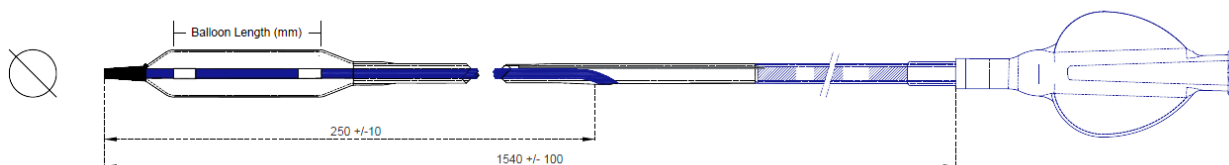


## Technical Specifications

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<p><b>Product description</b></p>	<p>The Force NC PTCA Balloon Dilatation Catheter, has a rapid exchange (Rx) catheter with a noncompliant balloon near the distal tip. The distal section of (Rx) catheters outer lumen is used for inflation of the balloon, and the inner lumen permits the use of guidewires <math>\leq 0.014</math> inch (0.36 mm) to facilitate advancement of the catheter to and through the stenosis or stent to be dilated. The proximal section of the catheter is a single-lumen, stainless steel Hypotube with a single luer port hub for inflation/deflation of the balloon. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. A balloon protector is placed over the balloon to maintain a low profile and an eyed stylet is placed into the inner lumen to protect the patency of the catheter. The catheter's tip is tapered to facilitate advancement of the catheter to and through the stenosis or stent. Distal section including balloon and tip is hydrophilic coated.</p>																																																																		
<p><b>Variants and ordering numbers</b></p>	<table border="1" style="width: 100%; text-align: center;"> <thead> <tr> <th colspan="2"></th> <th colspan="8">Diameter (mm)</th> </tr> <tr> <th colspan="2">L</th> <th>2.00</th> <th>2.50</th> <th>2.75</th> <th>3.00</th> <th>3.25</th> <th>3.50</th> <th>4.00</th> <th>4.50</th> </tr> </thead> <tbody> <tr> <th rowspan="5" style="writing-mode: vertical-rl; transform: rotate(180deg);">Length (mm)</th> <th>5</th> <td>XFOR2005</td> <td>XFOR2505</td> <td>XFOR2705</td> <td>XFOR3005</td> <td>XFOR3205</td> <td>XFOR3505</td> <td>XFOR4005</td> <td>XFOR4505</td> </tr> <tr> <th>10</th> <td>XFOR2010</td> <td>XFOR2510</td> <td>XFOR2710</td> <td>XFOR3010</td> <td>XFOR3210</td> <td>XFOR3510</td> <td>XFOR4010</td> <td>XFOR4510</td> </tr> <tr> <th>15</th> <td>XFOR2015</td> <td>XFOR2515</td> <td>XFOR2715</td> <td>XFOR3015</td> <td>XFOR3215</td> <td>XFOR3515</td> <td>XFOR4015</td> <td>XFOR4515</td> </tr> <tr> <th>20</th> <td>XFOR2020</td> <td>XFOR2520</td> <td>XFOR2720</td> <td>XFOR3020</td> <td>XFOR3220</td> <td>XFOR3520</td> <td>XFOR4020</td> <td>XFOR4520</td> </tr> <tr> <th>25</th> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p>ORDER NUMBER Description: XFOR DDLL (D=Diameter, L=Length)</p>			Diameter (mm)								L		2.00	2.50	2.75	3.00	3.25	3.50	4.00	4.50	Length (mm)	5	XFOR2005	XFOR2505	XFOR2705	XFOR3005	XFOR3205	XFOR3505	XFOR4005	XFOR4505	10	XFOR2010	XFOR2510	XFOR2710	XFOR3010	XFOR3210	XFOR3510	XFOR4010	XFOR4510	15	XFOR2015	XFOR2515	XFOR2715	XFOR3015	XFOR3215	XFOR3515	XFOR4015	XFOR4515	20	XFOR2020	XFOR2520	XFOR2720	XFOR3020	XFOR3220	XFOR3520	XFOR4020	XFOR4520	25								
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	25																																																																		
<p><b>Type of catheter</b></p>	<p>Rapid Exchange, guidewire exit at 250 mm from tip</p>																																																																		
<p><b>Balloon Nominal Pressure</b></p>	<p>12 bar</p>																																																																		
<p><b>Balloon Rated Burst Pressure</b></p>	<p><math>\varnothing</math> 2.00 - 3.00: 21 bar <math>\varnothing</math> 3.25 - 4.50: 19 bar</p>																																																																		
<p><b>Tensile strength</b></p>	<p>Force at break <math>\geq 5N</math></p>																																																																		
<p><b>Hub assembly</b></p>	<p>Proximal female luer lock connector. Design in accordance with ISO80369-1, ISO80369-7 and ISO80369-20</p>																																																																		

