SmartTools Knee

User Guide & Surgical Technique

Rev A draft

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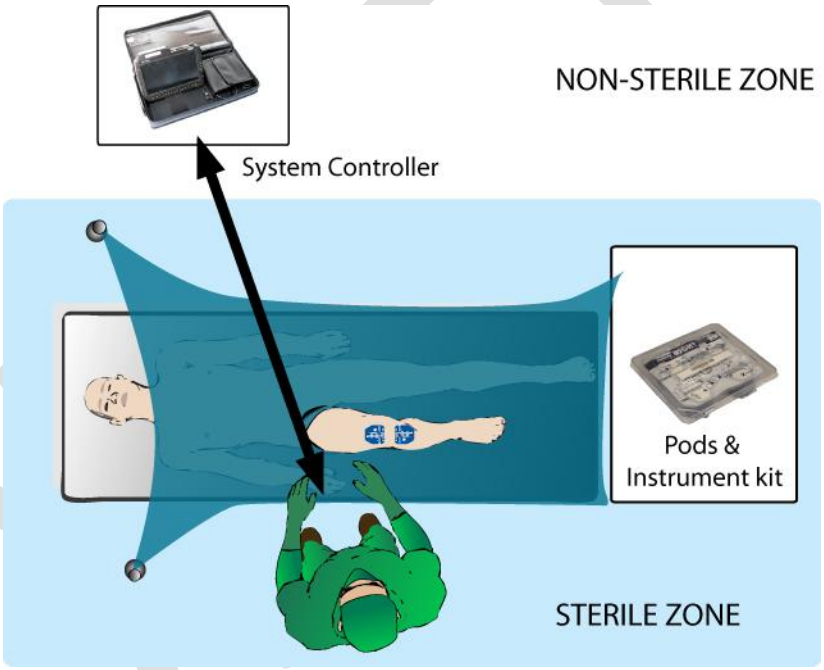
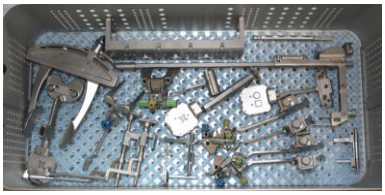
1. Overview

1.1 Indication for use

The Smart Tools 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 version SmartTools Knee systems is for Total Knee Arthroplasty.

1.2 System Overview



Principal components	Description
CAS Smart Tools Master Knee Instrument kit [KT-8011-010-01] 	**Smart Tools Master Knee Instrument kit**: reusable metal instruments are used to align the cut guides based on the alignment output provided by the Pods. Also, cut guides are designed to support comparison with conventional instrumentation.
Smart Tools Knee Pod Kit	When assembled with the instruments, the Pods are used to

Principal components	Description
[20-8011-049-00] 	provide alignment information. This allows computing the instrument orientations with respect to the bone. One Smart Tools Knee Pod Kit is required for each procedure. **Highlights:** • Single use, Disposable Pods x 4 (sterile use) • Wireless communication radio • Battery powered (up to 2 hours) • Inertial Sensors
System Controller Kit [KT-8011-070-01] 	The System Controller (non-sterile) is a computer system used to controls the flow of the procedure via wireless communication with the PODs. The System Controller is intended to be used by nurse or Zimmer Representative.

⚠	The procedure is to be performed in an operating room with a temperature ranging from 18°C to 30°C (59°F to 86°F). Pods shall be stored at 20 deg minimum before being brought in the OR.
⚠	After powering up the Pods, wait for at least 5 min before starting the intra-op calibration
⚠	In the following event occurs, the Navigation Application must be stopped and restarted with a new Smart Tools Knee Pod Kit [20-8011-049-00], or the user may revert to continuing the procedure with standard instrumentation: - If a Pod is dropped on the floor or is no longer sterile, - If a Pod battery reaches its end of life before the end of the procedure
⚠	Ensure that one Smart Tools Knee Pod Kit [20-8011-049-00] will be used per operated leg. User must close and restart the application with another Smart Tools Knee Pod Kit [20-8011-049-00] before operating another leg.
⚠	No modification of this “Smart Tools Knee System” equipment is allowed.

1.3 Implant indications

The knee implant, implanted with the Smart Tools Knee System, must be used in accordance with the appropriate package insert labeling.

The operation should be performed in accordance with the corresponding Surgical Technique published by the manufacturer for the specific implant.

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

1.4 Contraindications

Clinical

Zimmer CAS surgical navigation system should not be used:

1. In cases of hip pathology severely limiting its range of motion (e.g. arthodesis, severe contractures, chronic severe dislocation);
2. In cases of hip joint pathology or knee pathology with significant bone loss (e.g. evascular necrosis of the femoral head with collapse, severe dysplasia of the femoral head or the acetabulum, femoral condyle collapse); or
3. For any other contraindicated case, as given by the implant manufacturer.
4. For Total Knee Replacement in which the femoral anterior cut is performed first before the femoral distal cut.
5. For Total Knee Replacement using the Quad Sparing technique

General

Zimmer CAS surgical navigation system should not be used:

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

⚠ The current system is not compatible with the following technique: “anterior cut first on femur”.

1.5 Complications

Possible complications associated with the use of the Zimmer CAS surgical navigation system may include, but are not limited to, the following

1. Infection; and

2. 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

2.1 Computer Setup

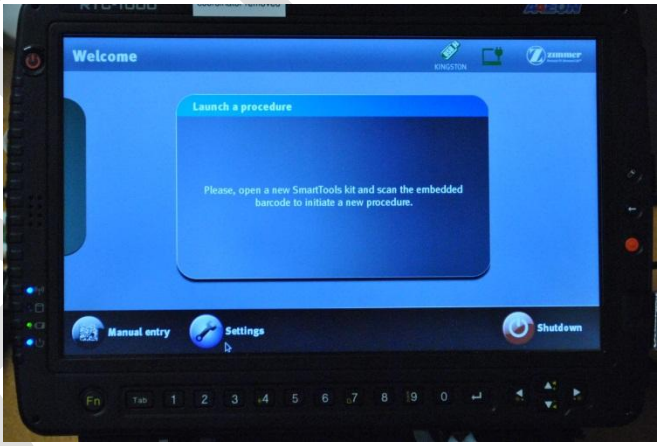
The System Controller serves to control and manage the functions of the pods. The System Controller shows system information not required by the surgeon during the surgery. It is to be placed outside of the sterile field.

⚠	During the procedure and in transport, leave the System Controller in the carrying case. The angled position of the System controller in the carrying case during use is important to maintain adequate wireless communication with the Pod sensors.
⚠	The System Controller is not intended to be used in the sterile zone.
⚠	Do not use the System Controller inside a sterile bag as it might overheat.
⚠	The System Controller is to be connected to the AC power during the entire surgery.

The figures below illustrate how to setup and power-up the System Controller:

	
1. Open the Shipping Case 2. Remove the Carrying Case from the Shipping Case	3. Place the Carrying Case on a stable flat surface outside the sterile zone 4. Open the Carrying Case
	
5. Fold the flap over and velcro it at the appropriate angle for the System Controller 6. Connect the power cord to the power supply.	7. Position the System Controller on the angled flap.

8. Connect the power cable to the computer port.
9. Connect the power cord to an AC outlet



10. Press the power button
11. Zimmer Logo will appear during boot-up.

12. Home screen will be displayed after boot-up is completed

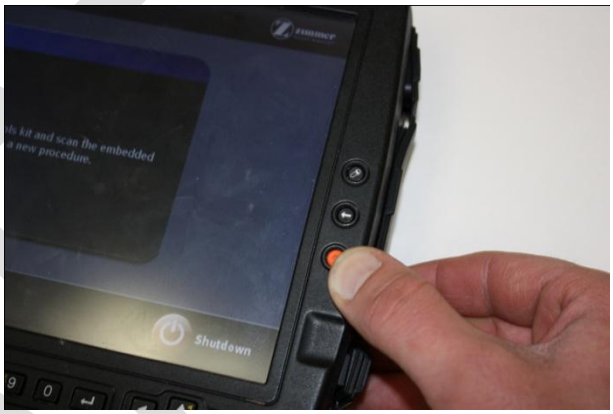
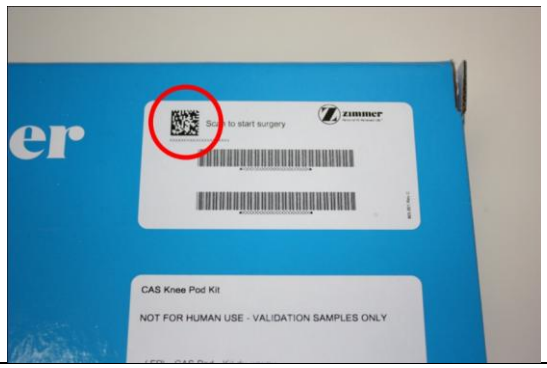
13. Place the System controller at a maximum distance of 4 meters from the Pods or the OR table.

