

UniCAP®

The Unicompartmental Knee Surface Arthroplasty (UniCAP®) System restores the unique articular surface geometry of the compartment by using an intraoperative 3 dimensional mapping system and contoured articular resurfacing implants.



Chapter One

UniCAP (Classic & Small)



Chapter Two

Tibial Component

Chapter One (Pages 3-18)

UniCAP (Classic & Small)



"We found that a **TKA does not restore normal knee function**, independent of the effects of age and gender. Although this procedure restores the patient's ability to do many routine activities, a substantial deficit remains in meeting the challenges of many functional tasks that are important to the patient, especially tasks involving kneeling or squatting."

Philip C. Noble, PhD; Michael J. Gordon, MD; Jennifer M. Weiss, MD; Robert N. Reddix, MD; Michael A. Conditt, PhD; Kenneth B. Mathis, MD; Does Total Knee Replacement Restore Normal Knee Function? Clinical Orthopaedics and Related Research, 2005

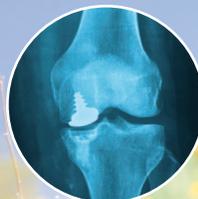
Chapter Two (Pages 19-26)

Tibial Component



"The key benefits of the UniCAP® Tibial implantation include: (1) Meniscal preservation maintains patients' natural knee biomechanics, (2) **Tibial inlay resurfacing preserves plateau integrity, meniscus and tibial bone stock**, and (3) Inlay components allow load sharing and transmission to surrounding bone and tissue creating a favorable environment for transarticular force dissipation."

UniCAP™ Meniscal Sparing Unicondylar Knee System Clinical Monograph, PN 0020-0404 Rev A, Arthrosurface, 2009



UniCAP®

Classic & Small



KEY FEATURES:

Inlay components match patient anatomy

Preserves meniscus & articular cartilage

Bone sparing for future UKA or TKA

Description

The **Unicompartmental Knee Resurfacing Prosthesis (UniCAP®)** incorporates a low-profile femoral articular component that mates to a taper post via a taper interlock. The femoral component articulates against an all-polyethylene tibial component. The UniCAP® implants allow resurfacing of the compartment utilizing the undisturbed compartmental structures and soft-tissues.

Materials

Articular Component:	Cobalt-Chromium Alloy (Co-Cr-Mo)
Surface Coating:	Titanium (CPTi)
Taper Post:	Titanium Alloy (Ti-6Al-4V)
Tibial Component:	Ultra-High-Molecular Weight Polyethylene (UHMWPE)

Indications

Partial replacement of the articulating surfaces of the knee when only one side of the joint is affected due to the compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty. This device is intended to be used with bone cement.

Contraindications

Absolute contraindications include:

- 1) Infection, sepsis, or osteomyelitis
- 2) Patients that have a known sensitivity to materials typically used in orthopedic prosthetic devices or bone cements

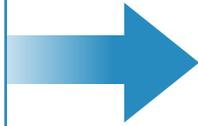
Relative contraindications include:

- 1) Uncooperative patient or patient incapable of following pre-operative and post-operative instructions
- 2) Osteoporosis
- 3) Metabolic disorders which may impair the formation or healing of bone
- 4) Infections at remote sites which may spread to the implant site
- 5) Rapid joint destruction or bone resorption visible on roentgenogram
- 6) Chronic instability or deficient soft tissues and other support structures
- 7) Vascular or muscular insufficiency
- 8) Inadequate skin, musculotendinus or neurovascular system status

