ORDERING INFORMATION

IN.PACT ADMIRAL

Ref. N° 80 cm Shaft Length	Ref. N° 130 cm Shaft Length	Balloon Diameter (mm)	Balloon Length (mm)
SBI 040 040 08P	SBI 040 040 13P	4.0	40
SBI 040 060 08P	SBI 040 060 13P	4.0	60
SBI 040 080 08P	SBI 040 080 13P	4.0	80
SBI 040 120 08P	SBI 040 120 13P	4.0	120
SBI 050 040 08P	SBI 050 040 13P	5.0	40
SBI 050 060 08P	SBI 050 060 13P	5.0	60
SBI 050 080 08P	SBI 050 080 13P	5.0	80
SBI 050 120 08P	SBI 050 120 13P	5.0	120
SBI 060 040 08P	SBI 060 040 13P	6.0	40
SBI 060 060 08P	SBI 060 060 13P	6.0	60
SBI 060 080 08P	SBI 060 080 13P	6.0	80
SBI 060 120 08P	SBI 060 120 13P	6.0	120
SBI 070 040 08P	SBI 070 040 13P	7.0	40
SBI 070 060 08P	SBI 070 060 13P	7.0	60
SBI 070 080 08P	SBI 070 080 13P	7.0	80

IN.PACT PACIFIC

Ref. N° 90 cm Shaft Length	Ref. N° 130 cm Shaft Length	Balloon Diameter (mm)	Balloon Length (mm)
PCF 040 040 09P	PCF 040 040 13P	4.0	40
PCF 040 060 09P	PCF 040 060 13P	4.0	60
PCF 040 080 09P	PCF 040 080 13P	4.0	80
PCF 040 120 09P	PCF 040 120 13P	4.0	120
PCF 050 040 09P	PCF 050 040 13P	5.0	40
PCF 050 060 09P	PCF 050 060 13P	5.0	60
PCF 050 080 09P	PCF 050 080 13P	5.0	80
PCF 050 120 09P	PCF 050 120 13P	5.0	120
PCF 060 040 09P	PCF 060 040 13P	6.0	40
PCF 060 060 09P	PCF 060 060 13P	6.0	60
PCF 060 080 09P	PCF 060 080 13P	6.0	80
PCF 060 120 09P	PCF 060 120 13P	6.0	120
PCF 070 040 09P	PCF 070 040 13P	7.0	40
PCF 070 060 09P	PCF 070 060 13P	7.0	60
PCF 070 080 09P	PCF 070 080 13P	7.0	80
PCF 070 120 09P	PCF 070 120 13P	7.0	120

IN.PACT AMPHIRION

Ref. N° 120 cm Shaft Length	Ref. N° 150 cm Shaft Length	Balloon Diameter (mm)	Balloon Length (mm)
AMD 020 040 00P	AMD 020 040 15P	2.0	40
AMD 020 080 00P	AMD 020 080 15P	2.0	80
AMD 020 120 00P	AMD 020 120 15P	2.0	120
AMD 025 040 00P	AMD 025 040 15P	2.5	40
AMD 025 080 00P	AMD 025 080 15P	2.5	80
AMD 025 120 00P	AMD 025 120 15P	2.5	120
AMD 030 040 00P	AMD 030 040 15P	3.0	40
AMD 030 080 00P	AMD 030 080 15P	3.0	80
AMD 030 120 00P	AMD 030 120 15P	3.0	120
AMD 035 040 00P	AMD 035 040 15P	3.5	40
AMD 035 080 00P	AMD 035 080 15P	3.5	80
AMD 035 120 00P	AMD 035 120 15P	3.5	120
AMD 040 040 00P	AMD 040 040 15P	4.0	40
AMD 040 080 00P	AMD 040 080 15P	4.0	80
AMD 040 120 00P	AMD 040 120 15P	4.0	120

