Instruction For Use of the Threaded PediGuard - USA

LP2-A086 - Version A

SpineGuard®

www.spineguard.com

For US market only

In no case can the PediGuard® Threaded device replaces the surgeon's experience or knowledge of anatomic structures. It is intended to assist the surgeon in the decision-making process during surgery in the operating room.

1. INTRODUCTION

The PediGuard® Threaded device is used in drilling pilot holes into the spinal vertebrae. This System serves to alert the surgeon to a possible vertebral cortex fracture while drilling a screw pilot hole in a pedicle or in a vertebral body.
It is strongly recommended that the working principle of the DSG® Technology be clearly understood before using the PediGuard® Threaded device.

2. TECHNICAL DESCRIPTION

The PediGuard® Threaded device is part of the DSG® product range. The PediGuard® Threaded device consists of:

- DSG® single-use instruments provided sterile:
  - DSG® Pin Ref. D1PUXXXX, which embeds the proprietary DSG® bipolar sensor
  - Electronic Handle Ref. P2HEXXXX, which houses the electronics that read and translate the electrical signals detected by the sensor. Note: An optional feature is available to transmit the conductivity data to an external display to allow signal visualization and recording. The handle equipped with this feature is labelled DSG Connect and is equipped with a communication module which transmits data through radio frequency (RF) communication (2.40 – 2.48 GHz, GFSK modulation and maximum RF output power of 9.9 dBm).
  - Optional accessory: Starter Pin – Ref. D1SPXXXX

- DSG® reusable instruments that must be cleaned and sterilized before use:
  - DSG® Ratcheting Handle - Ref. D1RHXXXX
  - DSG® Threaded Shafts - Ref. D1TAXXXX
  - DSG® Sleeve – Ref. D1STXXXX
  - DSG® Technology Instrument Tray: Base Ref. D1TT1XXX and Lid Ref. D1TT2XXX.

- Optional DSG Connect visualization software: DSG Connect App – Ref D1SW0001 to be used on a dedicated tablet and with the Electronic handle equipped with the DSG Connect feature

The proprietary DSG® bipolar sensor, allows for identifying tissue type and redirecting as necessary before the main threads of the DSG® Threaded Shaft engage with bone. The sensor also enables the surgeon to select a more optimal spinal implant (screw) length.

The threaded drilling step may reduce the surgical procedure time and minimize cortical wall breaches compromise.

The inherent design of the PediGuard® Threaded device makes it an optimal choice for use in MIS/percutaneous procedures. Additionally, the PediGuard® Threaded device allows the surgeons to take advantage of this unique technology without having to change the implant system they are familiar with.

The PediGuard® Threaded device provides several advantages with minimal change to a surgeon's surgical practice:

- The threads help to easily penetrate bone.
- The DSG® Ratcheting Handle allows for advancement into the vertebrae in small increments.
- Progression in small increments in bone is confirmed by steady auditory feedback.
- The intuitive tip allows for redirection without significantly enlarging the pre-drilled hole.
- Well-managed redirection based on real-time feedback from the DSG® Technology equipped tip.
- Controlled DSG® Threaded Shaft removal in MIS procedures when redirection is necessary.

The tip of the instrument is the applied part.

Note: The PediGuard® Threaded device is a battery-operated device with a maximum output current of 5.5 milliamps ("mA"). Published literature suggests that threshold level monitoring requires at least 8-10 mA. The PediGuard® Threaded device, which does not perform threshold recordings, is not intended to be used as a substitute for a threshold level monitoring device.

Essential Performances:

1 - Mechanics essential performance: the cutting ability during the bone drilling.
2 - Electronics essential performance: sound and visual signals lead the surgeon during the bone drilling. Those informing signals convey the conductivity information which characterizes the tissues in contact with the sensor tip.

3. BEFORE USE

3.1 Information related to single-use devices

The electrical and sensory components of the PediGuard® Threaded device are single use devices. The retreatment and the re-use of the single-use PediGuard® Threaded device components are forbidden.
Inspect the single-use instruments for integrity of packaging. ONLY USE INSTRUMENTS WITH INTACT PACKAGING.

DO NOT CLEAN, RE-STERILIZE, OR RE-USE THE SINGLE USE COMPONENTS OF THIS DEVICE.

Several potential dangers related to the re-use of the PediGuard® Threaded device can increase the risk to the patient. Some technical characteristics of the electrical and sensory components of the PediGuard® Threaded device are not compatible with the re-use of the instrument. Possible issues with re-sterilization and re-use are: non-functioning device, failure of some or all of the electronic functions, unknown changes to the electronic function of the device, non-sterile device, transfer of disease, cleaning agents or disinfectants.
Additionally, the re-use of a single use device will result in the loss of traceability of the medical device and the loss of the technical documentation, such as this instruction for use.

3.2 Information related to reusable devices

Preliminary Check

Before each use, all DSG® reusable instruments must be inspected, cleaned and sterilized.
All assembled instruments must be disassembled before inspection, cleaning and sterilization. To disassemble:

1. If still present, remove the DSG® Sleeve from the DSG® Threaded Shaft.
2. If still present, remove the Electronic Handle and the DSG® Pin from the DSG® Ratcheting Handle. Dispose of the Electronic Handle and the DSG® Pin (single use only).
3. If still assembled, separate the DSG® Threaded Shaft from the DSG® Ratcheting Handle.

