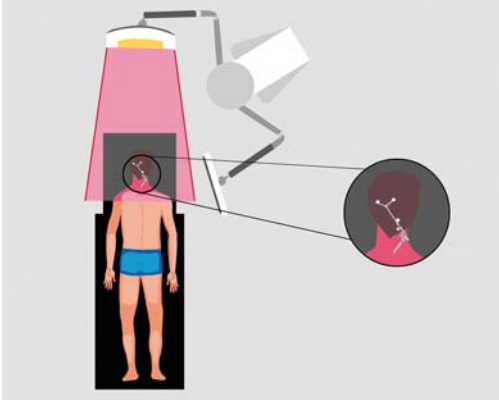


OR SETUP

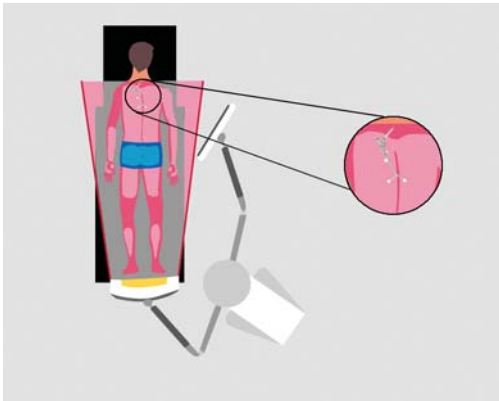
Software Versions: Spine 5.6.x



STEP 1 (OPTION 1)

Cervical procedures - C1/C2 according to Magerl:

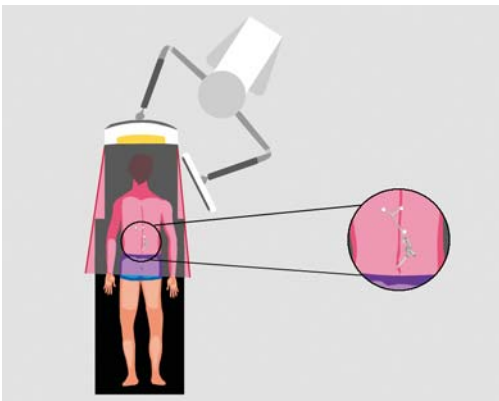
- Patient in prone position
- **Spine Reference X-Clamp** size S with Y-reference array attached to C2
- Monitor and camera at head of bed



STEP 1 (OPTION 2)

Cervical procedures - cervical dorsal instrumentation:

- Patient in prone position
- **Spine Reference X-Clamp** size S with Y-reference array attached to relevant vertebra
- Monitor opposite treatment side and camera at foot of bed



STEP 1 (OPTION 3)

Lumbar/thoracic procedures:

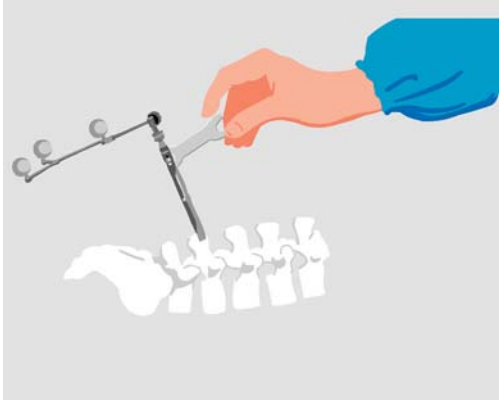
- Patient in prone position
- **Spine Reference X-Clamp** with Y-reference array attached to relevant vertebra:
 - If system is at head of bed: reference array in cranial direction (see image)
 - If system is at foot of bed: reference array in caudal direction



STEP 2

- Plug in the system
- Connect the network cable (if used)
- Turn the system on
- Press the **Spine** icon
- If you are performing a CT-based procedure, load scan data to the navigation station
- If you are performing a fluoro-based procedure or if CT data was loaded via network, insert empty Zip disk or USB flash drive to store surgery data

Note: This guide does not replace reading the user manuals.



