

# Press Book 2019

Accuracy



Real Time



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Free



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**DSG+**  
Dynamic Surgical Guidance



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Tool



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# SpineGuard announces its 2019 financial calendar

**PARIS & SAN FRANCISCO, January 9, 2019** – SpineGuard (FR0011464452 – ALSGD), an innovative company that designs, develops, and markets disposable medical devices intended to secure the placement of implants in the skeleton, announced today its schedule for the publication of financial information for 2019.

Event	Date*
2018 Full-Year Sales	January 24, 2019
2018 Full-Year Results	March 14, 2019
2019 First-Quarter Sales	April 11, 2019
Annual Shareholders Meeting	May 23, 2019
2019 First-Half Sales	July 11, 2019
2019 First-Half Results	September 18, 2019
2019 Third-Quarter Sales	October 15, 2019

*Note (\*): Press releases are published after stock market closes. This information is subject to modification.*

### About SpineGuard®

Founded in 2009 in France and the USA by Pierre Jérôme and Stéphane Bette, SpineGuard is an innovative company that designs, develops, and markets disposable medical devices intended to secure the placement of implants in the skeleton. SpineGuard’s primary objective is to establish its proprietary real-time digital DSG® (Dynamic Surgical Guidance) technology as a standard of care worldwide, the next step being its integration into robotic platforms. PediGuard®, the first device embedding 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 70,000 surgical procedures have been performed worldwide with DSG® enabled devices. Numerous studies published in peer-reviewed scientific journals have demonstrated the multiple benefits DSG® offers to patients, surgeons, surgical staff and hospitals. Building on these solid fundamentals, SpineGuard deploys its technology platform in a disruptive innovation: the « smart » pedicle screw launched late 2017 and is broadening the scope of applications in dental implantology and surgical robotics. SpineGuard has offices in San Francisco and Paris. For further information, visit [www.spineguard.com](http://www.spineguard.com).

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### Contacts

#### SpineGuard

Stéphane Bette  
Chief Executive Officer  
Tel : +33 (0)1 45 18 45 19  
[s.bette@spineguard.com](mailto:s.bette@spineguard.com)

Manuel Lanfossi  
Chief Financial Officer  
[m.lanfossi@spineguard.com](mailto:m.lanfossi@spineguard.com)

#### Europe / NewCap

Investor Relations & Financial Communication  
Mathilde Bohin/ Pierre Laurent  
Tel : +33 (0)1 44 71 94 94  
[spineguard@newcap.eu](mailto:spineguard@newcap.eu)



## SpineGuard reports 2018 revenue of €7.6M

- *Company historical record of DSG® units sold over 9,000*
- *US sales growth 0.5% on constant currency bases (cc)*
- *Over 120 DSG 'smart' screw surgeries in the US, a 50% growth over prior year*
  - *Positive EBITDA in the 4th quarter*
  - *US operations net income positive*

**PARIS and SAN FRANCISCO, Jan. 24, 2019 – 18:00 CET** – SpineGuard (FR0011464452 – ALSGD), an innovative company that designs, develops, and markets disposable medical devices intended to make spine surgery safer by bringing real-time digital technology into the operating room reported today its preliminary unaudited consolidated full-year 2018 revenue, EBITDA and cash position.

Stéphane Bette, CEO and co-founder of SpineGuard, said: *"In 2018, SpineGuard successfully undertook a strategic maneuver. Our main objectives were both to achieve EBITDA breakeven and continue to deploy the Company's technological platform into new applications. We also wanted to keep our commercial footprint in what is a complex market being upended by the massive influx of sophisticated surgery assistance platforms. We are therefore pleased with the results for the year: a positive EBITDA in the 4th quarter; confirmation of the clinical and economic value of the DSG screw shown by a significant increase of the number of surgeries; exciting developments and first commercial availability for the dental market with a 2018 CE mark; and, our partnership in robotics with the university in Paris. We achieved these results while maintaining our US revenue and preparing the conditions for a success in China. In 2019, we intend to continue to innovate and create strategic value by launching a new generation of products with the addition of visualization of the DSG signal to the audio feedback. We will also invest into our research program to develop our clinical and scientific data for the robotic usage of the DSG technology."*

€ milliers – IFRS	2018	2017	Variance
First Quarter	1,769	2,169	-18%
Second Quarter	1,857	2,030	-8%
<b>Half-Year</b>	<b>3,626</b>	<b>4,199</b>	<b>-14%</b>
Third Quarter	1,879	1,793	+5%
Fourth Quarter	2,070	2,182	-5%
<b>Second Half</b>	<b>3,949</b>	<b>3,975</b>	<b>-1%</b>
<b>Full year</b>	<b>7,575</b>	<b>8,174</b>	<b>-7%</b>

*Unaudited*

For the full year 2018, 9,001 DSG enabled devices were sold compared with 8,764 in FY 2017 (+3% growth).

5,336 units were sold in the United States, representing 59% of total units sold compared to 5,303 units in 2017(+1% growth). Revenue from the USA increased by 1% to \$ 7,557k compared with \$ 7,517k in FY 2017.

In the rest of the world, while units sold increased by +6%, revenue ended at €1,164k vs. €1,514 in FY 2017 a decrease of -23%.

The consolidated revenue decreased by -4% cc (-7% on reported bases)

### PRELIMINARY NON-AUDITED FINANCIAL INFORMATION

EBITDA is expected to be positive for the fourth quarter of 2018 and also expects a close to breakeven EBITDA over the second half of 2018 (vs. € -1,0M over the same period in 2017).

SpineGuard also expects full-year positive net income for its US operations for the first time in 2018.

The cash position at year-end of €1.1M plus the secured convertible bond facility for €2.8M means that the

total cash available to the Company is €3.9M. The Company, by reaching certain revenue milestones, could also draw the second tranche of a venture loan for a total €1.5M.

These preliminary results are unaudited and are based on management's initial analysis of operations for the period ended December 31, 2018, and are therefore subject to change. The company expects to announce its full year 2018 financial and operating results on March 14, 2019.

**Next financial press release:** 2018 annual results on March 14, 2019.

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[m.lanfossi@spineguard.com](mailto:m.lanfossi@spineguard.com)

#### Europe / NewCap

Investor Relations & Financial Communication  
Mathilde Bohin/ Pierre Laurent  
Tel : +33 (0)1 44 71 94 94  
[spineguard@newcap.eu](mailto:spineguard@newcap.eu)

# 70 000 surgeries secured with DSG® technology embedded devices

- 14 scientific publications confirm DSG benefits

**PARIS and SAN FRANCISCO, February 20, 2019** – 18:00 CET – SpineGuard (FR0011464452 – ALSGD), an innovative company that deploys its DSG® real time digital technology for surgical guidance intended to secure and streamline skeletal implant placement, reported today that 70,000 spine surgeries have been performed and secured with DSG® technology embedded devices. The company also announced 14 peer-reviewed scientific publications confirming its clinical and economic benefits.

