Less invasive, long lasting

The Ellipsys™ vascular access system offers a less invasive approach to creating an AV fistula for hemodialysis.[1,2]

Medtronic

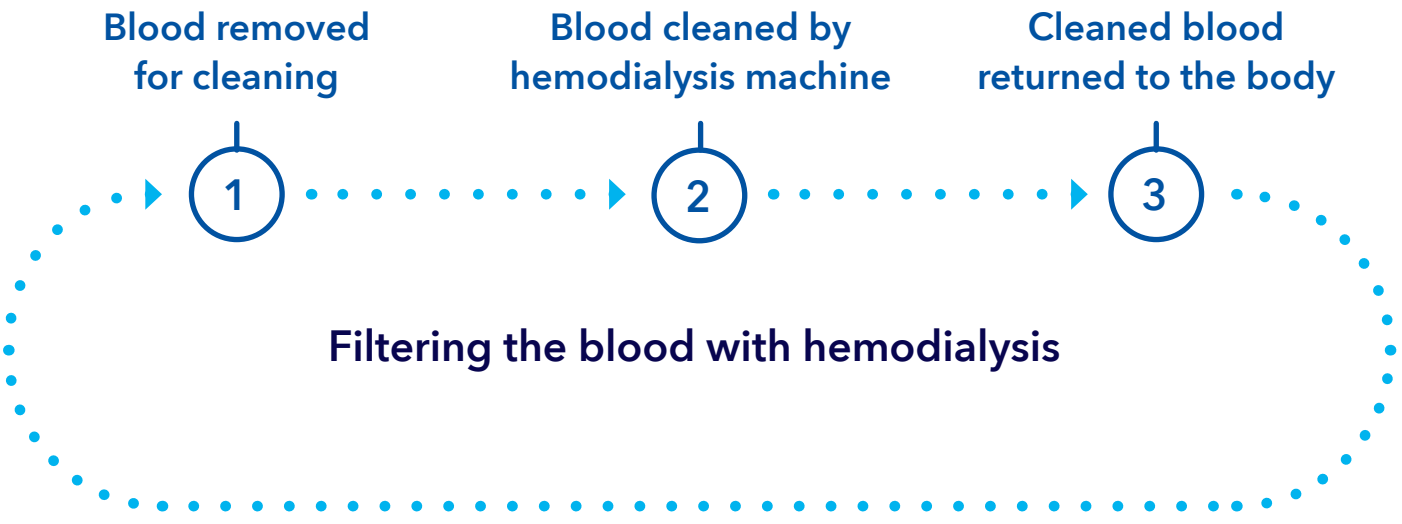
Understanding hemodialysis

What is dialysis?

Dialysis filters waste from your body, which helps overcome the loss of function caused by chronic kidney disease (CKD). Dialysis can be done with a machine, which is called hemodialysis. Hemodialysis is the most common way to treat CKD.

How hemodialysis works

During hemodialysis, your blood is filtered by a machine that removes waste and excess water, then returns the clean blood to your body. The process takes about three to five hours and is typically done three times a week.[3]



What is hemodialysis access?

Hemodialysis involves repeatedly gaining access to your bloodstream, so it can be moved to the dialysis machine and back again. There are three ways to enable access, each with a different preparation time before it is ready for use. Your doctor will explain each one and help you make the right choice.

Time until dialysis begins

Catheter: Immediate

- Used when an AV graft or fistula is not possible
- Used if dialysis is required immediately
- Catheter (soft plastic tube) placed in a large vein (neck or upper chest)

Arteriovenous (AV) Graft: 2 weeks

- Requires surgery
- Connects an artery and a vein with a small tube (implant)
- Increases blood flow for efficient dialysis

Arteriovenous (AV) Fistula: 4-16 weeks

- Most common option
- Connects an artery and a vein, typically in the arm
- Increases blood flow for efficient dialysis
- Widens vein for easier access

Creating your AV fistula

An AV fistula is the preferred[4] way to gain access for hemodialysis. If this option is right for you, there are two ways to create it. One is surgical and one is not.

Surgical

The most common way to create an AV fistula is surgery, during which the artery and vein are sutured together. This is typically done on an outpatient basis, and it usually takes an hour or more to perform.[5] Surgery has been the standard approach for more than 50 years. But it does require an open incision and leaves a scar.