STEP 3

- Drape the patient
- Attach reflective marker spheres to all instruments
- Attach the **Spine Reference X-Clamp** (alt. **MIRA** or **Spinal Reference Array**) securely to the bone
- Attach the reference array to the **Spine Reference X-Clamp** (alt. **MIRA** or **Spinal Reference Array**)
- Lock all joints using the wrench provided



STEP 4

Position the system so that:

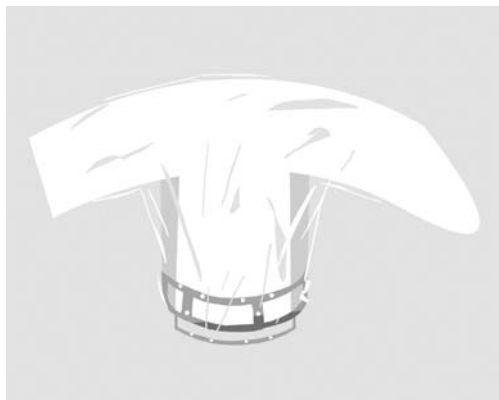
- The surgeon can easily view the monitor
- The camera is 5-7 feet (1.5-2.1 meters) away from the reference array
- The reference array and the navigated instruments are visible to the camera



STEP 5

Verify instrument and reference array visibility:

- Green status field = array and instruments visible
- Green spheres = pointer
- Yellow spheres = uncalibrated instrument or array before patient registration
- Red spheres = array after patient registration
- Blue spheres = registration kit or **ICM4**
- Gray spheres/circles = unidentified instrument



STEP 6

If you are performing a fluoro-based procedure:

- Attach a sterile registration kit to the draped C-arm; or
- Attach an unsterile registration kit and drape the C-arm making sure that the reflective discs are not covered by wrinkles of the drape

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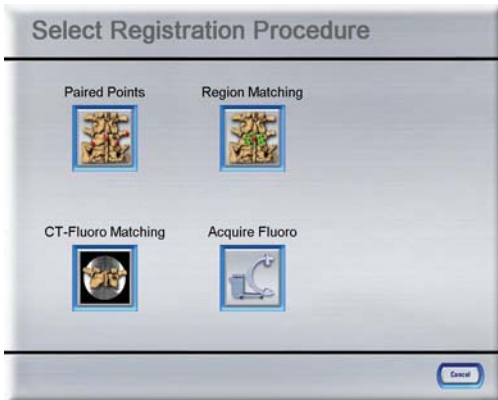
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REGION MATCHING

Software Versions: Spine 5.6.x



STEP 1

- Press the **Register** button in the menu bar
- Press **Region Matching**



STEP 2

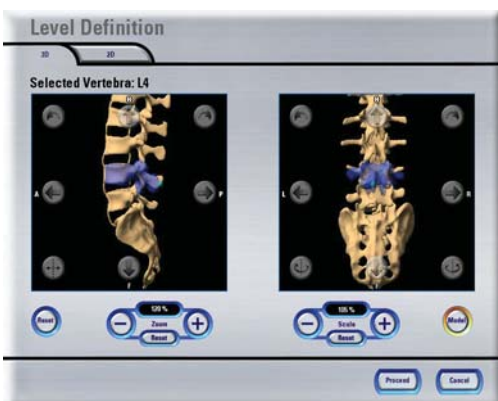
- In the **Bone Threshold** dialog, adjust the bone threshold using the **Detect** button or using the slider or arrow buttons (displayed bone surface should be smooth)
- Press **Proceed**

NOTE: If the **Bone Threshold** dialog does not open automatically, you can press the **Toolbox** button and select **Bone Threshold** in the **Settings** tab.



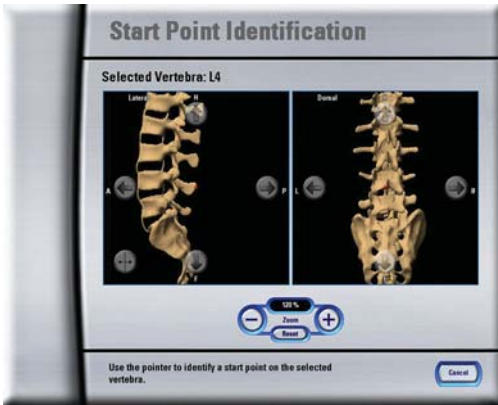
STEP 3

- Select the vertebra to be operated upon using either the arrows or pressing directly on the depicted spine in the **Select Vertebra** dialog
- Press **Level Definition**



STEP 4

- In the **Level Definition** dialog, position the blue model over the corresponding vertebra in the data set using the arrow buttons and **Scale** controls
- Press **Proceed**



STEP 5

- Position the start point (red sphere) on top of the spinous process or other prominent landmark of the selected vertebra
- Acquire the point on the vertebra as accurately as possible using the pointer
- A beep confirms start point acquisition

NOTE: After start point acquisition, the reference array may no longer be moved.



