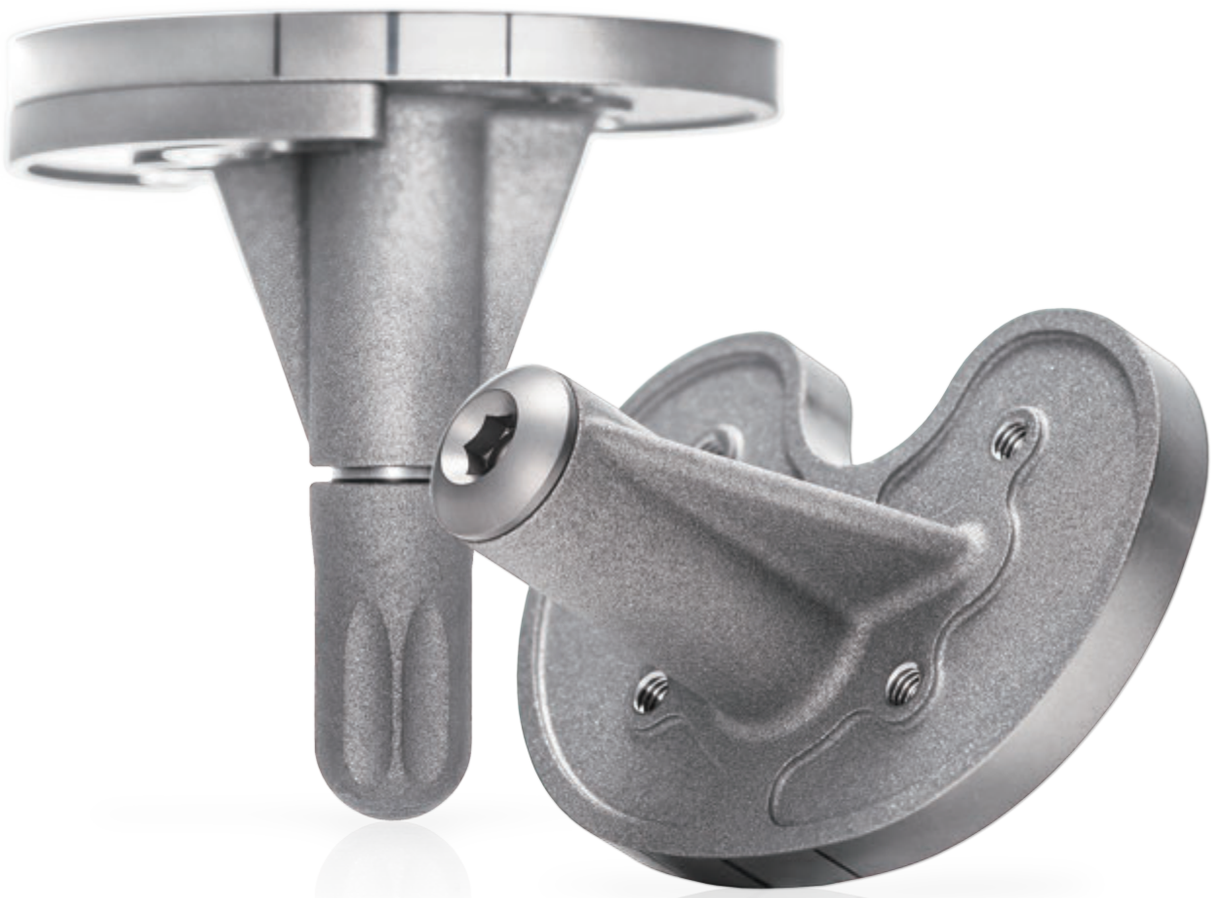
United®
Orthopedic Corporation



CMA™

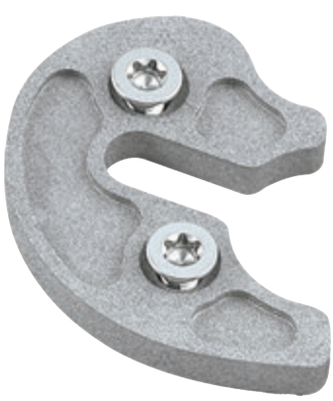
Cemented Modular Augmentable Baseplate

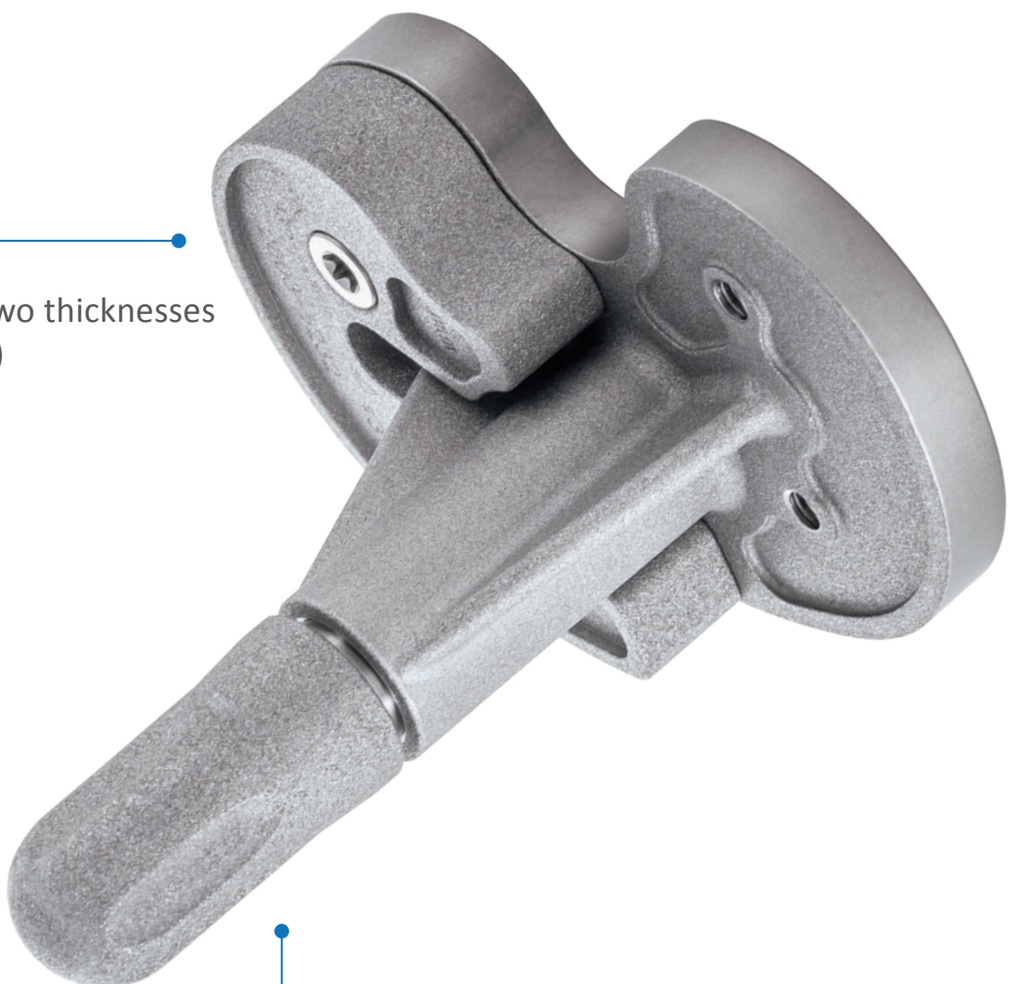
U2 Knee

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.

- Unilateral in two thicknesses (5 and 10 mm)
- Titanium alloy
- Screw fixation





- 30 mm stem to enhance stability
- Titanium alloy

Each Step We Care

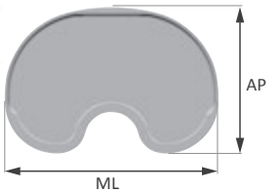
Without through hole design avoids potential backside wear

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

Distal end sealed with pre-assembled plug

Tibial Baseplate, CMA

Number		AP	ML
★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
★2203-3270	#7	58.5	84



★ *Special Order Items*

Accessories

Tibial Augment

Number	Description		Number	Description	
★2803-5201	#0	5 mm	★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
★2803-5271	#7	5 mm	★2803-5272	#7	10 mm

