eius™ UNI KNEE SYSTEM

Surgical Technique

The Minimally Invasive Uni Knee System

stryker Howmedica OSTEONICS

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SURGICAL PROTOCOL

CONTENTS PAGE NO

Bone Sparing Implant Design

EIUS™ Femoral Component

- Bone sparing, resurfacing design
- Anatomical bend and contoured anterior lip designed to promote optimal condylar fit and help prevent patella impingement

EIUS™ Tibial Component

- Designed to accommodate +/- 10° varus/valgus malalignment
- 1 up/1 down size interchangeability with femoral component

Precision Instrumentation

Tibial Preparation

- "Tibia-first" approach designed to promote accurate femoro-tibial alignment
- Low-profile, extramedullary guides designed to facilitate a minimally invasive procedure

Femoral Preparation

- Unique, patent-pending distal burring template and specialized bur designed for accurate and reproducible femoral resurfacing
- Extramedullary guides designed for true, minimally invasive technique with accurate alignment

Minimally Invasive with Confidence!

The EIUS™ Uni Knee combines a bone sparing implant and precision instrumentation to create a minimally invasive system with the ease of use of traditional "open" procedures.

Advantages include:

- Potential for shorter hospital stays and quicker rehabilitation[1,2]
- A small, 8-10 cm incision
- No eversion of the patella
- No reaming of the intramedullary canal

[1] Romagnoli, Sergio. The Adventures of Unicondylar Knee Replacement. Proceedings from Current Concepts in Joint Replacement. Spring 2001, Paper 33.

[2] Murry, David. Unicompartmental Knee Replacement: Now or Never? Orthopedics. September 2000, Vol. 23, page 980.

CLINICAL INDICATIONS/BONE CUTS

Appropriate indications are critical for a successful outcome in unicompartmental knee arthroplasty.

Recommended indications include:

- Osteoarthritis (medial or lateral)
- Unicompartmental post traumatic osteoarthritis
- Avascular Necrosis - medial femoral or tibial condyle
- Ahlback I-III

Possible contraindications include:

- Tricompartmental disease
- Multidirectional/ACL instability
- Severe tibial bone loss/deformity (over 15 degrees varus)
- Significant flexion contracture (over 12 degrees)
- Inflammatory arthritis
- Symptomatic patello-femoral disease or tracking abnormalities

The use of weight-bearing radiographs to determine the arthritic condition of the knee is recommended. These include the use of A/P, lateral and skyline views. Long-leg standing films can also be used for determination of the mechanical axis. Diagnostic arthroscopy of the opposite compartment and patello-femoral joint is optional as a pre-operative assessment.

Six Basic Bone Cuts

1 Sagittal tibial

2 Transverse tibial

3 Posterior femoral

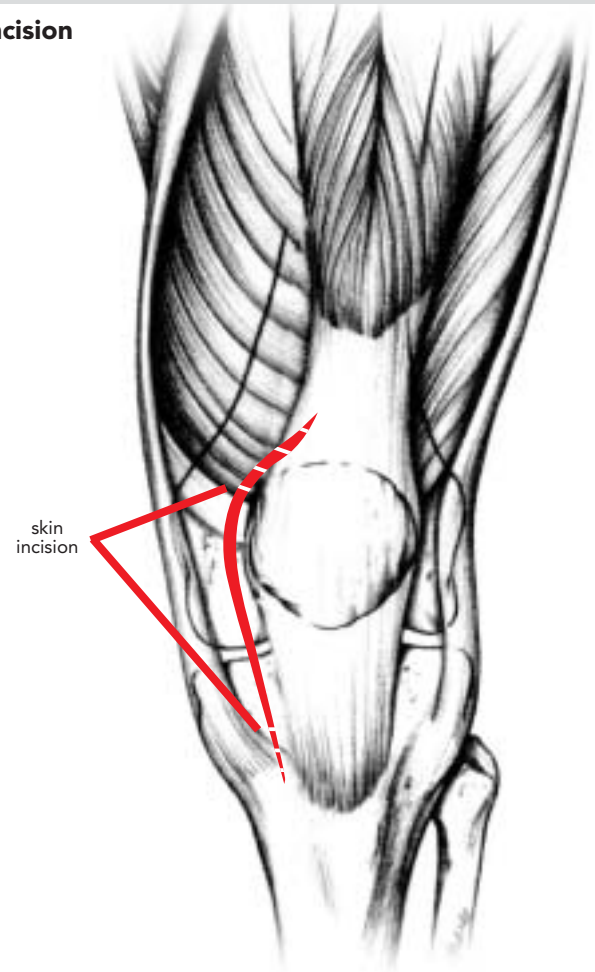
4 Femoral peg and fin

5 Distal femoral burring

6 Tibial keel

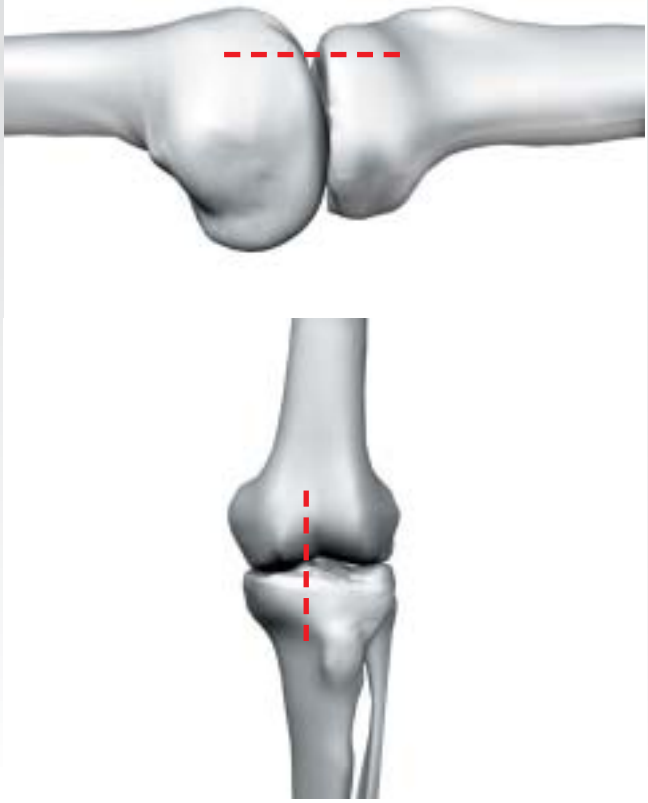
PREPARATION/INCISION

Incision



The skin incision should be approximately 1cm medial to the patella. Continue with an arched incision distally to the medial boundary of the patella tendon attachment. Following the skin incision, a medial capsular incision is made (as indicated by the red dotted lines). Expose the patella border and resect osteophytes. To improve visualization, resect the anterior menisci and the infrapatellar fat body until the intercondylar eminence is exposed.

