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PROTÉGÉ

DEB CATHETER

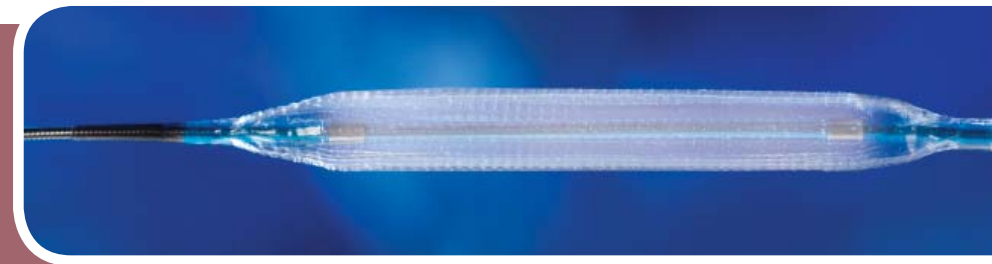
P r o t e c t w h a t i s v a l u e a b l e

PROTÉGÉ
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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 in the best possible manner. Supported by independent scientific evidence, we offer a safe, effective and reliable tool to further enhance patient care with accurate transient Local Drug Delivery.



RELIABLE TRANSIENT LOCAL DRUG DELIVERY WITH STATE OF THE ART CATHETER PERFORMANCE

Paclitaxel on Drug Eluting Balloon: Safe and Effective

- Load secured to achieve therapeutic window within 30 seconds inflation time.
- Paclitaxel is only active in the vessel wall for 3-5 days following delivery.
- Re-endothelialization starts within days after procedure.
- Vessel healing not interrupted and stable within days following procedure.

Balloon Drug Delivery Redefined

- Hydrophilic coating delivers Paclitaxel without any negative side-effects or inflammation.
- Drug component enclosed in folded balloon wings with Wing-Seal Technology.
- Fully stable Hydrophilic coating preventing any bio-chemical reactions.
- No coating or particles released or left behind at any time during use.
- Load optimized to 3 $\mu\text{g}/\text{mm}^2$ drug loaded balloon surface.
- Hydrophilic coating delivers Paclitaxel instantaneous to the vessel wall on contact.
- Homogeneous distribution of Paclitaxel to vessel tissue on contact.
- No increased late-thrombus risks.
- Reliable drug delivery with drug dose accuracy.

Safety for operator and patient

- Drug incorporated in hydrophilic coating and wings, no accidental release or airborne drug.
- Minimized drug content in contact with operator.
- Minimized drug loss in bloodstream prior to inflation.

Ease of use for effective treatment

- No procedural changes required.
- Therapeutic window achieved after 30 seconds inflation time.
- Up to 120 seconds inflation will not lead to toxic levels.
- Multiple inflations will not lead to toxic levels.
- Tight lesion crossing does not influence drug delivery, pre-dilatation not required.
- Full 6F Kissing Technology compatibility.
- Enhanced state of the art Drug Eluting Balloon treatment.

Drug Eluting Balloon with all desired Workhorse Standards

- Superior rewrap incorporated the latest insights on re-folding and rewrap interactions.
- Optimal pushability and trackability due to balanced proximal and distal shaft transitions.
- Full hydrophilic coating, tip to distal shaft, including the folded balloon.
- Clinically required atraumatic tip.
- Low profile Wig Shape Design "tip to balloon" transition for smoother crossing results.

Wing-Seal Technology

- Tight balloon wrapping for reduced crossing profile.
- A smooth profile transition.
- No balloon-wing flaring preserving drug load within the wings.



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

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

* 1bar = 100 kPa

TECHNICAL DATA

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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:	2.4F (0.80 mm)
Lesion entry profile:	0.016" (0.40 mm)
Usable Catheter Length:	154 cm
Deflation time:	3 seconds (Ø 3.0, L: 20)
Tapered tip:	3 mm
Catheter coating:	Hydrophilic coating
Shelf life:	3 Years from sterilization date

For the latest updates and additional technology details, refer to "DEB Technology Brochure" and our website, www.blumedical.com.

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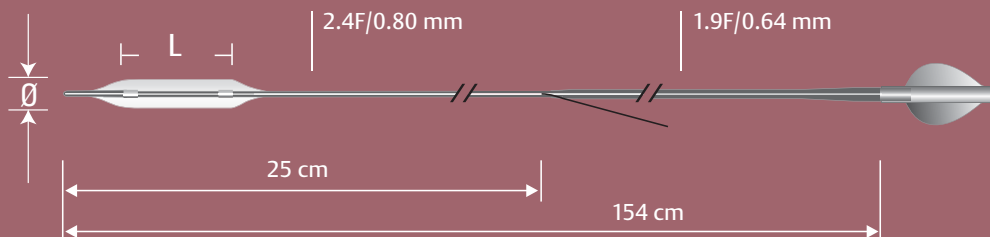
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ORDER NUMBERS

Diameter (mm)

Length (mm)	L \ Ø	Diameter (mm)				
		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

ORDER NUMBER Description: PRODDL (D=Diameter, L=Length)

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PRO9.0001.01 05/2010