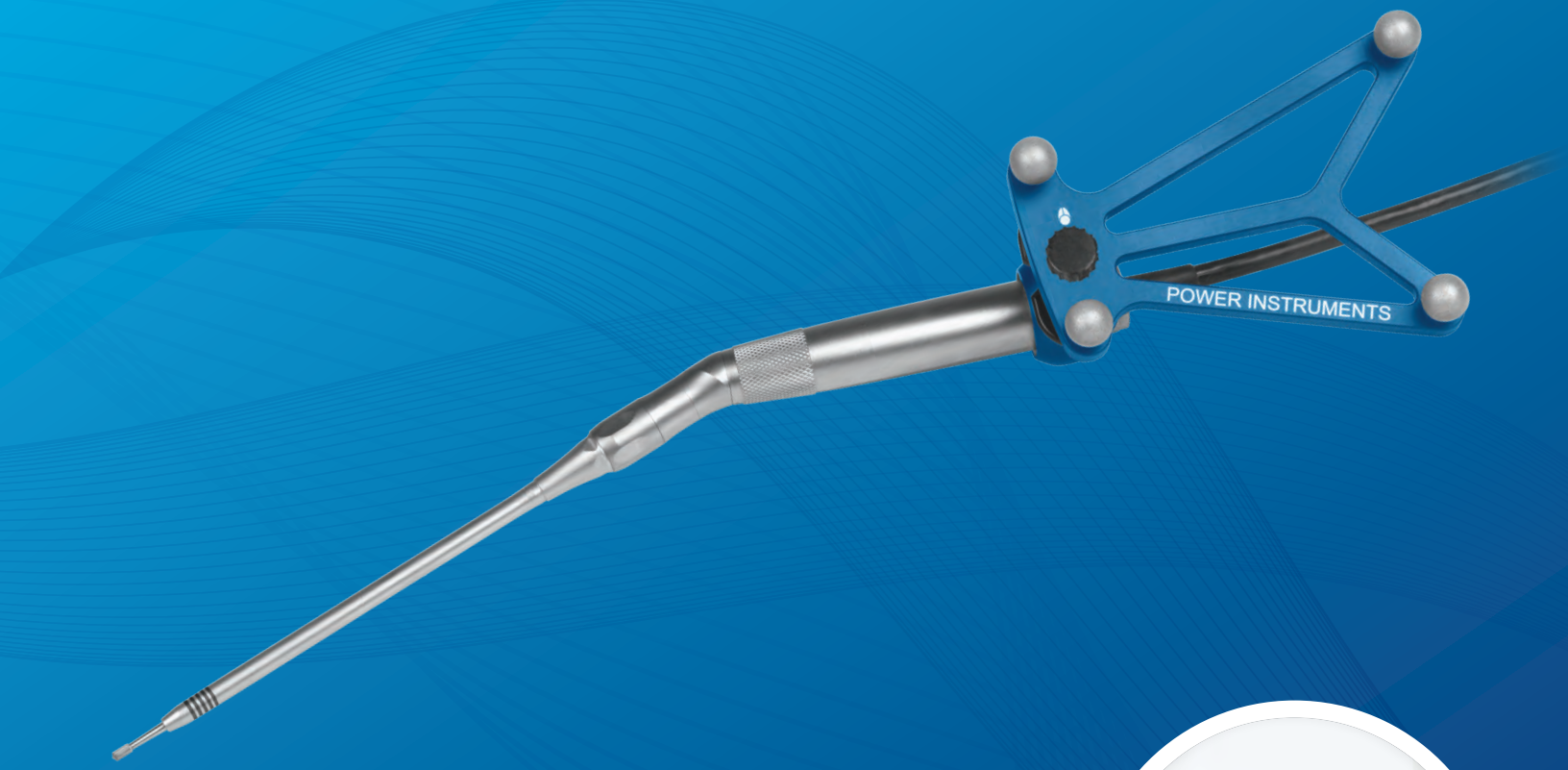
GLOBUS MEDICAL



VERZA™

Navigated High Speed Drill

USER MANUAL SUPPLEMENT

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GLOBUS MEDICAL

Our mission is to deliver cutting-edge technology, research, and innovative solutions to promote healing in patients with musculoskeletal disorders.

Life moves us

USER MANUAL SUPPLEMENT

VERZA™

INTRODUCTION

System Overview

VERZA™ High Speed Drills may be used in conjunction with ExcelsiusGPS® for freehand navigation or guided navigation. A special array is attached to the drill to allow navigation. The drills may be used freehand without navigation.

Refer to the **ExcelsiusGPS® Spine Module User Manual (GMUML09)** for detailed instructions and important information on this system.

Refer to the **NSK Primado2 Operation Manual (OM-SE0028E)** for standard instructions on using VERZA™ High Speed Drills without navigation.

Indications for Use

VERZA™ High Speed Drills are indicated for drilling, burring, removing, and otherwise manipulating hard tissue, bone, bone cement, prosthesis, implant, and other bone related tissue during spinal and orthopaedic procedures.

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 orthopaedic bone screws and interbody fusion devices.

ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures to be used by surgeons for navigating 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 orthopaedic bone screws and interbody fusion devices.

INSTRUMENT OVERVIEW

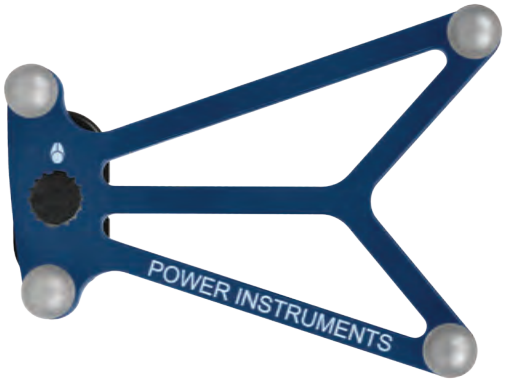
CAPITAL EQUIPMENT

VERZA™ Control Unit, 120V 6261.1101

VERZA™ Foot Pedal, Single Button Control 6261.1201

AUTOCLAVABLE INSTRUMENTS

VERZA™ Motor, GPS 6261.1301



Power Instruments Array, GPS 6261.1401

AUTOCLAVABLE INSTRUMENTS (CONT'D)

VERZA™ Straight Attachments, GPS

	Size	Part No.
	4.5cm	6261.2001
	6.5cm	6261.2002
	8.5cm	6261.2003
	11cm	6261.2004

VERZA™ Angled Attachments, GPS

	Size	Part No.
	4.5cm	6261.3001
	6.5cm	6261.3002
	8.5cm	6261.3003
	11cm	6261.3004

VERZA™ Straight Attachment, 22.5cm, GPS 6261.2007

VERZA™ End Effector Sleeve, 15mm 6261.1411

NON-NAVIGATED, MIS WORKFLOW INSTRUMENTS

Attachments are available for non-navigated workflows with an angled proximal bend.

