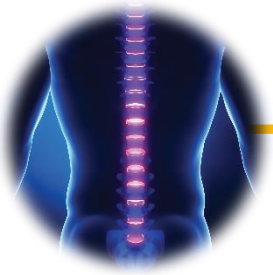
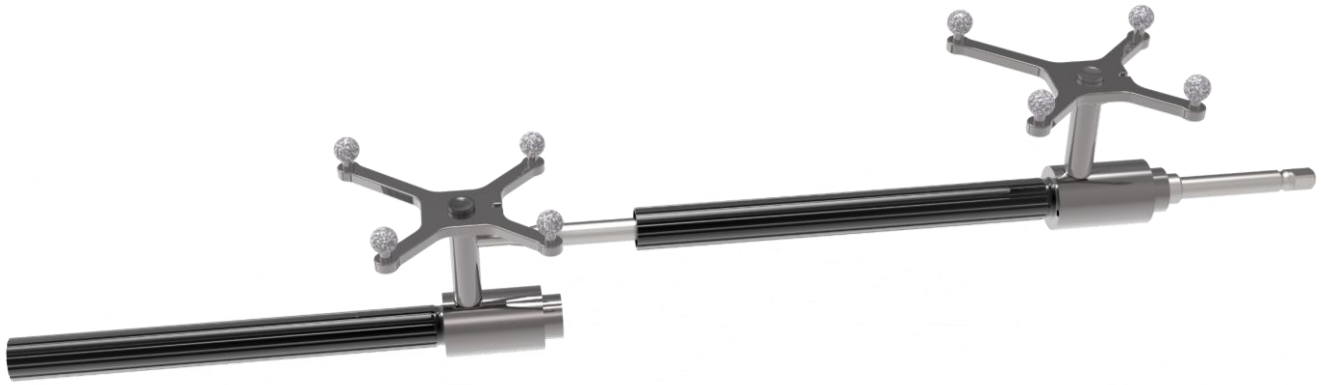


SURGICAL
TECHNIQUE

E-GPS
Navigated Instrument System

for use with

Reform *Ti* Pedicle Screw System
Reform *Ti* Modular Screw System
Reform *Ti HA* Pedicle Screw System
Reform *MC* Midline Cortical Screw System
Reform *Ti MIS CT Modular* Percutaneous Screw System



For manual calibrated use with the Globus Medical ExcelsiusGPS® Robotic Navigation Platform

PRECISION SPINE®
Discover the Difference

Made in the USA

TABLE OF CONTENTS

NAVIGATED INSTRUMENT SYSTEM OVERVIEW

INSTRUMENTS INTRODUCTION

This technique describes how to verify E-GPS Navigated Instruments to the Globus Medical ExcelsiusGPS® Robotic Navigation Platform. E-GPS Navigated Instruments are manual surgical instruments that may be used in conjunction with the Globus Medical ExcelsiusGPS® Robotic Navigation Platform. E-GPS Navigated Instrument compatibility with the Globus Medical Robotic Navigation Platform is facilitated by interface compatibility with Globus Medical Arrays.

E-GPS Navigated Instruments are only compatible with Globus Medical ExcelsiusGPS® Arrays. Reference the specific Precision Spine System surgical technique for system specific details (Reform® Ti, Reform Ti HA, Reform Ti Modular, Reform Ti MIS CT, and Reform MC Midline Cortical). Also reference Globus Medical ExcelsiusGPS® Robotic Navigation Platform software and user manuals/labeling for further details regarding system setup, usage, trouble shooting, warnings, precautions, indications for use, etc.

E-GPS Navigated Instruments were tested for compatibility utilizing the Globus Medical ExcelsiusGPS® Navigation Tap and Driver Arrays (Part Numbers 6143.2534, 6143.2535), and 15mm End Effector (Part Number 6143.2501) while utilizing the Spine Software Module (Part Number 999.893 Version 2021R1P1-_a6f196261e) for the ExcelsiusGPS® Robotic Navigation Platform.

IMPORTANT:

Precision Spine® E-GPS Navigated Instruments were successfully verified using ExcelsiusGPS® System. Precision Spine Inc. neither maintains nor controls changes to the hardware and software that is used to help navigate E-GPS Navigated Instruments. ***Each instrument needs to be successfully verified and landmark checks performed prior to navigation each time the system is used to confirm potential system changes have not impacted performance with E-GPS instrumentation. It is necessary to confirm that the navigated instrument depiction agrees with the instrument in use, and its location/orientation relative to bony landmarks are correct.*** Navigational accuracy of each navigated instrument should also be repeatedly reassessed throughout a procedure by positioning the instrument tip on known anatomical landmarks. If the navigation system does not appear to be accurate despite troubleshooting (e.g., resetting the system), do not rely on the navigation system. Reference Globus Medical's software and user guides for trouble shooting methods.

All navigated instruments, arrays, references, end effectors, and markers should be checked for signs of damage prior to use, and damaged parts should be sent back to the appropriate manufacturer for evaluation.

