

More AV Access Options for Your Dialysis

To access dialysis resources and learn more about kidney health, visit these websites:

www.kidney.org
www.kidneyfund.org
www.esrdncc.org

References

1. National Chronic Kidney Disease Fact Sheet, 2019. Chronic Kidney Disease in the United States, 2019. <https://www.cdc.gov/kidneydisease/publications-re-sources/2019-national-facts.html>.
2. A to Z Health Guide, Hemodialysis. National Kidney Foundation, 2019. <https://www.kidney.org/atoz/content/hemodialysis>.
3. Global Facts About Kidney Disease. National Kidney Foundation, 2015. <https://www.kidney.org/kidneydisease/global-facts-about-kidney-disease>.

Please consult product labels and instructions for use for indications, contraindications, hazards, warnings and precautions.

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WAVELINQ™ | 4F
EndoAVF System

15%

An estimated 15% of adults in the United States have chronic kidney disease.¹

You're Not Alone



Chronic kidney disease affects millions of people world-wide. The final stage of kidney disease is called End-Stage Kidney Disease (ESKD). When you have ESKD, your kidneys can no longer keep up with your body's need to remove extra waste and water.

In fact, once your kidneys only have 10-15% of normal function, dialysis treatments or a kidney transplant are necessary to sustain life.²



Did you know?

Globally, there are more than 2 million patients on hemodialysis with the majority depending on an arteriovenous fistula as their lifeline for dialysis therapy.³



What is Kidney Disease?

Healthy kidneys remove waste and excess water, help make red blood cells, and work to control blood pressure. When kidneys fail, they are unable to complete these functions. While there is no cure for kidney failure, treatment is available.

If you have failing kidneys, you may require dialysis to help filter waste products from your blood. For dialysis, a connection between your blood (vascular system) and a dialysis machine is needed.

This brochure is intended to introduce you to a minimally-invasive method of creating an arteriovenous fistula (AVF).

The Preferred Vascular Access Option

An “access” to the bloodstream is required in order to administer hemodialysis treatment. An arteriovenous fistula (AVF) creates a direct connection between a vein and an artery in your arm. This results in a closed circuit that provides adequate blood flow for dialysis. Blood can be withdrawn, cleaned through the dialysis machine, and returned to your body.

AVF is preferred for many patients over other vascular access options because:



It lasts longer once used for dialysis



Has lower risk of infection, and lower risk of serious complications



Did you know?

People with early kidney disease may not have any symptoms. Symptoms usually show up late in the progression of the disease.¹

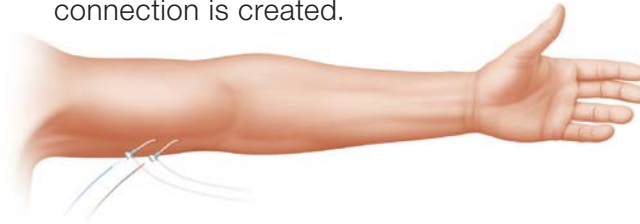
Surgery vs. WavelinQ™ 4F EndoAVF

Your AVF can be created either with an open surgery (surgical AVF) or with a minimally invasive procedure (endoAVF).

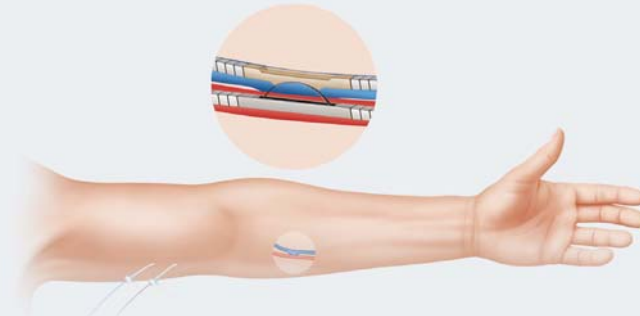
Procedural Overview

WavelinQ™ 4F EndoAVF System

Two thin devices create a connection between your vein and artery without the need for open surgery. The devices are removed from the body once the connection is created.



