

Press Book 2016

Accuracy



Real Time



Radiation Free



Safety

DSG+
Dynamic Surgical Guidance



Educational Tool

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www.spineguard.com



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World's first spinal fusion surgery performed with single-step insertion of DSG™ Technology enabled screws



"The direct insertion of pedicle screws along with real-time x-ray-free feedback represents a key step for spine surgery," said Charles Court, M.D., French orthopedic surgeon

PARIS and SAN FRANCISCO, Jan. 5, 2016 – SpineGuard (FR0011464452 – ALSGD), an innovative company that designs, develops and markets disposable medical devices designed to make spine surgery safer, announced today the world's first spinal fusion surgery performed with the one-step-insertion of pedicle "smart screws" guided by DSG™ (Dynamic Surgical Guidance) technology. This surgery was performed successfully by Dr. Court and his team at the Centre Hospitalier Universitaire Bicêtre Paris-Sud in France. Dr. Tropiano in Marseille, France, and Dr. Bolger in Ireland have scheduled surgeries in the coming days. For SpineGuard and Neuro France Implants, who announced their co-development partnership in early 2015, this successful first surgery performed immediately after obtaining CE mark is a critical milestone in preparation for the commercial launch of the G2S pedicle screw instrumentation that integrates the DSG technology.

"The direct insertion of pedicle screws along with real-time x-ray-free feedback represents a key step for spine surgery. This first case gave me a glimpse of the great potential of this innovation in terms of safety and precision. A multi-centric study will allow us to substantiate it," said Charles Court M.D., orthopedic surgeon at the Centre Hospitalier universitaire Bicêtre Paris-Sud in France.

Pierre Jérôme, CEO and co-founder of SpineGuard, said: *"This pioneering surgery validates the clinical utility of embedding our DSG technology into the vertebral implant itself, thus enabling its insertion without any preliminary step. I believe this major technological advancement will further secure and simplify the most commonly performed instrumented spine procedure, fusion."*

Patrice Moreau, CEO and co-founder of Neuro France, added: *"For 17 years Neuro France Implants has been focusing on simplifying and securing spine surgery through innovative implants. This first direct insertion of our G2S pedicle screws integrating the DSG technology is a real success, our collaboration with SpineGuard is bearing fruit."*

Pedicle screw-based fusion has become the gold standard for treating spine instabilities and deformities.

The market continues to grow globally due to the increasing number of patients requiring surgical treatment, a larger number of surgeons being trained, and technological advancements such as minimally invasive surgery, bone substitutes and dynamic stabilization. Worldwide there are about one million pedicle screw-based procedures performed annually. However, accuracy of pedicle screw placement remains a critical issue in spine surgery. In recently published papers studying screw placement accuracy, the average rate of misplaced screws is approximately 20%, with 2-11% of patients presenting neurologic or vascular complications due to misplaced screws .

More information on the DSG™ technology, its new applications and surgeons' testimonials [here](#).

Previous release: 45% of growth for 3Q 2015 revenue

Next Press Release: 2015 FY Sales on January 14, 2016

SpineGuard will participate to the 'Invest Securities Biomed' conference on January 27, 2016 in Paris

About SpineGuard®

Co-founded in 2009 in France and the USA by Pierre Jérôme and Stéphane Bette, SpineGuard's mission is to make spine surgery safer. Its primary objective is to establish its proprietary DSG™ (Dynamic Surgical Guidance) technology as the global standard of surgical care, initially for safer screw placement in spine surgery and then in other surgeries. PediGuard®, the first device designed using DSG was co-invented by Maurice Bourlion, Ph.D., Ciaran Bolger, M.D., Ph.D., and Alain Vanquaethem, Biomedical Engineer. It is the world's first and only handheld device capable of alerting surgeons to potential pedicular or vertebral breaches. Over 40,000 surgical procedures have been performed worldwide with PediGuard. Numerous studies published in peer-reviewed medical and scientific journals have demonstrated the multiple benefits that PediGuard delivers to patients, surgical staff and hospitals. In 2015, SpineGuard started to expand the applications of DSG into pedicle screws through partnerships with innovative surgical companies in France and the US. SpineGuard has offices in San Francisco and Paris. For further information, visit www.spineguard.com.

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¹ Source: I-Data Research

ⁱⁱ Source: [Bibliography](#)

SpineGuard secures €7.7M debt financing with Bpifrance and IPF Partners

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PARIS and SAN FRANCISCO, Jan. 11, 2016 – SpineGuard (FR0011464452 – ALSGD), an innovative company that designs, develops and markets disposable medical devices designed to make spine surgery safe and easier, announced today that it has secured a total €7.7M debt financing through an Innovation Loan of €1.5M with Bpifrance and the issuance of four tranches of bonds totaling €6.2M with IPF Partners. The first tranche of € 3M was drawn on December 28, 2015.

Manuel Lanfossi, CFO of SpineGuard, said: *“This funding from Bpifrance and IPF Partners endorses SpineGuard’s strategy and will underpin its sales momentum for the next 3 years. In addition, our new financial partners further validate the great clinical potential of our Dynamic Surgical Guidance platform. The funding strengthens our financial position in a flexible way and allows us to accelerate the new-product launches from our very exciting pipeline. In particular, we are excited about the upcoming launch of PediGuard Threaded and the ‘smart screws’ that we have been developing with our industry partners.”*

Previous press release, World’s first spinal fusion surgery performed with single-step insertion of DSG™ Technology enabled screws, on January 5, 2016.

The next financial press release, “2015 annual revenue”, on January 14, 2016.

SpineGuard will participate to the ‘Invest Securities Biomed Event’ on January 27 in Paris.

Bpifrance Innovation Loan (“Prêt Innovation”)

The agreement between SpineGuard and Bpifrance enables the company’s innovation financing, focused specifically on PediGuard Threaded and the DSG™ Smart Screw, through the InnovFin – EU Finance for Innovators program supported by the European Union. Bpifrance Prêt-Innovation

IPF Partners

IPF Partners is an investment platform founded by a team of 4 fund managers and healthcare sector leaders. The IPF I fund, which was launched in October 2011, provides bespoke debt and other financing solutions to healthcare companies that have reached commercial stage in order to help them handle their ongoing and acquisition financing requirements. IPF I has already committed c. 62 million euros to various European companies.

