Salto Talaris™

Total Ankle Prosthesis





SALTO TALARIS

SALTO TALARIS INSTRUMENTATION II TORNIER ()

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1. DESIGN RATIONALE

The Salto Talaris[™] Total Ankle Prosthesis is a precision fixed-bearing design founded on the Salto mobile-bearing ankle prosthesis, which has been in use since 1997 and at 6.4 year mean follow-up (5-8.5) has a 93% survivorship. ¹

Improvement in the precision of the instrumentation to achieve accurate and reproducible tibiotalar alignment enables the simplification of the implant system to a fixed-bearing design. A key principle is that the mobile-bearing concept has been moved from the implant to the instrumentation at the stage of the trial reduction. First, a measured resection with equal implant replacement is applied to the talus and distal tibia. Then, the trial tibial base, featuring a highly polished surface that remains mobile against the resected distal tibia, is allowed to rotate into proper position during ankle Range Of Motion (ROM) through a securely fixed, highly conforming articulating insert. Only after this intrinsic tibiotalar alignment is achieved are the bone cuts for the tibial keel and plug completed, fixing the tibial base and insert assembly into the optimized position.

The anatomic design of the talar component reproduces normal ankle kinematics without over - stressing the deltoid ligaments. The means of fixation for the tibial base and talar implant has not been altered from the Salto mobile-bearing design.

The key design principles of the Salto Total Ankle Prosthesis, that has provided excellent clinical results, were retained in the Salto Talaris[™] Total Ankle Prosthesis. The accuracy and reproducibility of the instrumentation has evolved to allow a precision fixed-bearing implant design that represents the philosophy "Less is Sometimes More".

The Salto Talaris Surgical Technique has been reviewed in conjunction with : Mark Casillas, MD (Foot and Ankle Center of South Texas) Brian Donley, MD (Cleveland Clinic Health Systems) Sheldon Lin, MD (New Jersey Medical School)

1. Bonnin M, Judet T, Piriou P, et al. Total ankle prosthesis: five to eight year results. Presented at the American Orthopaedic Foot and Ankle Society 22nd Annual Summer Meeting. July 14-16, 2006. La Jolla, CA.

2. SPECIFIC INDICATIONS FOR ANKLE REPLACEMENT SURGERY

INDICATIONS

The Salto Talaris[™] Total Ankle Prosthesis is indicated as a total ankle replacement in primary or revision surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

All components are intended for cemented use only.

CONTRAINDICATIONS

The Salto Talaris[™] Total Ankle Prosthesis is contraindicated for the following conditions: Sepsis, infection sequelae, systemic infection, elevated WBC count, fever and/or local inflammation, Complete talar necrosis or insufficient quality of bone stock, Persisting skin lesion or poor skin coverage around the ankle joint that would make the procedure unjustifiable, Important ligament laxity, Severe osteoporosis, Ankle arthrodesis with malleolar exeresis, Neuromuscular or mental disorders which might jeopardize fixation and post-operative care, Neurobiologic diseases, Nonfunctional lower limb muscle, Complete loss of ankle collateral ligament, Charcot's 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, Pregnancy.

WARNINGS AND PRECAUTIONS

The following conditions tend to adversely affect ankle replacement implants: Obesity or excessive patient weight, Manual labor, Active sports participation and/or high activity level, Likelihood of falls, Alcohol and/or drug addiction, Other disabilities, as appropriate, Poor bone stock, Metabolic disorders or systemic pharmacological treatments leading to progressive deterioration of solid bone support for the implant (e.g. diabetes, steroid usage, immunosuppressive treatments), Compromise of the ligaments or other supporting soft tissue structures such that they cannot withstand expected loads following arthroplasty, due to, for example, rheumatoid arthritis or other diseases affecting the quality of the soft tissue, Severe deformities of the joint, Tumors of the supporting bone structures, Sensitivity, allergy or other reactions to implant materials (i.e. polyethylene, bone cement or metal), Elevated sedimentation rate unexplained by rheumatoid arthritis.

ADVERSE EVENTS

The following are the most frequent adverse events after ankle arthroplasty: Dislocation, Infection, Poor wound healing, Loosening of components, Instability, Bone fracture, Secondary necrosis of the talus, Neuropathies, Disassembly or breakage of components, Possible metal sensitivity, Other diseases affecting the quality of the soft tissue, Severe deformities of the joint, T umors of the supporting bone structures, Sensitivity, Allergy or Other reactions to implant materials, (i.e. polyethylene, bone cement or metal).

3. INSTRUMENTATION CONCEPT

The instrumentation is designed to achieve accurate and reproducible tibiotalar alignment while adapting to various anatomical conditions, depending on the lesions encountered in the ankle or a particular morphotype. The broad steps of this operative technique can be summarized as follows.

• 1. Patient positioning

The patient is placed in a supine position with a bump under ipsilateral hip to reduce external rotation of the extremity. The heel is placed near the end of the table. A bump under the calf should be used throughout the surgery to keep the heel off the table.

• 2. Initial tibial preparation

The tibial cutting line is first determined using a resection guide to align the cut on the tibia and take into account the geometry and orientation of the tibiotalar joint.

-• 3. Talar preparation

The talar cuts are then refined to approach the resurfacing step in relation to the initial tibial cut.

