

Patient Information Brochure

Information for patients with a transjugular intrahepatic portosystemic shunt

BD Liverty™
TIPS Stent Graft

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Welcome

This brochure is designed to provide helpful information about the transjugular intrahepatic portosystemic shunt (TIPS) procedure with the Liverty™ TIPS Stent Graft. This procedure may help manage the symptoms associated with liver **cirrhosis**. If you or a loved one is considering a TIPS procedure, this guide will support your understanding of what it involves; its potential benefits and risks; and what to expect before, during, and after treatment.

This patient information brochure is not a substitute for medical advice, so please speak with your health care providers about any questions you have.



Understanding cirrhosis and portal hypertension

Your liver is a powerhouse—it's the largest internal organ inside your body and handles hundreds of vital tasks, from processing nutrients to filtering toxins. One of its key roles is managing blood flow from the digestive system. Most of the blood from your stomach and intestines travels through a major vessel called the **portal vein** (Figure 1), which leads straight to the liver.

When the liver becomes damaged, often due to chronic conditions like hepatitis or alcohol-related injury, it can develop scar tissue. This scarring, known as cirrhosis, disrupts normal blood flow. Instead of moving smoothly through the liver, blood hits a traffic jam, causing pressure to build up in the portal vein.

That pressure imbalance is what doctors call **portal hypertension.**

To deal with this increased pressure, the body tries to reroute the blood through nearby veins around the stomach and **esophagus**. But these backup routes aren't built for high traffic. They swell, twist, and weaken, forming what are known as **varices**. If these fragile veins burst, it can lead to serious bleeding that requires urgent care.

Another issue that can arise is **ascites**, where fluid collects in the abdomen, which causes swelling and discomfort.

These complications are treatable, and your health care team can guide you through the options.

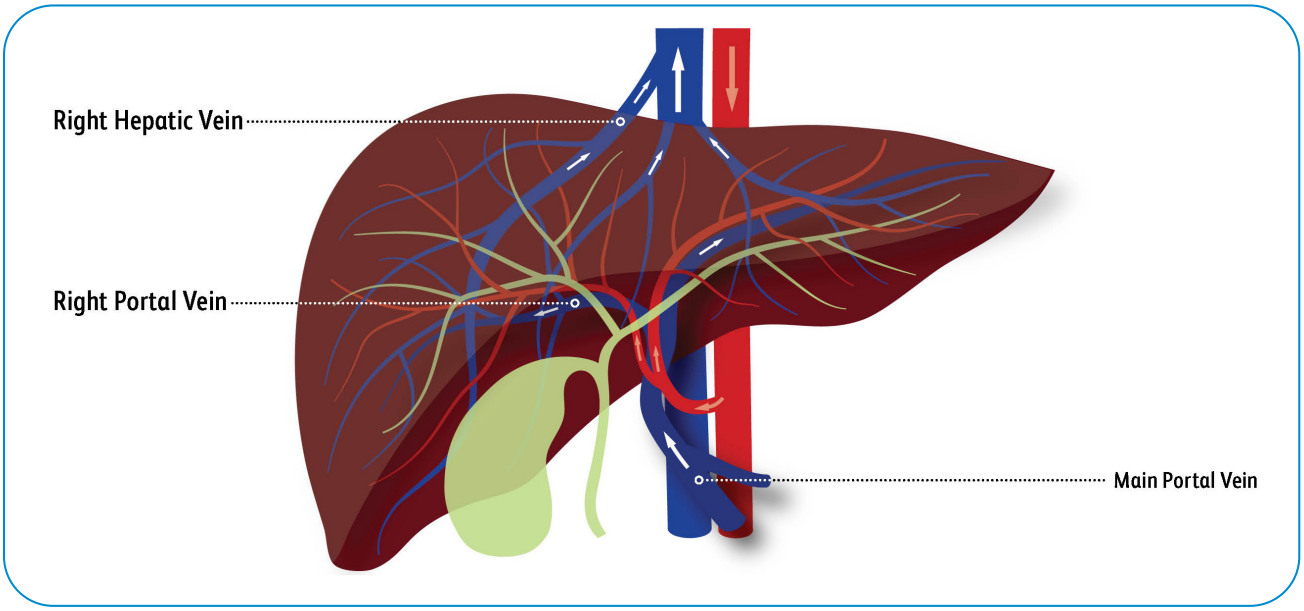


Figure 1

What is a TIPS procedure?

