Instruction For Use of the DSG® Zavation Screw System

LP2-A100 - Version I

SpineGuard®

www.spineguard.com

DSG® Zavation Screw System
USER MANUAL

1. INTRODUCTION

The DSG® Zavation Screw System (“DZSS”) is a modified version of SpineGuard’s DSG® Threaded Drill System that integrates with the Zavation Spinal System.

The purpose of this combination is:

- To optionally reduce the number of operative steps by allowing the insertion of the screw without the necessity of drilling a pilot hole prior to the screw insertion.
- To alert the surgeon to a possible vertebral cortex fracture while inserting the pedicle screw.

In order to be properly used, the DSG® Zavation Screw System requires the user to procure the Zavation Spinal System as well as the SpineGuard DSG® Threaded Drill System, and to respect the respective Instructions for Use, Assembly instructions, and Surgical Technique of these systems.

System	User Information and reference of document
DSG® Threaded Drill System	• Instructions For Use, Assembly Instructions and Surgical Technique Ref. LP2-A036
Zavation Spinal System	• Instructions For Use Ref. LBL-002 • Surgical Technique Ref. ST-002

This Instructions For Use document focuses on the utilization of the combination of certain components of the Zavation Screw System (Z-Direct pedicle screw, Z-Direct pedicle screw driver) with certain components of the DSG® Threaded Drill System (DSG® Pin, Electronic handle, ratcheting handle)

2. TECHNICAL DESCRIPTION

The components of each system that are designed to function in combination are listed below.

2.1 Components from the DSG® Threaded Drill System

2.1.1 Electronic Handle (Ref. P2HEXXXX)

The T-shape handle is used to manually provide torque during screw insertion. The handle contains all the electronics needed to sense if a vertebral body breach may have occurred using the DSG® technology. It is provided sterile and for single use only.
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)

2.1.2 DSG® Ratcheting Handle model A Ref. D1RH0001

The Ratcheting Handle is a reusable, user sterilized component made from Stainless Steel. As Zavation Pedicle Screws are inserted via twisting, the Ratcheting Handle is included in the system to allow free motion in the clockwise/counter-clockwise direction. The Ratcheting Handle connects the Electronic Handle Ref. P2HEXXXX and the DSG® Pin Ref. D1PUXXXX to the Cannulated Z-Direct Screw Driver Ref. 210-100X-XX.

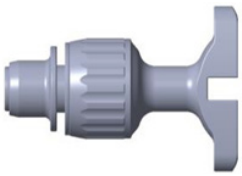


Figure 2. DSG® Ratcheting Handle

2.1.3 DSG® Pin Ref. D1PUXXXX (Active Stylet)

The DSG® D1PUXXXX is a single-use component that is provided sterile. It is inserted within the Cannulated Z-Direct Screw Driver Ref. 210-100X-XX, and its length is designed so that 3mm extends beyond the distal tip of the cannulated Zavation Z-Direct pedicle screws Ref. 210-XXXX, 212-XXXX or 213-XXXX. The distal tip of the Pin ensures the function of detection of cortical breach. The tip of the instrument is the applied part.

Figure 3. DSG® Pin

2.1.4 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.

2.2 Components from the Zavation Spinal System

2.2.1 Cannulated Z-Direct Screw Driver Ref. 210-100X-XX

The Z-Direct Screw Driver is a reusable, user sterilized component made from Stainless Steel. It connects to the DSG® Ratcheting Handle model A Ref. D1RH0001 on one end and to the Z-Direct screw Ref. 210-XXXX, 212-XXXX or 213-XXXX on the other. Various length options are available depending on the preferred technique. It provides adequate length for both open and minimally invasive procedures and allows the transfer of torque to the screw.

Figure 4. Cannulated Z-Direct Screw Driver

2.2.2 Z-Direct screws Ref. 210-XXXX or 212-XXXX or 213- XXXX

The Z-Direct screws range in diameter from 5.5 to 8.5 mm and in length from 25 to 100 mm. The screws contain a polyaxial head, allowing insertion over 50 degrees of angulation. The series 210, 212 and 213 feature regular, reduction and extended tab head respectively. The screws are made from titanium alloy as per ASTM F-136 and are provided non-sterile. All screws have a cannula of 1.7 mm diameter through which the DSG® Pin is inserted so that it protrudes 3 mm from the screw tip.

