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Minimum Incision Size Required for Implantation: A Comparison of Medtronic InterStim X™ and Axonics F15® Pulse Generator Dimensions

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ABSTRACT

Background: Sacral neuromodulation (SNM) is a guideline-recommended therapy for a variety of bladder and bowel dysfunctions. This study compares the physical dimensions of two SNM implantable pulse generators—Medtronic's InterStim X and Axonics's F15—and examines the potential clinical implications.

Methods: We extracted height, length, thickness, and weight data from manufacturer specifications and interpreted these in the context of the SNM surgical technique.

Results: Our analysis showed that the devices are similar in overall size (InterStim X: 44 × 51 × 8 mm, 22 g, ~12.5 cc; Axonics F15: 39 × 53 × 6.7 mm, 24.5 g, ~10 cc). Despite these similarities, other metrics can affect the minimum incision size required for implantation.

Conclusion: Overall, the two devices have comparable dimensions; however, InterStim X requires a smaller incision size for implantation than the Axonics F15.

***Keywords*:** Axonics F15; Device dimensions; Implantable pulse generator; InterStim X; Minimum incision size required for implantation; Sacral neuromodulation; Surgical technique

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INTRODUCTION

Sacral neuromodulation (SNM) is an established therapeutic approach for managing refractory voiding dysfunction and bowel control disorders. Currently, SNM is a recommended therapy for urinary urgency incontinence, urinary urgency and frequency, non-obstructive urinary retention, and fecal incontinence. While the exact mechanism of action is unknown, SNM is believed to work through local reflex pathways and higher brain centers involved in bladder and bowel control.

Three pathways have been suggested as reasonable mechanisms by which SNM may exert its effects: (i) spinal reflex pathways that inhibit detrusor muscle overactivity, (ii) supraspinal regions that normalize bladder function, and (iii) direct and indirect effects on the urethral sphincter. The spinal reflex pathway and supraspinal regions of the brain are thought to play primary roles in this process. The spinal reflex pathway is believed to act through inhibitory signals from somatic afferent nerves, particularly via the pudendal nerve, on efferent activity targeting the bladder.[1,2] Thus, SNM may stimulate this reflexive inhibitory afferent pathway, thereby treating the underlying dysfunction. While stimulation of this pathway remains a plausible mechanism, normalizing communication between the sacral spinal roots and supraspinal regions in the brain may restore physiological function. Abnormal brain activity contributing to pelvic floor dysfunction has been identified, and the restorative impact of SNM in reestablishing proper brain activity responsible for functional homeostasis has been demonstrated.[3] The third proposed pathway involves sympathetic activation to promote relaxation of dysfunctional organ systems. SNM may stimulate afferent pathways traveling to the central nervous system, where subsequent sympathetic motor neuron output leads to organ relaxation.[4]

Since its early approval in the United States in 1997, SNM therapy has evolved to allow for less invasive approaches in surgical candidates. Patients typically undergo an initial test procedure to determine whether they will respond to treatment. The test phase involves either a temporary lead placement (Percutaneous Nerve Evaluation) or a Stage 1 procedure, during which a tined lead is inserted along the S3 sacral nerve root, typically under fluoroscopic guidance. During the test period, patients receive nerve stimulation for 3–14 days using an external pulse generator.[5] If satisfactory improvement is observed, an implantable pulse generator (IPG) is placed in the lateral upper buttock (**Figure 1**).

For pocket creation, the site is identified below the iliac crest and lateral to the sacrum. After administration of a local anesthetic, an incision is made into the subcutaneous tissue. Blunt dissection is then used to create the pocket, and hemostasis must be achieved before inserting the IPG. Once inserted, the lead is brought to the IPG using a tunneling tool and secured to the device.

Medtronic (United States) and Axonics (United States) remain the major manufacturers providing SNM therapy systems. Medtronic's InterStim system was the first SNM therapy available, with its latest iteration, the recharge-free InterStim X™, approved in early 2022. Similarly, Axonics introduced the F15®, also approved in 2022, designed to address comparable clinical indications.

Electrical stimulation may be delivered using constant voltage (CV) or constant current (CC). In CV systems, the programmed voltage remains fixed, and the resulting current varies in response to impedance changes. In CC systems, when impedance changes, the device automatically adjusts the voltage so that current remains constant. CC systems may require less programming over time as electrode impedance fluctuates. Both InterStim X and Axonics F15 deliver energy using CC.

