FAQ Sheet For Clinicians

When is it appropriate to use the Neuro-Stim System (NSS)?

The generator itself is FDA cleared for targeting acute and chronic pain. As a rule of thumb any condition that is either sympathetically mediated or sympathetically maintained can be helped by the use of the device. At first most clinicians use them as a last ditch effort on patients with whom all other procedures have failed. As you gain experience in the clinical use of the devices you will get more comfortable and use them as an integral therapy according to the patient's needs.

Can I use the NSS along with other treatments?

Yes. The device can be used by itself (primary), after other treatments have been tried (secondary), or along with other co-treatments (tertiary). In fact many times because of the co-morbidities often associated with complex pain entities the NSS is utilized as a part of a pain management program.

How many devices are required?

As a rule of thumb long term chronic conditions (with neuroplasticity and mal-adaptation) take longer to treat. For instance a long term fibromyalgia patient will often require more devices than a patient with a short term condition. It is recommended in cases other than acute injury or surgery that the devices be used in a series of three. In other words treat initially with three devices and re-evaluate the patient. If the symptoms are not reduced to a satisfactory level then consider another series of three devices or treat with just one additional device with weekly re-evaluations. Again, a long term pain patient with associated central sensitization, spinal cord wind-up, etc. should be advised that this type of treatment is a process toward quiescence just like their progress to their present pain state was often a process. However each patient should be evaluated on an individual basis and treated according to their personal needs.

Can I place one device and see what happens?

It is normally not recommended to only treat with one device and “see what happens” unless device placement is used to help differentiate sympathetic involvement post surgically or part of a diagnostic process. It is common for patients to feel much better after one device placement and not see an equal effect with the second. In fact, it is very common for patients to say, “I don’t think the device is working” after the second placement. It is thought this is due to adaptive physiology and endorphin production. However after the third placement a residual effect can often be seen. It is important that both the clinician and the patient commit to treatment.

How often do I place the devices?

Each device runs for 120 hrs (5 days) and then turns itself off. It is recommended that there is a two day non-treatment period between applications to avoid attenuation and/or tissue breakdown. So each patient should be appointed no sooner than once every 7 days. The exceptions are outlined in the clinical protocols.
FAQ Sheet For Clinicians

Do I need to place all four leads?

Yes. It is recommended that all four leads are implanted according to the training videos, unless otherwise noted in the clinical protocols.

What about migraines?

Migraines are the exception to the rule. Use only one lead anterior to the tragus (trigeminal/superficial temporal artery) and the ground wire on the lobe. Implanting all the arrays may increase migraines. Also it is advised to not have any non-treatment times in between device application and place at least two back to back. Patients do not “kind of” have a migraine. They either do or they don’t. After two applications often the sympathetic cycle has been broken. Further device treatment is advised on a case by case basis. Remember, patients still need to avoid their migraine triggers. The longer they remain migraine free the more likely they are to remain quiescent.

How about use in conjunction with surgery?

Devices have been used successfully in hundreds of surgical situations. Placing a device several days pre-surgically will help reduce any sympathetic overlays (muscle pain, guarding, edema, ischemia, inflammation) and help patients achieve higher pre-surgical endorphin levels. Placing a device immediately post-surgically will assist in unwanted sympathetic reactions and help keep the patient’s surgical pain manageable often with minimal central acting opioids.
Scheduling

Patient scheduling can often be a challenge when treating chronic pain patients with IHS device therapy. Each patient is different and will require custom treatment by the treating physician. Other than in acute surgical situations multiple visits are needed for device placement. When this therapy is integrated into your routine you and your scheduling assistant will find scheduling a challenge. At first it is recommended that the treating clinician perform the total procedure to sharpen clinical skills. However many clinicians will delegate the intake, pain scales, device assembly and placement to a licensed assistant and complete the final implantation themselves to be more time effective. After a few placements the total time of the treating clinician may be five minutes or less.

Here’s some helpful tips:

1. Patients should commit to you and you to them. Make sure when initial therapy is initiated that your office can follow up with proper sequence. Skipping a week can cause relapse and should be avoided. It may be best to delay initial treatment until everyone can make their commitments. Convey this to your patients.

