DSG®
Dynamic Surgical Guidance

Scientific & Clinical Evidence

Updated July 2022

SpineGuard®
Making spine surgery safer

PediGuard® probes have assisted spine surgeons in accurately placing over 500,000[a] pedicle screws worldwide

With mounting clinical evidence confirming its efficacy, PediGuard devices, that integrate the DSG® Technology, are becoming a compelling answer to the clinical needs associated with safe and accurate pedicle screw placement.

Screw Placement Accuracy & Breach Detection

97% screw placement accuracy[1-8]

98% breach detection[9]

100% pedicle breach anticipation[10]

92.5% Complex deformity, accuracy upper thoracic[11]

3 times fewer pedicle perforations than with free-hand technique[4]

Surgical Education

58% breach rate reduction when used by residents[83]

Radiation Safey & Surgical Efficiency

73% reduction of X-Ray times in MIS[14]

30% reduction of X-Ray shots in open[4,5]

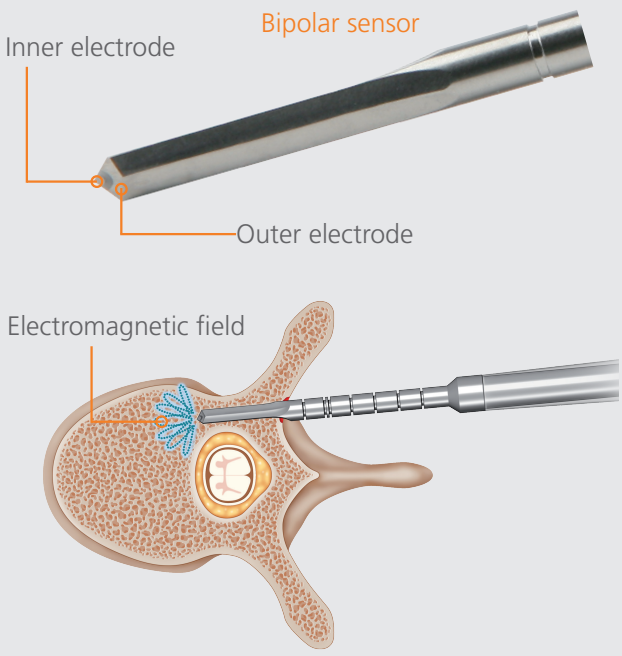
15% surgical time savings during screw placement[4]

New Applications & Techniques

New Techniques

Sacro-iliac fusion[15]

Anterior approach



The bipolar sensor of PediGuard emits an electrical current which flows locally through the bone from the inner electrode to the outer electrode, creating a circular electromagnetic detection field at the very tip of the instrument. The real time, local changes in electrical conductivity of the bone as measured by the sensor are translated into audio feedback that varies in pitch and cadence to inform the surgeon about the nature of the bone at the tip while advancing through the pedicle down the vertebral body.

The result is that PediGuard can alert the surgeon about a possible perforation of the cortex, and furthermore may help the surgeon anticipate a breach by detecting the approaching cortical wall.

The mission of SpineGuard is to help the surgeon make spine surgery safer – for the patient, for him/her and the OR staff.

Learn more about the DSG family of products at:
www.spineguard.com

[a]Estimation based on 5.5 screws per construct on average

Content

Pedicle Screw Challenges

Pedicle screw-based stabilization is the gold standard for treating spinal instabilities and deformities. Technological advancements such as screws in the Thoracic Spine, Cortical Bone Trajectory and Minimally Invasive Surgery are compounding the importance of pedicle screw placement.

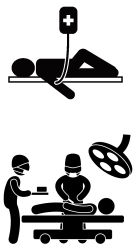
Accuracy of Pedicle Screw Placement remains a Critical Issue in Spine Surgery

"The main risk associated with placing pedicle screws is pedicle perforation, which occurs when the screw exits the vertebrae. This can result in dural tears, vascular injury, nerve injury or, rarely, spinal cord injury." (*NICE 2015*)[16]

Up to 20% of pedicle screws have been reported as misplaced when using conventional techniques (non-assisted techniques) and around **~5%** when using navigation or robotic-assisted[17, 18, 19, 20].

Consequences of Misplaced Pedicle Screws are not to be Underestimated

Neurological Complications and Revision Surgery



3.7% of the patients on average experience **neurological symptoms** after a spine surgery (from 0% to 11%).

4.4% of the patients on average have a **revision surgery** to correct a misplaced screw (range 1% to 11%)[a].

2nd **cause of reoperation** within 30 days of spine surgery inpatients is due to neurological complications after posterior lumbar instrumentation and/or in trauma patients[b].

Revision surgery for a misplaced screw is more common in trauma-cervical patients (15%) and deformity patients (10.7% for major deformity and 6.3% for spondylolisthesis)[62].

Vascular Complications

Vascular injuries are rare but life threatening. Many case reports have been published[37-58].

