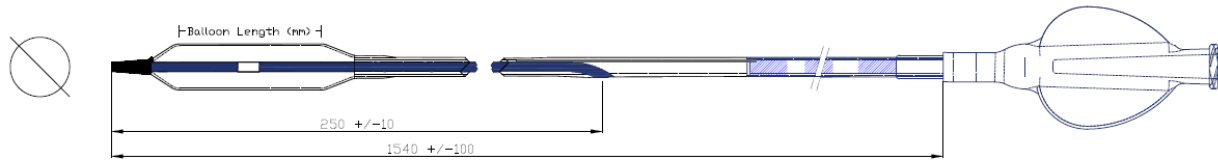


**Technical Specifications**



<p>Product description</p>	<p>The Summit CTO 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 a eyed stilet is placed into the inner lumen to protect the patency of the catheter. The catheter's tip is tapered to facilitate easy 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" style="background-color: #FFD700; text-align: center;"> <thead> <tr> <th colspan="2"></th> <th colspan="3">Diameter (mm)</th> </tr> <tr> <th colspan="2"></th> <th>1.10</th> <th>1.25</th> <th>1.50</th> </tr> <tr> <th rowspan="4" style="writing-mode: vertical-rl; transform: rotate(180deg);">Length (mm)</th> <th>L</th> <td></td> <td></td> <td></td> </tr> <tr> <th>10</th> <td>Sum1110</td> <td>Sum1210</td> <td>Sum1510</td> </tr> <tr> <th>15</th> <td>Sum1115</td> <td>Sum1215</td> <td>Sum1515</td> </tr> <tr> <th>20</th> <td>Sum1120</td> <td>Sum1220</td> <td>Sum1520</td> </tr> </thead> </table> <p>ORDER NUMBER Description: SUM DDLL (D=Diameter, L=Length)</p>			Diameter (mm)					1.10	1.25	1.50	Length (mm)	L				10	Sum1110	Sum1210	Sum1510	15	Sum1115	Sum1215	Sum1515	20	Sum1120	Sum1220	Sum1520
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	10	Sum1110	Sum1210	Sum1510																								
	15	Sum1115	Sum1215	Sum1515																								
	20	Sum1120	Sum1220	Sum1520																								
<p>Type of catheter</p>	<p>Rapid Exchange, guidewire exit at 250 mm from tip</p>																											
<p>Balloon Nominal Pressure</p>	<p>4 bar</p>																											
<p>Balloon Rated Burst Pressure</p>	<p><math>\varnothing</math> 1.10 – 1.50: 15 bar</p>																											
<p>Tensile strength</p>	<p>Force at break <math>\geq 5N</math></p>																											
<p>Hub assembly</p>	<p>Proximal female luer lock connector. Design in accordance with ISO80369-1, ISO80369-7 and ISO80369-20.</p>																											

