HINTEGRA®

Total Ankle Prosthesis

newdeal®
New ideas for foot surgery™

Surgical Technique

For Hintegra® total-ankle prosthesis

ORTHOPAEDICS
LOWER
EXTREMITY

INTEGRA™

Table of contents

Indications and contraindications

Indications

- Systemic arthritis of the ankle (e.g. rheumatoid arthritis).
- Primary osteoarthritis (e.g. degenerative disease).
- Secondary osteoarthritis
  (e.g. post-traumatic, infection, avascular necrosis*).
- Failed total ankle replacement.**
- Salvage for non-union and malunion of ankle joint fusion.**
- The size 0 of both Hintegra intermediary sliding core and talar components must not be implanted in a patient weighing more than 65 kilograms.

* if minimally 2/3 of the talar body are preserved.

** if bone stock is sufficient.

The patient's joint must be anatomically and structurally limited to receive the selected implant.

Contraindications

Relative contraindication

- Severe osteoporosis.
- Immunosuppressive therapy.
- The size 0 of both Hintegra intermediary sliding core and talar components must not be implanted in a patient weighing more than 65 kilograms.

Absolute Contraindications

- Recent infection.
- Avascular necrosis of the talus/tibia > 1/2.
- Severe misalignment.*
- Severe instability.*
- Diabetic syndrome.
- Suspected or documented metal allergy or intolerance.
  Cobalt chromium alloy contains up to 1% Nickel, stainless steel 316L contains 13 to 15% Nickel.
- High demanding sport activivities (e.g. contact sports, jumping).

* if not surgically correctable.

Surgical technique

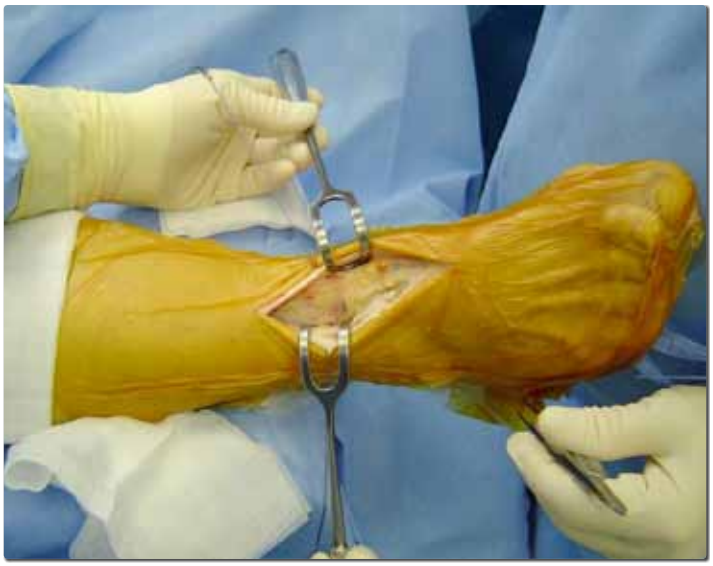
Developped with the cooperation of Pr. Beat Hintermann, Liestal - Switzerland.
NEWDEAL as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

1 • Positioning of the patient

- The patient is positioned with the feet on the edge of the table.
- The affected foot is maintained on a block to facilitate treatment of associated problems (e.g. subtalar arthrodesis, ligament reconstruction, tendon transfer).
- The ipsilateral back is lifted until a strictly upward position of the foot is obtained.

2 • Surgical approach

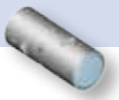
- An anterior longitudinal incision of 10 to 12cm length is made to expose the retinaculum.
- The retinaculum is dissected along the lateral border of the anterior tibial tendon, and the anterior aspect of the distal tibia is exposed.
- While the soft tissue mantel is dissected with the periosteum from the bone, attention is paid to the neurovascular bundle that runs behind the long extensor hallucis tendon.
- Arthrotomy is made, and hooks are inserted to carefully keep the soft tissue mantle away. A self-retaining distractor may be helpful; attention must be paid, however, that no tension is applied to the skin.
- Osteophytes on tibia are removed, particularly on antero-lateral aspect.
- Osteophytes on talar neck and anterior aspect of medial malleolus are also removed.
- The fibula can usually not be fully visualized at this stage.



309 753+773
Proximal & distal tibial cutting block

309 615
Tibial rod

309 625
Tibial positioning V



309 620
Alignment rod connector

309 630
Translation block

119 611
ø2.5 mm drill

Introduce the rods in the holes indicated by the arrows

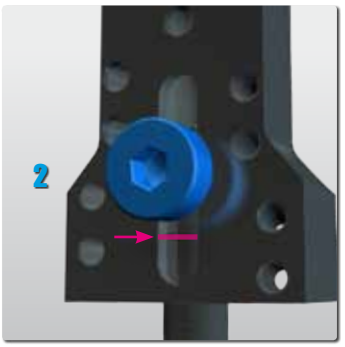
3 Positioning of the tibial cutting block

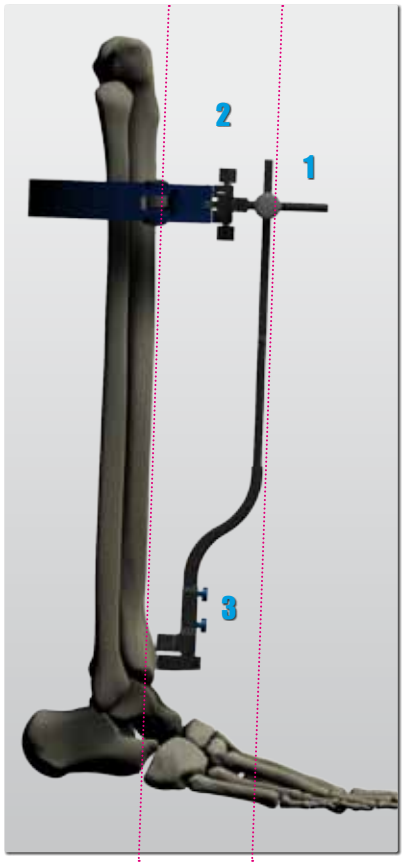
3.1 Preparation

- The tibial cutting block (309 753 + 309 773), the tibial rod (309 615), the tibial positioning V (309 625), alignment rod connector (309 620), and translation block (309 630) are assembled on the table before positioning on the patient. The distal cutting block (309 773) is fixed in a intermediate position to allow vertical adjustment later on.
- The proximal end of the tibial device (Tibial positioning V 309 625) is adjusted to the tibial tuberosity while its arms are held open and then closed.

Attention has to be paid not to expose the fibular head to compression (risk of nerve injury).

- Proximal neutral position of the tibial rod is obtained while the translation block (309 630) is positioned on the middle of the sliding part of the tibial positioning V (309 625).
- The distal tibial cutting block (309 773) is positioned on the center of the distal tibial metaphysis and fixed by 2 pins.





3.2 Settings

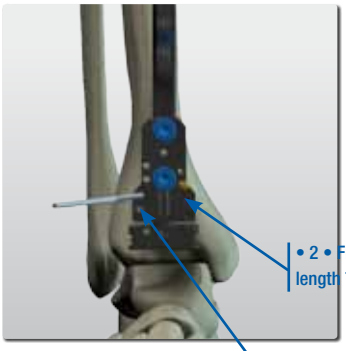
- For proper positioning, the following adjustments have to be made:

3.2a Sagittal plane

» The rod must be positioned parallel with the anterior border of the tibia.

3.2b Frontal (coronal) plane

» **The tibial rod must be placed in the center of the tibia**; proximally, it is projected onto the tibial tuberosity, and distally, it is projected onto the center of the distal tibia.