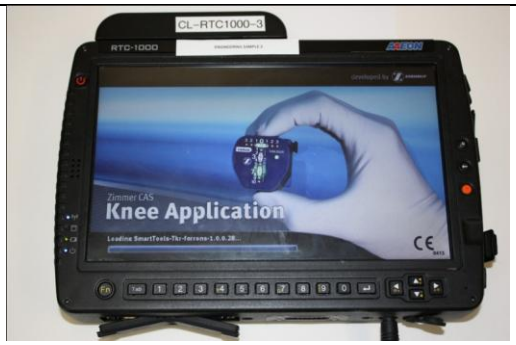
2.2 Surgical preferences and Application Launch

This section describes how to configure surgeon preferences for given navigation parameter, and how to start the navigation application with the bar code scanner.

⚠	For components provided sterile packaged, the protective packing must be checked for possible damage when opening the package before use as this could impair the sterility. The expiry date for the sterility of the product should also be verified.
⚠	While the Pods connect to the System Controller and if the “Show More” (defined into section 5.1.7) menu is displayed do not click on the “skip” button during this connection. Skipping this step

	could prevent other Pods from connecting. In this case, another Smart Tools Knee Pod Kit [20-8011-049-00] may have to be used.
⚠	After scanning and powering up the Pods, do not exit the application procedure unless the surgical procedure is ended. When exiting the application procedure, the software deactivates the single use Pods permanently. Once deactivated, the Pods cannot be restarted.
⚠	The Smart Tools Knee System does not allow replacement of Pods during a procedure. In the case the pods become no longer usable (e.g. become non-sterile from being dropped) the application must be re-started (new procedure) with a new Smart Tools Knee Pod Kit.

	
1. Click on Settings button and enter the desired targets: “Tibia Slope” and “Femur Flexion”. These settings can be modified either before or during a procedure; settings will remain in the system for preceding procedures.	2. Press and hold the barcode scanner button (orange button)
	

	
3. Align the barcode reader laser on the 2D barcode located on Smart Tools Knee Pod Kit. Note: If the 2D barcode cannot be read, the user can enter the barcode manually by activating the "Manual Entry" button in the bottom menu of the System Controller	4. When the barcode is successfully scanned, a confirmation sound will be triggered and the Smart Tools Knee application will launch. 5. Release the orange button

2.3 Pods: Power-up and Calibration

Prior to beginning the procedure, a six-step calibration is required as indicated below.

⚠	Make sure to power up the Pods not too early. Once powered on the Pods will function for approximately 2 hours.
⚠	The Pods are to be calibrated on a flat surface before surgical use, approximately horizontal. This is to ensure their intended performance.
⚠	Do not clip Pods on the Calibration Jig [20-8011-048-00] before powering them on. If this happens, unclip them before re-clipping them all and re-start the calibration.

<table>
<tr>
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<tr>
<td>1. Open the plastic tray with Pods inside</td>
<td>2. After removing the Pods from their packaging power ON each of the four (4) Pods by pressing each tab. Press until the tab is flush with the pod surface</td>
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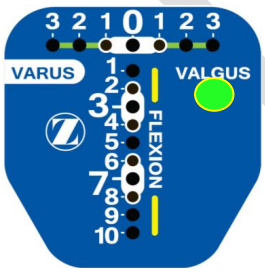
<td> 

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<tr>
<td>3. Wait for the Pods status light to start blinking green. This can also be observed on the status</td>
<td>4. Clip all Pods to the Calibration Jig [20-8011-048-00] in order to start the calibration</td>
</tr>
</table>

bar of the system controller while in 'Extended View', if the 'Show More' menu is enabled	procedure. When successfully clipped, the lights on the Pod will turn solid green
 	
5. For each of the six faces (1 to 6) of the calibration jig, orient in sequential order the Calibration Jig [20-8011-048-00] with the corresponding number on each face upward. Keep the Calibration Jig steady on the table to register a face ; the Pod Cut Guide will indicate which face is expected. Note: At each step, the expected upward face is specified on the F/E axis of both Pod cut guides	6. When the calibration is completed, the Pods will blink green. 7. Unclip and remove all Pods from the Calibration Jig [20-8011-048-00].

2.4 Instrumentation assembly

The following steps can be carried out in preparation for the procedure.

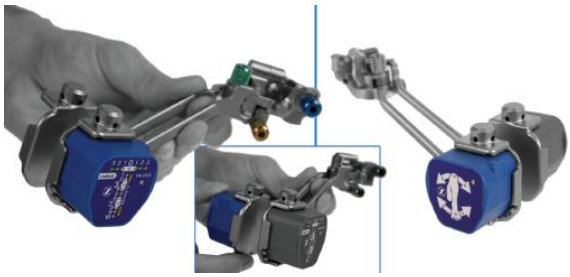
⚠ No POD should be left unclipped. A POD should always be clipped to an instrument, whether or not in use.

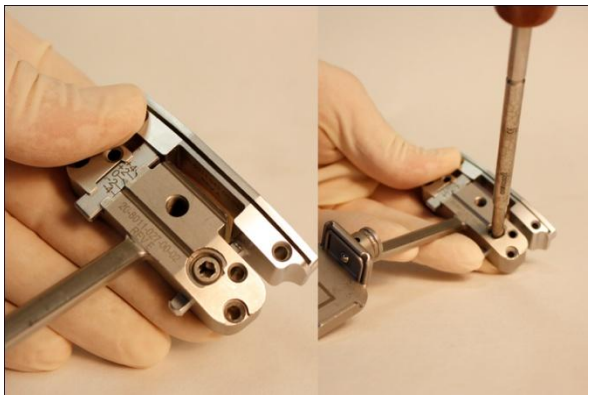
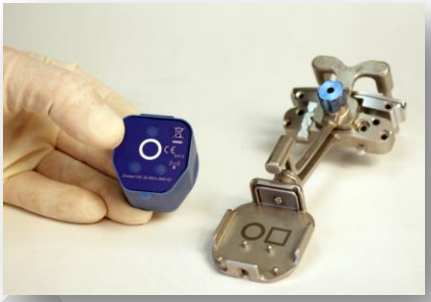
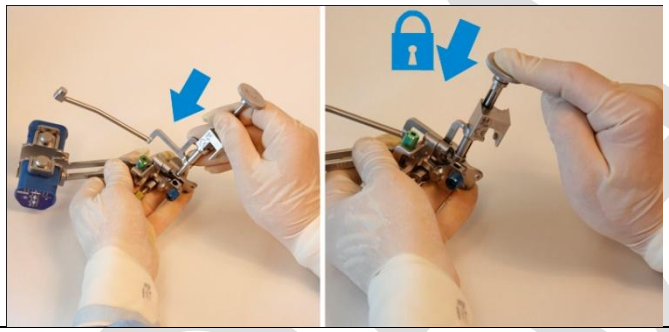
2.4.1 General introduction on how to connect a Pod to an instrument

Follow the preceding steps to connect a Pod to an instrument. Disassemble the Pods by reversing the steps.

	
1. When inserting the Pod, keep the interface facing upwards. 2. Look for the tab when inserting the Pod. Begin by inserting the tab in the matching slot.	3. Clip the other side of the Pod on the instrument until the spring holder engages. Note: The system will automatically monitor improper physical connections between the Pods and the instruments

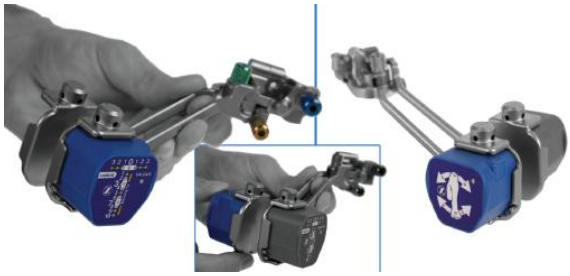
2.4.2 Instrument Assembly for Tibia Cut First

	
1. Clip 1 x reference Pod (identifiable with a cross 'X' on the back cover) on the Tibial Alignment Guide [20-8011-013-00]	2. Clip 2x Pods (one cut guide and one reference) on Tibial Left or Right Adjustment mechanism (left: 20-8011-017-00, or right: 20-8011-017-00), depending on operating leg. ⚠ For **Tibia Right**, use the Pod identified by a **square** ⚠ For **Tibia Left**, use the Pod identified by a

	circle
	
3. Insert the Femoral Saw Slot [20-8011-042-00] into the Femoral Distal Cut Guide [20-8011-027-00] 4. Tighten it with the 3.5 mm hex screw driver	5. Clip 1x cut guide Pod on the Femoral Distal Cut Guide [20-8011-027-00] Before executing this step, **only one POD should remain available** with either the circle or square symbol
	
6. Pull the handle of the Tibial Positioner (right - 20-8011-041-00- or left -20-8011-040-00-depending on the operated leg) 7. Clip the Tibial Positioner into the Tibial Adjustment Mechanism (left: 20-8011-017-00, or right: 20-8011-017-00). 8. Push on the Tibial Positioner to lock the mechanism	