STEP 6

- Acquire the first few points in the indicated green regions
- Acquire the remaining points over the entire surface area on the same vertebra

NOTE: Avoid taking points on the adjacent vertebra. This can lead to a failed registration.



STEP 7

- Hold the pointer to at least 3 landmarks on the patient's vertebra and verify the position shown on the screen compared to the actual position on the patient's spine
- If the registration is accurate, press **Proceed**

NOTE: If the accuracy is insufficient, manually adjust the acquired points (**Corrective Matching**) or press **Try Again** to repeat the registration.



STEP 8 (OPTIONAL FOR FAILED REGISTRATION)

Perform **Corrective Matching**:

- Use the arrow buttons to reorient the acquired points to anatomical landmarks
- Press **Match**

NOTE: In this view, the pointer can be used for orientation.

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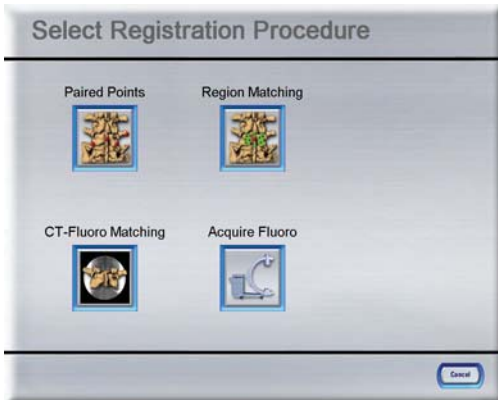
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PAIRED POINT REGISTRATION

Software Versions: Spine 5.6.x



STEP 1

- Press the **Register** button in the menu bar
- Press **Paired Points**



STEP 2

- In the **Bone Threshold** dialog, adjust the bone threshold using the **Detect** button or using the slider or arrow buttons (displayed bone surface should be smooth)
- Press **Proceed**

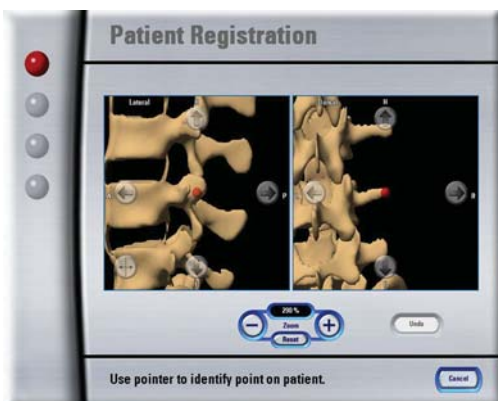
NOTE: If the **Bone Threshold** dialog does not open automatically, you can press the **Toolbox** button and select **Bone Threshold** in the **Settings** tab.



STEP 3 (OPTIONAL)

If you have added registration markers during preoperative planning with **iPlan Spine**:

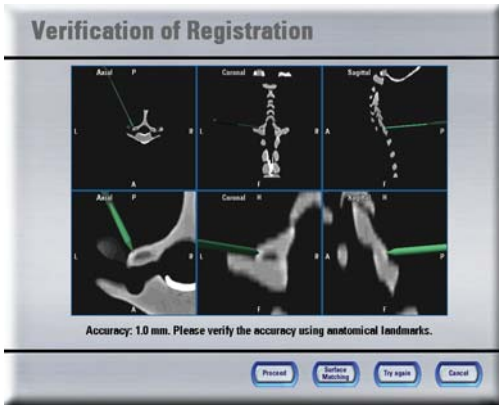
- Select the vertebra to be operated upon using either the arrows or pressing directly on the depicted spine in the **Select Vertebra** dialog
- Press **Proceed**



STEP 4

- Use the arrow buttons to position the active point (bright red dot) on the vertebra where you want to acquire it
- Acquire the point on the vertebra as accurately as possible using the pointer
- A beep confirms point acquisition
- Acquire 3 more points in the same way on the same vertebra
- Press **Proceed**

Note: This guide does not replace reading the user manuals.



