REFERENCES


As with any surgical procedure, there are risks. Laser delivery probe advancement into – or laser delivery in – cerebral vasculature can result in hemorrhage. Laser delivery probe trajectories which transect critical cortical-spinal pathways or overdosing with thermal energy can result in patient injury and permanent neurological deficits. Protracted patient immobilization can cause deep venous thrombosis (DVT).

Please visit our patient website at www.MyBrainSurgeryOptions.com

For complete instructions for use for the NeuroBlate® System, please go to www.monteris.com
Your doctor has recommended you for a procedure with the NeuroBlate® System because you have abnormal tissue – also referred to as a lesion – in your brain. This new yet proven technology uses precise, high-intensity laser light to destroy growths in the brain, while limiting injury to healthy tissue. The NeuroBlate System can be used with growths in nearly any location of the brain, and the procedure has been performed in hundreds of patients.

The NeuroBlate System is a tool to remove diseased tissue, such as tumors and lesions, in patients consulting with their doctors about conditions/symptoms that require brain surgery. In the hands of skilled physicians, the NeuroBlate System is frequently used together with other therapies described in this guide.

The next several pages give general answers to questions patients often ask about the NeuroBlate System. What you read here is not medical advice – please talk to your doctor about whether the NeuroBlate System may be right for you. Although many patients benefit from the NeuroBlate System, results differ from person to person. Like all surgical procedures, the NeuroBlate System carries risks, some of which are described on the following pages. Your doctor can tell you more about the potential benefits and risks, answer your specific questions and address concerns you may have.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

What Are Brain Lesions?

A lesion is an area of tissue that has been damaged through injury or disease. So a brain lesion is an area of injury or disease within the brain. While the definition sounds simple, understanding brain lesions can be complicated. That’s because there are many types of brain lesions. They can range from small to large, from few to many, from relatively harmless to life threatening.

Source: WebMD
How does the NeuroBlate® System work?

A. With NeuroBlate, the surgeon attempts to kill lesions in many locations in the brain, at the surface or deep inside. Unlike traditional brain surgery, NeuroBlate does not require a large opening in the skull. Instead, doctors make a small hole in the skull, about as big around as a pencil (Fig. A). While the head is secured in place, they guide a small laser device (probe) through that hole precisely into the lesion (Fig. B). The probe delivers laser light energy to heat up and destroy the lesion – a process called ablation (Fig. C, D). The precise nature of the procedure helps to lessen the likelihood of harm to nearby healthy brain tissue.\textsuperscript{1,2,3,4}

What will I experience during ablation with the NeuroBlate® System?

A. You will receive anesthesia before the procedure – your doctor will determine what level of anesthesia is right for you. After the procedure, you will have stitches over the point where the probe was inserted. You may also have scratches on your head from the device that held your head in position.

How soon after the procedure can I go home from the hospital?

A. That depends on a variety of factors – every person is different. However, experience shows that patients generally tolerate the procedure well. The NeuroBlate System is classified as a minimally invasive surgery, a type requiring only a small opening in the body instead of a large incision as in open surgery. In general, patients undergoing minimally invasive procedures are
likely to have less pain and discomfort afterward, be able to go home sooner and resume normal activity quicker, and have less scarring.  

Q **Why does my doctor believe the NeuroBlate® System may be appropriate for me?**

A. Doctors may prescribe this procedure when an abnormal growth is at a place where it could be difficult to treat without harming the brain and hurting the person’s ability to function. When dealing with a lesion, the doctor aims to remove or kill the diseased tissue while protecting the healthy tissue around it as much as possible. The NeuroBlate System may help your doctor do that.

Q **What makes the NeuroBlate® procedure so precise?**

A. The technology includes software that allows doctors to watch the progress of ablation on a computer screen with Magnetic Resonance Imaging (MRI), the same basic technology used to take pictures of injured joints and help diagnose various diseases. The MRI pictures help the doctors accurately guide the laser probe to the lesion, then apply heat to it a little bit at a time, until all the targeted tissue is destroyed.

Before the procedure, doctors use MRI pictures to view the lesion and outline the zone where ablation will occur. During the procedure, they can see the diseased tissue and the surrounding healthy tissue and use different probes to apply laser energy where it is needed, even to the edges of some lesions with irregular shapes. A special technology called MRI thermometry lets doctors constantly monitor the temperature, verifying that enough heat has been applied to kill the lesion. They also monitor the temperature of healthy tissue, helping to ensure that it is not
overheated and is protected as much as possible. After the procedure, the doctors can use MRI pictures to verify that the lesion has been destroyed within the ablation zone as outlined.

