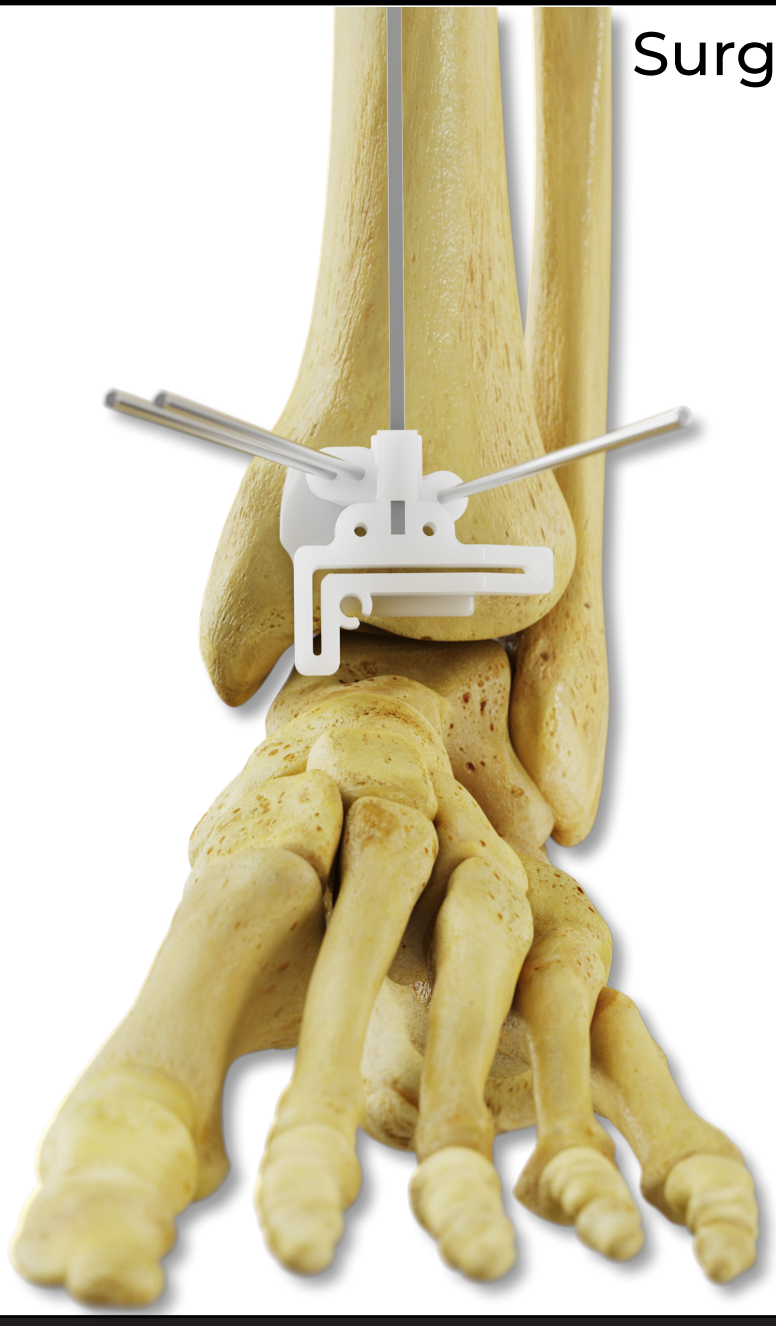
HINTERMANN SERIES H2®

Total Ankle Replacement Prosthesis with OPTIX Patient Specific Instrumentation

Surgical Technique



Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience. Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting Vilex, LLC or DT MedTech, LLC respectively.

The following information is intended for territories within the USA. Please consult with Vilex International, LLC for availability in territories outside the USA.

Table of Contents

Total Ankle Replacement Prosthesis

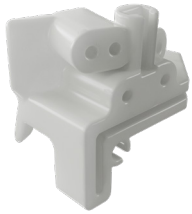
OPTIX® H2 Surgical Technique

Introduction

An Implant with a History of Clinical Excellence Paired with Custom-Made Instrumentation

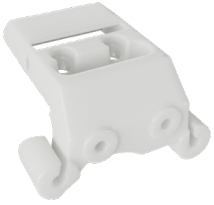
The OPTIX® H2 Patient Specific Instrumentation System is a set of patient-specific guides created to fit the contours of the patient's distal tibial and proximal talar anatomy. The guides and models are designed and manufactured from patient imaging data (CT) and are made from biocompatible nylon. The surgical guides in combination with Hintermann Series® reusable instruments, facilitate the positioning of the Hintermann Series H2® Total Ankle Replacement Implants. The OPTIX® H2 PSI System produces a variety of patient specific outputs including surgical guides, anatomic models, and case reports.

Patient Specific Guide Options



Tibial Guide
Description
PSI Tibia Cut Guide

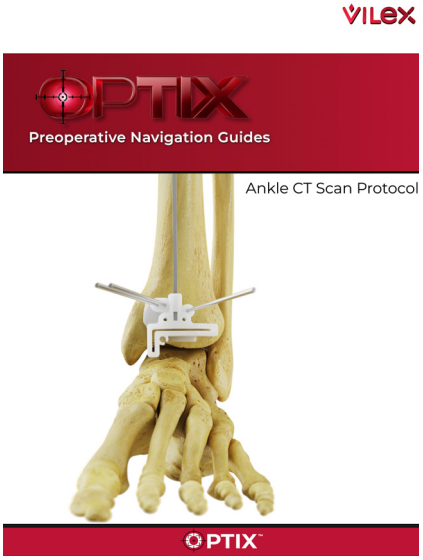
Talar Guide
Description
PSI Talus Cut Guide



Medial Lateral Talar
Description
PSI Chamfer M/L Cut Guide*
PSI Flat Cut M/L Cut Guide*
* Can be ordered individually or as a combination (one of each)

Scan Protocol

One significant requirement for a successful case is adhering to the OPTIX® Ankle CT Scan Protocol document. Engineers at Vilex, LLC have determined the necessary scanning parameters which are described in document #QSD-0100-01.



Hintermann Series H2® Surgical Technique

Implant Options

Tibial Component

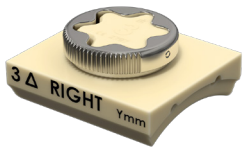
SIZE	THICKNESS OPTIONS		
1 LEFT	7MM	12MM	
2 LEFT	7MM	12MM	
3 LEFT	7MM	12MM	
4 LEFT	7MM	12MM	
5 LEFT	7MM	12MM	
1 RIGHT	7MM	12MM	
2 RIGHT	7MM	12MM	
3 RIGHT	7MM	12MM	
4 RIGHT	7MM	12MM	
5 RIGHT	7MM	12MM	

Standard Talar Component

SIZE	COATING OPTIONS*
0 LEFT	SINGLE
1 LEFT	SINGLE
2 LEFT	SINGLE
3 LEFT	SINGLE
4 LEFT	SINGLE
5 LEFT	SINGLE
0 RIGHT	SINGLE
1 RIGHT	SINGLE
2 RIGHT	SINGLE
3 RIGHT	SINGLE
4 RIGHT	SINGLE
5 RIGHT	SINGLE

Flat Cut Talar Component

SIZE	COATING OPTIONS*
1 LEFT	SINGLE
2 LEFT	SINGLE
3 LEFT	SINGLE
4 LEFT	SINGLE
5 LEFT	SINGLE
1 RIGHT	SINGLE
2 RIGHT	SINGLE
3 RIGHT	SINGLE
4 RIGHT	SINGLE
5 RIGHT	SINGLE



PE Inlay

SIZE	INLAY OFFSET OPTIONS		THICKNESS OPTIONS			
0 LEFT	ANTERIOR	NEUTRAL	5MM	6MM	7MM	9MM
1 LEFT	ANTERIOR	NEUTRAL	5MM	6MM	7MM	9MM
2 LEFT	ANTERIOR	NEUTRAL	5MM	6MM	7MM	9MM
3 LEFT	ANTERIOR	NEUTRAL	5MM	6MM	7MM	9MM
4 LEFT	ANTERIOR	NEUTRAL	5MM	6MM	7MM	9MM
5 LEFT	ANTERIOR	NEUTRAL	5MM	6MM	7MM	9MM
0 RIGHT	ANTERIOR	NEUTRAL	5MM	6MM	7MM	9MM
1 RIGHT	ANTERIOR	NEUTRAL	5MM	6MM	7MM	9MM
2 RIGHT	ANTERIOR	NEUTRAL	5MM	6MM	7MM	9MM
3 RIGHT	ANTERIOR	NEUTRAL	5MM	6MM	7MM	9MM
4 RIGHT	ANTERIOR	NEUTRAL	5MM	6MM	7MM	9MM
5 RIGHT	ANTERIOR	NEUTRAL	5MM	6MM	7MM	9MM

*US Market: Single-Coat / Outside US Market: Double-Coat)

Hintermann Series H2® Surgical Technique

Implant Features

Tibial Component

- Anatomical shape for minimized contact stress to the bone
- Minimal bone resection required
- Low profile anterior shield designed to provide rotational stability of tibial component and prevent scarring and bone formation that may hinder joint motion
- Titanium peaks designed for anchoring in subchondral bone toward increasing stability in translation and rotation
- Ti Plasma spray coating

Tibal Component

Sizes: 1, 2, 3, 4, 5
Thickness Options: 7mm & 12mm

Tray: Titanium Alloy Ti6Al4V AS® F136 & ISO 5832-3

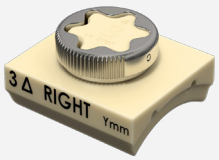
Slide: Titanium Alloy AS® F136/ PEEK AS® F2026

PE Inlay

- High congruency with the metal surfaces of both tibial and talar components
- Free sagittal plane motion on conically-shaped talar surface
- Large contact area with both tibial and talar components designed to provide:
  - low contact stresses
  - minimal wear
  - intrinsic stability against eversion-inversion forces
- X-ray Markers (Titanium Alloy Ti6Al4V)

PE Inlay

Sizes: 0, 1, 2, 3, 4, 5
Thickness Options: 5mm, 6mm, 7mm, 9mm
Offset Options: Neutral, Anterior



Inlay: Vitamin E Blended UHMWPE

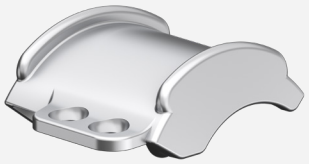
Ring & Pins: Titanium Alloy Ti6Al4V AS® F136

Talar Component: Standard and Flat Cut

- Anatomical shape (conical surface) designed:
  - To allow physiological talar motion
  - To minimize medial ligament stress
- Minimal bone resection required
- Anterior pegs designed to improve sagittal stability and positioning
- Medial and lateral rims designed to guide movement of the PE inlay
- Anterior shield designed to prevent ingrowth of osteophyte
- US Market: Ti Plasma spray coating
- OUS Market: Ti / HaP spray coating

Standard Talar Component

Sizes: 0, 1, 2, 3, 4, 5



Cobalt Chromiun Alloy (CoCr)
ISO 5832-4 & AS® F75

Flat Cut Talar Component

Sizes: 1, 2, 3, 4, 5

Cobalt Chromiun Alloy (CoCr)
ISO 5832-4 & AS® F75

OPTIX® H2 Surgical Technique

OPTIX® Indications & Contraindications

Indications

The OPTIX® H2 Patient Specific Instrumentation System is intended to be used as patient specific surgical planning and instrumentation to assist in the positioning of total ankle replacement components intraoperatively, and in guiding bone cutting. The OPTIX® H2 PSI System is intended for use with Vilex's Hintermann Series H2® Total Ankle Replacement Prosthesis and its approved indications for use. The OPTIX® H2 PSI System is indicated for single use only and is generated from CT imaging data.

