



*Patient Information*

VIATORR

TIPS ENDOPROSTHESIS



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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 disease. 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

The TIPS procedure provides the same benefit of **shunting** blood flow as the major surgical procedure without an **open surgical** operation. A radiologist performs the procedure in the x-ray room under x-ray guidance. The procedure is done through a small puncture site in a blood vessel. The TIPS procedure helps blood flow from your **portal vein** through the liver, into the **hepatic vein** and to the heart, thus helping to alleviate the problems associated with progressive liver disease. The TIPS procedure will be described in this brochure, as well as information on the GORE VIATORR® TIPS Endoprosthesis.

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.

For a person who has progressive or worsening liver disease, there are several treatment options other than the TIPS procedure that are 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 symptoms of your liver disease 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, major surgery may be required to help blood flow bypass your liver.

## ► 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.

### **Closed Surgery**

An operation 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 minimally invasive or percutaneous surgery.

### **Contrast (Dye)**

A drug injected into the blood vessels to show blood flow during x-ray images.

### **Delivery Catheter**

A long, thin, tube-like tool that helps in the positioning and delivery of the GORE VIATORR® TIPS Endoprosthesis via the vascular system.

### **Esophagus**

The passage extending from the mouth to the stomach.



### **Guidewire**

A long, flexible wire to guide the positioning of a device in an organ inside the body.

### **Hepatic Encephalopathy**

A condition describing the adverse effects of liver disease on the central nervous system. Presenting symptoms may range from slight disorientation to coma.

### **Hepatic Vein**

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

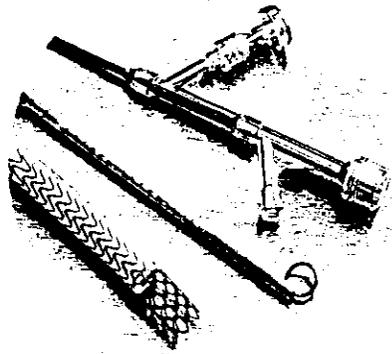
### **Jugular Vein**

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

### **MRI**

#### **(Magnetic Resonance Imaging)**

A procedure using magnetic fields and radio waves to form an image of structures inside the body.



**Nitinol**

A high-strength metal which is a mixture of nickel and titanium.

**Occlusion**

A blockage which stops the normal flow of blood.

**Open Surgery**

An operation where an incision is made into the body to get access to a particular organ.

**Paracentesis**

A needle puncture in the abdomen to remove fluid.

**Portal Hypertension**

The build up of pressure in the portal vein due to liver disease. 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 device used to provide support for tubular structures, such as blood vessels.

**TIPS**

A procedure called Transjugular Intrahepatic Portosystemic **Shunt** in which a new path through the liver is formed to carry blood back to the heart.

**Ultrasound**

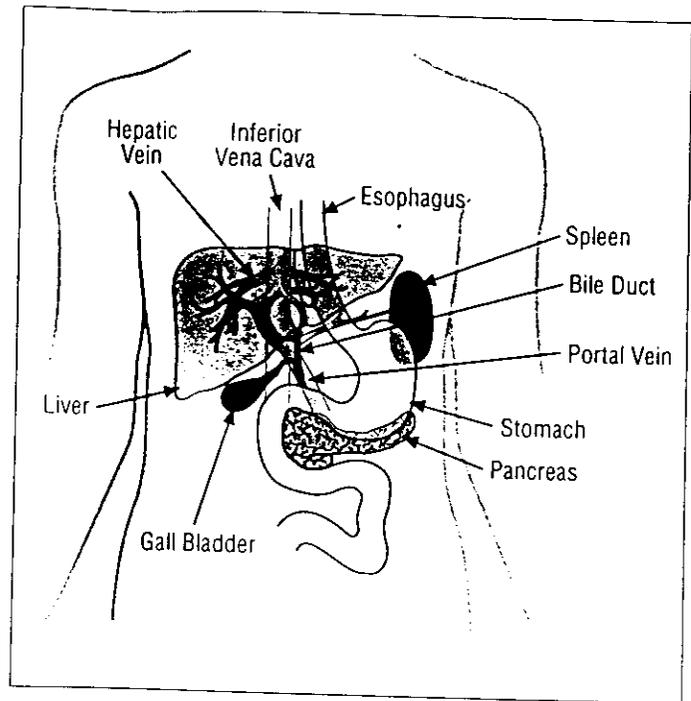
An image created through the use of high-frequency sound waves.