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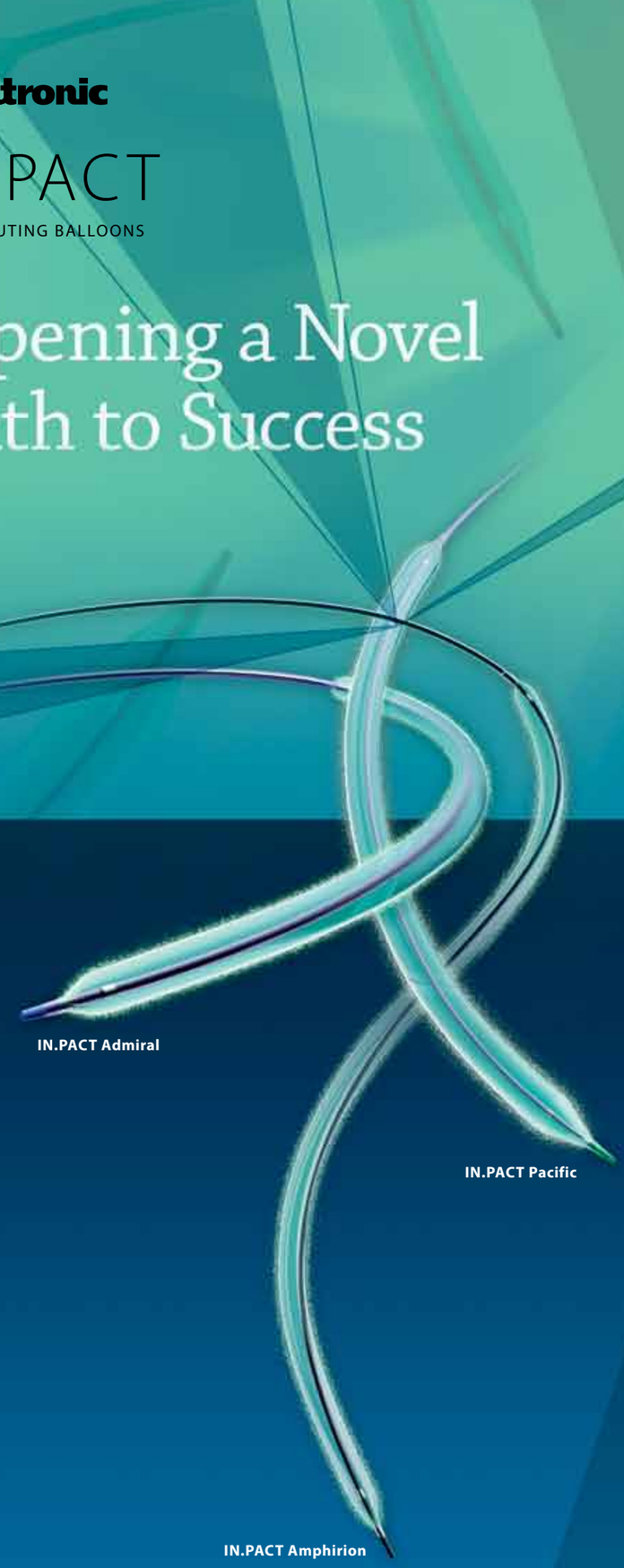
IN.PACT

DRUG ELUTING BALLOONS

Opening a Novel Path to Success



Innovating for life.

OPTIMISED & TRUSTED TECHNOLOGY

With drug eluting balloon technology (DEB), all components need to work together for maximum impact. IN.PACT DEBs employ such synergies with balloon design expertise, drug and excipient experience from collaboration with DEB inventors, and a proprietary coating process. These elements shape a reliable and effective product with the potential to change the way peripheral arterial disease is treated.

IMPROVING OUTCOMES & OPTIONS

IN.PACT DEBs have demonstrated favourable clinical results, showing restenosis reduction by employing a "leave no implant behind" strategy.

