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16	UNITED STATES D	DISTRICT COURT
17	SOUTHERN DISTRIC	
18	SAN DIEGO	
19	NUVASIVE, INC., a Delaware) CASE NO. <u>'18CV0347 GPC BLM</u>
20	corporation,) COMPLAINT FOR PATENT
21	Plaintiff,) INFRINGEMENT
22	V.)
23	AL DUA TEGULAL DINAGGINAG) JURY TRIAL DEMANDED
24	ALPHATEC HOLDINGS, INC., a Delaware corporation and ALPHATEC)
25	SPINE, INC., a California corporation,	,)
26	Defendants.)
27	Defendants.	/
28		
20		
	PATENT INFRINGEMENT COMPLAINT	

Plaintiff NuVasive, Inc. ("NuVasive") hereby files this Complaint against Defendants Alphatec Holdings, Inc. and Alphatec Spine, Inc. (collectively, "Alphatec" or "Defendants") for Alphatec's infringement of NuVasive's U.S. Patent No. 7,819,801; U.S. Patent No. 8,355,780; U.S. Patent No. 8,439,832; U.S. Patent No. 9,833,227; U.S. Patent No. 8,753,270; U.S. Patent No. 8,361,156; U.S. Design Patent No. D750,252; and U.S. Design Patent No. D652,519 (collectively, "the NuVasive Patents"). On personal knowledge as to NuVasive's own actions and on information and belief as to the actions of others, NuVasive alleges as follows:

I. THE PARTIES

- 1. Plaintiff NuVasive is a Delaware corporation with its principal place of business at 7475 Lusk Boulevard, San Diego, California 92121.
- 2. On information and belief, Defendant Alphatec Holdings, Inc. is a Delaware corporation with its principal place of business at 5818 El Camino Real, Carlsbad, California 92008.
- 3. On information and belief, Defendant Alphatec Spine, Inc. is a California corporation with its principal place of business at 5818 El Camino Real, Carlsbad, California 92008.
- 4. On information and belief, Defendant Alphatec Spine, Inc. operates as a wholly-owned subsidiary of Defendant Alphatec Holdings, Inc.

II. JURISDICTION AND VENUE

- 5. This Complaint arises under the patent laws of the United States, Title 35 of the United States Code. This Court has subject matter jurisdiction over this action under 35 U.S.C. § 271 *et seq.*, 28 U.S.C. §§ 1331 and 1338(a).
- 6. The Court has personal jurisdiction over Defendants because each Defendant transacts substantial business in the State of California, directly or through intermediaries, regularly does or solicits business in California, has committed acts in California giving rise to the causes of action alleged in this

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Complaint, maintains continuous and systematic contacts in California, purposefully avails itself of the privileges of doing business in California, and/or derives substantial revenue from goods and services provided to individuals in California. In addition, each Defendant is registered to do business in the State of California and maintains an agent for service of process in California.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) because each Defendant: (1) resides in this District, and/or (2) has committed acts of infringement and has a regular and established place of business in this District.

III. FACTUAL BACKGROUND

- A. NuVasive—The Pioneer Of Minimally Invasive Spine Surgery
 And Lateral Interbody Fusion Procedures
- 8. NuVasive, founded in 1997, is a leading medical device company focused on minimally disruptive surgical products and procedurally integrated solutions for the spine. NuVasive pioneered the market for minimally invasive spine surgery and lateral interbody fusion procedures. NuVasive has established itself as the market leader, and has a built a reputation as an innovator, of lateral spinal fusion technologies.
- 9. Spinal fusion surgery, at a basic level, is used to "fuse" two adjacent vertebrae of the spine together so that they heal into a single, solid bone. It is commonly performed to correct chronic back pain caused by diseased or damaged intervertebral discs. The procedure involves removing some, or all, of the diseased or damaged disc and inserting a spinal implant in the resulting disc space. The inserted implant restores height and induces bone growth between adjacent vertebrae.
- 10. NuVasive invented a spinal fusion procedure named the eXtreme Lateral Interbody Fusion, or "XLIF." Before XLIF, the surgical community believed lateral approaches to the spine (*i.e.*, approaching the spine from the side

of the patient) during spine surgeries, which required moving through the nerverich psoas muscle, posed too high of a risk of nerve damage to be workable. That changed, however, when NuVasive invented XLIF: the first spinal surgery using a lateral, transpsoas approach to the spine.

- 11. NuVasive invented not only the surgical methods, but also the first devices for performing lateral spinal surgeries. These devices include access tools which are used to create an operative corridor from the side of the patient to the spine. These access tools are compatible with neuromonitoring, which NuVasive also invented. The neuromonitoring compatible access tools allow a surgeon to locate nerves while navigating a path to the spine. NuVasive also invented CoRoent® implants, which include implants specially designed for lateral insertion. In comparison to spinal fusion procedures using other approaches, XLIF offers a number of benefits, including minimal disruption to the soft tissue, reduced operative time, shorter postoperative recovery time and less time in the hospital, lower complication rates, and smaller incision, among many more.
- 12. From 2001-2004, NuVasive expended substantial capital (between \$20,000,000 and \$30,000,000) and human resources in developing its innovations and in the commercialization of XLIF. Ex. A (IPR2014-00075, July 8, 2014 Declaration of Patrick Miles) at ¶ 10.
- 13. When XLIF was first introduced in 2003, it was met with substantial skepticism from the majority of the spine surgeon community. *Id.* at ¶ 12.
- 14. NuVasive put substantial resources into educating the spinal community to overcome that skepticism and show that XLIF was indeed a safer and more effective solution for spinal fusion, especially in the lower lumbar region. *Id.* at ¶ 14.
- 15. Through NuVasive's education efforts, surgeons began adopting XLIF into their practices at an ever-increasing rate, and saw improved patient outcomes. NuVasive saw the sea-change in attitude in a variety of ways, including

through the growth of NuVasive's business, through the interest at industry meetings, through the number of surgeons contacting NuVasive for training on XLIF over the years, and through publications regarding XLIF's revolutionary approach. *Id.* at ¶ 16.

- 16. NuVasive created the commercial market for lateral fusion products. *Id.* at \P 23. There was no lateral fusion market at the time of launch of the XLIF procedure. It is a testament to the procedure (and the instruments which enabled it) that NuVasive was able to essentially create a new market. *Id.* at \P 30.
- 17. NuVasive experienced unprecedented growth for a small spinal startup. *Id.* at ¶ 25. The growth of NuVasive has been a direct result of XLIF success. *Id.* XLIF has redefined minimally disruptive surgery by providing an efficient, reproducible lateral procedure that is minimally disruptive with associated benefits (*e.g.*, less blood loss, etc.). *Id.* And, at the center of NuVasive's success has been its XLIF procedure and associated equipment, which are at the core of NuVasive's business. *Id.* at ¶ 27.

B. NuVasive's XLIF Technology

- 18. One of the key components of NuVasive's XLIF technology is a system of specialized access tools that are compatible with neuromonitoring that NuVasive developed as part of the XLIF platform to create a small operative corridor through the side of the patient and through the nerve-rich psoas muscle to access the spine.
- 19. The access tools include sequential dilators, which are a series of successively larger dilators used to create and then incrementally widen an opening to the spine. Specifically, once a smaller dilator has been inserted, a larger dilator is slid over the previously inserted smaller dilator. The sequential dilators include directional electrodes at their distal ends which electrically stimulate nerves in the psoas muscle. The nerve responses are monitored and used by surgeons to assist in creating a surgical path to the spine.

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20. As part of the specialized access tools, NuVasive also developed a line of retractors which are referred to as the MaXcess® retractors. During the XLIF procedure, the MaXcess® retractor slides over the largest sequential dilator and gently enlarges and holds open the operating corridor. The MaXcess® retractors include an access driver and three independently adjustable blades: (1) a posterior blade (located towards the back of the patient), also referred to as the "C" or "central" blade; (2) a caudal blade (located towards the feet of the patient), also referred to as the "L" or "left" blade; and (3) a cephalad blade (located towards the head of the patient), also referred to as the "R" or "right" blade. The three-bladed design allows a surgeon to anchor the posterior blade using an Intradiscal Shim and stabilize the position of the retractor using an articulating arm. During the XLIF procedure, one end of the articulating arm is attached to the retractor while the other end is secured to the operating table. One of the blades of the MaXcess® retractor can also be equipped with a neuromonitoring electrode. The special design of the MaXcess® retractors provides maximum access to the target area of the spine with minimal disruption to the surrounding tissue, as illustrated in the figures below (screenshots of "MaXcess SD" video at 0:50, 0:25, 0:41, respectively, available at https://www.youtube.com/watch?v=J3aLnVD_ymU).

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implants. As depicted below, the CoRoent® XLIF implants are sized to span the entire width of the vertebral body to provide maximum vertebral body support. In comparison, implants inserted through non-lateral spinal fusion surgeries have a much smaller footprint and therefore provide weaker intervertebral support. Due to anatomical structures surrounding the spine, inserting implants having dimensions as large as CoRoent® using non-lateral spinal fusion surgeries (such as ALIF, PLIF, or TLIF)¹ would involve unacceptable risk. However, such implants are routinely inserted using a lateral approach to the spine with NuVasive's XLIF technology.

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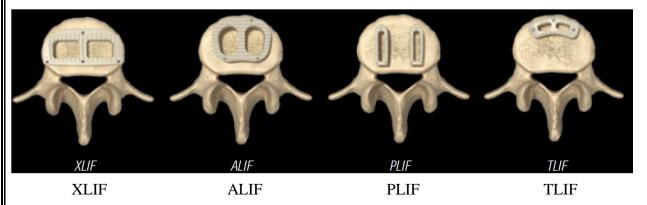
¹ "ALIF" refers to a spinal fusion surgery utilizing an anterior approach to the spine, "PLIF" a posterior approach to the spine, and "TLIF" a "transforaminal," or angled approached to the spine from the posterior.

PATENT INFRINGEMENT COMPLAINT

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Comparison of NuVasive's CoRoent® implant to Implants Placed in Non-Lateral Procedures



- 22. NuVasive's CoRoent[®] line of implants also includes radiopaque markers for a surgeon to determine whether the implant is correctly placed in the disc space. These markers are specially placed after considering the dimensions of CoRoent[®] and its intended orientation on the vertebral disc.
- 23. NuVasive is the pioneer of XLIF. To that end, NuVasive has and continues to offer on-site training sessions for surgeons to learn XLIF first-hand. In addition, NuVasive describes and demonstrates the XLIF procedure and instrumentation through XLIF Surgical Technique Guides, including a 2003, 2006, 2007, and 2013 edition. *E.g.*, Ex. D (NuVasive XLIF Surgical Technique (2013) ("2013 NuVasive Surgical Guide")); Ex. E (NuVasive XLIF Surgical Technique (2007) ("2007 NuVasive Surgical Guide")).
- 24. Over 400 published clinical studies support the XLIF procedure and hundreds of surgeons worldwide have successfully performed the XLIF procedure on thousands of patients.

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- 25. In order to protect its investments and cutting-edge intellectual property relating to XLIF, as well as other advancements in spinal developments, NuVasive regularly seeks and obtains patents from the United States Patent and Trademark Office ("USPTO"). As of February 13, 2018, NuVasive has been granted over 350 patents in the United States and has numerous pending patent applications.
 - Alphatec Has Struggled Since Its Inception In 2006 And, After C. Failing In Its Introduction Of Guided Lumbar Interbody Fusion ("GLIF"), Attempted To Reinvent Itself By Introducing Its **Battalion**TM **Lateral Technology**
- 26. Alphatec is a medical device company that provides hardware, equipment, and implants for use in spinal surgery. Since its inception, Alphatec has incurred net losses every year. In a 2018 corporate presentation, Alphatec described its history with phrases such as "Poor Decisions/Challenges," "Missed globalization expectations," and "Invested in technologies that never commercialized." Ex. F (Alphatec Corporate Presentation (January 2018)) at 4.
- 27. Alphatec reported that in 2006, the year that Alphatec went public, its net loss was nearly \$26 million. Ex. G (Excerpt from Alphatec Holdings Form 10-K Annual Report 2006) at 56.
- 28. On information and belief, Alphatec tried, but failed, to achieve success with a "lateral" spinal procedure and system. That procedure and system was named "Guided Lumbar Interbody Fusion," or "GLIF." GLIF approached the spine at an angle between the side and back of the patient.



Ex. H (Alphatec Spine Arc Portal Access System Guided Lumbar Interbody Fusion Surgical Technique Guide) at 1.

- 29. Starting from at least as early as 2008, Alphatec was developing prototypes and designing products for GLIF. Ex. I (Excerpt from Alphatec Holdings Form 10-K Annual Report 2008) at 12. Alphatec's press releases mention only one GLIF procedure ever being performed in 2011. Ex. J (January 4, 2011 Alphatec Press Release).
- 30. On information and belief, Alphatec stopped publicly discussing GLIF as of Alphatec's Annual Report for 2013.
- 31. By 2013, Alphatec's net losses had increased to approximately \$82 million, compared to a net loss of nearly \$26 million in 2006, the year that Alphatec went public. Ex. K (Excerpt from Alphatec Holdings Form 10-K Annual Report 2013) at 41; Ex. G (Alphatec Holdings Form 10-K Annual Report 2006) at 56. In just seven years, Alphatec's net losses had grown by over 300%.
- 32. Alphatec reported that Alphatec's debt due to contractual obligations (including lines of credit) and commercial commitments increased from \$27 million in 2006 to nearly \$190 million in 2013. Ex. G (Alphatec Holdings Form 10-K Annual Report 2006) at 68; Ex. K (Alphatec Holdings Form 10-K Annual Report 2013) at 51.

- 33. Alphatec reported that at the end of 2013, Alphatec's stock price was about \$2 dollars, compared to about \$5 at the end of 2009. Ex. K (Alphatec Holdings Form 10-K Annual Report) at F-28; Ex. L (Excerpt from Alphatec Holdings Form 10-K Annual Report 2009) at F-33.
- 34. In an effort to accumulate cash, Alphatec implemented major changes to its business in 2014-2015, including shifting its research and development resources, and refocusing its product portfolio pipeline, toward the lateral market for spine, the market that NuVasive had created. Ex. M (Excerpt from Alphatec Spine 2014 Annual Report) at 1. According to Alphatec's public statements, a few years later, in April 2017, Alphatec made a limited release of a lateral spinal surgery system, named the "BattalionTM Lateral System." Ex. N. On information and belief, it took Alphatec several years to launch BattalionTM Lateral System after initiating its lateral development program in part because Alphatec was distracted by financial hardships and efforts to restructure its business.
- 35. At the end of 2015, Alphatec's financial circumstances had become dire. Alphatec reported that at the end of 2015, Alphatec failed to comply with its financial covenants under its credit facility agreements, constituting an event of default. Ex. O (Excerpt from Alphatec Holdings Form 10-K Annual Report 2015) at 28. Alphatec's 2015 Annual Report expressly stated "[t]here is substantial doubt concerning our ability to continue as a going concern." *Id.* at 27.
- 36. Alphatec reported that in 2015, Alphatec incurred an annual net loss of approximately \$178 million, and its stock prices declined to \$0.30. *Id.* at 39, 50. Alphatec was in danger of being delisted for failing to comply with NASDAQ's requirement of maintaining a closing bid of \$1.00 per share. *Id.* at 31-32. However, Alphatec negotiated with NASDAQ and was able to obtain an extended deadline of September 2016 to regain compliance. Ex. P (Excerpt from Alphatec Holdings Form 10-Q Quarterly Report for the Period Ending June 30, 2016) at 31.

- 37. Meanwhile, Alphatec continued to face financial hardships. It failed to comply with its financial covenants with its credit facilities in 2016 for the months of January, February, March, April, May, and June. Ex. Q (Excerpt from Alphatec Holdings Form 10-K Annual Report 2016) at 29.
- 38. Alphatec reported that in July 2016, Alphatec sold its international business to Globus Medical, Inc. in exchange for \$80 million in cash and a credit line of \$30 million (the "Globus Transaction"). *Id.* at 8.
- 39. Alphatec reported that as part of the Globus Transaction, Alphatec agreed to exit the international market for a certain period of time. *Id*.
- 40. Alphatec reported that in 2016, Alphatec reduced its workforce to "reduce operating expenses" and "more appropriately size the Company's resources to better reflect the needs of a U.S.-focused organization." Ex. R (October 5, 2016 Alphatec Press Release).
- 41. Alphatec reported that after the Globus Transaction, Alphatec regained compliance with NASDAQ's listing requirements. Ex. Q (Alphatec Holdings Form 10-K Annual Report 2016) at 32.
- 42. Alphatec reported that in connection with the Globus Transaction, "[t]his enhanced liquidity will enable the company to support the continued expansion in the U.S. of ... the launches of our new Battalion Lateral System" Ex. S (July 26, 2016 Alphatec Press Release).
 - D. A Full Release Of Alphatec's BattalionTM Lateral Technology Took Place In October Of 2017
- 43. According to Alphatec's public statements, Alphatec made a limited release of the BattalionTM Lateral System with the SquadronTM Lateral Retractor, which is specifically designed for use in a lateral, transpsoas procedure ("Alphatec Lateral Procedure") in April 2017. Ex. N (April 7, 2017 Alphatec Press Release). On information and belief, Alphatec initiated a full launch of its BattalionTM

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PATENT INFRINGEMENT COMPLAINT

2013 NuVasive Surgical Guide Cover

Alphatec Surgical Guide Cover





- 62. The 2013 NuVasive Surgical Guide describes the following XLIF procedure steps: (1) Patient Positioning & Operating Room setup, (2) Anatomic Identification And Initial Incisions, (3) Retroperitoneal Access, (4) Retroperitoneal Approach, (5) Transpsoas Approach, (6) Retractor Assembly, (7) Access, (8) Annulotomy And Disc Space Preparation, (9) Implant Sizing, and (10) Implant Placement. *See* Ex. D.
- 63. The Alphatec Surgical Guide instructs surgeons how and when to perform these steps. *See* Ex. U.

(i) XLIF Patient Positioning And Operating Room Setup

64. NuVasive first instructs that the patient should be placed in the lateral decubitus position with the greater trochanter over a table break and secured to the operating room table by tape at specific locations: (A) below the iliac crest, (B) over the thoracic region, (C) from the iliac crest to the knee, then secured to the table, and (D) from the table to the knee, past the ankle, then secured to the table. *E.g.*, Ex. E (2007 NuVasive Surgical Guide) at 12.

PATENT INFRINGEMENT COMPLAINT -15-

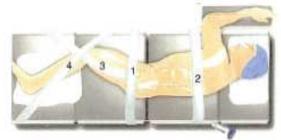
65. The Alphatec Surgical Guide instructs its surgeons to "[p]lace the patient in a lateral decubitus position on a bendable (breaking) table so that the patient's greater trochanter sits directly above the table break." Ex. U (Alphatec Surgical Guide) at 3. The Alphatec Surgical Guide further instructs that "the patient should be taped at the following locations: Below the iliac crest [;] Over the thoracic region [;] From the iliac crest to the knee ... (tape will then be secured to the table) [; and] From under the table on the ipsilateral side, to the knee, past the ankle and then to the contralateral side under the table." *Id*.

NuVasive XLIF Procedure



Ex. E (2007 NuVasive Surgical Guide) at 12 Fig. 1.

Alphatec Lateral Procedure

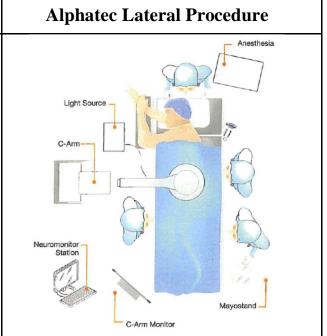


Ex. U (Alphatec Surgical Guide) at 3.

