

		250 +/-10
		1540 +/- 100
Ρ	roduct 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

	catheter with a non-compliant and semi compliant balloon near the distal tip. The distal section of the (Rx) catheter's outer lumen is use							sused	
	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 an eyed stylet is placed into the inner lumen to protect the patency								d an	
				ncement					
catheter to and through a stenosis or stent. The shaft has a							has a hyd	Irophilic	
Variants and	coating.								
ordering numbers									
	L Q	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	essure Ø 3.00 – 3.50:20 bar Ø 4.00 – 4.50:18 bar								
-									
	nsile strength Force at break ≥5N								
	p strength Force at break ≥3N ub assembly Proximal female luer lock connector.								
Hub assembly						20260-7 -	and ISO8	0360-20	
	Design in accordance with ISO80369-1, ISO80369-7 and ISO80369-20								

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-	DN-COMP				1

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Compliance chart									
Compliance chart		BALL	.00N (CATHE	TER CO	OMPLIA	NCE		
	Pressure		Ø2.75	Ø3.00	Ø3.25	Ø3.50	Ø4.00	Ø4.50	
	(bar)	(mm)	(mm)	(mm)	(mm)	(mm)	(mm)	(mm)	
	8	2.41	2.60	2.90	3.01	3.35	3.86	4.36	
	9	2.44	2.65	2.93	3.08	3.40	3.91	4.41	
	10	2.46	2.68	2.96	3.13	3.44	3.95	4.45	
	11	2.48	2.72	2.98	3.18	3.47	3.98	4.48	
	12 NP	2.50	2.75	3.00	3.25	3.50	4.00	4.50	
	13	2.52 2.54	2.77	3.02	3.27	3.52	4.03	4.53 4.56	
			2.79	3.04	3.30	3.55	4.06		
	15	2.56	2.82 2.84	3.06	3.33	3.58	4.08	4.58 4.61	
	17	2.50	2.84	3.11	3.41	3.63	4.14	4.64	
	18 RBP	2.60	2.89	3.13	3.41	3.65	4.14	4.64	
	19	2.64	2.05	3.15	3.44	3.68	4.20	4.70	
	20 RBP	2.66	2.93	3.18	3.50	3.71	4.23	4.73	
	20 10	2.69	2.96	3.20	3.54	3.74	4.26	4.76	
	22 RBP	2.71	2.99	3.23	3.58	3.77	4.32	4.82	
	23	2.74	3.02	3.25	3.61	3.81	4.35	4.85	S.
	24	2.76	3.05	3.30	3.64	3.85	4.39	4.89	1bar = 100 kPa
	25	2.79	3.08	3.34	3.68	3.89	4.45	4.95	L.
	26	2.82	3.11	3.38	3.71	3.95	4.51	5.01	1pa
			l Pressure			Pressure. D	o not exc	eed	
Compliance balloon	Compliance								
Balloon material	Non-compliant polyamide/polyetherblockamide								
Placement of	Two platinu	ım/iridiu	im ballo	on mark	ers are	position			ne
markers inside		ım/iridiu	im ballo	on mark	ers are	position			le
markers inside balloon	Two platinu working ler	im/iridiungth of t	im ballo he ballo	on mark on (outs	ters are side edg	position			le
markers inside balloon Balloon folds	Two platinu working ler 3 fold with	im/iridiungth of the stress of	im ballo he ballo balloon	on mark on (outs technol	ers are side edg	position			10
markers inside balloon Balloon folds Deflation time	Two platinu working ler 3 fold with <30 sec. D	im/iridiungth of t heated ependir	im ballo he ballo balloon ng on ba	on mark on (outs technol	ers are side edg	position			10