Figure 5: Z-Direct Screw (regular head)

Figure 6: Z-Direct Screw (reduction head)

Figure 7: Z-Direct Screw (extended tab head)

Essential Performances:

- Mechanics essential performance: pedicle screw insertion.
- 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.

3. FOR USE

3.1 Choice of components for proper assembly

The DSG® Zavation Screw System must be assembled so that the DSG® Pin extends 3 mm from the tip of the Z-Direct screw. In order to achieve proper extension of the DSG® Pin in front of the screw tip, select the screw driver shaft of the appropriate length to match the screw length as per the table below:

Z-Direct Screw Ref.	Description, note that: • 210 series: regular head • 212 series: reduction head • 213 series: extended tab head	To be assembled with Z-Direct Screw Driver Ref.	Description	Ratcheting Handle	DSG® Pin	Electronic Handle
210-XX25 212-XX25 213-XX25	Z-Direct Screw Diam. XX length 25mm	210-1005-25	Cannulated Z-Direct Screw driver, 25mm	DSG® Ratcheting Handle D1RH0001	DSG® Pin Ref. D1PU0001	Electronic Handle Ref. P2HEXXXX
210-XX30 212-XX30 213-XX30	Z-Direct Screw Diam. XX length 30mm	210-1005-30	Cannulated Z-Direct Screw driver, 30mm			
210-XX35 212-XX35 213-XX35	Z-Direct Screw Diam. XX length 35mm	210-1005-35	Cannulated Z-Direct Screw driver, 35mm			
210-XX40 212-XX40 213-XX40	Z-Direct Screw Diam. XX length 40mm	210-1005-40	Cannulated Z-Direct Screw driver, 40mm			
210-XX45 212-XX45 213-XX45	Z-Direct Screw Diam. XX length 45mm	210-1005-45	Cannulated Z-Direct Screw driver, 45mm			
210-XX50 212-XX50 213-XX50	Z-Direct Screw Diam. XX length 50mm	210-1005-50	Cannulated Z-Direct Screw driver, 50mm			
210-XX55 212-XX55 213-XX55	Z-Direct Screw Diam. XX length 55mm	210-1005-55	Cannulated Z-Direct Screw driver, 55mm			
210-XX60 212-XX60 213-XX60	Z-Direct Screw Diam. XX length 60mm	210-1005-60	Cannulated Z-Direct Screw driver, 60mm			

Z-Direct Screw Ref.	Description, note that: • 210 series: regular head • 212 series: reduction head • 213 series: extended tab head	To be assembled with Z-Direct Screw Driver Ref.	Description	Ratcheting Handle	DSG® Pin	Electronic Handle
210-XX25 212-XX25 213-XX25	Z-Direct Screw Diam. XX length 25mm	210-1001-25	Cannulated Z-Direct Screw driver, 25mm	DSG® Ratcheting Handle D1RH0001	DSG® Pin Ref. D1PU0005	Electronic Handle Ref. P2HEXXXX
210-XX30 212-XX30 213-XX30	Z-Direct Screw Diam. XX length 30mm	210-1001-30	Cannulated Z-Direct Screw driver, 30mm			
210-XX35 212-XX35 213-XX35	Z-Direct Screw Diam. XX length 35mm	210-1001-35	Cannulated Z-Direct Screw driver, 35mm			
210-XX40 212-XX40 213-XX40	Z-Direct Screw Diam. XX length 40mm	210-1001-40	Cannulated Z-Direct Screw driver, 40mm			
210-XX45 212-XX45 213-XX45	Z-Direct Screw Diam. XX length 45mm	210-1001-45	Cannulated Z-Direct Screw driver, 45mm			
210-XX50 212-XX50 213-XX50	Z-Direct Screw Diam. XX length 50mm	210-1001-50	Cannulated Z-Direct Screw driver, 50mm			
210-XX55 212-XX55 213-XX55	Z-Direct Screw Diam. XX length 55mm	210-1001-55	Cannulated Z-Direct Screw driver, 55mm			
210-XX60 212-XX60 213-XX60	Z-Direct Screw Diam. XX length 60mm	210-1001-60	Cannulated Z-Direct Screw driver, 60mm			