Hintermann Series H2® Compatibility

The OPTIX® H2 PSI System is intended to aid with the bone preparation for the Hintermann Series H2® Total Ankle System. The procedure of the Hintermann Series H2® Total Ankle System begins with the proper positioning of the patient and the proper opening of the surgical site. These beginning steps are also followed to initiate the OPTIX® H2 PSI System. After these initial positioning and opening steps, the OPTIX® H2 PSI System Surgical Technique is followed to perform bone preparation of the Hintermann Series H2® implants.

The bone preparation of the OPTIX® H2 PSI surgical technique concludes when the talar resection has been completed. After the talar resection, the placement of the Hintermann Series H2® implants is followed per the surgical technique, beginning with the placement of the Talar Trial. After implantation has concluded, the surgeon should take anterior and lateral fluoroscopic images of the final implants to confirm correct final implant placement as compared to the virtual surgical plan.

Use of Hintermann Series H2® Instrumentation

A full set of Hintermann Series H2® Total Ankle System instruments should be prepped and ready for use with the OPTIX® H2 PSI System. The Hintermann Series H2® instruments will be used during the implantation of the H2 implants per the Hintermann Series H2® surgical technique since the OPTIX® H2 PSI System only aids in bone preparation for the implants, not implantation.

If the OPTIX® H2 PSI System (Tibia Cut Guide, Talar Cut Guide or the Medial Lateral Cut Guide) does not fit patient anatomy at any point during the surgical procedure, the surgeon should switch to the use of the traditional Hintermann Series H2® Total Ankle System Instrumentation for bone preparation.

Detecting and Remedying Incorrect Guide Alignment

The OPTIX® H2 PSI Guides should be placed according to the surgical technique provided in the surgical technique section of this document. After placement of each guide, the surgeon should take a fluoroscopic image of the placed guides, as described in the surgical technique. If the guides appear to be incorrectly aligned with patient anatomy as compared with the fluoroscopic images from the pre-surgical plan provided with the guides, the surgeon should attempt to reposition the guides to match the pre-surgical plan.

Before placement of the guides, the surgeon should ensure that all the bone is properly exposed, and soft tissue removed, per the surgical technique. If the OPTIX® cut guide still does not properly fit against patient anatomy, the surgeon should revert to the Hintermann Series H2® surgical technique, as described in the section "Use of Hintermann Series H2® Total Ankle System Instrumentation" of this document.

Detecting and Remedying Incorrect Surgical Outcomes

At the conclusion of the implantation of the Hintermann Series H2® implants, the positioning of the final implants should be confirmed using anterior and lateral fluoroscopic images of the final implants. These fluoroscopic images should be confirmed through comparison against the fluoroscopic images contained in the virtual surgical plan. The surgeon should reposition the final implants to match the virtual surgical plan. If further bone resection is needed for correct final implant placement, the surgeon should use the Hintermann H2 instrumentation as necessary.

Warnings

- To avoid serious injury, patient identification on guides and models must be verified and confirmed against patient identification prior to use.
- Guides and models are designed for a specific patient. To avoid the potential for serious injury, guides and models should not be modified in any way.
- To avoid potentially serious allergic reactions, ensure that the patient is not allergic to the materials used in the guides and models prior to use.
- Device(s) are single use only and designed for use with a specific patient only. Guides and models may be re-sterilized a single time but may not be re-used for additional surgical procedures.
- Prior to use of any OPTIX® H2 PSI System, the user must thoroughly review this instruction for use and all other labeling provided with the devices.
- The presence of any moisture on the wrap should be visually monitored. If any moisture is observed after 60 minutes, then the cycle is not considered sterile.
- Adequate training and familiarity with the Hintermann Series H2® implant system surgical technique is required, to avoid increased risk of device failure due to improper surgical technique.
- Switch to standard Hintermann Series® instrumentation if the device is dropped in the surgical suite. (Guides and models may be re-sterilized a single time but may not be re-used for additional surgical procedures.)
- Switch to standard Hintermann Series® instrumentation if the device does not fit patient anatomy or pre-existing metal interferes with device use.

Contraindications

The guides and models from the OPTIX® H2 PSI System and the associated case report should not be used if any of the following occur:

- Patient has an active infection.
- Significant changes to patient's anatomy have occurred since the medical scan used for product definition was obtained.
- Immunosuppressive therapy.
- Skeletal Immaturity.
- Inadequate bone stock including but not limited to severe osteoporosis or avascular necrosis.
- Malalignment or severe deformity of the involved anatomic structures.
- Charcot joint or peripheral neuropathy.
- Neuromuscular disease resulting in lack of normal muscle function about the affected ankle.
- Lower extremity vascular insufficiency demonstrated by Doppler arterial pressure.
- Poor skin and soft tissue quality about surgical site.
- Prior fusion or revision of total ankle replacement.
- High demanding sporting activities. (e.g., contact sports, jumping)
- Suspected or documented metal allergy or intolerance.

OPTIX® H2 Surgical Technique

Operative Guide

General Overview

Vilex, LLC, as the manufacturer of OPTIX® device, does not practice medicine and this surgical technique is a general recommendation for how to conduct this surgery. Vilex, LLC, as the manufacturer of Hintermann Series H2® device, does not practice medicine and this surgical technique is a general recommendation for how to conduct this surgery. 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 affected foot on the edge of the table.

The affected foot is maintained on a block to facilitate trea®ent of associated problems (e.g., subtalar arthrodesis, ligament reconstruction, and 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 12 cm in 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 the tibia are removed, particularly on the antero-lateral aspect.

Osteophytes on the talar neck and anterior aspect of the medial malleolus are also removed.

3. PSI Preparation & Labeling Verifications

Before proceeding, confirm the work order number, patient information, and left / right identifier on the Tibia, Talus, and Medial / Lateral Talus Cut Guides are correct on all OPTIX® guides. All necessary information is shown on the guides. **FIGURE 1**

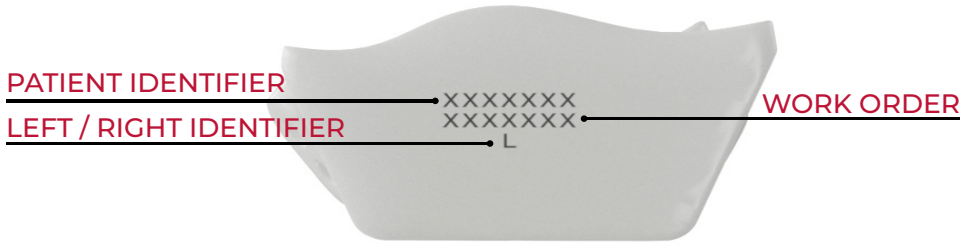


FIGURE 1

To aid in fluoroscopic imaging, perfect circle indicators and alignment pins may be prepared.

Optional: Prepare the Tibial Cut Guide (OX3-0002) by press-fitting the Perfect Circle Tibia Tube (OX-0007) into the guide. **FIGURE 2**

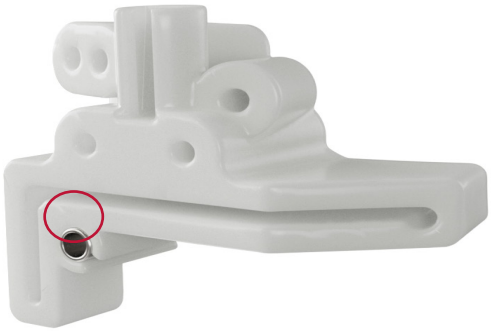


FIGURE 2

Optional: Prepare the Medial Lateral Talar Cut Guide (OX3-0006) by inserting the Talus Alignment Pin (OX-0008) into the lateral alignment pin hole. Ensure the alignment pin is inserted completely into the guide. **FIGURE 3.**

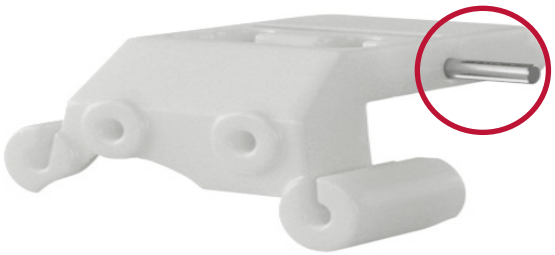
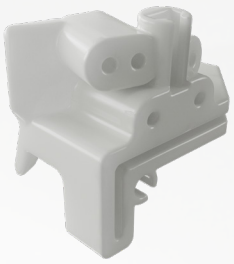


FIGURE 3

INSTRUMENTS USED

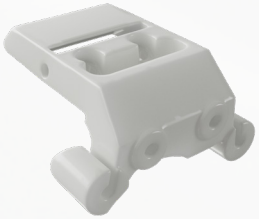


TIBIA CUT GUIDE

OX2-0002

PERFECT CIRCLE TIBIA TUBE

OX-0007



MEDIAL LATERAL TALUS CUT GUIDE

OX2-0006

TALUS ALIGNMENT PIN

OX-0008

Place the Tibia, Talus, and Medial / Lateral Talus Cut Guides against their respective anatomical models (OX2-0001, OX2-0003, OX2-0005) to confirm fi®ent and intended resection height. **FIGURE 4**

FIGURE 4

The Alignment Post is then assembled and inserted into the Tibial Cut Guide. To Prepare the Alignment Post, insert the Alignment Post (OX-0010) into the Alignment Connector (OX-0009). The Alignment Post assembly is inserted prior to radiographic imaging to aid in final alignment. **FIGURE 5**

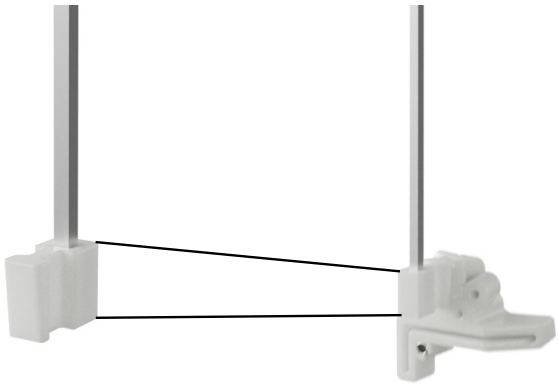


FIGURE 5

4. Tibial Resection

Ensure adequate dissection has been performed to accommodate a 0.5mm soft tissue tolerance. Place the Tibia Cut Guide (OX2-0002) in the best fit location, and visually confirm seating. **FIGURE 6**

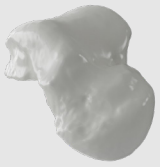
NOTE: Determining the best fit location may require applying pressure from multiple vectors and/or with two hands. Utilize the case report for visual reference of correct guide placement.

