

The Promise of ePTFE:

How to Harness Its
Potential in Medical Devices





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Prefer to listen?



Watch The Session

Meet The Experts

Our experts are quoted throughout this resource from a live session at DeviceTalks Boston 2025.



Eric Leopold

SVP and GM
Aptyx



Chris Steadham

VP of Technology
Aptyx



Beth Harrison Meyer

SVP Global Marketing
Aptyx



Introduction: The Quiet Revolution of a Material That's Changing Patient Lives

In the dynamic world of medical technology, innovation is the lifeblood that promises better patient outcomes and more effective treatments.

We're constantly seeking materials and methods that push the boundaries of what's possible. Yet, sometimes, a truly game-changing material, one with the power to revolutionize device design and patient care, remains underutilized, its full potential waiting to be unlocked.

Expanded Polytetrafluoroethylene (ePTFE) is one such material. As Beth Harrison Meyer, SVP of Marketing at Aptyx, highlighted, there's a shared purpose in med tech:

“Knowledge sharing is essential in this mission, as it really amplifies it and gives us an opportunity to truly, positively impact patient lives. That's why we are dedicated to sharing crucial knowledge about ePTFE.”

While its name might sound complex, its impact is profound. From its humble beginnings to its current role in sophisticated medical implants, ePTFE offers a unique combination of properties that few materials can match.

This ebook will guide you through its fascinating history, its unique scientific advantages, its diverse applications, and the critical considerations for “getting it right.”

Join the experts from Aptyx as we explore why ePTFE is not just another material, but a cornerstone for future medical breakthroughs.

Chapter 1: From Lab Accident to Lifesaver

The Surprising History of ePTFE

Every groundbreaking material has an origin story, and ePTFE's is particularly fascinating – a testament to scientific curiosity and serendipity.

The Birth of PTFE: An Accidental Discovery

Our story begins not with ePTFE, but with its precursor, Polytetrafluoroethylene (PTFE). Back in the 1930s at DuPont, scientist Roy Plunkett was working on identifying new fluorocarbons when he stumbled upon a “slippery white powder” in one of his experiments.

This accidental discovery remained relatively obscure until World War II, when its remarkable corrosion resistance found a critical application in the Manhattan Project, used for coating containers for uranium enrichment.

Once the war ended and secrecy orders were lifted, DuPont patented the material, and PTFE was trademarked as Teflon® – a name now recognized in households worldwide.



The “E” Factor: Gore’s Innovation

Fast forward about 25 years, to Bob Gore of W. L. Gore & Associates. He envisioned more for PTFE, seeking to introduce porosity to the material. After numerous attempts, he developed a breakthrough process involving high temperature and a rapid stretching technique. This innovation transformed PTFE into expanded PTFE, or ePTFE. This new material was trademarked as Gore-Tex®, famous for its use in outdoor apparel and other everyday items.

ePTFE Enters the Medical Arena

Following these developments, research into both Teflon® and ePTFE continued to flourish. It was in the 1970s that ePTFE truly began to make its mark in the medical device arena, heralding a new era of possibilities for implants and medical components.



What Makes ePTFE So Unique?

The journey from a “slippery white powder” to a high-performance medical material hinges on the intrinsic properties of PTFE and the transformative process of expansion.

The Foundation: PTFE's Intrinsic Qualities

PTFE’s uniqueness stems from its molecular structure. “PTFE, what makes it unique is it has the fluorine element on the backbone of the carbon,” explains Eric Leopold. “That fluorine is a large element. The bond to the carbon is long. It creates unique properties because of that structure.” These properties make it an exceptional organic polymer:



Low Surface Energy: Contributes to its characteristic slipperiness and biocompatibility.



Exceptional Chemical Resistance: It boasts the most chemical resistance of all organic polymers.



Thermal Stability: It remains stable across a wide range of temperatures.



High Melting Point: Further enhancing its durability in various conditions.

These inherent traits make PTFE, or Teflon®, “a very useful material” in many industries.



The Power of Expansion: Unlocking ePTFE's Potential

The magic truly happens when PTFE is expanded to create ePTFE. “Once you expand it, that's where you get the porosity,” Chris Steadham notes. “And the porosity is really what gives it a lot of the benefits we use with medical devices.” This expansion process doesn't just create pores; it enhances the material in several critical ways:



Increased Strength: The stretching process can align polymer chains, making it stronger.