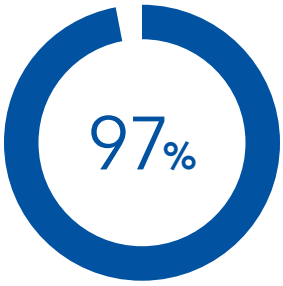
Non-surgical

A newer way to create an AV fistula is an endovascular approach, which uses a minimally invasive procedure that does not require open surgery. Instead, a special device fuses the artery and vein together without sutures or an implant. This approach leaves no scar, and in some cases reduces the risk of certain potential complications of AV fistula creation.[6,7]

Meet the Ellipsys system

The Ellipsys™ vascular access system offers a fast, non-surgical approach to AV fistula creation, using heat to fuse the artery and vein together during a procedure that usually takes 30 minutes or less.[2]

Using the Ellipsys system, 98.4% of patients have a working fistula at three months[2]



Using the Ellipsys system, 97% of patients with a prior access procedure rated their fistula as good or better[7]

Patients perceived the level of pain during the procedure as excellent or very good (manageable)[7]

Patients expressed satisfaction with avoiding surgery[7]

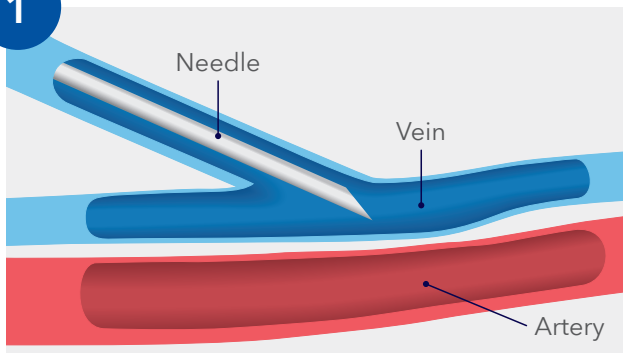
AV fistulas created with the Ellipsys system were associated with improved body image compared to surgical patients[7]

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.

The Ellipsys system experience

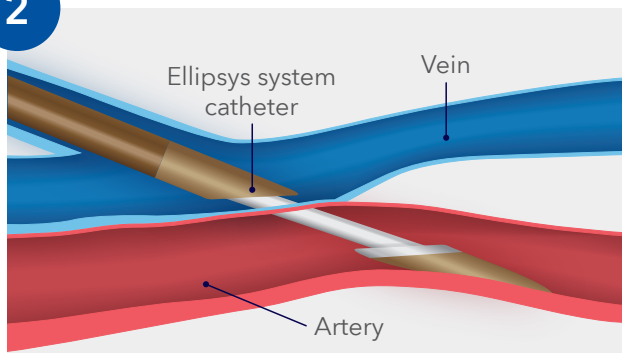
Steps in the procedure

1



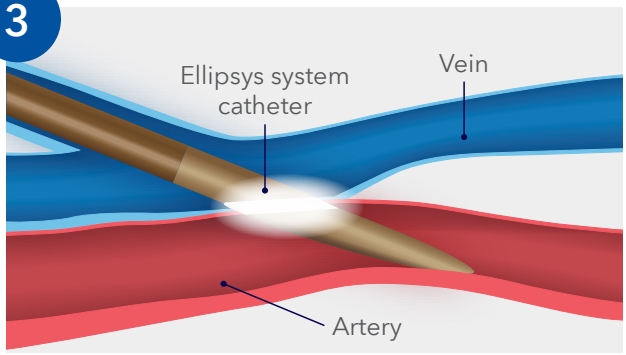
Venous puncture

2



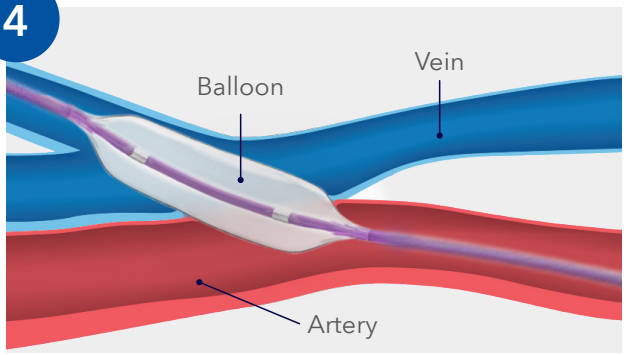
Radial artery puncture

3



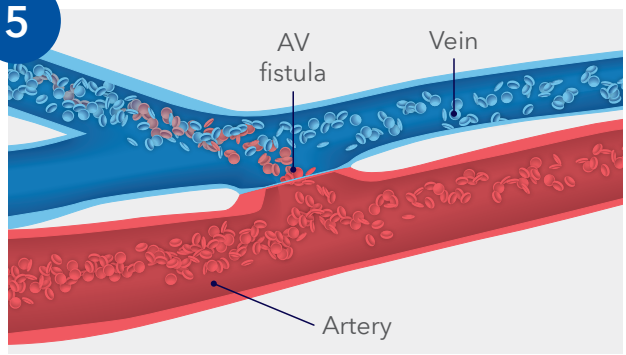
Catheter Positioning and activation

4



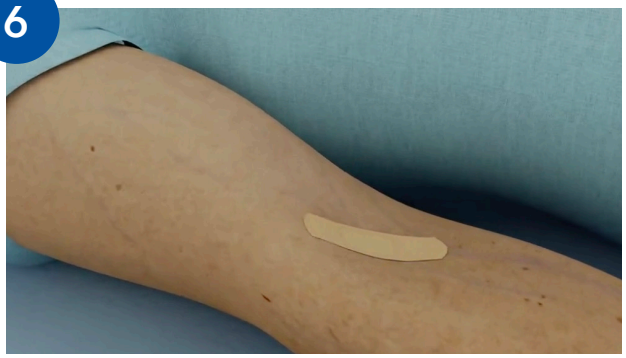
Balloon inflation

5



Fistula created

6



Post-op bandage

Talk to your doctor to see if the Ellipsys system is right for you.
Learn more at **medtronic.com/ellipsysAVF.**

Four stages of AV fistula creation

Getting an AV fistula with the Ellipsys system follows four stages:

1

Selection

A simple in-office test (ultrasound imaging) can determine if you are a good candidate for an endovascular AV fistula.

