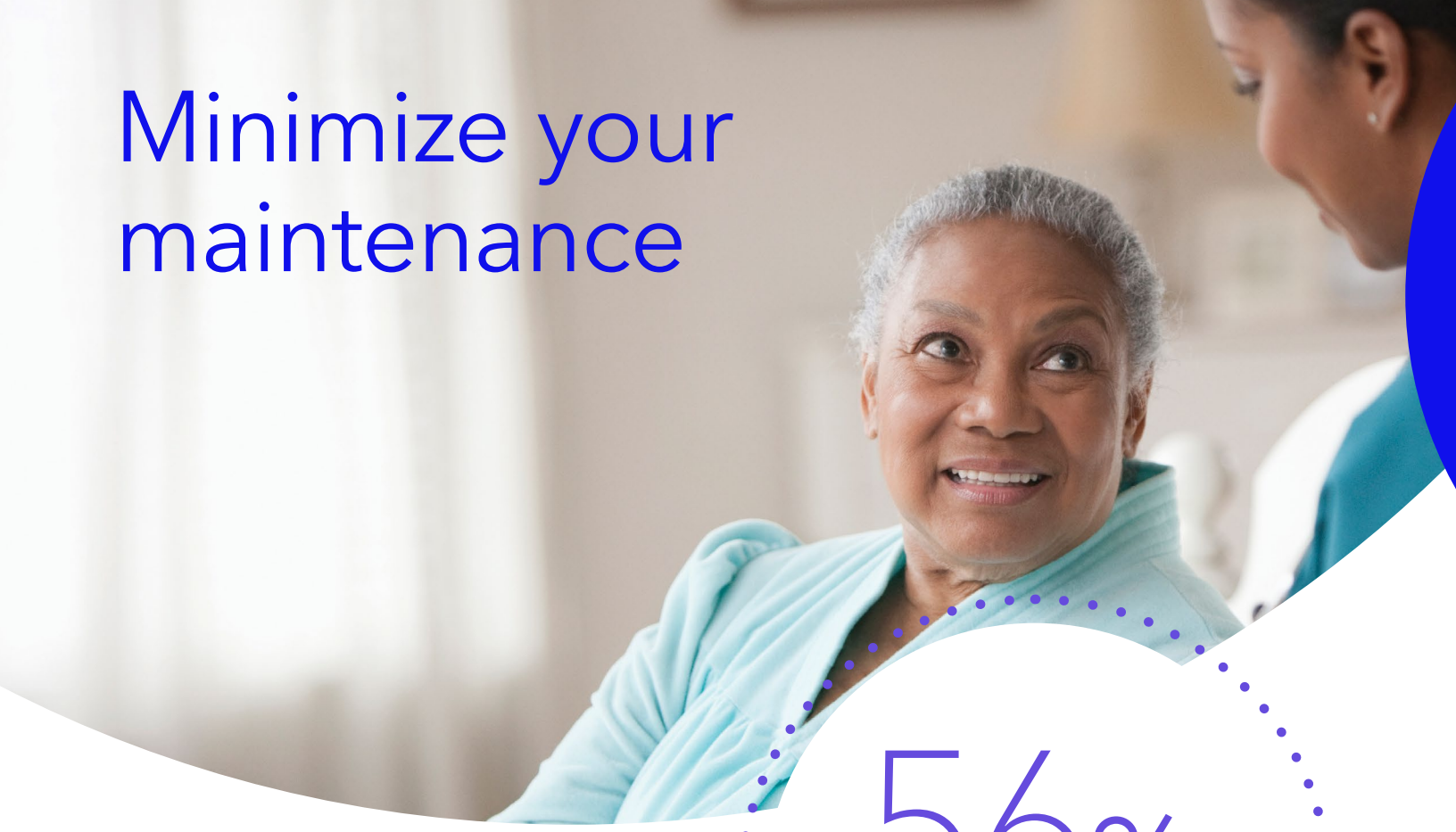
Medtronic

IN.PACT™ AV drug-coated balloon (DCB)

Proactive treatment, fewer interruptions

Explore a treatment option for people on dialysis with an AV fistula

Minimize your maintenance



What if you could reduce the number of procedures you need to keep your fistula open?