• 4. Final adjustments in the tibial implant position

The mobile-bearing concept has been moved from the implant to the instrumentation at the stage of the trial reduction.

The trial tibial base, featuring a highly polished surface that remains mobile against the resected distal tibia, is allowed to rotate into the proper position, thus self-aligning the prosthesis. After this optimal tibiotalar alignment is achieved, the preparation for the tibial keel and plug are completed.

The Salto Talaris[™] instrumentation ensures proper positioning of the tibial implant in relation to the talar implant for a successful arthroplasty.

4. PREOPERATIVE PLANNING

The preoperative planning for the Salto Talaris[™] Total Ankle Prosthesis is carried out using three standard weightbearing radiological views: Anterior view;

Anterior view with 30° internal rotation to expose the tibial-fibular joint space; Straight lateral.

Examination of the healthy side should be used for comparison.

Complementary imaging may be requested to:

• Confirm or reject the indication (CT scan examination for talar necrosis, a relative contraindication for prosthetic replacement);

• Discuss the need for an associated procedure (i.e. presence of subtalar osteoarthritis);

Special consideration should be given to two types of pre-existing conditions.

• Malunions responsible for malalignment of the tibia or imbalance of the malleoli, which may require an initial correction.

• Major ligamentous instabilities demonstrated by an examination under stress will require specific intervention (release of the retracted side or possible need for an associated ligamentoplasty on the lengthened side).

• 1. Key planning elements determined from the anterior view:

Choice of an implant size that does not impinge with the lateral malleolus;

• Determination of the ideal joint line level accommodating for articular wear. Comparative images are often necessary to assess the prosthetic joint space, which should be located at the theoretical anatomic joint space. The thickness of the tibial resection depends on this determination.

• 2. Key planning elements determined from the lateral view:

Confirmation of the implant size selected from the anterior view;

• Evaluation of the anterior osteophytic margin and assessment of the proposed bone resection required to expose the roof of the pilon;

· Evaluation of talar dome morphology, particularly its degree of convexity;

• Evaluation of talar positioning, which can be centered or retroplaced beneath the pilon. The relative positioning of the tibial and talar components should take into account a possible off-centered location with the understanding that the prosthesis adapts to this position and does not correct it. In extreme cases, a pronounced anterior or posterior talar subluxation may preclude implantation of a prosthesis.

• 3. Complementary imaging may be required:

To determine the need for an associated procedure:

- CT scan to evaluate adequacy of bone stock and the possible presence of contiguous joint arthritis.
- MRI to evaluate the extent of avascular necrosis (A VN).

Special consideration should be given to two types of situations:

- Malunions that produce malalignment of the ankle.
- Ligamentous instabilities.

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INSTRUMENTATION II

5. COMPATIBILITY RULES WHEN CHOOSING IMPLANT SIZE

• 1. General rules

- The Tibial component size is always the same or one size bigger than the T alar component size.

- The polyethylene insert (PE) matches the Talar component size except for the size 0 Talar component which has to be associated with the size 0 Tibial insert or size 00 Tibial insert.

• 2. Additional information

- The tibial implant comes in 4 symmetrical sizes that can all be implanted on either the right or the left ankle.

- The PE insert is clipped onto the tibial base to form a single-block component. The insert thicknesses are named for the tibial base thickness. The inserts therefore come in 4 thicknesses, from 8 to 11 mm (includes thickness of the metallic tibial base + thickness of PE). Unlike the tibial implant, the PE inserts are specific for each side, right and left.

- When the patient's anatomy requires using a size 0 tibial implant, a size 00 insert must be associated with it (available for each side, right and left), whose width and clipping system are compatible with the size 0 tibial implant, and whose curvature corresponds to that of the size 0 talar implant.

- However, when the patient's anatomy presents a tibia requiring size 1, but requires use of a size 0 talar component, the intermediary insert must be size 0, whose width and clipping system are compatible with the size 1 tibial implant, and whose curvature corresponds to that of the size 0 talar implant.



COMPATIBILITY CHART FOR SALTO TALARIS[™] TOTAL ANKLE PROSTHESIS

1. Surgical approach

An extensile approach to the ankle is made between the anterior tibial and extensor hallucis longus tendons (Fig. 1). The incision is followed by careful subcutaneous dissection. The superficial peroneal nerve is identified and retracted. The extensor retinaculum is divided between the anterior tibial and extensor hallucis longus tendons. Retraction of the tendons exposes the anterior aspect of the distal tibia, ankle joint, and talonavicular joint. The deep neurovascular structures are identified, mobilized, and protected. This allows for an anterior release and broad arthrolysis with resection of all the osteophytes. The top of the dome as well as the angles between the pilon and each of the malleoli can be identified precisely using this incision.

• 2. Exostectomy of the distal tibia

The distal anterior aspect of the tibia and osteophytes are removed with the osteotome (provided in the instrumentation), exposing the tibial pilon and providing a precise view of the talar dome (Fig. 2).

Resect until the end of the osteotome reaches the tibial pilon roof. The osteotome placed into the joint space determines the reference position for placement of the tibial guide (see next step).



Instruments used for this step

Osteotome - Ref : MJU357





(fig. 01) Anterior approach



(fig. 02)

• 3. Positioning the tibial alignment guide

Verify that all adjustments on the alignment guide are set to the 0 and neutral position:

- Rotation and medial/lateral (M/L) displacement in neutral position (Fig. 3 and 4).

