PATIENT INFORMATION LEAFLET

Penumbra

Penumbra Embolization Coils: Penumbra Coil 400, Ruby Coil, POD, and Smart Coil

English

Introduction

This document gives you information about your newly implanted coils. Talk to your healthcare provider if you have any questions or concerns that are not answered in this document.

Important Information

Your coils are a permanent implant. This means the devices will stay in your body for your entire life. Make sure all of your healthcare team including your primary care physician or specialist are aware of your coil implants.

Your health care provider may order follow up studies which may include needing a Magnetic Resonance Imaging (MRI). MRI is a special test that uses radio waves and a magnetic field to produce pictures of the body's organs and structures. Special considerations for your healthcare provider and radiology staff to follow are listed under the section "MRI Information".

Intended Purpose

The Penumbra Embolization Coils are intended to be a minimally invasive treatment for aneurysms or vascular abnormalities. The coils are made of soft platinum metal wires in the shape of a coil. The coils mechanically occlude (block) the space and induce clotting (embolization) to cut off blood flow to the affected site. The number of coils used depends on the size of the lesion.

Kind of Patient on Whom the Device Is Intended to Be Used

The Penumbra Embolization Coils are intended for any patient whom a healthcare professional has identified is a candidate for minimally invasive procedure for treatment of aneurysms or vascular abnormalities.

Potential Adverse Events

As with any interventional procedure, there is a chance that complications may occur, including but not limited to the following events. Ask your healthcare provider to discuss the risks of these complications.

Potential Adverse Event	Definition
Acute vessel occlusion	Sudden closing of a blood vessel that reduces or stops blood flow.
Air embolism	A blood vessel blockage caused by air within the blood vessel.
Allergic reaction and anaphylaxis from contrast media	An abnormal response to a medication or substance given (dye) for the pictures required for the procedure. Symptoms may include a rash, itching, hives, or difficulty breathing. A severe allergic reaction that is life threatening is called anaphylaxis.
Aneurysm rupture	An aneurysm is an outpouching/bulging area of a blood vessel due to a weak spot within the artery wall. A ruptured aneurysm occurs with the weakened area gives way and bleeding outside of the blood vessel occurs into the area of the brain called the subarachnoid space.
Arteriovenous fistula	An abnormal connection between a vein and artery.
Coagulopathy	A condition in which the blood's ability to clot is impaired.
Coil herniation into parent vessel	A portion of the coil implant (the medical device inserted into the vascular malformation) protruding out into the main blood vessel.
Death	Death
Device malfunction	Failure of the medical device to work per its intended design.
Distal embolization	Movement of an emboli away from the original location.
Emboli	A blood clot, air bubble, piece of fatty deposit, or other object which has been carried in the bloodstream and lodges in a blood vessel decreasing or stopping blood to the area.
Embolic Stroke and other cerebral ischemic events	Embolic stroke is a lack of blood supply to the brain caused by an emboli. Cerebral ischemic events are caused by a lack of blood supply to the brain that leads to tissue damage.
False aneurysm formation	A blood vessel wall is injured and leaks blood into the surrounding tissue/space. May also be called a pseudoaneurysm.
Hematoma or hemorrhage at access site	A collection of blood outside of a blood vessel (Hematoma); If close to the skin may note a discoloration or hard area. A collection of blood outside a blood vessel or blood loss at the site where the medical device was inserted in the body.
Incomplete aneurysm occlusion requiring retreatment	Incomplete aneurysm closure that would require additional procedure.
Infection	The growth of germs in the body. This may include bacteria, viruses, yeast, fungi, or other microorganisms. The seriousness of this will vary.

Potential Adverse Event	Definition
Intima dissection	A tear in the innermost part of the blood vessel.
Intracranial hemorrhage	Bleeding inside the skull.
Ischemia	Decreased blood supply to an organ and or tissue; usually because of decreased blood flow.
Myocardial infarction	Heart attack. Damage to the heart due to lack of blood flow.
Neurological deficits including stroke	A lack of blood supply to the brain which can cause abnormal function or sudden loss of function of the brain caused by bleeding or blockage of blood vessel.
Parent artery occlusion	Closing of a main blood vessel to the vascular malformation that reduces or stops blood flow.
Peripheral thromboembolic events	Formation of blood clots within the blood vessel that leaves the site and moves into the arms and legs causing lack of blood flow.
Premature device detachment	The medical device disengages from the delivery device before it is placed in the proper area.
Post-embolization syndrome	A group of symptoms caused by an inflammatory response. Symptoms include fever, headache, and inflammation.
Recanalization	Reopening of the previously closed aneurysm or vascular malformation.
Renal failure	Injury to the kidney.
Respiratory failure	The condition in which the lungs do not adequately exchange oxygen and carbon dioxide in the lungs resulting in not enough oxygen reaching the heart, brain, and the rest of the body.
Revascularization	Reopening of the area that was previously occluded.
Thromboembolic episodes	Formation of a clot that breaks loose, travels in the blood stream and blocks blood flow in another area.
Vessel spasm, thrombosis, dissection or perforation	A vessel spasm is tightening or constriction of a blood vessel which may result in pain; Thrombosis is formation of a blood clot inside a blood vessel; Dissection is a tear in the blood vessel wall which allows the blood to separate the blood vessel wall layers; Perforation is a hole or opening made in the blood vessel.