The agreement between SpineGuard and IPF Partners provides a very flexible financing solution for the company’s development and operating cycle with limited dilution to shareholders. www.ipfpartners.com

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SpineGuard reports 2015 revenue growth of 43% to €6.3 M

- Sales up 45% in 4Q

PARIS and SAN FRANCISCO, Jan. 14, 2016 – SpineGuard (FR0011464452 – ALSGD), an innovative company that develops and markets disposable medical devices designed to make spine surgery safer, reported today that its consolidated full-year 2015 revenue grew by 43%, to €6.3 million.

Pierre Jérôme, CEO and co-founder of SpineGuard, said: “We closed 2015 with another terrific quarter. It particularly reflects the excellent sales momentum in the USA and the solid progression in France, the two markets where SpineGuard sells directly. With the recent first DSG™ ‘smart’ screw surgery and €7.7M financing, we are entering 2016 with high confidence, strong optimism and significant resources.”

€ thousands - IFRS	2015	2014	Variance
First Quarter	1,517	1,035	+47%
Second Quarter	1,452	1,075	+35%
Half-Year	2,970	2,110	+41%
Third Quarter	1 646	1 133	+45%
Fourth Quarter	1 730	1 193	+45%
Second Half	3 376	2 326	+45%
Full year	6 346	4 436	+43%

Chiffres non audités

Global revenue in the fourth quarter of 2015 increased 45% to €1,730k, compared with €1,193k in the fourth quarter of 2014. In the USA, the growth was 64% and 44% at constant exchange rate (cc).

7,449 PediGuard units were sold in FY 2015 compared with 6,063 in FY 2014, including 4,306 in the United States, representing 58% of total units sold with a revenue increasing by 56% (31% cc) to €5,120k compared with €3,274k in FY 2014.

Previous press releases:

SpineGuard secures €7.7M debt financing with Bpifrance and IPF Partners, on January 11, 2016.

CE mark and world’s first spinal fusion surgery performed with single-step insertion of DSG™ Technology enabled screws, on January 5, 2016.

Next financial press release: 2015 annual results, on March 23, 2016.

SpineGuard will participate to the ‘Invest Securities Biomed Event’ on January 27 in Paris.

About SpineGuard®

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SpineGuard Expands Senior Management Team



Steve McAdoo – SpineGuard VP of Business Development

PARIS and SAN FRANCISCO, Jan. 25, 2016 – SpineGuard (FR0011464452 – ALSGD), a fast-growing company that develops and markets disposable medical devices designed to make spine surgery safer, today announced the addition of an experienced spine industry executive to the company's senior management team.

Steve McAdoo has joined SpineGuard as Vice President of Business Development with the global responsibility for driving industry partnerships to further leverage the company's core technology, Dynamic Surgical Guidance (DSG™); deploy new applications and initiate new revenue streams. Mr. McAdoo has over 27 years of global marketing, sales management and business development experience in the medical device industry, including spine, general orthopedics, trauma, cardiovascular and urology. Over the course of his career, he held roles in large corporations such as Medtronic, Smith & Nephew, and Biomet as well as in start-up companies like Danek Medical, Cerapedics, and SURx.

Pierre Jérôme, CEO and co-founder of SpineGuard, said: *"We are delighted to welcome Steve on board at this very exciting stage of SpineGuard's development where we have tremendous opportunities ahead of us. I am confident that his deep and broad medical device industry experience will help us capitalize on our current great momentum and rapidly expand the scope of our business."*

Steve McAdoo added *"I am very excited to join this great team and play a significant role in further leveraging DSG™ technology to drive additional growth. I believe it represents a unique differentiating factor in the market and look forward to working with SpineGuard's team, its customers and partners in the mission of making spine surgery safer."*

Previous press releases:

SpineGuard reports 2015 revenue growth of 43% to € 6.3M, on January 14, 2016.

SpineGuard secures € 7.7M debt financing with Bpifrance and IPF Partners, on January 11, 2016.

CE mark and world's first spinal fusion surgery performed with single-step insertion of DSG™ Technology enabled screws, on January 5, 2016.

Next financial press release: 2015 annual results, on March 23, 2016.

SpineGuard will participate to the 'Invest Securities Biomed Event' on January 27 in Paris.

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innovative surgical companies in France and the US. SpineGuard has offices in San Francisco and Paris. For further information, visit www.spineguard.com.

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Hospital Corporation of America (HCA) awards National Vendor Contract to SpineGuard

PARIS and SAN FRANCISCO, 17 Feb., 2016 – SpineGuard (FR0011464452 – ALSGD), an innovative company that develops and markets disposable medical devices designed to make spine surgery safer, today announced that it has been awarded a national vendor contract with the HCA network of hospital systems. The HCA network includes over 167 hospitals and 113 free-standing surgery centers in the United States, held under the HealthTrust Purchasing Group organization.

HealthTrust is committed to quality of care and patient safety, strengthening provider performance and clinical excellence. HealthTrust contracts with the best suppliers in the healthcare industry to support its commitment in all its member facilities. HealthTrust Purchasing Group negotiates contracts only with companies that supply products of the highest quality.

Patrick Dyar, Vice President of US Sales for SpineGuard, said: *“SpineGuard fully embraces its mission to provide the tools for making spine surgery safer for the surgeon, the hospital staff, and most importantly the patient. The vendor partnership with HCA to provide the PediGuard® devices with DSG™ Technology supports the alignment of SpineGuard’s mission with HealthTrust’s dedication to provide quality patient care.”*

Previous press releases:

SpineGuard expands Senior Management Team, Steve McAdoo VP Business Development, on January 25, 2016

SpineGuard reports 2015 revenue growth of 43% to € 6.3M, on January 14, 2016.