- Resection level set to 0.

All other screws are loosened.

The guide should be aligned parallel to the tibia's mechanical axis; this is a determining factor in all the resections performed during the procedure (Fig. 4).

Through the neutral hole position, place a 110-mm self-drilling pin perpendicular to the anterior tibial tubercle (Fig. 5), with the alignment guide parallel to the tibia's mechanical axis.

Do not rest the tibial alignment guide on the skin of the anterior tibia tubercle to prevent potential skin irritation.



(fig. 04)

(fig. 03) a: height adjustment b: mediolateral adjustment c: rotation adjustment

Instruments used for this step

- Tibial guide - Ref : MJU333



- 110-mm self-drilling pin included in - Ref : LJU095





(fig. 05)

Align the tibial alignment guide with the tibial shaft. The tibial alignment guide should rest flush with the distal tibia with just enough clearance to translate the guide proximally for adjusting the resection level. If necessary, position the osteotome in the joint space, so that it will be parallel with the distal plane of the tibial guide (Fig. 6). Then position the most distal part of the guide on the osteotome. Translation movement is possible as soon as the central knob of the tibial alignment guide is loosened. Tighten the central knob using a screwdriver and remove the osteotome.

Insert a second 110-mm self-drilling pin distally through the guide's medial hole, positioning the alignment guide's axis in the center of the inferior metaphysis (Fig. 7).



(fig. 06)

The other 75- and 45-mm pins provided in the instrumentation are not self-drilling. In the following steps, preparatory drilling with a Ø 3 mm drill bit is mandatory before pins can be inserted.

Instruments used for this step

- Screwdriver - Ref : MLN113



- 110-mm self-drilling pin included in - Ref : LJU095



(fig. 07)

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• 4. Adjusting the alignment guide

Frontal plane: The axis of the tibial resection guide should be made parallel to the tibia's mechanical axis by choosing the proper hole of the proximal pin guide (Fig. 8).

Sagittal plane: With both flanges in contact with the tibia, the resection guide is adjusted parallel to the anterior tibial crest (Fig. 9).

At this stage, a genu varum or a genu valgum deformation can be corrected by moving the proximal guide medially or laterally over the pin, making it possible to implant the prosthesis strictly parallel to the tibial axis to compensate for an axis defect, to give greater importance to the horizontality of the tibiotalar joint space. The timing and degree of this compensation should be discussed for each case (possibility of secondary knee surgery, subtalar joint stiffening in a position that compensates the axis).

Once the guide is positioned in the frontal and sagittal planes, the set-up is finalized by tightening the screw of the superior guide and the screw of the medial knob.



(fig. 08)

(fig. 09)

5. Final adjustment of cutting height, rotation, and lateral position

Height adjustment:

The cutting level determined during preoperative planning is transferred to the distal resection guide by translating it (Fig.10).

Warning: When determining the cutting level during surgery, any significant wear or loss of substance on the tibia must be taken into account.

From the initial reference position adjust the tibial alignment guide 9mm proximally. This number corresponds to the combined thickness of the PE insert and the tibial base. This allows for a tibial insert of one size smaller to be used if necessary without making additional resections. Firmly tighten screw a.



(fig. 10) a: height adjustment b: mediolateral adjustment c: rotation adjustment

Rotational and mediolateral positioning:

The tibial alignment jig used for mediolateral and rotational adjustment of the implant is attached to the tibial alignment guide. Adjustments are made as follows:

- Rotational adjustment: Insert a 75-mm pin in each of the medial and lateral gutters. A 110-mm pin slipped into the guide's articulated arm simulates the axis of the tibial implant and therefore should be positioned along the bisector axis of the medial and lateral gutter pins.

Once the rotational position has been adjusted, the guide's rotational adjustment knob (screw c) is firmly tightened with a screwdriver.

- Mediolateral adjustment: The tibial implant size planned preoperatively is confirmed through a series of lateral and medial holes on the guide (Fig. 11).

The different implant sizes available (0, 1, 2, and 3) are on the guide; hence the size is confirmed by inserting two 75mm pins in the medial and lateral holes and selecting the largest possible size that does not compromise the bone integrity of the malleoli. Once the mediolateral position has been adjusted, the guide's mediolateral adjustment knob (screw b) is firmly tightened with a screwdriver.

Precaution for use of the guide: Since this guide is not a cutting guide, do not drill through the holes. The pins inserted in the holes are used only to verify that the tibial plate is properly positioned. They are inserted in the holes but not drilled in.

(fig. 11)

The guide should be aligned on the bisecting line of the angle formed by the lateral and medial gutters.



Instruments used for this step

- Tibial alignment jig - Ref : MJU334



- 75-mm pin and 110-mm self-drilling pin included in - Ref : LJU095

• 6. Preselection of talar implant size

Before proceeding to resecting the tibia and to match the tibial and talar sizes, the size of the talar implant selected preoperatively can be confirmed.

Two gauges are included in the instrumentation for the talar implants.

The talar gauge (0, 1, 2, or 3) selected during preoperative planning is placed on the top of the talar dome (Fig. 12). It should have the same width as the talar dome width.