Enhanced Flexibility: Despite increased strength, it gains more flexibility.



Controlled Permeability: “We can control the permeability,” Chris adds. “So if you want it to be permeable, it can be. If you want it to be compatible for cell growth, it can be.”

This controlled porosity and enhanced physical properties are precisely why “that stretching...really led to the next generation of implants.” ePTFE retains the beneficial inertness and biocompatibility of PTFE while adding a new dimension of customizability vital for sophisticated medical applications.



If ePTFE is such a game-changing material, why isn't everyone using it to change the game?

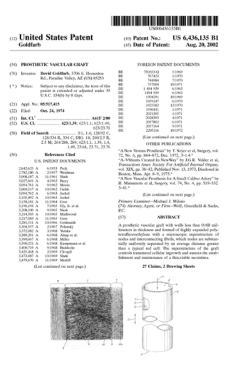
Realizing its true potential requires specialized expertise.

Historically, strong patent protection limited broader industry investigation and development. With those patents now expired, and the disruptions of COVID receding, the opportunity to innovate with ePTFE is wider than ever.

The benefits of ePTFE

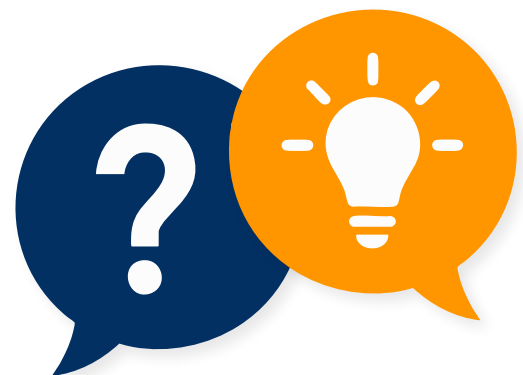
- Ultra-Thin & Ultra-Durable
- Built for Long-term Performance
- Supports Advanced Flexibility & Reduced Complications
- Provides Enhanced Safety & Biocompatibility

Patent



The Goldfarb patent held a tight hold on its use until it expired in 2019

Know-How



Specialized expertise is required, and it is not widespread

Meet the Aptyx Experts Guiding the Way



Eric Leopold

SVP and GM, Aptyx



Chris Steadham

VP of Technology, Aptyx

Successfully harnessing ePTFE demands deep knowledge. At Aptyx, this expertise is embodied by individuals like Eric Leopold and Chris Steadham.

Eric Leopold began his career 35 years ago with W. L. Gore, helping develop landmark products like the Gore Viabahn, thoracic TAG, and Excluder AAA devices. His journey continued with Lombard on the AlturaAAA device and the Artivion AMDS device, building an extensive knowledge base in ePTFE and polyester applications.

Chris Steadham has been working with ePTFE for about 25 years, starting at Cordis and the University of Florida. His experience spans B. Braun, Guidant (working on an ePTFE balloon with Gore), Machine Solutions, Bard Peripheral Vascular (as a technical manager for covered stents in Europe), and most recently Medical Murray, leading ePTFE product development.

Their collective experience underscores the nuanced understanding required to get ePTFE right.

Chapter 3:

The Material Landscape

ePTFE in Context and Navigating Clinical Risks

While ePTFE offers a remarkable array of benefits, it's essential for medical device innovators to understand its position relative to other material options and to be cognizant of the potential clinical risks associated with any implant material. Informed decisions require a comprehensive view of the landscape.

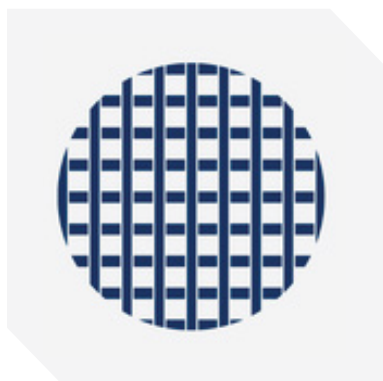


Limited Choices for Tissue Replacement



TISSUE

- Human
- Bovine
- Porcine



POLYESTER

- PET
- PE
- UHMWPE



ePTFE

- Traditional
- Electrospun

Comparing Your Options: ePTFE, Polyester, and Tissue

When considering materials for applications like tissue or vascular replacement, several options come to mind, each with its own history and property profile.

