Navigation System
Instruction for Use

ChoiceSpine, LLC
400 Erin Drive
Knoxville, TN 37919
USA

General Description:
The ChoiceSpine Navigation instruments are non-sterile, reusable instruments designed to function with the Medtronic® StealthStation® System and SureTrak® II System. Refer to the appropriate navigation system Instructions for Use and/or Surgical Technique Guide for details regarding navigation system use. The ChoiceSpine Navigation instruments are for use with ChoiceSpine screw systems, specifically, Lancer™, Thunderbolt™, and Blackbird™ Spinal Systems.

Indications for Use:
The ChoiceSpine Navigation reusable instruments are intended to be used during preparation and placement of ChoiceSpine Lancer™, Thunderbolt™, and Blackbird™ system during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The ChoiceSpine Navigation reusable instruments are specifically designed for use with the Medtronic Stealth Station System (V2.1.0), 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 a skull, along bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

Contraindication
Medical conditions which contraindicate the use of the ChoiceSpine Navigation System and its associated applications include any medical condition which may contraindicate the medical procedure itself.

Precautions
- Verify that all relevant instrumentation has been properly cleaned and sterilized before surgery. Clean and sterilize the components according to the parameters listed below.
- Federal law (U.S.A.) restricts this device to sale by or on the order of a physician
- System components are fragile. Use care when handling system components.
- Check the instrument verification and accuracy checkpoints frequency to ensure correct functionality.
- During navigated use, the instruments should be continually assessed for accuracy (e.g. intraoperatively checking the projected tip of the instrument against a pedicle to ensure proper tracking).

Warnings
- The system and its associated applications should be used only by qualified medical professionals who are thoroughly trained and experienced in performing surgery with computer-assisted surgery systems.
- Only use ChoiceSpine connector with approved ChoiceSpine Navigation instrumentation
- Any movement or repositioning (intentional or accidental) of the distal instrument tip with respect to the connected tracking array will result in an inaccurate display of the instrument location and/or trajectory. Calibration and verification per the surgical technique guide may need to be re-executed.
- The system and its associated applications should be used only as an adjunct for surgical guidance. They are not a replacement for the surgeon's knowledge, expertise, or judgement.
- If system navigation seems inaccurate and recommended steps to restore accuracy are not successful, abort use of the system.
- Inspect all instruments and system components before use. If visibly damaged, do not use the instrument.
- Because the position of the anatomy is defined by the position of the patient Reference Frame, it is important to ensure that the frame does not move with respect to the anatomy from the time of registration until navigation is complete. Slippage or rotation of the Reference Frame with respect to the anatomy after registration will result in inaccurate navigation.

Possible Adverse Events:
- Metal sensitivity has been reported following exposure to orthopedic implants. Common metallic sensitivities e.g. (nickel) are present in medical grade stainless steel.

For implant instruction for use information please refer to the appropriate ChoiceSpine System IFU: Lancer™ Open Pedicle Screw System IFU, the Thunderbolt™ Minimally Invasive Pedicle Screw System IFU, and Blackbird™ Spinal System IFU. For additional warnings/cautions/precautions of associated systems please refer to the labeling for StealthStation®and SureTrak® II. StealthStation® S7® system manual PN 9733782 and SureTrak® II instructions for use PN 9730510.

How Supplied:
The Navigation System devices are provided non-sterile and must be sterilized prior to use. Instruments can be reprocessed using the recommended cleaning instructions.

Cleaning and Decontamination:
All instruments are supplied to the health care facility clean but non-sterile. Additionally, all instruments that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning and disinfecting of instruments can be accomplished by using alkali aldehyde-free solvents at high temperatures. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

All products should be treated with care. Improper use and handling may lead to damage and possible improper functioning of the device.

These devices are packaged in a convenience caddy/case. All devices must be removed from the case, inspected and cleaned via one of the appropriate methods below. Where applicable, instruments should be disassembled prior to cleaning and reassembled prior to sterilization. All devices must be placed back into the caddy and case prior to steam sterilization.

Recommended Cleaning:
The terms "Steris 444", "Enzol®" and "Prolystica®" are tradenames of ultrasonic equipment and detergents utilized in the recommended cleaning instructions. Any ultrasonic washer or equivalent ultrasonic detergent can be utilized when used in accordance to the manufacturer's instructions and labeling.

Automated Cleaning:
1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.
2. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
3. Transfer instrument(s) into a STERIS 444 washer with the following parameters. Incline the instrument(s) to assist in drainage. Motor speed: High.

