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BioMotion™ 1st MPJ Cannulated Hemi Implant System Instructions for Use

Description

The BioMotion™ Cannulated Hemi System is a partial joint replacement system for the first metatarsophalangeal joint (MPJ). Available implants and instrumentation are packaged as a single system or as individual devices. Implants are available in sizes ranging from 15mm to 23mm. The system includes instruments (slide hammer, slide broach, guide wires, size gauges) to facilitate the placement of the implants.

Material

All BioMotion™ Cannulated Implants are made from Titanium Alloy (ASTM F-136). The instrumentation is made from titanium and stainless steel.

Indications

The METASURG BioMotion™ Cannulated Hemi Implant is considered for use in cases exhibiting degenerative arthritis of the first metatarsophalangeal joint, integrity of the metatarsal head, the presence of good bone stock and exhibiting the following clinical conditions:

- Osetoarthritis of the first MPJ
- Hallux rigidus/limitus
- Hallux valgus with degenerative joint disease
- As an alternative to first MTP arthrodesis

Contraindications

Use of the BioMotion™ Cannulated Hemi System is contraindicated in cases of active or suspected infection or in patients who are immunocompromised; in patients previously sensitized to titanium; or in patients with certain metabolic diseases. It is further contraindicated in patients exhibiting disorders which would cause the patient to ignore the limitations of prescribed post operative care. Other contraindications are as follows:

- Rheumatoid arthritis
- Non-reduced, high, inter-metatarsal angles
- Poor Bone Stock

Warnings

1. Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
2. Use of an incorrectly sized implant in areas of high functional stresses may lead to implant failure.

3. Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
4. Instruments, guide wires and screws are to be treated as sharps.
5. All BioMotion implants and guide wires are intended for single use only.

Maintaining Device Effectiveness

1. The surgeon should have sufficient training, experience, and thorough familiarity with the use of first MPJ implants.
2. The surgeon must exercise reasonable judgment when deciding which Hemi Implant type to use for specific indications.
3. The BioMotion Hemi Implants are not intended to endure excessive abnormal functional stresses.
4. All BioMotion Hemi Implants and instrumentation may be required for each surgery. Failure to use dedicated, unique MetaSurg instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
5. Carefully inspect the implant prior to use. Inspect the instruments before and after each procedure to assure they are in proper operating condition. Instruments which are faulty, damaged or suspect should not be used.
6. MetaSurg recommends the use of MetaSurg products in a sterile environment.

Directions for Use

Step 1 – Incision and Exposure

Make a 4 to 5 cm curvilinear incision over the dorsomedial aspect of the first MPJ. The capsular tissues around the joint should be released to maximize exposure of the joint. Care should be taken to preserve the superficial vessels and nerves of the surrounding area.

Step 2 – Base Resection of the Proximal Phalanx / Metatarsal Head Preparation

Using a bone clamp, secure the phalanx so a resection of the base of the proximal phalanx can be performed. Although the amount of bone resected will vary depending on the patient, a recommend amount is 3–5mm. A determining factor in the amount of bone removal is the amount of decompression needed. Resection of the appropriate amount of bone should be performed perpendicular to the long axis of the toe. When practical, care should be taken to maintain the insertion of the flexor and hallucis brevis tendons at the base of the proximal phalanx. Remodeling of the metatarsal head should be performed by resection of any osteophytes present. Chondroplasty with fenestration of the metatarsal head can be performed where appropriate.

Step 3 – Selection of Implant Size and Wire Placement

Place the color coded sizer flat against the resected portion of the phalanx. Select the sizer that most closely matches the base of the phalanx. Ensure that the sizer profile fits entirely within the profile of, and does not extend beyond, the outer margins of the osteotomized phalanx. Once the appropriate sizer has been determined, and positioned over the phalanx, drive the provided wire through the center hole in the sizer and into the center of the phalanx. Remove the sizer.

Step 4 – Broaching (Optional)

If it is determined that the medullary bone is in good condition but relatively soft, it is not necessary to use the included broach. Proceed to step 5.

Place the broach over the wire and verify the correct radial position of the broach using the marked line on the broach shank. This line indicates the correct dorsal positioning of the implant when situated in the phalanx. Using the sliding portion of the instrument, tap the broach tip into the bone until the shoulder of the broach is flush with the bone. To

remove the broach, tap the sliding portion of the implant against the rear stop. Remove the broach from the wire.

Step 5 – Implant Placement

Place the implant over the wire and verify the correct radial position. The flat side of the implant should be positioned towards the planter side of the phalanx to match the anatomical shape of the phalanx.

If the broaching option was utilized, place the tip of the implant into the broached location.

If the broaching option was bypassed, orient the implant correctly (as described above) and temporarily secure the implant into the bone with moderate finger pressure.

Slide the hammer over the wire and place the tip against the articulating surface of the implant. Using the sliding portion of the instrument, tap the implant into the bone until the back edge of the implant's articulating surface is flush with the bone. Remove the hammer.

Step 6 – Verification of Motion and Closure

Prior to closing the capsular tissues, the joint should be put through a full range of motion. If sufficient dorsiflexion and decompression cannot be demonstrated the metatarsal head can be further remodeled and the phalanx can be further resected.

After range of motion has been confirmed, the joint capsule is closed over the prosthesis and sutured. Post operative management corresponds to other arthroplasty procedures of this nature, however, an early post operative physical therapy regimen is recommended.

Sterility

The BioMotion™ Cannulated Hemi Implants (instruments and implants) are packaged non-sterile and must be sterilized prior to surgical use.

Pre-Vacuum Steam Sterilization:

Condition: Wrapped
Temperature: 270° F (132° C)
Time: 15 minutes

Gravity Steam Sterilization:

Condition: Wrapped
Temperature: 270° F (132° C)
Time: 15 minutes

Since MetaSurg is not familiar with individual hospital handling methods, cleaning methods and bioburden, MetaSurg cannot assume responsibility for sterility even though the guideline is followed.

Caution:

• **Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so.**

• **Do not attempt a surgical procedure with faulty, damaged or suspect MetaSurg instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively**