i.M.A.G.E.®

Patient-Specific knee instrumentation
For UNI SCORE® UKA

Supplement to
Surgical Technique

AMPLITUDE

INTRODUCTION

This Surgical Technique Supplement describes the use of patient-matched i.M.A.G.E.® instruments for implanting UNI SCORE® Unicompartmental Knee Arthroplasty (UKA).

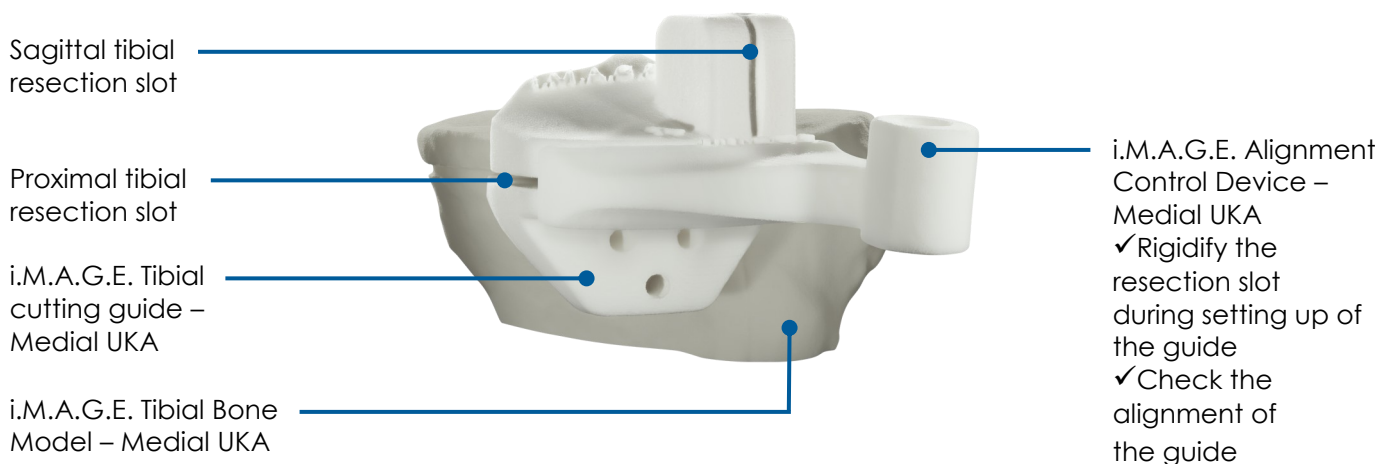It replaces the following paragraphs in the conventional Surgical Technique documents:

- **Conventional instrumentation: TO.G.GB.003**
  From the "Extramedullary tibial aiming" paragraph to the "Tibial cut" paragraph

- **Simplified conventional instrumentation: TO.G.GB.108**
  From the "Extramedullary tibial aiming" paragraph to the "Tibial cut" paragraph
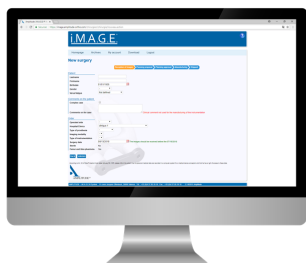
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GENERAL DESCRIPTION

- Single-use instrumentation based on the patient's anatomy. It allows to perform tibial proximal and sagittal resections of the UNI SCORE® UKA according to the three-dimensional preoperative planning.

- Instrumentation manufactured based on the patient's CT-scan or MRI images.

- It allows intraoperative check of:
    - contact areas comparing with bone model
    - tibial cut orientation

Sagittal tibial resection slot

Proximal tibial resection slot

i.M.A.G.E. Tibial cutting guide – Medial UKA

i.M.A.G.E. Tibial Bone Model – Medial UKA

i.M.A.G.E. Alignment Control Device – Medial UKA
✓Rigidify the resection slot during setting up of the guide
✓Check the alignment of the guide

i.M.A.G.E.® Instrumentation UNI SCORE® UKA

i.M.A.G.E.® PROCESS STEPS

1

Online ordering

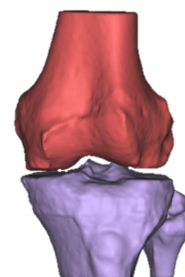https://image.amplitude-ortho.com/

2

CT-scan or MRI exam

Performed using Amplitude's protocol. DICOM files sent to Amplitude.

3

Image processing

Segmentation. Anatomical landmarks.

i.M.A.G.E.® PROCESS STEPS

4

3D planning

Performed using the i.M.A.G.E.® planning software

5

Manufacturing

Design of 3D model of instruments
Manufactured by Selective Laser Sintering.

