

FH ORTHO



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CONCEPT INTRODUCTION

The new Easy Move Total Ankle Replacement with fixed bearing from FH ORTHO is designed to restore the ankle joint while ensuring full respect of ankle anatomy. It conserves bone, minimizes resections thickness and achieves more natural biomechanics of the replaced ankle joint.

The tibial component is anatomically designed. The anterior part is wider than the posterior part. A natural arc-shape to maintain the native anatomy, minimises bone loss in the posterior part of the tibia (Volkmann Triangle) and reproduces the natural biomechanics during movement, ensuring physiological load transfer. The less invasive tibial design anchorage does not destroy the distal tibial cortex with aggressive anchors, such as pegs. The anterior tibial shield increases component stability and guarantees a bi-cortical support.

The talar component is designed with a bicondylar articulating surface. The design is a conical shape, which means the lateral radius of the talar component is wider than internal radius in order to replicate the native talar shape and allows a natural biomechanical movement.

The design guarantees a uniform load transfer from the implant to the prepared talar bone cuts. Both the lateral and medial shoulders of the implant are designed to give the component more stability and make the system more hermetic to possible joint fluid infiltration. This design will minimize complications, such as cyst formation or subsidence around the implant.

Another unique difference of the new Total Ankle Replacement from FH ORTHO is the introduction of a new Tibial/ Talar alignment guide concept, called the "spoon".

Currently, to adjust the various anatomical landmarks in both the tibia and the talus, only external tibial alignment guides are used, which are difficult to position and require many external adjustments.

The "spoon" used with the Easy Move Total Ankle Replacement from FH ORTHO provides a useful improvement which can overcome the drawbacks encountered with conventional surgical devices.

This innovative, patented surgical device simplifies and minimizes the number of adjustment steps, such as translation, rotation, Varus/Valgus, tibial slope and height adjustment, which are both necessary and complex with an external tibial alignment guide, and ensuring correct positioning of both tibia and talus prosthesis components.

Thank you for considering the new Easy Move Total Ankle Replacement. We believe this new design concept and the innovative instrumentation will be the start of a new generation of Total Ankle Replacements and are going to help to improve Total Ankle Arthroplasty.

The FH ORTHO Team



INDICATIONS AND CONTRAINDICATIONS

Indications

The total ankle prosthesis is indicated as a total ankle replacement for primary surgery in patients with ankle joints damaged by severe rheumatoid, post-traumatic or degenerative arthritis.

The components are intended for uncemented use.

Contraindications

- Infection;
- · Infection sequelae;
- Systemic infection, fever and/or local inflammation;
- Complete talar necrosis;
- Insufficient bone stock or poor skin coverage around the ankle joint that would render the procedure unjustifiable;
- · Persistent cutaneous lesion;
- · Significant ligamentous laxity;
- Severe osteoporosis;
- Ankle arthrodesis with malleolar exeresis;
- Neuromuscular or mental disorders which might jeopardise fixation and postoperative care:
- · Neurobiological disorders;
- · Nonfunctional lower limb muscles;
- Complete loss of collateral ligament of the ankle;
- Charcot arthropathy;
- Distant foci of infection from genitourinary, pulmonary, skin and other sites, dental focus infection which may cause hematogenous spread to the implant site;
- Bone immaturity;
- Known allergy to one of the materials;
- Vascular insufficiency at the ankle joint;
- Inability of the patient to follow the surgeon's recommendations and the physical therapy program;
- Patient pregnancy.



Please NOTE

Main Instrumentation

The main instrumentation consists of 5 sizes standard to the Easy Move Total Ankle Replacement System.

There is also the opportunity to have 2 extra large sizes (6 and 7) of each component (Tibia, Talus and PE-inlay) but available upon request. The list of necessary instruments is found on the instrumentation chapter of this surgical technique.

Special Instrumentation

In the case of severe deformity, there are two dedicated instruments included:

- One for the extension of the Anterior Tibial Axis Alignment Rod;
- One for the posterior cut rotation adjustment.

The use of which is described in the Additional Instrumentation chapter.

X-Ray

The use of X-rays during the surgery is at the discretion of the surgeon on a case-by-case basis. For this type of procedure, continual X-rays are not required, but recommended after insertion of the trial implant for evaluation of the final results.



SURGICAL TECHNIQUE

Patient position

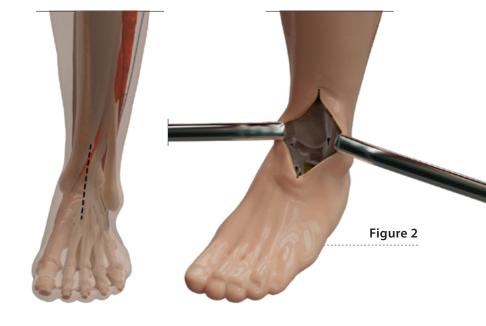
The patient is placed supine with the tibial tuberosity free on the operating table. Raise the affected side, either using a thigh support or by tilting the table, so that the view is directed at an angle of 20° from the lateral side.

Prepare the leg above the knee using a standard draping technique. Exsanguinate the limb by elevation and apply a tourniquet to the thigh. (Figure 1)

Surgical approach and soft tissue preparation

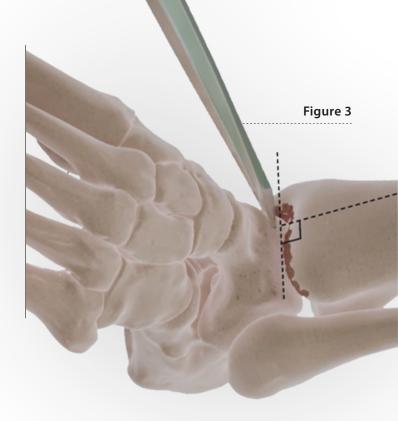
Make a 10-15 cm midline anterior incision with the centre over the middle of the talus at the level of the joint and over the extensor hallucis longus. Find and protect the superficial pereonal nerve in the subcutaneous tissue. Incise the superior and inferior extensor retinaculi between the tibialis anterior and the extensor hallucis longus tendons. (Figure 2)

Retract the neurovascular bundle laterally. Incise the ankle capsule vertically to expose the distal tibial plafond and talus. Continue the incision through this gap down to the bones of the tibia and talus. Use a retractor outside the medial and lateral malleoli to expose the anterior ankle joint completely.



Use a saw or osteotome to remove the anterior lip of the tibia or osteophytes. This should be done parallel to the articular surface and perpendicular to the tibia axis.

Centre the blade on the tibia to avoid medial and lateral malleolar fractures. Resect carefully until the end of the osteotome reaches the plafond of the tibial pilon. **(Figure 3)**





Extra large sizes (6 and 7) are available upon request.

Preselection of

tibial implant size

Once the joint is completely exposed and the anterior osteophytes have been removed, take the tibial gauge (available in sizes 1 to 5) and determine tibial size based on the lateral-medial width.

At this step it also recommended to note the distal tibial rotation of the individual patient anatomy. (Figure 4)

Instruments used

 Talar gauge
 Size 1-2 (ref. 271 690)
 Tray 1 Position 21

 Size 3-4 (ref. 271 691)
 Tray 1 Position 22

 Size 5 (ref. 271 692)
 Tray 1 Position 23



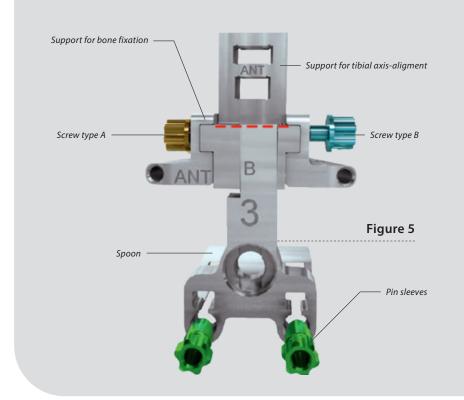
Intra-articular-alignment-

system (aka "spoon")

assembly and adjustment

Choose the correct "spoon" size based on the preselected tibial size. Assemble the "spoon" as shown in Figure 5.

- 1. Slide the support for tibial axis-aligment into the support for bone fixation.
- 2. Insert the "spoon" into the support for the tibial axis-alignment.
- 3. Insert the screw type B (blue) and type A (yellow) through the two mediolateral oblong holes using the screwdriver, without locking. Lock only the screw type B.
- 4. Insert the two pin sleeves into the holes of the "spoon" and screw into place.



Spoon assembly



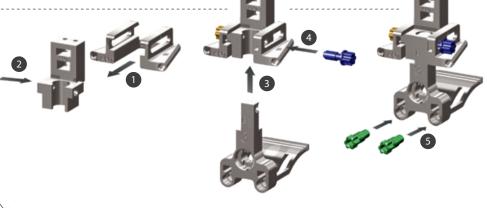
Screw type A

Insert the screwable handle axis into the handle. Insert it into the "spoon".

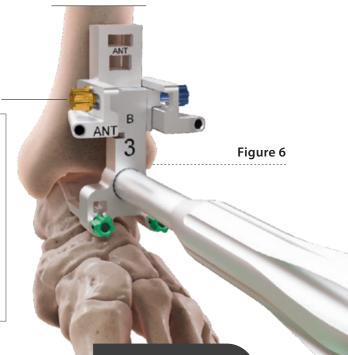


Insert the "spoon" into the ankle joint, making sure that it is well-centered between the mediolateral malleoli.

Lock the screw type A. (Figure 6)

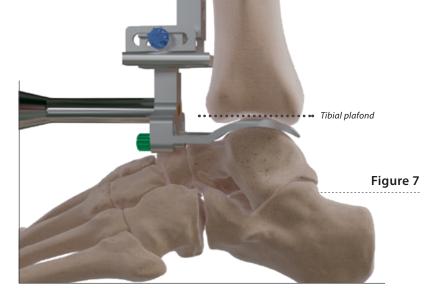


| Instruments used | |
|-----------------------------|---|
| Spoon Size 1 (ref. 271 696) | Tray 1 Position 13 Tray 1 Position 14 Tray 1 Position 15 Tray 1 Position 16 Tray 1 Position 19 Tray 1 Position 18 Tray 1 Position a Tray 1 Position b Tray 1 Position b Tray 1 Position 2 Tray 1 Position 2 Tray 1 Position 6 |
| | |



Tibial pilon plafond location

The location of the tibial pilon plafond is set automatically once the "spoon" has been inserted into the ankle joint. (Figure 7)



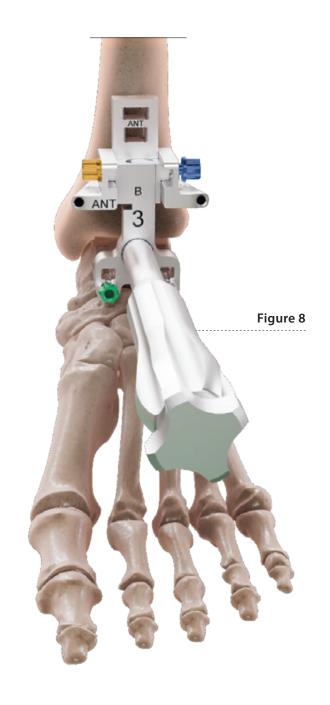
Rotation adjustment

To determine the distal tibial rotation, align the handle of the "spoon" according to the patient's anatomy. (Figure 8)

As shown and landmarked in the previous step. (Tibial gauge - Figure 4)

Translation adjustment

The mediolateral position is adjusted once the correct size has been chosen and properly aligned (centred) between the medial and lateral malleoli.

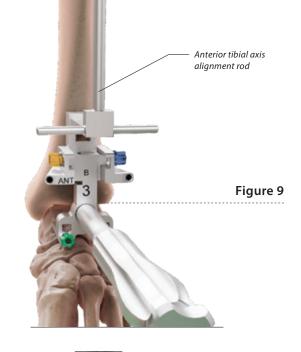


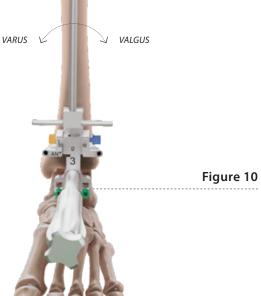
Varus/Valgus correction

Varus/Valgus can be adjusted using a specific anterior tibial axis alignment rod. (Figure 9) Insert the anterior alignment rod into the support and check the frontal plane. The rod should be parallel to the mechanical axis of the tibia. (Figure 10)

Varus/Valgus can be caused either by ligament imbalance, talar bone defect or, even frequently by a tibial bone defect!

If the varus or valgus deformation is caused by a ligament deficiency or a tibial bone defect, additional procedures will probably be required.



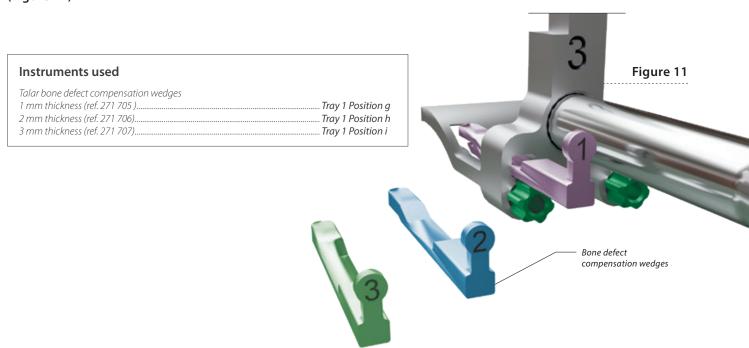


Instruments used

Anterior tibial axis alignment rod (ref. 271 708)..... .. Tray 1 Position 4

If the varus or valgus deformation is caused by a bone defect, insert the talar bone defect compensation wedges (available in 1, 2 and 3 mm thickness) into the slot provided.

(Figure 11)

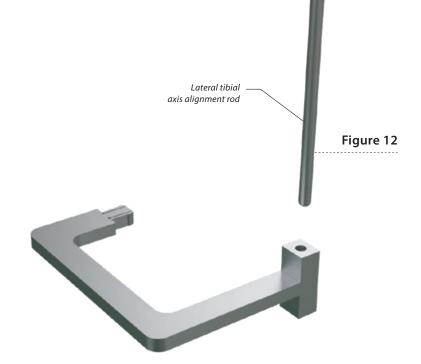


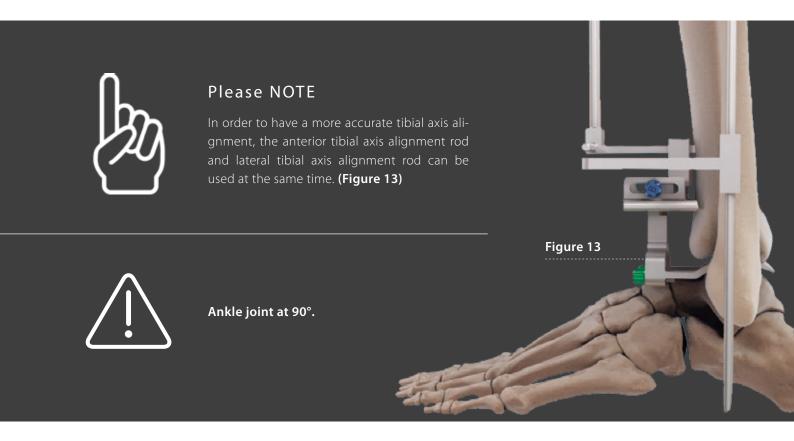
Posterior tibial

slope adjustment

When the frontal axis has been properly adjusted, check the tibial slope on the lateral view. To determine the posterior tibial slope, assemble the lateral-tibial-axis-alignment-rod with the specific support for the lateral-tibial-axis-alignment-rod. The rod should be aligned, in the distal part with the center of the fibula, and in the proximal part with the anterior aspect of the fibula head. **(Figure 12)**

Then insert the assembled tool into the support for tibial axis-alignment and check the lateral plane.

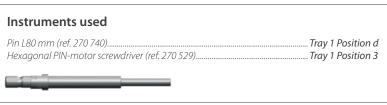


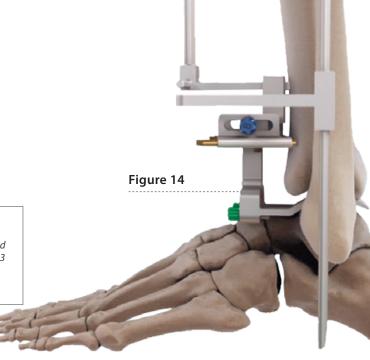


Instruments used

When all the initial reference points are properly adjusted, lock the system with 2 pins (L 80 mm), using the hexagonal PIN- motor screwdriver.

Make sure that the drill is stopped at least 10 mm from the edge of the support for bone fixation. (Figure 14)





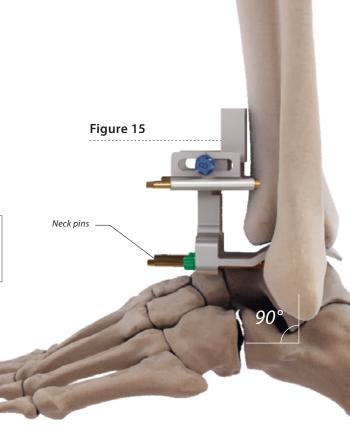
Talar dome cut adjustment

To adjust the correct position of the talar dome cut, put the hindfoot in the 90° position. If necessary, a lateral X-ray image can be taken to ensure correct alignment.

The correct hindfoot position avoids incorrect positioning of the final talar implant in terms of sagittal slope.

