Fistula Dysfunction & the LUTONIX® 035 Drug Coated Balloon PTA Catheter

LUTONIX® 035
Drug Coated Balloon PTA Catheter

Patient Care Brochure

BARD

Table of Contents

Caution: Federal law restricts this device to sale by or on the order of a physician

1. End Stage Renal Disease (ESRD) Background

Your kidneys work hard getting rid of waste and extra water from your body. But if your kidneys can't continue supporting your body's needs, then you may be at risk for chronic kidney disease.

End-Stage Renal Disease (ESRD) is the final stage of chronic kidney disease. The word "renal" means kidney, and renal and kidney are words that can be used interchangeably. When you have ESRD, your kidneys can no longer keep up your body's needs anymore. As a result, your body is in great danger, because its extra waste and water aren't getting removed. ESRD can occur long after chronic kidney disease begins, sometimes as long as 10-20 years later. ESRD is also sometimes called end-stage kidney disease and is also commonly known as kidney failure.

2. Renal Replacement Therapy, Hemodialysis & Arteriovenous (AV) Fistulae

Once kidney function goes below 10 to 15 percent of normal function, dialysis treatments or a kidney transplant are necessary to sustain life. There are two types of dialysis: hemodialysis and peritoneal dialysis. Both dialysis treatments are able to replace the kidneys' function of cleaning the blood of toxins and removing extra fluids for people with kidney failure.

Hemodialysis is performed by your blood being removed from the body and "cleaned" in an external machine before being returned to you.

An "access" to the blood stream is required in order to perform hemodialysis. Most commonly, this is an arteriovenous (AV) fistula. The creation of a fistula allows for high blood flow so that needles can be inserted to remove the blood for dialysis.

Fistulae are a natural option with a longer life and fewer complications than other access types. A working fistula is considered the preferred access type.

QUICK FACTS:
CHRONIC KIDNEY DISEASE &
END STAGE RENAL DISEASE

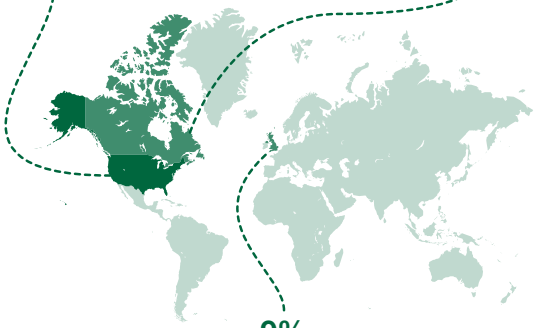
End-Stage Renal Disease (ESRD) is the final stage of chronic kidney disease. The word "renal" means kidney, and renal and kidney are words that can be used interchangeably. When you have ESRD, your kidneys can no longer keep up with your body's needs anymore. As a result, your body is in great danger because its extra waste and water aren't getting removed.

+33 MILLION

Over **33 million Americans** total have chronic kidney disease.

14.8%
of the population **in the U.S.** (age 20+) has chronic kidney disease according to 2016 estimates.

3.5-7%
of the population **in Canada** has chronic kidney disease according to estimates.



9%
of the population in **the United Kingdom** has chronic kidney disease according to 2009 estimates.

3. Fistula Dysfunction

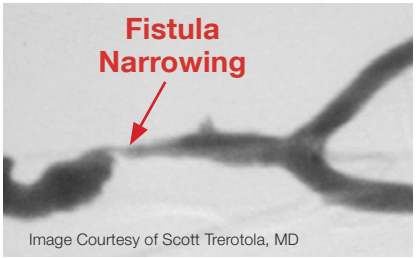
Globally, there are more than 2 million patients on hemodialysis with the majority depending on a fistula as their lifeline for renal replacement therapy. Sometimes, even when you are very careful, your fistula may stop working as well as it once did. The most common dialysis access problem is when a narrowed area in your fistula develops causing the blood flow to slow down and reduce the effectiveness of your dialysis.

4. How to Diagnose Fistula Dysfunction Caused by Narrowing

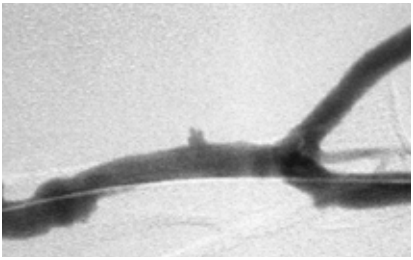
Once your doctor has confirmed fistula dysfunction caused by narrowing, they will determine whether a ***minimally invasive endovascular procedure*** or a ***surgical procedure*** is the best treatment to re-establish flow to your fistula.

Physical Exam: Your doctor may use their hands to feel the blood flow in your fistula.

Angiogram/Venogram: Your doctor may perform a contrast angiogram, which is a medical procedure that takes pictures of your blood vessels so the doctor can observe any narrowing or blockage.



1. Angiogram image of a fistula with a narrowing that is causing access dysfunction and reduced blood flow.



2. Angiogram after angioplasty showing the narrowing now open and faster blood flow resumed.

Warning Signs of Fistula Dysfunction due to Narrowing:

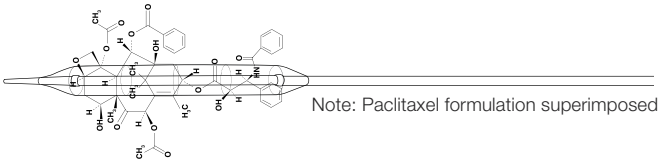
- Absence of the vibration (thrill) or sound (bruit) at your fistula site
- Swelling of your arm
- A decrease in your delivered dose of dialysis (Kt/V or URR)
- Changes in other lab values
- Difficult cannulation
- Increased bleeding after needle removal

5. How to Treat Fistula Dysfunction Caused by Narrowing

Minimally Invasive Endovascular Procedures

Conventional Balloon Angioplasty

The most common technique for opening a narrowed fistula. These balloons are inflated in a narrowed vessel.



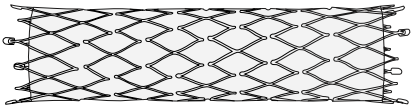
Note: Paclitaxel formulation superimposed over balloon.

Drug Coated Balloon Angioplasty

A balloon that is coated with a drug is used to open a narrowed fistula. The balloon delivers a therapeutic dose of drug intended to keep the vessel open longer than conventional angioplasty.

Stent

A stent is a small wire mesh tube that is placed in the fistula and remains in the body after the procedure and acts to help keep the fistula open.



Stent Graft

A stent graft is a small wire mesh tube that is covered with fabric, is placed in the fistula and remains in the body after the procedure and acts to help keep the fistula open.

Surgical Procedure

Surgical Revision

A surgical procedure where your doctor reroutes or bypasses the blood flow above and below the blockage.

6. LUTONIX® 035 Drug Coated Balloon

Indications for Use: The Lutonix® Catheter is indicated for percutaneous transluminal angioplasty (PTA), after pre-dilatation, for treatment of stenotic lesions of dysfunctional native arteriovenous dialysis fistulae that are 4 mm to 12 mm in diameter and up to 80 mm in length.

What is the LUTONIX® 035 Drug Coated Balloon?

LUTONIX® 035 Drug Coated Balloon is a balloon catheter with the drug paclitaxel applied to the balloon. With exception of the drug coating, the LUTONIX® 035 Drug Coated Balloon is similar to other conventional balloon catheters. A clinical study has demonstrated that the LUTONIX® 035 Drug Coated Balloon is as safe and effective in delaying renarrowing of the fistula as compared to conventional balloon catheters for treatment of patients with fistula dysfunction due to narrowing.

What is paclitaxel?

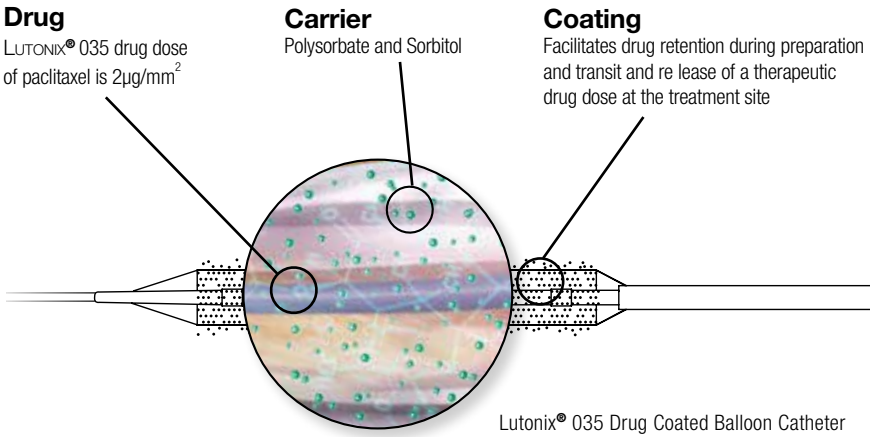
Paclitaxel is the active drug component of the LUTONIX® 035 Drug Coated Balloon. Paclitaxel is often known for its use in cancer treatments where it is used systemically (in the blood flow) in much larger doses and with greater frequency.

The LUTONIX® 035 Drug Coated Balloon uses a very small amount of paclitaxel (around 2% of a single cancer treatment) and the drug is applied directly to the narrowed vessel wall. After the drug is delivered to the area of narrowing, the removal of the drug is processed in the liver and the kidneys within hours.

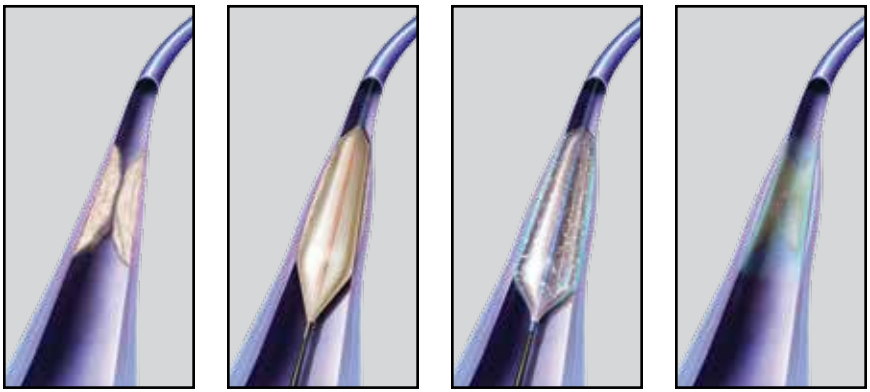
The safety of the Lutonix® Drug Coated Balloon use was evaluated in the Lutonix AV Clinical Trial and found to be comparable to using a conventional balloon catheter.

Who should not receive a LUTONIX® 035 Drug Coated Balloon?

- Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children over the next 2 years. It is unknown whether paclitaxel will be excreted in human milk and there is potential for adverse reaction in nursing infants from paclitaxel exposure.
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system.



Lutonix® 035 Drug Coated Balloon Catheter



Narrowed Vessel | Pre-Dilatation | Drug Coated Balloon | Treated Vessel

7. Adverse Events

What are the potential adverse events associated with the LUTONIX® 035 Drug Coated Balloon?

Potential adverse events which may be associated with a PTA balloon dilation procedure include, but are not limited to, the following:

- Additional intervention
- Allergic reaction to drugs or contrast medium
- Aneurysm or pseudoaneurysm
- Arrhythmias
- Embolization
- Hematoma
- Hemorrhage, including bleeding at the puncture site
- Hypotension/hypertension
- Inflammation
- Loss of permanent access
- Occlusion
- Pain or tenderness
- Sepsis/infection
- Shock
- Stroke
- Thrombosis
- Vessel dissection, perforation, rupture, or spasm

Potential adverse events, not described in the above source, which may be unique to the paclitaxel drug coating include, but are not limited to, the following:

- Allergic/immunologic reaction to the drug coating (paclitaxel)
- Alopecia
- Anemia
- Blood product transfusion
- Gastrointestinal symptoms
- Hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia)
- Hepatic enzyme changes
- Histologic changes in vessel wall, including inflammation, cellular damage, or necrosis
- Myalgia/Arthralgia
- Myelosuppression
- Peripheral neuropathy

