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12 Attorneys for Plaintiffs
 MEDTRONIC, INC.; MEDTRONIC PUERTO RICO OPERATIONS CO.;
 13 MEDTRONIC LOGISTICS, LLC; MEDTRONIC USA, INC.

14 **UNITED STATES DISTRICT COURT**
 15 **CENTRAL DISTRICT OF CALIFORNIA**

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

20 Plaintiffs,

21 v.

22 AXONICS MODULATION
 23 TECHNOLOGIES, INC.,

24 Defendant.

Case No. 8:19-cv-2115

**COMPLAINT FOR PATENT
 INFRINGEMENT**

JURY TRIAL DEMANDED

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

6 THE PARTIES

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

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

12 3. Plaintiff Medtronic Logistics is a Minnesota corporation having its
13 principal place of business located at 710 Medtronic Parkway, Minneapolis, MN
14 55432.

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

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

20 JURISDICTION AND VENUE

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

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

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

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

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

7 **FACTUAL BACKGROUND**

8 **Medtronic's Background**

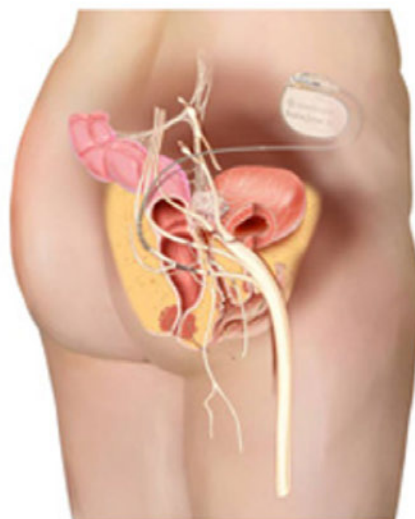
9 10. Medtronic is one of the world's largest medical technology, services, and
10 solutions companies with the focus of alleviating pain, restoring health, and extending
11 life for millions of people around the world. In 2018, Medtronic was winner of the
12 prestigious USPTO Patents for Humanity award.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

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

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

28 13. Generally, implantation of InterStim therapy involves surgically

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



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

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

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.

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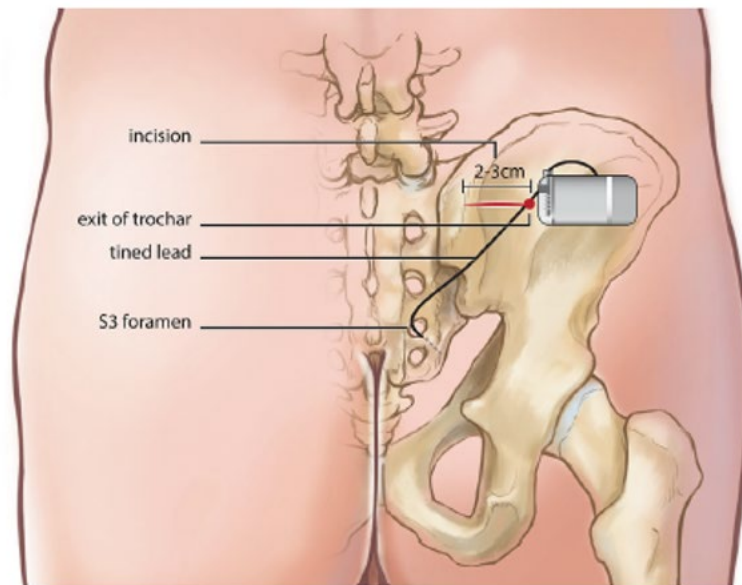
19. According to the FDA Summary of Safety and Effectiveness Data for Axonics’ r-SNM System, “[t]he components of the Axonics System are similar to those used in ... the Medtronic® InterStim® Therapy System.”⁵ According to the same regulatory filing, the Axonics r-SNM System is similar in design, technology, 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>.

1 Axonics r-SNM System.⁸ The image below shows the Axonics r-SNM system
 2 implanted.⁹



13 **FIGURE 11** Placement of the Axonics IPG

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

18 21. Axonics announced that the first commercial implants of the Axonics r-
 19 SNM System in the United States took place on October 29, 2019.¹¹

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

21 ⁹ See Elterman, “The novel Axonics® rechargeable sacral neuromodulation system:
 22 Procedural and technical impressions from an initial North American experience,” at
 23 7, Wiley Periodicals, *Neurology and Urodynamics* 2018;1–8 (December 19, 2017);
 available at: <https://doi.org/10.1002/nau.23482>.

24 ¹⁰ See, e.g., Axonics Sacral Neuromodulation System – Physician’s Neurostimulator
 25 Implant Manual (“FDA Physician Manual”) at 56–64; available at:
 26 https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190006c.pdf; see also Axonics
 27 Sacral Neuromodulation System – Tined Lead Implant Manual (Model 1201 Tined
 28 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>.

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

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

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

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

1 the '324 patent.

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

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

20 **COUNT I**

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

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

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

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

5 33. Upon information and belief, Axonics has indirectly infringed, and
6 continues to indirectly infringe, literally and/or by the doctrine of equivalents,
7 individually and/or jointly, at least claim 14 of the '756 patent by marketing and
8 selling its Axonics r-SNM System in the United States for use in accordance with and
9 as covered by one or more claims of the '756 patent, including at least claim 14.
10 When used or tested, the Axonics r-SNM System, and any other products, either alone
11 or in combination, that operate in substantially the same manner, directly infringe the
12 '756 patent.

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

14 *A method comprising:*

15 *percutaneously introducing an introducer comprising*
16 *an introducer lumen extending between an introducer lumen*
17 *proximal end opening and an introducer lumen distal end*
18 *opening through body tissue to locate the introducer lumen*
19 *distal end opening adjacent to a stimulation site;*

20 *disposing an implantable medical lead within the*
21 *introducer lumen, wherein the implantable medical lead*
22 *comprises:*

23 *a lead body extending between a lead proximal end*
24 *and a lead distal end;*

25 *a plurality of connector elements formed in a*
26 *connector array adjacent the lead proximal end;*

27 *a plurality of stimulation electrodes arranged in an*
28 *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

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

12 35. As a non-limiting example, the Axonics r-SNM System is implanted
13 according to a method. Upon information and belief, an implantation method of the
14 Axonics r-SNM System provides for percutaneously introducing an introducer
15 comprising an introducer lumen extending between an introducer lumen proximal end
16 opening and an introducer lumen distal end opening through body tissue to locate the
17 introducer lumen distal end opening adjacent to a stimulation site. Aspects of the
18 method of implantation of the Axonics r-SNM System corresponding to this step are
19 described in Axonics' product manuals as shown below:¹²
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27 ¹² See, e.g., Axonics Sacral Neuromodulation System – Tined Lead Implant Manual
28 (Model 1201 Tined Lead; Model 1801 Lead Implant Kit); see also Axonics SNM
Implant Technique Best Practices at 19–21.

