

# ORTHOsoft<sup>®</sup> Knee 2.4 Universal

User Manual





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## System Overview

### Indication for Use/Intended Use

The ORTHOsoft Knee Universal System is indicated for use as a stereotaxic instrument to assist in the positioning of total knee replacement components intraoperatively.

It is a computer controlled image-guidance system equipped with a three-dimensional tracking sub-system. It is intended to assist the surgeon in determining reference alignment axes in relation to anatomical landmarks, and in precisely positioning the alignment instruments relative to these axes by displaying their locations.

### Training

Prior to use of the system, surgeons must follow a training given by Zimmer CAS or the application distributor.

**Warning:** Zimmer CAS Surgical Navigation Systems should only be used by trained surgeons.

### Implant Indications

The knee implants installed with the system must be used in accordance with their package insert labeling.

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

The ORTHOsoft Knee Universal System is compatible with the femoral distal cut first and anterior cut first surgical techniques.

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

### Contraindications

#### Clinical

Zimmer CAS Surgical Navigation System should not be used:

1. In the case of a hip pathology severely limiting its range of motion (e.g. arthrodesis, severe contractures, chronic severe dislocation);
2. In the case of a 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); and
3. For any other contraindicated case, as given by the implant manufacturer.

#### General

Zimmer CAS Surgical Navigation System should not be used:

1. In the presence of strong infrared sources or infrared reflectors in the vicinity of the optical markers. This could cause interference with the Zimmer CAS Optical System and alter its performance; or
2. To perform surgery other than those specified in the surgical technique and the user guide.

### 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.

## Preoperative Guide

### Application Launch

**Step 1:** After turning on the Sesamoid Plasty Computer, press “ORTHOsoft TKA” and the Patient ID dialog box will launch.

**Step 2:** To launch the application:

**a.** Enter the desired information in the Patient ID dialog box and then click the “Continue” button;

or

**b.** Click on the “Skip” button.

**ⓘ Warning:** To comply with the US HIPAA regulation, this field should not contain any information that could identify the patient.

## Preoperative Guide (cont.)

### OR Setup

Given that the field of the optical tracking system is limited, appropriate positioning of the optical tracking equipment is crucial. A specific camera location must be selected to allow an unobstructed camera view of the operation field.

An appropriate camera placement should allow for the calibration of instruments and the navigation to be carried out with a single rotation of the camera. This will facilitate handling during surgery.

The OR setup must be determined according to the side of the operated knee (left or right knee), the specifications of the optical system and the standard instrument setup. Special care should be taken to ensure that the femoral reference is seen during the entire kinematics process (for more details about the kinematics, refer to the Femoral Landmarks section (p. 12).

**Warning:** Control of the line of sight is essential to the proper use of the optical tracking system.

Refer to the Figure 4.1 for the correct camera placement. The exact camera position depends on the OR setup, the surgeon preferences and the position of the tracked instruments relative to the patient.

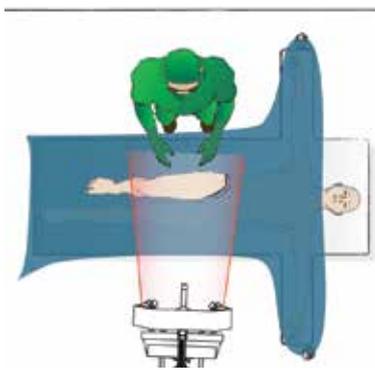


Figure 4.1  
Environment and OR Setup

## Intraoperative Guide

### Tracking System's Volume

The ORTHOsoft Knee Universal Application supports three different types of the optical system volumes. An automatic detection is performed when the application is launched. The appropriate Volume viewer is selected according to the camera's configuration, i.e. available tracking volumes and installed firmware.

The shape and dimensions of the three kinds of volumes, "Pyramid", "Arc" and "Silo", are shown in Figures 4.2 through 4.4.

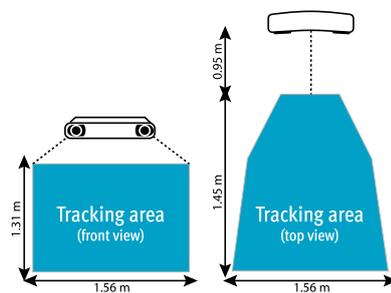


Figure 4.2  
Tracking Area of the "Pyramid" Volume  
1. Top View  
2. Front View  
3. Tracking Area

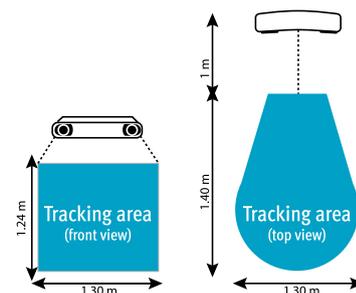


Figure 4.3  
Tracking Area of the "Arc" Volume  
1. Top View  
2. Front View  
3. Tracking Area

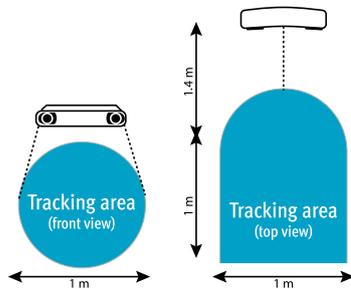


Figure 4.4  
Tracking Area of the "Silo" Volume  
1. Top View  
2. Front View  
3. Tracking Area



Figure 4.5  
Volume Viewer  
1. Pyramid Volume Viewer  
2. Arc Volume Viewer  
3. Silo Volume Viewer

The optimal visibility of the optical markers can be controlled with the Volume viewer. Be careful not to have two instruments with the same marker in the camera's field of view. All foreign objects should be removed from the path between the camera and the markers.

The Volume viewer helps to aim the camera and to verify that all tracked instruments are inside the camera field before any calibration/navigation steps. The markers that are seen by the optical tracking system are displayed in the graphical representation of the camera field. The application displays an icon marked with the "No" symbol each time that an instrument needed to complete the task is outside of the camera volume.

Two views of the Volume viewer are shown in Figure 4.5. The top view is used for the horizontal adjustment of the camera and the frontal view is used for the vertical adjustment. The grey area outlined in both views represents the optimal volume of the camera. It is recommended to position the markers within the grey area for the calibration of instruments.

**Warning:** It is preferable to calibrate or navigate instruments in the central region of the volume (identified in grey in every Volume viewer), rather than on the outside edges of the volume.

## Intraoperative Guide

### Remote Control in the Sterile Field

The system can be also controlled with the help of the CAS Registration Pointer, to activate the “Next” and “Previous” buttons. This feature allows navigation through the intraoperative procedure without user interaction with the screen or the mouse. The pointer tip placed on the femoral reference switches the “Next” button. The pointer tip placed on the tibial reference switches the “Previous” button.

The implant size can be modified by touching the bone reference with the CAS Universal Offset Paddle. The tip of the CAS Universal Offset Paddle placed on the femoral reference switches the “Size Increment” button, whereas the CAS Universal Offset Paddle placed on the tibial reference switches the “Size Decrement” button.

Through all navigation panels (except in Femoral and Tibial Landmarks panels), the snapshot can be triggered using the CAS Registration Pointer from the sterile field, by orienting the pointer’s tip upwards and respecting the stability criterion. In any landmarking task, orienting the pointer’s tip upwards and respecting the stability criterion will trigger activation of the Remote menu (Figure 4.7) for landmark reacquisition.

This menu will provide the ability to choose any available landmark to reactivate. By tilting the pointer on one side or the other, as shown with the feedback needle in Figure 4.7, the focus of the selector will change accordingly. Once the focus is on the desired landmark to reactivate, holding the pointer upwards and stable, in the OK section, will trigger selection of the item.



Figure 4.7  
Remote Menu

### Assembling Markers

The NavitrackER Markers must be installed on each instrument used for navigation. Push the marker onto the mounting studs until it is firmly seated (CAS NavitrackER Pliers can be used to facilitate the installation of the markers on the instruments). It is important to verify that the NavitrackER Markers remain clean throughout the surgery.

- ⓘ **Warning:** Always minimize handling of the NavitrackER Markers, since errors may result from the non-uniform reflection of their surface.
- ⓘ **Warning:** Always use unblemished markers.
- ⓘ **Warning:** Always ensure that reflective NavitrackER Markers are firmly seated.
- ⓘ **Warning:** The use of optical markers other than those provided by Zimmer CAS may lead to inaccuracies.

## Surgery Task Bar, Snapshot and Menu Buttons

The Surgery Task bar shown in Figure 4.8 allows direct access to a specific panel. Icons featuring a thick white color frame and blue background color indicate the currently active panel. Icons featuring a thin blue color frame and black background color indicate that the surgery task is directly accessible. Greyed out icons indicate that the surgery task is inactive.

Inactive surgery tasks become accessible once all preceding surgery tasks have been completed. The number and order of the displayed surgery tasks depend on the chosen Surgeon Profile settings.



Figure 4.8  
Surgery Task Bar

The “Snapshot” button allows to capture the screen display and save it to a file.

The “Menu” button gives access to a menu which includes: a “Volume Viewer” button to verify the instruments tracked by the optical tracking system, a “Help” button that displays contextual help, an “Audio Volume” button to set the volume, a “Language” sub-menu to select the language of the user interface and a “Quit Application” button to exit the application.

## Surgeon Profile

The system uses the concept of profiles to store particular surgical preferences. Once a profile is created, it can be used to perform a surgery without specifying the preferences again.

A list of the existing profiles is located on the left side of the Surgeon Profile panel. Three buttons are available to create (Create Profile), edit (Edit Profile) or permanently remove (Delete Profile) a selected profile. Each selected profile contains a list of preferences that are classified into the following categories: General, Workflow, Femur, Tibia and Targets.



Figure 4.9  
Surgeon Profile

## Intraoperative Guide

### General Preferences

#### Implant

This preference allows the surgeon to select the implant used in the total knee replacement surgery. The “Universal” choice can be selected to navigate only the distal femoral and proximal tibial cuts (orientation and resection levels) without navigating the femoral implant size selection, the axial rotation or the A/P position.

#### Pointer Type

This preference allows the surgeon to select the type of the CAS Registration Pointer that will be used for navigation. The US pointer is the pointer manufactured by Zimmer CAS with part number 20-8000-070-01. The EU pointer is a pointer manufactured by Zimmer Biomet with part number 05.00017.310.

#### Show 30°–60° in ROM (Range of Motion)

This option enables the 30 and 60 degrees of flexion indicators in the ROM panel in addition to the 0 and 90 Degrees of flexion indicators.

#### Positioning Instrument

This preference allows the surgeon to select between two instruments for adjusting varus/valgus, flexion/extension or tibial slope using femoral distal and tibial cutting guides.

1. CAS Universal Positioning Block  
(calibration is required)

**Warning:** The spring of the CAS Universal Positioning Block should not be bent with pliers. Doing so could damage the instrument.

2. CAS Universal Offset Paddle  
(calibration is not required)

#### Cutting Slot Thickness

This preference allows the surgeon to select the appropriate slot thickness. If the cutting blocks have saw guide slots, the surgeon must choose between the 1.00, 1.27, 1.35 or 1.45 mm thickness in accordance with the thickness of the slot used for the tibial and femoral cuts.

- If a 1.00 mm cutting block slot thickness (closed cutting block) is used to perform the cuts, the CAS Universal Offset Paddle 1.00 mm (P/N 108.115) should be used to navigate the cutting planes. In the Surgeon Profile settings, 1.00 mm must be selected as the Cutting Slot Thickness.

- If a 1.27 mm or thicker cutting block slot thickness (closed cutting block) is used to perform the cuts, the CAS Universal Offset Paddle 1.27 mm (P/N 108.116) should be used to navigate the cutting planes. In the Surgeon Profile settings, the selection for the Cutting Slot Thickness preference must be equal to the thickness of the saw slot used to perform the cuts even if thicker than 1.27 mm.

- If the cutting blocks have no integrated cutting slots (open cutting block), the CAS Universal Magnetic Offset Paddle (P/N 108.117) could be used to navigate the cutting planes. In the Surgeon Profile settings, “No Cutting Slot” must be selected as the Cutting Slot Thickness.

**Warning:** Make sure the appropriate Cutting Slot Thickness is selected for the saw slot of the cutting block.

**Warning:** The CAS Universal Magnetic Offset Paddle must not be used with cutting guide having a saw capture (closed cutting block).

**Warning:** Whenever using a CAS Universal Offset Paddle or the CAS Universal Positioning Block, ensure the blade is fully inserted in the slot to be navigated.

**Warning:** The MIS Innex A/P Cutting Guide\* should be used with the CAS Universal Magnetic Offset Paddle placed against the lower portion of the cutting saw slot. The 1.00 or 1.27 mm CAS Universal Offset Paddles should not be used with the MIS Innex A/P Cutting Guide\* and its saw capture which presents offsets.

**Warning:** The standard Innex A/P Cutting Guide\* should be used only with the 1.00 or 1.27 mm CAS Universal Offset Paddles because the shoulder is too narrow for it to provide stable support for the CAS Universal Magnetic Offset Paddle.

**Warning:** For the insertion of the CAS Universal Offset Paddle (1.00 mm or 1.27 mm) in the slot of the cutting block, avoid recessed holes since the instrument could remain trapped.

\*Innex Implant not available in the US

## Workflow

### First Cut

This preference allows the surgeon to select the preferred surgical technique starting with the anterior cut first (AC 1st) or distal cut first (DC 1st).

### Surgical Flow

This preference allows the surgeon to select the surgical flow for the surgery. The femur can be navigated first or the tibia.

### Perform Initial ROM

This option enables the preoperative Range of Motion (ROM) panel. It can be used to help evaluate the flexion contracture and the varus/valgus deformity at different flexion angles.

### Enable Femur Rotation Panel (DC 1st)

This option enables the Femoral Rotation panel in the distal cut first sequence. This panel allows selecting the implant size, set the Anterior/Posterior position and the axial rotation of the implant.

### Gap Balancing Technique

This option allows the selection of the preferred ligament balancing technique. The supported techniques are Insall Gap Balancing and Soft Tissue Balancing. Insall Gap Balancing is only available when the Femoral Rotation panel is enabled.

### Navigate CAS Tensor

This preference allows the surgeon to use the CAS Tensor for ligament balancing and placement of the femoral component. The CAS Tensor is only available when performing Insall Gap Balancing.

### Enable Varus/Valgus Panel (AC 1st)

This option enables the Varus/Valgus Adjustment panel that is used to set the desired varus/valgus of the cutting block.

## Femur Preferences

### Compute Distal Resection Level

This preference enables navigation of the distal resection level that requires digitization of the femoral distal condyles.

### Compute Posterior Resection Level

This preference enables navigation of the posterior resection level on the Femur Rotation Navigation panel or the Anterior Cut Navigation panel.

### Distal Condyles Acquisition Method

This preference allows the surgeon to select the preferred method for digitization of the distal femoral condyles.

The product supports two methods: acquisition of multiple points or digitization with the CAS Universal Validation Tool.

### Compute A/P Axis of Rotation

This preference triggers the application to display the femoral rotation angle with respect to Whiteside's line on the distal femur, as digitized by the user. If enabled, the A/P axis and rotation angle based on the Whiteside's line will be displayed in the Femur Rotation Navigation panel or the Anterior Cut Navigation panel.

### Compute Epicondylar Axis Rotation

This preference triggers the acquisition of two landmarks on the medial and lateral femoral epicondyles. If enabled, the femoral rotation angle, based on the line between the two epicondyles, will be displayed in the Femur Rotation Navigation panel or the Anterior Cut Navigation panel.

### Compute M/L Size

This option enables computation of the M/L sizing. The suggested M/L size of the implant will be displayed in the Femur Rotation Navigation panel and Anterior Cut Navigation panel.

For Gender Solutions® Implant families, the M/L sizing suggestion will provide information on the appropriate implant type (male or female) among the selected implant size. An M/L sizing suggestion displayed in red means that the smallest implant size is too wide in comparison to the digitized femur.

## Intraoperative Guide

### Tibia Preferences

#### Compute Resection Level

This preference enables the navigation of the resection level that requires the acquisition of two points on the tibial condyles.

#### Axial Acquisition Method

This preference allows the surgeon to select the preferred method for axial acquisition. The product supports two methods: acquisition of PCL-tubercle or acquisition of the relative position of the femur and tibia when the knee is flexed at 90 degrees (refer to the Tibial Landmarks section (p.13) for more details).

#### Show Natural Varus/Valgus

This preference triggers the calculation of the natural varus/valgus angle. If enabled, the natural varus/valgus angle will be displayed in the Tibia Navigation panel. The natural varus/valgus angle is the varus/valgus orientation of the intact tibial plateau as defined by the medial and lateral points digitized on the tibia.

#### Show Rotational Angles

This preference enables the display of the axial rotation angles in the Tibia Navigation panel.