- **Tissue (Human, Bovine, Porcine):** As Eric Leopold noted, “Tissue has the longest history – human, bovine, porcine. It has both a lot of history and demonstrated performance.” Its natural origin is a key characteristic, offering inherent biocompatibility in many scenarios. However, sourcing, consistency, and potential for immune response or disease transmission (though rigorously controlled) are factors to consider.
- **Polyester:** “Polyester also has a long history,” Eric explained. “It’s a very strong material that has performed well for vascular grafts in certain applications.” Key advantages of polyester include durability, good flexibility, strong tensile strength, high biocompatibility, and relatively low cost, making it a “nice performing material for grafts and other applications.”
- **ePTFE:** As we’ve begun to explore, ePTFE builds upon many of the strengths found in other materials but adds further dimensions. “ePTFE, as we’ll see, has a little more versatility. It has even greater opportunity,” stated Eric. Chris Steadham elaborated: “Looking at ePTFE, it’s very modifiable. We can create extremely low profiles. We can have strength in different directions, and we can control how much endothelialization we have with those implants.” In essence, ePTFE “brings all the benefits of polyester with a little more above and beyond.” Its applications have grown impressively, from grafts and sutures to complex stent-graft systems and even heart valves, demonstrating its adaptability to increasingly demanding clinical needs.

While alternatives exist, and Aptyx works with a wide range of materials, this discussion is on ePTFE.

“While we sew all kinds of materials onto frames, I truly believe that the benefits of ePTFE are above and beyond the other available materials,” Chris emphasizes.



Polyester vs. ePTFE

ePTFE delivers unmatched benefits for implants

POLYESTER

Durability
Flexibility
Strong tensile strength
Biocompatibility
Low cost

ePTFE

Durability
Flexibility
Strong tensile strength
Biocompatibility
Low profile
Endothelialization control
Modifiable
Resists dilation



Understanding and Mitigating Clinical Risks with ePTFE

Every medical device and the materials used within it carry inherent clinical risks that must be thoroughly understood and proactively mitigated in the design and manufacturing process. ePTFE is no exception.

Eric Leopold pointed out, “every product that’s made, all materials used, have clinical risks associated with them. For a simple vascular graft, for example, as it’s attached to a native artery, there’s risks of the suture tearing through the material. There’s risks of blood weeping through... on the end of a graft, you run the risk of getting an occlusion.”

Beyond the material itself, device performance risks include:

- Mechanical failures
- Adverse interactions with struts and stent frames
- Delamination when ePTFE is laminated onto frames
- Ensuring desired blood containment properties (preventing weeping)
- Suture retention strength

The key, as Chris Steadham highlighted, is that “all of those properties that contribute to those risks are modifiable.” This is where expertise in ePTFE processing and device design becomes paramount. Porosity control can affect weeping; composite systems can help address delamination; and suture retention can be improved by layer orientation or composite structures.

“

Many of the performance risks are easily addressable with the proper execution, Chris assures. This underscores the message: More expertise, less risk, greater performance.”



Chapter 4:

Mastering the Marvel

Key Considerations for Working with ePTFE

Five areas can be customized to get the best properties for each application:

- 1** Forms of ePTFE and Their Applications:
Tailoring the Material to the Mission
- 2** The ePTFE Manufacturing Journey:
Process Selection Impacts Material Properties
- 3** Dial in Multiple Parameters with Structural Manipulation
- 4** Structural Variations Enhancing ePTFE's capabilities: Layering and Bioactives
- 5** Integration with Other Components



1. Forms of ePTFE and Their Applications: Tailoring the Material to the Mission

ePTFE is not a one-size-fits-all material. Its true strength lies in its adaptability, starting with the various forms it can take. As Chris Steadham explains, “if we think of ePTFE, it can come in a membrane form. It can come in tubular form. We can create flat sheets, and it can be produced as a fiber.”

The choice of form is dictated by the specific clinical application and desired performance characteristics:



Membranes:

Ideal for “a very complex shape, where we need ultra-thin properties, and we want to build out different elements.”

