

**UNDERSTANDING  
CHRONIC KIDNEY DISEASE  
AND THE  
IN.PACT™ AV  
DRUG-COATED BALLOON  
FOR AV FISTULA  
MAINTENANCE**

Patient Information Booklet



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## Kidney Function and End-stage Renal Disease (ESRD)

Healthy kidneys are an essential part of a healthy body. Your kidneys are your body's waste and water management system. Healthy kidneys filter about a half cup of blood every minute, removing the waste and extra water found in your blood. When that system breaks down and can no longer effectively remove waste and excess water, you may be at risk for chronic kidney disease. Over time, chronic kidney disease can lead to end-stage renal disease (ESRD), commonly called kidney failure. The term "renal" means kidney.

ESRD is the final stage of chronic kidney disease, and because kidney function is critical to maintain life, a person with ESRD will likely require care.

### Options for Treating ESRD

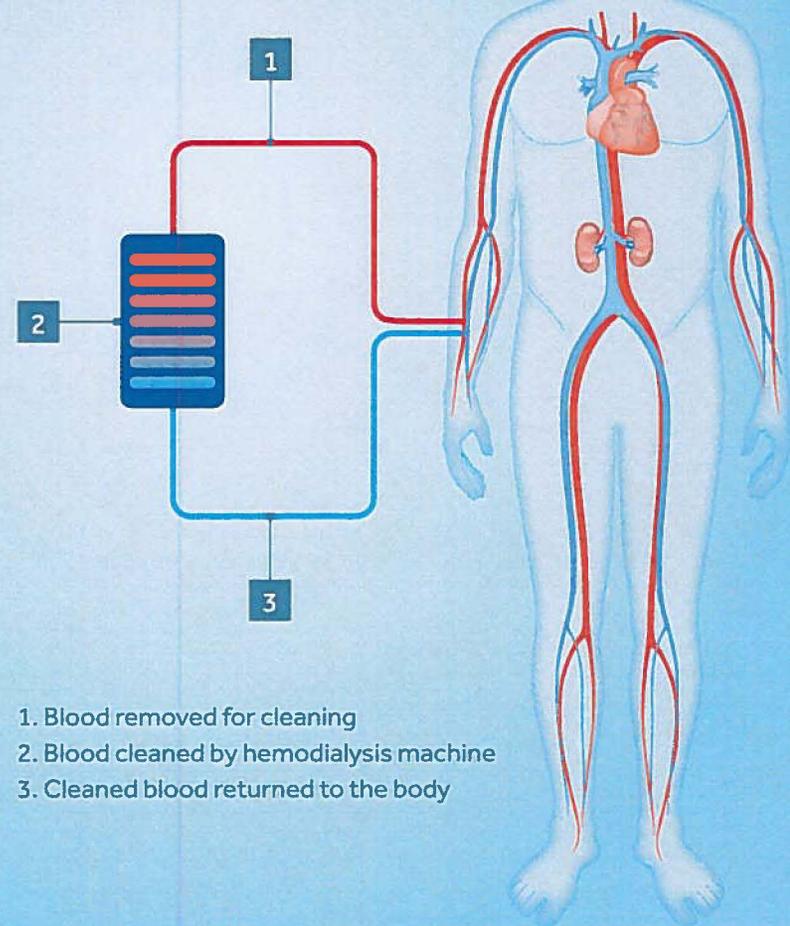
When your kidneys don't work to properly filter your blood, toxins build up. Over time, these toxins, excess water, and other fluids can make you feel sick, tired, or weak.

To help manage these problems, your doctor may prescribe renal replacement therapy (RRT), a therapy that replaces the normal blood-filtering functions of the kidneys. There are three main kinds of RRT: hemodialysis, peritoneal dialysis, or a kidney transplant. Hemodialysis and peritoneal dialysis replace the kidneys' job of filtering blood. Hemodialysis is the most common treatment. Your doctor will help you decide which option is best for you.

### Cleaning the Blood with Hemodialysis

Hemodialysis is done at a hospital or clinic, and is a process where blood is removed from the body and cleaned by an external artificial kidney machine. "Hemo" means blood, and "dialysis" means to filter. During hemodialysis your blood is filtered through the machine, which removes the waste and excess water, and then the cleaned blood is returned to your body. This process is typically done two to four times per week and takes three to five hours each time.