6

Delivery

Instrumentation delivered to hospital
Decontamination and sterilisation

PREOPERATIVE PLANNING

- i.M.A.G.E.® planning software is used to determine the size and the position of the UNI SCORE® UKA components before the surgery.
  Preoperative planning of the femoral component is only for information purposes, femoral resections are performed using the conventionnal instrumentation.

- The following parameters can be adjusted in the software:
  - On the tibia:
    - Anterior/posterior slope
    - Height of tibial cut
    - Insert thickness
    - Anterior/posterior positioning
    - Medial/lateral positioning
    - Varus/valgus positioning
    - Internal/external rotation
  - Estimated cartilage height for the tibial and distal femoral resections height references (only for planning based on CT-scan).
  - On the femur (for information purposes) :
    - Femoral component size
    - Height of distal cut
    - Medial/lateral positioning

- Changing these parameters will update in real-time the three-dimensional bone model generated based on the patient's CT or MRI images.

- The planning software, instructions for its use and the imaging protocols can be downloaded from https://image.amplitude-ortho.com. Please contact your Amplitude sales representative for access.

Recommendations

- We do not recommend using this system in patients who have an existing implant near the support surfaces of the device such as an osteotomy plate, nail, staple, screw, etc.
  This could induce artefacts that could alter the quality of the CT-scan or MRI images.

- Before starting the procedure, make sure the patient-specific data on i.M.A.G.E. Tibial cutting guide – Medial UKA, i.M.A.G.E. Alignment Control Device – Medial UKA and i.M.A.G.E. Tibial Bone Model – Medial UKA is correct. Do not use these items if the patient identification is not clearly visible.

  Example of patient identification: 0000001-F-SUR-X-PN
  - 0000001: 7-digit number
  - F: first letter of patient's first name
  - SUR: first 3 letters of patient's surname
  - X: operated side, left (L) or right (R)
  - PN: surgeon's initials

- **Do not resect any of the osteophytes** because they are needed to position the i.M.A.G.E. Tibial cutting guide – Medial UKA.

- If an osteophyte that is not under a contact point interferes with exact placement of the i.M.A.G.E. Tibial cutting guide – Medial UKA, remove this osteophyte and try again to set the i.M.A.G.E. Tibial cutting guide – Medial UKA in place.

REMINDER

The purpose of this surgical technique description is to provide instructions on how to use the instrumentation properly. The surgeon is fully responsible for choosing and performing the approach and surgical technique.

Summary of the Surgical Technique

Tibial technique

1 **Positioning of the i.M.A.G.E. Tibial cutting guide – Medial UKA**

2 **Fixation and tibial cuts orientation check**

3 **Tibial cuts**

Tibial technique

- Hyperflex the knee and dislocate the tibia forward.

- Use the i.M.A.G.E. Tibial Bone Model – Medial UKA to locate the contact areas on the tibia and make sure they are not covered by fibrous tissue.

- Insert the i.M.A.G.E. Alignment Control Device – Medial UKA in the i.M.A.G.E. Tibial cutting guide – Medial UKA.

- Place the assembly on the proximal tibia.

- Make sure the i.M.A.G.E. Tibial cutting guide – Medial UKA is stable (unique position) and rests against the anterior tibia.

- Place two parallel Headless pin length 80 mm in the superior holes of the i.M.A.G.E. Tibial cutting guide – Medial UKA.

- Check the tibial cuts orientation (varus/valgus and slope) by inserting the Extramedullary alignment rod in the hole on the i.M.A.G.E. Alignment Control Device – Medial UKA. The Extramedullary alignment rod must be parallel to the tibial mechanical axis, regardless the planned slope or varus.

- Insert a converging Headed pin length 70 mm in the inferior hole of the i.M.A.G.E. Tibial cutting guide – Medial UKA to stabilise it.

- Remove Extramedullary alignment rod and the i.M.A.G.E. Alignment Control Device – Medial UKA.

- Perform tibial resections using slots provided and Saw Blade that matches the instrumentation set and Motorized Handpiece.

TIBIAL TECHNIQUE

- Remove the Headed pin length 70 mm with the Pin extractor.

- Slide the i.M.A.G.E. Tibial cutting guide – Medial UKA off the Headless pin length 80 mm but leave them in place in case recutting is necessary.

- Control the size of the tibia using the Trial baseplate corresponding to the planned size. A hook provides secure fixing on the posterior edge of the tibial plateau.

- A Unicompartmental Trial Fixed Insert that has a known height and thickness can be used to check the tibial cut. During knee flexion, the anterior side of the Unicompartmental Trial Fixed Insert must not lift off; if it does, the tibial slope is not sufficient.

NOTE

If using a cementless tibial baseplate with fixed insert, the peg position relative to the anterior side of the tibia can be marked with a scalpel.

