Introducing the Cannulated PediGuard® for Minimally Invasive Spine Surgery (MIS): a handheld device that can detect possible vertebral cortex perforation during pedicle preparation for screw placement.

- Hear and feel what you cannot see
- Be reassured that your trajectory is sound
- Reduce your radiation exposure by relying on PediGuard feedback
- Anticipate possible breaches of the pedicular wall or vertebral body
- Redirect with complete confidence
- Safely cannulate deeper into the vertebral body than with traditional MIS techniques, then introduce the k-wire

Simple. Innovative. Smart.

The one-of-a-kind PediGuard technology is placing navigation back in your hands.

Minimally Invasive Spine Surgery: Benefits and Risks

Minimally invasive spine surgery has been developed to treat disorders of the spine with less blood loss and soft tissue destruction, allowing quicker recovery and faster patient return to normal function. However, this technique requires significant planning and changes in the approach to pedicle screw placement, such as using challenging fluoroscopy to navigate the pedicle. The Cannulated PediGuard can help you take advantage of the benefits of less invasive spine surgery while addressing some of these challenges.

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The PediGuard technology provides valuable feedback unmatched by fluoroscopy and other technologies without interrupting your surgical procedure. The result is continuous real-time navigation in a simple, handheld device.

Electromagnetic bipolar sensor

Monitors real-time changes
in electrical conductivity
5 times per second

Modelled Tip

Cortical bone breach

Cancellous bone

Rates of properly placed screws (%)

• 97% screw placement accuracy[2, 3, 4, 5, 6]
• 98% probability of breach detection[1]
• 87% breach anticipation[7]
• 3-fold reduction in neuro-monitoring alarms[8]
• 15% time saving during screw placement[6]

Studies show that the use of PediGuard can significantly reduce the radiation exposure to you and your staff:

• 73% radiation time reduction[9]
• 51% reduction in thyroid radiation exposure to the surgeon[9]
• 25% - 30% reduction in fluoroscopy shots during pedicle screw placement[2,6]

Surgeons’ greater reliance on fluoroscopy during procedures exposes the OR team to dangerous radiation.

• The average spine surgeon will receive the maximum allowable lifetime exposure of radiation for classified workers within 10 years of practice.[4]
• The radiation exposure in spine surgery has been found to be 10 to 12 times greater than the radiation exposure during other fluoroscopically assisted non-spinal musculoskeletal procedures.[4]

Studies show that the use of PediGuard can significantly reduce the radiation exposure to you and your staff:

• 73% radiation time reduction[9]
• 51% reduction in thyroid radiation exposure to the surgeon[9]
• 25% - 30% reduction in fluoroscopy shots during pedicle screw placement[2,6]

Delivered sterile, ready to use.
The PediGuard technology provides valuable feedback unmatched by fluoroscopy and other technologies without interrupting your surgical procedure. The result is continuous real-time navigation in a simple, handheld device.

Safety is our primary concern

Rates of properly placed screws (%)

Conventional Techniques

PediGuard®

- 93% accuracy
- 23% reduction in fluoroscopy shots to place screws
- 51% reduction in thyroid radiation exposure to the surgeon
- 25% to 30% reduction in fluoroscopy shots during pedicle screw placement

Surgeons’ greater reliance on fluoroscopy during procedures exposes the OR team to dangerous radiation.

- The average spine surgeon will receive the maximum allowable lifetime exposure of radiation for classified workers within 10 years of practice.
- The radiation exposure in spine surgery has been found to be 10 to 12 times greater than the radiation exposure during other fluoroscopically assisted non-spinal musculoskeletal procedures (Rampersaud 2000).

Studies show that the use of PediGuard can significantly reduce the radiation exposure to you and your staff:

- 25% radiation time reduction
- 51% reduction in thyroid radiation exposure to the surgeon
- 25% - 35% reduction in fluoroscopy shots during pedicle screw placement

Delivered sterile, ready to use.

Conventional

PediGuard®

Cannulated PediGuard® Handle ref. P2HE1000

Cannulated PediGuard® Starter Stylet - Trocar ref. P2ST1060

Cannulated PediGuard® Starter Stylet - Bevel ref. P2ST1050

Cannulated PediGuard® Needle ref. P2ND1001

Radiolucent T-handle
Low profile improves surgeon access and space

Universal low lock

Battery
No external power supply needed

LED
Alerts surgeon with changes in flashing LED cadence

Audio system
Alerts surgeon with changes in pitch and cadence

Universal luer Lock
Detachable handle with electromagnetic circuit board

Electromagnetic bipolar sensor
Sensitively monitors change in electrical conductivity 5 times per second

Flexible metal shaft and cannula
Internal thread height (BD) ensures for smooth insertion and removal

Cannulated PediGuard®
Needle ref. P2ND1001

Stainless steel shaft and cannula (160mm total length)
Stiff tapered tip for smooth insertion and removal

The PediGuard technology has demonstrated strong results in a wide number of clinical studies with more studies forthcoming:

- 97% screw placement accuracy
- 98% probability of breach detection
- 87% breach anticipation
- 3-fold reduction in neuro-monitoring alarms
- 15% time saving during screw placement

The PediGuard technology provides feedback unmatched by fluoroscopy and other technologies without interrupting your surgical procedure. The result is continuous real-time navigation in a simple, handheld device.

Cortical bone

Breach

Cancellous bone

50mm

100mm

150mm

30mm

50mm

70mm

GAUGE 8
Ø 3.3mm

GAUGE 7
Ø 3.7mm

GAUGE 6
Ø 4.2mm

Ø 3.0mm

≈ 73-85%

≈ 91-93%

≈ 94-99%
The PediGuard technology provides valuable feedback unmatched by fluoroscopy and other technologies without interrupting your surgical procedure. The result is continuous real-time navigation in a simple, handheld device.

Safety is our primary concern

Make your first pass the right pass

The PediGuard technology has demonstrated strong results in a wide number of clinical studies with more studies forthcoming:
- 97% screw placement accuracy
- 98% probability of breach detection
- 87% breach anticipation
- 3-fold reduction in neuro-monitoring alarms
- 15% time saving during screw placement

Hear what you cannot see

Reduce Radiation Exposure

Studies show that the use of PediGuard can significantly reduce the radiation exposure to you and your staff:
- 33% radiation time reduction
- 53% reduction in thyroid radiation exposure to the surgeon
- 25% - 35% reduction in fluoroscopy shots during pedicle screw placement

Surgical’s greater reliance on fluoroscopy during procedures exposes the OR team to dangerous radiation.
- The average spine surgeon will receive the maximum allowable lifetime exposure of radiation for classified workers within 10 years of practice.
- The radiation exposure in spine surgery has been found to be 10 to 12 times greater than the radiation exposure during other fluoroscopically assisted non-spatial musculoskeletal procedures.

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Minimally invasive spine surgery has been developed to treat disorders of the spine with less blood loss and soft tissue destruction, allowing quicker recovery and faster patient return to normal function. However, the pedicle screw placement (even in MIS) challenges in this less invasive approach, due to the lack of visual feedback and tactile feel, resulting in excessive use of fluoroscopy. The new Cannulated PediGuard can help you take advantage of the benefits of less invasive spine surgery while addressing some of these challenges.

Simple. Innovative. Smart.

PediGuard®

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Bibliography

Caution: See package insert for labeling limitations, intended uses, relevant warnings, precautions, side effects and contraindications.

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