SpineGuard secures € 7.7M debt financing with Bpifrance and IPF Partners, on January 11, 2016.

CE mark and world’s first spinal fusion surgery performed with single-step insertion of DSG™ Technology enabled screws, on January 5, 2016.

Next financial press release: 2015 annual results, on March 23, 2016.

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SpineGuard and OrthoPediatics announce national distribution agreement for US pediatric institutions

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PARIS, SAN FRANCISCO and WARSAW, March 17, 2016 – SpineGuard (FR0011464452 – ALSGD), an innovative company that designs, develops and markets disposable medical devices intended to make spine surgery safer, announced today a national stocking distribution agreement with OrthoPediatics for the exclusive commercialization of its PediGuard probes in pediatric institutions in the US. OrthoPediatics is the only medical device company focused exclusively on providing a comprehensive product offering to the pediatric orthopedic market in order to improve the lives of children with various orthopedic pathologies.

“We are delighted to partner with OrthoPediatics for the distribution of our smart drilling devices. I have been very impressed with the quality of their management team and their commitment to the cause of improving the lives of children with orthopedic conditions,” said Pierre Jérôme, CEO and Co-founder of SpineGuard. *“This partnership will enhance our exposure into US pediatric institutions where we believe our Dynamic Surgical Guidance technology can bring great clinical value.”*

Mark Throdahl, President and CEO of OrthoPediatics, said, *“OrthoPediatics’ goal is to advance the field of pediatric orthopedics with the broadest and most innovative product line in our industry. PediGuard probes are a valuable addition to our complex spine offering, addressing the safety needs of both patients and surgeons. We are pleased to partner with SpineGuard on the application of this innovative technology to pediatric orthopedic surgery.”*

Next financial press release: Full Year 2015 financial results, on March 23, 2016.

About SpineGuard®

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About OrthoPediatics Corp.

Founded in 2006, OrthoPediatics is the only orthopedic company focused exclusively on providing a comprehensive product offering to the pediatric orthopedic market in order to improve the lives of children with orthopedic conditions. OP currently markets 17 surgical systems that serve three of the largest categories within the pediatric orthopedic market. This offering spans trauma and deformity, complex spine, and ACL reconstruction procedures. OP also has the only global sales organization focused exclusively on pediatric orthopedics and distributes its products to 29 countries outside the USA. For more information, contact Mallory Trusty at 574-267-0825.

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SpineGuard reports full-year 2015 financial results

- Sales increase 43% to €6.3M
- Net loss reduced by €0.7M to -€3.9M
- Secured Financing of €10.5M
- CE Mark and 1st surgeries performed with DSG™ smart screw and PediGuard® Threaded
 - PediGuard Classic range approved in China

PARIS and SAN FRANCISCO, March 23, 2016 – SpineGuard (FR0011464452 – ALSGD), an innovative company that develops and markets disposable medical devices designed to make spine surgery safer, reported today its full-year 2015 financial results as approved by the Board of Directors on March 22, 2016.

€ thousands – IFRS Audited	Dec 31, 2015	Dec 31, 2014
Revenue	6 346	4 436
Gross margin	5 365	3 778
Gross margin (% of revenue)	84,5 %	85,2 %
Sales, distribution & marketing	6 514	5 416
Administrative costs	1 968	1 907
Research & Development	857	934
Operating profit / (loss)	-3 974	-4 479
Pre-tax profit / (loss)	-3 878	-4 539
Net profit / (loss)	-3 878	-4 539

Pierre Jérôme, CEO and co-founder of SpineGuard, said: “Whether you look at sales, financing or strategic achievements, 2015 was an excellent year for SpineGuard. The strong growth in the USA, Europe and Japan, as well as the regulatory approval in China, continue to validate the outstanding clinical value of the PediGuard range. Our Dynamic Surgical Guidance technology is now successfully integrated into the spinal implant itself thanks to the fruitful collaborations with our partners, Neuro France and Zavation. The CE-marking and successful first surgeries with DSG screws are already opening opportunities with great prospects for us.”

Manuel Lanfossi, CFO of SpineGuard, added: “By securing €7.7M financing with Bpifrance and IPF Partners, the company has reinforced its financial resources in a flexible way, providing the necessary means to properly deploy our new products worldwide. The solid growth achieved in 2015 combined with the control of the operating expenses and the working capital make us confident for the future.”

Financial performance highlights 2015

In 2015, SpineGuard reported full-year revenue of €6,346k compared with €4,436k for 2014, a 43% increase on reported basis and 24% cc. 7,449 PediGuard units were sold compared with 6,063 in 2014, including 4,306 in the United States.

The gross margin of 84.5% at Dec. 31, 2015 compared with the prior year of 85.2% remains strong. The 70 bps decrease year on year was mainly caused by a different country – product mix compared with 2014.

The Company reported a net loss of €3,878k for the full-year 2014 compared with a loss of €4,539k for the full-year 2014, an improvement of €661k. Operating expenses were €9,337k, an increase of 13% compared with 2014, mainly driven by investments in sales and marketing (+20%).

At December 31, 2015, cash and cash equivalents were €3,229k compared with €2,507k at December 31, 2014. The main variances between 2015 and 2014 were as follows:

- Operating cash flow was €-2,596k compared with the previous year of €-3,317k, i.e. a decrease of €721k.
- Full reimbursement of the bonds, subscribed by Norgine, of €1,235k including capital, interest and fees for tranche A and tranche B.
- Continued repayment of the Oséo Innovation loan for €100k.
- The increase in shareholders’ equity as a result of two Pacey® equity facility draws in April and May, totaling €345k (net of expenses) and of 2 equity financings for €2,359k.
- The first draw of the IPF Partners bonds for a net amount of €2,761k.
- The company also secured 3 export loans (COFACE) for a total of €61k.

Working capital was €-65k compared with €406k for the full-year 2014, continuing to illustrate the low and atypical level of cash required compared with industry standards.

