Facts about the Onyx® Liquid Embolic System for the treatment of Intracranial Aneurysms
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Definition of Medical Terms

Anesthesia (general or local)
Anesthesia means the loss of sensations, such as pain, temperature or touch. General anesthesia means you will be given a drug or gas to make you unconscious during a procedure. Local anesthesia, brought about by an anesthetic, means the loss of sensation limited to a specific area of the body.

Angiography
Angiography is a procedure used to help diagnose and treat blood vessel disease. A special type of liquid that can be seen with x-ray machines is injected into the blood vessel. X-ray machines can then be used to see the blood vessels, diagnose disease, and aid the doctor during treatment of the disease.

Aneurysm
A cerebral aneurysm is a pouch or protrusion from a blood vessel. Aneurysms may occur in various locations in the brain. They appear in a variety of shapes and sizes. Aneurysms are classified by size: Small: less than 10mm in dome width, Large: 10-25mm; and Giant: greater than 25mm. Aneurysms can also be classified by the width of the neck (or opening): some aneurysms are referred to as “wide necked.” Aneurysms can occur in certain shapes – such as “sidewall” aneurysms occurring directly from the side of a vessel, or such as “bifurcation” aneurysms that may occur where the vessel bifurcate.

Bifurcation/bifurcate
Aneurysms may have 2 branches or divisions. The aneurysm may be described as having a point of forking, or having a bifurcation.

Embolization Device (Material)
An embolization device is a material placed within an aneurysm to occlude or block blood flow into the aneurysm. Embolization procedures are performed to minimize the risk of rupture. The most common devices for the embolization of aneurysms are detachable coils. Coils have unique properties that make them more or less suitable for a particular embolization procedure.
Hypersensitivity (allergies)

Hypersensitivity is a condition in which there is an exaggerated response by the body to a material or medication. The reaction is commonly referred to as an allergic reaction. The reaction can be very serious and may increase in severity with each successive exposure to the medication.

Micro Catheter

A micro catheter is long, thin, tube-like device which is placed in the blood vessel to deliver various diagnostic and therapeutic materials. During an embolization procedure, a micro catheter is used to deliver the Onyx material into the aneurysm.

Balloon

A balloon is similar to a micro catheter. It is a long tube-like device which is placed along the opening of the aneurysm. During the embolization and delivery of Onyx, the balloon is inflated to temporarily seal the neck of the aneurysm to assist the proper placement of the Onyx material. The balloon is then removed after the procedure is complete.
Purpose of the Onyx Liquid Embolic System (LES)

The Onyx material is intended for the embolization of large and giant, wide-necked aneurysms. The material may offer a benefit in particular cases that other devices may not. For these reasons, your physician has recommended embolization using Onyx.

Description of the Onyx LES Device

Onyx is the trade name for a liquid polymeric embolization device manufactured by ev3 Neurovascular. The liquid Onyx is delivered through a micro catheter selectively placed within an aneurysm. Hardening of the Onyx begins immediately when it comes into contact with bodily fluids, such as blood.

When the Onyx LES Device Should Not Be Used

There are some contraindications for the Onyx LES System. The Onyx LES System is contraindicated:

- When your physician cannot optimally position the catheter to deliver the Onyx, and/or
- When your physician feels you may not tolerate the procedure

However, many factors can potentially affect the outcome of a procedure. The safety of Onyx has not been established for use if you are:

- Pregnant or nursing
- A young child
- Diagnosed with significant impairment of liver and kidney function

Be sure to inform your doctor of any known allergies or hypersensitivity to any drug, food or environmental condition.
Risks and Benefits

To achieve FDA clearance under a Humanitarian Use Designation, ev3 Neurovascular submitted clinical and technical information to the FDA for review. These data included results from international clinical experience as well as US clinical data from a company sponsored clinical trial.