2. Trying a device and “seeing how it goes” is not often recommended. You may get false success or false failure. As a rule of thumb chronic conditions should be treated in a series of three to achieve maximum sympathetic reduction and physiological adaptation. The exceptions are acute conditions, surgical use, use to help with a differential diagnosis and the clinician’s clinical judgment. All protocols should be considered guidelines not absolutes. All factors should be weighed and final device placement based accordingly.

3. Make sure that all procedures performed or delegated are within your state’s scope of practice and the individual’s licensure.

4. Financial arrangements should be made in advance. This includes any necessary third party arrangements, cash, etc. Many patients with chronic conditions have financial considerations that should be honored. Be sure to not pre-judge patients on what they can or cannot afford. That is not your job. Your job is to diagnose, offer suggested treatment outlines and let them make their own financial decisions.

IHS works with several coding companies which can help advise and guide you in this process. IHS has no financial ties to any recommended companies and does not make coding decisions. If further information is desired please contact IHS or your local representative.
5. Enjoy the process. Treating chronic conditions is always a challenge. You will find that using IHS device therapy will add a whole new dimension to your practice. Patients you were previously unable to help will often respond in a positive manner, be grateful and refer their friends. We at IHS are hopeful that using the device therapy will open many doors as an emerging science and encourage you to learn further to be a more effective diagnostician and treating clinician. We are dedicated to your support and education providing online learning modules and encourage communication. You will find your local representative to be a valuable, well trained asset to your practice. Any questions you may have will be researched and discussed. Our team of advisors will attempt to answer them to your satisfaction.

One last personal note...
The most common response I have received from my patients through the years is not that their pain has not gone away but that we have changed their lives allowing them to once again have a life not focused on their pain but rather focused on the things that make life enjoyable. That may be as simple as going to the mall, not missing a grandchild’s birthday party or not having their child comment “I hope we can go tomorrow if mommy doesn’t have a headache.” Many times patients with chronic conditions lose hope along the way knowing they are living a life of pain with an occasional short-term respite. Integrating the IHS family of devices into your practice can help you provide them with a life not centered around their pain.

While not every case is successful and not everyone qualifies for device treatment, you will find great success and satisfaction from those you help. The IHS family of devices designed for a target population of acute and chronic pain.

Christopher R. Brown DDS, MPS
Head of Scientific Research and Development
Innovative Health Solutions
Introduction to Protocols

The following are suggested guidelines for specific clinical entities. However it must be remembered that chronic conditions are often multi-factorial in nature and require a multi-modal approach. The use of an IHS device is therefore often a part of an ongoing process.

Along with mal-adaptive neuroplasticity often comes mal-adaptive behavior which may need to be addressed as well. Since the target population of this type of treatment is acute and chronic pain the clinician must be aware of the sustaining co-factors which contribute to the condition.

Entities such as Central Sensitization Syndrome, Fibromyalgia, and PTSD have a heavy sympathetic overlay by nature and often predictably respond satisfactorily to the use of the IHS devices. “Spinal wind-up”, neuroplasticity and micro-glial responses occur over an extended period of time and the patient as well as the clinician must be aware that it will often take time to “un-wind” the physiological adaptation processes.

Patients with long term pain conditions must set reasonable goals to assist in the process of acceptable pain reduction, increase in physical activity, and the amount of device therapy it may take to achieve these goals. Your treatment estimation is based upon a combination of their condition, their desire to get better, adhering to treatment guidelines, your clinical experience and rate of symptom reduction. These factors should be discussed before any treatment is initiated.

The treating clinician, the patient, and their significant support system all work together as a team to help achieve a more pain-free life. The IHS family of devices are wonderful tools to assist in achieving those goals.

If you have specific questions about technique or need educational support along the way IHS is accessible through the web site, our 24 hr. hot-line and your local rep. If you have questions about insurance coding please address them with the IHS certified representatives. Innovative Health Solutions does not give any coding advice but rather refers you to unaffiliated professional coders with whom you can directly work to assist you and your patient.

