

Implantable Electronic Stimulation Devices from Head to Sacrum: Imaging Features and Functions

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Abbreviations: DBS = deep brain stimulation, FDA = U.S. Food and Drug Administration, ICD = implantable cardioverter defibrillator, ONS = occipital nerve stimulation, SCS = spinal cord stimulation, SNS = sacral nerve stimulation, TNS = trigeminal nerve stimulation, VNS = vagal nerve stimulation

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SA-CME LEARNING OBJECTIVES

After completing this journal-based SA-CME activity, participants will be able to:

- Discuss the clinical uses of implantable electronic stimulation devices in the treatment of neurologic diseases.
- Identify the normal imaging appearances of electronic nerve stimulation devices and their leads and identify complications.
- Differentiate devices that are MRI conditional from those that are MRI unsafe.

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Electronic stimulation devices are implanted in various locations in the body to decrease pain, modulate nerve function, or stimulate various end organs. The authors describe these devices using a cranio-caudal approach, first describing deep brain stimulation (DBS) devices and ending with sacral nerve stimulation (SNS) devices. The radiology-relevant background information for each device and its imaging appearance are also described. These devices have a common design theme and include the following components: (a) a pulse generator that houses the battery and control electronics, (b) an insulated lead or wire that conveys signals to the last component, which is (c) an electrode that contacts the end organ and senses and/or acts on the end organ. DBS electrodes are inserted into various deep gray nuclei, most commonly to treat the symptoms of movement disorders. Occipital, trigeminal, and spinal nerve stimulation devices are used as second-line therapy to control craniofacial or back pain. For cardiac devices, the authors describe two newer devices, the subcutaneous implantable cardioverter defibrillator and the leadless pacemaker, both of which avoid complications related to having leads threaded through the venous system. Diaphragmatic stimulation devices stimulate the phrenic nerve to restore diaphragmatic movement. Gastric electrical stimulation devices act on various parts of the stomach for the treatment of gastroparesis or obesity. Finally, SNS devices are used to modulate urinary and defecatory functions. Common complications diagnosed at imaging include infection, hematoma, lead migration, and lead breakage. Understanding the components, normal function, and normal imaging appearance of each device allows the radiologist to identify complications.

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Introduction

For a range of medical conditions in which conventional medical treatments have failed, electronic stimulation devices can provide an alternative or adjunctive drug-free treatment option. There are devices on the market that modulate brain and spinal cord function, regulate the gastrointestinal and urinary tracts, and control respiration. All of these devices (aside from the leadless pacemaker) have a common design theme and device components. First, there is a pulse generator, which houses the battery and control electronics. Second, there is a lead, which is an insulated wire that connects the pulse generator with the final component, the electrode. The electrode, a noninsulated segment or appendage at the end of the lead, contacts and senses and/or acts on the end organ.

Owing to the similarities in design, failure or complications among these devices are similar and include namely lead breakage and electrode displacement. However, the unique placement locations, features, and functions of each device introduce the potential for a distinctive imaging appearance and complications.

TEACHING POINTS

- All of these devices (aside from the leadless pacemaker) have a common design theme and device components. First, there is a pulse generator, which houses the battery and control electronics. Second, there is a lead, which is an insulated wire that connects the pulse generator with the final component, the electrode. The electrode, a noninsulated segment or appendage at the end of the lead, contacts and senses and/or acts on the end organ.
- Owing to the similarities in design, failure or complications among these devices are similar and include namely lead breakage and electrode displacement.
- On frontal radiographs, the VNS pulse generator lies in the left infraclavicular region, and the leads extend to the left aspect of the lower cervical spine. Two small metallic ribbons, one superior to the other, represent the negative and positive electrodes, respectively, which straddle the vagus nerve. On lateral radiographs, the distal wire has a sinusoidal configuration to act as a strain relief when the head is turned to the side.
- The most common complications of SCS are related to device malfunction, which requires reprogramming, or lead and/or electrode displacement or breakage, which are best assessed at radiography rather than at CT.
- Complications of the Enterra device that may be diagnosed at imaging include pocket complications (pocket infection, pocket erosion, and generator movement), electrode perforation, small-bowel obstruction, and incisional hernia.

We discuss a variety of electronic stimulation devices that support deep brain stimulation (DBS), occipital nerve stimulation (ONS), trigeminal nerve stimulation (TNS), vagal nerve stimulation (VNS), spinal cord stimulation (SCS), cardiac stimulation (with a focus on recent devices including the subcutaneous implantable cardioverter defibrillator [ICD] and the leadless pacemaker), phrenic nerve stimulation, gastric electrical stimulation, and sacral nerve stimulation (SNS).

We discuss the types of devices available and the clinical indication(s), history of development, normal and abnormal appearances at imaging, and MRI conditionality of each, emphasizing aspects that are relevant to radiologists. With this information, the radiologist will be able to confidently identify each device and its components, understand its therapeutic goals, and detect complications.

DBS Devices

The U.S. Food and Drug Administration (FDA) approved thalamic DBS for treatment of essential tremor and Parkinson disease–related tremor in 1997 and subthalamic nucleus and globus pallidus internus DBS for treatment of Parkinson disease in 2003 (1). The FDA humanitarian device exemption for DBS was approved for the treatments of dystonia in 2003 and obsessive-compul-

sive disorder in 2009 (1). Other reported applications include treatment of Tourette syndrome, medically resistant depression, epilepsy, obesity, headache, chronic pain, and dementia (2).

The development of DBS for treatment of neurologic disorders was an outgrowth of functional neurosurgery's experience with destructive lesions in the treatment of movement disorders. DBS devices support reversible and adjustable targeting of specific brain areas in an effort to address symptoms that cannot be treated by medication or have been refractory to treatment. DBS does not treat the underlying disease; rather, it is used to control symptoms.

FDA-approved DBS systems are available from three vendors: (a) the Brio and Infinity neurostimulation systems (Abbott [formerly St Jude Medical], St. Paul, Minn), (b) the Vercise DBS System (Boston Scientific, Natick, Mass), and (c) the Activa and Reclaim DBS Therapy systems (Medtronic, Minneapolis, Minn). The features of each system, including size profile, current directionality, and MRI conditionality, vary.

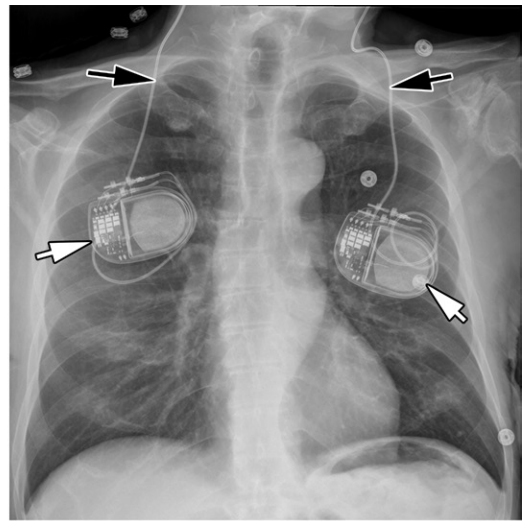
Implantation and Imaging of DBS Devices

Imaging plays a role in DBS device implantation planning and performance, although radiologists are generally not involved in the actual planning. There are several steps in DBS system implantation. The first step is selecting and planning the electrode placement locations. Electrode locations vary depending on the disease being treated and include the subthalamic nucleus, globus pallidus, ventral intermediate nucleus, striate areas, and inferior thalamic peduncle (3,4).

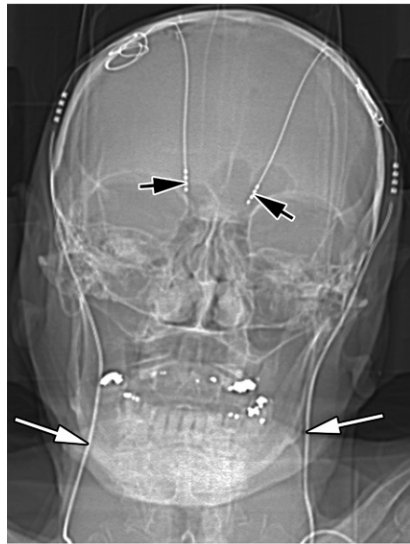
CT, MRI, or both are performed with a headframe or with fiducial markers alone (screwed into the skull) using a frameless technique (5). A common strategy is to perform CT with fiducial markers and register it to MRI performed without markers, which is then used to identify specific targets. Data are fed into the surgical guidance system, which plans a trajectory on the basis of the patient data and data from standard atlases or models, if necessary. With the help of MRI performed after the administration of contrast material (postcontrast), an entry point and trajectory are chosen to avoid the cortical veins, sulci, and lateral ventricles (6).

Intraoperatively, microelectrode recording and/or microstimulation are also used to localize the electrode tip. Intraoperative MRI may be performed for real-time guidance, thus allowing for a nonawake procedure, immediate detection of complications, and a more accurate delineation of the anatomy following brain shift secondary to dural opening, cerebrospinal fluid leakage, or subdural collections (7). Following the electrode

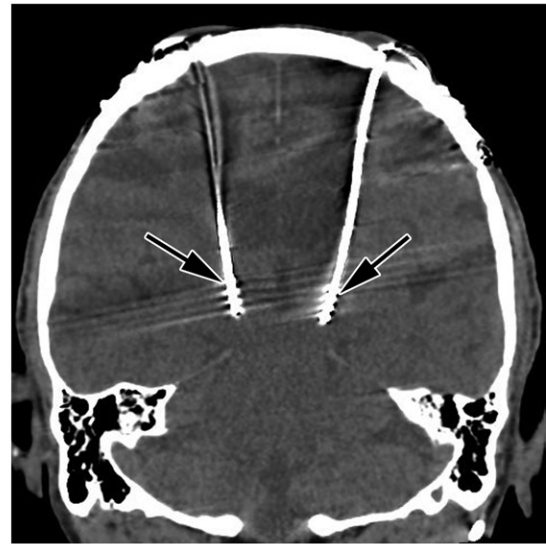
Figure 1. DBS system in a 68-year-old man. (a) Frontal radiograph of the chest shows bilateral pulse generators (white arrows) with bilateral wires extending cranially (black arrows). (b) Frontal scout CT image of the orbits shows bilateral wires (white arrows) connecting to electrodes that extend into the bilateral subthalamic nuclei (black arrows). (c) Coronal CT image shows the electrodes (arrows) and helps to confirm their position.



a.



b.



c.

implantation, the pulse generator is implanted in the upper chest, and the leads are tunneled and connected. After a recovery period, the device is programmed such that the optimal electrode elements are used to accomplish the clinical goal with minimal side effects.