OPTIMISED & TRUSTED TECHNOLOGY

A proven balloon platform is the foundation of the IN.PACT DEB product family, which is distinguished by rapid drug transfer and consistent quality. The coating process is no exception—Medtronic's proprietary FreePac coating is backed by robust science.

LEADING THE WAY IN EVIDENCE CREATION

Medtronic has DEB efficacy data in both SFA and BTK. With 18 studies, the IN.PACT trials represent a robust clinical program with a singular objective—evidence for better patient treatment.

PLATFORM	**INVATEC** Proven PTA full balloon line
DRUG	**PACLITAXEL** Hydrophobic, lipophilic, proven antiproliferative drug
EXCIPIENT	**UREA** Hydrophilic, naturally occuring, nontoxic
COATING TECHNOLOGY	**MEDTRONIC** Uniformity + stability + release Controlled and scalable
CLINICAL RESEARCH PROGRAM	**IN.PACT TRIALS** SFA *de novo*, SFA ISR, BTK

A BETTER BEGINNING

A primary therapy solution, IN.PACT Drug Eluting Balloons address both the anatomical and therapeutic challenges when treating PAD, providing precision therapy for a broad range of challenges, right from the start.

FEMPOP CHALLENGES:
HIGH MECHANICAL STRESS AREA, LONG LESIONS

BTK CHALLENGES:
SMALL VESSELS, LONG LESIONS AND DIFFUSE DISEASE

ADDRESSING CHALLENGES IN LOWER LIMB THERAPY

- Restenosis prevention is an unresolved issue in treating PAD
- Drug therapy with antiproliferative agents has been proven to successfully prevent restenosis
- DEBs combine balloon-like device deliverability with targeted drug therapy

With no implant left behind and more options for both initial and secondary intervention, **IN.PACT Drug Eluting Balloons** provide an innovative and advanced therapy for PAD.

DEB TECHNOLOGY: IMPROVING OPTIONS PRE- AND POST-TREATMENT

1 / TREATMENT PLANNING

Expanded anatomy applicability

2 / PERIPROCEDURAL

Leave a non-flow-limiting dissection

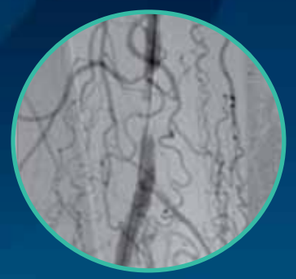
Potentially lower stenting rate

3 / FOLLOW-UP

Patent vessel without permanent implant

More options to treat restenosis

Less restenotic burden



BASELINE

POST IN.PACT DEB

6-MONTH FOLLOW-UP

Images courtesy of Dr. M. Werk, Berlin, Germany.

BEYOND THE EXPECTED

Balloon-based drug delivery exceeds expectations by providing high drug-in-tissue levels and favourable clinical results. Backed by robust science, FreePac combines the strong safety profile of paclitaxel and the proven drug transfer efficiency of urea.

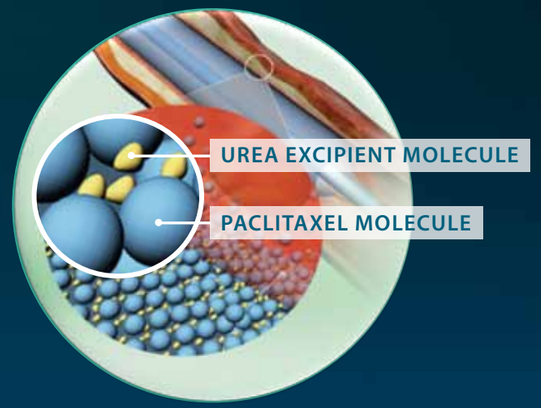
With paclitaxel, the drug of choice for short-term drug delivery, and urea, a naturally occurring excipient, FreePac is a proven mechanism for delivery. IN.PACT DEBs quickly achieve a loading dose, with contact time of 30–60 seconds, that also lasts long enough for the desired therapeutic effect.