The IHS family of neuro-stimulation devices, the modern non-narcotic alternatives for pain management.

Christopher R. Brown DDS, MPS  
Head of Scientific Research and Development  
Innovative Health Solutions

All protocols and recommendations are based upon anecdotal clinical evidence. Final application of devices should be determined on an individual basis. University and Department of Defense randomized double-blind clinical trials are on-going.
Protocol for Post Arthroscopy/Arthrocentesis

Arthroscopic and joint arthrocentesis intervention of any joint in the body is designed to be minimally invasive. The use of device therapy has proven successful in reducing unwanted sympathetic rebound reducing localized edema/ischemia and sympathetically mediated pain. Placement of a device pre-operatively or immediately post-operatively will help achieve maximum success. All four electrodes should be implanted per protocol (three ventral, one dorsal) for maximum neurovascular field effect.

The exception to this is for TMJ procedures. The device must be placed on the procedural side. The single pin ground lead is implanted on the ventral of the lobe. The first 4 pin array is implanted anterior/superior to the tragus, superior to the TMJ. This location is ascertained by palpation of the lateral aspect of the mandibular condyle. Have the patient open and close their mouth for definitive condylar palpation. This will allow implantation directly over the auriculo-temporal branch of Cranial V (trigeminal) and the superficial temporal artery which branches into the posterior lamina of the TMJ. The second 4 pin array will be implanted in the inner concha in the area of Cranial X (vagal). The third 4 pin array will be implanted into the upper third of the ear affecting cranial nerves V, VII, and branches of the superficial temporal artery.

As in all surgical procedures post-op care should be carefully instructed including physical therapy, exercises, etc.

**Summary:**

3 - 5 Days Pre-Op
(Chronic)  
One device is placed implanting all four leads followed by a device placed immediately post-surgically.

Day 1 Immediately Post-Op
(Acute)  
One device is placed immediately post-surgically.
Protocol for Central Sensitization Syndrome

Clinicians treating chronic often encounter patients who seem to hurt “all over”, have emotional co-factors, multiple chemical sensitivity, endocrine system hypo or hyper function, sleep disorders, chronic fatigue, and a seemingly exhaustive list of medications and myriads of doctor visits. These patients often have a component referred to as CSS. (For review please refer to the Robert’s paper in the IHS certification program.) This condition is multi-factorial with multiple sustaining co-factors commonly referred to as triggers all or most of which may need to be addressed. Chronic pain syndromes such as fibromyalgia and functional pain may involve central sensitization, spinal wind up, altered microl-glia and/or neuroplasticity. These conditions are often associated with a heavy sympathetic overlay via mediation or maintenance and respond to the use of IHS devices. Reduction of the sympathetic drive can often reduce the patient’s symptoms where individual “triggers” can be successfully addressed. These conditions are long term and progressive. Successful treatment will take time and multiple device applications. The patient needs to commit to three device placements placed once per week after which an evaluation should be performed to evaluate success. If symptoms have been reduced to an acceptable level than discontinue treatment until symptoms reappear. Device therapy can then be utilized on a PRN basis. If symptoms are not at an acceptable level and the patient desires to receive further treatment then another series of three are placed one/week. All four electrodes should be implanted per protocol (three ventral, one dorsal) for maximum neurovascular field effect. Please note with long term neuroplastic adaptation and spinal wind up these patients may relapse after a long period of quiescence and may need further treatment. If so treat one device at a time PRN.

Summary:

Week One-Three
One device placed each week with two days non treatment in between devices.

Week Four
Non-treatment for evaluation of residual effect. If patients symptoms begin to increase after several days then an additional set of three devices should be placed.

Week Five-Six
One device placed eachweek with two days non-treatment in between devices.

Week Seven
Non-treatment for evaluation of residual effect. Proceed as described.

Future Treatment
If relapse occurs devices should be utilized one at a time on a PRN basis.

