

Technology at the Core

Embracing a fundamental understanding of technology to fuel product innovation.

BY JOSH LOVEKAMP, PhD

Gore & Associates was founded by Bill and Vieve Gore in 1958 as a technology company focused on exploiting the unique properties of polytetrafluoroethylene (PTFE), a polymer that Bill had worked with as a chemical engineer and scientist at DuPont. Since the development of our first product, the MULTI-TET® Flat-Ribbon Cable for electronics applications, we have leveraged our ability to manipulate PTFE to develop thousands of products in numerous markets. In large part, this was made possible by Bob Gore, one of Bill and Vieve's five children, who is credited with many of the innovations responsible for the success of our company, including the process used to create expanded PTFE (ePTFE) (Figure 1). This basic process is still in use today to create ePTFE films, sheets, tapes, tubes, and fibers for use in applications ranging from consumer fabrics and energy-efficient fuel cells to vascular and endovascular grafts. In each case, we utilize our advanced ePTFE core technology in combination with a variety of enabling technologies and a fundamental understanding of each application in order to create and deliver reliable, high-value products that perform as promised to enhance quality of life.

Today, Gore & Associates is composed of four divisions that are defined primarily by the markets that they serve (Electronic Products, Industrial Products, Fabrics, and Medical Products). These product divisions are connected by a common reliance on our core technology expertise to lay the foundation for future new products and product innovation (Figure 2). This corporate architecture underscores the fact that we are a global enterprise dedicated to applying our unique materials, capabilities, and technical expertise to solving complex challenges. The success of this approach relies on our ability to continue to identify both the opportunities for technology advancement and the possible synergies that exist across relatively diverse product markets.

Some examples of relatively dissimilar product markets that benefit from the synergistic development of underlying core technologies include filtration membranes and gaskets for industrial applications, semipermeable barriers for sensitive electronics, and fabric garments to protect military and police personnel against environmental, chemical, and biologic threats. Each of these leverage the common know-how developed over decades of experience with the various forms of our core technology. In



Figure 1. Bill and Vieve Gore, founders of Gore & Associates (left), and their son, Bob Gore, recreating his 1969 discovery of the process for creating ePTFE (right).

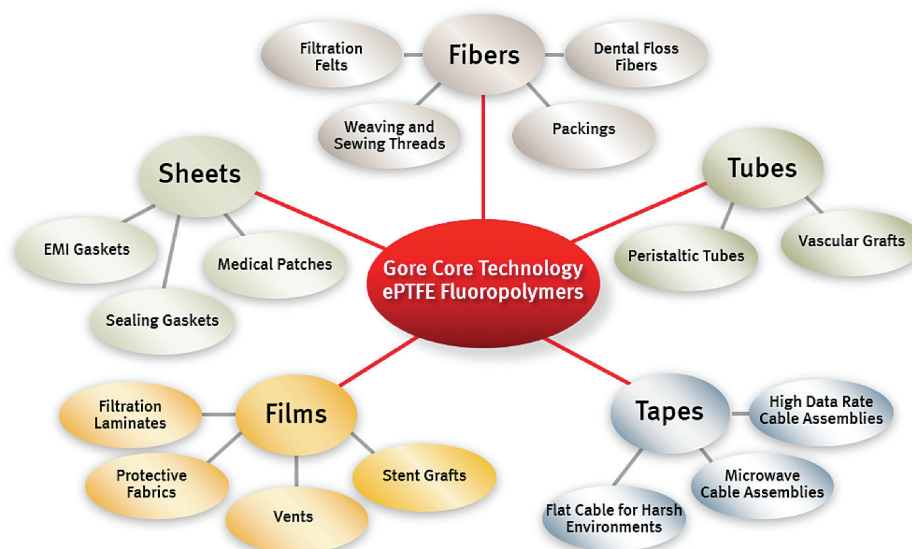


Figure 2. The commitment to our core and complementary technologies has resulted in a broad array of forms and modifications to support products in diverse applications across the four product divisions.

