

Deep Brain Stimulation Surgery Staging and Surgical Instructions

Stage 1: Outpatient MRI imaging and UPDRS On/Off testing (Parkinson's patients only)

MRI Date:

UPDRS On/Off Testing Date:

Stage 2: Outpatient fiducial insertion and CT scan(to allow the fabrication of the StarFix platform)

Anchor implantation and CT scan Date:

Stage 3: Inpatient DBS electrode mapping and lead insertion

Date:

Stage 4: Outpatient IPG (generator) implantation and electrode hookup

Date:

Stage 5: Initial programming of implant

Date

Surgery: Pre-Operative Instructions for Stages 1, 2, 3, 4

- Do not eat or drink anything after midnight the evening before your surgery. This includes water, coffee, chewing gum and mints. Eat a light meal in the evening: no fried or greasy foods and no alcohol. You can brush your teeth in morning.
- The following medications should be discontinued prior to your surgery: Blood thinners (anticoagulants). This class of drugs includes Coumadin, Ticlid, Plavix, and Lovenox. Please contact your primary doctor (PCP) or the prescribing physician to ask how this medication can be discontinued.
- Notify our office if you will not be stopping your anticoagulant
 - Aspirin and Ibuprofen for 7-10 days prior to the first surgery
 - Glucophage for 48-72 hours prior to the first surgery
 - Herbal supplements (garlic, ginseng, ginkgo biloba, vitamin E, Echinacea, kava, St. John's Wort and ephedra) for 2-3 weeks prior to your first surgery
- The following medications should be taken with a sip of water on the day of surgery, if you take a morning dose: Anti-seizure medications including: Dilantin, Tegretol, Lamictal, Phenobarbital, and Depakote
 - Heart/blood pressure medications, including Digoxin, HCTZ, Verapamil, Cardizem, Lopressor, Norvasc, and labetalol
 - Thyroid medication
 - Asthma medication (please bring this to the hospital with you)
 - Reflux medication

Stage 1: MRI and On/Off testing.

The purpose:

To acquire accurate and precise images (MRI scan) used by your neurosurgeon to plan the optimal target and pathway for the DBS electrode to be placed in your brain. The MRI is many times done with sedation and you will need someone to give you a ride home from the hospital after the MRI.

On/Off UPDRS testing is to document the response to Parkinson's medications and is important way to get a rough "estimate" of the benefit that DBS might offer to you. We do not do this testing for Essential Tremor.

Pre-Operative Instructions:

You should have nothing to eat or drink for at least 8 hours prior to your procedure. If you take blood pressure medicine, you should take these pills with a sip of water at your usual time. You may also take your anti-tremor/ anti-Parkinson's medications. An MRI scan will be done up to one month prior to the bone anchor placement.

Arrival at the Hospital:

Approximately 2 hours before your procedure you will need to arrive at the hospital and check in at admitting.

Stage 2: Placement of fiducials and imaging

The purpose of this procedure is two-fold:

. To acquire accurate and precise images (a CT scan) used by your neurosurgeon to plan the optimal target and pathway for the DBS electrode to be placed in your brain. CT is done with fiducials (bone anchors) in place.

. To implant several small, short-term anchors onto the surface of the skull. This allows imaging markers, and eventually, the Star Fix platform to be mounted securely on the skull. The imaging markers can be seen in the CT and provide your surgeon with reference points for the fabrication of the Star Fix platform that will be used during the surgery for DBS electrode implantation (see Stage 3).

The StarFix platform is a custom built platform that is made specifically to fit your head and allows the surgeon to accurately place the electrodes in the desired target within the brain. This has to be fabricated prior to stage 3 and this is one of the primary goals of stage 2.

Pre-Operative Instructions:

You should have nothing to eat or drink for at least 8 hours prior to your procedure. If you take blood pressure medicine, you should take these pills with a sip of water at your usual time. You may also take your anti-tremor/ anti-Parkinson's medications. An MRI scan will be done up to one month prior to the bone anchor placement.

