

BLUEMEDICAL



PROTÉGÉ

DEB CATHETER

PROTÉGÉ NC

NON-COMPLIANT DEB

Expand your
therapy options

PROTÉGÉ
DEB CATHETER

PROTÉGÉ NC
NON-COMPLIANT DEB

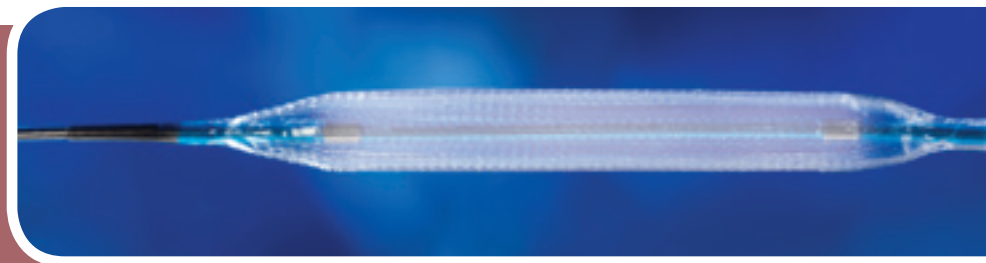
Drug eluting balloon catheter

Only innovations based on scientific evidence create the level of confidence required to transfer optimal treatment methods to higher quality of life.

Blue Medical has developed a drug eluting balloon that opens a window of opportunities with regard to treating coronary diseases. Supported by independent scientific evidence, we offer a safe, effective and reliable tool to further enhance patient care with accurate local drug delivery.



With Protégé NC, the non compliant DEB, safe and reproducible drug delivery is now combined with the proven treatment advantages of a high pressure, non compliant balloon.



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S A F E A N D R E

Safe and reproducible drug delivery

- Drug incorporated in hydrophilic coating
- No airborne particles at any time and no premature release of Paclitaxel
- Paclitaxel is only released when the balloon touches the vessel wall
- Hydrophilic coating delivers Paclitaxel homogeneous to the vessel wall instantaneously upon contact
- Paclitaxel is rapidly and maximally absorbed by the vessel wall
- Minimized drug content in contact with operator
- Minimized drug loss in bloodstream prior to inflation securing reliable drug dose delivery
- Load secured to achieve the therapeutic window within 30 seconds inflation time

Wing Seal Technology

- Drug component encapsulated in wings using Wing Seal Technology
- Wings remain closed prior to inflation: no balloon-wing flaring preserving drug load within the wings
- Prevents premature Paclitaxel release during handling
- Ensures tight balloon wrapping for reduced crossing profile

Fast and complete re-endothelialization

- Hydrophilic coating delivers Paclitaxel without any negative side effects or inflammation
- Vessel healing not interrupted and stable within days after procedure
- Re-endothelialization starts within days after procedure

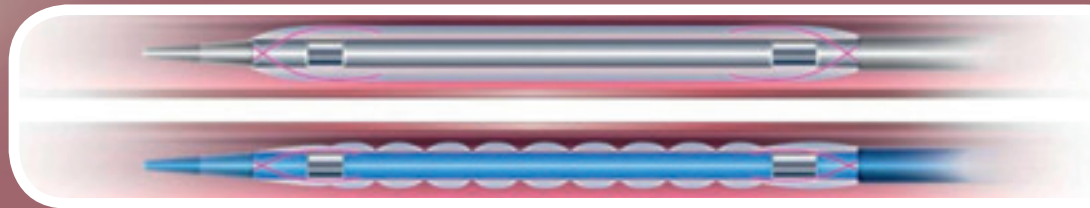
PRODUCIBLE DRUG DELIVERY

No procedural limitations

- No change in standard operating procedures or handling required
- No pre-dilatation required: tight lesion crossing does not influence drug delivery
- Multiple inflations will not lead to toxic levels
- Therapeutic window achieved after 30 seconds inflation time
- Flexibility and characteristics of a normal workhorse PTCA balloon

Proven balloon platform

- Based on Blue Medical's proven high-end PTCA catheters Everest and Force
- Incorporated latest insights on re-folding and re-wrap interactions
- Technology optimized to reach and cross the most difficult lesions
- Optimal pushability and trackability due to balanced proximal and distal shaft transitions
- Low profile wig shaped design tip-to-balloon transition for smoother crossing results



PROTÉGÉ NC

NON-COMPLIANT DEB

DRUG DELIVERY NOW COMBINED

Non compliant PTCA balloons are commonly used to post-dilate stents or to treat in stent restenosis (ISR). With the introduction of Drug Eluting Balloons medication was added to PTCA balloon treatment. But the need for precise and powerful dilatation remained.

With Protégé NC we succeeded in combining safe and reproducible drug delivery with the proven treatment advantages of a non compliant balloon. Thus reducing procedural costs and post procedural medication requirements and at the same time increasing procedure efficiency, safety and patients comfort. In addition to these advantages the catheter performance, profile and flexibility of a normal workhorse PTCA balloon is maintained, making the device easy to work with.

