important to note that the moisture issue is so significant that even placing a paper label inside the foil pouch can affect the moisture content of the implant.

“The Aquarelle™ implant is currently in human trials in Europe. Following this phase, we will submit for CE approval and then proceed with the process for obtaining approvals from the U.S. Food and Drug Administration,” said Williams. “We are very optimistic about the role that this new hydrogel disc nucleus implant can play in relieving the chronic lower back pain that so many people are suffering with around the world.”

When asked what advice he would give to his peers in other medical device manufacturing companies who have products with unique packaging requirements, Williams replied: “I would recommend that they contact an industry expert like Don Barcan. He provided invaluable assistance to our team by helping us get our new product safely into the hands of surgeons. Don recommended the best materials to meet our needs, such as Tyvek® for the lids, and came up with a simple, yet perfect multi-component package that protects our unique product through every phase — from sterilization and then dehydration to vacuum packing and transportation,” explained Williams. “Proper packaging is a key component to the success of every medical device. Our implant is no exception.”

The largest subsidiary of the \$2 billion Stryker Corporation, Howmedica Osteonics is a global leader in the development, manufacture and sales of innovative reconstructive orthopaedic devices. Howmedica Osteonics markets its products and services in more than 40 countries around the globe.

The Aquarelle™ Hydrogel Disc Nucleus is a trademark of Stryker® Howmedica Osteonics.