In addition, Gore has the unique ability to design each and every layer of ePTFE that goes into our products, beginning with the properties of a specific PTFE resin, through processing, and finally with the construction of a finished product. This depth of influence and expertise throughout the value stream enables the creation of sophisticated products with material properties that are engineered to uniquely suit the needs of the applications for which they are intended.

LEVERAGING TECHNOLOGY FOR MEDICAL PRODUCTS

Like the original MULTI-TET Wire Product, the development of the GORE-TEX® Vascular Graft was the result of Bill Gore's search for applications that might uniquely benefit from the properties of ePTFE. In this case, the inert nature of PTFE and the ability to tailor the biologic response by manipulating the microstructure through expansion contributed to making this an ideal application (Figure 3). However, early clinical experience emphasized the importance of our cross-discipline technology development. Physiologic pressurization of vascular grafts in some cases had led to creep, or gradual dilation, of the ePTFE tubes. Previous development of our high-strength ePTFE films for nonmedical applications allowed for the ability to rapidly address the problem by introducing a new version of the product that incorporated a reinforcing layer to ensure creep resistance.

Today, the evolution of vascular surgery has provided less-invasive endovascular options for patient care. From the perspective of implant manufacturers, this has come at the cost of additional device complexity and

technological demands. We have chosen to address this demand in much the same way that we have our ePTFE technology. That is, through the formation of a deep understanding of these complementary technologies. In this way, we not only enable our existing generation of products, but ultimately we can leverage this knowledge base in order to create additional unique, high-value products in the future. This approach is exemplified by the investments we have made in strategic technologies such as nitinol metallurgy, catheter-based delivery systems, and bioactive functionalization of ePTFE such as with the CBAS® Heparin Surface. These and other investments in technology and, consequently, our capabilities allow us to continue to innovate in areas where we have developed distinctive capabilities.

DISTINCTIVE CAPABILITIES FOR THE AORTIC ENDOVASCULAR MARKET

Within our aortic endovascular business, we have identified multiple vectors for product development where our technology expertise creates the opportunity to provide unique value. Specifically, these development vectors are low profile, conformability, controlled deployment, and branched technology (Table 1). While these vectors are by no means unique in that the demand has been created by the marketplace, our ability to execute upon them is believed to be unique as a result of the investments we have made in the underlying technologies required.

Our distinctive capabilities are brought about in two ways. First, having deep knowledge regarding the technology embedded in our devices provides a better

