Manufactured by:
SpineGuard®

# DSG® Electronic Handle Single-use

CE 0123

**This user manual is ONLY applicable in the U.S.A.**

## USER MANUAL — EN-USA

*The Electronic Handle is a medical device integrated into the following configurable medical devices: the Cannulated PediGuard (Part B and C), the Threaded PediGuard (Part B and D) and the Cannulated PsiFGuard (Part E).*
*In no case can this device replace 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.*

*The Electronic Handle is a medical device available in two versions:*

- *The DSG Handle (reference P2HE1000)*
- *The DSG Connect Handle (reference P2HE2000)*

*Unless otherwise indicated, this user manual applies to both references which will be identified as: the Electronic Handle.*

*For use with the Cannulated PediGuard, Part A, Part B and Part C of this User Manual apply.*

*For use with the PediGuard Threaded, Part A, Part B and Part D of this User Manual apply.*

*For use with the Cannulated PsiFGuard , Part A, Part E of this User Manual apply.*

## Part A : The Electronic Handle

### 1. GENERAL DESCRIPTION

The Electronic Handle is an electrical device designed to be used in surgery in combination with SpineGuard probes in drilling pilot holes into pedicles and vertebral bodies. It serves to alert the surgeon to a possible vertebral cortex fracture while drilling a pedicle screw pilot hole.

### 2. TECHNICAL DESCRIPTION

The Electronic Handle contains an electronic circuit and comes in the form of a ready-to-use sterile single-use instrument.
The Electronic Handle 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 Electronic Handle, which does not perform threshold recordings, is not intended to be used as a substitute for a threshold level monitoring device.

Essential Performances:

Electronics essential performances: Sound and visual signals lead the surgeon during the pedicle drilling. Those informing signals convey the conductivity information which characterizes the tissues in contact with the sensor tip.

About the DSG Connect Handle:

An optional feature is available to transmit conductivity data to an external display to allow signal visualization and recording. The devices equipped with this feature are labelled DSG Connect and are 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).

### 3. FOR USE

#### 3.1 Assembly instruction

Once you have removed the Electronic Handle from its sterile packaging, you must assemble it with the other configurable devices that make up the PediGuard Cannulated (Part C), the PediGuard Threaded (Part D) or the Cannulated PsiFGuard (Part E) depending on the intended use.

#### 3.2 Power-on

To activate the Electronic Handle, pull the contact tab out of the Handle. Activation is confirmed by a beeping sound and green LEDs.

#### 3.3 Safety features

Once assembled with the other devices making up the Cannulated PediGuard, the Threaded Pediguard or the PsiFGuard, the Electronic Handle is fitted with safety devices to check that it is working properly.

The PediGuard 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 | Continuous crackling | 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 handle, do not use the Electronic Handle.

#### 3.4 Preliminary checks

Once the electronic handle has been assembled with the desired configurable devices, place the tip of the instrument in saline (0.9% sodium chloride). A high rate high-pitched sound should be heard. The green LEDs should flash at the same frequency. If a metal bowl is used, do not touch the bowl.

If no sound is heard, it may be necessary to clean the tip of the instrument using a mild scrubber (e.g. electrocautery scrubber).

#### 3.5 Connection to the DSG Connect App (optional) only applies to DSG Connect Handle

The DSG Connect Handle 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.

#### 3.6 After use

The electronic handle 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.

### 4. TECHNICAL SPECIFICATIONS

**Storage**: Expiry date is mentioned on the outer package and must be respected. The Electronic Handle should be stored in a clean dry place under ambient temperature conditions

**Service life**: Once ON, the Electronic Handle cannot be turned OFF. The Electronic Handle battery provides sufficient autonomy for a standard spine surgery.

### 5. INFORMATION RELATED TO SINGLE USE DEVICES

The Electronic Handle is a single use device. The retreatment and the re-use of the Electronic Handle 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 Electronic Handle device can increase the risk to the patient. Some technical characteristics of the Electronic Handle 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 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, as the instruction for use.

