Medtronic

# Medtronic Pain Therapy

Inceptiv™, Inceptiv™ LT, Intellis™ Pro, Intellis™, Vanta™, Sequentia™ LT

neurostimulation systems for pain therapy

Information for prescribers

! USA Rx only

# Table of contents

**Information available for the system:**

**The information for prescribers manual provides information about contraindications, warnings, precautions, adverse events, sterilization, patient selection, individualization of treatment, and component disposal. For customers in Japan, the appropriate package insert provides information about safety, contraindications, warnings, precautions, and adverse events.**

**The indications sheet provides information about indications and related information. For customers in Japan, the appropriate package insert provides information about indications.**

**The system eligibility and battery longevity manual describes programming considerations and provides battery longevity information to aid in the appropriate neurostimulator selection.**

**MRI guidelines provide information about any MRI conditions and MRI-specific contraindications, warnings, and precautions for MRI scans with the neurostimulation system.**

**Product manuals, such as programming guides, recharging guides, and implant manuals provide device descriptions, package contents, device specifications, product-specific warnings and precautions, and instructions for use.**

! USA **The clinical summary provides information about the clinical study results for the neurostimulation system.**

# Contraindications

**Diathermy -** Do not use shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death. Refer to Appendix A: Electromagnetic interference for further information.

# Warnings

## Use as indicated and instructed

**Use as indicated and instructed -** Only use compatible products for the indicated therapy and indicated populations. Failure to use compatible products per labeling indications and instructions may result in product damage, patient injury, or death.

## Electromagnetic interference (EMI)

**Electromagnetic interference (EMI) -** Electromagnetic interference (EMI) is a field of energy generated by equipment found in the home, work, medical, or public environments that is strong enough to interfere with neurostimulator function. Neurostimulators include features that provide protection from EMI. However, sources of strong EMI can result in the following:

- **Serious patient injury or death,** resulting from heating of the implanted components of the neurostimulation system and damage to surrounding tissue
- **System damage,** resulting in a loss of or change in symptom control, and requiring surgical replacement
- **Operational changes to the neurostimulator,** causing it to reset and turn off stimulation, which may result in the return of underlying symptoms
- **Unexpected changes in stimulation,** causing a momentary increase in stimulation or intermittent stimulation, which some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation may feel uncomfortable, it does not damage the device or injure the patient directly. In rare cases, as a result of the unexpected change in stimulation, patients have fallen down and been injured

Refer to Table 1: Potential effects of EMI from equipment or procedures and Appendix A: Electromagnetic interference for information on sources of EMI, the effect of EMI on the patient and the neurostimulation system, and instructions on how to reduce the risk from EMI.

For information about the effects of EMI on programming, refer to the applicable clinician application programming manual.

***Table 1. Potential effects of EMI from equipment or procedures***

| Equipment or procedure | Serious patient injury | Device damage | Device turns off/on | Momentary increase in stimulation | Intermittent stimulation |
|---|---|---|---|---|---|
| Bone growth stimulators | | X | | X | X |
| CT scans | | | | X | |
| Defibrillation/cardioversion | X | X | | X | X |
| Dental drills and ultrasonic probes | | X | | | |
| Diathermy, therapeutic | X | X | | | X |
| Electrocautery | X | X | | X | X |
| Electrolysis | | X | | | X |
| Electromagnetic field devices: (eg, arc welding, power stations) | | | X | X | X |
| High-output ultrasonics | | X | | | |
| Lithotripsy | | X | | | |
| Household items | | | X | X | |
| Laser procedures | | X | | | |
| Magnetic resonance imaging (MRI) | X | X | X | X | X |
| Psychotherapeutic procedures | | X | X | X | X |
| Radiation therapy | | X | | | |
| Radio-frequency (RF) / microwave ablation | X | X | | X | X |
| Theft detector | | | X | X | X |
| Therapeutic ultrasound | X | X | | | X |
| Transcutaneous electrical nerve stimulation (TENS) | | | X | X | |

## Magnetic resonance imaging (MRI)

**Magnetic resonance imaging (MRI) -** Refer to the MRI guidelines manual associated with this product for the MRI conditions and MRI-specific warnings and precautions for conducting an MRI scan. Do not conduct an MRI examination on a patient with any

implanted neurostimulation system component until you read and fully understand all MRI information in the MRI guidelines manual. MR scans performed under different conditions can result in patient injury or damage to the implantable device.