309 645
3.5 mm Hex screwdriver

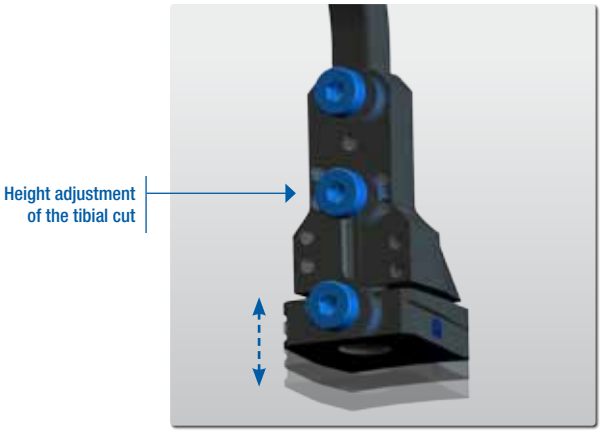
3.2c • Vertical setting

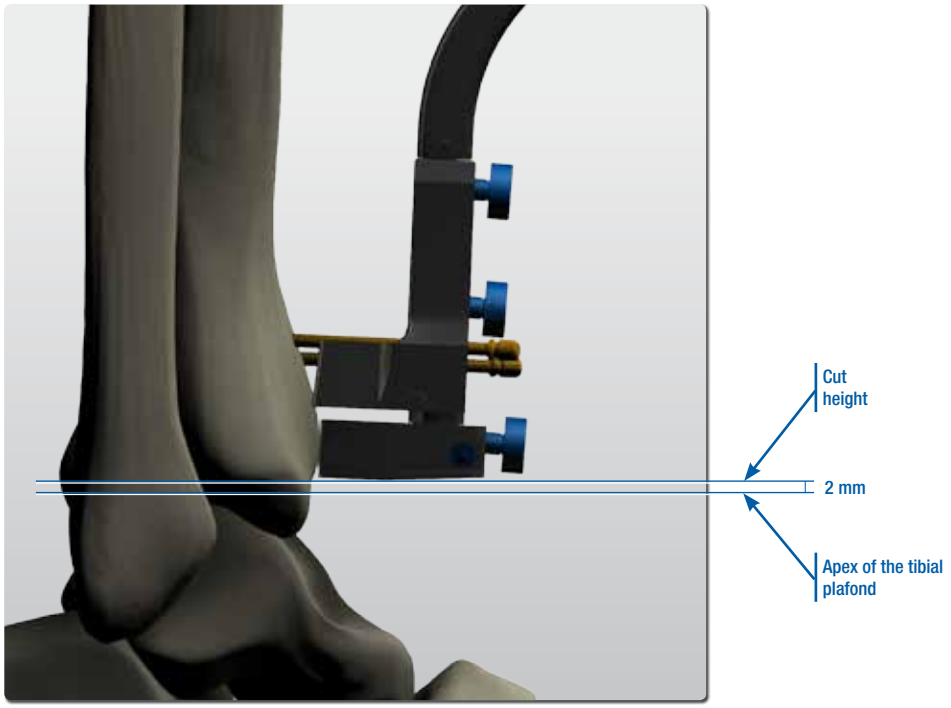
» The distal tibial cutting block (309 773) is moved proximally until the desired resection height is achieved. Usually, a resection of approximately 2 mm to 3 mm upper from the apex of the tibial plafond is desired.

» Tighten the knurl 2 with the screwdriver (309 645).

HINT

In varus ankles, thicker tibial resection is usually needed. Whereas, in valgus ankles, and/or in presence of high joint laxity, less bone resection is advised.

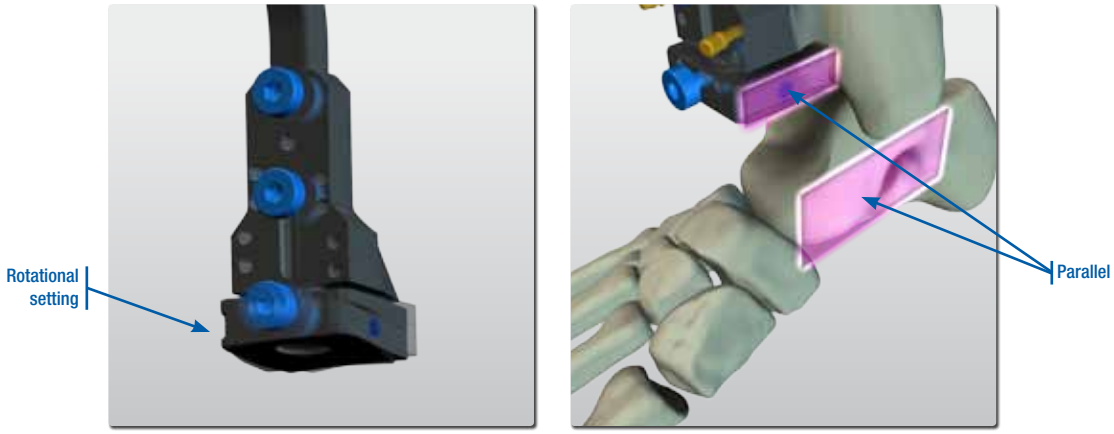




3.2d • Rotational setting

» If necessary, the distal tibial cutting block (309 773) is rotated to get a parallel position of its medial surface to the medial surface of the talus; this might prevent hitting the medial malleolus with the sawblade during resection.

» Tighten the knurl 3 with the screwdriver (119 645).

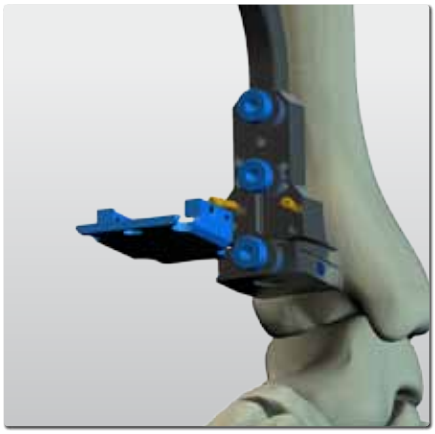


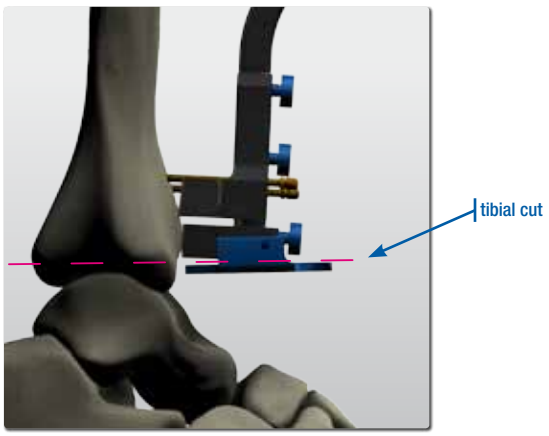
4 • Tibial resection

4.1 • Positioning of the tibial cutting guide

- The tibial cutting guide is selected, depending on the size of the tibia. 3 different cutting guides (SMALL - 309 637, MEDIUM/STANDARD - 309 636 and LARGE 309 635) are available; small and large are optional. Usually, the standard one (MEDIUM - 309 636) is used in order to protect the lateral and the medial malleoli.
  The largest one (LARGE - 309 635) should be used only for very large ankles but in that case, a special attention must be paid to the malleoli using the sawblade.
  The guide is sled into the cutting block creating a slot in which the sawblade will be guided.
  The width of the slot limits the excursion of the sawblade, thereby protecting the malleoli from hitting and fracturing.

! Attention should be paid to the proper contact of the tibial cutting block with the anterior surface of the tibia.





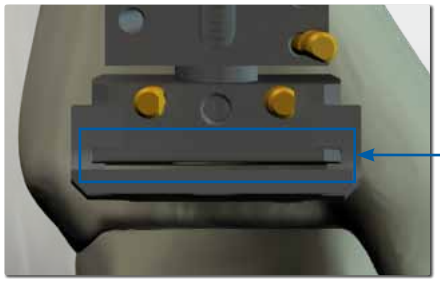
119 664
Hintermann distractor
Big model

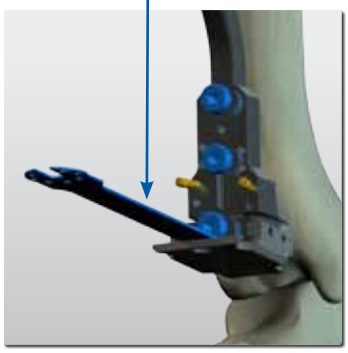
115 225
2.5 mm K-wire

4.2 First cut

- The tibial resection is performed with the adequate saw blade, inserted into the slot of the tibial cutting block.

Make sure that the saw blade is perfectly in an antero-posterior position in order to avoid any damage to the malleoli.





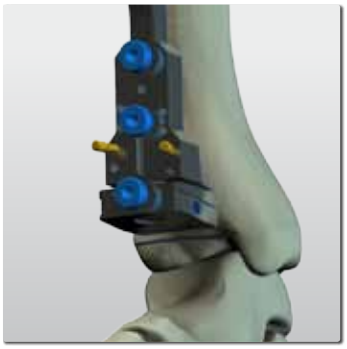
Several attachments are available for Newdeal® saw blades	
Aesculap® attachment (309 622)	
AO Synthes® attachment (309 623)	
Stryker® 6 attachment (309 624)	
Conmed Linvatec® attachment (309 627)	
Stryker® attachment (309 626)	

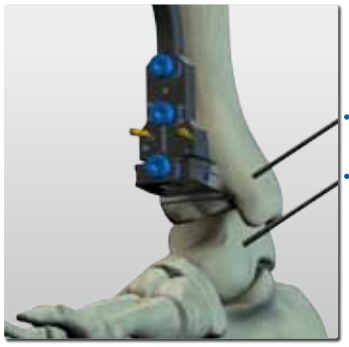
4.3 • Opening of the joint

- The tibial cutting guide is removed, and the Hintermann distractor (119 664) is mounted with provided K-wire 2.5 mm (115 225) to the antero-medial aspect of the distal tibia and the antero-medial talar neck, respectively.

K-wires should be placed in such a position that they do not hinder further preparation of the talus.

- Obtained distraction allows to get better insight into the tibiotalar joint, and to facilitate the removal of the posterior resected parts. K-wires can be cut to limit their bulkiness.





Opening of the tibio talar joint

309 656
Talar cutting block
STANDARD (MEDIUM)

309 657
Talar cutting block
SMALL

309 605
Pin L. 70 mm

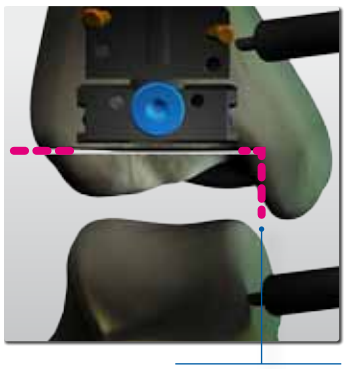
4.4 • Finalisation

- Once the tibial cut is made, a reciprocating saw may be used to finalize the cuts, particularly for the vertical cut on medial side.

