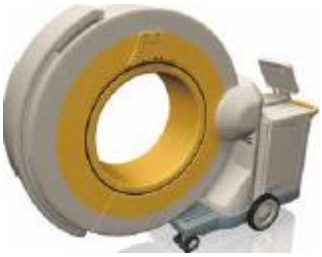
BLACK DIAMOND™
BY OSSEUS™

Navigation Instruments
Surgical Technique Guide

TECHNOLOGY OVERVIEW

O-arm® Image Acquisition System



Mobile Viewing Station

Staff Cart with Camera & Surgeon Monitor

INSTRUMENTS AND EQUIPMENT

StealthStation® Spine Referencing Set (9734495)

StealthStation® NavLock Instrument Set (9734833)

Spheres (8801074)

INSTRUMENTS & EQUIPMENT

Osseus Instrument Part Number	Osseus Instrument Description	Corresponding Medtronic StealthStation® Tool Card
1010-1002N	Black Diamond Straight Sharp Probe	Thoracic Probe
1010-1003N	Black Diamond Straight Blunt Probe	Thoracic Probe
1010-1022N	Black Diamond Open Pedicle Screw Inserter	Solera 5.5/6.0 Driver
1010-1016N	Black Diamond Ø4.5mm Open Tap	Solera Ø4.5mm Tap
1010-1017N	Black Diamond Ø5.5mm Open Tap	Solera Ø5.5mm Tap
1010-1018N	Black Diamond Ø6.5mm Open Tap	Solera Ø6.5mm Tap
1010-1019N	Black Diamond Ø7.5mm Open Tap	Solera Ø7.5mm Tap
1010-1020N	Black Diamond Ø8.5mm Open Tap	Solera Ø8.5mm Tap
1010-1041N	Black Diamond MIS Pedicle Screw Inserter	Voyager 5.5/6.0 Driver OR Solera Cannulated 5.5/6.0 Driver
1010-1006N	Black Diamond Ø5.5mm MIS Tap	Voyager Ø5.5mm Tap OR Solera Cannulated Ø5.5mm Tap
1010-1007N	Black Diamond Ø6.5mm MIS Tap	Voyager Ø6.5mm Tap OR Solera Cannulated Ø6.5mm Tap
1010-1008N	Black Diamond Ø7.5mm MIS Tap	Voyager Ø7.5mm Tap OR Solera Cannulated Ø7.5mm Tap
1010-1009N	Black Diamond Ø8.5mm MIS Tap	Voyager Ø8.5mm Tap OR Solera Cannulated Ø8.5mm Tap

EQUIPMENT AND ROOM SET-UP

For navigated surgery the OR should be equipped with the O-arm® Image Acquisition System, the Mobile Viewing Station (MVS), and the StealthStation® System (Figure 1a). Plug the MVS into a power source; connect the MVS to the O-arm® System, and power on the system. Next, power on the StealthStation® System and start the Synergy® Spine Software. Connect the MVS to the StealthStation® System network port with a network cable or a crossover cable.

The equipment set-up for Navigated Posterior Fixation Procedure
has the StealthStation® Staff Cart with Camera positioned near the patient's feet.

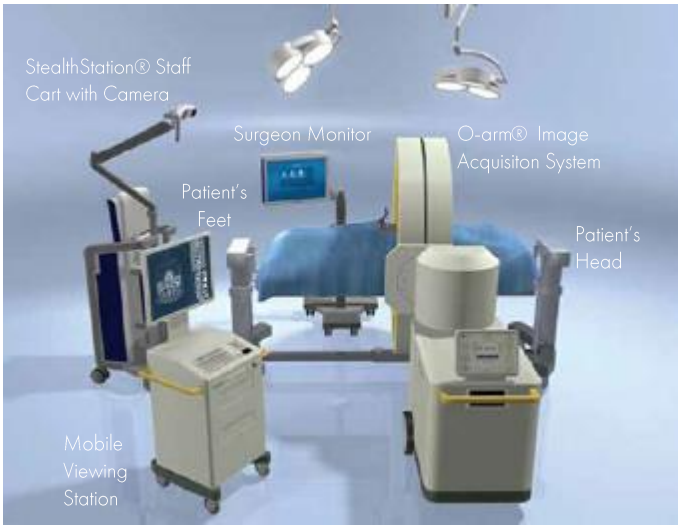


Figure 1a

When positioning the O-arm® System for the procedure, place it around the patient and translate it toward the area of the anatomy to be imaged, keeping in mind if the it is to remain in the sterile field throughout the procedure, the gantry can be "parked" (wagged, tilted, and translated) to allow the surgeon unobstructed access to the surgical site (Figures 1b, 1c, 1d, and 1e).

