GLOBUS MEDICAL

ExcelsiusGPS®

Robotic Navigation Platform

USER MANUAL

EXCELSIUS-GPS.COM | *Life moves us*

ExcelsiusGPS® USER MANUAL

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INTRODUCTION

System Overview

The ExcelsiusGPS® enables real-time surgical navigation using radiological patient images and guides the trajectory of specialized surgical instruments along a surgeon-specified path using a robotic arm. The system software reformats patient-specific CT images acquired before surgery, or fluoroscopic images acquired during surgery, and displays them on screen from a variety of views. Prior to operating, the surgeon may then create, store, access, and simulate trajectories. During surgery, the system guides the instruments to follow the trajectory specified by the user, and tracks the position of surgical instruments in or on the patient anatomy and continuously updates the instrument position on these images. The surgery is performed by the surgeon using the specialized surgical instruments.

The software can also show how the actual position and path during surgery relate to the pre-surgical plan and can help guide the surgeon along the planned trajectory. While the surgeon's judgment remains the ultimate authority, real-time positional and trajectory information obtained through the ExcelsiusGPS® can serve to validate this judgment.

User Manual Overview

This user manual describes important safety information regarding the use of the device and how to properly power on and off the system. This manual also describes how to position the system, set up navigation, plan trajectories, and position the arm. This manual should be readily available at all times. Operators should review the procedures and safety precautions periodically.

Intended Audience

This manual contains information that is intended for any operator responsible for setup or operation of the ExcelsiusGPS®. The operator of the system should either be a trained surgeon or qualified surgical assistant. This user manual, as well as all warnings, cautions, and labels should be read before using the system.

Device Description

The ExcelsiusGPS® is a Robotic Positioning System that includes a computer controlled robotic arm, hardware, and software that enables real time surgical navigation and robotic guidance using radiological patient images (preoperative CT, intraoperative CT and fluoroscopy), using a dynamic reference base and positioning camera. The navigation and guidance system determines the registration or mapping between the virtual patient (points on the patient images) and the physical patient (corresponding points on the patient's anatomy). Once this registration is created, the software displays the relative position of a tracked instrument, including the End Effector of the robotic arm, on the patient images. This visualization can help guide the surgeon's planning and approach. As an aid to visualization, the surgeon can plan implant placement on the patient images prior to surgery. The information of the plan coupled with the registration provides the necessary information to provide visual assistance to the surgeon during free hand navigation or during automatic robotic alignment of the End Effector.

During surgery, the system tracks the position of GPS compatible instruments, including the End Effector of the robotic arm, in or on the patient anatomy and continuously updates the instrument position on patient images utilizing optical tracking. Standard non-navigated metallic instruments that fit through the guide tube at the selected trajectory may be used without navigation while the guide tube is stationary, for uses such as bone preparation (e.g. rongeurs, reamers etc.) or placing MIS implants (e.g. rod inserters, locking cap drivers) that are not related to screw placement. Navigation can also be performed without guidance. System software is responsible for all motion control functions, navigation functions, data storage, network connectivity, user management, case management, and safety functions. ExcelsiusGPS® surgical instruments are non-sterile, re-usable instruments that can be operated manually or with the use of the positioning system.

ExcelsiusGPS® instruments consist of registration instruments, patient reference instruments, surgical instruments, and End Effectors. Registration instruments incorporate arrays of reflective markers, and are used to track patient anatomy and surgical instruments and implants; components include the verification probe, surveillance marker, surgical instrument arrays, intraoperative CT registration fixture, fluoroscopy registration fixture, and dynamic reference base (DRB). Patient reference instruments are either clamped or driven into any appropriate rigid anatomy that is considered safe and provides a point of rigid fixation for the DRB. Surgical instruments are used to prepare the implant site or implant the device, and include awls, drills, drivers, taps, and probes. End Effectors are wirelessly powered guide tubes that attach to the distal end of the robotic arm and provide a rigid structure for insertion of surgical instruments.

Indications for Use

The ExcelsiusGPS® is intended for use as an aid for precisely locating anatomical structures and for the spatial 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. The system is indicated for the placement of spinal and orthopedic bone screws.

Contraindications

Medical conditions which contraindicate the use of the ExcelsiusGPS® and its associated applications include any medical conditions which may contraindicate the medical procedure itself.

Related Information

Refer to the corresponding package insert and technique guide for specific instructions on the use of surgical instruments, including cleaning and sterilization. Refer to the manufacturer's labeling for peripheral devices. A custom drape is available; refer to the manufacturer's instructions for use.

Conventions

This document employs the following conventions:

	**WARNING** Warning messages indicate procedures or practices that, if not observed, could result in personal injury to the user or patient. Do not proceed beyond a WARNING message until all of the indicated conditions are fully understood and met.

	**CAUTION** Caution messages indicate procedures that, if not observed, could result in loss of data on the hard disk or damage to the equipment. Do not proceed beyond a CAUTION message until indicated conditions are fully understood and met.

Instructions to Click

- Click the intended object on the touch screen with your finger.
- If an external mouse is attached, place the pointer over the object and press and release the left mouse button.
- "Click", "Touch", "Tap", "Select", and "Press" are used interchangeably.

Instructions to Double-Click

- Double-click means to click twice in rapid succession.

Contact Information

Phone:	Customer Service	1-866-GLOBUS1 (or 1-866-456-2871)
Address:	Globus Medical Robotics 300 Griffin Brook Drive Methuen, MA 01844 USA	
Internet:	www.excelsius-gps.com	
Email:	serviceINR@globusmedical.com	

Ordering Disposables and Accessories

To order disposables or accessories, please contact Customer Service or your local Sales Representative.

SAFETY

Overview

Operators using the ExcelsiusGPS® should be aware of potential hazards and safety concerns that exist when operating the system. This section describes the relevant safety information related to the ExcelsiusGPS® and must be read carefully and understood by the operator prior to using the system.

The ExcelsiusGPS® should only be operated by qualified medical professionals trained on the proper use of the system. The system is only intended to assist the surgeon not to replace their expertise or judgment.

Additional safety information is presented throughout this manual. If additional safety training is required, please seek assistance from qualified Globus personnel.

General Use

Ensure annual preventative maintenance is performed on schedule to confirm all software, electrical components and hardware are working properly. Preventive maintenance must only be performed by Globus Medical Service Technicians.

Navigation Integrity

The ExcelsiusGPS® has built-in precautions to support navigation integrity but additional steps should be taken to verify the accuracy of the system during navigation. Specific steps include:

- Ensure the stabilizers have been engaged prior to using the robotic arm.
- Do not move the dynamic reference base after successful registration.
- Use a surveillance marker with every procedure to further confirm the accuracy of the images in relation to real-time patient anatomy.
    - If a surveillance marker alerts movement of patient relative to the dynamic reference base, perform a landmark check.
    - If a landmark check fails, re-register the patient.
- Use a verified navigation instrument to perform an anatomical landmark check prior to a procedure.
    - If a landmark check fails, re-register the patient.

Safety Labeling

	**Laser Radiation**	**Do not stare into the laser beam** **Class 2 laser product.** *For more information, please reference the *NDI-Passive Polaris Spectra User Guide*
	Emergency Stop	Stops all motor motion in case of an emergency.
	Mandatory: Instruction Manual	Refer to the User Manual for details before operating.

Electrical Safety

Only plug the ExcelsiusGPS® into hospital grade outlets.

	WARNING
	To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

	WARNING
	The system power cord plug is the primary means of isolating the system from AC Mains Voltage, do not position the ExcelsiusGPS® in such a way that it would be difficult to access and remove the plug from the wall.

	WARNING
	To avoid electrical shock only trained service personnel are authorized to access internal system components via tool removable covers.

	WARNING
	Prior to cleaning, remove power to the system entirely.

Mechanical Safety

	CAUTION
	Keep body parts away from moving components of the system to prevent interference with robotic arm motion.

	CAUTION
	System components must be in their docked position and docked together for transport. Ensure the camera stand is fully docked into the Robotic Base Station before transporting the system.

Emergency Shutdown

The Emergency Stop button on the control panel removes all motor power to the system and applies the mechanical brakes which stops/prevents robotic arm motion.

Emergency Stop

General Warnings

WARNINGS

- No modification of the ExcelsiusGPS® system is allowed.
- The system and its associated applications should be used only by qualified medical professionals who are thoroughly trained on the use of this system.
- The system and its associated applications should be used only as an adjunct for surgical guidance. They are not a replacement for the surgeon's knowledge, expertise, or judgment.
- If system navigation seems inaccurate and recommended steps to restore accuracy are not successful, abort use of the system.
- The system is not suitable for use in the presence of a flammable, anesthetic mixture with air or oxygen or nitrous oxide.
- Inspect the system and all instruments prior to use. If visibly damaged or bent, do not use the system or instruments.
- This system is not intended to be operated on battery power alone while instruments are connected to a patient. Ensure that the system is plugged into an appropriate AC power outlet.
- **WARNING** messages indicate procedures or practices that, if not observed, could result in injury to the user or patient. Do not proceed beyond a **WARNING** message until all of the indicated conditions are fully understood and met.

General Precautions

CAUTION

- Federal (U.S.) law restricts the sale, distribution, and use of this device to or on the order of a physician.
- The system and its associated applications contain no user-repairable parts. For repair or replacement of any part of the system or application, contact Globus Medical for technical support.
- The loading of software not provided with the system is not allowed because its effects on the system are unknown. Globus Medical Service Technicians will remove unknown software from the system if found. Contact Globus Medical for technical support if there are any questions concerning the installation of any software packages.
- Verify that all relevant instruments and accessories have been properly cleaned and sterilized prior to surgery, in accordance with the corresponding package inserts.
- Do not exceed the recommended electrical ratings for this system, as this could cause damage to the system.
- System components are fragile. Use care when handling system components.
- Repositioning of the system may require new sterile drapes to be applied if the robotic arm moved outside the sterile field.
- Be aware of the camera stand feet and power cords attached to the system to prevent tripping.
- Ensure the camera stand is fully docked into the Robotic Base Station before moving or transporting the system. System components must be in their docked position for transport.
- To secure the camera stand from unwanted movement, lock all caster wheels.
- Inspect the system for leaks to prevent slipping on grease.
- Do not place food or liquids on the system. Avoid dripping any fluids into any enclosure on the system. Disconnect the power and allow the system to dry if you suspect any fluids may have entered any part of the system and contact technical support.
- Limit external sources of vibration from the operating room containing the ExcelsiusGPS®.

Compliance with Standards

This product conforms to the requirements of council directive 93/42/EEC concerning medical devices, when it bears the CE Mark of Conformity shown at right.

This product conforms to the requirements of standards listed below when it bears the following NRTL Certification Compliance Mark, shown at right.

Electric and electromagnetic testing have been performed in accordance with the following applicable standards:

- ANSI/AAMI ES60601-1
- CSA C22.2#60601-1
- CISPR 11
- IEC 60601-1*
- IEC 60601-1-2
- IEC 60601-1-6
- IEC 60601-1-9
- IEC 60601-2-49**
- IEC 60825-1
- IEC 62304
- IEC 62366

*Includes all national deviations
**Only portions of this standard are used to demonstrate compliance and proper operation of the ExcelsiusGPS® when used with high frequency surgical equipment such as a cauterizer

HF Surgical Equipment

Based on the ExcelsiusGPS® floating applied part (type BF) and the safety testing performed, the system is compatible with the use of HF surgical equipment with no restrictions on the conditions of use.

EMC Compliance

In accordance with IEC 60601-1-2:2014 Edition 3 and 4, Medical Electrical Equipment needs special precautions regarding Electro Magnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the tables below. Portable and mobile RF communications equipment can adversely affect electrical medical equipment. The tables supply details about the level of compliance and provide information about potential interactions between devices. EMC Compliance tables from 3rd Edition are shown on the next page with values adjusted for 4th Edition where appropriate.

	CAUTION
	The ExcelsiusGPS® is intended for use in the electromagnetic environment specified on the following page. The customer/user should assure that it is used in such an environment.

	**WARNING** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

	**WARNING** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ExcelsiusGPS® including cables specified by the manufacturer. Otherwise, degradation in the performance of this equipment could occur.

The ExcelsiusGPS® system has an optional 802.11 g/b/n wireless router and tablet option. When installed, this transmits RF power at 2.4 GHz (2.412-2.484 GHz) using DSSS or OFDM with DQPSK or QAM modulation. Maximum RF transmit power is 100 mW.

GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC EMISSION

Emissions Test	Compliance Level	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The ExcelsiusGPS® must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The ExcelsiusGPS® is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC IMMUNITY

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ± kV line(s) to earth	±1 kV differential mode ± kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% UT* (100% dip in UT) for 0.5 and 1 cycle 70% UT (30% dip in UT) for 25 cycles 0% UT 100% dip in UT) for 5 sec	0% UT (100% dip in UT) for 0,5 and 1 cycle 70% UT (30% dip in UT) for 25 cycles 0% UT 100% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

UT = AC mains voltage prior to application of the test level.

GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC IMMUNITY

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHZ to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the ExcelsiusGPS®, including cables, than the recommended separation distanced calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance (d) is calculated as follows: $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2, 7 GHz 9 to 28 V/m 380 MHz to 5.8 GHz in set bands with various modulation	3 V/m 80 MHz to 2, 7 GHz 9 to 28 V/m all frequency bands per standard	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ExcelsiusGPS® issued exceeds the applicable RF compliance level above, the ExcelsiusGPS® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ExcelsiusGPS®.

b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

CAUTION

The ExcelsiusGPS® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer/user of the ExcelsiusGPS® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ExcelsiusGPS® as recommended below, according to the maximum output power of the communications equipment.

RECOMMENDED SEPARATION DISTANCES

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5GHz
	$d = 1,2\sqrt{P}$	$d = 1,2\sqrt{P}$	$d = 2,3\sqrt{P}$
0.01	0.3*	0.3*	0.3*
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

***30 cm is the minimum recommended separation distance even though the calculation would yield a shorter distance.**

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: **At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.**
NOTE 2: **These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.**

Cybersecurity

The ExcelsiusGPS® adheres to industry best practices and FDA guidance on cybersecurity in medical devices. This includes firewall protection and additional protection against virus, malware, data corruption, and unauthorized system access.

SYSTEM OVERVIEW

The ExcelsiusGPS® consists of four main components: Robotic Base Station (shown below), Camera Stand (shown below), Instruments, and System Software.

Robotic Base Station

Camera Stand

Robotic Base Station

The Robotic Base Station is the main control center for the ExcelsiusGPS® and consists of the components shown below.

Monitor

The monitor allows the surgeon to plan the surgery and visualize anatomical structures, instruments, and implants in real-time. It is a high resolution, flat panel touch screen liquid crystal display (LCD) located on the vertical column. The monitor can be adjusted to the desired location with two hands. An external mouse is available for optional use with the monitor. The mouse is not intended for use within the sterile field.

Tablet

In addition to the ExcelsiusGPS® system, an optional wireless tablet is available for use as a second touchscreen monitor for operative planning and software control. The main monitor remains active at all times during use. Use of the tablet may be locked out if desired. The tablet compartment is used to store the tablet. The tablet is not intended for use within the sterile field.

This following information describes how to connect the tablet to the robot to mirror the output of the main monitor and how to use the tablet for use with a preoperative CT scan.

Note: The tablet only supports connections to the robot for mirroring. Connections to other devices, such as PACS for DICOM transfer, are not supported.

TABLET SOFTWARE ICONS

Icon	Meaning	Action
	Connection	Click to connect robot with wi-fi or ethernet
	Service	Click to login as service engineer
	Return	Click to return to the login page
	Camera	Click to capture a screenshot
	Hard Drive	Click to view saved scans
	USB	Click to view scans in USB
	Case Summary	Click to the view the case summary
	Extended Search	Click to peform an extended search
	Network Toggle / Network Selector	Click to select mode of connection
	Export Case	Click to export a case

Connecting Tablet to the Robot for Mirroring

A Wi-Fi or Wired Connection may be used for the tablet.

WI-FI CONNECTION

1. Turn on the tablet. Select the connection icon at the top right corner of the screen.

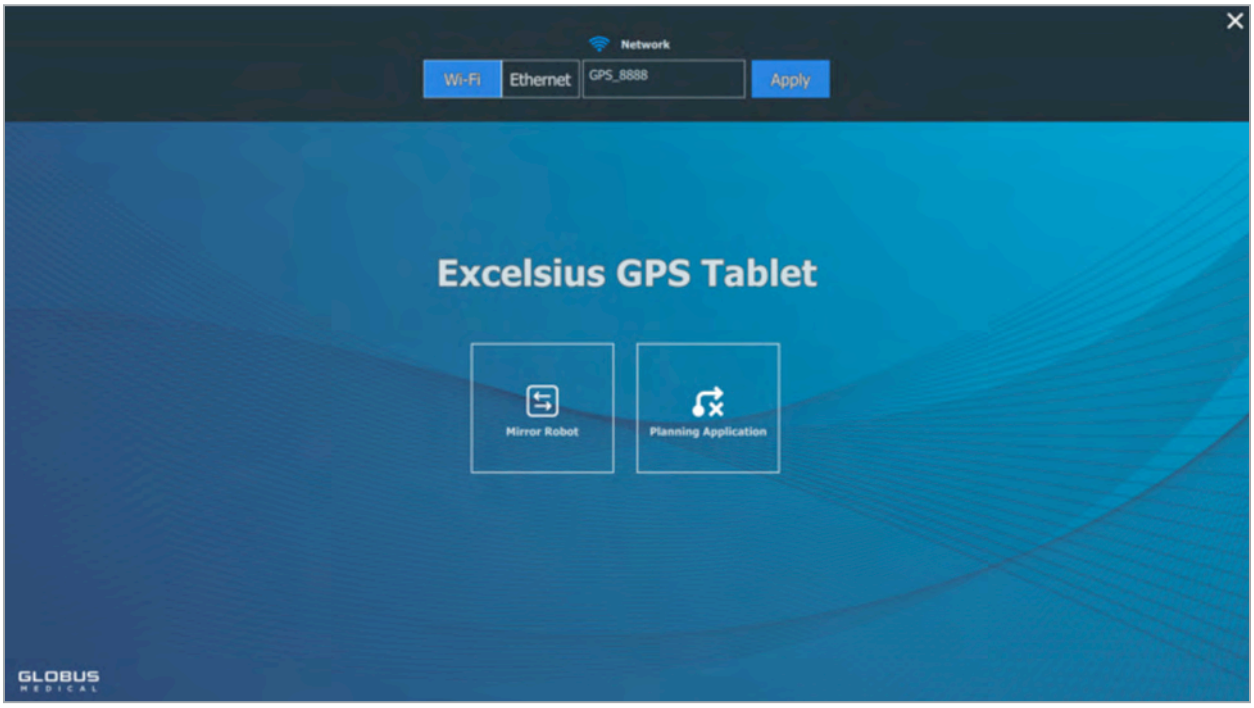
2. A connection menu appears at the top of the screen. In the network selector toggle, select Wi-Fi.

3. Select the text field next to the toggle. A virtual keyboard appears. Use this keyboard to enter the serial number of the robot system to connect remotely (e.g. GPS_8888).

4. Select Apply.

5. The Mirror Robot button will illuminate. Select the Mirror Robot button to connect to the robot.

Note: Some lag may occur, and the connection may occasionally drop. If this persists, connect through an Ethernet cable (see Wired Connection).



WIRED CONNECTION

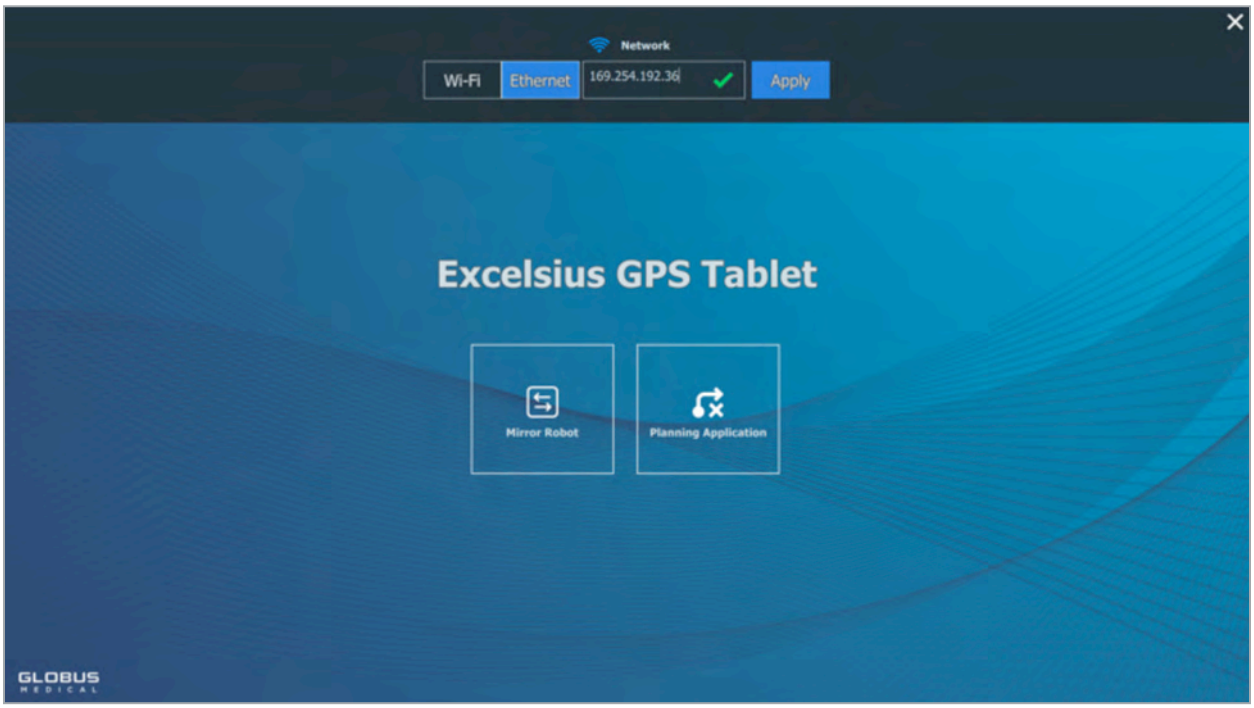
1. Turn on the tablet. Select the Connection icon at the top right corner of the screen.

2. A connection menu appears at the top of the screen. In the network selector toggle, select Ethernet.

3. Select the text field next to the toggle. A virtual keyboard appears. Use this keyboard to enter the IP address of the robot system to connect remotely (e.g. 196.254.192.36). If previously connected to the IP address, choose the IP address from the drop down list after selecting the text field.

4. Select Apply.

5. A green checkmark icon appears in front of the IP address if a connection is available. The Mirror Robot button also illuminates. Select the Mirror Robot to remotely connect to the robot.



RESTORING THE TABLET CONNECTION

1. If connection to the robot is lost, select the close button [X] in the team viewer window on the tablet.

2. The tablet controller application should continue running. Select the Mirror Robot button again to resume connection.

3. If the tablet controller crashes or does not respond to touch, restart the tablet using the physical power button at the top left of the device.

4. Follow the steps for Connecting Tablet to Robot for Mirroring.

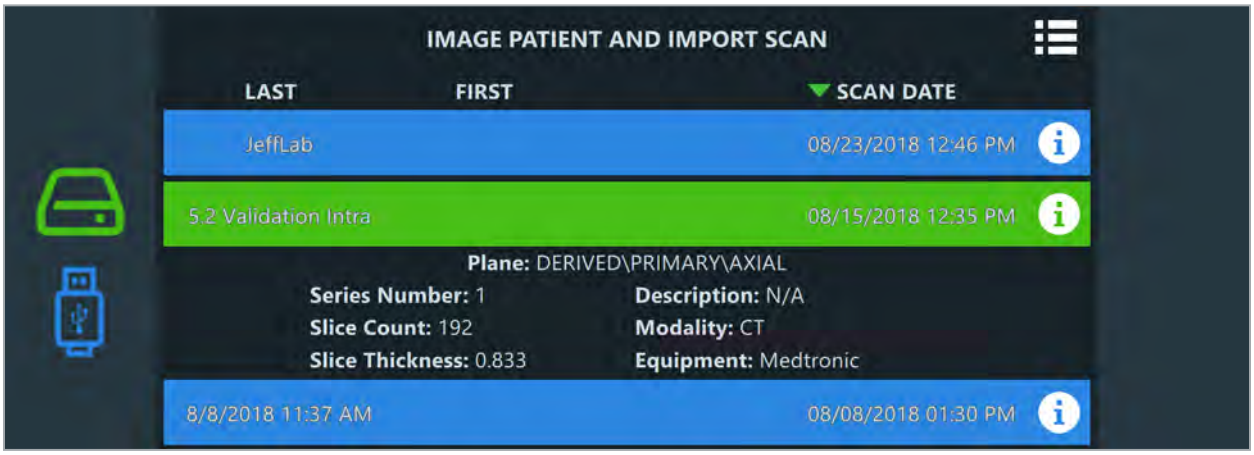
	WARNING
	If the connection from the ExcelsiusGPS® system to the tablet is lost, user input can be entered using the main monitor instead of the tablet.

Using the Tablet for Planning

To use the tablet for planning, select the Planning Application button .

LOADING CT SCAN FROM USB STORAGE DRIVE

1. Connect the USB storage device containing the CT scan to the tablet. USB flash drives and external CD/DVD drives connected through the USB are supported storage devices for loading scans.
2. Proceed to the IMAGE page and select the USB icon at the left.
3. When the scan list appears, select the desired scan. Select the icon to list scan information to ensure the correct scan is selected. If the desired scan does not appear, a DICOMDIR file may be missing. To retry, perform an extended search by checking the Extended Search checkbox Extended Search at the top right of the IMAGE page. To format files on the USB storage device, see *Organizing USB Storage Device*.
4. Proceed to the PLAN page and plan screws.
5. Select the Case Summary button at the bottom right of the PLAN page.
6. Select the Export Case button Export Case on the right of the CASE SUMMARY page to export the patient images. The exported case file has the extension ".gmc" on the USB storage drive. USB flash drives are the only supported storage device for exporting cases.



ORGANIZING THE USB STORAGE DEVICE

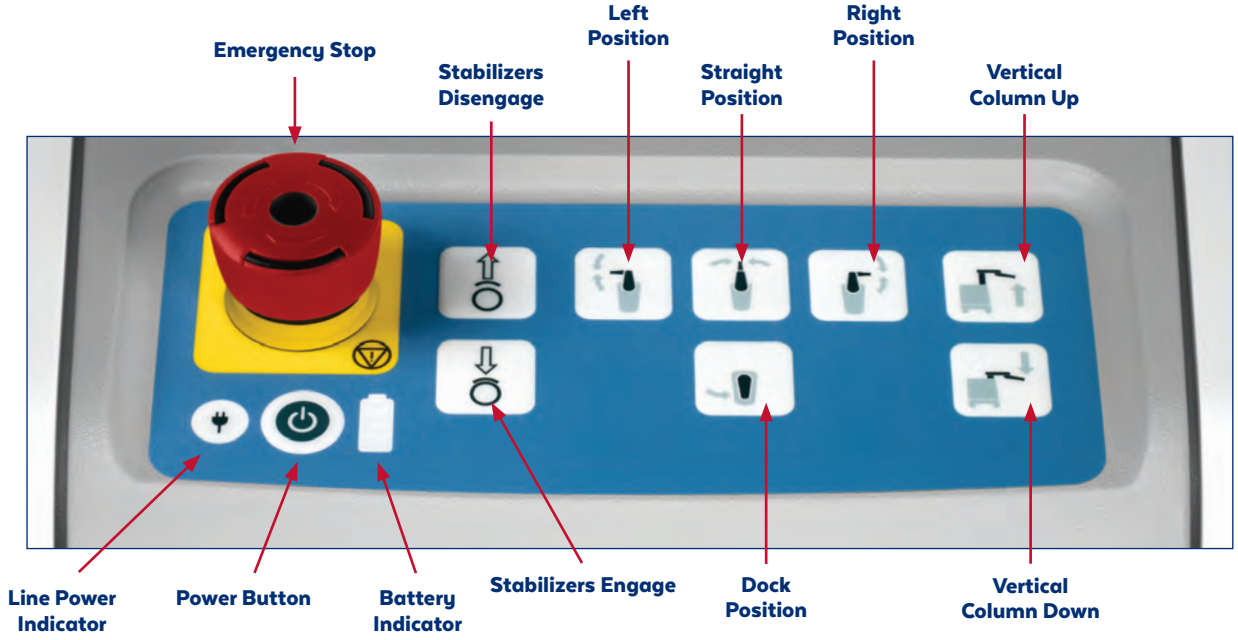
1. Each scan contains a folder named "patient" or "ID info" (e.g. BI-1-18-2018). These folders appear at the top level of the USB drive.
2. Each scan folder typically contains a folder of DICOM images which may have subfolders. This subfolder is typically named with a number, e.g. 312, or the text "DICOM".
3. The scan folder typically contains a DICOMDIR file which identifies the file structure of the scan, but this file is not always present.

LOADING THE CT SCAN FROM PACS SYSTEM

The tablet does not support direct file downloads from the PACS system. The files may be downloaded to the ExcelsiusGPS® system and exported to the tablet for planning using the Export Case button Export Case on the right of the CASE SUMMARY page.

Control Panel

The control panel is located at the rear of the Robotic Base Station. This panel is used to display and control system power and general positioning functions.

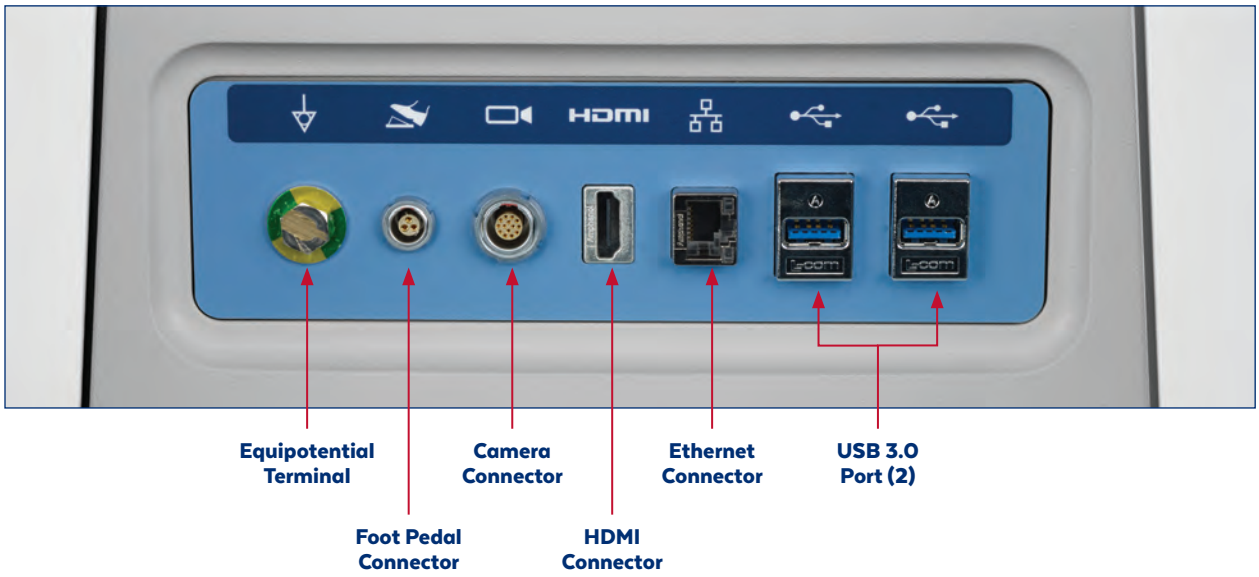


CONTROL PANEL FUNCTIONS

Button	Function	To Use
Emergency Stop	Removes power from motors and applies brake	Press down to activate. To deactivate and re-power, twist knob counterclockwise.
Line Power Indicator	Illuminates when system is plugged into AC power outlet	
Power Button	Powers the Robotic Base Station ON/OFF. Illuminated when ON.	Press to turn ON/OFF
Battery Indicator	Indicates level and state of charge • All bars are illuminated when fully charged • When operating on battery, number of illuminated bars indicates percent of charge • Bars progressively illuminate when charging	
Stabilizers Disengage	Illuminates when system is free to move	Press to disengage the stabilizers to allow movement of the system
Stabilizers Engage	Illuminates when system is secured to floor	Press to engage the stabilizer, to lock the system in place
Left Position	Moves upper arm forward and lower arm at a 90° angle to the left	Press and hold button. Operator may release button prior to final position to stop arm in current position.
Right Position	Moves upper arm forward and lower arm at a 90° angle to the right	
Straight Position	Moves upper and lower arm forward	
Dock Position	Moves upper and lower arm to rest over the cabinet	
Vertical Column Up	Moves vertical column up	Press and hold button. Operator should release button once the desired height is reached.
Vertical Column Down	Moves vertical column down	

Connector Panel

The connector panel is located at the rear of the Robotic Base Station. This panel contains external connection ports for various devices.



CONNECTOR PANEL FUNCTIONS

Item	Function
Equipotential Terminal	Connects to auxiliary equipment; used by service personnel
Foot Pedal Connector	Connects to the foot pedal cable
Camera Connector	Connects to the camera stand cable
HDMI Connector	Connects to an external monitor
Ethernet Connector	Connects to a network or intraoperative imaging system for image transfer
USB Port 3.0	Connects to a USB device for image transfer Connects to C-arm via video capture supplied with the Fluoroscopy Registration Fixture

WARNING

If other devices are connected to this system, the operator is responsible to ensure the integrity of the whole system continues to comply with appropriate medical safety standards (e.g. IEC 60601-1, ANSI/AAMI 60606-1).