As shown in the implant compatibility table (see p. 5), a talar implant that is one size smaller than the tibial implant can be used.

Instruments used for this step

- Talar gauge, size 0/1 Ref : MJU331
- Talar gauge, size 2/3 Ref : MJU364



7. Placing the cutting guide

Depending on the size chosen at the preoperative planning stage and in accordance with the size determined from the tibial alignment jig, tibial resection guide no. 0, 1, 2, or 3 is chosen. This unit is attached to the alignment guide by firmly tightening the knob (Fig. 13).

Precautions before use: Once all the adjustments have been made and before using the oscillating saw, make

sure that the guide is sitting on the anterior tibia and all the knobs have been firmly tightened properly with the screwdriver provided in the instrumentation.

Instruments used for this step

- Tibial resection guide: Ref : MJU370 - size 0 Ref : MJU371 - size 1 Ref : MJU372 - size 2 Ref : MJU373 - size 3





(fig. 12)



(fig. 13)

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8. Preparation for drilling medial and lateral sides of tibia

Using a drill bit (Ø 3 mm), drill through the two proximal holes. Two 75-mm pins are inserted into these proximal holes to protect the malleoli from the sweep of the saw blade during the horizontal cut (Fig. 14). An optional anterior fluoroscopy image is taken to confirm the correct sizing and alignment, and a lateral image is taken to confirm the pin placement.

Drilling the other distal holes bicortically prepares the vertical cuts. It is common for the distal hole of the tibial resection guide to miss drilling any bone.

• 9. Tibial cut

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The horizontal tibial resection is performed with the narrow saw blade (Fig. 15), extending carefully to the back, as far as the posterior cortex.

The resection block is then withdrawn to allow completion of the vertical resections with an osteotome, and the pins are extracted with the pin puller included in the instrumentation. Once the cuts have been made, the distal bone must be resected, or at least its anterior part, which is easily accessible.

The remaining posterior resection is easily completed after the talar resection. At this stage, the goal is to be able to straighten the foot to a right angle below the tibia.

Instruments used for this step

- Saw blades (Ref : see table p. 32)



- Drill bit Ø 3 mm included in - Ref : LJU095



- Pin puller - Ref : MJU359



- 75-mm pin included in - Ref : LJU095



(fig. 14)



(fig. 15)

• 10. Preparing the posterior talar cut

The posterior cut of the talus depends on the tibial cut performed earlier. The talar pin setting guide is positioned on the tibial alignment guide.

Drilling is performed while maintaining the foot at 90° , with no rotation, varus, or valgus. A hole will be chosen that allows drilling with the drill bit (Ø 3 mm) at the base of the talar neck (Fig.16).

Once drilling has been performed, the talar pin setting guide is withdrawn, a 75-mm cutting guide pin is inserted in the hole (Fig.17).

Instruments used for this step

- Talar pin setting guide - Ref : MJU335



- Drill bit Ø 3 mm included in - Ref : LJU095

- 75-mm pin included in - Ref : LJU095

11. Setting the talar resection guide and the talar pins

Two posterior talar dome resection guides are provided, one for size 1, 2, or 3 talar implants and the other for size 0. To take into account any symmetrical or asymmetrical wear of the talar dome, one or two height-compensating augments can be assembled on the guide selected.

Six augments are provided for 1-, 2-, or 3-mm height compensations.



(fig. 16)



(fig. 17)

The posterior talar dome resection guide with no heightcompensating augments should be used when there is no talar dome wear.

The posterior talar dome resection guide is placed onto the talar pin that has been attached on the neck; then its two paddles, with or without height compensating augments, are placed on the two edges of the talar dome.

The front knob stabilizes the resection guide position. (Comment: Before tightening the front knob, the guide can also be stabilized using two joint distractors, each leveraged on the paddles on one side and the tibial cut on the other side. In this case, care should be taken to position the leverage point of these forceps at the upper edges of the talar dome, to prevent the resection guide from tipping.)

Then four 75-mm pins are inserted through the guide, drilling with the drill bit, followed by placement of the pins. It is recommended to place the most medial and lateral pins first followed by the middle pins to ensure a flat talar dome resection.

The upper part of these pins defines where the talar resection will be made (Fig. 18).

At this stage, one can verify that the pins are properly positioned using a fluoroscopy in a sagittal view: the pins must exit posteriorly at the inferior part of the joint surface.

Instruments used for this step

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- Posterior talar resection guide, size 1/2/3 Ref : MJU376
- Posterior talar resection guide, size 0 Ref : MJU375
- Augments Thickness 1 mm - Ref : MJU381 Thickness 2 mm - Ref : MJU382 Thickness 3 mm - Ref : MJU383



- Joint Distractors - Ref : MJU345, MJU346





(fig. 18)

• 12. Talar resection on pins

With the guide removed, the posterior talar cut is made with the wide oscillating saw (Fig. 19). To protect the malleoli from the sweep of the saw blade, a set of ribbon retractors are provided in the instrumentation.

To follow the planned resection accurately, the saw should cut flush on the surface of the pins. The pins are then removed.

At this stage, after the talar dome is resected, the posterior portion of the distal tibial resection and the posterior arthrolysis can be completed. Any remnant of bone laterally on the distal tibia should be removed with rongeurs.



