White Paper

A Power Partnership for Building Medical Microstructures

DSM and Meister Provide Foundation for Medical Advancement

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In today's world, no one would argue that the engine powering medical advancement is increasingly being fueled by innovations in the device industry. In the spring and summer of 2013, *The New York Times*, *Wall Street Journal*, CNN and other top-tier media outlets gave novel device designs the kind of coverage formerly reserved for Big Pharma or cancer breakthroughs. And there's little wonder why. From mini robots designed to perform prostate surgeries, mechanical spiders that crawl through the colon monitoring for abnormalities, pills embedded with sensor technologies to release the right drug at the right time and miniscule "bombs" for creating nanoexplosions in tumors, doctors' best hopes for improving patient outcomes seem to rest largely on the ingenuity coming out of the medical device industry.

But while many of the measurable patient outcomes from the devices described above are years—if not decades—away from prescribed use (some do not even have FDA approval yet), dramatic improvements in cardiovascular, gastroenterology, orthopedic and urologic treatments are already being realized by a number of groundbreaking new medical devices. So if media want to examine proof rather than promise in healthcare advancements, they need look no farther than DSM and Meister Medical and the way their products are helping medical device companies (MDCs) to deliver advanced micro-structures utilizing a revolutionary medical fiber and the breakthrough structures created with it by a highly sophisticated textile processor.

Over the last two decades, increasing numbers of surgeons have been gravitating toward minimally invasive medical techniques that offer the potential to significantly improve overall medical outcomes while reducing costs to the healthcare system. Patients treated via minimally invasive surgeries (MIS) generally report less post-surgical pain and faster recoveries than those treated by traditional open surgeries. Surgeons report that MIS procedures are faster, easier to perform and require less time for recovery.

But while MIS offers many advantages over traditional techniques, they require smaller devices in order to succeed. As a result, the industry has been on the lookout for biomaterials and processor partners that can help reduce the profile of devices without compromising on strength, durability and biocompatibility or hampering surgeons' ability to successfully place devices in the body via smaller incisions.

At the forefront of this trend are DSM and Meister Medical. These two industry stalwarts have formed a powerful partnership to create novel microstructures that can help surgeons better treat patients with procedures that are more compatible and comfortable, and ultimately produce better outcomes.

Meister, a 154-year-old Switzerland-based textile processor, is well known and very highly regarded by medical device companies for its ability to engineer novel microbraid structures. The company's structures are utilized in a broad range of applications including those for mitral valve replacement, stent delivery systems, repair or stabilization of the vascular system as well as for the stabilization, replacement or joining of injured or degenerated parts of the nervous system.

To meet the growing need for lower profile devices, MDCs have been exploring a variety of new materials to utilize in their designs that will enable a smaller size without compromising strength or feature additional characteristics like softness and slipperiness. Meister is increasingly being sought out by those MDCs because of its commitment to continually forging partnerships with the best raw materials developers and creating the processing techniques, equipment and processes that capitalize on a material's best attributes.

So when a large, global MDC approached Meister for materials recommendations for a new orthopedic device under development, the company evaluated all the medical grade fibers available on the market for feasibility. Given its long history of textile processing and its deep familiarity with DSM's materials, Meister determined that Dyneema Purity® fiber—the market's first medical-grade ultra-high molecular weight polyethylene fiber might be the best option for supporting work in bringing this smaller sophisticated orthopedic device to market.

The Material Foundations of Device Innovation

While the Dyneema Purity® fiber requires a specialized expertise to process it, its unique characteristics make it ideal for next generation medical devices. But, more important, its Material Master file—coupled with Meister's processing expertise—guaranteed a more streamlined commercialization process, which is a key consideration in today's economic environment.

But while economic and development realities are top of mind for MDCs, Meister's overarching mission is to play a role in developing device applications that improve patient care via braided microstructures that are thinner, leaner and can be tailored to individual customer specifications.

Because of the specific production equipment, Meister is able to meet the precise specifications of specific customer designs. The first step is always to identify the raw material that will provide the ideal characteristics of the braided structure. The next step is to develop the microstructure, which in Meister's case can accommodate a range of specifications including but not limited to: those in diameters from some 10 micron up to 70mm; soft, tissue-friendly constructions; rigid wire-character constructions; tubular braided or micro-cord construction; single construction or core/cover-construction or even triple-cover construction; raw material blending; and absorbable, non-absorbable or partially absorbable.

And Meister's engineering know-how enables the company to develop the necessary equipment to meet customer's unique specifications and help MDCs develop products that will

enable surgeons to easily and effectively place textile structures into the body that are smoother, stronger and thinner than those built with more traditional metal or polyethylene fibers. In addition, Meister's structures are allowing MDCs to create neurosurgical, cardiovascular or urologic devices that were impossible to construct with existing materials.