Anatomical Landmarks



a) Before starting to prepare for the tibial resection extend the leg fully and mark on the femur with a pen the most anterior wear point between the femur and tibia. This point will be referred to as the tide mark, and represents the anterior boundary of the femoral component.
b) Also mark the antero medial (or antero lateral) contact area of the femur or tibia in order to assist in defining the position of the tibial sagittal cut.
c) Prior to the start of the procedure the center of the femoral head may be identified by placing an EKG load over the femoral pulse just below the inguinal ligament to estimate the center of rotation of the hip. This lead can then be palpated through the drapes and used to assess alignment.

1. Tibial Instrument Assembly

a) Assemble the Ankle Clamp, Tibial Alignment Rod, appropriate Tibial Alignment Guide, and Stylus as shown.

2. Tibial Alignment

a) With the knee flexed, place the Ankle Clamp around the distal tibia just above the malleoli. Place the stylus in the lowest point on the affected side of the tibial plateau.

b) The Tibial Alignment Rod should be in line with the anatomic axis in the frontal plane and parallel to the anatomic axis in the sagittal plane. A five degree posterior slope is built into the Tibial Alignment Guide.

c) An optional 1/8" (3.2mm) pin may be placed percutaneously into the anterior tibia through the Alignment Rod just below the locking knob to help stabilize the extramedullary guide while fine adjustments are made in its alignment.

8000-1040
E/M Tibial Ankle Clamp

8636-0040
Tibial E/M Alignment Rod

Tibial Alignment Guide
8636-0063L LM/RL
8636-0063R RM/LL

8636-0030
Tibial Stylus

1/8" Headless Pin
7650-1038 3.5" Long (4 pack)
7650-1039 2.5" Long (4 pack)

7650-1035
Headless Pin Driver

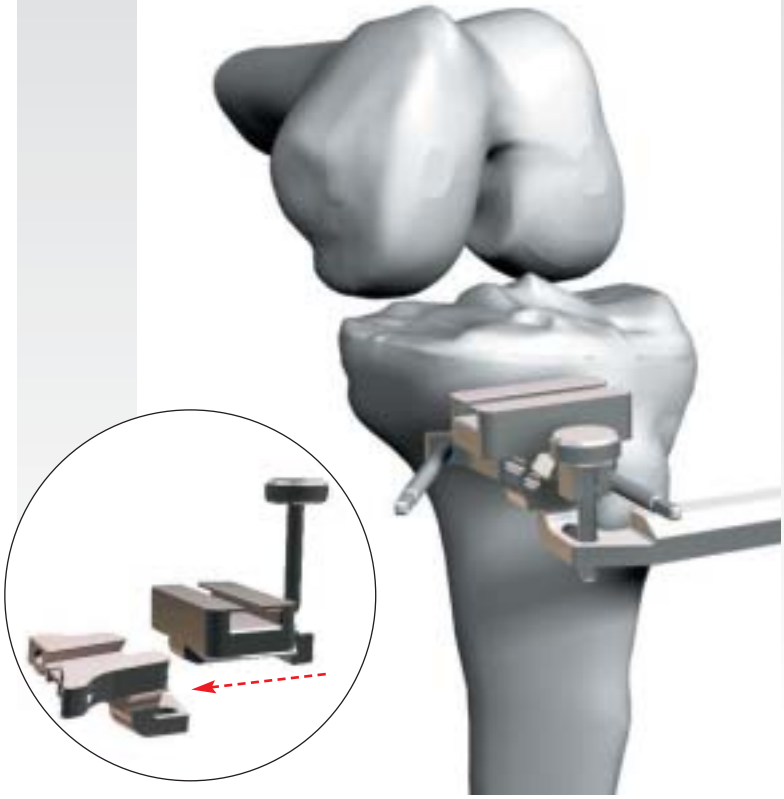
TIBIAL ALIGNMENT/TIBIAL RESECTION

3. Tibial Alignment Guide

a) Use 1/8" (3.2mm) pins to secure the Tibial Alignment Guide to the proximal tibia through the lower set of straight holes and through the angled hole furthest from the extensor mechanism.

b) Remove the Ankle Clamp, Tibial Alignment Rod and Tibial Stylus.

4. Tibial Resection Level



a) The goal of the tibial resection is to create a space which will accept the thinnest component necessary.

b) The Tibial Cutting Guides are designed to create a 2, 4, 6 or 8mm resection from the tip of the stylus. Slide the desired thickness Tibial Cutting Guide into the Tibial Alignment Guide. Secure the Cutting Guide by sliding the Retaining Pin through the triangular bracket on the anterior aspect of the Cutting Guide and into the slot in the Tibial Alignment Guide.

8636-0030
Tibial Stylus

Tibial Alignment Guide

8636-0063L	LM/RL
8636-0063R	RM/LL

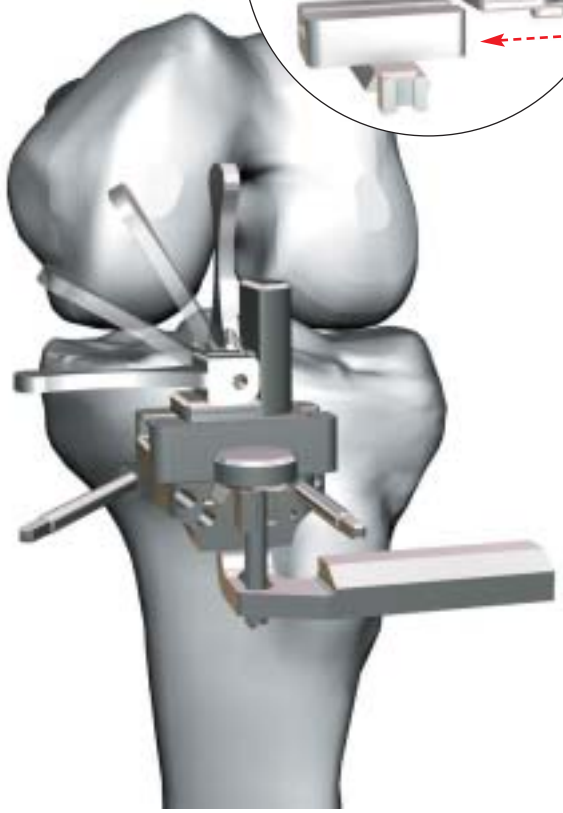
Tibial Cutting Guide

8636-0082	2mm
8636-0084	4mm
8636-0086	6mm
8636-0088	8mm

8636-0010
Tibial Cutting Guide Retaining Pin

TIBIAL SAGITTAL CUT/TRANSVERSE CUT

5. Tibial Sagittal Cut



a) Slide the Sagittal Cutting Guide into the Tibial Cutting Guide. Position the Guide to create a resection near the attachment of the anterior cruciate ligament. Lock the Guide into place and use a reciprocating saw against the rounded surface to make the sagittal wall cut to the level of the Tibial Cutting Guide.

Note: Be cautious when making the sagittal wall cut and use retractors to protect surrounding soft tissue and ligamentous structures.

6. Tibial Transverse Cut

a) Remove the Sagittal Cutting Guide.

b) Use an oscillating saw to make the transverse tibial resection while being careful not to cut beyond the sagittal wall. The reciprocating saw blade may be left in the cut to assist as a stop for the tranverse cut.

c) Remove the Tibial Cutting Guide, leaving the Tibial Alignment Guide in place.