Arrival at the Hospital:

Approximately two hours before your procedure you will need to arrive at the hospital and check in at admitting. **Please bring MRI scan on CD.**

During the Procedure:

The bone anchors are placed in a minor procedure room. Four small, stainless steel anchors will be placed into your skull through a small incision (less than a 1/4 of an inch) in the scalp. The anchors usually are arranged in a diamond-shaped pattern on your head. Imaging markers are temporarily attached to the anchors for visualization during the CT. After the CT is finished, the imaging markers are removed and the scalp incisions are closed with staples. The metal bone anchors will still be in your skull, but they will not be visible. After the CT scan is finished, you will be discharged to home. The CT and MRI scans are used by your neurosurgeon to create a customized surgical plan for placing the DBS electrode(s). Once the target is identified and the path is planned, this information is sent to a company that will manufacture a custom platform to be used in the next stage of surgery.

Post-Operative Instructions:

· Keep the bone anchor insertion sites clean by wiping with a Q-tip dipped in hydrogen peroxide once a day until you come back for the electrode implants. Gently wipe your scalp with a damp washcloth for general cleaning. Do not apply any ointments or creams. Do not get your head soaking wet! If you shower, use a shower cap to keep the incision/staple sites dry.

· You can wear a loose hat, scarf or turban when you go outside, but it is best to leave your incisions open to air as often as possible.

· For sleeping, any soft pillow should do.

· Tylenol is recommended for any mild discomfort that you experience during this time.

-Call our office if you develop a fever of 101.5 or higher or if you have any more than slight redness, swelling or drainage from the bone marker insertion sites.

· You may have some oozing of blood from the incision sites, especially right after the procedure and after cleaning the sites with peroxide. Applying firm pressure with a sterile gauze pad or clean washcloth for approximately 5- 10 minutes can stop this bleeding. In the unlikely event you are unable to stop the bleeding, go to the emergency room.

Stage 3: Stereotactic Mapping of the Target and DBS Electrode Implants

Purpose of this Procedure:

- . To identify the optimal target for the DBS electrode through electrical testing and motor examination
- . To place the DBS electrode into the optimal target identified during this surgery

Pre- Operative Instructions:

STOP ANTI-PARKINSON'S MEDICATIONS OR THOSE USED FOR TREMOR OR DYSTONIA BY 6:00 P.M. THE EVENING BEFORE SURGERY.

Arrival at the Hospital:

You need to arrive at hospital admitting 2 hours prior to surgery for the admission process. An IV (intra-venous catheter) will be inserted into your arm.

In the Operating Room:

There are numerous people that will be involved in your surgery and are part of the surgical team: the neurosurgeon and assistants, the anesthesiologist, a neurologist, and technical support staff. Please be assured that all members of the team work together routinely to ensure the safety and success of your surgery. You will be positioned on the operating room table in a reclined "beach chair" position and will be made as comfortable as possible. You will receive little or no sedation. This ensures that your symptoms are not masked and helps to keep your surgeon informed about the success or possible problems during the placement of the stimulator lead(s).

Various pieces of equipment will be attached to your body, including EKG leads, a blood pressure cuff and a pulse oximeter on your finger. These items help the nurses and anesthesiologist monitor your vital signs. . Since you will be unable to leave the operating room to go to them bathroom, a Foley catheter will be inserted into your bladder to drain your bladder during the surgery. Your head will be cleansed and draped with sterile sheets. A local anesthetic will be injected to numb your scalp. The staples from your first procedure will be removed, and 3-4 small incisions will be made in your scalp to expose bone anchors. Next, a custom-fitted platform, designed from your CT & MRI scans, will be fitted onto the bone anchors. This platform is used to precisely align the electrodes for testing and permanent placement. If adequately numbed, the remaining procedure is not painful, since there is no significant pain perceived below the scalp. Bone and brain

