Instructions for Use

Navigated Instrument System

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

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DEVICE DESCRIPTION

The Navigated Instrument System is comprised of subsets of instruments intended to be used in conjunction with the StealthStation® Navigation System by Medtronic Navigation, Inc. "Medtronic Navigation" to assist surgeons in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures for preparation and placement of pedicle screw system implants. This surgical imaging technology provides surgeons visualization for complex and MIS procedures and confirms the accuracy of advanced surgical procedures. Use of these navigation systems provides the surgeon access to real-time, multi-plane 3D images (and 2D images) providing confirmation of hardware placement. The Navigated Instruments are comprised of Bone Awls, Bone Taps, Bone Probes, Drills, Drill Guides (not navigated), and Screw Drivers.

The Navigated Instruments were tested for compatibility utilizing the Medtronic Navigation StealthStation S7 Orange, Violet, and Green NavLock Tracker (Part Numbers 9734683, 9733482, 9734734), and StealthAir Spine Frame (Part Number 9735249) while utilizing the Synergy Spine and Trauma Software for StealthStation S7 (Software Version 2.1.0) "Open Thoracolumbar Fusion" procedure. The products are supplied clean and "NON-STERILE".

INDICATIONS

The Navigated Instruments are indicated for use during the preparation and placement of Precision Spine screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Navigated Instruments are reusable and are specifically designed for use with the Medtronic Navigation StealthStation System which are 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 a skull, a long bone, or vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy. Use of the Navigated Instrument System is limited to use only with Reform®, Reform® HA, and SureLOK™ Spinal Fixation Systems.

PRECAUTIONS

The Navigated Instrument System instruments should only be used by surgeons who are fully experienced in the use of such instruments and the specialized navigated spinal surgery techniques.

CONTRAINDICATIONS

The **Navigated Instrument** System contraindications include, but are not limited to:

1. Morbid obesity
2. Mental Illness
3. Alcoholism or drug abuse
4. Fever or leukocytes
5. Pregnancy
6. Severe osteopenia
7. Metal sensitivity/allergies
8. Patients unwilling or unable to follow post-operative care instructions
9. Active infectious process or significant risk of infection
10. Any circumstances not listed in the indication of the device
11. Contraindications under the Reform® Spinal Fixation System, Reform® HA Coated Spinal Fixation System, SureLOK™ SLC Extended Tab Screw System, Medtronic Navigation StealthStation® System are all applicable to the use of the Navigated Instrument System.

POTENTIAL ADVERSE EFFECTS

All possible adverse effects associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:

1. Non-union
2. Fracture of the vertebra
3. Neurological injury
4. Vascular or visceral injury
5. Early or late loosening of any, or all, of the components
6. Loss of fixation
7. Device component fracture
8. Foreign body (allergic) reaction to implants, debris, corrosion products, and graft material, including metallosis, straining, tumor formation, and/or autoimmune disease
9. Disassembly and/or bending of any or all of the components
10. Infection
11. Hemorrhage
12. Change in mental status
13. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain
14. Pain, discomfort, or abnormal sensations due to the presence of the device
15. Post-operative change in spinal curvature, loss of correction, height, and/or reduction
16. Cessation of any potential growth of the operated portion of the spine
17. Loss of or increase in spinal mobility or function
18. Death

Note: Additional surgery may be required to correct some of these potential adverse events.

WARNINGS

The following are warnings for this device.

1. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
2. When used as a pedicle screw system, this system is intended for Grade 3 or 4 spondylolisthesis at the fifth lumbar/first sacral (L5-S1) vertebral joint.
3. Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebrae, neurological injury, and vascular or visceral injury.
4. Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
5. Single use only. AN IMPLANT SHOULD NEVER BE RE-USED. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure. These Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.
6. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
7. To facilitate fusion, a sufficient quantity of autograft bone should be used.
8. Do not reuse implants. Discard used, damaged, or otherwise suspect implants.
9. The implantation of pedicle screw systems should be performed only by experienced spinal surgeons with specific training in the use of pedicle screw spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.
10. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
11. Non-sterile; the screws, rods, locking cap screws, cross-links, connectors, hooks, and instruments are sold non-sterile, and therefore must be sterilized before use.
12. The components of this system should not be used with components of any other system or manufacturer.
13. Titanium components should not be used with stainless steel components within the same system.
14. This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical spine.
15. The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.
16. Precision Spine does not warrant Medtronic Navigation Software. It is the sole responsibility of the user to ensure instrument

calibration and/or registration.