**Stéphane Bette**, CEO and co-founder of SpineGuard says: *‘This milestone is the perfect confirmation of the reliability and the clinical value of our DSG technology, its ability to secure the placement of implants in the skeleton and the spine in particular. In addition, reaching EBITDA breakeven in the fourth quarter of 2018 allows us to reinforce our commitment to innovation and our focus on the integration of DSG Technology into robotic spinal surgery. The company’s 2019 roadmap also includes the commercial launch of ‘DSG Connect’, a visual interface that will enhance our product offering by complementing the existing audio feedback and adding new functionalities.’*

## Four additional scientific papers recently published

Since 2016, 4 new scientific papers were published in peer-reviewed medical journals. This brings to fourteen the total number of papers demonstrating the benefits of the DSG technology. Three papers were released in The European Spine Journal and one in World Neurosurgery.

The authors, two American surgeons, one German and one French, focused on measuring the clinical and technical benefits of the DSG technology in complex spinal procedures such as in the cervical region, in thoracic deformities and in ilio-sacral joint fusions. These papers published in leading journals, together with numerous addresses at medical congress, reinforce the reliability of the technology and enhance the opportunities for strategic partnerships.

For further information about clinical benefits, visit: [clinical](#)

**Next financial press release:** 2018 annual results on March 14, 2019.

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[m.lanfossi@spineguard.com](mailto:m.lanfossi@spineguard.com)

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Investor Relations & Financial Communication  
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# SpineGuard granted patent for ultrasound mapping of the spine

- Strengthened intellectual property portfolio for 13 patent families
- Novel utilization of ultrasound in surgical robotic platforms with less dependence on X-Ray

**PARIS and SAN FRANCISCO, March 7, 2019** – 18:00 CET – SpineGuard (FR0011464452 – ALSGD), an innovative company that deploys its DSG® real time digital technology for surgical guidance intended to secure and streamline skeletal implant placement, announced today the grant of a patent for the mapping of bony structures by ultrasound, in France and Japan.

The patent discloses a novel manner to use ultrasound in order to map bony structures, in particular the spine, through soft tissues. In association with systems such as robots, navigation platforms or PediGuard® devices, the technology has the potential to reduce the need for X-Ray for percutaneous guidance of instruments and implants.. After a grant in France, this patent was granted in Japan the 3rd largest spinal device market globally and an important market with manufacturers of ultrasound imaging platforms. Patent application has been submitted in the USA where it is currently under review by the US Patent Office.

**Stéphane Bette**, CEO and co-founder of SpineGuard says: *“This key patent grant in Japan is a major step for SpineGuard in its mission to secure and streamline the guidance of skeletal implants. Current guidance platforms require patients to undergo one or several CT scans, equivalent to several hundred X-Ray exposures with the potential for harmful effect. That is a major area for improvement for these platforms and our patent has the potential to decrease that risk while enhancing overall accuracy.”*

**Maurice Bourlion**, main inventor of the patent, co-inventor of the DSG® technology and Director of SpineGuard adds: *“Multiple studies over time have demonstrated that the DSG technology secures and streamlines the placement of implants in bone. These studies have also shown that beyond the accuracy it offers, DSG allows for a drastic decrease of X-Ray imaging in particular for pedicle screw placement in the spine. Unfortunately during minimally invasive surgeries, X-Ray images are still of major importance for the determination of the entry point to the vertebral pedicle. This patent, fruit of the close collaboration with reputable physicians, is a key piece in our broader vision for strategic innovation that aims at providing a complete platform for implant positioning in bone. This platform encompassing imaging, navigation and “smart” implant solutions will allow next generation robotic platforms to position implants safely in an autonomous manner.”*

## Thirteen patent families form a solid portfolio of intellectual property

Ever since its inception, SpineGuard has developed and maintained a significant portfolio of 13 patent families comprised of 60 individual patents in key geographies worldwide. Thanks to a tight collaboration with world-renown scientists and surgeons, these patents cover neurophysiology, electrical conductivity monitoring during drillings in bone (DSG®), “smart” implants, bone quality measurement, ultrasound mapping of bone and DSG integration in robotics. All these patents are aligned with our mission of securing implant placement in bone and carry a strong strategic value.

**Next financial press release:** 2018 annual results on March 14, 2019.

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## Contacts

### SpineGuard

Stéphane Bette  
Chief Executive Officer  
Tel : +33 (0)1 45 18 45 19  
[s.bette@spineguard.com](mailto:s.bette@spineguard.com)

Manuel Lanfossi  
Chief Financial Officer  
[m.lanfossi@spineguard.com](mailto:m.lanfossi@spineguard.com)

### Europe / NewCap

Investor Relations & Financial Communication  
Mathilde Bohin/ Pierre Laurent  
Tel : +33 (0)1 44 71 94 94  
[spineguard@newcap.eu](mailto:spineguard@newcap.eu)



# SpineGuard reports solid improvements in its full-year 2018 financial results

- Positive EBITDA in the fourth quarter of 2018
  - EBITDA improved by 79% in 2018
    - Net loss reduced by 43%
- Net Income positive US operations

**PARIS and SAN FRANCISCO, March 14, 2019** – 18:00 CET – SpineGuard (FR0011464452 – ALSGD), an innovative company that deploys its DSG® real time digital technology for surgical guidance intended to secure and streamline skeletal implant placement, reported today its full-year 2018 financial results as approved by the Board of Directors on March 13, 2019.

€ thousands – IFRS audited	Dec 31, 2018	Dec 31, 2017
Revenue	7 575	8 174
Gross Margin	6 553	6 952
Gross margin (% of revenue)	86,5%	85,1 %
Sales, distribution & marketing	4 840	6 116
Administrative costs	1 853	2 116
Research & Development	932	1 267
Operating profit / (loss)	-1 073	-2 547
Non-recurring operating costs	-37	-415
Financial Result	-1 205	-1 163
Income Tax	19	0
Net profit / (loss)	-2 334	-4 125
EBITDA	-586	-2 770

Stephane Bette, CEO of SpineGuard said: « The entire SpineGuard team is proud to report the company's full-year results demonstrating both the achievement of our target of operational profitability by the end of 2018 and the first net profitable year for SpineGuard's American operation. These results are a reward for all our stakeholders and validate both our goals for 2018 and our change in strategy to position SpineGuard as an innovator in robotics with a focus on partnerships. We enter 2019 with confidence. Our objective is to accelerate the creation of value for our DSG technology into robotic surgery and to launch our DSG-Connect visualization module this year. »

## EBITDA improved by 79% and is positive in the fourth quarter

EBITDA improved by 79% at € -586k compared to € -2 770k in 2017 while operating cash flow was reduced at €-669k (vs. € -2,513k). The fourth quarter was EBITDA positive and the second half of 2018 was close to EBITDA breakeven.

The operating loss was reduced by 56% to € - 1,073k (vs € -2,547k).

Gross margin remains improved by 1.4% at 86.5% thanks to stable average selling price in the USA and continuous improvements in manufacturing costs.

Operating expenses decreased by 20% or € 1,872k reflecting both the full impact of the company reorganization initiated in the second half of 2017 and the rigorous control of operational expenses.