Figure 1b

Figure 1c

The camera should be positioned so that the camera has an unobstructed line-of-sight to the Reference Frame which will be placed into the patient. Position the surgeon's monitor near the patient's side, opposite from the surgeon.

Figure 1d

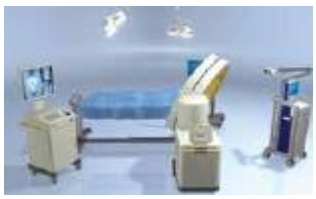


Figure 1e

Place the patient in the prone position, lying flat on a Jackson Spine top table or a Jackson table with the Wilson frame.

EQUIPMENT AND ROOM SET-UP

In the Synergy® Spine Software, complete the "Select Surgeon" and then "Select Procedure" tasks. Continue through the software by completing the "Set-Up Equipment" and "Verify Instruments" tasks to reach the "Acquire Scan" screen.

Synergy® Spine Software Workflow

1. Select surgeon

2. Select Procedure
Select the procedure type by selecting the imaging modality: O-arm® Imaging, Optical Tracking.

3. Set up Equipment
Ensure that all lines to essential equipment are green. If lines are dashed orange, check connections/cables.

4. Verify Instruments
Check that the toolcards for all navigated instruments needed for the procedure are shown on this screen. Instruments can be verified now or at a

5. Acquire Scan
The system will remain on this screen until the O-arm® System image acquisition step has been performed.

INSTRUMENT VERIFICATION

Attach the Spheres to a blue Reference Frame from the Spine Referencing Set and the NavLock® Trackers from the NavLock® Set. Check the Spheres to ensure they are secure. Next, attach the NavLock® Trackers to the instruments.

Place each instrument tip into the divot in the blue Reference Frame and hold perpendicular (Figure 2a) and visible to the camera until a confirmation color is seen. Use the tracking view in the lower right of the screen to ensure the camera is tracking the Reference Frame and instrument correctly (Figure 2b).

- Successful verification is indicated by a chime and a transaction to green on the instrument toolcard.
- Failed verification is indicated by a "bonk" sound and indicates that the instrument may be positioned improperly in the divot or is bent/damaged. Inspect the instrument; if it is bent/damaged, do not use.
- If no sound is heard when the instrument is touched to the divot, this may indicate that the camera cannot see either the instrument or the frame.

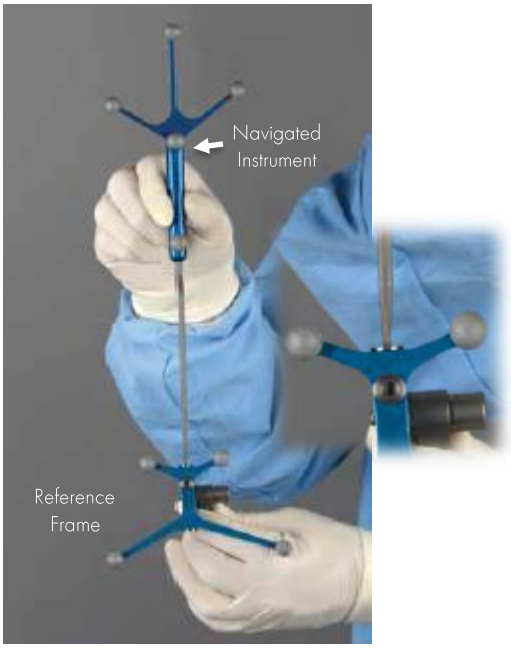


Figure 2a

Figure 2b

Helpful Hint:
Assigning an instrument to a specific-colored NavLock® Tracker will eliminate the need to switch the tracker from one instrument to the next throughout the procedure. As an example, the grey tracker could be assigned to the tap and the orange tracker could be assigned to the driver.

Helpful Hint:
OR Staff can verify instruments before the surgeon enters prior to reference frame placement.