Fluoroscopy or radiography is routinely used to confirm lead position during and after electrode insertion, and additional imaging is not routinely needed. However, if intraoperative MRI and routine postoperative CT are performed, the exact electrode position can be confirmed, and immediate complications may be identified (3,8,9).

On radiographs, which may be obtained for other reasons, the leads should be depicted exiting the skull through burr holes and coursing down the neck in the subcutaneous tissues to the pulse generator, which is typically placed in the anterior chest wall. On chest radiographs,

the leads should be continuous, depicted trailing upward and out of the field of view (Fig 1a).

On CT images of the head, the leads should be depicted entering the skull through burr holes and coursing toward the targeted structures. A small amount of pneumocephalus may be present postoperatively, but there should not be a large amount (10). The Medtronic systems (Activa and Reclaim) are currently the only ones that are MRI conditional; the other systems (Abbott/St Jude Medical and Boston Scientific) are MRI unsafe (11). Device-specific guidelines regarding MRI compatibility can be obtained from each of the manufacturer's websites.

Device-related Complications

When unexpected clinical features manifest postoperatively, such as mental status change, seizure, or focal neurologic findings, performing further imaging (generally CT) is indicated. Immediate

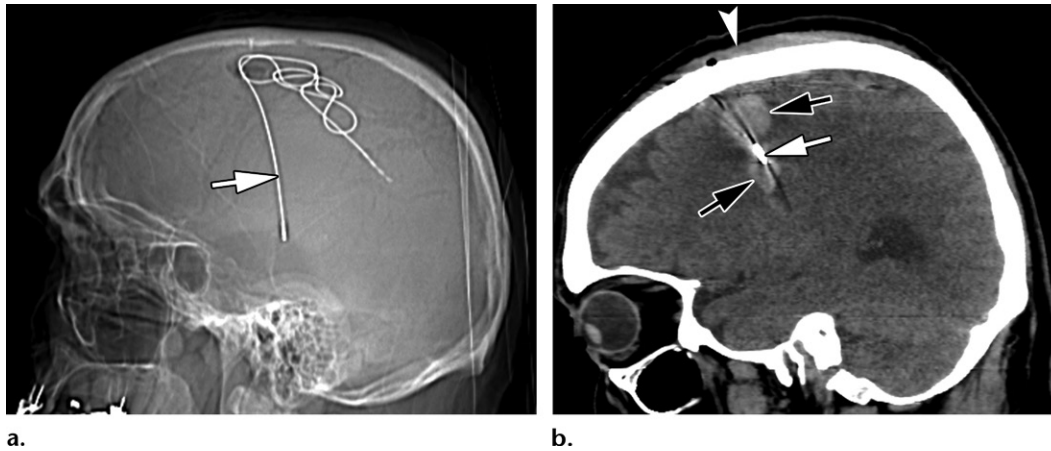


Figure 2. Postoperative intraparenchymal hemorrhage following DBS device placement in a 72-year-old man with Parkinson disease. The patient presented with altered mental status after placement. **(a)** Sagittal scout CT image of the head shows the lead (arrow). Note that the lead has not yet been connected to a pulse generator. **(b)** Sagittal CT image of the brain shows hemorrhage (black arrows) around the lead (white arrow). A scalp hematoma is also present (arrowhead). Despite the hemorrhage, the patient did well, and the hematoma resolved at follow-up CT 1 month later (not shown).



Figure 3. Small right subacute subdural hematoma 7 weeks after DBS lead placement in a 54-year-old man with Parkinson disease. Axial CT image shows a thin subdural hematoma (black arrows) with mixed attenuation over the right convexity. The DBS lead is also depicted (white arrow). The hematoma was visualized incidentally at imaging for system evaluation owing to a pulse generator infection in the chest. Subdural hematomas may be asymptomatic if they are small and if there is preexisting volume loss such that there is no or minimal mass effect.

complications following device implantation include hemorrhage and infarction (Fig 2). Hemorrhage may occur owing to a direct injury to an artery or vein, or venous infarction with resultant hemorrhage. Hemorrhage may be subdural, subarachnoid, or intraparenchymal (Fig 3). In a recent study, the hemorrhage rate was 1.4% (12).

Although infection may affect the leads or electrodes, it more commonly involves the pulse generator and its pocket (13). Unilateral or bilateral local brain parenchymal edema occurs along the lead after insertion in approximately 3% of patients, 4–120 days after surgery (14). The cause is unknown, and edema may be asymptomatic or accompanied by headache or seizures. If there are no signs of infection, this process is self-limited and will resolve with treatment with steroids and supportive care in 1 week to 2 months (Fig 4) (14,15). It is important to recognize this self-limited process so that the system is not removed needlessly.

Delayed lead fracture may lead to system failure and is detectable at radiography. One recent review of 249 patients showed that lead breakage was the second most common delayed complication, with a rate of 9.3% (preceded only by infection at 12.5%) (13).

ONS Devices

ONS devices are used in the treatment of severe occipital neuralgia or chronic migraine that has not responded adequately to conservative therapy (eg, occipital nerve block injections or medications). Although some studies have shown efficacy for the treatment of occipital neuralgia or chronic migraine, level 1 evidence to support this treatment option is currently lacking (16,17). As ONS is not currently an FDA-approved treatment, there are no devices being marketed for this purpose.

Implantation of the device is performed in one stage or following a trial period (see the section on “TNS Devices”) (18,19). Subcutaneous electrodes are implanted over the occiput in the region of the greater and/or lesser occipital nerves using bone landmarks alone, fluoroscopic guidance, or US guidance (17). Once the electrodes are placed, the leads are tunneled subcutaneously to a subcutaneous pulse generator.

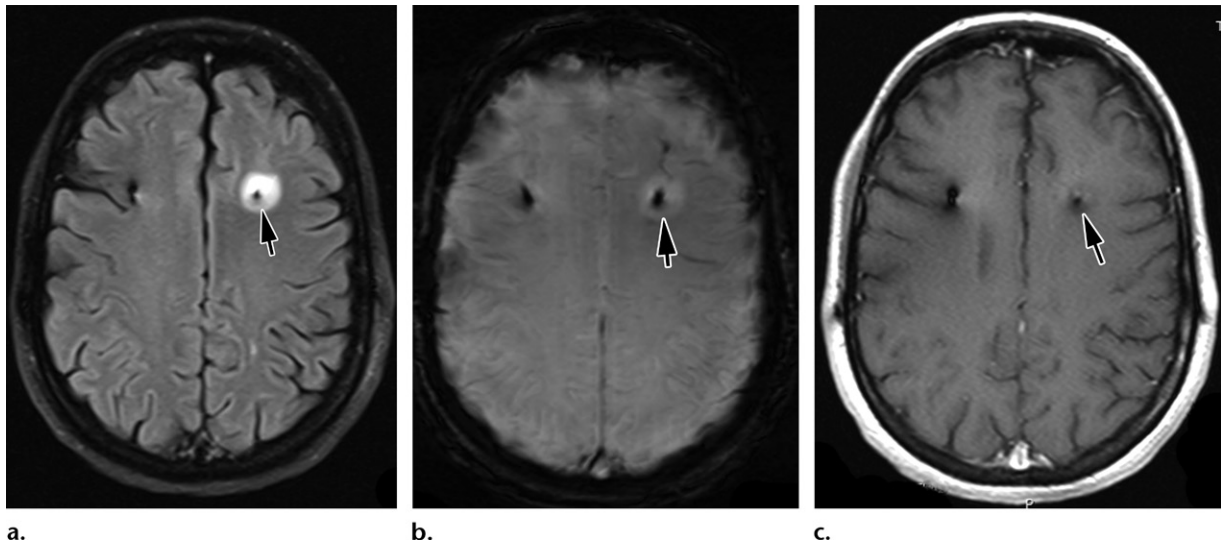


Figure 4. Local brain parenchymal edema in a 44-year-old woman 3 weeks after DBS lead insertion. The patient underwent MRI to evaluate for complications following clear drainage from the scalp incision. (a) Axial fluid-attenuated inversion-recovery (FLAIR) MR image shows high signal intensity surrounding the left lead (arrow). (b) Axial susceptibility-weighted MR image shows no evidence of blood products (arrow). (c) Axial T1-weighted postcontrast MR image shows no associated abnormal enhancement around the lead (arrow). There were no signs or symptoms of infection. The DBS system was interrogated, and all connections and impedances were normal. The system was left in place, and edema resolved at follow-up imaging.

Imaging of ONS Devices

Fluoroscopy or radiography is performed following implantation to document electrode and component placement (18). On radiographs, the leads should be continuous and depicted trailing from the occiput down to the subcutaneous pulse generator, which may be placed in the chest, abdomen, or back (Fig 5). A subcutaneous loop is introduced into the wire at the occiput to produce slack in the system and prevent electrode displacement when the neck is hyperflexed. Although some pulse generator and lead systems being used for ONS are FDA approved for other applications, there are no data or recommendations for MRI compatibility for ONS devices.

Device-related Complications

In a study using data from the Manufacturer and User Facility Device Experience (MAUDE) database, maintained by the FDA, the study authors reviewed 581 reports of device-related complications and found that 35% were reports of lead migration, 27% were reports of infection, 27% were reports of skin erosion, and 8% were reports of lead fracture (20). These complications are similar to those diagnosed following the placement of TNS devices.

