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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MEDTRONIC, INC.; MEDTRONIC PUERTO RICO OPERATIONS CO.; MEDTRONIC LOGISTICS, LLC; MEDTRONIC USA, INC.,

Plaintiffs,

v.

AXONICS MODULATION TECHNOLOGIES, INC.,

Defendant.

Case No. 8:19-cv-2115

COMPLAINT FOR PATENT INFRINGEMENT

JURY TRIAL DEMANDED

Plaintiffs Medtronic, Inc., Medtronic Puerto Rico Operations Co. ("MPROC"), Medtronic Logistics, LLC ("Medtronic Logistics"), Medtronic USA, Inc. ("MDT USA") (individually and collectively "Medtronic" or "Plaintiffs") bring this Complaint against Defendant Axonics Modulation Technologies, Inc., alleging as follows:

THE PARTIES

1. Plaintiff Medtronic, Inc. is a Minnesota corporation having its principal place of business located at 710 Medtronic Parkway, Minneapolis, MN 55432.

2. Plaintiff MPROC is a Cayman Islands corporation, having its principal place of business located at Ceiba Norte Industrial Park, 50 Road 31, Km. 24.4, Juncos, Puerto Rico 00777-3869.

3. Plaintiff Medtronic Logistics is a Minnesota corporation having its principal place of business located at 710 Medtronic Parkway, Minneapolis, MN 55432.

4. Plaintiff MDT USA is a Minnesota corporation having its principal place of business located at 710 Medtronic Parkway, Minneapolis, MN 55432.

5. Defendant Axonics Modulation Technologies, Inc. ("Axonics" or "Defendant") is a Delaware corporation having its principal place of business located at 26 Technology Dr., Irvine, CA 92618.

JURISDICTION AND VENUE

6. This is a civil action for patent infringement under 35 U.S.C. § 271 *et seq*.

7. This Court has subject matter jurisdiction over this action under the laws of the United States, 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has general personal jurisdiction over Axonics because Axonics is engaged in substantial and not isolated activity at its regular and established places of business within this judicial district. This Court has specific jurisdiction over Axonics because Axonics has committed acts giving rise to this

action and has established more than minimum contacts within this judicial district, such that the exercise of jurisdiction over Axonics in this Court would not offend traditional notions of fair play and substantial justice.

9. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b)-(c) and 1400(b) because Axonics maintains regular and establish places of business and has committed acts of patent infringement within this judicial district.

FACTUAL BACKGROUND

Medtronic's Background

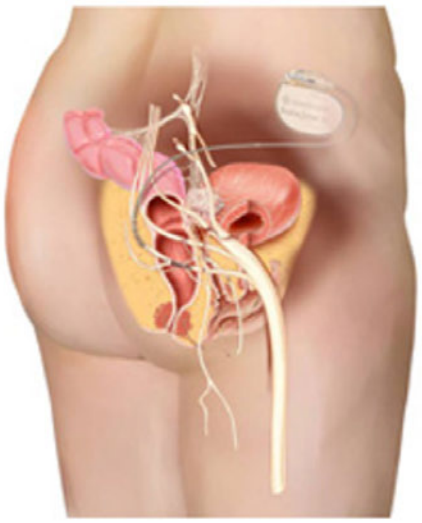
10. Medtronic is one of the world's largest medical technology, services, and solutions companies with the focus of alleviating pain, restoring health, and extending life for millions of people around the world. In 2018, Medtronic was winner of the prestigious USPTO Patents for Humanity award. Martin T. Gerber, an inventor on the patents-in-suit, is named on a series of patents for which Medtronic was presented this award.

11. Among its areas of specialty, Medtronic provides products and services in the area of pelvic health. Pelvic floor disorders adversely affect the health and quality of life of millions of people. Pelvic floor disorders include urinary control disorders such as overactive bladder, fecal control disorders, sexual dysfunction, and pelvic pain. Pelvic floor disorders can be treated with a variety of therapeutic options, including surgical intervention.

12. Medtronic is the pioneer and leading provider of neuromodulation solutions for bladder and bowel control issues. The Medtronic InterStim system for bladder control and bowel control helps to control symptoms of overactive bladder, non-obstructive urinary retention, and chronic fecal incontinence through direct modulation of the nerve activity. The InterStim system electrically stimulates the sacral nerves, which aims to normalize neural communication between the bladder and brain, and between the bowel and brain.

13. Generally, implantation of InterStim therapy involves surgically

implanting a stimulation lead near the sacral nerves. The stimulation lead is a very small, insulated electrical conductor with electrical stimulation contacts on the distal end placed near the sacral nerves, and an electrical connector on the opposite proximal end of the lead. The stimulation lead is connected to an implantable neurostimulator that delivers small electrical pulses for stimulation of the sacral nerves. InterStim therapy can improve the condition of a pelvic floor disorder and allow a patient to lead a full life. The image below shows an example of the implantation of an InterStim device.[1]



14. Examples of Medtronic InterStim products include the InterStim and InterStim II neurostimulators. In October 2019, Medtronic filed a pre-market approval (PMA) supplement with the FDA for approval of its InterStim Micro neurostimulator (a rechargeable, implantable sacral neuromodulation device) and InterStim SureScan MRI leads, which will be used in implants of the recharge-free InterStim II system and rechargeable InterStim Micro system, pending FDA approval. The image below shows an example of the Medtronic InterStim II and InterStim Micro devices.

[1] https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/urology/sacral-neuromodulation/education-training/about-the-therapy.html.

Accused Products and Activities

15. Upon information and belief, Axonics is a medical technology company that provides sacral neuromodulation solutions.[2] Upon information and belief, Axonics began working on a rechargeable Sacral Neuromodulation ("SNM") System ("r-SNM") ("Axonics r-SNM System"), and obtained regulatory approval in Europe and Canada for the first time in 2016.[3]

16. On September 9, 2019, Axonics announced that the Axonics r-SNM System had been approved by the FDA, granting Axonics the right to market the Axonics r-SNM System in the United States for the clinical indication of fecal incontinence.

17. As of the date of this Complaint, Axonics does not have approval from the FDA to market the Axonics r-SNM System in the United States for any other clinical indication, including the clinical indications of overactive bladder and urinary retention.

18. The Axonics r-SNM System includes various components, such as the Model 1101 neurostimulator, Model 1201 tined lead, Model 1801 lead implant kit, Model 1401 charging system, Model 1301 patient remote control, Model 1501 clinician programmer, and external trial system. The image below from the FDA website, shows an example of the components for Axonics' r-SNM System.[4]

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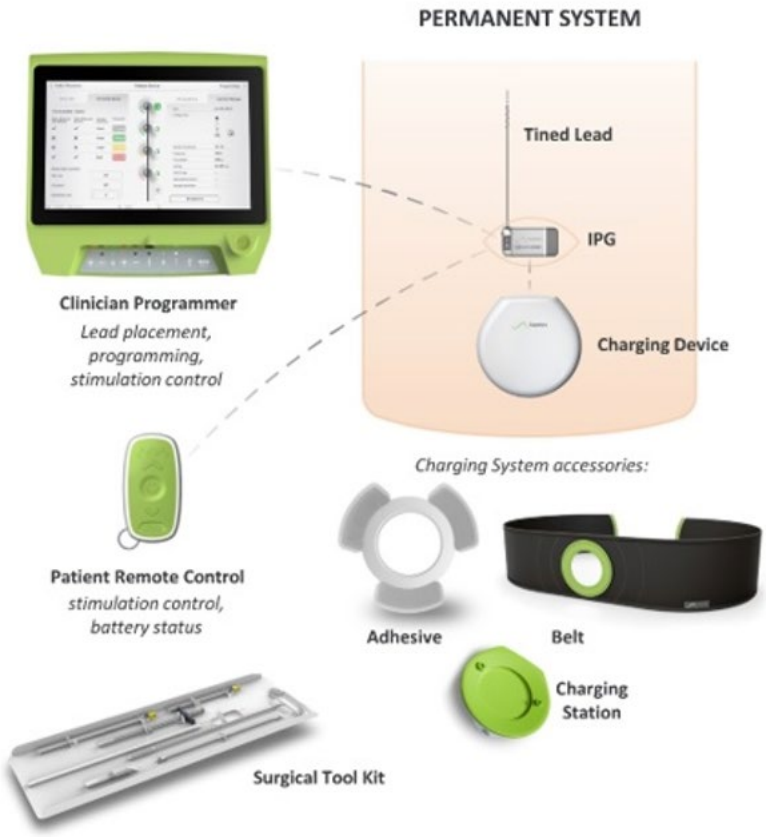
[2] http://www.axonicsmodulation.com/about/
[3] *See* https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190006B.pdf at 7.
[4] *See id.* at p. 6.



19. According to the FDA Summary of Safety and Effectiveness Data for Axonics' r-SNM System, "[t]he components of the Axonics System are similar to those used in … the Medtronic® InterStim® Therapy System."[5] According to the same regulatory filing, the Axonics r-SNM System is similar in design, technology, performance, indication for use, output characteristics, and patient population to the Medtronic InterStim System.[6] Axonics has designed the Axonics r-SNM System such that the implantation procedure is the same as that of the existing Medtronic SNM system.[7] Indeed, Axonics analyzed Medtronic's product in detail before making the

[5] *Id.* at p. 3–5.
[6] *Id*. at p. 25.
[7] *See, e.g.,* Joshua A. Cohn, Casey G. Kowalik, Melissa R. Kaufman, W. Stuart Reynolds, Douglas F. Milam & Roger R. Dmochowski (2017), "Evaluation of the axonics modulation technologies sacral neuromodulation system for the treatment of urinary and fecal dysfunction," *Expert Review of Medical Devices* (hereinafter "Cohn 2017"), at 4; *available at*: https://doi.org/10.1080/17434440.2017.1268913.

Axonics r-SNM System.[8] The image below shows the Axonics r-SNM system implanted.[9]

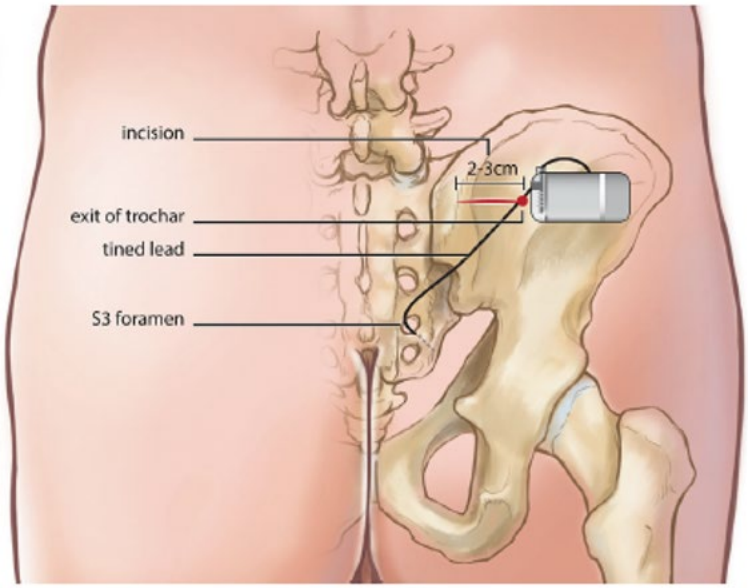


FIGURE 11 Placement of the Axonics IPG

20. In at least its product manuals, documents relating to regulatory filings, and, by and through its representatives and consultants, Axonics provides instructions to its customers and health-care professionals for using the Axonics r-SNM System and its components.[10]

21. Axonics announced that the first commercial implants of the Axonics r-SNM System in the United States took place on October 29, 2019.[11]

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[8] https://www.businessinfocusmagazine.com/2018/05/axonics-prepares-for-introduction-of-its-sacral-neuromodulation-system/

[9] *See* Elterman, "The novel Axonics® rechargeable sacral neuromodulation system: Procedural and technical impressions from an initial North American experience," at 7, Wiley Periodicals, Neurourology and Urodynamics 2018;1–8 (December 19, 2017); available at: https://doi.org/10.1002/nau.23482.