Despite their shared purpose and similar efficacy, these devices exhibit subtle variations in design, size, and form. To explore these distinctions, we

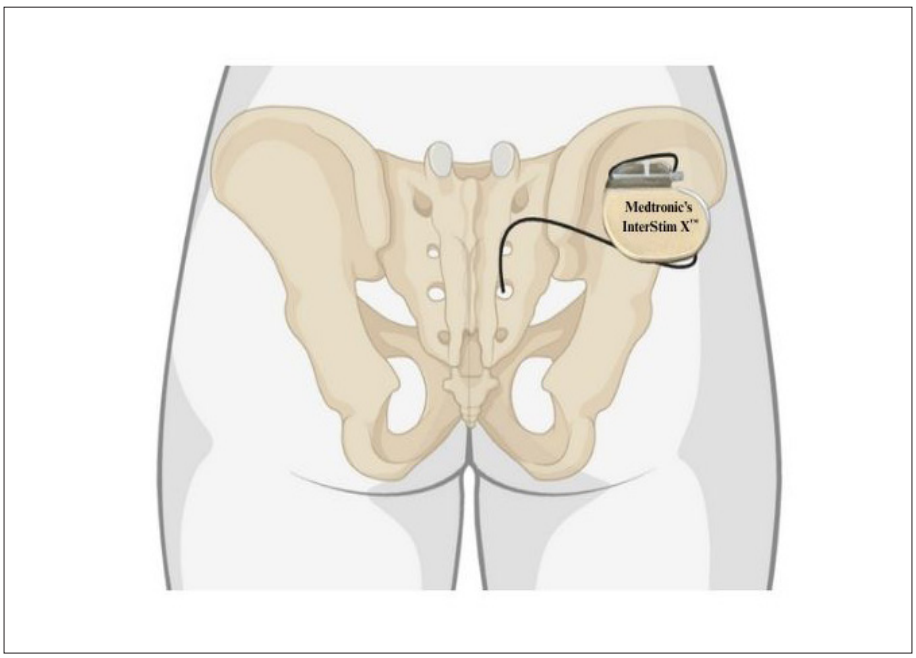

Figure 1. Medtronic's InterStim X™ implantable pulse generator and the quadripolar lead inserted at the S3 foramen. This figure is the authors' original work.

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conducted a comprehensive comparison of the specifications of the InterStim X and Axonics F15 systems, including their impact on the minimum incision size required for implantation (MISRFI). Furthermore, we reviewed surgical techniques and related clinical literature to provide context for our findings.[1,6]

METHODS

Manufacturer product literature and regulatory filings were reviewed to obtain the physical specifications of each IPG, including device height, length, thickness, and weight. **Table 1** presents the dimensions used in our assessment. These data were obtained from the manufacturers' official implant manuals.[7,8]

Figure 2 compares the width and length of each IPG device (A to B = Length and C to D = Width). Additional metrics relevant to implantation are also shown (points E to F). While **Table 1** displays comparable measurements for both IPG devices, our described technique introduces an additional metric that can affect the MISRFI (the E to F measurement). The distance between points E and F determines the MISRFI in the described technique.

We describe the following maneuvers for implantation (**Figure 3**):

i. After identifying the IPG pocket, the MISRFI is marked, and local anesthetic is administered (**Figure 3A**).

ii. An incision is made with a scalpel and carried through to the underlying subcutaneous tissue using a Bovie. At a depth of 1–2 cm, the pocket is created using blunt dissection, with the Bovie applied for hemostasis.

iii. The pocket is irrigated with an antibiotic or antiseptic solution, and hemostasis is optimized using cautery.

iv. With careful attention to avoid damage to the lead, the IPG is introduced into the incision with the plastic portion leading (**Figure 3B**).

v. Clockwise rotation of the device is performed (**Figure 3C**); the distance measured between points E and F (**Figure 2**) determines the MISRFI. The remainder of the device is then passed through the incision into the bluntly created pocket (**Figure 3D**).

vi. Counterclockwise rotation of the device is performed to achieve the final desired position.

vii. The incision is closed using absorbable sutures, followed by application of surgical glue (**Figure 3E**).

Table 1. Comparison of Medtronic's InterStim X™ and Axonics F15® pulse generator metrics

Brand	Device	Height (mm)	Length (mm)	Thickness (mm)	Weight (g)	Length of E to F (mm)	Length of E to F' (mm)	Length of E to F" (mm)
Medtronic	InterStim X™	44	51	7.7	22	35	34	33
Axonics	Axonics F15®	39	53	6.7	24.5	42	41	40

