

Package Insert**Device Description**

The Zavation Navigated Instrument System is comprised of subsets NON-STERILE of instruments intended to be used with the StealthStation™ Navigation System by Medtronic Navigation, Inc. “Medtronic Navigation” and NavLock® Tracker to assist surgeons in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures for preparation and placement of pedicle screw or OCT system implants. Refer to the Medtronic StealthStation System Manual and/or Navigation Operative Technique for additional details regarding system use. Subject instruments are intended for use only with Zavation pedicle or OCT screws.

This Supplemental Instructions for Use (IFU) contains only information regarding the Zavation Navigated Instruments. For pedicle screw or posterior cervical screw system Contraindications, Warnings, Precautions, and Possible Adverse Effects, please refer to the appropriate Zavation Screw System IFU.

Indications

Zavation Navigated Instrument System are indicated for use during the placement of Zavation Spine screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. Zavation 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 vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy. Use of Zavation Navigated Instrument System is limited to use only with Zavation Spinal System and Zavation Z-Link_{PC}™ System.

Please refer to the following Instructions for Use (IFU) and Surgical Techniques for complete system guides, descriptions, indications and warnings:

- Zavation Spinal System
 - Zavation Modular Screw System
 - Zavation Tiger 2° System
- Zavation Z-Link_{PC} Cervical System
- Medtronic StealthStation Navigation System

Materials:

The Zavation Navigated Instrument System patient contacting materials is Stainless Steel.

Precautions:

The **Zavation 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:

There are no specific contraindications associated with the Zavation Navigated Instrument System.

Warnings:

Zavation does not warrant Medtronic Navigation Software. It is the sole responsibility of the user to ensure instrument calibration and/or registration.

1. The use of Zavation’s Navigated Instrument System should only be used with the indicated spinal screw systems.
2. Users must complete verification steps as required per the Medtronic Navigation Operative Technique.

3. 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 comparing the actual tip location to that displayed by the system.
4. In the event of a registration failure or suspected inaccuracy, Zavation 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/Intraoperative Management:

- Inspect all instruments before use. If visibly damaged, do not use the instrument.
- The Zavation Navigated Instruments are designed to be used with the NavLock Instrument Set and StealthStation Spine Referencing Set. Other sets and disposables can be utilized at the discretion of the surgeon and should follow the manufacturer's instructions for use accordingly.
- Instruments designed for use with the StealthStation System have a precise instrument geometry and LED/Sphere configuration. The specific geometry of each instrument is stored in a file to which the computer refers to determine where the tip of the instrument is located in relation to the instruments LEDs or spheres. Before beginning navigation, the computer must be told which instrument has been chosen.
- When selecting the instrument from the list in the application software, the system will expect verification that the chosen instrument is not bent or otherwise damaged. To do this, place the tip of the instrument into a metal divot on the reference frame (e.g. StealthAIR Spine Frame). The camera and computer will then confirm that the instrument in use matches the specifications for the instrument selected in the software.
- Users must complete verification steps as required per the Medtronic StealthStation System Manual and/or Navigation Operative Technique.
- To maintain accuracy, the system must continuously track the position of the anatomy during registration and navigation. This is necessary because anatomy or the localizer may accidentally or unavoidably be moved after patient registration or image acquisition. If the system did not track the position of the anatomy via the patient reference frame, any movement of the patient or localizer after registration or image acquisition would result in inaccurate navigation.
- During surgery, the system tracks the position of specialized surgical instruments in or on the patient anatomy and continuously updates the instrument position on these images.
- The system continuously re-computes the relative spatial positions of the patient reference frame and instrument in the navigation field and relates this information to the patient registration data in order to identify the location of the instrument on the operative images.
- Surgical accuracy should be assessed repeatedly throughout a procedure when using a surgical navigation system by positioning the navigated instrument tip on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system. In the event of a registration failure or suspected inaccuracy, the instrument should not be used continuing with a replacement instrument or non-navigated procedure.

Postoperative:

- Detailed instructions should be given to the patient regarding care and limitations, if any.
- To achieve maximum results, the patient should not be exposed to excessive mechanical vibrations. The patient should not smoke or consume alcohol during the healing process.
- The patient should be advised of their limitations and taught to compensate for this permanent physical restriction in body motion.
- If a non-union develops, or if the components loosen, the devices should be revised or removed before serious injury occurs. Failure to immobilize the non-union, or a delay in such, will result in excessive and

repeated stresses on the implant. It is important that immobilization of the spinal segment be maintained until fusion has occurred.

-Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

Pre-Cleaning/Cleaning and Sterilization Procedure Recommended for Reusable Instruments (and Trays):

For safety reasons, reusable instruments must be pre-cleaned, cleaned and sterilized before use.

Moreover, for good maintenance, reusable instruments must be pre-cleaned, cleaned and sterilized immediately after surgery following the sequence of steps described in the following table.

Sterilization trays should be thoroughly cleaned using either the Automated or Manual procedure that is detailed below for instruments. It is acceptable to skip the ultrasonic cleaner step for the sterilization trays as long as the inspection criteria provided below are acceptable for the tray.

