

# EXHIBIT 5

DECLARATION OF TRENT D. TANNER  
IN SUPPORT OF  
NUVASIVE'S OPPOSITION TO  
DEFENDANTS' MOTIONS IN LIMINE NOS. 1-10

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF CALIFORNIA  
SAN DIEGO DIVISION

NuVasive, Inc.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 18-cv-0347-CAB-MDD
	)	
Alphatec Holdings, Inc. and Alphatec	)	
Spine, Inc.,	)	
	)	
Defendants.	)	
	)	
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**SUPPLEMENTAL EXPERT REPORT OF BLAKE INGLISH**  
**CONFIDENTIAL**  
**SUBJECT TO PROTECTIVE ORDER**

**November 20, 2020**

  
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 Blake B. English

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## **I INTRODUCTION**

### **I.A Experience / Qualifications**

1. I am a founder and Senior Managing Director of InFact Experts LLC (“InFact”) and a related entity<sup>1</sup> which provides intellectual property, financial, forensic, data analytics, and dispute advisory services to clients across the nation, as well as in other countries. I have approximately two decades of experience in providing litigation related and non-litigation related intellectual property services in areas such as economic damages, IP portfolio assessment management, licensing / settlement negotiations, licensing enforcement / compliance, strategy and commercialization, and valuation. I have analyzed and/or quantified the economic value of hundreds of intellectual property rights and/or assets, including patents, trademarks, copyrights, and trade secrets. I have assisted clients in efforts to monetize intellectual property outside of litigation through licensing, commercialization, and sales / acquisitions / mergers.

2. I have testified at trial and been qualified as an expert in intellectual property damages in multiple district courts, including the Southern District of California, Central District of California, Northern District of California, District of Delaware, District of Nevada, and the Eastern District of Texas. I have authored multiple publications focused on intellectual property issues. I have been a featured speaker, lecturer, and instructor in a wide array of settings, including state and national conferences, business schools, law schools and engineering schools in major universities, global consulting firms, AM Law 100 firms, and corporations.

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<sup>1</sup> My work in this matter is on behalf of Fact Synthesis LLC.

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properly consider this information, the opinions contained in this report should be considered preliminary in nature.<sup>2</sup>

**I.E Incomplete / Conflicting Information Provided by Alphatec**

*Comments Subsequent to Mr. Judd’s November 5, 2019 Deposition Testimony*

7. Due to incomplete / conflicting data and information provided by Alphatec, I am now required to make a number of assumptions in this report that I plan to revisit should more reliable or complete information become available. Examples of areas of Alphatec’s data and information that are incomplete or inconsistent include, but are not limited: (1) sales/usage data for the accused products; and (2) cost and profit information related to the accused products.

8. First, I understand from counsel for NuVasive, that Alphatec has failed to provide information sufficient to show the sales and/or usage of all accused products in a procedure, along with any other products sold or used in conjunction with the accused products in a procedure. I understand that Alphatec has produced spreadsheets created by filtering data stored in Alphatec’s “sales cube” system. I understand that Alphatec designated Robert Judd on NuVasive’s 30(b)(6) topics related to damages, including products sold with the accused products. Mr. Judd confirmed that the data in the sales cube had been filtered by “product code” to create the spreadsheets.<sup>3</sup> Mr. Judd testified that the list of “product codes” used to filter were not included in the spreadsheet and there would be no way to tell from the

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<sup>2</sup> I understand that on November 18, 2020, Alphatec produced new financial information: ATEC\_LLIF000971397, ATEC\_LLIF000971398, and ATEC\_LLIF000971399. As of the date of this report, I have not had the opportunity to properly analyze the impact that this new information has on my damages opinions. Accordingly, my opinions remain preliminary until I can perform this analysis, and supplement or revise my opinions, to the extent appropriate and allowed.

<sup>3</sup> 11/5/19 Deposition Transcript of Robert Judd, 150:5-151:11.

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Zimmer Biomet

In 2018, Zimmer Biomet held a 5% share of the total MIS interbody device market. Zimmer Biomet’s total share was contributed by its notable shares of the MIPLIF/MITLIF, LLIF and OLIF markets...In 2011, Zimmer introduced the PathFinder NXT, an improved version of the original PathFinder system developed by Abbott. The system facilitates both mini-open and percutaneous approaches. The PathFinder NXT provides surgeons with a MIS option in performing multi-level constructs.

RTI Surgical

RTI Surgical was the seventh-leading competitor in the MIS interbody device market, with a share of 1.1%. The company gained its share in this market through its 2013 acquisition of Pioneer Surgical. RTI Surgical had a modest share of the LLIF market, while the majority of its share in the total market was in the MIPLIF/MITLIF segment.

Other

[As noted in the Figure 6-8, other competitors in the MIS interbody device market include Alphatec Spine, Aurora Spine, Centinel Spine, Clariance, CoreLink Surgical, CTL Amedica, Life Spine, Medacta International, Orthofix, Osteomed, Pinnacle Spine Group, Spineart, Titan Spine, etc.]

**III.D.1.b Adoption of Procedures / Platforms**

49. It is my understanding, based on the expert opinions of Dr. Youssef, discussions with NuVasive representatives including Matt Link and Kyle Malone, and other information available, that the basis for the adoption and usage of lateral platforms/procedures, such as NuVasive’s MAS Platform/XLIF procedure and Alphatec’s LIF Platform, is at the procedure level and that each of these platforms includes integrated components that have been specifically designed to operate collectively as a functional unit in order to achieve a safe and reproducible, minimally invasive, and successful spinal fusion. Dr. Youssef has provided the following opinions related to this issue:

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**Expert Report of Dr. Jim Youssef<sup>129</sup>**

Based on my experience, surgeons base their usage/adoption decisions for lateral procedures at the platform-level versus the component-level. This is primarily based on the fact that lateral platforms such as NuVasive’s MAS platform include integrated components such as a neuromonitoring system, access system (including MaXcess retractor), neuromonitoring disposables, MaXcess disposables, and implants, each of which have been specifically designed to operate collectively as a functional unit in order to achieve a safe and reproducible, minimally invasive, and successful lateral spinal fusion. The three main components necessary for performance of an XLIF procedure – (1) access tools; (2) implants; and (3) neuromonitoring – collectively function in such a way that allows surgeons to achieve safe and reproducible, minimally invasive, and clinically successful interbody fusions. Additionally, because the absence of any one of these components would dramatically impair surgeons’ ability to achieve these objectives, it is my opinion that each of these components contributes equally but in different ways to the adoption and continued use of the XLIF procedure and platform. For example, the implant, by itself, is of little value without neuromonitoring and access systems as the surgeon would have no safe and reproducible way to place the implant in the targeted disc space. Similarly, the retractor and/or neuromonitoring components would provide significantly reduced value without an implant, which are required for fusion, restoring the disc height, and providing stability to the spine. Therefore, it is my opinion that no one of these three key components of XLIF has more clinical value to a surgeon than any other.

Moreover, it is my opinion that a surgeon who has chosen to perform spinal fusion surgery via a non-lateral approach (e.g., ALIF, PLIF, or TLIF) would not choose any of the components of XLIF for such a surgery because they are specifically designed for a lateral procedure, and as such do not work as well or provide the same level of utility of platforms specifically designed for these other approaches. The retractor, implants and neuromonitoring are specifically designed for lateral interbody fusion surgery or some variation of lateral surgery (i.e. corpectomy, lateral disc herniations, etc.). None of the implants for a lateral approach are designed for use in a method using a different approach (i.e. ALIF, TLIF, PLIF), and the retractor is not designed to provide visualization for different approaches. Additionally, the type of neuromonitoring used in XLIF is designed to navigate the lumbar plexus and not used in procedures using a different approach as it would be less relevant or clinically beneficial in those procedures. Furthermore, NuVasive’s MaXcess disposables and neuromonitoring disposals are designed specifically for use with the MaXcess retractor in an XLIF procedure.

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<sup>129</sup> Expert Report of Jim Youssef Re Damages, dated 11/8/19, para. 26, 29. Based on discussions with Dr. Youssef.

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**Supplemental Expert Report of Dr. Jim Youssef**<sup>130</sup>

In Section 4 of my November 8, 2019 Damages Report, I provided opinions regarding surgeons’ usage/adoption decisions and how they are based at the platform level versus the component level. I was asked to consider those opinions in relation to additional implants that have become relevant to this phase of the case. In particular, I was asked to consider Alphatec’s Transcend LIF and IdentiTi LIF implants. As detailed in my Analysis above in Section XV, Alphatec’s Transcend LIF Implants are interchangeable with NuVasive’s CoRoent XL and XLW implants while Alphatec’s IdentiTi LIF implants are interchangeable with NuVasive’s Modulus XL, XLW, and XLXW Ti implants. Thus, my opinions in Section 4 of my November 8, 2019 Damages Report apply to NuVasive’s MAS platform, including the CoRoent XL and Modulus implants. In particular, CoRoent XL and Modulus implants are one of the integrated components that have been specifically designed to operate collectively with the other integrated components of NuVasive’s MAS platform as a functional unit in order to achieve a safe and safe and reproducible, minimally invasive, and successful lateral spinal fusion. Based on my analysis of NuVasive’s Modulus implants and Alphatec’s Transcend and IdentiTi implants, nothing about them changes any of the opinions in Section 4 of my November 8, 2019 Damages report and I incorporate by reference the opinions in that section. Additionally, Alphatec’s press release for the Transcend and IdentiTi implants indicate that both are designed to function with the same instrumentation. This further supports my opinions that the (1) access tools; (2) implants; and (3) neuromonitoring components of NuVasive’s MAS Platform and Alphatec LIF platform are specifically designed to operate collectively as a functional unit in order to achieve a safe and reproducible, minimally invasive, and successful lateral spinal fusion.

50. The following testimony from Pat Miles has helped inform my understanding of

NuVasive’s procedure-driven strategy:

**Testimony of Pat Miles (Alphatec’s Executive Chairman & CEO; Former NuVasive COO)**

In little more than a decade, NuVasive has grown from a small medical device startup to the company it is today, helping thousands of patients. **At the center of NuVasive’s success has been its XLIF procedure and associated equipment.** (‘The majority of NuVasive’s revenue is directly related to XLIF procedures and its related devices. The XLIF procedure is the most rapidly growing MIS interbody fusion procedure, and comprises the vast majority of NuVasive’s market share in the LLIF segment.’) Without the invention of our method to safely and reproducibly traverse the psoas muscle along the lateral trans-psoas path using nerve monitoring-enabled distraction and retraction assemblies (that are also

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<sup>130</sup> Opening Expert Report of Jim Youssef, dated 11/20/20, para. 446. Based on discussions with Dr. Youssef.

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optionally nerve monitoring enabled) with a nerve monitoring system, none of this would have been possible.<sup>131</sup>

**Importantly, NuVasive’s success has been driven by our XLIF procedure and instruments, namely the nerve monitoring enabled distractor and a retractor (which is also optionally nerve monitoring enabled) that integrate NuVasive’s nerve monitoring system.**<sup>132</sup>

Q. Okay. Can you turn to paragraph 27 of your declaration. I think it's around page 27. Starts on 26. The first sentence of paragraph 26 -- excuse me, paragraph 27 on page 26, states (reading):

NuVasive's success has been driven by our XLIF procedure and instruments, namely, the nerve monitoring enabled distractor and a retractor. How did the retractor derive success?

...Q. Did the retractor derive success?

**A. I think whenever you're trying to fulfill the obligations of a surgery, and -- and you provide the necessary tools to predictably fulfill the obligation of surgery, those tools, in essence, enable success. And that was the -- that was a connotation of that description.**

Q. Which features of the retractor were important to the success?

...THE WITNESS: Yeah. The -- the intended communication was that **multiple items have been core to the fulfillment of a reproducible surgery, and those included nerve monitoring and a retractor.** And so if you'd like to read into it more, you're welcome to. That was the intent of this.

BY MR. OLIVER: Q. Was there anything special about the retractor that helped with the success?

...THE WITNESS: **In certain applications there -- there are certain benefits associated with the retractor that we have hopefully designed in for predictability sake.**

BY MR. OLIVER: Q. And what are those?

**A. A fixed posterior blade.**

Q. Okay. MR. MILLER: You can give more --

THE WITNESS: Yeah. **There's a multitude of them** that he's not interested in. But the --

BY MR. OLIVER: Q. That's fine.<sup>133</sup>

Q. Was the design of the CoRoent XL implant important to the success of the XLIF procedure?

...A. Which CoRoent implant?

Q. Any of the XLs.

...A. **The assembly of the technology was core to the success of the XLIF procedure.**

Q. What do you mean by "assembly of the technology"?

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<sup>131</sup> Exhibit-1069 – 7/8/14 Declaration of Patrick Miles, p. 20 [emphasis added].

<sup>132</sup> Exhibit-1069 – 7/8/14 Declaration of Patrick Miles, p. 24 [emphasis added].

<sup>133</sup> 9/4/14 Deposition Transcript of Pat Miles, pp. 90-92 [emphasis added].

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**A. The assembly of a retractor. The assembly of automated neurophysiology. The assembly of an implant.** The fulfillment of the requirements associated with a specific need a patient has creates the likelihood for success of a procedure.

Q. You said "assembly of the implant." Do you mean the design of the implant?

A. I didn't say that. I said the assembly of the -- of the goods.

Q. You said assembly of an implant. Could you -- are you talking about the design of the implant?

A. No. My -- my intended communication was that it is not in any one component. **It is in the assembly of all of those goods that creates an environment for safety and reproducibility that ultimately reflects commercial success.**

Q. And what are all of those goods?

A. The foundation goods for XLIF is a -- is a retractor called MaXcess, an automated neurophysiology system referred to as M5 and an interbody implant.

Q. And what's the interbody implant referred to as?

A. We refer to it as CoRoent XL. And it comes in a variety of sizes, shapes, forms, for all kinds of different things.<sup>134</sup>

**As I have stated repeatedly, XLIF’s success is directly related to the innovative procedure and systems** that combine nerve monitoring enabled distraction and retraction (also optionally nerve monitoring enabled) with NuVasive’s nerve monitoring system to safely and reproducibly navigate the psoas muscle, avoiding the nerve roots, to reach the target disc space to perform a fusion or other procedure. If the XLIF system and method could not safely traverse the nerve-rich psoas muscle, surgeons would never have adopted XLIF and there would have been no commercial success.

**The success of the XLIF procedure** is not due to brand name recognition or being a market leader. When the XLIF procedure hit the market, NuVasive was a small start-up company and it had no brand name recognition. Nor was XLIF’s success due to being part of an already growing market. There was no lateral fusion market at the time of the XLIF procedure. **It is a testament to the procedure (and the instruments which enabled it, especially nerve monitoring) that NuVasive was able to essentially create a new market.** Finally, XLIF’s success was not just a product of great marketing. Although marketing was and is important for XLIF, it did not create the demand for the XLIF procedure. XLIF was and continues to be such a success because of the efficacy and safety the procedure offers.”<sup>135</sup>

**Deposition Testimony of Matt Link (NuVasive’s former President)**

Q. But as far as the way in which NuVasive markets its products or tries to sell its products to surgeons and hospitals, NuVasive tries to sell those products as part

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<sup>134</sup> 9/4/14 Deposition Transcript of Pat Miles, pp. 145-146 [emphasis added].

<sup>135</sup> Exhibit-1069 – 7/8/14 Declaration of Patrick Miles, pp. 27-28 [emphasis added].

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of a platform, they want to sell them together to provide the hospital with implant, access tool, and neuromonitoring systems, correct?

A. So broadly across NuVasive's portfolio, we have focused our technology development efforts and commercial promotion on the ability to provide comprehensive solutions to surgeons based on specific patient anatomic and pathologic needs.

And so the intent is to market and promote a solution for any spine pathology, for any approach that provides a comprehensive and complete procedural solution.

Q. And part of the reason why NuVasive has focused on that particular strategy is because it makes it easier and more convenient for the surgeon to deliver that, correct?

...A. The reason why NuVasive -- in my experience and my opinion based on the 14 and a half years and years prior at another spine company, the reason why NuVasive focuses on that is because it supports safe and reproducible outcomes and the best likelihood of positive -- you know, clinical results for patients.

Q. Right, which I understand. But it also allows for an element of convenience for surgeons, correct?

A. I don't know that I'd characterize convenience as accurate.

Q. Why not?

A. Because I believe ultimately it is about providing the best and most safe and reproducible clinical intervention for a patient that supports the best outcome to the extent that clinical intervention and solution is different than what a surgeon is normally accustomed to. It may not be particularly convenient, but they may make that decision because it is in the best interest of their patient.<sup>136</sup>

Q. NuVasive provides all the materials the user needed to complete an XLIF as part of its business strategy to provide surgeons with a comprehensive set of tools needed to achieve a certain clinical outcome. Is that a fair characterization?

...A. In my experience, the business strategy was predicated on a clinical strategy which was providing the best tools and technology assembled in a manner to create a more predictable and reproducible and safe intervention. Our mantra at the time was good medicine is good business, not convenience is good business. And so, you know, with that in mind, good medicine is good business, the intent was to assemble the best tools and technology integrated in a manner to drive and support the safest and most producible clinical outcomes.

Q. Is that still NuVasive's motto?

A. I believe that our overarching goal and mission is to provide tools and technologies that support the safest most reproducible and predictable outcomes for patients, yes.<sup>137</sup>

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<sup>136</sup> 10/29/20 Deposition Transcript of Matt Link, pp. 75-76.

<sup>137</sup> 10/29/20 Deposition Transcript of Matt Link, pp. 78-79.



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Q. In your experience, in the way that the product is -- in the sort of marketing and commercialization of the CoRoent XL implant, have you ever received any feedback from surgeons commenting on how it's nice to be able to get everything that's needed from one provider, as opposed to having to do it piecemeal from various other providers?

A. On occasion, surgeons have certainly expressed their appreciation that NuVasive has the ability to provide complete solutions that support optimization in the O.R. and the outcome to their patients.

Q. And which surgeons are those?

A. Over 14 and a half years, numerous surgeons have indicated as such.

Q. Would you say it is more than a dozen?

A. I would say it is more than a dozen, yes.

Q. And they appreciate it because that means they don't have to have another provider in the O.R. or come up with equipment from different companies. Even though the equipment could be just as good, they don't have to do that, they can go to just one place, NuVasive; is that right?

A. My experience, most commonly, surgeons appreciate the fact that products are designed in a manner and supported in a manner that ultimately, you know, helps to provide an efficient clinical intervention and the best possible outcomes for the patients.

Q. Would it be more difficult, in your mind, for NuVasive to sell the implant alone and for surgeons to obtain a retractor or neuromonitoring equipment from another provider?

A. I think if NuVasive did not have a comprehensive procedural solution in numerous areas, including XLIF as well as others, surgeons would be less receptive to a solution that was incomplete in its ability to support – optimize interoperative workload, clinical efficiency, and the best possible patient outcomes.

Q. And that's even though the implant could be used with another provider's retractor or a competitor's neuromonitoring system; is that correct?

A. Yeah, my experience is surgeons have appreciated the comprehensive nature of the solutions we have provided, XLIF being one of them, procedurally. And the fact that components are designed to be well-integrated, and support -- optimize clinical workflow, surgical efficiency, and the best possible patient outcomes.<sup>138</sup>

51. Based on the following documents, Alphatec also appears to have adopted a procedure-driven strategy in developing and selling a LIF platform:

**Alphatec Earnings Call Transcripts:**

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<sup>138</sup> 10/29/20 Deposition Transcript of Matt Link, pp. 89-91.

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The overarching intention behind Alphatec's renewed development program is **to create value and deliver better outcomes by advancing this company from a simple implant manufacturer into a spine solutions architect.**

...

...the [SafeOp nerve monitoring] technology will **complete our lateral solution.**<sup>139</sup>

And the key is you need to start looking at spine surgery in a way that the spine surgeons view the world. **And spine surgeons view the world in terms of approaches.** And so what you'll hear us refer to ourselves as is spine approach technology, ATEC approach technology. And we must -- we really must create the clinical distinction by spine approach.<sup>140</sup>

And so if you go to the next slide and you say, "gosh, what is our responsibility as a company?" And I would tell you that we're stewards to the surgeons' goals. And not to give you an overt spine lesson, but spine surgery is fundamentally decompression, stabilization and alignment. That's what spine surgeons are trying to accomplish. And there becomes a myriad of different pathologies and then to say, what approach do I take to address this pathology to fulfill these goals? Our job as stewards becomes, what's the technology that we could provide the surgeon and create predictability associated with creating great outcome? **So what we do is we look within the approach itself and say, how can we be effectual with regard to the approach?**<sup>141</sup>

But this is really just a reminder that **we think of the world in spine approaches and we architect approaches with products.**<sup>142</sup>

There's a bit of an interesting situation in spine in that implants are the currency items, and they are the ones that generate most of the currency. The challenges is a currency that's been defined and what the surgeon requires to do predictable surgery are not one and the same. And so what happens is, is a lot of companies won't create the requirements of surgery because financially, they don't appear as viable. **But I think as you look at things with regard to a procedure and the integration of the tools being used to fulfill a specific surgical need,** what you see is you see the expanse of the currency items based upon the ability to deliver clear, objectionable -- clear, excuse me, objective actionable information. And so the opportunity there is that you will see a vast

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<sup>139</sup> Alphatec Holdings, Inc. FQ4 2017 Earnings Call Transcript (<https://seekingalpha.com/article/4154927-alphatec-holdings-atec-ceo-terry-rich-q4-2017-results-earnings-call-transcript?part=single>) [emphasis added].

<sup>140</sup> Alphatec Holdings, Inc. FQ4 2018 Earnings Call Transcript (<https://finance.yahoo.com/news/edited-transcript-atec-earnings-conference-014048724.html>) [emphasis added].

<sup>141</sup> Alphatec Holdings, Inc. FQ4 2018 Earnings Call Transcript (<https://finance.yahoo.com/news/edited-transcript-atec-earnings-conference-014048724.html>) [emphasis added].

<sup>142</sup> Alphatec Holdings, Inc. FQ1 2019 Earnings Call Transcript (<https://finance.yahoo.com/news/edited-transcript-atec-earnings-conference-033534388.html>) [emphasis added].

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minority in the contribution from the SafeOp platform, but it will be responsible for the revenue gained, if you will.<sup>143</sup>

And so we're so reliant upon building spine approaches. **And so the ability to start to apply technology that integrates with each other such that we're architecting the approach, which will be reflected in conveyed sales.**<sup>144</sup>

**We look at surgery through the lens of a procedure.** And how many products per procedure or per surgery we can sell into. That means what we've done is we've controlled more of the surgery, we've mitigated more variables based upon the architecture of the entire experience.<sup>145</sup>

And so, it's very gratifying to see SafeOp used with our retractors -- used with our fixation system or inner body systems. **And so, you really start to see the procedural strategy come into fruition.**<sup>146</sup>

#### **Alphatec 2017 Form 10-K**<sup>147</sup>

With a **focus on the entire procedure**, we expect to build awareness of the breadth of our product offering.<sup>148</sup>

#### **Strategy**

Our goal is to become the most respected, fastest growing spine player by pioneering meaningful innovation. With our new spine-experienced leadership team, and the high-performance culture we are creating, **we intend to advance Alphatec from an implant manufacturer to a spine solutions architect via two key principals:**

1. **Proceduralization.** We are determined to design complete surgical solutions that address unmet clinical needs and improve clinical outcomes by integrating Alphatec products and technologies to treat specific pathologies.
2. **Speed to Market.** We intend to build on proven team expertise to expedite product development by enhancing Alphatec's innovative dexterity and unique

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<sup>143</sup> Alphatec Holdings, Inc. FQ2 2019 Earnings Call Transcript (<https://finance.yahoo.com/news/edited-transcript-atec-earnings-conference-032604521.html>) [emphasis added].

<sup>144</sup> Alphatec Holdings, Inc. FQ2 2019 Earnings Call Transcript (<https://finance.yahoo.com/news/edited-transcript-atec-earnings-conference-032604521.html>) [emphasis added].

<sup>145</sup> Alphatec Holdings, Inc. FQ4 2019 Earnings Call Transcript (<https://www.fool.com/earnings/call-transcripts/2020/03/06/alphatec-holdings-inc-atec-q4-2019-earnings-call-t.aspx>) [emphasis added].

<sup>146</sup> Alphatec Holdings, Inc. FQ1 2020 Earnings Call Transcript (<https://www.fool.com/earnings/call-transcripts/2020/05/11/alphatec-holdings-inc-atec-q1-2020-earnings-call-t.aspx>) [emphasis added].

<sup>147</sup> Alphatec Holdings, Inc., Form 10-K for the fiscal year ended December 31, 2017.

<sup>148</sup> Alphatec Holdings, Inc., Form 10-K for the fiscal year ended December 31, 2017, p. 6 [emphasis added].

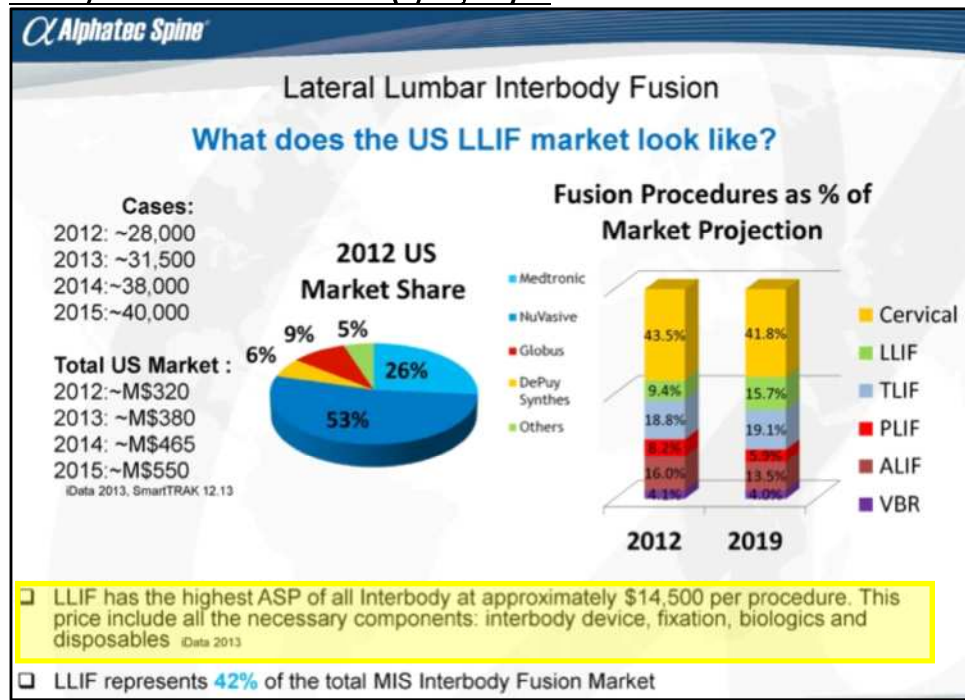
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market strategy and accelerating the commercial launch of our innovative product pipeline.<sup>149</sup>

**The Alphatec Solution**

Our principal product offering includes a wide variety of spinal solutions comprised of components such as access systems, interbody implants, fixation plates, screws and rods, instruments, and various biologics offerings all designed to enhance and promote spinal fusion. **Our business is focused on treating multiple spine pathologies and conditions through a variety of MIS and traditional procedures.**<sup>150</sup>

**Alphatec Presentation “Lateral Lumbar Interbody Fusion System – Market Need / Business Case PH: 1” (6/16/14)<sup>151</sup>**



<sup>149</sup> Alphatec Holdings, Inc., Form 10-K for the fiscal year ended December 31, 2017, p. 1 [emphasis added].

<sup>150</sup> Alphatec Holdings, Inc., Form 10-K for the fiscal year ended December 31, 2017, p. 3 [emphasis added].

<sup>151</sup> ATEC\_LLIF000137018 at -023, -025-026, -031 [emphasis added].

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**Alphatec Spine**

### Lateral Lumbar Interbody Fusion

- How does Alphatec add LLIF to the product portfolio?
  - Can we acquire a LLIF system?

**Options Comparison SWOT**

Plan A	Hybrid Plan	Plan B	Plan C
<b>S:</b> Quickest to Market, but only by a few weeks Least strain on resources for long term plan <b>W:</b> Short Term Fix 100% Licensed Very High COGS Basic system w/ limited Set Numbers, applications Negative Margins <b>O:</b> Sounds like ATEC's Bag test Distributor and Surgeon pull <b>T:</b> Big investment for instruments and implants Non-Acceptance Alphatec reputation	<b>S:</b> Strong Long Term Plan Surgeon and patient willing from why element impact Non-Acceptance Risk is lowered <b>W:</b> 80% Licensed, Industry very high COGS, highly Basic system w/ limited Set Numbers, applications Negative Margins <b>O:</b> Sounds like ATEC's Bag test Distributor and Surgeon pull Gradual shift to internal development <b>T:</b> Significant investment in development Alphatec reputation	<b>S:</b> Opportunity to Build Capabilities in Lateral Offering Medium Term Launch to Market - Quicker than full internal product <b>W:</b> Short Term Fix High Developer License Cost Hold Margins Current Business Build R&D Development Knowledge Stagger Move out of Education System More Consistency in Marketing Plan <b>T:</b> R&D/T&E Resources Investment in Instruments	<b>S:</b> Competitive, Comprehensive system Streamlined Product Offering <b>W:</b> Late to Market High Development Cost <b>O:</b> Internal Development Control Innovate on and Leverage existing LLIF technology <b>T:</b> Convert Business Pricing Pressures Critical Path Delays
<b>System Capabilities</b> DDD with MILD ~10° deformity Grade 1 spondy L4/L5: Limited, unknown r-arc	<b>System Capabilities</b> DDD with ~20-30° deformity Grade 1 and 2 spondy L4/L5: 50% Yes!	<b>System Capabilities</b> DDD with ~20-30° deformity Grade 1 and 2 spondy L4/L5: 50% Yes!	<b>System Capabilities</b> DDD with ~20-30° deformity Scoliosis Deformity Grade 1,2 and 3 spondy L4/L5: Absolutely Tumor/Trauma

**Alphatec Spine**

### Lateral Lumbar Interbody Fusion

#### Competitive Landscape

- Competitor Systems: More than 12

NuVasive, Medtronic, Globus, DePuy, Synthes, LANX, K2M, LDR

Aspect	XLIF (NuVasive)	DLIF (MSD)	LLIF (Globus)
<b>Market</b>	53%	26%	9%
<b>Retractor</b>	3 blade, Handheld "MaXcess" 	2 blade "DLIF Retractor" 	3 blade, Handheld Mars 3V 
<b>Interbody Offering</b>	CoRoent  H: 6 (th), 8-16mm L: 40 (th), 45-60mm W: 18, 22mm L°: 0°, 10°	Clydesdale  H: 9-17mm L: 45-60mm W: 22mm L°: 0°, 6°	Transcontinental  H: 7-17mm L: 40-60mm W: 18mm L°: 0°, 6°

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**Alphatec Spine**

### Lateral Lumbar Interbody Fusion

- How does Alphatec develop a LLIF system?
  - The project will have two stages**
    - Short term development that leads to a Beta Launch (est. 9-12 months)
    - Full development and commercial launch (est. 18-24 months)

<b>LLIF Beta Launch</b>	<b>LLIF Full Launch</b>
<b>Stage 1</b>	<b>Stage 2</b>
In'Tech Retractor	ATEC Lateral Retractor System
ATEC Standard Lateral Disc Prep Instruments	ATEC Specialized Lateral Disc Prep Instruments
ATEC Battalion LLIF Cage DDD Implant	ATEC Battalion LLIF Cage Deformity Implant

**Alphatec Market Need / Assessment Request, Concept: Direct Lateral (4/17/13)<sup>152</sup>**

**Describe how current Products do or do not address Need:**

.... We do have custom direct lateral sets being developed for the short term but without a retractor option growth in the market will be extremely limited.

		<b>Market Need/Assessment Request</b>	
<b>Concept:</b> Direct Lateral			
<b>Prepared By:</b> Derek Kuyper			
<b>Signature:</b> 		<b>Date:</b> 4/17/13	
<b>Market Need:</b>			
<b>Describe significance of need for Market and/or Alphatec Spine:</b> Direct lateral is one of the fastest growing segments in Spine. Not having a solid option losses both revenue and opportunity. As surgeon switch to Direct Laterals we miss their interbody business and give relationship opportunities to other companies. Additionally attracting bigger distributors is an issue when we have no direct lateral option and most have customers that perform direct lateral surgeries.			
<b>Describe how current Products do or do not address Need:</b> GLIF was not commercially successful, this was supposed to be our entry into the Direct Lateral market but this has never actually come to fruition. We do have custom direct lateral sets being developed for the short term but without a retractor option growth in the market will be extremely limited.			

<sup>152</sup> ATEC\_LLIF000003809 [emphasis added].

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**Deposition Testimony of Mike Aleali (Alphatec’s Senior Product Manager over Lateral and ALIF)**

Q. Does Alphatec intend for its Transcend lateral implants to be used with the Squadron lateral retractor?

A. I mean, holistically, with the system, yes.

Q. Does Alphatec ever sell either the Battalion lateral implants or the Transcend implants for use in lateral surgeries that don't use Alphatec access equipment?

A. I mean, we would be open to offering it as such, but as we have kind of discussed a couple times -- as we have discussed a couple times, there is really no differentiator with PEEK and lateral interbody market throughout the market. So it is not likely someone would use someone else's system and then just be gung-ho about Battalion or Transcend.

Q. Have there ever been any surgeries to date where a Battalion lateral or Transcend lateral implants have been placed using access equipment that is not Alphatec's?

A. I think so, before IdentiTi came out. And I think that may have been like literally a handful of cases, like, less than five or so.

Q. So a very, very small minority of the overall placements of Alphatec Battalion and Transcend lateral cages have been done using non-Alphatec access equipment, right?

A. Correct.<sup>153</sup>

52. In addition to the expert opinions of Dr. Youssef, discussions with John English, Matt Link and Kyle Malone, and documents referenced throughout this report, the following documents and testimony have helped inform my understanding that NuVasive’s MAS Platform/XLIF Procedure includes integrated components that have been specifically designed

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<sup>153</sup> 10/30/20 Deposition Transcript of Mike Aleali, pp. 117-118.

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to operate collectively as a functional unit in order to achieve a safe and reproducible, minimally invasive, and successful spinal fusion:<sup>154,155</sup>

**Expert Report of Dr. Jim Youssef<sup>156</sup>**

It is further my opinion that the components of XLIF are not sold together merely for convenience or some other non-clinical reason, but rather because they operate together as a functional unit that is specifically designed to improve surgical outcomes. Indeed, surgeons, clinics, and hospitals do not make product usage or adoption decisions based on an individual component of a larger procedure, such as an individual implant or an individual retractor. Rather, in reality, surgeons determine the spinal pathology to be addressed surgically and decide on an appropriate intervention. Once the surgical intervention is chosen, the surgeon then determines the appropriate system/platform to be used based on evaluating factors such as whether the overall system/platform used in the procedure provides a safe and reproducible, minimally invasive, and clinically successful interbody fusion. Thus, it is my experience that surgeons wishing to

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<sup>154</sup> Bold emphasis added in testimony excerpts and documents.

In addition, see for example NUVA\_ATEC0243731 (“With its differentiated nerve sensing technology, and as of late last year its unique XLIF lateral access retractor system, NuVasive has a distinct advantage against competitive players that primarily focus on spinal implants, but don’t offer a comprehensive solution.”), NUVA\_ATEC0244472 (“[NuVasive’s] MAS platform provides a unique and comprehensive solution for safe and reproducible minimally disruptive surgical treatment of spine disorders. The key components of [its] MAS platform, NeuroVision, MaXcess and specialized implants, provide a surgeon with enhanced visibility and access to the spine for fusion.”), NUVA\_ATEC0243580 (“XLIF was created to be a safer and more reproducible, minimally disruptive procedure that utilizes conventional surgical techniques and a seamlessly integrated Maximum Access Surgery (MAS) platform.”; “As first to market, with thousands of successful cases, NuVasive® continues to pioneer the development and advancement of lateral access spine surgery. No other company provides such a complete and proven lateral access solution.”), NUVA\_ATEC0244413 (“The MAS platform offers advantages for both patients and surgeons such as reduced surgery and hospitalization time and faster recovery. MAS combines three categories of current product offerings – NeuroVision, a proprietary software-driven nerve avoidance system; MaXcess, a unique split-blade design retraction system; and specialized implants, like SpheRx and CoRoent – that collectively minimize soft tissue disruption during spine surgery while allowing maximum visualization and surgical reproducibility.”), NuVasive 2004 Annual Report (“NuVasive’s suite of proprietary MAS technologies differentiates us from the competition. The MAS platform combines our NeuroVision® nerve monitoring system, MaXcess® access system and instruments, and specialized implants. Together, these systems provide the versatility to enable a wide variety of spine procedures: posterior, posterolateral, and lateral approaches to decompression and fusion, in a minimally disruptive fashion.”), “Fact Sheet: eXtreme Lateral Interbody Fusion (XLIF®)”: [https://www.rushortho.com/sites/default/files/images/PDFs/XLIF\\_Fact\\_Sheet1.pdf](https://www.rushortho.com/sites/default/files/images/PDFs/XLIF_Fact_Sheet1.pdf) (“Until now, widespread acceptance of minimally invasive techniques has evaded spine surgery. The primary reason for this was the inherent difficulty of introducing new technologies while attempting to achieve the same surgical objectives as conventional surgery. The XLIF surgical technique is different, however, because it incorporates two systems developed by NuVasive®: the MaXcess® System and the NVJBTM/M5® System. NuVasive has also developed other products to support the XLIF procedure, such as the XLP® Lateral Plate, the SpheRx® DBR® II System, and the CoRoent® XL device.”).

<sup>155</sup> Based on discussions with John English, I understand that it is exceedingly rare for any surgeon that has adopted the XLIF platform to also be trained on and use another lateral platform concurrently.

<sup>156</sup> Expert Report of Jim Youssef Re Damages, dated 11/8/19, para. 28. Based on discussions with Dr. Youssef.



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perform spinal fusion surgery via the lateral approach choose to use the XLIF platform as a whole because of the benefits provided collectively by the three key components of XLIF that allow for safe, reproducibly, effective and minimally invasive lateral spinal fusion surgery.

**Supplemental Expert Report of Dr. Jim Youssef**<sup>157</sup>

In particular, CoRoent XL and Modulus implants are one of the integrated components that have been specifically designed to operate collectively with the other integrated components of NuVasive’s MAS platform as a functional unit in order to achieve a safe and safe and reproducible, minimally invasive, and successful lateral spinal fusion. Based on my analysis of NuVasive’s Modulus implants and Alphatec’s Transcend and IdentiTi implants, nothing about them changes any of the opinions in Section 4 of my November 8, 2019 Damages report and I incorporate by reference the opinions in that section. Additionally, Alphatec’s press release for the Transcend and IdentiTi implants indicate that both are designed to function with the same instrumentation. This further supports my opinions that the (1) access tools; (2) implants; and (3) neuromonitoring components of NuVasive’s MAS Platform and Alphatec LIF platform are specifically designed to operate collectively as a functional unit in order to achieve a safe and reproducible, minimally invasive, and successful lateral spinal fusion.

**Testimony from Pat Miles (Alphatec’s Executive Chairman & CEO; Former NuVasive COO)**

The CoRoent is not the main element of the procedure. It is an assembled group of things that makes the thing successful.<sup>158</sup>

Q. Have you had requests from hospitals or customers to sell them implants CoRoent, etc., to do direct lateral surgery but they say, “We don’t want to use NeuroVision’?

A. Yes.

Q. How do you respond to those requests?

A. We have such a confidence in the verification in the safety and reproducibility, a very rote, step one, step two, step three, technique that when we do it, is **we drive them to sell the procedure, not specific elements of the procedure.**

Q. So you say no to some customers?

A. Absolutely.

Q. Even though you could make more money if you just sold them the implants?

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<sup>157</sup> Opening Expert Report of Jim Youssef, dated 11/20/20, para. 446. Based on discussions with Dr. Youssef.

<sup>158</sup> Trial Testimony of Patrick Miles, August 31, 2011 (Day 2, 421:7-9).

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**A. You can do short term phenomena. Our vision is we create value. We get paid reflective of the value and the value is only done when you do good work and you create safety and reproducibility. To make a little money on a single experience is not a business.**<sup>159</sup>

Q In terms of sales made in association with an XLIF, is it implant, retractor, stimulated dilators, and other disposables, or is there anything else?

A I would say all of the -- all the NeuroVision elements; all of the interbody implant elements; all of the fixation elements, be it posterior fixation or lateral fixation; the -- the biologic elements. So, you know, **our interest is in fulfilling the obligations of a procedure. And if the procedure defines an XLIF, then all those elements are assembled to create a predictable experience for the surgeon.**<sup>160</sup>

**Trial Testimony from Dr. Kevin Neels (Warsaw/Medtronic’s Damages Expert; Alphatec’s Previous Damages Expert in This Matter)**

It [PX1732 – “NuVasive XLIF Approach: MVP Surgical Presentation”] talks about **the neuro monitoring, it talks about the retractor, and it talks about the implant, as all being tools for safety and responsibility.**<sup>161</sup>

I think the way to think about this, is I showed a brochure before that talked about the contribution of the CoRoent to safety and reproducibility. It also talks about the contribution of the retractor. It also talks about the contribution of neuro monitoring. **I think about this as like a three legged stool. It’s stable, but if you saw one leg off, it doesn’t matter which one it is, it’s going to fall over, you need all three to carry it out successfully.**<sup>162</sup>

Q. And you provided the opinion that all of the products in your constructs are functionally related, correct?

A. I think the way I put it, **they’re all used together to achieve one result, which is the spinal fusion surgery, which is the point – the reason why all of these products are sold and demanded.**<sup>163</sup>

**SOLAS Presentation “XLIF Key Messaging: 2013 Proctor Meeting”**

XLIF is defined through the use of:

MaXcess

NeuroVision

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<sup>159</sup> Trial Testimony of Patrick Miles, September 1, 2011 (Day 3, 470:25-471:18).

<sup>160</sup> 11/22/13 Deposition Transcript of Pat Miles, p. 239.

<sup>161</sup> Trial Testimony of Dr. Kevin Neels, September 6, 2011 (Day 5, 1128:8-11).

<sup>162</sup> Trial Testimony of Dr. Kevin Neels, September 6, 2011 (Day 5, 1033:23-1034:5).

<sup>163</sup> Trial Testimony of Dr. Kevin Neels, September 6, 2011 (Day 5, 1082:8-13).

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CoRoent XL.<sup>164</sup>

**Trial Testimony from Keith Valentine**

Q. So you have got your suite of products, NeuroVision neuromonitoring, CoRoent implants, some version of a MaXcess retractor and together you market those as XLIF, right?

A. That’s correct.<sup>165</sup>

Q. Will NuVasive sell CoRoent implants to a hospital or surgeon who doesn’t also use NeuroVision or have some kind of neuro monitoring technology?

A. No. We feel that it’s an intimate part of the entire XLIF suite.

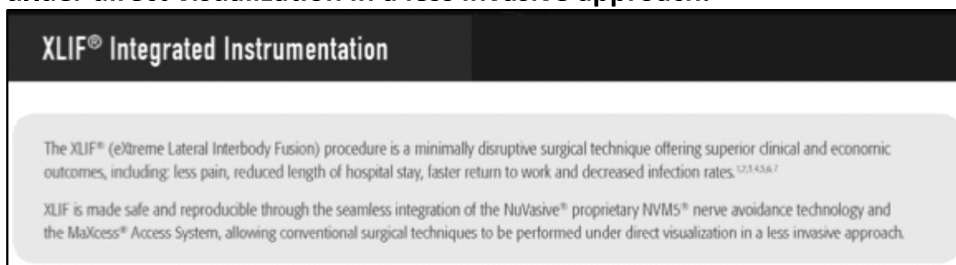
Q. Why will you not sell implants separately if somebody wants to buy them?

A. We have data, we have experience of thousands of cases a month that show when it’s used together, this is the safety profile you can expect. **And if you are to take pieces out, you’re going to change the safety profile. We feel it’s critical that we don’t allow that.**<sup>166</sup>

**NuVasive XLIF® Integrated Instrumentation Marketing Materials**<sup>167</sup>

The XLIF (eXtreme Lateral Interbody Fusion) procedure is a minimally disruptive surgical technique offering superior clinical and economic outcomes, including less pain, reduced length of hospital stay, faster return to work and decreased infection rates.

XLIF is made safe and reproducible through the **seamless integration of the NuVasive proprietary NVM5 nerve avoidance technology and the MaXcess Access System, allowing conventional surgical techniques to be performed under direct visualization in a less invasive approach.**



**NuVasive 2018 Form 10-K**<sup>168</sup>

<sup>164</sup> NUVA\_ATEC0243637.

<sup>165</sup> Trial Testimony of Keith Valentine, September 6, 2011 (Day 5, 1172:21-25).

<sup>166</sup> Trial Testimony of Keith Valentine, September 6, 2011 (Day 5, 1184:22-1185:8).

<sup>167</sup> NR0058619 – NR0058620.

<sup>168</sup> NuVasive, Inc. Form 10-K for the fiscal year ended December 31, 2018, pp. 6-7.

([https://www.sec.gov/Archives/edgar/data/1142596/000156459019003470/nuva-10k\\_20181231.htm](https://www.sec.gov/Archives/edgar/data/1142596/000156459019003470/nuva-10k_20181231.htm))

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Our MAS platform allows surgeons to perform a wide range of minimally disruptive spine procedures in all regions of the spine and from various surgical approaches, while overcoming the shortcomings of traditional minimally invasive spine surgical techniques. The MAS platform is designed to treat a wide range of spinal pathologies while accommodating a surgeon’s preferred surgical technique. We believe our approach improves clinical results and should continue to drive an expanded number of minimally disruptive procedures performed, lead the market away from open surgery, and make less invasive techniques the standard of care in spine fusion and non-fusion surgery. Our products facilitate minimally disruptive applications of the following spine surgery procedures, among others:

- Lumbar and thoracic fusion procedures in which the surgeon approaches the spine through the patient’s back, side or abdomen;
- Cervical fusion procedures for either the posterior occipito-cervico-thoracic region or the anterior cervical region; and
- Decompression, which is removal of a portion of bone or disc from over or under the nerve root to relieve pinching of the nerve.

**Our MAS platform combines three product categories: our MaXcess retractors, our specialized implants and fixation products, and our neuromonitoring systems and service offerings that collectively enable surgeons to detect and navigate around nerves while directing customized access to the spine for implant delivery.** Biologics are used to complement procedures by promoting bone fusion. In addition to our MAS platform and biologics, our comprehensive procedural solutions include our IOM services, Integrated Global Alignment, or iGA, and Pulse, our surgical automation platform.

***MaXcess***

MaXcess retractors have a split-blade design consisting of three blades that can be positioned to customize the surgical exposure in the shape and size specific to the surgical requirements rather than the more traditional fixed tube or two-blade designs of traditional minimally invasive spine surgical systems. This split-blade design also provides customizable access to the spine, which allows surgeons to perform surgical procedures using instruments that are similar to those used in open procedures but with a smaller incision and less tissue disruption. The ability to use familiar instruments reduces the learning curve for our procedures and facilitates the adoption of our products. Our system’s illumination of the operative corridor aids in providing surgeons with better direct visualization of the patient’s anatomy, without the need for additional technology or other special equipment such as endoscopes. Over the years, several improvements to our MaXcess systems have been made, including

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incorporating integrated neuromonitoring technology and improving the blade systems, and the MAS approach has broadened from the lumbar to the thoracic region. Our MaXcess products are used in the cervical spine for posterior application and anterior retraction, the lumbar spine for decompressions, transforaminal lumbar interbody fusions, or TLIFs, posterior lumbar interbody fusions, or PLIFs, the thoracolumbar spine for eXtreme Lateral Interbody Fusion, or XLIFs, and the thoracic region for tumors and trauma, as well as in adult degenerative scoliosis procedures.

***Implants and Fixation Products***

We have many implants and fixation devices designed to be used with our MAS platform. Our portfolio of implants used for interbody disc height restoration include implants made from allograft, titanium, and PEEK. Our titanium and PEEK implants are available in both porous and non-porous formats and come in a variety of shapes, sizes, and lordosis options to accommodate specific approach, pathology, alignment restoration, and anatomical requirements of the patient and the particular fusion procedure. Our implants are designed for insertion into the smallest possible space while maximizing surface area contact for fusion. Our fixation products, including pedicle screws, rods and plates, have been uniquely designed and include a highly differentiated percutaneous minimally invasive solution with advanced guide technology, superior rod insertion options, and multiple reduction capabilities to be delivered through our procedures to provide stabilization of the spine. Our fixation offerings include our Armada, Precept and Reline posterior fixation portfolios.

***Neuromonitoring***

Our neuromonitoring systems utilize electromyography, or EMG, as well as proprietary software hunting algorithms and graphical user interfaces to provide surgeons with an enhanced and intuitive nerve avoidance system. Our systems function by monitoring changes in electrical signals across muscle groups, which allows us to detect underlying changes in nerve activity. Through our neuromonitoring platforms, we give surgeons the option to connect their instruments to a computer system that provides discrete, real-time, surgeon directed and surgeon controlled feedback about the directionality and relative proximity of nerves during surgery. We believe our proprietary neuromonitoring platforms are a differentiator in the market and are unique in their ability to provide information about the directionality and proximity of nerves. Our systems analyze and then translate complex neurophysiologic data into simple, useful information to assist the surgeon’s clinical decision-making process. The health and integrity of the spinal cord and related nerves can also be assessed using motor evoked potentials, or MEPs, and somatosensory evoked potentials, SSEPs. Both of these methods of IOM involve applying stimulation and recording the response that must travel along the motor or sensory paths of the spinal cord. Surgeons can connect certain instruments to our neuromonitoring systems,

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thus creating an interactive set of instruments that better enable the safe navigation through the body’s nerve anatomy during surgery. The connection is accomplished using a clip that is attached to the instrument, effectively providing the benefits of our neuromonitoring systems through an instrument already familiar to the surgeon. Our proprietary software and easy to use graphical user interfaces allow the surgeon to make critical decisions in real time to help enable safer, faster, and more reproducible procedures to achieve improved patient outcomes.

**NuVasive Document “XLIF Surgical Technique”<sup>169</sup>**

Whereas previous attempts at minimally disruptive spine surgery (e.g., endoscopes, optical trocars, CO2) typically introduced an inherent difficulty in using the new technology, XLIF is minimally disruptive while utilizing conventional surgical techniques. Over the years, the XLIF procedure and technology have evolved. However, two systems, described below, were designed to help enable safer and more reproducible minimally disruptive spine surgery, compared to previous technologies.

The MaXcess<sup>®</sup> 4 Access system provides maximum surgical access while minimizing the soft tissue disruption that often occurs during open surgery. MaXcess 4 allows the fundamentals of conventional surgical techniques to be achieved, while eliminating the unfamiliar requirements of operating coaxially through tubular portals. Additionally, since there are no adjunctive visualization tools (e.g., endoscopes, monitors), the MaXcess 4 Access system enables direct, illuminated visualization of the patient’s anatomy through conventional methods.

The NVM5<sup>®</sup> system is another important technology that helps enable more reproducible, minimally disruptive techniques. This system is the only surgeon-driven technology that provides dynamic, discrete information on nerve location and condition. The XLIF technique described in this guide utilizes a lateral, retroperitoneal, transpsoas approach to access the intervertebral disc. NVM5 was designed to enable a safer trajectory past the nerves in the psoas muscle by communicating nerve proximity and directionality information. This enables the surgeon to locate and avoid the lumbar plexus while accessing the disc. NVM5 is the only clinically validated nerve avoidance system for reproducibility during a lateral transpsoas technique.

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<sup>169</sup> NUVA\_ATEC0048961.

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**EQUIPMENT REQUIREMENTS:**  
To successfully complete this technique, the following patient positioning supplies, instruments, implants, and fixation options are required.

**PATIENT POSITIONING:**

- 3-Inch Tape
- Axillary Roll
- Foam Padding
- Radiolucent Bendable Surgical Table

**INSTRUMENTS:**

- C-arm
- Light Source
- MaXcess® 4 Access System
- MaXcess 4 Articulating Arm Tray
- MaXcess 4 Kit
- MaXcess Fixation Shim Kit (optional)
- XLIF® Instruments
- Anterior/Lateral General Instruments
- NVM5®
- NVM5 XLIF Dilator Kit
- NVM5 EMG Module

**IMPLANTS:**

- CoRoent® (XL, XL-W, XL-XW, XL-CT, XL-F, XL-FW, XL-T)

**LATERAL FIXATION OPTIONS:**

- XLIF Decade™ Lateral Plate
- StruXure™ Lateral Deformity Fixation System

**POSTERIOR FIXATION OPTIONS:**

- Precept®
- Armada®
- SpheRx® DBR® III
- SpheRx PPS
- SpheRx PPS + EXT
- Radian® Facet Screws

**NuVasive 2005 Annual Report**<sup>170</sup>

<sup>170</sup> NuVasive 2005 Annual Report (<http://ir.nuvasive.com/static-files/8b0fa8a8-76f1-4151-8584-b7807049e000>).



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**NEUROVISION JIB**  
NERVE AVOIDANCE LEADER

**MAS™ Platform**

- Dynamic Screw Test
- InStim™ Percutaneous Screw Test
- Nerve Detection
- Free Run EMG
- Nerve Retractor
- I-PAS™ System

**MAS**  
MAXIMUM ACCESS  
MINIMAL DISRUPTION

**MAXCESS II**

- Access System
- Decompression
- TLIF/PLIF
- Micro-Access System
- Micro-Decompression
- XLIF®

**IMPLANTS**

- SpheRx® Spinal System
- SpheRx DBR™ Spinal System
- SmartPlate® Gradient CLP™
- ExtenSure™ Allograft System
- Triad® Facet Screws
- Triad Allograft
- CoRoent® Implants

NuVasive designs, develops and markets innovative products for the surgical treatment of spine disorders. Our product portfolio facilitates minimally disruptive spine surgery procedures, resulting in reduced surgery time and hospitalization costs and faster patient recovery. With a culture founded on the pursuit of Absolute Responsiveness®, we strive to bring products to market faster than our competitors while providing superior customer service. In doing so, we are addressing the critical needs of those people impacted by our innovative products and procedures — the patients, the surgeons and the hospitals.



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### III.D.1.c Procedure-Based Revenue Generation (“Razor / Razor blade”)

53. It is my understanding, based on discussions with Matt Link, and other information available, that implants and disposables are the currency for NuVasive’s XLIF and Alphatec’s LLIF procedures and that the prices of implants include compensation for other platform components. The following information has helped inform my understanding of this issue:

#### **Alphatec’s Earnings Call Transcripts:**

There's a bit of an interesting situation in spine in that **implants are the currency items, and they are the ones that generate most of the currency. The challenges is a currency that's been defined and what the surgeon requires to do predictable surgery are not one and the same. And so what happens is, is a lot of companies won't create the requirements of surgery because financially, they don't appear as viable. But I think as you look at things with regard to a procedure and the integration of the tools being used to fulfill a specific surgical need, what you see is you see the expanse of the currency items based upon the ability to deliver clear, objectionable -- clear, excuse me, objective actionable information.** And so the opportunity there is that you will see a vast minority in the contribution from the SafeOp platform, but it will be responsible for the revenue gained, if you will.<sup>171</sup>

*Brooks Gregory O'Neil, Lake Street Capital Markets, LLC, Research Division:*

Let me ask you a little bit about SafeOp. I have a sense of your excitement about the opportunity with SafeOp. I'm just curious if this is an element that we should expect to see revenue and earnings from. Or would you envision it more be a complement or a driver of revenue from the -- more of the product classifications you sell?

*Pat Miles, Alphatec Holdings, Inc., Executive Chairman & CEO:*

Yes. I think it's a great question, Brooks. The issue becomes is -- **the real currency items in surgery are going to be the implants.** And you're going to see revenue associated with the utility of SafeOp, but **the real revenue is going to be in the assembly of products that we can put together in an approach to fulfill the obligations of surgery.** So what that means, again, long-winded, is that we're pulling through some of the items that are going to have less of a financial upside. But we feel like that's our opportunity.<sup>172</sup>

<sup>171</sup> Alphatec Holdings, Inc. FQ2 2019 Earnings Call Transcript (<https://finance.yahoo.com/news/edited-transcript-atec-earnings-conference-032604521.html>) [emphasis added].

<sup>172</sup> Alphatec Holdings, Inc. FQ4 2018 Earnings Call Transcript (<https://finance.yahoo.com/news/edited-transcript-atec-earnings-conference-014048724.html>) [emphasis added].

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**Declaration of Kelli Howell (Alphatec Executive VP of Clinical Strategies; Former NuVasive VP)**<sup>173</sup>

Third, I would also like to clarify Mr. Link's statement that "NuVasive makes the significant investment upfront to loan or provide the hospitals and surgeons" with its retractor and neuromonitoring systems and "then makes up the difference in its initial investment with its specialized pricing for the implants and other disposables, such as the dilators and releasable shim." (Link Decl. if 44.) This is not unique to NuVasive. In my experience, this is how all of the major companies operate, and for its available retractors, also how Alphatec operates.

Moreover, in my experience, companies also control the use of their loaned or consigned apparatuses. If a hospital or surgeon is not using a company's revenue-generating products-e.g., implants and other disposables-the company can retrieve its loaned or consigned products. In such situations, surgeons can still use hospital-owned, in-house, or third-party devices and neuromonitoring systems. When surgeons use Alphatec's lateral products, they may use the hospital's in-house neuromonitoring or even NuVasive's neuromonitoring (if it is available), if a surgeon, in his or her discretion, chooses to use neuromonitoring.<sup>174</sup>

**Testimony of Pat Miles (Alphatec’s Executive Chairman & CEO; Former NuVasive COO)**

Q. Why is it that NuVasive charges for disposables and doesn't charge for things that are not disposables?

A. It's -- it's as much of an industry standard, you know, leaving -- leaving implants behind and leaving -- they're single use items. And so they requires a charge for most single use items.

Q. Does the fact that NuVasive charges for single use items suggest anything about their relative value to items that are not single use?

...A. No. It's -- it's -- I would -- I would suggest that **the currency of our industry has been defined by the implant. But it has -- it's inconsistent with regard to the value that each element plays in the role of surgery.**

Q. Based on your experience, what would the value of the CoRoent XL implant be if it could not be delivered safely and reproducibly through a lateral transposas approach to the spine by surgeons of all skill levels?

...A. It would be worth nothing. The inability to safely and reproducibly deliver an implant -- if you can't do it safely and reproducibly, there's no business there and so it would be worth nothing.<sup>175</sup>

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<sup>173</sup> 5/16/18 Declaration of Kelli Howell, para. 2-3.

<sup>174</sup> 5/16/18 Declaration of Kelli Howell, para. 19-20.

<sup>175</sup> 9/4/14 Deposition Transcript of Pat Miles, pp. 203-204 [emphasis added].

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**Declaration of Matt Link (NuVasive’s former President)**<sup>176</sup>

NuVasive knew that hospitals and surgeons were far more likely to buy XLIF offerings if they had easy access to the retractor access systems and the neuromonitoring control unit. Although the retractor and neuromonitoring systems were developed at significant cost to NuVasive, are critical components of the XLIF procedure, and are expensive to make, NuVasive makes the significant investment up front to loan or provide the hospitals and surgeons with the necessary equipment to perform the XLIF procedure. NuVasive then makes up the difference in its initial investment with its specialized pricing for the implants and other disposables, such as the dilators and releasable shim.<sup>177</sup>

**Trial Testimony from Dr. Kevin Neels (Warsaw/Medtronic’s Damages Expert; Alphatec’s Previous Damages Expert in This Matter)**

[R]etractors are being lent out at no charge. They’re being lent out at no charge because profits are being earned on the other products that are used with them. So it’s appropriate to include the items that are actually generating compensation for use of the retractors.<sup>178</sup>

**Trial Testimony from Keith Valentine**

Capital equipment sales...is not typical because it’s a big cash outlay for the hospital...So typically what we do is we try to create an environment where we can ship it in, or park it, no different than the model that was talked about earlier. It is a model used in orthopedics for over 20 years. Provide the case there and then use disposables that are in this billing event for us. We do make money. For lack of a better term, it can be compared to a razor of razor blades. You sometimes aren’t trying to...sell the razor itself, you are trying to sell the razor blade that’s disposable.<sup>179</sup>

**NuVasive 2018 Form 10-K**<sup>180</sup>

For many of our customers, we provide surgical instrumentation sets, including both implants and instruments, as well as our neuromonitoring systems in a manner tailored to fulfill our customer’s obligations to meet surgery schedules. We do not generally receive separate economic value specific to the surgical instrument sets from the surgeons or hospitals that utilize them. In many cases,

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<sup>176</sup> 3/30/18 Declaration of Matthew Link in Support of Motion for Preliminary Injunction.

<sup>177</sup> 3/30/18 Declaration of Matthew Link in Support of Motion for Preliminary Injunction, para. 44.

<sup>178</sup> Trial Testimony of Dr. Kevin Neels, September 6, 2011 (Day 5, 1057:14-18).

<sup>179</sup> Trial Testimony of Keith Valentine, September 6, 2011 (Day 5, 1183:7-19).

<sup>180</sup> NuVasive, Inc. Form 10-K for the fiscal year ended December 31, 2018, pp. 6-7.

([https://www.sec.gov/Archives/edgar/data/1142596/000156459019003470/nuva-10k\\_20181231.htm](https://www.sec.gov/Archives/edgar/data/1142596/000156459019003470/nuva-10k_20181231.htm))

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once the surgery is finished, the surgical instrument sets are returned to us, and we prepare them for shipment to meet future surgeries.

...

In certain cases we will sell either surgical instruments, implant sets or both to our customers. While this does not constitute a material component of our business, as customer penetration and volume increases, these sales of sets allows our customers to increase the amount of surgical volume performed locally.

#### **NuVasive 2005 Form 10-K**

The majority of our revenues are derived from the sale of disposables and implants and we expect this trend to continue in the near term. To date, we have derived less than 5% of our total revenues from the sale of MAS instrument sets, MaXcess devices, and NeuroVision systems. We do not expect these sales to contribute significantly to our revenues in the future because we intend to continue to (i) loan NeuroVision, MaXcess and surgical instrument sets to hospitals and surgeons who purchase our disposables and implants for use in individual procedures or (ii) place NeuroVision, MaXcess and surgical instrument sets with hospitals for an extended period at no up-front cost to them provided they commit to minimum monthly purchases of our disposables and implants. In the event a hospital or surgeon does not meet its minimum monthly purchase commitments, our sole remedy is to remove our products.

Our implants and disposables are sold and shipped from our facility or from limited disposable inventories stored at our distributors’ sites. We invoice hospitals a fee for using certain instruments and for any disposables or implants upon receiving notice of product use or implantation. For NeuroVision, we generally place the system in hospitals free of charge and allow it to remain on-site provided the hospital orders a minimum monthly quantity of our nerve avoidance disposable products. In addition, we have a program pursuant to which we loan, from a pool of fixed assets, NeuroVision, MaXcess and surgical instrument sets to hospitals without charge to support individual surgical procedures.<sup>181</sup>

#### **Excerpts from a June 22, 2004 Analyst Report**

[NuVasive’s] business model typically entails the placement of NuVasive's NeuroVision system with an interested surgeon free of charge. In exchange, the hospital agrees to make minimum monthly purchases of the company's various spinal fusion implants.<sup>182</sup>

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<sup>181</sup> NuVasive, Inc. Form 10-K for the fiscal year ended December 31, 2005, p.32 (<http://ir.nuvasive.com/static-files/b6213d94-620e-4dab-a610-c41f2a0fad72>), p. 32

<sup>182</sup>NUVA\_ATEC0243731.

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The company monetizes these two capital systems through the sale of its line of spinal implants and disposables and has experienced strong demand for its products by surgeons.<sup>183</sup>

**Deposition Testimony of Mike Aleali (Alphatec’s Senior Product Manager over Lateral and ALIF)**

Q. Now, Alphatec does not charge surgeons or hospitals for use of its lateral retractor, right?

...A. That is correct.

Q. But Alphatec does charge for the use of the Alphatec lateral implants Battalion and Transcend, right?

A. That's correct.

Q. Does Alphatec -- in a lateral surgery involving the full suite of Alphatec's equipment, does Alphatec charge for the Alphatec neuromonitoring equipment?

...A. We don't charge for the capital equipment, but we do charge for disposables.<sup>184</sup>

**III.D.2 Drivers of Demand**

54. In addition to my discussions with Dr. Youssef, Matt Link, and other current/former NuVasive personnel, as well as other information in my report, the following documents and testimony have contributed to my understanding that safety and reproducibility, minimal invasiveness, and clinical success represent the primary drivers of demand in the lateral interbody fusion market segment:<sup>185</sup>

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<sup>183</sup>NUVA\_ATEC0243731.

<sup>184</sup> 10/30/20 Deposition Transcript of Mike Aleali, pp. 168-169.

<sup>185</sup> Bold emphasis added in testimony excerpts and documents.

See also, for example, NR0106641 (“XLIF was created to be a **safer and more reproducible, minimally disruptive** procedure that utilizes conventional surgical techniques and a seamlessly integrated Maximum Access Surgery (MAS) platform...The XLIF solution is the first **clinically validated** lateral approach to the spine, allowing surgeons to accomplish fundamental surgical goals – anterior column connection and fusion.”), NuVasive, Inc. Amendment No. 3 to Form S-1, May 4, 2004 (“[NuVasive’s] MAS platform provides a unique and comprehensive solution for safe and reproducible minimally disruptive surgical treatment of spine disorders. The key components of [its] MAS platform, NeuroVision, MaXcess and specialized implants, provide a surgeon with enhanced visibility and access to the spine for fusion.”); “NuVasive Reports Fourth Quarter and Full Year 2005 Financial Results,” February 16, 2006, <http://ir.nuvasive.com/news-releases/news-release-details/nuvasive-reports-fourth-quarter-and-full-year-2005-financial> (“The MAS platform offers advantages for both patients and surgeons such as reduced surgery and hospitalization time and faster recovery. MAS combines three categories of current product offerings –

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**Expert Report of Dr. Jim Youssef<sup>186</sup>**

Each of the patents-in-suit individually, and collectively, provide significant contributions towards making a spinal fusion procedure more: (1) safe and reproducible, (2) minimally invasive, and (3) clinically successful, which, in my opinion, are the primary criteria surgeons consider when using / adopting a lateral platform, such as Alphatec’s Battalion platform and NuVasive’s MAS platform. Furthermore, I understand that they represent the three primary drivers of demand for Alphatec’s accused products.

**Supplemental Expert Report of Dr. Jim Youssef<sup>187</sup>**

Each of the asserted implant patents individually, and collectively, provides significant contributions towards making a spinal fusion procedure more: (1) safe and reproducible, (2) minimally invasive, and (3) clinically successful, which, in my opinion, are the primary criteria surgeons consider when using / adopting a lateral platform, such as Alphatec’s LIF Platform and NuVasive’s MAS platform. Furthermore, I understand that they represent the three primary drivers of demand for Alphatec’s accused products.

**iData Research Report “U.S. Market Report Suite for Minimally Invasive Spinal Implants”(June 2019)**

The major driving forces behind growth in MIS interbody procedures are the perceived physiological benefits to the patient, including reduced trauma, shorter hospital stays, lower post-operative medication use and an earlier return to motion.<sup>188</sup>

**Article “How companies are actively driving growth in the minimally invasive spinal surgery market” (3/28/18)<sup>189</sup>**

**The major procedural drivers for MIS technology are its widely-known clinical benefits. Rather than using a large opening, MIS approaches create small ports of entry for the procedure. This method reduces muscle and tissue damage, decreases complications and extends the intraoperative time limit.** As a result, recovery times can be lessened for patients while simultaneously increasing the

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NeuroVision, a proprietary software-driven nerve avoidance system; MaXcess, a unique split-blade design retraction system; and specialized implants, like SpheRx and CoRoent – that collectively minimize soft tissue disruption during spine surgery while allowing maximum visualization and surgical reproducibility.”), NUVA\_ATEC0243637, NUVA\_ATEC0243811, NUVA\_ATEC0243580, NUVA\_ATEC0243740, NUVA\_ATEC0114689, NUVA\_ATEC0244455, NUVA\_ATEC0040574.

<sup>186</sup> Expert Report of Jim Youssef Re Damages, dated 11/8/19, para. 16. Based on discussions with Dr. Youssef.

<sup>187</sup> Opening Expert Report of Jim Youssef, dated 11/20/20, para. 439. Based on discussions with Dr. Youssef.

<sup>188</sup> “U.S. Market Report Suite for Minimally Invasive Spinal Implants”, iData Research, June 2019, p. 167.

<sup>189</sup> <https://www.beckersspine.com/mis/item/40494-how-companies-are-actively-driving-growth-in-the-minimally-invasive-spinal-surgery-mark>.

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number of procedures a physician could perform within a given amount of time, compared to the open approach.

...

Physician education is one of the most important drivers for increased adoption, and it’s self-reinforcing. As physicians begin to use MIS devices, they will, in turn, make other patients and physicians aware of what is available. In addition to promotional work at physician and research conferences, companies will integrate MIS devices into their broader surgeon education programs. Some of the major limiters to MIS technology in its early stages were the unfamiliarity of physicians and the complexity of the procedure. This has been particularly true for retractor-based techniques, which can be harder to master than traditional open surgical approaches.

...

*Where is the MIS Spine Market Heading?*

The result of these various drivers is that strong growth within the MIS markets is expected to continue. In the United States, MIS spine technologies are expected to expand from an estimated \$1.7 billion in 2017 to over \$2 billion by 2024. MIS interbody devices and MIS pedicle screws will account for the largest segments in this market. Strong growth is also expected in markets outside of the United States. In many geographies, a demographic trend towards growing elderly populations will mean increasing demand for spinal surgical technologies. With many of these patients seeking more personalized solutions, companies have strong incentive to make sure that both institutions and patients are educated about MIS solutions.

**Article “Lateral Lumbar Interbody Fusion—Outcomes and Complications”<sup>190</sup>**

Lateral lumbar interbody fusion (LLIF) is a relatively new, minimally invasive technique for interbody fusion. This technique is also referred to as eXtreme Lateral Interbody Fusion (XLIF, NuVasive, Inc.) or Direct Lateral Interbody Fusion (DLIF, Medtronic Sofamor Danek). Since the first description of the technique, the indications for LLIF have expanded and the rate of LLIF procedures performed in the USA has increased. LLIF offers structurally sound support through a large footprint interbody cage spanning the dense apophyseal ring and indirectly decompresses neural elements. Using a retroperitoneal approach to the anterior spinal column, LLIF circumvents some of the challenges and morbidity risk of anterior or posterior lumbar interbody fusion techniques.

...

Besides the reported advantages of **minimally invasive** surgery, including minimal tissue trauma during the approach, less blood loss, decreased postoperative pain, and shorter hospital stays, there are several theoretical advantages specific to LLIF.

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<sup>190</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5685966/>.



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...

In a recent systematic review, Lehmen et al. reported on LLIF **outcome** profiles. Multiple studies showed favorable radiographic and clinical outcomes after LLIF, with some that had a minimum of 2-year follow-up. When reviewing outcomes, it is important to distinguish studies by indication such as degenerative versus deformity. Generally, there is good consistency of the reported data by clinical indication. Some of the variability of the reported outcomes can be explained by the heterogeneity in the treatment such as different types of fixation or cages sizes. Several high quality publications showed the efficacy of LLIF utilizing patient-reported outcome measures.

...

In summary, LLIF can be a **safe** and versatile procedure in patients indicated for anterior fusion with the use of a proper surgical technique.

**Article “Clinical Perspective – The Case for Adoption of LLIF”<sup>191</sup>**

Lateral lumbar interbody fusion (LLIF) has been used to treat shorter segments in thoracolumbar deformity **safely** and with excellent **results**. **Outcomes** include trans-lateral cage placement, non-disrupted posterior muscular tension bands, lower transfusion rates, shortened hospital stay with percutaneous screws, preserved posterior musculature, and reduced use of narcotics.

...

LLIF offers a **safe, reproducible, and durable** method of attaining spinal fusion.

**Trial Testimony from Dr. William Douglas Smith**

For routine open lumbar fusion surgery, it was standard for patients to donate their own blood a month or two before their surgery was scheduled because we were expecting to lose a lot of blood. One of the amazing things I found is that all of a sudden these patients were losing a teaspoon full of blood at most. That opened my eyes up more than just about anything else at that time.<sup>192</sup>

Q. What is it about XLIF that allows you to do spine surgery in an outpatient surgical suite?

A. I think when we talk about minimally invasive surgery, what we’re really talking about is **minimally disruptive** surgery. So by now, having the tools, the retractor, the neuromonitoring, our knowledge of the anatomy, I can go in, take care of a patient’s problem and leave a very minimal surgical footprint. I don’t have to disrupt the patient’s normal anatomy. What does that do? Makes them have an awful lot less post-operative pain. They can go home and take care of

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<sup>191</sup> ATEC\_LLIF000671339.

<sup>192</sup> Trial Testimony of Dr. William Douglas Smith, September 7, 2011 (Day 6, 1402:5-12).



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themselves, a lot fewer complications. They can get back to work or [their] recreational activities much, much faster.<sup>193</sup>

In my own practice, I try to follow my patients for at least two years after the surgery. And one of the questions we always ask our patients at the end of that two years is, ‘Knowing everything you went through, the good, the bad, the complications you may have had, the pain you went through surgery, what you felt like before surgery and to now, would you go through everything you went through?’

...[H]istorically in the literature, the answer to that question, indeed my practice 20 years ago, about 55, 58 percent patients say, Yeah, I’d go back to surgery again.

Last time I looked at my data, it’s about a year and a half ago, the answer to that question was 94 percent. So a huge difference, and not because I’m a great surgeon, but because these techniques allow me to be a much, much better surgeon.<sup>194</sup>

Well, one of the concerns, you know, society has is all these new techniques and bells and whistles can be so much more expensive. But what we’ve found, and I’ve looked at this compared to open surgeries to minimally invasive XLIF, in particular, surgeries in my hospital, we found that if we look at everything – that would be the cost of the implants, the length of the, the hospital costs, how long the patient was in the hospital, the food, the medications, the narcotics, pain pills after surgery – we found across the board there’s about a 15 percent cost savings doing these minimally invasive techniques.<sup>195</sup>

When I look at my own data and look at the data in the literature that I read, there’s a **logarithmically lower risk of complications** with an XLIF.<sup>196</sup>

Q. Are there features of the MaXcess retractor that, in your view, give you improved XLIF outcomes?

A. Absolutely.

Q. What are they?

A. Well, we already mentioned briefly about the neuromonitoring that’s built into the retractor itself, and it’s in that posterior blade, this middle blade; that’s where typically the nerve, where I want the nerve to be, and I want to know where the nerve is with this blade back here. It’s very, very important. The other thing that’s important about this is — again, **minimally invasive** surgery — I want to be able to get deep to the spine to take care of the patient’s problem, not disrupt the normal tissue. So I can open this retractor in a very independent

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<sup>193</sup> Trial Testimony of Dr. William Douglas Smith, September 7, 2011 (Day 6, 1405:2-14)

<sup>194</sup> Trial Testimony of Dr. William Douglas Smith, September 7, 2011 (Day 6, 1406:19-1407:9).

<sup>195</sup> Trial Testimony of Dr. William Douglas Smith, September 7, 2011 (Day 6, 1407:12-22).

<sup>196</sup> Trial Testimony of Dr. William Douglas Smith, September 7, 2011 (Day 6, 1428:11-14).

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way to make it so it’s different for every patient to dock it so I can just expose the exact anatomy of just the disc space at all; so I have to move any other tissue, psoas muscle, the nerves, blood vessels, away from the normal pathway. That’s very, very important; less pain for the patient, but it also prevents many, many complications.<sup>197</sup>

**Trial Testimony from Dr. Kevin Neels (Warsaw/Medtronic’s Damages Expert; Alphatec’s Previous Damages Expert in This Matter)**

It [PX1732 – NuVasive XLIF Approach: MVP Surgical Presentation] talks about the neuro monitoring, it talks about the retractor, and it talks about the implant, as all being tools for **safety and responsibility**.<sup>198</sup>

I think the way to think about this, is I showed a brochure before that talked about the contribution of the CoRoent to **safety and reproducibility**. It also talks about the contribution of the retractor. It also talks about the contribution of neuro monitoring. I think about this as like a three legged stool. It’s stable, but if you saw one leg off, it doesn’t matter which one it is, it’s going to fall over, you need all three to carry it out successfully.<sup>199</sup>

**Declaration of Kelli Howell (Alphatec Executive VP of Clinical Strategies; Former NuVasive VP)**<sup>200</sup>

The major players in the lateral, transpsoas interbody fusion market, generally in order of presence in the market (after NuVasive), are as follows: Globus, Medtronic, DePuy Synthes, K2M, Stryker, and Zimmer Biomet. Together with NuVasive, these companies control the vast majority of the lateral, transpsoas market and their products are used by surgeons to facilitate **safe and reproducible surgeries**. There are several other lateral offerings available from other companies that constitute smaller market participants.<sup>201</sup>

**Alphatec’s Earnings Call Transcripts**

The overarching intention behind Alphatec's renewed development program is to create value and **deliver better outcomes** by advancing this company from a simple implant manufacturer into a spine solutions architect.<sup>202</sup>

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<sup>197</sup> Trial Testimony of Dr. William Douglas Smith, September 7, 2011 (Day 6, 1416:13-28).

<sup>198</sup> Trial Testimony of Dr. Kevin Neels, September 6, 2011 (Day 5, 1128:8-11).

<sup>199</sup> Trial Testimony of Dr. Kevin Neels, September 6, 2011 (Day 5, 1033:23-1034:5).

<sup>200</sup> 5/16/18 Declaration of Kelli Howell, para. 2-3.

<sup>201</sup> 5/16/18 Declaration of Kelli Howell, para. 13.

<sup>202</sup> Alphatec Holdings, Inc. FQ4 2017 Earnings Call Transcript (<https://seekingalpha.com/article/4154927-alphatec-holdings-atec-ceo-terry-rich-q4-2017-results-earnings-call-transcript?part=single>).

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And so if you go to the next slide and you say, "gosh, what is our responsibility as a company?" And I would tell you that we're stewards to the surgeons' goals. And not to give you an overt spine lesson, but spine surgery is fundamentally decompression, stabilization and alignment. That's what spine surgeons are trying to accomplish. And there becomes a myriad of different pathologies and then to say, what approach do I take to address this pathology to fulfill these goals? Our job as stewards becomes, what's the technology that we could provide the surgeon and create **predictability** associated with creating **great outcome**? So what we do is we look within the approach itself and say, how can we be effectual with regard to the approach?<sup>203</sup>

**Alphatec Press Release “Alphatec Announces FDA Clearance of its Automated SafeOp Neuromonitoring System to Address Significant Unmet Needs in Spine Surgery” (2/25/19)**<sup>204</sup>

I could not be more excited to integrate this revolutionary technology into our growing number of spine approaches,” said Pat Miles, Chairman and Chief Executive Officer. “Many of us at ATEC were previously instrumental in developing, validating, and marketing a neuromonitoring platform that became foundational to a billion-dollar spine company. The SafeOp solution is better. It has no peer and it elevates the requirements for others to participate. Today, we have raised the bar in delivering objective actionable information that drives **safer and more reproducible** spine surgery.

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<sup>203</sup> <https://finance.yahoo.com/news/edited-transcript-atec-earnings-conference-014048724.html>.

<sup>204</sup> <http://investors.alphatecspine.com/news-releases/news-release-details/alphatec-announces-fda-clearance-its-automated-safeop>.

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**Alphatec Spine Management Presentation<sup>205</sup>**


### Battalion Platform Overview

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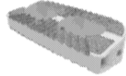
**Battalion: Interbody platform with full suite of Ti-coated products for the 2<sup>nd</sup> largest spine segment**

Market Need	Key Platform Features	Designed for Clinical & Economic Advantages
Interbody system promoting higher fusion rates and with broad range of sizes to address various procedures and pathologies	<ul style="list-style-type: none"> <li>✓ Titanium-coated PEEK for enhanced endplate contact and bone ingrowth</li> <li>✓ Chevron tooth patterns for back-out reduction</li> <li>✓ Wide range of sizes and shapes for optimal sizing</li> <li>✓ Innovative implant insertion instrument</li> <li>✓ High-quality, user-friendly disc prep instrumentation set</li> </ul>	<ul style="list-style-type: none"> <li>✓ Combines product advantages of both PEEK and titanium interbody devices</li> <li>✓ Reduced risk of infection</li> <li>✓ Enhanced bone incorporation and improved fusion rates</li> <li>✓ Improved MRI / imaging</li> <li>✓ Reduced time for disc space prep</li> </ul>

Universal IB Battalion



Battalion Lateral



\$1.5B

2015

2016

Market Opportunity

Market Release

Source: Market size per management estimates

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### Lateral Platform Overview


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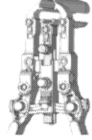
**Lateral: Highly differentiated and unique system**

Market Need	Key Platform Features	Designed for Clinical & Economic Advantages
Next-generation lateral lumbar retractor system with improved functionality and increased patient safety	<ul style="list-style-type: none"> <li>✓ Lateral retractor with unrivaled, unique design characteristics</li> <li>✓ 3-blade system with 4<sup>th</sup> blade option</li> <li>✓ Auto compensates to prevent blades from lifting when toed</li> <li>✓ Easy, in-situ blade height adjustment and blade replacement</li> <li>✓ DLC anti-glare and anti-scratch coating</li> </ul>	<ul style="list-style-type: none"> <li>✓ Reduced chance of tissue or muscle creep, enabling more clear view of the spine</li> <li>✓ Stable, reproducible surgical pathway</li> <li>✓ Increased ability to access the spine in more lateral difficult cases</li> <li>✓ Improved patient outcomes</li> <li>✓ Less operative time per surgical case</li> <li>✓ Increased safety</li> </ul>

Lateral Lumbar (LLIF) System







\$600M

2016

Market Opportunity

Market Release

Source: Market size per management estimates

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<sup>205</sup> ATEC\_LLIF000854436 at -457, -458.

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**Alphatec Presentation “Lateral Lumbar Interbody Fusion System – Market Need / Business Case PH: 1” (6/16/14)<sup>206</sup>**


The goal of LLIF surgery is create **safe and reproducible** access to the spine...while remaining **less disruptive** to the surrounding anatomy than traditional Lumbar Interbody Fusion (LIF) procedures, e.g. Anterior, Posterior and Trans-Foraminal.

**Alphatec Spine**

### What is Lateral Lumbar Interbody Fusion (LLIF)


#### The Surgical Approach

This is a spinal fusion procedure that accesses the anterior lumbar spine by securing the patient on their side (lateral decubitus) to create a safe, retroperitoneal, transpsoas surgical pathway to the disc segment



#### Goal of the Procedure

The goal of LLIF surgery is create safe and reproducible access to the spine to indirectly decompress the neural elements, restore proper alignment and create an anterior fusion bed while remaining less disruptive to the surrounding anatomy than traditional Lumbar Interbody Fusion (LIF) procedures, e.g. Anterior, Posterior and Trans-Foraminal



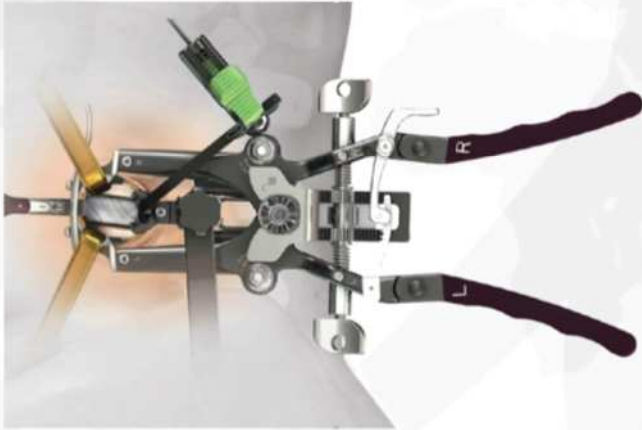
<sup>206</sup> ATEC\_LLIF000137018.

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**Alphatec Spine**

### Lateral Lumbar Interbody Fusion


- What is the project scope?
  - **Retractor System**
    - Access System specifically designed to create a safe, reproducible surgical pathway.



**Alphatec Spine**

### Lateral Lumbar Interbody Fusion


- What is the project scope?
  - **Implant System**
    - Implants specifically designed for lateral placement with the anterior thoraco-lumbar spine
    - Implants specifically designed to address the following indications: Degenerative Disc Disease, Low Grade Spondylolisthesis and Mild Deformities





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**Alphatec “Integrated Project Charter – Project: Lateral Lumbar Interbody Fusion (LLIF) System” (7/14/14)<sup>207</sup>**

		<b>Integrated Project Charter</b>	
Project No: 13-002			
Project: Lateral Lumbar Interbody Fusion (LLIF) System			Rev: A
Prepared By: David Blagborne			Date: 7/14/2014
<b>Business Context</b>			
Element	Definition	Element Description	
<b>Business Need</b>	Describe the business problem or need that this project is intended to address.	* Lateral Lumbar Interbody Fusion (LLIF) has proven to be an effective and reproducible surgery for thoraco-lumbar spine fusion. It currently holds 6% of the total spinal fusion market, with growth projections as high as 16% by 2019. This is the fastest growing segment of the spine market that Alphatec does not have a product offering within. The intent of this project is to create a product that will allow Alphatec to initially capture and then grow market share within the LLIF segment of the spinal fusion market. This system will do this by addressing the following pathological indications that encompass the majority of the LLIF market segment: degenerative disc disease (DDD), low grade spondylolisthesis and mild deformities. Advanced deformities, tumor and trauma indications represent very small portions of the market segment and will be addressed after the initial system has been created.	


**Describe critical technology required or anticipated and its availability.**

- Retractor performance will be critical to the acceptance of the product by the market. The largest two factors that will affect this are the retractor adjustment mechanisms and the retractor assembly materials.
- Implant performance has one critical area, the implant to instrument interface.
- Instrument performance has two critical areas: one area is the profile of the instruments with respect to the possibility that it can get stuck or hung up on the anatomy or other instrumentation, the second area is the ability of the instrumentation to provide anatomical measurement feedback intra-operatively.

<sup>207</sup> ATEC\_LLIF000004800.




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 <b>Integrated Project Charter</b>		
Project No: 13-002		
Project: Lateral Lumbar Interbody Fusion (LLIF) System		Rev: A
Prepared By: David Blagborne		Date: 7/14/2014
Other Product Information		
Element	Definition	Element Description
Preliminary Technology Assessment	Describe critical technology required or anticipated and its availability.	<ul style="list-style-type: none"> <li>Retractor performance will be critical to the acceptance of the product by the market. The largest two factors that will affect this are the retractor adjustment mechanisms and the retractor assembly materials. Manufacturing processes and coatings, new to Alphatec, may be explored as a mean to achieve performance. Materials new to Alphatec, such as fiber reinforced composites, may also be explored as options to achieve high performance. These will involve identification of key suppliers who currently posses these skills and knowledge so that the internal knowledoe can be built</li> <li>Implant performance has one critical area, the implant to instrument interface. Loads during insertion are typically high and failures of implant or instrument are not uncommon. This will require the use of nonstandard test methods to characterize component performance.</li> <li>Instrument performance has two critical areas: one area is the profile of the instruments with respect to the possibility that it can get stuck or hung up on the anatomy or other instrumentation, the second area is the ability of the instrumentation to provide anatomical measurement feedback intra-operatively. This will required the collection of user feedback to proper determine the effectiveness of proposed solutions.</li> </ul>

The purpose of the project is to develop a LLIF system that will directly challenge the top competitors for their market share. The means for accomplishing this will be to develop technologies and products that clinically outperform the current offerings of the top competitors. The high level project objective is to develop a comprehensive system that addresses the majority of the market’s LLIF needs.

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		<b>Integrated Project Charter</b>	
<b>Project No:</b> 13-002			
<b>Project:</b> Lateral Lumbar Interbody Fusion (LLIF) System		<b>Rev:</b> A	
<b>Prepared By:</b> David Blagborne		<b>Date:</b> 7/14/2014	
Other Product Information			
Element	Definition	Element Description	
Redacted			
<b>Product Interactions</b>	Describe the relationship of this product to other products and services.	<ul style="list-style-type: none"> <li>The LLIF system will receive indications that require supplemental posterior fixation. Alphatec products that can be used to satisfy supplemental fixation need are: Illico MIS, Illico FS, Arsenal, Arsenal CBX and Bridgepoint. Alternative Alphatec products that may be used when the LLIF system is contra-indicated for use are: Battalion P, Novel SD, Novel Tapered TL, Novel ALS, Epicage &amp; Alphatec Solus.</li> </ul>	
Project Context			
Element	Definition	Element Description	
<b>Project Purpose</b>	A concise description of the project objective, timeframe, and cost.	The purpose of the project is to develop a LLIF system that will directly challenge the top competitors for their market share. The means for accomplishing this will be to develop technologies and products that clinically outperform the current offerings of the top competitors. The high level project objective is to develop a comprehensive system that addresses the majority of the market's LLIF needs. This project is NOT intended to enter or create 'niche' LLIF markets. The timeframe for obtaining this objective will begin in Q3 2014 with an initial launch in Q3 2015 and will cost \$1.6M (R&D portion of the budget) to develop.	

NuVasive has set the current standard for LLIF systems with their MaXcess & CoRoent products. Their product offering is superior, comprehensive and experienced LLIF surgeons value this. When considering flexibility of scope, the options are limited because they pose large risks to the products['] competitiveness within the LLIF market. The only options that exist regarding scope pertain to the low volume or 'niche' LLIF products that represent small segments within the LLIF market.

Trade-Off Matrix			
Indicate where there is flexibility in the project if there is an adverse event that affects the critical path. Move the "X" to the appropriate square (only one "X" per column.) List the options available for each parameter.			
Parameter	Few Options	Some Options	Most Options
<b>Scope</b>	X		
<b>Options:</b>	NuVasive has set the current standard for LLIF systems with their MaXcess & CoRoent products. Their product offering is superior, comprehensive and experienced LLIF surgeons value this. When considering flexibility of scope, the options are limited because they pose large risks to the products competitiveness within the LLIF market. The only options that exist regarding scope pertain to the low volume or "niche" LLIF products that represent small segments within the LLIF market.		

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**Alphatec Document “Market Need / Assessment Request, Concept: Direct Lateral” (4/17/13)<sup>208</sup>**

...[W]hat are the key success factors?

Recent literature suggests that limiting the retraction window in the Psoas and limiting retraction time has greatly beneficial effects on the adverse events limited to the approach. We should focus efforts on a intuitive speedy system that requires as little retraction as possible for achieving desired exposure.

If so, what are the key success factors (?):

Recent literature suggests that limiting the retraction window in the Psoas and limiting retraction time has greatly beneficial effects on the adverse events limited to the approach. We should focus efforts on a intuitive speedy system that requires as little retraction as possible for achieving desired exposure.

Having a robust training program with reps trained on patient positioning prior to surgery, specific to unique anatomy's and competent in working with the fluoro tech help expedite surgery and encourage adoption.

Direct Lateral - Market Need

**Key System Features and benefits**

•Complications of approach:

- Exposure and length of retraction during the trans-psoas aspect of the procedure are linked to the most common complications of the approach. **System should be focused on minimal retraction, ease of use and speed.**

•Best Features of Current Systems

- 4 blade retractors are conceptually satisfying as they are naturally more anatomic to the working area needed (just the disc space).
- In-Situ expansion of retraction blades and a more rigid construct between patient-retractor-table arm will minimize fiddling with the retractor after targeting and docking.
- De-coupled blades can ease access to 4-5, and through ease and speed may lead to less damage of the Lumbar Plexus.
- Neuromonitoring is essential, companies seem to be doing well using the Cadwell set-up, only disposable probes are needed.

**Leapfrog strategy during design process utilizing broad based design team and BETA.**


*Alphatec Spine*

<sup>208</sup> ATEC\_LLIF000003809.

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**Alphatec Market Need Assessment Request, Concept: Lateral Lumbar Interbody Fusion System (12/17/12)<sup>209</sup>**

**Explain at what rate [market is growing] and what is this attributed to(?):**  
 Growth in MIS procedure knowledge, **promising clinical results of LLIF’s** particularly for Scoliosis, surgeon reimbursement cuts for TLIF/PLIF, reimbursement cuts to ALIF’s.

 <b>Market Need Assessment Request</b>	
Concept: Lateral Lumbar Interbody Fusion System	
Prepared By: Derek Kuyper	
Signature:	Date: 12/17/12
<b>Market Landscape (Summary of Top 3 Competitive Devices):</b> <ul style="list-style-type: none"> <li>• Nuvasive XLIF</li> <li>• Medtronic DLIF</li> <li>• Globus Mars 3V</li> </ul>	
<b>Market Assessment:</b> New Market?: <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES – Estimated Size: Established Market?: <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES – Size: Rationale for Estimated Size:  <div style="background-color: yellow; padding: 5px;">                     Is the Market Growing (?): <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO                      Explain, at what rate and what is this attributed to (?): Growth in MIS procedure knowledge, promising clinical results of LLIF’s particularly for Scoliosis, surgeon reimbursement cuts for TLIF/PLIF, reimbursement cuts to ALIF’s.                       20%                 </div>	
Does Alphatec currently Compete (?): <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	
Current Size of Alphatec Market & Marketshare?: \$GLIF is not a realistic player in the market.	
Estimate Entry for completion of Project and entry in Market?: Phase 1 by Q4 2013	
Declining Sales?: <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	

**Alphatec Website<sup>210</sup>**

**BATTALION® LATERAL LUMBAR SPACER SYSTEM**

The Battalion Lateral System with the Squadron Lateral Retractor provides surgeons with a next-generation lateral system with unrivaled, unique functionality designed to **improve clinical outcomes by reducing tissue creep, minimizing psoas retraction time, and achieving alignment and fusion objectives.** Battalion Lateral Spacer is available in Parallel and Lordotic with a variety of width and height options for the lumbar and thoracic spine.

The Squadron Lateral Retractor is compatible with most neuromonitoring platforms enabling access safely through the psoas. The system is recommended for use with the Arsenal Spinal Fixation System or the Illico® MIS Posterior

<sup>209</sup> ATEC\_LLIF000003825.

<sup>210</sup> <https://atecspine.com/product-portfolio/llif/battalion-lateral-spacer-system/>.

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Fixation System. The Battalion Lateral implant is also cleared for use with both autograft and allograft biologic materials.

### **SQUADRON® LATERAL RETRACTOR ACCESS SYSTEM**

The Battalion Lateral System with the Squadron Lateral Retractor provides surgeons with a next-generation lateral system with unrivaled, unique functionality **designed to improve clinical outcomes by reducing tissue creep, minimizing psoas retraction time, and achieving alignment and fusion objectives.**

The system is designed to allow surgeons to customize the access to match the patient’s unique anatomy including:

- Independent retraction of the cranial/caudal blades
- DepthControl™ technology that provides in-situ, low profile, blade height adjustment
- LevelToe™ mechanics ensure that the blades maintain a parallel plane when toed
- Straight, angled, and offset instrumentation to provide access to the L4/L5 segment
- Robust implant/insert interface with one step ETA (engage, twist, attach) loading
- Intelligent instrumentation featuring Stealth Coating™ to minimize glare, AlphaTexture™ handles, and modular instruments with depth and orientation markings

The Squadron Lateral Retractor is compatible with most neuromonitoring platforms enabling access safely through the psoas. The system is recommended for use with the Arsenal Spinal Fixation System or the Illico® MIS Posterior Fixation System. The Battalion Lateral implant is also cleared for use with both autograft and allograft biologic materials.

### **Alphatec Press Release “Alphatec Spine Launches Battalion™ Lateral System With Squadron™ Retractor To Support Minimally Invasive Lateral Access Procedures” (4/7/17)**<sup>211</sup>

- ***Opens up new \$500M market opportunity in one of the fastest growing segments in spine***
- ***Squadron™ Lateral Retractor designed to improve patient outcomes***

Alphatec Spine, Inc., a wholly owned subsidiary of Alphatec Holdings, Inc. (Nasdaq:A TEC) and a provider of spinal fusion technologies, announced today that the Company has launched its new Battalion Lateral System with the

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<sup>211</sup> <http://investors.alphatecspine.com/news-releases/news-release-details/alphatec-spine-launches-battaliontm-lateral-system-squadrontm>.

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Alphatec Squadron Lateral Retractor, and successfully completed initial patient surgeries including degenerative, multilevel and L4/L5 spinal segment cases. With the launch of the Battalion Lateral System, the Company is well positioned to begin to compete in the \$500M U.S. Lateral market.

"The launch of Battalion Lateral represents a significant milestone for Alphatec, opening up new commercial opportunities for us. With this launch, we are now able to compete in the MIS Lateral market—one of the fastest growing markets in spine," said Terry Rich, Alphatec Spine's Chief Executive Officer. "The Battalion Lateral System includes our proprietary Squadron Retractor that is designed to enhance the surgeon's experience and **improve clinical outcomes**. Early feedback from surgeon customers has been very positive regarding the system performance, differentiated feature set and ability to successfully treat even the most complex patient cases with a **minimally invasive approach**. The launch of Battalion Lateral also enables Alphatec to access new distributors with strong surgeon relationships in the Lateral space. We look forward to expanding into this new market and increasing surgeon adoption."

The Battalion Lateral System with the Alphatec Squadron Lateral Retractor provides surgeons with a next-generation Lateral system with innovative, unique functionality designed to **improve clinical outcomes by reducing tissue creep, minimizing psoas retraction time, and achieving alignment and fusion objectives**. The Battalion Lateral System includes numerous proprietary features, including the Squadron Lateral Retractor. The system is designed to allow surgeons to customize the access to match the patient's unique anatomy through independent retraction of the cranial/caudal blades, DepthControl™ technology that provides in-situ height adjustment for the low-profile blades, and LevelToe™ mechanics to ensure that the blades maintain a parallel plane when toed up to 15°. The Squadron Retractor is also fully compatible with most neuromonitoring platforms **enabling access safely** through the psoas. The Battalion Lateral Spacer is available in 0° and 15° lordosis with a variety of width and height options for lumbar and thoracic approaches as well as angled and offset instrumentation to provide access to the L4/L5 segment.

"Alphatec's Battalion Lateral System provides great options for accessing and preparing the space via the retractor, but the retractor itself completes the procedure," said Dr. Frank K. Kuwamura, a board-certified orthopedic spine surgeon, in San Antonio, Texas. "The ability to independently raise and lower blades to accommodate the anatomy really separates this retractor from other retractors available on the market. It saves time in the psoas and that supports better patient outcomes." Dr. Kuwamura was one of the first surgeons to use the system and completed the case with Alphatec's Illico® percutaneous pedicle screws. The patient had a previous fusion and had developed adjacent disc disease.



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Michael E. Russell, II, M.D., a board-certified orthopedic surgeon in Tyler, Texas, was also one of the first surgeons to use the Battalion Lateral System in a clinical setting. He used the system to perform a Lateral procedure at L3/L4 and instrumented posteriorly using Alphatec's Arsenal™ Spinal Fixation System. The Squadron Lateral Retractor allowed Dr. Russell to access the disc space from an offset trajectory.

Dr. Russell commented, "The Squadron Retractor enabled me to attach to multiple attachment points giving me the flexibility to use my preferred Lateral technique. The combination of the level toeing and the ability to lower the low-profile blades individually allowed me to successfully navigate osteophytes without the need for blade extenders."

**Alphatec 2017 Form 10-K**<sup>212</sup>

**Competition**

Although we believe that our current broad product portfolio and development pipeline is differentiated and has numerous competitive advantages, the spinal implant industry is highly competitive, subject to rapid technological change, and significantly affected by new product introductions. We believe that the principal competitive factors in our market include:

- **improved outcomes for spine pathology procedures;**
- ease of use, quality and reliability of product portfolio;
- effective and efficient sales, marketing and distribution;
- quality service and an educated and knowledgeable sales network;
- technical leadership and superiority;
- surgeon services, such as training and education;
- responsiveness to the needs of surgeons;
- acceptance by spine surgeons;
- product price and qualification for reimbursement; and
- speed to market.

Both our currently marketed products and any future products we commercialize are subject to intense competition. We believe that our most significant competitors are Medtronic Sofamor Danek, Johnson & Johnson (DePuy/Synthes), Stryker, NuVasive, Zimmer, Biomet, Globus, K2M Medical, SeaSpine and others, many of which have substantially greater financial resources than we do. In addition, these companies may have more established distribution networks, entrenched relationships with physicians and greater experience in developing, launching, marketing, distributing and selling spinal implant products.<sup>213</sup>

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<sup>212</sup> Alphatec Holdings, Inc., Form 10-K for the fiscal year ended December 31, 2017.

<sup>213</sup> Alphatec Holdings, Inc., Form 10-K for the fiscal year ended December 31, 2017, p. 7.



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### **Strategy**

Our goal is to become the most respected, fastest growing spine player by pioneering meaningful innovation. With our new spine-experienced leadership team, and the high-performance culture we are creating, we intend to advance Alphatec from an implant manufacturer to a spine solutions architect via two key principals:

1. *Proceduralization*. We are determined to design complete surgical solutions that address unmet clinical needs and **improve clinical outcomes** by integrating Alphatec products and technologies to treat specific pathologies.
2. *Speed to Market*. We intend to build on proven team expertise to expedite product development by enhancing Alphatec’s innovative dexterity and unique market strategy and accelerating the commercial launch of our innovative product pipeline.<sup>214</sup>

### **Testimony of Pat Miles (Alphatec’s Executive Chairman & CEO; Former NuVasive COO)**

The success of NuVasive’s XLIF procedure and system is due, in part, to the fact that our XLIF solution provides a **safe and reproducible minimally disruptive** lateral access path through the psoas muscle (i.e., “trans-psoas”) using tools and techniques that minimize tissue trauma, reduce blood loss, and allow direct visualization and customization of the operative corridor during lumbar spinal fusion procedures. XLIF allows a greater number of spine surgeons with varying skills and experience to perform a lateral approach to the lumbar spine through the highly innervated psoas muscle. Prior to XLIF, the lateral approach, which dates back to at least the 1980s, was limited to a handful of highly skilled surgeons performing techniques that were quickly abandoned because they provided mixed **results**. Those prior lateral techniques failed to achieve any level of success in the marketplace.<sup>215</sup>

In little more than a decade, NuVasive has grown from a small medical device startup to the company it is today, helping thousands of patients. At the center of NuVasive’s success has been its XLIF procedure and associated equipment. (‘The majority of NuVasive’s revenue is directly related to XLIF procedures and its related devices. The XLIF procedure is the most rapidly growing MIS interbody fusion procedure, and comprises the vast majority of NuVasive’s market share in the LLIF segment.’) Without the invention of our method to **safely and reproducible** traverse the psoas muscle along the lateral trans-psoas path using nerve monitoring-enabled distraction and retraction assemblies (that are also optionally nerve monitoring enabled) with a nerve monitoring system, none of this would have been possible.<sup>216</sup>

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<sup>214</sup> Alphatec Holdings, Inc., Form 10-K for the fiscal year ended December 31, 2017, p. 1.

<sup>215</sup> Exhibit-1032 - 3/10/14 Declaration of Patrick Miles, p. 4.

<sup>216</sup> Exhibit-1069 – 7/8/14 Declaration of Patrick Miles, p. 20.

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As I have stated repeatedly, XLIF’s success is directly related to the innovative procedure and systems that combine nerve monitoring enabled distraction and retraction (also optionally nerve monitoring enabled) with NuVasive’s nerve monitoring system to **safely and reproducibly** navigate the psoas muscle, avoiding the nerve roots, to reach the target disc space to perform a fusion or other procedure. If the XLIF system and method could not safely traverse the nerve-rich psoas muscle, surgeons would never have adopted XLIF and there would have been no commercial success.

The success of the XLIF procedure is not due to brand name recognition or being a market leader. When the XLIF procedure hit the market, NuVasive was a small start-up company and it had no brand name recognition. Nor was XLIF’s success due to being part of an already growing market. There was no lateral fusion market at the time of the XLIF procedure. It is a testament to the procedure (and the instruments which enabled it, especially nerve monitoring) that NuVasive was able to essentially create a new market. Finally, XLIF’s success was not just a product of great marketing. Although marketing was and is important for XLIF, it did not create the demand for the XLIF procedure. XLIF was and continues to be such a success because of **the efficacy and safety the procedure offers.**<sup>217</sup>

**Declaration of Matt Link (NuVasive’s former President)**<sup>218</sup>

NuVasive’s early business model concentrated on the development of surgical offerings for treating patients with chronic back pain due to degenerative disc disease in the spine. Doc. No. 1-2 (IPR 2014-00075, July 8, 2014 Declaration of Patrick Miles) at 7. At the time, there was an assortment of procedures available for treating these patients. Most involved approaching the lumbar spine either from the back (the posterior approach) or from the abdomen (the anterior approach), removing the diseased or damaged vertebral disc(s), and inserting an implant in the disc space to restore it to its proper height.

Based on my own experience in the spinal industry, including in-depth personal discussions with and observations of spinal surgeons over the last decade, I understand these posterior and anterior approaches came with numerous and significant drawbacks. These approaches required using a traditional open incision with a large surgical footprint, which resulted in lengthy operation times, an amount of blood loss that often required patients to donate their own blood a month or two before surgery, significant hospital stays (including in the ICU), postoperative pain, and high risk of serious complications and readmission to the hospital. Additionally, these common approaches often required the services of additional doctors during the procedure, including an “access surgeon” to make

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<sup>217</sup> Exhibit-1069 – 7/8/14 Declaration of Patrick Miles, pp. 27-28.

<sup>218</sup> 3/30/18 Declaration of Matthew Link in Support of Motion for Preliminary Injunction.

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sure that no important structures of the body were harmed (including major arteries and organs). Each of these factors also resulted in significant financial cost for hospitals, patients, and insurers.

Less commonly, in an effort to avoid the **safety** and cost issues of open approaches, surgeons would sometimes attempt various types of “minimally invasive” procedures involving smaller incisions. However, these early minimally invasive approaches were not **standardized** and often involved unfamiliar and awkward to use instruments, resulting in unpredictable **outcomes** for the patient. Thus, hospitals and surgeons generally avoided such procedures.

NuVasive recognized the market need for a solution to the problems inherent in these earlier procedures, and starting in 2001, began the development of such a solution. Doc. No. 1-2 (IPR 2014-00075, July 8, 2014 Declaration of Patrick Miles) at 7. NuVasive’s new procedure, ultimately called XLIF, utilized a **minimally invasive**, lateral approach to the spine (i.e., gaining access to the spine from the side of the patient). Before XLIF, lateral approaches to the spine were not widely used because they required traversing the nerve-rich psoas muscle, and thus carried a high risk of nerve damage that can lead to a host of medical issues for a patient. That changed, however, when NuVasive invented XLIF: the first **safe and reproducible** minimally invasive lateral trans-psoas approach to the spine.<sup>219</sup>

Each of the above described components – neuromonitoring capabilities, specialized access tools, and specialized implants – were essential in enabling NuVasive to become the first company to provide a **safe, effective, and reproducible minimally invasive** lateral trans-psoas approach to the lumbar spine.<sup>220</sup>

In my experience, technologies that contribute significantly to the **safety and reproducibility** of lateral procedures, such as the features in the XLIF platform that I understand are set forth in NuVasive’s XLIF patents, represent important drivers of demand for XLIF products and are highly desired by the surgeons that rely on them.<sup>221</sup>

**Deposition Testimony of Matt Link (NuVasive’s former President)**

Q. Would you agree with me that there is no single component within the XLIF procedure that is consistently the sole driver of the sale?

...A. I would say that, consistent with prior statements, having a complete and integrated assembly of technology that supports safe and reproducible surgery is

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<sup>219</sup> 3/30/18 Declaration of Matthew Link in Support of Motion for Preliminary Injunction, para. 7-10.

<sup>220</sup> 3/30/18 Declaration of Matthew Link in Support of Motion for Preliminary Injunction, para. 18.

<sup>221</sup> 6/14/18 Reply Declaration of Matthew Link in Support of Motion for Preliminary Injunction, para. 58.

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an important factor in the decision-making to utilize a procedure like XLIF in surgery.<sup>222</sup>

Q. The CoRoent XL implant is not consistently the sole driver of the sale of an XLIF procedure, correct?

...A. The CoRoent XL implant, I believe, is an important factor and component of the complete integrated procedural solution that supports safe and reproducible outcomes for patients.<sup>223</sup>

**NuVasive 2018 Form 10-K**<sup>224</sup>

The MAS platform is designed to treat a wide range of spinal pathologies while accommodating a surgeon’s preferred surgical technique. We believe our approach **improves clinical results** and should continue to drive an expanded number of **minimally disruptive** procedures performed, lead the market away from open surgery, and make less invasive techniques the standard of care in spine fusion and non-fusion surgery.

**NuVasive XLIF® Integrated Instrumentation Marketing Materials**<sup>225</sup>

The XLIF (eXtreme Lateral Interbody Fusion) procedure is a **minimally disruptive** surgical technique offering **superior clinical and economic outcomes**, including less pain, reduced length of hospital stay, faster return to work and decreased infection rates.

XLIF is made **safe and reproducible** through the seamless integration of the NuVasive proprietary NVM5 nerve avoidance technology and the MaXcess Access System, allowing conventional surgical techniques to be performed under direct visualization in a less invasive approach.

**NuVasive “Frequently Asked Questions: eXtreme Lateral Interbody Fusion (XLIF)”**

***How do NuVasive systems contribute to the success of the XLIF technique?***

The MaXcess® System provides customized maximum surgical access while **minimizing the soft tissue disruption** that often occurs during open surgery. The MaXcess System allows the fundamentals of conventional surgical techniques to be achieved, while eliminating the unfamiliar requirements of operating coaxially through tubular portals.

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<sup>222</sup> 10/29/20 Deposition Transcript of Matt Link, p. 103

<sup>223</sup> 10/29/20 Deposition Transcript of Matt Link, p. 106.

<sup>224</sup> NuVasive, Inc. Form 10-K for the fiscal year ended December 31, 2018, pp. 6-7.

([https://www.sec.gov/Archives/edgar/data/1142596/000156459019003470/nuva-10k\\_20181231.htm](https://www.sec.gov/Archives/edgar/data/1142596/000156459019003470/nuva-10k_20181231.htm))

<sup>225</sup> NR0058619.

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Additionally, since there are no adjunctive visualization tools (e.g., endoscope, monitor), the MaXcess System enables direct illuminated visualization of the patient’s anatomy through conventional methods.

The NeuroVision® JJB System is another important technology that enables **safety and reproducibility** during minimally disruptive techniques. This system is the only surgeon-driven technology that provides dynamic, discrete information about nerve location and condition. In the XLIF technique, NeuroVision is used to enable a safe trajectory past the nerves in the psoas muscle by communicating nerve proximity and directional information. This enables the surgeon to locate and avoid the lumbar plexus while accessing the disc. NeuroVision is the only nerve avoidance system that has demonstrated safety and reproducibility during a lateral transpsoas technique.

***What are the key advantages to the XLIF technique?***

The XLIF approach does not require dissection or retraction of the sensitive back muscles, bones, ligaments, or nerves and allows for more complete disc removal and implant insertion as compared with traditional posterior procedures. Nor does lateral access require the delicate abdominal exposure or present the same risk of vascular injury as traditional anterior approaches. As a result, operating time is often reduced, patient blood loss is minimized, and recovery time is significantly shorter.<sup>226</sup>

**NuVasive “Fact Sheet: eXtreme Lateral Interbody Fusion (XLIF)”**

**XLIF Patient Benefits**

- **Reduced operative time** – Traditional procedures can take many hours to perform; the XLIF procedure can be successfully completed in as little as one hour, reducing the amount of anesthesia time.
- **Reduced blood loss and minimal scarring** – The MaXcess® retractor dilates the tissue rather than cutting, resulting in much less trauma to the affected area.
- **Reduced post operative pain** – The XLIF procedure does not require entry through sensitive back muscles, bones, or ligaments, so many patients are usually walking the same day after surgery.
- **Reduced hospital stay** – XLIF requires only an overnight stay in the hospital, compared to several days of immobility and hospitalization typical of traditional open approaches.
- **Rapid return to normal activity** – Patients are usually walking the same day after surgery and recovery is typically around 6 weeks, compared to 6 months or more.<sup>227</sup>

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<sup>226</sup> NUVA\_ATECO243607.

<sup>227</sup> NUVA\_ATECO047917.

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**NuVasive Presentation “Selling the Value of XLIF®”, by Brian Snider [undated]<sup>228</sup>**

**NuVasive® is....**  
*The most dynamic, innovative, and surgeon responsive spine company in the world.*

**MAS® Platform**

- Dedicated to the pursuit of **SAFE and REPRODUCIBLE** access to the spine
- Embraces traditional surgical principles via **less invasive techniques**
- Delivers MIS benefits to patients, while meeting/exceeding traditional **clinical outcome** benchmarks

**THE SURGE**

**NuVasive Presentation “The XLIF Approach: MVP”<sup>229</sup>**

**Why Consider XLIF?**

<b>Clinical application</b>	<b>Anatomic benefits</b>
<ul style="list-style-type: none"> <li>• <b>“MIS” approach option</b></li> <li>• Alternative to ALIF, PLIF, TLIF</li> <li>• Adjacent level w/o extending constructs</li> <li>• Lumbar / Thoracic deformity</li> <li>• Revision TDR</li> <li>• Primary TDR?</li> </ul>	<ul style="list-style-type: none"> <li>• Muscle splitting</li> <li>• No muscle stripping</li> <li>• Ligament sparing</li> <li>• Large implant</li> <li>• Maximizes stability</li> <li>• Indirect decompression</li> <li>• Restores alignment</li> </ul>

<sup>228</sup> NR0061817.

<sup>229</sup> N0017072.

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## Surgical Benefits

- Conventional surgery through small incisions
- Minimal soft tissue/muscle damage
- Reduced post-operative morbidity
- Outpatient or 23 hr procedure
- Adequate exposure
- Safe and reproducible
- Meet or exceed traditional results

## Tools for Safety and Reproducibility

- Modular split-blade design
- Multiple blade lengths and shims conform to the spine’s natural contours and customizes to patients’ size
- Rigid fixation to the OR table and spine via anchoring shims
- Adjustable AP and cranial-caudal aperture
- EMG enabled posterior blade protects lumbar plexus
- Integrated illumination delivers unobstructed visualization



### NuVasive Brochure “MaXcess 4 Launch Guide”

Based on over 8 years of experience in lateral access surgery, the MaXcess 4 Access System was designed to deliver **safe and reproducible** XLIF outcomes by combining Strength, Precision, Fluro-visibility, and Integrated Neuromonitoring.”<sup>230</sup>

<sup>230</sup> NUVA\_ATEC0243707.



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**NuVasive Document “XLIF Surgical Technique”<sup>231</sup>**

The MaXcess® 4 Access system provides maximum surgical access while minimizing the soft tissue disruption that often occurs during open surgery. MaXcess 4 allows the fundamentals of conventional surgical techniques to be achieved, while eliminating the unfamiliar requirements of operating coaxially through tubular portals. Additionally, since there are no adjunctive visualization tools (e.g., endoscopes, monitors), the MaXcess 4 Access system enables direct, illuminated visualization of the patient’s anatomy through conventional methods.

55. Based on this and other information I have considered, features that contribute to safety and reproducibility, minimal invasiveness, and clinical success represent significant drivers of demand for the Accused Products.

**III.D.3 Longevity of Customer Relationships**

56. Based on discussions with Matt Link (NuVasive’s former President), John English (NuVasive’s Vice President of Global Professional Affairs and Distributor Engagement), and other current/former NuVasive personnel, as well as other information in my report, it is my understanding that customer relationships in the lateral market are “sticky” and long-lasting:

**Testimony of Matt Link (NuVasive’s former President)**

As I believe I stated previously, when there is a conversion of a customer from one technology or procedure to another, it can prove to be prohibitively difficult at times to convert it back.<sup>232</sup>

**Alphatec Presentation: “A Leading Provider of Advanced Spinal Fusion Platforms and Systems”<sup>233</sup>**

- Focused efforts on how to sell into **traditionally difficult-to-penetrate market segments**
- Complexity of lateral and deformity cases **results in strong company loyalty**
- **‘Stickiness’ of these market segments provides significant opportunity for incremental pull-through sales**

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<sup>231</sup> NUVA\_ATEC0048961.

<sup>232</sup> 4/19/18 Deposition Transcript of Matt Link, p. 120 (ATEC\_LLIF000846103 at 133).

<sup>233</sup> ATEC\_LLIF000854436 at-448, -450-452, -464 [emphasis added].

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## Sales Rep Training Initiative

**2016 Sales Training Programs**

Date	Sales Training	Location
Jan 28-29	Advanced Deformity Training	Carlsbad, CA
Feb 22-26	Basic Sales Training	Carlsbad, CA
Feb TBD	West Regional Deformity Training	TBD
Mar TBD	Central Regional Deformity Training	TBD
Mar TBD	East Regional Deformity Training	TBD
Mar 7-11	Basic Sales Training	Carlsbad, CA
Apr 18-22	Basic Sales Training	Carlsbad, CA
Apr 22-23	Advanced Deformity Training	Carlsbad, CA
May TBD	West Regional Lateral Training	TBD
May TBD	Central Regional Lateral Training	TBD
May 27-28	Advanced Deformity Training	Carlsbad, CA
Jun TBD	East Regional Lateral Training	TBD
Jun 20-24	Basic Sales Training	Carlsbad, CA
Jul 8-9	Advanced Deformity Training	Carlsbad, CA
Jul TBD	Lateral Training	Carlsbad, CA
Aug TBD	Basic Sales Training	Carlsbad, CA
Sep 9-10	Advanced Deformity Training	Carlsbad, CA
Sep TBD	Lateral Training	Carlsbad, CA
Oct 17-20	Basic Sales Training	Carlsbad, CA
Nov TBD	Lateral Training	Carlsbad, CA
Nov 18-19	Advanced Deformity Training	Carlsbad, CA

Deformity
Basic
Lateral

**Key Initiatives**

- Hired Senior Director of Sales Training & Clinical to Support Senior Director of Medical Education
- Key Focus Areas: Advanced Deformity and Lateral Training
  - Focused efforts on how to sell into traditionally difficult-to-penetrate market segments
  - Complexity of lateral and deformity cases results in strong company loyalty
  - "Stickiness" of these market segments provides significant opportunity for incremental pull-through sales

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**2017 Alphatec SEC Filing Form 10-K<sup>234</sup>**

We focus our surgeon training efforts on delivering critical technical skills needed on the entire spinal fusion procedure through a peer-to-peer approach to qualified surgeon customers. Well-timed surgeon education programs drive customer conversion and loyalty through leadership and excellence by focusing on delivering value through improved surgeon outcomes. We devote significant resources to training and education and are committed to a culture of scientific excellence and ethics.

We believe that one of the most effective ways to introduce and build market demand for our products is by training and educating spine surgeons, independent distributors, and direct sales representatives in the benefits and use of our products. Sales training programs will be a platform for learning and organizational development, ensuring the sales force is clinically competitive and considered an essential resource to all stakeholders. We focus on cross functional collaboration and alignment to deliver timely and relevant programs to meet surgeon and representative needs and positively impact the business.

Our training and education programs are designed to support new product introductions to the market as well as ongoing portfolio advancement. Our resources are nimble and responsive, and include field-based engagements to

<sup>234</sup> Alphatec Holdings, Inc., Form 10-K for the fiscal year ended December 31, 2017.

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supplement our core curriculum. We believe this is an effective way to increase overall surgeon adoption of our new products.

We believe that surgeons, independent distributors, and direct sales representatives will become exposed to the merits and distinguishing features of our products through our training and education programs, and that such exposure will increase the use and promotion of our products. With a focus on the entire procedure, we expect to build awareness of the breadth of our product offering. We are conscientious in the pursuit of delivering value to all stakeholders. Our goal is to provide surgeon education programs coupled with a growing and comprehensive sales training platform that create a sustainable competitive advantage for our organization.<sup>235</sup>

**CANACCORD Genuity Equity Research Report “2010 NASS Meeting”<sup>236</sup>**

We note that spine sales are heavily relationship-dependent...

**Alphatec Document “Market Need/Assessment Request: Project Lateral Lumbar Interbody Fusion (LLIF)”<sup>237</sup>**

Thorough training of both surgeons and sales agents has proven to be a critical success factor in the Lateral Space. NuVasive invested millions in their education programs and set the bar for all the competition. Not only have surgeons been trained, but sales representatives and marketing professionals have all been trained to a very high level.

Many surgeons are now demanding these highly capable, highly trained representatives to support their lateral cases. This level of education has led to a new surgeon/rep interaction standard where sales representative and surgeon review cases together to decide the best procedural steps, what instrumentation and implant options to order as well as other clinical considerations. It will be important to offer an education program that prepares Alphatec Spine reps for this level of ‘partnership’ with surgeons.


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<sup>235</sup> Alphatec Holdings, Inc., Form 10-K for the fiscal year ended December 31, 2017, p. 6.

<sup>236</sup> ATEC\_LLIF000091938 at -940.

<sup>237</sup> ATEC\_LLIF000003829 at -3829, -3835.

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 <b>Market Need/Assessment Request</b>	
<b>Concept:</b> Project Lateral Lumbar Interbody Fusion (LLIF)	
<b>Prepared By:</b> Bryan Larsen	
<b>Signature:</b>	<b>Date:</b>

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**Market Need:**

Lateral Lumbar Interbody Fusion (LLIF) has evolved since its early 2000 inception to become an effective and reproducible surgery for lumbar interbody fusion. Currently it holds ~6% of the total fusion market with growth projections as high as 16% by 2019. This is one of the fastest growing segments in spine with NuVasive holding the largest market share at 50%, Medtronic (MSD) holds 26% with all other spine companies sharing the remainder. Globus leads this small group holding around 9% of the market.

The goal of a lateral system is to deliver indirect decompression and alignment restoration while minimizing soft tissue and bony disruption typically required for access in an Anterior Fusion (ALIF), Posterior Fusion (PLIF), or TransForaminal Fusion (TLIF). This is accomplished by optimizing traditional instrumentation in a directly visualized, MIS style procedure. Alphatec Spine will break down the procedure into three phases of the procedure: 1- **access** to the retroperitoneal space and across the psoas via dilation, electromyography stimulation and retraction. 2- **Discectomy** with LLIF specific disc prep instrumentation. 3 - **Disc replacement** with a LLIF specific intervertebral disc spacer.

Complete lateral systems need to address the following pathologies: low grade spondylolisthesis, (≤Grade 3), Degenerative Disc Disease (DDD), mild to moderate Scoliotic Deformity, Tumor, and Trauma (including corpectomy). The L5-S1 disc level is contraindicated for anatomical reasons with all LLIF systems. System ability to target the L4/L5 Disc space is vital. Our initial launch will focus DDD and mild deformity, with subsequent launches adding instrumentation and implants optimized for more advanced indications.

Thorough training of both surgeons and sales agents has proven to be a critical success factor in the Lateral Space. NuVasive invested millions in their education programs and set the bar for all the competition. Not only have surgeons been trained, but sales representatives and marketing professionals have all been trained to a very high level. Companies that have not included extensive sales and surgeon lateral education have struggled to capture and hold market share as the surgeons have placed value on the knowledge of their agents in the operating room. Those with success have followed this style of extensive training regime set forth by NuVasive.

For sales representatives this includes standard procedural and set configuration training as well as advanced education of didactic anatomy/pathology, neurophysiology and radiology training. The opportunity to dissect the retroperitoneal space on a cadaver is utilized to solidify their understanding and abilities to convey to surgeons technique in the OR. Many surgeons are now demanding these highly capable, highly trained representatives to support their lateral cases. This level of education has led to a new surgeon/rep interaction standard where sales representative and surgeon review cases together to decide the best procedural steps, what instrumentation and implant options to order as well as other clinical considerations. It will be important to offer an education program that prepares Alphatec Spine reps for this level of 'partnership' with surgeons. To validate this training, a 'Cadaveric Certification' test that simulates walking a new surgeon through their first case is utilized. Sales Representatives are not allowed to cover their own cases until this Lateral Certification is complete.

As we grow our lateral proficiency, our reps will be more educated and valued in the OR. This has been proven to strengthen the relationship between rep and surgeon. The training provided for surgeons helps build loyalty between surgeon and the company that provides the thorough training.

The 'Surgeon Experience' offered by NuVasive has set a high bar for training.

57. According to Mr. Link, NuVasive has made significant investments in training and educating surgeons and sales representatives.<sup>238</sup> Mr. Link has indicated that Alphatec has hired away a number of NuVasive sales representatives, which may be further indication of the

<sup>238</sup> 3/30/18 Declaration of Matthew Link in Support of Motion for Preliminary Injunction, para. 26, 29.

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importance of relationships with surgeon-customers in the lateral market.<sup>239</sup> NuVasive reports “Customer Relationships” as an intangible asset, and amortizes the value of these relationships over 9 years<sup>240</sup>, which provides further insights into the expected longevity of its customers.

#### **IV LOST PROFITS**

58. The Federal Circuit has stated that a useful, but non-exclusive, way for a patentee to prove entitlement to lost profits is the Panduit four-factor test<sup>241</sup>:

The Panduit test requires that a patentee establish: (1) demand for the patented product; (2) absence of acceptable non-infringing substitutes; (3) manufacturing and marketing capability to exploit the demand; and (4) the amount of the profit it would have made.

59. Below is my analysis of these four *Panduit* factors. Some information contained or identified in other sections of this report or schedules may apply to one or more of the *Panduit* factors, but has not been replicated to avoid unnecessary duplication.

#### **IV.A Panduit Factor #1: Demand for Patented Product**

60. The first *Panduit* factor simply asks whether demand existed for the 'patented product,' i.e., a product that is 'covered by the patent in suit' or that 'directly competes with the infringing device.'<sup>242,243</sup>

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<sup>239</sup> 3/30/18 Declaration of Matthew Link in Support of Motion for Preliminary Injunction, para. 45-48.

<sup>240</sup> NuVasive, Inc. Form 10-K for the fiscal year ended December 31, 2019, pp. 86, 90. “Intangible assets with a finite life, such as acquired technology, customer relationships, manufacturing know-how, licensed technology, supply agreements and certain trade names and trademarks, are amortized on a straight-line basis over their estimated useful life, ranging from 1 to 17 years. In determining the useful lives of intangible assets, the Company considers the expected use of the assets and the effects of obsolescence, demand, competition, anticipated technological advances, changes in surgical techniques, market influences and other economic factors.” ([https://www.sec.gov/Archives/edgar/data/1142596/000156459019003470/nuva-10k\\_20181231.htm](https://www.sec.gov/Archives/edgar/data/1142596/000156459019003470/nuva-10k_20181231.htm))

<sup>241</sup> *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995) (citing *Panduit Corp. v. Stahl Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978)).

<sup>242</sup> *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1330 (Fed. Cir. 2009).

<sup>243</sup> A patentee may show demand under the first Panduit factor by showing demand for its own product *Georgetown Rail Equip. Co. v. Holland L.P.*, 867 F.3d 1229 (Fed. Cir. 2017). A patentee may show demand under

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61. Both Alphatec and NuVasive have sold products made under the patents-in-suit, which demonstrates demand for the Accused Products.<sup>244</sup>

62. As discussed in section III.D.2 of this report, the drivers of demand for the Accused Products are safety and reproducibility, minimal invasiveness, and clinical success. Below is an excerpt from Dr. Youssef’s expert report that describes how the patents-in-suit contribute to these drivers of demand.

**Expert Report of Dr. Jim Youssef<sup>245</sup>**

Each of the patents-in-suit individually, and collectively, provide significant contributions towards making a spinal fusion procedure more: (1) safe and reproducible, (2) minimally invasive, and (3) clinically successful, which, in my opinion, are the primary criteria surgeons consider when using / adopting a lateral platform, such as Alphatec’s Battalion platform and NuVasive’s MAS platform. Furthermore, I understand that they represent the three primary drivers of demand for Alphatec’s accused products.

**Supplemental Expert Report of Dr. Jim Youssef<sup>246</sup>**

Each of the asserted implant patents individually, and collectively, provides significant contributions towards making a spinal fusion procedure more: (1) safe and reproducible, (2) minimally invasive, and (3) clinically successful, which, in my opinion, are the primary criteria surgeons consider when using / adopting a lateral platform, such as Alphatec’s LIF Platform and NuVasive’s MAS platform. Furthermore, I understand that they represent the three primary drivers of demand for Alphatec’s accused products.

63. Based on the information I have considered, there is demand for the products made under the patents-in-suit.

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the first Panduit factor by showing demand for the infringer’s product. See *Smithkline Diagnostics v. Helena Lab* (“A substantial number of sales of the infringing slides by [defendant] is compelling evidence of a demand for [plaintiff’s] patented ... slides”); *Gyromat v. Champion Spark Plug*.

<sup>244</sup> See **Schedules 4 - Supplemental and 15 - Supplemental**.

<sup>245</sup> Expert Report of Jim Youssef Re Damages, dated 11/8/19, para. 16-25. Based on discussions with Dr. Youssef.

<sup>246</sup> Opening Expert Report of Jim Youssef, dated 11/20/20, para. 439. Based on discussions with Dr. Youssef.



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**IV.B Panduit Factor #2: Absence of Acceptable Non-Infringing Substitutes**

64. The second *Panduit* factor asks whether there was a lack of available and acceptable non-infringing alternatives to NuVasive’s MAS platform/XLIF Procedure. One part of analyzing this factor is establishing that NuVasive’s MAS platform/XLIF Procedure and Alphatec’s LIF Platform are sufficiently similar in characteristics and price.

*Interchangeability*

65. I understand that Dr. Youssef has compared the features of NuVasive’s MAS platform/XLIF Procedure and Alphatec’s LIF Platform and found them to be sufficiently similar to conclude that there are no distinguishing features of Alphatec’s LIF Platform that would have prevented the surgeons and hospitals continuing to use or migrating to NuVasive’s MAS platform/XLIF Procedure “but for” its alleged infringement.<sup>247</sup> Furthermore, Dr. Youssef concluded that NuVasive’s MAS platform/XLIF Procedure is the most directly comparable or interchangeable platform with Alphatec’s LIF Platform when compared to the lateral platforms offered by other market participants such as Medtronic, Globus Medical, Depuy Synthes, Stryker, Zimmer Biomet, and RTI Surgical.<sup>248</sup> Below are excerpts from Dr. Youssef’s expert report that summarize some of his opinions on this issue:

**Expert Report of Dr. Jim Youssef<sup>249</sup>**

In Section 21 of my Opening Report and Section 1 above, I have compared the features and components of NuVasive’s MAS platform and Alphatec’s Battalion platform and found them to be sufficiently similar to conclude that there are no distinguishing features of the Alphatec Battalion platform that would have prevented the surgeons and hospitals using the accused product from continuing to use or migrating to NuVasive’s MAS platform.

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<sup>247</sup> Expert Report of Jim Youssef Re Damages, dated 11/8/19, para. 27. Based on discussions with Dr. Youssef and Kyle Malone (NuVasive’s Senior Director of Medical Affairs).

<sup>248</sup> Expert Report of Jim Youssef Re Damages, dated 11/8/19, para. 30. Based on discussions with Dr. Youssef and Kyle Malone (NuVasive’s Senior Director of Medical Affairs).

<sup>249</sup> Expert Report of Jim Youssef Re Damages, dated 11/8/19, para. 27, 30. Based on discussions with Dr. Youssef.



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It is my opinion that NuVasive’s MAS platform is the most directly comparable or interchangeable platform with Alphatec’s Battalion platform when compared to the lateral platforms offered by other market participants such as Medtronic, Globus Medical, DePuy Synthes, Stryker, Zimmer Biomet, and RTI Surgical. As set forth in detail in Section 19 of my Opening Report, lateral platforms from companies such as DePuy, Synthes, Stryker, Zimmer and Biomet that are not accused of practicing the patents-in-suit are clinically inferior for a number of reasons. Additionally, there would be significant barriers to switching from XLIF to any of lateral platforms offered by other market participants such as Medtronic, Globus Medical, DePuy Synthes, Stryker, Zimmer Biomet, and RTI Surgical. Such a switch would require that a surgeon become familiar with using the different access tools required for the other lateral platforms. Thus, it would be much less burdensome and risky for a surgeon to switch from NuVasive’s XLIF to Alphatec’s LLIF as compared to other lateral platforms in the market. For all of these reasons, as well as others explained in more detail in my Opening Report, I have concluded that surgeons who have purchased Alphatec’s accused lateral products would not have found any of the available lateral products on the market to be acceptable substitutes to NuVasive’s MAS Platform of products, “but for” Alphatec’s infringement.

**Supplemental Expert Report of Dr. Jim Youssef<sup>250</sup>**

I was asked to assess from a technical and clinical standpoint whether Alphatec's Lateral platform utilizing the accused products (“LIF Platform” ) and NuVasive's Maximum Access Surgery (“MAS”) platform are interchangeable. Both NuVasive's MAS platform and Alphatec's accused products practice each of the asserted claims of the patents-in-suit, which recite the key features necessary for safe, reproducible, and effective lateral spinal fusion surgery. Moreover, based on the glaring similarities between the accused products and NuVasive's MAS platform (as exemplified by a comparison of Appendices A-G of my Opening Report with Exhibits A-G of my Opening Report, and a comparison of Appendices A & B and Exhibits A-F to this report), Alphatec's accused products are essentially a copy of their corresponding components within NuVasive's MAS platform.

The similarities between a procedure using Alphatec's LIF Platform and a procedure using NuVasive's MAS platform extend to more than just the use of products practicing/infringing the patents-in-suit. Similarities between the steps of the procedures and other products (not subject to my infringement analysis in my Opening Report) are reflected in Section III.E of NuVasive's Complaint, which I agree with and incorporate into my opinions.

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<sup>250</sup> Opening Expert Report of Jim Youssef, dated 11/20/20, para. 432-438. Based on discussions with Dr. Youssef.  
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From a technical and clinical perspective, it is my opinion that the components sold in these two platforms are sufficiently similar enough that there are no distinguishing features of the Alphatec’s LIF Platform that would have prevented surgeons and hospitals using the accused products from continuing to use or migrate to NuVasive’s MAS platform, had Alphatec not sold accused products.

It is my opinion that NuVasive's MAS platform is the most directly comparable or interchangeable platform with Alphatec’s LIF platform when compared to the lateral platforms offered by other market participants such as Medtronic, Globus Medical, DePuy Synthes, Stryker, Zimmer Biomet, and RTI Surgical. As set forth in detail in Section 19 of my Opening Report, lateral platforms from companies such as DePuy, Synthes, Stryker, Zimmer and Biomet that are not accused of practicing the patents-in-suit are clinically inferior for a number of reasons, including because many platforms do not provide integrated neuromonitoring and many systems offer a different number of blades, such as two or four. Additionally, there would be significant barriers to switching from XLIF to any of lateral platforms offered by other market participants such as Medtronic, Globus Medical, DePuy Synthes, Stryker, Zimmer Biomet, and RTI Surgical. Such a switch would require that a surgeon become familiar with using the different access tools required for the other lateral platforms. Thus, it would be much less burdensome and risky for a surgeon to switch from NuVasive's XLIF to Alphatec's LLIF as compared to other lateral platforms in the market because Alphatec LLIF does include integrated neuromonitoring and has an infringing three-blade retractor. Additionally, Alphatec’s accused implants are the most directly comparable to NuVasive’s CoRoent implant as they have all the key aspects of the asserted implant patents and also closely match the design of NuVasive’s CoRoent implants. Furthermore, the success of NuVasive’s XLIF Procedure / MAS Platform has gained widespread adoption amongst the spine surgery community as a result of clinical validation in the literature. None of the other competitors have this level of validation in the literature.

For all of these reasons, as well as others explained in more detail below, I have concluded that surgeons who have purchased Alphatec's accused lateral products would not have found any of the available lateral products on the market to be acceptable substitutes to NuVasive's MAS Platform of products, "but for" Alphatec's infringement.

Alphatec lowered the barriers to switch platforms by providing a level of interchangeability unmatched by any of the other lateral products on the market. For example, Alphatec’s LIF platform has a three-blade retractor with integrated neuromonitoring and lateral specific implants that include all of the key design aspects of NuVasive’s CoRoent XL implants. Thus, it is reasonable to conclude that the XLIF surgeons who transitioned from NuVasive’s XLIF MAS

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Platform with CoRoent XL implants to Alphatec’s LIF Platform would have remained with NuVasive absent Alphatec’s infringement.

It is my opinion that without access to any one of the Patents-in-Suit (access and implant), that Alphatec would have been unable to offer a lateral platform that could have successfully competed with NuVasive and others in the marketplace, as they all provide foundational contributions to the safety, minimally invasiveness, and/or clinical success of the Accused Products.

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66. In addition to having similar product characteristics, based on the pricing information I have considered, NuVasive’s MAS platform/XLIF Procedure prices and Alphatec’s LIF Platform prices appear substantially similar (see below):<sup>251</sup>

		Comparison of Average Prices of NuVasive MAS Platform/XLIF and Alphatec LIF Platform Components (PEEK Implant)								
		NuVasive MAS Platform/XLIF				Alphatec LIF Platform				
		2017 Average Price	2018 Average Price	2019 Average Price	2020 Average Price	2017 Average Price	2018 Average Price	2019 Average Price	2020 Average Price	
<b>Implants</b>	CoRoent XL/XLW/XLWX Implant	\$ 4,517	\$ 4,304	\$ 4,149	\$ 4,004	Battalion Lateral Spacer/Transcend LIF PEEK Spacer	\$ 4,370	\$ 4,198	\$ 4,348	\$ 3,764
<b>Access Disposables</b>	<b>MaXcess 4 Kit</b> Tyvek Pouch, 8" x 16" Carton, MaXcess Sterile Disposable Kit MaXcess IV Inner Tray, Kit MaXcess Sterile Dispos Kit - Outer Tray Inner Tyvek Lid, MaXcess Ster Dispos Ki Outer Tyvek Lid, MaXcess Ster Dispos Ki LBL MaXcess 4 Kit MaXcess 4 Shim, Intradiscal Locking  MaXcess 4 Shim, Standard Left MaXcess 4 Shim, Standard Right MaXcess IV Shim, Wide MaXcess Access Shim, Extra Wide Right MaXcess Access Shim, Extra Wide Left MaXcess IV Shim, Double Wide MaXcess 4 Electrode MaXcess 4 Light Cable, Angled  MaXcess Knife, Annulotomy Bent Perforated Labels w/NuVasive Logo Universal LBLSTK, Disposables <b>Total</b>	\$ 1,533   \$ 1,481   \$ 1,453   \$ 1,435	Battalion Lateral Intradiscal Shim, Sterile/LIF Intradiscal Shim, 25mm/35mm  Battalion, LIF Light Cable/Bifurcated Light Cable Tip/LIF Illumination System, Sterile Lacey, Sterile Packaged Bayonet Knife - 170mm  <b>Total</b>	\$ 668   \$ 1,364   \$ 1,361   \$ 1,056						
	<b>Neuromonitoring Disposables</b>	<b>NVMS XLIF Dilator Kit</b> LBL NVMS XLIF Disposable Kit Perforated Labels w/NuVasive Logo 6, 9, 12 mm Dilators Set  NVMS Probe Shaft, Long  XLIF Dilator K-Wire, Parylene Coated Inner Tray, NV MS XLIF Disp. Kit NVMS Outer Tray, Disp Dilator Inner Tyvek Lid, MaXcess Ster Dispos Kit Outer Tyvek Lid, MaXcess Ster Dispos Kit NVMS Carton, Disp Dilator NVJJBMS XLIF Dilator Notice NVMS Clips, Activator and Clip  Universal LBLSTK, Disposables <b>Total</b>		\$ 769   \$ 754   \$ 719   \$ 713	Insulated Dilators, 8 & 13MM/8, 13 & 18MM/SafeOp Insulated Dilator Kit, Sterile/Initial Dilator/Secondary Dilator/Tertiary Dilator RhythmLink Disposable 200mm, 2.3mm Tip, 2.5m/SafeOp Stimulating Ball-Tip Probe, Sterile/Arcus Stimulating Targeting Needle, Diamond Tip/Arcus Stimulating Targeting Needle, Bevel Tip Nitinol/Stainless Steel Guidewire (Various)  Multi-Stage Clip - Sterile, Single-Use/SafeOp Stimulating Clip, Sterile  <b>Total</b>	\$ 1,313   \$ 1,527   \$ 1,294   \$ 1,588				
<b>Total Platform</b>	1.5 Levels (Implants) per Procedure	\$ 9,077	\$ 8,689	\$ 8,396	\$ 8,154	1.5 Levels (Implants) per Procedure	\$ 8,536	\$ 9,187	\$ 9,178	\$ 8,290

<sup>251</sup> See Schedules 14A - Supplemental and 14B.