Cost Implications

$17,650 to **$27,768** **additional cost for a revision surgery** to correct a misplaced screw[c-d].

Lawsuits

Spine surgeons are at a higher risk of lawsuits than doctors from other specialties. Nerve injury is the cause of **41% of the claims** according to a recent medicolegal study in spine surgery[63].

Examples of liability issues related to misplaced screws:

- Teenage girl left paralyzed (Ireland, €4,8m)[64],
- Permanent nerve damage with drop foot (USA, $800,000)[60],
- New neurological symptoms (USA, $1,272m)[66].

Conclusion

- Revision surgery to correct misplaced screw happens on average in **4.4%** of the patients.
- Neurological complications occur in up to **11%** of the patients.
- Vascular complications and loss of stability should not be underestimated.
- Liability issues are rare but the settlement amount can be very high.
- Navigation improves pedicle screw placement but increases significantly radiation exposure for patients.

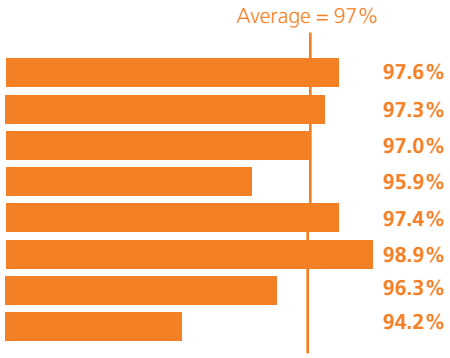
[a]Based on 11 studies[21-33] including totally 3,617 patients and 18,494 pedicle screws.
[b]Based on a large Japanese multi-center study[34].
[c]Those studies do not include indirect costs such as health care visits, diagnostic imaging, medication, injection, etc.
[d]Based on four US economic studies[59-62].

Dynamic Surgical Guidance Solution

PediGuard devices are the only handheld devices that can anticipate[10] and/or detect possible vertebral cortex perforation during pedicle preparation for screw placement. PediGuard probes can alert the surgeon prior to a breach by accurately analyzing the electrical conductivity of the surrounding tissues in real time.

Strong Results in a Wide Number of Clinical Studies Worldwide

	Type of the study[a] LoE[b]	Accurate screws	Number of screws
SUESS 2016[1]	R-IV	82	84
DEFINO 2015[2]	PR-I	292	300
HEIMEN 2014[3]	PR-I	197	203
BAI 2012[4]	PR-I	347	362
CHAPUT 2012[5]	PR - II	38	39
CHANG 2009[6]	R-IV	265	268
LUBANSU 2006[7]	P-IV	261	271
BOCQUET 2006[8]	P-IV	98	104
TOTAL		1580	1631

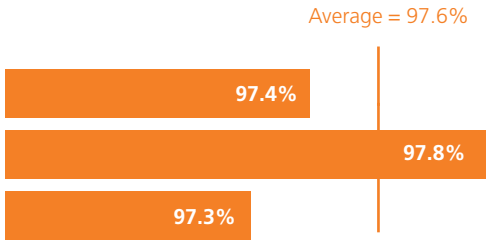


Very Accurate Technology

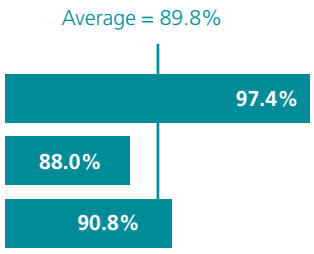
Those data suggest that accuracy of pedicle screw placement with the **PediGuard** device is drastically **improved** ranging from **94%** to **99%**.

Accuracy Increased in Three Randomized Clinical Studies

PediGuard	Level and indication	Accurate screws[c]	Number screw
CHAPUT 2012[5]	Lumbar degenerative spine	38	39
BAI 2012[4]	T1-L5 AIS	354	362
DEFINO 2015[2]	T3-S1 Osteoporosis	292	300
Total screws		684	701



Conventional technique with fluoroscopy	Level and indication	Accurate screws[c]	Number screw
CHAPUT 2012[5]	Lumbar degenerative spine	38	39
BAI 2012[4]	T1-L5 AIS	292	332
DEFINO 2015[2]	T3-S1 Osteoporosis	324	357
Total screws		654	728



There were no difference in Chaput's study because the surgeons relied on many fluoroscopic shots to provide a safe screw placement (7.5 fluoroscopic shots (range, 2-17) in the standard group versus 5.2 (range, 0-15) per screw in the PediGuard group, $P < 0.0001$)).

[a]PR: Prospective Randomized, R: Retrospective, P: Prospective.
[b]LoE: Level of Evidence.
[c]Screws fully inside the pedicle or screw breaching 2mm or less.

Consistent and Reliable Breach Anticipation and Detection

In an European multi-centre clinical trial with 11 senior surgeons in 9 centers, 521 pedicle drillings were performed on 97 patients. The PediGuard probe detected and therefore prevented **98%** of breaches (63/64)[9].