Endologix AFX® 2
Endovascular AAA System



Flat Sheets:

Often used in “structural heart applications, which require high mechanical strength and benefit from flat sheet technology.”

GORE® DUALMESH®
Biomaterial



Tubular Forms:

Well-suited “if we need high flexibility, like a graft.”

BD Venaflo™ II
Vascular Grafts



Fiber:

Commonly used in sutures. “A lot of times, ePTFE is sewn onto frames using ePTFE suture as well.”

GORE-TEX® Suture

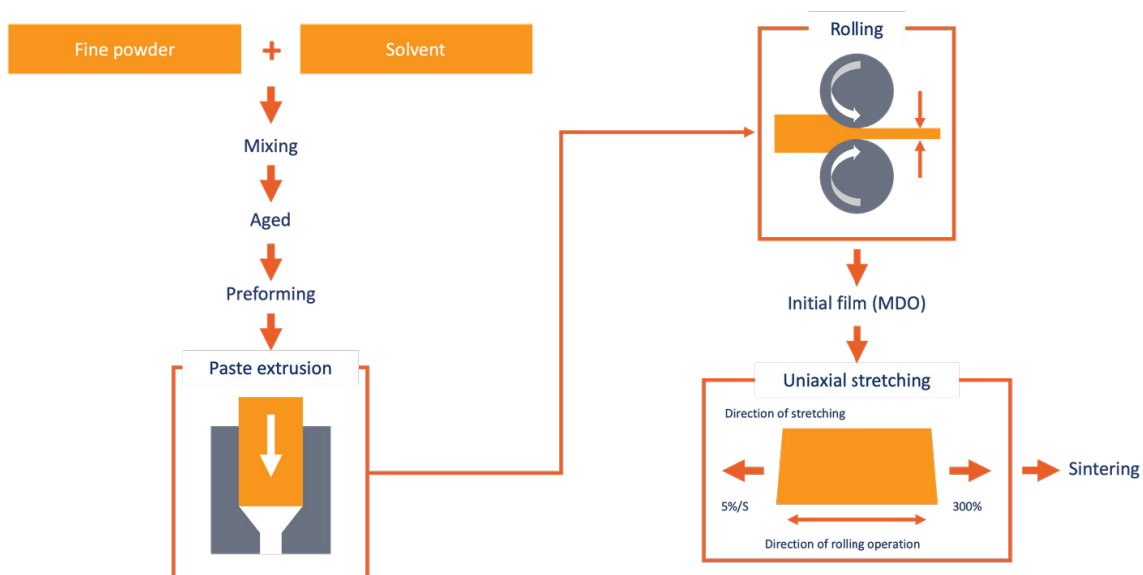
Images are representative products in market. All trademarks are the property of their respective owners.

2. ePTFE Manufacturing Journey: Process Selection Impacts Material Properties

While Aptyx doesn't currently manufacture raw ePTFE, understanding and influencing its creation is crucial. "We partner with several different companies to get the output we're looking for, because the requirements you have for a device vary from device to device, and it's important that you control it from the beginning," says Eric Leopold.

Aptyx "specify the resins directly into their selection, and we work with them on the extrusions itself, looking at different drawdown ratios, how much shear gets put into the material, and as well as expansion ratios all the way through the processing."

Process Example:



The process for thin films, for example, starts with the "white, slippery powder."

Control of solvents, lubricants, mixing, aging, and pre-forming all impact the final output. Paste extrusion parameters (pressures, temperatures) influence fibril formation.

Post-extrusion, calendaring (a rolling system) imparts the initial machine direction orientation and porosity. Further stretching on a tenter frame can create transverse orientation and biaxial properties for membranes.

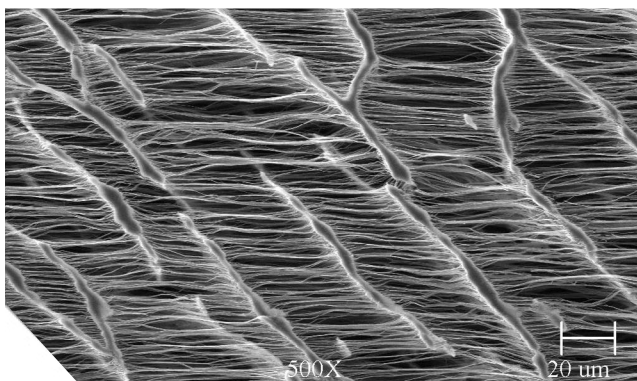
3. Dial in Multiple Parameters with Structural Manipulation

Some common methods include stretching, sintering and a combination of these. For example, the stretching process defines the material's structural properties with uniaxial and biaxial having different properties.