A 2.4mm K-Wire may be placed into the vertical alignment pin hole to aid with the fluoroscopic image.

INSTRUMENTS USED

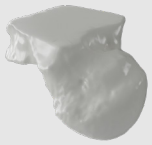
PSI TIBIA MODEL

OX2-0001



PSI TALUS MODEL

OX2-0003



PSI M/L TALUS MODEL

OX2-0005

ALIGNMENT POST

OX-0010

ALIGNMENT CONNECTOR

OX-0009

FIGURE 6

Place K-Wires (HT-39900) through the parallel wire holes of the Tibia Cut Guide for initial fixation of the device. **FIGURE 7**

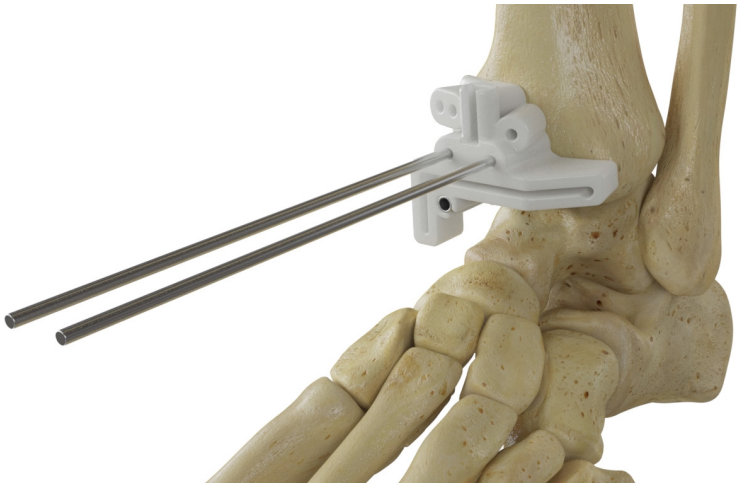


FIGURE 7

Place oblique fixation wires as desired to securely fixate the Tibia Cut Guide to the tibia. **FIGURE 8**

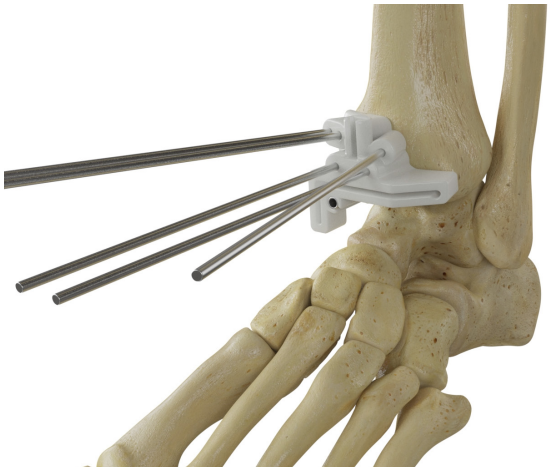
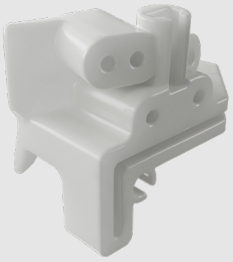


FIGURE 8

INSTRUMENTS USED



TIBIA CUT GUIDE

OX2-0002

2.4MM K-WIRE

HT-39900

Obtain an anterior fluoroscopic image to confirm placement of the guide matches the virtual surgical plan. Reposition the guide as necessary to match. Utilize the Alignment Post Assembly by inserting it in to the Tibial Cut Guide. The Perfect Circle Bushing may be used to aid in A/P view alignment. **FIGURE 9**

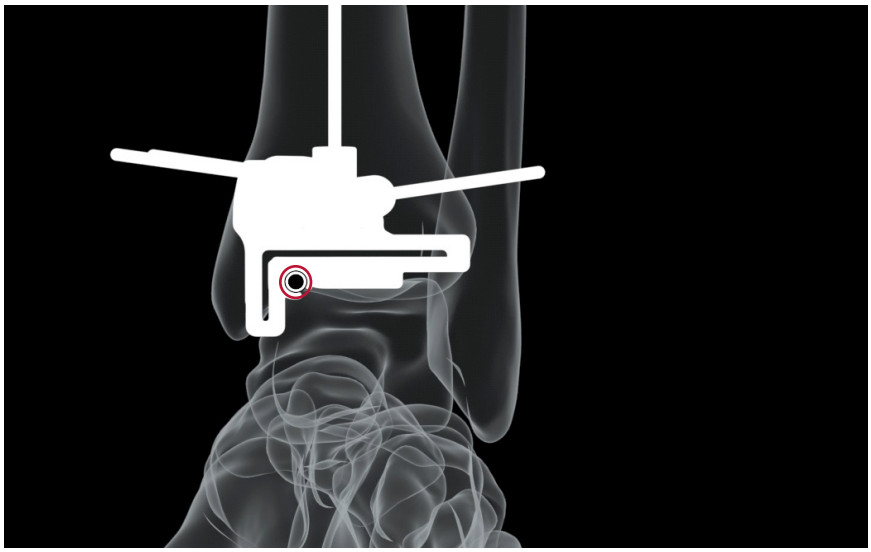


FIGURE 9

Insert the Angel Wing (HT-39952) into the slot of the Tibia Cut Guide. The Angel Wing should sit flush against the anterior surface of the guide.

Obtain a lateral fluoroscopic image to confirm the height and location of the tibia cut match the virtual surgical plan. Reposition the guide as necessary to match the virtual surgical plan. **FIGURE 10**

NOTE: The vertical Alignment Post is designed with 2° offset to accommodate soft tissue of the patient.

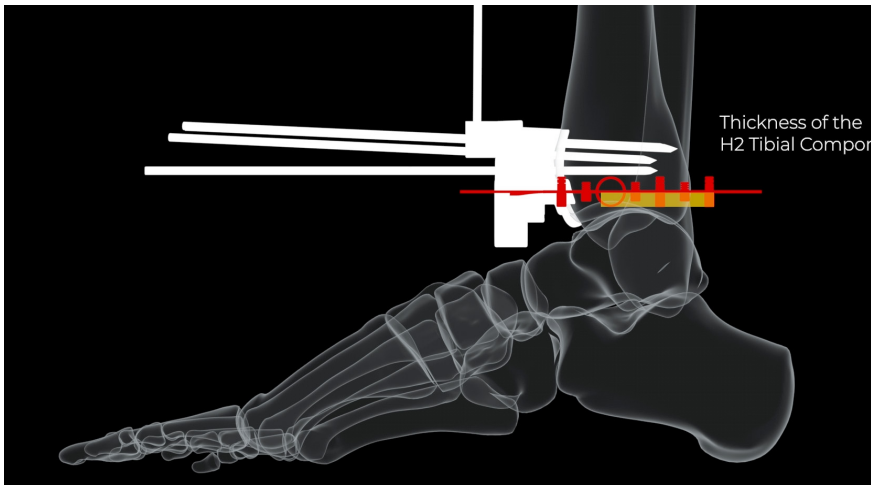


FIGURE 10

INSTRUMENTS USED

ANGEL WING

HT-39952

Place medial and lateral limit K-Wires into the Tibia Cut Guide to protect the Medial and Lateral Malleolus during resection. **FIGURE 11**

FIGURE 11

Cut the distal tibia using an oscillating saw, taking care not to penetrate through the posterior capsule where the neurovascular bundle is located. A small reciprocating saw may be used to cut the bone along the medial slot.

Remove all wires, and the Tibia Cut Guide from the tibia. Remove any generated bone debris. Remove the resection tibial bone.

NOTE: In the event that the OPTIX® Cut Guides do not fit appropriately on patient anatomy, the Hintermann Series H2® standard instruments should be used to perform the cuts.

5. Talar Resection

Ensure adequate dissection has been performed to accommodate the Talus Cut Guide (OX2-0004). Place the Talus Cut Guide in the best fit location. Visually confirm the Guide is seated evenly around the talus perimeter. **FIGURE 12**

FIGURE 12

INSTRUMENTS USED

TALUS CUT GUIDE

OX2-0004

NOTE: Determining the best fit location may require applying pressure from multiple vectors and/or with two hands. Use the case report for visual reference of correct guide placement.

Place K-Wires (HT-39900) through the Parallel Pin Holes of the Talus Cutting Guide for initial fixation of the device. **FIGURE 13**

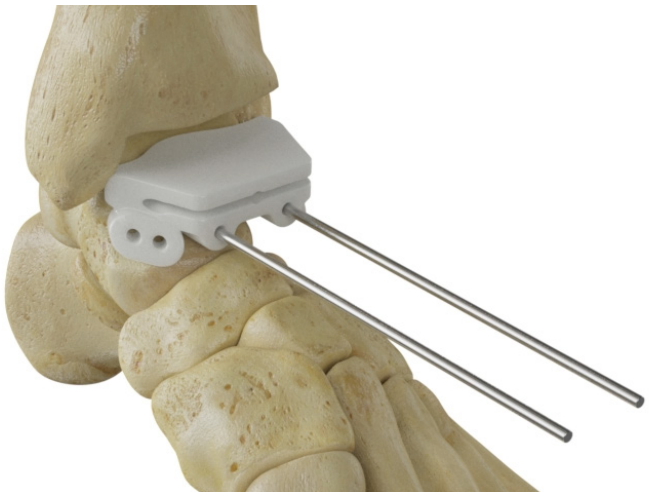


FIGURE 13

Place oblique fixation pins as needed for fixation on both the medial and lateral sides of the Talar Cut Guide. **FIGURE 14**

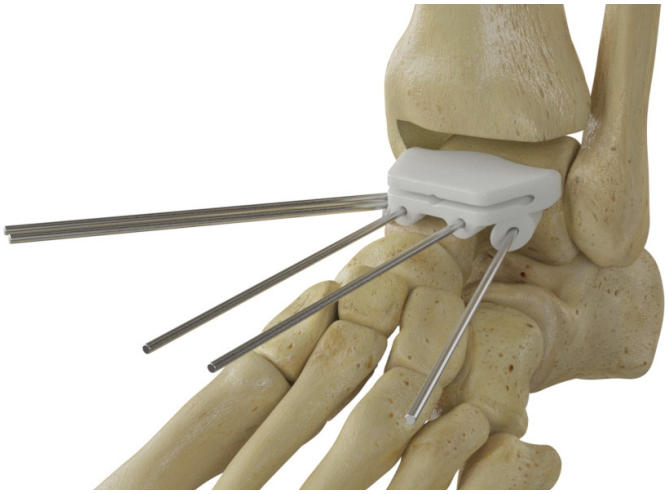


FIGURE 14

Obtain an anterior fluoroscopic image to confirm placement of the guide matches the virtual surgical plan.

