

Take control of pedicle navigation with DSG® Technology

SpineGuard®
Making spine surgery safer
www.spineguard.com

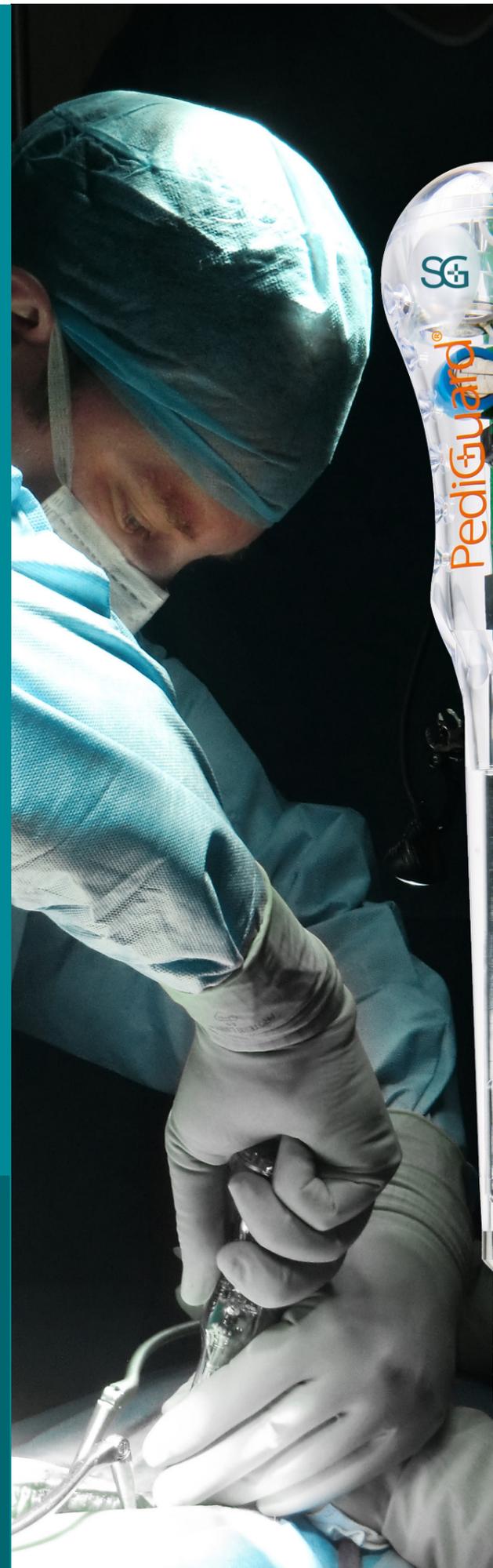
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Caution: See package insert for labeling limitations, intended uses, relevant warnings, precautions, side effects and contraindications. Federal (USA) law restricts the sale and use of this device to a prescription of a physician.

Non contractual document - Ref. GP1ST/19E



DSG® Technology
(Dynamic Surgical Guidance)

PediGuard®
Hear what you cannot see

Surgical Technique

SpineGuard®
Making spine surgery safer

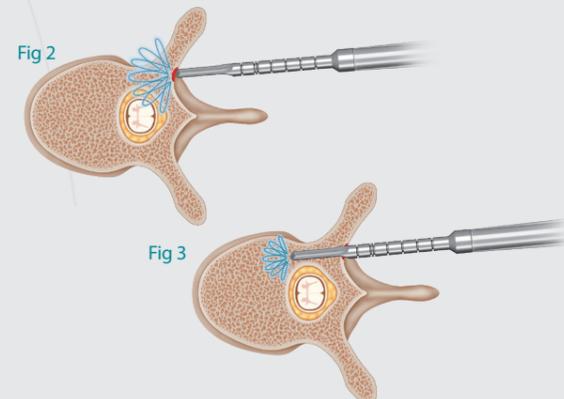
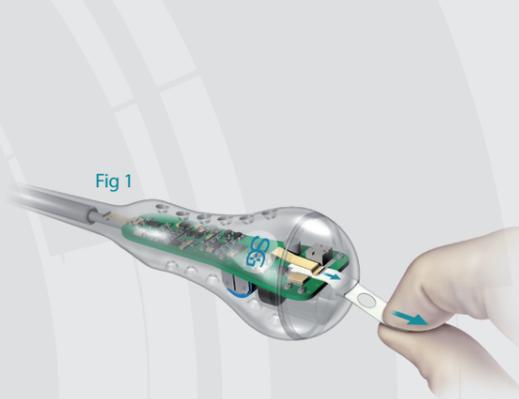
HOW TO USE THE PEDIGUARD PROBE



