

Speed Up Steerable Catheter Production with PTFE Sub-Lite-Wall™ Multi-Lumen Extrusions

Steerable catheters are becoming increasingly popular thanks to their higher levels of control over the distal tip, improved stability, and enhanced accessibility to complex anatomies when compared to non-steerable catheters. However, the design and production of steerable catheters can be considerably more challenging and time-intensive as they have traditionally required more complex tooling and complicated manufacturing steps. Additionally, the traditional process of bundling several individual liners into a single multi-lumen assembly is often prone to error with high scrap rates.

Introducing Sub-Lite-Wall™ Multi-Lumen Tubing – As a single, process-ready extrusion, PTFE Sub-Lite-Wall™ multi-lumen tubing helps simplify steerable catheter construction, reduce manufacturing steps, and improve yields.



Zeus PTFE Sub-Lite-Wall™ Multi-Lumen Tubing.

Testing Traditional vs. New Process

To test this new solution, two sets of four-way steerable catheter shafts were built. 20 shafts were built using the traditional method of gluing five individual PTFE liners together into an assembly, while another 20 were built using Zeus' single, process-ready PTFE Sub-Lite-Wall™ multi-lumen. Four operators with varying skill levels were tasked with the builds, and the loading, stretching, and bonding steps of each build were recorded for time.

	ID	Wall Thickness	ID	Wall Thickness	Braid	Jacketing	Heat Shrink
	Main Lumen	Main Lumen	Satellite Lumens	Satellite Lumens	SS	Pebax® 55D	FEP
Multiple PTFE Liners (traditional process)	0.073"	0.0015"	0.014"	0.001"	0.001" x 0.003"	0.012" Wall	0.013" Wall
	1.854 mm	0.0381 mm	0.356 mm	0.025 mm	0.025 mm x 0.076 mm	0.305 mm	0.330 mm
PTFE Sub-Lite-Wall™ Multi-Lumen (new process)	0.073" 0.854 mm	0.0035" max avg. 0.0889 mm max avg.	0.012" 0.305 mm	0.0035" max avg. 0.0889 mm max avg.	0.001" x 0.003" 0.025 mm x 0.076 mm	0.012" Wall 0.305 mm	0.013" Wall 0.330 mm

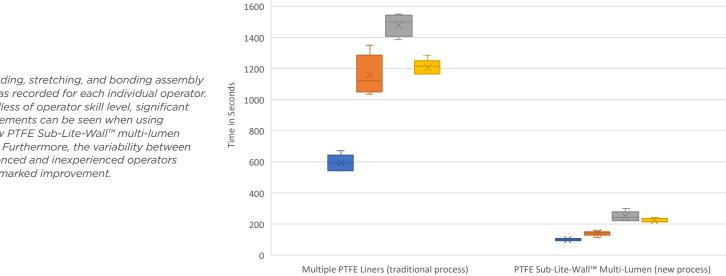
Average Time for Loading, Stretching, and Bonding Steps - Traditional vs. New Process

	Multiple PTFE Liners (traditional process)	PTFE Sub-Lite-Wall™ Multi-Lumen (new process)	
Step	Average Time (sec)	Average Time (sec)	
Load Main Lumen	15.04	9.91	
Stretch Main Liner	49.69	-	
Load Satellite 1	24.00	15.14	
Stretch Satellite Lumen 1	50.37	-	
Load Satellite 2	25.07	15.70	
Stretch Satellite Lumen 2	47.85	-	
Load Satellite 3	22.75	14.19	
Stretch Satellite Lumen 3	46.45	-	
Load Satellite 4	20.06	14.49	
Stretch Satellite Lumen 4	43.28	-	
Trim Tails (all at once)	24.63	-	
Bond Lumen 1	176.65	-	
Bond Lumen 2	177.87	-	
Bond Lumen 3	187.03	-	
Bond Lumen 4	200.44	-	
Stretch @ Align Main Mandrel	-	107.36	
Total Time (sec)	1111.20	176.80	
Total Time (min)	18.52	2.95	

Each of the four operators built five shafts using the traditional process, and five shafts using the new PTFE Sub-Lite-Wall™ multilumen process. Their individual times to complete each manufacturing step were recorded. The group average for each manufacturing step was then calculated. Testing was completed at a catheter-focused contract manufacturer.



Individual Operator Comparison Load, Stretch, Bonding Time by Method (Seconds)



1800

The loading, stretching, and bonding assembly time was recorded for each individual operator. Regardless of operator skill level, significant improvements can be seen when using the new PTFE Sub-Lite-Wall™ multi-lumen tubing. Furthermore, the variability between experienced and inexperienced operators shows marked improvement.

Potential Cost Savings as a Result of Improved Manufacturing Time							
Fully Burdened Hourly Rate	\$30/hr	\$50/hr	\$70/hr				
Minute Rate	\$0.50	\$0.83	\$1.16				
Traditional Process (Min)	18.52	18.52	18.52				
New Process (Min)	2.95	2.95	2.95				
Cost Per Shaft (Traditional)	\$9.26	\$15.37	\$21.48				
Cost Per Shaft (New Process)	\$1.48	\$2.45	\$3.42				
Savings Per Shaft (\$)	\$7.79	\$12.92	\$18.06				
Number of Shafts:		Cost Savings					
250	\$1,947.50	\$3,230.00	\$4,515.00				
500	\$3,895.00	\$6,460.00	\$9,030.00				
1000	\$7,790.00	\$12,920.00	\$18,060.00				
2000	\$15,580.00	\$28,540.00	\$36,120.00				

While improvements during the loading, stretching, and bonding steps alone could result in notable cost savings (up to 84%), additional factors like simplified BOM, reduced operator training cost, and other efficiencies should also be considered.

The Results

Operator 1 Operator 2 Operator 3 Operator 4

As a single, process-ready extrusion, Zeus' new PTFE Sub-Lite-Wall™ multi-lumen tubing greatly simplified steerable catheter construction. On average, operators could complete the liner loading, stretching, and bonding steps roughly six times faster when compared to the traditional method of bundling and gluing individual liners together.

These results suggest that Zeus' PTFE Sub-Lite-Wall™ multi-lumen extrusions could not only significantly reduce the time needed to manufacture steerable catheters, but also reduce manufacturing costs.

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zeusinc.com/SLW-multi-lumen

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