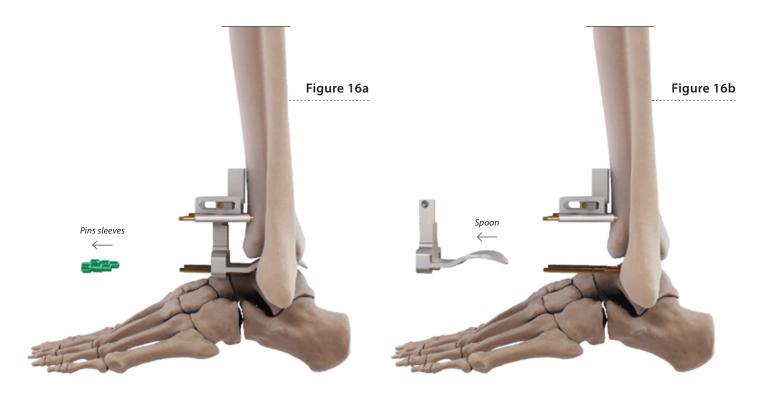
Once the talar dome cut has been properly aligned, lock the position by inserting two pins (60 mm) in the talar neck using the hexagonal PIN-motor screwdriver. **(Figure 15)**

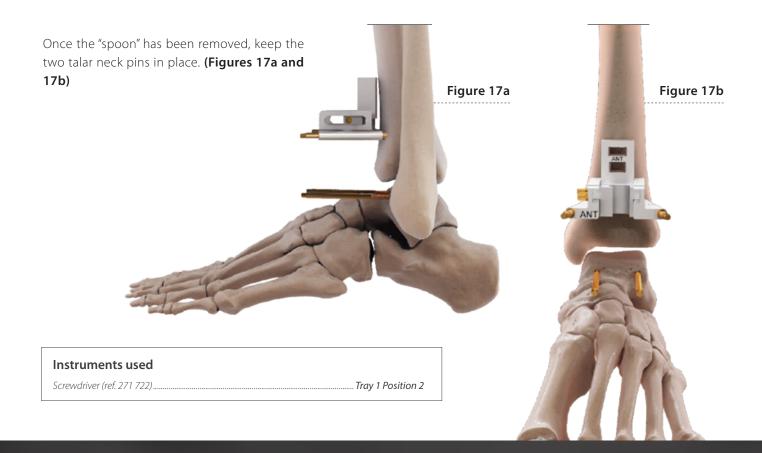




Remove the "spoon"

Once the talar top dome has properly aligned, unlock the two pin sleeves and the two screws (type A and B) using the screwdriver, and remove the "spoon". (Figures 16a and 16b)





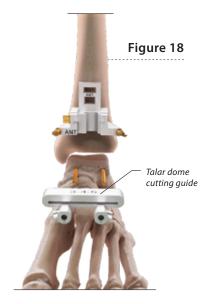
Preparation and performing

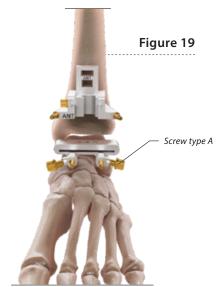
the talar dome cut

To prepare the talar dome cut, plantar flex the foot and select the appropriate talar dome cutting guide, **(Figure 18)**, which is available in sizes, 1-2 and 3-4-5.

Insert the guide into the two talar neck pins (60 mm) and fix it using the M/L screws.

(Figure 19)





Insert a straight oscillating saw blade into the slots provided and perform the talar dome cut. (Figure 20)

The bone thickness of the dome cut is 4 mm, which corresponds exactly to the thickness of the talar dome of the implant. Once the talar dome cut has been made, unlock the two screws (type A) using the screwdriver and remove the talar dome cutting guide, but keep the two talar neck pins in place. (Figure 21)







A set of ribbon retractors may be used to protect the mediolateral malleoli from the sweep of the saw blade. These are NOT provided in the instrumentation.

Instruments used

 Talar dome cutting guide

 Sizes 1, 2 (ref. 271 726)
 Tray 2 (insert) Position 10

 Sizes 3, 4, 5 (ref. 271 727)
 Tray 2 (insert) Position 11

 Screws type A (ref. 271 720)
 Tray 1 Position a

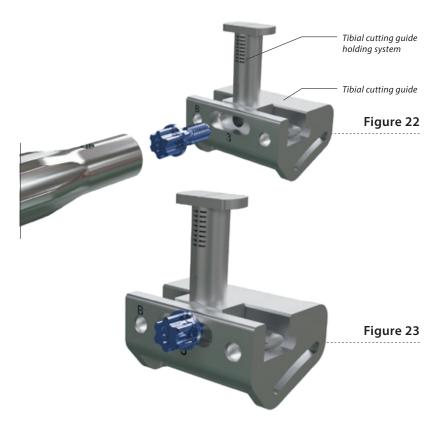
 Screwdriver (ref. 271 722)
 Tray 1 Position 2

Preparation and performing

the tibial curved cut

Choose the correct size of the tibial cutting guide available in 5 sizes. Slide the tibial cutting guide holding system into the tibial cutting guide.

Using the screw (type B) lock it as shown in **Figure 22 and 23.**

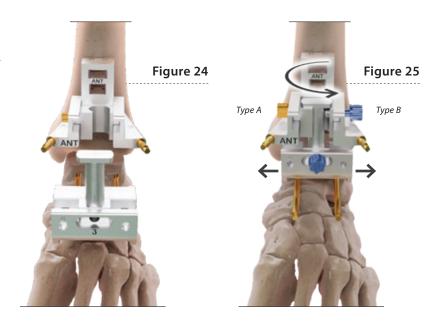


Put the tibial cutting guide holding system into the support for tibial axis-alignment. (Figure 24) Insert a screw type B into the oblong hole of the tibial cutting guide. Stabilize the system with the mediolateral screws type, A and B.

No height adjustment is necessary, as a height of 7 mm from the tibial plafond is already set inside the guide.

If required (according to the case), the height adjustment can be slightly modified using the screw type B.

Verify if the mediolateral position and the rotation of the tibial cutting guide are correct, and if necessary, adjust them using the dedicated screw, as shown below. **(Figure 25)**



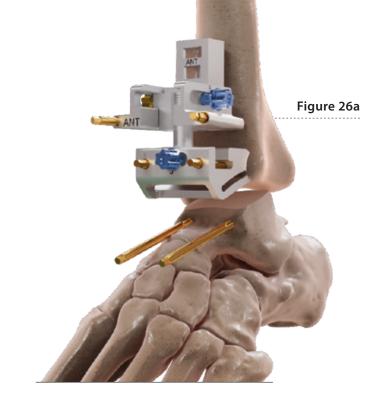
| Instruments used | |
|--|--------------------|
| Tibial cutting guide holding system (ref. 271 719) | Tray 1 Position 20 |
| Tibial cutting quide | |
| Size 1 (ref. 271 712) | Tray 1 Position 7 |
| Size 2 (ref. 271 713) | |
| Size 3 (ref. 271 714) | |
| Size 4 (ref. 271 715) | Tray 1 Position 10 |
| Size 5 (ref. 271 716) | • |
| Screws type B (ref. 271 721) | Tray 1 Position b |
| Screwdriver (ref. 271 722) | |
| Pin L60 (ref. 270 607) | Tray 1 Position e |
| Hexagonal PIN-motor screwdriver (ref. 270 529) | Tray 1 Position 3 |
| | |

In order to protect the mediolateral malleoli from the oscillating saw blade insert the protection pins (60 mm) using the hexagonal PINmotor screwdriver into the two holes located at the mediolateral of the tibial cutting guide.

The two mediolateral protection pins are also used to stabilize the complete cutting system.

To perform the tibial curved cut, use the dedicated oscillating curved saw blade, which is available in most common cutting systems.

Insert the blade into the slot of the cutting guide, add the chosen size of the trial implant, and draw a landmark on the blade to perform the curved cut. (Figure 26a and 26b)



Although the cut is guided and protected, PLEASE TAKE GREAT **CARE WHEN PERFORMING THIS DELICATE CUT. DO IT SLOWLY** AND WITH CAUTION, TAKING YOUR TIME FOR THIS VERY IMPORTANT STEP.

Keep the position of the saw blades stable inside the tibial cutting guide and in constant contact with the upper part of the guide without pushing or forcing to perform the curved cut.

Make sure not to penetrate the posterior capsule avoiding risk to injure the neurovascular bundle.

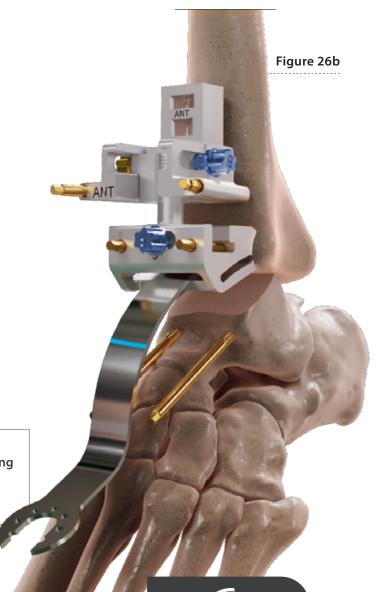
Scan the OR CODE to see the video





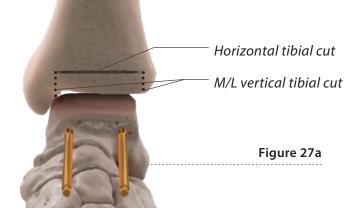
Instruments used: the common blades system are available in extra packaging

| ALL)ref. 270 666 | Curved saw blades (Linvatec |
|------------------|-----------------------------|
| ref. 270 667 | , |
| ref. 270 668 | |



Removing tibial resection cut

Once the horizontal tibial cut has been made, complete the medio-lateral vertical cuts using first a straight Lambotte osteotome or a small appropriate saw blade. (Figure 27a and 27b)





Pay particular attention to the medial malleous, making sure that the medial vertical cut reaches the posterial tibial part.