[10] *See, e.g.*, Axonics Sacral Neuromodulation System – Physician's Neurostimulator Implant Manual ("FDA Physician Manual") at 56–64; *available at*: https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190006c.pdf; s*ee also* Axonics Sacral Neuromodulation System – Tined Lead Implant Manual (Model 1201 Tined Lead; Model 1801 Lead Implant Kit), at 13–21.

[11] Axonics® Announces First Commercial U.S. Patient Implanted with its Sacral

THE PATENTS-IN-SUIT

22. Medtronic realleges and incorporates by reference, as if fully set forth herein, all of the allegations contained in paragraphs 1–2120 of this Complaint.

23. On October 11, 2011, the United States Patent and Trademark Office (PTO) issued United States Patent No. 8,036,756 ("the '756 patent"), titled - IMPLANTABLE MEDICAL ELECTRICAL STIMULATION LEAD FIXATION METHOD AND APPARATUS. The '756 patent lists the following individual as inventors: John M. Swoyer, Martin T. Gerber, Keith Carlton, George J. Mamo, Michele Spinelli, and Steven David Hartle. The '756 patent is valid and enforceable. A copy of the '756 patent is attached as Exhibit A.

24. Medtronic, Inc. is the owner of the '756 patent by written assignment. Medtronic, Inc. has granted to MPROC, via written agreements, the exclusive license under the '756 patent to use, make, have made, import, offer for sale, and sell. MPROC has granted to Medtronic Logistics, via written agreements, the exclusive sub-license under the '756 patent to import, offer for sale, and sell. Medtronic Logistics has granted to MDT USA, via written agreements, the exclusive sub-license under the '756 patent to offer for sale and sell. As a result of these agreements and Medtronic's ownership of the '756 patent, Plaintiffs Medtronic, Inc., MPROC, Medtronic Logistics, and MDT USA have standing to bring suit for infringement of the '756 patent.

25. On January 7, 2014, the PTO issued United States Patent No. 8,626,314 ("the '314 patent"), titled IMPLANTABLE MEDICAL LEAD INCLUDING PLURALITY OF TINE ELEMENTS. The '314 patent lists the following individuals as inventors: John M. Swoyer, Martin T. Gerber, Keith Carlton, George J. Mamo, Michele Spinelli, and Steven David Hartle. The '314 patent is valid and enforceable.

Neuromodulation System, *available at*: http://ir.axonicsmodulation.com/news-releases/news-release-details/axonicsr-announces-first-commercial-us-patient-implanted-its.

A copy of the '314 patent is attached as Exhibit B.

26. Medtronic, Inc. is the owner of the '314 patent by written assignment. Medtronic, Inc. has granted to MPROC, via written agreements, the exclusive license under the '314 patent to use, make, have made, import, offer for sale, and sell. MPROC has granted to Medtronic Logistics, via written agreements, the exclusive sub-license under the '314 patent to import, offer for sale, and sell. Medtronic Logistics has granted to MDT USA, via written agreements, the exclusive sub-license under the '314 patent to offer for sale and sell. As a result of these agreements and Medtronic's ownership of the '314 patent, Plaintiffs Medtronic, Inc., MPROC, Medtronic Logistics, and MDT USA have standing to bring suit for infringement of the '314 patent.

27. On October 11, 2016, the Patent and Trademark Office (PTO) issued United States Patent No. 9,463,324 ("the '324 patent"), titled INDUCTIVELY RECHARGEABLE EXTERNAL ENERGY SOURCE, CHARGER, SYSTEM AND METHOD FOR A TRANSCUTANEOUS INDUCTIVE CHARGER FOR AN IMPLANTABLE MEDICAL DEVICE. The '324 patent lists the following individuals as inventors: David P. Olson, William C. Phillips, and Andrew L. Schmeling. The '324 patent is valid and enforceable. A copy of the '324 patent is attached as Exhibit C.

28. Medtronic, Inc. is the owner of the '324 patent by written assignment. Medtronic, Inc. has granted to MPROC, via written agreements, the exclusive license under the '324 patent to use, make, have made, import, offer for sale, and sell. MPROC has granted to Medtronic Logistics, via written agreements, the exclusive sub-license under the '324 patent to import, offer for sale, and sell. Medtronic Logistics has granted to MDT USA, via written agreements, the exclusive sub-license under the '324 patent to offer for sale and sell. As a result of these agreements and Medtronic's ownership of the '324 patent, Plaintiffs Medtronic, Inc., MPROC, Medtronic Logistics, and MDT USA have standing to bring suit for infringement of

the '324 patent.

29. On November 21, 2017, the Patent and Trademark Office (PTO) issued United States Patent No. 9,821,112 ("the '112 patent"), titled INDUCTIVELY RECHARGEABLE EXTERNAL ENERGY SOURCE, CHARGER, SYSTEM AND METHOD FOR A TRANSCUTANEOUS INDUCTIVE CHARGER FOR AN IMPLANTABLE MEDICAL DEVICE. The '112 patent lists the following individuals as inventors: David P. Olson, William C. Phillips, and Andrew L. Schmeling. The '112 patent is valid and enforceable. A copy of the '112 patent is attached as Exhibit D.

30. Medtronic, Inc. is the owner of the '112 patent by written assignment. Medtronic, Inc. has granted to MPROC, via written agreements, the exclusive license under the '112 patent to use, make, have made, import, offer for sale, and sell. MPROC has granted to Medtronic Logistics, via written agreements, the exclusive sub-license under the '112 patent to import, offer for sale, and sell. Medtronic Logistics has granted to MDT USA, via written agreements, the exclusive sub-license under the '112 patent to offer for sale and sell. As a result of these agreements and Medtronic's ownership of the '112 patent, Plaintiffs Medtronic, Inc., MPROC, Medtronic Logistics, and MDT USA have standing to bring suit for infringement of the '112 patent.

COUNT I

(Infringement of U.S. Patent No. 8,036,756)

31. Medtronic realleges and incorporates by reference, as if fully set forth herein, all of the allegations contained in paragraphs 1–30 of this Complaint.

32. Upon information and belief, Axonics has directly infringed, and continues to directly infringe, literally and/or by the doctrine of equivalents, individually and/or jointly, at least claim 14 of the '756 patent by using and testing its Axonics r-SNM System in the United States in accordance with and as covered by one or more claims of the '756 patent, including at least claim 14. Products that when

used or tested infringe the '756 patent include, but are not limited to, Tined Lead Kit Model 1201 and Surgical Tool Kit Model 1801 (collectively referred to in Count I as the "Axonics r-SNM System"), and any other products, either alone or in combination, that operate in substantially the same manner.

33. Upon information and belief, Axonics has indirectly infringed, and continues to indirectly infringe, literally and/or by the doctrine of equivalents, individually and/or jointly, at least claim 14 of the '756 patent by marketing and selling its Axonics r-SNM System in the United States for use in accordance with and as covered by one or more claims of the '756 patent, including at least claim 14. When used or tested, the Axonics r-SNM System, and any other products, either alone or in combination, that operate in substantially the same manner, directly infringe the '756 patent.

34. Claim 14 of the '756 patent is reproduced below:

> *A method comprising:*
>
> *percutaneously introducing an introducer comprising an introducer lumen extending between an introducer lumen proximal end opening and an introducer lumen distal end opening through body tissue to locate the introducer lumen distal end opening adjacent to a stimulation site;*
>
> *disposing an implantable medical lead within the introducer lumen, wherein the implantable medical lead comprises:*
>
> *a lead body extending between a lead proximal end and a lead distal end;*
>
> *a plurality of connector elements formed in a connector array adjacent the lead proximal end;*
>
> *a plurality of stimulation electrodes arranged in an electrode array extending along a first segment of the lead body proximate to the lead distal end;*
>
> *a plurality of lead conductors extending between the connector elements and the stimulation electrodes; and*
>
> *a plurality of tine elements attached to the lead body along a second segment of the lead body between the first segment of the lead body and the lead proximal end, each tine element comprising a plurality of flexible tines that are*

> *adapted to be folded inward against the lead body when fitted into and constrained by the introducer lumen and adapted to deploy outward to engage body tissue when the introducer is withdrawn, wherein the plurality of tine elements are separate from and axially displaced from each of the stimulation electrodes, and wherein the plurality of stimulation electrodes is between the plurality of tine elements and the lead distal end; and*
>
> *withdrawing the introducer toward the lead proximal end from the plurality of tine elements to release the plurality of tines.*

35. As a non-limiting example, the Axonics r-SNM System is implanted according to a method. Upon information and belief, an implantation method of the Axonics r-SNM System provides for percutaneously introducing an introducer comprising an introducer lumen extending between an introducer lumen proximal end opening and an introducer lumen distal end opening through body tissue to locate the introducer lumen distal end opening adjacent to a stimulation site. Aspects of the method of implantation of the Axonics r-SNM System corresponding to this step are described in Axonics' product manuals as shown below:[12]

[12] *See, e.g.,* Axonics Sacral Neuromodulation System – Tined Lead Implant Manual (Model 1201 Tined Lead; Model 1801 Lead Implant Kit); *see also* Axonics SNM Implant Technique Best Practices at 19–21.

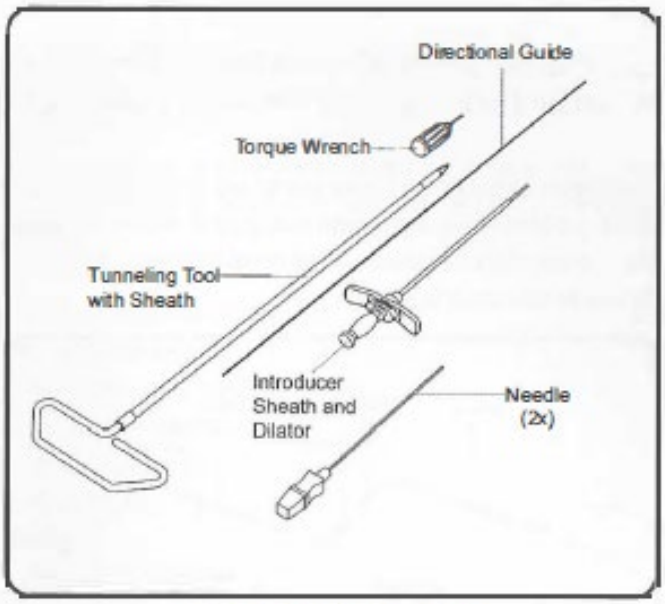


Figure 2. Lead implant tools.

LEAD IMPLANT PROCEDURE

The following section describes the procedure for implanting the Axonics tined lead.

Procedure supplies

In addition to the surgical tools required by the physician, the following supplies are needed for the implantation of the tined lead:

- Axonics Tined Lead Kit (Model 1201)
- Axonics Clinician Programmer (CP) (Model 1501)
- Axonics Lead Implant Kit (Model 1801)
- EMG cables (optional) (Model 9002)
- Medical images from previous test or permanent lead implants to be used to inform correct lead placement (if applicable).

4. While keeping the directional guide in place, gently slide the foramen needle out of the foramen over the directional guide, leaving the guide in place (**Figure 11**).

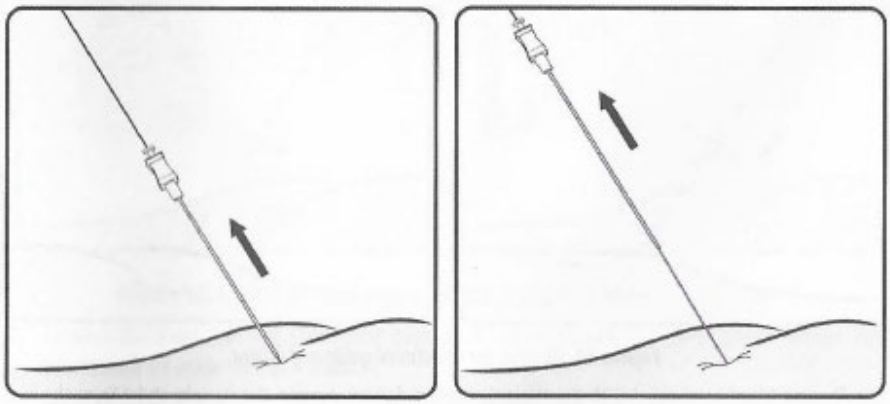


Figure 11. Remove the foramen needle.

