SURGICAL TECHNIQUE

Knee+

pixee medical

In this manual:

The presence of this symbol indicates an advice for use.

The presence of this symbol indicates a warning.

GENERAL INFORMATION

Description

Pixee Medical

Pixee Medical designs stereotaxic systems for orthopedic surgery. These systems include software medical devices and specific reusable instruments equipped with tracking markers.

Description of the device

Knee+ is a stereotaxic system dedicated to intraoperative use in knee surgery. It includes standalone KneePlus software and reusable KneeTools surgical instruments.

This document provides necessary information and guidelines for the safe and appropriate use of KneeTools instruments. KneeTools instruments are equipped with markers and are located in a 3D space using a specific software developed by Pixee Medical (KneePlus software, see dedicated instructions for use) in order to provide landmarks and anatomical axes as well as orientation values of the cutting guide.

Designation	Ref.	UDI-DI	CE Symbol
Pointer	KNI001	03760297030001	CE 0459
Bone reference	KNI005	03760297030032	CE 0459
Orientation mechanism	KNI006	03760297030049	CE 0459
Cutting guide adaptor	KNI007	03760297030056	CE 0459
Universal cutting guide	KNI008	03760297030063	CE 0459
Knee stylus	KNI009	03760297030070	CE 0459
Control tool	KNI010	03760297030087	CE 0459
Ankle clamp (option)	KNI004	03760297030025	CE 0459
Long pointer	KNI011	03760297030131	CE 0459
Slim bone reference	KNI012	03760297030155	CE 0459
Slim universal cutting guide	KNI013	03760297030162	CE 0459
Instruments Box	BIN002	03760297030193	CE
SHA Outer ring	PEA006	03760297030223	CE 0459
Right Proximal cutting guide	KNI014	03760297030179	CE 0459
Left Proximal cutting guide	KNI015	03760297030186	CE 0459

Symbols

	Consult the instructions for use		Serial number
	Caution		Non-sterile device
	Medical device EC		Country and date of manufacture
	Catalog reference		Manufacturer
	Lot number		Medical device
	Unique device identification		Caution: Federal (U.S) law restricts this device to sale by or on the order of a physician

Manufacturer: Pixee Medical, 18 rue Alain Savary - 25000 Besançon | France - www.pixee-medical.com
Year of CE marking apposition: May 2020
Publishing date: March 2022
Pixee Medical reserves the right to update this notice whenever necessary.

Intended use / Indication

Knee+:

Knee+ is a stereotaxic system including an intraoperative software as a medical device and surgical instruments. Knee+ is intended for primary Total Knee Replacement, to assist the surgeon in determining reference alignment axes in relation to anatomical landmarks, in order to position the cutting guide regarding computed mechanical axis. The Knee+ includes smart glasses as a Head Mounted Device (HMD) for displaying information to the user intraoperatively. The smart glasses should not be relied upon solely and should always be used in conjunction with traditional methods.

Surgical helmet adaptor (SHA):

The Surgical Helmet Adaptor is intended to be used in conjunction with surgical helmets certified from other medical device manufacturers and execution platforms supporting Pixee Medical's orthopedic navigation software. This adaptor is intended to be in contact with the execution platform and the visor of the surgical helmet in order to allow the surgeon to perform Pixee Medical surgery protocol while wearing a surgical helmet.

Contraindications

Contraindications to the use of KneeTools instruments are:

- The patient has not reached bone maturity, making bone reference identification difficult;
- The patient presents significant hip dysplasia or any other excessive pelvic deformation;
- The patient has an advanced osteoporosis;
- The patient is already equipped with medical devices which may conflict with the required instrumentation.

Claimed performance

KneeTools instruments are used by KneePlus software for angular measurement in the sagittal and coronal planes of an axis relative to a cutting instrument with respect to an axis calculated from anatomical references. The claimed angular accuracy for the measurement function is less than a degree.

Intended clinical benefits

The expected clinical benefit is a restoration of the alignment of the mechanical axis of the lower limbs to less than three degrees.

Potential adverse effects and residual risks

In rare cases:

- Poor positioning of the prosthesis
- Complications caused by prolonged operating time
- Infection

Other information

Packaging and storage: KneeTools instruments are delivered in a storage box suitable for hosting the instruments during the storage and reprocessing stages.

Installation, maintenance and calibration: All installation and maintenance operations are carried out by qualified Pixee Medical personnel. In case of need or if an anomaly is detected, it is strongly recommended to contact Pixee Medical or his distributor as soon as possible.

Instruments from the same kit must never be separated or replaced by the user. Any change of instrument or software version requires the intervention of Pixee Medical or his distributor.

Return: Any product presenting an anomaly must be returned to Pixee Medical and accompanied by the information necessary to identify the customer, the product and the fault.

Lifetime: The lifetime of KneeTools instruments and SHA Outer ring is 100 reprocessing cycles.

At the end of life, recycle the Instruments box, the instruments and the SHA Outer ring according to the procedure in force in your establishment.

Precautions for use and warnings

General

- Read all documentation, warnings and labeling carefully before using the KneeTools and SHA Outer ring products. This surgical technique is provided upon delivery of the products and a copy can be sent upon request. It details the required manipulations and the precautions for using the instruments.
- The use of the KneeTools product is exclusively reserved for orthopedic surgeons who have received specific training from Pixee Medical or an authorized distributor.
- The use of the KneeTools product is part of a standard surgical protocol for knee replacement surgery, by providing additional information to the orthopedic surgeon during the intervention via his KneePlus software interface. The surgeon remains responsible for the surgical procedure performed.
- The surgeon is responsible for complications that may result from the use of the device outside its intended destination, from a defective operating technique or from a lack of asepsis.
- KneeTools instruments require the use of specific software developed by Pixee Medical and integrated into an execution platform (augmented reality glasses): KneePlus software.
- A single execution platform can be used with multiple sets of instruments. To associate a set of instruments with the execution platform, a configuration QR Code provided by Pixee Medical must be scanned. It contains the metrology data of the instruments.
- The system uses tokens. One token is spent for each surgery. To add tokens for the use of Knee+, contact Pixee Medical to purchase a specific QR Code.
- Do not share the KneeTools product with an unauthorized person or any other person not registered by Pixee Medical.
- Never disassemble the instruments navigation marker.
- Never use an unidentified instrument.
- Never use an instrument that has a damaged navigation marker.
- Never use an instrument that is deformed / broken.
- Never use an uncleaned / unsterilized instrument.
- If an abnormality is detected, please use standard instrumentation and return the product to Pixee Medical or its distributor as soon as possible.
- For any assistance, claim or product return, please contact Pixee Medical or his distributor.
- Do not sterilize the SHA Connector (PEA007)

Before use

- KneeTools instruments and the SHA Outer ring must be sterilized according to the instructions in the reprocessing procedure.
- KneeTools instruments must be prepared and assembled preoperatively. Please ensure that the KneeTools instruments are compatible with the version of KneePlus available.
- Check the condition of the SHA Outer ring and KneeTools instruments before each use. Do not use an instrument if it is damaged (damaged or dismantled marker, deformed or broken instrument, ...).

