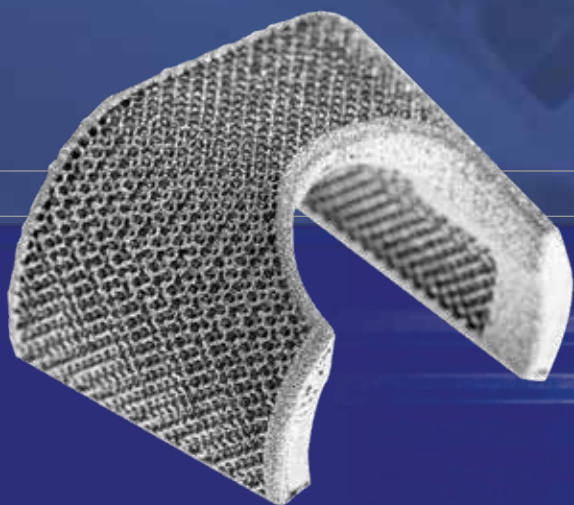


3D etal FEMORAL CONES



Surgical Technique

Joint

Spine

Sports Med

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1. INTRODUCTION

In cases where patients present with severe femoral bone defects that may compromise revision implant fixation, femoral cones are intended to be used in the diaphyseal side of the femoral component in order to fill and reconstruct large bone deficiencies and cavitory defects in the distal femur. Porous metal cones are intended to assist in recreating a distal structural foundation to support the intended revision implant and do so by achieving distal fixation and transmitting force to the remaining distal host bone. Cone fixation in distal host bone with additional distal stem fixation is superior to stem fixation alone. They are characterized by a conical shape which facilitates their insertion and seeks an optimal fit in the femoral canal.



1.1 INDICATIONS FOR USE

The 3DMetal Femoral Cones are indicated for use with the GMK Revision and GMK Hinge knee systems, as well as the femoral extension stems and offsets.

Specific indications are as follows:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis.
- Post traumatic loss of joint configuration.
- Considerable loss of function of the knee joint.
- High-grade joint destruction requiring additional stabilization and reconstruction of bone defects.
- Primary implantation failure.
- Former revision arthroplasty.

1.2 CONTRAINDICATIONS

3DMetal femoral cones are contraindicated in the following cases:

- Progressive local or systemic infection.
- Muscular loss, neuromuscular disease or vascular deficiency of the affected limb, making the operation unjustifiable.

It is the surgeon's responsibility to ensure that the patient has no known hypersensitivity to the materials used. Mental or neuromuscular disorders may create an unacceptable risk to the patient and can be a source of postoperative complications.

2. SURGICAL TECHNIQUE

NOTE: For the surgical steps not described in this addendum, please refer to the GMK Revision System surgical technique (ref. 99.27s.12 and 99.27s.12US).

NOTE: For this surgical technique it is suggested to use a high-speed burr. Broaching sclerotic bone may precipitate fracture. Removing bone with a high-speed burr reduces the risk of fracture by improving the fit of the broach and decreasing the force necessary to fully seat the broach.

2.1 FEMORAL FINISHING

Ream the femoral canal sequentially increasing the diameter of the reamer until the appropriate reamer is axially and rotationally stable. Perform all the femoral resections and box finishing, as explained in the GMK Revision System surgical technique.

2.2 EVALUATION OF THE BONY DEFECT

Insert the reamer back into the femoral canal.

Place the trial femoral cone of the size that best fits the defect into the femoral diaphysis. Clean the internal profile of the bony defect with a high speed burr if the trial cone doesn't fully fit into the bone. This will reduce the risk of fracture by improving the fit of the broach.

CAUTION

Check the compatibility between femoral cone and stem in the compatibility chart.

NOTE: Each femoral cone size can be used with any GMK Revision and GMK Hinge femoral component size, with or without 3.0 mm femoral offset

2.3 BROACHING

Remove the trial femoral cone using the dedicated femoral cone extractor (02.07.10.4785) and select the size matched femoral cone broach.

The femoral cone broach is then assembled to the impactor handle (02.07.10.4746) by a bayoned mount. Slide the assembly onto the reamer.

When the impactor handle is secured to the broach, the assembly can be impacted. The assembly can rotate around the reamer to find the best fit of the cone into the bony defect.

WARNING

Carefully evaluate the broaching depth against the pre-op evaluation made using x-ray images.

Once the desired position has been defined, impact the broach until proper stability and fit are reached.



When fully seated remove the assembly.

NOTE: Remove the assembly from the reamer by pulling the handle. Do NOT disengage the handle from the broach.

NOTE: If the broach does not sit stable in the defect, consider using the next larger size broach and repeat the previous broaching step.

FREE HAND OPTION: Remove the trial femoral cone using the femoral cone extractor. Impact and advance the broach into the bone evaluating the orientation of the broach. Subsequently, evaluate the compatibility of the prepared canal with the trial implants. If the positioning is not satisfactory repeat the broaching phase.

