



Patient Information Guide

River Stent System™

Humanitarian Device. Authorized by Federal law for use in the treatment of idiopathic intracranial hypertension in adult patients who have failed medical therapy. The effectiveness of this device for this use has not been demonstrated.

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1 Understanding Venous Sinus Stenosis in Idiopathic Intracranial Hypertension

What are the venous sinuses?

Venous sinuses are special wide blood channels that drain blood away from the brain and return it back to the heart. They are built into the tough outer covering of the brain, which is also known as the dura.

What is Idiopathic Intracranial Hypertension (IIH)?

Idiopathic intracranial hypertension (IIH) is a medical condition where the pressure in the brain is higher than normal, but doctors cannot find a clear cause. It may happen because the fluids inside your brain are not draining properly. The fluids can be the fluid around the brain cells, the cerebrospinal fluid (CSF) inside the cavities called the ventricles, and the blood within the venous sinuses. IIH is a chronic condition and may come back despite treatments, including treatment by stenting.

The transverse venous sinus (or transverse sinus) is one of the venous sinuses in the back of the head. In many patients with IIH, the transverse venous sinus becomes narrowed (stenosed) over time. When the transverse venous sinus is narrowed, less blood can flow through it. This narrowing in the transverse venous sinus can cause blood to not drain as easily and therefore increase the pressure in the brain.

The increased pressure in the brain can result in symptoms such as headaches, vision problems, and a whooshing sound (pulsatile tinnitus) in the ears.

What are risk factors for IIH?

Most often, IIH affects women of reproductive age who are overweight.

How is IIH diagnosed?

There are several evaluations that may be used to diagnose IIH:

- Review of symptoms such as headaches, blurred or double vision, temporary vision blackouts, or ringing in the ears.
- Eye exams may include an assessment of any swelling of the optic nerve (papilledema) and tests to identify problems with vision.
- Brain imaging helps doctors see if there is any other cause like a tumor, infection or other reason for the symptoms and the increased pressure in the brain. A special type of non-invasive brain imaging called contrast-enhanced magnetic resonance venography (CE-MRV) can be used to check if there is any narrowing of the venous sinuses.
- Lumbar puncture (spinal tap) uses a needle to enter the spinal canal. This procedure is used to check if the CSF has a normal makeup, to measure the pressure of the CSF and to remove excess CSF.

How is IIH treated?

Initial treatments for IIH include weight loss and medications. In extreme cases, bariatric

surgery may be used to help with weight loss. Medications aim to reduce the production of CSF with the goal of reducing the pressure in the brain.

If medications fail to control symptoms, surgical procedures may be recommended. Most commonly, procedures include placement of a small tube (shunt) to help drain excess CSF to reduce the pressure in the brain. This can include a ventriculoperitoneal (VP) shunt, a device that drains CSF from the brain to the abdomen, or a lumboperitoneal (LP) shunt, a device that drains CSF from the lower back (spine) to the abdomen.

Another type of surgical procedure is an optic nerve sheath fenestration for patients with severe vision problems. The optic nerve is surrounded by CSF. In IIH, the high pressure can make the optic nerve swell (also known as papilledema). Surgery to make a small opening in the sheath around the optic nerve can allow extra CSF to drain and can relieve pressure on the nerve.

Venous sinus stenting can be used to open a narrowed transverse sinus. A stent is a small, mesh-like tube made of metal that is placed in the narrowed area of the transverse sinus to make the fluid pathway bigger. Opening the venous sinuses can reduce the venous pressure in the brain. As the fluids in the brain (the fluid between the brain cells and the CSF) drain into the venous sinuses, opening the venous sinuses with the stent helps the absorption of the brain fluids into the veins and can reduce the pressure in the brain.

2 About the River Stent System™

What is the River™ Stent?

The River Stent (shown in the picture below) is a self-expanding, flexible stent that can be used to treat patients with IIH who have significant stenosis of the transverse sinus. A self-expanding stent opens by itself when placed in the target location in the transverse sinus. The flexibility of the stent allows it to take the shape of the surrounding sinus while the stiffness of the stent opens the narrowed cerebral vein. The River Stent is intended as a permanent implant, so it is not removed after it is placed.

The River Stent is made of nitinol. Nitinol is a combination of two metals: nickel and titanium. The stent comes in several different sizes.

The stenting procedure can be performed under sedation or under general anesthesia, according to your preference and the preference of your doctor. The procedure is performed using X-rays to help see the devices introduced into your veins and venous sinuses. The stenting procedure includes the following steps:

- 1) making a small hole in a large vein, usually the femoral vein, which is a large vein in the upper part of the leg;
- 2) placing a catheter (a small plastic tube) through the hole and moving it through the vein into the right or left jugular vein in the neck;
- 3) moving a microcatheter (very small plastic tube) through the first catheter into the transverse venous sinus;
- 4) perform a venography, which means looking at the venous sinuses using X-rays;
- 5) measuring the blood pressure into the venous sinuses both above and below the narrowed area to make sure that the narrowing should be treated;
- 6) position the delivery catheter and stent across the stenosis and place the stent; and
- 7) check that the stent placement was able to reopen the narrowing.



Who should receive a River Stent?