2.4.3 Instrumentation Assembly for Femur Cut First

1. Clip 1x reference Pod (identified with a cross 'X' on the back cover) on the Femoral Reference [20-8011-026-00]



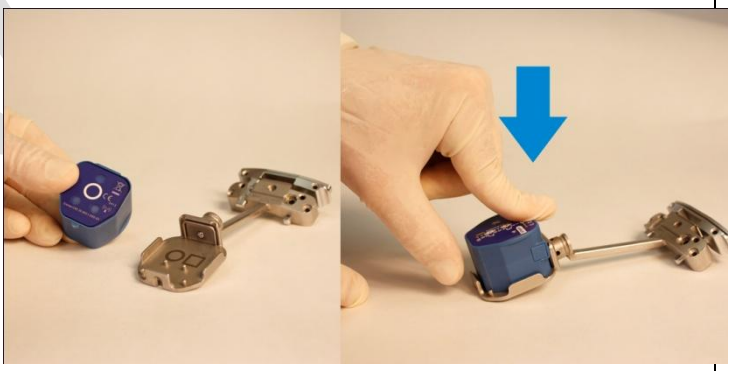
2. Clip 2x Pods (one cute guide and one reference) on Tibial Left or Right Adjustment mechanism (left: 20-8011-017-00, or right: 20-8011-017-00), depending on the operated leg

⚠ For **Tibia Right**, use the Pod identified by a **square**

⚠ For **Tibia Left**, use the Pod identified by a **circle**

Note: The Tibial Adjustment Mechanism (left: 20-8011-017-00 or right: 20-8011-017-00) is used even during the Distal Femoral Cut because the system uses this instrument to detect the patient side

9. Insert the Femoral Saw Slot [20-8011-042-00] into the Femoral Distal Cut Guide [20-8011-027-00]
10. Tighten it with a 3.5 mm hex screw driver (4812-45 or equivalent)



11. Clip 1x cut guide Pod on Femoral Distal Cut Guide [20-8011-027-00]

Before executing this step, **only one POD should remain available** with either the circle or square marking

	
3. Assemble the Femoral AP Slider [20-8011-028-00] with the Femoral Distal Cut Guide [20-8011-027-00] Lightly tighten the blue screw	

3. Intra-Operative Guide

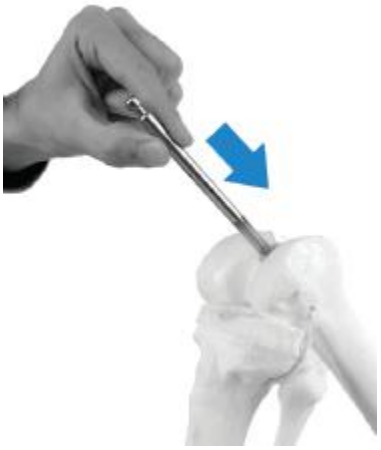
⚠	After wrapping / preparing the ankle, surgeon should still be able to palpate the malleoli.
⚠	Shoulder screw of the Cut Guide has to be inserted carefully to avoid piercing through the other side of the bone
⚠	For registration and navigation readings to be accurate, the instruments must remain stable.

3.1 Distal Femur Cut

3.1.1 Femoral Landmarks

💡	To restart the femoral landmark registration, press the “Z” button on the reference Pod (marked with “X” symbol).
⚠	Placement of the Femoral Reference should be performed with care to avoid physical interference with the femoral cut guide

The following steps describe how to digitize the anatomical landmarks of the femur in both frontal and sagittal planes.



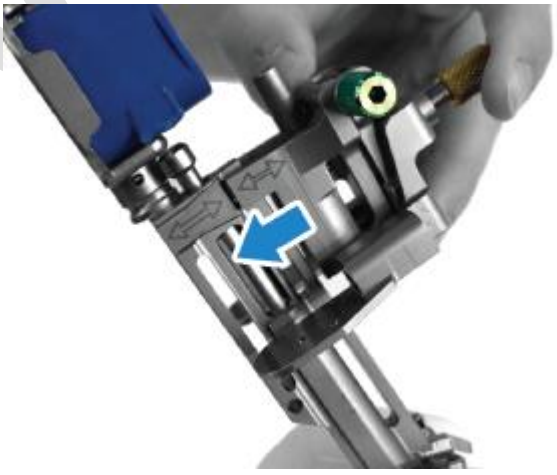
1. Break the cortex at the mechanical axis entry point with a cortex breaker or a 3.2mm drill bit (until the end of the spiked grooved, to have the spike fully down).
2. Impact the Distal Spike [108.108] into the distal femur (1-2 cm). Roughly align it in Varus/Valgus and in Flexion/Extension.

⚠ Be sure not to fixate the spike into excessive flexion or extension. Correct orientation is Parallel with the femoral sagittal plane.

3. Slide the Femoral Reference [20-8011-026-00] onto the Distal Spike [108.108]
4. Position the Femoral Reference based on Whiteside's line, Epicondyles, or Posterior Condyles to achieve desired femoral rotation.

A medio-lateral hole on the Femoral Reference can be used to insert a pin as a visual cue helping with axial rotation alignment

5. Secure the chosen axial rotation using two "3.5mm Hex head screw x 38mm" [20-8000-000-18] in the anterior fixation holes.



6. Place the Adjustment Mechanism [20-8011-025-00] on the anterior side of the Femoral Reference [20-8011-026-00] by aligning the arrows.
7. Leave the adjustment mechanism in locked position

	(away from bone) to start the registration ⚠ Do not slide the Adjustment mechanism forward at this stage as this would prevent you from acquiring femoral registration. If you have slid the Adjustment mechanism forward to the distal condyles, slide it backward until is locks in the “arrow to arrow” position

8. Move the leg by accelerating it and stopping it in a **star-shaped or circle pattern**, acquiring thirteen (13) stable positions. Visual and audible feedback will be generated after each acquisition, until completion.

This femoral registration cinematic can be achieved by going to opposite locations on the perimeter of the femur’s range of motion, in flexion-extension as well as in adduction/abduction.

Refer to the status light on POD for acquisitions. Circular display tells the user to keep on acquiring points. Audio feedback is also provided when acquisition is accepted or rejected.

⚠ Pelvis must remain immobile during femoral landmark registration process

⚠ User shall follow a star shaped or a circle shape pattern to properly register the femur.

3.1.2 Femoral Cut Guide Alignment

The following steps describe how to position the Femoral Cut Guide [20-8011-027-00] with respect to the femoral landmarks previously acquired.

Three 75 mm pins" [20-8000-000-16, or 00-5901-020-00] are to be used during this step. A recommended approach, as described below, is to use two parallel screws in the cut guide and one angular screw in the saw slot. User may decide to use an alternate approach with three screws in the cut guide (two straight and one angular).

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<tr>
<td>1. If not assembled during the pre-operative step, assemble the AP slider [20-8011-028-00] and Femoral Distal Cut Guide [20-8011-027-00]. Lock the assembly by tightening the blue screw.</td>
<td>2. Insert the two long pegs of the Cut Guide POD assembly into the Adjustment Mechanism [20-8011-025-00]
3. Slide the Adjustment Mechanism mid distance to the distal condyles</td>
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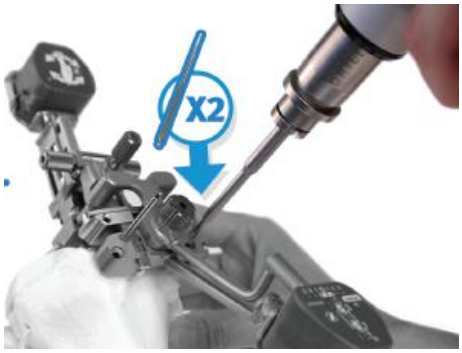
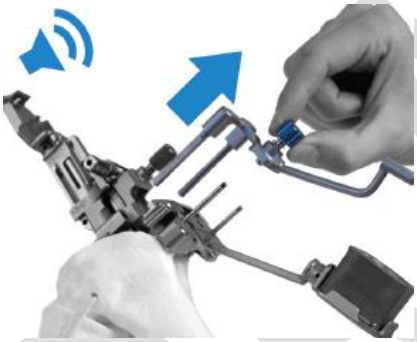
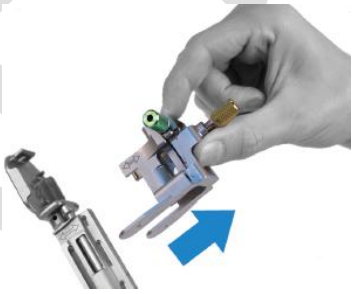
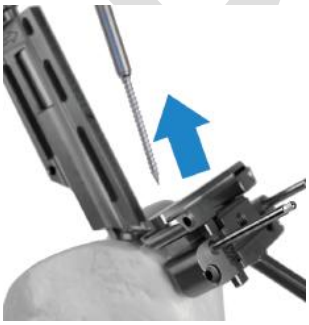
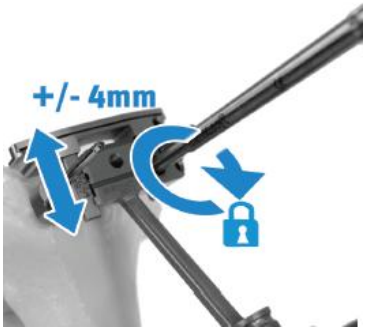
<tr>
<td>4. Follow feedback (red-green LED) and adjust Flexion/Extension and Varus/Valgus using the gold and green screws respectively.</td>
<td>5. Once 2 green lights are obtained slide the Adjustment Mechanism until fully seated to the distal condyles</td>
</tr>
</table>

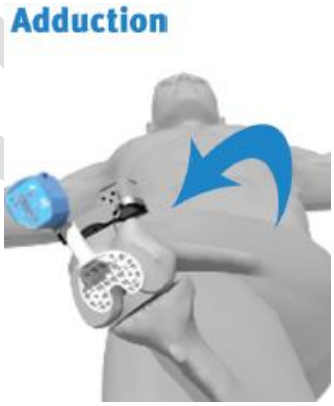
Note: Blue screw is always to lock or remove the A/P Slider	
	
