



# More can be addressed...

The **U2 Cemented Modular Augmentable Baseplate** is an optimal solution for tibial bone defect in primary total knee replacement. Indications such as **Unilateral Moderate Tibial Bone Deficiencies** can now be well addressed following simple instruments.







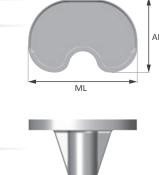
Design without through hole avoids potential backside wear



The roughen texture of the recessed undersurfaces ensure an ideal cement fixation

## Tibial Baseplate, CMA

Number		AP	ML	
<b>★</b> 2203-3200	#0	39.5	60	
2203-3210	#1	42	63	
2203-3220	#2	44.5	66	
2203-3230	#3	47	69	
2203-3240	#4	49.5	72	
2203-3250	#5	52.5	76	
2203-3260	#6	55.5	80	
<b>★</b> 2203-3270	#7	58.5	84	



# Accessories Tibial Augment



	Number	Des	cription	Number	Des	cription
٩P	<b>★</b> 2803-5201	#0	5 mm	<b>★</b> 2803-5202	#0	10 mm
	2803-5211	#1	5 mm	2803-5212	#1	10 mm
	2803-5221	#2	5 mm	2803-5222	#2	10 mm
	2803-5231	#3	5 mm	2803-5232	#3	10 mm
	2803-5241	#4	5 mm	2803-5242	#4	10 mm
	2803-5251	#5	5 mm	2803-5252	#5	10 mm
	2803-5261	#6	5 mm	2803-5262	#6	10 mm
	<b>★</b> 2803-5271	#7	5 mm	<b>★</b> 2803-5272	#7	10 mm

# Straight Stem

Number	Description
2703-5003	Ø14 x 30 mm



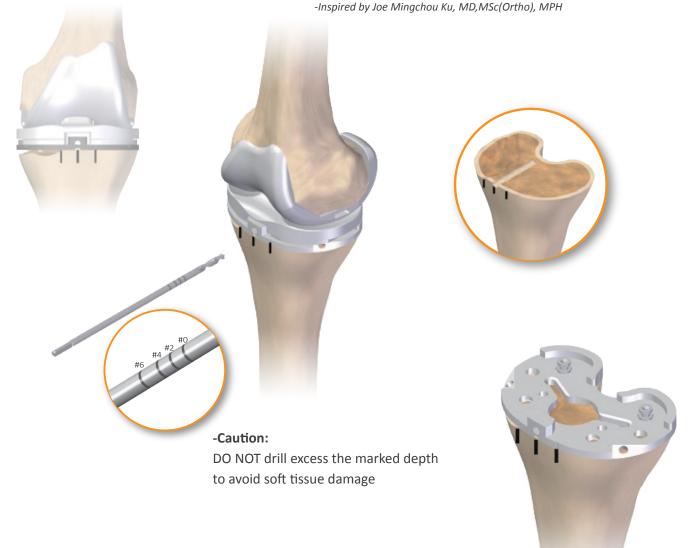
# **Surgical Procedure**

# Using the Tibial Augment / Straight Stem with U2 CMA Baseplate

Prepare the initial trial reduction as indicated in "Initial Tibial Baseplate Trial Insertion" --U2 *Knee Surgical Protocol, Step C.3.* Then continue with the following steps:

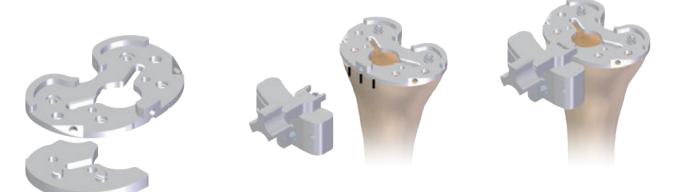
## A. Tibial Augment Resection

A desired alignment position was marked on the anterior tibia cortex after initial trial reduction. Then with the knee fully extended, drilling carefully through the center tunnel below the **Tibial Baseplate Trial** by utilizing the **CMA Twist Drill 3.2 mm**. Drill until reaching to the marked depth according to desired size of tibial baseplate. A center groove on the proximal tibia plane was formed as a vertical resection reference.