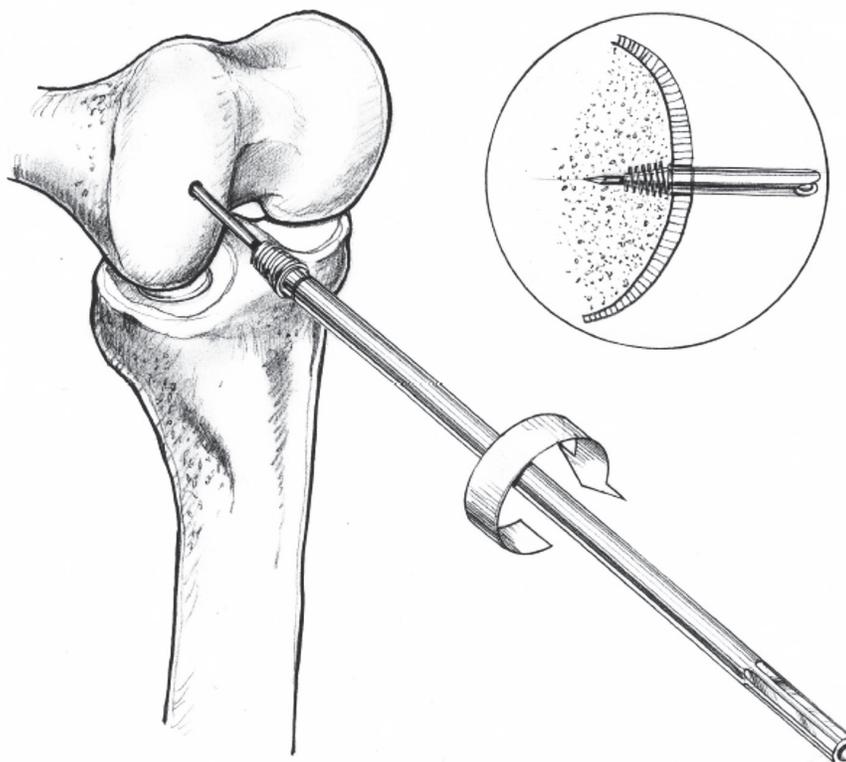
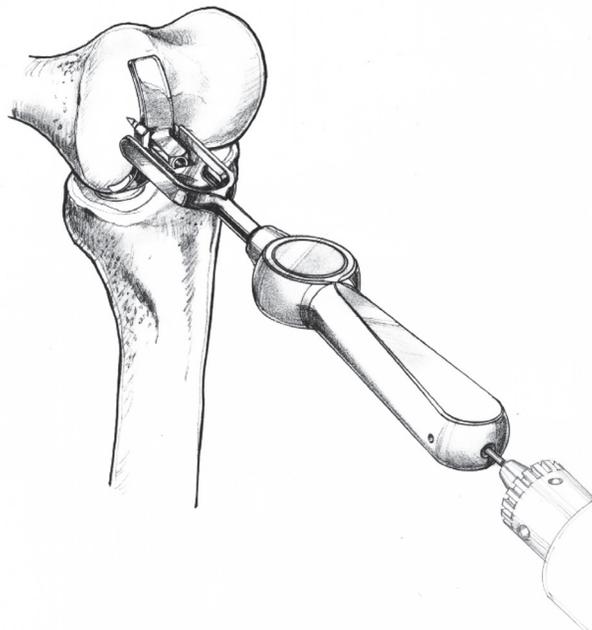


Surgical Technique (UniCAP Classic Femoral Component)

