Catheter Radial Tolerance Stack-Up Report

SUMMARY

```
Design            : 8.5 Fr bidirectional steerable sheath (illustrative) - deflectable tip
Generated         : 2026-11-17 19:26   (CathStack v5.0.0)
Units             : in
Overall status    : PASS

Final OD nominal  : 0.1548 in  (3.933 mm, 11.80 Fr)
Final OD band     : 0.1529 – 0.1567  [Monte Carlo]
OD ceiling (USL)  : 0.1575

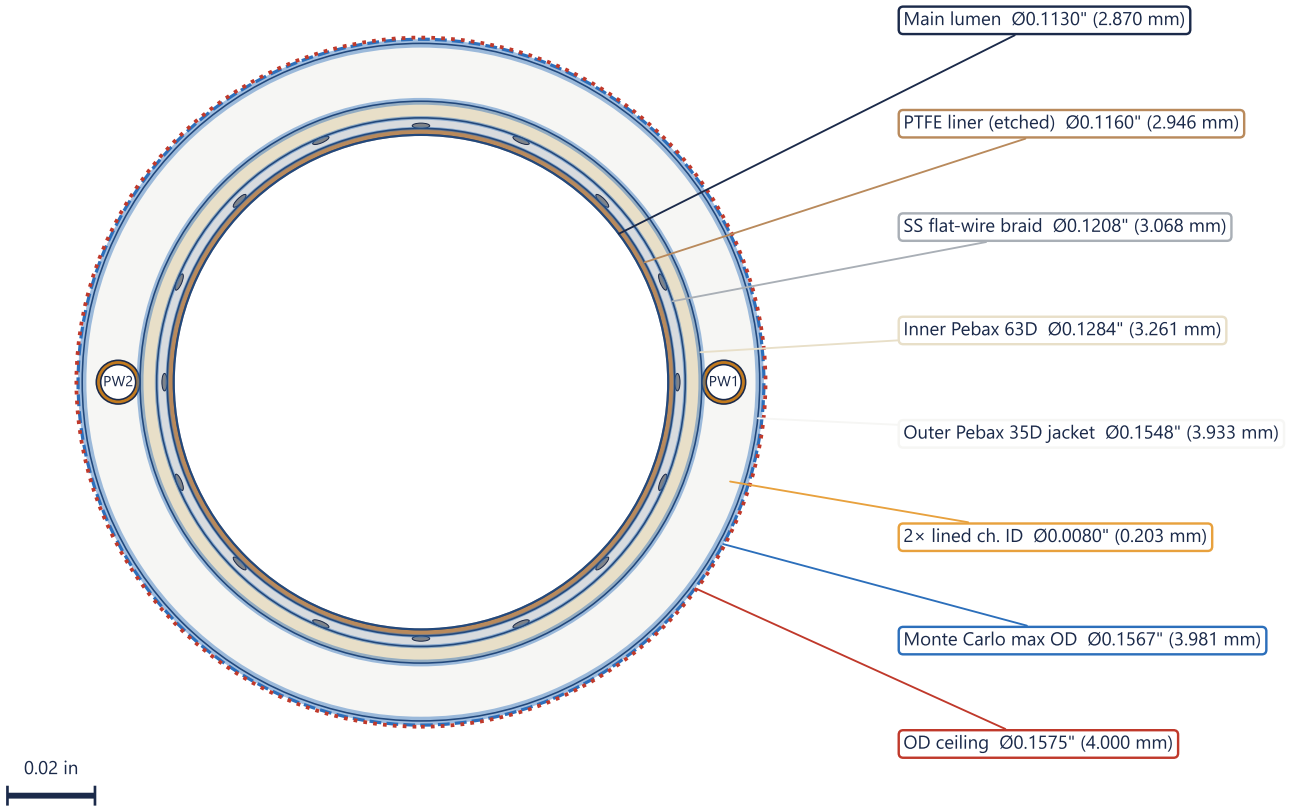
ANALYSIS SETTINGS
  acceptance method        : Monte Carlo
  worst-case evaluation    : extreme
  tolerance interpretation : ±3σ
  modified-RSS factor      : 1.5
  reflow model (global)    : exact; subtract channel area: True
  Monte Carlo              : on, N=20000, lhs, seed=12345, default dist=normal, truncated=True
  capability method        : normal

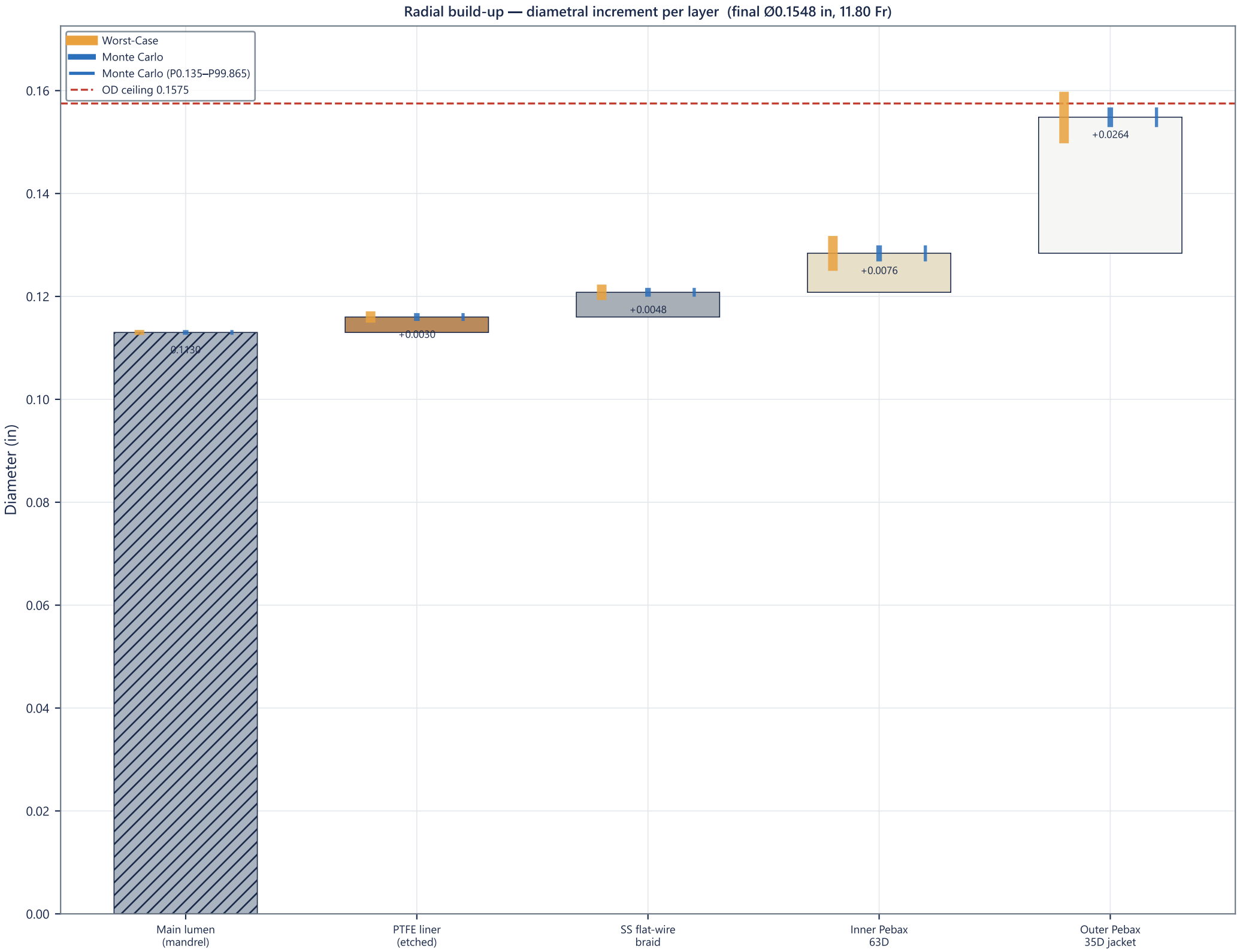
NOTES
  Representative of commercial 8.5 Fr bidirectional steerable sheaths (about 8.5 Fr ID / 12 Fr OD). Illustrative construction and tolerances, not any
manufacturer's design.
  Build: PTFE liner on a mandrel, flat-wire braid locked by an inner Pebax reflow, two polyimide pull-wire lumens at 0/180 deg laid on it, outer Pebax
jacket reflowed under FEP heat shrink.
  Judged on Monte Carlo: worst-case stacking of the seven layers fails the 12 Fr OD ceiling and the pull-wire cover, while the statistical result
passes with margin (OD Cpk about 1.3).
```