(fig. 19)

Instruments used for this step

- Ribbon retractors - Ref : MJU086



13. Anterior talar chamfer

The anterior chamfer determines the anteroposterior positioning of the talar implant beneath the tibial implant. After removal of the osteophytes from the talar neck, the anterior chamfer guide is placed on the posterior talar dome resection, with the inferior roughened surface flush with the talar dome resection (Fig. 20).

Before reaming, the guide is positioned in two steps: The talar position spacer is inserted in the oblong window (Fig. 21). The foot is maintained at 90° in the neutral position. The anterior cortex of the tibia should be tangent to the calibration line on the spacer (Fig. 22). If the guide is too far anterior, the talar neck must be exposed using the rongeur until the guide is optimally positioned (check the positioning described above).

- To avoid any rotational error, align the sides of the instrument with the third metatarsal.

- Ante- or retropositioning of the talar implant would result in poor alignment of the tibial implant, a potential source of premature deterioration.



(fig. 20)



(fig. 21)



(fig. 22) Foot at 90°

Instruments used for this step

- Anterior talar chamfer guide - Ref : MJU336



- Talar position spacer - Ref : MJU337



- Holding clamp - Ref : MJU048



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The anterior chamfer guide is then attached using 45-mm pins, with the pins impacted using a specific pin pusher so that there is no excessive exterior instrumentation while providing sufficient material for the pin puller to grasp. The guide can be further stabilized using one or two joint distractors whose ends fit into the guide's indentations. The reaming guide is assembled onto the anterior chamfer guide and the cut is made using the reamer in two steps by turning the reaming guide over (Fig. 23); finishing the resection at the medial and lateral margins requires trimming with a rongeur.



(fig. 23)

PRECAUTIONS BEFORE USE: THE REAMING GUIDE MUST BE USED FOR REAMING.

Instruments used for this step

- Reaming guide, R/L side - Ref : MJU339



- Anterior chamfer reamer - Ref : MJU338



- Pin pusher Ref : MJU365
- Anterior talar chamfer guide Ref : MJU336
- 45-mm pin included in Ref : LJU095

14. Positioning the lateral resection guide

The lateral chamfer guide is available in two versions: right and left (as indicated on the instrument). The removable handle should be screwed onto the guide. The plug-shaped mediolateral positioning gauge is inserted in the lateral talar resection guide corresponding to the operated side, with the wing inserted along the guide's groove. The guide is set on the anterior and posterior resected surfaces.

The guide's wing is positioned on the resulting apex between the anterior and posterior chamfers. The mediolateral position of the resection guide is determined

by the tip of the wing being aligned on the lateral cortex of the talus (Fig. 24).





Instruments used for this step

- Removable handle - Ref : MJU342



- Lateral chamfer guide Right side - Ref : MJU341 Left side - Ref : MJU340



- Positioning gauge (plug-shaped) - Ref : MJU343



- 45-mm pin included in - Ref : LJU095

15. Drilling the talar plug

Proper positioning of the lateral chamfer guide on the initial resected talar surfaces determines the final talar position. Once the lateral talar resection guide is secured to the talus, with a 45-mm pin and/or joint distractors, the talar plug is prepared with a bell saw (Fig. 25).

Reaming is complete when the bell saw is advanced to the hard stop.

The guide position is secured with the fixation plug driven completely in (Fig. 26).

To facilitate the lateral resection, the guide's removable handle can be removed at this stage.

The lateral cut on the flat surface is made using the narrow saw blade, with the saw blade following the external slope of the guide (Fig. 27). The lateral malleolus is protected with a ribbon retractor.





Instruments used for this step

- Bell saw - Ref : MJU344



- Fixation plug - Ref : MJU012



- 45-mm pin included in Ref : LJU095
- Joint distractors Ref : MJU345 and MJU346
- Lateral chamfer guides Ref : MJU340 and MJU341

(fig. 26)





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16. Precautions when using a size 0 for a lateral resection

If the talus size requires using a size 0 (see preselection of talar implant size step), the operative technique requires a specific mediolateral positioning bushing to affix to the lateral chamfer guide. This bushing guides the mediolateral positioning as well as serves as the drilling guide. This positioning and drilling bushing is inverted depending on the side operated, with the wing on the lateral side.

The resection guide is positioned by aligning the tip of the wing on the lateral cortex of the talus as for sizes 1, 2, and 3.

For a size 0 talar implant, the diameter of the fixation plug is narrower than the standard sizes, and the bell saw is replaced with the talar plug drill (Fig. 28). The size 0 plug replaces the standard fixation plug.

Warning: the instrumentation includes another, longer drill (Ø 7.9 mm); it is exclusively reserved for drilling the tibial keel. Take care not to confuse the drill bit of the tibial keel with the drill designed for the talar implant. Each instrument is clearly marked with its

intended use.



(fig. 28)

Instruments used for this step

- Mediolateral positioning bushing, size 0 - Ref : MJU377



- Talar drill size 0 - Ref : MJU362



- Fixation plug, size 0 - Ref : MJU082



• 17. Placing the trial talar implant

The trial talar implant corresponding to the operated side and the size that has been chosen beforehand is put in place first.