6. Insert two 75mm pins (see PN section 5.1.5) in the base of the Femoral Cut Guide, with an option of two more for added stability. Both parallel and converging holes are available	7. Insert a 75mm pin to secure the Femoral Cut Slot
	
8. Unlock the AP Slider [20-8011-028-00] using the blue screw, and remove the AP Slider from the assembly 9. Wait for the audible feedback. Navigation is now complete and the femoral validation will begin.	10. Slide the Adjustment Mech. Away from the distal femur so both arrows line up again and pull it off the assembly
	
11. Remove the shouldered screw holding the Femoral Reference	13. Remove the Distal Spike [108.108] using a slap-hammer [00-5785-097-00 (NexGen) or

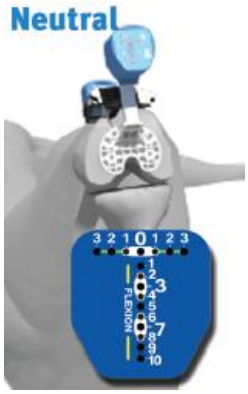
12. Remove the Femoral Reference [20-8011-026-00]	00-6290-00-015 (NKII)] Note: For an NKII technique, assemble the Slaphammer [00-6290-00-015] with the CAS Extractor Adaptor [20-8000-010-26].
	
14. Manually adjust the resection level. Note: Cutting block at the « 0 » position resects 10mm off the distal condyles. Loosen screw on the block to increase/decrease cut to +/-2 or +/-4mm.	15. Proceed to femoral resection

3.1.3 Femoral Validation

The following steps describe how to validate the distal femoral cut.

⚠	To confirm validation alignment, the Femoral Cut Guide base must not have moved up to this point.
⚠	Do not place the 4-1 into the holes created by the validation tool in case these holes do not have expected rotation / orientation. The 4-1 Posterior Referencing Sizer [00-5901-040-00] and the Validation Tool [20-8011-021-00] have the same distance between the pegs. Make sure to properly align the 4-1 Posterior Referencing Sizer in proper rotation independently of the validation tool; this may be achieved by using a pen to mark the rotation holes drilled with the PRI instrument.

	
1. Remove the Pod from the Femoral Reference (marked with "X" symbol on the back) [20-8011-026-00] and clip it onto the Validation tool [20-8011-021-00] . 2. Position the flat surface of the Validation Tool [20-8011-021-00] onto the distal cut	3. Secure the Validation Tool to the distal femur using the captive spikes or shoulder screws
	
4. From neutral position, bring the leg into abduction (laterally) until the blinking green light on the Pod of the Validation Tool [20-8011-021-00] stops blinking. Once the light becomes solid, hold the knee steady.	5. Bring the knee towards the medial side (in **adduction**) until the blinking green light on the Validation Tool stops blinking. Once the light becomes solid, hold the knee steady

	PIC
6. Bring the knee back to neutral position until the blinking green light on the Validation Tool stops blinking. Once the light becomes solid, hold the knee steady. 7. Read out the cut alignment values on the Femoral Cut Guide [20-8011-027-00]	8. Remove the Validation tool [20-8011-021-00] 9. Remove the screws which secures the Femoral Cut Guide 10. Remove the Femoral Cut Guide [20-8011-027-00] Note: A pin puller may be used to remove the pins instead of a pin driver

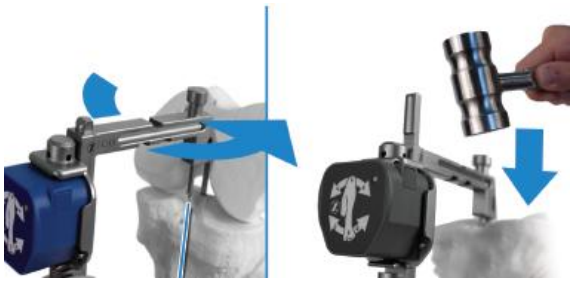
3.2 Proximal Tibial Cut

⚠ The two spikes of the Tibial Alignment Guide have to be positioned and inserted carefully in order to avoid loosening.

3.2.1 Tibial Landmarks

The following steps describe how to digitize the anatomical landmarks of the tibia in the frontal and sagittal planes.

	
1. Clip all reference Pods on the appropriate instruments, as described into section 2.4.2 . The Tibial Adjustment Mechanism (left: 20-8011-017-00, right: 20-8011-018-00) determines the patient operative side	2. Make sure that the blue knob on the Tibial Alignment Guide [20-8011-013-00] is unscrewed. 3. Position the Tibial Alignment Guide using the preset position (L or R) and adjust as needed to be parallel to the mechanical axis of the tibia.
	
4. Position the distal clamps on the palpated malleoli. The Tibial Alignment Guide is designed to be self-centering when placed around the malleoli (L or R)	5. Partially insert the longer spike into the mechanical axis entry point, without engaging the shorter spike.



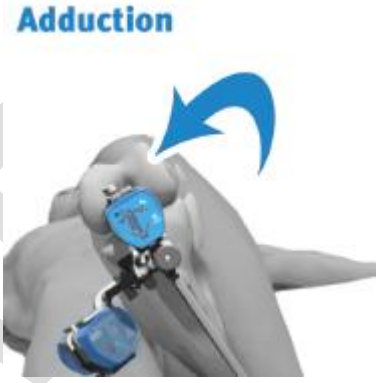
6. Orient in rotation the Tibial Alignment Guide [20-8011-013-00] to line-up with the medial one third of tubercle.
7. Impact the instrument until both spikes are fully inserted in the tibia

8. Tighten and lock the blue knob of the distal Tibial Alignment Guide while ensuring the Left/Right selector remains at the desired location.

9. Assemble the Tibial Positioner (already assembled with the Adjustment Mechanism) on the proximal end of the Tibial Alignment Guide.

10. Move the Positioner all the way down towards the bone

⚠ For a small tibia (size 1 and 2 Nexgen tibia size) the Positioner should be kept at the height of the tubercle and care must be taken to avoid any interference between the 38mm shouldered screws and the tibia spike.

11. Insert three 38mm shoulder screws [20-8000-000-18]; Control speed of the power tool or finish fixating the screws manually to avoid stripping the cortex of the tibia ⚠ Make sure that the Tibial Adjustment Mechanism (left: 20-8011-017-00, right: 20-8011-018-00) is properly fixated to the bone. ⚠ Avoid stripping the cortex of the tibia during screw insertion by controlling the speed of insertion.	12. Release the Adjustment Mechanism by pulling upwards on the Positioner handle ⚠ Both the Tibial Alignment Guide [20-8011-013-00] and the Tibial Adjustment Mechanisms must remain fixed on the bone during registration. ⚠ Make sure that Tibial Adjustment Mechanism is properly fixated to the bone before proceeding to the next steps.
	
13. From neutral position, bring the leg into abduction (laterally) until the blinking green light on the Pod of the Tibial Alignment Guide stops blinking. Once the light becomes solid, hold the knee steady.	14. Bring the knee towards the <u>medial</u> side (in adduction) until the blinking green light on the Tibial Alignment Guide stops blinking. Once the light becomes solid, hold the knee steady
	
15. Bring the knee back to neutral position until the blinking green light on the Tibial Alignment Guide stops blinking. Once the light becomes solid, hold the knee steady	16. Unlock the blue knob on the distal end of the Tibial Alignment Guide 17. Remove the Tibial Alignment Guide using a Slaphammer

	For NKII procedures, assemble the Slaphammer [00-6290-00-015] with the CAS Extractor Adaptor [20-8000-010-26].

3.2.2 Tibial Cut Guide Alignment

The following steps describe how to align the Tibial Cut Guide with respect to the tibial landmarks registered in the previous step.

1. Based on the feedback on the Pod of the Tibial Cut Guide (left: 20-8011-019-00, right: 20-8011-020-00), adjust the Flexion/Extension and Varus/Valgus angles using the gold and green screws respectively on the Tibial Adjustment Mechanism (left: 20-8011-017-00, right: 20-8011-018-00) .

2. Insert the Tibial Stylus (refer to 5.1.4 for list of compatible Stylus') in the Tibial Cut Guide (left: 20-8011-019-00, right: 20-8011-020-00), using the depth recommended per specific implant technique.

3. Insert the Tibial Cut Guide elevator rod into the Tibial Adjustment Mechanism (left: 20-8011-017-00, right: 20-8011-018-00)

Note:The NKII stylus is screwed on top of the Tibial Cut Guide.	
	
4. Palpate the deepest point on the chosen tibial plateau with the stylus to measure resection level. Lock the Tibial Cut Guide in place by turning the blue screw.	5. Secure the Tibial Cut Guide onto the tibia using either a 38mm shouldered screw on the medial side, or a 75mm pin on the lateral side (see screws PN section 5.1.5)
	
6. Remove stylus 7. Perform tibial resection	

3.2.3 Tibial Validation

The following steps describe how to validate the proximal tibial cut.

	
1. Remove the reference Pod from the Tibial	2. Position the flat surface of the Validation

<table>
<tr><td>Alignment Guide [20-8011-013-00] and clip it to the Validation Tool [20-8011-021-00].