tissue do not sense pain. A small, dime-sized hole will be made in the skull. The neurosurgeon will insert a test electrode deep into the brain through the planned target area. There are two types of test electrodes. One is used to record electrical activity and "listen" for the hyperactive area to be treated. The other is used to "test stimulate" small areas of the brain. We will observe what effect the test stimulation has on your movement, and whether there are any side effects from the stimulation. When the stimulator is turned on, your surgeon and neurologist will evaluate the lead location and stimulation strength by asking you to perform simple tasks, such as touching your fingers together or moving your wrist. Your speech will be evaluated along with sensations such as numbness and tingling. Once the desired responses are obtained, the test electrodes will be removed and the final location for the implant will be determined. The permanent electrode implant will then be placed precisely into the optimal location. The electrode implant will be secured and the incision closed. If you are doing well and there have not been any complications, the other side will be done, following the same set of steps. The entire operating room procedure takes between 5-6 hours. The bone anchors will be removed after surgery. You may feel tired or become restless after lying in one position for so long. The staff will do their best to make you comfortable. Once the surgery is complete, you will go to the recovery room. Sometime later in that day, you will be taken for a CT scan, which will document the electrode placement and will also check for any evidence of bleeding or a stroke. You will most likely spend 1-2 nights at the hospital before being discharged home.

Post- Operative Instructions:

- Resume taking your anti-Parkinson's medications as before. Keep wounds dry for 4 days. You can then shower and get your head wet AFTER 4 days. Do not apply any ointments or creams.
- Call our office if you experience a fever of 101.5 or higher; drainage from the incision; new weakness developing in your arms or legs; difficulty being aroused from sleep by your family/friends; or a persistent headache not relieved by medication. Call your neurologist for any changes related to movement or for questions about your medications.
- Take your antibiotic and/or pain medication as directed.
- We will see you for a brief office visit 2 weeks after electrode placement.
- You will be scheduled to return in approx 3-4 weeks for the generator implant.

What to Expect During the Recovery Period:

Sometimes air is introduced around the brain when the lining of the brain (the dura) is pierced to insert the DBS probe. Subsequently, you may experience a headache over your forehead, which will go away as the air is reabsorbed. Changes in behavior such as sleepiness, fatigue, difficulty with speech, and/or confusion may temporarily be seen for up to 4-6 weeks. Occasionally the surgery can make the dyskinesias become temporarily worse. This, too, will resolve with time. Often times the passage of the DBS probes through the brain tissue "stuns" the nerves cells and produces a "honeymoon" effect, whereby you will experience improved symptoms for several days similar to what you may expect once your internal pulse generators have been programmed. During this period of time, you might find that you need to decrease the medications you use to treat your Parkinson's disease, tremor, or dystonia. Sometimes fluid that accumulates under the scalp during the surgery will shift down the scalp and be noticeable as it is being reabsorbed over several days following the surgery. Patients often notice a swollen forehead or swollen eyes around the second to fourth day after the surgery. This is normal and should go away as the fluid is being reabsorbed within the first week after this surgery.

Stage 4: DBS Generator (IPG) Implant and Electrode Hook- Up

Purpose of this Procedure:

Hook-up of the previously placed DBS electrodes to the internal pulse generator (IPG) that produces and controls the stimulation.

Pre- Operative Instructions:

You may take your anti-Parkinson's, tremor or dystonia medications with a sip of water in the morning if that is your scheduled medication time.

Arrival at the Hospital:

You will arrive at hospital admitting two hours prior to your scheduled surgery time. As in Stage Two, you will be taken to the Pre-Surgery Unit and prepared for the operating room.

During the Procedure:

For this operation, you will be given general anesthesia and be asleep. The surgery takes approximately two hours. The internal pulse generator (IPG) will typically be implanted in the upper chest region, below your collarbone. Most people need only one IPG, but some patients may require two. Special positioning of the IPG or certain medical conditions may require a different location of the IPG, and this will be discussed by your surgeon prior to the surgery.