**Q What outlook can I expect after the NeuroBlate® procedure?**

A. Each patient and each brain lesion is unique. Your doctors are the best qualified to describe specifically how a procedure may affect your outlook. Although every case is unique and there can be no guarantees, many patients on whom the NeuroBlate System has been used have experienced extended life.⁶,⁷,⁸,⁹

**Q What other methods can be used to remove brain lesions?**

A. **Open Surgery** works well when an abnormal growth is not too deep in the brain or too close to regions of the brain that affect critical functions like vision, thought, speech and muscle control. Surgery involves shaving the head, removing part of the skull and cutting out the diseased tissue.

**Chemotherapy** treats the lesion with drugs given through the bloodstream or delivered directly to the growth region. Sometimes drugs may not kill the entire lesion. The majority of patients can tolerate the side effects associated with chemotherapy, but some cannot.

**Radiation Treatment** kills diseased cells by altering their DNA. It can be applied to broad areas of the brain or closely focused on the lesion. Sometimes radiation may not kill the entire lesion. The majority of patients can tolerate the side effects associated with radiation, but some cannot.

Often, no single approach is enough; different methods are commonly used together. Your doctor can explain in detail the benefits and risks of each method.

**Q What are the risks related to procedures using the NeuroBlate® System?**

A. As with any surgical procedure, the NeuroBlate System involves some risks. The technology is not appropriate for every lesion type and location. For example, it may be difficult to use the technology on certain large or irregularly shaped lesions. Certain placements of the laser probe into the brain, or too much heat applied, may cause bleeding or permanent brain damage. Some patients have temporary swelling after the procedure that may cause short-term abnormal brain or nervous system function. Any medical situation, including NeuroBlate, which requires a patient to stay still for long periods can cause dangerous blood clots (deep venous thrombosis). Talk to your physician about the risks of the procedure.

**Q Where can I get more information about the NeuroBlate® System?**

A. Consult with your doctors on all matters related to your procedure. You may also visit the Monteris Medical website at monteris.com or call 1 (866) 799-7655.
UNDERSTANDING ABNORMAL TISSUES IN THE BRAIN

“You have an abnormal growth in your brain.”

More than 300,000 people receive that frightening diagnosis each year in the United States. And tumors are not the only forms of abnormal tissue, or lesions, which can occur in the brain and cause health issues. Some are cancerous. Some are non-cancerous. Others can lead to epilepsy.

Today, new tools are available to doctors that create choices for patients who might otherwise have few options. There is no single way to deal with brain abnormalities – doctors can use a variety of strategies, alone or in combination. They include surgery, radiation, chemotherapy and thermal therapy (killing abnormal tissue with heat or cold). Here is a brief look at some of the common types of brain lesions.

Primary Brain Tumors. Primary tumors begin in the brain and tend to stay there. They account for about one-fourth of the brain tumors and affect people of all ages. About 63 percent of primary tumors are benign, but they can still cause pain and threaten life and brain function if not treated or removed. Primary brain tumors include Meningiomas and Gliomas. Meningiomas are tumors that arise from the coverings, or membranes, of the brain and spinal cord. They occur most frequently in middle-aged women. A glioma can be any tumor that forms in the supportive tissue, called glia, of the brain. Glial tissue is what keeps our neurons secured and functional. Gliomas are graded by their severity.

Secondary Brain Tumors. Secondary tumors come from elsewhere in the body, such as the lungs or breasts. Cells from these cancers travel, or metastasize, to the brain. These tumors are called Metastatic brain tumors, and they account for about three-fourths of diagnosed brain tumors. Metastatic tumors often appear in multiple places in the body, and new tumors may continue to form as long as the original disease remains active.

Other Brain Lesions. Disease, trauma, genetic defects, hemorrhages and more can result in abnormal tissue forming in the brain. Radiation Necrosis can occur as a complication of radiation therapy. Over time, radiation can cause brain tissue at the site of the tumor to become damaged. Damaged tissue can trigger abnormal nerve impulses in the brain and cause seizures, fits and loss of consciousness common to epilepsy and other brain abnormalities.

The key to dealing with lesions is to remove or destroy them while doing as little harm as possible to the surrounding brain tissue. This is because many areas of the brain are delicate, and if they are damaged, the person’s vital functions, like motion, senses, language and memory, could be impaired.

Tumors and other lesions are usually diagnosed only when a person has symptoms, such as headache, change in behavior or impaired visions or balance. The type of lesion, stage of advancement, location in the brain, the person’s medical history and overall health, and other factors determine what kinds of therapies are chosen. No matter what kind of lesion you have, your doctor, in consultation with other physicians, will be your best source of information on what options to pursue.
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Monteris Medical Corporation
Attn: Subscription Processing
16305 36th Ave. North, Suite 200
Plymouth, MN 55446