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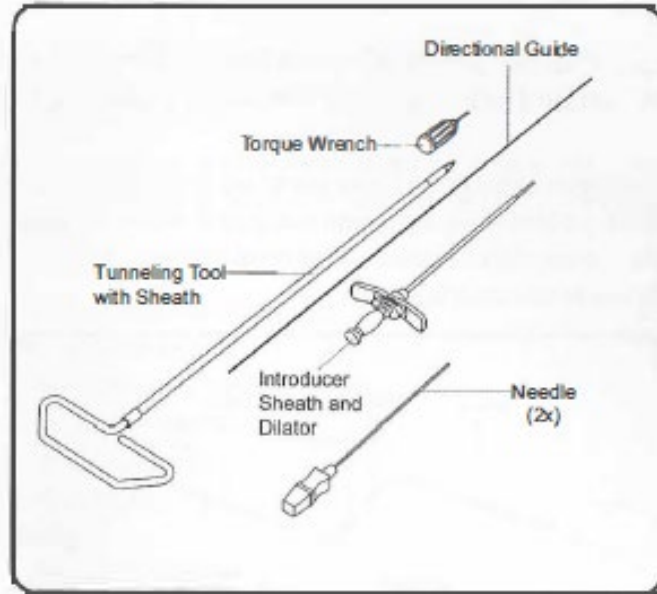


Figure 2. Lead implant tools.

LEAD IMPLANT PROCEDURE

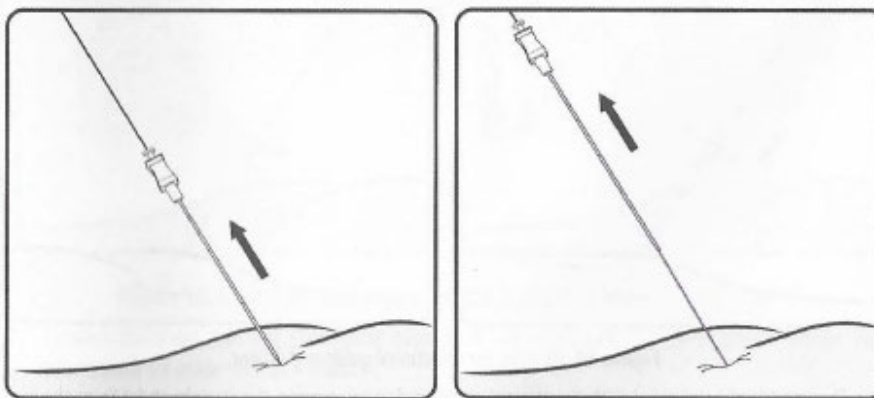
The following section describes the procedure for implanting the Axonics tined lead.

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).

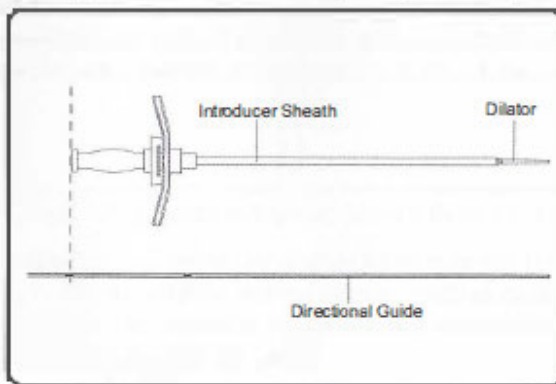
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4. While keeping the directional guide in place, gently slide the foramen needle out of the foramen over the directional guide, leaving the guide in place (Figure 11).



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Figure 11. Remove the foramen needle.

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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.



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

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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

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¹³ See, e.g., *id.*

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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.

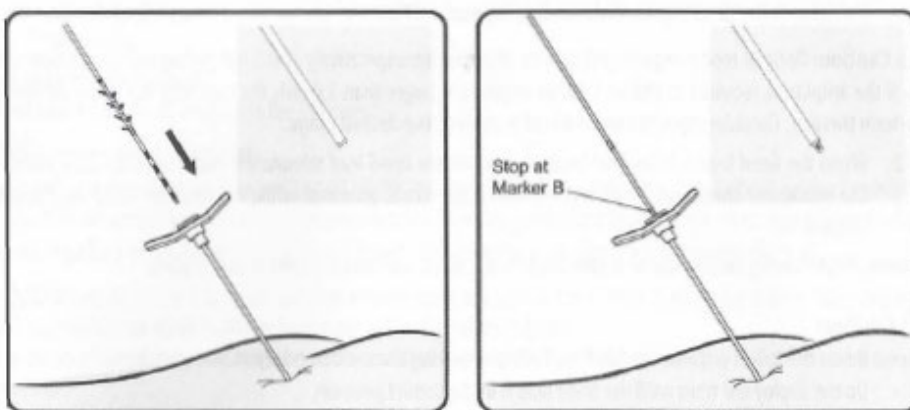


Figure 15. Insert the lead through the introducer sheath.

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**).

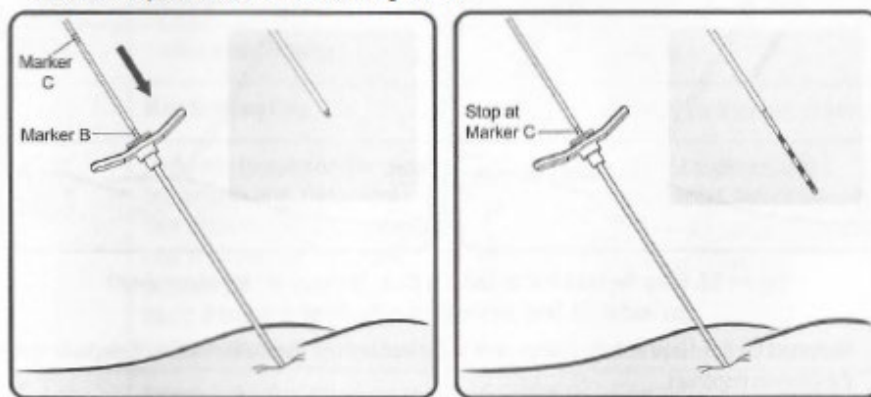
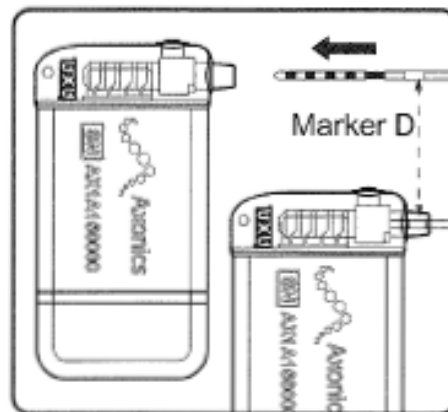
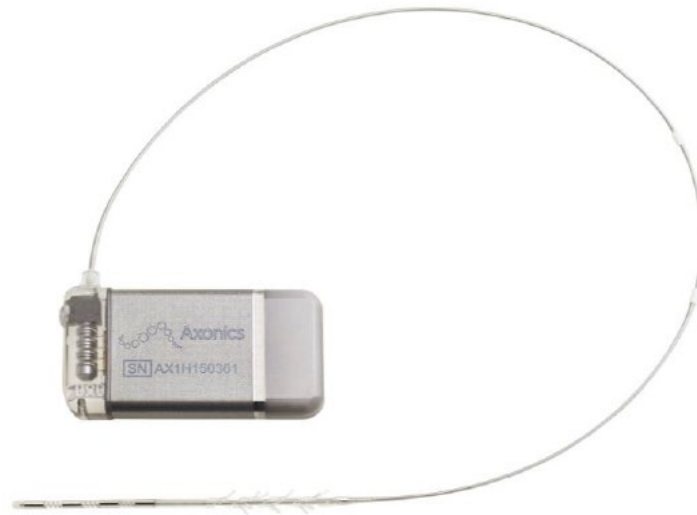