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Comparison of Average Prices of NuVasive MAS Platform/XLIF and Alphatec LIF Platform Components (Porous Titanium Implant)						
	NuVasive MAS Platform/XLIF		Alphatec LIF Platform			
	2019 Average Price	2020 Average Price	2019 Average Price	2020 Average Price		
<b>Implants</b>	Modulus XL/XLW/XLXW Implant	\$ 5,087	\$ 4,830	IdentiTi LIF Porous Ti Spacer	\$ 4,522	\$ 4,757
<b>Access Disposables</b>	<b>MaXcess 4 Kit</b> Tyvek Pouch, 8" x 16" Carton, MaXcess Sterile Disposable Kit MaXcess IV Inner Tray, Kit Maxcess Sterile Dispos Kit - Outer Tray Inner Tyvek Lid, MaXcess Ster Dispos Ki Outer Tyvek Lid, MaXcess Ster Dispos Ki LBL MaXcess 4 Kit MaXcess 4 Shim, Intradiscal Locking  MaXcess 4 Shim, Standard Left MaXcess 4 Shim, Standard Right MaXcess IV Shim, Wide MaXcess Access Shim, Extra Wide Right MaXcess Access Shim, Extra Wide Left MaXcess IV Shim, Double Wide MaXcess 4 Electrode MaXcess 4 Light Cable, Angled  MaXcess Knife, Annulotomy Bent Perforated Labels w/NuVasive Logo Universal LBLSTK, Disposables <b>Total</b>			Battalion Lateral Intradiscal Shim, Sterile/LIF Intradiscal Shim, 25mm/35mm  \$ 247 \$ 190   Battalion, LLIIF Light Cable/Bifurcated Light Cable Tip/LIF Illumination System, Sterile Lacey, Sterile Packaged Bayonet Knife - 170mm \$ 582 \$ 453 \$ 533 \$ 412  <b>Total</b>		
<b>Neuromonitoring Disposables</b>	<b>NVMS XLIF Dilator Kit</b> LBL NVMS XLIF Disposable Kit Perforated Labels w/NuVasive Logo 6, 9, 12 mm Dilators Set  NVMS Probe Shaft, Long  XLIF Dilator K-Wire, Parylene Coated Inner Tray, NV MS XLIF Disp. Kit NVMS Outer Tray , Disp Dilator Inner Tyvek Lid, MaXcess Ster Dispos Kit Outer Tyvek Lid, MaXcess Ster Dispos Kit NVMS Carton, Disp Dilator NVJJBMS XLIF Dilator Notice NVMS Clips, Activator and Clip  Universal LBLSTK, Disposables <b>Total</b>			Insulated Dilators, 8 & 13MM/8, 13 & 18MM/SafeOp Insulated Dilator Kit, Sterile/(Initial Dilator/Secondary Dilator/Tertiary Dilator \$ 550 \$ 782 Rhythmink Disposable 200mm, 2.3mm Tip, 2.5m/SafeOp Stimulating Ball-Tip Probe, Sterile/Arcus Stimulating Targeting Needle, Diamond Tip/Arcus Stimulating Targeting Needle, Bevel Tip \$ 479 \$ 489 Nitinol/Stainless Steel Guidewire (Various) \$ 86 \$ 70  Multi-Stage Clip - Sterile, Single-Use/SafeOp Stimulating Clip, Sterile \$ 179 \$ 247  <b>Total</b>		
<b>Total Platform</b>	1.5 Levels (Implants) per Procedure	\$ 9,803	\$ 9,393	1.5 Levels (Implants) per Procedure	\$ 9,438	\$ 9,779

67. The consistency of pricing between lateral platforms is also supported by declaration testimony from Kelli Howell (Alphatec’s Executive VP of Clinical Strategies; former NuVasive VP).<sup>252</sup>

<sup>252</sup> 5/16/18 Declaration of Kelli Howell, para. 21.

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Alternative Approaches and Product Offerings

68. As discussed in section III.D.1.a, there are a number of approaches to minimally invasive interbody fusion other than XLIF and LLIF, including PLIF, TLIF, DLIF, GLIF, and OLIF. Furthermore, as discussed in section III.D.1.a, there are companies other than NuVasive and Alphatec such as Globus Medical, Depuy Synthes, Stryker, Zimmer Biomet, and RTI that participate in the LLIF market. I also understand that companies including NuVasive and Alphatec offer lateral implants that are made with non-PEEK materials such as titanium.<sup>253</sup> It is my understanding that Dr. Youssef has considered the non-infringing alternatives identified by Alphatec and concluded that none of them represented available and acceptable non-infringing substitutes, in particular for XLIF surgeons.<sup>254,255</sup> It is my understanding from John English, Matt Link and other information that titanium implants have grown in acceptance in recent years, but there are many surgeons who have a strong preference for PEEK and who would not find Alphatec’s IdentiTi product an acceptable alternative to the accused implants because of the differences in materials, prices, and other factors. As identified in the steps below and the schedules to this report, I have performed a calculation to remove accused implants from my lost profits calculations for surgeons who have displayed a meaningful acceptance of Alphatec’s IdentiTi product by using them in lateral procedures. Based on discussions with John English,

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<sup>253</sup> See, for example, <https://www.nuvasive.com/news/nuvasive-launches-new-3d-printed-porous-titanium-implant-expanding-advanced-materials-science-portfolio/>, <https://atecspine.com/lif-identiti-lif/>; <https://www.stryker.com/us/en/spine/products/cascadia-lateral.html>; <https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/spinal-orthopaedic/interbody-science/interbody-products/titan.html>.

<sup>254</sup> Opening Expert Report of Jim Youssef, dated 11/1/19, para. 1275-1327; Expert Report of Jim Youssef Re Damages, dated 11/8/19, para. 29-30. Opening Expert Report of Jim Youssef, dated 11/20/20, para. 270-431. Based on discussions with Dr. Youssef.

<sup>255</sup> I am relying on Dr. Youssef and other information in this case for an understanding of the absence of available and acceptable non-infringing substitutes, and have no expert opinions on this topic.

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Matt Link and Dr. Youssef, it is my understanding that this calculation likely significantly overstates Alphatec’s capture rate, as there are a number of surgeons who use titanium implants for some procedures, but require PEEK implants for certain pathologies and patient profiles.

*High Volume of Overlapping Surgeons and LIF Platform Revenue*

69. Approximately 72% of Alphatec’s LIF Platform surgeons overlap with NuVasive MAS Platform/XLIF Procedure Surgeons.<sup>256</sup> Approximately 82% of Alphatec’s LIF Platform revenues were generated from surgeons who overlap with NuVasive.<sup>257</sup> The high volume of overlapping surgeons and LIF Platform Revenue that Alphatec has reported with surgeons who were using NuVasive’s MAS Platform/XLIF is consistent with Dr. Youssef’s opinions regarding the lack of available and acceptable substitutes in the market.

70. As previously discussed, it is my understanding that Dr. Youssef has concluded that there were no acceptable non-infringing alternatives as of the time of Alphatec’s alleged infringement because no other non-infringing surgical platform offers the key benefits and advantages of the patented surgical platform.<sup>258</sup> I understand that Dr. Youssef has concluded that “Alphatec lowered the barriers to switch platforms by providing a level of interchangeability unmatched by any of the other lateral products on the market” and “it is reasonable to conclude that the XLIF surgeons who transitioned from NuVasive’s XLIF MAS Platform with CoRoent XL implants to Alphatec’s LIF Platform would have remained with NuVasive absent Alphatec’s

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<sup>256</sup> See **Schedule 5 - Supplemental**.

<sup>257</sup> See **Schedule 15 - Supplemental**.

<sup>258</sup> Opening Expert Report of Jim Youssef, dated 11/1/19, para. 1276. Opening Expert Report of Jim Youssef, dated 11/20/20, para. 270-431. Based on discussions with Dr. Youssef.



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infringement.<sup>259</sup> Furthermore, I understand that Dr. Youssef has concluded that “without access to any one of the Patents-in-Suit (access and implant), that Alphatec would have been unable to offer a lateral platform that could have successfully competed with NuVasive and others in the marketplace, as they all provide foundational contributions to the safety, minimally invasiveness, and/or clinical success of the Accused Products.”<sup>260</sup> These opinions are consistent with my understanding of the long-term / sticky nature of NuVasive’s XLIF Procedure surgeon relationships,<sup>261</sup> and the significant barriers to transition that surgeons’ face when deciding to change lateral platforms.<sup>262</sup> To the extent that the trier of fact disagrees with Dr. Youssef’s opinions regarding the absence of available and acceptable substitutes and/or interchangeability of other lateral platform offerings, I have provided alternative lost profit calculations that takes into account NuVasive’s relative market share compared to other market participants.<sup>263</sup>

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<sup>259</sup> Opening Expert Report of Jim Youssef, dated 11/20/20, para. 437. Based on discussions with Dr. Youssef.

<sup>260</sup> Opening Expert Report of Jim Youssef, dated 11/20/20, para. 438. Based on discussions with Dr. Youssef.

<sup>261</sup> Based on discussions with Matt Link (NuVasive’s former President), John English (NuVasive’s Vice President of Global Affairs and Distributor Engagement at NuVasive), and Kyle Malone (NuVasive’s Senior Director of Medical Affairs).

<sup>262</sup> Based on discussions with Matt Link (NuVasive’s former President), John English (NuVasive’s Vice President of Global Affairs and Distributor Engagement at NuVasive), and Kyle Malone (NuVasive’s Senior Director of Medical Affairs). According to Matt Link and John English, surgeons and hospitals strongly prefer products that use established technologies (such as those taught by the patents-in-suit) that have been proven safe and clinically successful through large scale and personal use similar to what XLIF surgeons have demonstrated over the years. See also, 10/29/20 Deposition Transcript of Matt Link, pp. 274-275 (“In my experience, when a clinician is comfortable, the subset of technology and ultimately the outcome they provide for their patients, one of the elements that increases a likelihood that they would switch to another product is a similarity of product, i.e., their perceived ability to potentially achieve a similar outcome. And so in the absence of like products, or in this case potentially infringing products, that is harder. That is more difficult.”).

<sup>263</sup> See **Schedules 1A - Supplemental, 1B - Supplemental, 1C - Supplemental, 1D - Supplemental, 1E - Supplemental, 1F - Supplemental, 1G, 1H.**

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#### IV.C Panduit Factor #3: Manufacturing and Marketing Capacity

71. The third *Panduit* factor asks whether NuVasive had the available manufacturing and marketing capacity to satisfy the increase in demand “but for” Alphatec’s alleged infringement. When analyzing this factor, it’s important to first recognize the relatively small amount of lost revenue that is being claimed when compared to NuVasive’s total MAS Platform/XLIF Procedure revenue from 2017 through September 2020. During this time period, Alphatec’s total LIF Platform Revenue for diverted surgeons equaled approximately 4% of NuVasive’s total MAS Platform/XLIF Revenue.<sup>264</sup>

72. I understand from Dale Wolf, Vice President of Manufacturing at NuVasive, that since 2017, the company has maintained sufficient manufacturing capacity to handle this modest amount of increase in lateral procedure volume.<sup>265</sup> A review of NuVasive’s historical revenue growth as well as its historical MAS Platform/XLIF Procedure case volume<sup>266</sup> confirms its ability to scale its resources to cover increasing levels of demand:<sup>267</sup>

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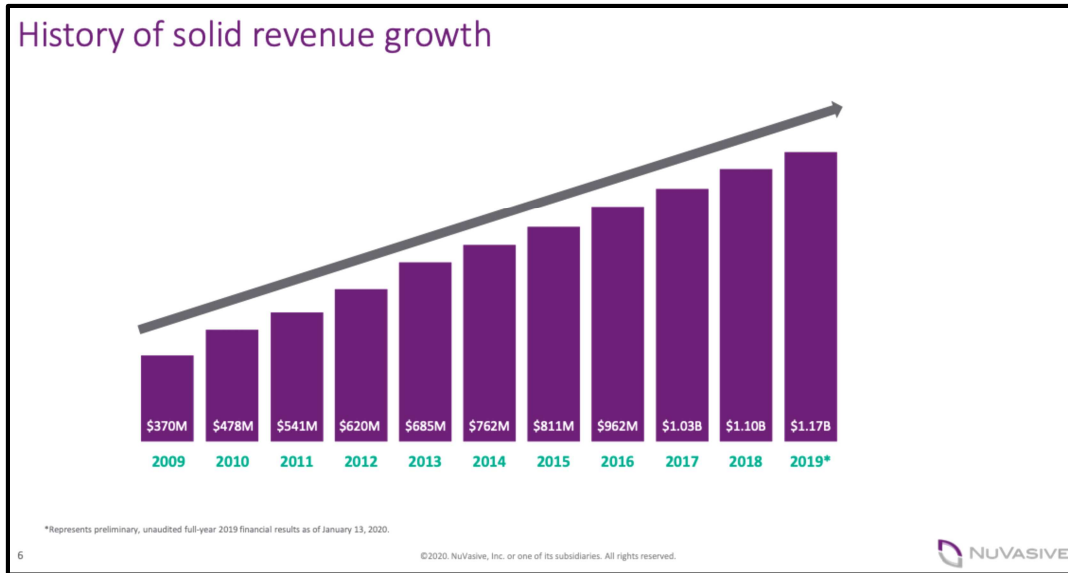
<sup>264</sup> See **Schedule 15 - Supplemental**.

<sup>265</sup> According to a May 2018 NuVasive earnings call, “While we have made considerable progress in reducing our operating expenses, our strategy to radically improve gross margins through self-manufacturing continues to lag our expectations due to a delay in hitting factory absorption rate targets.” ([https://alphastreet.com/earnings/earnings-call-transcripts/2018/05/01/288273-nuvasive-inc-nasdaq-nuva-q1-2018-earnings-conference-call?source\\_url=https%3A%2F%2Falphastreet.com%2Fearnings%2Fearnings-call-transcripts&page\\_section=presentation&page=3](https://alphastreet.com/earnings/earnings-call-transcripts/2018/05/01/288273-nuvasive-inc-nasdaq-nuva-q1-2018-earnings-conference-call?source_url=https%3A%2F%2Falphastreet.com%2Fearnings%2Fearnings-call-transcripts&page_section=presentation&page=3)).

<sup>266</sup> See **Schedule 18 - Supplemental**.

<sup>267</sup> 38th Annual J.P. Morgan Healthcare Conference Investor Presentation, dated 1/15/20 (<https://ir.nuvasive.com/static-files/de4d515c-f55d-499a-96dc-4f53dbc7eea2>).

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73. I understand from John English, Vice President of Global Affairs and Distributor Engagement at NuVasive, that since 2017, the company has maintained sufficient marketing/sales resources to service the increase in demand “but for” Alphatec’s alleged infringement. This is supported by the surgeon overlap between Alphatec’s LIF Platform and NuVasive MAS Platform/XLIF Procedure which is approximately 72%.<sup>268</sup> Furthermore, Alphatec’s own documents provide further confirmation regarding NuVasive’s position as the market leader, strong brand, significant sales/marketing resources, and overlap in customer bases.<sup>269</sup>

74. Based on the information I have considered, NuVasive had the available manufacturing and marketing capacity to satisfy the increase in demand “but for” Alphatec’s alleged infringement.

<sup>268</sup> See **Schedule 5 - Supplemental**.

<sup>269</sup> See **Schedule 5 - Supplemental**. See also, for example, ATEC\_LLIF000003809 at -3810, -3816, -3818; ATEC\_LLIF000137204 at -208, -209, -220; ATEC\_LLIF000004515 -4517; ATEC\_LLIF000137018 at -023, -026, ATEC\_LLIF000003829.

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#### IV.D Panduit Factor #4: Quantification of Profits

75. The fourth *Panduit* factor asks whether it is possible to quantify the amount of profits that NuVasive lost as a result of Alphatec’s alleged infringement. In addition to analyzing the information in other sections, schedules, and exhibits of this report, below is a summary of some of the steps I considered when quantifying NuVasive’s lost profits:<sup>270</sup>

**Step 1:** I evaluated demand for the patented product. Both NuVasive and Alphatec’s historical sales demonstrate demand in the market for lateral platforms incorporating the patents-in-suit.<sup>271</sup>

**Step 2:** I considered the availability of acceptable non-infringing substitutes. While NuVasive and Alphatec do not participate in a two-supplier market, the sales records show that 82%<sup>272</sup> of Alphatec’s accused sales (72%<sup>273</sup> of total Alphatec surgeon-customers) were to NuVasive surgeon-customers (who I understand are generally lifelong customers with low attrition rates<sup>274</sup>). According to Dr. Youssef, former XLIF surgeons who purchased Alphatec’s accused lateral products would not have found any of the available lateral products on the market to be acceptable substitutes to NuVasive’s MAS Platform of products, “but for” Alphatec’s alleged infringement.<sup>275,276</sup> It should also be

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<sup>270</sup> These steps were not necessarily performed in sequential order. The step numbers are provided for reference purposes.

<sup>271</sup> See **Schedules 4 - Supplemental and 15 - Supplemental**.

<sup>272</sup> See **Schedule 15 - Supplemental**.

<sup>273</sup> See **Schedule 5 - Supplemental**.

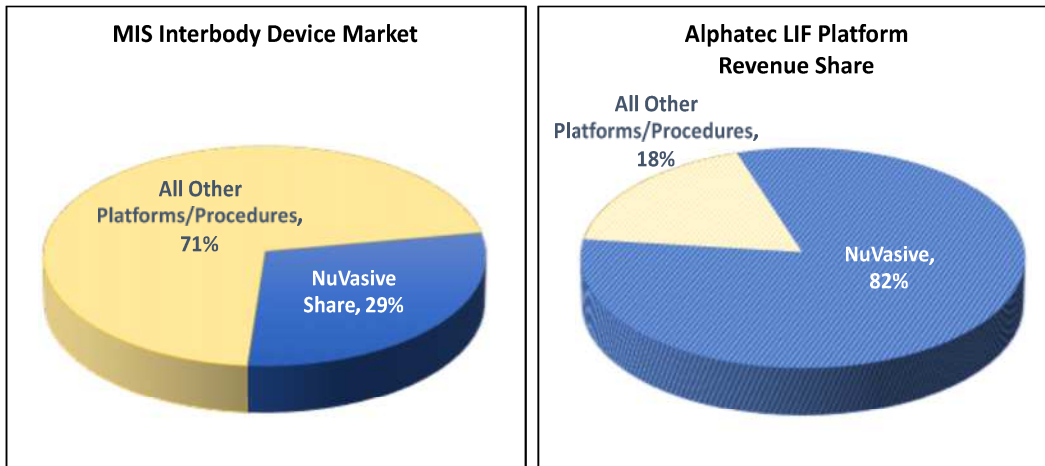
<sup>274</sup> Based on discussions with Matt Link (NuVasive’s former President) and John English (NuVasive’s Vice President of Global Affairs and Distributor Engagement at NuVasive).

<sup>275</sup> Expert Report of Jim Youssef Re Damages, dated 11/8/19, para. 30. Opening Expert Report of Jim Youssef, dated 11/20/20, para. 270-431. Based on discussions with Dr. Youssef.

<sup>276</sup> When analyzing lost profits for the asserted Implant Patents, I have assumed that all Alphatec surgeon-customers who demonstrated a meaningful level of acceptance of the IdentiTi titanium product would have been willing to substitute it for all of their accused implant purchases, subsequent to the surgeon-customer’s date of first sale of the IdentiTi titanium product. Based on discussions with John English and Dr. Youssef, it is my understanding that this assumption likely significantly overstates Alphatec’s capture rate, as there are a number of surgeons who use titanium implants for some procedures, but require PEEK implants for certain pathologies and patient profiles. Furthermore, I understand from John English and Matt Link that there are factors other than

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noted that Alphatec’s LIF Platform customers were disproportionately sourced from NuVasive relationships versus other competitor platforms that are offered in the MIS Interbody Device Market, which from an economic perspective supports that Alphatec’s customers found NuVasive’s MAS Platform/XLIF Procedure more interchangeable:<sup>277</sup>



In addition, Alphatec documents indicate that Alphatec was specifically targeting NuVasive and the LLIF segment of the MIS Interbody Device Market with its LIF Platform.<sup>278</sup>

**Step 3:** I considered whether NuVasive’s MAS Platform/XLIF Procedure was substantially similar to Alphatec’s LIF Platform. It is my understanding that Dr. Youssef has concluded that from a clinical perspective these platforms have similar characteristics, and that the Alphatec LIF platform did not offer distinguishing features that would have prevented surgeons/hospitals from continuing to use or migrate to NuVasive’s MAS Platform/XLIF Procedure.<sup>279</sup>

“availability” that can impact a surgeon’s decision to use titanium implants, including the length of time the implants have been on the market, use by influential doctors, and availability of clinical data.

<sup>277</sup> See **Schedule 15 - Supplemental**; “U.S. Market Report Suite for Minimally Invasive Spinal Implants”, iData Research, June 2019, p. 220.

<sup>278</sup> See, for example, ATEC\_LLIF000004515 at -517; ATEC\_LLIF000137018 at -019, -023, -026, -035; ATEC\_LLIF000004800 at -803, -811, -816; ATEC\_LLIF000002354 at -356, -367, -368, -370-371.

<sup>279</sup> Expert Report of Jim Youssef Re Damages, dated 11/8/19, para. 27, 30. Opening Expert Report of Jim Youssef, dated 11/20/20, para. 434. Based on discussions with Dr. Youssef.

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**Step 4:** I considered whether NuVasive’s MAS Platform/XLIF Procedure product offering had substantially similar pricing to the product offerings included in Alphatec’s LIF platform. With assistance from Dr. Youssef, I was able to match up comparable product offerings<sup>280</sup> from each platform and confirm that the prices appear to be substantially similar<sup>281</sup> (which is consistent with statements in a sworn declaration from Kelly Howell, Alphatec’s Executive VP of Clinical Strategies that is also a former NuVasive VP).<sup>282</sup>

**Step 5:** I considered whether NuVasive had the manufacturing capacity to achieve the increase in demand that would have occurred “but for” Alphatec’s alleged infringement. As part of this step, I analyzed the relative sales levels and found that the revenue and implant units related to Alphatec’s LIF Platform was very modest compared to NuVasive’s historical MAS Platform/XLIF Procedure revenue and implant units.<sup>283</sup> I gained further confirmation regarding NuVasive’s ability to achieve the additional level of demand by considering NuVasive’s historical sales levels<sup>284</sup>, representations provided by NuVasive<sup>285</sup>, and other information.

**Step 6:** I considered whether NuVasive had the marketing capacity sufficient to achieve the increase in demand that would have occurred “but for” Alphatec’s alleged infringement. Based on the significant amount of customer overlap that has been reported between NuVasive’s and Alphatec’s lateral platforms,<sup>286</sup>

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<sup>280</sup> Expert Report of Jim Youssef Re Damages, dated 11/8/19, para. 2. Opening Expert Report of Jim Youssef, dated 11/20/20, para. 433. Based on discussions with Dr. Youssef.

<sup>281</sup> See **Schedules 14A - Supplemental and 14B**.

<sup>282</sup> 5/16/18 Declaration of Kelli Howell, para. 21.

<sup>283</sup> See **Schedule 15 - Supplemental**.

<sup>284</sup> See **Schedule 18 - Supplemental**; 38th Annual J.P. Morgan Healthcare Conference Investor Presentation, dated 1/15/20 (<https://ir.nuvasive.com/static-files/de4d515c-f55d-499a-96dc-4f53dbc7eea2>).

<sup>285</sup> Based on discussions with Dale Wolf (NuVasive’s Vice President of Manufacturing) and John English (NuVasive’s Vice President of Global Affairs and Distributor Engagement).

<sup>286</sup> See **Schedule 5 - Supplemental**.

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Alphatec’s documents,<sup>287</sup> and representations by John English (NuVasive’s Vice President of Global Professional Affairs and Distributor Engagement), I have concluded that NuVasive had the available marketing capacity to satisfy the increase in demand “but for” Alphatec’s alleged infringement.

**Step 7:** I reconstructed the market to take Alphatec’s alleged infringement out of the picture. In performing this analysis I started with a customer-by-customer analysis that identified the overlap between surgeon-customers that had first used NuVasive’s MAS Platform/XLIF Procedure and then transitioned to using Alphatec’s LIF Platform.<sup>288</sup> This analysis revealed that approximately 68%<sup>289</sup> of Alphatec’s LIF Platform sales were to surgeon-customers who were previously using NuVasive’s MAS Platform/XLIF Procedure.

**Step 8:** I have had multiple detailed discussions with John English (NuVasive’s Vice President of Global Professional Affairs and Distributor Engagement) regarding several high volume MAS Platform/XLIF Procedure surgeon relationships to determine if there were reasons besides Alphatec’s infringement that may have caused surgeon relationships with NuVasive to end or result in lower procedure volumes. While Mr. English identified a number of surgeon relationships that diminished or ended because surgeons were winding down or ending their practice, he was only able to identify one surgeon who left NuVasive because of a relationship issue (Dr. Christopher Blanchard).

**Step 9:** Based on Dr. Youssef’s opinions regarding the NuVasive MAS Platform integrated consumable components that represent a functional unit

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<sup>287</sup> ATEC\_LLIF000003809 at -3810; ATEC\_LLIF000137204.

<sup>288</sup> Mr. English informed me that while hospitals are customers, it’s the surgeons that determine the adoption and use of minimally invasive spinal fusion platform products in lateral procedures.

<sup>289</sup> See **Schedule 15 - Supplemental**.



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(“NuVasive’s Set of Consumable Components”),<sup>290,291</sup> I calculated NuVasive’s average incremental profits (per implant) on neuromonitoring disposables, MaXcess disposables, and implants (accounting for incremental and capital costs).<sup>292</sup> As part of an alternative damages calculation I also consider NuVasive’s average incremental profits (per implant) on specific components.

**Step 10:** I identified orders in Alphatec’s reported sales that based on guidance from Dr. Youssef appear to include a set of consumable components (“Alphatec’s Set of Consumable Components”) that is generally consistent with NuVasive’s Set of Consumable Components.

**Step 11:** Based on the overlap in lateral customers determined in Step 7, I evaluated the level of procedure displacement that occurred (at an implant level) and have assumed, under one damages scenario, that these procedures were lost to NuVasive as a result of Alphatec’s alleged infringement. This assumption is based on my understanding that NuVasive’s customer relationships are long-term or sticky in nature. Furthermore, I have seen no evidence to confirm that “but for” Alphatec’s alleged infringement, surgeons that NuVasive lost to Alphatec, would have taken the necessary steps to transition to other types of procedures or platforms.

