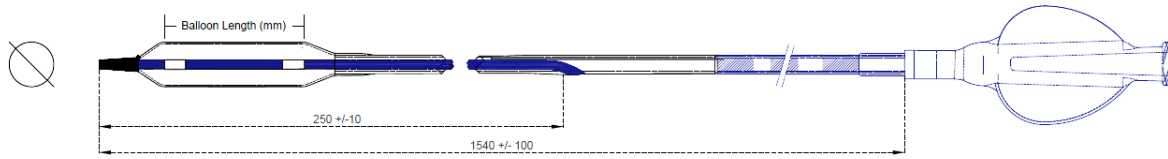


**Technical Specifications**



<p>Product description</p>	<p>The Everest PTCA balloon dilatation catheter, has a rapid exchange (Rx) catheter with a semi-compliant 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 stilet 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>Variants and ordering numbers</p>	<table border="1"> <thead> <tr> <th colspan="2"></th> <th colspan="6">Diameter (mm)</th> </tr> <tr> <th colspan="2"></th> <th>1.50</th> <th>2.00</th> <th>2.50</th> <th>3.00</th> <th>3.50</th> <th>4.00</th> </tr> </thead> <tbody> <tr> <th rowspan="5">Length (mm)</th> <th>10</th> <td>EVER1510</td> <td>EVER2010</td> <td>EVER2510</td> <td>EVER3010</td> <td>EVER3510</td> <td>EVER4010</td> </tr> <tr> <th>15</th> <td>EVER1515</td> <td>EVER2015</td> <td>EVER2515</td> <td>EVER3015</td> <td>EVER3515</td> <td>EVER4015</td> </tr> <tr> <th>20</th> <td>EVER1520</td> <td>EVER2020</td> <td>EVER2520</td> <td>EVER3020</td> <td>EVER3520</td> <td>EVER4020</td> </tr> <tr> <th>30</th> <td></td> <td></td> <td>EVER2530</td> <td>EVER3030</td> <td>EVER3530</td> <td>EVER4030</td> </tr> <tr> <th></th> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p>ORDER NUMBER Description: EVERDDL (D=Diameter, L=Length)</p>			Diameter (mm)								1.50	2.00	2.50	3.00	3.50	4.00	Length (mm)	10	EVER1510	EVER2010	EVER2510	EVER3010	EVER3510	EVER4010	15	EVER1515	EVER2015	EVER2515	EVER3015	EVER3515	EVER4015	20	EVER1520	EVER2020	EVER2520	EVER3020	EVER3520	EVER4020	30			EVER2530	EVER3030	EVER3530	EVER4030							
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<p>Type of catheter</p>	<p>Rapid Exchange, guide wire exit at 25 cm from tip</p>																																																				
<p>Balloon Nominal Pressure</p>	<p>6 bar</p>																																																				
<p>Balloon Rated Burst Pressure</p>	<p><math>\varnothing</math> 1.50 - 3.50: 16 bar <math>\varnothing</math> 4.00: 14 bar</p>																																																				
<p>Tensile strength</p>	<p>Force at break <math>\geq 5</math>N</p>																																																				
<p>Hub assembly</p>	<p>Proximal female luer lock connector Design in accordance with ISO80369-1, ISO80369-7 and ISO80369-20.</p>																																																				