**Technical Specifications**

Compliance chart

**BALLOON CATHETER COMPLIANCE CHART**

Pressure (bar)	Ø2.00 (mm)	Ø2.50 (mm)	Ø2.75 (mm)	Ø3.00 (mm)	Ø3.25 (mm)	Ø3.50 (mm)	Ø4.00 (mm)	Ø4.50 (mm)
4	1.74	2.27	2.46	2.75	2.83	3.13	3.57	4.07
5	1.78	2.31	2.48	2.80	2.86	3.16	3.65	4.15
6	1.82	2.35	2.51	2.84	2.91	3.23	3.73	4.23
7	1.85	2.38	2.55	2.87	2.96	3.30	3.80	4.30
8	1.90	2.41	2.60	2.90	3.01	3.35	3.86	4.36
9	1.93	2.44	2.65	2.93	3.08	3.40	3.91	4.41
10	1.96	2.46	2.68	2.96	3.13	3.44	3.95	4.45
11	1.98	2.48	2.72	2.98	3.18	3.47	3.98	4.48
12 NP	2.00	2.50	2.75	3.00	3.25	3.50	4.00	4.50
13	2.03	2.52	2.77	3.02	3.27	3.52	4.03	4.53
14	2.06	2.54	2.79	3.04	3.30	3.55	4.06	4.56
15	2.09	2.56	2.82	3.06	3.33	3.58	4.08	4.58
16	2.11	2.58	2.84	3.08	3.37	3.60	4.11	4.61
17	2.14	2.60	2.86	3.11	3.41	3.63	4.14	4.64
18	2.16	2.62	2.89	3.13	3.44	3.66	4.17	4.67
19 RBP	2.18	2.64	2.91	3.15	3.48	3.68	4.20	4.70
20	2.21	2.66	2.93	3.18	3.50	3.71	4.23	4.73
21 RBP	2.24	2.69	2.96	3.20	3.54	3.74	4.26	4.76
22	2.27	2.71	2.99	3.23	3.58	3.77	4.32	4.82
23	2.30	2.74	3.02	3.25	3.61	3.81	4.35	4.85
24	2.33	2.76	3.05	3.30	3.64	3.85	4.39	4.89
25	2.36	2.79	3.08	3.34	3.68	3.89	4.45	4.95
26	2.40	2.82	3.11	3.38	3.71	3.95	4.51	5.01

1 bar = 100 kPa

NP: Nominal Pressure RBP: Rated Burst Pressure. Do not exceed

Compliance balloon	Compliance chart ± 10% at NP and RBP.
Balloon material	Non-compliant polyamide/polyetherblockamide
Placement of markers inside balloon	Two platinum/iridium balloon markers are positioned to indicate the working length of the balloon (outside edges of markers). Force NC with 5 mm length has only 1 marker.
Balloon folds	3 fold with heated balloon technology
Deflation time	<30 sec. Depending on balloon size.
Balloon Profile	Balloon profile distal: Ø 2.00 : ≤0.90 mm (0.035") Ø 2.50 : ≤0.95 mm (0.037") Ø 2.75 : ≤1.05 mm (0.041") Ø 3.00-3.25 : ≤1.10 mm (0.043") Ø 3.50 : ≤1.30 mm (0.051") Ø 4.00-4.50 : ≤1.45 mm (0.057")
Lesion entry profile	0.016" (0.40 mm)
Proximal Shaft	1.9F (0.64 mm) Hypo tube
Distal Shaft	2.7F (0.90 mm)
Tip	Tapered soft tip (3.5 mm ± 0.5)
Shaft coating	Hydrophilic coating
Balloon coating	Hydrophilic coating
Effective catheter length	154 cm
Guidewire compatibility	Maximum Ø 0,014" (0.36 mm)
Guiding catheter compatibility	Minimum inner diameter 5F (0.056"/1.42 mm) for all sizes
Markers on shaft	Markers on proximal shaft for relative positioning of the guiding catheter

## Technical Specifications

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	tip using brachial or femoral approach at 900 and 1000 mm from tip.
Hub	Proximal female luer lock connector
Shelf life	3 Year shelf life from sterilization date
Sterilization	EtO sterilization
Packaging	Peelable Tyvek pouch packaged in individual card-board boxes Compliance chart on pouch. Instructions for use in card-board box