

# PTFE

## and Emerging Lubricious Polymer Platforms

in Catheter-Based Medical Devices



MATERIAL SCIENCE  
INNOVATION



SUPPLY CHAIN  
RESILIENCE



STERILIZATION  
FLEXIBILITY



ARCHITECTURAL  
INTEGRATION

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# PTFE and Emerging Lubricious Polymer Platforms in Catheter-Based Medical Devices

*A Technical Perspective on Material Selection, Supply Chain Concentration, Sterilization Compatibility, Bonding Challenges, Regulatory Landscape, and Design Optionality*

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<b>Dynaflex Technologies Inc.</b> Material Science & Catheter Architecture Platform ISO 13485:2016   <a href="http://www.dynaflextech.com">www.dynaflextech.com</a>	&	<b>Chamfr</b> Medical Device Component Marketplace <a href="http://www.chamfr.com">www.chamfr.com</a>
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## Scope and Disclaimer

This paper addresses catheter liner and shaft polymer selection for single-use, minimally invasive interventional devices. All technical claims are referenced to published scientific literature and publicly available regulatory and corporate disclosures. This document does not constitute regulatory or legal advice. Material selection for any specific device requires application-specific testing and validation per ISO 10993, ISO 11137, and AAMI TIR17.

## EXECUTIVE SUMMARY

Polytetrafluoroethylene (PTFE) has been a foundational material in catheter-based medical devices for over five decades. Its ultra-low coefficient of friction, chemical inertness, and well-established biocompatibility have made it the default liner material across a broad range of interventional device applications — and for most programs operating under EtO sterilization with well-characterized mechanical requirements, it remains the correct engineering choice.

The operating environment for polymer material selection, however, is meaningfully changing. Several converging industry signals reinforce a structural shift in how material decisions are being made:

- 3M's completed exit from all PFAS manufacturing by end of 2025 has concentrated medical-grade PTFE supply among three primary manufacturers — two headquartered in Japan.
- W. L. Gore & Associates — ePTFE's defining innovator — has publicly committed to transitioning its consumer fabrics portfolio away from ePTFE toward expanded polyethylene (ePE). The signal from the company that invented the material is directionally significant.
- The FDA held a dedicated webinar on December 10, 2025 providing a structured, least-burdensome framework for PTFE material changes in 510(k) devices — clarifying that thorough documentation may support a material transition without a full new submission.
- The EtO sterilization landscape faces sustained long-term regulatory pressure, while PTFE's fundamental susceptibility to radiation-induced chain scission limits its compatibility with gamma and e-beam alternatives.

Against this backdrop, this paper provides a technically grounded review of PTFE's performance profile and structural limitations; supply chain concentration dynamics; sterilization compatibility constraints; the FDA's evolving guidance on material change submissions; and the characteristics of alternative lubricious polymer platforms — with a specific focus on where current-generation material science has arrived after more than a decade of formulation development.

**The strategic conclusion: material selection is no longer a single-variable optimization problem. It is a strategic design choice that integrates performance, supply chain resilience, regulatory trajectory, and sterilization flexibility from the earliest stages of platform development.**

## 1 · PTFE: TECHNICAL PROFILE AND ESTABLISHED ROLE

### 1.1 Performance Attributes and Established Role

PTFE is a semi-crystalline fluoropolymer whose carbon-fluorine bond chemistry produces a surface with extremely low surface energy — the origin of its defining lubricity and chemical inertness. Three performance attributes have driven its adoption as the catheter liner gold standard:

- Lubricity benchmark — among the lowest CoF of any medical-grade engineering polymer under dry bench test conditions, and the reference point against which all alternative liner materials are evaluated.
- Ultra-thin wall extrusion capability — commercial production below 0.00075 inch wall thickness, a geometric precision that no current thermoplastic alternative system has demonstrated at commercial scale. This remains a durable and legitimate PTFE advantage for tight-profile applications.
- Biocompatibility depth — decades of clinical use, extensive ISO 10993 characterization data, and an extensive 510(k) predicate library that no alternative material currently matches in regulatory depth.

*PTFE's position as the catheter liner gold standard is well-earned. For programs operating within its constraints — particularly EtO sterilization and single-layer or lightly bonded architectures — it remains the technically superior choice. The analysis in this paper is not an argument against PTFE; it is an argument for understanding the full constraint set before committing to a 10–15 year device platform.*

### 1.2 The Bondability Constraint

The same chemical inertness that confers PTFE's lubricity renders it one of the most challenging engineering polymers to bond. PTFE's surface energy (~18–20 mN/m) is far below the threshold at which standard adhesive systems achieve meaningful wetting. In catheter manufacturing, achieving reliable adhesion between PTFE liners and thermoplastic jacket materials (Pebax, TPU, Nylon) requires chemical etching or plasma treatment to introduce polar functional groups — followed by a thermoplastic tie-layer to achieve bond strengths adequate for reflow lamination and clinical use.

This multi-step process adds manufacturing complexity, introduces variability, and creates additional delamination risk — particularly in high-deflection steerable designs. The engineering question is not whether PTFE can be bonded, but whether the bonding process reliability is sufficient for the mechanical demands of the specific catheter architecture — and at what cost in wall budget, process variability, and yield.

## 2 · PTFE SUPPLY CHAIN CONCENTRATION: A STRUCTURAL RISK

### 2.1 The 3M Exit and Industry Context

In December 2022, 3M Company announced its intention to exit all PFAS manufacturing globally by end of 2025, encompassing its fluoropolymer product lines including grades used in medical device applications. The withdrawal — driven by mounting PFAS litigation exposure — was completed as announced and is a matter of public record via SEC filings. The three primary remaining producers of medical-grade PTFE serving the medical device market are:

- Chemours Company (USA) — spun out from DuPont in 2015; a leading global producer of Teflon-brand fluoropolymers.
- Daikin Industries (Japan) — a major global fluorochemical manufacturer with significant medical-grade PTFE and FEP production capacity.
- AGC Inc. (Japan) — a diversified fluorochemical manufacturer with medical device market experience.

Two of the three primary producers are headquartered in Japan — a geographic concentration risk that OEM procurement teams managing 10–15 year device platform lifecycles must explicitly evaluate.

### 2.2 The W. L. Gore Signal

W. L. Gore & Associates — whose founder Robert W. Gore discovered expanded polytetrafluoroethylene (ePTFE) in 1969 — built one of the most recognized material platforms of the 20th century in Gore-Tex and an entire medical device business on ePTFE-based vascular grafts, stent-graft coverings, and catheter guidewires. Gore's medical products continue to use ePTFE: the GORE Viabahn Fortegra Venous Stent, FDA-approved January 2026, features an ePTFE polymer lattice.

Yet in 2022, Gore committed to transitioning its consumer fabrics portfolio to a PFAS-free platform by 2025 — centered on expanded polyethylene (ePE), produced through a similar process to ePTFE but using non-fluorinated polyethylene. This is not a medical device transition. But the signal from the institution most responsible for fluoropolymer-based membrane technology actively deploying non-fluoropolymer alternatives is directionally significant for the broader material science community.

*When the company that invented ePTFE invests in PFAS-free alternatives, the material science community is watching a leading indicator. The medical device industry will not follow on the same timeline — but the trajectory is informative.*

### 2.3 Supply Chain Risk Implications for OEMs

Three-supplier concentration in a critical medical device material category presents well-understood supply chain risks:

- Geographic concentration — two of three primary producers are Japan-based, creating single-region exposure.
- Reduced competitive pressure on pricing, lead times, and long-term supply agreement terms.
- Qualification switching costs — qualifying an alternative PTFE supplier for a regulated device typically requires 12–24 months of design verification and validation, creating lock-in that limits supply chain flexibility.
- Regulatory uncertainty feedback — ongoing PFAS proceedings in the US and EU create additional uncertainty about long-term investment appetite of remaining fluoropolymer producers in medical-grade product lines.

OEMs developing device platforms with projected 10–15 year commercial lifetimes should treat fluoropolymer supply chain concentration as a strategic risk requiring active mitigation — either through long-term supply agreements with remaining PTFE producers, or through parallel development of validated alternative liner material platforms.

## 3 · STERILIZATION COMPATIBILITY: A CRITICAL DESIGN CONSTRAINT

### 3.1 The EtO Regulatory Landscape

Ethylene oxide (EtO) is fully compatible with PTFE and has historically been the sterilization modality of choice for catheter devices — approximately 50% of all sterile medical devices in the United States are currently EtO-processed. The regulatory environment for EtO, however, is under sustained long-term pressure:

- The EPA finalized amendments to National Emission Standards for EtO commercial sterilization facilities in March 2024, targeting ~90% emission reductions across ~90 commercial facilities nationally.
- The Trump administration granted temporary compliance exemptions to certain facilities in 2025 and proposed amendments to the 2024 standards in March 2026 — reflecting genuine tension between public health objectives and medical device supply chain continuity.
- The EPA's FIFRA registration review (January 2025) established a 600 mg/L concentration ceiling for new sterilization cycles by 2035.
- The FDA launched a Radiation Sterilization Master File Pilot Program in April 2023 specifically to support transition of EtO-dependent devices to radiation-based modalities.

Near-term regulatory modifications provide temporary relief, but the long-term trajectory for EtO remains oriented toward reduced industrial use and tighter emissions control. Device platforms with projected commercial lifetimes extending 10–15 years should treat EtO availability as a long-term supply chain risk requiring active contingency planning.

### 3.2 PTFE and Ionizing Radiation: Mechanism and Consequences

PTFE is one of the least radiation-stable polymers in common medical device use. Unlike many engineering polymers — which respond to ionizing radiation primarily through crosslinking — PTFE undergoes predominant main-chain scission under gamma and e-beam irradiation. Free radicals react with oxygen to form peroxy radicals that propagate chain-scission, progressively reducing molecular weight. Published data report yield stress reductions of 35%–90% following standard-dose e-beam sterilization in air at 15–60 kGy. AAMI TIR17 ranks PTFE among the least radiation-stable polymers in the medical device classification.

Sterilization Modality	PTFE Compatibility Assessment
<b>EtO (Ethylene Oxide)</b>	Compatible. Long-standing primary modality; no degradation of PTFE properties under validated aeration protocols.
<b>Gamma (Co-60)</b>	Poor. Chain-scission dominant; embrittlement and loss of elongation at standard 25–40 kGy doses. AAMI TIR17 worst-class rating.
<b>Electron Beam (E-beam)</b>	Poor. Mechanistically similar to gamma. Yield stress reductions of 35–90% reported in air at 15–60 kGy.
<b>X-ray</b>	Poor. Mechanistically similar to gamma; degradation severity is dose-rate dependent.
<b>Steam / Autoclave</b>	Not applicable for catheter assemblies. Jacket materials (Pebax, TPU, Nylon) are not autoclave-compatible.

## 4 · FDA REGULATORY FRAMEWORK: MATERIAL CHANGE SUBMISSIONS

On December 10, 2025, FDA's CDRH held a dedicated public webinar — "Case Study: Material Substitutions in Devices Subject to 510(k) Using PTFE" — presented by senior CDRH scientists and archived at [fda.gov](https://www.fda.gov) with slides and transcript. The webinar's timing was tied to the supply chain disruption from 3M's PFAS exit, but its regulatory framework applies broadly to all material changes in 510(k)-cleared devices.

### 4.1 The Mods Guidance Framework

The governing document is FDA's 2017 final guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device." The central question: could the proposed change significantly affect the safety or effectiveness of the cleared device? For a material change, this flows through a risk-based biocompatibility evaluation under Section C of the guidance:

- C2: Is this a change in material type, formulation, composition, or processing in direct or indirect contact with body tissue or fluids?
- C4: Does the risk assessment identify new or increased biocompatibility concerns compared to the previously cleared material?
- C4.1: Has the same material been used by the same manufacturer in a similar cleared device of the same type and contact duration?
- C5: Could the change affect device performance specifications?