Prior to each use, perform a visual inspection of all the disassembled reusable instruments.
Ensure that the V-Shape in the DSG® Ratcheting Handle is not damaged (twisted or broken). Refer to Fig. 1

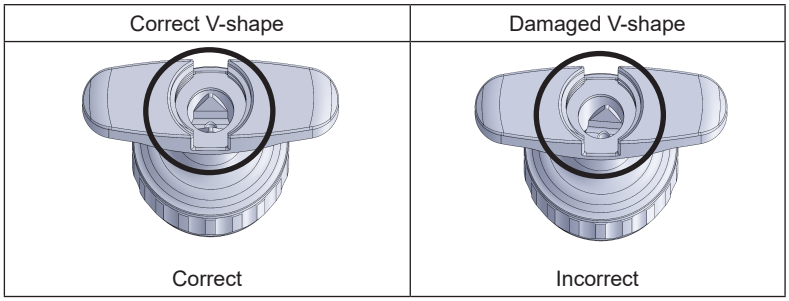


Fig.1

If any damage or excessive wear is noted on the DSG® reusable instruments, such as twisting, bending, breakage, pinching at tips, lack of integrity of the etch marks, discoloration or cracks, they should not be used and should be discarded following the hospital procedures for post-treatment of contaminated devices.

The ratcheting handle should be lubricated after each use with 1 drop of standard biocompatible autoclavable oil at the marked points (see fig.2). Lubricate the locking ring and the selector of the ratcheting mechanism and distribute the oil by moving the components back and forth several times. Wipe off the excess oil with a cloth.

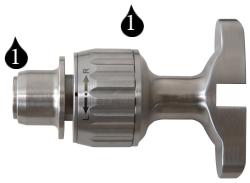


Fig.2

Cleaning for the DSG® reusable instruments

Disassembly of the instruments for cleaning should be performed in the designated cleaning area immediately following use at the point of care.
The DSG® reusable instruments are delivered clean but not sterile; therefore, they must be sterilized before use. The surfaces of all DSG® instruments must be cleaned and decontaminated before sterilization. Clean all DSG® reusable instruments after each surgery at the point of use with a disposable wipe to remove excessive soil.

For the initial and any subsequent cleaning, the recommended general protocol for the pre-disinfection, decontamination, and cleaning of all these instruments is as follows:

- In a pre-disinfection bath, immerse and soak the instruments in an enzymatic detergent solution (pH<11, equivalent to «Steris® Prolystica 2X Enzymatic cleaner») prepared in accordance to the manufacturer's instructions (0.2 to 0.8%) for a minimum of 15 minutes at room temperature (15-25°C).
- After soaking, use a soft-bristled nylon brush to gently scrub the instruments for at least 1 minute, until all visible soil has been removed. Actuate any moveable mechanisms while cleaning. Pay particular attention to lumen and all difficult-to-reach areas. To thoroughly scrub the lumen, push a long, narrow, soft nylon brush in and out of the lumen using a twisting motion.
- Use a syringe, pipette or water pistol to thoroughly flush lumen and all difficult-to-reach areas with an enzymatic detergent solution (pH<11, prepared in accordance to the manufacturer's instructions).
- Ultrasonically clean the instruments (completely immersed) for 15 minutes in enzymatic detergent solution (pH<11, prepared in accordance to the manufacturer's instructions) at ambient temperature (15-25°C).
- Rinse the instruments in distilled water for at least 1 minute at room temperature (15- 25°C). Actuate any moveable parts while rinsing. Thoroughly flush lumens and all difficult-to-reach areas.
- Visually inspect the device and repeat the manual pre-cleaning if there is any visible residual debris.
- Load the instruments into a validated washer/disinfector so that lumen can drain.
- Run an automatic cleaning cycle using the minimum parameters below:

Cycle	Minimum Time	Minimum Temperature	Type of Detergent / Water
Pre-cleaning	2 minutes	Cold < 45°C	Tap Water
Cleaning	10 minutes	Heated 55°C	Enzymatic Detergent (pH< 11, equivalent to «Steris® Prolystica 2X Enzymatic cleaner» 0.2 to 0.8%)
Rinse 1	2 minutes	Cold < 45°C	Tap Water
Rinse 2	2 minutes	Cold < 45°C	Tap Water
Thermal Rinse	5 minutes	Heated 90°C	High Purity Water*
Dry	20 minutes	Heated > 60°C	Not applicable

*Water extensively treated (usually by a multistep treatment process that may include a carbon bed, softening, DI, and RO or distillation) to ensure that the microorganisms and the inorganic and organic material are removed from the water (AAMI TIR 34)

- When unloading, visually inspect all instruments. Repeat the manual and automated washing if there is any residual debris.

Note: Certain washing solutions such as those containing bleach or formalin may damage the instruments and should not be used.
Note: Since no reprocessing methods have been validated for removal or inactivation of transmissible spongiform encephalopathy (TSE) agents (i.e., prions) from medical devices, this device should not be used for patients with known or suspected TSE agent disease.
The cleaning instructions provided by SpineGuard® were validated to demonstrate the adequacy of the cleaning instructions and methods. Users are separately responsible for implementing reprocessing following the instructions, training employees, and monitoring their ability to reprocess devices.

