Instruction For Use of the Cannulated PsiFGuard

LP2-A102 - Version A

Accuracy

Real Time

Radiation Free

Safety

DSG®

Dynamic Surgical Guidance

Educational Tool

SpineGuard®

www.spineguard.com

Manufactured by:
SpineGuard®

Cannulated PsiFGuard
Single-use

USER MANUAL EN

In no case can the Cannulated PsiFGuard 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.

1. INTRODUCTION

The Cannulated PsiFGuard is used in placing guidewires into the sacroiliac joint. The device serves to alert the surgeon to a possible contact with bone while placing a guidewire into the sacroiliac joint.

This device is intended to be used to assist with the implantation of a sacroiliac joint fusion device through guidewire placement per its surgical technique manual; it is not intended to be used with devices intended to be implanted with a trajectory across the sacroiliac joint.

2. TECHNICAL DESCRIPTION

The Cannulated PsiFGuard is a sterile single use instrument; its handle contains an electronic circuit. The tip of the instrument is the applied part.

The Cannulated PsiFGuard 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 Cannulated PsiFGuard, 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 guidewire placement.

2. Electronics essential performance: sound and visual signals lead the surgeon during the guidewire placement. Those informing signals convey the conductivity information which characterizes the tissues in contact with the sensor tip.

Components of the Cannulated PsiFGuard

Electronic Handle - Ref. P2HEXXXX

The Electronic Handle is a single-use component that is provided sterile. The Electronic Handle contains all the electronics needed to sense differences of impedance between tissues surrounding the sacroiliac joint using the DSG technology.

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).

Figure 1. Electronic Handle Ref. P2HEXXXX (DSG Handle or DSG Connect Handle)

Active Needle - Ref P2ND2201

The Active needle is a single-use component that is provided sterile. The Active needle is an assembly of 2 components: the Cannulated Shaft and the Sensory Stylet. The distal tip of the Stylet ensures the function of detection of cortical breach. The Tip of the instrument is the applied part.

Figure 2. Cannulated Shaft (Left) and Sensory Stylet (Right) Ref. P2ND2201

DSG Connect App – Ref D1SW0001

This optional visualization software can be used on a dedicated tablet and with the Electronic Handle equipped with the DSG Connect feature to allow signal visualization and recording.

3. FOR USE

Power-on

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

Safety features

The Cannulated PsiFGuard 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. The tip of the instrument either 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 activated/ON, or the battery does not work. Verify that the instrument is activated/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 Cannulated PsiFGuard.

Preliminary checks

Check the Cannulated PsiFGuard 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).

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 reach 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 where 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.

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 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.

4.2 Contraindications

- Acute, traumatic instability of the Sacroiliac Joint.
- 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 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.

4.4 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 damages 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 wound.
- Do not re-sterilize the instrument.

4.5 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.

5. TECHNICAL SPECIFICATIONS

Storage: Expiry date is mentioned on the outer package and must be respected. The Cannulated PsiFGuard should be stored in a clean dry place.

Service life: Once ON, the Cannulated PsiFGuard cannot be turned OFF. The Cannulated PsiFGuard battery provides sufficient autonomy.

6. INFORMATION RELATED TO SINGLE USE DEVICES

The Cannulated PsiFGuard is a single use device. The retreatment and the re-use of the Cannulated PsiFGuard are forbidden.

Several potential dangers related to the re-use of the Cannulated PsiFGuard can increase the risk to the patient. Some technical characteristics of the Cannulated PsiFGuard 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


"BF" (body floating) type insulation


Expiration date

Double sterile barrier system

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

Guidance and manufacturer's declaration – electromagnetic emissions		
The Cannulated PsiFGuard is intended for use in the electromagnetic environment specified below. The customer or the user of the Cannulated PsiFGuard should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF Emissions CISPR 11	Group 1	The Cannulated PsiFGuard 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 Cannulated PsiFGuard 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 Cannulated PsiFGuard is suitable for use in the electromagnetic environment specified below. The customer or the user of the Cannulated PsiFGuard 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	The Cannulated PsiFGuard 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 Cannulated PsiFGuard is suitable for use in the electromagnetic environment specified below. The customer or the user of the Cannulated PsiFGuard should assure that it is used in such an electromagnetic environment.			
Immunity test	**Test level**	**Compliance level**	**Electromagnetic environment – guidance**
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 Cannulated PsiFGuard, 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	-

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.