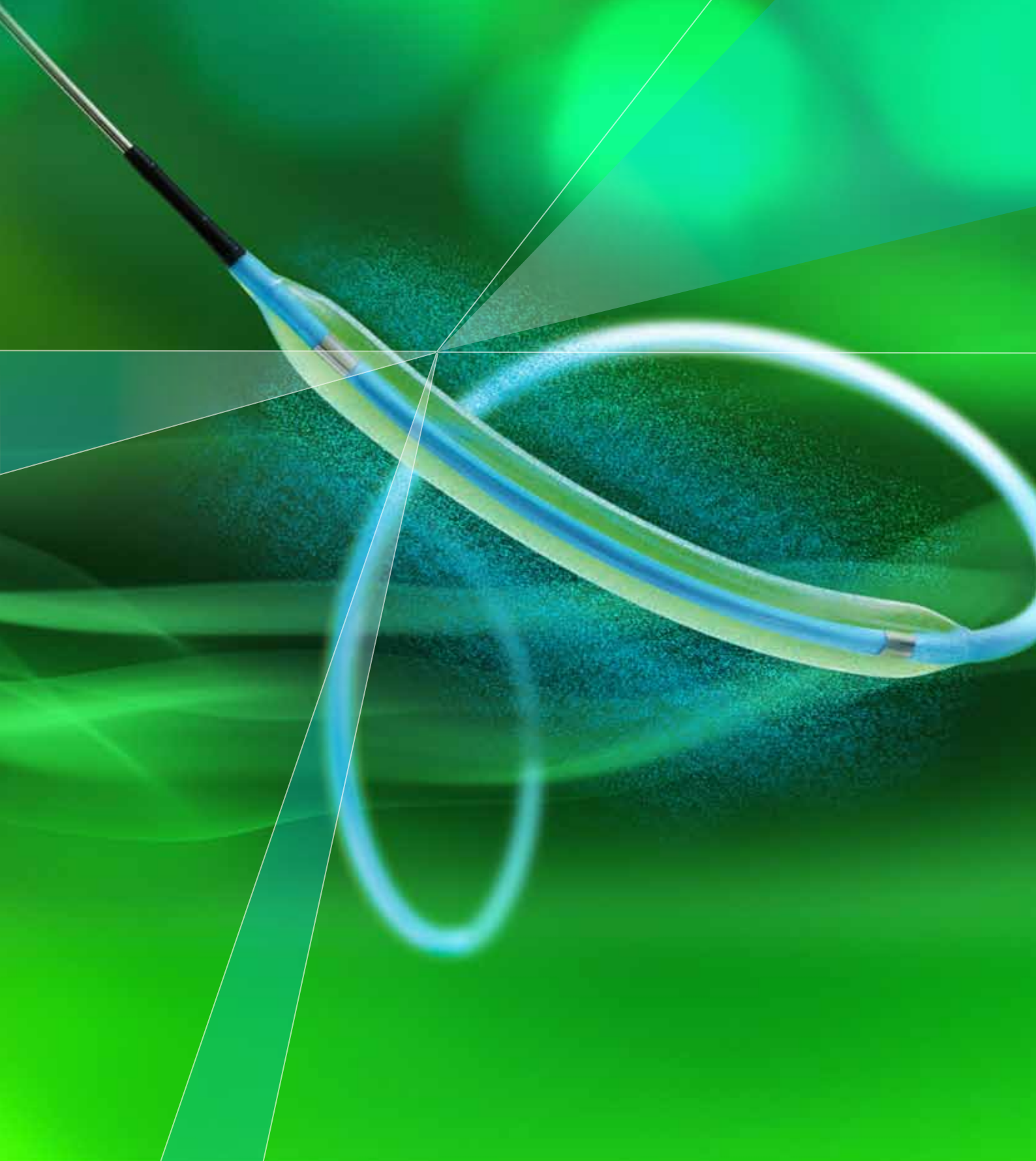




Medtronic

In.Pact Falcon

PACLITAXEL-ELUTING CORONARY BALLOON CATHETER





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Expanding Your Antirestenotic Therapy Options