2

Creation

The minimally invasive procedure using the Ellipsys system usually takes 30 minutes or less to perform.[2]

3

Maturation

Follow-ups over a six-week period help establish if the AV fistula is mature enough to support hemodialysis.

4

Cannulation

Cannulation occurs when the AV fistula is ready to allow regular hemodialysis.

References

[1] Shahverdyan R, et al. Comparison of Ellipsys percutaneous and proximal forearm gracz-type surgical arteriovenous fistulas. *Am J Kidney Disease.* Oct 2021; 78(4):520-529.

[2] 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.

[3] National Kidney Foundation. Hemodialysis. NKF Website. https://www.kidney.org/atoz/content/hemodialysis. Published 2015. Accessed Oct. 5, 2022.

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[5] 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.

[6] 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.

[7] Beathard GA, Litchfield T, Jennings WG. Two-year cumulative patency of endovascular arteriovenous fistula. *J Vasc Access.* May 2020; 21(3):350-356.

Brief Statement

Indications: The Ellipsys™ system is indicated for the creation of a proximal radial artery to perforating vein anastomosis via a retrograde venous access approach in patients with a minimum vessel diameter of 2.0 mm and less than 1.5 mm of separation between the artery and vein at the fistula creation site who have chronic kidney disease requiring dialysis. Contraindications: The Ellipsys™ system is contraindicated for use in patients with target vessels that are < 2 mm in diameter. The Ellipsys™ System is contraindicated for use in patients who have a distance between the target artery and vein > 1.5 mm.

Warnings:

- The Ellipsys™ system has only been studied for the creation of an AV fistula using the proximal radial artery and the adjacent perforating vein. It has not been studied in subjects who are candidates for surgical fistula creation at other locations, including sites distal to this location.
- The Ellipsys™ system is not intended to treat patients with significant vascular disease or calcification in the target vessels.
- The Ellipsys™ system has only been studied in subjects who had a patent palmar arch and no evidence of ulnar artery insufficiency.
- Use only with the Ellipsys™ Power Controller, Model No. AMI-1001.
- The Ellipsys™ Catheter has been designed to be used with the 6 F Terumo Glidesheath Slender™*. If using a different sheath, verify the catheter can be advanced through the sheath without resistance prior to use.
- Use ultrasound imaging to ensure proper placement of the catheter tip in the artery before retracting the sheath, since once the distal tip of the catheter has been advanced into the artery, it cannot be easily removed without creation of the anastomosis. If the distal tip is advanced into the artery at an improper location, complete the procedure and remove the catheter as indicated in the directions for use. It is recommended that a follow-up evaluation of the patient is performed using appropriate clinical standards of care for surgical fistulae to determine if any clinically significant flow develops that require further clinical action.

Precautions

- This product is sterilized by ethylene oxide gas.
- Additional procedures are expected to be required to increase and direct blood flow into the AVF target outflow vein and to maintain patency of the AVF. Care should be taken to proactively plan for any fistula maturation procedures when using the device.
- In the Ellipsys™ study, 99% of subjects required balloon dilatation (PTA) to increase flow to the optimal access vessel and 62% of subjects required embolization coil placement in competing veins to direct blood flow to the optimal access vessel. Prior to the procedure, care should be taken to assess the optimal access vessel for maturation, the additional procedures that may be required to successfully achieve maturation, and appropriate patient follow-up. Please refer to the "Arteriovenous
- Fistula (AVF) Maturation" section of the labeling for guidance about fistula flow, embolization coil placement, and other procedures to assist fistula maturation and maintenance.
- The Ellipsys™ System is intended to only be used by physicians trained in ultrasound guided percutaneous endovascular interventional techniques using appropriate clinical standards for care for fistula maintenance and maturation including balloon dilatation and coil embolization.
- Precautions to prevent or reduce acute or longer-term clotting potential should be considered. Physician experience and discretion will determine the appropriate anticoagulant/antiplatelet therapy for each patient using appropriate clinical standards of care.

Potential Adverse Events

Potential complications that may be associated with creation and maintenance of an arteriovenous fistula include, but may not be limited to, the following:

- Total occlusion, partial occlusion or stenosis of the anastomosis or adjacent outflow vein
- Stenosis of the central AVF outflow requiring treatment per the treatment center's standard of care
- Failure to achieve fistula maturation
- Incomplete vessel ligation when using embolization coil to direct flow
- Steal Syndrome
- Hematoma
- Infection or other complications
- Need for vessel superficialization or other maturation assistance procedures.

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.

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