5. Hold the directional guide in place at the incision. Place the dilator and introducer sheath over the directional guide and advance them into the foramen. The third most proximal depth marker on the directional guide should be aligned with the top of the dilator (**Figure 12**). If available, confirm with fluoroscopy that the introducer sheath radiopaque marker is 1/2-2/3rd the way through the sacral plate.

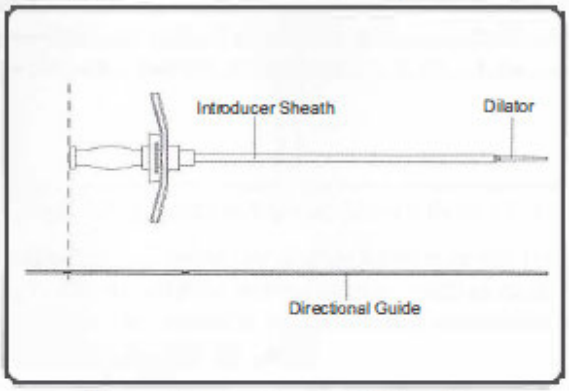


Figure 12. Align the dilator sheath hub with the appropriate mark on the directional guide.

36. Upon information and belief, an implantation method of the Axonics r-SNM System provides for disposing an implantable medical lead within the introducer lumen. Aspects of the method of implantation of the Axonics r-SNM System corresponding to this step are described in Axonics' SNM Manual as shown below:[13]

[13] *See, e.g., id.*

8. Carefully insert the tined lead (with stylet) into the introducer sheath until visual marker B on the tined lead is aligned with the top of the introducer sheath handle. Confirm with fluoroscopy that all electrodes on the lead are proximal to the distal tip of the sheath (**Figure 15**).

Notes:

- Use the tined lead markers to determine at what point the tines will be deployed. Refer to Figure 1 on page 16.
- The stylet supplied is 5mm longer than the tined lead and should not be forced into the lead.
- Sterile water can be used as a lubricant if necessary to insert the tined lead into the introducer sheath.

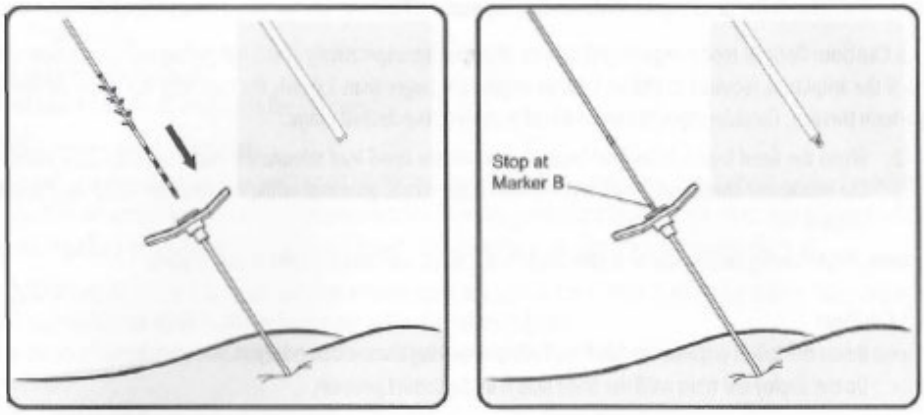


Figure 15. Insert the lead through the introducer sheath.

9. Advance the lead further through the introducer sheath until visual marker C is aligned with the introducer sheath handle while holding the introducer sheath in place. Use fluoroscopy to confirm that the distal tip of the sheath is proximal to the electrodes (**Figure 16**).

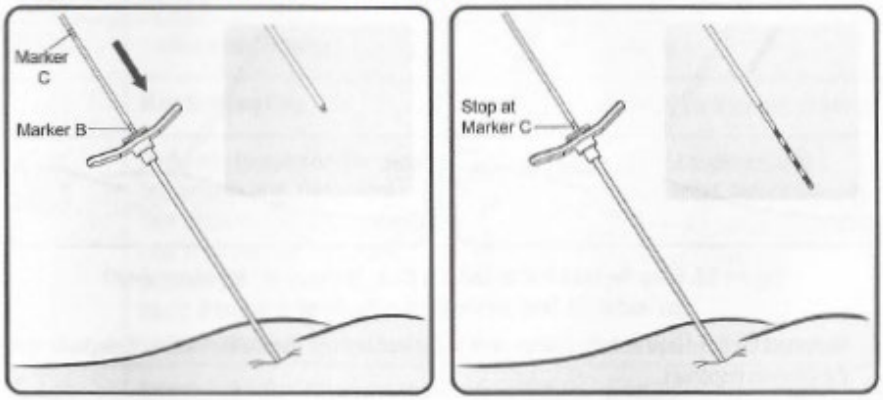
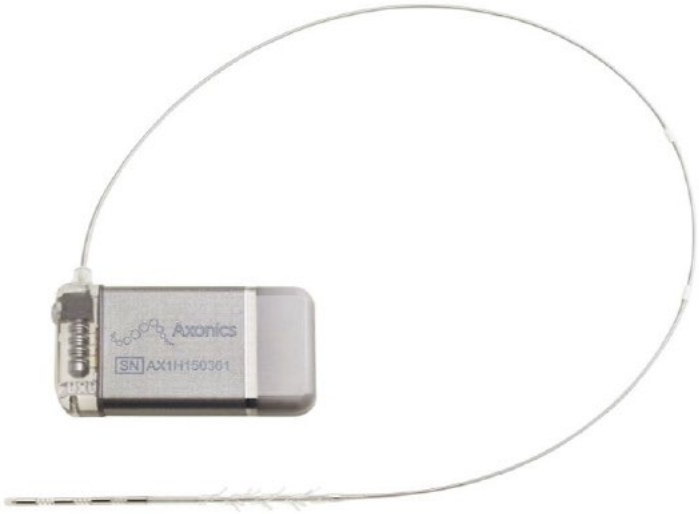


Figure 16. Advance the lead into the introducer sheath to expose the electrodes.

37. Upon information and belief, an implantable medical lead of the Axonics r-SNM System includes a lead body extending between a lead proximal end and a lead distal end, a plurality of connector elements formed in a connector array adjacent the lead proximal end, a plurality of stimulation electrodes arranged in an electrode array extending along a first segment of the lead body proximate to the lead distal end, plurality of lead conductors extending between the connector elements and the

stimulation electrodes. Aspects of the implantable medical lead of the Axonics r-SNM System corresponding to this aspect are identified in further detail below:[14]



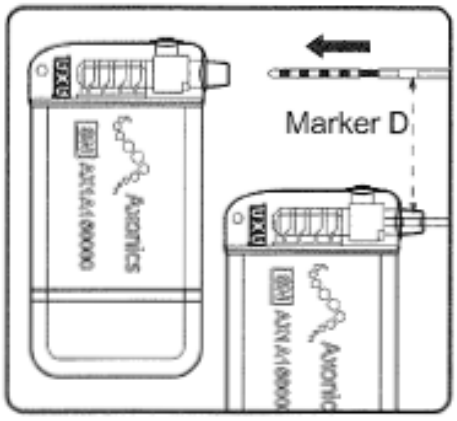


Figure 5: Insert lead fully into the Neurostimulator connector block.

[14] *See, e.g.,* Axonics Sacral Neuromodulation System – Tined Lead Implant Manual (Model 1201 Tined Lead; Model 1801 Lead Implant Kit); Axonics Sacral Neuromodulation System, Neurostimulator Implant Manual, Model 1101 Neurostimulator; Axonics SNM Implant Technique Best Practices at 38.

SPECIFICATIONS

Table 1 shows the Tined lead specifications. For detailed descriptions and specifications for other components and accessories, refer to the product literature packaged with those devices.

Table 1. Tined lead specifications

Physical and Electrical Properties	
Lead length	30 cm
Lead diameter	1.3 mm
Connector	In-line
Number of electrodes	4
Electrode shape	Cylindrical
Electrode length	3 mm
Electrode spacing	3 mm
Number of conductor wires	4
Conductor resistance	135 Ohms (maximum)
Materials	
• Conductor wires	35N LT
• Proximal connector	Platinum-iridium
• Stimulating electrodes	Platinum-iridium

38. Upon information and belief, an implantable medical lead of the Axonics r-SNM System includes a plurality of tine elements attached to the lead body along a second segment of the lead body between the first segment of the lead body and the lead proximal end, each tine element comprising a plurality of flexible tines that are adapted to be folded inward against the lead body when fitted into and constrained by the introducer lumen and adapted to deploy outward to engage body tissue when the introducer is withdrawn, where the plurality of tine elements are separate from and axially displaced from each of the stimulation electrodes, and wherein the plurality of stimulation electrodes is between the plurality of tine elements and the lead distal end. Aspects of the implantable medical lead of the Axonics r-SNM System corresponding to this aspect are identified in further detail below:[15]

[15] *See, e.g.,* Axonics Sacral Neuromodulation System – Tined Lead Implant Manual (Model 1201 Tined Lead; Model 1801 Lead Implant Kit); Elterman, "The novel Axonics® rechargeable sacral neuromodulation system: Procedural and technical impressions from an initial North American experience," Wiley Periodicals, Neurourology and Urodynamics 2018;1–8 (December 19, 2017); *available at*: https://doi.org/10.1002/nau.23482.

(B)

8. Carefully insert the tined lead (with stylet) into the introducer sheath until visual marker B on the tined lead is aligned with the top of the introducer sheath handle. Confirm with fluoroscopy that all electrodes on the lead are proximal to the distal tip of the sheath (**Figure 15**).

Notes:

- Use the tined lead markers to determine at what point the tines will be deployed. Refer to Figure 1 on page 16.
- The stylet supplied is 5mm longer than the tined lead and should not be forced into the lead.
- Sterile water can be used as a lubricant if necessary to insert the tined lead into the introducer sheath.

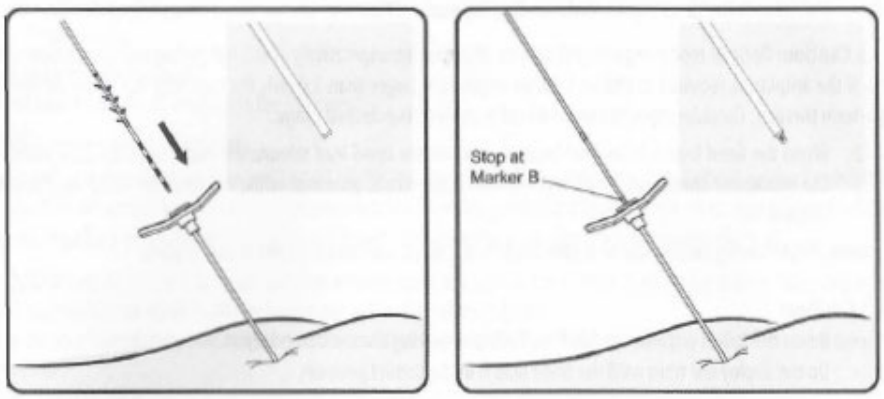


Figure 15. Insert the lead through the introducer sheath.

9. Advance the lead further through the introducer sheath until visual marker C is aligned with the introducer sheath handle while holding the introducer sheath in place. Use fluoroscopy to confirm that the distal tip of the sheath is proximal to the electrodes (**Figure 16**).

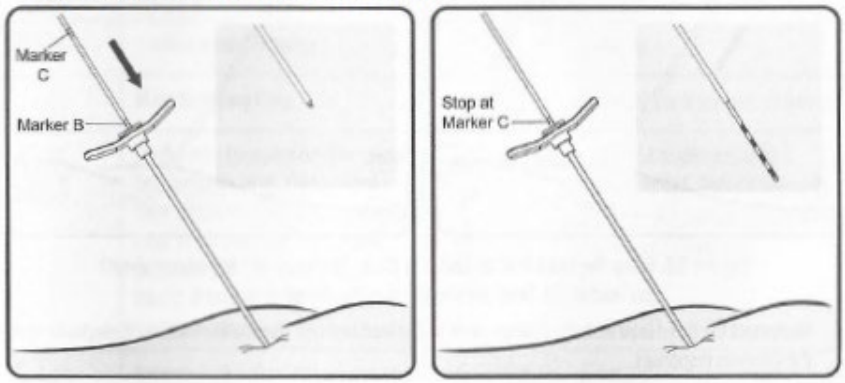


Figure 16. Advance the lead into the introducer sheath to expose the electrodes.