## Case damage

**Case damage -** If the neurostimulator case is ruptured or pierced due to outside forces, severe burns could result from exposure to the battery chemicals.

## Packaging, sterilization, and single use

**Component packaging -** Visually inspect the sterile packaging for damage that may invalidate device sterility before opening, and inspect the components before use. Do not implant a component if the following circumstances have occurred:

- The storage package has been pierced or altered because component sterility cannot be guaranteed and infection may occur.
- The component shows signs of damage because the component may not function properly.
- The use-by date has expired because component sterility cannot be guaranteed and infection may occur; also, neurostimulator battery longevity may be reduced and may require early replacement.

**Sterilization -** Medtronic has sterilized the package contents according to the process indicated on the package label before shipment.

**Single use -** Do not reuse, reprocess, or resterilize single use products. Reusing, reprocessing, or resterilizing may compromise the functional integrity of the products and may create a risk of contamination, which could result in patient injury, illness, or death.

## Effects on other implanted devices

**Neurostimulator interaction with implanted cardiac devices -** When a patient's medical condition requires both a neurostimulator and an implanted cardiac device (eg, pacemaker, defibrillator), physicians involved with both devices (eg, anesthesiologist, neurosurgeon, cardiologist, cardiac surgeon) should discuss the possible interactions between the devices before surgery.

The electrical pulses from the neurostimulation system may interact with the sensing operation from a cardiac device, and could result in an inappropriate response of the cardiac device. To minimize or prevent the cardiac device from sensing the neurostimulator output:

- Implant the devices on opposite sides of the body
- Program the neurostimulator therapy output to a bipolar configuration
- Consider using bipolar sensing on the cardiac device

Careful programming and review of each system's performance is necessary to ensure safe cardiac system operation with effective neurostimulation therapy.

See also "Programmer interaction with other active implanted devices."

**Programmer interaction with other active implanted devices -** When a patient has a neurostimulator and another active implanted device (eg, pacemaker, defibrillator,

neurostimulator), the radio-frequency (RF) signal used to program these devices may reset or reprogram the other device.

To verify that inadvertent programming did not occur, clinicians familiar with each device should check the programmed parameters of each device before the patient is discharged from the hospital, and after each programming session of either device (or as soon as possible after these times).

Also, inform patients to contact their physician immediately if they experience symptoms that could be related to either device, or to the medical condition treated by either device.

**Patient control devices may affect other implanted devices -** Patients should not place a patient control device (eg, handset, communicator, patient programmer, controller, recharger) over another active implanted medical device (eg, pacemaker, defibrillator, another neurostimulator). The patient control device could unintentionally change the operation of the other device.

## Charging system (for rechargeable neurostimulators)

**Wound contact -** DO NOT use the recharger on an unhealed wound. The recharging system is not sterile, and contact with the wound may cause an infection.

## Use in diabetic patients

**Surgical complications and adverse events may be more frequent and severe in diabetic patients -** The following additional considerations should be made for diabetic patients including:

- A preoperative risk assessment should be performed for patients with diabetes who are at high risk for ischemic heart disease, those with autonomic neuropathy or renal failure, and patients with a Hemoglobin A1C (HbA1c) ≥ 8% (64 mmol/mol).
- Monitor the patient's blood glucose levels in the perioperative period and instruct the patient to continue to monitor levels as they may fluctuate as a response to surgery or to complications. Implanting physicians and/or anesthesiologists should consult practice guidelines for the intraoperative management of diabetic patients during surgery.
- Closely monitor patient for signs of infection, delayed wound healing, or cerebrospinal fluid (CSF) leakage as the severity of these complications may be greater in diabetic patients.

# Precautions

## Physician training

**Implanting physicians -** Implanting physicians should be experienced in spinal procedures and should review the procedures described in the implant manual before surgery.

**Prescribing physicians -** Prescribing physicians should be experienced in the diagnosis and treatment of chronic intractable pain and should be familiar with using the neurostimulation system.

## Storage and operating temperature

**Storage and operating temperature -** Some products may be damaged if stored or operated outside the temperature range specified for the product. For products with limited storage and operating temperature ranges, see the applicable product manuals and package labels.