At Dec. 31, 2018, cash and cash equivalents were € 1.1M, plus the secured € 2.8M of convertible bonds (OCAP) for a total of € 3.9M. Working capital requirement were € 782k vs. € 706k in 2017.

Financial expenses correspond to the interest charges of the venture loans with IPF Partners, Norgine Venture and Harbert European Growth Capital and the corresponding early termination costs incurred with the former. There are € 201k of the total financial expenses are non-cash and related to the compliance with IFRS accounting principles.

## 2018: A successful strategic turn

**Robotics:** In 2017, the company achieved two critical milestones for the smooth integration of DSG® technology into surgical robots: i) a functional prototype of a DSG® equipped drill and ii) the world's first experimental validation in the laboratory Institut des Systèmes Intelligents et de Robotique of the Paris Sorbonne University (ISIR). This experiment demonstrated how DSG® technology stops a surgical robot automatically when an impending bone breach is detected. In 2018, SpineGuard concluded a three-year partnership with Carnot Interfaces. It will allow the company to demonstrate the efficacy and adequacy of DSG® as applied to robotic surgeries in order to automate breach detection. The long-term goal is to automate skeletal implant placements.

**Visualization of the signal (DSG® Connect):** The next generation of products will be enabled by visualization software embedded into a tablet coupled with 'bluetooth like' technology. The Company is aiming for pre-commercial launch in the USA by the end of 2019. With DSG®-Connect, we hope to increase surgeon adoption by adding visual features to audio feedback. SpineGuard will deliver a sophisticated, simple and affordable guiding solution to hospitals looking for alternatives to expensive and complex navigation solutions. DSG®-Connect will also allow data recording for clinico-legal audit and will prepare the path for data collection of bone quality measurement. This project is complementary to the integration of DSG® into surgical robots.

**Dental Implantology (worldwide licensing):** the partnership with ConfiDent ABC (a member of Adin Group) is fruitful. In 2018, we achieved two important milestones, the CE mark and the manufacturing of the first generation of products ('SafeGuard') dedicated to the dental market. ConfiDent ABC will use these products for a market test and clinical studies throughout 2019.

**Optimize Legacy Business (PediGuard®):** with over 9,000 units sold in 2018, the Company built a profitable commercial business with its range of single use drilling probes for spine surgeries equipped with DSG®. The Company intends to leverage the business for continued innovation in 2019.

## 2019: Continued development of DSG technology and focus on new growth drivers

- Bringing scientific evidence of DSG technology applied to robotic surgery and signing additional partnerships in this field
- Successful launch of the DSG Connect visualization module by the end of 2019
- Growing adoption of DSG 'smart screw' supported by clinical publications
- The successful market test for dental implantology in collaboration with ConfiDent ABC

**Next financial press release:** 2019 first quarter revenue on April 11, 2019

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Mathilde Bohin/ Pierre Laurent  
Tel : +33 (0)1 44 71 94 94  
[spineguard@newcap.eu](mailto:spineguard@newcap.eu)



# SpineGuard receives regulatory clearance in Taiwan and starts PediGuard® commercialization

- *Exclusive distribution partnership with Taiwanese Dreammed Biomedical*

**PARIS and SAN FRANCISCO, March 28, 2019** – 18h00 CET – SpineGuard (FR0011464452 – ALSGD), an innovative company that deploys its DSG® real time digital technology for surgical guidance intended to secure and streamline skeletal implant placement, announced today that it is ready to start sales of PediGuard in Taiwan by receiving regulatory clearance to market its Classic, Curved and Cannulated PediGuard range. SpineGuard appointed Dreammed Biomedical as its distributor and received a first stocking order.

*‘This regulatory clearance is the result of a strong collaborative process with Dreammed Biomedical Co., Ltd.’ said Patricia Lempereur, Sales and Marketing Director International at SpineGuard. ‘It is an important milestone for SpineGuard’s expansion in the Asia-Pacific area.’*

*‘I believe there is a strong need for a simple smart device like PediGuard consistently ensuring safe and accurate placement of pedicle screws.’ added Henry Lai, CEO of Dreammed Biomedical Co., Ltd and distributor for SpineGuard’s products in Taiwan.*

Spine Market in Taiwan is estimated at 8,000 surgeries per year requiring pedicle screw placements growing 2-3% annually.

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## Contacts

### SpineGuard

Stéphane Bette  
Chief Executive Officer  
Tel : +33 (0)1 45 18 45 19  
[s.bette@spineguard.com](mailto:s.bette@spineguard.com)

Manuel Lanfossi  
Chief Financial Officer  
[m.lanfossi@spineguard.com](mailto:m.lanfossi@spineguard.com)

### Europe / NewCap

Investor Relations & Financial Communication  
Mathilde Bohin/ Pierre Laurent  
Tel : +33 (0)1 44 71 94 94  
[spineguard@newcap.eu](mailto:spineguard@newcap.eu)

## ConfiDent ABC showcases DSG®- guided dental live surgeries and create huge buzz at IDS, the largest dental implantology congress worldwide



**Paris and Afula, April 9, 2019** – 18:00 CEST – SpineGuard (FR0011464452 – ALSGD), an innovative company that deploys its DSG® real time digital technology for surgical guidance intended to secure and streamline skeletal implant placement and ConfiDent ABC (a member of Adin Group, provider of affordable top-line dental solutions), report the huge success and crowded attendance to the live dental surgeries performed with DSG equipped SafeGuard's devices at IDS, the largest international dental congress held every two years in Koln, Germany.

The surgeries were performed in a special surgical bubble similar to the one used by Doctors without Borders in field operations. Professor Adi Lorean and Dr. Noa Barer performed one surgery every day. Four cases were recorded and showcased live on 4-LD wide screens plus leading social media.

[See one surgery here](#)

Every procedure was attended by around 300 viewers at the boot, while views on social media totaled circa 5,000 views for all the surgeries.

At the booth, ConfiDent ABC gathered VIP viewers as key opinion leaders in dentistry and scouts of big companies looking for new disruptive technologies such as DSG.

Professor Adi Lorean said: *"The launch of SafeGuard at IDS was a very important milestone in exposing and implementing the DSG technology for dental use. We can start training and building the core of surgeons that will march on, use and teach the DSG technology. In parallel we are working and committed to continue our fruitful cooperation with our partners at SpineGuard to continue to develop the next generation of SafeGuard products."*

Stephane Bette, CEO of SpineGuard added: *"We are thrilled by the exposure and the high level of interest received by the DSG SafeGuard products at the IDS tradeshow. It marks the success of a passionate and effective partnership with the ConfiDent ABC and Adin Group Teams. We are looking forward to seeing the commercial success buildup in dental applications and to further support ConfiDent ABC in the development of their next generation of guided tools for dental implantology."*

Eyal Milman, CEO and Chairman of Adin Group concluded: *"We are very proud to announce the formal launch of Safeguard empowered by DSG technology in the dental field. We believe the presentations and live surgeries were a huge success and we are excited by implementing and deploying the technology all over the world."*



**ConfiDent ABC estimates that, in 2019, the accessible market for dental implants that could be guided with DSG technology could add up to 3.7B\$ and growths around 6% per year.**

