

IN.PACT
ADMIRAL

Technical specifications

Catheter design	Over the Wire (OTW)
Balloon material	FLEXITEC™ Xtreme
Balloon coating	FreePac™ - Paclitaxel eluting formulation
Usable shaft lengths	80 and 130 cm
Shaft diameter	5F
Introducer sheath compatibility	5F - 6F
Max. recommended guidewire	0.035"
Nominal pressure	8 bar

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

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

Order information

Ref. N° 80 cm shaft length	Ref. N° 130 cm shaft length	Balloon Ø (mm)	Balloon length (mm)	Recom. introducer sheath (F)	Markers	RBP (bar)
SBI 040 040 08P	SBI 040 040 13P	4	40	5	2	18
SBI 040 060 08P	SBI 040 060 13P	4	60	5	2	18
SBI 040 080 08P	SBI 040 080 13P	4	80	5	2	18
SBI 040 120 08P	SBI 040 120 13P	4	120	5	2	18
SBI 050 040 08P	SBI 050 040 13P	5	40	6	2	17
SBI 050 060 08P	SBI 050 060 13P	5	60	6	2	17
SBI 050 080 08P	SBI 050 080 13P	5	80	6	2	15
SBI 050 120 08P	SBI 050 120 13P	5	120	6	2	15
SBI 060 040 08P	SBI 060 040 13P	6	40	6	2	17
SBI 060 060 08P	SBI 060 060 13P	6	60	6	2	17
SBI 060 080 08P	SBI 060 080 13P	6	80	6	2	15
SBI 060 120 08P	SBI 060 120 13P	6	120	6	2	15
SBI 070 040 08P	SBI 070 040 13P	7	40	6	2	16
SBI 070 060 08P	SBI 070 060 13P	7	60	6	2	14
SBI 070 080 08P	SBI 070 080 13P	7	80	6	2	14



- ① Balloon nominal diameter
- ② Balloon nominal length
- ③ Shaft diameter
- ④ Usable shaft length

Distributor

Manufacturer

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**Paclitaxel-eluting
PTA balloon catheter**

**A short-term therapy
for long-term success
in the SFA**

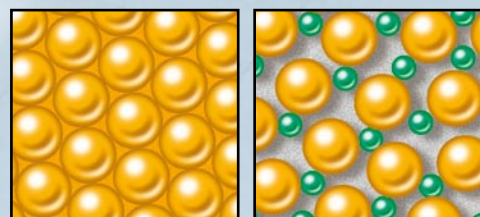
DRUG ELUTING BALLOON

INVATEC
Innovative Technologies
We make ideas come alive

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Short-term drug elution - a new therapeutic concept



Paclitaxel

Paclitaxel /
separator molecule

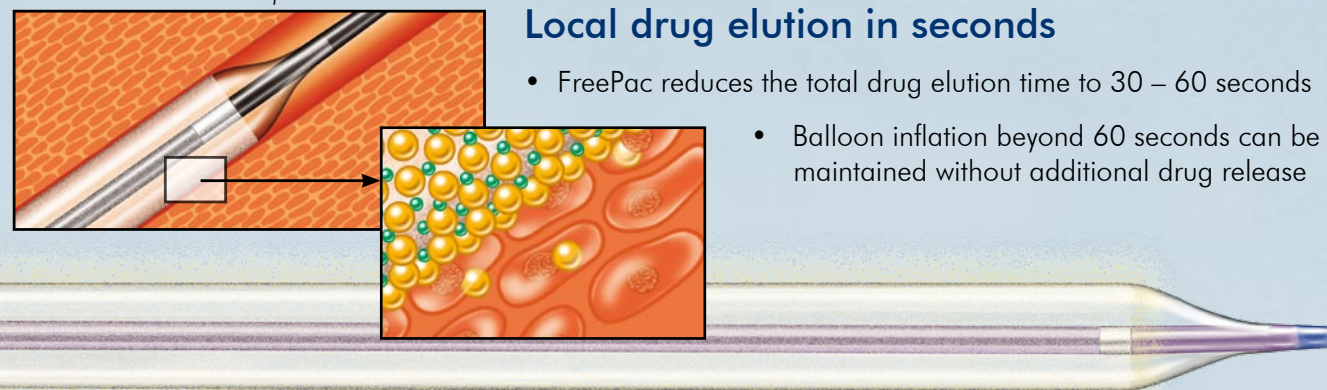
FreePac™

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
- Balloon inflation beyond 60 seconds can be maintained without additional drug release



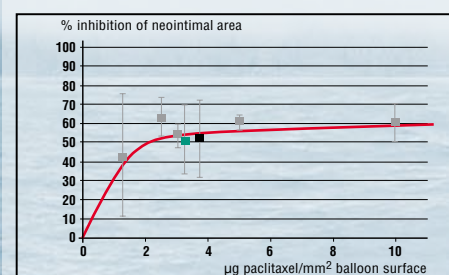
Control, no paclitaxel, cross section through porcine artery treated with conventional uncoated balloon; massive neointimal proliferation resulting in significant lumen narrowing 4 weeks after angioplasty.



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 Admiral 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

Proven Admiral Xtreme balloon platform

Superior dual lumen shaft design

- for improved pushability and kink resistance combined with excellent flexibility
- for contro-lateral maneuvers
- for large inflation lumen with fast deflation times



Dual lumen

6-folding balloon

for perfect re-wrapping, even after multiple inflations



6-folding

FLEXITEC™ Xtreme balloon material

- Reduced balloon wall-thickness
 - For improved flexibility
 - Facilitates controlateral maneuvers
- Excellent proven Controlled Low Compliance
 - For perfect adaptation to the vessel dimensions and disease condition
- High rated burst pressures
 - To achieve the desired angioplasty result