## System implant

**Compatibility, all components -** Follow these guidelines when selecting system components:

- **Medtronic components designed to interface with non Medtronic components:** For compatibility information for both Medtronic and non Medtronic components, refer to the manual for the Medtronic component designed to interface with the non Medtronic component. Do not rely on contact spacing for compatibility in connecting to Medtronic neurostimulators.

  **Note:** The Medtronic component designed to interface with a non Medtronic component may not be approved in all geographies.
- **Non Medtronic components:** No claims of safety or efficacy are made with regard to the use of components that are not supplied by Medtronic. Refer to the manufacturer's documentation for information.
- **Medtronic systems exclusively composed of Medtronic components:** For proper therapy, use only Medtronic neurostimulation components that are compatible or specified in an intended use statement (if present).
  Components are compatible when the following conditions are met:
  – Components have the same indication.
  – Components will not be connected to non Medtronic components. (See “Medtronic components designed to interface with non Medtronic components” above for compatibility information for that type of implant scenario.)
  – For implanted components, the contact spacing and the number of electrode contacts at the connections for the lead and extension/neurostimulator or extension and neurostimulator are the same.

  For each product, refer to the applicable indication insert and the package label for this information.

**Component handling -** Handle the implantable components of this system with extreme care. These components may be damaged by excessive traction or sharp instruments, which may result in intermittent or loss of stimulation, requiring surgical replacement. Refer to the appropriate implant manual for additional instructions.

**Neurostimulator location -** Select a location that is:

- Away from a second neurostimulator so that the external components (eg, antenna) do not overlap, to minimize possible interaction between the devices, and to minimize discomfort at the neurostimulator site
- On the opposite side of the body from another active implanted device (eg, pacemaker, defibrillator) to minimize possible interaction between the devices
- Away from bony structures to minimize discomfort at the neurostimulator site
- Away from areas of restriction or pressure to minimize the potential for skin erosion and patient discomfort
- In an area accessible to the patient for proper operation of patient control devices

**Device inversion -** To minimize the risk of device inversion or rotation:

- Do not make the neurostimulator pocket any larger than necessary to fit the neurostimulator and excess lead or extension.
- Use the suture holes in the connector block to secure the neurostimulator to the muscle fascia per the implant manual.

Device inversion may also occur from erosion of subcutaneous tissue within the pocket, pocket fluid, or hematoma. See also "Information for the patient" sections: "Activities requiring excessive twisting or stretching" and "Component manipulation by patient."

Refer to the appropriate implant manual for additional instructions.

**Patient detoxification -** Before placing leads for test stimulation, patients should be detoxified from narcotics. If patients are not detoxified, test stimulation may not be properly assessed.

## Clinician programming

**Programmer interaction with a cochlear implant -** When the patient has a cochlear implant, minimize possible interference (eg, audible clicks) between the programmer and cochlear implant by keeping the external portion of the cochlear system as far away as possible from the programming components or turn off the cochlear implant during programming.

**Programmer interaction with flammable atmospheres -** The programmer is not certified for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide. The consequences of using the programmer near flammable atmospheres are unknown.

**Testing stimulation with multiple external neurostimulators -** When performing test stimulation with a patient with two leads implanted, do not operate two external neurostimulators simultaneously. The stimulation from simultaneously operated external neurostimulators can interfere with each other and result in unintended therapy.

## Effect on electrocardiograms (ECGs)

**Effect on electrocardiograms (ECGs) -** Ensure the neurostimulator is programmed off prior to initiating an ECG. If the neurostimulator is on during an ECG, the ECG recording may be adversely affected, resulting in inaccurate ECG results. Inaccurate ECG results may lead to inappropriate treatment of the patient.

Refer to "Appendix A: Electromagnetic interference" on page 16 for information about other medical procedures that may interact with the neurostimulation system.

## Charging system (for rechargeable neurostimulators)

**Recharger use -** Check for skin irritation or redness near the neurostimulator during recharging. Do not sit or lie on the antenna, or apply excessive pressure to the antenna. Take periodic breaks during prolonged recharging. Although no direct cause and effect has been established, some patients have reported heating sensation, discomfort, blistering not caused by heating, skin irritation, or redness near the implanted neurostimulator during or after recharging. Contributing factors may include excessive pressure on the antenna, prolonged recharging periods, or individual patient physiological factors.