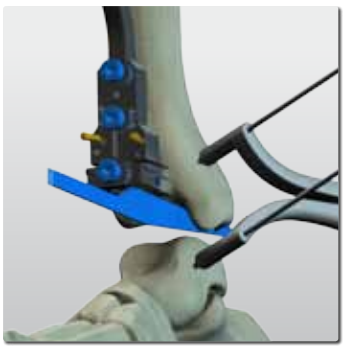
Attention should be paid not to insert the saw blade too deeply into the joint as the tibial nerve might be at risk.
Because the bone of the distal tibia is particularly hard postero-medially, an osteotome should be used only with caution: its use can easily break the malleolus.

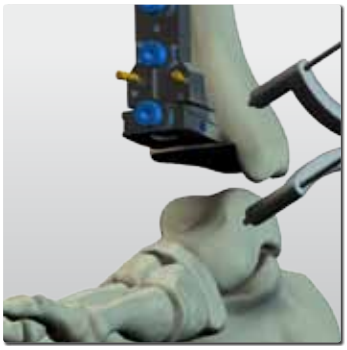
The distal part of the tibia being resected, emphasis should be given to achieve a properly edge-shaped cut (90°) along the medial malleolus. This will allow, later on, to insert the tibial component properly along the medial malleolus.

- In most instances, there is still some bone left on lateral side of the tibia. The horizontal cut is carefully completed with the oscillating saw until the fibula becomes completely visible.
- The resected bone is removed using a rongeur. Some bone and capsular tissue on posterior aspect of the joint might be left in place at this stage of surgery (it is more easily removed once the talar cuts are performed), as long as it may not hinder insertion of the talar cutting block.



Medial vertical cut along the malleolus



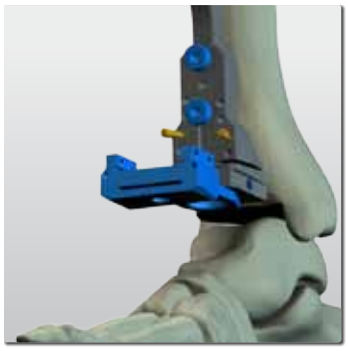


Tibial cut finalized

5 • Positioning of the talar cutting block

5.1 • Insertion of the block

- The talar cutting block (309 656 or 309 657) is inserted into the tibial cutting block (309 773) until it has been fixed by the snapping mechanism.
- The proximal tibial knurl (2) is unlocked and the distal tibial cutting block is moved as distally as possible until the collateral ligaments are tightened; now the knurl is locked.



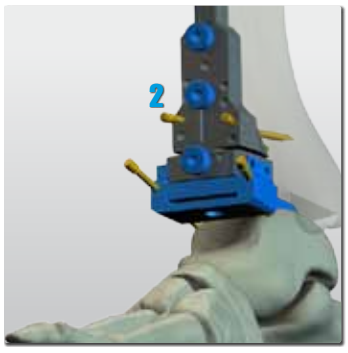
HINT

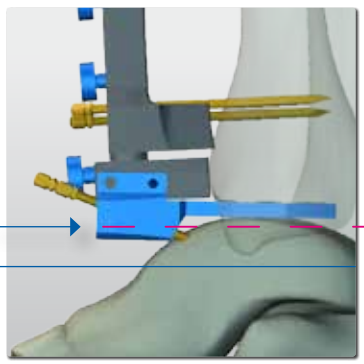
To achieve neutral foot position, it might be helpful to take the heel with one hand, and the forefoot with the other hand. If there are any osteophytes left on talar neck that hinder, they must be removed.

5.2 • Fixation of the block

While the foot is held in neutral position, 2 pins, 70 mm long (309 605), are inserted medially and laterally.

- Alignment of the hindfoot and flexion position of the foot are checked visually. If proper foot position is not achieved, the pins must be removed and the procedure should be done again.





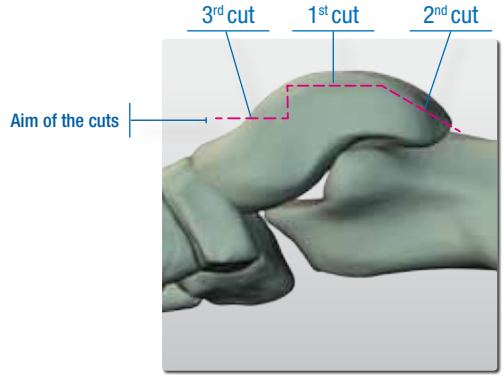
309 656
Talar cutting block
STANDARD (MEDIUM)

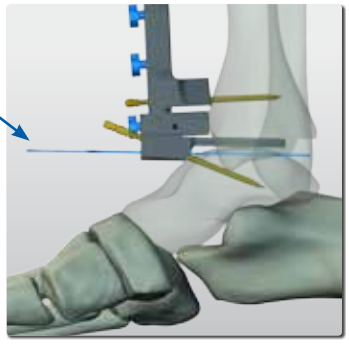
309 657
Talar cutting block
SMALL

6 Talar cuts

6.1 Superior cut

- The resection of the talar dome is done with the oscillating saw using a Newdeal® saw blade. The cut is done through the slot of the talar cutting block (309 656).





Several attachments are available for Newdeal® saw blades

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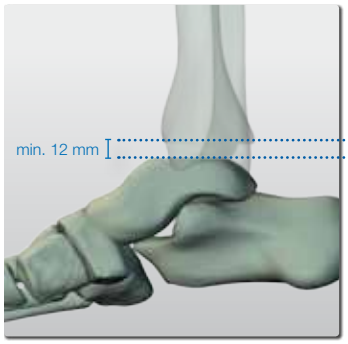
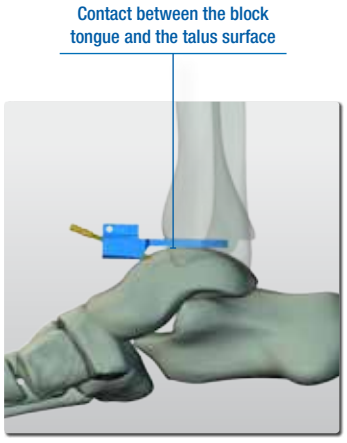


HINT

if necessary, appropriate positioning of talar cut can be checked (e.g. contact of the talar cutting block tongue to the upper surface of talus) by removing the tibial resection block or per fluoroscopy (lateral view).



309 360-366
Talar cutting guide
Right foot (green handle)
size 0 to 6

309 370-376
Talar cutting guide
Left foot (red handle)
size 0 to 6

119 751
Tibial impactor

309 604
Pin L. 30 mm

309 605
Pin L. 70 mm

309 606
Pin L. 45 mm

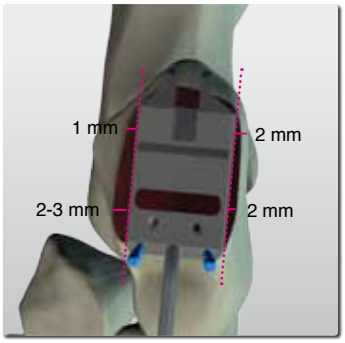
6.2 Posterior and collateral cuts

- The appropriate size of the talar cutting guide* is selected as follows :
  - » medial side :
    to resect 2 mm of bone (parallel cut)
  - » lateral side :
    to resect 1-3 mm of bone (e.g. 1 mm on posterior aspect and 2-3 mm on anterior aspect, as given by the anatomy of the talar body)
- The selected talar cutting guide is placed on the flat surface of the talus maintaining the hooks carefully positioned on the posterior aspect of the talus; the resection guide becomes in proper contact to the resection surface of the talus.
- While the foot is brought to a neutral position, the handle of the cutting guide should meet the second ray.

*309 360 to 309 366 for the right foot
309 370 to 309 376 for the left foot

HINT

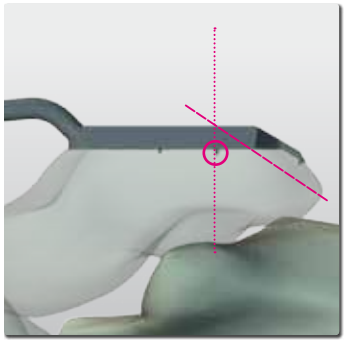
If there is any doubt about the selected size, the depth of the tibia can be measured now and the talus is selected according to the measured size of tibia.



HINT

In case of osteophytes or thick cartilage layer left on posterior talus, chisel is used to remove it.
The tibial impactor (119 751) can be used to get the cutting guide fitted firmly to the talar resection surface.

- 2 to 4 pins are used for fixation of the cutting guide to the talus

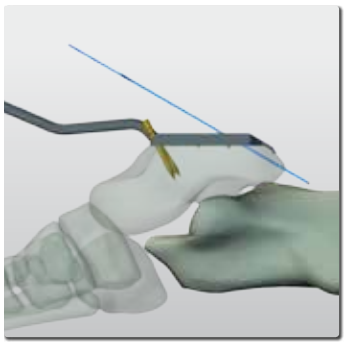


..... *middle of the talar component*
– – – *posterior cut*

HINT

Number and length of pins may be selected according to the quality of bone to obtain an appropriate fixation.
If necessary, the position of the cutting guide can be checked by fluoroscopy (e.g. proper fit of hooks on posterior aspect of talus and cutting guide on resection surface); the posterior peaks on the flat talar horizontal surface indicate the center of the talar component with regards to its antero-posterior position.

