

Medtronic

AV Fistula Maintenance

Doctor discussion guide

Understand your options and prepare for a clear, comfortable conversation.

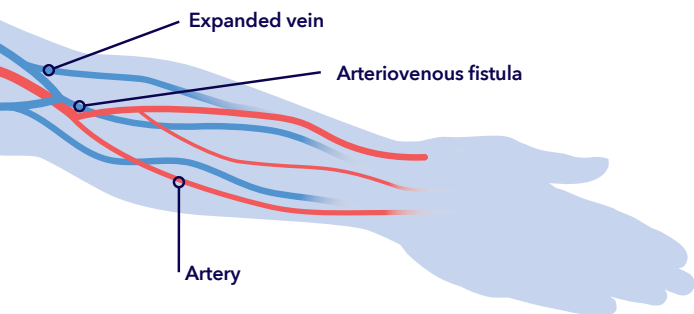


If you have an arteriovenous (AV) fistula for hemodialysis, this guide can help you understand fistula maintenance and have a productive conversation about these procedures with your doctor.

What is hemodialysis access?

Hemodialysis requires a way to safely and repeatedly gain access to your bloodstream. An AV fistula is the most common type of access. It connects an artery and a vein, typically in the arm, to:

- Increase blood flow for efficient dialysis
- Widen the vein for easier access



How does an AV fistula change over time?

A common issue with AV fistulas is that they get too narrow. Narrowing happens when your body sends extra cells to “repair” the fistula. These cells build up, slowing blood flow and making dialysis less effective.

Questions to ask

- How long will my AV fistula last?
- How long will my fistula allow effective dialysis?
- What are some warning signs of narrowing?
- How is narrowing typically treated?

How is a narrowed AV fistula treated?

If your fistula has narrowed, you will need a maintenance procedure. There are several minimally invasive options doctors use to do this, including traditional angioplasty balloons and drug-coated balloons.

Traditional angioplasty balloon



- Small inflatable balloon
- Placed in fistula through a catheter
- Inflated in the narrowed section
- Deflated and removed

Drug-coated balloon



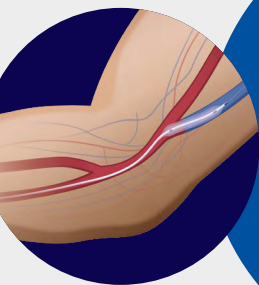
- Used after a traditional angioplasty balloon
- Coated with a specialized drug
- Drug helps delay re-narrowing
- Helps keep fistula open longer

Questions to ask

- What does a maintenance procedure feel like?
- What are the differences between these balloons?
- Do you recommend drug-coated balloons?
- How many maintenance procedures will I need every year?
- Could a drug-coated balloon reduce this number?

Minimizing your maintenance

Keeping your fistula open may require as many as three maintenance procedures every year.² You may be able to reduce this total with the Medtronic IN.PACT™ AV DCB. In fact, people treated with it had 56% fewer fistula maintenance procedures through six months.^{†1}



56%

fewer fistula
maintenance
procedures^{†1}

† Compared to angioplasty balloons

There are risks associated with this device which may include pain, hemorrhage, arterial or venous aneurysm/thrombosis, dissection, infection, perforation or rupture, death. Please refer to the last page of this brochure for important risk information and a full list of potential adverse events. Your doctor can explain the risks and benefits that are specific to you.

Questions to ask

- Is the IN.PACT AV DCB right for me?
- What are its advantages compared to other balloons?
- Could the IN.PACT AV DCB keep my fistula open longer?
- If my fistula stays open longer, does that mean fewer maintenance procedures?
- Do you recommend the IN.PACT AV DCB balloon?



Proactive treatment, fewer interruptions

The Medtronic IN.PACT AV drug-coated balloon (DCB) uses specially formulated technology to keep your fistula open longer than other options.^{†1}

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.

See for yourself

Learn more about the IN.PACT AV DCB. Scan the code or visit [medtronic.com/inpactAVdcb](https://www.medtronic.com/inpactAVdcb)



[†] Compared to angioplasty balloons

References

- ¹ 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.
- ² United States Renal Data System. 2022 USRDS annual data report.
- 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.

[medtronic.com/inpactAVdcb](https://www.medtronic.com/inpactAVdcb)

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