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

- Reform *Ti*
- Reform *Ti HA*
- Reform *Ti* Modular
- Reform *Ti MIS CT*
- Reform *MC Midline Cortical*
- E-GPS Navigated Instruments

PRECISION SPINE SCREW SYSTEMS OVERVIEW

Reform *Ti, Ti HA & Ti Modular* Pedicle Screw Systems

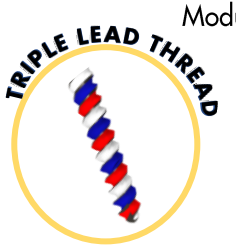
Non-Cannulated • Cannulated • HA • Modular Tulips

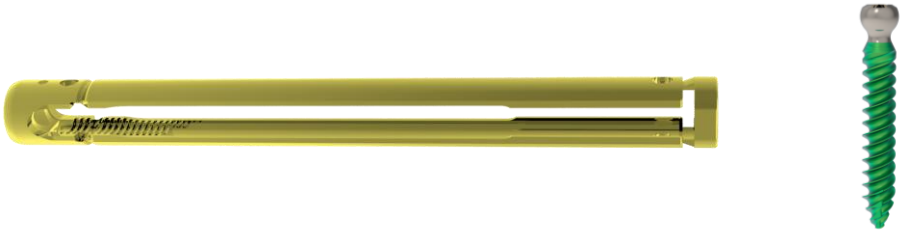
Reform *MC* Midline Cortical Screw System

Non-Cannulated • Cannulated • Modular 4.75mm & 5.5mm Tulips

Reform *Ti MIS CT* Modular Percutaneous Screw System

Modular Tulip & Bone Screws • Percutaneous Rod Insertion • Integrated Reduction





INSTRUMENTATION

Reform®/Reform Ti Taps, Cannulated **(Pending)** 75-RF-1555 to 75-RF-1595

Reform Ti Polyaxial Driver, Cannulated, T25 **(Pending)** 75-RT-1700
Reform Ti MIS CT Polyaxial Driver, Cannulated, T25 **(Pending)** 75-RT-1750

75-RT-1700: Reform Ti Polyaxial Driver

75-RT-1750: Reform Ti MIS CT Polyaxial Driver

Reform Ti/MC Modular Driver, Cannulated, T25 75-RT-1800

75-RT-1800: Modular Driver

Simulated Driver 75-SD-0700 (C3309)

75-RT-0700: Simulated Driver

Set Configuration(s) **Pending**

SURGICAL TECHNIQUE

1 PRELIMINARY SETUP

- Turn on ExcelsiusGPS®, confirm Excelsius Spine is loaded and the version on bottom right of the screen (Figure 1). Log in per the Screen immediately below.
    - If system version changes are observed, take the necessary steps to ensure safety.

Software Version:
2021R1P1-_a6f196261e
was used for verification

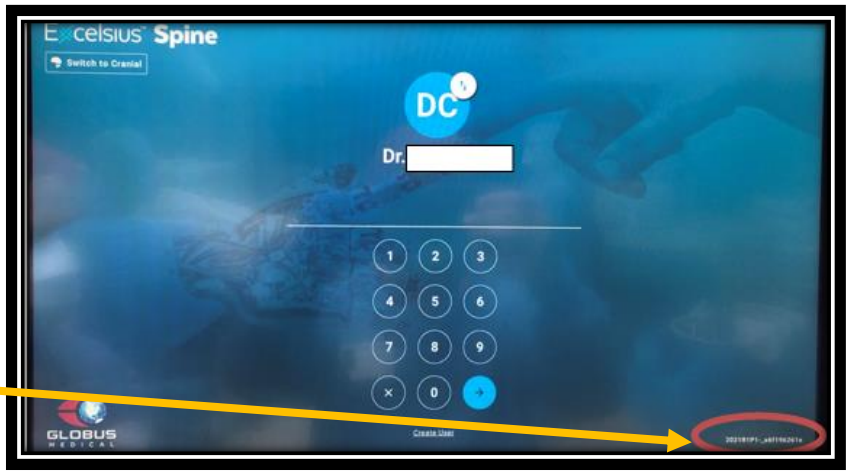


Figure 1

- In the "Workflow" screen, select the patient, initial Imaging (Pre-op, Intra-op, or Fluoro), the screw system (Select CREO MIS), the spine region (Thoracic, Lumbar, Sacroiliac) and Trajectories (instrumented levels) per the two screens (Figures 2 and 2a). Click the Right Arrow to advance to the "Verify" tab.
    - **DO NOT SELECT CERVICAL!**
      The Reform System is not indicated for Cervical use!

