

Tyvek® Rx

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STI™ Chooses DuPont™ Tyvek® Medical Packaging to Protect Integral Part of Image-Guided Surgery System from NDI®

Image-guided surgery (IGS), a technology similar to that used by global positioning satellite (GPS) systems, has revolutionized traditional surgical techniques. With IGS, surgeons no longer need to rely solely on two-dimensional diagnostic scans, such as X-rays, CT (computed tomography) scans and MRI (magnetic resonance imaging) when performing complicated surgeries. Nor must they deal with problems associated with matching pre-operative images when changes such as swelling and shifting occur during surgery. That's because IGS combines pre-operative images with live data during surgery, enabling surgeons to view patients in real-time 3D. This results in greater surgical accuracy and delivers a host of benefits for patients, including: greater use of minimally invasive procedures; reduced recovery times; and enhanced cosmetic and functional results.

The Polaris® System from NDI® (Northern Digital Inc.) is internationally recognized as an industry standard for optical tracking in IGS. The Polaris® System combines the highest level of precision measurement with unprecedented tracking flexibility and is capable of simultaneously tracking both active and passive tools. Single-use NDI Passive Spheres™ are an integral part of this system.

NDI Passive Spheres™ are made of a plastic core with a specially formulated reflective coating and measure 0.45 inch (11.5 mm) diameter. They snap fit to NDI mounting posts, ensuring a secure attachment to instruments. The reflective surface is soft, porous and heat sensitive. A minimum of three spheres must be used to obtain the required x-y-z coordinates of a tool. The exact number of spheres required depends on the type of surgery being performed and the instruments being used. Typically, ear, nose and throat (ENT) surgeries require three spheres per instrument; spinal surgeries require four spheres per instrument; and brain surgeries require five spheres per instrument. The number of instruments required ranges from one to three per surgery.

For more than five years, NDI sold the Passive Spheres™ through a network of original equipment manufacturers (OEMs), but decided to sell directly to the health care industry earlier this year. Scanlan WorldWide, Inc. was selected as NDI's distribution partner for both the domestic and international markets, providing professional end-user sales representation in more than 75 countries.

"When we began working with NDI on this project, there was a lot of discussion about the packaging," said Jesse Scanlan, technical sales



representative for STI™ (Surgical Technologies, Inc.), a member company of the Scanlan Group that assembles, packages and sterilizes NDI Passive Spheres™. "The spheres are vulnerable to scratches and nicks because the reflective coating makes the surface soft and porous," explained Scanlan. "The packaging needed to protect the spheres from contact with each other, from other sources of damage and from microbial contamination. It also needed to be low-linting and compatible with ethylene oxide (EtO) sterilization."

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STI™ Chooses DuPont™ Tyvek® Medical Packaging

If there is a scratch or nick on the sphere, it may not register the image and the monitor may "freeze." When this happens, the instrument must be removed from the patient and the damaged sphere must be identified and then replaced. This sometimes causes delays in the surgery.

In addition to the technical requirements, NDI and STI knew that the packaging had to meet end-users' needs to be successful. "We conducted extensive market research with surgical personnel to understand their concerns and learn how to better meet their needs," said Mitch Coyne, director of marketing for Scanlan International, a member company of the Scanlan Group. "We learned that end-users didn't like the current offering from competitors because the packaging, which contained five spheres, was sometimes difficult to open and there was a lot of waste because many procedures did not require all five spheres or multiples of five. However, once the package was opened, the unused spheres had to be discarded."

"After reviewing all of the requirements and the market research, it was clear that the best way to package this product was to place a single sphere inside a pouch made of DuPont™ Tyvek® brand protective material and polyethylene film, and then place the appropriate number of packaged spheres inside an outer pouch made of DuPont™ Tyvek® and polyethylene film," said Scanlan. The pre-formed pouches are manufactured by Mangar Industries, a sterile packaging manufacturer located in New Britain, Pa.

The typical number of spheres used for surgery varies. For example: three to eight for ENT surgery; eight to 12 for spinal surgery; and five to nine for brain surgery. For this reason, the spheres are being sold in quantities of one, three and four. Thus, the waste associated with the thermoformed tray containing five spheres is eliminated because a single package can be opened or a combination of packages can be opened to yield the exact number of spheres required. What's more, even if a larger outer pouch is opened, the unused spheres do not need to be discarded because they are individually packaged in pouches of DuPont™ Tyvek® and polyethylene film and will remain sterile until opened.

"DuPont™ Tyvek® enabled us to deliver the most user-friendly configuration while meeting all the technical requirements for superior microbial resistance, compatibility with EtO sterilization, strength and low-linting," said Scanlan.

Currently, Scanlan International is assisting NDI with CE labeling requirements. Plans are to begin selling NDI Passive Spheres™ in Europe later this year. "This is a very exciting product that is helping to advance surgical technology and enabling tremendous benefits for patients," said Joe Scanlan,

vice president of business development for STI. "We are very proud to partner with NDI to deliver this critical component for IGS. Under the Scanlan Group of companies, we are also proud to be able to offer 'one-stop shopping' and the resultant economies of scale to NDI and other innovative medical device companies."

Established more than 20 years ago, NDI provides the core technology for advanced 3D measurement and tracking applications developed in collaboration with many of the

world's top research and medical institutions. From computer-assisted therapy to human motion research, NDI technology is trusted for its accuracy and reliability. Today, the company supports more than 5,000 installations in more than 25 countries around the world. NDI is headquartered in Waterloo, Ontario, Canada.

The Scanlan Group of companies includes: Surgical Technologies, Inc. (STI); Scanlan International; McLean Medical and Scientific, Inc.; Vascular Innovations, Inc.;

Scanlan Group B.V.; and Scanlan WorldWide, Inc. This fourth-generation family-owned group of companies is a unique combination of enterprising businesses dedicated to providing high-quality products and services to the medical community. Designed to work independently and confidentially, each company is built on a wealth of knowledge gained from working with leading medical professionals for more than 80 years.

Headquartered in St. Paul, Minn., STI has been a pioneer in medical device contracting since 1981 and prides itself on an international reputation for dependable contract packaging, responsive service and the ability to adapt to the ever-changing needs of the health care industry. STI offers high-quality product development and assembly for medical product manufacturing; can create custom package designs; and provides a wide range of sterilization processes and testing services within its ISO 13485:1996 certified facilities.

Scanlan International, also headquartered in St. Paul, Minn., recently celebrated 85 years of excellence in the design and manufacture of surgical instrumentation. In addition to a full line of specialty and single-use surgical instruments, Scanlan International offers instrument care products and services; custom design services; and global distribution services.

Scanlan WorldWide was founded to answer the medical industry's ongoing need for effective distribution in the international marketplace. The distribution network of Scanlan WorldWide provides premier distribution of medical device products to more than 75 countries through an alliance of 57 exclusive distributors encompassing 350 sales professionals.



NDI Passive Sphere™