The IN.PACT™ AV Drug-Coated Balloon

GET AHEAD OF AV FISTULA RESTENOSIS™
Patients with end stage renal disease (ESRD) may need frequent AV fistula interventions to maintain proper flow for dialysis.

This can be hard on patients and their families. It's one more hardship for people already profoundly impacted by disease.

**The IN.PACT™ AV DCB can help.**

Unlike traditional percutaneous transluminal angioplasty (PTA), the IN.PACT™ AV DCB can help slow the progression of stenosis.

**As a result, patients may need 56% fewer maintenance interventions than with PTA.¹**

That's a good thing for your patients—and those who love them.
TREAT RESTENOSIS PROACTIVELY

The IN.PACT™ AV DCB treats the cause—not just the symptoms of fistula stenosis, enabling you to get ahead of restenosis and go longer between interventions.¹

Percutaneous transluminal angioplasty (PTA) mechanically opens the stenosed vessel, but without an anti-restenotic component, it often results in rapid restenosis.

The IN.PACT™ AV DCB works differently, delivering an antiproliferative drug (paclitaxel) to the vessel to inhibit neointimal hyperplasia (NIH), the primary cause of AV fistula stenosis.

Proprietary design enables the IN.PACT™ AV DCB to deliver sustained drug levels and unparalleled clinical results.¹⁻³

SCIENCE BEHIND THE OUTCOMES

EFFICIENT DELIVERY
A proprietary combination of paclitaxel drug and urea exipient allows rapid transfer of the antiproliferative drug to the vessel wall.²

SUSTAINED DURATION
Reservoirs of the drug stay in the vessel wall, capable of delivering effective paclitaxel levels by residing in the vessel for up to 180 days.²

EXTENDED EFFECT
Uniquely combining an appropriate amount of drug and time, the IN.PACT™ AV DCB dramatically reduces the need for repeat procedures.¹²
GET DEMONSTRATED SUPERIOR RESULTS

The IN.PACT™ AV DCB has been demonstrated superior to PTA in increasing patency and prolonging time between interventions. In separate IN.PACT AV and Lutonix AV clinical trials, only IN.PACT AV DCB met its effectiveness endpoints.

In the largest randomized global DCB study published on AV fistula patients, the IN.PACT™ AV DCB reduced the need for reinterventions by more than half.

Number of reinterventions required to maintain target lesion primary patency

PTA
IN.PACT™ AV DCB

56% REDUCTION

FEWER INTERVENTIONS VS. PTA

56%

Highest reported primary patency in an AV DCB study

TARGET LESION PRIMARY PATENCY AT 6 MONTHS

86.1%

ACCESS CIRCUIT PRIMARY PATENCY AT 6 MONTHS

78.1%

TIME AFTER INDEX PROCEDURE (DAYS)

IN.PACT™ AV DCB
STANDARD PTA
DELTA

Log-rank p < .001 at 180-day and at 210-day

The largest global, randomized, AV fistula drug-coated balloon study conducted, with subjects from Japan, New Zealand, and the United States.
MAKE AN IMPACT, WITH BOTTOM-LINE BENEFITS

Fewer is better. By enabling dramatically fewer AV fistula interventions, the IN.PACT™ AV DCB can make a real impact; clinically, financially and emotionally.

A MULTIBILLION DOLLAR BURDEN

Total direct expenditures annually in US

$5B

Vascular access management for ESRD patients costs billions of dollars in the US every year. Medtronic is helping address those costs— with innovative solutions like the IN.PACT™ AV DCB.

Δ = $14.8k PPPY
(per patient per year)

The difference in cost between a successfully working AV fistula and failure is $14.8k per patient per year.
**Ordering Information**

**Medtronic.com/inpactAV**

**Ordering Information**

- Do not move the guidewire during inflation of the IN.PACT AV DCB.
- Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.

**WARNINGS**

- Patients with known allergies or sensitivities to paclitaxel
- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy

**INDICATIONS FOR USE**

- The IN.PACT™ AV Paclitaxel-coated PT A Balloon Catheter is indicated for percutaneous transluminal
- Reduction in reinterventions: Defined as freedom from re-intervention in the access circuit or access circuit thrombosis calculated at 180 days post-procedure.

**POTENTIAL ADVERSE EFFECTS**

- Potential adverse effects which may be associated with balloon catheterization may include, but are not limited to:
- The safety of using multiple IN.PACT AV DCBs with a total drug dosage exceeding 16.105 μg paclitaxel has not been evaluated clinically.

**CONTRAINDICATIONS**

- The IN.PACT AV DCB is contraindicated for use in the following anatomy and patient types:
- Coronary arteries, renal arteries, and supra-aortic/extraaxillary arteries
- Patients who are breastfeeding, pregnant, or are intending to become pregnant, or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure

**WARNINGS**

- A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2-3 years post-treatment compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Inadequate information is available to evaluate the potential mortality risk associated with the use of paclitaxel-coated devices for the treatment of other diseases/conditions, including this device indicated for use in arteriovenous dialysis fistulas. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options for their specific disease/condition with their patients.
- Use the product prior to the Use-by date specified on the package.
- Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.
- Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution).
- Do not move the guidewire during inflation of the IN.PACT AV DCB

**REFERENCES**

1. Results from the IN.PACT™ AV Access Clinical Trial found in the IN.PACT™ AV drug-coated balloon (DCB) Instructions For Use (IFU).
2. Data on file at Medtronic.
3. Lutonix IFU LUTONIX® 035 Drug Coated Balloon PT A Catheter Model 9010
4. Medicare Costs Associated with Arteriovenous Fistulas Among US Hemodialysis Patients, Thamer et al., AJKD, March 2018; Patients who initiated HD with a catheter.

**Access Circuit Primary Patency Rate based on KM estimates:** Defined as freedom from clinically driven target lesion revascularization (CD- TLR) or access circuit thrombosis measured through 210 days post-procedure.

**Target Lesion Primary Patency Rate based on KM estimates:** Defined as freedom from clinically driven re-reintervention of the target lesion or access thrombosis at 180 days post-procedure.

**Availibility:** For distribution in the USA only. 10/2019

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