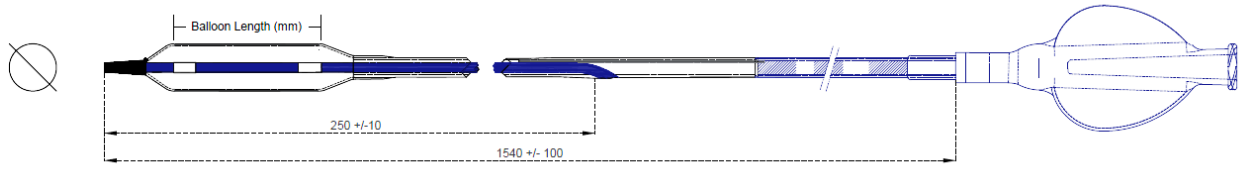
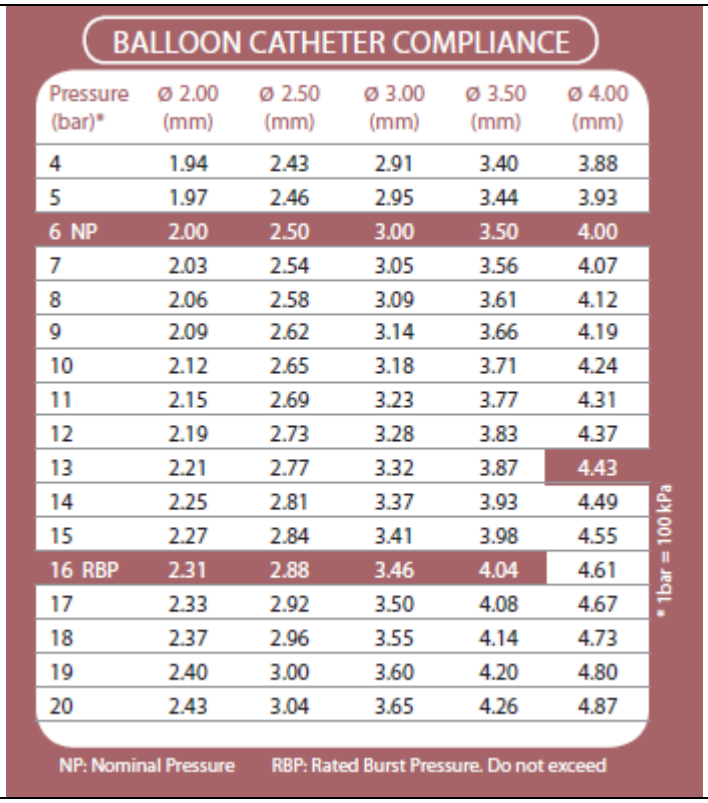


Product description	The Protégé DEB balloon catheter is a rapid exchange (Rx) catheter with a non-compliant and semi compliant balloon near the distal tip. The distal section of the (Rx) catheter's outer lumen is used for inflation of the balloon, and the inner lumen permits the use of guidewires ≤0.014 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 DEB CATHETER

L \ Ø	2.00	2.50	3.00	3.50	4.00
10	PRO2010	PRO2510	PRO3010	PRO3510	PRO4010
15	PRO2015	PRO2515	PRO3015	PRO3515	PRO4015
20	PRO2020	PRO2520	PRO3020	PRO3520	PRO4020
30	PRO2030	PRO2530	PRO3030	PRO3530	PRO4030

Type of catheter	Rapid Exchange, guidewire exit at 250 mm from tip
Balloon Nominal Pressure	6 bar
Balloon Rated Burst Pressure	Ø 2.00 - 3.50 :16 bar Ø 4.00 :13 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	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	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 : ≤1.00 mm (0.039”) Ø 3.00 : ≤1.05 mm (0.041”) Ø >3.00 : ≤1.20 mm (0.047”)
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 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.

BALLOON CATHETER COMPLIANCE

Pressure (bar)*	Ø 2.00 (mm)	Ø 2.50 (mm)	Ø 3.00 (mm)	Ø 3.50 (mm)	Ø 4.00 (mm)
4	1.94	2.43	2.91	3.40	3.88
5	1.97	2.46	2.95	3.44	3.93
6 NP	2.00	2.50	3.00	3.50	4.00
7	2.03	2.54	3.05	3.56	4.07
8	2.06	2.58	3.09	3.61	4.12
9	2.09	2.62	3.14	3.66	4.19
10	2.12	2.65	3.18	3.71	4.24
11	2.15	2.69	3.23	3.77	4.31
12	2.19	2.73	3.28	3.83	4.37
13	2.21	2.77	3.32	3.87	4.43
14	2.25	2.81	3.37	3.93	4.49
15	2.27	2.84	3.41	3.98	4.55
16 RBP	2.31	2.88	3.46	4.04	4.61
17	2.33	2.92	3.50	4.08	4.67
18	2.37	2.96	3.55	4.14	4.73
19	2.40	3.00	3.60	4.20	4.80
20	2.43	3.04	3.65	4.26	4.87

* 1bar = 100 kPa

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

Hub	Proximal female luer lock connector
Shelf life	18 Months 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