Your healthcare provider will monitor you during and after the procedure for complications. If a complication does occur, your healthcare provider will decide if you require treatment. In the event of complications, retreatment may be required.

Warning – Magnetic Resonance Imaging (MRI) Safety Information

You should talk to your healthcare provider about your coil implants before undergoing any imaging procedure including MRI. Before you undergo a medical procedure, tell your healthcare provider about your implanted coils. Show them your Patient Implant Card. Your coil is MR conditional. This means they have been tested for use in MRIs under specific conditions.

MR Conditional

MRI Information

This information is provided for your healthcare provider and radiology staff

Penumbra Coil 400, Ruby Coil, and POD:

Non-clinical testing has demonstrated the Penumbra Coil System is MR Conditional. It can be safely scanned immediately after implantation under the following conditions:

- Static magnetic field of 1.5 T or 3 T
- Spatial gradient field of 3000 Gauss/cm (30 T/m) or less
- A whole body averaged specific absorption rate (WBA SAR) of less than 2.0 W/kg and a head averaged SAR of less than 3.2 W/kg for 15 minutes of continuous scanning with a transmit body coil or a transmit head coil. Receive-only coils may be used in conjunction with transmit coils.

Non-clinical testing, using measurement and electromagnetic in-vivo simulation analyses, was performed to assess the in-vivo heating during MRI of the Penumbra coil arrays. The arrays produced an estimated in-vivo temperature rise < 3°C during 15 minutes of continuous MR scanning in the normal operating mode at a WBA SAR of 2.0 W/kg and a head averaged SAR of 3.2 W/kg for 15 minutes of continuous MR scanning in cylindrical bore MR systems. This temperature rise is conservative, as it does not include the cooling effects of blood flow.

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the Penumbra coil arrays. Therefore, it may be necessary to optimize parameters for the presence of this implant. In non-clinical testing:

- Artifact associated with a Penumbra coil array in the form of a 24 mm diameter sphere was assessed using spin echo and gradient echo sequences. The maximum artifact distance beyond the implant was 3 mm for the spin echo sequence and 8 mm for the gradient echo sequence.
- Artifact associated with a Penumbra coil array in the form of an 8 mm diameter sphere was assessed using a clinical MRA sequence. The maximum artifact distance beyond the implant was 2 mm using this sequence.

Smart Coil:

Non-clinical testing has demonstrated the Penumbra Smart Coil is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 T or 3 T
- Spatial gradient field of 3,000 Gauss/cm [30 T/m] or less (extrapolated)
- Normal operating mode only with a whole body averaged specific absorption rate (WBA SAR) of less than 2.0 W/kg and a head averaged SAR of less than 3.2 W/kg for 15 minutes of continuous scanning with the transmit body coil or the transmit head coil.

Non-clinical testing, using measurement and electromagnetic in-vivo simulation analyses, was performed to assess the in-vivo heating during MRI of the Penumbra Smart Coil. The Penumbra Smart Coil produced an estimated in-vivo temperature rise < 3°C during 15 minutes of continuous MR scanning in the normal operating mode at a WBA SAR of 2.0 W/kg and a head averaged SAR of 3.2 W/kg. This temperature rise is conservative, as it does not include the cooling effects of blood flow.

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Penumbra Smart Coil. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant. During non-clinical testing, the distance of maximum extent of the artifact beyond the metal of the array was 3 mm for the spin echo sequence and 18 mm for the gradient echo sequence.

Appointments With Your Healthcare Provider

After your coils are implanted, your healthcare provider will schedule follow-up appointments to see you. These follow up appointments are individualized meaning your follow up exams are based on the location and size of the area where the coils were placed. During your appointments, your healthcare provider will examine you to see how you feel and to make sure that your coils are working well for you. Consult with your healthcare provider for a follow up treatment plan.

Coil Materials

Your coil implants are composed of the following materials. Contact your healthcare provider if you have any concerns about these materials.

- Platinum/tungsten alloy
- Polyethylene
- Acrylated urethane
- Titanium
- Platinum/iridium alloy*
- Stainless steel 304V*
- Nickel/titanium alloy*†
- Polyethylene Terephthalate (PET)*†
- Gold/tin alloy†
- Cyanoacrylate†

*Present only on Smart Coil

†Present only on select versions of Penumbra Coil 400, Ruby Coil, and POD

Reporting Serious Incidents

If a serious incident related to the device occurs, you should report it immediately to your healthcare provider, Penumbra, Inc., and the Therapeutic Goods Administration (TGA).

https://www.tga.gov.au

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