*FDA's Dr. Ryan Ortega at the December 2025 webinar: "The answer to C4 may be a no if a knowledgeable individual reviews the differences in chemical composition or physical properties and determines that the change is minor enough that there is no new concern about biocompatibility — and internally documents their assessment." Thorough internal documentation is the foundation of the determination — and in cases where no new biocompatibility concerns arise and performance specifications are unaffected, may support a conclusion that a new 510(k) is not required.*

### 4.2 Practical Implications for PTFE-to-Alternative Transitions

For manufacturers evaluating a material change from PTFE to an alternative lubricious polymer platform in an existing cleared device, the regulatory pathway depends on a documented risk assessment rather than an automatic requirement for a new 510(k). Key factors: whether the alternative introduces new biocompatibility endpoints; whether it could affect device performance specifications; and whether the manufacturer can demonstrate the same or similar material in a cleared device of the same type and contact duration — a pathway the Mods Guidance explicitly identifies as potentially avoiding a new submission.

*For manufacturers that have already incorporated alternative lubricious polymer systems into other cleared catheters, a PTFE-to-alternative material change in a subsequent cleared device of the same type may qualify for a documented letter-to-file rather than a full new 510(k) — depending on the specific device, contact classification, and risk assessment outcome. This is the least-burdensome pathway the FDA has outlined, not a guarantee. New device programs*

*require their own premarket submission pathway regardless of material choice. Final regulatory determination remains the responsibility of the device manufacturer in consultation with qualified regulatory counsel.*

## 5 · ALTERNATIVE LUBRICIOUS POLYMER PLATFORMS: OLEFIN-BASED SYSTEMS

The principal non-fluoropolymer alternative for catheter liner and inner shaft applications with an established technical track record is the olefin-based polymer family — specifically HDPE and ultra-high molecular weight polyethylene (UHMWPE). Both are fully PFAS-free with established biocompatibility data and regulatory precedent in medical device applications.

UHMWPE is the more clinically relevant candidate for catheter liner applications. Its CoF — grade and test condition dependent — approaches PTFE performance in wet catheter use conditions, and its abrasion resistance exceeds PTFE in comparative testing. The extremely long polymer chains of UHMWPE (molecular weight 3.5–7.5 million g/mol) provide exceptional toughness and impact resistance — favorable for catheters subject to cyclic flexion and device passage.

Critically, both HDPE and UHMWPE offer substantially superior radiation stability compared to PTFE. Polyolefins respond to ionizing radiation primarily through crosslinking rather than chain scission — maintaining or modestly improving mechanical properties at moderate sterilization doses, making them inherently compatible with gamma and e-beam modalities without the packaging complexity PTFE requires.

### 5.1 The Bonding Challenge

Despite their radiation compatibility advantage, olefin-based polymers present a bonding challenge mechanistically similar to PTFE's — no polar functional groups means poor intrinsic adhesion to thermoplastic jacket materials. Achieving reliable bonding requires engineering solutions — tie-layer construction, surface activation, or reactive extrusion modification — each of which adds at least one material interface and one manufacturing process step. The radiation compatibility gain must be weighed against this added construction complexity for each specific program.

## 6 · BONDING SCIENCE AND INTERFACIAL RISK

PTFE, polyolefins, and early siloxane systems share a common bonding problem: low surface energy and no polar functional groups make them thermodynamically resistant to adhesive wetting. Catheter jacket materials — Pebax, TPU, Nylon — bond reliably to each other through polar functional groups in their polymer chains. Lubricious liners have none of these. The tie-layer concept addresses this gap at the adhesive level — but does not eliminate the more consequential structural problem that develops under cyclic loading.

### 6.1 Mechanical Impedance Mismatch: The Hidden Failure Mode

Beyond the thermodynamic challenge of wetting and adhesion, lubricious liner materials introduce a second, less commonly discussed structural problem: mechanical impedance mismatch. PTFE and polyolefin liners have elastic moduli that differ substantially from the thermoplastic jacket materials that surround them. Under cyclic deflection — the operating condition of every steerable catheter in clinical use — the liner and jacket experience different strain magnitudes at the same applied curvature. This differential strain concentrates stress at the material interface.

Even a well-bonded, properly etched PTFE liner is, in a mechanical sense, a foreign object inside the catheter shaft: it does not want to deform in concert with the surrounding structure. The interface becomes a slip plane. Tie-layers improve initial bond strength — they do not eliminate the underlying mechanical mismatch that drives fatigue-mode delamination under cyclic loading, which is the failure mode that matters clinically.

*The delamination failure mode most relevant to clinical performance is not the peel-strength failure that shows up in bench testing. It is the fatigue-mode crack propagation at a mechanically mismatched interface that accumulates over thousands of deflection cycles. Material selection and surface treatment address the former. Only architectural design decisions address the latter — a question this paper's companion in the series explores directly.*

