MEDICAL GRADE FIBER

HOW ADVANCED POLYETHYLENE FIBER MAKES MEDICAL DEVICES SMALLER, STRONGER AND MORE DURABLE

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TABLE OF CONTENTS

3 **Abstract**

3 **Introduction**

3 **Current Industry Trends**

4 **Important Design Innovations**

4 **Growing Industry Adoption**

4 1. Conformance to structure shapes

4 2. Higher breaking strength

4 3. Softer and more pliable

4 4. Inert and hypoallergenic

5 **Latest Technology Advancements**

5 **Typical Medical Applications**

6 Orthopedic

6 Cardiovascular

7 Neurovascular

7 Surgical Robots

7 General Surgery

8 **Benefits to Medical Stakeholders**

8 A. Device Manufacturers

8 B. Doctors

8 C. Hospitals

8 D. Patients

9 **Conclusion**

10 **References**

ABSTRACT

Growth in the medical device industry has long been driven by innovation, and lately that innovation is coming from the desire to make devices and implants smaller. This trend is exemplified by the move to minimally invasive implants and techniques such as laparoscopic and robotic surgery.

The minimally invasive approach leads to faster patient recovery times, less scarring (smaller devices mean the incisions can be smaller, too), shorter hospitalization, and a lower total cost of care.

New devices and techniques are driving medical device industry growth. The United States is the largest medical device market in the world, valued at $156 billion (in 2017) and expected to grow to $208 billion by 2023, up 33 percent, according to the U.S. Department of Commerce. The U.S. had 40 percent of the global medical device market in 2017.[1]

As applications for minimally invasive surgery (MIS) move to smaller devices and implants, ultra-high molecular weight polyethylene (UHMWPE) fiber will likely play a significant role in the development of new and promising innovations that contribute to the growth of the medical device market.

INTRODUCTION

Medical industry researchers seek to understand the properties of high-tech fibers and their ability to enhance the mechanical performance of end products such as medical devices and implants. High-performance fibers, in particular, are known and defined by their superior characteristics, including high modulus, high strength-to-weight ratio and improved chemical and higher temperature resistance.

During the first half of the 20th Century, nylon, polyester and acetate fibers were manufactured with outstanding technical properties. The second-generation of man-made fibers were produced from rigid and flexible polymers during the last half of the century.[1]

Honeywell has had extensive involvement with biomaterials for the medical device industry. From our experience, we have seen significant trends influencing the direction of ultra-high molecular weight polyethylene fiber for non-invasive medical devices and implants. These trends have implications for stakeholders in all aspects of device manufacturing, deployment and use.

High-performance fiber can be classified according to their chemical structure as follows:

- Aromatic Fibers (e.g., Aromatic Polyamides or Aramids, Aromatic Polyesters, Aromatic Polyimides, and Aromatic Heterocyclic Polymers)
- Polyolefin Fibers
- Carbon Fibers
- Inorganic Fibers

CURRENT INDUSTRY TRENDS

Health care costs are climbing annually around the world. Medical advances, such as minimally invasive surgery (MIS), are crucial to improving health care efficiency, enhancing the quality of care provided and decreasing overall expenses.

The performance of MIS using endoscopic, laparoscopic or catheter-based solutions has become widespread. Consequently, the demand for devices to conduct these procedures has increased exponentially. Medical device companies are seeking smaller and more effective solutions, and they often drive design innovations for sutures, catheters and subassemblies. Original equipment manufacturers who deliver value to the manufacturing process can have a significant impact on suppliers, providers and patients.

The MIS instruments market is constantly transforming based on innovative advancements, especially in the fields of cardiac, orthopedic, ophthalmic, and neurological surgical procedures. Technological developments in this field have resulted in higher-quality instruments that allow doctors to perform the surgical interventions efficiently without sacrificing patient safety. Enhanced surgical products provide a level of control and accuracy in the operating room.[2]

IMPORTANT DESIGN INNOVATIONS

Over the years, there has been growing demand for polyolefin fibers demonstrating exceptional performance, excellent chemical resistance and reasonable thermal stability with low production cost. Polyolefin fibers can be defined as a polymer formed by long chains via chain growth polymerization. These fibers are largely composed of olefins (alkenes) such as ethylene, propylene or other olefin units. [3]

A significant design innovation in fiber technology is ultra-high molecular weight polyethylene fiber, which has inherent performance advantages over alternatives such as steel, polyester and nylon fibers in MIS applications.

Ultra-high molecular weight polyethylene (UHMWPE) fiber is a high-strength, high-modulus material based on simple and flexible polyethylene molecules. This fiber is chemically identical to normal polyethylene (PE) fiber with some differences in chemical structure. It has extremely long chains, with a molecular mass usually between 3.5 and 7.5 million atomic mass units (amu). The longer chain serves to transfer load more effectively to the polymer backbone by strengthening intermolecular interactions. This results in a very tough material, with the highest impact strength of any thermoplastic fiber presently made.[4]

Polymerization of UHMWPE was commercialized in the 1950s and the processed material is available either as fiber or in consolidated form. UHMWPE fiber, commercialized in the late 1970s, is an excellent choice for high tension, moisture and abrasion applications.

UHMWPE fiber is produced through a solution/gel spinning technology with an ultra-high draw ratio to ensure minimal intermolecular entanglements. The process involves extruding a low-concentration solution of UHMWPE ($M>2\times10^6$) to form a gel precursor fiber, which is subsequently heat-drawn to produce a highly oriented molecular structure. The material is synthesized from ethylene with metallocene catalysis polymerization. This results in polymer fiber that is stronger and more flexible and durable than alternative solutions.[5]

GROWING INDUSTRY ADOPTION

To develop smaller devices and techniques for use in minimally invasive surgery, medical manufacturing companies look for biomaterials that reduce the profile of devices without compromising strength, durability, flexibility, and biocompatibility.

UHMWPE has achieved widespread adoption throughout the global medical device industry. Rising orthopedic surgical procedures and an increasing number of diseases such as osteoarthritis are expected to contribute to demand growth for the material in the coming years.

There are a number of important reasons for medical device suppliers to adopt UHMWPE technology over competing solutions:

1. Conformance to structure shapes
UHMWPE fiber is highly flexible and can be used to make sutures that conform to the bone without the potential for cuts.

2. Higher breaking strength
UHMWPE fiber is stronger than other materials used in sutures for in-tendon or muscle repair; sutures that break can cause further injury.

3. Softer and more pliable
UHMWPE fiber is soft and pliable, which allows surgeons to navigate sutures through narrower openings than steel cable. Sutures made from UHMWPE also do not leave sharp, jagged individual strands when cut.

4. Inert and hypoallergenic
UHMWPE is inert and hypoallergenic. In comparison, steel wire in a body can become brittle and disintegrate over time.

As a fully biocompatible material, UHMWPE possesses low absorption and self-lubricating properties, as well as superior abrasive and corrosive resistance, thinness and light weight. It has a coefficient of friction that is significantly lower than that of steel or synthetic fibers such as polyester, Vectran®, nylon, and acetal. UHMWPE's coefficient of friction is comparable to polytetrafluoroethylene (e.g., PTFE and Teflon™), however, it has better abrasion resistance than PTFE.[6][7]

UHMWPE-based implants have gained popularity for orthopedic and cardiovascular implants because of their long lifespan and high tensile strength. For these devices, UHMWPE fiber is gradually replacing polyester fibers owing to its small size and flexibility.[8]

UHMWPE fiber does not pose the same health risks as alternative fibers that can disintegrate over time and potentially enter a patient's bloodstream, causing infection and pain.

LATEST TECHNOLOGY ADVANCEMENTS

Advancements in biomaterial technology have yielded oriented-strand synthetic fibers of UHMWPE, which are one of the world's strongest and lightest fibers. In some forms, this biomaterial is 15 times stronger than steel and three times stronger than polyester. It exhibits high resistance to chemicals and water and possesses superior vibration characteristics. Compared with conventional fiber, UHMWPE has a very high molecular weight and degree of orientation, along with minimum chain folding.

With outstanding toughness and extraordinary viscoelastic properties, UHMWPE fiber offers a high level of ultraviolet (UV) resistance, very high initial modulus, and exceptional breaking and flex strength. The fiber also has extremely low moisture absorption.[8]

Gel-spun UHMWPE fiber can be formed into a variety of textile constructions. As such, this medical-grade material can enhance the design of implantable cardiovascular devices such as stent grafts and covered stents.

Ongoing development of UHMWPE technology has resulted in new grades of high-performance polyethylene fiber with the same strength characteristics as existing grades with much thinner diameters. The ultra-thin properties of this material can minimize the size/profile of cardiovascular devices, allowing for less invasive surgery that shortens patient recovery time and hospital stays. Moreover, reducing the size of the device enables doctors to access to smaller blood vessels.

Today's UHMWPE fibers have been rigorously tested for compliance with International Standards Organization (ISO) standards related to genotoxicity, cytotoxicity, sensitization/irritation, hemocompatibility, pyrogenicity, and mutagenicity.

