

IN.PACT
AMPHIRION

Technical specifications



Catheter design	Over the Wire (OTW)	
Balloon material	FLEXITEC™ Ultra	
Balloon coating	FreePac™ - Paclitaxel eluting formulation	
Usable shaft lengths	120 and 150 cm*	
Shaft diameter	proximal	3.3F for 120 cm shaft length 3.9F for 150 cm shaft length
	middle	3.3F
	distal	2.8F
Introducer sheath compatibility	4F	
Guiding catheter compatibility	5F (I.D. >0.056")	
Max. recommended guidewire	0.014"	
Nominal pressure	7 bar	

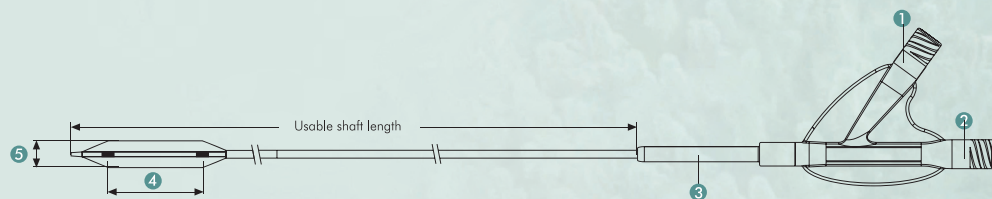
1 French (F) = 0.333 mm – 1 inch (") = 25.4 mm = 2.54 cm

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

Order information

Ref. N° 120 cm shaft length	Ref. N° 150 cm* shaft length	Balloon Ø (mm)	Balloon length (mm)	Markers	RBP (bar)
AMD 020 040 00P	AMD 020 040 15P	2.00	40	2	15
AMD 020 080 00P	AMD 020 080 15P	2.00	80	2	14
AMD 020 120 00P	AMD 020 120 15P	2.00	120	2	14
AMD 025 040 00P	AMD 025 040 15P	2.50	40	2	16
AMD 025 080 00P	AMD 025 080 15P	2.50	80	2	15
AMD 025 120 00P	AMD 025 120 15P	2.50	120	2	14
AMD 030 040 00P	AMD 030 040 15P	3.00	40	2	16
AMD 030 080 00P	AMD 030 080 15P	3.00	80	2	15
AMD 030 120 00P	AMD 030 120 15P	3.00	120	2	14
AMD 035 040 00P	AMD 035 040 15P	3.50	40	2	16
AMD 035 080 00P	AMD 035 080 15P	3.50	80	2	15
AMD 035 120 00P	AMD 035 120 15P	3.50	120	2	14
AMD 040 040 00P	AMD 040 040 15P	4.00	40	2	16
AMD 040 080 00P	AMD 040 080 15P	4.00	80	2	15
AMD 040 120 00P	AMD 040 120 15P	4.00	120	2	14

* Upon request



- 1 Balloon inflation port
- 2 Guidewire port
- 3 Kink protection
- 4 Balloon length
- 5 Balloon diameter

Sales partner

Manufacturer

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INVATEC
Innovative Technologies
We make ideas come alive

IN.PACT
AMPHIRION

Paclitaxel-eluting
PTA balloon catheter

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

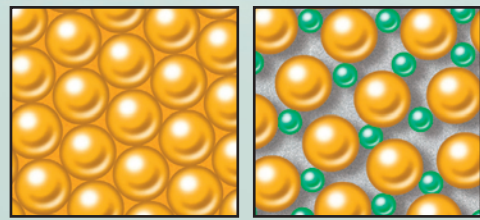
DRUG ELUTING BALLOON



IN.PACT AMPHIRION

Amphirion™ Deep performance -
the number one solution for intrapopliteal interventions