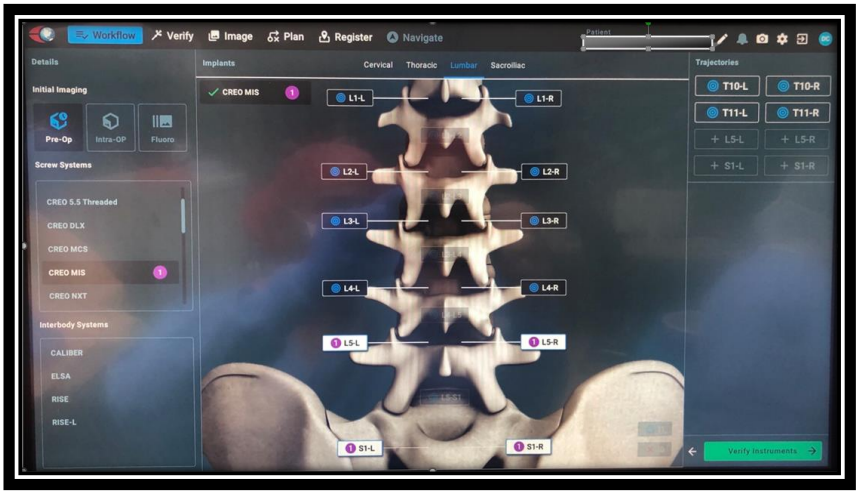


Figure 2

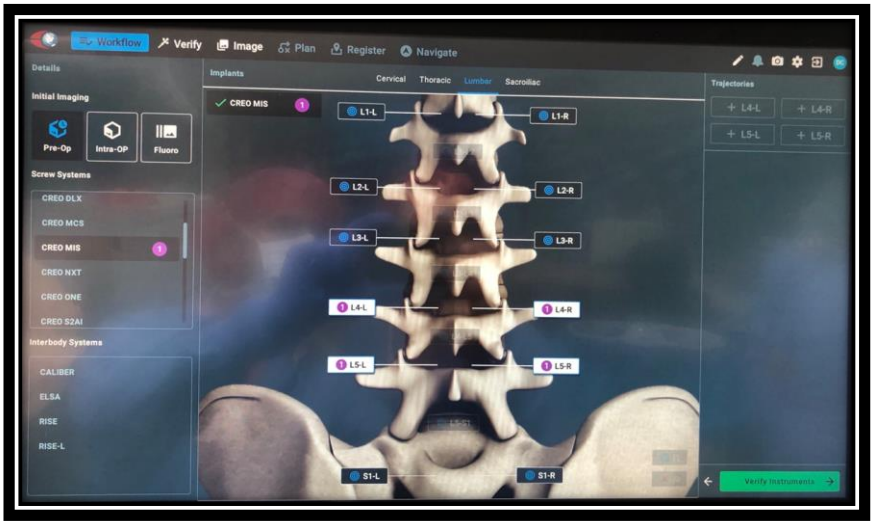


Figure 2a

6

SURGICAL TECHNIQUE

1 PRELIMINARY SETUP (continued)

- In the **VERIFY** screen, navigation details such as Visibility, Location and Instrument Verification Status are displayed. Navigation is only possible with Instruments that have been successfully Verified. In the image shown (Figure 3), all CREO MIS Crosshair symbols to the right of the Instrument descriptions are currently **GREYED** out, indicating no instruments have been verified at this point in the procedure.

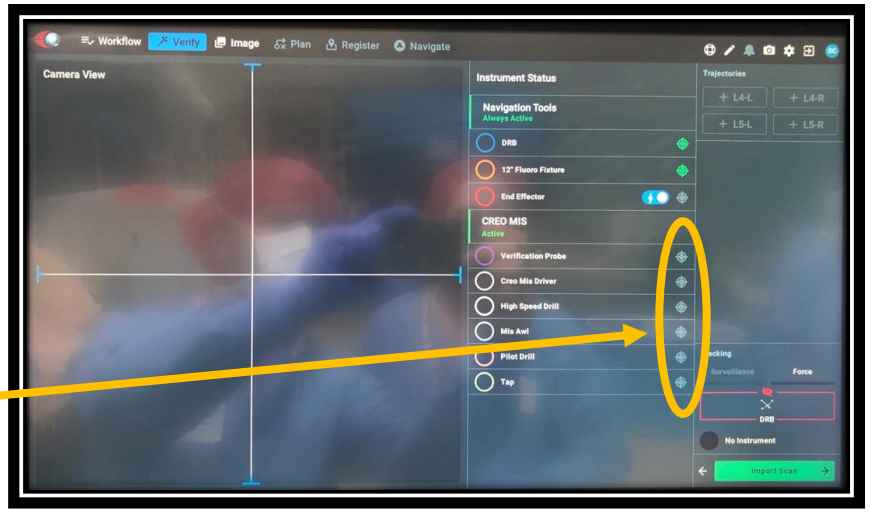


Figure 3

2 PRECISION SPINE E-GPS INSTRUMENT USAGE

- **Use of Precision Spine E-GPS Instruments under navigations requires that "CREO MIS" be selected as the Screw System being used and accomplishing successful Instrument Verification.**
- Instrument Verification consists of the following steps in sequence:
    - Assemble Instruments to their mating instrument Array and ensure that the arrays are fitted with markers. The chart (Figure 4) identifies the Arrays to be used with Precision Spine E-GPS Instruments. Images shown (Figures 5 & 6) depict instrument assembly.
- To remove any Instrument from the Array, press the Release button located on the Array.

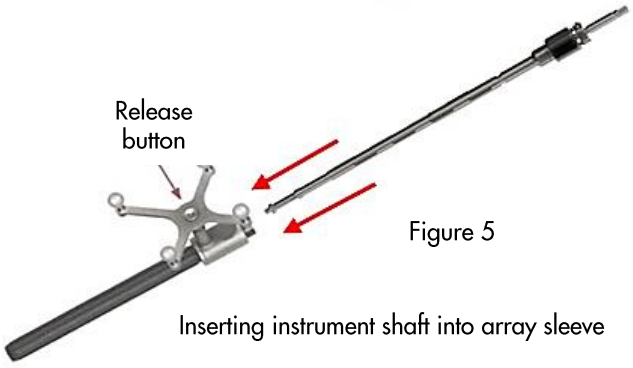


Figure 5

Inserting instrument shaft into array sleeve

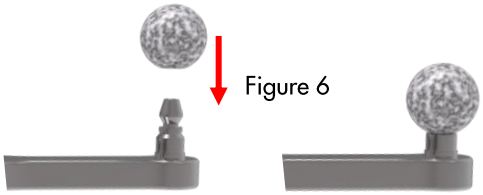


Figure 6

Marker attached to marker post

Part Number	Description	Corresponding Globus Medical Array
75-RF-1555 to 75-RF-1595	Reform Taps, Cannulated, 5.5mm to 9.5mm	Tap Array, 15mm Part Number 6143.2534
75-SD-0700	Simulated Driver	Driver Array, CREO MIS®, 15mm Part Number 6143.2536
75-RT-1700	Reform Ti Polyaxial Driver, Cannulated	
75-RT-1750	Reform Ti MIS Polyaxial Driver, Cannulated	
75-RT-1800	Reform Ti Modular Driver, Cannulated	

Figure 4

SURGICAL TECHNIQUE

2 PRECISION SPINE E-GPS INSTRUMENT USAGE (continued)

- Place the Instrument/Array assembly in the divot of another Array fitted with markers or in the divot of the 15mm End Effector (Figures 7 & 7a).

