ZIMMER BIOMET
Moving You Forward.™

iASSIST® Knee V2 System

Surgical Technique

Table of Contents

For iASSIST Knee Pod error information, please reference the iASSIST Knee Error Guide.

Overview

Intended Purpose

The iASSIST Knee System is intended to assist the surgeon in preparing the bone surfaces for positioning orthopedic implant system components intra-operatively.

Indications for Use

The iASSIST Knee System is a computer assisted stereotaxic surgical instrument system intended to assist the surgeon in preparing the bone surfaces for the positioning of orthopedic implant system components intra-operatively. It involves surgical instruments and inertial sensors to determine alignment axes in relation to anatomical landmarks and to precisely position alignment instruments and cut guides relative to these axes.

The present iASSIST Knee System is designed for Total Knee Arthroplasty.

Training

Prior to using the system, surgeons and healthcare professionals should follow a training given by Zimmer CAS or the distributor for the given applications. Contact your local Zimmer Biomet representative.

⚠ **Warning:** The system should only be used by trained surgeons and healthcare professionals.

Implant Indications

The prosthesis implanted with the system must be used in accordance with the appropriate package insert labeling.

The procedure is to be performed in accordance with the corresponding surgical technique published by the manufacturer for the specific implant.

The iASSIST Knee System has only been verified for use with Zimmer Biomet NexGen® Knee, Persona® Knee and Vanguard® Knee implant lines.

⚠ **Warning:** The system should only be used with the instruments provided by Zimmer CAS or by the distributor for the given application.

⚠ **Warning:** The Femur and Tibia v2 instrumentation each present two types of saw slots: one for Persona and NexGen saw and one for Vanguard saw. The Persona/NexGen Saw Slot is compatible with saw blades of 1.27 mm (0.05 inch) thickness. The Vanguard Saw Slot is compatible with saw blades of 1.37 mm (0.054 inch) thickness. Make sure the iAssist Saw Slot used matches the saw used.

Contraindications

Clinical

The system should not be used:

- In cases of hip pathology severely limiting range of motion (e.g. arthrodesis, severe contractures, chronic severe dislocation);
- In cases of hip joint pathology or knee pathology with significant bone loss (e.g. avascular necrosis of the femoral head with collapse, severe dysplasia of the femoral head or the acetabulum, femoral condyle collapse);
- For femoral anterior cut first surgical techniques;
- For total knee arthroplasty using the Quad-Sparing™ technique; or
- For any other contraindicated case, as given by the implant manufacturer.

General

The system should not be used:

- On a moving vehicle, or any mobile platform; or
- To perform surgical procedures other than those specified in the surgical technique defined in this document.

Complications

Possible complications associated with the use of the system may include but are not limited to the following:

- Infection; and
- Misplacement of the implants potentially leading to dislocation, impingement or leg length discrepancy.

The occurrence of one of these complications may affect the patient's mobility.

Metal sensitivity and hypersensitivity reaction has been reported following exposure to orthopedic instruments. The most common metallic sensitivities (nickel, cobalt, and chromium) are present in medical grade stainless steel and cobalt-chrome alloys. Patients/users hypersensitive to any of the instrument materials (e.g. Nickel, Cobalt, and Chromium) may suffer allergic reactions.

Target Population and Clinical Performance

The iASSIST Knee System is designed for use on a skeletally mature patient population.

The system is designed to provide an HKA (Hip-Knee-Ankle) angle within ±3° of the surgical plan cut decided by the surgeon intra-operatively in 90% of the cases.

Reporting Problems

The user and/or patient should report any suspected serious incident related to the device by informing the manufacturer and the competent authority of the member state in which the serious incident has occurred.

Preoperative Guide

Figure 1
Operating Room Setup

⚠ **Warning**: The surgical procedure must take place in an operating room theater with temperatures ranging from 15°C to 30°C (59°F to 86°F). Ensure that the pods are maintained in this temperature range before being use in a surgical procedure. Otherwise, the system will indicate that the pods are outside their operational temperature range and the pods cannot be used until they reach an adequate temperature.

Ensure that an iASSIST Knee V2 Pod Kit is not used for another surgical procedure. The user must exit and restart the application with a new pod kit to begin another surgical procedure. A bilateral knee procedure is considered as one procedure. As a backup, a second iASSIST Knee V2 Pod Kit should be brought in the operating room theater.

The iASSIST V2 Tablet should remain in the iASSIST V2 Tablet Shipping Case during transportation.

Note: A full set of the implant system's standard instrumentation is needed to perform a surgery in conjunction with the iASSIST Knee System and in case the iASSIST Components cannot be used. Effects that may prevent use of the iASSIST system include the unlikely possibility of unresolvable interference effects with the wireless communication of the system.

iASSIST V2 Tablet Setup

1. Open the iASSIST V2 Tablet Shipping Case.
2. Take out the iASSIST V2 Tablet and position it on the tablet holder on a stable flat surface outside the sterile zone at a maximum distance of four meters from the instruments and OR tables. Then take out the top level to access the components on the bottom level.

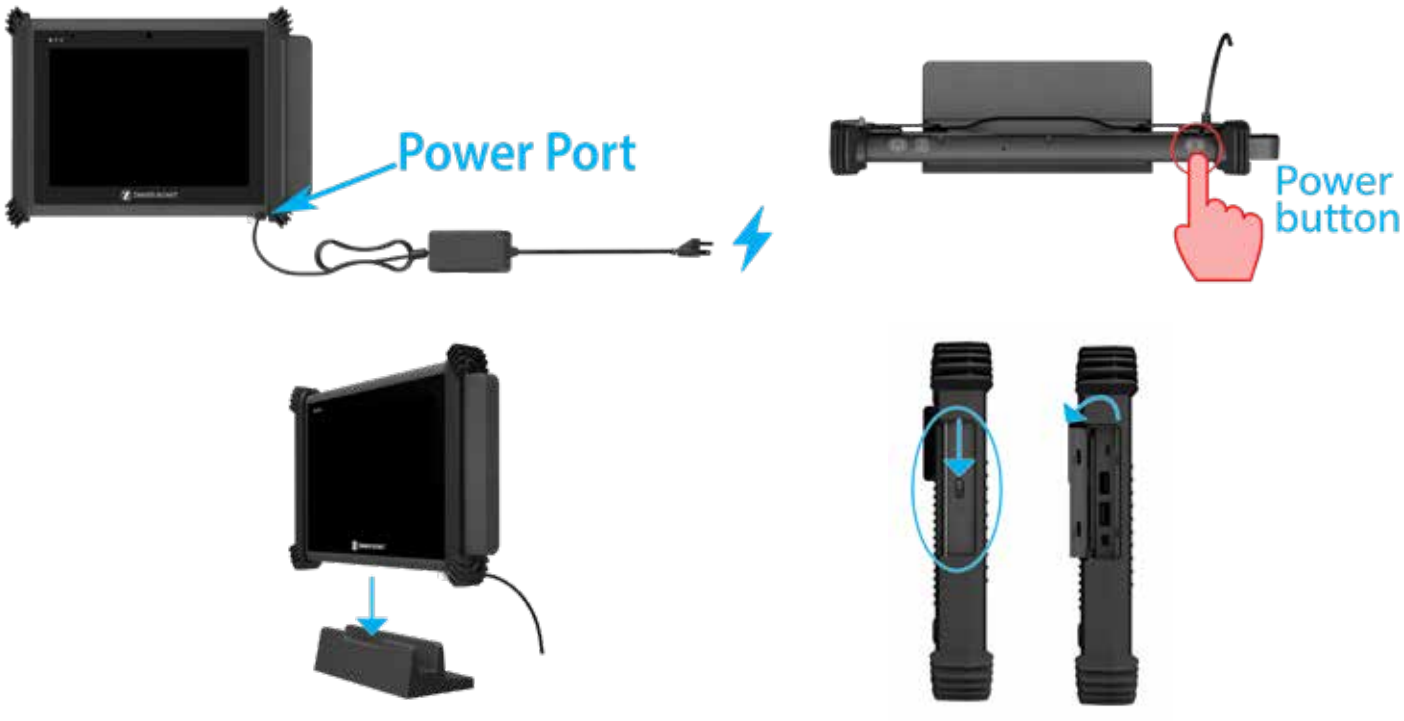


Figure 2
iASSIST V2 Tablet Setup

iASSIST V2 Tablet Setup (Continued)

3. Lift the **white silicon lid** located on the bottom right side of the tablet and connect the power supply to the Tablet port. Then connect the power cord to the power supply and plug it into an AC outlet.

   ⚠ **Warning**: The iASSIST V2 Tablet is:
   a. not intended to be used in the sterile zone; and
   b. to be connected to an AC outlet during the entire procedure. The tablet must not be placed in a sterile bag as it might overheat.

4. Press the power button located at the top right hand corner of the iASSIST V2 Tablet to turn on the computer. The home screen will be displayed after boot-up is completed.

   ⚠ **Warning**: Do not turn off the iASSIST V2 Tablet without having closed the application. Once the application or the tablet is closed, the pods will be permanently deactivated. Once deactivated, the pods cannot be restarted.

5. If necessary, see the "Connection to the Internet" section to know how to connect the tablet to the Internet. It is not necessary to connect to the Internet to do an iASSIST Procedure. This connection can be used, for example, to download system updates.

6. A strap can be installed on the shipping case to facilitate transport.

7. Two other buttons are located at the top left of the iASSIST V2 Tablet. The "P2" button activates and deactivates the Wi-Fi.

   Note: The Internet connection will be deactivated while the iASSIST Application is open.

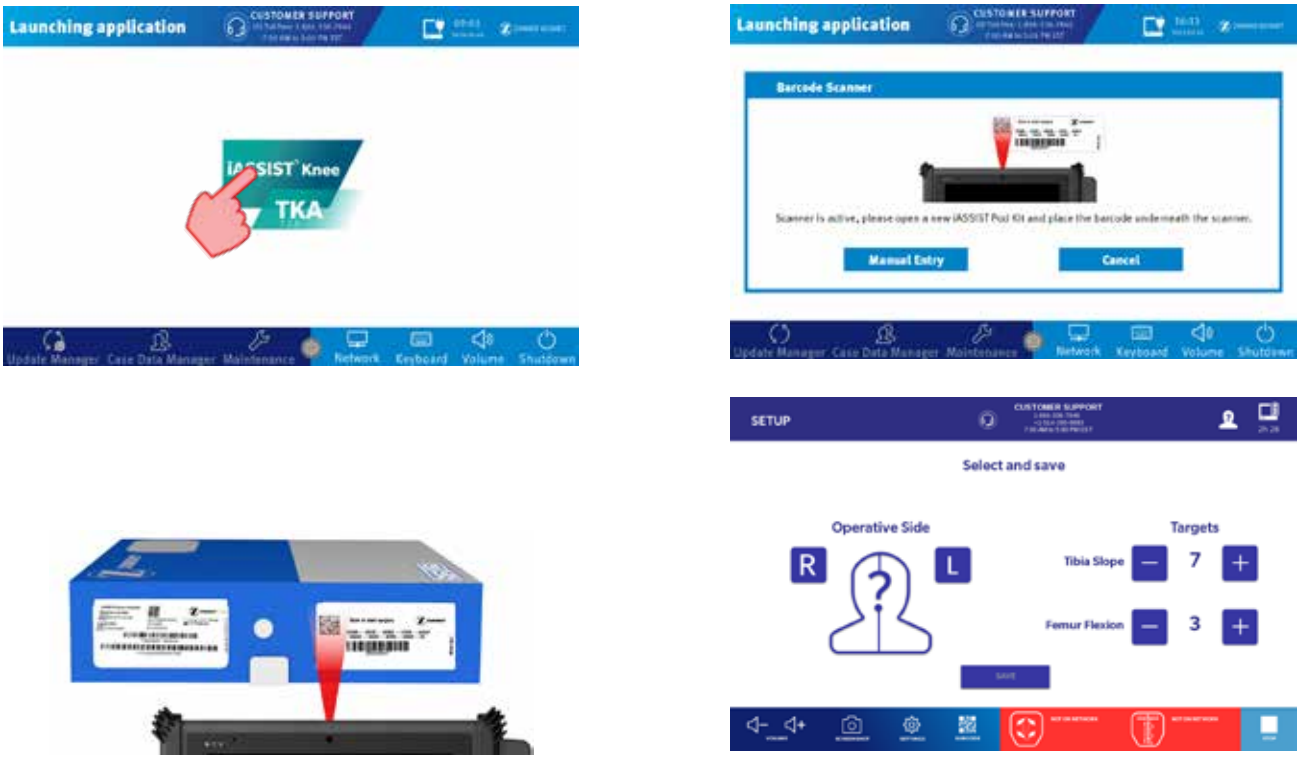


Figure 3
Application Launch

Application Launch and Patient Side Selection

1. Press the green iASSIST icon displayed on the iASSIST V2 Tablet home screen. The barcode scanner window will open and the barcode scanner will start automatically and stay active for 30 seconds.

2. Place the barcode in the barcode scanner field of view. Press on the "Scan" button to restart the scanner if needed.

   Note: If the 2D barcode on the outer box cannot be read: the loose 2D barcode in the outer box or the 2D barcode on the pod tray can be scanned. The barcode can also be entered manually by pressing the "Manual Entry" button on the screen.

   Warning: After having scanned the barcode and powered on the pods, do not exit the application unless the surgical procedure has ended. When exiting the application, the pods will be permanently deactivated. Once deactivated, the pods cannot be restarted.

3. If desired, enter a patient ID and press on the "Continue" button. The application will launch and the tablet will emit a confirmation sound.

4. The "Setup" window will be displayed. Select the operative side and adjust the target angles for the procedure. Click "Save" to continue.

   Note: If the wrong patient side is selected at the beginning of the surgery, the "Settings" button will be accessible once the pods have joined the network. It will then be possible to change the patient side.

   Warning: Ensure to enter a de-identified patient ID so that the patient cannot be identified from the data.

Figure 4
Settings and Screenshot Buttons

Figure 5
Audio and Barcode Buttons

Buttons, Icon and Pod Status Bar

Settings Button

Click the "Settings" button located at the bottom of the iASSIST V2 Tablet screen to modify the operative side or enter the desired cut targets for "Tibia Slope Target" and "Femur Flexion Target". These settings can be modified either before or during a surgical procedure. Settings will remain in the system for future surgical procedures. Clicking on the "Settings" buttons also allows to change the display language of the application. See the "Language Change" section for more information.

Screenshot Button

Click the "Screenshot" button located at the bottom of the iASSIST V2 Tablet screen to record a picture of the entire computer screen. This action can be performed at any time during the surgical procedure. All images will be saved in the surgery report found in the "Case Data Manager" (Refer to the "Case Data Manager" section).

Note: If a problem is encountered during the surgery, it is recommended to take a screenshot of the screen. This could be used in the instance when a complaint has to be filed.

Audio Button

Click on the "Volume down" or the "Volume up" buttons to adjust the volume of the tablet.

Barcode Button

Click the "Barcode" button located at the bottom of the iASSIST V2 Tablet screen if a new set of pods have to be connected to the tablet. The user will then be able to scan or manually enter the new barcode.

Figure 6a
Patient Side Icon: Right, Left, Undetermined

Figure 6b
Language abbreviation: German , Greek, English, Spanish, French, Italian, Dutch

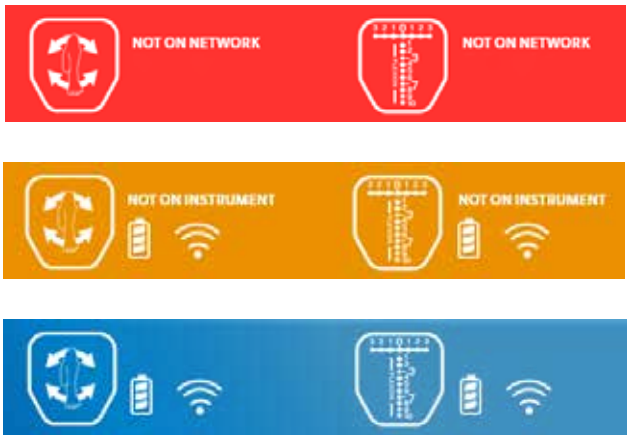


Figure 7
Pod Status Bar

Buttons, Icon and Pod Status Bar (Continued)

Patient Side Icon

The patient side is indicated at the top of the iASSIST V2 Tablet screen. When the patient side is set, the icon and letter are white on the selected side. If the patient side is not determined the icon is entirely white with a "?" symbol. Click on the "Settings" button to change the patient side if necessary (for a bilateral procedure, for example).

Pod Status Bar

The "Pod Status" bar is displayed at the bottom of the iASSIST V2 Tablet screen. The bar displays the status of each pod used in the procedure showing its user interface.

A pod which is not joined to the network is displayed in red.

A pod which has joined the network but is not connected to an instrument is displayed in orange.

A pod which has joined the network and is connected to an instrument is displayed in blue.

Status of the pod's battery life or communication is displayed on the "Pod Status" bar.

Language abbreviation icon

The display language of the application is displayed in abbreviation at the top of the iASSIST V2 Tablet screen. See the "Language Change" section for more information.

Figure 8
Tibia V2 Instrument Assembly

Instrument Assembly

Tibia V2 Instrument Assembly

(Tibia V2 instrumentation not available for European market)

The right/left Tibial A/P slider and Saw Slots are side specific. Depending on the patient side, choose the right or left A/P Slider and Saw Slot. Refer to the laser marking on the instrument: L for left and R for Right.

> ⚠ **Warning:** Saw slots are blade thickness specific: make sure that the saw slot corresponds to the surgical saw used. Refer to the laser marking on the instrument for specification on blade thickness.

1. Insert the Upper Tibial Reference on the rod of the Lower Tibial Reference.

2. Position the rod of the Tibial Reference to an initial starting orientation per the preset position (L or R) on the distal part of the Tibial Reference. **For a left knee** procedure, the preset position is L. **For a right knee** procedure, the preset position is R.

3. Using the green screw, set the varus/valgus of the Tibial Adjustment Mechanism to the neutral position by aligning the two arrows. This will enable instrument assembly.

4. Assemble the A/P slider to the Tibial Proximal Cut Guide so that the letters A are aligned with each other by tightening the blue screw.

5. Insert the two long pegs of the Tibial A/P Slider into the Tibial Adjustment Mechanism.

> **Note:** Assemble the Left A/P slider into the Adjustment Mechanism sliding holes that have the letter L laser-marked on them. Assemble the Right A/P slider into the the Adjustment Mechanism sliding holes that have the letter R laser-marked on them. Make sure the letters L or R are side by and side in the same orientation once the instruments are assembled.

Intraoperative Guide

Note: Through this surgical technique, images from a left knee procedure are shown.

Figure 9
Femoral Instrument Assembly

Instrument Assembly

Femur Instrument Assembly

1. Insert the femoral saw slot into the femoral distal cut guide and tighten it at the "0" position with a 3.5 mm hex head screwdriver.

   Note: The femoral saw slot, when secured at the "0" position on the femoral distal cut guide, resects 10 mm off the most distal condyle.

2. Assemble the femoral A/P slider to the distal femoral cut guide by tightening the blue screw.

   Note: A specific A/P slider and distal femoral cut guide are also available to fit high BMI patients. Contact your local Zimmer Biomet representative to order.

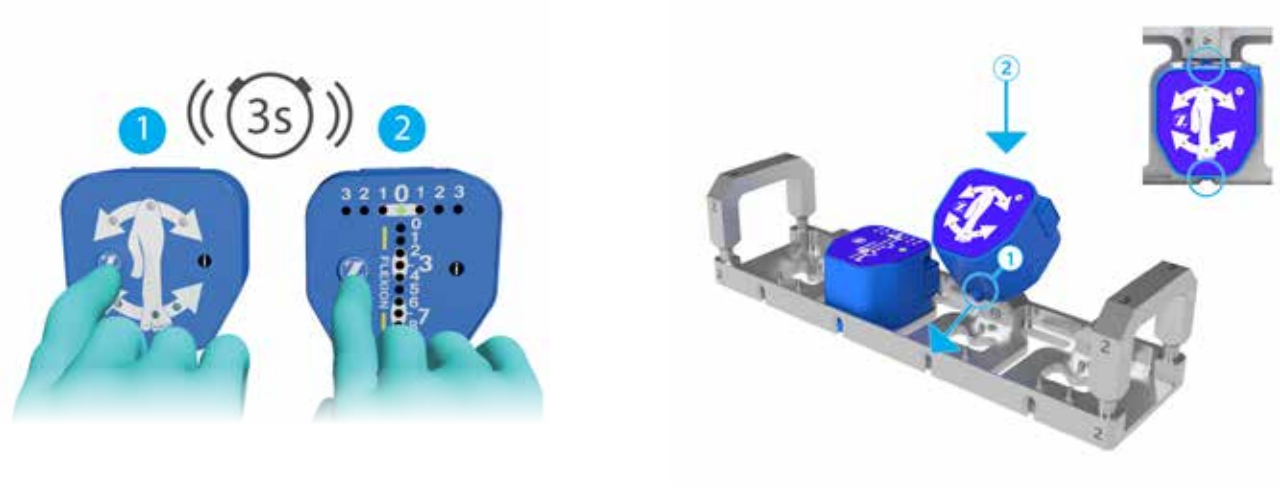


Figure 10a
Powering-On Pods and Intraoperative Calibration

Powering-On Pods and Intraoperative Calibration

⚠ **Warning**: Verify that the packaging is not damaged. A damaged package may affect the sterility of the pods. If damage to the sterile packaging is observed, discard the damaged pod kit and open another iASSIST Knee V2 Pod Kit.

1. Open an **iASSIST** Knee V2 Pod Kit and remove the pods from the pod tray. Place them on the sterile instrument table.

2. Power-on the pods by pressing the Z button of each for at least 3 seconds until their status LED powers on and flashes green.

   ⚠ **Warning**: The powering on of the pods must be performed wearing sterile attire.

   ⚠ **Warning**: Make sure to power-on the pods at the appropriate time i.e. five minutes before the start of the intraoperative calibration. Intraoperative calibration should be performed before incising the patient. After power-on, the pods will function for approximately two hours. While very unlikely, if a pod drains its battery before the end of a surgical procedure, the pod kit can be replaced by another pod kit following the instructions described in the "Pod Replacement" section without restarting the application.

   As a backup, a second iASSIST **Knee** V2 Pod Kit should be brought in the operating room theater.

3. Wait for the green status LED of all of the pods to start blinking slowly before continuing with the intraoperative calibration.

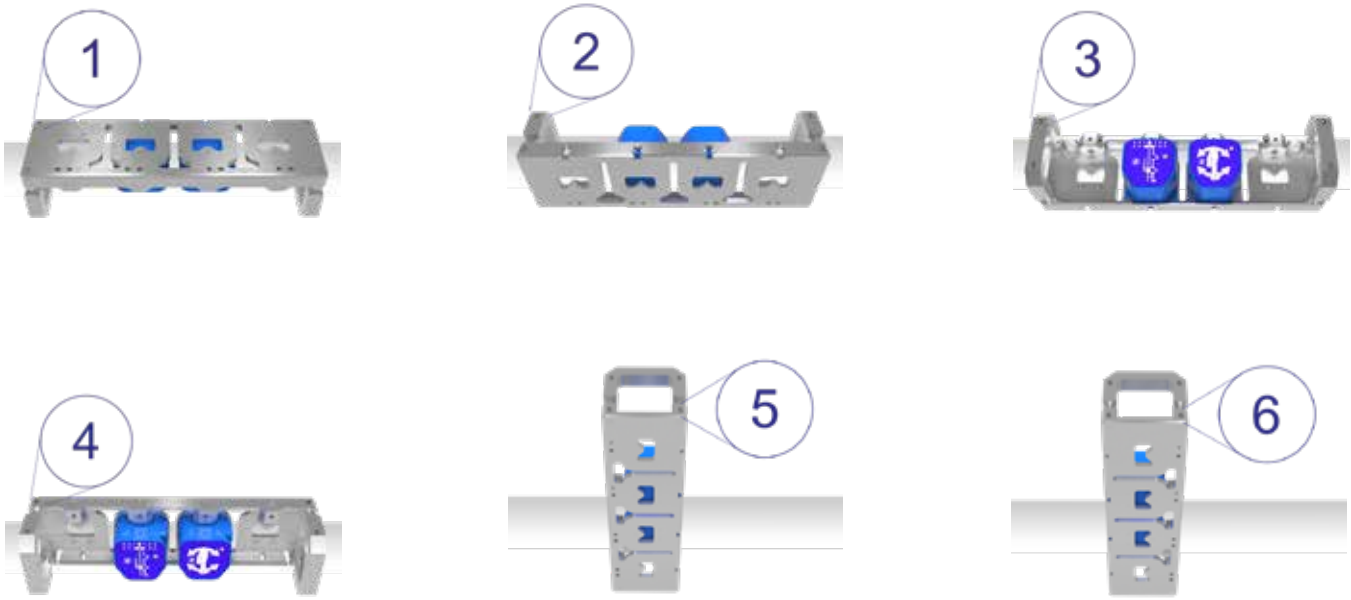


Figure 10b
Powering-On Pods and intraoperative Calibration (Continued)

Powering-On Pods and Intraoperative Calibration (Continued)

⚠ **Warning**: The calibration process including the pod calibration jig handling must be performed wearing sterile attire.

The pods need to be calibrated on a flat, approximately horizontal surface to ensure optimal performance. This surface must be sterile and free of any movement or vibrations.

4. Clip the pods to the pod calibration jig by identifying the nose and inserting it in the corresponding recess, then press down on the other side of the pod. When successfully clipped, the status LED on the pods will turn solid green.

5. Begin by placing face 1 of the pod calibration jig upwards on a sterile table. The numbers corresponding to each step of the calibration are laser-marked on the jig on the face that should face upwards for this step. Keep the jig steady until a sound is triggered. Continue the sequence by positioning the jig in its remaining five positions (2 through 6). Wait for the confirmation sound to confirm the acquisition between each position. When the calibration is completed, the green status LED of each pod will blink.

Note: The green LEDs on the flexion/extension axis of the cut guide pod indicate the expected position (1 through 6) of the pod calibration jig during calibration.