8636-0096
Sagittal Cutting Guide

Tibial Cutting Guide

8636-0082	2mm
8636-0084	4mm
8636-0086	6mm
8636-0088	8mm

Tibial Alignment Guide

8636-0063L	LM/RL
8636-0063R	RM/LL

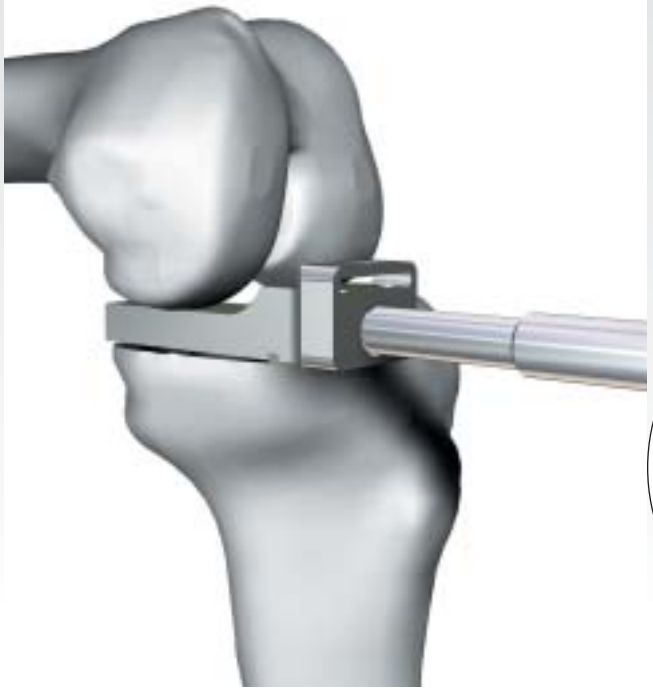
Recommended Equipment

277-96-300 (Stryker®)
Reciprocating Saw Blade
3.06" long x 0.025" thick

2108-103 (Stryker®)
Sagittal Saw Blade
3.53" long x 0.035" thick

JOINT SPACE ASSESSMENT/ FEMORAL SIZING

7. Joint Space Assessment



a) With the knee flexed 90° insert the appropriate Tensing Positioner into the joint space. Tensing Positioners are available in 4 sizes – 8, 9, 10 and 12mm, which correspond to tibial component thickness. Take the knee through a full range of motion with the Tensing Positioner in place to assess:

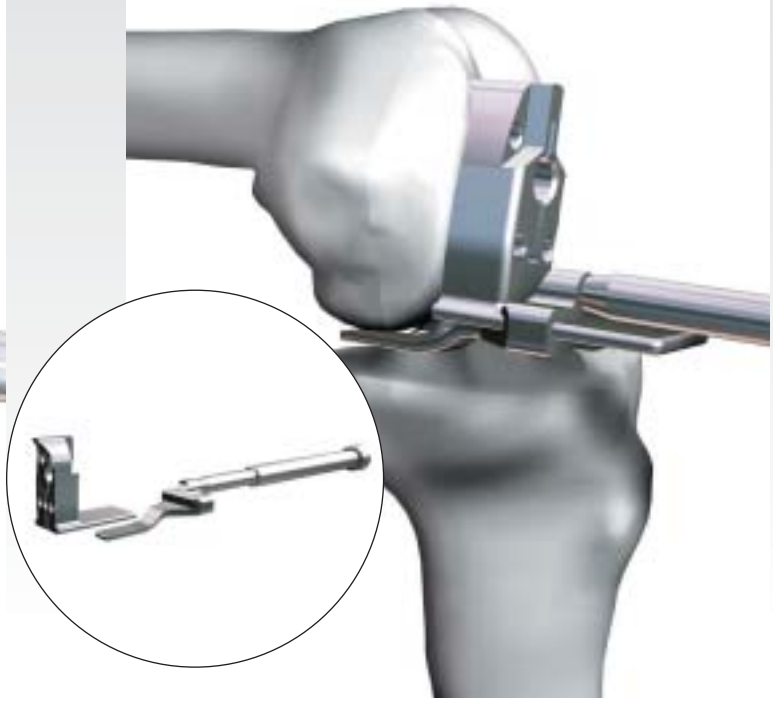
i) Flexion and extension gaps

ii) Estimated amount of correction

iii) Soft tissue balance.

b) Once the appropriate Tensing Positioner is identified, remove it from the joint space and set it aside.

8. Femoral Sizing



a) Based on the pre-operative assessment, select the appropriate Femoral Cutting Guide and assemble it to the Femoral Sizing Handle.

b) With the knee flexed to 90°, insert the assembly into the joint space. The tongue of the Sizing Handle should be against the posterior condyle and the contoured surface of the Femoral Cutting Guide should be against the distal femur. The proper size femoral component is determined when:

i) The Femoral Sizing Handle is parallel to the femoral shaft; and

ii) The anterior aspect of the Femoral Cutting Guide is at the tidemark; and

iii) Sufficient medio-lateral coverage is achieved.

Femoral Tensing Positioner

8636-0076	8mm
8636-0077	9mm
8636-0078	10mm
8636-0079	12mm

8636-0080

Tensing Positioner Handle

8636-0064

Femoral Sizing Handle

Femoral Cutting Guide

8636-0149L	XSmall	LM/RL
8636-0149R	XSmall	RM/LL
8636-0150L	Small	LM/RL
8636-0150R	Small	RM/LL
8636-0151L	Med	LM/RL
8636-0151R	Med	RM/LL
8636-0152L	Large	LM/RL
8636-0152R	Large	RM/LL
8636-0153L	XLge	LM/RL
8636-0153R	XLge	RM/LL

9. Femoral Alignment

a) Slide the selected Femoral Cutting Guide into the Tensing Positioner previously chosen. Assemble the Distal Femoral Alignment Guide to the Femoral Cutting Guide as shown. Place the assembly into the joint space and pass a long Alignment Rod through the Distal Femoral Alignment Guide.
The Femoral Cutting Guide is properly aligned when the following conditions are met:

i) The knee is flexed to 90° and the anterior aspect of the Femoral Cutting Guide is at the tidemark. This establishes proper flexion/extension position.

ii) The Alignment Rod references the femoral head, and is parallel to the femoral axis. This provides alignment with the mechanical axis and varus/valgus position.

10. Distal Alignment Guide

iii) Sufficient medio-lateral coverage is achieved. The Femoral Cutting Guide profile matches the corresponding implant.

b) By referencing the flat tibial cut while tensing the joint, the Tensing Positioner provides parallelism between the transverse tibial and posterior femoral resections.
The Positioner also sets the A-P position of the component relative to the posterior condyle to create a 6mm posterior femoral resection.

c) Once properly aligned, pin the Cutting Guide. Note that the two X-holes on the inferior aspect of the Cutting Guide angle downward.

8636-0042
Distal Femoral Alignment Guide

3180-2000
External Alignment Rod
(2 pack)

POSTERIOR FEMORAL RESECTION & PEG PREPARATION/FIN PREPARATION

11. Posterior Femoral Resection and Peg Preparation

a) Remove the Femoral Tensing Positioner and the Distal Femoral Alignment Guide. Advance the 1/8" Femoral Drill through the smaller drill hole on the fin until it stops.

b) Prepare for the femoral peg using the large Femoral Peg Drill with Stop.

c) Resect the posterior condyle by cutting along the bottom surface of the Femoral Cutting Guide, taking care to protect surrounding soft tissue. The resulting femoral resection is 6mm for all sizes.

Note: The femoral peg drill may be left in the cutting guide (as shown) for added stability while making the posterior resection.

12. Fin Preparation

a) Use an oscillating saw to prepare the fin slot so that it matches the geometry of the component. This is facilitated by inspecting the sagittal view of the femoral trial to estimate the proper depth of the fin slot preparation.

Note: The fin runs the entire length of the component and varies in depth.

8636-0026
1/8" Femoral Drill with Stop

8636-0024
Femoral Peg Drill with Stop

Recommended Equipment

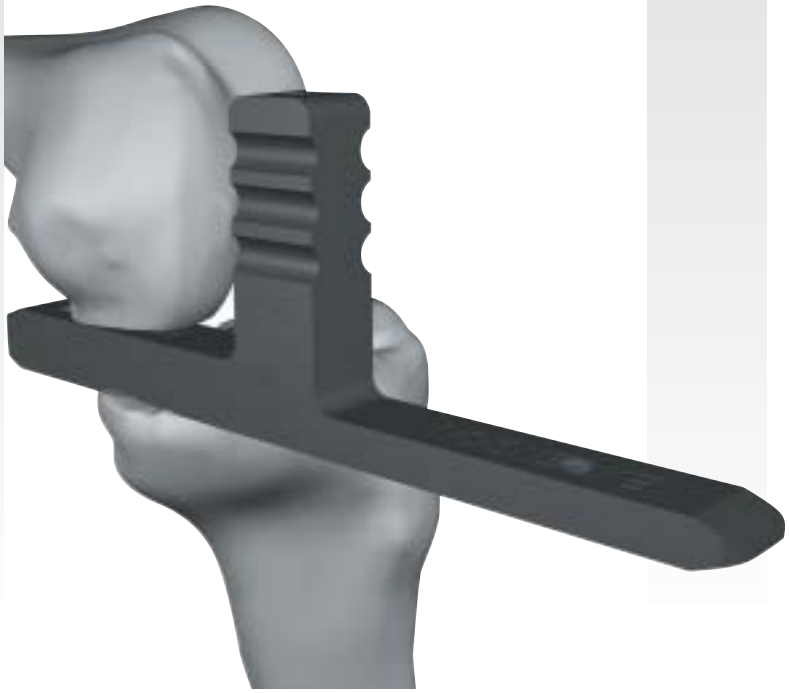
2108-103 (Stryker®)
Sagittal Saw Blade
3.53"long x 0.035"thick

EIUS™ Femoral Trials

6636-3-001	XSmall	LM/RL
6636-3-002	Small	LM/RL
6636-3-003	Medium	LM/RL
6636-3-004	Large	LM/RL
6636-3-005	XLarge	LM/RL
6636-3-011	XSmall	RM/LL
6636-3-012	Small	RM/LL
6636-3-013	Medium	RM/LL
6636-3-014	Large	RM/LL
6636-3-015	XLarge	RM/LL

FLEXION/ EXTENSION GAP CHECK/ BUR TEMPLATE PLACEMENT

13. Flexion/Extension Gap Check



a) An optional flexion/extension gap check may be performed using the Flexion/Extension Alignment Blocks which represent the tibial implant in extension and the sum of the tibial and femoral component thicknesses in flexion.

b) To assess the tension and alignment of the knee in extension, bring the leg into extension and insert the "extension" side of the Block into the joint space. Long alignment rods may be placed through the Block in both the superior and inferior directions to assess mechanical alignment. Tension and alignment of the knee in flexion may also be examined by taking the knee to 90° and inserting the "flexion" side of the block.

14. Bur Template Placement

a) Remove the Tibial Alignment Guide.

b) Select the proper Femoral Bur Template. Place the Template onto the distal femur, referencing the posterior resection, fin slot and 1/8" peg hole.

c) Using the Femoral Component Impactor, gently tap the template into place. The template is in the proper position when the posterior plate is flush against the posterior resection. Optional Pin holes on the Femoral Bur Template can be used for additional fixation.

3180-2000
External Alignment Rod
(2 pack)

Flex/Ext/Alignment Block

8636-0031	8mm
8636-0032	9mm
8636-0033	10mm
8636-0034	12mm

Femoral Bur Template

8636-0203L	XSmall	LM/RL
8636-0203R	XSmall	RM/LL
8636-0204L	Small	LM/RL
8636-0204R	Small	RM/LL
8636-0205L	Medium	LM/RL
8636-0205R	Medium	RM/LL
8636-0206L	Large	LM/RL
8636-0206R	Large	RM/LL
8636-0207L	XLarge	LM/RL
8636-0207R	XLarge	RM/LL

3140-0000
Eius™ Femoral Component Impactor

Recommended Equipment

5120-20-347
Stryker® TPS U-Drill fluted head drum bur Medium (Also fits Midas Rex and Zimmer UltraPower)

DISTAL FEMORAL BURRING/ FEMORAL TRIALING AND FINAL FIT

15. Distal Femoral Burring

a) Operate the EIUS™ system bur within the guide channel of the Femoral Bur Template. This prepares the distal femur to accept the profile of the femoral component. Proper depth is achieved when the bur stop is flush against the polished surface of the bur template.

b) Remove the femoral bur template from the femur. Complete the preparation by removing the middle strip of bone using a rongeur or bur.

16. Femoral Trialing and Final Fit

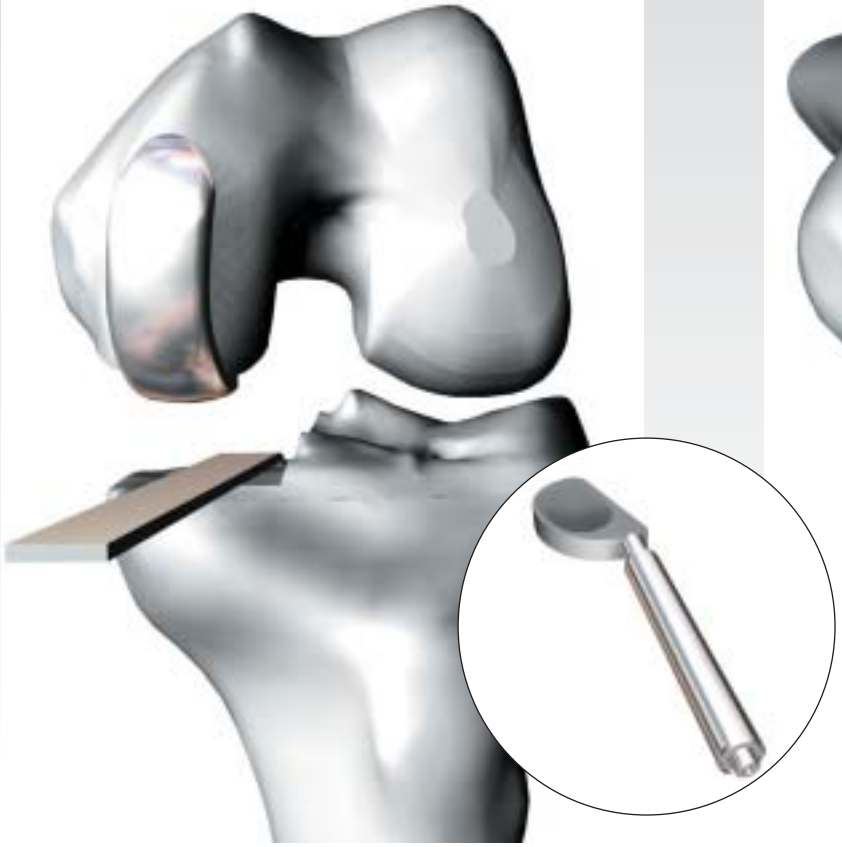
a) Place the trial component on the femur. Using the Femoral Component Impactor, tap the Femoral Trial until the trial sits fully into the prepared distal femur.