Figure 7

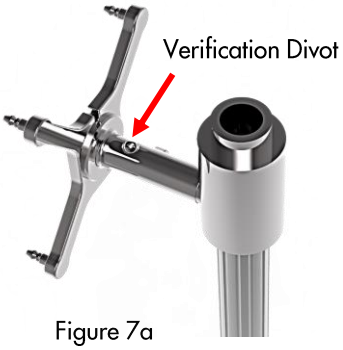


Figure 7a

- Hold the Instrument/Array stead and aligned with the other Array or End Effector. All components need to be visible to the camera. The ideal distance of the Instrument from the camera is approximately 2 meters (approximately 6 feet). Instrument/Array visibility to the camera is signified by the following:
    - A **SOLID FILLED CIRCLE** to the left of the instrument description indicates that the Instrument is **VISIBLE** to the camera (Figure 8).
    - A **HOLLOW CIRCLE** to the left of the Instrument description indicates that the Instrument is **NOT VISIBLE** to the camera

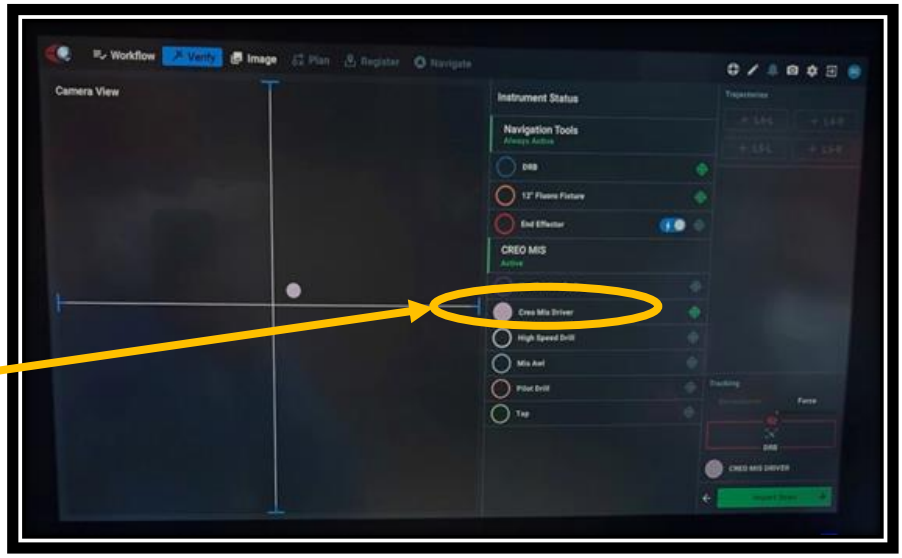


Figure 8

2 PRECISION SPINE E-GPS INSTRUMENT USAGE (continued)

- Instrument selection from the computer screen is NOT performed. Instead, the computer recognizes the instrument via the Array being used. If the correct Array is used with an Instrument of the correct length (Instrument tip to Array groove), and the Instrument is held steady and properly oriented in a mating divot within camera view, Instrument verification can be accomplished (Figure 9).
- Verified Instruments are signified by **GREEN** crosshairs to the right of the Instrument description. Arrows have been added to the screen shot (Figure 10) alongside the Precision Spine E-GPS Instruments to be verified. Figure 10 shows that the CREO MIS Driver has been verified and is ready for use while the Tap has yet to be verified as signified by the **GREY** crosshairs. Successful verification is only signified with a **GREEN** check mark circle.

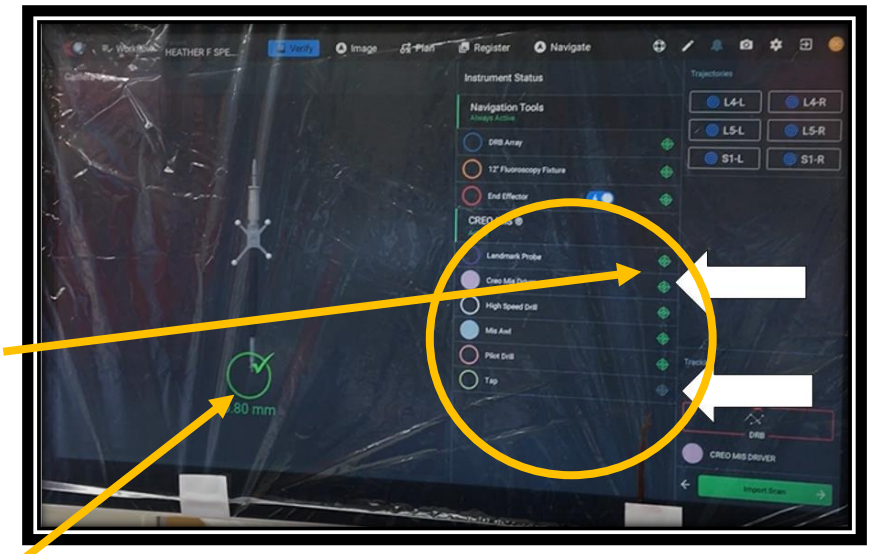


Figure 10

- Instruments need to be successfully verified to be navigated. If verification fails, repeat the verification process until it is successful, or proceed without the capability to navigate that Instrument. Failed verification is signified by a **RED** cross-lined circle (Figure 11).