WHY PACLITAXEL

- Potent antiproliferative agent
- Hydrophobic, resulting in limited washout
- Lipophilic, allowing for natural tissue absorption

WHY UREA

- Hydrophilic—catalyst for paclitaxel vessel wall absorption
- Naturally occurring
- No hypersensitivity reactions



IN.PACT DEB MECHANISM OF ACTION

1 / MECHANICAL DRUG TRANSFER

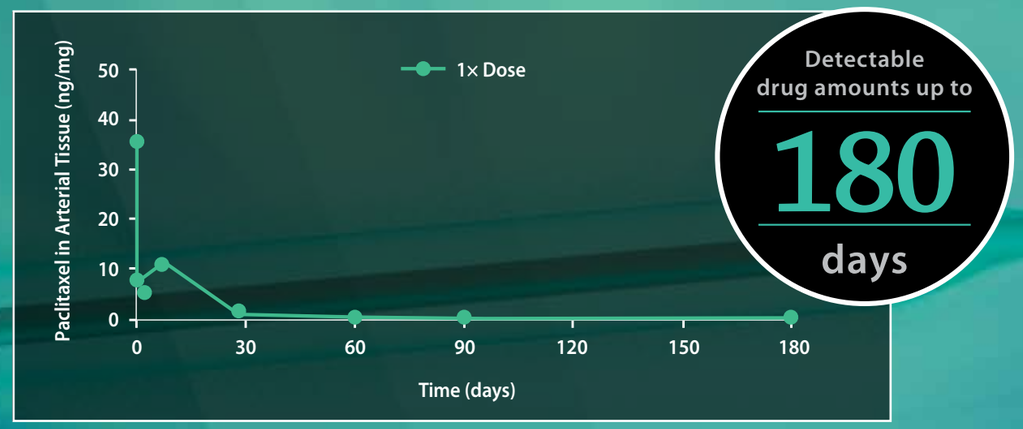
2 / LIPOPHILIC DRUG REDISTRIBUTION AND SEQUESTRATION

3 / SUSTAINED RETENTION OF LOW DRUG LEVELS

Urea increases drug solubility and facilitates drug release from balloon to the artery.

Experimental data on file at Medtronic.

PK ANIMAL MEASUREMENTS DEMONSTRATE HIGH INITIAL DRUG UPTAKE AND LOW BUT DETECTABLE DRUG AMOUNTS UP TO 180 DAYS



Paclitaxel resides long-term in the tissue as it forms depots. Adventitial washout is slow.

