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This document is an addendum to the GMK Revision System surgical technique (ref. 99.27s.12 and 99.27s.12US).

1. INTRODUCTION

In cases where patients present with severe tibial bone loss that may compromise revision implant fixation, tibial cones may be used to reinforce the proximal tibial cavity. Porous metal cones are intended to assist in recreating a proximal structural foundation to support the intended revision implant and do so by achieving proximal fixation in

remaining host bone and transmitting force to the remaining proximal host bone. Cone fixation in proximal host bone with additional distal stem fixation is superior to stem fixation alone.

Centred and Eccentric Tibial Cones are available (Fig. 1) as part of the GMK Revision and Hinge system.



2. INDICATIONS FOR USE

The 3DMetal Tibial Cones are indicated for use with the GMK Revision and GMK Hinge knee systems, as well as the GMK tibial 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

3. CONTRAINDICATIONS

3DMetal tibial 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.



4. 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.

NOTE: The surgical technique described in this addendum applies to both Centred and Eccentric tibial cones.

4.1 TIBIAL RESECTION

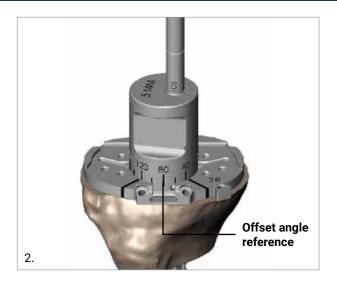
Ream the tibial canal sequentially, increasing the diameter of the reamer until the appropriate reamer is axially and rotationally stable. Perform the proximal resection using the intramedullary alignment system, as explained in the GMK Revision System surgical technique.

4.2 TIBIAL BASEPLATE POSITIONING

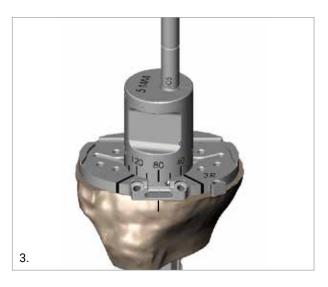
After having performed the tibial resection, remove the alignment system and cutting guide and replace the reamer to the appropriate depth.

Select the appropriate size trial tibial baseplate which achieves proper coverage of the proximal tibia and axial rotation. Slide the 0 mm neutral bushing (Ref. 02.07.10.9885) on the reamer and assemble the bushing on the trial tibial baseplate. If the tibial tray properly covers the resected tibial with this 0 mm bushing, no offset is needed.

Otherwise, replace the 0 mm neutral bushing with the 3 mm (Ref. 02.07.10.0092) or 5 mm offset bushing (Ref. 02.07.10.0094). Use the selected bushing to rotate the baseplate around the proximal tibia resection until coverage and axial rotation is maximized. When the tibial tray is properly positioned, read the offset angle by referring to the reference line at the middle of the trial baseplate. Each mark on the bush corresponds to 20° angle. In Figure 2, the angle is set to 80° .



When the final position is defined, mark the position of the trial baseplate reference line on the bone (Fig. 3) and fix the tibial baseplate with two pins. The mark on the bone will be used as a reference during placement of the tibial cone broach and final implant.

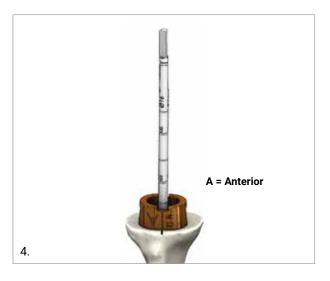


4.3 TIBIA FINISHING

Remove the offset bushing and the reamer from the bone. Perform the finishing of the tibia keel, the offset coupler (if needed) and the stem connection, as explained in the GMK Revision System surgical technique.

4.4 EVALUATION OF THE BONY DEFECT

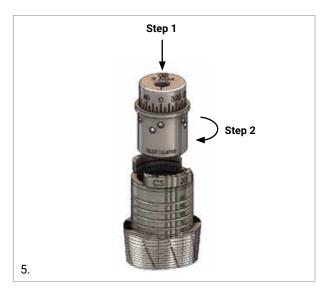
Insert the reamer back in the tibial canal. Flip the trial tibial cone of chosen size upside down and place on the tibial cut surface over the reamer ensuring that the anterior portion of the cone trial remains facing anterior. Flipping the cone upside down simulates the contour of proximal bone defect which the cone be required to accommodate. Assess the size and orientation of the bony defect by comparison with the trail tibial cones (Fig. 4).