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Protocol for CRPS (Complex Regional Pain Syndrome)

CRPS is by definition a sympathetic response often to a physical insult resulting in several stages of painful progression. IHS device therapy can be a very vital supportive adjunct to treatment. Reducing pain, reducing sympathetic stimulation, increasing range of motion and peripheral arterial perfusion often allows the patient to do the things they have been advised to do and as a result encourages physical therapy to be more effective. CRPS often has a traumatic onset but can also result from disease with a progressive onset of symptoms. The most effective use of devices is in sets of three allowing treatment for 21-28 days. If symptoms have been reduced give the patient a week of non-treatment to be able to observe for residual effect. If after a few days the patient’s symptoms ramp up then another set of three devices should be advised. As the patient improves a mutual decision should be made to extend non-treatment times in between devices but usually not before the initial three and often may continue beyond six. As soon as there are observable changes in the tissue, reduction in pain, and a restoration of function then device therapy can be discontinued.

Use of the IHS devices is often in conjunction with physical therapy and medications and should be considered adjunctive in nature as part of an overall treatment plan. The devices are the most effective when CRPS symptoms first occur and not waiting until the tertiary stage. Early use will reduce symptoms, the amount of devices used and speed of recovery.

All four leads should be used as indicated by IHS training to achieve maximum cranial neuro-vascular field effect.

**Summary:**

**Weeks One-Three**
One device placed each week with two days non-treatment in between devices.

**Week Four**
Non-treatment for evaluation of residual effect. If patients symptoms begin to increase after several days then an additional set of three devices should be placed.

**Weeks Five-Six**
One device placed/week with two days non-treatment in between devices.

**Week Seven**
Non-treatment for evaluation of residual effect. Proceed as described.

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NSS
The Neuro-Stim System
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Protocol for Chronic Pain

When reviewing chronic pain publications the term “chronic” is defined many different ways. There is evidence to support there is physiological and neuro-plastic adaptation as soon as 21-28 days. While this definition can be argued it is a reasonable working model for the use of the IHS devices designed for a target population of acute and chronic pain. Chronic pain is often a multi-factorial, multi-system entity with heavy sympathetic overlay. IHS device therapy can be a very vital supportive adjunct to treatment. Reducing pain, increasing sleep and increasing range of motion often allows the patient to do the things they have always been advised to do but couldn’t.

While chronic pain is by definition > 21-28 days the etiology can have an onset from trauma or disease and is often progressive accruing collective symptoms. The most effective use of devices is in sets of three allowing treatment for 21-28 days. If symptoms have been reduced give the patient a week of non-treatment to be able to observe for residual effect. If after a few days the patient’s symptoms elevate then another set of three devices should be advised. As the patient improves, a mutual decision should be made to extend non-treatment times in between devices but usually not before the initial three.

All four leads should be implanted as indicated by IHS training to achieve the maximum cranial neuro-vascular field effect

Summary:

Weeks One-Three
One device placement every week with two days of non treatment in between devices.

Week Four
Non-treatment for evaluation of residual effect. If patients symptoms begin to increase after several days then an additional set of three devices should be placed.

Weeks Five-Six
One device placement every week with two days of non-treatment in between devices.

Week Seven
Non-treatment for evaluation of residual effect. Proceed as described.
Protocol for Fibromyalgia

Fibromyalgia is a multi-factorial, multi-system entity with heavy sympathetic overlay. IHS device therapy can be a very vital supportive adjunct to treatment. Reducing pain, increasing the quality of sleep and increasing range of motion often allows the patient to do the things they have always been advised to do but couldn’t. Fibromyalgia which can have a rapid onset from trauma or disease is often however a chronic condition with progressive onset of collective symptoms. The most effective use of devices is in sets of three allowing treatment for 21-28 days. If symptoms have been reduced give the patient a week of non-treatment to be able to observe for residual effect. If after a few days the patient’s symptoms ramp up then another set of three devices should be advised. As the patient improves a mutual decision should be made to extend non-treatment times in between devices but usually not before the initial three and often continuation beyond six. All four leads should be used as indicated by your training to achieve maximum cranial neuro-vascular field effect.

Summary:

Weeks One-Three
One device placed each week with two days non-treatment in between devices.

Week Four
Non-treatment for evaluation of residual effect. If patient’s symptoms begin to increase after several days then an additional set of three devices should be placed.

Weeks Five-Six
One device placed each week with two days non-treatment in between devices.

Week Seven
Non-treatment for evaluation of residual effect. Proceed as described.
Protocol for Low Back Pain

Low back pain is one of the most ubiquitous conditions in the world, elusive to treatment and is one of the leading causes of disability in the United States. While LBP is a diagnostic entity it is often multi-factorial in etiology with a heavy sympathetic overlay and often requires a multi-disciplinary approach for resolution.

IHS device therapy can be a very vital supportive adjunct to treatment. Reducing pain, increasing quality of sleep and increasing range of motion often allows the patient to do the things they have always been advised to do but couldn’t. If symptoms have been reduced give the patient a week of non-treatment to be able to observe for residual effect. If after a few days the patient’s symptoms elevate then another series of three devices should be advised. As the patient improves a mutual decision should be made to extend non-treatment times in between devices but usually not before the initial three.

All four leads should be implanted as indicated by IHS training to achieve the maximum cranial neuro-vascular field effect.

A word of caution. Advise the patient NOT to increase their activity beyond normal during the first week of treatment. Patients often feel better and want to “get on with life” lifting too much, doing neglected chores and can easily re-injure themselves.

Summary:

Weeks One-Three
One device placed each week with two days non-treatment in between devices.

Week Four
Non-treatment for evaluation of residual effect. If patient’s symptoms begin to increase after several days then an additional series of three devices should be placed.

Weeks Five-Six
One device placed each week with two days non-treatment in between devices.

Week Seven
Non-treatment for evaluation of residual effect. Proceed as described.
Protocol for Migraines

The patients with migraines require a specific protocol different from all other device protocols. Only two leads are used which are placed in the following manner:

A. An array anterior/superior to the tragus (trigeminal and superficial temporal artery).
B. The single pin ground lead is implanted on the ventral aspect of the lobe.

This will reduce the risk of over-stimulation of the sympathetic system which may increase migraine intensity.

The second device is placed on the 5th day with no non-treatment period as in other protocols again using only two leads as per the first device.

If the headaches cycle is not broken than additional devices should be placed without interruption.
If there appears to be skin irritation at the implantation sites than consider switching ears for patient comfort.

As soon as the headache cycle is broken then treatment can be discontinued. Place devices as needed to help the patient reach quiescence.

Summary:

Days 1-5
First device placement. Implant only one array anterior/superior to the tragus and the single pin lead on the lobe.

Days 5-10
Second device placement. Continue stimulation as described without a non-treatment period to avoid rebound headache.

Days 10-15
Third device placement. As needed. If the headache cycle is broken then treatment can be discontinued.

The number of devices required will vary from patient to patient. Continue with device placement every 5 days PRN until quiescent.
Protocol for Narcotic Reduction

The patient with a background of central acting opioids must be handled cautiously. Patients on narcotics longer then 21-28 days may experience physical attenuation, addiction, or have developed an emotional or psychological dependence. This should be discussed and documented by the prescribing clinician, the clinician treating with the device and the patient.

It may take at least three weeks for the patient to regain the ability to produce endorphins. Therefore it is advisable that the base-line narcotics as prescribed, remained unchanged for up to three weeks even during device use. Reduction of breakthrough medications may begin immediately as determined by the prescribing clinician and the patient.

The devices may be implanted every fifth day for the first three devices to avoid rebound pain. After that time period once a week placement will normally suffice.

When the patient’s pain levels have reduced to a level acceptable by both patient and the clinician base-line central acting opioids can be reduced at a rate determined by the prescriber to minimize the physical symptoms of withdrawal.

The use of the device for the substitute for central acting opioids should be considered as adjunctive treatment along with counseling, physical therapy, alternative medications and other modalities as directed by the treating clinician.

Summary:

Days 1-5
First device placement. Break-through pain medications can be reduced but should be taken as needed with the aim of reduction of total dosage. Background opioids should remain the same.

Days 6-10
Second device placement. Continue reduction of break-through medications as tolerated.

Days 11-16
Third device placement. Continue reduction of break-through pain medications and background opioids can be reduced according to clinical guidelines and judgment.

Days 17-18
No device placement. Continue with medication reduction.

Days 19-23
Fourth device placement. Continue with reduction of break-through and background medications.

Days 24-25
No device placement. Evaluate patient opioid consumption and continue with device therapy if needed.
Protocol for Occipital Neuralgia and Cervicalgia

Patients with these conditions have often previously received multiple treatments. These conditions can be multi-factorial in nature and using the devices in conjunction with other modalities should be considered. Proper device placement will provide direct access into the occipital nerves and the upper cervical spine blocking both afferent and efferent stimuli.

The single pin ground lead should be implanted in the ventral aspect of the lobe. The first 4 pin array should be implanted in the lower third of the outer rim of the ear. The second 4 pin array should be implanted on the dorsal lower third of the ear near a branch of the posterior auricular artery. The third 4 pin array should be implanted on the superior aspect of the dorsal of the ear near an arterial branch. This placement will affect the peripheral branches of the lesser and greater occipital nerves and the posterior auricular arterial branches.

Summary:

Week One
One device placed followed by two days of non-treatment.

Week Two
One device placed followed by two days of non-treatment.

Week Three
One device placed followed by two days of non-treatment.

Week Four
No device placement.

Week Five
Evaluate and treat PRN.
Protocol for Peripheral Neuropathy

Peripheral neuropathy can be a primary diagnosis or a symptom as a result of other pathologies. PN can cause pain, alteration of movement, alteration of sensation, or even organ dysfunction. PN can be acute as a result of trauma, chemically induced (CIPN—see suggested protocol), or commonly found as a result of chronic conditions such as diabetes.

IHS device therapy has proven effective in helping relieve PN’s and helps restore patients to pain free or pain reduced function. Treatment is recommended at the first sign of symptoms and should continue on a PRN basis being careful to monitor all precipitating and/or perpetuating co-factors.

All four leads should be used as indicated by your training to achieve a maximum cranial neuro-vascular field effect.

Summary:

Weeks One-Three
One device placed each week with two days non treatment in between devices.

Week Four
Non-treatment for evaluation of residual effect. If patients symptoms begin to increase after several days then an additional set of three devices should be placed.

Weeks Five-Six
One device placed/ week with two days non treatment in between devices.

Week Seven
Non-treatment for evaluation of residual effect. Proceed as described.
Protocol for Surgery

Device use to augment surgery is designed to reduce unwanted sympathetic reactions (post-op edema/ischemia), sympathetically mediated/maintained pain and reduce the need for post-op opioids.

If surgery is required for a chronic condition with associated muscle guarding, edema/ischemia, localized inflammation and associated pain, device placement is recommended 3-5 days pre-op. All four leads should be implanted for maximum desired affect. A new device should be placed immediately post operatively which will result in a total of 8-10 days of stimulation.

If surgery is required for an acute situation with minimal pre-operative sympathetic involvement than one device placed immediately post surgically will suffice.

All four leads should be implanted as indicated by IHS training to achieve maximum cranial neuro-vascular field effect.

Summary:

3-5 Days Pre-Op
(Chronic)
One device is placed implanting all four leads followed by a device placed immediately post-surgically.

Day 1 Immediately Post-Op
(Acute)
One device is placed immediately post-surgically.
Protocol for Tinnitus

Tinnitus can have multiple etiologies and is often elusive to diagnose and treat. Use of the device has been effective but unpredictable from patient to patient. As in all chronic conditions realistic goals should be established before initiating treatment. Treatment may be completely successful or completely unsuccessful. The decision for treatment lies in a combination of the willingness of the clinician to treat and the patient to allow treatment knowing the variation of success.

