Ultra-High-Molecular-Weight Polyethylene Technology for Minimally Invasive Devices

Ultra-thin film and fiber are suitable for implantable cardiovascular devices.

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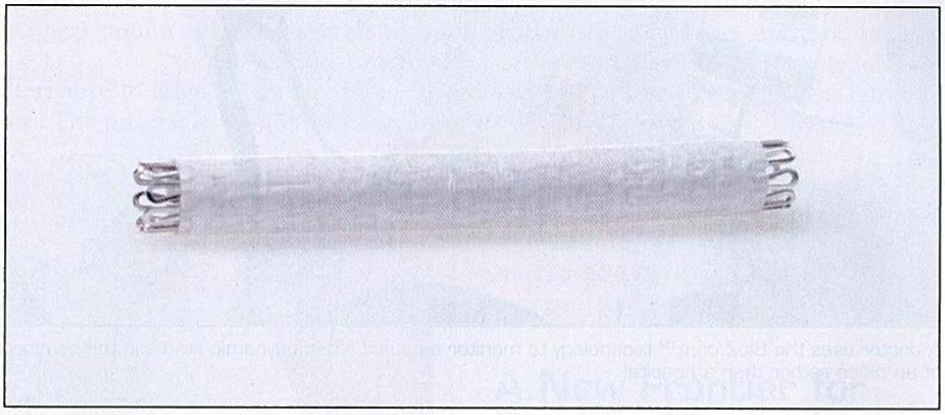
Ultra-high-molecular-weight polyethylene (UHMWPE) has been used for decades as a biomaterial in joint replacements. Recently, this technology was refined to serve the needs of minimally invasive surgical applications, particularly cardiovascular implants. UHMWPE fiber can be shaped into a range of textile constructions, including braids and woven tubes, while the film can be used as a very thin barrier or cover. As such, the medical-grade UHMWPE film and fiber are suitable for enhancing the design of various implantable cardiovascular devices, including stent grafts and covered stents.



Ultra-High-Molecular-Weight Polyethylene Film is used in covered stent applications.

The ultra-thin properties of UHMWPE film can reduce the size and profile of cardiovascular devices, facilitating the advancement of less invasive procedures that reduce patient trauma and risk, while shortening recovery time and hospital stays. The reduced size of the cardiovascular device can also allow access to smaller blood vessels that other devices cannot reach.

This advancement in UHMWPE technology allows for tailoring of the ultra-thin film thickness and film porosity (from 40% up to 85%), as well as pore size (>.05 μm). The film, characterized by a high mechanical robustness and smooth surface, is easy to handle and can be combined with other materials. It may be produced in single layers with a thickness range of 10 μm to 120 μm, or combined in multiple layers — both of which are useful options for covered stents. Recent test results indicate that UHMWPE film has no cytotoxic potential (ISO 10993-5) and meets the requirements of the USP guideline for Class VI Plastics – 70C.

Refinement of UHMWPE technology has also yielded new grades of high-performance polyethylene fiber that offer the same high specific strength as existing grades at significantly thinner diameters. These fibers were developed to help medical device manufacturers design smaller, lower-profile implants for minimally invasive surgical procedures, without sacrificing strength or durability. They have an exceptionally high tensile strength that enables manufacturers to develop lower-profile yet strong implants that meet the increasing demand for minimally invasive surgery. The fibers also offer pliability, smoothness, a low coefficient of friction, and fatigue and abrasion resistance. They have been fully and successfully tested according to ISO standards for genotoxicity, cytotoxicity, sensitization/irritation, hemocompatibility, pyrogenicity, and mutagenicity.

This technology was done by DSM, Geleen, The Netherlands. For more information, please visit ***http://info.hotims.com/28057-158.***