



# iASSIST™ Knee

Surgical Technique  
2-Pod Version





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## 1. Overview

### 1.1 Indication for Use

The *iASSIST*<sup>™</sup> Knee System is a computer assisted stereotaxic surgical instrument system to assist the surgeon in the positioning of orthopedic implant system components intra-operatively. It involves surgical instruments and position sensors to determine alignment axes in relation to anatomical landmarks and to precisely position alignment instruments and implant components relative to these axes.

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

### 1.2 Training

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



#### WARNING

*The system should only be used by trained surgeons.*

### 1.3 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.



#### WARNING

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

## 1.4 Contraindications

### 1.4.1 Clinical

The system should not be used:

- a. In cases of hip pathology severely limiting range of motion (e.g. arthrodesis, severe contractures, chronic severe dislocation);
- b. 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);
- c. For femoral anterior cut first surgical techniques;
- d. For Total Knee Arthroplasty using the *Quad-Sparing*<sup>™</sup> technique; or
- e. For any other contraindicated case, as given by the implant manufacturer.

### 1.4.2 General

The system should not be used:

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

## 1.5 Complications

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

- a. Infection; and
- b. 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.

## 2. Pre-Operative Guide



### 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 used in a surgical procedure. Otherwise, the system may indicate that the Pods are outside their operational temperature range and the Pods cannot be used until they reach an adequate temperature.

Ensure that one iASSIST Knee Pod Kit will be used per surgical procedure. 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.

The System Controller Computer should remain in the System Controller Carrying Case during transportation and in use.

*Note: A full set of the implant system's standard instrumentation is needed to perform a surgery in conjunction with the iASSIST 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.*

### 2.1 System Controller Computer Setup

1. Open and place the System Controller Carrying Case on a stable flat surface outside the sterile zone at a maximum distance of four meters from the instruments and OR tables.



### WARNING

The System Controller Computer 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 System Controller Computer must not be placed in a sterile bag as it might overheat.

2. Secure the inside flap in place to maintain the appropriate angle for the System Controller Computer.
3. Position the System Controller Computer on the angled flap.
4. Connect the power cord to the power supply and computer port. Plug it in to an AC outlet.
5. Press the power button (red button) located at the top left hand corner of the System Controller Computer to turn on the computer.
6. The home screen will be displayed after boot-up is completed.

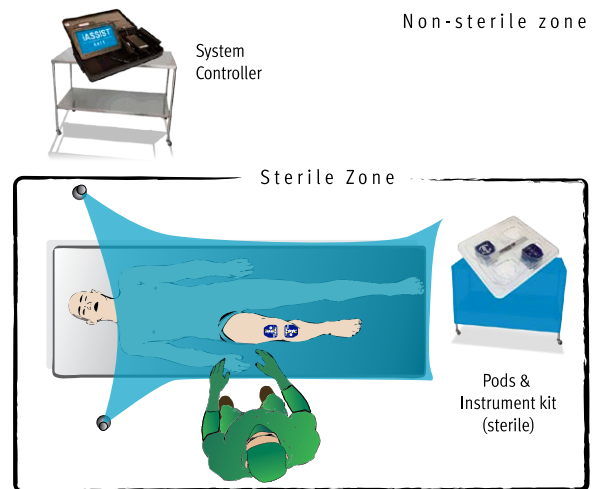


Figure 2.1 Operating Room Setup



Figure 2.2 System Controller Computer Setup

## 2.2 Application Launch and Patient Side Selection

1. Press and hold the barcode scanner button (orange button) located at the right of the System Controller Computer.
2. Scan the 2D barcode located on the *iASSIST* Knee Pod Kit.

*Note: If the 2D barcode cannot be read, the user can enter the barcode manually by activating the “Enter Barcode” button located at the bottom left corner of the computer screen.*

3. A confirmation sound will trigger and the application will launch.



### 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.*

4. The Patient Side View will be displayed. Click the “L” icon for a left knee or the “R” icon for a right knee to choose the patient side.

*Note: If the wrong patient side is selected at the beginning of the surgery, the “Side” button will be accessible once the Pods have joined the network. It will then be possible to change the patient side.*

## 2.3 Buttons, Icon and Pod Status Bar

### 2.3.1 Settings Button

Click the “Settings” button located at the bottom of the System Controller Computer screen and 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 following surgical procedures.

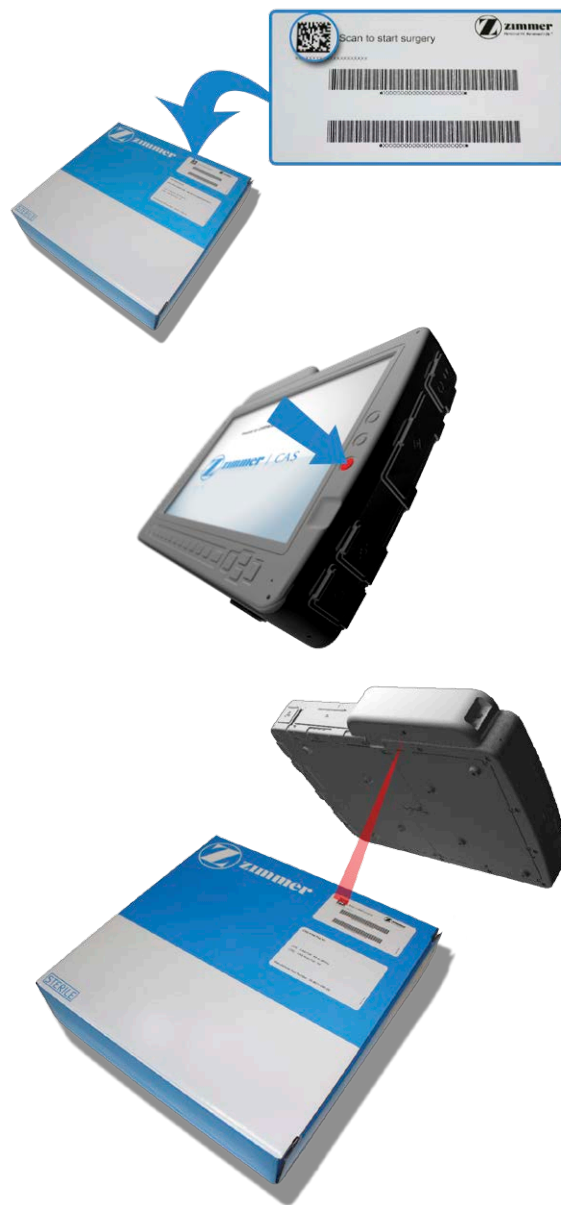


Figure 2.3 Application Launch

### 2.3.2 Snapshot Button

Click the “Snapshot” button located at the bottom of the System Controller Computer 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 snapshot directory found in the surgery folder of the “Copy Logs” feature.

### 2.3.3 Side Button

Click the “Side” button located at the bottom of the System Controller Computer screen to change the patient side. The patient side view will be displayed and the user will be able to click on the “L” icon for the left knee or the “R” icon for the right knee. When the patient side is set the selected side is green. If patient side is not determined the icon is grey with a “?” sign. This action can be performed at any moment during the surgery once the Pods have joined the network.

### 2.3.4 Barcode Button

Click the “Barcode” button located at the bottom of the System Controller Computer screen if the 2D barcode cannot be read. The user will then be able to manually enter the barcode.

### 2.3.5 Patient Side Icon

The patient side is indicated at the top of the System Controller Computer screen. When patient side is set, icon and letter are green on the selected side. If patient side is not determined the icon is grey with a “?” sign.

### 2.3.6 Pod Status Bar

The “Pod Status Bar” is displayed at the bottom of the System Controller Computer screen. The bar displays the status of each Pod connected to the System Controller Computer showing its user interface.

A Pod which has not joined the network will be displayed in red.

A Pod which has joined the network but has not been connected to an instrument will be displayed in yellow.

A Pod which has joined the network and is connected to an instrument will be displayed in grey. The name of the instrument on which the Pod is connected is also displayed.

Issues with the Pods battery life, temperature or communication will be displayed on the Pod Status Bar.



Figure 2.4 Settings, Snapshot, Side, Barcode and Quit Buttons



Figure 2.5 Patient Side Icon: Right, Undetermined, Left

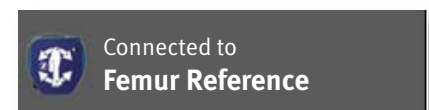


Figure 2.6 Pod Status Bar



### 3. Intra-Operative Guide

#### 3.1 Powering-On Pods and Intra-Operative Calibration

1. Open an *iASSIST* Knee Pod Kit and remove the Pods from the Pod Tray. Place them on the sterile instrument table.



#### 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, open another *iASSIST* Knee Pod Kit.

2. Power-on each of the Pods by depressing the power button until it is flush with the Pods surface. The green status LED (Light Emitting Diode) of each Pod will blink quickly.



#### WARNING

Make sure to power-on the Pods at the appropriate time i.e. when ready to perform the intra-operative calibration. Intra-operative 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 can be replaced by another one following the instructions described in section 5.5.2 “*iASSIST* Knee Pod Kit” without restarting the application.

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

The Pods should be powered-on five minutes before performing the intra-operative calibration.

3. Wait for the green status LED of all of the Pods to start blinking slowly before continuing with the intra-operative calibration.



#### WARNING

The calibration process including the Pod Calibration Jig handling should be performed wearing sterile attire.

4. Clip the Pods to the Pod Calibration Jig. When successfully clipped, the green status LED on the Pods will turn solid green.



Figure 3.1 Powering-On Pods and Intra-Operative Calibration



5. Begin by placing face 1 of the Pod Calibration Jig upwards on a sterile table. Keep the jig steady until a sound is triggered. Continue the sequence by positioning the jig in its remaining five positions (2 through 6). 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.*

**WARNING**

*The Pods need to be calibrated on a flat, approximately horizontal surface to ensure optimal performance. This surface must be sterile.*

6. Unclip all Pods from the Pod Calibration Jig.

### 3.2 Pod Assembly

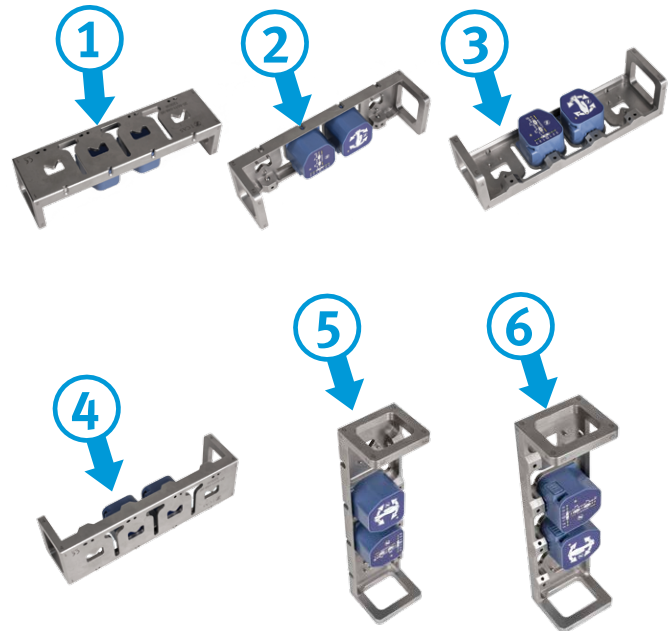
With the user interface of the Pod facing upwards,

1. Identify the nose 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.

*Note: There are no locking levers on the Pod Calibration Jig.*

**WARNING**

*Throughout the surgery, always ensure that the Pods are properly assembled to their corresponding instruments before use.*



**Figure 3.1 Powering-On Pods and Intra-Operative Calibration (Continued)**



**Figure 3.2 – Assembling a Pod to an Instrument**

### 3.3 Distal Femur Cut

#### 3.3.1 Instrument Assembly

The femoral instrumentation is not side specific, therefore it is used for left and right knees.

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 AP Slider to the Femoral Distal Cut Guide by tightening the blue screw.
3. Clip the “Cut Guide” Pod to the Femoral Distal Cut Guide.
4. Clip the “Reference” Pod to the Femoral Reference.