6. Unclip all pods from the pod calibration jig.

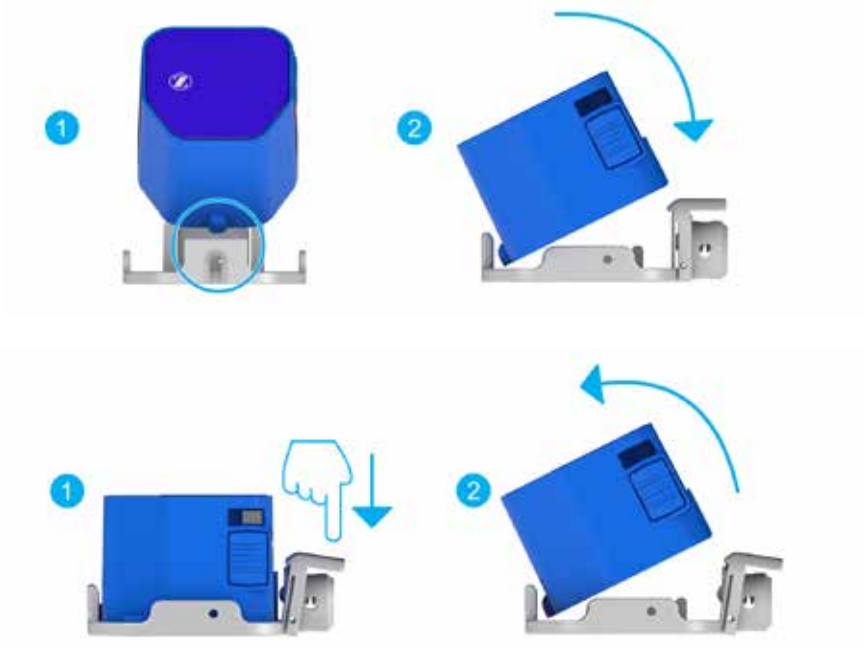


Figure 11
Assembling a Pod to an Instrument

Pod Assembly

To clip and unclip a pod on any of the iASSIST Knee Instruments (except the calibration jig) with the user interface of the pod facing upwards;

1. Identify the nose on the narrow side of the pod and insert it in the corresponding recess.
2. Clip the other side of the pod on the instrument until the spring holder engages. The system will automatically monitor any improper physical connections between the pods and the instruments.
3. To unclip the pod, press on the locking lever and pull on the pod to disengage the spring holder.

⚠**Warning**: Throughout the surgery, always ensure that the pods are properly assembled to their corresponding instruments before use.

Figure 12a
Workflow Selection

Femur Procedure

The iASSIST Knee System is compatible with the femur first and tibia first procedures. See the "Tibial Procedure" section to start with the tibia.

Workflow Selection for Femur

To start a femur first procedure:

1. Clip the reference pod to the femoral reference.
2. Identify the femur mechanical axis entry point.
3. Impact the femoral spike into the distal femoral mechanical axis entry point, aiming at the femoral head. Ensure that the star-shaped end is well inserted and stable into the bone.

   ⚠ **Warning:** The spike should be aligned within 15 degrees of the mechanical axis of the femur. This alignment is required because of the mechanical adjustment limit of the femoral adjustment mechanism.

Figure 12b
Workflow Selection (Continued)

Femur Procedure (Continued)

4. Slide the femoral reference onto the spike.

5. Align the femoral reference in a neutral rotation position.

   Note: The femoral rotation may be set by:
   a. Aligning the indicator arrow at the end of the femoral reference to Whiteside's line;
   b. Aligning a pin inserted in the dedicated medial-lateral hole on the body of the femoral reference to the epicondyles.

6. Affix the femoral reference on the bone with one 3.5 x 38 mm hex head screw in one of the anterior fixation holes.

7. Clip the reference pod to the femoral reference.

   Note: As provided by Zimmer Biomet, the 500 RPM adaptor of the Zimmer Universal Power System Surgical Instruments can be used to secure the screw.

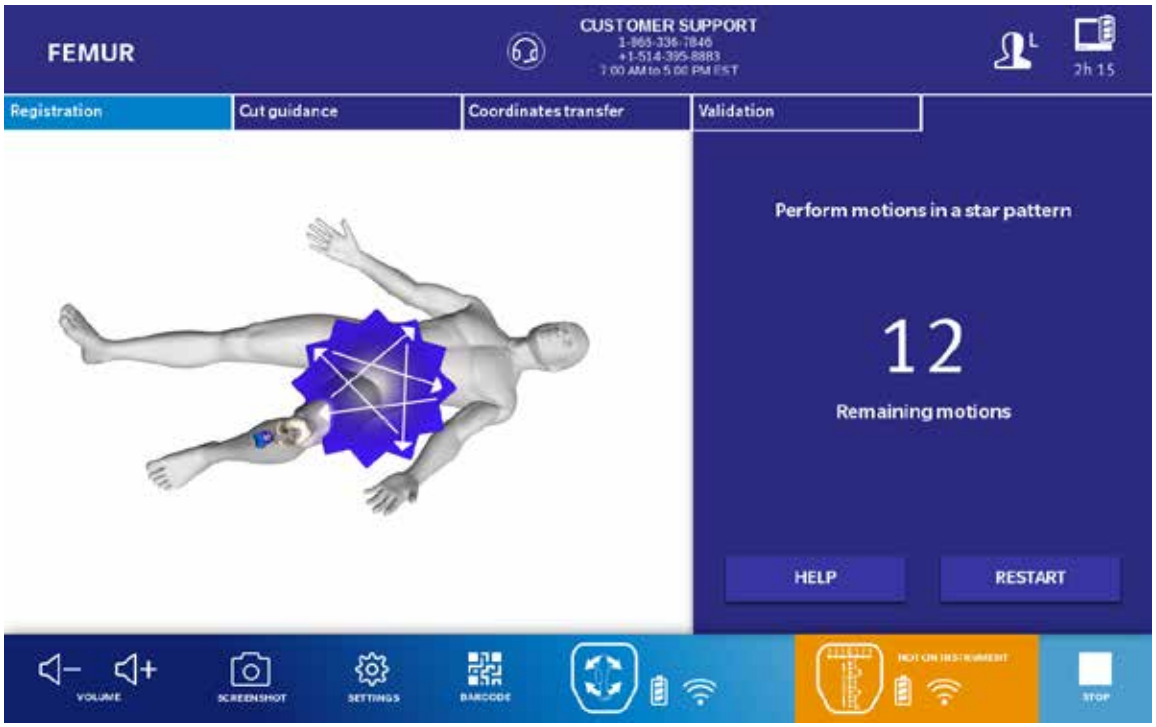


Figure 13
Femoral Registration

Femoral Registration

⚠ **Warning**: From registration to validation, the instruments must remain stable and properly fixated to the bone to ensure accuracy of the system.

1. Press the "Z" button on the pod attached to the femoral reference to initiate the registration procedure.

2. Acquire 13 stable positions by accelerating and stopping the leg to create a star-shaped pattern. An audio feedback will be generated from the iASSIST V2 Tablet after each acquisition until completion. The LEDs on the pod will blink sequentially until completion of the acquisition.

   Note: To restart the femoral registration, press the "Z" button on the pod attached to the femoral reference or on the "Restart" button on the tablet screen.

   If needed, click on the "Help" button to watch a video that explains the recommended pattern for the femoral registration movements.

⚠ **Warning**: The pelvis must remain immobile during the femoral registration.

Do not perform the femoral registration by moving the leg in a uniaxial direction, i.e. only in a flexion/extension, abduction/adduction and/or combination of both motions (e.g. T-shape).

Do not perform the registration by making circles with the leg.

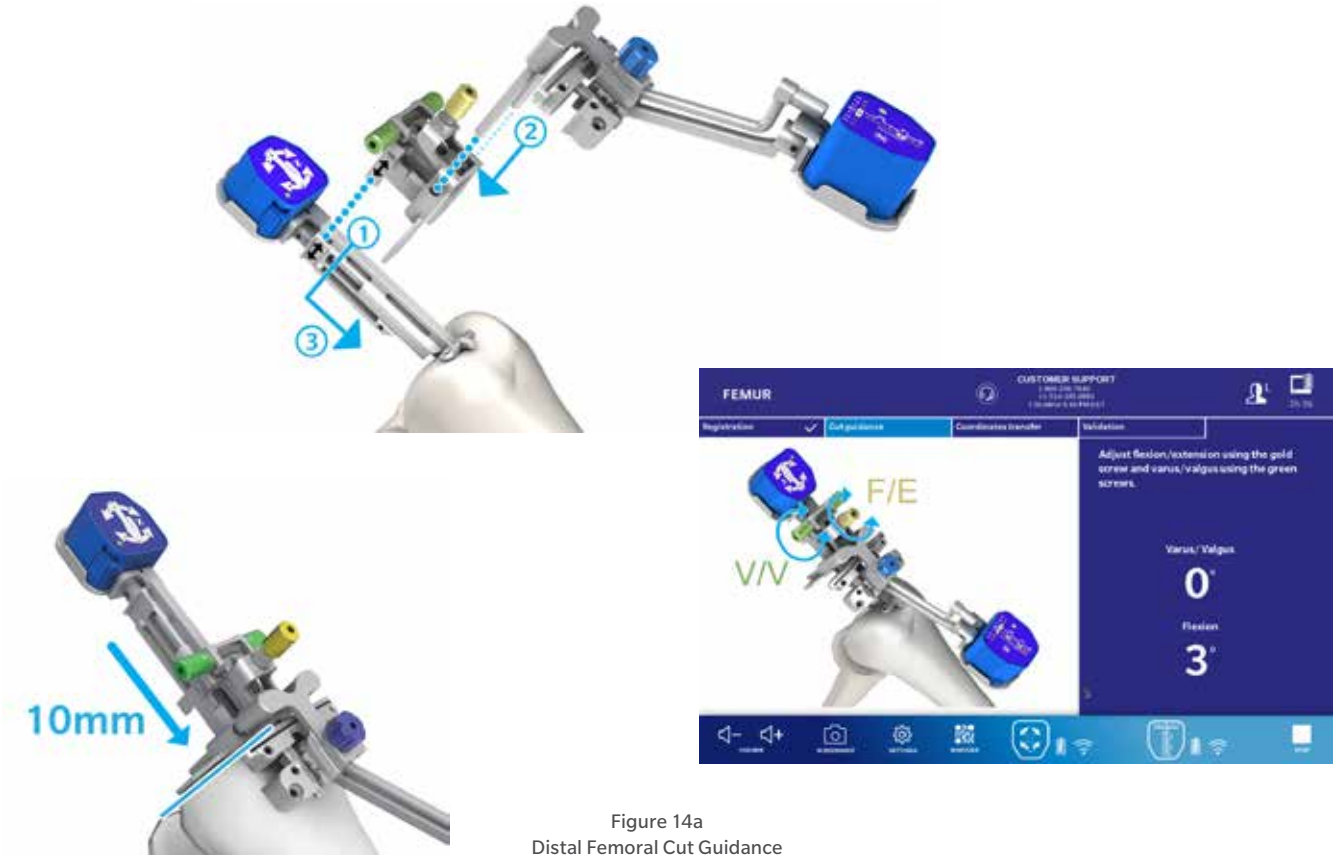


Figure 14a
Distal Femoral Cut Guidance

Distal Femoral Cut Guidance

1. Install the femoral adjustment mechanism on the anterior side of the femoral reference by aligning the arrows laser-marked on the instruments.

2. Clip the cut guide pod on the cut guide and insert the two long pegs of the femoral A/P slider into the femoral adjustment mechanism.

3. Slide the femoral adjustment mechanism down towards the distal condyles to the half way mark.

4. Adjust flexion/extension and varus/valgus angles using the gold screw for flexion/extension and green screw for varus/valgus.

   Note: The navigated values will be displayed on the cut guide pod: the LEDs will be green when the angle is less than two degrees off from the target angle, and red when the angle is two degrees off or more from the target angle. The navigated values will also be displayed on the iASSIST V2 Tablet: the numbers will be white when the angle is one degree in range of the target, and red when the angle is out of this range.

   Warning: It is suggested to colorblind users to rely on the numbers on the pod and tablet displays.

   Warning: The leg should be elevated to obtain more than 45 degrees flexion (in relation to the operating table plane) in order for the system to be able to compute angle values.

5. Once the adjustment is completed, slide the femoral adjustment mechanism towards the femur until it is fully seated on the most distal condyle.

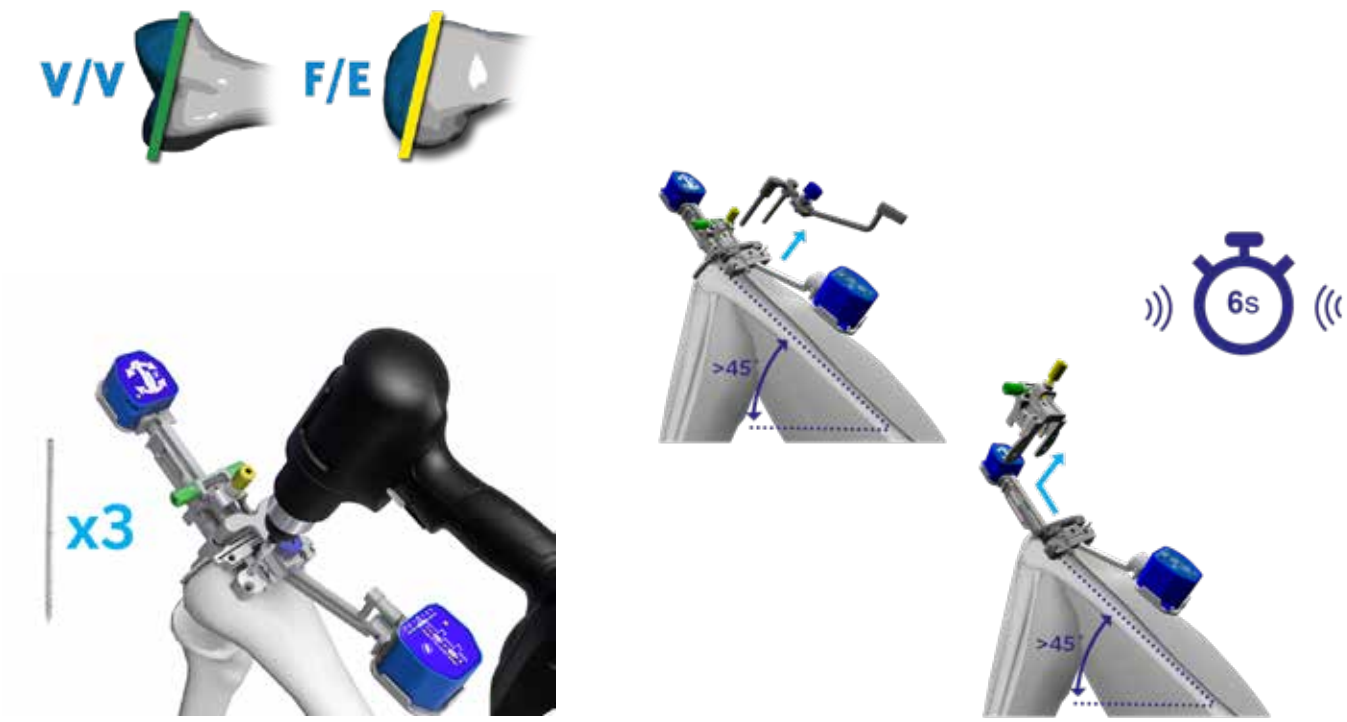


Figure 14b
Distal Femoral Cut Guidance (Continued)

Distal Femoral Cut Guidance (Continued)

6. Insert three 3.2 mm headless trocar drill pins in the base of the distal femoral cut guide using both parallel holes and one diagonal hole in the body of the guide.

7. With the knee stable and flexed more than 45 degrees, unlock the femoral A /P slider using the blue screw and remove it from the assembly. Hold the knee steady until the coordinate transfer confirmation sound is heard.

   ⚠**Warning**: When the A/P slider is removed, it indicates to the system that there's a commitment to a cut and prepares for the removal of the distal reference to enable the cut. It is therefore important to remain stable, hold the knee steady and flexed 45 degrees (in relation to the surgical table plane) when disconnecting the assembly. This allows for the information of the reference pod (being removed) to transfer to the cut guide pod (staying on the bone). A confirmation sound is heard when the disconnection and the information transfer has been completed between the two pods. This operation could take up to 6 seconds. If this step is not performed properly, the distal cut can be performed, though the cut validation won't be possible.

8. Once the coordinates transfer is completed, slide the femoral adjustment mechanism away from the distal femur so both arrows are aligned and pull it off the assembly.

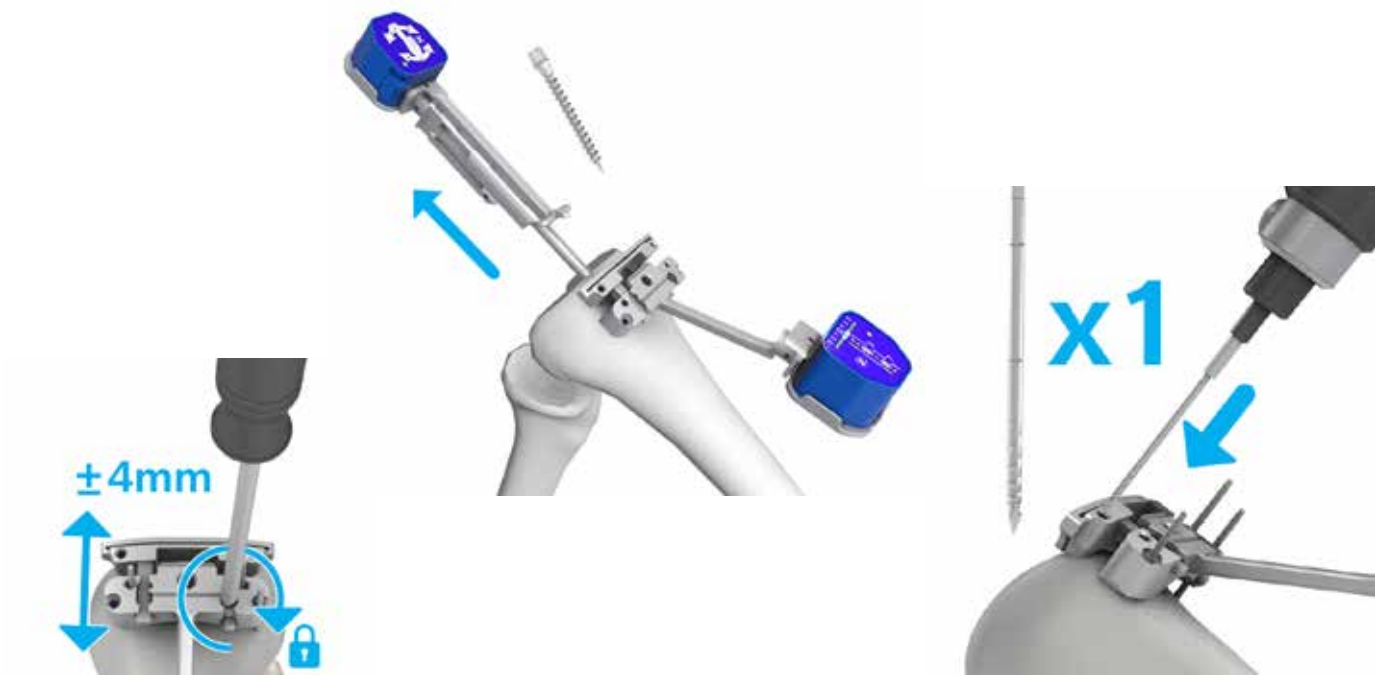


Figure 14c
Distal Femoral Cut Guidance (Continued)

Distal Femoral Cut Guidance (Continued)

9. Remove the 3.5 x 38 mm hex head screw and the femoral reference.

10. Remove the femoral spike using a slaphammer.

    Note: The Persona Slaphammer can be used to remove the femoral spike.

    Note: The NexGen Slaphammer Extractor can be used to remove the femoral spike or the CAS 7 .9 mm Small Spike.

11. Manually adjust the resection level if desired. Loosen the screw on the distal femoral cut guide to increase/decrease resection by 2 or 4 mm, then tighten the screw.

    Note: The femoral saw slot when secured at the "0" position on the distal femoral cut guide resects 10 mm off the most distal condyle.

12. Insert a 3.2 mm headless trocar drill pin in the femoral saw slot using the angular hole in the body of the saw slot to secure it to the bone.

    Warning: The 3.2 mm headless trocar drill pin used to secure the distal femoral cut guide and the femoral saw slot to the bone has to be inserted carefully to avoid perforating the second cortex.

Figure 14d
Distal Femoral Cut Guidance (Continued)

Distal Femoral Cut Guidance (Continued)

13. Optionally, a drop rod can be used to check the varus/valgus orientation of the cut before performing the resection. Insert the paddle section of the alignment arch into the femoral saw slot. Make sure that the arm of the alignment arch is aligned with the A/P plane of the femur. Then, slide a drop rod in the body of the alignment arch.

    Note: The alignment rod with coupler can be used to verify the cut.

14. Resect the distal femur.

    Warning: The saw has to be inserted in the femoral saw slot and not on top of it. The Persona/NexGen Saw Slot is compatible with saw blades of 1.27 mm (0.05 inch) thickness. The Vanguard Saw Slot is compatible with saw blades of 1.37 mm (0.054 inch) thickness.

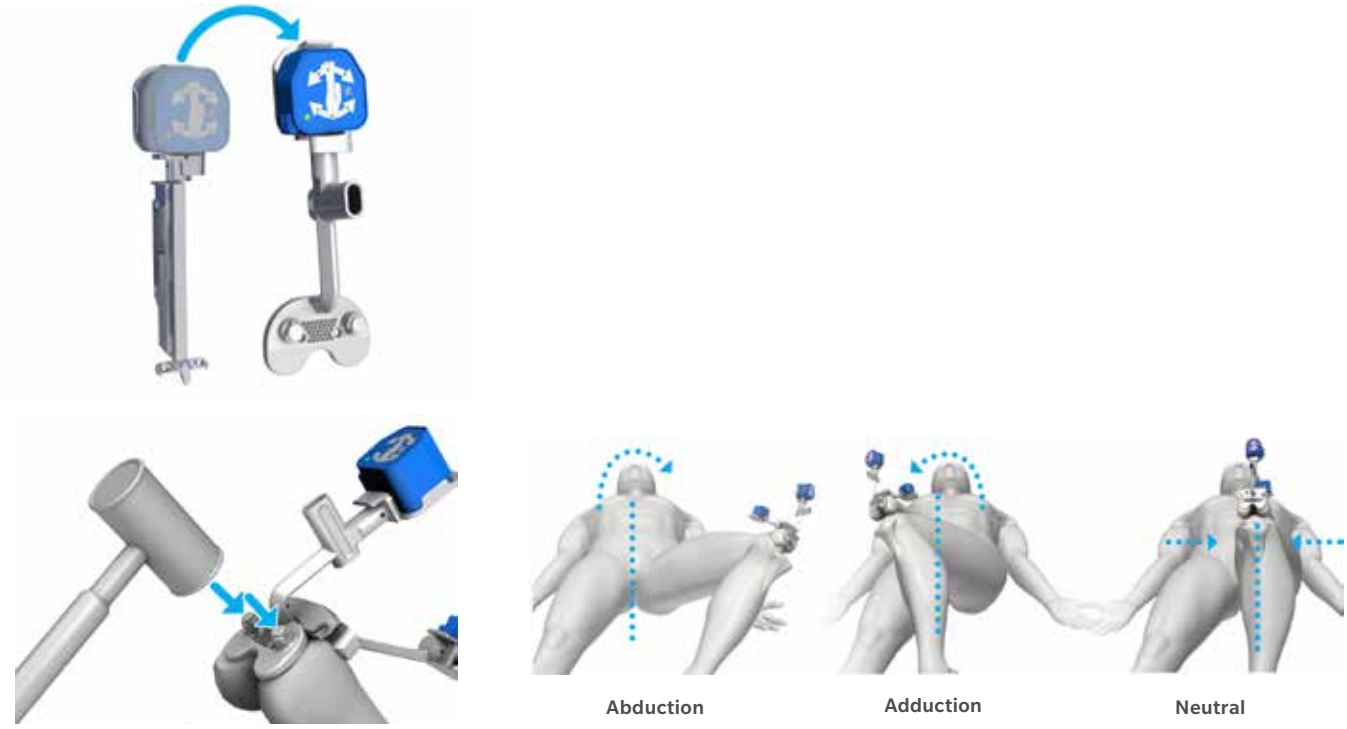


Figure 15a
Distal Femoral Cut Validation

Distal Femoral Cut Validation

1. Remove the pod attached to the femoral reference and clip it to the validation tool.

2. Position the flat surface of the validation tool onto the distal femoral cut.

3. Secure the validation tool on the distal femoral cut by gently impacting the captive spikes. Additionally two 3.5 x 38 mm hex head screw can be used for more stability.

   ⚠**Warning**: Care must be taken when impacting the spikes of the validation tool to avoid potential interference between the spikes and the pins used to secure the femoral distal cut guide and the femoral saw slot. If interference is felt, the validation tool should be shifted mediolaterally by 10 mm.

For steps 4-6, follow the feedback on the pod attached to the validation tool. The iASSIST V2 Tablet will also provide audio and visual feedback. The number of degrees to the target range for validation movements will be displayed on the tablet. Ensure adequate stability of the validation tool on the distal femoral cut by manually holding it in place.

4. Bring the leg into abduction until the green LED stops blinking and then hold the knee steady until the acquisition sound is heard.

5. Bring the leg into adduction until the green LED stops blinking and then hold the knee steady until the acquisition sound is heard.

6. Bring the leg into neutral position until the green LED stops blinking and then hold the knee steady until the acquisition sound is heard.

7. The distal femur cut values are displayed on the pod attached to the femoral distal cut guide and on the iASSIST V2 Tablet screen.

Figure 15b
Distal Femur Cut Validation (Continued)

Distal Femoral Cut Validation (Continued)

Note: To restart the distal femur cut validation, press the "Z" button on the pod attached to the validation tool or the "Restart" button on the bottom right of the iASSIST Tablet screen.

8. A drop rod can optionally be inserted in the handle of the validation tool to check the varus/valgus orientation of the cut. Make sure that the arm of the validation tool is aligned with the A/P plane of the femur.

   Warning: The femoral distal cut guide must not have moved in reference to the bone to perform an accurate distal cut validation. When setting femoral rotation after the cut is validated, pay attention not to use the holes created by the validation tool as they may have the same distance between pegs as other femoral rotational setting instruments.

9. If two 3.5 x 38 mm hex head screw were used, remove those screws. Remove the validation tool by lifting the tool off of the bone by hand, straight away from the cut plane.

10. Remove the 3.2 mm headless trocar drill pins, the femoral saw slot, and the distal femoral cut guide.

    Note: If the femur cut needs to be corrected, it is possible to navigate the orientation of the cut guide in order to execute the cut again. To do so: 1. Remove the reference pod attached to the validation tool and clip it to the femoral reference. 2. Press the "Quit" button, then the "Workflow" button and then "Confirm". 3. Proceed with femoral workflow selection and registration.

11. Proceed with the tibia registration if continuing with the proximal tibia cut. Refer to the "Workflow Selection" section for more details.

