Medtronic

Less invasive, long lasting

Ellipsys™ Vascular Access System

The Ellipsys™ vascular access system offers a single point of venous access that makes AVF creation easier on your ESKD patients.[1]

Table of contents

Medtronic

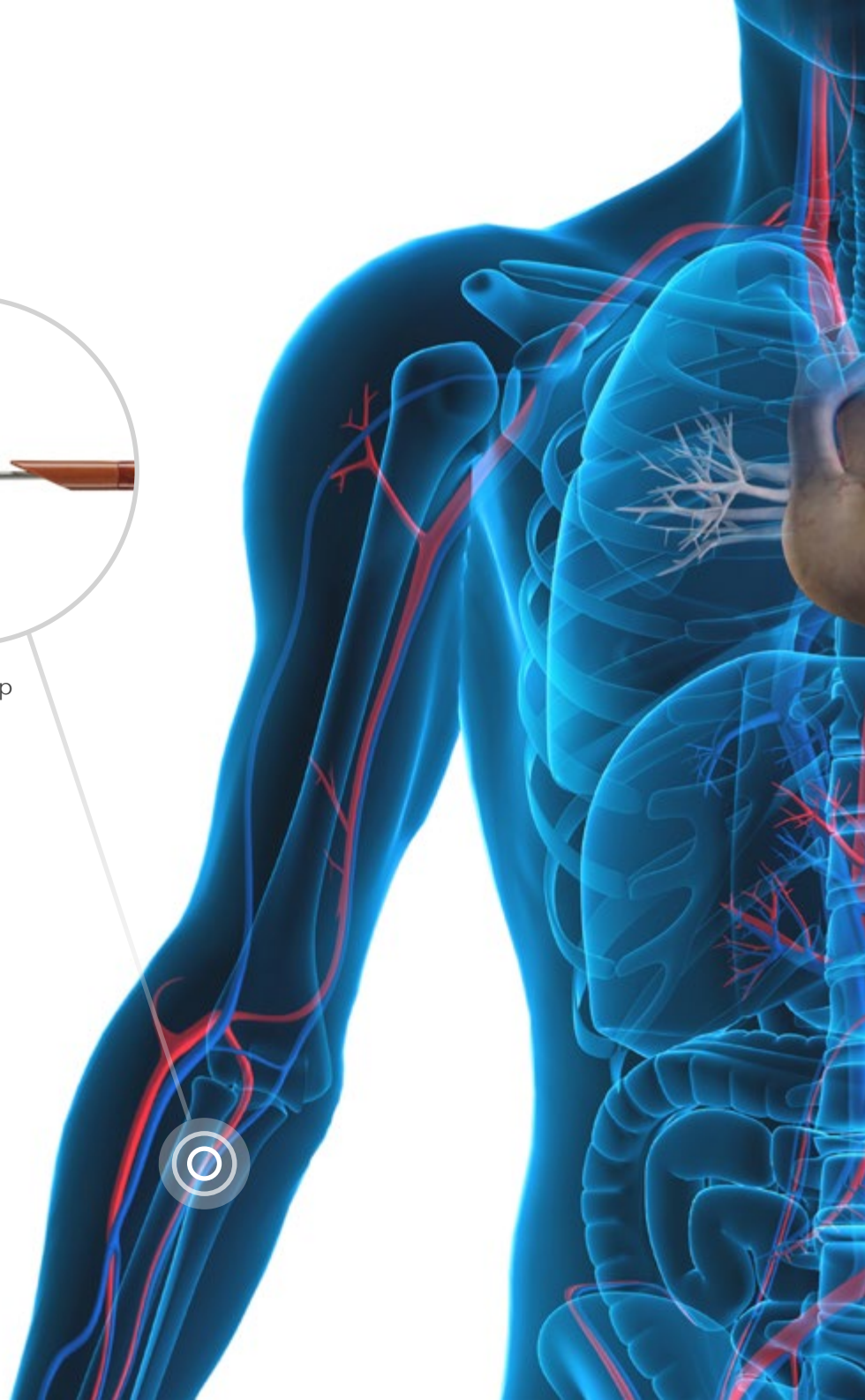
Take an easier way in

Only the Ellipsys vascular access system uses a single point of venous access,[1] offering the simplest, most minimally invasive option for arteriovenous fistula (AVF) creation.[1,2]

The Ellipsys fistula is a percutaneous equivalent to the surgical Gracz fistula, between the proximal radial artery (PRA) and perforating vein.[1]