Sterilization for the DSG® reusable instruments

Before use, the disassembled and cleaned reusable components of the PediGuard® Threaded device must be placed in the DSG® Technology Instrument Tray for steam sterilization with the maximum following quantity:

Maximum quantity of instruments per DSG® Technology Instrument Tray	
DSG® Ratcheting Handles	2
DSG® Threaded Shafts	6
DSG® Sleeves	2

The Tray should be wrapped with a double layer of sterilization wrap. In the United States, the wrapping paper must be FDA-cleared. Use a validated, properly maintained and calibrated steam sterilizer. Effective steam sterilization can be achieved using the following cycle:

GEOGRAPHIC AREA	METHOD	CYCLE TYPE	TEMPERATURE	EXPOSURE TIME	DRY TIME
U.S.A	Steam	Pre-Vacuum	270°F (132 °C)	4 minutes	20 minutes
Outside the U.S.A	Steam	Pre-Vacuum	274°F (134 °C)	18 minutes	>15 minutes

THESE REPROCESSING INSTRUCTIONS HAVE BEEN VALIDATED AS BEING CAPABLE OF PREPARING THE DSG® REUSABLE INSTRUMENTS FOR REUSE. THEREFORE, SPINEGUARD® ASSUMES NO RESPONSIBILITY FOR INAPPROPRIATE REPROCESSING BY THE USER.

4. USE

4.1 Selection of the appropriate PediGuard® Threaded components

The PediGuard® Threaded device reusable instruments must be used only with the DSG® Pin and the Electronic Handle.
Select the adequate DSG® Pin, DSG® Threaded Shaft and DSG® Ratcheting Handle as below:

DSG® Pin	DSG® Threaded Shaft	DSG® Ratcheting Handle
D1PU0001 – DSG® Pin #1	All except Family C (ex. D1TA0003)	D1RH0001 - DSG® Ratcheting Handle A
D1PU0005 – DSG® Pin #5	Family C only (ex. D1TA0003)	

The compatibility information is provided on the DSG® Pin packaging.

It is recommended to select a threaded shaft with a diameter smaller than the diameter of the screws intended to be used during the surgery.

4.2 Assembly Instructions and functional check

Set-up instructions:

1. Attach the selected Threaded Shaft to the Ratcheting Handle (Fig.3).

Fig.3

2. Check that the Threaded Shaft is fully engaged with the Ratcheting Handle - the alignment mark on the Threaded Shaft should be flush with the distal end of the Ratcheting Handle. This ensures the complete engagement of the Threaded Shaft with the Ratcheting Handle.

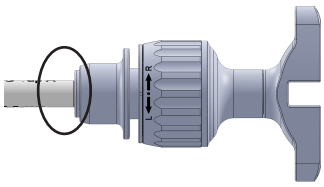
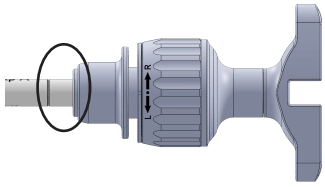
Correct engagement of the Threaded Shaft	Incorrect engagement of the Threaded Shaft
 Correct	 Incorrect

Fig.4

3. Insert the Pin through the Ratcheting Handle - Threaded Shaft assembly (from step 1) (Fig.5).

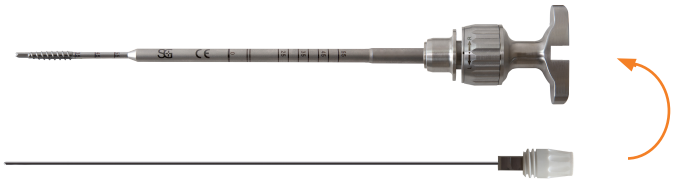


Fig.5

4. Check that the knob of the Pin is fully threaded into the Ratcheting Handle. The distal tip of the Pin should be visible (3mm +/- 1mm) at the distal end of the Threaded Shaft.

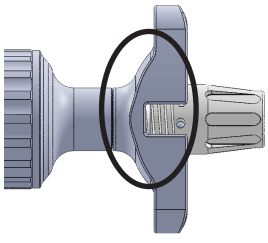
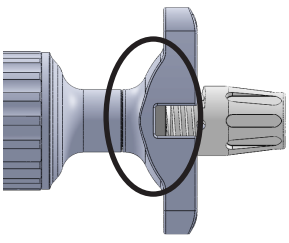
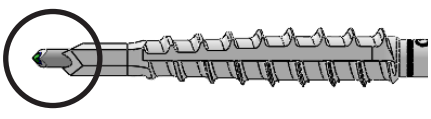
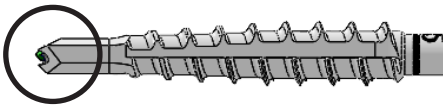
Correct threading of the Pin into the Ratcheting handle and Correct distal tip positioning of the Pin at the distal extremity of the Threaded Shaft	Incorrect threading of the Pin into the Ratcheting handle and Incorrect distal tip positioning of the Pin at the distal extremity of the Threaded Shaft
 Correct	 Incorrect
 Correct	 Incorrect

Fig.6

Ensure that the ratchet mechanism is fully functional after the Pin has been completely threaded. If necessary, adjust engagement of Pin with Ratcheting Handle.
If required by the surgeon the optional Starter Pin is available. The Starter Pin (black knob, Trocar tip) should be threaded completely into the Ratcheting Handle - Threaded Shaft assembly.