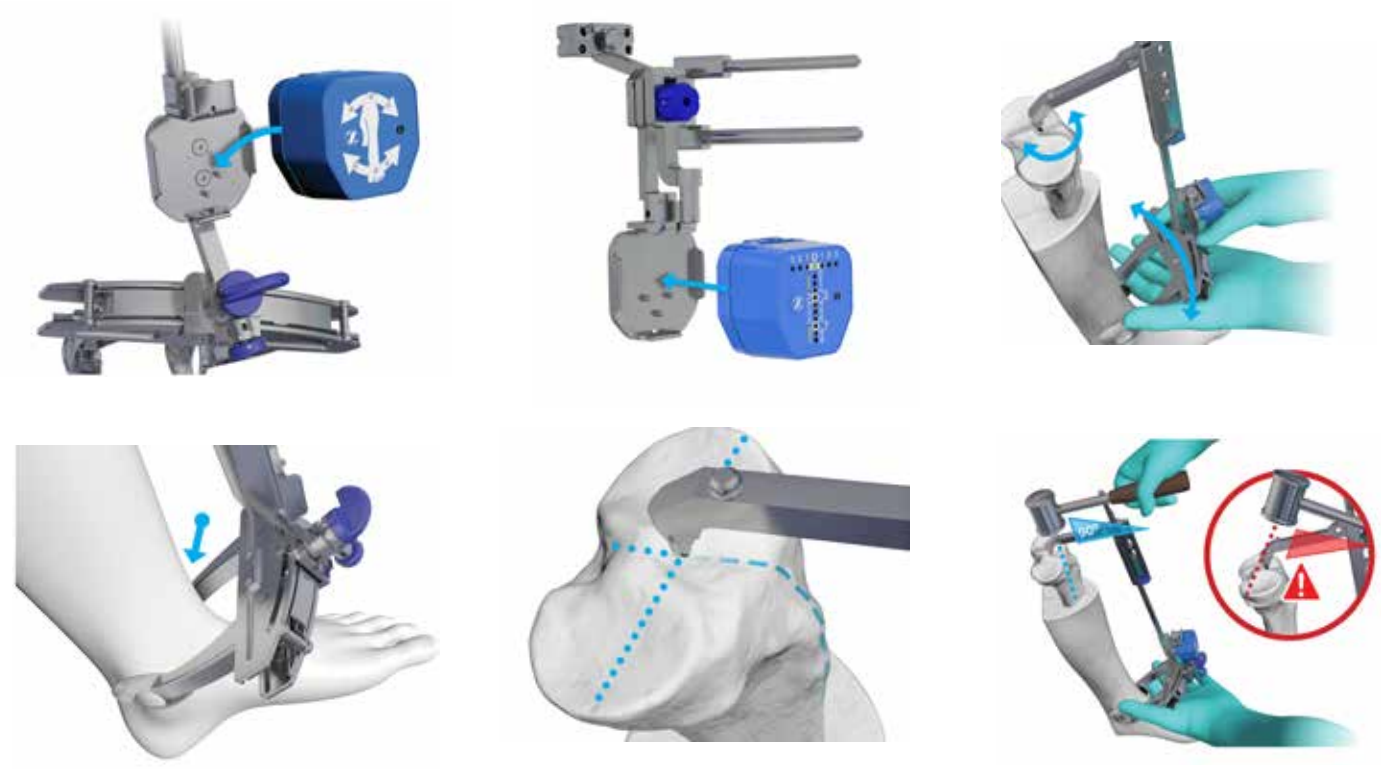


Figure 16a
Tibial V2 Workflow Selection

Tibial V2 Procedure (not available for European market)

⚠**Warning**: At patient draping, take care to leave the malleoli accessible to the surgeon.

⚠**Warning**: Tibia V2 instrumentation is not available for European market

Workflow Selection for the Tibia V2

To start a tibia first procedure:

1. Clip the Reference Pod to the Lower Tibial Reference.
2. Clip the Cut Guide Pod to the Tibial Proximal Cut Guide.
3. Mark the location of the malleoli with a marker.
4. Loosen the blue knob on the distal part of the Tibial Reference.
5. Install the distal part of the Tibial Reference on the ankle by firmly gripping the distal clamps around the marked malleoli. Verify the placement of the Tibial Reference ankle cups by looking if the malleoli marks are still visible through the cup holes.

   ⚠**Warning**: During the entirety of the Tibial Reference installation (steps 5 to 10), ensure to hold the malleoli clamps onto the malleoli at all times.
6. Place the tip of the spike of the Tibial Reference on the tibia mechanical axis entry point, without engaging it into the bone.
7. While continuing to firmly grip the distal clamps around the malleoli, set rotation using the Tibial Reference. Orient the instrument shaft to align with the medial third of the tubercle.
8. While continuing to firmly grip the distal clamps around the malleoli, impact the spike until the fins are fully inserted in the tibia.

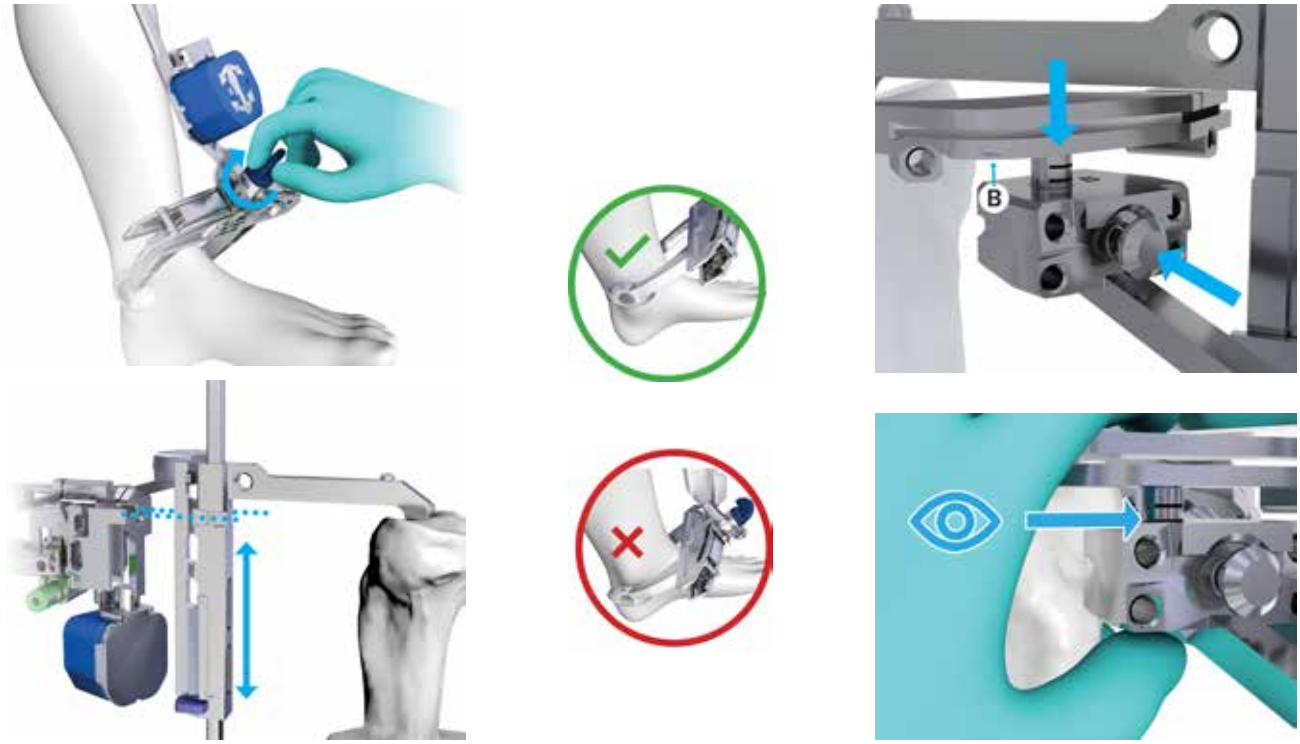


Figure 16b
Tibial V2 Workflow Selection Continued

Workflow Selection for the Tibia V2 (Continued)

⚠ **Warning**: Impact the Tibial Reference in-line with the spike of the instrument. The spike must be positioned and inserted carefully in order to avoid loosening.

9. Ensure the distal clamps of the Tibial Reference remain securely positioned on the malleoli. Verify that the malleoli holes allow seeing of the previously marked malleoli. If the marks are not visible anymore, restart the Tibial Reference installation and make sure to hold the malleoli clamps on the malleoli at all times during installation.

10. Lock the blue knob on the Lower Tibial Reference.

11. Insert the assembly of Tibial Proximal Cut Guide, A/P Slider and Adjustment Mechanism onto the upper Tibial Reference by aligning the arrows laser-marked on the instruments. Slide down the assembly until it is resting on the stopper.

Note: In order for step 11 to be easily executed, it is important to not assemble the Saw Slot before step 12, as it could mechanically interfere with the Tibial Reference rod during assembly.

12. Press on the button of the Proximal Cut Guide and insert the Saw Slot by having the two letters B aligned with each other at the desired depth. Release the button to lock the vertical movement of the Saw Slot. The instrument can still rotate to better fit the bone.

Note: To choose a Saw Slot height that allows for 2 or 4 mm of recut, place a finger on the lower part of the Saw Slot hole of the Cut Guide and push the Saw Slot until it touches the finger.

Figure 17a
Tibial V2 Cut Guidance

Tibia V2 Cut Guidance

1. To start Tibia V2 Cut Guidance, press on the Z button of either the Cut Guide Pod or the Reference Pod.

2. Follow feedback (red and green LEDs) on the Cut Guide Pod attached to the Proximal Cut Guide or on the iASSIST V2 Tablet and adjust the tibia slope and varus/valgus using the gold and green screws respectively.

   ⚠ **Warning**: Make sure to adjust the angles before pushing the Cut Guide until it touches the tibia. If the instrument is pushed too soon, its contact with the tibia could make the adjustments more difficult.

3. Insert a stylus in the Saw Slot

   ⚠ **Warning**: The leg should be elevated to obtain more than 45 degrees flexion (in relation to the operating table plane) in order for the system to be able to compute angle values.

   Note: The NexGen Tibia PRI Stylus 2/10 mm (00-5901-082-00) or 4/6 mm (00-5901-081-00) or the Persona Partial Knee Stylus 2/4mm (42-5399-005-24) can be used to set the resection.

4. Push the Proximal Cut Guide until it touches the bone.

5. Adjust the height to reach the desired resection level in accordance with the standard surgical technique by moving the Adjustment Mechanism – A/P Slider – Cut Guide – Saw slot assembly along the Upper Tibial Reference.

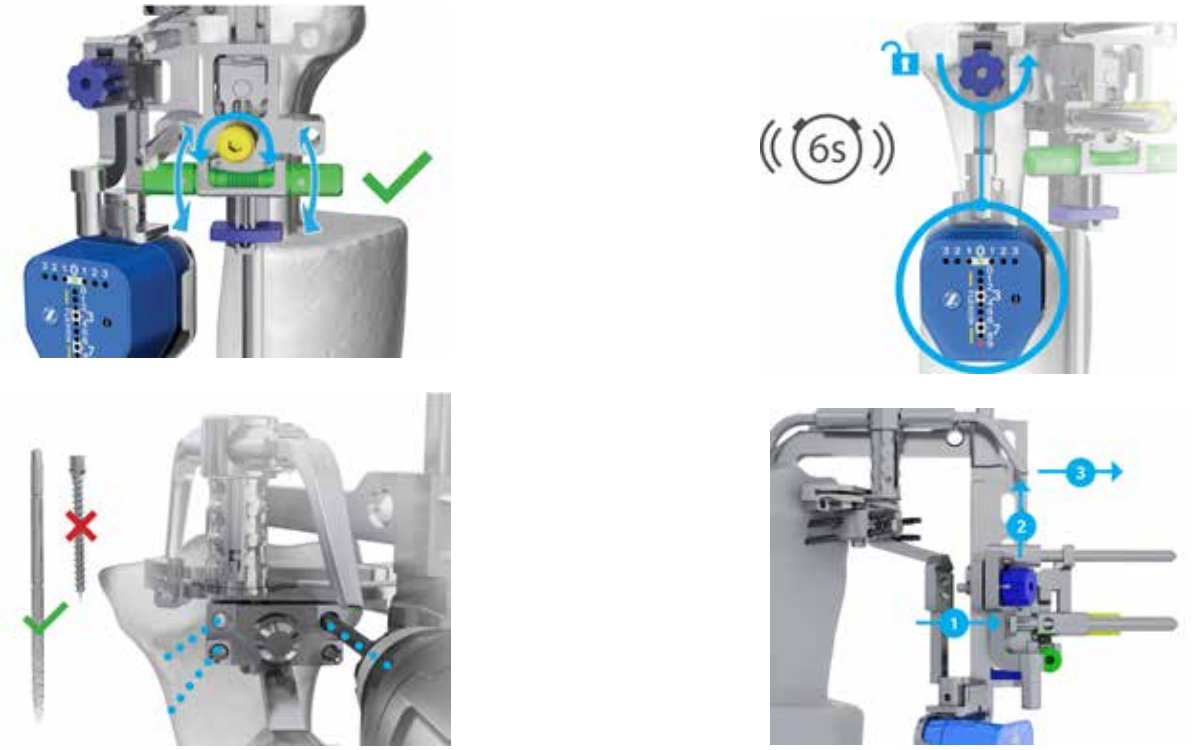


Figure 17b
Tibial V2 Cut Guidance (Continued)

Tibia V2 Cut Guidance (Continued)

6. Ensure the angles displayed on the cut guide pod and the tablet screen are still as desired.
7. Secure the Proximal Cut Guide onto the tibia by inserting three 3.2 mm headless trocar drill pins: two in the upper parallel holes and one in the lower diagonal medial hole.
8. Remove the stylus.
9. To finalize the instrument removal for cut preparation, with the leg flexed at more than 45° and the knee stable, unlock the Tibial A/P slider using the blue screw. Hold the knee steady until the confirmation sound is heard.
10. Once the confirmation sound is heard, pull the A/P slider back against the Adjustment Mechanism, slide the Tibial Adjustment Mechanism up on the Tibial Reference until both arrows are aligned and pull it off the assembly.

⚠ **Warning**: When the A/P slider is unlocked, it indicates to the system that there is a commitment to a cut and prepares for the removal of the Tibial Reference to enable the cut. It is therefore important to remain stable, hold the knee steady and flexed 45 degrees (in relation to the surgical table plane) when disconnecting the assembly. This allows for the information of the Reference Pod (being removed) to transfer to the Cut Guide Pod (staying on the bone). A confirmation sound is heard when the disconnection and the information transfer has been completed between the two pods. This operation could take up to 6 seconds. If this step is not performed properly, the distal cut can be performed, though the validation won't be possible.

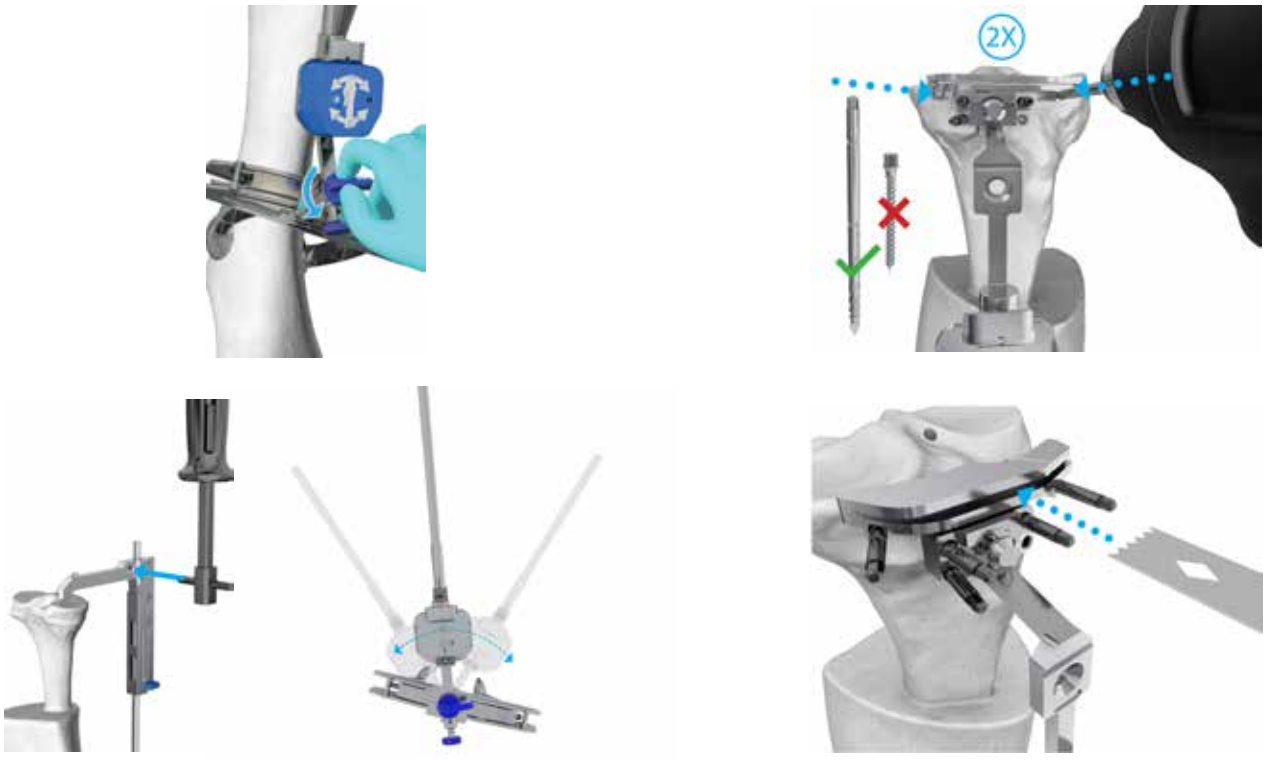


Figure 17c
Tibial V2 Cut Guidance (Continued)

Tibia V2 Cut Guidance (Continued)

11. Loosen the blue locking knob on the lower Tibial Reference.

12. Insert one of the short pegs of the Persona Slaphammer into the hole of the upper Tibial Reference and use the slaphammer to unspike the proximal part of the Tibial Reference.

13. Remove the lower part of the Tibial Reference from the malleoli to remove the Tibial reference.

    Note: To store the Lower Tibial Reference in its tray, pull on the blue pulling knob and rotate the Tibial Reference rod.

14. If necessary, readjust the height of the saw slot by pressing the push button on the Cut Guide instrument. Insert two 3.2 mm headless trocar drill pins into the Saw Slot.

15. A drop rod can optionally be used to check the varus/valgus orientation of the cut before performing the resection. Insert the paddle section of the Alignment Arch in the Saw Slot. Make sure that the arm of the Alignment Arch is aligned with the A/P plane of the tibia. Then, slide a drop rod in the body of the alignment arch.

    Note: An Alignment rod with coupler can be used to verify the cut.

16. If a drop rod and alignment arch were used, remove them from the Tibial Saw Slot.

    Note: at this point of the flow, only the tibial cut guide and saw slot should be positioned on the bone.

17. Resect the proximal tibia.

    Warning: The saw has to be inserted in the Tibial Saw Slot and not on top of it. The Persona/NexGen Saw Slot is compatible with saw blades of 1.27 mm (0.05 inch) thickness. The Vanguard Saw Slot is compatible with saw blades of 1.37 mm (0.054 inch) thickness.

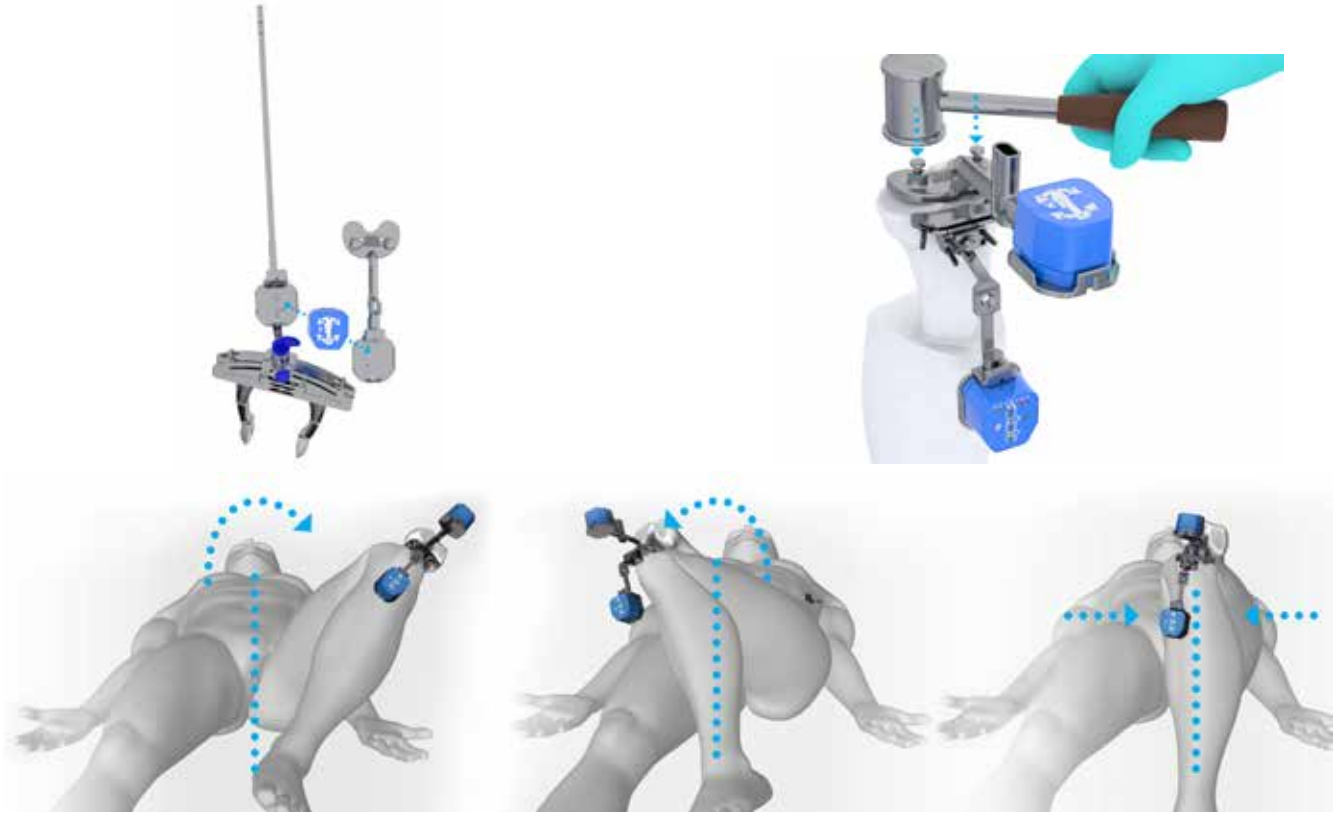


Figure 18a
Tibia V2 Validation

Tibia V2 Validation

1. Make sure the Cut Guide Pod is still clipped on the Tibial Proximal Cut Guide.
2. Remove the Reference Pod from the lower Tibial Reference and clip it to the Validation Tool.
3. Position the flat surface of the Validation Tool on the proximal tibia cut.
4. Secure the Validation Tool on the proximal tibia cut by gently impacting the captive spikes. Additionally, two 3.5 x 38 mm hex head screw can be used for more stability. The validation procedure will automatically start when the Reference Pod is clipped.

   ⚠ **Warning**: Care must be taken when impacting the spikes of the Validation Tool to avoid potential interference between the spikes and the pins used to secure the Saw Slot and Cut Guide. If interference is felt, the Validation Tool should be shifted by 10 mm mediolaterally.

For steps 5-7, make sure to hold the validation tool in place with one hand while performing the validation steps. The pod attached to the validation tool will provide the necessary abduction and adduction range to achieve in order to complete the validation. The LEDs will flash green in the direction of the required movement.

5. Bring the leg into abduction until the green LED stops blinking and then hold the knee steady until the acquisition sound is heard.
6. Bring the leg into adduction until the green LED stops blinking and then hold the knee steady until the acquisition sound is heard.
7. Bring the leg into neutral position until the green LED stops blinking and then hold the knee steady until the acquisition sound is heard.

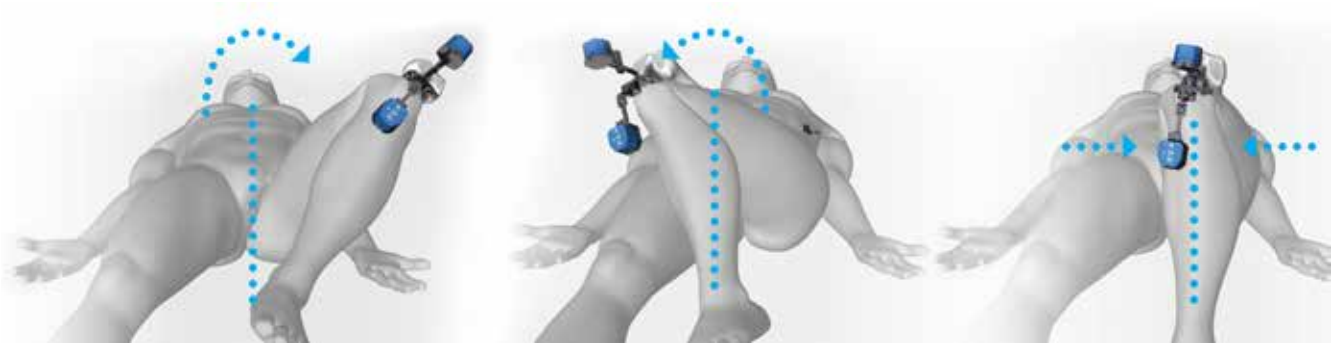


Figure 18b
Tibia V2 Validation (Continued)

Tibia V2 Validation (Continued)

8. The proximal tibia cut values are displayed on the pod attached to the Proximal Cut Guide and on the iASSIST V2 Tablet screen.

   Note: To restart the proximal tibia cut validation, press the Z button on the Pod attached to the Validation Tool or the "Restart" button on the bottom right of the iASSIST V2 Tablet screen.

9. A drop rod can optionally be inserted in the handle of the Validation Tool to verify the varus/valgus orientation of the cut. Make sure that the arm of the Validation Tool is aligned with the A/P plane of the tibia.

10. If two 3.5 x 38 mm hex head screws were used, remove those screws. Remove the Validation Tool by lifting the tool off the bone by hand, straight away from the cut plane.