WARNING

Any external devices attached to the ExcelsiusGPS® HDMI or USB ports, must be certified to the appropriate medical safety standards (e.g. IEC 60601-1, ANSI/AAMI 60606-1).

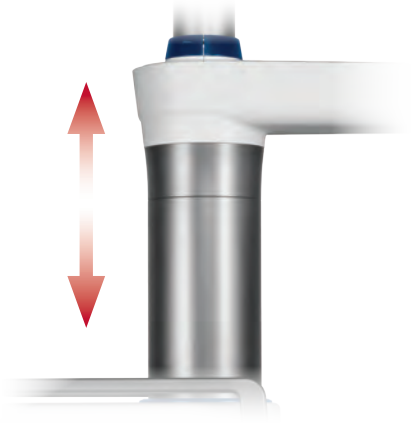
Casters and Stabilizers

The system consists of four casters with integrated stabilizers. The stabilizers are used to immobilize the system to ensure that it does not move during use.

Upper Arm, Lower Arm, and Vertical Column

The robotic arm, which consists of an upper and lower arm, is attached to the vertical column of the ExcelsiusGPS® Robotic Base Station. This configuration allows for a wide range of motion.

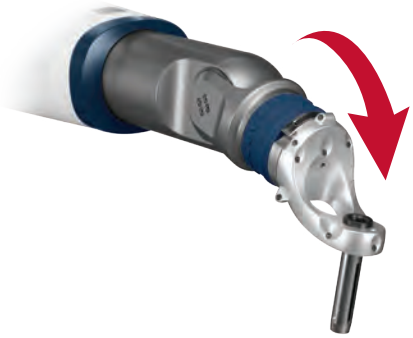
The ExcelsiusGPS® employs a state-of-the-art drive control system along with high performance servo drives to accurately position and control the 5-axis robotic arm in an operating room environment. The 5-axes of motion are identified below.



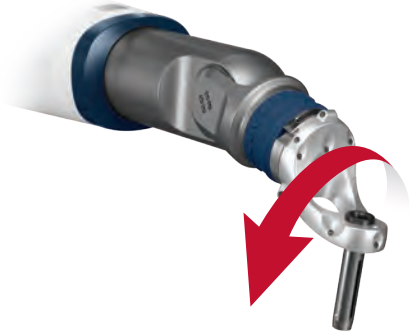
Vertical

Shoulder

Elbow



Pitch



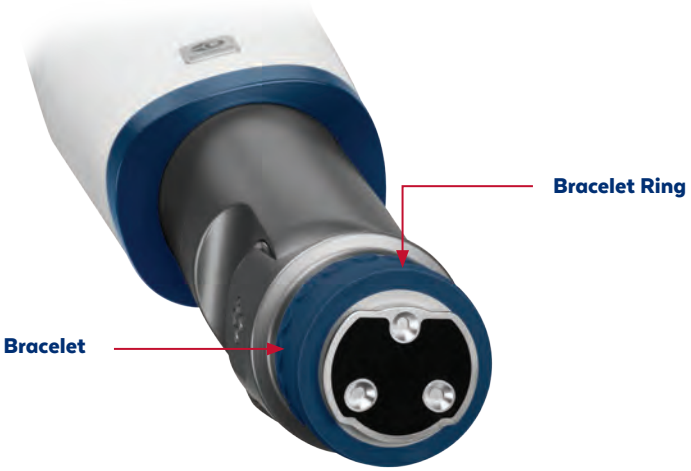
Roll

Axis	Travel Distance
Vertical	≥ 480mm
Shoulder	-150° to 180°
Elbow	-150° to 150°
Roll	-135° to 135°
Pitch	-70° to 70°

Bracelet

The bracelet is located at the distal end of the lower arm. It is a load-sensing component that allows user guided positioning of the robotic arm.

To initiate motion, squeeze the bracelet ring with the thumb and forefinger on opposite sides. While squeezed, apply light force toward the desired direction of motion. The robotic arm may be moved manually in any direction or along a trajectory if a screw plan is active.



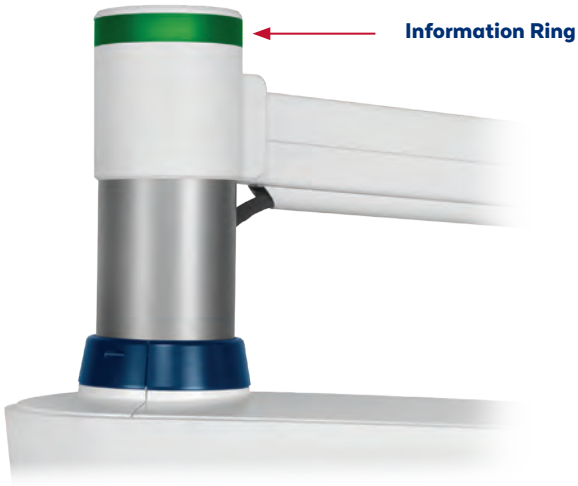
	CAUTION
⚠	Avoid applying excessive force on the bracelet; very little force is required to achieve the desired motion.

Information Ring

The information ring is located on the upper part of the vertical column. The information ring indicates the status of the ExcelsiusGPS®. The information ring light blinks while the system is booting up; a solid green light is displayed when the system is ready. Individual colors are used to indicate status, as shown in the table below.

INFORMATION RING COLOR INDICATIONS

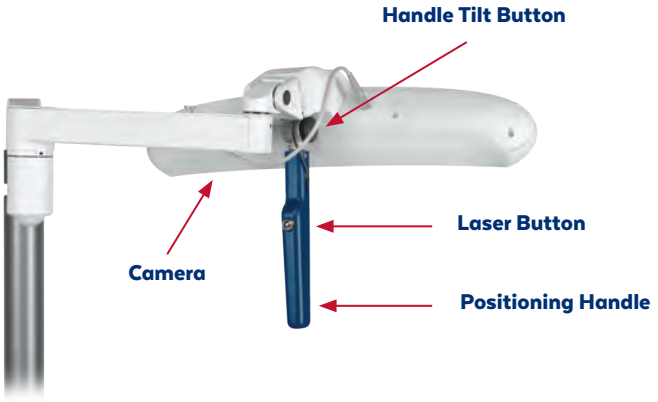
Color	Description
Red	System is in an error state. Stop all tasks and resolve the issue immediately as it is either a safety issue or a serious problem with the system.
Yellow	System is in a state in which user intervention is required before a planned trajectory can be activated.
Green	System is ready.



Camera Stand

The camera stand is mobile and adjustable to position the camera to a new operating field and optical markers.

Camera Stand



Rear view showing alignment buttons

CAMERA STAND FUNCTIONS

Item	Function
Camera	Used to detect the reflective markers and is attached to the top of the camera stand. (For more information, please refer to the *NDI Passive Polaris Spectra User Guide*.)
Positioning Handle	Used to adjust the camera position to ensure the surgical field is in view
Handle Tilt Button	Used to adjust the angle of the positioning handle with respect to the camera in the field of view
Laser Button	Turns the camera laser alignment light on and off. The laser light is used for assistance in aligning the camera in the field of view.
Arm	Provides a large range of positions for the camera
Height Adjustment Handle	Allows for adjustment of camera height
Locking Handle	Used to lock camera position
Docking Handle	Used to collapse the legs for docking the camera stand into the Robotic Base Station
Release Handle	Releases the camera from the Robotic Base Station
Casters	The camera stand contains four casters. The rear casters are lockable to prevent the camera stand from moving.
Legs	The camera stand legs swing inward for docking and outward when deployed
Cable Holder	Provides storage for the camera stand cable

WARNING

Eye injury may result from exposure to the camera laser alignment light.

Cabling

The following cable characteristics are required for connecting to external devices:

HDMI – Connecting to an external HDMI Monitor requires a shielded HDMI-Male to HDMI-Male cable.

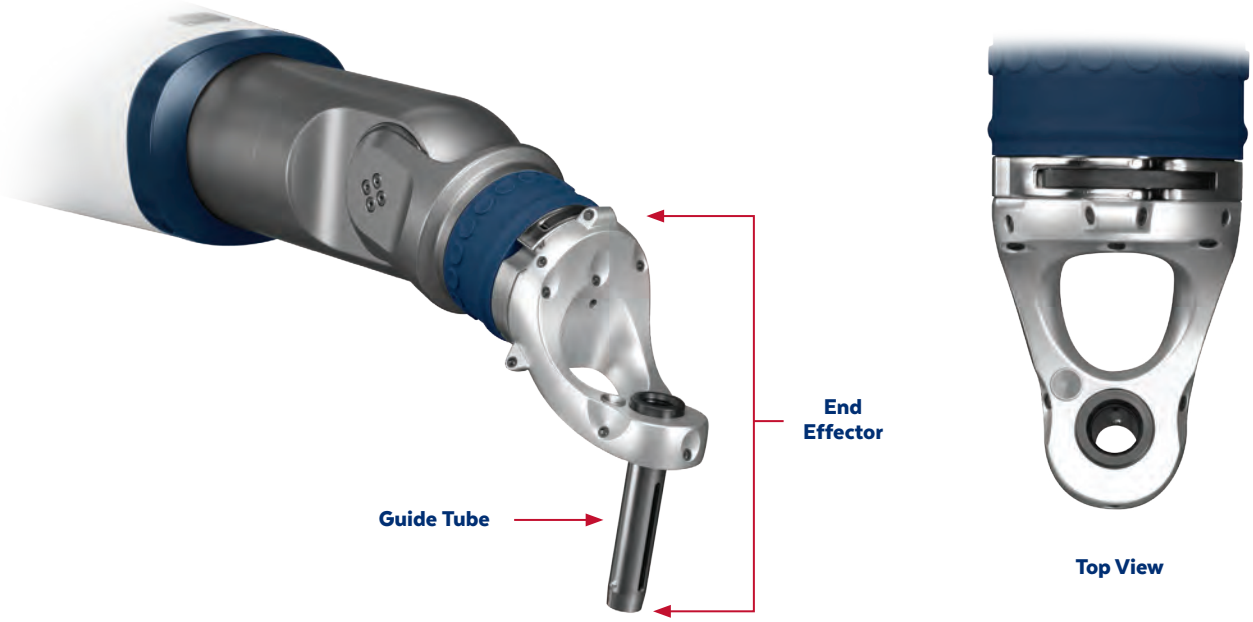
Network – Connecting to a Hospital network can be done with an unshielded CAT-5e Ethernet cable.

WARNING

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

End Effector

The End Effector is the interface between the robotic arm and the system specific surgical instruments. It allows for a rigid connection through the sterile drape to provide precise positioning of instruments placed within its guide tube. The End Effector is provided as a separate component and is sterilized by the user prior to use. Always use care when handling or transporting the End Effector as it contains sensitive electronics.



The End Effector is powered wirelessly from the robotic arm. This power is used to drive the active markers that are used by the camera to identify the location and orientation of the End Effector. The blue indicator LED illuminates when the End Effector is powered.

Two End Effectors are available to interface with various surgical instruments. They differ only in the diameter of the guide tube; the active markers have the same geometries. The End Effectors are etched with the guide tube diameter and are color-coded to help ensure that the corresponding size instruments are used.

The 15mm End Effector is used with all navigated instruments except REVOLVE® instruments and the 17mm End Effector is used with REVOLVE® instruments. Non-navigated Globus instruments may be used with either End Effector; they are not sized to the guide tube but must fit within the inner diameter.

	WARNING
	When using navigated Globus instruments through the End Effector, the instruments must be properly sized to ensure a snug fit in the guide tube.

	WARNING
	When using non-navigated Globus instruments through the End Effector, general trajectory guidance is provided, however navigation is not supported for these instruments.

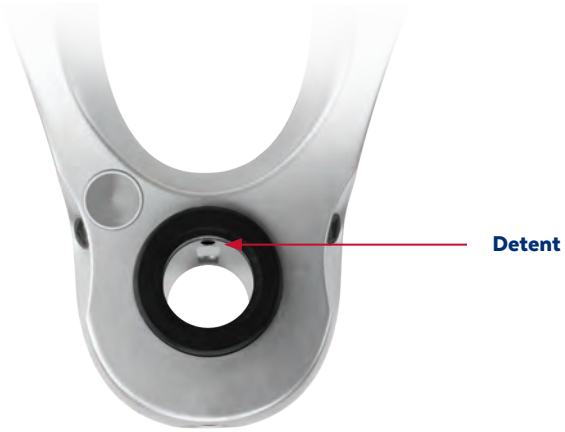
INSTRUMENT SENSING RING

Located within the guide tube of the End Effector is an instrument sensing ring. A detector circuit is embedded within the sensing ring that detects when a metal instrument is inserted through the guide tube and disables the active markers and prevents movement of the robotic arm. The visible LED on the End Effector does not illuminate when a metallic instrument is inserted, indicating that an instrument is detected and the active IR emitters are disabled. Disabling the IR emitters prevents the robotic arm from moving. Non-metallic instruments are not identified by the sensing ring and may not be used in the guide tube.

	WARNING
	Do not use non-metallic instruments within the guide tube, as they are not identified by the End Effector and the robotic arm will not be prevented from moving while in use.

DETENT MECHANISM

Size 15mm End Effectors have a detent mechanism on the inside of the tube which interfaces with grooves on the array sleeves to resist array rotation. This aids in holding the tracking array oriented toward the camera while the operator rotates the instrument.



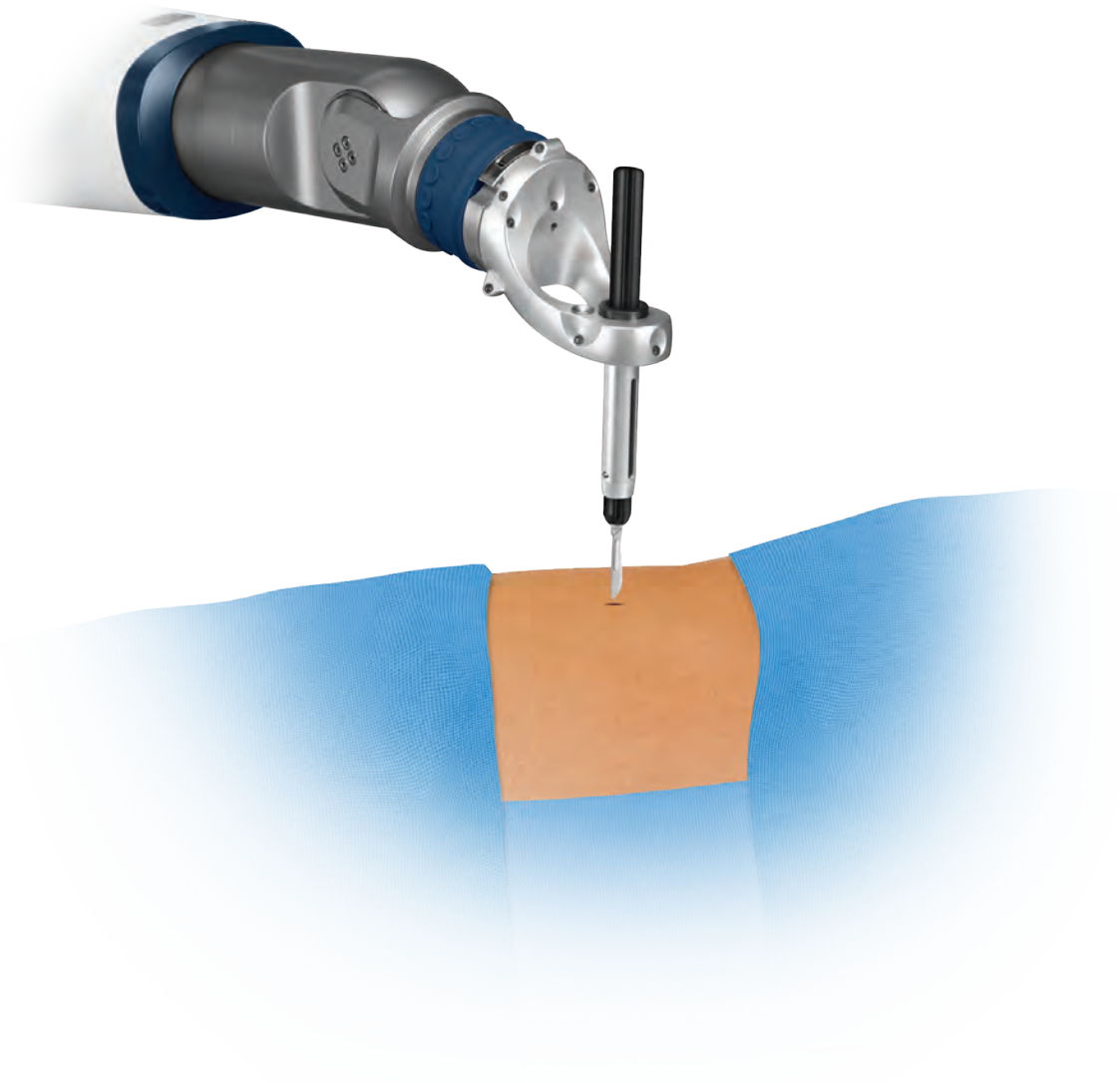
Detent mechanism on instrument sensing ring

Scalpel

A specialized scalpel can be used to create a skin mark at the planned trajectory. Attach a standard scalpel blade to the handle.

Position the guide tube on the End Effector to the planned trajectory. Adjust the End Effector up or down along the trajectory to allow the scalpel to be viewed. Ensure that scalpel tip can be viewed before making the skin mark.

Note: The scalpel has a metal core within the radiolucent PEEK material and is detected while in the guide tube.



Scalpel used through guide tube

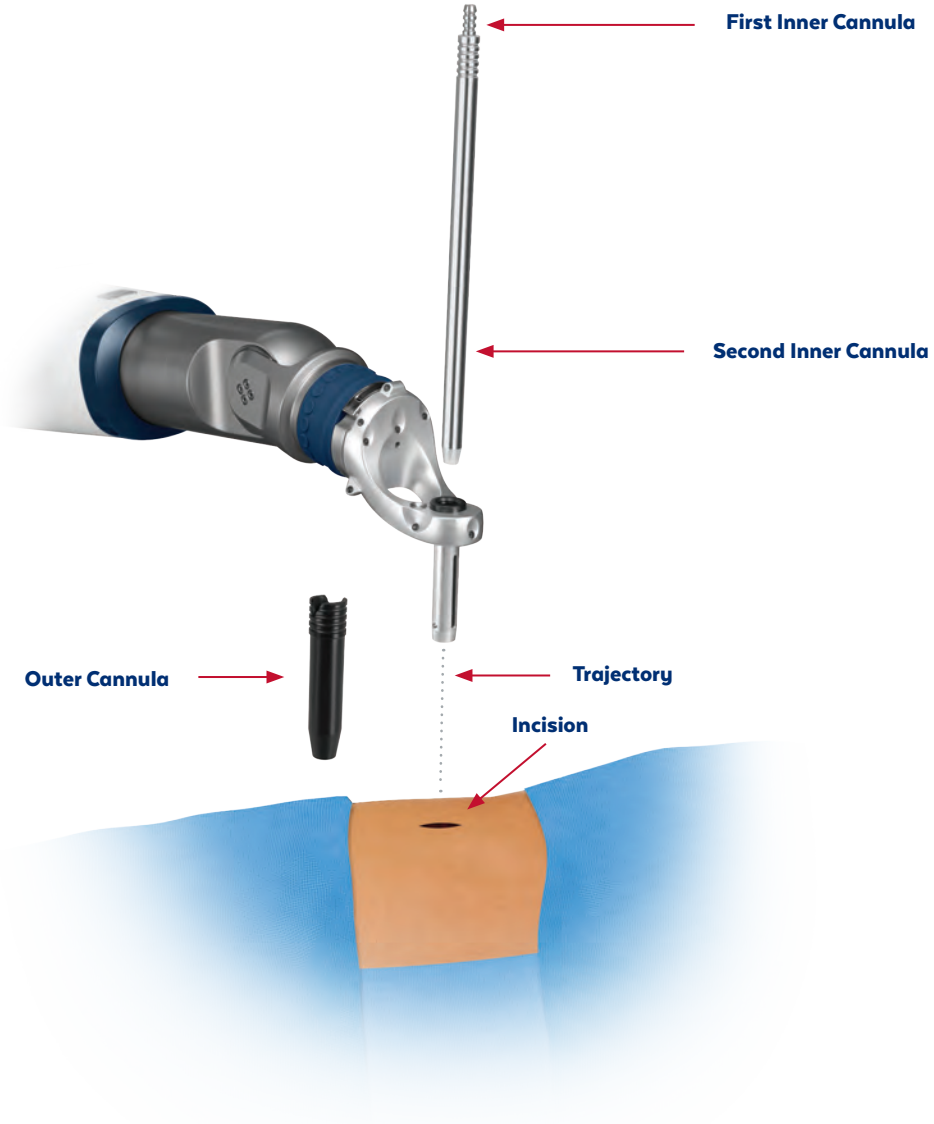
Cannulas

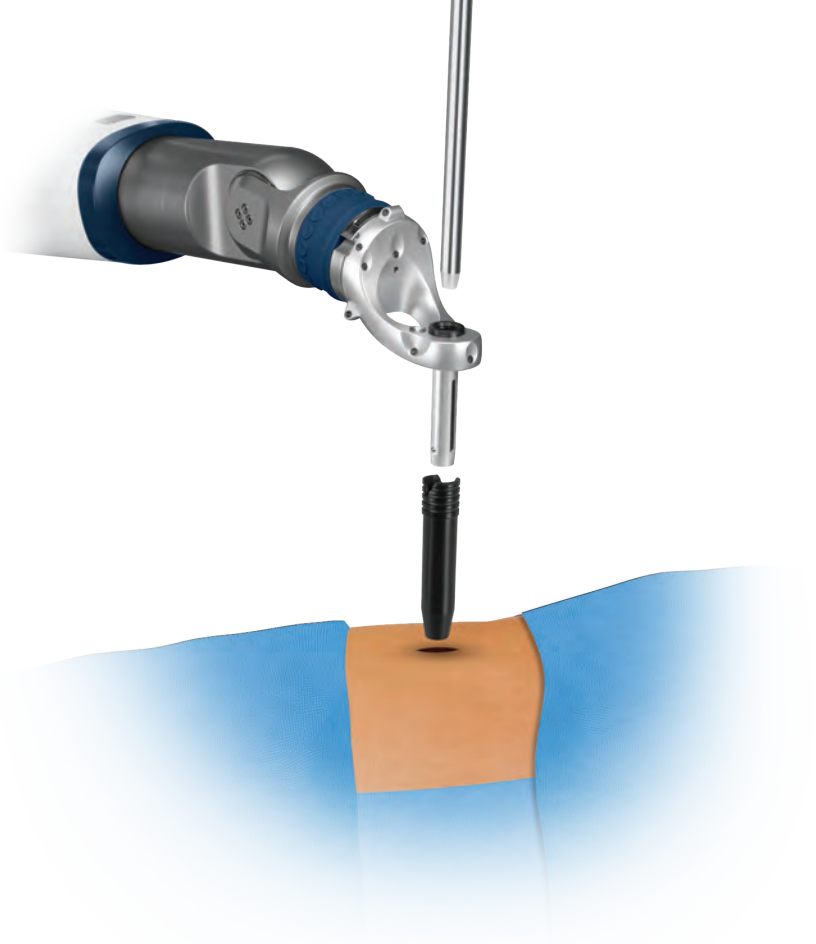
Cannulas, or dilators, can be used for performing minimally invasive or other techniques that require sequential tissue dilation. The cannulas should only be used under trajectory guidance. *Note: The terms "cannula" and "dilator" are used interchangeably.*

Prior to performing sequential tissue dilation, a scalpel may be used through the guide tube to create a skin mark at the desired trajectory. Move the guide tube away from the trajectory using the bracelet and create an incision with a scalpel. Refer to the Scalpel section of this manual for instructions.

	WARNING
	Do not use non-metallic instruments within the guide tube, as they are not identified by the End Effector and the robotic arm will not be prevented from moving while in use.

Once the guide tube is at the desired trajectory, position the outer cannula under the guide tube and above the incision, along the same trajectory. Insert the two inner cannulas into the guide tube and through the outer cannula and rest on the skin. To sequentially dilate the tissue, slowly insert the first (smallest) cannula into the incision using a cannula pusher. Then advance the second cannula in the same manner. Complete tissue dilation by slowly advancing the outer cannula over the inner cannulas. Remove the inner cannulas. Lower the guide tube until it sits just within the outer cannula. Perform surgery through the guide tube and outer cannula.





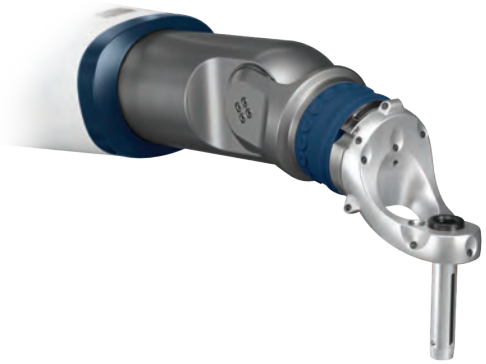
Position outer cannula above incision

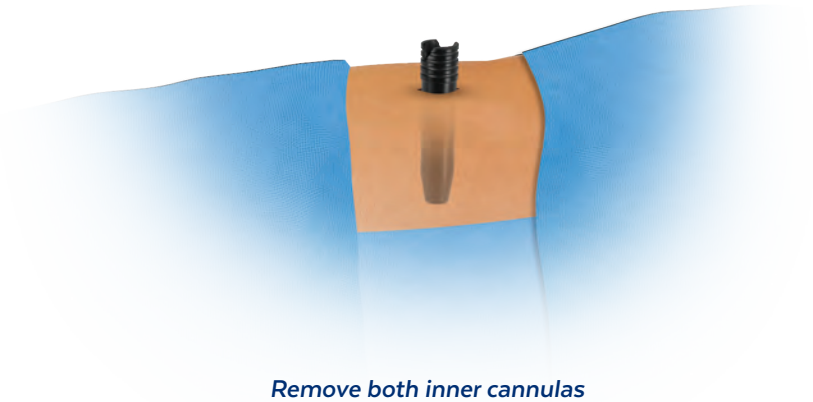
Place cannulas into guide tube and rest on skin

Insert the first inner cannula

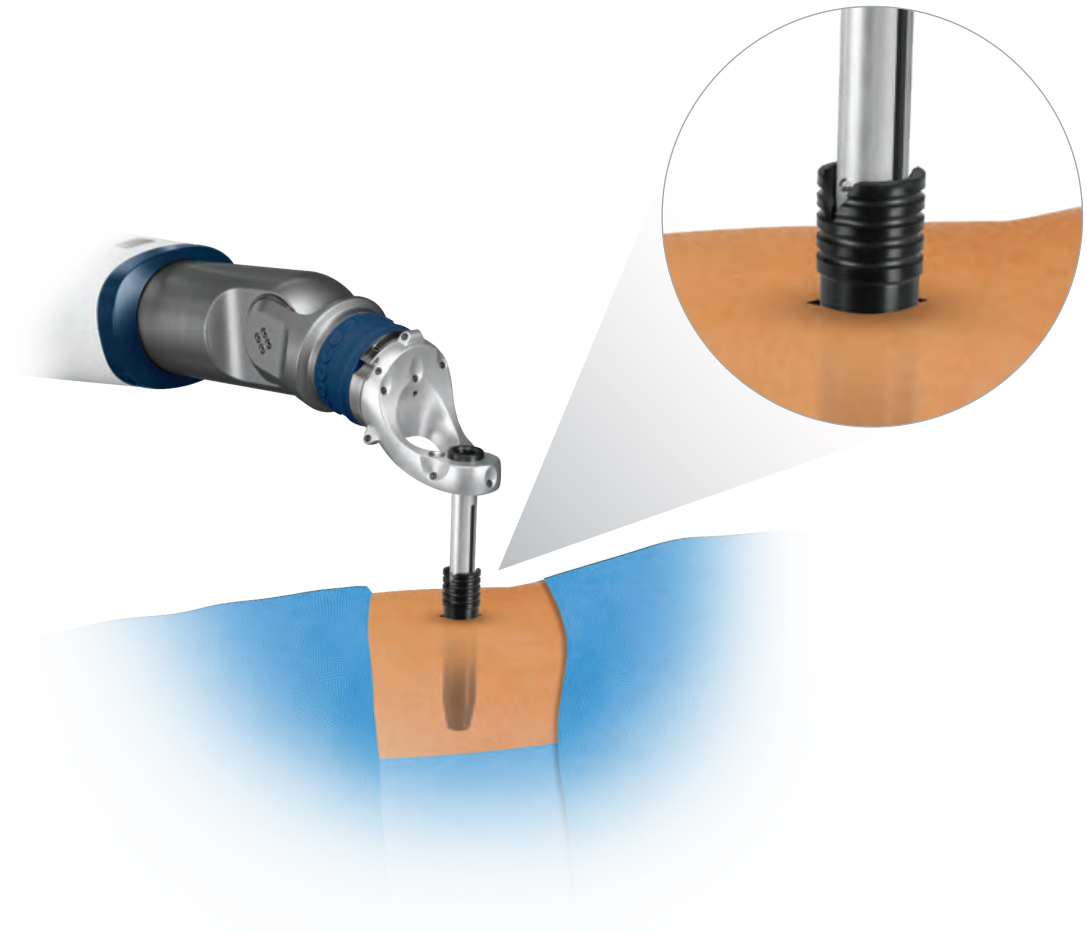
Insert the second inner cannula

Insert the outer cannula





Remove both inner cannulas

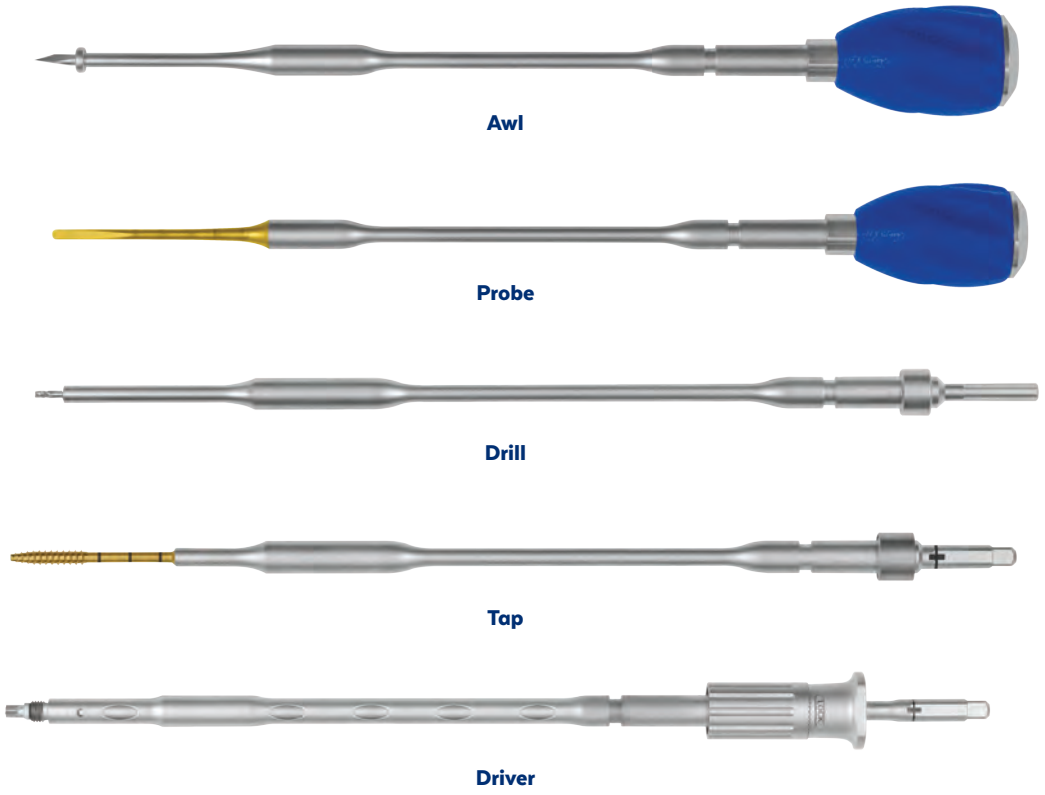


Using the bracelet, lower guide tube until it sits within the outer cannula

Navigated Instruments

The navigated surgical instruments for use with ExcelsiusGPS® include drills, awls, probes, taps, and drivers which may be used to insert Globus screws. These instruments can be used with arrays if navigation is desired or without arrays if navigation is not used. Each instrument and corresponding array must be assembled prior to use. Instruments are identified by a unique array pattern that is recognized by the camera.

Navigated instruments are available for each Globus implant system. Refer to the specific system instrument brochures for more information.



Navigated Surgical Instruments

	WARNING
	When using non-navigated Globus instruments through the End Effector, general trajectory guidance is provided, however navigation is not supported for these instruments.

