

Restoring Mobility

Cannulated Implants for Forefoot Joints

from Vilex



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Introduction

Vilex offers two types of cannulated hemi implants, CHI™: elliptical and concave to replace the base of the proximal phalanx and spherical to replace the head of a metatarsal. Ten concave and ten convex sizes are available to replace the first or lesser joints. Each CHI is individually machined. The articular surface is mirror finished to minimize friction and shaped to maintain range of motion without inducing pain or altering the foot biomechanics. **However, under no circumstance should both ends of a joint be replaced.** Without any condition or equivocation Vilex does not recommend the replacement of both the base of the phalanx and the metatarsal head of the same joint.

The cannulation provides a mechanism for precise positioning of the implant. A special driver is used to screw the implant into the desired position. The two positioning holes provide a mechanism for suturing (optional) the implant to the soft tissue while osseous integration proceeds naturally.



Indications

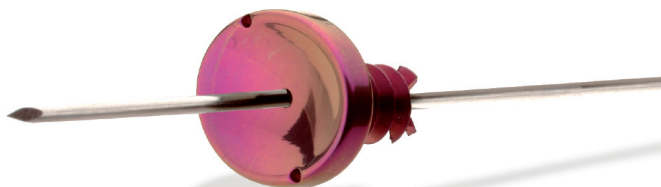
- Hallux limitus, hallux rigidus, or stiff joint.
- Pain due to impacted joint.
- Joint deterioration.

Contraindication

- Osteoporotic or poor bone stock
- Inadequate skin or musculotendinous system
- Unrealistic patient expectations
- Poor overall patient health
- History of bone infection
- Poor or inadequate neurovascular status

Features

- Anatomically compatible
- Elliptical/spherical shape for articular surface
- Cannulation for precise positioning
- CoCrMo or titanium



Before Proceeding

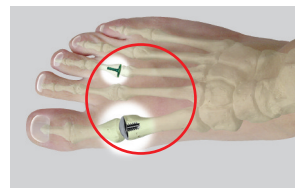
The surgeon should evaluate the overall health of the patient. An implant site may become infected, painful, swollen, or inflamed. The status of the adjacent bone and soft tissue may be inadequate to support the implant, resulting in instability, deformity, or both.

The benefits from implant surgery may not meet patient's expectations or may deteriorate with time, requiring revision surgery, which is common with implants. Vilex does not recommend a particular surgical procedure. The information and protocol provide an approach and not a required procedure. This brochure is not a training manual.

Typical 1st MPJ Procedure

A longitudinal incision is made on the dorsal aspect of the MPJ or PIP joint. The incision is deepened to the level of the joint, with sharp and blunt dissection while avoiding the exterior tendon, and the vital structures are retracted. A longitudinal capsulotomy is performed and the joint is resected free. All hypertrophic bone is resected from both the metatarsal and phalanx. The recipient bone is completely freed of its attachments on the medial, dorsal, and lateral aspects.

Depending on the condition of the joint, the surgeon has the option to replace either the head of the metatarsal or the base of the phalanx, **but not both**. If both ends are equally damaged, Vilex recommends the replacement of the base of the phalanx. If the metatarsal head is not salvageable, the head should be replaced.



For conventional first MPJ hemi implants, the base of the proximal phalanx is resected at the appropriate level. The resection line should bypass any tendon or critical tissue. The cut

should be neutral without lateral or medial orientation. A slight dorsal-plantar inclination is desirable. The width of the resected bone should be 4-5 mm to allow room for the implant and to decompress the joint. If the



metatarsal head is being replaced, again make a neutral cut and remove 1-1.5 mm beyond the width of the implant (see table below), which ranges between 4 and 5 mm.

After the base or metatarsal head is resected, a trial sizer (elliptical) is placed over the exposed surface to determine the correct size of the prosthesis. The sizer should cover the entire surface without protruding beyond the bone. With the sizer in position, manually insert a k-wire to mark the center. Remove the sizer and drive the wire into the phalanx, making sure the wire is in the center of and parallel to the axis of the proximal phalanx. Insert the implant over the K-wire and drive the implant into the intramedullary canal. The surgeon may adjust the orientation of the implant by turning it as much as one half turn.