Insert a K-Wire through the anterior slot of the Talar Cut Guide to aid in view alignment. **FIGURE 15**

INSTRUMENTS USED

K-WIRES

HT-39900

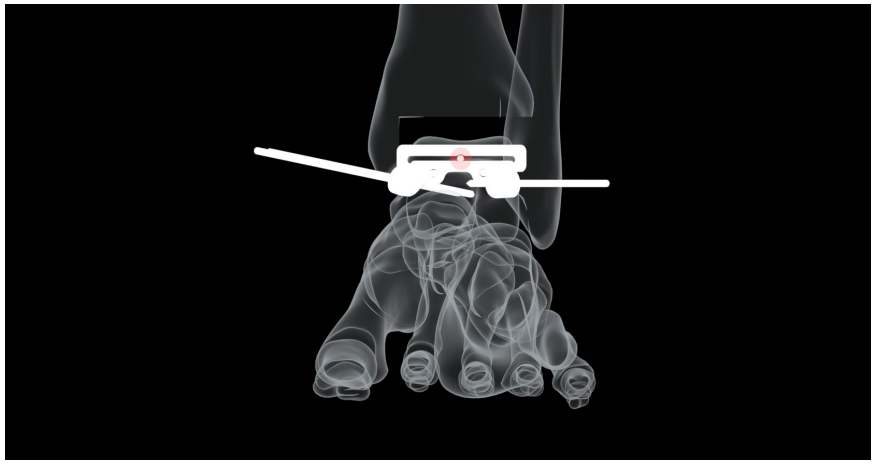


FIGURE 15

Insert the Angel Wing into the slot of the Talus Cutting Guide. The Angel Wing should sit flush against the anterior surface of the guide.

Obtain a lateral fluoroscopic image to confirm the height and location of the talus cut match the virtual surgical plan. Reposition the guide as necessary to match the plan. **FIGURE 16**

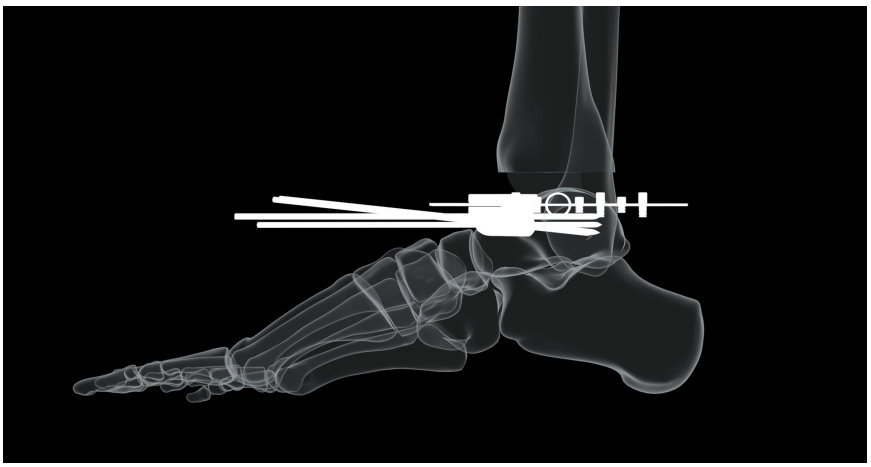


FIGURE 16

Remove the Angel Wing from the guide. Place the medial and lateral resection limit wires. **FIGURE 17**

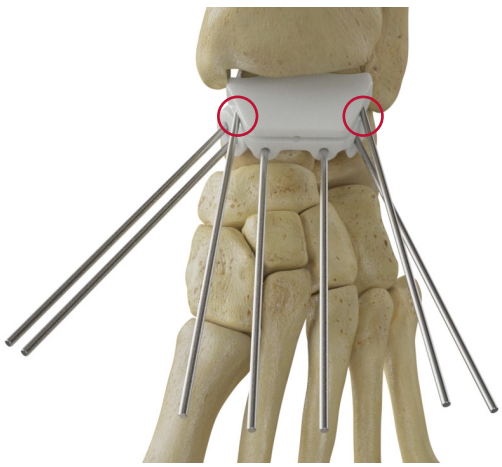


FIGURE 17

INSTRUMENTS USED

ANGEL WING

HT-39952

K-WIRE

HT-39900

Perform the talar cut with the oscillating saw. Leaving the talus parallel pins fixated to the talus, remove all other pins from the talus.

Carefully remove the Talus Cut Guide by sliding it off the talus parallel wires, keeping the parallel wires in place. Remove resected anatomy from the joint space. **FIGURE 18**

FIGURE 18

6. Chamfer Cut Talar Finishing

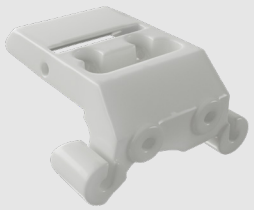
The Chamfer Cut Talar Resection technique preserves more talar bone stock than the Flat Cut Talar Resection technique.

If there is not enough bone stock left for shaping the contours as described in this section (e.g., insufficient bone stock as a result of severe flattened deformity of the talar dome, removal of large cystic or necrotic bone or, multiple cuts to talus intra-operatively), the Flat Cut Talar Component may be used. Refer to Section 13 (PAGE 26) for instructions for implanting the Flat Cut Talar Component utilizing the Flat Cut Talar Cut Block, Flat Cut Talar Trials, and the Flat Cut Talar Component.

Place the Medial / Lateral Talus Cut Guide over the remaining talus parallel wires. **FIGURE 19**

FIGURE 19

INSTRUMENTS USED



M/L TALUS CUT GUIDE

OX2-0006

Ensure the Medial / Lateral Talus Cut Guide is fully seated. Obtain a lateral fluoroscopic image to confirm the location of the medial / lateral talus cut guide matches the virtual surgical plan. Use the lateral Alignment Pin as a reference for the Lateral Process of the Talus. Reposition the guide as necessary to match the plan. **FIGURE 20**

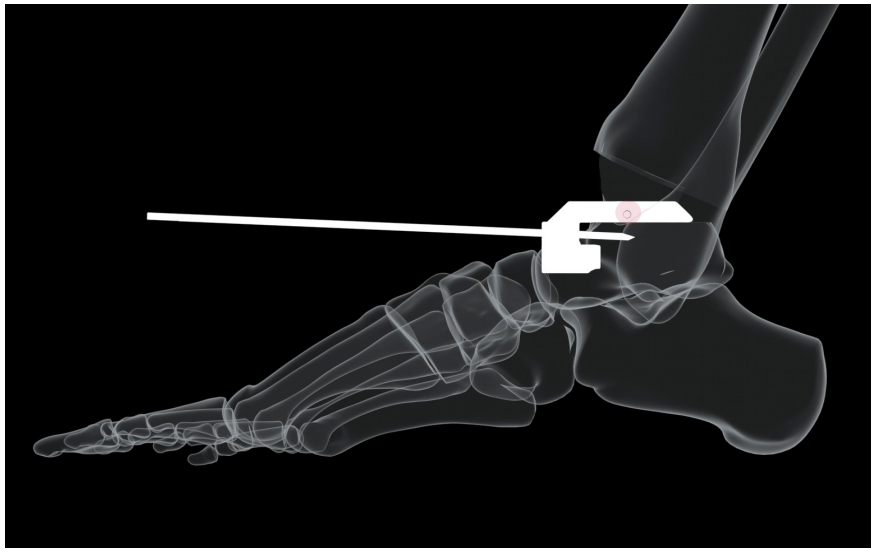


FIGURE 20

Place medial and lateral limit pins to finalize the placement of the guide and remove the talus parallel wires. After removing the wires, for additional fixation, Quick Screws (HT-39731) may be inserted through the guide utilizing the Quick Screw Driver (HT-39730). **FIGURE 21**

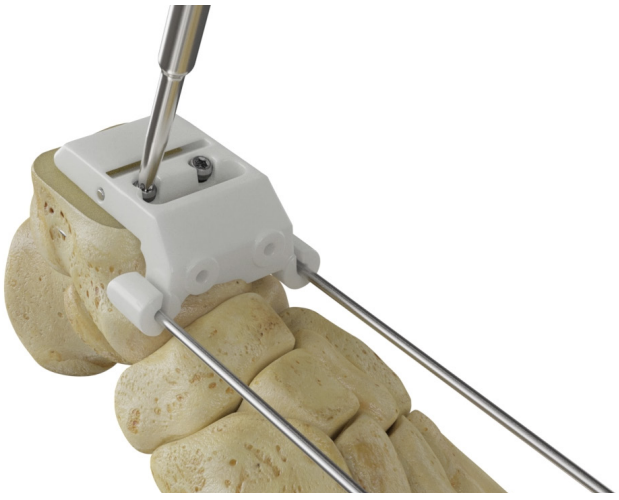


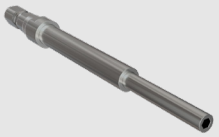
FIGURE 21

Once fixated, mill the anterior portion of the talus with the Talar Reamer (HT-39710). **FIGURE 22**

INSTRUMENTS USED

QUICK SCREW

HT-39731



QUICK SCREW DRIVER

HT-39730

TALAR REAMER

HT-39710

FIGURE 22

Utilizing and oscillating saw to chamfer the posterior portion of the talus. Finally, take a reciprocating saw down the medial and lateral sides of the guide to finish talus preparation. **FIGURE 23**

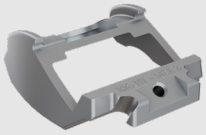
FIGURE 23

Remove the Quick Screws by utilizing the Quick Screw Driver. Remove the limit pins. Remove the Medial Lateral Talus Cutting Guide. Perform a standard pulsed lavage of the incision site to remove any potential debris generated from cut guides.

7. Anterior Cut of the Talus

The corresponding sized Talar trial (HT-3931X for the right side/ HT-3932X for the left side) is inserted using the Talar Trial Impactor (HT-39370). The window on the posterior aspect of the trial allows verification of proper fit to the posterior resected surface of the talus. **FIGURE 24**

INSTRUMENTS USED



TALAR TRIAL

HT-393XX

TALAR TRIAL IMPACTOR

HT-39370

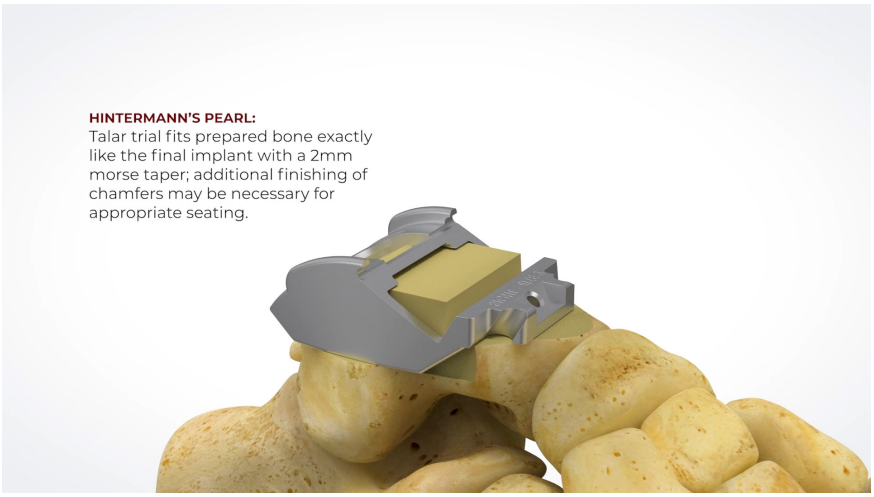


FIGURE 24

Care must be taken to avoid posterior displacement of the trial component while impacting. If proper seating 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.