Adult patients with Idiopathic Intracranial Hypertension who have symptoms (headaches or visual symptoms) who have failed medical therapy may be candidates to receive the River stent if they have a significant (narrowing more than 50%) stenosis of the venous sinus. Specifically, the device may be appropriate for such patients with severe headaches who have tried losing weight for at least 6 months, or patients with visual trouble or who are at risk of vision loss.

Who should not receive a River Stent?

Before placing the stent, your doctor will decide if this treatment is right for you.

The River Stent should not be used in people who:

- Cannot take blood-thinning medicines, including medicines that prevent blood clots or dissolve clots
- Have blood clotting problems, such as conditions that make the blood clot too easily
- Are allergic to nitinol (the metal used in the stent) or any of its parts (nickel, titanium).
- Have a known allergy to medicines used during the procedure, such as contrast dye or anesthesia, even if pre-treatment is given
- Have blood vessel anatomy that does not allow the stent to be placed safely
- Have an active bacterial infection
- Already have a stent in the transverse-sigmoid sinus
- Have serious kidney problems and are not on dialysis

What are the benefits of the River Stent?

The River Stent aims to relieve the narrowing of the transverse sinus, which may reduce the venous pressure and intracranial pressure. This may help reduce symptoms associated with IIH such as headache or papilledema (swelling of the nerve of the eye).

Clinical Data on the River Stent

The River Stent was evaluated in the River Clinical Study which included 39 patients. When patients were evaluated at one year and beyond results showed that the River Stent is safe and has probable benefit for the treatment of adult patients with IIH who have failed medical therapy. At long-term follow-up (3 years to 5 years after the stent procedure), patients had improvement in headache severity as well as improvement or stabilization of papilledema compared to before stent placement.

Safety of the River Stent in the River Study:

The clinical study for the River Stent looked at the number of patients who needed another surgical procedure to treat their IIH within one year of the stent procedure. Two patients (5.4%) needed a ventriculo-peritoneal shunt (another device). Additionally, one patient had a severe stomach bleed due to the blood thinners (antiplatelet) therapy two months after the River stent procedure. Antiplatelets are required immediately before and for several months after the stent

procedure, if determined by your doctor.

Stenting the venous sinus does not cure IIH. IIH symptoms may come back after stenting. A new stenosis (narrowing) of the cerebral vein can occur again after stenting, which happened in 14.3% (4 out of 28) patients within 1-year of stent placement in the River Study. Return of IIH symptoms after stenting may require additional therapies or surgeries.

Probable Benefit of the River Stent in the River Study:

After one year, the treatment was considered successful if the stent stayed open, pressure in the vein was reduced, and the patient's main symptoms (either headaches or visual symptoms) clearly improved. More than half (54.5%, 12 out of 22) of patients with complete 1-year follow-up data met all of the elements of the primary probable benefit endpoint.

At one-year after stent placement, headaches, papilledema and visual symptoms, pulsatile tinnitus, and quality of life scores were improved in the majority of patients. These benefits were maintained in the long-term (3 to 5 year) follow-up.

What are the risks associated with the River Stent?

Potential risks associated with use of the River Stent may include, but are not limited to:

- Problems where the catheter is inserted (bleeding or venous injury at the groin site)
- Allergic reaction to medications used for the procedure such as contrast medium and/or anti-platelet or anticoagulant agents
- Allergic reaction to nitinol, the metal used in the stent
- Embolism (a piece of the stent or blood clot blocks blood flow in a vessel)
- Death
- Headache
- Hematoma (blood trapped in a tissue layer)
- Hemorrhage/bleeding (excessive blood loss)
- Infection
- Neurological problems including stroke and death
- Pain
- Renal (kidney) problems or failure caused by contrast dye
- Thrombosis (formation of a blood clot) of the venous sinus
- Restenosis (narrowing of the stented sinus again after treatment)
- Vessel injury, such as a tear, hole or rupture

Fluoroscopy and angiography with X-Rays are used during the River Stent delivery procedure to allow the doctor to see an image of the blood vessels. Potential risks associated with radiation exposure may include, but are not limited to, alopecia (hair loss), burns ranging in severity from skin reddening to ulcers, cataracts, and delayed cancer. The probability of an adverse event happening increases as procedure time and the number of procedures increase.

3 Before and After the River Stent Procedure

Before the procedure

Your doctor will tell you how to prepare for the River Stent procedure. You will have to take antiplatelet medications to prevent blood clots for a few days before the procedure. Your doctor will provide guidance on when and how long to take these medications.

After the procedure

Medical staff will monitor you after your River Stent procedure. You may be released from the hospital on the same day or you may stay in hospital overnight. Your doctor will prescribe antiplatelet drugs after you receive the River Stent to prevent blood clots from forming. Patients in the River Clinical Study were prescribed antiplatelet drugs for at least 6 months. This included aspirin and clopidogrel (an antiplatelet medication) for 3 months, then aspirin only for at least 3 additional months. It is important to follow your doctor's instructions on when and how long to take these medications.

4 Patient Information Card

After your procedure, your doctor will give you a patient card. You should carry the patient card with you and be ready to provide it when receiving medical care in the future.

This patient card will let healthcare professionals know that you have a River Stent implant. The patient card should be shown to medical professionals if you need to undergo a magnetic resonance imaging (MRI) scan. This lets them know that you have a metal implant and which MRI scanner settings are safe to use with the stent.

5 Manufacturer Information



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CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician.