

Ordering Information: IN.PACT™ Admiral™ Drug-Coated Balloon⁺

Ref. Number Usable Length 40cm	8.1.10 Ref. Number Usable Length 80cm	8.1.10 Ref. Number Usable Length 130cm	8.1.8. Balloon Diameter (mm)	8.1.7. Balloon Length (mm)	8.1.9 Recommended Introducer Sheath (Fr)	8.1.5. RBP (atm)
SBI 040 040 04P	SBI 040 040 08P	SBI 040 040 13P	4	40	5	14
SBI 040 060 04P	SBI 040 060 08P	SBI 040 060 13P	4	60	5	14
SBI 040 080 04P	SBI 040 080 08P	SBI 040 080 13P	4	80	5	14
-	SBI 040 120 08P	SBI 040 120 13P	4	120	5	14
-	SBI 040 150 08P	SBI 040 150 13P	4	150	5	14
-	SBI04020008P	SBI04020013P	4	200	5	11
-	SBI04025008P	SBI04025013P	4	250	5	11
SBI 050 040 04P	SBI 050 040 08P	SBI 050 040 13P	5	40	6	14
SBI 050 060 04P	SBI 050 060 08P	SBI 050 060 13P	5	60	6	14
SBI 050 080 04P	SBI 050 080 08P	SBI 050 080 13P	5	80	6	14
-	SBI 050 120 08P	SBI 050 120 13P	5	120	6	14
-	SBI 050 150 08P	SBI 050 150 13P	5	150	6	14
-	SBI05020008P	SBI05020013P	5	200	6	11
-	SBI05025008P	SBI05025013P	5	250	6	11
SBI 060 040 04P	SBI 060 040 08P	SBI 060 040 13P	6	40	6	14
SBI 060 060 04P	SBI 060 060 08P	SBI 060 060 13P	6	60	6	14
SBI 060 080 04P	SBI 060 080 08P	SBI 060 080 13P	6	80	6	14
-	SBI 060 120 08P	SBI 060 120 13P	6	120	6	14
-	SBI 060 150 08P	SBI 060 150 13P	6	150	6	14
-	SBI06020008P	SBI06020013P	6	200	6	11
-	SBI06025008P	SBI06025013P	6	250	6	11
SBI 070 040 04P	SBI 070 040 08P	SBI 070 040 13P	7	40	7	14
SBI 070 060 04P	SBI 070 060 08P	SBI 070 060 13P	7	60	7	14
SBI 070 080 04P	SBI 070 080 08P	SBI 070 080 13P	7	80	7	14
SBI 080 040 04P	SBI 080 040 08P	SBI 080 040 13P	8	40	7	10
SBI 080 060 04P	SBI 080 060 08P	SBI 080 060 13P	8	60	7	10
SBI 080 080 04P	SBI 080 080 08P	SBI 080 080 13P	8	80	7	10
SBI 090 040 04P	SBI 090 040 08P	SBI 090 040 13P	9	40	7	10
SBI 090 060 04P	SBI 090 060 08P	SBI 090 060 13P	9	60	7	10
SBI 090 080 04P	SBI 090 080 08P	SBI 090 080 13P	9	80	7	10
SBI 100 040 04P	SBI 100 040 08P	SBI 100 040 13P	10	40	7	9
SBI 120 040 04P	SBI 120 040 08P	SBI 120 040 13P	12	40	9	9

Ordering Information: IN.PACT™ Pacific™ Drug-Eluting Balloon⁺

Ref. Number Usable Length 90cm	Ref. Number Usable Length 130cm	Balloon Diameter (mm)	Balloon Length (mm)	Recommended Introducer Sheath (Fr)	RBP (atm)
PCF 040 040 09P	PCF 040 040 13P	4	40	5	20
PCF 040 060 09P	PCF 040 060 13P	4	60	5	14
PCF 040 080 09P	PCF 040 080 13P	4	80	5	14
PCF 040 120 09P	PCF 040 120 13P	4	120	5	14
PCF 050 040 09P	PCF 050 040 13P	5	40	5	20
PCF 050 060 09P	PCF 050 060 13P	5	60	5	14
PCF 050 080 09P	PCF 050 080 13P	5	80	5	14
PCF 050 120 09P	PCF 050 120 13P	5	120	5	14
PCF 060 040 09P	PCF 060 040 13P	6	40	5	16
PCF 060 060 09P	PCF 060 060 13P	6	60	5	14
PCF 060 080 09P	PCF 060 080 13P	6	80	5	14
PCF 060 120 09P	PCF 060 120 13P	6	120	5	14
PCF 070 040 09P	PCF 070 040 13P	7	40	6	12
PCF 070 060 09P	PCF 070 060 13P	7	60	6	12
PCF 070 080 09P	PCF 070 080 13P	7	80	6	12
PCF 070 120 09P	PCF 070 120 13P	7	120	6	12

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References

1. IN.PACT Admiral 5Y data: Laird JA, Schneider PA, Jaff MR, et al. Long-Term Clinical Effectiveness of a Drug-Coated Balloon for the Treatment of Femoropopliteal Lesions. Circ Cardiovasc Interv. June 2019;12(6):e007702, presented by Thomas Zeller, M.D., at VIVA 2020.
2. Presented by Thomas Zeller, M.D., at VIVA 2020.
3. Based on clinical data for drug-coated balloons indicated to treat long SFA lesions (>180 mm): compared to Lutonix™ IFU BAW1387400r3. Per Stellarex™ IFU P011966-B, Stellarex is not indicated to treat lesions longer than 180 mm. Definitions of patency and lesion length may vary for different studies.
4. The IN.PACT Global Study Long Lesion Imaging Cohort D.Scheinert Circulation 2018.