**Symbols found on the product are described below:**

See instructions for use — Manufacturer — Single use only — Refer to instruction manual

"BF" (body floating) type insulation — Expiration date — Double sterile barrier system — Medical device

LOT Lot or batch Number — REF Catalog number

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

| **Guidance and manufacturer's declaration – electromagnetic emissions** | | |
|---|---|---|
| The Electronic Handle is intended for use in the electromagnetic environment specified below. The customer or the user of the Electronic Handle should assure that it is used in such an environment. | | |
| **Emissions test** | **Compliance** | **Electromagnetic environment – guidance** |
| RF Emissions CISPR 11 | Group 1 | The Electronic Handle 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 | The Electronic Handle 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 Electronic Handle is suitable for use in the electromagnetic environment specified below. The customer or the user of the Electronic Handle should assure that it is used in such an electromagnetic environment. | | | |
| **Immunity test** | **Test level** | **Compliance level** | **Electromagnetic environment – guidance** |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | ± 8 kV contact<br>± 15 kV air | ± 8 kV contact<br>± 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<br>IEC 61000-4-3 | 3 V/m<br>from 80 MHz to 2,5 GHz | 3 V/m | The Electronic Handle 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<br>IEC 61000-4-3<br>Proximity fields from RF wireless communications equipment | 380 - 390 MHz<br>27 V/m; PM 50%;<br>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 Electronic Handle, including cables specified by the manufacturer. |
| | 430 - 470 MHz<br>28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz | 28 V/m | |
| | 704 - 787 MHz<br>9 V/m; PM 50%;<br>217 Hz | 9 V/m | |
| | 800 - 960 MHz<br>28 V/m; PM 50%;<br>18 Hz | 28 V/m | |
| | 1700 - 1990 MHz<br>28 V/m; PM 50%;<br>217 Hz | 28 V/m | |
| | 2400 - 2570 MHz<br>28 V/m; PM 50%;<br>217 Hz | 28 V/m | |
| | 5100 - 5800 MHz<br>9 V/m; PM 50%;<br>217 Hz | 9 V/m | |
| Power frequency magnetic field (50/60Hz)<br>IEC 61000-4-8 | 30 A/m | 30 V/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.

## Part B: Important Information for the Electronic Handle in the Cannulated and the Threaded PediGuard configuration.

In Chapter 6, 7 and 8 "PediGuard" means the Electronic Handle assembled with the other dedicated medical devices in the Cannulated PediGuard or the Threaded PediGuard configuration.

### 6. IMPORTANT MEDICAL INFORMATION

#### 6.1 Indications

The PediGuard is indicated for use during 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 device is indicated for use in both open and percutaneous (MIS) surgical approaches to the spine. It is also indicated for use with fluoroscopic guidance in percutaneous (MIS) surgical approaches to the spine.

The PediGuard Threaded device is also indicated for use during vertebral body screw pilot hole drilling.

#### 6.2 Contraindications

The PediGuard 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 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 Electronic Handle must be used only with SpineGuard's DSG Pin, The Cannulated Needle 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 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 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 device in association with another electronic device requires special precautions: perturbations on the patient's ECG monitor may be observed while the PediGuard device is in use. These abnormalities will stop as soon as the Electronic Handle is removed.
- IMPORTANT: Do not allow fluids or foreign bodies in the Electronic Handle (immersion of the Electronic 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 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 is intended for use with skeletally mature patients 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 device diameter is determined by the diameter of the screws the surgeon wants to place and by the size of the vertebrae.
- As with any surgical instrument, this device should be carefully inspected before use.
- Before opening, always perform a visual check of the integrity of the sterile pouch. It must not show any damage or perforations and must be sealed. If the pouch is opened or damaged, the product must not be used.
- If any component of the PediGuard device is accidentally dropped on the ground during the procedure, do not use it.
- Do not use the PediGuard 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 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's wound.
- Do not re-sterilize the Electronic Handle.
- Light impacts are acceptable on the Electronic Handle, but it is recommended not to tap excessively in order to avoid damaging the electronic system.
- For the PediGuard Threaded in anterior approach, the lungs are selectively ventilated allowing the lung on the convex side to collapse creating the workspace, however there is a risk of perforation of lungs if not properly collapsed.

Note: whatever the surgical technique used, or the configuration of the medical device used, it is possible that muscular contractions may occur if the bone cortex is breached. In this case, stop the progression of the instrument and check the trajectory.

#### 6.5 Possible Adverse Effects

- 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.