## Information for the patient

**Activities requiring excessive twisting or stretching -** Patients should avoid activities that may put undue stress on the implanted components of the neurostimulation system. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause component fracture or dislodgement. Component fracture or dislodgement may result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery to replace or reposition the component. Spinal cord stimulation patients, in particular, should avoid excessive bending of the torso.

**Component manipulation by patient -** Patients should avoid manipulating or rubbing the neurostimulation system through the skin. Manipulation may cause component damage, lead dislodgement, skin erosion, or stimulation at the implant site.

**Scuba diving or hyperbaric chambers -** Patients should not dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA). Pressures below 10 meters (33 feet) of water (or above 2.0 ATA) could damage the neurostimulation system. Before diving or using a hyperbaric chamber, patients should discuss the effects of high pressure with their physician.

**Skydiving, skiing, or hiking in the mountains -** High altitudes should not affect the neurostimulator, however, the patient should consider the movements involved in any planned activity and take precaution to avoid putting undue stress on the implanted system.
Patients should be aware that during skydiving, the sudden jerking that occurs when the parachute opens may cause lead dislodgement or fractures, which may require surgery to repair or replace the lead.

**Unexpected changes in stimulation -** Electromagnetic interference, postural changes, and other activities may cause a perceived increase in stimulation, which some patients have described as uncomfortable stimulation (jolting or shocking sensation); therefore,

patients should turn off stimulation before engaging in activities that could be unsafe for themselves or others if they received an unexpected jolt or shock (eg, driving, operating power tools). Patients should discuss these activities with their physician.

**Group selection -** Patients should select the group recommended by the clinician for the current activity or posture. Use of another group may result in uncomfortable or unexpected stimulation (jolting or shocking) when stimulation is turned on.

# Component disposal

When explanting neurostimulation system components (eg, replacement, cessation of therapy, or postmortem), or when disposing of accessories, follow these guidelines:

- If possible, return the explanted component with completed paperwork to Medtronic for analysis and disposal.
- To allow for component analysis, do not autoclave the component or expose the component to ultrasonic cleaners.
- Dispose of any components not returned to Medtronic according to local environmental regulations; in some countries, explanting a battery-operated implantable device is mandatory.

**Precautions:**

- Follow appropriate biohazard controls for all explanted components or components coming into contact with bodily fluids. Only return such components to Medtronic in the appropriate packaging supplied by Medtronic.
- Do not incinerate or cremate the neurostimulator because it may explode if subjected to these temperatures.

# Individualization of Treatment

Best results are achieved when the patient is fully informed about the therapy risks and benefits, surgical procedure, follow-up requirements, and self-care responsibilities. Maximum benefits from the neurostimulation system require long-term postsurgical management.

## Intended target population

The target population is patients who have chronic pain consistent with the indications. See associated indications sheet for more information.

## Patient selection

Select patients carefully to ensure that:

- their symptoms are of physiological origin.
- they are appropriate candidates for surgery.
- they can properly operate the system.

- they received satisfactory results from a trial or test stimulation period.

## Use in specific populations

**Use in specific populations -** The safety and effectiveness of this therapy has not been established for:

- pregnancy, unborn fetus, or delivery.
- pediatric use (patients under the age of 18).

## Long-term effectiveness of neurostimulation

The long-term effectiveness of neurostimulation has been documented. Long-term clinical data regarding the efficacy of Medtronic neurostimulation systems is not yet available. Not all patients realize long-term benefits from neurostimulation.

# Adverse events summary

The implantation of a spinal cord stimulation system involves risks that are similar to other spinal procedures. In addition to those risks associated with surgery, the following adverse events may occur with implantation or use of a neurostimulation system. Certain adverse events may necessitate surgical intervention.

- Allergic or immune system response to the implanted materials
- Infection
- Lead, extension, or neurostimulator erosion through the skin or migration
- Leakage of cerebrospinal fluid
- Lack of effective therapy or loss of therapeutic effect resulting in return of baseline symptoms
- Patients on anticoagulation therapies may be at greater risk for postoperative complications such as hematomas that can result in paralysis
- Persistent pain at the neurostimulator site
- Placement of the epidural lead-extension is a surgical procedure that may expose patients to risks of epidural hemorrhage, hematoma, or paralysis
- Radicular chest wall stimulation
- Seroma or hematoma at the neurostimulator site
- Change in stimulation, possibly related to cellular changes around the electrode(s), shifts in electrode position, loose electrical connections, lead or extension fractures, which has been described by some patients as uncomfortable stimulation (jolting or shocking sensation).
- Formation of reactive tissue around the lead in the epidural space can result in delayed spinal cord compression and paralysis, requiring surgical intervention. Time to onset can range from weeks to many years after implant.
- Stimulation-dependent gastrointestinal symptoms such as nausea, diarrhea, incontinence, or constipation
- Stimulation-dependent bladder symptoms such as urinary retention, incontinence, or frequency
- Tissue damage at the implant site
- Changes in blood glucose levels in response to any adverse event

! USA For adverse events observed in SCS clinical studies, refer to the Clinical Summary.