VERZA™ MIS Attachment Hub, Angled 6261.3100

VERZA™ MIS Attachment Tube, Proximal Bent, 13cm 6261.3106

	WARNING
	Do not use sterile items if expired or packaging is damaged. Only use compatible burs manufactured by Globus Medical.

DISPOSABLE CUTTING BURS

Cutting burs are available in fluted ball, diamond ball, and match head styles in a variety of diameters and are specific to the Attachment length being used. See page 23 for the full list of available cutting burs.

Diamond Ball

Fluted Ball

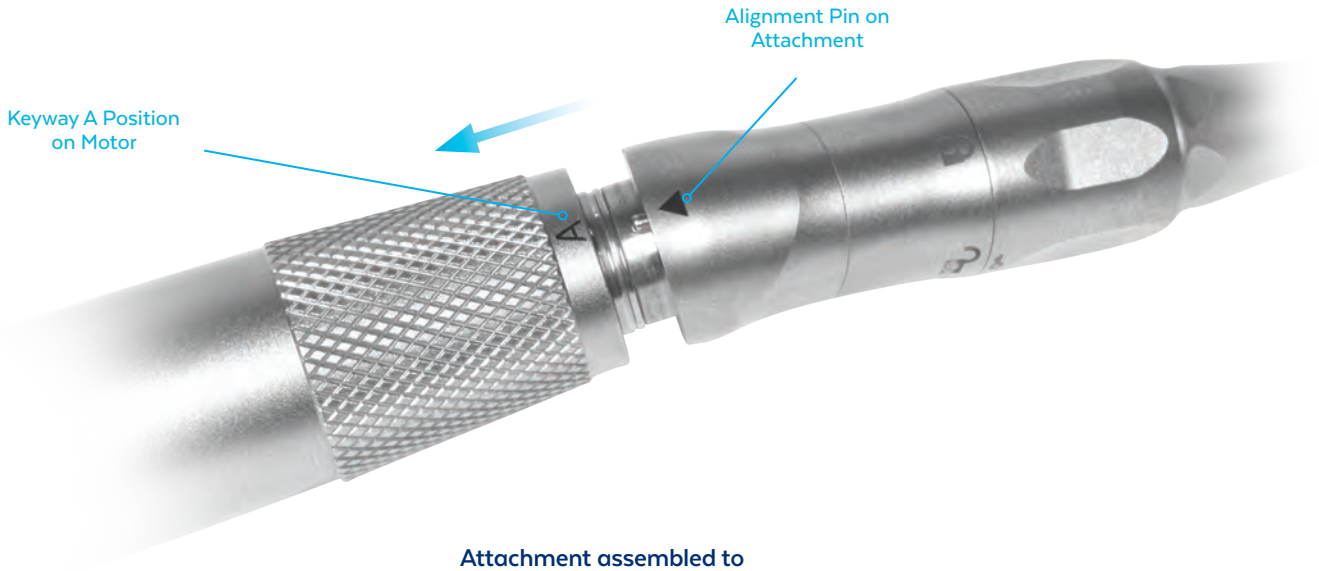
Match Head

Part No.	Bur Type	Head Diameter	Attachment Length
6261.5304S	Fluted Ball	3.0mm	11cm
6261.5404S		4.0mm	
6261.5504S		5.0mm	
6261.6224S	Match Head	2.2mm	
6261.6304S		3.0mm	
6261.7304S	Diamond Ball	3.0mm	
6261.7404S		4.0mm	
6261.7504S		5.0mm	
6261.5257S	Fluted Ball	2.5mm	22.5cm
6261.5357S		3.5mm	
6261.5457S		4.5mm	

VERZA™
NAVIGATED HIGH SPEED DRILL

SETUP AND ASSEMBLY

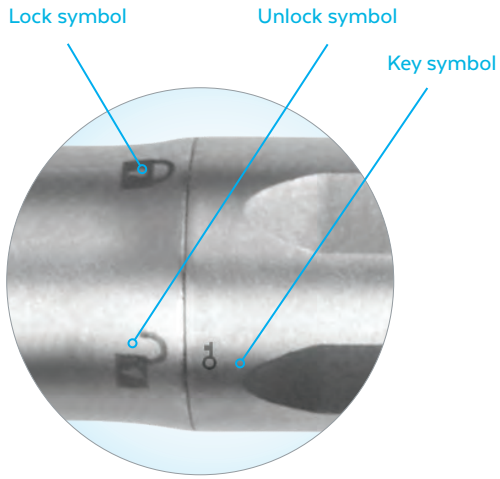
Assemble the selected Attachment to the Drill Motor. The Drill Motor allows for two orientations of the Attachment, etched as “A” or “C” keyway positions, to allow the Navigation Array orientation to match the camera positioning intraoperatively. Orient the alignment pin on the Attachment to the desired position on the motor. Press the two together until they click. Ensure that the Attachment is fully seated. To remove an Attachment, pull it out straight from the end of the motor.