Validate the size of the tibial cone that best fits the defect and visually check the compatibility between the position of the trial cone and the tibial keel.

4.5 BROACHING - OPTION 1

Remove the trial tibial cone and select the size matched tibial cone broach. In accordance with the selected offset (0, 3 or 5 mm), place the corresponding tibial cone offset bushing (Ref. 02.07.10.4764, 02.07.10.4765, 02.07.10.4766) into the broach. Rotate the bushing until the offset angle measured during the preparation of the tibial baseplate is aligned with the center mark etched on the upper surface of the broach (Fig. 5 and 6).



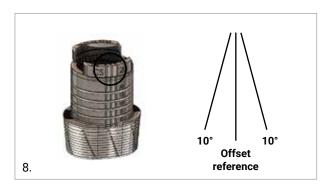


Slide the assembly (broach plus tibial cone offset bushing) over the reamer. As a visual check whether the correct offset has been reproduced, the broach must now be aligned with the mark previously made on the bone during the preparation of the tibial baseplate (Fig. 7).

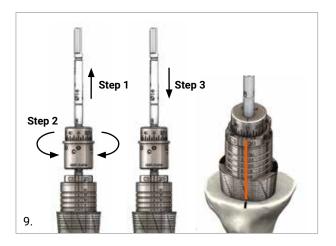




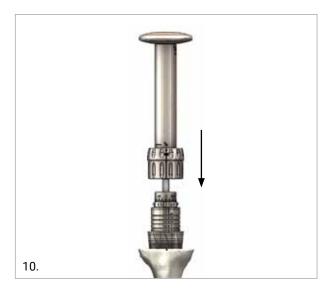
To correct the broach orientation, two additional reference lines are available (Fig. 8 red circle). By utilizing these lines, the position of the broach can be adjusted +/- 10° in order to better accommodate the bone defect.



In order to adjust by 10° , remove the offset bushing from the broach by lifting up. Reposition the broach by 10° in the desired direction by lining up the 10° reference line with the mark made on the tibia during the baseplate preparation. Then reinsert the offset bushing into the broach. Reset the desired offset position by aligning the offset degree previously determined with the 10° reference line and mark on tibia (Fig. 9).



Once the desired position of the assembly has been defined, slide the impactor handle (Ref. 02.07.10.4746) over the reamer shaft and connect the handle to the broach (Fig.10). When the impactor handle is secured to the broach, impact the assembly (Fig. 11).





If significant bone must be removed to fully seat the broach it is suggested to use a high speed burr to remove bone prior to fully seating the broach.

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

4.6 BROACHING - OPTION 2 (FREE HAND TECHINQUE)

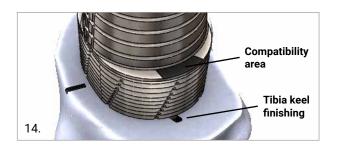
Mark the position of the trial tibial cone on the bone (Fig. 12 red mark).



Remove the reamer and the trial tibial cone from the bone. Select the size matched tibial cone broach. Secure the impactor handle to the broach.

Before broaching, check again the compatibility between the tibial cone and the assembly using the trial implants. Place the assembly on the bone using the position of the trial tibial cones previously marked on the bone (Fig. 13 red mark) as a reference. Check again the compatibility between the tibia keel and the tibial cone position using the lateral markings etched on the broach. To ensure compatibility, the medial and lateral tibial wings must be placed within the black area marked on the broach (Fig. 14).





Once the desired position of the assembly has been defined, impact the assembly until the broach is completely inserted into the bone (Fig. 15).

It is suggested to use a high speed burr to remove bone and improve the fit of the broach.



OPTION (ONLY with free hand technique): Centred tibial cone + Tibial augment

Perform the proximal resection for the tibial augment as explained in the GMK Revision System surgical technique. Verify the compatibility between the tibial cones and the augments as per the compatibility chart that is available in the Size Matching section.

Before broaching, check again the compatibility between the tibial cone and the assembly using the trial implants. Different broaching depths are engraved on each broach. If a tibial augment is used, align the depth marking (5 mm, 10 mm, 15 mm or 20 mm) to the existing tibial resection in order to reach the corresponding depth. Figure 16 shows the procedure for preparing the tibia when a 5 mm wedge is used. The most proximal resection must be aligned with the 5 mm line engraved on the broach.