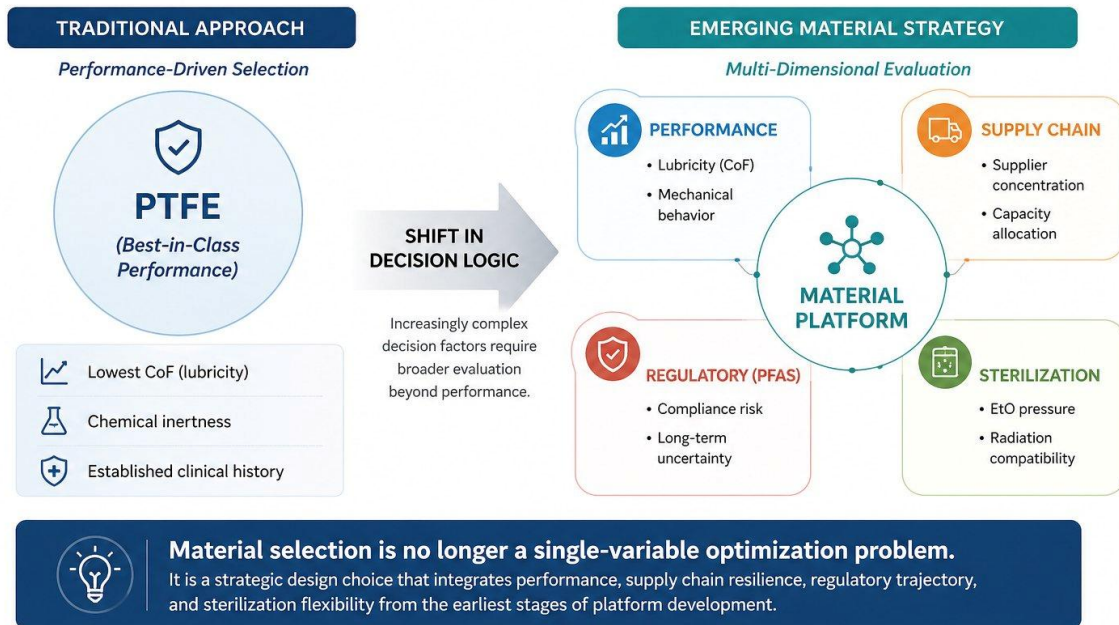
*In many programs, these risks remain invisible until late-stage verification and validation — when they are most expensive to address and least amenable to material or process changes without triggering requalification.*

# MATERIAL SELECTION: FROM PERFORMANCE TO MULTI-DIMENSIONAL RISK

The diagram below illustrates the shift in how materials are evaluated in catheter-based device development — from single-variable performance optimization to a multi-dimensional framework integrating performance, supply chain, regulatory trajectory, and sterilization compatibility.

## Material Selection Is Shifting from Performance Optimization to Multi-Dimensional Risk Management

Evolving industry dynamics are reshaping how materials are evaluated in catheter-based device development.



## 7 · COMPARATIVE MATERIAL ASSESSMENT

The comparison matrix below maps PTFE, olefin-based systems, and advanced compounded formulations across the key performance dimensions covered in this paper. Reading across any single row reveals why no currently available material dominates on all criteria simultaneously — and why the fourth column, advanced compounded formulations, warrants closer examination.

Attribute	PTFE	Olefin-Based (HDPE/UHMWPE)	Advanced Compounded Formulations
<b>Coefficient of Friction (CoF)</b>	Best-in-class under dry bench test conditions; performance in wet catheter use conditions is application-dependent and not directly comparable across material families by dry test data alone	Moderate; dry bench CoF higher than PTFE but gap narrows significantly in wet/lubricated catheter use conditions	Comparable to PTFE in wet catheter use conditions across commercial grades; dry bench values vary by grade and methodology
<b>Durometer Range</b>	Fixed ~Shore D 55–60; no formulation flexibility	Fixed by base resin; limited tunability	Shore D 20–60 across formulation grades; stiffness and lubricity specifiable independently
<b>Radiation Stability</b>	Poor — chain scission dominant	Good — crosslinking dominant	Good — crosslinking dominant
<b>EtO Compatibility</b>	Yes	Yes	Yes
<b>Intrinsic Bondability to Jacket</b>	Very Low — etching + tie-layer required	Low — no polar groups, tie-layer required	High in PA-backbone formulations — homogeneous bonding to Pebax/Nylon jacket without etching or tie-layer
<b>Bonding to Metal Reinforcement</b>	Poor — non-stick surface; contact interface only against braid, coil, hypotube	Moderate — requires surface treatment	Good — polyamide matrix wets and keys into braid interstices, coil gaps, and laser-cut hypotube geometry during thermal processing
<b>Tie-Layer Required?</b>	Often (after etching)	Typically yes	Eliminated in PA-backbone designs bonded to PA-family jackets
<b>PFAS Classification</b>	PFAS (fluoropolymer)	PFAS-free	PFAS-free
<b>Supply Chain Concentration</b>	High — 3 primary OEMs	Broad	Broad
<b>Ultra-Thin Wall (&lt;0.00075")</b>	Best-in-class	Limited	~0.00125" free extrusion / ~0.001" extrusion-over-wire; covers the majority of interventional catheter wall budget requirements. Sub-0.00075" capability not matched at commercial scale.
<b>Process Temperature Window</b>	Highest — 327°C melt; widest processing latitude	Moderate	Nylon-range melt temp; higher than Pebax/TPU

Attribute	PTFE	Olefin-Based (HDPE/UHMWPE)	Advanced Compounded Formulations
			jacket but requires managed reflow window
<b>Impedance Mismatch Risk</b>	High — significant modulus delta vs. jacket	Moderate — depends on host formulation	Lower — durometer selectable to reduce modulus delta vs. adjacent jacket; application dependent
<b>Biocompatibility Package Scope</b>	Single material; extensive clinical history	Single material; established data	PA-backbone formulations share material family with Pebax/Nylon jacket — single-family ISO 10993 characterization may cover liner and jacket interface

Note: CoF values are test-condition and methodology dependent. Dry bench test data should not be used for direct cross-material comparison without equivalent test conditions, counterface, load, and speed. Radiation stability classifications are consistent with AAMI TIR17. All materials require ISO 10993 biocompatibility assessment and sterilization validation per ISO 11137 for specific device applications.

## 7.1 The Case for Advanced Compounded Formulations — and Where Siloxane Science Has Arrived

The fourth column of the comparison matrix — advanced compounded formulations — represents the most architecturally integrated approach to solving the PTFE replacement challenge. Understanding why requires tracing the evolution of siloxane-based material science in catheter applications over the past decade.

