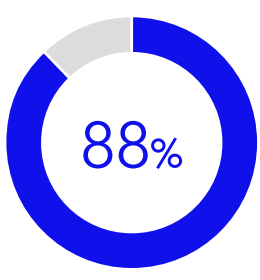
Ellipsys™ Vascular Access System

Less invasive, long lasting

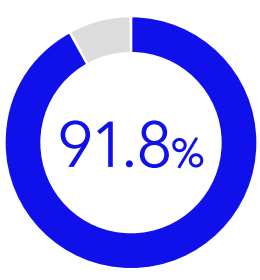
Only the Ellipsys™ Vascular Access System offers the most minimally invasive option for arteriovenous fistula (AVF) creation,[1,2] with the most clinical data and real-world experience in its class.[†1-21]

Proven performance

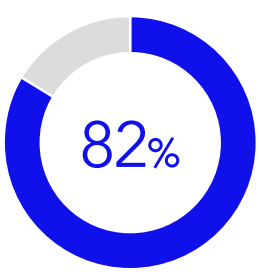
The Ellipsys system is the only one of its kind with 5-year U.S. clinical trial data[1,20] demonstrating three critical metrics.



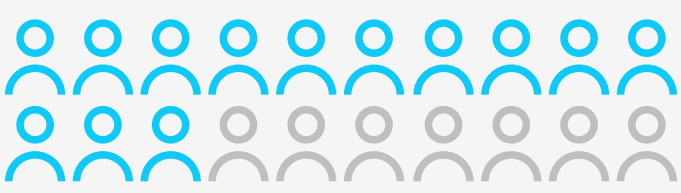
maturation rate at 90 days[1]



functional patency at five years[20]



cumulative patency at five years[20]



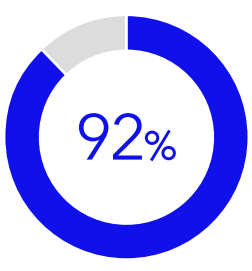
Candidate patients may include up to 65% of the general ESKD population.[1,2,6,9,17,21]

Robust outcomes published on >500 study participants

Ellipsys™ Vascular Access System – Peer-Reviewed Evidence			
Feasibility and Pivotal Studies		**Post-Market Studies**	
Phase II Trial[8] N=26	US Pivotal Study[1] N=107	**Paris Registry** • Technique refinement – inclusion of PTA at T=0[12] • 2-year results and algorithm of maintenance[4] • Comparison of surgical vs pAVF, Paris Retrospective Study[22]	 N=33 N=234 N=107 pAVF N=107 sAVF
	2-Year Results[3] N=105	**Hamburg Registry** • Comparison of Ellipsys and WavelinQ™* pAVF[17] • Comparison of pAVF (Ellipsys) and surgical (Gracz) AVF[2]	 N=100 N=89 pAVF N=69 sAVF
	5-Year Results[20] N=107	**RVC Registry** • Maturation study[9]	 N=60

Long-term results

The Ellipsys system is clinically proven to improve longevity[4,5,20] and reduce the risk of complications.[4,20]



Fistulas still in use through 5 years[20]

< 1
procedure per patient in years 1-5[20]

Patients with an AVF created by the Ellipsys system experienced less than one intervention per year for five years,[20] significantly less than the KDOQI goal of three interventions per year.[23]

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

Conclusion

The Ellipsys vascular access system offers the most minimally invasive approach to AVF creation,[1,2] one that is proven to increase longevity[4,5,20] and reduce the risk of complications[4,20] – all while improving acceptance among ESKD patients.[3]

Contact your sales rep for details

References

†Device class is endovascular arteriovenous fistula.

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

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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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