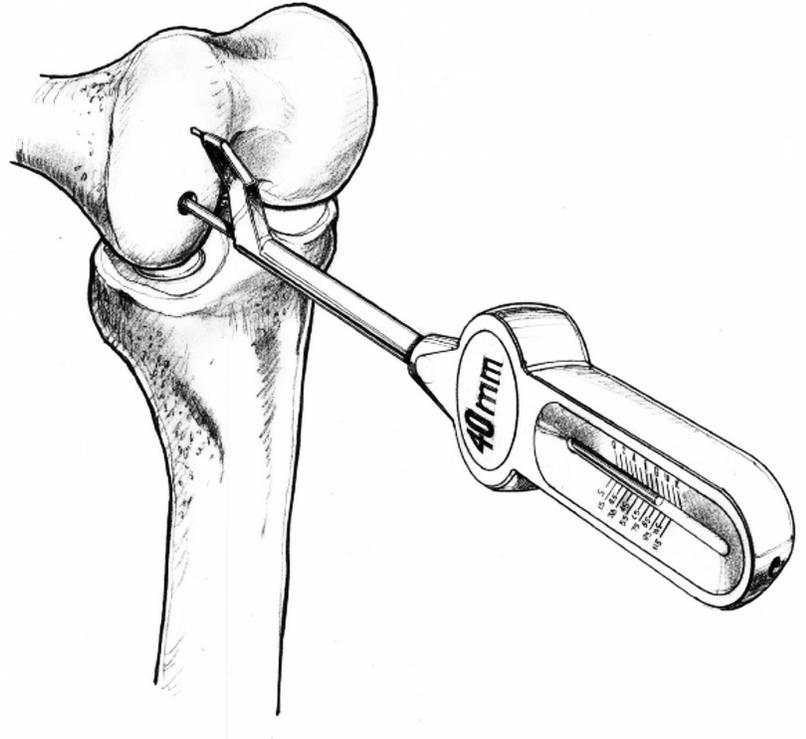
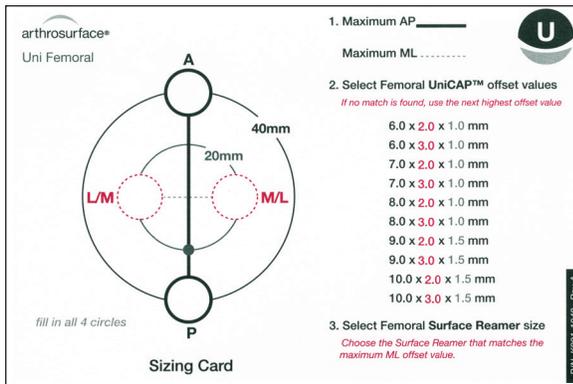
NOTE: Before implanting the **Femoral Component**, complete the implantation of **Tibial Component** (p. 21)



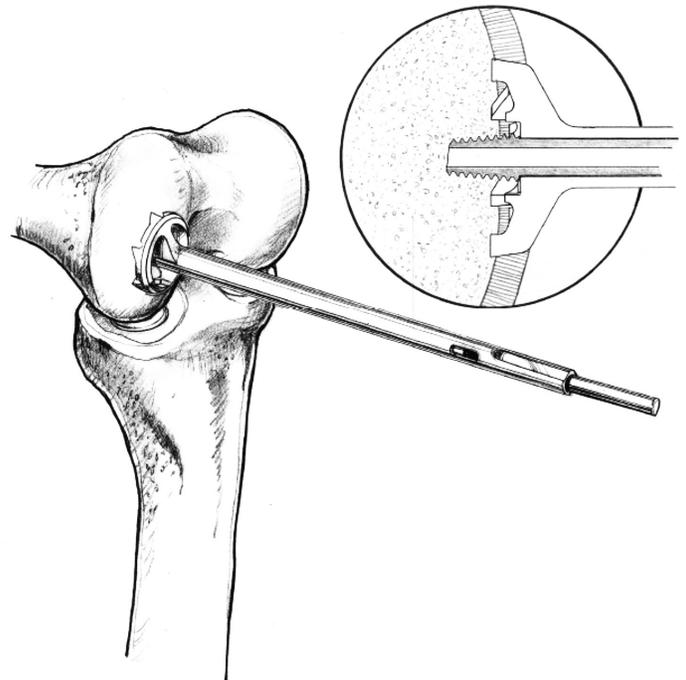
1. With the knee at 60 degrees of flexion and working through an anteromedial incision, locate the **Femoral Drill Guide** on the distal femur to develop a working axis perpendicular to the articular surface.
2. Drill the **2.0mm Threaded Pin** through the central axis of the **Femoral Drill Guide** into the bone to the laser mark line on the **2.0mm Threaded Pin**. Remove the **Femoral Drill Guide**.
3. Drive the **Femoral Centering Shaft** over the **Threaded Pin** so the laser mark line is at the height of the original articular surface. Leave the etch mark proud initially and then advance by hand with the **Driver**.



