Performance Without PFAS[1]

Comparing PFX Flex™ vs. PTFE Catheter Liners

PTFE has been widely regarded as the gold standard for many device designs due to its lubricity, flexibility, and precision manufacturability. However, PTFE has some well-known characteristics that device makers must consider when developing devices, such as its difficulty in bonding and having limited sterilization options. These considerations, combined with regulatory uncertainties and sustainability initiatives, have led to an increased demand for a viable alternative to PTFE that addresses these long-standing challenges.

Introducing PFX Flex™ Sub-Lite-Wall™ – Engineered as an alternative to film-cast PTFE, PFX Flex™ Sub-Lite-Wall™ is a next-gen catheter liner that delivers proven lubricity, enhanced bond strength, and expanded sterilization options – all without PFAS.[1]

PFX Flex™ Sub-Lite-Wall™ Liners

Physical Properties – PFX Flex™ vs. PTFE Liners

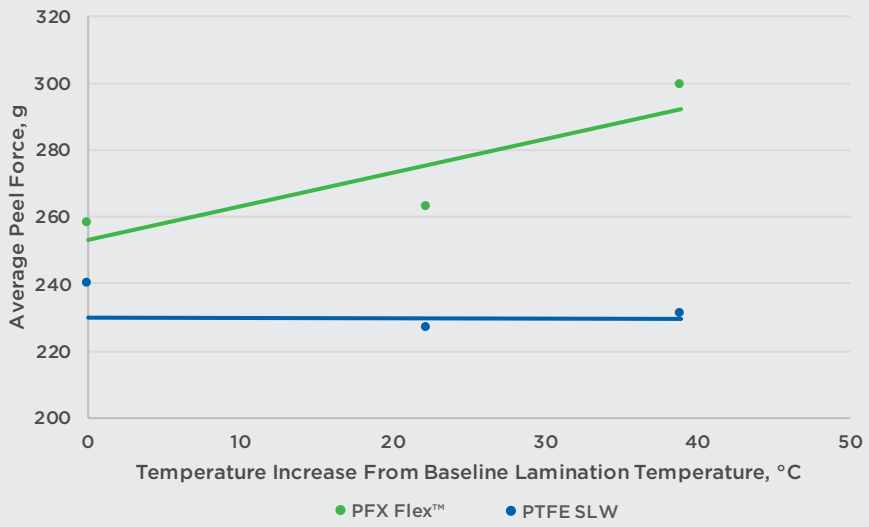
To characterize the physical attributes of PFX Flex Sub-Lite-Wall liners, four groups of comparatively sized liners were evaluated: 0.017" ID, 0.071" ID, 0.182"/0.200" ID, and 0.387" ID. For each size, a minimum of 30 PFX Flex liners and 30 PTFE liners were tested, and their average values were recorded. All film-cast PTFE liners were comprised of Zeus StreamLiner™ NG liners, while free-extruded PTFE liners consisted of Zeus Sub-Lite-Wall™ liners. Physical properties were obtained from production samples for illustrative purposes only.