**Technical Specifications**

Compliance chart	<div style="border: 1px solid black; padding: 10px;"> <p style="text-align: center; background-color: #FFD700; border-radius: 10px; margin-bottom: 10px;"><b>BALLOON CATHETER COMPLIANCE CHART</b></p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="padding: 5px;">Pressure (bar)*</th> <th style="padding: 5px;">Ø 1.1 (mm)</th> <th style="padding: 5px;">Ø 1.25 (mm)</th> <th style="padding: 5px;">Ø 1.5 (mm)</th> </tr> </thead> <tbody> <tr style="background-color: #FFD700;"><td style="padding: 2px 5px;">4 NP</td><td style="padding: 2px 5px;">1.10</td><td style="padding: 2px 5px;">1.25</td><td style="padding: 2px 5px;">1.50</td></tr> <tr><td style="padding: 2px 5px;">5</td><td style="padding: 2px 5px;">1.14</td><td style="padding: 2px 5px;">1.28</td><td style="padding: 2px 5px;">1.52</td></tr> <tr><td style="padding: 2px 5px;">6</td><td style="padding: 2px 5px;">1.18</td><td style="padding: 2px 5px;">1.33</td><td style="padding: 2px 5px;">1.57</td></tr> <tr><td style="padding: 2px 5px;">7</td><td style="padding: 2px 5px;">1.22</td><td style="padding: 2px 5px;">1.36</td><td style="padding: 2px 5px;">1.60</td></tr> <tr><td style="padding: 2px 5px;">8</td><td style="padding: 2px 5px;">1.27</td><td style="padding: 2px 5px;">1.40</td><td style="padding: 2px 5px;">1.63</td></tr> <tr><td style="padding: 2px 5px;">9</td><td style="padding: 2px 5px;">1.30</td><td style="padding: 2px 5px;">1.43</td><td style="padding: 2px 5px;">1.66</td></tr> <tr><td style="padding: 2px 5px;">10</td><td style="padding: 2px 5px;">1.33</td><td style="padding: 2px 5px;">1.46</td><td style="padding: 2px 5px;">1.68</td></tr> <tr><td style="padding: 2px 5px;">11</td><td style="padding: 2px 5px;">1.35</td><td style="padding: 2px 5px;">1.48</td><td style="padding: 2px 5px;">1.70</td></tr> <tr><td style="padding: 2px 5px;">12</td><td style="padding: 2px 5px;">1.37</td><td style="padding: 2px 5px;">1.50</td><td style="padding: 2px 5px;">1.72</td></tr> <tr><td style="padding: 2px 5px;">13</td><td style="padding: 2px 5px;">1.40</td><td style="padding: 2px 5px;">1.52</td><td style="padding: 2px 5px;">1.73</td></tr> <tr><td style="padding: 2px 5px;">14</td><td style="padding: 2px 5px;">1.42</td><td style="padding: 2px 5px;">1.54</td><td style="padding: 2px 5px;">1.75</td></tr> <tr style="background-color: #FFD700;"><td style="padding: 2px 5px;">15 RBP</td><td style="padding: 2px 5px;">1.45</td><td style="padding: 2px 5px;">1.56</td><td style="padding: 2px 5px;">1.77</td></tr> <tr><td style="padding: 2px 5px;">16</td><td style="padding: 2px 5px;">1.49</td><td style="padding: 2px 5px;">1.59</td><td style="padding: 2px 5px;">1.79</td></tr> <tr><td style="padding: 2px 5px;">17</td><td style="padding: 2px 5px;">1.53</td><td style="padding: 2px 5px;">1.62</td><td style="padding: 2px 5px;">1.81</td></tr> <tr><td style="padding: 2px 5px;">18</td><td style="padding: 2px 5px;">1.57</td><td style="padding: 2px 5px;">1.65</td><td style="padding: 2px 5px;">1.83</td></tr> <tr><td style="padding: 2px 5px;">19</td><td style="padding: 2px 5px;">1.61</td><td style="padding: 2px 5px;">1.68</td><td style="padding: 2px 5px;">1.85</td></tr> <tr><td style="padding: 2px 5px;">20</td><td style="padding: 2px 5px;">1.64</td><td style="padding: 2px 5px;">1.71</td><td style="padding: 2px 5px;">1.87</td></tr> </tbody> </table> <p style="font-size: small; margin-top: 10px;">NP: Nominal Pressure    RBP: Rated Burst Pressure. Do not exceed</p> <p style="font-size: x-small; margin-top: 5px;">*1 bar = 100kPa</p> </div>	Pressure (bar)*	Ø 1.1 (mm)	Ø 1.25 (mm)	Ø 1.5 (mm)	4 NP	1.10	1.25	1.50	5	1.14	1.28	1.52	6	1.18	1.33	1.57	7	1.22	1.36	1.60	8	1.27	1.40	1.63	9	1.30	1.43	1.66	10	1.33	1.46	1.68	11	1.35	1.48	1.70	12	1.37	1.50	1.72	13	1.40	1.52	1.73	14	1.42	1.54	1.75	15 RBP	1.45	1.56	1.77	16	1.49	1.59	1.79	17	1.53	1.62	1.81	18	1.57	1.65	1.83	19	1.61	1.68	1.85	20	1.64	1.71	1.87
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Compliance balloon	Compliance chart ± 10% at NP and RBP.																																																																								
Balloon material	Semi-compliant polyamide/polyetherblockamide																																																																								
Placement of markers inside balloon	One platinum/iridium balloon marker positioned in the middle of the balloon.																																																																								
Balloon folds	2 fold with heated balloon technology																																																																								
Deflation time	<15 sec. Depending on balloon size.																																																																								
Balloon Profile	Balloon profile distal: Ø 1.10 – 1.50 : ≤0.85 mm (0.033")																																																																								
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 tip using brachial or femoral approach at 900 and 1000 mm from tip.																																																																								



A Translumina Group Company

# Technical Specifications

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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