Available for both right and left sides, properly positioning the trial implant is vital to respect the patient's anatomy and ensure long-lasting postoperative results:

- In accordance with the talus anatomy, the talar implant is wider anteriorly than posteriorly.

- The lateral side of the malleolus reproduces the talofibular joint.

Once this has been checked, the trial implant plug is inserted in the blind hole that was made previously with the bell saw for sizes 1, 2, and 3, or with the drill for size 0.

- Trial talar implant: R - Ref : MJU100 to MJU103 (size 0 to 3) - Trial talar implant: L - Ref : MJU110 to MJU113 (size 0 to 3)

The trial implant is impacted with the talar component impactor (Fig. 29).

Instruments used for this step

- Talar component impactor - Ref : MJU351



(fig. 29)

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• 18. Dynamic test and drilling of tibial plug

The plastic trial insert is selected depending on:

- Size and side, which must be identical to the size of the talar implant. A color code is used to simplify this step (see compatibility table).

- Thickness: 4 different thicknesses from 8 to 11 mm corresponding to the combined thicknesses of the metallic base and the PE.

The trial tibial base is selected to conform to the planned tibial implant size.

The trial insert is secured on the trial tibial base forming a monoblock. A ROM test automatically checks that the trial insert is properly aligned on the tibial trial.

Prior to insertion of the tibial base monoblock, remove all loose debris and bony block from the malleolar shoulders preventing free rotation, allowing the subsequent dynamic flexion/extension test.

The tibial base is then inserted between the trial talar implant and the tibia.

A dynamic flexion/extension test is performed on the foot to check the joint's kinematics. The tibial trial will naturally find its optimal position in the frontal and sagittal planes as well as in the rotational plane (Fig. 30).

At this stage, one must check that the engraved line on the superior surface of the tibial trial (the side in contact with the tibial cut) is aligned with the anterior cortex of the tibia. If this line simulating the final anterior margin of the tibial implant is too far anterior, the alignment must be forced when drilling the tibial plug. On the other hand, if the line is located posterior to the anterior cortex of the tibia, the final tibial implant should be positioned in the same way. AT THIS POINT, IT IS ESSENTIAL TO VERIFY THAT THE TRIAL TIBIAL IMPLANT BASE IS PERFECTLY PLACED ON THE RESECTED TIBIA. A lateral fluoroscopy image is taken to confirm that the tibial plate is flush with the distal tibia prior to drilling. Preparation of the tibial implant keel begins using the drill bit (Ø 3 mm). The two inferior holes are drilled, then the trial tibial base is held by a 45-mm pin in the distal hole (Fig. 31). This operation will prepare for the tibial keel. The tibial plug is drilled using a drill bit (\emptyset 7.9 mm), guided into the trial's upper hole. Drilling through the tibial base guide gives a 4° angle from the tibial base plate, aiming for a press-fit of the final implant between the keel and the distal cut during impaction. Consideration must be given to possible adjunct soft tissue balancing procedure at this stage (i.e. Achilles tendon lengthening, ligament release and repair).



(fig. 30)



(fig. 31)

Instruments used for this step

- Trial tibial implant: Ref : MJU380 - size 0 Ref : MJU385 - size 2 Ref : MJU386 - size 3
- Tibial keel drill bit (Ø 7.9 mm) Ref : MJU353



- 45-mm pin included in - Ref : LJU095

COMPATIBILITY TABLE

- Drill bit Ø 3 mm included in - Ref : LJU095

- Trial insert PE Size 00 R - Ref : MJU545 to MJU548 L - Ref : MJU555 to MJU558
- Trial insert PE Size 0 R - Ref : MJU565 to MJU568 L - Ref : MJU575 to MJU578
- Trial insert PE Size 1 R - Ref : MJU585 to MJU588 L - Ref : MJU595 to MJU598
- Trial insert PE Size 2 R - Ref : MJU605 to MJU608 L - Ref : MJU615 to MJU618
- Trial insert PE Size 3 R - Ref : MJU625 to MJU628 L - Ref : MJU635 to MJU638

0 1 2 3 Tibial part 0 0 1 2 3 Insert 0 0 1 2 3 Talar part 0 1 2 3

1JU618 1JU628 1JU638

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• 19. Finishing touches on the tibial keel

Once the plug has been placed, the trial insert monoblock is removed.

The tibial holes are connected using a small osteotome; then the thickness and depth of the engraved line are checked with the graduated osteotome.

The distal part of the anterior groove of the tibia is beveled using the rasp, so that the tibial implant lies flush on the resection (Fig. 32).

Inadequate rounding of the edges will potentially cause the tibia to split at the time of tibial component implantation, or result in posterior gap or angulation of the tibial component as seen on lateral view.

With the different tibial implant sizes (0, 1, 2, and 3) marked on the upper surface of the rasp, the trimming done in this manner perfectly matches the length of the implant selected. The trial talar implant is then withdrawn.



(fig. 32)

Instruments used for this step

- Tibial keel graduated osteotome - Ref : MJU387



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- Osteotome - Ref : MJU357

• 20. Placing final implants

Recommendation: the final implants should be positioned identically to the trial implants. Prepare the bone and implant surfaces with cement before placing the final implants.

 1 – The talar implant is placed first, following the same procedure as described during the placement of the trial talar implant. It is impacted with the talar component impactor (Fig. 33).

The size and side selected during the implant trials must be retained.