39. Upon information and belief, the implantation method of the Axonics r-SNM System provides for withdrawing the introducer toward the lead proximal end from the plurality of tine elements to release the plurality of tines. Aspects of the method of implantation of the Axonics r-SNM System corresponding to this step are identified in further detail below:[16]

[16] *See, e.g.,* Axonics Sacral Neuromodulation System – Tined Lead Implant Manual (Model 1201 Tined Lead; Model 1801 Lead Implant Kit).

12. When the tined lead is in its final location, remove the tined lead stimulation cable then carefully withdraw the introducer sheath and lead stylet under fluoroscopic guidance while holding the tined lead in place (**Figure 18**).

Note: Withdrawing the introducer sheath deploys the tines, anchoring the tined lead in place.

Caution:

- Be careful to not displace the tined lead when removing the sheath and stylet.
- Do not deploy the tines until the tined lead is in the correct position.

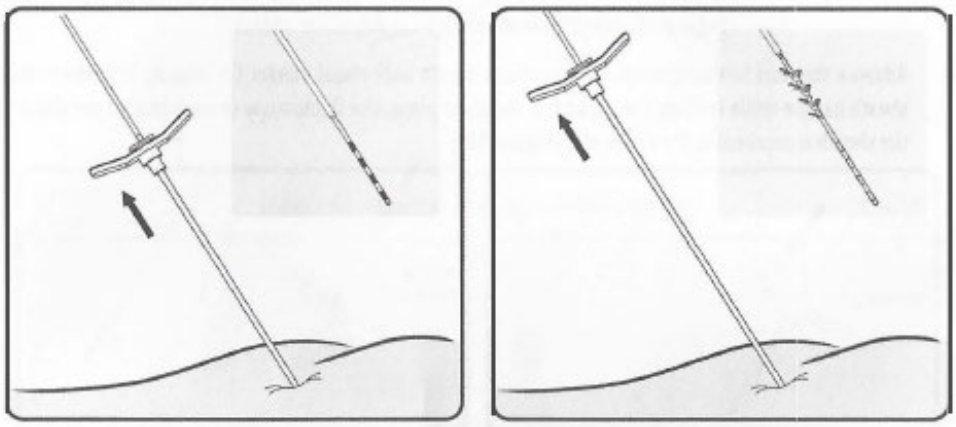


Figure 18. Grasp the tined lead to hold it in place. Withdraw the introducer sheath and lead stylet. Tines are deployed as the sheath is removed.

40. Upon information and belief, Axonics has been, and currently is engaged in actively inducing infringement of at least claim 14 of the '756 patent under 35 U.S.C. § 271(b) and contributory infringement of at least claim 14 of the '756 patent under 35 U.S.C. § 271(c) either literally and/or by the doctrine of equivalents.

41. Upon information and belief, Axonics has committed, and continues to commit, affirmative acts that cause infringement of at least claim 14 of the '756 patent with knowledge or willful blindness of the '756 patent and knowledge or willful blindness that the induced acts constitute infringement of at least claim 14 of the '756 patent. For example, Axonics induces such acts of infringement by its affirmative actions of intentionally providing products that when used in their normal and customary way as desired and intended by Axonics, infringe at least claim 14 of the '756 patent and by providing instructions for using its products in a manner or configuration that infringes at least claim 14 of the '756 patent.

42. Upon information and belief, Axonics provides the Axonics r-SNM System to others, such as hospitals, medical centers, clinics, clinicians, doctors, nurse

practitioners, and care providers, who, in turn, use, provision for use, or test the Axonics r-SNM System in a manner that directly infringes at least claim 14 of the '756 patent. Upon information and belief, Axonics provides user instructions and manuals accompanying its products for the Axonics r-SNM System as well as other marketing and promotional materials that instruct, direct, and intentionally induce others, such as hospitals, medical centers, clinics, clinicians, doctors, nurse practitioners, and care providers, to use the Axonics r-SNM System in a manner that directly infringes at least claim 14 of the '756 patent, for the reasons discussed above.

43. Moreover, upon information and belief, Axonics has hired a U.S. sales team, that includes former members of Medtronic's sales team who received training from Medtronic, and that team consists of at least 11 regional sales managers, between 85 and 90 sales professionals, and 30 clinical specialists. Upon information and belief, Axonics' U.S. sales team, who are fully trained regarding Axonics' product, have been and will be "strategically mapped to and located where current high volume implanters are practicing in the United States."[17] Upon information and belief, the sales team has been responsible for and continues to be responsible for "supporting cases in the [operating room], interacting with patients and programming the implanted [Axonics] device."[18] Upon information and belief, the sales team has been involved with and continues to be involved with the distribution of marketing, promotional, and training materials, which instruct Axonics' customers regarding the use of the Axonics r-SNM System in the United States in a manner that directly infringes one or more claims of the '756 patent.

44. Upon information and belief, Axonics has contributed to, and continues to contribute to, the infringement of the '756 patent by others by knowingly providing the Axonics r-SNM System for use in practicing at least claim 14 of the '756 patent,

[17] *See, e.g.,* Q1 2019 Axonics Modulation Technologies Inc. Earnings Call, (May 8, 2019, 8:30PM GMT).

[18] *Id.*

and knowing the Axonics r-SNM System to be especially made or especially adapted for use in infringement of the '756 patent. Upon information and belief, Axonics has also committed, and continues to commit contributory infringement by, *inter alia*, knowingly offering for sale and selling the Axonics r-SNM System, which has no substantial non-infringing uses, and which when used causes the direct infringement of at least claim 14 of the '756 patent by third parties, such as hospitals, medical centers, clinics, clinicians, doctors, nurse practitioners, and care providers.

45. As discussed above, the Axonics r-SNM System is designed and sold to be used only for implanting its components in a specific way, as directed by the instructions in the manuals and promotional materials. The manuals and promotional materials provide specific instructions for using the Axonics r-SNM System in a way that infringes at least one claim of the '756 patent, and they do not contemplate any non-infringing uses.

46. Upon information and belief, Axonics knew of the '756 patent or was willfully blind to its existence. Upon information and belief, Axonics had knowledge of the '756 patent and continues to have knowledge of the '756 patent, including but not limited to at least one or more of the following events: the filing of Medtronic's Complaint against Axonics; in the course of its due diligence and freedom to operate analyses, including the "many initial months [spent] examining patents and IP issues";[19] and as part of the due diligence investigation performed for SEC filings. By the time of trial, Axonics will have known and intended (since receiving such notice) that its continued actions would infringe and actively induce and contribute to the infringement of at least claim 14 of the '756 patent.

47. Upon information and belief, Axonics' infringement of the '756 patent has been and continues to be willful.

48. Axonics' infringement of the '756 patent has been without permission,

[19] https://www.businessinfocusmagazine.com/2018/05/axonics-prepares-for-introduction-of-its-sacral-neuromodulation-system/

consent, authorization, or license from Medtronic.

49. As a result of Axonics' infringement, Medtronic has suffered and will continue to suffer damages in an amount to be proved at trial. In addition, Axonics' infringement caused and will continue to cause Medtronic irreparable harm, for which there is no adequate remedy at law, warranting an injunction from the Court.

COUNT II

(Infringement of U.S. Patent No. 8,626,314)

50. Medtronic realleges and incorporates by reference, as if fully set forth herein, all of the allegations contained in paragraphs 1–49 of this Complaint.

51. Upon information and belief, Axonics has directly infringed, and continues to directly infringe, literally and/or by the doctrine of equivalents, individually and/or jointly, at least claim 11 of the '314 patent by making, using, testing, selling, offering for sale, and/or importing into the United States products covered by at least claim 11 of the '314 patent. Axonics' products that infringe the '314 patent include, but are not limited to, Implantable Pulse Generator Model 1101, Tined Lead Kit Model 1201, and Surgical Tool Kit Model 1801 (collectively referred to in Count II as the "Axonics r-SNM System"), and any other Axonics products, either alone or in combination, that operate in substantially the same manner.

52. Upon information and belief, Axonics has indirectly infringed, and continues to indirectly infringe, literally and/or by the doctrine of equivalents, individually and/or jointly, at least claim 11 of the '314 patent by marketing and selling its Axonics r-SNM System in the United States for use or sale in accordance with and as covered by one or more claims of the '314 patent, including at least claim 11. When used, tested, offered for sale, or sold, the Axonics r-SNM System, and any other products, either alone or in combination, that operate in substantially the same manner, directly infringe the '314 patent.

53. Claim 11 of the '314 patent is reproduced below:

A system comprising:

an implantable pulse generator configured to generate electrical stimulation;

an implantable medical lead configured to be electrically coupled to the implantable pulse generator and introduced through and released into body tissue via an introducer defining an introducer lumen, the implantable medical lead comprising:

a lead body extending between a proximal end and a distal end;

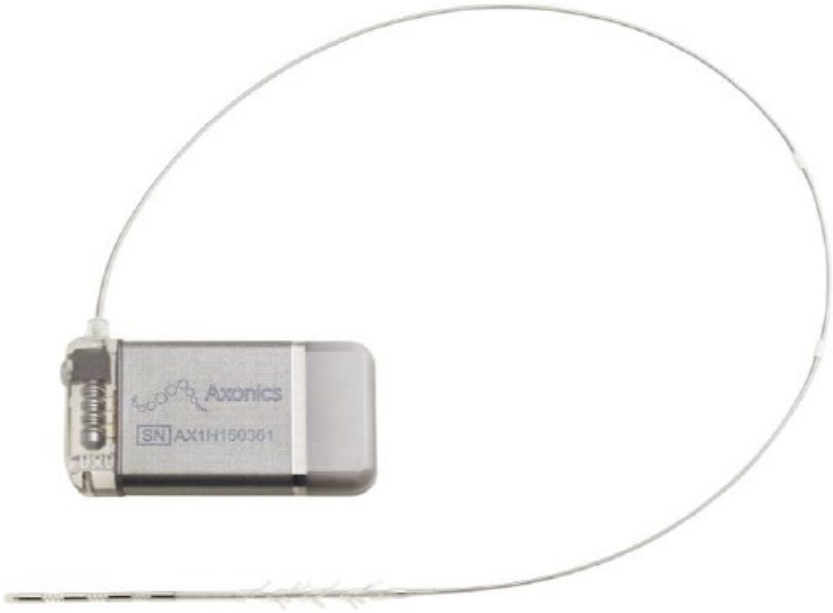
a plurality of conductors within the lead body;

a plurality of electrodes, wherein each electrode is electrically connected to a conductor of the plurality of conductors; and

a plurality of tine elements extending from the lead body, wherein all tine elements of the plurality of tine elements are positioned between a most proximal electrode of the plurality of electrodes and the proximal end of the lead body, each tine element comprising a plurality of flexible, pliant tines, each tine having a tine width and thickness and extending a tine length from an attached tine end to a free tine end, the attached tine end attached to the lead body from a tine attachment site and supporting the tine extending outwardly of the lead body and proximally toward the lead proximal end, wherein the plurality of tines of the plurality of tine elements are adapted to be folded inward against the lead body when fitted into and constrained by the lumen of the introducer without overlapping one another and deploy outward to engage body tissue when the introducer is withdrawn proximally, wherein the plurality of tine elements is separate from and axially displaced from the plurality of electrodes.