All four leads should be implanted per protocol (three ventral, one dorsal) for maximum neurovascular field effect. Patients need to commit to three placements as both a diagnostic and potentially therapeutic treatment. It is advisable to not have any non-treatment time in between devices for the first two placements to achieve maximum sympathetic suppression as symptoms can spontaneously re-appear. After the second device a two day non-treatment period can be utilized if desired. When the patient’s symptoms have reached MMI (maximum medical improvement) treat with one more device. This is known as “quiescence plus one”.

Summary:

Days 1-5
First device placement. Implantation in sites previously described on the symptomatic side.

Days 5-10
Second device placement. Implantation in sites of the first device.

Days 10-15
Third device placement. Evaluate and treat if the patient is still symptomatic. The number of devices needed is determined by remaining symptoms.
Protocol for Tonsillectomy Pain Control

The use of IHS device therapy has proven successful in post-tonsillectomy pain control. The device can be placed pre-operatively to help encourage endorphin production and reduce edema. A device can be placed immediately post-surgically as well to help reduce discomfort, swelling, and reduce pain medication consumption.

The device may be placed on the either ear. The single pin ground lead is placed on the ventral of the lobe. The first 4 pin array is implanted anterior/superior to the tragus superior to the TMJ. This location is ascertained by palpation of the lateral aspect of the mandibular condyle. Have the patient open and close their mouth for definitive condylar palpation. This will allow implantation directly over the auriculo-temporal branch of cranial V (trigeminal) and the superficial temporal artery which branches into the posterior lamina of the TMJ. The second 4 pin array will be implanted in the inner concha in the area of Cranial X (vagal). The third 4 pin array will be implanted into the upper third of the ear affecting Cranial nerves V, VII, and branches of the superficial temporal artery.

Summary:

3-5 Days Pre-Op
(Optional)
One device is placed implanting all four leads followed by a device placed immediately post-surgically.

Day 1 Immediately Post-Op
(Acute)
One device is placed immediately post-surgically.
Protocol for Trigeminal Neuralgia

Patients with trigeminal neuralgia can often be assisted with device use. Dramatic results can be obtained rapidly but follow up and elimination of triggers is imperative.

The device must be placed on the side of the TGN. The single pin ground lead is implanted on the ventral of the lobe. The first 4 pin array is implanted anterior/superior to the tragus superior to the TMJ. This location is ascertained by palpation of the lateral aspect of the mandibular condyle. Have the patient open and close their mouth for definitive condylar palpation. This will allow implantation directly over the auriculo-temporal branch of Cranial V (trigeminal) and the superficial temporal artery. The second 4 pin array will be implanted in the inner concha in the area of Cranial X (vagal). The third four pin array will be implanted near the outer rim of the lower third of the ear affecting Cranial nerves VII, X and branches of the posterior auricular artery. The second device must be implanted on the fifth day. All triggers should be avoided throughout this period.

A third device may need to be placed but the need is dictated by the patient’s symptoms and clinical judgment. Multiple applications may be necessary and non-treatment time will be symptomatically dictated.

Summary:

Days 1-5
First device placement. Implantation in sites previously described on the symptomatic side.

Days 5-10
Second device placement. Implantation at sites of the first device.

Days 10-15
Third device placement. Evaluate and treat if the patient is still symptomatic. The number of devices needed is determined by remaining symptoms.
Protocol for Vertigo

Vertigo can be one of the most debilitating conditions which can be effectively treated with the IHS devices if there is a sympathetic component. The use of the devices are often secondary in nature but if all pathological entities have been ruled out then it may be used as primary treatment. A reduction in symptoms may be noticed within minutes. It is recommended that patients are treated to “quiescence plus one” (usually two to three devices). All four leads should be implanted per protocol (three ventral, one dorsal) for maximum neurovascular field effect. The first two devices should be placed without a non-treatment period in between to break the sympathetic cycle. If symptomatic reduction has been achieved then a two day non-treatment period is used before placement of the third device.

Summary:

Days 1-5
First device placement. Implantation in sites previously described.

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<th>Days 5-10</th>
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<td>Second device placement. Implantation in sites of the first device.</td>
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Days 10-15
Third device placement. Evaluate and treat if the patient is still symptomatic. The number of devices needed is determined by remaining symptoms.