During use

- The use of KneeTools instruments requires a fixed spatial reference during the femoral head center assessment step. A standard articulated arm attached to the operating table can be used to hold the Pointer as a reference in a static position.
- For optimal use of KneeTools, it is better to use KneeTools instruments in an operating room not equipped with neon lights.
- Make sure the markers of KneeTools instruments are visible. If necessary, clean the markers with a sterile pad and sterile saline solution.

After use

- KneeTools instruments and SHA Outer ring are reusable. Immediately after use, rinse off any blood residue on KneeTools instruments or on the SHA Outer ring by adding them to a basin filled with water. Dried blood is more difficult to remove during the reprocessing process.
- After each use, clean and sterilize the KneeTools instruments and the SHA Outer ring according to the validated process presented in the appendix on the following page. The instruments must then be stored in such a way as to preserve their sterile state until their next use.

Any serious incident occurring in connection with the device must be notified to Pixee Medical and to the competent authority of the Country in which the user and/or patient is established.

Cleaning and sterilization procedure

Steps	Description
Limitations on reprocessing	▪ The useful life of the instrument is 100 reprocessing cycles.
Initial treatment at the point of use	▪ Rinse with clean, cold tap water (15-25 °C) or immerse the instruments in clean tap water (15-25 °C) and thoroughly wipe all accessible surfaces of the instruments with a clean soft bristle brush or non-linting cloth to remove visible organic matter and prevent coagulation of blood. ▪ In order to keep the instruments from drying after being soiled, soak the instrument in a basin with Critical Water1 or tap water (<45 °C) between the patient procedure and reprocessing steps.
Preparation before cleaning	▪ Disassemble instruments or open them, if feasible: for the Guiding Tool: Remove the Knee stylus from the Universal Cutting Guide, unscrew the front knob to release the body of the Knee stylus, press the spring trigger on the Cutting guide adaptor to release the Universal Cutting Guide, unscrew the front knob from the Cutting guide adaptor, release it from the Orientation Mechanism, then open the locking lever of the Bone Reference in order to release the Orientation Mechanism. (The Pointer and the Control Tool cannot be disassembled)
Automated cleaning with pre-manual cleaning	▪ Soak the instruments in an alkaline enzymatic detergent, such as Neodisher MediClean Forte for a minimum of 10 minutes. Whilst immersed, brush the instruments using a soft bristle brush for a minimum of 1 minute and actuate mobile parts at least twice. ▪ Rinse the instruments with Critical Water for a minimum of 2 minutes. ▪ Arrange the instruments into the washing racks without overloading them. Then set the racks on the wash supports of the washer-disinfector. ▪ Avoid any contact between the instruments, which may cause damage during washing. ▪ Using a validated washer disinfector (according to ISO 15883 requirements) and an alkaline enzymatic detergent, such as Neodisher MediClean Forte, use the minimal cycle parameters set points mentioned in the following table. ▪ Remove the instruments at the end of the cleaning cycle.

Cycle	Minimum duration	Minimum temperature	Type of detergent / water
Pre-cleaning	2 minutes	Cold (<45 °C)	Tap water
Cleaning	10 minutes	Heated (50-60 °C)	Neodisher MediClean Forte (0,2 - 1,0 %, according to the manufacturer's instructions)
Rinsing	2 minutes	Cold (<45 °C)	Treated water
Thermal rinse	5 minutes	Heated (90 °C)	Treated water
Drying	25 minutes	Heated (70 °C)	Not applicable

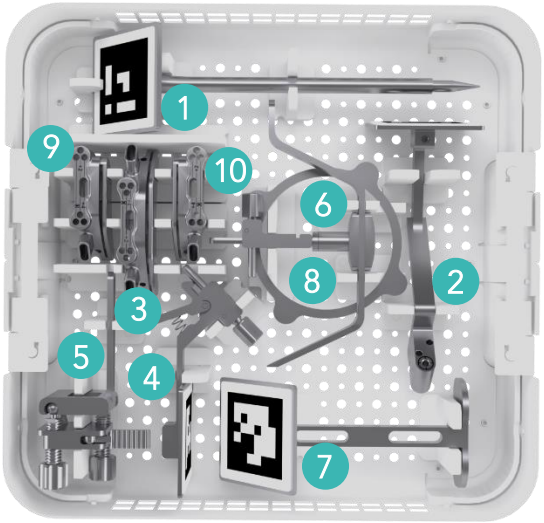
<table>
<tr><th>Steps</th><th>Description</th></tr>
<tr><td>Automated Disinfection</td><td>▪ For Europe, the thermal disinfection corresponds to the phase of 5 minutes at a minimum of 90 °C, listed in table above.</td></tr>
<tr><td>Drying</td><td>▪ Dry the instruments using a non-linting wipe.</td></tr>
<tr><td>Inspection and maintenance</td><td>▪ Visually inspect the instruments for cleanliness. If any residual matter is observed, repeat cleaning steps until instruments appear clean upon visual inspection.
▪ Inspect instruments and sort out those with defects. Instruments showing any deformation, damage or defects (loss of marking) affecting the resistance, the safety or the performance of the instrument must be returned to Pixee Medical or its distributor.</td></tr>
<tr><td>Packaging</td><td>▪ Reassemble the instruments prior to sterilization.
▪ Place the instruments in the specific storage box provided by Pixee Medical
▪ Double wrap the instruments box with sterilization wraps, conforming to ISO 11607 and ANSI/AAMI ST79, and appropriate for steam sterilization.
▪ Physical-chemical indicators may be used on or in the packaging system.
▪ For USA users, use FDA approved wraps.</td></tr>
<tr><td>Sterilization</td><td>▪ Use a steam sterilizer conforming to EN13060, EN 285, and ISO 17665.
▪ Use the sterilization parameters provided in table below, which have been validated.
▪ At the end of the cycle, check the physico-chemical indicator and controls to confirm the efficiency (packaging integrity, no humidity, color change of sterilization indicators, digital records of cycle parameters).