**Note:** Diabetic patients may have increased risks of infection, problems healing around the surgical site, and complications common to any surgical procedure. The severity of any surgical complication may be greater in diabetic patients, particularly those with inadequate pre-operative glycemic control.

If a serious incident related to a patient's therapy occurs, immediately report the incident to Medtronic and the applicable competent authority.

After the EUDAMED website is launched, the Summary of Safety and Clinical Performance (SSCP) can be found at https://ec.europa.eu/tools/eudamed.

# Patient Counseling Information

For applicable geographies, an International Implant Card, which contains identifying information about the implanted device, is included in each device package. After device implant, complete each card with the patient's name, the implant date, and the healthcare center's name and address. Give all cards to the patient.

Physicians should provide patients and caregivers with information about:

- the components of the neurostimulation system: lead, extension, and neurostimulator.
- instructions for using the neurostimulation system.
- the indications, contraindications, warnings, precautions, and adverse events for a neurostimulation system.

Physicians should also instruct patients to:

- always inform any health care personnel that they have an implanted neurostimulation system before any procedure is begun.
- contact their physician if they notice any unusual symptoms or signs.

# Intended Users

The primary users of implantable devices are implanting physicians who are experienced in spinal procedures. Physicians implanting the neurostimulators and percutaneous leads should be experienced in epidural-access and needle-access procedures. Physicians implanting surgical leads should be experienced in open spinal surgical procedures. Prescribing and managing physicians or clinicians should be experienced in the diagnosis and treatment of chronic intractable pain and should be familiar with using the neurostimulation system. Medtronic field personnel may provide therapy and product training to physicians, clinicians, and patients.

The patient ultimately receives the therapy and experiences pain relief. The patient also interacts with their patient programmer and the recharger to manage their therapy. A percentage of patients have a caregiver that adjusts their therapy.

# Appendix A: Electromagnetic interference

Please review Electromagnetic interference (EMI) under "Warnings" on page 5 and Table 1: Potential effects of EMI from equipment or procedures on page 6.

Before any medical procedure is begun, patients should always inform any health care personnel that they have an implanted neurostimulation system. The potential for the following effects results from an interaction of the neurostimulation system and equipment —even when both are working properly.

## Contraindications

**Diathermy -** Do not use shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy can also damage the neurostimulation system components, resulting in loss of therapy and requiring additional surgery for system explantation and replacement. Advise your patient to inform all their health care professionals that they should not be exposed to diathermy treatment.

Injury to the patient or damage to the device can occur during diathermy treatment when:

- the neurostimulation system is turned on or off.
- diathermy is used anywhere on the body—not just at the location of the neurostimulation system.
- diathermy delivers heat or no heat.
- any component of the neurostimulation system (lead, extension, neurostimulator) remains in the body.

## Warnings

EMI from the following medical procedures or equipment may damage the device, interfere with device operation, or cause harm to the patient. If these procedures are required, follow the guidelines below:

**CT scans -** Prior to the patient undergoing a CT scan, turn off stimulation. If these guidelines are not followed, the patient may experience a momentary increase in stimulation, which some patients have described as uncomfortable stimulation (jolting or shocking sensation).

**Defibrillation or cardioversion -** External defibrillation and cardioversion are therapies that deliver an electrical shock to the heart to convert an abnormal heart rhythm to a normal heart rhythm.

External defibrillation or cardioversion can damage a neurostimulation system and cause induced currents in the lead-extension portion of the system that can injure the patient.

When external defibrillation or cardioversion is required, the first consideration is patient survival. In nonemergent scenarios, refer to Table 2 for recommended neurostimulator settings to perform a cardioversion procedure.