Once the medial vertical cut is complete, carefully repeat the same procedure for the lateral vertical cut.

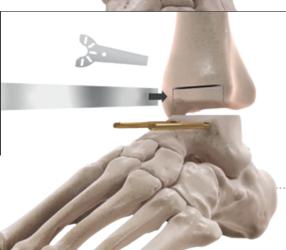


Figure 27b



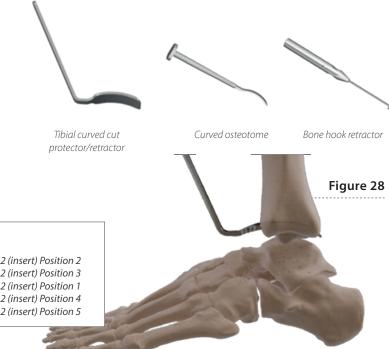
Only once you are sure that the vertical cuts have been completed (distal to proximal and anterior to posterior) will it be possible to use the curved osteotomes / L-curved chisels. (Figure 27c)



To preserve the integrity and quality of the tibial curved cut, use the tibial cut protector/ retractor or the curved osteotome to carefully lift as you very carefully work to release the posterior tibial capsule. (Figure 28)

In addition, inside the tray you will find a bone hook and a retractor.

Please use each of these tools with great care, to avoid damage to the tibial curved cut.



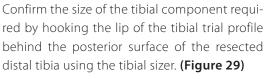
Instruments used

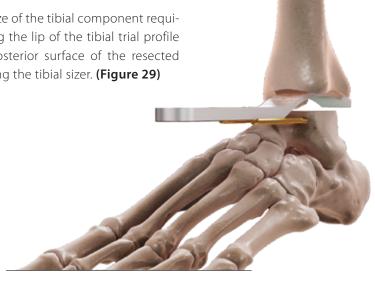
| L-Curved chisel right (ref. 270 574) | Tray 2 (insert) Position 2 |
|--|----------------------------|
| L-Curved chisel left (ref. 270 575) | Tray 2 (insert) Position 3 |
| Curved osteotome (ref. 271 723) | Tray 2 (insert) Position 1 |
| Bone hook retractor (ref. 271 724) | Tray 2 (insert) Position 4 |
| Tibial curved cut protector/retractor (ref. 271 725) | Tray 2 (insert) Position 5 |

Preselection of

the tibial sizes

Figure 29







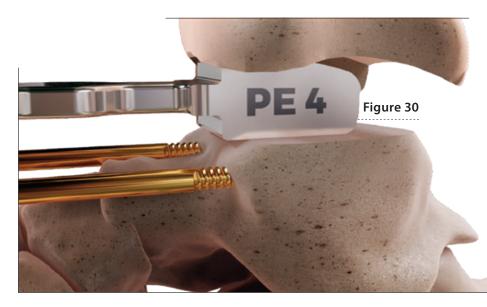
Preselection of

the PE-Inlay sizes

Insert the trial spacer (available in three different thicknesses) between the resected distal tibia and the resected talar dome.

The joint thickness trial spacer indicates the resection space required to implant the thinnest bearing insert. (Figure 30)

Total resection corresponds to bone loss of 12 mm.



Instruments used

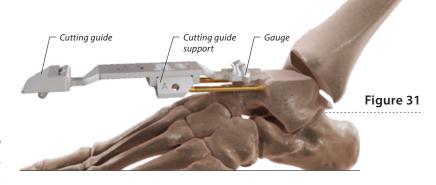
Tibial sizer (ref. 270 601)...Tray 2 (insert) Position 9

Trial insert spacer

4 mm (ref. 270 603). Tray 2 (insert) Position 6 6 mm (ref. 270 604).. ..Tray 2 (insert) Position 7 8 mm (ref. 270 605).. .Tray 2 (insert) Position 8

Preparation and performing the posterior talar cut

Select the appropriate posterior talar cutting guide, (available in five sizes). (Figure 31)
The posterior talar cutting guide is divided into two parts. The posterior part acts as a gauge, the anterior part acts as the actual cutting guide.



Assembly of the posterior talar cutting guide

Take the posterior cutting guide support (available in two sizes: 1-2 and 3-4-5).

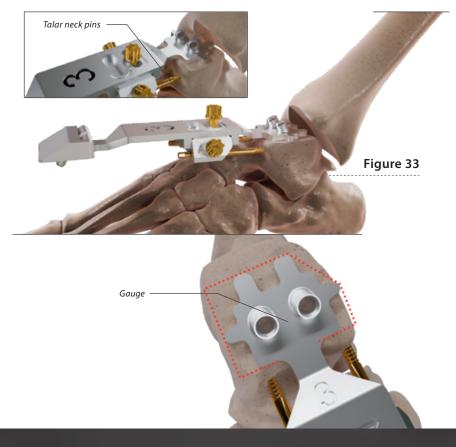
Slide the selected support into the dedicated space located below the posterior cutting guide. Insert the screws type A , without locking as shown. **(Figure 32)**



Determine the posterior cutting guide size and the correct position

Once the posterior talar cutting guide and the support has been assembled, plantar flex the foot and slide the guide onto the two talar neck pins, on the cut surface of the talar dome cut. (Figure 33)

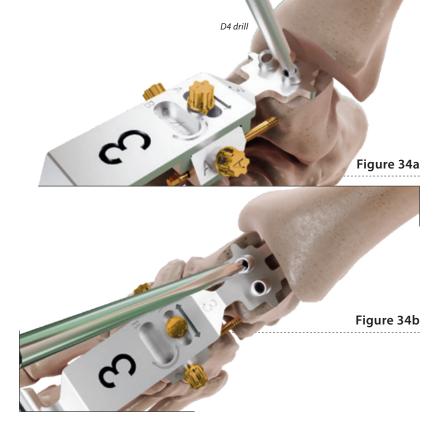
The outer outline of the gauge corresponds to the correct talar size component as soon as it comes up against the outer edge of the talar bone (red line).



Secure the posterior talar cutting guide with the medial, lateral and central screws (type A) and mark the position inside the two holes with the dedicated D4-drill.

Once the two holes have been marked, unlock the medial and lateral screws and remove the posterior cutting guide from the 2 talar neck pins. Also, remove the two talar neck pins.

(Figures 34a and 34b)



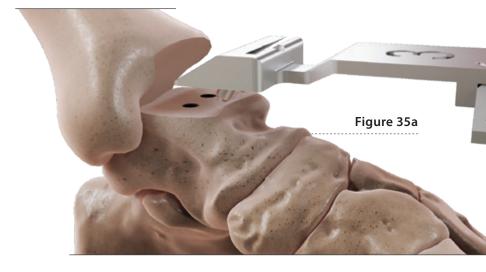
Perform the posterior

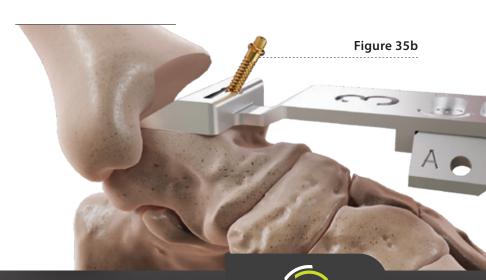
talar cut

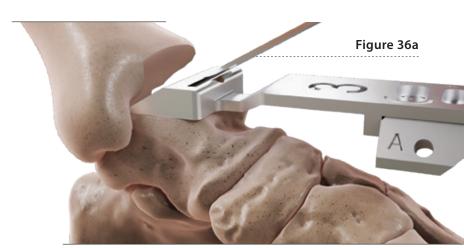
Turn the posterior talar cutting guide 180° and insert the two pegs located on the underside the posterior cutting guide into the two previously-made reference holes.

Fix the guide with one central compression pin L30 mm using the hexagonal PIN-motor screwdriver to stabilize the system.

(Figures 35a and 35b)







Check that the whole system is stable and, using a straight oscillating saw blade, make the posterior talar cut through the posterior cutting guide. (Figures 36a and 36b)



Tray 1 Position f

Pin L30 mm (ref. 271 764)....

Preparation and performing

the anterior talar chamfer

Once the posterior talar cut has been performed, remove the posterior cutting guide. Assembly the anterior talar chamfer guide holding component (available in sizes 1-2 and 3-4-5), with the dedicated handle (ref. 271 722).