<table><tr><th rowspan="2">Procedure</th><th colspan="3">Dynamic-air-removal Steam Sterilization Cycle</th></tr><tr><th>USA</th><th>Europe</th><th>UK</th></tr><tr><td>Exposure time</td><td>4 minutes</td><td>> 5 minutes</td><td>3 minutes</td></tr><tr><td>Temperature</td><td>132 °C</td><td>134 °C</td><td>134 °C</td></tr><tr><td>Drying Time</td><td>30 minutes</td><td>30 minutes</td><td>30 minutes</td></tr></table></td></tr>
<tr><td>Storage</td><td>▪ Keep instruments in sterilization packaging in a dry and clean environment.
▪ Sterility cannot be guaranteed if packaging is opened, damaged, or wet.
▪ Check packaging and instruments before use (packaging integrity, validity period and signs of excessive humidity).</td></tr>
</table>

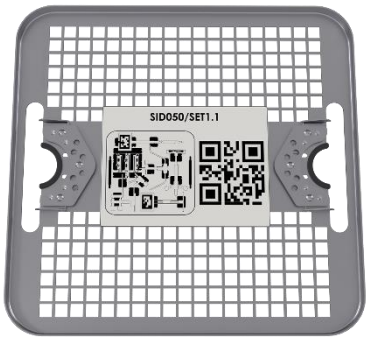
INSTRUMENTATION

Components

1. Pointer
2. Bone reference
3. Cutting guide
4. Cutting guide adaptor
5. Orientation mechanism
6. Knee stylus
7. Control tool
8. SHA Outer ring
9. Right Proximal cutting guide
10. Left Proximal cutting guide

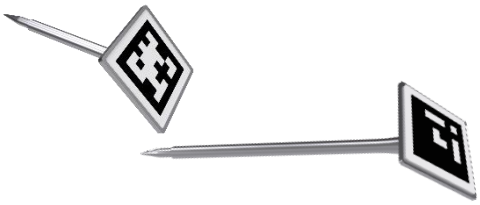


Each instrument equipped with a tracking marker has its own geometric properties. The software integrates this metrological data to ensure the accuracy of the displayed values. An instrumentation set combines these instruments equipped with markers by a reference SIDXXX, indicated on the configuration QR-CODE sheet of the instruments.



Do not mix instruments from different sets.

Pointer



The pointer is used as a fixed reference marker for the hip center acquisition.
It is also used to point the patient's malleoli for the ankle center acquisition.

Bone reference

The bone reference is attached to the bone to acquire the knee center and the anteroposterior axis orientation for the femur and the tibia. The bone reference is also involved during the hip center and ankle center acquisitions.
The holes are designed to receive 3.2 mm diameter pins.

Cutting guide

The cutting guide is used to perform the distal femoral cut and the proximal tibial cut.
The slot is designed for a saw blade of 1.27 mm thickness and 12 to 30 mm width.
The holes positioned at 0 mm, + 2 mm and + 4 mm are designed to receive 3.2 mm diameter pins.

Right/Left proximal cutting guides

The right and left proximal cutting guides are optional instruments used to perform the proximal tibial cut.
The slot is designed for a saw blade of 1.27 mm thickness and 12 to 30 mm width.
The holes positioned at 0 mm, + 2 mm and + 4 mm are designed to receive 3.2 mm diameter pins.

Cutting guide adaptor

The cutting guide adaptor attaches to the cutting guide. It includes the marker detected by the software to locate its orientation in space.

Orientation mechanism

The orientation mechanism adjusts the orientation of the cutting guide in the coronal and sagittal planes relative to the mechanical axis.

Knee stylus

The knee stylus is used to adjust the resection level between 0 and 16 mm based on its millimeter graduation.
The flat end is specific to the surface of the distal femoral condyles and the pointed end is specific to the tibial plateau.

Control tool

Once the cut is performed, the cut orientation values can be checked by using the control tool.
This step is optional and configurable when launching the KneePlus software.

Ankle clamp

The ankle clamp is optional as an alternative to the pointer in order to achieve the ankle center acquisition. It is positioned on either side of the patient's malleoli.

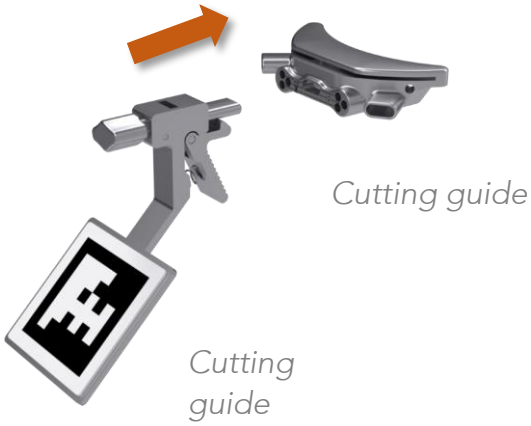
SHA Outer ring

The SHA (Surgical Helmet Adaptor) outer ring is an optional accessory for the use of Knee⁺ with a Surgical Hemet.
It has to be positioned outside the visor of the surgical helmet worn by the surgeon in order to be magnetically assembled with the SHA Connector component present inside the visor.

For more details about the surgical helmet installation see the practical guide SW001-KNEE_PLUS-DOAC-001

⚠ Never use a damaged or deformed tool. A bent component may register inaccurate coordinate information.

Guiding Tool assembly



Insert the cutting guide adaptor in the oblong hole of the universal cutting guide until a click sound is heard.

Slide the guide adaptor on the mast of the orientation mechanism, making sure the plates of the mechanism are parallel.

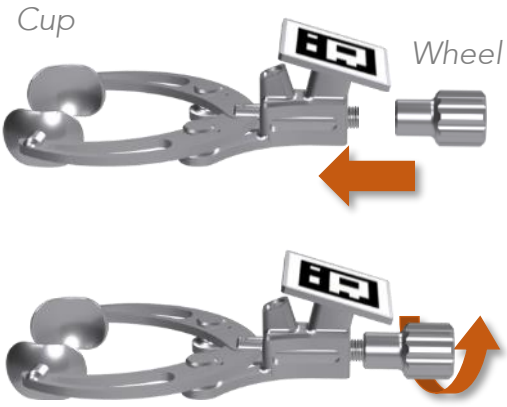
Tighten the front knob of the cutting guide adaptor to lock it on the orientation mechanism mast.

Knee stylus assembly

Slide the main body into the bottom part (make sure the graduation is visible in the oblong connector window).

Tighten the knob to lock the two components together in order to maintain the desired resection level.

Ankle clamp assembly



Screw the wheel on the threaded axis.