*Table 2. System considerations for cardioversion*

| Device type | Considerations for cardioversion |
|---|---|
| Inceptiv | Turn stimulation off. |
| Inceptiv LT | Turn stimulation off. |
| Intellis Pro | Turn stimulation off. |
| Vanta | Create a group with a program that includes two electrodes. Program neurostimulator to 0.1 mA, 50 Hz, and 300 µs and turn stimulation on. Confirm all active electrode impedances are within a normal range. |
| Sequentia LT | Create a group with a program that includes two electrodes. Program neurostimulator to 0.1 mA, 50 Hz, and 300 µs and turn stimulation on. Confirm all active electrode impedances are within a normal range. |
| Intellis | No stimulation adjustment required. |

Minimize the current flowing through the neurostimulation system by following these guidelines:

- Position defibrillation paddles as far from the neurostimulator as possible.
- Position defibrillation paddles perpendicular to the implanted neurostimulation system.
- Use the lowest clinically appropriate energy output [joules (watt seconds)].
- For a cardioversion procedure, wait at least 60 seconds between cardioversion attempts (as clinically appropriate) to allow the neurostimulator to recover.

After a defibrillation or cardioversion procedure, confirm that the neurostimulator is functioning as intended. Contact Medtronic if you have any questions.

**Electrocautery -** If electrocautery is used near an implantable device, or contacts a device or insertion needle, the following effects may occur:

- The tissue surrounding the insertion-needle (during placement of a percutaneous lead) may be damaged.
- The insulation on the lead or extension may be damaged, resulting in component failure, or induced currents into the patient that may damage tissue, or stimulate or shock the patient.
- The neurostimulator may be damaged, output may be temporarily suppressed or increased, or stimulation may stop.

When electrocautery is necessary, follow these precautions:

- Before using electrocautery, turn off the neurostimulator.
- Disconnect any cable connecting the lead or extension to a screener or external neurostimulator.
- Use only bipolar cautery.
- If unipolar cautery is necessary:
  - Use only a low-voltage mode.
  - Use the lowest possible power setting.
  - Keep the current path (ground plate) as far from the neurostimulator, extension, and lead as possible.
  - Do not use full-length operating room table grounding pads.
- After using electrocautery, confirm that the neurostimulator is functioning as intended.

**High-output ultrasonics -** Use of high-output ultrasonic devices is not recommended for patients who have an implanted neurostimulation system. If high-output ultrasonics must be used, do not focus the beam within 15 cm (6 in) of the neurostimulator.

**Lithotripsy -** Safety has not been established. Lithotripsy is not recommended for patients with an implanted neurostimulation system. If lithotripsy must be used, do not focus the beam on the neurostimulator, which may damage the device.

**Magnetic resonance imaging (MRI) -** Refer to the MRI guidelines manual associated with this product for the MRI conditions and MRI-specific warnings and precautions for conducting an MRI scan. Do not conduct an MRI examination on a patient with any implanted neurostimulation system component until you read and fully understand all MRI information in the MRI guidelines manual. MR scans performed under different conditions can result in patient injury or damage to the implantable device.

**Radio-frequency or microwave ablation -** Radio-frequency (RF) ablation is a surgical technique in which RF or microwave energy is used to destroy cells by creating heat. RF ablation used in patients with a neurostimulation system may result in, but is not limited to, overstimulation, unintended tissue damage, device damage, or device malfunction.

If ablation cannot be avoided, consider the following precautions:

- Avoid direct contact between the ablation catheter and the implanted system.
- Position the indifferent electrode patch so that the electrical current pathway does not pass through or near the device and lead system.

**Theft detectors and security screening devices -** Advise patients to use care when approaching theft detector and security screening devices (such as those found in airports, libraries, and some department stores). When approaching these devices, patients should do the following:

1. If possible, patients should request to bypass these devices. Patients should show the security personnel their patient identification card for the neurostimulator and request a manual search. Security personnel may use a handheld security wand but patients should ask the security personnel not to hold the security wand near the neurostimulator any longer than is absolutely necessary. Patients may wish to ask for another form of personal search.

2. If patients must pass through the theft detector or security screening device, they should turn off their neurostimulator, approach the center of the device and walk through normally (Figure 1).
   a. If two security gates are present, they should walk through the middle, keeping as far from each gate as possible.
   b. If one gate is present, they should walk as far from it as possible.

   **Note:** Some theft detectors may not be visible.
3. Patients should proceed through the security screening device. They should not linger near or lean on the security screening device.