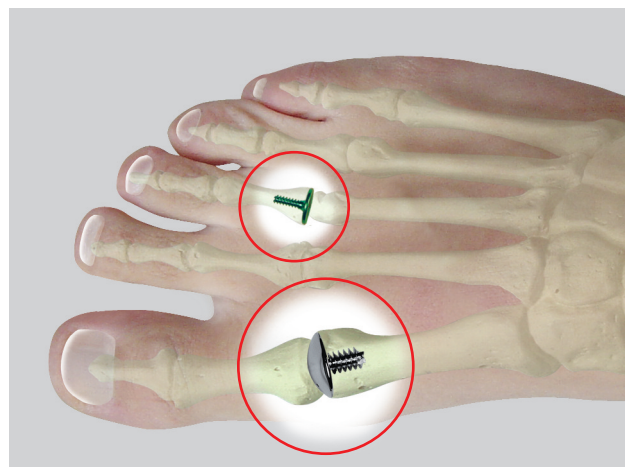


For metatarsal head replacement, a trial sizer (circular) is placed over the metatarsal to determine the correct size. With the sizer in position, manually insert a k-wire to mark the center. Remove the sizer and drive the wire into the metatarsal shaft, making sure the wire is in the center of and parallel to the axis. Insert the implant over the K-wire and drive the implant into the intramedullary canal.



Lesser-Joint Procedures

The procedure for lesser joints is very similar to the first MPJ, except that the implants are smaller and the amount of bone resected is 2-2.5 mm for either end. After the implant is seated and the range of motion checked, the joint capsule is closed over the prosthesis and sutured with a suture of the surgeon's choice. Bandaging and post-operative management corresponds to other arthroplasty procedures.



Post-Operative Considerations

Patient should be warned that the prosthesis device is not a substitute for the natural joint and will not enable the patient to function as if the joint is restored. The patient should avoid an active lifestyle. Excessive motion will accelerate the unavoidable wear and tear of the implant and may loosen the prosthesis. Serious consequences such as fracture or shattering of the bone, metal fatigue, or dislocation of the device are possible.

Precautions

The implants are provided non-sterile. Sterilize the implants in their tray as you would any bone screw. Steam sterilization at 270°F for 20 minutes is recommended. Implants should only be handled with blunt instruments to avoid scratching, cutting, or nicking the device. Meticulous preparation of the implant site and selection of the proper size implant increase the potential for successful outcome.

Adverse Results

Potential adverse events reported with toe joint prostheses include pain, loosening, fracture, dislocation, or infection. There have been some reports of patients with allergic reaction to certain metals. Implantation of materials such as cobalt chrome and/or titanium may result in foreign body reaction in tissue adjacent to the implant site. Injury to the surrounding nerves, blood vessels, tendons, or soft tissues can occur as a consequence of implanting this device.

Limited Warranty

Vilex warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse or abuse. Surgery involving Vilex small joint implants may be performed solely by qualified foot surgeons in a normal hospital setting.

Available Hemi Sizes

Style No	D	Stem Length	Stem D	Thick
Lesser Joint: Titanium Only				
MCHI-09	9.0	11.5	2.5	0.8
MCHI-10	10.0	11.5	3.0	0.8
MCHI-11	11.0	12.0	3.0	0.8
MCHI-12	12.0	12.0	3.0	0.8
MCHI-13	13.0	12.0	3.0	0.8
First MPJ: Titanium or CoCr, Oval				
CHI-1	13x15	9.0	6.5	1.0
CHI-2	15x17	10.0	6.5	2.0
CHI-3	17x19	11.0	7.5	2.1
CHI-4	19x22	12.0	7.5	2.2
CHI-5	21x24	13.0	7.5	2.3

Available Met Heads Sizes, all CoCr

Style No	D	Stem Length	Stem D	Thick
Lesser Joint				
MMHI-09	9.0	11.5	2.5	3.0
MMHI-10	10.0	11.5	3.0	3.0
MMHI-11	11.0	12.0	3.0	3.0
MMHI-12	12.0	12.0	3.0	3.0
MMHI-13	13.0	12.0	3.0	3.0
First MPJ				
CMHI-14	14.0	8.0	6.5	4.0
CMHI-16	16.0	10.0	6.5	4.0
CMHI-18	18.0	12.0	7.5	5.0
CMHI-20	20.0	13.0	7.5	5.0
CMHI-22	22.0	14.0	7.5	5.0



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