8. The LUTONIX® 035 Procedure

Background

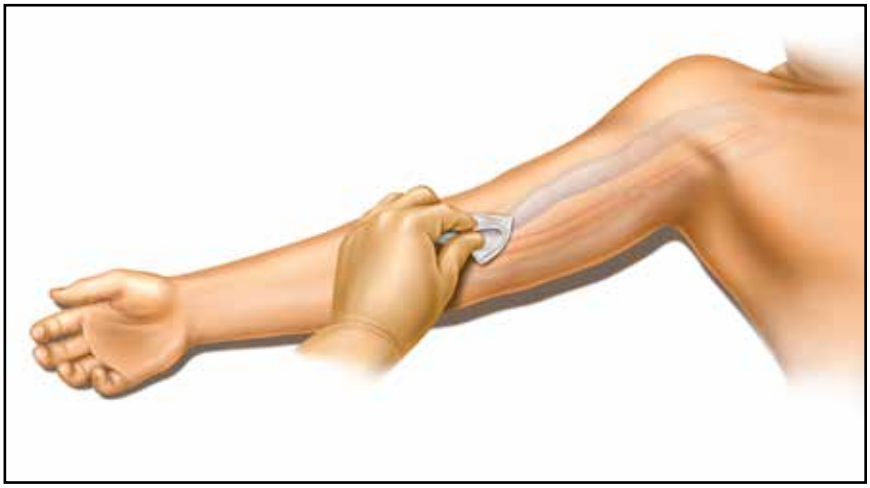
An angiogram is performed when there is dysfunction in the fistula that is interrupting hemodialysis. The procedure is typically performed in a hospital or a free-standing clinic by a physician trained in these procedures. Most commonly it will be an Interventional Nephrologist, Interventional Radiologist, or Vascular Surgeon.

Before the Procedure

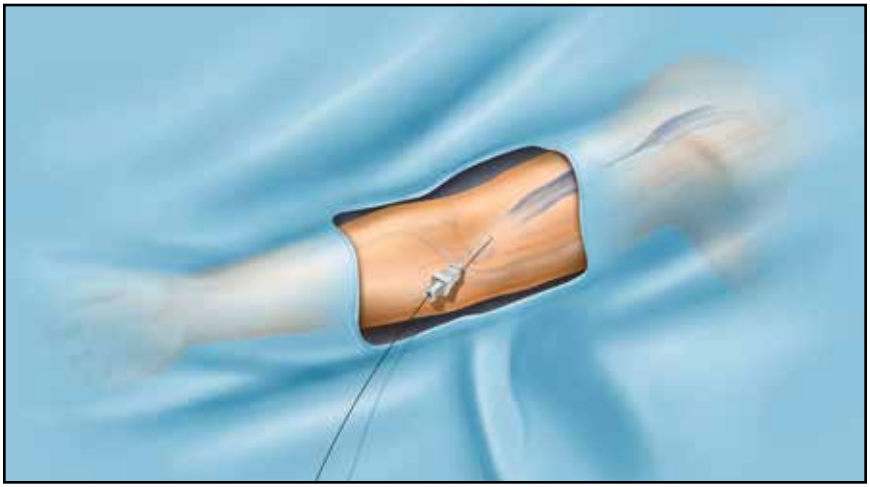
You may be asked to avoid eating or drinking anything after midnight the night before the procedure. You may also be asked to take aspirin or other medication for a few days prior to the procedure to thin your blood and prevent clots from forming. Upon arrival to the procedure room, you will lie on an x-ray table and be given medication to help you relax.