A fistula provides a critical lifeline during dialysis treatment. But keeping it open may require as many as three fistula maintenance procedures every year.[1]

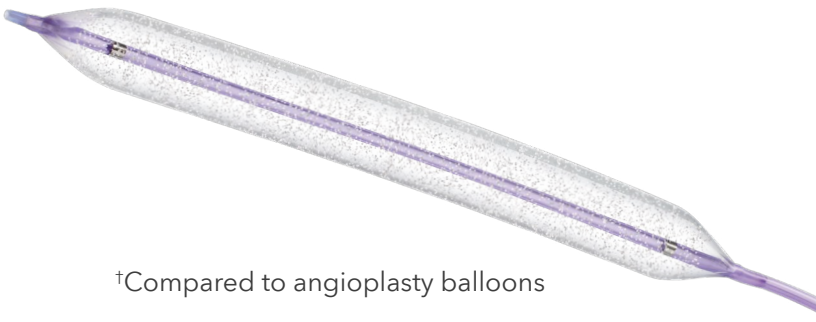
You may be able to reduce this total with a more effective, longer-lasting treatment: the Medtronic IN.PACT AV DCB.[2]

Treatment with the IN.PACT AV DCB is prescribed by your doctor. This treatment is not for everyone. Please talk to your doctor to see if it is right for you. Your doctor should discuss all potential benefits and risks with you. Risks may include pain, hemorrhage, arterial or venous aneurysm/thrombosis, dissection, infection, perforation or rupture, death. Although many patients benefit from the use of this treatment, results may vary.

56%

fewer fistula procedures†[2]

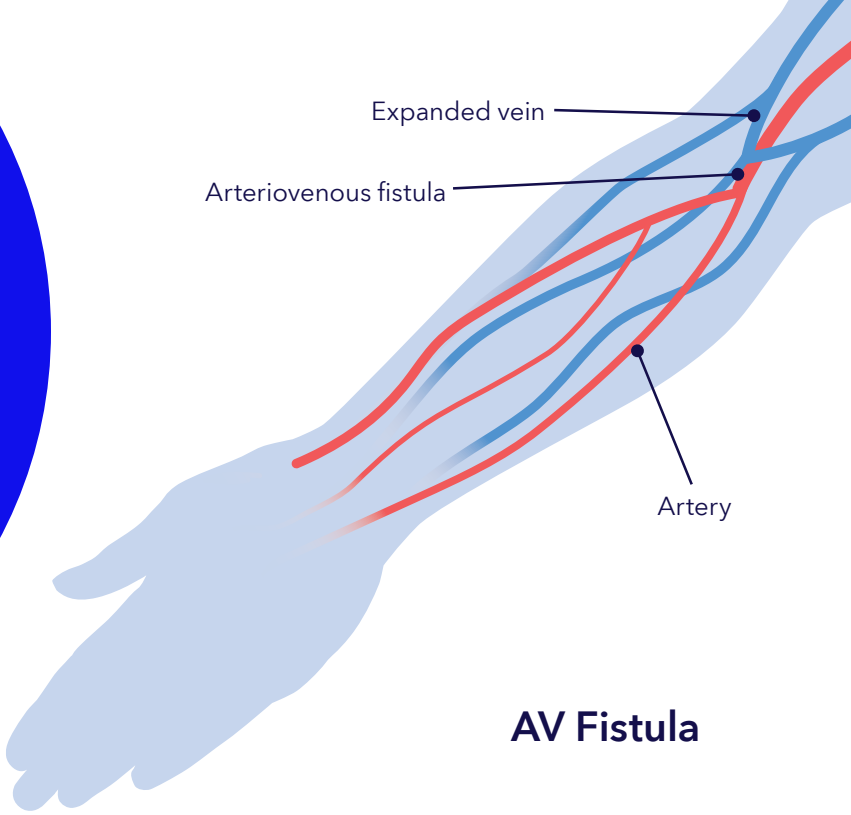
People treated with the Medtronic IN.PACT AV drug-coated balloon had 56% fewer fistula procedures through six months, so it could reduce the number of procedures you need.[2]



†Compared to angioplasty balloons

Understand your fistula

To perform hemodialysis, the doctor needs to move your blood to the dialysis machine and back again.



AV Fistula

The most common way to do this is with an arteriovenous (AV) fistula, which connects an artery and a vein, typically in the arm. An AV fistula increases blood flow, so you can receive dialysis. It also widens the vein, making it easier for the doctor to gain access to your bloodstream.

