ENGLISH – FOR US ONLY

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.
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. Denitive 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 those 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.

7. 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.

8. 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.

Clinical Inclusion and Exclusion Criteria
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 #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 %)
	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 previously mentioned, 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 27/273 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.
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)
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			
	H3 - PSE Cohort	**H3 Literature**	**Control-All**
DRAE-Percent of Patients	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)
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)		
-	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)
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)
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)
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)
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)

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).

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, 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

9. 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.

10. Re-use of the implants:
Orthopaedic implants already implanted must never be re-used.
The company accepts no responsibility for such re-use.

11. Re-sterilization of non-implanted products:
Re-sterilization is not allowed.

12. 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.

13. Storage:
Store in dry place.

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

15. 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 the Hintermann Series H3 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.

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ENGLISH - FOR US ONLY

INSTRUCTIONS FOR USE
HINTERMANN SERIES H2® TOTAL ANKLE SYSTEM
SINGLE USE

Caution: Federal (USA) law restricts the sale of this device to or on the order of a licensed physician.
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 H2® Total Ankle System (Hintermann Series H2) exists in different sizes. The Hintermann Series H2 is a system designed to replace the ankle joint, which includes the following implantable components: tibial assembly, polyethylene (PE) inlay assembly, and talar component.

2. Hintermann Series H2 Total Ankle System:
The Hintermann Series H2 tibial assembly is manufactured from a titanium alloy with a titanium plasma spray coating. The tibial assembly locking pin is manufactured from PEEK. The Hintermann Series H2 talar component is manufactured from cobalt chrome alloy (CoCr) also with a plasma spray titanium coating. The PE inlay assembly, designed to lock into the tibial component, is manufactured from UHMW polyethylene with titanium alloy x-ray markers. These components are delivered sterile and are non-pyrogenic.

3. Indications:
The Hintermann Series H2 is designed to treat ankle arthritis through replacement of the ankle joint with a prosthesis, thereby reducing pain, restoring alignment, replacing flexion and extension movement in the ankle joint, and allowing for movement at the replaced joint.
The Hintermann Series H2 is indicated as a total ankle replacement in primary or revision surgery of ankle joints damaged by:
- Systemic arthritis of the ankle (e.g., rheumatoid arthritis, hemochromatosis)
- Primary arthritis (e.g., degenerative disease)
- Secondary arthritis (e.g., post-traumatic, avascular necrosis, provided enough of the talus is preserved to support the implant)

The Hintermann Series H2 is also indicated for patients with a failed previous ankle surgery and revision surgeries following failed total ankle replacement or non-union/mal-union of an ankle arthrodesis, provided sufficient bone stock is present. Note: In the United States, this device is intended for cemented use only.

4. Contraindications:
- 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
- Immunosuppressive therapy
- 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

5. Warnings:
Serious post-operative complications may occur from use of the implant in a patient who:
- Lacks good general physical condition
- Has severe osteoporosis
- Demonstrates physiological or anatomical anomalies
- Has immunological responses, sensitization, or hypersensitivity to foreign materials
- Systemic or metabolic disorders
- Moreover, joint replacement may be contraindicated where there is severe deformity
- Obtaining accurate rotation of the tibial polyethylene is critical to the ultimate alignment and wear characteristics of the H2 device and needs to be meticulously ascertained by the surgeon prior to definitively fixing the rotation with the tibial assembly. Careful assessment of the tray orientation through multiple trials of flexion and extension throughout a full range of motion will be necessary to avoid inappropriate rotation and subsequent adverse edge loading of the polyethylene.

6. Precautions for use:
Physician must determine if implant is appropriate for patients who have any of the following conditions:
- Drug and/or alcohol and/or smoke addiction and/or abuse
- Infectious disease
- Malignancy
- Local bone tumors
- Systemic or metabolic disorders or replacement
- Compromised wound healing
- Obesity
- Demonstrated psychological instability, displayed a lack of understanding, inappropriate motivation, or attitude
- Unwillingness to accept the possibility of multiple surgeries for revision or replacement
- Lacks an understanding that a metallic implant is not as strong as normal healthy bone and will bend, loosen, or fracture if excessive demand is placed on it
- Lacks an understanding that their preoperative capacity may not be fully recovered even after successful implantation

Care must be taken that the correct and appropriate size implant is used in conjunction with the correct instrumentation and trial components. Definitive implants and trial components manufactured by DT MedTech, LLC must not be used in conjunction with those of any other manufacturer as component parts may not be compatible.
Knowledge of surgical techniques, proper reduction, selection and placement of implants, and post-operative patient management are considerations essential to a successful outcome. Criteria for patient selection is the responsibility of the surgeon. Information contained within this document should be taken into consideration during the selection process. Recognition of the appropriate indications and contraindications and the selection of the proper surgical procedures and techniques determined to be best for the patient are the responsibility of the surgeon. Each surgeon must evaluate the appropriateness of the procedure and instruments used during the procedure based on his or her own training and experience.
The surgeon should discuss with the patient prior to surgery possible risks, precautions, warnings, consequences, complications, and adverse reactions associated with the surgical procedure and implantation of the device.
Each patient must be evaluated by the surgeon to determine the specific risk/benefit relationship in light of the patient's condition and the surgeon's practice, training, experience, and knowledge of the related medical literature.

7. Complications
Complications with the use of joint prosthesis have been reported in the medical literature. Any patient undergoing a surgical procedure is subject to intra-operative and post-operative complications. Each patient's tolerance to surgery, medication, and implantation of a foreign object may be different. Possible risks, adverse reactions, and complications associated with surgery and the use of the prosthesis should be discussed with, and understood by, the patient prior to surgery. The implants are composed either of titanium alloy with a porous titanium coating, PEEK, cobalt-chromium alloy with a porous titanium coating, or high density polyethylene; therefore, it is subject to possible reactions and complications, including those listed herein. 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.
Complications may include, but are not limited to:
- Pain, discomfort, or abnormal sensations due to presence of the implant
- Bending, loosening, and/or breakage
- Risk of additional injury from post-operative trauma
- Migration of the implant position or implant material resulting in injury
- Malalignment
- Wound dehiscence (surgical complication in which a wound ruptures along a surgical incision), or delayed wound healing
- Dislocation
- Instability
- Cysts
- Nerve injury/palsy
- Loss of range of motion or stiffness
- Bone fracture during implantation
- Osteolysis (the pathological destruction or disappearance of bone tissue)
- Wear
- Avascular necrosis (AVN)
- Impingement
- Infections
- Hematoma (solid swelling of clotted blood within the tissues)
- Allergy
- Thrombosis (blood clot)
- Bone non-union or delayed union

Adverse effects may necessitate re-operation, revision or removal surgery, arthrodesis of the involved joint, and/or amputation of the limb.
Implant removal should be followed by adequate postoperative management to avoid fracture or re-fracture.
Interference risks during medical imaging: MRI/SCANNER: ask the patient to systematically mention that he/she has undergone a surgical intervention at the foot level.

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

8. Use of the implant:
- All implantable components are provided sterile.
- Check packaging and labelling integrity before use. The sterility is guaranteed if 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 instruments 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 availab le 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 instrument sets 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.

9. Re-use of the implants:
Implants previously 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 extreme position such as flexion-extension
- Wear external immobilization (e.g., splint, cast, boot, etc.) according to the surgeon's prescription.
- Receive prompt medical attention for any infection that could occur, whether at the operated extremity 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. Instrument Sterilization Information
Nonsterile instruments should be sterilized prior to use according to the following recommended sterilization parameters.
Recommended sterilization parameters

Method	Temperature	Time	Drying Time
Prevacuum	270°F (132°C)	4 minutes	30 minutes Open Door 15 minutes

Once used, the instruments must be cleaned AND sterilized prior to subsequent use. Additional information on cleaning and sterilization of instrumentation is provided in the Instructions for Use-Instruments.

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

15. MRI Safety Information
The Hintermann Series H2 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 the Hintermann Series H2 in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
INFORMATION: Should any information regarding the products or their use be required, please contact your representative or distributor, or directly contact the manufacturer.

Date of last revision: 20-Feb-2025

ENGLISH - FOR OUTSIDE OF THE US ONLY

INSTRUCTIONS FOR USE
HINTERMANN SERIES TOTAL ANKLE SYSTEM
STERILE MEDICAL DEVICES • SINGLE USE

This product must be handled and/or implanted by
WELL-TRAINED and QUALIFIED PERSONS, AWARE OF THESE DIRECTIONS FOR USE.

1. Description of the medical devices:
The Hintermann Series prosthesis exists in different sizes. The prosthesis is composed of a tibial component, a talar component and an intermediary sliding core. Optional fixation screws are also provided.

Hintermann Series H3™:
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 porous titanium and hydroxyapatite coating (Ti + HAP). The intermediary sliding core is made out of UHMW polyethylene, according to ISO 5834-2 and ASTM F648.

These devices do not contain phthalates unless this is indicated on the label.

Hintermann Series H2® (OUS):
The Hintermann Series H2® tibial component is manufactured from a titanium alloy with a bilayer titanium and hydroxyapatite plasma spray coating (Ti + HAP). The tibial component locking pin is manufactured from PEEK. The Hintermann Series H2® talar component is manufactured from Cobalt Chrome alloy (CoCr) also with a bilayer titanium and hydroxyapatite plasma spray coating (Ti + HAP). The bilayer coated devices are not available in the USA. The coating for US products are single coated with porous titanium. The PE inlay, designed to lock into the tibial component, is manufactured from UHMW polyethylene with titanium alloy boss and x-ray markers.

The tibial and talar components, as well as the intermediary sliding core, are delivered sterile.
These devices do not contain phthalates unless this is indicated on the label.

2. Indications:
- systemic caused arthritis of the ankle (e.g., rheumatoid arthritis, hemochromatosis)
- primary arthritis (e.g., degenerative disease)
- secondary arthritis (e.g., posttraumatic, infection, avascular necrosis*)
- salvage for failed total ankle replacement**
- salvage for non-union and malunion of ankle arthrodesis**

*if minimally 2/3 of the talus is preserved
**if bone stock is sufficient
The patient's joint must be anatomically and structurally suited to receive the selected implant(s).
The size 0 of both Hintermann Series H3™ intermediary sliding core and talar components must not be implanted in a patient weighing more than 65 kilos.

3. Contraindications:
Relative Contraindications:
- severe osteoporosis
- immunosuppressive therapy
- high demanding sport activities (e.g., contact sports, jumping)

Absolute Contraindications:
- infection
- suspected or documented metal allergy or intolerance
- avascular necrosis of the talus/tibia of > 1/2
- severe malalignment*
- severe instability*
- diabetic syndrome

*if not surgically correctable
The size 0 of both Hintermann Series H3™ intermediary sliding core and talar components must not be implanted in a patient weighing more than 65 kilos.

4. Warnings:
Serious post-operative complications may occur from use of the implant in a patient who:
- Lacks good general physical condition;
- Has severe osteoporosis;
- Demonstrates physiological or anatomical anomalies;
- Has immunological responses, sensitization, or hypersensitivity to foreign materials;
- Systemic or metabolic disorders;

Moreover, joint replacement may be contraindicated where there is severe deformity.

5. Precautions for use:
Physician must determine if implant is appropriate for patients who have any of the following conditions:
- Drug and/or alcohol and/or smoke addiction and/or abuse;
- Infectious disease;
- Malignancy;
- Local bone tumors;
- Systemic or metabolic disorders or replacement;
- Compromised wound healing;
- Obesity;
- Demonstrated psychological instability, displayed a lack of understanding, inappropriate motivation, or attitude;
- Unwillingness to accept the possibility of multiple surgeries for revision or replacement;
- Lacks an understanding that a metallic implant is not as strong as normal healthy bone and will bend, loosen, or fracture if excessive demand is placed on it;
- Lacks an understanding that their preoperative capacity may not be fully recovered even after successful implantation.

Care must be taken that the correct and appropriate size implant is used in conjunction with the correct instrumentation and trial otrmponents. 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.
Knowledge of surgical techniques, proper reduction, selection and placement of implants, and post-operative patient management are considerations essential to a successful outcome.
Criteria for patient selection is the responsibility of the surgeon. Information contained within this document should be taken into consideration during the selection process. Recognition of the appropriate indications and contraindications and the selection of the proper surgical procedures and techniques determined to be best for the patient are the responsibility of the surgeon. Each surgeon must evaluate the appropriateness of the procedure and instruments used during the procedure based on his or her own training and experience.
The surgeon should discuss with the patient prior to surgery possible risks, precautions, warnings, consequences, complications, and adverse reactions associated with the surgical procedure and implantation of the device.
Each patient must be evaluated by the surgeon to determine the specific risk/benefit relationship in light of the patient's condition and the surgeon's practice, training, experience, and knowledge of the related medical literature.
Complications with the use of joint prosthesis have been reported in the medical literature. Any patient undergoing a surgical procedure is subject to intra-operative and post-operative complications. Each patient's tolerance to surgery, medication, and implantation of a foreign object may be different.
Possible risks, adverse reactions, and complications associated with surgery and the use of the prosthesis should be discussed with and understood by the patient prior to surgery. The implant is composed either of cobalt-chromium alloy with a porous titanium and hydroxyapatite coating, or of high density polyethylene; therefore, it is subject to possible reactions and complications, including those listed herein.
The patient should not be led to unrealistic expectations as to the performance or results that the surgery and implant can provide. The patient should be informed that the life expectancy of the device is unpredictable once implanted, and that successful results cannot be guaranteed.

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

Complications may include but are not limited to:
- Pain, discomfort, or abnormal sensations due to presence of the implant;
- Bending, loosening, and/or breakage;
- Risk of additional injury from post-operative trauma;
- Migration of the implant position or implant material resulting in injury;
- Bone loss due to stress shielding;
- Side effects may include but are not limited to:
- Infections;
- Hematoma;
- Allergy;
- Thrombosis;
- Bone nonunion or delayed union.

Adverse effects may necessitate re-operation, revision or removal surgery, arthrodesis of the involved joint, and /or amputation of the limb. Implant removal should be followed by adequate postoperative management to avoid fracture or re-fracture.
Interference risks during medical imaging:
MRI/SCANNER: ask the patient to systematically mention that he/she has undergone a surgical intervention at the foot level.

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

7. Re-use of the implants:
Orthopaedic implants already implanted must never be re-used. Re-use would incur the risk of modifying the properties and performance of the implant, and of increasing the likelihood of the complications and/or undesirable effects mentioned earlier arising. The company accepts no responsibility for such re-use.

8. Re-sterilization of non-implanted products:
Re-sterilization is not allowed.

9. Preventative actions for the patient to avoid post-operative complications:
- Avoid extreme 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.

10. Storage:
Store in dry place.

11. Product information disclosure / Liability:
DT MedTech, LLC has exercised reasonable care in the selection of materials and the manufacture of these products. DT MedTech, LLC excludes all warranties, whether expressed or implied, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose. DT MedTech, LLC shall not be liable for any accidental or consequential, loss, damage or expense, directly or indirectly araising from use of this product. DT MedTech, LLC neither assume nor authorizes any person to assume for it any other or additional liability or responsability in connection with these products. DT MedTech, LLC intends that this device should be used only by physicians having received proper training in orthopedic surgery technique for use of the device.

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.
INFORMATION: Should any information regarding the products or their uses be required, please contact your representative or distributor or directly contact the manufacturer.

The products are manufactured and referenced within the frame of the standards in force. Implantation procedures are described in the surgical technique. Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.

Date of last revision: 20-Feb-2025

FRANÇAIS

NOTICE D'INSTRUCTIONS
HINTERMANN SERIES TOTAL ANKLE SYSTEM
DISPOSITIFS MEDICAUX STERILES • USAGE UNIQUE

Ce produit doit être manipulé et / ou implanté par des personnes FORMEES, QUALIFIEES et AYANT PRIS CONNAISSANCE de la présente NOTICE.

1. Description des dispositifs médicaux :
Les Prothèses de cheville Hintermann Series existent en différentes tailles. Les prothèses sont constituées d'un composant tibial, d'un composant talaire et d'un patin intermédiaire. Des vis de fixation optionnelles sont également fournies.

Hintermann Series H3™:
Les implants tibiaux et talaires Hintermann Series H3™ sont fabriqués en alliage de Cobalt-Chrome (CoCr) selon les normes ISO 5832-4 et ASTM F75, avec un revêtement de titane poreux et d'hydroxyapatite (Ti + HAP). Le patin intermédiaire est fabriqué en polyéthylène très haut poids moléculaire UHMW selon la norme ISO 5834-2 et ASTM F648.
Ces dispositifs médicaux ne contiennent pas de phtalates sauf indication contraire sur l'étiquette.

Hintermann Series H2®:
Le composant tibial Hintermann Series H2® est fabriqué à partir d'un alliage de titane avec un revêtement par projection de plasma bicouche de titane et d'hydroxyapatite (Ti HAP). La goupille de verrouillage du composant tibial est fabriquée en PEEK. Le composant Hintermann Series® H2 talar est fabriqué à partir d'un alliage de cobalt et de chrome, également avec un revêtement bicouche de titane et d'hydroxyapatite (Ti HAP).
Les dispositifs à revêtement bicouche ne sont pas disponibles aux États-Unis. Le revêtement pour les produits américains est composé d'un seul revêtement de titane poreux. L'insert en PE, conçu pour se verrouiller dans le composant tibial, est fabriqué en polyéthylène UHMW avec un bossage en alliage de titane et des marqueurs rayons X.
Les implants tibiaux et talaires, ainsi que le patin intermédiaire, sont livrés stériles.
Ces dispositifs médicaux ne contiennent pas de phtalates sauf indication contraire sur l'étiquette.

2. Indications :
- arthrite systémique de la cheville (arthrite rhumatoïde, hemochromatosis),
- arthrose primitive (maladie dégénérative),
- arthrose secondaire (post-traumatique, infection, nécrose avasculaire*),
- reprise d'échec d'arthroplastie de cheville,**
- reprise d'échec d'arthrodèse de cheville,**

* si au minimum 2/3 de l'astragale sont préservés
** si le stock osseux est suffisant
L'articulation du patient doit être anatomiquement et structurellement adaptée pour recevoir les implants sélectionnés.
La taille 0 du patin intermédiaire et du composant talaire ne doit pas être posée à des patients de poids supérieur à 65 kilogrammes.

3. Contre-indications :
Contre-indications relatives :
- ostéoporose sévère
- thérapie immuno-suppressive
- activités sportives exigeantes (sports de contact, saut)

Contre-indications absolues :
- infection
- allergie ou intolérance aux métaux suspectée ou connue
- nécrose avasculaire du tibia ou du talus > 1/2
- défaut d'alignement majeur *
- instabilité sévère *
- syndrome diabétique

* si non corrigible chirurgicalement
La taille 0 du patin intermédiaire et du composant talaire ne doit pas être posée à des patients de poids supérieur à 65 kilogrammes.

4. Avertissements :
Des complications post-opératoires sérieuses peuvent survenir suite à l'utilisation de cet implant chez un patient qui :
- n'est pas en bonne condition physique générale ;
- a une ostéoporose sévère ;
- présente des anomalies physiologiques et physiques ;
- a des réactions immunologiques, une sensibilité ou une hypersensibilité face à des corps étrangers ;
- a des carences générales ou du métabolisme ;

De plus, le remplacement articulaire peut être contre-indiqué en cas de déformité sévère.

5. Précautions d'emploi :
Le praticien doit déterminer si l'implant est approprié pour les patients qui présentent l'une des conditions suivantes :
- dépendance ou abus face à la drogue et/ou l'alcool et/ou le tabac ;
- maladies infectieuses ;
- des signes de malignité ;
- tumeurs osseuses locales ;
- difficultés ou modifications générales du métabolisme ;
- difficulté de cicatrisation ;
- obésité ;
- instabilité psychologique, fait preuve d'un manque de compréhension, présente une motivation ou une attitude inappropriée ;
- peu de disposition à accepter la possibilité de multiples interventions de révisions ou de remplacement ;
- manque de compréhension sur la nature de l'implant métallique qui n'est pas aussi résistant qu'un os en bonne santé et qui risque de se tordre, de se desceller ou de se casser si des contraintes excessives lui sont appliquées ;
- manque de compréhension sur le fait que ses capacités préopératoires peuvent ne pas être complètement retrouvées même après une intervention réussie.

Il convient de s'assurer que l'implant adéquat, de taille appropriée, est utilisé avec l'instrumentation et les implants d'essais qui conviennent. Les implants définitifs, et les implants d'essais DT MedTech, LLC ne doivent pas être utilisés avec des éléments provenant d'un autre fabricant, car les composants peuvent ne pas être compatibles.
La connaissance des techniques opératoires, la réduction osseuse appropriée, la sélection et du placement de l'implant et la gestion post-opératoire du patient sont les conditions essentielles pour un résultat satisfaisant.
Les critères de sélection du patient sont de la responsabilité du chirurgien. Les informations contenues dans ce document doivent être prises en considération pendant la phase de sélection. La détermination des indications appropriées, des contre-indications et le choix des procédures et de la technique chirurgicale pour chaque patient sont de la responsabilité du chirurgien. Chaque chirurgien doit évaluer la pertinence de la procédure et des instruments utilisés pendant l'intervention en tenant compte de sa formation et de son expérience.
Le chirurgien doit discuter au préalable avec le patient à propos des risques chirurgicaux possibles, des précautions, des avertissements, des conséquences, des complications et enfin des effets indésirables associés à l'intervention chirurgicale et à l'implantation du dispositif médical.
Chaque patient doit être évalué par le chirurgien afin de déterminer le rapport bénéfice / risque et les agréments aux vues de l'état de santé du patient, de la pratique du chirurgien de sa formation de son expérience et de ses connaissances vis à vis de la littérature médicale correspondante.
Les complications liées à l'utilisation des prothèses articulaires ont été débattues dans la littérature médicale. Chaque patient subissant une intervention chirurgicale peut être soumis à des complications per et post-opératoires. Les tolérances de chaque patient face à une opération, un traitement médical et l'implantation d'un corps étranger peuvent être différentes.
Les risques possibles, les effets indésirables et les complications associées avec l'intervention et avec l'utilisation de prothèses doivent être discutés et compris par le patient avant l'opération. Les implants sont composés d'un alliage de cobalt-chrome revêtu de titane poreux et d'HAP ou de polyéthylène UHMW ; ainsi ils peuvent être l'objet de réactions et de complications inclues dans la liste énoncée dans ce document.
Le patient ne doit pas être amené à une espérance irréaliste tant sur les performances, les résultats que l'opération et l'implant peuvent fournir. Le patient doit être informé que la durée de vie du dispositif est imprévisible tant qu'il est implanté et que le succès ne peut pas être garanti.

IL EST DE LA RESPONSABILITE DU CHIRURGIEN DE FOURNIR AU PATIENT TOUTES LES INFORMATIONS AVANT L'OPERATION.

Complications non limitatives qui peuvent apparaître :
- Douleurs, sensations inconfortables ou anormales liées à la présence de l'implant ;
- Fléchissement, descellement, et/ ou rupture du matériel qui pourraient rendre une ablation impossible ou difficile ;
- Risque de blessure supplémentaire suite à un traumatisme post-opératoire ;
- Migration de la position de l'implant entraînant une blessure ;
- Perte osseuse liée au stress shielding.
- Les effets secondaires non limitatifs peuvent inclure ;
- Infections ;
- Hématomes ;
- Allergies :
- Thromboses ;
- Pas de fusion osseuse ou fusion tardive.

Les effets indésirables peuvent nécessiter une nouvelle opération, une révision, une ablation, une arthrodèse de l'articulation concernée et/ou une amputation du membre. L'ablation de l'implant doit être suivi par une gestion post-opératoire adéquate afin d'éviter une fracture ou une refracture.
Les risques d'interférences avec l'imagerie médicale :
MRI/SCANNER : demander au patient de prévenir systématiquement qu'il a subit une intervention au niveau du pied.

6. Utilisation de l'implant :
Les implants tibiaux et talaires, ainsi que le patin intermédiaire sont vendus stériles.
Contrôler le conditionnement et l'étiquetage avant utilisation. La stérilisation est garantie tant que le conditionnement n'est pas endommagé (un film déchiré, une étiquette manquante, un conditionnement douteux, etc) et avant la date de péremption.
Ne pas utiliser d'implant pour lequel le conditionnement a été ouvert ou détérioré à l'extérieur du bloc opératoire. L'emballage interne doit être manipulé sous conditions stériles (personnes/instruments).
Le chirurgien doit utiliser l'instrumentation recommandée en conformité avec la technique opératoire mise à disposition par le fabricant. Le dispositif médical doit être utilisé suivant les usages normaux de la profession.
Un planning preopératoire précis doit être mené de façon routinière, sur la base de données radiographiques. Des calques sont disponibles dans ce but.
Ne pas tenter une intervention chirurgicale avec un instrument ou un implant cassé, suspect ou défectueux. Contrôler tous les composants avant l'intervention pour s'assurer de leur fonctionnement.
Un inventaire suffisant d'implants stériles de différentes tailles doit être disponible au moment de la chirurgie, pour s'assurer que la taille optimale pour le patient soit utilisée.
Une méthode alternative de fixation doit être disponible en cours d'intervention.
L'ouverture de la boite d'instruments doit être réalisée suivant les conditions aseptiques.
Lors de la manipulation des implants, éviter tout contact avec d'autres matériaux ou outils qui pourraient endommager sa surface. Dans aucune circonstance l'implant ne doit être retouché. Les implants revêtus d'HA ne doivent pas être implantés avec du ciment.

7. Réutilisation de l'implant :
Les implants orthopédiques déjà implantés ne doivent jamais être réutilisés. Une telle réutilisation risquerait d'altérer les caractéristiques et performances de l'implant, l'augmentation de la probabilité de survenue des complications et/ou effets secondaires décrits précédemment. La société décline toute responsabilité pour une telle ré-utilisation.

8. Ré stérilisation de produits non implantés :
La re-stérilisation n'est pas autorisée.

9. Actions préventives pour éviter au patient des complications post-opératoires :
- éviter les positions extrêmes comme flexion extension.
- porter une immobilisation externe (plâtre, attelle…) conformément aux prescriptions du chirurgien.
- recevoir des soins rapides en cas d'infection au niveau du membre opéré ou n'importe où ailleurs sur le corps.

Le chirurgien doit encourager son patient à lui faire part de tout changement inhabituel survenant au niveau de l'articulation ou de l'extrémité opérée. En cas de signe de descellement de l'implant (douleur particulière, modifications progressives des radiographies), un programme plus intense d'examens, de contrôles est conseillé et il peut être nécessaire de restreindre l'activité du patient, de nouvelles instructions et mises en garde doivent être alors adressées au patient.
Dans tous les cas, il convient de suivre des techniques éprouvées en matière de suivi post-opératoire.
Une activité physique excessive et un traumatisme touchant l'extrémité opérée peuvent être des facteurs d'échec prématuré d'arthroplastie par déplacement, fracture, usure et/ou rupture de l'implant. Actuellement, on ne connaît pas exactement la durée de vie fonctionnelle des implants prothétiques.

10. Stockage :
Stocker les implants dans un endroit sec.

11. Renseignements sur les produits / responsabilité :
DT MedTech, LLC a exercé un soin raisonnable dans le choix des matériaux et la fabrication de ces produits. DT MedTech, LLC exclut toute autre garantie, qu'elle soit explicite ou implicite, y compris, entre autres, toute garantie implicite de qualité marchande ou d'adaptation à un but particulier. DT MedTech, LLC ne sera pas tenue pour responsable de tout frais, dommage ou perte provenant directement ou indirectement de l'usage du produit. DT MedTech, LLC n'accepte, et n'autorise personne à accepter en son nom, aucune responsabilité ou obligation supplémentaire en ce qui concerne ces produits. DT MedTech, LLC réserve l'utilisation de ce dispositif aux médecins qui ont reçu une formation convenable dans les techniques de chirurgie orthopédique nécessitant l'utilisation du dispositif.

AVERTISSEMENT : Ce dispositif n'est pas approuvé pour la fixation ou le maintien dans la partie postérieure des corps vertébraux (pédicules) tant au niveau cervical, thoracique que lombaire.
INFORMATION : Pour toutes informations concernant le produit ou son utilisation, vous pouvez contacter le représentant, le distributeur ou le fabricant directement.

Tous les produits sont livrés, référencés et repertoriés dans le respect des normes en vigueur. Les conditions d'implantation sont décrites dans le mode opératoire. Document non contractuel. Le fabricant se réserve le droit d'effectuer sans préavis toute modification visant à améliorer la qualité de ses produits.

Date de la dernière révision : 20/02/2025

DEUTSCH

GEBRAUCHSANWEISUNG
HINTERMANN SERIES TOTAL ANKLE SYSTEM
STERILE MEDIZINPRODUKTE FÜR DEN EINMALGEBRAUCH

Handhabung und/oder Implantation dieses Produkts sind UMFASSEND AUSGEBILDETEN und QUALIFIZIERTEN PERSONEN VORBEHALTEN, DIE MIT DIESER GEBRAUCHSANWEISUNG VERTRAUT sind.

1. Beschreibung der Medizinprodukte:
Die Prothese der The Hintermann Series ist in verschiedenen Größen lieferbar. Die Prothese besteht aus einer tibialen Komponente, einer talaren Komponente und einem zentralen Gleitkern. Optional sind Befestigungsschrauben erhältlich.

Hintermann Series H3™ :
Bei Hintermann Series H3™ besteht sowohl die tibiale als auch die talare Komponente aus einer Kobalt-Chrom-Legierung (CoCr) gemäß ISO 5832-4 und ASTM F75 mit einer porösen Titan- und Hydroxylapatitbeschichtung (Ti + HAP). Der zentrale Gleitkern besteht aus UHMW-polyethylen gemäß ISO 5834-2 und ASTM F648.
Sofern nicht anders auf dem Etikett vermerkt, sind diese Produkte frei von Phthalaten.

Hintermann Series H2®:
Die Hintermann Series H2® Schienbein-Komponente ist aus einer Titanlegierung mit einer Doppelschicht aus Titan und Hydroxylapatit Plasma-Sprühbeschichtung (Ti + HAP) gefertigt. Der Sicherungsstift der Schienbein-Komponente ist aus PEEK hergestellt. Die Hintermann Series H2® Sprungbein-Komponente ist aus Cobalt-Chrom-Legierung und ebenfalls einer Doppelschicht aus Titan und Hydroxylapatit Plasma-Sprühbeschichtung (Ti + HAP) gefertigt. Die doppelt beschichteten Objekte sind in den USA nicht zu erhalten. Die Beschichtung für Produkte der USA ist eine Einfachbeschichtung aus porösem Titan. Die PE-Füllung, dazu gedacht mit der Schienbein-Komponente fixiert zu werden, ist aus UHMW-polyethylen mit titanlegierten Schrauben und Röntgenkennzeichen hergestellt.
Die tibiale und die talare Komponente sowie der zentrale Gleitkern werden steril geliefert.
Sofern nicht anders auf dem Etikett vermerkt, sind diese Produkte frei von Phthalaten.

2. Indikationen:
- Systemisch verursachte Arthritis des Sprunggelenks (z. B. rheumatoide Arthritis, Hämochromatose)
- Primäre Arthritis (z.B. degenerative Erkrankung)
- Sekundäre Arthritis (z.B. posttraumatisch, Infektion, avaskuläre Nekrose*)
- Als Abhilfe bei misslungenem Ersatz des gesamten Sprunggelenks**
- Als Abhilfe bei Pseudoarthrose und Nichtzusammenwachsen bei Sprungelenkarthrodese**

*sofern mindestens 2/3 des Talus erhalten bleiben
**bei ausreichender Knochenqualität
Das Gelenk des Patienten muss sowohl anatomisch als auch strukturell für die Aufnahme des (der) gewählten Implantats (Implantate) geeignet sein.
Der zentrale Gleitkern und die talaren Komponenten der Größe 0 dürfen nur bei Patienten verwendet werden, deren Körpergewicht maximal 65 kg beträgt.

3. Kontraindikationen:
Relative Kontraindikationen:
- Schwere Osteoporose
- Immunsuppressive Therapie
- Stark beanspruchende sportliche Aktivitäten (z. B. Kontaktsportarten, Springen)

Absolute Kontraindikationen:
- Infektion
- Vermutete oder belegte Metallallergie oder -intoleranz
- Avaskuläre Talus-/Tibianekrose von > 1/2
- Schwere Fehlstellung*
- Schwere Instabilität*
- Diabetisches Syndrom

*sofern nicht chirurgisch korrigierbar
Sowohl der zentrale Gleitkern als auch die talaren Komponenten von Hintermann Series H3™ in der Größe 0 dürfen nur bei Patienten verwendet werden, deren Körpergewicht maximal 65 kg beträgt.

4. Warnhinweise:
Bei folgenden Patienten können bedingt durch das Implantat schwere postoperative Komplikationen auftreten:
- Schlechter physischer Allgemeinzustand;
- Schwere Osteoporose;
- Patienten mit physiologischen oder anatomischen Anomalien;
- Patienten mit Immunreaktionen, Sensibilisierung oder Überempfindlichkeit gegenüber Fremdmaterialien;
- Systemische oder Stoffwechselerkrankungen;

Überdies kann das Ersetzen des Gelenks bei schweren Deformationen kontraindiziert sein.

5. Vorsichtsmaßnahmen bei der Anwendung:
Der Arzt muss entscheiden, ob ein Implantat für folgende Patienten geeignet ist:
- Drogen- und/oder Alkohol- und/oder Nikotinabhängigkeit und/oder -missbrauch;
- Infektionskrankheiten;
- Maligne Erkrankungen;
- Lokale Knochentumoren;
- Systemische oder Stoffwechselerkrankungen oder Ersatz;
- Wundheilungsstörungen;
- Adipositas;
- Psychische Instabilität, intellektuelle Inkompetenz, unzureichende Motiviertheit oder Haltung;
- Keine Akzeptanz der Möglichkeit mehrerer Operationen für Wiederherstellung oder Ersatz;
- Fehlendes Verständnis dafür, dass ein Metallimplantat nicht so belastungsfähig wie ein normaler gesunder Knochen ist und sich bei Überlastung verbiegen, lockern oder brechen kann;
- Fehlendes Verständnis dafür, dass die präoperative Kapazität selbst nach erfolgreicher Implantation unter Umständen nicht wieder vollständig hergestellt werden kann;

Es muss darauf geachtet werden, dass ein Implantat der richtigen und geeigneten Größe in Verbindung mit den richtigen Instrumenten und passenden Testimplantaten verwendet wird. Die definitiven Implantate und die Testkomponenten der Herstellers DT MedTech, LLC dürfen nicht zusammen mit Produkten eines anderen Herstellers verwendet werden, da die Komponenten möglicherweise nicht kompatibel sind.
Die Kenntnis der chirurgischen Techniken, die richtige Reduzierung, Auswahl und Platzierung der Implantate sowie das postoperative Patientenmanagement sind für ein erfolgreiches Ergebnis wesentlich.
Die Verantwortung für die Kriterien der Patientenauswahl liegt beim Chirurgen. Bei der Auswahl sind die in diesem Dokument enthaltenen Informationen zu berücksichtigen. Die Verantwortung für die Erkennung der Indikationen und Kontraindikationen sowie für die Auswahl der für den Patienten am besten geeigneten chirurgischen Verfahren und Techniken, trägt der Chirurg. Jeder Chirurg muss die Eignung des Verfahrens und der Instrumente, die bei der Operation verwendet werden, anhand seiner eigenen Schulung und Erfahrung beurteilen.
Der Chirurg muss vor dem Eingriff die möglichen Risiken, Vorsichtsmaßnahmen, Warnhinweise, Folgen, Komplikationen und Nebenwirkungen, die mit dem chirurgischen Eingriff und der Implantation des Produkts verbunden sind, mit dem Patienten erörtern.
Bei jedem Patienten muss der Chirurg das Risiko-/Nutzen-Verhältnis individuell unter Berücksichtigung des Zustands des Patienten sowie der Praxis, Schulung, Erfahrung und Kenntnis der medizinischen Literatur des Chirurgen abwägen.
Die medizinische Literatur berichtet über Komplikationen bei der Verwendung von Gelenkprothesen. Intraoperative und postoperative Komplikationen können bei jedem Patienten auftreten, der sich einem chirurgischen Eingriff unterzieht. Jeder Patient reagiert anders auf den chirurgischen Eingriff, Medikamente und die Implantation eines Fremdkörpers.
Die möglichen Risiken, unerwünschten Reaktionen und Komplikationen in Verbindung mit dem chirurgischen Eingriff und der Implantation der Prothese müssen vor der Operation mit dem Patienten erörtert und von diesem verstanden werden. Das Implantat besteht entweder aus einer Kobalt-Chrom-Legierung mit poröser Titan- und Hydroxylapatitbeschichtung oder aus Polyethylen hoher Dichte. Daher können Reaktionen und Komplikationen einschließlich der hier aufgezählten auftreten.
Der Patient sollte in Bezug auf das Operationsergebnis und das Implantat keine unrealistischen Erwartungen hegen. Der Patient sollte wissen, dass die Lebensdauer des eingesetzten Implantats nicht vorhersehbar ist und keine erfolgreichen Ergebnisse garantiert werden können.

DER CHIRURG IST VERPFLICHTET, DEN PATIENTEN VOR DER OPERATION ENTSPRECHEND ZU INFORMIEREN.

Mögliche Komplikationen sind unter anderem:
- Schmerzen, Beschwerden oder implantatbedingte ungewohnte Empfindungen;
- Verbiegen, Lockern und/oder Brechen;
- Risiko zusätzlicher Verletzungen durch postoperative Traumata;
- Verlagerung des Implantats oder des Implantatmaterials und hierdurch bedingte Verletzungen;
- Osteopenie infolge operativer Stressminderung;
- Mögliche Nebenwirkungen sind unter anderem:
- Infektionen;
- Hämatome;
- Allergien;
- Thrombosen;
- Pseudoarthrose oder verzögertes Zusammenwachsen des Knochens.

Die unerwünschten Wirkungen können eine erneute Operation, die Überprüfung oder chirurgische Entfernung des Implantats, die Arthrodese des betroffenen Gelenks und/oder die Amputation der Extremität erforderlich machen. Die Entfernung des Implantats erfordert ein entsprechendes postoperatives Management, um Frakturen oder erneute Frakturen zu vermeiden.
Interferenzrisiken bei bildgebenden Untersuchungen:
MRT/SCANNER: Der Patient ist aufzufordern, vor derartigen Untersuchungen grundsätzlich darauf hinzuweisen, dass ein chirurgischer Eingriff am Fuß durchgeführt wurde.

6. Verwendung des Implantats:
Die tibiale und die talare Komponente sowie der zentrale Gleitkern werden steril geliefert.
Vor der Verwendung sind Verpackung und Etikett auf Unversehrtheit zu überprüfen. Die Sterilität ist nur bei nicht beschädigter Verpackung (verkratzte Folienverpackung, fehlendes Etikett, zweifelhafte Verpackung ...) und vor Ablauf des Verfallsdatums gewährleistet.
Bitte verwenden Sie keine Implantate, deren Verpackung außerhalb des Operationssaals geöffnet oder beschädigt wurde. Die innere Verpackung ist unter sterilen Bedingungen (Personen/Instrumente) zu handhaben.
Der Chirurg muss die vom Hersteller für die jeweilige Operationstechnik empfohlenen und von diesem lieferbaren Instrumente verwenden. Das Implantat ist in Übereinstimmung mit den professionellen Praktiken und dem Stand der Wissenschaft anzuwenden.
Die Operation ist routinemäßig auf der Grundlage von Röntgenaufnahmen sorgfältig im Voraus zu planen. Zu diesem Zweck stehen Röntgenvorlagen zur Verfügung.
Versuche, einen chirurgischen Eingriff mit defekten, schadhaften bzw. vermutlich nicht einwandfreien Instrumenten oder Implantaten durchzuführen, müssen unterbleiben. Untersuchen Sie alle Komponenten vor der Operation, um deren Eignung sicherzustellen.
Zum Zeitpunkt der Operation muss ein angemessener Bestand an sterilen Implantaten unterschiedlicher Größen zur Verfügung stehen, um sicherzustellen, dass die für den Patienten optimale Größe verwendet wird.
Während der Operation sollten alternative Befestigungsmethoden verfügbar sein.
Die Öffnung des Instrumenten-Sets muss unter aseptischen Bedingungen erfolgen.
Vermeiden Sie bei der Handhabung der Implantate jeglichen Kontakt mit anderen Materialien oder Werkzeugen, durch welche die Oberfläche des Implantats beschädigt werden könnte. Am Implantat dürfen keinesfalls Änderungen vorgenommen werden.
HA-beschichtete Implantate dürfen nicht mit Zement implantiert werden.

7. Wiederverwendung der Implantate:
Bereits implantierte orthopädische Implantate dürfen niemals wiederverwendet werden. Die Wiederverwendung birgt das Risiko einer Änderung der Eigenschaften und Leistung des Implantats und erhöht die Wahrscheinlichkeit der bereits beschriebenen Komplikationen und/oder unerwünschten Wirkungen. Das Unternehmen übernimmt im Falle der Wiederverwendung keinerlei Verantwortung.

8. Neusterilisation nicht implantierter Produkte:
Die Neusterilisation ist unzulässig.

9. Präventivmaßnahmen für den Patienten zur Vermeidung postoperativer Komplikationen:
- Extreme Positionen wie Biegen und Strecken vermeiden
- Eine externe Immobilisationshilfe (Gips, Schiene…) gemäß ärztlicher Verordnung ist zu tragen.
- Bei Infektionen an der operierten Extremität oder anderswo im Körper ist unverzüglich der Arzt zu Rate zu ziehen.

Der Patient ist dazu anzuhalten, den Chirurgen über etwaige ungewöhnliche Veränderungen der operierten Extremität zu informieren. Bei Hinweisen auf eine Ablösung des Implantats (insbesondere Schmerzen, fortschreitende Veränderungen auf der Röntgenaufnahme) müssen genaue Untersuchungen vorgenommen werden. Überdies sind dem Patienten unter Umständen neue Warnhinweise und Verhaltensmaßregeln in Bezug auf weitere Aktivitätseinschränkungen zu erteilen.
In jedem Fall müssen die bewährten postoperativen Praktiken eingehalten werden.
Übermäßige körperliche Aktivität und Verletzungen der operierten Extremität können zu vorzeitigem Versagen der Gelenkarthroplastik infolge Verlagerung, Fraktur und/oder Verschleiß des Implantats führen. Die genaue Dauer der Funktionstüchtigkeit prothetischer Implantate ist derzeit noch nicht eindeutig erwiesen.

10. Lagerung:
Trocken lagern.

11. Weitergabe von Produktinformationen / Haftung:
DT MedTech, LLC ist bei der Materialauswahl und Herstellung der Produkte mit angemessener Sorgfalt vorgegangen. DT MedTech, LLC schließt alle anderen ausdrücklichen oder stillschweigenden Gewährleistungen aus, u. a. etwaige stillschweigende Gewährleistungen der Gebrauchstauglichkeit oder der Eignung für einen bestimmten Zweck. DT MedTech, LLC übernimmt keine Haftung für etwaige beiläufig oder in der Folge entstandene Verluste, Schäden oder Kosten, die direkt oder indirekt durch die Verwendung dieses Produkts entstehen. DT MedTech, LLC übernimmt keinerlei sonstige oder zusätzliche Haftung oder Verantwortung in Verbindung mit diesen Produkten und autorisiert niemanden, diese zu übernehmen. DT MedTech, LLC hat dieses Produkt ausschließlich zur Verwendung durch Ärzten vorgesehen, die ordnungsgemäß im Gebrauch des Produkts für orthopädische Operationstechniken geschult wurden.

WARNHINWEIS: Dieses Produkt ist nicht für die Schraubbefestigung oder Fixierung an den hinteren Elementen (Pedikeln) der Hals-, Brust- oder Lendenwirbelsäule zugelassen.
INFORMATIONSMATERIAL: Sollten Sie ausführliche Informationen zu den Produkten oder deren Verwendung benötigen, setzen Sie sich bitte mit der zuständigen Vertretung bzw. Ihrem Händler oder direkt mit dem Hersteller in Verbindung.

Die Herstellung und Kennzeichnung der Produkte erfolgt unter Einhaltung der geltenden Standards. Das Implantationsverfahren richtet sich nach der jeweiligen chirurgischen Technik. Kein Vertragsdokument. Der Hersteller behält sich das Recht vor, ohne vorherige Ankündigung zwecks Qualitätsverbesserung Änderungen an den Produkten durchzuführen.

Datum der letzten Überprüfung: 20/02/2025

DANSK

BRUGSANVISNING
HINTERMANN SERIES TOTAL ANKLE SYSTEM
STERILE MEDICINSKE ANORDNINGER + ENGANGSBRUG

Dette produkt skal tilføres udelukkende af LEGEMDELANDE og KVALIFICEREDE PERSONER, DER HAR FÅET DENNE BRUGSANVISNING.

1. Beskrivelse af de medicinske anordninger:

Protesesæt i Hintermann Series findes i forskellige størrelser. Protesen består af en tibia-komponent, en talus-komponent og et mellemliggende bindelag. Der mellem bærende fladeder vægtfre suspendere fastgjorte leverandøren.

Hintermann Series HS2™:
Tibia- og talus-implantaterne fra Hintermann Series HS2™ er fremstillet i kobolt-krom-legering (CoCr) som beskrevet i ISO 5832-4 og ASTM F75, med en bedækning i porøst titanium og hydroxyapatit (Ti + HAP). Det mellemliggende fodplade produceres i polyethylen med høj massefylde (UHMW) i overensstemmelse med standarderne ISO 5834-2 og ASTM F648.
Disse instrumenter indeholder ingen flasker, medmindre andet er angivet på etiketten.

Hintermann Series H2™:
Hintermann Series H2™ Skinnebens Komponent er fremstillet af en titanium legering med et dobbeltlag af titanium og hydroxyapatit plasma-sprøj-belægning (Ti + HAP). Udeslibtiden til skinnebens komponenter er fremstillet af PEEK. Hintermann Series H2™ Ankel Komponent er fremstillet af kobolt krom legering, også med et dobbeltlag af titanium og hydroxyapatit plasma-sprøj-belægning (Ti + HAP). De dobbeltlag af titanium og hydroxyapatit er ikke tilgængelige i USA. Belægningen fra amerikanske producenter er belagt med et enkelt lag porøs titanium. PE-bærekraven, designet til at blæse op, er fremstillet af polyethylen med høj massefylde (UHMW) i overensstemmelse med standarderne ISO 5834-2 og ASTM F648.
Tibia- og talus-komponenterne samt det mellemliggende fodplade leveres steriltil.
Disse instrumenter indeholder ingen flasker, medmindre andet er angivet på etiketten.

2. Indikationer:

- artrekartrit af systemisk oprindelse (f.eks. reumatoid artrit, hæmokromatose)
- primær artrit (f.eks. degenerativ osteoartrit)
- sekundær artrit (f.eks. posttraumatisk, infektion, avasikular nekrose)*
- operation for mislykket total endotalning af ankler**
- operation for mangelende sammenvokning og forhørt sammenvokning af ankelbrudsskader***

*Ikke mindst 2/3 af talus er beskadiget
**Ikke kosystemstabilitet er tilstrækkelig!
Patienters led skal være anatomisk og strukturelt velegnet til at modtage dette valgte implantatsystem.
Stamoss U af Stille Hintermann Series HS2™ mellemliggende fodplade og talus-komponenter må ikke implanteres i patienter med en vægt over 65 kilogram.

3. Kontraindikationer:

Relative kontraindikationer:
- svær osteoporose
- immunosuppressive therapier
- mangel kræverede sportsaktiviteter (f.eks. kontaktsport, springe)

Absolute kontraindikationer:
- infektion
- mistanke om eller dokumenteret allergi eller intolerance over for metal
- avasikular nekrose af talus/tibia på > ½
- over fejlstilling*
- svær ustabilitet*
- diabetisk syndrom
- som det ikke er muligt at korrigere med skurup

Stamoss U af Stille Hintermann Series HS2™ mellemliggende fodplade og talus-komponenter må ikke implanteres i patienter med en vægt over 65 kilogram.

4. Advarsler:

Alvorlige postoperative komplikationer kan opstå ved brug af implantater hos patienter, som:
- ikke er i good general fysisk form;
- har svær osteoporose;
- udøver fysiskkrige eller anstrengende aktiviteter;
- har immunologiske reaktioner, sensibilisering eller overfølsomhed over for fremmede materialer;
- har systemiske eller metabolske forstyrrelser.

Udslæbning af et led kan skaades ved kraftige bevægelser i tilfælde af svaer deformitet.

5. Forsigtighedsregler for brug:

Lægen skal afgøre, om implantatet er egnet til patienter, som præsenterer en af følgende tilstande:
- Stof- sygdoms alkoholmisbrug og/eller afhængighed og/eller misbrug af tobak;
- Infektionssygdom;
- Malign sygdom;
- Lokale kvæstelser;
- Systemiske eller metabolske forstyrrelser eller substitution;
- Kompromitteret dæmpning;
- Sygdig fedme;
- Tilknyttede psykologisk udgangspunkt, mangel på forståelse, uposende motivation eller attitude;
- Medicin med at accepterer muligheden for flere kirurgiske indgreb for revision eller reoperation;
- Mangel på forståelse af, at et metallaminat ikke er så stærkt som en normal, sund knogle og vil tage, lavse sig eller kraekke, hvis der stilles for store krav til det;
- Ikke at kunne eller ikke forstå at det er den postoperative evne ikke kan gøre gennem det sund, som er en vellykket operation.

Man skal ikke sætte, at der bruges et velegnet implantat i passende størrelse sammen med passende instrumentation og grøvemiddelsæt. De anvendte implantater og DT MedTech, LLC-grøvemiddelsæterne må ikke bruges sammen med komponenter fra andre producenter, da komponenterne muligvis ikke er forenlige.
Kendskab til de kirurgiske teknikker, korrekt reposition, valg og placering af implantater og postoperative patientbehandling er af afgørende betydning for et vellykket resultat.
Kirterier for udvælgelse af patienter hører ind under kirurgens ansvar. Der bør tages hensyn til informationerne indeholdt i dette dokument under udvælgelsesprocessen. Det hører ind under kirurgens ansvar at skelne mellem de passende indikationer og kontraindikationer samt at vælge de egnede forsigtighedsregler og teknikker, der anses for at være mest velegnede i den enkelte patient. Kirurgen skal evaluere velegnetheden af anvende firmagrundlæggelse og instrumenter under indgrebet på grundlag af en sigt om udstimerede og ærlig.
Far indgrebet bør kirurgen tale med patienten om mulige risici, forsigtighedsregler, advarsler, kontraindikationer, komplikationer og uønskede reaktioner forbundet med det kirurgiske indgreb og indopereringen af implantatet.
Kirurgen skal evaluere hver enkelt patient for at fastslå dens specifikke risiko-/udbytteforhold i betragtning af patientens tilstand og kirurgens praksis, erefaring og kendskab til den relevante medicinske litteratur.
Der er blevet rapporteret om komplikationer som følge af brydninger i den medicinske litteratur. Alle patienter, som udsættes af kirurgisk indgreb, kan risikere intraoperative og postoperative komplikationer. Tilsiarelsen over for kirurgi, medicinske behandling og implantation af et tremmedlegeme kan ikke forhindre fy her enkelt patient.
Far det kirurgiske indgreb finder sted, bør patienten underrettes om og forstå de mulige risici, uønskede reaktioner og komplikationer forbundet med det kirurgiske indgreb og implantatet. Patienten skal underrettes om, at der er en risiko for, at implantatet ikke vil give en vellykket behandling af den pågældende sygdom eller tilstand, og at det ikke er muligt at forudsige implantatets forventede levetid, eller det er indopeneret, og at et vellykket resultat ikke kan garanteres.

DET ER KIRURGENS ANSVAR AT GIVE PATIENTEN INFORMATION, FOR DET KIRURGISKE INDGREB FORETAGES.

Komplikationer kan omfatte, men er ikke begrænset til:
- Smerter, utaelige eller unormale hvirrenmerker på ground af implantatets tilstedeværelse;
- Bøjning, løsning og/eller afbrækning;
- Risiko for ande laesioner fra postoperative traumer;
- Forøgelsen af implantatets position eller af implantatmaterialet, som medfører laesioner;
- Knogletab på ground af spændinger over og under det opererede ovrrade.
- Beskrivelser kan omfatte men er ikke begrænsede til:
- Infektioner;
- Hæmatomer;
- Allergi;
- Trombose;
- Manglende eller forsinket sammenvokning.

Uønskede bivirkninger kan nedbrydningen af suspenderede indpint, revision eller fjernelse af materialet, arbrydese af det involverede led og/eller amputation af eksterminere. Fjernelse af implantatet bør tages af passende postoperativ behandling for at undgå fraktur eller refrakturering.
Interferenstest under magnetgrøft:
MR/SCANNER: Dedikeret patien om systematisk at varone, at hun/hun bar gennemgået et kirurgisk indgreb på foden.

6. Brug af implantatet:

Tibia- og talus-komponenterne samt det mellemliggende fodplade saelges steriltil.
Kontrolere emballagens og etikettringens integritet før anvendelsen. Steriliseringen er garanteret, så længe emballagen er uskadeligt, dvs. der må ikke være eller I tilnæs, og eftersom det ikke vaere tænkt som en del af det medicinske udstyr, er det ikke omfattet af DT MedTech garanteri.
Brug aldrig instrumenter, hvis denne emballage er blevet åbnet eller beskadiget uden for operationsstuen. Den ikke emballage bør behandles under kontrol af hospitalets gasmaskeforholdsregler.
Kirurgen skal slaage de anbefalede instrumenter og/eller andre operationsrelaterede beskrivelser, som producenten stiller til rådighed. Den kirurgiske anordning skal anvendes i overensstemmelse med gaengse metoder og standarder.
Det er af afgørende betydning, at implantatet placeres i den korrekte position og ikke udsaettes for for mange belastninger.
Forsøg ikke at udlette et kirurgisk implantat med mangelfulde, beskadigede eller mistankevaekkende instrumenter eller implantater. Undersøg alle komponenter for sporadiske for at dette deres ønnesvindighed.
Et tilstrækkeligt udvalg af sterile implantater i forskellige størrelser skal vaere tilgaengelige under det kirurgiske indgreb for at sikre, at den optimale størrelse bruges til patienten.
Skiftende fleksionsvinkler bør vaere tilgaengelige under operationen.
Instrumenterne skal ikke genanvendes forhold.
Når implantatene fjernes, skal enhver kontakt med andre materialer eller redskaber, som kunne beskadige implantatets overflade, undgås.
Implantat mil under ingen omstændigheder vaerk. Implantater beskadt med f.eks. slibning eller med ikke indopeneret med cement.

7. Genbrug af implantater:

Ortopædiske implantater, som har vaeret indopeneret, må aldrig genbruges. En sidaen genanvendelse risikerer at aendre implantatets egenskaber og ydeevne, eller aendsynlighed for opstaaende komplikationer og/eller sekundaere vikninger som beskaedet tilbage. Gebskadet gibage og inlet anskue for en sidan genanvendelse.

8. Gensterilisation af ikke implanterede produkter:

Gensterilisation er ikke tilladt.

9. Forebyggende handlinger som kan afvaerge postoperative komplikationer for patienten:

- Undgå eksterne positioner som fleksion-ekstension
- Brug moderen immobilisering (gips, skinne . . .) i overensstemmelse med kirurgens anvisning
- Undgaa opstaaelsig begrydsels for enhver infektion, som kunne opstå, hvad enten den benaerer det opererede omraade eller en anden del af kroppen.

Kirurgen skal oplyse en patient om at meddele hans/hendes eventuelle uaesbaerhed angaaende det opererede ekstremitet. Hvis der er tegn på laesning af implantatet gaerdet smerte og progressive aendringer af vaegtbaerelsen, bør der straksbestaaende undersøgelses- og kontrolprogram, og det kan vaere nødvendigt at indskraenke patientens aktivitet; i så fald skal nye instruktioner og adaerder fremsendes til patienten.
Lad tilbøjelig dele gangse tekniker med hensyn til postoperative behandling bølges.
En overdreven fysisk aktivitet og/ef traume, som benaerer den opererede ekstremitet, kan vaere faktorer, som medvirker til for tidlig mislykket artroplasti ved fraktogning, fraktur, slid og/eller brud af implantatet. Man kender ikke i dag den nøjagtige fundamentale levetid for protesesaetninge.

10. Opbevaring:

Opbevaring tørt

11. Rudegestelse for produktinformation / Answar:

DT MedTech, LLC-kancerren, har udviet formult og omhu i alt valg af materialer og fremstilling af disse produkter. DT MedTech, LLC udelukker enhver andet garanti, udtrykt eller underforstået, som ikke er skriftlig. Der er ingen garanti for salgsfaerd eller egnethed for et bestemt formål. DT MedTech, LLC kan ikke holdes ansvarlig for eventuelle omkostninger, skader eller tab, der direkte eller indirekte skyldes brug af produktet. DT MedTech, LLC pålægger og ikke og godkender ikke, at andre i dems vaen pålægger og noget ansvar eller nogen yderligere forpligtelse med hensyn til disse produkter. DT MedTech, LLC forbeholder anvendelsen af denne anordning til laeger, der har modtaget en passende undervisning i de ortopædkirurgiske teknikker, der kraeves til anvendelse af anordningen.

ADVARSEL: Denne anordning er ikke godkendt til fastskruning eller fixation af implantater (pedicle!) ikke bagerste cervikale, brystkage eller lumbale del af hvirvelsøjlen.

INFORMATION: Hvis du har behov for nærmere oplysninger vedrørende produkterne eller dens anvendelse, bedes du kontakte din repraesentant eller forhandler eller kontakte produktcenter direkte.

Produkterne er fremstillede og refereres inden for rammen af gaeldende standarder. Implantationsindgrebet er beskrevet i den kirurgiske teknik. Ikke-kontraindikt dokument. Producenten forbehelder sig retten til uden forudgaaende varsel af modificere produkterne for at forbedre dems kvalitet.

Dato for seneste revision: 20/2/2025

NEDERLANDS

GEBRUIKSINSTRUCTIES
HINTERMANN SERIES TOTAL ANKLE SYSTEM
STERIELE MEDISCHE APPARATUUR + EENMALIG GEBRUIK

Dit product moet worden geïmplanteerd en / of gemplantueerd door GESCHOOLDE EN KWALIFICEERDE PERSONEN DIE KENNIS HEBBEN GENOMEN van de huidige HANDLEIDING.

1. Beschrijving van de medische apparatuur:

De Hintermann Series protheses bestaan in verschillende afmetingen. De protheses worden gevormd door een tibiaal bestandeel, een taliaarbestandeel en een centraal glij-element. Optionele bevestigingsschrauven zijn ook voorzien.

Hintermann Series HS2™:
De Hintermann Series HS2™ tibiale en talaire implantaten zijn vervaardigd uit een legering van Kobalt-Chroom (CoCr) binnen het kader van de normen ISO 5832-4 en ASTM F75, met een porseuze coating van titanium en hydroxyapatiet (Ti + HAP). Het centrale glij-element wordt gemaakt van polyethylen met een ultrahoog molecuulgewicht (UHMW), volgens de ISO 5834-2 norm en ASTM F648.
Deze instrumenten bevatten geen flessen, tenzij anders op het etiket is aangegeven.

Hintermann Series H2™:
De Hintermann Series H2™ tibiale component is geproduceerd van een titaniumlegering met een dubbellaagje titanium en hydroxyapatiet plasmaspuitlag (Ti + HAP). De borgen van het tibiale component is geproduceerd van PEEK. Het talaire component van de Hintermann Series H2™ is geproduceerd van kobalt chroom legering, opnieuw met een dubbellaagje titanium en hydroxyapatiet plasmaspuitlag (Ti + HAP). De dubbellagen van titanium en hydroxyapatiet zijn niet beschikbaar in de VS. De dubbellagen van de Amerikaanse producenten is voorzien van een porseuze titanium coating. De producten in de Hintermann Series H2™ Talar Component zijn vervaardigd van polyethylene met een ultrahoge molecuulgewicht (UHMW) in overeenstemming met de normen ISO 5834-2 en ASTM F648.
De tibiale en talaire implantaten, alsook het centraal glij-element, worden steriel verkocht.
Controleer de integriteit van de verpakking en etikettering voorafgaand aan de implantatie van het gebruik. De steriliteit wordt gegarandeerd zo lang de verpakking niet is beschadigd (bekeken fijn, ontbrekend etiket, verdachte verpakking...) en) en niet de afdraai van de geïnjecteerd van de steriliteit. Geen afdeling instrumenten/implantaten die niet zijn gebruikt voor de operatie. Deze verpakking dient te worden behandeld onder toezicht van de ziekenhuis gasmaskeerregels.
Kirurgen skal anbefalede instrumenter og/eller andre operationsrelaterede beskrivelser, som producenten stiller til rådighed. Den kirurgiske anordning skal anvendes i overensstemmelse med gaengse metoder og standarder.
De chirurgische implantaat moet worden geïmplanteerd in de juiste positie en mag niet onderworpen worden aan overmatige belastingen.
Forsøg ikke at udlette et kirurgisk implantat med mangelfulde, beskadigede eller mistankevaekkende instrumenter eller implantater. Undersøg alle komponenter for sporadiske for at dette deres ønnesvindighed.
Et tilstrækkeligt udvalg af sterile implantater i forskellige størrelser skal vaere tilgaengelige under det kirurgiske indgreb for at sikre, at den optimale størrelse bruges til patienten.
Skiftende fleksionsvinkler bør vaere tilgaengelige under operationen.
Instrumenterne skal ikke genanvendes forhold.
Når implantatene fjernes, skal enhver kontakt med andre materialer eller redskaber, som kunne beskadige implantatets overflade, undgås.
Implantat mil under ingen omstændigheden aendre. Implantaten beskadigd raekt HAP ikke indopeneret mere cement.

7. Genbrug af implantaten:

Ortopædische implantaten, zoor hun vaerst indopeneert, mag aldrig gebruiksgeen. En sidaen genanvendelse risikeren at aendre implantaten's egenskaber en/of ydeevne, aeje aandsynlighed for opstaanende komplicaties en/of sekundaire vikringen zoor beschaedigd achterlaten. Gebskadet gibage mag inlet anskue for een sidaen gebruiksgeen.

8. Gensterilisatie van niet-implanterende producten:

Gensterilisatie is niet toegestaan.

9. Preventieve maatregelen voor de patiënt om postoperatieve complicaties te vermijden:

- Vermijd extreme posities zoals flexie-extensie
- Draag de eerste immobiliteit (gips, spalk, ...) volgens de aanwijzingen van de chirurg
- Zorg voor een snelle medische aandacht voor elke infectie die zich zou kunnen voordoen, hetzij in de peperende ledemaat, hetzij elders in het lichaam.

De chirurg moet zijn patiënt aanmoedigen om hem in kennis te stellen van elke ongebruikaeldige vreemdering die zich bij de geopereerde ledemaat voordoet. In geval van tekenen van losslaan van het implantaat (pijnlijkheid, progressieve veranderingen van de draagkracht), moet een intensief programma van onderzoeken en controles aangevangen; het kan nodig zijn de activiteit van de patiënt te beperken.
Ik alle gewoon dienen bepaalde technieken inzake postoperatieve follow-up te worden gevolgd.
Een bovenmatige fysieke activiteit en een traumatisme met betrekking tot de geopereerde extremiteit kunnen factoren zijn voor een voortijdig mislukken van geïmplantatieprothese van artroplastiek, fractuur, slijtage en/of breuk van het implantaat. Momenteel is de functionele levensduur van de prothetische implantaten niet vaststaand.

10. Opbergen:

Op droge plaats opbergen

11. Beknopte aanwijzingen aangaande productinformatie / Aansprakelijkheid:

DT MedTech, LLC heeft redelijke zorg betracht bij het kiezen van materialen en de vervaardiging van hun producten. DT MedTech, LLC stuit elke andere garantie uit, expliciet en impliciet, met inbegrip van onder meer alle impliciete garanties van handelsleefbaarheid of van de aangeboop voor een speciaal doel. DT MedTech, LLC wordt niet aansprakelijk gesteld voor kosten, schade of verlies, die direct of indirect uit het gebruik van het product voortvloeien. DT MedTech, LLC bevestigt of autoriseert geen andere persoon om namens haar enige verplichting of aansprakelijkheid in verband met deze producten te aanvaarden. DT MedTech, LLC Toebehoren aanbevolgen en dessa apparatur tilt klaer som gjennomgått passende tilrettelegg i kirurgisk teknikker tilrettelegger for vilka den skal brukes. Ikke-kontraindikt dokument. Producenten forbehold seg retten til uten forutgående varsel å modifisere produktene for å forbedre dems kvalitet.

Datum van laatste herziening: 20/02/2025

SVENSKA

ANDVÄNDARINSTRUKTIONER
HINTERMANN SERIES TOTAL ANKLE SYSTEM
STERILA MEDICINSKA ENHETER + ENGÅNGSANVÄNDNING

Denna produkt måste hanteras av/och implanteras av VÅRDTIDIGA och KVALIFICERADE PERSONER som har KÄNNDOM OM DESSA BRUKSANVISNINGAR.

1. Beskrivning av de medicinska anordningarna:

Hintermann Series protesuppsatser finns i olika storlekar. Protesen är tillverkade av en skenbenskomponent, en talusskomponent och en mellanliggande glidande kärna. Valfria fixeringsskruvar finns också.

Hintermann Series HS2™:
Hintermann Series HS2™ skenbens- och talusskomponenter är tillverkade av kobolt-kromlegering (CoCr) enligt med NF ISO 5832-4 och ASTM F75, med ett poröst titan och hydroxiapatit höljt (Ti + HAP). Den mellanliggande glidande kärnan är tillverkad av UMHW polyten, i enlighet med ISO 5834-2 och ASTM F648.
Dessa enheter innehåller inte flaskor om det inte anges på etiketten.

Hintermann Series H2™:
Hintermann Series H2™ tibiakomponenten är tillverkad av en titanlegering med en dubbelskiktsbeläggning av titan och hydroxiapatit plasmasprutning (Ti + HAP). De borgen van het tibiale component is geproduceerd van PEEK. Det talusgenom som ska implanteras i Hintermann Series H2™ Talar komponenten är tillverkad av kobolt-krom legering, igen med en dubbelskiktsbeläggning av titan och hydroxiapatit plasmasprutning (Ti + HAP). De dubbelskikten av titan och hydroxiapatit zijn niet verkrijgbaar in de Verenigde Staten. De producten in de Hintermann Series H2™ Talar Component zijn vervaardigd van titanium coating. De polyethylene producten, ontworpen om in het tibiale component te vergrendelen, is geproduceerd van UHMW polyethylen met een titaniumcoating nok en ribgrenzwerken.
De tibiale en talaire implantaten, alsook het centraal glij-element, worden steriel verkocht.
Deze apparatuur bevat geen flessen, tenzij anders op het etiket is aangegeven.

2. Indicaties:

- Artritis i fotleden med systemiska orsaker (t.ex. reumatisk artrit, hemokromatos)
- Primär artrit (t.ex. degenerativ sjukdom)
- Sekundär artrit (t.ex. posttraumatisk, infektion, avaskulär nekros)*
- Revisionskirurgi ("takvage" efter misslyckad total ankelprotes)**
- Revisionskirurgi ("takvage") efter otillräcklig eller felaktig frakturläkning vid fotsvikt***

*Ett minst 2/3 av talus är bortfallet.
**Ledstabilitet är tillräcklig!
Patientens leder skall vara anatomiskt och strukturellt lämpliga för det valda implantatet.
Medelanliggande implantatet i Stamoss U är inte avsedda för patienter som väger över 65 kilogram.

3. Kontraindikationer:

Relativa kontraindikationer:
- svår osteoporos
- immunosuppressiva terapier
- vederlagen sportaktiviteter (t.ex. kontaktsport, springa)

Absoluta kontraindikationer:
- infektion
- misstänkt eller dokumenterad metallallergi eller intolerans
- avaskulär nekros i talus/tibia > 1/2
- svårt fotdeformitet
- svårt fotdeformitet
- diabetisk syndrom
- om det inte är möjligt att korrigera med skurup

Stamoss U av Stille Hintermann Series HS2™ mellanliggande fotplåt och talus-komponenter med en vikt som inte skall vara mer än 65 kilogram.

4. Varningar:

Allvarliga postoperativa komplikationer kan uppstå om implantat används på patienter som:
- inte befinner sig i gott allmänt fysiskt tillstånd;
- har allvarlig osteoporos;
- utsätter fysiskkrige eller anstrenkna anomalier;
- har immunologiska reaktioner, känslighet eller överkänslighet mot främmande material;
- har systemiska eller ämnesomsättningsstörningar.

Vidare kan det utsätta av leden vid svaera deformiteter.

5. Försiktighetsåtgärder vid bruk:

Läkaren ska avgöra om implantatet är lämpligt för patienter som uppvisar något av följande tillstånd:
- Beroende av/och missbruk av narkotika och/eller alkohol och/eller rökning;
- Infektionssjukdom;
- Malignitet;
- Lokala frakturer;
- Systemiska eller metabolska rubbningar eller substitution;
- Nedsatt vårdskärgrjöfdmåga;
- Övervikt;
- Föreligger psykologisk inställnad, tecken på bristande förståelse, nedsatt motivation eller inställning;
- Om det är acceptera eventuell behov av en implantat revision eller kirurgisk revision av det kirurgiska indgreb;
- Om det inte är möjligt att det metallimplantat inte är lika stark som normal frisk ben och kan komma att bryta, lasna eller brytas av om det utsätts för alltför stora krav;
- Brittsprödhet i leden som det inte är möjligt att korrigera.

Man skall inte sätta, att det är den postoperative evne inte kan gjøre det sund, som det er en vellykket operation.
Kendskab til de kirurgiske teknikker, korrekt repositioning, valg og placering af implantater og postoperative patientbehandling er af afgørende betydning for et vellykket resultat.
Kriterier for udvælgelse af patienter hører ind under kirurgens ansvar. Der bør tages hensyn til informationerne indeholdt i dette dokument under udvælgelsesprocessen. Det hører ind under kirurgens ansvar at skelne mellem de passende indikationer og kontraindikationer samt at vælge de egnede forsigtighedsregler og teknikker, der anses for at være mest velegnede i den enkelte patient. Kirurgen skal evaluere velegnetheden af anvende firmagrundlæggelse og instrumenter under indgrebet på grundlag af en sigt om udstimerede og ærlig.
Far indgrebet bør kirurgen tale med patienten om mulige risici, forsigtighedsregler, advarsler, kontraindikationer, komplikationer og uønskede reaktioner forbundet med det kirurgiske indgreb og indopeneringen af implantatet.
Kirurgen skal evaluere hver enkelt patient for at fastslå dens specifikke risiko-/udbytteforhold i betragtning af patientens tilstand og kirurgens praksis, erefaring og kendskab til den relevante medicinske litteratur.
Der er blevet rapporteret om komplikationer som følge af brydninger i den medicinske litteratur. Alle patienter, som udsættes af kirurgisk indgreb, kan risikere intraoperative og postoperative komplikationer. Tilsiarelsen over for kirurgi, medicinske behandling og implantation af et tremmedlegeme kan ikke forhindre fy her enkelt patient.
Far det kirurgiske indgreb finder sted, bør patienten underrettes om og forstå de mulige risici, uønskede reaktioner og komplikationer forbundet med det kirurgiske indgreb og implantatet. Patienten skal underrettes om, at der er en risiko for, at implantatet ikke vil give en vellykket behandling af den pågældende sygdom eller tilstand, og at det ikke er muligt at forudsige implantatets forventede levetid, eller det er indopeneret, og at et vellykket resultat ikke kan garanteres.

DET ER KIRURGENS ANSVAR AT GIVE PATIENTEN INFORMATION, FOR DET KIRURGISKE INDGREB FORETAGES.

Komplikationer kan omfatte, men er ikke begrænset til:
- Smerter, utaelige eller unormale hvirrenmerker på ground af implantatets tilstedeværelse;
- Bøjning, løsning og/eller afbrækning;
- Risiko for ande laesioner fra postoperative traumer;
- Forøgelsen af implantatets position eller af implantatmaterialet, som medfører laesioner;
- Knogletab på ground af spændinger over og under det opererede omraade.
- Beskrivelser kan omfatte men er ikke begrænsede til:
- Infektioner;
- Hæmatomer;
- Allergi;
- Trombose;
- Manglende eller forsinket sammenvokning.