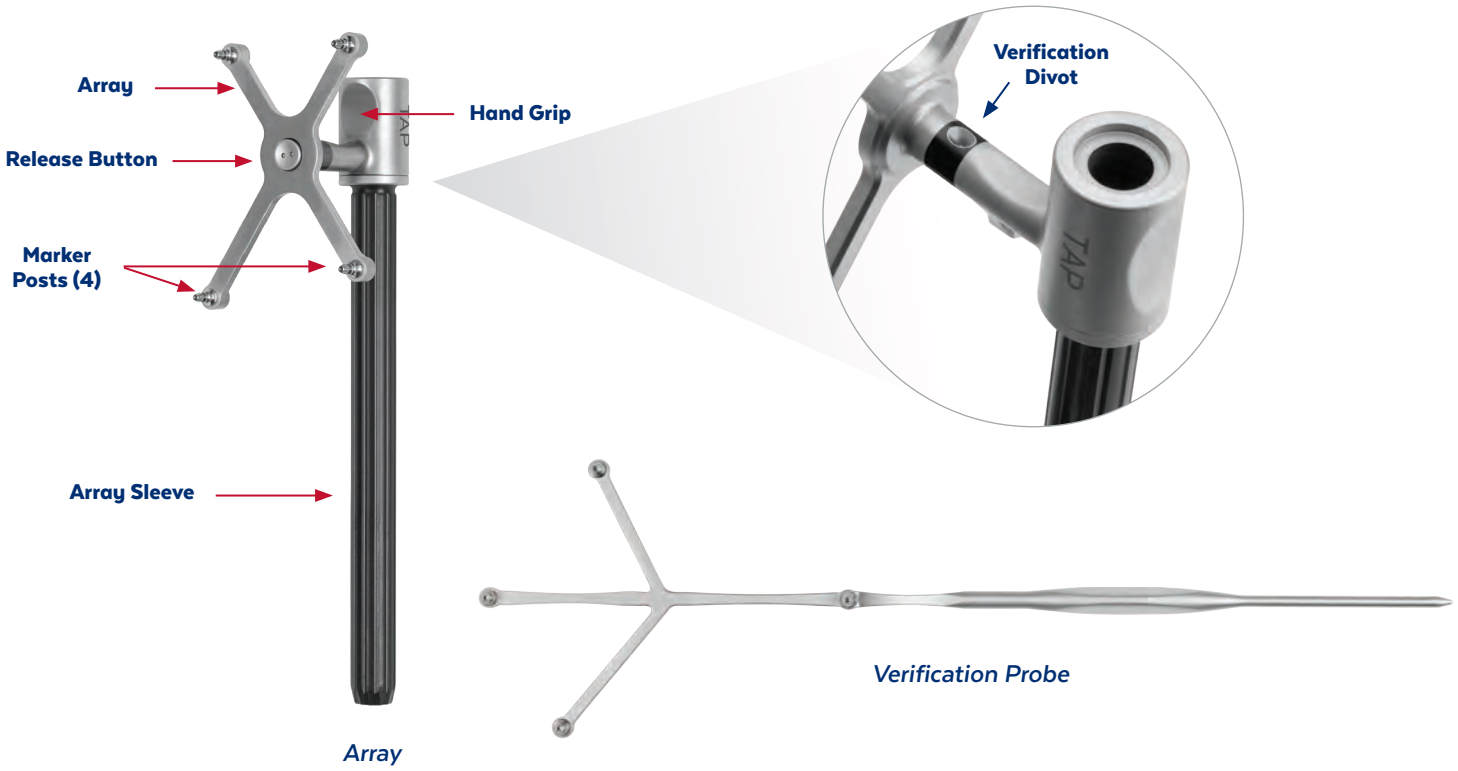
	WARNING
	Third party instruments may not be used with this system.

Arrays

Arrays have 4 posts for attaching reflective markers and are available for use with the surgical instruments. The navigated surgical instruments are assembled to a corresponding instrument array, designed with a unique marker pattern which identifies the instrument type. The array is etched with the specific instrument type, e.g. “AWL”, “PROBE”, “DRILL”, “TAP”, “DRIVER”. Each instrument array has a verification divot used for instrument verification.

The verification probe has a built-in array with posts for the reflective markers and is used to verify each instrument before use.

Arrays used with instruments for the standard 15mm End Effector are identified by a black sleeve. Arrays used with instruments for the 17mm End Effector are identified by a tan sleeve.



PASSIVE TUBE ARRAY

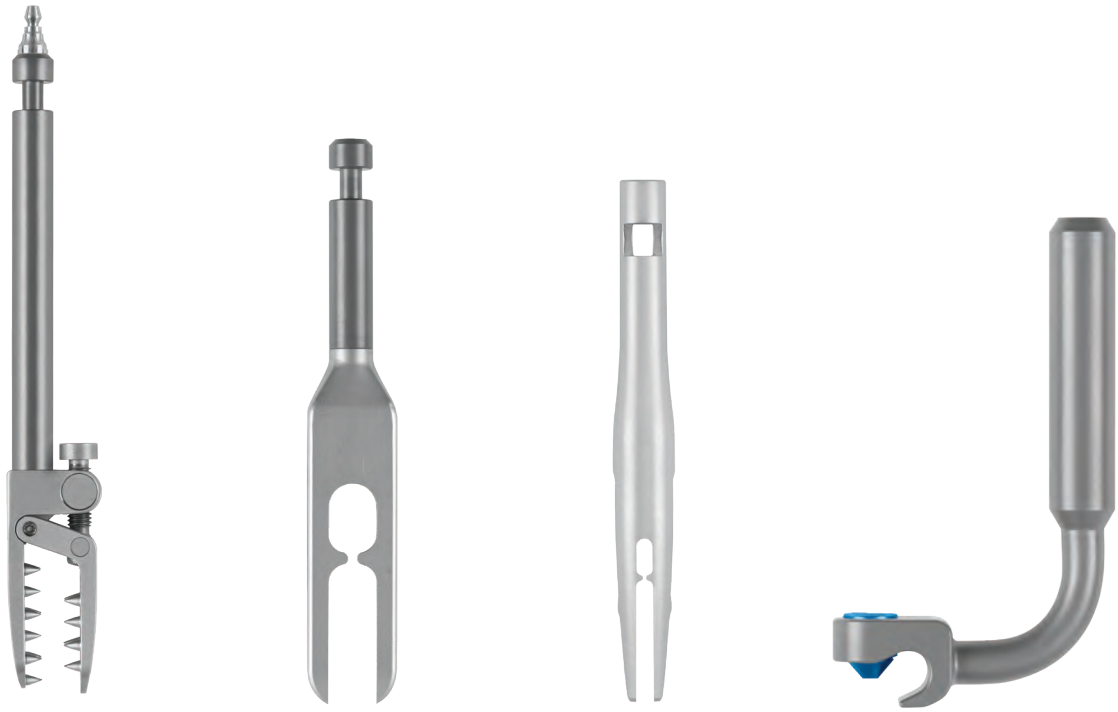
The Passive Tube Array (PTA) is a unique passive array that may be used to identify the location and orientation of the End Effector when it is not active. It is inserted into the guide tube of the 15mm End Effector. The PTA has two array faces, each having four posts. Attach reflective markers to all eight posts

Patient Attachment Instruments

Patient attachment instruments are secured to the patient's rigid anatomy, depending on the specific surgical procedure or preference, and are available in various configurations. These instruments may be secured to a variety of anatomical sites. The rod attachment instrument is designed to attach to an existing spinal rod.

Patient attachment instruments must be safely and rigidly secured to the patient to achieve navigation and guidance accuracy. Verify secure attachment by applying a light force to the distal end of the attachment instrument in all directions. If secure attachment is not maintained during the procedure, the surveillance marker will demonstrate excessive movement; if this occurs, reposition the patient attachment instrument and re-register the patient to the patient images.

Refer to the specific procedure in the Application section of this manual for recommended anatomical locations.



Bone Clamp with Surveillance Marker
6143.2509 Long
6143.2510 Short

Quattro Spike
6143.2515 Long
6143.2516 Short

Low Profile Quattro Spike
6143.2518 Short
6143.2519 Long

5.5mm Rod Attachment
6143.2562 Short
6143.2563 Long

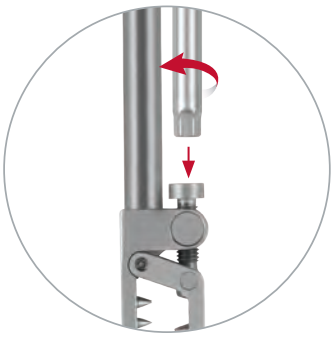
Patient Attachment Instruments

	WARNING
	Ensure rigid fixation of the patient attachment instrument to the patient.

BONE CLAMPS

Bone clamps are clamped onto anatomical structures such as the spinous process, iliac crest, long bone, or any rigid bony structure that can be safely clamped.

The bone clamp is placed onto rigid bony anatomy. The clamp driver is used to tighten the bone clamp. To remove, loosen the bone clamp with the clamp driver, attach the removal tool, and lift up the bone clamp.



Tightening bone clamp using clamp driver

QUATTRO SPIKES

Quattro spikes are inserted into rigid bone of the iliac crest or long bone.

The quattro spike is inserted into rigid bony anatomy and gently impacted with a mallet.

The low profile quattro spike is inserted using a guide post and impaction cap. Find the desired anatomy using the guide post. Place the patient attachment instrument over the guide post. Attach the impaction cap (for low profile quattro spike). Gently impact the assembly with a mallet to insert into bony anatomy. Remove the impaction cap and guide post from the spike.

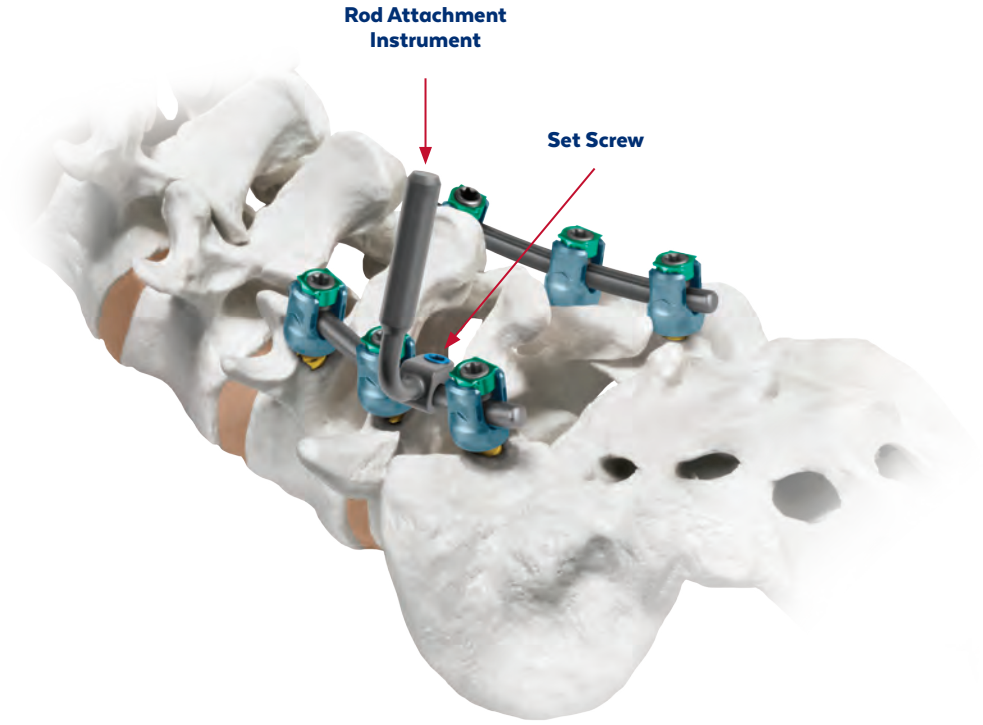
Inserting the Low Profile Quattro Spike

ROD ATTACHMENT INSTRUMENT

The rod attachment instrument is designed to attach to an existing spinal rod (4.5mm to 6.35mm diameter).

Position the instrument on the existing spinal rod and tighten the set screw with a driver. Ensure a rigid connection.

To remove, loosen the set screw and disengage from the rod.



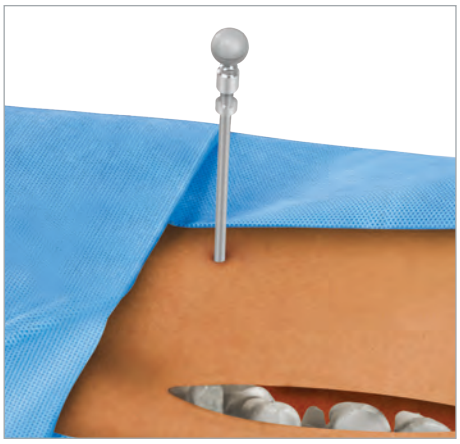
Inserting the Rod Attachment Instrument

Surveillance Marker

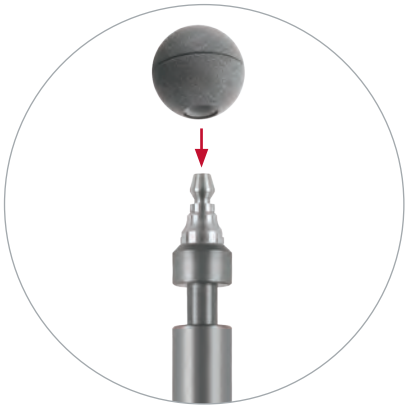
The surveillance marker is a single reflective marker used to monitor a shift in the Dynamic Reference Base (DRB). Surveillance markers may be used alone or in conjunction with a bone clamp.

Surveillance markers are directly inserted into the iliac crest or long bone, or may be attached to the spinous process using a bone clamp. To use a bone clamp with the marker, attach a disposable marker onto the tip of the bone clamp. Use the clamp driver to secure the bone clamp. Verify that the clamp is rigidly secured.

Refer to the specific procedure in the Applications section of this manual for recommended anatomical locations.



Surveillance Marker



Attaching Reflective Marker

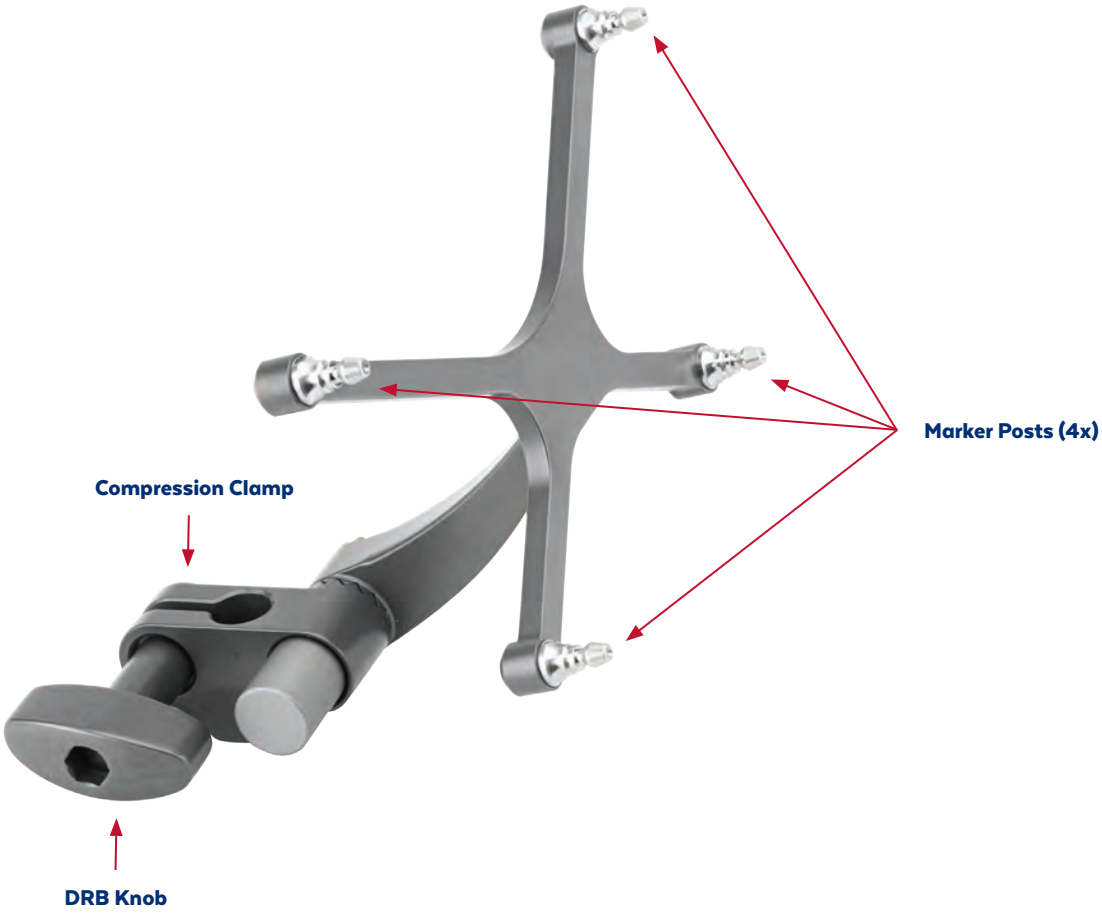
Surveillance Marker with Bone Clamp

	WARNING
	Under normal operation, movement should not occur between the DRB and the surveillance marker.

Registration Instruments

The Dynamic Reference Base (DRB) and patient attachment instruments are used in the patient registration process.

The DRB is an array with 4 posts for reflective markers and allows the camera to track the location of the patient. The DRB may be attached to any of the patient attachment instruments using the knob and compression clamp.



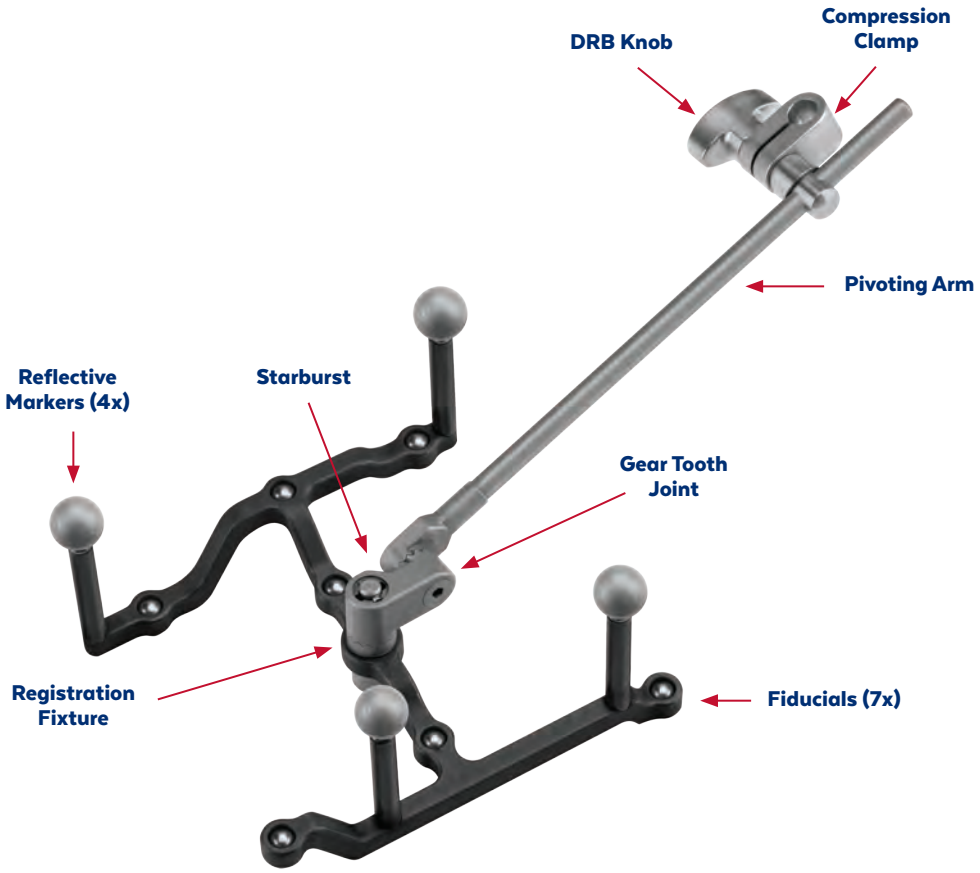
Dynamic Reference Base

Registration Fixtures

INTRAOPERATIVE CT REGISTRATION FIXTURE

The intraoperative CT registration fixture, consisting of a registration fixture and pivoting arm, allows for any intraoperative CT image to be used with the ExcelsiusGPS® software application. The pivoting arm and registration fixture are assembled prior to use by matching the starburst gears and snapping the two components together.

The intraoperative registration fixture is placed onto a patient attachment instrument by clamping the compression clamp onto the shaft of the attachment instrument, allowing the fixture to hover over the surgical site. The fiducials are detected automatically in the intraoperative scan and are used to register the patient's anatomy during the scan to the DRB, which is tracked by the camera throughout the procedure. The reflective markers are detected by the camera. Once the registration is transferred to the DRB, the intraoperative registration fixture is removed to provide access to the surgical site.



Intraoperative CT Registration Fixture and Pivoting Arm

Fluoroscopy Registration Fixture

The Fluoroscopy Registration Fixture allows for any intraoperative fluoroscopic image to be used with the ExcelsiusGPS® software application. The fluoroscopy fixture is attached to the image intensifier of the fluoroscope using the integrated clamps. The fluoroscope and Fluoroscopy Registration Fixture are draped and the reflective markers are placed on the fixture outside of the drape. The fixture should be positioned such that the reflective markers are seen by the camera in all intended fluoroscope positions (AP, lateral, etc).

Fluoroscopy Registration Fixture

Robotic Arm Motion

The ExcelsiusGPS® robotic arm positions the End Effector to guide instruments for screw insertion at the desired trajectory. The surgeon manually performs surgery while the instruments are aligned in the desired trajectory for accurate screw placement. *Note: The terms "screw plan", "screw trajectory" and "trajectory" are used interchangeably in this manual.*

Motion of the robotic arm is only allowed with continuous pressing of the bracelet or foot pedal. The arm is manually moved by the user in Wrist mode or is automatically moved to the selected trajectory in Trajectory mode.

In Wrist mode, the arm may be moved manually to any position within reach of the arm.

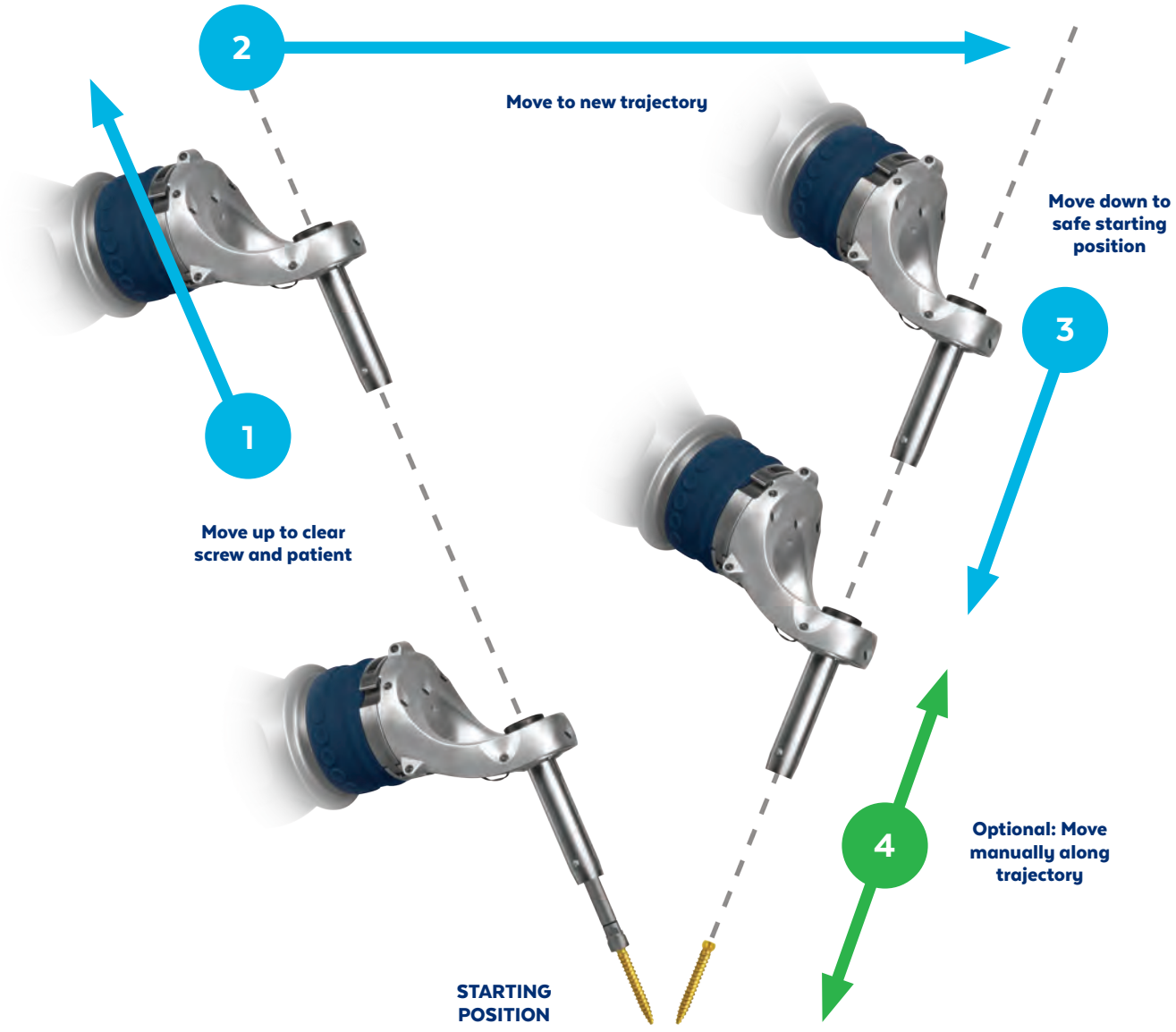
In Trajectory mode, the arm is automatically moved from the current position to the next screw plan when ready or may be moved manually along a selected trajectory.

When moving from one screw plan to the next, the arm moves outward along the current trajectory to a safe distance (200mm) from the surgical site before moving to the new trajectory and downward along the current trajectory to the anatomy.

ROBOTIC ARM MOTION MODES

Mode	Software	User Action	Automatic Motion	Manual Motion
Wrist Mode	No Plan Selected	Press Foot Pedal or Squeeze Bracelet	n/a	User may move arm in the desired direction
Trajectory mode	Plan Selected	Press Foot Pedal or Squeeze Bracelet	Arm moves automatically to new screw trajectory	After reaching the trajectory, user may move arm along trajectory only

Automatic motion of the arm occurs when moving the guide tube from the current position (either initially or at a current trajectory) to a new screw plan. Once the End Effector and attached guide tube have moved to a new screw plan, the guide tube is locked onto the trajectory and can be moved up and down along the trajectory.



End Effector motion when moving from one trajectory to the next. 1, 2, and 3 are automatic movements; 4 is manual and optional.

Automatic motion of the robotic arm may be stopped by the user, stopped by the system, or prevented.

- To stop motion at any time, press the Emergency Stop button located on the base station.
- End Effector detects a force greater than 50N (11 lbs) in the direction opposite of motion.
- End Effector detects a force greater than 100N (22 lbs) in any direction.
- Motion is also stopped in Trajectory mode when the DRB or the End Effector is not in view of the camera.
- Motion is prevented when the sensing ring in the guide tube detects a metallic instrument.
- When a trajectory is selected, motion of the arm with guide tube is only allowed along the trajectory.

STOPPING OR PREVENTING ROBOTIC ARM MOTION

Method
Emergency Stop button pressed
End Effector detects a force greater than 50N (11 lbs) in the direction opposite of motion
End Effector detects a force greater than 100N (22 lbs) in any direction
Dynamic reference base not in view of camera (Trajectory mode only)
End Effector not in view of camera (Trajectory mode only)
Sensing ring detects a metallic instrument in the guide tube

If the robotic arm is not able to reach a safe starting location due to its current position, an error message is shown. The message states “The arm cannot move back any further along the current End Effector trajectory.” Acknowledging this message enables the arm to move to the selected plan trajectory from its current position. The user may choose to move forward with the planned trajectory because the shorter starting position is acceptable. If the shorter starting position is not acceptable, a new trajectory must be used or the base must be repositioned.

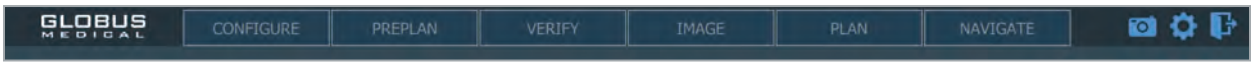
- To select a new trajectory, the user clears the selected trajectory and positions the robotic arm using the bracelet to a clear position. The bracelet provides flexibility for the user to move the arm around an obstacle.
- To reposition the base, the stabilizers on the casters are disengaged, the station is moved to the desired location, and the stabilizers are re-engaged. Registration is unaffected because the patient reference (attachment instruments and DRB) has not moved with respect to the patient.

Prior to use, confirm that the robotic arm can be moved using the wrist mode and arm position buttons on the control panel.

System Software

The system software is responsible for all motion control functions, navigation functions, data storage, network connectivity, user management, case management, and safety functions.

The top navigation bar guides the user through individual screens for each step of the procedure.



The respective tab for each step is highlighted when selected and the corresponding screen displayed. The activities performed under each tab are shown in the table below.

SYSTEM SOFTWARE TABS

Tab	Meaning
CONFIGURE	Surgeon, imaging workflow, and anatomy selection
PREPLAN	Implant system selection and desired anatomical location identification
VERIFY	Navigated instrument verification
IMAGE	Loading of patient images used for planning and navigation
PLAN	Estimation of desired implant location with respect to patient images
REGISTER	Preoperative CT image with planned screws merged with intraoperative fluoroscopic images
NAVIGATE	Screw plan with real-time display of navigated instrument and implant (actual plan) with respect to patient images

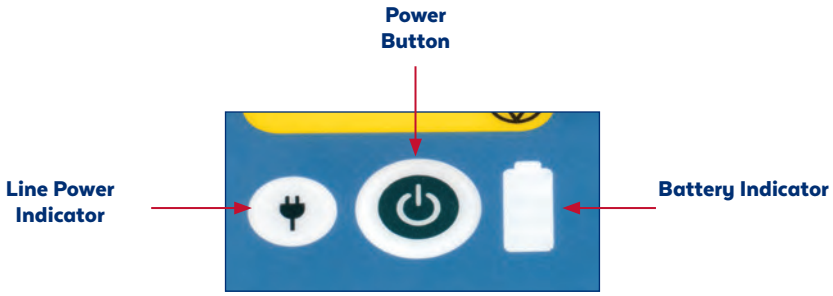
SYSTEM SOFTWARE ICONS

Icon	Meaning	Action
	Return	Click to return to the login page
	Settings	Click to access the settings
	Camera	Click to take a screenshot

SYSTEM SETUP

POWER UP

Press the Power Button on the control panel to turn the system on. The Power Button is illuminated when the system is on.



UNDOCKING AND POSITIONING CAMERA STAND

To release the camera stand from the Robotic Base Station, unwrap the cord holding the monitor arm and the camera arm together, and pull up on the release handle located on the camera stand. Once the legs of the camera stand have cleared the base station, they will automatically release and move outward.

Camera Stand undocking

	CAUTION
	The camera position sensor requires a warm-up time every time it is powered on. The power LED on the camera will flash while the position sensor warms up. Once the LED is steady, the system is ready for use. The warm-up time is typically two (2) minutes if the position sensor is stored at low temperatures, the warm-up time may be longer.

Unwrap the camera cord from the cord holder and plug into the connector panel on the base station.

Move the camera to the O.R. table and engage the wheel brakes by stepping on the lever located on the wheel. Align the camera to view the surgical field.

Connection of camera to connector panel

Camera positioning

Press and hold the laser button located on the positioning handle of the camera to activate the camera's alignment laser and adjust the position so the laser points to the center of the surgical field.

Pressing laser button to align

Draping

A special surgical drape is designed for the ExcelsiusGPS® Robotic Base Station. Drape the robotic arm, monitor, and front of the base station by following the instructions detailed in the package insert provided with the sterile drape.

System with sterile drape

	WARNING
	Follow the instructions in the sterile drape instructions for use to ensure the sterile field is not compromised.

	WARNING
	Avoid sharp objects near the sterile drapes.

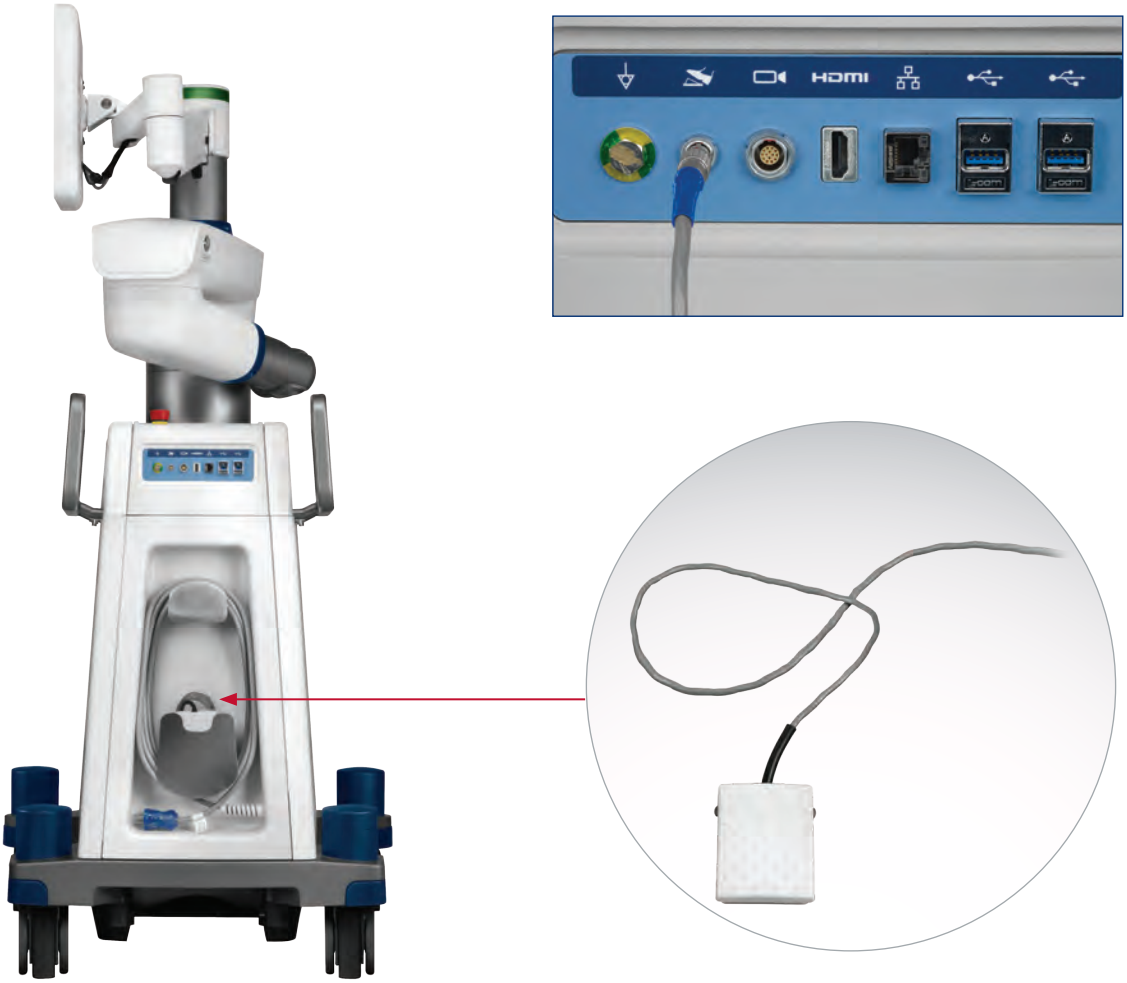
Positioning the Robotic Base Station

Unwrap the foot pedal from the foot pedal basket and position it on the level ground at a comfortable distance from the operator's feet. The foot pedal is IPX68 rated and is acceptable for use in areas where liquids are likely to be found. Plug the foot pedal cord into the connector panel. The foot pedal allows the arm to move to the active trajectory, similar to the action of the bracelet on the lower arm.