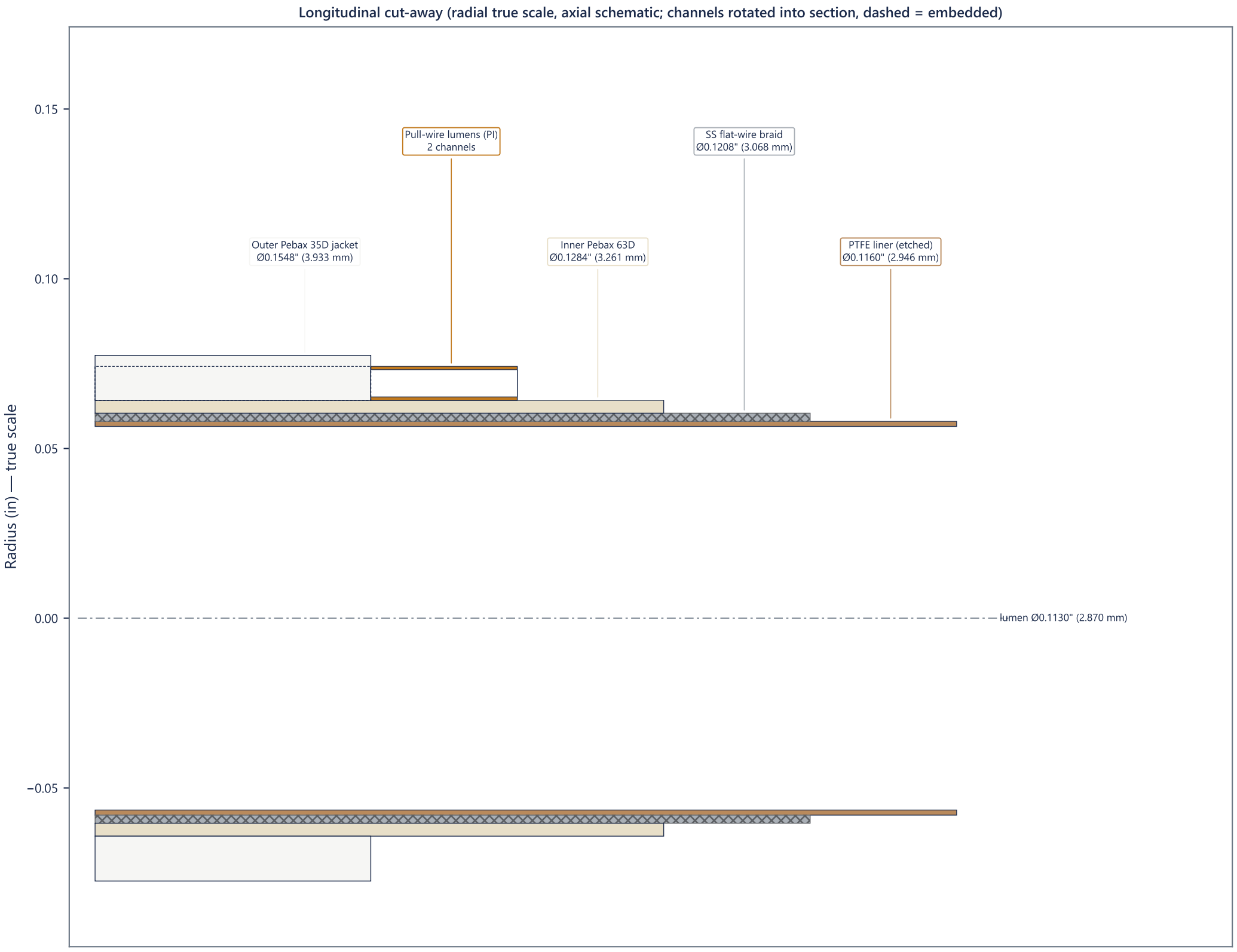
CHECKS

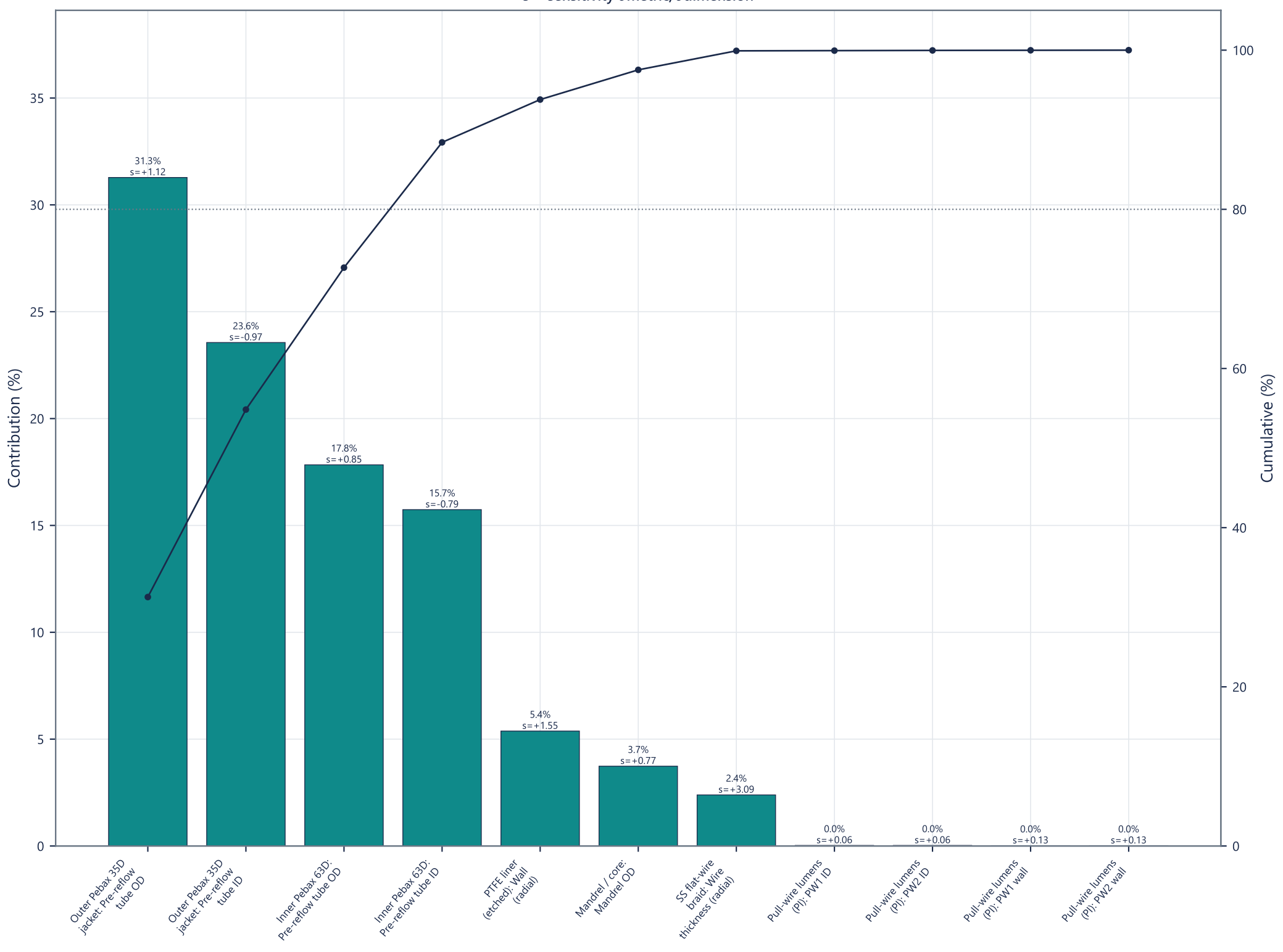
Status	Check	LSL	USL	Nominal	Bound min (Monte Carlo)	Bound max (Monte Carlo)	Margin	MC yield %	Cpk	Cpk source
PASS	Inner Pebax 63D loads over substrate	0.00000		0.00320	0.00193	0.00449	0.00193	100.0000	2.46	MC
PASS	Web PW1–PW2	0.00100		0.12840	0.12681	0.12993	0.12581	100.0000	79.48	MC
PASS	Outer Pebax 35D jacket loads over substrate	0.00000		0.00260	0.00022	0.00452	0.00022	99.9350	1.09	MC
PASS	Outer Pebax 35D jacket buries channels	0.00000		0.00644	0.00435	0.00794	0.00435	100.0000	3.45	MC
PASS	FEP heat shrink: expanded ID ≥ loaded OD + clr	0.00000		0.00800	0.00589	0.01012	0.00589	100.0000	3.64	MC
PASS	FEP heat shrink: recovered ID < OD (drive)	0.00000		0.01984	0.01704	0.02258	0.01704	100.0000	7.10	MC
PASS	FEP heat shrink: recovered ID > crown OD (no c	0.00000		0.01420	0.01215	0.01630	0.01215	100.0000	6.57	MC
PASS	FEP heat shrink: shrink ratio ≥ 1.20	1.200		1.370	1.347	1.395	0.147	100.0000	6.91	MC
PASS	Final OD within spec		0.15750	0.15484	0.15291	0.15674	0.00076	99.9950	1.35	MC
PASS	Main lumen ID ≥ minimum	0.11150		0.11300	0.11254	0.11346	0.00104	100.0000	3.04	MC
PASS	PW1 wall to OD	0.00200		0.00322	0.00224	0.00419	0.00024	99.9950	1.26	MC
PASS	PW2 wall to OD	0.00200		0.00322	0.00226	0.00416	0.00026	99.9950	1.27	MC

