Manufactured by:
SpineGuard®

Instruction for Use and Assembly Instructions of the devices configuring the PediGuard Threaded

CE 0123

This IFU is ONLY applicable in the U.S.A.

In no case can the PediGuard® Threaded 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.

USER MANUAL — EN-USA

1. GENERAL DEVICE DESCRIPTION

The PediGuard® Threaded is a configurable device, that only operates once all devices are assembled.

The PediGuard Threaded is made of:
- Electronic Handle P2HEXXXX;
- DSG® Pin D1PUXXXX;
- DSG® Threaded Shaft D1TAXXXX;
- DSG® Ratcheting Handle D1RHXXXX;
- Optionally DSG® Sleeve D1STXXXX.

The PediGuard Threaded device is a bone preparation device that helps surgeons to drill a pilot hole in the pedicle and the vertebral body during spinal surgery. The PediGuard Threaded device serves to alert the surgeons prior to a possible cortex perforation while drilling the bone, by accurately analyzing the electrical conductivity of the surrounding tissues.

Therefore, this general description is for the complete device, the individual devices having no functions when taken separately.

It is strongly recommended that the operating principle of the DSG Technology be clearly understood before using the PediGuard Threaded device.

This assembly instruction is complementary to the Electronic Handle P2HEXXXX eIFU (LP2-A113-US-Web) available on the SpineGuard website. It defines how to assemble the different components to constitute the PediGuard Threaded, and how the reusable devices should be reprocessed.

For the indications for use, intended purpose, warnings, precautions, possible adverse events or surgical techniques, refer to the Electronic Handle P2HEXXXX eIFU (LP2-A113-US-Web) available on the SpineGuard website.

This Instruction is also applicable for the DSG® Technology Instrument Tray, which is the box in which reusable devices are placed in order to be sterilized.

2. TECHNICAL DESCRIPTION

The PediGuard Threaded device consists of:

- 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.
- 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.

Note: "X" represents the different numbers possible and refers to the different available references of the device. Example: DSG Threaded shaft A - Ø4.5mm : D1TA0007.

The tip of the DSG Pin and the DSG Threaded Shafts are the applied part, in contact with patient.

Essential Performances:

Mechanics essential performance: the cutting ability during the bone drilling.

3. BEFORE USE

3.1 Information related to DSG Pin Ref. D1PUXXXX

The DSG Pin Ref. D1PUXXXX is a single use device. The retreatment and the re-use of the DSG Pin are forbidden.
Inspect the DSG Pin for integrity of the sterile packaging before use. 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.
DO NOT CLEAN, RE-STERILIZE, OR RE-USE THE SINGLE USE COMPONENTS OF THIS DEVICE.

Warnings

Several potential dangers related to the re-use of the DSG Pin device can increase the risk to the patient. Some technical characteristics of the electrical and sensory components of the DSG Pin 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 reusable instruments must be inspected, cleaned and sterilized.
All assembled instruments must be disassembled before inspection, cleaning and sterilization.
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*

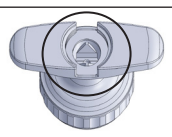
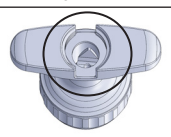
Correct V-shape	Damaged V-shape
	
Correct	Incorrect

Fig.1

If any damage or excessive wear is noted on the 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.

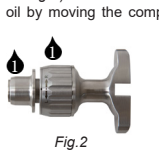


Fig.2

Cleaning of the reusable instruments

- The reusable instruments are delivered clean but not sterile; therefore, they must be sterilized before use. The plastic packaging in which the reusable devices are supplied is not validated to be sterilized, this packaging must be removed and destroyed. The protective tip of the threaded shaft must be removed before sterilization.
- The surfaces of all reusable instruments must be cleaned and decontaminated before sterilization.
- 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 (59-77°F or 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 (59-77°F or 15-25°C).
  - Rinse the instruments in distilled water for at least 1 minute at room temperature (59-77°F or 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 to EN ISO 15883 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 < 113°F (45°C)	Tap Water
Cleaning	10 minutes	Heated (131°F) 55°C	Enzymatic Detergent (pH< 11, equivalent to «Steris® Prolystica 2X Enzymatic cleaner» 0.2 to 0.8%)
Rinse 1	2 minutes	Cold < 113°F (45°C)	Tap Water
Rinse 2	2 minutes	Cold < 113°F (45°C)	Tap Water
Thermal Rinse	5 minutes	Heated 194°F (90°C)	High Purity Water*
Dry	20 minutes	Heated > 140°F (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 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. it must comply with the requirements of the ISO11607 standard. The wrapping paper must be FDA-cleared. Use validated, properly maintained and calibrated steam sterilizer. For an effective steam sterilization, SpineGuard recommend a moist heat sterilization process according to EN ISO 17665, and 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

