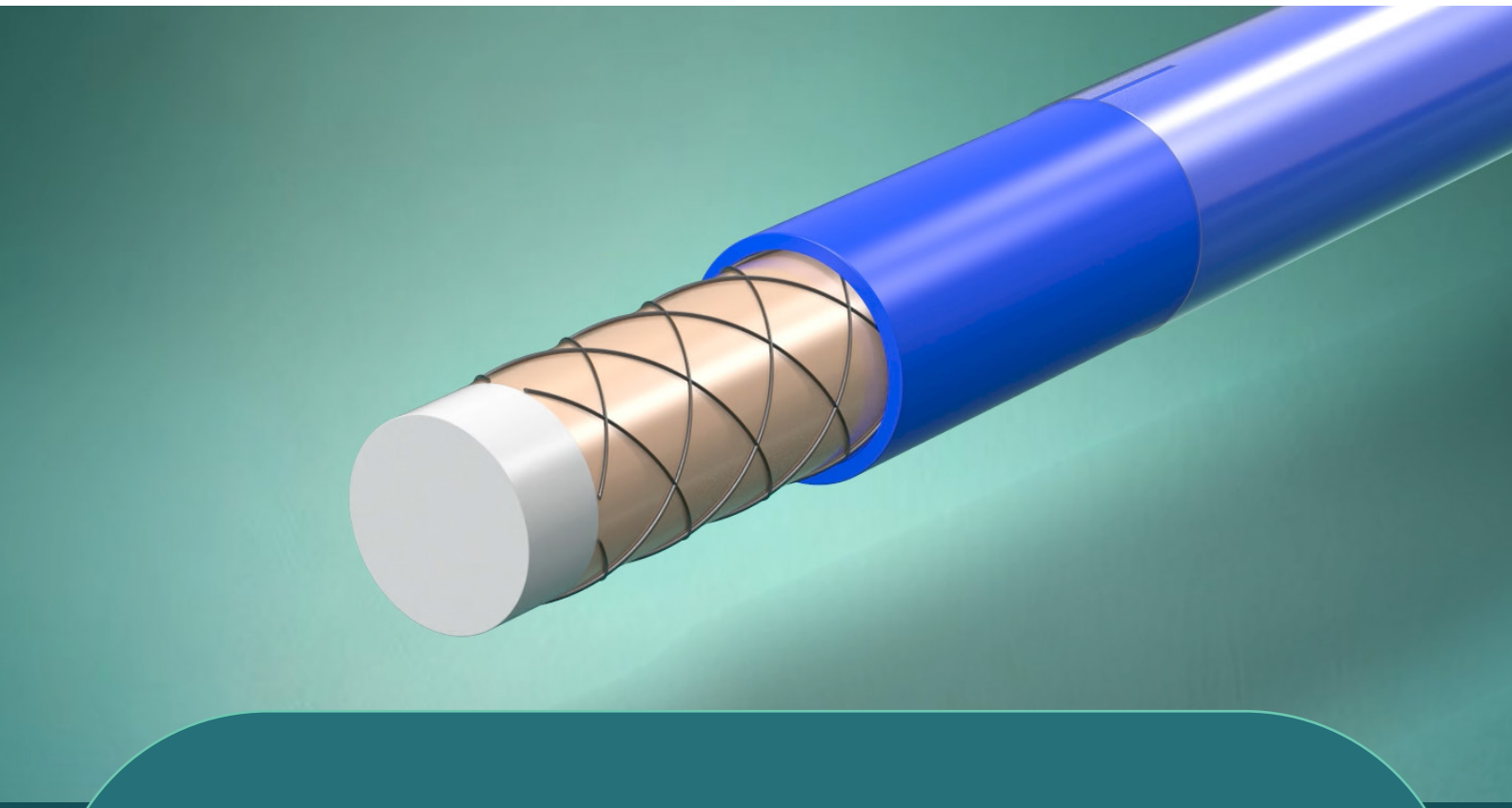
optinova
WHEN QUALITY MATTERS



Technical Brief
2026

A Strategic Approach to PFAS in Advanced Catheter Technologies.