OPERATING PROCEDURE

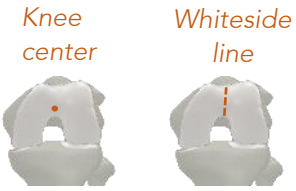
FEMORAL PART

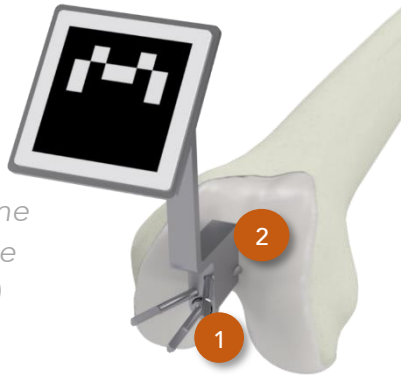
Positioning of the bone reference

1 Install the bone reference on the femur by pointing the center of the knee with a **collared 3.2 mm pins diameter in the central hole or the hole marked "FEM"** depending on the bone reference used. *This is the same entry point as an intramedullary rod.*

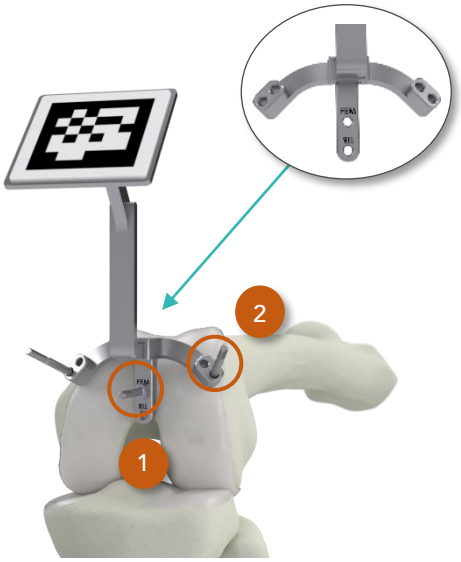
2 Align the bone reference with the Whiteside line.
Fix the bone reference with a second and third 3.2mm diameter fixation pin.

⚠ The bone reference must be securely attached.





Slim bone reference (KNI012)



Bone reference (KNI005)

The mast of the bone reference must be positioned as perpendicularly as possible to the mechanical femoral axis to have the necessary range of motion for the cutting guide.

Hip center acquisition

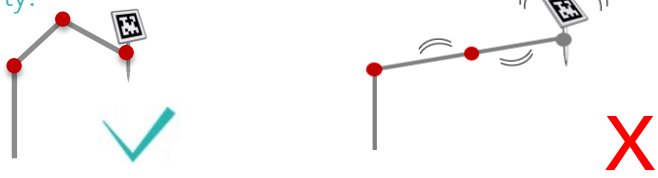
This step consists in collecting femoral head center coordinates in order to obtain the mechanical femoral axis.

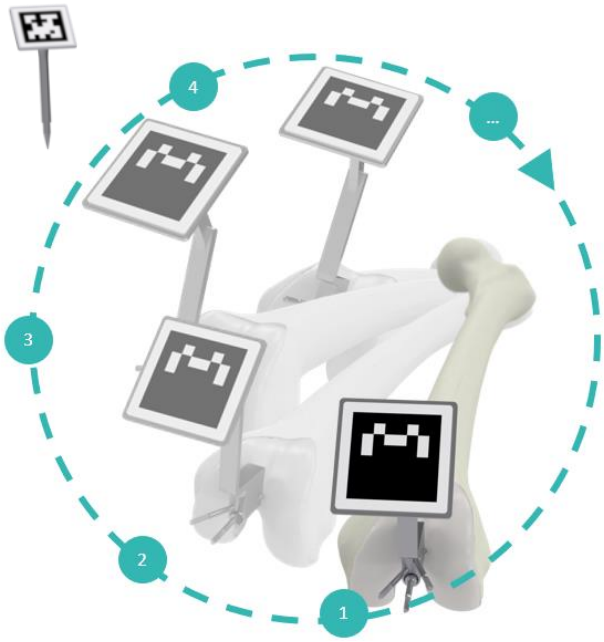
Position the pointer at the end of a sterile articulated arm.
Ensure that its position **in relation to the camera** meets the criteria of marker detection:

- Distance entre 30 et 80 cm
- Inclinaison entre 10 et 60°

⚠ The pointer must remain stable during the hip center acquisition.

Make sure that the articulated sterile instrument arm is positioned correctly to ensure its stability.



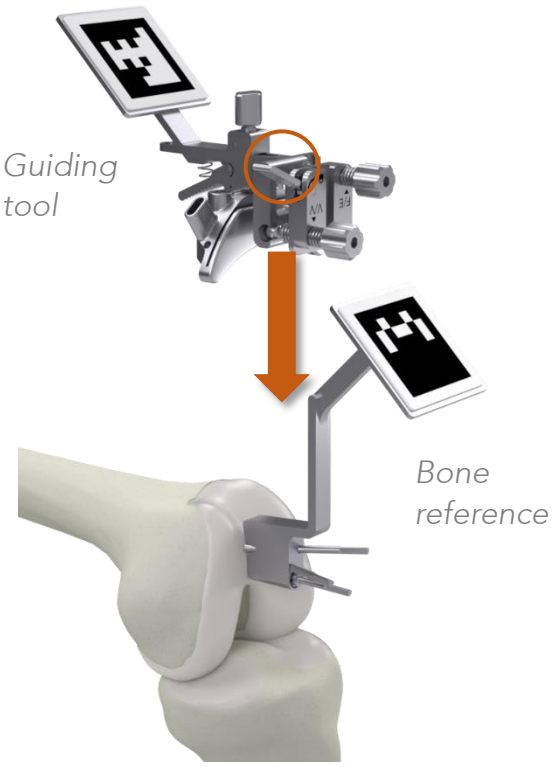


Record 10 static positions by rotating the patient's lower limb in such a way that the distal femur makes a circular movement. Remain stable at each of the 10 positions so that the marker is identified and the point recorded.

⚠ The pelvis of the patient must remain stable during all the acquisition.

Navigation of the distal femoral cut

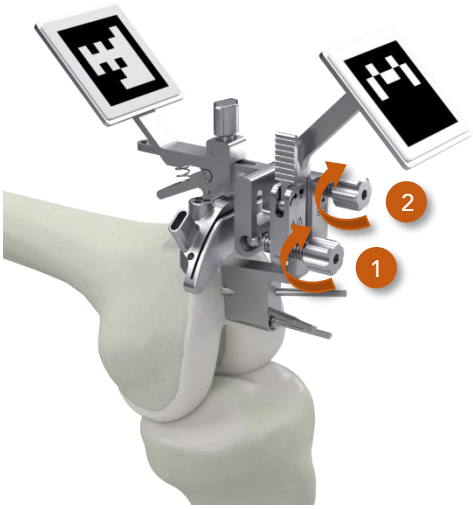
The varus/valgus and flexion/extension values of the cutting guide are calculated in relation to the **mechanical axis**.



Install the guiding tool assembly on the bone reference by sliding it over the bone reference mast.

