

IN.PACT FALCON

Technical specifications

Catheter design	Rapid Exchange (RX)	
Balloon material	FLEXITEC™ HF	
Balloon coating	FreePac™ - Paclitaxel eluting formulation	
Balloon marker	1 or 2 swaged (zero profile) Platinum Iridium	
Shaft diameter	proximal	2.0F
	distal	2.5F
Usable shaft length	145 cm	
Guidewire compatibility	0.014"	

1 French (F) = 0.333 mm - 1 inch (") = 25.4 mm = 2.54 cm - 1 cm = 10 mm

Under continuous product development program, Invatec reserves the right to modify specifications without prior notice.

DRUG ELUTING BALLOON



keywords
1609

IN.PACT FALCON

Paclitaxel-eluting
PTCA balloon catheter

DRUG ELUTING BALLOON



A short-term therapy
for long-term success
in coronary
interventions

Order information

Ref N°	Balloon diameter (mm)	Balloon length (mm)	OTW / RX	Usable shaft length (cm)	N° of markers
FLC P20 014 B12	2.00	14	RX	145	2
FLC P20 020 B12	2.00	20	RX	145	2
FLC P20 030 B12	2.00	30	RX	145	2
FLC P22 014 B12	2.25	14	RX	145	2
FLC P22 020 B12	2.25	20	RX	145	2
FLC P22 030 B12	2.25	30	RX	145	2
FLC P25 014 B12	2.50	14	RX	145	2
FLC P25 020 B12	2.50	20	RX	145	2
FLC P25 030 B12	2.50	30	RX	145	2
FLC P25 040 B12	2.50	40	RX	145	2
FLC P27 014 B12	2.75	14	RX	145	2
FLC P27 020 B12	2.75	20	RX	145	2
FLC P27 030 B12	2.75	30	RX	145	2
FLC P30 014 B12	3.00	14	RX	145	2
FLC P30 020 B12	3.00	20	RX	145	2
FLC P30 030 B12	3.00	30	RX	145	2
FLC P30 040 B12	3.00	40	RX	145	2
FLC P32 014 B12	3.25	14	RX	145	2
FLC P32 020 B12	3.25	20	RX	145	2
FLC P32 030 B12	3.25	30	RX	145	2
FLC P35 014 B12	3.50	14	RX	145	2
FLC P35 020 B12	3.50	20	RX	145	2
FLC P35 030 B12	3.50	30	RX	145	2
FLC P35 040 B12	3.50	40	RX	145	2
FLC P37 014 B12	3.75	14	RX	145	2
FLC P37 020 B12	3.75	20	RX	145	2
FLC P37 030 B12	3.75	30	RX	145	2
FLC P40 014 B12	4.00	14	RX	145	2
FLC P40 020 B12	4.00	20	RX	145	2

Compliance Chart

Pressure (bar)	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00
5	1.90	2.15	2.40	2.65	2.90	3.15	3.40	3.65	3.90
6	1.95	2.20	2.45	2.70	2.95	3.20	3.45	3.70	3.95
7(nominal)	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00
8	2.02	2.27	2.52	2.78	3.03	3.28	3.54	3.80	4.05
9	2.04	2.29	2.54	2.82	3.07	3.32	3.58	3.85	4.10
10	2.06	2.31	2.57	2.86	3.11	3.36	3.62	3.90	4.15
11	2.08	2.34	2.60	2.90	3.15	3.40	3.66	3.95	4.20
12	2.11	2.37	2.63	2.94	3.19	3.45	3.70	4.00	4.25
13	2.14	2.40	2.67	2.98	3.23	3.50	3.75	4.05	4.30
14	2.17	2.43	2.71	3.02	3.27	3.55	3.80	4.10	4.35
15	2.20	2.46	2.75	3.06	3.31	3.60	3.85	4.15	4.40
16	2.23	2.50	2.80						
17	2.26								

in vitro results do not exceed RBP

Sales partner

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Innovative Technologie

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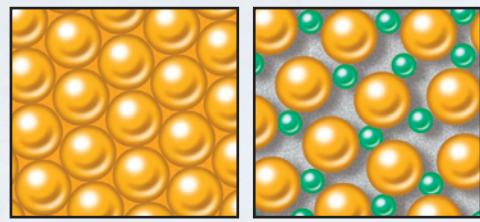
We make ideas come alive

0170313-6

IN.PACT FALCON

IN.PACT Falcon performance: The solution for instent restenosis, small vessels and de novo lesions