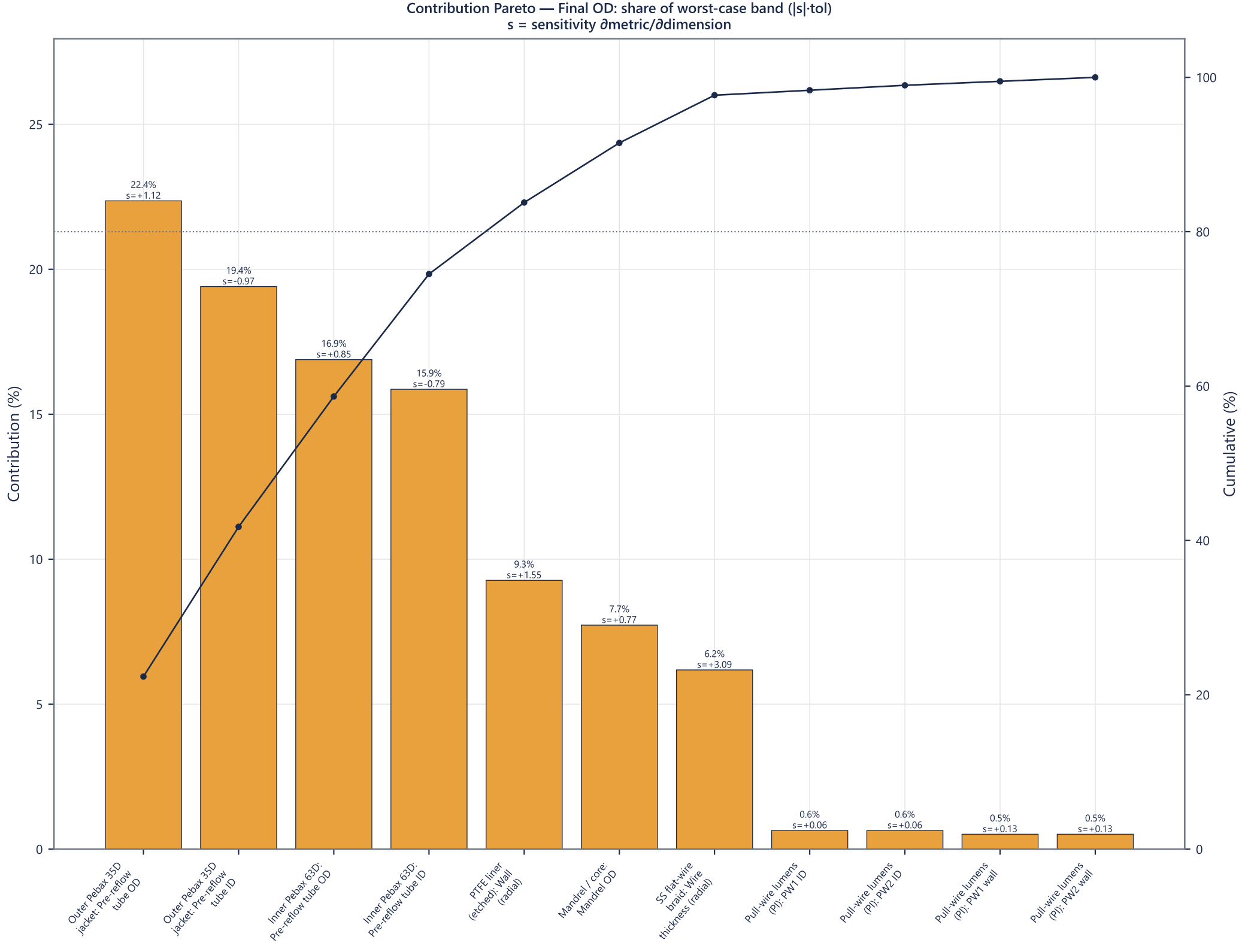
8.5 Fr bidirectional steerable sheath (illustrative) - deflectable tip
True scale · 11.80 Fr nominal · shaded = Monte Carlo OD band

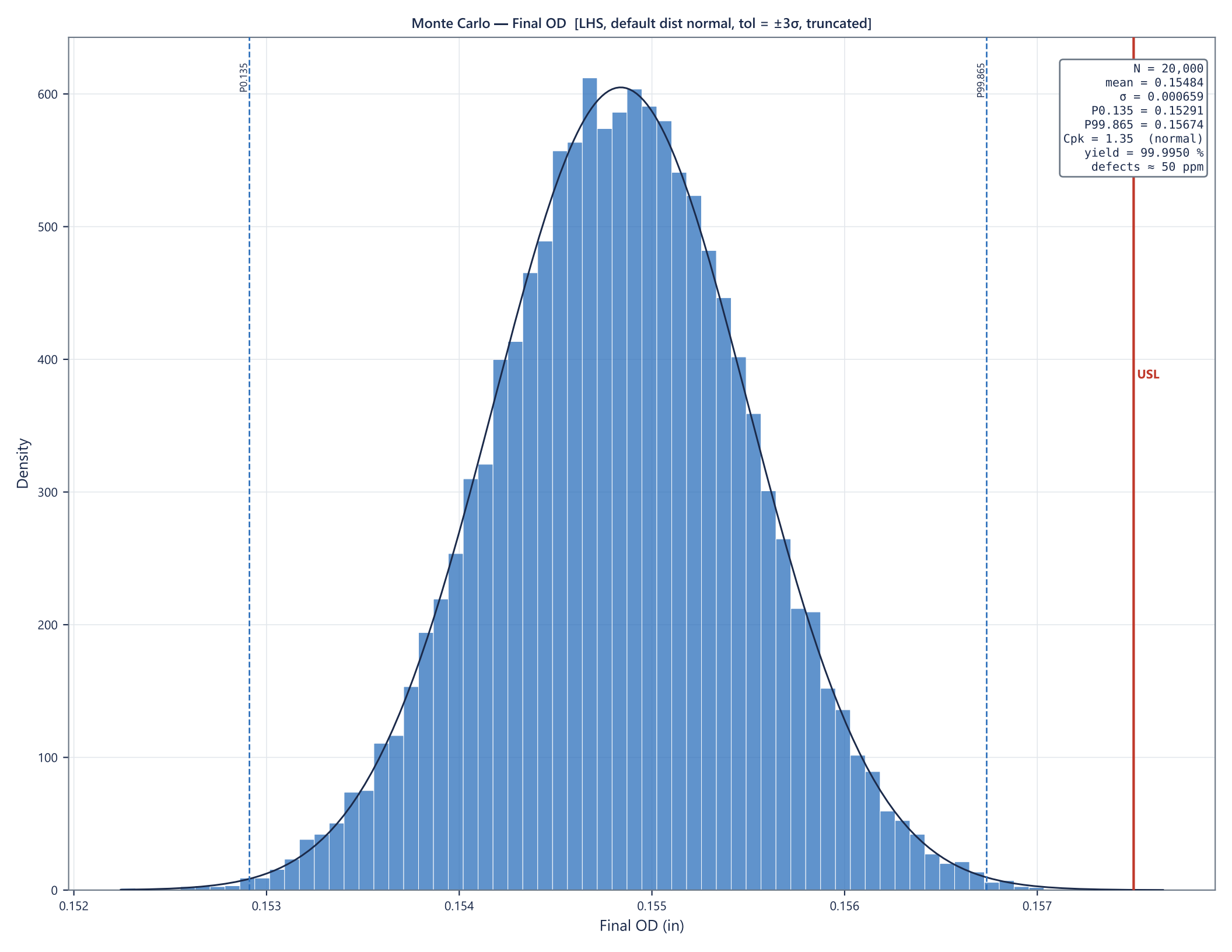


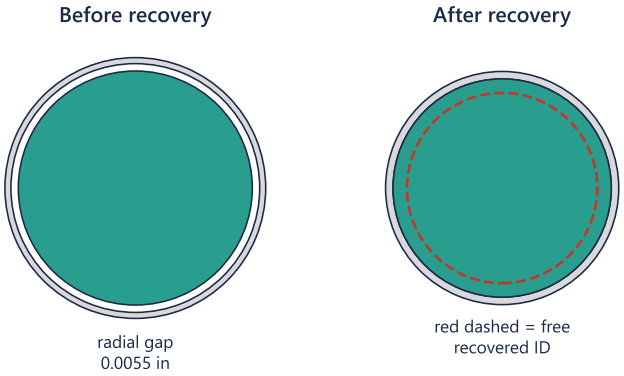

Radial build-up — diametral increment per layer (final Ø0.1548 in, 11.80 Fr)
Worst-Case
Monte Carlo
Monte Carlo (P0.135–P99.865)
OD ceiling 0.1575
Diameter (in)
0.00
0.02
0.04
0.06
0.08
0.10
0.12
0.14
0.16
0.1130
+0.0030
+0.0048
+0.0076
+0.0264
Main lumen (mandrel)
PTFE liner (etched)
SS flat-wire braid
Inner Pebax 63D
Outer Pebax 35D jacket