PATIENT PREPARATION

Reference Frame Placement

When performing Navigated Posterior Fixation Procedure use of the Percutaneous Reference Pin with the Percutaneous Reference Frame is recommended. Pins are available in 100mm and 150mm lengths. For L5-S1 procedures, the surgeon should consider medializing the pin to avoid line of sight obstructions between the camera and the navigated instruments.
The preferred method, places the pin down the posterior superior iliac spine (PSIS) much like the trajectory of an iliac screw, which drops the reference frame out of the way and does not pose potential line-of-sight obstacles between the camera and the screw placement (Figure 3a). This option is described below.
Using palpation, locate the PSIS on the patient. Mark the skin a little medial and inferior to the PSIS to verify the appropriate location to place the pin.
Make a stab incision and locate the Cannula with the Dilator over the PSIS. Place the Dilator/Cannula into the incision through the tissue until it contacts bone.

Figure 3a

Helpful Hint:
To keep the frame close to the patient and out of the way of surgical instruments, use the 100mm Percutaneous Reference Pin, if possible.

Important Note:
Ensure the Reference Frame is properly secured to anatomy. Neglecting to verify that the Reference Frame is secured could result in navigational inaccuracy if the hardware moves in relation to the anatomy after registration is complete.

Once docked, the Dilator/Cannula assembly is tapped with a mallet to make an indentation in the bone for the pin. While holding the Cannula in place remove the Dilator and insert the pin through the Cannula. Place the Tap Cap on the pin and rotate the cap so the arrow on the Tap Cap points toward the camera. Orient the Pin/Tap Cap assembly approximately 30° toward the midline of the patient and then angle it 30° toward the foot of the patient.
Use an impactor to drive the pin into the bone until the Tap Cap contacts the top of the Cannula (Figure 3b). Remove the Tap Cap from the pin and attach the Percutaneous Reference Frame to the pin (Figure 3c).
Alternatively, the Spinous Process Clamp with the Small Passive Reference Frame can also be used. The clamp should be firmly attached to the spinous process inferior or superior to the planned instrumented levels. With the camera positioned at the patient's feet, the clamp should be within an unobstructed view of the camera and the instruments.

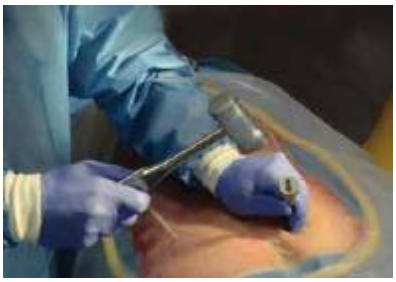


Figure 3b

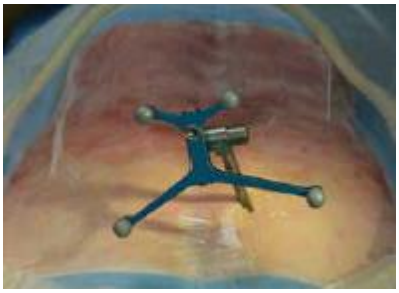


Figure 3c

IMAGE ACQUISITION

At any time when fluoroscopy is used (2D or 3D acquisition) all personnel who are not wearing protective lead apparel should stand at least 15 feet (457.2cm) from the O-arm® System with a certified moveable lead shield between themselves and the O-arm® System to avoid unnecessary radiation exposure (Figure 4).

Establish the surgery site using 2D fluoroscopy scout images as needed. On the control panel, select the patient size, anatomy, and orientation.

With the patient isocenter, position the O-arm® System gantry to perform a 3D spin. Following the 3D spin, the images are transferred automatically to the StealthStation® System. Should 2D images or a second 3D spin be desired, four preset O-arm® System gantry positions may be set up and saved. Once the images are transferred, the O-arm® System can be moved out of the way and into the park position.