3-Fold Reduction in Neurophysiological Alarms[13]

Screw placement in 248 scoliosis patients[13] was retrospectively studied, and when a PediGuard probe was used:

- **3 times less** neuromonitoring alarms per screw were recorded,
- **Almost twice as many** screws were inserted per patient.

Comparison of PediGuard to EMG shows an Improvement in Sensitivity and Specificity Rates

	EMG[67, 68] (based on 2 systematic reviews and meta-analysis)	**PediGuard**
Overall sensitivity and specificity of the probe *Sensitivity: Probability of breach detection given that there is a breach* *Specificity: Probability of NO breach detection given that there is NO breach*	(threshold 5-15 mA) sensitivity 91% specificity 75%	(Bolger 2007[9]) sensitivity 98% specificity 99%
Pedicle breach anticipation	No	100% (Williams[10])
Medial detection	Yes	100% (Williams[10])
Lateral or anterior breach detection	No	Yes (Williams[10], Guillen[83])
Detection in case of chronically compressed nerve root	Unlikely	Independent of the nerve condition
Misplaced screw	Up to 22%	3% on average[1-7]

Updated Guidelines for Intra-Operative Monitoring (IOM), 2014

The **American Association of Neurological Surgeons** have updated their **guidelines** regarding **IOM** during lumbar fusion for degenerative spine disease[69]:

- There is no evidence to date **that IOM can prevent injury to the nerve roots.**
- There is limited evidence that a **threshold below 5 mA** from direct stimulation of the screw can **indicate a medial pedicle breach by the screw.**
- Unfortunately, once a nerve root injury has taken place, changing the direction of the screw **does not** alter the outcome.

Additionally, Reviews of national databases[70,71] demonstrated that the use of EMG and neuromonitoring for spine fusions does not decrease the risk of neurological injuries.

The Dynamic Surgical Guidance technology provides valuable feedback without interrupting the surgical procedure.

Safe Placement in Patients with Poor Bone Quality

Clinical Study part #1[2]

In a randomized clinical study including 108 patients[2], 97 patients had osteoporosis and 11 patients had osteopenia:

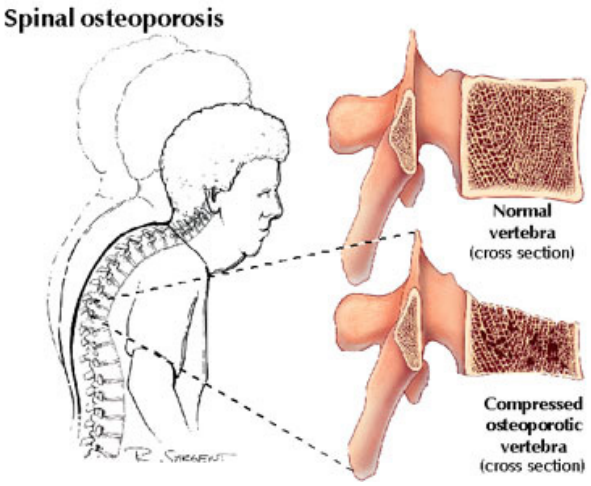
- **97.3%** of the screws accurately placed with the PediGuard probe instead of **90.8%** without the PediGuard probe,
- **54%** less fluoroscopic shots with the PediGuard.

Even in patients with osteoporosis or osteopenia, the PediGuard probe demonstrates at least **3 times** less pedicle breaches (>2mm).

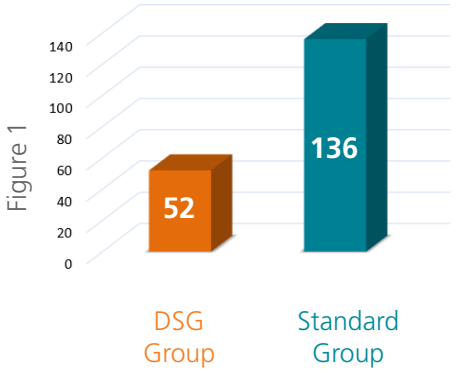
Clinical Study part #2[2]

Operative levels were from T3 to S1. Pedicle preparation was using either DSG or the free-hand technique. A total of 657 pedicle screws were placed.

- Reduction of radiation was decreased by **74%** (P<0.0001) (Fig. 1).
- This combination of pedicle preservation and reduction of pedicle breaches during preparation led to a higher screw placement accuracy rate in the DSG assisted group. There was a **11%** breach rate in the Standard Technique group and a **2.6%** breach rate in the DSG assisted group (P<0.0001) (Fig. 2).