Figure 16. Advance the lead into the introducer sheath to expose the electrodes.

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

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



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

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26 ¹⁴ See, e.g., Axonics Sacral Neuromodulation System – Tined Lead Implant Manual
27 (Model 1201 Tined Lead; Model 1801 Lead Implant Kit); Axonics Sacral
28 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>.

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(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.

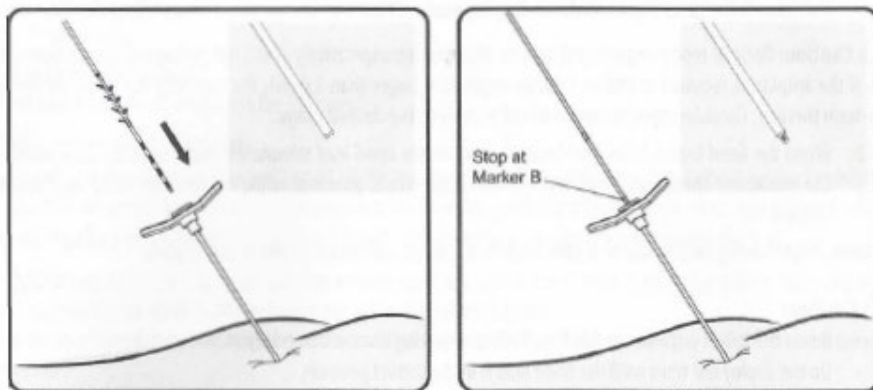


Figure 15. Insert the lead through the introducer sheath.

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).

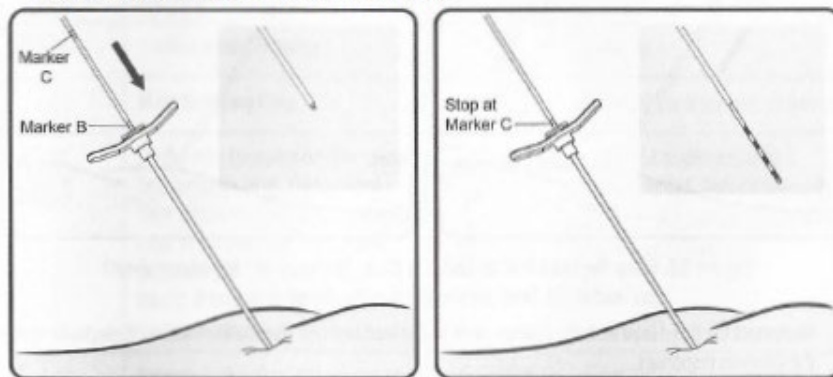


Figure 16. Advance the lead into the introducer sheath to expose the electrodes.

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).

1 12. When the tined lead is in its final location, remove the tined lead stimulation cable then carefully withdraw
2 the introducer sheath and lead stylet under fluoroscopic guidance while holding the tined lead in place
3 (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.

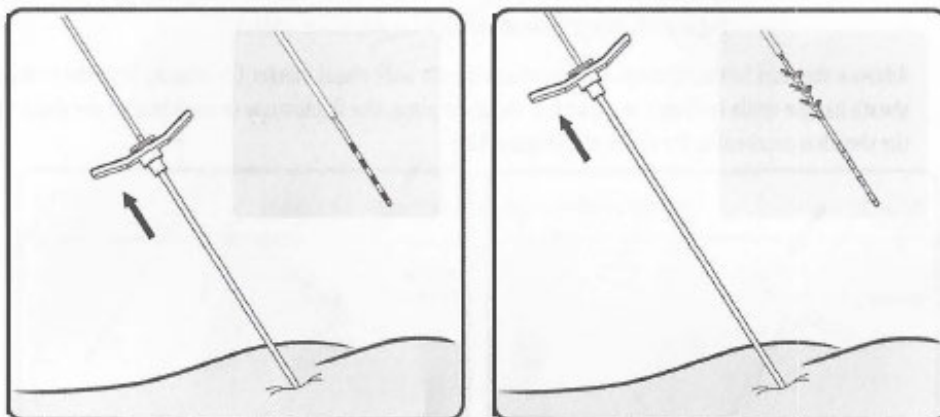


Figure 18. Grasp the tined lead to hold it in place. Withdraw the introducer sheath and lead stylet. Tines are deployed as the sheath is removed.

4 40. Upon information and belief, Axonics has been, and currently is engaged
5 in actively inducing infringement of at least claim 14 of the '756 patent under 35
6 U.S.C. § 271(b) and contributory infringement of at least claim 14 of the '756 patent
7 under 35 U.S.C. § 271(c) either literally and/or by the doctrine of equivalents.
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10 41. Upon information and belief, Axonics has committed, and continues to
11 commit, affirmative acts that cause infringement of at least claim 14 of the '756 patent
12 with knowledge or willful blindness of the '756 patent and knowledge or willful
13 blindness that the induced acts constitute infringement of at least claim 14 of the '756
14 patent. For example, Axonics induces such acts of infringement by its affirmative
15 actions of intentionally providing products that when used in their normal and
16 customary way as desired and intended by Axonics, infringe at least claim 14 of the
17 '756 patent and by providing instructions for using its products in a manner or
18 configuration that infringes at least claim 14 of the '756 patent.
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27 42. Upon information and belief, Axonics provides the Axonics r-SNM
28 System to others, such as hospitals, medical centers, clinics, clinicians, doctors, nurse

1 practitioners, and care providers, who, in turn, use, provision for use, or test the
2 Axonics r-SNM System in a manner that directly infringes at least claim 14 of the
3 '756 patent. Upon information and belief, Axonics provides user instructions and
4 manuals accompanying its products for the Axonics r-SNM System as well as other
5 marketing and promotional materials that instruct, direct, and intentionally induce
6 others, such as hospitals, medical centers, clinics, clinicians, doctors, nurse
7 practitioners, and care providers, to use the Axonics r-SNM System in a manner that
8 directly infringes at least claim 14 of the '756 patent, for the reasons discussed above.