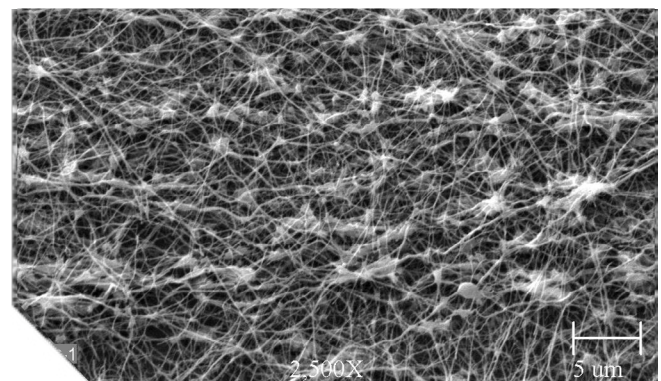
- **Uniaxial (or MDO - Machine Direction Orientation) ePTFE:** Typically seen in vascular grafts, this material is stretched primarily in one direction. It may “still have some room to be stretched in the other.”
- **Biaxial ePTFE:** Achieved through transverse expansion (e.g., on a tenter frame), this form is common in membranes. It offers properties like thinness and controlled density/porosity, with strength distributed in multiple directions.

“

We can control those ratios and fully expand material or partially expand material, depending on the property we want with the finished device,” Chris explains.



Uniaxial

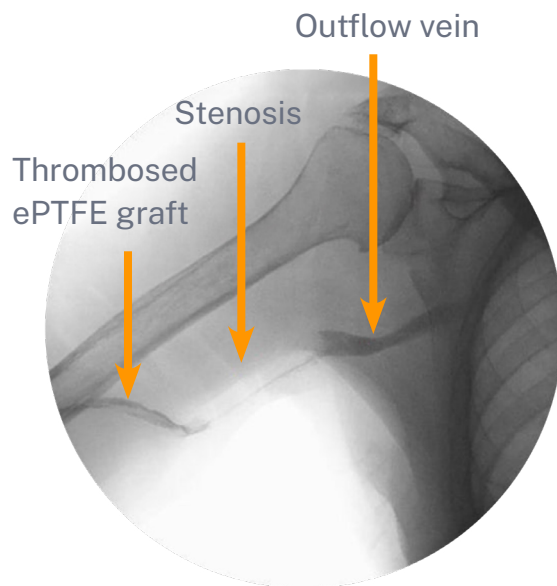


Biaxial

4. Layering and Bioactives: Enhancing ePTFE's Capabilities

Beyond its basic forms, ePTFE shines when combined with other elements:

- **Layering:** Building structures by layering ePTFE allows for fine-tuning material properties for specific applications.
- **Bioactive Components:** “A common enhancement is adding heparin to vascular grafts in order to improve the thrombogenicity reactivity of the material,” notes Eric. Other components, like carbon (favored by Bard, while Gore favors heparin), can also be integrated to achieve specific therapeutic targets. “Adding these different bioactive components, adding layers allows us to really dial in the material for the given application,” Eric states.



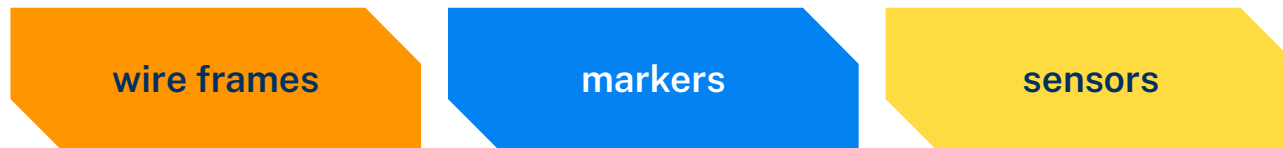
COMMON VARIATIONS

- Heparin
- Carbon
- FEP
- Urethane

Chris summarizes, “It’s very versatile. There are many different materials, additives and combinations that can create a variety of finished devices.”

