Patient Information on TIPS

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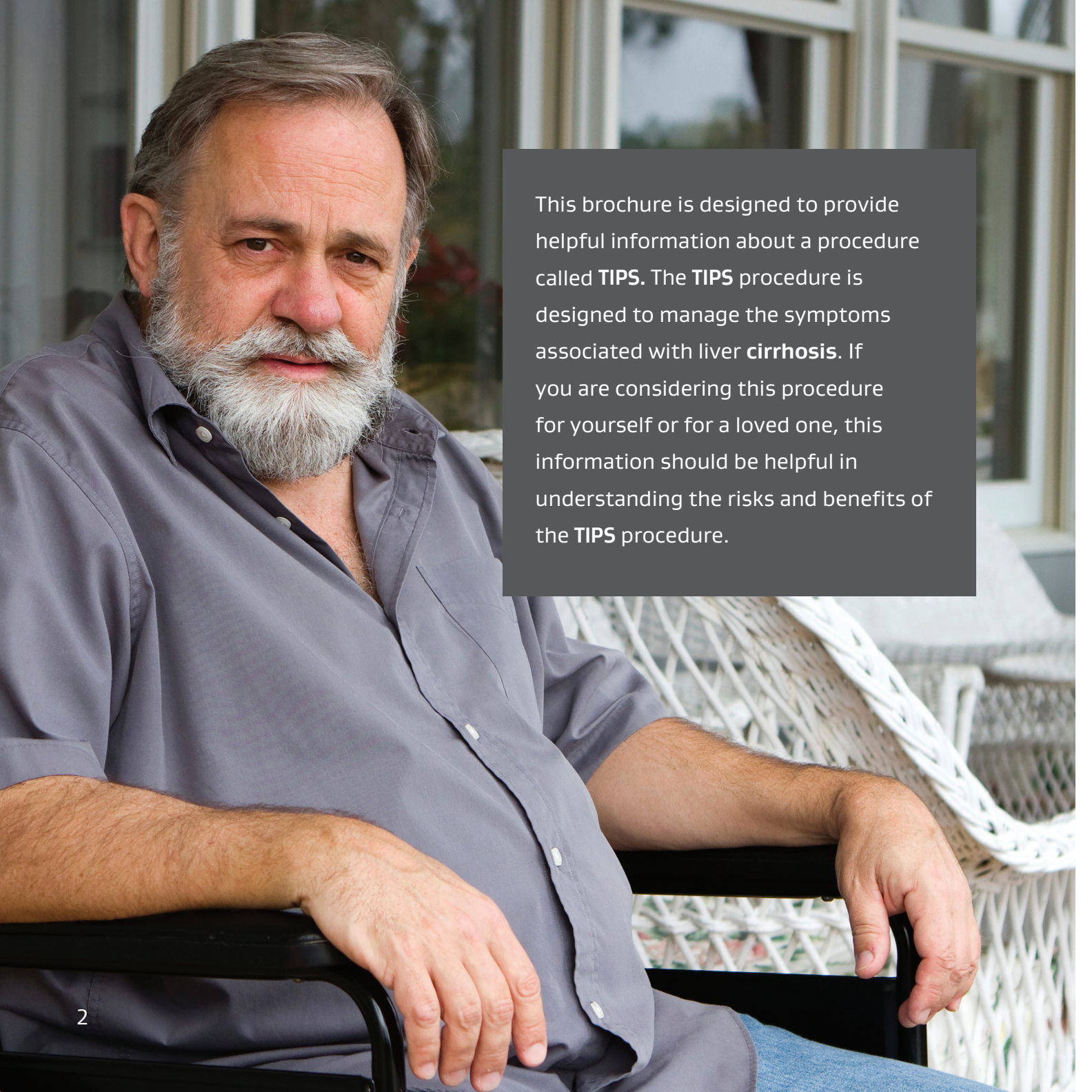


This brochure is designed to provide helpful information about a procedure called **TIPS.** The **TIPS** procedure is designed to manage the symptoms associated with liver **cirrhosis**. If you are considering this procedure for yourself or for a loved one, this information should be helpful in understanding the risks and benefits of the **TIPS** procedure.

Introduction

Normally, blood flows from the bowel to the liver through the **portal vein. Cirrhosis** (or scarring) of the liver restricts the flow, increasing pressure in the **portal vein. TIPS** (Transjugular Intrahepatic Portosystemic Shunt) is a **minimally invasive procedure** in which a new path is made through the liver to carry blood from the portal vein to the heart, thus helping to alleviate the problems associated with elevated **portal vein** pressure. The **TIPS** procedure will be described in this brochure.

This brochure is an informational and referral guide only, and is not intended to diagnose a medical condition. As with any surgery or medical procedure, the best resource for information and advice is your doctor.