### About SpineGuard®

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### About Adin Dental Implant Systems Ltd

Adin was founded in 2001 by Eyal Milman and Yechezkel Adin. Adin develops, manufactures and sells products and services in the dental field, including dental implant systems, to more than 60 countries around the world. The company employs over 160 workers in Israel, and a further 100 employees worldwide. Adin strives to be at the forefront of technology, to seek and manufacture innovative technological solutions for the benefit of its customers worldwide, and provide high-quality products and services that allow the treat of any case with unmatched success rates, whilst ensuring the entire assortment of its dental solutions is accessible and affordable to every clinician and every patient anywhere. Among other things, Adin has developed an Intra-Oral Scanner that will lead doctors into the digital world. For further information, visit [www.adin-group.com](http://www.adin-group.com)

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Manuel Lanfossi  
Chief Financial Officer  
[m.lanfossi@spineguard.com](mailto:m.lanfossi@spineguard.com)

#### ConfiDent ABC

Ron Askayo  
Chief Executive Officer  
[ron@confidentabc.com](mailto:ron@confidentabc.com)

#### Europe / NewCap

Investor Relations & Financial Communication  
Mathilde Bohin/ Pierre Laurent  
Tel : +33 (0)1 44 71 94 94  
[spineguard@newcap.eu](mailto:spineguard@newcap.eu)

## SpineGuard reports Q1 2019 revenue

- Revenue : €1,7m
- OUS sales growth +6%
- DSG® Smart Screw and PediGuard Threaded +85%

**PARIS and SAN FRANCISCO, April 11, 2019** – 18h00 CEST – SpineGuard (FR0011464452 – ALSGD), an innovative company that deploys its DSG® real time digital technology for surgical guidance intended to secure and streamline skeletal implant placement, announced today that reported today its first-quarter 2019 revenue of €1.69m.

Global revenue in the first quarter of 2019 was €1,692k vs. €1,769k in Q1 2018, a 6.9% decrease.

**Stéphane Bette, CEO and co-founder of SpineGuard, said:** *“The 85% growth for our most recent products, DSG Smart Screw and PediGuard Threaded, did not compensate the headwinds encountered by our legacy PediGuard range during this quarter. In the difficult current market conditions, it is critical to pursue our innovations as evidenced by the launch of our signal visualization module “DSG Connect” later this year. In addition, our continuous progress with robotic and dental R&D programs reinforces our belief that we will be able to enter into new strategic and structuring partnerships that will place SpineGuard’s technology at the forefront of innovation in the sector”.*

SpineGuard sold 2,028 DSG® units in the first quarter of 2019 vs. 2,351 units in Q1 2018.

1,056 units were sold in the USA with significant growth for the PediGuard Threaded and the Smart Screw but with a decrease for the legacy PediGuard range. Overall, US revenue decreased 9% as reported (-16% cc) at €1,365k vs. €1,502k.

Outside the USA, the activity was solid with a new order for China and the first order for Taiwan. Latin America had a promising rebound thanks to the area agent activity that starts to pay off in coordinating and managing the national distributors all over the area. Europe’s performance was also solid (+9%). Lastly, Middle-East returned to growth yet with a heterogeneous performance as key markets such as Saudi Arabia and Turkey did not materialize during the first quarter.

### Événements récents :

February 2019      SpineGuard Inc. will relocate to Denver (Colorado) from July 1st 2019.

March 2019      SpineGuard S.A (Paris) passed successfully the CE mark annual renewal audit by the TÜV SÜD.

**Next financial press release:** 2019 Half-year revenue: July 11, 2019

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Mathilde Bohin/ Pierre Laurent  
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[spineguard@newcap.eu](mailto:spineguard@newcap.eu)



# Robotic guidance via DSG® real time sensing: SpineGuard and ISIR receive acceptance for a first scientific communication at Hamlyn Symposium

**PARIS and SAN FRANCISCO, May 13, 2019** – 18h00 CEST – SpineGuard (FR0011464452 – ALSGD), an innovative company that deploys its DSG® real time digital technology for surgical guidance intended to secure and streamline skeletal implant placement, announced today the acceptance of the first scientific paper on the usage of its DSG sensing technology for guidance of robotic surgical platforms at the Hamlyn Symposium on Medical Robotics June 24-26th 2019 in London, United Kingdom.

The feasibility study will present the utilization of DSG measurements, performed directly in contact with bone during drilling, without the necessity of X-Rays. The purpose is to provide real-time feedback to surgical robots and prevent breaches through the cortical bone barrier, potentially harmful when undetected. The publication is the result of collaboration between SpineGuard and the ISIR (Institut des Systèmes Intelligents et de Robotique) of Sorbonne University, CNRS (Centre National de la Recherche Scientifique) and INSERM (Institut National de la Santé et de la Recherche Médicale). The Hamlyn Symposium is recognized as one of the top meetings worldwide about medical robotics.

**Stéphane Bette, CEO and co-founder of SpineGuard, said:** *“We previously announced our collaboration in the field of surgical robotics with the ISIR of Sorbonne University, and the resulting intellectual property. This is the first publication of the experimental results. We are of course delighted by this major advancement in the demonstration of DSG utility in robotics. On the heels of our agreements, for the “smart” DSG embedded pedicle screw and DSG for the dental applications, this is an important step in our search for strategic industry partners who wish to incorporate the DSG technology in their surgical assistance platforms. Capitalizing on our organic PediGuard device business, optimized and profitable, SpineGuard pursues the strategic turn it engaged in 2015: the deployment of its DSG technology in new clinically relevant applications in order to create further growth drivers.”*

**Guillaume Morel, Professor at the Sorbonne University, adds:** *“This publication is a first step we were looking forward to. The Hamlyn Symposium on Medical Robotics is a conference that regroups every year to present all that is new and significant in the world of surgical robotic research. The peer-review process is very strict and uses very strong selection criteria. It first requires demonstrating novelty and technical relevance, which is obvious here because no robots have ever shown autonomous navigation capabilities in bone using a sensing tool that they manipulate. Moreover, a specificity of this conference is to also include the clinical relevance in its selection criteria, as assessed by world-class surgeons in terms of innovation. Precisely on this aspect, our paper received excellent recognition, which is quite rare for such novel work. All this encourages us to persevere; we have a very robust work plan in front of us to explore the multiple possibilities offered by these first results.”*

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Chief Executive Officer  
Tel : +33 (0)1 45 18 45 19  
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[m.lanfossi@spineguard.com](mailto:m.lanfossi@spineguard.com)

### Europe / NewCap

Investor Relations & Financial Communication  
Mathilde Bohin/ Pierre Laurent  
Tel : +33 (0)1 44 71 94 94  
[spineguard@newcap.eu](mailto:spineguard@newcap.eu)



# SpineGuard highlights its strategy in Shareholder Letter before Annual General Meeting

**PARIS and SAN FRANCISCO, May 20, 2019** – 18h00 CEST – SpineGuard (FR0011464452 – ALSGD), an innovative company that deploys its DSG® real time digital technology for surgical guidance intended to secure and streamline skeletal implant placement, announced today the publication of its Shareholder Letter to highlight its strategy before Annual General Meeting to be held on May 23, 2019.