Note: The Drop Rod (refer to section 5.1.4 for PN) may be used at this point to validate results</td><td>Tool on the tibial resection.
3. Secure the instrument to the tibia using the captive spikes and/or shouldered screws</td></tr>
<tr><td> 
</td><td> 
</td></tr>
<tr><td>4. Press on the Z-button on the Validation Tool [20-8011-021-00]to initiate the validation procedure
5. From neutral position, bring the leg into abduction (laterally) until the blinking green light on the Pod of the Validation Tool stops blinking. Once the light becomes solid, hold the knee steady</td><td>6. Bring the knee towards the <u>medial</u> side (in adduction) until the blinking green light, on the Validation Tool stops blinking. Once the light becomes solid, hold the knee steady.</td></tr>
<tr><td> 
</td><td rowspan="2">Note: After validation, if additional resection is required, press the Z button of the Pod of the Tibial Adjustment Mechanism [left: 20-8011-017-00, right: 20-8011-018-00]. This will restart the Tibial Cut Alignment step</td></tr>
<tr><td>7. Bring the knee back to neutral position until the blinking green light on the Validation Tool stops blinking. Once the light becomes solid, hold the knee steady
8. Read out the static cut alignment on the Tibial Cut Guide [left: 20-8011-019-00, right: 20-8011-020-00]</td></tr>
</table>

4. Post-Operative Guide

4.1 How to clean and disinfect the System Controller

⚠	Before cleaning the System Controller [20-8011-070-01], always unplug the System Controller from the AC power to prevent electrical shocks. Only use a damp cloth for cleaning. Do not use aerosols, solvents, or strong detergents. Never allow water or other liquids to enter the system since this may cause subsequent short-circuits or corrosion. Never use corrosive or solvent disinfectants. If doubts exist, do not use it.
⚠	Disinfecting medical equipment with sprays is not recommended since the vapor can enter the equipment which may cause electrical short-circuits or corrosion.

4.2 How to safely dispose Pod's batteries in the European Community

Since September 2008, the Batteries Directive 2006/66/EC require removing batteries from waste equipment in EU Member States. To comply with this Directive, this device has been designed for safe battery removal at end-of-life by a waste treatment facility. Infected units should be de-contaminated as per hospital procedure. Lithium battery risks (e.g.: do not expose to auto-clave) should be considered before they are sent for recycling. If it is not possible to decontaminate the Pod 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.

Decontamination before sending….the Pod sensor must be opened …. Screws etc.. and exposed to EO as follows:
------.

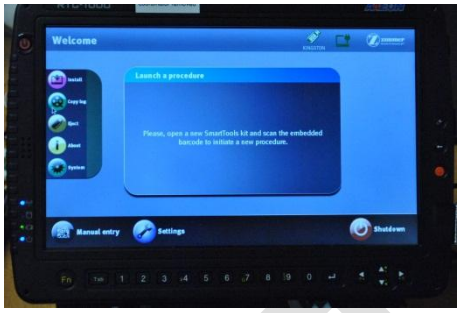
⚠	Because of risks related to lithium battery explosion, PODs shall not be submitted to extreme heat such as autoclave.
	Do not re-sterilize Pods.

4.3 How to retrieve surgical procedures archives

The System Controller [20-8011-070-01] has an archiving function to retrieve previous surgical procedure logs. When retrieving on a USB key, all logs will be copied in a single directory.

1. Make sure there is no procedure in progress

2. Insert a USB key (must be FAT32 and NTFS). Note that Password protected USB keys are not supported by the system controller.
3. Click on the “System Utilities” tab and then click on the “Copy Logs” button. 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.

4.4 How to activate the Field Issue recorder function

The Field Issue Recorder is a utility that extracts useful data for the investigation of anomalies. It transfers a file containing necessary system logs to a removable USB drive. This file can later be sent to a customer service representative for further investigations of the field issue.

The Field Issue Recorder program is located in the "Maintenance" mode. To access the maintenance mode please follow these steps:

1. Press 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.

4.5 How to record snapshots during a surgical procedure

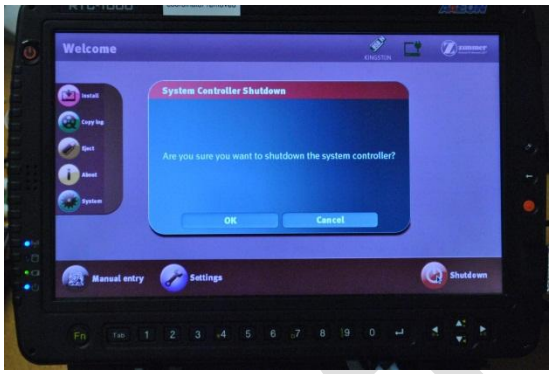
The Snapshot button can be pressed at any time during the procedure on the System Controller screen. All images will be saved in the snapshot directory found in the surgery folder of the Copy Logs option.

4.6 How to shut down the System Controller

To shut down the system controller, follow the below steps:

1. Exit current procedure, if any.
2. Click on the “System Utilities” and then on the “shutdown” button.

3. Or press the “power” button and confirm you want to exit.
4. Confirm request by clicking the Ok button



⚠ Do not unplug the power cord from the system to initiate a shutdown. The proper way to turn of the computer requires exiting all tasks and applications in use before initiating the shutdown task Improper shutdown may result in loss of data or may cause hardware damage

5. Appendices

5.1 Material information, cleaning and sterilization

The following warnings apply to all equipment included in the Smart Tools Knee system (such as surgical instruments, system controller, disposables).

⚠ If one of the following situations arises, check the equipment by a qualified service personnel:

a. The instrument or the system controller has been exposed to moisture.
b. The equipment does not work well, or you cannot get it to work as per instructions.
c. The instrument or the system controller has been dropped and damaged.
d. The equipment has obvious/visible signs of breakage or fatigue.
e. Liquid has entered the system controller.

⚠ If an instrument marked with the below symbol is dropped, check the equipment by a qualified service personnel.

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

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

5.1.1 Instruments Sterilization / Cleaning methods

Section 5.1.3 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 5 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 as required with a medical grade surgical lubricant. The above instructions that are instrument type dependent are indicated in Section 5.1.3 as applicable to each instrument.

5.1.2 Sterilization Parameters

The following parameters are given for reference. Refer to the package insert included in each instrument package for more details or updates.

Steam Sterilization (Autoclave)

Cycle type	Temperature	Time
Pre-Vacuum	132°C (270°F)	4 minutes

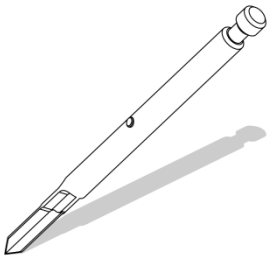
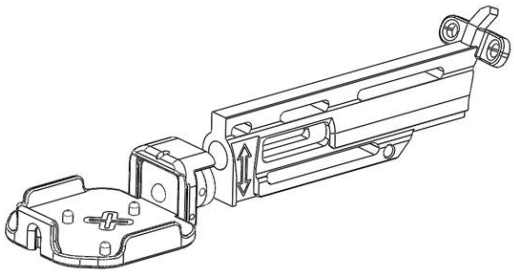
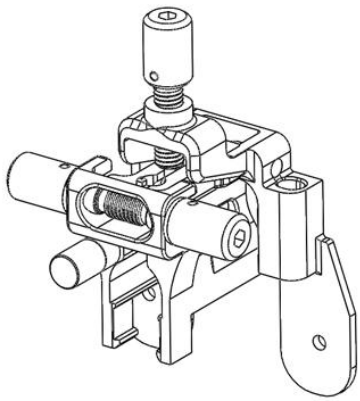
Indicated cycle temperature and time can be increased to 134°C + 3°C (273.2°F + 5.4°F) and 18 minutes according to local requirements as prescribed in the European Union.

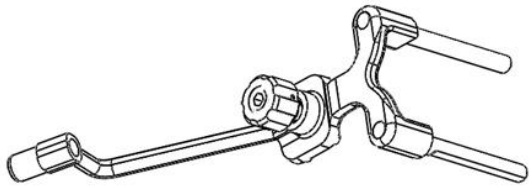
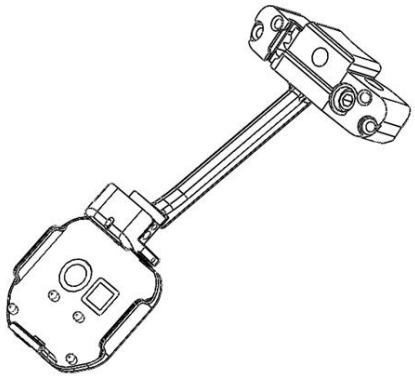
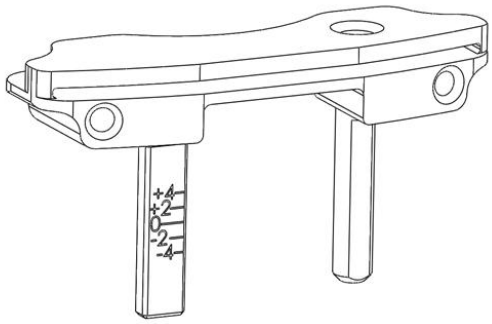
5.1.3 Master Instrumentation kit