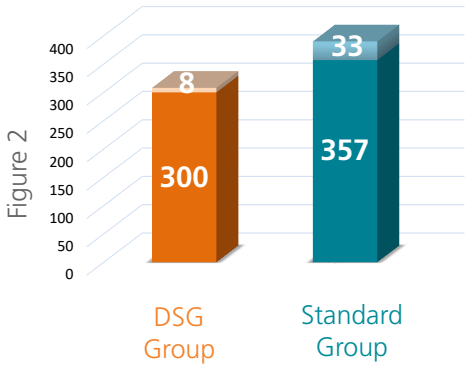


Reduction of Radiation (Fluoroscopy)



Number of Fluoro Shots

Screw Placement Accuracy



Top: Total of Screw Breaches

Low: Total Number of Screws

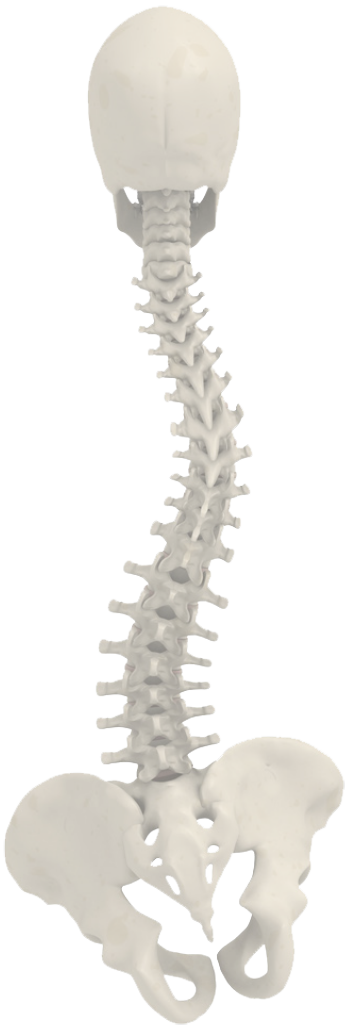
The use of Dynamic Surgical Guidance showed statistical significant differences in radiation exposure, screw placement accuracy and intra-operative pedicle preparation breaches.

These studies demonstrate that DSG has the potential for safely and effectively treating patients with demineralized bone.

Scoliosis Patients

A Large Number of Patients Treated for Scoliosis Emerge from Surgery with Screws of Concern

Screws at risk impinging anatomic structures such as the **aorta, esophagus, trachea or lung** and screws causing **neurologic deficits or injuries** are reported in two recent large studies[63,72].



Risk of Vascular Complications

In patients with deformity, revision surgery to remove a screw at **risk for the aorta** is recommended in **4.7%** (7/148[24] and 6/127[72]) of the patients.

Instability

Misplaced screws without clinical symptoms can lead to **screw loosening** (1.4%: 3/208 patients[74]; 3.5%, 3/86 patients[75]).

Cerebrospinal Fluid (CSF) Leaks

- **CSF leakage** without clinical symptoms from screw holes in 3.5% (3/86) patients[75].
- **Dural leak** causing **positional headaches** in 0.9% (3/322) patients[76].

Revision Surgery

Pedicle screw misplacement is the **first cause of reoperation** wihtin 30 days of spine surgery in **1.7% AIS**[a] patients in a US multi center study[77].

Radiation Exposure on Young Patients

- The **radiation exposure** is greater during **scoliosis surgery**[78].
- **Young people** are very **sensitive** to radiation exposure during their childhood[79].
- **Girls** are at a **higher risk** of cancer development[80].

How the DSG Technology can Help

A randomized clinical trial[4] assessed the accuracy and time for pedicle screw placement with the DSG Technology and the Free-Hand technique for posterior scoliosis surgery.

- There were totally **3 times less pedicle perforations** in the DSG group (4.1%) than in the Free-Hand group (14.2%) (15 versus 47 (P<0.001)).
- The average **screw insertion time** was **decreased by 15%** in the DSG group.

A retorspective study[11] in patients with severe deformities showed a greater screw placement accuracy compared with the Free-Hand technique, especially in the thoracic region (**92.5%** DSG Group vs 87% FH group).

A retorspective study[81] in patients with severe syndromic and neuromuscular scoliosis, demonstrated a **10.2%** higher screw placement accuracy when using PediGuard and twice lower abandonment rate due to liquorrhea or perforation.

….“the PediGuard can reduce exposure to fluoroscopy, has high sensitivity and specificity for detecting pedicle perforations, and can significantly reduce the number of malpositioned screws” (NICE 2015)[16].

[a]AIS: Adolescent Idiopathic Scoliosis

The PediGuard Probe for Residents

In a study, 2.1% of the patients (11/531) presented after a TLIF procedure[76] with worsening postoperative pain resulting from nerve root impingement by a pedicle screw. At least 50% of all pedicle screws had been placed by neurosurgical residents of varying experience. All implicated screws were removed and revised subsequently.

Experimental studies with the DSG Technology have demonstrated the added value of the PediGuard probe as a teaching tool for residents.

Reduction of the Learning Curve for Spine Surgery Residents

In a cadaveric study[12], 5 residents were randomized and assigned 3 specimens each to prepare bilateral pedicles from T8 to L5 (60 pedicles per resident) using either PediGuard devices or the Free-Hand technique.