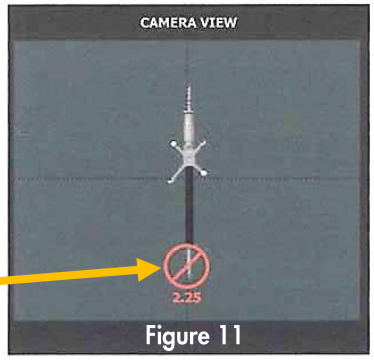


Figure 11

Verification failed

- E-GPS Instrument/Computer Verify Screen cross reference is indicated in the chart (Figure 12). When one of the drivers is verified, the CREO MIS Driver crosshairs should turn **GREEN** and when one of the Taps is verified, the Tap crosshairs symbols should turn **GREEN**.

E-GPS Instrument / Computer Verify Screen Cross Reference		
E-GPS Instruments		Computer Verify Screen: CREO MIS Instrument
Part Number(s)	Description	
75-RF-1555	E-GPS 5.5mm Cannulated Tap	Tap
75-RF-1565	E-GPS 6.5mm Cannulated Tap	
75-RF-1575	E-GPS 7.5mm Cannulated Tap	
75-RF-1585	E-GPS 8.5mm Cannulated Tap	
75-RF-1595	E-GPS 9.5mm Cannulated Tap	
75-SD-0700	Simulated Driver	Creo Mis Driver
75-RT-1700	Reform Ti Polyaxial Driver, Cannulated	
75-RT-1750	Reform Ti MIS Polyaxial Driver, Cannulated	
75-RT-1800	Reform Ti Modular Driver, Cannulated	

Figure 12

9

3 INSTRUMENT-SPECIFIC VERIFICATION GUIDELINES

Polyaxial Screw Drivers • Modular Screw Drivers

A Simulated Screw Driver is included in the set to aid in Verification of all E-GPS Screw Drivers. Verification methods follow:

SIMULATED DRIVER VERIFICATION

- Press the Release button on the Driver Array Sleeve and insert the Simulated Driver Shaft (P/N 75-SD-0700) into the Driver Array Sleeve until it "clicks" into place (Figure 13). Gently pull up on the Simulated Driver Shaft to confirm that it is locked in the Array Sleeve.

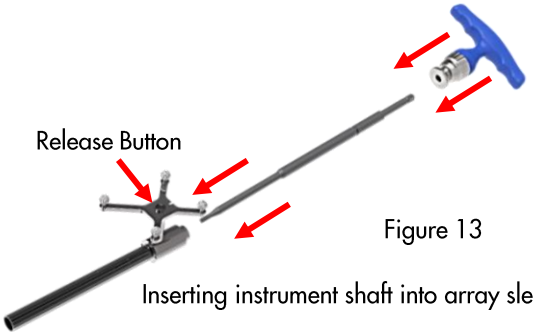


Figure 13

Inserting instrument shaft into array sleeve

- Securely attach the desired Handle to the proximal end of the Instrument Shaft (Figure 14). Confirm secure engagement of the Handle by gently pulling on the Handle.

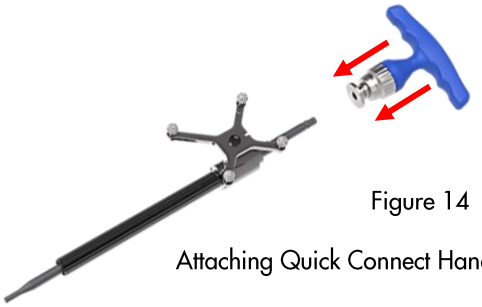


Figure 14

Attaching Quick Connect Handle

- Attach the Disposable Reflective Markers to each end of the Marker Posts on the Driver Array (Figure 15). Ensure that the Markers are fully seated on the posts.
- Place the tip of the Simulator Instrument into the Verification Divot of the End Effector or another other Instrument Array (Figure 16).
- Hold both Instruments steady and ensure that they are visible to the camera.
- A screen appears on the VERIFY tab to indicate the Verification progress.
- Be sure to successfully verify the Simulated Driver prior to attaching the Screw Driver.

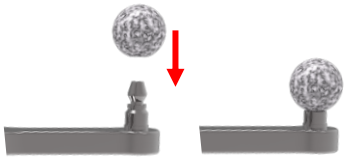


Figure 15

Marker attached to marker post

Figure 16

3 INSTRUMENT-SPECIFIC VERIFICATION GUIDELINES (continued)

Polyaxial Screw Drivers • Modular Screw Drivers

A Simulated Screw Driver is included in the set to aid in Verification of all E-GPS Screw Drivers. Verification methods follow:

SCREW DRIVER ATTACHMENT

- After successful Verification of the Simulated Driver, press the Release button on the Driver Array and remove the Simulated Driver.
- Press the Release button on the Driver Array and insert the desired Screw Driver into the Driver Array Sleeve until it "clicks" into place (Figure 17). Gently pull up on the Screw Driver Shaft to confirm that it is locked in the Array Sleeve.

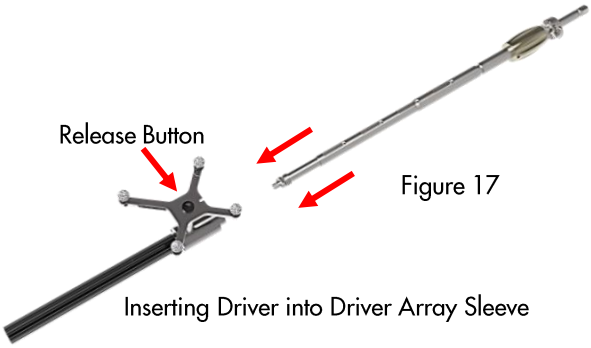


Figure 17

Inserting Driver into Driver Array Sleeve

- Securely attached the desired Handle to the proximal end of the Instrument Shaft (Figure 18). Confirm secure engagement of the Handle by gently pulling on the Handle.
- Utilizing Tables 1-3 in Section 8, confirm the proper mating Screw Driver/Screw combinations, as well as the corresponding Global Medical Screw System.
- Once confirmed, attach the proper screw to the Screw Driver.

