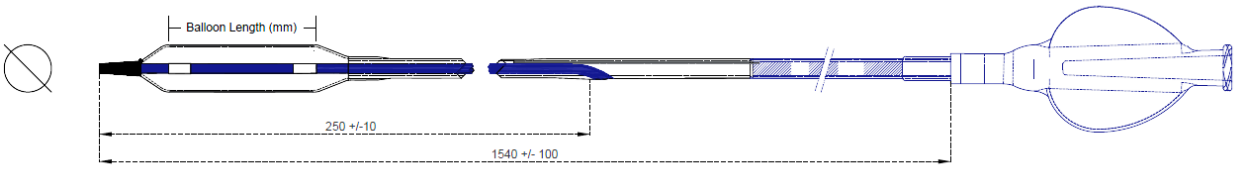
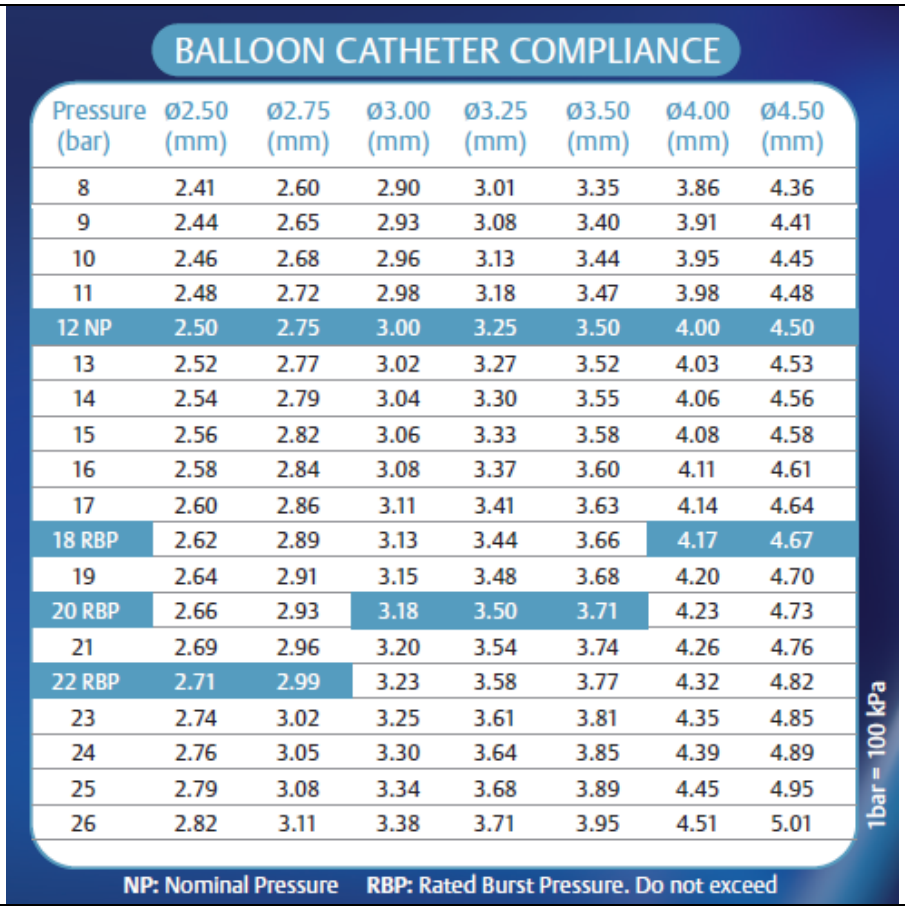
Technical Specifications



Product description	The Protégé NC DEB balloon catheter is a rapid exchange (Rx) catheter with a non-compliant and semi compliant balloon near the distal tip. The distal section of the (Rx) catheter's outer lumen is used for inflation of the balloon, and the inner lumen permits the use of guidewires ≤0.014 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, PTFE coated 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. During inflation, a controlled dosage of paclitaxel is delivered to the vessel wall. 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 a stenosis or stent. The shaft has a hydrophilic coating.
Variants and ordering numbers	PROTÉGÉ NC NON-COMPLIANT DEB

L \ Ø	2.50	2.75	3.00	3.25	3.50	4.00	4.50
10	PNC2510	PNC2710	PNC3010	PNC3210	PNC3510	PNC4010	PNC4510
15	PNC2515	PNC2715	PNC3015	PNC3215	PNC3515	PNC4015	PNC4515
20	PNC2520	PNC2720	PNC3020	PNC3220	PNC3520	PNC4020	PNC4520

Type of catheter	Rapid Exchange, guidewire exit at 250 mm from tip
Balloon Nominal Pressure	12 bar
Balloon Rated Burst Pressure	Ø 2.50 – 2.75: 22 bar Ø 3.00 – 3.50: 20 bar Ø 4.00 – 4.50: 18 bar
Tensile strength	Force at break ≥5N
Tip strength	Force at break ≥3N
Hub assembly	Proximal female luer lock connector. Design in accordance with ISO80369-1, ISO80369-7 and ISO80369-20

Compliance chart	

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).
Balloon folds	3 fold with heated balloon technology
Deflation time	<30 sec. Depending on balloon size.
Balloon Profile	Balloon profile distal: 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
Drug	Paclitaxel (3.0 µg/mm^2, Drug loaded balloon surface)
Effective catheter length	154 cm
Guidewire	Maximum Ø 0,014” (0.36 mm)

compatibility	
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.
Hub	Proximal female luer lock connector
Shelf life	18 Months 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