The letter to shareholders is available on SpineGuard’s website:  
<https://www.spineguard.com/investors/documentation/>

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**Europe / NewCap**

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Mathilde Bohin/ Pierre Laurent  
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## SpineGuard announces 1st International Training Center in China for the PediGuard



**PARIS and SAN FRANCISCO, June 13, 2019** – 18h00 CEST – SpineGuard (FR0011464452 – ALSGD), an innovative company that deploys its DSG® real time digital technology for surgical guidance intended to secure and streamline skeletal implant placement, announced the completion of its training program attended by 30 Chinese spine surgeons at its first official training center for the PediGuard in China. This 2-day training was held on June 3-4, 2019 at the Drum Tower Hospital in Nanjing and hosted by Professor Yong Qiu.

Pr. Yong Qiu is one of the most recognized surgeons in China for scoliosis treatment, he is the Chairman of Orthopedic Surgery Center at Nanjing Drum Tower Hospital where about 800 scoliosis surgeries are performed per year, the majority of which are among the most complex cases in China. He is also President of the Chinese Scoliosis Research Society, and Vice-President of the Chinese Association of Orthopedic Surgeons.

*"As the largest scoliosis center in China, we are honored to open the SpineGuard International Training Center by cooperating with SpineGuard and XinRong Medical (XRMED). The PediGuard devices from SpineGuard bring a higher success rate for spinal screw placements and can reduce patient complications, especially for less experienced surgeons when adopting the technology in the surgery effectively. The course we organized this week will provide an opportunity for spine surgeons to expand their knowledge and improve their skills through live training and discussions with our leading spinal deformity surgeons together with hands-on opportunity. I*

*believe by leveraging SpineGuard's advanced techniques and rich experience of XRMED in surgeon education in China, we can bring the skills of the younger generation of spine surgeons to new heights and ultimately benefit the patients. We are passionate about this!" said Professor Yong Qiu, Chairman of Orthopedic Surgery of Nanjing Drum Tower Hospital.*

*"This training is a great achievement as a result of a strong collaboration with Prof. Qiu and his team. The establishment of the first training center for the PediGuard at the Drum Tower hospital happened just one year after the first scoliosis surgery performed with the PediGuard in the same hospital. It was crucial for the promotion of the PediGuard in China, the second largest market in the world in our sector. The training was efficiently organized by our exclusive distributor in China, XRMED. Surgeons participating the training attended lectures on DSG® Technology by Prof. Ciaran Bolger (co-inventor of the PediGuard from Dublin, Ireland). Participating surgeons also observed live surgeries where the PediGuard was used" added Patricia Lempereur, International Director of Sales and Marketing at SpineGuard.*

*"We are very excited to establish the SpineGuard International Training Center in Nanjing Drum Tower Hospital. This center is a place where surgeons can be trained in a collaborative and engaging environment to achieve surgical excellence with SpineGuard products. This center is part of XRMED CSE (Continuous Surgeon Education) Institute which was established in 2014. For four years, XRMED CSE has increased surgeons' success especially in China's value-segment market and builds vital community partnerships with global KOLs. We are looking forward to establish more level #2 training centers around China in the near future!" said Christine Zhang, XinRong Medical Group's CEO.*

The event was also reported by Chinese television news program, watch [here](#).

In China, the market size is about 1 million of instrumented spinal fusion cases with pedicle screws per year with a CAGR at 18% .

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Mathilde Bohin/ Pierre Laurent  
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[spineguard@newcap.eu](mailto:spineguard@newcap.eu)



## SpineGuard and ISIR win best Paper Award for Robotic guidance using DSG® real time sensing at Hamlyn Symposium

**PARIS and SAN FRANCISCO, June 26, 2019** – 18h15 CEST – SpineGuard (FR0011464452 – ALSGD), an innovative company that deploys its DSG® real time digital technology for surgical guidance intended to secure and streamline skeletal implant placement, announced today that the first scientific paper on the usage of its DSG sensing technology for guidance of robotic surgical platforms won best paper 1st prize at the Hamlyn Symposium on Medical Robotics June 24-26th 2019 in London, United Kingdom.



The pre-clinical feasibility awarded study presented the utilization of DSG measurements, performed directly in contact with bone during drilling, without the necessity of X-rays. The purpose is to provide real-time feedback to surgical robots and prevent breaches through the cortical bone barrier, potentially harmful when undetected. The publication is the result of collaboration between SpineGuard and ISIR (Institut des Systèmes Intelligents et de Robotique), a laboratory affiliated to Sorbonne University, CNRS (Centre National de la Recherche Scientifique) and INSERM (Institut National de la Santé et de la Recherche Médicale). The Hamlyn Symposium is recognized as one of the top meetings worldwide regarding medical robotics and is at the forefront of research in imaging, sensing and robotics for addressing global health challenges associated with demographic, environmental, social and economic changes.

**Stéphane Bette, CEO and co-founder of SpineGuard, said:** *"This was the first publication of the experimental results with DSG applied to robotics, and we are delighted to receive the best paper award. Receiving first prize provides a meaningful recognition by experts in the scientific community and underscores the potential of DSG technology application in medical robots. It rewards the quality of our collaborative research with ISIR and is a key asset to trigger strategic industry partnerships to incorporate the DSG technology in surgical assistance platforms. After validating the "smart" DSG-embedded pedicle screw for spine surgery and the DSG drill for dental implantology, we are now advancing the proof and value of DSG sensing for surgical robots in skeletal procedures as described in the corresponding intellectual property filed in 2017. We want to reiterate our optimism as SpineGuard pursues the strategic turn it engaged in 2015 with the deployment of its DSG technology in new clinically relevant applications to drive further growth, capitalizing on our optimized and profitable historic PediGuard device business".*

**Guillaume Morel, Professor at the Sorbonne University, adds:** *"The paper is co-authored by a mixed team, with Jimmy da Silva, a SpineGuard engineer enrolled in a PhD program at Sorbonne University, Thibault Chandanson, SpineGuard R&D Manager and me. This reflects the nature of our partnership: it is not just transferring research results from my lab to SpineGuard. Rather, we closely work, on a daily basis, on producing advances towards future innovation with a central focus on the combination between DSG and robotics. The national Carnot label, attributed to our lab within Carnot Interfaces, promotes this approach. It is fruitful, as it produces not only intellectual property but also major research contributions. This is not that frequent in public-private partnerships. We are particularly honored by this prize, as a jury that enrolls members from academia, industry, and clinical world has awarded it. They liked the limpidity and efficiency of the proposed method: just a simple idea that generates new safety functions for robotic spine surgery without using X-rays. Nice to have? Indeed. But I would say that we're heading towards something that may become soon a must-have in the next generation of robotic orthopedic surgery."*

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### À propos de Carnot Interfaces