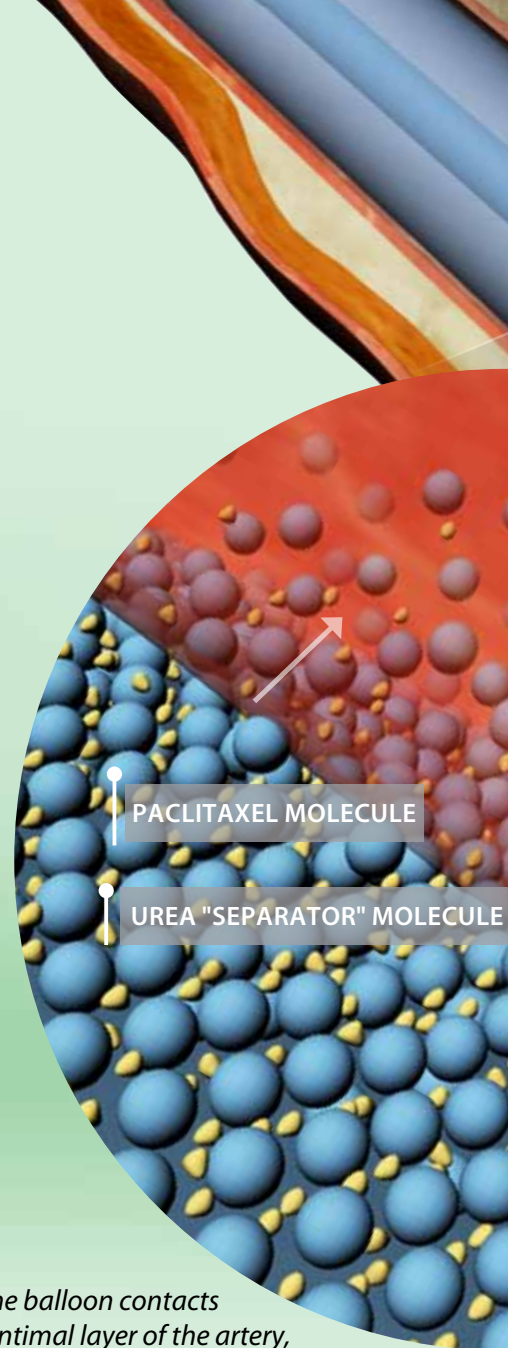
The In.Pact Falcon paclitaxel-eluting balloon increases your antirestenotic therapy options by treating restenosis in cases where implanting a layer of scaffolding may be undesirable or where placing a stent may be difficult.

How It Works

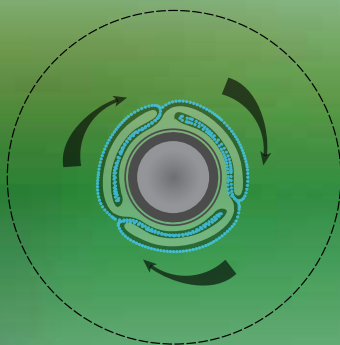
The proprietary FreePac urea-paclitaxel coating optimises drug delivery:

- The In.Pact Falcon DEB is delivered to the lesion following preparation by a semicompliant balloon
- As the balloon unwraps, the FreePac coating is fully exposed and presented to the vessel wall
- Urea molecules in the coating separate and free the paclitaxel molecules, increasing their bioavailability and facilitating their absorption into the artery

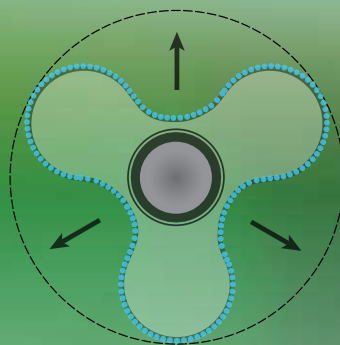
As the balloon contacts the intimal layer of the artery, urea and paclitaxel molecules are delivered across the vessel wall