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

+ The approved product name for the drug-coated balloon is IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter

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2.0 Product Description

The IN.PACT Admiral paclitaxel-coated PTA balloon catheter is an over-the-wire [OTW] balloon catheter with a drug-coated balloon at the distal tip. The drug component, referred to as the FreePac™ drug coating, consists of the drug paclitaxel and the excipient urea. **The device component physically dilates the vessel lumen by PTA, and the drug is intended to reduce the proliferative response that is associated with restenosis.** Product Component Description (Table 1) summarizes the characteristics of the device, hereafter referred to as IN.PACT Admiral DCB.

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Table 1: Product Component Description

Available Balloon Diameters (mm) and Lengths (mm)	Balloon Diameter (mm)	Balloon Length (mm)				
		20	40	60	80	120
	4.0	X	X	X	X	X
	5.0	X	X	X	X	X
	6.0	X	X	X	X	X
	7.0	X	X	X	X	---
Note: “---” indicates size not offered; “x” indicates sizes offered						
Balloon Coating (Drug Component)	Paclitaxel (Active Pharmaceutical Ingredient) and Urea (excipient)					
Catheter Design	Over-the-Wire (OTW)					
Usable Catheter Lengths	80 cm and 130 cm					
Balloon Inflation Pressure	Nominal Pressure: 8 atm (811 kPa) Rated Burst Pressure: 14 atm (1419 kPa)					
Minimum Introducer Sheath Compatibility	Balloon Diameter	Max Crossing Profile		Introducer Sheath		
	4.0 mm (all lengths)	5.6 Fr (1.88 mm)		5 Fr		
	5.0 mm (all lengths)	6.0Fr (2.00 mm)		6 Fr		
	6.0 mm (all lengths except 120 mm)	6.3Fr (2.10mm)				
	6.0 mm (120 mm length)	7.0 Fr (2.33 mm)		7 Fr		
7.0 mm (all lengths)	7.0 Fr (2.33 mm)					
Guidewire Compatibility	The catheter is compatible with a guidewire diameter of 0.035 in (0.89 mm).					

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8.1.5

2.1 Device Component Description

The OTW balloon catheter consists of a proximal hub, dual-lumen shaft, and a distal dilatation balloon. The central lumen extends to the **distal low profile tip** and is used to pass the catheter over a guidewire with a diameter of 0.035 in (0.89 mm). The balloon-inflation lumen is used to inflate and deflate the balloon with a mixture of contrast medium and saline **solution. Two radiopaque platinum-iridium** markers indicate the working length of the balloon to position the balloon across the target lesion during fluoroscopy. See image of the device, IN.PACT Admiral Paclitaxel-coated PTA Balloon Catheter (Figure 1).

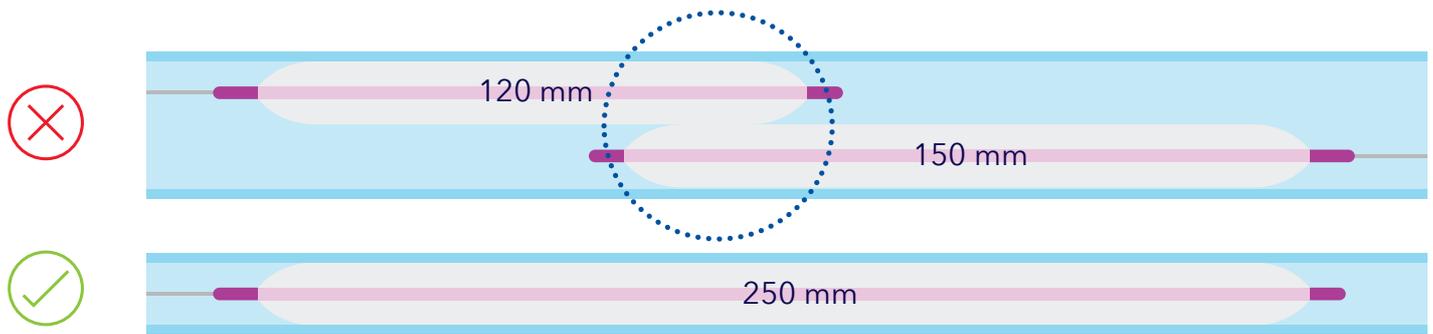
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Going strong. Now going long.

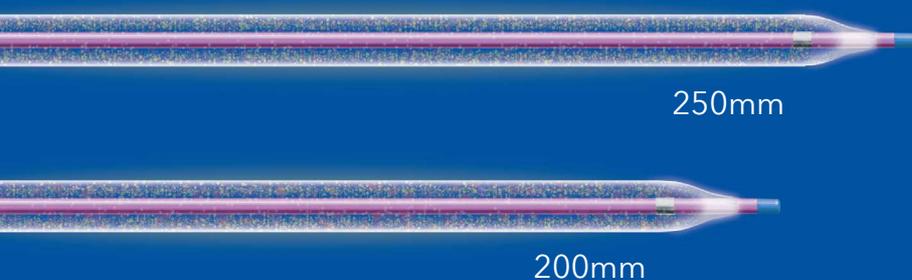
IN.PACT™ Admiral™+

Use one long DCB instead of two standard sizes



8.1.7 poz. ilgis iki 250mm

Extra long. Extra efficient.



**Saves time
and costs**

91%⁴
Highest primary patency³

26cm
Mean lesion length