WITH PRECISE POWERFUL DILATATION

High rated burst pressure

- Rated burst pressure 24 bar, nominal pressure 12 bar
- Providing an extensive and safe working range

Real non compliant

- No longitudinal growth for controlled expansion, even at high pressures
- No balloon deformations up to rated burst pressure for precise stent apposition
- No dog boning between nominal and rated burst pressure
- Precise compliance ensuring exact and protected sizing

No compromise on flexibility and profile

- Optimized materials and design for unsurpassed flexibility and low profiles
- Ease of use equal to high performance workhorse catheters



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

PROTÉGÉ

DEB CATHETER



TECHNICAL DATA Protégé DEB

Nominal Pressure:	6 bar
Rated Burst Pressure:	16 bar (except Ø 4.00=13 bar)
Balloon material:	Semi-compliant polyamide
Folding:	3-folds; Wing-Seal Technology
Drug:	Paclitaxel (3.0 µg/mm ² , Drug loaded balloon surface)
Guiding catheter compatibility:	5F (min ID 0.056"/1.42 mm) 6F Kissing Technology
Guide wire compatibility:	max 0.014" (0.36 mm)
Catheter type:	Rapid Exchange
Proximal shaft:	1.9F (0.64 mm)
Distal shaft:	2.6F (0.86 mm)
Lesion entry profile:	0.016" (0.40 mm)
Usable Catheter Length:	154 cm
Average deflation time:	3 seconds (Ø 3.0, L: 20)
Tapered tip:	3 mm
Catheter coating:	Hydrophilic coating

For additional details please refer to our website www.blumedical.com.

BALLOON CATHETER COMPLIANCE

Pressure (bar)	Ø2.50 (mm)	Ø2.75 (mm)	Ø3.00 (mm)	Ø3.25 (mm)	Ø3.50 (mm)	Ø4.00 (mm)	Ø4.50 (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	2.77	3.02	3.27	3.52	4.03	4.53
14	2.54	2.79	3.04	3.30	3.55	4.06	4.56
15	2.56	2.82	3.06	3.33	3.58	4.08*	4.58*
16	2.58	2.84	3.08	3.37	3.60	4.11	4.61
17	2.60	2.86	3.11	3.41	3.63	4.14	4.64
18 RBP	2.62	2.89	3.13	3.44	3.66	4.17	4.67
19	2.64	2.91	3.15*	3.48*	3.68*	4.20	4.70
20	2.66	2.93	3.18	3.50	3.71	4.23	4.73
21	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
24 RBP	2.76	3.05	3.30	3.64	3.85	4.39	4.89
25	2.79	3.08	3.34	3.68	3.89	4.45	4.95
26	2.82	3.11	3.38	3.71	3.95	4.51	5.01

1 bar = 100 kPa

NP: Nominal Pressure **RBP:** Rated Burst Pressure. Do not exceed
* Max. recommended inflation pressure

PROTÉGÉ NC

NON-COMPLIANT DEB



TECHNICAL DATA

Protégé non compliant DEB

Nominal Pressure:	12 bar
Rated Burst Pressure:	Ø 2.50 - 2.75 =24 bar Ø 3.00 - 3.50 =22 bar Ø 4.00 - 4.50 =18 bar
Balloon material:	Non-compliant polyamide
Folding:	3-folds; Wing-Seal Technology
Drug:	Paclitaxel (3.0 µg/mm ² , Drug loaded balloon surface)
Guiding catheter compatibility:	5F (min ID 0.056"/1.42 mm)
Guide wire compatibility:	max 0.014" (0.36 mm)
Catheter type:	Rapid Exchange
Proximal shaft:	1.9F (0.64 mm)
Distal shaft:	2.7F (0.90 mm)
Lesion entry profile:	0.016" (0.40 mm)
Usable Catheter Length:	154 cm
Average deflation time:	4 seconds (Ø 3.0, L: 20)
Tapered tip:	3 mm
Catheter coating:	Hydrophilic coating

For additional details please refer to our website www.blumedical.com.

ORDER NUMBERS

Diameter (mm)

Length (mm)

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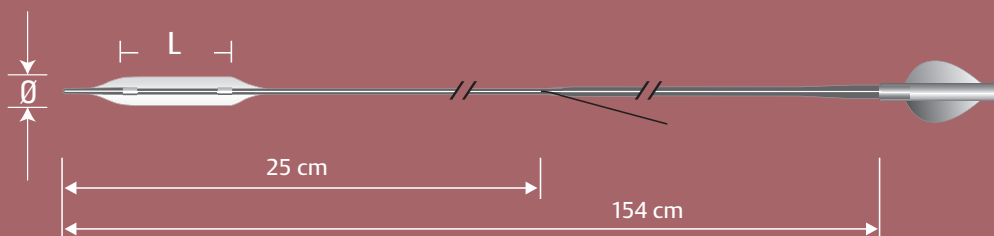
L \ Ø	2.00	2.50	3.00	3.50	4.00
10	PRO2010	PRO2510	PRO3010	PRO3510	PRO4010
15	PRO2015	PRO2515	PRO3015	PRO3515	PRO4015
20	PRO2020	PRO2520	PRO3020	PRO3520	PRO4020
30	PRO2030	PRO2530	PRO3030	PRO3530	PRO4030

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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

Order number description: PNC DDLL / PRO DDLL (D=Diameter, L=Length)



BLUEMEDICAL

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Indications, contraindications, warnings and instruction for use can be found in the product labeling.
 CAUTION: restricted to sale by or on the order of a physician

PRO9.0001.04 02/2015