- Check the gaps, proceed with the femoral cuts, femoral and tibial trials, femoral and tibial preparations, and then insert the final implants as set out in the conventional Surgical Technique document:

    - **Conventional instrumentation: TO.G.GB.003**

    From the "Verification of flexion gaps" paragraph to the "Insertion of final implants " paragraph

    - **Simplified conventional instrumentation: TO.G.GB.108**

    From the "Verification of flexion gaps" paragraph to the "Insertion of final implants " paragraph

INSTRUMENTATION

The i.M.A.G.E.® instrumentation for UNI SCORE® UKA requires:

- **An i.M.A.G.E. set CT or MRI – T Cutting Guide With Bone Model - Medial UKA - Non-Sterile**
- **The conventional instrumentation for the specific TKA model**

The conventional instrumentations for UNI SCORE® UKA are described in the following Surgical Technique documents:

- **Conventional instrumentation: TO.G.FR.003**
- **Simplified conventional instrumentation: TO.G.FR.108**

INSTRUMENTATION

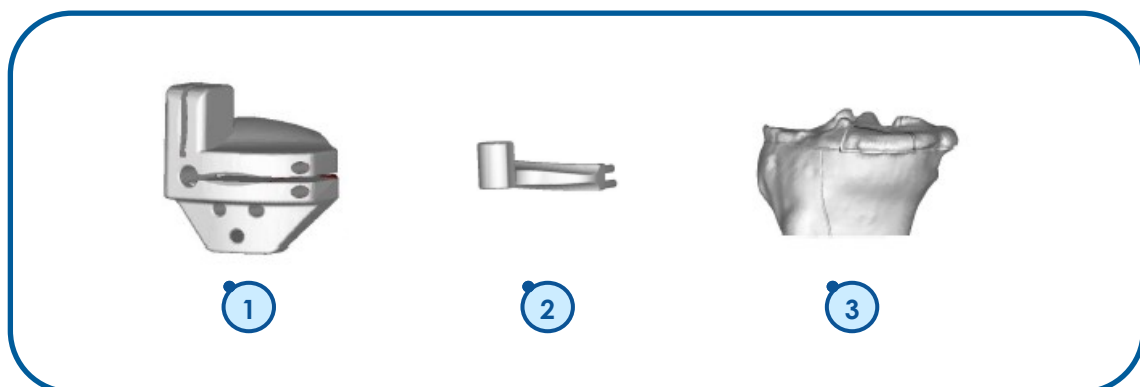## i.M.A.G.E. set CT – T Cutting Guide With Bone Model - Medial UKA - Non-Sterile   9-0201130
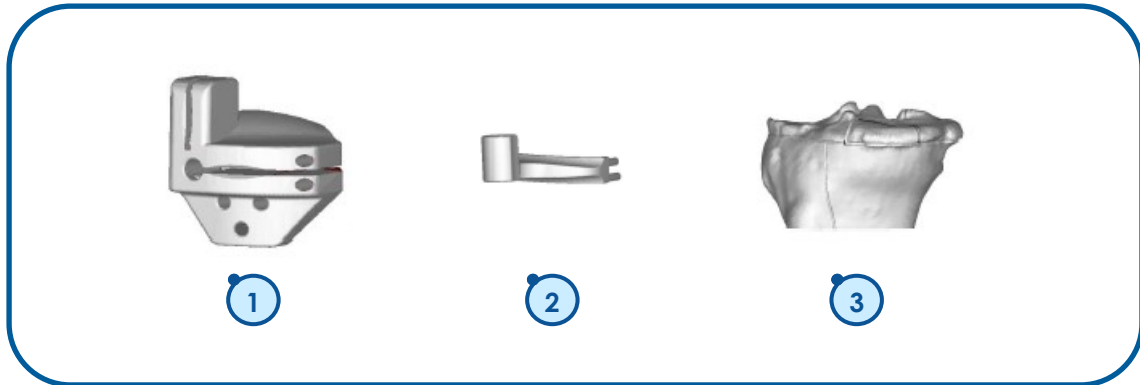
Item	Name	Product No.	Qty
1	i.M.A.G.E. Tibial cutting guide – Medial UKA	-	1
2	i.M.A.G.E. Alignment Control Device – Medial UKA	-	1
3	i.M.A.G.E. Tibial Bone Model – Medial UKA	-	1

i.M.A.G.E. set MRI – T Cutting Guide With Bone Model - Medial UKA - Non-Sterile   9-0201110

Item	Name	Product No.	Qty
1	i.M.A.G.E. Tibial cutting guide – Medial UKA	-	1
2	i.M.A.G.E. Alignment Control Device – Medial UKA	-	1
3	i.M.A.G.E. Tibial Bone Model – Medial UKA	-	1

AMPLITUDE

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