Founded in 2016 in Paris, Carnot Interfaces consolidates five labs (LIP6, ISIR, LIB, LIMICS and UMR.S1158) specializing in IT, Robotics and healthcare technologies with the vision of developing R&D partnerships with the industry. The institute holds the "Tremplin Carnot" labelling, a proof of excellence under the stewardship of Sorbonne University, CNRS and INSERM, all internationally recognized between the most innovative R&D actors. Carnot Interfaces regroups over 800 R&D professionals with standards of excellence in research, dynamic teams and a proven track of record in partnerships with the industry. It is a key player in the fields of digital with over 15 million euros of deals in its first year after inception. For further information, visit [www.carnot-interfaces.fr](http://www.carnot-interfaces.fr)



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### Contacts

#### SpineGuard

Stéphane Bette  
Chief Executive Officer  
Tel : +33 (0)1 45 18 45 19  
[s.bette@spineguard.com](mailto:s.bette@spineguard.com)

Manuel Lanfossi  
Chief Financial Officer  
[m.lanfossi@spineguard.com](mailto:m.lanfossi@spineguard.com)

#### Europe / NewCap

Investor Relations & Financial Communication  
Mathilde Bohin/ Pierre Laurent  
Tel : +33 (0)1 44 71 94 94  
[spineguard@newcap.eu](mailto:spineguard@newcap.eu)

# SpineGuard posts H1 2019 revenue

- First half 2019 revenue 3.5M€
- New products sales growth of 74%%
- Net consolidated operating result improved by +50% at -0.4M€
  - Restructured US subsidiary to report net profit in H1
- Cash available: 1M€ plus secured convertible bond facility of 1.8M€

**Paris (France) and Boulder (CO, USA), July 11, 2019** – 18:30 CEST – SpineGuard (FR0011464452 – ALSGD), an innovative company that deploys its DSG® (Dynamic Surgical Guidance) sensing technology to secure and streamline the placement of bone implants, announced today that its first half 2019 revenue was 3.5M€, a decrease of -5%, and that its preliminary non audited operating result improved by close to +50% at -0.4M€ compared to the first half of 2018.

Stéphane Bette, Co-founder and CEO of SpineGuard, declared: *“These results highlight our strategic moves and are in line with our expectations. The company’s priority is to deploy the innovations of the DSG technology platform while leveraging the legacy PediGuard business. In the highly competitive US market, which continues to be the main area of commercial focus for SpineGuard, we reorganized and relocated our US subsidiary to Boulder (Colorado) to further enhance profitability and concentrate our efforts towards our four strategic objectives: robotic applications for DSG; prepare the launch of the DSG-Connect visual solution; continue the growth of the DSG “smart” screws and support dental application success. We also want to maintain financial discipline to minimize our cash burn. As announced in our last letter to shareholders, the mandate to Healthios Capital Market is now effective. The objective is the signature of strategic alliances to continue expanding the scope of DSG technology and create enterprise value for our shareholders by maximizing the new market opportunities.”*

€ thousands – IFRS (Unaudited)	2019	2018	Variance
First Quarter	1,648	1,769	-7%
Second Quarter	1,797	1,857	-3%
Half-Year	3,445	3,626	-5%

Chiffres non audités

In the United States, the revenue of the second quarter 2019 decreased by 7% to 1,688K\$ from 1,807K\$. The revenue of the first half 2019 decreased by 11% to 3,238K\$ from 3,652K\$. The competitive landscape on the US market maintains significant pressure on the PediGuard legacy business. Business lost to large hospitals that are eager to acquire navigation and robotic platforms has not been fully compensated by new accounts, typically smaller hospitals. DSG “smart” screw surgeries crossed the 300 threshold and new products sales growth (DSG Screw and PediGuard Threaded) remains solid at +74%. In the first half of the year, the United States accounted for 83% of the company’s revenue. In constant currency, the revenue decreased by -5%.

Outside the United States, sales activity was stabilized with good performances in Europe, China and certain countries in Latin America. Activity in Middle East was behind expectations as the opportunities identified in Turkey and Saudi Arabia have yet to materialize.

3,875 DSG units were sold in the first half of 2018 (from 4,352 units in 2018) of which 2,256 units (58%) were sold in the United States.

## Preliminary analysis of first half 2019 non audited financial result<sup>1</sup>

In the first half of 2019, SpineGuard estimates that its net operating loss improved by approximately +50% and should reach -0.4M€ (vs. -0.8M€ in H1 2018).

The company also estimates that the American subsidiary SpineGuard Inc. will generate net income (non-

audited) in the first half of 2019.

In the USA, under the leadership of industry veteran Steve McAdoo, the Company restructured its operations in order to be aligned with market trends and optimize profitability. After the outsourcing of its logistic platform in mid-2018, the management team was downsized and offices were relocated from San Francisco to Boulder (CO) as of July 1st. SpineGuard continues to commercialize its range of products via a network of 84 agencies throughout the USA supported by a team of field clinical experts.

The cash position as of June 30, 2019 of 1.0M€ plus the secured convertible bond facility for €1.8M means that the total cash available to the Company is 2.8M€.

Considering the current cash position, the secured convertible bond facility and the recurring expected business, the Company estimates that it can fund its needs until April 2020. To cover future need, the Company is actively working on the signature of strategic alliances, researching new investors through private placements and discussing the rescheduling of its existing financial debt (Bpifrance, Norgine Ventures and Harbert European Capital Growth)

These preliminary results are unaudited and based on management’s initial analysis of operations for the period ended June 30, 2019, and are therefore subject to change. The company expects to announce its half-year 2019 financial results on September 18, 2019.

## PERSPECTIVES

The Company remains focused on the four objectives presented in the letter to shareholders in May 2019:

1. Continue to publicize the scientific evidence for the value of DSG in surgical robotics and create one or several strategic alliances in this field.
2. Beta-launch a new generation of PediGuard equipped with the DSG-Connect wireless module, a tablet that adds visual to auditory feedback. The value is in maximizing the usefulness of the PediGuard signal to the user and to enable data recording for medico-legal purposes. In addition, the device may assist in clinical studies of bone quality.
3. Double the number of surgeries performed with DSG “smart” screws in the USA, publish the first clinical data to support their clinical value and seek the right partnership to sell “smart” screws plus DSG-connect to non-robot equipped hospitals and ambulatory surgery centers.
4. Execute a successful market test with the first generation SafeGuard products for dental implantology with our partner ConfiDent ABC, and prepare future DSG products to be fully integrated into dental equipment.

## Next financial press release: 2019 Half-year financial results on September 18, 2019

<sup>1</sup>Preliminary non-audited results based on the first estimates by company’s management through June 30th, 2019

### About SpineGuard®

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**Contacts**

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Tel : +33 (0)1 45 18 45 19  
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Manuel Lanfossi  
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[m.lanfossi@spineguard.com](mailto:m.lanfossi@spineguard.com)

**Europe / NewCap**

Investor Relations & Financial Communication  
Mathilde Bohin/ Pierre Laurent  
Tel : +33 (0)1 44 71 94 94  
[spineguard@newcap.eu](mailto:spineguard@newcap.eu)

# SpineGuard Reports Six-Month 2019 Financial Results

- Net consolidated operating result improved by +51%
  - EBITDA improves by 27%
  - Gross Margin remains solid at 84.6%
- Cash available: 1M€ plus secured convertible bond facility of 1.8M€

**Paris (France) and Boulder (CO, USA), September 18, 2019** – 18:00 CEST – SpineGuard (FR0011464452 – ALSGD), an innovative company that deploys its DSG® (Dynamic Surgical Guidance) sensing technology to secure and streamline the placement of bone implants, announced today financial results for the half year ending June 30, 2019, as approved by the Board of Directors on September 17, 2019.