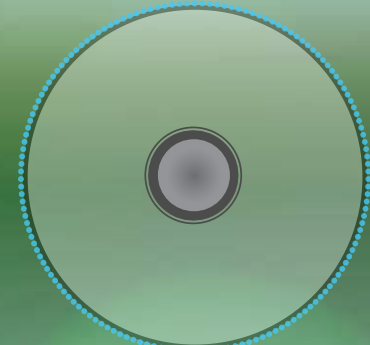
IN.PACT FALCON PACLITAXEL ELUTING



WRAPPED BALLOON
The In.Pact Falcon DEB is delivered to the target site



FOLDS UNWRAPPING
The balloon unwraps to expose the FreePac coating
:10 seconds



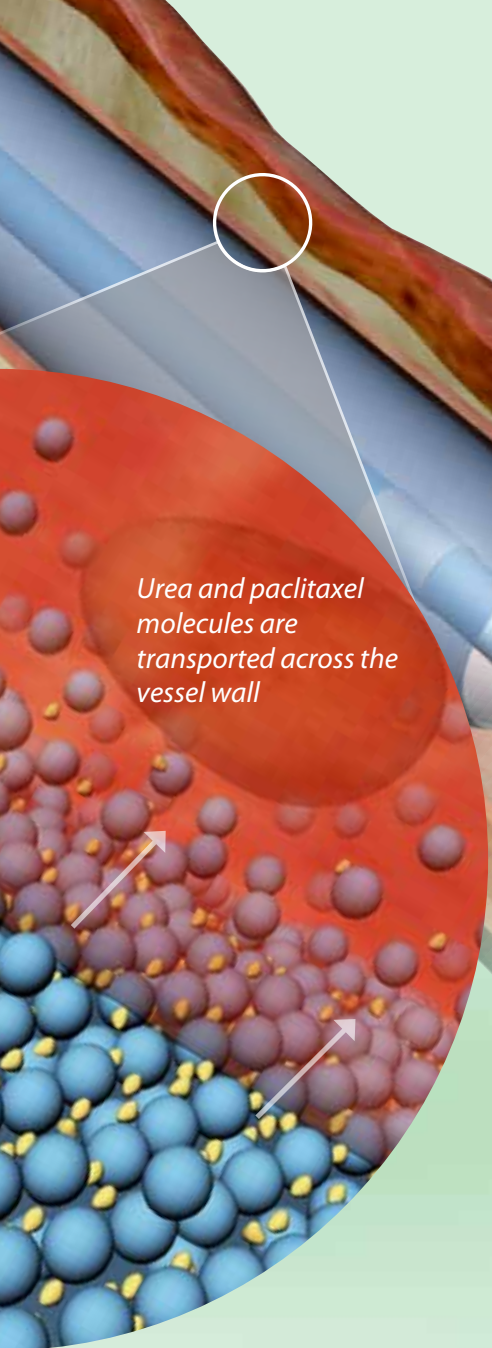
BALLOON INFLATED AND ELUTING
Urea molecules facilitate carriage of paclitaxel molecules across the vessel wall
:15 seconds

Why It's Different

The In.Pact Falcon balloon is the only DEB on today's market that uses a naturally occurring molecule (urea) as a drug carrier instead of a foreign molecule such as contrast.

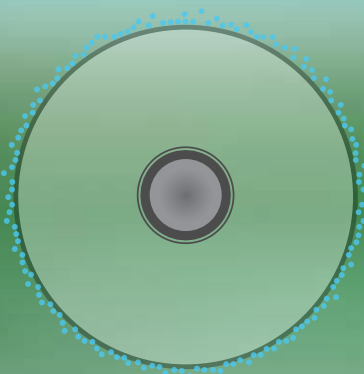
The balloon's unique FreePac coating combines urea and paclitaxel molecules into a single compound that provides:

- Increased drug solubility and optimal diffusion into the vessel wall
- Rapid, short-term drug delivery within 30–60 seconds
- Continued antirestenotic protection for 28 days
- Alleviation of potential risks involving allergic reactions and toxicity (the total urea concentration in the FreePac coating is a small fraction of what exists naturally in the body)