5. Integration with Other Components

ePTFE can be integrated directly with other components such as:



Integration with other components doesn't require sewing, but rather expertise to adjust based on the device. One significant advantage of ePTFE processing is the potential for efficiency. Encapsulation via sintering "can be an extremely fast process," Chris notes, potentially reducing what could be hours or even a day of sewing to under an hour.

Pushing technological boundaries with ePTFE requires vigilance. Chris Steadham points out key "watch outs":

- **High-Temperature Processing:** When encapsulating and sintering, the high temperatures involved can impact substrates.
- **Delamination:** "Anytime you're putting two materials together, you want to make sure they stay together." The sintering or sewing process, or composite structures, are vital for adhesion.
- **Material Tearing:** When loading implants, preventing tears is crucial.
- **Suture Retention:** Ensuring adequate suture pull-out strength is a key design consideration.

Chapter 5:

Beyond the Horizon

The Future of ePTFE is Now

The story of ePTFE is far from over. Its unique properties and adaptability make it a fertile ground for ongoing innovation in medical devices.

Here are some exciting frontiers being explored:

- **Advanced Material Combinations & Bioactives:** “More bioactives are being developed, are being engaged with the material,” says Eric. This includes new ways to control the material’s interaction with arteries and the addition of new physical properties by creating novel compounds and layers. Chris adds, “those new compounds are real, and your imagination is the only limitation we have.”
- **Ultra-Low Profiles:** The ability to work with incredibly thin ePTFE is pushing the boundaries of device miniaturization. “We can work with ePTFE that’s 1/10 thousandths of an inch – human hair is three thousandths,” Chris highlights. This is a significant factor in developing less invasive devices.
- **Sensor Integration:** The potential to integrate sensors directly into ePTFE components opens doors for smart implants that can monitor physiological conditions or device performance in real-time.
- **Drug Elution Capabilities:** “Because of the porosity that ePTFE has, you can use it for drug elution as well,” Chris explains. This could lead to devices that not only provide mechanical support but also deliver therapeutic agents locally.

“There’s many capabilities that you’ll see coming to market over the coming years,” Chris states. The enduring need for biocompatible, versatile, and high-performance materials ensures that ePTFE will remain at the forefront of medical innovation.



Conclusion: The Time to Innovate with ePTFE is Today

The journey of ePTFE, from an accidental discovery to a cornerstone of advanced medical devices, is a testament to its remarkable properties. Its biocompatibility, durability, versatility, and the ability to tailor its characteristics for specific clinical needs make it an unparalleled material in the medtech landscape.

As we've explored, the historical barriers to its wider adoption have diminished, opening new avenues for innovation. From life-saving vascular grafts and complex heart valves to the next generation of ultra-low-profile devices with integrated sensors and drug-eluting capabilities, ePTFE is poised to play an even more significant role in advancing patient care.

However, "getting it right" with ePTFE requires a depth of understanding that goes beyond textbook knowledge. It demands hands-on experience, an appreciation for the nuances of its various forms and manufacturing processes, and the foresight to mitigate potential risks while maximizing performance.



Let's Build the Future of MedTech, Together

You've seen the potential. You understand the possibilities. Now, let's explore how ePTFE can revolutionize your next medical device.

The experts at Aptyx are ready to partner with you, bringing decades of specialized ePTFE knowledge to your most complex challenges. Whether you are in the early stages of concept development or looking to optimize an existing design, we can help you get ePTFE right.

Ready to discuss your project?

Contact us today
for a consultation at
info@aptyx.com

Learn more about
Aptyx's capabilities
www.aptyx.com



About the Experts

Eric Leopold is a seasoned expert in the medical device field with three decades of experience, primarily focused on ePTFE and other advanced fabrics. His distinguished career began at W. L. Gore & Associates, where he played a pivotal role in the development of groundbreaking products such as the Gore Viabahn endoprosthesis, the TAG thoracic endoprosthesis, and the Excluder AAA endoprosthesis. Following his tenure at Gore, Eric continued to contribute his expertise to companies like Lombard Medical, working on the Altura AAA device, and Artivion, focusing on the AMDS device. His extensive hands-on experience has provided him with a profound understanding of ePTFE's application in complex medical implants.