SpineGuard secured an innovation loan with Bpifrance of €1.5M and also has the option to exercise the 3 remaining tranches with IPF Partners for a total of €3.2M for the bonds until the end of 2016.

The Company has an available equity line (Pacey) of 265.000 shares representing an estimated €1.3M net of expenses at March 22, 2016 stock price.

The Company’s workforce count was 26 at the end of 2015, compared with 25 in December 2014.

2015: Excellent sales momentum and strategic objectives achieved

Sales and marketing:

The sales and marketing team now counts 10 people in the United States and 4 in Paris managing a network of:

- 77 agencies in the United States,
- 40 distributors in the rest of the world,
- 1 agent in France and Luxemburg.

Since the implementation of the Affordable Care Act (ACA) in 2014, US healthcare institutions have increasingly been made financially accountable for clinical outcomes improvements as well as reductions in complication and re-operation rates. This trend is favorable to medical devices which make health economic differences such as PediGuard. It explains the excellent commercial performance of 2015, in particular within hospital systems, which have referenced PediGuard in their product offering.

The Company continues to expand its distribution network throughout the United States and to enhance PediGuard’s adoption in teaching institutions. 35 centers (compared to 25 end of 2014) are now using DSG enabled devices in their curriculum.

In the rest of the world, the Company continued to focus on training and marketing activities to support its distributors across geographies:

- In Europe, SpineGuard delivered significant revenue growth in France (+20%), the UK (+53%) and Germany (+23%). In Russia, numerous surgeons were trained in coordination with the distributor. However, the market there remains challenging due macro-economic factors and the weakening of the Ruble vs. the Euro.
- In Asia, the revenue growth in Japan remained strong with +60% after +54% in 2014 and SpineGuard continues to invest in this large market through its congress and field presence. Singapore also grew by +47% in Euro. In China, following the regulatory clearance by the Chinese Food & Drug Administration (CFDA) for the Classic PediGuard, the Company is selecting local distributors. Like in Japan, SpineGuard is taking a long term view to anchor its presence and success in what is now the world’s second biggest market for pedicle screw surgeries.
- In Latin America, Chile and Peru grew +15% and +121% in value, respectively, while 2015 was a consolidation year in Mexico (-6%). Brazil did not recover both for macro-economic reasons but also due to distributor specific causes and the Company has begun discussions with other possible distributors.

- In the Middle-East, the global performance (+12% in value) was underwritten by winning a tender in Saudi Arabia which resulted in the sale of over 400 units.

In a major milestone, PediGuard Threaded (with DSG technology) received CE mark and first surgeries took place during the fourth quarter of 2015. The Company also deployed new marketing tools for surgeons and the sales teams, such as technical and sales brochures and videos that are also accessible on the Company's website.

Clinical:

2015 was a productive year. Eight surgeons presented their experience with PediGuard in international scientific conventions and six new clinical studies were completed:

- Prospective study regarding osteoporotic patients including a US and a Brazilian center.
- Retrospective study on scoliosis (France).
- Prospective study on scoliosis (Chile).
- In vitro study about the placement and use of PediGuard in cervical surgery.
- In vitro study about the placement and use of PediGuard in minimally invasive surgeries (MIS).
- Meta-analysis about screw misplacements covering more than 100 publications.

These studies will be published and / or presented at future congresses.

R&D:

Smart DSG Screw & PediGuard Threaded

The Company completed the design, launched the first batches of industrialized products and successfully performed first surgeries for both the PediGuard Threaded and the DSG screw developed with Neuro France Implants. In the United States, the design of the smart screw developed with Zavation was validated in 2015. Production started so we can perform surgeries in the US as soon as we receive clearance from the FDA..

Robotics

A detailed roadmap and schedule was defined laying out key steps and resources needed for this promising DSG application.

New IP and brands

Patents granted in Europe for the DSG screw, in China and Japan for bone quality measurement and in France for bony fusion monitoring. International extension of two patents regarding with the aim to determine the pedicle entry point without x-ray. Filing in France and international plus registration in France of the « DSG » brand standing for « Dynamic Surgical Guidance ».

Événements récents :

- 5 Jan. 2016: World's first spinal fusion surgery performed with the one-step-insertion of pedicle "smart screws" guided by the DSG technology. This surgery was performed successfully by Dr. Court and his team in Paris. Additional surgeries have been performed since, in particular, by Dr. Bolger in Ireland.
- 11 Jan. 2016 : A total €7.7M debt financing was secured through an Innovation Loan of €1.5M with Bpifrance and the issuance of four tranches of bonds totaling €6.2M with IPF Partners. The first tranche of €3M was drawn on December 28, 2015.
- 25 Jan. 2016 : Steve McAdoo reinforces the company's senior management team as Vice President of Business Development.
- 16 Mar. 2016 : Bpifrance loan of €1.5M received.
- 17 Mar. 2016: National stocking distribution agreement with OrthoPediatrics for the exclusive commercialization of its PediGuard probes in pediatric institutions in the US.

Next financial press release: First Quarter 2016 revenue, on April 6, 2016.

About SpineGuard®

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safer. Its primary objective is to establish its proprietary DSG™ (Dynamic Surgical Guidance) technology as the global standard of surgical care, initially for safer screw placement in spine surgery and then in other surgeries. PediGuard®, the first device designed using DSG was co-invented by Maurice Boursion, Ph.D., Ciaran Bolger, M.D., Ph.D., and Alain Vanquaethem, Biomedical Engineer. It is the world's first and only handheld device capable of alerting surgeons to potential pedicular or vertebral breaches. Over 40,000 surgical procedures have been performed worldwide with PediGuard. Numerous studies published in peer-reviewed medical and scientific journals have demonstrated the multiple benefits that PediGuard delivers to patients, surgical staff and hospitals. In 2015, SpineGuard started to expand the applications of DSG into pedicle screws through partnerships with innovative surgical companies in France and the US. SpineGuard has offices in San Francisco and Paris. For further information, visit www.spineguard.com.