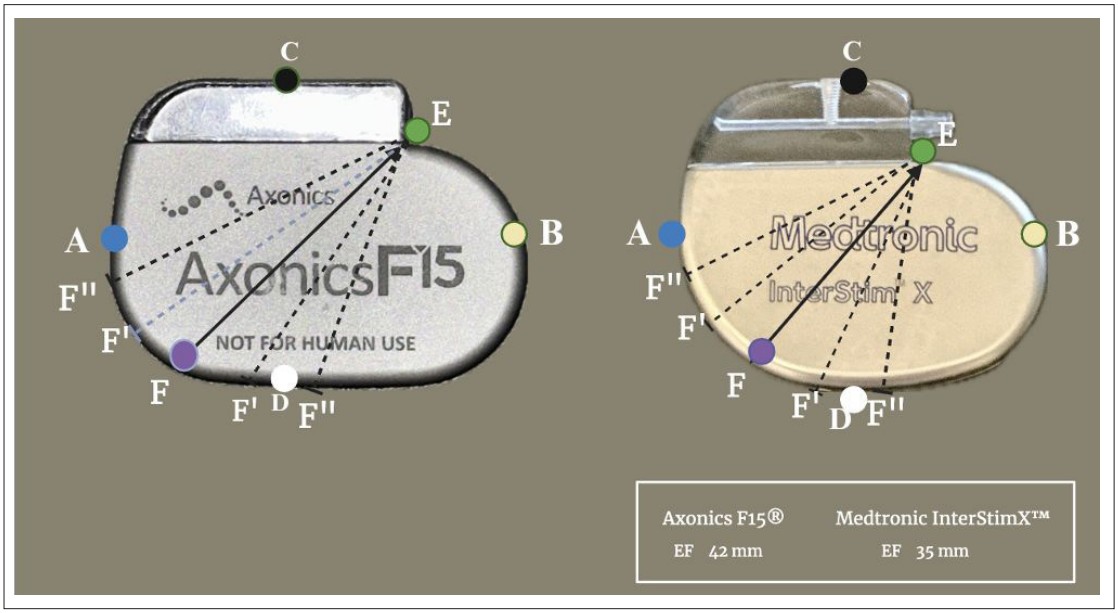

Figure 2. Comparative visualization of the Medtronic InterStim X™ and Axonics F15® sacral neuromodulation devices with labeled measurement points: points in blue to yellow (A to B) indicate length; points in black to white (C to D) indicate width; point E is highlighted in green; point F is highlighted in purple; points F' and F" are indicated with dotted lines to demonstrate additional measurement positions, illustrating that E to F is the longest measurement in that dimension. This figure is the authors' original work.

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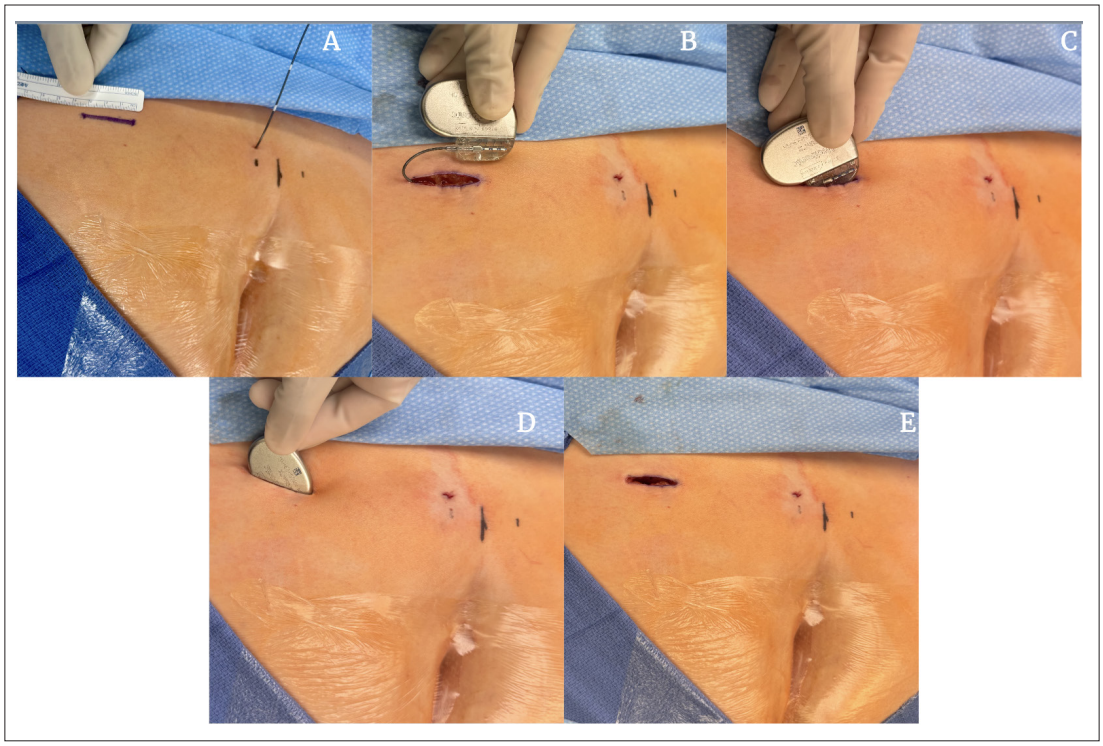

Figure 3. Illustration of key procedural steps in sacral neuromodulator device implantation, including surgical incision and pocket formation, insertion and positioning of the implantable pulse generator through controlled rotational movements, and final closure of the surgical site. These figures are the authors' original work.