O-arm® System Isodose Curve

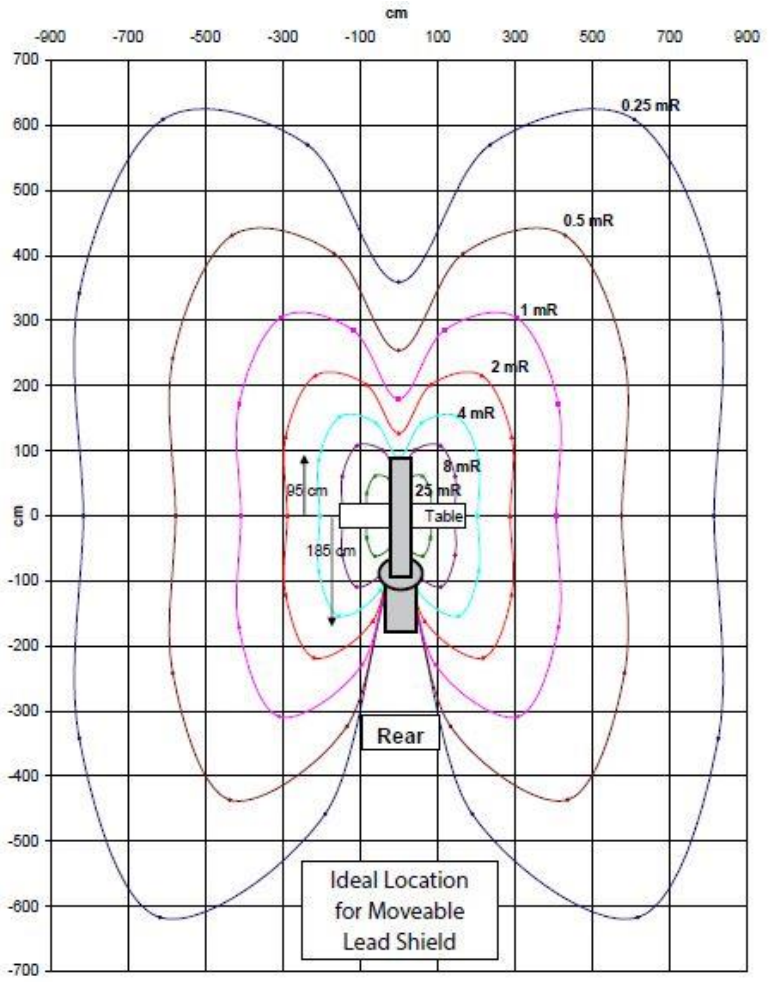


Figure 4a

Scatter plot showing the shape of isodose curves for the maximum technique factors
-Protocol: Abdomen HD3D XL
-Technique: 120 kVp, 600 mAs

CONFIRMATION IMAGE ACQUISITION

Black Diamond Pedicle Screw System Surgical Technique Guide

For more information about using the Black Diamond Open and MIS Pedicle Screw Systems, please reference supplemental surgical technique guides.

Confirmation Image Acquisition

The Reference Frame should be left in place during the confirmation image acquisition to ensure that navigation can still be performed if any changes are required.

With the patient isocenter, position the O-arm® System to perform a 3D image acquisition (Figure 6a). During the acquisition process all personnel who are not wearing protective lead apparel should stand at least 15 feet from the O-arm® System with a certified moveable lead shield between themselves and the O-arm® System to avoid unnecessary radiation exposure. Perform the image acquisition to confirm construct placement (Figure 6b). Following confirmation, the Reference Frame should be removed.

Figure 6a

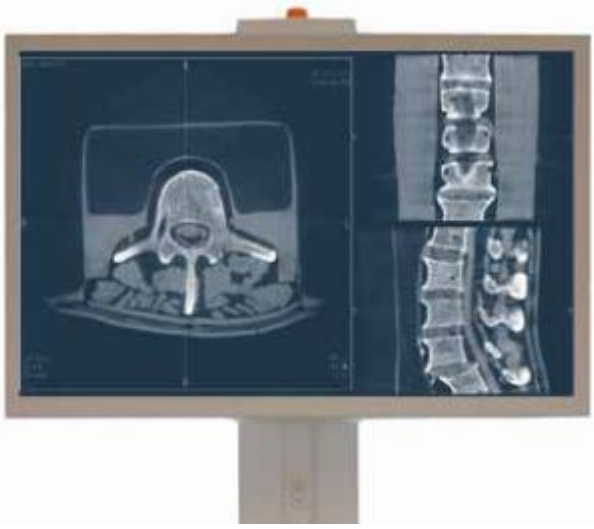


Figure 6b

Osseus Black Diamond Pedicle Screw System Navigation Instruments

1931 Greenville Ave., Ste 200
Dallas, TX 75206
(888) 330-5960

CAUTION: USA law restricts this device to sale by or on the order of physician.

DESCRIPTION

The Black Diamond Navigation Instruments are manual, reusable surgical instruments for use with the Medtronic® StealthStation™ Navigation System 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.

The Black Diamond Navigation Instruments include the following: Drivers, Taps, and Probes.

The Black Diamond Navigation Instruments are to be used with the following Osseus Fusion System:

- Black Diamond Open Pedicle Screw System
- Black Diamond MIS Pedicle Screw System

The Osseus navigated instruments are designed for use only with Medtronic StealthStation Navigation System hardware and software.