If proper position of the Talar Trial has been achieved, resection of the anterior surface of the talus is performed either with the oscillating saw using a feathering technique or by attaching the Anterior Mill Window Guide (HT-39400) by aligning the knob and turning it clock-wise. Ream through the slots with the Talar Reamer (HT-39710). **FIGURE 25**

The Hintermann Distractor (HT-39005) may be used to distract the joint for visualization.

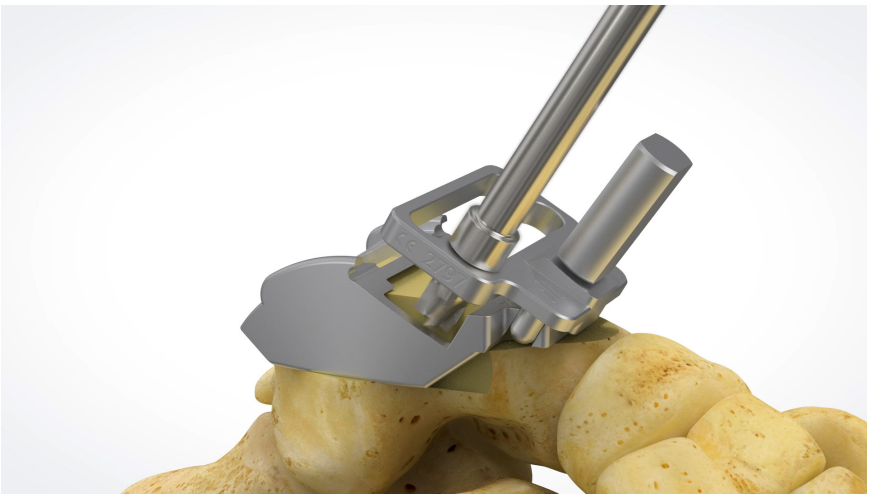


FIGURE 25

Remove the Anterior Mill Window Guide by turning the knob counter-clockwise. Do not remove the Talar Trial.

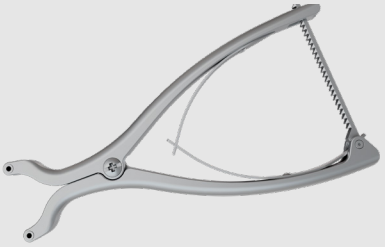
INSTRUMENTS USED

ANTERIOR MILL WINDOW

HT-39400

TALAR REAMER

HT-39710



HINTERMANN DISTRACTOR

HT-39005

8. Drilling of the Peg Holes for Chamfer Implant

The Talar Drilling Guide (same size as the talar trials: HT-3941X) is fixed to the Talar Trial by aligning and turning the knob clockwise.

Using the guide, 2 holes are drilled with the 4.5 mm Peg Drill (HT-39711) until the shoulder of the peg drill meets the drill guide surface. **FIGURE 26**

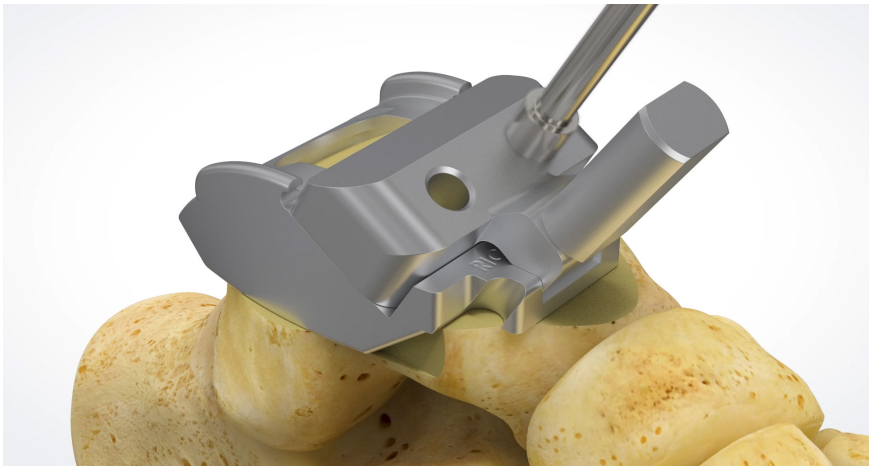


FIGURE 26

The assembly is then removed.

NOTE: 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.

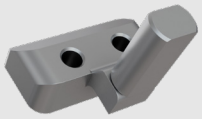
9. Tibial & Talar Implant Insertion

After removing the Hintermann Series Distractor, the definitive implants are inserted as follows:

First take care to align the 2 Talar Component pegs with the created drill holes. The implant is first impacted using a mallet and the Talar Impactor (HT-39430) anteriorly to fully seat the implant pegs. Then impact the posterior aspect to fit of the component to the bone. **FIGURE 27**

FIGURE 27

INSTRUMENTS USED



TALAR DRILL GUIDE

HT-3941X

4.5MM PEG DRILL

HT-39711

TALAR IMPACTOR

HT-39430

The Tibial Component is inserted along the medial malleolus until proper fit to the anterior border of the tibia is achieved.

The implant is impacted using a mallet and the H2 Tibial Impactor (HT-39502) to ensure a proper fit of the component to the bone. Ensure that the Tibial Component and Talar Component do not touch during insertion to avoid implant scratching. **FIGURE 28**

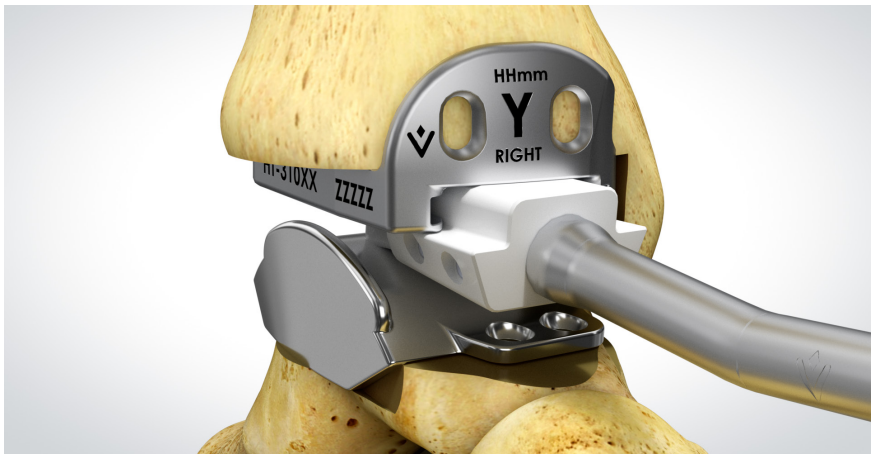


FIGURE 28

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

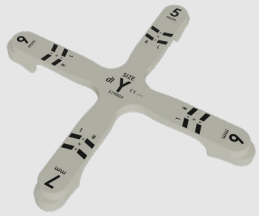
NOTE: To avoid any contact between the metallic surfaces, retrograde insertion on the trial inlay is advised. The Straight Tibial Impactor (HT-39503) may also be used to help fully seat posterior aspect of the tibial tray. When inserted, axial pressure to heel may be applied to push up on the tibial tray. Check with fluoroscopy, if necessary.

10. Inlay Trial & Insertion

The 5 mm H2 Offset Measurement Tool of the corresponding Talar Implant Size (HT-3954X) is inserted. If sufficient soft tissue tension cannot be achieved, the 6 mm, 7 mm, or 9 mm trial inlay sides can be used which would correspond to the implant thickness chosen to complete the implantation. **FIGURE 29**

FIGURE 29

INSTRUMENTS USED



H2 OFFSET MEASUREMENT TOOL

HT-3954X

H2 TIBIAL IMPACTOR

HT-39502

STRAIGHT TIBIAL IMPACTOR

HT-39503

Extend and plantar flex the foot a few cycles to ensure proper size.

The Trial Inlay Offset Measurement Tool (HT-39541-HT-3945) is also used to verify the relative anterior/neutral position of the talar and tibial implants.

In order to determine the relative (anterior/posterior) position of the Talar and Tibial Component and to choose the appropriate PE Inlay (neutral or anterior), lateral fluoroscopy of the joint should first be taken with the foot in maximal dorsiflexion, before taking the measurement.

The following letters are used on the tool to indicate offset measurement: (A) Anterior Position **or** (N) Neutral Position **FIGURE**

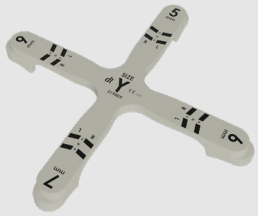
Ex: Neutral Position Offset

FIGURE 30

The inlay (size matched to the talar component) is selected and loaded onto the Poly Inserter (HT-39951). To load the inlay on the poly inserter, ensure that the red, center nut is in the front position (closer to the metal grasp). Press the top button of the Poly Inserter to open to metal grasp on the inserter. Align the notches on the inlay with the pegs on the metal grasp and release the button. **FIGURE 31**

FIGURE 31

INSTRUMENTS USED



H2 OFFSET MEASUREMENT TOOL

HT-3954X

POLY INSERTER

HT-39951

Tighten the red center nut clock-wise to the full back position (closest to the top handle) and insert the inlay. **FIGURE 32**

FIGURE 32

Once the inlay is in place, remove the Poly Inserter by twisting the red center nut counter-clockwise to loosen and press the top button to release.

The teeth of the metallic ring of the inlay must face anteriorly toward the surgeon. The marked face (RIGHT/LEFT) on the implant should be realized anteriorly. **FIGURE 33**

The contact surface on the talus is conical. This creates difference between the load bearing radii on medial and lateral aspects of the talus. The anterior facing teeth of the ring are necessary for locking the poly implant.

Proper insertion of the inlay is mandatory! If teeth are not facing anteriorly, the poly has been placed or chosen incorrectly. The Poly Inserter may be used to remove and replace the inlay, if necessary.

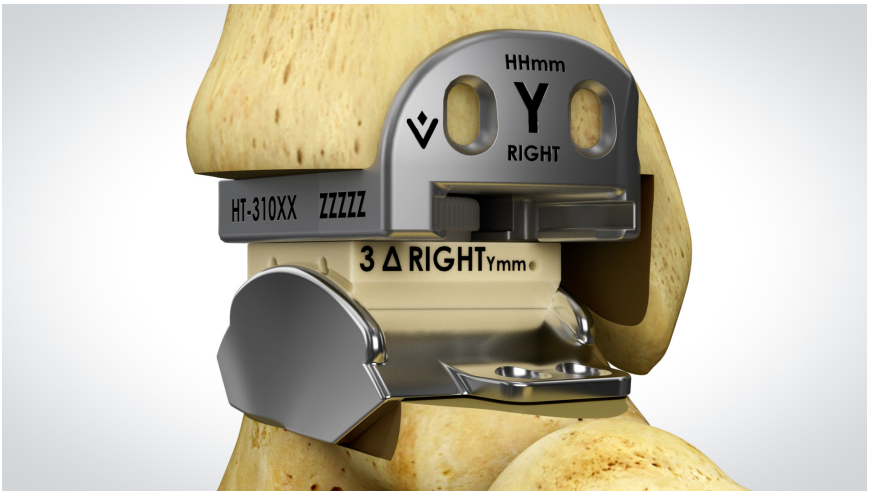


FIGURE 33

Manually insert the tibial slide until it seats into the tibial implant. The rails of the tibial implant are designed to only accept the tibial slide in a single orientation. **FIGURE 34**

FIGURE 34

It is highly recommended to verify the position of the implants by fluoroscopy in A/P and lateral positions against the planned final placement positions provided in the OPTIX® H2 Case Report.