Compliance chart	<p style="text-align: center;"><b>BALLOON CATHETER COMPLIANCE CHART</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Pressure (bar)*</th> <th>Ø 1.50 (mm)</th> <th>Ø 2.00 (mm)</th> <th>Ø 2.50 (mm)</th> <th>Ø 3.00 (mm)</th> <th>Ø 3.50 (mm)</th> <th>Ø 4.00 (mm)</th> </tr> </thead> <tbody> <tr><td>4</td><td>1.46</td><td>1.94</td><td>2.43</td><td>2.91</td><td>3.40</td><td>3.88</td></tr> <tr><td>5</td><td>1.48</td><td>1.97</td><td>2.46</td><td>2.95</td><td>3.44</td><td>3.93</td></tr> <tr><td>6 NP</td><td>1.50</td><td>2.00</td><td>2.50</td><td>3.00</td><td>3.50</td><td>4.00</td></tr> <tr><td>7</td><td>1.53</td><td>2.03</td><td>2.54</td><td>3.05</td><td>3.56</td><td>4.07</td></tr> <tr><td>8</td><td>1.55</td><td>2.06</td><td>2.58</td><td>3.09</td><td>3.61</td><td>4.12</td></tr> <tr><td>9</td><td>1.57</td><td>2.09</td><td>2.62</td><td>3.14</td><td>3.66</td><td>4.19</td></tr> <tr><td>10</td><td>1.59</td><td>2.12</td><td>2.65</td><td>3.18</td><td>3.71</td><td>4.24</td></tr> <tr><td>11</td><td>1.62</td><td>2.15</td><td>2.69</td><td>3.23</td><td>3.77</td><td>4.31</td></tr> <tr><td>12</td><td>1.64</td><td>2.19</td><td>2.73</td><td>3.28</td><td>3.83</td><td>4.37</td></tr> <tr><td>13</td><td>1.66</td><td>2.21</td><td>2.77</td><td>3.32</td><td>3.87</td><td>4.43</td></tr> <tr><td>14</td><td>1.69</td><td>2.25</td><td>2.81</td><td>3.37</td><td>3.93</td><td>4.49</td></tr> <tr><td>15</td><td>1.71</td><td>2.27</td><td>2.84</td><td>3.41</td><td>3.98</td><td>4.55</td></tr> <tr><td>16 RBP</td><td>1.73</td><td>2.31</td><td>2.88</td><td>3.46</td><td>4.04</td><td>4.61</td></tr> <tr><td>17</td><td>1.75</td><td>2.33</td><td>2.92</td><td>3.50</td><td>4.08</td><td>4.67</td></tr> <tr><td>18</td><td>1.78</td><td>2.37</td><td>2.96</td><td>3.55</td><td>4.14</td><td>4.73</td></tr> <tr><td>19</td><td>1.80</td><td>2.40</td><td>3.00</td><td>3.60</td><td>4.20</td><td>4.80</td></tr> <tr><td>20</td><td>1.83</td><td>2.43</td><td>3.04</td><td>3.65</td><td>4.26</td><td>4.87</td></tr> </tbody> </table> <p style="text-align: right; font-size: small;">* 1bar = 100 kPa</p> <p style="text-align: center; font-size: x-small;">NP: Nominal Pressure RBP: Rated Burst Pressure. Do not exceed</p>	Pressure (bar)*	Ø 1.50 (mm)	Ø 2.00 (mm)	Ø 2.50 (mm)	Ø 3.00 (mm)	Ø 3.50 (mm)	Ø 4.00 (mm)	4	1.46	1.94	2.43	2.91	3.40	3.88	5	1.48	1.97	2.46	2.95	3.44	3.93	6 NP	1.50	2.00	2.50	3.00	3.50	4.00	7	1.53	2.03	2.54	3.05	3.56	4.07	8	1.55	2.06	2.58	3.09	3.61	4.12	9	1.57	2.09	2.62	3.14	3.66	4.19	10	1.59	2.12	2.65	3.18	3.71	4.24	11	1.62	2.15	2.69	3.23	3.77	4.31	12	1.64	2.19	2.73	3.28	3.83	4.37	13	1.66	2.21	2.77	3.32	3.87	4.43	14	1.69	2.25	2.81	3.37	3.93	4.49	15	1.71	2.27	2.84	3.41	3.98	4.55	16 RBP	1.73	2.31	2.88	3.46	4.04	4.61	17	1.75	2.33	2.92	3.50	4.08	4.67	18	1.78	2.37	2.96	3.55	4.14	4.73	19	1.80	2.40	3.00	3.60	4.20	4.80	20	1.83	2.43	3.04	3.65	4.26	4.87
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Compliance balloon	Compliance chart ± 10% at NP and RBP.																																																																																																																														
Balloon material	Semi-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).																																																																																																																														
Balloon folds	Ø 1.50: 2 folds, Wingseal technology Ø 2.00 – 4.00: 3 folds, Wingseal technology																																																																																																																														
Deflation time	<30 sec. Depending on balloon size.																																																																																																																														
Balloon Profile	Balloon profile distal: Ø 1.50 : ≤ 0.85 mm (0.033") Ø 2.00 : ≤ 0.90 mm (0.035") Ø 2.50 : ≤ 1.00 mm (0.039") Ø 3.00 : ≤ 1.05 mm (0.041") Ø >3.00 : ≤ 1.10 mm (0.043")																																																																																																																														
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																																																																																																																														



# Technical Specifications

Markers on shaft	Markers on proximal shaft for relative positioning of the guiding catheter tip using brachial or femoral approach at 90 and 100 cm from tip.
Hub	Proximal female luer lock connector
Shelf life	3 Year shelf life from sterilization date
Sterilization	Gamma sterilization
Packaging	Peelable Tyvek pouch packaged in individual card-board boxes Compliance chart on pouch. Instructions for use in card-board box