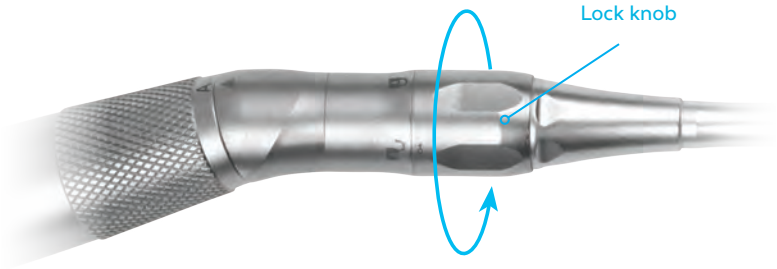
Attachment assembled to Drill Motor at A Position

Assembled Drill Motor and Attachment

Assemble the selected Bur to the Attachment. Rotate the lock knob on the Attachment until the unlock symbol is aligned with the key symbol. The knob will click when it is fully open. Insert the Bur into the distal end of the Attachment.



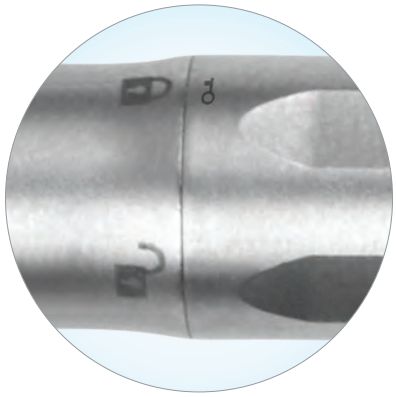
Unlocked position



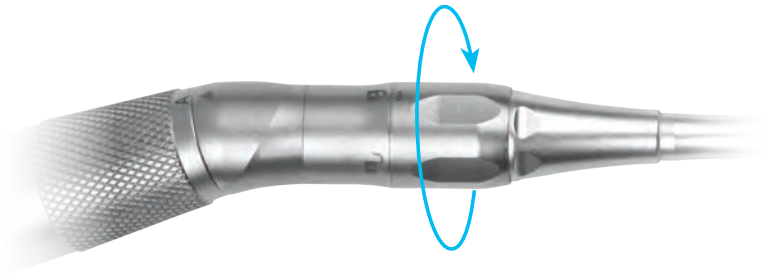
Rotate lock knob until unlock symbol is aligned with key symbol before inserting Bur

Secure the Bur by rotating the lock knob until the lock symbol is aligned with the key symbol. The knob will click when it is locked. Gently pull the Bur to confirm that it is securely connected to the Attachment. To remove the Bur, unlock the knob and pull the Bur straight out.

Bur inserted from distal end of Attachment



Locked position

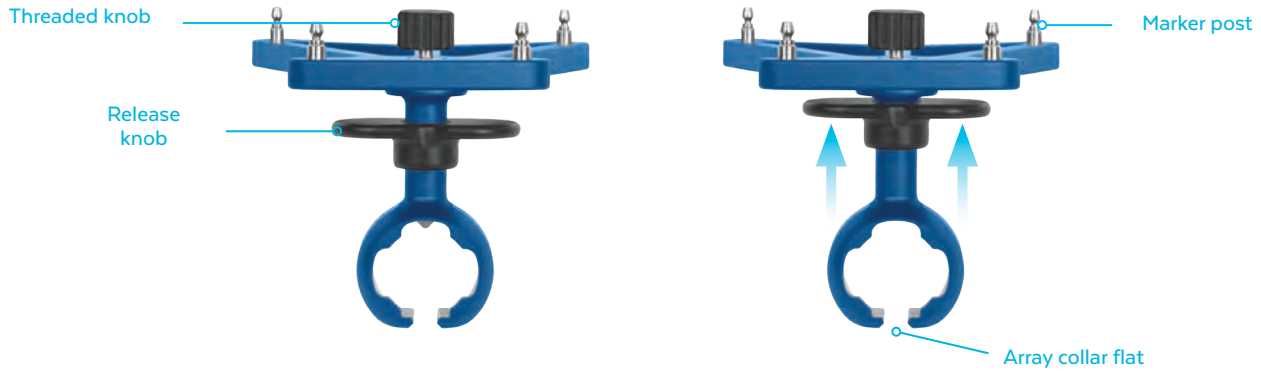


Rotate lock knob until lock symbol is aligned with key symbol to secure Bur

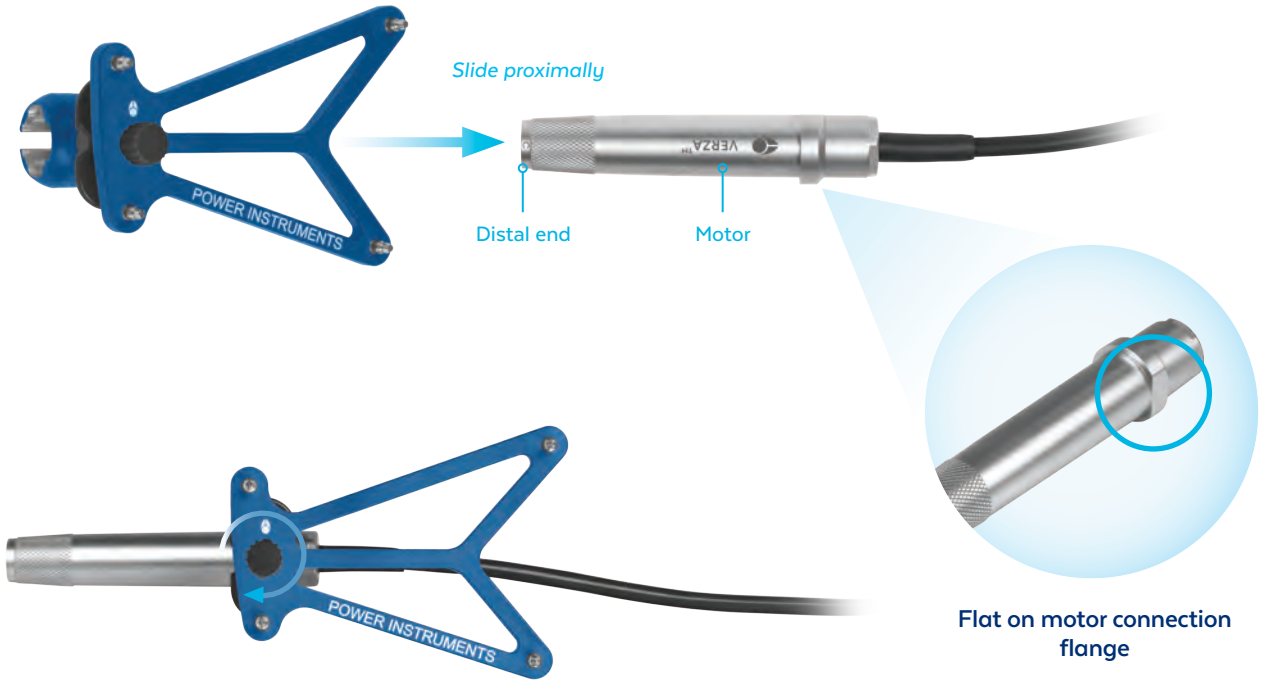
Fully assembled

ATTACHING THE ARRAY WITH THE VERZA™ DRILL

To assemble the array onto the drill, pull up on the black release knob on the array to release the internal locking pin and slide the array over the motor/Attachment assembly from the distal end.