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SpineGuard reports 16% growth on €1.8M revenue for 1Q16

- **5th consecutive quarter with over 20% cc growth in the US**
- **2,000 units sold in a single quarter is a new milestone**

PARIS and SAN FRANCISCO, April 6, 2016 – SpineGuard (FR0011464452 – ALSGD), an innovative company that develops and markets disposable medical devices designed to make spine surgery safer, reported today that its first-quarter 2016 revenue grew by 16%, to €1.8 million.

Pierre Jérôme, CEO and co-founder of SpineGuard, said: « *For the first time, we exceeded 2,000 PediGuard units sold in one quarter, and our growth continues to be strong despite an unfavorable base effect due to a large tender in the Middle-East invoiced in March 2015. In the US, by far our number-one market, we delivered a fifth consecutive quarter with over 20% cc growth. We are on track with our strategic roadmap and confident about the quarters to come.* »

Global revenue in the first quarter of 2016 increased 16.0% to €1,760k, compared with €1,517k in the first quarter of 2015. At constant exchange rate (cc), the growth rate was 14.3%.

2,134 PediGuard units were sold in the first quarter of 2016 compared with 1,977 in the first quarter of 2015, including 1,134 (53%) in the United States, where revenue grew 22.6% (20.2% cc) to €1,377k compared with €1,123k.

Recent events:

5 Jan. 2016: World's first spinal fusion surgery performed with the one-step-insertion of pedicle "smart screws" guided by the DSG technology. This surgery was performed successfully by Dr. Court and his team in Paris. Additional surgeries have been performed since, in particular, by Dr. Bolger in Ireland

16 Mar. 2016: Company received Bpifrance loan of €1.5M.

17 Mar. 2016: National stocking distribution agreement signed with OrthoPediatrics for the exclusive commercialization of its PediGuard probes in pediatric institutions in the US

Latest media article:

[Becker Spine How value-based spine care shapes technology development: Key thoughts on SpineGuard](#) (March 31)

Next financial press release: 2016 Half-year revenue: July 12, 2016

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Co-founded in 2009 in France and the USA by Pierre Jérôme and Stéphane Bette, SpineGuard's mission is to make spine surgery safer. Its primary objective is to establish its proprietary DSG™ (Dynamic Surgical Guidance) technology as the global standard of surgical care, initially for safer screw placement in spine surgery and then in other surgeries. PediGuard®, the first device designed using DSG was co-invented by Maurice Bourlion, Ph.D., Ciaran Bolger, M.D., Ph.D., and Alain Vanquaethem, Biomedical Engineer. It is the world's first and only handheld device capable of alerting surgeons to potential pedicular or vertebral breaches. Over 40,000 surgical procedures have been performed worldwide with PediGuard. Numerous studies published in peer-reviewed medical and scientific journals have demonstrated the multiple benefits that PediGuard delivers to patients, surgical staff and hospitals. In 2015, SpineGuard started to expand the applications of DSG into pedicle screws through partnerships with innovative surgical companies in France and the US. SpineGuard has offices in San Francisco and Paris.

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SpineGuard will launch PediGuard Threaded DSG™ device at “SpineWeek 2016” world conference in Singapore

- Three scientific presentations reinforcing clinical utility of DSG™ Technology are scheduled during the conference



PARIS and SAN FRANCISCO, May 10, 2016 – SpineGuard (FR0011464452 – ALSGD), an innovative company that develops and markets disposable medical devices designed to make spine surgery safer, announced today the commercial launch of its new PediGuard Threaded device at the occasion of the “SpineWeek 2016” world conference which is scheduled to take place in Singapore from May 16 to May 20. This launch follows successful clinical evaluations performed by seven surgical teams in Europe and Asia.

«As a regular user of the DSG™ technology, I particularly appreciate the PediGuard Threaded device because this novel « three in one » instrument enables me to optimize both the insertion, the positioning and the anchorage of screws into the vertebra without the need for fluoroscopy,” said Ciaran Bolger, M.D., Neurosurgeon, Dublin, Ireland.

Pierre Jérôme, CEO and co-founder of SpineGuard, added: « *PediGuard Threaded completes our range of smart drilling devices whose clinical value keeps on being reinforced by new studies in terms of implant placement accuracy, x-ray exposure diminution and OR time-reduction. Three of them will be presented next week by eminent spine surgeons at the SpineWeek world conference in Singapore.* »

Eighteen major international spine societies come together every four years during the SpineWeek conference. Between 3,500 and 4,000 orthopedists and neurosurgeons are expected from all over the world next week in Singapore where the DSG™ technology will be featured in three scientific podium presentations listed below:

Monday May 16th

Accuracy of a Dynamic Surgical Guidance (DSG™) probe for screw insertion in the cervical spine

Dixon D., Darden B., Casamitjana J., Weismann K., Powell D., Baluch D. (USA, Spain & Chile)

Tuesday May 17th

Does the use of Dynamic Surgical Guidance (DSG™) assist with accurate pedicle screw placement in patients with osteoporosis or osteopenia?

Defino H., Williams J., da Silva Herrero C.F., Betz R., Powell D., Gaughan J. (Brazil & USA)

Thursday May 19th

Reducing pedicle drilling radiation by using Dynamic Surgical Guidance (DSG™) with a Jamshidi needle while maintaining screw placement accuracy

Williams J., Khoo L., Gaughan J., Betz R. (USA)

Recent events:

5 Jan. 2016: World’s first spinal fusion surgery performed with the one-step-insertion of pedicle “smart screws” guided by the DSG technology. This surgery was performed successfully by Dr. Court and his team in Paris. Additional surgeries have been performed since, in particular, by Dr. Bolger in Ireland.

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Latest media article:

[Becker Spine How value-based spine care shapes technology development: Key thoughts on SpineGuard](#)
(31 Mars)

Next financial press release: 2016 Half-year revenue: July 12, 2016

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SpineGuard® receives US FDA clearance to market PediGuard® Threaded DSG™ device



PARIS and SAN FRANCISCO, June 16, 2016 – SpineGuard (FR0011464452 – ALSGD), an innovative company that develops and markets disposable medical devices that empower surgeons to enhance clinical outcomes and simplify surgeries, announced today it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its new PediGuard Threaded DSG™ device.