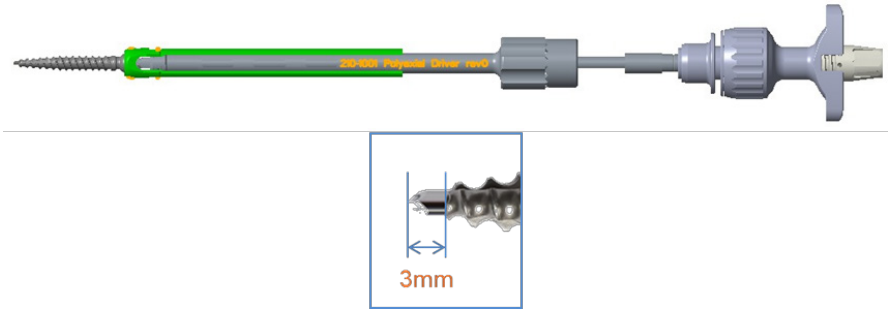
The tip of the DSG® Pin in combination with the tip of the Z-Direct screw simultaneously drills into the bone and senses possible cortical breaches using DSG® technology.

3.2 Assembly and set-up procedure including preliminary checks

1- Assemble the Z-Direct screw with the appropriate Z-Direct Screw Driver as per Zavation's Surgical Technique Ref. ST-002 and assembly table above in Section 3.1.

2- Attach the DSG® Ratcheting Handle model A Ref. D1RH0001 to the end of the Z-Direct Screw Driver. Make sure it is fully engaged, that will also be confirmed in step #6 below.

3- Insert a DSG® Pin Ref. D1PUXXXX through the cannula of the screw/screw driver/ratcheting handle assembly (from steps 1 and 2). Fully thread the knob of the Pin into the ratcheting handle. The tip of the Pin should be visible (approx. 3mm) at the distal end of the Z-Direct screw.



4- Connect the Electronic Handle Ref. P2HEXXXX to the Pin/Ratcheting Handle assembly (from step 3). Ensure that the Electronic Handle is securely connected to the Ratcheting Handle by pressing firmly and confirmed by an audible click.

5- Activate the Electronic Handle by pulling the contact tab. Activation is confirmed visually by green LEDs lighting up and an audible sound.
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.

6- Check the functionality of the DSG® Zavation Screw System assembly (from steps 1 to 4) by placing the distal tip of the assembly in saline solution (0.9% sodium chloride). A high pitch and high cadence sound should be heard. The green LEDs situated in the Electronic Handle should flash at the same frequency. If a metal bowl is used, do not touch the bowl with the tip of the Pin. If no sound is heard, it may be necessary to clean the tip of the Pin using a mild scrubber (e.g., electrocautery scrubber).

7- The DSG® Zavation Screw System assembly is now ready for use.

3.3 Safety features

The DSG® Zavation Screw System 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 DSG® Zavation Screw System.

3.4 Surgical Technique

The surgeon can either drill and/or tap the screw hole prior to inserting the pedicle screw, or can use the system to directly insert the screw into the bone without a pilot hole. As the screw is manually advanced into the bone, the distal sensor measures the electrical impedance of the immediately surrounding tissues. The device produces real-time visual and audible signals to indicate changes in impedance associated with possible vertebral perforation.

3.4.1 Direct insertion technique

With the help of pre-operative images, determine the length and diameter of the screw that will be used at the considered level. Choose the type of screw head according to the operative plan (regular or reduction for Open approach, or extended tab for MIS approach). Proceed with assembly of the DSG® Zavation Screw System as per previous paragraph (“Assembly and set-up procedure including preliminary checks”). Start by placing the Ratcheting Handle in the “neutral” position.

3.4.1.1 Specific steps to Open approach – entry point

Prepare the intended entry points for the pedicle screws using preferred open techniques to expose the posterior surface of the spine and decorticate the entry of the pedicle (*e.g.*, utilization of a rongeur or a burr). The correct location for the entry point and angle of entry may be checked by using fluoroscopy.

Direct the tip of the DSG® Zavation Screw System to the soft tissue (wound) to initiate a rated high-pitched “beep”.

Position the DSG® Zavation Screw System at the entry point and advance through cancellous bone in the expected position of the screw. See “common step to both Open and MIS approaches” below.

3.4.1.2 Specific steps to MIS approach – entry point

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

Directly introduce the DSG® Zavation Screw System through soft tissues.

Position the DSG® Zavation Screw System at the pedicle entry point and along the desired angle of entry using fluoroscopy, and perforate the cortical bone with the tip of the DSG® Zavation Screw System. Note that the Electronic Handle Ref. P2HEXXXX may be removed at this stage should the surgeon prefer not to hear the beeping sound emitted by the handle while determining the entry point.