Orient the flat of the array collar with the flat on the motor connection flange. Slide the array proximally until the array collar covers the motor connection flange and cannot slide further proximally. Once in place, release the black release knob. Rotate the black threaded knob clockwise until finger tight to advance the internal locking pin into final position to lock the array to the motor.



Attaching array to motor

Flat on motor connection flange

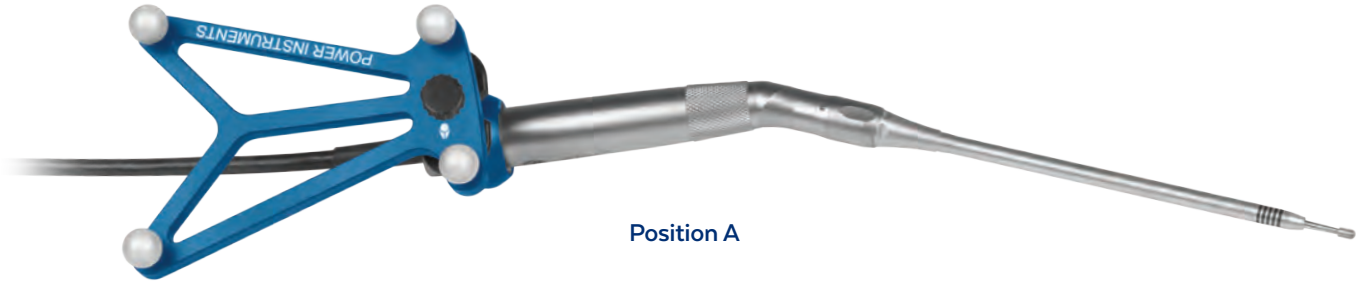
Attach reflective markers to each marker post on the array. Ensure that the markers are fully seated on the posts.

Attaching reflective marker to post on array

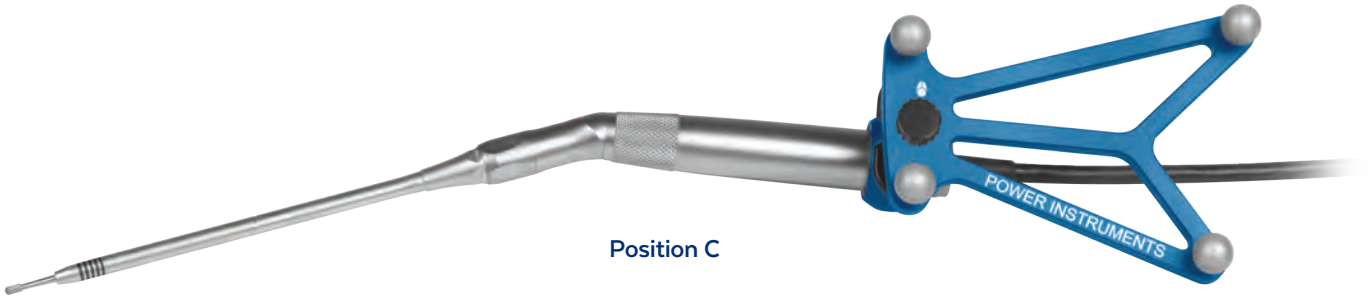
To remove the array, rotate the black threaded knob counterclockwise. Then, pull up on the black release knob and slide the array off the motor connection and over the distal end of the motor.

Array fully assembled with Attachment

The Navigation Array can only be assembled to the motor in one discrete orientation with both flat surfaces aligned. Attachments can be assembled in either the “A” position or “C” position on the motor to allow visibility of the array in relation to the ExcelsiusGPS® camera, surgeon, and patient position in the operating room. The two assembly positions are shown below.



Position A



Position C

OPERATING THE SYSTEM

Control Unit Setup

Connect the Power Cord to the inlet box located at the back of the Control Unit.

Connecting Power Cord to Control Unit

Foot Pedal

Connect the Foot Pedal cable to the front of the Control Unit. Align the red marks on the cable end and connector, and press the cable in until fully seated. To disconnect the Foot Pedal, hold the Foot Pedal plug and pull straight out.

Red markings aligned on cable end and connector

Foot Pedal connected to Control Unit

Connecting the Drill Motor

Connect the Drill Motor cable to the front of the Control Unit. Align the red mark on the motor cable plug with the red mark on either the A or B port on the Control Unit. Press the cable all the way into the port. Two motors may be used during a procedure by connecting them to both the A and B ports.

Drill Motor

Red markings aligned on cable and port

Drill Motor and Foot Pedal connected to Control Unit

LCD TOUCHSCREEN OPERATION OVERVIEW

The LCD touchscreen on the Control Unit is used to control all functions of the VERZA™ Drill System. The diagram below shows the major functions and locations on the screen to select specific functions and make desired adjustments.

Use the track bar feature to adjust and set the speed or irrigation volume. Push the up/down button or move the track bar to set the speed or volume. The track bar moves to the position that you have touched, within the adjustment area. Use the up/down button adjustments to fine-tune settings.

Please refer to the **NSK Primado2 Operation Manual (OM-SE0028E)** for more details**.**

Note: The default speed setting on the Control Unit is 64,000 rpm, but can be adjusted for a maximum of 80,000 rpm.