11. Remove the 3.2 mm headless trocar drill pins from the Cut Guide and the Saw Slot to remove them from the bone.

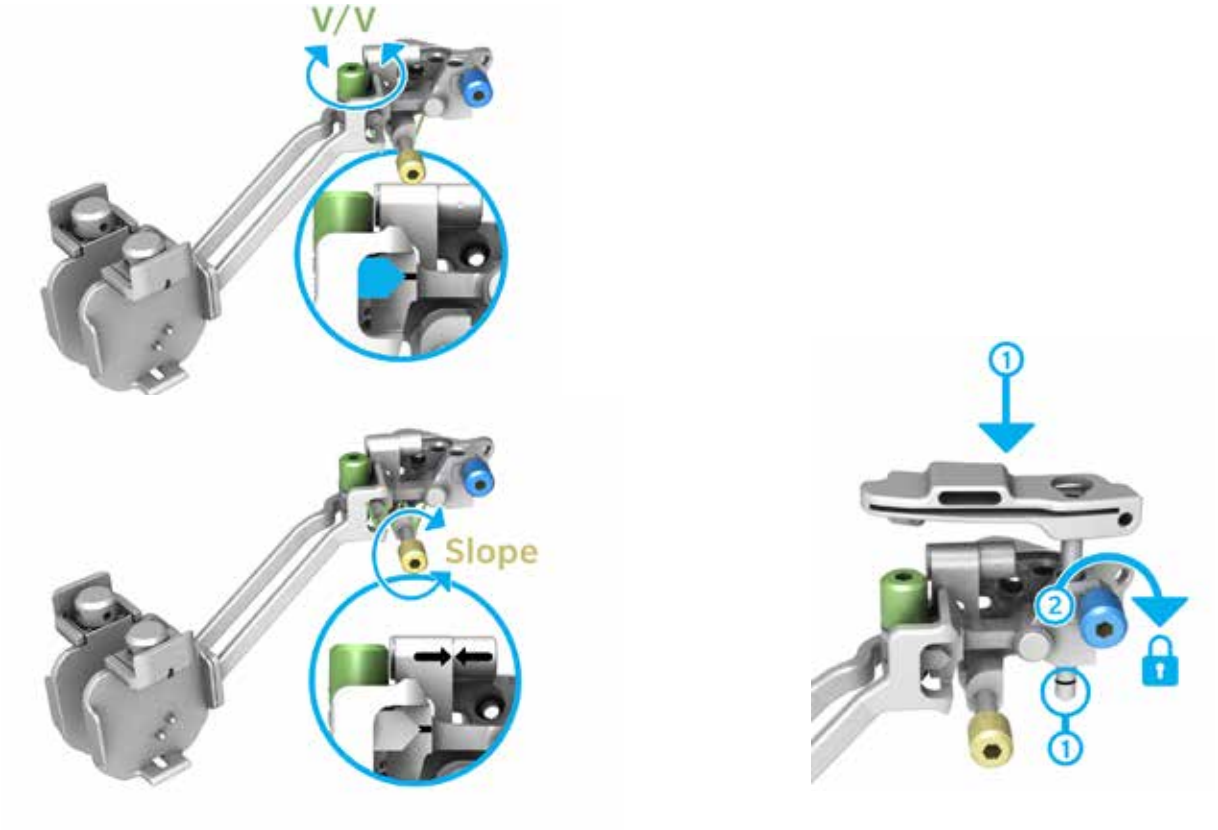


Figure 19
Tibia V1 Instrument Assembly

Tibia V1 Instrument Assembly

Tibia V1 Instrument Assembly

Note: There are three different techniques for tibial resection. The first one is the Freehand Positioning of the Tibial Adjustment Mechanism and will be described here. Two more techniques will be described in the "Alternate Techniques to Prepare Tibia V1 Cut" section.

The right/left tibial cut guides are side specific and must be used per the corresponding right/left tibial adjustment mechanism. Depending on the patient side, choose the right or left cut guide and adjustment mechanism.

1. Using the green screw, set the varus/valgus of the tibial adjustment mechanism to the neutral position by aligning the arrow with the laser marking (V/V). (Figure19)
2. Using the gold screw, set the tibia slope of the tibial adjustment mechanism to the neutral position by aligning the laser marked arrows (slope) respectively. (See Figure 19)
3. Insert the tibial cut guide elevator rod into the tibial adjustment mechanism until the lowest line increment is aligned with the bottom edge of the insertion point.
4. Lock the tibial cut guide by hand tightening the blue screw on the tibial adjustment mechanism.

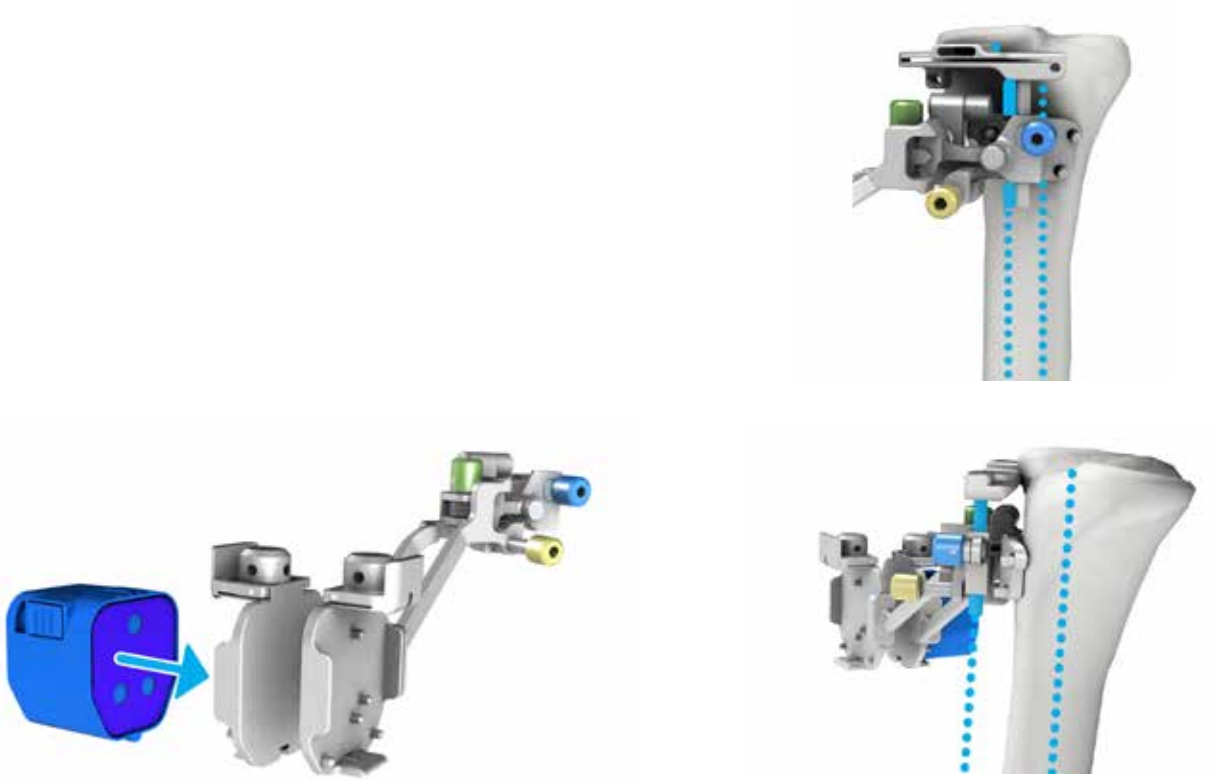


Figure 20a
Tibial V1 Workflow Selection

Tibial V1 Procedure

⚠ **Warning**: At patient draping, take care to leave the malleoli accessible to the surgeon.

The iASSIST Knee System is compatible with femur first and tibia first procedures. See the "Femur Procedure" section to start with the femur.

Note: There are three different techniques for tibia resection. The first one is the freehand positioning of the tibial adjustment mechanism and will be described here. Two more techniques will be described in the "Alternate Techniques to Prepare Tibia V1 Cut" section.

Workflow Selection for the Tibia V1

1. To start a tibia first procedure:
   For a left knee procedure, clip the reference pod to the back receptacle of the left tibial adjustment mechanism.

   For a right knee procedure, clip the reference pod to the back receptable of the right tibial adjustment mechanism.

2. Position the tibial adjustment mechanism so that the concave shape at the rear of the instrument hugs the convex ridge of the tibial tubercle. Ensure the position is low enough for the tibial cut guide to attain the desired level of resection.

   Note: As the tubercle may be obscured by the tibial adjustment mechanism, the medial third of the tubercle can be marked with a surgical marking pen in order to ease the rotational alignment of the tibial alignment guide later on.

3. Visually align the elevator rod of the tibial cut guide with the tibial mechanical axis in both the frontal and lateral planes aiming to achieve a neutral orientation.

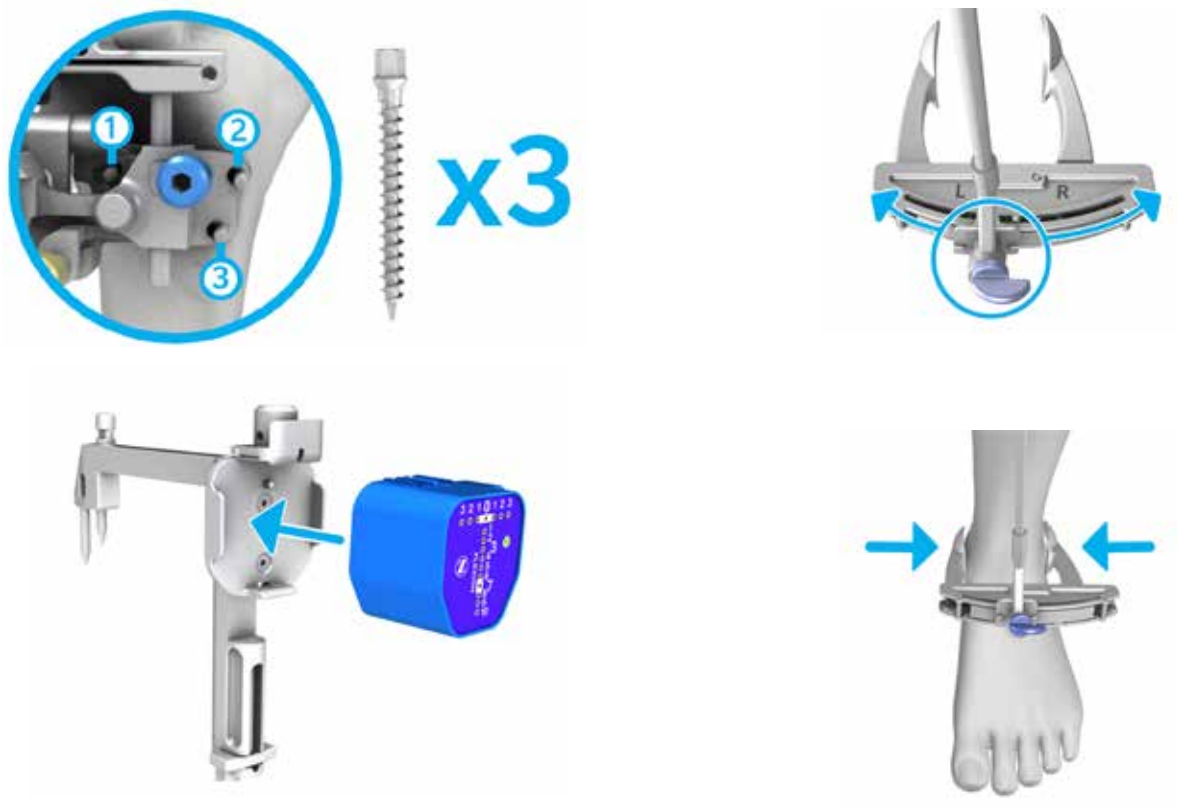


Figure 20b
Tibial V1 Workflow Selection (Continued)

Workflow Selection for the Tibia V1 (Continued)

4. Use three 3.5 x 38 mm hex head screws to secure the tibial adjustment mechanism to the bone by securing a screw in the (1) medial hole, (2) upper lateral hole, (3) lower lateral hole.

   ⚠**Warning**: Control the speed of the power tool or finish tightening the screws manually to avoid stripping the cortex of the tibia. As provided by Zimmer Biomet, the 500 RPM adaptor of the Zimmer Universal Power System Surgical Instruments can be used to secure screws.

   ⚠**Warning**: From registration to validation, the instruments must remain stable and properly secured to the bone to ensure accuracy of the system.

5. Clip the cut guide pod to the tibial alignment guide and loosen the blue knob on the distal part of the tibial alignment guide.

   Position the rod of the tibial alignment guide to an initial starting orientation per the preset position (L or R) on the distal part of the tibial alignment guide. **For a left knee** procedure, the preset position is L. **For a right knee** procedure, the preset position is R.

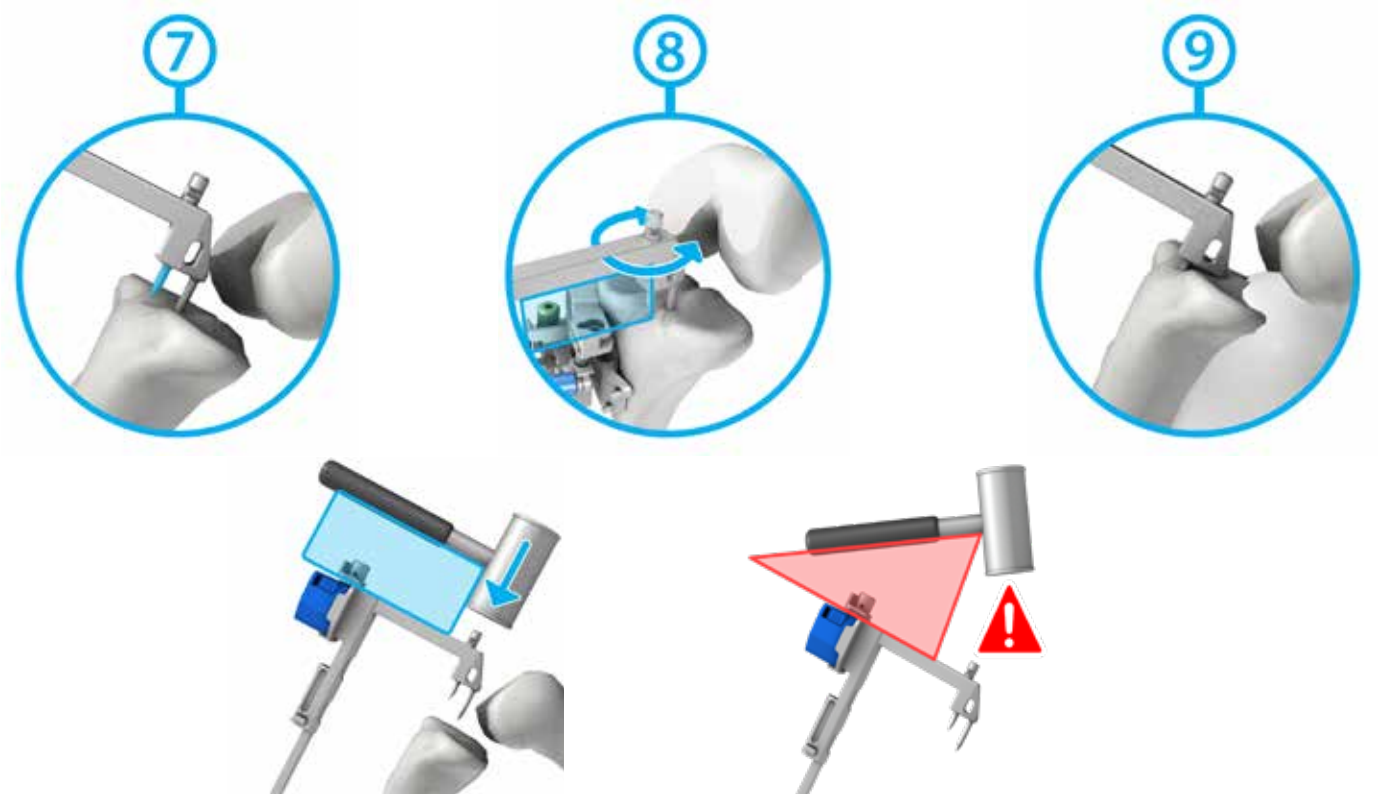


Figure 20c
Tibial V1 Workflow Selection (Continued)

Workflow Selection for the Tibia V1 (Continued)

6. Install the distal part of the tibial alignment guide on the ankle by firmly gripping the distal clamps around the malleoli.

   Note: The tibial alignment guide is designed to be self-centering when placed around the malleoli.

   Warning: Care must be taken when impacting the spikes of the tibial alignment guide to avoid potential interference between the spikes and the screws used to secure the tibial adjustment mechanism.

   Impact the tibial alignment guide in-line with the spikes of the instrument. Off-axis impaction may result in bending of the spikes. The two spikes of the tibial alignment guide must be positioned and inserted carefully in order to avoid loosening.

7. While continuing to firmly grip the distal clamps around the malleoli, partially insert (2-3 mm) the longer spike of the proximal part of the tibial alignment guide into the mechanical axis entry point, without engaging the shorter spike.

8. While continuing to firmly grip the distal clamps around the malleoli, set rotation using the tibial alignment guide. Orient the instrument shaft to align with the medial third of the tubercle.

   Warning: If the medial third of the tubercle was previously marked with a surgical marking pen, the instrument shaft can be aligned with this reference.

Figure 20d
Tibial V1 Workflow Selection (continued)

Workflow Selection for the Tibia V1 (Continued)

⚠ **Warning**: Do not pull on the distal part of the tibial alignment guide once both spikes have been inserted into the tibia. Doing so may result in bending of the spikes.

9. While continuing to firmly grip the distal clamps around the malleoli, impact the instrument until both spikes are fully inserted in the tibia.
10. Ensure the distal clamps of the tibial alignment guide remain securely positioned on the malleoli. If a readjustment is necessary, ensure the shaft of the guide remains immobile and in proper alignment. Adjust by rotating the distal part of the guide and resecure the clamps around the malleoli.
11. Lock the blue knob on the distal tibial alignment guide.

Abduction **Adduction** **Neutral**

Figure 21a
Tibia V1 Registration

Tibia V1 Registration

1. Ensure the cut guide pod is clipped to the tibial alignment guide.
2. Press the "Z" button on the pod attached to the tibial alignment guide to initiate the registration procedure.

For steps 3-5, follow the feedback on the pod attached to the tibial alignment guide. The iASSIST V2 Tablet will also provide audio and visual feedback. The number of degrees to the target range for registration movements will be displayed on the tablet.

3. Bring the leg into abduction until the green LED stops blinking and then hold the knee steady until the acquisition sound is heard.
4. Bring the leg into adduction until the green LED stops blinking and then hold the knee steady until the acquisition sound is heard.
5. Bring the leg into neutral position until the green LED stops blinking and then hold the knee steady until the acquisition sound is heard.

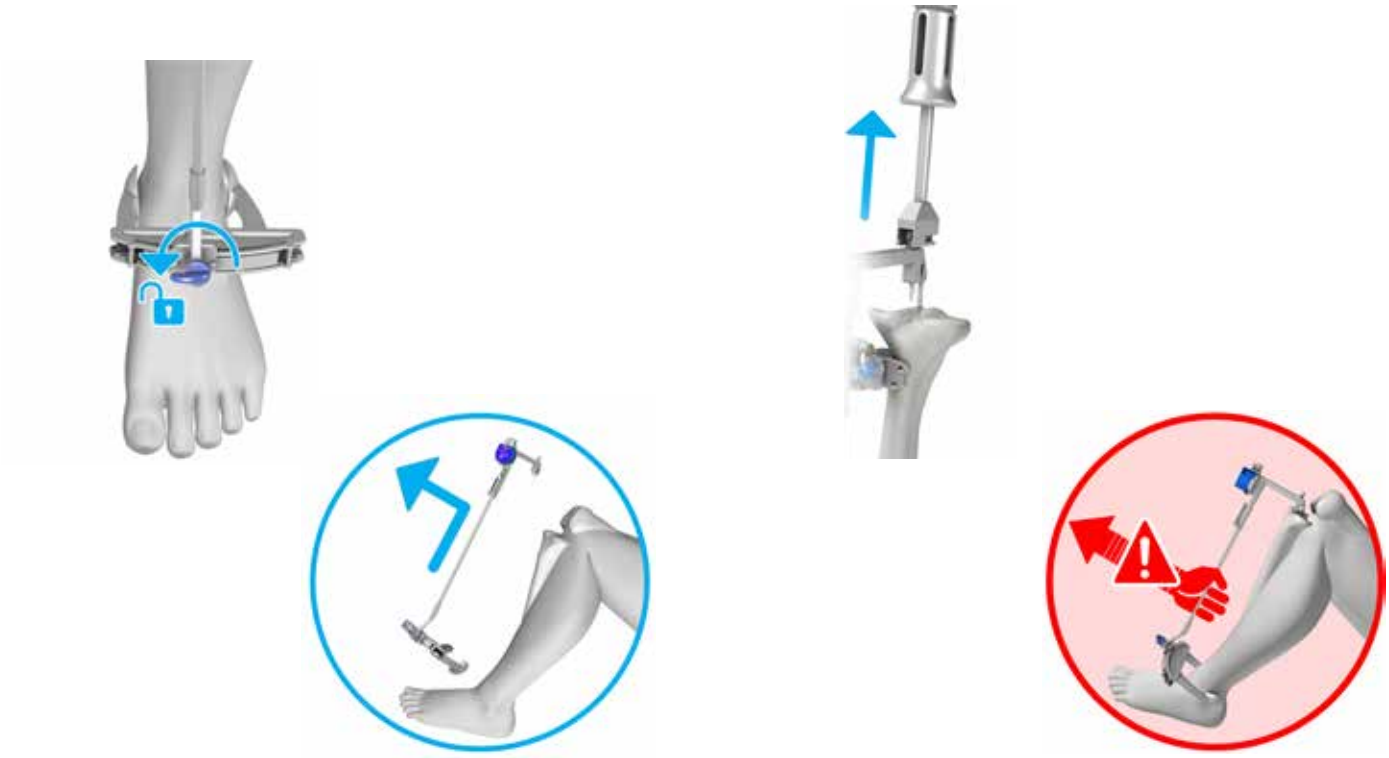


Figure 21b
Tibia V1 Registration (Continued)

Tibia V1 Registration (Continued)

Note: To restart the tibial registration, press the "Z" button on the pod attached to the tibial alignment guide or the "Restart" button on the bottom right of the iASSIST V2 Tablet Screen.

6. Loosen the blue knob on the distal end of the tibial alignment guide.

7. Unspike the proximal part of the tibial alignment guide from the tibia using a slaphammer.

Note: The Persona Slaphammer or the NexGen Slaphammer Extractor can be used to remove the tibial alignment guide.

8. Remove the distal part of the tibial alignment guide from the malleoli.

Note: Do not pull on the distal part of the tibial alignment guide until both spikes are disengaged from the tibia. Doing so may result in bending of the spikes.

Figure 22a
Proximal Tibial V1 Cut Guidance

Proximal Tibial V1 Cut Guidance

1. Unclip the cut guide pod from the tibial alignment guide and clip it to the front receptable of the tibial adjustment mechanism.

2. Follow feedback (red and green LEDs) on the cut guide pod attached to the tibial adjustment mechanism and adjust tibia slope and varus/valgus using the gold and green screws respectively.

3. Insert stylus in the tibial cut guide.

   ⚠ **Warning**: The leg should be elevated to obtain more than 45 degrees flexion (in relation to the operating table plane) in order for the system to be able to compute angle values.

   Note: The NexGen Posterior Referencing Instruments 2/10 mm or 4/6 mm Tibial Depth Resection Stylus or the NexGen Tibial Depth Resection Stylus can be used to set the resection.

4. Insert the tibial cut guide elevator rod into the tibial adjustment mechanism.

   Note: The right/left tibial cut guides are side specific and must be used per the corresponding right/left tibial adjustment mechanism.

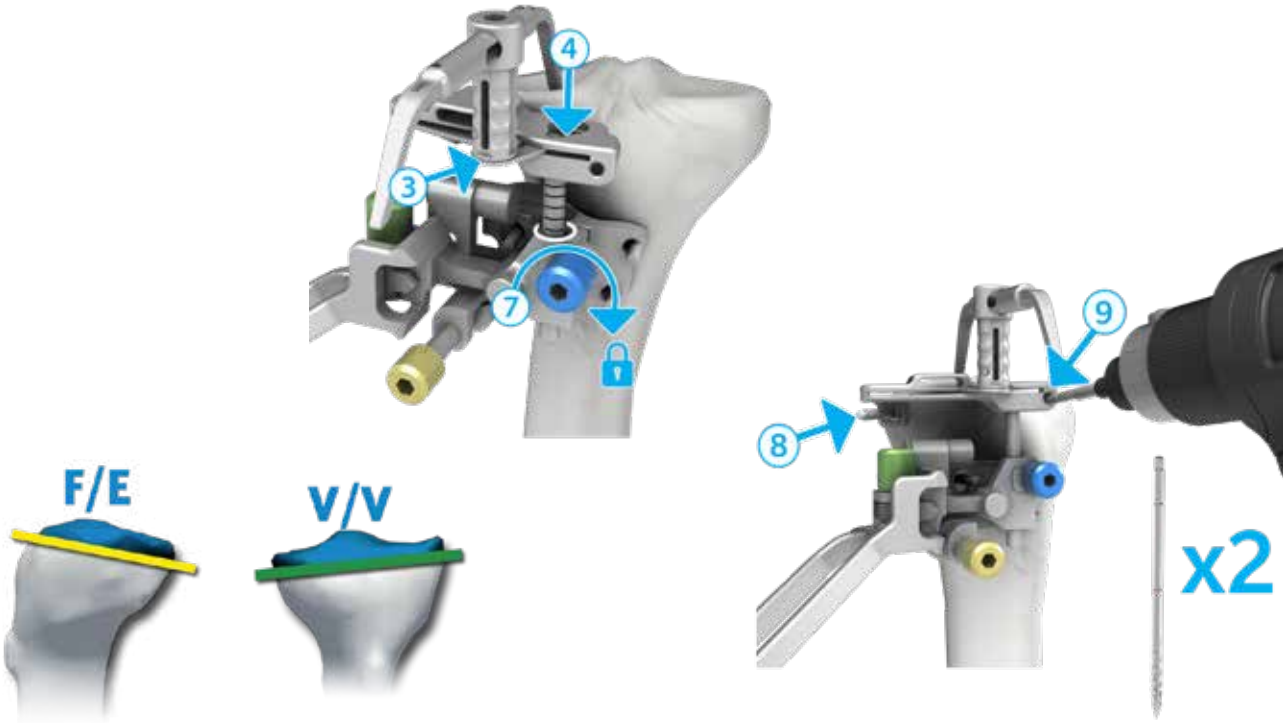


Figure 22b
Proximal Tibial V1 Cut Guidance (Continued)

Proximal Tibial V1 Cut Guidance (Continued)

Note: Each line increment on the elevator rod measures 2 mm.

5. Set the resection level in accordance with the standard surgical technique.

6. Ensure that the tibial cut guide is well seated on the anterior contour of the tibia (i.e. medial side of the tibial cut guide must be in contact with the tibia).

7. Lock the tibial cut guide in place by hand-tightening the blue screw on the tibial adjustment mechanism.

8. Secure the tibial cut guide onto the tibia by inserting a 3.2 mm headless trocar drill pin in the medial hole.

9. Further stabilize the tibial cut guide onto the tibia by inserting a 3.2 mm headless trocar drill pin in the lateral hole.

   Warning: The fasteners used to secure the tibial cut guide to the bone must be inserted carefully to avoid perforating the second cortex and to avoid potential interference with the screws used to secure the tibial adjustment mechanism.

   Note: Alternatively, a 3.5 x 38 mm hex head screw can be inserted in the medial hole instead of the 3.2 mm headless trocar drill pin. When using a 3.5 x 38 mm hex head screw, the screw must only be inserted halfway as to avoid movement of the tibial cut guide.

10. Remove the stylus.

Figure 22c
Proximal Tibial V1 Cut Guidance (Continued)

Proximal Tibial V1 Cut Guidance (Continued)

⚠ **Warning**: If the tibial adjustment mechanism is not fixed securely or moves, the tibia registration should be performed again. Repeat the steps described in the "Tibial Registration" section.

11. A drop rod can optionally be used to check the varus/valgus orientation of the cut before performing the resection. Insert the paddle section of the alignment arch in the tibial cut guide. Make sure that the arm of the alignment arch is aligned with the A/P plane of the tibia. Then, slide a drop rod in the body of the alignment arch.

Note: alignment rod with coupler can be used to verify the cut.

12. If a drop rod and an alignment arch were used, remove them from the tibial cut guide.

13. Resect the proximal tibia.

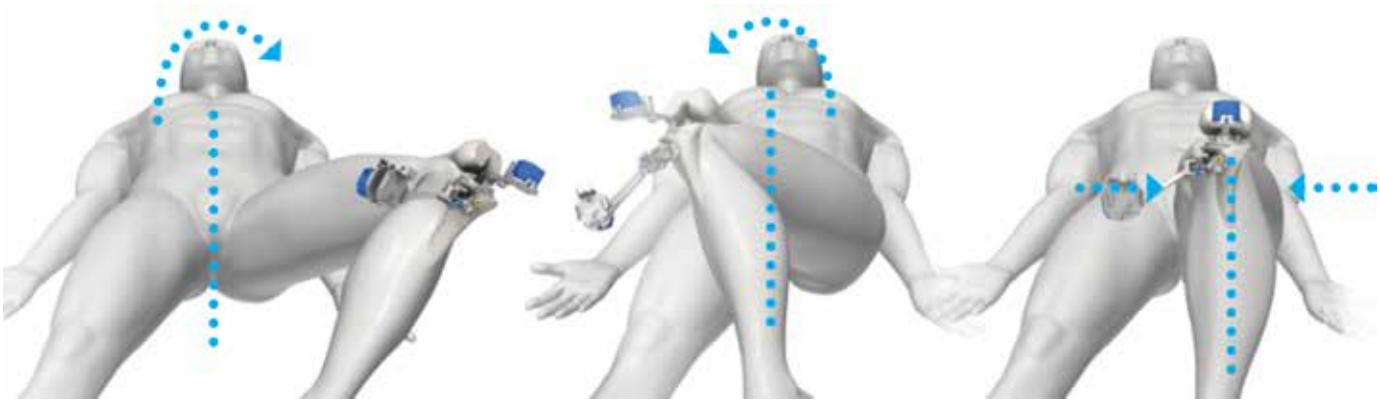
⚠ **Warning**: The saw has to be inserted in the tibial cut guide saw slot and not on top of it. The tibial cut guide is compatible with saw blades of 1.27 mm (0.05 inch) thickness.

Figure 23a
Proximal Tibial V1 Cut Validation

Proximal Tibial V1 Cut Validation

1. Remove the cut guide pod attached to the front receptacle of the tibial adjustment mechanism and clip it to the validation tool.
2. Position the flat surface of the validation tool on the proximal tibia cut.
3. Secure the validation tool on the proximal tibia cut by gently impacting the captive spikes. Additionally, two 3.5 x 38 mm hex head screw can be used for more stability. The validation procedure will automatically start.

⚠ **Warning**: Care must be taken when impacting the spikes of the validation tool to avoid potential interference between the spikes and the screws used to secure the tibial adjustment mechanism and the tibial cut guide. If interference is felt, the validation tool should be shifted by 10 mm mediolaterally.



Abduction **Adduction** **Neutral**

Figure 23b
Proximal Tibial V1 Cut Validation (Continued)

Proximal Tibial V1 Cut Validation (Continued)

For steps 4-6, make sure to hold the validation tool in place with one hand while performing the validation steps and follow the feedback on the pod attached to the validation tool. The iASSIST V2 Tablet will also provide audio and visual feedback. The number of degrees to the target range for validation movements will be displayed on the tablet.

4. Bring the leg into abduction until the green LED stops blinking and then hold the knee steady until the acquisition sound is heard.

5. Bring the leg into adduction until the green LED stops blinking and then hold the knee steady until the acquisition sound is heard.

6. Bring the leg into neutral position until the green LED stops blinking and then hold the knee steady until the acquisition sound is heard.

7. The proximal tibia cut values are displayed on the pod attached to the validation tool and on the iASSIST V2 Tablet screen.

   Note: To restart the proximal tibia cut validation, press the "Z" button on the pod attached to the validation tool or the "Restart" button on the bottom right of the iASSIST V2 Tablet screen.

8. A drop rod can optionally be inserted in the handle of the validation tool to verify the varus/valgus orientation of the cut. Make sure that the arm of the validation tool is aligned with the A/P plane of the tibia.

9. If two 3.5 x 38 mm hex head screw were used, remove those screws. Remove the validation tool by lifting the tool off of the bone by hand, straight away from the cut plane.

Proximal Tibial V1 Cut Validation (Continued)

Figure 23c
Proximal Tibial V1 Cut Validation (Continued)

⚠ **Warning**: Ensure to hold the tibial adjustment mechanism while removing the 3.5 x 38 mm hex head screws from it. Make sure to remove those screws in the angular orientation of the initial hole. Removing the last scew that was put in first (first screw in, last screw out) can help to keep the right orientation.

Note: If the proximal tibial cut needs to be corrected, it is possible to navigate the orientation of the cut guide in order to execute the cut again. To do so: 1. Remove the cut guide pod attached to the validation tool and clip it to the front receptacle of the tibial adjustment mechanism. 2. Press the "Z" button on the pod attached to the front receptacle of the tibial adjustment mechanism. 3. Follow feedback (red and green LEDs) on the pod attached to the tibial adjustment mechanism and adjust tibia slope and varus/valgus using the gold and green screws respectively.

10. Remove the 3.2 mm headless trocar drill pins,, the tibial cut guide, the 3.5 x 38 mm hex head screws and the tibial adjustment mechanism.

11. Proceed with the femur registration if continuing with the distal femur cut. Refer to the "Workflow Selection" section for more details.

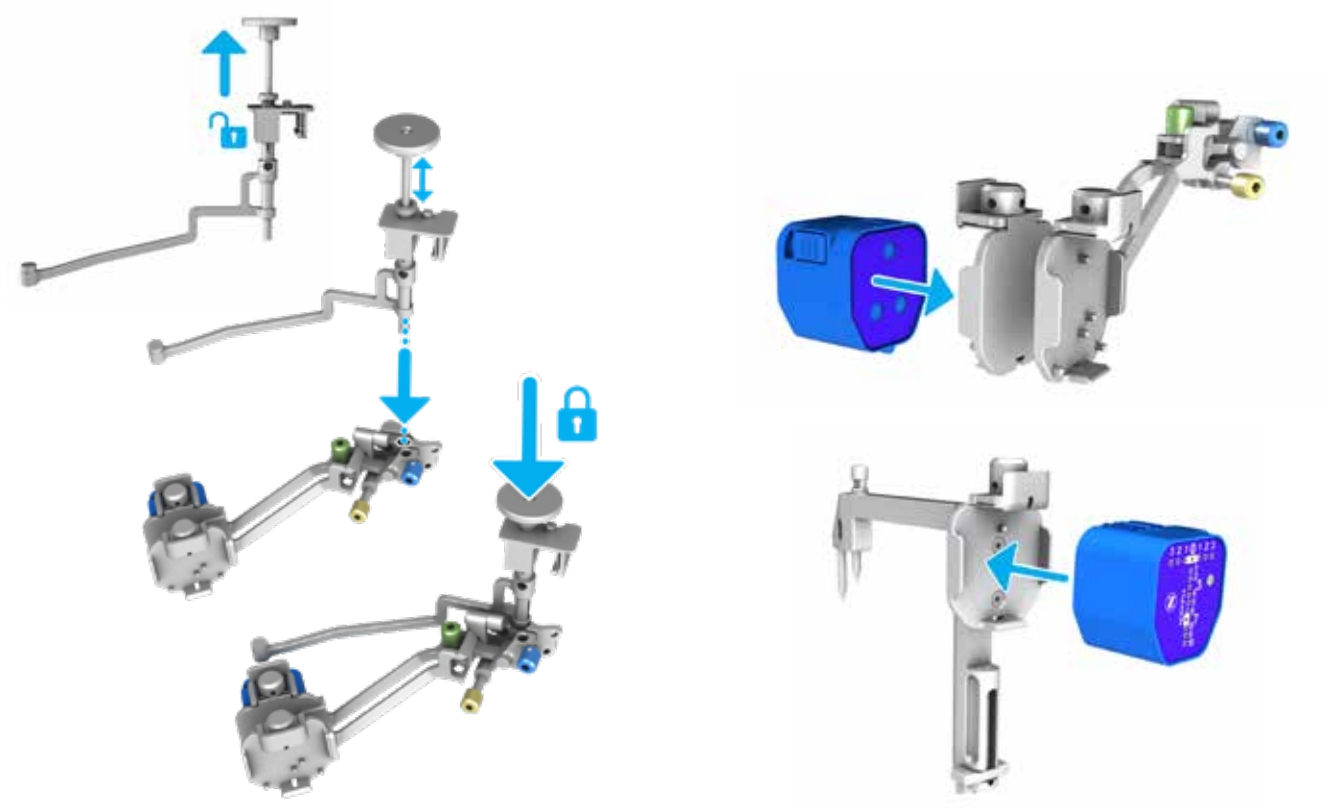


Figure 24
Tibial V1 Positioner Technique - Instrument Assembly

Alternate Techniques to Prepare Tibia V1 Cut

The following section describes two alternate techniques for positioning the tibial adjustment mechanism on the tibia.

Tibial V1 Positioner Technique

Instrument assembly

Note: The tibial positioners are side specific and must be used with the corresponding tibial adjustment mechanism. Ensure to pick the appropriate instruments according to the patient side.

1. Pull out the handle of the tibial positioner.
2. Connect the tibial positioner to the tibial adjustment mechanism while still pulling on the handle.
3. Push on the handle of the tibial positioner to lock the mechanism in place.
4. Clip the reference pod to the back receptacle of the tibial adjustment mechanism.
5. Clip the cut guide pod to the tibial alignment guide.

Workflow Selection

1. Loosen the blue knob on the distal part of the tibial alignment guide.
2. Position the rod of the tibial alignment guide to an initial starting orientation per the preset position (L or R) on the distal part of the tibial alignment guide. **For a left knee** procedure, the preset position is L. **For a right knee** procedure, the preset position is R.

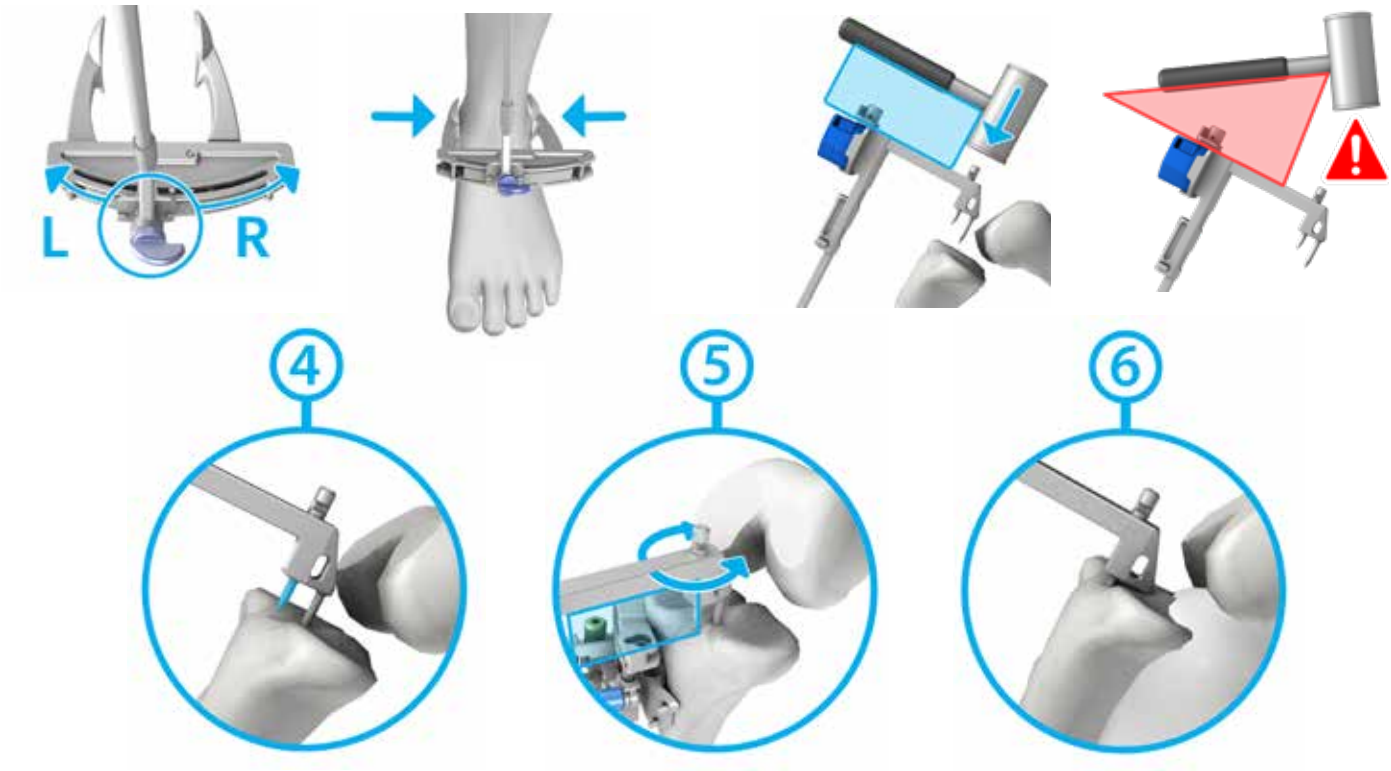


Figure 25a
Tibial V1 Positioner Technique - Workflow Selection

Tibial V1 Positioner Technique (Continued)

3. Install the distal part of the tibial alignment guide on the ankle by firmly gripping the distal clamps around the malleoli.

   Note: The tibial alignment guide is designed to be self-centering when placed around malleoli.

   Warning: After wrapping/preparing the ankle, the surgeon should still be able to palpate the malleoli.

4. While continuing to firmly grip the distal clamps around the malleoli, partially insert (2-3 mm) the longer spike of the proximal part of the tibial alignment guide through the mechanical axis entry point, without engaging the shorter spike.

5. While continuing to firmly grip the distal clamps around the malleoli, set rotation using the tibial alignment guide. Orient the instrument shaft to align with the medial third of the tubercle.

6. While continuing to firmly grip the distal clamps around the malleoli, impact the instrument until both spikes are fully inserted in the tibia.

7. Ensure the distal clamps of the tibial alignment guide remain securely positioned on the malleoli. If a readjustment is necessary, ensure the shaft of the guide remains immobile and in proper alignment. Adjust by rotating the distal part of the guide and resecure the clamps around the malleoli.

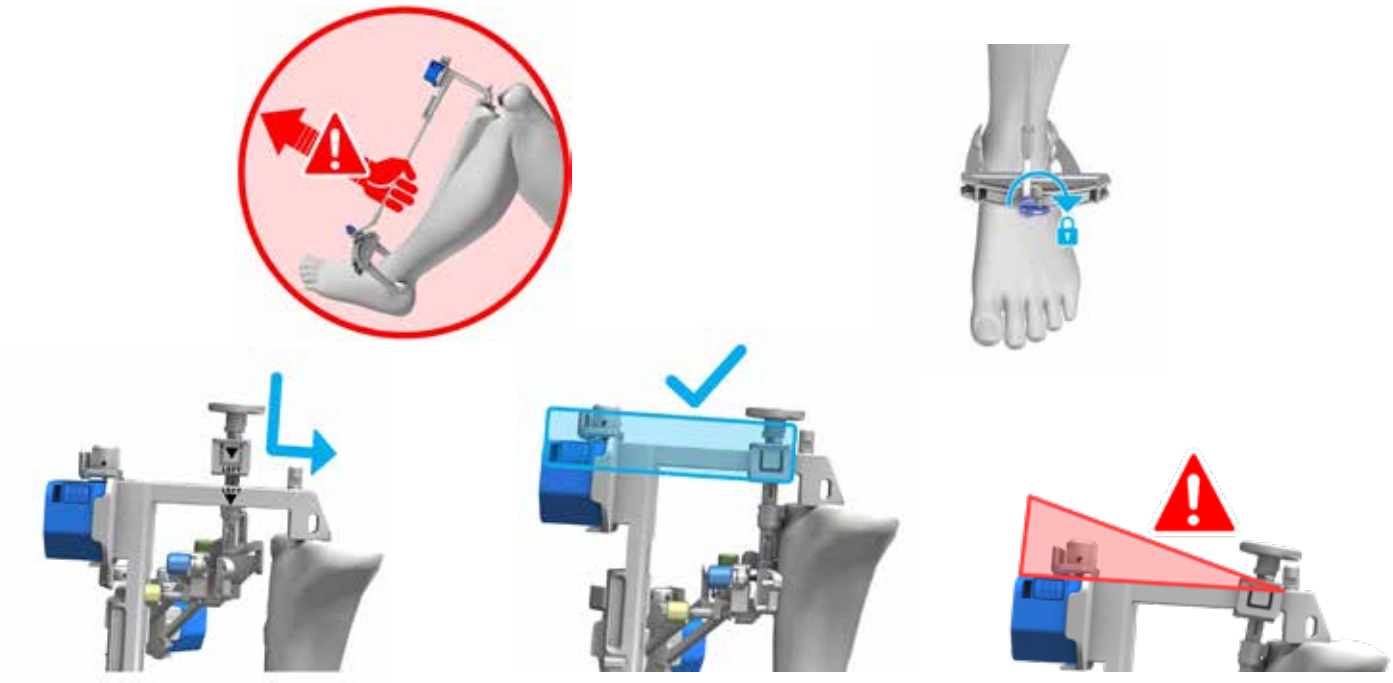


Figure 25b
Tibial V1 Positioner Technique - Workflow Selection (Continued)

Tibial V1 Positioner Technique (Continued)

⚠**Warning**: Impact the tibial alignment guide in-line with the spikes of the instrument. Off-axis impaction may result in bending of the spikes. The two spikes of the tibial alignment guidemust be positioned and inserted carefully in order to avoid loosening.

⚠**Warning**: Do not pull on the distal part of the tibial alignment guide until both spikes have been fully removed from the tibia. Doing so might result in bending of the spikes.

8. Lock the blue knob on the distal tibial alignment guide.

9. Attach the tibial positioner and the tibial adjustment mechanism assembly onto the proximal part of the tibial alignment guide by aligning the arrows laser-marked on the instruments.

10. Slide the tibial positioner towards the bone until the tibial adjustment mechanism sits on the anterior cortex of the tibia.

⚠**Warning**: Ensure that the tibial positioner is well seated on the horizontal shaft of the tibial alignment guide.

⚠**Warning**: For a small size tibia, the tibial adjustment mechanism should be placed on the tubercle. In this case, care must be taken when securing the tibial adjustment mechanism to the bone using the 3.5 x 38 mm hex head screw to avoid potential interference between the screws and the spikes of the tibial alignment guide.

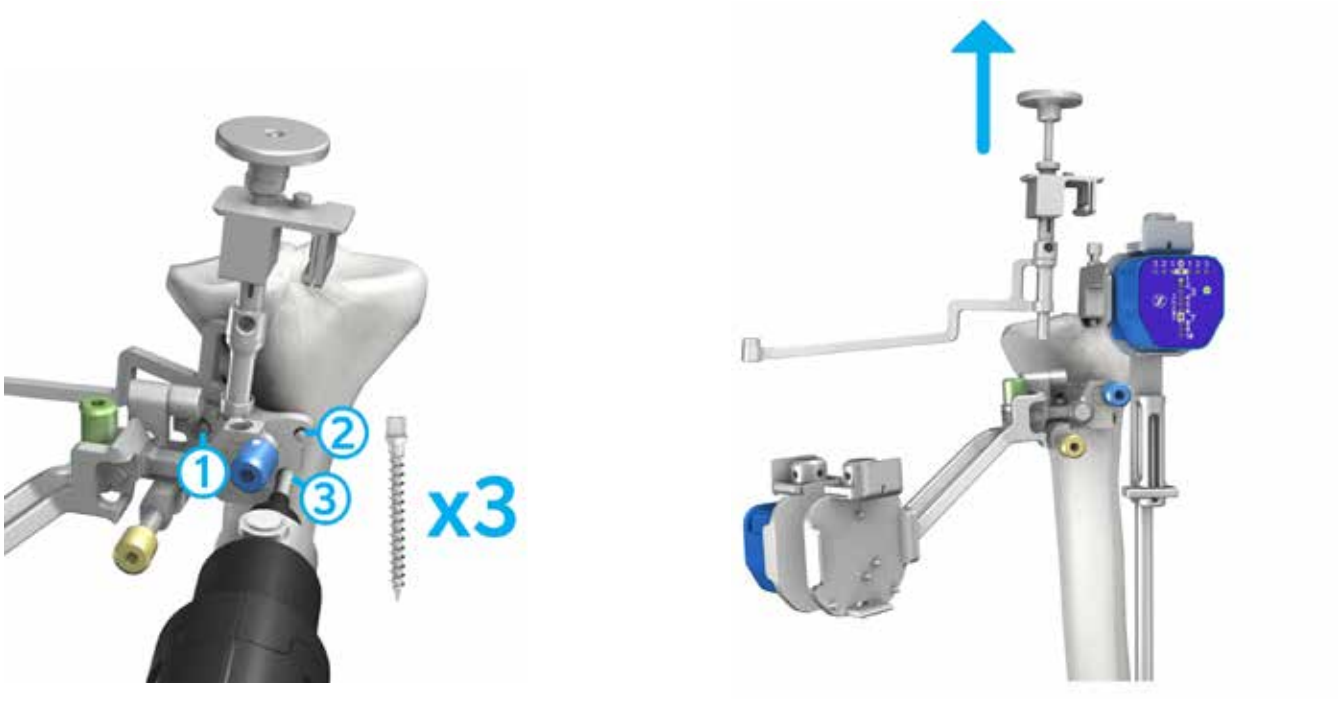


Figure 25c
Tibial V1 Positioner Technique - Workflow Selection (Continued)

Tibial V1 Positioner Technique (Continued)

11. Use three 3.5 x 38 mm hex head screw to secure the tibial adjustment mechanism to the bone. Secure the tibial adjustment mechanism to the bone by first securing screws in the medial hole, secondly in the upper lateral hole, and finally in the lateral lower hole.

12. To initiate the tibial registration, release the tibial positioner from the tibial adjustment mechanism by pulling upwards on the tibial positioner handle.

13. To complete the procedure, resume from step 1 of the "Tibial V1 Registration" section.

⚠ **Warning**: Control the speed of the power tool or finish fixating the screws manually to avoid stripping the cortex of the tibia. As provided by Zimmer Biomet, the 500 RPM adaptor of the Zimmer Universal Power System Surgical Instruments can be used to secure screws. From registration to validation, the instruments must remain stable and properly fixated to the bone to ensure accuracy of the system.

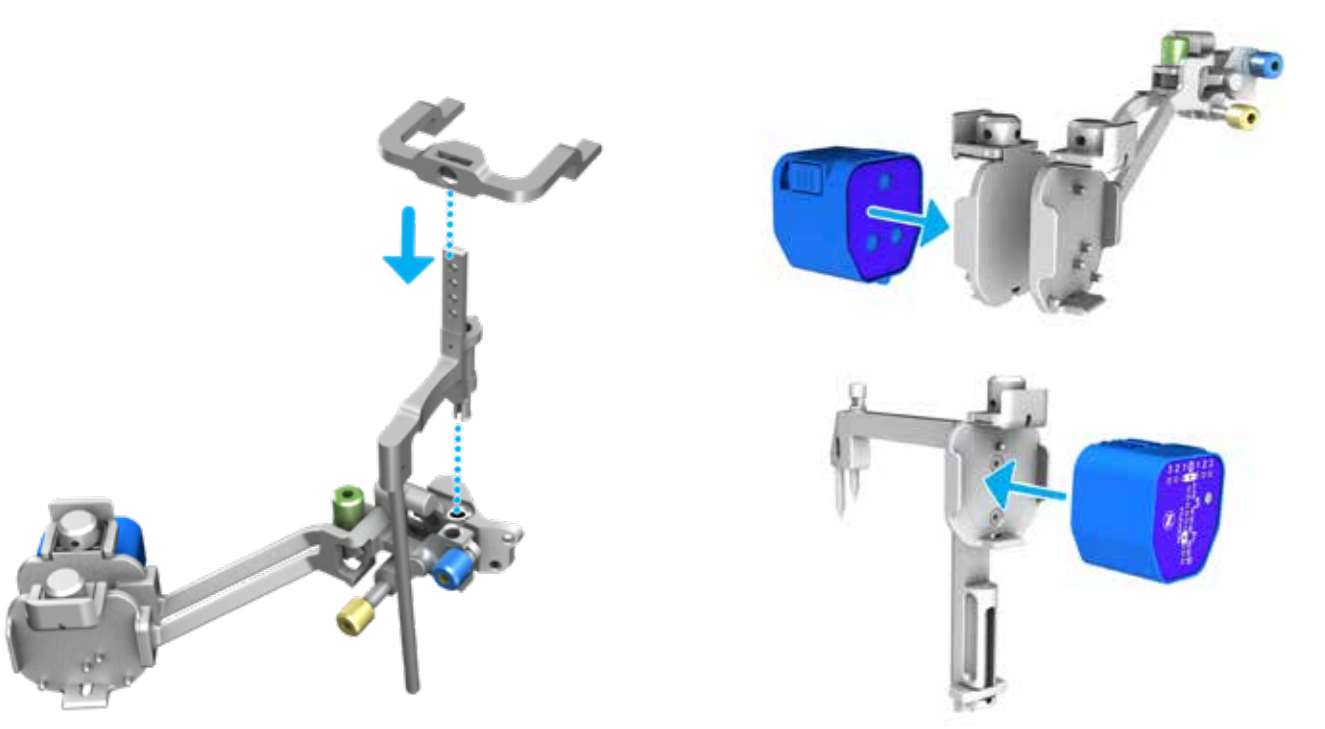


Figure 26
Tibial V1 Aligner Technique - Instrument Assembly

Tibial V1 Aligner Technique

The following section describes an alternate technique for positioning the tibial adjustment mechanism on the tibia using the tibial aligner rather than the Tibial Positioner.

⚠ **Warning**: After wrapping/preparing the ankle, the surgeon should still be able to palpate the malleoli.

Instruments Assembly

1. **For a left knee** procedure, clip the reference pod to the back receptacle of the left tibial adjustment mechanism.
   For a right knee procedure, clip the reference pod to the back receptable of the right tibial adjustment mechanism.
2. Clip the cut guide pod to the tibial alignment guide.
3. Assemble the tibial aligner by aligning the markings of the tibial aligner upper assemblyy and the tibial aligner lower assembly.

   Note: If desired, the tibial aligner can be used without the upper assembly.
4. Connect the tibial aligner to the tibial adjustment mechanism.