6636-3-XXX
Femoral Trial

3140-0000
Femoral Component Impactor

8636-0070
Femoral Trial Extractor Pliers

17. Tibial Sizing

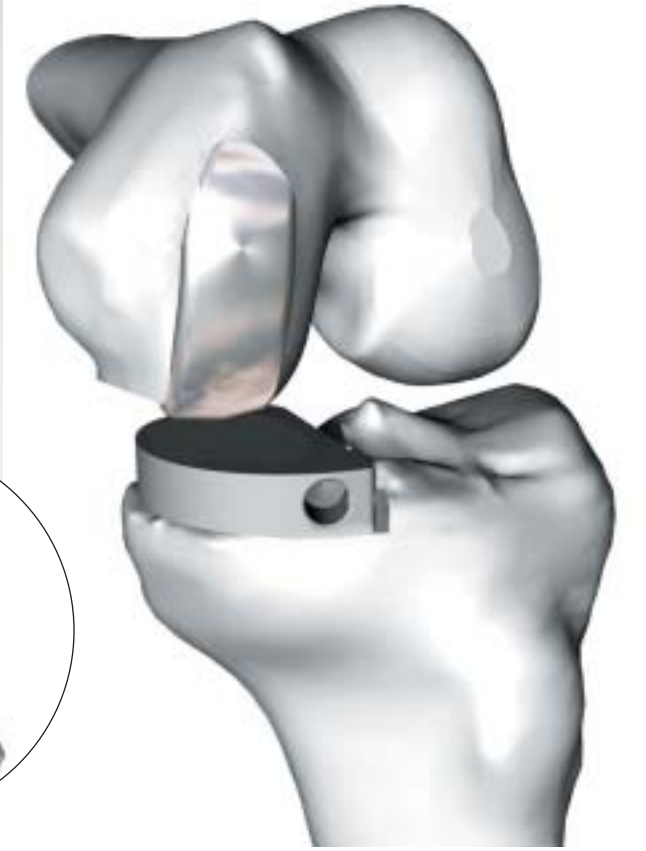


a) Place the Tibial Sizing Guide along the sagittal cut, hooking it over the posterior edge of the tibial resection, note the size indicated.

b) Connect the appropriate size keel-less Tibial Trial to the Quick Connect Handle. Place the Tibial Trial on the tibial resection and assess for correct fit. If the margins of the trial extend past the cortical rim, the sagittal cut can be advanced in order to eliminate the overhang.

Note: Size interchangeability between the femoral and tibial components is limited to one up/one down.

18. Trial Reduction



a) With the femoral trial and tibial trial in place, take the knee through full ROM. In this way, a check is made to ensure that the components are well centered and that there is no component displacement. The tibial component should be stable and should not lift off or move in the sagittal plane during ROM testing.

b) Care should be taken to ensure that there is slight under correction of the overall alignment. Ligamentous tension should be well balanced.

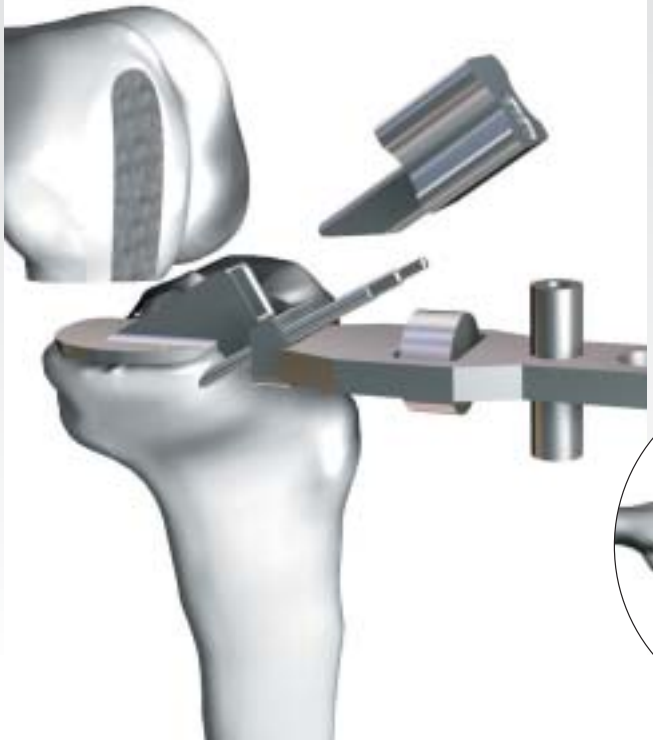
8000-0000
Quick Connect Handle 1/4”