## Cleaning the Blood with Hemodialysis



1. Blood removed for cleaning
2. Blood cleaned by hemodialysis machine
3. Cleaned blood returned to the body

## Gaining Access to the Bloodstream for Hemodialysis

To perform hemodialysis, the doctor needs a way to repeatedly reach — or access — your bloodstream. This access is used to carry your blood from your body to the dialysis machine where it is cleaned and returned to you.

There are three different types of access used for hemodialysis: an arteriovenous (AV) fistula, an arteriovenous (AV) graft, and a catheter. Your doctor will explain more about each option and help you choose what is best for your body.

### AV Fistula

The most common type of access is through an AV fistula. An AV fistula is made during a minor surgery by connecting an artery and a vein, typically in the arm. An AV fistula widens the vein, making it easier to access the bloodstream. A fistula can create increased blood flow for dialysis and usually takes one to four months to enlarge. When ready for use, blood is taken from the body through a needle inserted into the fistula.

### AV Graft

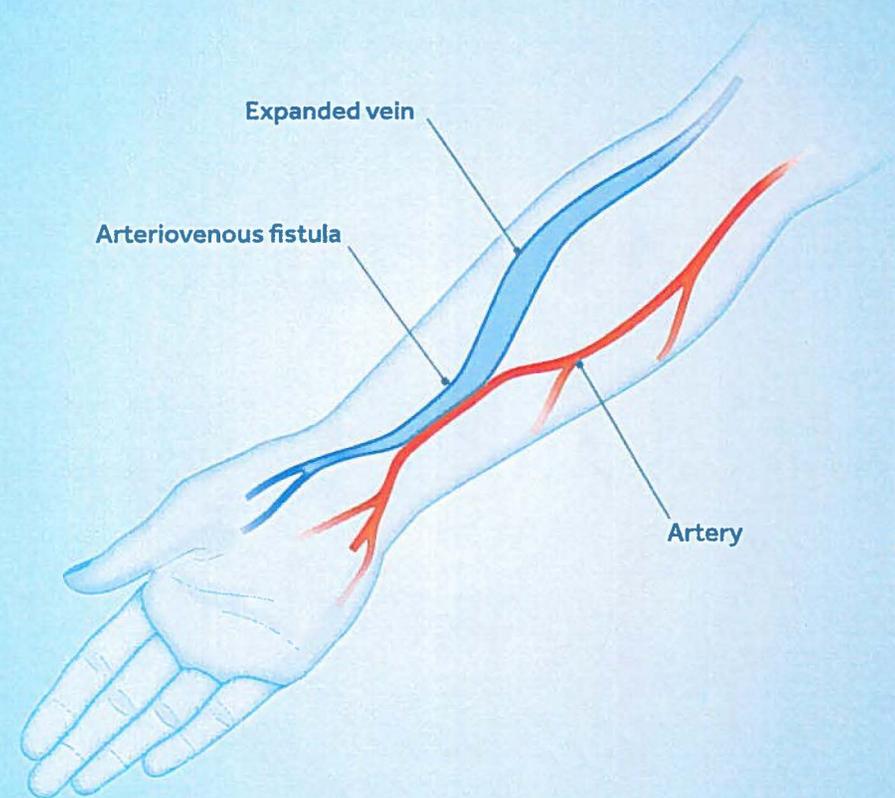
An AV graft is another way to access your bloodstream for hemodialysis. During this minor surgery, the doctor makes a connection between a vein and artery by placing a small tube between the vessels. A graft is often placed about two weeks prior to hemodialysis treatments.

### Catheter

The third option is a catheter. If you need to have hemodialysis before your fistula or graft are ready, or if a fistula or graft don't work for you, your doctor may choose to place a catheter for temporary access. A catheter is made of soft plastic tubing and is placed in a large vein, usually in the neck but sometimes in the upper chest. It is placed just prior to hemodialysis and can be used immediately. The catheter remains in place until it is no longer needed, or an alternative access is created and ready for use.

Once you and your doctor decide which access option is best for you, be sure to follow your doctor's instructions about caring for your access.

## AV Fistula

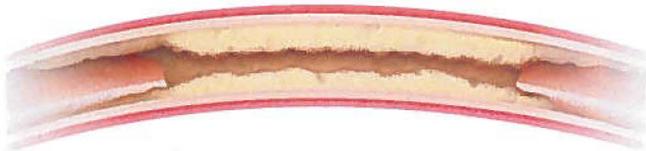


## Caring for Your Fistula

If you and your doctor determine that a fistula is the appropriate approach for you, it is very important that you take good care of your fistula. If your fistula isn't working well, it can mean you aren't getting enough of the dialysis your body needs.