Short-term drug elution - a new therapeutic concept



Paclitaxel

Paclitaxel /
separator molecule

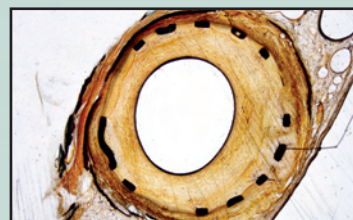
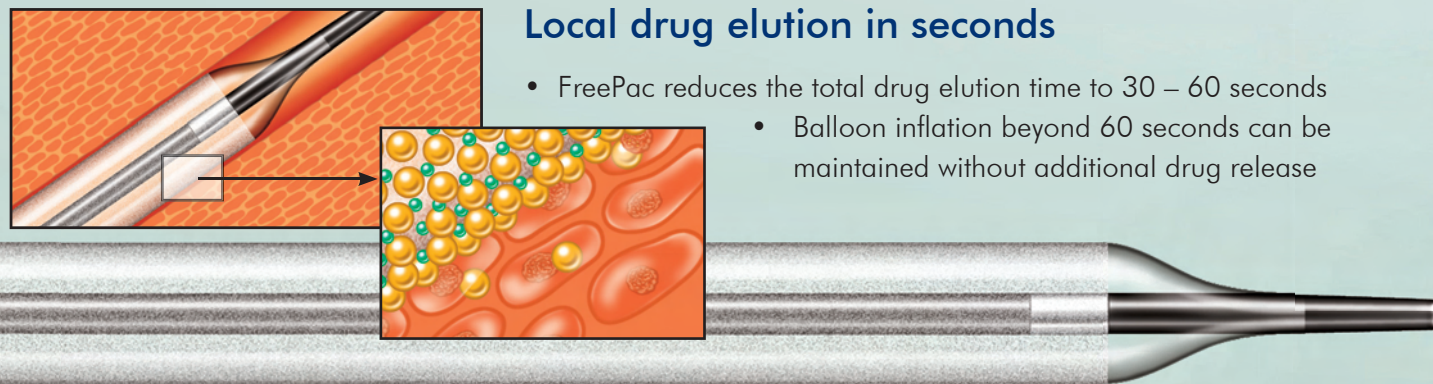
FreePac™

Proprietary hydrophilic coating formulation

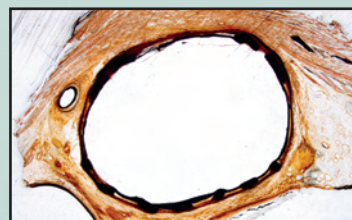
- separates Paclitaxel molecules
- balances hydrophilic and lipophilic properties
- facilitates Paclitaxel elution into the vessel wall

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.

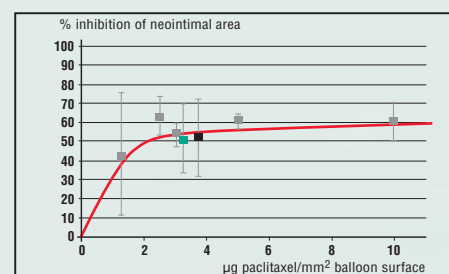
Tested Bio-equivalence

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

Low dose effectiveness - High safety margin

Several trials⁴⁻⁷ have confirmed:

- A low dosage of 3 µg 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 Amphirion meets the criteria for a wide therapeutic window with a high safety margin



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.

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

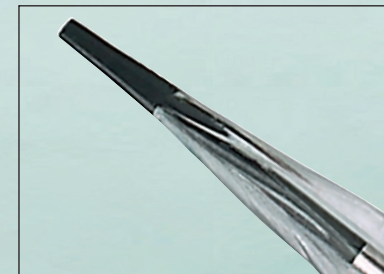
5 Scheller B et al. Clin Res Cardiol 2008;97:773-781

6 Tepe G et al. New Engl J Med 2008;358:689-699

7 Werk M et al. Circulation 2008;118:1358-1365

Low tip entry profile - 0.017"

crosses the tightest lesions with high procedural success



Example of Amphirion™ Deep conformability (picture has been included with permission of Dr. Lanfroi Graziani, Clinica Città di Brescia, Italy)

Flexitec™ Ultra balloon material

- conforms to vessel anatomy and tortuosity
- minimizes the risk of dissections
- assures smooth and effective balloon angioplasty

Up to 120 mm balloon length

allows one-step dilatation with a single PTA Balloon in long lesions

Proprietary shaft

designed for optimized trackability and pushability, specifically for the treatment of intrapopliteal lesions