Cautions: Long, narrow cannulations and blind holes require particular attention during cleaning.	
Limitations on reprocessing: Repeated processing has minimal effect on these instruments. End of life is determined by wear and damage due to use confirmed by visual inspection of each instrument.	
1-Point of use: Remove all visual soil with disposable cloth/paper wipe. Soiled instruments must be kept moist to prevent soil from drying. If the instruments cannot be soaked immediately place a moist towel around them until they can be cleaned.	
2-Containment and transportation: Avoid damage and minimize time before cleaning.	
3-Preparation for cleaning: Ensure that all instruments have been disassembled and placed in their dedicated locations in the sterilization tray after cleaning. Remove any handles attached to instruments. Remove Navigation array from designated instrument (Driver, Tap, or Probe).	
4 Thoroughly clean instruments per one of the following (Manual or Automated)	
Manual	Automated
4.1 Pre-Cleaning-Manual: • Prepare a pH neutral, enzymatic detergent soak per the instructions of the enzymatic solution manufacturer. • Soak the instrument for a minimum of 15 minutes. Actuate any mechanisms and slide moving parts to the extreme positions to ensure the cleaning solution contacts all the surfaces. • Change the soak solution if the solution becomes visibly soiled. • While still in the soak solution, use a soft brush to remove all exterior soil. Thoroughly scrub any grooves, slots, threads, teeth, ratchets, or hinges. Use an appropriate size cleaning brush to thoroughly brush the entire length of any internal lumens a minimum of five times per lumen. • Rinse instruments thoroughly with warm (approximately 35-40°C) critical water, such as reverse osmosis, distilled, and/or deionized water, taking care to flush all lumens or crevices, for at least one minute, until water runs clear. Use a tubing attachment to the water outlet in order to	4.1 Pre-Cleaning-Automated: Automated washing shall be conducted in a validated washer-disinfector. Refer to labeling of automated washer for detailed instructions of use. An example of a validated cycle used for cleaning validation includes: • Wash 45°C 4 minutes (with detergent recommended by washer-disinfector) dose pump 4 (detergent) 5mL • Wash 60°C 3 minutes • Rinse with unheated critical water, such as reverse osmosis, distilled, and/or deionized water for 1 minute • Rinse 60°C 1 minute

direct the rinse flow into any lumens, crevices, grooves, or slots and flush them completely until water runs clear.	
4.2 Cleaning-Manual: • Prepare a fresh pH neutral enzymatic cleaning solution and sonicate the instruments and subassemblies for a minimum of 15 minutes in an ultrasonic bath. After sonication, rinse instruments again under running critical water, such as reverse osmosis, distilled, and/or deionized water for a least one minute until water runs clear. Use a tubing attachment to the water outlet in order to direct the rinse flow into any lumens, crevices, grooves, or slots and flush them completely until the water runs clear. • Dry the exterior of the instruments with a clean, soft cloth. Use clean compressed air or 70% isopropyl alcohol to dry any lumens or crevices where water may become trapped.	4.2 Washer Disinfect: Automated washing shall be conducted in a validated washer-disinfecter. Refer to labeling of automated washer for detailed instructions of use. An example of a validated cycle used for cleaning validation includes: • Thermal Disinfection A₀ 93°C • A₀ value: A₀3000 • Dry 123°C air 14 minutes
Inspection: • Visually inspect each disassembled device to ensure all visible blood and soil has been removed. If not visually clean repeat step 4 above until clean or appropriately dispose of device if unable to get visually clean. • Visually Check disassembled instruments with long slender features for distortion. • Visually Inspect the disassembled devices for any cracking, pitting, or other signs of deterioration. • If distortion or any signs of deterioration are found, discontinue use, return device to Zavation, and request a replacement device from Zavation Medical Products, LLC.	
Packaging: Instruments are loaded into dedicated instrument trays. Wrap the trays using appropriate FDA cleared wrap.	
Sterilization: See sterilization procedure	
Storage: Control environment	
Additional information: When sterilizing multiple instruments/trays in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded. Before next use, to reassemble inserter, thread inserter stylus down central shaft of inserter until stop is reached. To reassemble removable handles, pull back outer metal sleeve on handle, place desired instrument (tap or drill) in open slot and slide outer sleeve back over to original position to lock instrument in place.	
Manufacturer contact: Contact local representative or call customer service at 601-919-1119	

Sterilization: The Zavation Navigated Instrument System should be sterilized by the hospital using the recommended cycle:

Do not stack trays in the chamber.

Method	Cycle	Temperature	Exposure Time	Drying Times
Steam	Gravity	270°F (132°C)	15 Minutes	15 Minutes
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes	30 Minutes



Product Complaints: Any Healthcare Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Zavation Medical Products LLC, 3670 Flowood Drive, Flowood, MS 39232, USA, Telephone: 601-919-1119.

Further Information: A recommended surgical technique for the use of this system is available upon request from Zavation Medical Products LLC, 3670 Flowood Drive, Flowood, MS 39232, USA, Telephone: 601-919-1119.

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



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Signatory Table

Action Name	User Name	Title	Signature Date
Send for Review (Written By)	FELICIA SMITH	VP OF QUALITY	04-Feb-2025 16:15
Send for Required Approval(s)	STEPHEN C. GORDON	CHIEF QUALITY OFFICER	06-Feb-2025 19:34
Approve	STEPHEN C. GORDON	CHIEF QUALITY OFFICER	06-Feb-2025 19:34
QA Approval	STEPHEN C. GORDON	CHIEF QUALITY OFFICER	06-Feb-2025 19:35
Scheduled Release	FELICIA SMITH	VP OF QUALITY	13-Feb-2025 11:24

* Dates are displayed according to the system time zone: (GMT-06:00) Central Standard Time (America/Chicago)