What is cirrhosis and portal hypertension?

The liver is the largest organ in the body, weighing about three pounds, and is responsible for over 500 functions. Most of the blood that leaves the stomach and the small intestines must pass through the liver. **Cirrhosis** of the liver occurs when normal liver tissue is damaged and replaced by scar tissue. Most of the blood flowing through the liver comes from the **portal vein,** and in a cirrhotic liver, the scar tissue significantly slows the flow of blood from the **portal vein** through the liver. This reduction of blood flow due to **cirrhosis** causes a large difference in the pressure of blood entering the liver and the pressure of blood exiting the liver to return to the heart. This difference in pressures is called **portal hypertension.**

Due to reduced blood flow through the liver, blood must now find a different way to reach the heart. The body diverts blood away from the liver by increasing blood flow through vessels surrounding the stomach and lower portion of the **esophagus.** This increased blood flow changes these vessels into swollen, twisted, and weak veins called **varices. Varices** can potentially rupture leading to bleeding which requires immediate medical attention.

Another complication of **portal hypertension** is called **ascites. Ascites** is the accumulation of fluid in the peritoneal cavity which can cause abdominal swelling. Your doctor can provide you with additional information about these complications.

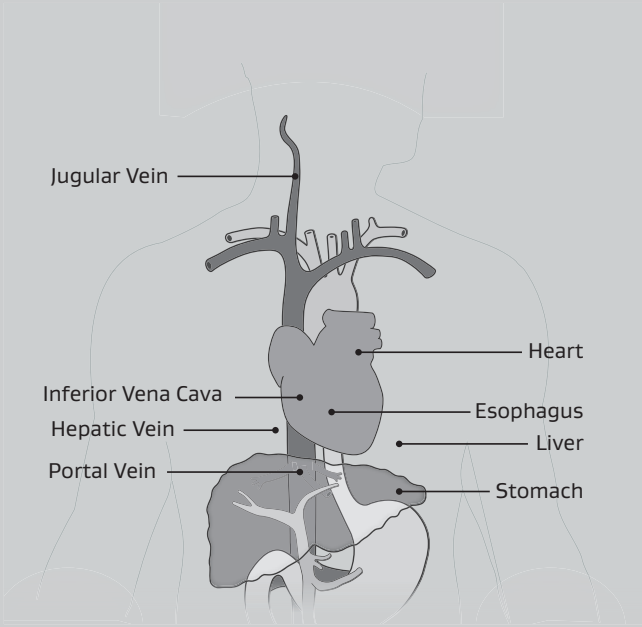
Treatment options

For a person who has progressive or worsening liver **cirrhosis** and **portal hypertension** there are several treatment options available:

1. Your doctor may put you on medication in combination with a low salt and restricted protein diet.
2. You may require additional procedures to treat the complications of your liver **cirrhosis** such as:
   - Needle drainage of **ascites** fluid accumulating in your abdomen
   - Treatment of enlarged veins in your **esophagus** or stomach with banding or injections through a flexible scope
3. If the above treatments are ineffective, a **TIPS** procedure, open surgical interventions, or liver transplantation may be required.

How does a TIPS help a person with portal hypertension?

A **TIPS** procedure creates a new channel to route blood flow through the damaged liver and into the main blood vessels that lead blood back to the heart. A **TIPS stent** placed inside this channel allows a portion of excess blood to bypass the liver, reducing **portal hypertension** and the associated complications.



What is a TIPS?

TIPS is an abbreviation for a procedure that helps correct blood flow problems in the liver by connecting two blood vessels with an implanted device:

Transjugular	through the **jugular vein**
Intrahepatic	within the liver
Portosystemic	from the **portal vein** to the general circulation
Shunt	a channel for blood to flow

What are the benefits of TIPS?

There are several benefits to having a **TIPS** procedure to correct blood flow problems in the liver and treat the consequences of **portal hypertension** such as **ascites** and **varices.** The TIPS procedure is a **minimally invasive procedure** which reduces recovery time and the time spent in the hospital. The **TIPS** procedure routes a portion of the excess blood flow through the liver and reduces the **portal hypertension,** so that alternative treatments such as medications, **paracentesis** for **ascites,** and the treatment of **varices** may be needed less frequently or not at all. Your doctor will provide more information regarding your **TIPS** treatment plan.

What are the risks of TIPS?

While all surgical procedures have risks, the risks associated with a **TIPS** procedure include:[1]

- Damage to blood vessels
- Fever
- **Hepatic encephalopathy**
- Infection, bruising, or bleeding
- Reactions to medicines or the dye
- Stiffness, bruising, or soreness in the neck

Rare risks are:

- Bleeding in the belly
- Blockage in the **stent**
- Cutting of blood vessels in the liver
- Heart problems or abnormal heart rhythms
- Infection of the **stent**
- Death

Everyone is different, so there may be additional risks that are not mentioned here. The risks to each individual should be discussed in more detail with your doctor.