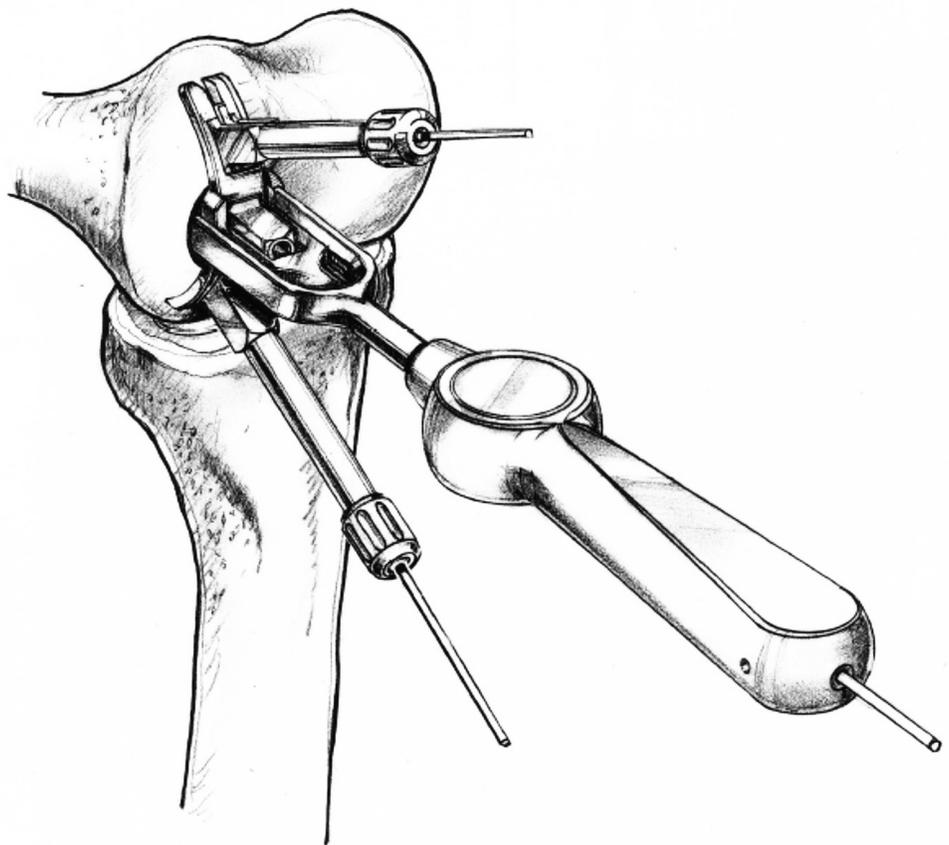
- Place the **40mm Contact Probe** over the **Femoral Centering Shaft**. Read the **Contact Probe** to take the superior and inferior offsets and mark them onto the appropriate **Sizing Card**. Repeat using the **20mm Contact Probe** to obtain the offsets medially and laterally and mark the **Sizing Card**.



- Select the appropriately sized **Central Femoral Reamer** based on the average medial to lateral mapped offset. This will either be a 2mm or 3mm reamer. Prepare central femoral cut by advancing the **Central Femoral Reamer** over the **Centering Shaft** until it contacts the stop. Remove the **Centering Shaft**.