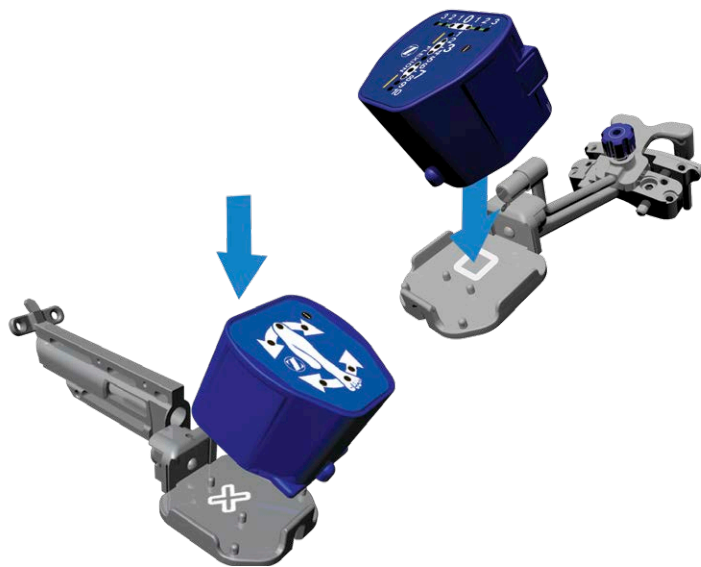
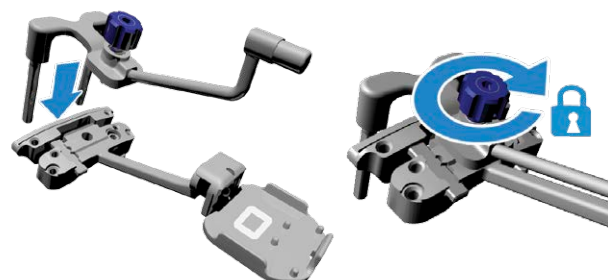
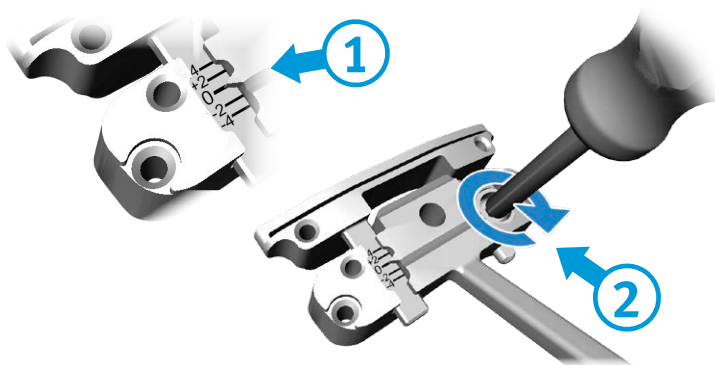


Figure 3.3 Distal Femur Cut – Instrument Assembly

### 3.3.2 Femur Registration

1. Break the cortex at the mechanical axis entry point with a cortex breaker or a 3.2 mm drill bit.
2. Impact the Femoral Spike or the CAS Small Spike 7.9 mm into the distal femur (2.5-3.5 cm).



#### WARNING

The spike should be aligned within 15° of the mechanical axis of the femur and be within 15° perpendicular to the final required orientation of the cut. This alignment is required because of the mechanical adjustment limit of the Femoral Adjustment Mechanism.

3. Slide the Femoral Reference onto the spike.
4. 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.

5. Affix the Femoral Reference on the bone with one 3.5 mm Hex Head Screw x 38 mm in one of the anterior fixation holes.

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



#### WARNING

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

6. Press the "Z" button on the Pod attached to the Femoral Reference to initiate the registration procedure.
7. Acquire 13 stable positions by accelerating and stopping the leg to create a star-shaped or circle pattern. An audio feedback will be generated from the System Controller Computer 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.

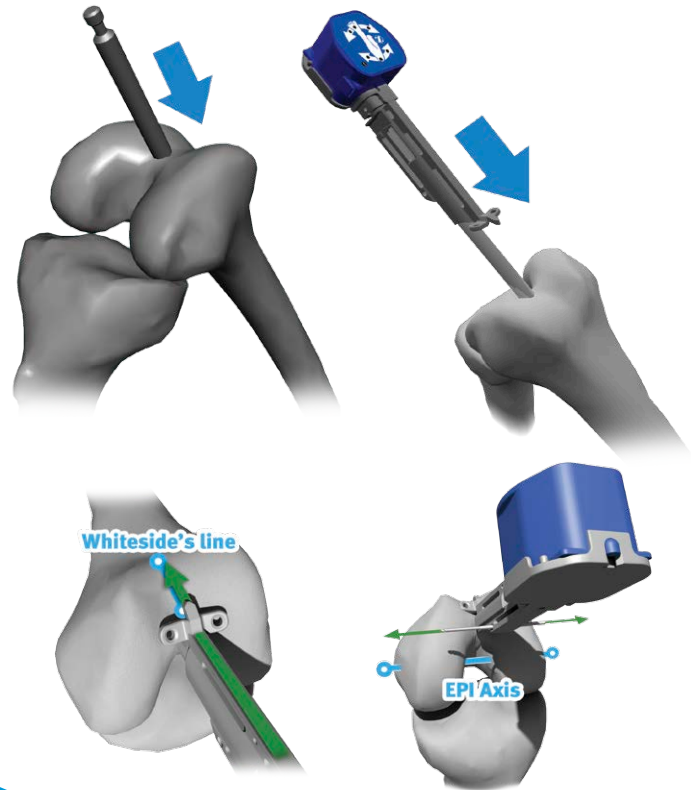


Figure 3.3.1 Distal Femur Cut – Femur Rotation Alignment

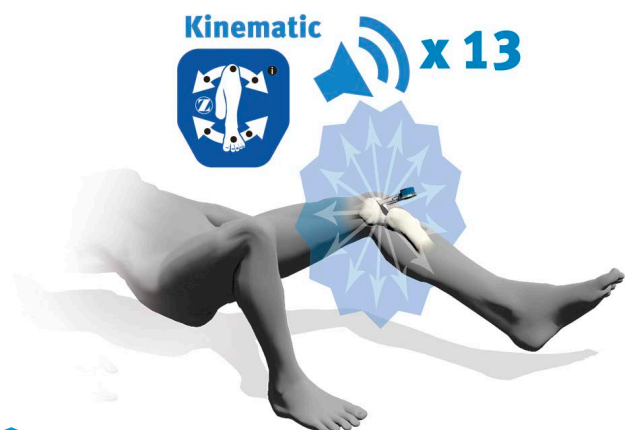


Figure 3.4 Distal Femur Cut – Femur Registration

**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).

**3.3.3 Distal Femur Cut**

1. Install the Femoral Adjustment Mechanism on the anterior side of the Femoral Reference by aligning the arrows.
2. Insert the two long pegs of the Femoral AP Slider into the Femoral Adjustment Mechanism.
3. Slide the Femoral Adjustment Mechanism down towards the distal condyles to the half way mark.
4. Follow feedback (red and green LEDs) on the Pod attached to the Femoral Distal Cut Guide and adjust flexion/extension and varus/valgus using the gold and green screws respectively.

**WARNING**

The knee should be flexed between  $45^\circ$  and  $80^\circ$  in order for the system to be able to compute angle values.

Whenever using the 3.5 mm Hex Head Knob, remove the knob before performing the cut.

5. Once the adjustment is completed, slide the Femoral Adjustment Mechanism towards the femur until it is fully seated on the most distal condyle.
6. Insert three 3.2 mm Headless Trocar Drill Pins in the base of the Femoral Distal Cut Guide using both parallel holes and one diagonal hole in the body of the guide.
7. With the knee stable and flexed between  $45^\circ$  and  $80^\circ$ , unlock the Femoral AP Slider using the blue screw and remove it from the assembly. Hold the knee steady until the confirmation sound is heard.

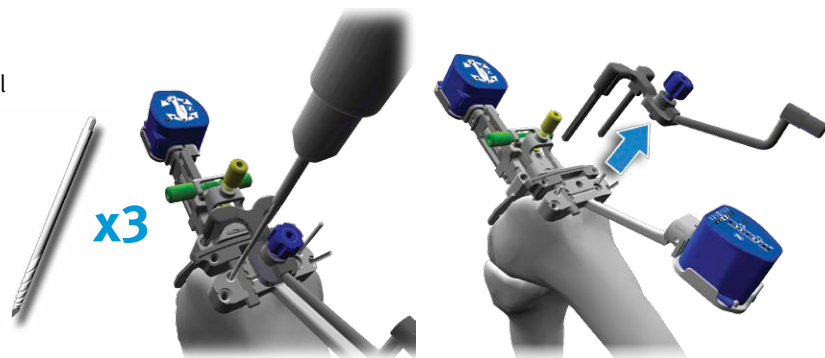
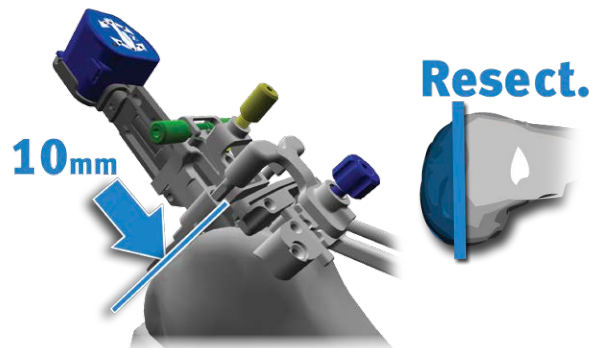
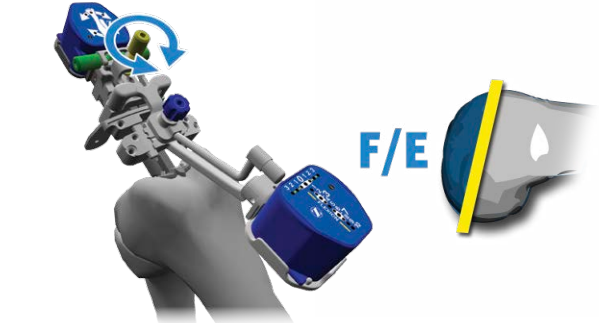
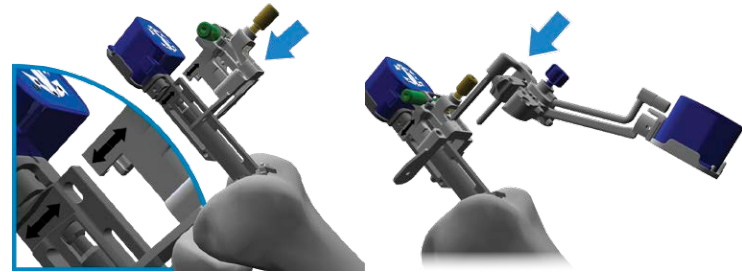


Figure 3.5 Distal Femur Cut

8. Slide the Femoral Adjustment Mechanism away from the distal femur so both arrows are aligned and pull it off the assembly.
9. Remove the 3.5 mm Hex Head Screw x 38 mm and the Femoral Reference.
10. Remove the spike using a slaphammer.

*Note: As provided by Zimmer, the Persona® Slaphammer (42-5099-037-00) can be used to remove the Femoral Spike.*

*Note: As provided by Zimmer, the NexGen® Slaphammer Extractor (00-5785-097-00) can be used to remove the Femoral Spike or the CAS Small Spike 7.9 mm.*

11. Manually adjust the resection level if desired. Loosen the screw on the Femoral Distal Cut Guide to increase/decrease resection by 2 or 4 mm.

*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.*

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 Femoral Distal Cut Guide and the Femoral Saw Slot to the bone has to be inserted carefully to avoid perforating the second cortex.

13. 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 into the Femoral Saw Slot. Make sure that the arm of the Alignment Arch is aligned with the AP plane of the femur. Then, slide a drop rod in the body of the Alignment Arch.

*Note: As provided by Zimmer, the Alignment Rod with Coupler (00-5785-080-00) can be used to verify the cut.*

*Note: Alternatively, as provided by Zimmer, the Natural-Knee® II Axial Alignment Rod (00-6290-00-005) can be used to verify the cut.*

14. Resect the distal femur.



#### WARNING

The Femoral Saw Slot is compatible with saw blades of 1.27 mm (0.05”) thickness.

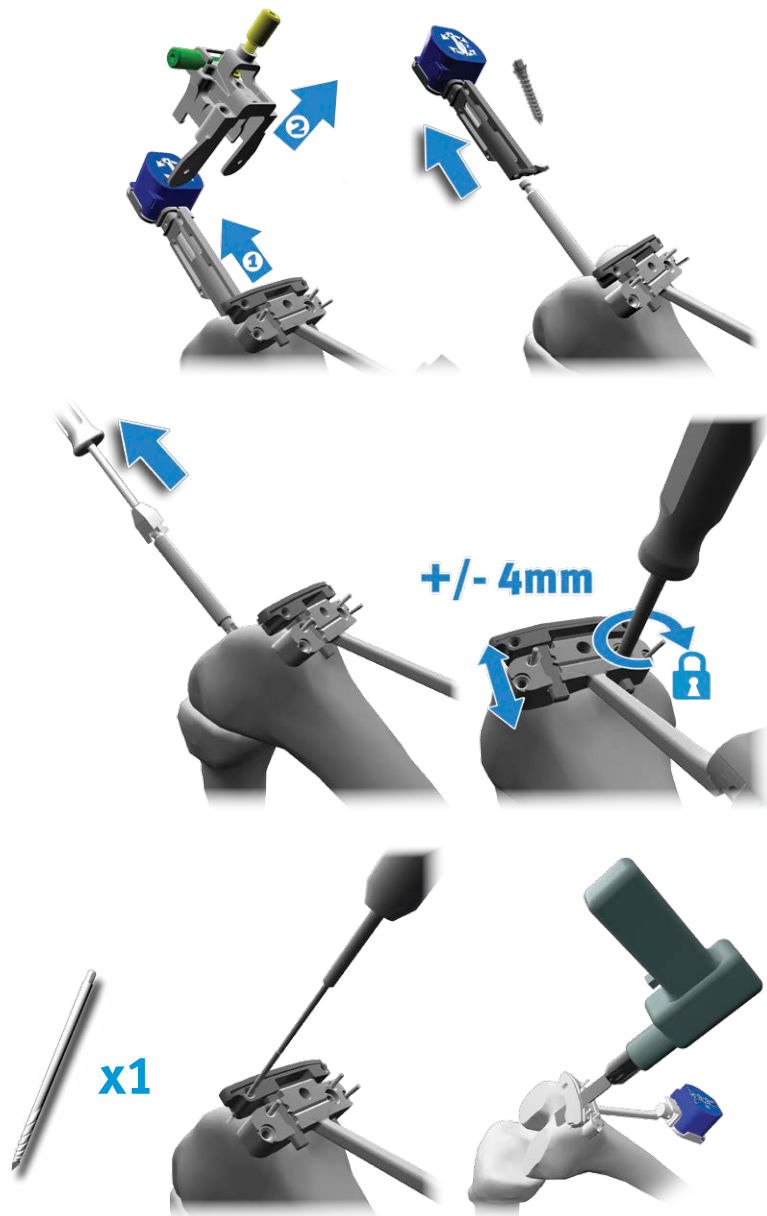


Figure 3.5 Distal Femur Cut (Continued)



### 3.3.4 Distal Femur 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 using the captive spikes. Additionally two 3.5 mm Hex Head Screw x 38 mm 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 medio-laterally by 10 mm.

For steps 4-6, follow the feedback on the Pod attached to the Validation Tool.

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

*Note: To restart the distal femur cut validation, press the “Z” button on the Pod attached to the Validation Tool.*

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 AP plane of the femur.
9. Remove the Validation Tool, the 3.2 mm Headless Trocar Drill Pins, the Femoral Saw Slot, and the Femoral Distal Cut Guide.
10. Proceed with the tibia registration if continuing with the proximal tibia cut.

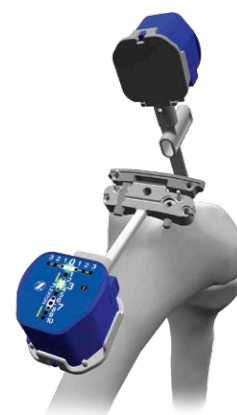
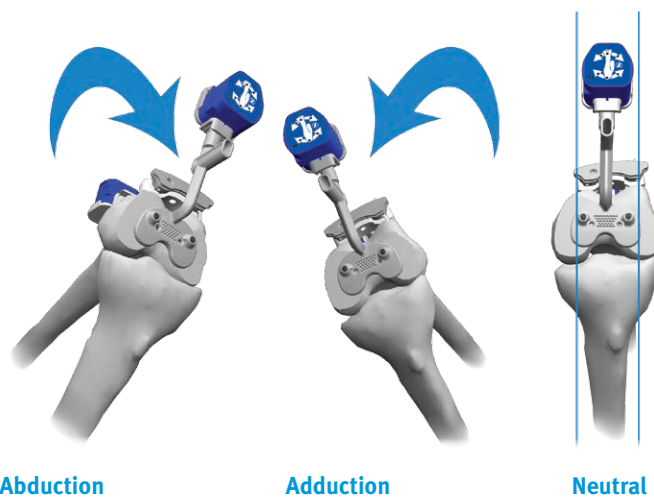


Figure 3.6 Distal Femur Cut – Validation

**WARNINGS**

The Femoral Distal Cut Guide must not have moved to perform an accurate distal cut validation.

In reference to lot #110623 and #120264 of the Validation Tool and the Zimmer NexGen Posterior Referencing Instruments: Do not place the Posterior Referencing 4-in-1 Flex Femoral Cut Guide (00-5901-043/048-00) into the holes created by the Validation Tool. The Posterior Referencing Sizer (00-5901-040-00) which creates the peg holes for the 4-1 cut guide and the Validation Tool have equal distances between their pegs.

### 3.4 Proximal Tibia Cut

#### 3.4.1 Instrument Assembly

The Tibial Adjustment Mechanisms are side specific. Depending on the patient side:

1. Pull out the handle of the Tibial Positioner.
2. Connect the Tibial Positioner to the Tibial Adjustment Mechanism.

*Note: The Tibial Right/Left Positioners are side specific and must be used with the corresponding Tibial Right/Left Adjustment Mechanism.*

3. Push on the handle of the Tibial Positioner to lock the mechanism in place.
4. **For a left knee** procedure, clip the “Reference” Pod to the back receptacle of the Tibial Left Adjustment Mechanism.
- For a right knee** procedure, clip the “Reference” Pod to the back receptacle of the Tibial Right Adjustment Mechanism.
5. Clip the “Cut Guide” Pod to the Tibial Alignment Guide.

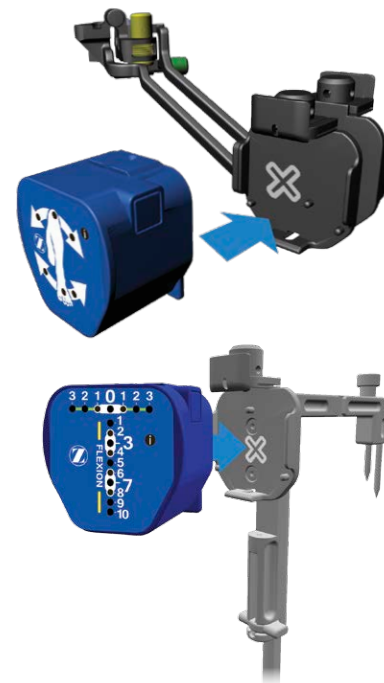
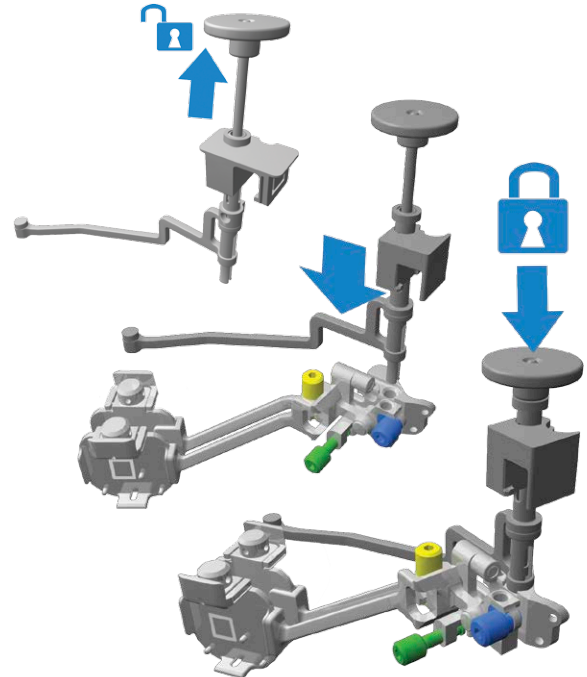


Figure 3.7 Proximal Tibia Cut – Instrument Assembly



### 3.4.2 Tibia Registration

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.
3. Install the distal part of the Tibial Alignment Guide on 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.*



#### WARNING

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

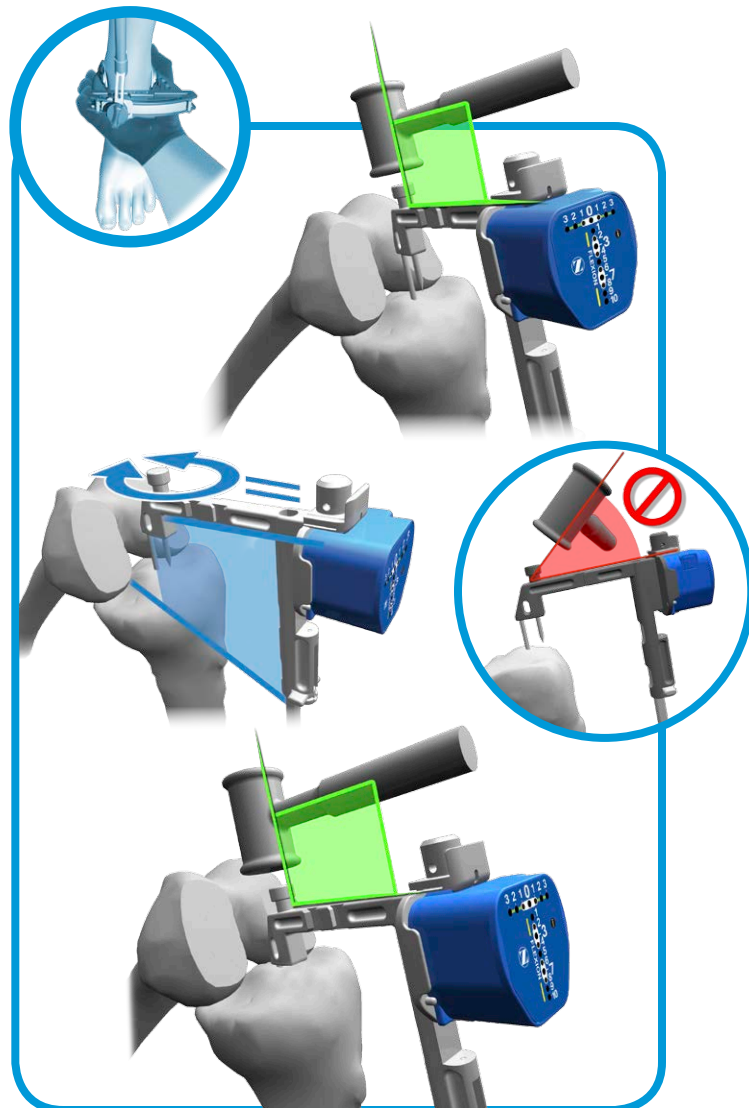
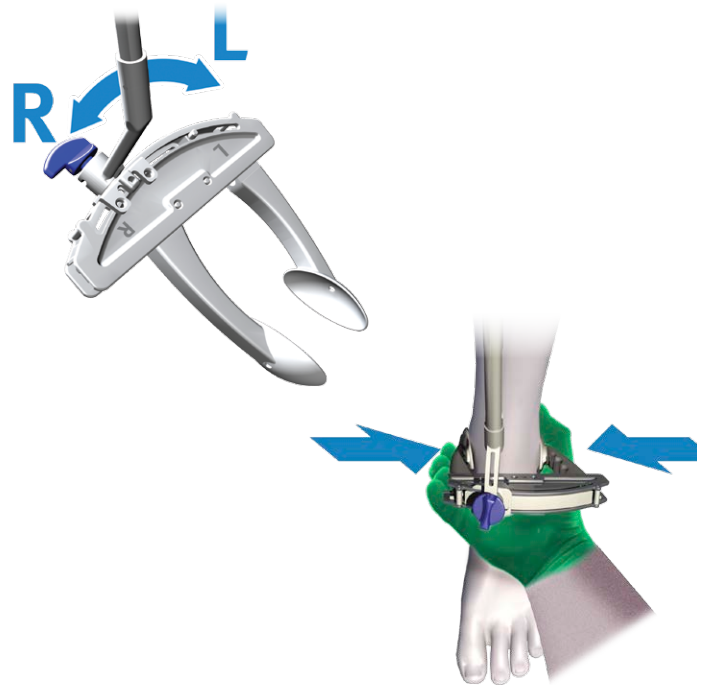
4. While continuing to firmly grip the distal clamps around the malleoli, partially insert (2-3 mm) the longer spike of the proximal part of the Tibial Alignment Guide through the mechanical axis entry point, without engaging the shorter spike.
5. While continuing to firmly grip the distal clamps around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



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



- 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 re-secure the clamps around the malleoli.

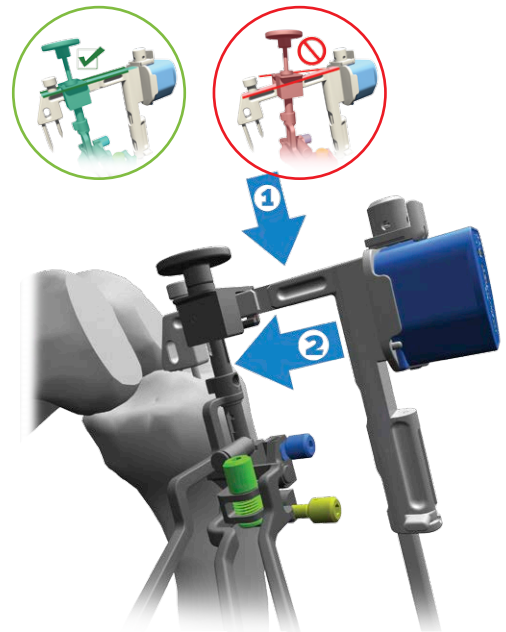
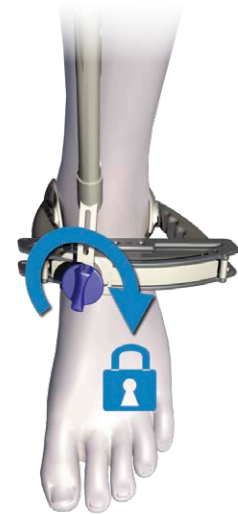
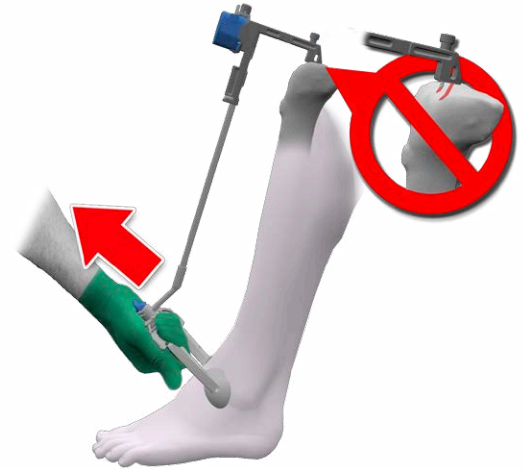
**WARNING**

*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.*

- Lock the blue knob on the distal Tibial Alignment Guide.
- Attach the Tibial Positioner and the Tibial Adjustment Mechanism assembly onto the proximal part of the Tibial Alignment Guide.
- 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.*



**Figure 3.8 Proximal Tibia Cut – Tibia Registration**

**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 mm Hex Head Screw x 38 mm to avoid potential interference between the screws and the spikes of the Tibial Alignment Guide.

11. Use three 3.5 mm Hex Head Screw x 38 mm to secure the Tibial Adjustment Mechanism to the bone.

*Note: 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.*

**WARNINGS**

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

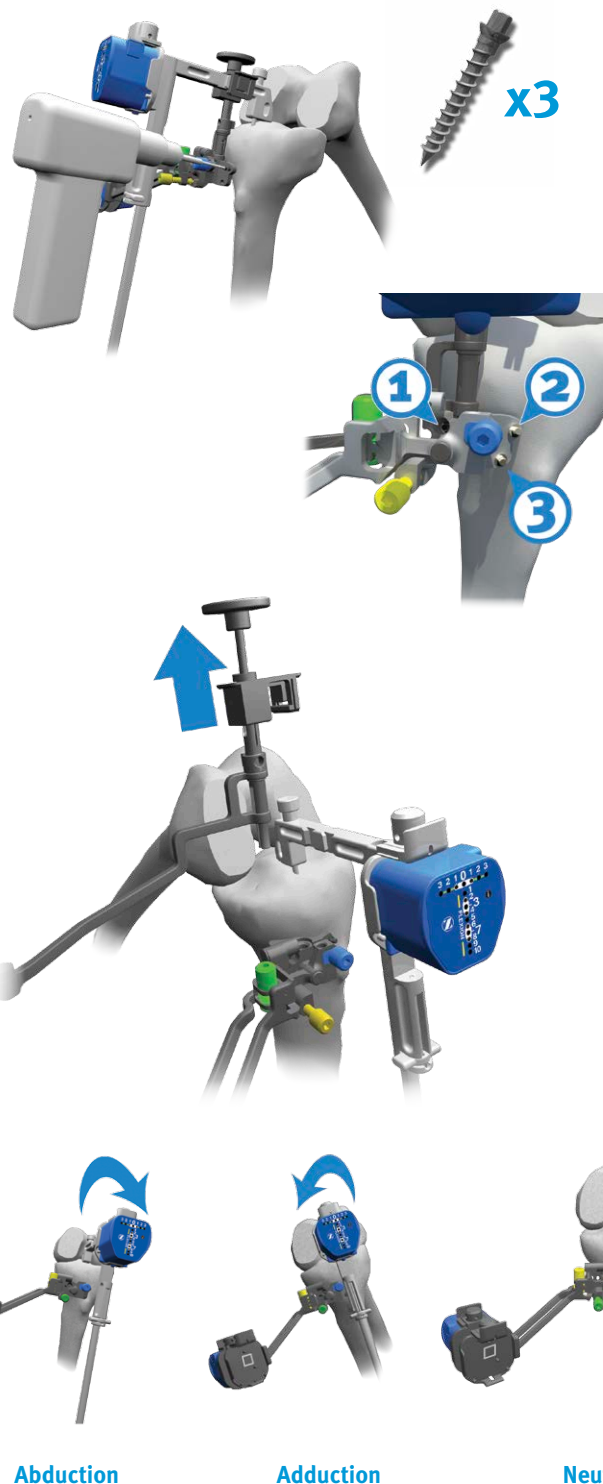
From registration to validation, the instruments must remain stable and properly fixated to the bone to ensure accuracy of the system.

12. To initiate the tibial registration, release the Tibial Positioner from the Tibial Adjustment Mechanism by pulling upwards on the Tibial Positioner handle.

For steps 13-15, follow the feedback on the Pod attached to the Tibial Alignment Guide.

13. Bring the leg into abduction. Once the green LED stops blinking hold the knee steady until the acquisition sound is heard.
14. Bring the leg into adduction. Once the green LED stops blinking hold the knee steady until the acquisition sound is heard.
15. Bring the leg into neutral position. Once the green LED stops blinking hold the knee steady until the acquisition sound is heard.

*Note: To restart the tibial registration, press the “Z” button on the Pod attached to the Tibial Alignment Guide.*

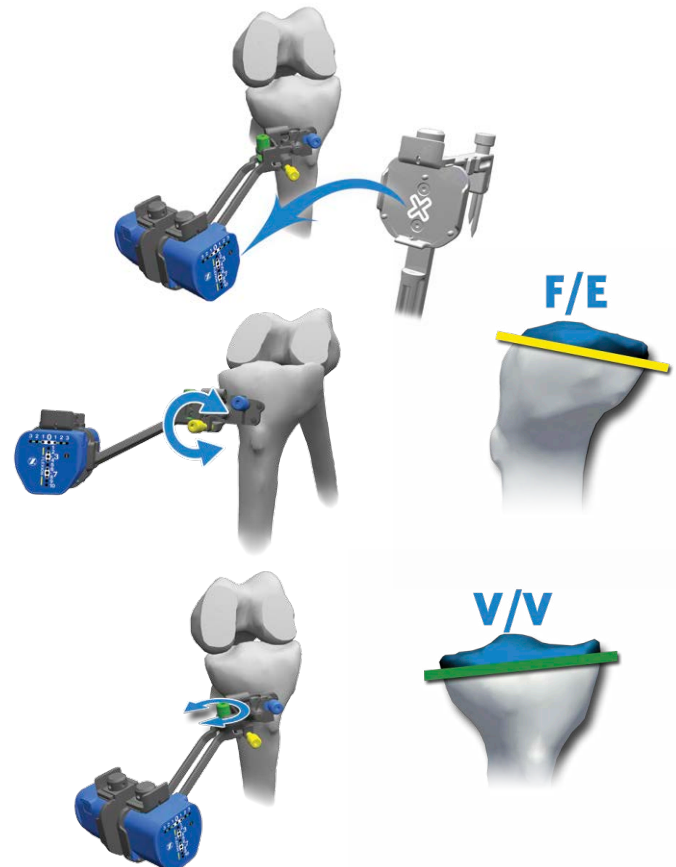
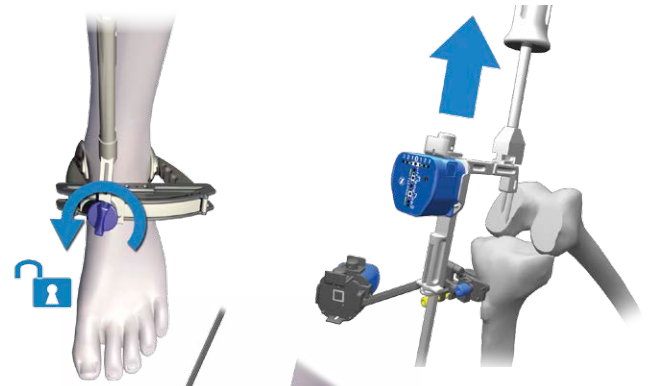


**Figure 3.8 Proximal Tibia Cut – Tibia Registration (Continued)**

16. Loosen the blue knob on the distal end of the Tibial Alignment Guide.
17. Unspike the proximal part of the Tibial Alignment Guide from the tibia using a slaphammer.

*Note: As provided by Zimmer, the Persona Slaphammer (42-5099-037-00) or the NexGen Slaphammer Extractor (00-5785-09700) can be used to remove the guide.*

18. Remove the distal part of the Tibial Alignment Guide from the malleoli.

**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.*

**3.4.3 Proximal Tibia Cut**

1. Unclip the “Cut Guide” Pod from the Tibial Alignment Guide and clip it to the front receptacle of the Tibial Adjustment Mechanism.
2. Follow feedback (red and green LEDs) on the Pod attached to the Tibial Adjustment Mechanism and adjust flexion/extension and varus/valgus using the gold and green screws respectively.

**WARNINGS**

*The knee should be flexed between 45° and 80° in order for the system to be able to compute angle values.*

*When using the 3.5 mm Hex Head Knob, remove the knob before performing the cut.*

3. Insert a stylus in the Tibial Cut Guide.

*Note: As provided by Zimmer, the Zimmer NexGen Posterior Referencing Instruments Tibial Depth Resection Stylus 2/10 mm (00-5901-082-00) or the Tibial Depth Resection Stylus 4/6 mm (00-5901-081-00) can be used to set the resection.*

*Note: Alternatively, as provided by Zimmer, the Natural-Knee II Tibial Stylus (00-6290-00-542 or 00-6299-00-250) can be used to set the resection. The stylus must be screwed on top of the Tibial Cut Guide instead of being inserted in its slot.*

4. Insert the Tibial Cut Guide elevator rod into the Tibial Adjustment Mechanism.

*Note: The Tibial Right/Left Cut Guides are side specific and must be used per the corresponding Tibial Right/Left Adjustment Mechanism.*

*Note: Each line increment on the 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.

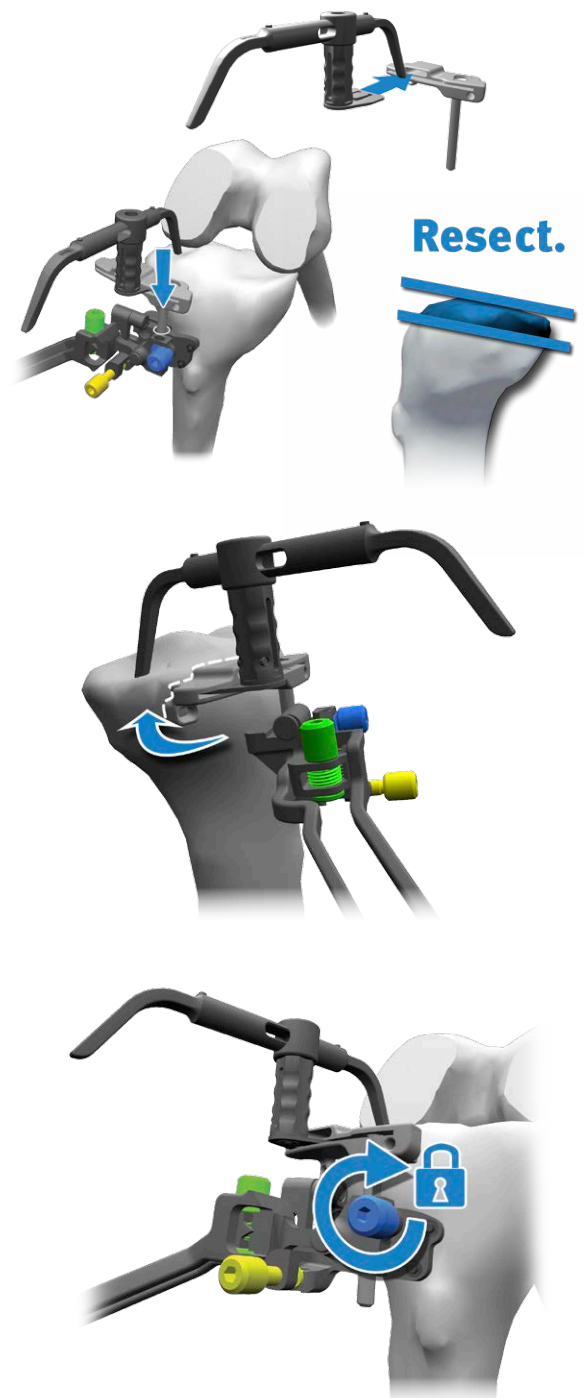


Figure 3.9 Proximal Tibia Cut



8. Secure the Tibial Cut Guide onto the tibia by inserting a 3.2 mm Headless Trocar Drill Pin in the lateral hole.
9. Further stabilize the Tibial Cut Guide onto the tibia by inserting a 3.2 mm Headless Trocar Drill Pin in the medial hole.

*Note: Alternatively, a 3.5 mm Hex Head Screw x 38 mm can be inserted in the medial hole instead of the 3.2 mm Headless Trocar Drill Pin. When using a 3.5 mm Hex Head Screw x 38 mm, the screw must only be inserted halfway as to avoid movement of the Tibial Cut Guide.*

**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.

10. Remove the stylus.

**WARNING**

If the Tibial Adjustment Mechanism is not fixated securely or moves, the tibia registration should be performed again. Repeat the steps described in section 3.4.2 "Tibia Registration".

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 AP plane of the tibia. Then, slide a drop rod in the body of the Alignment Arch.

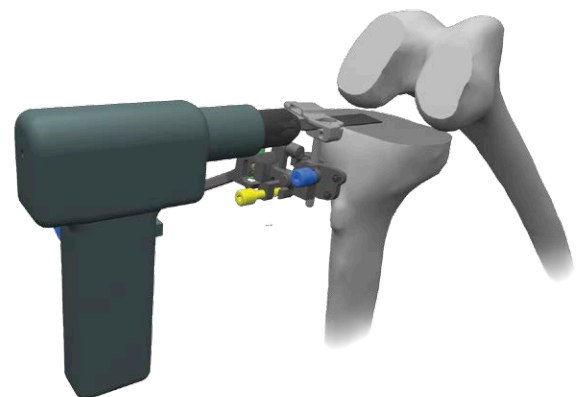
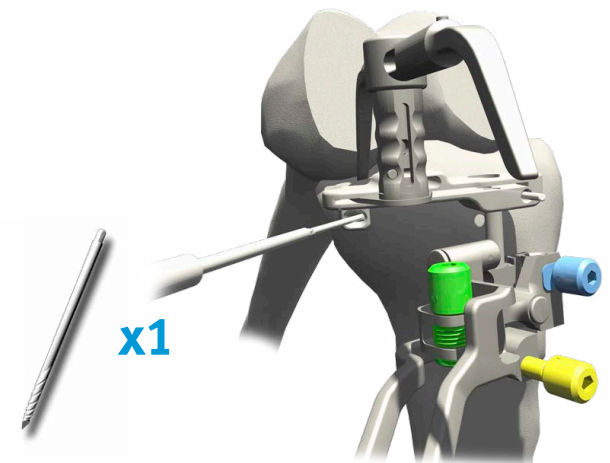
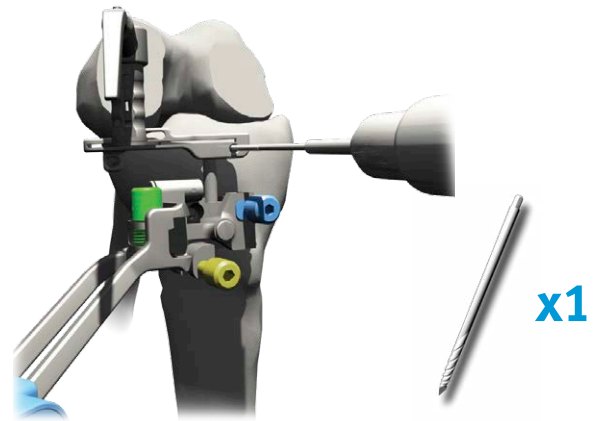
*Note: As provided by Zimmer, the Alignment Rod with Coupler (00-5785-080-00) can be used to verify the cut.*

*Note: Alternatively, as provided by Zimmer, the Natural-Knee II Axial Alignment Rod (00-6290-00-005) can be used to verify the cut.*

12. Resect the proximal tibia.

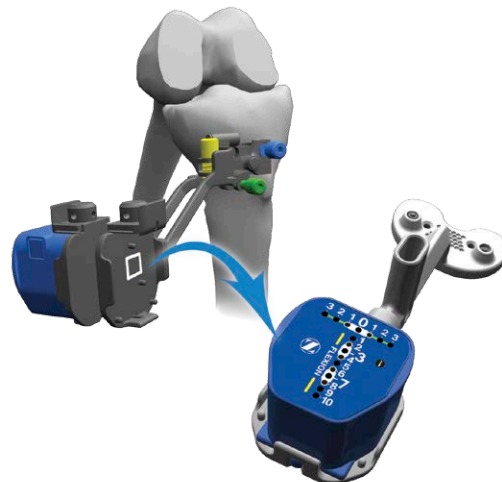
**WARNING**

The Tibial Cut Guide is compatible with saw blades of 1.27 mm (0.05") thickness.



### 3.4.4 Proximal Tibia 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 using the captive spikes. Additionally two 3.5 mm Hex Head Screw x 38 mm 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 screws used to secure the Tibial Adjustment Mechanism and the Tibial Cut Guide. If interference is felt, the Validation Tool should be shifted medio-laterally by 10 mm.*

4. Press the “Z” button on the Pod attached to the Validation Tool to initiate the validation procedure.

For steps 5-7, follow the feedback on the Pod attached to the Validation Tool.

5. Bring the leg into abduction. Once the green LED stops blinking hold the knee steady until the acquisition sound is heard.
6. Bring the leg into adduction. Once the green LED stops blinking hold the knee steady until the acquisition sound is heard.
7. Bring the leg into neutral position. Once the green LED stops blinking hold the knee steady until the acquisition sound is heard.
8. The proximal tibia cut values are displayed on the Pod attached to the Validation Tool.

*Note: To restart the proximal tibia cut validation, press the “Z” button on the Pod attached to the Validation Tool.*

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 AP plane of the tibia.
10. Remove the Validation Tool, the 3.2 mm Headless Trocar Drill Pins, the Tibial Cut Guide, the 3.5 mm Hex Head Screws x 38 mm and the Tibial Adjustment Mechanism.
11. Proceed with the femur registration if continuing with the distal femur cut.

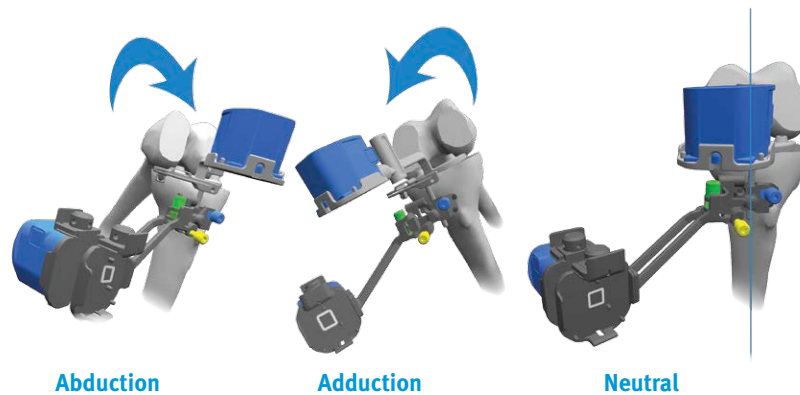
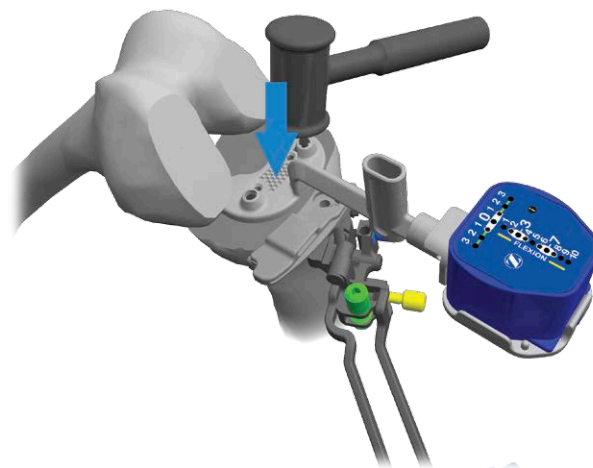


Figure 3.10 Proximal Tibia Cut – Validation



### 3.5 Surgical Technique for Bilateral Procedure

The user can perform a bilateral procedure using the same *iAS-SIST* Knee Pod Kit without restarting the application.

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 “Side” button located at the bottom of the System Controller Computer screen.
3. Choose the opposite 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 section 3.3.1 “Instrument Assembly” when performing the femur first or section 3.4.1 “Instrument Assembly” when performing the tibia first.
6. Press the “Z” button on the Pod clipped to the Femur Reference or the Tibial Alignment Guide to start the registration.

*Note: Intra-operative calibration does not have to be repeated if the same iASSIST Knee Pod Kit is used.*



#### WARNINGS

*Always ensure that an additional iASSIST Knee Pod Kit is available since battery life could be insufficient for a bilateral procedure. In this case follow the Pod replacement procedure detailed in section 5.5.2 “iASSIST Knee Pod Kit”.*

*Do not re-use the 3.2 mm Headless Trocar Drill Pins and the 3.5 mm Hex Head Screw x 38 mm. Use four new 3.2 mm Headless Trocar Drill Pins and four new 3.5 mm Hex Head Screw x 38 mm for the second leg since they are single-use.*

### 3.6 Freehand Positioning of the Tibial Adjustment Mechanism

The following section describes an alternate technique for positioning the Tibial Adjustment Mechanism on the tibia without using the Tibial Positioner.

#### 3.6.1 Instrument Assembly

1. Follow steps 4 and 5 of section 3.4.1 “Instrument Assembly”.
2. Using the green and gold screws, set the varus/valgus and flexion/extension of the Tibial Adjustment Mechanism to the neutral position by aligning the arrow with the laser marking (v/v) and by aligning the arrows (f/e) respectively.
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.

**Note:** The Tibial Right/Left Cut Guides are side specific and must be used per the corresponding Tibial Right/Left Adjustment Mechanism.

4. Lock the Tibial Cut Guide by hand tightening the blue screw on the Tibial Adjustment Mechanism.

#### 3.6.2 Tibia Registration

1. 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.

2. Visually align the Tibial Adjustment Mechanism in varus/valgus and in flexion/extension by aligning the elevator rod of the Tibial Cut Guide parallel to the tibial mechanical axis in both the frontal and sagittal planes.
3. Use three 3.5 mm Hex Head Screw x 38 mm to secure the Tibial Adjustment Mechanism to the bone.

**Note:** Secure the Tibial Adjustment Mechanism to the bone by first securing screws in the upper lateral hole, secondly in the lower lateral hole, and finally in the medial hole.

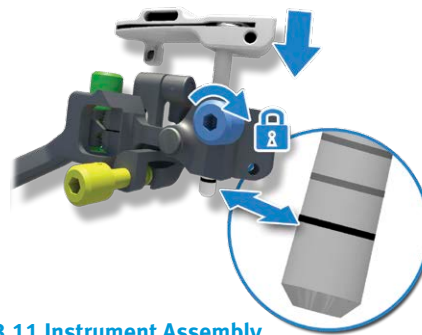


Figure 3.11 Instrument Assembly

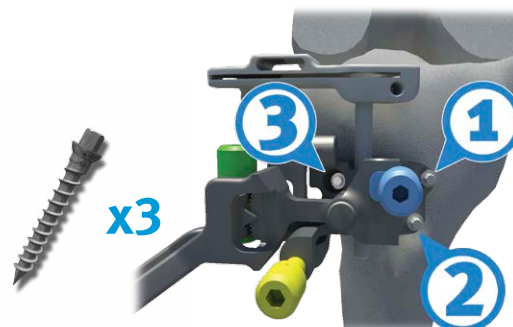
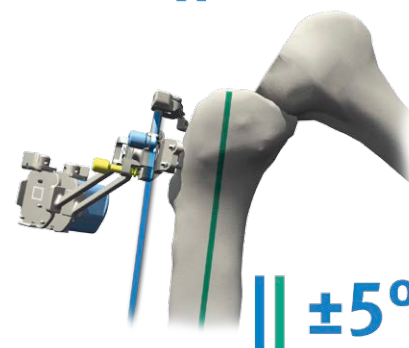
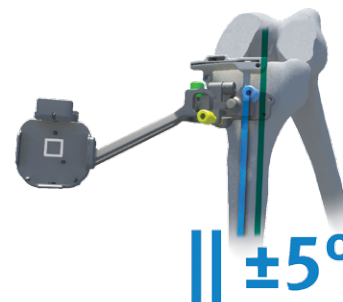


Figure 3.12 Tibia Registration

#### WARNINGS

Control the speed of the power tool or finish fixing the screws manually to avoid stripping the cortex of the tibia. As provided by Zimmer, 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 fixated to the bone to ensure accuracy of the system.

4. Loosen the blue knob on the distal part of the Tibial Alignment Guide.
5. 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.
6. Install the distal part of the Tibial Alignment Guide on 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.*

**WARNING**

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

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 through 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.

*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.*

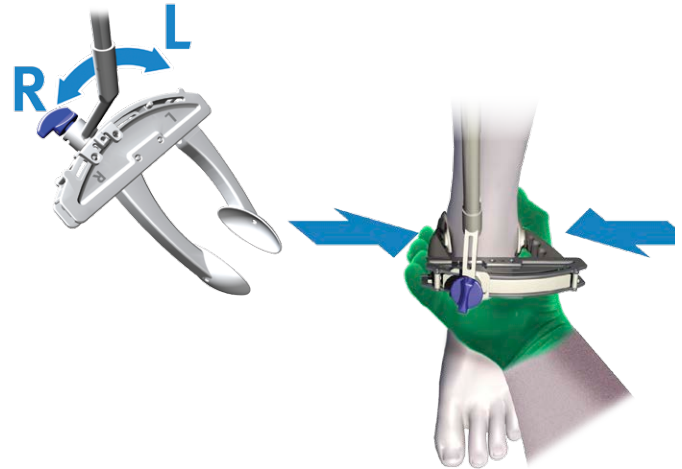
9. While continuing to firmly grip the distal clamps around the malleoli, impact the instrument until both spikes are fully inserted in the tibia.

**WARNINGS**

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.



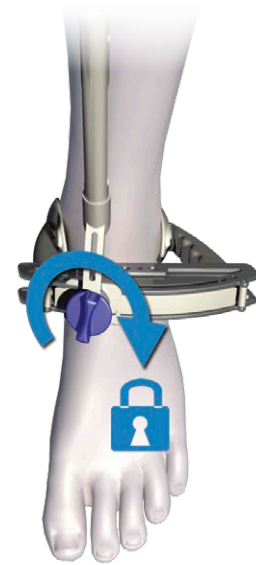
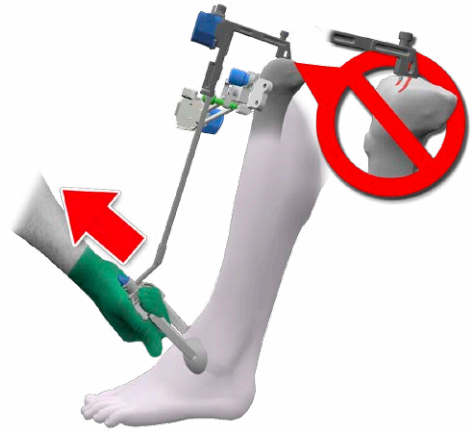
**Figure 3.12 Tibia Registration (Continued)**

10. Ensure the distal clamps of the Tibial Alignment Guide remain securely positioned on the malleoli. If a re-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 re-secure 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.*

11. Lock the blue knob on the distal Tibial Alignment Guide.
12. Press the “Z” button on the Pod attached to the Tibial Alignment Guide to initiate the registration procedure.
13. To complete the procedure, resume from step 13 of section 3.4.2 “Tibia Registration”.



**Figure 3.12 Tibia Registration (Continued)**

### 3.7 Tibial 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.

#### 3.7.1 Instrument Assembly

1. Follow steps 4 and 5 of section 3.4.1 “Instrument Assembly”.
2. Assemble the Tibial Aligner by aligning the markings of the Tibial Aligner Upper Assembly (20-8011-056-51) and the Tibial Aligner Lower Assembly (20-8011-056-52).

**Note:** If desired, the Tibial Aligner can be used without the upper assembly.

3. Connect the Tibial Aligner to the Tibial Adjustment Mechanism.

#### 3.7.2 Tibia Registration

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 Tibia Alignment Guide later on.



Figure 3.13 Instrument Assembly

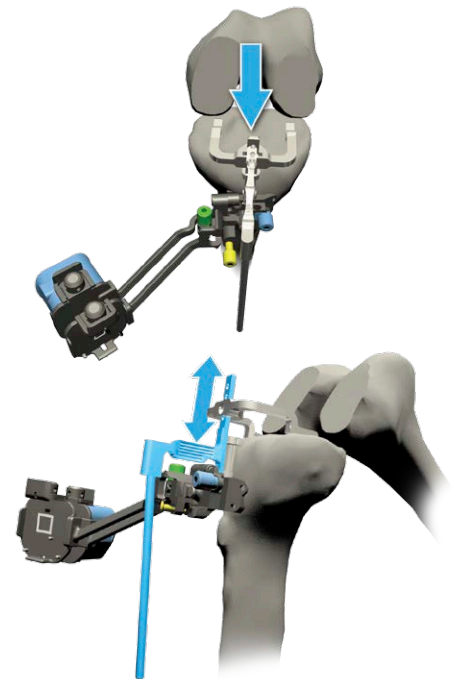


Figure 3.14 Tibia Registration



4. Visually align the Tibial Adjustment Mechanism in varus/valgus and in flexion/extension 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°.*



#### 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.

5. Use three 3.5 mm Hex Head Screw x 38 mm to secure the Tibial Adjustment Mechanism to the bone.

*Note: Secure the Tibial Adjustment Mechanism to the bone by first securing screws in the upper lateral hole, secondly in the lower lateral hole, and finally in the medial hole.*



#### WARNINGS

Control the speed of the power tool or finish fixing the screws manually to avoid stripping the cortex of the tibia. As provided by Zimmer, 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 (blue highlight) 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 is R.**
9. Install the distal part of the Tibial Alignment Guide on 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.*

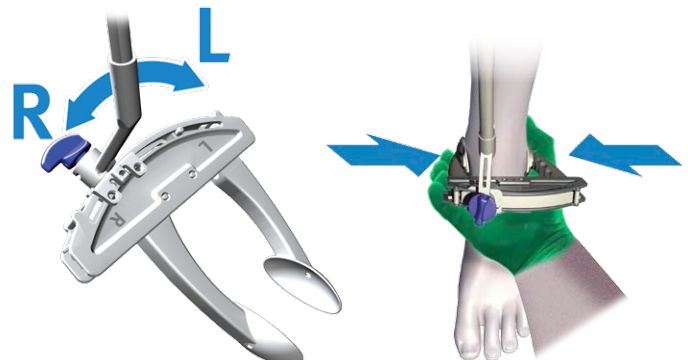
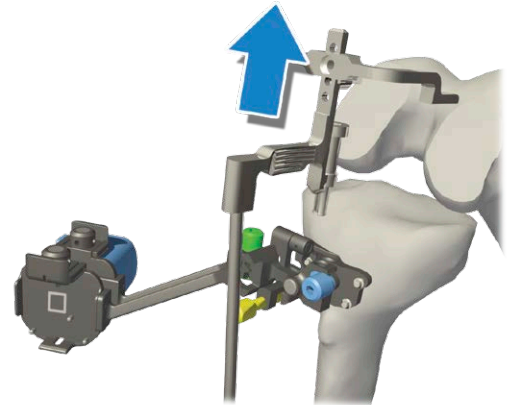
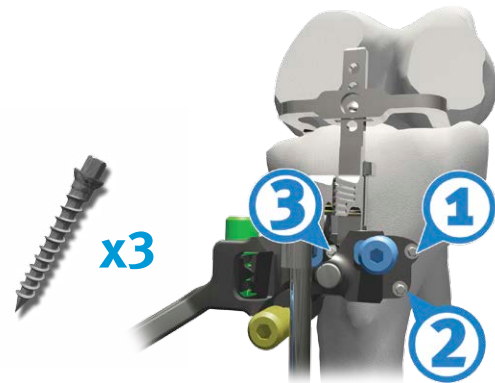
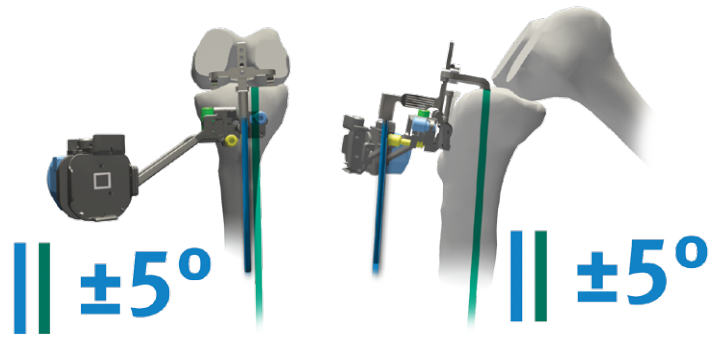


Figure 3.14 Tibia Registration (Continued)

**WARNING**

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

**WARNINGS**

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.

13. Ensure the distal clamps of the Tibial Alignment Guide remain securely positioned on the malleoli. If a re-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 re-secure 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 13 of section 3.4.2 “Tibia Registration”.

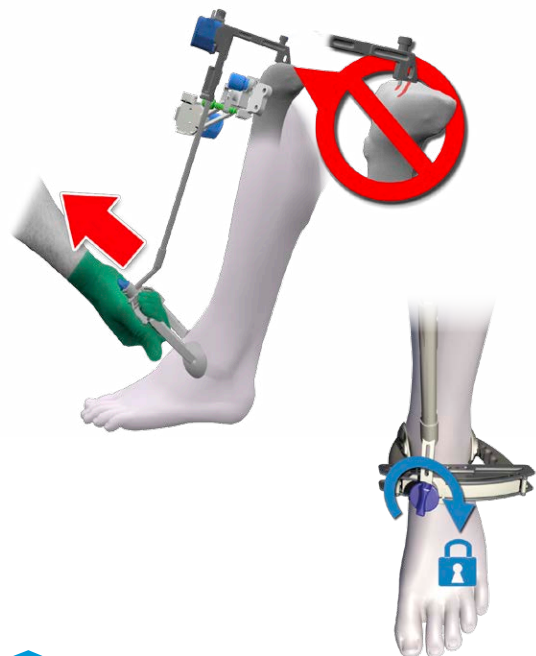


Figure 3.14 Tibia Registration (Continued)



## 4. Post-Operative Guide

### 4.1 Retrieve Surgical Procedures Archives

The System Controller Computer has an archiving function to retrieve previous surgical procedure logs.

1. Insert a USB key (must be FAT32 or NTFS format) in the USB port of the System Controller Computer.

*Note: Password protected USB keys are not supported by the System Controller Computer.*

2. On the main screen of the System Controller Computer, click on the “System Utilities” tab.
3. Click on the “Copy Logs” button.

*Note: The “Copy Logs” button will not be available until a valid USB key is connected to the system.*

4. The system will copy the logs on the USB key and will inform the user when the archiving is successful.

### 4.2 Activate the Field Issue Recorder

The Field Issue Recorder is a utility that extracts useful data for the investigation of anomalies.

1. On the main screen of the System Controller Computer, click on the “System Utilities” tab.
2. Click on the “System” button.
3. Press “OK” on the pop-up “Are you sure you want to switch to maintenance mode?”
4. In the Maintenance mode, launch the Field Issue Recorder program and follow the instructions.

### 4.3 Shut Down the System Controller Computer

1. Exit all applications in use, if any.
2. Click on the “Shutdown” button.
3. Or press the power button (red button) located on the top left hand corner of the System Controller Computer.
4. Confirm by clicking the “OK” button.



#### WARNING

*Do not unplug the power cord from the computer 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.*

## 5. Equipment Inventory and Cleaning/Sterilization Methods

Section 5.2 lists the instruments supplied by Zimmer CAS and describes the sterilization methods recommended for each instrument. Re-usable 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, re-usable instruments require manual cleaning steps as follows: all multi-components instruments should be disassembled and pre-soaked in an enzyme solution followed by scrubbing with a soft bristle brush to remove all visible soil. Use a water jet to flush difficult to access areas and closely mated surfaces. For threaded interfaces, screw/unscrew components while flushing the areas. Ultrasound cleaning (Sonication) in an enzyme solution is recommended thereafter in all cases to complete the cleaning steps, with minimum cycle times of five minutes and, for those instruments with difficult to access areas, cycle times of at least 10 minutes.

Following these steps, in all cases a thorough rinse is required thereafter. Screws and other mechanisms should be checked and lubricated with a medical grade surgical lubricant normally after each cleaning as determined upon inspection. The above instructions that are instrument type dependent are indicated in section 5.2 as applicable to each instrument.



### WARNING

*Before every surgery, the user must verify that all instruments have been sterilized.*

### 5.1 Sterilization Parameters

#### Steam Sterilization (Autoclave)

Cycle Type	Temperature <sup>1</sup>	Exposure Time <sup>1</sup>	Minimum Dry Time <sup>2</sup>	Minimum Cool Time <sup>3</sup>
Pre-Vacuum	132 °C (270 °F)	4 minutes	30 minutes	30 minutes

<sup>1</sup> Both the given cycle temperature and time can be increased to 134°C + 3°C (273.2°F + 5.4°F) and 18 minutes according to local requirements outside of the United States such as in the European Union.

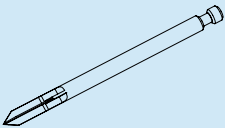
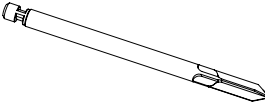
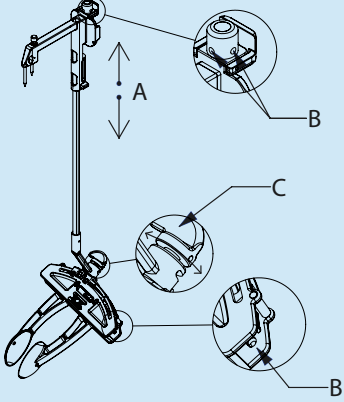

<sup>2</sup> Drying times vary according to load size and should be increased for larger loads.