Steps to the Procedure

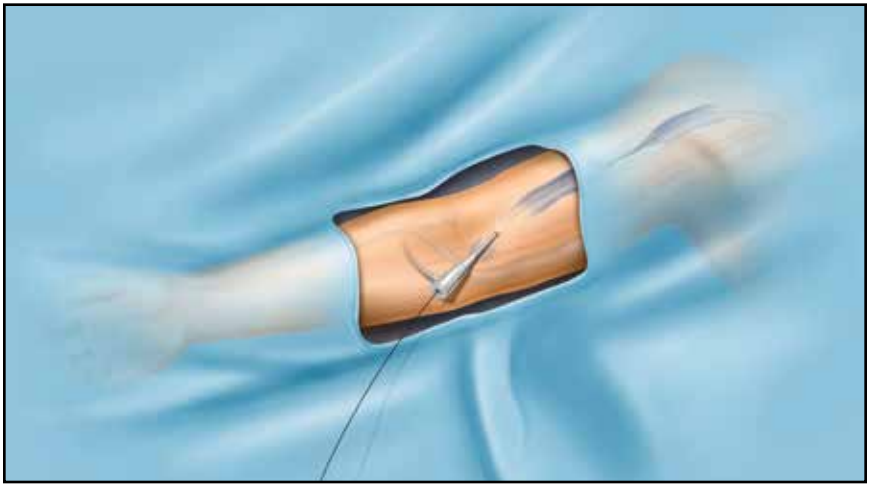
1. Your doctor will be accessing your fistula through your arm. Your skin will be scrubbed with antiseptic and then you will be injected with lidocaine/numbing medicine.



2. A tapered needle with a hollow middle will be inserted into your fistula. A small wire will be inserted through the needle and travel through your fistula to the location that contains the blockage.

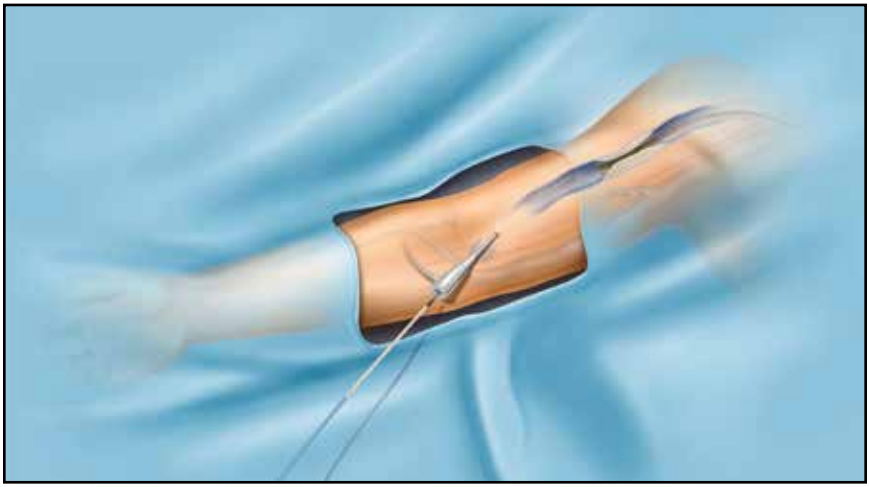


3. The needle will be removed and an introducer sheath will replace it.

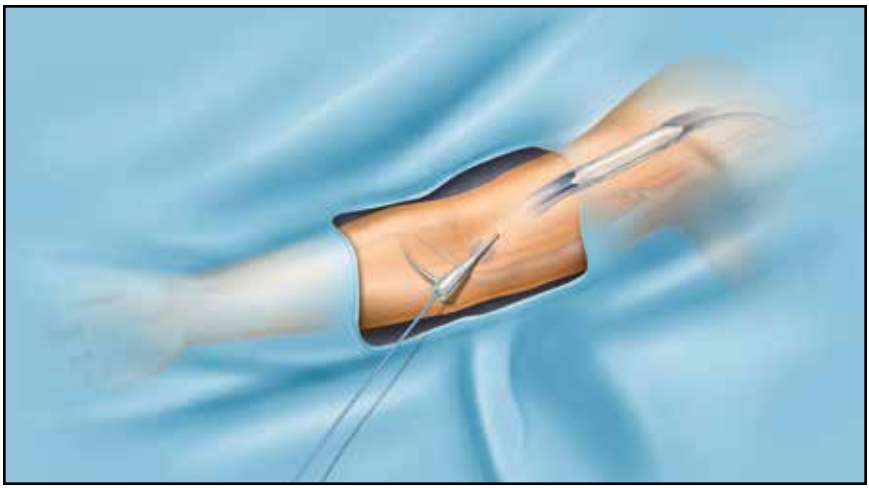


4. A series of X rays (angiogram) will then be performed for visualization of your fistula to diagnose the area of the blockage.