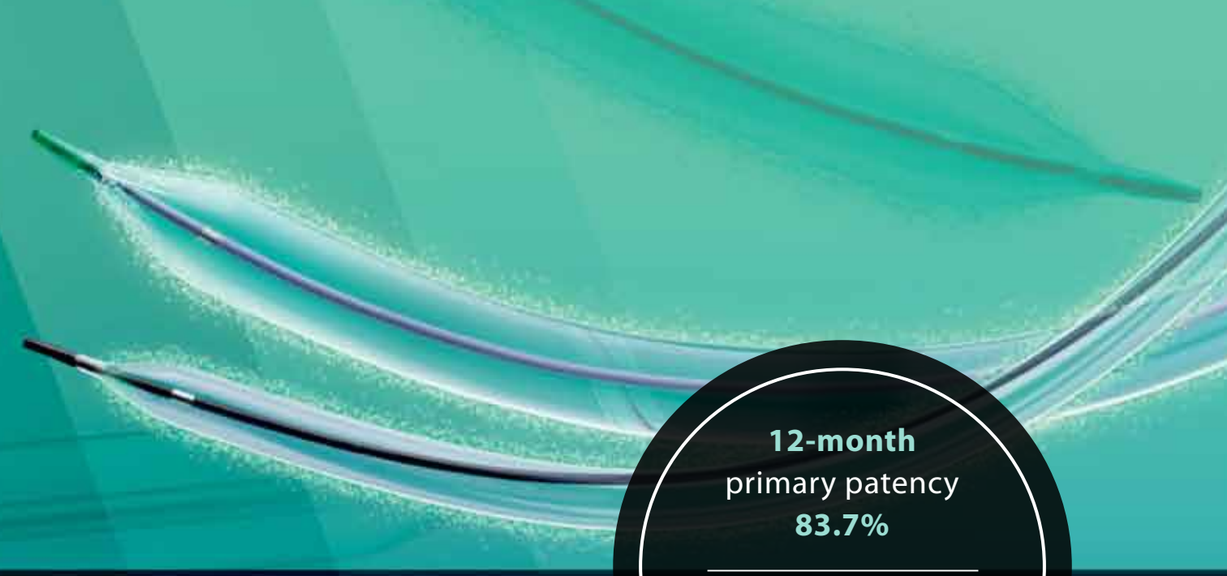
MANUFACTURING EXCELLENCE LEADS TO A HIGH-QUALITY COATING

	TASK	PROOF
DURABILITY	Ensure therapeutic dose of drug reaches lesion	60–70% of drug is protected within balloon folds; drug loss will be <15% during transfer
UNIFORMITY	Ensure uniform drug dose is applied to vessel wall	Proprietary FreePac coating process leads to uniform coating thickness
DRUG TRANSFER	Fast release to vessel wall	Pharmacokinetics testing shows therapeutic drug arterial tissue concentrations within 30–60 seconds
SAFETY	Minimize vessel wall inflammation	Animal testing shows endothelization within one month post-DEB. There are no signs for aneurysm, thrombosis or distal embolization. Systemic drug levels are low. DAPT is limited to four weeks.

Experimental data on file at Medtronic.

IMPROVING OUTCOMES & OPTIONS

The most studied peripheral DEB on the market, IN.PACT is backed by a clinical program profound in its thoroughness and outcomes. What's more, IN.PACT Drug Eluting Balloons prove efficacy in both SFA and BTK.



12-month
primary patency
83.7%

27-month
primary patency
72.4%

FEMPOP IN.PACT STUDY RESULTS

1 / PACIFIER

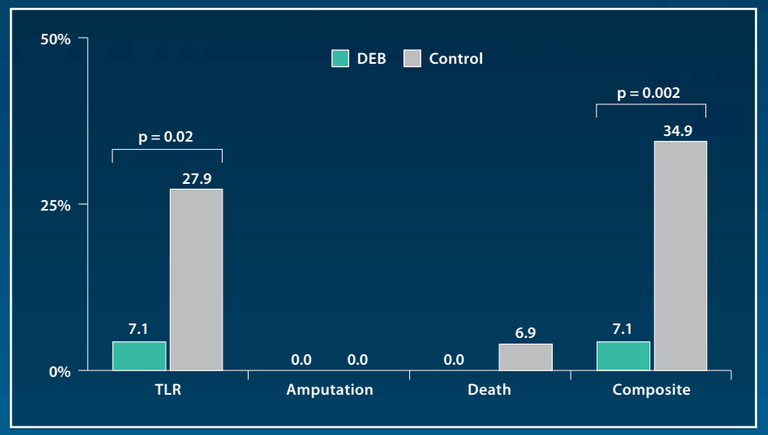
Randomised trial with 91 patients, IN.PACT Pacific vs. PTA

6-MONTH ANGIOGRAPHIC FOLLOW-UP

	DEB	Control	*p-Value*
DIAMETER STENOSIS (%)	29.7	39.4	0.05
MIN. LUMEN DIAMETER (MM)	3.61	2.94	0.0014
BINARY RESTENOSIS n/M (%)	3/35 (8.6)	11/34 (32.4)	0.01
LATE LUMEN LOSS (MM)	**-0.01**	**0.65**	**0.0014**