54. As a non-limiting example, upon information and belief, the Axonics r-SNM System includes an implantable pulse generator configured to generate electrical stimulation and an implantable medical lead configured to be electrically coupled to the implantable pulse generator and introduced through and released into body tissue via an introducer defining an introducer lumen. Aspects of the implantable pulse generator and medical lead of the Axonics r-SNM System corresponding to this aspect

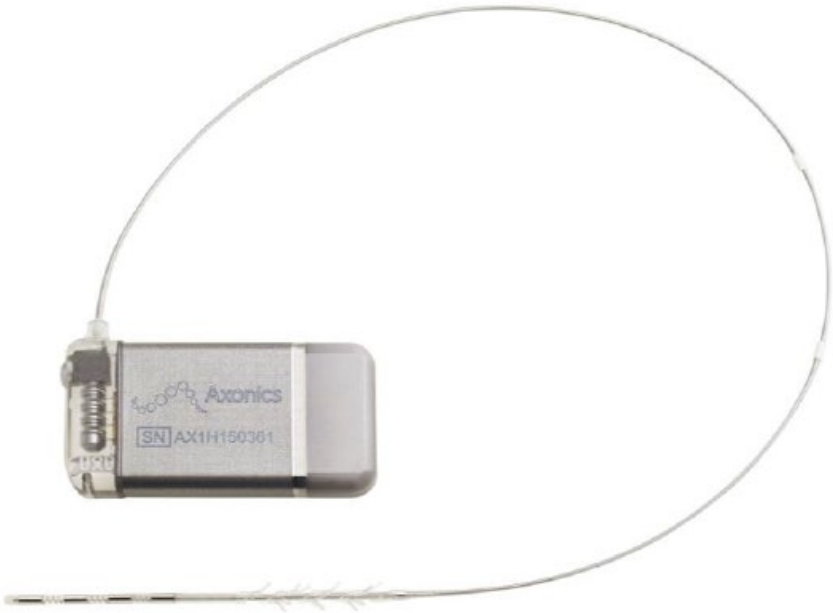
are identified in further detail below:[20]



55. Upon information and belief, an implantable medical lead of the Axonics r-SNM System includes a lead body extending between a proximal end and a distal end, a plurality of conductors within the lead body, and a plurality of electrodes, wherein each electrode is electrically connected to a conductor of the plurality of conductors. Aspects of the implantable medical lead of the Axonics r-SNM System corresponding to this aspect are identified in further detail below: [21]

[20] *See, e.g.,* Axonics Sacral Neuromodulation System – Tined Lead Implant Manual (Model 1201 Tined Lead; Model 1801 Lead Implant Kit); Axonics SNM Implant Technique Best Practices at 38.

[21] *See, e.g., id*; Axonics Sacral Neuromodulation System, Neurostimulator Implant Manual, Model 1101 Neurostimulator.



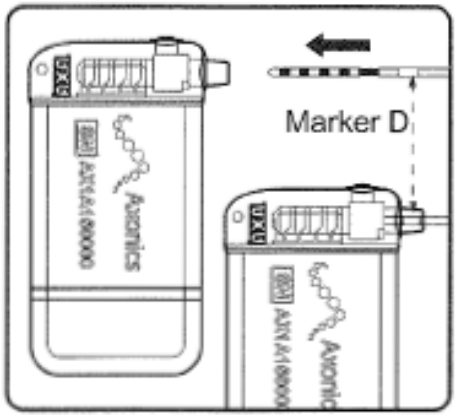


Figure 5: Insert lead fully into the Neurostimulator connector block.

SPECIFICATIONS

Table 1 shows the Tined lead specifications. For detailed descriptions and specifications for other components and accessories, refer to the product literature packaged with those devices.

Table 1. Tined lead specifications

Physical and Electrical Properties	
Lead length	30 cm
Lead diameter	1.3 mm
Connector	In-line
Number of electrodes	4
Electrode shape	Cylindrical
Electrode length	3 mm
Electrode spacing	3 mm
Number of conductor wires	4
Conductor resistance	135 Ohms (maximum)
Materials	
• Conductor wires	35N LT
• Proximal connector	Platinum-iridium
• Stimulating electrodes	Platinum-iridium

56. Upon information and belief, an implantable medical lead of the Axonics r-SNM System includes a plurality of tine elements extending from the lead body, wherein all tine elements of the plurality of tine elements are positioned between a most proximal electrode of the plurality of electrodes and the proximal end of the lead body, each tine element comprising a plurality of flexible, pliant tines, each tine having a tine width and thickness and extending a tine length from an attached tine end to a free tine end, the attached tine end attached to the lead body from a tine attachment site and supporting the tine extending outwardly of the lead body and proximally toward the lead proximal end, wherein the plurality of tines of the plurality of tine elements are adapted to be folded inward against the lead body when fitted into and constrained by the lumen of the introducer without overlapping one another and deploy outward to engage body tissue when the introducer is withdrawn proximally, wherein the plurality of tine elements is separate from and axially displaced from the plurality of electrodes. Aspects of the implantable medical lead of the Axonics r-

SNM System corresponding to this aspect are identified in further detail below:[22]

(B)

8. Carefully insert the tined lead (with stylet) into the introducer sheath until visual marker B on the tined lead is aligned with the top of the introducer sheath handle. Confirm with fluoroscopy that all electrodes on the lead are proximal to the distal tip of the sheath (**Figure 15**).

Notes:

- Use the tined lead markers to determine at what point the tines will be deployed. Refer to Figure 1 on page 16.
- The stylet supplied is 5mm longer than the tined lead and should not be forced into the lead.
- Sterile water can be used as a lubricant if necessary to insert the tined lead into the introducer sheath.

[22] *See, e.g., id*; Elterman, "The novel Axonics® rechargeable sacral neuromodulation system: Procedural and technical impressions from an initial North American experience," at 7, Wiley Periodicals, Neurourology and Urodynamics 2018;1–8 (December 19, 2017); available at: https://doi.org/10.1002/nau.23482.

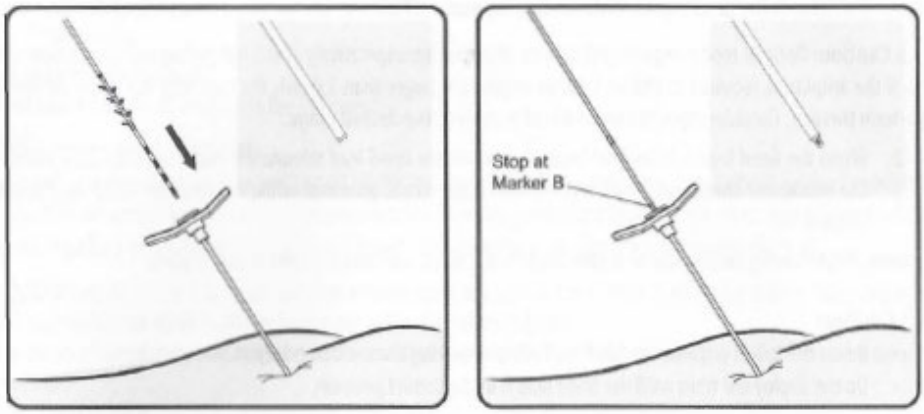


Figure 15. Insert the lead through the introducer sheath.

9. Advance the lead further through the introducer sheath until visual marker C is aligned with the introducer sheath handle while holding the introducer sheath in place. Use fluoroscopy to confirm that the distal tip of the sheath is proximal to the electrodes (**Figure 16**).

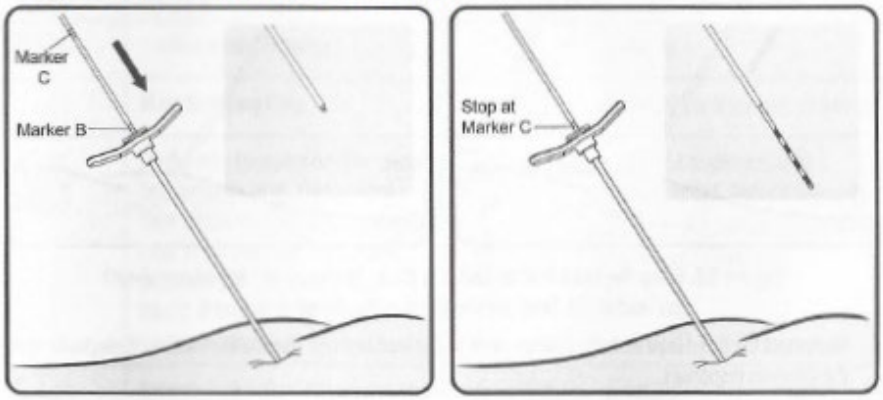


Figure 16. Advance the lead into the introducer sheath to expose the electrodes.

12. When the tined lead is in its final location, remove the tined lead stimulation cable then carefully withdraw the introducer sheath and lead stylet under fluoroscopic guidance while holding the tined lead in place (**Figure 18**).

Note: Withdrawing the introducer sheath deploys the tines, anchoring the tined lead in place.

Caution:

- Be careful to not displace the tined lead when removing the sheath and stylet.
- Do not deploy the tines until the tined lead is in the correct position.

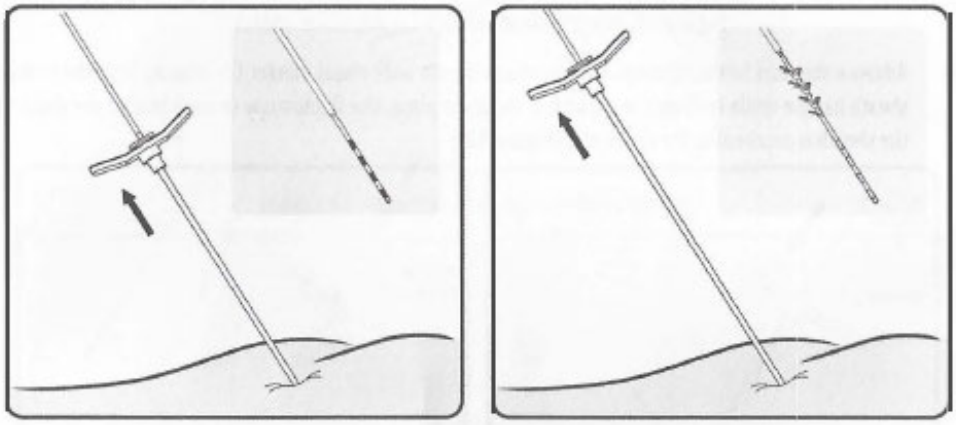


Figure 18. Grasp the tined lead to hold it in place. Withdraw the introducer sheath and lead stylet. Tines are deployed as the sheath is removed.

57. Upon information and belief, Axonics has been and is currently engaged in actively inducing infringement of at least claim 11 of the '314 patent under 35 U.S.C. § 271(b) and contributory infringement of at least claim 11 of the '314 patent under 35 U.S.C. § 271(c) either literally and/or by the doctrine of equivalents.

58. Upon information and belief, Axonics has committed, and continues to commit, affirmative acts that cause infringement of at least claim 11 of the '314 patent with knowledge or willful blindness of the '314 patent, and knowledge or willful blindness that the induced acts constitute infringement of at least claim 11 of the '314 patent. For example, Axonics induces such acts of infringement by its affirmative actions of intentionally providing products that when used in their normal and customary way as desired and intended by Axonics, infringe at least claim 11 of the '314 patent and by providing instructions for using its products in a manner or configuration that infringes at least claim 11 of the '314 patent.

59. Upon information and belief, Axonics provides the Axonics r-SNM System to others, such as customers, hospitals, medical centers, clinics, clinicians,

doctors, nurse practitioners, care providers, sales representatives, suppliers, distributors, and resellers, who, in turn, use, provision for use, test, offer for sale, or sell the Axonics r-SNM System in a manner that directly infringes at least claim 11 of the '314 patent. Upon information and belief, Axonics provides user instructions and manuals accompanying its products for the Axonics r-SNM System, as well as other marketing and promotional materials that instruct, direct, and intentionally induce others, such as customers, hospitals, medical centers, clinics, clinicians, doctors, nurse practitioners, and care providers, to use the Axonics r-SNM System in a manner that directly infringes as least claim 11 of the '314 patent.

60. Moreover, upon information and belief, Axonics has hired a U.S. sales team that includes former members of Medtronic's sales team who received training from Medtronic, and that team consists of at least 11 regional sales managers, between 85 and 90 sales professionals, and 30 clinical specialists. Upon information and belief, Axonics' U.S. sales team, who are fully trained regarding Axonics' product, have been and will be "strategically mapped to and located where current high volume implanters are practicing in the United States."[23] Upon information and belief, the sales team has been responsible for and continues to be responsible for "supporting cases in the [operating room], interacting with patients and programming the implanted [Axonics] device."[24] Upon information and belief, the sales team has been involved with and continues to be involved with the distribution of marketing, promotional, and training materials, which instruct Axonics' customers regarding the use of the Axonics r-SNM System in the United States in a manner that directly infringes one or more claims of the '314 patent.

