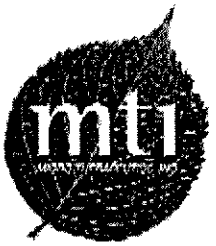

DRAFT

PATIENT INFORMATION BROCHURE

Facts about the

Onyx® Liquid Embolic System

for the treatment of brain Arteriovenous Malformations

Printed: July-2005

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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.

Brain Arteriovenous Malformation ("brain AVM" or "BAVM")

An arteriovenous malformation (AVM) of the brain is an abnormal development of arteries and veins. Normally, blood flows from the arteries to smaller diameter vessels called capillaries. Blood from the capillaries then flows back into the veins. AVMs are an abnormal tangle of vessels where the arteries are connected directly to the veins without the smaller capillaries. The capillaries serve to dampen or reduce blood pressure as blood flows from the arteries to the veins. Without capillaries to slow the blood flow, high pressure blood flowing into the veins causes them to widen and sometimes rupture and hemorrhage (bleed).

Embolization Device (Material)

An embolization device is a material placed in a blood vessel to occlude or block-off blood flow in the vessel. Embolization of the vessels in an AVM is intended to reduce blood loss during surgical removal of the AVM. In addition to Onyx, there are a several other embolization materials approved for treatment of AVMs such as cyanoacrylate polymer (n-BCA) and polyvinyl alcohol foam particles. Each of these has unique properties making them more or less suitable for a particular embolization procedure. Your doctor can provide additional information on these materials if desired.

Feeding Pedicle

A feeding pedicle is a small artery supplying blood to the central part of the AVM called the nidus. The AVM nidus may have many feeding pedicles, some or all of which will be embolized during the procedure. Very large AVMs may have many feeding pedicles requiring multiple embolization procedures. Your doctor will decide when enough vessels have been blocked to reduce blood loss during surgical removal of the AVM.

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 to the small vessels feeding the AVM.

Surgical Resection

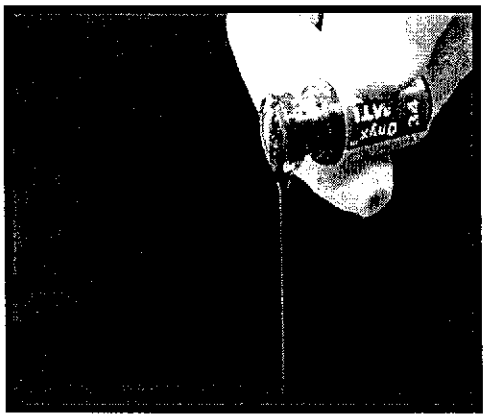
Surgical resection simply means the AVM will be removed from your brain by surgery after embolization procedures have been completed. Typically, several doctors are working closely together to determine the appropriate amount of embolization needed to optimize preparation of the AVM for a safe surgical removal.

Purpose of the Onyx Liquid Embolic System (LES)

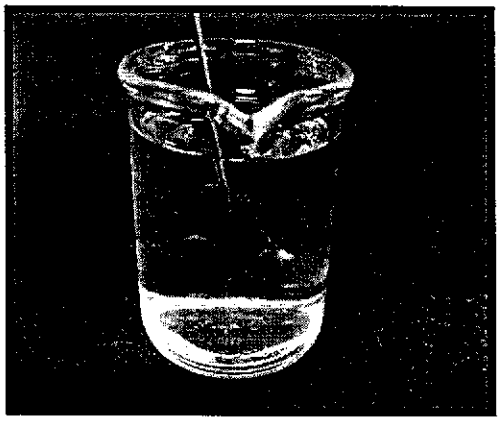
Direct surgical resection is the generally accepted standard of care for treating brain AVMs. Surgery provides immediate protection from future hemorrhage and has a long proven track record in the treatment of small and large AVMs. Many adverse events, however, are attributable to too much blood loss and brain tissue damage during the surgical procedure. For these reasons, your doctor has recommended pre-surgical embolization of your AVM with the Onyx Liquid Embolic System (LES).

Description of the Onyx LES Device

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



Onyx in liquid form



Onyx precipitation in saline

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 physicián 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 in the following patients:

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- Pregnant or nursing women
- Children
- Individuals with significant liver function impairment.

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

Risks and Benefits

To understand the risks and benefits of the Onyx LES system, a clinical trial was conducted. One-hundred-seventeen patients participated in the trial with approximately half the patients treated with Onyx and half treated with a control device. The control device, known as TRUFILL, is an FDA approved material also intended for treatment of AVMs. The results of this trial demonstrated that Onyx was effective in blocking off blood vessels. Adverse events attributable to Onyx were no worse than those for the TRUFILL material. The potential risks and benefits of the Onyx material follow.

Potential Risks

The embolization material Onyx could unexpectedly enter a wrong blood vessel. Although rare in occurrence, in some cases these events may lead to the travel of the embolization material to the lung or other organ, or create an undesirable blockage of a blood vessel. A serious concern is that of temporary or permanent disability, bleeding, or stroke from blockage of vital blood vessels supplying the brain or the spinal cord. If stroke or bleeding occurs, it 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 AVM 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 AVM 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 in selected blood vessels in the AVM. It is anticipated that embolization of the

AVM and surrounding blood vessels may help in correcting or lessening of some or all of your symptoms. Pre-surgical embolization with Onyx is expected to have the following benefits:

- Make surgical removal easier and more complete
- Reduce surgical complications
- Reduce blood loss during surgery

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 for most embolization materials. There are no special or unique procedures associated with the use of Onyx for treating AVMs.