- The posterior cut is made through the posterior slot using the oscillating sawblade.



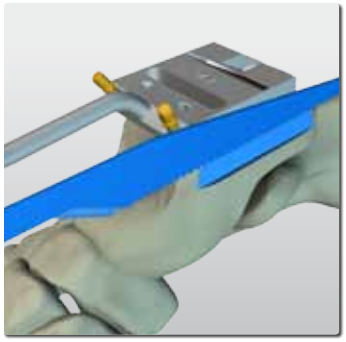
309 200
ø6mm talar reamer

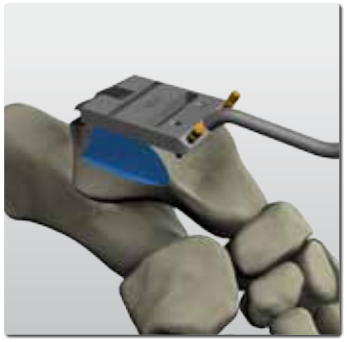
- Then, medial and lateral cuts are made using the reciprocating saw, paying attention that the sawblade follows strictly the cutting guide.
  - » medial side: approximately 6 mm deep.
  - » lateral side: approximately 8 mm deep.

HINT

If necessary, a chisel might be used to finish the cut at its medial and lateral borders.

In order to make further talar trial impaction easier, it may be helpful to slightly resurface the postero-lateral corner of the talus, according to the cutting guide.

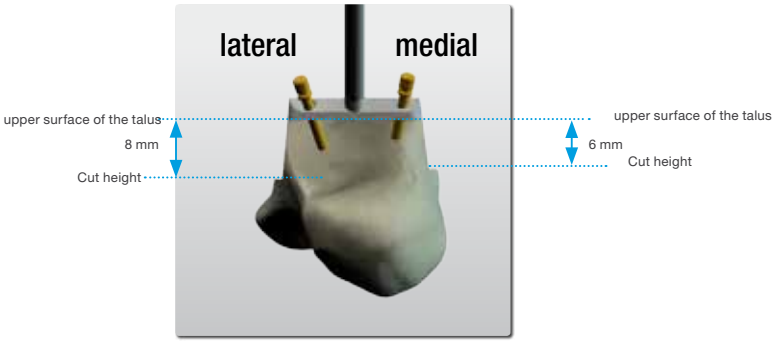




- The resected bone is removed with a rongeur.
- Remaining bony and capsular structures on posterior aspect are carefully removed.

HINT

A chisel is used to mobilize the medial and lateral resections of the talus
If necessary (e.g. hard bone), the posterior corner of collateral cuts might be smoothen with a chisel or rongeur to allow proper insertion of the talar trial.

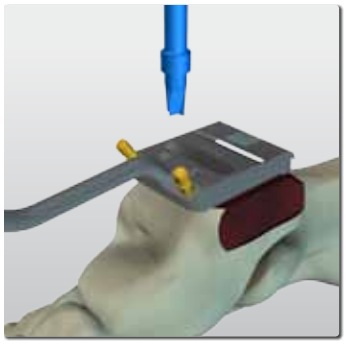


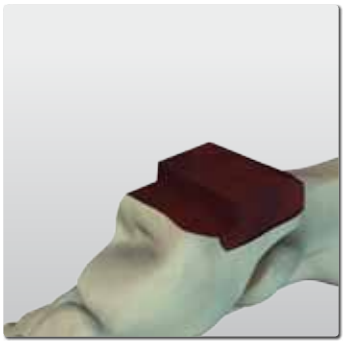
6.3 • Anterior cut

- The provided talar reamer (diam. 6 mm 309 200) is used to make the anterior cut through the slot, and the created step is debrided with a rongeur.

! Attention should be paid to keep the reamer perpendicular to the slot and to go as deep as possible as allowed by the end-stop.

- The flange of the reamer should sit properly and perfectly perpendicular to the cutting guide.

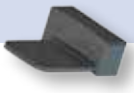




HINT

In case of hard bone, more than one lateral movement should be performed

309 608
12 mm thick spacer



119641
Tibial revision
Cutting guide

119 664
Hintermann distractor
Big model

7 • Checking of the cuts, alignment and stability

- After having removed the Hintermann distractor (119 664), the 12 mm thick spacer (309 608) representing the thickness of the tibial and talar components and the thinnest 5 mm inlay is inserted into the created joint space. While the foot is held in neutral flexion position, it allows to check the following points.

3 cases

A. If insufficient quantity of bone has been resected.

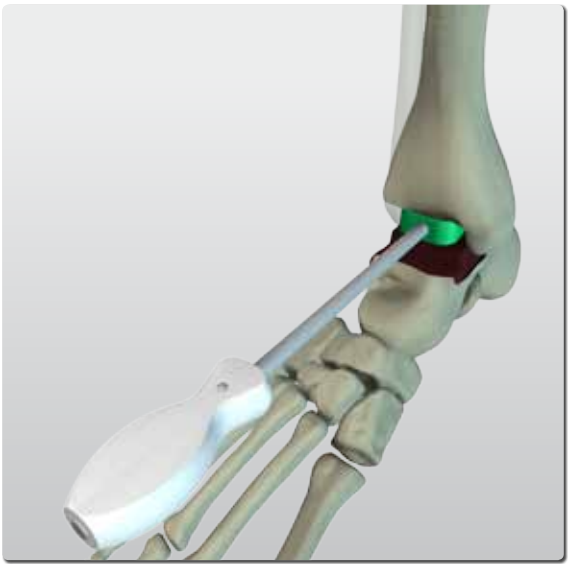
If the spacer cannot be properly inserted into the joint space, and if there is no obvious contracture of the remaining posterior capsular, additional bony resection might be considered. In most instances, such additional resection should be done on tibial side. The tibial cutting block is repositioned using the same fixation holes for the pins. The distal resection block is moved proximally as desired, and a new cut is performed with the saw blade. Alternately, the tibial revision cutting guide (119 641) can be used on the tibial cut to remove exactly 2 mm of bone.

B. If the achieved alignment is inappropriate.

If the alignment is not appropriate, and if an associated deformity of the foot itself (e.g. varus, valgus heel) can be excluded, a corrective cut should be considered. In most instances, the resection should be done on tibial side. The desired angular correction on tibial resection cutting is made, and the tibial cutting block is repositioned using other fixation holes for the pins. The distal resection block is moved proximally or distally to match with the height of the original cut such as an angular bony resection will result.

C. If the medial and lateral stability are inappropriate.

If the ankle is not stable on both sides, the use of a thicker inlay might be advised. If the ankle is not stable on one side, a release of the contro-lateral ligaments, and/or ligament reconstruction on affected side should be considered. Ligament reconstruction is better done once the definitive implants have been inserted, and if there is still an obvious instability.

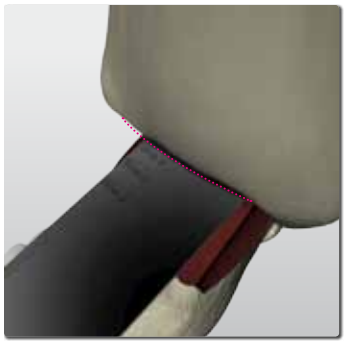


309 607
Tibial depth gauge

997 034
Curved chisel

8 Assessment of the tibial size

- The tibial depth gauge (309 607) is used to determine the size of tibial implant.
- The gauge is inserted with the appropriate side (right/left) against the tibial surface, and the posterior edge is hooked on the posterior border of the tibia. The size to be selected can be read from the scale on depth gauge, located on its upper side (tibia side).



HINT

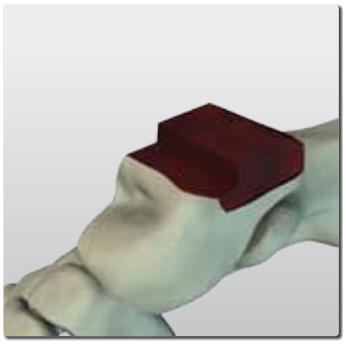
If the anterior border of the tibia is between 2 marks, the biggest size should be selected between both.

The anterior tibia might be shaped to the indicated mark to allow appropriate positioning of the tibial component (e.g. no medial or lateral gapping that may irritate soft tissues). The curved chisel (997 034) can be helpful for this procedure.

The talar size should not be higher nor smaller of more than 1 size than the size of the tibial component, e.g. if tibial component size is 2, talar component size must be 1,2 or 3.

9.5 Finalisation

- On medial and lateral sides, the cuts are finalized using a chisel to make an almost horizontal cut along the base of the cuts previously done. Thereby, this will avoid extended loss of bone stock and potential damage of the vascular supply of the talus.
- The medial and lateral gutters are cleaned using a rongeur.
- The remaining bone and capsule of the posterior compartment are removed.



HINT

The posterior capsule should be removed completely until fat tissue and tendon structures are visible, in order to achieve full dorsiflexion.