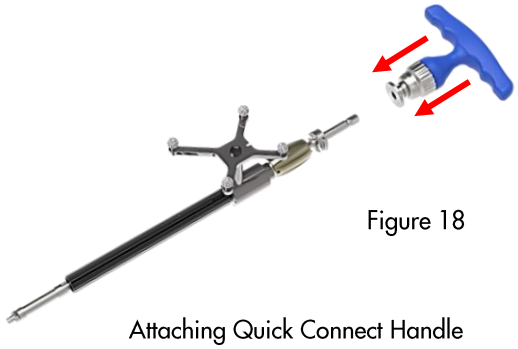


Figure 18

Attaching Quick Connect Handle

3 INSTRUMENT-SPECIFIC VERIFICATION GUIDELINES (continued)

Polyaxial Screw Drivers • Modular Screw Drivers

A Simulated Screw Driver is included in the set to aid in Verification of all E-GPS Screw Drivers. Verification methods follow:

PASSIVE TUBE ARRAY (PTA) VERIFICATION

The PTA may be used when the End Effector is not active to identify the location and orientation of the End Effector. The PTA has two (2) Array faces with four (4) posts each. Attach the Disposable Reflective Markers to all eight (8) marker posts. Ensure that all markers are fully seated on the posts.

On the VERIFY tab, toggle the End Effector Power switch to OFF. Ensure that the End Effector Power switch on the display screen is now GREY and the color circle is YELLOW.

"ON" **BLUE** switch and color circle is **RED**

"OFF" **GREY** switch and color circle is **YELLOW**

Verify both PTA faces per the following instructions:

- Place the tip of the PTA into the Verification Divot of any other Instrument Array (Figure 19). The End Effector Divot CANNOT be used to verify the PTA.
- Hold both the Instrument Array and the PTA Array stead and ensure that they are visible to the camera.
- A screen appears on the VERIFY tab to indicate Verification progress. Securely hold the PTA until both faces have been verified.

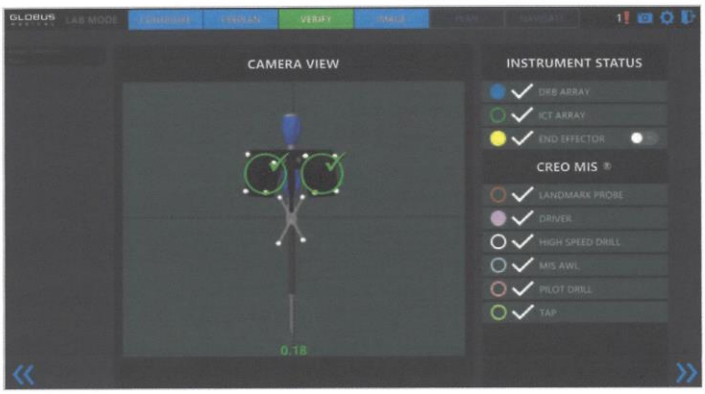
SUCCESSFUL VERIFICATION: **GREEN circle** and the tip error displayed in millimeters (mm) (Figure 20).

FAILED VERIFICATION:
RED crossed circle and Verification process must be repeated until it is successful.

Click the right arrows to advance to the next tab.

Figure 19

Positioning the PTA for verification



Verification of PTA complete

Figure 20

12

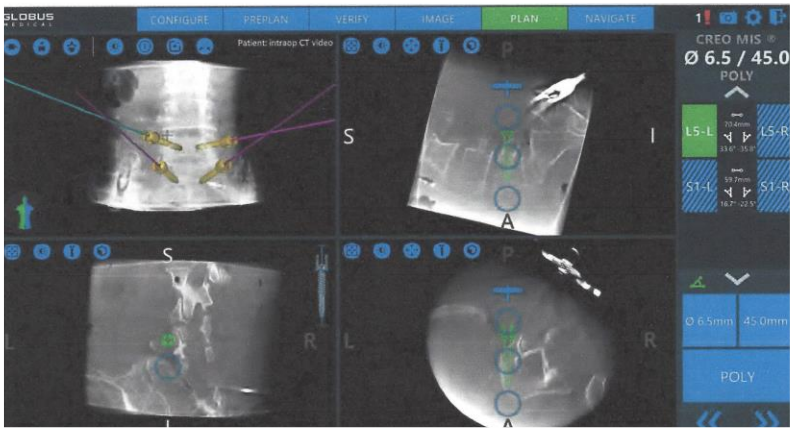
SURGICAL TECHNIQUE

4 ACQUIRING SCANS (IMAGE TAB)

- Install the Patient Attachment Instruments, Dynamic Reference Base (DRB) and Surveillance Marker on rigid landmarks per the Globus Medical ExcelsiusGPS® Robotic Navigation Platform instructions.
- After installing the appropriate Registration Fixture, obtain or load CT or fluoroscopic images of the desired anatomical area.
- After automatic or manual registration is complete, perform an Anatomical Landmark Verification and check per the Globus Medical ExcelsiusGPS® Robotic Navigation Platform instructions,
- Click on the right arrows to advance to the next tab.

5 IMAGING WORKFLOW (PLAN TAB)

- Plan all screw trajectories on the patient image in the PLAN tab (Figure 21) .
- To add a screw to the Planning Page, drag and drop the appropriate Screw Label onto the image. The Active Screw Plan is shown in **GREEN**. Details of the Active Screw Plan, such as Screw Family, Diameter and Length, are shown on the lower right portion of the screen,
- Once all the Screw Plans are complete, click on the Right Arrows to advance to the next slide.