#### Compute Post. Plateau Rotation

This preference triggers the calculation of the rotation angle with respect to the points acquired on the medial and lateral posterior plateau of the tibia. If enabled, the posterior plateau rotation angle will be displayed in the Tibia Navigation panel.

### Targets

#### Distal Resection Level

This preference sets the targeted resection level of the distal cut in the Femur Navigation panel.

#### Implant Distal Cut Angle

This preference is available only when the “Universal” implant is navigated in the Anterior Cut First sequence. This option is required to pre-set the targeted implant distal cut angle (flexion/extension).

#### Tibia Posterior Slope

This preference sets the targeted posterior slope of the tibial cut in the Tibia Navigation panel.

#### Tibia Resection Level

This preference sets the targeted resection level of the tibia cut in the Tibia Navigation panel.

### Patient Information

The Patient Information panel allows selection of the operative side. Click the “L” icon for a left knee or the “R” icon for a right knee (Figure 4.11). The selected operative side is highlighted in blue.

- ⓘ **Warning:** Make sure that the correct patient side is selected before starting the navigation.



Figure 4.11  
Patient Information

### Calibration of the Navigated Instruments

- ⓘ **Note:** The following instruments can be calibrated while the patient is being prepared in order to minimize the time of the surgery:
- ⓘ **Warning:** Verify that the tools are in good condition to perform the operation. If you notice any signs of bending, fatigue or deterioration, do not use the application and contact technical support.
- ⓘ **Warning:** Avoid placement of markers on both sides of the CAS Universal Validation Tool Body.

## US and EU CAS Registration Pointer

The instructions related to the pointer calibration procedure are illustrated in Figure 4.12.



Figure 4.12  
CAS Registration Pointer Calibration

1. Attach the size 4 Navitracker Marker on the side of the CAS Universal Validation Tool Body that will face the camera.
  2. Attach the CAS Short Posterior Condyles Digitizer (with the applicable drill guide) or the CAS Posterior/Distal Condyles Digitizer to the CAS Universal Validation Tool Body and secure the locking mechanism.
  3. Place the assembly on the CAS Calibration Star Holder.
  4. Insert the CAS Registration Pointer in the CAS Universal Validation Tool Body and tighten the wing screw.
  5. Make sure that the tip of CAS Registration Pointer is in contact with the base of the pointer hole.
- ⚠ Warning:** Make sure that the tip of the CAS Registration Pointer is in contact with the base of the pointer hole. If not, calibration of the pointer may be inaccurate and lead to inaccurate positioning of the implant.
6. Position the assembly in the optimal part of the camera volume (grey zone).
  7. Successful calibration will be confirmed by a check mark and a sound.

## CAS Universal Positioning Block

The instructions related to the CAS Universal Positioning Block Calibration procedure are illustrated in Figure 4.13.

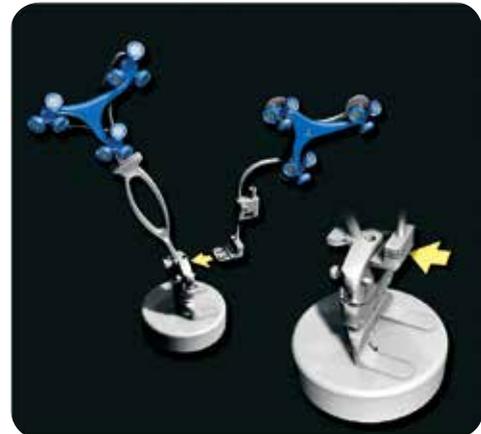


Figure 4.13  
CAS Universal Positioning Block Calibration

1. Attach Navitracker Markers, sizes 2 and 9, to the CAS Universal Positioning Block.
  2. Insert the CAS Universal Positioning Block into the CAS Universal Validation Tool Body. Make sure it is fully entered into the slot to the shoulder limit.
  3. Orient optical markers towards the camera and secure the rotational tracker (if applicable).
  4. Position the assembly in the optimal part of the camera volume (grey zone).
  5. Successful calibration will be confirmed by a check mark and a sound.
- ⚠ Warning:** Whenever using the CAS Universal Offset Paddle or the CAS Universal Positioning Block, ensure the blade is fully inserted in the slot to be navigated with the blade's shoulder against the edge of the slot.

## Intraoperative Guide

### Positioning of the Bone References

The bone references are used to track the patient's femur and tibia and show the navigated instruments in relation to their respective positions.

- ⓘ **Warning:** Bone references MUST be firmly attached to the bone and MUST NOT move at any moment during surgery. In the case of a bone reference has moved, the landmarks digitized on that bone must be digitized again.
- ⓘ **Warning:** Beware that muscle fibers may apply bending forces on the pins.
- ⓘ **Warning:** Make sure that the pins are not positioned close to the bone cuts. Placing the pins close to the bone cuts location will increase the risk of breaking the pins with the cutting tools.

#### Femoral Reference

In order to install the femoral reference, use two CAS Fix Pin Fluted or pins of equivalent type (Steinmann). The pins can be inserted percutaneously through the vastus medialis in the femur, as proximal as possible, to stay clear of the working area. The pins should be set bicortically in the bone to ensure maximum stability. However, when an intramedullary rod is used, place the pins in the distal part of the femur to avoid interference between the pins and the rod.

- ⓘ **Warning:** Be alert to the risk of causing damage to the saphenous artery and vein, femoral artery and vein, or the popliteal artery and vein while installing the bone reference.

#### Tibial Reference

Two CAS Fix Pin Fluted are used to install the tibial reference. To obtain a non-obstructed working area, the pins are inserted percutaneously into the medial surface of the tibial diaphysis at approximately mid-tibia. They should be set bi-cortically to ensure maximal stability in the bone. In cases where an intramedullary rod is used, place the pins in the proximal part of the tibia to avoid interference between the pins and the rod.

If a keeled implant is used and the pins are placed more proximally, ensure that the pins are not placed in an area of interference with the keel. Impact with the keel or its broaching instruments can cause breakage of the pins as well as movement of the reference, which could result in inaccuracies.

### Digitization of the Bony Landmarks

Digitization of the bony landmarks is required to display the relevant information in the navigation panels. This system allows automatic registration of points using a stability criterion with the pointer. An initial movement of the instrument is first required to initialize the registration of the points. Confirmation sounds are played to advise the user that a point has been acquired successfully or unsuccessfully.

Furthermore, two points may not be digitized at the same location. Therefore a minimal displacement of 5 mm is required between two points.

#### Exceptions

1. The posterior tibia and healthy plateau points on the same M/L side can be digitized at the same position, as well as the distal femoral condylar points and the M/L landmarks. Also, no proximity criterion is applied between the mechanical tibial entry point and the PCL entry point.
2. The minimum distance between the femur mechanical entry point and the A/P trochlear groove points is 3 mm.
3. A minimal distance of 20 mm must be observed between two points used to create an axis (e.g. epicondylar axis, tibial tubercle-PCL axis, etc.).

## Femoral Landmarks

Successful digitization of the femoral landmarks enables the Femur Navigation panels.

### Femoral Head

Detection of the femoral head center is performed by recording 14 static positions of the leg. For each acquired point, the leg should be stabilized until a confirmation sound is played. The points should be taken in a large conical pattern with respect to the femoral reference.

If a non-recommended pattern such as two unique positions in flexion/extension or a small cone is performed, the center of rotation algorithm will reject the result. As a result, a pop-up will appear asking the user to redo the acquisition (Figure 4.14). If a center was already acquired and accepted, the user will be asked to retry or keep the previous accepted center of the femoral head.



Figure 4.14

Failure of the Center of Rotation Algorithm

The pelvis and the optical camera must remain stable during the whole process to obtain a good level of accuracy. The minimum distance between each position is 20 mm. The algorithm automatically validates the kinematics.

Femoral head detection is a crucial process that will influence the end result of the surgery. The contraindications for the femoral head detection are hip pathologies severely limiting its range of motion (e.g. arthritis and hip dysplasia). In order to verify the contraindications, place the femur in internal rotation and verify that the hip does not move during the kinematics procedure.

**Warning:** The pelvis and the optical camera must remain immobile during the whole femoral head digitization process to ensure system accuracy.

**Warning:** To ensure an accurate detection of the center of the femoral head, cover a wide circle with the leg when completing the process.

### Mechanical Axis Entry Point

The entry point of the mechanical axis is defined as the deepest point of the intercondylar notch.<sup>1</sup>

It is recommended to determine the desired entry point on a preoperative radiograph and compare it with the intraoperative location in situ.

Together with the femoral head, the entry point forms the femoral mechanical axis that is used as the main axis of the femoral coordinate system. The varus/valgus, flexion/extension and rotation values are computed relative to the mechanical axis.

### Anterior Cortex Points

These points are digitized on the anterior cortex and are then used for the sizing of the femur and to gage notching. Three points have to be acquired along the femoral mechanical axis. The length between each of the three points should be 2–2.5 cm, totaling approximately 4–5 cm between the first and last point.

**Warning:** If the digitization of the anterior cortex is done on the extension of the lateral condyle, the implant sizing suggestion will be over-estimated.

### Epicondylar Axis (Optional)

The epicondylar axis is used for the femoral rotational alignment. It is determined according to the digitization of the medial and lateral epicondyles.

### M/L (Optional)

The two points are digitized on the medial and lateral edges of the femoral distal condyles. Then the M/L sizing of the femoral component is suggested based on the digitized points.

### A/P Axis (Optional)

The A/P axis is also used for the femoral rotational alignment. It is determined according to the digitization of a point right above the femoral notch and a second one in the deepest section of the trochlea.

#### References

- Oswald MH *et al.* (1993). Radiological analysis of normal axial alignment of femur and tibia in view of total knee arthroplasty. *J Arthroplasty*. Aug;8(4): 419-26.

## Intraoperative Guide

### Femoral Landmarks (cont.)

#### Distal Condyles

These points are digitized on the distal femoral condyles. They are used to compute the distal resection level that is displayed in the Distal Cut Navigation panel.

#### Multiple Points Method

One of the methods to digitize the distal femoral condyles is to acquire multiple points (six points) with the CAS Registration Pointer.

- ⓘ **Warning:** Care must be taken not to penetrate through the cartilage with the pointer tip.
- ⓘ **Warning:** Final results depend on the accurate acquisition of landmarks. For accurate depth results, ensure that distal condyles are digitized most distally with respect to the distal cut, taking into account the flexion of the cut.

#### CAS Universal Validation Tool Body Method

The distal femoral condyles can also be acquired with the CAS Universal Validation Tool Body. Refer to Figure 4.15 for the detailed instruction.

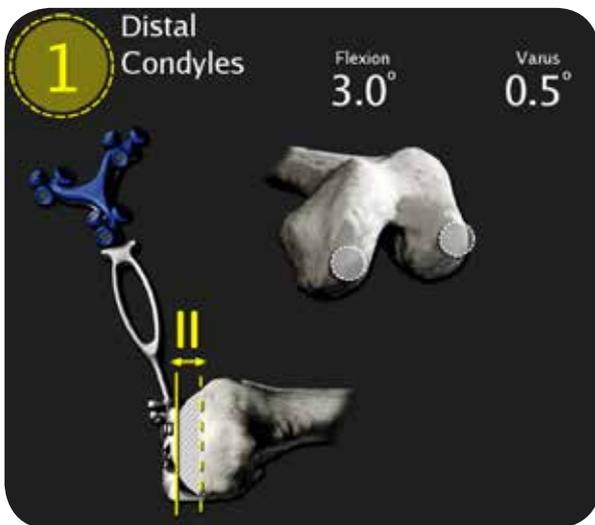


Figure 4.15

Acquisition of the Distal Femoral Condyles with CAS Universal Validation Tool Body

1. Position the CAS Universal Validation Tool Body such that the edge of the instrument is in contact with the referenced (e.g. healthy) distal condyle.
2. Adjust flexion/extension and varus/valgus angles of the instrument to the target angles of the distal femoral cut.
3. Stabilize the instrument.

#### Posterior Condyles

The most posterior points of the femoral condyles are digitized using the CAS Universal Validation Tool Body with the CAS Posterior Condyles Digitizer. Depending on the curvature of the distal femur in sagittal view, a slight flexion should be set before digitization of the points. During acquisition, verify that the CAS Posterior Condyles Digitizer is in contact with both posterior condyles. If proper contact is not achieved, sizing problems and rotational misalignment might occur.

### Tibial Landmarks

Successful digitization of the tibial landmarks enables the Tibia Navigation panel.

#### Mechanical Axis Entry Point

The entry point is identified as the entrance point of the intramedullary canal. This point should be centered along medial/lateral axis. A/P positioning should fall between the middle and one-third of the anterior edge of the tibial plateau.

#### Healthy Plateau Points (Optional)

The resection level displayed in the Tibia Cut Navigation panel is computed with two points digitized on healthy areas of the medial and lateral plateau of the tibia.

- ⓘ **Warning:** Care must be taken not to penetrate through the cartilage with the pointer tip. Avoid damaged areas.
- ⓘ **Warning:** Whenever the digitization of a healthy plateau is not possible, either due to spatial limitation in the incision or due to specific anatomical issues, register the inaccessible plateau on the anterior distal tibia. The resection level from that side will not be displayed, which will prevent confusion in the tibial resection levels.

## Tibial Landmarks (cont.)

### Axial Acquisition Method

#### Tubercle - PCL

The neutral rotation is defined by a point in the middle of the PCL insertion area on the tibial plateau and one on the medial third of the tibial tuberosity. This axis should lie perpendicular to the posterior edges of the proximal tibia.

#### Flexion Acquisition

In digitizing the A/P axis of the tibia, an acquisition in flexion can be used to transfer the alignment of the femoral mechanical axis to the tibial coordinate system. It must be noted that an initial movement of the leg is first required to initialize the acquisition in flexion. On average, this rotational axis option is aligned with the posterior aspect of the tibial plateau, which could differ from the tubercle-PCL alignment.

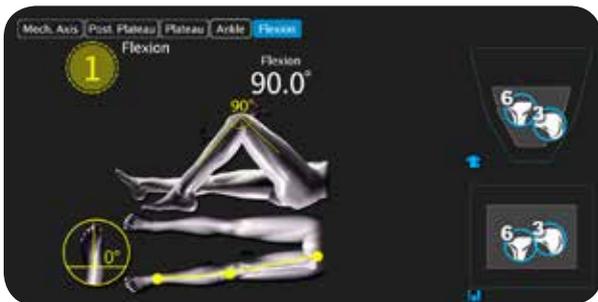


Figure 4.16  
Flexion Acquisition

**Warning:** Care should be taken to avoid any torsion of the tibia during acquisition with the leg in flexion, i.e. aligning the unstressed foot forward (neutral rotation).

#### Posterior Plateau (Optional)

The posterior plane rotation angle displayed in the Tibia Navigation panel is based on these two points. They must be digitized on the posterior limit of both the medial and lateral plateaus.

#### Ankle points

In order to recreate the mechanical axis of the tibia, two points are digitized on the medial and the lateral malleolus. The varus/valgus, flexion/extension and rotation values are computed relative to the mechanical axis.

## Surgical Technique: Distal Cut First

This technique can be applied to NexGen Complete Knee Solution, Persona® Knee Implants, Vanguard® Complete Knee System\* or Natural-Knee System Implants. The workflow for cutting the distal femur first is as follows:

1. Initial Range of Motion
2. Tibial Cut Navigation
3. Distal Cut Navigation
4. Femoral Rotation Navigation (anterior cut)
5. Postoperative Range of Motion

The sequence of tibia or femur first is user selectable in the Surgeon Profile panel settings.

**Warning:** During ligament balancing procedure do not apply excessive stress to the knee joint compartments in order to avoid permanent damage to the ligaments.

## Initial Range of Motion (ROM)

The initial Range of Motion panel can be used to evaluate the preoperative flexion contracture and the varus/valgus (V/V) deformity. The panel is shown in Figure 4.17.



Figure 4.17  
ROM Panel

\*Vanguard XP not supported

## Intraoperative Guide

### Initial Range of Motion (cont.)

The varus/valgus (HKA) angle is displayed under the Left viewer that displays the lower limb alignment in an A/P view. The flexion angle is displayed under the Right viewer, which displays a sagittal view of the lower limb alignment.

An initial movement of the leg is required first to initialize the procedure. Then, evaluate the varus/valgus stability in full extension (0 degrees of flexion) by applying medial and lateral stresses to the knee joint to assess the amount of passive correction obtainable.

The amount of varus/valgus can be also assessed at 30 degrees, 60 degrees and 90 degrees of flexion. The maximum varus/valgus angle values are recorded in the indicators for each of the four angles of flexion (0 degrees, 30 degrees, 60 degrees and 90 degrees).

During the ROM procedure, the application will switch automatically from one indicator to another as the user goes to each flexion angle. In addition, the “Clear All” button is available to reset the indicators and restart the ROM procedure.