Proper insertion of the tibial slide is mandatory; “M” marking on the slide must be medial.

NOTE: Poly inlays contain two radiographic markers which can be seen fluoroscopically indicating the alignment of the poly implant

Obtaining accurate rotation of the tibial polyethylene is critical to the ultimate alignment and wear characteristics of the H2 device and needs to be meticulously ascertained by the surgeon prior to definitively fixing the rotation with the Tibial Slide Device. Careful assessment of the tray orientation through multiple trials of flexion and extension throughout a full range of motion will be necessary to avoid inappropriate rotation and subsequent adverse edge loading of the polyethylene.

NOTE: After the insertion of the final components and the PE inlay, and with the spacer in place, it can then be determined whether or not additional surgeries might be necessary in order to obtain a more balanced ankle.

With the implants in place, while visually observing the congruency of the implants, the ankle should be flexed to its maximum allowable range of motion to provide for the poly implant to find its anatomic position which accommodates the relative rotation of the talar component to the tibial component.

Once the range of motion evaluation is complete, the foot is returned to its plantar grade position.

The poly inlay is locked in place utilizing the torque limiting Tibial Slide Screwdriver (Torque Handle HT-39901 and Screwdriver Tip T8 HT-39720).

The screwdriver is inserted into the tibial slide screw and is turned clockwise until 1.2 Nm, there will be an audible and tactile click.
FIGURE 35

FIGURE 35

After locking the poly inlay, the ankle should be flexed to its maximum allowable range of motion while observing congruency of the implants and proper tensioning of the joint. Ensure the poly does not rotate, the tibial slide must be fully locked.

NOTE: If the poly is able to rotate, the tibial slide is not fully locked.

While the foot is moved in dorsiflexion with sufficient force, remaining soft tissue contracture on posterior aspect of the ankle should be released. Proper soft tissue balancing is critical to implant function.

In order to confirm the relative A/P rotational orientation of the implant construct, lateral A/P radiographs of the joint should be taken.

INSTRUMENTS USED

TORQUE HANDLE

HT-39901

T8 SCREWDRIVER TIP

HT-39720

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

11. Wound Closure

Insertion of a drain is recommended.

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 (plantar-grade) position.

12. Postoperative Care

(Recommended by Prof. B. Hintermann; Liestal, 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 to protect the ankle against eversion, inversion, and plantar flexion movements for 6 weeks.

Weight bearing as tolerated. Full weight bearing may be achieved as early as 1 week postoperatively.

A rehabilitation program should be started fort he foot and ankle after cast or walker removal, including stretching and strengthening of the tricep surae.

The first clinical and radiological evaluation is made at 6 weeks to verify wound status, osteointegrations, and position of implants.

It is recommended that the patient should be advised to wear a compression stocking to avoid extremity swelling for an additional 4-6 months.

13. Flat Cut Talar Component Implant

Place the Flat Cut Medial / Lateral Talus Cut Guide over the remaining talus parallel pins. **FIGURE 36**

FIGURE 36

Ensure the Medial / Lateral Talus Cut Guide is fully seated. Take a lateral fluoroscopic image to confirm the location of the medial / lateral talus cut guide matches the virtual surgical plan. Use the lateral alignment pin as a reference. Reposition the guide as necessary to match the virtual surgical plan. **FIGURE 37**

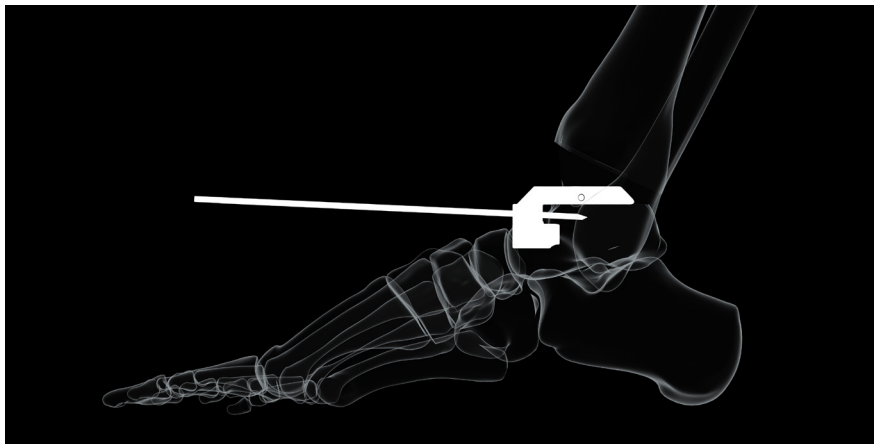
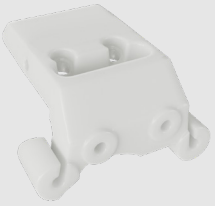


FIGURE 37

Place medial and lateral limit wires to finalize the placement of the guide and remove the talus parallel pins. After removing the pins, utilizing the Quick Screw Driver (HT-39730), insert the Quick Screws (HT-39731). **FIGURE 38**

INSTRUMENTS USED

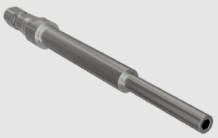


FLAT CUT MEDIAL / LATERAL TALUS

OX2-0006

QUICK SCREW

HT-39731



QUICK SCREW DRIVER

HT-39730

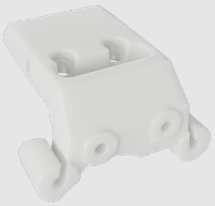
FIGURE 38

Once fixated, take a reciprocating saw down the medial and lateral sides of the guide to finish talus preparation. No milling or posterior cut is performed during this flat talar cut technique. **FIGURE 39**

FIGURE 40

Remove the Quick Screws and limit wires, remove the medial lateral talus cutting guide.

Perform a standard pulsed lavage of the incision site to remove any potential debris generated from cut guides.



FLAT CUT MEDIAL / LATERAL TALUS

OX2-0006

14. Drilling of the Peg Holes for Flat Cut Implant

The corresponding Flat Cut Talar Trial (HT-393XX) is press-fit to the talus. Temporary fixation can be achieved through inserting Shoulder Pins (HT-39770) through the two front holes on the trial to aid in temporary fixation. Alternatively, the Flat Cut Talar Trial Clamp (HT-39371) may be used through the front two holes.

Using the guide, 2 holes are drilled with the 4.5 mm Peg Drill (HT-39711) until the shoulder of the peg drill meets the drill guide surface. **FIGURE 41**

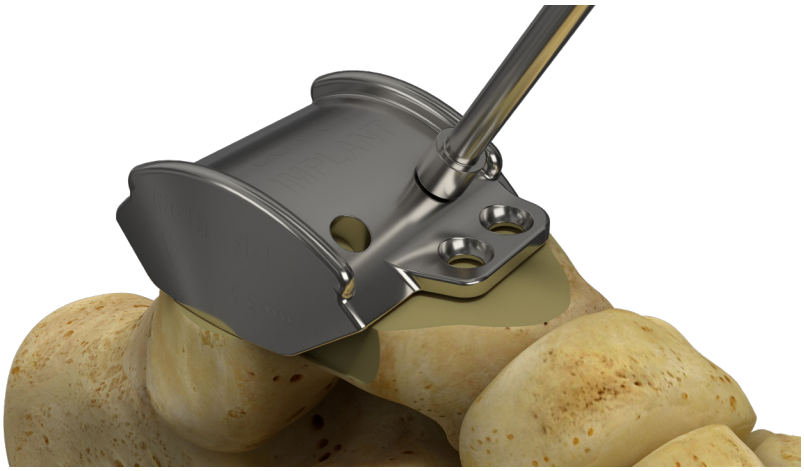


FIGURE 41

The assembly is then removed.

NOTE: A saline lavage of the wound site is recommended. 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.

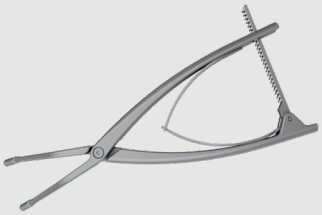
INSTRUMENTS USED

FLAT CUT TALAR TRIAL

HT-393XX

SHOULDER PIN

HT-39770



FLAT CUT TALAR TRIAL CLAMP

HT-39371

4.5MM PEG DRILL

HT-39711

[Return to Section 9 to continue Surgical Technique]

15. Implant Removal

A primary anterior incision exposes the ankle joint. Scar tissue and prominent bone spurs are removed.

The polyethylene insert is removed.

The stability of the metallic components is proved.

Unstable components are removed paying attention not to damage the remaining bone stock; if necessary, an impactor is used for axial mobilization of the implant

On the talar side, the impactor can be inserted percutaneously from the plantar aspect of the foot to meet the anterolateral corner of the implant

In patients with stemmed tibial components, a window through the anterior cortex is created to remove the tibial component

A stable tibial implant is revised in the following cases:

- If the tibial component is malpositioned in the coronal plane (e.g., in varus or valgus) or
- sagittal plane (e.g., anterior or posterior tilt) that would not allow to achieve a well-balanced ankle
- If the articulating surface of the tibial implant is damaged (e.g., due to metallic wear)
- If the polyethylene insert would not be covered by the tibial component during the whole range of motion (which may result in edge loading of the insert with subsequent pathologically increased wear), which is typically the case for a too medially, laterally, or malrotated position of the tibial component

A stable talar component is revised in the following cases:

- If the talar component is malpositioned in the coronal plane (e.g., in varus or valgus) or sagittal plane (e.g., too anterior or posterior position) that would not allow to achieve a well-balanced ankle
- If the talar component is malrotated that would not allow to achieve an appropriate mechanical play
- If the articulating surface of the talar implant is damaged (e.g., due to metallic wear)

Once one or both metal components are removed, the bone surface and gutters are carefully debrided

The posterior capsule of the tibiotalar joint is resected paying attention not to damage the neurovascular structures in this area

After debridement of bone surfaces, preoperative planning is verified by assessing the amount of talar and tibial bony defect. In the case of uneventful increase of bone defect, the trea®ent is adapted accordingly.