Straight Stem

Number	Description
2703-5003	Ø14 x 30 mm

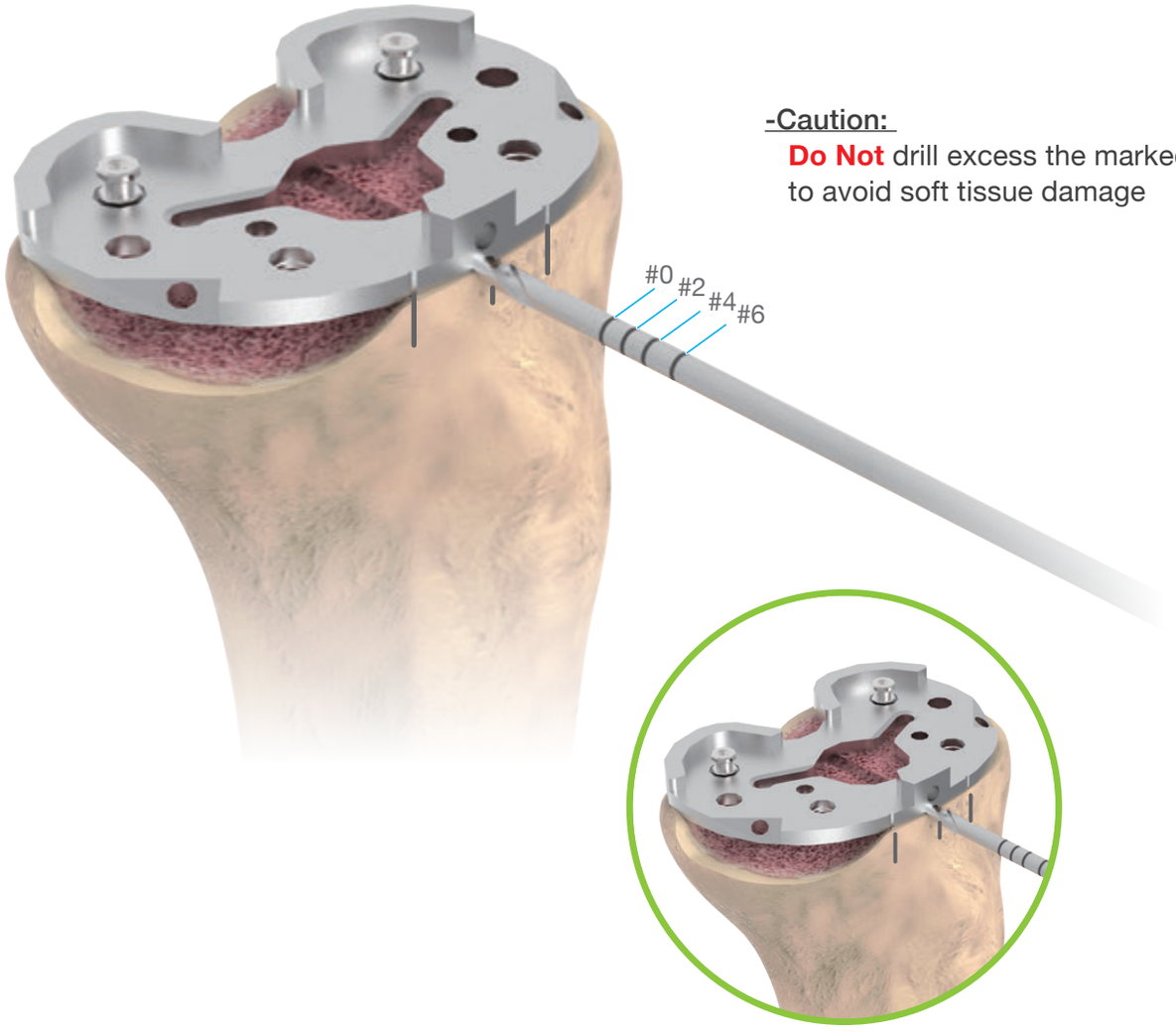
Surgical Procedure

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.2.* Then continue with the following steps:

A. Tibial Augment Resection

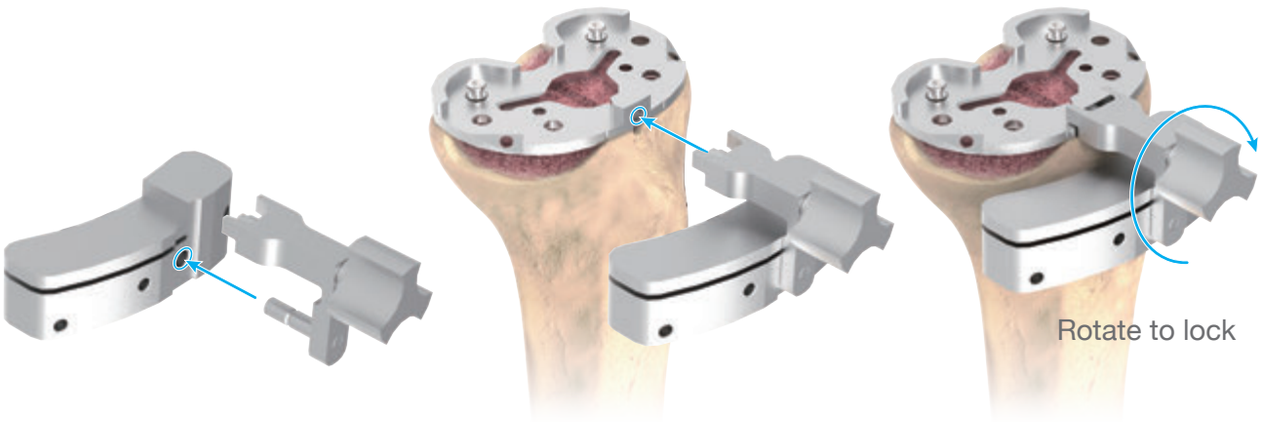
Align the **Tibial Baseplate Trial** with resected tibia surface and secure the baseplate trial to the proximal tibia with **2 Head Pins** according to the rotational orientation. Use the **CMA 3.2 mm Drill** to drill carefully through the center tunnel below the **Tibial Baseplate Trial**. Stop drilling when reaching to the marked depth according to desired size of tibial baseplate. A center groove on the proximal tibia plane is formed as a vertical resection reference.



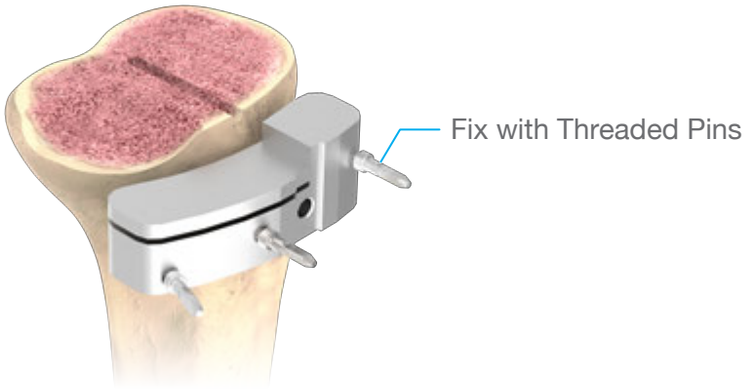
-Caution:

Do Not drill excess the marked depth to avoid soft tissue damage

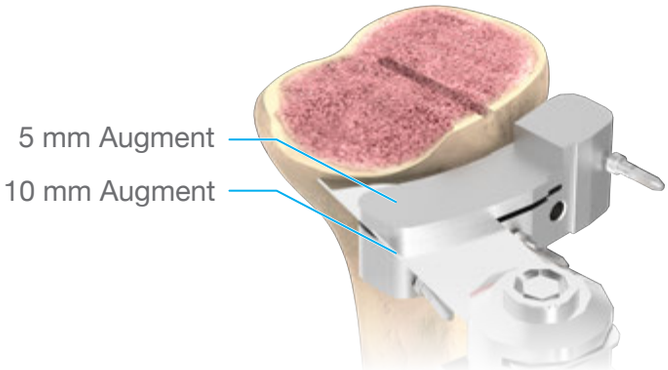
Assemble the appropriate **Tibial Augment Resection Guide** (left or right) and the **Tibial Augment Resection Guide Adaptor** onto the **Tibial Baseplate Trial**.