NOTE: When a tibial augment of the same thickness is used in both compartments, the tibial resection must be aligned to the 0 mm depth marking.

4.7 TRIAL IMPLANT EVALUATION

Insert the trial tibial cone into the prepared tibial cavity using the tibial impactor (Ref. 02.07.10.2187).

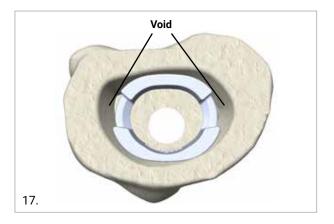
Next, insert through the trial cone into the tibial canal the entire trial tibia assembly which includes the trial baseplate and the trial keel as well as any selected offset, extension stem and augment.

NOTE: When using a tibial offset, the trial tibial cone must be pre-assembled to the trial tibial baseplate prior to implantation.

Prepare the femoral component utilizing the GMK Revision System surgical technique. Then determine the appropriate thickness for the polyethylene insert. Once the femoral component and trial insert chosen, proceed to test the knee through range of motion.

NOTE: The external surface of the cone must be in contact with the remaining tibial bone.

In case of any gaps between the outside of the tibial cone and the internal surface of the tibia, use grafting material or cement to fill the void (Fig. 17).



4.8 FINAL IMPLANTATION

After the evaluation with the trial implants, the trial tibial cone can be removed by hand or using the extractor clamp (Ref. 02.07.10.4785).

Assemble the final tibial component as described in the GMK Revision System surgical technique.

When a tibial offset is not used, impact the final tibial cone into the bone defect using the tibial impactor (Ref. 02.07.10.2187). Apply bone cement on the undersurface of the tibial baseplate and on the surface of the tibial keel. Spread cement abundantly on the internal surface of the tibial cone, so that cement fills the space between tibial keel and cone, yet avoiding excessive quantity of cement that may be pushed down to the intramedullary canal. Insert the assembled baseplate into the tibial cone and impact the implant assembly.

When using a tibial offset, the final tibial cone must be preassembled to the tibial baseplate prior to implantation. Apply bone cement on the undersurface of the tibial baseplate and on the surface of the tibial keel. Spread cement abundantly on the internal surface of the tibial cone and insert the assembled baseplate into the tibial cone. Then, impact the assembly to the bone.

Carefully remove any bone cement protruding from the cone.

5. SIZE MATCHING

	3DMetal		Tibial Tray								
T	0:	Height	GMK Primary and Revision				GMK Hinge				
Type	Size	(mm)	Size 1-2	Size 3-4	Size 5-6	Size 1-2	Size 3-4	Size 5-6			
	Extra Small	20	✓	✓	✓	✓	✓	✓			
	Extra Small	25	✓	✓	✓	✓	✓	✓			
3DMetal	Small	20	✓	✓	✓	✓	✓	✓			
CENTRED	Small	25	✓	✓	✓	✓	✓	✓			
	Medium	25	✓	✓	✓	✓	✓	✓			
	Large	25	✓	✓	✓	✓	✓	✓			
	Small	20	✓			✓					
3DMetal	Small	25	✓			✓					
ECCENTRIC	Medium	25	✓	✓		✓	✓				
	Large	25	✓	✓	✓	✓	✓	✓			



			Extension	on Stem	(diame	eter) + 0 mm Tibial Offset						
Туре	Size	Height (mm)	10 mm	11 mm	12 mm	13 mm	14 mm	15 mm	16 mm	18 mm	20 mm	22 mm
	Extra Small	20	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	Extra Small	25	✓	✓	✓	✓	✓	✓	✓	✓		
Cones	Small	20	✓	✓	✓	✓	✓	✓	✓	✓	✓	
CENTRED	Small	25	√	√	√	✓	✓	✓	✓	✓		
	Medium	25	√	√	√	✓	✓	✓	✓	✓	√	
	Large	25	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Small	20	√	√	✓	✓	✓	✓	✓			
Cones ECCENTRIC	Small	25	✓	√	✓	✓	✓	✓	✓			
	Medium	25	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	Large	25	✓	✓	✓	✓	✓	✓	✓	✓	✓	