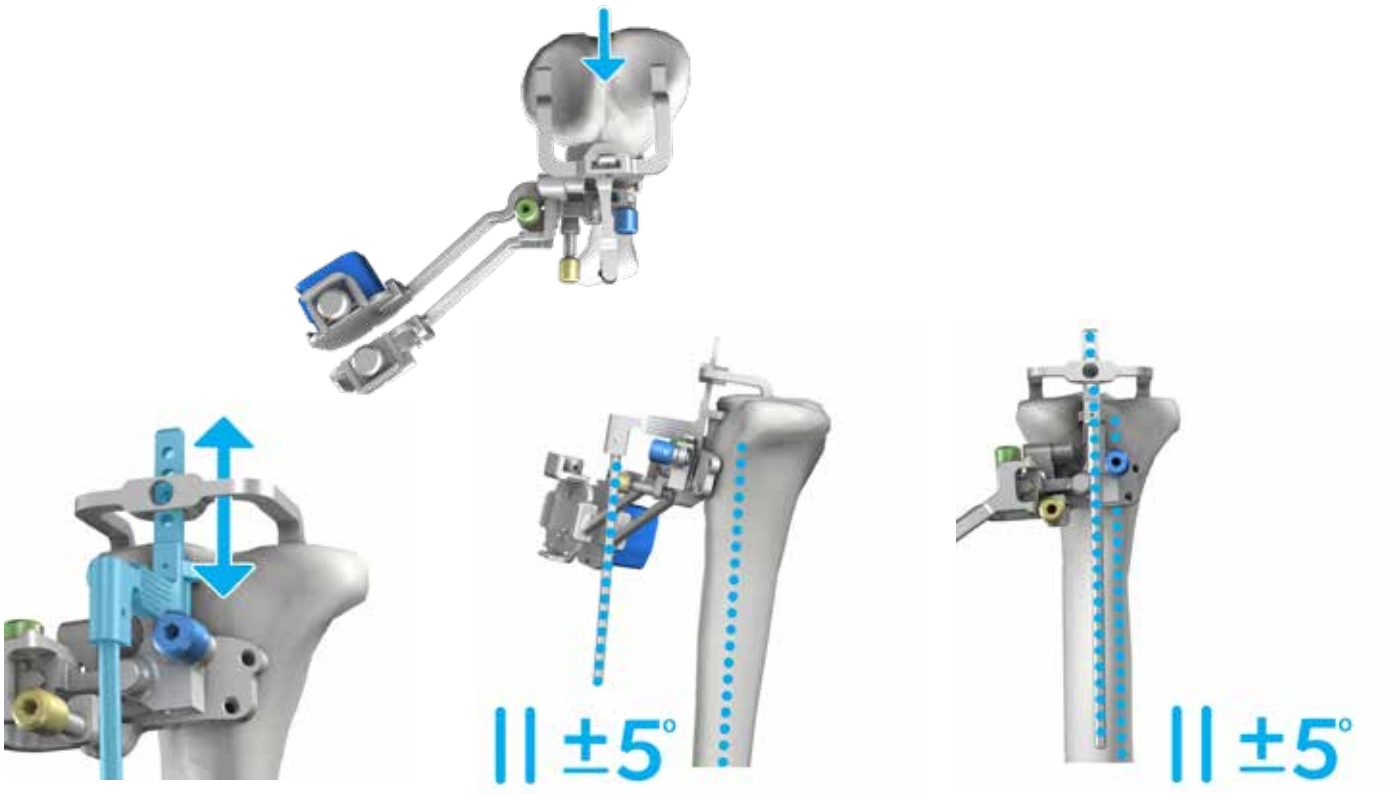


Figure 27a
Tibial V1 Aligner Technique - Tibial V1 Workflow Selection

Tibial V1 Workflow Selection

1. Place the pegs of the tibial aligner on the proximal tibial plateau and sit the tibial adjustment mechanism on the anterior cortex of the tibia.
2. Preset the height of the tibial adjustment mechanism by moving the lower part of the Tibial Aligner up or down.

   Note: Each position represents 6 mm increments.
3. Position the tibial adjustment mechanism so that the concave shape at the rear of the instrument hugs the convex ridge of the tibial tubercle. Ensure the position is low enough for the tibial cut guide to attain the desired level of resection.

   Note: As the tubercle may be obscured by the tibial adjustment mechanism, the medial third of the tubercle can be marked with a surgical marking pen in order to ease the rotational alignment of the tibial alignment guide later on.
4. Visually align the tibial adjustment mechanism in varus/valgus and in tibia slope by aligning the rod of the tibial aligner parallel to the tibial mechanical axis in both the frontal and sagittal planes.

Note: The rod of the tibial aligner has a built-in slope of 5 degrees.

Warning: Ensure that the tibial adjustment mechanism is positioned within the specified ranges. Not doing so may result in potential interference between the screws and the spikes of the tibial alignment guide when the spikes of the latter instrument are impacted into the tibia.

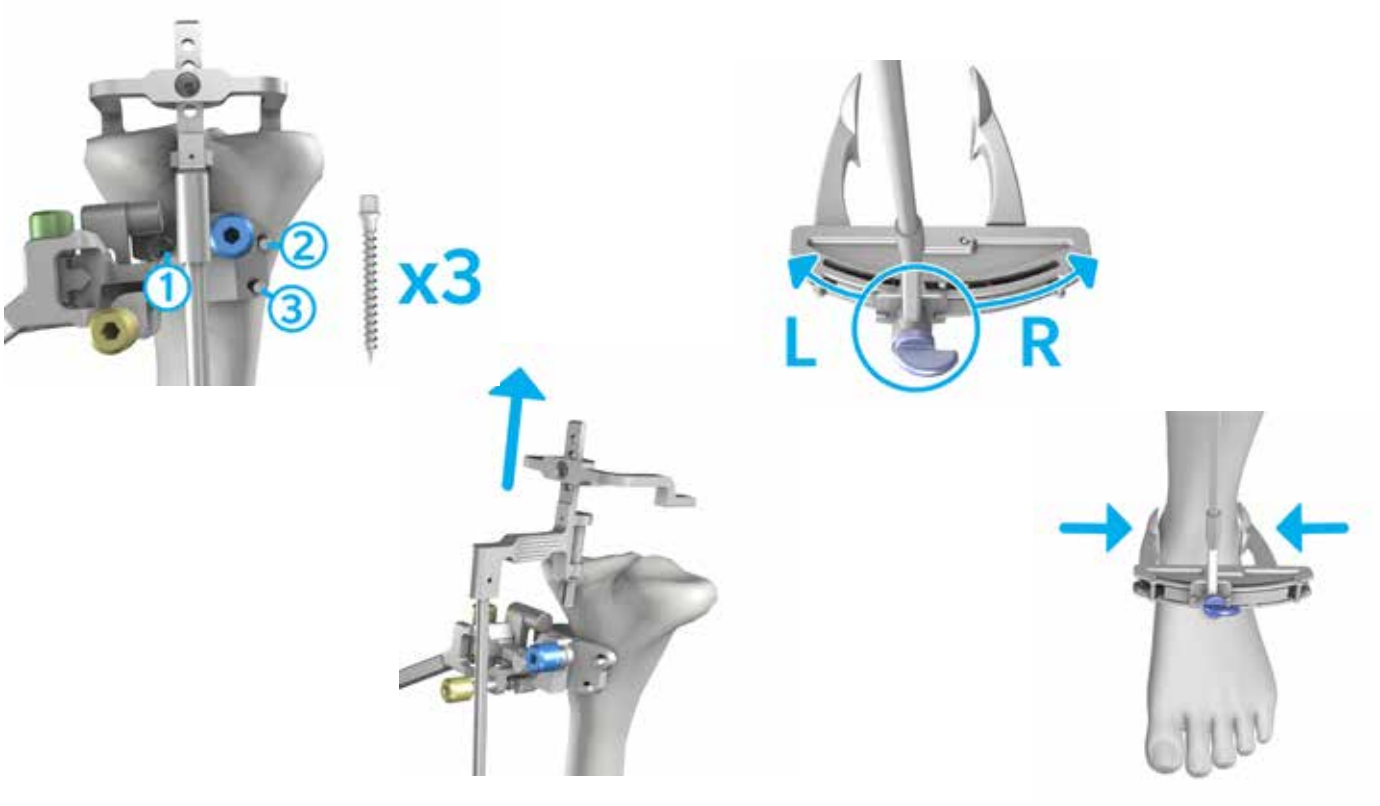


Figure 27b
Tibial V1 Aligner Technique - Tibial V1 Workflow Selection (Continued)

Tibial V1 Workflow Selection (Continued)

5. Use three 3.5 x 38 mm hex head screw to secure the tibial adjustment mechanism to the bone, by first securing screws in the medial hole, secondly in the upper lateral hole and finally in the lower lateral hole.

   ⚠ **Warning**: Control the speed of the power tool or finish fixating the screws manually to avoid stripping the cortex of the tibia. As provided by Zimmer Biomet, the 500 RPM adaptor of the Zimmer Universal Power System Surgical Instruments can be used to secure screws. From registration to validation, the instruments must remain stable and properly fixated to the bone to ensure accuracy of the system.

6. Disconnect the tibial aligner by grasping the instrument by the grip and pulling it up and away from the tibial adjustment mechanism.

7. Loosen the blue knob on the distal part of the tibial alignment guide.

8. Position the rod of the tibial alignment guide to an initial starting orientation per the preset position (L or R) on the distal part of the Tibial Alignment Guide.

   For a left knee procedure, the preset position is L.
   For a right knee procedure, the preset position

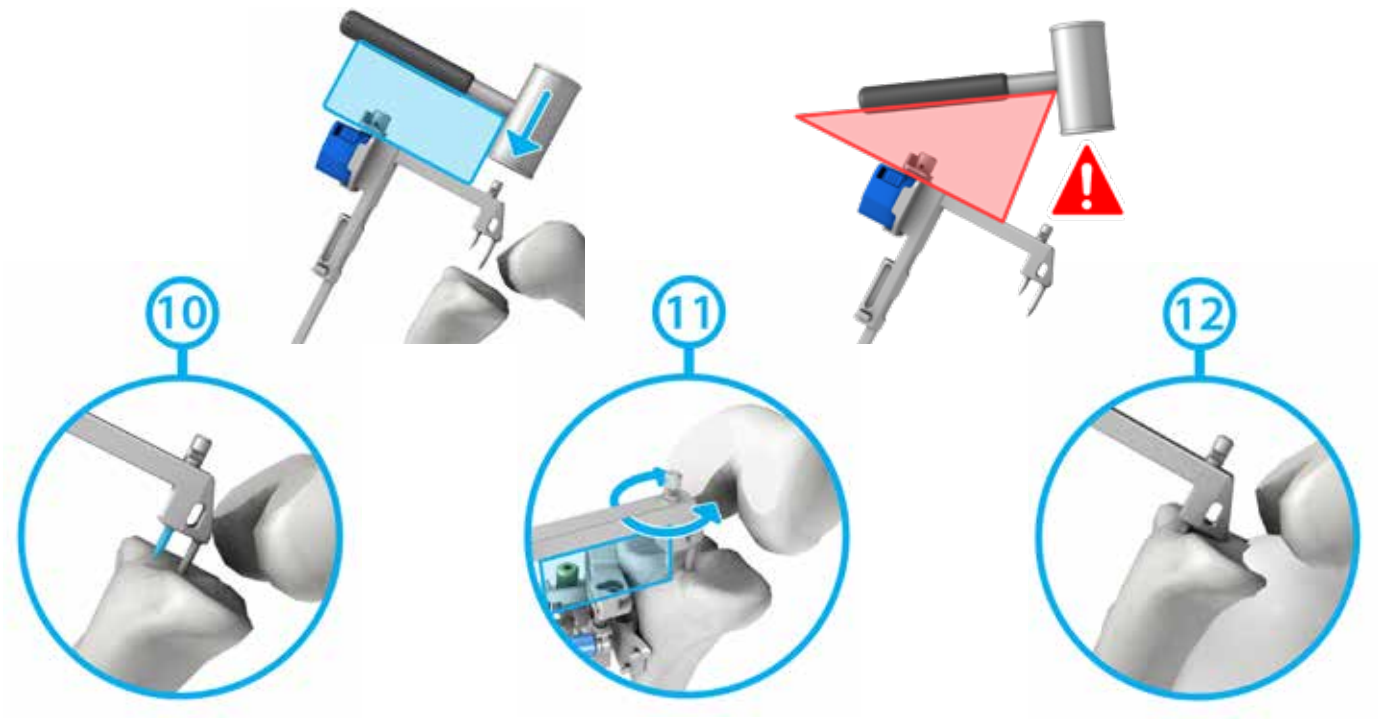


Figure 27c
Tibial V1 Aligner Technique - Tibial V1 Workflow Selection (Continued)

is R.

Tibial V1 Workflow Selection (Continued)

9. Install the distal part of the tibial alignment guideon the ankle by firmly gripping the distal clamps around the malleoli until both spikes are fully inserted into the tibia.

   Note: The tibial alignment guide is designed to be self-centered when placed around the malleoli.

10. While continuing to firmly grip the distal clamps around the malleoli, partially insert (2-3 mm) the longer spike of the proximal part of the tibial alignment guide through the mechanical axis entry point, without engaging the shorter spike.

11. While continuing to firmly grip the distal clamps around the malleoli, set rotation using the tibial alignment guide. Orient the instrument shaft to align with the medial third of the tubercle.

    Note: If the medial third of the tubercle was previously marked with a surgical marking pen, the instrument shaft can be aligned with this reference.

12. While continuing to firmly grip the distal clamps around the malleoli, impact the instrument until both spikes are fully inserted in the tibia.

    Warning: Impact the tibial alignment guide in-line with the spikes of the instrument. Off-axis impaction may result in bending of the spikes. The two spikes of the tibial alignment guide

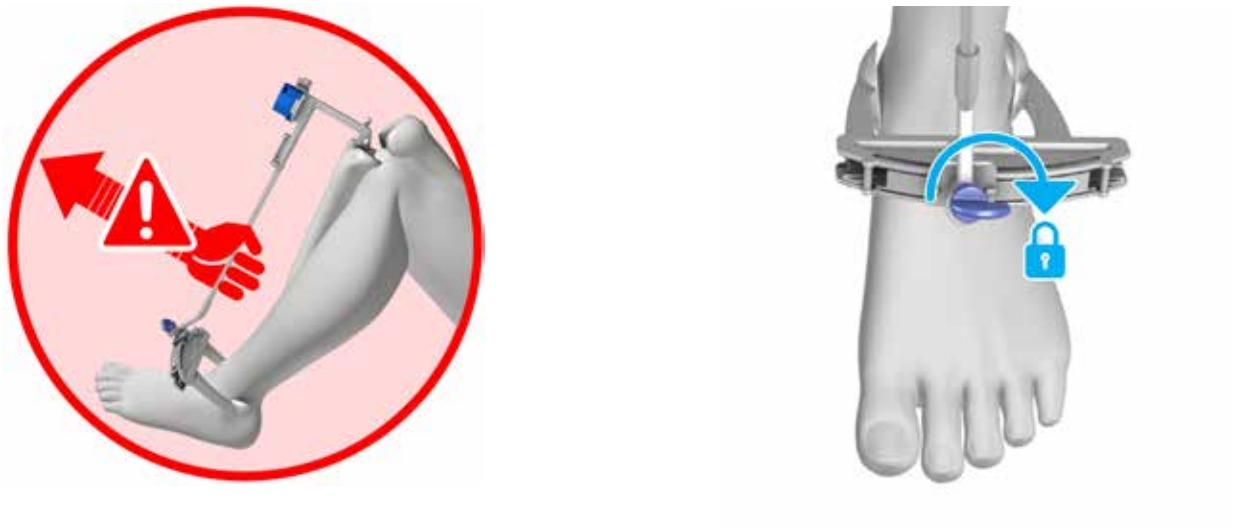


Figure 27d
Tibial V1 Aligner Technique - Tibial V1 Workflow Selection (Continued)

must be positioned and inserted carefully in order to avoid loosening.

Tibial V1 Workflow Selection (Continued)

13. Ensure the distal clamps of the tibial alignment guide remain securely positioned on the malleoli. If an adjustment is necessary, ensure the shaft of the guide remains immobile and in proper alignment. Adjust by rotating the distal part of the guide and resecure the clamps around the malleoli.

    ⚠ **Warning**: Do not pull on the distal part of the tibial alignment guide once both spikes have been inserted into the tibia. Doing so may result in bending of the spikes.

14. Lock the blue knob on the distal tibial alignment guide.

15. Press the "Z" button on the pod attached to the tibial alignment guide to initiate the registration procedure.

16. To complete the procedure, resume from step 1 of the "Tibia Registration" section.

Figure 28
Bilateral Procedure

Surgical Technique for Bilateral Procedure

Note: The same iASSIST Knee V2 Pod Kit can be used only if the application was not closed. Intraoperative calibration does not have to be repeated if the same iASSIST Knee V2 Pod Kit is used.

To perform a bilateral procedure, perform the following steps:

1. Once the cut and the validation have been performed on the first knee (distal femur and proximal tibia), unclip the pods from the instruments to preserve battery life.

2. When ready to perform the second knee, press on the "Settings" button located at the bottom of the iASSIST V2 Tablet screen.

   Warning: Always ensure that an additional iASSIST Knee V2 Pod Kit is available since battery life could be insufficient for a bilateral procedure. In this case follow the pod replacement procedure detailed in the "Pod Replacement" section. Do not reuse the 3.2 mm headless trocar drill pins and the 3.5 x 38 mm hex head screw. Use four new 3.2 mm headless trocar drill pins and four new 3.5 x 38 mm hex head screw for the second leg since they are single-use.

3. Select the patient side by clicking on the "L" icon for the left knee or the "R" icon for the right knee.

4. Confirm by clicking the "Save" button.

5. Assemble the instruments and the pods as described in the "Instrument Assembly" section.

6. Proceed with the femoral or tibial registration.

   Note: It is possible to get detailed instructions on the bilateral procedure by clicking on the "Stop" button and then clicking on the "Workflow" button.

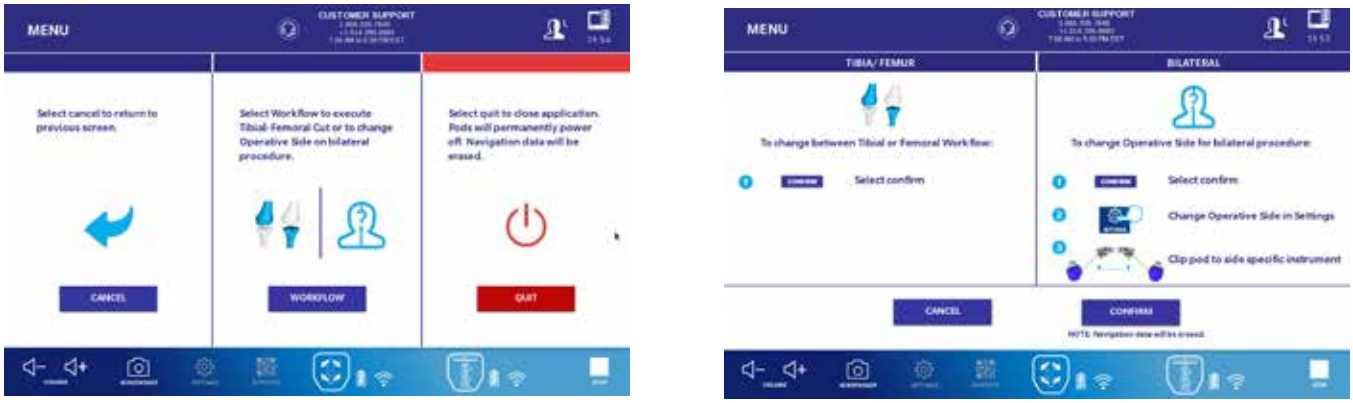


Figure 29
Stop Panel

Surgical Transition (Stop Button)

To stop and exit the application at the end of the surgery, click on the "Stop" button on the bottom right side of the iASSIST V2 Tablet screen. The "Menu" panel will then be displayed with three different options.

Cancel

If the "Stop" button was clicked accidentally, it is possible to go back to the previous panel by clicking the "Cancel" button on the left of the screen.

Workflow Selection

To change operative side on a bilateral procedure or to change between tibial or femoral procedures, click on the "Worklow" button. A new panel will then open with the appropriate instructions.

Quit the Application

To quit the application, click on the red "Quit" button on the right side of the screen.

⚠ **Warning**: The application must be restarted between two surgeries and a new pod kit has to be used.

Pod Replacement (Sterility Compromised - Faulty Pod)

In the case a pod drains its battery before the end of a surgical procedure or if a pod gets contaminated, or malfunctions, it can be replaced by another one without restarting the application following these instructions:

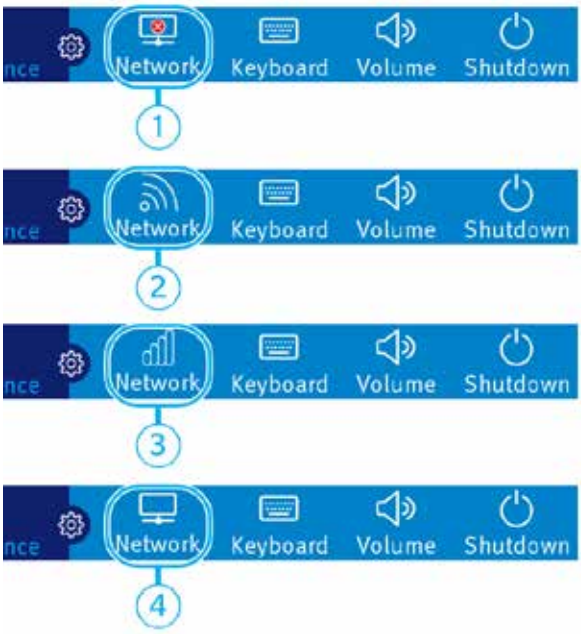
1. Open another iASSIST Knee 2-Pod Kit.
2. Press on the barcode button.
3. Scan the 2D barcode located on the iASSIST Knee Pod Kit.
4. Power-on each of the new pods.
5. Once all the pods have joined the network, perform the intraoperative calibration as described in the "Powering-On Pods and Intraoperative Calibration" section.
6. Once the new pod kit is calibrated, discard the kit with the drained or contaminated pods. If the drained or contaminated pod kit were on instruments, ensure to replace both pods with the respective newly calibrated pods (for example, if a reference pod attached to the validation tool has drained its battery, remove the pod from the validation tool and attach the newly calibrated reference pod to the validation tool).
7. Continue the surgical procedure where it was stopped to replace the pod.

Language Change

It is possible to change the display language of the iASSIST clinical application to the following languages: English, French, German, Dutch, Greek, Italian and Spanish. To change the language, press the “Settings” button on the bottom bar and then use the left and right arrows to select your preferred language option. Press the “Save” button to confirm the change. The language of the tablet changes upon confirmation. If the application is relaunched, its language will be the last selected language option.

Postoperative Guide

All the operations described in this section must be performed from the tablet's home screen.



1) **The iASSIST V2 Tablet is not connected to the Internet or the Internet is deactivated**

2) **The iASSIST V2 Tablet is trying to connect to the Wi-Fi**

3) **The iASSIST V2 Tablet is connected to the Internet via Wi-Fi**

4) **The iASSIST V2 Tablet is connected to the Internet via Ethernet cable**

Figure 30
Internet Connection

Connecting to the Internet

Although it is not necessary to perform an iASSIST Knee case, the iASSIST V2 Tablet can be connected to the Internet either by Ethernet cable or by Wi-Fi. This connection can be used, for example, to download system upgrades.

Note: The Internet connection will be deactivated while the iASSIST Application is open.

Connection by Ethernet Cable

1. Open the hatch on the left side of the iASSIST V2 Tablet (See Figure 2) to connect the Ethernet adapter (which is included in the iASSIST V2 Tablet Shipping Case) to one of the two USB slots.
2. Connect the Ethernet adapter to the tablet and to the local Ethernet cable.

Connection by Wi-Fi

In order to connect the system via Wi-Fi:

1. From the home menu, ensure the Wi-Fi is activated on the tablet (see Figure 30 for explanations on the network status). If not, press on the "P2" button on the top left side of the iASSIST V2 Tablet.
2. Click on the "Network" button.
3. Select an available network. If needed, enter appropriate credentials for the chosen network, then click on the "Connect" button.

Warning: It is strongly recommended to protect against malicious unauthorized use by ensuring that the iASSIST V2 Tablet is never left unattended while powered on. Only Zimmer Biomet Representatives are authorized to update the system with approved software. Zimmer Biomet takes no responsibility for malicious activity that may result from lack of current, appropriate IT security practices.

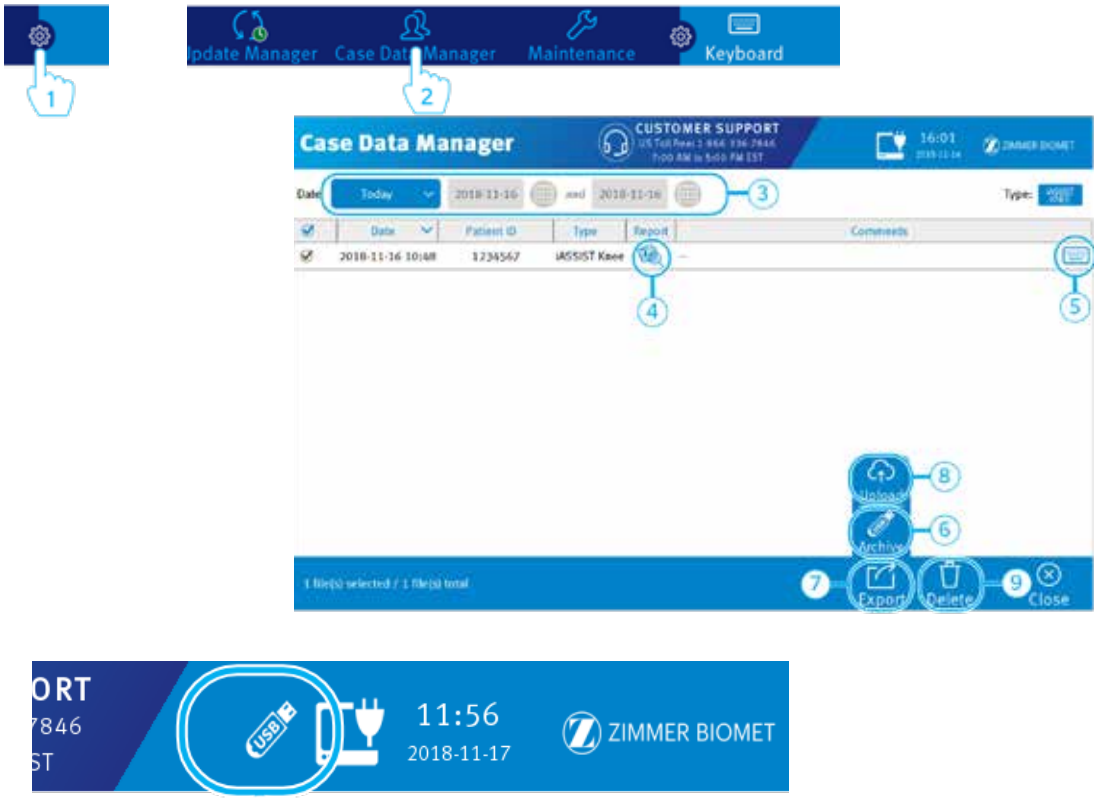


Figure 31a
Case Data Manager

Case Data Manager

The "Case Data" manager is used to store, access, archive and upload surgery related information on cases treated with the system.

Starting the Case Data Manager

1. After turning on the system, click the "Gear" icon (1) on the left bottom of the screen to open the "System Utilities" menu.

2. Click on the "Case Data Manager" icon (2). Enter the "Case Data Manager" password.

Navigating the Case Data Manager

Displayed cases can be sorted by date, patient ID or case selection by clicking the appropriate header. Cases can be filtered by date using the date selection (3). Surgical information about a case can be displayed by clicking the "Report" icon (4). The "Type" selector enables to display the cases performed with the iASSIST Knee Application.