PediGuard probes decreased:

- The **learning curve** for placing pedicle screws,
- The **breach rate by 58%** (19.7% in the non PediGuard vs 8.2% in the PediGuard group),
- **Surgery** time by **21%** when placing pedicle screws.

Detection of Pedicle Breach with only 20 minutes of Didactic Training about the DSG Technology

Individuals of 3 levels of training (attending spine surgeon, orthopedic surgery resident and medical student) used the Cannulated PediGuard device to cannulate each levels between T2 and S1[72].

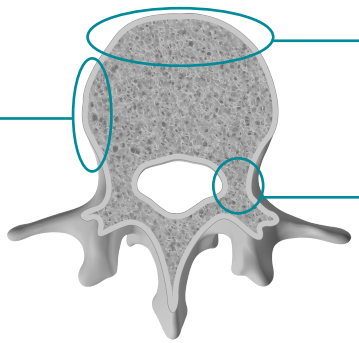
Sensitivity of the Cannulated PediGuard probe to detect impending breach or breach of 4 mm or less.

Real Time Breach Detection and Anticipation

In a cadaver study in the U.S.[10], the PediGuard probe warned the surgeons for an impending breach:

87% breach anticipations

79% in the lateral vertebral body



72% in the anterior vertebral body

100% anticipation into the pedicle

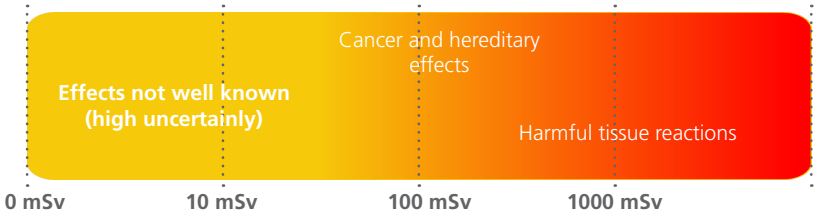
100% successful redirection without a breach after anticipation of an impending pedicle wall breach.

Dangers of Radiation

Radiation exposure in spine surgery is excessive, protection is underutilized, and the long-term biological effects can be deadly. Fortunately, there is a growing concern among influential spine surgeons who are calling for the reduction of radiation vulnerability in the OR.

Surgeons' Greater Reliance on Fluoroscopy during Procedures exposes the Entire OR Team to Dangerous Radiation

- Surgeons are **highly exposed** especially in **MIS surgeries**[84] and **scoliosis surgeries**[85].
- The **annual limit dose to the eye of 20 mSv/year**[86,87] can be **exceeded** after:
  - **220 open TLIF** with 3.4 levels per case on average[88],
  - **112 MIS TLIF** with one level per case[89].



- Short-term to long-term consequences due to repetitive fluoroscopic procedures are:
  - **Back pain** due to heavy protections[90],
  - **Lens opacities**[91-93],
  - **Cancer** (breast, neck, brain)[79,95,96].

- Other limitations are observed:
  - Protective equipment is low or insufficient especially at the eyes and neck[97],
  - Lead aprons are subject to internal wear and their protection can be weakened without visible changes[98-100],
  - Operator's legs, arms and head are usually not fully protected.

Randal Betz, MD
Pediatric Orthopaedic Surgeon
Lawrenceville, New Jersey

"I am very concerned not only for myself but my colleagues about the amount of radiation we are all receiving during spine surgery."