TNS Devices

TNS devices are currently being studied for the treatment of neuropathic trigeminal nerve pain such as trigeminal neuralgia and postherpetic, postsurgical, or multiple sclerosis-associated

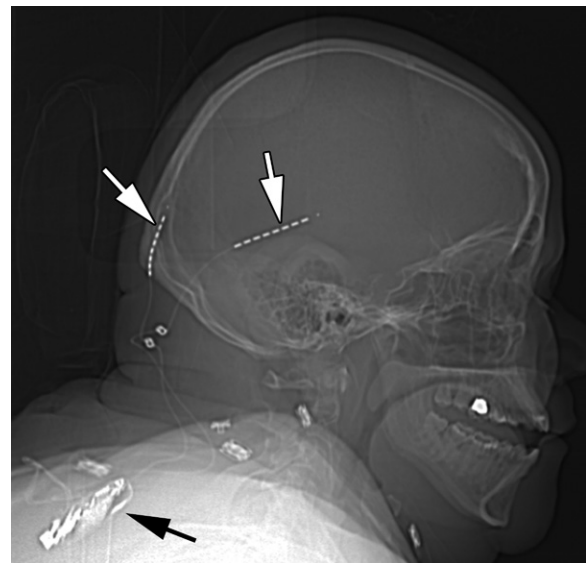


Figure 5. ONS device in a 46-year-old woman with chronic bilateral occipital headaches that began after a concussion and had been refractory to medical management. Lateral CT scout image of the head shows the pulse generator (black arrow) in the right suprascapular region. There are bilateral subcutaneous electrodes in the occipital region (white arrows).

trigeminal neuropathy. Pain may occur in one or more divisions of the trigeminal nerve. The first-line treatment option is pharmacologic, with the administration of opioids, carbamazepine, or gabapentin. Second-line treatments include trigeminal nerve block injections, microvascular decompression, or destructive treatments, including radiofrequency ablation, balloon compression, glycerol injection, and γ -knife radiosurgery (21). As TNS as treatment for neuropathic pain is not

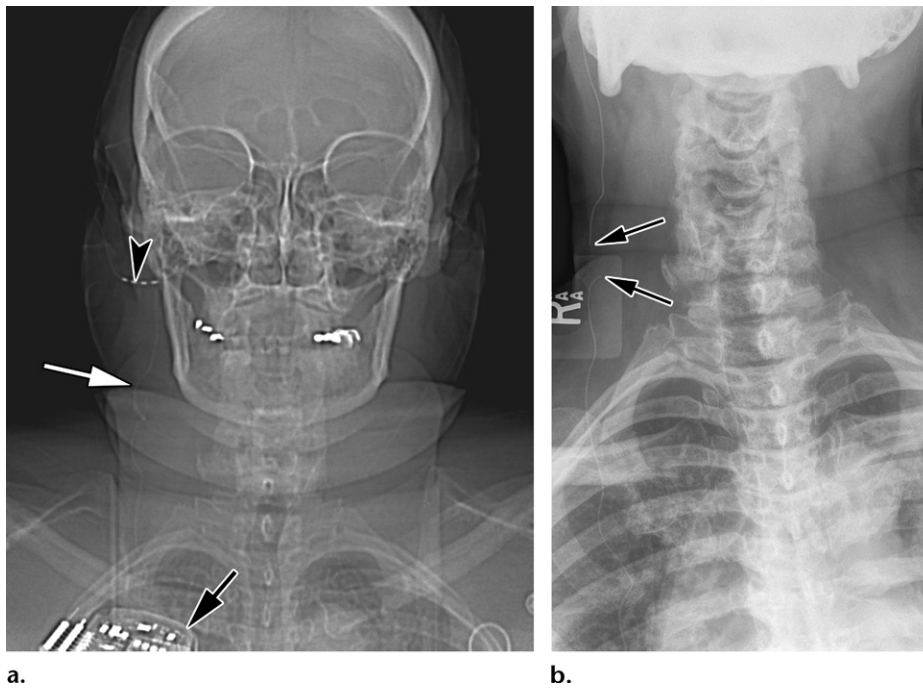


Figure 6. TNS device in a 69-year-old woman with right trigeminal neuralgia of the V2 branch. (a) Frontal scout CT image of the cervical spine shows a portion of the pulse generator (black arrow), the lead (white arrow), and the electrode (arrowhead) in the right V2 distribution. The device lost efficacy 3 years later. (b) Follow-up radiograph of the cervical spine shows a break (arrows) in the lead at the level of the C6 vertebral body.

FDA approved and is considered off-label usage, there are no devices marketed for this purpose.

For TNS, single or multiple temporary electrodes are implanted into the involved ophthalmic (V1), maxillary (V2), and/or mandibular (V3) trigeminal nerve distribution(s) and attached to an external generator during an outpatient procedure. Radiography is performed to confirm lead placement.

During a 1–2-week trial period, the patient rates his or her pain. If the patient reports improvement (defined as $\geq 50\%$ improvement of pain symptoms), the temporary lead is removed and a permanent four- or eight-point-contact electrode is implanted with an infraclavicular internal pulse generator (22). Although there have been numerous case series and case reports demonstrating its efficacy, level 1 evidence is lacking for this treatment option, and prospective randomized trials are needed (23).

Imaging of TNS Devices

Skull radiography is performed following the placement of temporary electrodes to document lead placement but is not required following the placement of permanent leads (22). On radiographs or CT images, the electrodes should be depicted in the subcutaneous tissues corresponding to the targeted distribution(s) of the trigeminal nerve and should be continuous throughout their course toward the implanted pulse genera-

tor. As no neuromodulation system is FDA-approved for TNS, there are no data available for MRI compatibility for this application.

Device-related Complications

Pain over the generator or lead(s) may indicate infection; this may occur immediately postimplantation or years later (24). US or CT can be performed to help localize or delineate a collection. Loss of pain relief indicates a delayed complication such as electrode dislocation or lead breakage, and radiography should be performed to evaluate for these possibilities (Fig 6) (24). Lead migration is most confidently diagnosed when there is a previous study available for comparison.

VNS Devices

VNS has been used for the treatment of a wide range of conditions, including seizure disorders, depression, heart failure, and other systemic disorders. The VNS Therapy system (LivaNova [formerly Cyberonics], Houston, Tex) was FDA-approved in 1997 for the treatment of focal seizures in adult and adolescent patients with medical refractory epilepsy (25). It is also often used as off-label therapy for other seizure disorders such as Lennox-Gastaut syndrome, a severe childhood seizure disorder that is generally resistant to medical management but commonly responsive to VNS (26).

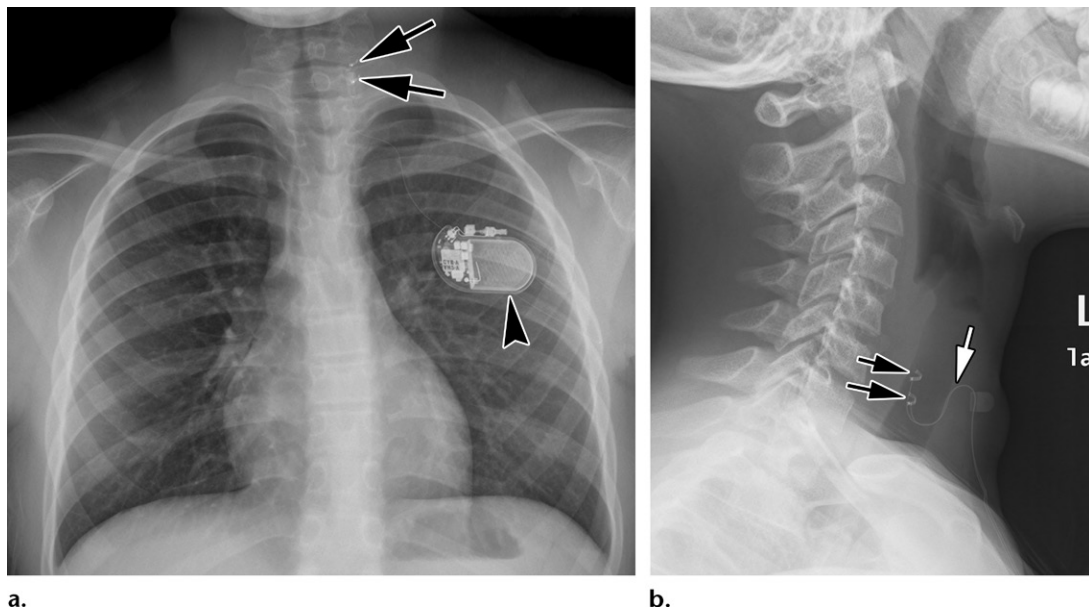


Figure 7. VNS device in a 10-year-old girl with Lennox-Gastaut syndrome. **(a)** Frontal radiograph of the chest shows the left-sided pulse generator (arrowhead), which lies in the left infraclavicular region. The electrodes (arrows) are also depicted. **(b)** Lateral radiograph of the neck shows the leads (white arrow) extending cranially, with two ribbon electrodes (black arrows) depicted in the region of the left vagus nerve. Note the sinusoidal configuration of the lead, which was positioned this way for strain relief.

In 2015, an updated device (AspireSR; LivaNova) that augments stimulation in response to heart rate increase was approved by the FDA. As patients typically cannot activate the device during a seizure for on-demand therapy and because having electroencephalographic electrodes constantly in place is not practical, heart rate increase (which generally occurs during a seizure) is used as a surrogate marker for an active seizure (27).

VNS was approved for chronic treatment-resistant depression in 2005 (28). Additional applications are also under development. The CardioFit System (BioControl Medical, Yehud, Israel), a unidirectional VNS device, is being developed as a treatment of heart failure by stimulating the right vagus nerve, which is believed to have greater cardiac activity than that of the left (28). In 2017, Setpoint Medical (Santa Clarita, Calif) received an investigational device exemption from the FDA to begin a pilot study on a VNS device used in the treatment of drug-refractory rheumatoid arthritis (29). Additional applications, including the treatment of headache, obesity, asthma, and movement disorders, are also under development (28).