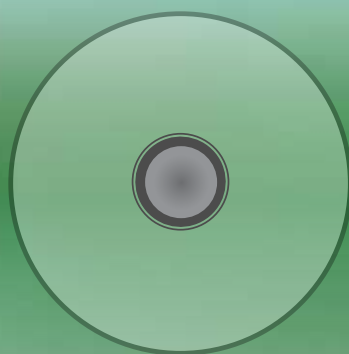


Urea and paclitaxel molecules are transported across the vessel wall

ELUTION TIMELINE



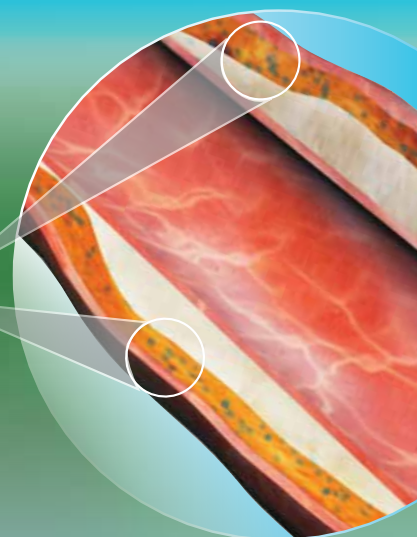
ELUTION
Drug elution takes place within 45 seconds



MOST ELUTION DONE BY 60 SECONDS

:60 seconds

The FreePac coating ensures that drug delivery occurs within 30–60 seconds. Paclitaxel's ongoing retention in the medial layer provides continual antirestenotic protection to the target site for up to 28 days.



28 days

Where It Works

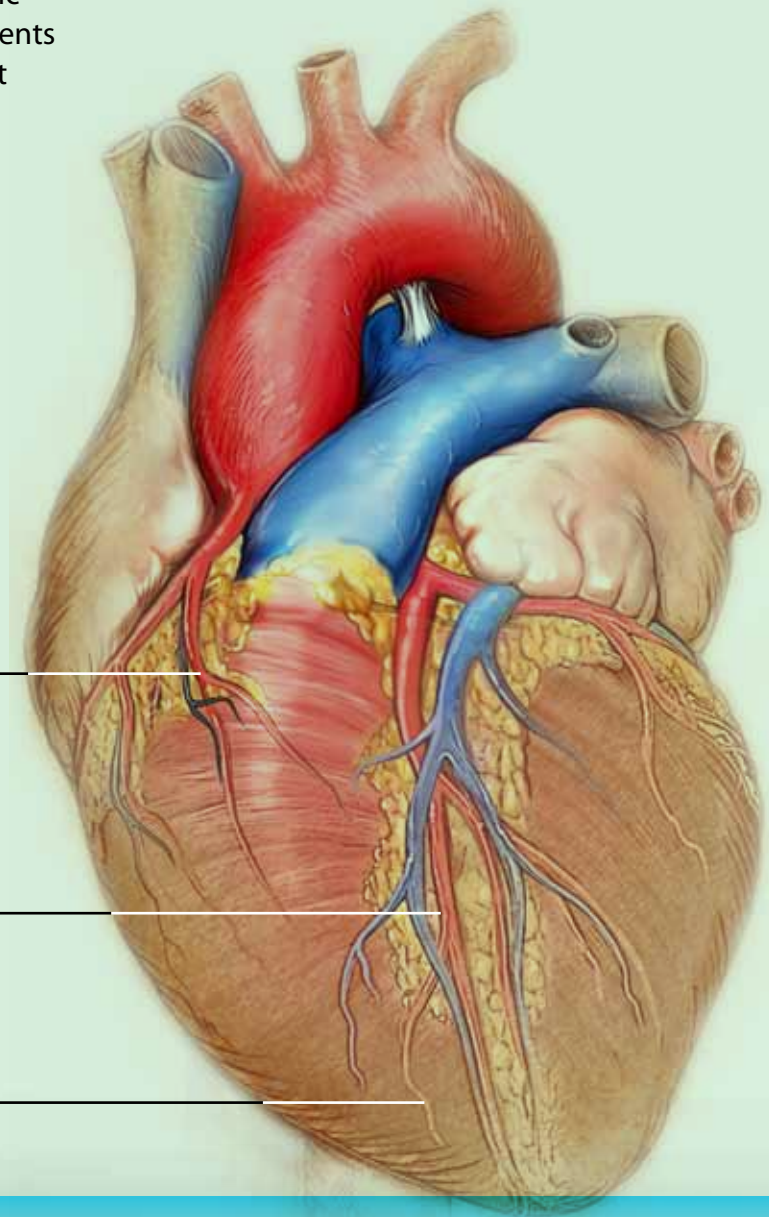
Designed specifically to treat restenotic disease in areas where drug-eluting stents may not be an ideal option, the In.Pact Falcon balloon provides a potential therapeutic option for:

- In-stent restenosis
- Small vessels
- Bifurcation sidebranches

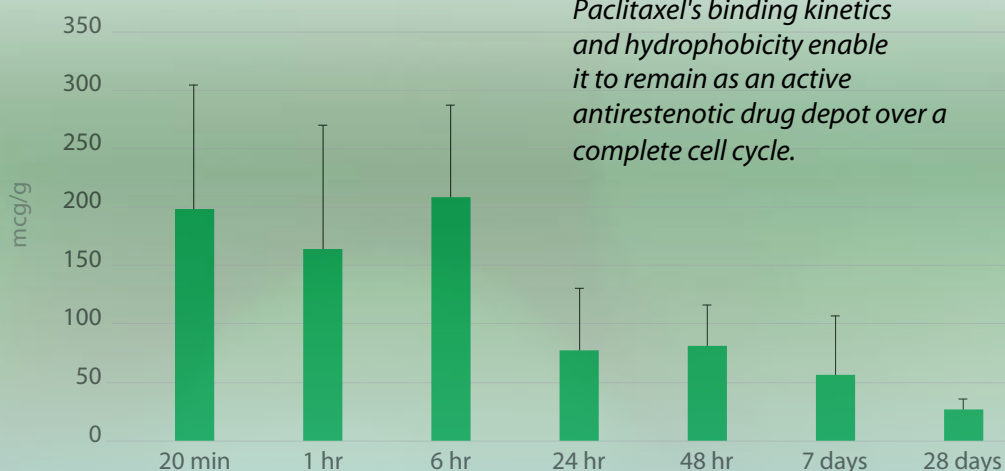
**Bifurcation
sidebranches**

**In-stent
restenosis**

Small vessels



Elution Time

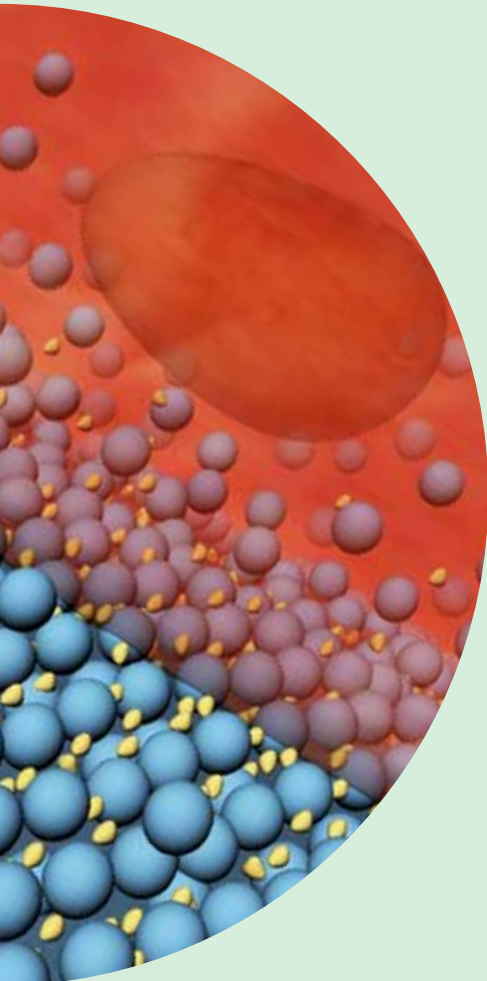


Paclitaxel's binding kinetics and hydrophobicity enable it to remain as an active antirestenotic drug depot over a complete cell cycle.