### Tibial Cut Navigation

The purpose of the Tibia Navigation panel is to assist the surgeon to perform the desired tibial proximal resection. This panel allows the positioning of the tibial cutting guide with respect to the tibial mechanical axis and adjustment of the resection level. The panel consists of three subtasks: Navigate Bone Fixation (only for CAS Universal Positioning Block Instrumentation, refer to Appendix E on page 53 for more details), Navigate Cutting Block, and Tibial Cut Validation.

**Warning:** Make sure to use the appropriate CAS Universal Offset Paddle for the Cutting Block Navigation. The paddle used should be the selected from one of the preferences. Use of the wrong CAS Universal Offset Paddle could lead to resection level inaccuracies.

**Warning:** The CAS Universal Offset Paddle is compatible with standard cutting blocks that have cutting slots or planar surfaces for cut alignment. The use of a CAS Universal Offset Paddle with any incompatible cutting block could lead to inaccuracies.

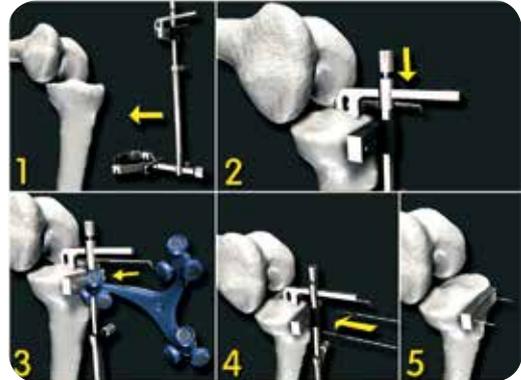


Figure 4.18

Installation and use of the CAS Universal Offset Paddle

1. Place the standard extramedullary jig on the tibia.
2. Fix the jig on the tibial plateau.
3. Slide the CAS Universal Offset Paddle and navigate the tibial cut.
4. Insert pins through the cutting guide to the bone.
5. Remove the extramedullary jig to perform the tibial cut.

## Tibial Cut Navigation (cont.)

### Navigate Cutting Block

The intent of the Navigate Cutting Block subtask is to set the appropriate orientation of the standard tibial cutting guide with respect to the mechanical tibial axis. In the panel, the medial and lateral Resection Level indicators are displayed under the Frontal viewer. Note that if a plateau was inaccessible and registered on the recommended anterior distal tibia, the resection level from that side will not be shown. The Posterior Slope indicator is displayed under the Lateral viewer. In addition, the varus/valgus and axial rotation angles of the navigated cutting guide are located in between the two viewers. In order to navigate and position the tibial cutting guide, refer to Figure 4.19 for the detailed instructions.



Figure 4.19  
Navigate Cutting Block

1. Use the extramedullary instruments (from the standard instrumentation system) to adjust varus/valgus, posterior slope and the resection level.
2. Secure the position of the tibial cutting guide with the drive pins.
3. Remove the extramedullary assembly.
4. Perform the tibial resection with the help of the positioned tibial cutting guide.

**Warning:** The CAS Universal Offset Paddle should not be used as a lever arm to correct the cutting block orientation. Doing so could bend the tip of the instrument and result in inaccurate measurements for all subsequent navigated surgeries.

### Tibial Cut Validation

The purpose of the tibial cut validation is to verify if the tibial resection was achieved as desired. It is mainly used to inspect the orientation and, if needed, introduce the necessary corrections to the tibial cut. In order to validate the tibial resection, refer to Figure 4.20 for the detailed instructions.



Figure 4.20  
Tibial Cut Validation

1. Attach the CAS Short Posterior Condyles Digitizer (with the applicable drill guide) or the CAS Posterior and Distal Condyles Digitizer to the CAS Universal Validation Tool Body.
2. Place the CAS Universal Validation Tool Body on the tibial cut.
3. Stabilize the instrument to acquire the varus/valgus, posterior slope and resection level of the cut.
4. Verify the values and introduce the corrections if needed.
5. To restart the Tibial Cut Validation subtask move the CAS Universal Validation Tool Body in the camera volume.

## Intraoperative Guide

### Distal Cut Navigation

The intent of the Distal Cut Navigation panel is to assist the surgeon to perform the desired femoral distal resection. This panel is designed to allow accurate positioning of the distal cutting guide with respect to the femoral mechanical axis, adjustment the resection level of the cut, and estimation of the implant size. The panel consists of three subtasks: Navigate Bone Fixation (only for CAS Universal Positioning Block Instrumentation; refer to page 53 of Appendix E for more details), Navigate Cutting Block, and Distal Cut Validation.

#### Instrument Setup

In distal cut first, follow these steps to align the cutting guide as desired.

1. Assemble the CAS Distal First Spike with the CAS Extractor Adaptor, making sure the rotation limiting pin is properly aligned, as shown in Figure 4.21. Pierce the cortex at the mechanical axis entry point with a cortex breaker or a 3.2 mm drill bit (only a few millimeters in depth). Align the CAS Extractor Adaptor Arm in the anterior direction (along the Whiteside's line). Impact the spike into the distal femur, as shown in Figure 4.21. Do not impact deeper than the end of the four blades on the spike.

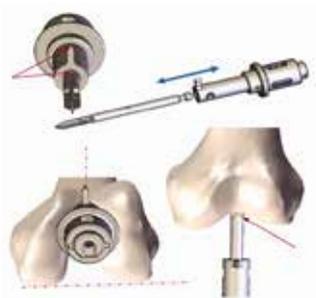


Figure 4.21  
Installation of the CAS Distal First Spike

2. It is recommended to add some extension during insertion of the spike to counter the common tendency of inserting with excess flexion. Only gross spike alignment is necessary since the adjustment mechanism allows for a fine adjustment of 30 degrees in extension and 15 degrees in flexion.



Figure 4.22  
Insertion of the Spike in Proper Flexion

- ⚠ **Warning:** Make sure the spike is stable before performing manipulations relative to the next steps.
3. In order to save time and ease intraoperative manipulations, the scrub nurse should align the varus/valgus (green screw) and the flexion/extension (AO fitting) at zero degrees as a starting point. Loosening the rotation locking lever (yellow) prior to installation will ease manipulations. See Figure 4.23.

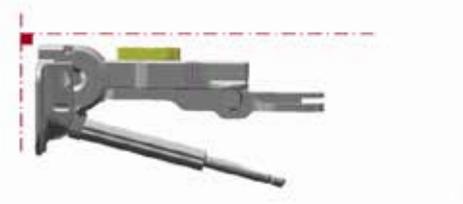
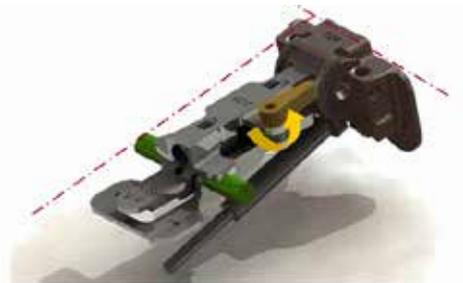


Figure 4.23  
Adjust the CAS Femoral Cut Alignment Guide.

## Distal Cut Navigation (cont.)

4. Assemble the CAS Mini Cutting Block 1.27 mm to the CAS Distal Cutting Block Platform using the CAS Cutting Block Screw and slide the assembly in the main alignment guide, as shown in Figure 4.24. The cutting guide can be positioned in three locations (medial, lateral, or centered). It is suggested to use the center position, but particular circumstances and patient conditions may require using another position per surgeon preference.

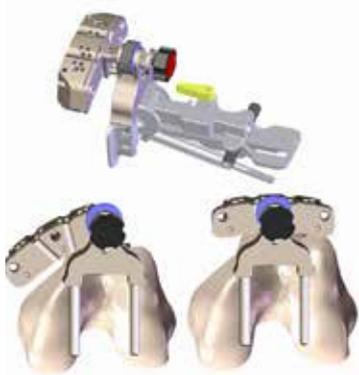


Figure 4.24

Assembly of the CAS Mini Cutting Block 1.27 mm with the CAS Distal Cutting Block Platform.

5. Slide the complete assembly on the inserted spike.



Figure 4.25

Assembly Fixed on the Femur

- ⚠ **Warning:** Using the CAS Universal Offset Paddle 1.0 mm in the CAS Mini Cutting Block 1.27 mm can be permitted if the thumb screw is tightened slightly more than usually to remove the free-play in the cutting slot.
- ⚠ **Warning:** The CAS Mini Cutting Block 1.27 mm can be disassembled from the CAS Distal Cutting Block Platform if the user unscrews the CAS Cutting Block Screw (108.089.06) too much.

## Navigate Cutting Block

The intent of the Navigate Cutting Block subtask is to set the appropriate orientation of the cutting guide with respect to the femoral mechanical axis. In the panel, the angles of varus/valgus and flexion/extension of the navigated cutting block are displayed under the Frontal and Lateral viewers. In addition, the resection level and the suggested size of the implant are displayed in the indicators that are located between the two viewers. In order to navigate and position the distal femoral cutting guide, refer to Figures 4.26, 4.27 and 4.28 for the detailed instructions.

6. After releasing the T-handle, adjust the flexion/extension angle and lock it in desired position by tightening that same T-handle.

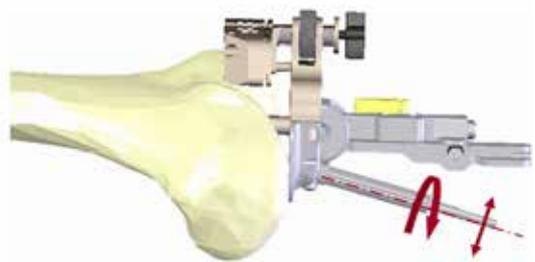


Figure 4.26

Locking the Flexion/Extension Adjustment

7. Adjust varus/valgus angle by pressing on the “V-V” fork and releasing it in the desired position, as shown in Figure 4.28. Using the green screws, on both medial and lateral sides, finely adjust the varus/valgus angle either by hand or using a screwdriver.
8. Adjust distal resection to the desired value by rotating the blue wheel on the distal platform, as shown in Figure 4.28.

## Intraoperative Guide

### Distal Cut Navigation (cont.)



Figure 4.27  
Distal Cut Screen

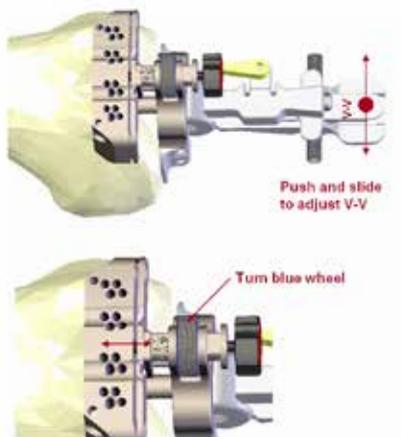


Figure 4.28  
Adjustment of the Varus/Valgus and Resection Level with the Femoral Cutting Guide Alignment

9. Ensure that the alignment guide mates with at least one distal condyle and place pins in the 0 mm holes of the cutting guide.

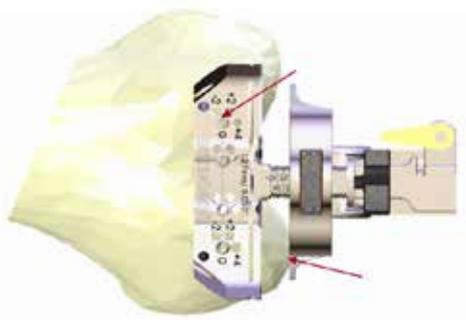


Figure 4.29  
Position Pins in the "0 mm" Holes

10. Once the distal cutting guide is firmly positioned on the bone, unscrew the knob holding the cutting guide, and remove the assembly, leaving the cutting block in place as shown in Figure 4.30 below.



Figure 4.30  
Remove the Assembly, Leaving the Cutting Block in Place

11. If the resection level is not satisfactory after removing the assembly, alternate holes (-2 mm, +2 mm, +4 mm, +6 mm) can be used to achieve the desired bone resection level.

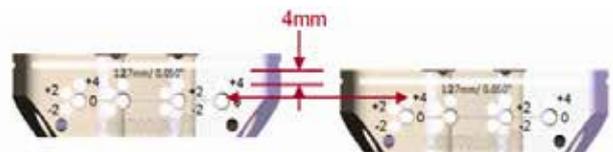


Figure 4.31  
Move Block to Other Pinholes as Necessary

12. Extracting the CAS distal first spike:

- NexGen Complete Knee Solution: Directly use the NexGen slap hammer on the spike.
- Natural-Knee II System, Persona Knee Implants and Innex Total Knee System\*: Use the CAS Extractor Adaptor by pulling the sleeve and assembling it on the spike. Then, use the Natural-Knee II, Persona Knee or Innex\* slap hammer for removal.
- Vanguard Complete Knee System\*\*: Directly use the NexGen Slap Hammer on the spike.
- Other: Use slap hammer by assembling it on the CAS Extractor Adaptor and, then, pulling the sleeve to assemble it on the spike. Finally, use the Natural-Knee II Slap Hammer for removal.

\*Not available in the US  
\*\* Vanguard XP not supported

## Distal Cut Navigation (cont.)



Figure 4.32  
Extraction of the CAS Distal First Spike

### Distal Cut Validation

The purpose of the Distal Cut Validation is to verify if the distal femoral resection was achieved as desired. It is mainly used to inspect the orientation and if needed introduce the necessary corrections to the distal femoral cut. In order to validate the distal femoral resection, refer to Figure 4.33 for the detailed instructions.



Figure 4.33  
Distal Cut Validation

1. Remove the CAS Posterior Condyle Digitizer from the CAS Universal Validation Tool Body.
2. Place the CAS Universal Validation Tool Body on the distal femoral cut.
3. Stabilize the instrument to acquire the varus/valgus, flexion/extension and resection level of the cut.
4. Verify the values and introduce the corrections if needed.
5. To restart the Distal Cut Validation subtask move the CAS Universal Validation Tool Body in the camera volume.

## Femur Rotation Navigation (only available when an implant is selected)

The purpose of this panel is to select the proper implant size, set the A/P position and the axial rotation of the implant. In addition, the medial and lateral posterior condyles resection level can be navigated. The Femur Rotation Navigation panel is shown in Figure 4.34 and the detailed instructions are shown in Figures 4.35, 4.36 and 4.37.

### Implant Sizing, Anterior/Posterior Placement, and Posterior Resection Level

Depending on the implant type, this task is completed with the CAS Universal Validation Tool Body assembled with the corresponding drill guide, or the CAS Universal Offset Paddle inserted in the anterior cutting slot of the appropriate A/P cutting block (4-in-1 type).

A 3D phantom model of the femoral distal lateral plane is displayed with transparency. The posterior condyles and anterior cortex points are superimposed on the model. The anterior plane, distal plane and posterior plane of the selected implant size are also superimposed on the model. The sizing of the implant can be performed while the instrument is positioned on the distal cut surface. It can be performed according to the green anterior cortex line attached to the bone, in the lateral view or with the pointer tip, if it is positioned on the anterior cortex.



Figure 4.34  
Femur Rotation Navigation

## Intraoperative Guide

### Femur Rotation Navigation (only available when an implant is selected) (cont.)

For distal cut first procedures, the optimal A/P size is calculated based on the current distal cut and shown in the sizing indicator (ruler in the Figure 4.33 for instance). This optimal A/P size is converted into a sizing suggestion in the femoral rotation panel.

If the optimal A/P size lies between two implant sizes, the system suggests the largest of both implants in order to avoid notching. If the optimal A/P size cannot be computed (for instance, if the distal cut was not validated, or if the largest implant in the family would still cause notching), no A/P sizing suggestion is made in the Femur Rotation Navigation panel.

The implant selector is initialized with the suggested A/P size, shown next to the selector. If the suggested A/P size is unavailable, the selector is initialized with the suggested M/L size, if enabled, or the smallest implant in the family. In all cases, the surgeon should validate this suggestion based on the information provided in the Lateral viewer and the Sizing indicator.

Refer to Figure 4.35 for the detailed instructions about implant sizing and A/P placement.

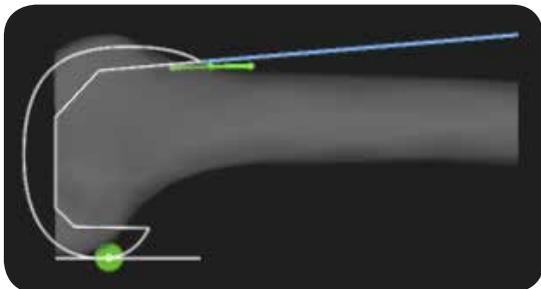


Figure 4.35  
Implant Sizing and A/P Placement

1. Position the navigation instrument on the distal femoral cut.
2. Adjust the A/P position of the instrument such that the bottom horizontal line is aligned with the green marker (posterior condyles).
3. To avoid notching, select the size of the implant such that the implant flange line is positioned above the anterior cortex line.