Intraoperative CT Imaging Workflow
PLAN Tab
Figure 21

ADJUSTING SCREW TRAJECTORY

Screw Body	Press and move along screen to translate the screw along the current plane of the anatomy
Screw Head	Press and move to change the angle of the trajectory, pivoting along the screw tip
Screw Tip	Press and move to change the angle of the trajectory, pivoting along the screw head
Scroll Bar	The scroll bar is the dial control located above the screw head. Press the scroll bar and move to rotate the anatomy 360° about the screw.

ADJUSTING SCREW SIZE

Screw Tip	Press and move longitudinally to automatically adjust the length of the screw to available screw sizes
Screw Diameter	Press the screw diameter button located on the right hand side of the screen to select other options available with the selected implant set
Screw Length	Press the screw length button located on the right hand side of the screen to select other options available with the selected implant set

6 NAVIGATING INSTRUMENTS (NAVIGATE TAB)

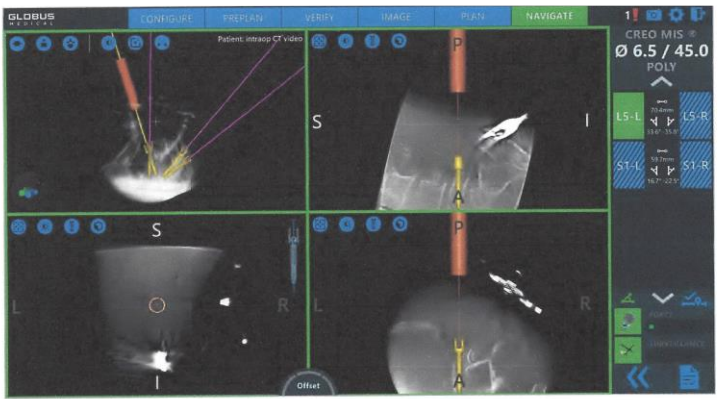
In the NAVIGATE Tab, visualize the Navigated Instrument Trajectory and the Planned Trajectory with respect to the patient anatomy (Figure 22).

Navigated Instruments are displayed as they pass through the End Effector. Ensure consistency between tactile and navigation feedback by monitoring the screen and surgical site.

Select the desired screw label on the right side of the screen. The Screw Plan is Active when it is highlighted and the Robotic Arm can be moved. The Robotic Arm will precisely align the End Effector to the Planned Trajectory and does not move off the trajectory unless the Screw Plan is deselected.

Both the Real-Time and Planned Screw Trajectories are displayed on the patient images. If the Real-Time Trajectory is not acceptable, return to the PLAN Tab to select another trajectory. If the Real-Time Trajectory is acceptable, continue to insert the screw according to the instrument's current trajectory to the desired depth.

CAUTION: Accuracy assessments should be accomplished by confirming that the Real-Time Navigated Instrument/Implant Trajectory is in agreement with the Planned Screw Trajectory shown on the screen.



Intraoperative CT Imaging Workflow
NAVIGATE Tab
Figure 22

NAVIGATING WITH THE PTA

- Securely insert the PTA into the 15mm End Effector Guide Tube (Figure 23).
- Select the desired screw label on the right side of the screen. The Screw Plan is Active when it is highlighted and the Robotic Arm can be moved. The Robotic Arm will precisely align to the Planned Trajectory and does not move off the trajectory unless the Screw Plan is deselected.
- Remove the PTA from the 15mm End Effector Guide Tube once the Robotic Arm reaches the trajectory.
- Navigated Instruments may now be inserted through the Guide Tube.

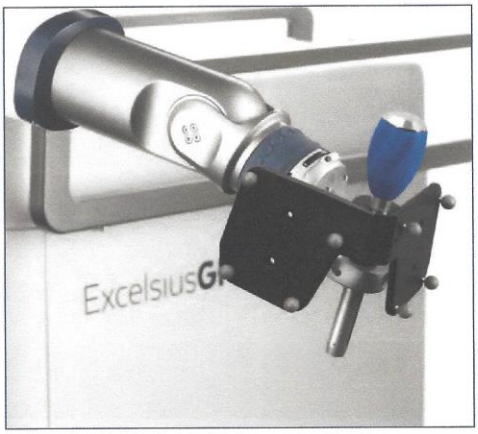


Figure 23

14

SURGICAL TECHNIQUE

7 NAVIGATION-ONLY PROCEDURES

(Navigation without Robotic Arm and End Effector)

All Navigated Instruments are visible on patient images when within the camera view and displayed with respect to the patient (Figure 24).

Use the IMAGE Tab to load the desired patient images. After Registration is complete, perform an Anatomical Landmark Verification and check per the Globus Medical ExcelsiusGPS® Robotic Navigation Platform instructions.

OPTIONAL:
Use the PLAN Tab to set the screw trajectory and select the screw label on the right side of the screen to choose the Screw Plan. Use the NAVIGATE Tab to display the Navigated Instruments and Screw.