Paclitaxel concentration in the vessel wall as measured by high-performance liquid chromatography (HPLC)

Testing on file at Medtronic, Inc.

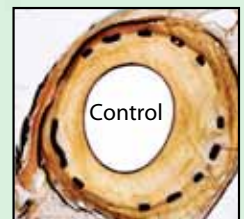
The Natural Choice



Urea and paclitaxel molecules are transported across the vessel wall

The FreePac urea-paclitaxel coating demonstrates excellent performance in clinical and preclinical studies:

- The FreePac coating shows equivalent performance in preclinical studies (right) compared with Paccocath contrast-based coating¹
- The IN.PACT CORO ISR study² adds to the existing clinical evidence of drug-eluting balloons in ISR^{3,4,5} and further confirms and reinforces the capacity of the In.Pact Falcon balloon to inhibit neointimal hyperplasia and reduce angiographic and clinical restenosis at 6 months
- The maximum amount of urea on the In.Pact Falcon balloon is equal to that contained in approximately 10 ml of serum



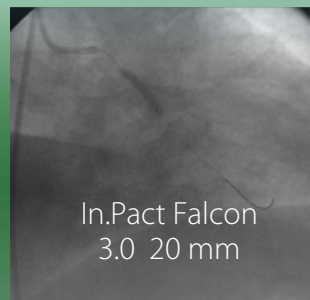
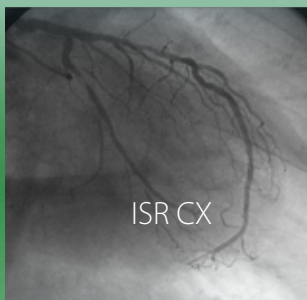
¹ Schnorr B et al. Paclitaxel-coated balloons—Survey of preclinical data. *Minerva Cardioangiol.* 2010;58(5):567–582.

² Cremers B et al. Treatment of coronary in-stent restenosis with a novel paclitaxel urea-coated balloon. *Minerva Cardioangiol.* 2010;58(5):583–588.

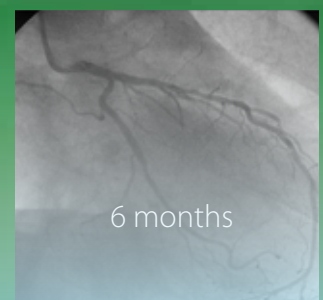
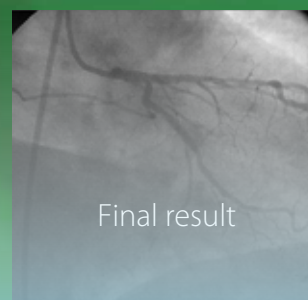
³ Unverdorben M et al. Paclitaxel-coated balloon catheter vs. paclitaxel-coated stent for the treatment of coronary in-stent restenosis. *Circulation.* 2009;119:2986–2994.

⁴ Scheller B et al. Treatment of coronary in-stent restenosis with a paclitaxel-coated balloon catheter. *New Engl J Med.* 2006;355:2113–2124.

⁵ Scheller B et al. Two-year follow up after treatment of coronary in-stent restenosis with a paclitaxel-coated balloon catheter. *Clin Res Cardiol.* 2008;97:773–781.



6-month angiographic results in BMS ISR patients treated with the In.Pact Falcon balloon show sustained luminal area gains.