Position the Robotic Base Station next to the patient at a comfortable distance from the surgeon. Move the robotic arm using the bracelet around the planned trajectories to ensure the arm can reach all locations before engaging the stabilizers.

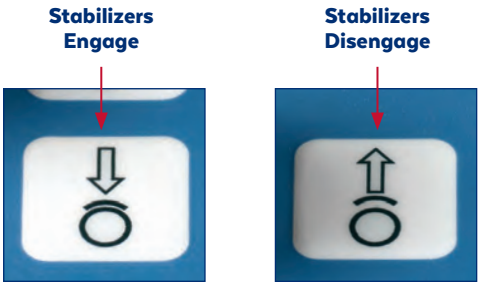
	**WARNING** Do not move the patient or surgical table while a planned trajectory is active.

	**WARNING** The stabilizers on the casters must always be in the engaged position prior to activating the robotic arm.



Foot pedal cable connection

Press the Stabilizers Engage button on the control panel to lower the stabilizers on the casters. The button is illuminated when the stabilizers are engaged.



WARNING
The stabilizers on the casters must always be in the engaged (down) position prior to activating the robotic arm.

Attaching End Effector to Robotic Arm

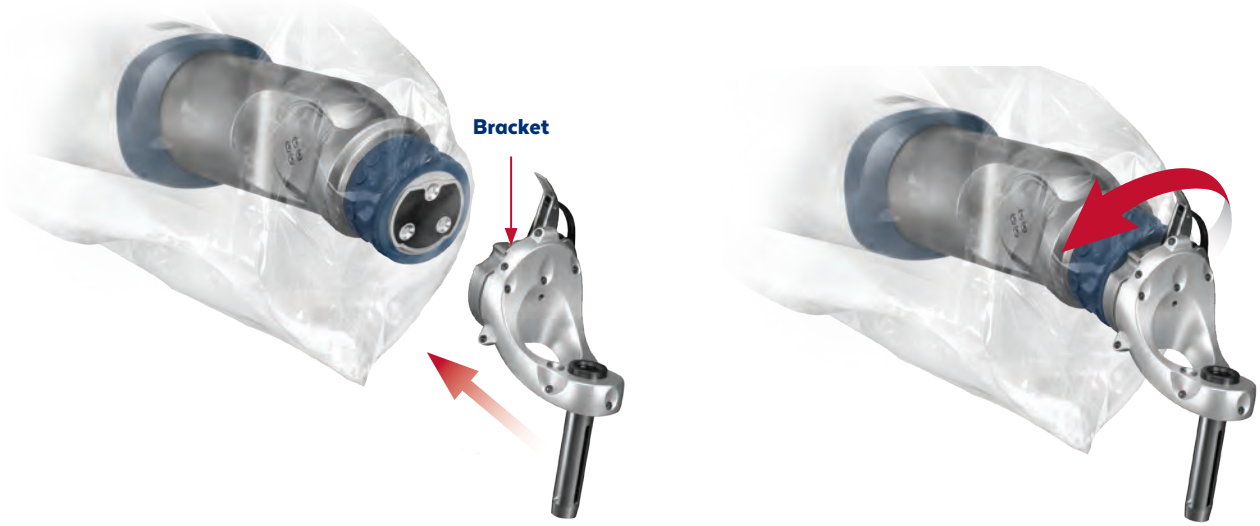
The End Effector connects to the robotic arm through the interface plate over the custom drape. A magnetic assist helps to position and self-align the End Effector.

The End Effector is equipped with a drape-friendly clamp that allows it to be removed and reattached up to 3 times during a procedure without damaging the drape.

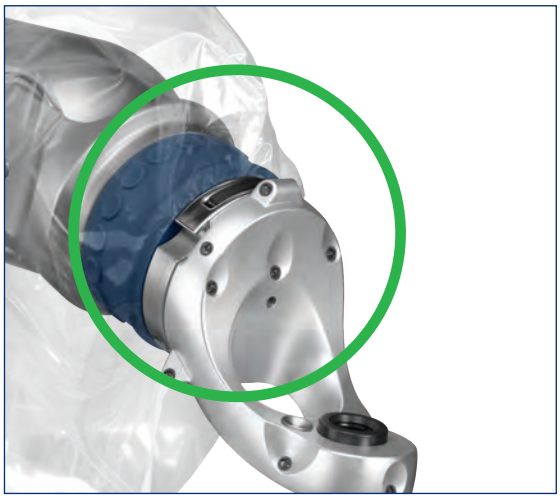
Robotic Arm interface plate for connection to End Effector

WARNING
Sterile draping must be replaced if the End Effector is removed and reattached more than three times.

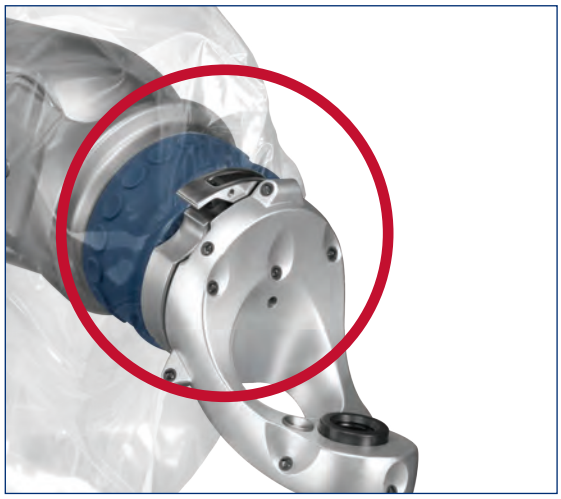
Open the brackets on the End Effector and place the End Effector on the interface plate by aligning the V grooves and alignment spheres. Squeeze the brackets on both sides of the End Effector and press the handle down to lock into place.



Attaching End Effector to Robotic Arm



CORRECT

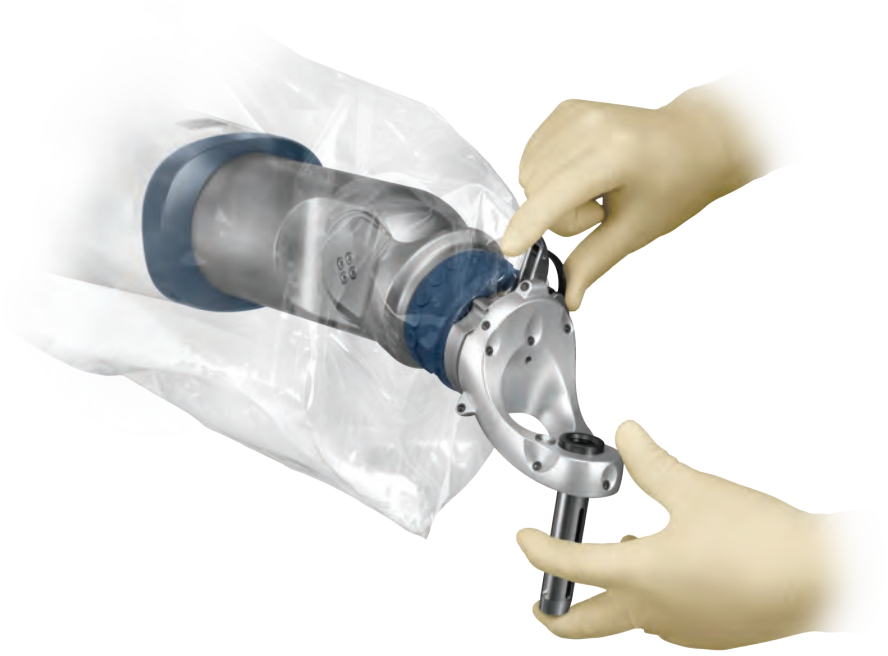


INCORRECT

	WARNING
	If the End Effector is not correctly positioned on the interface plate, the brackets will not close completely. The system should not be used if the End Effector is not properly mounted.

REMOVING THE END EFFECTOR

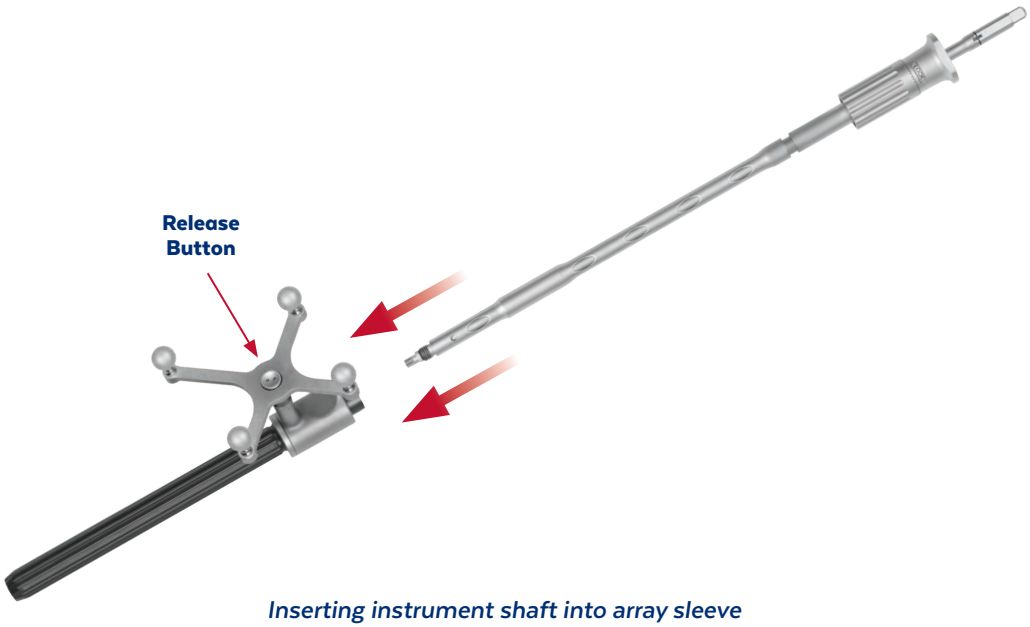
To remove the End Effector from the robotic arm, pull up on the handle to release the spring and side brackets.



Removing End Effector from robotic arm

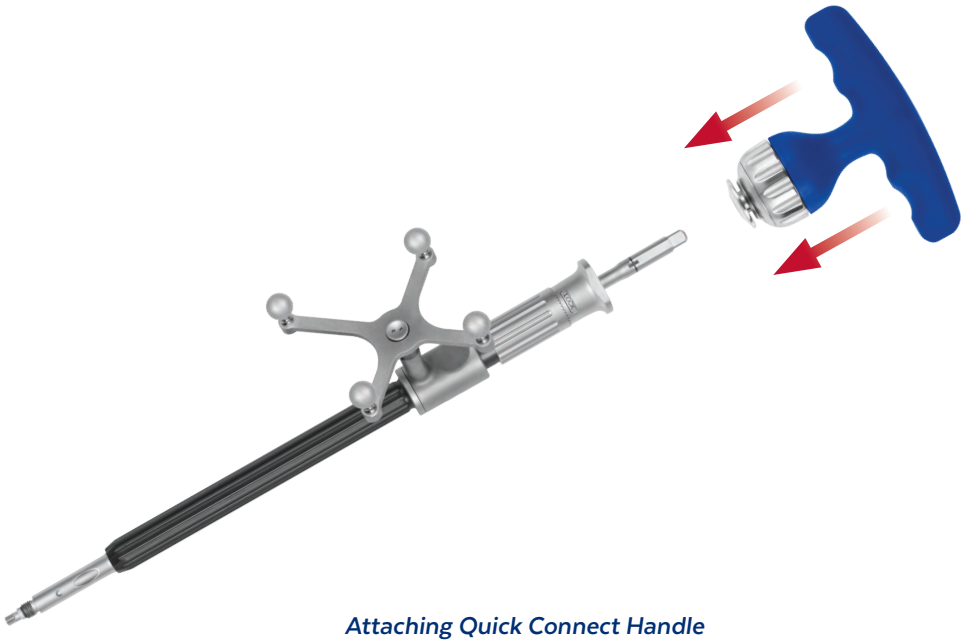
Surgical Instrument Assembly

To assemble the surgical instruments for navigation, press the release button on the array sleeve and insert the instrument shaft into the sleeve of the respective instrument array. Slide the shaft through the sleeve until it clicks into place. Gently pull up on the instrument shaft to confirm it is locked.



Inserting instrument shaft into array sleeve

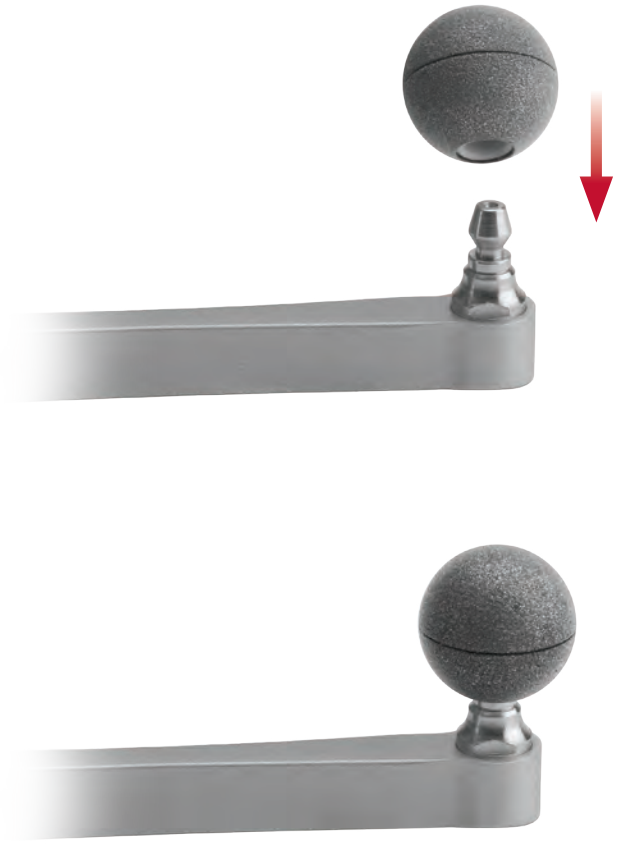
Attach the Quick Connect Handle on the proximal end of the shaft when needed. To remove the instrument from the array, push the release button located on the middle of the array.



Attaching Quick Connect Handle

Surgical Instrument Assembly

Attach the disposable reflective markers to each of the marker posts of each instrument assembly. Ensure that the markers are fully seated on the posts as shown below.



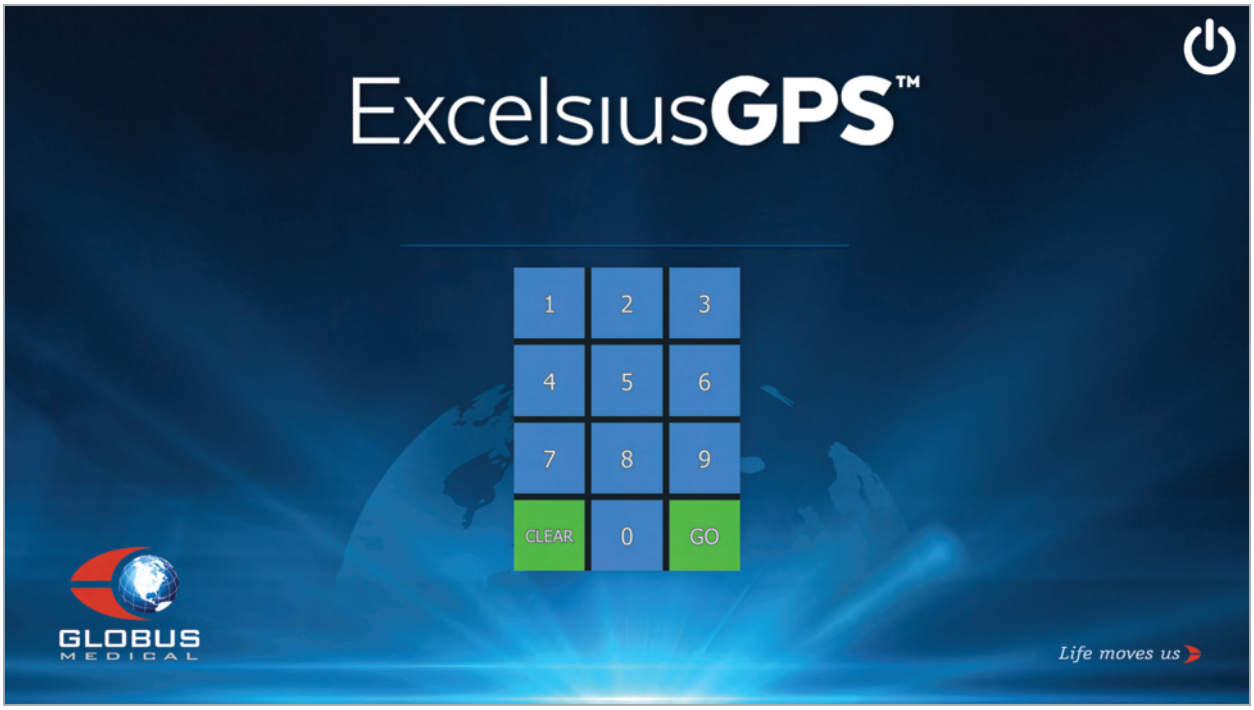
Marker attached to marker post

	CAUTION
	Check reflective markers prior to assembly to ensure they are clean and to maintain proper handling throughout assembly and procedure.

	WARNING
	Reflective markers are single use only.

Login

To login, type the four-digit pin on the touch screen of the monitor. The four-digit pin is provided during system installation and can be changed by contacting Tech Support.

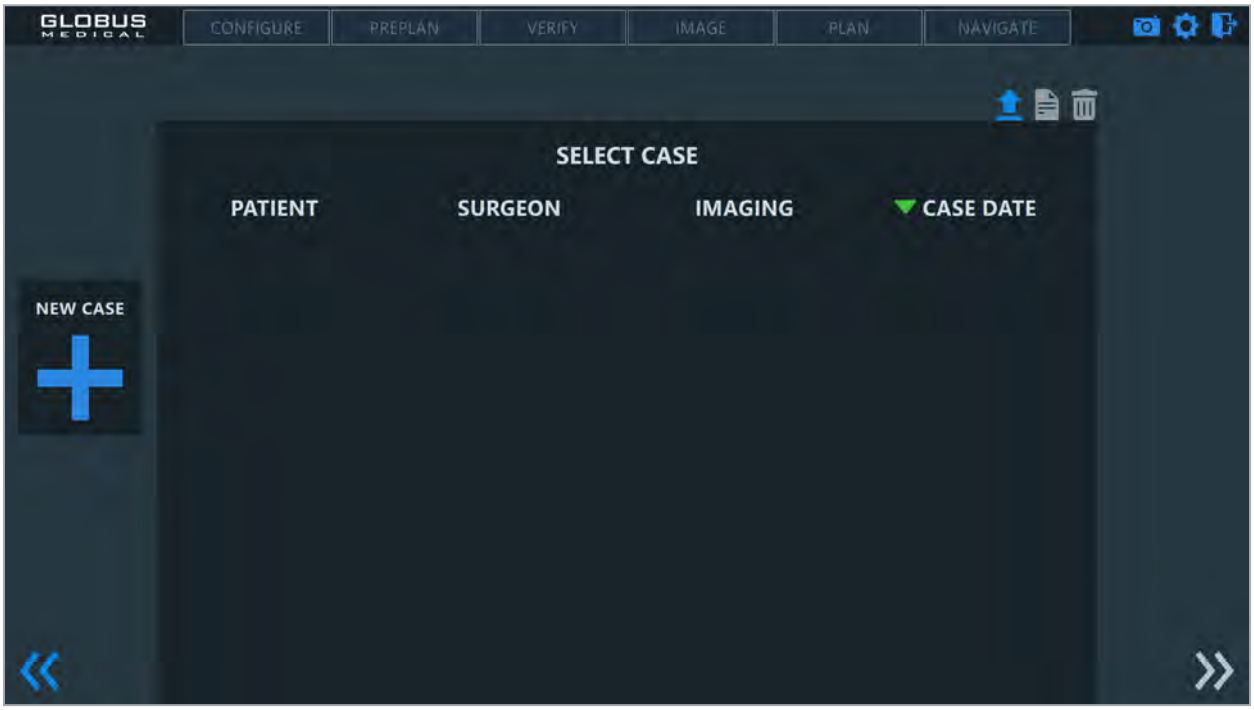


Case Management

A case encompasses all of the data associated with performing a procedure, including surgeon preferences, medical images, and plans.

After logging in, the SELECT CASE page is displayed on the monitor.

To select an existing case, select the corresponding row from the case list. To start a new case, click the new case icon. To load a preoperatively planned case, click the upload button and choose case. Click the right arrows to advance to the next tab.

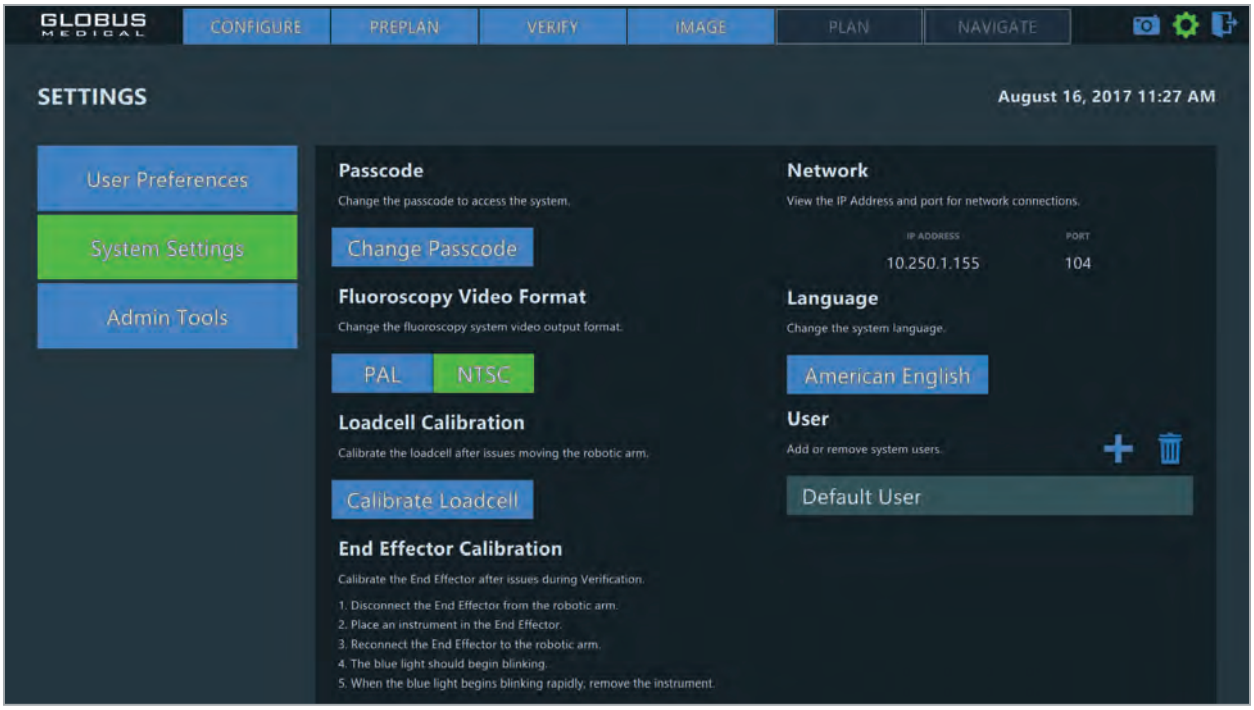


SYSTEM SOFTWARE ICONS

Icon	Meaning	Action
	Add New Case	Click to start a new case
	Advance to next tab	Click to advance to the next tab
	Return to previous tab	Click to return to the previous tab

Setting Up Preferences

Select the Settings icon to set preferences. The system uses default settings if no preferences are setup prior to a procedure. Preferences are saved for each user.



To adjust volume control or time out control preferences, click the plus or minus icon to increase or decrease the volume and time out settings. The default is set at 50% volume and a 60 minute time out session.

NETWORK CONFIGURATION

The system is pre-configured to use Dynamic Host Configuration Protocol (DHCP) to negotiate an Internet Protocol (IP) address when connected to a router. Contact Tech Support if these settings need to be changed.

LANGUAGE PREFERENCES

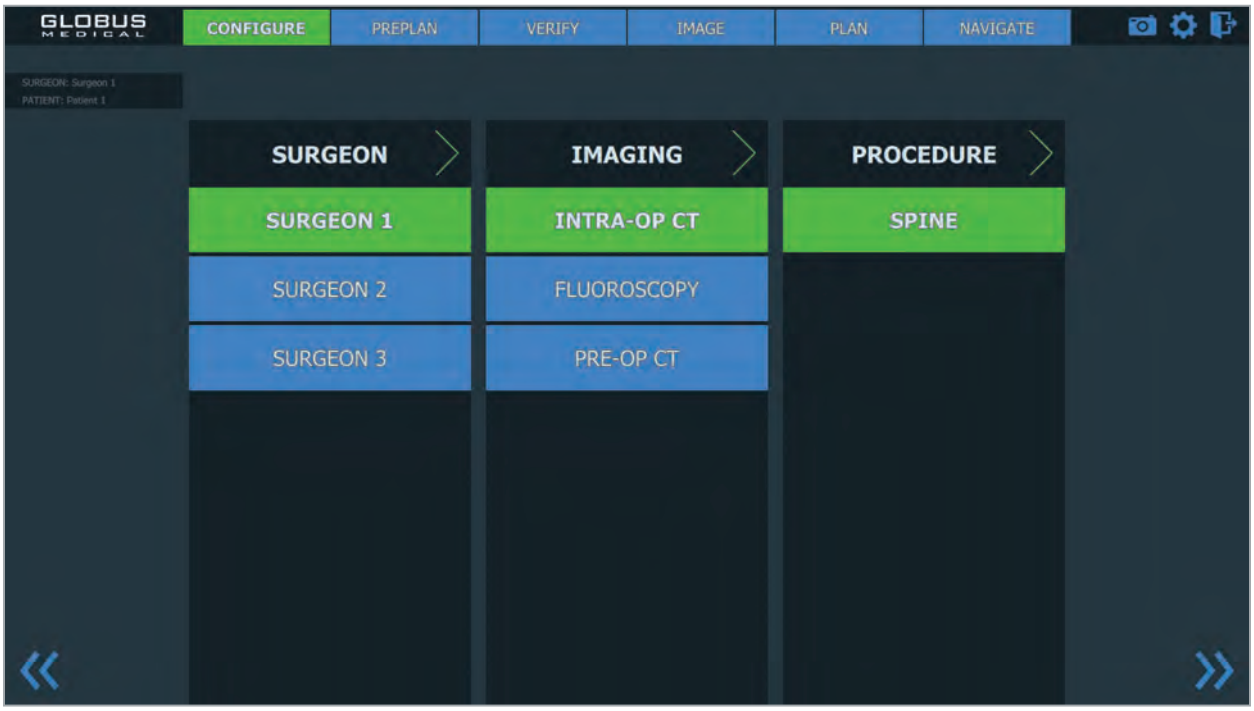
The system language is set during system installation. Contact Tech Support if a different language is desired.

DATE AND TIME

The system date/time is set during system installation. Contact Tech Support if the date and/or time is not correct.

APPLICATIONS

Spine surgical procedures are supported by the ExcelsiusGPS® system. The CONFIGURE tab displays procedure types.



Spine Procedures

Spinal surgical applications supported by the ExcelsiusGPS® system are listed below.

SUPPORTED SPINE PROCEDURES

Procedures	Patient Position
Posterior Cervical	Prone
Posterior Thoracic	Prone
Anterolateral Thoracic	Lateral
Posterior Lumbar	Prone
Lateral Lumbar	Lateral

Globus spinal implant systems compatible with the ExcelsiusGPS® system are listed below.

COMPATIBLE SPINAL IMPLANT SYSTEMS

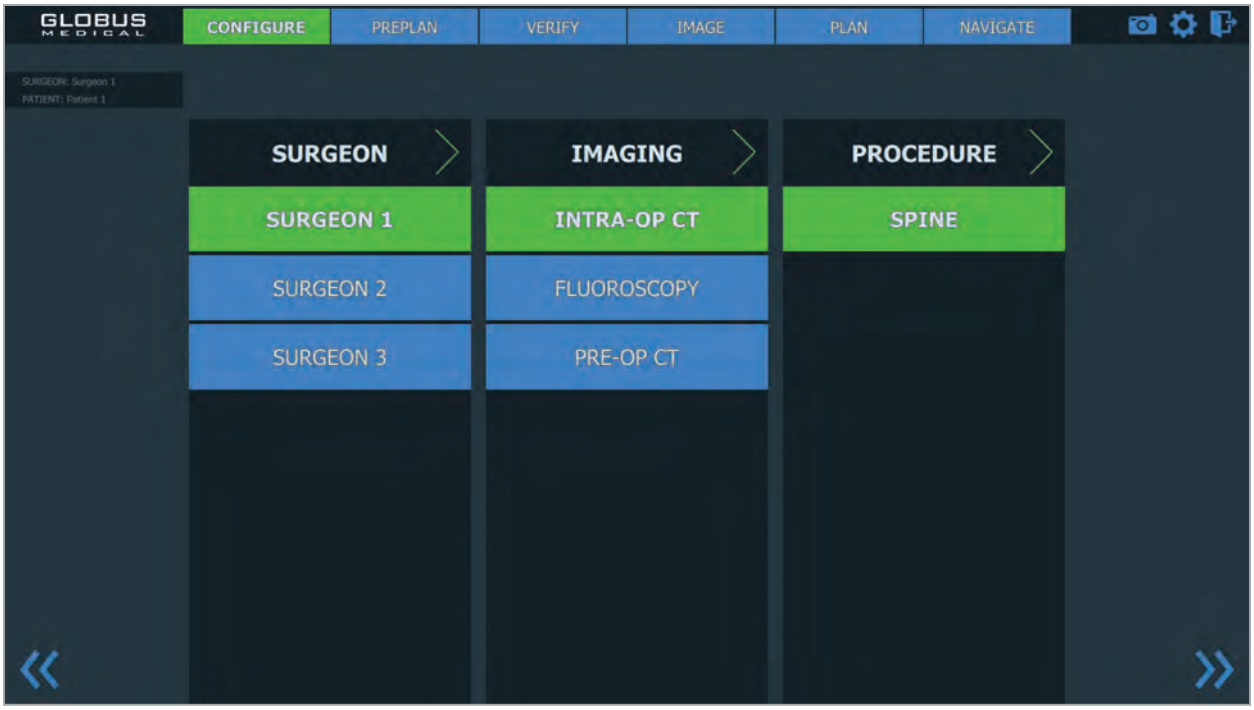
CREO® Stabilization System
REVERE® Stabilization System
REVOLVE® Stabilization System
ELLIPSE® Occipito-Cervico-Thoracic Spinal System
QUARTEX® Occipito-Cervico-Thoracic Spinal System
SI-LOK® Sacroiliac Joint Fusion System

Procedure Setup

CONFIGURE TAB

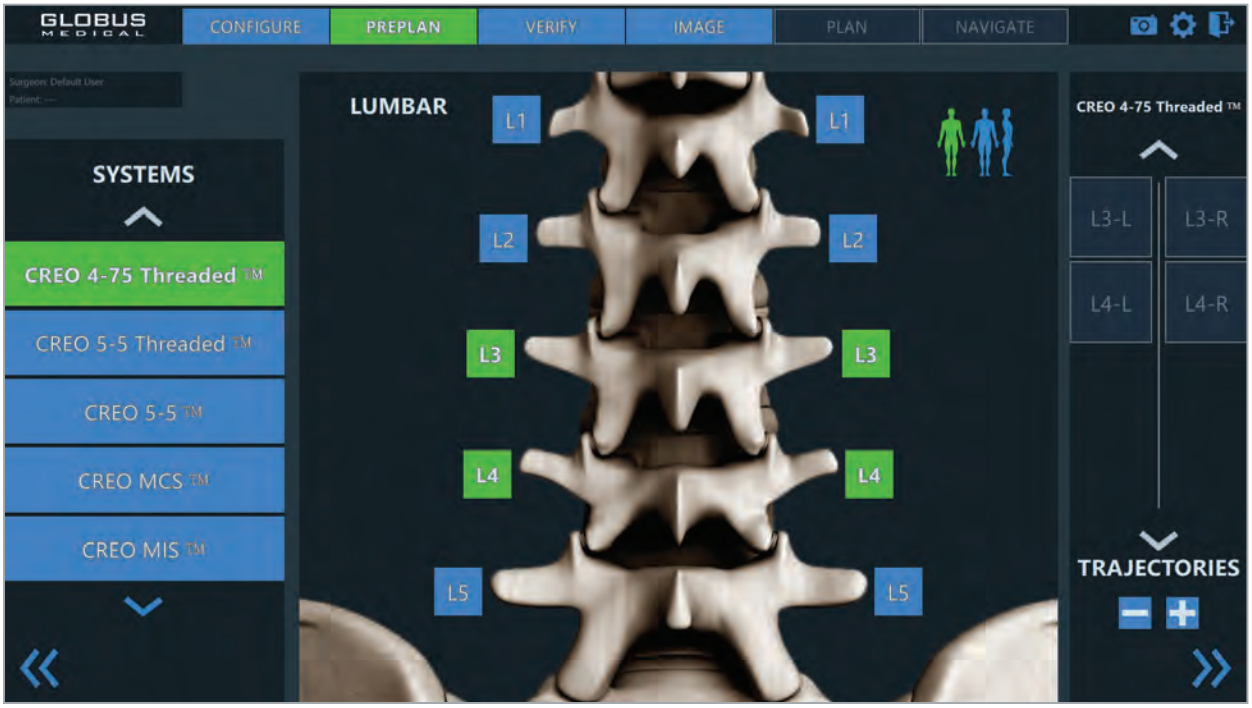
After selecting a case, the CONFIGURE tab is displayed on the monitor.