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Executive Summary.

As regulatory scrutiny of PFAS increases, catheter manufacturers are evaluating new material strategies while maintaining the performance standards required for advanced medical devices. Because catheter performance depends on the interaction of multiple components, PFAS transition requires a system-level engineering approach rather than a simple material substitution.

This technical brief explores three practical pathways: Responsible Fluoropolymer Continuity, Next-Generation PFAS-Free Innovation, and Low-PFAS Transitional Solutions. Optinova believes the optimal pathway depends on the intended application, performance requirements, and manufacturing strategy, with successful innovation driven by selecting the right technology for the right catheter design.

Key Takeaways.

1. PFAS transition requires a system-level engineering approach, not a simple material replacement.
2. PTFE remains the benchmark for many high-performance catheter applications.
3. PFAS-free alternatives are emerging, enabled by advances in materials and manufacturing technologies.
4. Three pathways exist: fluoropolymer continuity, PFAS-free innovation, and low-PFAS transitional solutions.
5. The best solution depends on the application, performance requirements, and regulatory strategy.

1. Introduction.

Navigating the Transition Away from PFAS in Catheter Liner Technologies

The medical device industry is entering a period of significant change. Increasing regulatory attention surrounding per and polyfluoroalkyl substances (PFAS), together with growing sustainability expectations, is prompting medical device manufacturers to reassess the materials used throughout catheter systems.

For decades, fluoropolymers such as PTFE have been the benchmark for catheter liner performance, providing exceptional lubricity, chemical resistance, thermal stability and proven clinical reliability. These properties have enabled the development of high performance catheter systems used across a wide range of minimally invasive procedures.

Although catheter shafts consist of multiple engineered components, including liners, reinforcement layers, jackets and processing materials, the liner remains one of the primary areas affected by PFAS transition.

Replacing a catheter liner is not simply a material substitution exercise. Because each layer contributes to overall device performance, changing one component influences the entire catheter system. Successful innovation therefore requires system level engineering rather than one to one material replacement.

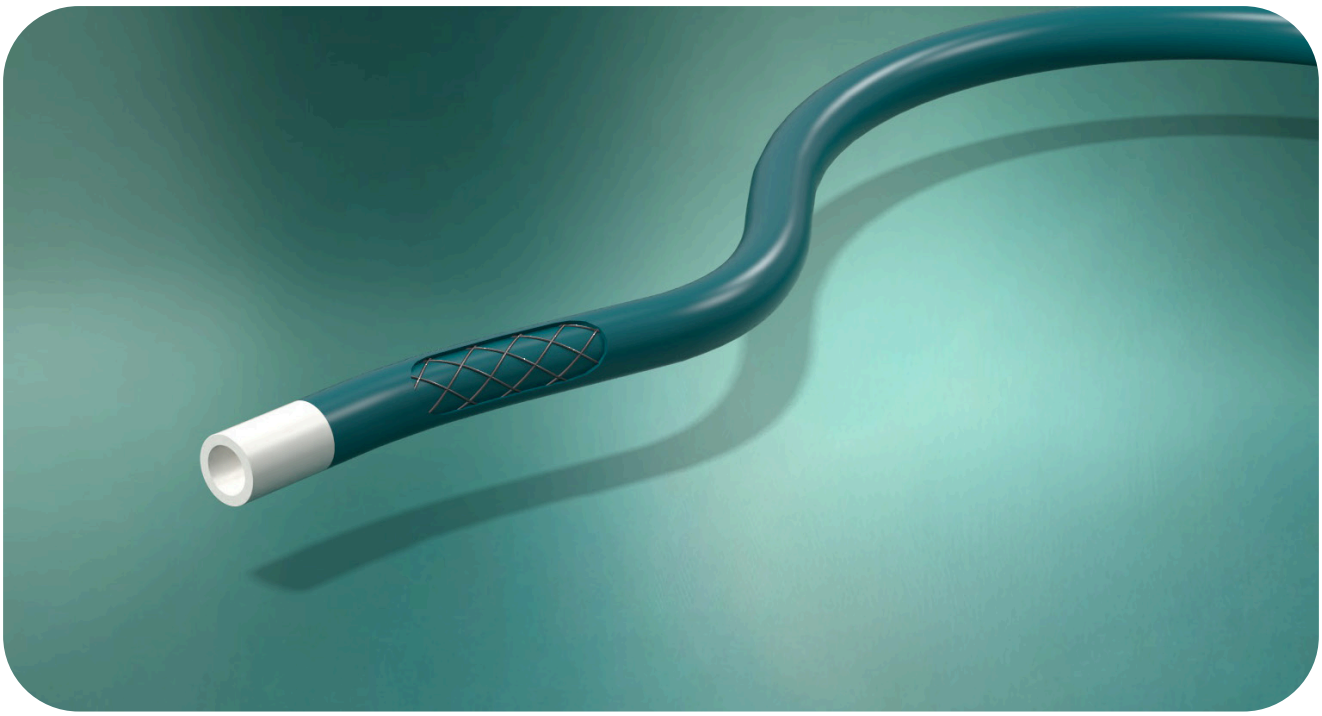
Can PTFE catheter liners be replaced by PFAS free alternatives without compromising clinical performance?