Re-connect the Electronic Handle if it was removed previously, and advance through cancellous bone in the expected position of the screw. See “common step to both Open and MIS approaches” below. Progress of the positioning of the DSG® Zavation Screw System through the body of the vertebral pedicle and into the vertebral body may be routinely checked with fluoroscopy.

3.4.1.3 Common steps to both Open and MIS approaches – insertion of screw in pedicle

After the first thread of the screw has come in contact with bone, engage the ratchet mechanism by turning it clockwise. Now turning the DSG® Zavation Screw System clockwise will advance the instrument down the pedicle. The ratchet mechanism allows for advancement in small increments. Insert the DSG® Zavation Screw System into the pedicle along the targeted screw trajectory. As it is being advanced into the pedicle through cancellous bone, a medium pitch and medium cadence audio signal should be heard.

Before inserting a new screw, clean the tip of the DSG® Pin 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 DSG® Zavation Screw System. If the audio signal changes to a low pitch and low cadence, it indicates that the DSG® Zavation Screw System may be approaching the cortical wall.

At this time, the DSG® Zavation Screw System may be redirected using anatomical landmarks. Further drilling without redirection could result in a high pitch high cadence audio signal that indicates a possible imminent cortical breach. In that case, proceed according to the following steps:

- Change the ratchet mechanism to the neutral/locked position
- Turn the DSG® Zavation Screw System 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 ratchet mechanism in clockwise position
- Continue advancing the DSG® Zavation Screw System.

3.4.2 Insertion after preparation of the pedicle with a pilot hole

- Prepare the pilot hole with the help of the DSG® Threaded Drill System, according to the Instructions For Use, Assembly Instructions and Surgical Technique Ref. LP2-A036.
- Use the Zavation Spinal System with Z-Direct screws as per Zavation's surgical technique Ref. ST-002.
- Do not use the DSG® Pin, Electronic Handle or DSG® Ratcheting Handle with the Z-Direct screw and screwdriver.

3.5 After surgery

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.

For the reusable instruments, follow the procedure described:

- In Zavation's IFU Ref. LBL-002 for the reusable instruments of the Zavation Spinal System;
- In SpineGuard's Instructions For Use, Assembly Instructions and Surgical Technique Ref. LP2-A036 for the reusable instruments of the DSG® Threaded Drill System

4. IMPORTANT MEDICAL INFORMATION

4.1 Indications

The DSG® Zavation Screw System is indicated for use with the Zavation Spinal System during pedicle screw insertion to provide feedback to the surgeon via visual and audible alerts that indicate a change in impedance at the tip of the pedicle screw and may indicate contact of the tip with soft tissues and possible vertebral cortex perforation. The DSG® Zavation Screw System is indicated for use in both open and percutaneous (MIS) surgical approaches to the spine, with options of direct insertion of the screw in bone or after a step of preparation of the pilot hole with sensor equipped instruments.

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 DSG® Zavation Screw System 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® and Zavation as listed in paragraphs #1 and 2 of the present document. 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 DSG® Zavation Screw System for "EMG" surveillance.
- 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 DSG® Zavation Screw System 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 DSG® Zavation Screw System in association with another electronic device requires special precautions: perturbations on the patient's ECG monitor may be observed while the DSG® Zavation Screw System is in use. These abnormalities will stop as soon as the device 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 the DSG® Zavation Screw System adjacent to other electromagnetic 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.
- Use of 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 DSG® Zavation Screw System. 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.

4.4 Precautions

- With the direct insertion technique, it is necessary to determine the length of the screw that will be used at the considered level by using pre-op images, as there will be no step of pilot hole preparation.
- After system assembly, make sure that the tip of the DSG® Pin is visible (approximately 3 mm) at the distal end of the Z-Direct screw. Refer to Section 3.2 for proper assembly directions.
- When used as an EMG stimulator, do not let muscular contractions last too long to avoid undue patient fatigue.
- As with any surgical device, this system should be carefully inspected before use.
- Always check the integrity of the single use sterile packaging before use. Do not use instrument with opened or damaged packaging.
- If any component of the DSG® Zavation Screw System is accidentally dropped on the ground during the procedure, do not use it.
- Do not use the DSG® Zavation Screw System 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 DSG® Zavation Screw System.
- 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 single-use components.
- Mallet moderately on the Electronic Handle Ref. P2HEXXXX if malletting is necessary.