61. Upon information and belief, Axonics has contributed to, and continues to contribute to, the infringement of the '314 patent by others by knowingly providing

[23] *See* Q1 2019 Axonics Modulation Technologies Inc. Earnings Call, May 8, 2019, 8:30PM GMT).

[24] *Id.*

the Axonics r-SNM System that constitutes a material part of at least claim 11 of the '314 patent, with knowledge that the Axonics r-SNM System is to be especially made or especially adapted for use in infringement of the '314 patent. Upon information and belief, Axonics has also committed, and continues to commit contributory infringement by, *inter alia*, knowingly offering for sale and selling the Axonics r-SNM System, which has no substantial non-infringing uses, and which constitutes a material part of at least claim 11 of the '314 patent.

62. As discussed above, the Axonics r-SNM System is designed and sold to be used only for implanting its components in a specific way, as directed by the instructions in the manuals and promotional materials. The manuals and promotional materials provide specific instructions for using the Axonics r-SNM System in a way that infringes at least one claim of the '314 patent, and they do not contemplate any non-infringing uses.

63. Upon information and belief, Axonics knew of the '314 patent or was willfully blind to its existence. Upon information and belief, Axonics had knowledge of the '314 patent and continues to have knowledge of the '314 patent, including but not limited to at least one or more of the following events: the filing of Medtronic's Complaint against Axonics; in the course of its due diligence and freedom to operate analyses, including the "many initial months [spent] examining patents and IP issues";[25] and as part of the due-diligence investigation performed for SEC filings. By the time of trial, Axonics will have known and intended (since receiving such notice) that its continued actions would infringe and actively induce and contribute to the infringement of at least claim 11 of the '314 patent.

64. Upon information and belief, Axonics' infringement of the '314 patent has been and continues to be willful.

65. Axonics' infringement of the '314 patent has been without permission,

[25] https://www.businessinfocusmagazine.com/2018/05/axonics-prepares-for-introduction-of-its-sacral-neuromodulation-system/

consent, authorization, or license of Medtronic.

66. As a result of Axonics' infringement, Medtronic has suffered and will continue to suffer damages in an amount to be proved at trial. In addition, Axonics' infringement caused and will continue to cause Medtronic irreparable harm, for which there is no adequate remedy at law, warranting an injunction from the Court.

COUNT III

(Infringement of U.S. Patent No. 9,463,324)

67. Medtronic realleges and incorporates by reference, as if fully set forth herein, all of the allegations contained in paragraphs 1–66 of this Complaint.

68. Upon information and belief, Axonics has directly infringed, and continues to directly infringe, literally and/or by the doctrine of equivalents, individually and/or jointly, at least claims 1, 4, and 11 of the '324 patent by making, using, testing, selling, offering for sale, and/or importing into the United States products covered by at least claims 1, 4, and 11 of the '324 patent. Axonics' products that infringe the '324 patent include, but are not limited to, the Model 1101 Neurostimulator and Model 1401 charging system, (collectively referred to in Count III as the "Axonics r-SNM System"), and any other Axonics products, either alone or in combination, that operate in substantially the same manner.

69. Upon information and belief, Axonics has indirectly infringed, and continues to indirectly infringe, literally and/or by the doctrine of equivalents, individually and/or jointly, at least claims 1, 4, and 11 of the '324 patent by marketing and selling its Axonics r-SNM System in the United States for use or sale in accordance with and as covered by one or more claims of the '324 patent, including at least claims 1, 4, and 11. When used, tested, offered for sale, or sold, the Axonics r-SNM System, and any other products, either alone or in combination, that operate in substantially the same manner, directly infringe the '324 patent.

70. Claim 1 of the '324 patent is reproduced below:

A system, comprising:

an implantable medical device comprising a secondary coil; and

an external device comprising:

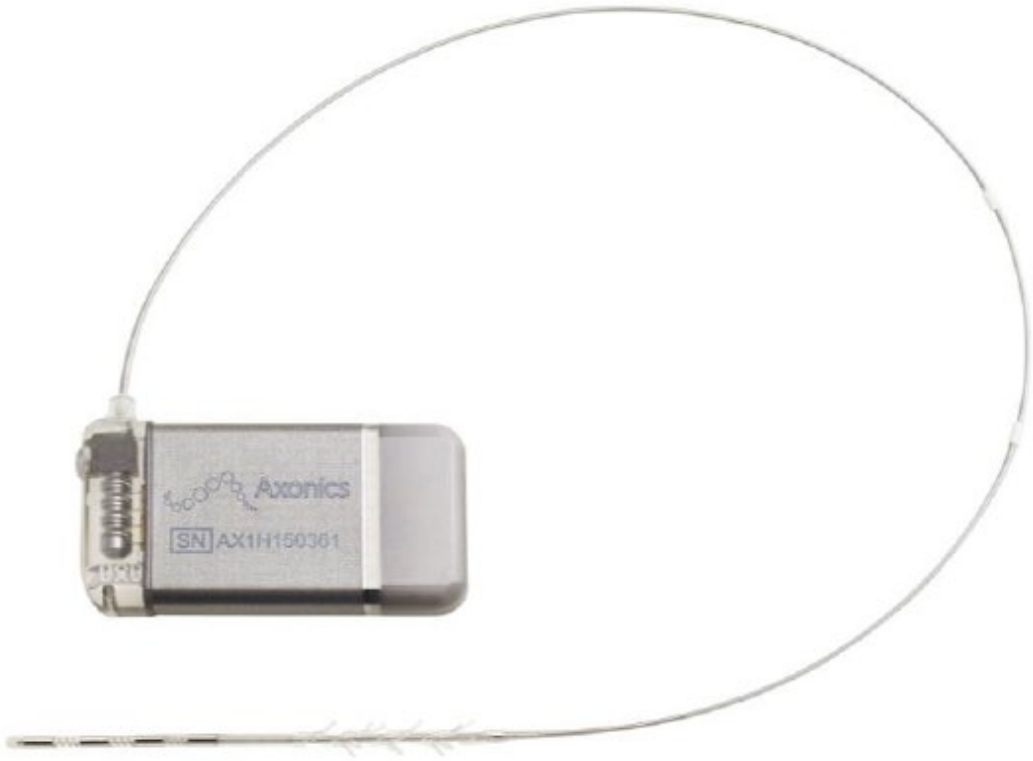
a primary coil adapted to be transcutaneously coupled to the secondary coil to transfer energy to the implantable medical device;

a housing having a side adapted to be positioned in proximity to the secondary coil when the primary coil is transcutaneously coupled to the secondary coil;

a temperature sensor adapted to provide an output indicative of a temperature of the side of the housing; and control circuitry adapted to control the transfer of energy to the implantable medical device based on the output of the temperature sensor to limit a temperature to which a patient is exposed during the transfer of energy to the implantable medical device.

71. As a non-limiting example, upon information and belief, the Axonics r-SNM System includes an implantable medical device comprising a secondary coil. Aspects of the implantable pulse generator of the Axonics r-SNM System corresponding to this aspect are identified in further detail below:[26]

[26] *See, e.g.,* Axonics Sacral Neuromodulation System – Tined Lead Implant Manual (Model 1201 Tined Lead; Model 1801 Lead Implant Kit); Axonics SNM Implant Technique Best Practices; Elterman, "The novel Axonics® rechargeable sacral neuromodulation system: Procedural and technical impressions from an initial North American experience," at 7, Wiley Periodicals, Neurourology and Urodynamics 2018;1–8 (December 19, 2017); *available at*: https://doi.org/10.1002/nau.23482.



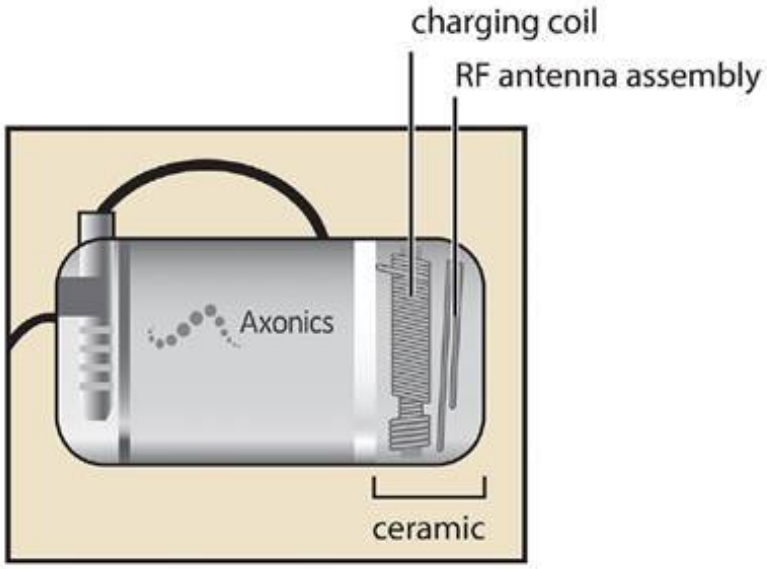


FIGURE 2 Illustration of the Axonics IPG, highlighting the location of the recharging coil and communication antennae enclosed in the ceramic portion of the IPG

72. Upon information and belief, the Axonics r-SNM System includes an external device comprising a primary coil adapted to be transcutaneously coupled to

the secondary coil to transfer energy to the implantable medical device and a housing having a side adapted to be positioned in proximity to the secondary coil when the primary coil is transcutaneously coupled to the secondary coil. Aspects of the external recharger of the Axonics r-SNM System corresponding to this aspect are identified in further detail below:[27]

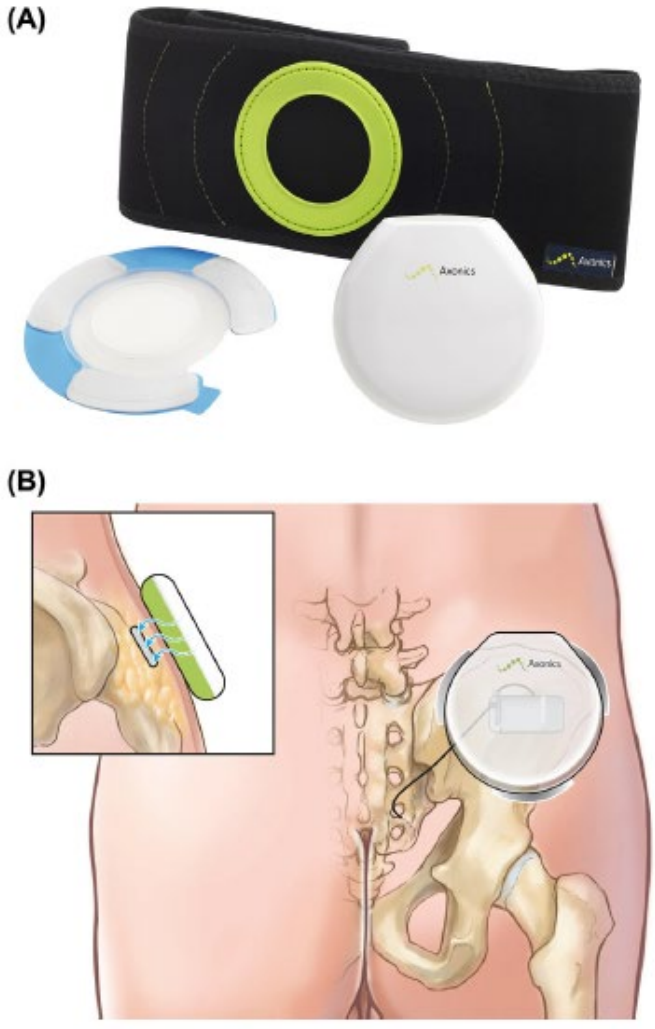


FIGURE 12 Charging the Axonics IPG using the Axonics Charging System. A, Photo of the Axonics Charging System. B, Illustration of the Charger placed over the IPG to recharge the IPG

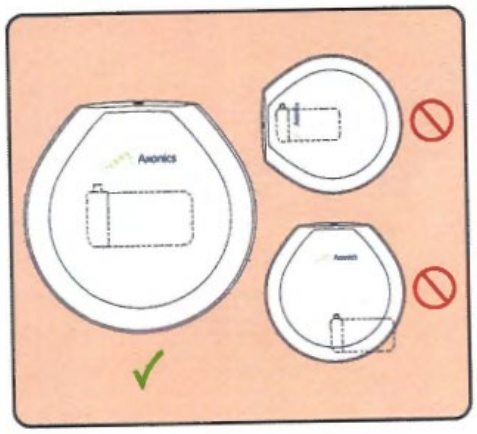
[27] *See, e.g., id.*; Axonics r-SNM System Charging System User Manual. at p. 18.