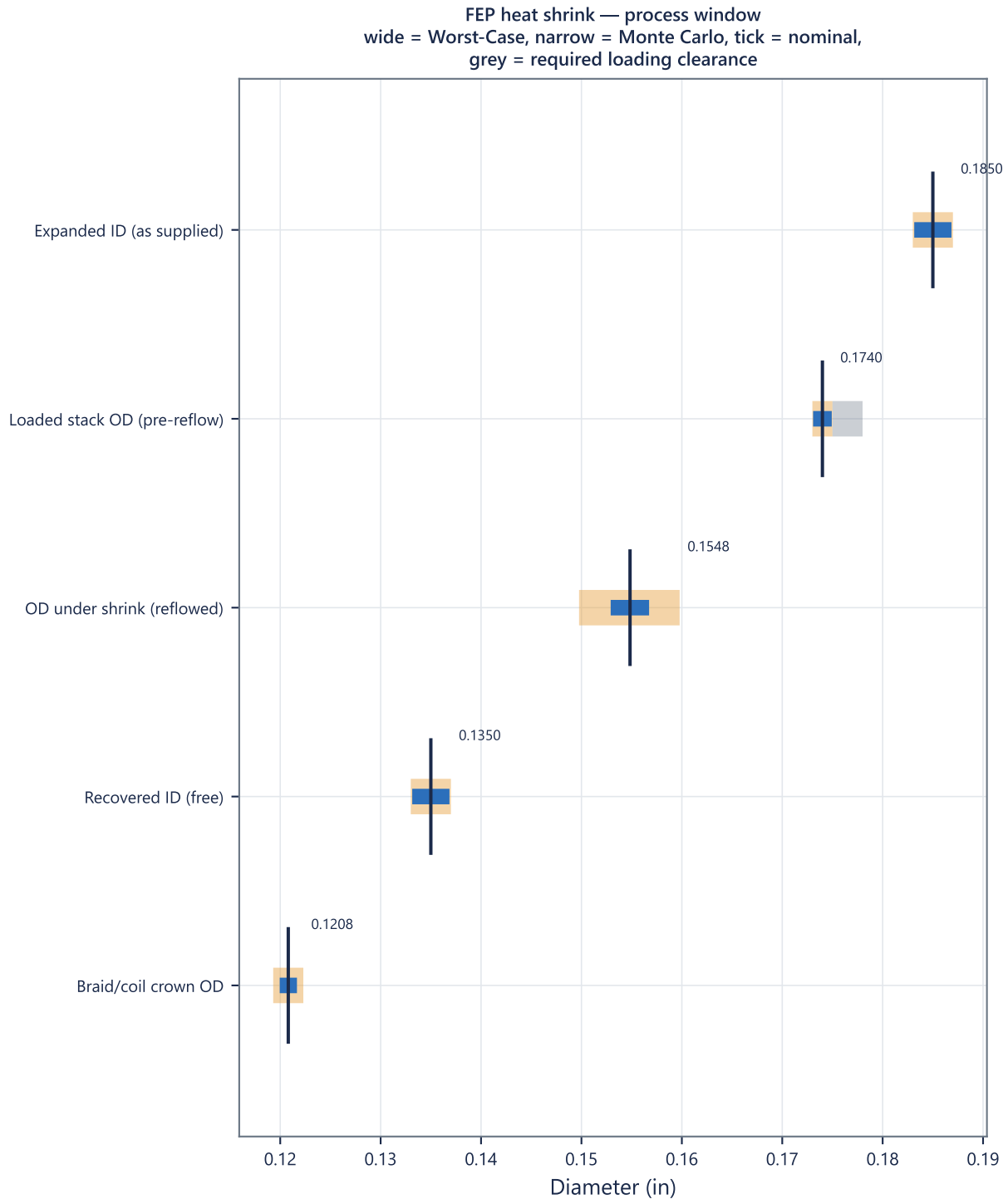

Longitudinal cut-away (radial true scale, axial schematic; channels rotated into section, dashed = embedded)
Radius (in) — true scale
0.15
0.10
0.05
0.00
−0.05
Outer Pebax 35D jacket
Ø0.1548" (3.933 mm)
Pull-wire lumens (PI)
2 channels
Inner Pebax 63D
Ø0.1284" (3.261 mm)
SS flat-wire braid
Ø0.1208" (3.068 mm)
PTFE liner (etched)
Ø0.1160" (2.946 mm)
lumen Ø0.1130" (2.870 mm)


Contribution Pareto — Final OD: variance share (RSS)
s = sensitivity ∂metric/∂dimension
Contribution (%)
Cumulative (%)
0
5
10
15
20
25
30
35
0
20
40
60
80
100
31.3%
s=+1.12
23.6%
s=-0.97
17.8%
s=+0.85
15.7%
s=-0.79
5.4%
s=+1.55
3.7%
s=+0.77
2.4%
s=+3.09
0.0%
s=+0.06
0.0%
s=+0.06
0.0%
s=+0.13
0.0%
s=+0.13
Outer Pebax 35D jacket: Pre-reflow tube OD
Outer Pebax 35D jacket: Pre-reflow tube ID
Inner Pebax 63D: Pre-reflow tube OD
Inner Pebax 63D: Pre-reflow tube ID
PTFE liner (etched): Wall (radial)
Mandrel / core: Mandrel OD
SS flat-wire braid: Wire thickness (radial)
Pull-wire lumens (PI): PW1 ID
Pull-wire lumens (PI): PW2 ID
Pull-wire lumens (PI): PW1 wall
Pull-wire lumens (PI): PW2 wall


Contribution Pareto — Final OD: share of worst-case band (|s|·tol)
s = sensitivity ∂metric/∂dimension
Contribution (%)
Cumulative (%)
0
5
10
15
20
25
0
20
40
60
80
100
22.4%
s=+1.12
19.4%
s=-0.97
16.9%
s=+0.85
15.9%
s=-0.79
9.3%
s=+1.55
7.7%
s=+0.77
6.2%
s=+3.09
0.6%
s=+0.06
0.6%
s=+0.06
0.5%
s=+0.13
0.5%
s=+0.13
Outer Pebax 35D jacket: Pre-reflow tube OD
Outer Pebax 35D jacket: Pre-reflow tube ID
Inner Pebax 63D: Pre-reflow tube OD
Inner Pebax 63D: Pre-reflow tube ID
PTFE liner (etched): Wall (radial)
Mandrel / core: Mandrel OD
SS flat-wire braid: Wire thickness (radial)
Pull-wire lumens (PI): PW1 ID
Pull-wire lumens (PI): PW2 ID
Pull-wire lumens (PI): PW1 wall
Pull-wire lumens (PI): PW2 wall


Monte Carlo — Final OD [LHS, default dist normal, tol = ±3σ, truncated]
N = 20,000
mean = 0.15484
σ = 0.000659
P0.135 = 0.15291
P99.865 = 0.15674
Cpk = 1.35 (normal)
yield = 99.9950 %
defects ≈ 50 ppm
P0.135
P99.865
USL
Density
Final OD (in)
0
100
200
300
400
500
600
0.152
0.153
0.154
0.155
0.156
0.157





Checks judged on Monte Carlo:

[PASS] expanded ID ≥ loaded OD + clr
margin +0.0059 MC yield 100.000%

[PASS] recovered ID < OD (drive)
margin +0.0170 MC yield 100.000%

[PASS] recovered ID > crown OD (no crush)
margin +0.0121 MC yield 100.000%

[PASS] shrink ratio ≥ 1.20
margin +0.1467 MC yield 100.000%

Results - all metrics

Metric	Unit	Nominal	Worst-Case min	Worst-Case max	RSS (3σ) min	RSS (3σ) max	Modified RSS min	Modified RSS max	Monte Carlo min	Monte Carlo max
Main lumen ID	in	0.11300	0.11250	0.11350	0.11250	0.11350	0.11250	0.11350	0.11254	0.11346
OD over PTFE liner (etched)	in	0.11600	0.11490	0.11710	0.11522	0.11678	0.11490	0.11710	0.11523	0.11676
OD over SS flat-wire braid	in	0.12080	0.11930	0.12230	0.11992	0.12168	0.11948	0.12212	0.11995	0.12166
Inner Pebax 63D: loading clearance	in	0.00320	0.00070	0.00570	0.00187	0.00453	0.00120	0.00520	0.00193	0.00449
Inner Pebax 63D: effective wall	in	0.00380	0.00276	0.00484	0.00310	0.00450	0.00276	0.00484	0.00311	0.00446
OD over Inner Pebax 63D	in	0.12840	0.12497	0.13175	0.12677	0.13003	0.12596	0.13084	0.12681	0.12993
PW1: ID	in	0.00800	0.00750	0.00850	0.00750	0.00850	0.00750	0.00850	0.00754	0.00846
PW2: ID	in	0.00800	0.00750	0.00850	0.00750	0.00850	0.00750	0.00850	0.00754	0.00846
Web PW1–PW2	in	0.12840	0.12497	0.13175	0.12677	0.13003	0.12596	0.13084	0.12681	0.12993
Outer Pebax 35D jacket: loading clearance	in	0.00260	-0.00355	0.00883	0.00049	0.00471	-0.00057	0.00577	0.00022	0.00452
Outer Pebax 35D jacket: channel burial margin	in	0.00644	0.00212	0.01085	0.00471	0.00817	0.00384	0.00904	0.00435	0.00794
Outer Pebax 35D jacket: effective wall	in	0.01322	0.01185	0.01464	0.01247	0.01398	0.01209	0.01435	0.01249	0.01394
OD over Outer Pebax 35D jacket	in	0.15484	0.14976	0.15978	0.15284	0.15684	0.15184	0.15784	0.15291	0.15674
FEP heat shrink: loaded stack OD	in	0.17400	0.17300	0.17500	0.17300	0.17500	0.17300	0.17500	0.17307	0.17493
FEP heat shrink: OD under shrink	in	0.15484	0.14976	0.15978	0.15284	0.15684	0.15184	0.15784	0.15291	0.15674
FEP heat shrink: expanded ID	in	0.18500	0.18300	0.18700	0.18300	0.18700	0.18300	0.18700	0.18315	0.18685
FEP heat shrink: recovered ID	in	0.13500	0.13300	0.13700	0.13300	0.13700	0.13300	0.13700	0.13315	0.13685
FEP heat shrink: loading margin	in	0.00800	0.00500	0.01100	0.00576	0.01024	0.00500	0.01100	0.00589	0.01012
FEP heat shrink: recovery interference (Ø)	in	0.01984	0.01276	0.02678	0.01701	0.02267	0.01559	0.02408	0.01704	0.02258
FEP heat shrink: reinforcement crown OD	in	0.12080	0.11930	0.12230	0.11992	0.12168	0.11948	0.12212	0.11995	0.12166
FEP heat shrink: crush margin (Ø)	in	0.01420	0.01070	0.01770	0.01202	0.01638	0.01092	0.01748	0.01215	0.01630
FEP heat shrink: shrink ratio	—	1.370	1.336	1.406	1.345	1.396	1.336	1.405	1.347	1.395
Final OD	in	0.15484	0.14976	0.15978	0.15284	0.15684	0.15184	0.15784	0.15291	0.15674
PW1: wall to final OD	in	0.00322	0.00100	0.00548	0.00224	0.00420	0.00176	0.00468	0.00224	0.00419
PW2: wall to final OD	in	0.00322	0.00100	0.00548	0.00224	0.00420	0.00176	0.00468	0.00226	0.00416
Axial stiffness EA	N	718.9	576.5	865.3	658.7	779.2	628.5	809.3	660.2	777.3
Bending stiffness EI (min)	N·mm²	793.6	621.6	977.8	712.2	874.9	671.5	915.6	714.7	872.7
Bending stiffness EI (max)	N·mm²	1,028	783.3	1,300	932.2	1,123	884.4	1,171	935	1,124
Torsional stiffness GJ	N·mm²	8,330	6,903	9,910	7,432	9,229	6,982	9,678	7,469	9,212
Torque response GJ/EI	—	10.497	7.916	14.042	9.207	11.787	8.563	12.432	9.317	11.878
Torque for 1 turn over 100 mm	N·mm	523.4	433.7	622.7	466.9	579.8	438.7	608.1	469.3	578.8
Burst pressure (estimate)	psi	1,469	1,237	1,704	1,363	1,574	1,311	1,627	1,369	1,573
Collapse pressure (vacuum)	psi	145	102	200	125	166	115	176	127	165
Tensile load at first yield	N	29.1	23.33	35.02	26.66	31.54	25.44	32.75	26.72	31.46
Tensile break load (estimate)	N	205.8	177.3	234.4	192.5	219.1	185.8	225.8	193	218.8
Minimum kink radius (estimate)	in	0.66126	0.59850	0.73651	0.63284	0.68967	0.61863	0.70388	0.63474	0.68929
Column load (Euler, pushability)	N	78.32	61.35	96.5	70.29	86.35	66.27	90.37	70.54	86.13

Contributions to final OD

Contributor	Sensitivity	Half-tol	WC share %	Variance share %
Outer Pebax 35D jacket: Pre-reflow tube OD	+1.1194	0.001	22.36	31.28
Outer Pebax 35D jacket: Pre-reflow tube ID	-0.9714	0.001	19.40	23.56
Inner Pebax 63D: Pre-reflow tube OD	+0.8453	0.001	16.88	17.84
Inner Pebax 63D: Pre-reflow tube ID	-0.7940	0.001	15.86	15.74
PTFE liner (etched): Wall (radial)	+1.5471	0.0003	9.27	5.38
Mandrel / core: Mandrel OD	+0.7735	0.0005	7.73	3.73
SS flat-wire braid: Wire thickness (radial)	+3.0942	0.0001	6.18	2.39
Pull-wire lumens (PI): PW1 ID	+0.0643	0.0005	0.64	0.03
Pull-wire lumens (PI): PW2 ID	+0.0643	0.0005	0.64	0.03
Pull-wire lumens (PI): PW1 wall	+0.1287	0.0002	0.51	0.02
Pull-wire lumens (PI): PW2 wall	+0.1287	0.0002	0.51	0.02

Inputs

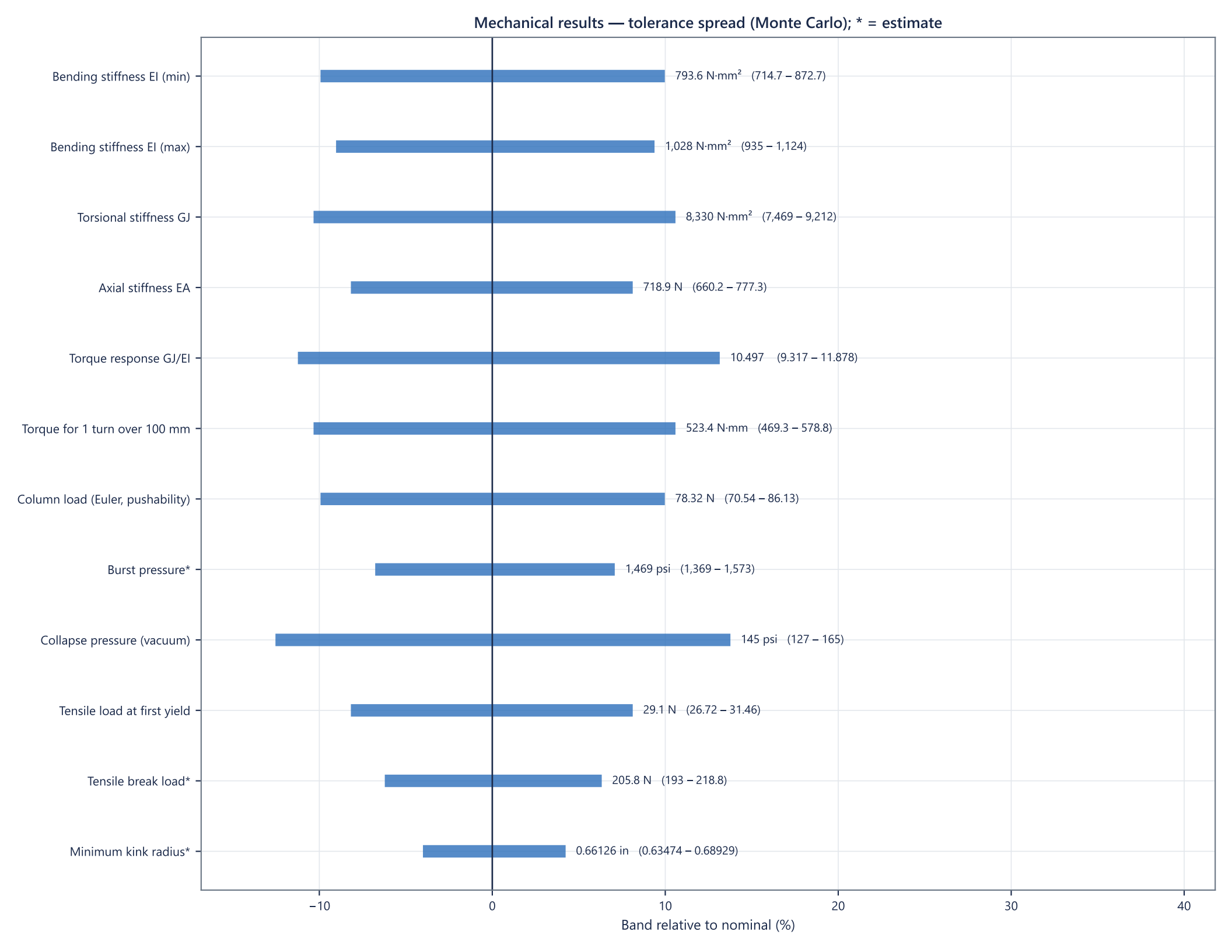
Layer	Dimension	Nominal	+Tol	−Tol	Distribution
Mandrel / core	Mandrel OD	0.11300	0.00050	0.00050	default
PTFE liner (etched)	Wall (radial)	0.00150	0.00030	0.00030	default
SS flat-wire braid	Wire thickness (radial)	0.00120	0.00010	0.00010	default
SS flat-wire braid	Wire width (OD-neutral)	0.00400	0.00030	0.00030	default
SS flat-wire braid	[option] shape	flat			
SS flat-wire braid	[option] stack	2			
SS flat-wire braid	[option] carriers	16			
SS flat-wire braid	[option] ppi	45.0			
SS flat-wire braid	[option] pattern	2-over-2			
Inner Pebax 63D	Pre-reflow tube ID	0.12400	0.00100	0.00100	default
Inner Pebax 63D	Pre-reflow tube OD	0.13200	0.00100	0.00100	default
Inner Pebax 63D	Interstice penetration (radial)	0.00030	0.00000	0.00000	default
Inner Pebax 63D	Min loading clearance (diametral)	0.00000	—	—	
Inner Pebax 63D	[option] check_fit	True			
Inner Pebax 63D	[option] model	global			
Pull-wire lumens (PI)	Radial gap to substrate (auto radius)	0.00000	0.00000	0.00000	default
Pull-wire lumens (PI)	[option] radius_mode	auto			
Pull-wire lumens (PI)	PW1 ID (lined)	0.00800	0.00050	0.00050	default
Pull-wire lumens (PI)	PW1 wall (lined)	0.00100	0.00020	0.00020	default
Pull-wire lumens (PI)	PW1 angle (lined)	0.00	0.00	0.00	default
Pull-wire lumens (PI)	PW2 ID (lined)	0.00800	0.00050	0.00050	default
Pull-wire lumens (PI)	PW2 wall (lined)	0.00100	0.00020	0.00020	default
Pull-wire lumens (PI)	PW2 angle (lined)	180.00	0.00	0.00	default
Outer Pebax 35D jacket	Pre-reflow tube ID	0.15100	0.00100	0.00100	default
Outer Pebax 35D jacket	Pre-reflow tube OD	0.17400	0.00100	0.00100	default
Outer Pebax 35D jacket	Interstice penetration (radial)	0.00030	0.00000	0.00000	default
Outer Pebax 35D jacket	Min loading clearance (diametral)	0.00000	—	—	
Outer Pebax 35D jacket	[option] check_fit	True			
Outer Pebax 35D jacket	[option] model	global			
FEP heat shrink	Expanded ID (as supplied)	0.18500	0.00200	0.00200	default
FEP heat shrink	Recovered ID (free)	0.13500	0.00200	0.00200	default
FEP heat shrink	Recovered wall (info)	0.00600	—	—	
FEP heat shrink	Required loading clearance (Ø)	0.00300	—	—	
FEP heat shrink	[option] min_ratio	1.2			

