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 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.¹⁻²
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\(^1\) 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.

### Highest reported primary patency in an AV DCB study\(^1\)

- **86.1% Target Lesion Primary Patency**
  - At 6 months

- **78.1% Access Circuit Primary Patency**
  - At 6 months

![Diagram showing patency rates and number of reinterventions](image)

Number of reinterventions required to maintain target lesion primary patency\(^2\)

- **PTA**: 91
- **IN.PACT™ AV DCB**: 40

**56% Reduction**

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.

AVF Success:
AVF used for dialysis, working through 1st year

AVF Failure:
Primary patency loss in year 1

Secondary patency loss in year 1

2.5 year annualized costs for AVF maintenance

Δ = $14.8k PPPY (per patient per year)
### Ordering Information

<table>
<thead>
<tr>
<th>Ref. Number Usable Length 40 cm</th>
<th>Ref. Number Usable Length 80 cm</th>
<th>Ref. Number Usable Length 130 cm</th>
<th>Balloon Diameter (mm)</th>
<th>Balloon Length (mm)</th>
<th>Recommended Introductory Sheath (F)</th>
<th>Nominal Pressure (atm)</th>
<th>RBP (atm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IAV04004004P</td>
<td>IAV04004008P</td>
<td>-</td>
<td>4.0</td>
<td>40</td>
<td>5</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>IAV04006004P</td>
<td>IAV04006008P</td>
<td>-</td>
<td>4.0</td>
<td>60</td>
<td>5</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>IAV04008004P</td>
<td>IAV04008008P</td>
<td>-</td>
<td>4.0</td>
<td>80</td>
<td>5</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>IAV04120004P</td>
<td>IAV04120008P</td>
<td>-</td>
<td>4.0</td>
<td>120</td>
<td>5</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>IAV05004004P</td>
<td>IAV05004008P</td>
<td>-</td>
<td>5.0</td>
<td>40</td>
<td>6</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>IAV05006004P</td>
<td>IAV05006008P</td>
<td>-</td>
<td>5.0</td>
<td>60</td>
<td>6</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>IAV05008004P</td>
<td>IAV05008008P</td>
<td>-</td>
<td>5.0</td>
<td>80</td>
<td>6</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>IAV05120004P</td>
<td>IAV05120008P</td>
<td>-</td>
<td>5.0</td>
<td>120</td>
<td>6</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>IAV06004004P</td>
<td>IAV06004008P</td>
<td>-</td>
<td>6.0</td>
<td>40</td>
<td>6</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>IAV06006004P</td>
<td>IAV06006008P</td>
<td>-</td>
<td>6.0</td>
<td>60</td>
<td>6</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>IAV06008004P</td>
<td>IAV06008008P</td>
<td>-</td>
<td>6.0</td>
<td>80</td>
<td>6</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>IAV06120004P</td>
<td>IAV06120008P</td>
<td>-</td>
<td>6.0</td>
<td>120</td>
<td>6</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>IAV07004004P</td>
<td>IAV07004008P</td>
<td>-</td>
<td>7.0</td>
<td>40</td>
<td>7</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>IAV07006004P</td>
<td>IAV07006008P</td>
<td>-</td>
<td>7.0</td>
<td>60</td>
<td>7</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>IAV07008004P</td>
<td>IAV07008008P</td>
<td>-</td>
<td>7.0</td>
<td>80</td>
<td>7</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>IAV08004004P</td>
<td>IAV08004008P</td>
<td>IAV0804013P</td>
<td>8.0</td>
<td>40</td>
<td>7</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>IAV08006004P</td>
<td>IAV08006008P</td>
<td>IAV0806013P</td>
<td>8.0</td>
<td>60</td>
<td>7</td>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>IAV08008004P</td>
<td>IAV08008008P</td>
<td>IAV0808013P</td>
<td>8.0</td>
<td>80</td>
<td>7</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>IAV09004004P</td>
<td>IAV09004008P</td>
<td>IAV0904013P</td>
<td>9.0</td>
<td>40</td>
<td>7</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>IAV09006004P</td>
<td>IAV09006008P</td>
<td>IAV0906013P</td>
<td>9.0</td>
<td>60</td>
<td>7</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>IAV09008004P</td>
<td>IAV09008008P</td>
<td>IAV0908013P</td>
<td>9.0</td>
<td>80</td>
<td>7</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>IAV10004004P</td>
<td>IAV10004008P</td>
<td>IAV1004013P</td>
<td>10.0</td>
<td>40</td>
<td>7</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>IAV12004004P</td>
<td>IAV12004008P</td>
<td>IAV1200413P</td>
<td>12.0</td>
<td>40</td>
<td>9</td>
<td>6</td>
<td>9</td>
</tr>
</tbody>
</table>

**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™ DES Drug Coated Balloon PTA Catheter Model 9010.

**INDICATIONS FOR USE**

- Appropriate vessel preparation, as determined by the physician to achieve residual stenosis of ≤ 30%, is required prior to use of the IN.PACT AV DCB. Vessel preparation of the target lesion using high-pressure PTA for pre-dilation was studied in the IN.PACT AV Access clinical study. Other methods of vessel preparation, such as atherectomy, have not been studied clinically with IN.PACT AV DCB.

**CONTRAINDICATIONS**

- Coronal arteries, renal arteries, and supra-aortic cerebrovascular arteries
- Patients who cannot receive recommended antithrombotic and/or anticoagulant therapy
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
- Patients with known allergies or sensitivities to paclitaxel
- Women 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 paclitaxel content.

**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.

**CAUTION**

- 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 a ruptured 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 antithrombotic 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 pre-dilation or for post-dilation.
- This product is designed for single patient use only. Do not re-use, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- The use of this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events.
- The safety and effectiveness of the IN.PACT AV DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure has not been evaluated.
- The extent of the patient’s exposure to the drug coating is directly related to the number of balloons used. Refer to the Instructions for Use (IFU) for details regarding the use of multiple balloons and paclitaxel content.
- Appropriate vessel preparation, as determined by the physician to achieve residual stenosis of ≤ 30%, is required prior to use of the IN.PACT AV DCB. Vessel preparation of the target lesion using high-pressure PTA for pre-dilation was studied in the IN.PACT AV Access clinical study. Other methods of vessel preparation, such as atherectomy, have not been studied clinically with IN.PACT AV DCB.

**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, hemoptoma, hemorrhage, hypertension/ hyperextension, infection, ischemia or infarction of tissue/organ, loss of permanent access, pain, perforation or rupture of the artery or vein, pseudoaneurysm, restenosis of the dilated vessel, shock, stroke, vessel spasms or recoil.

**REFERENCES**

UC202003713 EN ©2019 Medtronic. All Rights Reserved.
Medtronic and Medtronic logo are trademarks of Medtronic. All other brands are trademarks of a Medtronic company. For distribution in the USA only. 10/2019