Stéphane Bette, CEO of SpineGuard, said: ‘Our financial performance reflects the company’s strategic turn and is in line with our expectations. The operating result improved by 51% while continuing to invest in the company’s future. We funded our R&D programs for the DSG robotic platform and the preparation of the launch of DSG-Connect. We supported the growth of the DSG smart screw and the dental application integrating DSG. Moving forward, we are continuing our efforts to control our cash by leveraging the PediGuard legacy business. Lastly, we are actively working with Healthios Capital Market toward signing significant partnerships to extend the use of DSG technology. We believe this will foster the return to growth and the creation of value for our shareholders.’

€ thousands – IFRS	H1 2019	H1 2018	H1 2017
Revenue	3,445	3,626	4,199
Gross margin	2,914	3,131	3,613
Gross margin (% of revenue)	84,6%	86,3%	86,0%
Sales, distribution, marketing	-1,868	-2,436	-3,400
Administrative costs	- 986	- 980	-1,055
Research & Development	-470	-554	-684
Non-recurring operating profit / (loss)	- 409	- 839	-1,526
Non-recurring operating costs	-92	0	-152
Operating profit / (loss)	-501	-839	-1,678
Financial result	-326	-229	-566
Income tax	21	0	0
Net profit / (loss)	-805	-1,086	-2,244
EBITDA	-351	-483	- 1,612

NB: unaudited

## Non-recurring Operating loss improves by 51% at -0.4M€

Non-recurring operating loss improves by 51% at - €409K- vs. - €839K and EBITDA improves by 27% at € -351K at June 30, 2019 compared to - €483K at June 30, 2018.

Operating expenses were €3,332K compared with €3,970K for H1 2018, a decrease of €648K (16%) compared with June 30, 2018.

Gross margin of 84.6% at June 30, 2019 remains consistent compared with prior year result of 86.3%. The change mainly reflects a lower 2% ASP in the USA within the PediGuard Classic range that was partially offset by improved manufacturing costs.

For H1 2019, the Company reported revenues of €3,445K, down 5% (10% cc) compared with H1 2018.

Revenue in the United States decreased 5% cc (-11% reported) to €2,867K in the first half of 2019, compared with €3,022K in the first half of 2018. In the rest of the world, revenue decreased by 4% during the first half of 2019 to €578K compared with €604K in the first half of 2018.

3,875 DSG units were sold in the first half of 2018 compared with 4,352 in the first half of 2018, including 2,256 in the United States, representing 58% of total units sold.

Working capital requirements were €919K compared with €806K at December 31, 2018.

At June 30, 2019, cash and cash equivalents were €988K compared with €1,062K at December 31, 2018, and is explained as follows:

- Operating cash flow of €(491)K compared with the same period last year of €(566)K.
- Equity funding using the equity line (OCAP) for a gross amount of €1,000K throughout the period.
- The payment of interests to Norgine Ventures and Harbert European Growth of €223K and to Bpifrance of €31K.
- The repayment of capital to Bpifrance of €150K.

The Company’s workforce count is 16 at H1 2019, compared to 19 at the end of December 2018.

## Recent events and outlook:

In line with 2018, the Company maintained strong financial discipline and improved EBITDA by 27% at €-351K as of June 30, 2019 compared to €-483K in the same period of 2018.

Implementing strategic alliances to extend the use of the DSG technology is the priority for the Company. The market opportunities creating the highest value are well identified. As announced in the May Letter to Shareholders, SpineGuard hired the US based bank Healthios Capital Markets to support its initiatives.

These new partnerships will cover Spine and the broader musculoskeletal sector with a focus on navigation applications and robotics. Notably, we can remind of:

- The 3-year partnership for robotics with Tremplin Carnot (University of Paris) at the end of 2018 with a first patent filing published in April 2019.
- The relevance of the DSG technology beyond Spine applications materialized by the worldwide exclusive licensing for dental implantology to ConfiDent ABC ( Adin Group) and the CE marking of the first generation of products.

SpineGuard is currently developing its DSG-Connect module adding visual to auditory feedback and taking a key step toward an easy integration of DSG technology into robots through automatic breach detection algorithms. DSG-Connect will also enable the launch of a new generation of PediGuard devices by adding a wireless module for the transmission of the measured signal and its visualization via an app on a tablet.

The DSG platform remains is the only technology with the ability to differentiate tissues in real time without X-ray exposure to the patient, OR team and surgeon.

SpineGuard Inc. transferred its US operations from San Francisco to Boulder (Colorado) as of July 1 2019.

## Outlook

The Company focuses on its four key objectives as listed in the May 2019 Letter to Shareholders:

1. Continue to publicize the scientific evidence for the value of DSG in surgical robotics and create one or several strategic alliances in this field.
2. Beta-launch a new generation of PediGuard equipped with the DSG-Connect wireless module, a tablet that adds visual to auditory feedback to optimize the usefulness of the DSG signal, enable data recording for medical-legal purposes and assist in clinical studies of bone quality.

3. Double the number of surgeries performed with DSG “smart” screws in the USA; publish the first clinical data and seek the right partnership to sell “smart” screws plus DSG-connect to non-robot equipped hospitals.
4. Execute a successful market test with the first generation SafeGuard products for dental implantology with our partner ConfiDent ABC, and prepare the future DSG products to be fully integrated into dental equipment.

### Ongoing concern

As of 30 June 2019, cash and cash equivalents amount to €988K. Considering the cash position as of June 30, 2019, the availability of the equity line facility (OCAPI) and the recurring expected business, the Company estimates that it has cash available until April 2020. In order to cover future cash needs, the Board of Directors decided to:

- Optimize the usage of the available equity line (no warrants attached) implemented in November 2019 with Nice & Green totaling €3M€ over a 15 months period. The available balance as of 30 June 2019 is €1.8M.
- Consider a new equity line.
- Negotiate the restructuring and re-scheduling of the existing venture debt with the company’s lenders.
- As indicated in its May Letter to Shareholders, the Company hired the US based bank Healthios Capital Markets to assist in reaching partnership agreements such as the one for dental implantology.
- Pursue equity funding opportunities through those partnership agreements or a private placement.

The company’s half-year financial report is available in the Investors > Exchange filings section of the [www.spineguard.com](http://www.spineguard.com) website.