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

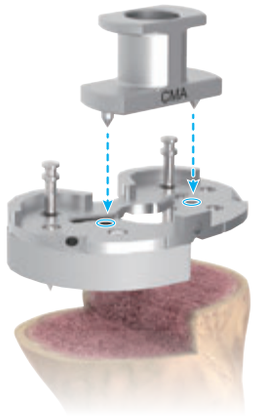


Perform the horizontal resection by referencing the upper plane for 5 mm augment or the slot for 10 mm augment. Finish the vertical resection referring to the center groove on the top of proximal tibial plane.



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 head pins. Then, attach the **CMA Tibial Drill Guide**, to the baseplate trial.



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.3.)*

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	Description
⋆ 2203-4000-RB	#0 Baseplate Trial, CMA
2203-4010-RB	#1 Baseplate Trial, CMA
2203-4020-RB	#2 Baseplate Trial, CMA
2203-4030-RB	#3 Baseplate Trial, CMA
2203-4040-RB	#4 Baseplate Trial, CMA
2203-4050-RB	#5 Baseplate Trial, CMA
2203-4060-RB	#6 Baseplate Trial, CMA
⋆ 2203-4070-RB	#7 Baseplate Trial, CMA

Number	Description				Number	Description			
⋆ 2803-6101	Left	#0	5mm	Augment Trial	⋆ 2803-6201	Right	#0	5mm	Augment Trial
2803-6111	Left	#1	5mm	Augment Trial	2803-6211	Right	#1	5mm	Augment Trial
2803-6121	Left	#2	5mm	Augment Trial	2803-6221	Right	#2	5mm	Augment Trial
2803-6131	Left	#3	5mm	Augment Trial	2803-6231	Right	#3	5mm	Augment Trial
2803-6141	Left	#4	5mm	Augment Trial	2803-6241	Right	#4	5mm	Augment Trial
2803-6151	Left	#5	5mm	Augment Trial	2803-6251	Right	#5	5mm	Augment Trial
2803-6161	Left	#6	5mm	Augment Trial	2803-6261	Right	#6	5mm	Augment Trial
⋆ 2803-6171	Left	#7	5mm	Augment Trial	⋆ 2803-6271	Right	#7	5mm	Augment Trial
⋆ 2803-6102	Left	#0	10mm	Augment Trial	⋆ 2803-6202	Right	#0	10mm	Augment Trial
2803-6112	Left	#1	10mm	Augment Trial	2803-6212	Right	#1	10mm	Augment Trial
2803-6122	Left	#2	10mm	Augment Trial	2803-6222	Right	#2	10mm	Augment Trial
2803-6132	Left	#3	10mm	Augment Trial	2803-6232	Right	#3	10mm	Augment Trial
2803-6142	Left	#4	10mm	Augment Trial	2803-6242	Right	#4	10mm	Augment Trial
2803-6152	Left	#5	10mm	Augment Trial	2803-6252	Right	#5	10mm	Augment Trial
2803-6162	Left	#6	10mm	Augment Trial	2803-6262	Right	#6	10mm	Augment Trial
⋆ 2803-6172	Left	#7	10mm	Augment Trial	⋆ 2803-6272	Right	#7	10mm	Augment Trial

Instruments

Number	Description
9401-5307	Screw Driver

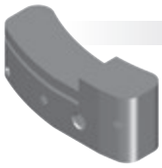
Number	Description
9403-3214-RA	Straight Stem Drill, Ø 14mm

Number	Description
9403-1302-RA	Driver Handle

Number	Description
9403-5111	Tibial Augment Resection Guide Adaptor

Number	Description
9403-2105-RB	Tibial Drill Guide, CMA

Number	Description
9403-5331-RA	Screw Deiver Adaptor, T20



Number	Description
9403-2119-RE	Tibial Augment Resection Guide, Left
9403-2219-RE	Tibial Augment Resection Guide, Right

Number	Description
9403-5340	Stem Impactor

Number	Description
9403-3002	CMA Twist Drill 3.2mm

Number	Description
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

United® Orthopedic Corporation

Each Step **We Care**

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