The answer depends on the specific application. Advances in polymer science and manufacturing technologies are creating new opportunities for PFAS free and reduced PFAS catheter liner solutions, while maintaining performance remains the primary engineering objective.

The following sections outline the three development pathways that Optinova believes provide the most practical approach to catheter liner innovation. In parallel, Optinova's R&D

engineers are actively investigating new polymer solutions that may offer viable alternatives to PFAS based materials for future catheter liner applications. Research is focused on evaluating advanced polymer technologies and processing methods that can meet the demanding performance requirements of catheter systems, including lubricity, mechanical performance, manufacturability and long term reliability. Together with advances in extrusion and lower temperature processing technologies, these developments are creating new opportunities for PFAS free and reduced PFAS catheter architectures.

An area of particular interest is ultra high molecular weight polymer technologies, which offer promising combinations of low friction, wear resistance and mechanical performance. Together with advances in extrusion technology and lower temperature processing methods, these materials are creating new opportunities for PFAS free and PFAS reduced catheter architectures.



2. Three Technical Pathways.

There is no single pathway for transitioning away from PFAS. Different catheter applications require different material combinations, manufacturing processes and performance requirements. Optinova therefore supports three complementary development pathways.

Pathway 1:

Responsible fluoropolymer continuity

Pathway 2:

Next generation PFAS free innovation

Pathway 3:

Low PFAS transitional solutions

Pathway 1: Responsible Fluoropolymer Continuity

For OEMs that require proven clinical performance, validated product platforms and established manufacturing processes, fluoropolymer based catheter liners remain the preferred solution. PTFE based liners continue to represent the benchmark for many high performance catheter applications due to their exceptional lubricity, thermal stability, chemical resistance and long established clinical performance.

For applications where fluoropolymer performance remains the optimal technical solution, Optinova advocates a responsible fluoropolymer pathway based on controlled material selection, robust manufacturing processes and continuous process optimisation to minimise environmental impact. This approach combines fluoropolymer materials produced under stringent process controls with manufacturing practices designed to reduce emissions, improve process efficiency and maintain consistent product quality while supporting evolving regulatory expectations.

Advantages

- Proven clinical performance
- Excellent lubricity
- High thermal and chemical resistance
- Established manufacturing consistency
- Known regulatory pathway