**Varices**

Enlarged blood vessels which are prone to bleeding

*The liver is the largest organ in the body, weighing about 3 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. A serious problem that occurs when the blood flow through the liver is decreased in any way is called **portal hypertension**.*



#### ▶ **WHAT IS A TIPS?**

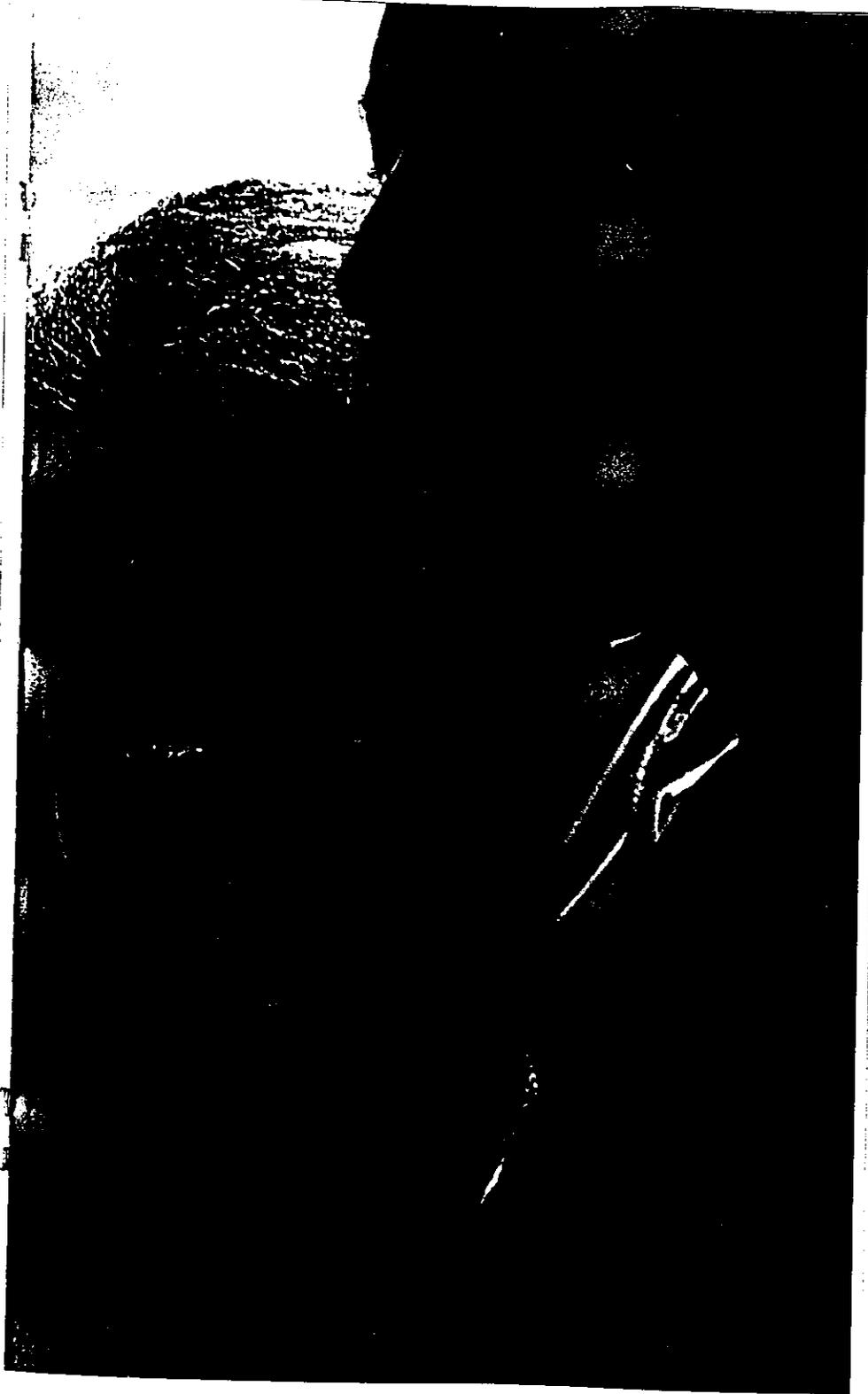
**TIPS** is an abbreviation for a procedure that helps correct blood flow problems in the liver:

- |                      |  |
|----------------------|--|
| <b>Transjugular</b>  | across the <b>jugular vein</b>                         |
| <b>Intrahepatic</b>  | within the liver                                       |
| <b>Portosystemic</b> | from the <b>portal vein</b> to the general circulation |
| <b>Shunt</b>         | a channel for blood to flow                            |

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▶ **HOW DOES A TIPS HELP A PERSON WITH LIVER DISEASE?**

Most of the blood flowing through the liver comes from the **portal vein**. **Portal hypertension** occurs when there is reduced blood flow through the liver and there is a large difference in the pressure between the blood entering the liver and exiting the liver to return to the heart. A common cause of **portal hypertension** is **cirrhosis** of the liver. With **cirrhosis**, the normal liver cells are damaged and replaced by scar tissue. When blood tries to pass through the liver, it meets resistance due to the scarring, and must find another channel. The body diverts this blood through vessels surrounding the stomach and lower portion of the **esophagus**. This increased blood flow causes these veins to become swollen, twisted and have weakened walls. These are called **varices**. The **varices** can rupture and cause life-threatening bleeding. Fluid called **ascites** can also accumulate in the abdomen due to poor liver circulation.

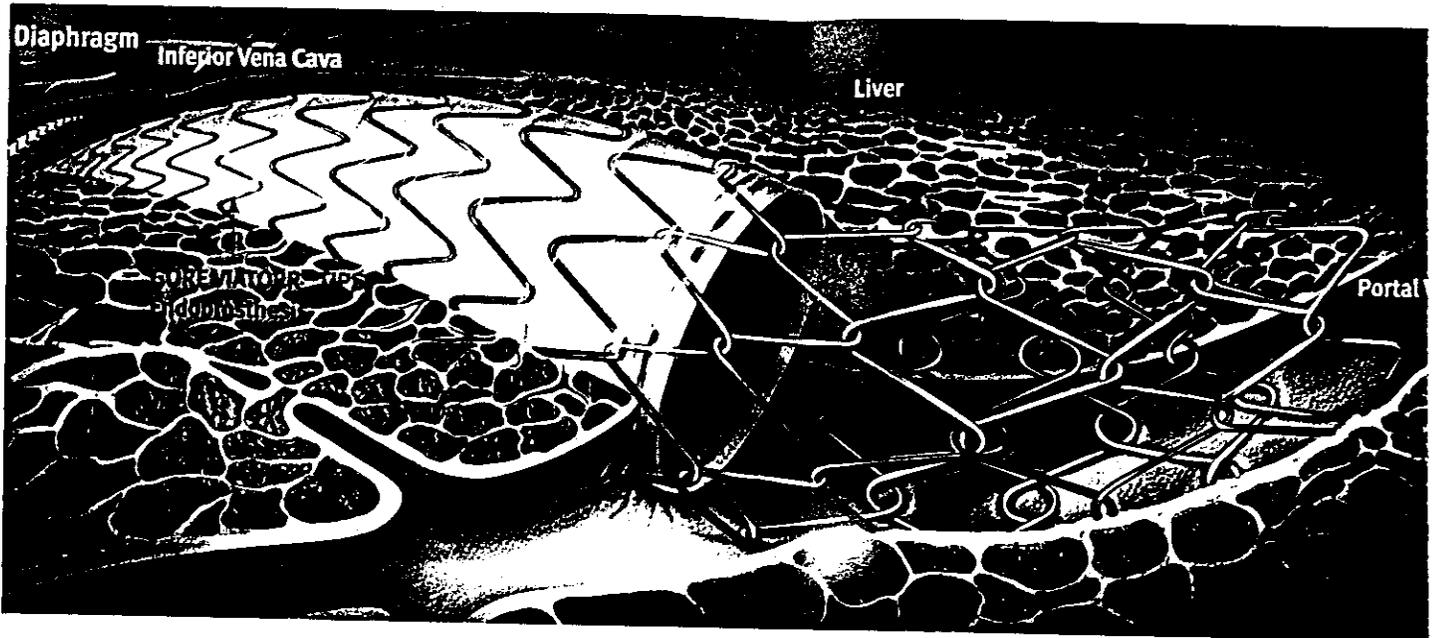


*There is evidence that the  
GORE VIATORR® TIPS  
Endoprosthesis may stay open  
for longer periods as compared  
to the other stent products used  
for TIPS which are available  
at this time. A recent clinical  
study followed patients for  
6 months and established  
that the device is safe and  
effective for TIPS creation.*

To treat **portal hypertension**, **ascites**, and **varices**, physicians can use a procedure called transjugular intrahepatic portosystemic **shunt (TIPS)**. A TIPS 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.