5. If it is determined that your fistula dysfunction is caused by narrowing, an angioplasty balloon will be inserted into your fistula over the wire.

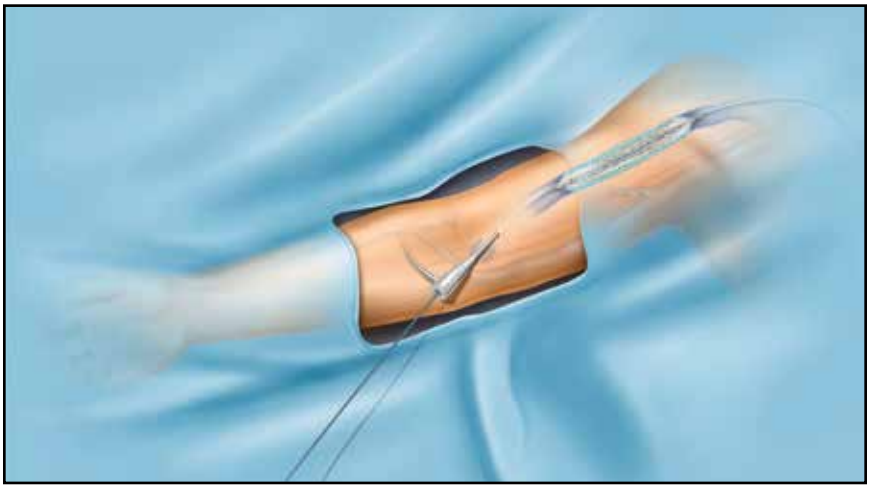


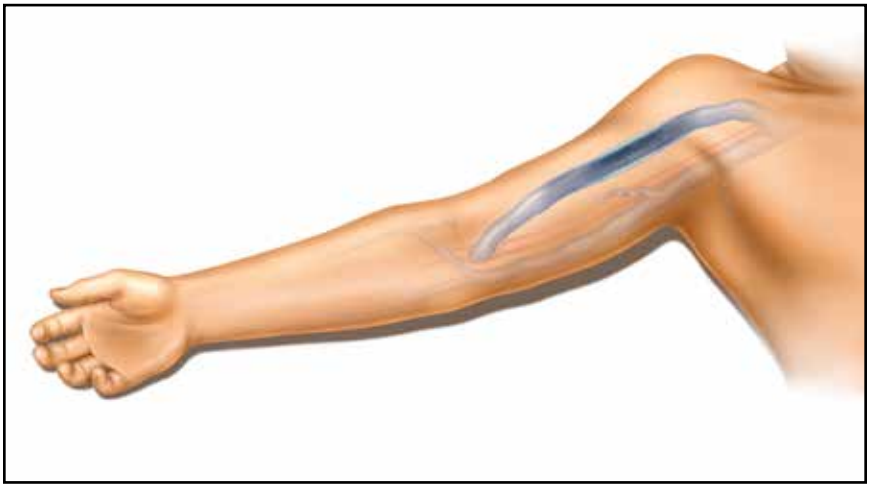
6. The balloon is inflated and deflated at the area of narrowing, and then removed (angioplasty).