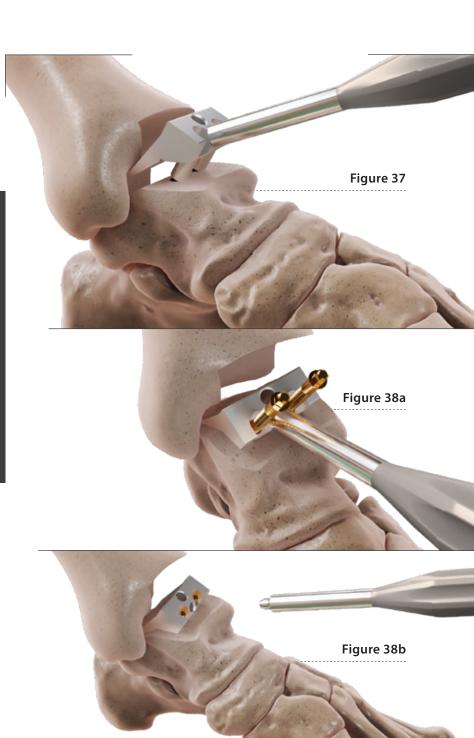
Please NOTE

The universal screwdriver provided (*Screwdriver - ref. 271 722 - Tray 1 Position 2*) has a double function. One part acts as a screwdriver, the other part acts as handle for the anterior talar chamfer guide holding component.

Place the holding component on the talar dome cut and the posterior cut, made previously. Introduce the two pegs located on the underside the holding component into the two previously-made reference holes.

(Figure 37)

Drill two compression pins, through the two pegs using the hexagonal PIN-motor Screwdriver (L30 mm). **(Figures 38a and 38b)**Then remove the Handle.



Instruments used

| Anterior Talar chamfer guide holding component | |
|--|-------------------|
| Size 1 (ref. 271 747) | Tray 2 Position 1 |
| Size 2 (ref. 271 748) | Tray 2 Position 2 |
| Size 3 (ref. 271 749) | Tray 2 Position 3 |
| Size 4 (ref. 271 750) | Tray 2 Position 5 |
| Size 5 (ref. 271 751) | Tray 2 Position 5 |
| Handle for the anterior talar chamfer guide holding component (ref. 271 722) | Tray 1 Position 2 |
| Pin L30 mm (ref. 271 764) | Tray 1 Position f |

Once the anterior chamfer guide holding component has been placed and completely stabilized, place the anterior chamfer guide (available in sizes 1-2 and 3-4-5), onto the holding component and lock with the central screw (type B).

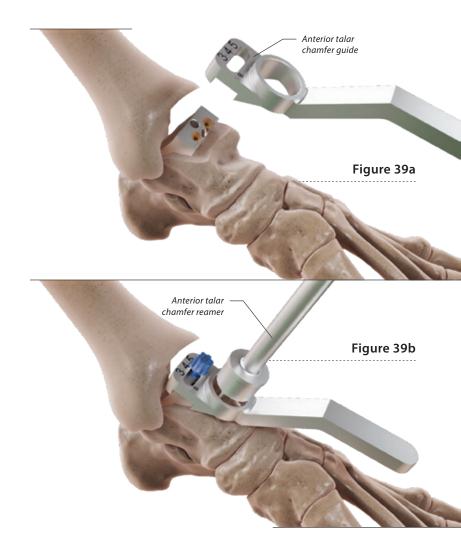
Use the appropriate anterior talar chamfer reamer (available in sizes 1-2 and 3-4-5), and proceed with the anterior chamfer through the hole.

To ensure bone cuts are the right depth, make sure the shoulder of the reamer is flush against the guide for each reaming step.

To perform the finishing cuts for the anterior talar chamfer, unlock the central screw and, by sliding the anterior chamfer guide inside the holding component, place the anterior chamfer guide in the new position.

Use the reamer and perform the cut. Repeat the procedure on both sides. (Figures 39a and 39b)

Check the quality of the chamfer and if necessary repeat the procedure.



| Instruments used | |
|---|-------------------|
| Anterior talar chamfer guide Sizes 1-2 (ref. 271 754) Sizes 3-4-5 (ref. 271 755) | |
| Anterior talar chamfer reamer Sizes 1-2 (ref. 270 564) Sizes 3-4-5 (ref. 270 565) Screw type B (ref. 271 721) | Tray 2 Position 9 |

Preparation and performing the medial/lateral talar cut

Once the anterior talar chamfer has been performed, remove all the blocks and pins.

Place the medial/lateral talar cutting guide, (available in 5 sizes), onto the anterior/posterior and dome cuts.

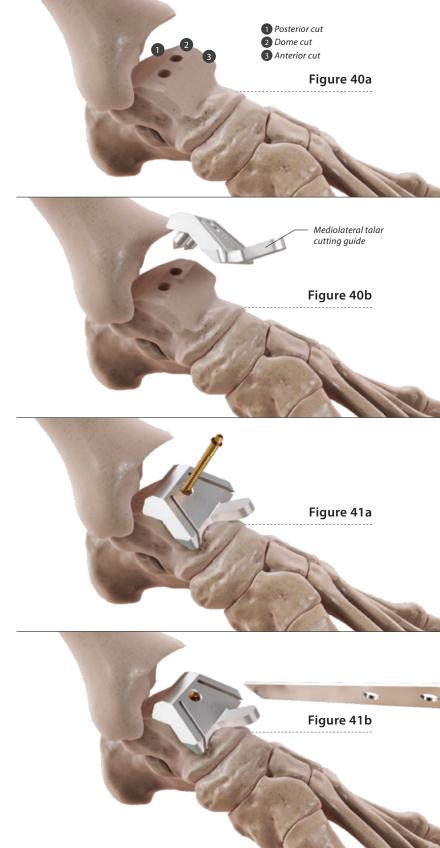
Introduce the two pegs located on the underside of the medial/lateral talar cutting guide into the two -previously made reference holes.

Lock the guide with a central compression pin (L30 mm), using the hexagonal PIN-motor screwdriver. (**Figures 40a and 40b**)



With an oscillating straight saw, make the medial/lateral talar cut through the dedicated slot of the guide.

Once the medial/lateral cut has been performed, remove the pin and the guide. Check the quality of the cuts. (Figure 41a, 41b and 41c)



Instruments used Medial/lateral talar cutting guide

| Medial/lateral talar cutting guide | |
|--------------------------------------|--------------------|
| Size 1 (ref. 271 757) | Tray 2 Position 10 |
| Size 2 (ref. 271 758) | Tray 2 Position 11 |
| Size 3 (ref. 271 759) | |
| Size 4 (ref. 271 760) | Tray 2 Position 13 |
| Size 5 (ref. 271 761) | Tray 2 Position 14 |
| Compression pin 30 mm (ref. 271 764) | Tray 1 Position f |



Easy Move implants sizes

There are 5 sizes of each Easy Move implant.



Tibial implant

5 SIZES same implant for both right and left



PE-Inlay implant

5 SIZES for left

5 SIZES

for right



Talar implant

5 SIZES

for left

5 SIZES

for right

Implants compatibility

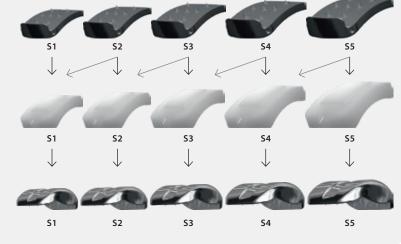
- The **talar implant** must be the same size or smaller than the tibial implant.
- The **PE-Inlay** matches the talar implant and must be the same size.
- The **tibial implant** however can be larger than the talar implant in each sizes as all the PE-Inlay can be connected to each tibial implant.



PE-Inlay implant

left/right Th. 4-6-8 mm

Talar implant left/right



Trial implant

There are 5 sizes of each trial implant (tibia, PE-Inlay and talus) and 3 PE-Inlay thicknesses (4 mm, 6 mm, and 8 mm).

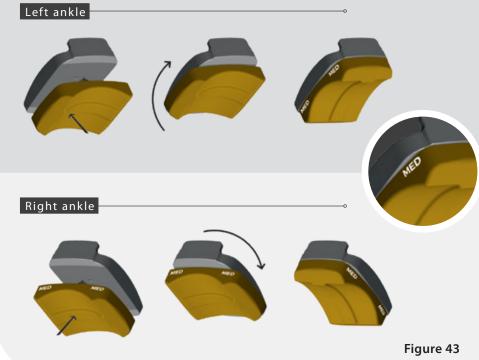
The talar trial implant is placed first. Select the appropriate size and insert it freehand. Once the talar trial implants are in place, ensure that the implant is correctly centered on the cut surface and properly seated in the posterior position. (Figure 42)



Select the appropriate sizes of the tibial and PE-Inlay trial implant . The trial PE-Inlay is clipped to the tibial trial base, forming a monoblock. **(Figure 43)**

Slide the assembled monoblock (trial PE-inlay + trial tibial implant) over the talar implant.

(Figure 44a)



Once the trial implants are in place, a dynamic flexion/extension test should be performed. Check joint kinematics and verify the alignment of the trial implants. Use a cautery and mark the tibial position.