**Warning:** Do not use the pictorial representation of the bones for component positioning purposes. They are provided solely to visualize axis orientation and do not represent the actual bone anatomy.

**Warning:** If standard cutting guides are used, make sure that the size of the cutting guide that you are using corresponds to the size displayed by the system.

Refer to Figure 4.36 for the detailed instructions about the posterior resection level.

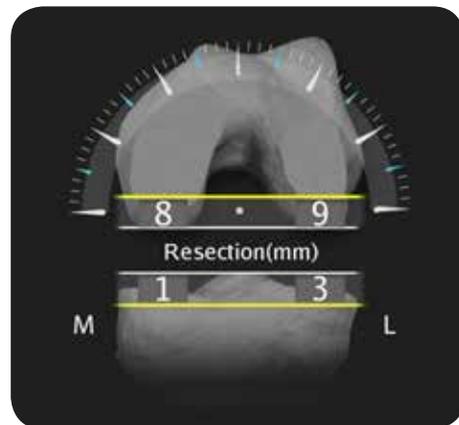


Figure 4.36  
Posterior Resection Level (Optional)

1. Adjust the A/P position of the implant to navigate the medial and lateral resection level of the posterior condyles (shown on the posterior condyles in grey).

## Femur Rotation Navigation (only available when an implant is selected) (cont.)

### Adjustment of the Axial Rotation

Three rotational parameters are displayed below the Axial viewer according to the femoral landmarks that were digitized (A/P rotation, epicondylar rotation, posterior condylar rotation). The rotation angles should be used to determine the desired orientation. Refer to Figure 4.37 for the detailed instructions on the implant axial rotation adjustment



Figure 4.37  
Axial Rotation Parameters

1. When the navigation instrument is positioned on the distal femoral cut, perform implant axial rotation adjustment. The A/P, epicondylar and posterior axis indicators can be used as a reference to set the desired rotation of the implant.
2. Secure the navigated block on the femur with the drive pins.
3. Drill the peg holes.

## Soft Tissue Balancing (option only available if an implant is selected)

This panel is intended for ligament balancing when the femoral and tibial cuts are finished. To obtain a defined stress, spacer blocks or a spreader with a force-measuring tool can be used. Refer to Figures 4.38, 4.39 and 4.40 for the detailed instructions on the soft tissue balancing procedure.



Figure 4.38  
Acquire Posterior Plane

1. Position CAS Universal Validation Tool Body with the CAS Posterior Condyle Digitizer against the distal and posterior cut surfaces.
2. Stabilize the instrument.
3. Acquire the posterior femoral cut plane.



Figure 4.39  
Flexion Gap

1. Bring the leg into flexion.
2. Position spacer block or spreader device between the tibial cut and femoral posterior cut.
3. Perform laxity test and ligament adjustment if necessary.
4. Position the pointer in the area of the knee joint to record the flexion gap value or directly click on the "Record Gap" button.

## Intraoperative Guide

### Soft Tissue Balancing (option only available if an implant is selected) (cont.)



Figure 4.40  
Extension Gap

1. Bring the leg into extension.
2. Position spacer block or spreader device between the tibial cut and femoral distal cut.
3. Perform laxity test and ligament adjustment if necessary.
4. Position the pointer in the area of the knee joint to record the extension gap value or directly click on the "Record Gap" button.

### Postoperative Range of Motion

The postoperative range of motion is similar to the Initial Range of Motion task. Refer to the Initial Range of Motion section (p. 14) of the present document.

## Surgical Technique: Anterior Cut First with Insall Gap Balancing Technique

This technique can be applied to Innex\*, NexGen Flex and Gender Solutions Total Knee System\*\* Implants.

The workflow for the Anterior Cut First with Insall Gap Balancing Technique is the following:

1. Initial Range of Motion
2. Tibial Cut Navigation
3. Extension Gap
4. Anterior Cut Navigation (Femur)
5. Distal Cut Navigation (Femur)
6. Postoperative Range of Motion

**Warning:** During ligament balancing procedure do not apply excessive stress to the knee joint compartments in order to avoid permanent damage to the ligaments.

### Initial Range of Motion

This task is similar to the Initial Range of Motion task described in the Initial Range of Motion section (p.14) of the present document.

### Tibial Cut Navigation

This task is similar to the tibial cut navigation described in the Tibial Cut Navigation section (p. 15) of the present document.



Figure 4.41  
Tibial Cut Navigation

- Cut the tibia at the optimal level.
- Tibial cut navigation: The tibia cut will influence the flexion and extension gap.
- Validation of tibial cut: The cut needs to be validated to activate the gap calculation.

### Extension Gap

The purpose of this panel is to perform ligament balancing in extension. In addition, the preliminary gap in extension between the tibia and femur can be recorded. This panel is available only if the Insall Gap Balancing option is enabled in the Surgical preferences. The Extension Gap panel is shown in Figure 4.42.

To start this task, place the knee in full extension and insert an implant system spacer/distracter guide between the resected surface of the tibia. The flexion/extension and varus/valgus angles of the knee joint will be displayed in the panel. In addition, a Frontal viewer will display the gap alignment including an indicator for the gap measurement. If necessary, perform ligament balancing to achieve a rectangular gap. Then stabilize the leg and position the pointer in the area of the knee joint. As a result the gap in extension and the alignment values will be recorded in the system to be used as a reference when adjusting the flexion gap.



Figure 4.42  
Extension Gap

\*Not available in the US

\*\*When using Flexion Balancing Instruments.

## Intraoperative Guide

### Extension Gap (cont.)

#### Obtain ligament balance

Install the CAS Tensor (or any other tensioning device) in extension and measure the proper extension gap.



Figure 4.43  
Tensor in Extension

1. The proper tension in the joint is achieved when a laxity test can give  $\pm 4$  degrees of varus/valgus from its neutral position. Over 4 degrees of HKA deviation, the surgeon may want to release ligaments to correct the deformity.
2. Gap is recorded only when the "Record Gap" button is activated at 0–10 degrees of flexion. This button could be activated by the pointer inserted in the joint area.

### Anterior Cut Navigation

The purpose of this panel is to select the proper implant size, set the A/P position and the axial rotation of the implant. In addition, the flexion gap can be measured and adjusted to match the preliminary extension gap, and the medial and lateral posterior condyles resection level can be navigated. The Anterior Cut Navigation panel is shown in Figure 4.44.



Figure 4.44  
Anterior Cut Navigation

#### Instruments Setup

Flex the leg and position the CAS Tensor in the joint space. Use two pins to attach the base of the CAS Tensor to the tibial surface. During the procedure, ensure that the base remains stable and mating parallel to the tibial surface. Perform laxity tests to evaluate the ligament tension. If the tension is not equal, it is possible to elevate independently any side of the CAS Tensor by 1.2 mm increments using a screwdriver. When equal tension in the ligaments is reached, mount the dedicated drill-guide on the tensor and adjust position such that the drill-guide is in contact with the distal femoral condyles. Insert the CAS Universal Offset Paddle in the dedicated A/P drill guide. When the assembly is complete, flexion/extension, varus/valgus, A/P position, posterior resection level and the axial rotation of the implant can be adjusted.



Figure 4.45  
CAS Tensor in Flexion

1. Insert the tensor in 90 degrees of flexion and use the CAS Universal Offset Paddle to navigate the implant specific drill guide.
2. The proper tension in the joint is achieved when a laxity test gives a feeling of a normal joint.
3. Use the elevator to properly adjust the anterior flange of the implant in order to avoid notching.

## Anterior Cut Navigation (cont.)

### Implant Sizing and Anterior/Posterior Placement

In the panel a 3D phantom model of the femoral distal bone is displayed with transparency (Figure 4.46). The posterior condyles and anterior cortex points are superimposed on the model. The anterior, distal and posterior planes of the selected implant size are superimposed on the model. Sizing can be performed according to the green anterior cortex line attached to the bone, in the lateral view, or with the pointer tip, if it is positioned on the anterior cortex.

For anterior cut first procedures, no A/P sizing suggestion is provided. The implant selector in the anterior cut panel is initialized based on the M/L suggested size, if enabled, or the smallest implant in the family.

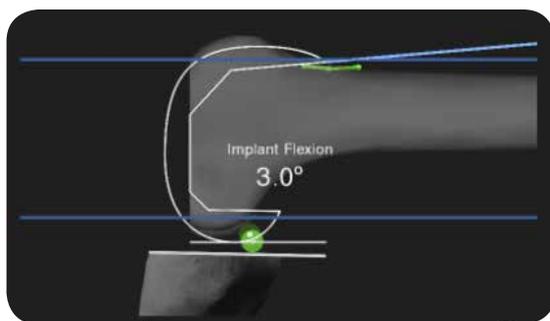


Figure 4.46

#### Implant Sizing and Anterior/Posterior Placement

1. Set the flexion/extension angle of the implant by flexing or extending the tibia.
2. To avoid notching, adjust the A/P position of the instrument such that the implant flange line is positioned above the anterior cortex line.
3. Select the size of the implant such that the bottom horizontal line of the implant is aligned with the femoral posterior condyles (green point).
4. The selected size should give the closest flexion gap to the extension gap.

For the Flexion Balancing Instrumentation, the positioning of the preliminary A/P cutting guide will define the position of the final A/P cuts. Hence, the notching detection should be performed prior to fixing the preliminary A/P cutting guide.

- ⓘ **Warning:** Do not use the pictorial representation of the bones for component positioning purposes. They are provided solely to visualize axis orientation and do not represent the actual bone anatomy.
- ⓘ **Warning:** If standard cutting guides are used, make sure that the size of the cutting guide that you are using corresponds to the size displayed by the system.
- ⓘ **Warning:** Whenever using the CAS Universal Offset Paddle or the CAS Universal Positioning Block, ensure that the blade is fully inserted in the slot to be navigated, with the blade's shoulder against the edge of the slot.
- ⓘ **Warning:** The NexGen LPS-Flex System has an embedded 2 mm difference between flexion and extension gaps A/P due to an augmented posterior condyle cut.
- ⓘ **Warning:** The insertion of the bone reference pins on the femur can obstruct the insertion of the intramedullary rod in the canal.
- ⓘ **Warning:** Due to other potential interferences with navigation instruments, the intramedullary rod should only be inserted when positioning the anterior/posterior preliminary cutting block.

### Adjustment of the Implant Varus/Valgus and Axial Rotation

Three rotational parameters are displayed below the Axial viewer according to the femoral landmarks that were digitized (posterior condyles rotation, epicondylar rotation, A/P rotation). The rotation angles should be used to determine the desired axial orientation of the implant. Refer to Figure 4.47 for the detailed instructions on the implant varus/valgus and axial rotation adjustment.



Figure 4.47

#### Axial Rotation Alignment

## Intraoperative Guide

### Anterior Cut Navigation (cont.)

1. The A/P, epicondylar and posterior axis (Figure 4.47), and gap angle indicators (Figure 4.48) can be used as a reference to set the desired rotation of the implant.
2. Adjust femoral rotation according to the tension of the ligaments (usually some external rotation).
3. Once the tension has been applied, the drill guide will be automatically rotated to be parallel to the tibia cut in order to achieve a rectangular gap.
4. If rotation is considered too high (by the surgeon) internally or externally with respect to natural landmarks (i.e. posterior condylar axis), the surgeon may want to make a compromise between tension and rotation and correct rotation by removing tension from one of the affected sides.
5. Perform implant varus/valgus adjustment by turning the drill guide and locking it in the desired position.
6. Secure the navigated block on the femur with the drive pins.

When all the adjustments are completed and the drive pins are positioned in the femur, position the pointer in the area of the knee joint to record the flexion gap value.

**Note:** The flexion gap must be stored in order to enable optimization of the distal femoral resection.

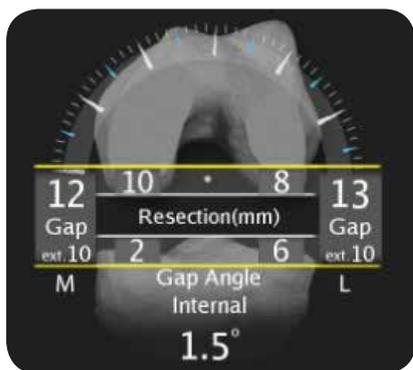


Figure 4.48

Flexion Gap Alignment and Posterior Resection Level (Optional)

Use of the CAS Tensor is recommended with the Flexion Balancing Instruments (FBI). By convention, the uppermost drill-holes of the bottom holes section are navigated by the CAS Tensor, as shown by the yellow arrows in the instrument verification pop-up (Figure 4.49).

Then, the Flexion Balancing Instruments preliminary cutting guide should be inserted in the appropriate drill holes, as shown in the application



Figure 4.49

Instrument Verification Pop-Up for Flexion Balancing Instruments

### Distal Cut Navigation

The intent of the Distal Cut Navigation panel is to assist the surgeon to perform the desired femoral distal resection and match the gap in extension with the previously measured flexion gap. This panel allows to accurately position the distal cutting guide with respect to the femoral mechanical axis and adjust the resection level of the cut.

#### Navigate Cutting Block

The main intent of the Navigate Cutting Block subtask is to set the appropriate orientation and position of the cutting guide with respect to the femoral mechanical axis. In the panel, the angles of varus/valgus and flexion/extension of the navigated cutting block are displayed under the Frontal and Lateral viewers. In addition, the resection level is displayed in the indicators that are located between the two viewers. In order to navigate and position the distal femoral cutting guide refer to Figure 4.50 for the detailed instructions.

## Distal Cut Navigation (cont.)



Figure 4.50  
Navigate Cutting Block

1. Insert the CAS Universal Offset Paddle in the distal cutting guide of the standard instrumentation system.
2. Position the distal cutting guide on the anterior surface of the femur.
3. Verify the varus/valgus angle of the implant (adjust if applicable).
4. Verify the flexion/extension angle of the implant.
5. Adjust the resection level to match the extension gap with the previously acquired flexion gap. Secure the position of the distal femoral cutting guide on the femur with the drive pins.
6. Perform the distal femur resection with the help of the positioned distal cutting guide.

### Distal Cut Validation

The purpose of the Distal Cut Validation subtask is to verify if the distal femoral resection was achieved as desired. It is mainly used to inspect the orientation and if needed introduce the necessary corrections to the distal femoral cut. In order to validate the distal femoral resection, refer to Figure 4.51 for the detailed instructions.

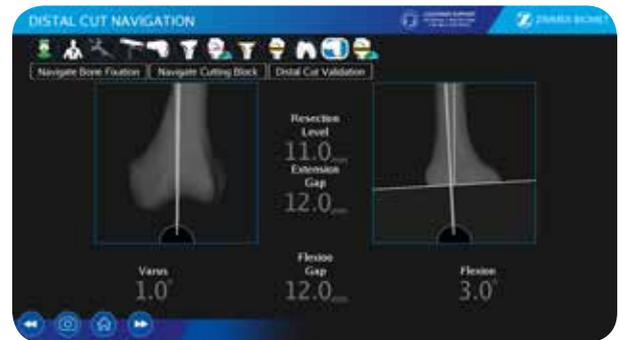


Figure 4.51  
Distal Cut Validation

1. Remove the CAS Posterior Condyle Digitizer from the CAS Universal Validation Tool Body.
2. Place the CAS Universal Validation Tool Body on the distal femoral cut.
3. Stabilize the instrument to acquire the varus/valgus, flexion/extension and resection level of the cut.
4. Verify the values and introduce the corrections if needed.
5. To restart Distal Cut Validation subtask move the CAS Universal Validation Tool Body in the camera volume.

## Postoperative Range of Motion

The postoperative range of motion is similar to the initial Range of Motion task. Refer to the Initial Range of Motion section (p. 14) of the present document.

## Postoperative Guide

### Exiting the Application

To exit the application, click on the “Menu” button. Then click on “Quit Application” and answer “Yes” to the question, “Are you sure you want to quit the application?”



Figure 5.1  
Menu Button

### Case Data Manager

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

#### Starting the Case Data Manager

After turning on the system, click the “Gear” icon  to open the System Utilities menu and click the “Case Data Manager” icon .

#### Managing Cases

Displayed cases can be sorted by date, patient ID or case selection by clicking the appropriate header.

Cases can be filtered by date using the date widget.



Surgical information about a case can be displayed by clicking the “Report” icon .

Comments can be entered about a case by clicking the “Keyboard” icon .

#### Archiving cases on a USB key

**Step 1:** Ensure that a USB key is connected to the Sesamoid Plasty Computer and that its icon  is displayed on the top right corner of the computer screen.

**Step 2:** Select the cases to archive by clicking their checkboxes.

**Step 3:** Click the “Export” icon  and then click the “Archive” icon . All information relative to the selected cases will be archived on a USB key.

### Uploading Cases on the Zimmer Biomet Case Database

To upload cases on the Zimmer Biomet case database, when reporting an incident in a complaint:

**Step 1:** Ensure that the system has an active internet connection .

**Step 2:** Select all cases to upload by clicking their checkboxes.

**Step 3:** Click the “Export” icon  and then click the “Upload” icon . All information relative to the selected cases will be uploaded to the Zimmer Biomet case database.