STEP 5

- Hold the pointer to at least 3 landmarks on the patient's vertebra and verify the position shown on the screen compared to the actual position on the patient's spine
- If the registration is accurate, press **Proceed**

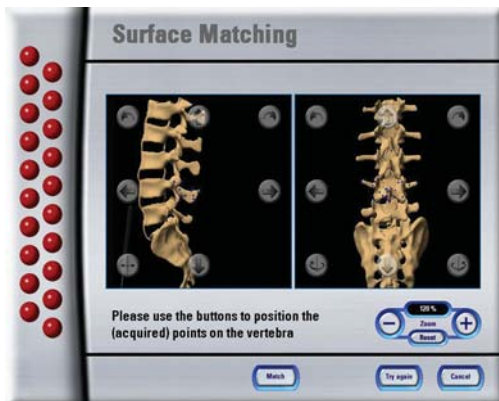
NOTE: If the accuracy is insufficient, press **Try Again** to repeat the registration or press **Surface Matching** to acquire 20 more points.



STEP 6 (OPTIONAL)

- In the **Surface Matching** dialog, acquire 20 additional surface points with the pointer on the same vertebra
- If the registration is accurate, press **Proceed**

NOTE: If the accuracy is insufficient, manually adjust the acquired points (**Corrective Matching**) or press **Try Again** to repeat the entire registration.



STEP 7 (OPTIONAL FOR FAILED REGISTRATION)

Perform **Corrective Matching**:

- Use the arrow buttons to reorient the acquired points to anatomical landmarks
- Press **Match**

NOTE: In this view, the pointer can be used for orientation.

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2D IMAGE ACQUISITION

Software Versions: Spine 5.6.x



STEP 1

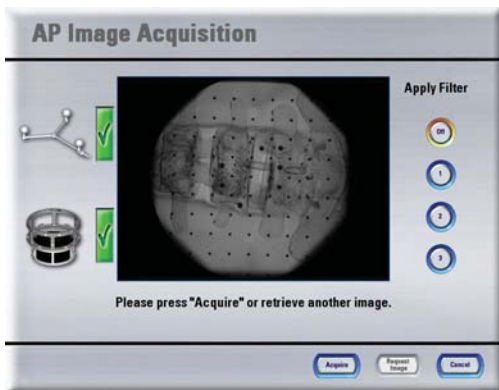
- Press the **Register** button in the menu bar
- Press **Acquire Fluoro**
- Select the image type (fluoro or calibration image) and the image direction (AP, lateral or oblique)
- Make sure that the camera has an unobstructed view of the registration kit and the reference array



STEP 2

- Position the patient so that the region of interest is accessible for image acquisition
- If possible, remove any metal hardware in the region of interest that may interfere with the image acquisition

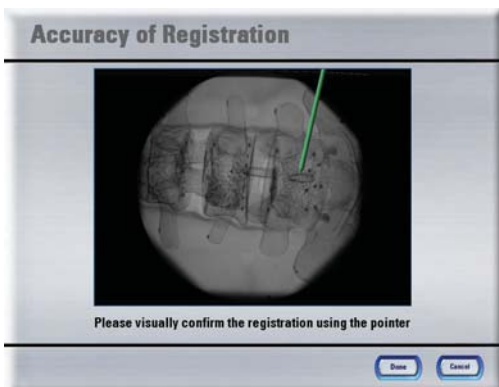
NOTE: Repeated failed image acquisitions may require a calibration image.



STEP 3

- To acquire the desired image from the C-arm for navigation, press **Acquire**
- After image acquisition, press one of the **Apply Filter** buttons to optimize brightness and contrast

NOTE: To modify the acquired images on the C-arm, it is necessary to press the **Acquire** button first.



STEP 4

- Hold the pointer to at least 3 landmarks on the patient's vertebra and verify the position shown on the screen compared to the actual position on the patient's spine
- If the registration is accurate, press **Proceed**
- Repeat step 3 for each AP, lateral or oblique position to be navigated

Note: This guide does not replace reading the user manuals.