5. Connect the Electronic Handle to the DSG® Pin - Threaded Shaft assembly. Ensure that the Electronic Handle is securely connected to the Ratcheting Handle. (Fig.7-8)

Fig.7

Fig.8

6. Activate the PediGuard® Threaded device by pulling the contact tab out of the Electronic Handle. Activation is confirmed by a beeping sound and green LEDs lighting up. Once ON, the PediGuard® Threaded device cannot be turned off. The PediGuard® Threaded device battery provides sufficient autonomy to perform a complete spinal surgery.
   Note: The devices equipped with the DSG Connect feature can be paired to an external display. The pairing instructions and specific instructions for use are available within the DSG Connect App.
7. Check the functionality of the PediGuard® Threaded device assembly by placing the distal tip in saline solution (0.9% sodium chloride). A high pitch and high cadence sound should be heard. The green LEDs should flash at the same frequency. This confirms that the PediGuard® Threaded device is fully functional and ready for use. If a metal bowl is used, do not touch the bowl with the tip of the instrument. If no sound is heard, it may be necessary to clean the tip of the instrument using a mild scrubber (e.g., electrocautery scrubber).
8. The PediGuard® Threaded device assembly is now ready for use

The PediGuard® Threaded device has several safety features which allow easy checking of proper operation:

Green LEDs	ON	Flashing	OFF	OFF	OFF
Yellow LEDs	OFF	OFF	OFF	OFF	ON
Sound	None	Rated sound	ON	None	None
Case	①	②	③	④	⑤

① The instrument is ON. Either the tip of the instrument does not make contact with tissue or is in contact with bone that has very low conductivity.

② The tip of the instrument is in contact with tissue.

③ The battery is too low: do not use the instrument.

④ Either the instrument is not ON, or the battery does not work. Verify that the instrument is ON. If the instrument is ON but the LEDs remain OFF, do not use the instrument.

⑤ The instrument tip is not functioning properly: do not use the instrument.

If the LEDs are not visible through the clear wall of the electronic handle, do not use the PediGuard® Threaded device.

9. When deemed necessary, the DSG® Sleeve may be used with the PediGuard® Threaded device by inserting the Threaded Shaft (with pin) through the sleeve. This is done prior to inserting the PediGuard® Threaded device assembly into the surgical site. (Fig.9-10)

Fig.9

Fig.10

4.3 Surgical Technique – Pedicle pilot hole open and Mini-Open Techniques

The surgeon should prepare the intended entry points for the pedicle screws using preferred open or mini-open techniques to expose the posterior surface of the spine. The correct location for the entry point and angle of entry may be checked by using fluoroscopy.

In the case of a mini-open procedure, use the retractor provided with the pedicle screw instrumentation set until the entry point can be directly visualized.

Prior to drilling the pedicle with the PediGuard® Threaded device, prepare the entry point of the pedicle and perforate the dorsal cortex using standard techniques.

Before and during initial insertion of the assembly into the pedicle, ensure that the ratcheting mechanism is in the neutral position. This will enhance the ease of penetration into the pedicle. (Fig.11)

Fig.11

Direct the tip of the PediGuard® Threaded device to the soft tissue (wound) to initiate a rated high-pitched “beep”.
Place the tip of the PediGuard® Threaded device (Fig. 13) at the entry point of the pedicle (Fig. 12).

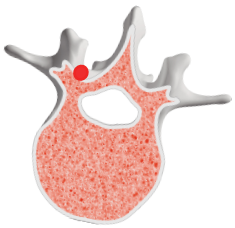


Fig. 12 Entry point

Fig. 13 Drilling through the pedicle

Pay close attention to the audio feedback provided as the PediGuard® Threaded device is being advanced while applying constant pressure.

Advance the PediGuard® Threaded device into the pedicle along the targeted screw trajectory. Drilling into the pedicle through cancellous bone, a medium pitch and medium cadence audio signal should be heard (Fig 14).

Fig. 14 Drilling through the pedicle

The graduated marks on the Threaded Shaft indicate the progression of the distal tip of the instrument into the pedicle. Use the distal set of marks on the Threaded Shaft to estimate depth.
After the tip of the PediGuard® Threaded device has been inserted into the pedicle and the first thread has engaged with the bone, enable the ratcheting mechanism by turning it clockwise (Fig.15).
This will allow to advance the instrument down the pedicle in small increments.

Fig. 15

Advance the tip through cancellous bone in the expected position of the screw. The marks on the DSG® Threaded Shaft can be used to estimate the length of the screw to be inserted. Note that the etch marks on the Threaded Shaft include ~3mm for the tip of the pin at the distal end of the PediGuard® Threaded device.

Muscular contractions may occur if the cortex has been fractured. In this case, the surgeon must stop advancement of the tip, and check and/or alter the initial trajectory.

Before drilling a new hole, clean the tip of the instrument with a soft cloth impregnated with saline solution.

In Case Redirection Is Necessary

A change in pitch and cadence of the audio feedback indicates a change in the type of tissue around the tip of the PediGuard® Threaded device.
If the audio signal changes to a low pitch and low cadence this indicates that the PediGuard® Threaded device is approaching the cortical wall (Fig. 16).

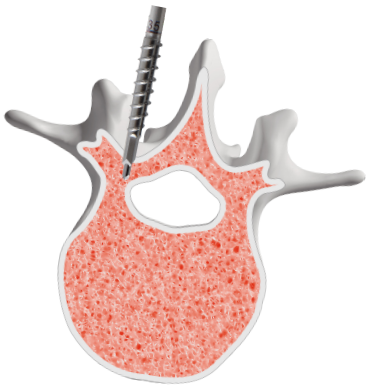


Fig. 16 Breach anticipation

At this time the PediGuard® Threaded device may be redirected using anatomical landmarks and discretion. Further drilling without redirection could result in a high pitch and high cadence audio signal that indicates an imminent cortical breach (Fig 17).