### Deleting Cases

To delete cases:

**Step 1:** Select all cases to delete by clicking their checkboxes.

**Step 2:** Click the “Delete” icon .

### Updating the System

System updates must be performed by sales or distribution representatives.

#### Update via Internet Connection

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

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

## Updating the System (cont.)

### Update via Internet Connection (cont.)

**Step 2:** Click the “Gear” icon  to open the System Utilities menu and click the “Update Manager” icon .

Available operating system updates are installed automatically and a reboot might be required to complete the installation.

The release reports for available application updates are then displayed for review.

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

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

### Update via USB Key

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

**Step 1:** Before starting the installation process, ensure that the USB key is connected to the system and that its icon  is displayed on the top right corner of the computer screen; also ensure that the system is connected to an AC outlet.

**Step 2:** Click the “Gear” icon  to open the System Utilities menu and click the “Update Manager” icon .

Available operating system updates are installed automatically and a reboot might be required to complete the installation.

The release reports for available application updates are then displayed for review.

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

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

**Step 3:** If the application update is accepted, enter the installation license key in the dialog box that opens.

## Update According to Regulatory Region

The system is configured for a specific regulatory region. If the system changes the regulatory region, contact customer support.

## Shut Down Sesamoid Plasty Computer

**Step 1:** Exit all applications in use, if any.

**Step 2:** Click the “Shutdown” button located at the bottom right corner of the Sesamoid Plasty Computer screen or press the “Power” button (luminous button) located on the bottom left hand edge of the Sesamoid Plasty Computer screen.

**Step 3:** 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.

## Ordering and Instrument Cleaning/Sterilization Information

### Instrument Inventory and Sterilization/Cleaning Methods

Table 3.1 lists the instruments supplied by Zimmer CAS and Zimmer Biomet and describes the sterilization methods recommended for each instrument. Reusable instruments must be cleaned after use prior to sterilization. They should not be sterilized in the protective bag or packaging supplied with them. All sterilizations should be performed using standard and regularly maintained equipment.

For cleaning, reusable instruments require manual cleaning steps as follows. All multi-component instruments must be disassembled. Every instrument must be pre-soaked for 10 minutes 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. Remove instruments from the cleaning solution and rinse in purified water for a minimum of 1 minute. Place instruments in a suitable washer/disinfector basket and process through a standard instrument washer/disinfector cleaning cycle. The following minimum parameters are essential for thorough cleaning and disinfection.

#### Typical US Automated Washer/Disinfector Cycle for Surgical Instruments

Step	Description
1	2 minutes prewash with cold tap water
2	20 seconds enzyme spray with hot tap water
3	1 minute enzyme soak
4	15 seconds cold tap water rinse (X2)
5	2 minutes detergent wash with hot tap water (64-66°C/146-150°F)
6	15 seconds hot tap water rinse
7	2 minutes thermal rinse (80-93°C/176-200°F)
8	10 seconds purified water rinse with optional lubricant (64-66°C/146-150°F)
9	7 to 30 minutes hot air drying (116°C/240°F)

#### Typical European Automated Washer/Disinfector Cycle for Surgical Instruments

Step	Description
1	5 minutes pre-rinse with cold tap water
2	10 minutes alkaline cleaning agent wash at 55°C
3	2 minutes rinse with neutralizer
4	1 minute rinse with cold tap water
5	Disinfection at 93°C with hot purified water until A0 3000 is reached (approx. 10 minutes)
6	40 minutes hot air drying at 110°C

**Warning:** The washer/disinfector manufacturer's instructions should be strictly adhered to. Use only cleaning agents recommended for the specific type of automated washer/ disinfector. A washer/ disinfector with approved efficacy (e.g. CE mark, FDA approval, and validation according to ISO 15883) should be used.

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 Table 3.1 as applicable to each instrument.

The methodology, "Combination Cleaning and Disinfection Instructions", described in the Reprocessing Manual, available at <http://www.zimmer.com>, is also applicable.

## Ordering and Instrument Cleaning/Sterilization Information (cont.)

### Instrument Inventory and Sterilization/ Cleaning Methods (cont.)

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

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

**Warning:** All instruments are delivered with a package insert, which indicates the applicable cleaning and sterilization specifications. The specifications given on the inserts take precedence over the ones included in this text.

### 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

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 as in the European Union.

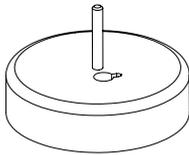
## Ordering and Instrument Cleaning/Sterilization Information (cont.)

**Table 3.1:** List of instruments with sterilization and cleaning requirements. 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 10 minutes ultrasonic cleaning cycle in an enzymatic solution
- E** Screw/mechanism should be checked and lubricated as required

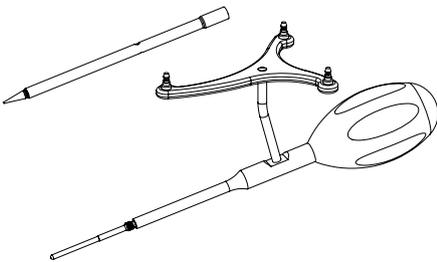
Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
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CAS Calibration Star Holder	20-8000-010-01	100.026	Autoclave
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Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
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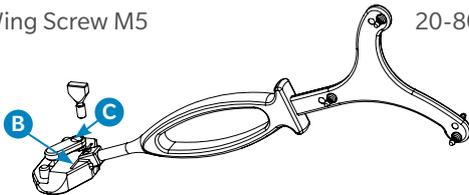
CAS Registration Pointer Kit	20-8000-070-01	104.034	Autoclave <b>A</b>
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Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
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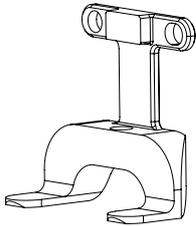
CAS Universal Validation Tool Body	20-8000-010-06	108.050	Autoclave <b>A B C E</b>
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Wing Screw M5	20-8000-010-37	111.006	Autoclave <b>A</b>
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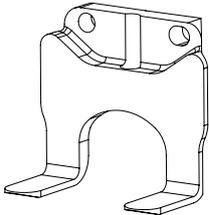


## Ordering and Instrument Cleaning/Sterilization Information (cont.)

Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Short Posterior Condyles Digitizer	20-8000-010-09	108.056	Autoclave



Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Posterior and Distal Condyles Digitizer	20-8000-010-17	108.077	Autoclave



Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Spike 7.9 mm	20-8000-010-18	108.080	Autoclave



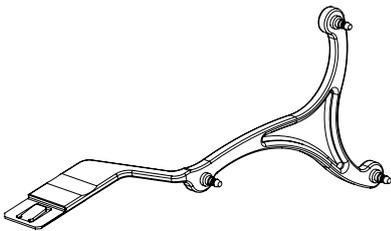
## Ordering and Instrument Cleaning/Sterilization Information (cont.)

**Table 3.1:** List of instruments with sterilization and cleaning requirements. 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 10 minutes ultrasonic cleaning cycle in an enzymatic solution
- E** Screw/mechanism should be checked and lubricated as required

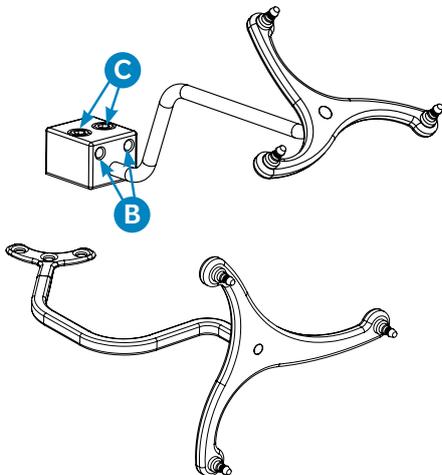
### CAS Universal Offset Paddles

Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Universal Offset Paddle 1.00 mm	20-8000-010-28	108.115	Autoclave
CAS Universal Offset Paddle 1.27 mm	20-8000-010-29	108.116	Autoclave
CAS Universal Magnetic Offset Paddle	20-8000-010-30	108.117	Autoclave



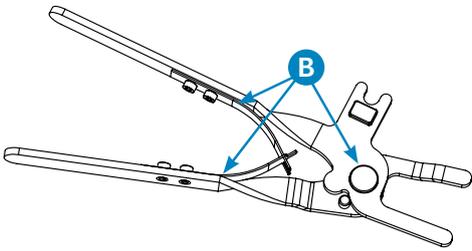
### Femur and Tibia References

Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS 2 Pins Reference Femur - TS3	20-8000-010-33	110.025	Autoclave <b>B C D E</b>
CAS Offset 2 Pins Reference Right Tibia Size 6	20-8000-010-35	110.037	Autoclave <b>B C D E</b>
CAS Offset 2 Pins Reference Left Tibia Size 6	20-8000-010-36	110.038	Autoclave <b>B C D E</b>
CAS Same Incision Tracker - Femur	20-8000-010-60	20-8000-010-60	Autoclave
CAS Same Incision Tracker - Tibia	20-8000-010-59	20-8000-010-59	Autoclave

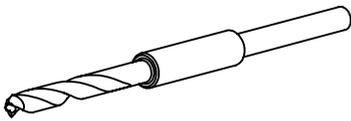


## Ordering and Instrument Cleaning/Sterilization Information (cont.)

Description	Product Number	Manufacturer Number	Specific Cleaning Instructions
CAS Navitracker® Pliers (Optional)	20-8000-070-05	116.017	Autoclave <b>B</b> <b>D</b> <b>E</b>



Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Stop Drill 6 mm	20-8000-010-45	117.002	Autoclave



Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
Hexagonal Screwdriver 3.5 mm*	00-4812-045-00	-	Autoclave



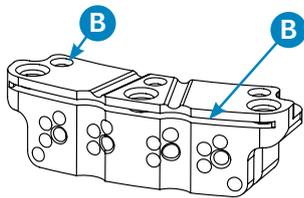
\*The screwdriver is manufactured by Zimmer Biomet (not Zimmer CAS). It is ordered directly from Zimmer Biomet.

## Ordering and Instrument Cleaning/Sterilization Information (cont.)

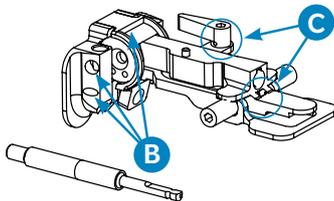
**Table 3.1:** List of instruments with sterilization and cleaning requirements. Additional specific cleaning instructions as defined in the text are indicated as applicable to each instrument as follows:

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

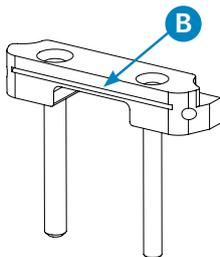
Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Mini Cutting Guide Block 1.27 mm	20-8000-010-19	108.083	Autoclave <b>B</b>



Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Femoral Cut Alignment Guide	20-8000-010-22	108.087	Autoclave <b>A B C D E</b>
AO M6 Screw	20-8000-010-49	108.087.11	Autoclave <b>A</b>

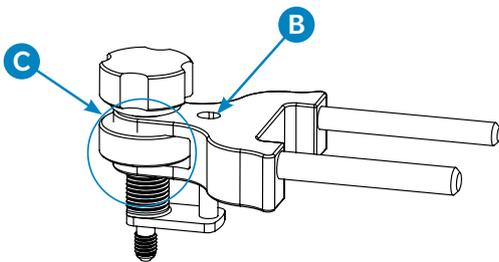


Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Anterior Cutting Block	20-8000-010-23	108.088	Autoclave <b>B</b>



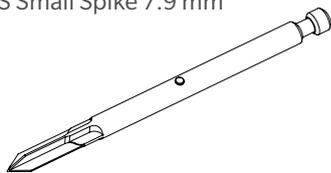
## Ordering and Instrument Cleaning/Sterilization Information (cont.)

Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Distal Cutting Block Platform	20-8000-010-24	108.089	Autoclave <b>B C D E</b>
CAS Cutting Block Screw	20-8000-010-50	108.089.06	Autoclave

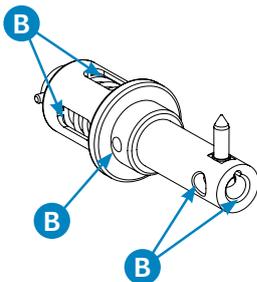


### Spikes for CAS Femoral Cut Alignment Guide

Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Distal Cut First Spike	20-8000-010-25	108.106	Autoclave
CAS Small Spike 7.9 mm	20-8000-010-27	108.108	Autoclave



Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Extractor Adaptor	20-8000-010-26	108.107	Autoclave <b>B</b>

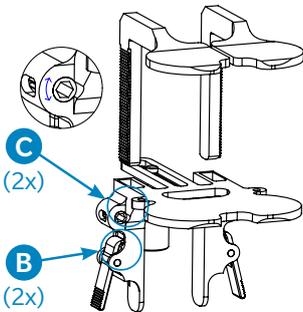


## Ordering and Instrument Cleaning/Sterilization Information (cont.)

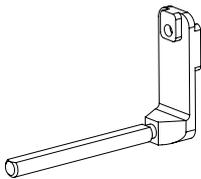
**Table 3.1:** List of instruments with sterilization and cleaning requirements. Additional specific cleaning instructions as defined in the text are indicated as applicable to each instrument as follows:

- 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 10 minutes ultrasonic cleaning cycle in an enzymatic solution
- E** Screw/mechanism should be checked and lubricated as required

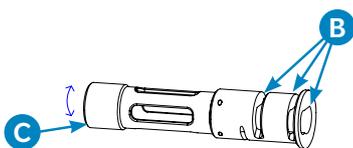
Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Adjustable Spacer (ORTHOsoft Tensor subassembly)	20-8000-010-11	108.060	Autoclave <b>A B C D</b>



Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS A/P Positioning Base (ORTHOsoft Tensor subassembly)	20-8000-010-12	108.061	Autoclave



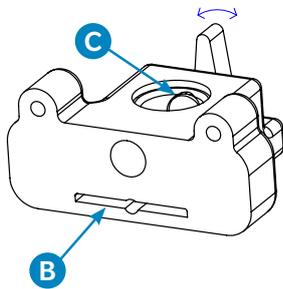
Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS A/P Positioning Elevator (ORTHOsoft Tensor subassembly)	20-8000-010-13		Autoclave <b>B C E</b>



## Ordering and Instrument Cleaning/Sterilization Information (cont.)

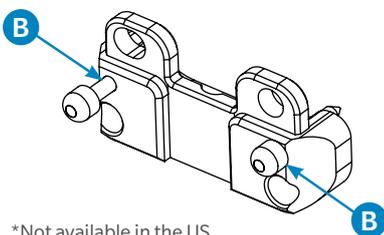
### A/P Drill Guide (Optional) (ORTHOsoft Tensor subassembly)

Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Natural-Knee® II A/P Drill Guide	20-8000-010-14	108.063	Autoclave <b>B C E</b>
CAS NexGen® A/P Drill Guide	20-8000-010-15	108.065	Autoclave <b>B C E</b>
CAS Innex® Std. A/P Drill Guide*	20-8000-010-16	108.066	Autoclave <b>B C E</b>
CAS Innex MIS A/P Drill Guide*	20-8000-010-32	108.166	Autoclave <b>B C E</b>
CAS FBI A/P Drill Guide	20-8000-010-52	108.173	Autoclave <b>B C E</b>
Biomet Vanguard A/P Drill Guide	20-8000-080-11	108.096	Autoclave <b>B C E</b>
Persona A-Ref A/P Drill Guide	20-8000-010-61	20-8000-010-61	Autoclave <b>B C E</b>
Persona P-Ref A/P Drill Guide	20-8000-010-63	20-8000-010-63	Autoclave <b>B C E</b>



### Drill Guides (Optional)

Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Natural-Knee II Drill Guide	20-8000-010-07	108.051	Autoclave <b>B D</b>
CAS Natural-Knee Flex Drill Guide	20-8000-010-53	108.123	Autoclave <b>B D</b>
Biomet Vanguard Drill Guide	20-8000-080-10	108.095	Autoclave <b>B D</b>
Drill Guide Persona A-Ref	20-8000-010-65	20-8000-010-65	Autoclave <b>B D</b>
Drill Guide Persona P-Ref	20-8000-010-67	20-8000-010-67	Autoclave <b>B D</b>



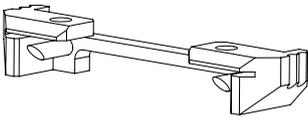
\*Not available in the US

## Ordering and Instrument Cleaning/Sterilization Information (cont.)

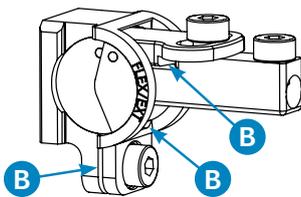
**Table 3.1:** List of instruments with sterilization and cleaning requirements. Additional specific cleaning instructions as defined in the text are indicated as applicable to each instrument as follows:

- 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 10 minutes ultrasonic cleaning cycle in an enzymatic solution
- E** Screw/mechanism should be checked and lubricated as required

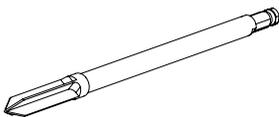
Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Natural-Knee II Saw Capture (Optional)	20-8000-010-10	108.058	Autoclave



Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Independent Adjustment Mechanism*	20-8000-010-20	108.085	Autoclave <b>A B D E</b>
Hex 3.5 mm Screw	20-8000-010-54	108.085.07	Autoclave <b>A</b>



Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Spike 6.75 mm*	20-8000-010-21	108.086	Autoclave



\*Not available in the US

## Ordering and Instrument Cleaning/Sterilization Information (cont.)

### CAS Fix Pin Fluted (for CAS 2 Pins References)

Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Fix Pin Fluted 3.2 x 150 mm	20-8000-000-01	116.015	Autoclave
CAS Fix Pin Fluted 3.2 x 80 mm	20-8000-000-02	116.018	Autoclave
CAS Fixation Pin Fluted 3.2 x 150 mm Sterile	20-8000-000-10	20-8000-000-10	Provided sterile (single use)
CAS Fixation Pin Fluted 3.2 x 80 mm Sterile	20-8000-000-11	20-8000-000-11	Provided sterile (single use)
CAS Fix Pin Fluted 3.2 x 150 mm-12X	20-8000-000-04	116.021	Autoclave
CAS Fix Pin Fluted 3.2 x 80 mm-12X	20-8000-000-03	116.020	Autoclave



### Headed Screw (for CAS Same Incision Trackers)

Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS 3.5 mm Hex Headed Screw x 33 mm	20-8000-000-12	-	Autoclave
3.5 mm Hex Headed Screw x 33 mm**	00-5901-035-33	-	Provided sterile (single use)
MIS Quad-Sparing™ Total Knee Procedure Headed Screw**	00-5983-040-33	-	Provided sterile (single use)



Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
NavitrackER Kit A - Knee	20-8000-000-07	201.116	Provided sterile (single use)



\*\*These are manufactured by Zimmer Biomet (not Zimmer CAS). They are ordered directly from Zimmer Biomet.