In.Pact Falcon Ordering Information

Balloon Diameter (mm)	Balloon Length (mm)			
	14	20	30	40
2.00	FLC P20 014 B12	FLC P20 020 B12	FLC P20 030 B12	—
2.25	FLC P22 014 B12	FLC P22 020 B12	FLC P22 030 B12	—
2.50	FLC P25 014 B12	FLC P25 020 B12	FLC P25 030 B12	FLC P25 040 B12
2.75	FLC P27 014 B12	FLC P27 020 B12	FLC P27 030 B12	—
3.00	FLC P30 014 B12	FLC P30 020 B12	FLC P30 030 B12	FLC P30 040 B12
3.25	FLC P32 014 B12	FLC P32 020 B12	FLC P32 030 B12	—
3.50	FLC P35 014 B12	FLC P35 020 B12	FLC P35 030 B12	FLC P35 040 B12
3.75	FLC P37 014 B12	FLC P37 020 B12	FLC P37 030 B12	—
4.00	FLC P40 014 B12	FLC P40 020 B12	—	FLC P40 040 B12

In.Pact Falcon Compliance

Pressure kPa (atm)	Balloon Diameter (mm)								
	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00
507 (5)	1.90	2.15	2.40	2.65	2.90	3.15	3.40	3.65	3.90
608 (6)	1.95	2.20	2.45	2.70	2.95	3.20	3.45	3.70	3.95
709 (7)	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.35
811 (8)	2.02	2.27	2.52	2.78	3.03	3.28	3.54	3.80	4.05
912 (9)	2.04	2.29	2.54	2.82	3.07	3.32	3.58	3.85	4.10
1013 (10)	2.06	2.31	2.57	2.86	3.11	3.36	3.62	3.90	4.15
1115 (11)	2.08	2.34	2.60	2.90	3.15	3.40	3.66	3.95	4.20
1216 (12)	2.11	2.37	2.63	2.94	3.19	3.45	3.70	4.00	4.25
1317 (13)	2.14	2.40	2.67	2.98	3.23	3.50	3.75	4.05	4.30
1419 (14)	2.17	2.43	2.71	3.02	3.27	3.55	3.80	4.10	4.35
1520 (15)	2.20	2.46	2.75	3.06	3.31	3.60	3.85	4.15	4.40
1621 (16)	2.23	2.50	2.80	—	—	—	—	—	—
1723 (17)	2.26	—	—	—	—	—	—	—	—

Nominal pressure

Rated burst pressure*

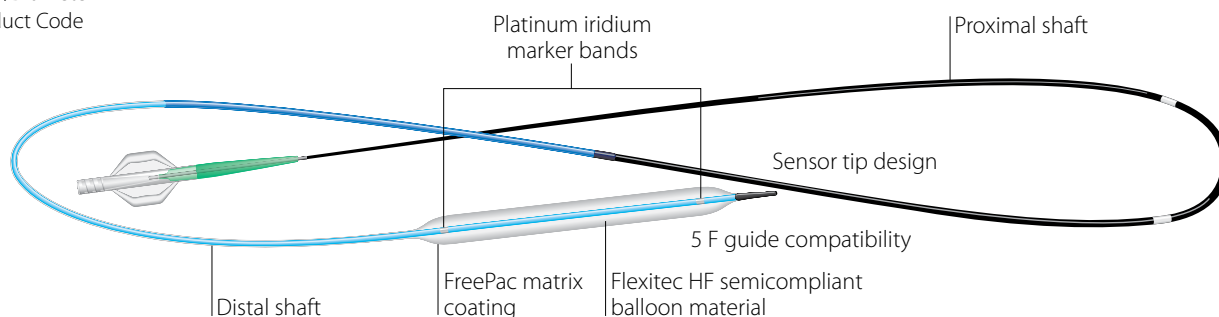
Test data on file at Medtronic, Inc.
*Rated burst pressure—do not exceed.

For technical questions, please contact your local sales representative or e-mail rs.cstechsupport@medtronic.com

In.Pact Falcon Product Code

FLC P20 014 B12

Product Code
Diameter
Length
Semicompliant Construction



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