For best charging, place the Charger over your implanted Stimulator.

You should place your Charger with the button facing up if your Stimulator is placed horizontally (as shown to the right). Your doctor will inform you if your Stimulator is placed in a different way.

The white outline on the bottom of the Charger represents how the Charger should be placed over the Stimulator.

Good placement will ensure fast charging.



73. Upon information and belief, the Axonics r-SNM System includes an external device comprising a temperature sensor adapted to provide an output indicative of a temperature of the side of the housing, and control circuitry adapted to control the transfer of energy to the implantable medical device based on the output of the temperature sensor to limit a temperature to which a patient is exposed during the transfer of energy to the implantable medical device. Aspects of the external recharger of the Axonics r-SNM System corresponding to this aspect are identified in further detail below:[28]

able SCS devices. Additionally, the system has temperature sensors and software controls that pause charging if the patient's skin temperature increases significantly. These

[28] *See, e.g., id* at p. 33; Blok, "Programming settings and recharge interval in a prospective study of a rechargeable sacral neuromodulation system for the treatment of overactive bladder," Wiley Periodicals, Neurourology and Urodynamics 2018;1–6 (November 29, 2017); *available at*: https://doi.org/10.1002/nau.23476.

Environmental Specifications – Charger, Dock, Power Supply, Carrier and Belt

Item	Specification
Operating Conditions	
Temperature	5°C - 40°C (41°F – 104°F)
Pressure	70kPa – 106kPa
Humidity	15% - 95%
Storage & Shipment Conditions – Short Term (3 days or less)	
Temperature	-25°C - 70°C (-13°F – 158°F)
Pressure	57kPa – 106kPa
Humidity	15% - 95%
Storage & Shipment Conditions – Long Term (over 3 days)	
Temperature	20°C - 30°C (68°F – 86°F)
Pressure	70kPa – 106kPa
Humidity	30% - 85%

74. Upon information and belief, Axonics has been and is currently engaged in actively inducing infringement of at least claims 1, 4, and 11 of the '324 patent under 35 U.S.C. § 271(b) and contributory infringement of at least claims 1, 4, and 11 of the '324 patent under 35 U.S.C. § 271(c) either literally and/or by the doctrine of equivalents.

75. Upon information and belief, Axonics has committed, and continues to commit, affirmative acts that cause infringement of at least claims 1, 4, and 11 of the '324 patent with knowledge or willful blindness of the '324 patent, and knowledge or willful blindness that the induced acts constitute infringement of at least claims 1, 4, and 11 of the '324 patent. For example, Axonics induces such acts of infringement by its affirmative actions of intentionally providing products that when used in their normal and customary way as desired and intended by Axonics, infringe at least claims 1, 4, and 11 of the '324 patent and by providing instructions for using its products in a manner or configuration that infringes at least claims 1, 4, and 11 of the '324 patent.

76. Upon information and belief, Axonics provides the Axonics r-SNM System to others, such as customers, patients, hospitals, medical centers, clinics,

clinicians, doctors, nurse practitioners, care providers, sales representatives, suppliers, distributors, and resellers, who, in turn, use, provision for use, test, offer for sale, or sell the Axonics r-SNM System in a manner that directly infringes at least claims 1, 4, and 11 of the '324 patent. Upon information and belief, Axonics provides user instructions and manuals accompanying its products for the Axonics r-SNM System, as well as other marketing and promotional materials that instruct, direct, and intentionally induce others, such as customers, patients, hospitals, medical centers, clinics, clinicians, doctors, nurse practitioners, and care providers, to use the Axonics r-SNM System in a manner that directly infringes as least claims 1, 4, and 11 of the '324 patent.

77. Moreover, upon information and belief, Axonics has hired a U.S. sales team that includes former members of Medtronic's sales team who received training from Medtronic, and that team consists of at least 11 regional sales managers, between 85 and 90 sales professionals, and 30 clinical specialists. Upon information and belief, Axonics' U.S. sales team, who are fully trained regarding Axonics' product, have been and will be "strategically mapped to and located where current high volume implanters are practicing in the United States."[29] Upon information and belief, the sales team has been responsible for and continues to be responsible for "supporting cases in the [operating room], interacting with patients and programming the implanted [Axonics] device."[30] Upon information and belief, the sales team has been involved with and continues to be involved with the distribution of marketing, promotional, and training materials, which instruct Axonics' customers regarding the use of the Axonics r-SNM System in the United States in a manner that directly infringes one or more claims of the '324 patent.

78. Upon information and belief, Axonics has contributed to, and continues

[29] *See* Q1 2019 Axonics Modulation Technologies Inc. Earnings Call, May 8, 2019, 8:30PM GMT).

[30] *Id.*

to contribute to, the infringement of the '324 patent by others by knowingly providing the Axonics r-SNM System that constitutes a material part of at least claims 1, 4, and 11 of the '324 patent, with knowledge that the Axonics r-SNM System is to be especially made or especially adapted for use in infringement of the '324 patent. Upon information and belief, Axonics has also committed, and continues to commit contributory infringement by, *inter alia*, knowingly offering for sale and selling the Axonics r-SNM System, which has no substantial non-infringing uses, and which constitutes a material part of at least claims 1, 4, and 11 of the '324 patent.

79. As discussed above, the Axonics r-SNM System is designed and sold to be used only for recharging in a specific way, as directed by the instructions in the manuals and promotional materials. The manuals and promotional materials provide specific instructions for using the Axonics r-SNM System in a way that infringes at least one claim of the '324 patent, and they do not contemplate any non-infringing uses.

80. Upon information and belief, Axonics knew of the '324 patent or was willfully blind to its existence. Upon information and belief, Axonics had knowledge of the '324 patent and continues to have knowledge of the '324 patent, including but not limited to at least one or more of the following events: the filing of Medtronic's Complaint against Axonics; in the course of its due diligence and freedom to operate analyses, including the "many initial months [spent] examining patents and IP issues";[31] and as part of the due-diligence investigation performed for SEC filings. By the time of trial, Axonics will have known and intended (since receiving such notice) that its continued actions would infringe and actively induce and contribute to the infringement of at least claims 1, 4, and 11 of the '324 patent.

81. Upon information and belief, Axonics' infringement of the '324 patent has been and continues to be willful.

[31] https://www.businessinfocusmagazine.com/2018/05/axonics-prepares-for-introduction-of-its-sacral-neuromodulation-system/.

82. Axonics' infringement of the '324 patent has been without permission, consent, authorization, or license of Medtronic.

83. As a result of Axonics' infringement, Medtronic has suffered and will continue to suffer damages in an amount to be proved at trial. In addition, Axonics' infringement caused and will continue to cause Medtronic irreparable harm, for which there is no adequate remedy at law, warranting an injunction from the Court.

COUNT IV

(Infringement of U.S. Patent No. 9,821,112)

84. Medtronic realleges and incorporates by reference, as if fully set forth herein, all of the allegations contained in paragraphs 1–83 of this Complaint.

85. Upon information and belief, Axonics has directly infringed, and continues to directly infringe, literally and/or by the doctrine of equivalents, individually and/or jointly, at least claim 1 of the '112 patent by making, using, testing, selling, offering for sale, and/or importing into the United States products covered by at least claim 1 of the '112 patent. Axonics' products that infringe the '112 patent include, but are not limited to, the Model 1101 Neurostimulator and Model 1401 charging system, (collectively referred to in Count IV as the "Axonics r-SNM System"), and any other Axonics products, either alone or in combination, that operate in substantially the same manner.

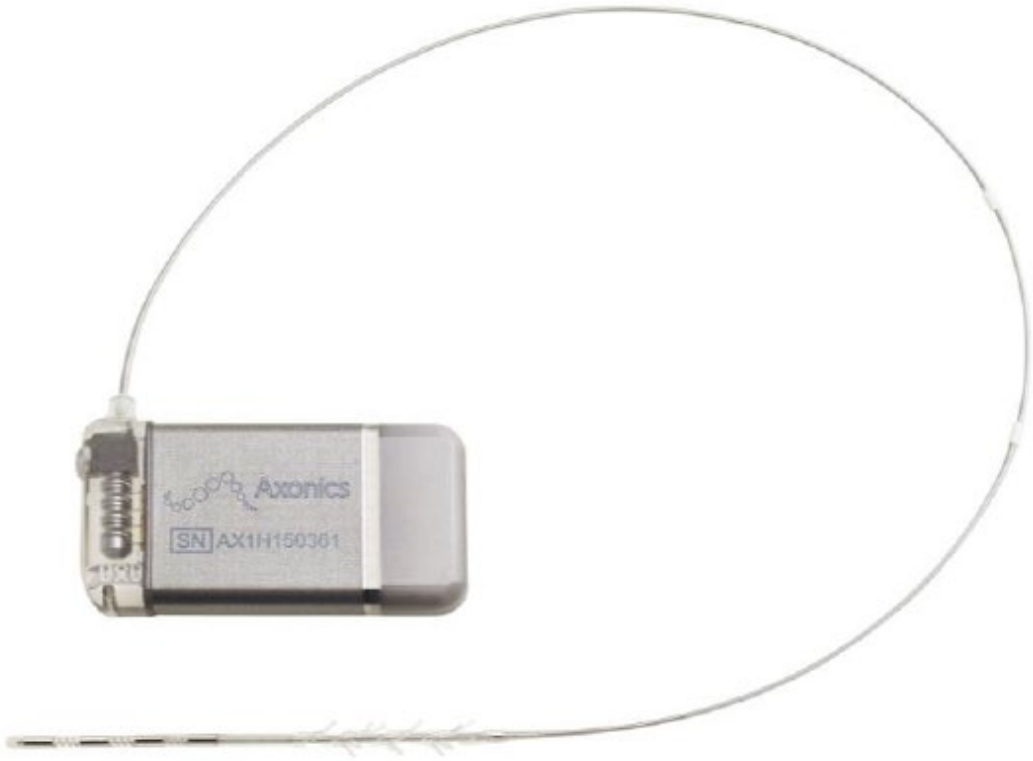
86. Upon information and belief, Axonics has indirectly infringed, and continues to indirectly infringe, literally and/or by the doctrine of equivalents, individually and/or jointly, at least claim 1 of the '112 patent by marketing and selling its Axonics r-SNM System in the United States for use or sale in accordance with and as covered by one or more claims of the '112 patent, including at least claim 1. When used, tested, offered for sale, or sold, the Axonics r-SNM System, and any other products, either alone or in combination, that operate in substantially the same manner, directly infringe the '112 patent.

87. Claim 1 of the '112 patent is reproduced below:

A medical system, comprising:
an implantable medical device;
an external charging device configured to transcutaneously transfer energy to the implantable medical device comprising;
a sensor configured to measure a temperature indicative of heat resulting from the transcutaneous transfer of energy to the implantable medical device;
a control circuit configured to compare the measured temperature to a programmable limit and to control the transfer of energy based on the comparison; and
a memory configured to store the programmable limit.

88. As a non-limiting example, upon information and belief, the Axonics r-SNM System is a medical system that includes an implantable medical device. Aspects of the implantable pulse generator of the Axonics r-SNM System corresponding to this aspect are identified in further detail below:[32]

[32] *See, e.g.,* Axonics Sacral Neuromodulation System – Tined Lead Implant Manual (Model 1201 Tined Lead; Model 1801 Lead Implant Kit); Axonics SNM Implant Technique Best Practices; Elterman, "The novel Axonics® rechargeable sacral neuromodulation system: Procedural and technical impressions from an initial North American experience," at 7, Wiley Periodicals, Neurourology and Urodynamics 2018;1–8 (December 19, 2017); *available at*: https://doi.org/10.1002/nau.23482.