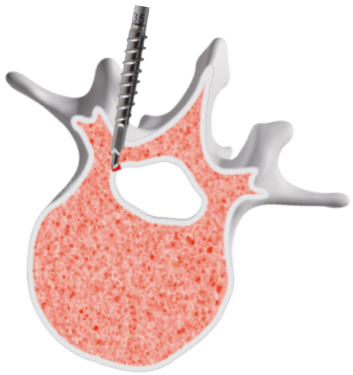


Fig. 17 Imminent breach

Redirect according to the following:

- Change the ratcheting mechanism to neutral position.
- Turn the PediGuard® Threaded device counterclockwise (a high cadence and high pitch audio feedback should be expected, this is due to the blood around the tip).
- Redirect until medium pitch medium cadence signal resumes.
- Engage ratcheting mechanism in the forward position.
- Continue advancing the PediGuard® Threaded device.

4.4 Surgical Technique – Pedicle pilot hole MIS or Percutaneous Techniques

The surgeon should locate the intended entry point for the pedicle screws using fluoroscopy and determine the anticipated angle of entry using his knowledge of MIS procedure for pedicle screw placement including the analysis of pre-op images of the spine of the patient.

Make a short incision on the skin over the targeted pedicle.

Before and during initial insertion of the assembly into the pedicle, ensure that the ratcheting mechanism is in the neutral position. This will enhance the ease of penetration into the pedicle.

Remove the Electronic Handle from the PediGuard® Threaded device and directly introduce the PediGuard® Threaded device through soft tissues. The DSG® Sleeve may be used to protect the soft tissues: load the DSG® Sleeve onto the DSG® Threaded Shaft before introducing the PediGuard® Threaded device through soft tissues (Fig.18-19). Ensure that the Sleeve is always in contact with the dorsal end of the pedicle. The etch marks on the Threaded Shaft, visible above the Sleeve, should be read. NOTE: Do not use the DSG® Sleeve with DSG® Threaded Shafts with diameters larger than 7.0 mm.

Fig. 18

Fig. 19

Position the PediGuard® Threaded device at the pedicle entry point and along the desired angle of entry using fluoroscopy, and perforate the cortical bone with the tip of the PediGuard® Threaded device. Mild malletting on the knob (of the DSG® Pin) may be required to advance the tip past the entry point. Note: If required by the surgeon, the optional Starter Pin is available. Once the instrument is docked in bone, the starter pin should be removed and replaced by a DSG® Pin before to connect the Electronic Handle.

Then connect the Electronic Handle. As the PediGuard® Threaded device is inserted past the entry point into the pedicle a high pitch and high cadence feedback may be heard (Fig 20). This is due to the tip being advanced past the blood collected at the entry point.

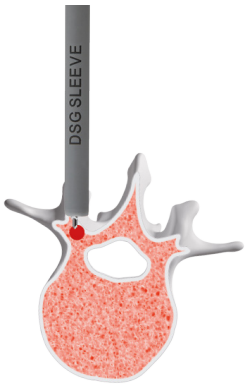


Fig. 20 Device at the entry point

Pay close attention to the audio feedback provided as the PediGuard® Threaded device is being advanced while applying constant pressure. Advance the PediGuard® Threaded device into the pedicle along the targeted screw trajectory. Drilling into the pedicle through cancellous bone, a medium pitch and medium cadence audio signal should be heard (Fig.21).

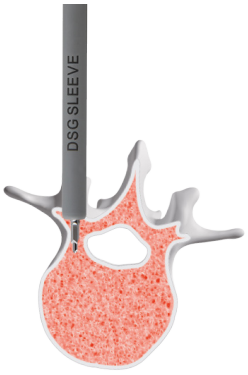


Fig. 21 Drilling into the pedicle

When the DSG® Sleeve is used with the PediGuard® Threaded device:

- Slide down the sleeve to put it in contact with the bone.
- The graduated marks on the threaded shaft, visible above the Sleeve, indicate the progression of the distal tip of the instrument into the pedicle. The double lines on the threaded shaft indicate that the first thread has been engaged with the bone enabling the use of the ratcheting mechanism (Fig.22).

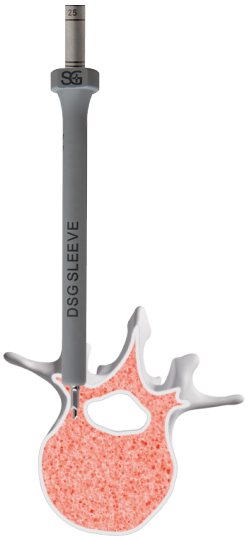


Fig. 22 Marks on the Threaded shaft

- The measurement will be accurate only when the DSG® Sleeve is well-seated on the dorsal end of the pedicle (Fig.23).

Fig. 23 Full drilling

After the tip of the PediGuard® Threaded device has been inserted into the pedicle and the first thread has engaged with the bone, enable the ratcheting mechanism by turning it clockwise (Fig.24). This will allow to advance the instrument down the pedicle in small increments

Fig. 24

Advance its tip through cancellous bone in the expected position of the screw. The marks on the DSG® Threaded Shaft can be used to estimate the length of the screw to be inserted. Note that the etch marks on the Threaded Shaft include ~3mm for the tip of the pin at the distal end of the PediGuard® Threaded device. When the DSG® Sleeve is being used, the etch marks on the Threaded Shaft, visible above the Sleeve, should be read. Progress of the positioning of the tip of the PediGuard® Threaded device through the body of the vertebral pedicle and into the vertebral body may be routinely checked with fluoroscopy.