2 –The final PE and tibial implant form a single-block unit and therefore they should be assembled with the implant assembly clamp available in the instrument set.

ASSEMBLY OF THE INSERT ON THE TIBIAL IMPLANT

The implant assembly clamp has two distinct parts (Fig. 34): - the first one has a system to maintain the final tibial base;

- the second one has a hood or mobile metallic jaw .

The keel of the tibial implant is slipped onto the longest stump until contact is made with the posterior edge of the implant with the clamp.

The PE insert is manually slipped on the central fixation gutter and pushed until translation movement is no longer possible (Fig. 35).

Instruments used for this step

- Assembly clamp - Ref : MJU091



- Talar component impactor - Ref : MJU351



(fig. 33)



(fig. 34)



(fig. 35)

The jaw is raised as much as possible. Thus the jaw will take leverage on the insert's anterior chamfer (Fig. 36). Finally, tightening the clamp locks the two components together. The final assembly is felt by the operator and generally an audible "click" is heard.

The tibial component now composed of the base and PE insert, is grasped in the implant assembly between the metallic plug and the central anterior zone of the tibial, using the tibial impactor.

Prepare the bone and implant surfaces with cement and seat the talar implant first using the impactor.

The tibial implant is impacted until the position of the tibial trial is reproduced.

During tibial implant impaction, maintain good contact between the upper side of the implant and the tibial resection to prevent any risk of a posterior gap between the tibial cut and the implant (Fig. 37).

Fill the tibial window with bone graft. An optional fluoroscopy image is taken to confirm the final position and alignment of the implants and to rule out iatrogenic fracture (Fig. 38).

Fluoroscopy imaging during this step ensures proper positioning.

Assess the soft tissue balance and perform any appropriate adjunct procedure at this stage (i.e. Achilles tendon lengthening, ligament release and repair) Close the wound in layers.

Instruments used for this step

- Tibial impactor - Ref : MJU361



- Tibial plug revision osteotome - Ref : MJU356



- Osteotome - Ref : MJU357



(fig. 36)









• 21. Rehabilitation protocol

Different steps have to be followed after surgery :

- Splint in neutral position
- Remove sutures and evaluate wound at 2-3 weeks
- < 3 weeks
 - Cast or splint
 - Non-weight bearing
- 3-6 weeks
 - Cast boot
 - Non-weight bearing
 - Self-directed ROM
- 7th week
 - Cast boot or ankle brace/shoe
 - Weight bearing as tolerated
 - Physical therapy for ROM, resistive strengthening

Associated procedures performed along with the arthroplasty such as Achilles tendon lengthening may require a rehabilitation protocol appropriate to the associated procedure.

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• 22. Revising or removing implants

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If the implant must be revised, revision should begin by removing the PE insert.

This is disassembled from the tibial base by inserting the tibial insert extractor blade between the base and the PE. A towel clamp holds the PE component for its extraction, after a lever maneuver using the extractor has separated the two components.

If necessary, the tibial base can then be removed as follows:

- To precut the bone around the tibial plug, use the tibial plug revision osteotome and osteotome provided for this purpose in the instrumentation.
- Hook the posterior aspect of the tibial implant with the tibial component extractor.
- Insert the extractor plug by screwing the slap hammer on the tibial extractor.
- Push and pull vigorously with the slap hammer until the implant is fully removed.
- The talar implant is separated from the talus with the osteotome.

Instruments used for this step

- Insert extractor - Ref : MJU058



- Tibial component extractor - Ref : MJU368



- Slap hammer - Ref : MJU358



- Osteotomes - Ref : MJU356 and MJU357



INSTRUMENTS

INSTRUMENTATION CASE Ref : YKAL11 – Top tray, Ref : YRAL112



ltem		Ref	Quantity
1	Tibial guide	MJU333	1
2	Tibial alignment jig	MJU334	1
	Tibial resection guide, size 0		1
	③ Tibial resection guide, size 1 Tibial resection guide, size 2		1
3			1
	Tibial resection guide, size 3	MJU373	1
4	Talar pin setting guide	MJU335	1
5	Talar gauge, size O/1	MJU331	1
5	Talar gauge, size 2/3	MJU364	1
	Posterior talar resection guide, size 0	MJU375	1
	Posterior talar resection guide, size1/2/3	MJU376	1
	Augment, thickness 1 mm	MJU381	2
7	Augment, thickness 2 mm	MJU382	2
	Augment, thickness 3 mm	MJU383	2
8	Anterior talar chamfer guide	MJU336	1
9	Talar position spacer	MJU337	1
10	Anterior chamfer reamer	MJU338	1
(1)	Anterior chamfer reaming guide	MJU339	1
(1)	Left lateral chamfer guide	MJU340	1
	Right lateral chamfer guide	MJU341	1
(13)	Removable handle	MJU342	1
(14)	Positioning gauge (plug shaped)	MJU343	1
(15)	Bell saw	MJU344	1
(16)	(i) Fixation plug		1
1)	Mediolateral positioning bushing, size 0	MJU377	1
(18)	Talar drill bit, Ø7.9 mm, size 0	MJU362	1
(19)	Fixation plug, size 0	MJU082	1
20	Pin puller	MJU359	1
21	Holding clamp	MJU048	1
22	Screwdriver	MLN113	1