Phase	Time (min)	Temperature	Detergent
Pre-Wash 1	1:00	Cold Tap Water	N/A
Enzyme Wash	1:00	Hot Tap Water	Enzol® at 1 oz. per 1 gal. Water
Wash 1	2:00	60°C	Prolystica® 2x conc. Neutral at 1/8 oz. per 1 gal. Water
Rinse 1	1:00	Hot Tap Water	N/A
Drying	7:00	115°C	N/A

4. Remove instruments and inspect for soil, repeat cleaning if necessary.

Mechanical Cleaning (Ultrasonic):
1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
5. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.
6. Remove instrument(s) from detergent & rinse with cool tap water (< 35°C) for at least one (1) minute.
7. Prepare the ultrasonic cleaner with an Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55°C).
8. Load instrument(s) into the cleaner & sonicate for ten (10) minutes.
9. Remove instrument(s) from cleaner & thoroughly rinse using reverse osmosis/deionized (RO/DI) water for at least one (1) minute.
10. Dry instrument(s) using a clean, soft towel & filtered, pressurized air (20 psi).
11. Visually inspect for soil. Repeat if necessary

Manual Cleaning:
1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through & around cracks, crevices, & hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & hard to reach areas.
5. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.
6. Remove instrument(s) from detergent & thoroughly rinse with reverse osmosis/deionized (RO/DI) water for at least one (1) minute. Use a sterile syringe to aid in rinsing.
7. Dry instrument(s) using a clean, soft cloth & filtered, pressurized air (20 psi).
8. Visually inspect for soil. Repeat if necessary.

Care and Handling:
- All products should be treated with care. Improper use and handling may lead to damage and possible improper functioning of the device.
- Refer to ASTM standard F1744-96, "Standard Guide for Care and Handling of Stainless Steel Surgical Instruments" for additional information.
- Before use, instruments should be visually inspected, and function should be tested to ensure instruments are functioning properly. If instruments are discolored, have loose screws/pins, are out of alignment, cracked, show excessive wear, or have other irregularities, DO NOT use.
- Lubricate instruments to protect instruments during sterilization and storage. This should be done with a water soluble, preserved lubricant after each cleaning. The lubricant should contain a chemical preservative to prevent bacterial growth and be made with distilled water. Excess lubricant should be wiped off prior to storage and sterilization.
- All instruments should be re-inspected for damage prior to use. If they are bent or damaged in any way, the instruments should not be used, regardless of navigated or manual procedures.
- Discontinue use in the event of a registration/calibration failure or suspected inaccuracy. In the event the instrument should not be used with the navigation system and should be inspected for damage before continuing with a traditional, non-navigated procedure.

Sterilization:
ChoiceSpine instruments are provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. Instruments are recommended to be steam sterilized by the hospital using the following process parameters:

Steam Sterilizer Type: Pre-Vacuum
Temperature: 132°C
Duration: 4 minutes
Drying Time: 40 minutes

All devices are to be wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600 or equivalent) using various wrapping techniques per ANSI/AAMI ST79.

This steam sterilization cycle is not considered by the FDA to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps or pouches, chemical or biological indicators, and sterilization cassettes) that have been cleared by the FDA for the sterilization cycle specifications (time and temperature). Alternative sterilization methods or cycles may be used but should be validated according to hospital practices and procedures. The use of an FDA cleared wrap is recommended to ensure devices remain sterile prior to implantation.

Limitations and Restrictions:
Repeated sterilization according to these instructions has a minimal effect on ChoiceSpine devices. Sterilization equipment varies in performance characteristics and must be validated accordingly. The sterilizing facility is responsible for the routine validation and monitoring of all equipment, materials and personnel used in their facility to ensure the desired results are achieved. These instructions have been validated as being capable of sterilizing these ChoiceSpine implants and instruments. Any deviations from these procedures must be evaluated for efficacy by the sterilizing facility.

Surgical Technique Manual:
The ChoiceSpine Navigation System Surgical Technique Manual is available by contacting ChoiceSpine Customer Service.

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

Product Complaints:
The customer or health care provider should report any dissatisfaction with the product quality, labeling, packaging or performance to ChoiceSpine immediately. Furthermore, if any of the implants "malfunction" (i.e., do not meet any of their performance specifications or otherwise do not perform as intended) and may have caused or contributed to the death or serious injury of the patient, ChoiceSpine should be notified immediately by telephone, fax or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

Some components may not be currently available. Please contact your ChoiceSpine representative for additional information. The products discussed herein may be available under different trademarks in different countries. All copyrights and pending and registered trademarks are property of ChoiceSpine. For more information on a specific product or trademark, please contact your local ChoiceSpine representative.

Information:
See choicespine.com for more information.

See choicespine.com/patents/ for patent information.

For product complaints please contact:
ChoiceSpine, LLC
Quality/Regulatory Department
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333; Fax: 865-588-4045

For additional Product information please contact:
ChoiceSpine, LLC
Customer Service Department
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333; Fax: 865-588-4045
customerservice@choicespine.com

Symbol Legend:

Symbol	Definition
	Do not reuse
	Caution, consult instructions for use for warnings and precautions
	Consult instructions for use
	Do not use if package is damaged
LOT	Lot number
REF	Reference number
SN	Serial Number
STERILE R	Sterilized by irradiation
	Use by
	Manufacturer
	Date of Manufacture
Rx only	Federal law (USA) restricts this device to sale by or on the order of a physician
NON STERILE	Non-Sterile
CE	European Medical Devices
EC REP	Authorized representative in the European Community