1 US National Library of Medicine, MedlinePlus
https://medlineplus.gov/ency/article/007210.htm

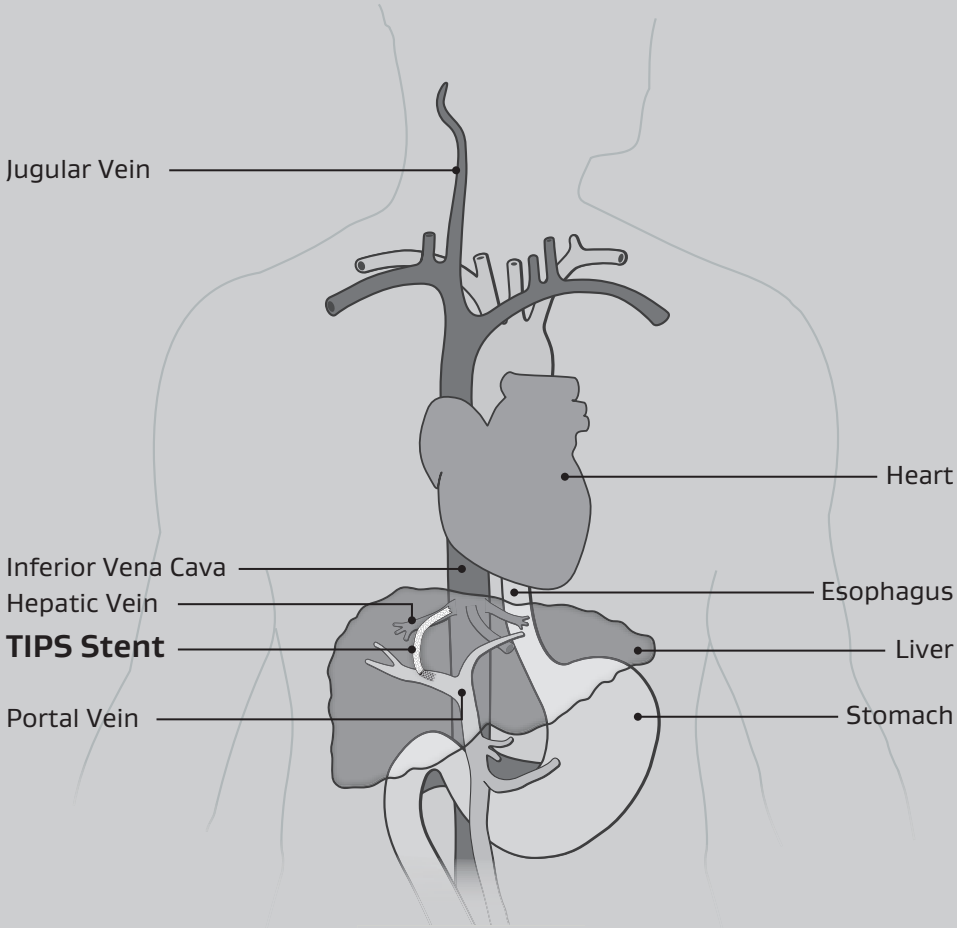

Jugular Vein
Heart
Inferior Vena Cava
Hepatic Vein
Esophagus
TIPS Stent
Liver
Portal Vein
Stomach

Figure 1

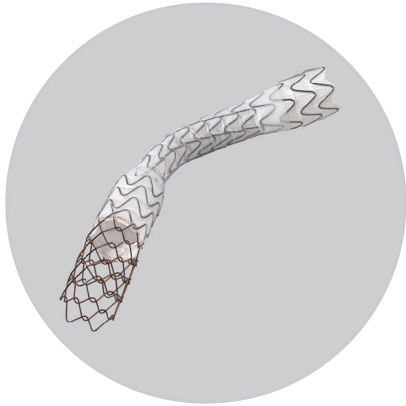
What happens during a TIPS procedure?

The **TIPS** procedure is accomplished through a **minimally invasive procedure** under general anesthesia and is performed by specially trained doctors (sometimes known as interventional radiologists) in the interventional radiology suite or occasionally the operating room of the hospital. You will not have anything to eat or drink for several hours before the procedure. During the **TIPS** procedure, you will be connected to monitors to track your heart rate and blood pressure. You will also have an intravenous line in your arm to administer medications during the procedure.

