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Device System Name:
Navigated Instrument System

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Device System Name:

Navigated Instrument System

Description:

The Navigated Instrument System is comprised of two sets of manual surgical instruments for use with the Brainlab VectorVision™ System by BrainLab AG Inc. "Brainlab" (denoted with BL) and the StealthStation® Navigation System by Medtronic Navigation, Inc. "Medtronic Navigation" (denoted with MDT) 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. Use of the Navigated Instrument System is limited to Taps ranging in sizes of 4.5mm to 8.5mm and bone screws ranging from 4.5mm to 8.5mm with lengths ranging from 25mm to 55mm.

The Navigated Instrument System Medtronic Navigation and Brainlab compatible instruments are comprised of Bone Awls, Bone Taps, Bone Probes and a variety of Screw Drivers.

The Navigated Instrument System instruments were tested for compatibility utilizing the Medtronic Navigation StealthStation S7 Orange, Violet, and Gray Navlock Tracker (Part Numbers 9734683, 9733482, 9734590 and 9732353), Medtronic Navigation Instrument Driver (Part Number 9734279) and the Navlock Reference Frame (Part Number 9732353) while utilizing the Navigated CD Horizon Solera Operative Technique with control number PMD016466-1.0 31441.

Indications for Use:

The Navigated Instrument System is indicated for use during the preparation and placement of Orthofix screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Navigated Instrument System reusable instruments are specifically designed for use with the Brainlab VectorVision system and 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 the Firebird® Spinal Fixation Systems.

Contraindications:

The Navigated Instrument System, as with other orthopedic implants, is contraindicated for use in patients with:

1. Morbid obesity
2. Mental Illness
3. Alcoholism or drug abuse
4. Pregnancy
5. Metal sensitivity/allergies
6. Severe osteopenia
7. Patients unwilling or unable to follow post-operative care instructions
8. Contraindications under the Firebird Spinal Fixation System / Phoenix® MIS Spinal Fixation System, Medtronic Navigation StealthStation and BrainLab VectorVision Systems are all applicable to the use of the Navigated Instrument System.
9. Any circumstances not listed under the heading indications.

Potential Adverse Events:

Potential adverse events include, but are not limited to:

1. Inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions, distorted anatomy).
2. Pedicle screw malpositioning, with or without neurological or vascular injury.
3. Proximal or distal junctional kyphosis.
4. Pancreatitis.
5. Device component fracture.
6. Fracture of the vertebra.
7. Neurological injury.
8. Vascular or visceral injury.
9. Foreign body (allergic) reaction to instruments, debris and corrosion products, including metallosis, straining, tumor formation, and/or auto-immune disease.
10. Infection.
11. Pain, discomfort, or abnormal sensations due to the presence of the device.
12. Hemorrhage.
13. Death.

Note: As with any major surgical procedure, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications known to occur are: early or late infection, which may result in the need for additional surgeries, damage to blood vessels, spinal cord or peripheral nerves, pulmonary emboli, loss of sensory and/or motor function, impotence, permanent pain and/or deformity. Rarely, some complications may be fatal.

Warnings and Precautions:

1. The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury. Patients who are not skeletally mature undergoing spinal fusion procedures may have reduced longitudinal spinal growth or may be at risk for rotational spinal deformities (the "crankshaft phenomenon") due to continued differential growth of the anterior spine.
2. The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient.
3. Preoperative and operative procedures, including knowledge of surgical techniques, good reduction and proper selection and placement of the implants are important considerations in the successful utilization of the system in pediatric patients.
4. The selection of the proper size, shape and design of the implant for each patient is crucial to the safe use of the device in pediatric patients.
5. The safety and effectiveness of pedicle screw 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 (pseudoarthrosis). The safety and effectiveness of these devices for any other condition are unknown.
6. The benefit of spinal fusion utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
7. The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of the pedicle screw spinal system because they are technically demanding procedures presenting a risk of serious injury to the patient.
8. The safety, efficacy and performance of the system have been established for conditions in which the system is used as intended and when used as identified in the Indications for Use. Performance of the system has not been evaluated for use that is contrary to the Intended Use, Indications for Use or for use that is contraindicated. Failure to use the system as indicated could detrimentally affect the performance of its components.
9. Orthofix does not warrant Medtronic and Brainlab Navigation Software. It is the sole responsibility of the user to ensure instrument calibration and/or registration.
10. The use of the Navigated Instrument System should only be used with the indicated pedicle screw systems.
11. Users must complete verification steps as required per the Medtronic Navigation Operative Technique.
12. Users must complete the manual calibration steps as required per the Brainlab Operative Technique.
13. 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.
14. 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.

Cleaning:

Navigated Instrument System instruments are provided clean but not sterile.

All instruments must be thoroughly cleaned after each use.

None of the instruments in the system require disassembly prior to cleaning.

From Point of Use:

Whenever possible, do not allow blood, debris or body fluids to dry on instruments. For best results and to prolong the life of the surgical instrument, reprocess immediately after use.

Preparation for Cleaning:

1. All instruments with moving parts (e.g., knobs, triggers, hinges) should be placed in the open position to allow access of the cleaning fluid to areas which are difficult to clean.
2. Soak the instruments for a minimum of 10 minutes in sterile water prior to the manual or automated cleaning process.
3. Use a soft cloth or a soft plastic bristle brush to remove any visible soil from the instruments prior to manual or automated cleaning. Use a soft plastic bristle brush or a pipe cleaner to remove soil from any inner lumens.