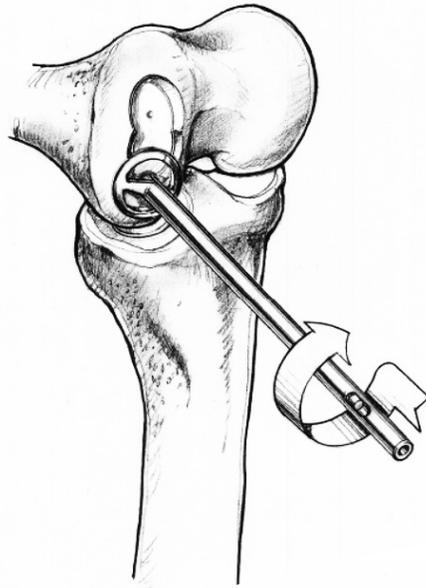


6. Select the appropriately sized **Guide Block** based on the average anterior/posterior offset from the **Sizing Card** (6mm to 10mm by 1mm increments) and attach it to the **Femoral Drill Guide**. Realign the **Femoral Drill Guide** on the distal femur. Maintain four points of contact to ensure accurate placement of the **Guide Pins**. Insert the **Pin Sleeves** into the slots located superior and inferior on the **Femoral Drill Guide**. Beginning with the superior **Pin Sleeve**, drill the **Short Threaded Pins** through the **Pin Sleeves** into the bone to the laser mark line on the **Short Threaded Pin**. Remove the **Pin Sleeves** and remove the **Femoral Drill Guide**.

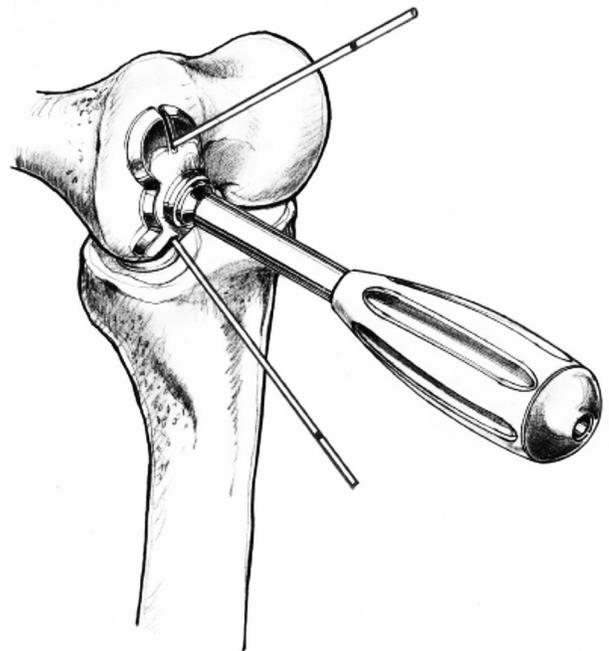


7. Confirm proper pin alignment before continuing. The short pins should intersect the central reamed circle or within 1mm of its outside margins. From a sagittal view, the pins should be equally spaced. If the pins are not in the indicated position, reattach the **Femoral Guide** and reinsert the short pins.

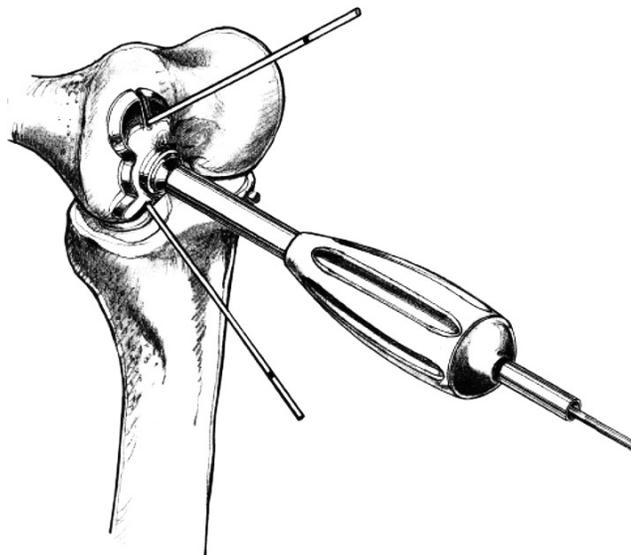
8. Select the appropriate **Outer Femoral Reamer** based on the medial/lateral mapped offsets (same size as the **Central Reamer** - 2 or 3mm). Beginning with the inferior **Threaded Pin**, advance the **Outer Femoral Reamer** until it contacts the stop in the slotted window.