Touchscreen

Touchscreen example displaying Motor A speed setting and irrigation flow rate

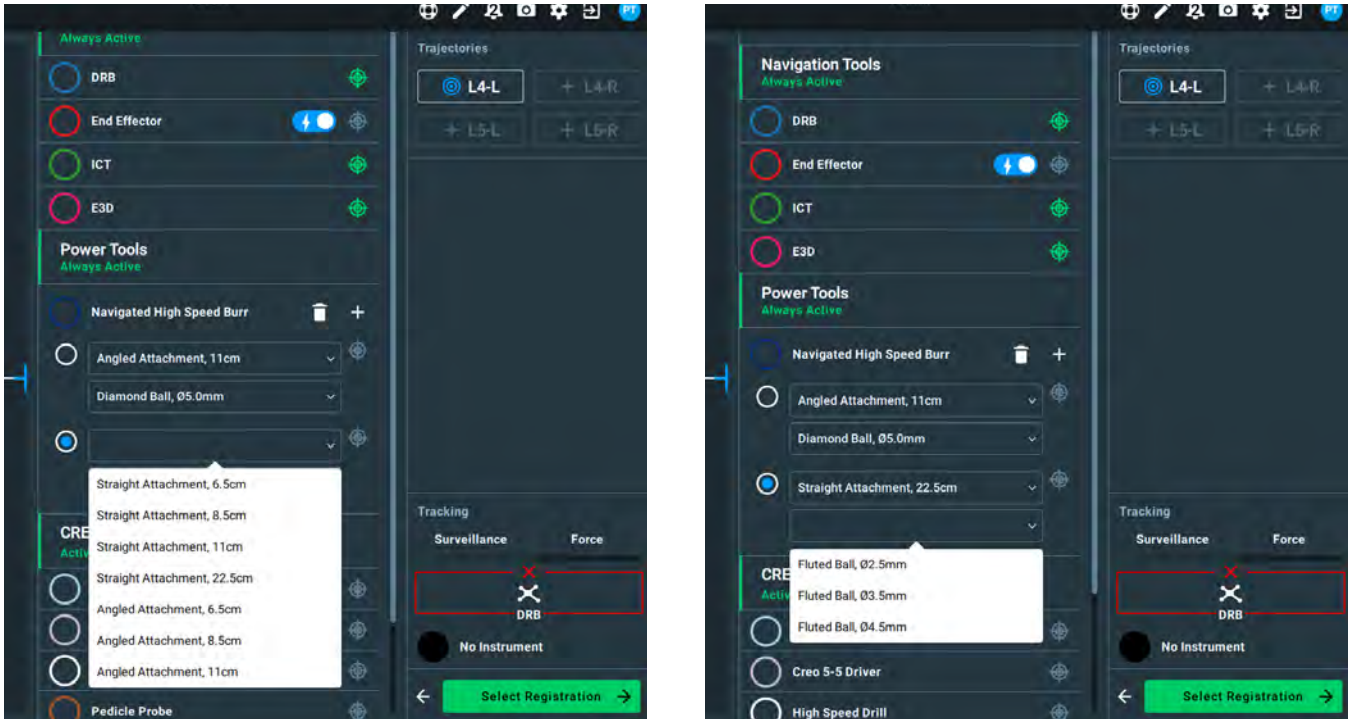
ExcelsiusGPS® SYSTEM SETUP AND REGISTRATION

The VERZA™ Drill System can be used with all three ExcelsiusGPS® workflows (intra-op CT, pre-op CT, and fluoro). Refer to the **ExcelsiusGPS® Spine Module User Manual (GMUML09)** for system use, indications, contraindications, warnings, and precautions.

Instrument Verification

Prior to using the VERZA™ Drill System instruments with ExcelsiusGPS®, reflective markers need to be assembled to the posts of the navigation array (refer to the Attaching the Array with the VERZA™ Drill section). Once the VERZA™ Drill is assembled with its array, the instrument must be verified for navigation. Complete verification of the assembled drill using the ExcelsiusGPS® software and the navigation camera.

Select the specific Attachment and Bur combination of the assembly from the VERZA™ instrument dropdown list in the ExcelsiusGPS® software. Each physical combination of Motor, Array, Attachment, and Bur must be verified. VERZA™ Drill instruments must be verified in the "A" position. Multiple Attachment and Bur combinations may be verified by selecting the "+" sign and inputting additional configurations.



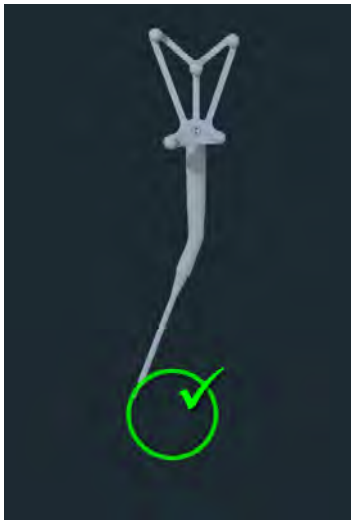
Dropdown menu showing Attachment and Bur options for selection

ExcelsiusGPS® SYSTEM SETUP AND REGISTRATION (CONT'D)

Verify Drill Assembly

- Place the tip of the assembled VERZA™ Drill into a verification divot located on the End Effector or on any other instrument array.
- Ensure both instruments are visible and held steady.
- A pop-up screen appears on the Verify tab of the monitor to indicate the verification process.
- Verification status is indicated on the screen with the tip error displayed in millimeters. If verification has failed (red crossed circle), verification must be repeated until it is successful (green circle).

Drill verification with other instrument array verification divot



Successful verification

Failed verification

	CAUTION
⚠	If there is any concern or doubt regarding navigation accuracy at any time, re-verify the instrument being used.

	CAUTION
⚠	Ensure that instrument settings are correct and correspond to the instrument being used. If the instrument has an index position, ensure that the position is correctly entered.

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

Proceed to the Navigate tab. Instruments that have been successfully verified may be used for freehand navigation with ExcelsiusGPS® or robotic navigation using ExcelsiusGPS®.