[Table 1] Typical Properties: PFX Flex vs. PTFE

Liner Size	0.017" ID		0.071" ID		0.182" ID	0.200" ID	0.387" ID	
Material	PFX Flex	PTFE	PFX Flex	PTFE	PFX Flex	PTFE	PFX Flex	PTFE
Process	Proprietary Film-Cast	Proprietary Film-Cast	Proprietary Film-Cast	Proprietary Film-Cast	Proprietary Film-Cast	Free-Extruded	Proprietary Film-Cast	Free-Extruded
Outer Diameter	0.0200" (0.508 mm)	0.0182" (0.4623 mm)	0.0742" (1.8847 mm)	0.0727" (1.8466 mm)	0.1839" (4.6711 mm)	0.2031" (5.1587 mm)	0.3926" (9.9720 mm)	0.3921" (9.9593 mm)
Inner Diameter	0.0168" (0.4267 mm)	0.0172" (0.4369 mm)	0.0710" (1.8034 mm)	0.0711" (1.8059 mm)	0.1799" (4.5695 mm)	0.1995" (5.0673 mm)	0.3886" (0.9870 mm)	0.3873" (9.837 mm)
Wall Thickness	0.0016" (0.0406 mm)	0.0005" (0.0127 mm)	0.0016" (0.0406 mm)	0.0008" (0.0203 mm)	0.0020" (0.0508 mm)	0.0018" (0.0457 mm)	0.0020" (0.0508 mm)	0.0024" (0.0610 mm)
Stress @ Yield, psi	1,150	1,740	920	2,000	1,160	7,860	1,110	7,400
Stress @ Break, psi	1,450	2,850	1100	4,000	1,260	12,500	1,270	11,100
Strain @ Break, %	340	390	85	460	110	370	120	360
Modulus, psi	9,600	24,500	26,300	52,300	15,700	109,600	18,400	101,200
COF (37 °C, saline, SS)	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
COF (23 °C, air, SS)	≈ 0.1	≈ 0.1	≈ 0.1	≈ 0.1	≈ 0.1	≈ 0.1	≈ 0.1	≈ 0.1

To examine the bondability of the liners, 15 PFX Flex liners and 15 PTFE liners from the 0.071" group were bonded to Pebax® 55D jacketing material at various lamination temperatures, and the average peel force was recorded [Figure 1].

[Figure 1] Bond Strength to Pebax® 55D: PFX Flex vs. PTFE



Test data [Table 1] revealed that PFX Flex liners exhibit a coefficient of friction comparable to that of PTFE liners, indicating high levels of lubricity for smooth device tracking. Interestingly, PFX Flex Sub-Lite-Wall liners displayed a significantly lower modulus than comparably sized PTFE liners, indicating greater flexibility than PTFE liners despite the difference in wall thickness. Additionally, although PFX Flex liners exhibited lower strength than both free-extruded and film-cast PTFE liners at the component level, this was offset by stronger (covalent) bonding to jacketing material, which increased as lamination temperatures rose [Figure 1].

Sterilization Performance – PFX Flex-Lined vs. PTFE-Lined Catheter Shafts

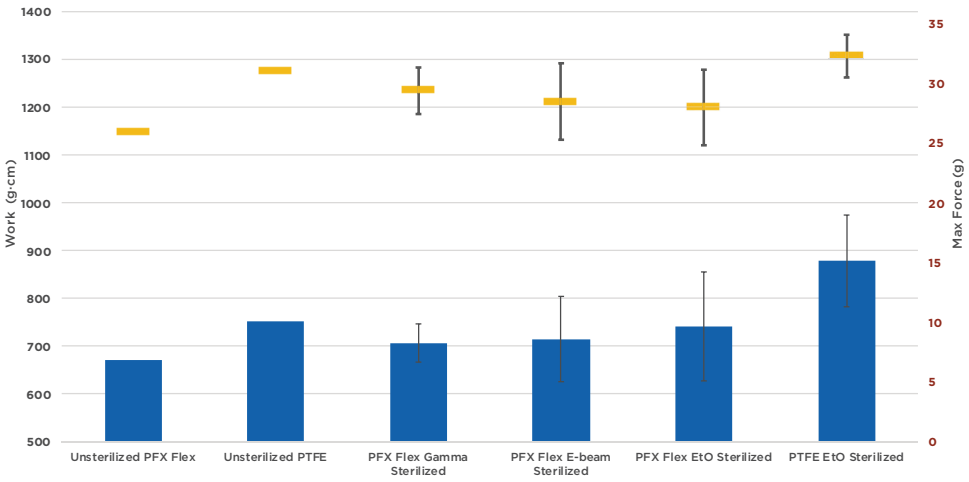
To evaluate compatibility with various sterilization protocols, a series of 0.021" ID catheter shafts [Table 2] were constructed using PFX Flex Sub-Lite-Wall and PTFE StreamLiner NG liners. The assembled catheter shafts were tested at Zeus' Innovation Center by tracking a 0.018" guidewire through the shafts on an IDTE 3000 S-track [Figure 3] to measure the maximum force (Max Force) and the total energy required (Advancing Work) to move the guidewire through the shaft. Five shafts built with PTFE underwent EtO sterilization prior to testing, while 15 shafts built with PFX Flex liners underwent EtO, Gamma, and E-beam sterilization prior to testing (five per sterilization protocol). One shaft constructed with PTFE, and one shaft constructed with PFX Flex, did not undergo sterilization prior to S-track testing.