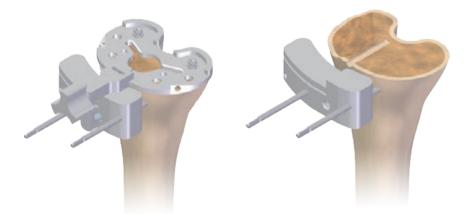


Secure the **Tibial Baseplate Trial** to the proximal tibia with two spikes according to the rotational orientation.

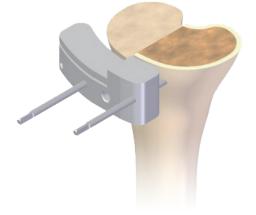
Assemble the appropriate **Tibial Augment Resection Guide** (left or right) and the **Tibial Augment Resection Guide Adaptor** onto the **Tibial Baseplate Trial**.



Apply two drills to secure the **Tibial Augment Resection Guide** to the tibia. Then, remove the **Tibial Augment Resection Guide Adaptor** and the **Tibial Baseplate Trial**.



Perform the horizontal resection by referencing the upper plane for 5 mm augment or the slot for 10 mm augment. Finish the vertical resection referring to the center groove on the top of proximal tibial plane.

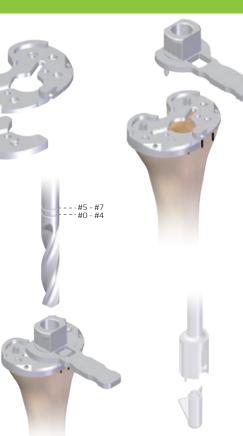


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### B. Tibial Fin Slot Preparation

Assemble the desired **Tibial Augment Trial** to the backside of the **CMA Tibial Baseplate Trial** and fix the trial combination onto the resected tibial surface with two spikes.

To ensure the stability of tibial component, an 30 mm distal stem is recommended. Advance the **Straight Stem Drill** through the **Tibial Drill Guide** until the depth reaches the laser mark of the "0-4" or "5-7"line according to the selected size of the **CMA Tibial Baseplate Trial**. The drill and drill guide are then removed.



Continue with tibial punching to finish the fin slot preparation. (Referring to U2 Knee Surgical Protocol, Step C.4.)

### C. Implant Assembling

After final trial reduction, assemble the **Screw Driver Adaptor** to the **Driver Handle**, then fasten the determined augment onto the baseplate.

If the straight stem is required, unscrew the plug at the bottom of the baseplate via **Screw Driver**.

Insert the trunnion of the stem into the implant taper. Solidly tap the stem onto the baseplate with the **Stem Impactor** to make sure the stem is firmly set.



# Trials



Number	Desc	ription	
* 2203-4000-RB 2203-4010-RB 2203-4020-RB 2203-4030-RB 2203-4040-RB 2203-4050-RB 2203-4060-RB	#0 #1 #2 #3 #4 #5 #6	Baseplate Trial, CMA Baseplate Trial, CMA Baseplate Trial, CMA Baseplate Trial, CMA Baseplate Trial, CMA Baseplate Trial, CMA Baseplate Trial, CMA	



Number	Description			Number	er Description			٦	
* 2803-6101 2803-6111 2803-6121 2803-6131 2803-6141 2803-6151 2803-6161 * 2803-6102 2803-6112 2803-6122 2803-6132 2803-6142	Left Left Left Left Left Left Left Left	#0 #1 #2 #3 #4 #5 #6 #0 #1 #2 #3 #4	5mm 5mm 5mm 5mm 5mm 5mm 10mm 10mm 10mm 1	Augment Trial Augment Trial	* 2803-6201 2803-6211 2803-6221 2803-6231 2803-6241 2803-6251 2803-6261 * 2803-6202 2803-6212 2803-6222 2803-6232 2803-6242	Right Right Right Right Right Right Right Right Right Right Right	#0 #1 #2 #3 #4 #5 #6 #0 #1 #2 #3 #4	5mm 5mm 5mm 5mm 5mm 5mm 5mm 10mm 10mm 10	Augment Trial Augment Trial
2803-6152 2803-6162	Left Left	#5 #6	10mm 10mm	Augment Trial Augment Trial	2803-6252 2803-6262	Right Right	#5 #6	10mm 10mm	Augment Trial Augment Trial