### Narrowed Vessel

Sometimes, even when you are very careful, there can be issues with your fistula. The most common issue is when a fistula becomes narrowed, causing a slowing of the blood flow and making dialysis less effective. If your doctor determines that the fistula has become narrowed, they will determine if a minimally invasive procedure or if a surgical procedure is the best way to repair your fistula.



## How to Know If a Fistula Has Narrowed

Your care team will monitor your dialysis to be sure enough waste is being removed from your blood. They may conduct a physical exam using a stethoscope or their hands to feel how the blood is flowing, or may use an ultrasound, which takes pictures of your blood vessels. This will help your doctor look for narrowing or blockage.

When a fistula is working well, it makes a soft rumbling sound that you can hear (bruit) and feel (thrill). You can help spot possible issues with your fistula by watching for a few warning signs. Contact your doctor if you experience any of the following symptoms of fistula narrowing:

- Absence of the vibration (thrill) or sound (bruit) at your fistula site
- Arm swelling
- Prolonged bleeding from the access site
- Numbness, tingling, coldness, or weakness in the arm
- Blue fingers or sores on fingertips

## How to Treat a Narrowed Fistula

There are several minimally invasive endovascular options doctors use to open a narrowed fistula.

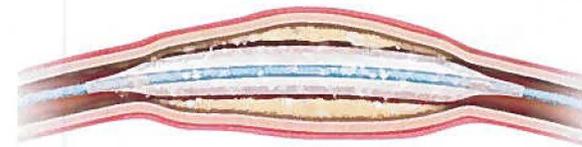
### Balloon Angioplasty

This is the most common way to open a narrowed vessel. An inflatable balloon is placed into the fistula through a small catheter. The balloon is inflated in the narrowed section of the fistula to increase its size by pushing plaque away; then the balloon is deflated and removed.



### Drug-Coated Balloon Angioplasty

The technique for drug-coated balloon angioplasty is the same as with regular balloon angioplasty, but the balloon itself is coated with a specialized drug. This drug is delivered to the vessel when the balloon is inflated, and the drug is intended to prevent re-narrowing of the vessel.



### Stenting

Sometimes following balloon angioplasty, a doctor may place a stent in the vessel to help hold it open. A stent is a small flexible tube made of mesh wire that remains in the body after the procedure and acts as a scaffold, to help keep the vessel open.



There are times when surgery is required to open a narrowed vessel because the less invasive options are not possible for the patient. During the surgery, the doctor reroutes the blood flow above and below the narrowed or blocked section of the fistula.

## Medtronic IN.PACT™ AV Drug-Coated Balloon (DCB) for AV Fistula Maintenance

The IN.PACT AV drug-coated balloon is used for angioplasty in patients with a narrowed AV fistula, and is intended to limit the re-narrowing of the vessel. It is coated with a low dose of a drug called Paclitaxel.

### What is Paclitaxel?

Paclitaxel is a drug that can help limit the growth of scar tissue. In large doses, it is used to treat various kinds of cancer. The IN.PACT AV DCB uses about 2% of the dose of an average cancer treatment and can help delay the narrowing of a fistula compared to regular angioplasty balloons.



## What to Expect in the IN.PACT AV Drug-Coated Balloon Procedure

The IN.PACT AV DCB procedure is performed in a hospital or clinic setting and includes a few key steps.

### Before Your Procedure

Your doctor may ask you to take — or stop taking — certain medications a few days before your procedure, and you will likely be asked not to eat or drink anything for several hours before your procedure. Just prior to treatment, you will be given medicine to help you relax.

### During Your Procedure



### PROCEDURE ACCESS:

The skin on your arm will be cleaned with antiseptic and then injected with a small amount of numbing medication. Your doctor will then access your fistula by placing a thin wire through a catheter into your arm and will take X-rays — called angiograms — to confirm that your fistula is narrowed and needs treatment.

### TYPICAL PROCEDURE TREATMENT:

If it is determined your fistula requires treatment to be opened up, the following steps may be applied:

- 1 Your doctor will place an angioplasty balloon over a guidewire into your fistula via a needle.
- 2 The balloon will be inflated and deflated to open up your fistula.
- 3 The angioplasty balloon will then be removed, leaving the vessel prepared for treatment by the drug-coated balloon.
- 4 The IN.PACT AV drug-coated balloon will then be placed over the guidewire to the same location as the first balloon. When the doctor inflates the balloon, the Paclitaxel drug is delivered. The balloon is then deflated and removed. The drug can help keep your fistula open and working.