Our discussion focuses on the LivaNova VNS Therapy system, as it is the most well established of these devices. The exact mechanism of action of VNS is unknown. It is believed that stimulation of vagal nerve afferent fibers, the largest component of the vagus nerve, electrically suppresses neuronal activity in a wide distribution of brain areas and modulates neurochemicals including

serotonin metabolites and γ -aminobutyric acid (GABA) (30). The VNS Therapy system consists of a subcutaneous pulse generator, which lies in the left infraclavicular region, and two leads, which are tunneled to the vagus nerve in the lower neck. In patients who are at risk for wound tampering, interscapular pulse generator placement has been successfully used (31).

The leads connect to thin ribbon electrodes that are held in contact with the vagus nerve by plastic and metal helices, which encircle the nerve. Although there have been reports of successful seizure control with right VNS, the left vagus nerve is generally used, as stimulation of the right vagus nerve carries the risk of bradycardia owing to sinoatrial node stimulation (32,33).

Imaging of VNS Devices

A postprocedure radiograph should be obtained to confirm correct positioning of device components (34). On frontal radiographs, the VNS pulse generator lies in the left infraclavicular region, and the leads extend to the left aspect of the lower cervical spine. Two small metallic ribbons, one superior to the other, represent the negative and positive electrodes, respectively, which straddle the vagus nerve (Fig 7). On lateral radiographs, the distal wire has a sinusoidal configuration to act as a strain relief when the head is turned to the side (Fig 7).

The LivaNova VNS Therapy devices are MRI conditional at field strengths of 1.5 T and 3.0 T. Other MRI parameters are dependent on the

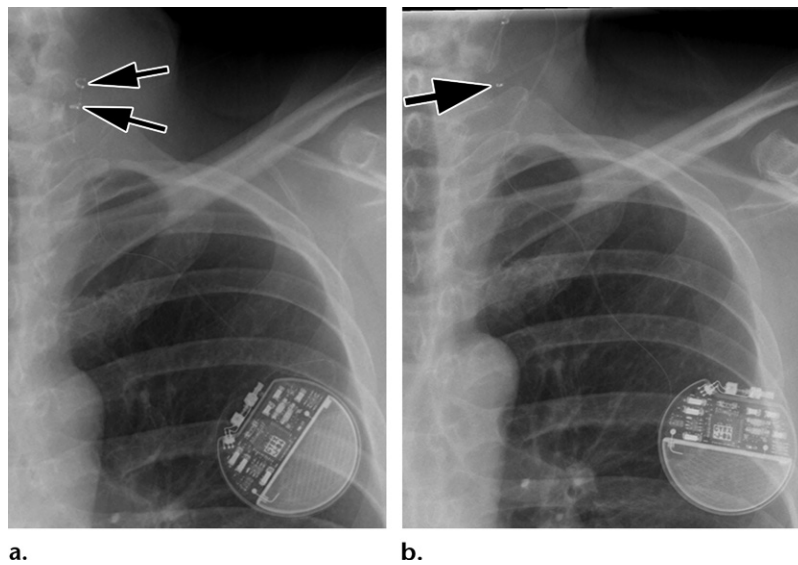


Figure 8. VNS device in a 50-year-old man. (a) Initial chest radiograph shows ribbon electrodes (arrows) with connected wires projecting at the left C6-C7 level. The patient presented 6 years later with a flurry of seizures. The results of a device and battery test were normal. (b) Follow-up radiograph of the chest shows a fragment of the inferior ribbon electrode dissociated from the wire (arrow).

specific model and placement location but generally include an imaging exclusion zone within the chest. Full details can be found on the manufacturer's website (35).

Device-related Complications

An early complication of implantation is hoarseness, which may be due to surgical injury. Alternatively, this may be a persistent problem owing to the effect of stimulation on the recurrent laryngeal nerve. Early or long-term side effects include throat pain, coughing, shortness of breath, muscle pain, and paresthesias in areas innervated by the vagus nerve. These effects are not discernible at imaging.

Wound infection or hematoma is uncommon and may be detectable at US or CT. Postimplantation pneumothorax has also been reported. Loss of device efficacy may be due to device malfunction or end of battery life, but it may also be caused by lead and/or electrode breakage or displacement. Lead and/or electrode breakage or displacement is routinely evaluated at radiography (Fig 8).

SCS Devices

SCS, also known as dorsal column stimulation, is used to treat a wide variety of chronic pain conditions, most commonly chronic back and limb pain, including failed back surgery syndrome, complex regional pain syndrome, and chronic limb pain owing to painful peripheral neuropathy, all of which are FDA-approved indications. Additional off-label indications include refractory angina, abdominal pain, and peripheral vascular disease.

In 1967, Shealy et al (36) placed the first SCS system, and in 1989 the FDA approved the first SCS system for chronic back and limb pain.

When placing an SCS system, the electrodes are placed adjacent to the dorsal columns, which conduct touch and proprioception information to the brain. The mechanism of action was originally explained by the gate control theory, whereby stimulation of sensory signals in the dorsal columns activates inhibitory interneurons in the dorsal horn, which blocks the transmission of pain signals through the shared gate. However, additional mechanisms are currently thought to play a role, including action on neurochemical signaling systems, effects on the brain, and modulation of the end-organ blood flow (37).

SCS systems are available from multiple vendors. A patient typically undergoes an initial trial with temporary externalized leads to determine if he or she experiences meaningful pain relief. If so, then a permanent system is implanted.

The SCS system consists of an implantable pulse generator, epidural electrodes placed at the required level, and leads connecting the generator to the electrodes. The electrodes can be cylindrical and placed percutaneously using fluoroscopic guidance, or they can be paddle electrodes, which require laminectomy or laminotomy for placement (Figs 9, 10). Paddle electrodes are less prone to migration, provide directional stimulation, and provide better long-term pain relief outcomes but require a surgical procedure for placement (38). A thin percutaneous paddle system is now also available (S-Series percutaneous paddle lead; Abbott/St Jude Medical). The electrodes are placed using fluoroscopic guidance, and routine additional postprocedure imaging is therefore not necessary.

Imaging of SCS Devices

If imaging is obtained for other reasons, the pulse generator should be depicted in a subcutaneous

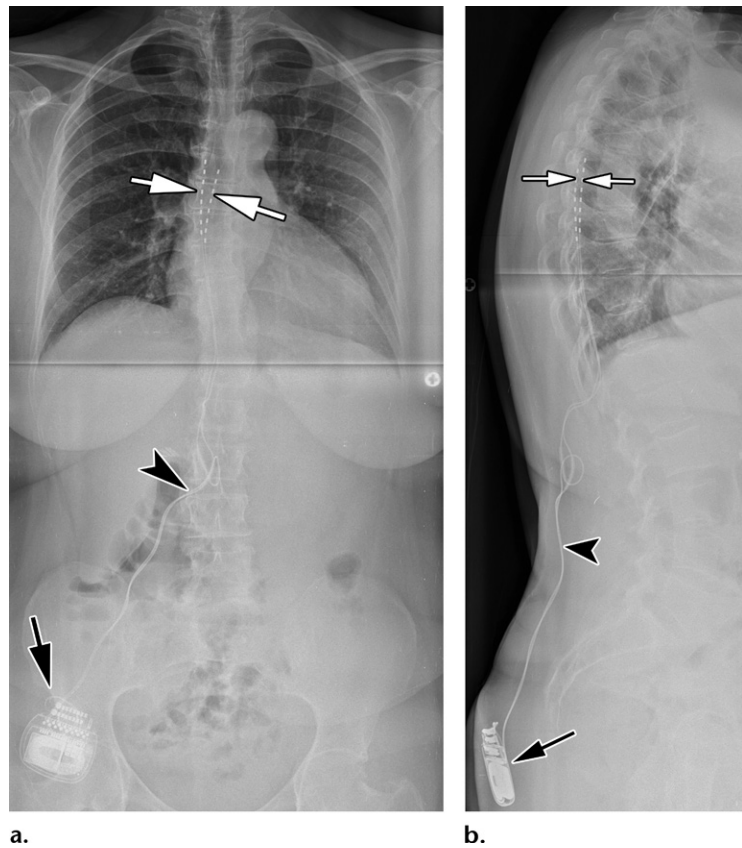


Figure 9. SCS device in a 48-year-old woman with intractable back pain despite undergoing maximal medical therapy. Frontal (**a**) and lateral (**b**) stitched radiographs of the chest, abdomen, and pelvis show a pulse generator (black arrow) in the right buttock region. The leads (arrowhead) ascend and enter the spinal canal at the T12-L1 level, and the electrodes (white arrows) are positioned with their cranial margin at T6.

location, usually in the flank, abdomen, upper buttock, or paraspinal region (Fig 9). Continuous leads should be depicted extending from the pulse generator into the posterior epidural space, where paddle or cylindrical electrodes are visualized at the lead tips. On the lateral view, the electrodes should be located in the posterior third of the spinal canal, adjacent to the dorsal columns (39). A posterior paramedian electrode location may be intentional if symptoms are unilateral (39).

SCS devices are available from multiple vendors, with many systems being MRI conditional. MRI conditional cylindrical and paddle electrodes are also available from multiple vendors (40). The documentation for the specific device and leads should be consulted to determine the MRI safety status.

Device-related Complications

The most common complications of SCS are related to device malfunction, which requires reprogramming, or lead and/or electrode displacement or breakage, which are best assessed at radiography rather than at CT (Fig 11) (39). Electrode migration is more common with percutaneously placed cylindrical electrodes but may also occur with surgically placed paddle electrodes (41).

The most common biologic (not related to the actual system components) complications are infection, fluid collection, or wound dehiscence

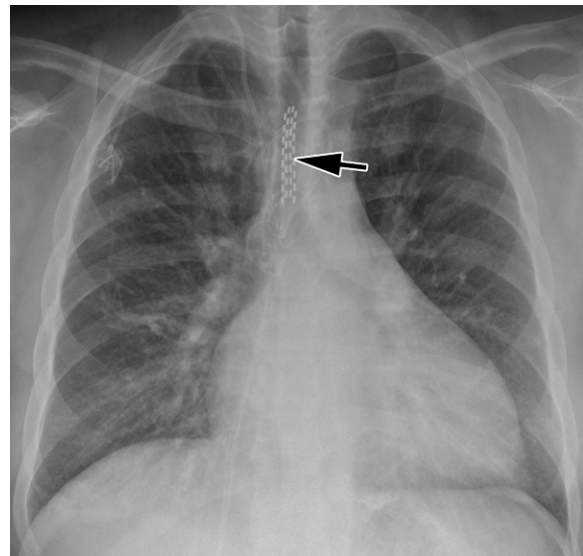


Figure 10. SCS device paddle electrode in a 48-year-old man. Frontal radiograph of the chest shows a paddle electrode (arrow), with the superior margin at T4.

(Fig 12) (42). Clinical information such as pain, purulent drainage, fever, and fluid aspiration will help in determining whether a fluid collection about the pulse generator or lead is due to a seroma, hematoma, or abscess.

Imaging can help assess the extent and depth of involvement. For example, if only the generator is involved, treatment by removing the generator,

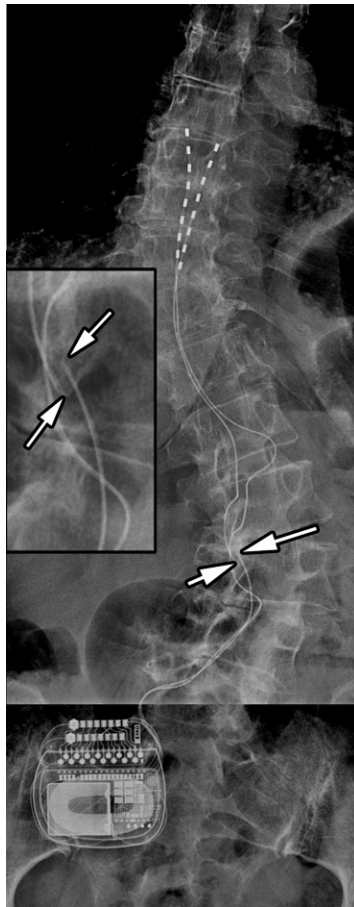


Figure 11. Broken SCS device lead in a 70-year-old woman with chronic low back pain. Frontal stitched radiograph and magnified image (inset) show a right-sided pulse generator and two eight-element electrodes, with tips at the T7-T8 level. The left lead (arrows) is broken at the L3 level. This lead was subsequently replaced.

administering antibiotics, and leaving the leads in place may be attempted (41). The most serious complications are uncommon. These include cerebrospinal fluid leak owing to accidental dural puncture during lead placement, traumatic neurologic injury during lead placement, and epidural hematoma or abscess. If severe pain, developing weakness, or paralysis manifest, the diagnosis of epidural abscess or hematoma should be considered. Performing CT or MRI (if the system is MRI conditional) is required for diagnosis (43,44).

Pacemakers and ICDs

Imaging of transvenous pacemakers and ICDs has previously been reviewed in the literature (45,46). Typical complications for these devices include pocket complications (including bleeding, infection, and erosion), lead and vascular complications (including lead infection and venous thrombosis), and cardiac complications (including lead perforation and tricuspid valve dysfunction). We focus on two more recently developed devices, the subcutaneous ICD and the leadless pacemaker.

Subcutaneous ICD

The subcutaneous ICD is indicated for the treatment of life-threatening tachyarrhythmias in patients who do not have symptomatic bradycardia

(ie, they do not also have a need for continuous pacing). There are many advantages of using this device over using other transvenous systems. As there are no intravascular or intracardiac components, complications such as bacteremia, endocarditis, venous injury or thrombosis, cardiac perforation, and tricuspid valve dysfunction have been eliminated for this device. Furthermore, as the lead is not subject to constant cardiac motion, lead longevity is expected to be longer than that of other systems.

A subcutaneous ICD system is available only from Boston Scientific (Emblem MRI S-ICD System) and was approved for use in Europe in 2009 and in the United States by the FDA in 2012 (47). The system has two components: the pulse generator and the subcutaneous lead-electrode (Fig 13). The relatively large pulse generator is implanted in the left midaxillary line at the fifth or sixth intercostal space and contains the battery, capacitors, and electronics. The subcutaneous lead is positioned vertically just to the left of the sternum and contains an 8-cm shocking coil, with sensing electrodes just proximal and distal to the coil. When a shockable arrhythmia is detected, the device delivers up to five 80-J shocks followed by 30 seconds of transthoracic pacing, if necessary (47).

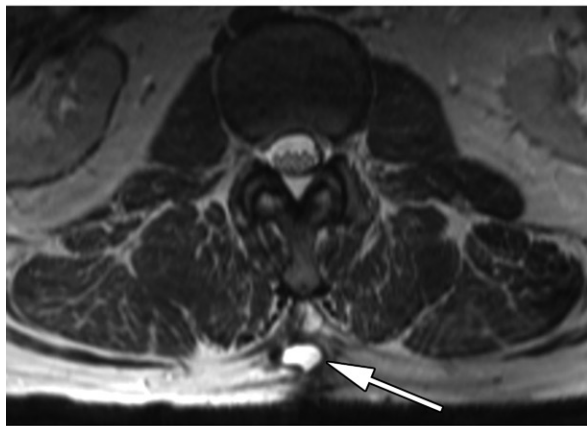
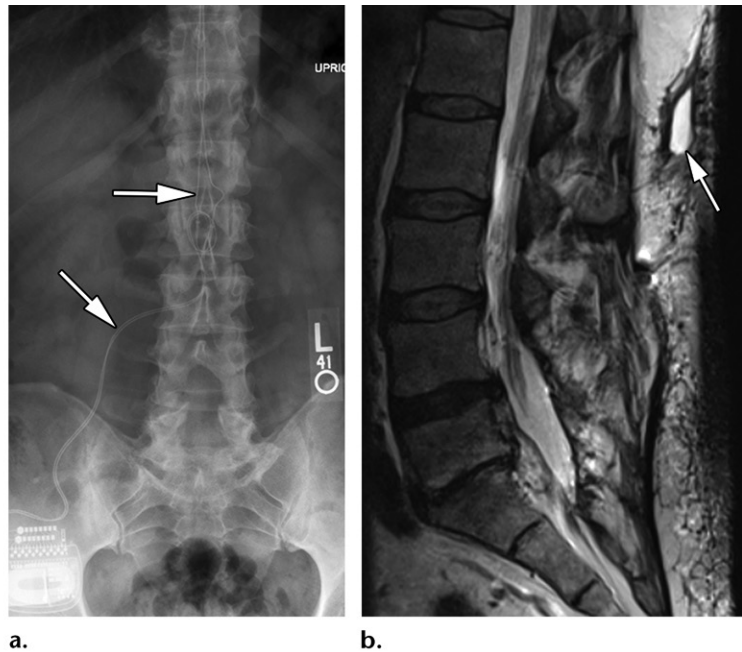
As the device is commonly placed using bone landmarks alone and without performing fluoroscopy, appropriate component positioning is verified at radiography following implantation. The lead should be continuous, running from the midaxillary pulse generator to the vertically oriented parasternal coil (Fig 13).

The Emblem system is MRI conditional at 1.5 T for whole-body applications. Most adverse events occur following device implantation and include pocket hematoma or infection (48). Device erosion is also a possible complication (48). Lead breakage has not been reported for this system, presumably because the lead is not under the constant stress of cardiac motion. Coil and/or electrode migration has been reported for the Emblem system and is diagnosed at radiography. However, even this complication has been greatly reduced with the inclusion of a suture sleeve at the proximal portion of the coil (47).

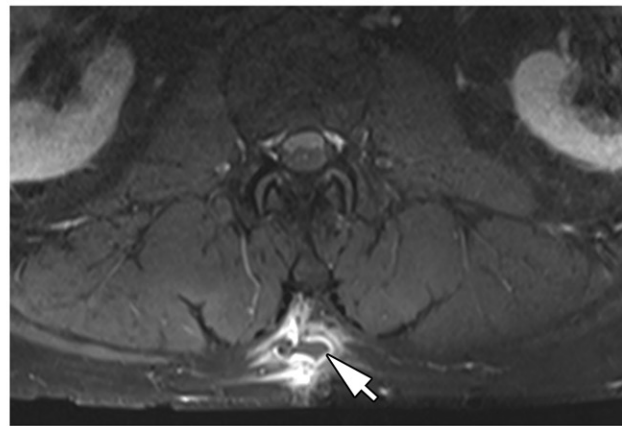
Leadless Pacemaker

Implantable pacemakers are devices used for treating sinoatrial node and conduction abnormalities such as symptomatic bradycardia and atrioventricular block (49). With advances in battery technology, wireless communication, and the miniaturization of electronics, leadless pacemakers have been developed in recent years to eliminate the need for a subcutaneous pulse generator

Figure 12. Abscess around the leads of an SCS device in a 48-year-old man. (a) Frontal radiograph of the lumbar spine shows a right-sided pulse generator, with leads (arrows) ascending along the midline. (b, c) Sagittal (b) and axial (c) T2-weighted MR images of the lumbar spine show a small subcutaneous fluid signal collection (arrow) at the L1-L2 level. (d) Axial fat-suppressed T1-weighted postcontrast MR image of the lumbar spine obtained at the L1-L2 level shows a rim-enhancing subcutaneous collection (arrow) involving the lead, a finding consistent with an abscess. The collection was drained, and the SCS system was removed.



c.



d.

or transvenous leads in patients who require only right ventricular pacing.

The Micra transcatheter pacing system (Medtronic) was approved in Europe in April 2015 and in the United States by the FDA in April 2016. The system has a volume of 0.8 mL and is anchored to the right ventricle myocardium with four nitinol tines (Fig 14).