309 697
Talar trial holder

309 680-686
Right talar trial

309 690-696
Left talar trial

309 699
Trial talar impactor

119 665-666-667-669
Trial inlays
Thickness 5, 6, 7 and 9mm

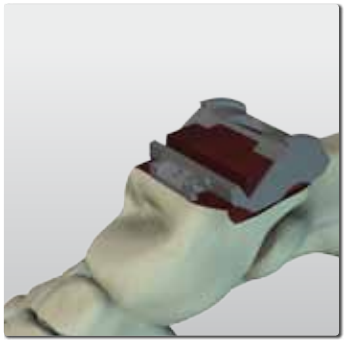
119 690-694 + 778
Right tibial trials
119 646
Right tibial trial size 0

119 695-699 + 779
Left tibial trials
119 647
Left tibial trial size 0

10 Insertion of trial components

10.1 Talar trial at first

- A specific holder (309 697) can be used to bring the talar trial onto the talar cuts.
- The selected talar trial (309 680-686 for right side / 309 690-696 for left side) is inserted using the specific impactor (309 699). The window on the posterior aspect of the trial allows to check its proper fit to the posterior resected surface of the talus.



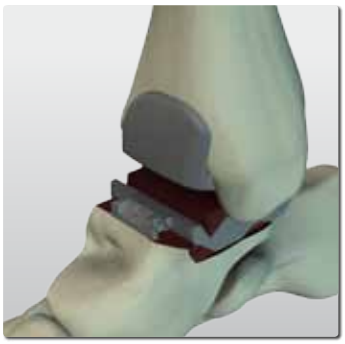
HINT

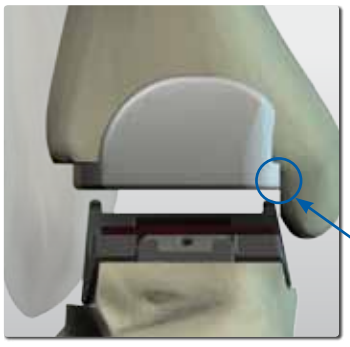
A chisel, when pressed against the anterior tibial border and the posterior aspect of the talar trial, may avoid posterior displacement of the trial component while impacting. If proper settling of the component cannot be achieved, the medial and/or lateral gutters must be cleaned again. In most instances, remaining bone after inappropriate resection may be the cause.

10.2 Tibial trial

- The tibial trial (119 690-119 699 / 119 778-779 / 119 646-647), as selected before, is inserted.

! Attention should be paid to get the tibial component in close contact with the medial malleolus.



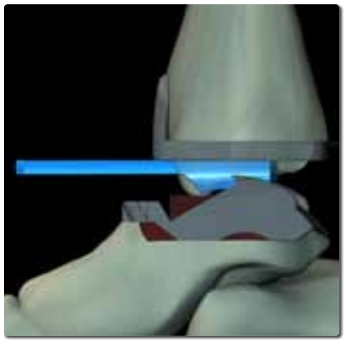


HINT

If remaining osteophytes on lateral side avoid proper contact of the shield of the component and/or if close contact along the medial malleolus cannot be achieved while the tibial shield is fitted against the anterior border of tibia, removal of the osteophytes and/or smoothening of the anterolateral tibia are advised.

10.3 Trial inlay

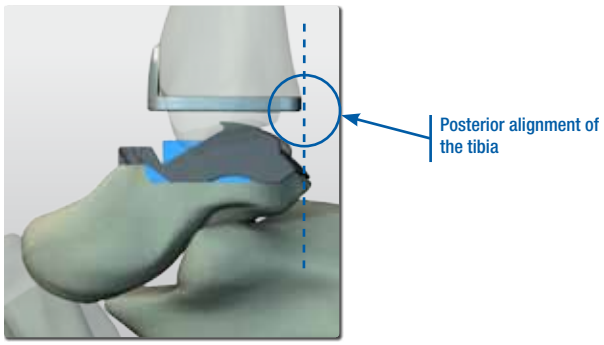
- The 5 mm trial inlay (119 665) is inserted and the Hintermann distractor is removed; if not enough soft tissue tension can be achieved, the 6 mm, 7 mm or 9 mm trials (119 666 / 119 667 / 119 669) are inserted.



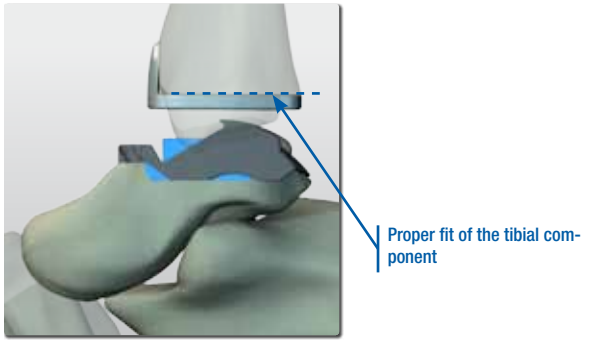
10.4 • Checking

- It is highly recommended to use fluoroscopy to check the position of implants while the foot is held in neutral position, particularly :

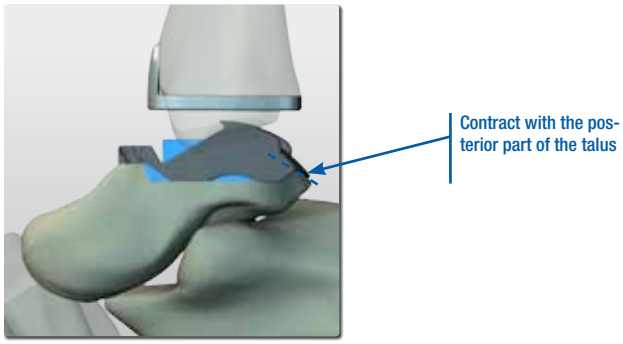
10.4a • Appropriate length of tibial component, i.e. its posterior border should be aligned with the posterior aspect of the tibia, thereby the tibial surface is fully covered.



10.4b • Proper fit of tibial component to the tibial surface.

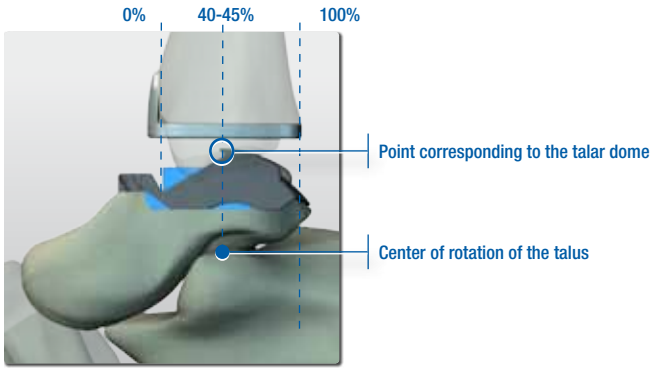


10.4c • Proper fit of the posterior edge of talar component to the posterior surface of the talus.



10.4d • Point of contact of talar component to the tibial component.

This contact point should be positioned between 40 and 45% of tibial component when the anterior border is taken as 0% and the posterior border as 100%, respectively. If the point of contact is too posterior, ligament balance would not be able to be achieved.

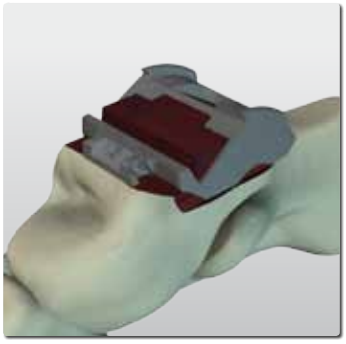


309 300-306
Talar drilling guide
(size 0 to 6)

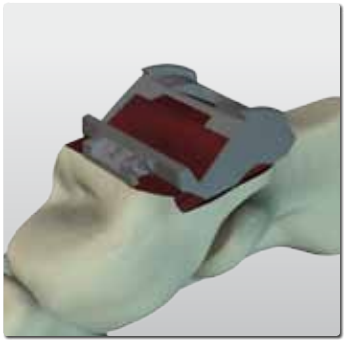
309 309
ø4.5 mm peg drill

11 • Anterior cut of the talus

- If proper position of the talar trial has been achieved, resection of the anterior surface of the talus is done, using a rongeur.
- The Hintermann distractor is mounted using the remaining k-wires.



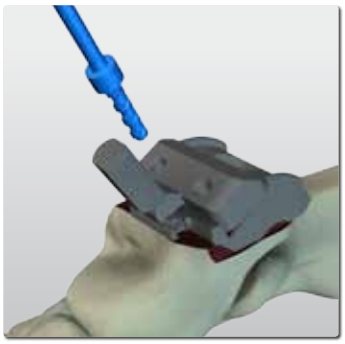
Anterior step to be resected



Resection completed

12 • Drilling of the pegs holes

- The talar drilling guide (same size as the talar trials: 309 300-306) is screwed to the talar trial still in place.
- 2 holes are made with the ø4.5 mm peg drill (309 309) .
  The assembly is then removed.



HINT

The bony surfaces are carefully checked. If there are any cysts, they should be removed with a curette, and filled with cancellous bone taken from the removed bony material. If sclerotic bone is left on the surfaces, drilling with a 2.0 mm drill is advised.