17. The use of the Navigated Instrument System should only be used with the indicated pedicle screw systems.
18. Users must complete verification steps as required per the Medtronic Navigation Operative Technique.
19. Users must ensure that surgical accuracy be assessed before the procedure and repeatedly throughout the procedure by positioning the tip of each navigated instrument on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system. When verifying the accuracy of the Navigated Drivers, the accuracy test must include the Screw (of which diameter and length are selected/entered in the software) assembled securely onto the driver. The screw tip will be placed on an identifiable anatomical landmark and compared to the tip location as displayed on the screen.
20. In the event of a registration failure or suspected inaccuracy, the Navigated Instruments should not be used with the Navigation System and the instruments should be inspected for damage before continuing with the traditional, non-navigated procedure.

PREOPERATIVE

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. The implant components should be handled and stored carefully, protected from any damage, including corrosive environments.
4. Correct selection of the implant is very important.
5. An adequate inventory of implant sizes should be available at the time of surgery.
6. All implants and instruments must be unpacked, inspected for damage, cleaned and sterilized prior to use in the operative field. Instruments requiring sharp tips and/or edges to function should be inspected prior to use. If such instruments have dulled and will not function optimally, they should be returned to Precision Spine for replacement.

INTRAOPERATIVE

1. The primary goal of this surgery is to arthrodese selected vertebrae.
2. Adequate exposure bony preparation and grafting is essential to achieving this result.
3. Extreme caution should be used around the spinal cord and nerve roots, especially when inserting the screws.
4. Breakage, slippage, misuse, or mishandling of the instruments or implant components may cause injury to the patient or hospital personnel.
5. The implants must be handled and contoured carefully to avoid notching or scratching the surface.
6. Before closing the soft tissues, all of the locking cap screws should be tightened firmly according to the operative technique.
7. Ex-planted implants must never be reused.
8. The placement of screws should be checked radiographically prior to assembly of the rod construct.
9. During construct assembly do not cross thread locking cap screws. Rotate locking cap screws counter clockwise for 1 to 2 revolutions in screw head before attempting to thread locking cap screw into screw head.

POSTOPERATIVE

1. Detailed instructions on the use and limitations of the implant should be given to the patient. The patient must be made aware of the limitations of the implant. Physical activity and load bearing have been implicated in premature loosening, bending, or fracture of internal fixation devices.
2. Surgical implants must be never reused. Any retrieved devices should never be reused in another surgical procedure. The retrieved parts should be handled and disposed of in such a manner as to ensure that reuse is not possible.
3. Adequate postoperative management to avoid fracture, re-fracture or other complications should follow implant removal.

STERILIZATION

The **Navigated Instrument** System is supplied clean and non-sterile and must be sterilized prior to use. Remove all packaging before sterilization. Implants and instruments should be autoclave sterilized using one of the following validated cycle parameters.

Note: Flash sterilization is not recommended for the Navigated Instrument System.

Method	Cycle Type	Sterilization Temperature	Minimum Exposure Time
Steam	Gravity Displacement	270°F (132°C)	15 minutes
Steam	Pre-vacuum	270°F (132°C)	4 minutes

To assure maintenance of sterility we recommend:

- Utilization of a minimum drying time of 20 minutes in accordance with ANSI/AAMI ST79:2006, Comprehensive guide to steam sterilization and sterility assurance in health facilities.
- For USA: Use only FDA cleared sterilization wraps to enclose the sterilization tray.

MAGNETIC RESONANCE ENVIRONMENT

The **Navigated Instrument** System has not been evaluated for safety and compatibility in the Magnetic Resonance environment. The **Navigated Instrument** System has not been tested for heating or migration in the Magnetic Resonance environment. Components may interfere with the quality of the imaging obtained using MRI.

STORAGE INSTRUCTIONS

All products should be stored in a cool, dry place.

HOW SUPPLIED

The required components and specialized instruments are supplied non-sterile in a container suitable for steam sterilization or individually packaged as replacement product. All components and instruments may be purchased independently.

CARE AND HANDLING

- Please refer to ASTM standards such as F1744-96, "Standard Guide for Care and Handling of Stainless Steel Surgical Instruments" for additional information.
- Surgical instruments are subject to wear with normal usage. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Surgical instruments should be used only for their intended purpose.
- **Precision Spine®** recommends that all instruments be visually inspected for wear and disfigurement, as well as tested to ensure instruments are functioning properly prior to use. If instruments are discolored, have loose screws/pins, are out of alignment, are cracked or have other irregularities, **DO NOT USE**.