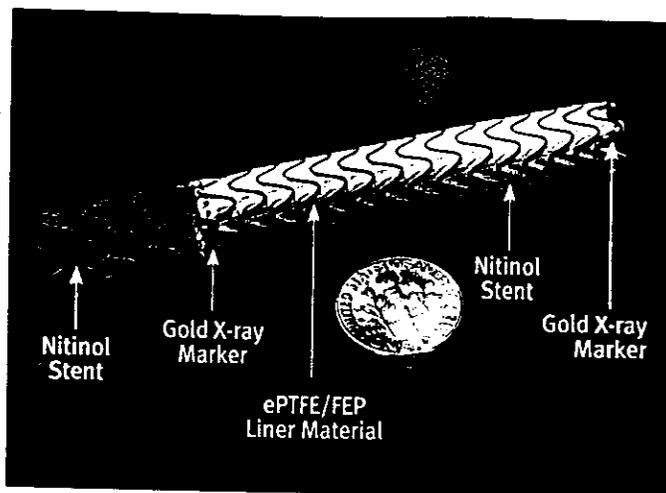
### ► **WHAT ARE THE BENEFITS OF TIPS?**

There are several benefits to having a TIPS procedure to correct blood flow problems in the liver and treat the consequences of poor liver circulation such as **ascites** and **varices**. The procedure is done with **closed surgery** utilizing a technique called minimally invasive or percutaneous surgery, so the recovery time may be quicker and the time spent in the hospital may be shorter than with **open surgery**. Because the TIPS procedure is a **closed surgery**, only a small puncture is made in the **jugular vein** for insertion of the TIPS **stent**. Also, general anesthesia may not be needed. The TIPS procedure routes the blood flow through the liver and subsequently reduces the **portal hypertension**, so that alternative treatments such as medications, **paracentesis** for **ascites**, and the treatment of **varices** may not be



*The GORE VIATORR<sup>®</sup> TIPS*

*Endoprosthesis is the tube (stent) that is placed permanently in the liver and remains in the liver to redirect blood flow through the liver. It looks like a tube made of chain link fence with a white material lining most of the metal tube's inner surface.*

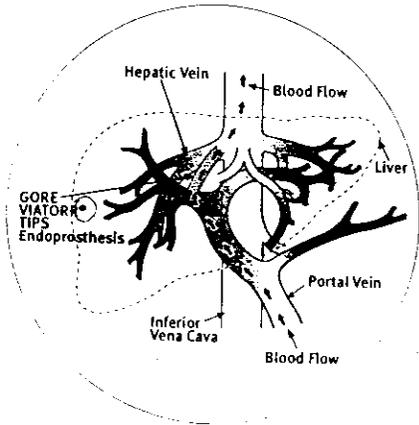
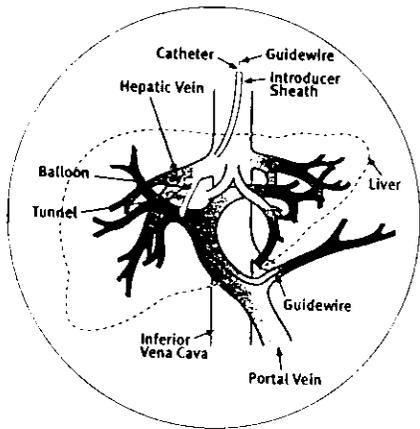
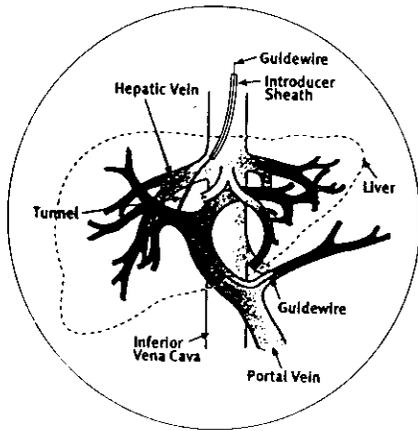


### ▶ WHAT IS THE GORE VIATORR® TIPS ENDOPROSTHESIS?

needed as often.