Comments can be entered about a case by clicking the "Keyboard" icon (5).

Archiving cases on a USB key

Note: Two options are available for cases exportation: one for exporting all the surgery logs (for reporting problems and customer service) and another one for exporting only the surgery report (for surgeons).

To archive a case on a USB key:

1. Ensure that a USB key is connected to the iASSIST V2 Tablet and that its icon is displayed on the top right corner of the computer screen. To connect a USB key, open the hatch on the left side of the tablet (See Figure 2) to connect it to one of the two USB slots.

2. Select the cases to archive by clicking their checkboxes.

3. Click the "Export" icon (7). Click the "Archive" icon for surgery logs exportation. Click the "Report" icon for surgery report exportation.

Warning: Exporting the surgery report means exporting Personally Identifiable Data.

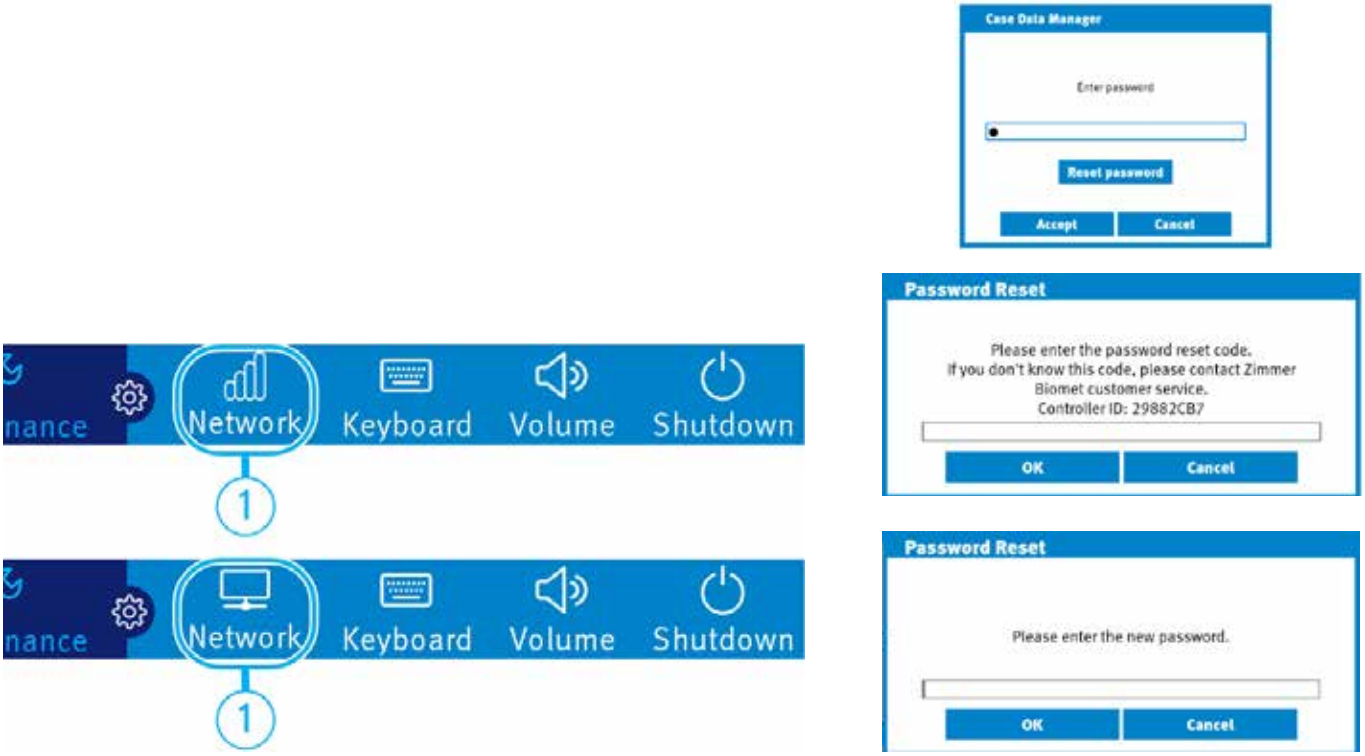


Figure 31b
Case Data Manager (Continued)

Case Data Manager (continued)

Uploading Cases on the Zimmer Biomet Case Database

To upload cases on the Zimmer Biomet Case Database, when reporting an incident or to collect information related to a PER when filing a complaint:

1. Ensure that the system has an active Internet connection.
2. Select the cases to upload by clicking their checkboxes.
3. Click the "Export" icon (7) and then click the "Upload" icon (8). All information relative to the selected cases will be uploaded to the Zimmer Biomet Case Database.

Deleting Cases

To delete cases:

1. Select all cases to delete by clicking their checkboxes.
2. Click the "Delete" icon.

To exit the Case Data manager, click on the "Close" button on the bottom right of the screen.

Changing the Case Data Manager and Maintenance Mode Password

The Case Data Manager and the Maintenance Mode are password protected.

To change the password, press the "Reset Password" button.

Follow the instructions and call the Zimmer Biomet customer service. The Controller ID displayed on the screen window will be used by the customer service to generate a code that will allow to choose a new password.

Figure 32a
Updating the System

Updating the System

System updates must be performed by sales representatives.

Update via Internet Connection

1. Before starting the installation process, ensure that the system has an active Internet connection, and that the system is connected to an AC outlet.

   Note: Public networks using captive portals to enable Internet connection are not supported.

2. Click the "Gear" icon to open the "System Utilities" menu and click the "Update Manager" icon.

Update via USB Key

If no Internet connection is available, contact customer support to obtain a USB key containing the installation files and an installation license key.

1. Before starting the installation process, ensure that the USB key is connected to the system and that its icon is displayed on the top right corner of the computer screen; also ensure that the system is connected to an AC outlet. To connect a USB key, open the hatch on the left side of the iASSIST V2 Tablet (see Figure 2) to connect it to one of the two USB slots.

2. Click the "Gear" icon to open the "System Utilities"menu and click the "Update Manager" icon. Available operating system updates are installed automatically and a reboot might be required to complete the installation. The release reports for available application updates are then displayed for review.

Figure 32b
Updating the System (Continued)

Updating the System (Continued)

3. To update the application, click on "Accept" and enter the installation license key in the dialog box that opens.

   ⚠**Warning**: When prompted to install an application update, it is important to review the associated release report to determine if the changes are understood well enough to continue using the system. If training has not yet been received by all users of the system, it is recommended to decline installation and contact customer support to request training.

   ⚠**Warning**: In rare cases, where the use of the product could have serious negative impacts on the user or patient health and a field action is in effect, application updates will be mandatory and the user will have five days to update the system with this application. After those five days, there will be no possibility to decline. If training has not yet been received by all system users, contact customer support to arrange for training as soon as possible.

Figure 33
Date, Time and Regulatory Region

Date, Time and Regulatory Region

The system is configured for a specific regulatory region. If it changes, the region should be updated through the regulatory region button in the maintenance mode.

It is also possible to change the date and time of the tablet through the maintenance mode button. Contact customer support to obtain the password needed to access the maintenance mode.

Shutdown of the iASSIST V2 Tablet

1. Exit all applications in use, if any.
2. Click on the "Shutdown" button in the bottom right of the home screen or press the "Power" button on the top right hand corner of the iASSIST V2 Tablet.
3. Confirm by clicking the "OK" button.

⚠**Warning**: Do not unplug the power cord from the tablet or try to force close it by long pressing on the power button to initiate a shutdown as it may result in loss of data or cause hardware damage. The proper way to turn off the computer requires exiting all applications in use before initiating the shutdown task.

Equipment Inventory and Cleaning/Sterilization Methods

The "iASSIST Knee Master Instruments Kit" section below lists the instruments supplied by Zimmer CAS and Zimmer Biomet for iASSIST TKA surgeries and describes the sterilization and specific cleaning instructions recommended for each instrument.

Reusable instruments must be cleaned after use prior to sterilization. They should not be sterilized in the protective bag or packaging supplied with them. All sterilizations should be performed using standard and regularly maintained equipment. For cleaning, reusable instruments require a manual or automated process. All multi-component instruments must be disassembled before cleaning.

For general cleaning and sterilization instructions, refer to Surgical Instrument Package insert 803.029 (for US market) or 803.006 (for European market).

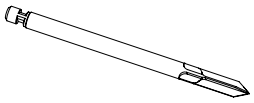
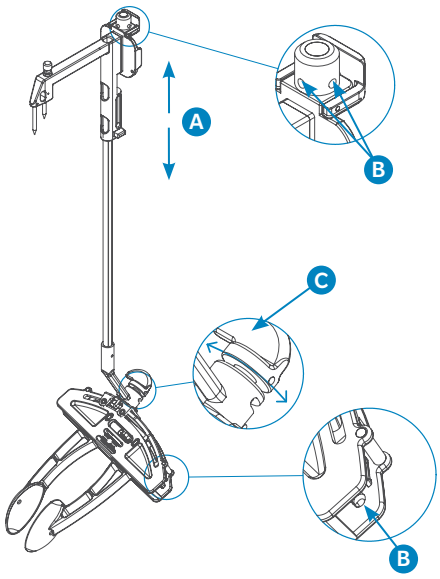
⚠**Warning**: Before every surgery the user must:

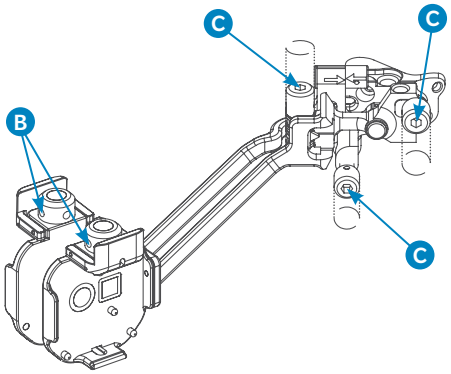
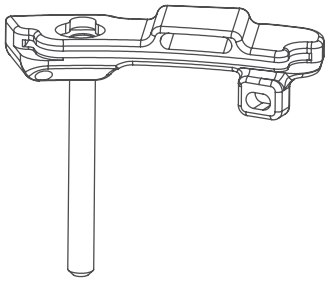
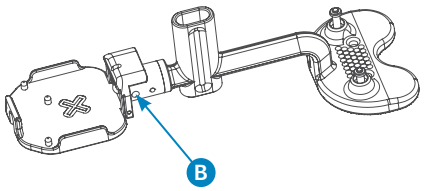
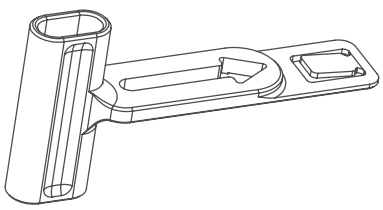
1. Verify that all instruments have been sterilized.
2. Verify that the instruments are in good condition to perform the operation. If any signs of fatigue or deteriorationare noticed, do not use the iAssist Knee System and contact the Zimmer CAS technical support.

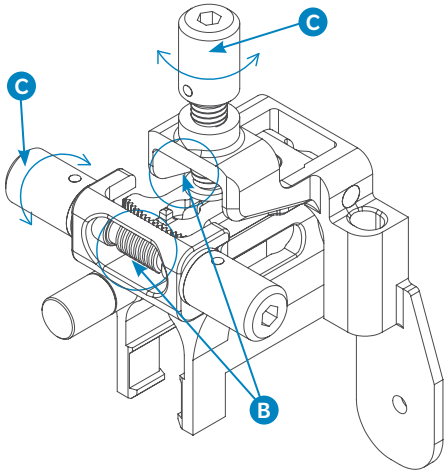
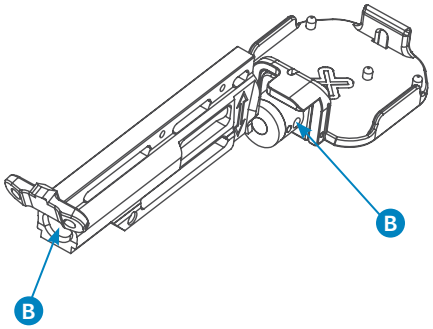
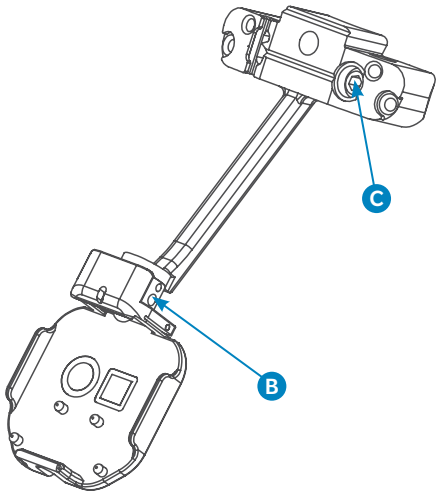
iASSIST Knee Master Instruments Kit

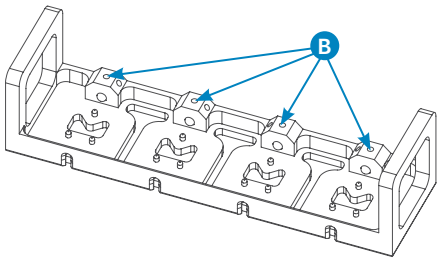
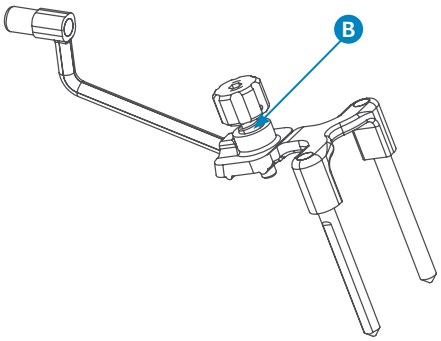
Additional specific cleaning instructions as defined in the text are indicated as applicable to each instrument as follows:

- **A** Requires disassembly
- **B** Requires water jet to flush difficult to access areas
- **C** Screw/unscrew components while flushing the area
- **D** Screw/mechanism should be checked and lubricated with a medical grade surgical lubricant normally after each cleaning as determined upon inspection

Description	Product ID	Qty	Sterilization and Specific Cleaning Instructions	Additional Notes
Femoral Spike 	20-8011-051-00	1	Autoclave	
Tibial Alignment Guide 	20-8011-013-00	1	Autoclave Additional specific cleaning requirements: **A B C D**	

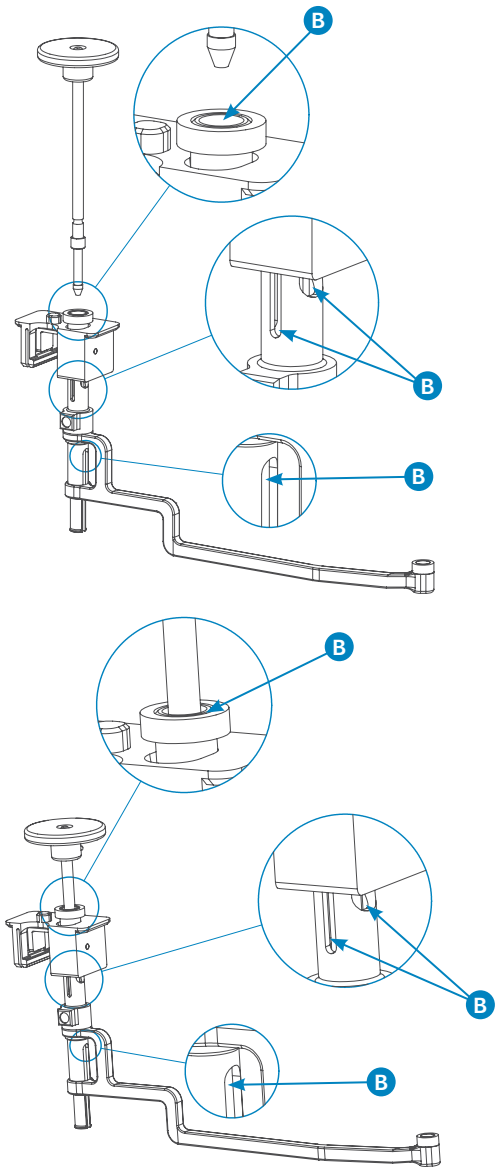
Description	Product ID	Qty	Sterilization and Specific Cleaning Instructions	Additional Notes
Tibial Left Adjustment Mechanism Tibial Right Adjustment Mechanism (Left instrument displayed) 	20-8011-017-00 20-8011-018-00	1	Autoclave Additional specific cleaning requirements: B C D	
Tibial Left Cut Guide Tibial Right Cut Guide (Left instrument displayed) 	20-8011-019-00 20-8011-020-00	1	Autoclave	Cut guides are compatible with saw blades of 1.27 mm (0.05”) thickness
Validation Tool 	20-8011-021-00	1	Autoclave Additional specific cleaning requirements: B	
Alignment Arch 	20-8011-022-00	1	Autoclave	

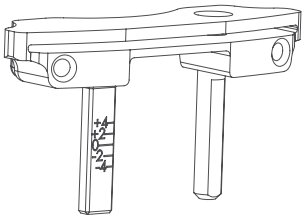
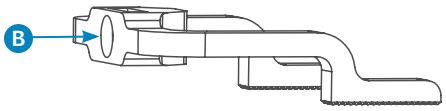
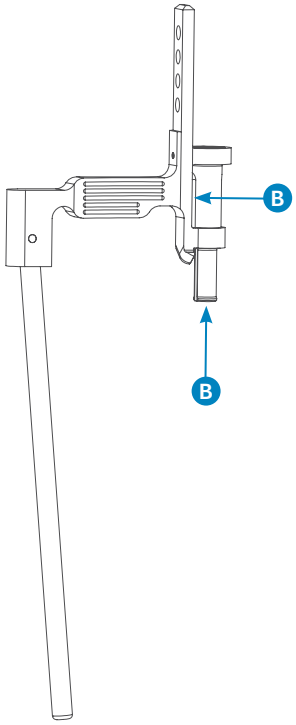
Description	Product ID	Qty	Sterilization and specific cleaning instructions	Additional Notes
Femoral Adjustment Mechanism 	20-8011-025-00	1	Autoclave Additional specific cleaning requirements: B C D	
Femoral Reference 	20-8011-026-00	1	Autoclave Additional specific cleaning requirements: B	
Femoral Distal Cut Guide HBMI Femoral Distal Cut Guide 	20-8011-027-00 20-8011-027-50	1	Autoclave Additional specific cleaning requirements: B C D	

Description	Product ID	Qty	Sterilization and specific cleaning instructions	Additional Notes
Pod Calibration Jig 	20-8011-048-00	1	Autoclave Additional specific cleaning requirements: B	
Femoral A/P Slider HBMI Femoral A/P Slider 	20-8011-028-00 20-8011-028-50	1	Autoclave Additional specific cleaning requirements: B	

Do not apply excessive force to the instruments as this may cause deformation or breakage.

Description	Product ID	Qty	Sterilization and specific cleaning instructions	Additional Notes
Tibial Left Positioner Tibial Right Positioner (Left instrument displayed)	20-8011-040-00 20-8011-041-00	1	Autoclave Additional specific cleaning requirements: B D	



Description	Product ID	Qty	Sterilization and specific cleaning instructions	Additional Notes
Femoral Saw Slot Femoral Saw Slot Vanguard 	20-8011-042-00 20-8011-542-00	1	Autoclave	Saw slot is compatible with saw blades of 1.27 mm (0.05”) thickness
Tibial Aligner - Upper Assembly 	20-8011-056-51	1	Autoclave Additional specific cleaning requirements: B	
Tibial Aligner - Lower Assembly 	20-8011-056-52	1	Autoclave Additional specific cleaning requirements: B	

Description	Product ID	Qty	Sterilization and specific cleaning instructions	Additional Notes
Upper Tibial Reference 	20-8011-509-00	1	Autoclave Additional specific cleaning requirements: B	
Lower Tibial Reference 	20-8011-510-00	1	Autoclave Additional specific cleaning requirements: B C D	
Tibial Adjustment Mechanism 	20-8011-511-00	1	Autoclave Additional specific cleaning requirements: B C D	
Tibial Proximal Cut Guide 	20-8011-513-00	1	Autoclave Additional specific cleaning requirements: B	

Description	Product ID	Qty	Sterilization and specific cleaning instructions	Additional Notes
Left Persona/NexGen Tibial Saw Slot Right Persona/NexGen Tibial Saw Slot (Left instrument displayed 	20-8011-514-00 20-8011-515-00	1	Autoclave	Saw slot is compatible with saw blades of 1.27 mm (0.05”) thickness
Left Vanguard Tibial Saw Slot Right Vanguard Tibial Saw Slot (Left instrument displayed) 	20-8011-516-00 20-8011-517-00	1	Autoclave	Saw slot is compatible with saw blades of 1.37 mm (0.054”) thickness
Left Tibial A/P Slider Right Tibial A/P Slider 	20-8011-520-00 20-8011-521-00	1	Autoclave Additional specific cleaning requirements: B	

The reusable instruments of the iASSIST Knee System shall remain within specifications for a minimum period of 3 years, representing 150 surgeries. To determine whether a reusable instrument has worn to an extent that it is no longer suitable for use, please refer to the Reusable Instrument Lifespan Manual (1219).

Safe Disposal

The instruments and their components are subject to wear and therefore have to be considered as non-durable material. The integrity of the instruments has to be checked before use and if necessary, instruments must be returned to the responsible local representative for repair or disposal.

Disposables

Instrument	Product ID	Qty	Sterilization and specific cleaning instructions	Additional Notes
iASSIST Knee V2 Pod Kit	20-8011-501-00	1	Not Applicable (provided sterile (ETO), do not re-sterilize)	Single use Provided sterile
3.5 x 38mm Hex Head Screw	20-8000-000-18	4	Autoclave for first use	Single use Provided non-sterile
3.2 mm Headless Trocar Drill Pin x 1[(a)]	20-8000-000-16	4	Autoclave for first use	Single use Provided non-sterile
Headless trocar drill pin, 75 mm[(a)] Note: This pin is manufactured by Zimmer (not Zimmer CAS). It should be ordered directly from Zimmer.	00-5901-020-00	4	See package insert for re-sterilization instructions if permissible	Single use Provided sterile
iASSIST Pin and Screw Pack (for Femur & Tibia V1)	20-8000-000-20	1	Not applicable (provided sterile (irradiation), do not re-sterilize)	Single use Provided sterile
iASSIST V2 Pin and Screw Pack (for Femur & Tibia V2)	20-8011-505-00	1	Not applicable (provided sterile (irradiation), do not re-sterilize)	Single use Provided sterile

[(a)] **These pins are equivalent in material and dimensions.**

Do not use pins or any other fasteners than those recommended above.If a bilateral surgery is performed, ensure to user different pins ans screws for each side.

⚠ **Warning**: Verify that the packaging for the instruments that are provided sterile is not damaged. A damaged package may affect the sterility of the instruments. If damage to the sterile packaging is observed, discard the damaged instruments and open another one.

Safe Disposal

After use, all wastes and residues must follow the hospital recycling guidelines. Especially attention must be paid to instruments which could be potential biohazards, since they may be contaminated with blood or other body fluids, bone or other tissue. Handle and dispose this product in accordance with accepted medical practice and with applicable local, state and national laws and regulations.

iASSIST V2 Tablet Kit

Before cleaning the iASSIST V2 Tablet Kit, always unplug and power off the tablet from the AC power outlet to prevent electrical shocks.

Clean the tablet screen only with a soft cloth dampened with 60% or more isopropyl alcohol or 60% or more ethyl alcohol. Wipe the screen and exterior with a soft, damp cloth moistened only with water. Do not use liquid or aerosol cleaners on the screen, as these will discolor the finish and damage the screen.

⚠ **Warning**: Disinfecting computer equipment with sprays is not recommended since the vapor can enter the equipment which may cause electrical short-circuits or corrosion. Never allow water or other liquids to enter the tablet since this may cause subsequent short-circuits or corrosion.

Hardware	Product ID	Qty	Cleaning Instructions
iASSIST V2 Tablet	**20-8011-070-19**	1	See above
iASSIST V2 Tablet Power Supply	**20-8011-070-20**	1	See above
iASSIST V2 Tablet Shipping Case	**20-8011-070-21**	1	See above
iASSIST V2 Tablet Holder	**20-8011-070-23**	1	See above

Software	Product ID
iASSIST V2 Clinical Application	**20-8011-900-13**
iASSIST Operating System 4	**302.4021**

General Equipment Information

Warning: If one of the following situations arises, have the equipment verified by a qualified service personnel:

a. The equipment is not functioning properly;

b. The iASSIST V2 Tablet or the instruments have obvious/visible signs of breakage or fatigue;

c. The iASSIST V2 Tablet or the instruments have been dropped and are damaged;

d. Liquid has entered the tablet;

e. The power cord or plug is damaged; or

f. If the date and time function of the tablet stops functioning properly.

If an instrument marked with the below symbol is dropped, have the instrument verified by a qualified service personnel. 

Note: When these instruments are dropped, their precision may be impaired. The mechanical deformity may be difficult to detect visually.

iASSIST V2 Tablet Kit

The iASSIST V2 Tablet has an internal battery that allows a minimum of 30 minutes of autonomy. This power backup is provided to prevent data loss if there is a main power outage.

If the tablet needs to be shipped with a carrier, place it in the provided iASSIST V2 Tablet Shipping Case. The iASSIST V2 Tablet Shipping Case is specifically designed to withstand carrier shipping conditions.

The expected life of the tablet under normal usage conditions is three years.

iASSIST V2 Tablet Kit (Continued)

⚠**Warning**: Never open the casing of the iASSIST V2 Tablet. The tablet does not contain replaceable parts. For safety reasons, only qualified service personnel should open the equipment.

Protect the iASSIST V2 Tablet from overheating. The openings on the enclosure are for ventilation purpose. Do not block the openings.

Never insert foreign objects in the iASSIST V2 Tablet openings. This may cause electric shock or fire, or it may damage hardware components.

Make sure the computer is properly shutdown before closing the iASSIST V2 Tablet Shipping Case. If not, the system may overheat and be damaged.

The iASSIST V2 Tablet must never be submerged in water or exposed to high level of humidity.

Do not leave the iASSIST V2 Tablet in an uncontrolled environment where the storage temperature is below -10°C (14°F) or above 49°C (120°F), 90% relative humidity, non-condensing. This may damage the equipment.

Make sure that no objects, including wires, are left on the iASSIST V2 Tablet screen when closing the iASSIST V2 Tablet Shipping Case. Any objects on the computer screen may damage it during transportation or storage.

The iASSIST V2 Tablet should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the tablet should be observed to verify normal operation in the configuration in which it will be used.

For safety reasons, the iASSIST V2 Tablet must be send to repair if the battery capacity is significantly reduced.

Because of risks related to lithium battery explosion, the iASSIST V2 Tablet should not be exposed to extreme heat.

Do not use or store the iASSIST V2 Tablet near a source of heat or dust.

Do not use another power supply, or cables other than the ones provided, other than the ones provided as this may negatively affect EMC performances.

Make sure that the power cord provided with the tablet is compatible with your local power requirements.

Do not step on or place anything on the power cord.

To avoid any damages to the power cables, make sure they are not bent at sharp angles.

Never force a cable connection.