TIPS is a medical procedure that reduces portal hypertension by improving blood flow in people with liver disease. It involves placing a small tube (called a **stent graft**) inside the liver to connect two major blood vessels—the **portal vein** and the **hepatic vein**. This new pathway helps blood move more easily through the body when the liver is too scarred or damaged to do it on its own (Figure 2).

The name "TIPS" is an acronym which describes the procedure.

- **Transjugular** – through a vein in the neck
- **Intrahepatic** – inside the liver
- **Portosystemic** – linking the portal vein (which carries blood from the digestive organs) to the body's main circulation
- **Shunt** – a shortcut or channel for blood to flow

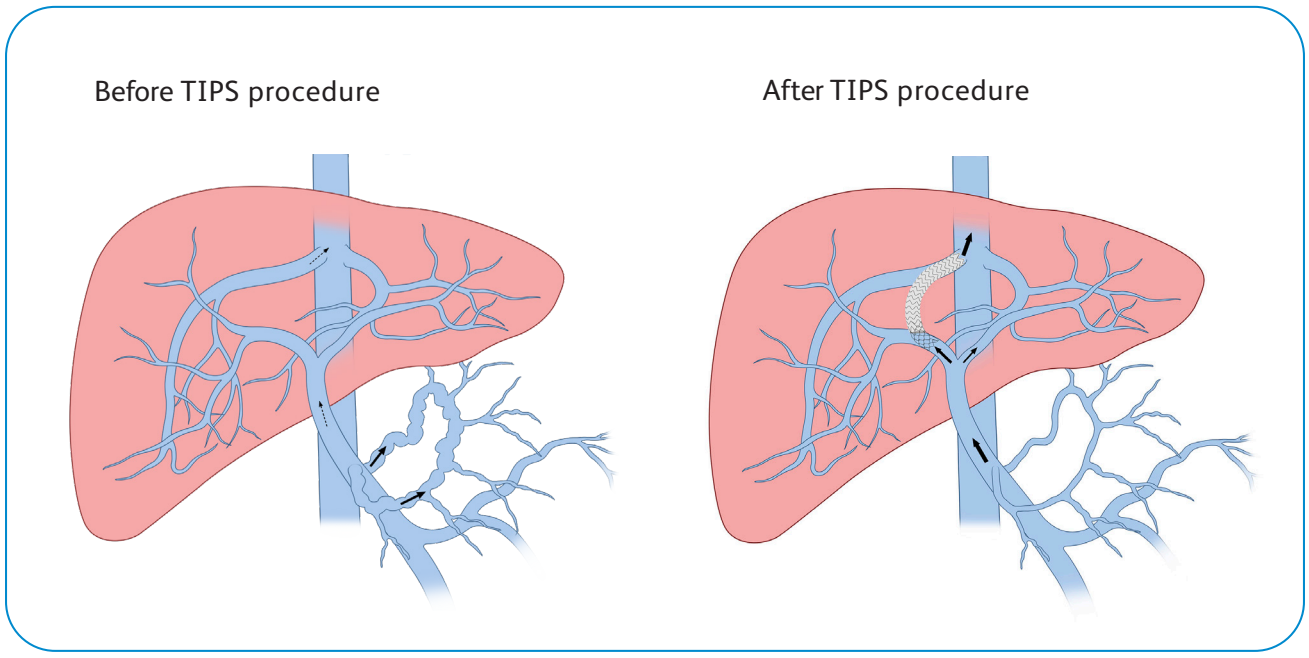


Figure 2

Understanding the risks of a TIPS Stent Graft implantation procedure

As with any medical procedure, the TIPS procedure comes with some risks. It is important to be aware of possible side effects that may be associated with your TIPS procedure so you can make informed decisions with your care team.

