QUALITY SYSTEM DOCUMENT

INSTRUCTIONS FOR USE

HINTERMANN SERIES H2® TOTAL ANKLE SYSTEM – ENGLISH US ONLY

QSD 8.12-68

REVISION HISTORY

Rev	CO#
A	CO25-036

THIS PAGE IS NOT TO BE INCLUDED IN DOCUMENTS THAT UTILIZE THIS TEMPLATE.

THIS PAGE IS ONLY FOR REVISION HISTORY OF THE FORM.

Instructions for Use

Hintermann Series H2® Total Ankle System

ENGLISH – FOR US ONLY

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.

Device Description

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: Hintermann Series H2 tibial assembly, Hintermann Series H2 vitamin E polyethylene (PE) inlay assembly, and Hintermann Series talar component.

Materials

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 talar component is manufactured from cobalt chrome alloy (CoCr) also with a titanium plasma spray coating. The PE inlay assembly, designed to lock into the tibial component, is manufactured from vitamin E blended UHMW polyethylene with titanium alloy x-ray markers.

Indications for Use

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 the ankle arthrodesis, provided sufficient bone stock is present.

NOTE: In the United States, this device is intended for cemented use only.

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

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.

This device is not approved for screw attachment.

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 an 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 Vilex, LLC may only be used in conjunction with compatible parts manufactured by Vilex, LLC and DT MedTech, LLC (a Vilex company). Vilex, LLC implants and trial components 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

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. Based on material composition, implants are 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.

Use of the Implants

- All implantable components are provided sterile and are SINGLE USE ONLY. Implantable components are sterilized by gamma irradiation. Re-sterilization is not allowed.
- Implants already implanted must never be re-used. Vilex accepts no responsibility for such re-use.
- Check packaging and labeling 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 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.
- 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.

Preventive 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.

Storage and Handling

- Store in a dry place.
- Surgical implants, packaging and labeling should be checked for defects and damage before use and to verify appropriate sizing and sterility validity. If the packaging integrity has been compromised or if the packaging is unintentionally opened before use, do not use the implant.

Instrument Sterilization Information

Non-sterile instruments should be sterilized prior to use according to the following recommended sterilization parameters:

Method	Temperature	Time	Drying Time
Prevacuum	132°C (270°F)	4 minutes	60 minutes*
OR			
Prevacuum	134°C (273°F)	3 minutes	60 minutes**

* Specified Drying Time must be followed by an Open Door Time of 30 minutes, and a Cool-Down Time of 30 minutes outside of chamber on a wire rack.

** Specified Drying Time must be followed by a Cool-Down Time of 30 minutes outside of chamber on a wire rack.

Once used, the instruments must be cleaned AND sterilized prior to subsequent use. Additional information on cleaning of instrumentation is provided in the instructions for Processing Non-Sterile Medical Devices – Implants, Reusable Instruments and Trays (QSD 8.13-1).

Product Information Disclosure/Liability

Vilex, LLC 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. Vilex excludes all warranties, whether expressed or implied, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Vilex shall not be liable for any accidental or consequential, loss, damage, or expense, directly or indirectly arising from use of this product. Vilex neither assumes nor authorizes any person to assume for it, any other or additional liability or

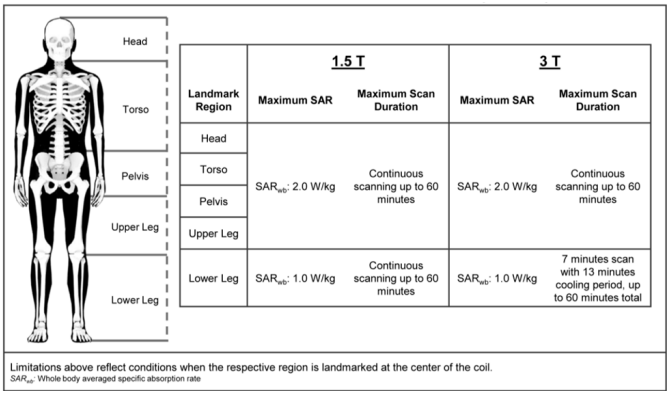
responsibility in connection with these products. Vilex intends that this device should be used only by physicians having received proper training in orthopedic surgery technique for use of the device.

MRI Safety Information

Non-clinical testing and MRI simulations have demonstrated that every version of the Hintermann Series H2 is MR Conditional. A patient with this device may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Device Name	Hintermann Series H2
Static magnetic field strength (B_0)	1.5 T or 3.0 T
MR Scanner Type	Cylindrical
B_0 Field Orientation	Horizontal
Maximum spatial field gradient	35 T/m (3,500 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	**Head through Upper Leg:** SAR_{wb} ≤ 2.0 W/kg **Lower Leg:** SAR_{wb} ≤ 1.0 W/kg
Scan Duration	**1.5 T:** Scan duration up to 60 minutes as detailed in ***Figure 1*** below for all landmark locations. **3.0 T:** **Head through Upper Leg:** Scan duration up to 60 minutes as detailed in ***Figure 1*** below **Lower Leg:** Maximum duration of 7 minutes, followed by a minimum cooling period of 13 minutes, repeated for up to 60 minutes as detailed in ***Figure 1*** below
Scan Regions	Landmark restrictions as detailed in the Operating Mode and Scan Duration sections and in ***Figure 1*** below.

The presence of this implant may produce an image artifact. The safety of this item during scanning has not been proven if there is another implant within 2 cm.



Landmark Region	1.5 T Maximum SAR	1.5 T Maximum Scan Duration	3 T Maximum SAR	3 T Maximum Scan Duration
Head	SAR_{wb}: 2.0 W/kg	Continuous scanning up to 60 minutes	SAR_{wb}: 2.0 W/kg	Continuous scanning up to 60 minutes
Torso				
Pelvis				
Upper Leg				
Lower Leg	SAR_{wb}: 1.0 W/kg	Continuous scanning up to 60 minutes	SAR_{wb}: 1.0 W/kg	7 minutes scan with 13 minutes cooling period, up to 60 minutes total

Limitations above reflect conditions when the respective region is landmarked at the center of the coil.
SAR_{wb}: Whole body averaged specific absorption rate

Figure 1: *Hintermann Series H2 MRI Restricted Zone Summary*

Information

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

Vilex, LLC.
111 Moffitt Street
McMinnville, TN 37110
USA
Phone: +1 800-521-5002
Fax: 855-748-7437
Email: info@vilex.com
Website: www.vilex.com

SYMBOLS GLOSSARY	
	Manufacturer
	Use-by date
LOT	Batch code
REF	Catalogue number
STERILE R	Sterilized using irradiation Double sterile barrier system
NON STERILE	Non-sterile
	Keep dry
	Do not re-use
	Consult instructions for use or consult electronic instructions for use
MD	Medical device
UDI	Unique device identifier
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
MR	MR Conditional