- 66. NuVasive then depicts the appropriate placement of the surgical equipment. *E.g.*, Ex. E (2007 NuVasive Surgical Guide) at 12.
- 67. The Alphatec Surgical Guide depicts the appropriate placement of the surgical equipment. Ex. U (Alphatec Surgical Guide) at 3.

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NuVasive XLIF Procedure Neurovision FLUORO MONITOR Ex. E (2007 NuVasive Surgical Guide) at 12 Fig. 4.



Ex. U (Alphatec Surgical Guide) at 3. ²

(ii) XLIF Anatomic Landmark Identification And Initial Incisions

- 68. NuVasive then instructs surgeons to localize the disc space using lateral fluoroscopy and mark the skin to serve as the location of the skin incision. *E.g.*, Ex. D (2013 NuVasive Alphatec Surgical Guide) at 7.
- 69. The Alphatec Surgical Guide instructs surgeons to "localize the operative level using true lateral fluoroscopy. With ink, make a mark on the skin to serve as the location for the initial skin incision at the operative level." Ex. U (Alphatec Surgical Guide) at 4.

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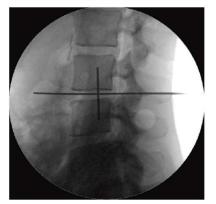
² "FLUORO" in NuVasive's figure and "C-Arm" in Alphatec's figure refer to the same machine: a C-arm fluoroscopic X-ray machine.

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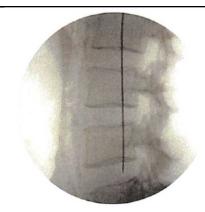
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NuVasive XLIF Procedure



Ex. E (2007 NuVasive Surgical Guide) at 7 Fig. 9(3).

Alphatec Lateral Procedure



Ex. U (Alphatec Surgical Guide) at 3.

XLIF Retroperitoneal Access (iii)

- 70. NuVasive next teaches that the subcutaneous tissue layers "are dissected using alternating blunt scissor and finger dissection." E.g., Ex. D (2013 NuVasive Surgical Guide) at 8. "Once inside the retroperitoneal space, the index finger is used to create space and release the peritoneum anteriorly []. When the peritoneum is released, the finger is then used to palpate the psoas muscle." Id.
- 71. Alphatec instructs surgeons to "dissect subcutaneous tissue layers by alternating with blunt scissors and finger dissection until the retroperitoneal space is reached. Once inside the retroperitoneal space, carefully sweep the peritoneum anteriorly. Once the peritoneum has been swept anteriorly, use the index finger to palpate the psoas muscle." Ex. U (Alphatec Surgical Guide) at 4-5.

NuVasive XLIF Procedure	Alphatec Lateral Procedure
Ex. D (2013 NuVasive Surgical Guide) at 8 Fig. 12.	Ex. U (Alphatec Surgical Guide) at 5.

- 72. Next, NuVasive describes that "[t]he index finger is brought up to the inside abdominal wall underneath the lateral skin mark []. This step ensures that a safe pathway exists between the abdominal wall and the psoas muscle." *E.g.*, Ex. D (2013 NuVasive Surgical Guide) at 9.
- 73. The Alphatec Surgical Guide instructs surgeons to "[c]reate a safe pathway between the abdominal wall and the psoas muscle by using the index finger to sweep up to the inside of the abdominal wall directly underneath the lateral skin incision." Ex. U (Alphatec Surgical Guide) at 5.

NuVasive XLIF Procedure	Alphatec Lateral Procedure
(C; 10)	
Ex. D (2013 NuVasive Surgical Guide) at 9 Fig. 13.	Ex. U (Alphatec Surgical Guide) at 5.

(iv) XLIF Retroperitoneal Approach

- 74. During the XLIF procedure, "[t]he index finger that is inside the retroperitoneal space is then used to escort the initial Dilator down to the psoas muscle." Ex. D (2013 NuVasive Alphatec Surgical Guide) at 9.
- 75. The Alphatec Surgical Guide instructs its surgeons "[o]nce a safe pathway has been created, insert the Initial Dilator into the space. Use the index finger to guide the Dilator to the psoas muscle." Ex. U (Alphatec Surgical Guide) at 6.

NuVasive's XLIF Procedure	Alphatec Lateral Procedure
Ex. D (2013 NuVasive Surgical Guide) at 9 Fig. 13.	Ex. U (Alphatec Surgical Guide) at 6.
Guide) at 9 Fig. 13.	

(v) XLIF Transpsoas Approach

- 76. To traverse the psoas muscle while avoiding damage to the nerves, NuVasive employs neuromonitoring, such that XLIF Dilators are equipped with stimulating electrodes at their distal tips, while a stimulating clip is attached at their proximal ends. *E.g.*, Ex. D (2013 NuVasive Alphatec Surgical Guide) at 10.
- 77. The Alphatec Surgical Guide instructs surgeons to "[p]lace the Universal Clip onto exposed silver ring at the proximal end of the Dilator and connect to the appropriate neuromonitoring platform" and that "[n]euromonitoring

NuVasive's XLIF Procedure	Alphatec Lateral Procedure
Ex. D (2013 NuVasive Surgical Guide) at 11 Fig. 23.	Ex. U (Alphatec Surgical Guide) at 5.

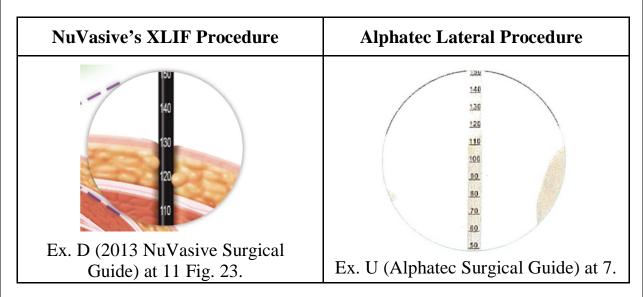
78. NuVasive next explains that the initial Dilator is used to split the fibers of the psoas muscle by advancing it through the psoas while rotating it. *E.g.*, Ex. E (2007 NuVasive Alphatec Surgical Guide) at 16. A line on the proximal end of the Dilator indicates the stimulation direction. *E.g.*, *Id.* at 16-17.

79. The Alphatec Surgical Guide instructs surgeons to "[c]arefully split the muscle fibers of the psoas by advancing the Dilator in a clockwise to counterclockwise motion." Ex. U (Alphatec Surgical Guide) at 6. Referring to the Dilator, the Alphatec Surgical Guide also explains that "Black Lines and Silver triangle indicate orientation." *Id.* at 5.

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NuVasive's XLIF Procedure	Alphatec Lateral Procedure
Ex. E (2007 NuVasive Surgical Guide) at 17 Fig. A.	Black Lines and Silver triangle indicate orientation
	Ex. U (Alphatec Surgical Guide) at 5.

- 80. NuVasive describes that "[o]nce the initial Dilator is docked on the disc, fluoroscopy should be used to confirm proper positioning." *E.g.*, Ex. D (2013 NuVasive Surgical Guide) at 11. "A cross-table AP image should confirm the Dilator is in the plane of, and flush with, the disc space []. Following confirmation of the initial Dilator's position, a K-Wire is introduced about halfway down the disc space to secure the position." *Id.* "Depth markings on the Dilator indicate the size of the appropriate length Blades to be attached to the MaXcess® [] Access Driver []." *Id.*
- 81. The Alphatec Surgical Guide instructs surgeons "[o]nce the Initial Dilator has been placed on the disc space, confirm its position with lateral fluoroscopy. Adjust the Dilator's position so it is flush with the disc space and confirm with AP fluoroscopy. Once the Dilator's appropriate position is confirmed, introduce the K-wire through the Dilator halfway into the disc space. Take note of the Dilator depth and add 10mm to determine the desired blade length." Ex. U (Alphatec Surgical Guide) at 7.



- 82. During XLIF, successive dilators "are subsequently introduced over the initial Dilator using a twisting motion," each larger in diameter than the previous. Neuromonitoring "is used with the previous Dilator to determine nerve proximity." *E.g.*, Ex. D (2013 NuVasive Surgical Guide) at 11.
- 83. After instructing surgeons to switch the neuromonitoring clip to the Secondary Dilator, the Alphatec Surgical Guide instructs surgeons to "[i]ntroduce the Secondary Dilator over the Initial Dilator using a clockwise, counter-clockwise motion." Ex. U (Alphatec Surgical Guide) at 8.

(vi) XLIF Retractor Assembly

- 84. Next, NuVasive instructs surgeons to load the retractor blades onto the MaXcess® retractor. *E.g.*, Ex. D (2013 NuVasive Surgical Guide) at 13.
- 85. Alphatec instructs surgeons to "[l]oad appropriately sized blades onto the Retractor" Ex. U (Alphatec Surgical Guide) at 9.

(vii) XLIF Access

- 86. NuVasive then explains that the MaXcess[®] retractor is placed over the largest dilator and docked on the lateral aspect of the disc space. *E.g.* Ex. D (2013 NuVasive Surgical Guide) at 14.
- 87. The Alphatec Surgical Guide instructs that the "[r]etractor is then introduced into the space over the Second Dilator using a clockwise, counter-

clockwise motion until the Retractor is flush with the disc space." Ex. U (Alphatec Surgical Guide) at 10.

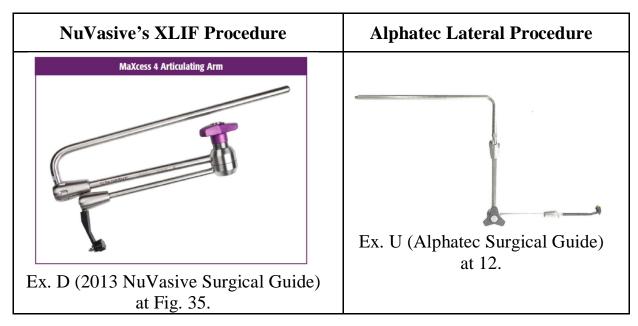
NuVasive's XLIF Procedure Alphatec Lateral Procedure Ex. D (2013 NuVasive Surgical Guide) at 14 Fig. 29. Ex. U (Alphatec Surgical Guide) at 10.

- 88. NuVasive next explains that the Articulating Arm bedrail attachment should be secured to the surgical table. *E.g.* Ex. D (2013 NuVasive Surgical Guide) at 15.
- 89. The Alphatec Surgical Guide instructs surgeons to "[s]ecure the Table Fixation Arm Bed Rail Clamp to the surgical table" Ex. U (Alphatec Surgical Guide) at 12.

NuVasive's XLIF Procedure	Alphatec Lateral Procedure
Ex. D (2013 NuVasive Surgical Guide) at Fig. 35.	Ex. U (Alphatec Surgical Guide) at 12.

90. NuVasive describes that the Articulating Arm post is attached to the Articulating Arm bedrail attachment and adjusted to the desired height. *E.g.* Ex. D (2013 NuVasive Surgical Guide) at 15. "The opposite end of the Articulating Arm is attached to the Access Driver [of the MaXcess® retractor]." *Id.*

91. Alphatec instructs surgeons to "[a]ttach the Table Fixation Arm post to the Bed Rail Clamp and adjust to the preferred height. The opposite end of the Arm will then be attached to the Retractor." Ex. U (Alphatec Surgical Guide) at 12.



- 92. Next, NuVasive teaches that the Articulating Arm can connect to the MaXcess® retractor at two attachment points. *E.g.* Ex. D (2013 NuVasive Surgical Guide) at 16. One of the attachment points "fixes the C Blade relative to the table and results in the L and R Blades moving anteriorly" *Id*.
- 93. The Alphatec Surgical Guide states that the "Table Fixation Arm can be attached to the Retractor in two locations: **Position 1** holds the posterior blade

³ The "C Blade," "L Blade, and "R Blade" refer to the posterior, caudal, and cranial blades, respectively.

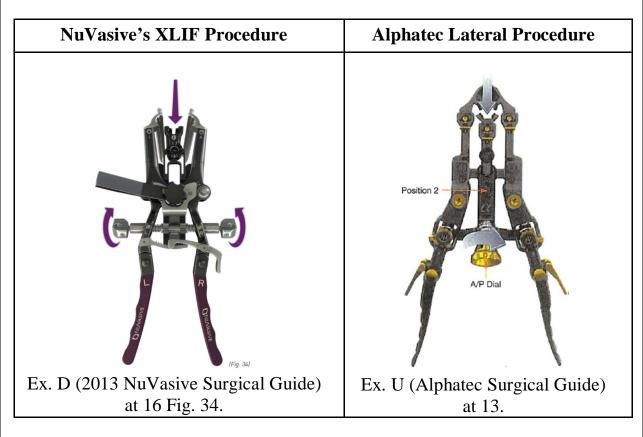
stationary while the left and right blades are free to traverse" Ex. U (Alphatec Surgical Guide) at 13 (emphasis in original).

NuVasive's XLIF Procedure	Alphatec Lateral Procedure
R Drowsove (Fig. 33)	Position 1
Ex. D (2013 NuVasive Surgical	Ex. U (Alphatec Surgical Guide)
Guide) at 16 Fig. 33.	at 13.

- 94. In NuVasive's MaXcess® retractor, the second attachment point "affixes the L and R blades to the table which results in the C Blade moving posteriorly" *E.g.* Ex. D (2013 NuVasive Surgical Guide) at 16.
- 95. The Alphatec Surgical Guide describes that "**Position 2** holds the left and right blades stationary while the posterior blade is free to traverse" Ex. U (Alphatec Surgical Guide) at 13 (emphasis in original).

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- 96. During XLIF, once the MaXcess[®] retractor has been secured to the operating table, the left and right blades of the MaXcess retractor can be expanded to widen the access space and gain optimal access for the surgeon. *E.g.* Ex. D (2013 NuVasive Surgical Guide) at 17. A light cable is then placed about halfway down the retractor blades. *Id*.
- 97. During the Alphatec Lateral Procedure, the surgeon "[e]xpands the right and/or left blade to expose the disc space and gain optimal access for the procedure." Ex. U (Alphatec Surgical Guide) at 20. In addition, Alphatec explains that a light cable is "placed halfway down the right or left blade" *Id*.

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NuVasive's XLIF Procedure



Ex. D (2013 NuVasive Surgical Guide) at 17 Fig. 35.

Alphatec Lateral Procedure



Ex. U (Alphatec Surgical Guide) at 15.

98. During XLIF, an "Intradiscal Shim may be placed into the disc space to further stabilize the retractor" *E.g.* Ex. D (2013 NuVasive Surgical Guide) at 18. NuVasive instructs surgeons "[t]o load the Locking Intradiscal Shim onto the Locking Shim Repositioning Tool." *Id.* After the Intradiscal Shim is advanced into the disc space, the surgeon presses a button to disengage the Locking Shim Repositioning Tool from the Intradiscal Shim. *Id.*

99. The Alphatec Lateral Procedure utilizes shims. The Alphatec Surgical Guide explains that the Intradiscal Shim can be used to "stabilize the Retractor." Ex. U (Alphatec Surgical Guide) at 19. The Alphatec Surgical Guide also instructs surgeons to "[1]oad the Intradiscal Shim onto the Shim inserter." *Id.* After the Intradiscal Shim is advanced into the disc space, the surgeon "[p]ress[es] the gold button at the proximal end of the Inserter to disengage the Shim." *Id.*

NuVasive's XLIF Procedure Alphatec Lateral Procedure (Fig. 40) Ex. D (2013 NuVasive Surgical Guide) 18 Fig. 40. XLIF — 5mm (Screenshot of "XLIF NuVasive Ex. U (Alphatec Surgical Guide) at 19. HD" video at 0:14, available at https://www.youtube.com/watch?v= nUHIU6giAHI). Lock Shim Inserter / Repositioning Too

100. Next, during XLIF, a Blade Rotation Driver can be used to rotate the left and/or right blades and expand the distal exposure to the disc space. Ex. D (2013 NuVasive Surgical Guide) at 20. NuVasive warns that "exposure should only be as wide as is necessary to prepare the disc space" because "[w]ider

101. The Alphatec Surgical Guide explains that the "Blade Toe Driver" may be used to increase "Blade Toe," which expands the distal exposure to the disc space. Ex. U (Alphatec Surgical Guide) at 16, 20. In addition, the Alphatec

PATENT INFRINGEMENT COMPLAINT -29-

exposure unnecessarily increases psoas muscle trauma." Id.

Ex. D (2013 NuVasive Surgical Guide) at 34.

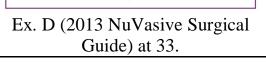
Surgical Guide instructs surgeons to "[1]imit expansion of the Retractor to the disc space as over-expanding the retractor may cause trauma to the psoas." *Id.* at 20.

NuVasive's XLIF Procedure Alphatec Lateral Procedure Ex. D (2013 NuVasive Surgical Guide) at 20 Fig. 49. Ex. U (Alphatec Surgical Guide) at 16.

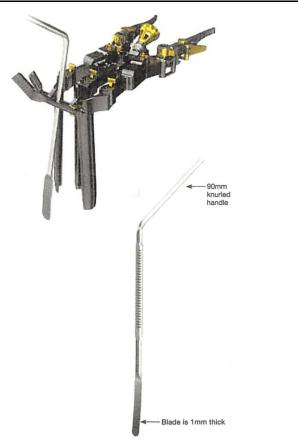
102. Next, during XLIF, a "nerve root retractor" or "anterior retractor" can be secured to MaXcess[®] using a crossbar. Ex. D (2013 NuVasive Surgical Guide) at 20. The nerve root or anterior retractor can be used to retract tissue to the Anterior Longitudinal Ligament ("ALL"). *Id*.

103. The Alphatec Surgical Guide states that surgeons can secure a "4th blade" to the Squadron[®] Lateral Retractor using an "Attachment Cross Bar." Ex. U (Alphatec Surgical Guide) at 20. In conjunction with this step, the Alphatec Surgical Guide instructs surgeons to "[l]ocalize the ALL." *Id*.

NuVasive's XLIF Procedure (https://www.nuvasive.com/wp-content/uploads/2017/03/xcor2_tg_p_mx4_retractor-.png) Wide Anterior Retractor, Short



Alphatec Lateral Procedure



Ex. U (Alphatec Surgical Guide) at 20.

(viii) XLIF Annulotomy And Disc Space Preparation

104. Next, during XLIF, the surgeon uses an Annulotomy Knife to create an annulotomy. E.g. Ex. D (2013 NuVasive Surgical Guide) at 22. The size of the annulotomy, as measured from anterior to posterior, depends on the size of the desired implant. *Id.* After the annulotomy, various tools are used to evacuate the disc and prepare the endplates for fusion such as through the use of a Cobb elevator by releasing the contralateral annulus. *Id.*

105. The Alphatec Surgical Guide states "[p]erform an annulotomy to accommodate the selected implant width (anterior to posterior) with the

⁴ An annulotomy is an incision on an intervertebral disc.

PATENT INFRINGEMENT COMPLAINT -31-

Annulotomy Knife. A Cobb Elevator is then passed through the disc space to release the contralateral annulus." Ex. U (Alphatec Surgical Guide) at 21. A variety of additional disc preparation instrumentation is utilized to prepare the disc space and end plates. *Id.*

(ix) XLIF Implant Sizing

106. During XLIF, after the disc and endplates are prepared for fusion, "[t]he XLIF Distractor and Paddle Sizes are used to distract the disc space and gauge the appropriately sized Trial [implant]." *E.g.*, Ex. E (2007 NuVasive Surgical Guide) at 25. Next, "[t]he selected Trial is placed onto the Inserter and the thumb-wheel lock is tightened to secure the Trial." *Id*.