markers inside balloon Balloon folds	Two platinu working ler 3 fold with <30 sec. D Balloon pro	im/iridiungth of t heated ependir	im ballo he ballo <u>balloon</u> ng on ba al:	on mark on (outs technol lloon si	ters are side edg ogy ze.	position			ne
markers inside balloon Balloon folds Deflation time	Two platinu working ler 3 fold with <30 sec. D Balloon pro Ø 2.50	im/iridiu ngth of t heated ependir file dist ∶≤0	im ballo he ballo balloon ng on ba al: 0.95 mm	technol Iloon siz	ers are side edg ogy ze.	position			ne
markers inside balloon Balloon folds Deflation time	Two platinu working ler 3 fold with <30 sec. D Balloon pro Ø 2.50 Ø 2.75	$\frac{\text{Im/iridiu}}{\text{heated}}$ $\frac{\text{heated}}{\text{ependir}}$ $\frac{\text{ofile dist}}{\text{ist}} \leq 0$ $\frac{1}{\text{ist}} \leq 1$	im ballo he ballo balloon ng on ba al: .95 mm .05 mm	on mark on (outs technol lloon si (0.037" (0.041"	ers are side edg ogy ze.)	position			
markers inside balloon Balloon folds Deflation time	Two platinu working ler 3 fold with <30 sec. D Balloon pro Ø 2.50 Ø 2.75 Ø 3.00 - 3.1	im/iridiu ngth of t <u>heated</u> ependir ofile dist : ≤0 : ≤1 25 : ≤1	im ballo he ballo balloon ing on ba al: .05 mm .10 mm	on mark on (outs technol illoon siz (0.037" (0.041" (0.043"	ers are side edg ogy ze.))	position			
markers inside balloon Balloon folds Deflation time	Two platinu working ler 3 fold with <30 sec. D Balloon pro Ø 2.50 Ø 2.75 Ø 3.00 - 3.5 Ø 3.50	im/iridiu ngth of t <u>heated</u> ependir ofile dist : ≤0 : ≤1 25 : ≤1 : ≤1	im ballo he ballo balloon ig on ba al: .95 mm .05 mm .10 mm .30 mm	on mark on (outs technol lloon si: (0.037" (0.041" (0.043" (0.051"	ers are side edg ogy ze.)))	position			
markers inside balloon Balloon folds Deflation time	Two platinu working ler 3 fold with <30 sec. D Balloon pro Ø 2.50 Ø 2.75 Ø 3.00 - 3.1	im/iridiu ngth of t <u>heated</u> ependir ofile dist : ≤0 : ≤1 25 : ≤1 : ≤1	im ballo he ballo balloon ig on ba al: .95 mm .05 mm .10 mm .30 mm	on mark on (outs technol lloon si: (0.037" (0.041" (0.043" (0.051"	ers are side edg ogy ze.)))	position			
markers inside balloon Balloon folds Deflation time Balloon Profile	Two platinu working ler <u>3 fold with</u> <30 sec. D Balloon pro Ø 2.50 Ø 2.75 Ø 3.00 - 3.1 Ø 3.50 Ø 4.00 - 4.1	im/iridiu ngth of t <u>heated</u> ependir file dist : ≤1 25 : ≤1 : ≤1 50 : ≤1	im ballo he ballo balloon ig on ba al: .95 mm .05 mm .10 mm .30 mm	on mark on (outs technol lloon si: (0.037" (0.041" (0.043" (0.051"	ers are side edg ogy ze.)))	position			
markers inside balloon Balloon folds Deflation time	Two platinu working ler <u>3 fold with</u> < <u>30 sec. D</u> Balloon pro Ø 2.50 Ø 2.75 Ø 3.00 - 3.2 Ø 3.50 Ø 4.00 - 4.2 0.016" (0.4	im/iridiu ngth of t <u>heated</u> ependir ofile dist : ≤1 25 : ≤1 : ≤1 50 : ≤1 0 mm)	im ballo he ballo balloon ig on ba al: .95 mm .05 mm .10 mm .30 mm .45 mm	on mark on (outs technol lloon si: (0.037" (0.041" (0.043" (0.051" (0.057"	ers are side edg ogy ze.)))	position			