An extension wire is used to connect the DBS electrode to the IPG. It is threaded under your skin from the top of your head, behind the ear, to the IPG. The incision in your chest will be closed with stitches that dissolve. The outer skin is stapled or sutured. If stapled, these will need to be removed **2-3 weeks** following surgery. After your neurosurgeon has finished your surgery, you will be taken to the Recovery Room, and discharged to either home or rehab if you have Parkinson's disease. If you have essential tremor you will be discharged home. You are typically discharged 2-3 hours after *your* surgery is complete.

Post-Operative Instructions:

- Keep your dressing on for two days, and keep your wounds dry for four days. Then you can shower as usual. Just keep the incisions clean and dry.
- Call our office immediately if you have a fever of 101.5 degrees or higher, or if you develop any redness that spreads out like a sunburn, swelling, or drainage from your incisions.
- A post- op surgery check and staple removal needs to be scheduled for **2-3 weeks following** surgery.

Stage 5: Programming of Stimulator

Purpose of this Procedure:

Program the implanted device and instruct the patient on the use of the stimulator and hand held controller. Your stimulator will be programmed by your neurologist. This gives the probes a chance to stabilize as the swelling goes down and the tissue heals. Please remember to keep the patient programmer you receive after the operation and bring it to your first programming session for instruction in its use.

During this visit the neurologist will test the implanted device to make sure that it is working properly. Each of the four contacts on the implanted lead(s) will be tested for symptom benefit and possible side effects. The purpose of this visit is to determine which of the four contacts offers the best symptom benefit. At the conclusion of this visit, the neurologist will provide instructions concerning the use of the Access Review device, medications and stimulation. Things can be replaced as needed, with the battery life lasting generally about 5 years. Follow-up visits will occur every one to two months for the first six to 12 months, and then as needed.

After You Receive Your Implant

Always carry your identification card, as your internal pulse generator may set off metal detectors.

Dental drills ultrasonic probes - turn OFF the neurostimulator. Ask your dentist to keep the drill or probe 6" away from the neurostimulator.

Dental Work after DBS. We recommend avoiding routine dental prophylaxis and simple procedures for 3 months following a stimulator placement, but between 4 and 24 months we suggest antibiotic prophylaxis. After 24 months, you will not need antibiotic prophylaxis unless you have a compromised immune system, Type 1 diabetes mellitus, previous infection of a prosthetic joint or a spinal fusion, hemophilia, or malnourishment. The choice of antibiotic is a decision for you and your primary care doctor. Please contact their office for antibiotics or further advice. We are happy to discuss this with them should they need to contact us. If you have significant immune compromise, Type 1 diabetes mellitus, history of previous infected spinal fusions or joint replacements, hemophilia or malnourishment then we suggest antibiotic prophylaxis for ALL future dental procedures regardless of timing, but this again is something that needs to be resolved through your primary care physician and not your neurosurgeon. If there is any confusion please have them call us.

Deep Heat Therapy - Never have any diathermy!

Lithotripsy (a treatment for kidney stones) is not recommended for patients with an implanted neurostimulation system, as it can damage the circuitry.

Scuba Diving - patients should not dive below 33 feet of water.

Tens Units - do not place TENS electrodes so that the TENS current passes over any part of the neurostimulation system.

MRI Examinations - you can no longer undergo a full body MRI examination. If your doctor orders an MRI of the head, inform the x-ray staff about your implant. Imaging centers have protocols for imaging stimulator systems. Be sure to turn off your pulse generator before the procedure. During the examination, immediately inform the x-ray technician if you experience any heat in your head, neck or chest; pain; shocking sensations/uncomfortable stimulation; or unusual sensations. Your examination will most likely be stopped. These symptoms occur very rarely. You may turn on your IPG after the MRI exam is finished. If you suspect that your settings have been changed, contact your neurologist.

At least 80,000 people worldwide have undergone DBS implantation. Most patients enjoy an improved quality of life and few experience complications. These complications can be severe and life threatening. The decision to proceed with DBS is a personal one and we look forward to helping you make the best decisions regarding DBS surgery.

For additional questions and 24 Hour Technical Support call Medtronic at 1-800-707-0933