Siloxane chemistry — based on the Si-O-Si backbone of polydimethylsiloxane (PDMS) — was explored early as a lubricity-enabling system in catheter materials. First-generation implementations introduced medical-grade silicone fluid as a surface additive or bulk component. The approach demonstrated proof of concept, but carried four limitations that constrained clinical adoption:

- Leachability — early siloxane fluid additives were not permanently entrapped within the host polymer matrix, raising extractables concerns under ISO 10993 and long-term in-vivo stability evaluation.
- Formulation instability — siloxane migration to the surface, while the mechanism of lubricity, also resulted in unpredictable blooming behavior and potential additive depletion under sterilization or storage conditions.
- Bonding interference — surface-migrated siloxane created a low-energy boundary layer that actively degraded adhesion to adjacent jacket materials, compounding rather than resolving the bondability challenge.
- Structural limitations — bulk silicone formulations in Shore A durometer ranges required reinforcement strategies for pushability and torque transmission in high-performance interventional designs.

Engineers who evaluated siloxane-based lubricity a decade ago were right to be cautious. The limitations were real. What has changed is the formulation science.

Current-generation systems — among them Everglide+, one of the earlier hybrid formulations to reach commercial catheter deployment, alongside other emerging platforms in active development — compound a chemically engineered, non-leachable siloxane into a thermoplastic host resin — HDPE, TPU, or Nylon — through a mechanism fundamentally different from free siloxane fluid migration. Rather than a surface-applied additive that migrates and depletes, the siloxane is permanently integrated into the polymer matrix, with controlled surface expression providing the lubricious interface. The host polymer retains its bulk mechanical and bonding properties.

The architectural implications are significant:

- The thermoplastic host matrix retains the polar functional groups required for reliable bonding to adjacent catheter layers — reducing or in some designs eliminating tie-layer construction entirely.
- Lubricity is tunable by additive loading and host resin selection, allowing CoF optimization without changing the base polymer system.
- Non-leachable formulation design directly addresses the ISO 10993 extractables concern that limited earlier siloxane approaches.
- E-beam compatibility — an HDPE or TPU host matrix crosslinks under ionizing radiation rather than undergoing chain scission, providing inherent radiation stability that both PTFE and first-generation siloxane systems lack.
- Host resin modulus can be selected or tuned to reduce mechanical impedance mismatch with adjacent jacket materials — addressing the fatigue-mode failure risk that tie-layer engineering alone cannot solve.

## 7.2 Durometer as a Design Variable: What PTFE Cannot Offer

One of the most consequential — and least discussed — limitations of PTFE as a catheter liner material is its fixed mechanical stiffness. PTFE extrudes at approximately Shore D 55–60 regardless of formulation, leaving catheter architects with no ability to tune liner stiffness independently of surface lubricity. In a multi-durometer shaft design where the engineer wants a stiffer proximal body and a progressively softer distal segment, PTFE requires a material transition — which means an interface, a bonding step, and a delamination risk site.

Polyamide-backbone siloxane-compounded formulations are available across a Shore D 20–60 durometer range. This means stiffness and lubricity can be specified independently for the first time in a single material family. A catheter architect can specify a 60D liner in the proximal shaft for pushability and torque transmission, transition to a 40D mid-shaft for trackability, and terminate in a 20D distal segment for atraumatic tip compliance — all within the same base material system, without introducing a new material interface at any transition point.

The development efficiency implication is also meaningful: iterating distal stiffness profile no longer requires changing material suppliers, rerunning biocompatibility, or requalifying a new liner material. Durometer grade selection becomes a formulation parameter within an already-characterized material system — compressing design iteration cycles at a stage of development where schedule pressure is typically highest.

*PTFE is fixed at Shore D 55–60. A lubricious liner material available from Shore D 20 to 60 in a*

*single material family is not just a PTFE alternative — it is a new design variable that changes what catheter architectures are possible.*

### 7.3 Thin-Wall Capability: Honest Assessment Across Material Families

PTFE retains a genuine and durable advantage at the extreme ultra-thin wall end of the performance envelope. Commercial PTFE liner production below 0.00075 inch wall thickness is established and repeatable — a capability no current thermoplastic alternative matches at commercial scale. For tight-profile applications where this wall range is a design requirement, PTFE remains the technically superior choice.

For the majority of interventional catheter programs, practical liner wall requirements fall within ranges where advanced compounded formulations are fully commercially competitive — approximately 0.00125 inch in free-extrusion format and approximately 0.001 inch in extrusion-over-wire constructions, depending on geometry and process conditions. These ranges encompass the liner wall budgets of a broad cross-section of neurovascular, cardiovascular, and peripheral vascular catheter designs currently in development and commercial production.

The practical implication: for programs where sub-0.00075 inch wall is not a design constraint — which represents the majority of interventional catheter platforms — the thin-wall differential between PTFE and advanced compounded formulations does not constitute a material selection driver. Programs requiring the extreme ultra-thin wall space should continue to treat PTFE as the reference.

### 7.4 Wet-Environment Performance: Where Clinical Conditions Amplify the Advantage

Most catheter applications operate in a wet environment. Vascular intervention involves continuous saline flush, blood contact, and contrast media exposure. Urological applications involve urine. Neurointerventional procedures involve cerebrospinal fluid. In the majority of clinical use cases, the dry bench test condition against which CoF data is typically reported does not reflect the actual operating environment — and this distinction matters significantly for how lubricious liner materials perform in use.

Everglide+ achieves its lubricity through a siloxane compound that is integrated throughout the polymer matrix — not applied as a surface coating or additive layer. This is a fundamental formulation distinction: the lubricious character of the material is a bulk property expressed at the surface through controlled migration of the permanently bound siloxane component, rather than a coating that sits on top of a substrate. The practical consequence is that the lubricious surface cannot be depleted by abrasion, repeated device passage, or sterilization cycling in the way that applied hydrophilic coatings can.