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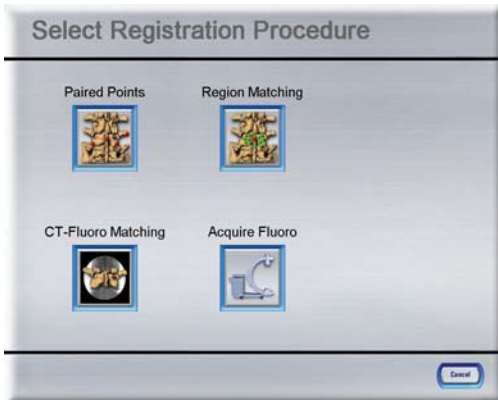
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CT-FLUORO MATCHING

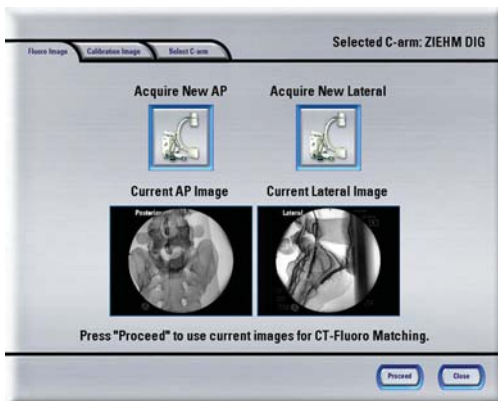
Software Versions: Spine 5.6.x



STEP 1

- Press the **Register** button in the menu bar
- Press **CT-Fluoro Matching**
- In the **Bone Threshold** dialog, adjust the bone threshold using the **Detect** button or using the slider or arrow buttons (bone surface should be smooth)
- Press **Proceed**

NOTE: If the **Bone Threshold** dialog does not open automatically, you can press the **Toolbox** button and select **Bone Threshold** in the **Settings** tab.



STEP 2

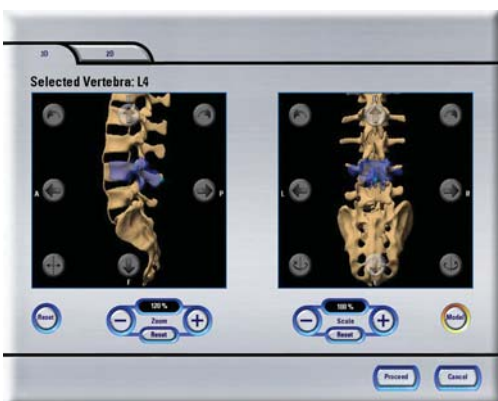
- Acquire the AP and lateral fluoroscopic images from the C-arm (see 2D Image Acquisition) by pressing the corresponding buttons in the **Fluoro Image** tab
- Press **Proceed**

NOTE: You can also acquire corresponding calibration images.



STEP 3

- Select the vertebra to be operated upon using either the arrows or pressing directly on the depicted spine in the **Select Vertebra** dialog
- Press **Segmentation**



STEP 4

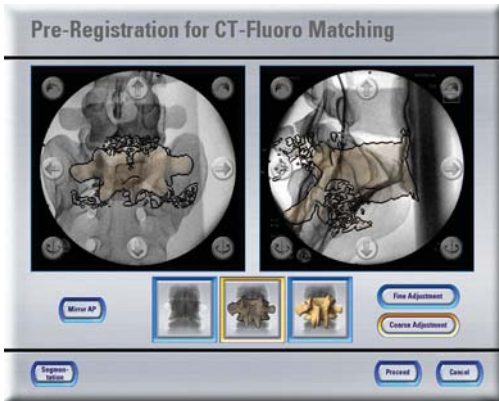
- Use the arrow buttons to position the blue model vertebra onto the vertebra to be registered
- Use the **Scale** controls to adjust the size of the model vertebra
- Press **Proceed** to start segmentation and again in the **Select Vertebra** dialog to continue

Note: This guide does not replace reading the user manuals.



STEP 5

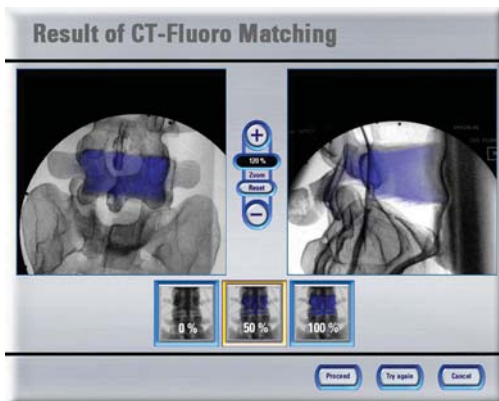
- Use the human figure to define the head direction by touching the screen
- Press **Proceed**



