INSTRUCTIONS FOR USE

HINTERMANN SERIES H3™ STERILE MEDICAL DEVICES - SINGLE USE

Caution: Federal (USA) law restricts the sale of this device to or on the order of a licensed physician.

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.

1. Description of the medical devices:

The Hintermann Series H3™ Total Ankle Replacement prosthesis, also referred to as the H3, exists in different sizes. The prosthesis is composed of a tibial component, a talar component, and an intermediary sliding core.

2. Hintermann Series H3™ Total Ankle replacement prosthesis:

Both Hintermann Series H3™ tibial and talar components are made out of Cobalt Chrome alloy (CoCr) according to ISO 5832-4 and ASTM F75, with a titanium plasma spray and hydroxyapatite coating (Ti + HAP). The intermediary sliding core (i.e., Poly Inlay) is made out of UHMW Polyethylene, according to ISO 5834-2 and ASTM F648. The Poly Inlay also includes radiographic markers manufactured from titanium (ISO 5832-3 and ASTM F136).

The tibial and talar components, as well as the Poly Inlay, are delivered sterile and are non-pyrogenic.

3. Indications:

The Hintermann Series H3™ Total Ankle Replacement System is indicated for use as a non-cemented implant to replace a painful arthritic ankle joint due to primary osteoarthritis, post-traumatic osteoarthritis or arthritis secondary to inflammatory disease.

The device system is for prescription use.

4. Contraindications:

The Hintermann Series H3™ Total Ankle Replacement prosthesis should not be implanted in patients with the following conditions:

- Skeletal immaturity
- Bone stock inadequate to support the device including:
  - Severe osteoporotic or osteopenic condition or other conditions resulting in poor bone quality
  - Avascular necrosis of the talus
- Active or prior deep infection in the ankle joint or adjacent bones
- Malalignment or severe deformity of involved or adjacent anatomic structures including:
  - Hindfoot or forefoot malalignment precluding plantigrade foot
  - Significant malalignment of the knee joint

- Insufficient ligament support that cannot be repaired with soft tissue stabilization
- Charcot joint or peripheral neuropathy that may lead to Charcot joint of the affected ankle.
- 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 the surgical site
- Immunosuppressive therapy
- Prior ankle fusion or revision of total ankle replacement
- High demand sport activities (e.g. contact sports, jumping)
- Suspected or documented metal allergy or intolerance

5. Warnings:

Serious post-operative complications may occur from use of the implant in a patient with:

- Lack of good general physical condition
- Severe osteoporosis
- Physiological or anatomical anomalies
- Immunological responses, sensitization, or hypersensitivity to foreign materials
- Systemic or metabolic disorders

6. Precautions for use:

The safety and effectiveness of this device has not been established in patients with 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 DT MedTech, LLC must not be used in conjunction with those of any other manufacturer as component parts may not be compatible.

This product must be handled and/or implanted by well-trained, qualified persons, aware of these directions for use. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and post-operative patient management are considerations essential to a successful outcome. Information contained within this document should be taken into consideration during the patient 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

Complications with the use of joint prostheses 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 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.

Below is a list of the potential adverse events (complications) associated with the use of the device. This listing was derived from results of the Hintermann Series H3™ Total Ankle Replacement System clinical data and published clinical literature for clinical experiences within the same patient population.

Intraoperative events:

- Fractures of bones adjacent to the implant site (medial or lateral malleolus, distal tibia, talus)
- Soft tissue injuries at or adjacent to the surgical site (nerves, tendons, or blood vessels)
- Malalignment of the tibia or talus

Postoperative events:

- Infection (superficial or periprosthetic)
- Aseptic loosening of the tibial or talar device components
- Osteolysis of the tibia, talus or fibula
- Subsidence of the tibial or talar device components
- Problems with the polyethylene device component (fracture, instability, wear)
- Fractures of bones adjacent to the implant site (medial or lateral malleolus, distal tibia, talus)
- Adjacent joint arthritis

- Arthrofibrosis / impingement
- Avascular necrosis of the talus
- Chronic pain
- Complex regional pain syndrome (CRPS)
- Edema
- Equinus contracture
- Heterotopic ossification
- Hindfoot malalignment
- Ligamentous instability
- Metal component issues
- Syndesmosis nonunion
- Tarsal tunnel syndrome
- Thromboembolism
- Wound healing problems

Adverse effects may necessitate a non-operative treatment, reoperation, revision, or non-revision surgery.

IT IS THE RESPONSIBILITY OF THE SURGEON TO PROVIDE THE PATIENT WITH INFORMATION PRIOR TO SURGERY.

7. Clinical Data

The study was a retrospective, non-randomized, single-arm study in which clinical data for the Hintermann Series H3™ Total Ankle Replacement System was compared to Performance Goals (PGs). The data on Hintermann Series H3™ Total Ankle Replacement System were abstracted from data collected prospectively in the Foot and Ankle Registry currently maintained at Kantonsspital Baselland (H3 Registry). Kantonsspital Baselland (Canton Hospital, Basel, Switzerland) is a teaching hospital affiliated with the University of Basel. Data from this clinical study were the basis for the PMA approval decision.

Data for the investigational subjects included in the Primary Safety and Effectiveness (PSE) Cohort have been audited to verify their accuracy and completeness. Subject selection for the PSE Cohort was performed programmatically without regard to outcomes, and a listing of subjects not selected for the PSE Cohort with the reason(s) was generated. Additionally, the subject selection criteria were finalized prior to the completion of data abstraction.

<u>Clinical Inclusion and Exclusion Criteria</u>

Enrollment in the PSE Cohort was limited to patients who met the following inclusion criteria:

- Skeletally mature
- Primary diagnosis of osteoarthritis, post-traumatic arthritis or rheumatoid arthritis
- Primary total ankle replacement (TAR)
- Unilateral or the first ankle implanted if bilateral and the surgery dates for both sides are at least 6 months apart

- Implanted with the correct device without screws (for investigational arm, a 3rd generation Hintermann Series H3™ Total Ankle Replacement; for control arm, the only legally marketed mobile bearing total ankle system device in the US at the time of the study)
- Poor pre-operative AOFAS Hindfoot Score (< 60 points)
- Eligible for at least 2 years of follow-up (implanted in 2013 or earlier). Note that all subjects implanted in 2013 or earlier were included regardless of whether they were revised prior to the 2-year endpoint.
- Gave informed consent (unless IRB/Ethics Committee waived this requirement)

Patients were not permitted to enroll in the study if they met the following exclusion criterion:

- Prior TAR or arthrodesis at the involved ankle joint

Follow-up Schedule

All subjects were eligible for a minimum of 2 years follow-up. At the time of database closure, the maximum follow-up was 10 years for the Hintermann subjects enrolled in the H3 Registry.

Clinical Endpoints

The primary endpoints in this study consist of three individual co-primary endpoints, as follows:

1. American Orthopaedic Foot and Ankle Society (AOFAS) Hindfoot Score at 2 years or later.
2. Survivorship (absence of revision/removal) within 5 years
3. Occurrence of a Serious Device-Related Adverse event (SADE), as determined by the independent Clinical Events Committee) other than a removal/revision within 2 years

These endpoints were treated as co-primary endpoints, in which statistical significance must be shown on all three endpoints individually in order for the study to be successful.

The primary safety assessment for this study is based on a comparison of the serious device related adverse event rates recorded for the H3 study population to the serious device related adverse event rates from the studies that were selected for the meta-analysis which served as the basis for the PG.

Patient Accountability

As of August 20, 2018, there were 1,316 ankles with H3 implants maintained in the H3 registry, of which 428 met all inclusion / exclusion criteria and were included in the Primary Safety and Effectiveness (PSE) cohort. Of these 428 ankles, 298 have H3 devices that were implanted without the use of optional fixation screws and therefore these 298 ankles are the subjects included in the PSE Cohort referenced throughout this report.

Table 1: PSE Cohort

Criterion	Excluded Ankles	Included Ankles
Original Database	-	1316

Criterion	Excluded Ankles	Included Ankles
Criterion #1: Surgery Group (Primary TAR only)	276	1040
Criterion #2: Surgery Date <=2014	0	1040
Criterion #3: Generation 3 (H3) device	167	873
Criterion #4: Enrolled at Kantonsspital Baselland	192	681
Criterion #5: Preoperative AOFAS Total Score < 60	196	485
Criterion #6: No use of revision or sensitive components	7	478
Criterion #7: Unilateral Total Ankle Replacement or if qualifying Bilateral*, earliest qualifying ankle is included.	50	428
Criterion #8: H3 device implanted without the use of screws	130	298

*Bilateral where surgical dates for both sides are at least 6 months apart

The first H3 subject was enrolled in the Foot and Ankle Registry at Kantonsspital Baselland on 08/17/2006 and the last follow-up visit prior to database closure was conducted on 8/20/2018.

At the Month 3-6 follow-up interval, any data were available on 122 of the 298 subjects (40.9%). At the Year 1 follow-up, any data were available for 217 of the 298 subjects (Actual Follow-up rate 73.1%). At the Year 2 follow-up, any data were available for 255 of the 298 subjects (Actual Follow-up rate 88.9%). At the Year 2+ follow-up interval, any data were available for 273 of the 298 subjects (Actual Follow-up rate 95.5%). Finally, at the Year 5+ follow-up interval, the actual follow-up rate was 61.9%.

Table 2. Subject Accountability by Visit, PSE Cohorts

	3-6 MONTH	1 YEAR	2 YEAR	2+ YEAR	5+ YEAR
Theoretical	298	298	298	298	298
Deaths(cumulative)	0	1	11	12	20[c]
Expected[a]	298	297	287	286	278
Revision (cumulative)[b]	14	19	22	24[d]	27[e]
Actual: Any Follow-Up Data	122	217	255	273	172
% Follow-Up	40.9%	73.1%	88.9%	95.5%	61.9%
Actual: All Primary Endpoint Data Available	.	.	.	253	.

[a] Expected = Theoretical – Deaths

[b] Revisions are considered as "any data", as they are part of the co-primary endpoints. Thus, they are included in the Actual: Any Follow-up Data row and also included in the "Expected" row.

[c] There are 21 total deaths. One subject had a 5+-year follow-up visit but then a subsequent death. Thus, the subject is considered to be "expected" at this visit.

[d] There are 24 revisions at or prior to the 5 year visit, and 3 additional revisions occurring after the 5-year upper window limit.

[e] Total 27 revisions; 24 at or prior to 5 years and 25 at or prior to 7 years.

Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a clinical study of subjects undergoing total ankle arthroplasty in the US.

Demographic data collected at baseline for the PSE Cohort are presented in the table below. There are 298 subjects in this cohort, 43.6% female and 56.4% male. The mean age is 63.2 years, and mean body mass index (BMI) is 27.7.

Table 3: Demographic Data, PSE Cohort

Demographic Data (PSE Cohort)		
Characteristic	**Statistic/Category**	**H3 (N=298)**
Age	N	298
	Mean±SD	63.2 ± 12.38
	Range	21.0 to 88.0
	Median	64.5
Gender	Female	130 (43.6%)
	Male	168 (56.4%)
BMI	N	298
	Mean±SD	27.7 ± 4.78
	Range	16.5 to 48.4
	Median	26.9
Height (cm)	N	298
	Mean±SD	171.4 ± 9.56
	Range	147.0 to 204.0
	Median	171.0
Weight (kg)	N	298
	Mean±SD	81.3 ± 15.81
	Range	45.0 to 140.0
	Median	82.0

Table 4: Baseline Characteristics: Primary Diagnosis, PSE Cohorts

Characteristic	**Statistic/Category**	**H3 (N=298)**
Primary Diagnosis	Posttraumatic Arthritis	215 (72.1 %)
	Primary Arthritis	48 (16.1 %)
	Rheumatoid Arthritis	19 (6.4 %)
	Other	16 (5.4 %)

Table 5: Baseline Characteristics: Smoking Status, PSE Cohort

Characteristic	**Statistic/Category**	**H3 (N=298)**
Smoking Status	Current Smoker	36 (12.1 %)
	Never Smoked	237 (79.5 %)
	Previous Smoker	23 (7.7 %)

Characteristic	Statistic/Category	H3 (N=298)
	Unknown	2 (0.7 %)

Table 6: Baseline Characteristics: AOFAS Scores, PSE Cohort

Characteristic	Statistic/Category	H3 (N=298)
AOFAS Score	N	298
	Mean ± SD	39.2 ± 12.40
	Range	7.0 to 59.0
	Median	41.0
AOFAS Alignment	Poor	90 (30.2 %)
	Fair	116 (38.9 %)
	Good	92 (30.9 %)

Table 7: Baseline Characteristics: Device Sizes and Side, PSE Cohort

Characteristic	Statistic/Category	Investigational (N=298)
Tibial Size	Large (Sizes 4-6)	138 (46.3 %)
	Small (Sizes 1-3)	160 (53.7 %)
Talar Size	Large (Sizes 4-6)	38 (12.8 %)
	Small (Sizes 1-3)	260 (87.2 %)
Side	Left	130 (43.6 %)
	Right	168 (56.4 %)

Safety and Effectiveness Results

Construction of Performance Goals (PGs)

As mentioned above, this study was a retrospective, non-randomized, single-arm study in which clinical data for the Hintermann Series H3™ Total Ankle Replacement System was compared to Performance Goals (PGs). The PGs used in this study are based on a prospectively defined, systematic meta-analysis of available published literature and registry data for a control mobile bearing total ankle system legally marketed in the United States at the time of the study. The screening and selection of studies used in the development of this PG were completed by independent reviewers who were blinded to the H3 registry data and any prior data analyses. The other steps in the process of the development of the PGs, including the literature search and meta-analysis methods, were prospectively specified prior to the literature selection in order to avoid bias during the meta-analysis phase.

Primary Study Endpoint

These three endpoints are treated as co-primary endpoints:

1. American Orthopaedic Foot and Ankle Society (AOFAS) Hindfoot Score at 2 years or later.
2. Survivorship (absence of revision/removal) within 5 years
3. Occurrence of a SADE, (as determined by the independent Clinical Events Committee) other than a removal/revision within 2 years

Statistical significance must be shown on all three endpoints individually in order for the study to be successful, and each endpoint is tested independently using alpha = 0.05. The results of the analyses of each co-primary endpoint is presented and discussed below.

American Orthopaedic Foot and Ankle Society (AOFAS) Hindfoot Score: For this endpoint, the AOFAS score at 2 years was used if possible; if it was not available then the AOFAS at the next available time point was used. The Performance Goal for this endpoint was 71 points.

The AOFAS study hypotheses was evaluated using a one-sided, 95% confidence interval for the mean AOFAS score at 2 years or greater, displayed in the table below.

Table 8: AOFAS at 2+ Years – PSE Cohort

N	Mean	Std Dev	Min	Max	Lower 95% Confidence Limit for Mean
253	78.0	18.08	13.0	100	76.12

The lower limit of this confidence interval is 76.12 points, which is greater than the fixed PG of 71 points for this endpoint.

Absence of Revision at 5 Years: Another of the three co-primary endpoints is the Absence of Revision at the 5-year time point. The occurrence of a revision intervention was defined as specified in the methods developed by Mercer, et al. and was adjudicated by an independent Clinical Events Committee (CEC).

The Performance Goal for this endpoint was 0.83. The Absence of Revision/Removal study hypotheses was evaluated using a one-sided, 95% Exact Clopper-Pearson confidence interval for the proportion of subjects that have not had a revision/removal within 5 years.

Table 9: Absence of Revision at 5 Years - Updated PSE

Proportion Unrevised	CI Type	Lower 95% Confidence Limit
0.912 (248/272)	Clopper-Pearson (Exact)	0.878

The lower limit of this confidence interval is 0.878, which is greater than the fixed PG of 0.83 for this endpoint.

Absence of Serious Device-Related Adverse Events at 2 Years: Another of the three co-primary endpoints in this study is the Absence of SADE (as adjudicated by the independent CEC) at the 2-year time point.

The Performance Goal for this endpoint was 0.937. The Absence of SADE study hypothesis was evaluated using a one-sided, 95% Exact Clopper-Pearson confidence interval for the proportion of subjects that have not had a SADE within 2 years.

Table 10: Absence of SADE at 2 Years - Updated PSE

Proportion Without SADE	CI Type	Lower 95% Confidence Limit
0.963 (263/273)	Clopper-Pearson (Exact)	0.939

The lower limit of this confidence interval is 0.939 points, which is greater than the fixed PG of 0.937 for this endpoint.

Thus, the primary effectiveness evaluation demonstrates that the PSE cohort has exceeded the Performance Goals to show that the Hintermann Series H3™ TAR is effective to replace a painful arthritic ankle joint due to primary osteoarthritis, post-traumatic osteoarthritis or arthritis secondary to inflammatory disease.

- The 95% lower confidence limit for the mean AOFAS score at 2+ years was 76.12 points for the PSE cohort, which is greater than the fixed PG of 71 points for this endpoint.
- The 95% lower confidence limit for the proportion of subjects without a metal component revision at 5 years was 0.878, which is greater than the fixed PG of 0.83 for this endpoint.
- The 95% lower confidence limit for the proportion of subjects without a SADE at 2 years was 0.939, which is greater than the fixed PG of 0.937 for this endpoint.

Safety Results

The primary safety assessment for this study compares the serious device related adverse event rates recorded for the H3 study population to those from the studies that were selected for the meta-analysis of PGs. A comprehensive search of the published literature was conducted according to a prospective protocol, and adverse event data were recorded and classified according to the method described by Mercer et al. Adverse event data from national joint registries were also recorded and classified, and the adverse event data recorded in the H3 registry were also classified according to the Mercer method. The adverse event data classifications were reviewed and confirmed by a Clinical Events Committee (CEC), and adjudicated for severity and device relatedness.

Among the three groups compared, the H3 PSE cohort had the lowest percentage of serious device-related adverse events (SADE), although the SADE percentage for the H3 literature was very similar. The SADE percentage for the control group was 10.5%, higher than that for the H3 PSE Cohort or the rate calculated for the published reports and national joint registry reports for the H3. Please note that the SADE rates are not based on a specific time point and some devices may have been implanted longer than others.

Table 11: Primary Safety Assessment: Serious Device-Related Adverse Events (SADE)

Percent of Patients with Serious Device-Related Adverse Events Hintermann Registry, H3 and Control Literature and National Joint Registries (NJR)			
SADE-Percent of Patients	**H3 - PSE cohort**	**H3 Literature**	**Control-All**
	5.9% (16/273)	6.0% (146/2437)	10.5% (316/3020)

There were no unanticipated adverse events, and all adverse event information reported in this study is consistent with the types, incidences and occurrences of adverse events reported in the literature to be associated with total ankle replacement.

A revision of the TAR device as defined by the Mercer classifications was associated with the H3 in 27/273subjects (9.9%). Based on data extracted from the published literature and from national joint registries, the revision rate for the H3 was 5.5%, but was 12.9% for the control device.

The analysis of the primary safety endpoint showed that the percent of patients with serious device related adverse events associated with the H3 device was significantly lower than the percent of patients with serious device related adverse events associated with the control device. The percent of patients in the H3 PSE Cohort with serious device related adverse events was consistent with the percent of patients in the H3 literature.

Adverse effects that occurred in the PMA clinical study:

Table 12: Serious Device Related Adverse Events - Listing

Hintermann Series H3™ Total Ankle Replacement System Serious Device Related Adverse Events H3 and Control Literature and NJR				
Mercer Classification 1	**Mercer Classification 2**	**H3 - Updated PSE cohort**	**H3 Literature**	**Control-All**
-	Chronic Pain	0.4% (1/ 273)		
-	Chronic Pain, Stiffness			0.2% (5/3020)
Aseptic Loosening	-	0.7% (2/ 273)	2.5% (60/2437)	3.5% (105/3020)
Aseptic Loosening	Talus		0.2% (6/2437)	0.4% (12/3020)
Aseptic Loosening	Tibia	0.4% (1/ 273)	0.2% (5/2437)	0.4% (11/3020)
Aseptic Loosening	Tibia, Talus			0.1% (4/3020)
Aseptic Loosening, Infection, Fracture	Tibia, Talus		0.6% (14/2437)	
Aseptic Loosening, Metal Component Fracture, Malalignment	-			0.2% (6/3020)
Aseptic Loosening, Osteolysis, Infection, Fracture	Impingement		0.5% (12/2437)	
Fracture, Other	-			0.4% (11/3020)
Loosening	-		0.4% (10/2437)	
Loosening	Talus			0.1% (2/3020)
Loosening	Tibia			0.2% (5/3020)
Loosening	Tibia, Ossification			0.1% (3/3020)

Hintermann Series H3™ Total Ankle Replacement System Serious Device Related Adverse Events H3 and Control Literature and NJR				
Mercer Classification 1	**Mercer Classification 2**	**H3 - Updated PSE cohort**	**H3 Literature**	**Control-All**
Loosening	Tibia, Talus			0.1% (3/3020)
Lysis	-		0.1% (2/2437)	
Malalignment	Tibia Or Talus			0.3% (9/3020)
Osteolysis	-		0.5% (13/2437)	0.4% (13/3020)
Osteolysis	Talus	0.4% (1/ 273)		
Osteolysis	Tibia	0.4% (1/ 273)		0.5% (15/3020)
Other	-		0.0% (1/2437)	0.7% (20/3020)
Other, Polyethylene Problems	-		0.2% (5/2437)	
Polyethylene Problems	-		0.1% (2/2437)	0.7% (21/3020)
Polyethylene Problems	Fracture	0.7% (2/ 273)	0.3% (7/2437)	1.6% (49/3020)
Polyethylene Problems	Instability		0.1% (3/2437)	
Polyethylene Problems	Ossification			0.0% (1/3020)
Polyethylene Problems	Wear	0.7% (2/ 273)	0.1% (2/2437)	
Polyethylene Problems, Other	Fracture			0.0% (1/3020)
Subsidence	-		0.2% (4/2437)	0.7% (20/3020)
Subsidence	Talus	1.5% (4/ 273)		0.0% (1/3020)
Subsidence	Talus & Tibia	0.4% (1/ 273)		
Subsidence	Tibia	0.4% (1/ 273)		0.0% (1/3020)

1Mercer et al. Provides a classification system for adverse events in TAR. Classification 1 is the proposed adverse event category. Each category is then subclassified further by type of adverse event, or specific anatomic location (Classification 2). (Mercer J., Penner M. et al. Inconsistency in the Reporting of Adverse Events in Total Ankle Arthroplasty: A Systemic Review of the Literature. Foot & Ankle International 2016, Vol. 37(2) 127-136).

Device Related Adverse Events

In the PSE Cohort, a device related adverse event was associated with the H3 device in 18/273 subjects (6.6%). Based on data extracted from the published literature and from national joint registries, the device related adverse event rate for the H3 device was 6.0% and was 14.0% for the control device. The DRAE rate for the H3 PSE Cohort was the same as the DRAE rate for the H3 device reported in the published literature.

Table 13: Device Related Adverse Events - Summary

Hintermann Series H3™ Total Ankle Replacement System: Percent of Patients with Device-Related Adverse Events Hintermann Registry, H3 and Control Literature and NJR			
DRAE-Percent of Patients	**H3 - PSE Cohort**	**H3 Literature**	**Control-All**
	6.6% (18/273)	6.0% (147/2437)	14.0% (424/3020)

The following table lists the device related adverse events organized by Mercer classifications as reviewed and adjudicated by the CEC.

Table 14: Device Related Adverse Events - Listing

Hintermann Series H3™ Total Ankle Replacement System Device Related Adverse Events: H3 and Control Literature and NJR				
Mercer Classification 1	**Mercer Classification 2**	**H3 – Updated PSE Cohort**	**H3 Literature**	**Control-All**
-	Chronic Pain	0.4% (1/ 273)		
-	Chronic Pain, Stiffness			0.2% (5/3020)
-	Ossification			0.0% (1/3020)
Aseptic Loosening, Subsidence	-			0.2% (5/3020)
Aseptic Loosening	-	0.7% (2/ 273)	2.5% (60/2437)	3.7% (112/3020)
Aseptic Loosening	Talus		0.2% (6/2437)	0.4% (12/3020)
Aseptic Loosening	Tibia	0.4% (1/ 273)	0.2% (5/2437)	0.4% (11/3020)
Aseptic Loosening	Tibia, Talus			0.2% (5/3020)
Aseptic Loosening, Infection, Fracture	Tibia, Talus		0.6% (14/2437)	
Aseptic Loosening, Metal Component Fracture, Malalignment	-			0.2% (6/3020)
Aseptic Loosening, Osteolysis, Infection, Fracture	Impingement		0.5% (12/2437)	
Fracture, Other	-			0.4% (11/3020)
Loosening	-		0.4% (10/2437)	
Loosening	Talus			0.1% (2/3020)
Loosening	Tibia			0.2% (5/3020)

Hintermann Series H3™ Total Ankle Replacement System Device Related Adverse Events: H3 and Control Literature and NJR				
Mercer Classification 1	**Mercer Classification 2**	**H3 – Updated PSE Cohort**	**H3 Literature**	**Control-All**
Loosening	Tibia, Ossification			0.1% (3/3020)
Loosening	Tibia, Talus			0.1% (3/3020)
Lysis	-		0.1% (2/2437)	
Malalignment	Talus			0.0% (1/3020)
Malalignment	Tibia Or Talus			0.3% (9/3020)
Osteolysis	-	0.4% (1/ 273)	0.5% (13/2437)	0.8% (25/3020)
Osteolysis	Talus	0.4% (1/ 273)		
Osteolysis	Tibia	0.7% (2/ 273)		0.8% (24/3020)
Other	-		0.0% (1/2437)	0.7% (21/3020)
Other, Polyethylene Problems	-		0.2% (5/2437)	
Polyethylene Problems	-		0.1% (2/2437)	1.6% (47/3020)
Polyethylene Problems	Fracture	0.7% (2/ 273)	0.3% (7/2437)	1.6% (49/3020)
Polyethylene Problems	Instability		0.1% (3/2437)	
Polyethylene Problems	Ossification			0.0% (1/3020)
Polyethylene Problems	Wear	0.7% (2/ 273)	0.1% (2/2437)	0.1% (2/3020)
Polyethylene Problems, Other	Fracture			0.0% (1/3020)
Subsidence	-		0.2% (5/2437)	0.7% (21/3020)
Subsidence	Talus	1.5% (4/ 273)		0.9% (27/3020)
Subsidence	Talus & Tibia	0.4% (1/ 273)		
Subsidence	Tibia	0.4% (1/ 273)		0.6% (17/3020)

1Mercer et al. Provides a classification system for adverse events in TAR. Classification 1 is the proposed adverse event category. Each category is then subclassified further by type of adverse event, or specific anatomic location (Classification 2). (Mercer J., Penner M. et al. Inconsistency in

the Reporting of Adverse Events in Total Ankle Arthroplasty: A Systemic Review of the Literature. Foot & Ankle International 2016, Vol. 37(2) 127-136).

Serious Adverse Events

In the PSE Cohort, a serious adverse event was associated with the H3 device in 92/273 subjects (33.7%). Based on data extracted from the published literature and from national joint registries, the serious adverse event rate for the H3 device was only 9.8% and was 21.9% for the control device.

Table 15: Serious Adverse Events (SAE)

Hintermann Series H3™ Total Ankle Replacement System Percent of Patients with Serious Adverse Events Hintermann Registry, H3 and Control Literature and NJR			
SAE-Percent of Patients	**H3 - PSE Cohort**	**H3 Literature**	**Control-All**
	33.7% (92/273)	9.8% (238/2437)	21.9% (660/3020)

The reason for increased SAEs in the H3 PSE cohort is unknown.

Table 16: Serious Adverse Events / Serious Device Related Adverse Events

Comparison of Serious Adverse Events to Serious Device Related Adverse Events: H3 PSE Cohort, H3 Literature, Control			
SAE-Percent of Patients	**H3 - PSE Cohort**	**H3 Literature**	**Control-All**
	33.7% (92/273)	9.8% (238/2437)	21.9% (660/3020)
SADE-Percent of Patients	**H3 - PSE Cohort**	**H3 Literature**	**Control-All**
	5.9% (16/273)	6.0% (146/2437)	10.5% (316/3020)

The following table lists the serious adverse events organized by Mercer classifications as reviewed and adjudicated by the CEC.

Table 17: Serious Adverse Events - Listing

Hintermann Series H3™ Total Ankle Replacement System Serious Adverse Events H3 and Control Literature and NJR				
Mercer Classification 1	**Mercer Classification 2**	**H3 - PSE Cohort**	**H3 Literature**	**Control-All**
-	Arthritis			0.0% (1/3020)
-	Arthritis, Pain			0.0% (1/3020)
-	Arthrofibrosis	0.4% (1/ 273)	0.0% (1/2437)	
-	Pain, Arthrofibrosis		0.2% (5/2437)	
-	Avascular Necrosis Of Talus	0.4% (1/ 273)		0.0% (1/3020)
-	Chronic Pain	0.4% (1/ 273)	0.1% (2/2437)	0.7% (22/3020)
-	Chronic Pain, Hindfoot Malalignment	0.4% (1/ 273)		

Hintermann Series H3™ Total Ankle Replacement System Serious Adverse Events H3 and Control Literature and NJR				
Mercer Classification 1	**Mercer Classification 2**	**H3 - PSE Cohort**	**H3 Literature**	**Control-All**
-	Chronic Pain, Stiffness			0.4% (12/3020)
-	Edema	0.4% (1/ 273)		
-	Equinus Contracture	0.4% (1/ 273)		
-	Heterotopic Ossification, Chronic Pain			0.2% (6/3020)
-	Hindfoot Malalignment	0.4% (1/ 273)		0.2% (7/3020)
-	Hindfoot Malalignment, Ligamentous Instability	0.8% (2/273)		
-	Hindfoot Malalignment			0.0% (1/3020)
-	Impingement	0.4% (1/ 273)	0.0% (1/2437)	
-	Lateral Instability			0.0% (1/3020)
-	Ligamentous Instability	4.0% (11/273)	0.1% (2/2437)	0.2% (6/3020)
-	Lateral Malleolus			0.2% (6/3020)
-	Ossification			0.0% (1/3020)
-	Tarsal Tunnel Syndrome	0.8% (2/273)	0.1% (2/2437)	
-	Tarsal Tunnel Syndrome, Arthrofibrosis	0.4% (1/ 273)		
-	Thromboembolism			0.1% (2/3020)
-	Wound Healing Problem		0.1% (2/2437)	0.1% (3/3020)
-	Wound Healing Problems			0.6% (19/3020)
Aseptic Loosening	-	0.8% (2/273)	2.5% (61/2437)	3.5% (105/3020)
Aseptic Loosening	Talus		0.2% (6/2437)	0.4% (12/3020)
Aseptic Loosening	Tibia	0.4% (1/ 273)	0.2% (5/2437)	0.4% (11/3020)
Aseptic Loosening	Tibia, Talus			0.1% (4/3020)
Aseptic Loosening, Infection, Fracture	Tibia, Talus		0.6% (14/2437)	
Aseptic Loosening, Metal Component Fracture, Malalignment	-			0.2% (6/3020)

Hintermann Series H3™ Total Ankle Replacement System Serious Adverse Events H3 and Control Literature and NJR				
Mercer Classification 1	**Mercer Classification 2**	**H3 - PSE Cohort**	**H3 Literature**	**Control-All**
Aseptic Loosening, Osteolysis, Infection, Fracture	Impingement		0.5% (12/2437)	
Fracture	-	0.4% (1/ 273)	0.1% (2/2437)	0.5% (14/3020)
Fracture	Arthritis			0.0% (1/3020)
Fracture	Fibula	0.8% (2/273)		
Fracture	Lateral Malleolus		0.0% (1/2437)	0.3% (9/3020)
Fracture	Malleolus		0.3% (8/2437)	1.1% (33/3020)
Fracture	Medial Malleolus	10.3% (28/273)		0.8% (25/3020)
Fracture	Talus	0.8% (2/273)		
Fracture	Tibia	1.5% (4/273)		
Fracture, Other	-			0.4% (11/3020)
Infection	-	2.6% (7/273)	0.7% (16/2437)	1.1% (34/3020)
Infection	Periprosthetic	2.6% (7/273)	0.2% (4/2437)	0.8% (24/3020)
Infection	Superficial	0.4% (1/ 273)		
Infection	Wound Healing Problems		0.4% (9/2437)	1.5% (44/3020)
Loosening	-		0.4% (10/2437)	
Loosening	Talus			0.1% (2/3020)
Loosening	Tibia			0.2% (5/3020)
Loosening	Tibia, Ossification			0.1% (3/3020)
Loosening	Tibia, Talus			0.1% (3/3020)
Lysis	-		0.1% (2/2437)	
Malalignment	-			0.3% (8/3020)
Malalignment	Talus	0.4% (1/ 273)		
Malalignment	Tibia	1.1% (3/273)		0.4% (11/3020)
Malalignment	Tibia Or Talus	0.8% (2/273)		0.9% (27/3020)

Hintermann Series H3™ Total Ankle Replacement System Serious Adverse Events H3 and Control Literature and NJR				
Mercer Classification 1	**Mercer Classification 2**	**H3 - PSE Cohort**	**H3 Literature**	**Control-All**
Malalignment Tibia	-		0.1% (3/2437)	
Malalignment Tibia	Tibia Or Talus		0.1% (2/2437)	
Malalignment Tibia And Talus	-			0.0% (1/3020)
Malalignment Tibia/Talus	Tibia Talus	0.4% (1/ 273)		
Osteolysis	-		0.5% (13/2437)	0.4% (13/3020)
Osteolysis	Talus	0.4% (1/ 273)		
Osteolysis	Tibia	0.4% (1/ 273)		0.5% (15/3020)
Other	-	1.1% (3/273)	0.9% (22/2437)	2.1% (62/3020)
Other	Wound Healing Problems			0.1% (3/3020)
Other, Polyethylene Problems	-		0.2% (5/2437)	
Polyethylene Problems	-		0.1% (2/2437)	0.7% (21/3020)
Polyethylene Problems	Fracture	0.8% (2/273)	0.3% (7/2437)	1.6% (49/3020)
Polyethylene Problems	Instability	2.2% (6/273)	0.2% (4/2437)	
Polyethylene Problems	Ossification			0.0% (1/3020)
Polyethylene Problems	Wear	0.8% (2/273)	0.1% (2/2437)	
Polyethylene Problems, Other	Fracture			0.0% (1/3020)
Soft Tissue	Nerve		0.1% (2/2437)	
Soft Tissue	Nerve Injury	0.4% (1/ 273)		
Soft Tissue	Tarsal Tunnel Syndrome, Nerve		0.3% (7/2437)	
Soft Tissue	Tendon Injury	0.4% (1/ 273)		
Subsidence	-		0.2% (4/2437)	0.7% (20/3020)
Subsidence	Talus	1.5% (4/273)		0.0% (1/3020)
Subsidence	Talus & Tibia	0.4% (1/ 273)		
Subsidence	Tibia	0.4% (1/ 273)		0.0% (1/3020)

1Mercer et al. Provides a classification system for adverse events in TAR. Classification 1 is the proposed adverse event category. Each category is then subclassified further by type of adverse event, or specific anatomic location (Classification 2). (Mercer J., Penner M. et al. Inconsistency in the Reporting of Adverse Events in Total Ankle Arthroplasty: A Systemic Review of the Literature. Foot & Ankle International 2016, Vol. 37(2) 127-136).

Revisions

A revision of the TAR device as defined by the Mercer classifications was associated with the H3 in 27/273 subjects (9.9%). Based on data extracted from the published literature and from national joint registries, the revision rate for the H3 was 5.5%, but was 12.9% for the control device.

Table 18: Revisions - Summary

Hintermann Series H3™ Total Ankle Replacement System: Percent of Patients with Revisions Hintermann Registry, H3 and Control Literature and NJR			
Revisions-Percent of Patients	**H3 - PSE Cohort**	**H3 Literature**	**Control-All**
	9.9% (27/273)	5.5% (134/2437)	12.9% (391/3020)

Table 19: Revisions - Listing

Hintermann Series H3™ Total Ankle Replacement System Revision Intervention: H3 and Control Literature and NJR				
Mercer Classification 1	**Mercer Classification 2**	**H3 - Updated PSE Cohort**	**H3 Literature**	**Control-All**
-	Arthritis, Pain			0.0% (1/3020)
-	Arthrofibrosis		0.0% (1/2437)	
-	Avascular Necrosis Of Talus	0.4% (1/ 273)		
-	Avascular Necrosis Talus			0.0% (1/3020)
-	Chronic Pain	0.4% (1/ 273)	0.1% (2/2437)	0.7% (22/3020)
-	Equinus Contracture	0.4% (1/ 273)		0.0% (1/3020)
-	Hindfoot Malalignment	0.4% (1/ 273)		
-	Impingement	0.4% (1/ 273)	0.0% (1/2437)	
-	Lateral Malleolus			0.2% (6/3020)
-	Ligamentous Instability	0.4% (1/ 273)	0.0% (1/2437)	0.2% (6/3020)
-	Pain, Arthrofibrosis		0.2% (5/2437)	
-	Wound Healing Problems			0.3% (10/3020)
Aseptic Loosening	-	0.4% (1/ 273)	2.3% (56/2437)	3.5% (105/3020)

Hintermann Series H3™ Total Ankle Replacement System Revision Intervention: H3 and Control Literature and NJR				
Mercer Classification 1	**Mercer Classification 2**	**H3 - Updated PSE Cohort**	**H3 Literature**	**Control-All**
Aseptic Loosening	Talus		0.2% (6/2437)	0.4% (12/3020)
Aseptic Loosening	Tibia	0.4% (1/ 273)	0.2% (5/2437)	0.4% (11/3020)
Aseptic Loosening	Tibia, Talus			0.1% (4/3020)
Aseptic Loosening, Infection, Fracture	Tibia, Talus		0.6% (14/2437)	
Aseptic Loosening, Metal Component Fracture, Malalignment	-			0.2% (6/3020)
Fracture	-			0.4% (13/3020)
Fracture	Arthritis			0.0% (1/3020)
Fracture	Malleolus			0.6% (19/3020)
Fracture	Tibia	0.4% (1/ 273)		
Fracture, Other	-			0.4% (11/3020)
Infection	-	0.4% (1/ 273)	0.4% (10/2437)	0.7% (21/3020)
Infection	Periprosthetic	1.8% (5/ 273)	0.2% (4/2437)	0.2% (6/3020)
Loosening	Talus			0.1% (2/3020)
Loosening	Tibia			0.1% (4/3020)
Loosening	Tibia, Ossification			0.1% (2/3020)
Loosening	Tibia, Talus			0.1% (3/3020)
Malalignment	-			0.1% (4/3020)
Malalignment	Talus	0.4% (1/ 273)		
Malalignment	Tibia	0.4% (1/ 273)		0.2% (5/3020)
Malalignment	Tibia Or Talus	0.4% (1/ 273)		0.7% (20/3020)
Malalignment Tibia	Tibia Or Talus		0.1% (2/2437)	
Malalignment Tibia And Talus	-			0.0% (1/3020)
Malalignment Tibia/Talus	Tibia Talus	0.4% (1/ 273)		
Osteolysis	-			0.4% (11/3020)

Hintermann Series H3™ Total Ankle Replacement System Revision Intervention: H3 and Control Literature and NJR				
Mercer Classification 1	**Mercer Classification 2**	**H3 - Updated PSE Cohort**	**H3 Literature**	**Control-All**
Osteolysis	Talus	0.4% (1/ 273)		
Other	-	0.4% (1/ 273)	1.0% (24/2437)	1.7% (52/3020)
Polyethylene Problems	Fracture	0.4% (1/ 273)		0.3% (8/3020)
Polyethylene Problems	Instability		0.1% (3/2437)	
Polyethylene Problems	Ossification			0.0% (1/3020)
Polyethylene Problems	Wear	0.4% (1/ 273)		
Soft Tissue	Tendon Injury	0.4% (1/ 273)		
Subsidence	-			0.7% (20/3020)
Subsidence	Talus	0.7% (2/ 273)		0.0% (1/3020)
Subsidence	Tibia	0.4% (1/ 273)		0.0% (1/3020)

[1]Mercer et al. Provides a classification system for adverse events in TAR. Classification 1 is the proposed adverse event category. Each category is then subclassified further by type of adverse event, or specific anatomic location (Classification 2). (Mercer J., Penner M. et al. Inconsistency in the Reporting of Adverse Events in Total Ankle Arthroplasty: A Systemic Review of the Literature. Foot & Ankle International 2016, Vol. 37(2) 127-136).

Survivorship: Kaplan Meier Analysis

Kaplan Meier survivorship estimate at 2 years is 0.93 (95% CI: 0.900-0.959), at 5 years is 0.92 (95% CI: 0.887-0.952), and at 7 years is 0.88 (95% CI: 0.824-0.936).

Table 20: Kaplan Meier Survivorship – Metal Components, PSE Cohort

Year	Survival	N*Revised (Cumulative)	N*Remaining at Risk	95% Confidence Interval
0	1.00	0	298	NA*
1	0.94	18	259	0.909, 0.965
2	0.93	20	226	0.900, 0.959
3	0.93	21	172	0.894, 0.956
4	0.92	22	153	0.887, 0.952
5	0.92	22	129	0.887, 0.952
6	0.90	24	63	0.856, 0.942
7	0.88	25	31	0.824, 0.936

Subgroup Analysis

There appeared to be a trend for lower effectiveness in the smaller tibial sizes. A subgroup analysis of effectiveness by tibial size showed that the trend was driven by the AOFAS scores.

Table 21: Tibial size vs. Overall Success

	Size 1	2	3	4	5	6
Overall Success	0% (0/1)	59% (20/34)	69% (66/95)	76% (65/86)	88% (30/34)	66% (2/3)
Female	0% (0/1)	58% (19/33)	73% (43/59)	80% (12/15)	100% (1/1)	--
Male	--	100% (1/1)	64% (23/26)	75% (23/71)	88% (29/33)	66% (2/3)

Table 22: Tibial size vs. Components of Overall Success

	Size 1	2	3	4	5	6
AOFAS Success	0% (0/1)	59% (20/34)	72% (68/95)	78% (67/86)	91% (31/34)	66% (2/3)
Absence of SADE	100% (1/1)	100% (39/39)	92% (96/104)	98% (91/93)	100% (33/33)	100% (3/3)
Absence of Revision	100% (1/1)	90% (35/39)	85% (88/103)	96% (89/93)	97% (32/33)	100% (3/3)

Although the mean AOFAS at 2+ Years showed a trend for lower effectiveness in the smaller sizes, it was also true that the mean AOFAS at baseline for the H3 PSE cohort shows that subjects with smaller tibial sizes tended to have lower baseline scores than those with larger tibial sizes subjects. Thus, at 2+ years the mean changes from baseline still showed a minimal clinically important difference (MCID).

Table 23: Tibial size vs. AOFAS score

Tibial Size	N	Mean Score At Baseline	Mean Score at 2+ Years	AOFAS Change from Baseline
1	1	36.0	60.0	24
2	34	35.9 ± 14.8	68.4 ± 23	32.4 ± 24.2
3	95	40.6 ± 12.3	76.6 ± 19.5	36.1 ± 21.5
4	86	40.5 ± 10.8	80.6 ± 14.6	40.1 ± 16.9
5	34	39.9 ± 12.1	86.0 ± 10.5	46.2 ± 14.3
6	3	39.3 ± 3.5	71.7 ± 20.3	32.3 ±23.7

8. 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, etc.) 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.

- Opening of the instruments set must be done according to aseptic condition. When handling the implants, avoid any contact with other materials 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.

9. Re-use of the implants:

Orthopaedic implants already implanted must never be re-used.

The company accepts no responsibility for such re-use.

10. Re-sterilization of non-implanted products:

Re-sterilization is not allowed.

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

- Avoid excessive position such as flexion-extension

- Wear external immobilization (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.

12. Storage:

Store in dry place.

13. Product information disclosure/Liability:

DT MedTech, LLC, (DTMT), a Data Trace 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. DTMT excludes all warranties, whether expressed or implied, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose. DTMT shall not be liable for any accidental or consequential, loss, damage, or expense, directly or indirectly arising from use of this product. DTMT neither assumes nor authorizes any person to assume for it, any other or additional liability or responsibility in connection with these products. DTMT intends that this device should be used only by physicians having received proper training in orthopedic surgery technique for use of the device.

14. MRI Safety Information

The Hintermann Series H3™ Total Ankle System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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

DT MedTech, LLC
110 West Road/Suite 110
Towson, MD 21204
USA

Phone: 410-427-0003
Toll-free: 877-494-2252
FAX: 410-494-0515
Email: info@dtmedtech.com
Website: dtmedtech.com

International Customer Service:
Phone: +1 (410) 427-0003
Fax: +1 (410) 494-0515

Last revision: 05/20/2019. PMA Draft Rev 2

DT MedTech, LLC
A DATA TRACE COMPANY

Hintermann Series H3™
Total Ankle Replacement Prosthesis

Surgical Technique

SURGICAL TECHNIQUE

Table of Contents

1. Description

• **The Hintermann Series H3™Total Ankle Replacement Prosthesis** is a mobile bearing ankle incorporating both non-constrained and semi-constrained articulating surfaces that:

– resurfaces the tibia and talus by minimal bone resection

– incorporates a mobile polyethylene inlay

• The anatomical shape of the unique design of the Hintermann Series H3 Total Ankle Replacement Prosthesis is designed to provide:

– high intrinsic stability

– low contact stresses to the bone

– low ligament stress

– minimized wear

• The double-coated surface (titanium plasma spray + HaP) allows:

– uncemented fixation, biologic or bone fixation

2. Technical Features

2.1 Tibial Component

- Anatomical shape for minimized contact stress to the bone
- Minimal bone resection required
- Double-coated with titanium plasma spray and HaP for uncemented, biological or bone fixation
- Low profile anterior shield designed to provide rotational stability of tibial component
- Pyramidal peaks for anchoring in subchondral bone thus increasing stability in translation and rotation

Tibial Component
Sizes: 1, 2, 3, 4, 5, 6

2.2 PE Inlay

- Ultra-high molecular weight polyethylene, UHMWPE
- High congruency with the metal surfaces of both tibial and talar components
- Unconstrained rotatory gliding (sagittal and frontal plane) on flat tibial surface
- Free sagittal plane motion on conically-shaped talar surface (semi-constrained articulating surface)
- Large contact area with both tibial and talar components designed to provide:
  - minimized contact stresses
  - minimized wear
  - intrinsic stability against eversion-inversion forces
- X-ray markers (titanium alloy Ti6Al4V)

PE Inlay
Sizes: 1, 2, 3, 4, 5, 6
Thicknesses: 5mm, 6mm, 7mm, 9mm

2.3 Talar Component

- Anatomical shape (conical surface) designed:
  - to allow physiological talar motion
  - to minimize medial ligament stress
- Minimal bone resection required
- Double-coated with (titanium plasma spray and HaP) for uncemented, biological or bone fixation
- 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 minimize ingrowth of osteophytes

Talar Component
Sizes: 1, 2, 3, 4, 5, 6

2.4 Talar Flat Cut

- Anatomical shape (conical surface) designed:

– to allow physiological talar motion
– to minimize medial ligament stress

- Double-coated with (titanium plasma spray and HaP) for uncemented, biological or bone fixation
- Medial and lateral rims designed to guide movement of the PE inlay
- Anterior shield designed to minimize ingrowth of osteophytes

Talar Flat Cut Component
Sizes: 1, 2, 3, 4, 5

3. Materials

3.1 Introduction

The Hintermann Series H3™ Total Ankle Replacement Prosthesis is composed of:

- Tibia and talar components - Cobalt chromium alloy (containing up to 1% nickel)
- Poly inlays - UHMWPE with Ti radiographic markers

3.2 Materials

Talar and Tibial Component	PE Inlay
Cobalt chromium alloy (CoCr) ISO 5832-4 & ASTM F75 Double Coated Titanium plasma spray and hydroxyapatite (Ti + HaP) 	UHMW polyethylene ISO 5834-2 & ASTM F648 Titanium ISO 5832-3 & ASTM F136 

Indications

The Hintermann Series H3™ Total Ankle Replacement System is indicated for use as a non-cemented implant to replace a painful arthritic ankle joint due to primary osteoarthritis, post-traumatic osteoarthritis or arthritis secondary to inflammatory disease.

The device system is for prescription use.

Contraindications

The Hintermann Series H3™ Total Ankle Replacement prosthesis should not be implanted in patients with the following conditions:

- Skeletal immaturity
- Bone stock inadequate to support the device including:
  - O Severe osteoporotic or osteopenic condition or other conditions resulting in poor bone quality
  - O Avascular necrosis of the talus
- Active or prior deep infection in the ankle joint or adjacent bones
- Malalignment or severe deformity of involved or adjacent anatomic structures including:
  - O Hindfoot or forefoot malalignment precluding plantigrade foot
  - O Significant malalignment of the knee joint
  - O Insufficient ligament support that cannot be repaired with soft tissue stabilization
- Charcot joint or peripheral neuropathy that may lead to Charcot joint of the affected ankle.
- 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 the surgical site
- Immunosuppressive therapy
- Prior ankle fusion or revision of total ankle replacement
- High demand sporting activities (e.g. contact sports, jumping)
- Suspected or documented metal allergy or intolerance

Warnings

Serious post-operative complications may occur from use of the implant in a patient with:

- Lack of good general physical condition
- Severe osteoporosis
- Physiological or anatomical anomalies
- Immunological responses, sensitization, or hypersensitivity to foreign materials
- Systemic or metabolic disorders

Precautions for Use

The safety and effectiveness of this device has not been established in patients with 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 DT MedTech, LLC must not be used in conjunction with those of any other manufacturer as component parts may not be compatible.

This product must be handled and/or implanted by well-trained, qualified persons, aware of these directions for use. 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.

Surgical Technique

DT MedTech, LLC, as the manufacturer of this 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 treatment 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 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.

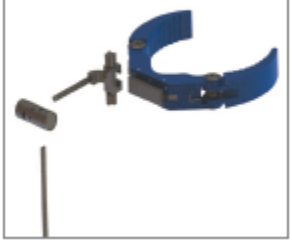
3. Positioning of the Tibial Cutting Block

3.1 Preparation

a. The tibial cutting block (309753 and 309773), the tibial rod (309615), the tibial positioning V (319625), alignment rod connector (309620), and translation block (309630) are assembled before positioning on the patient. The distal cutting block (309773) is fixed with central thumb screw in a most superior position to allow vertical adjustment.

b. The proximal end of the tibial positioning V (319625) is adjusted to the tibial tuberosity while its arms are held open and then closed.

3.1-a-1



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

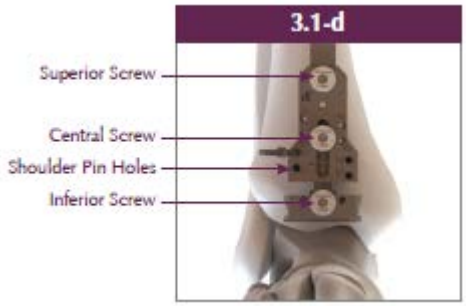
3.1-a-2

c. Proximal neutral position of the tibial rod is obtained while the translation block (309630) is positioned on the middle of the sliding rail of the tibial positioning V (319625).

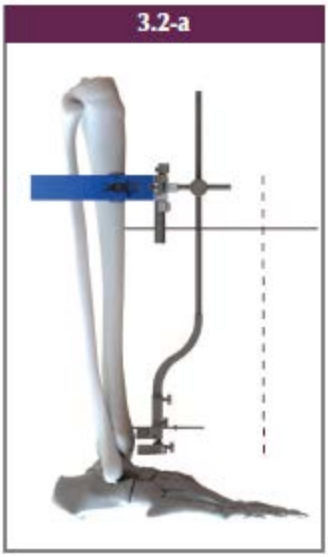
d. The distal tibial cutting block (309773) is positioned on the center of the distal tibial metaphysis and fixed by two shoulder pins (309605, 309664, 309665, or 309666).

3.1-a-3

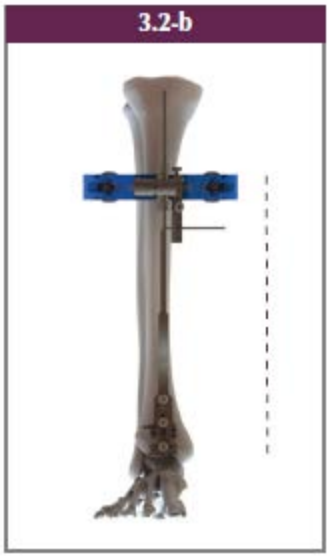
3.1-d



3.2-a



3.2-b



3.2 Settings

For proper positioning, the following adjustments must be made:

a. Sagittal plane

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

b. 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.

c. Optional Pin Outrigger

The Optional Pin Outrigger (309725): May be attached to the tibial positioning V (319625) rail for additional stability. The pin outrigger can be oriented in the proximal or distal direction on either side of the translation block (309630). One screw is used to lock the translation of the pin outrigger relative to the tibial positioning V rail. The other is used to lock the motion of the pin outrigger head. Screws may be tightened with the screwdriver (319645). The three holes are present to give multiple pin placement options. One 2.4 mm K-wire (309225) is sufficient for fixation.

3.2-c-1

3.2-c-2

3.2-c-3

3.2-c

3.2-c-4

3.2-c-5

d. Vertical adjustment

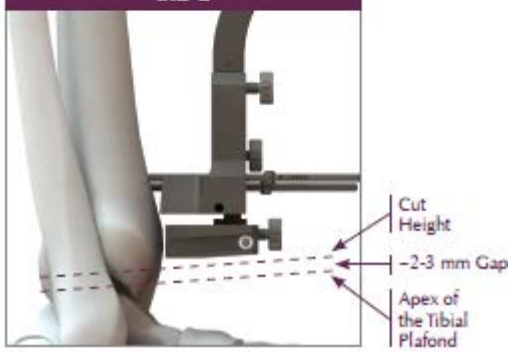
• The distal tibial cutting block (309773) is moved proximally until the desired resection height is achieved. As a general rule, a resection of approximately 2 mm to 3 mm from the apex of the tibial plafond is desired.

• Tighten the central screw with the screwdriver (319645).

3.2-d-1

3.2-d-2

3.2-d



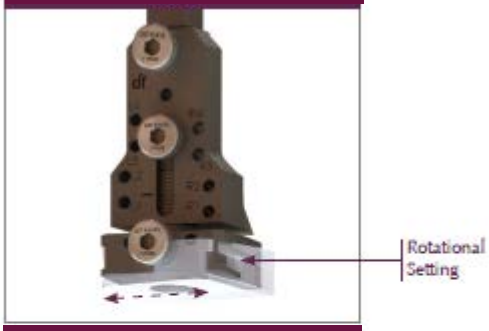
NOTE: In varus ankles, thicker tibial resection is usually needed. Whereas, in valgus ankles, and/or in presence of high joint laxity, less bone resection is advised.

e. Rotational setting

• If necessary, the distal tibial cutting block (309773) may be rotated to get a parallel position of its medial surface to the medial surface of the talus; this helps prevent damaging the medial malleolus with the saw blade during resection.

• Tighten the inferior screw with the screwdriver (319645).

3.2-e-1



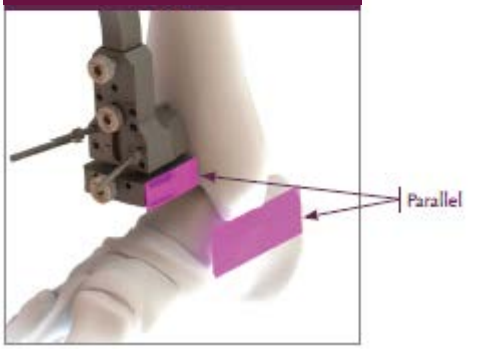
4. Tibial Resection

4.1 Positioning of the Tibial Cutting Guide

• The tibial cutting guide is selected depending on the size of the tibia. Three cutting guide sizes (SMALL– 309637, MEDIUM – 309636, and LARGE – 309635) are available. Typically, the medium guide is used to protect the lateral and the medial malleoli. The large guide should be used only for very large ankles. Special attention must be paid to the malleoli when using the saw blade.

• The guide is fixed in the slots of the cutting block creating a window in which the saw blade will be captured. The width of the window limits the excursion of the saw blade, thereby helping to protect the malleoli from being damaged.

3.2-e-2



4.1-1

4.1-2

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

4.2 First Cut

• The tibial resection is performed with the appropriate saw blade (listed below), inserted into the window of the tibial cutting block.

Several attachments are available for Hintermann Series saw blades	
Aesculap® attachment (309622)	
AO Synthes® attachment (309623)	
Stryker® 6 attachment (309624)	
Conmed Linvatec® attachment (309627)	
Stryker® attachment (309626)	

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

4.2-1

4.2-2

4.3 Opening of the Joint

• The tibial cutting guide is removed, and the Hintermann Series distractor (119664) is mounted with provided 2.4 mm K-wire (309225) 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 provides further visualization of the tibiotalar joint and facilitates the removal of the posterior resected bone and tissue fragments. K-wires may be cut to limit interference.

4.3-1

4.3-2

4.3-3

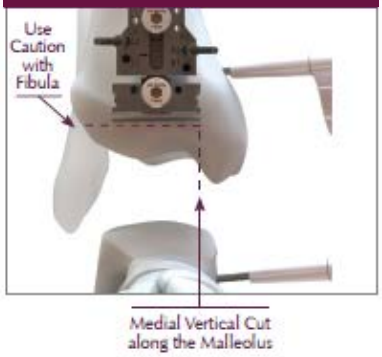
4.4 Finalization

• 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 so 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 with caution. The malleolus can fracture easily!

• While the distal part of the tibia is being resected, emphasis should be given to achieve a properly edge-shaped cut (90°) along the medial malleolus. This will allow insertion of the tibial component properly along the medial malleolus.
• In most cases, bone remains on the 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 the posterior aspect of the joint might be left in place at this stage of surgery. These are more easily removed once the talar cuts are performed, provided they do not hinder insertion of the talar cutting block.

4.4-1



4.4-2

4.4-3

5. Talar Resection

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 intraoperatively), the Flat Cut Talar Component would be used. Refer to Section 15 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.

5.1 Insertion of the Block

• The talar cutting block (309655, 309656, or 309657) is inserted into the corresponding slots of the tibial cutting block (309773) until it has been fixed by the detent.
• The central screw is unlocked and the distal tibial cutting block is translated as distally as possible until the collateral ligaments are tightened. Re-tighten the screw.
• Once the central screw is locked, the distractor is removed, leaving the K-wires in place.

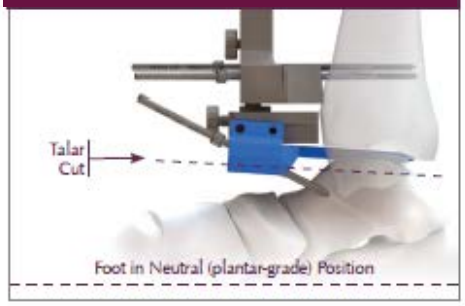
5.2 Fixation of the Block

• While the foot is held in its neutral (plantar-grade) position, 2 pins (309605 or 309665) are inserted medially and laterally to secure the talar cut guide to the talus.
• 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 repeated.

5.2-1

5.2-2

5.2-3

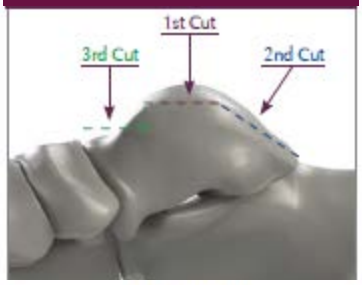


NOTE: To achieve neutral foot position, it may be helpful to take the heel with one hand, and the forefoot with the other hand. If there are any osteophytes left on talar neck that hinder, they must be removed.

5.3 Superior Cut

• The resection of the talar dome is performed with the oscillating saw. The saw blade is inserted through the slot of the talar cutting block (309655, 309656, or 309657) to affect the cut.

5.3-1



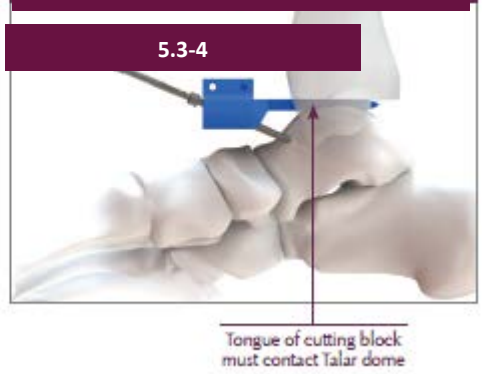
5.3-2

5.3 – NOTE - 1

5.3-3

5.3 – NOTE - 2

5.3-4



Several attachments are available for Hintermann Series saw blades	
Aesculap® attachment (309622)	
AO Synthes® attachment (309623)	
Stryker® 6 attachment (309624)	
Conmed Linvatec® attachment (309627)	
Stryker® attachment (309626)	

NOTE: If necessary, depth of the talar cut can be verified by removing the tibial resection block, distracting and visualizing the saw blade through the window or by fluoroscopy (lateral view).

5.4 Assessment of the Implant Size

• The tibial depth gauge (309607) is used to determine the size of tibial implant.

• The gauge is inserted with the appropriate face (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).

5.4

NOTE: If the anterior border of the tibia is between two 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 talar size should be within 1 size of tibial component (e.g., if tibial component size is 2, talar component size must be 1, 2, or 3).

5.5 Posterior and Collateral Cuts

• The appropriate size of the talar cutting guide* and talar cut guide handle (319380) is selected based on tibial measurement.

• 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 comes in proper contact to the resection surface of the talus.

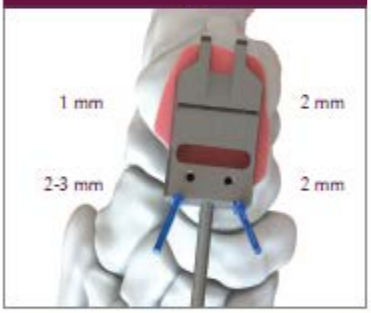
• The following bony margins around the guide should be visualized as follows:

– medial side: 2 mm margin for cuts

– lateral side: 1 to 3 mm margin (1 to 2 posterior, 2 - 3 anterior)

5.5-1

5.5-2



NOTE: If margins are larger or smaller than indicated above, the surgeon chooses a size up or down, ensuring that the size is matched to the tibial implant size plus/minus one size.

• While the foot is brought to a neutral position, the handle of the cutting guide should meet the second ray.

* 309361 to 309366 for the right foot/309371 to 309376 for the left foot

NOTE: In case of osteophytes or thick cartilage layer left on posterior talus, a chisel may be used. The tibial impactor (319751) may also be used to get the cutting guide fitted firmly to the talar resection surface.

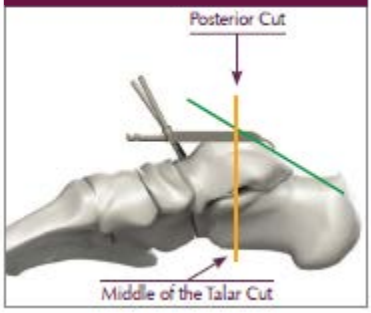
5.5-3

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

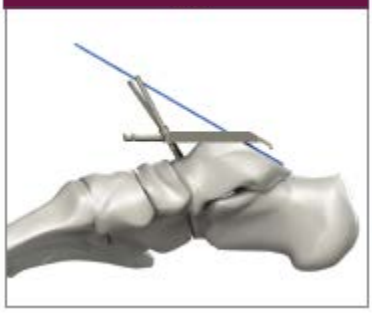
NOTE: The number and length of pins may be selected per the quality of bone to obtain an appropriate fixation. If necessary, the position of the cutting guide can be checked by fluoroscopy (e.g., proper fit of hooks on posterior aspect of talus and cutting guide on resection surface); the posterior peaks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

• The handle should be removed once the resection block is firmly fixed to the talus by pins.
• The posterior cut is made through the posterior slot using the oscillating saw blade.
• Medial and lateral cuts are made using a reciprocating saw, paying attention that the saw blade strictly follows the cutting guide.
  – Medial size: approximately 6 mm deep
  – Lateral size: approximately 8 mm deep

5.5-4



5.5-5



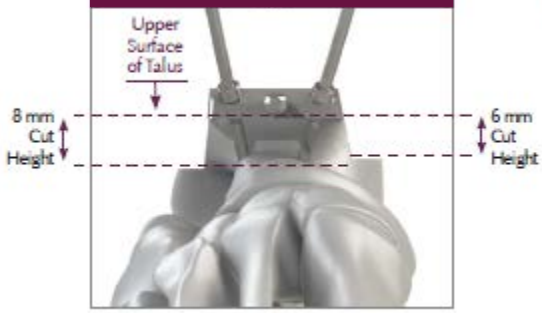
NOTE: If necessary, a chisel may be used to finish the cut at its medial and lateral borders. In order to make further talar trial impaction easier, it may be helpful to slightly resurface the postero-lateral corner of the talus, per the cutting guide.

5.5-6

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

NOTE: 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 may be softened with a chisel or rongeur to allow proper insertion of the talar trial.

5.5-7



5.5-8

5.6 Anterior Cut

• The talar reamer (diam. 6 mm, 319200) is used to make the anterior cut through the slot, and the created step is squared 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.

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

5.6-1

5.6-2

6. Checking of the Cuts, Alignment, and Stability

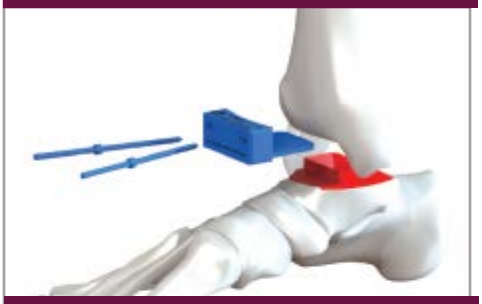
• After having removed the Hintermann Series distractor (119664), the spacer handle (309670, 309671, or 309672), representing the thickness of the tibial and talar components and the thinnest 5 mm inlay, is inserted into the created joint space. While the foot is held in neutral flexion position, it allows a check of the following points:

6.0-1

:

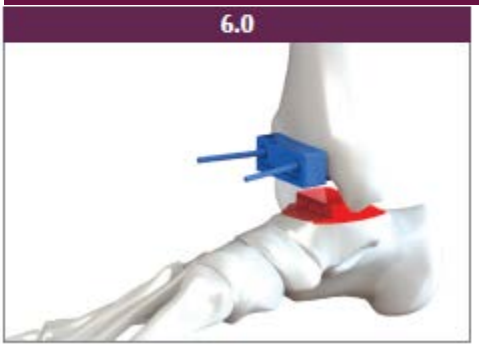
1. Resection of a sufficient quantity of bone.
If the spacer cannot be properly inserted into the joint space, and if there is no obvious contracture of the remaining posterior capsular, additional bony resection might be considered. In most instances, such additional resection should be done on the 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 2 mm tibial cutting guide (119641) can be used on the tibial cut to remove 2 mm of bone.

6.0-2



6.0-3

6.0



2. Achievement of appropriate alignment.
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 the 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 with an angular bony resection.

3. Presence of medial and lateral stability.
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 contra-lateral ligaments and/or ligament reconstruction on affected side should be considered. Ligament reconstruction is best performed once the definitive implants have been inserted, and if there is still an obvious instability.

7. Final Bone Prep

• On medial and lateral sides, the cuts are finalized using a chisel to make an almost horizontal (anterior to posterior, parallel to the floor) cut along the base of the cuts previously performed. 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.

7.0

NOTE: To achieve full dorsiflexion, the posterior capsule should be removed completely until fat tissue and tendon structures are visible.

NOTE: If using flat-cut talar component, talus will appear flat at this step if Section 15 was used.

8. Insertion of Trial Components

8.1 Talar Trial

• The selected talar trial (319680-319686 for right side/319690-319696 for left side) is inserted using the talar trial impactor (319699). The window on the posterior aspect of the trial allows verification of
proper fit to the posterior resected surface of the talus.

NOTE: If using flat-cut talar component, flat-cut trial is not shown in the images, but is placed on talus in a manner similar to what is shown in Image 8.1.

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.

8.2 Tibial Trial

• The tibial trial (129680-129686 for right side/129690-120696 for left side), as selected before, is inserted.

NOTE: 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 the tibia, removal of the osteophytes and/or smoothening of the anterolateral tibia is advised.
NOTE: If using flat-cut talar component, flat-cut trial is not shown in the images, but same principles are used to check fit of components relative to one another.

Attention should be paid to approximate tibial component against the medial malleolus.

8.3 Trial Inlay

• The 5 mm trial inlay (319865) is inserted and the Hintermann Series distractor is removed; if not enough soft tissue tension can be achieved, the 6 mm, 7 mm, or 9 mm trials (319866, 319867, or 319869) are inserted.

8.4 Trial Verification

• It is highly recommended to use fluoroscopy to check the position of implant trials with foot held in neutral position, particularly:

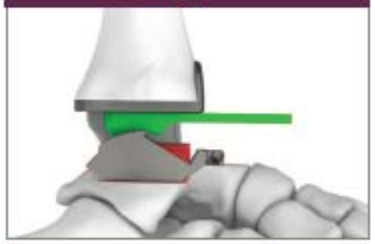
a. Appropriate length of tibial component, i.e., its posterior border should be aligned with the posterior aspect of the tibia, thereby the tibial surface is fully covered.

8.1

8.2-1

8.2-2

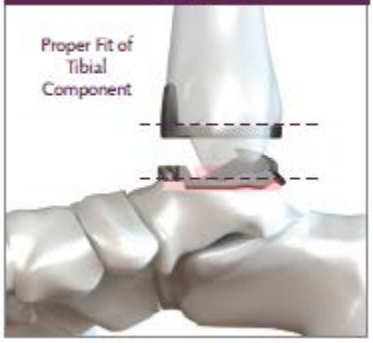
8.3



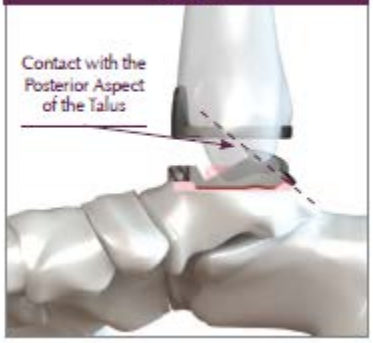
8.4-a

b. Proper fit of tibial and talar components to the prepared bone surface and parallel to each other.
c. Proper fit of the posterior edge of talar component to the posterior surface of the talus.

8.4-b



8.4-c



NOTE: If using flat-cut talar component, flat-cut trial is not shown in the images 8.4-a, 8.4-b, and 8.4-c, but same principles are used to check fit of components relative to one another.

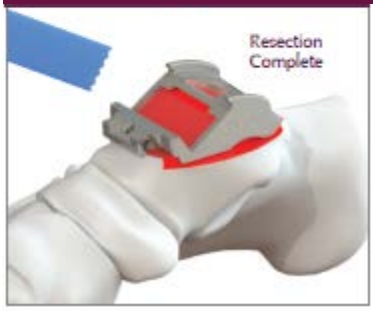
9. Anterior Cut of the Talus

• If proper position of the talar trial has been achieved, resection of the anterior surface of the talus is performed with the oscillating saw using a feathering technique.
• The Hintermann Series distractor is again used to distract the joint for visualization.

NOTE: If using flat-cut talar component, Section 9 is not needed.

9.0-1

9.0-2



10. Drilling of the Peg Holes

• The talar drilling guide (same size as the talar trials: 309300-309306) is fixed to the talar trial.
• Using the guide, 2 holes are drilled with the 4.5 mm peg drill (319309) until the shoulder of the peg drill meets the drill guide surface.
• The assembly is then removed.

10.0-1

10.0-2

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.

11. Implant Insertion

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

11.1 Talar Component

• The talar component is implanted by hand such that the pegs can be readily inserted into the 2 holes. The implant is impacted using a mallet and the talar impactor (319609) to ensure a proper fit of the component to the bone.

11.1-1

11.1-2

11.1-3

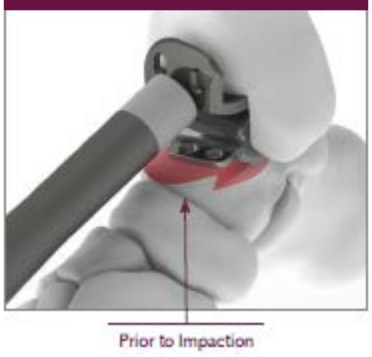
11.2 Tibial Component

• 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 tibial impactor (319751) to ensure a proper fit of the component to the bone.

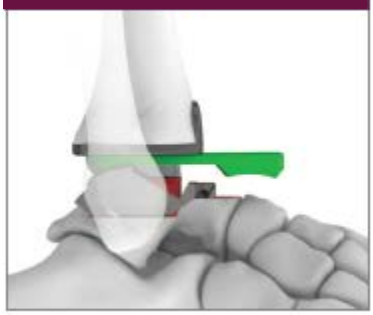
In order to obtain good contact between the tibial cut and the tibial component on the entire surface, the impactor handle should be in an oblique position regarding the tibial component axis.

11.2-1



11.2-2

11.2-3



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

11.3 Inlay

• The inlay (size matched to the talar component) is selected and inserted by hand. The 'M' marking on the implant should be realized medially.

The contact surface on the talus is conical. This creates difference between the load bearing radii on medial and lateral aspects of the talus. Proper insertion of the inlay is mandatory! The markers for right and left ankle on anterior aspect of the inlay must be respected.

11.4 Verification

• It is highly recommended to verify the position of the implants by fluoroscopy, as described for the trial implants. Note that poly inlays contain two radiographic markers which can be seen fluoroscopically indicating the alignment of the poly implant relative to the tibial and talar implants.

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.

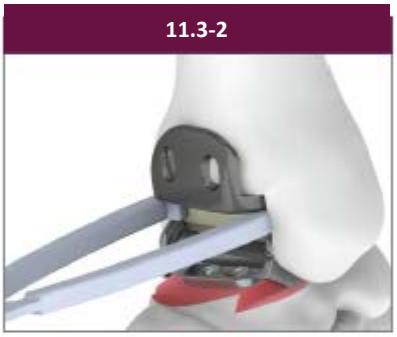
While the foot is moved in dorsiflexion with sufficient force, remaining soft tissue contracture on posterior aspect of the ankle should be released. Proper soft tissue balancing is critical to implant function.

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

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

11.3-1

11.3-2



11.3-3

11.3-4

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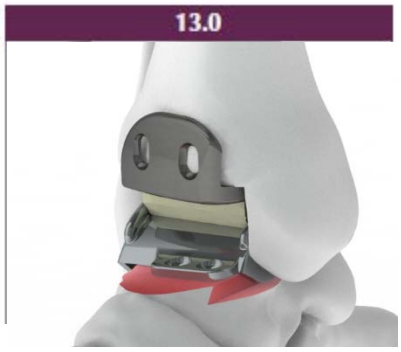
13. Wound Closure



• 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.

14. 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 for the foot and ankle after cast or walker removal, including stretching and strengthening of the triceps surae.
• The first clinical and radiological evaluation is made at 6 weeks to verify wound status, osteointegration, and position of the implants.
• It is recommended that the patient should be advised to wear a compression stocking to avoid extremity swelling for an additional 4 to 6 months.

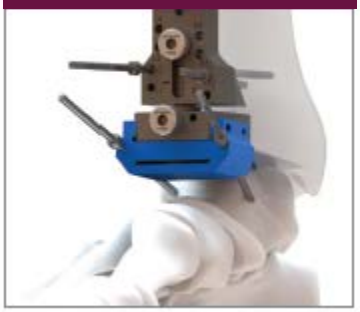
15. Flat Cut Talar Implant

15.1 Fixation of the Block

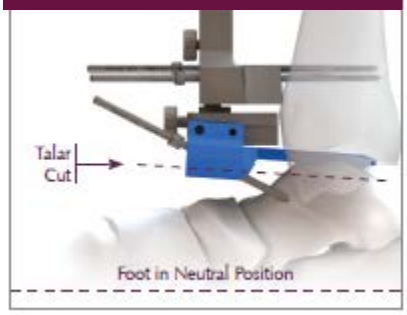
• The Flat Cut Talar cutting block (309658) is inserted into the corresponding slots of the tibial cutting block (309773) until it has been fixed by the detent.
• While the foot is held in neutral position, 2 pins (309605 or 309665) are inserted medially and laterally.
• Alignment of the hindfoot and 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.

15.1-1

15.1-2



15.1-3



NOTE: 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.

NOTE: If there is substantial bone loss of the talus, the talus should be held in its desired position to the tibia while holding the Hintermann Series distractor that tensions the ligaments. Then a free-hand flat cut is made parallel to the tibial resection surface for minimal resection of additional bone on the talar side.

15.2 Superior Cut

• The resection of the talar dome is performed with the oscillating saw. Saw blade is inserted through the window of the flat cut talar cutting block (309658) to guide and affect the cut and protect the malleoli.

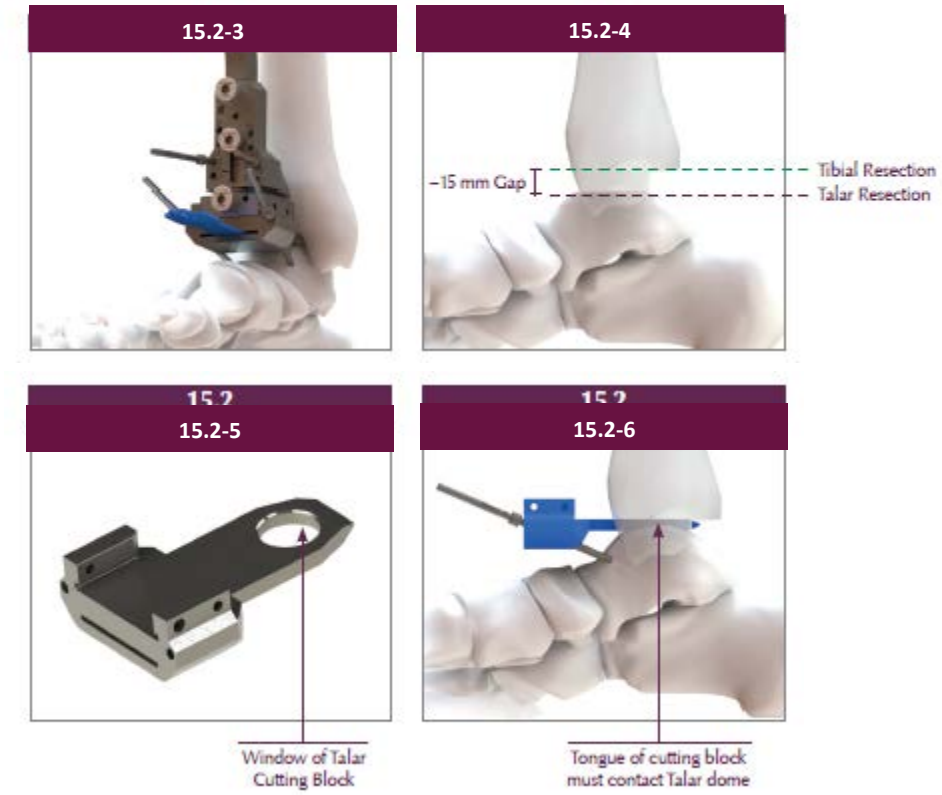
15.2-1

15.2-2

Several attachments are available for Hintermann Series saw blades

Aesculap® attachment (309622)	
AO Synthes® attachment (309623)	
Stryker® 6 attachment (309624)	
Conmed Linvatec® attachment (309627)	
Stryker® attachment (309626)	

NOTE: If necessary, depth of the talar cut can be verified by removing the tibial resection block, distracting and visualizing the saw blade through the window or by fluoroscopy (lateral view).



15.3 Assessment of the Implant Size

• The tibial depth gauge (309607) is used to determine the size of tibial implant.

• The gauge is inserted with the appropriate face (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 depth gauge, located on its upper side (tibia side).

NOTE: If the anterior border of the tibia is between two 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 talar size should be within 1 size of tibial component (e.g., if tibial component size is 2, talar component size must be 1, 2, or 3).

15.4 Collateral Cuts

• The appropriate size of the talar cutting guide* and talar cut guide handle (319380) is selected based on tibial measurement. The resection block is used for reference only for the medial and lateral cuts and should not be used for posterior and anterior shaping of the talus.

• 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.

• The following bony margins around the guide should be visualized as follows:

– Medial side: 3 mm margin for cuts

– Lateral side: 2 to 4 mm margin (2 to 3 posterior, 3 to 4 anterior)

NOTE: If margins are larger or smaller than indicated above, the surgeon chooses a size up or down, ensuring that the size is matched to the tibial implant size plus/minus one size.

• While the foot is brought to a neutral position, the handle of the cutting guide should meet the second ray.

*309361 to 309366 for the right foot/309371 to 309376 for the left foot

NOTE: In case of osteophytes or thick cartilage layer left on posterior talus, a chisel may be used. The tibial impactor (319751) may also 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.

NOTE: Number and length of pins may be selected per 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 indicates the center of the talar component with regards to its antero-posterior position.

15.4-1

15.4-2

15.4-3

• The handle should be removed once the resection block is firmly fixed to the talus by pins.
• Medial and lateral cuts are performed using a reciprocating saw, paying attention that the saw blade strictly follows the cutting guide.
  – Medial side: approximately 3 mm deep
  – Lateral side: approximately 5 mm deep

NOTE: If necessary, a chisel may 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, per the cutting guide.

15.4-4

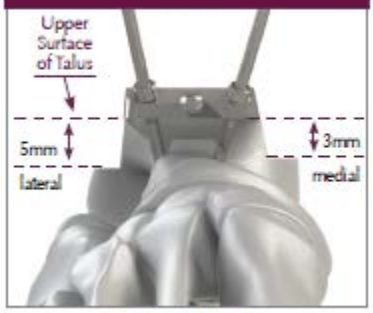
• The resected bone is removed with a rongeur.
• Remaining bony and capsular structures on posterior aspect are carefully excised.

NOTE: 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 softened with a chisel or rongeur to allow proper insertion of the talar trial.

15.4-5

15.4-6

15.4-7



(Right Foot Shown)

[Return to Section 6 to continue Surgical Technique]

16. Implant Removal

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

- The polyethylene insert (in cases where 3-component ankle prosthesis with mobile bearing was used) is removed
- The stability of 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 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 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 (FIG 8) 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 treatment is adapted accordingly

17. 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

Surgical Technique developed with the cooperation of Prof. Beat Hintermann, Liestal - Switzerland.

References

Complete Tray and Lid Set

Reference	*Description*
399900	**Instrument Case**
399901	Instrument Case (2 Full, Double Layer Trays)

Hintermann Series Total Ankle Replacement Prosthesis Instrument List:

Instrument Case (Lower Layer)	
119664	Hintermann Distractor
309615	Tibial Rod
309620	Rod Connector
319625	Tibial Positioning V
309630	Translation Block
319645	Screwdriver 3.5 mm Hex
309725	Pin Outrigger
309753	Tibial Cutting Block - Proximal
309773	Tibial Cutting Block - Distal
309635	Tibial Cut Guide Large
309636	Tibial Cut Guide Medium
309637	Tibial Cut Guide Small
309655	Talar Cut Block Large
309656	Talar Cut Block Medium
309657	Talar Cut Block Small
309607	Tibial Depth Gauge
309652	Parallel Pliers
319385	Straight Chisel
309790	Angel Wing

Instrument Case (Upper Layer)	
319609	Talar Impactor
319751	Tibial Impactor
319699	Talar Trial Impactor
309670	Spacer 12 mm
309671	Spacer 15 mm
309672	Spacer 18 mm
309361	Talar Cut Guide Right Size 1
309362	Talar Cut Guide Right Size 2
309363	Talar Cut Guide Right Size 3
309364	Talar Cut Guide Right Size 4
309365	Talar Cut Guide Right Size 5
309366	Talar Cut Guide Right Size 6
309371	Talar Cut Guide Left Size 1
309372	Talar Cut Guide Left Size 2
309373	Talar Cut Guide Left Size 3
309374	Talar Cut Guide Left Size 4
309375	Talar Cut Guide Left Size 5
309376	Talar Cut Guide Left Size 6
319380	Talar Cut Guide Handle

Instrument Case (Pin Caddy)	
119602	M4 x 0.7 Thumb Screw
319200	Talar Reamer ø 6 mm
319309	Talar Peg Drill ø 4.5 mm
309225	K-wire 1 sharp 1 blunt ø 2.4 mm L 230 mm
309605	Shoulder Pin L 70 mm, Non-Threaded
309664	Shoulder Pin L 30 mm, Threaded
309665	Shoulder Pin L 70 mm, Threaded
309666	Shoulder Pin L 45 mm, Threaded

Trial Case (Lower Layer – Includes Pin Caddy)	
119631	Tibial Spacer 4 mm
119632	Tibial Spacer 8 mm
319790	Flat Cut Talar Trial, Right, Size 1
319791	Flat Cut Talar Trial, Right, Size 2
319792	Flat Cut Talar Trial, Right, Size 3
319793	Flat Cut Talar Trial, Right, Size 4
319794	Flat Cut Talar Trial, Right, Size 5
319795	Flat Cut Talar Trial, Left, Size 1
319796	Flat Cut Talar Trial, Left, Size 2
319797	Flat Cut Talar Trial, Left, Size 3
319798	Flat Cut Talar Trial, Left, Size 4
319799	Flat Cut Talar Trial, Left, Size 5
129681	Tibial Trial, Right, Size 1
129682	Tibial Trial, Right, Size 2
129683	Tibial Trial, Right, Size 3
129684	Tibial Trial, Right, Size 4
129685	Tibial Trial, Right, Size 5
129686	Tibial Trial, Right, Size 6
129691	Tibial Trial, Left, Size 1
129692	Tibial Trial, Left, Size 2
129693	Tibial Trial, Left, Size 3
129694	Tibial Trial, Left, Size 4
129695	Tibial Trial, Left, Size 5
129696	Tibial Trial, Left, Size 6
119641	Tibial 2 mm Cut Guide
309658	Talar Cut Block - Flat Cut

Trial Case (Upper Layer)	
319765	Torque Handle
319865	Trial Inlays Thickness 5 mm
319866	Trial Inlays Thickness 6 mm
319867	Trial Inlays Thickness 7 mm
319868	Trial Inlays Thickness 9 mm
319400	Talar Anterior Mill Window
309301	Talar Drill Guide Assembly, Size 1
309302	Talar Drill Guide Assembly, Size 2
309303	Talar Drill Guide Assembly, Size 3
309304	Talar Drill Guide Assembly, Size 4
309305	Talar Drill Guide Assembly, Size 5
309306	Talar Drill Guide Assembly, Size 6
319681	Talar Trial, Right, Size 1

319682	Talar Trial, Right, Size 2
319683	Talar Trial, Right, Size 3
319684	Talar Trial, Right, Size 4
319685	Talar Trial, Right, Size 5
319686	Talar Trial, Right, Size 6
319691	Talar Trial, Left, Size 1
319692	Talar Trial, Left, Size 2
319693	Talar Trial, Left, Size 3
319694	Talar Trial, Left, Size 4
319695	Talar Trial, Left, Size 5
319696	Talar Trial, Left, Size 6

Hintermann Series H3™ Tibial Components

Reference	***Description***
301201	H3 Tibial Implant Size 1 - Right
301202	H3 Tibial Implant Size 2 - Right
301203	H3 Tibial Implant Size 3 - Right
301204	H3 Tibial Implant Size 4 - Right
301205	H3 Tibial Implant Size 5 - Right
301206	H3 Tibial Implant Size 6 - Right
302201	H3 Tibial Implant Size 1 - Left
302202	H3 Tibial Implant Size 2 - Left
302203	H3 Tibial Implant Size 3 - Left
302204	H3 Tibial Implant Size 4 - Left
302205	H3 Tibial Implant Size 5 - Left
302206	H3 Tibial Implant Size 6 - Left