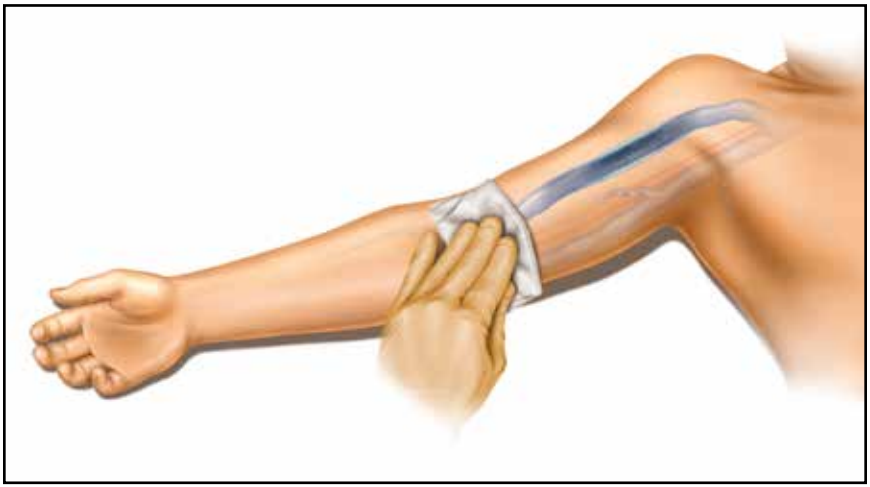
7. An additional angiogram will be performed to help the doctor determine when the narrowing has improved.

8. The LUTONIX® 035 DCB Catheter will then be advanced over the wire and through the sheath to the same location as the previous balloon. The paclitaxel drug is delivered to the target site when the balloon is inflated. The balloon is then deflated and removed with the wire and the sheath. A therapeutic dose of the drug remains on the vessel wall.



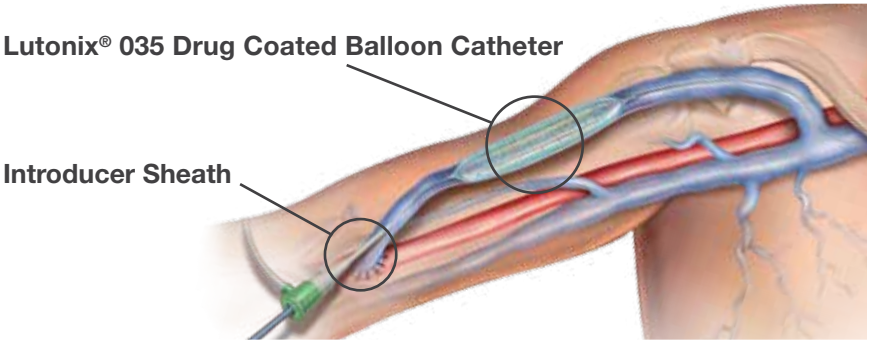


9. Your doctor or nurse will put light pressure on the small hole where the needle was inserted until bleeding has stopped.



After the Procedure

After your procedure is finished, you will be moved to a recovery area. Your doctor as well as the standard protocol of the facility where your procedure was performed will determine when you are allowed to go home.



Upper arm fistula with an inflated Lutonix® 035 Drug Coated Balloon Catheter. After balloon has been inflated for a few minutes and the therapeutic dose of drug is delivered to the vessel wall, it will be deflated and removed from the fistula through the sheath.

9. Summary of Clinical Information

The LUTONIX® 035 Drug Coated Balloon was evaluated in the LUTONIX® AV Clinical Trial, which enrolled 285 patients. Through 12 months, it was determined that the procedure was successful in most patients and that the LUTONIX® 035 Drug Coated Balloon was successful in delaying renarrowing of the fistula as compared to conventional balloon catheters. The safety of using a LUTONIX® 035 Drug Coated Balloon was comparable to using a conventional balloon catheter.

The results of this study showed that the LUTONIX® 035 Drug Coated Balloon is safe and effective for treating stenotic lesions in dysfunctional fistulae and may lengthen the time to restenosis compared to standard angioplasty. Your doctor can explain the risks and benefits that are specific to you.

10. Taking Care of Your Fistula

Keeping your fistula working well will help you get the most from hemodialysis, and help you feel your best. The following are recommended care procedures for fistulae.