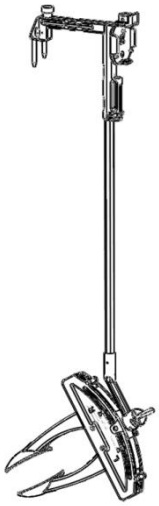
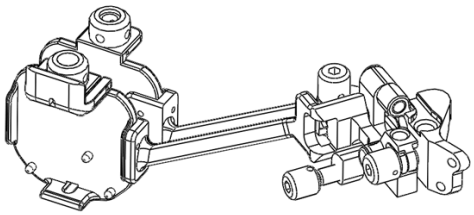
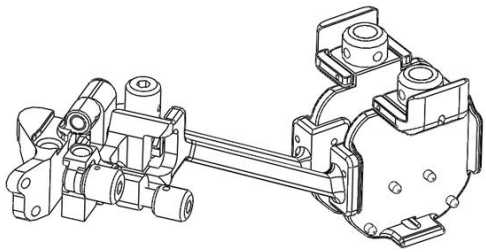
Additional specific cleaning instructions as defined in the text are indicated as applicable to each instrument as follows:

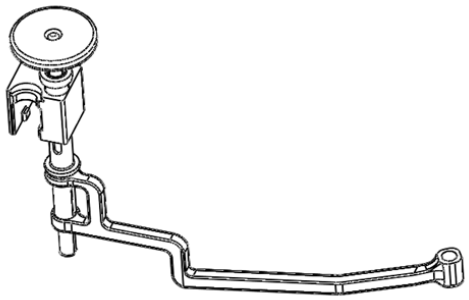
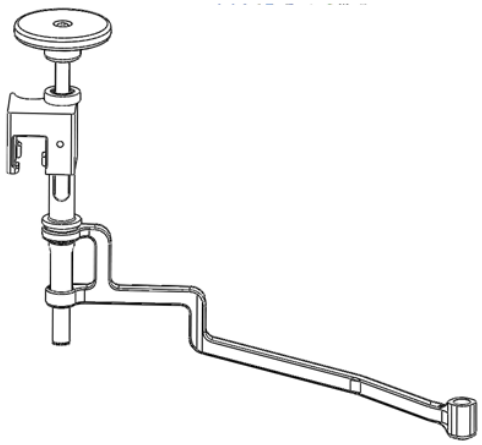
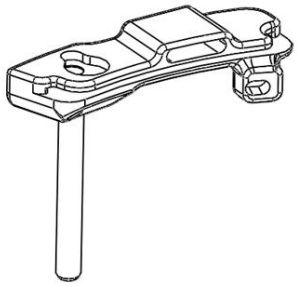
A. Requires disassembly.
B. Requires water jet to flush difficult to access areas.
C. Screw/unscrew components while flushing the area
D. Requires a minimum of 10 minutes ultrasonic cleaning cycle in an enzymatic solution.
E. Screws/mechanisms should be checked and lubricated as required.

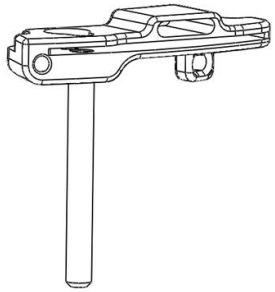
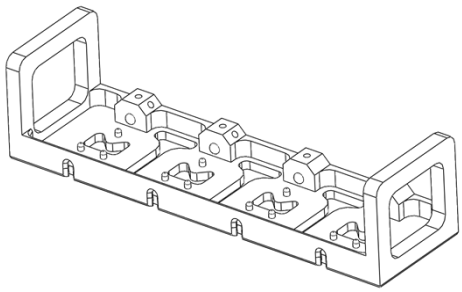
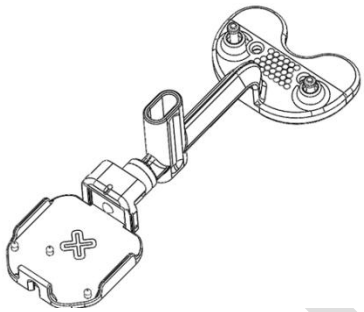
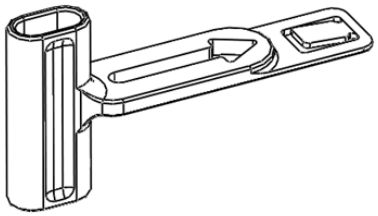
⚠ Cut guides are compatible with saw blades of thickness 1.27mm (0.05”).

Instrument	Manuf. No	Qty	Sterilization and specific cleaning instructions	Additional notes
CAS Smart Tools Master Knee Instrument kit	**KT-8011-010-01**	**1**		
CAS Small spike 7.9 mm 	108.108 Zimmer catalog No: 20-8000-010-27	1	Autoclave	
Femoral Reference 	20-8011-026-00	1	Autoclave (Additional specific cleaning requirements: B-D of section 5.1.1)	
Femoral Adjustment Mechanism 	20-8011-025-00	1	Autoclave (Additional specific cleaning requirements : B-C-D-E of section 5.1.1)	

Instrument	Manuf. No	Qty	Sterilization and specific cleaning instructions	Additional notes
Femoral AP Slider 	20-8011-028-00	1	Autoclave (Additional specific cleaning requirements : B of section 5.1.1)	
Femoral Distal Cut Guide 	20-8011-027-00	1	Autoclave (Additional specific cleaning requirements : B-C-D-E of section 5.1.1)	 OR
Femoral Saw Slot 	20-8011-042-00	1	Autoclave	
Tibial Alignment Guide	20-8011-013-00	1	Autoclave (Additional specific cleaning	

Instrument	Manuf. No	Qty	Sterilization and specific cleaning instructions	Additional notes
			requirements : A-B-C-D-E of section 5.1.1)	
Tibial Left Adjustment Mechanism 	20-8011-017-00	1	Autoclave (Additional specific cleaning requirements : B-C-D-E of section 5.1.1	Back side:  Front side  Note: Use square for **Tibia Right**. Use circle for **Tibia Left**
Tibial Right Adjustment Mechanism 	20-8011-018-00	1	Autoclave (Additional specific cleaning requirements : B-C-D-E of section 5.1.1)	Back side:  Front side 

Instrument	Manuf. No	Qty	Sterilization and specific cleaning instructions	Additional notes
Tibial Left Positioner 	20-8011-040-00	1	Autoclave (Additional specific cleaning requirements : A-B-C-D-E of section 5.1.1)	
Tibial Right Positioner 	20-8011-041-00		Autoclave (Additional specific cleaning requirements : A-B-C-D-E of section 5.1.1)	
Tibial Left Cut Guide 	20-8011-019-00	1	Autoclave	
Tibial Right Cut Guide	20-8011-020-00	1	Autoclave	

Instrument	Manuf. No	Qty	Sterilization and specific cleaning instructions	Additional notes
				
Calibration Jig 	20-8011-048-00	1	Autoclave (specifically follow steps B-D of section 5.1.1	
Validation Tool 	20-8011-021-00	1	Autoclave (Additional specific cleaning requirements : B-D of section 5.1.1)	
Alignment Arch 	20-8011-022-00	1	Autoclave	

Instrument	Manuf. No	Qty	Sterilization and specific cleaning instructions	Additional notes
Instrument Tray	20-8000-070-02	1	Autoclave	
Instrument Tray Lid	20-8000-070-03	1	Autoclave	
ORTHOsoft Diamond Grid Mat	20-8000-070-04	1	Autoclave	

5.1.4 Implant specific instrumentation

The table below summarizes the additional instruments required when using implants of type NexGen or NKII.

	Optional instruments	Quantity	Required for			Part Number	
			NexGen	PRI	NKII		
OR	MG II Hex Head Screwdriver, Hex Size 3.5mm	1	x	x	x	00-5120-087-00	(*)
OR	Hex Screwdriver 3.5mm	1	x	x	x	4812-45	**Autoclave**
	Pin / Screw Inserter	1	(1)	(1)	(2)	00-5901-021-00	(*)
	Tibial Depth Resection Stylus 4/6mm	1	(1)	(1)	-	00-5901-081-00	(*)
	Tibial Depth Resection Stylus 2/10mm	1	(1)	(1)	-	00-5901-082-00	(*)
OR	Multi Pin Puller	1	x	x		00-5901-022-00	(*)
OR	Headless Pin Puller	1	x	x		00-5983-099-00	(*)
	Intramedullary Slaphammer Extractor	1	x	x		00-5785-097-00	(*)
OR	Alignment Rod	1	x	x		00-5785-079-00	(*)
OR	Alignment Rod w/Coupler	1	x	x		00-5785-080-00	(*)
	Resection Guide	1	x	x		00-5977-084-00	(*)
	Drill Pin Extractor	1			x	00-6290-00-065	(*)
	Slaphammer/Extractor	1			x	00-6290-00-015	(*)
	Tibial Stylus	1			x	6290-00-542	(*)
	NK II MIS Tibial Stylus	1			x	6299-00-250	(*)
	Axial Alignment Rod Femur/Tibia	1			x	00-6290-00-005	(*)
	CAS Extraction Adaptor	1			x	20-8000-010-26 (formely 108.107)	**Autoclave** (specifically follow steps **B** of section 5.1.1

(1) Included into NexGen kit KT-8011-010-02

(2) Included into NKII kit KT-8011-010-03

(3) This instrument needs to be added on the SlapHammer to extract Pins.