RESULTS

Table 1 compares the physical specifications of the sacral neuromodulator devices. The InterStim X measures approximately 44 × 51 × 8 mm (height × length × thickness) and weighs 22 g. The F15 measures approximately 39 × 53 × 6.7 mm and weighs 24.5 g. In terms of volume, the devices measure approximately 12.5 and 10 cc, respectively.[7,8] From point E, starting at the neurostimulator connector (shown in **Figure 1**), to point F, the InterStim X measures 35 mm diagonally, whereas the F15 measures 42 mm. Overall, the two devices have similar dimensions; however, Medtronic's InterStim X requires a smaller incision size for implantation than Axonics's F15 and thus a smaller MISRFI.

DISCUSSION

In this comparison, the Medtronic InterStim X and Axonics F15 devices are nearly identical in size, with only minor dimensional differences. The Axonics F15 IPG is slightly shorter and thinner, while the Medtronic InterStim X IPG is marginally longer and thicker. These variations result in a modest volume advantage for the Axonics device (~10 vs. ~12.5 cc).[7,8] Despite these differences, both IPGs are designed for placement within small subcutaneous pockets. Clinically, SNM devices are typically implanted through a small incision in the upper lateral buttock, with an additional incision over the sacral foramen for proper lead placement.[1] Given their similarity, device choice is often guided more by factors such as battery life, patient-specific anatomy, and surgeon preference than size alone.

Although slight, these dimensional differences can influence surgical implantation techniques. For example, a thinner profile may allow for a smaller subcutaneous pocket or reduced tension on the overlying tissue, thus improving patient comfort and reducing the risk of skin erosion. However, the lack of robust clinical data linking these size differences to clinical outcomes makes such effects speculative.

Surgical site infection, wound dehiscence, blood loss, postoperative pain, and incisional paresthesia are important clinical considerations when evaluating the impact of incision size and device selection. Smaller incisions and less tissue dissection typically result in reduced pain, faster recovery, more desirable cosmetic outcomes, and improved overall patient satisfaction.

Infection also remains a significant complication of SNM. Recent studies have reported infection rates ranging from 2% to 12% following Stage I and II procedures.[6] Carbone et al.[9] emphasized the importance of infection-prevention strategies, including perioperative antibiotic prophylaxis, stringent skin preparation, and the use of sterile technique. Ensuring stable lead placement and creating a well-fitted subcutaneous pocket for the IPG device housing are crucial to reducing risks such as lead migration and device-related infections.

Although there is a lack of literature demonstrating the clinical significance of incision size differences for these implantable devices, surgeons consistently strive to minimize incision size. While both SNM devices are designed for implantation through relatively small incisions, minor dimensional differences could affect the ease of device insertion and pocket creation.

While both the InterStim X and F15 are suited for small-incision implantation, the Axonics F15's slightly thinner profile might contribute to reduced tis-

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sue tension during pocket formation. At the same time, the InterStim X requires a smaller incision for implantation. However, these potential benefits remain theoretical and require further investigation in clinical studies.

CONCLUSION

The Medtronic InterStim X and Axonics F15 IPGs exhibit comparable dimensions and weights, with minor variations in height and thickness. Based on our analysis, the Medtronic InterStim X requires a smaller minimum incision size compared to the Axonics F15.

When designing implantable devices, manufacturers should consider metrics that enable surgeons to create the smallest incision possible. Despite a lack of strong evidence showing their benefits, smaller incisions may be preferred to minimize postoperative pain, incision-related paresthesia, surgical site infection, and wound dehiscence, to reduce the amount of suture material required for closure, and to improve cosmesis and overall patient satisfaction. Surgeons should apply techniques to optimize the MISRFI.

AUTHORS' DISCLOSURE

The authors declare no conflicts of interest related to this work. No external funding was received for this comparative analysis. The study was reviewed by the Institutional Review Board at Marchand Institute for Minimally Invasive Surgery and was determined to be exempted from formal IRB oversight (May 2025). As this work consists solely of a comparative analysis of publicly available manufacturer specifications and previously published literature, with no human subjects or patient-specific data involved, the requirement for informed consent was waived. (EXEM052025-008). Additionally, patient consent was not obtained as the images in **Figure 3** were only intended to demonstrate the implantation of the devices as opposed to explaining a disease or condition. Data generated during this study are available within the manuscript.

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