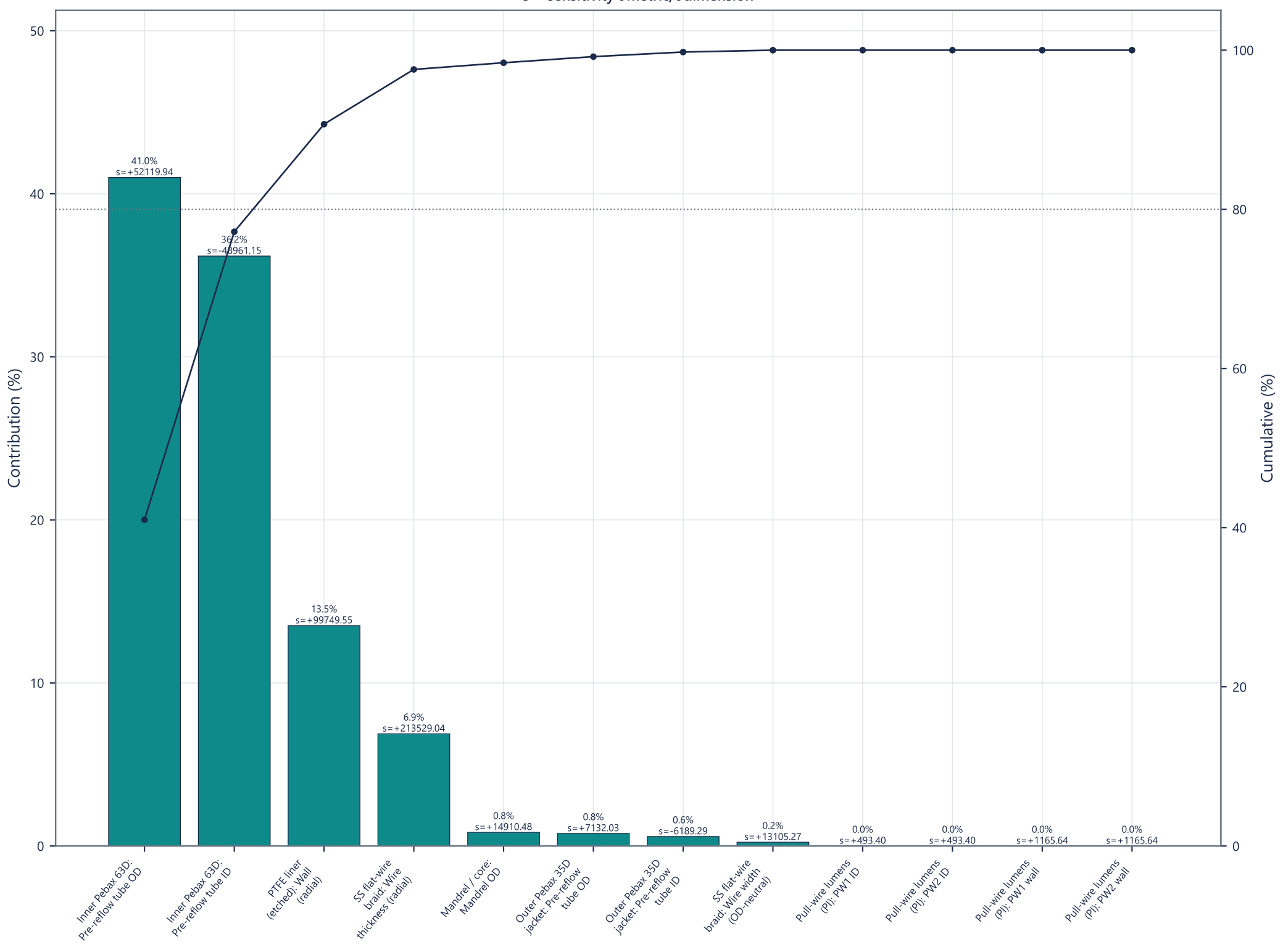
Mechanical performance

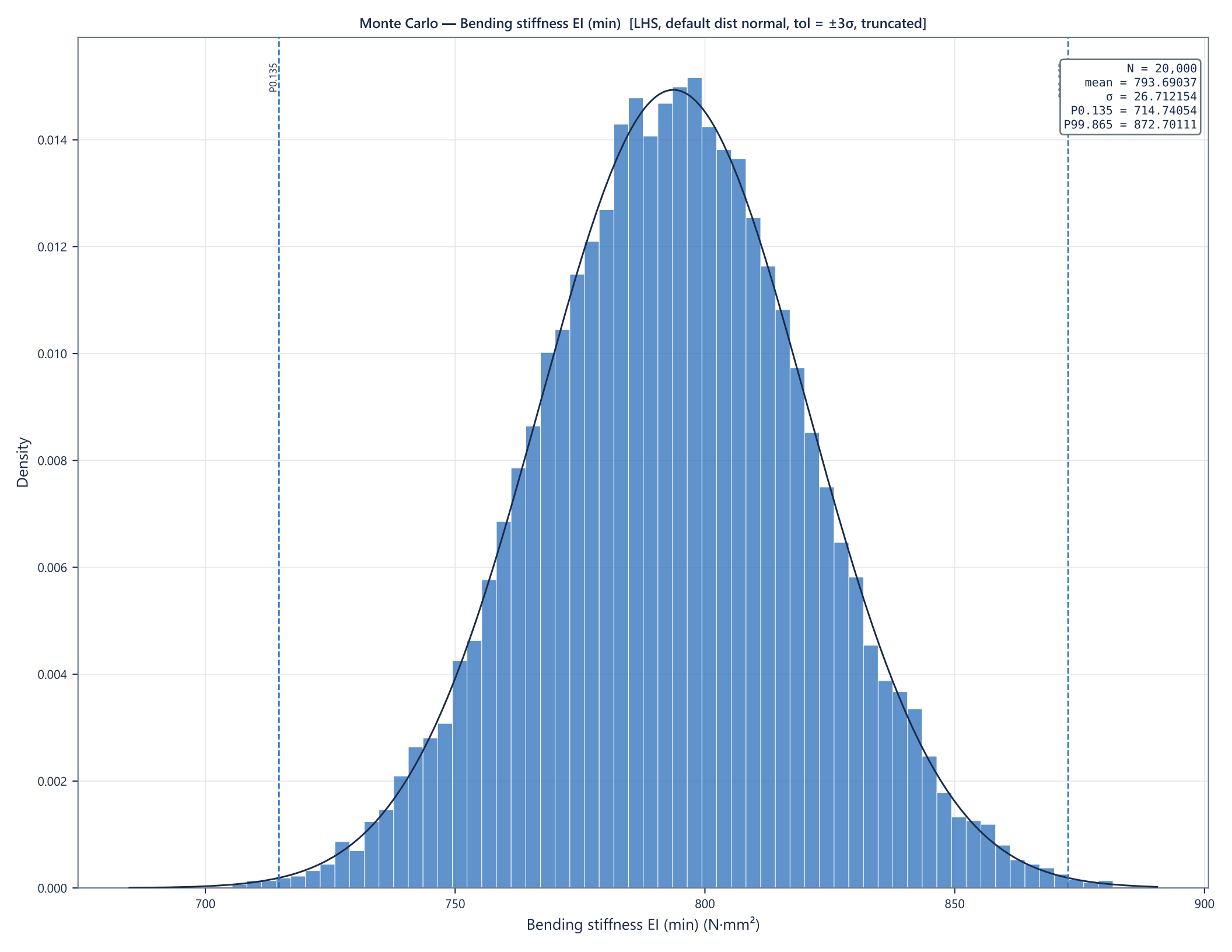
RESULTS (estimates marked in the label)