107. The Alphatec Surgical Guide instructs surgeons to "[i]ntroduce a Primary Distractor to distract the disc space and estimate the appropriate implant height." Ex. U (Alphatec Surgical Guide) at 22. Next, the Alphatec Surgical Guide states "[a]ttach the Trial to the Battalion LLIF Inserter by ... rotating the Inserter 180 degrees." *Id.* at 23.

NuVasive's XLIF Procedure	Alphatec Lateral Procedure
	— Gel brien
Ex. E (2007 NuVasive Surgical	Ex. U (Alphatec Surgical Guide) at
Guide at 25 Fig. 41.	23.

(x) XLIF Implant Placement

108. NuVasive teaches that after securing the Trial to the Inserter, the Trial is gently impacted into the disc space to determine the implant size. *E.g.* Ex. D (2013 NuVasive Surgical Guide) at 23. The surgeon then selects the appropriate implant and fills the implant with graft material. *Id.* at 25.

109. The Alphatec Surgical Guide states "impact the Trial into the disc space. Confirm correct size and width for the patient anatomy." Ex. U (Alphatec Surgical Guide) at 23. The Alphatec Surgical Guide states "[c]hoose the appropriate implant by width, length, lordosis, and height" and "[p]repack the implant with the appropriate biologics, allograft of autograft" before inserting into the disc space. *Id.* at 24.

NuVasive's XLIF Procedure	Alphatec Lateral Procedure
Ex. D (2013 NuVasive Surgical Guide) at 25.	Ex. U (Alphatec Surgical Guide) at 24.

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Perspective views of NuVasive's CoRoent® XLIF implant and Alphatec's BattalionTM Lateral Spacer are shown below.

NuVasive's Alphatec's CoRoent® XLIF Implant BattalionTM Lateral Spacer Ex. V (Alphatec's webpage Ex. B (XLIF Patient Education advertising the BattalionTM Lateral Brochure) at 6. Spacer)

- NuVasive explains that the CoRoent® implants may be inserted with 111. the TL Graft Containment Slide. Ex. D (2013 NuVasive Surgical Guide) at 27. The implant is attached to the Inserter, and the TL Graft Containment Slide is placed over the inserter. Id.
- Alphatec explains that the implant may be inserted using Graft 112. Containment Slides. Ex. U (Alphatec Surgical Guide) at 25. "Graft Containment Slides may be attached to the proximal end of the inserter and advanced until they cover the implant." Id.

NuVasive's XLIF Procedure	Alphatec Lateral Procedure
Ex. D (2013 NuVasive Surgical Guide) at 27.	Ex. U (Alphatec Surgical Guide) at 25.

- 113. As evidenced by the foregoing comparison of the Alphatec Surgical Guide and the NuVasive XLIF Surgical Technique Guide, Alphatec's BattalionTM Lateral Technology was knowingly and willfully copied from NuVasive.
 - F. In October of 2017, A Pioneering Member Of NuVasive's
 Original XLIF Team And Prolific XLIF Inventor, Mr. Miles, Left
 His Position As NuVasive's Vice Chairman To Become Alphatec's
 Executive Chairman
- 114. Mr. Patrick Miles was employed at NuVasive from 2001 to 2017, and actively participated in the research, development, commercialization, and marketing of XLIF since its inception.
- of Marketing from 2001 to 2004; (2) Senior Vice President of Marketing from 2004 to 2007; (3) Executive Vice President of Product Marketing and Development from 2007 to 2009; (4) President of the Americas from 2010 to 2011; (5) Executive Vice President of Global Products and Services from 2011 to 2015; and (6) President and Chief Operating Officer from 2015 to 2016.
- 116. On information and belief, at least as early as January 2016 Alphatec was interested in being acquired by NuVasive to mend Alphatec's financial

 PATENT INFRINGEMENT COMPLAINT

 -35-

difficulties. In January 2016, NuVasive was contacted by UBS Financial Services to explore NuVasive's interest in acquiring Alphatec. At the time, Mr. Pat Miles was still working at NuVasive and held the role of President and Chief Operating Officer, a position which required heavy involvement with the acquisition process. In addition, because Mr. Miles had been a key leader and visionary of NuVasive's product development, his opinions were given substantial weight by NuVasive.

117. In assessing the acquisition opportunity, Mr. Miles agreed that Alphatec's portfolio was "aged, undifferentiated."

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Pat,
Please see the draft of Project Titan summary attached. Please let me know if you have a minute to chat.
The major assumptions that effect the US business projections are:

? ~50% erosion in current business based on sales dis-synergies

? Aged, undifferentiated portfolio
?

Want to capture any additional feedback and confirm your recommendation as PASS.
I am available.
Best,
Gusty
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This is dead on the mark. No changes and you are being kind with 50% erosion

Thanks for packaging and putting away. Hope you and family are having good Presidents' Day weekend....PM

Pat Miles

President, Chief Operating Officer | NuVasive, Inc. | Speed of Innovation direct.858.909.1803 | fax.858.909.2003 | mobile.858.243.0021 | email. pmiles@nuvasive.com

7475 Lusk Boulevard | San Diego | CA | 92121
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118. In addition, Mr. Miles viewed the acquisition opportunity as a "waste of time."

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- G. With The Undisclosed Assistance Of Mr. Miles As Early As
 March Of 2017, Alphatec Has Attempted To Re-invent The
 Company Not Only By Copying NuVasive's XLIF Technology,
 But Also By Hiring Other Members Of NuVasive's Management
 Team And Multiple NuVasive Employees
- 125. Mr. Miles departure to join Alphatec in October 2017 made him one of many NuVasive employees, inventors and upper level management that were specifically targeted by Alphatec.
- 126. On information and belief, upon the September 2016 closing of the Globus Transaction, Alphatec began to make changes to its leadership team targeting NuVasive employees, inventors and upper level management.
- 127. On information and belief, beginning in September 2016, Alphatec recruited and hired away the following NuVasive employees: (1) Alphatec's Executive Chairman of the Board Patrick Miles; (2) Alphatec's Executive Vice President of Strategic Marketing and Product Development Brian Snider; (3) Alphatec's Vice President Operations Mike Dendinger; (4) Alphatec's Vice President Development Posterior Scott Lish; and (5) Alphatec Board member Quentin Blackford.
- 128. In connection with Alphatec's March 2017 hiring of ex-NuVasive employee Brian Snider, Alphatec publicly stated: "Mr. Snider spent nine years at NuVasive, Inc. where he ... had substantial responsibility over the anterior column business, including XLIF[®]... We look forward to leveraging [Mr. Snider's] energy and expertise, as we launch our new products, including Battalion Lateral." Ex. W (March 24, 2017 Alphatec Press Release). On information and belief, upon hiring Mr. Snider, Alphatec awarded Mr. Snider an inducement award of 75,000 restricted stock units and an option to purchase 75,000 shares of common stock. *Id.*

- 129. According to Alphatec's public statements, Alphatec plans to expand its surgeon customer base and drive growth through launch of the BattalionTM Lateral products. Ex. X (March 23, 2017 Alphatec Press Release). In connection with a private placement, Alphatec announced "[w]e believe the additional capital [from the private placement] will allow us to execute on our plans to expand our surgeon customer base, drive growth through the launch our new products ... BattalionTM Lateral" *Id*.
- 130. On information and belief, in March 2017, Alphatec completed a private placement of its securities, generating \$18.9 million in proceeds. Ex. Q (Alphatec Holdings Form 10-K Annual Report 2016) at 1. On information and belief, one of the March 2017 investors was Mr. Miles, who was still employed by NuVasive at the time. Upon information and belief, in or around March of 2017, Mr. Miles executed a securities purchase agreement to purchase \$500,000 of Alphatec stock without informing NuVasive.
- 131. According to Alphatec's public statements, in April of 2017, Alphatec initiated a limited release of the BattalionTM Lateral System with the SquadronTM Lateral Retractor, which is specifically designed for use in a lateral, transpsoas procedure. Ex. N (Alphatec April 7, 2017 press release). According to Alphatec's public statements, at that time, Alphatec was "well positioned to begin to compete in the \$500M U.S. Lateral market." *Id*.
- 132. On information and belief, a few months later in June 2017, Mr. Miles sold over \$1 million worth of NuVasive stock. On information and belief, when Mr. Miles joined Alphatec in October 2017, Mr. Miles agreed to purchase more shares of Alphatec stock worth nearly \$3 million. Ex. Y (Alphatec Holdings Schedule 13D (December 28, 2017)) at Item 3. On information and belief, taking into account Mr. Miles' previous purchase of \$500,000 of Alphatec stock, Mr. Miles invested approximately \$3.5 million into Alphatec. On information and belief, Mr. Miles also received a five-year warrant to purchase up to an additional

Release) at 2.

1.3 million shares of common stock. Ex. Z (October 2, 2017 Alphatec Press

Alphatec in or around the time that Mr. Miles joined Alphatec, Alphatec awarded Mr. Miles 1,000,000 restricted stock units. Ex. AA (Alphatec Holdings Form 8-K (October 2, 2017)) at Item 5.02. On information and belief, due to the size of the 1,000,000 restricted stock grant to Mr. Miles, Alphatec amended its 2016 Employment Inducement Award Plan to increase the shares reserved for issuance by 1 million shares. *Id.* On information and belief, that amendment was made effective on October 2, 2017, the same day as Mr. Miles' appointment as Executive Chairman of Alphatec became effective. *Id.*

134. On information and belief, Alphatec has and is executing plans to increase Alphatec's stock prices and intends to erode NuVasive's business using the BattalionTM Lateral System to infringe NuVasive's patents. On information and belief, Alphatec's plans include recruiting former NuVasive employees and upper management, including Mr. Miles and other inventors of the NuVasive Patents.

- H. In Light of The Foregoing And Mr. Miles Significant Investments
 In And Leadership At Alphatec, There Has Been And Continues
 to Be A Privity Relationship Between Alphatec And Mr. Miles
- 135. On information and belief, as of December 28, 2017, the aggregate number of Alphatec shares owned by Mr. Miles was approximately 1.8 million, representing 9.1% of Alphatec's common stock. Ex. Y (Alphatec Holdings Schedule 13D (December 28, 2017)) at Item 5. In addition, on information and belief, Mr. Miles beneficially owns more shares of Alphatec's common stock by virtue of his role as the manager of MOM, LLC. *Id.* at Item 2. Accordingly, on information and belief, as of December 28, 2017, MOM, LLC owned 500,000 shares of Alphatec's stock, representing 2.5% of Alphatec's common stock. *Id.* at

Item 5. On information and belief, Mr. Miles and MOM, LLC collectively owned 11.6% of Alphatec's common stock as of December 28, 2017. *Id*.

Mr. Miles maintains a key leadership role. According to Alphatec's public statements, as the Executive Chairman of Alphatec, Mr. Miles' job responsibilities are to "lead the organization" and "be fully engaged, focusing on further defining and implementing Alphatec's strategic initiatives, expanding and fortifying [Alphatec's] relationships with surgeon customers, and leading Alphatec's new technology development." Ex. Z (October 2, 2017 Alphatec press release) at 1. According to Alphatec's public statements, Mr. Miles is "position[ed] extraordinarily well to lead [Alphatec]." *Id.* Alphatec has also stated that "[Mr. Miles'] influence on daily operations, product development decisions, and surgeon engagement will accelerate the business transformation that [Alphatec is] driving." *Id.*

137. Mr. Miles was hired by Alphatec, at least in part, to expand Alphatec's market share by using the Battalion™ Lateral System. In recruiting Mr. Miles as well as former NuVasive CFO Quentin Blackford, Alphatec's CEO stated "Pat and Quentin have decades of industry experience and well-deserved reputations that speak for themselves." *Id.* Alphatec's CEO continued, Mr. Miles "is a proven driver of market-share expansion." *Id.* Consistent with these statements, Mr. Miles announced that he "look[s] forward to driving ... market share expansion." *Id.*

138. Upon Mr. Miles recruitment, Alphatec reported "continued execution of our vision to reposition Alphatec as the most respected, fastest-growing company in U.S. spine" based on Mr. Miles' 17-year tenure at NuVasive. *Id.* To achieve this vision, Alphatec is investing in a "vital few" initiatives, including "[d]riving new product development." Ex. C (Excerpt from Alphatec Holdings Amendment No. 1 to Form S-3 (November 14, 2017)) at 5. Pursuant to this

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"vital" initiative, Alphatec plans to focus on "platforms that address sizable new market opportunities: 1) lateral surgery" Id.

I. Alphatec Has Been, And Intends to Continue To Infringe On **NuVasive's Valuable Patented Technology**

As discussed above, Alphatec has been and intends to continue to 139. trade on NuVasive's valuable patented technology in the industry that NuVasive created as a last ditch effort to save a business that has struggled and failed since its inception. Accordingly, NuVasive now seeks relief from the Court for this egregious, tortious behavior.

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FIRST CAUSE OF ACTION — Infringement of U.S. Patent IV. No. 7,819,801

- 140. NuVasive repeats and realleges the allegations of paragraphs 1 through 139 in their entirety.
- 141. On October 26, 2010, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 7,819,801 ("the '801 patent"), entitled "Surgical Access System and Related Methods," to Patrick Miles, Scot Martinelli, Eric Finley, James Gharib, Allen Farquhar, Norbert Kaula, Jeffrey Blewett and Goretti Medeiros (legal representative). A true and correct copy of the '801 patent is attached hereto as Exhibit AB.
- 142. At all relevant times, NuVasive is and has been the owner, by valid assignment, of all right, title, and interest in and to the '801 Patent.
- 143. On information and belief, Alphatec had knowledge of the '801 patent prior to the filing of this Complaint.
- 144. On information and belief, Alphatec has been monitoring and continues to monitor NuVasive's patent portfolio, including patents and applications that are directed to lateral, transpsoas spinal procedures, systems, and devices, such as the '801 patent.
- 145. On information and belief, Alphatec had knowledge of the '801 patent at least as early as August 5, 2015, as evidenced by Alphatec's submission of an Information Disclosure Statement identifying the '801 patent to the U.S. Patent and Trademark Office, which occurred on August 5, 2015 in connection with prosecution of Alphatec's U.S. Patent No. 9,693,762.
- 146. As an independent basis for Alphatec's knowledge of the '801 patent, on information and belief, Alphatec gained knowledge of the '801 patent through its privity relationship with Mr. Miles, which formed at least as early as October 2, 2017.

- 147. Mr. Miles is a named inventor of the '801 patent and therefore had and continues to have knowledge of the '801 patent.
- 148. A privity relationship between Alphatec and Mr. Miles formed at least as early as October 2, 2017, when Mr. Miles joined Alphatec as its Executive Chairman.
 - 149. Alphatec continues to be in privity with Mr. Miles.
- 150. Upon the formation of Alphatec's privity relationship with Mr. Miles, Alphatec was imputed with, and continues to be imputed with, Mr. Miles' knowledge of the '801 patent.
- 151. Alphatec has and continues to avail itself of Mr. Miles' knowledge and assistance to infringe the '801 patent, which Mr. Miles had assigned to NuVasive.
- 152. At the very latest, Alphatec has knowledge of the '801 patent as of the filing of this Complaint.
- 153. In violation of 35 U.SC. § 271(a), Alphatec has and continues to directly infringe one or more claims of the '801 patent.
- 154. In particular, and without limitation, Alphatec directly infringes the '801 patent by making, using, selling, offering for sale, and/or importing into the United States products and systems including, but not limited to the Initial Dilator, the Secondary Dilator, the SquadronTM Lateral Retractor Body, the SquadronTM Lateral Retractor Right Blade, the SquadronTM Lateral Retractor Left Blade, the SquadronTM Lateral Retractor Posterior Blade, the SquadronTM Lateral Retractor Right Handle Arm, the SquadronTM Lateral Retractor Left Handle Arm, and the Intradiscal Shim (collectively, "the '801 Infringing System"), which are components of the BattalionTM Lateral System, without the permission of NuVasive.
- 155. The '801 Infringing System infringes at least claim 1 of the '801 patent.

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156. As explained in the Alphatec Surgical Guide, the '801 Infringing System is a system for accessing a surgical target site.

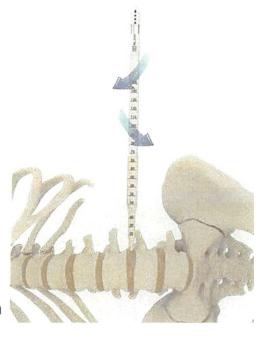
157. The Alphatec Surgical Guide discloses a dilator system comprising a plurality of sequential dilators deliverable along a lateral, transpsoas path to a targeted spine site to create a distraction corridor (Ex. U at 6-8):

Introduce the Secondary Dilator over the Initial Dilator using a clockwise, counter-clockwise motion. Advance the Second Dilator until it is flush with the disc space.

TRAVERSING THE PSOAS

Carefully split the muscle fibers of the psoas by advancing the Dilator in a clockwise to counter-clockwise motion. Neuromonitoring may be used to detect the location and proximity of the nerves as the psoas is traversed.

Adjust the Dilator's position so it is flush with the disc space and confirm with AP fluoroscopy.

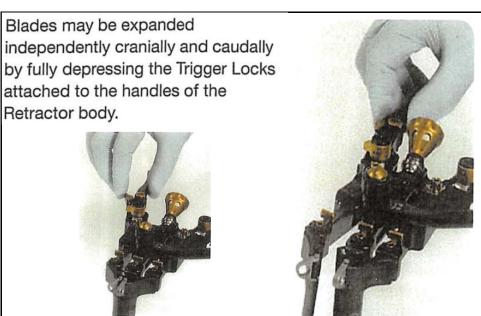


158. The Alphatec Surgical Guide discloses a SquadronTM Lateral Retractor, which contains a handle assembly which includes a first pivotable arm member and a second pivotable arm member that pivots relative to the first pivotable arm member, in response to manual adjustment of a component of the handle assembly (Ex. U at 1, 15):

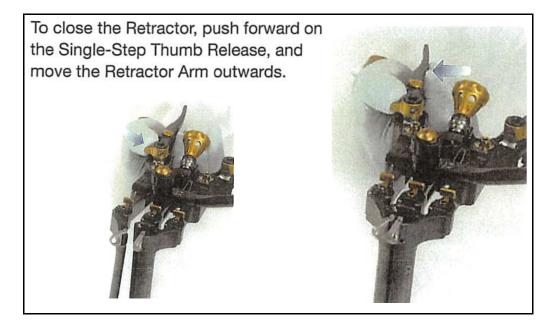
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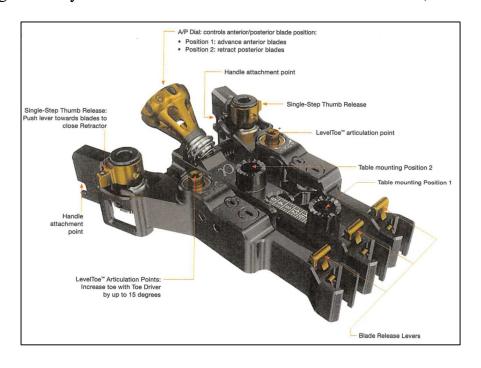




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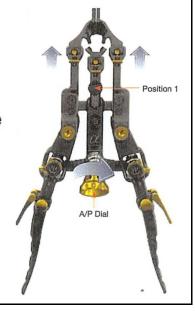
159. The Alphatec Surgical Guide discloses a translating member that can move longitudinally relative to the first and second arm members (Ex. U at 13, 17):



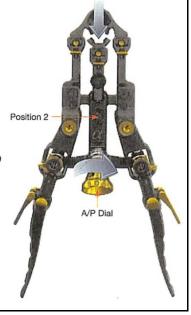
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The Table Fixation Arm can be attached to the Retractor in two locations:

Position 1 holds the posterior blade stationary while the left and right blades are free to traverse when the A/P Dial is rotated.