Manual Cleaning:

1. Upon completing the preparation for the cleaning procedure, prepare the Vesphene® Ilse agent per the dilution recommended on the label directions (1 ounce per gallon), or 1 mL of Vesphene® Ilse to each 128 mL of potable tap water per the manufacturer's Directions for Use label.
2. Bathe instruments in prepared room temperature solution.
3. Manually agitate instruments in Vesphene® Ilse solution for 15 minutes.
4. If visible soil is noted, scrub instruments with a soft plastic bristle brush and use the brush or a pipe cleaner long enough to reach the entire length of any interior lumen(s) to remove the soil.
5. Rinse the instruments in USP <1231> purified water for 1.5 minutes.
6. Hang dry the device.
7. Inspect the instruments for visible soil.
8. If visible soil is noted, repeat the steps listed above.

Automated Cleaning:

1. Upon completing the preparation for the cleaning procedure, set up the washer/disinfectant detergent dose at ½ ounce of Endozime AW Plus® per gallon of water or according to the manufacturer recommendations.
2. If visible soil is noted, scrub instruments with a soft plastic bristle brush and use the brush or a pipe cleaner long enough to reach the entire length of any interior lumen(s) to remove the soil.
3. Place scrubbed instruments into the washer baskets.
4. Orient instruments in the automated washer's carriers as recommended by the washer manufacturer.
5. The following automated cleaning cycle is recommended (minimum recommended times are provided for each stage):
 - a. Pre-Wash 1: cold potable water, 2 minutes
 - b. Enzyme/Detergent treatment:
 1. Spray with enzyme/detergent, 20 seconds
 2. Soak, 1 minute
 3. Rinse cold potable water, 15 seconds
 4. Rinse cold potable water, 15 seconds
 - c. Wash ≥ 65°C, 2 minutes using Endozime AW Plus®
 - d. Rinse 1: hot potable water, 15 seconds
 - e. Rinse 2: hot pot able water, 15 seconds
 - f. Rinse 3: hot potable water, 15 seconds
 - g. Rinse 4: hot potable water, 15 seconds
 - h. Thermal rinse ≥ 93°C, 1 minute
 - i. Heated USP <1231> Purified Water Rinse 1: re-circulating 10 seconds
 - j. Heated USP <1231> Purified Water Rinse 2: non re-circulating 10 seconds
 - k. Dry at 115°C, 7 minutes
6. Inspect the instruments for visible soil.
7. If visible soil is noted, repeat the above listed steps until no visible soil is noted.

Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach, and/or other alkaline cleaners may damage instruments. These solutions should not be used.

Note: Visually inspect instruments after cleaning and prior to each use. Discard or return to Orthofix any instruments that are broken, discolored, corroded, have cracked components, pits, gouges, or are otherwise found defective. Do not use defective instruments.

Sterilization:**Sterilization with Blue Wrap:**

The Navigated Instrument System instruments are supplied NON-STERILE. Prior to use, all instruments should be placed in the appropriate Orthofix case which will be wrapped in a FDA cleared sterilization wrap, or individually wrapped, and placed in the autoclave for sterilization by the hospital using one of the following recommended cycles:

Method: Steam	or:	Method: Steam
Cycle: Gravity		Cycle: Prevac
Temperature: 270°F (132°C)		Temperature: 270°F (132°C)
Exposure time: 15 minutes		Preconditioning: Per manufacturer's settings
Drying time: 30 minutes		Exposure time: 4 minutes
Double wrapped		Drying time: 30 minutes
		Double wrapped

Validation and routine monitoring should be performed per ANSI/AAMI ST79 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. Other cycles may be used (International Use Only, Not for US) as long as they comply with the above practices and provide a sterility assurance level of 10⁻⁶.

Packaging:

Packages for each of the components should be intact upon receipt. If a consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for damage prior to use. Damaged packages or products should not be used and should be returned to Orthofix.

The Navigated Instrument System instruments are provided in a modular case specifically intended to contain and organize the system's components. The system's instruments are organized into trays within each modular case for easy retrieval during surgery. These trays also provide protection to the system components during shipping. Additionally, individual instruments and implants are provided in sealed poly bags with individual product labels.

Product Complaints:

Any Health Care Professional (e.g., customer or user of this system of products) who has any complaints or who has experienced any dissatisfaction with the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Orthofix Inc., 3451 Plano Parkway, Lewisville, TX 75056, USA, by telephone at 1-214-937-3199 or 1-888-298-5700 or by e-mail at complaints@orthofix.com.

Further Information:

A recommended operative technique for the use of this system is available upon request from Orthofix at the phone numbers provided above.

Latex Information:

The instruments and/or packaging material for the Navigated Instrument System are not formulated with and do not contain natural rubber. The term "natural rubber" includes natural rubber latex, dry natural rubber, and synthetic latex or synthetic rubber that contains natural rubber in its formulation.

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

	See Instructions for Use		Manufacturer
	Orthofix.com/IFU		Authorized Representative
	Catalogue Number		Lot Number
	Provided Non-Sterile		

All third party trademarks used herein are the trademarks of their respective owners. StealthStation® is a registered trademark of Medtronic Navigation, Inc. Brainlab VectorVision™ System is a trademark of BrainLab AG Inc. Orthofix is not associated with or sponsored by Medtronic Navigation, Inc. or BrainLab AG Inc.