The Nanostim Leadless Pacemaker System (Abbott/St Jude Medical) received approval in Europe in October 2013 but was removed from the market in October 2016 owing to battery malfunction (50). The Nanostim device has a smaller diameter than that of the Micra system (6.0 mm vs 6.7 mm, respectively) but has a larger volume at 1 mL (49). Boston Scientific is also currently developing a leadless pacemaker system, which will communicate and function with its subcutaneous ICD, discussed previously (51).

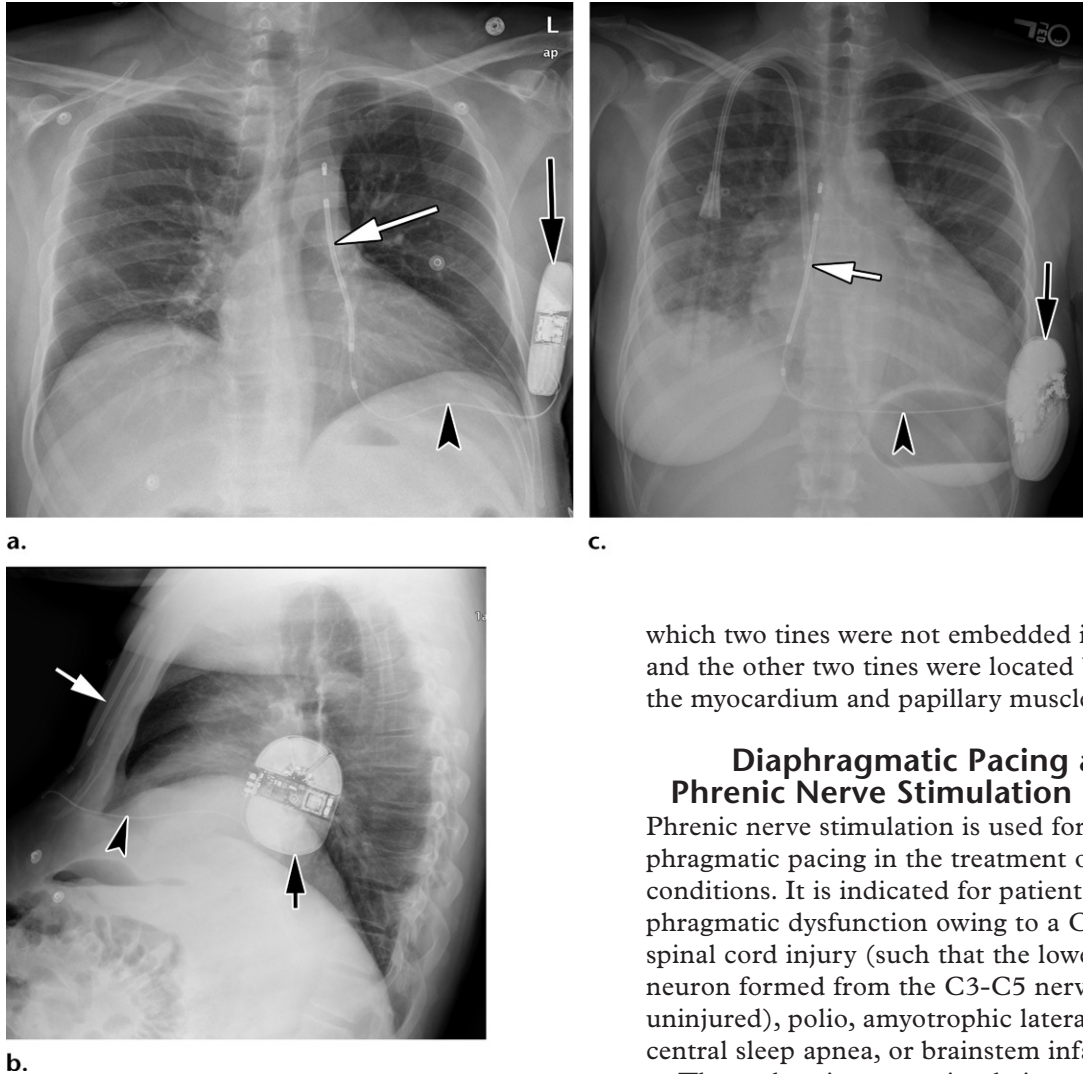
Leadless pacemakers are inserted under fluoroscopic guidance through the femoral vein,

inferior vena cava, and right atrium into the right ventricle. Because positioning is confirmed at fluoroscopy, performing routine radiography is not necessary. These devices are most commonly seen incidentally on chest radiographs obtained for other reasons.

Both the Micra and Nanostim systems have methods of safe retrieval (52). However, as each device has a volume of 1 mL or less, it may be left in place after being turned off, and a second (or third) device may be added (53). Therefore, it is possible for a patient to have more than one device in the right ventricle. The Micra device is FDA approved as MRI conditional at 1.5 T and 3 T (54).

Leadless pacemakers eliminate the potential for pocket site complications. There is no risk of long-term venous complications such as thrombosis, fibrosis, or infection, although risks related to vascular access remain for the implantation procedure itself (49). While

Figure 13. Subcutaneous ICD in two patients. (a, b) Subcutaneous ICD in a 54-year-old man who underwent removal of a prior transvenous ICD owing to infection. Frontal (a) and lateral (b) radiographs show the pulse generator (black arrow) of the Emblem MRI S-ICD system, located at the midaxillary line, with the electrode (white arrow) ascending along the left parasternal border. The connecting wire (arrowhead) is also depicted. (c) Subcutaneous ICD in a 24-year-old woman with nonischemic cardiomyopathy, cardiomegaly, and an ejection fraction of 20%. Frontal radiograph shows the coil (white arrow) located in the uncommon right parasternal position owing to unacceptable sensing along the left parasternal border. The pulse generator (black arrow) and connecting wire (arrowhead) are also depicted, and a dialysis catheter is present.



tricuspid regurgitation is not an issue, as there is no lead traversing the valve, the potential remains for complications related to the device being implanted in the right ventricular myocardium and remaining in the myocardium, such as thrombus formation (53). The rate of myocardial perforation is 1%–2%, and it may manifest with hemopericardium and rarely with tamponade, which is generally detected at echocardiography but can also be depicted on CT images (55).

Although radiography can theoretically be used to detect device dislodgement, this finding would be extremely unexpected. Only one case of local dislodgement without embolization has been reported with the Micra device, a case in

which two tines were not embedded in the tissue and the other two tines were located between the myocardium and papillary muscle (56).

Diaphragmatic Pacing and Phrenic Nerve Stimulation Devices

Phrenic nerve stimulation is used for diaphragmatic pacing in the treatment of multiple conditions. It is indicated for patients with diaphragmatic dysfunction owing to a C3 or higher spinal cord injury (such that the lower motor neuron formed from the C3–C5 nerve roots is uninjured), polio, amyotrophic lateral sclerosis, central sleep apnea, or brainstem infarction.

Three phrenic nerve stimulation systems are commercially available in the United States, and they each use different strategies to stimulate the phrenic nerve, which ultimately leads to diaphragmatic contraction.

For diaphragmatic pacing to be successful, the phrenic nerve must be intact, the diaphragm must be functional, and there must be adequate oxygenation across the alveoli (57). Diaphragmatic pacing has the advantage over mechanical ventilation of permitting greater independence, providing the ability to speak, and allowing decreased tracheostomy-related complications (although the patient may also require a tracheostomy when the device is not in use).

The three systems have major differences in implantation techniques and imaging appearances and are discussed separately.

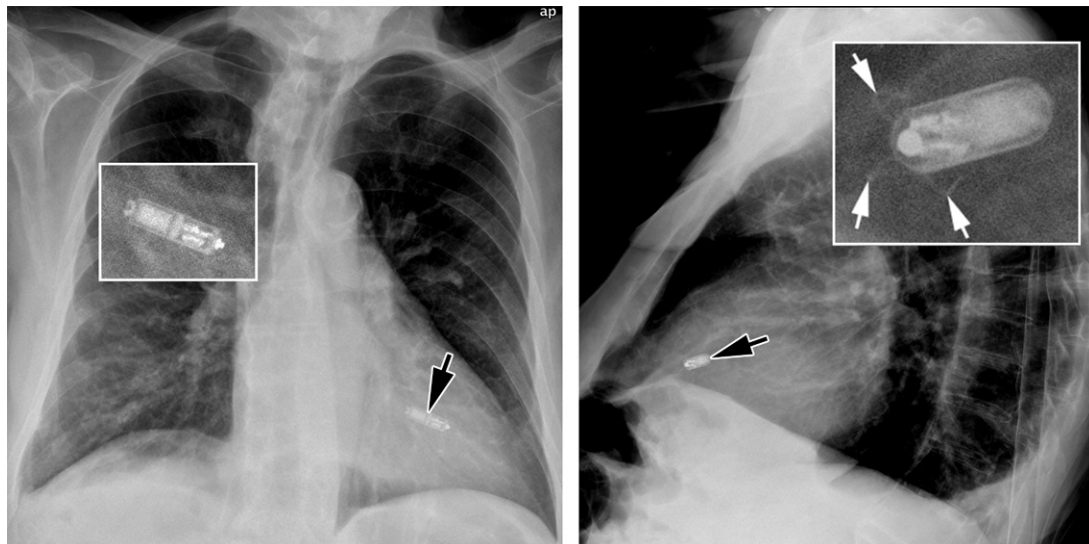


Figure 14. Micra leadless pacemaker in a 78-year-old man with atrial fibrillation, slow ventricular rate, and symptomatic bradycardia. Frontal (**a**) and lateral (**b**) radiographs of the chest with magnified views (insets) show the Micra device in the right ventricle (black arrow). The fixation tines (white arrows in inset in **b**) can be seen on the magnified view of the lateral radiograph.