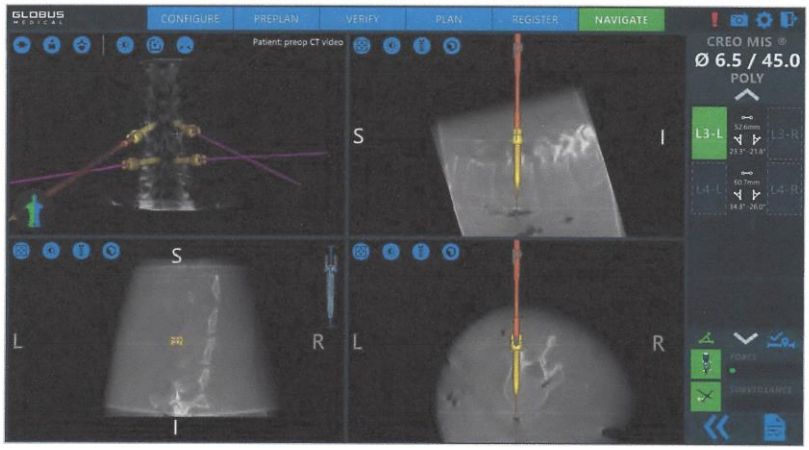


Figure 24

NAVIGATING INSTRUMENTS

Perform surgery as indicated by the surgical technique guide for the corresponding implant system.

- Reform *Ti*
- Reform *Ti HA*
- Reform *Ti* Modular
- Reform *Ti MIS CT*
- Reform *MC Midline Cortical*

NAVIGATED INSTRUMENT ACCESSORIES

- Simulated Driver to aid in Driver Registration

CAUTION:

Instrument verification and accuracy checks need to be assessed prior to every use! Accuracy assessments can be accomplished by placing each navigated instrument at known anatomical landmarks and confirming that the instrument tip location and orientation is in agreement with the simulated depiction in the screen.

Reassessing system accuracy should be performed throughout the procedure including whenever any changes are made to the instrument being navigated, or the manner in which the instrument is depicted in the simulation (Ex. Change in implant size or change in trajectory, etc.).

Do not use bent or otherwise damaged instrumentation. Patient repositioning, spinal manipulation, and significant movement of the DRB can all affect accuracy. If the surveillance marker indicates significant movement of the DRB, perform and anatomical landmark check. If the landmark check is successful, re-register the surveillance marker. If the landmark check fails, re-register the patient. Follow the manufacturer's (Globus Medical) instructions for system setup, use, trouble shooting, and all warnings and precautions.

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

INDICATIONS

INSTRUMENT SYSTEM INDICATIONS

The E-GPS Navigated Instruments are indicated for use during the preparation and placement of Precision Spine screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The E-GPS Navigated Instruments are reusable and are specifically designed for use with the Globus Medical ExcelsiusGPS® Robotic Navigation Platform which is intended for use as an aid for precisely locating anatomical structures and for the special positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. Use of the E-GPS Navigated Instrument System is limited to use only with the Reform® Spinal Fixation System (Reform® Ti, Reform Ti Modular, Reform Ti CT Modular MIS, Reform Modular, and Reform MC).

PRECAUTIONS

The E-GPS 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

The E-GPS Navigated Instrument System contraindications include, but are not limited to:

1. Morbid obesity
2. Mental Illness
3. Alcoholism or drug abuse
4. Fever or leukocytes
5. Pregnancy
6. Severe osteopenia
7. Metal sensitivity/allergies
8. Patients unwilling or unable to follow post-operative care instructions
9. Active infectious process or significant risk of infection
10. Any circumstances not listed in the indication of the device
11. Contraindications to the Reform Spinal Fixation System are all applicable to the use of the E-GPS Navigated Instrument System.
12. Contraindications to the Globus Medical ExcelsiusGPS® Robotic Navigation Platform are applicable to the use of the E-GPS Navigated Instrument System.

POTENTIAL ADVERSE EFFECTS

All possible adverse effects associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:

1. Non-union
2. Fracture of the vertebra
3. Neurological injury
4. Vascular or visceral injury
5. Early or late loosening of any, or all, of the components
6. Loss of fixation
7. Device component fracture
8. Foreign body (allergic) reaction to implants, debris, corrosion products, and graft material, including metallosis, straining, tumor formation, and/or autoimmune disease
9. Disassembly and/or bending of any or all of the components
10. Infection
11. Hemorrhage
12. Change in mental status
13. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain
14. Pain, discomfort, or abnormal sensations due to the presence of the device
15. Post-operative change in spinal curvature, loss of correction, height, and/or reduction
16. Cessation of any potential growth of the operated portion of the spine
17. Loss of or increase in spinal mobility or function
18. Death

Note: Additional surgery may be required to correct some of these potential adverse events.

WARNINGS

The following are warnings for this device.

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1. The safety and effectiveness of pedicle screw spinal 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 (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
2. When used as a pedicle screw system, this system is intended for Grade 3 or 4 spondylolisthesis at the fifth lumbar/first sacral (L5-S1) vertebral joint.
3. Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebrae, neurological injury, and vascular or visceral injury.
4. Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
5. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
6. To facilitate fusion, a sufficient quantity of autograft bone should be used.
7. The implantation of pedicle screw systems should be performed only by experienced spinal surgeons with specific training in the use of pedicle screw spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.
8. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
9. Non-sterile; the screws, rods, locking cap screws, cross-links, connectors, hooks, and instruments are sold non-sterile, and therefore must be sterilized before use.
10. The components of this system should not be used with components of any other system or manufacturer.
11. Titanium components should not be used with stainless steel components within the same system.
12. This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical spine.
13. The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.
14. Precision Spine does not warrant Globus Medical ExcelsiusGPS® Navigation Software. It is the sole responsibility of the user to ensure instrument calibration and/or verification.
15. The use of the Navigated Instrument System should only be used with the indicated pedicle screw systems.
16. Users must complete verification steps as required per the Globus Medical ExcelsiusGPS® Robotic Navigation Platform Operative Technique.
17. 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.
18. In the event of a verification 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.
19. Additional warnings may be present in the labeling for screws and other components used in the procedure that should be carefully considered prior to surgery.

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