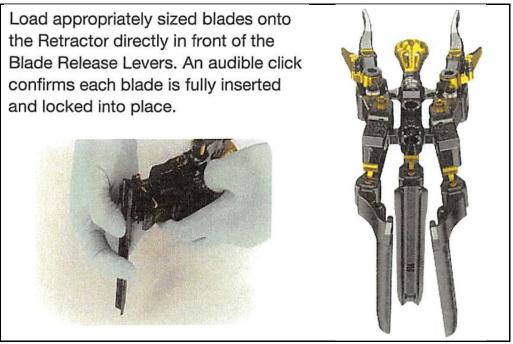
Position 2 holds the left and right blades stationary while the posterior blade is free to traverse when the A/P Dial is rotated.



160. The Alphatec Surgical Guide discloses that the Squadron™ Lateral Retractor includes a first retractor blade having a generally concave inner-facing surface and rigidly coupled to the first pivotable arm member, a second retractor blade having a generally concave inner-facing surface and rigidly coupled to the

translating member prior to the introduction toward the targeted spinal site (Ex. U at 9, 14, 29):

second pivotable arm member, and a third retractor blade rigidly coupled to the





161. The Alphatec Surgical Guide discloses an Intradiscal Shim element that releasably mounts to the third retractor blade such that a maximum length of PATENT INFRINGEMENT COMPLAINT -49-

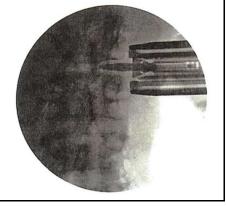
the Intradiscal Shim element extends generally parallel to the maximum length of the third retractor blade and a distal tip portion of the Intradiscal Shim element extends distally of the distal end of the third retractor blade. The Intradiscal Shim element engages with a groove defined by the third retractor blade to penetrate into the spinal disc at a targeted spinal site when the Intradiscal Shim element is mounted to the third retractor blade (Ex. U at19):

To stabilize the Retractor, place the Intradiscal Shim through the center blade of the Retractor ensuring that the tabs on either side of the Inserter engage into the tracks on the inside of the blade. Advance the Shim until it engages into the disc space and locks at the bottom of the blade. Press the gold button at the proximal end of the Inserter to disengage the Shim.





Confirm under AP and lateral fluoroscopy that the Shim is within the disc space.



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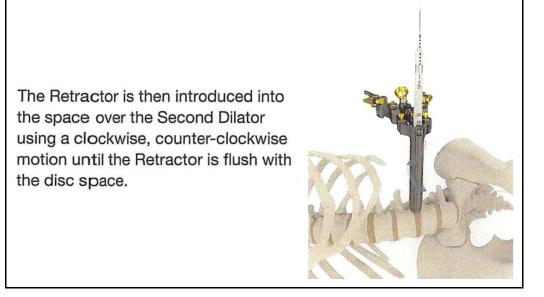
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162. The Alphatec Surgical Guide discloses that the Squadron[™] Lateral Retractor includes a handle assembly which is configured to simultaneously introduce the first, second, and third retractor blades along a lateral, transpsoas path in a closed position while the generally concave inner-facing surfaces of the first and second retractor blades engage with the outermost dilator (Ex. U at 10):



163. The Alphatec Surgical Guide discloses that the first and second retractor blades are thereafter opened by pivoting the first and second pivotable arm members relative to one another to create an operative corridor to the surgical target site (Ex. U at 1, 20):



See supra, ¶ 158 (showing that pivoting of each pivotable arm members each expands the right or left blade)



- 164. Alphatec is, thus, liable for direct infringement of the '801 patent pursuant to 35 U.S.C. § 271(a).
- 165. In violation of 35 U.S.C. § 271(b) Alphatec has and continues to induce infringement of at least claim 1 of the '801 patent.
- 166. With knowledge of the '801 patent, Alphatec has and continues to induce jointly and separately the direct infringement of at least claim 1 of the '801 patent by others, such as surgeons, by actively encouraging them to use at least the '801 Infringing System in an infringing manner, with specific intent to induce such actions knowing, or being willfully blind to, the fact that the induced actions constitute infringement of at least claim 1 of the '801 patent.
- 167. On information and belief, Alphatec had and continues to have specific intent to induce surgeons to use the '801 Infringing System to perform Alphatec's Lateral Procedure, knowing, or being willfully blind to, the fact that the induced actions constitute infringement of at least claim 1 of the '801 patent.
- 168. The Alphatec Surgical Guide provides specific instructions teaching surgeons how to use the '801 Infringing System during the Alphatec Lateral Procedure.

- 169. The Alphatec Surgical Guide describes the '801 Infringing System with detailed information about its features, which match each and every element of at least claim 1 of the '801 patent, as outlined above.
- 170. Alphatec has and continues to actively encourage others, such as surgeons, to directly infringe at least claim 1 of the '801 patent.
- other things: (1) publishing surgical techniques, conducting organized surgical training courses, and engaging in other marketing activities, to promote the BattalionTM Lateral System which includes the '801 Infringing System; (2) teaching, instructing, and training surgeons how to use the '801 Infringing System for the Alphatec Lateral Procedure; and (3) supplying one or more components of the '801 Infringing System, the components including, but not limited to, the Initial Dilator, the Secondary Dilator, the SquadronTM Lateral Retractor Body, the SquadronTM Lateral Retractor Right Blade, the SquadronTM Lateral Retractor Left Blade, the SquadronTM Lateral Retractor Left Retractor Right Handle Arm, the SquadronTM Lateral Retractor Left Handle Arm and the Intradiscal Shim (individually, a "'801 Infringing Component').
- 172. On information and belief, following Alphatec's active encouragement, surgeons have used and continue to use the '801 Infringing System in performing the Alphatec Lateral Procedure, and thus have directly infringed and continue to directly infringe at least claim 1 of the '801 patent.
- 173. Alphatec is, thus, liable for induced infringement of the '801 patent pursuant to 35 U.S.C. § 271(b).
- 174. In violation of 35 U.S.C. § 271(c) Alphatec has and continues to contribute to the direct infringement by others, such as surgeons, of at least claim 1 of the '801 patent.
- 175. Alphatec has and continues to offer for sell, sell, and/or import one or more the '801 Infringing Components which constitute a material part of at least

claim 1 of the '801 patent and lack any substantial non-infringing use, knowing, or being willfully blind to, the fact that those components are especially made or adapted for use in infringing at least claim 1 of the '801 patent.

- 176. On information and belief, following Alphatec's contributory actions, others, such as surgeons, have used and continue to use the '801 Infringing System for the Alphatec Lateral Procedure and thus have directly infringed and continue to directly infringe at least claim 1 of the '801 patent.
- 177. On information and belief, Alphatec knew and does now know, or was willfully blind to, the fact that use of the '801 Infringing System by surgeons for the Alphatec Lateral Procedure infringes at least claim 1 of the '801 patent, as outlined above.
- 178. On information and belief, Alphatec purposefully designed each of the '801 Infringing Components as part of the '801 Infringing System for use in performing the Alphatec Lateral Procedure and for no other purpose. For example, the Right, Left and Posterior Blades of the SquadronTM Lateral Retractor are sized to match the distance from the side of a patient to the lumbar spine of the patient, and the size of the Blades is determined using the depth markings on the Initial Dilator. As another example, the Intradiscal Shim and the Posterior Blade are especially designed to engage with each other at a groove on the Posterior Blade.
- 179. On information and belief, Alphatec thus knew and does now know the '801 Infringing Components are each especially made or adapted for use in infringing the at least claim 1 of the '801 patent.
- 180. On information and belief, Alphatec thus knew and does now know the '801 Infringing Components are each not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 181. On information and belief, Alphatec thus knew and does now know that the '801 Infringing Components are each essential to and enable the use of the

'801 Infringing System for performing the Alphatec Lateral Procedure by surgeons.

- 182. Each of the '801 Infringing Components embodies at least a majority of the limitations of at least claim 1 of the '801 patent.
- 183. Alphatec is, thus, liable for contributory infringement of the '801 patent pursuant to 35 U.S.C. § 271(c).
- 184. In violation of 35 U.S.C. § 271(f)(1), on information and belief, Alphatec has been and continues to supply or cause to be supplied in or from the United States all or a substantial portion of the components of the '801 Infringing System including, but not limited to, one or more of the '801 Infringing Components, where such components are uncombined in whole or in part, in such a manner to actively induce the combination of such components outside of the United States in a manner that practices at least claim 1 of the '801 patent.
- 185. Alphatec is, thus, liable for infringement of the '801 patent pursuant to 35 U.S.C. § 271(f)(1).
- 186. In violation of 35 U.S.C. § 271(f)(2), on information and belief, Alphatec has been and continues to supply or cause to be supplied in or from the United States one or more of the '801 Infringing Components, where such component is uncombined in whole or part, intending that such component will be combined outside of the United States in a manner that practices at least claim 1 of the '801 patent.
- 187. On information and belief, Alphatec knew and does now know, or was willfully blind to, the fact that the '801 Infringing Components are each especially made or adapted for use in the '801 Infringing System and are each not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 188. Alphatec is, thus, liable for infringement of the '801 patent pursuant to 35 U.S.C. § 271(f)(2).

189. Unless enjoined by this Court, Alphatec will continue to infringe one or more claims of the '801 patent, and NuVasive will continue to suffer irreparable harm for which there is no adequate remedy at law. Accordingly, NuVasive is entitled to preliminary and permanent injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

190. As a result of Alphatec's infringement of one or more claims of the '801 patent, NuVasive has been and continues to be injured in its business and property rights, and is entitled to recover damages for such injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

- 191. On information and belief, at all times that infringement has occurred or will occur, Alphatec had and has actual and/or constructive knowledge of the '801 patent.
- 192. On information and belief, Alphatec's infringement of one or more claims of the '801 patent is and has been willful, deliberate, and egregious.

 Accordingly, NuVasive is entitled to enhanced damages pursuant to 35 U.S.C. § 284 and to an award of attorney's fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285.
- 193. Alphatec is precluded from challenging the validity of the '801 patent, including particularly under the doctrine of equitable estoppel.
- 194. Alphatec is in privity with Mr. Miles, who is an assignor and inventor of the '801 patent, as outlined above.
- 195. On information and belief, Alphatec has and continues to avail itself of Mr. Miles' knowledge and assistance to infringe the '801 patent.
- 196. Mr. Miles swore to the U.S. Patent Office that he is an inventor of the '801 patent.
- 197. On April 11, 2005, Mr. Miles signed a declaration, swearing that he believes he is an inventor on U.S. Patent Application No. 10/789,797 ("the '797 application"), which issued as the '801 patent. Ex. AC at 1-2.

- 198. Mr. Miles' inventor declaration (Ex. AC) was filed on May 16, 2005 as an official declaration of record for the '801 patent.
- 199. For good and valuable consideration, Mr. Miles assigned NuVasive all right, title and interest to the '801 patent.

V. SECOND CAUSE OF ACTION — Infringement of U.S. Patent No. 8,355,780

- 200. NuVasive repeats and realleges the allegations of paragraphs 1 through 199 in their entirety.
- 201. On January 15, 2013, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 8,355,780 ("the '780 patent"), entitled "Surgical Access System and Related Methods," to Patrick Miles, Scot Martinelli and Eric Finley. A true and correct copy of the '780 patent is attached hereto as Exhibit AD.
- 202. At all relevant times, NuVasive is and has been the owner, by valid assignment, of all right, title, and interest in and to the '780 patent.
- 203. On information and belief, Alphatec had knowledge of the '780 patent prior to the filing of this Complaint.
- 204. On information and belief, Alphatec has been monitoring and continues to monitor NuVasive's patent portfolio, including patents and applications that are directed to lateral, transpsoas spinal procedures, systems, and devices, such as the '780 patent.
- 205. On information and belief, Alphatec gained knowledge of the '780 patent through its privity relationship with Mr. Miles, which formed at least as early as October 2, 2017.
- 206. Mr. Miles is a named inventor of the '780 patent and therefore has and continues to have knowledge of the '780 patent.

- 207. A privity relationship between Alphatec and Mr. Miles formed at least as early as October 2, 2017, when Mr. Miles joined Alphatec as its Executive Chairman.
 - 208. Alphatec continues to be in privity with Mr. Miles.
- 209. Upon the formation of Alphatec's privity relationship with Mr. Miles, Alphatec was imputed with, and continues to be imputed with, Mr. Miles' knowledge of the '780 patent.
- 210. Alphatec has and continues to avail itself of Mr. Miles' knowledge and assistance to infringe the '780 patent, which Mr. Miles had assigned to NuVasive.
- 211. At the very latest, Alphatec has knowledge of the '780 patent as of the filing of this Complaint.
- 212. In violation of 35 U.SC. § 271(a), Alphatec has and continues to directly infringe one or more claims of the '780 patent.
- 213. In particular, and without limitation, Alphatec directly infringes the '780 patent by making, using, selling, offering for sale, and/or importing into the United States products and systems including, but not limited to, the Initial Dilator, the Secondary Dilator, the SquadronTM Lateral Retractor Body, the SquadronTM Lateral Retractor Right Blade, the SquadronTM Lateral Retractor Left Blade, and the SquadronTM Lateral Retractor Posterior Blade (collectively, "the '780 Infringing System"), which are components of the BattalionTM Lateral System, without the permission of NuVasive.
- 214. The '780 Infringing System infringes at least claim 21 of the '780 patent.
- 215. As explained in the Alphatec Surgical Guide, the '780 Infringing System is a system for forming an operating corridor to a lumbar spine.
- 216. The Alphatec Surgical Guide discloses a dilator system to create a distraction corridor along a lateral, transpsoas path to the lumbar spine. The

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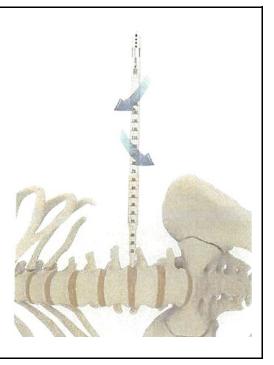
Alphatec Surgical Guide discloses that the dilator system includes at least two dilators of sequentially larger widths deliverable to a spinal disc along a lateral, trans-psoas path to the lumbar spine. The second dilator of the two dilators slidably engages the exterior of the first dilator of the two dilators (Ex. U at 6-8):

Introduce the Secondary Dilator over the Initial Dilator using a clockwise, counter-clockwise motion. Advance the Second Dilator until it is flush with the disc space.

TRAVERSING THE PSOAS

Carefully split the muscle fibers of the psoas by advancing the Dilator in a clockwise to counter-clockwise motion. Neuromonitoring may be used to detect the location and proximity of the nerves as the psoas is traversed.

Adjust the Dilator's position so it is flush with the disc space and confirm with AP fluoroscopy.



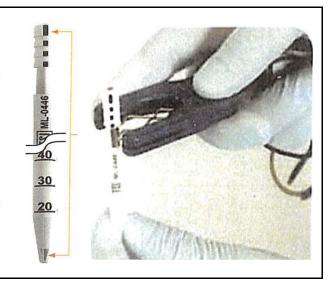
217. The Alphatec Surgical Guide discloses that at least one of the first and second dilators includes a stimulation electrode to deliver electrical stimulation for nerve monitoring when the stimulation electrode is positioned along the lateral, trans-psoas path to the lumbar spine (Ex. U at 5-6):

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Place the Universal Clip onto exposed silver ring at the proximal end of the Dilator and connect to the appropriate neuromonitoring platform.

TRAVERSING THE PSOAS

Carefully split the muscle fibers of the psoas by advancing the Dilator in a clockwise to counter-clockwise motion. Neuromonitoring may be used to detect the location and proximity of the nerves as the psoas is traversed.

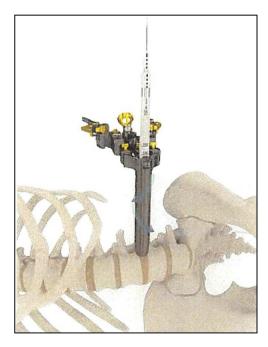


218. The Alphatec Surgical Guide discloses the SquadronTM Lateral Retractor, which includes a blade holder assembly and three blades. The Alphatec Surgical Guide discloses that the SquadronTM Lateral Retractor is slidable over the dilator system along the lateral, transpsoas path. The blade holder assembly and first, second and third retractor blades extend generally perpendicularly relative to arm members of the blade holder assembly (Ex. U at 10, 14):

The Retractor is then introduced into the space over the Second Dilator using a clockwise, counter-clockwise motion until the Retractor is flush with the disc space.

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219. The Alphatec Surgical Guide discloses that the Squadron[™] Lateral Retractor is adjustable from a first position in which the three blades are adjacent to one another and slidable over the dilator system to a second position in which the second and third retractor blades move away from the first retractor blade to enlarge the distraction corridor, forming an operative corridor along the lateral, transpsoas path to the lumbar spine (Ex. U at 1, 20):

Exp

DISC SPACE ACCESS

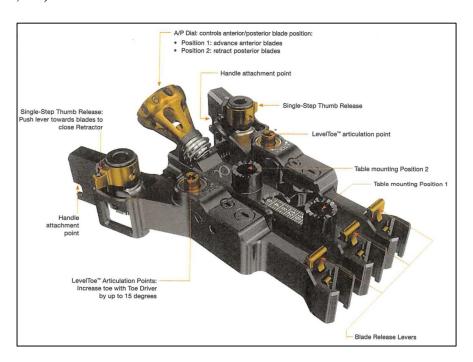
Expand the right and/or left blade to expose the disc space and gain optimal access for the procedure.

Retract the psoas anterior to visualize the disc space by rotating the gold A/P Dial. The Blade Toe Driver may be used for additional torque.

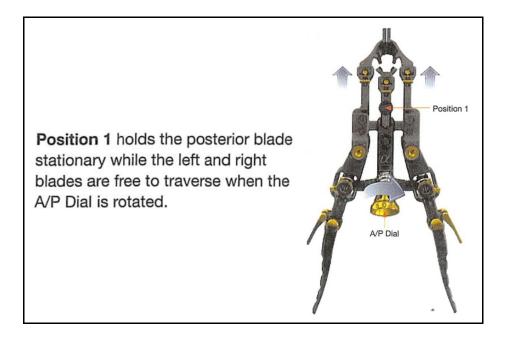


220. The Alphatec Surgical Guide discloses that the first blade of the SquadronTM Lateral Retractor is linearly movable relative to the second and third PATENT INFRINGEMENT COMPLAINT -61-

blades in response to the rotation of a knob element on the blade holder assembly (Ex. U at 13, 17):



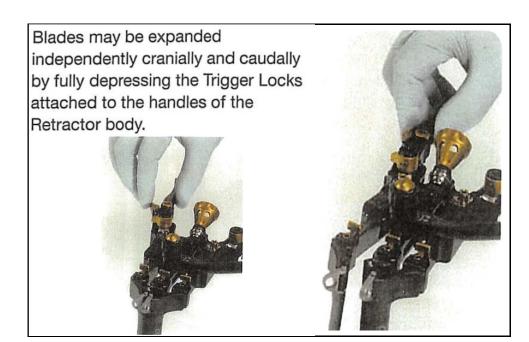
The Table Fixation Arm can be attached to the Retractor in two locations:

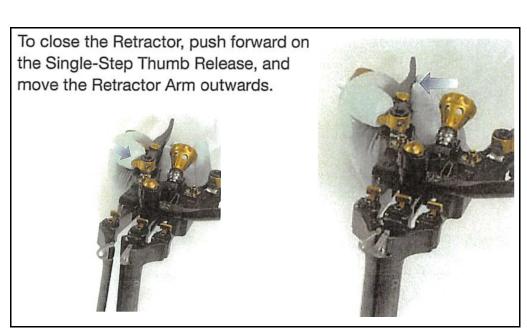


Position 2 holds the left and right blades stationary while the posterior blade is free to traverse when the A/P Dial is rotated.