TYPICAL MEDICAL APPLICATIONS

Demanding medical applications require improved performance from surgical devices and implants. Manufacturers supplying solutions to doctors and hospitals are seeking to utilize new and innovative technology to enable the next generation of stronger and thinner medical products.

When developing implantable medical devices, it is essential to use a biomaterial that has excellent flex and bending fatigue performance and ensures superior abrasion and cut resistance. The biomaterial should offer smoothness and low elongation, and at the same time, be chemically inert, hydrophobic and biocompatible to reduce inflammation and irritation in patients.

The typical therapeutic areas for advanced biomaterials include:

ORTHOPEDIC

Orthopedic therapies require biomaterials providing superior mechanical and biological properties for bone grafting and fusion; spinal preservation; tissue fixation; and cartilage, tendon, ligament, and meniscal repair. In particular, they call for biomedical textile structures accommodating static or dynamic loads, while facilitating tissue ingrowth. The biomedical structure's geometry can also affect factors such as porosity and tissue integration.

Orthopedic surgeons need implantable devices such as:

- Anterior/posterior cruciate ligament (ACL/PCL) products
- Tethers
- Orthopedic sutures
- Bone anchors
- Synthetic ligaments
- Load-sharing scaffolds
- Biologic containment sleeves

CARDIOVASCULAR

Today, the rise in heart valve disease and other cardiovascular conditions is driving increased demand for minimally invasive technologies. Medical devices have to meet the specified tissue response and durability criteria for long-term repair. Biomedical structures are key to eliciting specific biologic responses such as cellular adhesion or controlled tissue integration.

UHMWPE fiber allows for the design of durable, lower profile catheters, grafts and other medical products. Due to its strength, small size and low coefficient of friction, the fiber optimizes reinforcement or pulling mechanisms in catheter design. It can also serve as a guidewire in cardiovascular procedures, snaking through a catheter to deliver and/or retract a medical device or implant. Although steel wire is often used in this procedure, the UHMWPE fiber is smaller, lighter, stronger, and more flexible.

In cardiovascular treatment, medical devices employing advanced fibers typically include:

- Heart valves (surgical and transcatheter)
- Annuloplasty rings
- Vascular grafts

NEUROVASCULAR

In neurovascular treatment, it is important to maximize medical device performance while minimizing the implant's deliverable profile. Precision-controlled components are crucial to surgical outcomes. Device manufacturers are focused on combining advanced materials with biomedical textile forming technologies to enable the minimally invasive expansion and compaction of neurovascular devices.

Neurovascular procedures call for superior biomaterials to be used in:

- Stents
- Coils
- Clot retrieval devices
- Embolic filtration

SURGICAL ROBOTS

UHMWPE fiber offers a low coefficient of strength and bending radius so medical device manufacturers can develop smaller profile surgical robots, stents and other devices. The fiber serves as an actuator mechanism in these applications, helping robotic arms move to perform minimally invasive procedures. The fibers essentially act as the robot's muscles and tendons.

GENERAL SURGERY

Throughout the field of general surgery, including applications in tissue reinforcement and wound support, effective biomedical textile structures are needed to support hernia repair, urethral suspension, gastric restriction, adhesion prevention, advanced wound care, and soft tissue repair. These devices are crucial to achieving the desired tissue response and, as such, must provide adequate porosity, biomimetic elasticity and secure fixation to promote healing.

For example, sutures made with advanced UHMWPE fiber are stronger, lighter and more flexible compared to sutures with other synthetic fibers such as polyester or nylon. This fiber exceeds the strength offered by current materials such as steel, silk and polyester, yet remains soft in the surgeon's hands.

Common applications for high-performance fibers in general surgery include:

- Endoluminal sleeves
- Hernia mesh
- Specialty sutures
- Abdominal wall barriers

BENEFITS TO MEDICAL STAKEHOLDERS

As evidenced throughout the global medical community, UHMWPE technology delivers a stronger and lighter fiber for MIS applications. The technology demonstrates high resistance to chemicals, water and ultraviolet light, while having superior abrasion and internal fiber-friction characteristics. Compared with conventional polyethylene fiber, the UHMWPE solution has a very high molecular weight and degree of orientation, as well as crystallinity.