Lock the guiding tool by closing the lever.

Keep some clearance between the cutting guide and the bone cortical to avoid conflict during orientation settings.

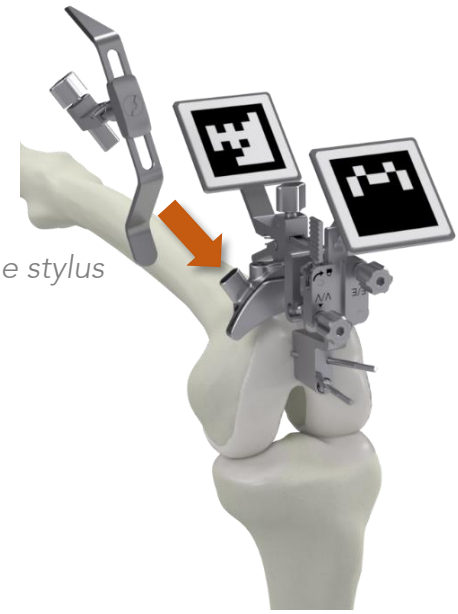


Turn the wheels to adjust the orientation of the cutting guide:

1. Wheel marked V/V for the **varus/valgus** adjustment in the coronal plane.
2. Wheel marked F/E for the **flexion/extension** adjustment in the sagittal plane.

Adjusting the resection level

Adjust the desired resection level by sliding the stylus mast while reading the graduation. Lock it by tightening the central knob.



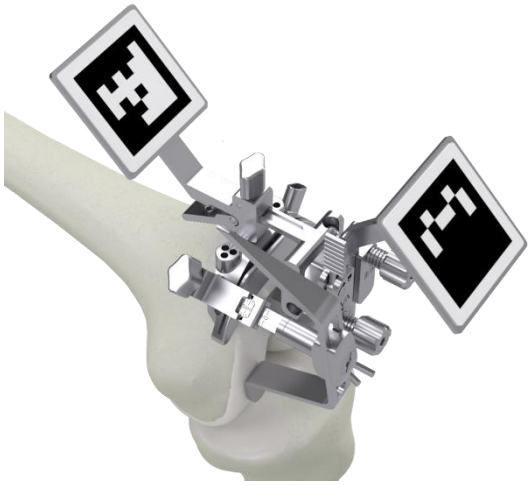
Knee stylus

Guiding tool

Insert the knee stylus into one of the oblong holes of the cutting guide.

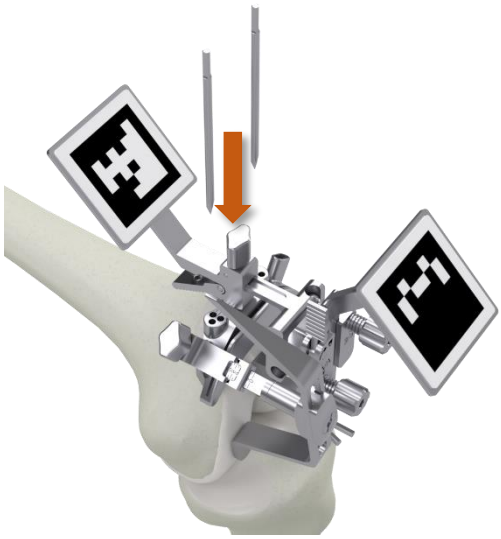
Adjust the position of the stylus **flat tip** so that it's just in front of the top of the distal femoral condyle.

- Unlock the cutting guide adaptor translation by loosening the central knob.
- Slide the cutting assembly until the stylus lays flat on the bone surface
- Lock the resection level by tightening the central knob



⚠ Check the level of resection with a control blade.

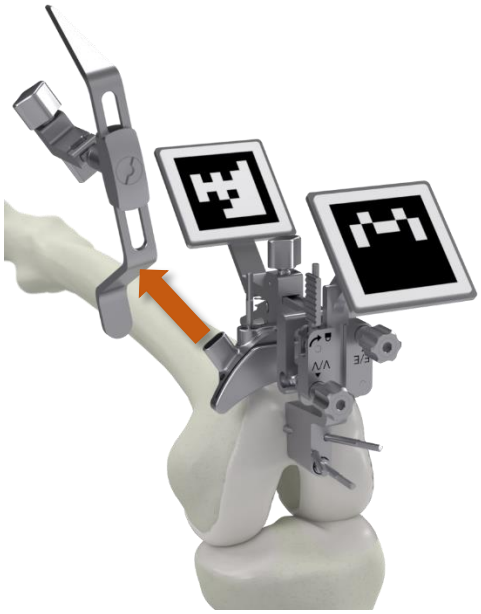
Distal femoral cut



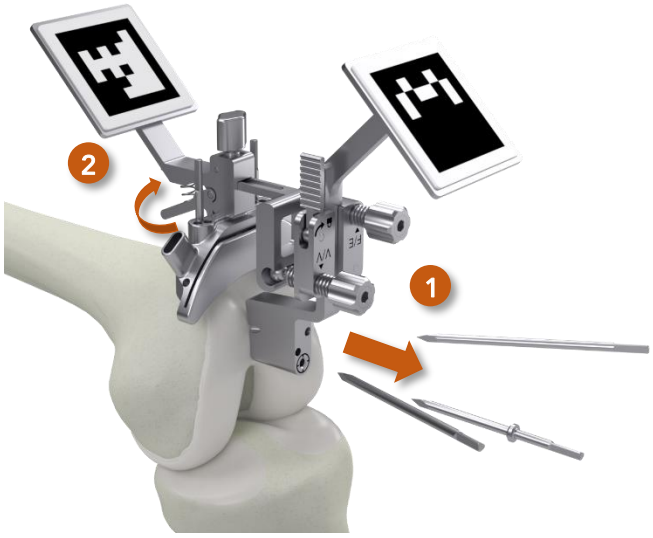
Secure the cutting guide with **3.2mm diameter pins.**

In order to avoid possible collisions between the pins of the cutting guide and those of the bone reference it is possible to:

- Pre-attach the cutting guide with 3.2 mm diameter pins without pushing them in completely while making sure that the cutting guide is stable.

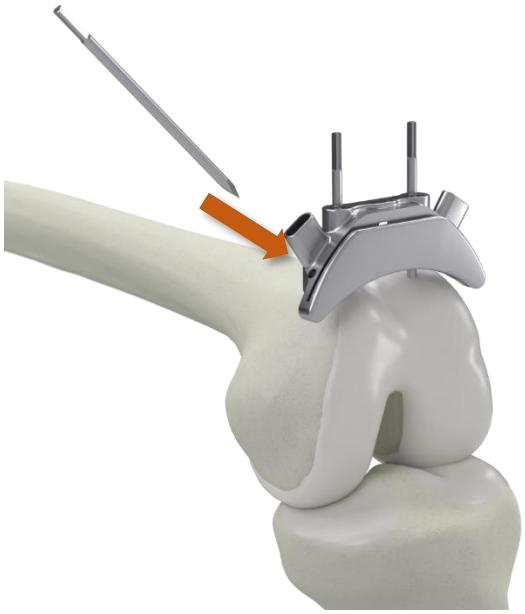


Remove the knee stylus.