Considerations

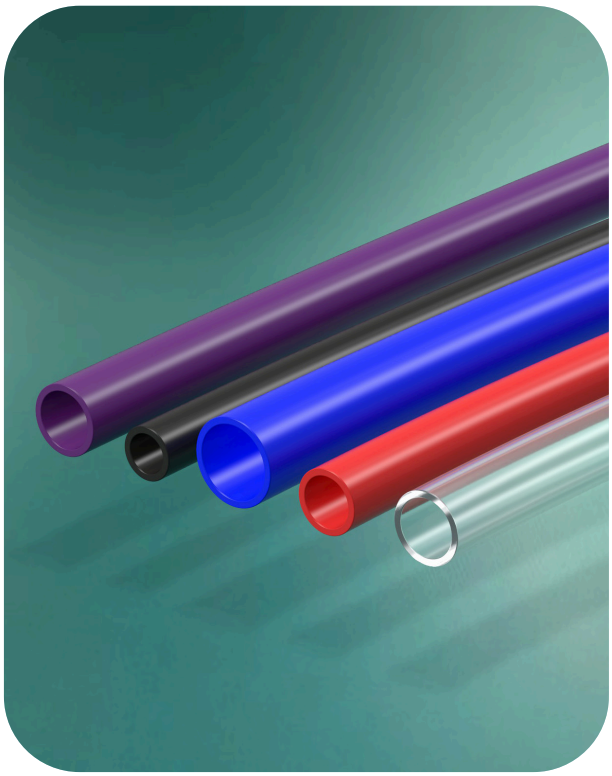
- Increasing regulatory scrutiny of PFAS
- Long term material and legislative uncertainty

Pathway 2: Next Generation PFAS Free Innovation

For OEMs developing next generation catheter platforms or preparing for future PFAS regulations, PFAS free liner technologies offer an opportunity to redesign catheter systems for emerging clinical and regulatory requirements.

Transitioning to PFAS free catheter liners requires more than replacing PTFE with an alternative polymer. It requires a redesigned catheter system that combines alternative liner materials with compatible manufacturing processes to achieve the required balance of lubricity, mechanical performance and manufacturability. While several PFAS free materials are available today, no single material currently replicates the full range of performance characteristics offered by PTFE. As a result, successful implementation depends on careful material selection, catheter design and application specific validation.

One example is the use of **PEBA materials, including Pebax®**, as alternative liner technologies. Compared with PTFE, PEBA liners have lower thermal resistance and can be challenging to process using conventional reflow methods, which typically operate at temperatures above **200°C (400°F)**. To address this challenge, Optinova combines alternative liner materials with enabling manufacturing technologies such as **QuickShrink®**, which can initiate shrink at approximately **100°C (212°F)**. By reducing the thermal load during reflow, this approach can support the processing of thermally sensitive liner materials while helping maintain catheter shaft integrity.



A second example is PFAS free heat shrink technology. Optinova can produce PFAS free heat shrink solutions with shrink ratios of up to 1.4:1, while providing performance characteristics comparable to conventional fluoropolymer based heat shrink products. Together with advances in liner materials and lower temperature processing technologies, these developments demonstrate how innovation across multiple catheter components can enable the next generation of PFAS free and reduced PFAS catheter architectures.

When evaluating PFAS free catheter concepts, it is also important to consider manufacturability, scalability and regulatory compliance. Novel material combinations and processing technologies may require additional validation and can result in a longer pathway to commercialisation compared with established fluoropolymer based solutions.

Advantages

- Eliminates fluoropolymer liner materials
- Supports future regulatory objectives
- Enables innovative catheter architectures
- Facilitates lower temperature processing of alternative liner materials

Considerations

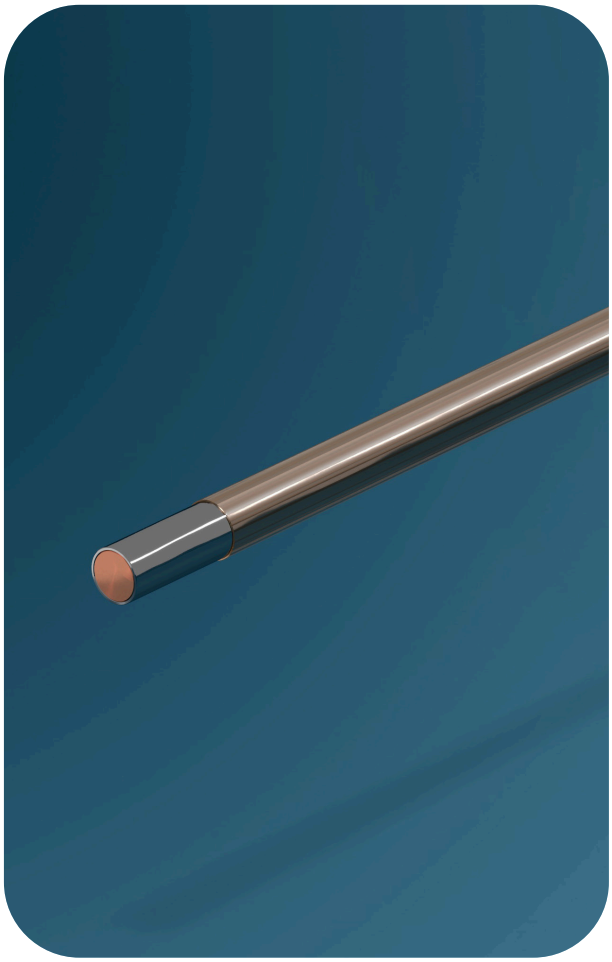
- Lower thermal resistance than PTFE for some alternative liner materials
- Performance depends on catheter design and intended application
- Requires application specific validation
- May require a longer regulatory and validation pathway to market