2.4 TRIAL IMPLANT EVALUATION

Assemble the trial femoral component with stem, offset and augments as explained in the GMK Revision system surgical technique. Insert the trial femoral cone into the prepared femoral cavity using the dedicated femoral impactor.

CAUTION

Pay attention to the trial femoral cone anterior side marked "A". It must be oriented towards the anterior cortex of the femur



Before impacting the trial femoral cone, the broach must be removed from the impactor handle. Secure the dedicated converter to the impactor handle, and match the trial femoral cone with this assembly.

NOTE: After positioning the femoral cone, ensure it is fully stable when seated in the femoral canal.

NOTE: If the broach does not sit stable in the defect, consider using the next larger broach size.

Insert the entire pre-assembled trial femoral component into the femoral canal. Complete the tibial finishing, tibial component assembly and impaction following the steps described in the GMK Revision system surgical technique and proceed to test the knee through the full range of motion.

2.5 FINAL IMPLANTATION

Remove the trial assembled femoral component. The trial femoral cone can be removed by hand or using the dedicated femoral cone extractor (Ref. 02.07.10.4785). Assemble the final implant as described in the GMK Revision System surgical technique.

The cone implant can now be impacted into the femoral canal. Impact the final femoral cone into the bone defect using the femoral impactor handle (02.07.10.4746). The femoral cone is fixed to the impactor handle by the femoral cone adapter (02.07.10.4896).



NOTE: If there are any gaps between the femoral cone and the inner surface of the femur, fill these voids with cement or grafting material.

Spread the cement abundantly on the internal surface of the femoral cone.

Apply bone cement on the inner surface of the femoral implant and on the surface of the femoral stem. Insert the assembled implant through the femoral cone fixed to the bone and impact the assembly to the bone. Carefully remove any bone cement protruding.

NOTE: Prepare the tibial component following the GMK Revision System surgical technique. Use tibial components sizes that have been chosen during trial implant evaluation. When the final implant has been positioned, proceed to test the knee through the full range of motion. Carefully remove any bone cement protruding.

3. SIZE MATCHING

3DMetal			Femoral component					
Type	Size	Height (mm)	GMK Revision			GMK Hinge		
			Size 1-2	Size 3-4	Size 5-6	Size 1-2	Size 3-4	Size 5-6
Femoral Cones	Small	20	✓	✓	✓	✓	✓	✓
	Medium	25	✓	✓	✓	✓	✓	✓
	Large	30	✓	✓	✓	✓	✓	✓
	Extra large	30	✓	✓	✓	✓	✓	✓

3DMetal			Extension Stem (diameter)									
Type	Size	Height (mm)	10 mm	11 mm	12 mm	13 mm	14 mm	15 mm	16 mm	18 mm	20 mm	22 mm
			Femoral Cones	Small	20	✓	✓	✓	✓	✓	✓	✓
Mediuml	25	✓		✓	✓	✓	✓	✓	✓	✓	✓	✗
Large	30	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓
Extra large	30	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓


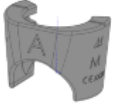








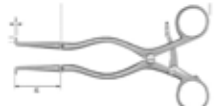
4. IMPLANT NOMENCLATURE

3DMETAL FEMORAL CONES

Size	Height (mm)	Reference	Description
S	20	02.07.FCS20	3DMetal Diaphyseal Femoral Cone Size Small
M	25	02.07.FCM25	3DMetal Diaphyseal Femoral Cone Size Medium
L	30	02.07.FCL30	3DMetal Diaphyseal Femoral Cone Size Large
XL	30	02.07.FCXL30	3DMetal Diaphyseal Femoral Cone Size Extra Large

5. INSTRUMENTATION NOMENCLATURE

3Dmetal femoral cones instrument set 02.07S.Femcones

Reference	Description	Image	Qty
02.07.10.4888	3DMetal Femoral Cone Small Trial		1
02.07.10.4889	3DMetal Femoral Cone Medium Trial		1
02.07.10.4890	3DMetal Femoral Cone Large Trial		1
02.07.10.4891	3DMetal Femoral Cone Extra Large Trial		1
02.07.10.4892	Femoral cones broach size S		1
02.07.10.4893	Femoral cones broach size M		1
02.07.10.4894	Femoral cones broach size L		1
02.07.10.4895	Femoral cones broach size XL		1
02.07.10.4896	Femoral cones adapter		1
02.07.10.4746*	Tibial cones impactor handle		0
02.07.10.4785*	Tibial cones trial extractor		0
02.07.10.8857	3D Metal Femoral Cones X-Ray Template 100%		1

*Both items are included in the PL 02.07s.TIBCONES.

Part numbers subject to change.

NOTE FOR STERILIZATION

The instrumentation is not sterile upon delivery. Instruments must be cleaned before use and sterilized in an autoclave respecting the US regulations, directives where applicable, and following the manufactures instructions for use of the autoclave. For detailed instructions please refer to the document "Recommendations for cleaning decontamination and sterilisation of Medacta International orthopaedic devices" available at www.medacta.com.



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