**Step 12:** For the non-displaced portion of Alphatec’s Set of Consumable Components (that may not be a direct displacement of procedure volume from surgeon-customers who transitioned from NuVasive’s MAS Platform/XLIF

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<sup>290</sup> It is my understanding from discussions with John English, that a neuromonitoring disposable kit, MaXcess disposable kit, and a PEEK (i.e., CoRoent or Cohere) or porous titanium (i.e., Modulus) implant are used in almost 100% of all XLIF Procedures.

<sup>291</sup> I am relying on the technical and clinical opinions of Dr. Youssef and other information in this case regarding what constitutes a functional unit, and have no independent expert opinions on this subject.

<sup>292</sup> I considered financial records and discussions with Jeff Hoffman, Director of Strategic Pricing at NuVasive for sales/pricing and other information. I considered financial records and discussions with Chris Burton, Senior Director of Finance at NuVasive for incremental cost and other information. I considered financial records and discussions with Megan Price, Director of Finance at NuVasive for capital costs, turns, and other information.

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Procedure to Alphatec’s LIF Platform), I have applied *State Industries, Inc. v. Mor-Flo Industries, Inc.*, 883 F.2d 1573, 1577–80 (Fed. Cir. 1989). This calculation assumes that “but for” Alphatec’s alleged infringement, NuVasive would have captured a share of the non-displaced procedures, in which Alphatec’s Set of Consumable Components were used, that is proportionate to NuVasive’s market share.<sup>293</sup>

**Step 13:** As part of an alternative damages calculation that can be considered should a trier of fact disagree with Dr. Youssef’s opinions regarding the absence of acceptable non-infringing substitutes in the market, I have applied *State Industries, Inc. v. Mor-Flo Industries, Inc.*, 883 F.2d 1573, 1577–80 (Fed. Cir. 1989) to all of the procedure volume related to Alphatec’s Set of Consumable Components. This calculation assumes that “but for” Alphatec’s alleged infringement, NuVasive would have captured a share of Alphatec’s Set of Consumable Components’ procedure volume that is proportionate to NuVasive’s market share.<sup>294</sup>

**Step 14:** I considered evidence in the case regarding the use of implants and disposables as currency for all the platform components used in the procedure and found that, from an economic perspective, this “razor / razor blade” pricing structure adopted by NuVasive and Alphatec appears supportive of and consistent with Dr. Youssef’s functional unit opinions. However, as an alternative damages calculation, I have calculated lost profits in a similar manner to the steps identified above, limiting my analysis to just the incremental profits of the implants or disposables (versus incremental profits on NuVasive’s Set of Consumable Components). These calculations could be considered by a trier of

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<sup>293</sup> See Schedules 1A - Supplemental, 1B - Supplemental, 1C - Supplemental, 1D - Supplemental, 1E - Supplemental, 1F - Supplemental (“Diverted Surgeons and Interbody Device Unit Market Share”).

<sup>294</sup> See Schedules 1A - Supplemental, 1B - Supplemental, 1C - Supplemental, 1D - Supplemental, 1E - Supplemental, 1F - Supplemental (“Interbody Device Unit Market Share Only”).

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fact, to the extent that they disagree with Dr. Youssef’s opinions on a functional unit.

**Step 15:** I limited my lost profits analysis, as described above, to just orders that include components that I understand from counsel are required to be sold together to constitute infringement.<sup>295</sup>

76. **Schedule 1 - Supplemental** summarizes my lost profits conclusions.

## **V REASONABLE ROYALTY**

77. The patent damages statute, 35 U.S.C. § 284, provides that a prevailing patent claimant shall recover “damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use of the invention made by the infringer, together with interest and costs as fixed by the court.” I have performed an analysis of a reasonable royalty for each of the patents-in-suit, that I understand from counsel, can be used as a basis for damages on allegedly infringing sales that are not awarded as lost profits. The following *Georgia-Pacific* factors have been accepted by a number of courts as a list of factors potentially relevant to the determinate of a reasonable royalty:

1. The royalties received by the patent owner for the licensing of the patent-in-suit, proving or tending to prove an established royalty.
2. The rates paid by the licensee for the use of other patents comparable to the patent-in-suit.
3. The nature and scope of the license, as exclusive or non-exclusive, or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold.

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<sup>295</sup> See **Schedule 4 - Supplemental**.

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4. The licensor’s established policy and marketing program to maintain its patent monopoly by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that monopoly.
5. The commercial relationship between the licensor and the licensee, such as whether they are competitors in the same territory in the same line of business, or whether they are inventor and promoter.
6. The effect of selling the patented specialty in promoting sales of other products of the licensee; the existing value of the invention to the licensor as a generator of sales of its non-patented items; and the extent of such derivative or conveyed sales.
7. The duration of the patent and the term of the license.
8. The established profitability of the product made under the patent; its commercial success; and its current popularity.
9. The utility and advantages of the patent property over the old modes or devices, if any, that had been used for working out similar results.
10. The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention.
11. The extent to which the infringer has made use of the invention, and any evidence probative of the value of that use.
12. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.
13. The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.
14. The opinion testimony of qualified experts.
15. The amount that a licensor (such as the patent owner) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount that a prudent licensee – who desired, as a

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business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention – would have been willing to pay as a royalty and yet be able to make a reasonable profit, and which amount would have been acceptable by a prudent patent owner who was willing to grant a license.

78. I have been instructed by counsel to assume the following hypothetical negotiation dates when performing my economic analysis:

- ‘801 Patent, ‘780 Patent, ‘531 Patent<sup>296</sup>, ‘832 Patent, ‘270 Patent, ‘156 Patent, and ‘334 Patent: Just prior to date of first sale on February 14, 2017;
- ‘227 Patent: December 5, 2017; and
- ‘859 Patent: March 27, 2018.

**V.A Factual Support for NuVasive’s Reasonable Royalty Damages**

79. Below is an analysis of some of the facts in the case specific to determining a reasonable royalty. I have organized this analysis (and the related *Georgia-Pacific* factors) into four categories: (1) benefits of the patents-in-suit, (2) licensing factors, (3) profit contribution of the patents-in-suit, and (4) relative bargaining position / hypothetical negotiation. Some information contained or identified in other sections of this report or schedules may apply to one or more of the *Georgia Pacific* factors, but has not been replicated to avoid unnecessary duplication.

**V.A.1 BENEFITS OF THE PATENTS-IN-SUIT**

80. Below is a list of the *GP* Factors that generally relate to gaining an understanding of the benefits of the patents-in-suit.

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<sup>296</sup> I understand from outside counsel for NuVasive that the ‘531 Patent is a continuation of the ‘780 Patent, and that as a result of the relationship between these two patents, I should assume that they would share the same hypothetical negotiation date, just prior to the first sale of accused products.

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**Factor 9:** *The utility and advantages of the patent property over the old modes or devices, if any, that had been used for working out similar results.*

**Factor 10:** *The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention.*

**Factor 11:** *The extent to which the infringer has made use of the invention, and any evidence probative of the value of that use.*

**Factor 14:** *The opinion testimony of qualified experts.*<sup>297</sup>

81. Below is an excerpt from Dr. Youssef’s expert report that summarizes his opinions regarding: (1) the nature of the patents-in-suit, (2) the utility and advantages of the patents-in-suit over old modes, and (3) the benefits of the teachings of the patents-in-suit to Alphatec, its physician customers, and their patients:

**Expert Report of Dr. Jim Youssef**<sup>298</sup>

Throughout my Opening Report, I addressed the (1) the nature of the patents-in-suit, (2) the utility and advantages of the patents-in-suit over old modes, and (3) the benefits of the teachings of the patents-in-suit to Alphatec, its physician customers, and their patients. Opening Report at Sections 10–21. Below, I further address the (1) the nature of the patents-in-suit, (2) the utility and advantages of the patents-in-suit over old modes, and (3) the benefits of the teachings of the patents-in-suit to Alphatec, its physician customers, and their patients.

The ’801 patent, ’780 patent, ’832 patent, ’227 patent, ’859 patent, and ’531 patent each provide systems and methods for the critical steps of a lateral minimally-invasive lumbar trans-psoas interbody fusion—specifically, the critical steps involved in traversing the psoas muscle. In my opinion, because the systems and methods provided by these patents enable the critical steps of a lateral minimally-invasive lumbar trans-psoas interbody fusion, they are the gateway to such a lateral procedure. In addition, the ’801 patent, ’780 patent, ’832 patent, ’227 patent, ’859 patent, and ’531 patent provide other features and benefits that are very important to a (1) safe and reproducible, (2) minimally invasive, and (3) clinically successful procedure. These features and benefits are listed below:

- **Sequential dilators** – provides minimal footprint when creating and maintaining an operative corridor;

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<sup>297</sup> As cited in my report, I have considered expert opinions from other qualified technical and industry experts in this case.

<sup>298</sup> Expert Report of Jim Youssef Re Damages, dated 11/8/19, para. 17-24. Based on discussions with Dr. Youssef.

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- **Neuromonitoring-enabled dilators** – detects the nerves located in the psoas muscle that form the lumbar plexus to avoid nerve damages while forming operative corridor;
- **Three-bladed retractor** – maintains the operative corridor in a lateral approach by reducing unnecessary retraction in the cranial and caudal directions and minimizing potential injury to the nerves;
- **Movement of retractor blades (cranial/caudal move away from each other; posterior blade moves linearly away from cranial/caudal blades)** - allows expansion of operative corridor to (1) expose only the annulus contributing to minimization of trauma to the psoas muscle and nerves; (2) prevents tissue creep; and (3) accommodate sufficient size implant;
- **Pivoting cranial/caudal retractor blades** – allows for further customization of operative corridor, including to provide access to lateral plate fixation or during corpectomy rather than placing a lateral interbody fusion implant alone;
- **Releasable coupling of retractor blades** – allows for use of different length blades to accommodate different anatomic requirements of a patient, such as deformity or when there are other anatomic variances;
- **Generally concave blades** - allow for placement of the light emitting device to allow the surgeon to have better visualization through the operative corridor (without the light source getting in the way).

The '801 patent, '780 patent, '832 patent, '270 patent, '859 patent, and '531 patent each provide another very important technical and clinical contribution in the form of an intradiscal shim. The intradiscal shim synergistically functions with the other components used in the procedure to stabilize the retractor and provide an operative corridor through which a surgeon can place an implant. Thus, the '801 patent, '780 patent, '832 patent, '270 patent, '859 patent, and '531 patent provide a feature that is very important to a (1) safe and reproducible, (2) minimally invasive, and (3) clinically successful procedure. This feature is listed below:

- **Shim** – engages the posterior retractor blade to minimize overexpansion of operative corridor, stabilizes the retractor, and helps minimize tissue/nerve creep.

The '801 patent provides another technical and clinical contribution in the form of a shim inserter that is very important to a (1) safe and reproducible, (2) minimally invasive, and (3) clinically successful procedure:

- **Shim inserter** – allows detachable placement of shim to a retractor blade.

The '801 patent, '780 patent, '832 patent, '859 patent, and '531 patent each provide another technical and clinical contribution in the form of a K-wire that is very important to a (1) safe and reproducible, (2) minimally invasive, and (3) clinically successful procedure:



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- **K-Wire** – guides and stabilizes minimally invasive tools.

The '832 patent provides another technical and clinical contribution in the form of a light emitting device that is very important to a (1) safe and reproducible, (2) minimally invasive, and (3) clinically successful procedure:

- **Light emitting device** – permits better visualization through operative corridor.

The '859 patent provides other technical and clinical contributions in the form of a fourth retractor blade, attachment crossbar, and table fixation arm. These contributions are very important to a (1) safe and reproducible, (2) minimally invasive, and (3) clinically successful procedure:

- **Fourth retractor blade** – permits further stabilization of the retractor and protects great vessels during resection of the anterior longitudinal ligament (ALL);
- **Fourth retractor blade attachment crossbar / depth markings** – allows for greater control over 4th blade (including control over the depth) and placement of the fourth blade to identify the anterior longitudinal ligament and the anterior boundary of the spine at the desired operative level; also helps avoid tissue creep and allows for placement of larger (i.e. 22or 26mm) implants;
- **Table fixation arm** – allows for stabilization of the retractor position.

The '531 patent provides other technical and clinical contributions as it extends beyond just the access tools and also covers the use of implants. While there are features of Alphatec’s LIF implant that are not claimed by the '531 Patent (i.e. the implant is made of PEEK material, is available in parallel and lordotic varieties, is available in a variety of width and height options, and is cleared for use with autograft and allograft biologic materials), it is important to recognize that the use of the '531 Patent provides a gateway to these benefits. Thus, '531 patent provides features that are very important to a (1) safe and reproducible, (2) minimally invasive, and (3) clinically successful procedure:

- **Placement of an implant** – allows for spinal fusion.

**Supplemental Expert Report of Dr. Jim Youssef**<sup>299</sup>

439. Each of the asserted implant patents individually, and collectively, provides significant contributions towards making a spinal fusion procedure more: (1) safe and reproducible, (2) minimally invasive, and (3) clinically successful, which, in my opinion, are the primary criteria surgeons consider when using / adopting a lateral platform, such as Alphatec's LIF Platform and NuVasive's MAS platform. Furthermore, I understand that they represent the

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<sup>299</sup> Opening Expert Report of Jim Youssef, dated 11/20/20, para. 439-445. Based on discussions with Dr. Youssef.

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three primary drivers of demand for Alphatec's accused products. Throughout my Opening Report and this report, I addressed the (1) the nature of the asserted implant patents, (2) the utility and advantages of the asserted implant patents over old modes, and (3) the benefits of the teachings of the asserted implant patents to Alphatec, its physician customers, and their patients. Opening Report at Sections 10–21; Section X above. Below I further address (1) the nature of the asserted implant patents, (2) the utilities and advantages of the asserted implant patents over old modes, and (3) the benefits of the teachings of the asserted implant patents to Alphatec, its physician customers, and their patients: 440. The '156 patent and '334 patent each provide the key aspects of implant design for lateral minimally-invasive lumbar trans-psoas interbody fusion—specifically, key design aspects in the following categories: (1) design and dimensions; (2) implant material; (3) radiopaque markers; and (4) anti-migration elements. All of these key aspects allow a lateral implant to achieve fusion of two contiguous vertebrae in a safe and reproduceable, minimally-invasive, and clinically-successful way. I address each in turn below.

441. Design and Dimensions. The '156 patent and the '334 patent both teach the design and dimensions of a spinal implant that provides important benefits for a lateral lumbar interbody fusion procedure. Generally, the patents in suit claim an elongated implant, i.e. the implant's longitudinal length is greater than a maximum lateral width. This allows a large implant to be placed in a minimally invasive procedure while reducing the amount that the psoas muscle must be distracted in order to place the implant. The elongated shape also allows the implant to span the ring apophysis (the disc space). Because the implant spans the ring apophysis it provides the best stability and maximum vertebral body support. Additionally, the elongated shape provides a greater surface area in contact with the vertebral bodies, which lowers the risk of subsidence, increases spinal stability, and provides improved indirect compression. This help to reduce the risk of post-operative infection. Moreover, the implant has at least one fusion aperture that allows placement of bone graft material to promote better fusion. The elongated shape allows for the apertures to be larger, which allows placement of more bone growth material and a greater likelihood of achieving a successful fusion due to the large apertures that allow more bone growth through the implant. Additionally, the '156 patent teach alternatively using parallel or angled surfaces to accommodates alignment for different patient anatomy, such as lordosis. The '156 patent also it teaches a medial support, which creates two fusion apertures. The medial support strengthens the implant, provides additional stability and also aids with graft containment. As to the '334 patent, it teaches an implant with a longitudinal length that is 2.5 times greater than the implants maximum lateral width which provides an elongated implant that can be used in a lateral procedure yet still provide substantial coverage of the vertebral bodies.

442. Implant Material. The '156 patent and the '334 patent both teach an implant made of radiolucent material, such as PEEK. This provides a number of

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important benefits. First, it allows the surgeon to view radiopaque markers to visualize proper alignment in the disc space via anterior/posterior and lateral fluoroscopy (which the surgeon would otherwise be unable to do with an implant made from a radiopaque material). Second, it allows the surgeon to view bone growth radiographically in post-op imaging and confirm that a successful fusion has occurred. Additionally, the '156 patent teaches the use of PEEK, a biocompatible, non-bone, radiolucent material with significant compressive and fatigue strength and material properties that closely approximate the properties of bone. The modulus of elasticity for PEEK is similar to bone, which means that once fusion has occurred and the fused vertebrae are loaded, the load is shared equally between the new bone growth due to fusion and the body of the implant. Implants made of other materials that are too stiff (such as titanium) do not perform as well under load because they do not achieve optimal load sharing. Additionally, implants made of titanium, which is radiopaque, create problems during the procedure because it is harder to determine with standard fluoroscopy if there is damage to the vertebral endplates, whether the implant has gone beyond the confines of the interbody space, and whether the implant is aligned correctly. Furthermore, in post-op imaging using CT or MRI, titanium causes scatter, which exacerbates those problems and also makes it difficult to assess fusion and whether certain complications have occurred potential problems, such as subsidence, loosening, and whether there is residual stenosis.

443. Markers. The '156 and '334 patents both teach radiopaque markers that provide important benefits. The location of the markers allows the surgeon to visualize proper alignment and placement in the disc space via anterior/posterior and lateral fluoroscopy. The patents teach that the markers are placed in locations that are critical to alignment. The '156 patent teaches markers parallel to the height of the implant in the first and second sidewall proximate to the medial plane of the implant. The '334 patent teaches at least three markers, one in the distal wall, a second in the proximal wall, and at least one in a central region. Markers placed in these locations allow the surgeon to see the boundaries of the implant and where the medial plane is located. This is important so that the surgeon can avoid injuring nearby anatomic structures during placement of implant. For lordotic implants, the markers also allow a surgeon to confirm alignment for lordosis. The location of markers proximate to the medial plane (in the central region) is beneficial because it allows a surgeon to assure that the implant is in the midpoint of vertebral body. This placement is optimal because it provides the best stability and maximum vertebral body support. The location of markers in the distal and proximal walls is important because it allows the surgeon to confirm that the implant is the correct length, to avoid impacting the implant to far, and to make sure that the implant is not protruding.

444. Anti-Migration Elements. The '156 and '334 patents both teach anti-migration elements that provide important benefits. The antimigration elements that engage the adjacent vertebral endplates to prevent migration out of the

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disc space. When the implants are made of a radiolucent material like PEEK, the top and bottom surfaces would typically be smooth which could allow migration of the implant before or during bone growth to achieve fusion. The claimed antimigration elements create interference to keep implants from moving during the critical period after a fusion surgery when bone is growing through the fusion apertures.

445. As I explained in Paragraph 6 of my November 8, 2019 Damages Report, implants are one of the three main components necessary for performance of an XLIF procedure – (1) access tools; (2) implants; and (3) neuromonitoring. As I further explained, each of these components contributes equally but in different ways to the adoption and continued use of the XLIF procedure and platform. Based on my analysis of the technical and clinical contributions of the asserted implant patents, each provides important contributions to the safety and reproducibility, minimally-invasiveness, and successful clinical outcome of a lateral lumbar interbody fusion procedure.

82. Alphatec has reported approximately \$24.5 million in LIF Platform sales from February 2017 through September 2020.<sup>300</sup> Alphatec’s own documents and testimony provide insights into the importance of the patented features in the LIF Platform to its overall product offering, as well as to its physician customers and their patients.

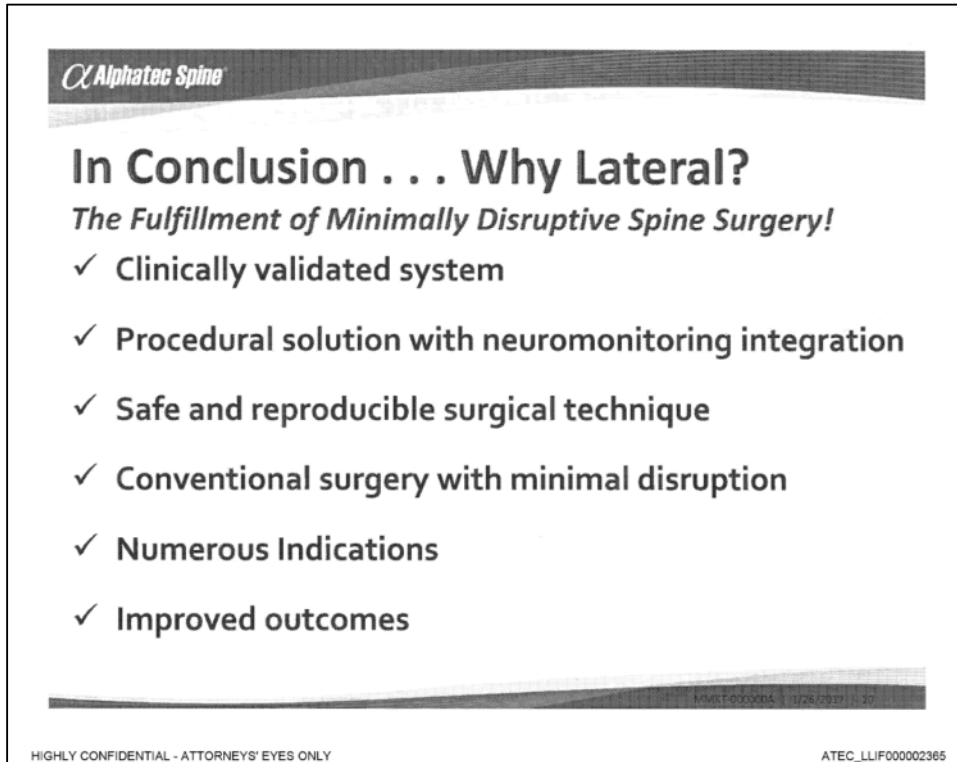
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<sup>300</sup> See Schedule 4 - Supplemental.

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**Benefits to Alphatec**

**Alphatec Presentation: “2017 LLIF Information Session” (December 2016)**<sup>301</sup>




**Alphatec “Integrated Project Charter for “Lateral Lumbar Interbody Fusion (LLIF) System” (7/14/14)**<sup>302</sup>

Retractor performance will be critical to the acceptance of the product by the market.

<sup>301</sup> ATEC\_LLIF000002354 at -356, -365-366.


<sup>302</sup> ATEC\_LLIF000004800 at -803, -810-811.

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		<b>Integrated Project Charter</b>
<b>Project No:</b> 13-002		
<b>Project:</b> Lateral Lumbar Interbody Fusion (LLIF) System		<b>Rev:</b> A
<b>Prepared By:</b> David Blagborne		<b>Date:</b> 7/14/2014
Other Product Information		
Element	Definition	Element Description
<b>Preliminary Technology Assessment</b>	Describe critical technology required or anticipated and its availability.	<ul style="list-style-type: none"> <li>▪ Retractor performance will be critical to the acceptance of the product by the market. The largest two factors that will affect this are the retractor adjustment mechanisms and the retractor assembly materials. Manufacturing processes and coatings, new to Alphatec, may be explored as a mean to achieve performance. Materials new to Alphatec, such as fiber reinforced composites, may also be explored as options to achieve high performance. These will involve identification of key suppliers who currently possess these skills and knowledge so that the internal knowledge can be built.</li> <li>▪ Implant performance has one critical area, the implant to instrument interface. Loads during insertion are typically high and failures of implant or instrument are not uncommon. This will require the use of nonstandard test methods to characterize component performance.</li> <li>▪ Instrument performance has two critical areas: one area is the profile of the instruments with respect to the possibility that it can get stuck or hung up on the anatomy or other instrumentation, the second area is the ability of the instrumentation to provide anatomical measurement feedback intra-operatively. This will require the collection of user feedback to properly determine the effectiveness of proposed solutions.</li> </ul>

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The purpose of the project is to develop a LLIF system that will directly challenge the top competitors for their market share. The means for accomplishing this will be to develop technologies and products that clinically outperform the current offerings of the top competitors. **The high level project objective is to develop a comprehensive system** that addresses the majority of the market’s LLIF needs.

			<b>Integrated Project Charter</b>		
<b>Project No:</b> 13-002					
<b>Project:</b> Lateral Lumbar Interbody Fusion (LLIF) System				<b>Rev:</b> A	
<b>Prepared By:</b> David Blagborne				<b>Date:</b> 7/14/2014	
<b>Other Product Information</b>					
<b>Element</b>		<b>Definition</b>		<b>Element Description</b>	
<b>Redacted</b>					
<b>Product Interactions</b>		Describe the relationship of this product to other products and services.		<ul style="list-style-type: none"> <li>The LLIF system will receive indications that require supplemental posterior fixation. Alphatec products that can be used to satisfy supplemental fixation need are: ilico MIS, ilico FS, Arsenal, Arsenal CBX and Bridgepoint. Alternative Alphatec products that may be used when the LLIF system is contra-indicated for use are: Battalion P, Novel SD, Novel Tapered TL, Novel ALS, Epicage &amp; Alphatec Solus.</li> </ul>	
<b>Project Context</b>					
<b>Element</b>		<b>Definition</b>		<b>Element Description</b>	
<b>Project Purpose</b>		A concise description of the project objective, timeframe, and cost.		The purpose of the project is to develop a LLIF system that will directly challenge the top competitors for their market share. The means for accomplishing this will be to develop technologies and products that clinically outperform the current offerings of the top competitors. The high level project objective is to develop a comprehensive system that addresses the majority of the market’s LLIF needs. This project is NOT intended to enter or create ‘niche’ LLIF markets. The timeframe for obtaining this objective will begin in Q3 2014 with an initial launch in Q3 2015 and will cost \$1.6M (R&D portion of the budget) to develop.	

**Alphatec Document “Market Need / Assessment Request, Concept: Direct Lateral” (4/17/13)<sup>303</sup>**

**Describe significance of need for Market and/or Alphatec Spine:**

Direct lateral is one of the fastest growing segments in Spine. Not having a solid option losses [sic] both revenue and opportunity. As surgeon[s] switch to Direct Laterals we miss their interbody business and give relationship opportunities to other companies. Additionally attracting bigger distributors is an issue when we have not direct lateral option and most have customers that perform direct lateral surgeries.



<sup>303</sup> ATEC\_LLIF000003809.



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**Describe how current Products do or do not address Need:**

...We do have custom direct lateral sets being developed for the short term but without a retractor option growth in the market will be extremely limited.

 <b>Market Need/Assessment Request</b>	
<b>Concept:</b> Direct Lateral	
<b>Prepared By:</b> Derek Kuypers	
<b>Signature:</b> 	<b>Date:</b> 4/17/13
<b>Market Need:</b>	
<p><b>Describe significance of need for Market and/or Alphatec Spine:</b>                  Direct lateral is one of the fastest growing segments in Spine. Not having a solid option losses both revenue and opportunity. As surgeon switch to Direct Laterals we miss their interbody business and give relationship opportunities to other companies. Additionally attracting bigger distributors is an issue when we have no direct lateral option and most have customers that perform direct lateral surgeries.</p>	
<p><b>Describe how current Products do or do not address Need:</b>                  GLIF was not commercially successful, this was supposed to be our entry into the Direct Lateral market but this has never actually come to fruition. We do have custom direct lateral sets being developed for the short term but without a retractor option growth in the market will be extremely limited.</p>	

**Key Features/Benefits – Business:**

1. Entry into a highly profitable (still good pricing to its recent entry into the market) and high growth market.

**...[W]hat are the key success factors?**

Recent literature suggests that limiting the retraction window in the Psoas and limiting retraction time has greatly beneficial effects on the adverse events limited to the approach. We should focus efforts on a intuitive speedy system that requires as little retraction as possible for achieving desired exposure.

<p><b>If so, what are the key success factors (?):</b></p> <p>Recent literature suggests that limiting the retraction window in the Psoas and limiting retraction time has greatly beneficial effects on the adverse events limited to the approach. We should focus efforts on a intuitive speedy system that requires as little retraction as possible for achieving desired exposure.</p> <p>Having a robust training program with reps trained on patient positioning prior to surgery, specific to unique anatomy's and competent in working with the fluoro tech help expedite surgery and encourage adoption.</p>
--

**State Key Upsides:**

- Stop losing current customers switching to the direct lateral approach.
- Attract better and larger distributors by having a good direct lateral option.