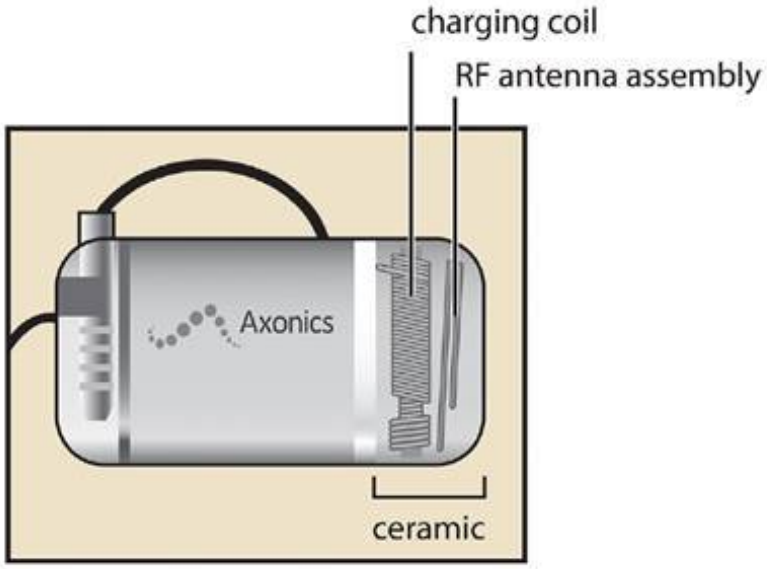


FIGURE 2 Illustration of the Axonics IPG, highlighting the location of the recharging coil and communication antennae enclosed in the ceramic portion of the IPG

89. Upon information and belief, the Axonics r-SNM System includes an external charging device configured to transcutaneously transfer energy to the

implantable medical device. Aspects of the external recharger of the Axonics r-SNM System corresponding to this aspect are identified in further detail below:[33]

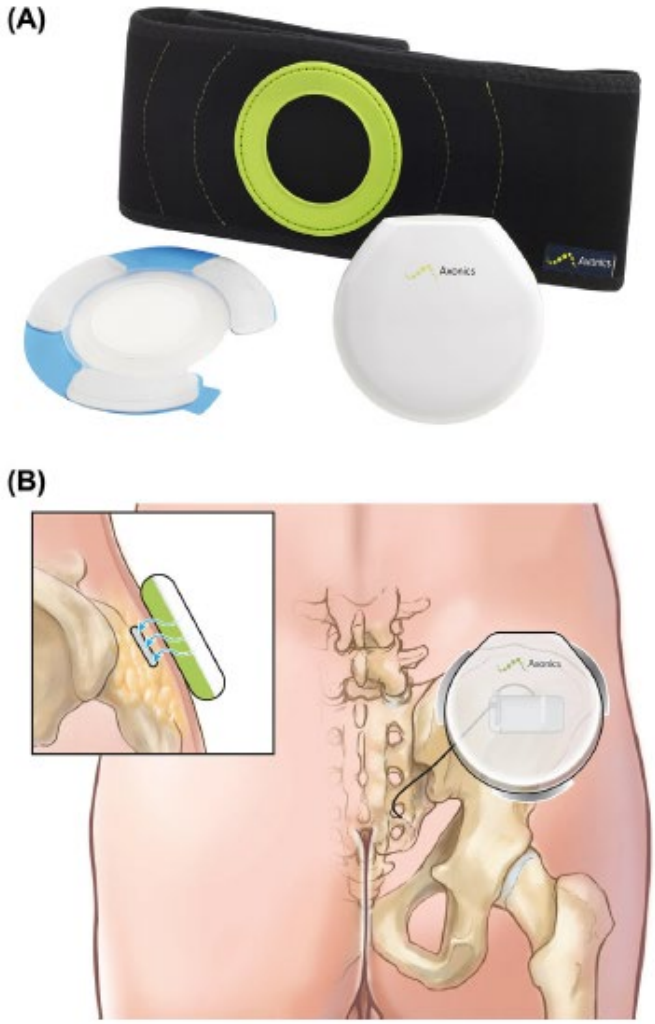


FIGURE 12 Charging the Axonics IPG using the Axonics Charging System. A, Photo of the Axonics Charging System. B, Illustration of the Charger placed over the IPG to recharge the IPG

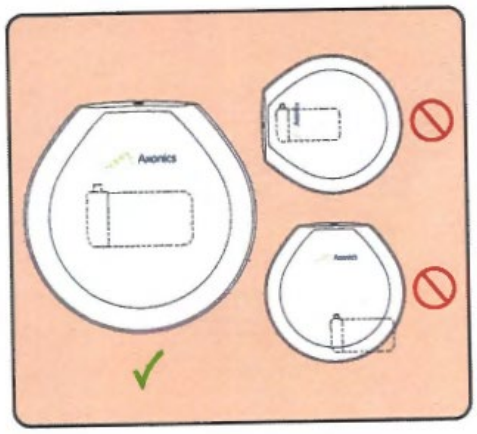
[33] *See, e.g., id.*; Axonics r-SNM System Charging System User Manual.

For best charging, place the Charger over your implanted Stimulator.

You should place your Charger with the button facing up if your Stimulator is placed horizontally (as shown to the right). Your doctor will inform you if your Stimulator is placed in a different way.

The white outline on the bottom of the Charger represents how the Charger should be placed over the Stimulator.

Good placement will ensure fast charging.



90. Upon information and belief, the Axonics r-SNM System includes an external device comprising a sensor configured to measure a temperature indicative of heat resulting from the transcutaneous transfer of energy to the implantable medical device, a control circuit configured to compare the measured temperature to a programmable limit and to control the transfer of energy based on the comparison, and a memory configured to store the programmable limit. Aspects of the external recharger of the Axonics r-SNM System corresponding to this aspect are identified in further detail below:[34]

> able SCS devices. Additionally, the system has temperature sensors and software controls that pause charging if the patient's skin temperature increases significantly. These

[34] *See, e.g., id*; Blok, "Programming settings and recharge interval in a prospective study of a rechargeable sacral neuromodulation system for the treatment of overactive bladder," Wiley Periodicals, Neurourology and Urodynamics 2018;1–6 (November 29, 2017); *available at*: https://doi.org/10.1002/nau.23476.

Environmental Specifications – Charger, Dock, Power Supply, Carrier and Belt

Item	Specification
Operating Conditions	
Temperature	5°C - 40°C (41°F – 104°F)
Pressure	70kPa – 106kPa
Humidity	15% - 95%
Storage & Shipment Conditions – Short Term (3 days or less)	
Temperature	-25°C - 70°C (-13°F – 158°F)
Pressure	57kPa – 106kPa
Humidity	15% - 95%
Storage & Shipment Conditions – Long Term (over 3 days)	
Temperature	20°C - 30°C (68°F – 86°F)
Pressure	70kPa – 106kPa
Humidity	30% - 85%

91. Upon information and belief, Axonics has been and is currently engaged in actively inducing infringement of at least claim 1 of the '112 patent under 35 U.S.C. § 271(b) and contributory infringement of at least claim 1 of the '112 patent under 35 U.S.C. § 271(c) either literally and/or by the doctrine of equivalents.

92. Upon information and belief, Axonics has committed, and continues to commit, affirmative acts that cause infringement of at least claim 1 of the '112 patent with knowledge or willful blindness of the '112 patent, and knowledge or willful blindness that the induced acts constitute infringement of at least claim 1 of the '112 patent. For example, Axonics induces such acts of infringement by its affirmative actions of intentionally providing products that when used in their normal and customary way as desired and intended by Axonics, infringe at least claim 1 of the '112 patent and by providing instructions for using its products in a manner or configuration that infringes at least claim 1 of the '112 patent.

93. Upon information and belief, Axonics provides the Axonics r-SNM System to others, such as customers, patients, hospitals, medical centers, clinics, clinicians, doctors, nurse practitioners, care providers, sales representatives, suppliers, distributors, and resellers, who, in turn, use, provision for use, test, offer for sale, or

sell the Axonics r-SNM System in a manner that directly infringes at least claim 1 of the '112 patent. Upon information and belief, Axonics provides user instructions and manuals accompanying its products for the Axonics r-SNM System, as well as other marketing and promotional materials that instruct, direct, and intentionally induce others, such as customers, patients, hospitals, medical centers, clinics, clinicians, doctors, nurse practitioners, and care providers, to use the Axonics r-SNM System in a manner that directly infringes as least claim 1 of the '112 patent.

94. Moreover, upon information and belief, Axonics has hired a U.S. sales team that includes former members of Medtronic's sales team who received training from Medtronic, and that team consists of at least 11 regional sales managers, between 85 and 90 sales professionals, and 30 clinical specialists. Upon information and belief, Axonics' U.S. sales team, who are fully trained regarding Axonics' product, have been and will be "strategically mapped to and located where current high volume implanters are practicing in the United States."[35] Upon information and belief, the sales team has been responsible for and continues to be responsible for "supporting cases in the [operating room], interacting with patients and programming the implanted [Axonics] device."[36] Upon information and belief, the sales team has been involved with and continues to be involved with the distribution of marketing, promotional, and training materials, which instruct Axonics' customers regarding the use of the Axonics r-SNM System in the United States in a manner that directly infringes one or more claims of the '112 patent.

95. Upon information and belief, Axonics has contributed to, and continues to contribute to, the infringement of the '112 patent by others by knowingly providing the Axonics r-SNM System that constitutes a material part of at least claim 1 of the '112 patent, with knowledge that the Axonics r-SNM System is to be especially made

[35] *See* Q1 2019 Axonics Modulation Technologies Inc. Earnings Call, May 8, 2019, 8:30PM GMT).

[36] *Id.*

or especially adapted for use in infringement of the '112 patent. Upon information and belief, Axonics has also committed, and continues to commit contributory infringement by, *inter alia*, knowingly offering for sale and selling the Axonics r-SNM System, which has no substantial non-infringing uses, and which constitutes a material part of at least claim 1 of the '112 patent.

96. As discussed above, the Axonics r-SNM System is designed and sold to be used only for recharging in a specific way, as directed by the instructions in the manuals and promotional materials. The manuals and promotional materials provide specific instructions for using the Axonics r-SNM System in a way that infringes at least one claim of the '112 patent, and they do not contemplate any non-infringing uses.

97. Upon information and belief, Axonics knew of the '112 patent or was willfully blind to its existence. Upon information and belief, Axonics had knowledge of the '112 patent and continues to have knowledge of the '112 patent, including but not limited to at least one or more of the following events: the filing of Medtronic's Complaint against Axonics; in the course of its due diligence and freedom to operate analyses, including the "many initial months [spent] examining patents and IP issues";[37] and as part of the due-diligence investigation performed for SEC filings. By the time of trial, Axonics will have known and intended (since receiving such notice) that its continued actions would infringe and actively induce and contribute to the infringement of at least claim 1 of the '112 patent.

98. Upon information and belief, Axonics' infringement of the '112 patent has been and continues to be willful.

99. Axonics' infringement of the '112 patent has been without permission, consent, authorization, or license of Medtronic.

100. As a result of Axonics' infringement, Medtronic has suffered and will

[37] https://www.businessinfocusmagazine.com/2018/05/axonics-prepares-for-introduction-of-its-sacral-neuromodulation-system/

continue to suffer damages in an amount to be proved at trial. In addition, Axonics' infringement caused and will continue to cause Medtronic irreparable harm, for which there is no adequate remedy at law, warranting an injunction from the Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that the Court:

A. Adjudge that Axonics has infringed and is infringing one or more claims of each of the above patents-in-suit, directly and/or indirectly, literally, and/or under the doctrine of equivalents;

B. Award damages sufficient to compensate Plaintiffs for Axonics' infringement under 35 U.S.C. § 284, including an award of treble damages for willful infringement;

C. Find this case exceptional under 35 U.S.C. § 285 and awarding Medtronic its reasonable attorneys' fees;

D. Permanently enjoin Axonics, and all persons in concert or participation with it, from directly or indirectly infringing one or more claims of each of the above patents-in-suit, directly and/or indirectly, literally, and/or under the doctrine of equivalents;

E. Award Plaintiffs their costs and expenses incurred in this action;

F. Award Plaintiffs pre-judgment and post-judgment interest; and

G. Grant Plaintiffs such further relief as the Court deems just and appropriate.

DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury of all claims so triable.

Dated: November 4, 2019

WINSTON & STRAWN LLP

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