Hydrophobic surfaces of this type interact with aqueous fluids in a mechanically favorable way under clinical conditions. Rather than absorbing water molecules into the surface structure, the hydrophobic matrix repels them — causing saline, blood, or contrast media to form a thin, low-shear hydrodynamic boundary layer at the polymer-fluid interface. Under the sliding contact conditions of catheter navigation — guidewire passage, device exchange, catheter advancement through tortuous anatomy — this boundary layer provides sustained lubrication driven by the clinical fluid environment itself. Based on application feedback across commercial deployments, lubricity performance in aqueous clinical environments is generally comparable to or better than dry bench test performance — the opposite performance curve from many coating-based systems that degrade with repeated fluid exposure.

For catheter programs where device exchange frequency is high, lumen reuse within a single procedure is expected, or contrast media compatibility is a design requirement, this wet-environment

performance stability is a clinically meaningful design attribute that dry CoF benchmarks alone do not capture.

*PTFE's lubricity derives from its intrinsic surface chemistry — it performs consistently across wet and dry conditions without degradation, which is part of its clinical track record value. Everglide+'s matrix-compounded siloxane mechanism provides comparable wet-condition performance through a fundamentally different approach — one that is e-beam compatible, PFAS-free, and inherent to the bulk material rather than dependent on a surface treatment.*

## 7.5 Architectural Integration: Bonding to Jacket Materials and Metal Reinforcement

Two additional performance dimensions of polyamide-backbone formulations deserve specific attention for reinforced and multi-layer catheter designs: jacket compatibility and metal reinforcement bonding. Both follow directly from the Nylon-family chemistry of the host matrix.

Pebax — the dominant catheter jacket material for high-performance interventional devices — is a polyether block amide (PEBA). Its hard segment is a polyamide chain. Everglide+, as a Nylon-backbone compounded formulation, shares the polyamide chemical family with Pebax's structural hard segment. During reflow lamination, this chemical compatibility enables homogeneous bonding at the molecular level — chain entanglement between polyamide segments of the liner and the Pebax jacket — rather than the mechanical interlocking that etched PTFE relies on after surface activation. The liner and jacket become a continuous polyamide-family material system. There is no dissimilar-polymer interface to delaminate, no tie-layer to fail, and no etching variability to control. This directly addresses the slip plane and impedance mismatch mechanisms described in Section 6.

For reinforced shaft designs incorporating braided wire, coiled wire, or laser-cut hypotube (LCHT) as the structural layer, the polyamide matrix provides a second bonding advantage. PTFE's non-stick surface character means it does not wet metal surfaces during thermal processing — the liner sits against the reinforcement structure rather than flowing into it, creating a contact interface rather than a structural bond. Torque transmission, pushability, and resistance to liner separation under torsional and compressive load all depend on the quality of this polymer-to-metal interface in clinical use.

Polyamide matrix formulations wet and mechanically key into metal reinforcement structures during thermal processing — engaging braid interstices and coil gaps to create a structural polymer-metal interface rather than the contact-dependent surface relationship that PTFE's non-stick character produces. For braided and coiled reinforcement designs, this translates directly to more consistent torque transmission, improved pushability predictability, and greater resistance to liner migration under axial and torsional loads.

For laser-cut hypotube (LCHT) designs, the interaction between polyamide matrix and kerf geometry warrants specific process engineering attention. The degree to which liner material flows into kerf slots during thermal processing is a function of reflow temperature, dwell time, and applied pressure — all controllable process parameters. Managed correctly, controlled kerf engagement improves structural bonding between liner and hypotube while preserving the designed flex pattern and lumen geometry. Unmanaged, excessive flow into kerf width can affect hypotube flexibility characteristics and restrict lumen communication between cuts. This is not a material limitation — it is a thermal processing parameter that requires deliberate optimization for each LCHT geometry and hypotube design, and one

that experienced catheter process engineers will recognize as analogous to the reflow control discipline already required for any thermoplastic-over-hypotube construction.

One processing constraint to note: polyamide-backbone formulations carry a melt temperature in the Nylon range — substantially lower than PTFE's 327°C but higher than typical Pebax and TPU jacket materials. Reflow process windows must be managed to avoid liner deformation in high-temperature jacket processing scenarios. This is a well-understood process engineering consideration, not a fundamental material limitation, but it requires attention in process development for high-temperature jacket systems.

## 7.6 Process Efficiency and Total Cost of Ownership

The manufacturing process simplification enabled by eliminating etching and tie-layer construction is not merely a convenience — it has direct implications for process control, yield, and total cost of ownership that procurement and operations teams should evaluate alongside the material performance data. Internal manufacturing studies across multiple catheter programs indicate that delamination-related yield losses represent the single largest manufacturing cost driver in PTFE-lined reinforced catheter designs — followed by liner stretch process time, post-processing stability losses, and mandrel removal damage. The table below maps the primary cost categories affected by material architecture selection.

Cost Category	Impact: Advanced Compounded Formulation vs. PTFE Architecture
<b>Delamination scrap &amp; rework</b>	Substantially reduced — polyamide-family bonding eliminates the primary interface failure mechanism driving fatigue-mode delamination
<b>Chemical etching process</b>	Eliminated — removes regulated chemical waste stream, lot-to-lot bonding variability, activated surface shelf-life management, and supplier qualification dependency simultaneously
<b>Tie-layer co-extrusion</b>	Eliminated in PA-backbone designs — removes a material cost, wall budget line item, co-extrusion process variable, and qualification scope item simultaneously
<b>Reflow process variables</b>	Reduced — fewer process interfaces to control; more predictable reflow behavior with same-family polymer chemistry at liner-jacket boundary
<b>Secondary coating dependency</b>	Reduced or eliminated — lubricity is a bulk material property, not a surface coating; no depletion under repeated device passage or sterilization cycling
<b>ISO 10993 characterization scope</b>	Potentially reduced — single polyamide material family may cover liner-jacket interface within one characterization package vs. independent assessment of each dissimilar material boundary (application-specific testing still required)
<b>Wall budget efficiency</b>	Improved — tie-layer elimination recovers wall budget; meaningful for profile-critical small-bore catheter designs where every 0.001" matters

Chemical etching of PTFE liners introduces a multi-variable process step: etchant concentration, contact time, temperature, and post-etch handling all affect surface activation quality and shelf life of the activated surface. Each variable is a source of lot-to-lot bonding variability, and the etchant itself is a regulated chemical waste stream requiring handling and disposal infrastructure. Eliminating this step removes a quality control burden, a manufacturing cost, and a supplier qualification dependency simultaneously.