It may carry risks such as:

- Bleeding at the insertion site in the neck (access site bleeding)
- Unintended puncture or hole made during the procedure (accidental puncture)
- Damage to the bile ducts that carry bile to the liver (biliary injury)
- Slowing or blockage of bile flow (cholestasis)
- Heart not pumping blood as well as it should (congestive heart failure)
- Death
- Blockage of a blood vessel by a blood clot, air bubble, or material put into the body (embolism)
- Blood collecting in the abdomen (hemoperitoneum)
- Severe bleeding (hemorrhage)
- Problems with thinking, behavior, and/or movement caused by liver failure (hepatic encephalopathy)
- Loss of blood flow to part of the liver causing tissue damage (hepatic infarction)
- Infection
- Problems caused by the liver not working correctly (liver failure/dysfunction)
- Blockage (occlusion) of the stent graft or a blood vessel
- Small tear (perforation) in a vessel or organ
- Inflammation or infection of the lining of the abdomen (peritonitis)
- Fluid in your abdomen causing a swollen belly (recurrence of ascites)
- Kidneys not working properly (renal failure)
- Narrowing in a blood vessel or the stent graft (stenosis)/recurrence of a narrowing in a blood vessel or the stent graft (restenosis)
- Formation of blood clots within a blood vessel or the stent graft (thrombosis)
- Damage to tissue or organs (tissue/organ injury)
- Damage to a vessel (vessel injury)

What is the Liverty™ TIPS Stent Graft?

The Liverty™ TIPS Stent Graft is a small, flexible tube that is placed inside the liver to help improve blood flow in people with portal hypertension. It is used during a TIPS procedure to create a new pathway for blood to move more easily through the body when the liver is too scarred to do so on its own.

The stent graft is made from a special metal called **nitinol**, which gently expands to fit your body, and is partly covered with a smooth material called ePTFE. These materials are known to work safely inside the body, unless you have an allergy or hypersensitivity to them.

The stent graft is compressed in a long thin tube for placement inside your liver via a **minimally invasive procedure**. This procedure is described on the next page.

What should you inform your doctor about?

Before your procedure, be sure to tell your doctor about any allergies or sensitivities you may have, especially to metals or medical materials.

When can the Liverty™ TIPS Stent Graft be used?

Indication for Use: The Liverty™ TIPS Stent Graft is indicated for the treatment of complications of portal hypertension.

Contraindications: None known.

For further information about the device, refer to the Instructions for Use located at eifu.bd.com. The Liverty™ TIPS Stent Graft is for prescription use only.

Clinical Study Overview

A clinical study was conducted to evaluate the safety and effectiveness of the Liverty™ TIPS Stent Graft. In this study, 177 people with complications of portal hypertension such as ascites and variceal bleeding were treated with the Liverty™ TIPS Stent Graft.

This study looked at how many patients experienced major complications within 30 days after their TIPS procedure. A major complication was defined as a major health problem related to the device or procedure that required hospitalization, caused lasting harm, or was life-threatening. 14.2% patients experienced major complications through 30 days.

This study also looked at how many patients maintained blood flow through their TIPS (patency) within 6 months after their TIPS procedure. 90.4% patients experienced shunt patency through 6 months. Secondary procedures to manage continued symptoms of portal hypertension occurred in 25.2% of patients.

The results of this clinical study demonstrate that the Liverty™ TIPS Stent Graft is safe and effective in the treatment of complications of portal hypertension.

What happens during a TIPS procedure?