STEP 6

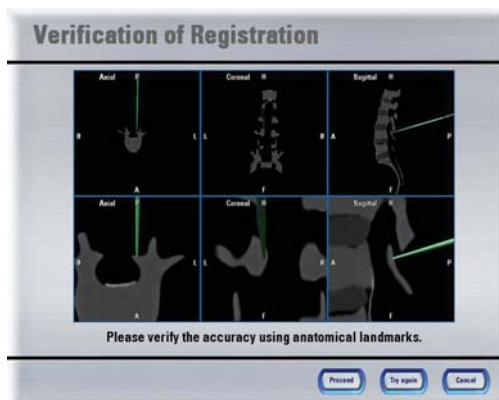
- Position the segmented vertebra as precisely as possible over the AP and lateral fluoroscopic images
- Use the **Fine** and **Coarse Adjustment** buttons to fine-tune the alignment
- Press **Proceed** to start automatic CT-fluoro matching

NOTE: If the segmentation of the vertebra is not satisfactory (e.g., spinous or transverse process cut off), press **Segmentation** to repeat.



STEP 7

- Check the accuracy of the CT-fluoro matching result by comparing anatomical landmarks in the fluoro images with the same landmarks in the overlaid CT image
- If the registration is accurate, press **Proceed**. Otherwise, press **Try Again** to repeat the matching process.



STEP 8

- Hold the pointer to at least 3 landmarks on the patient's vertebra and verify the position shown on the screen compared to the actual position on the patient's spine
- If the registration is accurate, press **Proceed**. Otherwise, press **Try Again** to repeat registration.

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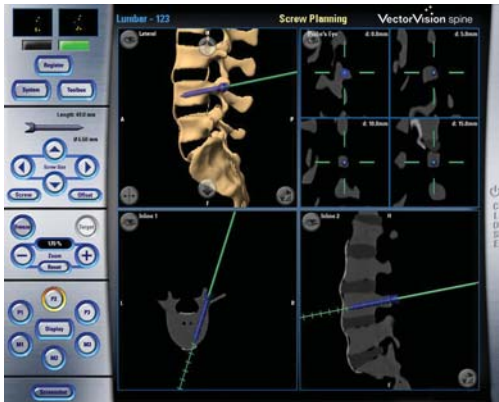
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PLANNING & NAVIGATION

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STEP 1

Perform screw planning:

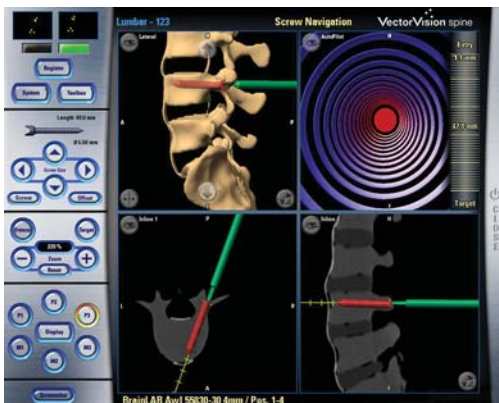
- Press **P2** and navigate to the required implant location
- Define the implant dimensions in the menu bar
- Press **P2** again to plan additional screws or press **P3** to navigate

NOTE: Covering a reflective marker sphere and removing the instrument from the field of view also stores the implant position.



STEP 2

- Check the planned screw position
- Press **Yes** to accept the planned screw or press **No** to repeat planning



STEP 3

- Navigate the instrument to the planned position
- Press:
 - P2** to plan the next screw,
 - P1** to return to the navigation overview or
 - P3** to navigate another planned screw

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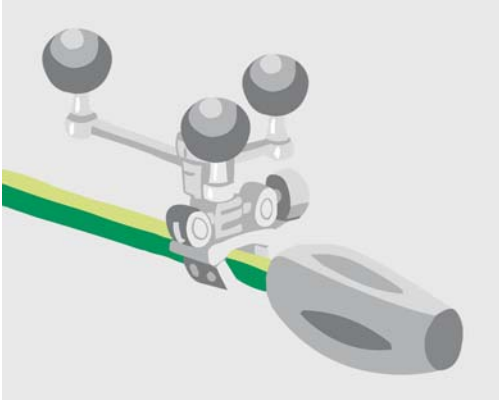
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INSTRUMENT CALIBRATION