Using the CONFIGURE tab, select the surgeon, the imaging modality, and the procedure type. Click the right arrows to advance to the next tab.



PREPLAN TAB

Using the PREPLAN tab, select the implant system, desired vertebral level and orientation, and click the desired implant location on the anatomical model. Click the right arrows to advance to the next tab.

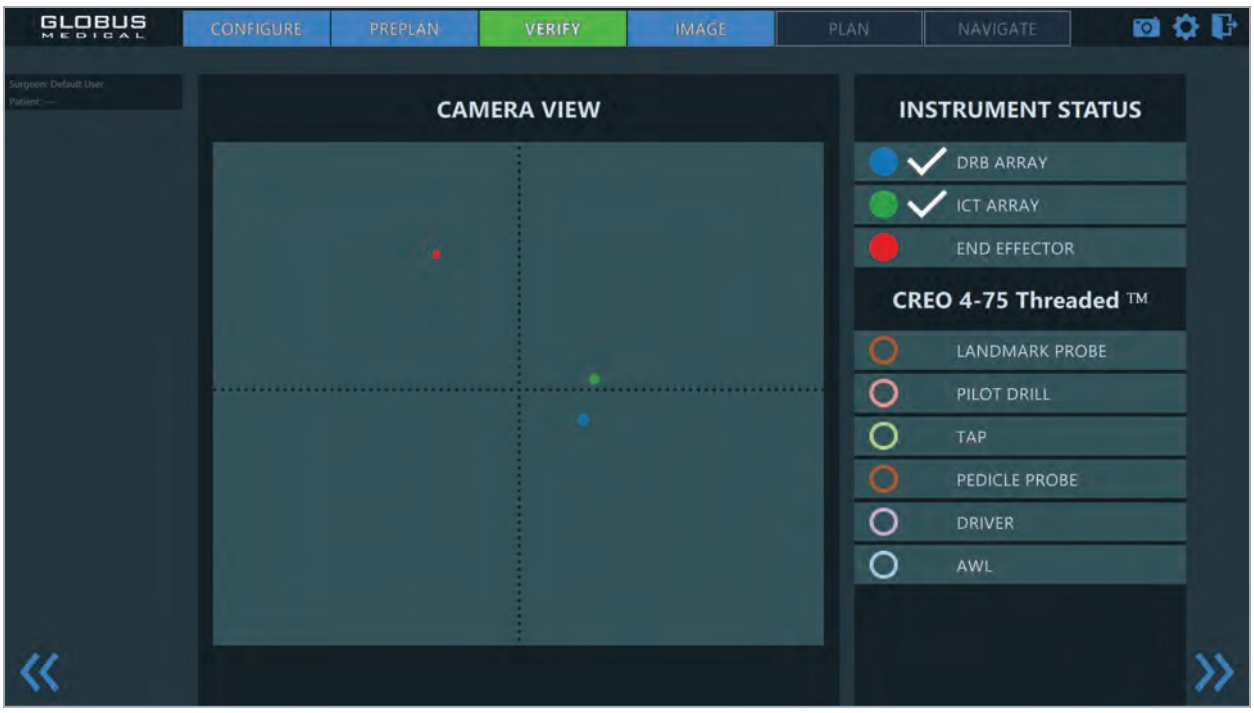


PREPLAN TAB ICONS

Icon	Meaning	Action
	Selection of spinal levels	Double-click on the spinal level squares to select or de-select for planning

VERIFY TAB

The VERIFY tab displays navigation details including visibility, location, and verification status of the instruments selected on the PREPLAN tab. Verification is used to ensure all instruments are accurate and have not been damaged during handling and sterilization. The operator must assemble all instruments prior to verification (see Surgical Instrument Assembly).



The VERIFY tab shows CAMERA VIEW and INSTRUMENT STATUS.

CAMERA VIEW is a real-time view from the perspective of the camera with color circles indicating instrument location. A solid colored circle indicates that the instrument is visible by the camera, while a hollow circle indicates that it is not visible. The colored circle grows larger as the instrument is moved closer to the physical camera and smaller as it moves away from the camera. The ideal distance from the camera is approximately 2 meters or 6 feet.

INSTRUMENT STATUS lists each instrument and its verification status with corresponding color circles to identify each instrument. Verification status symbols are shown in the table below. When no icon appears, the instrument is not verified.

VERIFICATION STATUS SYMBOLS

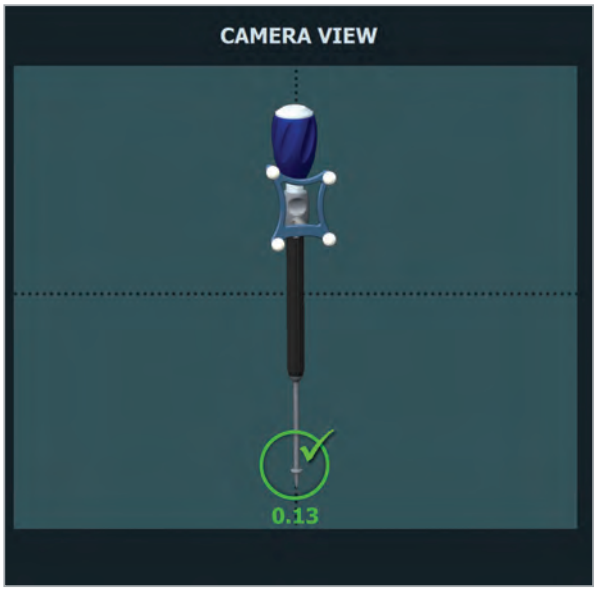
Symbol	Meaning
	Successful Verification
	Failed Verification

INSTRUMENT VERIFICATION

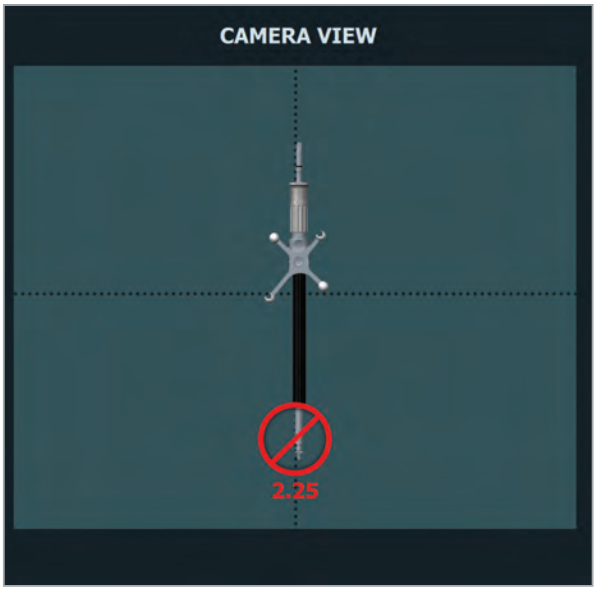
Verify each instrument as follows:

- Place the tip of the instrument to be verified into a verification divot. Divots are located on the End Effector and on any other instrument array for convenience.
- Ensure both instruments are visible and held steady.
- A pop-up screen appears on the VERIFY tab to indicate the verification progress.

Once verification is complete, verification status is indicated on the screen with the tip error displayed in millimeters (mm). If verification has failed (red crossed circle), verification must be repeated until it is successful (green circle). When all instruments are successfully verified, click the right arrows to advance to the next tab.



Verification successful



Verification failed

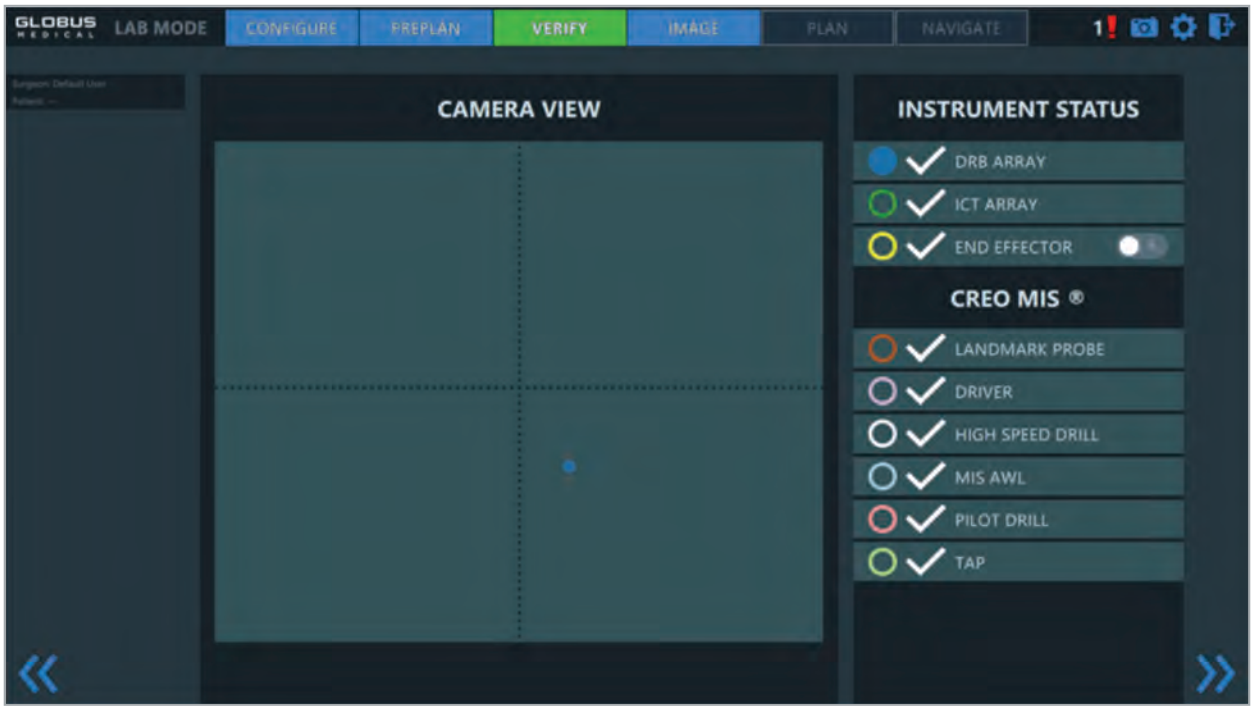
	CAUTION
	Do not use with navigation instruments that are not intended for use with this system.

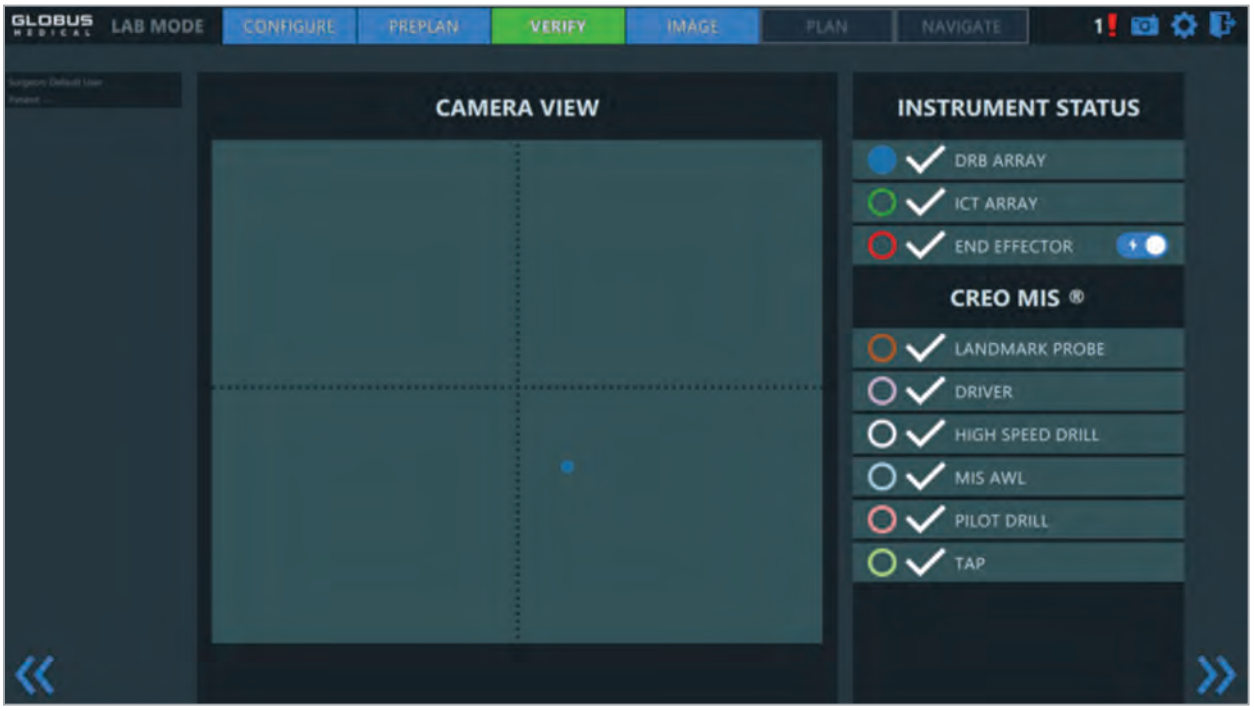
PASSIVE TUBE ARRAY VERIFICATION

The Passive Tube Array (PTA) is a unique passive array that may be used when the end effector is not active to identify the location and orientation of the End Effector. Toggle the End Effector Power switch to off.

The switch is blue ( ) when “ON” and grey ( ) when “OFF”.

Ensure the corresponding color circle for the End Effector on the display screen turns from red (End Effector “ON”) to yellow (End Effector “OFF”).



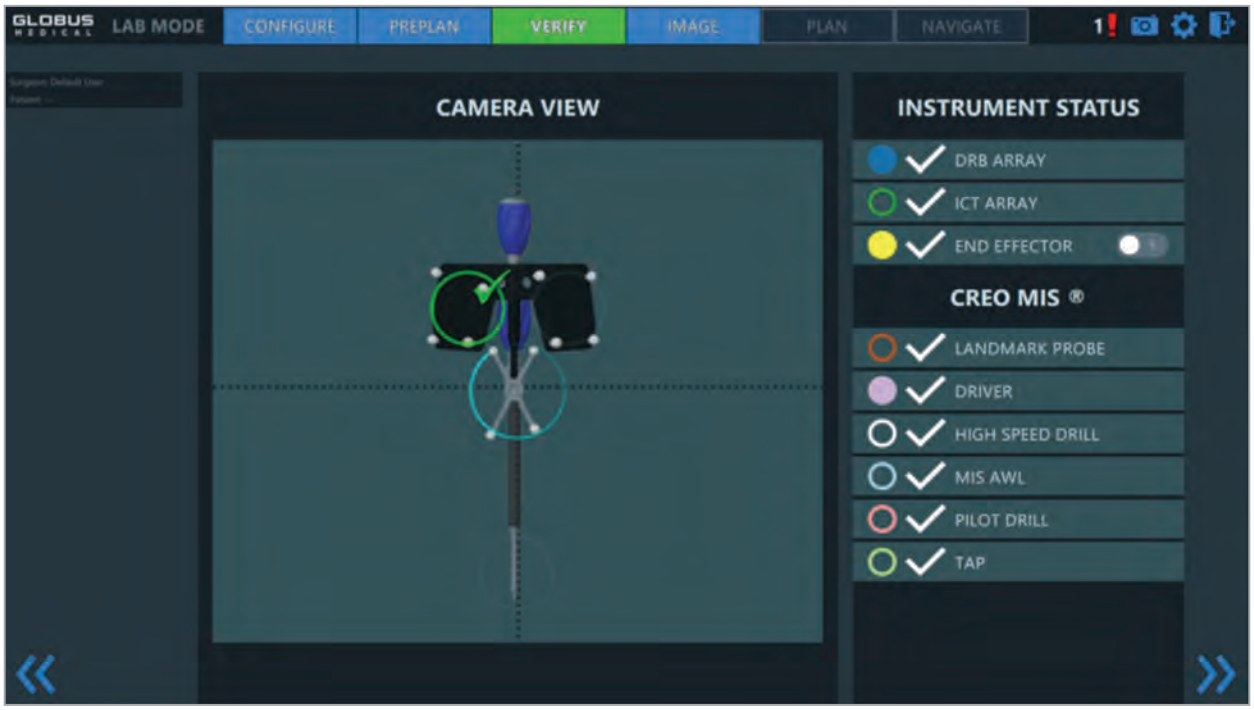


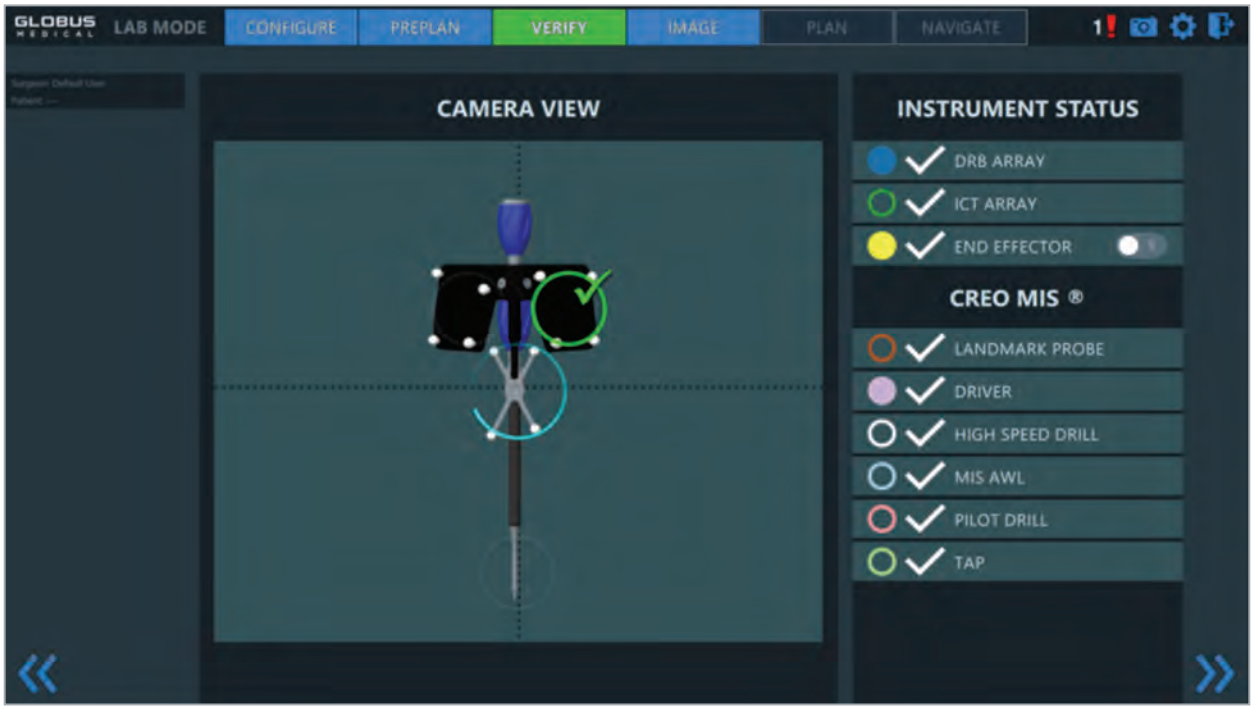
Verify both PTA array faces as follows:

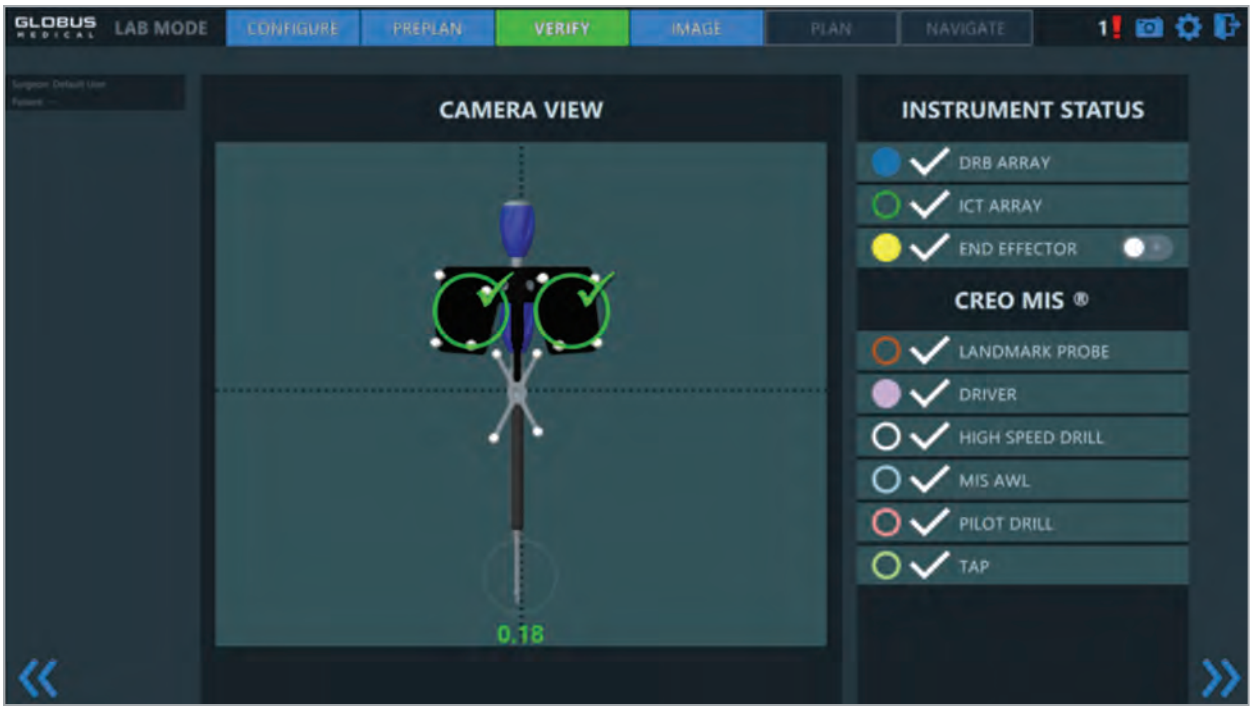
1) Place the tip of the PTA to be verified into a verification divot of any other instrument array. The End Effector divot cannot be used to verify the PTA.
2) The instrument array and the PTA array face being verified must be visible by the camera and must be held steady during verification.
3) A pop-up screen appears on the VERIFY tab to show progress. Securely hold the PTA until both faces have been verified.

Positioning the PTA for verification

Once verification is complete, verification status is indicated on the screen with the tip error displayed in millimeters (mm). If verification has failed (red crossed circle), verification must be repeated until it is successful (green circle). When the PTA is successfully verified, click the right arrows to advance to the next tab.







Verification of PTA complete

PATIENT ATTACHMENT INSTRUMENTS

Patient attachment instruments are secured to rigid bony anatomy neighboring the surgical site. Select the desired instrument. Patient attachment instruments should be placed no more than 185mm from the center of the surgical site to maintain accuracy.

Bone clamps are clamped onto anatomical structures such as the spinous process, iliac crest, long bone, or any rigid bony structure that can be safely clamped.

Quattro spikes are inserted into the iliac crest or a long bone.

Rod attachments are secured to an existing spinal rod, 4.5mm to 6.35mm in diameter.

Refer to the table below for recommended anatomic locations for the various patient attachment instruments.

PATIENT ATTACHMENT INSTRUMENTS – RECOMMENDED ANATOMIC LOCATIONS

Spine Procedures	Patient Position	Patient Attachment Instrument	Recommended Patient Attachment Instrument Location
Posterior Cervical	Prone	Bone Clamp	Spinous Process C2-T3
		Rod Attachment	Existing Rod
Posterior Thoracic	Prone	Bone Clamp	Spinous Process T1-L1
		Rod Attachment	Existing Rod
Anterolateral Thoracic	Lateral	Bone Clamp	Spinous Process T1-L1
Posterior Lumbar	Prone	Quattro Spike	Iliac Crest
		Low Profile Quattro Spike	Iliac Crest
		Bone Clamp	Spinous Process T12-L5
		Rod Attachment	Existing Rod
Lateral Lumbar	Lateral	Quattro Spike	Iliac Crest
		Low Profile Quattro Spike	Iliac Crest
		Bone Clamp	Spinous Process T12-L5
		Rod Attachment	Existing Rod

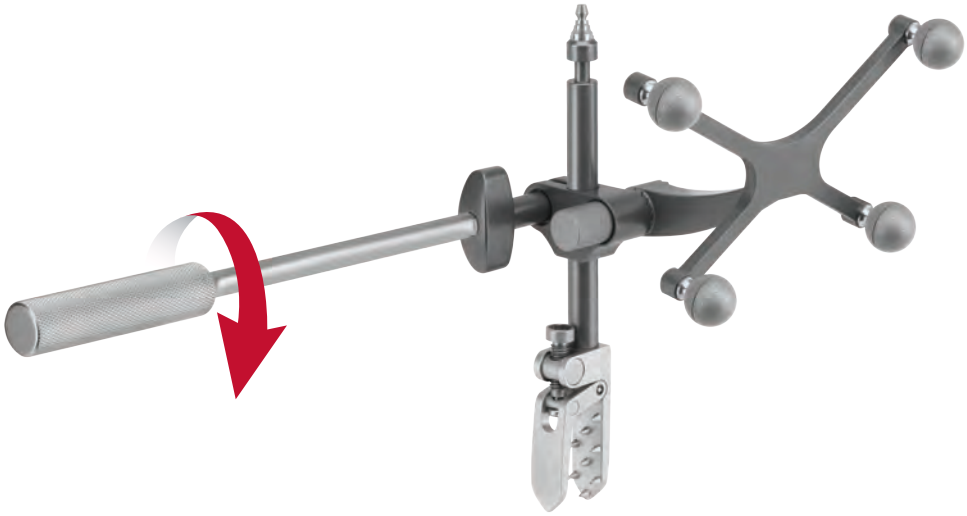
DYNAMIC REFERENCE BASE INSERTION

Position the compression clamp on the Dynamic Reference Base (DRB) over the patient attachment instrument and tighten the knob. If needed, the clamp driver can be used to further tighten the knob.

Position the reflective markers on the DRB in the direction of the camera. Excercise care with initial placement of the patient reference instrument as to not interfere with the surgical procedure.

Following navigation, remove the patient attachment instrument.

Securing DRB to patient attachment instrument



Using clamp driver to tighten the knob

	WARNING
	Once the Dynamic Reference Base is inserted onto the patient attachment instrument, it should not be touched, moved, or adjusted until the procedure is completed. Movement of the Dynamic Reference Base will compromise navigation integrity. If this occurs, re-register the patient, or discontinue use of the ExcelsiusGPS® for the procedure.

SURVEILLANCE MARKER

The surveillance marker is inserted into rigid bony anatomy to track the relative distance to the DRB to identify unwanted shifts in the DRB during the procedure.

Surveillance markers are inserted into the iliac crest or long bone or may be attached to the spinous process using a bone clamp. Verify that the clamp is rigidly secured. The surveillance marker should be placed no more than 185mm from the Dynamic Reference Base. Refer to the table below for recommended anatomic locations.

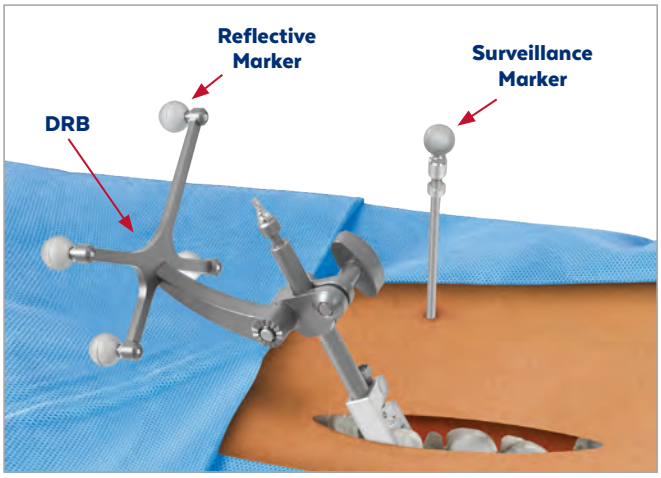
SURVEILLANCE MARKER – RECOMMENDED ANATOMIC LOCATIONS

Spine Procedures	Patient Position	Patient Attachment Instrument	Recommended Patient Attachment Instrument Location
Posterior Cervical	Prone	Bone Clamp	Spinous Process C2-T3
Posterior Thoracic	Prone	Single	Iliac Crest
		Bone Clamp	Spinous Process T1-L1
Anterolateral Thoracic	Lateral	Bone Clamp	Spinous Process T1-L1
Posterior Lumbar	Prone	Single	Iliac Crest
		Bone Clamp	Spinous Process T12-L5
Lateral Lumbar	Lateral	Single	Iliac Crest
		Bone Clamp	Spinous Process T12-L5

Attach a disposable reflective marker to the marker post of the surveillance marker. Attach the impaction cap, designed to fit over the reflective marker sphere, onto the surveillance marker.

Insert the surveillance marker into rigid bony anatomy near the surgical site and gently impact with a mallet. Remove the impaction cap. Remove the reflective marker prior to using the removal tool.

To use a bone clamp with the marker, attach a disposable marker onto the tip of the bone clamp. Use the clamp driver to secure the bone clamp. Verify that the clamp is rigidly secured.



Placement of DRB and Surveillance Marker

CAUTION

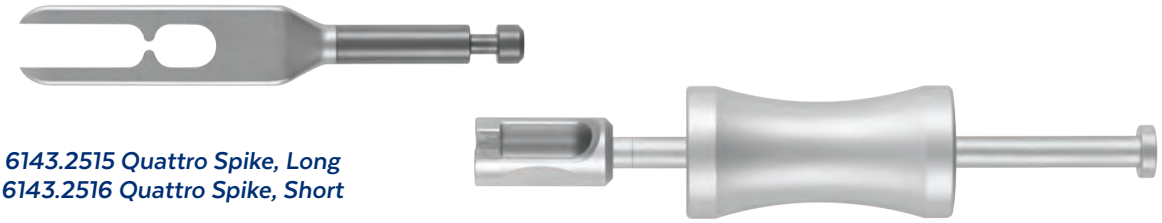
Check reflective markers prior to assembly to ensure they are clean and maintain proper handling throughout assembly and procedure.

WARNING

Reflective markers are single use only.

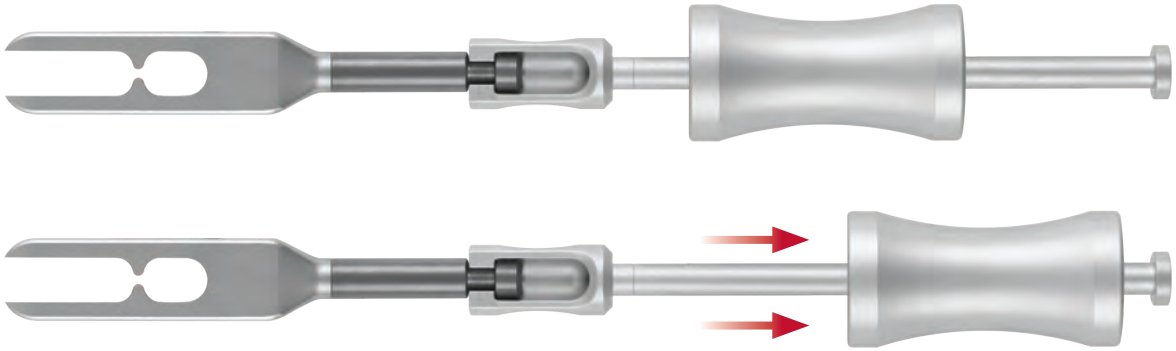
REMOVAL

The quattro spikes and surveillance marker are removed from bony anatomy manually or using the removal tool. The bone clamp is removed by loosening the clamp with the clamp driver, attaching the removal tool, and lifting up the bone clamp.