A TIPS procedure is a **minimally invasive procedure** used to improve blood flow in the liver. It is performed under general anesthesia by a specialist, typically an interventional radiologist, in a hospital setting.

The procedure begins with a small puncture in the **jugular vein** (usually on the right side of the neck) (Figure 3). Through this access point, the doctor inserts a thin tube to reach the veins inside your liver.

Using real-time imaging and **contrast,** the doctor guides a needle from the hepatic vein into the portal vein, creating a new channel between them (Figure 4). This channel is gently widened using a balloon, and the TIPS stent graft is placed in the channel to keep it open and allow blood to flow more easily.

Once the stent graft is in place (Figure 5), the doctor checks blood flow and pressure to confirm the **channel** is working properly. Only the stent graft remains in your body after the procedure.

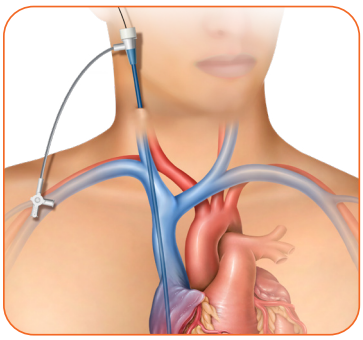


Figure 3

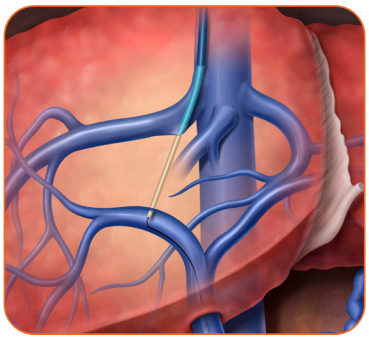


Figure 4

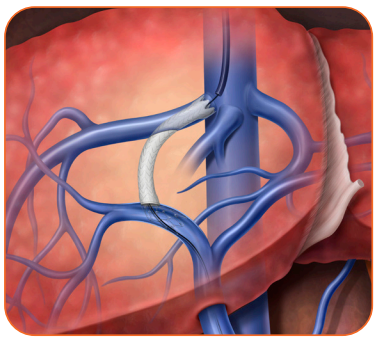


Figure 5

After your Liverty™ TIPS Stent Graft procedure

What to expect in the hospital

Most patients stay in the hospital for 1 to 3 days after a TIPS procedure. During this time, your care team will monitor your recovery, including your blood pressure and liver function. Imaging tests may be performed to confirm that the stent graft is working properly.

Before you're discharged, your doctor will explain:

- Which activities are safe to resume
- What kind of diet may support your recovery
- Any medications you'll need to take

It is important to follow these instructions closely and attend all scheduled follow-up visits.

Living with your Liverty™ TIPS Stent Graft

Ongoing care is essential to ensure your stent graft continues to function well and to detect any potential complications early. Your follow-up plan may include:

- **Ultrasound imaging**: Typically done within the first month and then every 3–6 months to check blood flow and stent graft condition.
- **Routine blood tests:** To monitor liver and kidney function, and check for clotting or signs of liver stress.
- **Health care provider visit:** Regular check-ins to adjust medications and manage symptoms.
- **Lifestyle guidance:** You may be advised to follow a low-sodium, liver-friendly diet, avoid alcohol, and manage other health conditions.
- **Symptom awareness:** Learn to recognize signs of complications such as confusion, abdominal swelling, or jaundice. Contact your doctor if these occur.
- **Secondary procedures:** If symptoms persist or worsen, you may need additional procedures to manage your portal hypertension.

Can the Liverty™ TIPS Stent Graft be removed?

The Liverty™ TIPS Stent Graft is designed to be a permanent implant. Removal is not typically required and would only be considered if medically necessary.

Can I still receive liver transplant after the TIPS creation?

Please consult your doctor to discuss how TIPS may affect future liver transplant options.