8636-0055
Tibial Sizing Guide

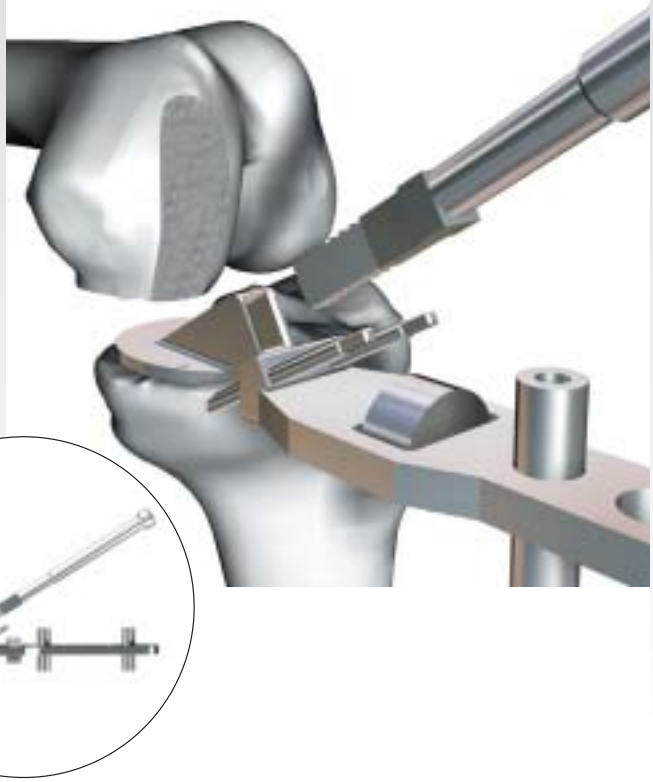
Tibial Trial

6636-3-308	XSmall	8mm	**6636-3-510**	Med	10mm
6636-3-309	XSmall	9mm	**6636-3-512**	Med	12mm
6636-3-310	XSmall	10mm	**6636-3-608**	Large	8mm
6636-3-312	XSmall	12mm	**6636-3-609**	Large	9mm
6636-3-408	Small	8mm	**6636-3-610**	Large	10mm
6636-3-409	Small	9mm	**6636-3-612**	Large	12mm
6636-3-410	Small	10mm	**6636-3-708**	XLarge	8mm
6636-3-412	Small	12mm	**6636-3-709**	XLarge	9mm
6636-3-508	Med	8mm	**6636-3-710**	XLarge	10mm
6636-3-509	Med	9mm	**6636-3-712**	XLarge	12mm

19. Tibial Keel Preparation



20. Tibial Keel Preparation (continued)



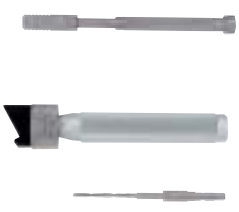
a) Attach the Alignment Handle to the appropriate Tibial Punch Guide and position on the prepared tibia.

b) Use the Tibial Impactor on the top rounded edge of the Punch Guide to advance the spikes into the tibia and seat the Guide flush on the tibia. If additional fixation is required, 1/8" headless pins may be drilled into the tibia through the angled anterior holes just above the Alignment Handle.

Note: A long Alignment Rod can be passed through the Alignment Handle distally as an additional tibial placement check.

c) Place the appropriate Tibial Drill Bushing into the slot of the Punch Guide. Pass the Tibial Keel Drill with Stop through each hole of the Drill Bushing.

d) Remove the Drill Bushing and impact the appropriate Tibial Punch into the same slot in the Punch Guide until it hits the stop.



Tibial Punch

8636-0060	XS/S
8636-0061	M/L
8636-0062	XL

8636-0081

Eius™ Tibial Impactor

8636-0025

Tibial Keel Drill with Stop

Tibial Punch Guide

8636-0015L	XS	LM/RL
8636-0015R	XS	RM/LL
8636-0016L	S	LM/RL
8636-0016R	S	RM/LL
8636-0017L	M	LM/RL
8636-0017R	M	RM/LL
8636-0018L	L	LM/RL
8636-0018R	L	RM/LL
8636-0019L	XL	LM/RL
8636-0019R	XL	RM/LL

Tibial Drill Bushing

8636-0020	XS/S
8636-0021	M/L
8636-0022	XL

3180-1000

External Alignment Handle

21. Final Implantation

a) Placement of the final implants is facilitated by cementing the tibial component first.

b) When cementing each component, apply cement to the keel and peg preparations as well as the components. Impactors are provided for both the tibia and femur.

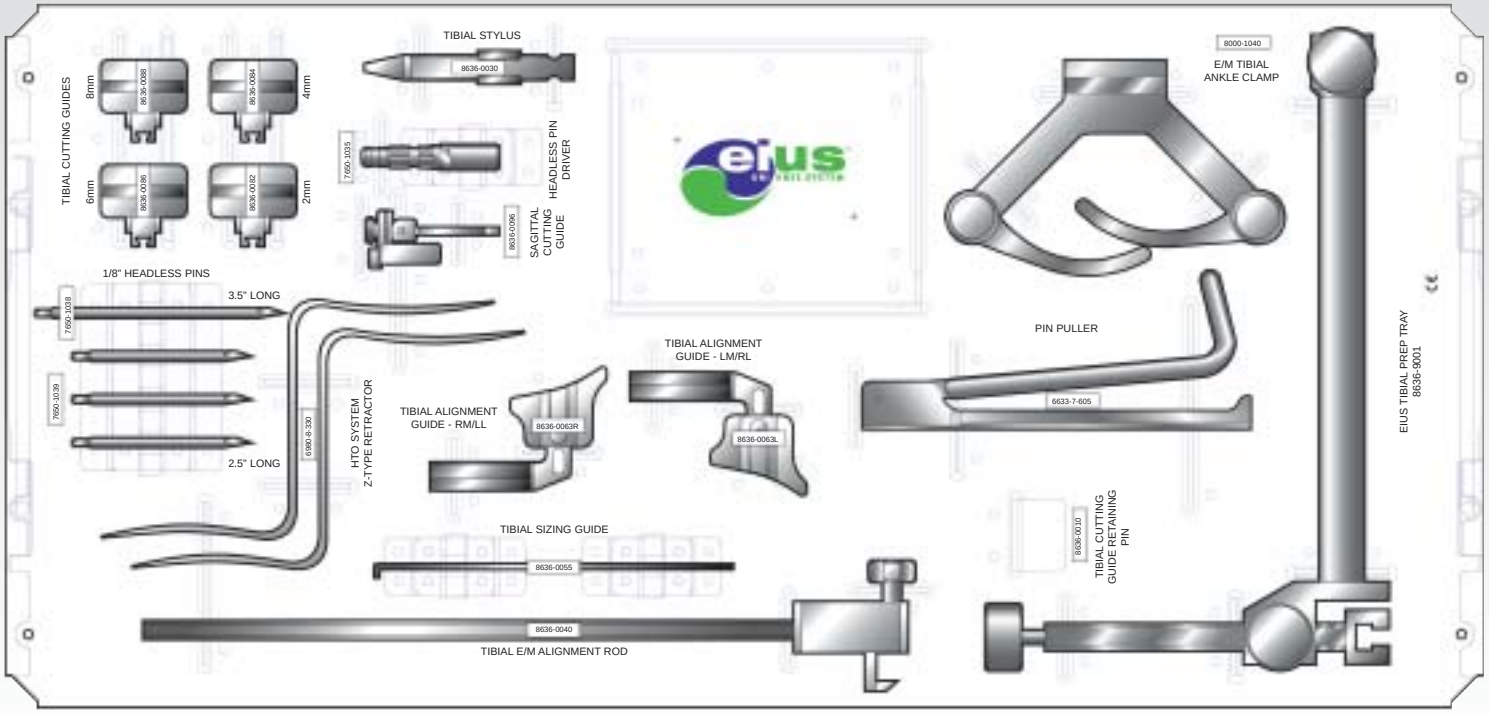
c) A curette or bent nerve hook may be used to clear out any excess cement paying particular attention to the posterior region of the implant and margins of the tibial eminence.

Note: If sclerotic bone is present, a drill or bur may be used to perforate the bone to improve cement penetration.

Note: Placing a sterile gauze or similar cloth in the posterior joint capsule prior to implantation and slowly removing the cloth after implantation may drag excess cement out of the joint. A dental mirror may also be useful in cement removal.