119 662
Implant holder

119 609
Talar impactor

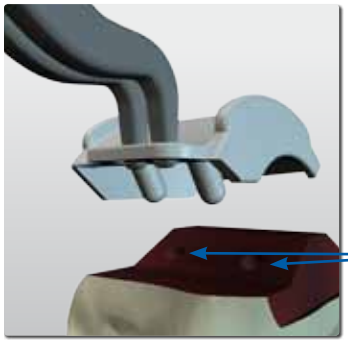
119 751
Tibial impactor

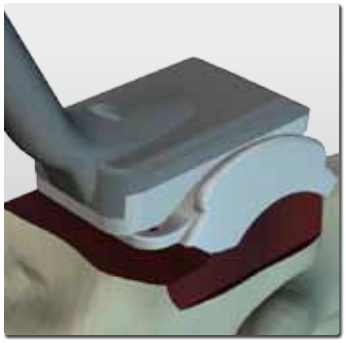
13 Implants insertion

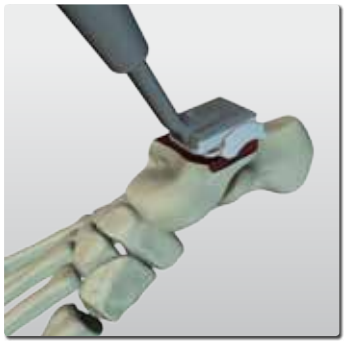
- The definitive implants are inserted as follows:

13.1 Talar component

- The talar component is implanted using the implant holder (119 662) such as the pegs can glide into the 2 holes; hammer and impactor (119 609) are used to get a proper fit of the component to the bone.





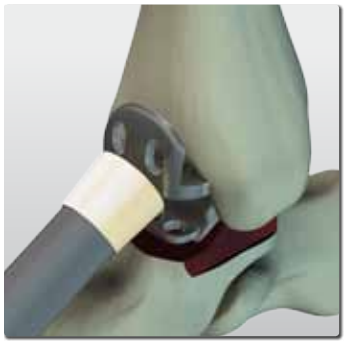


13.2 Tibial component

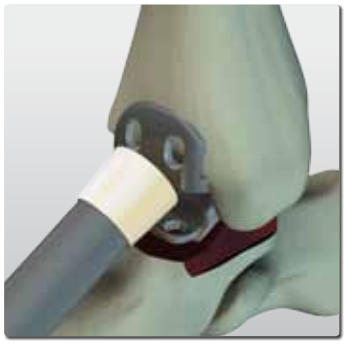
- The tibial component is inserted using the implant holder (119 662) along the medial malleolus until proper fit to the anterior border of the tibia is achieved. Hammer and impactor (119 751) might be used for impaction.

The impactor handle should be in an oblique position regarding the tibial component axis, in order to obtain a good contact between the tibial cut and the tibial component on the whole surface.

Before impaction

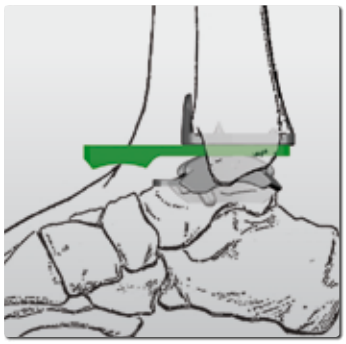


Impaction completed



HINT

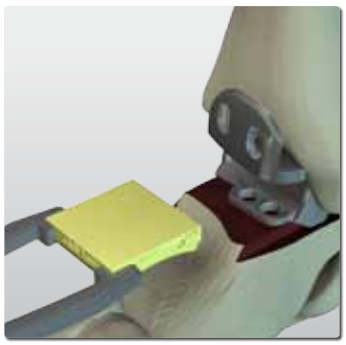
To avoid any contact between the metallic surfaces, retrograde insertion on the trial inlay is advised.

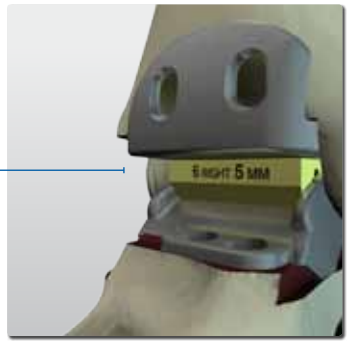


13.3 Inlay

- The inlay (same size as the talar component) is inserted; the implant holder may be used (309 661).

As the contact surface on the talus is conical, there is a difference between the radii on medial and lateral aspects of the talus. So adequate insertion of the inlay is mandatory! The markers for right and left ankle on anterior aspect of the inlay must be respected.





13.4 Checking

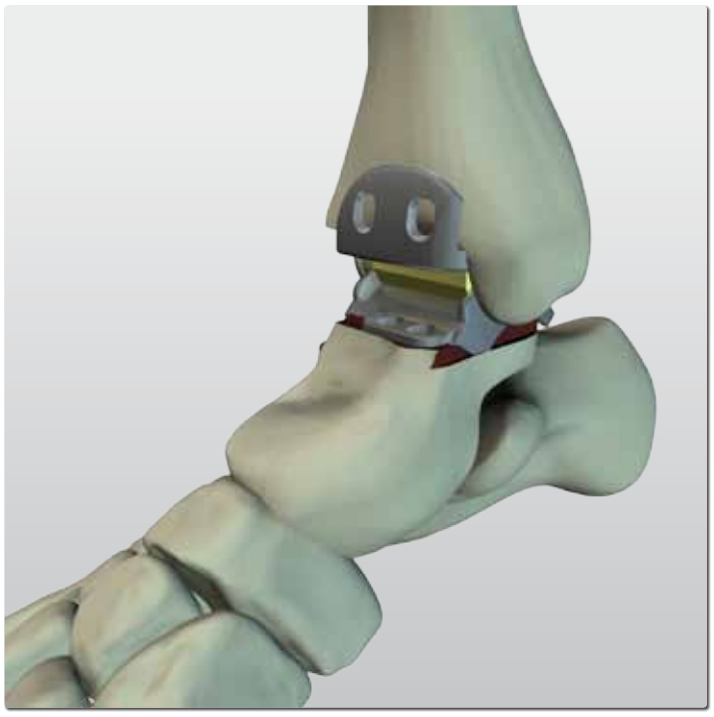
- The Hintermann distractor is removed, and achieved stability and motion are checked clinically.
- It is also highly recommended to check the position of the implants by fluoroscopy, as described for the trial implants. Please note that polyethylene inlays embed 2 metallic rods that can be seen fluoroscopically.

HINT

While the foot is moved in dorsiflexion with maximal strength, settling of the implant might be improved, and remaining soft tissue contracture on posterior aspect of the ankle might be released.

HINT

Fluoroscopy allows also to detect any remaining bony fragments or osteophytes that could be a potential source of pain or motion limitation.

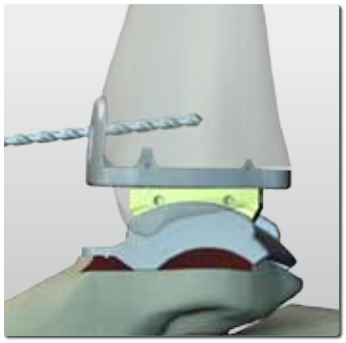


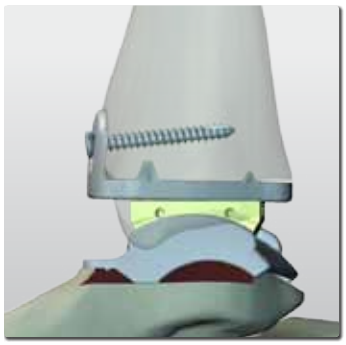
119 611
ø2.5 mm drill

159 127
ø2.7 mm drilling guide

14 Tibial Screw fixation (optional)

- Screw fixation of the tibia may be used if there is any doubt on enough stability against rotational and translational forces during the osteointegration process.
- The holes are drilled with the 2.5 mm drill (119 611) using the drilling guide ø2.7 mm (159 127).
- In order not to hinder the initial settling process of the implant, the holes are drilled at the cranial aspect of the 2 oval holes of tibial component, and slightly upwards.
- The screws are inserted and tightened until contact to the implant is obtained. Excessive tightening of the screws should be avoided in order not to create a tilting moment on the implant.





HINT

A controled trial of 120 cases has shown no evidence of increased primary stability with additional tibial screw fixation. (B. Hintermann, unpublished data).

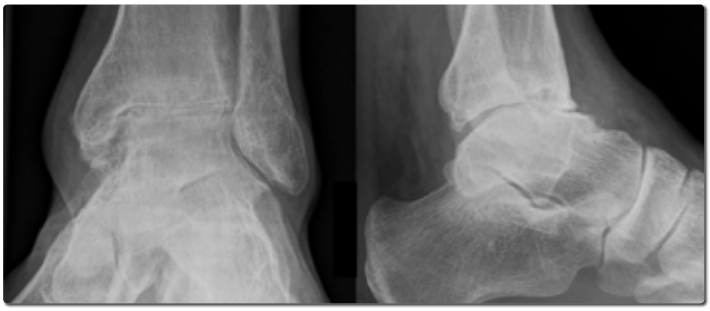
15 Wound closure

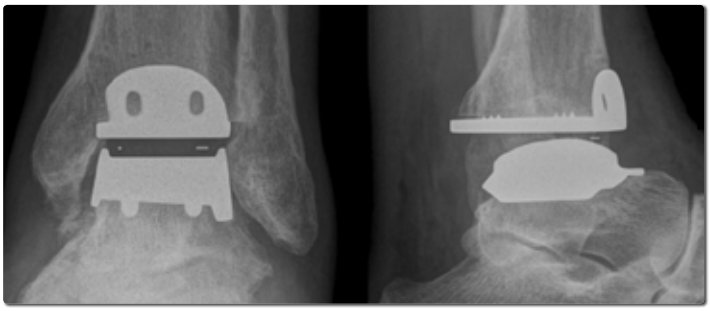
- Wound closure is obtained by suture of the tendon sheath and retinaculum, respectively, and the skin.
- Careful dressing is made to avoid any pressure to the skin.
- A splint is used to keep the foot in neutral position.