Once desired trajectory and depth is reached detach the electronic handle. The DSG® Pin is then removed to insert a guidewire through the threaded shaft – ratcheting handle assembly into the pedicle. Be extremely careful with the position of the guidewire. Unintentional advancement of the wire can potentially be very dangerous. Once the guidewire is inserted, reverse the direction of the ratcheting mechanism and unscrew the Threaded Shaft.

Muscular contractions may occur if the cortex has been fractured. In this case, the surgeon must stop advancement of the tip, and check and/or alter the initial trajectory.
Before drilling a new hole, clean the tip of the instrument with a soft cloth impregnated with saline solution.

In Case Redirection Is Necessary

A change in pitch and cadence of the audio feedback indicates a change in the type of tissue around the tip of the PediGuard® Threaded device.

If the audio signal changes to a low pitch and low cadence this indicates that the PediGuard® Threaded device is approaching the cortical wall (Fig.25).

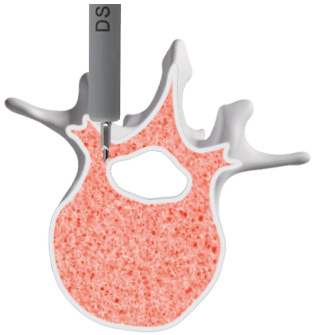


Fig. 25 Breach anticipation

At this time the PediGuard® Threaded device may be redirected using anatomical landmarks and discretion. Further drilling without redirection could result in a high pitch and high cadence audio signal that indicates an imminent cortical breach (Fig 26).

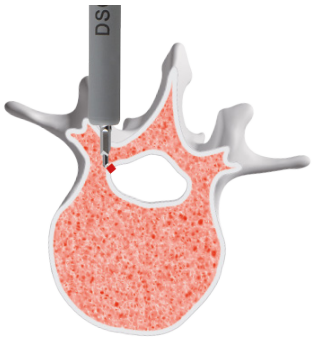


Fig. 26 Imminent breach

Redirect according to the following:

- Change the ratcheting mechanism to neutral position.
- Turn the PediGuard® Threaded device counterclockwise (a high cadence and high pitch audio feedback should be expected – this is due to the blood around the tip).
- Redirect until medium pitch medium cadence signal resumes.
- Engage ratcheting mechanism.
- Continue advancing the PediGuard® Threaded device.

4.5. Surgical Technique – Vertebral body pilot hole Anterior approach

The surgeon should prepare the intended entry points for the spinal implant using preferred technique to expose the surface of the vertebral body. The correct location for the entry point and angle of entry may be checked by using fluoroscopy.

Prior to drilling the vertebrae with the PediGuard® Threaded device, prepare the entry point and perforate the vertebral cortex using standard techniques.

Before and during initial insertion of the assembly into the vertebrae, ensure that the ratcheting mechanism is in the neutral position. This will enhance the ease of penetration into the vertebrae. (Fig.27)

Fig. 27

Direct the tip of the PediGuard® Threaded device to the soft tissue (wound) to initiate a rated high-pitched “beep”. The DSG® Sleeve may be used to protect soft tissue.

Place the tip of the PediGuard® Threaded device at the entry point of the vertebral body.

As the PediGuard® Threaded device is inserted at the entry point, a high pitch and high cadence feedback may be heard. This is due to the tip being advanced through the blood collected at the entry point (Fig 28).

Fig. 28 Entry point

Pay close attention to the audio feedback provided as the PediGuard® Threaded device is being advanced while applying constant pressure. Advance the PediGuard® Threaded device into the vertebral body along the targeted screw trajectory. Drilling from the entry point through cancellous bone, a medium pitch and medium cadence audio signal should be heard (Fig 29).

Fig. 29 Full drilling

The graduated marks on the Threaded Shaft indicate the progression of the distal tip of the instrument into the vertebrae. Use the distal set of marks on the Threaded Shaft to estimate depth. If the sleeve is used, the depth could also be determined by using the proximal set of marks on the threaded.

After the tip of the PediGuard® Threaded device has been inserted into the vertebrae and the first thread has engaged with the bone, enable the ratcheting mechanism by turning it clockwise (Fig.30). This will allow to advance the instrument down the vertebrae in small increments.

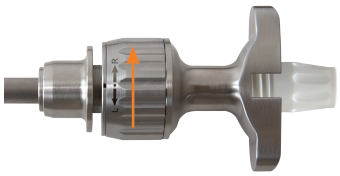


Fig. 30

Advance the tip through cancellous bone in the expected position of the screw. The marks on the DSG® Threaded Shaft can be used to estimate the length of the screw to be inserted. Note that the etch marks on the Threaded Shaft include ~3mm for the tip of the pin at the distal end of the PediGuard® Threaded device.

Muscular contractions may occur if the cortex has been fractured. In this case, the surgeon must stop advancement of the tip, and check and/or alter the initial trajectory.

Before drilling a new hole, clean the tip of the instrument with a soft cloth impregnated with saline solution.

In Case Redirection Is Necessary

A change in pitch and cadence of the audio feedback indicates a change in the type of tissue around the tip of the PediGuard® Threaded device.

If the audio signal changes to a low pitch and low cadence this indicates that the PediGuard® Threaded device is approaching the cortical wall (Fig 31).