Pre-Procedure Exams

You will undergo a series of exams and diagnostic procedures to fully assess the size, shape, and location of your AVM. 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

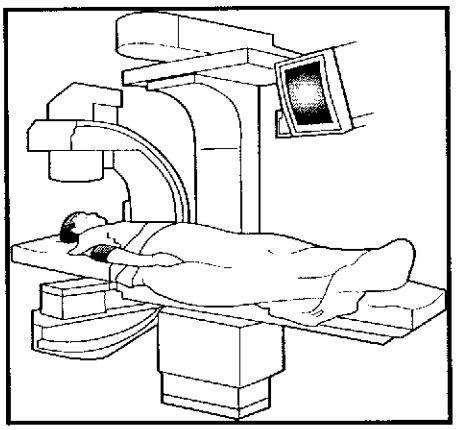
Pre-Procedure Medications

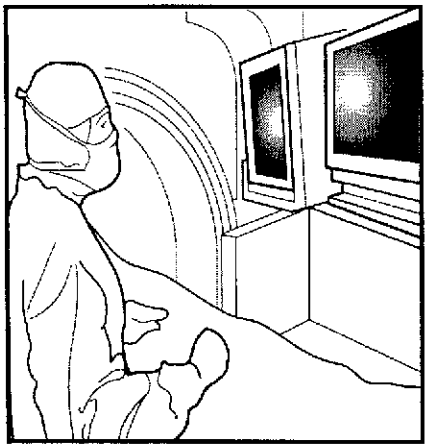
Your doctor may require you to prepare for the procedure a few days in advance. Preparation may include taking aspirin for 2-3 days before the procedure. Additional medications may be prescribed by your doctor depending on your general health and other medications you are taking.

Embolization Procedure

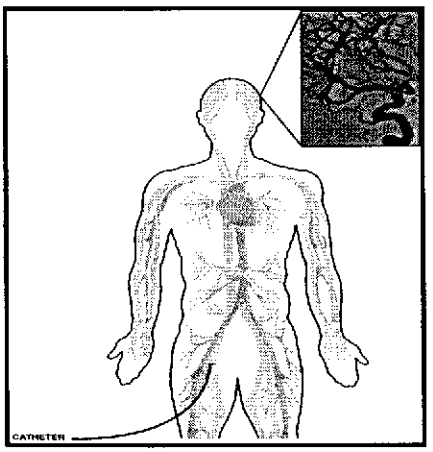
The procedure may be done under local or general anesthesia. Because patients must remain still for long periods of time, general anesthesia is usually preferred. Your doctor will determine the best and safest method for treating your AVM.

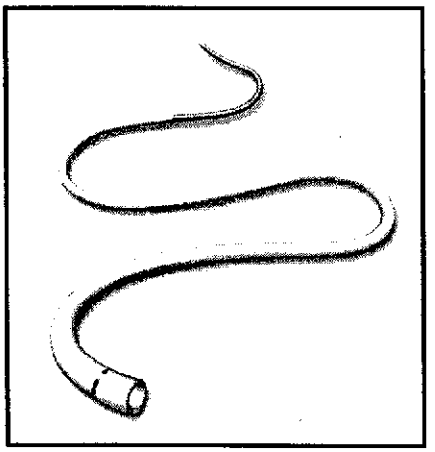
The actual embolization procedure takes only a few minutes. However, considerable time may be involved in preparation and placement of the micro catheter in the small vessels supplying blood to the AVM. The entire procedure may only take an hour, but 2-3 hours is not uncommon. Your doctor will try to reduce the size of your AVM as much as safely possible in a single procedure. Occasionally, additional procedures are required to optimize AVM size reduction.



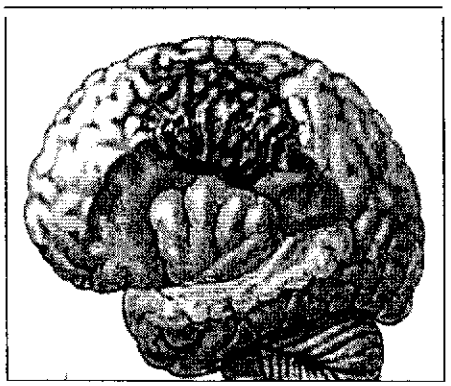


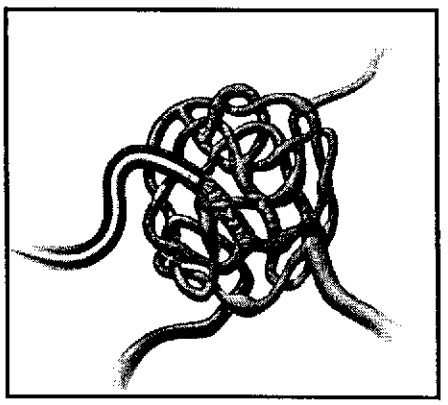
In the neuro angiography suite, the patient lies on a table with special X-ray and monitoring equipment that allows the physician to navigate catheters to the AVM for embolization.





A very small catheter is entered into the arterial system to navigate to the brain for embolization treatment.





The tip of the catheter is placed at the AVM site, where Onyx can be delivered into the AVM.

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.

Surgical Resection

If your AVM was sufficiently reduced in size by the embolization procedure, you will be scheduled for surgical resection of the AVM. Usually, this will occur within a few days after the embolization procedure. Your doctor will prescribe appropriate medications to prepare you for the surgery.

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 AVMs and Onyx LES system.

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8. The n-BCA Trial Investigators. N-Butyl Cyanoacrylate Embolization of Cerebral Arteriovenous: Results of a Prospective, Randomized, Multi-center Trial. American Journal of Neuroradiology 23:74a8-755, May 2002

User Assistance Information

Additional information may be requested from:

Micro Therapeutics, Inc.
2 Goodyear
Irvine, CA 92618

Customer Service: 800-684-6733
e-mail: http://www.microtherapeutics.com

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