16. Additional Surgeries

According to overall conditions, additional surgeries might be necessary to get a balanced ankle:

- Arthrodesis of adjacent joints
- Osteotomy of distal tibia
- Osteotomy of fibula
- Osteotomy of calcaneus
- Ligament reconstruction
- Tendon transfer

Hintermann Series H2® Surgical Technique

Part Reference Guide

Complete Tray and Lid Set:

Reference	Description
HT-39990	Instrument Case
HT-39991	Trial Case
HT-39992	Captured Cut Guide Instrument Tray (Upon Request Only)
HT-39993	Horseshoe Pin Caddy (Upon Request Only)

Instrument List:

Instrument Case (Lower Layer)

Part Number	Description
HT-39005	Hintermann Distractor
HT-39001	Tibial Rob
HT-39002	Rod Connector
HT-39003	Tibial Calf Clamp
HT-39004	Translation Block
HT-39908	Screwdriver 3.5mm Hex
HT-39955	M/L Adjusting Block
HT-39009	Tibial Cut Guide Large
HT-39008	Tibial Cut Guide Medium
HT-39007	Tibial Cut Guide Small
HT-39014	Talar Cut Block Large
HT-39013	Talar Cut Block Medium
HT-39012	Talar Cut Block Small
HT-39015	Talar Cut Block - FLAT CUT
HT-39016	Tibial Depth Gauge
HT-39017	Lamina Spreader
HT-39018	Magic Chisel
HT-39011	Tibial 2mm Cut Guide
HT-39952	Angel Wing
HT-39902	Cobb Elevator
HT-39903	Curette 90°
HT-39010	Tibial Fragment Remover

Instrument Case (Upper Layer)

Part Number	Description
HT-39430	Talar Impactor
HT-39502	Straight Tibial Impactor
HT-39503	H2 Tibial Impactor
HT-39370	Talar Trial Impactor
HT-39615	Spacer 15 mm - H2 Standard
HT-39620	Spacer 20mm - H2 Flat Top
HT-39020	Talar Cut Guide Right Size 0
HT-39021	Talar Cut Guide Right Size 1
HT-39022	Talar Cut Guide Right Size 2
HT-39023	Talar Cut Guide Right Size 3
HT-39024	Talar Cut Guide Right Size 4
HT-39025	Talar Cut Guide Right Size 5
HT-39030	Talar Cut Guide Left Size 0
HT-39031	Talar Cut Guide Left Size 1
HT-39032	Talar Cut Guide Left Size 2
HT-39033	Talar Cut Guide Left Size 3
HT-39034	Talar Cut Guide Left Size 4
HT-39035	Talar Cut Guide Left Size 5
HT-39019	Talar Cut Guide Handle
HT-39041	Flat Cut Talar Cut Guide Size 1 - Right
HT-39042	Flat Cut Talar Cut Guide Size 2 - Right
HT-39043	Flat Cut Talar Cut Guide Size 3 - Right
HT-39044	Flat Cut Talar Cut Guide Size 4 - Right
HT-39045	Flat Cut Talar Cut Guide Size 5 - Right
HT-39051	Flat Cut Talar Cut Guide Size 1 - Left
HT-39052	Flat Cut Talar Cut Guide Size 2 - Left
HT-39053	Flat Cut Talar Cut Guide Size 3 - Left
HT-39054	Flat Cut Talar Cut Guide Size 4 - Left
HT-39055	Flat Cut Talar Cut Guide Size 5 - Left

Trial Case (Lower Layer)

Part Number	Description
HT-39280	Tibial Spacer 12mm (Revision)
HT-39351	Flat Cut Talar Trial, Right, Size 1
HT-39352	Flat Cut Talar Trial, Right, Size 2
HT-39353	Flat Cut Talar Trial, Right, Size 3
HT-39354	Flat Cut Talar Trial, Right, Size 4
HT-39355	Flat Cut Talar Trial, Right, Size 5
HT-39361	Flat Cut Talar Trial, Left, Size 1
HT-39362	Flat Cut Talar Trial, Left, Size 2
HT-39363	Flat Cut Talar Trial, Left, Size 3
HT-39364	Flat Cut Talar Trial, Left, Size 4
HT-39365	Flat Cut Talar Trial, Left, Size 5
HT-39101	Tibial Trial, Right, Size 1
HT-39102	Tibial Trial, Right, Size 2
HT-39103	Tibial Trial, Right, Size 3
HT-39104	Tibial Trial, Right, Size 4
HT-39105	Tibial Trial, Right, Size 5
HT-39201	Tibial Trial, Left, Size 1
HT-39202	Tibial Trial, Left, Size 2
HT-39203	Tibial Trial, Left, Size 3
HT-39204	Tibial Trial, Left, Size 4
HT-39205	Tibial Trial, Left, Size 5
HT-39951	Poly Inserter
HT-39901	Torque Handle
HT-39371	Flat Cut Talar Trial Clamp

Trial Case (Upper Layer)

Part Number	Description
HT-39525	Trial Inlays Thickness 5 mm
HT-39526	Trial Inlays Thickness 6 mm
HT-39527	Trial Inlays Thickness 7 mm
HT-39529	Trial Inlays Thickness 9 mm
HT-39400	Talar Anterior Mill Window
HT-39410	Talar Drill Guide Assembly, Size 0
HT-39411	Talar Drill Guide Assembly, Size 1
HT-39412	Talar Drill Guide Assembly, Size 2
HT-39413	Talar Drill Guide Assembly, Size 3
HT-39414	Talar Drill Guide Assembly, Size 4
HT-39415	Talar Drill Guide Assembly, Size 5
HT-39310	Talar Trial, Right, Size 0
HT-39311	Talar Trial, Right, Size 1
HT-39312	Talar Trial, Right, Size 2
HT-39313	Talar Trial, Right, Size 3
HT-39314	Talar Trial, Right, Size 4
HT-39315	Talar Trial, Right, Size 5
HT-39320	Talar Trial, Left, Size 0
HT-39321	Talar Trial, Left, Size 1
HT-39322	Talar Trial, Left, Size 2
HT-39323	Talar Trial, Left, Size 3
HT-39324	Talar Trial, Left, Size 4
HT-39325	Talar Trial, Left, Size 5
HT-39541	H2 Offset Measurement Tool - Size 1
HT-39542	H2 Offset Measurement Tool - Size 2
HT-39543	H2 Offset Measurement Tool - Size 3
HT-39544	H2 Offset Measurement Tool - Size 4
HT-39545	H2 Offset Measurement Tool - Size 5

Trial Case (Pin Caddy)

Part Number	Description
HT-39700	M4 x 0.7 Thumb Screw
HT-39710	Talar Reamer Ø 6mm
HT-39711	Talar Peg Drill Ø 4.5mm
HT-39720	Tibial Slide Screwdriver Tip T8
HT-39721	Tibial Slide Screwdriver Tip HEX
HT-39730	Quick Screw Driver
HT-39731	Quick Screw
HT-39900	K-wire 1 sharp 1 blunt Ø 2.4mm L 230mm
HT-39870	105mm Smooth Pin, Non-Threaded
HT-39895	130mm Smooth Pin, Non-Threaded
HT-39770	Shoulder Pin L 70mm, Threaded
HT-39855	Shoulder Pin L 45mm, Threaded

Captured Cut Guide Instrument Tray

Part Number	Description
HT-39950	Talar Cut Guide Distractor Assembly
HT-39953	Tibial M/L Cut Guide Sz 1-3 Assembly
HT-39954	Tibial M/L Cut Guide Sz 4-6 Assembly
HT-39960	Talar Collateral Guide RT Sz 0
HT-39961	Talar Collateral Guide RT Sz 1
HT-39962	Talar Collateral Guide RT Sz 2
HT-39963	Talar Collateral Guide RT Sz 3
HT-39964	Talar Collateral Guide RT Sz 4
HT-39965	Talar Collateral Guide RT Sz 5
HT-39970	Talar Collateral Guide LT Sz 0
HT-39971	Talar Collateral Guide LT Sz 1
HT-39972	Talar Collateral Guide LT Sz 2
HT-39973	Talar Collateral Guide LT Sz 3
HT-39974	Talar Collateral Guide LT Sz 4
HT-39975	Talar Collateral Guide LT Sz 5

Horseshoe Pin Caddy

Part Number	Description
HT-39600	Parallel Pliers
HT-39601	Pin Tamp
HT-39604	Fixation Pin, Non-threaded, Short
HT-39605	Fixation Pin, Non-threaded, Medium
HT-39606	Fixation Pin, Non-threaded, Long

OPTIX®

Part Number	Description
OX2-0001	OPTIX H2 PSI PATIENT SPECIFIC TIBIA MODEL
OX2-0002	OPTIX H2 PSI TIBIA CUT GUIDE
OX2-0003	OPTIX H2 PSI PATIENT SPECIFIC TALUS MODEL
OX2-0004	OPTIX H2 PSI TALUS CUT GUIDE
OX2-0005	OPTIX H2 PSI PATIENT SPECIFIC M/L TALUS MODEL
OX2-0006	OPTIX H2 PSI MEDIAL LATERAL TALUS CUT GUIDE
OX-0007	OPTIX PERFECT CIRCLE TIBIA TUBE
OX-0008	OPTIX MEDIAL / LATERAL TALUS ALIGNMENT PIN
OX-0009	OPTIX ALIGNMENT CONNECTOR
OX-0010	OPTIX ALIGNMENT POST

Hintermann Series H2® Tibial Components

Part Number	Description
HT-32801	H2 Tibia Implant, Sz 1 Left, 7mm
HT-32831	H2 Tibia Implant, Sz 1 Left, 12mm
HT-32802	H2 Tibia Implant, Sz 2 Left, 7mm
HT-32832	H2 Tibia Implant, Sz 2 Left, 12mm
HT-32803	H2 Tibia Implant, Sz 3 Left, 7mm
HT-32833	H2 Tibia Implant, Sz 3 Left, 12mm
HT-32804	H2 Tibia Implant, Sz 4 Left, 7mm
HT-32834	H2 Tibia Implant, Sz 4 Left, 12mm
HT-32805	H2 Tibia Implant, Sz 5 Left, 7mm
HT-32835	H2 Tibia Implant, Sz 5 Left, 12mm

Part Number	Description
HT-31801	H2 Tibia Implant, Sz 1 Right, 7mm
HT-31831	H2 Tibia Implant, Sz 1 Right, 12mm
HT-31802	H2 Tibia Implant, Sz 2 Right, 7mm
HT-31832	H2 Tibia Implant, Sz 2 Right, 12mm
HT-31803	H2 Tibia Implant, Sz 3 Right, 7mm
HT-31833	H2 Tibia Implant, Sz 3 Right, 12mm
HT-31804	H2 Tibia Implant, Sz 4 Right, 7mm
HT-31834	H2 Tibia Implant, Sz 4 Right, 12mm
HT-31805	H2 Tibia Implant, Sz 5 Right, 7mm
HT-31835	H2 Tibia Implant, Sz 5 Right, 12mm

Hintermann Series H2® Talar Components

Single Coating

Part Number	Description
HT-402110	Talar Implant, Sz0 Left- SINGLE COAT
HT-402111	Talar Implant, Sz1 Left- SINGLE COAT
HT-402112	Talar Implant, Sz2 Left- SINGLE COAT
HT-402113	Talar Implant, Sz3 Left- SINGLE COAT
HT-402114	Talar Implant, Sz4 Left- SINGLE COAT
HT-402115	Talar Implant, Sz5 Left- SINGLE COAT
HT-401110	Talar Implant, Sz0 Right- SINGLE COAT
HT-401111	Talar Implant, Sz1 Right- SINGLE COAT
HT-401112	Talar Implant, Sz2 Right- SINGLE COAT
HT-401113	Talar Implant, Sz3 Right- SINGLE COAT
HT-401114	Talar Implant, Sz4 Right- SINGLE COAT
HT-401115	Talar Implant, Sz5 Right- SINGLE COAT
HT-402121	Talar Implant, Sz1 Left, Flat Cut- SINGLE COAT
HT-402122	Talar Implant, Sz2 Left, Flat Cut- SINGLE COAT
HT-402123	Talar Implant, Sz3 Left, Flat Cut- SINGLE COAT
HT-402124	Talar Implant, Sz4 Left, Flat Cut- SINGLE COAT
HT-402125	Talar Implant, Sz5 Left, Flat Cut- SINGLE COAT
HT-401121	Talar Implant, Sz1 Right, Flat Cut- SINGLE COAT
HT-401122	Talar Implant, Sz2 Right, Flat Cut- SINGLE COAT
HT-401123	Talar Implant, Sz3 Right, Flat Cut- SINGLE COAT
HT-401124	Talar Implant, Sz4 RIght, Flat Cut- SINGLE COAT
HT-401125	Talar Implant, Sz5 Right, Flat Cut- SINGLE COAT