## Part C: The Electronic Handle used in the Cannulated PediGuard configuration

In this configuration, the Electronic Handle must be assembled with the P2NDXXXX Needle, a single-use device manufactured by SpineGuard.

It cannot be assembled with other medical devices, manufactured by other manufacturers than SpineGuard.

***Set-up instructions***

1. Before connecting the P2NDXXXX Needle to the handle, check that the active stylet (orange cap) is fully screwed into the cannula. The distal tip of the active stylet should be visible at the end of the cannula.
2. Connect the Needle into the Electronic Handle. You should feel it click into place. Check that the needle is fully engaged in the Electronic Handle.
3. Activate the device by pulling the contact tab out of the Electronic Handle. Activation is confirmed by a beeping sound and green LEDs lighting up.
4. The Cannulated PediGuard is ready for use.

**For more information regarding the assembly instruction, refer to the Assembly Instructions provided in the Needle boxes or on the SpineGuard website, user manual section: Cannulated PediGuard.**

***Surgical technique – Open Techniques***

The surgeon should prepare the intended entry points for the pedicle screws using preferred 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.
Each hole should be drilled using the following technique:

- Prepare the entry point for drilling by removing the cortical bone.
- Direct the tip of the PediGuard to the soft tissue (wound) to initiate a rated high-pitched "beep".
- Position the PediGuard at the entry point and advance its tip through cancellous bone in the expected position of the screw. Use constant hand pressure and gentle alternate rotating motions. Light impacts are acceptable on the Electronic Handle, but it is recommended not to tap excessively in order to avoid damaging the electronic system.

Muscular contractions may occur if the cortex has been fractured. In this case, the surgeon must stop advancement of the tip and check the trajectory. If redirection is necessary, the instrument should be pulled back before to adjust trajectory.
Before drilling a new hole, clean the tip of the instrument with a soft cloth impregnated with saline solution.

***Surgical technique – 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. Each hole should be drilled using the following technique:

- In the case of a percutaneous procedure, directly introduce the PediGuard through soft tissues.
- In the case of a mini-open procedure, use the specific retractor provided with the pedicle screw instrumentation set until the entry point can be directly visualized. Then refer to open technique for usage of the PediGuard.
- Position the PediGuard 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.
- Advance the PediGuard tip through cancellous bone in the expected position of the screw. Use constant hand pressure and gentle alternate rotating motions.
- Progress of the positioning of the tip of the PediGuard through the body of the vertebral pedicle and into the vertebral body may be routinely checked with fluoroscopy. Muscular contractions may occur if the cortex has been fractured. In this case, the surgeon must stop advancement of the tip and check the trajectory. If redirection is necessary, the instrument should be pulled back before to adjust trajectory.
- Before drilling a new hole, clean the tip of the instrument with a soft cloth impregnated with saline solution.

## Part D: The Electronic Handle used in the PediGuard Threaded configuration

In this configuration the Electronic Handle must be used with the following devices exclusively manufactured by SpineGuard:

- DSG single-use instruments provided sterile:
  - DSG Pin Ref. D1PUXXXX, which embeds the proprietary DSG bipolar sensor
- 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.

It cannot be assembled with other medical devices manufactured by manufacturers other than SpineGuard.

***Set-up instructions***

1. Attach the selected Threaded Shaft to the Ratcheting Handle. 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.

2. Insert the Pin through the Ratcheting Handle - Threaded Shaft assembly (from step 1), Check that the knob of the Pin is fully screwed into the Ratcheting Handle. The distal tip of the Pin should be visible (3mm +/- 1mm) at the distal end of the Threaded Shaft.
3. Connect the Electronic Handle to the DSG Pin - Threaded Shaft assembly. Ensure that the Electronic Handle is securely connected to the Ratcheting Handle.
4. Activate the PediGuard Threaded (according to chapter 3.2). 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.
5. Check the functionality of the PediGuard Threaded device according to chapter 3.4.
6. The PediGuard Threaded device assembly is now ready for use.
7. 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.

For more information regarding the assembly instruction, refer to the IFU for the DSG Pin on the SpineGuard website, user manual section: *PediGuard Threaded.*

***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 device into the pedicle, ensure that the ratcheting mechanism is in the neutral position. This will enhance the ease of penetration into the pedicle.
- 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 at the entry point of 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.
- 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. This will allow to advance the instrument down the pedicle in small increments.
- 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.
- 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
- 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.

***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 patient’s spine.

- Make a short incision on the skin over the targeted pedicle.
- Before and during initial insertion of the device 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. 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 7.0mm.
- 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.
- 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. This is due to the tip being advanced past the blood collected 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.
- 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.
  - The measurement will be accurate only when the DSG Sleeve is well-seated on the dorsal end of the pedicle.

  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. This will allow to advance the instrument down the pedicle in small increments.
- 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.
- 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.
- 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.

***Surgical Technique – Vertebral body pilot hole anterior approach***

The surgeon should prepare the intended entry points for the spinal implant using the 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.
- 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.
- 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.
- 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 shaft.
- 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. This will allow to advance the instrument down the vertebrae in small increments.
- 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.
- If deemed necessary, 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.
- 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.

## Part E : The Electronic Handle in Cannulated PsiFGuard configuration

### 8. IMPORTANT MEDICAL INFORMATION

#### 8.1 Indications

The Cannulated PsiFGuard is an accessory to systems intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. It is indicated for use during sacroiliac joint guidewire placement 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 bone and possible vertebral cortex perforation.

#### 8.2 Contraindications

- Acute, traumatic instability of the Sacroiliac Joint.
- Patients who have received a pacemaker or any other active medical device.

#### 8.3 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 Cannulated PsiFGuard 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.
- 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 Cannulated PsiFGuard.
- 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 Cannulated PsiFGuard and the patient while using an electrocautery device or defibrillator.
- Using the Cannulated PsiFGuard in association with another electronic device requires special precautions: perturbations on the patient’s ECG monitor may be observed while the Cannulated PsiFGuard 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 externals antennas) should be used no closer than 30 cm (12 inches) to any part of the Cannulated PsiFGuard. Otherwise, degradation of the performance of this equipment could result.
- Operation in close proximity (e.g. 1m) to a shortwave or microwave therapy ME equipment may produce instability in the device output.

#### 8.4 Precautions

- As with any surgical instrument, this device should be carefully inspected before use.
- Before opening, always perform a visual check of the integrity of the sterile pouch. It must not show any damage or perforations and must be sealed. If the pouch is opened or damaged, the product must not be used.
- If the Cannulated PsiFGuard is accidentally dropped on the ground, do not use it.
- Do not use Cannulated PsiFGuard 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 Cannulated PsiFGuard.
- Always make sure that the “beep” is heard, and the green LED lights are on when the tip of the instrument touches the patient’s wound.
- Do not re-sterilize the instrument.

#### 8.5 Possible adverse effects

The possible adverse effects while using the Cannulated PsiFGuard are:

- Incapacity to resume the activities of normal everyday life.
- Soft tissue damage.
- Infection.

***Surgical technique***

The surgeon should prepare the intended entry points using anatomical landmarks. The correct location for the entry point and angle of entry may be checked by using fluoroscopy.

Guidewire should be placed using the following technique:

- After an initial incision to access the sacrum, advance the Cannulated PsiFGuard through the joint, between the sacrum and the ilium. The user will rely on audio and LED feedback provided by the device: high pitch needs to be heard till the tip of the device reaches the anterior part of the joint. If low pitch is heard prematurely, redirection might be required. The pin trajectory will vary based upon the orientation and curvature of the SI joint.
- Remove sensory stylet and place guidewire through the cannulated shaft. The final guidewire trajectory and placement should be confirmed using fluoroscopy. Continue with placement of the sacroiliac joint fusion device per its implantation instructions.
- Before placing another guidewire, 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 Cannulated PsiFGuard. If the audio changes to a low pitch and low cadence prematurely, it indicates that the Cannulated PsiFGuard may be entering the cortical wall.

At this time, the Cannulated PsiFGuard may be redirected using anatomical landmarks. In that case, pull the device out by hand until high pitch and high cadence signal resume, and proceed with the operation.

Important information: Any serious incident relating to the device must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established. For such a report, or for any other problem or malfunction, please contact: complaints@spineguard.com

ONLY USE INSTRUMENTS WITH INTACT PACKAGING. DO NOT CLEAN, RE-STERILIZE, OR RE-USE THIS DEVICE. 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:

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