9 43. Moreover, upon information and belief, Axonics has hired a U.S. sales
10 team, that includes former members of Medtronic's sales team who received training
11 from Medtronic, and that team consists of at least 11 regional sales managers, between
12 85 and 90 sales professionals, and 30 clinical specialists. Upon information and
13 belief, Axonics' U.S. sales team, who are fully trained regarding Axonics' product,
14 have been and will be "strategically mapped to and located where current high volume
15 implanters are practicing in the United States."¹⁷ Upon information and belief, the
16 sales team has been responsible for and continues to be responsible for "supporting
17 cases in the [operating room], interacting with patients and programming the
18 implanted [Axonics] device."¹⁸ Upon information and belief, the sales team has been
19 involved with and continues to be involved with the distribution of marketing,
20 promotional, and training materials, which instruct Axonics' customers regarding the
21 use of the Axonics r-SNM System in the United States in a manner that directly
22 infringes one or more claims of the '756 patent.

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

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

28 ¹⁸ *Id.*

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

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

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

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

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

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

1 consent, authorization, or license from Medtronic.

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

6 **COUNT II**

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

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

10 51. Upon information and belief, Axonics has directly infringed, and
11 continues to directly infringe, literally and/or by the doctrine of equivalents,
12 individually and/or jointly, at least claim 11 of the '314 patent by making, using,
13 testing, selling, offering for sale, and/or importing into the United States products
14 covered by at least claim 11 of the '314 patent. Axonics' products that infringe the
15 '314 patent include, but are not limited to, Implantable Pulse Generator Model 1101,
16 Tined Lead Kit Model 1201, and Surgical Tool Kit Model 1801 (collectively referred
17 to in Count II as the "Axonics r-SNM System"), and any other Axonics products,
18 either alone or in combination, that operate in substantially the same manner.

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

27 53. Claim 11 of the '314 patent is reproduced below:
28

1 *A system comprising:*

2 *an implantable pulse generator configured to*
3 *generate electrical stimulation;*

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

9 *a lead body extending between a proximal end and a*
10 *distal end;*

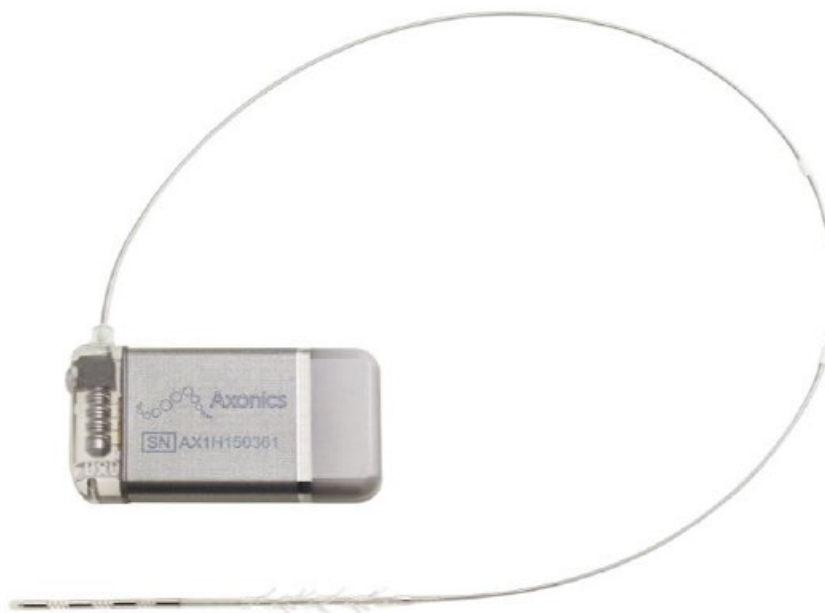
11 *a plurality of conductors within the lead body;*

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

15 *a plurality of tine elements extending from the lead*
16 *body, wherein all tine elements of the plurality of tine*
17 *elements are positioned between a most proximal electrode*
18 *of the plurality of electrodes and the proximal end of the*
19 *lead body, each tine element comprising a plurality of*
20 *flexible, pliant tines, each tine having a tine width and*
21 *thickness and extending a tine length from an attached tine*
22 *end to a free tine end, the attached tine end attached to the*
23 *lead body from a tine attachment site and supporting the*
24 *tine extending outwardly of the lead body and proximally*
25 *toward the lead proximal end, wherein the plurality of tines*
26 *of the plurality of tine elements are adapted to be folded*
27 *inward against the lead body when fitted into and*
28 *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

1 are identified in further detail below:²⁰



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

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

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

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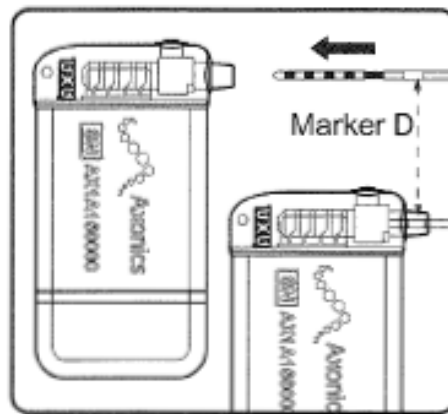
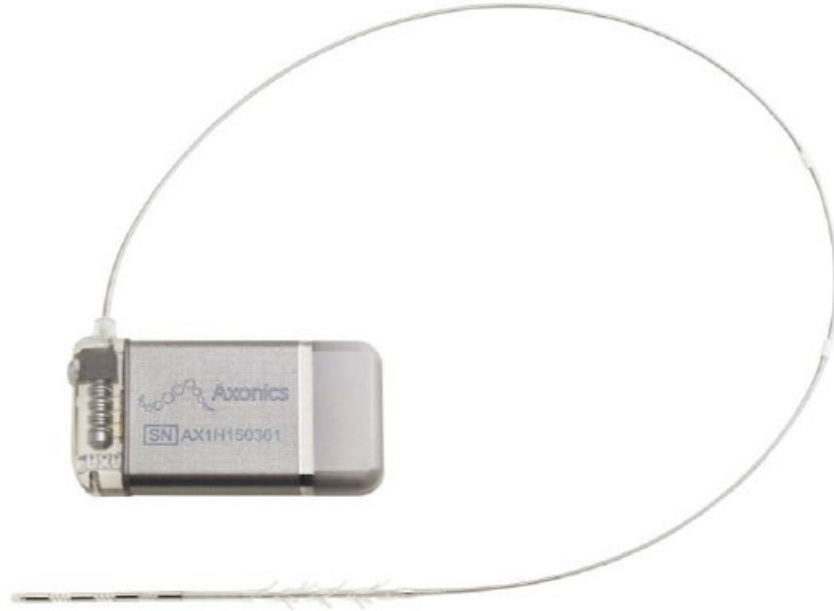


Figure 5: Insert lead fully into the Neurostimulator connector block.



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-

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



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6 (B)



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15 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).

16 **Notes:**

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- 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.

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

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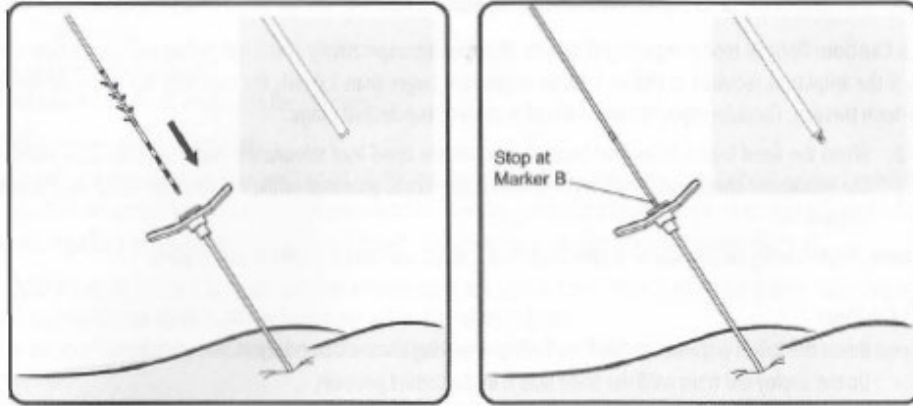


Figure 15. Insert the lead through the introducer sheath.

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**).

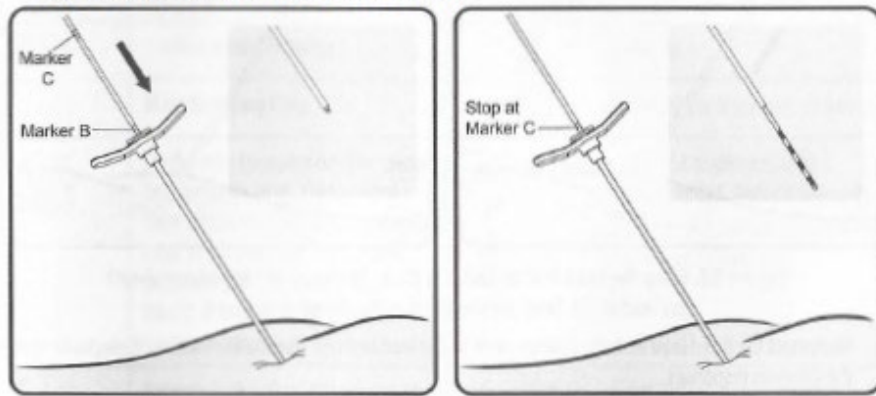


Figure 16. Advance the lead into the introducer sheath to expose the electrodes.

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.

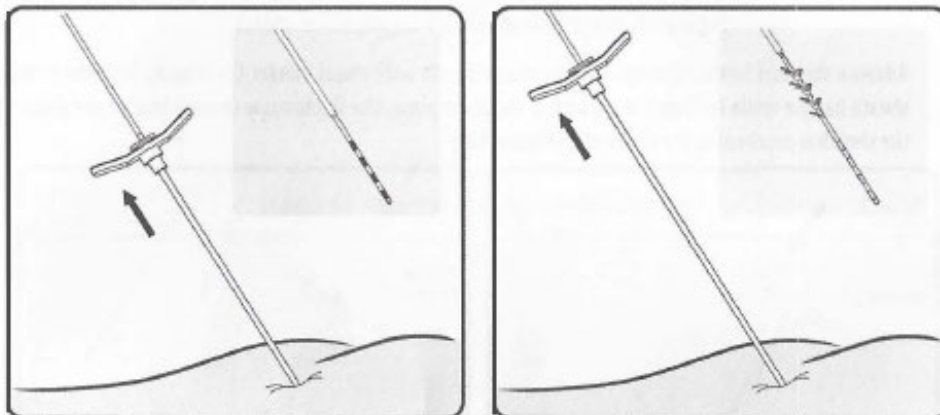


Figure 18. Grasp the tined lead to hold it in place. Withdraw the introducer sheath and lead stylet. Tines are deployed as the sheath is removed.

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,

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

10 60. Moreover, upon information and belief, Axonics has hired a U.S. sales
11 team that includes former members of Medtronic's sales team who received training
12 from Medtronic, and that team consists of at least 11 regional sales managers, between
13 85 and 90 sales professionals, and 30 clinical specialists. Upon information and
14 belief, Axonics' U.S. sales team, who are fully trained regarding Axonics' product,
15 have been and will be "strategically mapped to and located where current high volume
16 implanters are practicing in the United States."²³ Upon information and belief, the
17 sales team has been responsible for and continues to be responsible for "supporting
18 cases in the [operating room], interacting with patients and programming the
19 implanted [Axonics] device."²⁴ Upon information and belief, the sales team has been
20 involved with and continues to be involved with the distribution of marketing,
21 promotional, and training materials, which instruct Axonics' customers regarding the
22 use of the Axonics r-SNM System in the United States in a manner that directly
23 infringes one or more claims of the '314 patent.

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

26 _____
27 ²³ See Q1 2019 Axonics Modulation Technologies Inc. Earnings Call, May 8, 2019,
28 8:30PM GMT).

²⁴ *Id.*

1 the Axonics r-SNM System that constitutes a material part of at least claim 11 of the
2 '314 patent, with knowledge that the Axonics r-SNM System is to be especially made
3 or especially adapted for use in infringement of the '314 patent. Upon information
4 and belief, Axonics has also committed, and continues to commit contributory
5 infringement by, *inter alia*, knowingly offering for sale and selling the Axonics r-
6 SNM System, which has no substantial non-infringing uses, and which constitutes a
7 material part of at least claim 11 of the '314 patent.

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

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

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

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

27 _____
28 ²⁵ <https://www.businessinfocusmagazine.com/2018/05/axonics-prepares-for-introduction-of-its-sacral-neuromodulation-system/>

1 consent, authorization, or license of Medtronic.

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

6 **COUNT III**

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

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

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

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

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

28 *A system, comprising:*

1 *an implantable medical device comprising a*
2 *secondary coil; and*
3 *an external device comprising:*
4 *a primary coil adapted to be transcutaneously*
5 *coupled to the secondary coil to transfer energy to the*
6 *implantable medical device;*
7 *a housing having a side adapted to be positioned in*
8 *proximity to the secondary coil when the primary coil is*
9 *transcutaneously coupled to the secondary coil;*
10 *a temperature sensor adapted to provide an output*
11 *indicative of a temperature of the side of the housing; and*
12 *control circuitry adapted to control the transfer of energy to*
13 *the implantable medical device based on the output of the*
14 *temperature sensor to limit a temperature to which a patient*
15 *is exposed during the transfer of energy to the implantable*
16 *medical device.*

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

25 ²⁶ See, e.g., Axonics Sacral Neuromodulation System – Tined Lead Implant Manual
26 (Model 1201 Tined Lead; Model 1801 Lead Implant Kit); Axonics SNM Implant
27 Technique Best Practices; Elterman, “The novel Axonics® rechargeable sacral
28 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>.

