



## Navigation Instruments

### DESCRIPTION

Spineology Navigation Instruments are non-sterile, reusable instruments that are manufactured from stainless steel and operated manually.

Spineology Navigation Instruments for Pedicular Fixation include awls, bone taps, drills, screwdrivers, and an adapter. These instruments are compatible with Spineology's Fortress™, Threshold™, Threshold™ V2, and Palisade™ Pedicular Fixation Systems and the Medtronic StealthStation® Spine System.

Spineology Navigation Instruments for Portal Placement include a dilator, portal, tightener, wrench, and a portal surrogate. These instruments are compatible with Spineology's OptiMesh® Multiplanar Expandable Interbody Fusion System for access portal placement and the Medtronic StealthStation® Spine System.

Spineology Navigation Instruments are intended to be used during the preparation and placement of spinal implants in optically navigated procedures.

For additional information regarding Spineology Pedicular Fixation or Interbody Fusion Systems, refer to the following Surgical Technique Guides (STG) and Package Inserts:

- Fortress™ Pedicular Fixation System STG, L290
- Threshold™ Pedicular Fixation System STG, L238
- Threshold™ V2 Pedicular Fixation System STG, L459
- Palisade™ Pedicular Fixation System STG, L427
- OptiMesh Multiplanar Expandable Interbody Fusion System STG, L583
- Pedicular Fixation Systems Package Insert, 10-15-45
- OptiMesh Multiplanar Expandable Interbody Fusion System Package Insert, 10-15-51

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### INDICATIONS FOR USE

Spineology Navigation Instruments are indicated for use during the preparation and placement of:

- Spineology's Fortress™, Threshold™, Threshold™ V2, and Palisade™ pedicle screws
- Spineology's OptiMesh Portal Assembly

during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, minimally invasive, or percutaneous orthopedic procedures. These instruments are designed for use with the Medtronic StealthStation® Spine System, which is indicated for any medical condition in which the use of

stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the spine or pelvis, can be identified relative to images of the anatomy.

### CONTRAINDICATIONS

Contraindications include, but are not limited to:

- Infection
- Morbid obesity
- Mental illness
- Fever or leukocytosis
- Pregnancy
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis
- Prior fusion surgery at the involved level(s)
- Cardiovascular complications
- Any patient unwilling to cooperate with the postoperative instructions
- Known or suspected sensitivity to implant materials
- Any medical condition that would preclude the patient from having surgery or would impede the benefit of implant surgery

Spineology Navigation Instruments are not compatible with or indicated for use with implants from other manufacturers.

### PRECAUTIONS

- Spineology is not a navigation provider. Spineology Navigation Instruments have been validated for use with the Medtronic StealthStation navigation system. Instructions for use and handling of third-party navigation systems are the responsibility of the hospital and/or the navigation company. Refer to navigation company's software and use guides for calibration and navigation guidance.
- The navigation system should be set up and operated per the manufacturer's instructions.

**Note:** For information on use of disposable reflective marker spheres, refer to navigation manufacturers' user guides.

### WARNINGS

- Inspect all instruments prior to use. If an instrument is visibly damaged, do not use the instrument.
- Navigated instruments are highly accurate and sensitive medical devices. Handle instruments with extreme care. If an instrument is dropped or otherwise damaged, verify its calibration accuracy. Failure to do so may lead to serious injury to the patient.
- Care should be taken to limit bending forces on calibrated instruments as deflection can influence navigation accuracy.
- Plan the setup of the OR and instrument array orientation prior to surgery. The navigation camera must have an unobstructed and simultaneous view of the instrument and navigation array.

### INSTRUMENT HANDLING

Surgical instruments must be handled with care. Improper handling may result in damage and may impair proper functioning of the device. Instruments which exhibit signs of damage or deterioration, including discoloration or corrosion, must be replaced. Ensure that all components

of the system are available for use prior to surgery. Instruments must be sterilized before use and are to be cleaned, decontaminated, and re-sterilized immediately after use.

### INSTRUMENT CLEANING, DECONTAMINATION, AND STERILIZATION

All instruments must be cleaned, decontaminated, and sterilized by the hospital before use. Please refer to Navigation Reprocessing Instructions for Spineology Surgical Instruments documents L463 or L545 for instructions. Please contact your Spineology representative if you need a replacement document.

### FURTHER INFORMATION OR PRODUCT COMPLAINTS

Contact Spineology at:

Spineology Inc.

7800 3rd Street N., Suite 600

Saint Paul, MN 55128-5455

Phone: 1.651.256.8500

Fax: 1.651.256.8505

Federal law (USA) restricts this device to sale by or on the order of a physician.