markers inside balloon Balloon folds Deflation time Balloon Profile Lesion entry profile	Two platinu working ler <u>3 fold with</u> <30 sec. D Balloon pro Ø 2.50 Ø 2.75 Ø 3.00 - 3.1 Ø 3.50 Ø 4.00 - 4.1	im/iridiu ngth of t <u>heated</u> ependir ofile dist : ≤1 25 : ≤1 50 : ≤1 0 mm) Hy	im ballo he ballo balloon ig on ba al: .95 mm .05 mm .10 mm .30 mm .45 mm	on mark on (outs technol lloon si: (0.037" (0.041" (0.043" (0.051" (0.057"	ers are side edg ogy ze.)))	position			
markers inside balloon Balloon folds Deflation time Balloon Profile Lesion entry profile Proximal Shaft	Two platinu working ler <u>3 fold with</u> < <u>30 sec. D</u> Balloon pro Ø 2.50 Ø 2.75 Ø 3.00 - 3.1 Ø 3.50 Ø 4.00 - 4.1 0.016" (0.4 1.9F (0.64	$\begin{array}{c} \text{Im/iridiu}\\ \text{ingth of t}\\ \hline \\ \text{ependir}\\ \text{ependir}\\ \text{ifile dist}\\ & : \leq 1\\ \hline \\ 25 & : \leq 1\\ \hline \\ 50 & : \leq 1\\ \hline \\ \hline \\ \hline \\ 0 \text{ mm}) \text{ Hy}\\ \hline \\ \hline \\ \hline \end{array}$	im ballo he ballo balloon ng on ba al: .05 mm .10 mm .30 mm .45 mm	on mark on (outs technol lloon siz (0.041" (0.043" (0.057"	ers are side edg ogy ze.)))	position			
markers inside balloon Balloon folds Deflation time Balloon Profile Lesion entry profile Proximal Shaft Distal Shaft	Two platinu working ler 3 fold with <30 sec. D Balloon pro Ø 2.50 Ø 2.75 Ø 3.00 - 3.3 Ø 3.50 Ø 4.00 - 4.3 0.016" (0.4 1.9F (0.64 2.7F (0.90	im/iridiu ngth of t <u>heated</u> ependir ofile dist : ≤1 25 : ≤1 : ≤1 50 : ≤1 0 mm) <u>mm) Hy</u> mm) ft tip (3	im ballo he ballo balloon ng on ba al: .95 mm .05 mm .10 mm .30 mm .45 mm .45 mm	on mark on (outs technol lloon siz (0.041" (0.043" (0.057"	ers are side edg ogy ze.)))	position			
markers inside balloon Balloon folds Deflation time Balloon Profile Lesion entry profile Proximal Shaft Distal Shaft Tip	Two platinu working ler 3 fold with <30 sec. D Balloon pro Ø 2.50 Ø 2.75 Ø 3.00 - 3.5 Ø 3.50 Ø 4.00 - 4.5 0.016" (0.4 1.9F (0.64 2.7F (0.90 Tapered so Hydrophilio Hydrophilio	$\frac{\text{Im}/\text{iridiu}}{\text{lngth of t}}$ $\frac{\text{heated}}{\text{ependir}}$ $\frac{\text{ependir}}{\text{if edist}}$ $\frac{\text{s} \leq 0}{\text{if } \leq 1}$ $\frac{25 \text{s} \leq 1}{\text{50} \text{s} \leq 1}$ $\frac{0 \text{ mm}}{\text{mm}}$ $\frac{\text{mm}}{\text{ft tip } (3)}$ $\frac{\text{s coating}}{\text{s coating}}$	im ballo he ballo balloon ig on ba al: .95 mm .05 mm .10 mm .30 mm .45 mm .45 mm <u>po tube</u>	on mark on (outs technol lloon siz (0.037" (0.041" (0.043" (0.051" (0.057"	ers are side edg ogy ze.))))	position les of m	arkers).		