CLEANING AND DECONTAMINATION

- These instructions are to be followed prior to initial use and reprocessing of the instruments.
- Reprocessing the instruments using the methods described herein, will not limit the useful life of the instruments. The useful life of the product is typically determined by wear and damage due to use.
- Transport trays should be considered reusable devices, and inspected for visible soils and must be cleaned.
- **WARNING**: The following Cleaning instructions have been validated. Failure to follow all steps may result in an improperly cleaned and sterilized instrument (Non-Sterile).
- **CAUTION**: To preserve optimal efficiency and safety of the instruments, the following instructions must be followed.
    - The use of metallic brushes, scrub pads or other articles that are likely to damage the instrument must be avoided.
    - Chemicals, such as chlorine or soda as well as organic or ammoniated acids or solvents (e.g. Acetone) that are likely to damage the instrument, must not be used.
    - Mercurial solutions are not recommended, as they corrode metal parts.
    - If applicable, disassemble instruments prior to Cleaning. Articulated instruments must be opened to allow the cleaning of all interstices.
    - Immediately after the surgical procedure, disallowing organic debris to dry on the instruments, remove as much debris as possible from each instrument using a water moistened gauze pad or wipe, exchanging the gauze pad or wipe as it becomes soiled. Do not allow organic debris to dry.
    - Prepare a neutral pH enzymatic cleaning solution per the manufacturer's instructions with warm tap water (35-40°C).
    - Immerse the instruments in the cleaning solution for a minimum of 10 minutes, activating any mechanisms 5X, so the enzymatic cleaner contacts all mated surfaces. Thoroughly scrub all instruments with a soft bristle cleaning brush while immersed in the enzymatic cleaning solutions. Be sure that thorough scrubbing also includes any lumens with an appropriately sized brush that contacts all surfaces. Change the soak solution after each utilization or if grossly soiled.
    - Rinse the instruments in warm tap water (35-40°C) for at least one minute.
    - Transfer the instruments into fresh enzymatic cleaning solution. Sonicate the instruments while immersed in the cleaning solution for a minimum of 15 minutes.
    - Thoroughly rinse all instruments and lumens with warm running water (35-40°C), for at least one minute each until flushing water runs clear. Use a hose or water jet to rinse any lumens, holes, or complex interfaces. Perform a second rinse with DI water, again using a hose or water jet to rinse any lumens, holes, or complex interfaces.
    - Dry with a sterile gauze, clean cloth and/or clean compressed air. Inspect instruments for cleanliness, function, and residual moisture. Any device that is not visually clean must be reprocessed.

LUBRICATION

To protect instruments from staining and rusting during sterilization and storage, they should be lubricated with a water-soluble, preserved lubricant after each cleaning. Since effective ultrasonic cleaning removes all lubricant, relubrication is important. The lubricant should contain a chemical preservative to prevent bacterial growth in the lubricant bath. The bath solution should be made with demineralized water. A lubricant containing a rust inhibitor helps prevent electrolytic corrosion of points and edges. Immediately after cleaning, instrument should be immersed for 30 seconds and allowed to drain off, not wiped off. A lubricant film will remain through the sterilization to protect them during storage.

MATERIAL SPECIFICATION

All components are made from medical grade stainless steel, per ASTM F899. The products are supplied clean and “NON-STERILE”.

CLINICAL HISTORY

These instructions for use are based upon current experience. The physician may wish to vary the procedure in accordance with clinical judgment.

PRODUCT COMPLAINTS

Any complaint or dissatisfaction with product quality, performance, labeling, and/or safety should be reported to **Precision Spine.** If any of the implants or instruments “malfunction” (i.e. do not meet any of their performance specifications or do not perform as intended) and/or are suspected to have caused or contributed to the death or serious injury of the patient, **Precision Spine** should be notified immediately by phone, fax or written correspondence. When filing a complaint, please provide the product description, product number, lot number, your name and address, and the nature of the complaint.

ADDITIONAL INFORMATION

Surgical technique guides / brochures for Precision Spine Navigated Instruments and associated Precision Spine implant systems (Reform® Pedicle Screw System, Reform® Modular Pedicle Screw System, Reform® HA Pedicle Screw System, Reform® Ti Pedicle Screw System, Reform® MC Pedicle Screw System, SureLok Pedicle Screw System, SureLok MIS 3L Pedicle Screw System) are available upon request. If further information is required, please contact the manufacturer.

Precision Spine, Inc.
2050 Executive Drive
Pearl, MS 39208
USA
Phone: 1-601-420-4244
Toll Free: 1-888-241-4773
Fax: 1-601-420-5501

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