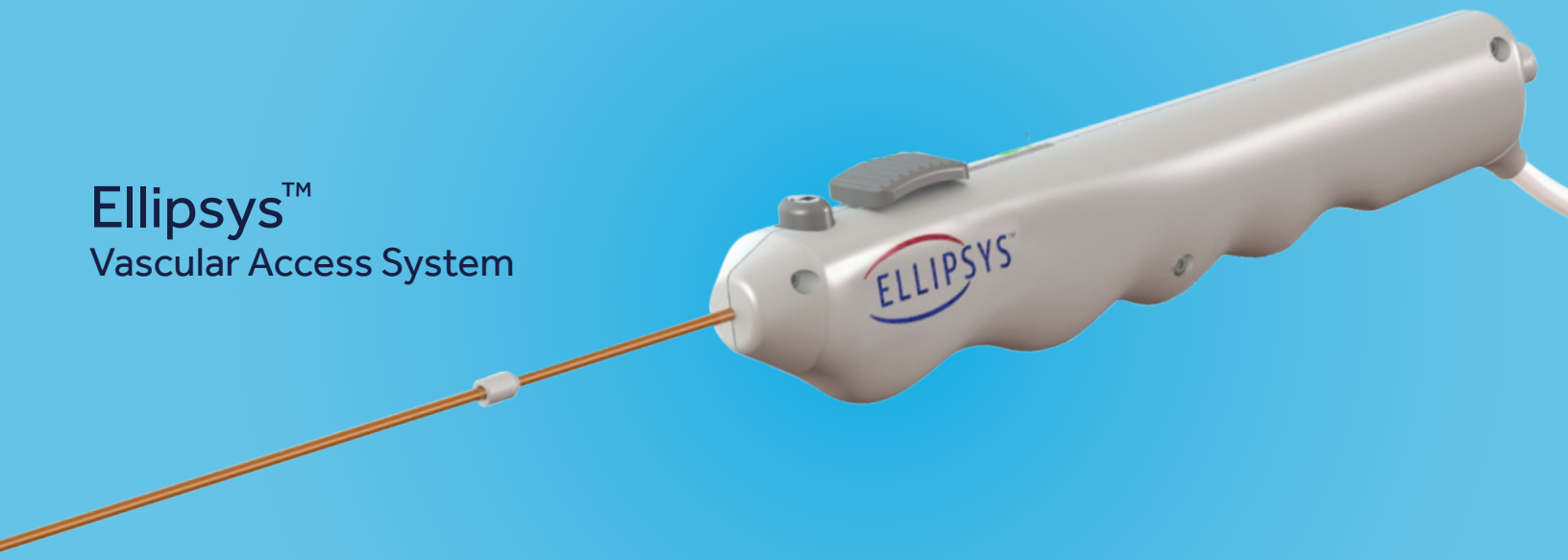
TRANSFORM YOUR AV FISTULA CREATION

Ellipsys™
Vascular Access System



91.6%
cumulative patency at 2 years[1]

3,000+
successful endoAVF procedures[2]

18+
peer-reviewed publications[3]

Medtronic
Further, Together

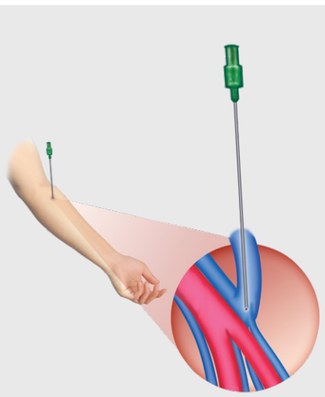
A FASTER, MORE EFFICIENT, NON-SURGICAL APPROACH TO FISTULA CREATION

The Ellipsys™ Vascular Access System transforms the standard surgical AV fistula creation into a reproducible, minimally invasive procedure that requires no implant or suture, and allows patients to leave with just a single puncture.[4]

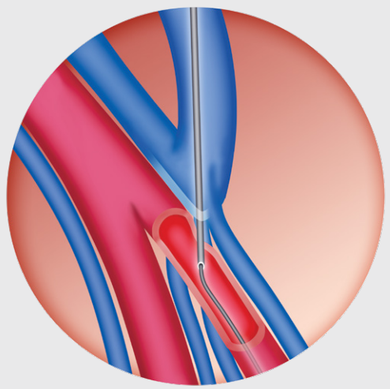
The FDA-cleared Ellipsys™ system is a unique and less invasive way to create an AV fistula for hemodialysis and offers:

- Patented tissue fusion technology, enabling immediate, minimally invasive creation of permanently fused anastomosis.[4]
- A track record of achievement in over 3,000 procedures[2] in HOPD, ASC, and OBL settings.
- The only endoAVF system with pivotal trial data conducted in the United States[4] with a peer-reviewed publication of patency outcomes through 2 years.[2]

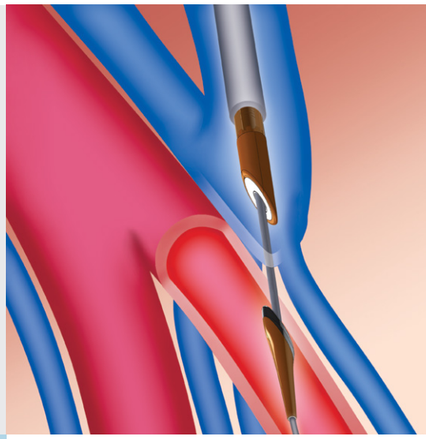
And that's reason enough to learn more about Ellipsys today.



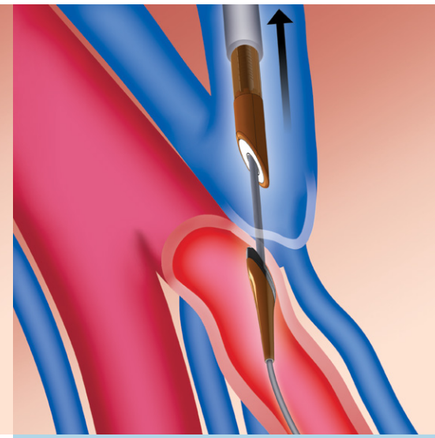
1. Under ultrasound guidance, a micropuncture needle is used to access the deep communicating vein.



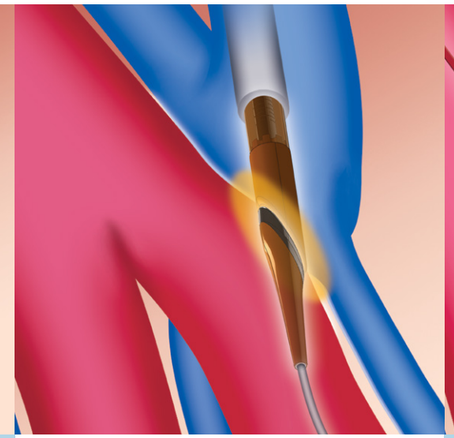
2. The needle is advanced into the radial artery (RA) allowing the placement of a guidewire into the artery. The needle is removed and an access sheath is advanced into the RA (not shown).



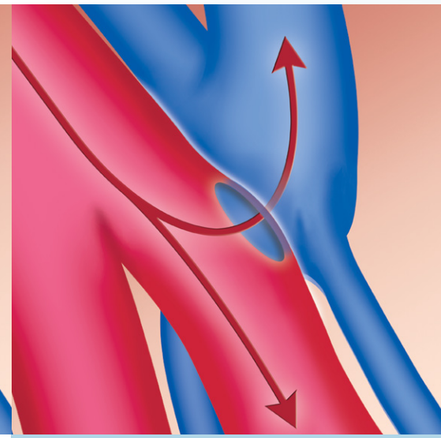
3. The Ellipsys catheter is advanced over-the-wire until the catheter tip is positioned within the RA.



4. Light tension is applied to the catheter to ensure the tip is seated against the arterial wall.



5. The catheter is closed and activated, creating a fused and permanent anastomosis. No implants or sutures required.



6. Catheter is removed resulting in AVF flow.

Ellipsys™ Vascular Access System

	MODEL	DESCRIPTION
	AMI 6005	Ellipsys™ Vascular Access Catheter (6F, disposable)
	AMI 1001	Ellipsys™ Power Controller (110-240V, 50/60Hz, reusable)

References

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

[2] Data on file at Medtronic.

[3] Data on file at Medtronic.

[4] Hull JE, Jennings WC, Cooper RI, Waheed U, Schaefer ME, Narayan R. The Pivotal Multicenter Trial of Ultrasound-Guided Percutaneous Arteriovenous Fistula Creation for Hemodialysis Access. *J Vasc Interv Radiol*. February 2018;29(2):149-158.e5.

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 resistant 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 labelling supplied with each device.

Aortic | **Peripheral** | Venous
3033 Campus Drive, N550
Plymouth, MN 55441
USA

24-hour Technical Support
Toll free: +1.800.328.2518

Orders
Tel: +1.763.514.8510
Toll free: +1.800.716.6700
Fax: +1.877.697.4841
Email: rs.cusvasorders@medtronic.com

CardioVascular LifeLine Customer Support
Tel: +1.763.526.7890
Toll free: +1.877.526.7890

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