Manufactured by:
SpineGuard®

PediGuard®
Single-use

CE 0123

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

USER MANUAL EN-USA

In no case can the PediGuard® 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® System is used in drilling pilot holes into the spinal vertebrae. The System serves to alert the surgeon to a possible vertebral cortex fracture while drilling a pedicle screw pilot hole.

2. TECHNICAL DESCRIPTION

The PediGuard is a sterile single use instrument; its handle contains an electronic circuit. The tip of the instrument is the applied part.
The PediGuard® 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®, 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 pedicle drilling.
2. Electronics essential performance: 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.

DSG Connect only:
An optional feature is available to transmit the conductivity data to an external display to allow signal visualization and recording. The PediGuard® 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

Power-on

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

Safety features

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	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 handle, do not use the PediGuard®.

Preliminary checks

Check the PediGuard® System for accurate assembly and function by placing 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 a high rate. 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).

Connection to the DSG Connect App (optional)
The PediGuard® 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.

Surgical technique

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 *(never use mallet blows)*.

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, 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, 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.

After surgery

The instrument 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. IMPORTANT MEDICAL INFORMATION

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

4.2 Contraindications

- Pathologies involving the vertebral cortex
- Patients who have received a pacemaker or any other active medical device.

4.3 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 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 PediGuard System.
• 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 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 in association with another electronic device requires special precautions: perturbations on the patient's ECG monitor may be observed while the PediGuard 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 PediGuard System. 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.

4.4 Precautions

• The choice of the PediGuard diameter is determined by the diameter of the screws the surgeon wants to place and by the pedicle size.
• 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.
• Before opening, always perform a visual check of the integrity of the sterile pouch. It must not show any damages or perforations and must be sealed. If the pouch is opened or damaged, the product must not be used.
• If the PediGuard is accidentally dropped on the ground, do not use it.
• Do not use the PediGuard 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.
• 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 instrument.

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

4.5 Possible adverse effects

The possible adverse effects while using the PediGuard® System 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. Cerbrospinal 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.

5. 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.

6. STATEMENT [RELATED TO EUROPEAN REGULATION 93/42/EEC]

The PediGuard is not intended to be used in direct contact with the Central Nervous System. The contact with any part of the dura mater, may it be the part sheathing the medulla spinalis or the part sheathing the roots of the nerves up to the spinal ganglia, shall be avoided.

7. TECHNICAL SPECIFICATIONS

Storage: Expiry date is mentioned on the outer package and must be respected. The PediGuard should be stored in a clean dry place.
Service life: Once ON, the PediGuard cannot be turned off. The PediGuard battery provides sufficient autonomy.

8. INFORMATION RELATED TO SINGLE USE DEVICES

PediGuard is a single use device. The retreatment and the re-use of the PediGuard are forbidden.
Several potential dangers related to the re-use of the PediGuard can increase the risk to the patient. Some technical characteristics of the PediGuard 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, as the instruction for use.

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:

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 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 or batch Number

Catalog number

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 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.