1. Single puncture with venous access only[1]
2. Immediate, suture-free, permanently-fused anastomosis[1]
3. Ultrasound guidance, no fluoroscopy
4. Proven to increase longevity and reduce the risk of cardiovascular complications:[3-5]
   - Cannulation segment aneurysms[3,4]
   - Cephalic arch stenosis[4]
   - High-output cardiac failures[3,4]

Distal Tip

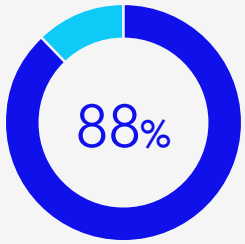


Extensive clinical evidence

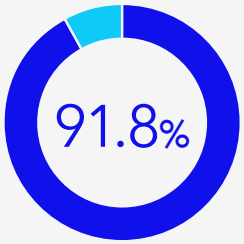
The Ellipsys system offers the most clinical data and real-world experience in its class.[†1-20]

Clear clinical outcomes

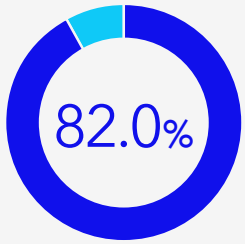
The Ellipsys system is the only one of its kind with five-year U.S. clinical trial data[1,20] demonstrating three critical metrics.



maturation rate at 90 days[1]



functional patency at five years[20]



cumulative patency at five years[20]

[†]Device class is endovascular arteriovenous fistula.

More than **3,000** successful procedures[21] and **20+** peer-reviewed publications[1-20]

Equivalent real-world results

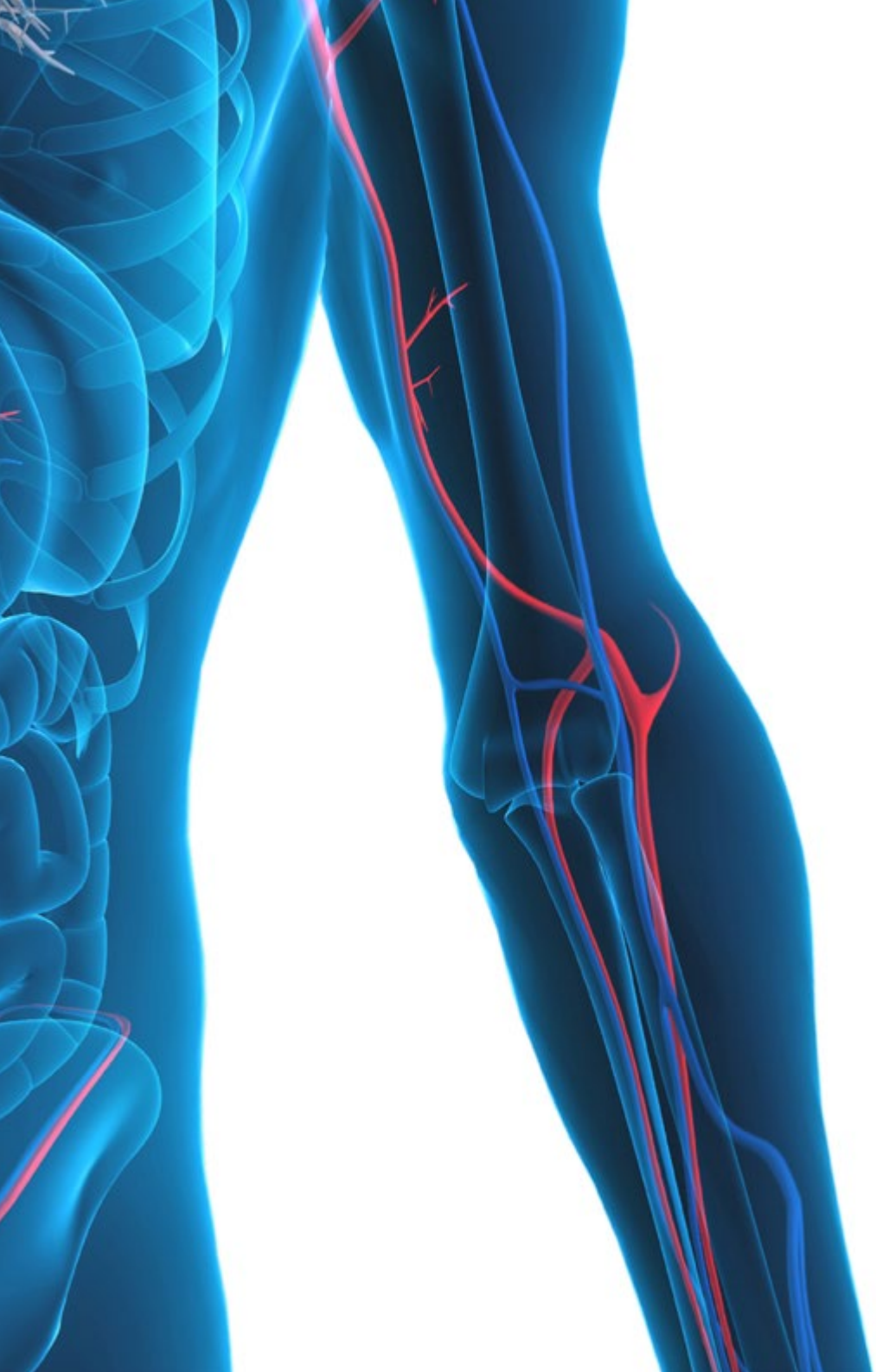
These clinical trial maturation and patency rates have also been demonstrated in registry trial data from more than 500 real-world patients in France, Germany, and the U.S.[4,9,17]