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STEP 1

- Attach reflective marker spheres to a suitable instrument adapter and to the **Instrument Calibration Matrix Rev. 4 (ICM4)**
- Mount the instrument adapter to the instrument you want to navigate



STEP 2

- Hold the **ICM4** and the selected instrument in the camera's field of view to activate the calibration procedure (distance to camera: 5-7 feet [1.5-2.1 meters])



STEP 3 (OPTION 1)

Performing V-inset calibration:

- Calibrate the axis using the V-inset
- Select the instrument tip (e.g., pointed, chisel)
- Press the corresponding button again to perform a tip calibration (optional)

NOTE: The tip calibration is mandatory if the instrument tip does not touch the reference plane or if you would like to refine the calibration.



STEP 3 (OPTION 2)

Performing receptacle calibration:

- Insert the instrument tip into the smallest receptacle possible and rotate the instrument
- A progress bar indicates the calibration status

NOTE: The instrument tip must touch the bottom of the calibration receptacle throughout this procedure.

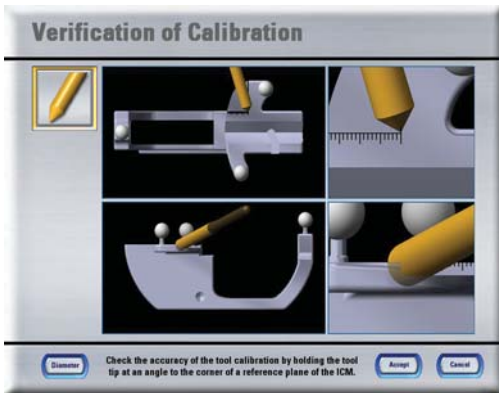
Note: This guide does not replace reading the user manuals.



STEP 3 (OPTION 3)

Performing manual calibration:

- Press the **Manual** button
- Insert the instrument tip into the smallest receptacle possible
- Select the corresponding receptacle on the screen
- Hold the instrument still until the progress bar is complete



STEP 4

- Verify the calibration accuracy using the **ICM4** (e.g., V-inset, pivot point or reference plane)

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PRECALIBRATED INSTRUMENTS

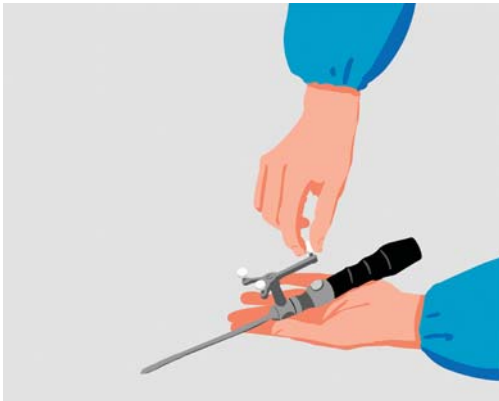
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STEP 1

If you are using a **Drill Guide**, assemble it:

- Attach the tracking array to the handle by mounting the nut
- Attach the drill guide tube to the tracking array
- Attach reflective marker spheres to the tracking array



STEP 2

If you are using the **Spine Instrument Set**, assemble it:

- Attach the required tip to the tracking array (labelled "Pre-Calibrated")
- Attach the required handle
- Attach reflective marker spheres to the tracking array



STEP 3

Activate the instrument:

- Open the **Toolbox**
- Select **Brainlab** (or other instrument manufacturer)
- Select the required instrument (check product code)



STEP 4

Verify the instrument:

- Instrument counter = 0 → Proceed to **STEP 5**
- Instrument counter > 0 → Verify the instrument. If inaccurate, proceed to **STEP 5**.
- If you are using a **Drill Guide**, hold it in the indicated receptacle for verification
- If you are using the **Spine Instrument Set**, hold it in the pivot point for verification

Note: This guide does not replace reading the user manuals.



STEP 5

- Validate the instrument according to the instructions on the screen

NOTE: Instrument validation is mandatory if the instrument counter has reached zero.



STEP 6

If the verification/validation was successful, the instrument is now activated.

If the validation was not successful or if the verification appears to be inaccurate, check that:

- The correct instrument is selected
- The instrument is correctly assembled
- The reflective marker spheres of the instrument and the **ICM4** are clean, dry and screwed tight

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