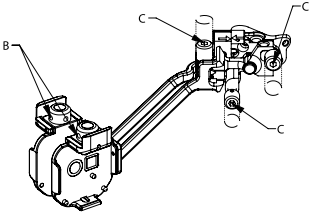
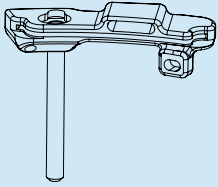

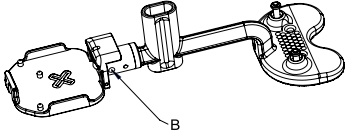
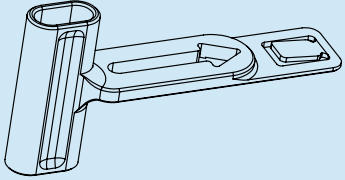
<sup>3</sup> Cooling times vary according to the type of sterilizer used, device design, temperature and humidity of ambient environment, and type of packaging used. Cooling process should comply with ANSI/AAMI ST79.

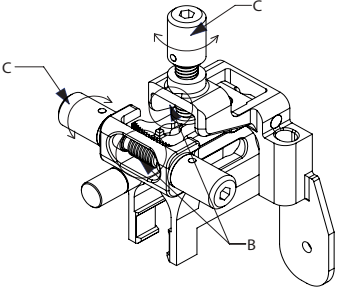
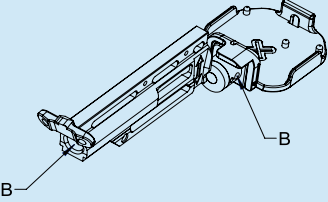

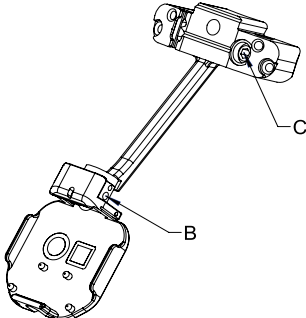

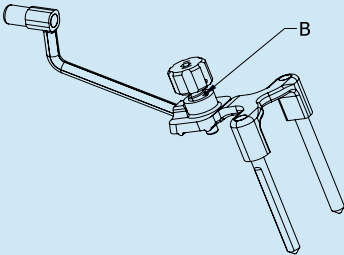
## 5.2 iASSIST Knee Master Instruments Kit

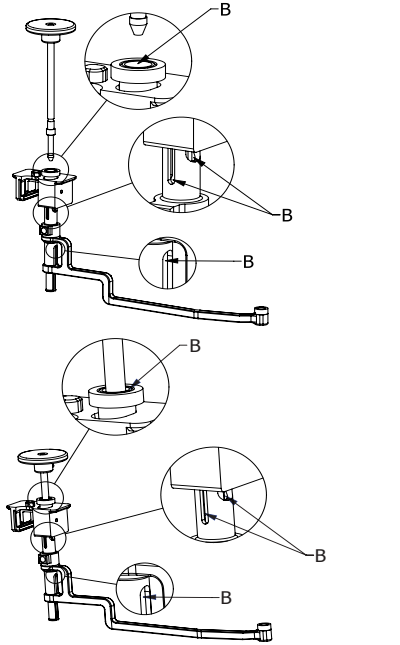
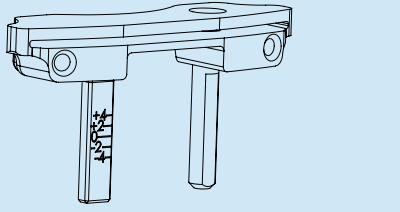
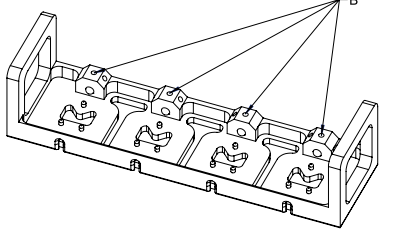
Additional specific cleaning instructions as defined in the text are indicated as applicable to each instrument as follows:

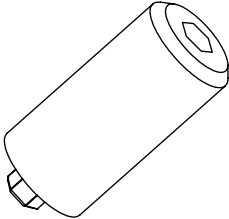
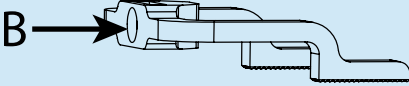
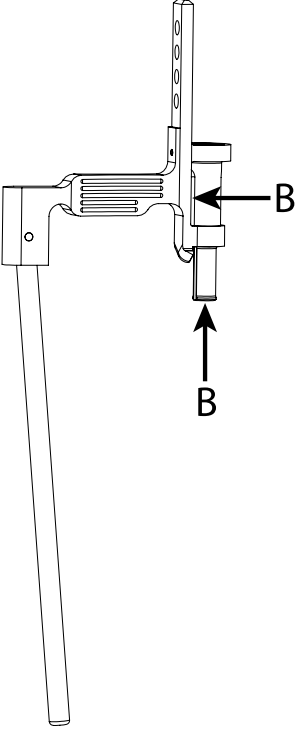
- A. Requires disassembly.
- B. Requires water jet to flush difficult to access areas.
- C. Screw/unscrew components while flushing the area.
- D. Requires a minimum of 10 minutes ultrasonic cleaning cycle in an enzymatic solution.
- E. Screws/mechanisms should be checked and lubricated with a medical grade surgical lubricant normally after each cleaning as determined upon inspection.

Catalog No.	Instrument	Qty	Sterilization and specific cleaning instructions	Additional Notes
20-8000-010-27	CAS Small Spike 7.9 mm 	1	Autoclave	Manuf. No. 108.108
20-8011-051-00	Femoral Spike 	1	Autoclave	
20-8000-013-00	Tibial Alignment Guide 	1	Autoclave Additional specific cleaning requirements: A-B-C-D-E	

Catalog No.	Instrument	Qty	Sterilization and specific cleaning instructions	Additional Notes
20-8011-017-00 20-8011-018-00	Tibial Left Adjustment Mechanism Tibial Right Adjustment Mechanism (Left instrument displayed)	1	Autoclave Additional specific cleaning requirements: B-C-D-E	Front Side  Back Side 
				
20-8011-019-00 20-8011-020-00	Tibial Left Cut Guide Tibial Right Cut Guide (Left instrument displayed)	1	Autoclave	Cut guides are compatible with saw blades of 1.27 mm (0.05") thickness
				
20-8011-021-00	Validation Tool	1	Autoclave Additional specific cleaning requirements: B-D	
				
20-8011-022-00	Alignment Arch	1	Autoclave	
				

Catalog No.	Instrument	Qty	Sterilization and specific cleaning instructions	Additional Notes
20-8011-025-00	Femoral Adjustment Mechanism 	1	Autoclave Additional specific cleaning requirements: B-C-D-E	
20-8011-026-00	Femoral Reference 	1	Autoclave Additional specific cleaning requirements: B-D	
20-8011-027-00	Femoral Distal Cut Guide 	1	Autoclave Additional specific cleaning requirements: B-C-D-E	
20-8011-028-00	Femoral AP Slider 	1	Autoclave Additional specific cleaning requirements: B	

Catalog No.	Instrument	Qty	Sterilization and specific cleaning instructions	Additional Notes
20-8011-040-00 20-8011-041-00	Tibial Left Positioner Tibial Right Positioner (Left instrument displayed)	1	Autoclave Additional specific cleaning requirements: A-B-C-D-E	
				
20-8011-042-00	Femoral Saw Slot	1	Autoclave	Saw slot is compatible with saw blades of 1.27 mm (0.05") thickness
				
20-8011-048-00	Pod Calibration Jig	1	Autoclave Additional specific cleaning requirements: B-D	
				





Catalog No.	Instrument	Qty	Sterilization and specific cleaning instructions	Additional Notes
20-8011-050-00	3.5 mm Hex Head Knob 	1	Autoclave	Optional
20-8011-056-51	Tibial Aligner - Upper Assembly 	1	Autoclave  Additional specific cleaning requirements: B-D	
20-8011-056-52	Tibial Aligner - Lower Assembly 	1	Autoclave  Additional specific cleaning requirements: B-D	

**WARNING**

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



### 5.3 Disposables

Catalog No.	Instrument	Qty	Sterilization and specific cleaning instructions	Additional Notes
20-8011-002-00	iASSIST Knee 2-Pod Kit	1	Not Applicable (provided sterile (ETO), do not re-sterilize)	Single use Provided sterile 
20-8000-000-18	3.5 mm Hex Head Screw x 38mm	4	Autoclave for first use	Single use Provided non-sterile 
20-8000-000-16	3.2 mm Headless Trocar Drill Pin x 1 <sup>(a)</sup>	4	Autoclave for first use	Single use Provided non-sterile 
00-5901-020-00	Headless trocar drill pin, 75 mm <sup>(a)</sup> Note: This pin is manufactured by Zimmer (not Zimmer CAS). It should be ordered directly from Zimmer.	4	See package insert for re-sterilization instructions if permissible	Single use Provided sterile 

<sup>(a)</sup> These pins are equivalent in material and dimensions.



#### WARNING

Do not use pins or any other fasteners than those recommended above.

### 5.4 System Controller Kit

Before cleaning the System Controller Computer, always unplug computer from the AC power outlet to prevent electrical shocks.

Use ready to use surface disinfectant wipes (for example *Accel*<sup>™</sup> TB Wipes) for cleaning/disinfection. Carefully wipe all surfaces of the System Controller Computer including the touch screen if necessary.

Do not use aerosols, solvents, strong detergents, or corrosive products. Never allow water or other liquids to enter the computer since this may cause subsequent short-circuits or corrosion.



#### WARNING

Disinfecting computer equipment with sprays is not recommended since the vapor can enter the equipment which may cause electrical short-circuits or corrosion.

Catalog No.	Hardware	Qty	Cleaning Instructions
20-8011-070-01	System Controller Computer	1	See above
20-8011-070-02	System Controller Power Supply	1	See above
20-8011-070-04	System Controller Carrying Case	1	See above
20-8011-070-08	System Controller Shipping Case	1	See above

## 5.5 General Equipment Information



### WARNINGS

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

- a. The equipment is not functioning properly nor functioning as per instructions;
- b. The System Controller Computer or the instruments have obvious/visible signs of breakage or fatigue;
- c. The System Controller Computer or the instruments have been dropped and are damaged;
- d. Liquid has entered the System Controller Computer;
- e. The power cord or plug is damaged; or
- f. If the date and time function of the System Controller Computer 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.

### 5.5.1 System Controller Kit

The System Controller Computer has an internal battery that allows three hours of autonomy. This power backup is provided to prevent data loss if there is a main power outage.

If the System Controller Computer needs to be shipped with a carrier, place the System Controller Carrying Case in the System Controller Shipping Case. The shipping case is specifically designed to withstand carrier shipping conditions.

The expected life of the computer under normal usage conditions is five years.



### WARNINGS

*Never open the System Controller Computer. The computer does not contain replaceable parts. For safety reasons, only qualified service personnel should open the equipment.*

*Protect the System Controller Computer from overheating. The openings on the enclosure are for ventilation purpose. Do not block the openings.*

*Never insert foreign objects in the System Controller Computer openings. This may cause electric shock or fire, or it may damage hardware components.*

*Make sure the computer is properly shutdown before closing the System Controller Carrying Case. If not, the system may overheat and be damaged.*

*The System Controller Computer must never be submerged in water or exposed to high level of humidity.*

*Do not leave the System Controller Computer in an uncontrolled environment where the storage temperature is below -20°C (-4°F) or above 70°C (158°F). This may damage the equipment.*

*Make sure that no objects, including wires, are left on the System Controller Computer screen when closing the System Controller Carrying Case. Any objects on the computer screen may damage it during transportation or storage.*

*The System Controller Computer should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the computer should be observed to verify normal operation in the configuration in which it will be used.*

*For safety reasons, the System Controller Computer must be sent to repair if the battery capacity is significantly reduced.*

*Because of risks related to lithium battery explosion, the System Controller Computer should not be exposed to extreme heat.*

*Do not use or store the System Controller Computer near a source of heat or dust.*

*Do not use another power supply, or cables other than the one provided.*

*Make sure that the power cord provided with the computer 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.*

### Volume Adjustment

To adjust the volume, press:

- Fn + Down arrow to decrease the volume level.
- Fn + Up arrow to increase the volume level.

### Brightness Adjustment

To adjust the LCD brightness press:

- Fn + Arrow left key to decrease the brightness.
- Fn + Arrow right key to increase brightness.

### Touchscreen Calibration

If the system touch screen gets de-calibrated, please call customer support for assistance.

### Stylus

The System Controller Computer is equipped with a stylus allowing users to precisely press on the display without fingerprints. The stylus is attached to the rear casing on the computer.