4.5 Possible adverse effects

The possible adverse effects while using the DSG® Zavation Screw System are:

- Disassembly, bending, and/or breakage of any or all of the components;
- 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;
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain;
- Foreign body (allergic) reaction to implants, debris corrosion products, graft materials, including metallosis, straining, tumor formation and/or auto-immune disease;
- Infection;
- Hemorrhage;
- 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. TECHNICAL SPECIFICATIONS

Storage: Expiry date is mentioned on the single use instruments’ outer package and must be respected. The DSG® Zavation Screw System should be stored in a clean dry place.

Service life: Once ON, the Electronic Handle cannot be turned off. The Electronic Handle device battery provides sufficient autonomy.

7. INFORMATION RELATED TO SINGLE USE DEVICES

The electrical and sensory components of the DSG® Zavation Screw System are single use devices. The retreatment and the re-use of the single-use DSG® Zavation Screw System components are forbidden.

Several potential dangers related to the re-use of the DSG® Zavation Screw System can increase the risk to the patient. Some technical characteristics of the electrical and sensory components of the DSG® Zavation Screw System are not compatible with the re-use of the device. 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 instructions for use.

8. INFORMATION RELATED TO REUSABLE DEVICES

The inspection, cleaning and sterilization instructions for the re-usable components of the DSG® Zavation Screw System can be found in:

- Zavation's IFU Ref. LBL-002 for the reusable instruments of the Zavation Spinal System;
- SpineGuard's Instructions For Use, Assembly Instructions and Surgical Technique Ref. LP2-A036 for the reusable instruments of the DSG® Threaded Drill System

IN NO CASE CAN THE DSG® ZAVATION SCREW SYSTEM REPLACE THE SURGEON'S EXPERIENCE OR KNOWLEDGE OF ANATOMIC STRUCTURES. THE DEVICE IS INTENDED TO ASSIST THE SURGEON IN THE DECISION-MAKING PROCESS DURING SURGERY.

CAUTION: FEDERAL LAW (US) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN.

Symbols found on the products are described below:

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

IF YOU HAVE QUESTIONS ABOUT THIS DEVICE, PLEASE CONTACT:

SpineGuard, S.A.
Manufacturer of
DSG® Zavation Screw System

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94300 Vincennes France
Phone: +33 (0) 1 45 18 45 19
Fax: +33 (0) 1 45 18 45 20

Zavation LLC Manufacturer of
Zavation Spinal System

3670 Flowood Drive
Flowood, MS 39232 - USA
Phone: 601 919 1119

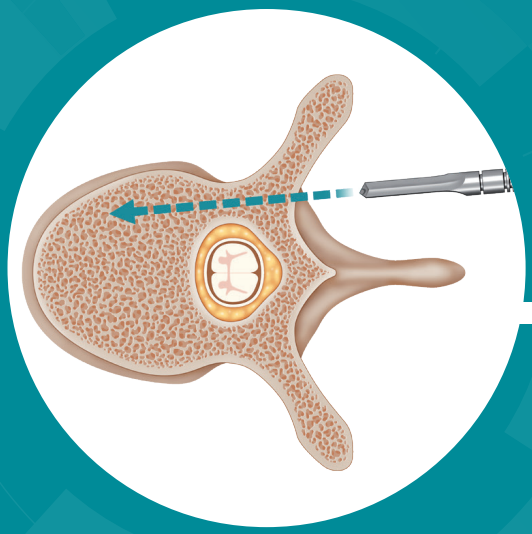
Information and manufacturer's declaration concerning electromagnetic compatibility (EMC)

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

Guidance and manufacturer's declaration – electromagnetic immunity			
The PediGuard is suitable for use in the electromagnetic environment specified below. The customer or the user of the Pediguard should assure that it is used in such an electromagnetic environment.			
Immunity test	**Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Radiated RF IEC 61000-4-3	3 V/m from 80 MHz to 2,5 GHz	3 V/m	PediGuard is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Radiated RF IEC 61000-4-3 Proximity fields from RF wireless communications equipment	380 - 390 MHz 27 V/m; PM 50%; 18 Hz	27 V/m	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the PediGuard, including cables specified by the manufacturer.
	430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz	28 V/m	
	704 - 787 MHz 9 V/m; PM 50%; 217 Hz	9 V/m	
	800 - 960 MHz 28 V/m; PM 50%; 18 Hz	28 V/m	
	1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz	28 V/m	
	2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz	28 V/m	
	5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	9 V/m	
Power frequency magnetic field (50/60Hz) IEC 61000-4-8	30 A/m	30 A/m	–

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



Take control of pedicle navigation with DSG Technology

SpineGuard®
Making spine surgery safer

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