compatibility with 5/10/15/20 mm tibial augment

	3DMetal			Extension Stem (diameter) + 3 mm Tibial Offset								
Туре	Size	Height (mm)	10 mm	11 mm	12 mm	13 mm	14 mm	15 mm	16 mm	18 mm	20 mm	22 mm
	Extra Small	20	√	✓	✓	✓	✓	✓	✓	✓		
	Extra Small	25	✓	✓	✓	✓	✓	✓	✓			
Cones	Small	20	✓	✓	✓	✓	✓	✓	✓	✓		
CENTRED	Small	25	✓	✓	✓	✓	✓	✓	✓	✓		
	Medium	25	✓	✓	✓	✓	✓	✓	✓	✓	✓	
	Large	25	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Small	20	✓	✓	✓	✓	✓	✓	✓			
Cones	Small	25	✓	✓	✓	✓	✓	✓	✓			
ECCENTRIC	Medium	25	√	✓	✓	✓	✓	√	✓	✓		
	Large	25	✓	√	√	✓	✓	√	✓	✓		

compatibility with 5 mm tibial augment

compatibility with 5/10 mm tibial augment



	3DMetal		Extension Stem (diameter) + 5 mm Tibial Offset									
Туре	Size	Height (mm)	10 mm	11 mm	12 mm	13 mm	14 mm	15 mm	16 mm	18 mm	20 mm	22 mm
	Extra Small	20										
	Extra Small	25										
Cones	Small	20	✓	✓	✓	✓	✓	✓	✓			
CENTRED	Small	25	✓	√	✓	✓	√	√				
	Medium	25	✓	√	✓	✓	✓	✓	√			
	Large	25	✓	√	✓	✓	✓	√	√	✓	√	
	Small	20	✓	✓	✓	✓	✓					
Cones	Small	25	✓	√	√	✓	✓					
ECCENTRIC	Medium	25	✓	✓	✓	✓	✓	✓	✓			
	Large	25	✓	√	✓	✓	✓	✓	✓			

compatibility with 5 mm tibial augment

compatibility with 5/10 mm tibial augment

6. IMPLANT NOMENCLATURE

	3DMetal Tibial Cones							
Size	Height (mm)	Centred	Eccentric					
XS	20	02.07.CXS20	n.a.					
V2	25	02.07.CXS25	n.a.					
S	20	02.07.CS20	02.07.ES20					
3	25	02.07.CS25	02.07.ES25					
М	25	02.07.CM25	02.07.EM25					
L	25	02.07.CL25	02.07.EL25					



7. INSTRUMENTATION NOMENCLATURE

3DMETAL TIBIAL CONES INSTRUMENT SET 02.07S.TIBCONES

Reference	Description	Quantity
02.07.10.4746	Tibial cones impactor handle	1
02.07.10.4747	Tibial cones broach size CXS20	1
02.07.10.4748	Tibial cones broach size CXS25	1
02.07.10.4749	Tibial cones broach size CS20	1
02.07.10.4750	Tibial cones broach size CS25	1
02.07.10.4751	Tibial cones broach size CM25	1
02.07.10.4752	Tibial cones broach size CL25	1
02.07.10.4753	Tibial cones broach size ES20	1
02.07.10.4754	Tibial cones broach size ES25	1
02.07.10.4755	Tibial cones broach size EM25	1
02.07.10.4756	Tibial cones broach size EL25	1
02.07.10.4764	Tibial cones 0 mm bush	1
02.07.10.4765	Tibial cones 3 mm offset bush	1
02.07.10.4766	Tibial cones 5 mm offset bush	1
02.07.10.4775	Tibial cones trial implant size CXS20	1
02.07.10.4776	Tibial cones trial implant size CXS25	1
02.07.10.4777	Tibial cones trial implant size CS20	1
02.07.10.4778	Tibial cones trial implant size CS25	1
02.07.10.4779	Tibial cones trial implant size CM25	1
02.07.10.4780	Tibial cones trial implant size CL25	1
02.07.10.4781	Tibial cones trial implant size ES20	1
02.07.10.4782	Tibial cones trial implant size ES25	1
02.07.10.4783	Tibial cones trial implant size EM25	1
02.07.10.4784	Tibial cones trial implant size EL25	1
02.07.10.4785	Tibial cones trial extractor	1
02.07.10.8851	3DMetal Tibial Cones - X-Ray Template 100%	1
02.07.10.8070	3DMetal Tibial Cones - Tray 1	1

Part numbers subject to change.

NOTE FOR STERILISATION

The instrumentation is not sterile upon delivery. It must be cleaned before use and sterilised in an autoclave in accordance with the regulations of the country, EU directives where applicable and following the instructions for use of the autoclave manufacturer. 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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3DMetal Tibial Cones

Surgical Technique

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