ROBOTIC NAVIGATION WITH ExcelsiusGPS®

VERZA™ drills may be used for guided navigation with ExcelsiusGPS®, such as drilling pilot holes for pedicle screws. After all navigated instruments have been successfully verified for use and implant planning is complete, the VERZA™ Drill System can be used to create pilot holes for pedicle screw placement with the ExcelsiusGPS® system.

Note: Only the 22.5cm length Attachment can be used with ExcelsiusGPS®. This is the only length that will fit the End Effector Guide Tube.

After planning of the pedicle screw trajectories is complete, step on the ExcelsiusGPS® foot pedal to align the robotic arm on the selected trajectory. Make an incision.

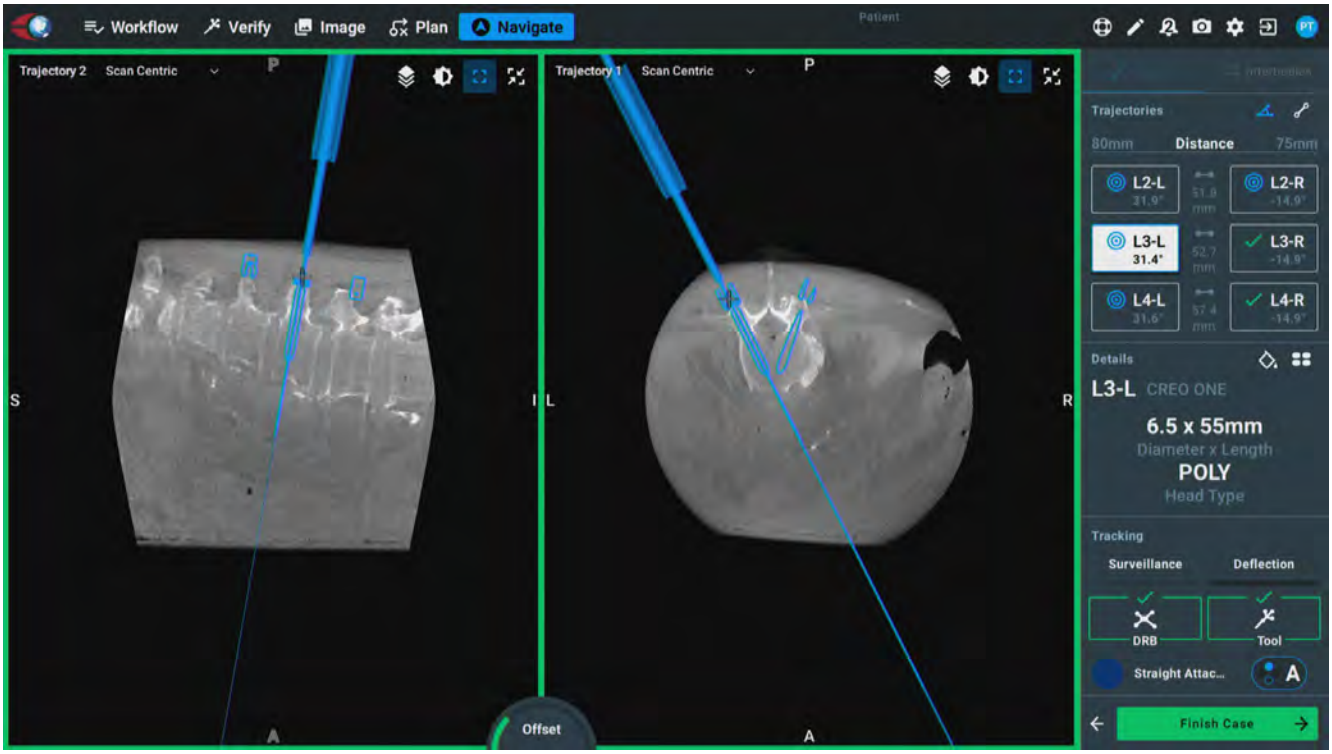
Insert the End Effector Sleeve into the End Effector Guide Tube. Insert the VERZA™ Drill assembly into the End Effector Sleeve, ensuring that the array is facing the camera. Verify that the drill is displayed in real time on the screen.

Advance the drill through the End Effector until it reaches bone. Confirm that the trajectory looks accurate on the ExcelsiusGPS® navigation screen, then withdraw the drill slightly, depress the foot pedal to turn the motor on, and advance the drill into bone. Monitor the ExcelsiusGPS® navigation screen to confirm the desired trajectory and position the drill to the desired depth.

Note: For efficiency, it is recommended to run the Pilot Hole Attachment at 30,000 rpm.

ROBOTIC NAVIGATION WITH ExcelsiusGPS® (CONT'D)

When pilot hole drilling is complete, remove the VERZA™ Drill and End Effector Sleeve from the End Effector and proceed with desired instruments for subsequent pedicle prep and screw insertion according to the **ExcelsiusGPS® Spine Module User Manual (GMUML09)**.