Helton Defino, MD
Orthopedic Surgeon
Ribeirao Preto, Brazil

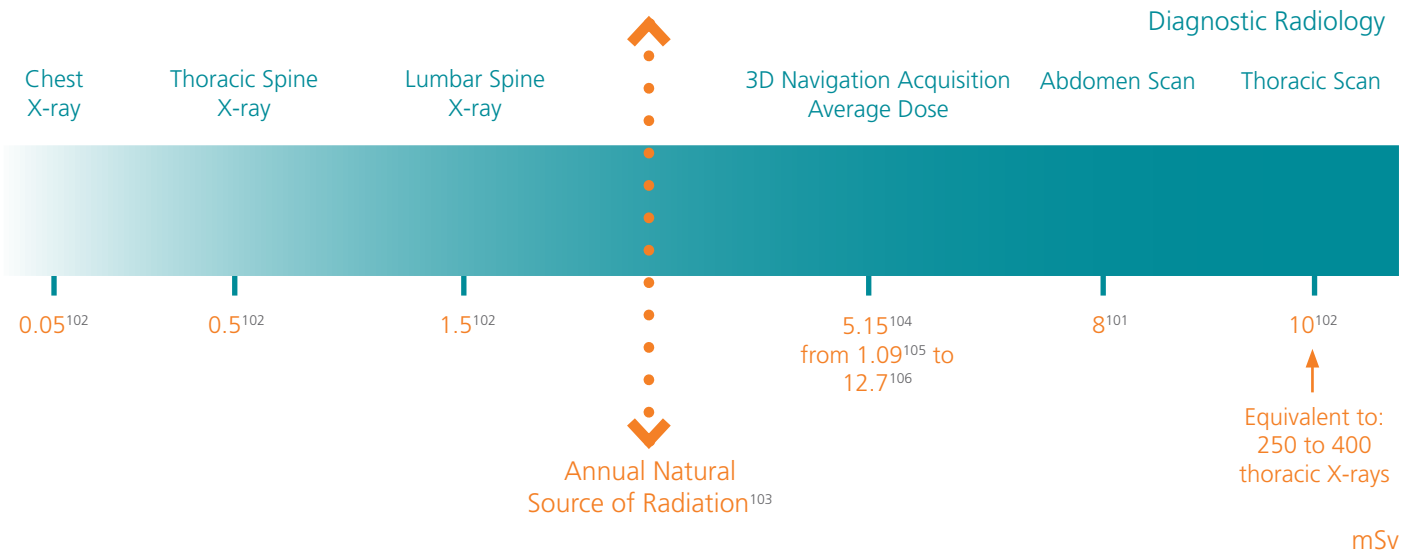
"We are very concerned about repeated radiation especially now with new techniques since minimally invasive surgery was introduced in spinal surgery."

Larry T. Khoo, MD
Neurosurgeon, The Spine Clinic of Los Angeles, California

"Decreasing overall radiation exposure both shielded and un-shielded is very important because even when we are shielded parts of us are still exposed. This rings true personally for me because one of my practice partners passed away from what we believe was radiation thyroid malignancy. These are not just abstractions of fear but are real things that we can measure and knowing that radiation is a quantitative, a cumulative dose and anything that we can do to cut down 10 to 20% would have a tremendous impact on our safety and practice."

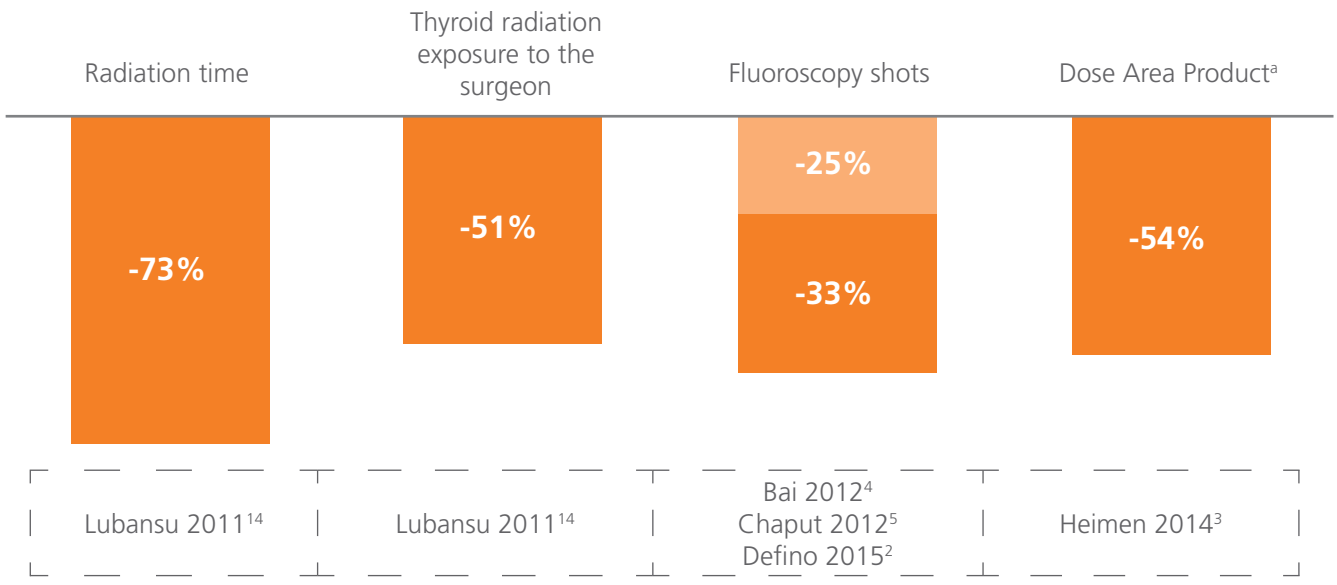
Ciaran Bolger, MD
Neurosurgeon, Beaumont Hospital
Dublin, Ireland

"I am very concerned about repeated exposure to radiation over a lifetime of work. I think it is a significant problem and it's a problem that is becoming an increasing problem because with minimally invasive techniques we are using far more radiation then our predecessors were."



PediGuard Devices can significantly reduce Radiation

Studies show that the PediGuard probe can significantly reduce the radiation exposure to the surgeon and the OR team:



PediGuard family of products complies with the recommendations of the International Commission for Radiation Protection (ICRP) and the ALARA principle As Low as Reasonably Achievable[107].