The Alphatec Surgical Guide discloses that the second blade is movable relative to the first blade in response to a pivoting movement of the first arm member coupled to the second blade, and that the third blade is movable relative to the first blade in response to a pivoting movement of the second pivotable arm coupled to the third retractor blade (Ex. U at 1, 14-15):









222. The Alphatec Surgical Guide discloses that the Squadron Lateral RetractorTM is adjusted to the second position to form the operative corridor along the lateral, trans-psoas path to the lumbar spine, where the first blade is the posterior-most retractor blade among the first, second and third blades. *Supra*, ¶¶ 218-219.

223. The Alphatec Surgical Guide discloses that the operative corridor is dimensioned so as to pass an implant through the operative corridor and into the lumbar spine (Ex. U at 24):

10 IMPLANT INSERTION

- Choose the appropriate implant by width, length, lordosis, and height as determined by trialing.
- 224. Alphatec is, thus, liable for direct infringement of the '780 patent pursuant to 35 U.S.C. § 271(a).
- 225. In violation of 35 U.S.C. § 271(b), Alphatec has and continues to induce infringement of at least claim 21 of the '780 patent.
- 226. With knowledge of the '780 patent, Alphatec has and continues to induce jointly and separately the direct infringement of at least claim 21 of the '780 patent by others, such as surgeons, by actively encouraging them to use at least the '780 Infringing System in an infringing manner, with specific intent to induce such actions knowing, or being willfully blind to, the fact that the induced actions constitute infringement of at least claim 21 of the '780 patent.
- 227. On information and belief, Alphatec had and continues to have specific intent to induce direct infringement by surgeons of at least claim 21 of the '780 patent, knowing, or being willfully blind to, the fact that the induced actions constitute infringement.

- 228. The Alphatec Surgical Guide provides specific instructions teaching surgeons how to use the '780 Infringing System to perform the Alphatec Lateral Procedure
- 229. The Alphatec Surgical Guide describes the '780 Infringing System with detailed information about its features, which match each and every element of at least claim 21 of the '780 patent, as outlined above.
- 230. Alphatec has and continues to actively encourage others, such as surgeons, to directly infringe at least claim 21 of '780 patent.
- 231. Alphatec's affirmative acts of active encouragement include, among other things: (1) publishing surgical techniques, conducting organized surgical training courses, and engaging in other marketing activities, to promote the BattalionTM Lateral System which includes the '780 Infringing System; (2) teaching, instructing, and training surgeons how to use the '780 Infringing System for the Alphatec Lateral Procedure; and (3) supplying one or more components of the '780 Infringing System, the components including, but not limited to, the Initial Dilator, the Secondary Dilator, the SquadronTM Lateral Retractor Body, the SquadronTM Lateral Retractor Right Blade, the SquadronTM Lateral Retractor Left Blade, and the SquadronTM Lateral Retractor Posterior Blade (individually, a "'780 Infringing Component").
- 232. On information and belief, following Alphatec's active encouragement, others, such as surgeons, have used and continue to use the '780 Infringing System in performing the Alphatec Lateral Procedure, and thus have and continue to directly infringe at least claim 21 of the '780 patent.
- 233. Alphatec is, thus, liable for induced infringement of the '780 patent pursuant to 35 U.S.C. § 271(b).

- 234. In violation of 35 U.S.C. § 271(c) Alphatec has and continues to contribute to the direct infringement by others, such as surgeons, of at least claim 21 of the '780 patent.
- 235. Alphatec has and continues to offer for sell, sell, and/or import one or more the '780 Infringing Components which constitute a material part of at least claim 21 of the '780 patent and lack any substantial non-infringing use, knowing, or being willfully blind to, the fact that those components are especially made or adapted for use in infringing at least claim 21 of the '780 patent.
- 236. On information and belief, following Alphatec's contributory actions, others, such as surgeons, have used and continue to use the '780 Infringing System for the Alphatec Lateral Procedure and thus have directly infringed and continue to directly infringe at least claim 21 of the '780 patent.
- 237. On information and belief, Alphatec knew and does now know, or was willfully blind to, the fact that use of the '780 Infringing System by surgeons for the Alphatec Lateral Procedure infringes at least claim 21 of the '780 patent, as outlined above.
- 238. On information and belief, Alphatec purposefully designed each of the '780 Infringing Components as part of the '780 Infringing System for use in performing the Alphatec Lateral Procedure and for no other purpose. For example, the Right, Left and Posterior Blades of the SquadronTM Lateral Retractor are sized to match the distance from the side of a patient to the lumbar spine of the patient, and the size of the Blades is determined using the depth markings on the Initial Dilator.
- 239. On information and belief, Alphatec thus knew and does now know the '780 Infringing Components are each especially made or adapted for use in infringing the at least claim 21 of the '780 patent.

- 240. On information and belief, Alphatec thus knew and does now know the '780 Infringing Components are each not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 241. On information and belief, Alphatec thus knew and does now know that the '780 Infringing Components are each essential to and enable the use of the '780 Infringing System for performing the Alphatec Lateral Procedure by surgeons.
- 242. Each of the '780 Infringing Components embodies at least a majority of the limitations of at least claim 21 of the '780 patent.
- 243. Alphatec is, thus, liable for contributory infringement of the '780 patent pursuant to 35 U.S.C. § 271(c).
- 244. In violation of 35 U.S.C. § 271(f)(1), on information and belief, Alphatec has been and continues to supply or cause to be supplied in or from the United States all or a substantial portion of the components of the '780 Infringing System including, but not limited to, one or more of the '780 Infringing Components, where such components are uncombined in whole or in part, in such a manner to actively induce the combination of such components outside of the United States in a manner that practices at least claim 21 of the '780 patent.
- 245. Alphatec is, thus, liable for infringement of the '780 patent pursuant to 35 U.S.C. § 271(f)(1).
- 246. In violation of 35 U.S.C. § 271(f)(2), on information and belief, Alphatec has been and continues to supply or cause to be supplied in or from the United States one or more of the '780 Infringing Components, where such component is uncombined in whole or part, intending that such component will be combined outside of the United States in a manner that practices at least claim 21 of the '780 patent.
- 247. On information and belief, Alphatec knew and does now know, or was willfully blind to, the fact that the '780 Infringing Components are each

especially made or adapted for use in the '780 Infringing System and are each not a staple article or commodity of commerce suitable for substantial non-infringing use.

- 248. Alphatec is, thus, liable for infringement of the '780 patent pursuant to 35 U.S.C. § 271(f)(2).
- 249. Unless enjoined by this Court, Alphatec will continue to infringe one or more claims of the '780 patent, and NuVasive will continue to suffer irreparable harm for which there is no adequate remedy at law. Accordingly, NuVasive is entitled to preliminary and permanent injunctive relief against such infringement pursuant to 35 U.S.C. § 283.
- 250. As a result of Alphatec's infringement of one or more claims of the '780 patent, NuVasive has been and continues to be injured in its business and property rights, and is entitled to recover damages for such injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.
- 251. On information and belief, at all times that infringement has occurred or will occur, Alphatec had and has actual and/or constructive knowledge of the '780 patent.
- 252. On information and belief, Alphatec's infringement of one or more claims of the '780 patent is willful, deliberate, and egregious. Accordingly, NuVasive is entitled to enhanced damages pursuant to 35 U.S.C. § 284 and to an award of attorney's fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285.
- 253. Alphatec is precluded from challenging the validity of the '780 patent, including particularly under the doctrine of equitable estoppel.
- 254. Alphatec is in privity with Mr. Miles, who is an assignor and inventor of the '780 patent.
- 255. On information and belief, Alphatec has and continues to avail itself of Mr. Miles' knowledge and assistance to infringe the '780 patent.

- 256. Mr. Miles swore to the U.S. Patent Office that he is an inventor of the '780 patent.
- 257. On October 24, 2005, Mr. Miles signed a declaration, swearing that he believes he is an inventor of U.S. Patent Application No. 11/137,169 ("the '169 application"), which is an application to which the '780 patent claims priority without any intervening continuation-in-part applications. Ex. AE at 2-3.
- 258. Mr. Miles' inventor declaration (Ex. AE) was filed on April 23, 2007 as an official declaration of record for the '780 patent.
- 259. For good and valuable consideration, Mr. Miles assigned NuVasive all right, title and interest to the '780 patent.

VI. THIRD CAUSE OF ACTION — Infringement of U.S. Patent No. 8,439,832

- 260. NuVasive repeats and realleges the allegations of paragraphs 1 through 259 in their entirety.
- 261. On May 14, 2013, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 8,439,832 ("the '832 patent"), entitled "Surgical Access System and Related Methods," to Patrick Miles, Scot Martinelli, Eric Finley, James Gharib, Allen Farquhar, Norbert Kaula, Jeffrey Blewett, and Goretti Medeiros (legal representative). A true and correct copy of the '832 patent is attached hereto as Exhibit AF.
- 262. At all relevant times, NuVasive is and has been the owner, by valid assignment, of all right, title, and interest in and to the '832 patent.
- 263. On information and belief, Alphatec had knowledge of the '832 patent prior to the filing of this Complaint.
- 264. On information and belief, Alphatec has been monitoring and continues to monitor NuVasive's patent portfolio, including patents and applications that are directed to lateral, transpsoas spinal procedures, systems, and devices, such as the '832 patent.

- 265. On information and belief, Alphatec gained knowledge of the '832 patent through its privity relationship with Mr. Miles, which formed at least as early as October 2, 2017.
- 266. Mr. Miles is a named inventor of the '832 patent and therefore had and continues to have knowledge of the '832 patent.
- 267. A privity relationship between Alphatec and Mr. Miles formed at least as early as October 2, 2017, when Mr. Miles joined Alphatec as its Executive Chairman.
 - 268. Alphatec continues to be in privity with Mr. Miles.
- 269. Upon the formation of Alphatec's privity relationship with Mr. Miles, Alphatec was imputed with, and continues to be imputed with, Mr. Miles' knowledge of the '832 patent.
- 270. Alphatec has and continues to avail itself of Mr. Miles' knowledge and assistance to infringe the '832 patent, which Mr. Miles had assigned to NuVasive.
- 271. At the very latest, Alphatec has knowledge of the '832 patent as of the filing of this Complaint.
- 272. In violation of 35 U.SC. § 271(a), Alphatec has and continues to directly infringe one or more claims of the '832 patent.
- 273. In particular, and without limitation, Alphatec directly infringes the '832 patent, by making, using, selling, offering for sale, and/or importing into the United States products and systems including, but not limited to the K-wire, the Initial Dilator, the Secondary Dilator, the SquadronTM Lateral Retractor Body, the SquadronTM Lateral Retractor Right Blade, the SquadronTM Lateral Retractor Left Blade, and the SquadronTM Lateral Retractor Posterior Blade (collectively, "the '832 Infringing System"), which are components of the BattalionTM Lateral System, without the permission of NuVasive.

274. The '832 Infringing System infringes at least claim 1 of the '832 patent.

275. As explained in the Alphatec Surgical Guide, the '832 Infringing System is a system for forming an operating corridor to a lumbar spine.

276. The Alphatec Surgical Guide discloses a distraction assembly to create a tissue distraction corridor in a lateral, transpsoas path to a lumbar spine. The distraction assembly includes an elongate inner element and a plurality of dilators. The plurality of dilators is configured to be sequentially advanced along the lateral, transpsoas path to the lumbar spine. The elongate inner element is positionable in a lumen of the initial dilator (Ex. U at 5-7):

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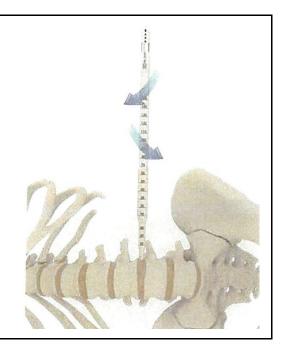
Once a safe pathway has been created, insert the Initial Dilator into the space. Use the index finger to guide the Dilator to the psoas muscle.	A B B B B B B B B B B B B B B B B B B B
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TRAVERSING THE PSOAS

Carefully split the muscle fibers of the psoas by advancing the Dilator in a clockwise to counter-clockwise motion.

Once the Dilator's appropriate position is confirmed, introduce the K-wire through the Dilator halfway into the disc space.

Introduce the Secondary Dilator over the Initial Dilator using a clockwise, counter-clockwise motion. Advance the Second Dilator until it is flush with the disc space.

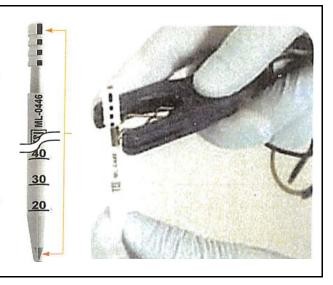


277. At least one of the dilators or elongate member includes a stimulation electrode that outputs electrical stimulation for nerve monitoring when positioned in the psoas muscle (Ex. U at 5-6):

Place the Universal Clip onto exposed silver ring at the proximal end of the Dilator and connect to the appropriate neuromonitoring platform.

TRAVERSING THE PSOAS

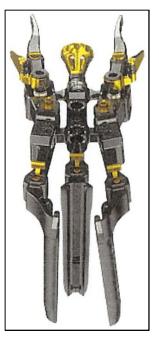
Carefully split the muscle fibers of the psoas by advancing the Dilator in a clockwise to counter-clockwise motion. Neuromonitoring may be used to detect the location and proximity of the nerves as the psoas is traversed.

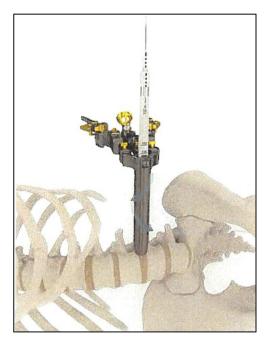


278. The Alphatec Surgical Guide discloses the SquadronTM Lateral Retractor. The SquadronTM Lateral Retractor includes a blade-holder assembly, a posterior-most retractor blade, a cephalad-most retractor blade, and a caudal-most retractor blade. The SquadronTM Lateral Retractor is slidable over the exterior of the outer dilator toward the targeted disc along the lateral, transpsoas path. The

posterior-most, cephalad-most, and caudal-most retractor blades are slidably advanced over the exterior of the outermost sequential dilator while in a first position (Ex. U at 10, 14):

The Retractor is then introduced into the space over the Second Dilator using a clockwise, counter-clockwise motion until the Retractor is flush with the disc space.





279. The blade holder assembly on the SquadronTM Lateral Retractor is adjustable to move the cephalad-most and caudal-most blades to a second position in which those blades are spaced apart from the posterior-most blade to define an operative corridor. The SquadronTM Lateral Retractor is configured to define the operative corridor along the lateral, transpsoas path to the lumbar spine (Ex. U at 1, 20):

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to expose the disc space and gain optimal access for the procedure.

Retract the psoas anterior to visualize the disc space by rotating the gold A/P Dial. The Blade Toe Driver may be used for additional torque.



280. The Alphatec Surgical Guide discloses that the space extending to the targeted spinal disc in the operative corridor is dimensioned so as to pass an implant through the operative corridor along the lateral, transpsoas path to the lumbar spine (Ex. U at 24):

10 IMPLANT INSERTION

- Choose the appropriate implant by width, length, lordosis, and height as determined by trialing.
- 281. Alphatec is, thus, liable for direct infringement of the '832 patent pursuant to 35 U.S.C. § 271(a).
- 282. In violation of 35 U.S.C. § 271(b), Alphatec has and continues to induce infringement of at least claim 1 of the '832 patent.
- 283. With knowledge of the '832 patent, Alphatec has and continues to induce jointly and separately the direct infringement of at least claim 1 of the '832 patent by others, such as surgeons, by actively encouraging use of at least the '832 Infringing System in an infringing manner, with specific intent to induce such actions knowing that the induced actions constitute infringement of at least claim 1 of the '832 patent.

- 284. On information and belief, Alphatec had and continues to have specific intent to induce direct infringement by surgeons of at least claim 1 of the '832 patent, knowing, or being willfully blind to, the fact that the induced actions constitute infringement.
- 285. The Alphatec Surgical Guide provides specific instruction teaching surgeons how to use the '832 Infringing System during the Alphatec Lateral Procedure.
- 286. The Alphatec Surgical Guide describes the '832 Infringing System with detailed information about its features, which match each and every element of at least claim 1 of the '832 patent, as outlined above.
- 287. Alphatec has and continues to actively encourage others, such as surgeons, to directly infringe at least claim 1 of '832 patent.
- 288. Alphatec's affirmative acts of active encouragement include, among other things: (1) publishing surgical techniques, conducting organized surgical training courses, and engaging in other marketing activities, to promote the BattalionTM Lateral System which includes the '832 Infringing System; (2) teaching, instructing, and training surgeons how to use the '832 Infringing System for the Alphatec Lateral Procedure; and (3) supplying one or more components of the '832 Infringing System, the components including, but not limited to, K-wire, the Initial Dilator, the Secondary Dilator, the SquadronTM Lateral Retractor Body, the SquadronTM Lateral Retractor Right Blade, the SquadronTM Lateral Retractor Left Blade, and the SquadronTM Lateral Retractor Posterior Blade (individually, a "'832 Infringing Component").
- 289. On information and belief, following Alphatec's active encouragement, surgeons have used and continue to use the '832 Infringing System in performing the Alphatec Lateral Procedure, and thus have and continue to directly infringe at least claim 1 of the '832 patent.

290. Alphatec is, thus, liable for induced infringement of the '832 patent pursuant to 35 U.S.C. § 271(b).

- 291. In violation of 35 U.S.C. § 271(c) Alphatec has and continues to contribute to the direct infringement by others, such as surgeons, of at least claim 1 of the '832 patent.
- 292. Alphatec has and continues to offer for sell, sell, and/or import one or more the '832 Infringing Components which constitute a material part of at least claim 1 of the '832 patent and lack any substantial non-infringing use, knowing, or being willfully blind to, the fact that those components are especially made or adapted for use in infringing at least claim 1 of the '832 patent.
- 293. On information and belief, following Alphatec's contributory actions, others, such as surgeons, have used and continue to use the '832 Infringing System for the Alphatec Lateral Procedure and thus have directly infringed and continue to directly infringe at least claim 1 of the '832 patent.
- 294. On information and belief, Alphatec knew and does now know, or was willfully blind to, the fact that use of the '832 Infringing System by surgeons for the Alphatec Lateral Procedure infringes at least claim 1 of the '832 patent, as outlined above.
- 295. On information and belief, Alphatec purposefully designed each of the '832 Infringing Components as part of the '832 Infringing System for use in performing the Alphatec Lateral Procedure and for no other purpose. For example, the Right, Left and Posterior Blades of the SquadronTM Lateral Retractor are sized to match the distance from the side of a patient to the lumbar spine of the patient, and the size of the Blades is determined using the depth markings on the Initial Dilator.
- 296. On information and belief, Alphatec thus knew and does now know the '832 Infringing Components are each especially made or adapted for use in infringing the at least claim 1 of the '832 patent.