Pathway 3: Low PFAS Transitional Solutions

For many OEMs, a phased transition represents the most practical approach. Rather than replacing fluoropolymers entirely, hybrid liner concepts combine fluoropolymer and non-fluoropolymer materials to reduce PFAS dependency while maintaining the performance characteristics required for demanding catheter applications. This approach enables manufacturers to evaluate lower PFAS designs while leveraging existing manufacturing knowledge and validated processes.

One example is the use of **hybrid material technologies**, including blend materials containing a controlled proportion of PTFE. These materials are designed to combine the mechanical strength, thermal resistance, and processing characteristics of the base polymer with the low friction properties of PTFE. While they do not eliminate PFAS entirely, they can significantly reduce PFAS content while maintaining key functional performance and supporting the development of advanced catheter architectures.

Hybrid solutions may also provide a practical transition pathway by reducing development risk and enabling manufacturers to balance performance, manufacturability and evolving regulatory expectations without requiring a complete redesign of the catheter system.

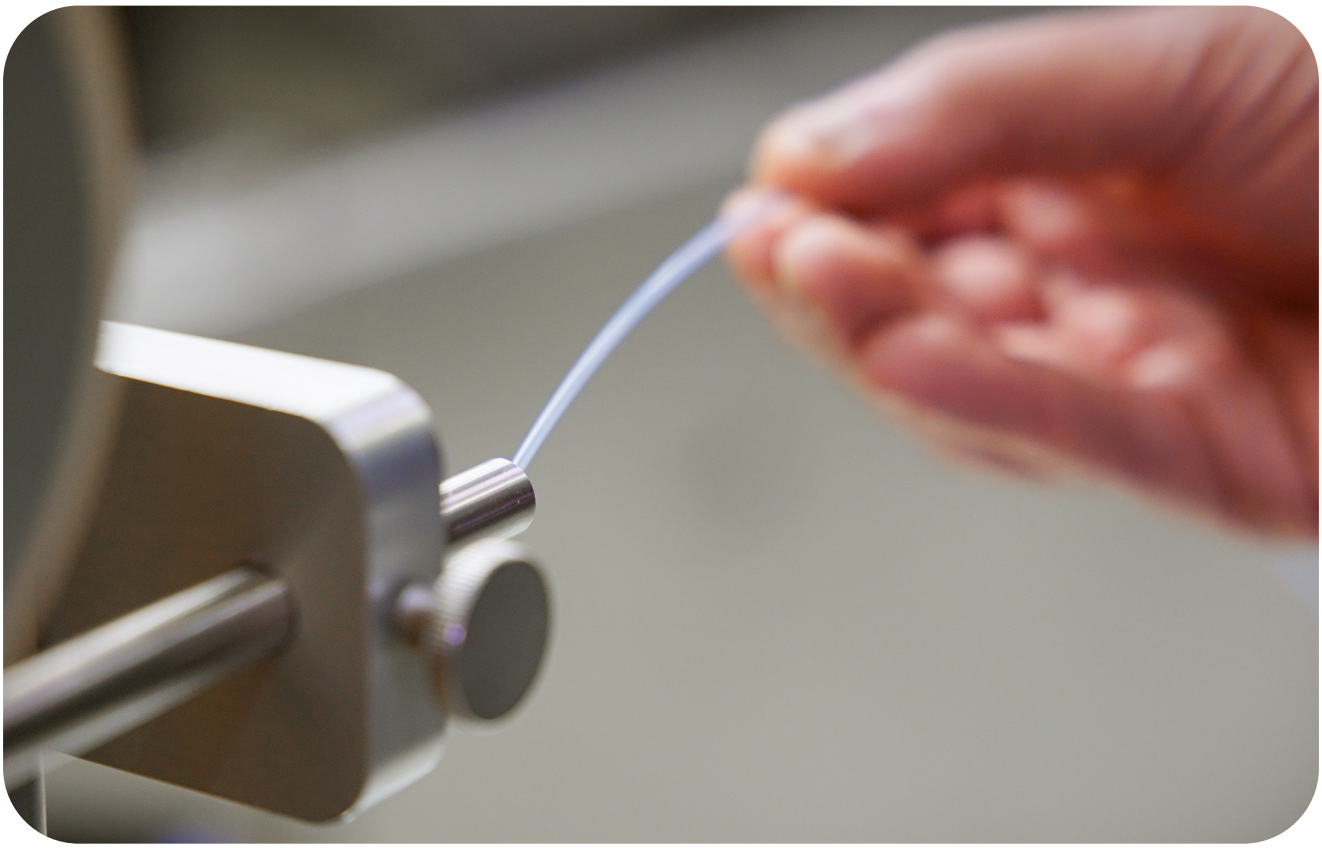


Advantages

- Reduced PFAS dependency
- Lower development risk
- Supports phased product transitions
- Leverages established manufacturing knowledge

Considerations

- Not fully PFAS free
- Material selection depends on the intended application
- Performance and PFAS reduction must be balanced according to device requirements



3. Optinova's Position.

The transition toward PFAS free catheter liner technologies is not defined by a universal material replacement. It is an engineering challenge requiring the right balance between clinical performance, manufacturability and regulatory expectations.

PTFE remains the benchmark for many catheter liner applications where maximum lubricity, thermal stability and proven clinical performance are required.

At the same time, advances in polymer science, extrusion technology and catheter design are creating viable PFAS free and reduced PFAS alternatives for selected applications.