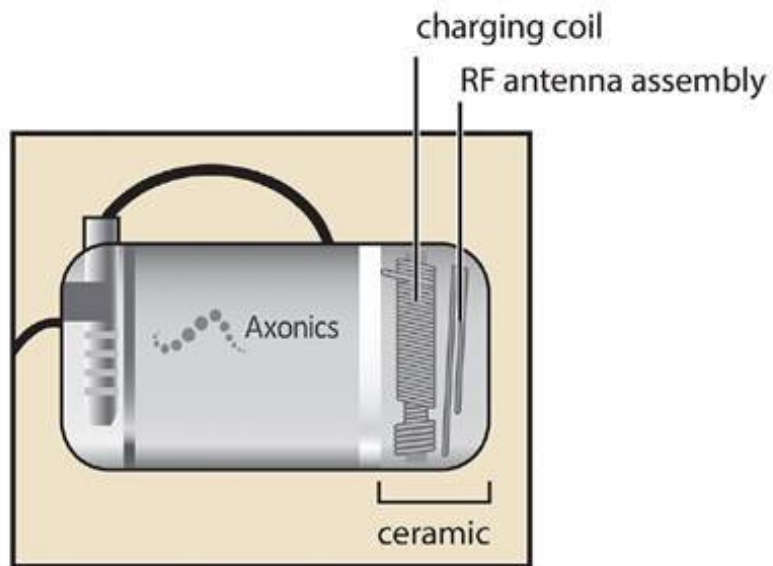
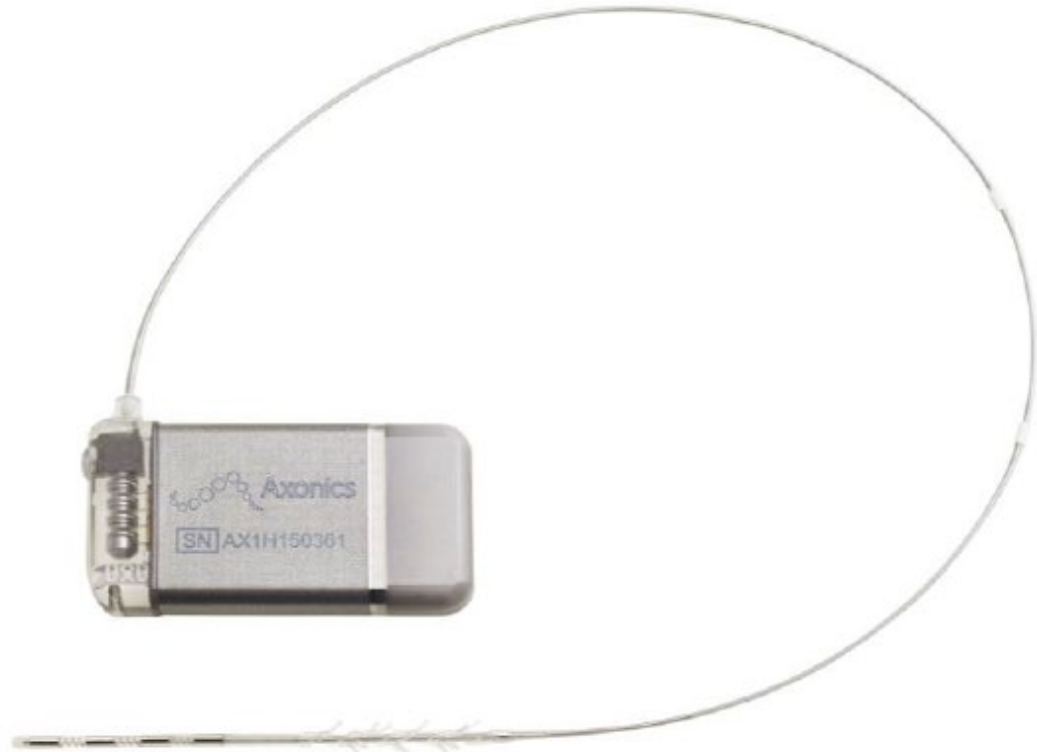
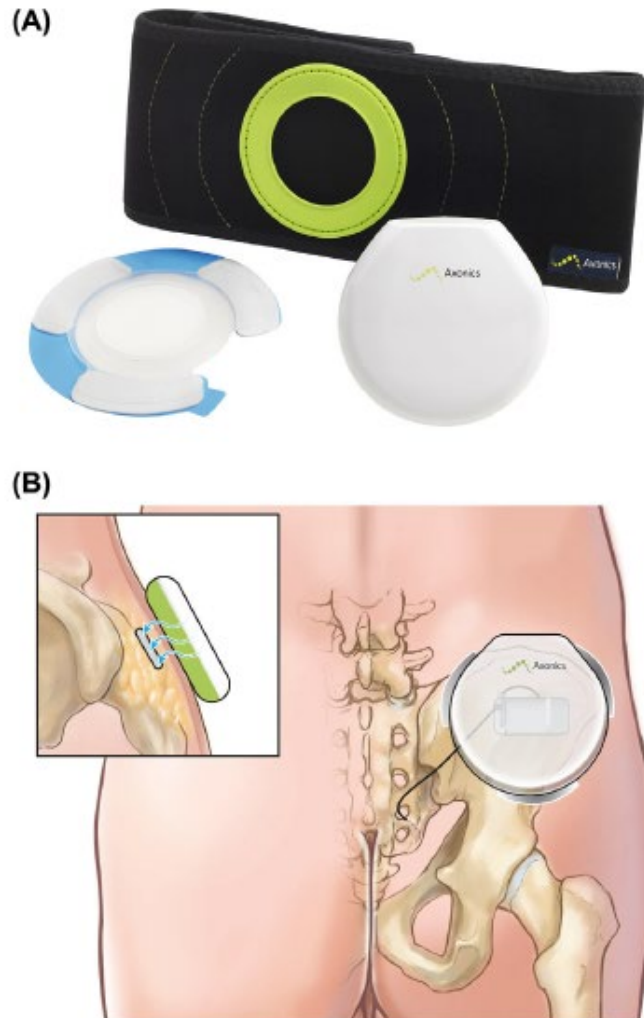


FIGURE 2 Illustration of the Axonics IPG, highlighting the location of the recharging coil and communication antennae enclosed in the ceramic portion of the IPG

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

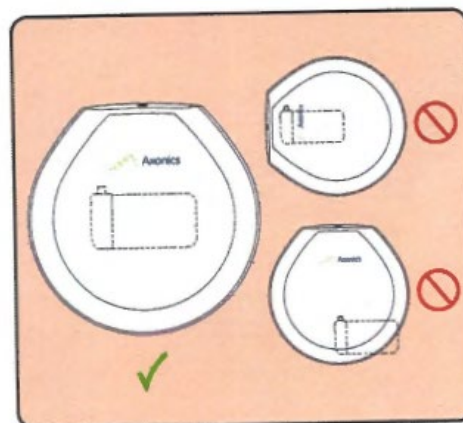
1 the secondary coil to transfer energy to the implantable medical device and a housing
2 having a side adapted to be positioned in proximity to the secondary coil when the
3 primary coil is transcutaneously coupled to the secondary coil. Aspects of the
4 external recharger of the Axonics r-SNM System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



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

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

1 For best charging, place the
 2 Charger over your implanted
 3 Stimulator.
 4 You should place your Charger
 5 with the button facing up if your
 6 Stimulator is placed horizontally
 7 (as shown to the right). Your
 8 doctor will inform you if your
 9 Stimulator is placed in a different
 10 way.