[a]Dose measured on the fluoroscopic system

Biomechanical studies with DSG

Perfect anchorage of screws in the pedicles is a crucial feature to achieve a good stabilization of the spinal construct.

Two biomechanical studies demonstrated that the DSG Technology may help to reach this objective.

Study #1

Pilot hole done with the Threaded PediGuard

A biomechanical study[108] has the objective to experimentally evaluate the influence of the pilot hole tapping using the Threaded PediGuard and a screw with a different pitch from the Threaded PediGuard.

Three types of tapping were performed to do the pilot holes in polyurethane blocks:

1. Line-to-line tapping (tap with same pitch and external diameter of the screw),

2. Undertapping with congruent pitch (tap with the same pitch and 1mm smaller external diameter than the screw),

3. Undertapping with incongruent pitch (Threaded PediGuard with different pitch and/or different number of lead and 1mm smaller external diameter than the screw).

After screw insertion, pullout strength was evaluated.

Conclusion: **The shape and pitch of the undertapping tool (Threaded PediGuard) has no influence on the pullout strength of the screw;** [rather, it is the appropriate undertapping diameter that matters to optimize pull out strength].

Study #2

One-step screw direct insertion with DSG Screw

A biomechanical study[109] has the objective to evaluate ***in vitro*** the direct pedicle screw insertion pullout strength.

A further development of Dynamic Surgical Guidance technique was the combination of DSG technology and a pedicle screw in just one device to develop a "A Dynamic Surgical Guidance Screw" (DSG Screw). The DSG Screw (SpineGuard/Zavation Dynamic Surgical Guidance Z-Direct Screw) is a pedicle screw system with a breach anticipation sensor located at the tip of the screw. The device provides a real-time surgical guidance and the ability to insert directly the screw into the pedicle without drilling a pilot hole neither tapping.

Screws directly inserted without a pilot hole and without tapping showed, statistically higher pullout strength than pedicle screws that were either tapped or screws that followed a pilot hole.

Conclusion: **DSG Screw showed the highest pullout strength** after its insertion without pilot hole and tapping.

DSG Technology in robotics applications

Using an electrical conductivity loop control system for automated breach prevention during robotic powered drilling of bone.

Studies[110, 111, 112]

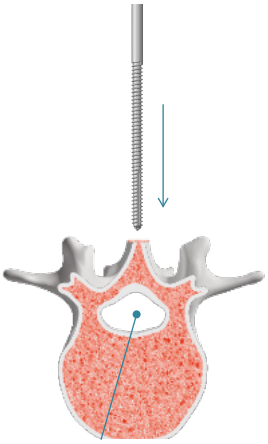
The objective of the study was to quantify the performance of tissue electrical conductivity measurement in real time to automatically detect and prevent bone breaches without utilization of imaging technologies in an ex-vivo animal model

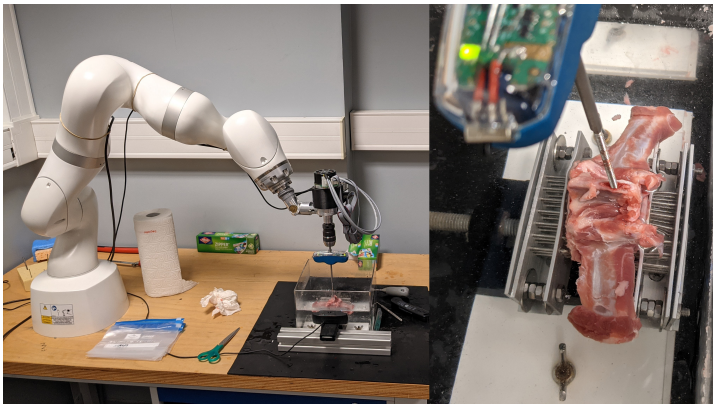
Method

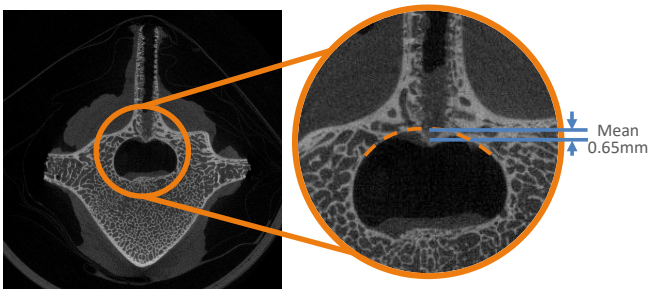
- A first series of 100 drill-through to collect data on measured electrical conductivity and penetration depth as a function of time
- An analysis work to optimize breach detection algorithms based on the collected data
- A second series of 104 drillings with real-time prospective application of the algorithms in order to automatically stop the robot with the instrument tip as close as possible to the bone/canal interface during the drilling

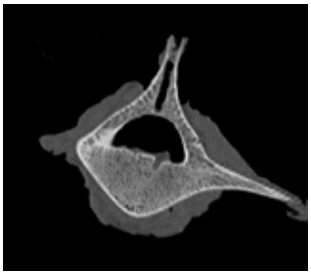
Success criteria

- PASS if tip is within +/- 2mm from the bone/canal interface (grade B)
- FAIL if tip is more than 2mm before (false positive) or more than 2mm after (false negative) the bone/canal interface.