“We are very excited by the clearance of our PediGuard Threaded device, which brings a new generation of DSG™-enabled probes to the US market, offering spine surgeons the added clinical benefit of reducing surgical steps in fusion surgery. This clearance allows our network of agents to initiate the commercial phase of this unique value proposition in a \$7-billion market that is under price pressure and in tremendous need for differentiation,” said Stéphane Bette, Co-founder, CTO and US General Manager of SpineGuard.

Pierre Jérôme, Co-founder and CEO of SpineGuard, concluded: *“We have received very positive feedback on our new DSG™ device from our spine surgeon customers in Europe and Asia since its introduction earlier this year. We were eager to extend its benefits to surgeons, patients and hospitals in the US. In line with healthcare systems’ expectations of better clinical outcomes and surgical efficiency, SpineGuard continues to bring real-time digital technology to the operating room.”*

The PediGuard Threaded device with DSG technology embedded inside may be used in open or minimally invasive approaches for pedicle screw insertion. It is available in various designs to accommodate surgeons’ preferences and patients’ anatomy. A single-use DSG pin embedded with the bipolar sensor is inserted into the cannula of the threaded shaft and connected to the electronic processor inside the single-use DSG handle. The distal tip of the threaded shaft includes an awl-like tip to facilitate redirection of the device until the tip is past the pedicle isthmus.

More information on the DSG™ technology, its new applications and surgeons’ testimonials [here](#).

Latest news release: PediGuard Threaded devices launched at SpineWeek (May 10, 2016).

Next financial press release: 2016 Half-year revenue on July 12, 2016.

About SpineGuard®

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SpineGuard reports 29% growth and €1.9M revenue for the second quarter 2016

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PARIS and SAN FRANCISCO, July 12, 2016 – SpineGuard (FR0011464452 – ALSGD), an innovative company that develops and markets disposable medical devices that empower surgeons to enhance clinical outcomes and simplify surgeries, reported today that its second quarter 2016 revenue grew by 29%, to €1.9 million.

Pierre Jérôme, Co-founder and CEO of SpineGuard, said: “Our second quarter sales performance is very satisfactory, in line with management’s expectations. The PediGuard Threaded, launched in May at the international congress ‘SpineWeek’ and approved in the USA mid-June, is beginning to contribute to our strong revenue growth. It confirms the excellent feedback received from the surgeons involved in its limited release earlier this year.”

€ thousands - IFRS	2016	2015	Variance
First Quarter	1,760	1,517	+16%
Second Quarter	1,873	1,452	+29%
Half-Year	3,633	2,970	+22%

Unaudited

Global revenue in the second quarter of 2016 increased 29% on a reported basis and 31% at constant exchange rate (cc). In the first half, global revenue increased 22% (same at cc) to €3,633k, compared with €2,970k in the first half of 2015.

In the first half of 2016 4,351 PediGuard units were sold compared with 3,716 in the first half of 2015, including 2,449 (56%) in the United States, where revenue grew 26% (same at cc) to €2,866k in the first half of 2016 compared with €2,274k in the same period last year.

Latest news release: US FDA clearance to market PediGuard Threaded (June 16, 2016).

Next financial press release: 2016 Half-year financial results on September 14, 2016.

About SpineGuard®

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SpineGuard Reports Six-Month 2016 Financial Results

- Sales up 22% at €3.3M
- Gross margin at 85.5%
- Net operating loss reduced to €2.2M

PARIS and SAN FRANCISCO, Sept. 14, 2016 – SpineGuard (FR0011464452 – ALSGD), an innovative company that designs, develops, and markets disposable medical devices intended to make spine surgery safer, announced today financial results for the half year ending June 30, 2016, as approved by the Board of Directors on September 13, 2016.

Pierre Jérôme, CEO of SpineGuard, said: “We are very pleased with these results for the first half of 2016. The combination of sustained strong growth in sales with good operating cost control allowed us to invest further in the deployment of our Dynamic Surgical Guidance platform. At the same time, we improved our operating results. In a market constantly seeking innovation and better clinical outcomes, SpineGuard continues to demonstrate the great medico-economic value of its DSG™ technology, unique in its ability to enable surgeons to make spine surgeries safer.”

€ thousands - IFRS	H1 2016	H1 2015
Revenue	3,633	2,970
Gross margin	3,105	2,557
Gross margin (% of revenue)	85,5%	86,1%
Sales, distribution, marketing	-3,477	-3,098
Administrative costs	-1,076	-1,146
Research & Development	-764	-646
Operating profit / (loss)	-2,212	-2,332
Pre-tax profit / (loss)	-2,472	-2,180
Net profit / (loss)	-2,472	-2,180

NB: Unaudited

Sales growth and reduced operating loss

For H1 2016, the Company reported revenue of €3,633k, up 22% (cc) compared with H1 2015.

Revenue in the United States increased 26% (26% cc) to €2,866k in the first half of 2016, compared with €2,274k in the first half of 2015. In the rest of the world, revenue increased 10% during the first half of 2016 to €767k compared with €696k in the first half of 2015.

4,351 PediGuard units were sold in the first half of 2016 compared with 3,716 in the first half of 2015, including 2,441 in the United States, representing 56% of total units sold.

Gross margin of 85.5% at June 30, 2016, compared with the prior year of 86.1% and remains solid. The change mainly reflects the lower ASP with the US stocking distributors but this is offset by the absence of sales commissions. Excluding stock distributors, ASP remained flat in the US while ASP was down 4% OUS due to a different country mix compared to the same period of 2015.

Operating expenses were €5,318k compared with €4,890k for H1 2015, an increase of €428k compared with June 30, 2015. This increase is due to the agents' commissions proportioned to sales, to the hires made in sales R&D, to the gathering of the scientific advisory board in the first half of 2016 and to the accrual of variable compensation in line with the performance of the company.