(*)refer to implant system instrument package inserts

5.1.5 Disposables

Instrument	Manuf. No	Qty	Sterilization and specific cleaning instructions	Additional notes
Smart Tools Knee Pod Kit	20-8011-049-00	1	ETO	• Single use • Disposable  
38 mm screws				
3.5mm Hex head screw x 38mm	20-8000-000-18	4	Autoclave	• Provided Sterile • **Single use**
75 mm screws				
3.2mm Headless Trocar drill pin x 1 (a)	20-8000-000-15	3	Autoclave	• Provided Sterile • **Single Use**
Headless trocar drill pin, 75mm (a)	00-5901-020-00	3	Autoclave	• Provided Sterile • **Single Use**

(a) These three pins are equivalent in material and dimensions. The 20-8000-000-16 is provided non-sterile.

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

.

5.1.6 POD specific information

Note that the Pod's consumption is optimized to provide two-hours of use from power-up, which is when the button is pushed on the Pod's side.

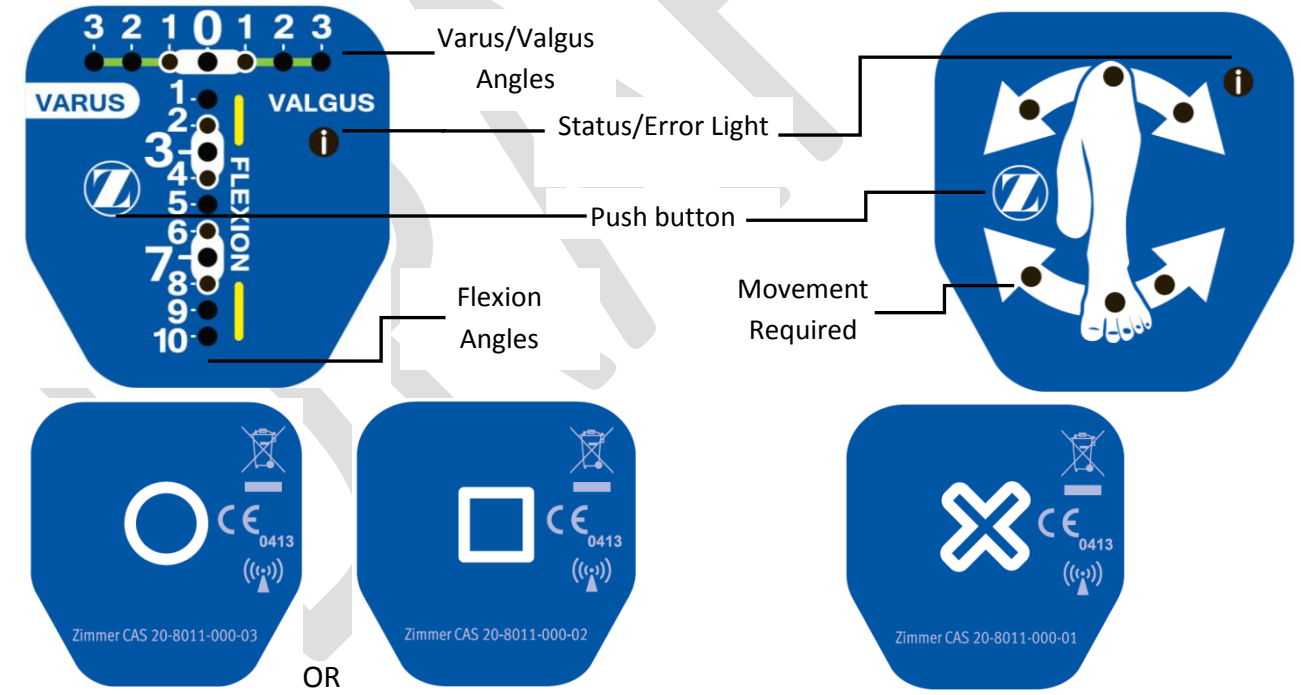
These Pods are contained in a custom plastic tray preventing activation prior to use including during ethylene oxide sterilization.

Pods complies with IPx7 standard to be protected against the effects of temporary immersion in water

⚠	Pods must be kept in their plastic tray during ethylene oxide sterilization to prevent potential explosions.
⚠	Pods should be properly connected to the instrument to provide strong fixation between both parts.
⚠	Pods should be connected to the instrument according to the same symbol visible on the Pod membrane and on the instrument

⚠	Care must be taken not to submit 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 are not affected).
⚠	Functionality of the Pods while exposed to x-ray may not be possible.
⚠	Colorblind users may rely on the numbers displayed next to navigation numbers. Also, the system controller gives more details on the system status.
⚠	Be careful to not expose the Pods to water until the “power on” button is pressed. The power on button activates a watertight barrier.
⚠	Pods can be washed using distilled water. Any excess water should be wiped off since it could affect wireless communication.

Pods User Interface



(a) Navigation Pod (b) Reference Pod

Figure 1: User interface of each Pod type.

Key Features

Pods (20-8011-000-01, 20-8011-000-02, 20-8011-000-03) features are:

Characteristic / Pod	Value
Weight	35 g / Pod
Size	41.75 x 38 x 28.7 mm
Battery duration	Approximately 2 hours
Other	Single use Disposable

Pod battery

The Pod battery has several stages during its lifespan. For each stage, indications are visible to the user on the Pod and on the System Controller:

Battery Stage	Pod indication	System Controller Indication (when "Show More" menu is visible)	User Recommendation
Healthy	Status light is solid green	Pod battery icon is green	Continue surgery
Warning Low level	Status light is blinking red	Pod battery icon is orange	Battery may switch to end of life within the next 30 min
End Of Life	Status light is solid red	Pod battery icon is red	Battery is ready to die, consider switching to conventional instrumentation.

5.1.7 System Controller Kit

Instrument	Manuf. No	Qty	Sterilization and cleaning instructions	Additional notes
System Controller Kit	**KT-8011-070-01**			
System Controller computer	20-8011-070-01		See 4.1	
System Controller power supply	20-8011-070-02		See 4.1	
System Controller **carrying** case	20-8011-070-04		See 4.1	
System Controller shipping case	20-8011-070-08		See 4.1	

⚠	The system controller has an internal battery that allows 3 hours of autonomy. This power backup is provided to prevent data loss if there is a main power outage.
⚠	A warning is provided to the user if the main power is disconnected and the computer battery has less than 20 minutes of power available.
⚠	Protect the equipment from overheating. The openings on the enclosure are for ventilation purpose. Do not block the openings. Do not use or store the system controller near a source of heat or dust.
⚠	If one of the following situations arises, get the equipment checked by service personnel: a. The Power cord or plug is damaged. b. If the date and time function stops functioning properly.
⚠	Never open the equipment. The System controller does not contain replaceable parts. For safety reasons, only qualified service personnel should open the equipment.
⚠	Never insert foreign objects in the system controller openings. This may cause electric shock or fire, or it may damage hardware components.
⚠	Do not step on or place anything on the power cord.
⚠	Never force a cable connection.
⚠	Make sure that the power cord provided with the system is compatible with your local power requirements.
⚠	Do not use another power supply other than the one provided

Volume Adjustment

To adjust the volume press:

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

A volume status bar will be shown to display the current volume level and a sound will be played that gives feedback.

Brightness Adjustment

To adjust the LCD brightness press:

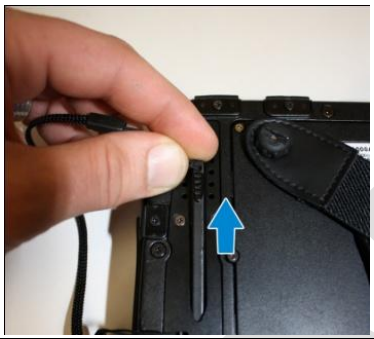
- Fn + Arrow Left key to decrease the brightness
- Fn + Arrow Right to increase it.

Touchscreen Calibration

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

Stylus

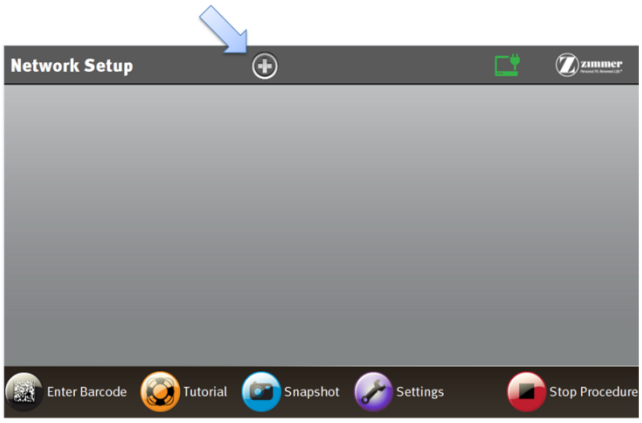
System Controller is equipped with a stylus allowing users to precisely press on the display without fingerprints.



1.1.4.4 Show more

During the procedure, additional details are visible when clicking the “show more” button.

Show less	Show More



1.1.4.3 Software Installation

To install a new Zimmer CAS Smart Tools Knee application on the system controller, you need to have a USB key with the appropriate release. To obtain an installation USB key, call Zimmer CAS Customer Support (see contact information in Section **Erreur ! Source du renvoi introuvable.**).