The Black Diamond Navigation Instruments are NOT compatible with implants from other manufacturers.

MATERIALS

Stainless Steel

INDICATIONS

The Black Diamond Navigation Instruments are intended to be used during the preparation and placement of Black Diamond pedicle screws during spinal surgery to aid the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Black Diamond Navigation Instruments are specifically designed for use with the Medtronic Stealth Station System, 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 vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

CLEANING/DISINFECTION

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Osseus Fusion Systems LLC. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must 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 other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel. Use a cleaning brush and/or cloth to remove visible soil.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them carefully with warm (30°C to 40°C) tap water a minimum of 30 seconds until no visible soil remains.
9. Visually inspect devices. Repeat pre-cleaning procedure until no visible soil remains.
10. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
11. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
12. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
13. Dry instruments using a clean soft cloth and filtered pressurized air.
14. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.
15. For difficult to view design features, such as cannulation, apply 3% hydrogen peroxide. Bubbling is indicative of the presence of blood.

Note: Rinse the instruments thoroughly with warm water following hydrogen eroxide testing. Repeat cleaning if not visibly clean and re-inspect.

For devices with challenging design features (cannulations, handle interfaces, hinged instruments, instruments with crevices):

1. Immerse instrument and soak for a minimum of five (5) minutes in enzymatic detergent.
2. Use cleaning brushes/pipe cleaners to remove additional soil from challenging design features and areas of high exposure, accumulation, or retention of soil such as: cannulations, handle/ chuck interfaces, hinged instruments, or instruments with crevices.
   a. Scrub interfaces several times using a twisting action if possible. If components of the instrument can be retracted or moved, it is necessary to retract or open the part in order to access and clean these areas.
   b. Scrub inside cannulas/holes with a tight-fitting brush or pipe cleaner using a twisting action. The brush or pipe cleaner should be of an appropriate size to ensure that full depth of the feature is reached.
   c. Scrub around hinged/mating surface areas with a brush or pipe cleaner.
   d. Scrub all crevices, such as those found around color bands, using a cleaning brush or pipe cleaner.
3. Sonicate instrument in its fully opened position for a minimum of 15 minutes in an ultrasonic cleaner containing warm enzymatic detergent.
4. Rinse thoroughly with warm water, making sure to irrigate the challenging design features. If the components of the instrument are moveable or can be retracted, it is necessary to retract or open the part for thorough rinsing at these locations. Blind holes should be repeatedly filled and emptied.
5. Check instruments for visible soil (see "Verifying Cleaning"). Repeat cleaning if soil is visible.

Verifying cleaning:

1. After thoroughly cleaning, visually inspect devices under normal lighting for the removal of visible soil.
2. For difficult to view design features, apply 3% hydrogen peroxide. Bubbling is indicative of the presence ofblood.
   Note: **Rinse the instruments thoroughly with warm water following hydrogen peroxide testing.**
3. Repeat cleaning if not visibly clean and re-inspect.

Inspection and function testing:

Device/ Feature	Flaw
All reusable devices	Visually inspect for damage or wear.
Hinged instruments	Check for smooth movement of hinge without excessive "play."
Locking mechanisms	Check for action.
Cutting features	Check edges for distortion/large nicks. Edges should be continuous.
Trials	Articular surfaces should be smooth and free of cracks and deep nicks.
Mating parts	Check to make sure that mating parts fit together without complications.
Reamer/drill bits	Inspect "chuck" end for burrs and distortion that might hinder insertion into a drill.
Hammering surfaces	Inspect for burrs and large nicks.
Driving instruments	Inspect plastic ends for cracks and large nicks.
Metal surfaces	Inspect for corrosion and major deformation.

Maintenance:

- For devices with hinged/mating surfaces, surgical-grade lubricant should be added to the hinged area while in the open position.
- If the any of instruments exhibit any of the flaws listed above adequately dispose of the devices.