6143.2515 Quattro Spike, Long
6143.2516 Quattro Spike, Short

6143.2523 Spike Removal Tool

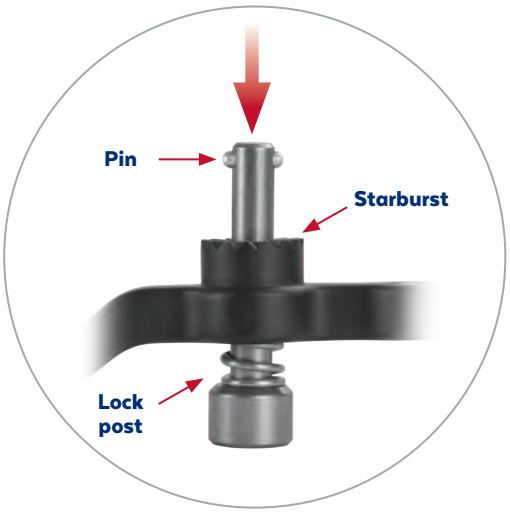


Removing Quattro Spike with Spike Removal Tool

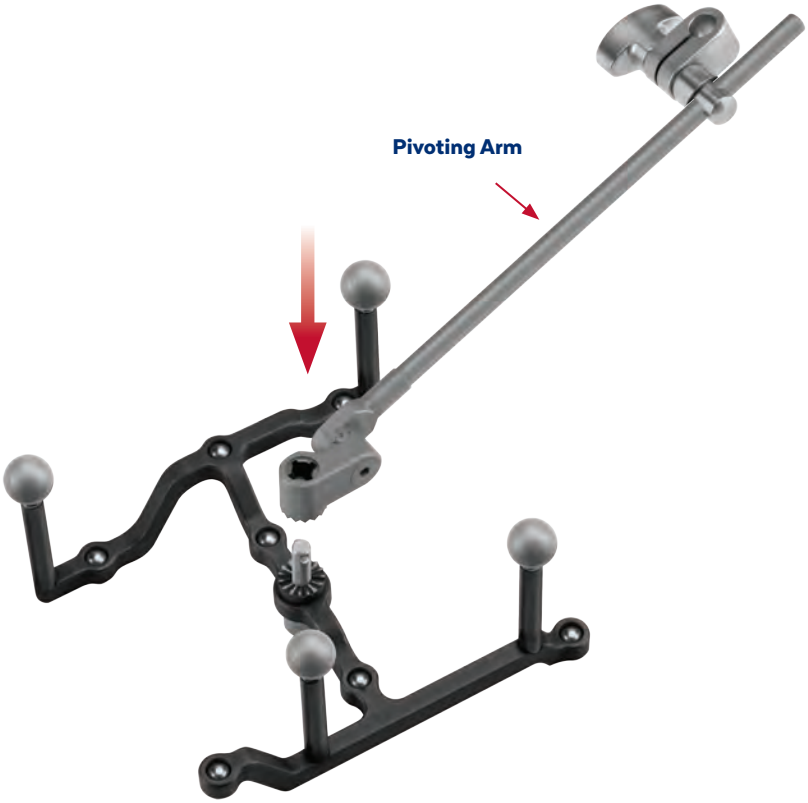
Intraoperative CT Imaging Workflow
IMAGE Tab

INTRAOPERATIVE CT REGISTRATION FIXTURE SETUP

Place the pivoting arm starburst over the starburst on the registration fixture and rotate 90° to secure. Push the lock post from the bottom and rotate the arm 90° until the pin is seated to secure the fixture.



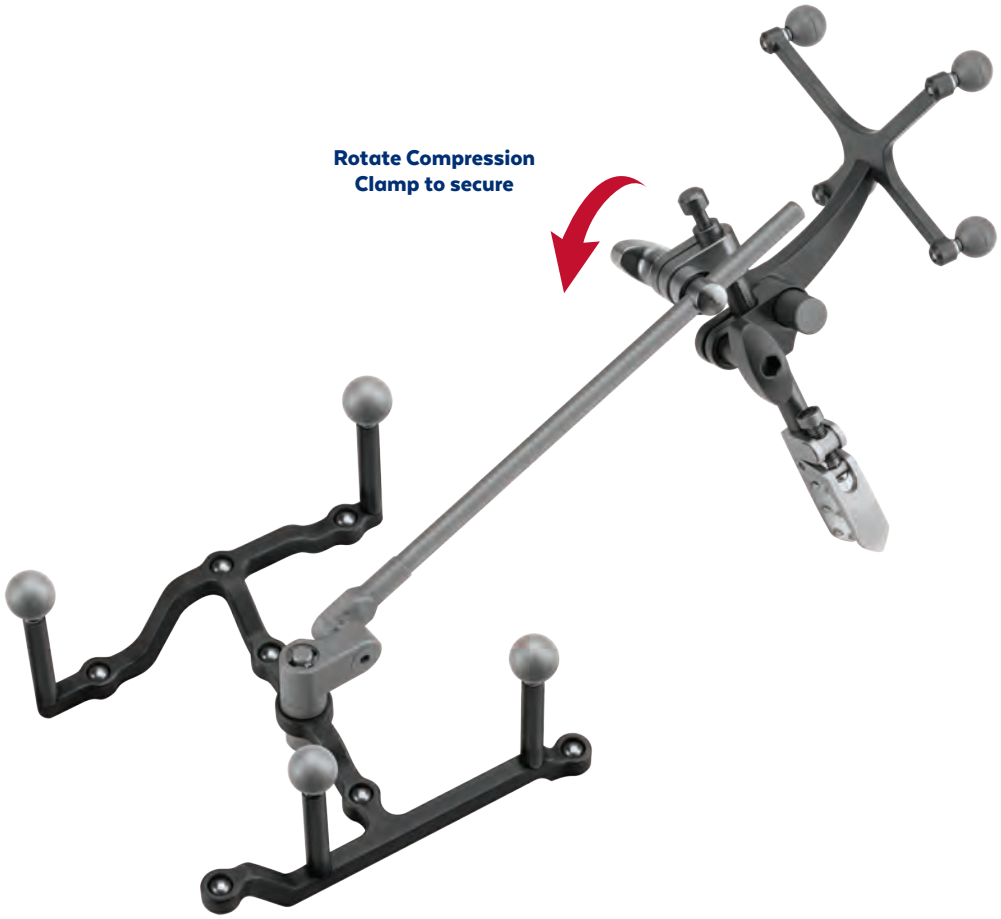
Pivoting Arm positioned over the starburst (side view)



Pivoting Arm attached and rotated to secure

Position the fixture on the patient attachment instrument post and tighten the compression clamp knob. If needed, use the clamp driver to further tighten the knob. The complete assembly is shown below.

To release the pivoting arm, push the lock post on the fixture, rotate the pivoting arm 90°, and pull up.



Registration Fixture with Patient Attachment Instrument

The Intraoperative CT Registration Fixture has six degrees of freedom and can be moved by adjusting one of the three joints so it is stable and hovering over the surgical site. Only the metal fiducials embedded in the fixture need to be in the 3D scan (not the reflective markers). It is important that the Intraoperative CT Registration Fixture does not move between the image acquisition and performing an anatomical landmark check.

	CAUTION
⚠	The operator should confirm that the Dynamic Reference Base and Intraoperative CT Registration Fixture markers are in view of the camera prior to image acquisition.

LOADING THE IMAGE

The IMAGE tab shows the steps needed to load a CT scan image. The image can be loaded from a USB drive or hard drive. If the image is transferred via the Ethernet, it automatically appears on the hard drive when the transfer is complete.

To view images on a USB drive, insert the USB drive into the USB port on the connector panel. To load an image, select the hard drive or USB drive icon and select the desired patient image. Select the ⓘ icon for patient information to verify that the correct patient scan is selected. Click the right arrows to load the patient images and advance to the next tab.

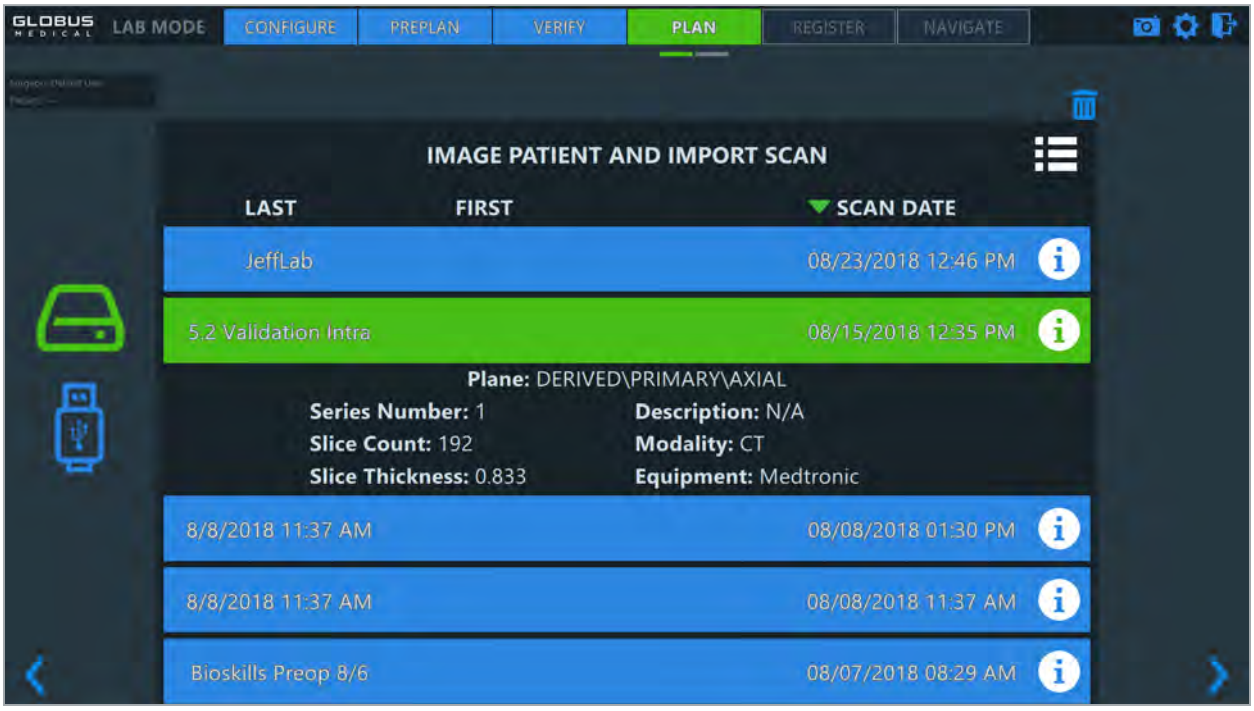
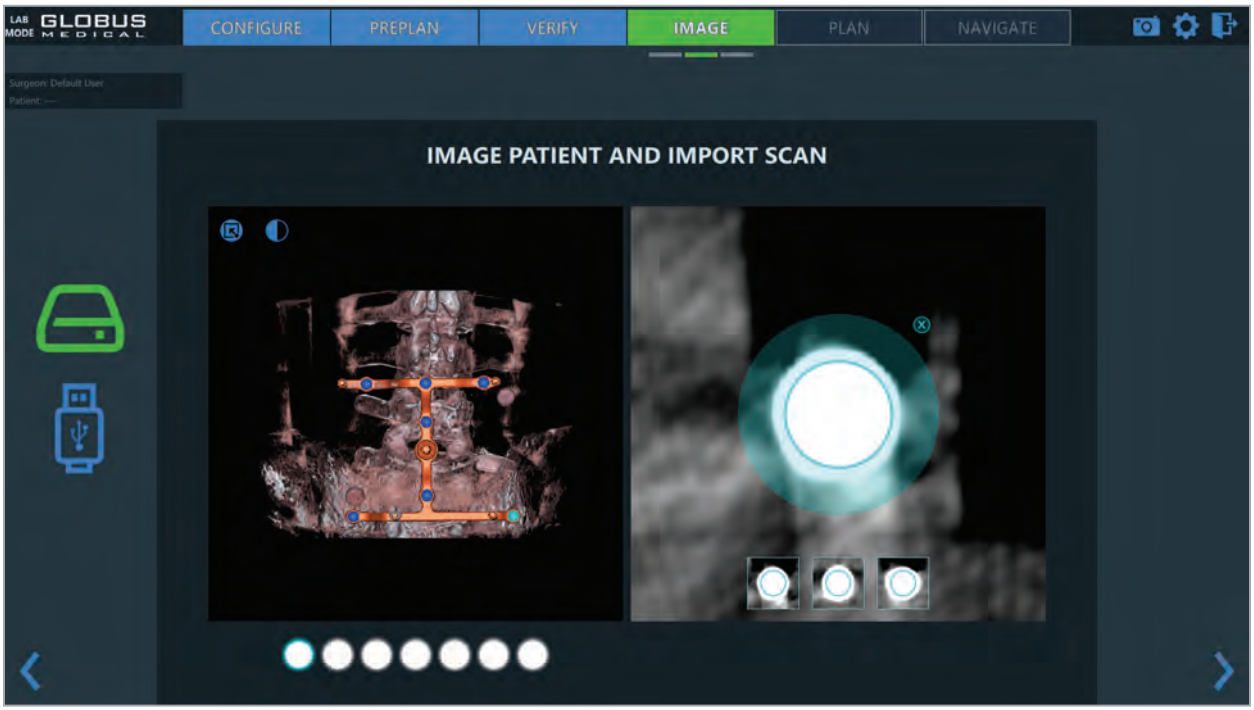


IMAGE TAB ICONS

Icon	Meaning	Action
	Hard drive	Click to show images on hard drive
	USB	Click to show images on USB drive
	Advance to next sub tab	Click to advance to the next sub tab
	Return to previous sub tab	Click to return to the previous sub tab

MANUAL REGISTRATION

Automatic registration is performed when loading images. If this step fails, the manual registration screen is shown to allow manual registration as described below.



The image on the left panel of the registration screen is a full scan with a depiction of the intraoperative CT.

The registration fixture and the seven fiducials should be visible below the image. Fiducials that are not registered need to be adjusted by the operator. On the screen, select a fiducial that is not registered; that image will appear on the right. Move the blue circle on the screen until it surrounds the white fiducial marker. The three small boxes at the bottom of the right panel show the x, y and z direction of the fiducial and all must be adjusted until the blue circle is centered. Ensure that all seven fiducials are properly identified by viewing the 3D model of the Intraoperative CT Registration Fixture.

REGISTRATION STATUS SYMBOLS

Symbol	Meaning
	Registered
	Partially visible
	Not visible

A fiducial may be deleted by selecting the delete icon on the right panel.
Click the right arrows to confirm that the fiducials have been properly identified before proceeding to the next step.

LANDMARK CHECK

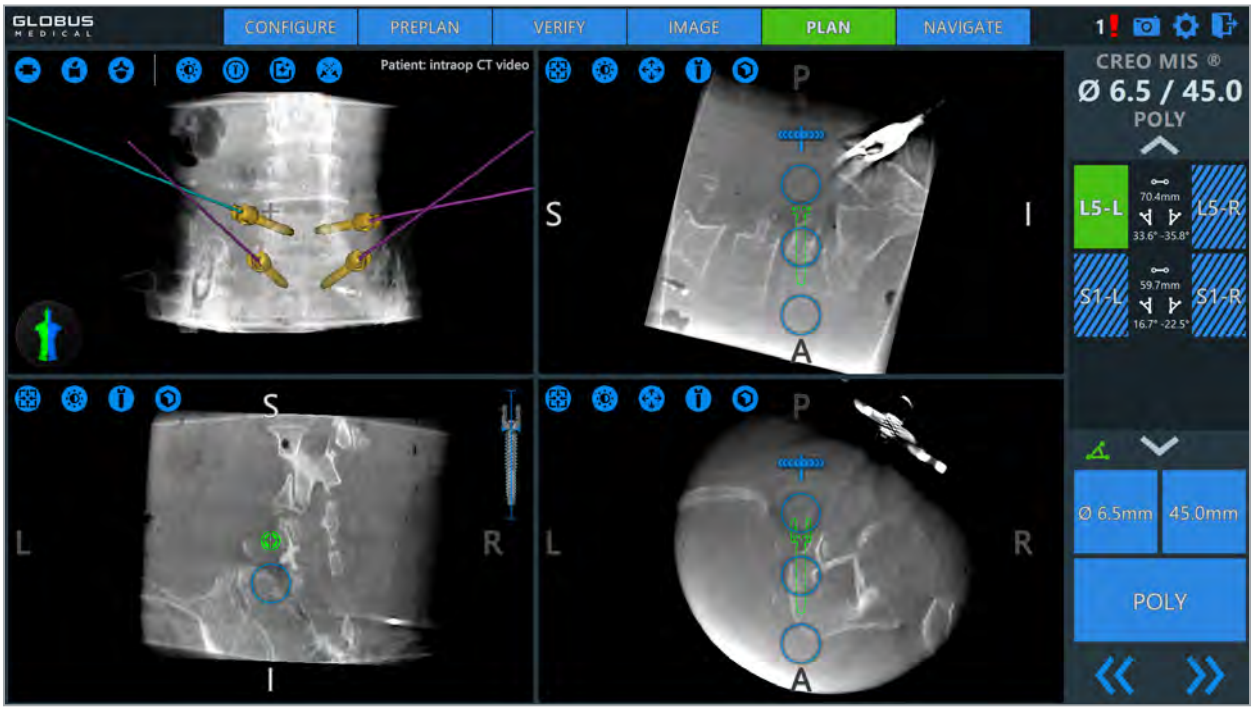
After registration has been completed, a landmark check should be performed to ensure that the registration was calculated successfully. Using the verification probe, touch an anatomical landmark or a fiducial on the registration fixture and verify that the corresponding location is shown on the system monitor. Repeat this process using 2-3 landmarks.

REMOVING REGISTRATION FIXTURE

Carefully remove the registration fixture. Ensure the patient attachment instrument does not move.

Intraoperative CT Imaging Workflow
PLAN Tab

The PLAN tab allows the user to plan all screw trajectories on the patient image. Screws are preloaded on the right hand side of the screen based on selections made in the PREPLAN tab.



To add a screw to the planning page, drag and drop the appropriate screw label on the image at the desired slice. The active screw plan is shown in green (L3-L). Details of the active screw plan are shown on the lower right of the screen, including screw family, diameter, and length. Click on the right arrows to advance to the next tab once all screw plans are complete.

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

Intraoperative CT Imaging Workflow
NAVIGATE Tab

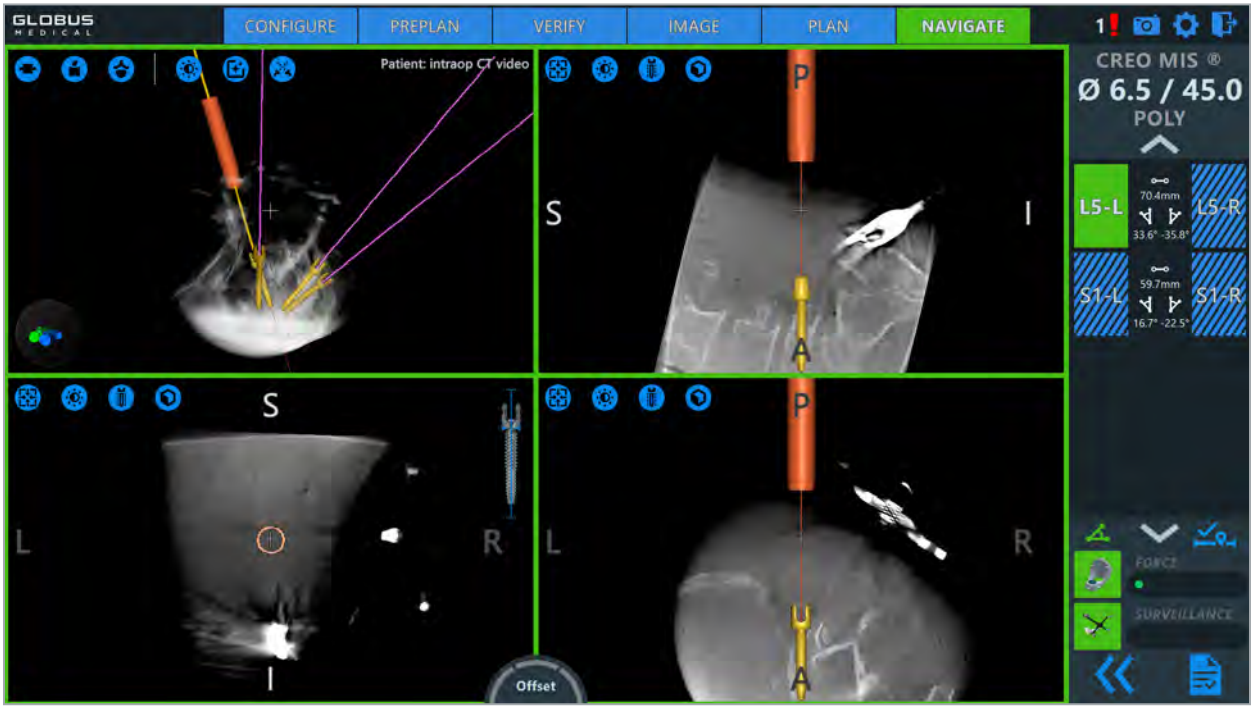
The NAVIGATE tab allows the user to visualize the navigated instrument trajectory and the planned trajectory with respect to patient anatomy.

The robotic arm precisely aligns the End Effector to the planned trajectory. Select the desired screw label on the right of the screen. The screw plan is active when the screw label is highlighted and the robotic arm can be moved by the bracelet or pressing the foot pedal. The robotic arm first moves up to clear obstacles in the surgical field and then down along the trajectory. Once on the trajectory, the robotic arm can move up/down along the trajectory but does not move off of the trajectory unless the screw plan is deselected.

The real-time instrument/implant trajectory is displayed on the patient images along with the planned screw allowing the user to confirm the desired trajectory. If the real-time trajectory is not acceptable, the user can return to the PLAN tab to select another trajectory. If the real-time trajectory is acceptable, the user can insert the screw according to the instrument's current trajectory to the desired depth.

GPS instruments are displayed as they are advanced through the End Effector. While navigating the instruments, periodically observe the monitor and surgical site to ensure consistency between tactile and navigation feedback. Non-navigated metallic Globus instruments may be used through the guide tube while it is stationary for surgical applications unrelated to screw placement.

Monitor the surveillance marker during the procedure. If the surveillance marker indicates significant movement of the DRB, perform an anatomical landmark check. If the landmark check is satisfactory, re-register the surveillance marker. If the landmark check fails, re-register the patient.



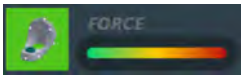
OPTIONAL: NAVIGATING WITH PASSIVE TUBE ARRAY

When the End Effector is not active, the PTA may be used.

Insert and secure the PTA into the 15mm End Effector guide tube. Select the desired screw label on the right of the screen. The screw plan is active when the screw label is highlighted and the robotic arm can be moved by the bracelet or pressing the foot pedal. The robotic arm first moves up to clear obstacles in the surgical field and then down along the trajectory. Once on the trajectory, the robotic arm can move up/down along the trajectory but does not move off of the trajectory unless the screw plan is deselected.

Remove the PTA from the 15mm End Effector guide tube once the selected trajectory is reached. GPS instruments may now be inserted through the guide tube and navigated.

NAVIGATE TAB ICONS

Icon	Meaning
	The force gauge indicates the force exerted on the End Effector. It shows an image of the the active instrument in the End Effector or an image of the End Effector (if no instrument inserted).
	The surveillance marker error gauge indicates the distance that the patient reference has moved in relation to the surveillance marker. The full range of the scale is 2mm.
	Indicates DRB visibility. If the DRB is visible by the camera, the background is green. If the DRB is not visible by the camera, the background is red.

	WARNING
	When using non-navigated Globus instruments through the End Effector, general trajectory guidance is provided however navigation is not supported for these instruments.

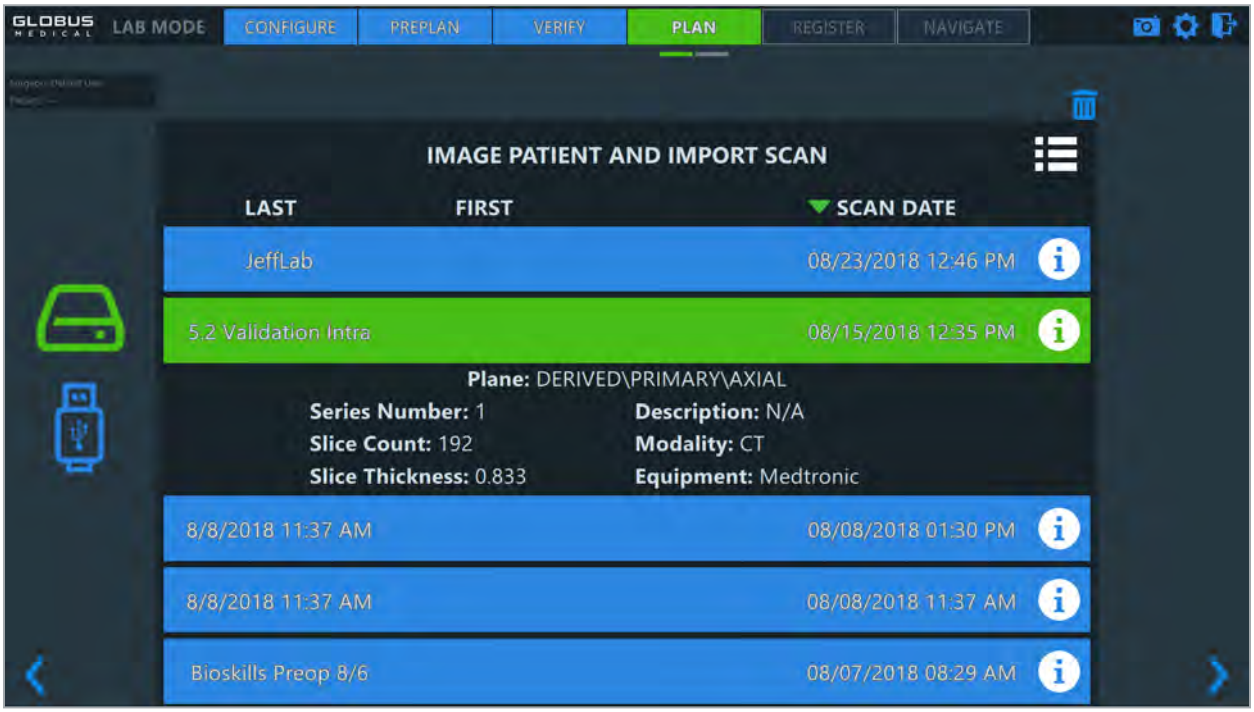
	WARNING
	Do not use non-metallic instruments within the guide tube as they are not identified by the End Effector and the robotic arm will not be prevented from moving while in use.

Preoperative CT Imaging Workflow
PLAN Tab

LOADING THE IMAGE

The PLAN tab shows the steps needed to load a CT scan image. The image can be transferred from a USB drive or hard drive. If the image is transferred through the Ethernet, it automatically appears on the hard drive when the transfer is complete.

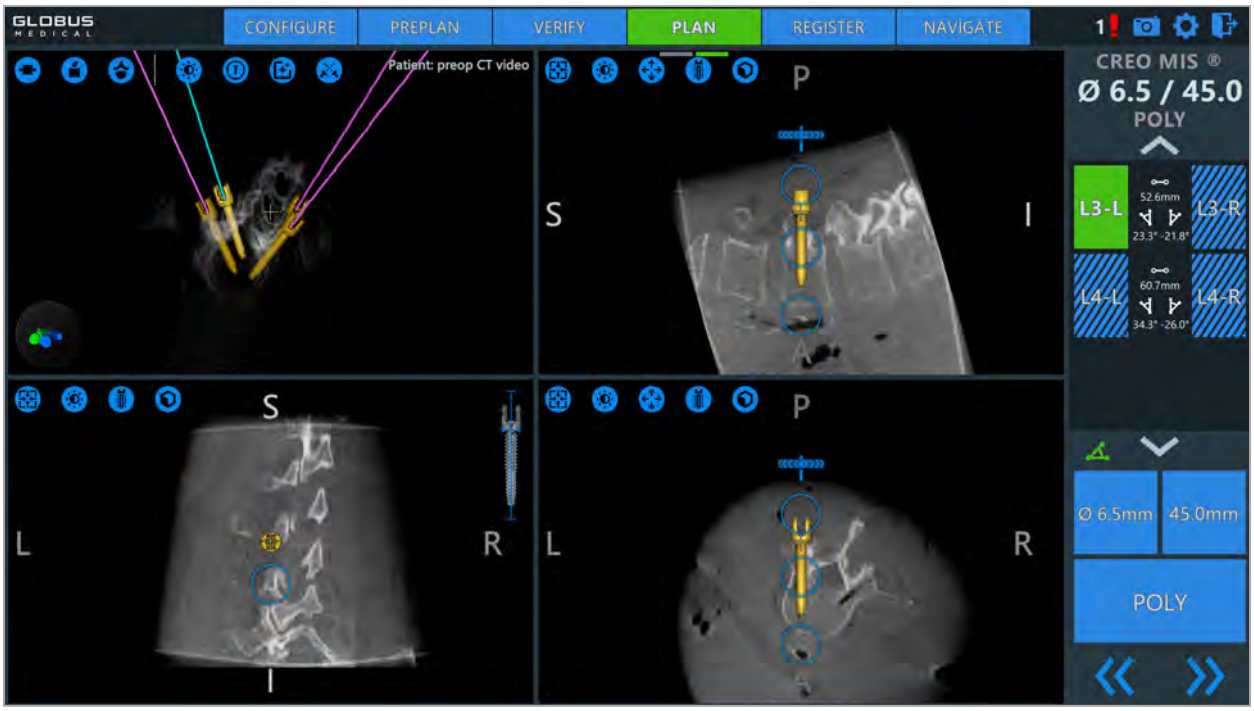
To view images on a USB drive, insert the USB drive into the USB port on the connector panel. To transfer an image, select the hard drive or USB drive icon and select the desired patient image. Select the ⓘ icon for patient information to verify that the correct patient scan is selected. Click the right arrows to load the patient images and advance to the next tab.



If the case has been planned on the tablet prior to entering the operating room, the image does not need to be transferred. The PLAN tab automatically appears.

SCREW PLANNING

The PLAN tab allows the user to plan all screw trajectories on the patient image. Screws are preloaded on the right hand side of the screen, based on selections made in the PREPLAN tab. If the case has been planned on the tablet prior to entering the operating room, the planned screws automatically load.



To add a screw onto the planning page, drag and drop the appropriate screw label on the image at the desired slice. The active screw plan is shown in green (L5-L). Details of the active screw plan are shown on the lower right of the screen, including screw family, diameter, and length. Click on the right arrows to advance to the next tab once screw plans are complete.

ADJUSTING SCREW TRAJECTORY

Screw Body	Press and move along screen to translate the screw along the current plane of anatomy
Screw Head	Press and move to 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° around 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

Preoperative CT Imaging Workflow
REGISTER Tab

REGISTRATION SETUP

Attach the Fluoroscopy Registration Fixture to the image intensifier on the C-arm by turning the clamp clockwise until tight. Drape the fluoroscope and Fluoroscopy Registration Fixture and attach new reflective markers outside of the drape. Position the fixture so that the reflective markers are facing the camera. Attach the video capture cable (yellow jack) to the C-arm viewing station. Plug the video capture USB cable into either of the two USB ports on the ExcelsiusGPS® connector panel.

Ensure that the Dynamic Registration Base is visible to the camera after the C-arm is in place.

Register the surveillance marker by placing an instrument close to the reflective sphere on the surveillance marker but not touching. The box turns green when it is activated.

Fluoroscopy Registration Fixture attached to image intensifier

	WARNING
	Any equipment attached to the ExcelsiusGPS® must be certified to the appropriate medical safety standards (e.g. IEC 60601-1, ANSI/AAMI 60606-1).

IMAGE ACQUISITION AND REGISTRATION

Acquire the intraoperative fluoroscopic images: one AP and one lateral for each level planned. The same image may be used for multiple levels. Ensure that the C-arm has stopped moving before capturing images.