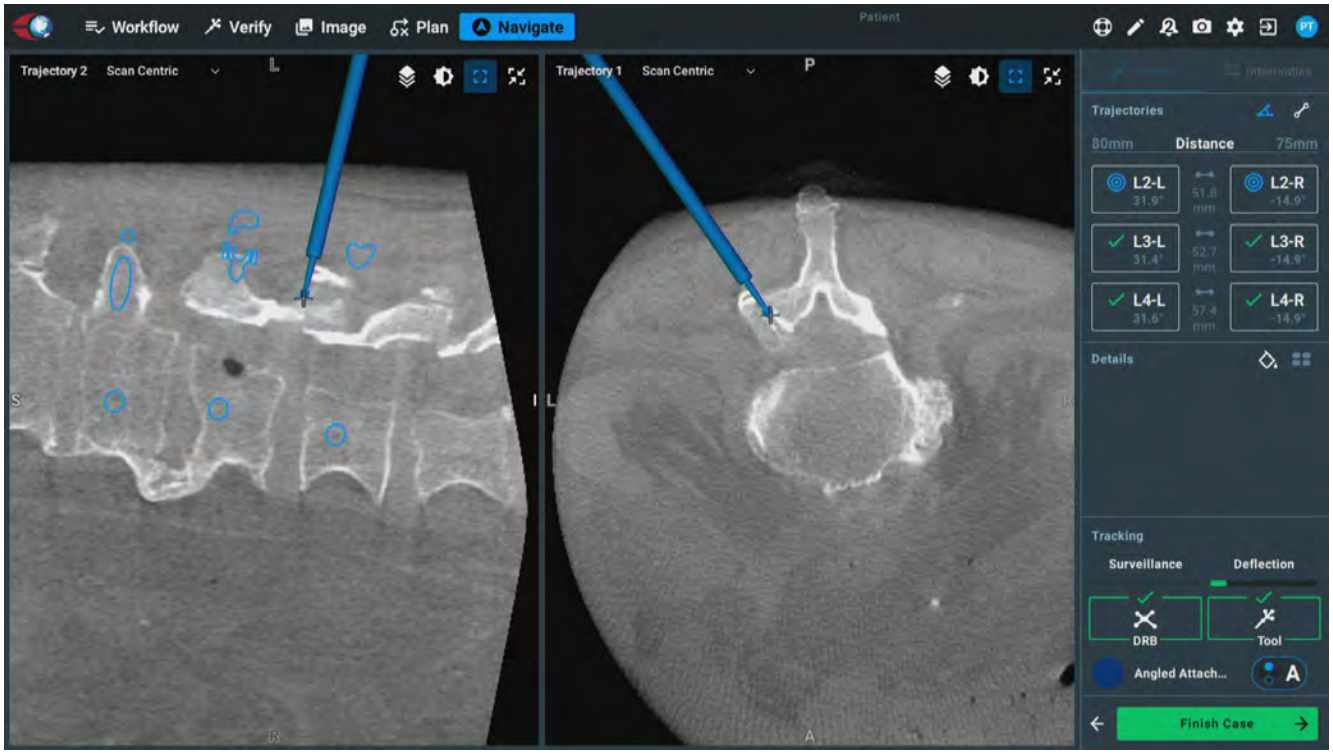


FREEHAND NAVIGATION

VERZA™ Drills may be used for freehand navigation with ExcelsiusGPS® (without the robotic arm). Once the Drills are registered as previously described, they will be displayed on the navigation screen during the procedure.

During operation, the user may change the Attachment orientation (from the “A” to “C” position) as desired and must input this change in the software by selecting the correct physical assembly orientation onscreen.

Refer to the **ExcelsiusGPS® Spine Module User Manual (GMUML09)** for additional system use information, indications, contraindications, warnings, and precautions.

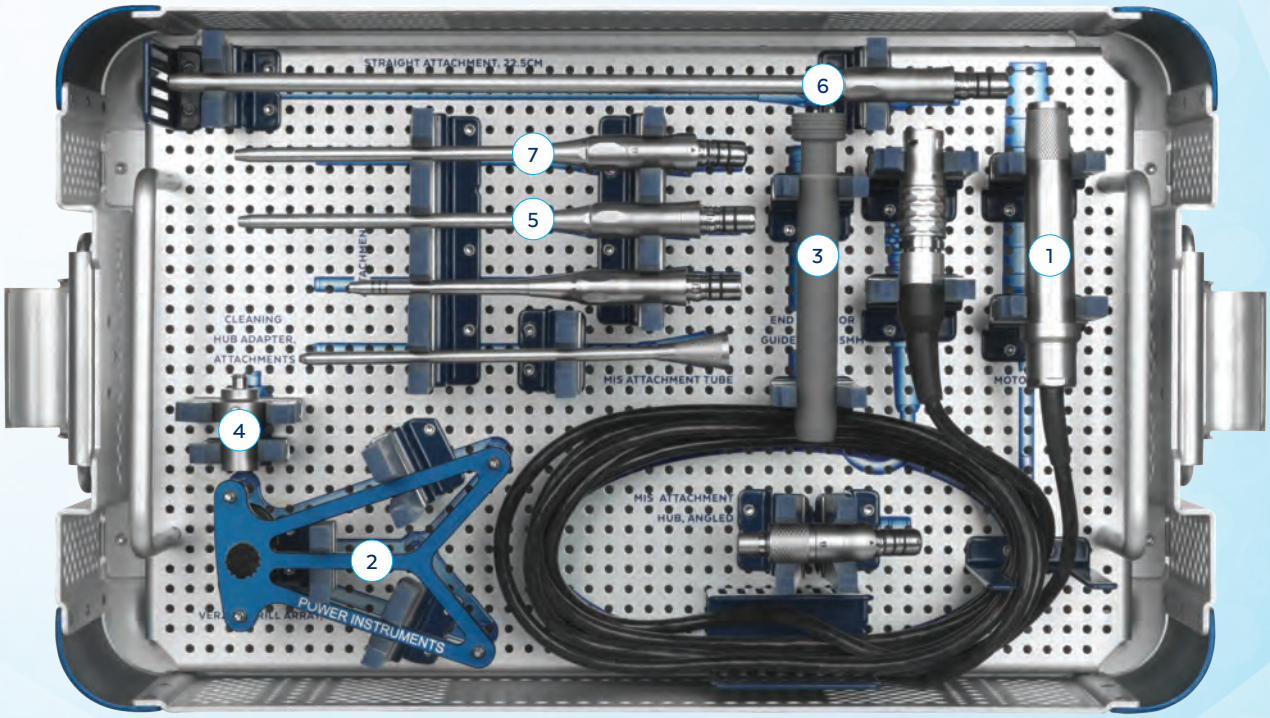


VERZA™
CAPITAL EQUIPMENT SET 9261.9002

Part No.	Description	Qty
6261.1101	VERZA™ Control Unit, 120V	1
6261.1103	VERZA™ Power Console Power Cord, 120V	1
6261.1104	VERZA™ Irrigation Pole	1
6261.1201	VERZA™ Foot Pedal, Single Button Control	1
9261.0002	Capital Equipment Hard Case	

VERZA™
INSTRUMENT SET 9261.9001

	Part No.	Description	Qty
1	6261.1301	VERZA™ Drill Motor, GPS	1
2	6261.1401	Power Instruments Array, GPS	1
3	6261.1411	VERZA™ End Effector Sleeve, 15mm, GPS	1
	6261.1412	VERZA™ End Effector Sleeve, 17mm, GPS	0
4	6261.1606	VERZA™ Cleaning Hub Adapter, Attachments	1
	6261.2002	VERZA™ Straight Attachment, 6.5cm, GPS	0
5	6261.2004	VERZA™ Straight Attachment, 11cm, GPS	1
6	6261.2007	VERZA™ Straight Attachment, 22.5cm, GPS	1
7	6261.3004	VERZA™ Angled Attachment, 11cm, GPS	1
	6261.3100	VERZA™ MIS Attachment Hub, Angled	0
	6261.3106	VERZA™ MIS Attachment Tube, Proximal Bent, 13cm	0
	9261.0001	VERZA™ Instruments Graphic Case	



VERZA™
LUBRICATION SET 9261.9003

For information on maintenance and lubrication instructions, refer to **NSK Surgical Attachment P300 Attachment Operation Manual (OM-SH0911EN)**.