Mark IV Breathing Pacemaker

The Mark IV Breathing Pacemaker (Avery Biomedical Devices, Commack, NY) received full FDA premarket approval in 1987 and is the most widely available system (57). The system is partially implanted and contains three internal components: electrodes, leads, and receivers (Fig 15). Electrodes are implanted on the phrenic nerves in the chest or in the neck. Cervical leads and electrodes can be placed in a single procedure, whereas thoracic leads and electrodes require separate procedures for each side, either by performing a video-assisted thoracoscopic surgery or an open thoracotomy. On the other hand, cervical electrodes have the disadvantage of requiring high current amplitude, which may stimulate the brachial plexus. In addition, constant neck movement may lead to phrenic nerve injury or lead breakage and/or migration.

Through the leads, the electrodes connect to subcutaneous radiofrequency receivers implanted in the chest or upper abdomen. An external controller sends signals to external antennae, which induce an electrical current through the skin within the underlying internal receivers. The receivers then transmit this current through the leads to the phrenic nerve electrodes, thereby stimulating the diaphragm to contract.

When the system is implanted using thoracoscopy, performing postoperative radiography is recommended to ensure that there is no pneumothorax (58). Performing radiography is also recommended before revision of the system to clearly identify the location of the internal components (58).

This system is MRI unsafe. The use of this device is rare, and there are no studies describing imaging findings during a system failure. When a system failure occurs, the manufacturer recommends testing the external system components individually and evaluating whether there is infection anywhere in the body that may have caused the pacing system to become ineffective. If this is unrevealing, damaged internal components should be considered (58). Performing radiography would be a good option to confirm that components are correctly positioned and not fractured.

NeuRx DPS system

The NeuRx Diaphragm Pacing System (Synapse Biomedical, Oberlin, Ohio) received FDA approval under a humanitarian device exemption in 2008 for the treatment of diaphragmatic paralysis in adult patients with high spinal cord injury and in 2011 for patients with amyotrophic lateral sclerosis (59).

The system consists of four electrodes that are laparoscopically implanted (ie, by an abdominal approach with no thoracic surgery required) directly into the diaphragm following identification of the motor points, where stimulation will cause maximal contraction of the diaphragm. The leads extend through the skin and connect to an external pulse generator. A chest radiograph should be obtained following lead insertion to determine whether the carbon dioxide used during laparoscopy has escaped into the chest during diaphragmatic lead placement (also known as capnothorax), which has been reported in 19%–42% of cases (60).

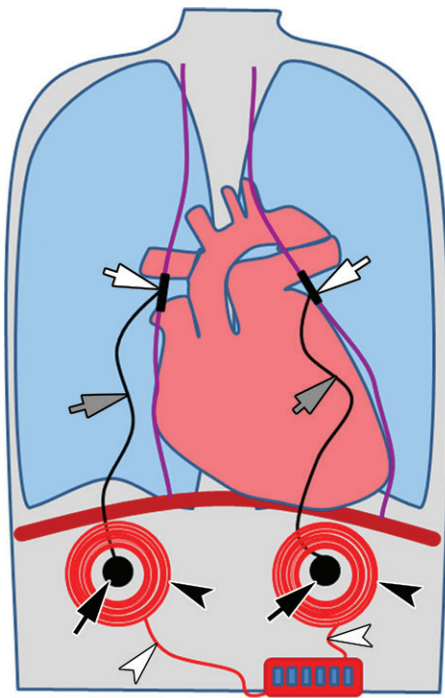
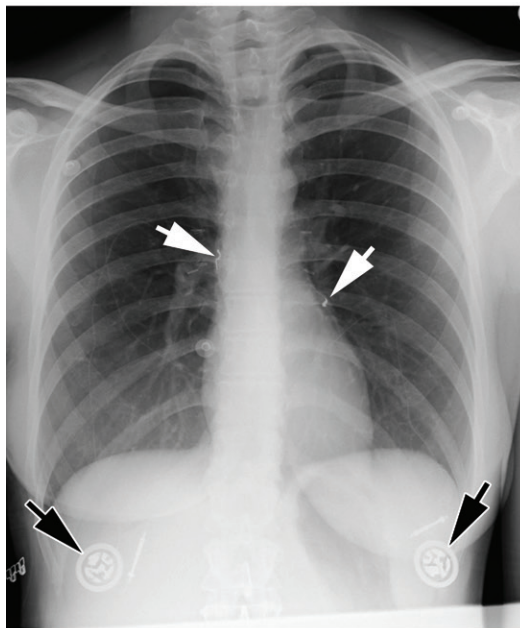
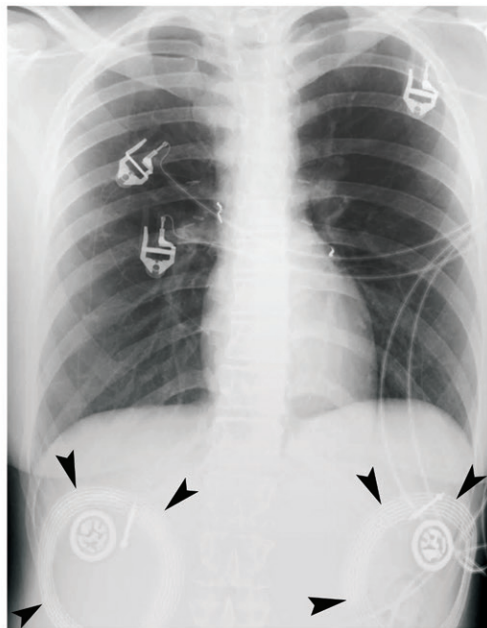


Figure 15. Avery Mark IV diaphragmatic pacemaker system. **(a)** Illustration of the components of the Avery Mark IV diaphragmatic pacemaker system show all of the implanted components in black and all external components in red. The phrenic nerves (purple) are contacted by electrodes (white arrows), which are connected to receivers (black arrows) through the leads (gray arrows). External antennas (black arrowheads) overlie the receivers and are connected to the transmitter by wires (white arrowheads). **(b)** Frontal radiograph of the chest shows implanted electrodes located adjacent to the phrenic nerves (white arrows) in a 23-year-old woman with central hypoventilation owing to chemoradiation treatment of medulloblastoma. The electrodes connect to subcutaneous radiofrequency receivers (black arrows) through the leads, which are difficult to visualize on radiographs. **(c)** Frontal radiograph of the chest in the same patient on a different date shows the circular external antennae (arrowheads) overlying the receivers.

a.



b.



c.

This system is MRI unsafe. Due to the rarity of this device, there are no reports on the use of imaging to diagnose complications. The wires traversing the anterior abdominal wall may provide an entry point for infection. Therefore, if there is concern for the presence of a subcutaneous or deep collection, performing US or CT would be prudent for evaluation.

Remede System

The Remede system (Respicardia, Minnetonka, Minn) is the newest diaphragmatic pacing system

and was FDA approved in 2017 to treat moderate to severe central sleep apnea (61). The system is completely implanted (as opposed to the two previously discussed systems, which have external components) and performs unilateral phrenic nerve stimulation, which generally results in bilateral diaphragm contraction.

The system contains three components, and it is commonly implanted by a cardiologist, as it contains pacemaker-like transvenous leads (Fig 16). The pulse generator lies in the pectoral region. A stimulation electrode is implanted

through the subclavian vein into the left pericardiophrenic vein and stimulates the adjacent left phrenic nerve through the wall of the vein. Respiratory sensing is performed with a second electrode located in the azygos vein or through the stimulation electrode.

Because the leads are placed using fluoroscopic guidance, there is no need to perform radiography to determine correct lead placement. An upright chest radiograph may be obtained to rule out pneumothorax. This system is MRI unsafe.

As this device has been on the market for only a short time, there are no reports of imaging aiding in the diagnosis of device complications. The electrodes and leads are well depicted on radiographs, and migration or breakage can be diagnosed at radiography.

Gastric Electrical Stimulation Devices

Gastric pacemakers are used in the treatment of gastroparesis and obesity. In the treatment of gastroparesis, the device applies low-energy high-frequency cycles of short pulses to the stomach. The exact mechanism of action remains unclear, as symptom improvement does not correlate with gastric emptying parameters. Currently, on the basis of findings depicted at PET imaging, it is thought that the device acts on deep gray nuclei through the vagal afferent and efferent pathways to decrease the sensation of nausea.

In the treatment of obesity, vagal blockade by a stimulation device would theoretically have the same advantages as those of vagotomy for delayed gastric emptying, early satiety, and reduced hunger, without the adaptation that occurs following surgical vagotomy (62).

The Enterra system (Medtronic) is used for the treatment of gastroparesis and was approved by the FDA under a humanitarian device exemption in 2000. The Maestro RC vagal blocking system (EnteroMedics, St. Paul, Minn) for obesity control was approved by the FDA in 2015 for the treatment of obesity in patients with a body mass index (BMI) between 40 and 45 kg/m² or in patients with a BMI between 35 and 39.9 kg/m² who also have a related health condition (eg, hypertension or hypercholesterolemia) (63).

In both systems, the electrodes are implanted at laparotomy or laparoscopy, and the pulse generator is generally placed subcutaneously in the right upper quadrant. In the Enterra system, two electrodes are implanted on the greater curvature of the stomach, 10 cm from the pylorus in the region of the intrinsic gastric pacemaker (Fig 17) (64). Upper endoscopy is performed intraoperatively to ensure that the electrodes have not perforated the stomach. In the Maestro system, electrodes

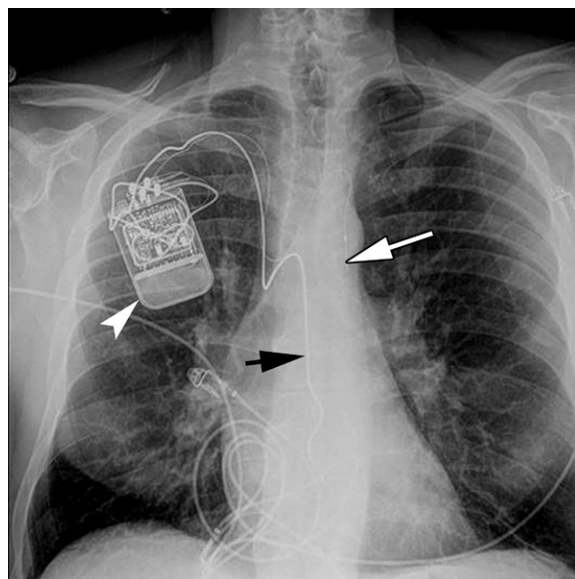


Figure 16. Remede system. Frontal radiograph of the chest shows the pulse generator (arrowhead) in the right pectoral region. The stimulation electrode (white arrow) extends into the left pericardiophrenic vein through the right subclavian vein, right brachiocephalic vein, and left brachiocephalic vein. The sensing lead (black arrow) extends into the azygos vein. (Case courtesy of Respicardia).