An **introducer sheath** is placed through a small skin puncture in the **jugular vein** usually on the right side of the neck. The entire **TIPS** procedure is performed through this **introducer sheath.**

The doctor will use X-ray pictures and X-ray dye (also called **contrast dye**) to guide the procedure. A long thin needle is next guided through the **introducer sheath** to the **hepatic vein.** Using X-ray guidance, the needle is directed from the **hepatic vein** into the **portal vein** creating a tunnel between the hepatic and **portal veins.** A special balloon is used to enlarge the liver tunnel and the doctor inserts the **TIPS stent** into the tunnel to help it remain open (*Figure 1*).

When the procedure is finished, blood flow and pressures will be measured from the **hepatic vein** across the **TIPS stent** to the **hepatic vein.** At the completion of the procedure, only the TIPS stent will remain in your body. A **TIPS** procedure typically takes 2–3 hours to perform.



The GORE® VIATORR® TIPS Endoprosthesis, pictured above, is an example of a TIPS stent.

Following the TIPS procedure

The typical hospital stay after the **TIPS** procedure is one to three days or possibly longer. During that time, your doctor will monitor blood pressure and may conduct an **ultrasound** study of the liver and **stent** to make sure the device stays open. After going home, a diet low in protein and salt may be suggested. In addition, medications may be prescribed to minimize the accumulation of blood toxins. **Contact your doctor immediately if you experience disorientation or confusion.**

It's important that the **TIPS** is carefully monitored over the following three years. Advised follow-up may include check-ups at one month, six months, and each year after that. The follow-up exams may consist of routine X-rays, an **ultrasound** study and blood tests. Please ask your doctor if you have any questions regarding these tests and exams.

How will I know if the TIPS is working?

The symptoms of **portal hypertension** that you have experienced may get better or go away. The swollen blood vessels may shrink and not be as prone to bleeding, which means you may not experience additional bleeding episodes. There may also be a reduction or complete resolution of the fluid that accumulates in the abdomen, which may reduce or eliminate the need for removing the fluid by **paracentesis.** Of course, **if your symptoms get worse, you should contact your doctor immediately.**

Signs and symptoms of device failure: when should I call my doctor?

An indication that the TIPS stent is not working correctly would be returning or worsening of symptoms such as ascites or bleeding from varices. Consult your doctor for any other unanticipated symptoms or concerns.

Where can I get more information?

American Liver Foundation
www.liverfoundation.org

European Association for the Study of the Liver (EASL)
www.easl.eu

Society of Interventional Radiology
www.sirweb.org

US National Library of Medicine
www.medlineplus.gov

US Department of Health and Human Services Food and Drug Administration
www.fda.gov

W. L. Gore & Associates, Inc.
www.goremedical.com

Glossary of Medical Terms

Words included in the **Glossary of Medical Terms** are typed in **bold** throughout the brochure.

Ascites: An accumulation of fluid in the abdomen.

Cirrhosis: A general classification of liver disease characterized by scarring of the liver.

Contrast dye: A dye injected into the blood vessels
to show blood flow during X-ray images.

Esophagus: The food passage extending from the mouth to the stomach.

Hepatic encephalopathy: A condition describing an adverse effect of liver disease on the central nervous system due to the accumulation of blood toxins. Symptoms may range from slight disorientation to coma.

Hepatic vein: The vein which carries blood from the liver back to the heart.

Introducer sheath: A long, thin, tube-like tool that helps in the delivery and placement of the **TIPS stent** through the body's veins.

Jugular vein: A neck vein which returns blood from the head back to the heart.

Minimally invasive procedure: A procedure in which access to the internal organs or blood vessels of the body is through a small incision or puncture in a blood vessel or skin. This type of surgery is also referred to as an endovascular or percutaneous procedure.

Paracentesis: A procedure in which a needle is inserted into the abdomen to remove fluid.

Portal hypertension: The build up of pressure in the portal vein commonly caused by liver cirrhosis. It may result in bleeding or **ascites.**

Portal vein: The main vein that carries blood from the stomach and intestines to the liver.

Shunt: A passage created between two natural channels, especially between blood vessels.

Stent: A tube-like device that helps a blood channel remain open.

TIPS: An abbreviation for Transjugular Intrahepatic Portosystemic Shunt. A **minimally invasive procedure** in which a new path through the liver is formed to carry blood back to the heart.

Ultrasound: An image created through the use of high-frequency sound waves.

Varices: Enlarged blood vessels which are prone to bleeding.

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Consult Instructions for Use
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Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

INDICATIONS FOR USE IN THE U.S.: The GORE® VIATORR® TIPS Endoprosthesis is indicated for use in the de novo and revision treatment of portal hypertension and its complications such as variceal bleeding, gastropathy, ascites which recurs despite conventional treatment, and/or hepatic hydrothorax. **CONTRAINDICATIONS:** There are no known contraindications for this device.

Products listed may not be available in all markets.

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