Working capital requirements were €728k compared with € -65k at December 31, 2015. This continues to illustrate the relatively low operating cash needs of the Company and the efficient management of its

financial resources. It should also be noted that the Company; i) sourced several raw materials and finished products in order to cover manufacturing requirements for the entire product line, and ii) is impacted by longer payment terms agreed upon for the Saudi tender that are secured by letters of credit, of which €105k was paid on July 25, as anticipated.

At June 30, 2016, cash and cash equivalents were €3,257k compared with €3,229k at December 31, 2015, and is explained as follows:

- The operating cash flow of €(2,732)k compared with the same period last year of €(1,943)k.
- The payment of interests to IPF Partners of €145k and to Bpifrance of €22k.
- The on-going repayment of the BPI Innovation loan, of €63k.
- The second draw of the IPF Partners bonds for a gross amount of €1,500k.
- The Innovation loan received from Bpifrance for a gross amount of €1,500k.

The Company also has access to the following financing:

- Tranche C of the loan with IPF Partners for an amount of 1,500 K€ by December 31, 2016 with the condition of attaining a 12-month rolling revenue threshold;
- An equity line (Paceo) in place since 2014 for a maximum number of 265,000 shares.

The Company's workforce count is 28 at H1 2016, compared with 26 at the end of December 2015.

Recent events and outlook:

The half-year revenue for 2016 is encouraging and follows the excellent performance of 2015. PediGuard® Threaded, which was launched in May at the international SpineWeek congress and cleared by the US FDA mid-June, has started to contribute to revenue growth, confirming the excellent feedback received by the surgeons who performed the first cases.

The commercial launch of the PediGuard® Threaded in the USA will occur at the NASS (North American Spine Society) annual conference at the end of October in Boston. Prior to NASS, the DSG™ screw will be presented in a symposium at the European congress for spine surgery (Eurospine), and its US-FDA clearance is progressing well with the company planning to file the 510k in the third quarter of 2016.

Next financial press release: 2016 third quarter revenue, October 12, 2016.

SpineGuard will participate at the Large & Midcap Event 2016 on October 5 and 6 in Paris.

SpineGuard will participate at Actionaria on November 18 and 19 in Paris.

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SpineGuard reports €1.7M revenue for 3Q 2016, and 9 months growth of 15%

PARIS and SAN FRANCISCO, Oct. 12, 2016 – SpineGuard (FR0011464452 – ALSGD), an innovative company that designs, develops, and markets disposable medical devices intended to make spine surgery safer, announced today that its third quarter revenue grew to €1.7 million, a 2% increase compared with 3Q 2015.

Pierre Jérôme, CEO and co-founder of SpineGuard, said: “After six consecutive quarters of more than 20% growth in the US, sales growth slowed in the third quarter of 2016. Since the US FDA clearance of the PediGuard Threaded in June, the US team has been actively preparing the commercial launch of this breakthrough product scheduled for the NASS (North American Spine Society) congress at the end of October in Boston. Our sales managers and product specialists are already promoting this very promising new extension of SpineGuard’s DSG™ technology with agents, surgeons and hospital purchasing committees. We experienced similar situations in the past when launching the PediGuard Curved, the PediGuard Cannulated and the PediGuard XS. In the rest of world, the quarter growth was solid, mainly driven by Europe and the Middle East.”

€ thousands - IFRS	2016	2015	Variance
First Quarter	1 760	1 517	+16%
Second Quarter	1 873	1 452	+29%
Half-Year	3 633	2 970	+22%
Third Quarter	1 678	1 646	+2%
Year to Date 9 Months	5 311	4 616	+15%

Chiffres non audités

Global revenue in the third quarter of 2016 increased 2% to €1,678k, compared with €1,646k in the third quarter of 2015. In the USA, the decrease was 3% both as reported and at constant exchange rate (cc), while the rest of the world increased 29%.

For the 9 months, global revenue increased 15% to €5,311k, compared with € 4,616k in the first nine months of 2015. The growth in the United States was 15% at both actual exchange rate and cc.

6,324 PediGuard units were sold in the first nine months of 2015 compared with 5,580 in the first nine months of 2015, including 3,581 in the United States, representing 57% of total units sold.

Next financial press release: 2016 full year revenue, January 5, 2017

SpineGuard will participate at Actionaria retail investor show on November 18 and 19 in Paris.

About SpineGuard®

Co-founded in 2009 in France and the USA by Pierre Jérôme and Stéphane Bette, SpineGuard’s mission is to make spine surgery safer. Its primary objective is to establish its proprietary DSG™ (Dynamic Surgical Guidance) technology as the global standard of surgical care, initially for safer screw placement in spine surgery and then in other surgeries. PediGuard®, the first device designed using DSG was co-invented by Maurice Bourlion, Ph.D., Ciaran Bolger, M.D., Ph.D., and Alain Vanquaethem, Biomedical Engineer. It is the world’s first and only handheld device capable of alerting surgeons to potential pedicular or vertebral breaches. Over 40,000 surgical procedures have been performed worldwide with PediGuard. Numerous studies published in peer-reviewed medical and scientific journals have demonstrated the multiple benefits that PediGuard delivers to patients, surgical staff and hospitals. In 2015, SpineGuard started to expand the applications of DSG into pedicle screws through partnerships with innovative surgical companies in France and the US. SpineGuard has offices in San Francisco and Paris.

For further information, visit www.spineguard.com.

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SpineGuard® expands “PediGuard®” franchise, will launch “PediGuard Threaded” drilling device at North American Spine Society (NASS) annual meeting

50,000 spine procedures have now been performed using the family of PediGuard devices for accurate pedicle screw placement



PARIS and SAN FRANCISCO, October 19, 2016 – SpineGuard (FR0011464452 – ALSGD) announced today that it will launch its next-generation PediGuard “Threaded” device enabled by DSG™ (Dynamic Surgical Guidance) technology at next week’s 31st annual meeting of the North American Spine Society (NASS) in Boston on October 26-29.