16 Postoperative care (Recommended by Prof. B. Hintermann, *Switzerland)*

- Dressing and splint are removed and changed after 2 days.
- When the wound condition is dry and proper, typically 2 to 4 days after surgery, the foot is placed in a stabilizing cast or walker that protect the ankle against eversion, inversion, and plantar flexion movements for 6 weeks.
- Weight bearing is allowed as tolerated. Usually, full weight bearing is achieved after 1 week.
- A rehabilitation program should be started for the foot and ankle after cast or walker removal, including stretching and strengthening of the triceps surae.
- First clinical and radiological control is made at 6 weeks, to check wound status, osteointegration and position of the implants.
- The patient should be advised to wear a compression stocking to avoid swelling for further 4 to 6 months.

Pre-op X-Ray





Post-op X-Ray (6 weeks)

Instructions for use

Hintegra® - Hintegra® SENSITIVE
STERILE MEDICAL DEVICES - SINGLE USE
In accordance with EEC directive 93/42 relative to medical devices, this product must be handled and/or implanted by WELL-TRAINED, QUALIFIED PERSONS, AWARE OF THESE DIRECTIONS FOR USE.

Description of the medical devices:

The Hintegra® and Hintegra® Sensitive Ankle prosthesis exist in different sizes. The prosthesis is composed of a tibial component, a talar component and an intermediary sliding core. Optional fixation screws are also provided.

Hintegra:
Both Hintegra® tibial and talar components are made out of Cobalt Chrome alloy (CoCr) according to NF ISO 5832-4 and ASTM F75, with a porous titanium and hydroxyapatite coating (Ti + HAP). The intermediary sliding core is made out of UHMW Polyethylene, according to ISO 5834-2 and ASTM F648.
Fixation screws are made out of stainless steel according to ISO 5832-9 and ASTM F1586.

Hintegra® Sensitive:
Both Hintegra® Sensitive tibial and talar components are made out of Cobalt Chrome alloy (CoCr) according to NF ISO 5832-4 and ASTM F75, with a Titanium Nitride coating (TiN) and with a porous titanium and hydroxyapatite coating (Ti + HAP).
Both Hintegra® Sensitive tibial and talar components must be used with the intermediary sliding core labeled « Hintegra® sensitive compatible »
The intermediary sliding core labeled « Hintegra® sensitive compatible »
is intended to be used with Hintegra® prosthesis and Hintegra® Sensitive prosthesis. It is made out of UHMW Polyethylene, according to ISO 5834-2 and ASTM F648 with X-rays markers made out of Titanium Alloy according to ISO 5832-3 and ASTM F136.
Fixation screws are made out of titanium alloy according to ISO 5832-3 and ASTM F136.
The tibial and talar components, as well as the intermediary sliding core, are delivered sterile.

Indications:

systemic caused arthritis of the ankle (e.g. rheumatoid arthritis, hemochromatosis)
primary arthritis (e.g. degenerative disease)
secondary arthritis (e.g. posttraumatic, infection, avascular necrosis*)
salvage for failed total ankle replacement**
salvage for non-union and malunion of ankle arthrodesis**
*if minimally 2/3 of the talus are preserved
**if bone stock is sufficient
The patient's joint must be anatomically and structurally suited to receive the selected implant(s).
The size 0 of both Hintegra® intermediary sliding core and talar components must not be implanted in a patient weighing more than 65 kilos.

Hintegra® sensitive :
The prosthesis Hintegra® Sensitive is designed to minimise the risks of allergies to chrome-cobalt alloy.

Contraindications

Relative Contraindications:
•severe osteoporosis
•immunosuppressive therapy.
Absolute Contraindications:
•infection
•high demanding sport activivities (e.g. contact sports, jumping)
•suspected or documented metal allergy or intolerance
•avascular necrosis of the talus/tibia of > 1/2
•evere malalignment*
•severe instability*
•diabetic syndrom
**if not surgically correctale*

The size 0 of both Hintegra® intermediary sliding core and talar components must not be implanted in a patient weighing more than 65 kilos.

Warnings:

Serious post-operative complications may occur from use of the implant in a patient who:
•Lacks good general physical condition;
•Has severe osteoporosis;
•Demonstrates physiological or anatomical anomalies ;
•Has immunological responses, sensitisation, or hypersensitivity to foreign materials;
•Systemic or metabolic disorders;
•Moreover, joint replacement may be contraindicated where there is severe deformity.

Precautions for use:

Physician must determine if implant is appropriate for patients who have any of the following conditions:
•Drug and/or alcohol and/or smoke addiction and/or abuse;
•Infectious disease;
•Malignancy;
•Local bone tumors;
•Systemic or metabolic disorders or replacement;
•Compromised wound healing;
•Obesity;
•Demonstrated psychological instability, displayed a lack of understanding, inappropriate motivation, or attitude;
•Unwillingness to accept the possibility of multiple surgeries for revision or replacement;
•Lacks an understanding that a metallic implant is not as strong as normal healthy bone and will bend, loosen, or fracture if excessive demand is placed on it;
•Lacks an understanding that their preoperative capacity may not be fully recovered even after successful implantation;
Care must be taken that the correct and appropriate size implant is used in conjunction with the correct instrumentation and trial components. Definitive implants and trial components manufactured by Newdeal must not be used in conjunction with those of any other manufacturer as component parts may not be compatible.
Knowledge of surgical techniques, proper reduction, selection and placement of implants, and post-operative patient management are considerations essential to a successful outcome.
Criteria for patient selection is the responsibility of the surgeon. Information contained within this document should be taken into consideration during the selection process. Recognition of the appropriate indications and contraindications and the selection of the proper surgical procedures and techniques determined to be best for the patient are the responsibility of the surgeon. Each surgeon must evaluate the appropriateness of the procedure and instruments used during the procedure based on his or her own training and experience.
The surgeon should discuss with the patient prior to surgery possible risks, precautions, warnings, consequences, complications, and adverse reactions associated with the surgical procedure and implantation of the device.
Each patient must be evaluated by the surgeon to determine the specific risk/benefit relationship in light of the patient's condition and the surgeon's practice, training, experience, and knowledge of the related medical literature.
Complications with the use of joint prosthesis have been reported in the medical literature. Any patient undergoing a surgical procedure is subject to intra-operative and post-operative complications. Each patient's tolerance to surgery, medication, and implantation of a foreign object may be different.
Possible risks, adverse reactions, and complications associated with surgery and the use of the prosthesis should be discussed with and understood by the patient prior to surgery. The implant are composed either of cobalt-chromium alloy with a porous titanium and hydroxyapatite coating, or of high density polyethylene ; therefore, it is subject to possible reactions and complications, including those listed herein. The choice between the use of Hintegra® prosthesis and Hintegra® Sensitive prosthesis is determined by the surgeon.
The patient should not be led to unrealistic expectations as to the performance or results that the surgery and implant can provide.
The patient should be informed that the life expectancy of the device is unpredictable once implanted, and that successful results cannot be guaranteed.
IT IS THE RESPONSIBILITY OF THE SURGEON TO PROVIDE THE PATIENT WITH INFORMATION PRIOR TO SURGERY.
Complications may include but are not limited to:
•Pain, discomfort, or abnormal sensations due to presence of the implant ;
•Bending, loosening , and/or breakage ;
•Risk of additional injury from post-operative trauma ;
•Migration of the implant position or implant material resulting in injury ;
•Bone loss due to stress shielding ;
•Side effects may include but are not limited to:
•Infections ;
•Hematoma ;
•Allergy ;
•Thrombosis ;
•Bone non union or delayed union .
Adverse effects may necessitate re-operation, revision or removal surgery, arthrodesis of the involved joint, and /or amputation of the limb.
Implant removal should be followed by adequate postoperative management to avoid fracture or re-fracture.
Interference risks during medical imaging:
MRI/SCANNER: ask the patient to systematically mention that he/she has undergone a surgical intervention at the foot level.

Use of the implant:

The tibial and talar components, as well as the intermediary sliding core are sold sterile.
Check packaging and labelling integrity before use. The sterility is guaranteed as long as the packaging has not been damaged (film scratched, label missing, questionable packing…) and before the end of the sterility validity.
Do not use any implant for which the packaging has been opened or damaged outside the operating theatre.
Inner packaging should be handled under sterile conditions (persons/instruments).
The surgeon must use the instrumentations recommended in accordance with the operative technique available from the manufacturer. The medical device must be used in compliance with the use of the profession and the standard of art.
Careful preoperative planning on the basis of radiographic findings should be carried out routinely. Radiographic templates are available for that purpose.
Do not attempt a surgical procedure with faulty, damaged or suspect instruments or implants. Inspect all components preoperatively to assure utility.
An adequate inventory of sterile implant sizes should be on hand at the time of surgery to ensure the optimum size for the patient.
Alternative fixation methods should be available intraoperatively.
Opening of the instruments set must be done according to aseptic condition.
When handling the implants, avoid any contact with other material or tools which may damage the implant surface. Under no circumstances should the implant be modified HA coated implant should not be implanted with cement.