- 297. On information and belief, Alphatec thus knew and does now know the '832 Infringing Components are each not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 298. On information and belief, Alphatec thus knew and does now know that the '832 Infringing Components are each essential to and enable the use of the '832 Infringing System for performing the Alphatec Lateral Procedure by surgeons.
- 299. Each of the '832 Infringing Components embodies at least a majority of the limitations of at least claim 1 of the '832 patent.
- 300. Alphatec is, thus, liable for contributory infringement of the '832 patent pursuant to 35 U.S.C. § 271(c).
- 301. In violation of 35 U.S.C. § 271(f)(1), on information and belief, Alphatec has been and continues to supply or cause to be supplied in or from the United States all or a substantial portion of the components of the '832 Infringing System including, but not limited to, one or more of the '832 Infringing Components, where such components are uncombined in whole or in part, in such a manner to actively induce the combination of such components outside of the United States in a manner that practices at least claim 1 of the '832 patent.
- 302. Alphatec is, thus, liable for infringement of the '832 patent pursuant to 35 U.S.C. § 271(f)(1).
- 303. In violation of 35 U.S.C. § 271(f)(2), on information and belief, Alphatec has been and continues to supply or cause to be supplied in or from the United States one or more of the '832 Infringing Components, where such component is uncombined in whole or part, intending that such component will be combined outside of the United States in a manner that practices at least claim 1 of the '832 patent.
- 304. On information and belief, Alphatec knew and does now know, or was willfully blind to, the fact that the '832 Infringing Components are each

especially made or adapted for use in the '832 Infringing System and are each not a staple article or commodity of commerce suitable for substantial non-infringing use.

305. Alphatec is, thus, liable for infringement of the '832 patent pursuant to 35 U.S.C. § 271(f)(2).

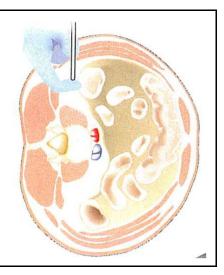
306. In violation of 35 U.SC. § 271(a), Alphatec also has and continues to directly infringe at least claim 12 of the '832 patent. In particular, and without limitation, Alphatec performs the method of claim 12 by demonstrating the Alphatec Lateral Procedure using at least using the K-Wire, Initial Dilator, the Secondary Dilator, the SquadronTM Lateral Retractor Body, the SquadronTM Lateral Retractor Right Blade, the SquadronTM Lateral Retractor Left Blade, and the SquadronTM Lateral Retractor Posterior Blade, and the BattalionTM Lateral Spacer in an infringing manner, which are components of the BattalionTM Lateral System, during promotional, educational, and training activities, such as in-person courses for surgeons.

307. As explained in the Alphatec Surgical Guide, the Alphatec Lateral Procedure is a method for accessing a spinal disc of a lumbar spine of a patient.

308. As explained in the Alphatec Surgical Guide, a plurality of sequentially larger diameter dilators is sequentially inserted into a patient along a lateral, transpsoas path to create a distraction corridor along the lateral, transpsoas path toward a targeted spinal disc, wherein the initial dilator is configured to receive an elongate inner element (Ex. U at 5-7):

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Once a safe pathway has been created, insert the Initial Dilator into the space. Use the index finger to guide the Dilator to the psoas muscle.

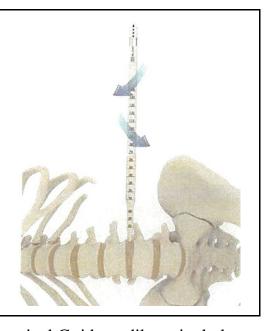


TRAVERSING THE PSOAS

Carefully split the muscle fibers of the psoas by advancing the Dilator in a clockwise to counter-clockwise motion.

Once the Dilator's appropriate position is confirmed, introduce the K-wire through the Dilator halfway into the disc space.

Introduce the Secondary Dilator over the Initial Dilator using a clockwise, counter-clockwise motion. Advance the Second Dilator until it is flush with the disc space.



309. As explained in the Alphatec Surgical Guide, a dilator includes a stimulation electrode that outputs electrical stimulation for nerve monitoring when positioned in the lateral, transpsoas path (Ex. U at 5-6):

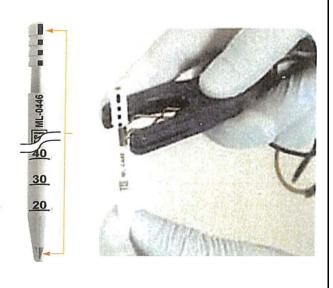
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Place the Universal Clip onto exposed silver ring at the proximal end of the Dilator and connect to the appropriate neuromonitoring platform.

TRAVERSING THE PSOAS

Carefully split the muscle fibers of the psoas by advancing the Dilator in a clockwise to counter-clockwise motion. Neuromonitoring may be used to detect the location and proximity of the nerves as the psoas is traversed.



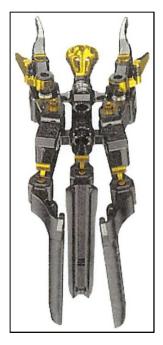
310. As explained in the Alphatec Surgical Guide, the Squadron™ Lateral Retractor is a three-bladed retractor tool that includes a posterior-most retractor blade, a cephalad-most retractor blade, and a caudal-most retractor blade, which are simultaneously advanced along a lateral, transpsoas path and over an exterior of an outermost dilator of the plurality of sequentially larger dilators (Ex. U at 10, 14):

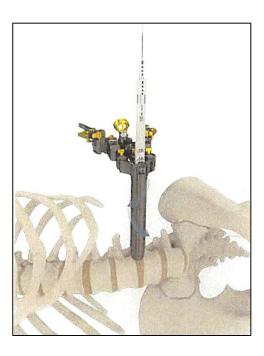
The Retractor is then introduced into the space over the Second Dilator using a clockwise, counter-clockwise motion until the Retractor is flush with the disc space.

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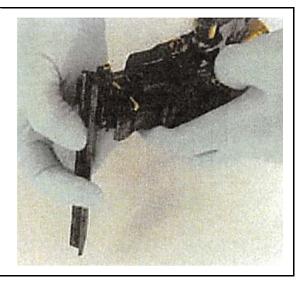




311. As explained in the Alphatec Surgical Guide, the Squadron[™] Lateral Retractor includes a blade holder assembly, which is attached to the posterior-most retractor blade, cephalad-most retractor blade, and caudal-most retractor blade (Ex. U at 9-10):

Load appropriately sized blades onto the Retractor directly in front of the Blade Release Levers. An audible click confirms each blade is fully inserted and locked into place.

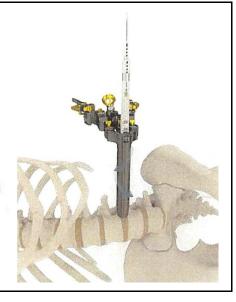




312. As explained in the Alphatec Surgical Guide, the plurality of sequentially larger diameter dilators is removed from the patient after the posterior-most retractor blade, cephalad-most retractor blade, and caudal-most retractor blade are advanced through the psoas muscle. (Ex. U at 10, 18):

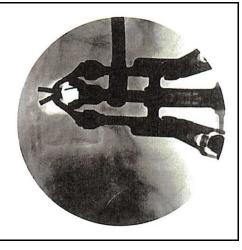
TRAVERSING THE PSOAS

The Retractor is then introduced into the space over the Second Dilator using a clockwise, counter-clockwise motion until the Retractor is flush with the disc space.



DISC SPACE ACCESS

Remove the Dilators, taking care to keep the K-wire in place.



313. As explained in the Alphatec Surgical Guide, the operative corridor along the lateral, transpsoas path to the targeted spinal disc is at least partially defined by the posterior-most retractor blade, cephalad-most retractor blade, and caudal-most retractor blade. The operative corridor is maintained along the lateral, tranpsoas path using the SquadronTM Lateral Retractor while delivering a spinal implant to a disc space of the targeted spinal disc (Ex. U at 1, 20, 24, 28):

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DISC SPACE ACCESS

Expand the right and/or left blade to expose the disc space and gain optimal access for the procedure.

Retract the psoas anterior to visualize the disc space by rotating the gold A/P Dial. The Blade Toe Driver may be used for additional torque.



IMPLANT INSERTION

Choose the appropriate implant by width, length, lordosis, and height as determined by trialing.



Battalion Lateral — Lumbar Spacer System

The Battalion Universal Spacer System (Battalion System) is an intervertebral body fusion device with implants of various lengths, widths, heights, and degrees of lordosis to accommodate individual patient anatomy.

- 314. Alphatec is, thus, liable for direct infringement of the '832 patent pursuant to 35 U.S.C. § 271(a).
- 315. In violation of 35 U.S.C. § 271(b), Alphatec has and continues to induce infringement of at least claim 12 of the '832 patent.
- 316. With knowledge of the '832 patent, Alphatec has and continues to induce jointly and separately the direct infringement of at least claim 12 of the '832 patent by others, such as surgeons, by actively encouraging them to perform surgical techniques using at least the K-Wire, Initial Dilator, the Secondary Dilator, the SquadronTM Lateral Retractor Body, the SquadronTM Lateral Retractor Right Blade, the SquadronTM Lateral Retractor Left Blade, the SquadronTM Lateral Retractor Posterior Blade, and the BattalionTM Lateral Spacer in an infringing manner, with specific intent to induce such actions knowing that the induced actions constitute infringement of at least claim 12 of the '832 patent.
- 317. On information and belief, Alphatec had and continues to have specific intent to induce surgeons to perform Alphatec's Lateral Procedure, PATENT INFRINGEMENT COMPLAINT -84-

knowing, or being willfully blind to, the fact that the induced actions constitute infringement of at least claim 12 of the '832 patent. For example, the Alphatec Surgical Guide instructs surgeons to perform each and every step of claim 12, as outlined above.

- 318. Alphatec has and continues to actively encourage others, such as surgeons, to directly infringe at least claim 12 of the '832 patent.
- 319. Alphatec's affirmative acts of active encouragement include, among other things: (1) publishing surgical techniques, conducting organized surgical training courses, and engaging in other marketing activities, to promote the BattalionTM Lateral System which includes the K-Wire, Initial Dilator, the Secondary Dilator, the SquadronTM Lateral Retractor Body, the SquadronTM Lateral Retractor Right Blade, the SquadronTM Lateral Retractor Left Blade, the SquadronTM Lateral Retractor Posterior Blade, and the BattalionTM Lateral Spacer; (2) teaching, instructing, and training surgeons to perform the Alphatec Lateral Procedure using at least the K-Wire, Initial Dilator, the Secondary Dilator, the SquadronTM Lateral Retractor Body, the SquadronTM Lateral Retractor Right Blade, the SquadronTM Lateral Retractor Left Blade, the SquadronTM Lateral Retractor Posterior Blade, and the BattalionTM Lateral Spacer; and (3) supplying at least the K-Wire, Initial Dilator, the Secondary Dilator, the SquadronTM Lateral Retractor Body, the SquadronTM Lateral Retractor Right Blade, the SquadronTM Lateral Retractor Left Blade, the SquadronTM Lateral Retractor Posterior Blade, and/or the BattalionTM Lateral Spacer to surgeons (individually, a "'832 Accused Component").
- 320. On information and belief, following Alphatec's active encouragement, surgeons have performed and continue to perform the Alphatec Lateral Procedure using one or more of the '832 Accused Components, in a manner that directly infringes at least claim 12 of the '832 patent.

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- 321. Alphatec is, thus, liable for induced infringement of the '832 patent pursuant to 35 U.S.C. § 271(b).
- 322. In violation of 35 U.S.C. § 271(c), Alphatec has and continues to contribute to the direct infringement by others, such as surgeons, of at least claim 12 of the '832 patent.
- 323. Alphatec has and continues to offer for sell, sell, and/or import one or more components of the '832 Accused Components, which constitute a material part of at least claim 12 of the '832 patent and lack any substantial non-infringing use, knowing, or being willfully blind to, the fact that those components are especially made or adapted for use in infringing at least claim 12 of the '832 patent.
- 324. On information and belief, following Alphatec's contributory actions, others, such as surgeons, have performed the Alphatec Lateral Procedure using one of more of the '832 Accused Components and thus have directly infringed and continue to directly infringe at least claim 12 of the '832 patent.
- 325. On information and belief, Alphatec knew and does now know, or was willfully blind to, the fact that performance of the Alphatec Lateral Procedure by surgeons infringes at least claim 12 of the '832 patent, as outlined above.
- 326. On information and belief, Alphatec purposefully designed each of the '832 Accused Components for use by surgeons in performing the Alphatec Lateral Procedure and for no other purpose. For example, the Right, Left and Posterior Blades of the SquadronTM Lateral Retractor are sized to match the distance from the side of a patient to the lumbar spine of the patient, and the size of the Blades is determined using the depth markings on the Initial Dilator.
- 327. On information and belief, Alphatec thus knew and does now know the '832 Accused Components are each especially made or adapted for use in infringing at least claim 1 of the '832 patent.

- 328. On information and belief, Alphatec thus knew and does now know the '832 Accused Components are each not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 329. On information and belief, Alphatec thus knew and does now know that the '832 Accused Components are each essential to and enable the performance of the Alphatec Lateral Procedure by surgeons.
- 330. Each of the '832 Accused Components is used to perform at least a majority of the steps of at least claim 12 of the '832 patent.
- 331. Alphatec is, thus, liable for contributory infringement of the '832 patent pursuant to 35 U.S.C. § 271(c).
- 332. Unless enjoined by this Court, Alphatec will continue to infringe one or more claims of the '832 patent, and NuVasive will continue to suffer irreparable harm for which there is no adequate remedy at law. Accordingly, NuVasive is entitled to preliminary and permanent injunctive relief against such infringement pursuant to 35 U.S.C. § 283.
- 333. As a result of Alphatec's infringement of one or more claims of the '832 patent, NuVasive has been and continues to be injured in its business and property rights, and is entitled to recover damages for such injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.
- 334. On information and belief, at all times that infringement has occurred or will occur, Alphatec had and has actual and/or constructive knowledge of the '832 patent.
- 335. On information and belief, Alphatec's infringement of one or more claims of the '832 patent is willful, deliberate, and egregious. Accordingly, NuVasive is entitled to enhanced damages pursuant to 35 U.S.C. § 284 and to an award of attorney's fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285.

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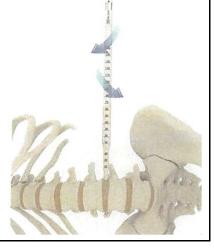
PATENT INFRINGEMENT COMPLAINT

- 346. On information and belief, Alphatec had knowledge of the '227 patent prior to the filing of this Complaint.
- 347. On information and belief, Alphatec has been monitoring and continues to monitor NuVasive's patent portfolio, including patents and applications that are directed to lateral, transpsoas spinal procedures, systems, and devices, such as the '227 patent.
- 348. On information and belief, Alphatec gained knowledge of the '227 patent on December 5, 2017, when the patent issued.
- 349. A privity relationship between Alphatec and Mr. Miles formed at least as early as October 2, 2017, when Mr. Miles joined Alphatec as its Executive Chairman.
- 350. Mr. Miles is a named inventor of the '227 patent and therefore had and continues to have knowledge of the '227 patent, as soon as it was issued on December 5, 2017.
 - 351. Alphatec continues to be in privity with Mr. Miles.
- 352. Upon the formation of Alphatec's privity relationship with Mr. Miles, Alphatec was imputed with, and continues to be imputed with, Mr. Miles' knowledge of the '227 patent.
- 353. Alphatec has and continues to avail itself of Mr. Miles' knowledge and assistance to infringe the '227 patent, which Mr. Miles had assigned to NuVasive.
- 354. At the very latest, Alphatec has knowledge of the '227 patent as of the filing of this Complaint.
- 355. In violation of 35 U.SC. § 271(a), Alphatec has and continues to directly infringe one or more claims of the '227 patent.
- 356. In particular, and without limitation, Alphatec performs the methods claimed therein without the permission of NuVasive. For example, Alphatec demonstrates the Alphatec Lateral Procedure using at least the Initial Dilator, the

Secondary Dilator, the SquadronTM Lateral Retractor Right Blade, the SquadronTM Lateral Retractor Left Blade, the SquadronTM Lateral Retractor Posterior Blade, and the BattalionTM Lateral Spacer, which are components of the BattalionTM Lateral System, during promotional, educational, and training activities, such as inperson courses for surgeons.

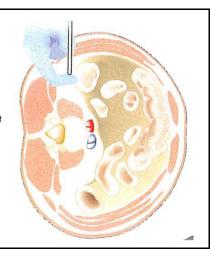
- 357. Alphatec infringes at least claim 16 of the '227 patent.
- 358. As explained in the Alphatec Surgical Guide, the Alphatec Lateral Procedure is a method for forming an operating corridor to the lumbar spine of a patient.
- 359. As explained in the Alphatec Surgical Guide, a plurality of dilators is inserted into one of two anatomically lateral aspects of the patient, the diameter of the first dilator being smaller than the diameter of the second dilator (Ex. U at 8):

Introduce the Secondary Dilator over the Initial Dilator using a clockwise, counter-clockwise motion. Advance the Second Dilator until it is flush with the disc space.



360. As explained in the Alphatec Surgical Guide, the plurality of dilators is advanced along a lateral, transpsoas path from one anatomically lateral aspect of the patient to the other anatomically laterally aspect of the patient to create a tissue distraction corridor along the lateral, transpsoas path to the target intervertebral disc, the lateral, transpsoas path extending through a region of the psoas muscle containing nerves and negotiating past the nerves (Ex. U at 5-7):

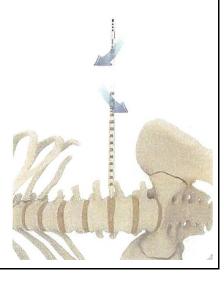
Once a safe pathway has been created, insert the Initial Dilator into the space. Use the index finger to guide the Dilator to the psoas muscle.



TRAVERSING THE PSOAS

Carefully split the muscle fibers of the psoas by advancing the Dilator in a clockwise to counter-clockwise motion. Neuromonitoring may be used to detect the location and proximity of the nerves as the psoas is traversed.

Adjust the Dilator's position so it is flush with the disc space and confirm with AP fluoroscopy.



361. As explained in the Alphatec Surgical Guide, the distal region of a dilator includes a stimulation electrode (Ex. U at 5):

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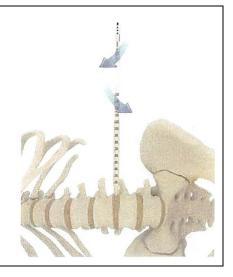
362. As explained in the Alphatec Surgical Guide, the stimulation electrode is used to electrically stimulate the nerves of the psoas muscle and monitor a nerve response. The dilator is advanced along the lateral, transpsoas path based on the monitoring to avoid impairment of the nerves of the psoas muscle (Ex. U at 5, 6):

Place the Universal Clip onto exposed silver ring at the proximal end of the Dilator and connect to the appropriate neuromonitoring platform.



TRAVERSING THE PSOAS

Carefully split the muscle fibers of the psoas by advancing the Dilator in a clockwise to counter-clockwise motion. Neuromonitoring may be used to detect the location and proximity of the nerves as the psoas is traversed. EMG or MMG are always recommended to monitor motor function. Additionally, SSEPs may be used to monitor sensory nerves throughout the procedure.



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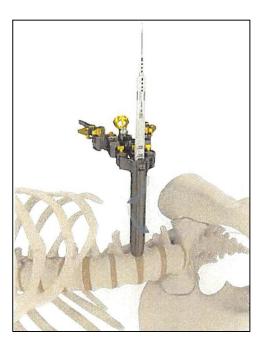
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363. As explained in the Alphatec Surgical Guide, the SquadronTM Lateral Retractor includes a plurality of retractor blades. The retractor blades are moved along the lateral, transpsoas path and over the plurality of dilators to form an operative corridor along the lateral, transpsoas path (Ex. U at 10, 14):

The Retractor is then introduced into the space over the Second Dilator using a clockwise, counter-clockwise motion until the Retractor is flush with the disc space.





364. The Alphatec Surgical Guide discloses that the operative corridor is dimensioned to pass an implant along the lateral, transpsoas path toward the target intervertebral disc of the lumbar spine (Ex. U at 24):

10 IMPLANT INSERTION

Choose the appropriate implant by width, length, lordosis, and height as determined by trialing.