PREPARATION AND TRIAL TRAYS

TIBIAL PREPARATION TRAY



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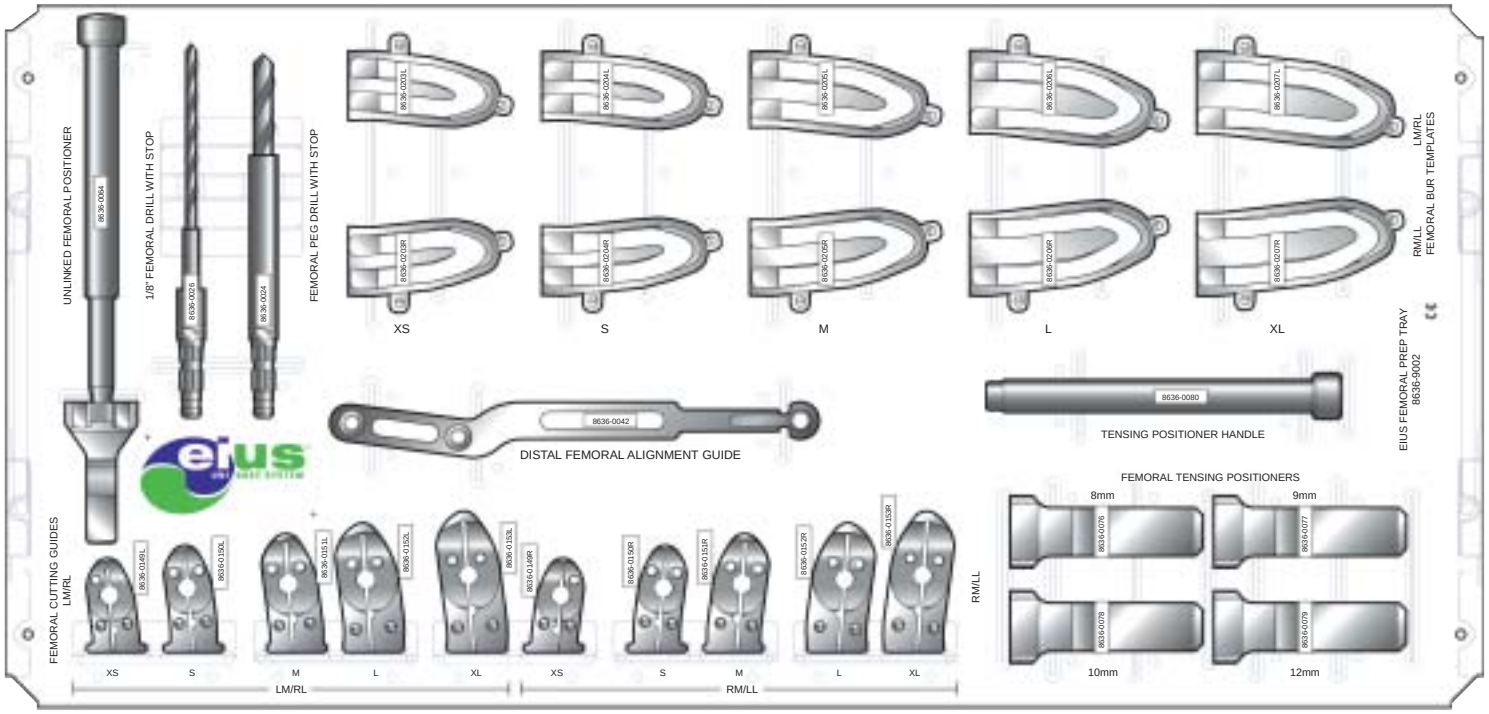
FEMORAL PREPARATION TRAY



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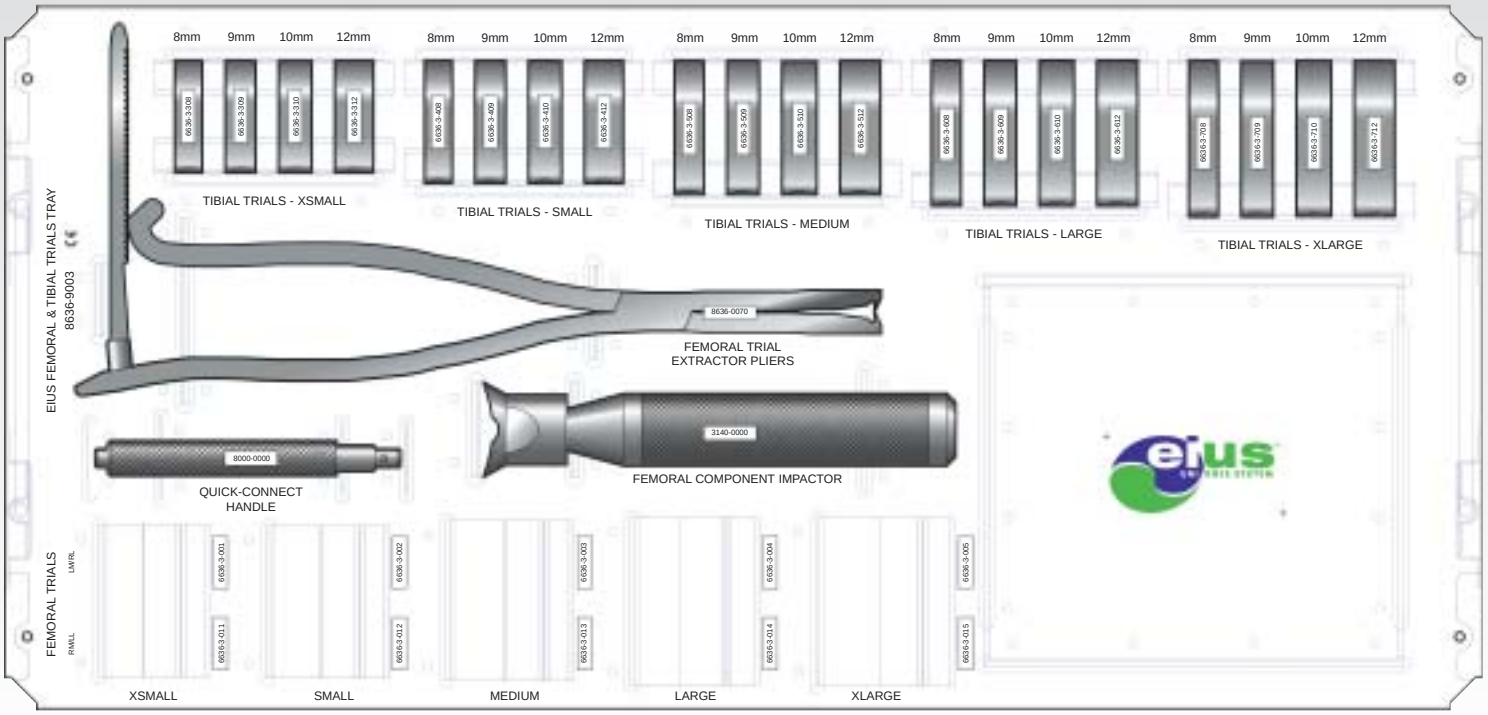
PREPARATION AND TRIAL TRAYS