1. The doctor inserts two thin devices into the artery and the vein through small needle punctures.



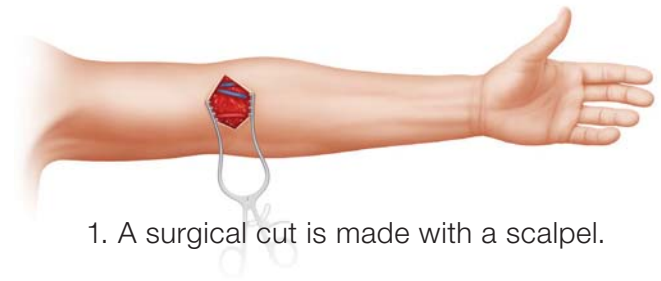
2. Magnets align the devices and a connection is made between the vein and artery in the forearm. The doctor then removes the devices.



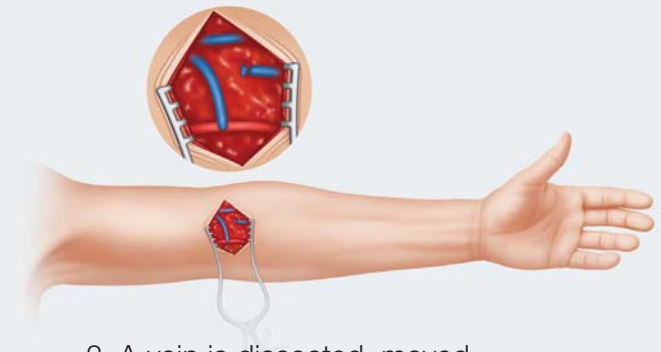
3. The arm heals without stitches with little to no scarring.

Surgical AVF

A surgeon dissects one of your veins with a scalpel and sews it to one of your arteries during an open surgery.



1. A surgical cut is made with a scalpel.



2. A vein is dissected, moved, and sewn to an artery.



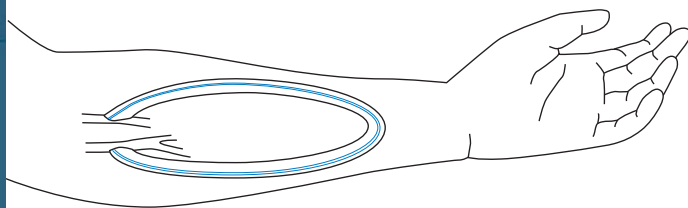
3. The surgical wound is stitched closed and heals over the next few weeks.

Surgery vs. WavelinQ™ 4F EndoAVF

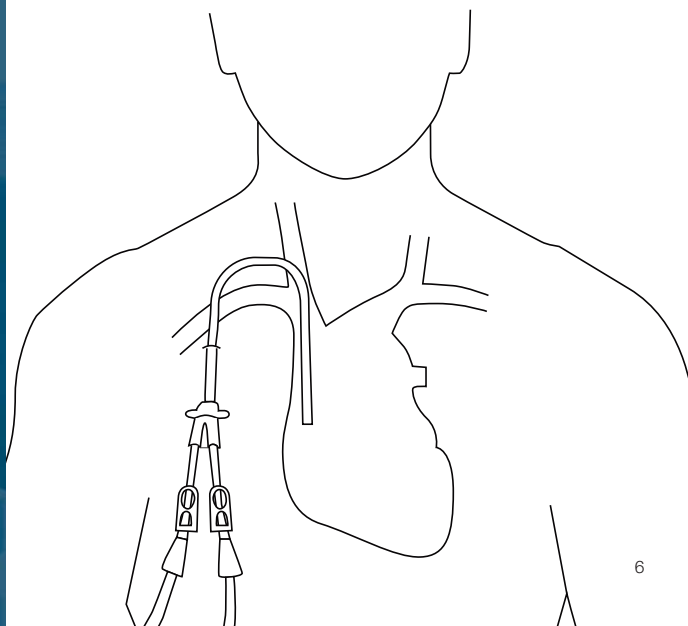
Your AVF can be created either with an open surgery (surgical AVF) or with a minimally invasive procedure (endoAVF).