## Appendix A - CAS Same Incision Trackers

The same incision trackers are designed to be fixed on the bones through the surgical opening and allow navigating only the femoral distal and tibial cuts.

**Warning:** It is mandatory to deactivate other options in the Surgeon Profile settings such as navigation of the femoral rotation and gap balancing when using the CAS Same Incision Trackers.

1. Calibrate the CAS Registration Pointer as described in the US and EU CAS Registration Pointer section (p. 10).
2. Install the same incision femoral reference.

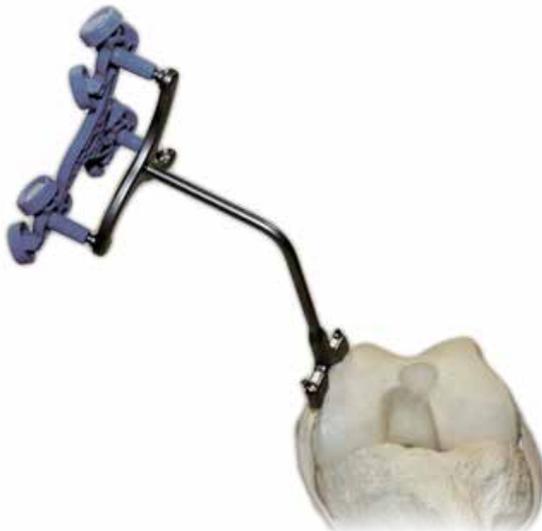


Figure A.1  
Installation of the CAS Same Incision Femoral Reference

The reference must be positioned on the edge of the medial condyle, the tracker rod at the level of the epicondyles to stay clear of the working area. If the user is using the CAS Femoral Cut Alignment Guide, make sure to clear enough space on the distal condyles to sit the instrument on the bone. This should be performed, before installation of the reference, by placing the CAS Femoral Cut Alignment Guide on the distal condyles in a centered position and marking the condyle to indicate the position of the guide. The user should then reference to this mark to ensure the same incision tracker is placed medially without interfering with the guide.

Use three screws to secure the reference in place. Make sure the screws are fully engaged in the reference base so that the reference is solidly fixed on the femur. Test the fixation by gently shaking the reference to detect any movement of the reference. If the reference moves, remove the screws and install the reference in a better location.

**Warning:** Do not use 3.2 mm pins or any fasteners other than those recommended for the CAS Same Incision Trackers. They are compatible with the fixation requirements of the CAS Same Incision Trackers on the bones.

3. Acquire the femoral coordinate system as described in the Femoral Landmarks section (p. 12).

The femoral landmarks to be acquired are:

- Femoral head center of rotation
- Mechanical axis entry point
- Anterior cortex points
- Distal condyles
- Posterior condyles

## Appendix A - CAS Same Incision Trackers (cont.)

### 4. Install the same incision tibial reference

The reference must be positioned on the anterior side of the medial plateau. Its shape has been designed to match the contour of the plateau.

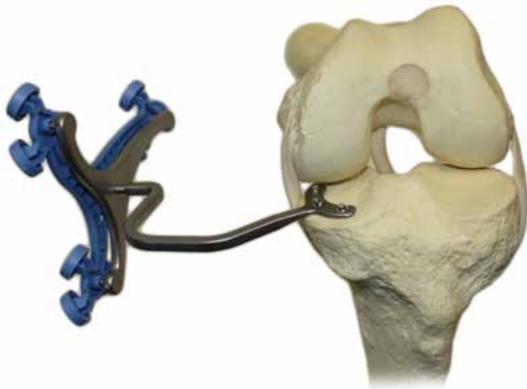


Figure A.2

Installation of the CAS Same Incision Tibial Reference

As a rule of thumb, the reference should be positioned sufficiently on the medial side of the plateau so there is space for a finger between the mechanical axis entry point and the reference base.



Figure A.3

Correct Same Incision Tibial Reference Position

In case of a very small tibial plateau where the reference would be installed closer to the center of the plateau, the cutting guide may be brought farther in anterior direction, by about 5 to 10 mm to avoid interference between the reference and the cutting guide.

The surgeon can also check with the cutting guide to ensure there is enough clearance before installing the reference on the tibial plateau.

**Warning:** Placement of the tibial reference on the tibial plateau should be performed with care to avoid physical interference between the reference and other conventional (EM guide) or navigated instruments.

Use three screws to secure the reference in place. Make sure the screws are fully engaged in the reference base so that the reference is solidly fixed on the tibia. Test the fixation by gently shaking the reference to detect any movement of the reference. If the reference moves, remove the screws and install the reference in a better location.

**Warning:** Do not use 3.2 mm pins or any fasteners other than those recommended for the CAS Same Incision Trackers. They are compatible with the fixation requirements of the CAS Same Incision Trackers on the bones.

The screws can be angled to  $\pm 35$  degrees in every direction on the tibial reference. To reduce the risk of interference between the cutting guide fixation pins and the same incision tibial tracker fixation screws, the reference's most lateral screw should be oriented as parallel as possible to the sagittal plane (Refer to Figure A.4).

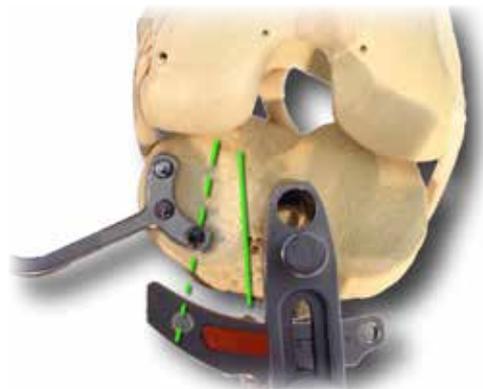


Figure A.4

Screws angulation

5. Acquire the tibial coordinate system as described in the Tibial Landmarks section (p. 13).

## Appendix A - CAS Same Incision Trackers (cont.)

The tibial landmarks to be acquired are:

- Mechanical axis entry point
  - Healthy plateau points
  - Tubercle-PCL points
  - Ankle points
6. Navigate the distal cut as described in the Distal Cut Navigation section (p. 17).

In general, there will be no interference between the cutting guide pins and the reference fixation pins. However, for a small femur, if the cutting guide is not centered on the femur and is located toward the medial side, interference could happen with the most medial cut-guide pin. Therefore, using the most medial hole of the 1.27 mm CAS Mini Cutting Block to avoid such interference is not recommended.

7. Remove the same incision femoral reference.
8. Perform the distal cut.
9. Navigate the tibial cut as described in the Tibial Cut Navigation section (p. 15).
10. Remove the same incision tibial reference.
11. Perform the tibial cut.

The surgical flow can be modified to perform a tibia first sequence instead of femur first.

Cut Validation subtasks are accessible in the surgical flow, but cannot be performed because the references on the femur and tibia are removed before the cuts are performed. Cuts might be validated using standard known techniques such as the use of an alignment rod from the standard instrumentation system.

The Range of Motion panel is still accessible in the flow of the application, but the final HKA cannot be assessed with the navigation system since both bone references are removed before performing the distal and tibial cuts. The HKA must be verified using standard known techniques such as the use of an alignment rod from the standard instrumentation system.

## Appendix B - Posterior Referencing Instrumentation

The posterior referencing instruments are a set of instruments designed by Zimmer Biomet for the NexGen CR-Flex and LPS-Flex Implant families (part of standard implant instrumentation) that utilizes a posterior referencing surgical technique. The posterior referencing instruments are compatible with the navigation application and its dedicated instrumentation.

The standard surgical technique remains mostly the same, except that some steps are navigated.

The conventional steps to perform the femoral distal cut are replaced by the navigation of the cutting guide with the CAS Femoral Cut Alignment Guide. The navigation of the distal cut is described in the Distal Cut Navigation section (p. 17).



Figure B.1  
Navigating the distal cut with the CAS Femoral Cut Alignment Guide

## Appendix B - Posterior Referencing Instrumentation (cont.)

Sizing the femur and establishing rotation is manually performed with the standard posterior referencing sizer, placed on the resected distal femur and its feet against the posterior condyles, and the holes for the pegs on the NexGen Posterior Referencing 4-in-1 Flex Femoral Cut Guide are drilled.



Figure B.2  
Sizing the femur and establishing rotation

Before inserting the 3.2 mm trocar-tipped pins in the oblique holes in the cut guide, insert the 1.27 mm CAS Offset Paddle in the anterior slot of the cutting guide. Verify that notching of the anterior cortex is avoided.



Then, the 4-in-1 cut guide is placed on the femur by aligning the two pins on the back of the guide with the previously drilled positioning holes.



Figure B.3  
Placing the posterior referencing 4-in-1 Flex Femoral Cut Guide on the resected distal cut



Figure B.4  
Verifying that notching of the anterior cortex is avoided

In case of potential notching of the anterior cortex, drill through the holes marked “+2 mm” on the anterior face of the cut guide, remove the cut guide and replace in the anteriorized holes in the femur. Recheck if notching is avoided before performing the resection.

The remaining preparation steps for the femur remain the same.

## Appendix B - Posterior Referencing Instrumentation (cont.)

The conventional steps to perform the tibial cut are replaced by the navigation of the cutting guide with the CAS Offset Paddle. The positioning of the extramedullary alignment guide is performed as described in the standard surgical technique. The 1.27 mm CAS Offset Paddle, inserted in the cutting slot of the guide allows verifying the orientation of the cutting guide and the resection level during the positioning of the EM guide. The navigation of the tibial cut is described in the Tibial Cut Navigation section (p. 12).

The remaining preparation steps for the tibia remain the same.

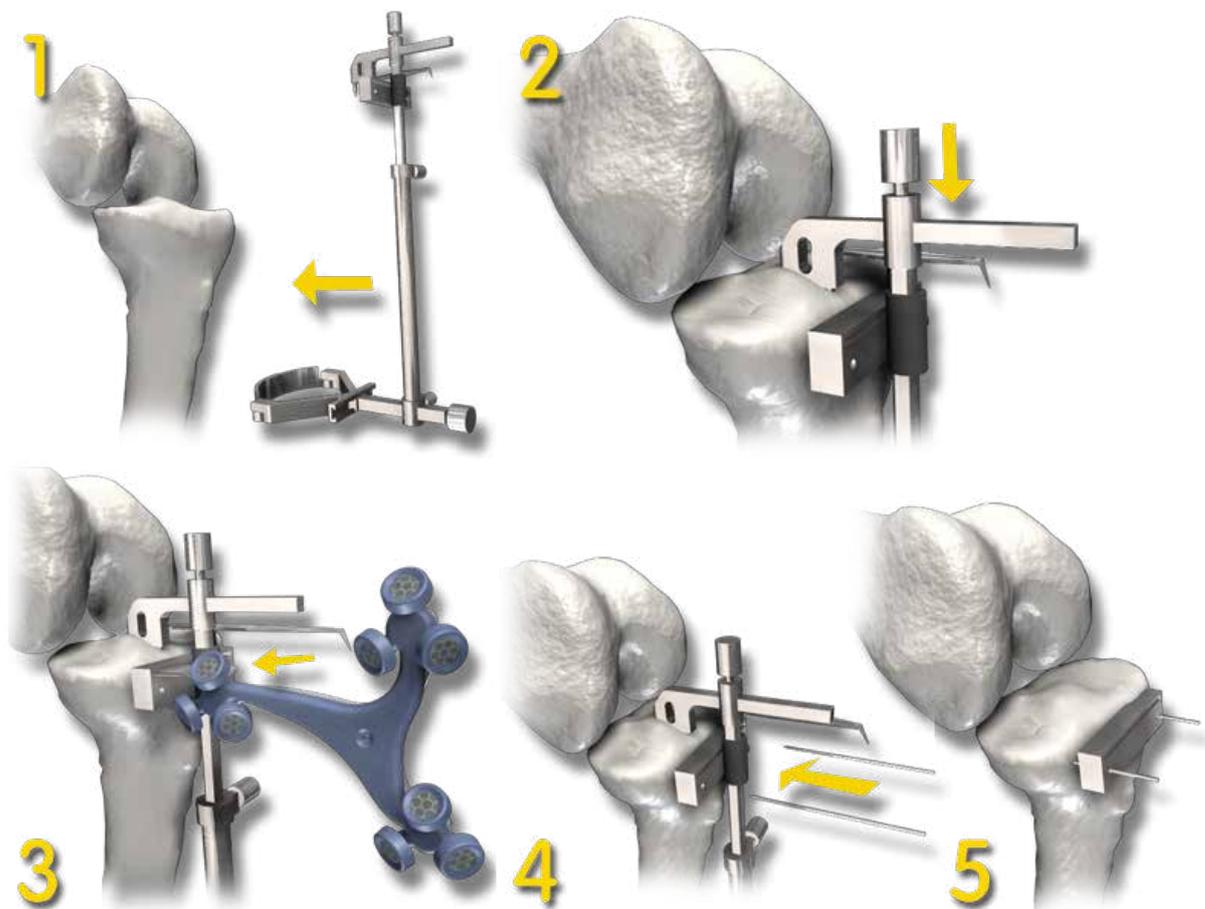


Figure B.5  
Navigating the tibial cut with the CAS Offset Paddle inserted in the  
standard extramedullary guide

## Appendix C - CAS Femoral Cut Alignment Guide used in Anterior Cut First

In anterior cut first, follow these steps to align the cutting guide as desired.

1. Pierce the cortex at the mechanical axis entry point with a cortex breaker or a 3.2 mm drill bit (only a few millimeters in depth). Impact the CAS Small Spike 7.9 mm into the distal femur. Do not impact deeper than the end of the four blades on the spike.
2. It is recommended to add some extension during insertion of the spike to counter the common tendency of inserting with excess flexion. Also, only a gross alignment is necessary with the spike since plenty of adjustment range will be available with the fine adjustment mechanism: 30 degrees in extension and 15 degrees in flexion.



Figure C.1

Insertion of the Spike in Proper Flexion

**Warning:** Make sure the spike is stable before performing manipulations relative to the fixation.

3. In order to save time and ease intraoperative manipulations, the scrub nurse should align the varus/valgus (green screw) and the flexion/extension (AO fitting) at zero degrees as a starting point. Also, loosening the rotation locking lever (yellow) prior to installation on the patient will ease manipulations. See Figure C.2.