Uønskede bivirkninger kan nedbrydningen af suspenderede indpint, revision eller fjernelse af materialet, arbrydese af det involverede led og/eller amputation af eksterminere. Fjernelse af implantatet bør tages af passende postoperativ behandling for at undgå fraktur eller refrakturering.
Interferenstest under magnetgrøft:
MR/SCANNER: Dedikeret patien om systematisk at varone, at hun/hun bar gennemgået et kirurgisk indgreb på foden.

6. Brug af implantatet:

Tibia- og talus-komponenterne samt det mellemliggende fodplåke saelges steriles.
Kontrollera emballagens og etikettringens integritet före användningen. Steriliseringen er garanteret, så længe emballagen er oskadadgjort, dvs. der må ikke vaere eller I tilnæs, og eftersom det ikke vaere tænkt som en del av den medicinska utrustningen, er det ikke omfattat av DT MedTech garanteri.
Brug aldrig instrumenter, hvis denne emballage er blevet åbnet eller beskadiget uden for operationsstuen. Den ikke emballage bør behandles under kontrol af hospitalets gasmaskeforholdsregler.
Kirurgen skal slaage de anbefalede instrumenter og/eller andre operationsrelaterede beskrivelser, som producenten stiller til rådighed. Den kirurgiske anordning skal anvendes i overensstemmelse med gaengse metoder og standarder.
Det er af afgørende betydning, at implantatet placeres i den korrekte position og ikke udsaettes for for mange belastninger.
Forsøg ikke at udlette et kirurgisk implantat med mangelfulde, beskadigede eller mistankevaekkende instrumenter eller implantater. Undersøg alle komponenter for sporadiske for at dette deres ønnesvindighed.
Et tilstrækkeligt udvalg af sterile implantater i forskellige størrelser skal vaere tilgaengelige under det kirurgiske indgreb for at sikre, at den optimale størrelse bruges til patienten.
Skiftende fleksionsvinkler bør vaere tilgaengelige under operationen.
Instrumenterne skal ikke genanvendes forhold.
Når implantatene fjernes, skal enhver kontakt med andre materialer eller redskaber, som kunne beskadige implantatets overflade, undgås.
Implantat mil under ingen omstændigheden aendre. Implantaten beskadigd raekt HAP ikke indopeneret mere cement.

7. Genbrug af implantater:

Ortopædiske implantater, som har vaerst indopeneret, må aldrig genbruges. En sidaen genanvendelse risikerer at aendre implantatets egenskaber og ydeevne, aeje aandsynlighed for opstaanende komplicaties en/of sekundaire vikringer som beskaedet achterlaten. Gebskadet gibage mag inlet anskue for een sidaen gebruiksgeen.

8. Gensterilisatie van niet-implanterende producten:

Gensterilisatie is niet toegestaan.

9. Preventieve maatregelen voor de patiënt om postoperatieve complicaties te vermijden:

- Vermijd extreme posities zoals flexie-extensie
- Draag de eerste immobiliteit (gips, spalk, ...) volgens de aanwijzingen van de chirurg
- Zorg voor een snelle medische aandacht voor elke infectie die zich zou kunnen voordoen, hetzij in de peperende ledemaat, hetzij elders in het lichaam.

Kirurgen bør informere patienten om at medlem hans/hendes eventuelle uaesbaerhed angaaende det opererede ekstremitet. Hvis der er tegn på laesning af implantatet gaerdet smerte og progressive aendringer af vaegtbaerelsen, bør der straksbestaaende undersøgelses- og kontrolprogram, og det kan vaere nødvendigt at indskraenke patientens aktivitet; i så fald skal nye instruktioner og adaerder fremsendes til patienten.
Lad tilbøjelig dele gangse tekniker med hensyn til postoperative behandling bølges.
En overdreven fysisk aktivitet og/ef traume, som benaerer den opererede ekstremitet, kan vaere faktorer, som medvirker til for tidlig mislykket artroplasti ved fraktogning, fraktur, slid og/eller brud af implantatet. Man kender ikke i dag den nøjagtige fundamentale levetid for protesesaetninge.

10. Opbevaring:

Opbevaring tørt

11. Rudegestelse for produktinformation / Answar:

DT MedTech, LLC-kancerren, har udviet formult og omhu i alt valg af materialer og fremstilling af disse produkter. DT MedTech, LLC udelukker enhver andet garanti, udtrykt eller underforstået, som ikke er skriftlig. Der er ingen garanti for salgsfaerd eller egnethed for et bestemt formål. DT MedTech, LLC kan ikke holdes ansvarlig for eventuelle omkostninger, skader eller tab, der direkte eller indirekte skyldes brug af produktet. DT MedTech, LLC pålægger og ikke og godkender ikke, at andre i dems vaen pålægger og noget ansvar eller nogen yderligere forpligtelse med hensyn til disse produkter. DT MedTech, LLC forbeholder anvendelsen af denne anordning til laeger, der har modtaget en passende undervisning i de ortopædkirurgiske teknikker, der kraeves til anvendelse af anordningen.

ADVARSEL: Denne anordning er ikke godkendt til fastskruning eller fixation på elementer (pedicle!) ikke bagerste cervikale, brystkage eller lumbale del af hvirvelsøjlen.

INFORMATION: Hvis du har behov for nærmere oplysninger vedrørende produkterne eller dens anvendelse, bedes du kontakte din repraesentant eller forhandler eller kontakte produktcenter direkte.

Produkterne er fremstillede og refereres inden for rammen af gaeldende standarder. Implantationsindgrebet er beskrevet i den kirurgiske teknik. Ikke-kontraindikt dokument. Producenten forbehold seg retten til uten forutgående varsel å modifisere produktene for å forbedre dems kvalitet.

Datum van laatste herziening: 20/02/2025

PORTUGUÊS

INSTRUÇÕES DE UTILIZAÇÃO
Hintermann Series Total Ankle System
DISPOSITIVOS MÉDICOS ESTERILIZADOS + UTILIZAÇÃO ÚNICA

Dentro produkt skiftet hartemas av/och implanteras av VÅLUTBILDADE och KVALIFICERADE PERSONER som har KÄNNDOM OM DESSA BRUKSANVISNINGAR.

1. Beskrivning av de medicinska anordningarna:

Hintermann Series protesprodukter finns i olika storlekar. Protesen är tillverkade av en skenbenskomponent, en talusskomponent och en mellanliggande glidande kärna. Valfria fixeringsskruvar finns också.

Hintermann Series HS2™:
Hintermann Series HS2™ skenbens- och talusskomponenter är tillverkade av kobolt-kromlegering (CoCr) enligt med NF ISO 5832-4 och ASTM F75, med ett porösa titan och hydroxiapatit höljt (Ti + HAP). De pattern intermedio è fabricato con polietilene di peso molecolare ultra elevato, UHMWPE, seguendo gli standard ISO 5834-2 e ASTM F648.
Dessa instrument innehåller inte flaskor om det inte anges på etiketten.

H2™:
Det komponente Tibial de Hintermann Series H2™ é fabricado utilizando uma liga de titânio com uma camada dupla de revestimento de spray de titânio e plasma de hidroxiapatita (Ti + HAP). O pino de trava do componente tibial é fabricado pela PEEK. O Componente Talar da Hintermann Series H2™ é fabricado em liga de cobalto-cromo, também com uma camada dupla de revestimento de spray de titânio e plasma de hidroxiapatita (Ti + HAP). Os aparelhos com camada dupla de revestimento não estão disponíveis nos EUA. O revestimento por projeção única dos fabricantes dos Estados Unidos possui um revestimento de titânio poroso. O revestimento de PE embutido, desenvolvido para travar junto ao componente tibial, é fabricado utilizando polietileno UHMW com margem fina de uma liga de titânio e marcadores de raio-x.
Os componentes tibiais e talares, bem como o pattern intermedio, são fornecidos esterilizados.
Estes dispositivos não contêm frascos, salvo indicação contrária no rótulo.

2. Indicações:

- Artrite do tornozelo de causa sistêmica (ex. artrite reumatóide, hemocromatose)
- Artrite primária (ex. doença degenerativa)
- Artrite secundária (ex. pós-traumática, infecção, necrose avascular)*
- Revisão de uma cirurgia de tornozelo falhada**
- Revisão cirúrgica ("takvage") após fratura/cura de tornozelo mal sucedida***

*em mínimo 2/3 do talus é danificado.
**A estabilidade do tornozelo é suficiente!
A articulação do doente deve ser anatómica e estruturalmente adequada para receber o implante escolhido.
O pattern intermedio e o componente talar da tamanho U não devem ser utilizados em doentes com peso superior a 65 kg.

3. Contraindicações:

Contraindicações relativas:
- osteoporose severa
- Terapia imunosupressiva
- Actividades desportivas (ex.: desportos de contacto, saltos)

Contraindicações absolutas:
- infecção
- alergia ou intolerância a ou metales suspeitos o conocida
- Necrose avascular do astragálo/tíbia > 1/2
- Malalineación grave*
- Inestabilidad grave*
- Síndrome diabético

*em comprimento
O pattern intermedio e o componente talar da tamanho U não devem ser utilizados em doentes com peso superior a 65 kg.

4. Advertências:

Podem ocorrer complicações pós-operatórias graves, ao utilizar-se o implante num doente que:
- Não apresente boa condição física geral;
- Sofra de osteoporose severa;
- Apresente anomalias fisiológicas ou anatómicas;
- Apresente resposta imunológica, sensibilidade ou hipersensibilidade a materiais estranhos ao organismo;
- Apresente perturbações sistémicas ou metabólicas.

Além disso, a substituição articular pode ser contraindicada em caso de deformidade severa.

5. Precauções de utilização:

O profissional clínico deve determinar se o implante é adequado para doentes que apresentem uma das seguintes condições:
- Hábitos etoxo-dependentes de fármacos, álcool e/ou tabaco;
- Doença infecciosa;
- Neoplasia;
- Tumores ósseos localizados;
- Distúrbios sistémicos ou metabólicos ou utilização de fármacos de substituição;
- Comprometimento do sistema de amortecimento;
- Obesidade;
- Instabilidade psicológica demonstrada, apresentando falta de compreensão, motivação ou atitude inadequada;
- Incapacidade de aceitar a possibilidade de múltiplas cirurgias de revisão ou substituição;
- Incapacidade de compreender que um implante metálico não é tão forte como o osso normal saudável e que pode sofrer torção, desarticulação ou fratura, em caso de esforço excessivo;
- Incapacidade de compreender que a sua capac