Alternative options for AV access

Arteriovenous Graft: A soft tube that joins an artery and a vein in your arm



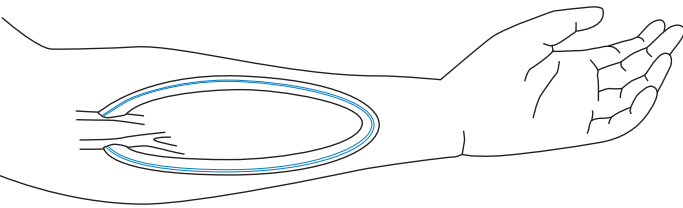
Hemodialysis Catheter: A soft tube that is placed in a large vein, usually in your neck



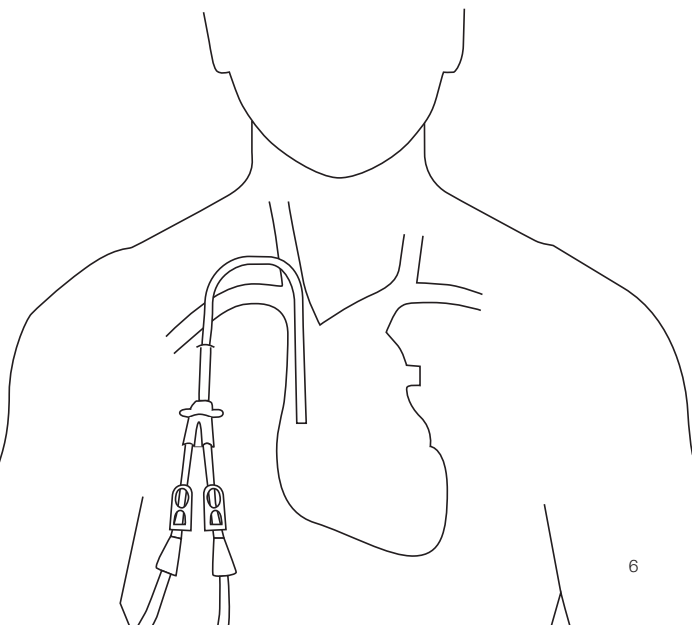
Post-Procedure Steps

Alternative options for AV access

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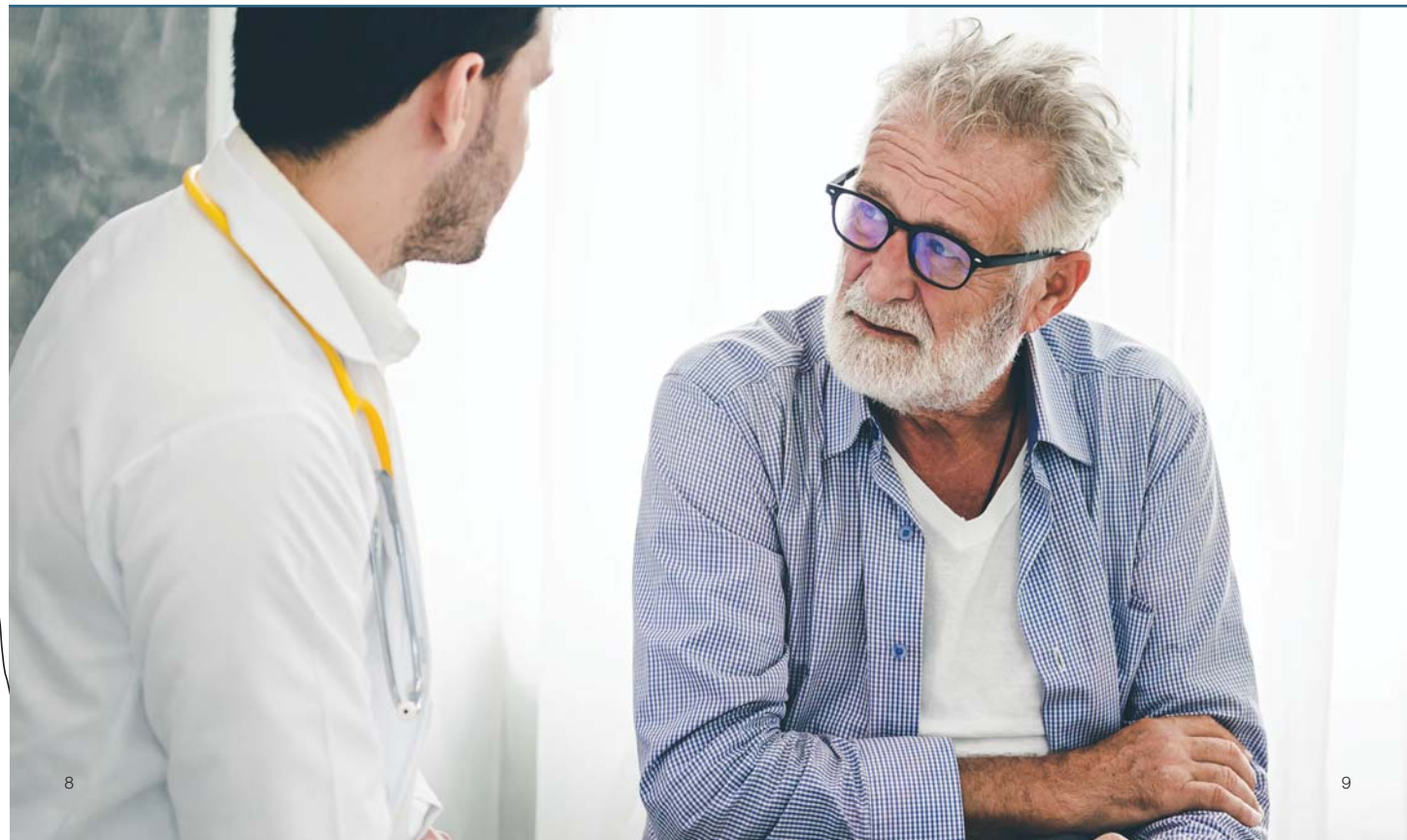
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WavelinQ™ 4F EndoAVF System