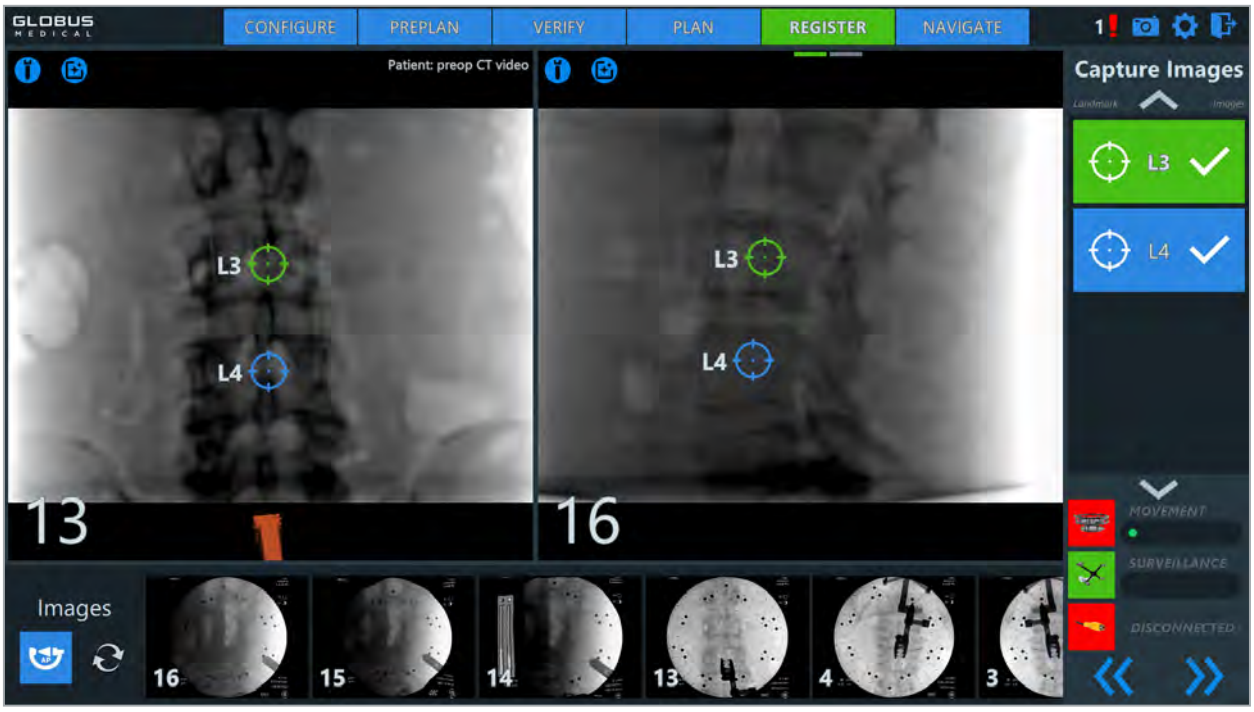
The following three conditions must be met prior to acquiring the images:

1) The DRB is visible by the camera

2) The Fluoroscopy Registration Fixture is attached to the C-arm and visible by the camera.

3) The C-arm is stationary.

Each of the three images on the lower right corner of the screen turns green when ready for image capture. When all three images on the lower right corner of the screen turn green, acquire intraoperative fluoroscopic images until all desired images are captured. All intraoperative fluoroscopic images are stored by the system and are displayed below the two main images.

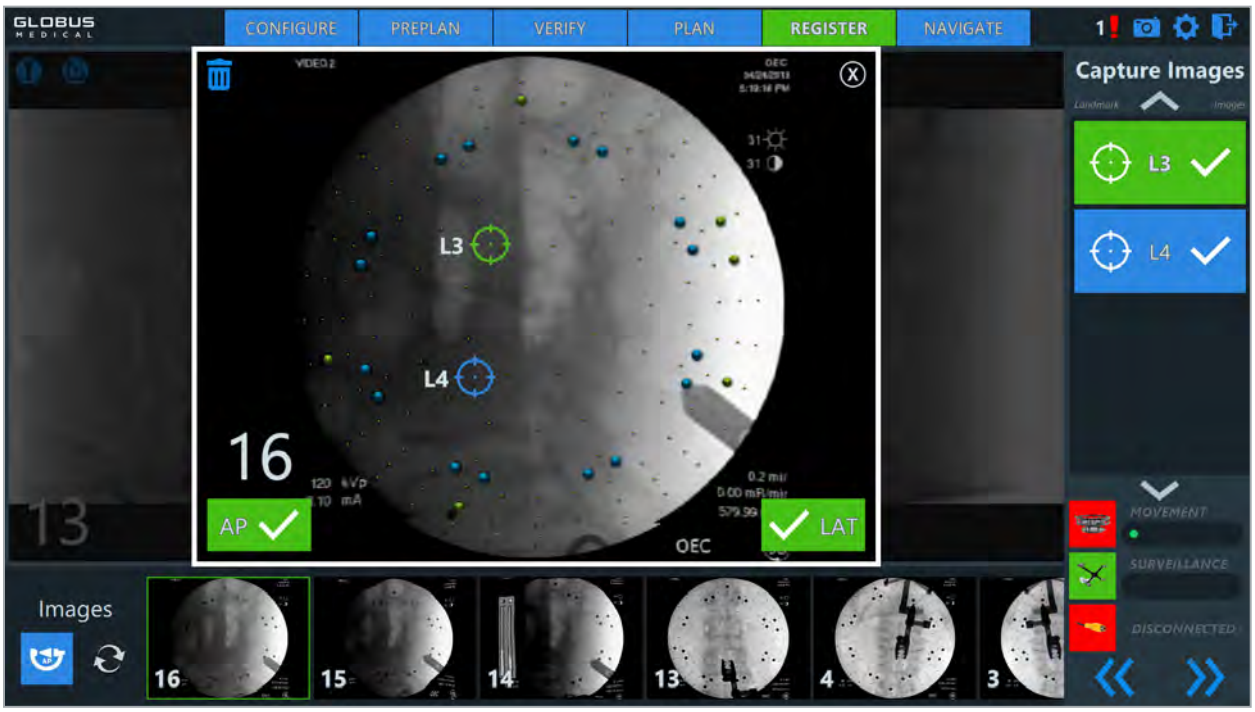


Select the best images for each operative level. Select the desired image from the stored images and then choose AP or lateral in the bottom left and right corners of the pop-up screen, respectively.

	WARNING
	Any equipment attached to the ExcelsiusGPS® must be certified to the appropriate medical safety standards (e.g. IEC 60601-1, ANSI/AAMI 60606-1).

Once both images are successfully captured, the spinal level on the right side of the screen displays a check mark. Select the desired level. Drag and drop the level indicator onto the fluoroscopic images. Use the circle control points to position the level indicator within the center of the vertebral body on the AP and lateral images. Perform this action for each level. A check mark is shown next to the active level when the level indicator is placed.

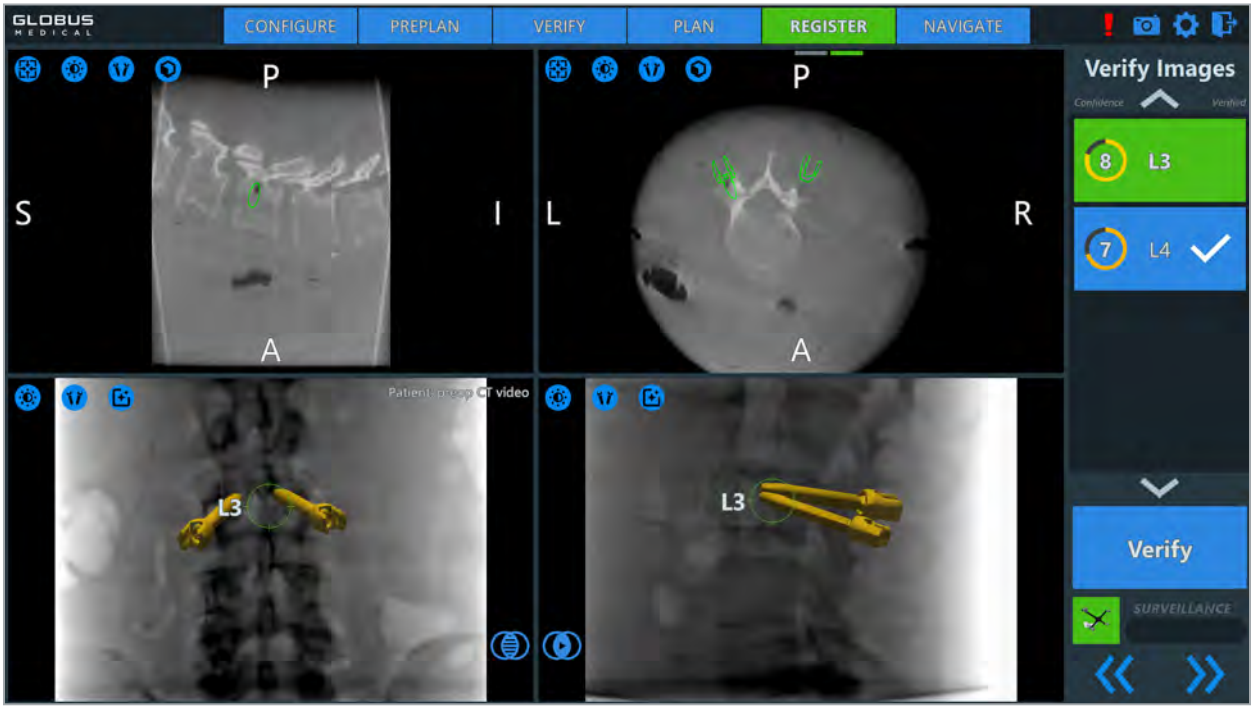
Click the right arrows when complete to allow registration of the CT scan to the intraoperative fluoroscopic images.



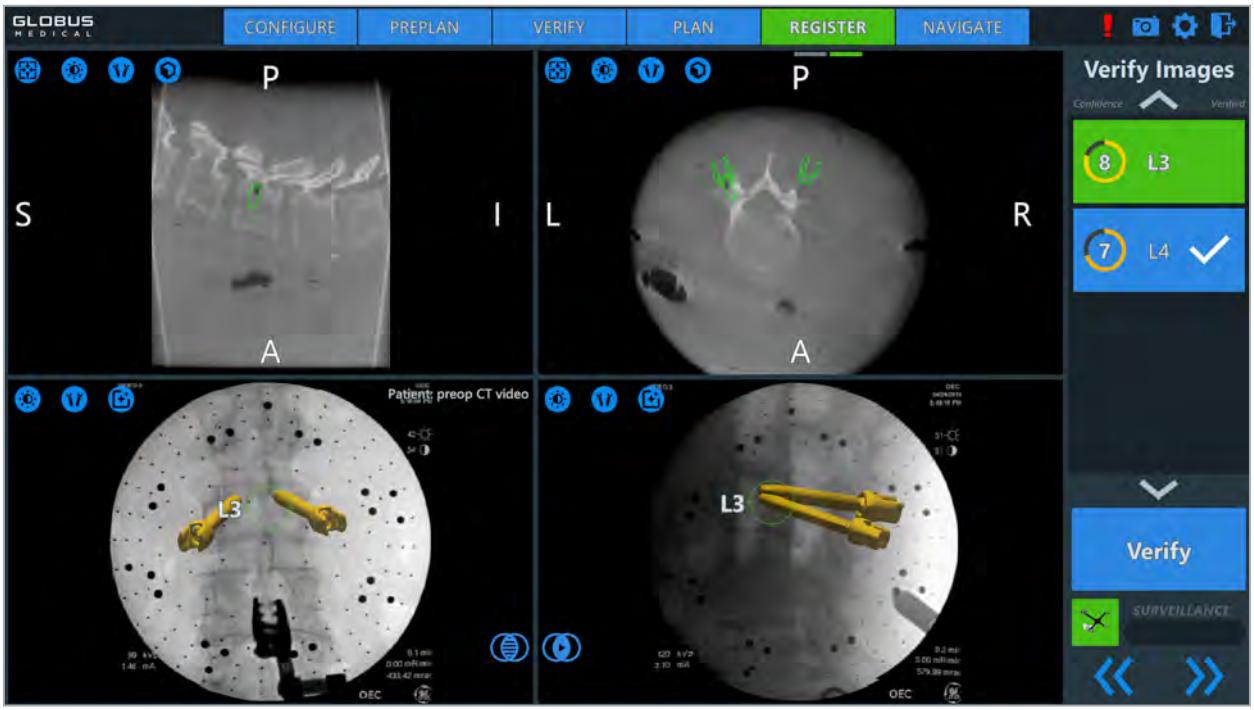
REGISTRATION VERIFICATION

Verify registration for each level prior to navigation. Alternate between the CT scan images with the planned screws and the fluoroscopic images with the level indicator at each level to confirm proper registration.

Use the merge scale (1 to 10) to confirm image registration. Scores 6–10 indicate good image alignment. For scores 5 or less, double check the images, perform a landmark check or retake images before proceeding.



CT Scan view

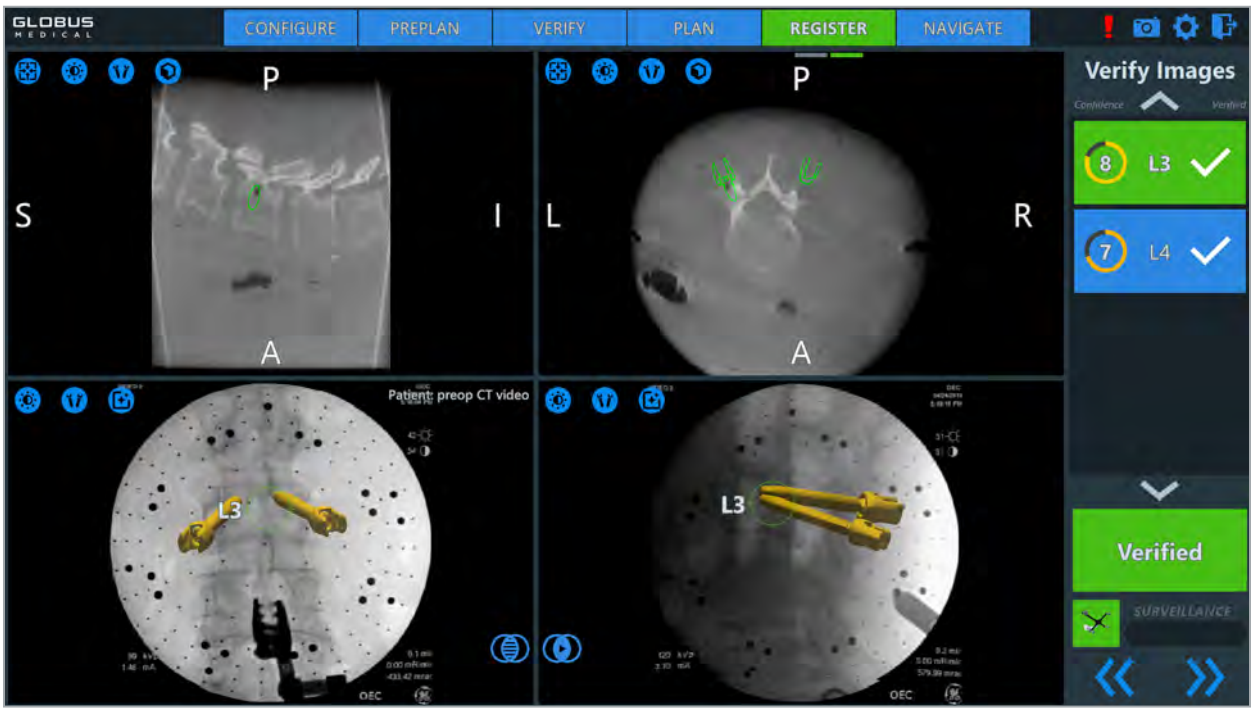


Fluoroscopic scan view

LANDMARK CHECK

After registration is complete, perform a landmark check or verification check to ensure registration was calculated successfully. Using the verification probe, touch an anatomical landmark and verify that the corresponding location is shown on the system monitor. Repeat this process using 2-3 landmarks.

Click “Verify” on the bottom right side of the screen to finalize registration. A check mark is shown next to the active level. The Verify button turns green and is denoted as “Verified” when registration is confirmed.



Preoperative CT Imaging Workflow
NAVIGATE Tab

The NAVIGATE tab allows the user to visualize the navigated instruments and trajectory alignment with respect to patient anatomy, according to the screw plan.

The robotic arm precisely aligns the End Effector on the planned trajectory. Select the desired screw label on the right of the screen.

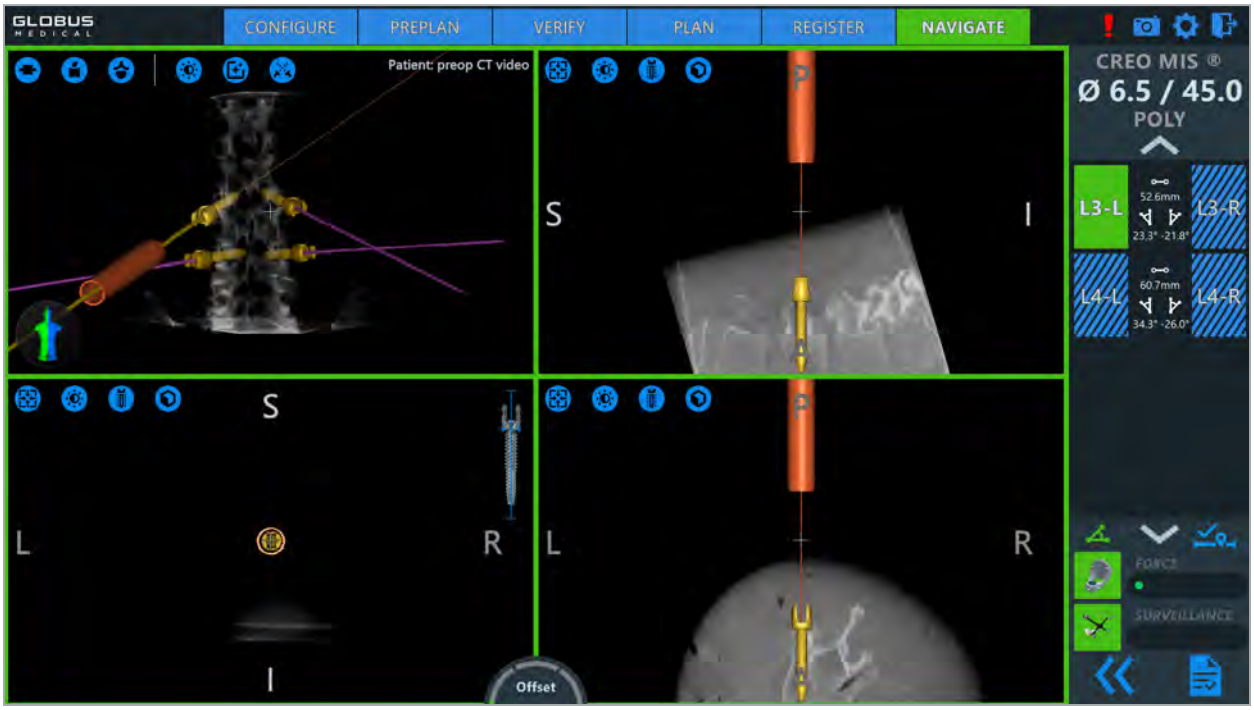
The screw plan is active when the screw label is highlighted and the robotic arm is moved by the bracelet or pressing the foot pedal. The robotic arm first moves up to clear obstacles in the surgical field and then down along the trajectory. Once on the trajectory, the robotic arm can moves up/down along the trajectory but does not move off of the trajectory unless the screw is deselected.

The real-time instrument/implant trajectory is displayed on the patient images along with the planned screw allowing the user to confirm the desired trajectory. If the real-time trajectory is not acceptable, the user can return to the PLAN tab to select another trajectory. If the real-time trajectory is acceptable, the user inserts the screw according to the instrument's current trajectory to the desired depth.

GPS instruments are displayed as they are advanced through the End Effector. While navigating the instruments, periodically observe the monitor and surgical site to ensure consistency between tactile and navigation feedback.

Non-navigated metallic Globus instruments may be used through the guide tube while it is stationary for surgical applications unrelated to screw placement.

Monitor the surveillance marker during the procedure. If the surveillance marker indicates significant movement of the DRB, perform an anatomical landmark check. If the landmark check is satisfactory, re-register the surveillance marker. If the landmark check fails, re-register the patient.



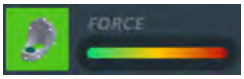
OPTIONAL: NAVIGATING WITH PASSIVE TUBE ARRAY

When the End Effector is not active, the PTA may be used.

Insert and secure the PTA into the 15mm End Effector guide tube. Select the desired screw label on the right of the screen. The screw plan is active when the screw label is highlighted and the robotic arm can be moved by the bracelet or pressing the foot pedal. The robotic arm first moves up to clear obstacles in the surgical field and then down along the trajectory. Once on the trajectory, the robotic arm can move up/down along the trajectory but does not move off of the trajectory unless the screw plan is deselected.

Remove the PTA from the 15mm End Effector guide tube once the selected trajectory is reached. GPS instruments may now be inserted through the guide tube and navigated.

NAVIGATE TAB ICONS

Icon	Meaning
	The force gauge indicates the force exerted on the End Effector. It shows an image of the the active instrument in the End Effector or an image of the End Effector (if no instrument inserted).
	The surveillance marker error gauge indicates the distance that the patient reference has moved in relation to the surveillance marker. The full range of the scale is 2mm.
	Indicates DRB visibility. If the DRB is visible by the camera, the background is green. If the DRB is not visible by the camera, the background is red.

	WARNING
	When using non-navigated Globus instruments through the End Effector, general trajectory guidance is provided however navigation is not supported for these instruments.

	WARNING
	Do not use non-metallic instruments within the guide tube as they are not identified by the End Effector and the robotic arm will not be prevented from moving while in use.

Fluoroscopic Imaging Workflow
IMAGE Tab

REGISTRATION SETUP

Attach the Fluoroscopy Registration Fixture to the image intensifier on the C-arm by tightening the clamps. Drape the fluoroscope and Fluoroscopy Registration Fixture and attach new reflective markers outside of the drape. Position the fixture so the reflective markers are facing the camera. Attach the video capture cable (yellow jack) to the C-arm viewing station. Plug the video capture USB cable into either of the two USB ports on the ExcelsiusGPS® connector panel.

Ensure that the Dynamic Registration Base is visible to the camera after the C-arm is in place.

Register the surveillance marker by placing an instrument close to the reflective sphere on the surveillance marker but not touching. The box turns green when it is activated.

Fluoroscopy Registration Fixture attached to image intensifier

	WARNING
	Any equipment attached to the ExcelsiusGPS® must be certified to the appropriate medical safety standards (e.g. IEC 60601-1, ANSI/AAMI 60606-1).

IMAGE ACQUISITION

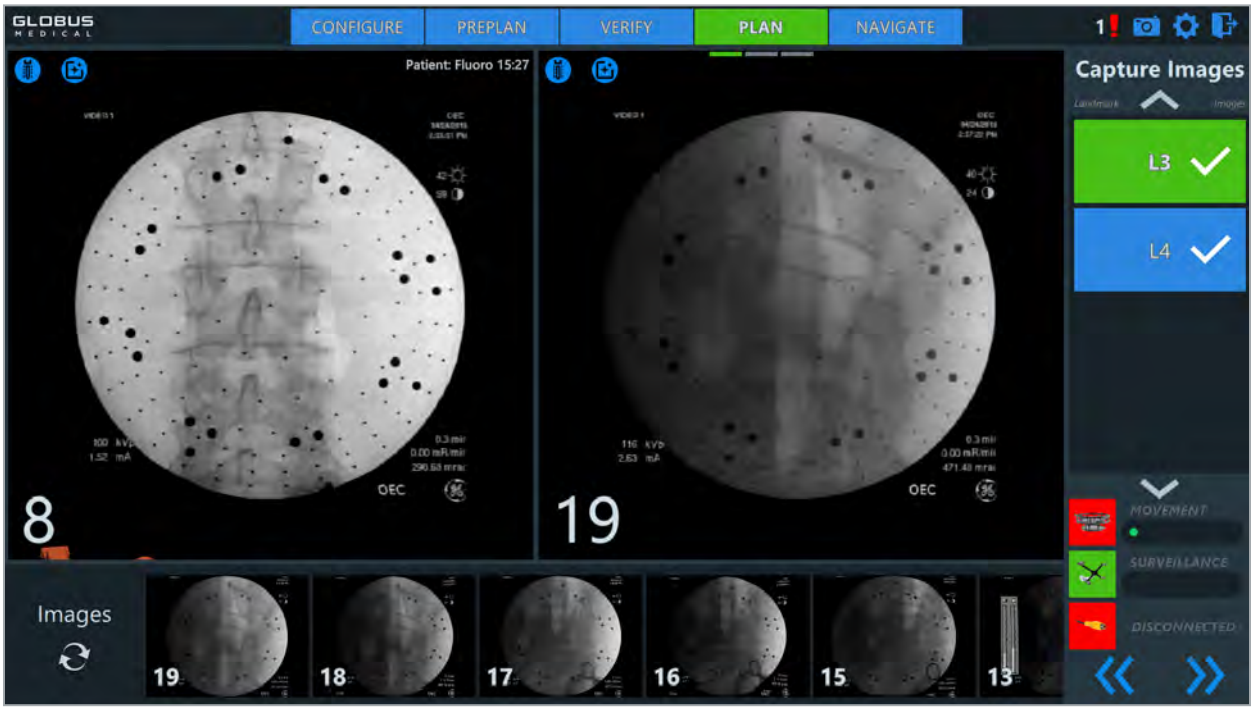
Acquire the intraoperative fluoroscopic images: one AP and one lateral for each level planned. The same image may be used for multiple levels.

The following two conditions must be met prior to acquiring the images:

1) The DRB is visible by the camera

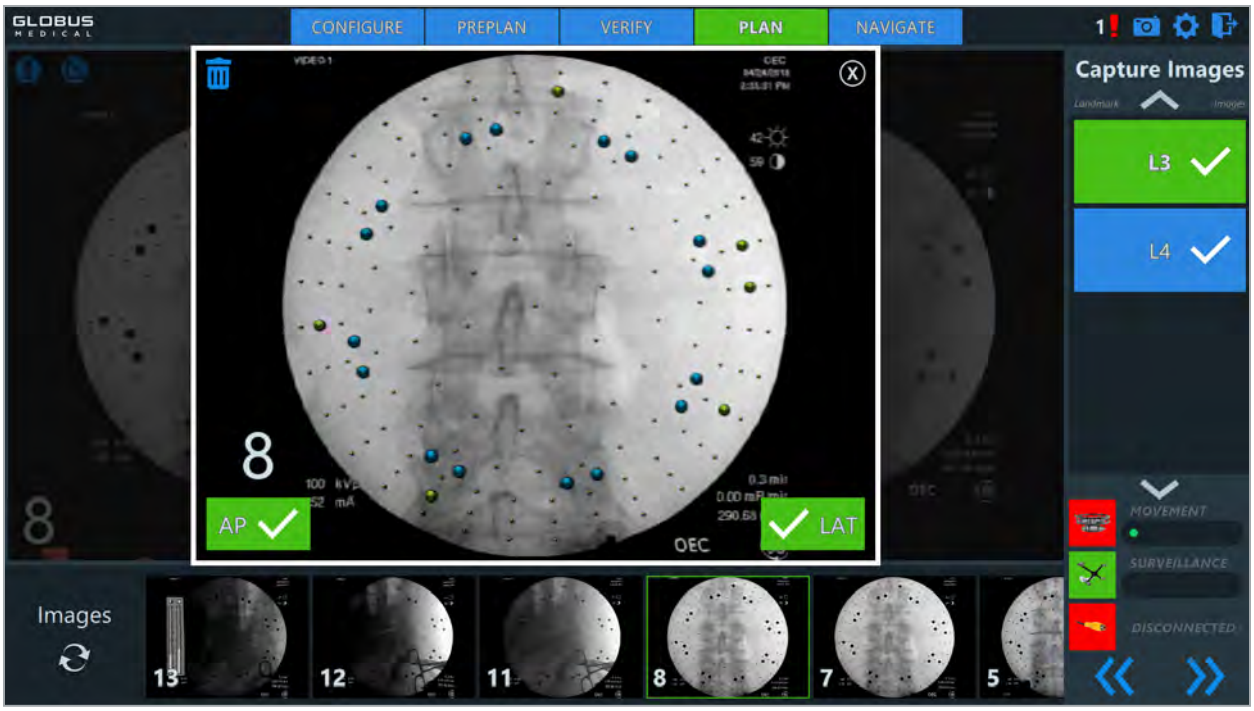
2) The Fluoroscopy Registration Fixture is attached to the C-arm and visible by the camera

Each of the three images on the lower right corner of the screen turns green when ready for image capture. When all three images on the lower right corner of the screen turn green, acquire intraoperative fluoroscopic images until desired images are captured. All intraoperative fluoroscopic images are stored by the system and are displayed below the large central AP and Lateral images.



Select the best images for each operative level. Select the desired image from the stored images and then choose AP or lateral in the bottom left and right corners of the pop-up screen, respectively.

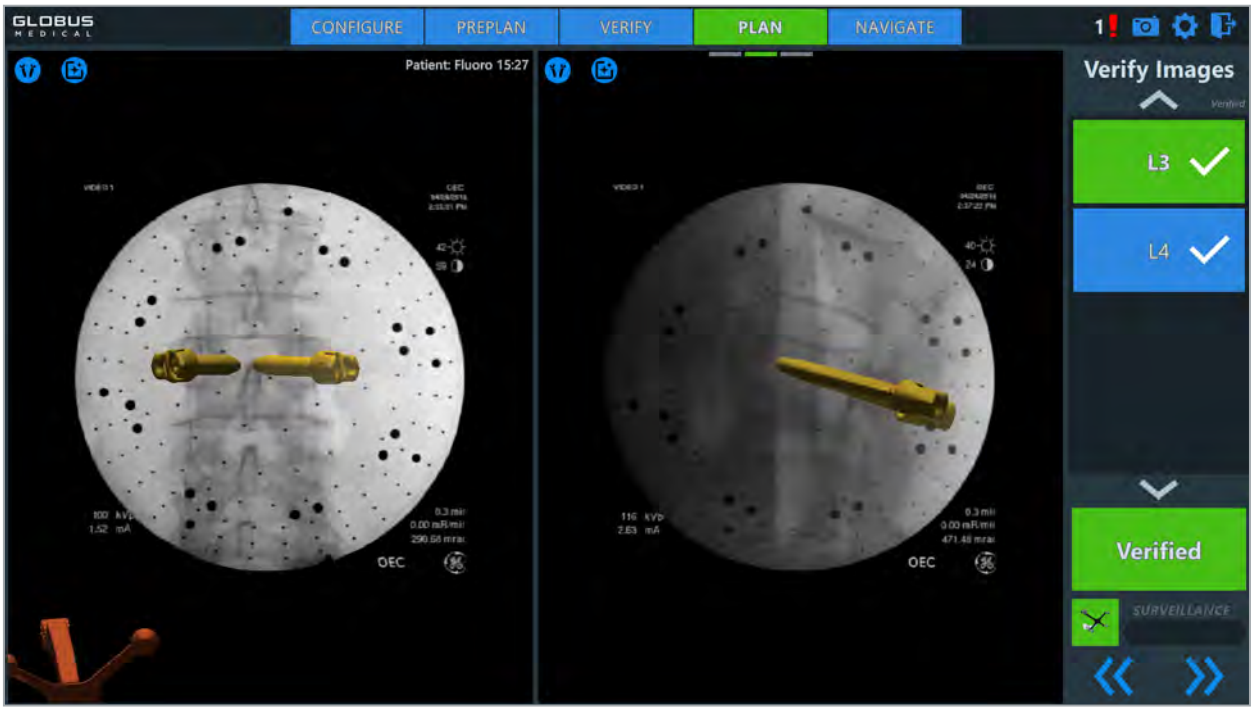
Once both images are successfully captured, the spinal level on the right side of the screen displays a check mark. Once the appropriate images have been loaded and selected, click on the right arrows to proceed.



LANDMARK CHECK

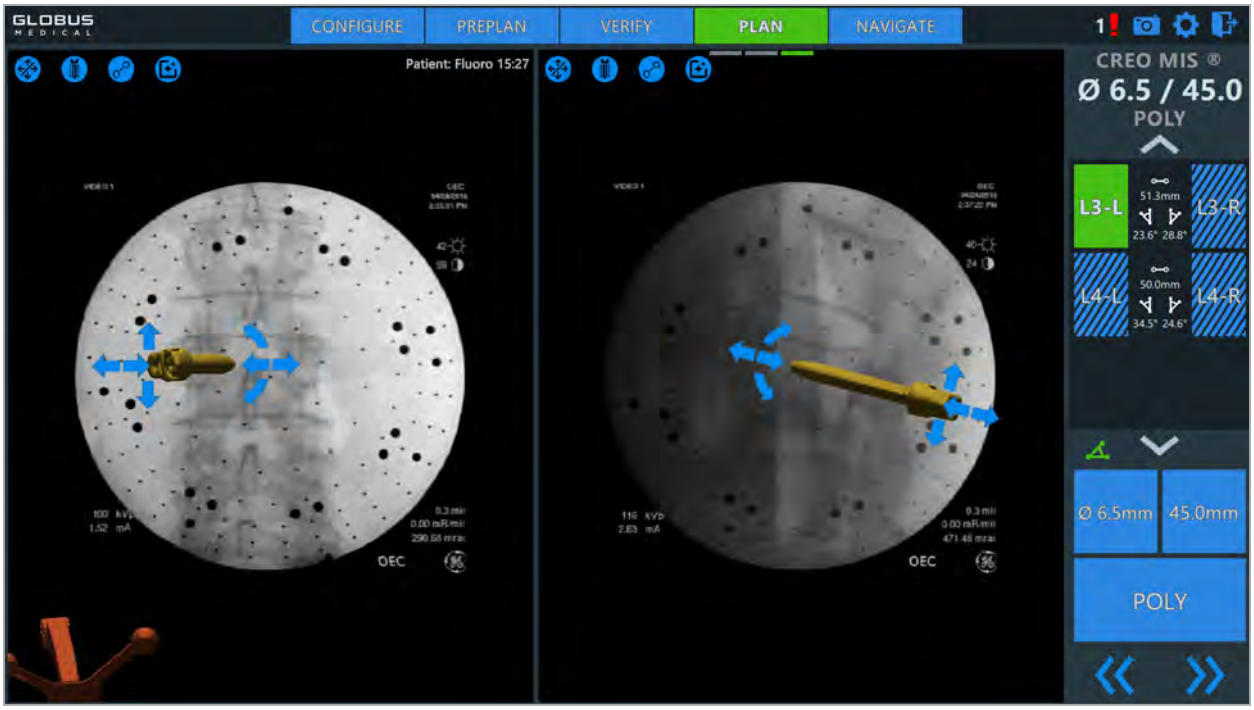
After registration has been completed, perform a landmark check or verification to ensure that the registration was successfully calculated. Using the navigated verification probe, touch an anatomical landmark and verify that the corresponding location is shown on the system monitor. Repeat this process using 2–3 landmarks.