Keep your implant card handy

Your Liverty™ TIPS Stent Graft implant card contains important details about your device. Always carry it with you and show it to any health care provider involved in your care.

If you need a **magnetic resonance imaging (MRI) scan**, inform your doctor or MRI technician that you have a stent graft implant. They should follow the safety instructions provided on your implant card or in the guidance below to ensure the scan is performed safely.

Safety during Magnetic Resonance Imaging (MRI)

Your Liverty™ TIPS Stent Graft has been classified as MR Conditional. This means that an MRI can be done safely if specific testing conditions are followed. These conditions are outlined on the implant card that was provided to you as part of your procedure. Please provide this information to anyone assisting you with an MRI. A copy of the information located on the card is also provided below.

A person with a single and/or overlapped Liverty™ TIPS Stent Graft may be safely scanned under the following conditions:



MR Conditional

Static Magnetic Field Strength (B0)	1.5 T or 3.0 T
Maximum Spatial Field Gradient	40 T/m (4000 Gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body Transmit Coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2.0 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	2.0 W/kg whole-body average SAR for 15 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The presence of the Liverty™ TIPS Stent Graft may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.

Note: Failure to follow these conditions may result in injury to the patient. The effect of heating in the MRI environment for stents with fractured struts is not known.

Your doctor can access further MRI information in the BD Liverty™ TIPS Stent Graft Instructions for Use (IFU) located at eifu.bd.com.

Glossary

Term	Definition
Ascites	An abnormal buildup of fluid in the abdomen, often due to liver disease.
Cirrhosis	A condition where the liver becomes scarred and loses its ability to function properly.
Contrast	A liquid injected into blood vessels to help visualize blood flow during imaging tests like X-rays.
Esophagus	The organ that carries food from the mouth to the stomach.
ePTFE (expanded Polytetrafluoroethylene)	A soft, smooth material often used in medical products. It's proven to be compatible with the body and allows blood to flow easily through the graft lumen.
Hepatic vein	A vein that carries blood away from the liver to the heart.
Intrahepatic	A term that means "inside the liver." In the TIPS procedure, it refers to the part of the treatment that takes place within the liver itself.
Jugular vein	A large vein in the neck that returns blood from the head to the heart. In the TIPS procedure, it is used as an entry point to get to the veins in the liver.
Minimally invasive procedure	A medical procedure performed through a small incision or puncture, often using imaging guidance.
MRI (Magnetic Resonance Imaging)	A type of scan that uses magnets and radio waves to take detailed pictures of the inside of your body—especially soft tissues like the liver, brain, or blood vessels. You'll lie still inside a tube-shaped machine while it creates images that help doctors see what is going on inside.
Nitinol	A metal made from nickel and titanium. It's flexible and gently expands to fit the shunt diameter. Because of these properties, it's commonly used in certain medical devices like stent grafts.
Portosystemic	Describes a connection between the portal vein (which carries blood from the digestive organs to the liver) and the body's main circulation system. In a TIPS procedure, this connection helps blood bypass the damaged liver and flow more easily.
Portal hypertension	Increased pressure in the portal vein, usually caused by cirrhosis, which can lead to bleeding in other places (varices) or fluid buildup in the abdomen (ascites).
Portal vein	The main vein that carries blood from the digestive organs to the liver.
Shunt	An artificial passage created to redirect blood flow between vessels.
Stent Graft	A stent graft is a small, tube-shaped device made of metal mesh and soft fabric. It is placed inside the body to help keep a passageway open and guide blood flow.
TIPS	Transjugular Intrahepatic Portosystemic Shunt—a procedure that creates a new channel through the liver to improve blood flow.
Transjugular	A medical approach where doctors access the liver through the jugular vein—a large vein in the neck that carries blood from the brain back to the heart.
Ultrasound	A type of imaging that uses sound waves to create images of organs and blood flow.
Varices	Enlarged veins, often in the esophagus or stomach, that are prone to bleeding. Often due to portal hypertension.



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