markers inside balloon Balloon folds Deflation time Balloon Profile Lesion entry profile Proximal Shaft Distal Shaft Tip Shaft coating Balloon coating Drug	Two platinu working ler 3 fold with <30 sec. D Balloon pro Ø 2.50 Ø 2.75 Ø 3.00 - 3.5 Ø 3.50 Ø 4.00 - 4.5 0.016" (0.4 1.9F (0.64 2.7F (0.90 Tapered so Hydrophilio	$\frac{\text{Im}/\text{iridiu}}{\text{lngth of t}}$ $\frac{\text{heated}}{\text{ependir}}$ $\frac{\text{ependir}}{\text{if edist}}$ $\frac{\text{s} \leq 0}{\text{if } \leq 1}$ $\frac{25 \text{s} \leq 1}{\text{50} \text{s} \leq 1}$ $\frac{0 \text{ mm}}{\text{mm}}$ $\frac{\text{mm}}{\text{ft tip } (3)}$ $\frac{\text{s coating}}{\text{s coating}}$	im ballo he ballo balloon ig on ba al: .95 mm .05 mm .10 mm .30 mm .45 mm .45 mm <u>po tube</u>	on mark on (outs technol lloon siz (0.037" (0.041" (0.043" (0.051" (0.057"	ers are side edg ogy ze.))))	position les of m	arkers).		
markers inside balloon Balloon folds Deflation time Balloon Profile Lesion entry profile Proximal Shaft Distal Shaft Tip Shaft coating Balloon coating Drug Effective catheter	Two platinu working ler 3 fold with <30 sec. D Balloon pro Ø 2.50 Ø 2.75 Ø 3.00 - 3.5 Ø 3.50 Ø 4.00 - 4.5 0.016" (0.4 1.9F (0.64 2.7F (0.90 Tapered so Hydrophilio Hydrophilio	$\frac{\text{Im}/\text{iridiu}}{\text{lngth of t}}$ $\frac{\text{heated}}{\text{ependir}}$ $\frac{\text{ependir}}{\text{if edist}}$ $\frac{\text{s} \leq 0}{\text{if } \leq 1}$ $\frac{25 \text{s} \leq 1}{\text{50} \text{s} \leq 1}$ $\frac{0 \text{ mm}}{\text{mm}}$ $\frac{\text{mm}}{\text{ft tip } (3)}$ $\frac{\text{s coating}}{\text{s coating}}$	im ballo he ballo balloon ig on ba al: .95 mm .05 mm .10 mm .30 mm .45 mm .45 mm <u>po tube</u>	on mark on (outs technol lloon siz (0.037" (0.041" (0.043" (0.051" (0.057"	ers are side edg ogy ze.))))	position les of m	arkers).		
markers inside balloon Balloon folds Deflation time Balloon Profile Lesion entry profile Proximal Shaft Distal Shaft Tip Shaft coating Balloon coating Drug	Two platinu working ler 3 fold with <30 sec. D Balloon pro Ø 2.50 Ø 2.75 Ø 3.00 - 3.3 Ø 3.50 Ø 4.00 - 4.3 0.016" (0.4 1.9F (0.64 2.7F (0.90 Tapered so Hydrophilic Paclitaxel ($\frac{\text{Im}/\text{iridiu}}{\text{lngth of t}}$ $\frac{\text{heated}}{\text{ependir}}$ $\frac{\text{of ile dist}}{\text{i } \leq 0}$ $\frac{1}{25} \leq 1$ $\frac{25}{50} \leq 1$ $\frac{0 \text{ mm}}{\text{mm}}$ $\frac{1}{\text{mm}} (3)$ $\frac{1}{3} = \frac{1}{20}$	im ballo he ballo balloon ig on ba al: .95 mm .05 mm .10 mm .30 mm .45 mm .45 mm <u>po tube</u> .5 mm <u>+</u> .5 mm <u>+</u> .0 .5 mm <u>+</u> .0	on mark on (outs technol lloon si: (0.037" (0.041" (0.043" (0.051" (0.057" 0.5) ug load	ers are side edg ogy ze.))))	position les of m	arkers).		

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PROTÉGÉ NC NON-COMPLIANT DEB

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Technical Specifications

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compatibility	
Guiding catheter	Minimum inner diameter 5F (0.056"/1.42 mm) for all sizes
compatibility	
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