Chris Steadham brings over 20 years of dedicated experience in ePTFE research, development, and application. His journey with this versatile material began during his material science program at the University of Florida and continued at Cordis. Chris further honed his expertise at B. Braun and Guidant, where he collaborated with Gore on an ePTFE balloon project. He later served as a technical manager for covered stents in Europe at Bard Peripheral Vascular. For the nine years prior to joining Aptyx via the Medical Murray acquisition, Chris led an office at Medical Murray, spearheading the development of innovative ePTFE products. His passion for ePTFE is driven by both its technical capabilities and its potential to significantly improve patient lives.



ePTFE Capability Brief



ePTFE Solutions for Medical Devices

At Aptyx, we deliver breakthrough ePTFE (expanded polytetrafluoroethylene) solutions crafted for advanced medical devices. Our ePTFE products are precision-engineered to provide unrivaled biocompatibility, flexibility, and durability — making them the ultimate choice for vascular, gastrointestinal, and surgical applications. From concept to commercialization, we turn complex challenges into high performance solutions with ePTFE.



Key Applications at Aptyx

 Covered Stents & Frames
  Vascular Grafts
  Heart Leaflets
  Pericardial & Vascular Patches
  Gastrointestinal Sleeves

Key Benefits of ePTFE

ULTRA-THIN, ULTRA-DURABLE

Our ePTFE is engineered to be exceptionally thin without compromising strength. This means thinner wall implants, smaller delivery system profiles, fewer contraindications, and a broader target market — all while maintaining unmatched reliability.

ADVANCED FLEXIBILITY & REDUCED COMPLICATIONS

ePTFE's flexibility allows it to conform to complex anatomical pathways, making it ideal for precision applications like vascular grafts and gastrointestinal sleeves. Its low tissue adhesion reduces complications, simplifying device adjustments for a smoother experience for patients and healthcare providers.

BUILT FOR LONG-TERM PERFORMANCE

Chemically inert and highly resilient, ePTFE won't degrade over time — making it perfect for long-term implants and grafts. Its durability reduces the need for replacement and minimizes the risk of complications.

ENHANCED SAFETY & BIOCOMPATIBILITY

ePTFE offers a smooth surface that reduces blood clotting, ensuring optimal hemodynamics ideal for small-diameter vessels. Its unmatched biocompatibility minimizes immune response, reducing inflammation and rejection risks, making it perfect for long-term implants like vascular and stent grafts.

What Sets Aptyx Apart

COMPREHENSIVE ePTFE CONVERSION CAPABILITIES

At Aptyx, we transform ePTFE — whether extruded tubing, unsintered membrane, or sheets — into high-quality finished devices. Our comprehensive expertise ensures exceptional performance and quality for vascular, gastrointestinal, and implantable applications.

COST-EFFECTIVE INNOVATION

Despite higher material costs, ePTFE's labor-efficient production process ensures cost-effectiveness, delivering greater value in overall production (COGS).

For more information

Visit us at [Aptyx.com](https://www.aptyx.com)
info@aptyx.com

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About Aptyx

Aptyx is a global design and manufacturing services provider with a rich heritage and a forward-thinking approach. With over 10 locations worldwide, we bring together the collective strength and specialized expertise of more than a dozen companies, built on a 70-year track record of helping customers manufacture their competitive edge.

At our core, engineering is the heartbeat of Aptyx. Our team thrives on partnering with customers to solve complex challenges, from design and development (D&D) to finished device assembly. We offer specialized capabilities in areas such as:

D&D // Engineering

**Molding (injection, dip,
and blow molding)**

Extrusion

Coating solutions

**Manufacturing
& Assembly**

Aptyx stands ready with the expertise, the “Make It Happen” mindset, and the collaborative spirit to help you navigate the complexities of ePTFE and unlock its full game-changing potential for your next medical device innovation.

Ready to discuss your project?

Contact us today for a consultation at info@aptyx.com

Want to learn more about Aptyx’s capabilities?

Visit our website at www.aptyx.com