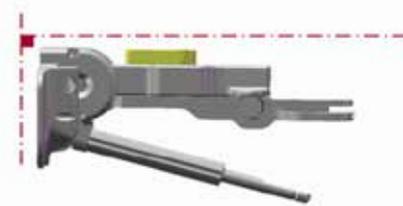
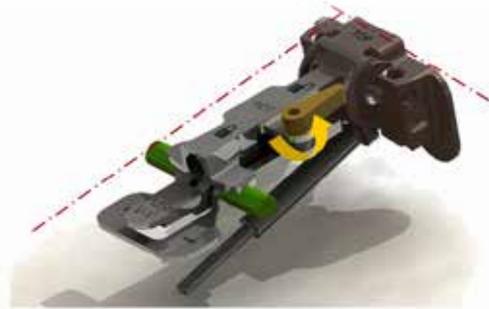


Figure C.2

Adjust the CAS Femoral Cut Alignment Guide.

4. Assemble the CAS Anterior Cutting Block on the CAS Femoral Cut Alignment Guide.
5. Slide the complete assembly on the inserted spike.

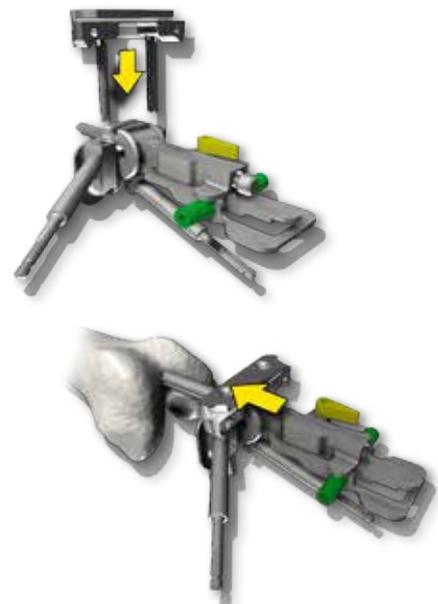


Figure C.3

Installation of the Anterior Cutting Guide

## Appendix C - CAS Femoral Cut Alignment Guide used in Anterior Cut First (cont.)

6. Lock the A/P translation with the set screw.

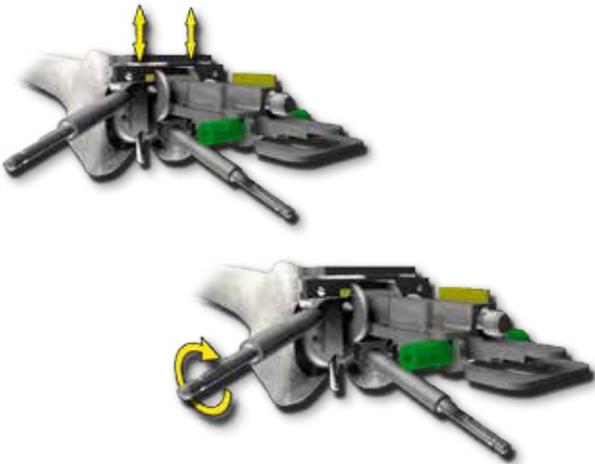


Figure C.4  
Lock the A/P Translation

7. After releasing the T-handle, adjust the flexion/extension angle and lock it in desired position by tightening the T-handle.

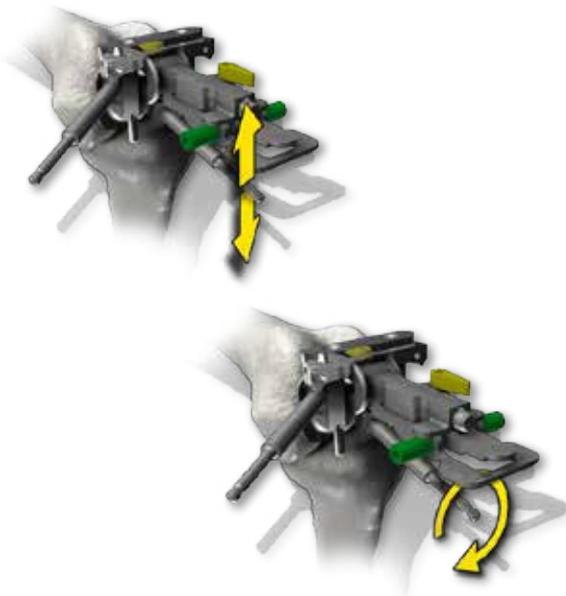


Figure C.5  
Adjustment of the Flexion/Extension Angle

8. Adjust the varus/valgus angle by pressing on the “V-V” fork and releasing it in the desired position, as shown in Figure C.6. Using the green screws, on both medial and lateral sides, finely adjust the varus/valgus angle.



Figure C.6  
Adjustment of the varus/valgus angle

9. To avoid notching, adjust the A/P position of the instrument such that the implant flange is positioned above the anterior cortex line (green line in Figure C.7).

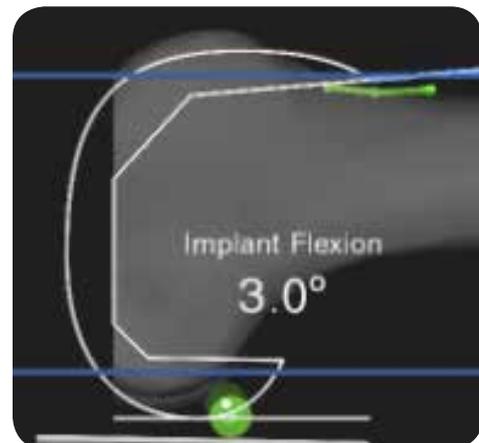


Figure C.7  
Adjustment of the A/P Position

10. Once the anterior cutting guide is firmly positioned on the bone, cut the bone and remove the assembly from the spike as shown in Figure C.8.

## Appendix C - CAS Femoral Cut Alignment Guide used in Anterior Cut First (cont.)

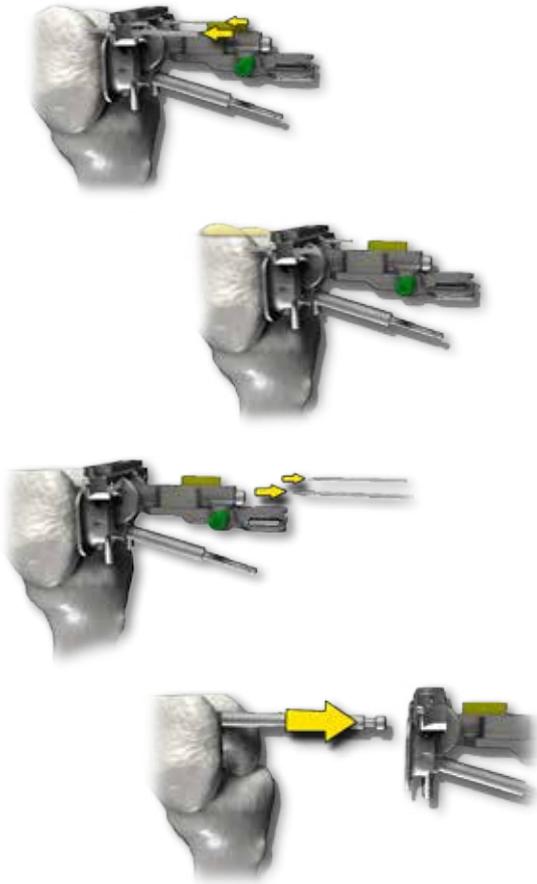


Figure C.8

Fix the cutting guide in place, cut the bone and remove the assembly

**Warning:** When using the CAS Universal Offset Paddle (or the CAS Universal Positioning Block) in the CAS Anterior Cutting Guide, ensure the blade is fully inserted in the slot to be navigated. Make sure that the shoulder rests against the edge of the cutting guide.

## Appendix D- CAS Independent Adjustment Mechanism Technique

This technique can be applied with Innex Total Knee System\*.

An alternate instrumentation has been designed to support the femoral component placement where the preferred surgical technique is anterior cut first (femur first). The instrumentation presented in this document represents a solution for the Innex Total Knee System\* users. This may be used alternatively to the existing CAS Tensor technique.

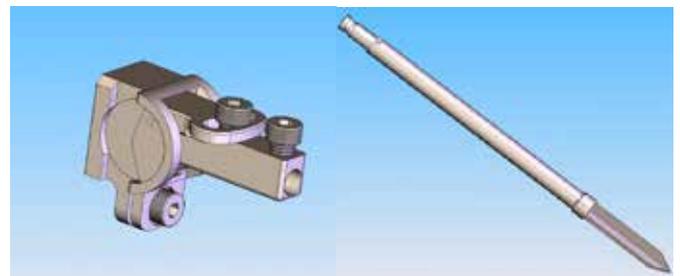


Figure D.1

Independent Adjustment Mechanism (108.085)  
and 6.75 mm Spike (108.086)

The standard surgical technique remains the same, except that the intramedullary rod is replaced by the 6.75 mm Spike and the standard angular guide is substituted by the CAS Independent Adjustment Mechanism. Since the surgical technique is unchanged, except for the use of these new instruments; this document will only describe the recommended use of these instruments. The first step consists of correctly inserting the 6.75 mm spike in the femur. The following steps describe the procedure for this insertion:

- Pre-drill the distal femoral cortex, at the mechanical axis entry point, to avoid damaging the instrumentation and avoid risk of fracture on the distal femur.
- Impact the spike in the distal femur while aligning it with the intramedullary canal (anatomical axis). The CAS Independent Adjustment Mechanism has a range of adjustment of up to 15 degrees in all directions.

**Warning:** Ensure not to position the spike too close to the anterior or posterior side since an unusually large anteroposterior translation might lead to difficulties in reaching the desired anteroposterior position.

## Appendix D- CAS Independent Adjustment Mechanism Technique (cont.)

- Verify the stability of the inserted spike prior to continuing the procedure since it might lead to difficulties in aligning the cutting guides properly.

**Warning:** Note that if the head of the spike is damaged (caused by hammering), it may be possible that the assembly of the spike and the CAS Independent Adjustment Mechanism becomes difficult. In this case, a new spike should be used. The spike has a quick coupling adaptor of the “Zimmer small” type, which may be used as an attachment point for insertion and removal.

The following steps describe how to use the CAS Independent Adjustment Mechanism in combination with the 6.75 mm spike and with the standard Innex Femoral Cutting Block\*.

- Insert the CAS Independent Adjustment Mechanism in the Innex Femoral Cutting Block\* (standard instrumentation) as shown in Figure D.2.

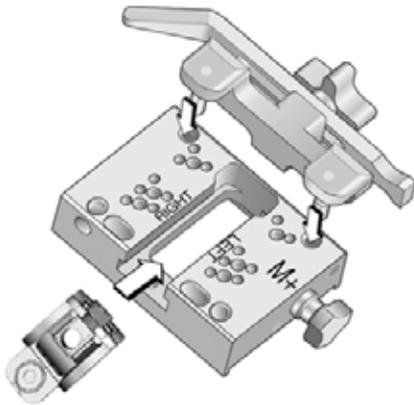


Figure D.2  
Assembly of Mechanism

- Unlock the screw used to adjust the rotation angle and the proximal-distal translation (“rotation screw”) shown in Figure D.3.

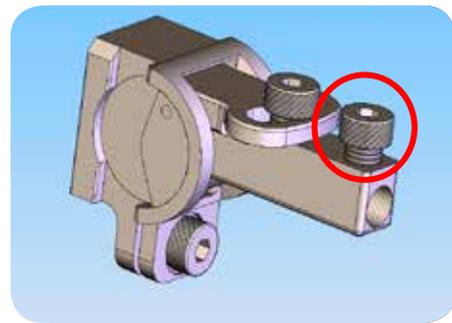


Figure D.3  
Unlock the Rotation Screw

- **Warning:** Note that the screws are not captive, so care must be taken not to loosen them completely during the surgery since they may fall.
- Slide the assembly of the CAS Independent Adjustment Mechanism and the Innex Femoral Cutting Block\* on the spike, but keep a space of approximately 1 cm between the block and the distal bone to facilitate the adjustments.
- Then, position the saw capture, and slide the CAS Universal Offset Paddle in the saw capture to allow navigation of the assembly.
- **Warning:** When positioning the CAS Universal Offset Paddle (or CAS Universal Positioning Block), ensure not to obstruct screwdriver access necessary for locking/unlocking of the screws.
- **Warning:** Furthermore, the CAS Universal Offset Paddle (or CAS Universal Positioning Block) should never be used as a handle to adjust the position of the block.

## Appendix D- CAS Independent Adjustment Mechanism Technique (cont.)

- Roughly adjust the rotation angle (to approximately 5 degrees of accuracy) and then lock the rotational screw. To facilitate the adjustment, keep the screwdriver inserted in the screw and use it to adjust the rotation angle.
- Unlock the flexion/extension adjustment screw shown in Figure D.4. To facilitate the adjustment, leave some resistance in the flexion/extension locking mechanism. Then, finely adjust the flexion/extension angle and lock the flexion/extension screw once the desired value is attained.
- Unlock the rotational screw, slide the assembly against the distal femur and adjust the rotation angle. To facilitate the adjustment, keep the screwdriver inserted in the screw and use it to finely adjust the rotation angle. Then, lock the rotational screw once the desired value is attained.
- Finally, adjust the A/P translation as it is usually performed with the standard instrumentation, i.e. using the adjustment provided for that purpose on the Innex Femoral Cutting Block\*.

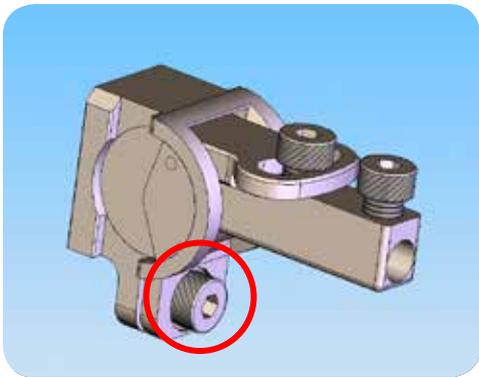


Figure D.4  
Unlock the flexion/extension screw

- Unlock the screw used to adjust the varus/valgus (V/V) shown in Figure D.5. To facilitate the adjustment, leave some resistance in the locking mechanism. Then, finely adjust the varus/valgus angle and lock the V/V screw once the desired value is achieved.

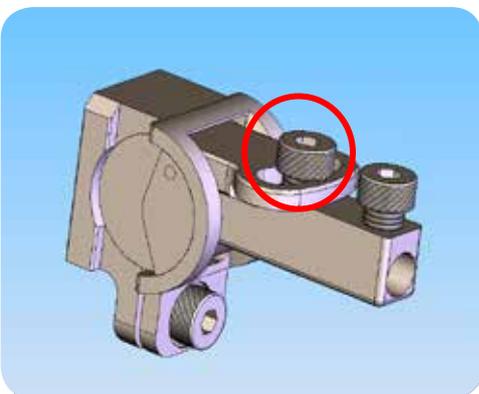


Figure D.5  
Unlock the varus/valgus screw

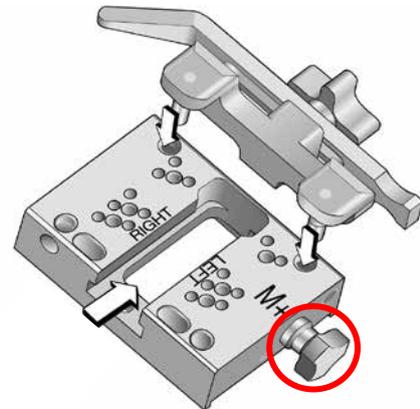


Figure D.6  
Adjust the A/P Translation

Note that this is not the representation of the latest version of the femoral cutting block.

Note that if the spike has been positioned too anterior, it may not be possible to adjust the A/P translation as desired. In this case, the user has to re-position the spike and redo the previous steps, or adjust the A/P translation by using the different holes for the pins (-2 mm, 0 mm, +2 mm, etc.) on the femoral cutting block prior to performing the anterior cut.

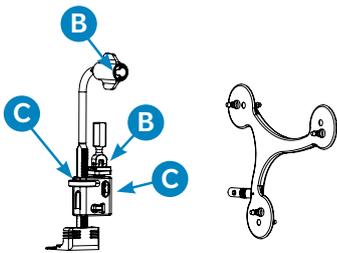
## Appendix E - Universal Positioning Block Technique

**Table E.1:** Lists instruments no longer distributed by Zimmer CAS but are still in use, and describes the sterilization and cleaning methods recommended for each instrument. Refer to the Ordering and Instrument Cleaning/Sterilization Information section (p. 31) for a description of methods.

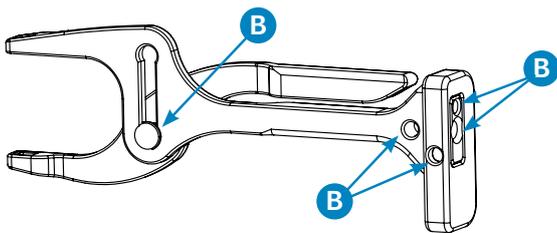
- A** Requires disassembly
- B** Requires water jet to flush difficult to access areas
- C** Screw/unscrew components while flushing the area
- D** Requires a minimum 10 minutes ultrasonic cleaning cycle in an enzymatic solution
- E** Screw/mechanism should be checked and lubricated as required

### CAS Universal Positioning Block

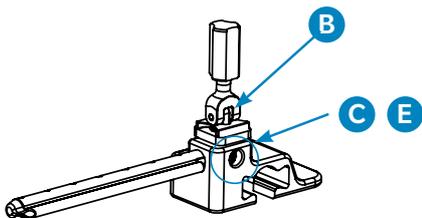
Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
Universal Positioning Block - Holding Platform	20-8000-010-02	108.039	Autoclave <b>A B C D E</b>
Universal Positioning Block - Holding Platform Tracker	20-8000-010-46	201.050	Autoclave <b>A</b>



Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Bone Fixation Installation Tool	20-8000-010-03	108.040	Autoclave <b>B E</b>

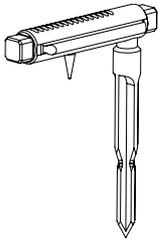


Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Universal Position Block Body	20-8000-010-04	108.041	Autoclave <b>A B C D E</b>

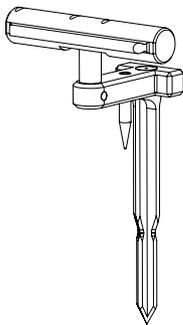


## Appendix E - Universal Positioning Block Technique (cont.)

Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS MIS L-Shaped Bone Fixation	20-8000-010-05	108.046	Autoclave



Description	Product Number	Manufacturer Number	Specific Cleaning Requirements
CAS Offset Tibial Fixation	20-8000-010-08	108.053	Autoclave



## Appendix E - Universal Positioning Block Technique (cont.)

- Warning:** Before every surgery the user must:
1. Verify that all instruments have been sterilized.
  2. Verify that the instruments are in good condition to perform the operation. If any signs of fatigue or deterioration are noticed, do not use the Zimmer CAS Surgical Navigation System and contact the technical support.

- Warning:** All instruments are delivered with a package insert, which indicates the applicable cleaning and sterilization specifications. The specifications given on the inserts take precedence over the ones included in this text.

### Tibial Cut Navigation

The panel consists of three subtasks: Navigate Bone Fixation, Navigate Cutting Block, and Tibial Cut Validation.

#### Navigate Bone Fixation

The tibial CAS Offset Fixation has to be inserted into the tibial mid-plateau and slightly anterior to the tibial spine. The bone fixation must be aligned within  $\pm 12$  degrees of the tibial mechanical axis in both frontal and lateral planes. The bone fixation orientation in varus/valgus and flexion can be predetermined with the help of the pointer (Figure E.1).



Figure E.1  
Navigate Bone Fixation

Following the insertion of the bone fixation, the CAS Universal Positioning Block has to be assembled. Refer to Figure E.2 for the detailed instruction on the installation and manipulation of the CAS Universal Positioning Block Assembly.

- Warning:** Before inserting the CAS L-shaped Fixation, the femoral cortex must be pre-drilled to avoid breakage of the fixation.

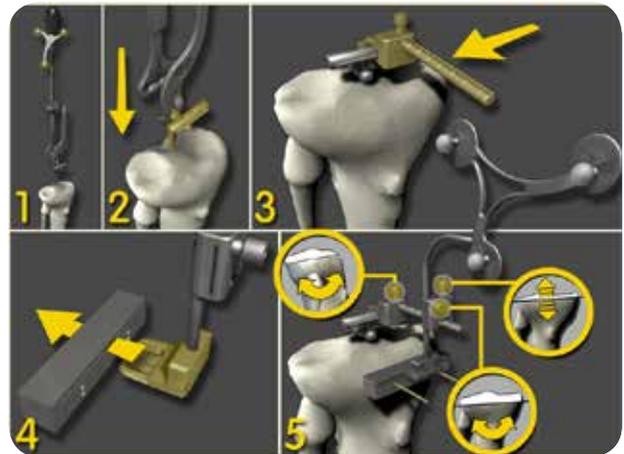


Figure E.2  
Installation and Manipulation of the CAS Universal Positioning Block Assembly

1. Use the CAS Registration Pointer to align the axis of the fixation along the tibial mechanical axis.
2. Insert the CAS Offset Fixation into the tibial canal.
3. Attach the CAS Universal Positioning Block Body to the CAS Offset Fixation.
4. Insert the CAS Universal Positioning Block into the tibial cutting guide.
5. Slide the CAS Universal Positioning Block on the CAS Universal Positioning Block Body.
6. Use the adjustable thumbscrews on the CAS Universal Positioning Block to set the desired varus/valgus, posterior slope and resection level.

## Appendix E - Universal Positioning Block Technique (cont.)

### Tibial Cut Navigation

The panel consists of three subtasks: Navigate Bone Fixation, Navigate Cutting Block, and Distal Cut Validation.

#### Navigated Bone Fixation

The Navigate Bone Fixation subtask is used for the positioning of the CAS L-shaped Fixation. The bone fixation has to be placed in the distal part of the femur and centered in the trochlear groove (more or less corresponding with the entry point of an intramedullary rod), a few millimeters above the roof of the intercondylar notch. The stop-drill must be used to pre-drill the femoral cortex by 2 cm at the point of insertion. The bone fixation must be aligned within  $\pm 12$  degrees of the femoral mechanical axis in both frontal and lateral planes. The pointer can be used to orient the insertion of the bone fixation (Figure E.3).

The bone fixation orientation in varus/valgus and flexion can be navigated when the CAS Registration Pointer is inserted in the CAS Bone Fixation Impactor. The angles of varus/valgus and flexion/extension of the inserted bone fixation will then be displayed under the Frontal and Lateral viewers. Following the insertion of the bone fixation, the CAS Universal Positioning Block has to be assembled. Refer to Figure E.4 for the detailed instruction on the installation and manipulation of the CAS Universal Positioning Block.



Figure E.3  
Navigate Bone Fixation

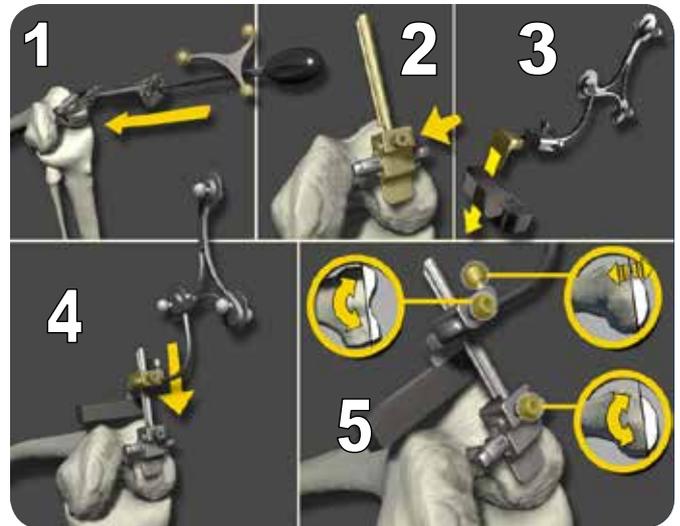


Figure E.4  
Installation and Manipulation of the Universal  
Positioning Block

1. Insert the CAS L-shaped Fixation into the femoral canal. Use pointer to align the axis of the fixation along the femoral mechanical axis.
2. Attach the CAS Universal Positioning Block Body to the L-shaped fixation.
3. Insert the CAS Universal Positioning Block into the distal femoral cutting guide.
4. Slide the CAS Universal Positioning Block on top of the CAS Universal Positioning Block Body assembly.
5. Use the adjustable thumbscrews on the CAS Universal Positioning Block to set the desired varus/valgus, flexion/extension and resection level.

## Appendix F - Distal Cut Navigation with Natural-Knee II System

This technique is intended for users of the Natural-Knee II Standard Instrumentation.

### Placement of the Intramedullary Spike

The 7.9 mm CAS Spike has to be used instead of the standard intramedullary rod. The spike has to be placed in the distal part of the femur and centered in the trochlear groove (in the area of the entry point of an intramedullary rod, and a few millimeters above the roof of the intercondylar notch). The stop-drill must be used to pre-drill the femoral cortex by 10 mm at the point of insertion. Once the femur is pre-drilled, slowly insert the spike into the distal femur for not more than 20 mm.

### Navigate Cutting Block

The intent of the Navigate Cutting Block subtask is to set the appropriate orientation of the cutting guide with respect to the femoral mechanical axis. In order to navigate and position the distal femoral cutting guide refer to Figure F.1 for the detailed instructions.



Figure F.1  
Navigate Cutting Block

1. Slide the distal femoral alignment guide (from the standard instrumentation system) on the 7.9 mm CAS Spike until the guide is in contact with the distal femoral condyle.
2. Attach the CAS Natural-Knee II Saw Capture to the standard femoral cutting guide.

3. Insert the CAS Universal Offset Paddle into the cutting slot.
4. Gently apply the pressure on the spike to adjust flexion/extension and varus/valgus of the cutting guide.
5. Verify the resection level.
6. Inspect the suggested implant size (green parallel lines) in the sizing indicator.

ⓘ **Note:** Adding flexion will reduce the suggested implant size. Therefore, it is possible to adjust the Flexion/Extension in order to avoid an excessive flange overhang.

7. Secure the position of the distal femoral cutting guide on the femur with the drive pins.
8. Slide the distal femoral alignment guide from the spike.
9. Extract the spike from the femur.

ⓘ **Note:** At the end of the procedure, the slap hammer from the NexGen Instrument Kit has to be used in order to extract the 7.9 mm CAS Spike. In case the slap hammer is not available, the spike can be removed with a standard pin-puller.

10. Perform distal femur resection with the help of the positioned distal cutting guide.

### Distal Cut Validation

The validation of the distal cut is similar to the task described in the Distal Cut Navigation section (p. 17). Refer to Figure 4.33 for the detailed instructions.

## Appendix G - Implant “Universal” - Anterior Cut First with Insall Gap Balancing Technique

The workflow for the Implant “Universal” - Anterior Cut First with Insall Gap Balancing Technique is the following:

1. Initial Range of Motion
2. Tibial Cut Navigation
3. Extension Gap
4. Acquire Anterior/Posterior Cutting Plane
5. Anterior Cut Navigation (Femur)
6. Distal Cut Navigation (Femur)
7. Postoperative range of motion

This technique is used with the standard implant instrumentation.

**Warning:** During the ligament balancing procedure do not apply excessive stress to the knee joint compartments in order to avoid permanent damage to the ligaments.

### Initial Range of Motion

This task is similar to the Initial Range of Motion task described in the present document (p. 14).

### Tibial Cut Navigation

This task is similar to the Tibial Cut Navigation section (p. 15) described in the present document.

### Extension Gap

The purpose of this panel is to perform ligament balancing in extension. In addition the preliminary gap in extension between the tibia and femur can be recorded. This panel is available only if the Insall Gap Balancing option is enabled in the Surgical preferences. The Extension Gap panel is shown in Figure G.1.

To start this task, set the target distal resection level and the implant distal cut angle. This can also be done in the Surgeon Profile panel. Then, place the knee in full extension and insert an implant system spacer/distracter guide between the resected surface of the tibia. The flexion/extension and varus/valgus angles of the knee joint will be displayed in the panel. In addition, the Frontal viewer will display the gap alignment including an indicator for the gap measurement. If necessary, perform ligament balancing to achieve a rectangular gap. Then stabilize the leg and position the pointer in the area of the knee joint. As a result, the gap in extension and the alignment values will be recorded in the system to be used as a reference when adjusting the flexion gap.



Figure G.1  
Extension Gap

## Appendix G - Implant “Universal” - Anterior Cut First with Insall Gap Balancing Technique (cont.)

### Acquire Anterior/Posterior Cutting Plane

This panel is used to acquire the A/P cutting planes on the standard implant A/P cutting guide. The size of the cutting guide must be determined by the surgeon prior to the digitization of the cutting planes. Refer to Figure G.2 for the detailed instructions on the acquisition of the A/P cutting planes.



Figure G.2

Acquire the Anterior/Posterior Cutting Plane

1. Attach the A/P cutting guide to the intramedullary rod of the standard instrumentation system inserted in the femur.
2. Stabilize the position of the block with pins from the standard instrumentation system.
3. Insert the CAS Universal Offset Paddle in the posterior cutting slot and acquire the posterior cutting plane.
4. Do not move the block.
5. Insert the CAS Universal Offset Paddle in the anterior cutting slot and acquire the anterior cutting plane.

**Warning:** The A/P cutting block must remain stable during acquisition of the anterior/posterior cutting planes.

### Anterior Cut Navigation

The purpose of this panel is to set the A/P position and the axial rotation of the implant. In addition, the flexion gap can be measured and adjusted to match the preliminary extension gap.

#### Anterior/Posterior Placement

In the panel, a 3D phantom model of the femoral distal lateral plane is displayed with transparency. The posterior condyles and anterior cortex points are displayed on the model. The anterior plane and posterior plane of the navigated A/P cutting guide are displayed on the model.

Insert the CAS Universal Offset Paddle in the anterior cutting slot to start navigation. To avoid notching, adjust the A/P position of the cutting block such that the anterior cutting plane is positioned above the anterior cortex line. The flexion gap can be observed between the posterior cutting plane and tibial cut.

**Warning:** Do not use the pictorial representation of the bones for component positioning purposes. They are provided solely to visualize axis orientation and do not represent the actual bone anatomy.

## Appendix G - Implant “Universal” - Anterior Cut First with Insall Gap Balancing Technique (cont.)

### Anterior Cut Navigation (cont.)

#### Adjustment of the Implant Axial Rotation

Three rotational parameters are displayed below the Axial viewer according to the femoral landmarks that were digitized (posterior condyles rotation, epicondylar rotation, AP rotation). The rotation angles should be used to determine the desired axial orientation of the implant. Refer to Figure G.3 for the detailed instructions on the implant axial rotation adjustment.



Figure G.3  
Axial Rotation and Flexion Gap Alignment

1. The epicondylar, A/P, posterior axis, and gap angle indicators can be used as a reference to set the desired rotation of the implant.

**Note:** Resetting the implant axial rotation will affect the flexion gap angle.

2. Verify varus/valgus angle of the implant.
  3. Secure the navigated block on the femur with the drive pins from the standard instrumentation system.
  4. When all the adjustments are completed and the drive pins are positioned in the femur, position the pointer in the area of the knee joint to record the flexion gap value.
- Note:** The flexion gap must be stored in order to enable optimization of the distal femoral resection.
5. Perform the cut(s) per standard technique.

### Distal Cut Navigation

The intent of the Distal Cut Navigation panel is to assist the surgeon to perform the desired femoral distal resection and match the gap in extension with the previously measured flexion gap. This panel allows accurate positioning of the distal cutting guide with respect to the femoral mechanical axis and adjustment of the resection level.

#### Navigate Cutting Block

The main intent of the Navigate Cutting Block subtask is to set the appropriate orientation of the cutting guide with respect to the femoral mechanical axis. In the panel, the angles of varus/valgus and flexion/extension of the navigated cutting block are displayed under the Frontal and Lateral viewers. In addition, the resection level is displayed in the indicator that is located between the two viewers. In order to navigate and position the distal femoral cutting guide, refer to Figure G.4 for the detailed instructions.



Figure G.4  
Navigate Cutting Block

1. Insert the CAS Universal Offset Paddle in the distal cutting guide of the standard instrumentation system.
2. Position the distal cutting guide on the anterior surface of the femur.
3. Verify the varus/valgus angle of the implant (adjust if applicable).
4. Verify the flexion/extension angle of the implant.
5. Adjust the resection level to match the extension gap with the previously acquired flexion gap. Secure the position of the distal femoral cutting guide on the femur with the drive pins of the standard instrumentation system.
6. Perform the distal femur resection with the help of the positioned distal cutting guide.

## Appendix G - Implant “Universal” - Anterior Cut First with Insall Gap Balancing Technique (cont.)

### Distal Cut Navigation (cont.)

#### Distal Cut Validation

The purpose of the Distal Cut Validation task is to verify if the desired distal femoral resection was achieved. It is mainly used to inspect the orientation and, if needed, introduce the necessary corrections to the distal femoral cut. Refer to Figure G.5 for the detailed instructions.



Figure G.5  
Distal Cut Validation

1. Remove the CAS Posterior Condyle Digitizer from the CAS Universal Validation Tool Body.
2. Place the CAS Universal Validation Tool Body on the distal femoral cut.
3. Stabilize the instrument to acquire the varus/valgus, flexion/extension and resection level of the cut.
4. Verify the values and introduce the corrections if needed.
5. To restart the Distal Cut Validation subtask, move the CAS Universal Validation Tool Body in the camera volume.

### Postoperative Range of Motion

The postoperative range of motion is similar to the Initial Range of Motion task. Refer to the Initial Range of Motion section (p. 14) of the present document.



## General Information

### Caution

Federal (US) 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 Navitrack® Navigation System users.

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