- Make sure your dialysis care team checks your access often.
- Do not let anyone measure your blood pressure on your access arm, or take blood from your access arm when you are not getting dialysis. Your other arm should be used to measure blood pressure and do blood tests.
- Do not be afraid to ask your dialysis care team to rotate needle sites.
- Track your important test results, such as your Kt/V and your URR.
- Ask your dialysis care team if you have any questions about your access or any other aspects of your hemodialysis care.
- Check the blood flow several times each day by feeling for vibration, also called pulse or thrill, as well as for sound, also called bruit. If either is absent or there is a change, call your doctor or dialysis center.
- Do not wear tight clothes or jewelry on your access arm.
- Do not carry anything heavy or do anything that would put pressure on the access.
- Do not sleep with your head on the arm that has your access.
- Apply only gentle pressure to the access site after the needle is removed. Too much pressure will stop the flow of blood through the access.

Glossary

Access - *A method of gaining entry to the bloodstream to allow dialysis. Access methods used for hemodialysis include a catheter, fistula or graft.*

Anastomosis - *The site(s) of surgical connection between an AV access graft or artery (fistula) and venous structures.*

Angiogram - *A type of X-ray that allows physicians to visualize the inside of a blood vessel. If dye is used, put into the blood vessels via a tube that is inserted into the groin and passed up to the kidneys.*

Angioplasty - *The use of a balloon catheter to stretch/open the narrowing in a blood vessel.*

Arteriovenous Fistula - *Surgically created connections between the artery and vein in an extremity. These direct connections are called arteriovenous fistulae (AVFs).*

Arteriovenous Graft - *A natural or synthetic tube structure used for AV access.*

Balloon Catheter - *See angioplasty.*

Bruit - *The sound of the blood flow in a graft of fistula.*

Catheter - *A flexible plastic tube used to enter the interior of the body. A catheter is one of the access options for patients on hemodialysis. For patients on peritoneal dialysis, a catheter allows dialysis fluid to be put into, and removed from the peritoneal cavity.*

Catheter-directed Thrombolysis - *A procedure that dissolves blood clots that build up in fistulas and grafts by injecting a medicine.*

Catheter-directed Mechanical Thrombolysis - *A procedure where blood clots are physically removed or mashed up to re-open a closed fistula or graft.*

Conventional Balloon Angioplasty - *See angioplasty*

DCB - *Drug coated balloon, see* LUTONIX®

Dysfunctional Fistula - *A fistula that is not able to support adequate dialysis function. Common signs of dysfunction include decreased blood flow or dialysis dose, prolonged bleeding, difficult puncture, pulling clots, arm swelling, and elevated venous pressures.*

Fistula - *An enlarged vein, usually at the wrist or elbow, that gives access to the bloodstream for hemodialysis. The fistula is created by a surgeon in a small operation. It is created by joining a vein to an artery. This increases the flow of blood through the vein and causes it to enlarge, making it suitable for hemodialysis needles.*

Introducer Sheath - *A hollow tube that is placed in a blood vessel prior to medical devices being inserted.*

KT/V - *A measure of dialysis adequacy. The calculation is rather complicated, but it measures the amount of dialysis given and corrects for body size.*

LUTONIX® 035 Drug Coated Balloon - *Balloon catheter with the drug paclitaxel applied to the balloon. With exception of the drug coating, the LUTONIX® 035 Drug Coated Balloon is similar to other conventional balloon catheters.*

PTA - *Percutaneous Transluminal Angioplasty. See angioplasty*

Stenosis - *Narrowing of the blood vessel. Percent (%) stenosis or residual stenosis is measured in comparison to the reference vessel diameter.*

Stent - *A small wire mesh tube that is placed into a blood vessel after angioplasty and remains in the body after the procedure to help keep the blood vessel open and helps precent further narrowing of the vessel.*

Stent Grafts - *A small wire mesh tube that is covered with fabric, placed in the fistula and remains in the body after the procedure and acts to help keep the fistula open.*

Thrill - *The vibration or tremble of blood flow in a graft or fistula.*

URR (Urea Reduction Ratio) - *A measure of dialysis adequacy. It is the fall in blood urea levels over a session of hemodialysis, expressed as a percentage.*

For more information on End Stage Renal Disease, the following websites are designed for further patient education:

www.CRBard.com/en-US/Patients-Caregivers/End-Stage-Renal-Disease
www.Kidney.org/Patients
www.DPCEDCenter.org
www.NIDDK.NIH.gov/health-information/Kidney-Disease

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Notes

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