The design of the GORE VIATORR® TIPS Endoprosthesis is unique. The material that lines the stent can cut down on the amount of liver tissue which may get into the channel and block the blood flow. The wire is made of a flexible high-strength metal called **Nitinol** which is a mixture of nickel and titanium.

The liner material used on the GORE VIATORR® TIPS Endoprosthesis is made from chemically inert fluoropolymers (expanded polytetrafluoroethylene or "ePTFE" and fluorinated ethylene propylene or "FEP") and this material has been used safely in other artificial blood flow tubes for over 25 years.



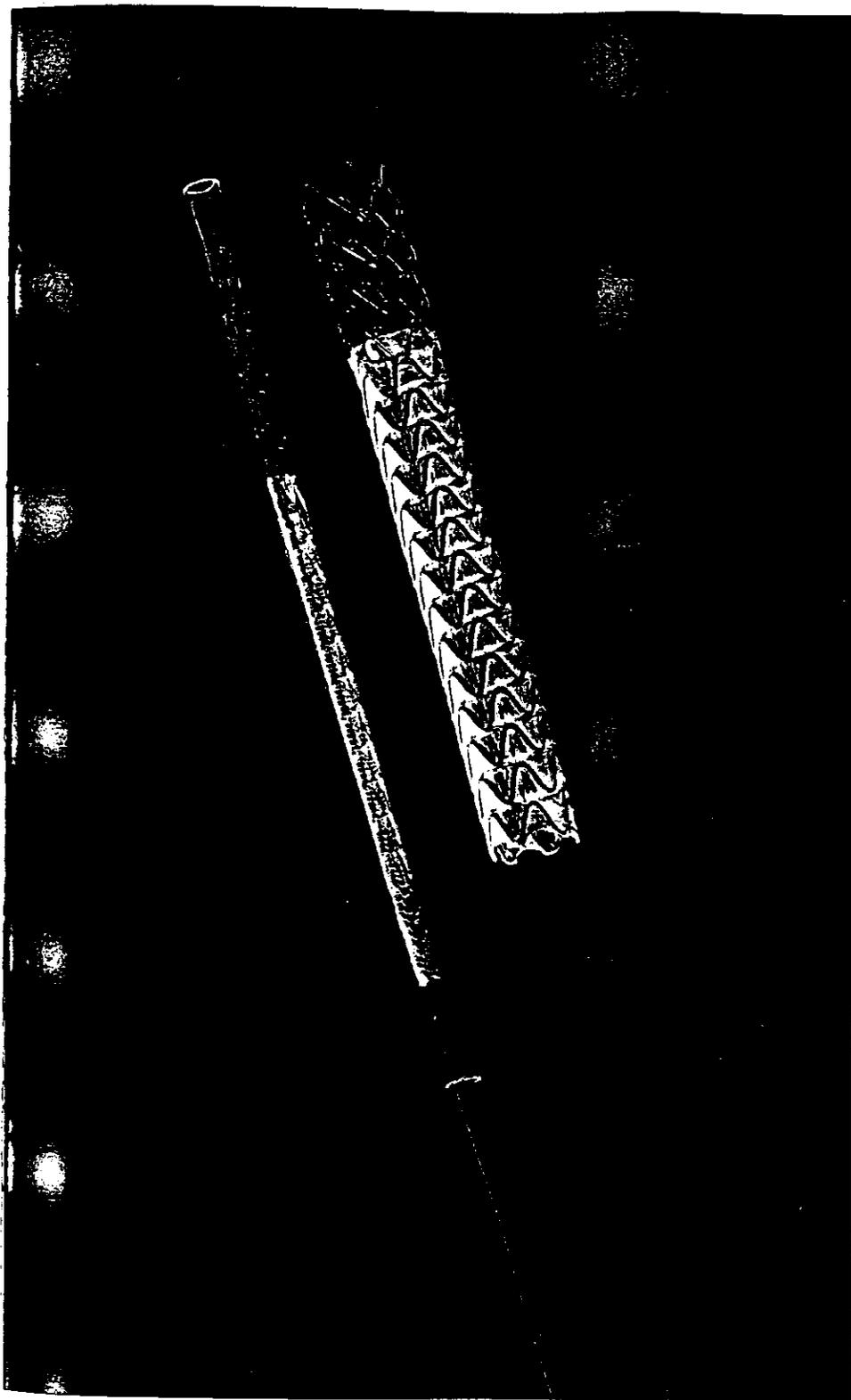
## ▶ WHAT HAPPENS DURING A TIPS PROCEDURE?