Caring for your fistula

It is very important to take care of the fistula. If it isn't working well, you may not be getting enough dialysis. Sometimes, however, there can be issues. The most common issue is when a fistula narrows because your body sends extra cells to "repair" the fistula. These cells build up, slowing blood flow and making dialysis less effective. Warning signs of a narrowed fistula include:

- Absence of vibration (or, "thrill") or sound (or, "bruit") at your fistula site
- Arm swelling
- Prolonged bleeding from the access site
- Numbness, tingling, coldness, or weakness in the arm
- Blue fingers or sores on fingertips

If your fistula has narrowed, you may need a maintenance procedure to treat it

Treating a narrowed fistula

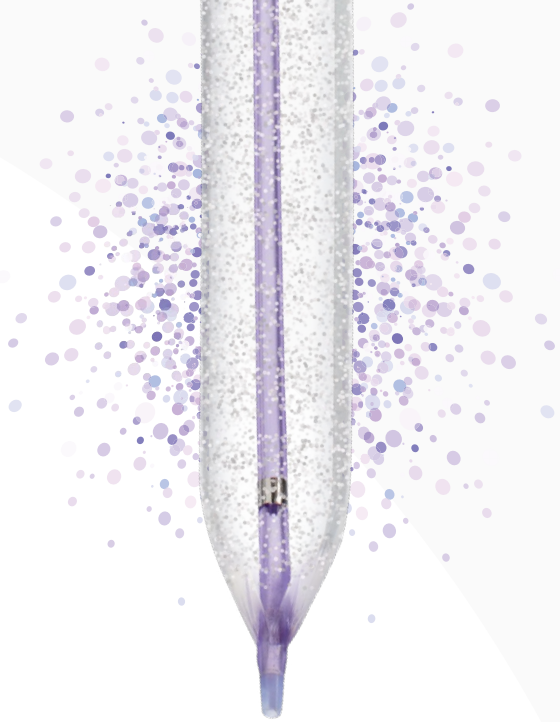
There are several minimally invasive (non-surgical) options doctors use to open a narrowed fistula. Two of the most common include:

Traditional angioplasty balloon

During this procedure, an inflatable balloon is placed into the fistula through a small tube (catheter). The balloon is inflated in the narrowed section of the fistula to open it back up again. Then the balloon is deflated and removed.

Drug-coated balloon

A drug-coated balloon uses the same procedure as a traditional angioplasty balloon, but with one important difference. This balloon is coated with a specialized drug called Paclitaxel that can help delay the re-narrowing of your fistula in the future. So it not only widens the fistula, it also helps keep it open longer.



Explore a new option

The Medtronic IN.PACT AV drug-coated balloon uses specially formulated technology to keep your fistula open longer than other options.[†2]

It works like a traditional angioplasty balloon: it is placed in the fistula, inflated in the narrow part, deflated, and removed. But it is also coated with medicine that remains in the vessel to help it stay open.

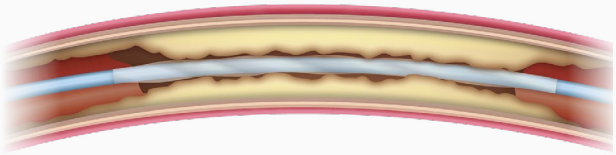
There are risks associated with this device. Please refer to the last page of this brochure for important risk information and potential adverse events. Your doctor can explain the risks and benefits that are specific to you.

[†]Compared to angioplasty balloons

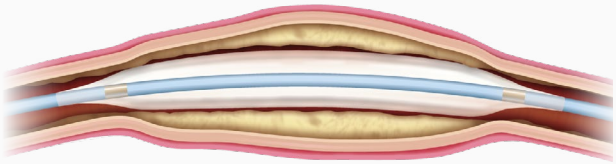
What to expect

The IN.PACT AV DCB procedure is performed in a hospital or clinic and includes a few key steps:

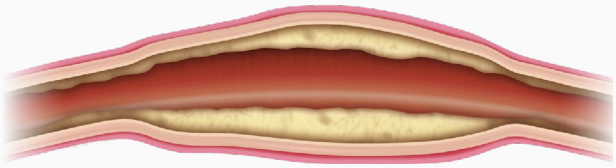
1. Placing a traditional angioplasty balloon over a guidewire into your fistula



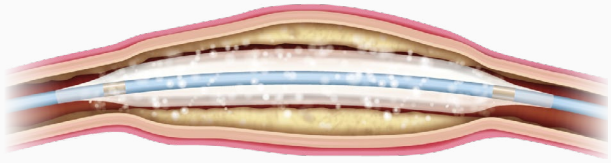
2. Inflating and deflating the balloon to open up your fistula