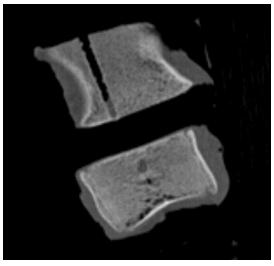




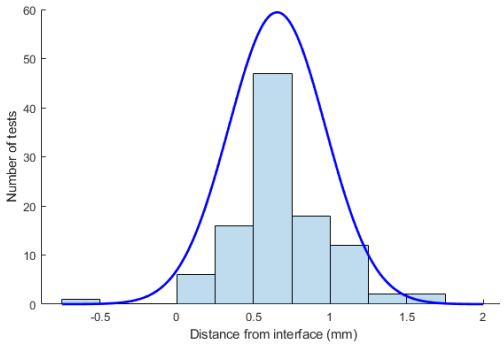




Axial view



Saggital view



Conclusion:

These results demonstrate in an ex-vivo experiment the **robustness and efficacy of tissue electrical conductivity measured in real-time to detect bone boundaries and prevent breaches**.

Beyond that, it opens appealing perspectives since the methodology articulating data collection, algorithm fine-tuning, and experimental verification is validated and can be repeated.

We are currently testing other algorithms of Artificial Intelligence learning, and evaluating what can be done from actual surgery data collected

In the context of the FAROS European project, we are evaluating how to combine DSG with other robot-generated or additional sensor-generated signals in order to produce even more advanced functions than breach detection and demonstrate the technical feasibility of automatic screw insertion without X-ray imaging.

This updated brochure presents 9 new publications (in blue) since the previous version of March 2019 and includes 20 papers on PediGuard (in orange) as follows:

- 12 published articles (2 in Spine, 1 in Journal of Spinal Disorders, 3 in European Spine Journal, 1 in Journal of Neurosurgery Spine, 1 in Coluna/Columna, 1 in Advances in Medicine, 1 in World Neurosurgery, 2 in Brazilian Journal of Orthopaedics)[a].

- 8 oral presentations or posters in major congresses (Belgian Society of Neurosurgery 2006, IMAST 2006, AANS 2009, Eurospine 2011, CNS 2014, Congresso Brasileiro de Coluna 2015, DWG Meeting 2014, SRS 2015).

- 1 publication by the NICE (National Institute for Health and Care Excellence, UK) 2015.

[a]We can also add 5 peer-reviewed publications on PediGuard that are not referenced in the brochure (1 in Spine, 3 in European Spine Journal, 1 in Coluna/Columna).

References

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Straight

Curved

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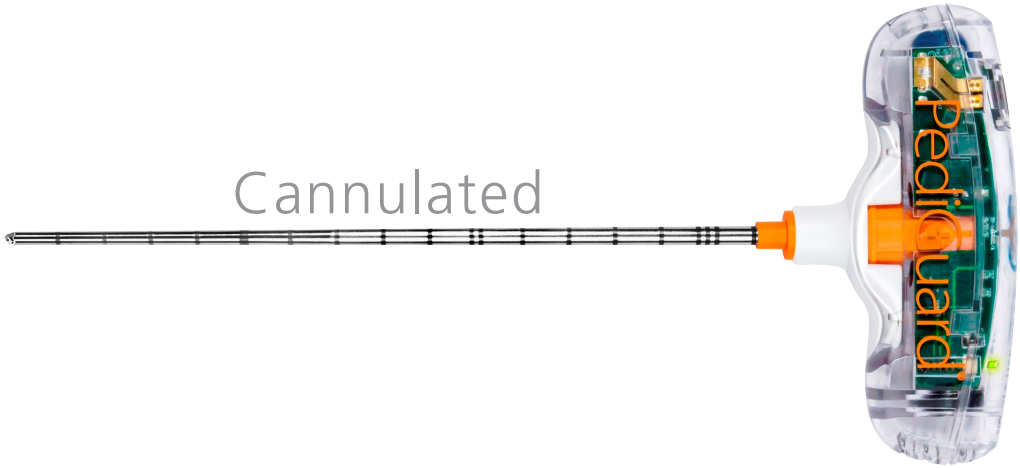

Threaded

Notes

Ref. GPICLINIC/122US - July 2022

Caution: See package insert for labeling limitations, intended uses, relevant warnings, precautions, side effects and contraindications.
Federal (USA) law restricts the sale and use of this device to a prescription of a physician

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