Hintermann Series H3™ PE Inlays

Reference	***Description***
300105	H3 PE Inlay Size 1 - 5 mm
300106	H3 PE Inlay Size 1 - 6 mm
300107	H3 PE Inlay Size 1 - 7 mm
300109	H3 PE Inlay Size 1 – 9 mm
300205	H3 PE Inlay Size 2 - 5 mm
300206	H3 PE Inlay Size 2 - 6 mm
300207	H3 PE Inlay Size 2 - 7 mm
300209	H3 PE Inlay Size 2 – 9 mm
300305	H3 PE Inlay Size 3 - 5 mm
300306	H3 PE Inlay Size 3 - 6 mm
300307	H3 PE Inlay Size 3 - 7 mm
300309	H3 PE Inlay Size 3 – 9 mm
300405	H3 PE Inlay Size 4 - 5 mm
300406	H3 PE Inlay Size 4 - 6 mm
300407	H3 PE Inlay Size 4 - 7 mm
300409	H3 PE Inlay Size 4 – 9 mm
300505	H3 PE Inlay Size 5 - 5 mm
300506	H3 PE Inlay Size 5 - 6 mm
300507	H3 PE Inlay Size 5 - 7 mm
300509	H3 PE Inlay Size 5 – 9 mm
300605	H3 PE Inlay Size 6 - 5 mm
300606	H3 PE Inlay Size 6 - 6 mm
300607	H3 PE Inlay Size 6 - 7 mm

300609	H3 PE Inlay Size 6 – 9 mm

Hintermann Series Talar Components

Standard Component	***Description***	***Flat Cut Component***	***Description***
301111	Right – Size 1	301121	Right – Size 1
301112	Right – Size 2	301122	Right – Size 2
301113	Right – Size 3	301123	Right – Size 3
301114	Right – Size 4	301124	Right – Size 4
301115	Right – Size 5	301125	Right – Size 5
301116	Right – Size 6		
302111	Left – Size 1	302121	Left – Size 1
302112	Left – Size 2	302122	Left – Size 2
302113	Left – Size 3	302123	Left – Size 3
302114	Left – Size 4	302124	Left – Size 4
302115	Left – Size 5	302125	Left – Size 5
302116	Left – Size 6		

DT MedTech, LLC

Corporate Offices:
110 West Road | Suite 227 | Towson, MD USA 21204
Phone: (US) **410.427.0003** *(OUS)* **+1 410 427 0003**
Fax: (US) **410.494.0515** *(OUS)* **+1 410 494 0515**
Email: **info@dtmedtech.com**
Website: **dtmedtech.com**

DT MedTech International Limited

Customer Service:
Phone: **+31 73 303 2537**
Email: **CustomerService@DTMedTech.com**

Manufacturer: EU Authorized Rep:
DT MedTech, LLC Healthlink Europe BV
110 West Road, Suite 227 De Tweeling 20-22

Baltimore, MD 21204 5215 MC's-Hertogenbosch
The United States of America The Netherlands
(US) **410.427.0003 +31 73 303 2537**
(OUS) **+1 410 427 0003**

H3ST-001 REV A

INSTRUCTIONS FOR USE - INSTRUMENTS

Please see SYMBOLS GLOSSARY at the end of this IFU for additional information regarding symbols

In accordance with the directive 93/42/EEC relative to medical devices and its amendments, this product must be handled and/or implanted by WELL- TRAINED and QUALIFIED PERSONS, AWARE OF THESE DIRECTIONS FOR USE.

These instruments are intended for use in surgery and should be used only for the introduction of associated Hintermann Series H3® Products. None of the instruments should be implanted. Only medical professionals who are thoroughly familiar with the instruments function, application, and use should use them in surgery. Only a surgeon qualified to perform the orthopedic surgery required by the particular patient should use the surgical instruments.

Improper maintenance, handling, or poor cleaning procedures can render the instrument unsuitable for its intended purpose, or even dangerous to the patient or surgical staff. These devices do not contain phthalates unless this is indicated on the label. Products are sold either sterile or non-sterile.

1. **Single use instruments**:

The single use orthopaedic instruments manufactured by DT MedTech LLC must not be re-used. Re-use would incur the risk of modifying the properties and performance of the instrument. DT MedTech LLC accepts no responsibility for such re-use.

2. **Packaging (product sold STERILE only)**:

Instruments manufactured by DT MedTech LLC and sold sterile have been sterilized either by gamma radiation or using ethylene oxide (ETO).

The sterilization method is specified on the packaging. Components sterilized by radiation are exposed to a minimum of 25 kGy of gamma irradiation. Check packaging and labeling integrity before use. The sterility is guaranteed as long as the packaging has not been damaged within the expiration date.

Do not use any product in which the packaging has been opened or damaged outside the operating theatre. Inner packaging should be handled under sterile conditions (persons/instruments).

Recommendations for (re)sterilization:

Re-sterilization is only allowed for non-used products. Remove delivery packaging in compliance with current regulations to (re)sterilize non-sterile products. DT MedTech LLC recommends to sterilize its products by the steam autoclaving procedure regularly used in the hospital. (cf. Handling and Reprocessing).

3. **Re-use of the instruments**:

Unless labelled for single use, the instruments could be re-used. Active surgical instruments such as those used with powered equipment, impact or bone manipulation have a limited lifespan.

4. **Handling and reprocessing (NON-STERILE product or considered to be)**:

Check the integrity of the packaging and labeling before opening the packing. Remove all the products from their packaging prior to sterilization.

All products should be cleaned, decontaminated, and sterilized before use. Always immediately clean and decontaminate all devices that have been soiled. Repeated reprocessing has little effect on these products.

Preparation: There are no individual instruments that require disassembly prior to cleaning. Some instruments are used in combination as referenced in the Surgical Technique. Combinations of instruments are to be disassembled to a single part number prior to cleaning.

Cleaning: Cleaning can be performed manually in accordance with the specifications designated by the manufacturer of the hospital's equipment.

<u>Manual cleaning:</u>

Rinse the devices under cool, running tap water to remove gross soil. Manual cleaning consists of the use of a soft bristled cleaning brush (e.g., Spectrum M16) with an aldehyde-free cleaner. Special care is taken

for threaded, difficult to reach, and lumened devices; flush devices with a minimum of 60ml of the detergent solution and use a soft lumen brush (size 4-5mm diameter x 24") to clean the devices. Visually inspect until all areas are clean.

Steps	Conditions	Results
Steps 1 and 2 Soak and brush instruments	Product used	ENZOL or other aldehyde-free, phenol-free and QUAT - free solutions or concentrates
	Concentration	Manufacturer's recommended 7.8 ml/L (1 oz/gallon)
	Soak bath temperature	≥ 35ºC (95º F)
	Soak time	Minimum of 1 minute
	Brush devices with soft bristled brush Use lumen brushes for all lumens	Spectrum M16 or equivalent Lumen brush 5mm x 24" or equivalent
	Flush Lumens	60 ml using manufacturer's recommended 7.8ml/L (1 oz/gallon)
Step 3 Rinse instruments	Tap water temperature	≤ 20ºC (≤ 68 º F)
	Rinsing time	1 minute per device
Steps 4, 5 and 6 Soak and brush instruments	Product Used	VALSURE Neutral detergent
	Concentration	Manufacturer's recommended concentration 1.9ml/L (¼ oz/gallon)
	Soak bath temperature	≤ 20ºC (≤ 68 º F)
	Ultrasonic action	Minimum of 10 minutes
	Brush devices with soft bristled brush Use lumen brushes for all lumens	Spectrum M16 or equivalent Lumen brush 5mm x 24" or equivalent
Step 7 Rinse instruments	RO/DI water temperature	22-28ºC (71 - 82 º F)
	Rinse time	Minimum of 1 minute per device
Step 8 Visual inspect	Inspection	Visual clean and not slippery. Repeat steps 1-7 until no visual residue remains.
Step 9 Dry instruments and re-assemble	Drying	Yes

Cleaning should be immediately followed by profusely rinsing with deionized water.
Check that water flows out the cannulated parts.
Drying: Drying temperature should not exceed 95°C (200° F).
Packaging: No specific requirements.

Sterilization:
Ensure that sterilization trays are thoroughly cleaned and visually inspected prior to use. Repeat cleaning until no visual residue remains.
USE an FDA-Cleared Wrap
Do not stack trays during sterilization.

Sterilization trays	Pre-Vacuum
Minimum Temperature	132°C (270° F)
Exposure Time	4 minutes
Dry	30 minutes

The autoclave must be properly installed, maintained and calibrated. These sterilization parameters assume that all instruments have been properly cleaned and decontaminated prior to sterilization. The sterilization parameters have been validated with specific configurations as noted in the tray markings. If other products are added to the tray or to the sterilizer, the recommended parameters may not be valid and new cycle parameters may need to be validated by the user.
Other sterilization methods and cycles may also be used. However, individuals or hospitals not using the recommended method are advised to validate the alternative method using appropriate laboratory techniques. EtO sterilization or cold sterilization techniques are not recommended.

5. **Examination**:
Instruments must always be examined by the user prior to use in surgery.
Examination should be thorough, and in particular should take into account the presence of any visible defects, cracks, bending, or distortion, and that all components of the instrument and instrumentation are complete.
Never use instruments with obvious signs of excessive wear, damage, incomplete or which are otherwise non-functional.

6. **Safety (active surgical instruments)**:
Safety glasses are recommended when using any active surgical instrument.
Cannulated active surgical instruments should not be used without the appropriate corresponding K-wire or guide-wire inside the cannulated instrument. Use of wires not matched to the diameter of the cannulation may affect the performance of or damage the instrument.
K-wires are single use and must be replaced for each procedure.
The surgeon using the active surgical instrument is responsible for the proper operation of the instrument as well as any accessories or equipment, including power equipment that may be necessary for the use of the active surgical instrument.
Avoid using excessive force, twisting, or bending of the active surgical instrument in any unnatural or unintended way.
The active surgical instrument must be properly inserted and securely locked into the proper instrument before the instrument is turned on and/or operated. All accessories must be properly inserted, sealed, and locked before turning on and/or engaging the active surgical instrument.
The surgical instrument may become heated from friction and the surgeon should take appropriate care to ensure that the patient is not harmed. Minimize the tissue contact to avoid possibility of tissue damage due to excessive heat effects.
The surgical instrument must not be used for any purpose other than its intended use in the orthopedic surgical procedure. The surgical instrument must not be modified.
Resharpening of active surgical instrument should not be performed under any circumstances.
Contact with other metal objects could cause damage to the surgical instrument and may necessitate replacement.
DT MedTech LLC informs the surgeon that repeated uses of the active surgical instrument can lead to incidents which would compromise the surgical technique or the results of the procedure.

7. **Measuring instruments**:
Some surgeries require the use of instruments which incorporate a measuring function. Ensure that these markings are not worn, and any surface engravings are clearly visible.
Unless otherwise indicated on the instrument itself, the measures provided by these instruments have the following characteristics: Length Measurement Units: millimeter (mm) with accuracy in reading +/- 1mm.

Angle Measurement Units: degrees (°) with accuracy in reading of +/- 1°.

8. **Responsibility of the Surgeon**:

DT MedTech LLC does not practice medicine and does not recommend any specific surgical technique.
It is the surgeon's responsibility to select the appropriate surgical technique and instruments for each individual patient in accordance with the surgeon's practice, experience, training, standard of care and knowledge of the relevant medical literature.
DT MedTech LLC is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.
Criteria for patient selection are the responsibility of the surgeon. Prior to surgery, the surgeon should discuss with the patient possible risks, precautions, warnings, consequences, complications, and potential adverse effects associated with the surgical procedure and device being implanted during the surgical procedure. The surgeon should refer to the instructions for use accompanying the device.
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.

9. Product information disclosure / Liability:

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SYMBOLS GLOSSARY

Symbol	Reference ID*	Meaning
	1051	Single use - Do not reuse
	2607	Use by date
	2492	Batch code/number
	2493	Catalogue number
	1641	Consult instructions for use

Symbol	Reference ID*	Meaning
	2502	Sterilized by irradiation
		EO sterilization
	2609	Non-sterile
	2497	Date of manufacturer
	3082	Indicates medical device manufacturer
	0434A	Caution, consult the instructions for use for important cautionary information

* ISO 7000: Graphical Symbols For Use On Equipment - Registered Symbols. If a symbol is added from another standard, please note the standard in the table.

CE 0086

- Productcomplieswithrequirementsofdirective93/42/EECformedicaldevices
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Rx ONLY

- CAUTION:Federal(USA)lawrestrictsthisdevicetosalebyorontheorderofa physician or practitioner.

Manufacturer:
DT MedTech, LLC
110 West Road, Suite 227
Towson, MD 21024

EC REP

EU Authorized Rep:
Healthlink International BV

DeTweeling20-22
5215MC's-Hertogenbosch The Netherlands

Date of last revision: 3/12/2019