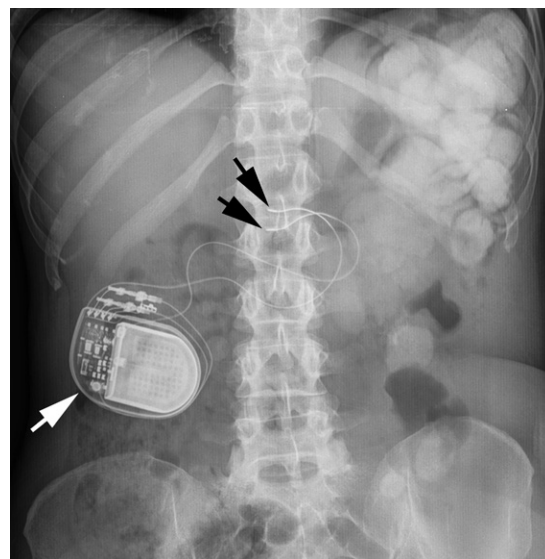


Figure 17. Enterra system in a 35-year-old woman with type 1 diabetes mellitus and gastroparesis. Frontal abdominal radiograph shows a subcutaneous pulse generator (white arrow) in the right abdomen. Two electrodes (black arrows) project over the distal stomach in the expected location of the intrinsic gastric pacemaker.

are placed around the anterior and posterior vagus nerves at the esophagogastric junction.

Imaging of Gastric Electrical Stimulation Devices

Routine abdominal radiography should be performed postprocedure to document correct placement (65). Two leads should be depicted ex-

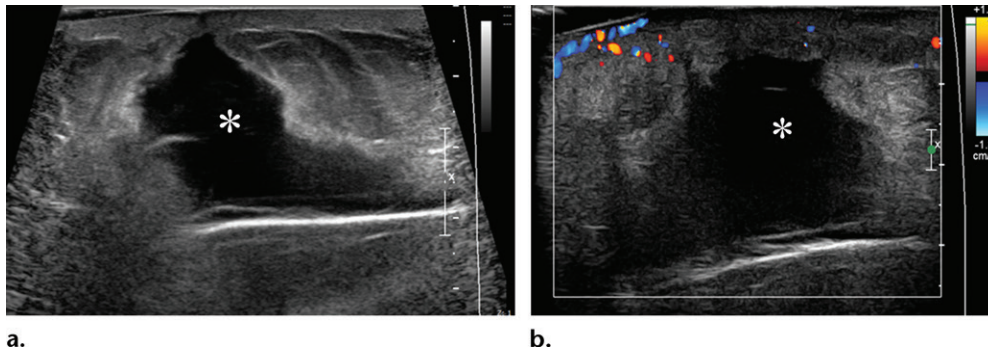


Figure 18. Fluid collection around a gastric pacemaker in a 44-year-old woman with a history of gastroparesis. Two weeks after implantation, the patient had erythema and drainage at the surgical site. Gray-scale (**a**) and color Doppler (**b**) US images show a subcutaneous fluid collection (*) superficial to the pulse generator. A seroma was the favored diagnosis owing to the lack of hyperemia. Antibiotics were still administered empirically, but the fluid was not drained. The patient's symptoms resolved.

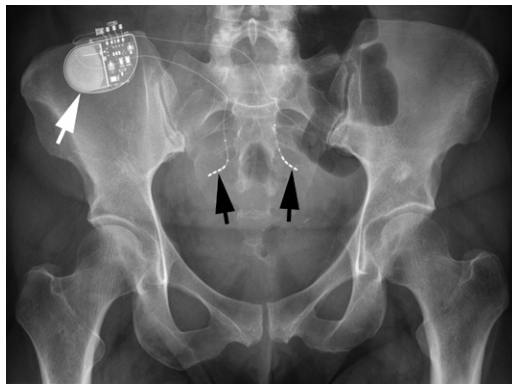


Figure 19. InterStim system implanted in a 37-year-old woman for fecal incontinence. Frontal radiograph of the pelvis shows an InterStim pulse generator (white arrow) overlying the right buttock, with electrodes (black arrows) extending through each S3 foramen.

tending to the expected location of the proximal stomach or esophagogastric junction. Both the Enterra and Maestro systems are MRI unsafe.

Complications of the Enterra device that may be diagnosed at imaging include pocket complications (pocket infection, pocket erosion, and generator movement), electrode perforation, small-bowel obstruction, and incisional hernia (Fig 18) (66). The imaging findings of small-bowel obstruction and incisional hernia would be similar to the findings from other causes (eg, dilated fluid-filled loops of bowel and protruding bowel loops, respectively) (67). Electrode perforation may not manifest with free air and may be occult on radiographs or CT images. The diagnosis may be made on clinical grounds when the electrode perforates through the gastric wall and loses contact with the gastric surface, thereby altering the system's impedance (65). Because of the shorter time that the Maestro device has been on the market, there are fewer experiences with, and therefore fewer reports of complications for, the Maestro device than the Enterra device.

SNS Devices

SNS or sacral neuromodulation is used to treat symptoms related to voiding and defecation. There also have been case reports of SNS for the treatment of pelvic pain syndromes such as pudendal neuralgia (68). SNS with the InterStim system (Medtronic) was FDA approved in 1997 for urge incontinence, in 1999 for urinary retention and urinary frequency, and in 2011 for the treatment of chronic fecal incontinence (69). A new smaller Interstim II device (Medtronic) has since become available on the market. A rechargeable SNS device is manufactured by Axonics (Irvine, Calif); however, it is not FDA approved in the United States.

System placement is completed in two phases, beginning with electrode placement under fluoroscopic guidance. CT-guided placement has also been reported (70). During the test phase, a temporary lead and electrode with an external pulse generator is left in place for 1–2 weeks, during which the efficacy is assessed by the patient who keeps a diary to document symptoms. Patients with urinary retention symptoms may require a longer test period. If the patient experiences symptom improvement, the temporary system is removed and a permanent lead-electrode and implanted subcutaneous pulse generator are placed in the lower back or buttocks.

As the electrode(s) are placed using imaging guidance, correct positioning is confirmed during the procedure and additional radiography is not required. SNS system components are well depicted on radiographs. The system includes an electrode threaded through the S3 neural foramen, a subcutaneous pulse generator, and an external programmer unit (Fig 19). Interestingly, the exact depth and angle of the Interstim electrode at follow-up radiography do not correlate with SNS response.

The InterStim II Model 3058 and certain InterStim Model 3023 devices are MRI conditional

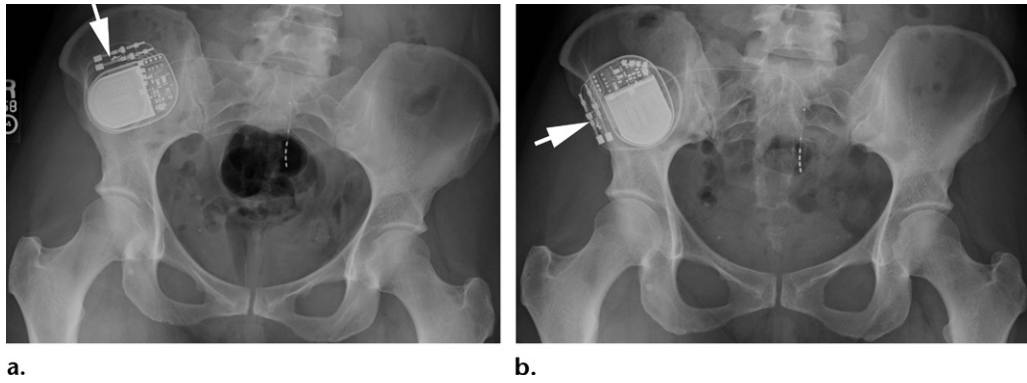


Figure 20. Unilateral InterStim system in a 42-year-old woman with urinary incontinence. **(a)** Initial radiograph shows the lead connectors (arrow) oriented superiorly. **(b)** Follow-up lateral radiograph obtained 2 months later shows that the connectors (arrow) are directed to the right. Although the electrode position was unchanged, the pulse generator rotation may indicate a loose pocket or twiddling, in which the patient consciously or subconsciously spins the generator in a capacious pocket and may cause lead retraction. The device was repositioned by the clinician and placement was confirmed at radiography (not shown).

for head MRI only at 1.5 T. Device-specific MRI guidelines for each device can be obtained from the manufacturer's website. In patients with MR-unsafe devices or with conditional devices who require MRI of body parts aside from the head, the device will have to be removed. In one study, this was done for some patients, with only 10% ultimately undergoing reimplantation (71).

In a survey of 207 patients with sacral neuromodulation for bowel and/or bladder complaints, satisfaction ratings were 90% (72). Still, the reported complication rate is relatively high, particularly in older studies (73). Among 120 patients with an InterStim device for fecal incontinence, the infection rate was 11%, with 69% of those cases occurring within 1 month following implantation (74). Imaging-detectable complications include infection, migration, and lead breakage (Fig 20). Infection, including deep infection, is well depicted on CT and MR images (75). Lead breakage and migration can be detected at radiography.

Conclusion

Electronic stimulation devices are becoming extremely common as a mode of treatment in patients who have certain diseases that are refractory to medical therapy. As these devices become more common and more sophisticated, the radiologist will be called on to identify these devices and detect causes of failure or complications. By understanding the purpose, expected location, and potential modes of failure of these devices, the radiologist will best be able to participate in the care of these patients.

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