1.1.4.4 Technical Specifications

Power	100-240 VA, 47-63Hz, 1.22-0.68A
Operating Conditions	0°C to 50°C
Transport/Storage condition	-20°C to 70°C
User Devices	Touch Screen 2D barcode scanner
Dimensions	273.5mm x 207.5mm x 36mm (irregular)
Weight	About 1.9kg (4.2 lbs)

5.1.1 Wireless communication

The System Controller and 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 (Pod), 4 dBm (System Controller)

5.2 Transporting and Storing

5.2.1 System Controller

System Provider is coming from the kit [KT-8011-010-01]

The System Controller should be placed back in its Carrying Case. Make sure to securely bundle the chord in the case and secure with the Velcro strap.

If the System Controller needs to be shipped with a carrier (ex. FedEx), place the Carrying Case in the Shipping Case. The Shipping Case is specifically designed to withstand carrier shipping conditions. Please contact Customer Service for more information.

⚠	To avoid any damages on the cables, make sure they are not bent at sharp angles
⚠	If wires are not properly packaged, they might interfere the system controller touch screen and damage the system.
⚠	Make sure that no objects are leaned on the system controller touch screen when closing the carrying case. Any objects on the touch screen may damage it during the system transportation or storage.
⚠	Make sure the computer is properly shutdown before closing the carrying case. If not, the system may overheat and be damaged.
⚠	Do not leave the system in an uncontrolled environment where the storage temperature is below -20°C or above 70°C. This may damage the equipment.
⚠	The System Controller must never be submerged in water or exposed to high level of humidity.
⚠	Use of transducers and cables other than those specified, with the exception of transducers and cables sold by Zimmer as replacement parts for internal components, may result in increased emissions or decreased immunity of the System Controller.
⚠	The System Controller should not be used adjacent to or stacked with other equipment. if adjacent or stacked use is necessary, the System controller should be observed to verify normal operation in the configuration in which it will be used.

5.2.1 Smart Tools Knee Pod Kit

Please contact Customer Service for more information about transportation and storage of Pods

Smart Tools Knee Pod Kit [20-8011-049-00] shall be shipped within temperature from –18°C up to +49°C, 80% relative humidity at high temperature.

5.2.1 Instrumentation

Ship in instrument cases or otherwise standard packaging materials.

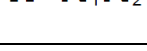
5.3 Training

.

Zimmer CAS Smart Tools systems should only be used by trained surgeons.

5.4 Symbols and Icons

The following symbols and icons can be found on the Smart Tools Knee system components:

	Symbol for “Disposal of WEEE (Waste Electrical and Electronic Equipment)” In the EU, refer to *www.weee.zimmer.eu* for information. Here, this is applicable to the Smart Tools Knee Pod Kit, as labeled on the items.
	Symbol for “Caution, consult operating instructions for use”
	Symbol for “Protection against harmful ingress of water or particulate matter”
	Symbol for “Manufacturer”
	Symbol indicating the "date of manufacture."
	Symbol for “Authorized EC Representative”
	Symbol for “Quantity”

	Symbol for “Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.”
	Symbol for “Sterile” and “Sterilized using ethylene oxide gas”
	Symbol for “Contents packed without sterilization”
	Symbol for “Not to be reused”
	Symbol for “Do not re-sterilize”
	Symbol for “To be used by… (Year, Month)”
	Symbol for “Intentional Emitter of Non-Ionizing Radiation”
	Symbol for “Do Not Drop”
	UL Classification Mark
	ETL Classification Mark
	Certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission
	Product is made of recyclable material

	C-Tick compliant
	Comply with Restriction of Hazardous Substances Directive
	European Conformity

5.5 General Warnings

⚠	The Pods and the System Controller 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 Smart Tools Knee System. Turning off 2.5GHz band Radio Frequency (RF) devices around the system (such as Bluetooth signals, Wifi) can improve communication performance between the Pods and the System Controller.

5.6 Certification Information

5.6.1 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.
—Consult the dealer or an experienced radio/TV technician for help.

5.6.2 System Controller

Table 1 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS –

Guidance and manufacturer's declaration – electromagnetic emissions		
The System Controller is intended for use in the electromagnetic environment specified below. The customer or the user of the System Controller should assure that it is used in such an environment.		
RF emissions CISPR 11	Group 1	The System Controller uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group 2	The System Controller must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class [A or B]	
Harmonic emissions IEC 61000-3-2	[Class A, B, C, D, or Not applicable]	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	[Complies or Not applicable]	
	TBD	The System Controller is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
	TBD	The System Controller is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the System Controller or shielding the location.
	TBD	The System Controller is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 14-1	Complies	The System Controller is not suitable for interconnection with other equipment.
RF emissions CISPR 15	Complies	The System Controller is not suitable for interconnection with other equipment.

Table 2 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity

The [ME EQUIPMENT or ME SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [ME EQUIPMENT or ME SYSTEM] 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	TBD	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	TBD	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	TBD	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 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	TBD	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [ME EQUIPMENT or ME SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [ME EQUIPMENT or ME SYSTEM] be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	TBD	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 3 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for LIFE-SUPPORTING ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The [ME EQUIPMENT or ME SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [ME EQUIPMENT or ME SYSTEM] should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz outside ISM bandsa 10 Vrms 150 kHz to 80 MHz in ISM bands a 10 V/m 80 MHz to 2,5 GHz	[$V1$] V [$V2$] V [$E1$] V/m	Portable and mobile RF communications equipment should be used no closer to any part of the [ME EQUIPMENT or ME SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**

			$d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{23}{E_1}]\sqrt{P}$ 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 metres (m). (b) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,© should be less than the compliance level in each frequency range.(d) Interference may occur in the vicinity of equipment marked with the following symbol: 

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

a The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.
b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.
c 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 [ME EQUIPMENT or ME SYSTEM] is used exceeds the applicable RF compliance level above, the [ME EQUIPMENT or ME SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM].
d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [$V1$] V/m.

Table 4 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The [ME EQUIPMENT or ME SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [ME EQUIPMENT or ME SYSTEM] should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – Guidance**

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	[$V1$] V [$E1$] V/m	Portable and mobile RF communications equipment should be used no closer to any part of the [ME EQUIPMENT or ME SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey(a) should be less than the compliance level in each frequency range.(b) Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [ME EQUIPMENT or ME SYSTEM] is used exceeds the applicable RF compliance level above, the [ME EQUIPMENT or ME SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM]. (b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [$V1$] V/m.			

5.6.1 Pods

The following table apply to Pod PN: 20-8011-000-01, 20-8011-000-02, 20-8011-000-03

Table 1 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS –

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 System Controller should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions 20-8011-000-01 20-8011-000-02 20-8011-000-03	Group 1	The Pods use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions 20-8011-000-01 20-8011-000-02 20-8011-000-03	Group 2	The System Controller must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions 20-8011-000-01 20-8011-000-02 20-8011-000-03	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	
		The Pods are suitable for use in all establishments, including domestic establishments.
RF emissions 20-8011-000-01 20-8011-000-02 20-8011-000-03	Complies	The System Controller is not suitable for interconnection with other equipment.
RF emissions 20-8011-000-01 20-8011-000-02 20-8011-000-03	Complies	The System Controller is not suitable for interconnection with other equipment.

Table 2 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The [ME EQUIPMENT or ME SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [ME EQUIPMENT or ME SYSTEM] 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	As specified	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	N/A	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	N/A	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*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Pod requires continued operation during power mains interruptions, it is recommended that the Pod be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	As specified	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 4 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for Pod that are not LIFE-SUPPORTING ME

Guidance and manufacturer's declaration – electromagnetic immunity			
The Pod is intended for use in the electromagnetic environment specified below. The customer or the user of the Pod should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	(V1) Vrms (E1) V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Pod than the recommended separation distance calculated below. **Recommended separation distance** D=(3.5/V1)(Sqrt P) D=(3.5/E1)(Sqrt P) 80 to 800 Mhz D=(7/E1)(Sqrt P) 800 Mhz to 2.5 Ghz where P is the maximum output power in watts and D is the recommended separation distance in metres (m). Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance level (V1 and E1) Interference may occur in the vicinity of equipment

Table 6 – Recommended separation distances between portable and mobile RF communications equipment and the Pod that are not LIFE-Supporting

Recommended Separations Distances for the Pod
The Pod are intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the Pod can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the Pod as recommended below, according to maximum output power of the communications equipment.

Max Output Power (Watts)	Separation (m) 150 kHz to 80 MHz D=(3.5/V1)(Sqrt P)	Separation (m) 80 to 800 MHz D=(3.5/E1)(Sqrt P)	Separation (m) 800 MHz to 2.5 GHz D=(7/E1)(Sqrt P)
0.01	.1166	.1166	.2333
0.1	.3689	.3689	.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.37786
100	11.6666	11.6666	23.3333

5.7 General & Contact Information

5.7.1 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 Smart Tools Knee® Navigation System users.

5.7.2 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

5.7.3 EC Representative

Zimmer U.K. Ltd.
9 Lancaster Place
South Marston Park
Swindon, SN3 4FP, UK

5.7.4 Customer Support

Phone number: 1 (866) 336-7846