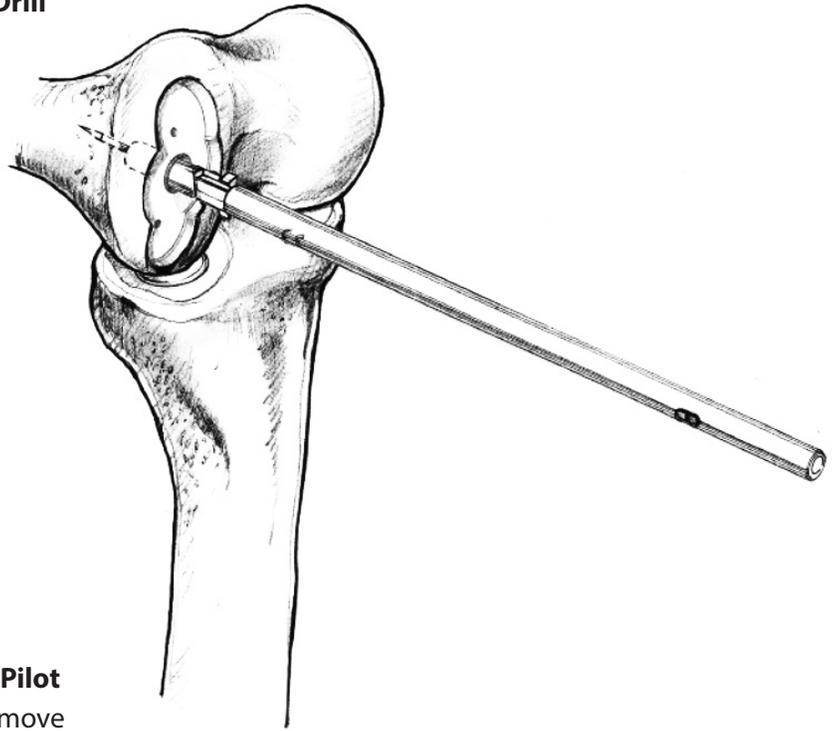
9. Select the appropriately sized **Femoral Sizing Trial**, attach to the **Sizing Trial Handle** and place into position. Leave the superior and inferior **Short Threaded Pins** in place. Confirm the fit at the anterior/posterior margins and the medial/lateral margins of the **Femoral Sizing Trial**.