The innovative PediGuard Threaded device with DSG is a drilling instrument with a threaded shaft design available in various sizes. It may be used to streamline surgical steps while maintaining the accuracy of pedicle preparation for screw placement. Additionally, it may reduce the use of intraoperative imaging in standard and MIS procedures.

“The PediGuard Threaded device is a transformative product in spine surgery. It combines the need to make a pilot hole and do a tap into one-step. As it is threaded, surgeons can get a very nice controlled advancement of the tip down through the pedicle, which gives steady feedback regarding the positioning of the pedicle screw pilot hole,” said Ciaran Bolger, MD, PhD, Professor of Clinical Neuroscience, Beaumont Hospital, Dublin, Ireland.

“Because we can be confident in our guided placement, we have been able to reduce the amount of fluoroscopy used during minimally invasive procedures. I estimate that, at our spine center, we have reduced the number of fluoroscopy images by about 50%,” said Larry T. Khoo, MD, The Spine Clinic of Los Angeles, California. *“My practice is 90-100% minimally invasive, so I routinely use the PediGuard Threaded device in the vast majority of my cases. I use it in everything from routine lumbar to thoracic screw cannulations.”*

«I have used the PediGuard Threaded device for CBT (cortical bone trajectory),» added Richard A. Hynes, MD, FACS, President of The B.A.C.K. Center in Melbourne, Florida. *“Due to the significant cortical bone in this pedicle screw method, tapping of the bone is recommended. With the PediGuard Threaded device, I am able to benefit from a prospective warning of breaching the bone while performing the tapping step simultaneously. This may result in improved safety, efficiency and accuracy while consistently facilitating the longest possible screw lengths.»*

Stéphane Bette, CTO and Co-Founder of SpineGuard, concluded, *“Learning now on 50,000 surgeries secured with DSG™ technology, SpineGuard continues to enhance the value offered to surgeons and hospitals with the US launch of our new, finely designed PediGuard Threaded range, further demonstrating how our DSG technology can be integrated within pedicle screw instrumentation for additional clinical benefits and efficiencies.”*

SpineGuard reports 50,000 spine procedures performed using its family of PediGuard devices for accurate pedicle screw placement. The PediGuard product line includes the PediGuard Straight, PediGuard Curved,

PediGuard Cannulated, and now, PediGuard Threaded.

Find more information on the [PediGuard Threaded device](#) with DSG technology and [product information](#).

Recent events:

The DSG™ screw was presented in a symposium on October 5 at the EUROSPINE Annual meeting in Berlin, Germany. The US-FDA clearance is progressing well with the company submission of the 510k on October 14.

Latest news release: SpineGuard reports €1.7M revenue for 3Q 2016, and 9 months growth of 15%

Next financial press release: 2016 full year revenue, January 5, 2017

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SpineGuard® DSG™ Screw Recognized as One of the Best New Spine Technologies for 2016

Receives Orthopedics This Week Spine Technology Award



PARIS and SAN FRANCISCO, Nov. 16, 2016 – SpineGuard (FR0011464452 – ALSGD) announced today that it has received an award from Orthopedics this Week, one of the most widely read publications in the Orthopedics industry, recognizing SpineGuard’s innovative DSG™ (Dynamic Surgical Guidance) Screw as one of the BEST spine care technologies for 2016. The award was received during the 31st annual meeting of the North American Spine Society (NASS) in Boston.

Pictured left to right, SpineGuard executives: Pierre Jérôme , CEO/co-founder; Patricia Lempereur, Director of Marketing; Steve McAdoo, VP of Business Development; Olivier Frezal, Director of R&D; and Stephane Bette, Co-founder, CTO and US General Manager.

The DSG™ Screw is a pedicle screw with a unique combination of a bipolar sensor with a pedicle screw—in just one device. The technology gives surgeons real-time guidance and the ability to insert the screw directly into a vertebra without drilling a pilot hole.

The DSG™ sensor differentiates various tissue types based on an analysis of the local electrical conductivity (cancellous bone, cortical bone, blood and soft tissues). Real-time feedback informs the surgeon of changes in tissue type by changes in the pitch and cadence of an audio signal and a flashing LED light. This in turn alerts the surgeon of potential pedicular or vertebral breaches during pedicle screw placement.

Moreover, the use of the DSG™ screw in MIS (Minimally Invasive Spine surgery) obviates the need for a k-wire. The outcome is a single-step pedicle screw insertion with an unprecedented degree of accuracy along with the added benefits of the potential for reduced radiation exposure and streamlined surgical steps, with resulting time- and cost-savings.

The US FDA clearance process for the DSG™ Screw is in progress. The FDA dossier was submitted in conjunction with Zavation, a spinal implant company that SpineGuard has partnered with to license and co-develop a DSG-enabled Zavation SmartScrew. Once cleared, Zavation will market and sell the first DSG-enabled screw in the USA.

Pierre Jérôme, Co-founder and CEO of SpineGuard, concluded: *“This award is a great recognition for the SpineGuard R&D and marketing teams, the co-inventors of the DSG™ technology, the surgeons involved in the product design, as well as NeuroFrance and Zavation, our pedicle screw partners. Given the quality of the panel who made the selection, this award is very encouraging for the future adoption of our DSG™ integration system.”*

A DSG™-enabled SmartScrew co-developed with Neuro France Implants (La ville-aux-Clercs, France) is

currently in alpha launch in Europe with five surgeons having started to use the system.

More information on the DSG™ technology, its new applications and surgeons’ testimonials [here](#).

Recent events:

SpineGuard reports 50,000 spine procedures performed using its family of PediGuard devices for accurate pedicle screw placement. The PediGuard product line includes the PediGuard Straight, PediGuard Curved, PediGuard Cannulated, and PediGuard Threaded.

Latest news release: SpineGuard® expands “PediGuard®” franchise, will launch “PediGuard Threaded” drilling device at North American Spine Society (NASS) annual meeting, October 19, 2106

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