Tie-layer co-extrusion adds a material, a process step, a wall budget line item, and a co-extrusion process control variable. In tight-tolerance small-profile catheters where total wall budget is a primary design constraint, every eliminated layer has dimensional value. In high-volume production, every eliminated process step has yield and cycle time value.

From a regulatory characterization perspective, when liner and jacket share the same polyamide material family, the ISO 10993 biocompatibility package may cover the liner-jacket interface within a single material family assessment rather than requiring independent characterization of each dissimilar material boundary. This does not eliminate the biocompatibility requirement — application-specific testing remains mandatory — but it can meaningfully reduce the scope and cost of the characterization package for programs transitioning from multi-material to same-family construction.

To be clear on context: PTFE remains the right answer for many catheter programs. Its ultra-thin wall capability, established biocompatibility history, and deep clinical precedent mean it will continue to anchor liner design in EtO-sterilized programs where bondability complexity is manageable and commercial lifetime is well-defined. Olefin-based systems address the radiation stability and PFAS classification gaps while offering broad supply chain optionality. The advanced compounded formulation category does not replace either — it addresses programs where the full constraint set cannot be solved by PTFE or olefin systems alone.

It is worth noting that not all lubricity additives used in catheter materials are PFAS-free. Perfluoropolyether (PFPE) oils — a class of fully fluorinated synthetic lubricants — have been used in some catheter material and processing applications for their low surface tension and thermal stability. PFPE compounds are classified as PFAS under both EPA and ECHA definitions, carrying the same long-term regulatory trajectory risk as PTFE. Device programs evaluating lubricious additive systems should explicitly confirm the PFAS classification of any fluorinated oil or additive component in the formulation, not just the base polymer.

Everglide+ is one commercially proven example within the advanced compounded formulation category — a PFAS-free, non-leachable, e-beam compatible, polyamide-backbone siloxane-compounded formulation with approximately three years of commercial deployment in catheter liner and shaft applications. The Everglide platform is currently incorporated in cleared, commercialized catheter programs deployed across the market, spanning both established OEM and emerging device company customers in neurovascular and interventional vascular applications. Customer names are not disclosed in this document absent explicit approval; programs operating in similar applications can request reference information through Dynaflex directly. Other advanced hybrid formulations addressing similar design objectives are in active development across the industry, though most remain in early-stage development or limited commercial deployment without the clinical data depth that established platforms carry. These emerging platforms reflect the direction the industry is moving — but for programs requiring validated material performance data today, the distinction between an established commercial platform and a platform still accumulating deployment history is a meaningful procurement and risk management consideration.

*The generational distinction matters to device engineers evaluating alternatives: early siloxane approaches created new problems while solving lubricity. Current-generation non-leachable polyamide-backbone formulations are engineered to address lubricity, bondability, radiation stability, durometer tunability, metal reinforcement integration, and extractables simultaneously*

*— the full constraint set that PTFE's architecture has historically required engineers to work around rather than through.*

## 8 · STRATEGIC FRAMEWORK FOR MATERIAL SELECTION

Material selection for catheter liner and shaft applications is a multi-dimensional decision encompassing technical performance, sterilization strategy, supply chain resilience, regulatory trajectory, and product lifecycle planning. The framework below maps representative program scenarios to material strategy considerations — including the PFAS regulatory context that applies across all platforms.

Design / Program Scenario	Strategic Material Consideration
<b>Established, EtO-sterilized application</b>	PTFE remains the preferred choice where EtO sterilization is reliable and bondability is manageable. Evaluate supply chain concentration risk explicitly for platforms with 10+ year lifecycles.
<b>Radiation sterilization required or preferred</b>	Olefin-based systems or advanced compounded formulations offer substantially superior radiation stability. Should be evaluated as primary alternatives when gamma or e-beam is mandated or preferred.
<b>Multi-layer / multi-durometer catheter design</b>	Advanced compounded formulations with Shore D 20–60 durometer range enable stiffness profiling along shaft length within a single material family — eliminating material interfaces at durometer transition points and the delamination risk they introduce.
<b>Reinforced shaft design (braid, coil, or LCHT)</b>	Polyamide-backbone formulations wet and key into metal reinforcement geometry during thermal processing, creating a structural polymer-metal interface. Evaluate against PTFE designs where liner migration or torque transmission consistency are known program risks.
<b>PA-jacket (Pebax / Nylon) construction</b>	Polyamide-backbone liner formulations are chemically compatible with Pebax and Nylon jacket materials at the molecular level — enabling homogeneous reflow bonding without etching, tie-layer, or surface activation. Reduces interface count, process variability, and delamination risk simultaneously.
<b>PFAS-free program mandate</b>	PTFE is classified as PFAS under EPA and ECHA frameworks. FDA has affirmed fluoropolymers in medical devices are safe and currently irreplaceable for many applications — but OEMs should evaluate 10–15 year regulatory trajectory for new programs. Olefin-based and advanced compounded formulations are PFAS-free.
<b>Process simplification / yield improvement objective</b>	Eliminating chemical etching removes a regulated process step, a waste stream, and a bonding variability source. Eliminating tie-layer co-extrusion removes a material, a wall budget line item, and a co-extrusion process control variable. Both have direct yield and total cost of ownership implications in volume production.
<b>Biocompatibility characterization efficiency</b>	When liner and jacket share the same polyamide material family, ISO 10993 characterization may cover the liner-jacket interface within a single-family assessment. Application-specific testing remains mandatory — but the characterization scope and cost of a same-family construction may be meaningfully lower than a multi-material boundary approach.
<b>Supply chain resilience objective</b>	A validated alternative liner platform developed in parallel with the primary PTFE design provides meaningful sourcing optionality given three-supplier concentration of medical-grade PTFE supply.
<b>Material change in cleared device</b>	Per FDA's December 2025 Mods Guidance webinar: for changes to existing cleared devices, a well-documented risk assessment showing no new biocompatibility concerns and no significant safety/effectiveness impact may support a conclusion that a new 510(k) is not required. Internal documentation under the Mods Guidance framework is the required foundation. New device programs require their own premarket submission pathway. Final regulatory determination remains the responsibility of the device manufacturer in consultation with qualified regulatory counsel.