FEMORAL AND TIBIAL TRIAL TRAY



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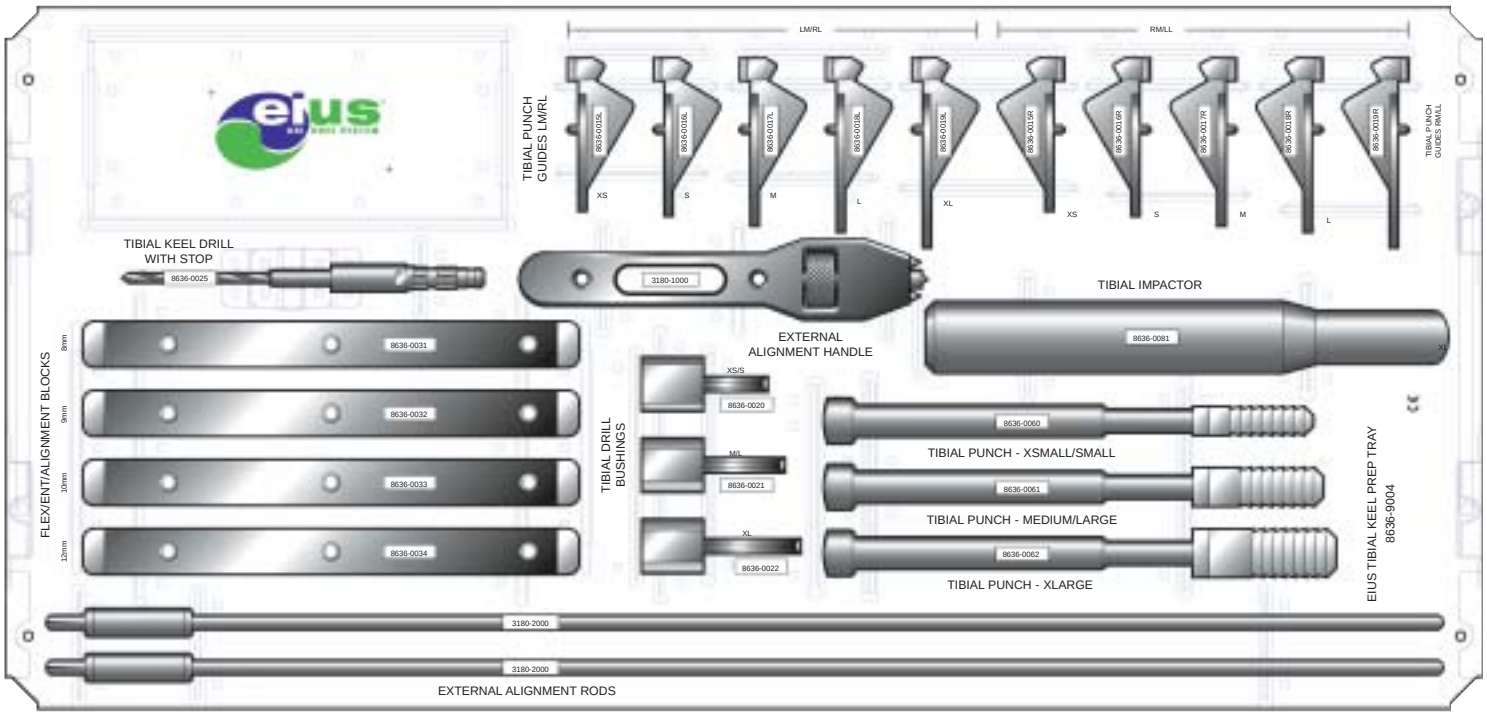
TIBIAL KEEL PREPARATION TRAY



8636-9004

EIUS Unicompartmental Knee System

IMPLANTS	FEMORAL COMPONENT	TRIALS
LEFT MEDIAL/RIGHT LATERAL	**SIZE**	**LEFT MEDIAL/RIGHT LATERAL**
6636-2-001	Extra Small	6636-3-001
6636-2-002	Small	6636-3-002
6636-2-003	Medium	6636-3-003
6636-2-004	Large	6636-3-004
6636-2-005	Extra Large	6636-3-005
RIGHT MEDIAL/LEFT LATERAL	**SIZE**	**RIGHT MEDIAL/LEFT LATERAL**
6636-2-011	Extra Small	6636-3-011
6636-2-012	Small	6636-3-012
6636-2-013	Medium	6636-3-013
6636-2-014	Large	6636-3-014
6636-2-015	Extra Large	6636-3-015

EIUS Unicompartmental Knee System

IMPLANTS	TIBIAL COMPONENT		TRIALS
LEFT MEDIAL/RIGHT LATERAL	**SIZE**		**LEFT MEDIAL/RIGHT LATERAL**
6636-2-308	Extra Small	8mm	6636-3-308
6636-2-309	Extra Small	9mm	6636-3-309
6636-2-310	Extra Small	10mm	6636-3-310
6636-2-312	Extra Small	12mm	6636-3-312
6636-2-408	Small	8mm	6636-3-408
6636-2-409	Small	9mm	6636-3-409
6636-2-410	Small	10mm	6636-3-410
6636-2-412	Small	12mm	6636-3-412
6636-2-508	Medium	8mm	6636-3-508
6636-2-509	Medium	9mm	6636-3-509
6636-2-510	Medium	10mm	6636-3-510
6636-2-512	Medium	12mm	6636-3-512
6636-2-608	Large	8mm	6636-3-608
6636-2-609	Large	9mm	6636-3-609
6636-2-610	Large	10mm	6636-3-610
6636-2-612	Large	12mm	6636-3-612
6636-2-708	Extra Large	8mm	6636-3-708
6636-2-709	Extra Large	9mm	6636-3-709
6636-2-710	Extra Large	10mm	6636-3-710
6636-2-712	Extra Large	12mm	6636-3-712
RIGHT MEDIAL/LEFT LATERAL	**SIZE**		**RIGHT MEDIAL/LEFT LATERAL**
6636-2-318	Extra Small	8mm	6636-3-308
6636-2-319	Extra Small	9mm	6636-3-309
6636-2-320	Extra Small	10mm	6636-3-310
6636-2-322	Extra Small	12mm	6636-3-312
6636-2-418	Small	8mm	6636-3-408
6636-2-419	Small	9mm	6636-3-409
6636-2-420	Small	10mm	6636-3-410
6636-2-422	Small	12mm	6636-3-412
6636-2-518	Medium	8mm	6636-3-508
6636-2-519	Medium	9mm	6636-3-509
6636-2-520	Medium	10mm	6636-3-510
6636-2-522	Medium	12mm	6636-3-512
6636-2-618	Large	8mm	6636-3-608
6636-2-619	Large	9mm	6636-3-609
6636-2-620	Large	10mm	6636-3-610
6636-2-622	Large	12mm	6636-3-612
6636-2-718	Extra Large	8mm	6636-3-708
6636-2-719	Extra Large	9mm	6636-3-709
6636-2-720	Extra Large	10mm	6636-3-710
6636-2-722	Extra Large	12mm	6636-3-712

NOTES

NOTES

For cemented use only in the U.S.

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