PACIFIER shows significant reduction of 6-month Late Lumen Loss vs. PTA

PACIFIER—12-MONTH CLINICAL RESULTS



Significant reduction in TLR and MAE rates in IN.PACT DEB vs. PTA at 12 months

2 / IN.PACT SFA ITALIAN REGISTRY

105 Fempop patient registry with IN.PACT Admiral

- IN.PACT Drug Eluting Balloons demonstrate high primary patency with low stent rate (12.4%)
- Low TLR rates of 8.7% at 1-year follow-up and 14.3% at 27-month follow-up
- Clinical benefit is consistently shown across multiple endpoints

BTK IN.PACT STUDY RESULTS

1 / IN.PACT BTK LEIPZIG REGISTRY

Long lesion BTK, 104-patient registry with IN.PACT Amphirion

ANGIOGRAPHIC RESULTS
Low restenotic burden at 3-month follow-up

Rate of completely occluded arteries	9.5%
Binary restenosis rate at 3 months	27.4%

CLINICAL RESULTS
Favourable clinical results and a limb salvage rate of 95.4%

TLR at 12 months	17.4%
Clinical improvements	95.6%
Complete wound healing	74.2%

Remarkably low restenosis rate

Low rate of occluded arteries

IN.PACT Pacifier: Werk, presentation at CX 2012.
IN.PACT SFA: Micari et al. *J Am Coll Cardiol Intv.* 2012;5:331-8 / Micari, presentation at PCR 2012.
IN. PACT BTK: Schmidt et al. *J Am Coll Cardiol.* 2011;58:1105-9.

LEADING THE WAY IN EVIDENCE CREATION

With 18 clinical trials covering 2000 patients and 100 sites, IN.PACT Drug Eluting Balloons are the most studied peripheral DEB. The clinical research program includes analysis of *de-novo* lesions, in-stent restenosis, BTK lesions and combination therapies of debulking plus DEB.

18 TRIALS | **10** RCTS | **>2000** PATIENTS

Significant clinical research effort to create evidence for DEB in lower limb treatment

IN.PACT SFA I + II SFA RANDOMIZED TRIAL

DESIGN: MULTICENTER RANDOMIZED (2:1) DEB VS. PTA, 430 PATIENTS

Rutherford Class 2-3-4 Patients

IN.PACT Admiral — RANDOM 2:1 — PTA

PRIMARY ENDPOINTS

- Efficacy: 12-month Primary Patency
- Safety: 30-day device/procedure death + 12-month amp/TVR

IN.PACT DEEP BTK RANDOMIZED TRIAL

DESIGN	Multicenter randomized (2:1) DEB vs. PTA
ELIGIBLE POPULATION	CLI
NR PATIENTS/SITES	357/15 in EU
PRIMARY ENDPOINTS	12 m LLL (angio cohort) 12 m clinically driven TLR All-cause death major amputation and TLR at 6m
SECONDARY ENDPOINT	Wound healing (by objective wound assessment)
FU TIMEPOINTS	30 d, 3 m, 6 m, 1y, 2 y, 3 y, 4y, 5 y
STATUS	Running

IN.PACT GLOBAL TRIAL SINGLE-ARM STUDY

STUDY PURPOSE

Prospectively collect and assess global safety and efficacy data on the IN.PACT Admiral Drug Eluting Balloon in the treatment of atherosclerotic disease of the superficial femoral and/or popliteal arteries in a real-world patient population.

The largest DEB trial with 1500 patients at 80 centers globally.

ADDITIONAL IN.PACT CLINICAL RESEARCH

Additional clinical research includes RCT and single-arm studies on **SFA In-Stent Restenosis**, DEB in combination with **atherectomy** or **laser debulking** and evaluation of high-risk **subgroups** (e.g., calcified lesions).