Check that the correct PE-Inlay thickness has been chosen and test ligament tensioning. If necessary, use an x-ray to check that the implants are properly seated and perfectly placed. (Figures 44a and 44b)



Trial components

Talar trial implant Right sizes 1-5Tray 2 Position 23 to 27Talar trial implant Left sizes 1-5Tray 2 Position 18 to 22PE-Inlay trial implant sizes 1-5 (available in 4, 6, 8 mm)Tray 2 Position 28 to 42Tibial trial implant Sizes 1-5Tray 2 Position 43 to 47

Figure 44b

Placing final implants

The contact surfaces between the implant and the bone must be clean and free of any tissue or bone debris that might hinder their positioning.



Please NOTE

Before placing the final talar implant, it is recommended to close the two existing holes on the upper part of the talar dome with bone graft, using a bone impactor. (Figure 45a)

Talar implant

The talar implant is to be placed first, following the same procedure as described for the placement of the trial implant or using the dedicated clamp or mosquito clamp (see the chapter

Tips to know & additional information).

Impact the talar implant using the talar impactor. This may require plantar flexion of the foot. Ensure that the talar implant is correctly centered on the cut surface and properly seated in the posterior position. (Figures 45b and 45c)

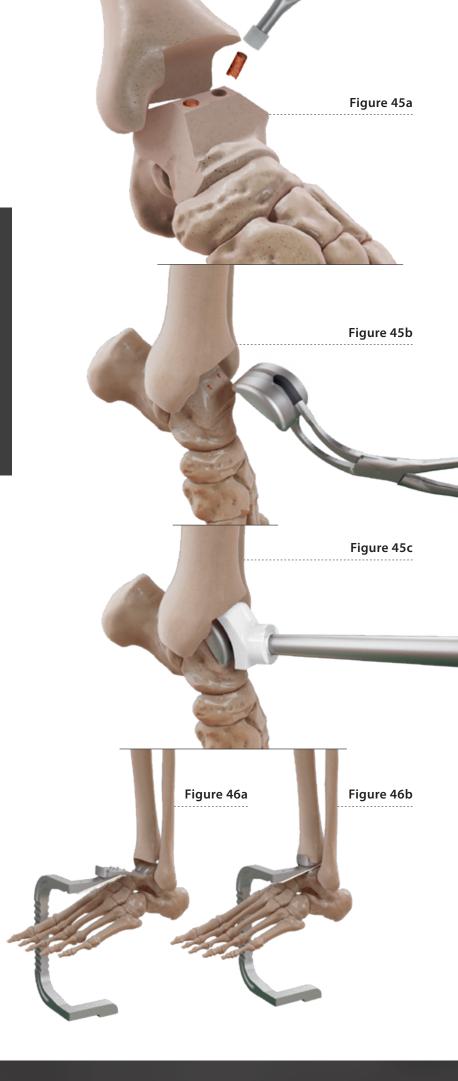
Tibial implant

Insert the tibial implant freehand and make sure that the tibial implant is well aligned with the mark made previously with the cautery.

Apply slight pressure to insert the first part of the tibial spikes into the bone to ensure initial stability.

Use the tibial impactor and impact the tibia very carefully (see the chapter Tips to know & additional information).

Ensure that the tibial implant is seated firmly on the resected distal surface. (Figures 46a and 46b)



PE-Inlay

The PE-Inlay must be snapped into the tibial implant once the latter has been positioned inside the joint.

Slide the PE-Inlay over the talar implant until it stops at the rear part of the tibial clip.

Then, using the impactor, carefully push the PE-Inlay in order to snap the PE-Inlay into the tibial component.

Check visually and manually that the PE-Inlay insert is stable and clipped to the tibial component. **(Figure 47)**



Instruments used

| Talar impactor (ref. 271 779) | Tray 2 Position 16 |
|--|---------------------------------------|
| PE-Inlay impactor (ref. 270 585) | • |
| Tibial impactor (ref. 271 780) | · · · · · · · · · · · · · · · · · · · |
| Talar positionina clamp (ref. 270 738) | Trav 2 (insert) Position 27 |



Post-op treatment

The post-operative treatment described below is only a recommendation.



The final post-OP treatment decision is at the doctor's descretion, according to the specific situation, which varies from patient to patient.

6-Week post-op period: Conservative

0------

2 weeks

of wound healing, NO movements, 30 kg load, in a cast or boot

4 weeks

pain-adapted full load, but NO movement, in a cast or boot

6-Week post-op period: Less conservative

O------

2 weeks of wound healing, NO movements, pain adapted load, in a cast or boots 2 weeks in the boot, pain-adapted full load, but NO movement 2 weeks
in the boot, pain-adapted
full load and progressive
movements

IMPLANTS



| PE-INLAY (UHMWPE) | | |
|-------------------|-----------|------------|
| SIZE | REF. LEFT | REF. RIGHT |
| S1 (4 mm) | 269 797 | 269 832 |
| S1 (6 mm) | 269 799 | 269 834 |
| S1 (8 mm) | 269 801 | 269 836 |
| S2 (4 mm) | 269 802 | 269 837 |
| S2 (6 mm) | 269 804 | 269 839 |
| S2 (8 mm) | 269 806 | 269 841 |
| S3 (4 mm) | 269 807 | 269 842 |
| S3 (6 mm) | 269 809 | 269 844 |
| S3 (8 mm) | 269 811 | 269 846 |
| S4 (4 mm) | 269 812 | 269 847 |
| S4 (6 mm) | 269 814 | 269 849 |
| S4 (8 mm) | 269 816 | 269 851 |
| S5 (4 mm) | 269 817 | 269 852 |
| S5 (6 mm) | 269 819 | 269 854 |
| S5 (8 mm) | 269 821 | 269 856 |



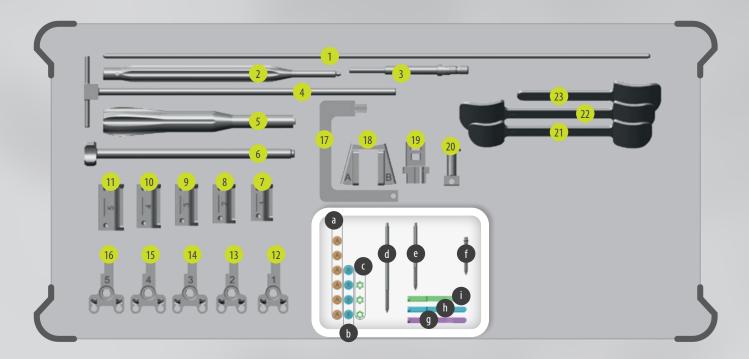
| | TIBIA COMPONENT (Ti6AI4V) |
|----------|---------------------------|
| SIZE | REF. |
| Tibia S1 | 269 776 |
| Tibia S2 | 269 777 |
| Tibia S3 | 269 778 |
| Tibia S4 | 269 779 |
| Tibia S5 | 269 780 |



| TALAR COMPONENT (CrCo) | | |
|------------------------|-----------|------------|
| SIZE | REF. LEFT | REF. RIGHT |
| Talus S1 | 269 783 | 269 790 |
| Talus S2 | 269 784 | 269 791 |
| Talus S3 | 269 785 | 269 792 |
| Talus S4 | 269 786 | 269 793 |
| Talus S5 | 269 787 | 269 794 |

INSTRUMENTATION

Tray 1



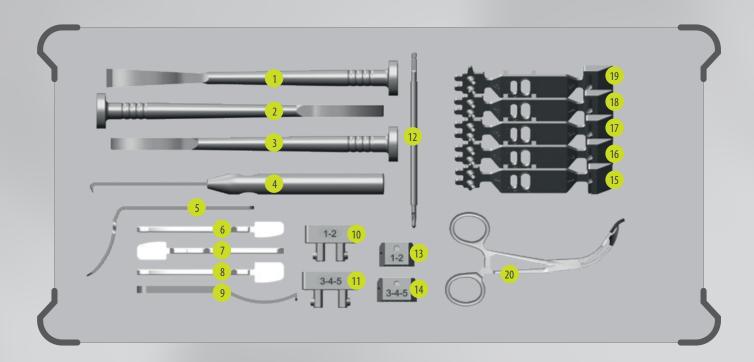
| 1. | Lateral tibial axis alignment rodref. 236 620 |
|-----|---|
| 2. | Screwdriver and handle for the anterior talar chamfer holding componentref. 271 722 |
| 3. | Hexagonal pin motor screwdriverref. 270 529 or GS900-100-000 |
| 4. | Anterior tibial axis alignment rodref. 271 708 |
| 5. | Removable handle ref. 271 703 |
| 6. | Screwable handle axisref. 271 704 |
| 7. | Tibial cutting guide S1ref. 271 712 |
| 8. | Tibial cutting guide S2ref. 271 713 |
| 9. | Tibial cutting guide S3ref. 271 714 |
| 10. | Tibial cutting guide S4ref. 271 715 |
| 11. | Tibial cutting guide S5ref. 271 716 |
| 12. | Ankle intra-articular-alignment system S1ref. 271 696 |

| Ankle intra-articular-alignment system S2 | ref. 271 697 |
|---|---|
| Ankle intra-articular-alignment system S3 | ref. 271 698 |
| Ankle intra-articular-alignment system S4 | ref. 271 699 |
| Ankle intra-articular-alignment system S5 | ref. 271 700 |
| Support for the lateral tibial axis alignment | ref. 271 711 |
| Support for bone fixation | ref. 271 694 |
| Support for tibial axis-alignment rod | ref. 271 695 |
| Tibial cutting guide holding system | ref. 271 719 |
| Intra-articular-tibial gauge S1-S2 | ref. 271 690 |
| Intra-articular-tibial gauge S3-S4 | ref. 271 691 |
| Intra-articular-tibial gauge S5 | ref. 271 692 |
| | Ankle intra-articular-alignment system S2 |

| b. c. | Screw type A (x6) | ref. 271 721 ref. 271 789 |
|----------|-------------------|------------------------------|
| | Pin L80 (x4) | |
| | | |

| f. | Compression pin L30 (x4) | ref. 271 764 or GS901-033-032 |
|----|--|-------------------------------|
| g. | Talar bone defect compensation wedges 1 mm thickne | essref. 271 705 |
| h. | Talar bone defect compensation wedges 2 mm thickne | essref. 271 706 |
| i. | Talar bone defect compensation wedges 3 mm thickne | essref. 271 707 |