#### 5.5.2 iASSIST Knee 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.



### WARNINGS

*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 until the power button is depressed. Once depressed, the power button will seal the inner compartment of the Pod.*

*The Pods can be washed using distilled water. 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.*

### 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 re-scan the barcode, which will re-initialize the RF session allowing lost Pods to reconnect the computer.

### Pods User Interface

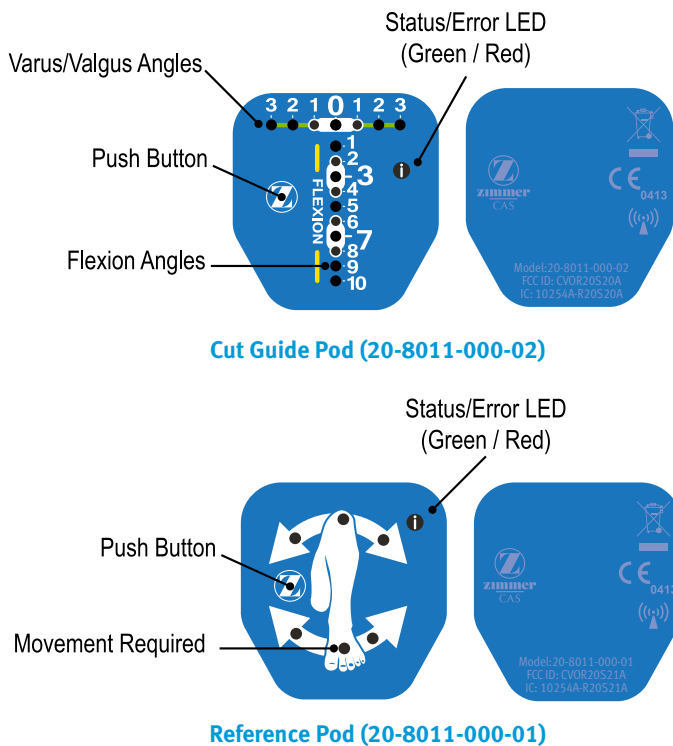


Figure 5.1 Pods User Interface

### Pod Battery

Battery life indication is visible on the Pod and in the “Pod Status Bar” on the System Controller Computer screen.

Status/Error LED Indication	System Controller Computer Indication	Required Action
Solid green	Pod battery icon is green	No action needed. Continue surgery.
Blinking red	Pod battery icon is orange	No action needed. Battery may end of life within the next 30 minutes.
Solid red	Pod battery icon is red	Battery end of life. Consider opening a new <i>iASSIST</i> Knee Pod Kit or switching to conventional instrumentation.

### Pod Replacement during a Procedure

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

1. Use another *iASSIST* Knee 2-Pod Kit.
2. Scan the 2D barcode located on the *iASSIST* Knee Pod Kit.
3. Open the *iASSIST* Knee Pod Kit, power-on each of the new Pods.
4. Once all the Pods have joined the network, perform the intra-operative calibration as described in section 3.1 “Powering-On Pods and Intra-Operative Calibration”.
5. Once the new Pods are calibrated, discard the drained or contaminated Pod and replace it by the same type of Pod from the 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 Pod to the instrument).
6. Continue the surgical procedure where it was stopped to replace the drained Pod.

### Pod Battery Disposal

The Pods contain batteries that require safe handling. They may leak or explode 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.

For Europe 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 the battery safe removal to waste disposal is also possible but requires special decontamination steps as follow:

For safe battery removal at end-of-life by a waste treatment facility, infected units should be de-contaminated as per hospital procedure. However lithium 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. The following steps are recommended:

1. The Pod outer surfaces are first wiped down.
2. Remove the back cover (flexible) from the Pod. Separate a corner or side of the back cover from the body using a flat screwdriver to allow peeling off the complete back cover in order to expose the undersurface. The exposed opening of the undersurface will allow the inner portions of the Pod to be exposed to the sterilization gas for safe disposal per the following step.

3. Expose the Pod to an Ethylene Oxide (ETO) sterilization cycle per the following parameters:
  - a. Preconditioning set points:
    - Temperature: 55°C
    - Relative Humidity: 55%
    - Vacuum set point: 2.61 pounds per square inch
    - Preconditioning time: 30 minutes
  - b. Exposure:
    - Temperature: 55 °C
    - Relative Humidity: 55%
    - EO gas concentration: 725 mg/L
    - 100% EO gas
    - Gas Exposure time: 60 minutes
  - c. Aeration:
    - Aeration time: 8 hours
    - Aeration temperature: 51-59°C
4. Send the Pod to the treatment facility identifiable on Zimmer web site: <http://www.weee.zimmer.eu>

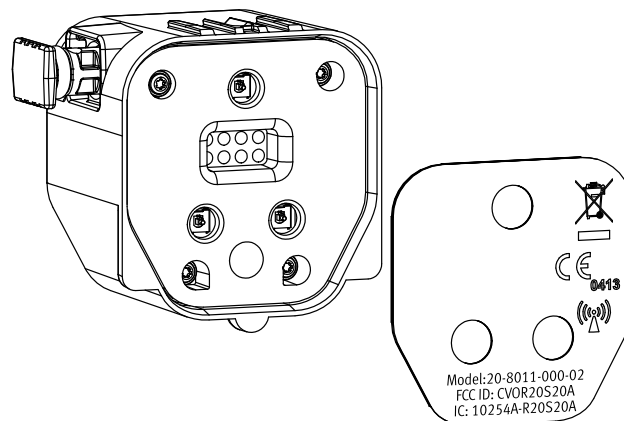


Figure 5.2 Pod Battery Disposal

## 5.6 Product Specifications and Regulatory Notices

### 5.6.1 System Controller Kit

#### Specifications

- Weight: About 1.9 kg
- Dimensions: 273.5 mm x 207.5 mm x 36 mm (irregular)
- Power: 100-240 VA, 47-63 Hz, 1.22-0.68 A
- Operating conditions: 0°C to 50°C
- Transport/storage condition: -20°C to 70°C
- User devices: Touch screen, 2D barcode scanner

#### Wireless Communications

The System Controller Computer (20-80011-070-01) contains 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



#### WARNINGS

*The System Controller Computer 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 System Controller Computer.*

#### FCC Notice

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. 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.

## Guidance and Manufacturer's Declaration

Table 5.1

Guidance and Manufacturer's Declaration - ELECTROMAGNETIC EMISSIONS		
The System Controller Computer is intended for use in the electromagnetic environment specified below. The customer or the user of the System Controller Computer should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The System Controller 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 B	The System Controller Computer is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class D	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 5.2

Guidance and Manufacturer's Declaration - ELECTROMAGNETIC IMMUNITY			
The System Controller Computer is intended for use in the electromagnetic environment specified below. The customer or the user of the System Controller Computer should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst- IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	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	< 5 % $U_T$ (> 95 % dip in $U_p$ ) for 0.5 cycle  40 % $U_T$ (60 % dip in $U_p$ ) for 5 cycles  70 % $U_T$ (30 % dip in $U_p$ ) for 25 cycles  < 5 % $U_T$ (> 95 % dip in $U_p$ ) for 5 s	< 5 % $U_T$ (> 95 % dip in $U_p$ ) for 0.5 cycle  40 % $U_T$ (60 % dip in $U_p$ ) for 5 cycles  70 % $U_T$ (30 % dip in $U_p$ ) for 25 cycles  < 5 % $U_T$ (> 95 % dip in $U_p$ ) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the System Controller Computer requires continued operation during power mains interruptions, it is recommended that the System Controller Computer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	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 a.c. mains voltage prior to application of the test level.

Table 5.3


Guidance and Manufacturer's Declaration - ELECTROMAGNETIC IMMUNITY			
The System Controller Computer is intended for use in the electromagnetic environment specified below. The customer or the user of the System Controller Computer should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601	Compliance level	Electromagnetic environment – guidance
			<p>Portable and mobile RF communications equipment should be used no closer to any part of the System Controller Computer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance:</b></p>
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d=1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d=1.2 \sqrt{P}$ 80 to 800 MHz $d=2.3 \sqrt{P}$ 800 MHz to 2,5 GHz
			<p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup>, should be less than the compliance level in each frequency range<sup>b</sup>.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the System Controller is used exceeds the applicable RF compliance level above, the System Controller should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the System Controller.			
<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			



Table 5.4

<b>Recommended separation distances between portable and mobile RF communications equipment and the System Controller Computer</b>			
The System Controller Computer is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System Controller Computer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System Controller Computer as recommended below, according to the maximum output power of the communications equipment.			
<b>Rated maximum output power of transmitter W</b>	<b>Separation distance according to frequency of transmitter m</b>		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

**NOTE 1** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

### 5.6.2 iASSIST Knee Pod Kit

#### Specifications

- Weight: 35 g
- Size: 41.75 mm x 38 mm x 28.7 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 comply with IPx7 standard to protect against the effects of temporary immersion in water.

#### Wireless Communications

The Pods contain 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



#### WARNINGS

*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 System Controller Computer.*

#### FCC Notice

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. 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.

## Guidance and Manufacturer's Declarations

Table 5.5

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.  The Pods are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 5.6

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 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % $U_T$ (> 95 % dip in $U_p$ ) for 0.5 cycle  40 % $U_T$ (60 % dip in $U_p$ ) for 5 cycles  70 % $U_T$ (30 % dip in $U_p$ ) for 25 cycles  < 5 % $U_T$ (> 95 % dip in $U_p$ ) for 5 s	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	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 a.c. mains voltage prior to application of the test level.*

Table 5.7











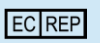






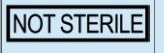


Guidance and Manufacturer's Declaration – ELECTROMAGNETIC IMMUNITY			
The Pods are intended for use in the electromagnetic environment specified below. The customer or the user of the Pods should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Pods than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance:</b>
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	$d=1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d=1.2 \sqrt{P}$ 80 to 800 MHz $d=2.3 \sqrt{P}$ 800 MHz to 2,5 GHz
			where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> , should be less than the compliance level in each frequency range <sup>b</sup> .  Interference may occur in the vicinity of equipment marked with the following symbol: 
<b>NOTE 1</b> At 80 MHz and 800 MHz, the higher frequency range applies.			
<b>NOTE 2</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Pods are used exceeds the applicable RF compliance level above, the Pods should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Pods.			
<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 5.8

<b>Recommended separation distances between portable and mobile RF communications equipment and the Pods</b>			
The Pods are intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pods can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pods as recommended below, according to the maximum output power of the communications equipment.			
<b>Rated maximum output power of transmitter W</b>	<b>Separation distance according to frequency of transmitter m</b>		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
<i>NOTE 1</i> At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
<i>NOTE 2</i> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

## 5.7 Symbols and Icons

	Symbol for “Disposal of WEEE (Waste Electrical and Electronic Equipment)” In the EU, refer to <a href="http://www.weee.zimmer.eu">www.weee.zimmer.eu</a> for information.		Symbol for “Do not re-sterilize”
	Symbol for “Caution, consult operating instructions for use”		Symbol for “To be used by... (Year, Month)”
<b>IPN<sub>1</sub>N<sub>2</sub></b>	Symbol for “Protection against harmful ingress of water or particulate matter”		Symbol for “Intentional Emitter of Non-Ionizing Radiation”
	Symbol for “Manufacturer”		Symbol for “Do Not Drop”
	Symbol indicating the “date of manufacture”		UL Classification Mark
	Symbol for “Authorized EC Representative”		ETL Classification Mark
	Symbol for “Quantity”		Certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission
<b>R<sub>x</sub>only</b>	Symbol for “Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.”		Product is made of recyclable material
	Symbol for “Sterile” and “Sterilized using ethylene oxide gas”		C-Tick compliant
	Symbol for “Contents packed without sterilization”		Comply with Restriction of Hazardous Substances Directive
	Symbol for “Not to be reused”		European Conformity



## 6. General & Contact Information

### 6.1.1 General Information

**Caution**

Federal (U.S.) law restricts this device to sale by or on the order of a physician.

**Warnings**

The warnings included in this guide are intended for trained iASSIST Knee System users.



### 6.1.2 Manufacturer

**Zimmer CAS**

75, Queen Street, Suite 3300  
Montreal (Quebec) H3C 2N6  
CANADA  
Tel: 1 (514) 395-8883  
Fax: 1 (514) 878-3801

Web site: [www.zimmer.com](http://www.zimmer.com)

### 6.1.3 EC Representative

**Zimmer U.K. Ltd.**

9 Lancaster Place  
South Marston Park  
Swindon, SN3 4FP, UK

### 6.1.4 Customer Support

Phone number: 1 (514) 395-8883  
US toll free phone number: 1 (866) 336-7846  
7:00 AM to 5:00 PM EST

Outside business hours, contact your local Zimmer office for support.

*Note: Accel™ is a trademark of Virox Technologies Inc.*





### **Disclaimer**

This documentation is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part. Please refer to the package inserts for important product information, including, but not limited to, contraindications, warnings, precautions, and adverse effects.

The CE mark is only valid if it is also printed on the product label.

Contact your Zimmer representative or visit us at [www.zimmer.com](http://www.zimmer.com)

