A Patient’s Guide

NeuroBlate® SYSTEM

A new and precise tool for destroying tumors in the brain

www.MyBrainTumorOptions.com
Your doctor has recommended you for a procedure with the NeuroBlate System because you have an abnormal growth 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. It can be used with growths in nearly any location in the brain. The procedure has been used with hundreds of patients and has been shown to be successful in reducing or removing diseased tissue. Here are the answers to questions patients often ask about the NeuroBlate System.

The NeuroBlate System is a tool to remove diseased tissue, such as tumors and lesions, in patients consulting with their doctors about cancer, epilepsy, and other conditions in the brain. In the hands of skilled physicians, the NeuroBlate System is frequently used together with other therapies described on the next page of this brochure.

This brochure gives 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 and why 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.

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

A. Doctors may prescribe this procedure when a tumor 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 tumor, 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 other methods can be used to remove brain tumors?

A. Open Surgery can work when a tumor 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 tumor.

Chemotherapy treats the tumor with drugs given through the bloodstream or delivered directly to the tumor region. The drugs may not kill the entire tumor, and they may have side effects that some people cannot tolerate.

Radiation treatment kills tumor cells by altering their DNA. It can be applied to broad areas of the brain or closely focused on the tumor. Not all tumors are killed by radiation, and some patients cannot tolerate the large and repeated radiation dosages that are needed.

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.
How does the NeuroBlate System work?

A. With NeuroBlate, the surgeon attempts to kill tumors in many locations of the brain, at the surface or deep inside. Unlike traditional brain surgery, it 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 tumor (Fig. B). The probe delivers laser light energy to heat up and destroy the tumor – a process called ablation (Fig. C, D). The precise nature of the procedure helps to lessen the likelihood of harm to healthy brain tissue.

What makes the 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 tumor, 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 tumor and outline the zone where ablation will occur. During the procedure, they can see the tumor and the surrounding healthy tissue and use different probes to apply laser energy where it is needed, even to the edges of some tumors with irregular shapes.
technology called MRI thermometry lets them constantly monitor the temperature, verifying that enough heat has been applied to kill the tumor. 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 tumor has been destroyed within the ablation zone as outlined.

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 tumor type and location. For example, it may be difficult to use the technology on certain large or irregularly shaped tumors. 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, that 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.

Doctors use magnetic resonance imaging (MRI) to view the tumor and define the area in which to perform the ablation. MRI imaging also lets doctors watch the procedure in real time, helping to ensure accurate ablation and protecting healthy tissue as much as possible.

These magnetic resonance images show an actual tumor in the brain, and the brain after the tumor was destroyed by the NeuroBlate System.
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 three 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.¹

What outlook can I expect after the procedure?

A. Each patient and each tumor or other growth in the brain is unique. Your doctors are the best qualified to describe specifically how a procedure may affect your outlook. Many patients on whom the NeuroBlate System has been used have experienced extended life.²,³,⁴,⁵
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 a brain tumor.”

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 (lesions) that 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 the tumor tissue with heat or cold). Here is a brief look at three common kinds of brain lesions.

**Primary tumors.** These tumors begin in the brain and tend to stay there. They account for about one-fourth of 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.

**Metastatic tumors.** These tumors come from cancer elsewhere in the body, such as the lungs or breasts. Cells from those cancers travel (metastasize) to the brain. Metastatic tumors account for about three-fourths of diagnosed brain tumors. They are more common in adults than in children. Metastatic tumors often appear in multiple places in the body, and new tumors may continue to occur as long as the original disease remains active.

**Lesions.** These are damaged areas that can trigger abnormal nerve impulses in the brain and cause the seizures, fits, and loss of consciousness common to epilepsy and other brain abnormalities. Brain lesions can take various forms, including tumors, scar tissue from an injury, infections, abnormal blood vessels, hemorrhages, genetic defects, and others.

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 tumor you have, your doctor, in consultation with other physicians, will be your best source of information on what options to pursue.
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.MyBrainTumorOptions.com

For complete instructions for use for the NeuroBlate® System, please go to www.monteris.com/IFU