- The small needle punctures heal quickly with minimal need for wound care
- Additional procedures may be needed to prepare the endoAVF for dialysis
- Follow-up visits will be required over the next few weeks to determine when the AVF is ready for dialysis

Surgical AVF

- Your healthcare provider will give you detailed instructions on how to care for your surgical wound
- It's fairly common to need multiple procedures to make the surgical AVF ready for dialysis access
- Follow-up visits will be required over the next few weeks to determine when the AVF is ready for dialysis



8

9

Ask Your Physician If WavelinQ™ 4F EndoAVF System Could Be Right for You

When it comes to creating access to your bloodstream to administer hemodialysis, there are several access options. Your access options may vary greatly depending on your condition.

Keep in mind, risks with all ESKD access options should be discussed with your physician.



Which patients are able to get an endoAVF with WavelinQ™ 4F EndoAVF System? (Indications for Use)

Patients who may benefit from an endoAVF are chronic kidney disease patients who need dialysis. In addition, a patient must meet certain anatomical characteristics that support the use of the WavelinQ™ 4F EndoAVF System procedure. Patients should consult their physician to determine if they are a candidate for an endoAVF procedure.

Who performs the dialysis access procedure?

The WavelinQ™ 4F EndoAVF System procedure can be performed by nephrologists, interventional radiologists and surgeons.

Where are AV fistulas located and how long do they last?

AV fistulas can be created in your wrist, forearm, inner elbow or upper arm. WavelinQ™ 4F EndoAVFs are created in the upper forearm. While maturation varies, some AV fistulas are able to function for many years.

Why is there a need for the endoAVF technique?

Worldwide, 2 million people with ESKD receive hemodialysis therapy and require vascular access to connect their blood circulation to a dialysis machine. AV fistulas are the preferred approach to achieve vascular access and until the introduction of the minimally invasive endoAVF procedure, a surgical procedure was required for creation. EndoAVF creation offers patients and clinicians more AV access options.

What are the potential adverse events associated with WavelinQ™ 4F EndoAVF System?

Potential adverse events include: aborted (terminated) or longer procedure; additional procedures; bleeding, hematoma (bruise) or hemorrhage (bleeding); bruising; burns; death; electrocution; embolism (occlusion/blockage of vessels); failure to mature; fever; increased risk of congestive heart failure; infection; numbness, tingling, and/or coolness; occlusion/stenosis (blockage/narrowing); problem due to sedation or anesthesia; pseudoaneurysm (false swelling); sepsis (infection); steal syndrome or ischemia (not enough blood flow); swelling, irritation, or pain; thrombosis (clotting); toxic or allergic reaction; venous hypertension (arm swelling); vessel, nerve, or AVF damage or rupture; wound problem.