Meister has long recommended DSM's Dyneema Purity® fiber to its development partners as a superior biomaterial with which to develop breakthrough micro-structures. Meister knows its innovative microstructures benefit from the great strength and slipperiness of Dyneema Purity® fiber and that its unique characteristics have the potential to support a broad range of applications. Dyneema Purity® fiber is the industry's only medical-grade ultra-high molecular weight polyethylene designed for use in medical devices. Dyneema Purity® fiber is well known among innovation-focused MDCs for its unique properties that enable the development of smaller, high-performing, fiber-based devices, including:

- 15 times stronger than medical steel, yet soft and highly pliable which can improve comfort and compliance
- Ultra high fatigue and abrasion resistance, which are advantageous in cardiovascular applications, lowering the risk of complications due to internal or external stresses
- Near-zero stretch, which add value to non-compliant balloon catheters
- A commitment to create the fine denier fibers the vascular market demands. DSM's Dyneema Purity® fiber's 25 dtex TG product is the finest medical grade UHMWPE fiber on the market today and a new product is in active development at DSM that is even finer.
- DSM's new North Carolina manufacturing facility for Dyneema Purity® fiber is the only plant worldwide that is dedicated solely to medical yarns

It's not just the unique characteristics of Dyneema Purity® fiber that causes Meister to recommend DSM to its development partners. Meister recognizes that time-to-market is a critical issue for MDCs and Dyneema Purity's Material Master File ensures a more streamlined commercialization process than could be achieved with other materials.

A Processing Powerhouse

In addition to the fiber and Material Master file, Meister values DSM as a partner because the materials developer shares the processor's commitment to supporting the invention of new product lines that enable surgeons to utilize very small, very narrow devices. These, in fact, are Meister's specialty—microstructures that utilize braided textiles that the company can produce in an incredibly diverse range of shapes—tubings, cables or overbraidings—in order to meet individual client specifications and enable new device features.

Meister, in fact, ranks among the very few processors able to produce braids in such a variety of forms. Its braids are used as components in short- and long-term medical devices used in cardiovascular, urologic, orthopedic and hydrocephaletic surgery and are designed to provide an incremental clinical benefit over existing products.

The company's skill in processing Dyneema Purity® fiber illustrates Meister's expertise in converting biocompatible raw materials into components for medical devices that are characterized by biocompatibility, high precision on diameter and surfaces and the appropriate elongation of the braid. Its manufacturing facility features state-of-art equipment and an in-house controlled engineering environment that is always tailored to customer specifications. When processing, the equipment used is dedicated to a single

product, which eliminates any risk of product contamination by unwanted raw materials. Meister is operating a cleanroom compliant with ISO 14644-1 and a quality management system in place certified to ISO 9001 and ISO 13485, thereby providing customers the benefit from a fast time to market and a high cost-efficiency.

Meister's expertise in processing Dyneema Purity® fiber into novel braided constructions has made it a valued partner to medical device companies intent on developing and commercializing innovative, low-profile devices that reduce patients' post-surgical pain and speed recovery time thus promoting better outcomes.

DSM's Dyneema Purity® fiber offers the strength of steel with more flexibility. The high strength stiffness and excellent wear properties of these constructions make them ideal for low profile devices that don't compromise on necessary mechanics. In addition, the fiber's high resistance to flex fatigue is an advantage in the development of cardiovascular innovations where continuous motion (of the heart beating) can cause flex stresses in more traditional materials.

Another requirement for next-generation vascular applications—and another reason Meister utilizes DSM's Dyneema Purity® fiber for such applications—is the elongation characteristics of the material. To work successfully, cardiovascular constructions should have as little elongation as possible and Dyneema Purity® fiber is well recognized for that benefit.

Also advantageous is the abrasion resistance of the material—the higher the better in device design. In addition, the fiber has an extremely low friction coefficient, great smoothness, flexibility and a silk-like feel, all which help surgeons work more easily and effectively.

For all its unique features, Dyneema Purity® fiber has unique nuances that can only be accommodated by experienced processors such as Meister that have custom equipment and specialized expertise to optimize both the properties and the yield of this premium material.

Meister continually recommends Dyneema Purity® fiber to its device development partners because it believes that the material is the best positioned for enabling the next generation of medical devices.

While there is a growing array of options on the table for medical device companies to create microstructures, it is only by combining the latest advancements in fiber technology with processing innovation that will enable MDCs to create the innovative new microstructures that will meet surgeons needs and improve patient outcomes. Working together with their device development partners, Meister and DSM are helping to realize this goal while maintaining the fast time to market and high cost efficiency developers are looking for in today's environment.