**Next financial press release:** Third quarter 2019 revenue on October 15, 2019.

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### Contacts

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Stéphane Bette  
Chief Executive Officer  
Tel : +33 (0)1 45 18 45 19  
[s.bette@spineguard.com](mailto:s.bette@spineguard.com)

Manuel Lanfossi  
Chief Financial Officer  
[m.lanfossi@spineguard.com](mailto:m.lanfossi@spineguard.com)

#### Europe / NewCap

Investor Relations & Financial Communication  
Mathilde Bohin/ Pierre Laurent  
Tel : +33 (0)1 44 71 94 94  
[spineguard@newcap.eu](mailto:spineguard@newcap.eu)

# SpineGuard reports third-quarter 2019 revenue

- 9 months consolidated revenue decreases by 6%
- 39% growth for the most recent products globally over the last 9mths
  - 43% growth outside the US in Q3
- Over 400 surgeries performed in the USA with DSG equipped ‘smart screw’
- CE mark filing for DSG-Connect (visualization of signal)

**PARIS and BOULDER (CO), Oct. 15, 2019** – 18h00 CEST – SpineGuard (FR0011464452 – ALSGD), an innovative company that designs, develops, and markets disposable medical devices intended to make spine surgery safer by bringing real-time digital technology into the operating room, announced today that its third-quarter revenue was €1.7 million.

Stéphane Bette, CEO and co-founder of SpineGuard, said: *“These results are in line with our strategic plan implemented since 2017 consisting in refocusing the company on value-generating activities: innovation and technology deployment. In the United States, our two most recently launched products produced a nice growth: PediGuard Threaded and “Smart” DSG – embedded screw. The performance of our US subsidiary, although mitigated, should be appreciated in light of the reorganization in the first semester with the primary goal of profitability. We reached that goal in challenging market conditions for the legacy range of PediGuard products. We are otherwise satisfied by the sales improvement in other geographies and the contribution of our dental partnership. As we just attended NASS, the world largest Spine Surgery congress in America, we observed the relevance of our progress with DSG Connect (CE mark filing for a launch in the first half of 2020) and its robotic application that will allow us to reach sizable strategic alliances in order to get back to growth and create shareholder value.”*

€ thousands - IFRS	2018	2017	Variation
First Quarter	1 648	1 769	-7%
Second Quarter	1 797	1 857	-3%
Half-year	3 445	3 626	-5%
<b>Third Quarter</b>	<b>1 721</b>	<b>1 879</b>	<b>-8%</b>
<b>Year to Date 9 Months</b>	<b>5 166</b>	<b>5 505</b>	<b>-6%</b>

Unaudited

Global revenue in the third quarter of 2019 decreased 8% to €1,721k, compared with €1,879k in the third quarter of 2018.

Outside the USA, the revenue increased by +43% at €279k compared with €196k in the third quarter of 2018. The performance reflects new orders from China and continuous progress with ConfiDent ABC for dental implantology. Units sold were 953 vs. 525 in 2018.

In the USA, the decrease was 14% as reported and 18% in constant currency (cc).

Over the first 9 months of the financial year, revenue decreased by 6% to €5,166k compared to €5,505k for the same period in 2018. The latest products, PediGuard Threaded, Smart Screw and SafeGuard for dental implantology, recorded growth of 39%.

6,014 DSG equipped units were sold in the first nine months of 2019 (3,442 in the USA, 57% of total units sold) compared with 6,226 (3,948 in the USA) in the first nine months of 2018, a decrease in units of 3% worldwide.

## Outlook

The Company focuses on its four key objectives as listed in the May 2019 Letter to Shareholders:

1. Continue to publicize the scientific evidence for the value of DSG in surgical robotics and create one or

several strategic alliances in this field.

2. Beta-launch a new generation of PediGuard equipped with the DSG-Connect wireless module, a tablet that adds visual to auditory feedback to optimize the usefulness of the DSG signal, enable data recording for medical-legal purposes and assist in clinical studies of bone quality.
3. Double the number of surgeries performed with DSG “smart” screws in the USA; publish the first clinical data and seek the right partnership to sell “smart” screws plus DSG-connect to non-robot equipped hospitals.
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### Europe / NewCap

Investor Relations & Financial Communication  
Mathilde Bohin/ Pierre Laurent  
Tel : +33 (0)1 44 71 94 94  
[spineguard@newcap.eu](mailto:spineguard@newcap.eu)



# First clinical publication in Japan for the SpineGuard DSG® technology

## Cervical screw guidance

**PARIS and BOULDER (CO), Dec. 16, 2019** – 08h00 CEST – SpineGuard (FR0011464452 – ALSGD), an innovative company that deploys its DSG® (Dynamic Surgical Guidance) sensing technology to secure and streamline the placement of bone implants, announced today the first clinical publication in Japan for its DSG technology.

This technical note published in Neurologia medico-chirurgica (the official peer-reviewed scientific journal of the Japan Neurosurgical Society) presents the clinical usefulness of PediGuard for an optimal positioning of bi-cortical screws in the lateral mass of the 1st cervical vertebra. These screws require an extremely precise positioning in order to avoid the vertebral artery as well as the internal carotid artery.

[Link to publication abstract](#)

**Stéphane Bette, CEO of SpineGuard, said:** “It is the first scientific publication about our DSG technology in Japan, the 2nd largest market worldwide in our sector . Furthermore, in a degenerative cervical spine application that requires extreme precision and sensitivity to screw placement, a specialty for Japanese surgeons due to the prevalence of such pathologies in this country. We are thus very happy about this 15th peer-reviewed journal publication documenting the clinical value of our DSG Technology in Spine. It strengthens the solid base of clinical evidence in support of our DSG technology that we are determined to deploy throughout new and promising clinical applications. We are actively working with the venture bank Healthios Capital Markets in order to find significant industry partnerships and generate growth and value for our shareholders.”

**Dr. Hiroto Kageyama, Assistant Professor of neurosurgery at Hyogo College of Medicine, Nishinomyia, Hyogo, Japon adds:** “We found the PediGuard device useful in our practice for the insertion of C1 lateral mass screws because it is easy to detect the anterior cortical wall of the Atlas on the basis of its auditory signal. After measuring the actual probe length, the screw length can be decided and the bicortical screwing can be performed safely and tightly.”

<sup>1</sup>Source: «Spinal Surgery Devices Market: Global Market Analysis, Dynamics, Country Share, Trends, Competitor Analysis 2013 - 2017 and Forecast 2018 - 2025», Kenneth Research, Dec. 2019

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Investor Relations & Financial Communication  
Mathilde Bohin/ Pierre Laurent  
Tel : +33 (0)1 44 71 94 94  
[spineguard@newcap.eu](mailto:spineguard@newcap.eu)

Manufacturer:  
**SpineGuard® S.A.**  
10 cours Louis Lumière  
93400 Vincennes - France  
Phone: +33 1 45 18 45 19  
Fax: +33 1 45 18 45 20

**SpineGuard®**  
Making spine surgery safer  
[www.spineguard.com](http://www.spineguard.com)

Distributor:  
**SpineGuard® Inc.**  
1434 Spruce Street, Suite 100  
Boulder, Colorado, 80302 - USA  
**Phone: +1 720 726 8085**  
**Fax: +1 720 726 8001**