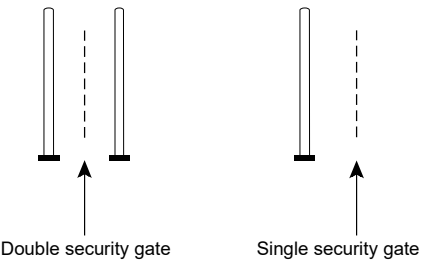


***Figure 1.*** *Approaching security gates.*

4. After patients pass through the security screening device, they should turn on their neurostimulator.

## Precautions

EMI from the following equipment is unlikely to affect the neurostimulation system if the guidelines below are followed. Consult other equipment manufacturer's product labeling for additional guidance.

**Bone growth stimulators -** Keep external magnetic field bone growth stimulator coils away from the neurostimulation system. When using either an implantable or external bone growth stimulator, ensure that both the bone stimulator and neurostimulator are working as intended.

**Dental drills and ultrasonic probes -** Turn off the neurostimulator. Keep the drill or probe 15 cm (6 in) away from the neurostimulator.

**Electrolysis -** Turn off the neurostimulator. Keep the electrolysis wand away from the neurostimulator.

**Electromagnetic field devices -** Patients should exercise care or avoid the following equipment or environments:

- Antenna of citizens band (CB) radio or ham radio
- Electric arc welding equipment
- Electric induction heaters used in industry to bend plastic
- Electric steel furnaces
- High-power amateur transmitters
- High-voltage areas (safe if outside the fenced area)
- Linear power amplifiers
- Magnetic degaussing equipment
- Magnets or other equipment that generates strong magnetic fields
- Microwave communication transmitters (safe if outside the fenced area)
- Perfusion systems
- Resistance welders
- Television and radio transmitting towers (safe if outside the fenced area)

If patients suspect that equipment is interfering with neurostimulator function, they should do the following:

1. Move away from the equipment or object.
2. If possible, turn off the equipment or object.
3. Then, if necessary, use the patient control device to return the neurostimulator to the desired on and off state.
4. Inform the equipment owner or operator of the occurrence.

If the above actions do not resolve the effects of the interference, or the patients suspect that their therapy is not effective after exposure to EMI, they should contact their physician.

**Laser procedures -** Turn off the neurostimulator. Keep the laser directed away from the neurostimulation system.

**Psychotherapeutic procedures -** Safety has not been established for psychotherapeutic procedures using equipment that generates electromagnetic interference (eg, electroconvulsive therapy, transcranial magnetic stimulation) in patients who have an implanted neurostimulation system. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.

**Radiation therapy -** High-radiation sources should not be directed at the neurostimulator. High-radiation exposure may temporarily interfere with neurostimulator operation and may damage the neurostimulator. Damage may not be immediately apparent. To limit device exposure, use appropriate shielding or other measures, such as making beam angle adjustments to avoid the device.

**Transcutaneous electrical nerve stimulation -** Do not place transcutaneous electrical nerve stimulation (TENS) electrodes so that the TENS current passes over any part of the neurostimulation system. If patients feel that the TENS may be interfering with the neurostimulator, patients should discontinue using the TENS until they talk with their doctor.

## Notes

**Household items -** Most household appliances and equipment that are working properly and grounded properly will not interfere with the neurostimulation system. The following equipment is generally safe if patients follow these guidelines:

- **Induction range:** Keep the neurostimulator away from the burners while the burners are turned on.
- **Power tools:** Keep the motor away from the neurostimulator, lead, and extension.

**Other medical procedures -** EMI from the following medical procedures is unlikely to affect the neurostimulation system:

- Diagnostic ultrasound (eg, carotid scan, doppler studies)

  **Note:** To minimize potential image distortion, turn off the neurostimulator and keep the transducer 15 cm (6 in) away from the neurostimulation system.
- Diagnostic x-rays or fluoroscopy

  **Notes:**
  - To minimize potential image distortion, turn off the neurostimulator.
  - Tight pressure such as used during mammography may damage the neurostimulator or disconnect the neurostimulation system components, which may require surgery to reconnect or replace components. During x-ray procedures that require external compression around implanted components, the x-ray equipment should be adjusted to limit the amount of pressure exerted on the neurostimulator.
- Magnetoencephalography (MEG)
- Positron emission tomography (PET) scans

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