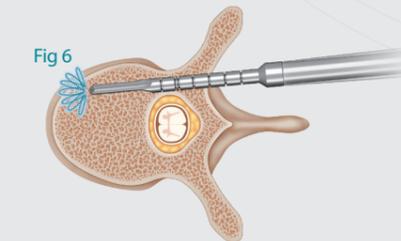
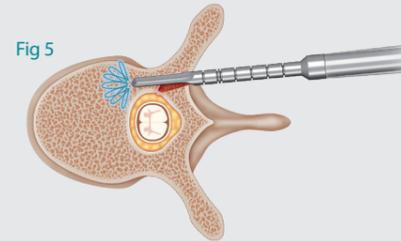
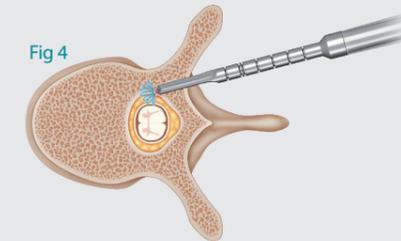
It is strongly recommended that the working principle of the PediGuard probe be clearly understood before reading this surgical technique.

As part of the preparation for surgery, select the desired shape and appropriate size of the PediGuard probe for the pedicle to be drilled. Please review the products catalog for the various sizes and shapes available in the PediGuard family of products.

Prior to drilling the pedicle with the PediGuard probe, prepare the entry point of the pedicle and perforate the dorsal cortex using standard techniques.



The audio feedback should be discerned only when pressure is being applied and the PediGuard probe is being advanced into the pedicle and/or the vertebral body.



Activate

Activate the PediGuard probe by pulling out the paper tab on top of the plastic handle (Fig 1).

A beeping activation sound must be heard and the green LED light in the handle must turn on.

Check the functionality of the PediGuard probe by placing the distal tip of the instrument 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.

Drill and Listen

Advance the PediGuard probe into the pedicle along the target trajectory for screw placement.

Pay close attention to the audio feedback provided as the probe is being advanced while applying constant pressure.

As the probe is inserted past the entry point into the pedicle a high pitch and high cadence feedback might be heard. This is due to the tip being advanced past the blood collected at the entry point (Fig 2).

A mid-range pitch and medium cadence audio signal can be heard as the probe is being advanced into the pedicle through cancellous bone (Fig 3).

As the probe is being retracted from the pedicle, a high cadence and high pitch audio feedback should be expected – this is due to the blood around the tip of the probe.

Interpret and Redirect (as required)

A change in pitch and cadence of the audio feedback indicates a change in the tissue around the tip of the PediGuard probe.

A low pitch and low cadence audio signal can be heard as the probe is approaching the cortical wall. This is the first indication of a potential breach (Fig 4).

Further drilling without redirection could result in a high pitch high cadence that indicates an imminent cortical breach.

Therefore, if there is such a change in the audio feedback, using anatomical landmarks and discretion, redirect the PediGuard probe as necessary (Fig 5).

Determine Screw Length

Using the graduated markings on the PediGuard probe note the depth to which the probe has been inserted into the pedicle and vertebral body (Fig 6).

These markings may be used to determine the length of screw to be implanted.

Prior to using the PediGuard probe in another pedicle, clean the tip of the probe with a dry soft cloth.

For additional information, please refer to the IFU provided with the PediGuard probes.

The PediGuard is frequently referred as a “smart probe” or “smart jamshidi” because it does not change the technique/steps to prepare the pedicle prior to screw placement.

NOTE

All PediGuard devices are for single surgery use only. They must be discarded appropriately at the end of each surgery.