Touchscreen Calibration

No calibration is necessary for the iAssist V2 Tablet touch screen.

iASSIST Knee V2 Pod Kit

The pods should be stored at normal ambient temperature (15°C to 30°C, 59°F to 86°F) and shipped within temperatures from –18°C (-0.4°F) up to +49°C (120°F), 80% relative humidity, non-condensing.

The pods are packaged in a custom plastic tray preventing activation prior to use.

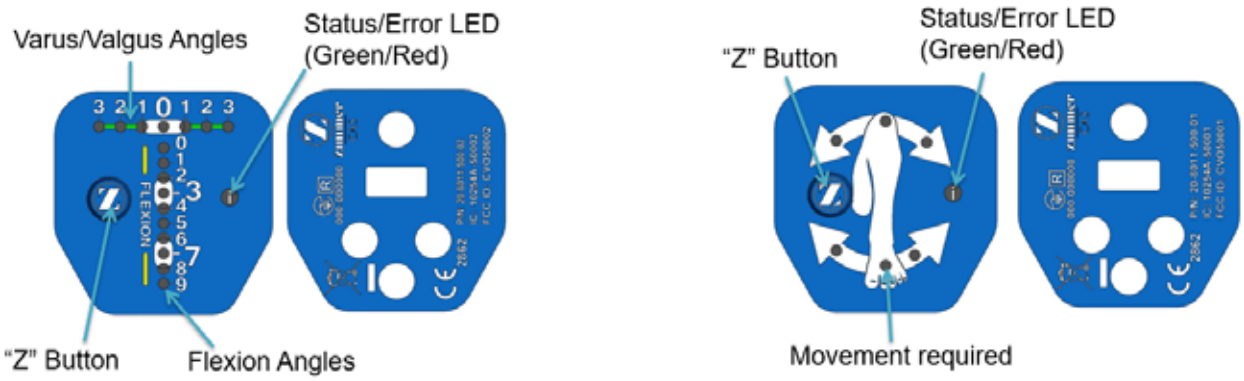
⚠**Warning:** Because of risks related to lithium battery explosion, the pods should not be exposed to extreme heat such as an autoclave.

Care must be taken not to expose the pods to strong impacts. Strong magnetic fields should not approach the pods. This may erroneously trigger switches affecting the surgical flow (accuracy of sensors is not affected).

Functionality and accuracy of the pods may be affected if exposed to X-ray radiation.

Be careful to not expose the pods to water during the procedure. The pods can be wiped with a cloth damped with sterile NaCL 0,9%. Any excess water should be wiped off since it could affect wireless communication.

Colorblind users may rely on the numbers displayed next to navigation numbers. Also, the system controller computer screen displays more details.



Cut Guide Pod (20-8011-500-02)

Reference Pod (20-8011-500-01)

Figure 34
Pods User Interface

Work Around

In some rare condition, it is known that the pods may lose network connection and may not be able to reconnect to the system controller computer. In this case, the user can rescan the barcode, which will reinitialize the RF session allowing lost pods to reconnect the computer.

LED Information

As illustrated in Figure 34, the pods each have an emplacement for the status/error LED and navigation LEDS. The status and error LEDs are at the same location and are distinguished by their color and general meaning (green for the status LED indicating normal functioning of the pods and the system in general and red for the error LED indicating that an action is required from the user in order to proceed with the surgery.

The navigation LEDs display indication on the resection angles during navigation and on the manipulations needed from the user in the actual step.

Specific information on the LEDs' behavior is detailed in the following table.

Status/Error LED	Navigation LEDs	Status	Required Action
Pod Power-Up			
Blinks rapidly (green)	N/A	The pods are trying to join the system network for procedure.	Wait for the blinking to slow down, indicating that the network is up.
Blinks slowly (green)	N/A	The network is up and ready for the procedure.	Proceed with surgery.
Solid red	N/A	Pod has failed self-test.	Open new pod kit.
Calibration			
Blinking green	N/A	The pod needs to be clipped to the calibration jig for intraoperative calibration or intraoperative calibration is over and the pods can be unclipped from the calibration jig to proceed with surgery.	Follow instructions onscreen to clip or unclip pods from the calibration jig.
Solid green	N/A	The pods are adequately clipped to the calibration and ready for the calibration process.	Proceed with surgery.
N/A	Solid green	Indicates the expected calibration jig position for the intraoperative calibration.	Position the calibration jig so that the face marked with that number is directed upward and wait for the acquisition to be completed.
Registration and Validation			
N/A	Blinking green	Manipulations are needed to complete the registration / validation acquisitions.	Use the pattern of the LEDs or the indications onscreen to perform necessary manipulation.
N/A	Steady green	The leg is in the required orientation for the next acquisition.	Stabilize the leg in the actual position until the registration sound is heard and another movement is needed.
Blinking green	N/A	Successful computation after a sequence of acquisitions.	No action needed. Continue with next step of surgery.
Navigation			
N/A	Solid red	Resection angle is not aligned with target.	Use the gold (F/E -Slope) and green (V/V) screws to adjust the resection angles.
N/A	Solid green	Resection angle is aligned with target.	Proceed with surgery.
Anytime during procedure			
Solid red	N/A	System or pod error.	Follow indications on the iASSIST V2 Tablet display in order to resolve the error.
	N/A	End of battery life.	Consider opening a new iASSIST Knee V2 Pod Kit or switching to conventional instrumentation.
Blinking green	N/A	Everything is working as it should.	Proceed with surgery.

Pod Battery Disposal

The pods contain batteries that require safe handling. They may leak if exposed to heat or disposed of improperly. Dispose of the batteries in accordance with applicable federal, state and local regulations as applicable in the United States of America, or equivalently as may be applicable in other countries.

Within the European Union, disposal of small amounts of portable batteries to landfills and incinerations are allowed under the Batteries Directive 2006/66/EC and Member State regulations.

Alternate instructions for safe battery removal to waste disposal is also possible but requires special decontamination steps as follow:

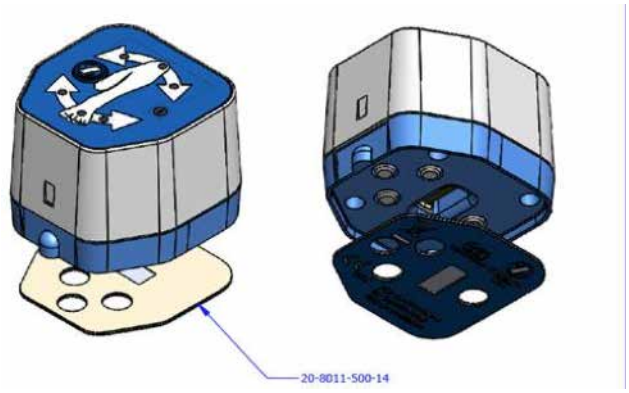
For safe battery removal at the end-of-life by a waste treatment facility, infected units should be decontaminated as per hospital procedure. However, alkaline battery risks (e.g. do not expose to autoclave because of risk of explosion) should be considered before they are sent for recycling. Instructions for decontamination are provided below. If it is not possible to decontaminate the pods before recycling, the hospital should not attempt to remove the batteries from the waste. Disposal of small amounts of portable batteries to landfills and incinerations are allowed under the Batteries Directive 2006/66/EC and Member State regulations.

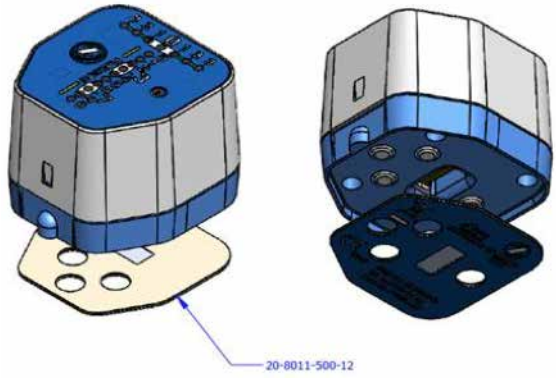
Prior to sending electronic waste for recycling, the pods are required to go through a complete cleaning and disinfection cycle. Before starting the cycle, make sure the pod battery is drained: pods no longer blink. The following steps are recommended:

1. The pod's outer surfaces are wiped down first.
2. Expose the pod to an Ethylene Oxide (ETO) sterilization cycle per the following parameters:
   a. Preconditioning set points:
      - Temperature: 100-125˚F (38-52˚C)
      - Relative humidity: 35-80%
      - Vacuum set point: 2.61 pounds per square inch
      - Preconditioning time: under 60 minutes
   b. Exposure:
      - Temperature: 105-145˚F (41-63˚C)
      - Relative humidity: 30-90%
      - EO gas concentration: 725 mg/L
      - 100% EO gas
      - Gas exposure time: 60 minutes
      - Pressure: 3.8 - 4.8 HgA
   c. Aeration:
      - Aeration time: 8 hours
      - Aeration temperature: 51-59˚C
3. To find the appropriate pod treatment facility, please visit: http://www.weee.zimmer.eu

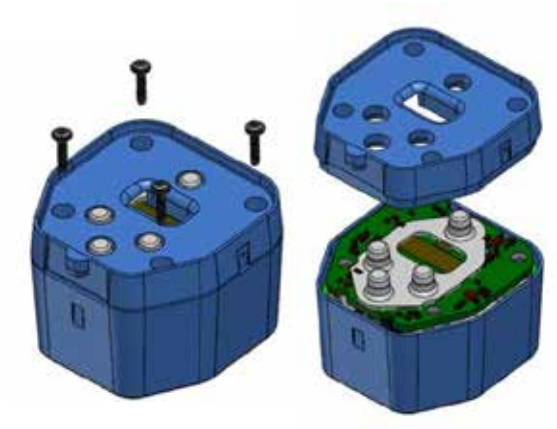
To remove the battery from the Pods, the following steps are recommended:

1. Remove the back sticker from the Pod by inserting any tool with a sharp end between the sticker and the bottom of the Pod.

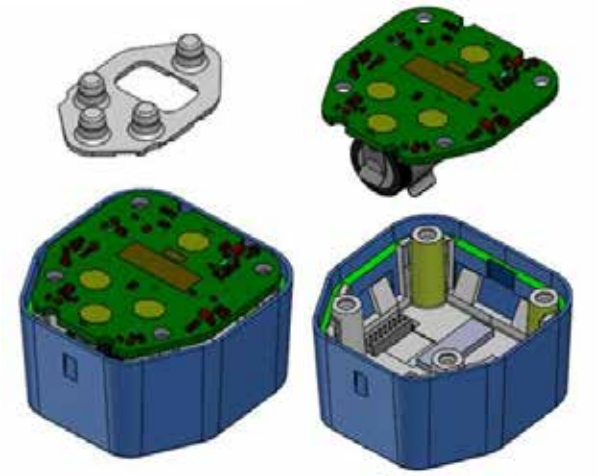




2. Use a torx screwdriver to remove the 4 screws on the bottom of the Pod.
3. Remove the base casing.



4. Remove the grey rubber keypad.
5. Remove the circuit board.



6. Remove the foam and the battery.

Tablet Disposal

The iASSIST V2 Tablet contains a battery that requires safe handling when disposal of the Tablet is necessary. It may leak or explode if exposed to heat or disposed of improperly. Dispose of the Tablet in accordance with applicable federal, state and local regulations as applicable in the United States of America, or equivalently as may be applicable in other countries.

Within the European Union, disposal of small amounts of portable batteries to landfills and incinerations are allowed under the Batteries Directive 2013/66/EC and Member State regulations. The iASSIST V2 Tablet battery must be removed (see Figure 35) before disposal.

As per directive 2012/19/EU on WEEE, the rest of the Tablet (without the battery) must be disposed of following regulations.

To find the appropriate treatment facility, please visit: http://www.weee.zimmer.eu

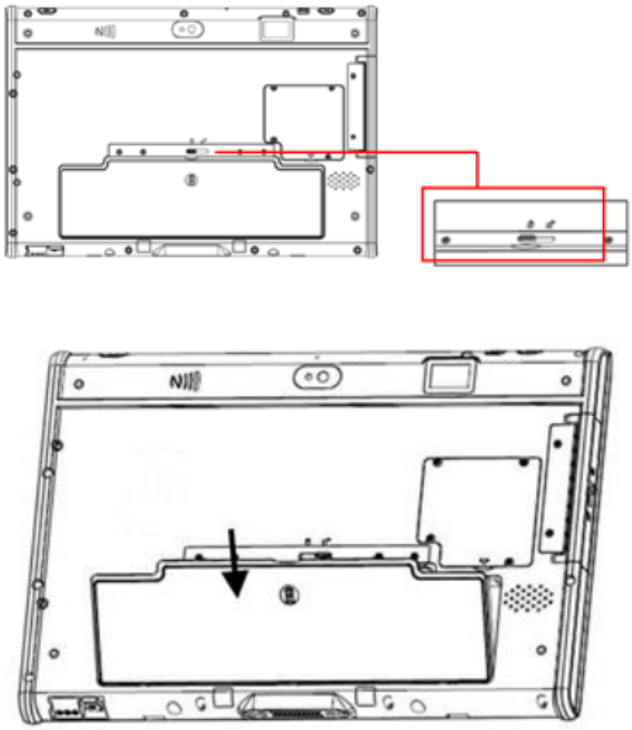


Figure 35
iASSIST V2 Tablet Battery Removal

Product Specifications and Regulatory Notices

Essential Performances for the System

The System is composed of the iASSIST V2 Tablet Kit and the iAssist Knee V2 Pod Kit. The iAssist Pod contains inertial sensors (accelerometers and gydroscopes) and instrument identification switches. The following performances have been identified as essential to the system:

1. iASSIST V2 Tablet display.
2. Communication between the iASSIST V2 Tablet and the Pods contains accurate data. Complete loss of communication is not consireded an essential performance.
3. The accelerometer inclination measurements of the Pods on all axes are stable within ±1.0°.
4. The gyroscope rotation speed measurements of the Pods on all axes are stable within ±1.0°/sec.
5. Pod identification switches report accurate instrument connection.
6. Pod temperature changes are detected at ±1.0°C.

The essential performances 1, 3, 4, 5 and 6 have been tested during electromagnetic immunity tests up to the levels shown in the tables in this section. Loss or degradation of essential performance can result in navigation errors and/or instruments misidentification.

iASSIST V2 Tablet Kit

Specifications

- Weight: About 1.42 kg
- Dimensions: 335 mm x 220 mm x 43 mm (irregular)
- Power: 100-240 VAC, 47-63 Hz, 1.62-0.72 A
- Operating conditions: 15°C (59°F) to 30°C (86°F), 20% to 90% relative humidity, 70 kPa to 106 kPa
- Transport conditions: -10°C (14°F) to 49°C (120°F) at 10 to 90% non-condensing relative humidity
- Storage conditions: -10°C (14°F) to 49°C (120°F) at 10 to 90% non-condensing relative humidity
- User devices: Touch screen, 2D barcode scanner

⚠ **Warning:** The iASSIST V2 Tablet has been tested and is in compliance with the EMC (Electro-Magnetic Compatibility) requirements for emissions. In some situations it is still possible that radiated electromagnetic fields such as those from portable and mobile devices may cause performance degradation. Portable and mobile RF communications equipment can affect the iASSIST Knee System. Turning off 2.4GHz band Radio Frequency (RF) devices around the system (such as Bluetooth, Wi-Fi) can improve communication performance between the pods and the iASSIST V2 Tablet.

Wireless Communications

The iASSIST V2 Tablet (20-8011-070-19) contains IEEE 802.15.4 RF transmitter with the following characteristics:

- Transmission frequency: 2.405 GHz to 2.48 GHz
- Modulation: Offset Quadrature Phase-Shift Keying (OQPSK)
- Coding: Direct Sequence Spread Spectrum (DSSS)
- Transmission bandwidth: 2 MHz
- Effective isotropic radiated power: 4 dBm

The iASSIST V2 Tablet contains IEEE 802.11 RF transmitter with the following characteristics:

- Transmission frequency: 2.4 and 5 GHz
- Network Standard: Compliant with IEEE 802.11a/b/g/n/ac
- Modulation: OFDM with BPSK, QPSK, 16 QAM, 64 QAM;DQPSK, CCK, G-FSK, π/4-DQPSK, 8-DPSK
- Effective isotropic radiated power: 19.06 dBm
- Transmission bandwidth: Depends on network standard

⚠ **Warning:** If the iASSIST V2 Tablet is not used for a long time, ensure the tablet is recharged periodically.

FCC Notice

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna;
- Increase the separation between the equipment and receiver;
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected; and
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Caution: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

IC Statements

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Health Canada RF Exposure Warning Statement

This device complies with Health Canada's Safety Code. The installer of this device should ensure that RF radiation is not emitted in excess of the Health Canada's requirement. Information can be obtained at http:/ www.hc-sc.gc.ca/ewh-semt/pubs/radiation/radio_guide-lignes_direct/index-eng.php

Guidance and Manufacturer's Declaration

In order for the Tablet to attain its expected service life of three years, it must not be subjected to levels of electromagnetic disturbance higher than those specified in Tables 3,4, 5 and 6. Failure to respect those levels may lead to a degradation of the system's basic safety and essential performances.

Table 3: Guidance and Manufacturer's Declaration - ELECTROMAGNETIC EMISSIONS

The iASSIST V2 Tablet is intended for use in the electromagnetic environment specified below. The customer or the user of the iASSIST V2 Tablet should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The iASSIST Tablet uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment. Caution: This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.
Harmonic emissions IEC 61000-3-2	Class D	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
Conducted RF emissions CISPR 11	Complies	

Table 4: Guidance and Manufacturer's Declaration - ELECTROMAGNETIC IMMUNITY

The iASSIST V2 Tablet is intended for use in the electromagnetic environment specified below. The customer or the user of the iASSIST V2 Tablet should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 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 input power port (a.c. and d.c) 100 kHz repetition frequency ± 1 kV for signal input/output parts 100 kHz repetition frequency	± 2 kV for input power port (a.c. and d.c) 100 kHz repetition frequency ± 1 kV for signal input/output parts 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV line-to line for input power port (a.c. and d.c.) ± 0.5 kV , ± 1 kV , ± 2 kV line-to-ground for input power port (a.c. and d.c.) ± 2 kV line-to-ground for signal input/output parts	± 0.5 kV, ± 1 kV line-to line for input power port (a.c. and d.c.) ± 0.5 kV , ± 1 kV , ± 2 kV line-to-ground for input power port (a.c. and d.c.) ± 2 kV line-to-ground for signal input/output parts	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 % U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° ans 315° 0% U_T ; 1 cycle 70 % U_T ; 25/30 cycles 0% U_T; 250/300 cycles Single phase: at 0°	0 % U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° ans 315° 0% U_T ; 1 cycle 70 % U_T ; 25/30 cycles 0% U_T; 250/300 cycles Single phase: at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the iASSIST Tablet requires continued operation during power mains interruptions, it is recommended that the iASSIST Tablet be powered from an uninterruptible power supply or a battery.

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.
Proximity magnetic fields	30 kHz, CW, 8A/m 134.2 kHz, Pulse mod 2.1 kHz, 65A/m 13.56 MHz, Pulse mod 50 kHz, 7.5A/m	30 kHz, CW, 8A/m 134.2 kHz, Pulse mod 2.1 kHz, 65A/m 13.56 MHz, Pulse mod 50 kHz, 7.5A/m	

NOTE: UT is the AC mains voltage prior to application of the test level.

Table 5: Guidance and Manufacturer's Declaration - ELECTROMAGNETIC IMMUNITY

The iASSIST V2 Tablet is intended for use in the electromagnetic environment specified below. The customer or the user of the iASSIST V2 Tablet should assure that it is used in such an environment			
IMMUNITY test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 0.15 MHz - 80 MHz 6 VRMS in ISM bands between 0.15 mHz and 80 Mhz 80% AM at 1 kH	Not applicable	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz - 2,7 GHz 80% AM at 1 kHz	3 V/m 80 MHz - 2,7 GHz 80% AM at 1 kHz	d=1.2 √P 80 to 800 MHz d=2.3 √P 800 MHz to 2.5 GHz
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See Table 6	See Table 6	

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be user no closer than 30 cm (12 inches) to any part of the iASSIST V2 Tablet, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Table 6: Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The iASSIST V2 Tablet is intended for use in the electromagnetic environment specified below. The customer or the user of the iASSIST V2 Tablet should assure that it is used in such an environment.				
Immunity test	**Test Frequency**	**Modulation**	**IEC 60601 test level**	**Compliance level**
Proximity field from RF wireless communication equipment IEC 61000-4-3	385 MHz	Pulse Modulation : 18 Hz	27 V/m	27 V/m
	450 MHz	☐ FM ± 5 Hz deviation: 1kHz sine ☒ Pulse Modulation : 18Hz	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	Pulse Modulation : 217Hz	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	Pulse Modulation : 18 Hz	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	Pulse Modulation : 217 Hz	28 V/m	28 V/m
	2450 MHz	Pulse Modulation : 217 Hz	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	Pulse Modulation : 217 Hz	9 V/m	9 V/m

iASSIST Knee V2 Pod Kit

Specifications

- Weight: 38 g
- Size: 42 mm x 40 mm x 30 mm
- Operating conditions:15°C to 30°C, 20% to 90% relative humidity, 70 kPa to 106 kPa
- Storage conditions: 15°C to 30°C
- Transport conditions: -18°C to +49°C, 80% relative humidity, non-condensing
- Battery duration: Approximately 2 hours
- Other: Single use, disposable.

The pods are rated IP21 according to the IEC 60529 standard for degree of protection provided by enclosure. External surfaces of the pods have been tested as applied parts type BF per IEC 60601- 1 ed 3.1.

Wireless Communications

The pods contain IEEE 802.15.4 RF transmitters with the following characteristics:

- Transmission frequency: 2.405 GHz to 2.48 GHz
- Modulation: Offset Quadrature Phase-Shift Keying (OQPSK)
- Coding: Direct Sequence Spread Spectrum (DSSS)
- Transmission bandwidth: 2 MHz
- Effective isotropic radiated power: 0 dBm

⚠ **Warning:** The pods have been tested and are in compliance with the EMC (Electro-Magnetic Compatibility) requirements for emissions. In some situations it is still possible that radiated electromagnetic fields such as those from portable and mobile devices may cause performance degradation. Portable and mobile RF communications equipment can affect the iASSIST Knee System. Turning off 2.4GHz band Radio Frequency (RF) devices around the system (such as Bluetooth, Wi-Fi) can improve communication performance between the pods and the iASSIST Tablet.

FCC Notice

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna;
- Increase the separation between the equipment and receiver;
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected; and
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Caution: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

IC Statements

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Health Canada RF Exposure Warning Statement

This device complies with Health Canada's Safety Code. The installer of this device should ensure that RF radiation is not emitted in excess of the Health Canada's requirement. Information can be obtained at http:/ www.hc-sc.gc.ca/ewh-semt/pubs/radiation/radio_guide-lignes_direct/index-eng.php

Guidance and Manufacturer's Declarations

In order for the Pod to attain its expected service life of three years, it must not be subjected to levels of electromagnetic disturbance higher than those specified in Tables 7,8, 9 and 10. Failure to respect those levels may lead to a degradation of the system's basic safety and essential performances.

Table 7: Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The pods are intended for use in the electromagnetic environment specified below. The customer or the user of the pods should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The pods use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment. **Caution**: This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 8: Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The pods are intended for use in the electromagnetic environment specified below. The customer or the user of the pods should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 2 kV, ± 4 kV, ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 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 input power port (AC and DC) 100 kHz repetition frequency ± 1 kV for signal input/output parts 100 kHz repetition frequency	Not applicable	Not applicable
Surge IEC 61000-4-5	± 0,5 kV, ± 1 kV line-to-line for input power port (AC and DC) ± 0,5 kV, ± 1 kV, ± 2 kV line-to-ground for input power port (AC and DC) ± 2 kV line-to-ground for signal input/output parts	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°	Not applicable	Not applicable
Voltage interruptions on power supply lines IEC 61000-4-11	0 % U_T; 250/300 cycles	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz and 60 Hz (because it is battery powered)	30 A/m 50 Hz and 60 Hz (because it is battery powered)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the AC mains voltage prior to application of the test level.

Table 9: Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The pods are intended for use in the electromagnetic environment specified below. The customer or the user of the pods should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 VRMS 0,15 MHz – 80 MHz 6 VRMS in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Not applicable	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 6 GHz 80 % AM at 1 kHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See Table 10	See Table 10	
Proximity magnetic fields	30 kHz, CW, 8A/m 134.2 kHz, Pulse mod 2.1 kHz, 65A/m 13.56 MHz, Pulse mod 50 kHz, 7.5A/m	30 kHz, CW, 8A/m 134.2 kHz, Pulse mod 2.1 kHz, 65A/m 13.56 MHz, Pulse mod 50 kHz, 7.5A/m	

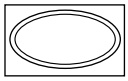
WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the iASSIST Pod, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment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

Table 10: Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The pods are intended for use in the electromagnetic environment specified below. The customer or the user of the pods should assure that it is used in such an environment.				
Immunity test	**Test Frequency**	**Modulation**	**IEC 60601 test level**	**Compliance level**
Proximity field from RF wireless communication equipment IEC 61000-4-3	385 MHz	Pulse Modulation : 18 Hz	27 V/m	27 V/m
	450 MHz	☐ FM ± 5 Hz deviation: 1kHz sine ☒ Pulse Modulation : 18Hz	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	Pulse Modulation : 217Hz	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	Pulse Modulation : 18 Hz	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	Pulse Modulation : 217 Hz	28 V/m	28 V/m
	2450 MHz	Pulse Modulation : 217 Hz	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	Pulse Modulation : 217 Hz	9 V/m	9 V/m

Symbols and Icons

	Symbol for "Disposal of WEEE (Waste Electrical and Electronic Equipment)" In the EU, refer to www.weee.zimmer.eu for information.		Symbol for "Do not resterilize"
	Symbol for "Caution, consult operating instructions for use"		Symbol for "To be used by... (Year, Month)"
	Symbol for "Protection against harmful ingress of water or particulate matter"		Symbol for "Intentional Emitter of Non-Ionizing Radiation"
	Symbol for "Manufacturer"		Symbol for "Japan Radio Mark"
	Symbol for "Temperature Range"		Symbol for "UL Classification Mark"
	Symbol for "Authorized EC Representative"		Symbol for "Nemko Classification Mark"
	Symbol for "Humidity Range"		Certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission.
	Symbol for "Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician."		Symbol for "RCM compliance mark"

	Symbol for “Sterile” and “Sterilized using ethylene oxide gas”		Symbol for “Type BF Applied Part”
	Symbol for “Contents packed without sterilization”		Symbol for “European Conformity”
	Symbol for “Not to be reused”		Symbol for “Should not be used if the package has been damaged or opened”
	Symbol for “Compliance with Singapour’s IMDA Standards”		Symbol for “Caution”
	Symbol for “Double Sterile Barrier System”		Symbol for “Icasa”
	Symbol for “Batch Code”		Symbol for “Catalogue Number”
	Symbol for “Serial Number”		Symbol for “Compliance with Singapour’s IMDA-Standards”
	Symbol for “Consult Instructions for use”		Symbol for “Date of Manufacture”

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Check for country product clearances and reference product specific instructions for use.

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