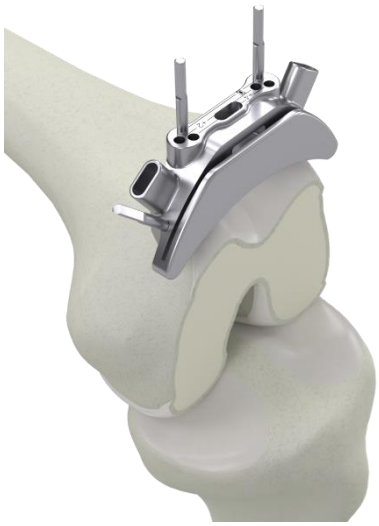
1. Remove the pins from the bone reference.
2. Press the trigger on the guiding tool. To remove it from the cutting guide.

Do not leave the cutting guide adaptor in place when cutting.



If necessary, finish inserting the two pins in the cutting guide.

Insert an oblique pin for more stability

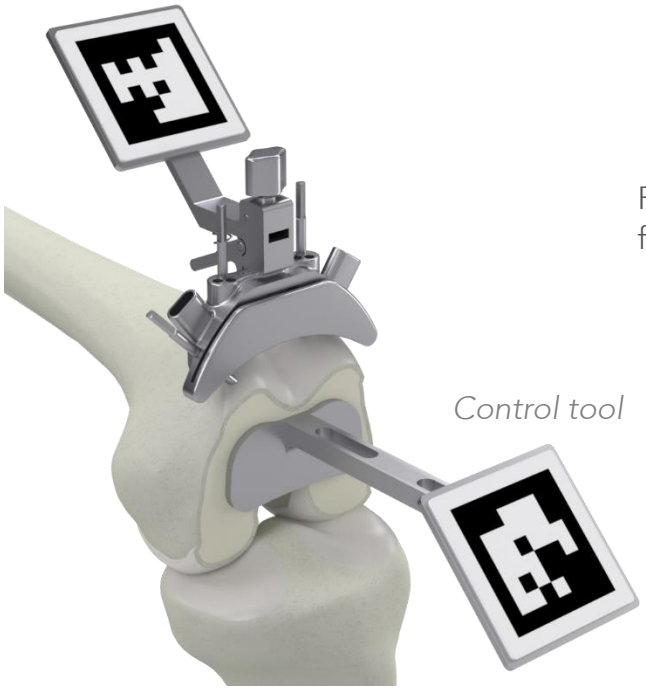


Perform the distal femoral cut with a **1.27 mm saw blade** through the cutting guide slot.

Control of the distal femoral cut

Cutting guide adaptor

Reposition the cutting guide adaptor into the oblong hole of the cutting guide.



Control tool

Position the control tool on the distal femoral cut area.

TIBIAL PART

Positioning of the bone reference

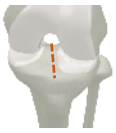
1 Install the bone reference on the tibia by pointing the knee center with a **collared pins 3.2 mm diameter in the central hole or the hole marked "TIB"** depending on the bone reference used.
This is the same entry point as an intramedullary rod.

2 Align the bone reference instrument in such a way that its orientation follows the anteroposterior axis defined by the insertion of the Posterior Cruciate Ligament and the Medial Third of the Tibial Tuberosity.
Fix the bone reference with a second and third 3.2mm diameter fixation pin.

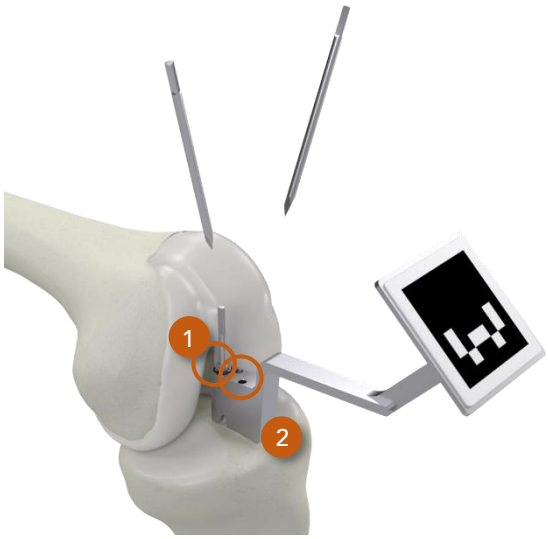
⚠ The bone reference must be securely fixed.

Knee center

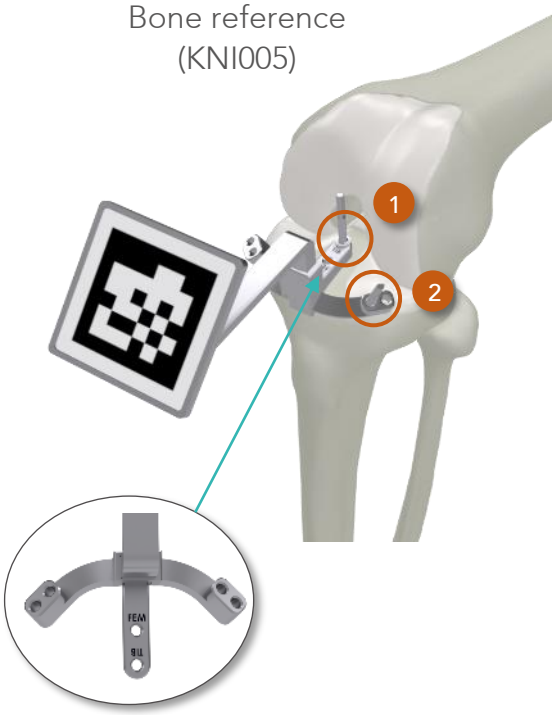
Anteroposterior axis

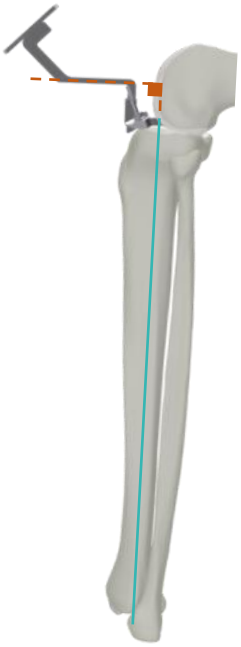


Slim bone reference
(KNI012)