STERILIZATION

The Osseus Black Diamond Navigation Instruments are supplied clean and not sterile. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that are designed for the selected sterilization cycle specifications (time and temperature). When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Osseus Fusion System LLC's devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 $inch^2$ total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

In a properly functioning calibrated steam sterilizer effective sterilization may be achieved using the following parameters:

Cycle:	Pre-Vacuum
Temperature:	132° C (270°F)
Full Cycle Time:	4 Minutes
Minimum Dry Time:	40 Minutes
Condition:	Wrapped
Wrap:	The wrap should be FDA cleared for the proposed cycle specifications

CONTRAINDICATIONS

Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices. Active system infection or infection localized to the site of the proposed implantation is contraindications to implantation. Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus prevent the use of this or any other spinal instrumentation system. Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, or osteopenia is a relative contra indication. Other relative contraindications include obesity, certain degenerative diseases, and foreign

body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure. See also the WARNINGS, PRECAUTIONS AND POSSIBLE

The Black Diamond Navigation Instruments are indicated for spinal surgery and therefore are only appropriate for use with Medtronic StealthStation software packages. All other navigation software packages are contraindicated.

WARNINGS PRECAUTIONS AND POSSIBLE ADVERSE EFFECTS

Following are specific warnings and precautions that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general but are important considerations particular to implantation of internal fixation devices using navigation instruments. General surgical risks should be explained to the patient prior to surgery.

WARNINGS

1. Osseus Fusion Systems is not a navigation provider. The navigation instruments have been validated for use with a third-party navigation system, the Medtronic StealthStation. Instructions for use and handling of third-party navigation systems are the responsibility of the hospital and navigation company. Refer to the navigation company's software and user guides for calibration and navigation guidance.

2. The navigated instrument is a highly accurate and sensitive medical device. Handle it with extreme care. If you drop or otherwise damage it, verify its calibration accuracy. Failure to do so may lead to severe injury to the patient.

3. Care should be taken to limit bending forces on calibrated instruments as deflection can influence navigation accuracy.

4. Plan the setup of the OR and instrument array orientation prior to surgery. The navigation camera must have an unobstructed and simultaneous view of the instrument and navigation array.

5. The navigation system should be set up per the manufacturer's instructions.

6. Black Diamond instruments should only be used with Black Diamond implants. Do not try to use with other competitive devices.

7. Avoid application of excessive stress on surgical instrumentation.

8. Carefully read and follow any package insert which accompanies the implants to be used with this instrumentation.

9. Instruments must be cleaned and decontaminated before they are returned to the manufacturer for any reason.

CAUTION

Assess navigational accuracy repeatedly throughout a procedure when using a surgical navigation system.

Reconfirm accuracy by positioning the navigated instrument tip on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system.

If the stereotaxic navigation system does not appear to be accurate despite troubleshooting (e.g., resetting the system), do not rely on the navigation system.

DIRECTIONS FOR USE/DEVICE OPERATIONS

- Before clinical use, the physicians/surgeons should thoroughly understand all aspects of the system guide and the limitations of the instrumentation.
- It is recommended that physicians and operators should be thoroughly familiar with, and complete a training program of the navigation software, as well as supervised support sessions with a navigation software representative prior to any surgical procedure using the Black Diamond Navigation Instruments.
- When using the Osseus Black Diamond Open Pedicle Screw System with the Stealth Station, select the settings for the ***OPEN THORACOLUMBAR FUSION PROCEDURE***. Utilize Within this STEALTH setting:
    - Osseus Open Pedicle Screwdriver = select the SOLERA 5.5/6.0 DRIVER
    - Osseus straight probe = select the THORACIC PROBE
    - Osseus XXmm open tap = select the SOLERA TAPS
- When using the Osseus Black Diamond MIS Pedicle Screw System with the Stealth Station, select the OPEN ***THORACOLUMBAR PROCEDURE***. Utilize within this STEALTH setting:
    - Osseus MIS Pedicle Screw Inserter = select the MEDTRONIC VOYAGER MIS DRIVER OR the SOLERA 5.5/6.0 REDUCTION DRIVER
    - Osseus XXmm MIS tap = select the MEDTRONIC VOYAGER TAPS OR SOLERA 5.5/6.0 TAPS

Physicians should be thoroughly familiar with the Black Diamond Pedicle Screw System prior to using this system with the Black Diamond Navigation Instruments. Physicians and operators of the system should read the user guides carefully before handling the equipment and have access to the user guides at all times. Prior to using the Black Diamond Navigation Instruments, the physicians and operators should review the Black Diamond Pedicle Screw System surgical technique and navigation systems user guides (provided by navigation systems' manufacturers) for their indications for use.

Symbol	Used For	Symbol	Used For
	Single use only		Catalog number
	Lot number		Consult Instructions for Use
	See package insert for labeling limitations		Quantity
	Non-sterile. To be sterilized prior to use.		CAUTION: USA law restricts this device to sale by or on the order of physician.
	Manufacturer		