365. Alphatec is, thus, liable for direct infringement of the '227 patent pursuant to 35 U.S.C. § 271(a).

PATENT INFRINGEMENT COMPLAINT -93-

366. In violation of 35 U.S.C. § 271(b), Alphatec has and continues to induce infringement of at least claim 16 of the '227 patent.

367. With knowledge of the '227 patent, Alphatec has and continues to induce jointly and separately the direct infringement of at least claim 16 of the '227 patent by others, such as surgeons, by actively encouraging them to perform surgical techniques using at least the Initial Dilator, the Secondary Dilator, the SquadronTM Lateral Retractor Right Blade, the SquadronTM Lateral Retractor Left Blade, the SquadronTM Lateral Retractor Posterior Blade, and the BattalionTM Lateral Spacer, in an infringing manner, with specific intent to induce such actions knowing that the induced actions constitute infringement of at least claim 16 of the '227 patent.

368. On information and belief, Alphatec had and continues to have specific intent to induce surgeons to perform Alphatec's Lateral Procedure, knowing, or being willfully blind to, the fact that the induced actions constitute infringement of at least claim 16 of the '227 patent. For example, the Alphatec Surgical Guide instructs surgeons to perform each and every step of claim 16, as outlined above.

- 369. Alphatec has and continues to actively encourage others, such as surgeons, to directly infringe at least claim 16 of the '227 patent.
- 370. Alphatec's affirmative acts of active encouragement include, among other things: (1) publishing surgical techniques, conducting organized surgical training courses, and engaging in other marketing activities, to promote the BattalionTM Lateral System which includes the Initial Dilator, the Secondary Dilator, the SquadronTM Lateral Retractor Right Blade, the SquadronTM Lateral Retractor Posterior Blade, and the BattalionTM Lateral Spacer; (2) teaching, instructing, and training surgeons to perform the Alphatec Lateral Procedure using at least the Initial Dilator, the Secondary Dilator, the SquadronTM Lateral Retractor Right Blade, the SquadronTM

Lateral Retractor Left Blade, the SquadronTM Lateral Retractor Posterior Blade, and the BattalionTM Lateral Spacer; and (3) supplying at least the Initial Dilator, the Secondary Dilator, the SquadronTM Lateral Retractor Right Blade, the SquadronTM Lateral Retractor Posterior Blade, and/or the BattalionTM Lateral Spacer to surgeons (individually, a "'227 Accused Component").

- 371. On information and belief, following Alphatec's active encouragement, surgeons have performed and continue to perform the Alphatec Lateral Procedure using one or more of the '227 Accused Components, in a manner that directly infringes at least claim 16 of the '227 patent.
- 372. Alphatec is, thus, liable for induced infringement of the '227 patent pursuant to 35 U.S.C. § 271(b).
- 373. In violation of 35 U.S.C. § 271(c), Alphatec has and continues to contribute to the direct infringement by others, such as surgeons, of at least claim 16 of the '227 patent.
- 374. Alphatec has and continues to offer for sell, sell, and/or import one or more components of the '227 Accused Components, which constitute a material part of at least claim 16 of the '227 patent and lack any substantial non-infringing use, knowing, or being willfully blind to, the fact that those components are especially made or adapted for use in infringing at least claim 16 of the '227 patent.
- 375. On information and belief, following Alphatec's contributory actions, others, such as surgeons, have performed the Alphatec Lateral Procedure using one of more of the '227 Accused Components and thus have directly infringed and continue to directly infringe at least claim 16 of the '227 patent.
- 376. On information and belief, Alphatec knew and does now know, or was willfully blind to, the fact that performance of the Alphatec Lateral Procedure by surgeons infringes at least claim 16 of the '227 patent, as outlined above.

- 377. On information and belief, Alphatec purposefully designed each of the '227 Accused Components for use by surgeons in performing the Alphatec Lateral Procedure and for no other purpose. For example, the Right, Left and Posterior Blades of the SquadronTM Lateral Retractor are sized to match the distance from the side of a patient to the lumbar spine of the patient, and the size of the Blades is determined using the depth markings on the Initial Dilator.
- 378. On information and belief, Alphatec thus knew and does now know the '227 Accused Components are each especially made or adapted for use in infringing the at least claim 16 of the '227 patent.
- 379. On information and belief, Alphatec thus knew and does now know the '227 Accused Components are each not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 380. On information and belief, Alphatec thus knew and does now know that the '227 Accused Components are each essential to and enable the performance of the Alphatec Lateral Procedure by surgeons.
- 381. Each of the '227 Accused Components is used to perform at least a majority of the steps of at least claim 16 of the '227 patent.
- 382. Alphatec is, thus, liable for contributory infringement of the '227 patent pursuant to 35 U.S.C. § 271(c).
- 383. Unless enjoined by this Court, Alphatec will continue to infringe one or more claims of the '227 patent, and NuVasive will continue to suffer irreparable harm for which there is no adequate remedy at law. Accordingly, NuVasive is entitled to preliminary and permanent injunctive relief against such infringement pursuant to 35 U.S.C. § 283.
- 384. As a result of Alphatec's infringement of one or more claims of the '227 patent, NuVasive has been and continues to be injured in its business and property rights, and is entitled to recover damages for such injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

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through 393 in their entirety.

395. On June 17, 2014, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 8,753,270 ("the '270 patent"), entitled "Surgical Access System and Related Methods," to Patrick Miles, Scot Martinelli and Eric Finley. A true and correct copy of the '270 patent is attached hereto as Exhibit AJ.

- 396. At all relevant times, NuVasive is and has been the owner, by valid assignment, of all right, title, and interest in and to the '270 patent.
- 397. On information and belief, Alphatec had knowledge of the '270 patent prior to the filing of this Complaint.
- 398. On information and belief, Alphatec has been monitoring and continues to monitor NuVasive's patent portfolio, including patents and applications that are directed to lateral, transpsoas spinal procedures, systems, and devices, such as the '270 patent.
- 399. On information and belief, Alphatec gained knowledge of the '270 patent through its privity relationship with Mr. Miles, which formed at least as early as October 2, 2017.
- 400. Mr. Miles is a named inventor of the '270 patent and therefore had and continues to have knowledge of the '270 patent.
- 401. A privity relationship between Alphatec and Mr. Miles formed at least as early as October 2, 2017, when Mr. Miles joined Alphatec as its Executive Chairman.
 - 402. Alphatec continues to be in privity with Mr. Miles.
- 403. Upon the formation of Alphatec's privity relationship with Mr. Miles, Alphatec was imputed with, and continues to be imputed with, Mr. Miles' knowledge of the '270 patent.
- 404. Alphatec has and continues to avail itself of Mr. Miles' knowledge and assistance to infringe the '270 patent, which Mr. Miles had assigned to NuVasive.

405. At the very latest, Alphatec has knowledge of the '270 patent as of the filing of this Complaint.

406. In violation of 35 U.SC. § 271(a), Alphatec has and continues to directly infringe one or more claims of the '270 patent.

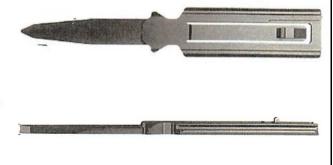
407. In particular, and without limitation, Alphatec directly infringes the '270 patent, by making, using, selling, offering for sale, and/or importing into the United States products and systems including, but not limited to the Intradiscal Shim which is a component of the BattalionTM Lateral System ("the BattalionTM Intradiscal Shim"), without the permission of NuVasive.

408. The BattalionTM Intradiscal Shim infringes at least claim 1 of the '270 patent.

409. As explained in the Alphatec Surgical Guide, the BattalionTM Intradiscal Shim is a spinal shim device configured to releasably attach to a spinal access retractor blade of the SquadronTM Lateral Retractor. The BattalionTM Intradiscal Shim is configured to penetrate into the spinal disc for anchoring the spinal access retractor blade of the SquadronTM Lateral Retractor to the disc space.

410. As explained in the Alphatec Surgical Guide, the Battalion[™] Intradiscal Shim comprises a proximal portion configured to releasably attach to the spinal access retractor blade (Ex. U at 19):

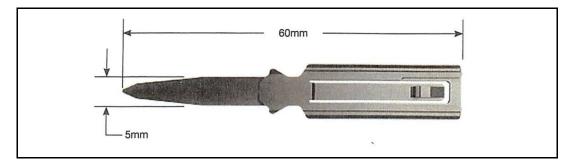
To stabilize the Retractor, place the Intradiscal Shim through the center blade of the Retractor ensuring that the tabs on either side of the Inserter engage into the tracks on the inside of the blade. Advance the Shim until it engages into the disc space and locks at the bottom of the blade. Press the gold button at the proximal end of the Inserter to disengage the Shim.



411. As explained in the Alphatec Surgical Guide, the BattalionTM Intradiscal Shim comprises a distal extension. The distal extension is configured to extend distally of the spinal access retractor blade and penetrate into a disc space between two adjacent vertebrae (Ex. U at 19):

Confirm under AP and lateral fluoroscopy that the Shim is within the disc space.

412. As explained in the Alphatec Surgical Guide, the BattalionTM Intradiscal Shim comprises a maximum longitudinal length extending from a proximal-most end of the proximal portion to a distal-most end of the distal extension. The maximum longitudinal length of the BattalionTM Intradiscal Shim extends parallel to a longitudinal axis of the BattalionTM Intradiscal Shim, and that is less than the maximum longitudinal length of the spinal access retractor blade to which the proximal portion is configured to releasably attach (Ex. U at 7, 16, 19):

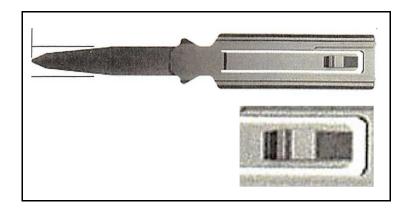


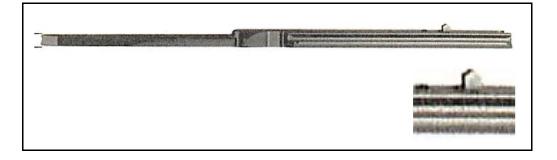
Take note of the Dilator depth and add 10mm to determine the desired blade length. Blade lengths are laser marked on the outside of each Retractor blade.

If a different length of blade is desired, blades may be changed by depressing the gold Blade Release Levers and removing the blade.

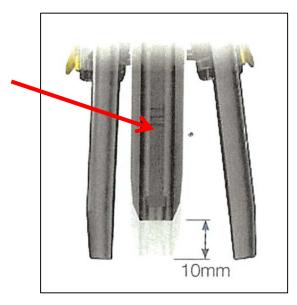
413. As explained in the Alphatec Surgical Guide, the distal extension includes a tapered tip region. The distal extension includes a maximum lateral width of the distal extension located proximally away from the distal-most end. The proximal portion has a proximal lateral width that is greater than the maximum lateral width of the distal extension. (Ex. U at 19).

414. As explained in the Alphatec Surgical Guide, the proximal portion defines a forward surface portion. The proximal portion includes a rearwardly extending ridge structure (Ex. U at 19):





415. As explained in the Alphatec Surgical Guide, the ridge structure releasably engages with a corresponding groove along an interior face of the spinal access retractor blade when the proximal portion releasably attaches to the spinal access retractor blade (Ex. U at 16):



- 416. As explained in the Alphatec Surgical Guide, the ridge structure has a length that extends parallel to the longitudinal axis of the BattalionTM Intradiscal Shim and is bisected by a longitudinal plane. The longitudinal plane passes through the longitudinal axis of BattalionTM Intradiscal Shim. (Ex. U at 19.)
- 417. Alphatec is, thus, liable for direct infringement of the '270 patent pursuant to 35 U.S.C. § 271(a).
- 418. In violation of 35 U.S.C. § 271(b), Alphatec has and continues to induce infringement of at least claim 1 of the '270 patent.
- 419. With knowledge of the '270 patent, Alphatec has and continues to induce jointly and separately the direct infringement of at least claim 1 of the '270 patent by others, such as surgeons, by actively encouraging them to use at least the BattalionTM Intradiscal Shim in an infringing manner, with specific intent to induce such actions knowing that the induced actions constitute infringement of at least claim 1 of the '270 patent.

- 420. On information and belief, Alphatec had and continues to have specific intent to induce direct infringement by surgeons of at least claim 1 of the '270 patent, knowing, or being willfully blind to, the fact that the induced actions constitute infringement.
- 421. The Alphatec Surgical Guide provides specific instruction teaching surgeons how to use the BattalionTM Intradiscal Shim to during the Alphatec Lateral Procedure.
- 422. The Alphatec Surgical Guide describes the BattalionTM Intradiscal Shim with detailed information about its features, which match each and every element of at least claim 1 of the '270 patent, as outlined above.
- 423. Alphatec has and continues to actively encourage others, such as surgeons, to directly infringe at least claim 1 of '270 patent.
- 424. Alphatec's affirmative acts of active encouragement include, among other things: (1) publishing surgical techniques, conducting organized surgical training courses, and engaging in other marketing activities, to promote the BattalionTM Lateral System which includes the BattalionTM Intradiscal Shim; (2) teaching, instructing, and training surgeons how to use the BattalionTM Intradiscal Shim for the Alphatec Lateral Procedure; and (3) supplying the BattalionTM Intradiscal Shim to surgeons.
- 425. On information and belief, following Alphatec's active encouragement, surgeons have used and continue to use the BattalionTM Intradiscal Shim in performing the Alphatec Lateral Procedure, and thus have directly infringed and continue to directly infringe at least claim 1 of the '270 patent.
- 426. Alphatec is, thus, liable for induced infringement of the '270 patent pursuant to 35 U.S.C. § 271(b).
- 427. In violation of 35 U.S.C. § 271(c) Alphatec has and continues to contribute to the direct infringement by others, such as surgeons, of at least claim 1 of the '270 patent.

428. Alphatec has and continues to offer for sell, sell, and/or import one or more components which constitute a material part of at least claim 1 of the '270 patent and lack any substantial non-infringing use, knowing, or being willfully blind to, the fact that those components are especially made or adapted for use in infringing at least claim 1 of the '270 patent.

- 429. On information and belief, following Alphatec's contributory actions, others, such as surgeons, have used and continue to use the BattalionTM Intradiscal Shim for the Alphatec Lateral Procedure and thus have directly infringed and continue to directly infringe at least claim 1 of the '270 patent.
- 430. On information and belief, Alphatec knew and does now know, or was willfully blind to, the fact that use of the BattalionTM Intradiscal Shim by surgeons for the Alphatec Lateral Procedure infringes at least claim 1 of the '270 patent, as outlined above.
- 431. On information and belief, Alphatec purposefully designed the accused components as part of the BattalionTM Intradiscal Shim for use in performing the Alphatec Lateral Procedure and for no other purpose.
- 432. On information and belief, Alphatec thus knew and does now know the accused components are each especially made or adapted for use in infringing the at least claim 1 of the '270 patent.
- 433. On information and belief, Alphatec thus knew and does now know the accused components are each not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 434. On information and belief, Alphatec thus knew and does now know that the accused components are each essential to and enable the use of the BattalionTM Intradiscal Shim for performing the Alphatec Lateral Procedure by surgeons.
- 435. Each of the accused components embodies at least a majority of the limitations of at least claim 1 of the '270 patent.

436. Alphatec is, thus, liable for contributory infringement of the '270 patent pursuant to 35 U.S.C. § 271(c).

In violation of 35 U.S.C. § 271(f)(1), on information and belief, 437. Alphatec has been and continues to supply or cause to be supplied in or from the United States all or a substantial portion of the components of the BattalionTM Intradiscal Shim including, but not limited to, one or more of the accused components, where such components are uncombined in whole or in part, in such a manner to actively induce the combination of such components outside of the United States in a manner that practices at least claim 1 of the '270 patent.

- 438. Alphatec is, thus, liable for infringement of the '270 patent pursuant to 35 U.S.C. § 271(f)(1).
- 439. In violation of 35 U.S.C. § 271(f)(2), on information and belief, Alphatec has been and continues to supply or cause to be supplied in or from the United States one or more of the accused components, where such component is uncombined in whole or part, intending that such component will be combined outside of the United States in a manner that practices at least claim 1 of the '270 patent.
- 440. On information and belief, Alphatec knew and does now know, or was willfully blind to, the fact that the accused components are each especially made or adapted for use in the BattalionTM Intradiscal Shim and are each not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 441. Alphatec is, thus, liable for infringement of the '270 patent pursuant to 35 U.S.C. § 271(f)(2).
- 442. Unless enjoined by this Court, Alphatec will continue to infringe one or more claims of the '270 patent, and NuVasive will continue to suffer irreparable harm for which there is no adequate remedy at law. Accordingly, NuVasive is

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entitled to preliminary and permanent injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

- 443. As a result of Alphatec's infringement of one or more claims of the '270 patent, NuVasive has been and continues to be injured in its business and property rights, and is entitled to recover damages for such injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.
- 444. On information and belief, at all times that infringement has occurred or will occur, Alphatec had and has actual and/or constructive knowledge of the '270 patent.
- 445. On information and belief, Alphatec's infringement of one or more claims of the '270 patent is and has been willful, deliberate, and egregious.

 Accordingly, NuVasive is entitled to enhanced damages pursuant to 35 U.S.C. § 284 and to an award of attorney's fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285.
- 446. Alphatec is precluded from challenging the validity of the '270 patent, particularly under the doctrine of equitable estoppel.
- 447. Alphatec is in privity with Mr. Miles, who is an assignor and inventor of the '270 patent.
- 448. On information and belief, Alphatec has and continues to avail itself of Mr. Miles' knowledge and assistance to infringe the '270 patent.
- 449. Mr. Miles swore to the U.S. Patent Office that he is an inventor of the '270 patent.
- 450. On May 2, 2014, Mr. Miles signed a declaration, swearing that he believes he is an inventor on U.S. Patent Application No. 13/955,950, which issued as the '270 patent. Ex. AK at 1.
- 451. Mr. Miles' inventor declaration (Ex. AK) was filed on May 6, 2014 as an official declaration of record for the '270 patent.

452. For good and valuable consideration, Mr. Miles assigned NuVasive all right, title and interest to the '270 patent.

IX. SIXTH CAUSE OF ACTION — Infringement of U.S. Patent No. 8,361,156

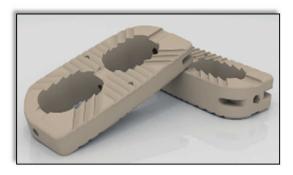
- 453. NuVasive repeats and realleges the allegations of paragraphs 1 through 452 in their entirety.
- 454. On January 29, 2013, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 8,361,156 ("the '156 patent"), entitled "Systems and Methods for Spinal Fusion," to Matthew Curran, Mark Peterson and Luiz Pimenta. A true and correct copy of the '156 patent is attached hereto as Exhibit AL. An as-filed certificate of correction filed June 25, 2013, is included in Exhibit AL at 31.
- 455. At all relevant times, NuVasive is and has been the owner, by valid assignment, of all right, title, and interest in and to the '156 patent.
- 456. On information and belief, Alphatec had knowledge of the '156 patent prior to the filing of this Complaint.
- 457. On information and belief, Alphatec has been monitoring and continues to monitor NuVasive's patent portfolio, including patents and applications that are directed to lateral, transpsoas spinal procedures, systems, and devices, such as the '156 patent.
- 458. At the very latest, Alphatec has knowledge of the '156 patent as of the filing of this Complaint.
- 459. In violation of 35 U.SC. § 271(a), Alphatec has and continues to directly infringe one or more claims of the '156 patent.
- 460. In particular, and without limitation, Alphatec directly infringes the '156 patent by making, using, selling, offering for sale, and/or importing into the United States products and systems including, but not limited to the BattalionTM

Lateral Spacer which is a component of the BattalionTM Lateral System, without the permission of NuVasive.