Click “Verify” on the bottom right side of the screen to finalize registration. A check mark is shown next to the active level. The Verify button turns green and is denoted as “Verified” when registration is confirmed.



Fluoroscopic Imaging Workflow
PLAN Tab

The PLAN tab allows the user to plan all screw trajectories on the patient image. Screws are preloaded on the right side of the screen based on selections made in the PREPLAN tab.



To add a screw onto the planning page, drag and drop the appropriate screw label on the image at the desired slice. The active screw plan is shown in green (L3-L). Details of the active screw plan are shown on the lower right of the screen, including screw family, diameter, and length. Click on the right arrows to advance to the next tab once all screw plans are complete.

ADJUSTING SCREW TRAJECTORY

Screw Body	Press and move along screen to translate the screw along the current plane of anatomy
Screw Head	Press and move along screen to adjust the screw along the current plane of the anatomy
Screw Tip	Press and move to change the angle of the trajectory, pivoting along the screw head
Screw Trajectory	Press and move the screw along the 3D trajectory. This is useful to simulate actual advancement of the screw in 3D space. AP and lateral images are updated to reflect the new screw position.

ADJUSTING SCREW SIZE

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

Fluoroscopic Imaging Workflow
NAVIGATE Tab

The NAVIGATE tab allows the user to visualize the navigated instrument trajectory and the planned trajectory with respect to patient anatomy.

The robotic arm precisely aligns the End Effector to the planned trajectory. Select the desired screw label on the right of the screen.

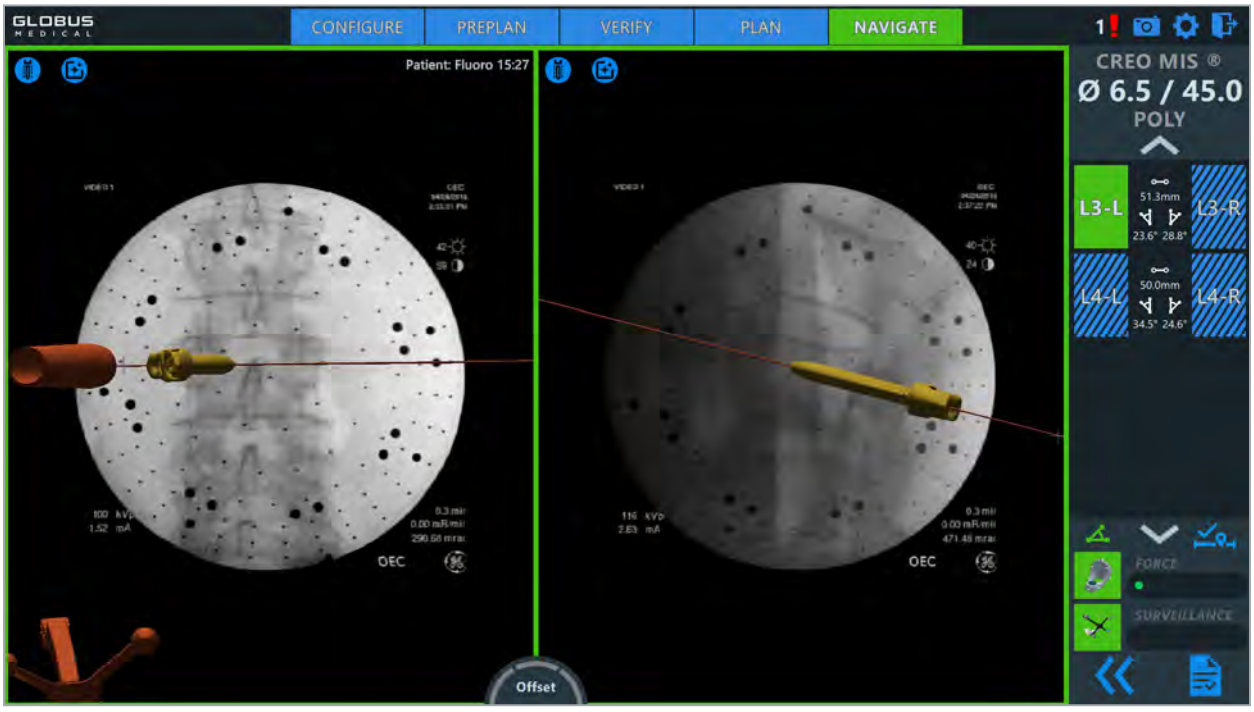
The screw plan is active when the screw label is highlighted and the robotic arm can be moved by the bracelet or pressing the foot pedal. The robotic arm first moves up to clear obstacles in the surgical field and then down along the trajectory. Once on the trajectory, the robotic arm moves up/down along the trajectory but does not move off of the trajectory unless the screw plan is deselected.

The real-time instrument/implant trajectory is displayed on the patient images along with the planned screw, allowing the user to confirm the desired trajectory. If the real-time trajectory is not acceptable, the user can return to the PLAN tab to select another trajectory. If the real-time trajectory is acceptable, the user inserts the screw according to the instrument's current trajectory to the desired depth.

GPS instruments are displayed as they are advanced through the End Effector. While navigating the instruments, periodically observe the monitor and surgical site to ensure consistency between tactile and navigation feedback.

Non-navigated metallic Globus instruments may be used through the guide tube while it is stationary for surgical applications unrelated to screw placement.

Monitor the surveillance marker during the procedure. If the surveillance marker indicates significant movement of the DRB, perform an anatomical landmark check. If the landmark check is satisfactory, re-register the surveillance marker. If the landmark check fails, re-register the patient.



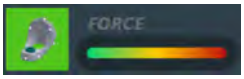
OPTIONAL: NAVIGATING WITH PASSIVE TUBE ARRAY

When the End Effector is not active, the PTA may be used.

Insert and secure the PTA into the 15mm End Effector guide tube. Select the desired screw label on the right of the screen. The screw plan is active when the screw label is highlighted and the robotic arm can be moved by the bracelet or pressing the foot pedal. The robotic arm first moves up to clear obstacles in the surgical field and then down along the trajectory. Once on the trajectory, the robotic arm can move up/down along the trajectory but does not move off of the trajectory unless the screw plan is deselected.

Remove the PTA from the 15mm End Effector guide tube once the selected trajectory is reached. GPS instruments may now be inserted through the guide tube and navigated.

NAVIGATE TAB ICONS

Icon	Meaning
	The force gauge indicates the force exerted on the End Effector. It shows an image of the the active instrument in the End Effector or an image of the End Effector (if no instrument inserted).
	The surveillance marker error gauge indicates the distance that the patient reference has moved in relation to the surveillance marker. The full range of the scale is 2mm.
	Indicates DRB visibility. If the DRB is visible by the camera, the background is green. If the DRB is not visible by the camera, the background is red.

	WARNING
	When using non-navigated Globus instruments through the End Effector, general trajectory guidance is provided however navigation is not supported for these instruments.

	WARNING
	Do not use non-metallic instruments within the guide tube as they are not identified by the End Effector and the robotic arm will not be prevented from moving while in use.

Navigation-Only Procedures

The ExcelsiusGPS® System may be used for navigation without the robotic arm and End Effector. Pre-surgical planning is optional. All verified GPS instruments are visible on loaded patient images when moved within the view of the camera. The instruments are displayed with respect to the patient.

Refer to the corresponding application and imaging workflow for the imaging modality (preoperative CT, intraoperative CT, or fluoroscopy).

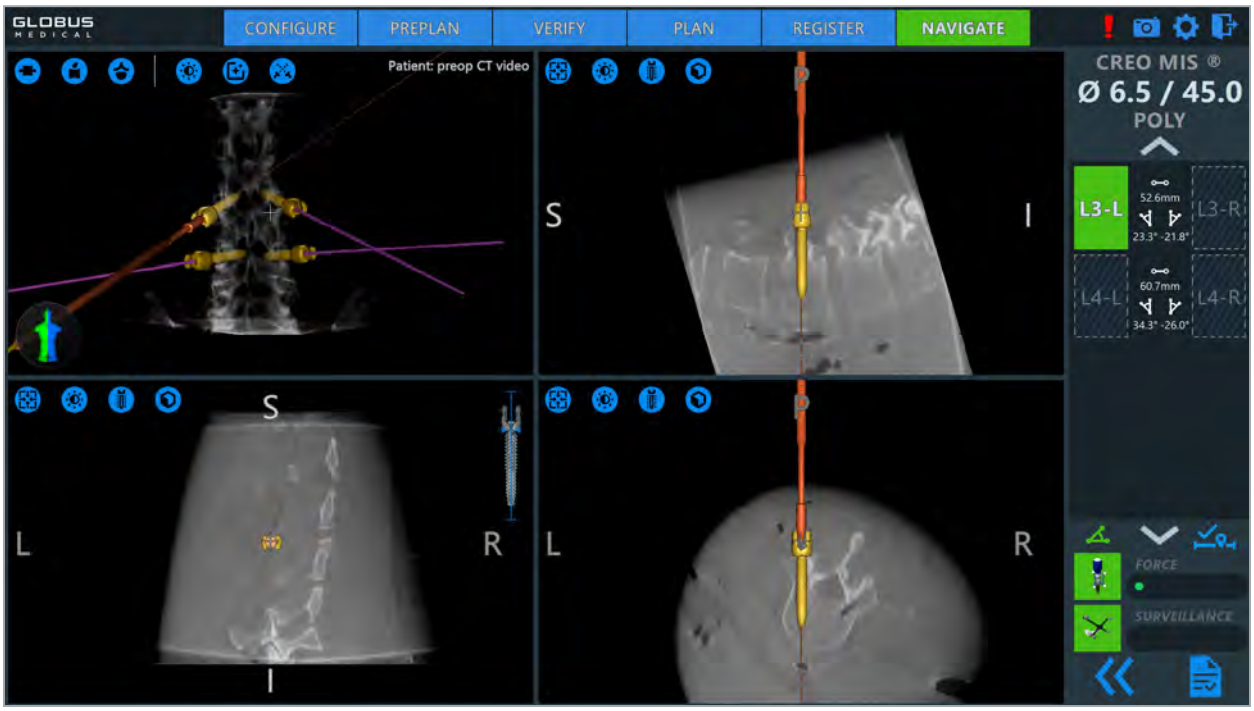
Use the IMAGE tab to load the desired patient images.

After instrument registration has been completed, perform a landmark check or verification to ensure that the registration was calculated successfully. Using the navigated verification probe, touch an anatomical landmark and verify that the corresponding location is shown on the system monitor. Repeat this process using 2-3 landmarks.

Use the PLAN tab to plan screw placement if desired. Select the desired screw label on the right of the screen to choose the screw plan.

Use the NAVIGATE tab to display the screw and navigated instruments during the procedure.

Monitor the surveillance marker during the procedure. If the surveillance marker indicates significant movement of the DRB, perform an anatomical landmark check. If the landmark check is satisfactory, re-register the surveillance marker. If the landmark check fails, re-register the patient.



Trajectory-Only Procedures

The ExcelsiusGPS® System may be used for trajectory guidance using the robotic arm without navigated instruments. The guide tube serves as a rigid retractor that can be moved within the surgical field or aligned to a trajectory automatically or manually.

Refer to the corresponding application and imaging workflow for the imaging modality (preoperative CT, intraoperative CT, or fluoroscopy).

Use the IMAGE tab to load the desired patient images.

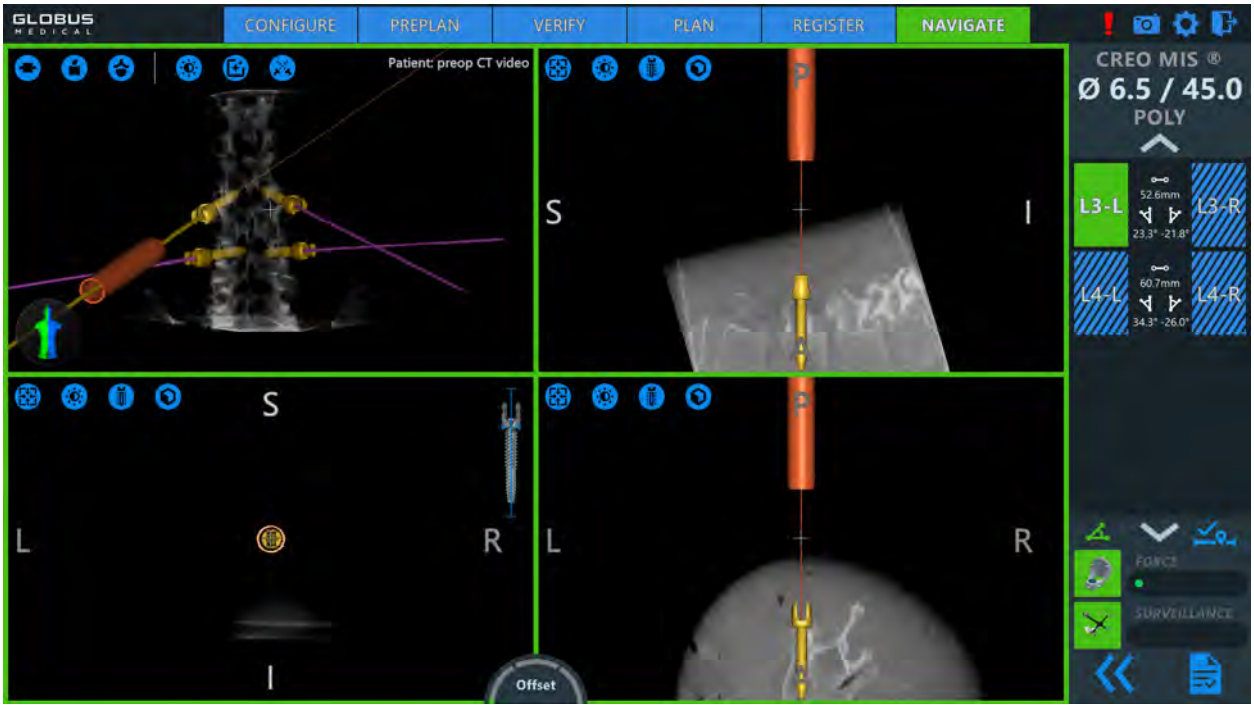
A landmark check, or verification, should be performed to ensure that the registration was calculated successfully. Using the navigated verification probe, touch an anatomical landmark and verify that the corresponding location is shown on the system monitor. Repeat this process using 2–3 landmarks.

Use the PLAN tab to plan screw placement. Select the desired screw label on the right of the screen. The screw plan is active when the screw label is highlighted, and the robotic arm can be moved by the bracelet or by pressing the foot pedal and moving the arm. The robotic arm first moves up to clear obstacles in the surgical field and then down along the specified trajectory. Once on the trajectory, the robotic arm can be moved up/down along the trajectory but does not move off of the trajectory unless the screw is deselected.

If using K-wires, use the cannulated awl to prepare the starting hole and place the K-wire into bone at the desired trajectory through the guide tube. The End Effector should be moved away from the trajectory so the screw can be placed by K-wire guidance. Deselect the screw plan.

Perform the surgical procedure using non-navigated metallic surgical instruments that fit through the guide tube diameter.

Monitor the surveillance marker during the procedure. If the surveillance marker indicates significant movement of the DRB, perform an anatomical landmark check. If the landmark check is satisfactory, re-register the surveillance marker. If the landmark check fails, re-register the patient.



SHUTDOWN

Press the power button on the control panel to turn off the system. Ensure the stabilizers on the base station casters are up. A power down request pop-up window appears on the main display, requiring confirmation of the power down request. Once the request is acknowledged, the system powers down. The system is off when the power button is not illuminated.

The power button may be pressed for approximately 10 seconds to force the system to power down in the event that the software is not responding.

Camera Cable Storage

STORAGE

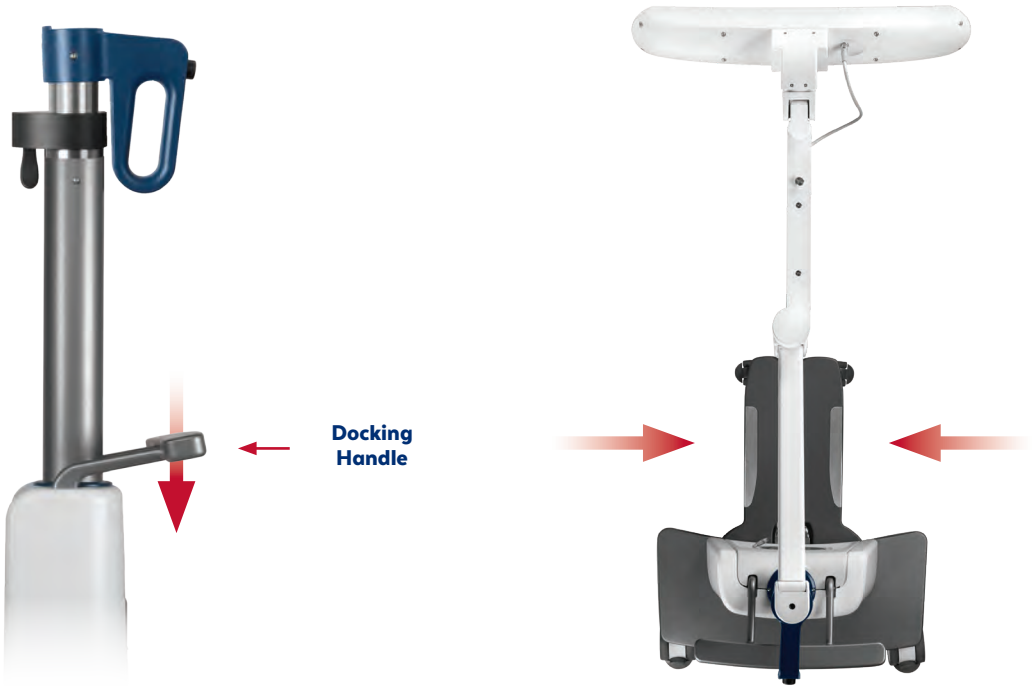
For storage and movement, dock the camera stand into the back of the Robotic Base Station. Unplug the camera cord from the connector panel on the Robotic Base Station and wrap cord tightly on the cord holder on the camera stand. Remove any USB drives inserted in the connector panel on the cabinet.

Unplug the foot pedal, wrap the cord around itself, and place in the foot pedal basket on the back of the Robotic Base Station.

Move the camera stand behind the Robotic Base Station and ensure the stabilizers on the base station casters are up.

Docking Camera Stand

Depress the docking handle to close the camera legs.



Docking Camera Legs

Push the camera stand with the docking handle up the inner ramp of the Robotic Base Station until the camera stand is lifted off of the ground and clicks into place. An inner locking mechanism secures the system automatically.

Place cover over the ExcelsiusGPS® system after camera has been docked with the Robotic Base System. The cover protects the camera, monitors, and controls when the system is not in use.

System docked

System docked with cover

System docked (top view)

	CAUTION
	If system is stored for more than 60 days, it is recommended that the system is plugged into AC power for at least 24 hours before use to ensure proper battery capacity.

CLEANING AND STERILIZATION

System Hardware

Clean the ExcelsiusGPS® in a location away from the patient environment or immediately after use in its surgical location. To avoid exposure to blood-borne pathogens and chemicals, use personal protective equipment.

Read the labels on all approved cleaning agents, detergents, and solvents and use only per the manufacturer's instructions. The approved cleaning materials include mild disinfectants, such as bleach or sodium hypochlorite-based solutions, ethanol (70%), or isopropyl alcohol at 70%-90% concentration.

Prior to cleaning, remove disposable drapes from the system.

Clean outer surfaces with a lint-free cloth and approved mild disinfectant per the disinfectant manufacturer's instructions. Use caution not to drip or splash any liquid onto the interior of the equipment. Read the labels on all cleaning agents, solvents, and detergents to ensure that they will not cause damage or discolor the finishes of the outer surfaces.

Using a cloth and disinfectant, wipe all surfaces including cables. Replace cloth after cleaning surfaces that are heavily soiled to avoid cross-contamination.

Avoid the use of phenol-based, corrosive, or solvent disinfectant agents that may harm the surface material on equipment. If you are unsure of the properties of a disinfectant agent, do not use it.

WARNING

Do not use flammable or potentially explosive disinfectant sprays. The use of such sprays can create vapors that cause explosion and fire resulting in serious personal injury or death

CAUTION

The system is not waterproof. If water or cleaning liquids enter the equipment, electrical short circuits can result once power is returned.

CAUTION

The use of sprays to disinfect medical equipment is not recommended. The vapor from the spray can enter the equipment and cause electrical short circuits and corrosion.

CAUTION

Failure to correctly clean and sterilize reusable components could result in patient infection.

Monitor and Camera Lenses

Refer to the NDI Passive Polaris Spectra User Guide for camera lens cleaning instructions.

Instruments

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 the product to Globus Medical. Handle the End Effector with care during cleaning as it contains sensitive electronics.

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. Hand wash the End Effector.

Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments, and 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.
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 in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. 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.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

Sterilization

ExcelsiusGPS® instruments are available non-sterile and sterile. The disposable drapes and reflective markers are provided sterile.

The sterile drapes and markers are sterilized by ethylene oxide. The expiration date is provided on the package label. These components are considered sterile unless the packaging has been opened or damaged. They are single use and should be discarded properly after surgery; do not autoclave or re-use.

WARNING

Do not use sterile items if expired or packaging is damaged.

Non-sterile ExcelsiusGPS® instruments have been validated to ensure an SAL of 10^{-6}. The use of an FDA cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. 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 have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature). It is recommended that these instruments are sterilized in a graphic case, especially the End Effector which contains sensitive electronics.

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared 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 in^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.

Use the following parameters to sterilize instruments discussed within this manual:

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

These parameters are validated to sterilize only these instruments. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

LABELS AND TECHNICAL REFERENCE

Labels and Symbols

Requirement	Label Content	Location
Globus Logo		Product Label
Product Name	ExcelsiusGPS®	Product Label
Manufacturer Name and Address	Globus Medical Inc. 2560 General Armistead Ave Audubon, PA 19403	Product Label and Product Insert
Telephone Number	US: 1-866-GLOBUS1 (1-866-456-2871)	Product Label
ETL Intertek Symbol		Product Label
Manufacturer Symbol		Product Label
Date of Manufacturer Symbol		Product Label
Date of Manufacture	YYYY-MM-DD	Product Label
Catalog Number		Product Label
Serial Number		Product Label

Requirement	Label Content	Location
Consult Instructions for Use Symbol		Product Label
Authorized Representative in the European Community	EC REP	Product Label
CE Mark Symbol	CE	Product Label
Electrical Ratings	Voltage, Amperage, Power, Frequency	Product Label
RoHs Compliance Symbol	RoHS COMPLIANT	Product Label
Waste Electrical and Electronic Equipment (WEEE)		Product Label
List of Patents	Patent Numbers	Product Label
Weight of Unit		Product Label
Label Part of Number	Label P/N XXXX Rev X	Product Label
Robot UDI Label **Instrument UDI Label**	(01)XXXXXXXXXXXXX(11)MFG date[YYMMDD](21)Serial# (01)XXXXXXXXXXXXX(10)LOT	Product Label
Equipotentiality		Connector Panel

Requirement	Label Content	Location
Type BF Applied Part		End Effector
Main Power On/Off		Control Panel
Emergency Stop		Control Panel
Laser Radiation		Camera
Mandatory: Instruction Manual		Next to Product Label
Atmospheric Pressure Limitation		Shipping Containers
Temperature Limit		Shipping Containers
Humidity Limit		Shipping Containers

SYSTEM SPECIFICATIONS

Operating Conditions

- Temperature: 10°C (50°F) to 27°C (80°F)
- Operating Air Pressure: 70 to 102 kPa
- Humidity: 20% to 75% non-condensing

System Transportation and Storage Conditions

The system components can be shipped under the following conditions:

- Temperature: -10°C (14°F) to 50°C (122°F)
- Altitude: Up to 35,000 ft (air cargo)
- Air Pressure: 57 to 102 kPa (typical air cargo)
- Humidity: 5% to 95% condensing permitted

- Vibration
  - Frequency: 4 to 200 Hz
  - G Value: Random 1.14 g RMS
  - Amplitude: 0 to 0.15mm

- Shock
  - G Value: 0 to 10g
  - Pulse duration: 6 to 10ms

Dry heated storage is required for any extended period of storage more than a few days:

- Temperature: 5°C (41°F) to 40°C (104°F)
- Air Pressure: 70 to 102 kPa
- Humidity: 5% to 75% non-condensing

Power Requirements

- 100 VAC 50/60Hz
- 120 VAC 60Hz
- 220-240 VAC 50/60Hz
- Power Requirements ≤700 VA

General Specifications

- System Weight: 371 kg (818 lbs)
- Docked Dimensions: 122cm x 79cm x 179cm (48" x 31" x 70")

System Dimensions

Maximum Height and Length

Docked Width

Operational Width

Handling

The ExcelsiusGPS® and all associated instruments should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Instruments should be checked to ensure that they are in working order prior to surgery. Discard any blunt or damaged instruments. Surgical grade instrument lubricant or oil may be used to lubricate joints and hinges.

System Disposal at End of Life

It is the responsibility of the equipment owner to dispose of the system in a manner that conforms to local and country regulations. This normally requires the equipment to be collected separately from the municipal waste as indicated by the symbol shown at right.

The equipment may have resale value on the market or as parts. Your distributor or Globus Medical should be contacted before disposal for potential assistance and to determine if the parts can be recycled through these companies. In the event the user chooses to dispose of the system locally, to reduce risk to the environment and to the persons discarding the equipment, a service engineer trained on the maintenance and installation of the ExcelsiusGPS® should be contacted to assist in the safe decommissioning of the system.

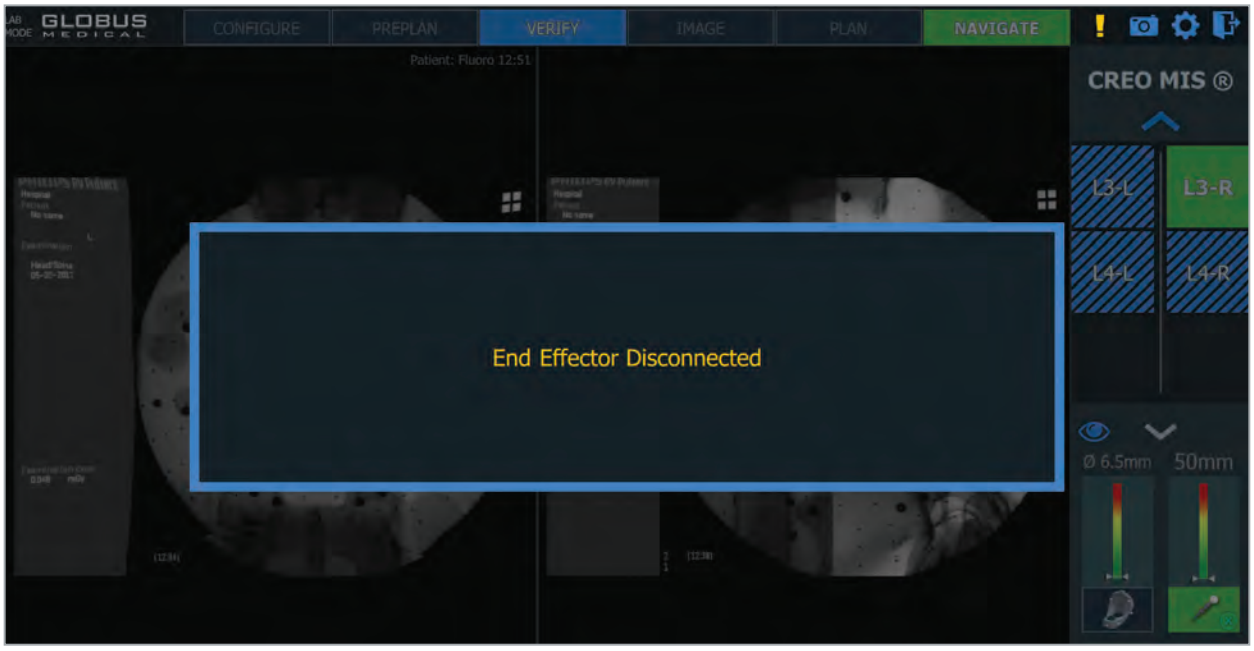
The sealed lead acid batteries can be discarded with a battery recycling company.

All components are RoHS compliant.

MAINTENANCE AND TROUBLESHOOTING

Software Error Messages

The system alerts the operator of errors through pop-up messages. The following list describes all possible errors and the actions to correct them.



Message	Description	Proposed Remedy
End Effector Disconnected	The End Effector is not attached to the robotic arm.	Ensure that the End Effector is properly attached.
Stabilizer Not Down	Stabilizers have not been deployed.	Engage stabilizer.
Registration Not Completed	The patient scan did not pass automatic registration or was unregistered through the registration view.	Complete registration.
Registration Not Transfered	Registration has not yet been transferred from the intraoperative CT registration fixture to the Dynamic Reference Base.	Transfer registration.
Camera Disconnected	The connection to the camera was dropped, most likely as a result of a loose cable.	Ensure the camera is properly connected.
Camera Frame Rate Dropped	The frame rate of the camera has dropped below the system's safe limit. This is usually due to too many tracked instruments/objects in the camera's view.	Too many instruments in view of the camera. Removing instruments increases the camera frame rate.
Camera CRC Mismatch	Data from camera is not valid or there has been a camera communication problem.	Disconnect camera from Robotic Base Station and reconnect.
End Effector Not Visible	The End Effector is not currently visible to the camera. (This will stop or prevent motion as the End Effector fiducials must be visible to move the robotic arm.)	Ensure the End Effector is in view of the camera.

Message	Description	Proposed Remedy
DRB Not Visible	The Dynamic Reference Base is not currently visible to the camera (this will stop motion as the Dynamic Reference Base fiducials must be visible to move the robot arm).	Ensure the Dynamic Reference Base is in view of the camera.
E-Stop Pressed	Someone has physically pressed the E-Stop or Emergency Stop button on the Robot Base Station. This stops motion.	Rotate the E-Stop button to release.
PIB Communication Dropped	Communication to the PIB (Platform Interface Board) has been lost. This severs communication to the robotic arm, which stops or prevents motion.	Restart the system.
Surveillance Marker Moved	The surveillance marker has moved beyond its safety-critical limit in relation to the Dynamic Reference Base.	Perform an anatomical landmark check to ensure navigation is still accurate. If navigation is inaccurate, re-register the patient or discontinue use for that procedure.
Surveillance Marker Not Visible	The surveillance marker has either shifted dramatically or moved a great distance, which causes the camera to no longer see it.	Perform an anatomical landmark check to ensure navigation is still accurate. If navigation is inaccurate, re-register the patient or discontinue use for that procedure.
Active Trajectory Not Reachable	The robotic arm cannot create a table of position points to move to a trajectory, based on the kinematics equations used.	Move Robotic Base Station to allow the arm to reach the trajectory.
Maximum Trajectory Error Exceeded	When the robot arm is locked onto a trajectory, if the actual position of the robot arm exceeds a certain distance from the perceived trajectory, this error will occur. Could be related to excessive force on the End Effector or kinematics issues.	Restart the move.
Excessive Force on the End Effector	Excessive force has been applied to the load cell, over a certain limit (50N or 11 lbs)	Remove the force.
Excessive Dynamic Reference Base Movement	The Dynamic Reference Base position has shifted relatively quickly, without movement of other objects in the view of the camera.	Perform an anatomical landmark check to ensure navigation is still accurate. If navigation is inaccurate, either re-register the patient or discontinue use for that procedure.
Move Enabled Press Error	Move enabled is pressed while activating trajectory. Prevents the robot from instantly entering auto-move mode immediately after activating a trajectory.	Release the foot pedal or bracelet, then activate the trajectory.
GMAS Communication Failure	Communication with the GMAS controller has been lost. This will stop or prevent motion as GMAS is no longer receiving updates from the client about trajectory and camera.	The system should automatically connect. If not, restart the system.
Move Enabled Timeout	Move enable has been active for longer than the threshold (90 seconds or more). This is a failsafe for accidentally leaving the arm engaged.	Release the foot pedal or bracelet, then re-engage the foot pedal or bracelet.
Camera Bumped	Massive bump to the camera, where the camera is likely to be permanently damaged. This is an error identified internally by the NDI software.	Contact Tech Support.

Message	Description	Proposed Remedy
Tool in End Effector	If an instrument is in the End Effector when attempting to move, motion will be disallowed and this error will be displayed.	Remove instrument from End Effector.
Move Enabled Test Failure	The move enabled test has failed.	Ensure no buttons are pressed on the system; the system will automatically retry.
Motion Homing Failure	The homing routine for the robot has failed, causing the robotic arm to lose its relative positions.	Contact Tech Support.
Need to Home	Robot has not run its homing routine, causing the robotic arm to not know its relative position.	Contact Tech Support.

Mechanical Troubleshooting

CASTER STABILIZER MANUAL OVERRIDE

If the stabilizers are not responding to the buttons on the control panel, the stabilizers can be individually lowered and raised manually. Remove the stabilizer cover and rotate the knob clockwise to raise the stabilizer. The caster is shown with the cover removed below.

Caster with Stabilizer

Globus Medical
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
www.globusmedical.com

Customer Service:
Phone 1-866-GLOBUS1 (or 1-866-456-2871)
Fax 1-866-GLOBUS3 (or 1-866-456-2873)

GMUML01
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