Re-use of the implants:

Orthopaedic implants already implanted must never be re-used. The company accepts no responsibility for such re-use.

Re-sterilization of non implanted products:

Re-sterilisation is not allowed.

Preventative actions for the patient to avoid post-operative complications:

Avoid extreme position such as flexion-extension
Wear external immobilisation (plaster, splint…) according to the surgeon's prescription.
receive prompt medical attention for any infection that could occur, whether at the operated-member level or elsewhere in the body.
The patient should be encouraged to report to his/her surgeon any unusual changes of the operated extremity. If evidence suggests loosening of the implant (particular pain and progressive changes in the radiographs) an intensified schedule of check-ups is advised and new warning and instructions to the patient may be appropriate regarding further activity restrictions. In every case, accepted practices should be followed in postoperative care.
Excessive physical activity and trauma affecting the operated extremity have been implicated in the premature failure of joint arthroplasty as a result of position change, fracture and/or wear and tear of the implant. The functional life expectancy of prosthetic implants is at present not clearly established.

Storage:

Store in dry place

Product information disclosure / Liability:

Newdeal, an Integra LifeSciences Company, has exercised reasonable care in the selection of materials and the manufacture of these products and warrants that the products are free from manufacturing defects. Newdeal excludes all warranties, whether expressed or implied, including but not llimited to, any implied warranties of merchantability or fitness for a particular purpose. Newdeal shall not be liable for any accidental or consequential, loss, damage or expense, directly or indirectly araising from use of this product. Newdeal neither assumes nor authorizes any person to assume for it any other or additionnal liability or responsability in connection with these products. Newdeal intends that this device should be used only by physicians having received proper training in orthopedic surgery technique for use of the device.

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

INFORMATION: Should any information regarding the products or their uses be required, please contact your representative or distributor or directly contact the manufacturer.

References

Containers

Reference	Description
309 902	**STAINLESS STEEL BASE UPPER**
including	
309 920	GENERIC BASE
309 940	PINS INSERT
309 942	LID PINS INSERT

Containers

Reference	Description
309 904	**STAINLESS STEEL BASE LOWER**
including	
309 960	TALAR BASE
309 980	THERMO INSERT TRIAL IMPLANTS
309 970	LID TRIAL IMPLANTS
996 350	LID STAINLESS STEEL BASE

Containers

Reference	Description
309 900	**CONTAINER HINTEGRA**
including	
996350	LID STAINLESS STEEL BASE
309902	STAINLESS STEEL BASE UPPER
309904	STAINLESS STEEL BASE LOWER

Talar instruments for Hintegra® ankle-prosthesis

Reference	Description
119609	TALAR IMPACTOR
309200	REAMER TALAR DIA. 6MM
309300	DRILLING GUIDE TALUS - SIZE 0
309301	DRILLING GUIDE TALUS - SIZE 1
309302	DRILLING GUIDE TALUS - SIZE 2
309303	DRILLING GUIDE TALUS - SIZE 3
309304	DRILLING GUIDE TALUS - SIZE 4
309305	DRILLING GUIDE TALUS - SIZE 5
309306	DRILLING GUIDE TALUS - SIZE 6
309309	PEG DRILL TALUS - DIA. 4.5MM
309360	TAL. CUT. GUIDE RIGHT - SIZE 0
309361	TAL. CUT. GUIDE RIGHT - SIZE 1
309362	TAL. CUT. GUIDE RIGHT - SIZE 2
309363	TAL. CUT. GUIDE RIGHT - SIZE 3
309364	TAL. CUT. GUIDE RIGHT - SIZE 4
309365	TAL. CUT. GUIDE RIGHT - SIZE 5
309366	TAL. CUT. GUIDE RIGHT - SIZE 6
309370	TAL. CUT. GUIDE LEFT - SIZE 0
309371	TAL. CUT. GUIDE LEFT - SIZE 1
309372	TAL. CUT. GUIDE LEFT - SIZE 2
309373	TAL. CUT. GUIDE LEFT - SIZE 3
309374	TAL. CUT. GUIDE LEFT - SIZE 4
309375	TAL. CUT. GUIDE LEFT - SIZE 5
309376	TAL. CUT. GUIDE LEFT - SIZE 6
309656	CUTTING BLOCK TALAR CUT - STANDARD / MEDIUM
309657	CUTTING BLOCK TALAR CUT - SMALL
309697	HOLDER TRIAL TALAR IMPLANT
309699	IMPACTOR TRIAL TALAR IMPLANT

Tibial instruments for Hintegra® ankle-prosthesis

Reference	Description
119 611	DRILL DIA. 2.5 MM x L.150 MM
119 641	CUTTING GUIDE TIBIAL REVISION
119 751	TIBIAL IMPACTOR
159 127	DRILLING GUIDE DIA. 2.7MM
309 601	SCREWDRIVER TIBIAL SCREWS
309 607	DEPTH GAUGE TIBIAL
309 615	ALIGNMENT ROD TIBIAL
309 620	CONNECTOR V - TIBIAL ROD
309 625	TIBIAL V POSITIONING
309 630	TIBIAL POSITIONNING V
309 635	TIB. CUT. GUIDE LARGE
309 636	TIB. CUT. GUIDE STANDARD / MEDIUM
309 637	TIB. CUT. GUIDE SMALL
309 753	CUTTING BLOCK PROXIMAL - TIBIAL
309 773	CUTTING BLOCK DISTAL - TIBIAL

Other instruments for Hintegra® ankle-prosthesis

Reference	Description
115 116	K-WIRE 1 SHARP 1 BLUNT DIA. 1.6mm L. 150mm
115 225	K-WIRE 1 SHARP 1 BLUNT DIA. 2.5mm L. 200mm
119 662	TIBIAL - TALAR HOLDER
119 664	HINTERMANN® DISTRACTOR BIG MODEL
309 604	PINS L. 30 MM
309 605	PINS L. 70 MM
309 606	PINS L. 45 MM
309 608	SPACER H. 12 MM
309 622	SAW BLADE AESCULAP® ATTACHMENT
309 623	SAW BLADE AO SYNTHES® ATTACHMENT
309 624	SAW BLADE STRYKER® 6 ATTACHMENT
309 626	SAW BLADE STRYKER® ATTACHMENT
309 627	SAW BLADE CONMED LINVATEC® ATTACHMENT
309 645	SCREWDRIVER 3,5MM HEX
309 652	IMP / EXTRACT PINS
997 034	CURVED CHISEL 20MM R40MM
997 035	STRAIGHT CHISEL 10MM

HINTEGRA®
Total Ankle Prosthesis

Trial inlays

Reference	Description
119 665	TRIAL INLAY THICKNESS 5MM
119 666	TRIAL INLAY THICKNESS 6MM
119 667	TRIAL INLAY THICKNESS 7MM
119 669	TRIAL INLAY THICKNESS 9MM
309 661	HOLDER PE INLAYS

Hintegra® Corresponding PE inlays

Thickness	Talar size 0	Talar size 1	Talar size 2	Talar size 3	Talar size 4	Talar size 5	Talar size 6
5 mm	300 005	300 105	300 205	300 305	300 405	300 505	300 605
6 mm	300 006	300 106	300 206	300 306	300 406	300 506	300 606
7 mm	300 007	300 107	300 207	300 307	300 407	300 507	300 607
9 mm	300 009	300 109	300 209	300 309	300 409	300 509	300 609

Tibial trials and Hintegra® components

Trial	Component	Description
119 646	301 200	RIGHT - SIZE 0
119 690	301 201	RIGHT - SIZE 1
119 691	301 202	RIGHT - SIZE 2
119 692	301 203	RIGHT - SIZE 3
119 693	301 204	RIGHT - SIZE 4
119 694	301 205	RIGHT - SIZE 5
119 778	301 206	RIGHT - SIZE 6
119 647	302 200	LEFT - SIZE 0
119 695	302 201	LEFT - SIZE 1
119 696	302 202	LEFT - SIZE 2
119 697	302 203	LEFT - SIZE 3
119 698	302 204	LEFT - SIZE 4
119 699	302 205	LEFT - SIZE 5
119 779	302 206	LEFT - SIZE 6

Talar trials and Hintegra® components

Trial	Component	Description
309 680	301 110	RIGHT - SIZE 0
309 681	301 111	RIGHT - SIZE 1
309 682	301 112	RIGHT - SIZE 2
309 683	301 113	RIGHT - SIZE 3
309 684	301 114	RIGHT - SIZE 4
309 685	301 115	RIGHT - SIZE 5
309 686	301 116	RIGHT - SIZE 6
309 690	302 110	LEFT - SIZE 0
309 691	302 111	LEFT - SIZE 1
309 692	302 112	LEFT - SIZE 2
309 693	302 113	LEFT - SIZE 3
309 694	302 114	LEFT - SIZE 4
309 695	302 115	LEFT - SIZE 5
309 696	302 116	LEFT - SIZE 6

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