Short-term drug elution - preserve your acute result



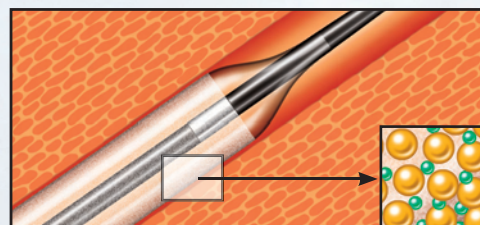
Paclitaxel

Paclitaxel / separator molecule

FreePac™

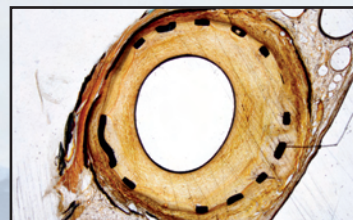
Proprietary hydrophilic coating formulation

- separates Paclitaxel molecules
- balances hydrophilic and lipophilic properties
- facilitates Paclitaxel elution into the vessel wall

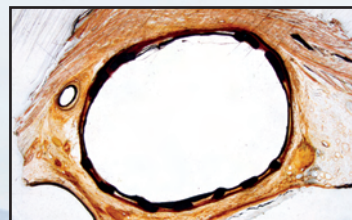


Local drug elution in seconds

- FreePac reduces the total drug elution time to 30 – 60 seconds



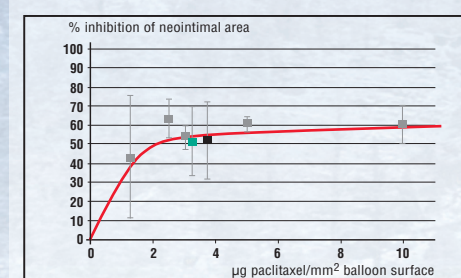
Control, no paclitaxel, cross section through porcine artery treated with conventional uncoated balloon; massive neointimal proliferation resulting in significant lumen narrowing 4 weeks after angioplasty.



Same animal study, porcine artery treated with a FreePac coated balloon catheter; thin layer of neointima and almost pristine, open lumen 4 weeks after angioplasty.

Tested Bio-equivalence

Pre-clinical studies have shown the bio-equivalence of the new FreePac coating to the Ac/Matrix coating that has been used in several pre-clinical and clinical trials.¹⁻⁷



Randomized porcine study comparing FreePac™ (green) and Ac/Matrix (black) – coating with uncoated control and pooled results (grey) out of three published studies¹⁻³ testing different paclitaxel dosages; areas normalized versus controls; mean ± standard deviation.

Low dose effectiveness - High safety margin

Several trials⁴⁻⁷ have confirmed:

- A low dosage of 3µg per mm² balloon surface and immediate release of paclitaxel result in effective treatment outcomes
- No adverse events or additional effects detected at higher dosages
- Conclusion: IN.PACT Falcon meets the criteria for a wide therapeutic window with a high safety margin

1 Scheller B et al. Circulation 2004; 110: 810-814
2 Speck U et al. Radiology 2006;240:56-64
3 Cremers B et al. Thromb Haemost 2009;101:201-206

4 Scheller B et al. N Engl J Med 2006;255:2113-2124
5 Scheller B et al. Clin Res Cardiol 2008;97:773-781
6 Tepe G et al. New Engl J Med 2008;358:689-699
7 Werk M et al. Circulation 2008;118:1358-1365

“Sensor tip” design

- enhances tactile feel
- slides into lesion for smooth crossing

Flexitec™ HF balloon material

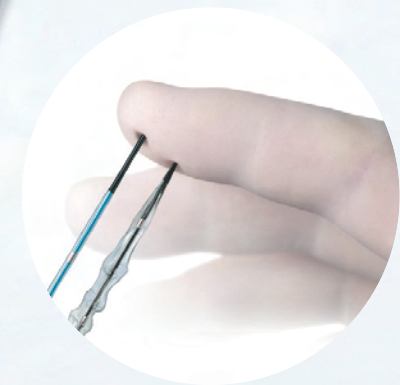
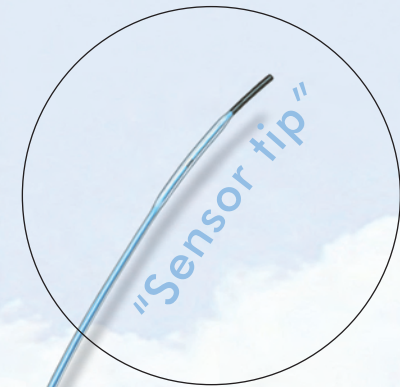
- Robust ultra-low profile balloon performance
- High flexibility without compromising RBP
- Balancing optimal compliance with high pressure capability

Tack-welded inner tube

Shaft maintains structural integrity during multiple passes

Proprietary shaft

- Designed for maximum trackability and pushability
- Efficient transmission of energy
- Designed specifically for coronary lesions



IN.PACT Falcon: No accordion effects while crossing and re-crossing

full length response