<p><b>Declining Sales?:</b> <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO</p> <p><b>If Yes, Reason for decline (?):</b></p> <p>As surgeons learn the lateral approach they stop performing ALIF's and TLIF's with the same volumes. Without an option we miss this percentage of their cases.</p> <p><b>State Key Upsides (i.e. – pull through of other product lines)?:</b></p> <ul style="list-style-type: none"> <li>• Stop losing current customers switching to the direct lateral approach.</li> <li>• Attract better and larger distributors by having a good direct lateral option.</li> <li>• With the release of an eventual deformity system new lab's focused on advanced techniques for deformity correction should be a large draw for many surgeons. We can also train on new trauma techniques with the release of an expanding corpectomy and thoracic plating/lateral access system.</li> </ul>
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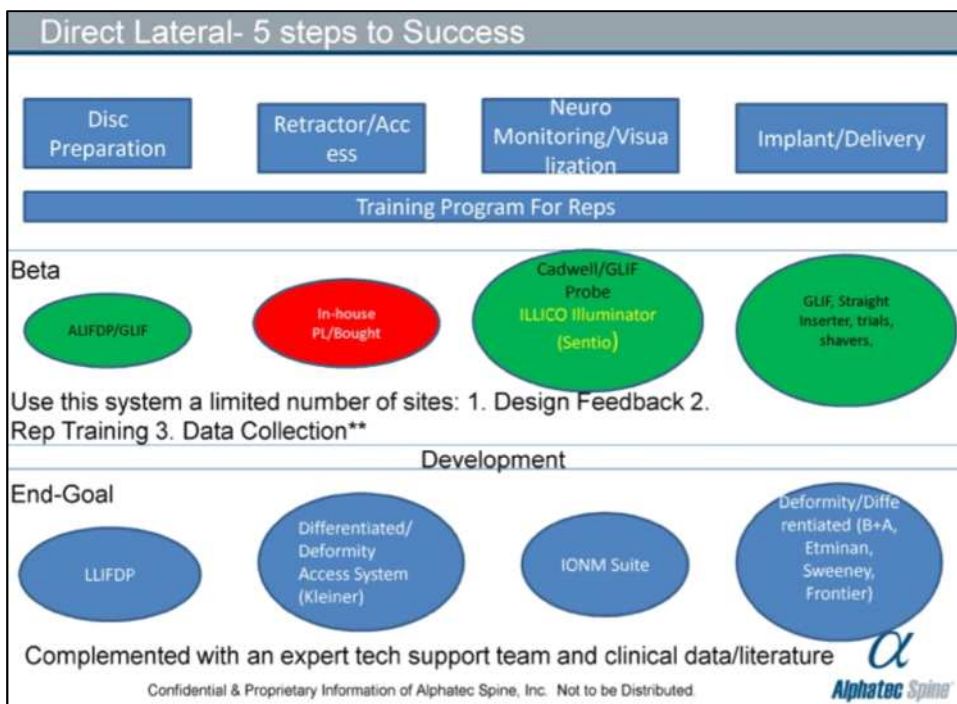
**Direct Lateral - Market Need**

**Market Need**

•Significance of Need

- Direct Lateral has and continues to be one of the fastest growth markets in Spine.
- Secondary Research sources report the market in 2013 to be worth 300-400 million and at around an 8% growth rate.
- We lose business as surgeons switch X% of their practice to direct lateral procedures.
- Attributing larger distributors and new distributors becomes problematic without a direct lateral option. This gives them the option to carry other products in their bag, making exclusivity contracts problematic.
- Surgeons are introduced to competitive product reps/companies when they perform direct laterals currently.
- GLIF is not a sustainable option due to its failure to commercialize which has proven multi-factorial.
- IMPORTANT TO ADDRESS (“Preaching to the choir?”)!

**Alphatec Presentation “Direct Lateral Project: Phase 0 Update”<sup>304</sup>**



<sup>304</sup> ATEC\_LLIF000004515.

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**Alphatec Press Release: “Alphatec Spine Launches Battalion™ Lateral System with Squadron™ Retractor to Support Minimally Invasive Lateral Access Procedures” (4/7/17)**<sup>305</sup>

Squadron™ Lateral Retractor designed to improve patient outcomes

The launch of Battalion Lateral represents a significant milestone for Alphatec, opening up new commercial opportunities for us. With this launch, we are now able to compete in the MIS Lateral market—one of the fastest growing markets in spine,” said Terry Rich, Alphatec Spine’s Chief Executive Officer. ‘The Battalion Lateral System includes our proprietary Squadron Retractor that is designed to enhance the surgeon’s experience and improve clinical outcomes. Early feedback from surgeon customers has been very positive regarding the system performance, differentiated feature set and ability to successfully treat even the most complex patient cases with a minimally invasive approach. The launch of Battalion Lateral also enables Alphatec to access new distributors with strong surgeon relationships in the Lateral space. We look forward to expanding into this new market and increasing surgeon adoption.

**4/7/17 Article “Alphatec launches device for MIS lateral access procedures — 5 takeaways”**<sup>306</sup>

The company hopes the new device helps it compete in the \$500 million U.S. lateral market.

**Alphatec Earnings Call Transcripts**

We are extremely excited for the full commercial launch of the Battalion Lateral System late this year. This innovative product fills a gap in our portfolio, opening up a large, \$500 million dollar market opportunity, and allowing us to compete for the first time in one of the fastest growing segments in spine. The Battalion Lateral System is truly the next generation in MIS lateral spine surgery. The Squadron Lateral Retractor, a key component of the system, has been uniquely designed with considerable surgeon input to improve outcomes by minimizing psoas retraction time.<sup>307</sup>

We just returned from a very successful North American Spine Society Conference in late October. There, we met with prominent spine surgeons from around the world, enthusiastically driving home the message of the revolution and the spirit of innovation that is building at the new Alphatec. The reception

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<sup>305</sup> <http://investors.alphatecspine.com/news-releases/news-release-details/alphatec-spine-launches-battaliontm-lateral-system-squadrontm>. See also ATEC\_LLIF000847568.

<sup>306</sup> <https://www.beckersspine.com/orthopedic-a-spine-device-a-implant-news/item/36140-alphatec-launches-device-for-mis-lateral-access-procedures-5-takeaways.html?tmpl=component&print=1>.

<sup>307</sup> ATEC\_LLIF000496089 at -094-095 [emphasis added].

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we received was exceptional, with strong surgeon interest in our new spine-experienced team and in our portfolio. Surgeons were especially impressed with the official introduction of the Battalion Lateral System, our next-generation procedural solution for lateral spine surgery.

*Brooks Gregory O’Neil, Lake Street Capital Markets, LLC, Research Division:*

Great. And then could you talk a little bit about Squadron? I noticed that in the press release you highlighted the success with Battalion at North American Spine. What does Squadron do for you?

*Terry M. Rich, Chief Executive Officer and Director:*

Yes. So Battalion is really the name that outlines our current interbody portfolio, and Squadron is a retractor. So what we're talking about is the combination of the 2 as our lateral procedural solution. And the initial launch of this was at NASS, and it's been received very well. We're very excited about the surgeon feedback that we've gotten and look forward to continuing to build out on that platform.<sup>308</sup>

**11/9/17 Alphatec Press Release “Alphatec Holdings, Inc. Reports Third Quarter 2017 Financial Results”<sup>309</sup>**

*Organizational, Commercial, and Product Highlights*

Commercially launched the **Alphatec Squadron™ Lateral Retractor, a key component of the Battalion® Lateral System**, in October. [emphasis added]

**Alphatec Document “Market Need/Assessment Request: Project Lateral Lumbar Interbody Fusion (LLIF)” [undated]<sup>310</sup>**

**Describe how current Products do or do not address Need:**

A lateral interbody cage rests from apothecial ring to apothecial ring, laterally across the disc space. Alphatec does not have a cage in its portfolio that is appropriate for this space.

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<sup>308</sup> Alphatec Holdings, Inc. FQ3 2017 Earnings Call Transcript.

<sup>309</sup> <http://investors.alphatecspine.com/news-releases/news-release-details/alphatec-holdings-inc-reports-third-quarter-2017-financial>.

<sup>310</sup> ATEC\_LLIF000003829.

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**Key Features/Benefits:**

*Initial clearance for the Lateral cage offering will include required testing parameters for all future planned platforms.*

**Stage 1: (BETA)**

- Standard and wide offering on interbody cages ( market standard is 18mm and 22mm wide)
- Heights from 8mm-16mm (2mm increments)
- Lengths from 40mm to 60mm (5mm increments)
- 0° and a lordotic offering
- InTech Retractor (Licensed)
- Beta disc preparation instruments (*specified below*)

FRM-000196B – Market Need-Assessment Request (MNAR) Form Page 2 of 7

**State Key Upsides (i.e. – pull through of other product lines)?:**

With LLIF currently at ~10% of the fusion market, Alphatec has left revenue on the table by not having a Lateral System to sell. Medium to Large distributors are looking for a ‘complete bag’ to sell and without a LLIF option, we may are [sic] not considered as an option for them to partner with.

As we grow our lateral proficiency, our reps will be more educated and valued in the OR. This has been proven to strengthen the relationship between rep and surgeon. The training provided for surgeons helps build loyalty between surgeon and the company that provides the thorough training.

LLIF as a product group at full execution would likely include a series of surgeon and rep trainings including Thoracic LLIF, Lateral Corpectomy, Advanced Deformity, etc. All these training can include pull through products such as pedicle screws, interspinous clamps, facet screws, new products such as lateral plates, lateral staple systems, etc.

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**V.A.1.a Benefits to Surgeon-Customers and Patients**

**V.A.1.a.1 Benefits to Surgeon-Customers and Patients: Access Patents**

**Alphatec Presentation: “A Leading Provider of Advanced Spinal Fusion Platforms and Systems”<sup>311</sup>**

“Stable, reproducible surgical pathway”

“Improved patient outcomes”

“Increased safety”

**Lateral Platform Overview**

Lateral: Highly differentiated and unique system

Market Need	Key Platform Features	Designed for Clinical & Economic Advantages
Next-generation lateral lumbar retractor system with improved functionality and increased patient safety	<ul style="list-style-type: none"> <li>✓ Lateral retractor with unrivaled, unique design characteristics</li> <li>✓ 3-blade system with 4<sup>th</sup> blade option</li> <li>✓ Auto compensates to prevent blades from lifting when toed</li> <li>✓ Easy, in-situ blade height adjustment and blade replacement</li> <li>✓ DLC anti-glare and anti-scratch coating</li> </ul>	<ul style="list-style-type: none"> <li>✓ Reduced chance of tissue or muscle creep, enabling more clear view of the spine</li> <li>✓ Stable, reproducible surgical pathway</li> <li>✓ Increased ability to access the spine in more lateral difficult cases</li> <li>✓ Improved patient outcomes</li> <li>✓ Less operative time per surgical case</li> <li>✓ Increased safety</li> </ul>

Lateral Lumbar (LLIF) System

\$600M  
2016

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**Alphatec’s Battalion Lateral Surgical Technique Guide<sup>312</sup>**

The Squadron Retractor Lateral Access System has been designed to allow for the use of neuromonitoring based on the surgeon’s discretion and may be used with many commercially available neuromonitoring systems.

**Alphatec Document “Integrated Project Charter – Project: Lateral Lumbar Interbody Fusion (LLIF) System” (7/14/14)<sup>313</sup>**

**Describe critical technology required or anticipated and its availability.**

<sup>311</sup> ATEC\_LLIF000854436 at-458.

<sup>312</sup> Exhibit U to the Complaint.

<sup>313</sup> ATEC\_LLIF000137204.



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- Retractor performance will be critical to the acceptance of the product by the market. The largest two factors that will affect this are the retractor adjustment mechanisms and the retractor assembly materials.
- Implant performance has one critical area, the implant to instrument interface.
- Instrument performance has two critical areas: one area is the profile of the instruments with respect to the possibility that it can get stuck or hung up on the anatomy or other instrumentation, the second area is the ability of the instrumentation to provide anatomical measurement feedback intra-operatively.

Other Product Information		
Element	Definition	Element Description
Preliminary Technology Assessment	Describe critical technology required or anticipated and its availability.	<ul style="list-style-type: none"> <li>Retractor performance will be critical to the acceptance of the product by the market. The largest two factors that will affect this are the retractor adjustment mechanisms and the retractor assembly materials. Manufacturing processes and coatings, new to Alphatec, may be explored as a means to achieve performance. Materials new to Alphatec, such as fiber reinforced composites, may also be explored as options to achieve high performance. These will involve identification of key suppliers who currently possess these skills and knowledge so that the internal knowledge can be built.</li> <li>Implant performance has one critical area, the implant to instrument interface. Loads during insertion are typically high and failures of implant or instrument are not uncommon. This will require the use of nonstandard test methods to characterize component performance.</li> <li>Instrument performance has two critical areas: one area is the profile of the instruments with respect to the possibility that it can get stuck or hung up on the anatomy or other instrumentation, the second area is the ability of the instrumentation to provide anatomical measurement feedback intra-operatively. This will require the collection of user feedback to properly determine the effectiveness of proposed solutions.</li> </ul>

**4/7/17 Article “Alphatec launches device for MIS lateral access procedures — 5 takeaways”<sup>314</sup>**

The Squadron Retractor is fully compatible with most neuromonitoring platforms allowing safe access through the psos.

<sup>314</sup> <https://www.beckersspine.com/orthopedic-a-spine-device-a-implant-news/item/36140-alphatec-launches-device-for-mis-lateral-access-procedures-5-takeaways.html?tmpl=component&print=1>.



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**2Q2017 Alphatec Earnings Call Transcript**<sup>315</sup>

The second key initiative that we are prioritizing as we reposition the Alphatec brand is innovation focused on improving clinical outcomes. And to that point, we are expanding Alphatec's comprehensive spine fusion offering this year with 3 advanced platforms that will address sizable new market opportunities. We are extremely excited for the full commercial launch of Battalion Lateral System late this year. This innovative product fills a gap in our portfolio, opening up a large \$500 million market opportunity and allowing us to compete for the first time in one of the fastest-growing segments in spine. The Battalion Lateral System is truly the next-generation MIS lateral spine surgery. The Squadron Lateral Retractor, a key component of the system, has been uniquely designed with considerable surgeon input to improve outcomes by minimizing psoas retraction time.

**2017 Alphatec SEC Filing Form 10-K**<sup>316</sup>

**MIS Products**

*Battalion Lateral Spacer System and Squadron Lateral Retractor*

The Battalion Lateral Spacer System with the Alphatec Squadron Lateral Retractor provides surgeons with a next-generation lateral system with innovative, unique design characteristics including, blade control technology that allows the surgeon to maintain approach aperture throughout the procedure, blade height adjustment and blade replacement, combined with the Battalion Lateral Spacer is available in a variety of width and height options for lumbar and thoracic approaches. Our Battalion lateral spacer system and Squadron lateral retractor received clearance of a FDA 510-(k) premarket notification from the U.S. Food and Drug Administration, or FDA, in 2016 and we commercially launched this solution in late 2017.<sup>317</sup>

**Article “How companies are actively driving growth in the minimally invasive spinal surgery market” (3/28/18)**<sup>318</sup>

The major procedural drivers for MIS technology are its widely-known clinical benefits. Rather than using a large opening, MIS approaches create small ports of entry for the procedure. This method reduces muscle and tissue damage, decreases complications and extends the intraoperative time limit. As a result, recovery times can be lessened for patients while simultaneously increasing the

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<sup>315</sup> Alphatec Holdings, Inc. FQ2 2017 Earnings Call Transcript.

<sup>316</sup> Alphatec Holdings, Inc., Form 10-K for the fiscal year ended December 31, 2017.

<sup>317</sup> Alphatec Holdings, Inc., Form 10-K for the fiscal year ended December 31, 2017.

<sup>318</sup> <https://www.beckersspine.com/mis/item/40494-how-companies-are-actively-driving-growth-in-the-minimally-invasive-spinal-surgery-mark>.

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number of procedures a physician could perform within a given amount of time, compared to the open approach.

....

While these benefits appear obvious, promoting and publicizing clinical research is important for companies. Fortunately, the innovative nature of the MIS market means that studies are often underway or being published. This includes ongoing studies on established segments of the MIS industry. In February 2017, the U.K.-based National Industry for Clinical Excellence (NICE) published a comprehensive literature review on the efficacy of the lateral approach. Reviewing over 200 articles, the study found a weighted average rate of fusion of 94%, as well as a weighted average of 60% for improvement in pain. This is a positive endorsement for MIS technologies, such as the lateral XLIF® procedure through which NuVasive established itself. The company reported that it had submitted a body of internal data for the purposes of the study.

....

MIS interbody devices tended to be priced more highly compared to standard counterparts. Companies marketing both categories will be able to make use of the opportunities afforded by each. The incentive for such variance may be one reason why MIS companies are rapidly expanding their portfolios.

**iData Market Report “U.S. Market Report Suite for Minimally Invasive Spinal Implants – 2017”<sup>319</sup>**

*6.1.1.5 eXtreme Lateral Interbody Fusion*

The extreme lateral interbody fusion (XLIF®) procedure is a popular lateral fusion approach developed by NuVasive. The procedure involves a lateral, or side, approach to the patient, rather than from the back or front. The XLIF® approach provides direct access to the disc space, allowing for complete disc removal and implant insertion. The XLIF® procedure also makes use of NuVasive’s NeuroVision® neuromonitoring software to protect nerve bodies.

When compared to traditional spine procedures, which approach patients from the back or front and take many hours to complete, the XLIF® procedure may be successfully completed in as little as one hour, reducing the length of time that the patient must be anesthetized. Because the procedure does not require entry through the sensitive back muscles, bones or ligaments, many patients walk the same day after surgery. Patients who undergo an XLIF® procedure typically require only an overnight hospital stay and generally complete their recovery in approximately six weeks. Patients of traditional procedures can experience several days of immobility and may require six months or more to fully recover.

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<sup>319</sup> NR0058023.

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**Reply Declaration of Matt Link (NuVasive’s former President)**<sup>320</sup>

During this period, NuVasive developed nerve monitoring enabled dilators and access tools along with specialized implants. These specialized components allowed surgeons to safely and reproducibly perform spinal fusion surgery by accessing the patient’s lumbar spine along a lateral path through the nerve-rich psoas muscle. They included what ultimately became the MaXcess® line of retractors, which have a unique three-bladed design with specialized fixation elements and may also be nerve monitoring enabled. They also included what ultimately became the CoRoent® XL line of implants, which are specifically designed for lateral insertion.<sup>321</sup>

Additionally, NuVasive developed a number of implants specially designed for use in the XLIF procedure. One such set of implants is the CoRoent® XL line of implants. The CoRoent® XL implants are elongated (allowing the implant to span across the disc space), incorporate radiopaque markers that allow the surgeon to visualize proper alignment in the disc space via anterior/posterior and lateral fluoroscopy (which the surgeon would otherwise be unable to do), and contain ridges and teeth that engage the adjacent vertebral endplates to prevent migration out of the disc space. The figures below depict the CoRoent® XL implants.<sup>322</sup>

In my experience, technologies that contribute significantly to the safety and reproducibility of lateral procedures, such as the features in the XLIF platform that I understand are set forth in NuVasive’s XLIF patents, represent important drivers of demand for XLIF products and are highly desired by the surgeons that rely on them.

The first key differentiating feature NuVasive has long emphasized as providing safer and more reproducible surgeries over its lateral competitors is a three-bladed retractor that allows the cranial and caudal blades to retract away from the fixed posterior blade. NuVasive markets this feature to surgeons as creating an operative corridor that is only as large as the surgeon needs to remove the diseased/damaged disk and place the implant, with the resulting minimized retraction leading to reduced psoas and nerve trauma, unlike other two- and three-bladed retractors on the market without this feature. I note that Ms. Howell confirmed the benefits of such a three-bladed retractor during her deposition, Reply Devine Ex. H (Howell Tr.) at 80:6-81:19, and in fact noted that surgeons preferred NuVasive’s three-bladed retractor “open[ing] the space in that front-to-back orientation versus top-to-bottom orientation” because it provided “anatomical[.]” benefits, id. at 118:9-119:7.<sup>323</sup>

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<sup>320</sup> 6/14/18 Reply Declaration of Matthew Link in Support of Motion for Preliminary Injunction.

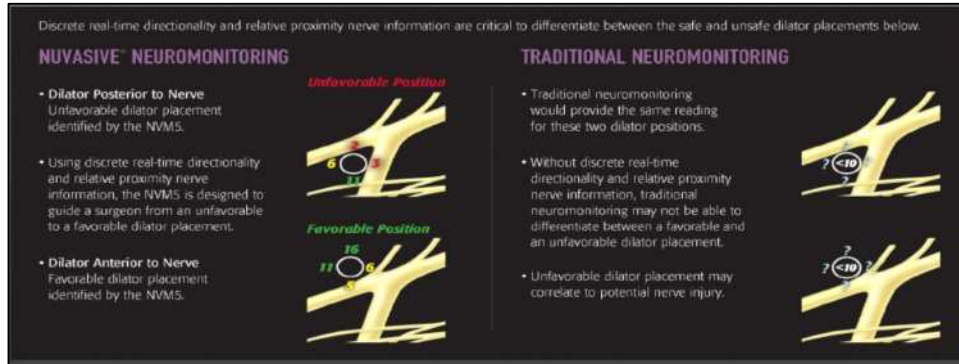
<sup>321</sup> 6/14/18 Reply Declaration of Matthew Link in Support of Motion for Preliminary Injunction, para. 12.

<sup>322</sup> 6/14/18 Reply Declaration of Matthew Link in Support of Motion for Preliminary Injunction, para. 17.

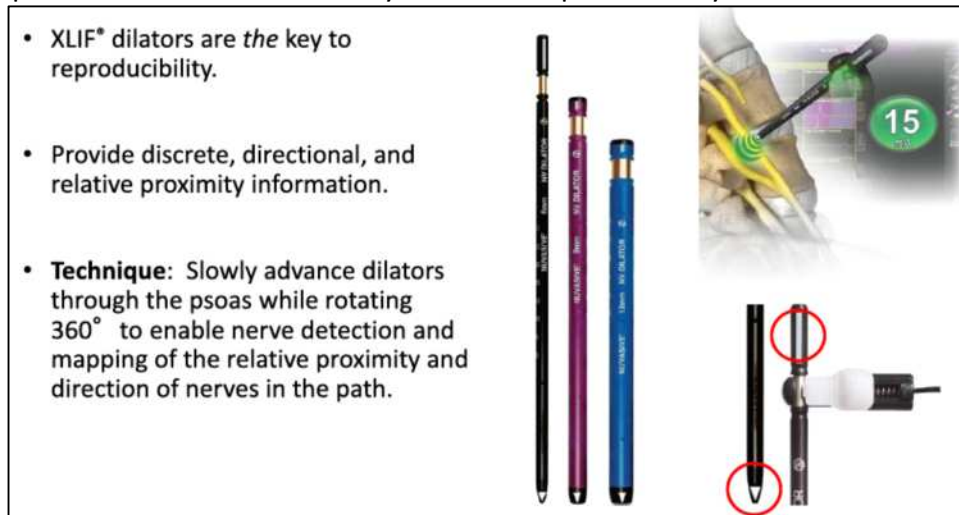
<sup>323</sup> 6/14/18 Reply Declaration of Matthew Link in Support of Motion for Preliminary Injunction, para. 58-59.

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Another key differentiating feature marketed by XLIF as setting apart XLIF from the lateral competition is its dilators equipped with electrodes located specifically on the ends of the dilators. These specifically placed electrodes allow the surgeon to tell both the proximity and direction of adjacent nerves, allowing for safer and more reproducible navigation through the highly innervated psoas muscle:



Ex. 33 (Excerpt of Ms. Howell’s presentation “XLIF Compared to Alternative Lateral Approaches: A literature-based perspective”) at 4. In fact, as set forth in the XLIF marketing materials below, NuVasive has repeatedly called out these specialized dilators as “the key” to XLIF’s reproducibility.



Doc. No. 37-43 at 8; see also Ex. 32 (Excerpts of “Adopting XLIF Into Your Practice”), at 2.<sup>324</sup>

Another differentiating feature called out in NuVasive’s surgical guides and materials is its intradiscal shim that stabilizes retractor and prevents nerves from slipping under center/posterior blade. See Doc. No. 37-17 at 21. As recognized by Dr. Sachs, Medtronic and Stryker do not offer this feature. Doc. No. 49-5 at 28.<sup>325</sup>

<sup>324</sup> 6/14/18 Reply Declaration of Matthew Link in Support of Motion for Preliminary Injunction, para. 63.

<sup>325</sup> 6/14/18 Reply Declaration of Matthew Link in Support of Motion for Preliminary Injunction, para. 68.

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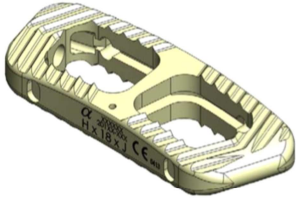
**V.A.1.a.2 Benefits to Surgeon-Customers and Patients: Implant Patents**

**February 2013 Alphatec Document “Direct Lateral: Lateral Cage Concepts & Key Features”<sup>326</sup>**

**DLAT Cage Features**

**Key Features for Lateral Cage**

- Anatomical Variants
  - Shape & Foot Print
  - Heights
  - Lordotic Angles
  - Concavity
- Anti-Migration
- Graft Windows
- Radiographic Markers
- Instrument Interface
- \*Supplemental Fixation Options



<sup>326</sup> ATEC\_LLIF000004530.

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**DLAT Cage Features**


**CoRoent Lateral Cage**



- Anatomical Variants
  - Footprint
    - Rectangular Shape with Rounded Ends
    - Lengths: 45mm, 50mm, 55mm & 60mm
    - Widths: 18mm & 22mm
  - Heights
    - Heights: 8mm, 10mm, 12mm, 14mm & 16mm
  - Lordotic Angles
    - 0 , 10 & 20
  - Concavity
    - Parallel planes with Lordotic Angles




**DLAT Cage Features**

**CoRoent Lateral Cage**

- Anti-Migration
  - Straight serrations on inferior & superior surfaces parallel to the sagittal plane
- Graft Windows
  - Typically 2 large windows with a graft self retention feature
    - \* XL-Thoracic only has 1 large window due to smaller foot print
    - \*\* XL-Keeled has 4 small window due to the keel occupying the center of the implant
- Radiographic Markers
  - 6 vertical “rod” markers
- Instrument Interface
  - Internal attachment feature located on 1 face of the implant

**July 2014 Alphatec Document “Integrated Project Charter for “Lateral Lumbar Interbody Fusion (LLIF) System”<sup>327</sup>**

<sup>327</sup> ATEC\_LLIF000004800.



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**Implant System**


- General Implant Specifications
  - 16mm-26mm width
  - 5mm-20mm height
  - 30mm-60mm length
  - 0°- 40° lordotic angle
  - 0°- 20° sagittal angle
  - Bone graft containment
  - Lumbar and Thoracic implant designs
  - Radiographic markers specific to lateral implant placement
  - Boney fusion promoting implant coatings
  - Parallel and contoured shapes that accommodate endplate geometry and are specific to implant placement from a lateral approach
  - Hyper lordotic implants
  - Coronal taper implants
  - Integrated implant anchoring mechanism

**Alphatec Presentation “Lateral Lumbar Interbody Fusion System” [undated]<sup>328</sup>**

*Alphatec Spine*

### LLIF Advantages/Market Drivers

- ALIF style surgery through a minimally disruptive approach
  - Minimal muscular and neural disruption
  - no ligament or bony structural damage
  - **Large interbody implant spans ring apophysis**
  - Creates distraction, indirect decompression, sagittal alignment correction and stability.
- True Indirect Decompression with Optimal Anterior Column Correction
- Increase in key demographics of patient population
  - Decreased risk for older patient population because there are less comorbidities



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<sup>328</sup> ATEC\_LLIF000862492 at -507, -530, -531, -533.