Once the procedure is complete, light pressure is placed on the small hole where the needle was inserted. This will help to stop any bleeding. An adhesive bandage or small suture will be placed at the site, and you will be moved to a recovery area.



### Immediately after Your Procedure

- You will be moved to a recovery area and may be monitored for several hours or overnight.
- The puncture site may be sore or bruised after the procedure but typically will feel better in a few days. Watch for bleeding, swelling, pain, or discomfort at the puncture site. If you experience any of these symptoms, tell your doctor.
- You may be prescribed medication to take after the procedure.
- If you feel any of the following: faintness, weakness, fever, or redness or swelling in your arm, tell your doctor.

### Follow-up Care

- Take medications as directed.
- Avoid strenuous activity for at least 48 hours.
- Follow-up with your doctor as directed.

Follow your doctor's instructions about when to return for your next dialysis session.

## When IN.PACT™ AV DCB Is Not Recommended for Use

Your doctor will decide what is best, but may not recommend DCB treatment if any of the following are true:

- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
- Patients with known allergies or sensitivities to Pacitaxel
- Women who are breastfeeding, pregnant, or are intending to become pregnant, or men intending to father children. It is unknown whether Pacitaxel will be excreted in human milk and whether there is a potential for adverse reactions in nursing infants from Pacitaxel exposure

## Words to Know — Glossary

**Access:** A way to reach the bloodstream so it can be connected to the dialysis machine and then returned to the body. There are 3 types: fistula, graft, and catheter.

**Angiogram:** A type of X-ray that lets physicians see the inside of a blood vessel.

**Angioplasty:** The use of a balloon catheter to open up a narrowing blood vessel.

**Arteriovenous fistula:** A type of vascular access made by surgically joining an artery to a vein. This is also more simply called a fistula.

**Arteriovenous graft:** A natural or synthetic tube used for AV access.

**Artery:** A blood vessel that carries blood from the heart to the body.

**Bruit:** A swish sound heard when listening with a stethoscope over a fistula or graft.

**Catheter:** A small tube outside the skin used for short-term vascular access. It is usually placed in the neck or chest.

**Chronic kidney disease (CKD):** This is a slow, progressive, permanent loss of kidney function over months or years. It is also called chronic renal failure.

**Dialysis:** A process to take wastes or fluids out of the blood through a filter. See also hemodialysis and peritoneal dialysis.

**Drug-coated balloon (DCB):** A balloon catheter that is coated with a drug, which is delivered to the vessel when the balloon is inflated. The drug can help keep the narrowed vessel open for a longer period.

**End-stage renal disease (ESRD):** Permanent damage to the kidneys.

**Endovascular:** A surgical procedure in which the blood vessels are accessed through a small incision or cut in the skin.

**Fistula:** A type of vascular access made by surgically joining an artery to a vein. This is also called arteriovenous fistula (AVF).

**Graft:** A type of vascular access made by surgically joining an artery and vein with a special tube.

**Hemodialysis:** The use of a machine and dialyzer to take wastes and extra fluid out of the blood for a person with kidney failure.

**IN.PACT AV Drug-Coated Balloon:** A balloon used for angioplasty in patients with narrowed AV fistula to help prevent the re-narrowing of the vessel. It is coated with a very small dose of a drug called Pacitaxel, which may help limit the growth of scar tissue.

**Kidney:** A bean shaped organ that takes wastes and extra fluid out of the body.

**Kidney failure:** Loss of kidney function.

**Lesion:** an abnormal change to any tissue or organ due to disease or injury.

**Minimally Invasive:** Procedures that limit the size and number of cuts, or incisions, that a physician needs to make.

**Obstruction:** A blockage.

**Pacitaxel:** A drug that inhibits cell growth. It prevents cellular division and replication. Historically, in larger doses, it has been used to treat various types of cancer.

**Peritoneal dialysis:** A process that uses the inside lining of a person's belly as a filter to take wastes and extra fluid out of the blood for a person with kidney failure.