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

15 Good placement will ensure fast
 16 charging.

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

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

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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,

1 clinicians, doctors, nurse practitioners, care providers, sales representatives, suppliers,
2 distributors, and resellers, who, in turn, use, provision for use, test, offer for sale, or
3 sell the Axonics r-SNM System in a manner that directly infringes at least claims 1, 4,
4 and 11 of the '324 patent. Upon information and belief, Axonics provides user
5 instructions and manuals accompanying its products for the Axonics r-SNM System,
6 as well as other marketing and promotional materials that instruct, direct, and
7 intentionally induce others, such as customers, patients, hospitals, medical centers,
8 clinics, clinicians, doctors, nurse practitioners, and care providers, to use the Axonics
9 r-SNM System in a manner that directly infringes as least claims 1, 4, and 11 of the
10 '324 patent.

11 77. Moreover, upon information and belief, Axonics has hired a U.S. sales
12 team that includes former members of Medtronic's sales team who received training
13 from Medtronic, and that team consists of at least 11 regional sales managers, between
14 85 and 90 sales professionals, and 30 clinical specialists. Upon information and
15 belief, Axonics' U.S. sales team, who are fully trained regarding Axonics' product,
16 have been and will be "strategically mapped to and located where current high volume
17 implanters are practicing in the United States."²⁹ Upon information and belief, the
18 sales team has been responsible for and continues to be responsible for "supporting
19 cases in the [operating room], interacting with patients and programming the
20 implanted [Axonics] device."³⁰ Upon information and belief, the sales team has been
21 involved with and continues to be involved with the distribution of marketing,
22 promotional, and training materials, which instruct Axonics' customers regarding the
23 use of the Axonics r-SNM System in the United States in a manner that directly
24 infringes one or more claims of the '324 patent.

25 78. Upon information and belief, Axonics has contributed to, and continues
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27 ²⁹ See Q1 2019 Axonics Modulation Technologies Inc. Earnings Call, May 8, 2019,
28 8:30PM GMT).

³⁰ *Id.*

1 to contribute to, the infringement of the '324 patent by others by knowingly providing
2 the Axonics r-SNM System that constitutes a material part of at least claims 1, 4, and
3 11 of the '324 patent, with knowledge that the Axonics r-SNM System is to be
4 especially made or especially adapted for use in infringement of the '324 patent.
5 Upon information and belief, Axonics has also committed, and continues to commit
6 contributory infringement by, *inter alia*, knowingly offering for sale and selling the
7 Axonics r-SNM System, which has no substantial non-infringing uses, and which
8 constitutes a material part of at least claims 1, 4, and 11 of the '324 patent.

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

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

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

27 _____
28 ³¹ <https://www.businessinfocusmagazine.com/2018/05/axonics-prepares-for-introduction-of-its-sacral-neuromodulation-system/>.

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

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

7 **COUNT IV**

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

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

11 85. Upon information and belief, Axonics has directly infringed, and
12 continues to directly infringe, literally and/or by the doctrine of equivalents,
13 individually and/or jointly, at least claim 1 of the '112 patent by making, using,
14 testing, selling, offering for sale, and/or importing into the United States products
15 covered by at least claim 1 of the '112 patent. Axonics' products that infringe the
16 '112 patent include, but are not limited to, the Model 1101 Neurostimulator and
17 Model 1401 charging system, (collectively referred to in Count IV as the "Axonics r-
18 SNM System"), and any other Axonics products, either alone or in combination, that
19 operate in substantially the same manner.

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

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

1 *A medical system, comprising:*
2 *an implantable medical device;*
3 *an external charging device configured to*
4 *transcutaneously transfer energy to the implantable medical*
5 *device comprising;*
6 *a sensor configured to measure a temperature*
7 *indicative of heat resulting from the transcutaneous transfer*
8 *of energy to the implantable medical device;*
9 *a control circuit configured to compare the measured*
10 *temperature to a programmable limit and to control the*
11 *transfer of energy based on the comparison; and*
12 *a memory configured to store the programmable limit.*

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

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25 ³² See, e.g., Axonics Sacral Neuromodulation System – Tined Lead Implant Manual
26 (Model 1201 Tined Lead; Model 1801 Lead Implant Kit); Axonics SNM Implant
27 Technique Best Practices; Elterman, “The novel Axonics® rechargeable sacral
28 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>.