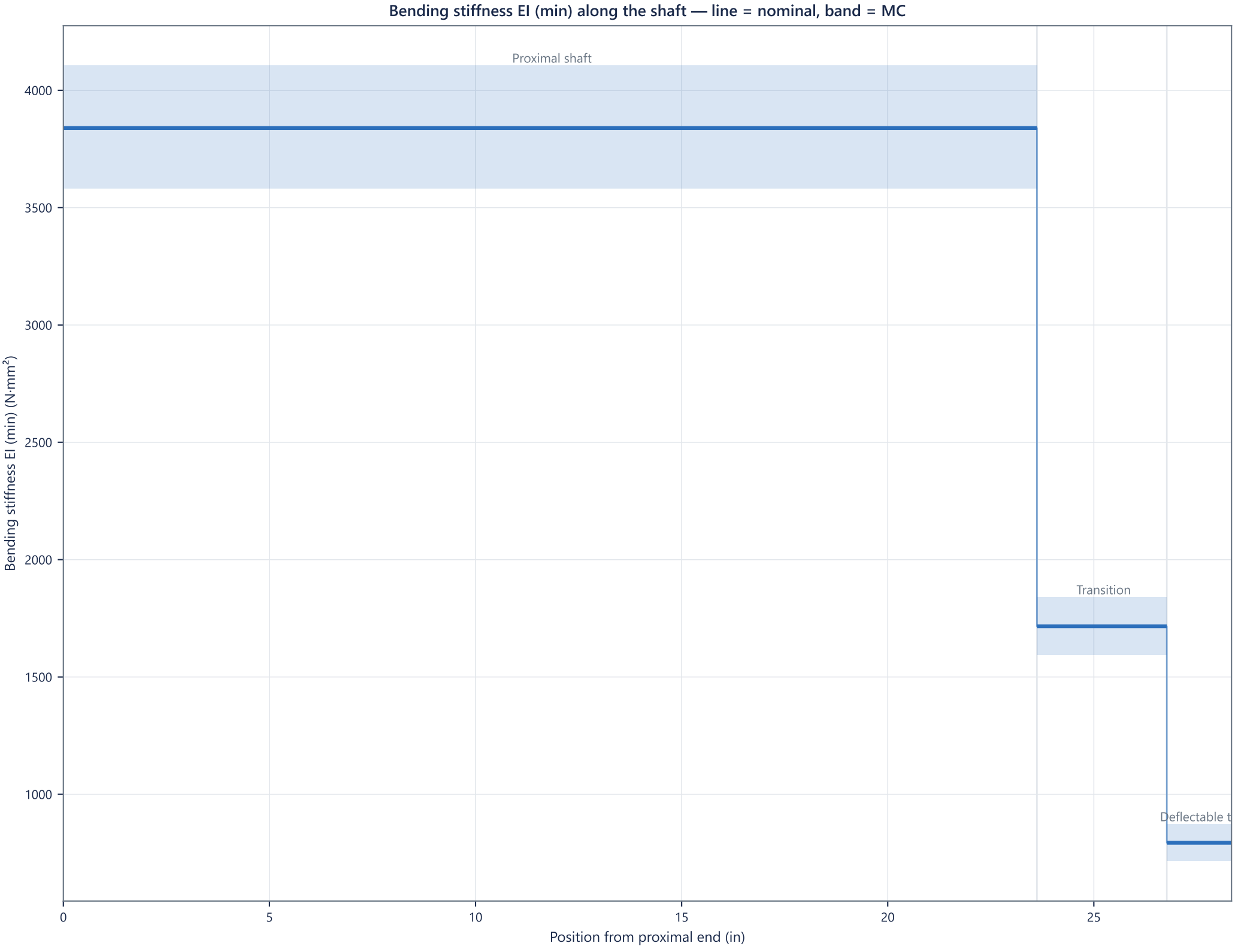
Result	Unit	Nominal	Worst-Case min	Worst-Case max	RSS (3 σ) min	RSS (3σ) max	Modified RSS min	Modified RSS max	Monte Carlo min	Monte Carlo max
Bending stiffness EI (min)	N·mm²	793.6	621.6	977.8	712.2	874.9	671.5	915.6	714.7	872.7
Bending stiffness EI (max)	N·mm²	1,028	783.3	1,300	932.2	1,123	884.4	1,171	935	1,124
Torsional stiffness GJ	N·mm²	8,330	6,903	9,910	7,432	9,229	6,982	9,678	7,469	9,212
Axial stiffness EA	N	718.9	576.5	865.3	658.7	779.2	628.5	809.3	660.2	777.3
Torque response GJ/EI		10.497	7.916	14.042	9.207	11.787	8.563	12.432	9.317	11.878
Torque for 1 turn over 100 mm	N·mm	523.4	433.7	622.7	466.9	579.8	438.7	608.1	469.3	578.8
Column load (Euler, pushability)	N	78.32	61.35	96.5	70.29	86.35	66.27	90.37	70.54	86.13
Burst pressure (estimate)	psi	1,469	1,237	1,704	1,363	1,574	1,311	1,627	1,369	1,573
Collapse pressure (vacuum)	psi	145	102	200	125	166	115	176	127	165
Tensile load at first yield	N	29.1	23.33	35.02	26.66	31.54	25.44	32.75	26.72	31.46
Tensile break load (estimate)	N	205.8	177.3	234.4	192.5	219.1	185.8	225.8	193	218.8
Minimum kink radius (estimate)	in	0.66126	0.59850	0.73651	0.63284	0.68967	0.61863	0.70388	0.63474	0.68929

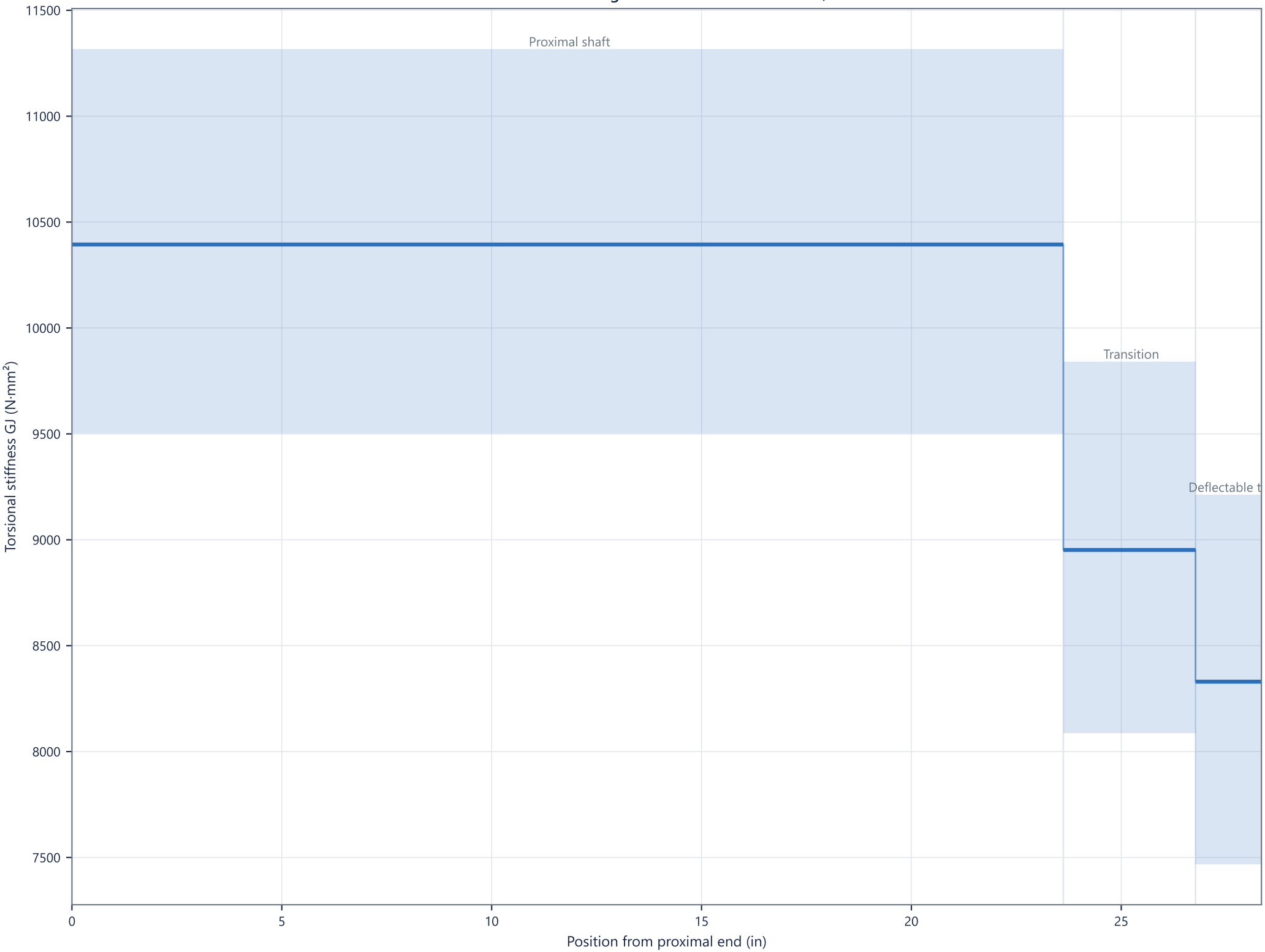
Closed-form models (laminate theory, Barlow + braid netting, ring buckling, Brazier) with typical material data; every value carries the band of the dimensional tolerances. Burst, kink and break are estimates: confirm by test.

