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 expient 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
GET DEMONSTRATED SUPERIOR RESULTS

The IN.PACT™ AV DCB has been demonstrated superior to PTA in increasing patency and prolonging time between interventions.\(^1\) In separate IN.PACT AV\(^1\) and Lutonix AV\(^{11}\) clinical trials, only IN.PACT AV DCB met its effectiveness endpoints.\(^{1,2}\)

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\(^1\)**

Number of reinterventions required to maintain target lesion primary patency\(^1\)

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<thead>
<tr>
<th>PTA</th>
<th>IN.PACT™ AV DCB</th>
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**86.1% TARGET LESION PRIMARY PATENCY AT 6 MONTHS**

**78.1% ACCESS CIRCUIT PRIMARY PATENCY AT 6 MONTHS**

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

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.

$5B Total direct expenditures annually in US

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

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

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

AVF Success
AVF Failure

Medtronic
Ordering Information

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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 PTA Catheter Model 9010.
5. Patients who initiated HD with a catheter.
6. Thamer et al., AJKD, March 2018; Patients who initiated HD with a catheter.
7. Lutonix AV Clinical Trial: Target Lesion Primary Patency Rate based on KM estimates.

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 fistulae.

WARNINGs
• Do not exceed the rated burst pressure (RBP). The RBP is based on the results of in vitro testing. Use of pressures higher than RBP may result in napped balloon with possible internal damage and dissection.
• The safety of using multiple IN.PACT AV DCBs with a total drug dosage exceeding 15,105 μg paclitaxel has not been evaluated clinically.

PRECAUTIONS
• This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).
• Assess risks and benefits before treating patients with a history of severe reaction to contrast agents. Identify allergic reactions to contrast media and antiplatelet therapy before treatment and consider alternatives for appropriate management prior to the procedure.
• This product is not intended for the expansion or delivery of a stent.
• Do not use the IN.PACT AV DCB for predilation or for post-dilation.
• This product is designed for single patient use only. Do not reuse, reprocess, or resterilize this product.

POTENTIAL ADVERSE EFFECTS
• Potential adverse effects which may be associated with balloon catheterization may include, but are not limited to, the following:
  - Abrupt vessel closure, allergic reaction, arrhythmias, arterial or venous aneurysm, arterial or venous thrombosis, death, dissection, embolization, hemorrhoma, hemorrhage, hypotension/ hyperventilation, infection, ischemia or infarction of tissue/organ, loss of permanent access, gain, perforation or rupture of the artery or vein, pseudoaneurysm, restenosis of the diluted vessel, shock, stroke, vessel spasm or recoil.

Potential complications of peripheral balloon catheterization 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 effects.

Although systemic effects are not anticipated, potential adverse effects not captured above that may be unique to the paclitaxel drug coating include, but are not limited to, the following: allergic/immunologic reaction, anaphylaxis, anemia, gastrointestinal symptoms, hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia), hepatic enzyme changes, histologic changes in vessel wall, including inflammation, cellular damage, or necrosis, myalgia/myalgia, myositis, suppression, peripheral neuropathy.

POTENTIAL ADVERSE EFFECTS
- Refer to the Physician’s Desk Reference for more information on the potential adverse effects observed with paclitaxel. There may be other potential adverse effects that are unforeseen at this time.

Please refer appropriate product Instructions for Use for a detailed list of indications, warnings, precautions and potential adverse effects. This content is available electronically at products manuals.medtronic.com.

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