[Table 2] IDTE Track Testing: Catheter Shaft Construction

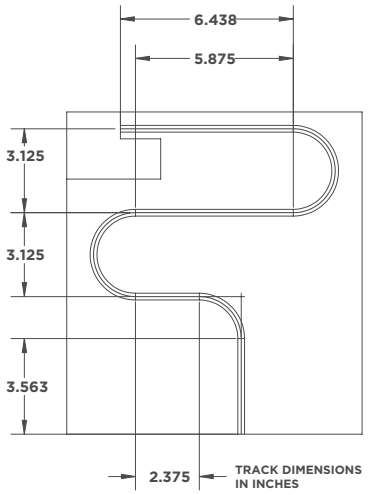
Liner	Liner ID	Liner Wall	Reinforcement	Jacket Wall
PFX Flex Sub-Lite-Wall	0.021" (0.533 mm)	0.0015" (0.0381 mm)	0.0005" x 0.0015" 80 PPI (0.0127 mm x 0.0381 mm)	Pebax® 25D - 0.002" (0.051 mm) Pebax® 35D - 0.002" (0.051 mm) Pebax® 55D - 0.002" (0.051 mm) Vestamid® ML 21 - 0.003" (0.076 mm)
PTFE StreamLiner NG	0.021" (0.533 mm)	0.0007" (0.0178 mm)	0.0005" x 0.0015" 80 PPI (0.0127 mm x 0.0381 mm)	Pebax® 25D - 0.002" (0.051 mm) Pebax® 35D - 0.002" (0.051 mm) Pebax® 55D - 0.002" (0.051 mm) Vestamid® ML 21 - 0.003" (0.076 mm)

[Table 3] IDTE Track Testing: PFX Flex Sub-Lite-Wall vs. PTFE StreamLiner NG						
Sterilization Method	Unsterilized		EtO Sterilized		Radiation Sterilized (33.4 - 37.6 kGy)	
					Gamma	E-Beam
Material	PFX Flex	PTFE	PFX Flex	PTFE	PFX Flex	PFX Flex
Max Force, gf	26	31	28	32.3	28.5	29.4
Advancing Work, gf·cm	671	753	742	879	715	707