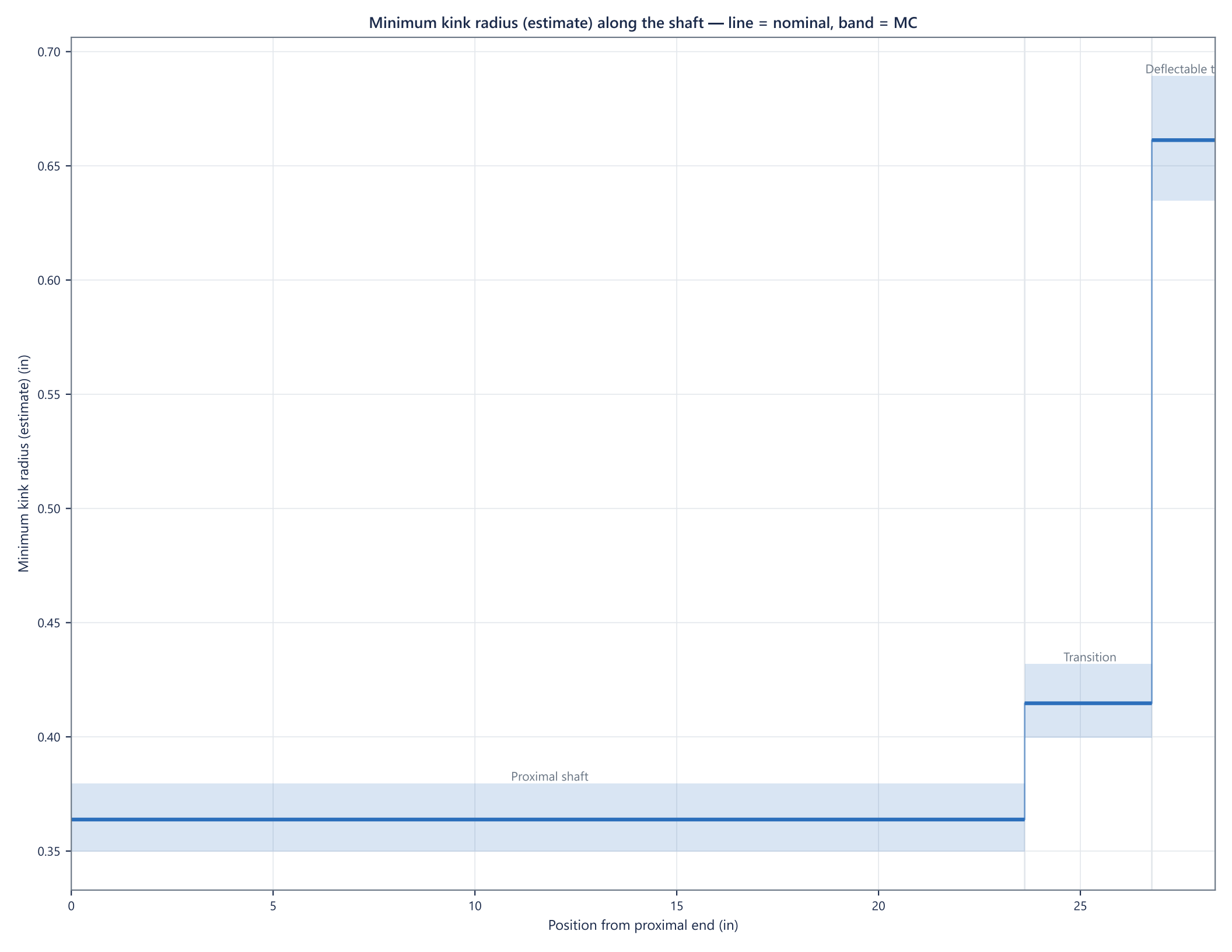

Mechanical results — tolerance spread (Monte Carlo); * = estimate
Bending stiffness EI (min)
793.6 N·mm² (714.7 – 872.7)
Bending stiffness EI (max)
1,028 N·mm² (935 – 1,124)
Torsional stiffness GJ
8,330 N·mm² (7,469 – 9,212)
Axial stiffness EA
718.9 N (660.2 – 777.3)
Torque response GJ/EI
10.497 (9.317 – 11.878)
Torque for 1 turn over 100 mm
523.4 N·mm (469.3 – 578.8)
Column load (Euler, pushability)
78.32 N (70.54 – 86.13)
Burst pressure*
1,469 psi (1,369 – 1,573)
Collapse pressure (vacuum)
145 psi (127 – 165)
Tensile load at first yield
29.1 N (26.72 – 31.46)
Tensile break load*
205.8 N (193 – 218.8)
Minimum kink radius*
0.66126 in (0.63474 – 0.68929)
−10
0
10
20
30
40
Band relative to nominal (%)


Contribution Pareto — Bending stiffness EI (min): variance share (RSS)
s = sensitivity ∂metric/∂dimension
Contribution (%)
Cumulative (%)
0
10
20
30
40
50
0
20
40
60
80
100
41.0%
s=+52119.94
36.2%
s=-46961.15
13.5%
s=+99749.55
6.9%
s=+213529.04
0.8%
s=+14910.48
0.8%
s=+7132.03
0.6%
s=-6189.29
0.2%
s=+13105.27
0.0%
s=+493.40
0.0%
s=+493.40
0.0%
s=+1165.64
0.0%
s=+1165.64
Inner Pebax 63D: Pre-reflow tube OD
Inner Pebax 63D: Pre-reflow tube ID
PTFE liner (etched): Wall (radial)
SS flat-wire braid: Wire thickness (radial)
Mandrel / core: Mandrel OD
Outer Pebax 35D jacket: Pre-reflow tube OD
Outer Pebax 35D jacket: Pre-reflow tube ID
SS flat-wire braid: Wire width (OD-neutral)
Pull-wire lumens (PI): PW1 ID
Pull-wire lumens (PI): PW2 ID
Pull-wire lumens (PI): PW1 wall
Pull-wire lumens (PI): PW2 wall


Monte Carlo — Bending stiffness EI (min) [LHS, default dist normal, tol = ±3σ, truncated]
N = 20,000
mean = 793.69037
σ = 26.712154
P0.135 = 714.74054
P99.865 = 872.70111
P0.135
Density
0.000
0.002
0.004
0.006
0.008
0.010
0.012
0.014
700
750
800
850
900
Bending stiffness EI (min) (N·mm²)


Bending stiffness EI (min) along the shaft — line = nominal, band = MC
Proximal shaft
Transition
Deflectable t
Bending stiffness EI (min) (N·mm²)
4000
3500
3000
2500
2000
1500
1000
0
5
10
15
20
25
Position from proximal end (in)


Torsional stiffness GJ along the shaft — line = nominal, band = MC
Proximal shaft
Transition
Deflectable t
Torsional stiffness GJ (N·mm²)
11500
11000
10500
10000
9500
9000
8500
8000
7500
0
5
10
15
20
25
Position from proximal end (in)


Minimum kink radius (estimate) along the shaft — line = nominal, band = MC
Minimum kink radius (estimate) (in)
0.70
0.65
0.60
0.55
0.50
0.45
0.40
0.35
Deflectable t
Transition
Proximal shaft
0
5
10
15
20
25
Position from proximal end (in)

Material data used

Layer	Material	E (MPa)	nu	Yield (MPa)	UTS (MPa)	Source
PTFE liner (etched)	PTFE (liner)	296.5	0.46	12	20	typical
SS flat-wire braid	Stainless steel 304V (spring)	196000	0.29	1931	2303	typical
Inner Pebax 63D	Pebax 63D	285	0.45	18	53	typical
Pull-wire lumens (PI)	Polyimide	2137	0.34	69	137.9	typical
Outer Pebax 35D jacket	Pebax 35D	21	0.48	4	39	typical
FEP heat shrink	FEP	480	0.48	12	21	typical