Optinova believes there is no universal solution. The appropriate pathway should always be determined by the intended clinical application, performance requirements and manufacturing strategy.

Successful innovation depends on selecting the right technology for the right application.

4. Engineering Better Outcomes Through Collaboration.

Selecting the appropriate development pathway requires balancing materials, catheter architecture, manufacturing processes and clinical performance across the complete device.

Recognising that every catheter programme presents unique technical, clinical and regulatory requirements, Optinova works collaboratively with OEM partners to identify the development pathway best suited to each application.

Our Collaborative Development Process

1. **Application Requirements:** Understand clinical, technical and manufacturing objectives.
2. **Engineering Assessment:** Evaluate the most appropriate pathway: Responsible Fluoropolymer Continuity, Next Generation PFAS Free Innovation or Low PFAS Transitional Solutions.
3. **Concept Development:** Develop catheter liner concepts and manufacturing approaches.
4. **Prototype Manufacturing:** Produce prototypes for engineering evaluation.
5. **Performance Evaluation:** Verify performance against application requirements.
6. **Industrialisation Planning:** Support transition into scalable manufacturing.

By combining expertise in polymer science, precision extrusion, catheter liner manufacturing and process development, Optinova helps customers reduce technical risk while accelerating informed engineering decisions.

Let's Start the Conversation!

Is your organisation considering:

- Evaluating future PFAS strategies
- Exploring reduced PFAS alternatives
- Developing next generation PFAS free catheter liner technologies

Whether you are evaluating fluoropolymer continuity, low PFAS transition or PFAS free innovation, Optinova is ready to collaborate on your next catheter development programme.

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About Optinova

Optinova is a global leader in manufacturing advanced tubing solutions for medical and industrial applications, with operations across Europe, the United States, and Asia.

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