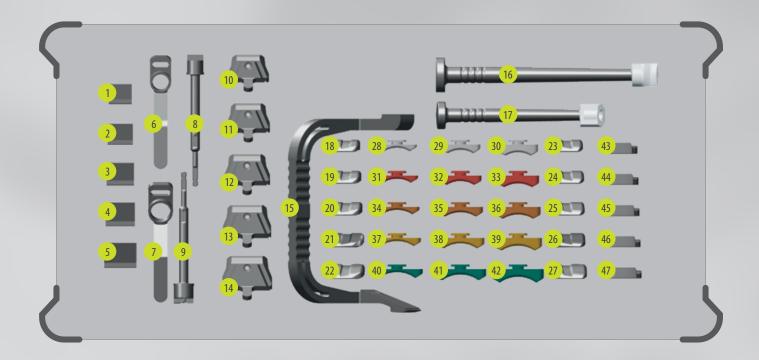
Tray 2 - insert



| 1. | Curved osteotome | ref 271 723 |
|-----|--|--------------|
| 2. | L-curved chisel right V2 | |
| 3. | L-curved chisel left V2 | |
| 4. | Bone hook retractor | ref. 271 724 |
| 5. | Tibial curved cut protection/retractor | ref. 271 725 |
| 6. | Spacer PE-inlay 4 mm | ref. 270 603 |
| 7. | Spacer PE-inlay 6 mm | ref. 270 604 |
| 8. | Spacer PE-inlay 8 mm | ref. 270 605 |
| 9. | Tibia size gauge | ref. 270 601 |
| 10. | Talar dome cutting guide S1-S2 | ref. 271 726 |

| 11. | Talar dome cutting guide S3-S4-S5 | ref. 271 727 |
|-----|--|--------------|
| 12. | Drill D4 | ref. 253 257 |
| 13. | Posterior cutting guide support: fix-adjustment S1-S2 | ref. 271 732 |
| 14. | Posterior cutting guide support: fix-adjustment S3-S4-S5 | ref. 271 733 |
| 15. | Posterior talar cutting guide S1 | ref. 271 739 |
| | Posterior talar cutting guide S2 | |
| 17. | Posterior talar cutting guide S3 | ref. 271 741 |
| 18. | Posterior talar cutting guide S4 | ref. 271 742 |
| 19. | Posterior talar cutting guide S5 | ref. 271 743 |
| 20. | Talar positioning clamp | ref 270 738 |

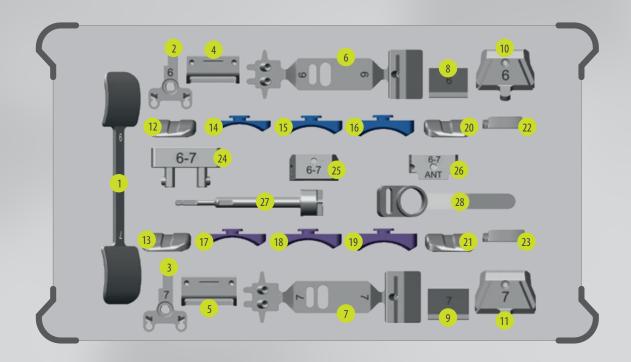
Tray 2



| 1. | Anterior talar chamfer guide holding component \$1 | ref. 271 747 |
|-----|--|--------------|
| 2. | Anterior talar chamfer guide holding component S2 | ref. 271 748 |
| 3. | Anterior talar chamfer guide holding component S3 | ref. 271 749 |
| 4. | Anterior talar chamfer guide holding component S4 | ref. 271 750 |
| 5. | Anterior talar chamfer guide holding component S5 | ref. 271 751 |
| 6. | Anterior talar chamfer guide S1-S2 | ref. 271 754 |
| 7. | Anterior talar chamfer guide S3-S4-S5 | |
| 8. | Anterior talar chamfer reamer S1-S2 | ref. 270 564 |
| 9. | Anterior talar chamfer reamer S3-S4-S5 | ref. 270 565 |
| 10. | M/L talar cutting guide S1 | ref. 271 757 |
| 11. | M/L talar cutting guide S2 | ref. 271 758 |
| 12. | M/L talar cutting guide S3 | ref. 271 759 |
| 13. | M/L talar cutting guide S4 | |
| 14. | M/L talar cutting guide S5 | ref. 271 761 |
| 15. | Tibial impactor | ref. 271 780 |
| 16. | Talar impactor | ref. 271 779 |
| 17. | PE-inlay impactor | ref. 270 585 |
| 18. | Talar trial implant left S1 | ref. 270 608 |
| 19. | Talar trial implant left S2 | ref. 270 609 |
| 20. | Talar trial implant left S3 | ref. 270 610 |
| 21. | Talar trial implant left S4 | ref. 270 611 |
| 22. | Talar trial implant left S5 | ref. 270 612 |
| 23. | Talar trial implant right S1 | ref. 270 615 |
| 24. | Talar trial implant right S2 | ref. 270 616 |
| | | |

| 25. | Talar trial implant right S3 | ref. 270 617 |
|-----|-------------------------------|--------------|
| 26. | Talar trial implant right S4 | ref. 270 618 |
| 27. | Talar trial implant right S5 | ref. 270 619 |
| 28. | PE-inlay trial implant S1 Th4 | ref. 270 629 |
| 29. | PE-inlay trial implant S1 Th6 | ref. 270 631 |
| 30. | PE-inlay trial implant S1 Th8 | ref. 270 633 |
| 31. | PE-inlay trial implant S2 Th4 | ref. 270 634 |
| 32. | PE-inlay trial implant S2 Th6 | ref. 270 636 |
| 33. | PE-inlay trial implant S2 Th8 | ref. 270 638 |
| 34. | PE-inlay trial implant S3 Th4 | ref. 270 639 |
| 35. | PE-inlay trial implant S3 Th6 | ref. 270 641 |
| 36. | PE-inlay trial implant S3 Th8 | ref. 270 643 |
| 37. | PE-inlay trial implant S4 Th4 | |
| 38. | PE-inlay trial implant S4 Th6 | ref. 270 646 |
| 39. | PE-inlay trial implant S4 Th8 | ref. 270 648 |
| 40. | PE-inlay trial implant S5 Th4 | ref. 270 649 |
| 41. | PE-inlay trial implant S5 Th6 | ref. 270 651 |
| 42. | PE-inlay trial implant S5 Th8 | |
| 43. | Tibia trial implant S1 | ref. 270 622 |
| 44. | Tibia trial implant S2 | ref. 270 623 |
| 45. | Tibia trial implant S3 | ref. 270 624 |
| 46. | Tibia trial implant S4 | ref. 270 625 |
| 47. | Tibia trial implant S5 | |
| 47. | · | |