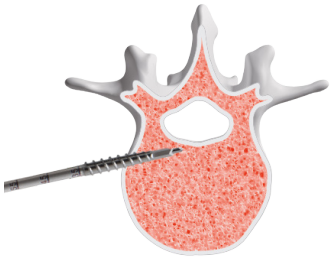


Fig. 31 Breach anticipation

At this time the PediGuard® Threaded device may be redirected using anatomical landmarks and discretion. Further drilling without redirection could result in a high pitch and high cadence audio signal that indicates an imminent cortical breach (Fig 32).

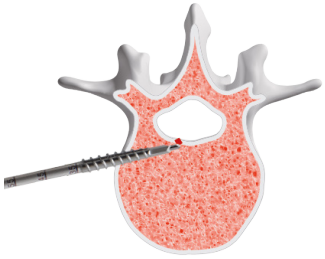


Fig. 32 Imminent breach

Redirect according to the following:

- Change the ratcheting mechanism to neutral position.
- Turn the PediGuard® Threaded device counterclockwise (a high cadence and high pitch audio feedback should be expected, this is due to the blood around the tip).
- Redirect until medium pitch medium cadence signal resumes.
- Engage ratcheting mechanism in the forward position.
- Continue advancing the PediGuard® Threaded device.

5. AFTER USE

The single use instruments must be discarded after the surgical procedure.

Discard the instrument in appropriate containers so that destruction can be performed in a manner that preserves the environment. For detailed information concerning this procedure, please contact your local SpineGuard representative.

All assembled instruments must be disassembled at the point of use before cleaning. Clean all DSG® reusable instruments after each surgery at the point of use with a disposable wipe to remove excessive soil within a maximum of 2 hours from time of soiling.

To disassemble:

1. Remove the DSG® Sleeve from the DSG® Threaded Shaft.
2. Remove the Electronic Handle and the DSG® Pin from the DSG® Ratcheting Handle. Dispose of the Electronic Handle and the DSG® Pin (single use only).
3. Separate the DSG® Threaded Shaft from the DSG® Ratcheting Handle.

Then follow the “before use”: “cleaning” and “sterilization” procedures mentioned above as soon as possible after use.
If cleaning must be delayed, immerse all DSG® reusable instruments in an enzymatic detergent solution (pH<11) or water at room temperature (15-25°C) to prevent drying of soil and contaminants in and on the device.

6. IMPORTANT MEDICAL INFORMATION

6.1 Indications

The PediGuard® Threaded device is indicated for use during vertebral body and pedicle screw pilot hole drilling to provide feedback to the surgeon via visual and audible alerts that indicate a change in impedance at the tip of the probe and may indicate contact of the tip with soft tissues and possible vertebral cortex perforation. PediGuard® Threaded device is indicated for use in both open and percutaneous (MIS) surgical approaches to the spine. PediGuard® Threaded device is also indicated for use with fluoroscopic guidance in percutaneous (MIS) surgical approaches to the spine. PediGuard® Threaded device also is specifically indicated for use in intraoperative electromyographic (“EMG”) surveillance to assist in the location and evaluation of spinal nerves during surgery of the spine, by administration of low voltage electrical energy to tissues and nerves at the operative site, and EMG monitoring of muscle groups associated with those nerves.

6.2 Contraindications

The PediGuard® Threaded device is contra-indicated for:
- Pathologies involving the vertebral cortex
- Patients who have received a pacemaker or any other active medical device.

6.3 Warnings

- Do not use the device:
  - In the presence of flammable anesthetics
  - At room temperature above 30°C
  - In a humid environment.
- Use of the PediGuard® Threaded device in conditions of extreme osteoporosis is not recommended. The condition of the bone in this situation must be closely evaluated prior to use of the device.
- Only use components provided by SpineGuard®. Using components from another manufacturer may cause malfunction of the device and be harmful to the patient.
- The DSG® Pin must be used only with SpineGuard’s Electronic Handle and the DSG® reusable instruments.
- No modification of this equipment is allowed
- Intraoperative use of muscle relaxants inhibits muscular contractions which are normally used as a means of detection. Use of muscle relaxants is therefore discouraged when using the PediGuard® Threaded device.
- Patient positioning on the operating table is critical: ensure that leg motions (if any) will not cause any injury to the patient or a fall from the operating table.
- Avoid any contact between the PediGuard® Threaded device and the patient while using an electrocautery device or defibrillator.
- Use of the device near the thorax may increase the risk of cardiac fibrillation.
- Using the PediGuard® Threaded device in association with another electronic device requires special precautions: perturbations on the patient’s ECG monitor may be observed while the PediGuard® Threaded device is in use. These abnormalities will stop as soon as the instrument is removed.
- IMPORTANT: Do not allow fluids or foreign bodies in the handle (immersion of the handle, even for a short period of time, is prohibited). In case of fluids or foreign bodies ingress in the electronics casing, do not use the device.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the PediGuard® Threaded device. Otherwise degradation of the performance of this equipment could result.
- Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy ME equipment may produce instability in the device output.
- For anterior approach, the aorta may be just behind the vertebral body. Aorta impingement may result in hemorrhage.

6.4 Precautions

- The PediGuard Threaded is intended for use with skeletally mature patient when used with implants in the pediatric populations. Any such implants must be used in accordance with FDA cleared indications.
- The choice of the PediGuard® Threaded device diameter is determined by the diameter of the screws the surgeon wants to place and by the size of the vertebrae.

- When used as an EMG stimulator, do not let muscular contractions last too long to avoid undue patient fatigue.
- As with any surgical instrument, this device should be carefully inspected before use.
- Always check the integrity of the single use sterile packaging before use. Do not use instrument with opened or damaged packaging.
- If any component of the PediGuard® Threaded device is accidentally dropped on the ground during the procedure, do not use it.
- Do not use the PediGuard® Threaded device if no rhythmic beep is heard when dipped in a saline solution.
- If the green LED lights are on but do not flash when dipped in a saline solution (circuit is open), do not use the PediGuard® Threaded device.
- Always make sure that the “beep” is heard and the green LED lights are on when the tip of the instrument touches the patient wound.
- Do not re-sterilize the DSG® single-use instruments.
- Do not mallet on the Electronic Handle Ref. P2HEXXXX
- Do not use the DSG® Sleeve with DSG® Threaded Shafts with diameters larger than 7.0 mm.
- The lungs are selectively ventilated allowing the lung on the convex side to collapse creating the workspace, however there is a rick of perforation of lungs if not properly collapsed.

6.5 Possible adverse effects

The possible adverse effects while using the PediGuard® Threaded device are:

- Penetration of the vertebrae resulting in injury or paralysis;
- Muscular contractions induced by nerve root stimulation;
- Loss of neurological functions, appearance of radiculopathies, dural injuries and/or pain. Neurovascular insufficiency, including paralysis or other serious lesions. Cerebrospinal fluid leak;
- Gastrointestinal, urological and/or reproductive tract disorders, including sterility impotence;
- Incapacity to resume the activities of normal everyday life;
- Soft tissue damage;
- Infection;
- Fracture of the vertebral body;
- Death.

7. CLINICAL USE (the clinical study was conducted using the originally cleared PediGuard model (K030526))

A clinical study was performed in which 147 manual pedicle drillings were performed during 28 spinal surgeries using the PediGuard® device in addition to conventional techniques of detecting pedicle screw fracture. Investigators received PediGuard® output when detecting fractures in addition to their conventional surgical methods. A total of 23 vertebral cortex perforations (16%) were confirmed, of which the PediGuard® detected 22. One false positive occurred during the study.

8. TECHNICAL SPECIFICATIONS

Storage: Expiry date is mentioned on the single use instruments outer package and must be respected. The PediGuard® Threaded device should be stored in a clean dry place.

All the DSG® reusable instruments should be stored in the DSG® Technology Instrument Tray, in a clean dry place.

End of life: If any damage or excessive wear is noted on the DSG® reusable instruments, such as twisting, bending, breakage, pinching at tips, lack of integrity of the etch marks, discoloration or cracks, the DSG® reusable instruments should not be used and should be discarded following the hospital procedures for post-treatment of contaminated devices. In case of complaint, please contact SpineGuard®.

CAUTION: FEDERAL LAW (US) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN.
IF YOU HAVE QUESTIONS ABOUT THIS DEVICE, PLEASE CONTACT:

SpineGuard, S.A. (Manufacturer)
10, Cours Louis Lumière
94300 Vincennes France
Phone: +33 (0) 1 45 18 45 19
Fax: +33 (0) 1 45 18 45 20

Symbols found on the products are described below:

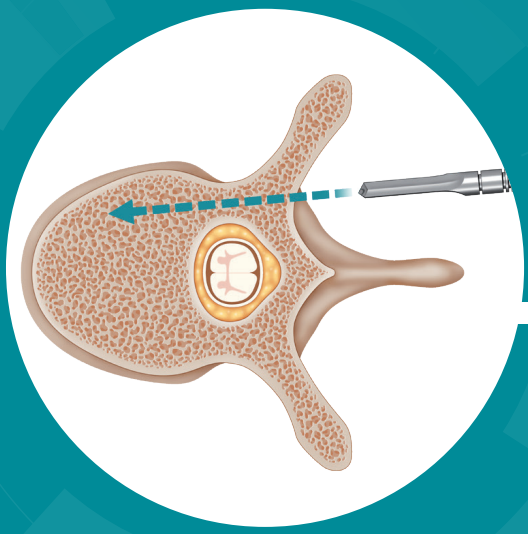
	See Instructions for Use		Single use only		Lot or batch Number
	Manufacturer		Expiration date		Catalog number
	“BF” (body floating) type insulation		Sterilized using ethylene oxide		Non-sterile

Information and manufacturer's declaration concerning electromagnetic compatibility (EMC)

Guidance and manufacturer's declaration – electromagnetic emissions		
The PediGuard is intended for use in the electromagnetic environment specified below. The customer or the user of the PediGuard should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF Emissions CISPR 11	Group 1	PediGuard uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	PediGuard is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration – electromagnetic immunity			
The PediGuard is suitable for use in the electromagnetic environment specified below. The customer or the user of the Pediguard should assure that it is used in such an electromagnetic environment.			
Immunity test	**Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Radiated RF IEC 61000-4-3	3 V/m from 80 MHz to 2,5 GHz	3 V/m	PediGuard is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Radiated RF IEC 61000-4-3 Proximity fields from RF wireless communications equipment	380 - 390 MHz 27 V/m; PM 50%; 18 Hz	27 V/m	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the PediGuard, including cables specified by the manufacturer.
	430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz	28 V/m	
	704 - 787 MHz 9 V/m; PM 50%; 217 Hz	9 V/m	
	800 - 960 MHz 28 V/m; PM 50%; 18 Hz	28 V/m	
	1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz	28 V/m	
	2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz	28 V/m	
	5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	9 V/m	
Power frequency magnetic field (50/60Hz) IEC 61000-4-8	30 A/m	30 A/m	–

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.



Take control of pedicle navigation with DSG Technology

SpineGuard®
Making spine surgery safer

www.spineguard.com

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