Potential Risks

The embolization material Onyx could unexpectedly enter the parent vessel from where the aneurysm arises. Although rare in occurrence, in some cases the material could travel into the blood vessel and possibly create an undesirable blockage of the blood vessel or a smaller blood vessel. Temporary or permanent disability, bleeding, or stroke could result from blockage of vital blood vessels supplying the brain or the spinal cord. Stroke or bleeding could result in muscle weakening or paralysis, numbness, hearing problems, sensory problems, visual disturbances or defects, mental or physical disability, speech problems, or death.

You may experience pain, headache, nausea, infection or other symptoms of illness or temporary discomfort during and after the procedure. Medications may be required for these symptoms.

Use of Onyx to treat your aneurysm may present risks to you which are currently unknown or unforeseeable. The degree of the specific risks of embolization varies from patient to patient depending upon the type and location of the aneurysm and other risk factors related to your condition.

Many of the risks for this procedure are also reported for procedures with other embolization devices. If you do not understand any of the potential risks, ask your doctor to explain them to you.

Potential Benefits

The Onyx embolization material is expected to stop or reduce blood flow into the aneurysm. It is anticipated that embolization of the aneurysm may help in correcting or lessening of some or all of your symptoms.
Expectations of the Device and the Procedure Associated with the Device

Preparing for the procedure, the procedure itself, and post-procedure care are essentially the same as for most embolization materials. There are no special or unique procedures associated with the use of Onyx for treating aneurysms.

Pre-Procedure Exams
You will undergo a series of exams and diagnostic procedures to fully assess the size, shape, and location of your aneurysm. Your doctor will use this information to plan the most appropriate course of treatment. Exams and procedures will generally include the following:

- Medical history review
- Physical examination
- Blood tests
- Neurological examination
- Imaging (CT, MRI)
- Angiography

Pre-Procedure Medications
Your doctor may require you to prepare for the procedure a few days in advance. Preparation may include taking aspirin or anti-clotting medication for 2-3 days before the procedure. Additional medications may be prescribed by your doctor depending on your general health and other medications you are taking.

Embolization Procedure
The procedure may be done under local or general anesthesia. Because patients must remain still for long periods of time, general anesthesia is usually preferred. Your doctor will determine the best and safest method for treating your aneurysm.

The actual embolization procedure can take a few hours. Time is taken to place the micro catheter into the aneurysm. Your doctor will try to fill the aneurysm completely with Onyx so no blood flow enters the aneurysm space.
In the neuro angiography suite, the patient lies on a table with special X-ray and monitoring equipment that allows the physician to navigate catheters to the aneurysm for embolization.

A small catheter (tube) is used for delivery of Onyx into the aneurysm.

The Onyx delivery catheter is inserted through an artery in the upper leg. The catheter is pushed gently through the artery to the aneurysm site.
After the tip of the catheter is placed within the aneurysm, where Onyx can be delivered, a small catheter with a balloon at the tip is positioned alongside the aneurysm to seal the opening during the delivery of Onyx into the aneurysm.

After the Onyx material has been injected into the aneurysm, the balloon catheter and Onyx delivery catheters are removed.

Post-Procedure Care
After the procedure is complete, you will be moved to a recovery room. You will likely experience some pain and tenderness in the groin area where the micro catheter was inserted into your blood vessel. Additionally, many patients have reported headache and nausea, as well as a strong garlic-like odor following procedures with Onyx. This is caused by metabolism of the DMSO solvent that was in the Onyx system. The odor usually disappears in 24-48 hours.
The Importance of Adhering to a Care Regimen

There are no pre or post procedure care regimens specifically required for the Onyx material. However, your doctor(s) may prescribe certain medications before and after the embolization and surgical procedures. It is important for your safety to carefully follow the directions and medications prescribed by your doctor.

Additional Information

The following publications are available for additional information on the treatment of aneurysm and Onyx LES system.


2. Late angiographic and clinical follow up results of 100 consecutive aneurysms treated with Onyx reconstruction: largest single-center experience by H.S. Cekirge, I. Saatci, B. Cil, A. Arat

User Assistance Information

Additional information may be requested from:

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Customer Service: 800-716-6700

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