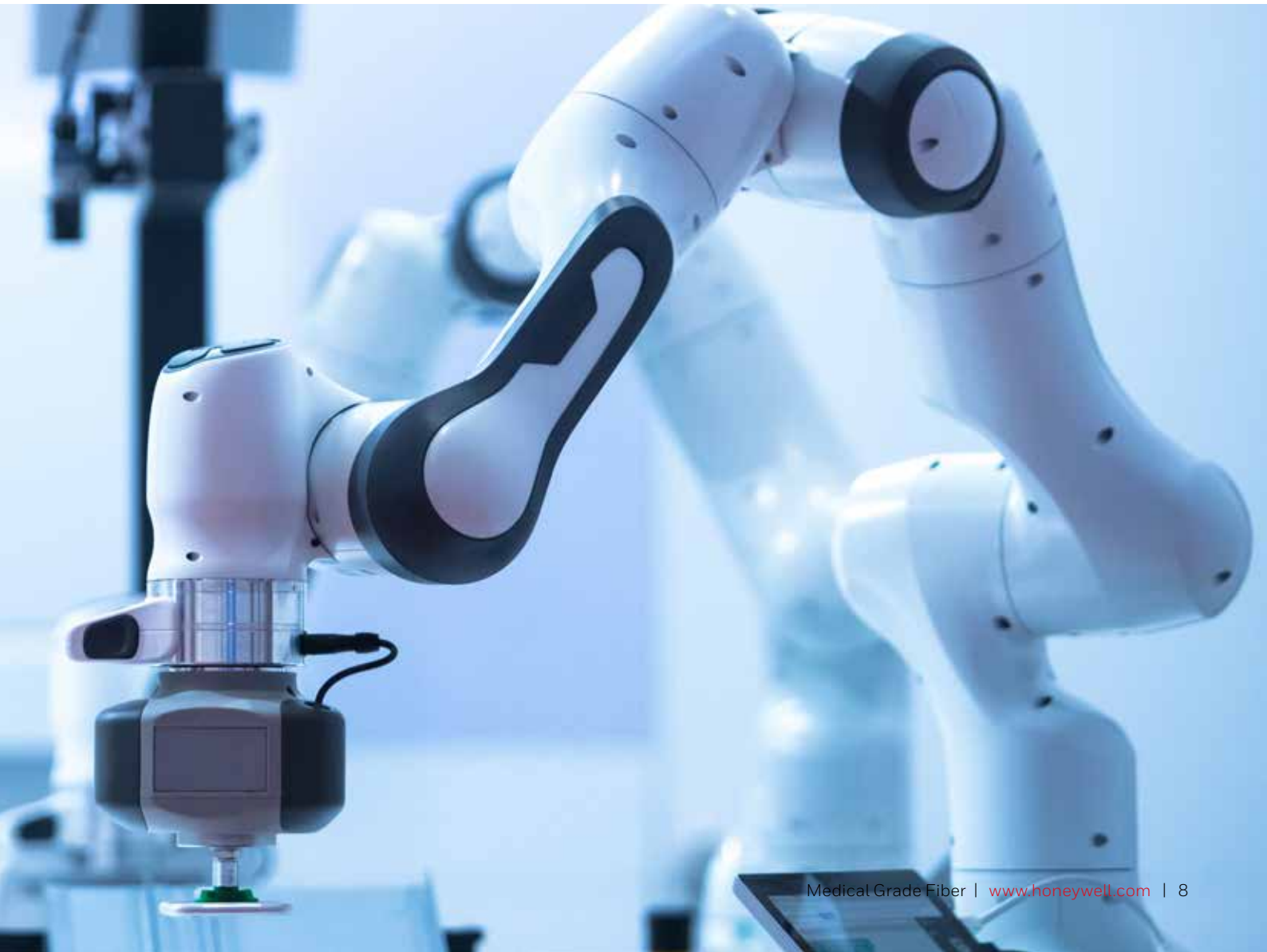
UHMWPE fiber provides benefits to key stakeholders in the medical device market:

A. Device Manufacturers
With access to high-performance, medical-grade biomaterial, medical device companies can develop smaller and more durable devices that improve the performance of physicians and surgeons, thus enabling improved procedural outcomes.

B. Doctors
Doctors deploying stents, catheters and other medical devices can achieve higher accuracy rates with the availability of reliable and easy to use products.

C. Hospitals
Improved medical device technology helps drive better outcomes and lower complication rates associated with surgeries performed at hospitals.

D. Patients
Patients also derive benefits from the advancement of medical-grade biomaterial. The use of improved medical devices in surgical procedures results in faster recovery, reduced trauma and shorter hospital stays.



CONCLUSION

The continued refinement of UHMWPE fiber technology will make a new generation of advanced medical devices and implants possible.

This technology, helping to optimize the outcomes of MIS techniques, will likely play a significant role in the development of new and effective innovations that help expand the medical device market.

Experience has shown that ultra-high strength, ultra-lightweight UHMWPE fiber gives medical device manufacturers greater flexibility to design and build smaller, stronger and lighter devices that improve patient safety and comfort during minimally invasive surgical procedures.

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