Part No.	Description	Qty
6261.1701	Lubrication Spray, 480ml	1
6261.1703	Lubrication Spray Adapter, Attachments	1
6261.1704	Lubrication Spray Dispenser	1
9261.0003	Lubrication Accessory Case	

VERZA™
DISPOSABLES

Part No.	Description
6261.1510S	Irrigation Tubes (5pcs/set)
6261.5201S	2.0mm Round Fluted Bur, 4.5cm, GPS
6261.5202S	2.0mm Round Fluted Bur, 6.5cm, GPS
6261.5203S	2.0mm Round Fluted Bur, 8.5cm, GPS
6261.5204S	2.0mm Round Fluted Bur, 11cm, GPS
6261.5206S	2.0mm Round Fluted Bur, 13cm, MIS
6261.5257S	2.5mm Round Fluted Bur, 22.5cm, GPS
6261.5301S	3.0mm Round Fluted Bur, 4.5cm, GPS
6261.5302S	3.0mm Round Fluted Bur, 6.5cm, GPS
6261.5303S	3.0mm Round Fluted Bur, 8.5cm, GPS
6261.5304S	3.0mm Round Fluted Bur, 11cm, GPS
6261.5306S	3.0mm Round Fluted Bur, 13cm, MIS
6261.5307S	3.0mm Round Fluted Bur, 22.5cm, GPS
6261.5357S	3.5mm Round Fluted Bur, 22.5cm, GPS
6261.5401S	4.0mm Round Fluted Bur, 4.5cm, GPS
6261.5402S	4.0mm Round Fluted Bur, 6.5cm, GPS
6261.5403S	4.0mm Round Fluted Bur, 8.5cm, GPS
6261.5404S	4.0mm Round Fluted Bur, 11cm, GPS
6261.5406S	4.0mm Round Fluted Bur, 13cm, MIS
6261.5407S	4.0mm Round Fluted Bur, 22.5cm, GPS
6261.5457S	4.5mm Round Fluted Bur, 22.5cm, GPS
6261.5501S	5.0mm Round Fluted Bur, 4.5cm, GPS
6261.5502S	5.0mm Round Fluted Bur, 6.5cm, GPS
6261.5503S	5.0mm Round Fluted Bur, 8.5cm, GPS
6261.5504S	5.0mm Round Fluted Bur, 11cm, GPS
6261.5506S	5.0mm Round Fluted Bur, 13cm, MIS
6261.5507S	5.0mm Round Fluted Bur, 22.5cm, GPS
6261.5557S	5.5mm Round Fluted Bur, 22.5cm, GPS

Part No.	Description
6261.6181S	1.8mm Match Head Bur, 4.5cm, GPS
6261.6182S	1.8mm Match Head Bur, 6.5cm, GPS
6261.6183S	1.8mm Match Head Bur, 8.5cm, GPS
6261.6184S	1.8mm Match Head Bur, 11cm, GPS
6261.6221S	2.2mm Match Head Bur, 4.5cm, GPS
6261.6222S	2.2mm Match Head Bur, 6.5cm, GPS
6261.6223S	2.2mm Match Head Bur, 8.5cm, GPS
6261.6224S	2.2mm Match Head Bur, 11cm, GPS
6261.6256S	2.5mm Match Head Bur, 13cm, MIS
6261.6301S	3.0mm Match Head Bur, 4.5cm, GPS
6261.6302S	3.0mm Match Head Bur, 6.5cm, GPS
6261.6303S	3.0mm Match Head Bur, 8.5cm, GPS
6261.6304S	3.0mm Match Head Bur, 11cm, GPS
6261.6306S	3.0mm Match Head Bur, 13cm, MIS
6261.7201S	2.0mm Round Diamond Bur, 4.5cm, GPS
6261.7202S	2.0mm Round Diamond Bur, 6.5cm, GPS
6261.7203S	2.0mm Round Diamond Bur, 8.5cm, GPS
6261.7204S	2.0mm Round Diamond Bur, 11cm, GPS
6261.7206S	2.0mm Round Diamond Bur, 13cm, MIS
6261.7301S	3.0mm Round Diamond Bur, 4.5cm, GPS
6261.7302S	3.0mm Round Diamond Bur, 6.5cm, GPS
6261.7303S	3.0mm Round Diamond Bur, 8.5cm, GPS
6261.7304S	3.0mm Round Diamond Bur, 11cm, GPS
6261.7306S	3.0mm Round Diamond Bur, 13cm, MIS
6261.7401S	4.0mm Round Diamond Bur, 4.5cm, GPS
6261.7402S	4.0mm Round Diamond Bur, 6.5cm, GPS
6261.7403S	4.0mm Round Diamond Bur, 8.5cm, GPS
6261.7404S	4.0mm Round Diamond Bur, 11cm, GPS
6261.7406S	4.0mm Round Diamond Bur, 13cm, MIS
6261.7501S	5.0mm Round Diamond Bur, 4.5cm, GPS
6261.7502S	5.0mm Round Diamond Bur, 6.5cm, GPS
6261.7503S	5.0mm Round Diamond Bur, 8.5cm, GPS
6261.7504S	5.0mm Round Diamond Bur, 11cm, GPS
6261.7506S	5.0mm Round Diamond Bur, 13cm, MIS

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