- 461. The BattalionTM Lateral Spacer infringes at least claim 1 of the '156 patent.
- 462. The BattalionTM Lateral Spacer is a spinal fusion implant of non-bone construction positionable within an interbody space between a first and second vertebra (Ex. U at 28):

The Battalion Universal Spacer System (Battalion System) is an intervertebral body fusion device with implants of various lengths, widths, heights, and degrees of lordosis to accommodate individual patient anatomy. The implants are manufactured from PEEK Optima LT1 with/without titanium coated endplates and tantalum markers. All materials are surgical grade conforming to ASTM F2026 (PEEK), ASTM F1580 (titanium coating), and ASTM F560 (tantalum).

463. The BattalionTM Lateral Spacer comprises an upper surface including anti-migration elements to contact a first vertebra and a lower surface including anti-migration elements to contact a second vertebra (Ex. V at 1):



The BattalionTM Lateral Spacer comprises a distal wall, a proximal wall, a first sidewall, and a second sidewall generally opposite from the first sidewall. The distal wall, the proximal wall, the first sidewall, and the second sidewall comprise a radiolucent material (Ex. U at 28):

The implants are manufactured from PEEK Optima LT1 with/without titanium coated endplates and tantalum markers. All materials are surgical grade conforming to ASTM F2026 (PEEK), ASTM F1580 (titanium coating), and ASTM F560 (tantalum).

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465. The BattalionTM Lateral Spacer has a longitudinal length and a maximum lateral width extending from a proximal end of the proximal wall to a distal end of the distal wall. The maximum lateral width extends from the first sidewall to the second sidewall along a medial plane that is generally perpendicular to the longitudinal length. The longitudinal length is greater than the maximum lateral width. All versions of the BattalionTM Lateral Spacer have the features described in this paragraph. As one example only, one version of the BattalionTM Lateral Spacer with these features is described below (Ex. AM (FDA Access GUDID Database search results for "Battalion Lateral") at 1):

Battalion Lateral Spinal Spacer System - 00190376039466

Battalion Lateral Spacer, PEEK, 0°, 18 mm Wide, 16 x 60 mm

Company Name: ALPHATEC SPINE, INC.

Device IDs:

00190376039466 (Primary)

Metal-polymer composite spinal fusion cage

Length: 60 Millimeter

Width: 18 Millimeter

Height: 16 Millimeter

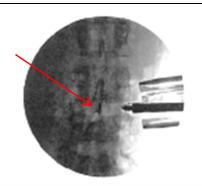
466. The BattalionTM Lateral Spacer has a fusion aperture extending through the upper surface and the lower surface. The fusion aperture is configured to permit bone growth between the first and second vertebrae when the implant is positioned within the interbody space. *Supra* at ¶ 463 (showing a fusion aperture extending through the upper and lower surface of the BattalionTM Lateral Spacer.)

467. The fusion aperture has a longitudinal aperture length generally parallel to the implant longitudinal length. The fusion aperture has a lateral aperture width extending between the first sidewall to the second sidewall. The longitudinal aperture length is greater than the lateral aperture width. *Supra* at ¶ 463 (showing a fusion aperture extending through the upper and lower surface of the BattalionTM Lateral Spacer.)

468. The BattalionTM Lateral Spacer has at least first and second radiopaque markers oriented generally parallel to the height of the implant. The first radiopaque marker extends into the first sidewall at a position proximate to the medial plane. The second radiopaque marker extends into the second sidewall at a position proximate to the medial plane (Ex. U at 25, 28; Ex. V at 1):

The implants are manufactured from PEEK Optima LT1 with/without titanium coated endplates and tantalum markers. All materials are surgical grade conforming to ASTM F2026 (PEEK), ASTM F1580 (titanium coating), and ASTM F560 (tantalum).





Confirm appropriate implant placement by using A/P fluoroscopy.

- 469. Alphatec is, thus, liable for direct infringement of the '156 patent pursuant to 35 U.S.C. § 271(a).
- 470. In violation of 35 U.S.C. § 271(b), Alphatec has and continues to induce infringement of at least claim 1 of the '156 patent.
- 471. With knowledge of the '156 patent, Alphatec has and continues to induce jointly and separately the direct infringement of at least claim 1 of the '156 patent by others, such as surgeons, by actively encouraging them to use at least the BattalionTM Lateral Spacer in an infringing manner, with specific intent to induce such actions knowing that the induced actions constitute infringement of at least claim 1 of the '156 patent.
- 472. On information and belief, Alphatec had and continues to have specific intent to induce direct infringement by surgeons of at least claim 1 of the

'156 patent, knowing, or being willfully blind to, the fact that the induced actions constitute infringement.

- 473. The Alphatec Surgical Guide provides specific instructions teaching surgeons how to use the BattalionTM Lateral Spacer during the Alphatec Lateral Procedure.
- 474. The Alphatec Surgical Guide describes the BattalionTM Lateral Spacer with detailed information about its features, which match each and every element of at least claim 1 of the '156 patent, as outlined above.
- 475. Alphatec has and continues to actively encourage others, such as surgeons, to directly infringe at least claim 1 of the '156 patent.
- 476. Alphatec's affirmative acts of active encouragement include, among other things: (1) publishing surgical techniques, conducting organized surgical training courses, and engaging in other marketing activities, to promote the BattalionTM Lateral Spacer; (2) teaching, instructing, and training surgeons how to implant the BattalionTM Lateral Spacer into human patients during the Alphatec Lateral Procedure; and (3) supplying the BattalionTM Lateral Spacer to surgeons.
- 477. On information and belief, following Alphatec's active encouragement, surgeons have used and continue to use the BattalionTM Lateral Spacer in performing the Alphatec Lateral Procedure, and thus have directly infringed and continue to directly infringe at least claim 1 of the '156 patent.
- 478. Alphatec is, thus, liable for induced infringement of the '156 patent pursuant to 35 U.S.C. § 271(b).
- 479. In violation of 35 U.S.C. § 271(c) Alphatec has and continues to contribute to the direct infringement by others, such as surgeons, of at least claim 1 of the '156 patent.
- 480. Alphatec has and continues to offer for sell, sell, and/or import one or more components which constitute a material part of at least claim 1 of the '156 patent and lack any substantial non-infringing use, knowing, or being willfully blind

to, the fact that those components are especially made or adapted for use in infringing at least claim 1 of the '156 patent.

- 481. On information and belief, following Alphatec's contributory actions, others, such as surgeons, have used and continue to use the BattalionTM Lateral Spacer for the Alphatec Lateral Procedure and thus have directly infringed and continue to directly infringe at least claim 1 of the '156 patent.
- 482. On information and belief, Alphatec knew and does now know, or was willfully blind to, the fact that use of the BattalionTM Lateral Spacer by surgeons for the Alphatec Lateral Procedure infringes at least claim 1 of the '156 patent, as outlined above.
- 483. On information and belief, Alphatec purposefully designed each of the accused components as part of the BattalionTM Lateral Spacer for use in performing the Alphatec Lateral Procedure and for no other purpose.
- 484. On information and belief, Alphatec thus knew and does now know the accused components are each especially made or adapted for use in infringing the at least claim 1 of the '156 patent.
- 485. On information and belief, Alphatec thus knew and does now know the accused components are each not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 486. On information and belief, Alphatec thus knew and does now know that the accused components are each essential to and enable the use of the BattalionTM Lateral Spacer for performing the Alphatec Lateral Procedure by surgeons.
- 487. Each of the accused components embodies at least a majority of the limitations of at least claim 1 of the '156 patent.
- 488. Alphatec is, thus, liable for contributory infringement of the '156 patent pursuant to 35 U.S.C. § 271(c).

- 489. In violation of 35 U.S.C. § 271(f)(1), on information and belief, Alphatec has been and continues to supply or cause to be supplied in or from the United States all or a substantial portion of the components of the BattalionTM Lateral Spacer including, but not limited to, one or more of the accused components, where such components are uncombined in whole or in part, in such a manner to actively induce the combination of such components outside of the United States in a manner that practices at least claim 1 of the '156 patent.
- 490. Alphatec is, thus, liable for infringement of the '156 patent pursuant to 35 U.S.C. § 271(f)(1).
- 491. In violation of 35 U.S.C. § 271(f)(2), on information and belief, Alphatec has been and continues to supply or cause to be supplied in or from the United States one or more of the accused components, where such component is uncombined in whole or part, intending that such component will be combined outside of the United States in a manner that practices at least claim 1 of the '156 patent.
- 492. On information and belief, Alphatec knew and does now know, or was willfully blind to, the fact that the accused components are each especially made or adapted for use in the BattalionTM Lateral Spacer and are each not a staple article or commodity of commerce suitable for substantial non-infringing use.
- 493. Alphatec is, thus, liable for infringement of the '156 patent pursuant to 35 U.S.C. § 271(f)(2).
- 494. Unless enjoined by this Court, Alphatec will continue to infringe one or more claims of the '156 patent, and NuVasive will continue to suffer irreparable harm for which there is no adequate remedy at law. Accordingly, NuVasive is entitled to preliminary and permanent injunctive relief against such infringement pursuant to 35 U.S.C. § 283.
- 495. As a result of Alphatec's infringement of one or more claims of the '156 patent, NuVasive has been and continues to be injured in its business and

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504. In violation of 35 U.SC. § 271(a), Alphatec has and continues to directly infringe the '252 patent.

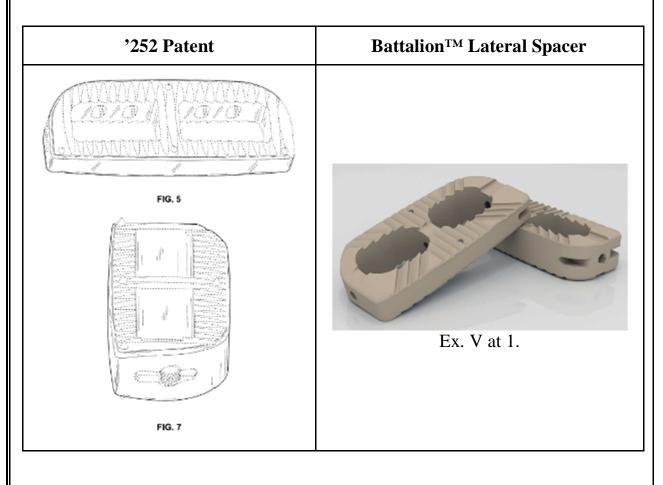
505. In particular, and without limitation, Alphatec directly infringes the '252 patent by making, using, selling, offering for sale, and/or importing into the United States products and systems including, but not limited to the BattalionTM Lateral Spacer which is a component of the BattalionTM Lateral System, without the permission of NuVasive.

506. Alphatec has and continues to apply the patented design of the '252 patent, and/or a colorable imitation thereof, to the BattalionTM Lateral Spacer for the purpose of sale, without the permission of NuVasive.

507. Alphatec has and continues to sell or expose for sale the BattalionTM Lateral Spacer to which the patented design of the '252 patent, and/or a colorable imitation thereof, has been applied.

508. Alphatec is liable to NuVasive to the extent of Alphatec's total profit pursuant to 35 U.S.C. § 289.

509. An ordinary observer, familiar with the prior art, giving such attention as a purchaser usually gives, would be deceived by the resemblance and substantial similarity of the design of the Battalion™ Lateral Spacer and the claimed design in the '252 patent, and would thus be induced to purchase one supposing it to be the other, taking into account that the scope of a design patent claim does not cover functional features, that broken lines form no part of the claimed design, and unclaimed features are irrelevant.



- 510. Unless enjoined by this Court, Alphatec will continue to infringe one or more claims of the '252 patent, and NuVasive will continue to suffer irreparable harm for which there is no adequate remedy at law. Accordingly, NuVasive is entitled to preliminary and permanent injunctive relief against such infringement pursuant to 35 U.S.C. § 283.
- 511. As a result of Alphatec's infringement of the claim of the '252 patent, NuVasive has been and continues to be injured in its business and property rights, and is entitled to recover damages for such injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial. As a further result of Alphatec's infringement of the claim of the '252 patent, Alphatec is liable to NuVasive to the extent of its total profit pursuant to 35 U.S.C. § 289.
- 512. On information and belief, at all times that infringement has occurred or will occur, Alphatec had and has actual and/or constructive knowledge of the '252 patent.

513. On information and belief, Alphatec's infringement of the claim of the '252 patent is willful, deliberate, and egregious. Accordingly, NuVasive is entitled to enhanced damages pursuant to 35 U.S.C. § 284 and to an award of attorney's fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285.

XI. EIGHTH CAUSE OF ACTION — Infringement of U.S. Design Patent No. D652,519

- 514. NuVasive repeats and realleges the allegations of paragraphs 1 through 513 in their entirety.
- 515. On January 17, 2012, the United States Patent and Trademark Office duly and legally issued U.S. Design Patent No. D652,519 ("the '519 patent"), entitled "Dilator," to Patrick Miles, Scot Martinelli, and Eric Finley. A true and correct copy of the '519 patent is attached hereto as Exhibit AO.
- 516. At all relevant times, NuVasive is and has been the owner, by valid assignment, of all right, title, and interest in and to the '519 patent.
- 517. On information and belief, Alphatec had knowledge of the '519 patent prior to the filing of this Complaint.
- 518. On information and belief, Alphatec has been monitoring and continues to monitor NuVasive's patent portfolio, including patents and applications that are directed to lateral, transposoas spinal procedures, systems, and devices, such as the '519 patent.
- 519. On information and belief, Alphatec gained knowledge of the '519 patent through its privity relationship with Mr. Miles, which formed at least as early as October 2, 2017.
- 520. Mr. Miles is a named inventor of the '519 patent and therefore had and continues to have knowledge of the '519 patent.
- 521. A privity relationship between Alphatec and Mr. Miles formed at least as early as October 2, 2017, when Mr. Miles joined Alphatec as its Executive Chairman.

- 522. Alphatec continues to be in privity with Mr. Miles.
- 523. Upon the formation of Alphatec's privity relationship with Mr. Miles, Alphatec was imputed with, and continues to be imputed with, Mr. Miles' knowledge of the '519 patent.
- 524. Alphatec has and continues to avail itself of Mr. Miles' knowledge and assistance to infringe the '519 patent, which Mr. Miles had assigned to NuVasive.
- 525. At the very least, Alphatec has knowledge of the '519 patent as of the filing of this Complaint.
- 526. In violation of 35 U.SC. § 271(a), Alphatec has and continues to directly infringe the '519 patent.
- 527. In particular, and without limitation, Alphatec directly infringes the '519 patent, by making, using, selling, offering for sale, and/or importing into the United States products and systems including, but not limited to, the Initial Dilator which is a component of the BattalionTM Lateral System ("the BattalionTM Initial Dilator), without the permission of NuVasive.
- 528. Alphatec has and continues to apply the patented design of the '519 patent, and/or a colorable imitation thereof, to the BattalionTM Initial Dilator for the purpose of sale, without the permission of NuVasive.
- 529. Alphatec has and continues to sell or expose for sale the BattalionTM Initial Dilator to which the patented design of the '519 patent, and/or a colorable imitation thereof, has been applied.
- 530. Alphatec is liable to NuVasive to the extent of Alphatec's total profit pursuant to 35 U.S.C. § 289.
- 531. An ordinary observer, familiar with the prior art, giving such attention as a purchaser usually gives, would be deceived by the resemblance and substantial similarity of the design of the BattalionTM Initial Dilator and the claimed design in the '519 patent, and would thus be induced to purchase one supposing it to be the

other, taking into account that the scope of a design patent claim does not cover functional features, that broken lines form no part of the claimed design, and that unclaimed features are irrelevant.

'519 Patent	Battalion TM Initial Dilator
	40 30 20
	Ex. U (Alphatec Surgical Guide) at 5.

532. Unless enjoined by this Court, Alphatec will continue to infringe one or more claims of the '519 patent, and NuVasive will continue to suffer irreparable harm for which there is no adequate remedy at law. Accordingly, NuVasive is entitled to preliminary and permanent injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

533. As a result of Alphatec's infringement of the claim of the '519 patent, NuVasive has been and continues to be injured in its business and property rights, and is entitled to recover damages for such injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial. As a further result of Alphatec's infringement of the claim of the '519 patent, Alphatec is liable to NuVasive to the extent of its total profit pursuant to 35 U.S.C. § 289.

- 534. On information and belief, at all times that infringement has occurred or will occur, Alphatec had and has actual and/or constructive knowledge of the '519 patent.
- 535. On information and belief, Alphatec's infringement of the claim of the '519 patent is willful, deliberate, and egregious. Accordingly, NuVasive is entitled to enhanced damages pursuant to 35 U.S.C. § 284 and to an award of attorney's fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285.
- 536. Alphatec is precluded from challenging the validity of the '519 patent, including particularly under the doctrine of equitable estoppel.
- 537. Alphatec is in privity with Mr. Miles, who is an assignor and inventor of the '519 patent.
- 538. On information and belief, Alphatec has and continues to avail itself of Mr. Miles' knowledge and assistance to infringe the '519 patent.
- 539. Mr. Miles swore to the U.S. Patent Office that he is an inventor of the '519 patent.
- 540. On June 25, 2010, Mr. Miles signed a declaration, swearing that he believes he is an inventor on U.S. Design Patent Application No. 29/360,370, which issued as the '519 patent. Ex. AP at 3-4.
- 541. Mr. Miles' inventor declaration (Ex. AP) was filed on July 2, 2010 as an official declaration of record for the '519 patent.
- 542. For good and valuable consideration, Mr. Miles assigned NuVasive all right, title and interest to the '519 patent.

PRAYER FOR RELIEF

- WHEREFORE, plaintiff NuVasive requests entry of judgment in its favor and against defendant Alphatec as follows:
- a. Declaring that the NuVasive Patents are valid and enforceable, and that Alphatec has infringed one or more claims of each of the NuVasive Patents;

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1	b.	Declaring that Alphatec has willfully infringed each of the NuVasive		
2	Patents;			
3	c.	Preliminarily and permanently enjoining Alphatec, its officers,		
4	partners, ei	employees, agents, parents, subsidiaries, attorneys, and anyone acting in		
5	concert or	ncert or participation with any of them, from further infringing, contributing to		
6	and/or inducing the infringement of each of the NuVasive Patents, in accordance			
7	with 35 U.S.C. § 283.			
8	d.	Awarding NuVasive damages in lost profits, price erosion and/or		
9	reasonable royalty an amount adequate to compensate NuVasive for Alphatec's			
10	infringement, in accordance with 35 U.S.C. § 284;			
11	e.	Awarding NuVasive damages in the form Alphatec's profits in		
12	accordance with 35 U.S.C. § 289;			
13	f.	Awarding NuVasive treble damages based on Alphatec's willful		
14	infringement of the NuVasive Patents, in accordance with 35 U.S.C. § 284;			
15	g.	Awarding NuVasive attorney's fees and costs incurred by NuVasive		
16	in accordance with 35 U.S.C. § 285; and			
17	h.	h. Granting such other and further relief as this Court may deem just and		
18	appropriate	2.		
19				
20	Dated: Feb	ruary 13, 2018 WILSON SONSINI GOODRICH & ROSATI PC		
21		By: <u>/s/ Paul D. Tripodi II</u>		
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1	DEMAND FOR JURY TRIAL		
2	Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, plaintiff		
3	NuVasive, Inc. demands a trial by jury of this action.		
4			
5	Dated: February 13, 2018	WILSON SONSINI GOODRICH & ROSATI PO	
6 7		By: <u>/s/ Paul D. Tripodi II</u> Paul D. Tripodi II	
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23		Attorneys for Plaintiff NuVasive, Inc.	

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