The TIPS procedure is done utilizing closed surgery and is performed by specially trained radiologists in the radiology department of the hospital (known as "interventional radiologists"). 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 which will relax you during the procedure.

The interventional radiologist will make a tunnel in the liver through which blood can flow called a **shunt**. An intravenous tube (referred to as an introducer sheath) is placed through a small puncture in the **jugular vein** usually on the right side of the neck. The TIPS procedure will take place through this intravenous tube. A **guidewire** is threaded through the heart to the **hepatic vein**.

A long thin needle is then passed along the **guidewire** through the wall of the **hepatic vein**, creating a tunnel through the body of the liver and into the **portal vein**. The **guidewire** is directed through the liver and into the **portal vein** to maintain a tunnel in the liver between the **hepatic and portal veins**.

A balloon may be used across the tunnel to widen the new tract through the liver and the holes in the **hepatic**



and portal veins.

After the tunnel is made, the doctor will insert the lined metal GORE VIATORR<sup>®</sup> TIPS Endoprosthesis (called a stent) along the passage to help the tunnel remain open. The doctor will use x-ray pictures and x-ray dye (also called **contrast dye**) to guide the procedure. When the procedure is done, blood flow and pressures will be measured from the **portal vein** across the **stent** device to the **hepatic vein**. At the completion of the procedure, only the **stent** device will remain in your body. The success rate using the TIPS procedure is 95%, and it takes approximately two to three hours to perform.

## ▶ WHAT ARE THE RISKS OF TIPS?

TIPS may cause complications. It is a procedure involving blood vessels, and there is a risk of bleeding. Also, some additional complications may include:

Confusion or disorientation (**encephalopathy** which is usually temporary and can be treated with medications)

Infection

Stenosis (narrowing of the tunnel)

**Occlusion** (a complete blockage of the tunnel)

Accelerated liver dysfunction

Fever

Muscle stiffness

Bruising on the neck or nerve damage near the insertion point

Allergic reaction to the x-ray dye or other procedural components (including metals in the device)

Abnormal heart rhythms

Death (extremely rare)

## ▶ FOLLOWING THE TIPS PROCEDURE

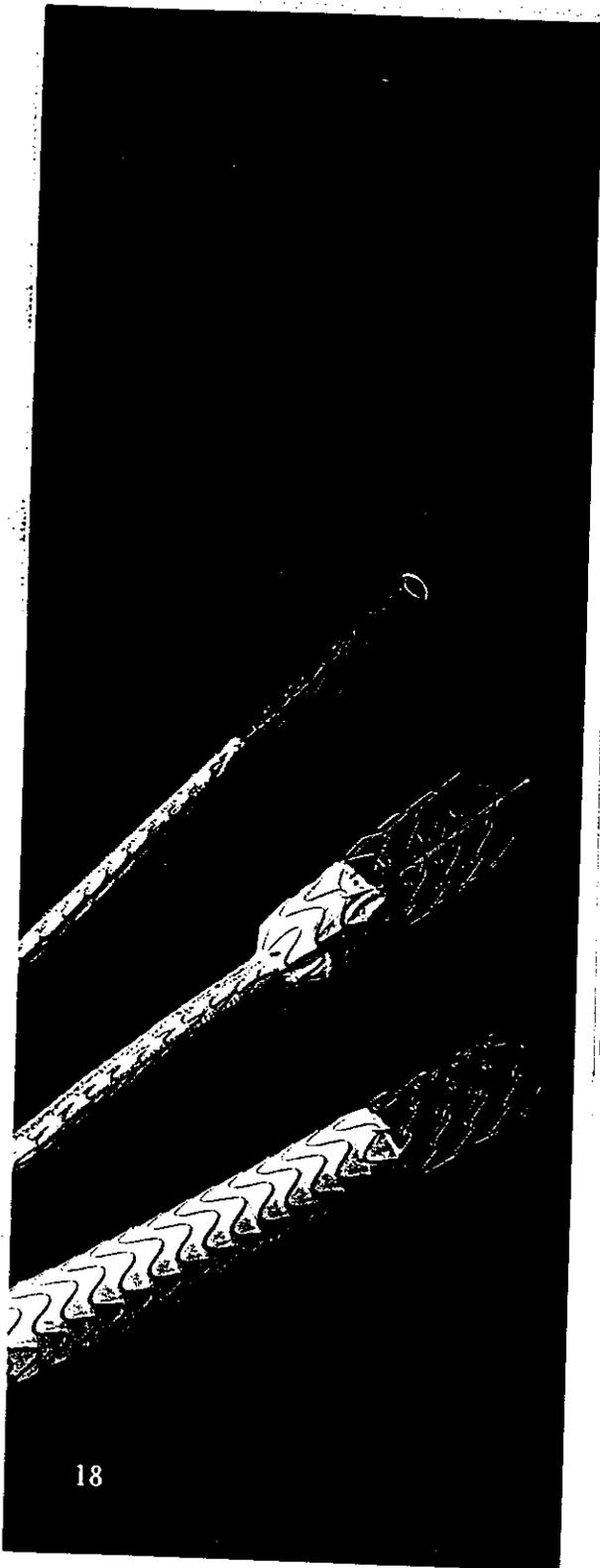
The typical hospital stay after the TIPS procedure is 1-3 days. During that time, the doctor will monitor blood pressure and may conduct an **ultrasound** analysis of the liver to make sure the device stays open. After going home, a diet low in protein and salt may be suggested. In addition, medications may be prescribed to minimize the accumulation of blood toxins. If disorientation or confusion does occur, it is usually temporary.