# Instruments

	Number 9401-5307	Description Screw Driver	and the second second	Number 9403-3214-RA	Description Straight Stem Drill,
	Number	Description	C.T.	Number	Ø 14mm Description
a l	9403-1302-RA	Driver Handle		9403-5111	Tibial Augment Resection Guide Adaptor
	Number	Description		Number	Description
CHA	9403-2105	Tibial drill guide, CMA		9403-5331-RA	Screw Driver Adaptor
	Number	Description		Number	Description
	9403-2119-RE 9403-2219-RE	Tibial Augment Resection Guide, Left Tibial Augment Resection Guide, Right	OWN	9403-5340	Stem Impactor
	Number	Description	4	Number	Description
~	9403-3002	CMA Twist Drill 3.2mm	R. A	9303-8052	U2 Knee CMA Case

## Safety Statement of "UNITED" U2 Total Knee System CMA Type

### Important

This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information

### INDICATIONS

This device is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion contraction. This device may also be indicated in the salvage or previously failed surgical attempts or for knee in which satisfactory stability in flexion cannot be obtained at the time of surgery. This device system is designed for cemented use only.

### CONTRAINDICATIONS

The U2 Tibial Baseplate, CMA type is contraindicated in patients who with:

- any active or suspected latent of infection in the affected joint.
- skeletal immaturity.
- either mental or neuromuscular disorders which would create an unacceptable risk of prosthesis instability or complications in postoperative care
- rheumatoid arthritis and an ulcer of the skin or a history of recurrent breakdown of the skin.

#### **ADVERSE EFFECTS**

Potential adverse effects include infection, loosening of the components, breakage or bending of the components, or change in position of the components. Dislocation can occur due to inappropriate patient activity, trauma or other biomechanical considerations. Loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis, component malalignment, osteolysis or trauma. Breakage or bending may result due to inadequate support of the component by the underlying bone or poor component fixation. Wear of polyethylene components has occurred and literature reports have associated its occurrence with bone resorption, loosening and infection. Other potential adverse effects of total knee surgery include genitourinary disorders; gastrointestinal disorders; neurovascular damage, thromboembolic disease, myocardial infarction and other less common adverse effects. Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, and/or amputation of the limb. Due to the many biological, mechanical and physicochemical factors which affect these devices, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.

#### WARNINGS AND PRECAUTIONS

Familiarity with and attention to appropriate surgical technique for total knee arthroplasty and the U2 Tibial Baseplate, CMA type is essential for success of the total knee procedure. Only surgeons who have reviewed the literature regarding total knee surgery and have been training in the technique should utilize the device. Patients should be instructed the limitations of the prosthesis, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. If the patient is involved in an occupation or activity which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.

Accordingly, strict adherence to the indications, contraindications, precaution and warnings for this product is essential to potentially maximize service life. Appropriate selection, placement and fixation of the total knee components are critical factors that affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic biomechanic and other extrinsic factors, which limit their service life.

The surgeon must not allow damage to polished bearing surfaces because this may accelerate wear of the components. Discard all damaged or mishandled implants. Keep bearing areas clean and free of debris prior to assembly. Components of the U2 Tibial Baseplate, CMA type should not be used with those of another manufacturer's total knee component since articular and dimensional compatibility cannot be assured. Femoral component and tibial insert should belong to the one single system; therefore, femoral component of U2 Total Knee System – PSA Type cannot be coupled with tibial insert of U2 Total Knee System, vice versa. Intentional removal of the plastic tibial insert after its assembly into the tibial tray results in the destruction of the plastic insert. Care should be taken not to nick or notch the surface of the tibial tray during insert removal. Return all packages with flaws in the sterile barrier to the supplier. This device is for single use only. Do not reuse and Do not resterilize. Reuse of this product will cause the risk of cross infection and unpredictable health threat.

For more information about UOC products, visit our web site at www.uoc.com.tw



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