4. USE

4.1 Selection of the appropriate PediGuard Threaded components

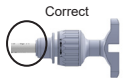
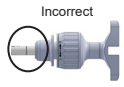
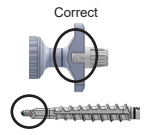
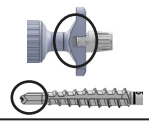
The PediGuard Threaded device reusable instruments must be used only with the DSG Pin and the Electronic Handle. Select the adequate DSG Pin, DSG Threaded Shaft and DSG Sleeve as below:

DSG Pin	DSG Threaded Shaft	DSG Sleeve
D1PU0001 – DSG Pin #1	D1TA0001 DSG Threaded Shaft A - Ø5.5mm	D1ST0001 - DSG Sleeve #1
	D1TA0006 DSG Threaded Shaft F – Ø4.0mm	
	D1TA0007 DSG Threaded Shaft A – Ø4.5mm	
	D1TA0008 DSG Threaded Shaft G – Ø5.0mm	
	D1TA0012 DSG Threaded Shaft B – Ø6.5mm	
D1PU0005 – DSG Pin #5	D1TA0003 DSG Threaded Shaft C - Ø5.5mm	
D1PU0006 – DSG Pin #6	D1TA0020 DSG Threaded Shaft L - Ø5.0mm	Not compatible
	D1TA0021 DSG Threaded Shaft L - Ø4.5mm	

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:

STEP	DESCRIPTION	VERIFICATION
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. Correct  Incorrect 
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. Ensure that the ratchet mechanism is fully functional after the Pin has been completely screwed. If necessary, adjust engagement of Pin with Ratcheting Handle. Correct  Incorrect 
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 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.	
5	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). The PediGuard Threaded device assembly is now ready for use.	
6	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. 	

4.3 Surgical Technique: please refer to the Electronic Handle P2HEXXXX eIFU (LP2-A113-US-Web) available on the Spineguard website

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.

Disassembly of the instruments for cleaning should be performed in the designated cleaning area immediately following use.

All assembled instruments must be disassembled at the point of use before cleaning. Clean all 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 (59-77°F or 15-25°C) to prevent drying of soil and contaminants in and on the device.

6. IMPORTANT MEDICAL INFORMATION

As the PediGuard Threaded is a configurable device, it can only be used when all components are assembled together. It is necessary to refer to *Chapter 6 - Important Medical Information* of the Electronic Handle P2HEXXXX eIFU (LP2-A113-US-Web) available on the Spineguard website, for the: Indications, Contraindications, Warnings, Precautions, Possible adverse effects.

In addition the following is specific to the DSG Pin and the reusable devices:

6.1 The intended use of the DSG Pin Device and reusable devices of the PediGuard Threaded

- DSG Pin D1PUXXXX: The DSG Pin transmits the electrical signal back and forth between the electronic handle and the tip of the pin during drilling of the pedicle or the vertebral body of the vertebra.
- DSG Threaded Shaft D1TAXXXX: The DSG threaded shaft drills the bone to create a pilot hole in the pedicle or the vertebral body. It is also a housing for the DSG Pin.
- DSG Ratcheting Handle D1RHXXXX: The ratcheting handle mechanically connects the electronic handle (DSG connect handle or DSG Handle), the DSG Threaded Shaft and the DSG Pin. It also includes a ratcheting mechanism for the screwing motion.
- DSG Sleeve D1STXXXX (optional device): The DSG Sleeve protects soft tissues during drilling in MIS approach.

6.2 Precautions

- As with any surgical instrument, this device should be carefully inspected before use.
- If any device is accidentally dropped on the ground during the procedure, do not use it.
- Do not re-sterilize the DSG single-use instruments.
- Do not use the DSG Sleeve with DSG Threaded Shafts with diameters larger than 7.0 mm.
- Do not use the DSG Sleeve #1 with DSG Threaded Shafts from Family L.

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

7. TECHNICAL SPECIFICATIONS

Storage: Expiry date is mentioned on the DSG Pin outer package and must be respected.
The device configuring the PediGuard Threaded should be stored in a clean dry place in ambient conditions. All the 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 reusable instruments, such as twisting, bending, breakage, pinching at tips, lack of integrity of the etch marks, discoloration or cracks, the 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:

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94300 Vincennes, France
Phone: +33 (0) 1 45 18 45 19
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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 — Non-sterile

Ref: LP2-A114-US-WEB / A - February 2026