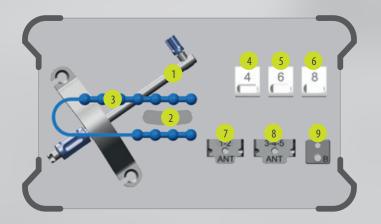
Tray 3 (on request)



| 1. | Intra-articular-tibial gauge S6-S7 | ref. 271 693 |
|-----|--|--------------|
| 2. | Ankle intra-articular-alignment system S6 | ref. 271 701 |
| 3. | Ankle intra-articular-alignment system S7 | ref. 271 702 |
| 4. | Tibial cutting guide S6 | ref. 271 717 |
| 5. | Tibial cutting guide S7 | ref. 271 718 |
| 6. | Posterior talar cutting guide S6 | ref. 271 744 |
| 7. | Posterior talar cutting guide S7 | ref. 271 745 |
| 8. | Anterior talar chamfer guide holding system component S6 | ref. 271 752 |
| 9. | Anterior talar chamfer guide holding system component S7 | ref. 271 753 |
| 10. | M/L talar cutting guide S6 | ref. 271 762 |
| 11. | M/L talar cutting guide S7 | ref. 271 763 |
| 12. | Talar trial implant left S6 | ref. 270 613 |
| 13. | Talar trial implant left S7 | ref. 270 614 |
| 14. | PE-inlay trial implant S6 - 4 mm | ref. 270 654 |

| 15. | PE-inlay trial implant S6 - 6 mm | ref. 270 656 |
|-----|---|--------------|
| 16. | PE-inlay trial implant S6 - 8 mm | ref. 270 658 |
| 17. | PE-inlay trial implant S7 - 4 mm | ref. 270 659 |
| 18. | PE-inlay trial implant S7 - 6 mm | ref. 270 661 |
| 19. | PE-inlay trial implant S7 - 8 mm | ref. 270 663 |
| 20. | Talar trial implant right S6 | ref. 270 620 |
| 21. | Talar trial implant right S7 | ref. 270 621 |
| 22. | Tibia trial implant S6 | ref. 270 627 |
| 23. | Tibial trial implant S7 | ref. 270 628 |
| 24. | Talar dome cutting guide S6-S7 | ref. 271 728 |
| 25. | Posterior cutting guide support: fix adjustment S6-S7 | ref. 271 734 |
| 26. | Support for posterior cutting guide rotation adjustment S6-S7 | ref. 271 737 |
| 27. | Anterior talar chamfer reamer S6-S7 | ref. 270 566 |
| 28. | Anterior talar chamfer guide S6-S7 | ref. 271 756 |

Special instrumentation (on request)



| 1. | Rod extension for anterior tibial axis alignment | ref. 271 709 |
|----|--|--------------|
| 2. | Pin fixation guide for anterior tibial axis alignment system | ref. 271 710 |
| 3. | Malleolus strap | ref. 236 646 |
| 4. | PE-inlay spacer for rotation adjustment: 4 mm | ref. 271 729 |
| 5. | PE-inlay spacer for rotation adjustment: 6 mm | ref. 271 730 |
| 6. | PE-inlay spacer for rotation adjustment: 8 mm | ref. 271 731 |
| 7. | Support for posterior cutting guide rotation adjustment S1-S2 | ref. 271 735 |
| 8. | Support for posterior cutting guide rotation adjustment S3-S4-S5 | ref. 271 736 |
| 9 | Component for posterior cutting quide rotation adjustment | ref 271 738 |

Blades

STERILE (STRAIGHT)



Synthes blade (L. 90 x W. 13 x Th. 1,27 max)....ref. 271 653



Stryker System 6 narrow blade blade (L. 90 x W. 13 x Th. 1,27 max).... ref. 269 715

NON-STERILE (CURVED)



Linvatec Hall stainless steel curved bladeref. 270 666



Synthes stainless steel curved blade.....ref. 270 667



Stryker stainless steel curved bladeref. 270 668

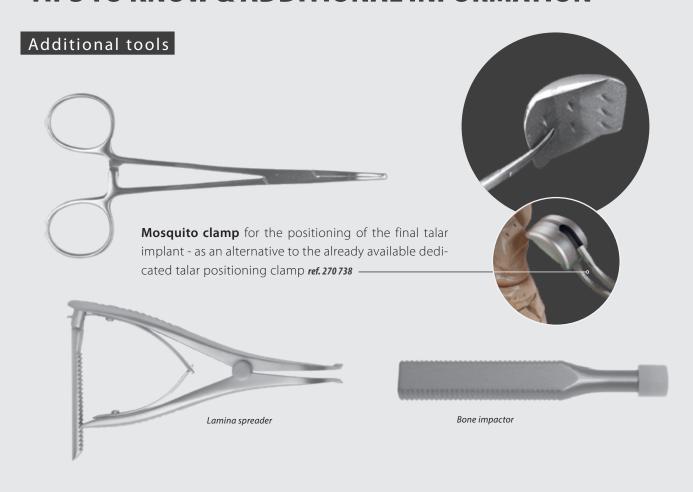
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Radiological templates

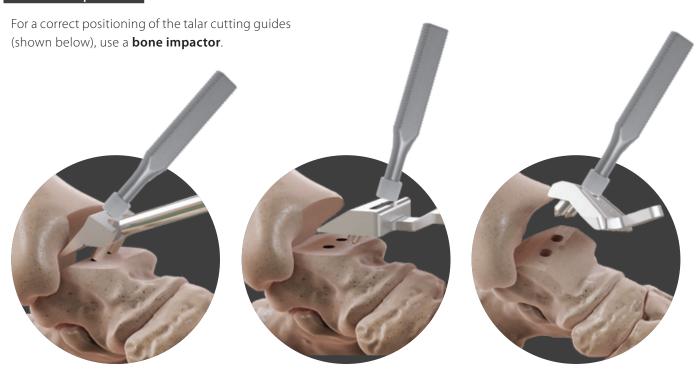
Radiological templates in scale 1/1 are available in sizes 1 to 5 (inlay thickness 4, 6 and 8 mm): ref. 271 146



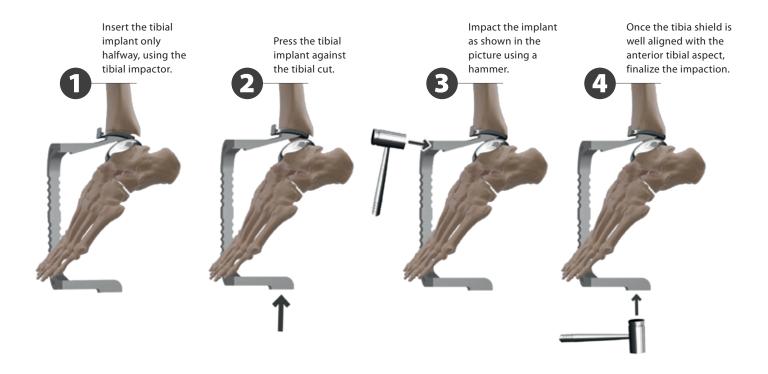
TIPS TO KNOW & ADDITIONAL INFORMATION



Bone impactor



Placing the tibial final implant



| NOTES | | |
|-------|--|--|
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SPECIAL INSTRUMENTATION

Rod extension for the anterior

tibial axis alignment

In case of severe tibial deformity, a rod extension for the tibial axis alignment is available in the instruments tray.

The system can be stabilized by introducing a pin into the Tuberositas Tibiae using the dedicated pins fixation guide.

If it is not necessary to secure the system with a pin, use the supplied melleolus strap. (**Figure 48**)

Additional instruments used for rod extension of the anterior tibial axis alignment



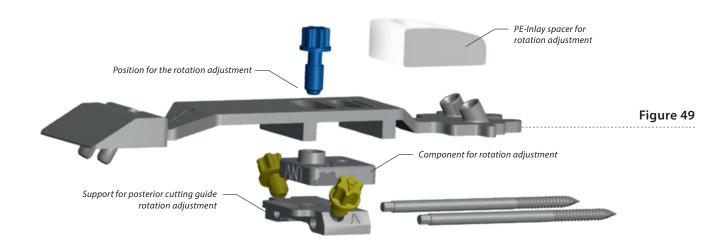
Figure 48

Posterior talar cutting guide rotation adjustment

Before performing the posterior talar cut, check the axis alignment between the tibial cut and the anatomic talar position. In case of evident mal-alignment between both, it will be possible to correct the rotation of the posterior talar cutting guide using a dedicated instrument (component for the posterior cutting guide rotation adjustment).

Assemble the posterior cutting guide using the follow special instruments, as shown in Figure 49.

- Support for posterior cutting guide rotation adjustment (available in sizes 1-2 and in sizes 3-4-5)
- Component for posterior cutting guide rotation adjustment
- PE-Inlay Spacer for posterior cutting guide rotation adjustment (available in 4-6-8 mm)



Once the posterior talar cutting guide (in the rotation adjustment version) has been assembled, lock the system with the screw (type B), using the dedicated screwdriver.

Plantar flex the foot, and slide the **support** onto the two talar neck pins on the cut surface of the talar dome cut.

Adjust the anteroposterior and mediolateral position of the posterior cutting guide gauge, and lock the system with the medial/lateral screws (type A).

Put the **PE-Inlay spacer** on the gauge and then insert it into the ankle joint.

Put the foot in a 90° neutral position.

Check the rotation between the tibial curved cut and the talar anatomic position.

In case of mal-alignment, unlock the screw (Type B), adjust the guide to the correct rotation position and lock the screw again.

Once all adjustments have been made, proceed with the "posterior talar cut" as explained in the dedicated chapter.

| Additional instruments used for the posterior talar cutting guide | | | | |
|---|---|--|--|--|
| Support for posterior cutting guide rotation adjustment | | | | |
| Sizes 1-2 (ref. 271 735) | • | | | |
| Sizes 3-4-5 (ref. 271 736) | Special instrumentation Position 8 | | | |
| Component for posterior cutting guide | | | | |
| rotation adjustment (ref. 271 738) | Special instrumentation Position 9 | | | |
| Posterior cutting guide PE-Inlay spacer for rotation adjustme 4 mm (ref. 271 729) | Special instrumentation Position 4 Special instrumentation Position 5 Special instrumentation Position 6 Tray 1 Position a | | | |





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