INSTRUMENTS

INSTRUMENTATION CASE Ref : YKAL11 – Bottom tray, Ref : YRAL111



Item		Ref	Quantity
	Joint distractor, model A	MJU345	1
	Joint distractor, model B	MJU346	1
2	Tibial keel graduated osteotome	MJU387	1
3	Rasp	MJU350	1
4	Talar component impactor	MJU351	1
5	Curette	MJU085	1
6	Tibial keel drill bit, Ø7.9 mm	MJU353	1
7	Tibial plug revision osteotome	MJU356	1
8	Osteotome	MJU357	1
9	Tibial component extractor	MJU368	1
10	Slap hammer	MJU358	2
	Right talar trial implant, size 0	MJU100	2
(1)	Right talar trial implant, size 1	MJU101	1
	W Right talar trial implant, size 2		1
	Right talar trial implant, size 3	MJU103	1
	Left talar trial implant, size 0	MJU110	1
(12)	Left talar trial implant, size 1	MJU111	1
	Left talar trial implant, size 2	MJU112	1
	Left talar trial implant, size 3	MJU113	1
Instru	iment case		1
	Screw M5	MJU073	5
	Ribbon retractors	MJU086	2
	Pin pusher	MJU365	1

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INSTRUMENTS

REMOVABLE CASE Ref : YKAL13 – Tray Ref : YRAL13



Iten	n	Ref	Quantity	Item	1	Ref	Quantity
1	Assembly clamp	MJU091	1		Insert trial Right size 3 th 9	MJU626	1
2	Tibial Impactor	MJU361	1	5	Insert trial Right size 3 th 10	MJU627	1
3	Insert extractor	MJU058	1		Insert trial Right size 3 th 11	MJU628	1
	Tibial trial size 0	MJU380	1		Insert trial Left size 00 th 8	MJU555	1
	Tibial trial size 1	MJU384	1		Insert trial Left size 00 th 9	MJU556	1
(4)	Tibial trial size 2	MJU385	1		Insert trial Left size 00 th 10	MJU557	1
	Tibial trial size 3	MJU386	1		Insert trial Left size 00 th 11	MJU558	1
	Insert trial Right size 00 th 8	MJU545	1		Insert trial Left size 0 th 8	MJU575	1
	Insert trial Right size 00 th 9	MJU546	1		Insert trial Left size 0 th 9	MJU576	1
	Insert trial Right size 00 th 10	MJU547	1		Insert trial Left size 0 th 10	MJU577	1
	Insert trial Right size 00 th 11	MJU548	1		Insert trial Left size 0 th 11	MJU578	1
	Insert trial Right size 0 th 8	MJU565	1		Insert trial Left size 1 th 8	MJU595	1
	Insert trial Right size 0 th 9	MJU566	1		Insert trial Left size 1 th 9	MJU596	1
	Insert trial Right size 0 th 10	MJU567	1	6	Insert trial Left size 1 th 10	MJU597	1
	Insert trial Right size 0 th 11	MJU568	1		Insert trial Left size 1 th 11	MJU598	1
5	Insert trial Right size 1 th 8	MJU585	1		Insert trial Left size 2 th 8	MJU615	1
	Insert trial Right size 1 th 9	MJU586	1		Insert trial Left size 2 th 9	MJU616	1
	Insert trial Right size 1 th 10	MJU587	1		Insert trial Left size 2 th 10	MJU617	1
	Insert trial Right size 1 th 11	MJU588	1		Insert trial Left size 2 th 11	MJU618	1
	Insert trial Right size 2 th 8	MJU605	1		Insert trial Left size 3 th 8	MJU635	1
	Insert trial Right size 2 th 9	MJU606	1		Insert trial Left size 3 th 9	MJU636	1
	Insert trial Right size 2 th 10	MJU607	1		Insert trial Left size 3 th 10	MJU637	1
	Insert trial Right size 2 th 11	MJU608	1		Insert trial Left size 3 th 11	MJU638	1
	Insert trial Bight size 3 th 8	MJU625	1				

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SINGLE USE ITEMS

SAW BLADES

Hub Connector	System	70mm long x 8 - 13mm wide x 1.27mm thick	90mm long x 13 - 21mm wide x 1.27mm thick
		Narrow saw blade	Wide saw blade
IS I II STATUS	Stryker- EHD & Systems 2000,4,5	SAW608	SAW721
STRUGGTE STA	Linvatec / Hall-Power Pro / Versipower Plus	SAW614	SAW723
	Linvatec / Hall- Versipower	SAW609	SAW724

The following saw blades are special order items and available only by contacting Tornier Customer Service.

PIN PACK

Sterile Single Use Pin Pack : LJU095	
3 x 110-mm self-drilling pins	
5 x 75-mm pins	
3 x 45-mm pins	
1 x drill bit ø 3 mm	

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IMPLANTS



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TIBIAL COMPONENTS - CoCr				
	References			
Size O	LJU220			
Size 1	LJU221			
Size 2	LJU222			
Size 3	LJU223			





TALAR COMPONENTS - CoCr				
	Left	Right		
Size 0	LJU210	LJU200		
Size 1	LJU211	LJU201		
Size 2	LJU212	LJU202		
Size 3	LJU213	LJU203		



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