Kalitec Navigated Instrument System

Product Instructions for Use

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Non-Sterile Product

BEFORE USING THIS PRODUCT READ THE FOLLOWING THOROUGHLY.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Important Information on the Kalitec Navigated Instrument System

Description:

The Kalitec Navigated Instrument System is comprised of manual surgical instruments for use with 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 a navigation system provides the surgeon access to real-time, multi-plane 3D images (and 2D images) providing confirmation of hardware placement. Use of the Kalitec Navigated Instrument System is limited to Taps ranging in sizes of 4.5mm to 7.5mm and bone screws ranging in diameter from 4.75mm to 8.5mm with lengths ranging from 25mm to 110mm.

The Kalitec Navigated Instrument System instruments which are MDT compatible are comprised of Bone Awls, Bone Taps, Bone Probes and a variety of Screw Drivers.

The Kalitec Navigated Instrument System instruments were tested for compatibility utilizing the Medtronic Navigation StealthStation S8 Violet and Gray Navlock Trackers (PNs 9734682 and 9734590), Bone Clamp Array and Bone Clamp (PNs 973065 and 9735715), Medtronic Solera Cannulated Driver (PN 9735024), Medtronic Straight Lumbar Probe (PN 9734679), Medtronic Solera Awl Tip Tap 4.5mm (PN NAV202), Medtronic StealthStation Reference Probe (PN 960-559) while utilizing the Navigated CD Horizon Solera Operative Technique.

Indications for Use:

The Kalitec Navigated Instrument System is indicated for use during the preparation and placement of screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Kalitec Navigated Instruments System reusable instruments 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 vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

Use of the Kalitec Navigated Instrument System instruments is limited to use only with Kalitec pedicle screw systems.

Contraindications:

The Kalitec Navigated Instrument System, as with other orthopedic implant systems, are 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 pedicle screw system in use and Medtronic Navigation StealthStation Systems are all applicable to the use of the Kalitec Navigated Instrument System instruments.
9. Any circumstances not listed under the heading "Indications for Use".

Possible Adverse Effects:

Possible adverse effects 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 in contraindicated. Failure to use the system as indicated could detrimentally affect the performance of its components.
9. Kalitec Medical does not warrant Medtronic Navigation Software. It is the sole responsibility of the user to ensure instrument calibration and/or registration.
10. The use of the Kalitec Navigated Instrument System instruments should only be used with Kalitec pedicle screw systems.
11. Users must complete verification steps as required per the Medtronic Navigation Operative Technique.
12. 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.
13. In the event of a registration failure or suspected inaccuracy, the Kalitec Navigated Instrument System 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.

If a reusable device is/was used in a patient with, or suspected of having, Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize and eliminate the risk of cross-contamination.

Packaging:

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Kalitec Medical.

Cleaning and Decontamination:

Instruments are supplied clean and NOT STERILE, and must be sterilized prior to use.

All instruments must be thoroughly cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Kalitec Medical. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

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

Immediately after the procedure, place the instruments in a tray and cover with a towel moistened with sterile water and transport to decontamination environment.

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

Some device materials may develop changes in mechanical, physical or chemical characteristics under conditions of repeated use, cleaning and re-sterilization that may compromise the integrity of the design and/or material leading to diminished safety, performance and/or compliance with relevant specifications.

The instruments should be inspected and checked following a thorough cleaning to make certain they are functioning properly. Visually inspect all devices for any evidence of deterioration, corrosion, and/or discoloration and if found, the instrument should be replaced.

Precleaning:

Remove debris from instruments with sterile water and sponge during the procedure to prevent drying of blood and bodily fluids. Blood and bodily fluids are highly corrosive and can produce stains that are difficult to remove.

Manual Cleaning:

Prepare an enzymatic cleaning solution per manufacturer's specifications. Separate dissimilar metal instruments and disassemble all instruments. Fully immerse and soak all instruments in enzymatic cleaner for 15 minutes. Fill all cannulations with enzymatic detergent. Use a small soft-bristle brush to remove visible soil from all surfaces of the instrument while fully immersed in the solution paying special attention to remove soil from hinges, jaws, tips, box locks, and ratchets. Agitate the instruments in the solution while scrubbing. Never use steel wool, wire brushes, or highly abrasive detergents or cleaners to remove soil from instruments. Actuate any movable parts to loosen any trapped soil. Rinse instruments under warm (38-49°C) running water until all evidence of detergent is removed. Place the instrument into a bath containing warm (38-49°C) water. Agitate the instruments by hand for at least three minutes. All

cannulations must be fully flushed until rinse water runs clear. If there is any visual contamination, repeat the steps as necessary until the instruments are visually clean. Prepare an enzymatic cleaning solution to the manufacturer's specifications using distilled water. Ultrasonicate devices for 10 minutes, ensuring the devices are completely submerged. Rinse instruments under warm running water for at least one minute or until all evidence of detergent is removed. All cannulations must be fully flushed until rinse water runs clear. If there is any visual contamination, repeat the steps as necessary until the instruments are visually clean. Dry with clean lint-free cloth and/or allow to air dry.

Automated Cleaning:

Automated cleaning should be performed after manual removal of debris using the manual cleaning process identified above.

The washer/disinfector manufacturer's instructions should be strictly adhered to. Use only cleaning agents recommended for the specific type of automated washer/disinfector. A washer/disinfector with the approved efficacy (e.g., FDA approval, complying with and validated according to the ISO 15883 series) should be used.

Place the instruments in a suitable washer/disinfector basket and process following the minimum recommended wash cycle parameters below:

Cycle	Description
1	Prewash- Cold tap water- 2 minutes
2	Enzymatic wash – Hot tap water - 43C min, 5 minutes using enzymatic detergent
3	Detergent wash - Hot tap water – 55C min- 5 minutes using neutral detergent
4	Rinse 1 - Hot tap water - 2 minutes
5	Rinse 2 - Pure water - 90C- 1 minute
6	Dry – Hot air – 90C- 15 minutes

Sterilization:

The Kalitec Navigated Instrument System instruments are provided non-sterile. All instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using the process parameters below:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-vacuum	270°F (132°C)	4 minutes	30 minutes

Note: *Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g., temperatures, times) used for their equipment.*

Wrap tray with a towel placed between tray and FDA cleared wrap.

The Sterility Assurance Level (SAL) is 1×10^{-6}, via the indicated methods. No claims of pyrogenicity are made.

Always immediately re-sterilize all instruments used in surgery. This process must be performed before handling or returning to Kalitec Medical.

Product Complaints:

Any Health Care Professional who has any complaints or who has experienced any dissatisfaction relating to the product quality, durability, reliability, safety, effectiveness and/or performance, should notify Kalitec Medical or its representative.

If any Kalitec Medical product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the distributor or Kalitec Medical should be notified immediately by telephone or in writing.

For all complaints, please include the device name, reference number, and lot number of the component(s), your name, address, and the nature of the event to help Kalitec Medical understand the cause of the complaint.

Further Information:

If further information is needed or required, please contact:

Kalitec Medical

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