[Figure 2] IDTE Track Testing: PFX Flex Sub-Lite Wall vs. PTFE Streamliner NG



[Figure 3] IDTE Test Track



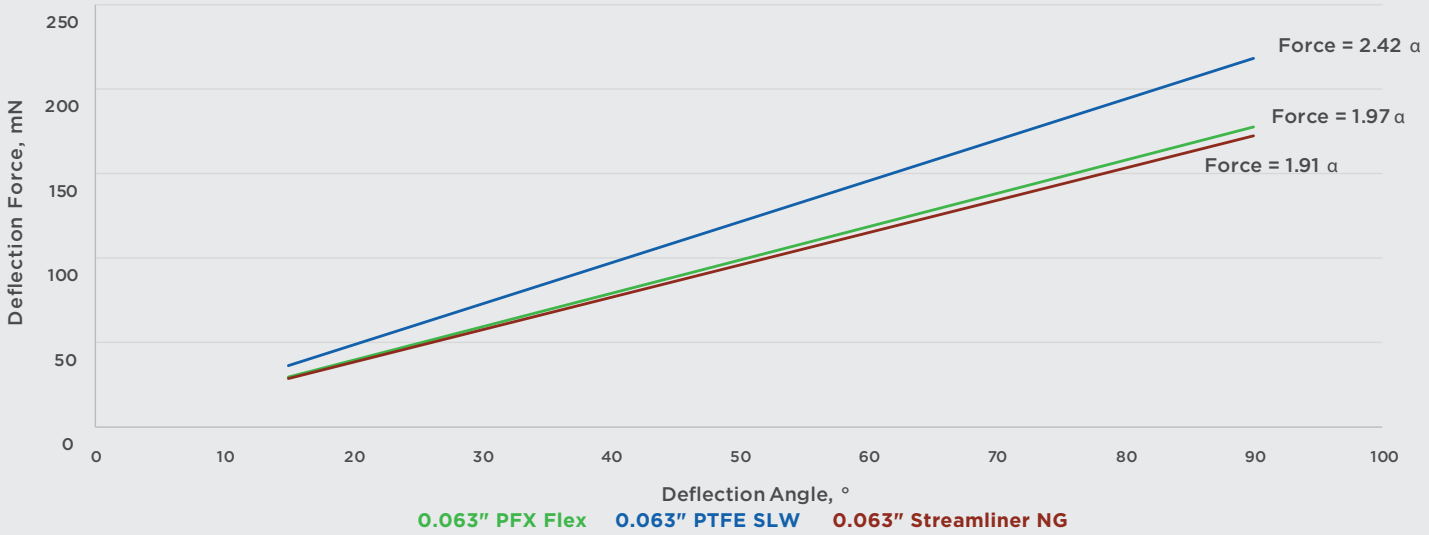
Results [Table 3, Figure 2] showed that PFX Flex Sub-Lite-Wall liners exhibited no significant loss of IDTE properties and maintained excellent lubricity post-sterilization, regardless of the sterilization method used. While PTFE liners are restricted to EtO sterilization due to well-known radiation-induced performance degradation, our testing demonstrated that catheter shafts constructed with PFX Flex Sub-Lite-Wall liners can be sterilized by EtO, Gamma, and E-beam with no significant impact on performance.

Flexibility – PFX Flex-Lined vs. PTFE-Lined Catheter Shafts

In addition to previous modulus testing, which indicated the superior flexibility of PFX Flex liners at the component level [Table 1], further flexibility testing was performed on a series of assembled 0.063" ID catheter shafts. Five catheter shafts were built using PTFE Sub-Lite-Wall liners (free-extruded), 10 shafts were built using PFX Sub-Lite-Wall, and another 10 were built using PTFE StreamLiner NG (film-cast). Flexibility was measured by performing a tip deflection test, in which the distal tip deflection force was measured at 15°, 45°, and 90° angles. Deflection force versus deflection angle (α) data were fit to linear models to obtain the modulus in deflection values shown below.

[Table 4] Tip Deflection: Catheter Shaft Construction				
Liner	Liner ID	Liner Wall	Reinforcement	Jacket Wall
PFX Flex Sub-Lite-Wall	0.063" (1.600 mm)	0.0015" (0.0381 mm)	0.001" x 0.003" 80 PPI (0.025 mm x 0.076 mm)	Pebax® 25D - 0.0035" (0.0889 mm)
PTFE Sub-Lite-Wall	0.063" (1.600 mm)	0.0015" (0.0381 mm)	0.001" x 0.003" 80 PPI (0.025 mm x 0.076 mm)	Pebax® 25D - 0.0035" (0.0889 mm)
PTFE StreamLiner NG	0.063" (1.600 mm)	0.0007" (0.0178 mm)	0.001" x 0.003" 80 PPI (0.025 mm x 0.076 mm)	Pebax® 25D - 0.0035" (0.0889 mm)