Bone reference
(KNI005)

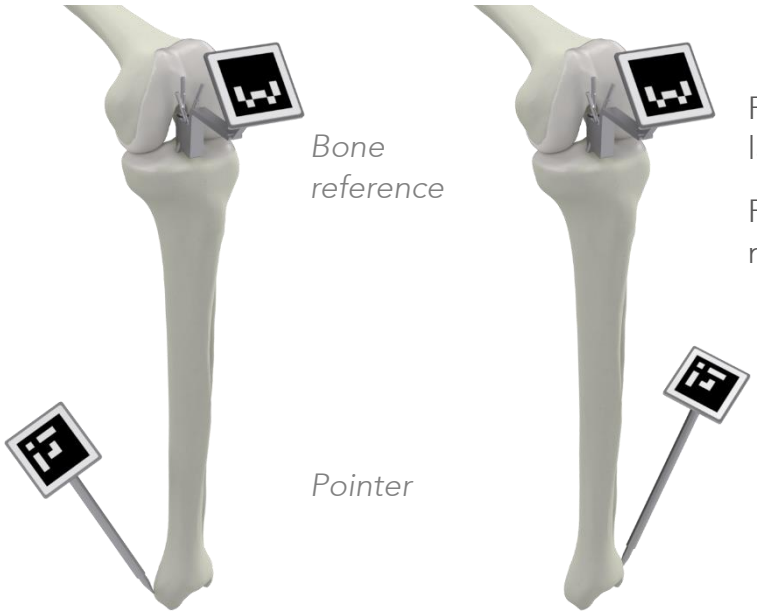




The mast of the bone reference must be positioned as perpendicularly as possible to the (mechanical) tibial axis in order to have the necessary range of motion for cutting guide.

Ankle center acquisition

This step involves collecting the coordinates of the center of the malleoli in order to obtain the mechanical tibial axis.



Using the pointer

Position the pointer's tip against the lateral malleolus.

Position the pointer's tip against the medial malleolus.

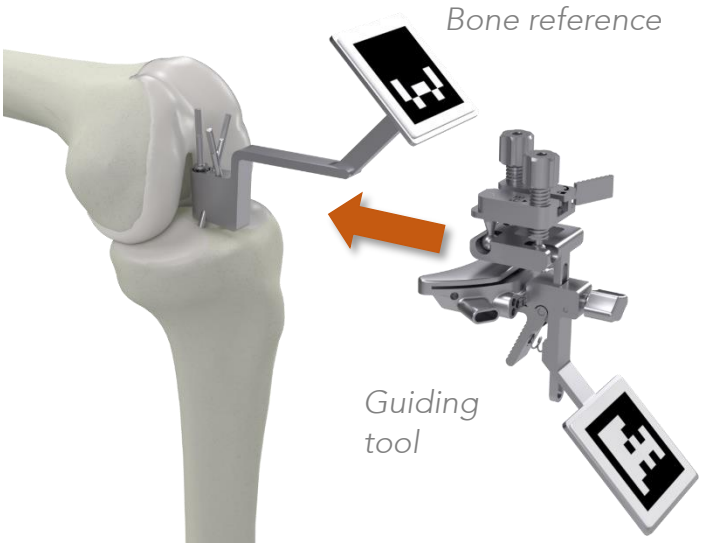
Using the ankle clamp

Spread the two cups apart by unscrewing the wheel, then position the two cups of the ankle clamp on the patient's malleoli.

Screw the wheel for the cups to achieve good contact with the patient's ankle and ensure that the ankle clamp holds in position.

Navigation of the proximal tibial cut

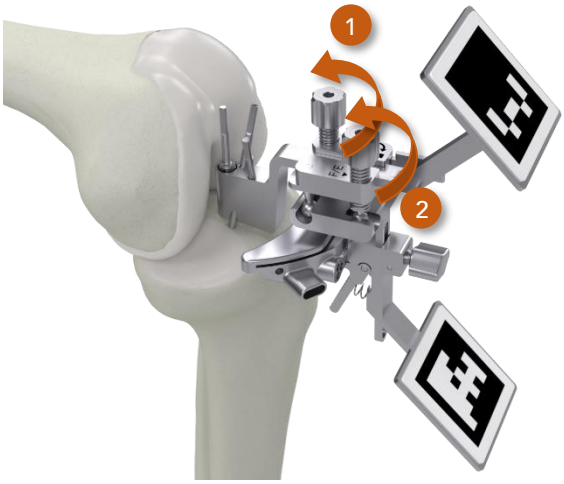
Varus / valgus and slope values of the cutting guide are calculated in relation to the mechanical tibial axis.



Install the guiding tool assembly on the bone reference by sliding it over the bone reference mast.

Lock the guiding tool by closing the lever.

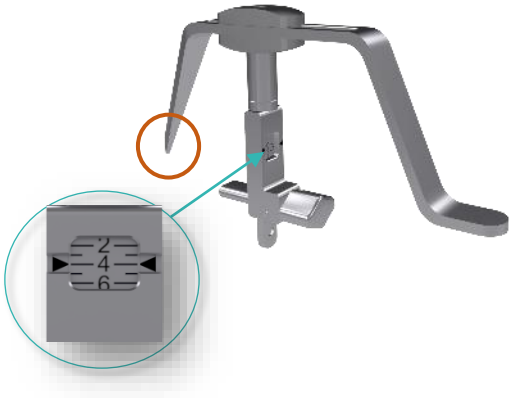
Keep some clearance between the cutting guide and the bone cortical to avoid conflict orientation settings.



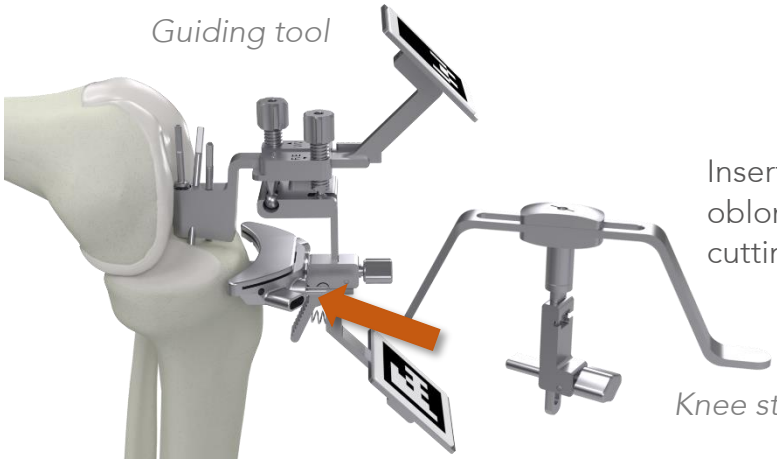
Turn the wheels to adjust the orientation of the cutting guide:

1. Wheel marked V/V for the **varus/valgus** adjustment in the coronal plane.
2. Wheel marked F/E for the **slope** adjustment in the sagittal plane.