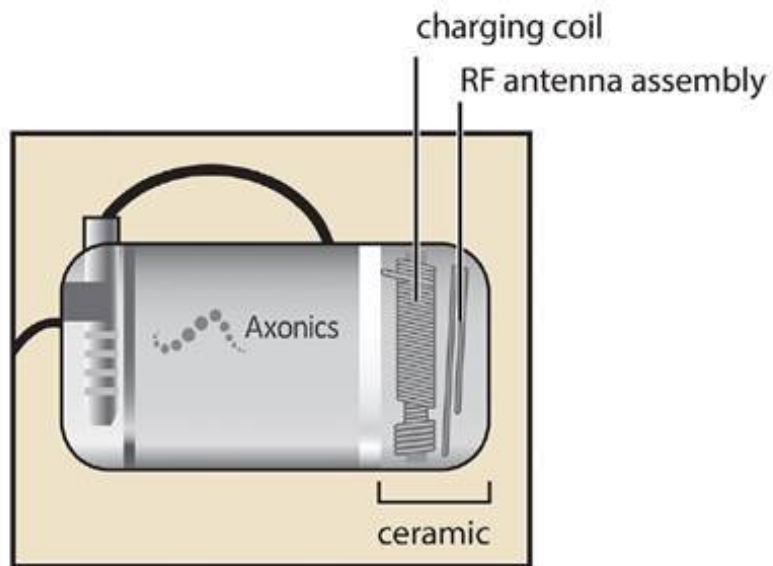
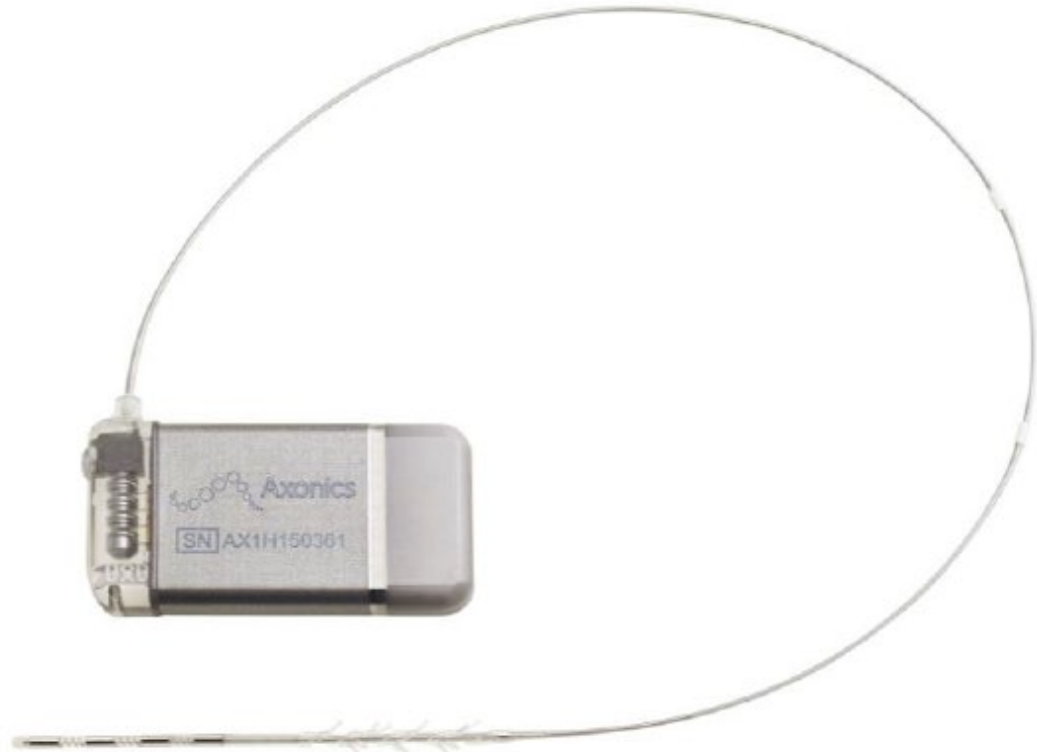
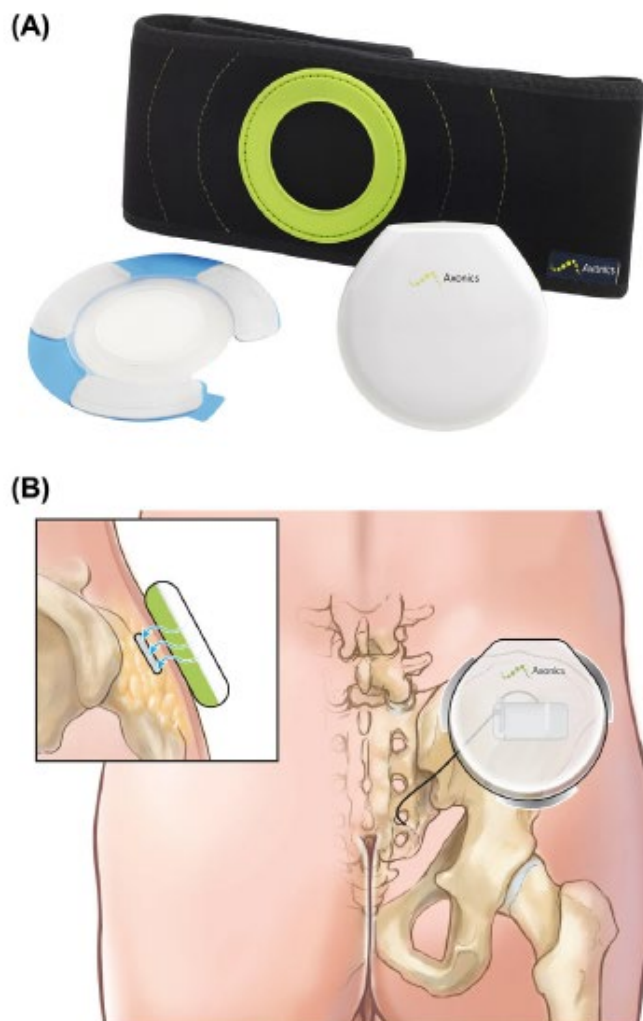


FIGURE 2 Illustration of the Axonics IPG, highlighting the location of the recharging coil and communication antennae enclosed in the ceramic portion of the IPG

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

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

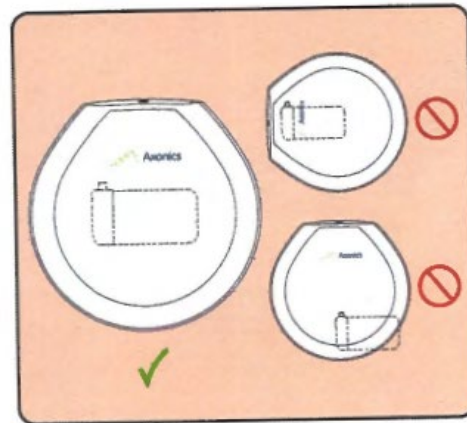


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FIGURE 12 Charging the Axonics IPG using the Axonics Charging System. A, Photo of the Axonics Charging System. B, Illustration of the Charger placed over the IPG to recharge the IPG

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

1 For best charging, place the
 2 Charger over your implanted
 3 Stimulator.
 4 You should place your Charger
 5 with the button facing up if your
 6 Stimulator is placed horizontally
 7 (as shown to the right). Your
 8 doctor will inform you if your
 9 Stimulator is placed in a different
 10 way.



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

15 Good placement will ensure fast
 16 charging.

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

25
 26 **able SCS devices. Additionally, the system has temperature**
 27 **sensors and software controls that pause charging if the**
 28 **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

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

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

22 95. Upon information and belief, Axonics has contributed to, and continues
23 to contribute to, the infringement of the '112 patent by others by knowingly providing
24 the Axonics r-SNM System that constitutes a material part of at least claim 1 of the
25 '112 patent, with knowledge that the Axonics r-SNM System is to be especially made

26 _____
27 ³⁵ See Q1 2019 Axonics Modulation Technologies Inc. Earnings Call, May 8, 2019,
28 8:30PM GMT).

³⁶ *Id.*

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

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

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

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

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

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

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

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

4 **PRAYER FOR RELIEF**

5 WHEREFORE, Plaintiffs request that the Court:

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

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

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

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

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

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

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

22 **DEMAND FOR JURY TRIAL**

23 Plaintiffs demand trial by jury of all claims so triable.

24
25 Dated: November 4, 2019

WINSTON & STRAWN LLP

26
27 By: /s/ Nimalka Wickramasekera
George C. Lombardi
Nimalka Wickramasekera
28 J.R. McNair

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