[Figure 4] Tip Deflection: PFX Flex vs. PTFE-Lined Catheter Shafts



The tip deflection testing [Figure 4] revealed that catheter shafts lined with PTFE Sub-Lite-Wall were about 20% stiffer than those lined with PFX Flex, while catheter shafts lined with PFX Flex were just as flexible as those lined with PTFE StreamLiner NG, despite the significantly thinner walls of the PTFE StreamLiner NG liners. These tests indicate that PFX Flex liners can be highly flexible alternatives to both free-extruded and film-cast PTFE liners.

Abrasion Resistance – PFX Flex vs. PTFE Liners

Considering the prevalence of minimally invasive procedures that require intraluminal tools and other devices to pass through the central working lumen of the catheter to reach the treatment site, particulate generation testing was conducted to evaluate the cleanliness and abrasion resistance of PFX Flex liners. Particulate generation was evaluated with 0.021" ID microcatheters lined with PFX Flex Sub-Lite-Wall and compared to on-market products lined with PTFE Sub-Lite-Wall. Testing was performed according to AAMI TIR42:2021, Evaluation of Particulate Associated With Vascular Medical Devices, to simulate the insertion and advancement of neurovascular coils and stent-retrievers through the catheters.

[Table 5] Particulate Generation: PFX Flex Sub-Lite-Wall vs. PTFE Sub-Lite-Wall

Particulate Size	Number of Particles	
	PFX Flex Sub-Lite-Wall	PTFE Sub-Lite-Wall
> 10 µm	5.4 – 7.4	1.8 – 6.3
> 25 µm	0.1 – 0.3	0.1 – 0.3
> 50 µm	0	0.1 max

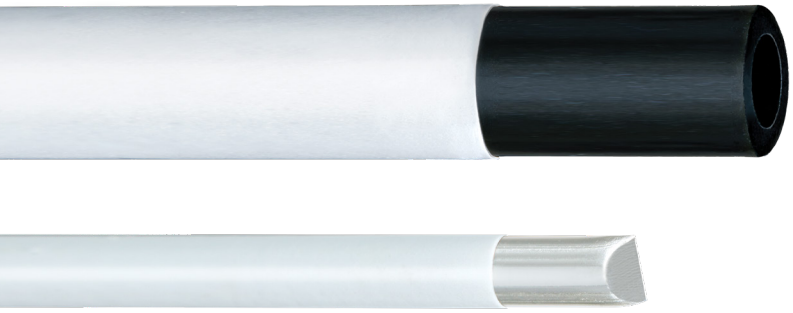
Particulate testing [Table 5] revealed that the PFX Flex-lined microcatheters were comparable to on-market PTFE-lined microcatheters for particulate generation and shed no particles over 50 µm, indicating exceptional abrasion resistance.

The Results

Comparing PFX Flex™ vs. PTFE Catheter Liners

PFX Flex Sub-Lite-Wall liners combine high lubricity and flexibility with enhanced bond strength, improved sterilization compatibility, and ID ranges that exceed current industry offerings for film-cast PTFE.

These results suggest that *PFX Flex Sub-Lite-Wall liners achieve PTFE-like performance with inherent sustainability benefits* – helping provide more design freedom, manufacturing flexibility, and compliance confidence in a world moving beyond PFAS.



Request Access to Samples

To request access to PFX Flex™ Sub-Lite-Wall™ samples for your next project, visit zeusinc.com/PFX-Flex .

Request Access to Samples

1. PFX Flex™ Sub-Lite-Wall™ liners are made using a non-fluorinated polymer resin alternative to PTFE and without the intentional addition of any per- or polyfluoroalkyl substances (PFAS). Independent third-party laboratory analysis on representative samples of PFX Flex™ Sub-Lite-Wall™ liners has confirmed total fluorine levels of less than 20 ppm in liner samples analyzed."