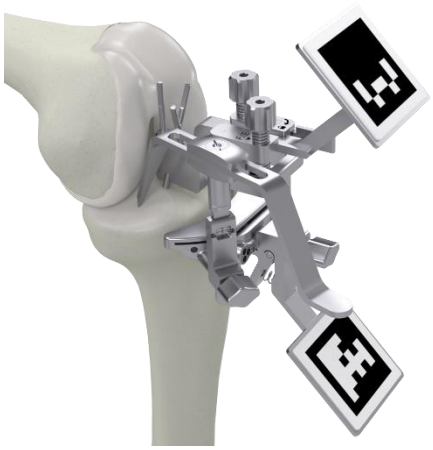
Adjusting the resection level



Adjust the desired resection level by sliding the stylus mast while reading the graduation. Lock it by tightening the central knob.



Insert the knee stylus into one of the oblong holes (medial or lateral) of the cutting guide.

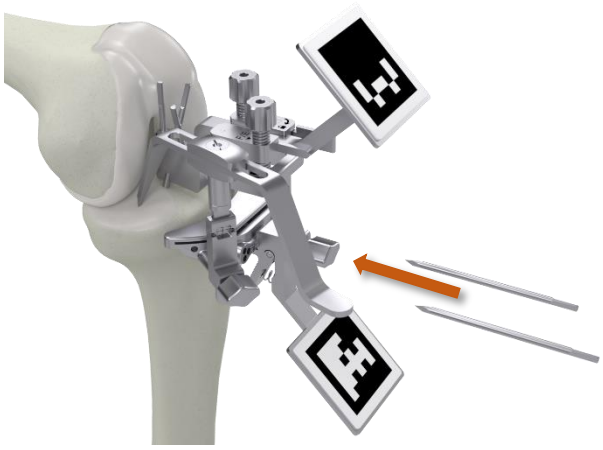


Adjust the position of the stylus **flat tip** so that its points the tibial plateau center.

- Unlock the cutting guide adaptor translation by loosening the central knob.
- Slide the cutting assembly until the stylus lays flat on the bone surface
- Lock the resection level by tightening the central knob.

⚠ Check the level of resection with a control blade.

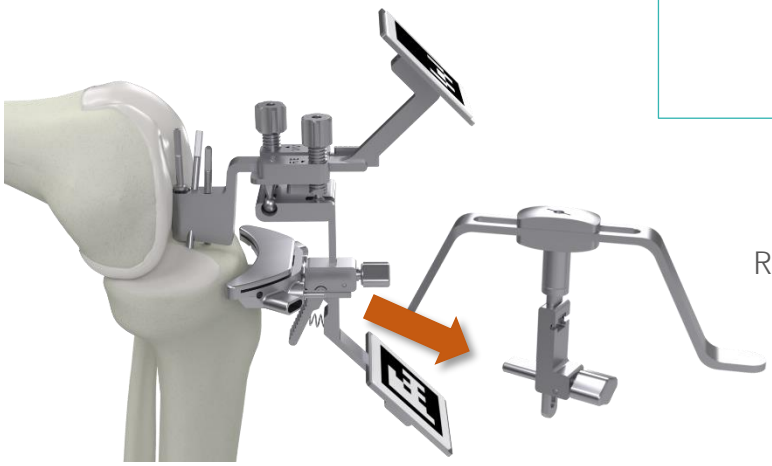
Proximal tibial cut



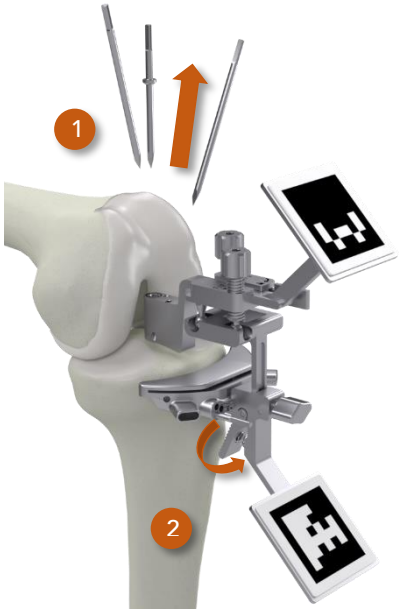
Secure the cutting guide with **3.2mm diameter pins.**

In order to avoid possible collisions between the pins of the cutting guide and those of the bone reference it is possible to:

- Pre-attach the cutting guide with 3.2 mm diameter pins without pushing them in completely while making sure that the cutting guide is stable.

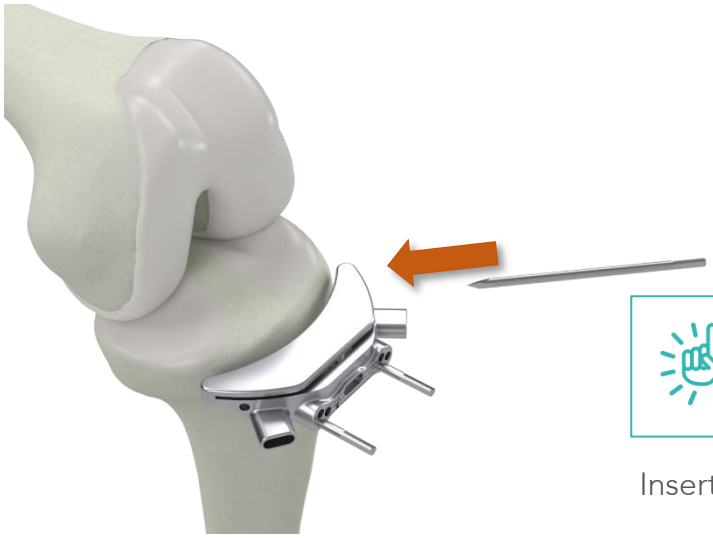


Remove the knee stylus.



1. Remove the pins from the bone reference.
2. Press the trigger on the guiding tool. To remove it from the cutting guide.

Do not leave the cutting guide adaptor in place when cutting.



If necessary, finish inserting the two pins in the cutting guide.

Insert an oblique pin for more stability.

Perform the proximal tibial cut with a **1.27 mm saw blade** through the cutting guide slot.

Control of the proximal tibial cut

Cutting guide adaptor

Replace the cutting guide adaptor into the oblong hole of the cutting guide.

Control tool

Position the control tool on the tibial cut area.

SUPPORT

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