Strengthen patient acceptance

Patient reluctance can often be a barrier to proper treatment. The Ellipsys system makes AVF creation easier on patients,[1,3] improving their likelihood of acceptance[4] with the most minimally invasive procedure available.[1]

No surgery, sutures, surgical scar, or implant

Lower risk of cannulation segment aneurysms[3,4]



Who is right for Ellipsys?

Candidate patients may include up to 65% of the general ESKD population.[1,2,6,9,17,22]

Outflow vein anatomy‡

Verify patency of the basilic and cephalic veins

Check for thrombosis

Diameter (>2mm)

Perforator requirements‡

Diameter (>2mm)

Proximity to artery (<1.5mm)

Must be straight enough to allow 21 Ga needle to be guided inside the lumen

Arterial requirements‡

Proximal radial artery diameter (>2mm)

No inflow restrictions

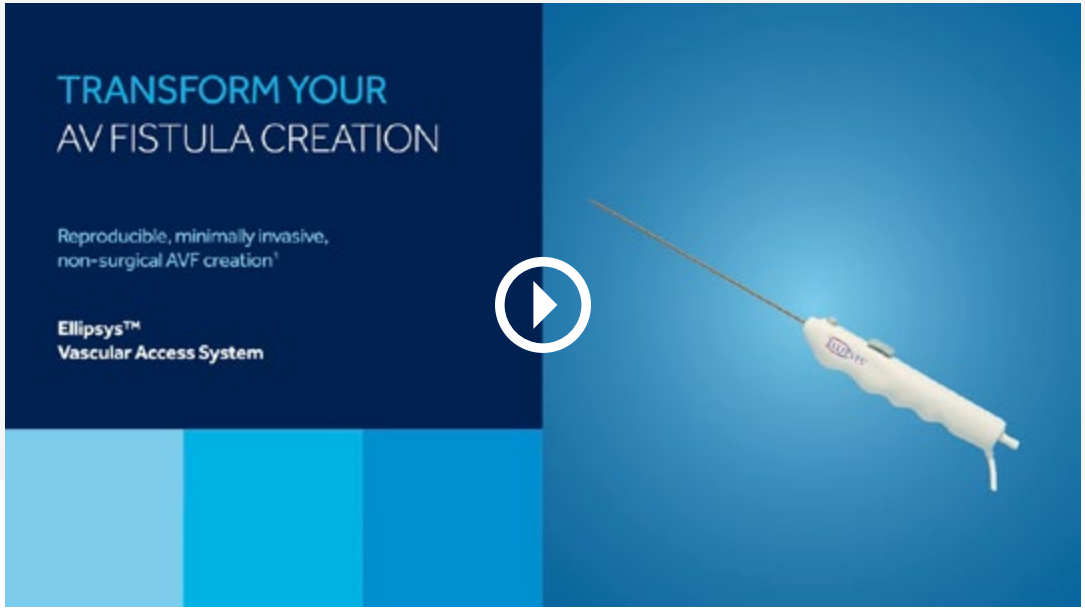
Calcification (non-occlusive)

Patent palmar arch

‡Per IFU

Explore the procedure

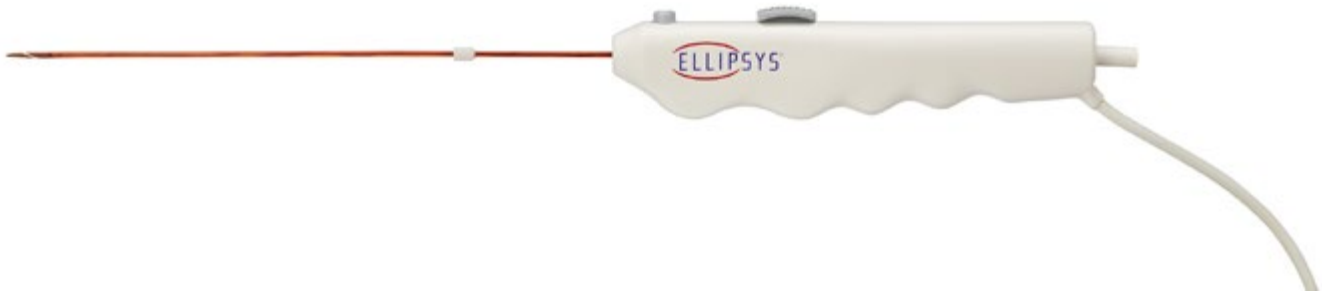
Watch a full demonstration of the Ellipsys procedure.

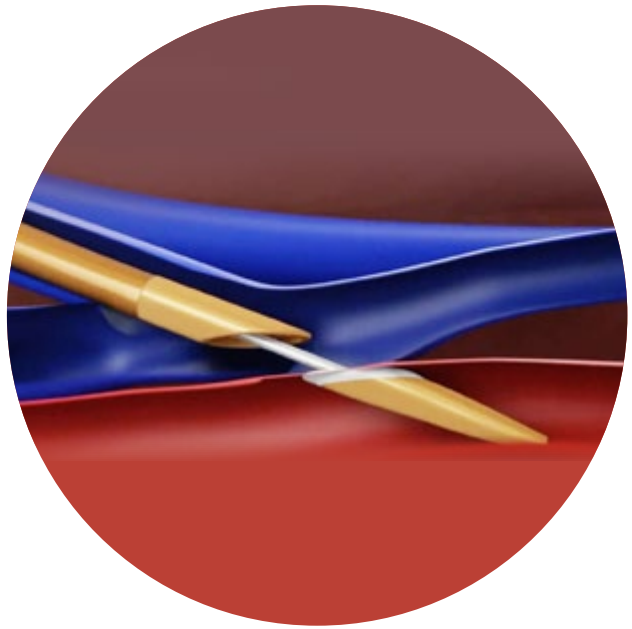


How is the Ellipsys system different than surgery?

The fistula created with the Ellipsys system typically provides more moderate flow than a surgical fistula and has multiple outflows.[3,4,5]

- Anastomosis made distal to the elbow crease
- Moderate flow (800-1100 mL/min) reduces steal, heart complications, and outflow thrombus[3,4,23]
- Split outflow reduces shear stress on each vessel to help prevent aneurysm formation and central stenosis[3,4]
- Maturing multiple vessels often requires a maturation procedure four weeks post-creation





Improve maturation and time to dialysis

Follow-up is recommended at one week and four weeks to assess fistula development.

1 Monitor and complete maturation assessment of dialysis readiness:

Track flow volume of the fistula to determine appropriate vessel maturation strategy for a target cannulation vessel with:

diameter	depth	volume flow
>6mm	<6mm	>500mL/min

Palpable/visible access vein required for many dialysis units

2 Perform maturation if needed to meet cannulation criteria

- Balloon dilation
- Deep vein embolization coils
- Cubital vein banding/ligation
- Transpositions/lipectomy

3 Recommendations to follow for initial cannulation

- Ensure in-service is scheduled to educate the dialysis center
- Mark the outflow path and suggested needle placement with permanent marker
- Always use a tourniquet to engorge the fistula
- Use a shallow needle angle to avoid infiltration and damage
- Suggest the centers to start dialysis with 17G needles and 250 mL/min flow rates

Find education and training resources for the maturation and cannulation of Ellipsys fistulas at Medtronic Academy.

Build a successful program

Medtronic can help you build an efficient program for the Ellipsys system with comprehensive services and support for mapping, creation, maturation, and cannulation.

Best-in-class training and support

Training and support help the care team understand how to select the right patients, educate them on the process, and perform the procedure easily and effectively.

- Hands-on training with an ultrasound model
- Literature-based training for ultrasound and procedure
- Nurse and tech training
- In-servicing for hospital departments and staff
- Cannulation education for dialysis units
- Coding and reimbursement support

Access a larger portfolio

The Ellipsys system belongs to a portfolio designed to improve outcomes for hemodialysis patients through AVF creation and maintenance as well as PTA and drug-coated balloons.

Unmatched commitment

Medtronic continues to invest in the solutions and services necessary to support ESKD patients and all of the practitioners who care for them.

Give patients more options

The Ellipsys vascular access system offers the most minimally invasive approach to AVF creation,[1,2] one that is proven to increase longevity[3-5] and reduce the risk of complications[3,4] – all while improving acceptance among ESKD patients.[3]

Get started now

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]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.

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

[4]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.

[5]Franco G, et al. Ultrasound evaluation of percutaneously created arteriovenous fistulae between radial artery and perforating vein at the elbow. *J Vasc Access*. Sept 2020; 21(5):694-700.

[6]Franco G, et al. Feasibility for arteriovenous fistula creation with Ellipsys. *J Vasc Access*. Sept 2020; 21(5):701-704.

[7]Hebibi H, et al. Clinical hemodialysis experience with percutaneous arteriovenous fistulas created using the Ellipsys vascular access system. *Hemodial Int*. Apr 2019; 23(2):168-172.

[8]Hull JE, et al. Thermal resistance anastomosis device for the percutaneous creation of arteriovenous fistulae for hemodialysis. *J Vasc Interv Radiol*. Mar 2017; 28: 380-387.

[9]Hull JE, et al. Maturation for hemodialysis in the Ellipsys endoAVF post-market registry. *J Vasc Interv Radiol*. Sept 2020; 31(9):1373-1381.

[10]Mallios A, et al. Early cannulation of percutaneously created arteriovenous hemodialysis fistulae. *J Vasc Access*. Nov 2020; 21(6):997-1002.

[11]Mallios A, et al. Percutaneous creation of proximal radio-radial arteriovenous hemodialysis fistula before secondary brachial vein elevation. *J Vasc Access*. Mar 2021; 22(2):238-242.

[12]Mallios A, et al. Early results of percutaneous arteriovenous fistula creation with the Ellipsys Vascular Access System. *J Vasc Surg*. Oct 2018; 68(4):1150-1156.

[13]Mallios A, et al. Creating percutaneous arteriovenous fistulas at the wrist. *J Vasc Access*. Mar 2021; 22(2):299-303.

[14]Sultan S, et al. Initial 6-month quality review of a percutaneous endovascular arteriovenous fistula program. *J Vasc Access*. July 2021; 22(4):540-546.

[15]Dawoud D, et al. Recent advances in arteriovenous access creation for hemodialysis: New horizons in dialysis vascular access. *Adv Chronic Kidney Dis*. May 2020; 27(3):191-198.

[16]Jones RG, Morgan RA. A Review of the current status of percutaneous endovascular arteriovenous fistula creation for haemodialysis access. *Cardiovasc Intervent Radiol*. Jan 2019; 42(1):1-9.

[17]Shahverdyan R, et al. Comparison of outcomes of percutaneous arteriovenous fistulae creation by Ellipsys and WavelinQ devices. *J Vasc Interv Radiol*. Sept 2020; 31(9):1365-1372.

[18]Wee IJY, et al. A systematic review, meta-analysis, and meta-regression of the efficacy and safety of endovascular arteriovenous fistula creation. *J Vasc Surg*. Mar 2020; 71:309-317.e.5.

[19]Wasse H, et al. Patient selection, education and cannulation of percutaneous arteriovenous fistulae: An ASDIN White Paper. *J Vasc Access*. Nov 2020; 21(6):810-817.

[20]Hull JE, et al. Long-term results from the pivotal multicenter trial of ultrasound-guided percutaneous arteriovenous fistula creation for hemodialysis access. *J Vasc Interv Radiol*. 2022. https://doi.org/10.1016/j.jvir.2022.05.016.

[21]Data on file at Medtronic.

[22]Popli K, et al. Anatomic suitability for commercially available percutaneous arteriovenous fistula creation systems. *J Vasc Surg*. Mar 2021; 73(3):999-1004.

[23]Shahverdyan R, et al. The past and the future of vascular access surgery: Creation of percutaneous arteriovenous fistula using Ellipsys vascular access system in a patient with previous ipsilateral Scribner-shunt. *J Vasc Access*. Nov 2021; 22(6):1032-1035.

Medtronic

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.

medtronic.com/ellipsys

Medtronic