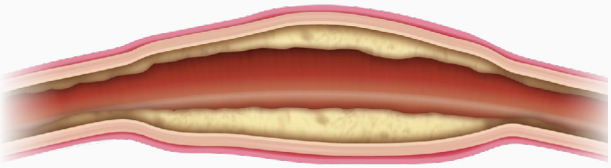
3. Removing the balloon, leaving the vessel prepared for the Medtronic IN.PACT AV DCB



4. Placing the IN.PACT AV DCB in the same location and inflating it to deliver the drug



5. Deflating the IN.PACT AV DCB and removing it



After your procedure

Once the procedure is complete, light pressure is placed on the small hole where the needle was inserted. This will help to stop any bleeding. An adhesive bandage or small suture will be placed at the site, and you will be moved to a recovery area.

The puncture site may be sore or bruised after the procedure but typically will feel better in a few days. Watch for bleeding, swelling, pain, or discomfort at the puncture site. If you experience any of these symptoms, tell your doctor.

When is the IN.PACT AV DCB not recommended?

Your doctor will decide what is best, but may not recommend DCB treatment if any of the following are true:

- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy.
- Patients judged to have a lesion that prevents complete inflation of a traditional 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 there is a potential for adverse reactions in nursing infants from Paclitaxel exposure.

Ask your care team today

Talk to your care team

Ask your care team if the Medtronic IN.PACT AV drug-coated balloon could minimize your maintenance procedures and help you experience longer periods of uninterrupted dialysis.

Questions you can ask include:

- Do I qualify for treatment with a drug-coated balloon?
- Could the IN.PACT AV drug-coated balloon reduce the number of maintenance procedures I need in the future?
- Can you tell me more about the IN.PACT AV drug-coated balloon?
- Is the IN.PACT AV drug-coated balloon available where I receive maintenance procedures?

References

[1]United States Renal Data System. 2022 USRDS annual data report.

[2]Lookstein RA, Haruguchi H, Ouriel K, et al. IN.PACT AV Access Investigators. Drug-Coated Balloons for Dysfunctional Dialysis Arteriovenous Fistulas. *N Engl J Med*. August 20, 2020; 383(8):733-742. Highlighted results reported at both 180 and 210 days.

[3]Katsanos K, Spiliopoulos S, Kitrou P, Krokidis M, Karnabatidis D. Risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the leg: a systematic review and meta-analysis of randomized controlled trials. *J. Am. Heart Assoc.* 2018 Dec 18;7(24):e011245.

Warnings

A study published in December 2018 in the Journal of the American Heart Association reported an increased risk of death starting at 2 years and up to 5 years after treatment with paclitaxel-coated devices in the upper leg compared to treatment with uncoated devices.[3] The U.S. Food and Drug Administration also observed this increased risk of death associated with paclitaxel-coated devices in the upper leg that are approved in the U.S. Additional studies are being conducted to better understand this risk. This device is a paclitaxel-coated device used in dialysis fistula. The risk for this device is unknown. However, this is important information for you to have when making a decision about treatment options. Your doctor can explain the risks and benefits of paclitaxel-coated devices that are specific to you.

Potential Adverse Effects Associated with the IN.PACT AV DCB

Potential adverse effects that 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
- Hematoma
- Hemorrhage
- Hypotension/hypertension
- Ischemia or infarction of tissue/organ
- Infection
- 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

Although systemic effects are not anticipated, potential adverse effects that may be unique to the Paclitaxel drug coating include, but are not limited to, the following:

- Allergic/immunologic reaction
- Alopecia
- Anemia
- Gastrointestinal symptoms
- Hematologic dyscrasia (including leucopenia, neutropenia, thrombocytopenia)
- Hepatic enzyme changes
- Histologic changes in vessel wall, including inflammation, cellular damage, or necrosis
- Myalgia/arthralgia
- Myelosuppression
- Peripheral neuropathy

IN.PACT AV: Summary of Clinical Information

The IN.PACT AV drug-coated balloon was evaluated in the IN.PACT AV Access Study. The IN.PACT AV Access Study enrolled 330 patients in the United States, Japan, and New Zealand. The clinical trial conclusively demonstrated safety and effectiveness of the IN.PACT AV DCB when compared to conventional balloon catheters. The results of this study showed that the IN.PACT AV DCB is safe and effective for treating restenotic obstructive lesions of an AV both de novo and restenotic obstructive lesions. Your doctor can explain the risks and benefits that are specific to you.

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