

Medtronic

Hemodialysis Access

Doctor discussion guide

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



This guide can help you understand the basics of hemodialysis access, ask informed questions, and have a productive conversation when you meet with your doctor.



Explore a new option

The Ellipsys™ vascular access system offers a minimally invasive way to create an AV fistula for hemodialysis.¹

- No surgery, no sutures, no surgical scar, no implant
- Presents fewer complications over the lifetime of the dialysis access¹

This procedure is not for everyone. Please talk to your doctor to see if it is right for you. Risks may include total/partial occlusion or stenosis of the anastomosis, failure to achieve fistula maturation, Steal Syndrome, hematoma, infection, and need for vessel superficialization or other maturation assistance procedures. Although many patients benefit from the use of this device, results may vary. Your doctor should discuss all terms, potential benefits, and risks with you.

What is hemodialysis access?

Hemodialysis requires a way to safely and repeatedly gain access to your bloodstream.

There are three ways to do this. Your doctor will explain more about each and help you choose the best one.

1. Arteriovenous (AV) Fistula

- Most common access type
- Connects an artery and a vein, typically in the arm
- Takes one to four months to prepare

2. Arteriovenous (AV) Graft

- Requires surgery that connects an artery and a vein with a small tube (implant)
- Takes two weeks to prepare

3. Catheter

- Made of soft plastic tubing
- Placed in a large vein in the neck or upper chest
- Ready to use immediately

Questions to ask

- How will I feel after treatment?
When will I feel better?
- How long will I be on dialysis?
- How can I get the most out of every dialysis session?
- Will I need to take any new medications or over-the-counter treatments?
- What if I need to travel?

How is an AV fistula created?

An AV fistula is the most common access point for hemodialysis. If your doctor recommends this option, it is important to know there are two ways to create an AV fistula.

Surgery

- Most common option
- Connects the artery and vein with sutures during an outpatient surgery
- Usually takes an hour or more to perform²
- Requires an open incision that leaves a scar

Endovascular: Medtronic Ellipsys vascular access system

- More recent option
- Connects the artery and vein with heat during a minimally invasive procedure
- Procedure usually takes 30 minutes or less¹
- Does not require an incision or sutures – only a small needle stick
- May place less stress on the heart compared to a traditional upper-arm surgical fistula³

There are risks associated with this procedure which may include total/partial occlusion or stenosis of the anastomosis, failure to achieve fistula maturation, Steal Syndrome, hematoma, infection, and need for vessel superficialization or other maturation assistance procedures. 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

Access options

- Which access option is right for me?
- What are the advantages of each option?
- What are the side effects?
- How soon will we need to make a decision?

AV fistula creation

- Which options are available to me?
- What are the advantages of each option?
- What are the side effects?
- Which option has better long-term results?

Endovascular AV fistula creation

- What options are available for endovascular AV fistula creation?
- Is the Ellipsys system right for me?
- What are the advantages of the Ellipsys system compared to other approaches?
- What complications does the Ellipsys system help reduce?
- Do you recommend the Ellipsys system?



**See for
yourself**

Learn more about the Ellipsys system. Scan the code or visit [Medtronic.com/ellipsysAVF](https://www.Medtronic.com/ellipsysAVF)



References

- ¹ Hull JE, et al. The pivotal multicenter trial of ultrasound-guided percutaneous arteriovenous fistula creation for hemodialysis access. *J Vasc Interv Radiol*. Feb 2018; 29(2):149-158.e5.
- ² University of Utah. Arteriovenous Fistula (AV Fistula). University of Utah Health website. <https://healthcare.utah.edu/cardiovascular/treatments/arteriovenous-fistula.php>. Published 2022. Accessed Oct. 5, 2022.
- ³ Mallios A, et al. Mid-term results of percutaneous arteriovenous fistula creation with the Ellipsys vascular access system, technical recommendations and an algorithm for maintenance. *J Vasc Surg*. Dec 2020; 72(6):2097-2106.

Risks and Warnings

Contraindications: The Ellipsys™ system is not indicated for patients with target blood vessels that are too small to be used with the Ellipsys system.

Warnings: The Ellipsys system has only been studied for the creation of an arteriovenous fistula (AV Fistula or AVF) using the proximal radial artery and the adjacent perforating vein. The Ellipsys system is not intended to treat patients with significant vascular disease or blockage in the target vessels. It is recommended that a follow-up evaluation is performed to determine if any additional treatment is needed.

Precautions:

- Additional treatment may be needed to increase and direct blood flow into the target vein and to keep the AVF open.
- Short-term or long-term treatment to slow down or stop the coagulation of blood may be needed, as determined by your doctor.

Potential Adverse Events: As with any procedure, there is a chance that complications may occur. The following are some of the risks that may be associated with the creation or maintenance of your arteriovenous fistula. Discuss any questions you may have with your doctor. Risks include but are not limited to the following:

- Total blockage, partial blockage or narrowing of the fistula or outflow vein next to the fistula
- Narrowing of the central AVF outflow vein which requires treatment
- Vein may not get big enough, after the AVF is created
- If embolization coil is used to direct blood flow, the coil may not completely tie off the vessels, which could require an additional coil
- Lack of blood flow to the hand (Steal Syndrome), which can cause symptoms including but not limited to hand numbness, pain, coldness, and/or weakness
- Solid swelling of clotted blood within the arm
- Infection or other complications
- Need for additional procedures to help access the AVF for dialysis
- Need for additional procedures to help the vein get bigger after the AVF is created

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

Important Information: Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device.

Medtronic

[Medtronic.com/ellipsysAVF](https://www.Medtronic.com/ellipsysAVF)

UC202308176 EN ©2023 Medtronic. Medtronic, Medtronic logo, and Engineering the extraordinary are trademarks of Medtronic. All other brands are trademarks of a Medtronic company. 03/2023