

BLUEMEDICAL



PIONEER

CoCr STENT ON DEB

Science Based Evolutions lead
to Revolutionary Solutions



Combine the best of both worlds

A next step in cardiovascular treatment should consist of increasing treatment effectiveness while reducing risk and medication requirements. This has led to the obvious solution of a CoCr stent on an drug eluting balloon.

Picking up where DES and BMS left of, Pioneer ensures the best of both worlds in one, setting a new standard in treating coronary disease.

Entering the next phase in coronary intervention

Reduced late lumen loss normally associated with drug eluting stents is now combined with the **ease of use and proven safety** of bare metal stents represented in:

- Fast and complete re-endothelialization
- No increased risk of late thrombus
- No long term dual anti-platelet therapy





COMBINE THE BEST OF BOTH

Increased treatment effectiveness, reduced risk and medication requirements

- 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
- No increased late thrombus risk
- No pre-dilatation required, direct stenting does not influence drug delivery
- Anti platelet therapy can be reduced to BMS standards

Safe and reproducible drug delivery

- Drug incorporated in hydrophilic coating, no accidental release or airborne drug particles
- Drug component encapsulated using unique Wing-Seal Technology
- Minimized drug content in contact with operator
- Minimized drug loss in bloodstream prior to inflation securing reliable drug dose delivery
- Hydrophilic coating delivers Paclitaxel to the vessel wall instantaneously upon contact
- Homogeneous distribution of Paclitaxel to vessel tissue in contact
- Load secured to achieve the therapeutic window within 30 seconds inflation time



WORLDS: CoCr STENT ON DEB

Proven stent technology ensures easy deliverability and use

- Pioneer delivery system based on the proven CoCr stent of the Track family
- Stent technology optimized to reach and cross the most difficult lesions
- Low profile atraumatic tip: lesion entry profile 0.016" (0.40mm)
- Wig shaped transition from tip to balloon for smoother crossing
- Hydrophilic coated balloon cushions embedding stent struts reducing entry friction and profile
- Superior push, track, re-wrap and re-fold
- Unsurpassed stent retention guarantees safety and delivery success
- Precise balloon to stent length fitting ensures no balloon overhang
- 5F guiding catheter compatible

The recognized and appreciated proven characteristics of the Track CoCr stent are all maintained in the Pioneer. The stent's extreme flexibility provided an unsurpassed ability to reach through challenging anatomy and to conform to the vessel without straightening the artery.

Image: Stent



10 - 28 mm
2.50 - 4.00 Diameter

CoCr Coronary Stent COMPLIANCE CHART

Pressure (bar)*	Ø 2.50 (mm)	Ø 2.75 (mm)	Ø 3.00 (mm)	Ø 3.25 (mm)	Ø 3.50 (mm)	Ø 4.00 (mm)
5	2.17	2.45	2.66	2.88	3.10	3.60
6	2.23	2.49	2.71	2.94	3.17	3.67
7	2.28	2.54	2.77	3.01	3.24	3.74
8	2.34	2.59	2.82	3.07	3.31	3.81
9	2.40	2.65	2.88	3.13	3.38	3.88
10	2.45	2.70	2.94	3.19	3.45	3.94
11 ^{NP}	2.50	2.75	3.00	3.25	3.50	4.00
12	2.53	2.81	3.05	3.32	3.58	4.06
13	2.56	2.86	3.10	3.37	3.64	4.12
14	2.61	2.91	3.16	3.43	3.70	4.18
15	2.65	2.96	3.20	3.48	3.75	4.23
16	2.69	3.01	3.25	3.53	3.80	4.28
17	2.72	3.06	3.29	3.57	3.85	4.33
18 ^{RBP}	2.76	3.11	3.34	3.62	3.90	4.38
19	2.80	3.15	3.38	3.67	3.95	4.44
20	2.83	3.19	3.42	3.71	4.00	4.49
21	2.87	3.24	3.46	3.76	4.06	4.55
22	2.91	3.29	3.51	3.82	4.12	4.62

* 1bar = 100 kPa

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

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CoCr STENT ON DEB

TECHNICAL DATA



Stent

Stent material:	F562 Cobalt Chromium
Strut thickness:	0.0035" (0.088 mm)
Strut width:	0.0034" (0.086 mm)
Maximum expansion diameter:	4.7 mm
Metal to artery ratio:	~14%
Average recoil:	Low <4%
Average foreshortening:	Minimal <2.5%
Crush resistance:	High; 0.15N/ mm
Radiopacity:	High
Stent flexibility:	Very high

Delivery system

Nominal Pressure:	11 bar
Rated Burst Pressure:	18 bar (except Ø 4.0 = 15 bar)
Balloon material:	Semi-compliant polyamide
Balloon folds:	3-folds; Wing-Seal Technology
Drug	Paclitaxel (3.0 µg/mm ² , Drug loaded balloon surface)
Balloon overhang:	Minimal
Average deflation time:	3 seconds (Ø 3.0)
Guiding catheter compatibility:	5F (min ID 0.056")
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)
Tip:	Short, thin and soft 3 mm tip
Lesion entry profile:	0.016" (0.40 mm)
Average crossing profile:	1.0 – 1.1 mm (0.039" - 0.043")
Catheter coating:	Hydrophilic coating
Usable catheter length:	154 cm

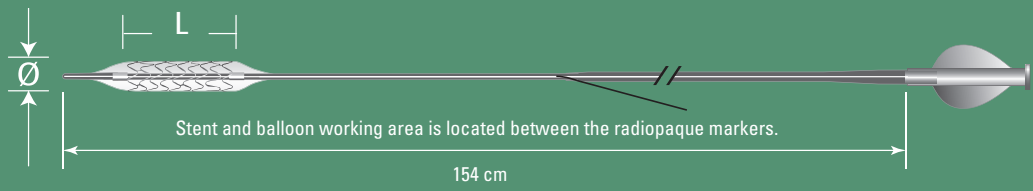
For additional details please refer to our website www.blumedical.com.



ORDER NUMBERS

		Diameter (mm)					
Length (mm)	L / \varnothing	2.50	2.75	3.00	3.25	3.50	4.00
	10	PIO2510	PIO2710	PIO3010	PIO3210	PIO3510	PIO4010
	14	PIO2514	PIO2714	PIO3014	PIO3214	PIO3514	PIO4014
	18	PIO2518	PIO2718	PIO3018	PIO3218	PIO3518	PIO4018
	22	PIO2522	PIO2722	PIO3022	PIO3222	PIO3522	PIO4022
	28	PIO2528	PIO2728	PIO3028	PIO3228	PIO3528	PIO4028

Order number description: PIO DDLL (D=Diameter, L=Length)



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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