GET AHEAD OF AV FISTULA RESTENOSIS

The IN.PACT™ AV Drug-Coated Balloon
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.
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 antirestenotic 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 excipient 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.¹⁻²
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.

56% FEWER INTERVENTIONS VS. PTA

Highest reported primary patency in an AV DCB study

86.1% TARGET LESION PRIMARY PATENCY AT 6 MONTHS

78.1% ACCESS CIRCUIT PRIMARY PATENCY AT 6 MONTHS

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

$5B Total direct expenditures annually in US

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.

AVF Success: AVF used for dialysis, working through 1st year
AVF Failure: Primary patency loss in year 1
AVF Failure: Secondary patency loss in year 1
AVF Failure: 2.5 year annualized costs for AVF maintenance

$7.9k
$13.3k
$17.8k
$22.7k

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

- Do not move the guidewire during inflation of the IN.PACT AV DCB.
- 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.

**REFERENCE**
1. Results from the IN.PACT AV Access Clinical Trial found in the IN.PACT AV drug-coated balloon (DCB) Instructions For Use (IFU).

**POTENTIAL ADVERSE EFFECTS**
- Potential adverse effects which may be associated with balloon catheterization may include, but are not limited to; the following: balloon rupture, detachment of a component of the balloon and/or catheter system, failure of the balloon to perform as intended, failure to cross the lesion. These complications may result in adverse events.

**CAUTION**
Federal law (USA) restricts this device to sale by or on the order of a physician.