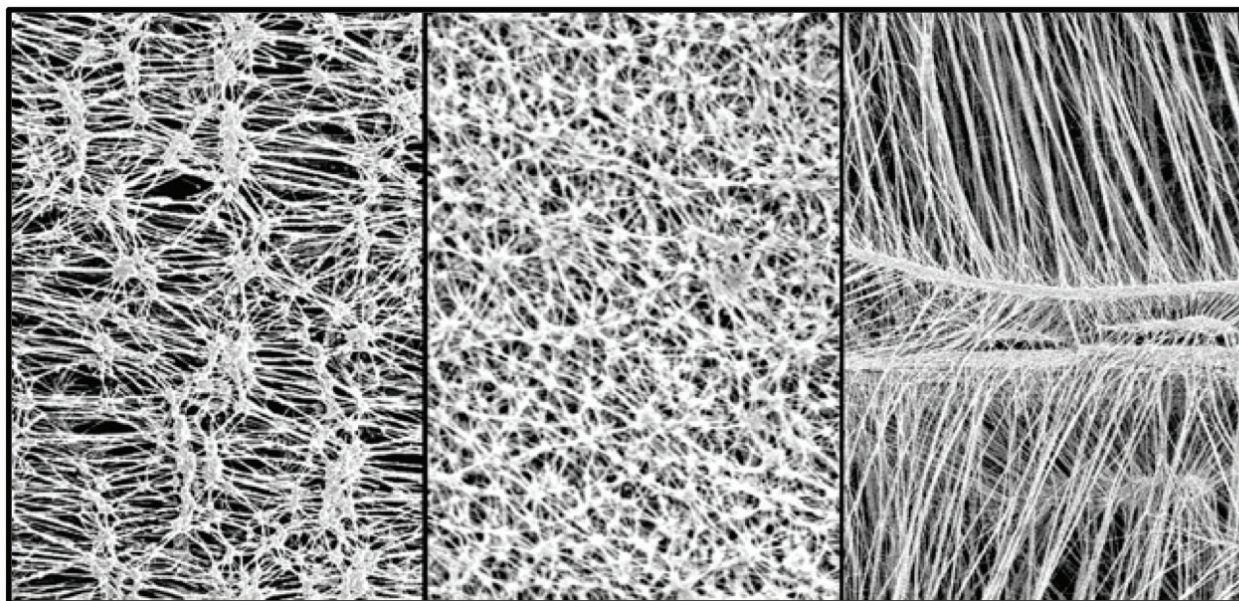


Figure 3. Various microstructures of ePTFE membranes.

framework to drive future innovation. Second, this deep knowledge also affords us the opportunity to influence the design of products with many more knobs to turn. In other words, because we design, create, and understand our products, including the critical components and subcomponents, we have the freedom to tailor the properties of each in ways that allow us to tune the performance of the final product to achieve the desired result (e.g., PTFE resin properties, ePTFE film tensile strength, ePTFE film porosity, nitinol wire processing conditions).

The Conformable GORE® TAG® Thoracic Endoprosthesis is a good example of the value we are

able to derive from our distinctive capabilities. The primary motivation for this effort was to design a thoracic endograft that was safe and effective in the treatment of patients with traumatic aortic transections. In the delivery of the final product, we leveraged our deep knowledge in nitinol technology to provide a stent frame with expanded oversizing windows and improved fatigue and compression resistance. The design also incorporated changes to the ePTFE graft construction and the mechanism of graft attachment that provided a more flexible, conformable design. As a result, we were successful in bringing a device to

TABLE 1. AORTIC DEVELOPMENT VECTORS LEVERAGE DISTINCTIVE CAPABILITIES THAT ARE MADE POSSIBLE BY OUR CORE AND STRATEGIC ENABLING TECHNOLOGIES

LOW PROFILE

Utilizing advanced fluoropolymers, coupled with our deep expertise in nitinol technology, enables us to engineer materials that have the potential to reduce profile while maintaining device durability.

CONFORMABILITY

Building on more than 55 years of ePTFE experience enables us to optimize fluoropolymer forms and structures, stent geometry and a proprietary stent-to-graft bonding process resulting in durable and dependable solutions to maintain wall apposition and seal in complex anatomies.

CONTROLLED DEPLOYMENT

Combining innovative catheter technology with ePTFE fiber-actuated deployment, we actively engineer intuitive delivery systems designed to optimize precise placement and enhanced control throughout the deployment process.

BRANCHED TECHNOLOGY

Our proprietary ePTFE and CBAS® Heparin Surface technology and extensive experience designing both large- and small-diameter stent grafts enable us to engineer both aortic and branch components to create durable, off-the-shelf designs for the safe and reliable treatment of the entire aorta, including the branch vessels.

market that not only met the needs of the transection patient population (e.g., expanded oversizing windows, improved fatigue resistance, enhanced conformability), but also provided benefits over previous thoracic endograft designs in all etiologies.

LOOKING FORWARD

New examples of how Gore is leveraging the fundamental understanding of our core and strategic-enabling technologies are currently under development or nearing market introduction. These include products that incorporate advances in each of the development vectors

identified for the aortic endovascular market, as enabled by our distinctive capabilities.

We share our customers' priorities and perspectives. Our close working relationships help us understand the problems that they face and uncover the best solutions for each in order to improve patient outcomes. We are committed to delivering meaningful advancements that set the standard of performance for today and tomorrow. ■

Josh Lovekamp, PhD, is a Technical Leader for the Aortic Business Unit of Gore & Associates. He may be reached at jlovekam@wlgore.com.