**Renal:** Related to the kidney.

**Restenosis:** Abnormal narrowing of an artery after surgery.

**Scar tissue:** The fibrous connective tissue that forms a scar.

**Stent:** A small, flexible tube made of mesh wire that remains in the body after the procedure and acts as a scaffold.

**Thrill:** A vibration felt when lightly pressing down over a fistula or graft.

**Toxins:** Another term for waste products that build up in the body.

**Transplant:** Movement from one location to another.

**Ultrasound:** A noninvasive imaging method that uses sound waves to create pictures of the inside of the body.

**Vein:** A blood vessel that carries blood from the body to the heart.

## Warnings

A study published in December 2018 in the Journal of the American Heart Association reported an increased risk of death starting at 2 years and up to 5 years after treatment with paclitaxel-coated devices in the upper leg compared to treatment with uncoated devices. The U.S. Food and Drug Administration also observed this increased risk of death associated with paclitaxel-coated devices in the upper leg that are approved in the U.S. Additional studies are being conducted to better understand this risk. This device is a paclitaxel-coated device used in dialysis fistula. The risk for this device is unknown. However, this is important information for you to have when making a decision about treatment options. Your doctor can explain the risks and benefits of paclitaxel-coated devices that are specific to you.

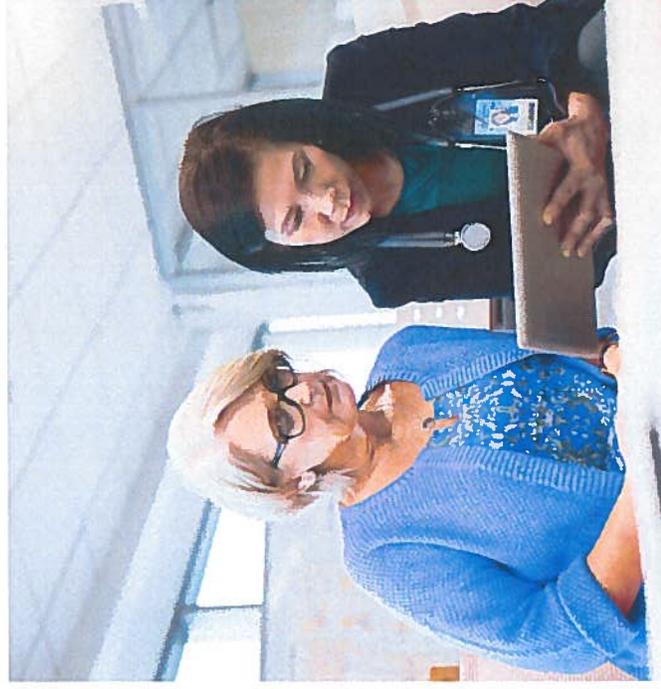
## Potential Adverse Effects Associated with the IN.PACT™ AV DCB

Potential adverse effects that may be associated with balloon catheterization may include, but are not limited to, the following:

- Abrupt vessel closure
- Allergic reaction
- Arrhythmias
- Arterial or venous aneurysm
- Arterial or venous thrombosis
- Death
- Dissection
- Embolization
- Hematoma
- Hemorrhage
- Hypotension/hypertension
- Ischemia or infarction of tissue/organ
- Infection
- Loss of permanent access
- Pain
- Perforation or rupture of the artery or vein
- Pseudoaneurysm
- Restenosis of the dilated vessel
- Shock
- Stroke
- Vessel spasms or recoil

Although systemic effects are not anticipated, potential adverse effects that may be unique to the Paclitaxel drug coating include, but are not limited to, the following:

- Allergic/immunologic reaction
- Alopecia
- Anemia
- Gastrointestinal symptoms
- Hematologic dyscrasia (including leucopenia, neutropenia, thrombocytopenia)
- Hepatic enzyme changes
- Histologic changes in vessel wall, including inflammation, cellular damage, or necrosis
- Myalgia/arthralgia
- Myelosuppression
- Peripheral neuropathy



## IN.PACT AV: Summary of Clinical Information

The IN.PACT AV drug-coated balloon was evaluated in the IN.PACT AV Access Study. The IN.PACT AV Access Study enrolled 330 patients in the United States, Japan, and New Zealand. The clinical trial conclusively demonstrated safety and effectiveness of the IN.PACT AV DCB when compared to conventional balloon catheters. The results of this study showed that the IN.PACT AV DCB is safe and effective for treating restenotic obstructive lesions of an AV both *de novo* and restenotic obstructive lesions. Your doctor can explain the risks and benefits that are specific to you.