## CONCLUSION

PTFE has earned its position as the catheter liner gold standard through decades of reliable clinical performance, a well-understood regulatory history, and an unmatched intrinsic lubricity profile — including thin-wall extrusion capabilities below 0.00075 inch that no current thermoplastic alternative matches at commercial scale. For many device programs — particularly those designed around EtO sterilization with well-characterized mechanical requirements — PTFE will remain the correct material choice, and the FDA has affirmed its safety profile in medical devices.

What has changed is the context in which that choice is made. The medical-grade PTFE supply base has contracted materially following 3M's completed PFAS exit. The EtO regulatory environment faces sustained long-term pressure. Ionizing radiation sterilization is constrained by PTFE's fundamental susceptibility to chain scission. PFAS regulatory frameworks continue to evolve in ways that create long-term uncertainty for fluoropolymer-containing platforms with extended commercial lifecycles.

Against this backdrop, olefin-based systems offer credible radiation-compatible alternatives, and current-generation advanced compounded formulations — where non-leachable siloxane-based chemistry is integrated into thermoplastic host matrices — represent the most architecturally complete answer to the full constraint set: PFAS-free, e-beam compatible, tunable lubricity, improved bondability, and reduced impedance mismatch risk. The FDA's December 2025 Mods Guidance webinar further clarifies that a well-documented risk assessment may support a material transition without a full new 510(k) — reducing the regulatory barrier to parallel material qualification.

**Material selection is no longer a single-variable optimization problem. It is a strategic design choice that integrates performance, supply chain resilience, regulatory trajectory, and sterilization flexibility from the earliest stages of platform development.**

Platforms such as Everglide+ and other advanced hybrid formulations currently in development represent a promising early indication of where this material category is heading — addressing the full constraint set that has historically required catheter engineers to choose between lubricity, bondability, radiation stability, and design flexibility rather than optimize across all simultaneously.

*There is, however, a more fundamental question that material substitution alone cannot answer. The multi-layer catheter construction — liner, tie-layer, jacket — grew up as an engineering response to PTFE's bondability constraint. Every interface in that stack is a potential slip plane, a site of mechanical impedance mismatch, a location where fatigue-mode failure can initiate under cyclic deflection. Solving the material supply problem while preserving the architectural pattern that created the interface risk addresses only half the engineering challenge.*

*If interfacial failure is the dominant long-term risk mechanism in modern catheter design, then the more fundamental question is whether multi-layer architecture itself remains the optimal engineering approach. The next paper in this series examines that question directly — and explores how integrated shaft architectures may eliminate the interface problem at its source rather than engineer around it.*

## STANDARDS AND REFERENCES

- AAMI TIR17: Compatibility of materials subject to sterilization — primary reference for radiation stability classification of PTFE and alternative polymer systems cited in this paper
- ISO 11137-1/2/3: Sterilization of health care products — Radiation
- ISO 10993: Biological evaluation of medical devices
- EPA NESHAP 40 CFR Part 63, Subpart O: EtO Commercial Sterilizers Final Rule (March 2024)
- EPA FIFRA Interim Decision for Ethylene Oxide (January 2025)
- EPA TSCA Section 8(a)(7): PFAS Reporting and Recordkeeping Rule
- FDA Radiation Sterilization Master File Pilot Program (April 2023)
- FDA Guidance: Deciding When to Submit a 510(k) for a Change to an Existing Device (2017)
- FDA CDRH Webinar: Case Study — Material Substitutions in Devices Subject to 510(k) Using PTFE (December 10, 2025). Transcript: [fda.gov/media/190296/download](https://www.fda.gov/media/190296/download)
- FDA Statement on PFAS in Medical Devices (August 2025)
- 3M Company: PFAS Manufacturing Exit Announcement (December 2022, SEC Form 8-K)
- W. L. Gore & Associates: ePE (Expanded Polyethylene) Platform — PFAS-free consumer fabrics transition commitment (2022)
- Gore Medical: GORE Viabahn Fortegra Venous Stent — FDA Approval (January 2026)

## ABOUT THE PUBLISHER

<p><b>Dynaflex Technologies Inc.</b></p> <p>Dynaflex is a materials science and catheter technology platform company focused on advanced catheter development and commercialization. The company develops and manufactures advanced catheter systems for neurovascular, cardiovascular, structural heart, and vascular therapy applications, with deep expertise across PTFE, polyolefin, and advanced compounded polymer systems — including Everglide+, a PFAS-free, non-leachable, e-beam compatible siloxane-based platform with a growing commercial track record in catheter applications.</p> <p>Dynaflex combines proprietary materials, catheter architecture, process engineering, and scalable manufacturing capabilities, operating four manufacturing facilities across California and Taiwan under ISO 13485:2016 certification.</p> <p>This technical white paper was developed by Dynaflex Technologies as part of its ongoing technical leadership initiative supporting catheter innovation, materials development, and commercialization within the medical device community. <a href="http://www.dynaflextech.com">www.dynaflextech.com</a></p>	<p>&amp;</p>	<p><b>Chamfr</b></p> <p>Chamfr is the distribution partner for this technical series, providing access to the catheter development community through its medical device marketplace platform. Chamfr connects R&amp;D engineers and procurement professionals across the MedTech industry with hundreds of qualified component suppliers — accelerating prototype development and sourcing from concept to commercialization.</p> <p><a href="http://www.chamfr.com">www.chamfr.com</a></p>
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