Currently, follow-up is advised to include check-ups at one month, six months and each year after that. The follow-up exams will consist of routine x-rays, an **ultrasound** image and possibly blood tests. These follow-up exams carry some minimal risk, however, the benefits of these tests clearly outweigh any potential risks. There is a rare risk of allergic reaction related to the **contrast dye** used in the x-rays. Please ask your doctor if you have any questions regarding these tests and exams.

## ▶ WARNING

No health conditions have been identified that would prevent your treatment with the device. However, the safety of the device has not been studied in children, patients on blood thinning drugs, pregnant women, those with cardiac pacers or implanted cardiac devices, patients with prosthetic heart valves, patients who have had radiation therapy, or patients who have recently had right internal **jugular vein** procedures.

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.



## ▶ POTENTIAL COMPLICATIONS AFTER THE TIPS PROCEDURE

After TIPS, possible complications that MAY occur include:

1. **Encephalopathy** or mental confusion. This may happen to as many as 1 in 3 persons who have the TIPS procedure. **Encephalopathy** can be treated with diet, medication, or by revising the **shunt**.
2. Bleeding into the liver or around the liver.
3. Blockage or narrowing of the **shunt**. This can occur anytime after the procedure, and may be found on the routinely scheduled **ultrasound** tests. Signs of a blockage in the TIPS may include worsening **ascites**, or rebleeding from **varices**. Narrowing or blockage can be treated by a radiologist through additional procedures. The original device stays in the liver.

## ▶ HOW WILL I KNOW IF THE TIPS IS WORKING?

The symptoms of **portal hypertension** you are experiencing now may get better or go away. This means that you may not experience the bleeding episodes from the swollen veins. The blood vessels may shrink and not be as prone to bleeding. The fluid that accumulates in the abdomen may also be reduced, so that the need for removing the fluid by **paracentesis** is less. The **ascites** fluid may go away totally. Of course, if your symptoms get worse, you should see your doctor as soon as possible.



▶ **SIGNS AND SYMPTOMS  
OF DEVICE FAILURE:  
WHEN SHOULD I CALL  
MY DOCTOR?**

An indication that the GORE VIATORR<sup>®</sup> TIPS Endoprosthesis is not working correctly would be a return of the symptoms for which you originally had the TIPS procedure, such as ascites or bleeding from varices or increased breathing difficulties. Also, if you develop disorientation or confusion, you must see your doctor immediately. It is important to discuss with your doctor other potential symptoms or warning signs that indicate that the device is not working properly.

► WHERE CAN I GET MORE INFORMATION?

American Liver Foundation  
[www.liverfoundation.org](http://www.liverfoundation.org)

Society of Interventional Radiology  
[www.sirweb.org](http://www.sirweb.org)

US National Library of Medicine  
[www.medlineplus.gov](http://www.medlineplus.gov)

US Department of Health and Human Services  
Food and Drug Administration  
[www.fda.gov](http://www.fda.gov)

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