OUS Market ONLY- Double Coating

Part Number	Description
HT-302110	Talar Implant, Sz 0 Left
HT-302111	Talar Implant, Sz 1 Left
HT-302112	Talar Implant, Sz 2 Left
HT-302113	Talar Implant, Sz 3 Left
HT-302114	Talar Implant, Sz 4 Left
HT-302115	Talar Implant, Sz 5 Left
HT-301110	Talar Implant, Sz 0 Right
HT-301111	Talar Implant, Sz 1 Right
HT-301112	Talar Implant, Sz 2 Right
HT-301113	Talar Implant, Sz 3 Right
HT-301114	Talar Implant, Sz 4 Right
HT-301115	Talar Implant, Sz 5 Right
HT-302121	Talar Implant, Sz 1 Left, Flat Cut
HT-302122	Talar Implant, Sz 2 Left, Flat Cut
HT-302123	Talar Implant, Sz 3 Left, Flat Cut
HT-302124	Talar Implant, Sz 4 Left, Flat Cut
HT-302125	Talar Implant, Sz 5 Left, Flat Cut
HT-301121	Talar Implant, Sz 1 Right, Flat Cut
HT-301122	Talar Implant, Sz 2 Right, Flat Cut
HT-301123	Talar Implant, Sz 3 Right, Flat Cut
HT-301124	Talar Implant, Sz 4 RIght, Flat Cut
HT-301125	Talar Implant, Sz 5 Right, Flat Cut

Hintermann Series H2® Poly (PE) Components

Part Number	Description
HT-38005	H2 Vit E Poly, Sz 0, Left, 5mm, Neutral
HT-38006	H2 Vit E Poly, Sz 0, Left, 6mm, Neutral
HT-38007	H2 Vit E Poly, Sz 0, Left, 7mm, Neutral
HT-38009	H2 Vit E Poly, Sz 0, Left, 9mm, Neutral
HT-38015	H2 Vit E Poly, Sz 0, Left, 5mm, Anterior
HT-38016	H2 Vit E Poly, Sz 0, Left, 6mm, Anterior
HT-38017	H2 Vit E Poly, Sz 0, Left, 7mm, Anterior
HT-38019	H2 Vit E Poly, Sz 0, Left, 9mm, Anterior
HT-38105	H2 Vit E Poly, Sz 1, Left, 5mm, Neutral
HT-38106	H2 Vit E Poly, Sz 1, Left, 6mm, Neutral
HT-38107	H2 Vit E Poly, Sz 1, Left, 7mm, Neutral
HT-38109	H2 Vit E Poly, Sz 1, Left, 9mm, Neutral
HT-38115	H2 Vit E Poly, Sz 1, Left, 5mm, Anterior
HT-38116	H2 Vit E Poly, Sz 1, Left, 6mm, Anterior
HT-38117	H2 Vit E Poly, Sz 1, Left, 7mm, Anterior
HT-38119	H2 Vit E Poly, Sz 1, Left, 9mm, Anterior
HT-38205	H2 Vit E Poly, Sz 2, Left, 5mm, Neutral
HT-38206	H2 Vit E Poly, Sz 2, Left, 6mm, Neutral
HT-38207	H2 Vit E Poly, Sz 2, Left, 7mm, Neutral
HT-38209	H2 Vit E Poly, Sz 2, Left, 9mm, Neutral
HT-38215	H2 Vit E Poly, Sz 2, Left, 5mm, Anterior
HT-38216	H2 Vit E Poly, Sz 2, Left, 6mm, Anterior
HT-38217	H2 Vit E Poly, Sz 2, Left, 7mm, Anterior
HT-38219	H2 Vit E Poly, Sz 2, Left, 9mm, Anterior
HT-38305	H2 Vit E Poly, Sz 3, Left, 5mm, Neutral
HT-38306	H2 Vit E Poly, Sz 3, Left, 6mm, Neutral
HT-38307	H2 Vit E Poly, Sz 3, Left, 7mm, Neutral
HT-38309	H2 Vit E Poly, Sz 3, Left, 9mm, Neutral
HT-38315	H2 Vit E Poly, Sz 3, Left, 5mm, Anterior
HT-38316	H2 Vit E Poly, Sz 3, Left, 6mm, Anterior
HT-38317	H2 Vit E Poly, Sz 3, Left, 7mm, Anterior
HT-38319	H2 Vit E Poly, Sz 3, Left, 9mm, Anterior
HT-38405	H2 Vit E Poly, Sz 4, Left, 5mm, Neutral
HT-38406	H2 Vit E Poly, Sz 4, Left, 6mm, Neutral
HT-38407	H2 Vit E Poly, Sz 4, Left, 7mm, Neutral
HT-38409	H2 Vit E Poly, Sz 4, Left, 9mm, Neutral
HT-38415	H2 Vit E Poly, Sz 4, Left, 5mm, Anterior
HT-38416	H2 Vit E Poly, Sz 4, Left, 6mm, Anterior
HT-38417	H2 Vit E Poly, Sz 4, Left, 7mm, Anterior
HT-38419	H2 Vit E Poly, Sz 4, Left, 9mm, Anterior
HT-38505	H2 Vit E Poly, Sz 5, Left, 5mm, Neutral
HT-38506	H2 Vit E Poly, Sz 5, Left, 6mm, Neutral

Part Number	Description
HT-37005	H2 Vit E Poly, Sz 0, Right, 5mm, Neutral
HT-37006	H2 Vit E Poly, Sz 0, Right, 6mm, Neutral
HT-37007	H2 Vit E Poly, Sz 0, Right, 7mm, Neutral
HT-37009	H2 Vit E Poly, Sz 0, Right, 9mm, Neutral
HT-37015	H2 Vit E Poly, Sz 0, Right, 5mm, Anterior
HT-37016	H2 Vit E Poly, Sz 0, Right, 6mm, Anterior
HT-37017	H2 Vit E Poly, Sz 0, Right, 7mm, Anterior
HT-37019	H2 Vit E Poly, Sz 0, Right, 9mm, Anterior
HT-37105	H2 Vit E Poly, Sz 1, Right, 5mm, Neutral
HT-37106	H2 Vit E Poly, Sz 1, Right, 6mm, Neutral
HT-37107	H2 Vit E Poly, Sz 1, Right, 7mm, Neutral
HT-37109	H2 Vit E Poly, Sz 1, Right, 9mm, Neutral
HT-37115	H2 Vit E Poly, Sz 1, Right, 5mm, Anterior
HT-37116	H2 Vit E Poly, Sz 1, Right, 6mm, Anterior
HT-37117	H2 Vit E Poly, Sz 1, Right, 7mm, Anterior
HT-37119	H2 Vit E Poly, Sz 1, Right, 9mm, Anterior
HT-37205	H2 Vit E Poly Sz 2, Right, 5mm, Neutral
HT-37206	H2 Vit E Poly, Sz 2, Right, 6mm, Neutral
HT-37207	H2 Vit E Poly, Sz 2, Right, 7mm, Neutral
HT-37209	H2 Vit E Poly, Sz 2, Right, 9mm, Neutral
HT-37215	H2 Vit E Poly, Sz 2, Right, 5mm, Anterior
HT-37216	H2 Vit E Poly, Sz 2, Right, 6mm, Anterior
HT-37217	H2 Vit E Poly, Sz 2, Right, 7mm, Anterior
HT-37219	H2 Vit E Poly, Sz 2, Right, 9mm, Anterior
HT-37305	H2 Vit E Poly, Sz 3, Right, 5mm, Neutral
HT-37306	H2 Vit E Poly, Sz 3, Right, 6mm, Neutral
HT-37307	H2 Vit E Poly, Sz 3, Right, 7mm, Neutral
HT-37309	H2 Vit E Poly, Sz 3, Right, 9mm, Neutral
HT-37315	H2 Vit E Poly, Sz 3, Right, 5mm, Anterior
HT-37316	H2 Vit E Poly, Sz 3, Right, 6mm, Anterior
HT-37317	H2 Vit E Poly, Sz 3, Right, 7mm, Anterior
HT-37319	H2 Vit E Poly, Sz 3, Right, 9mm, Anterior
HT-37405	H2 Vit E Poly, Sz 4, Right, 5mm, Neutral
HT-37406	H2 Vit E Poly, Sz 4, Right, 6mm, Neutral
HT-37407	H2 Vit E Poly, Sz 4, Right, 7mm, Neutral
HT-37409	H2 Vit E Poly, Sz 4, Right, 9mm, Neutral
HT-37415	H2 Vit E Poly, Sz 4, Right, 5mm, Anterior
HT-37416	H2 Vit E Poly, Sz 4, Right, 6mm, Anterior
HT-37417	H2 Vit E Poly, Sz 4, Right, 7mm, Anterior
HT-37419	H2 Vit E Poly Sz 4, Right, 9mm, Anterior
HT-37505	H2 Vit E Poly, Sz 5, Right, 5mm, Neutral
HT-37506	H2 Vit E Poly, Sz 5, Right, 6mm, Neutral

Part Number	Description
HT-38507	H2 Vit E Poly, Sz 5, Left, 7mm, Neutral
HT-38509	H2 Vit E Poly, Sz 5, Left, 9mm, Neutral
HT-38515	H2 Vit E Poly, Sz 5, Left, 5mm, Anterior
HT-38516	H2 Vit E Poly, Sz 5, Left, 6mm, Anterior
HT-38517	H2 Vit E Poly, Sz 5, Left, 7mm, Anterior
HT-38519	H2 Vit E Poly, Sz 5, Left, 9mm, Anterior

Part Number	Description
HT-37507	H2 Vit E Poly, Sz 5, Right, 7mm, Neutral
HT-37509	H2 Vit E Poly, Sz 5, Right, 9mm, Neutral
HT-37515	H2 Vit E Poly, Sz 5, Right, 5mm, Anterior
HT-37516	H2 Vit E Poly, Sz 5, Right, 6mm, Anterior
HT-37517	H2 Vit E Poly, Sz 5, Right, 7mm, Anterior
HT-37519	H2 Vit E Poly, Sz 5, Right, 9mm, Anterior

Learn more about the
OPTIX® System

This document is intended solely for the use of healthcare professionals.

The Instructions for Use, Surgical Techniques, Cleaning instructions, and other associated labeling may be requested online at www.vilex.com.

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