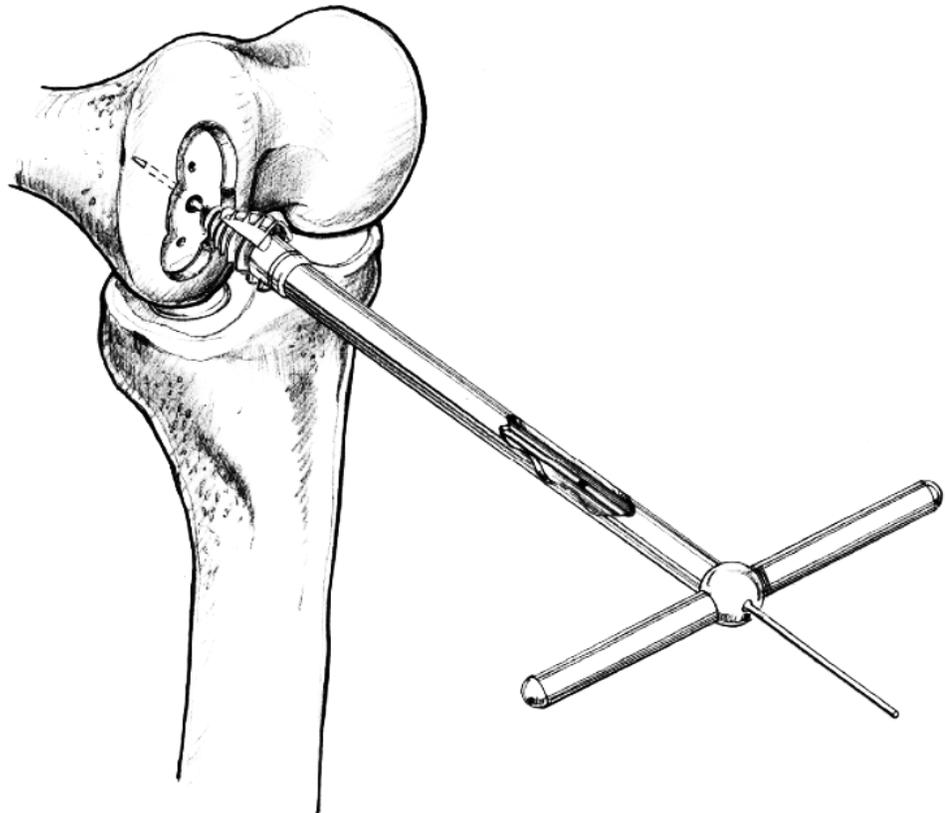
10. Before preparing the pilot hole for the **Taper Post**, be sure the **Femoral Trial** is seated so the edges are flush or slightly recessed to the cartilage. Advance the **Femoral Pilot Drill** through the **Sizing Trial Handle** until the laser mark is flush with the end of the handle and leave it in position. Replace the **2.0mm Threaded Pin**.



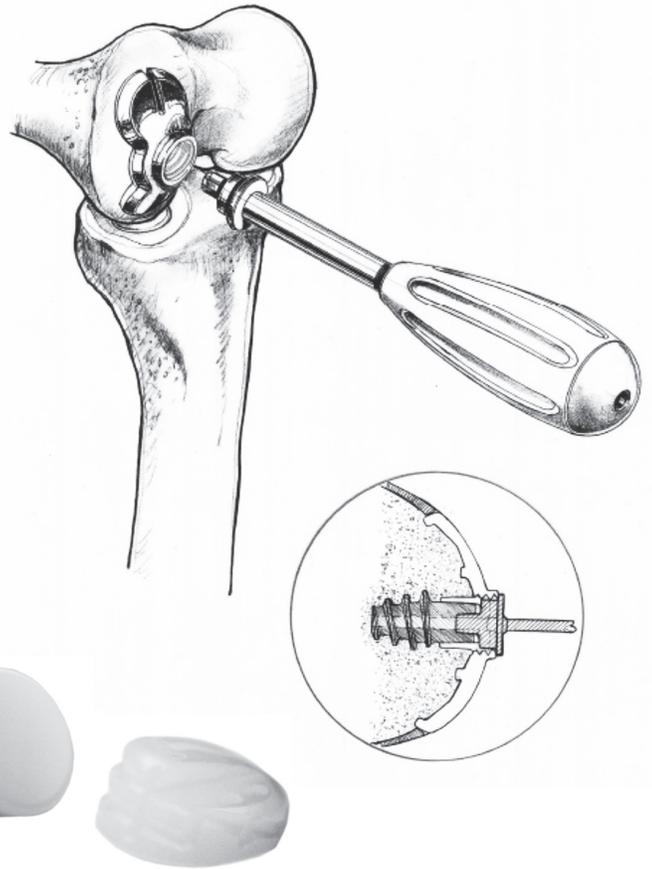
11. Remove the **Sizing Trial Handle**. Advance the **Femoral Step Drill** over the **Femoral Pilot Drill** until it contacts the stop on the **Femoral Pilot Drill** in the slotted window.



12. Advance the **Tap** until the back of the **Femoral Pilot Drill** is flush with the end of the **Tap** handle. Remove the **Tap** and **Femoral Pilot Drill**.

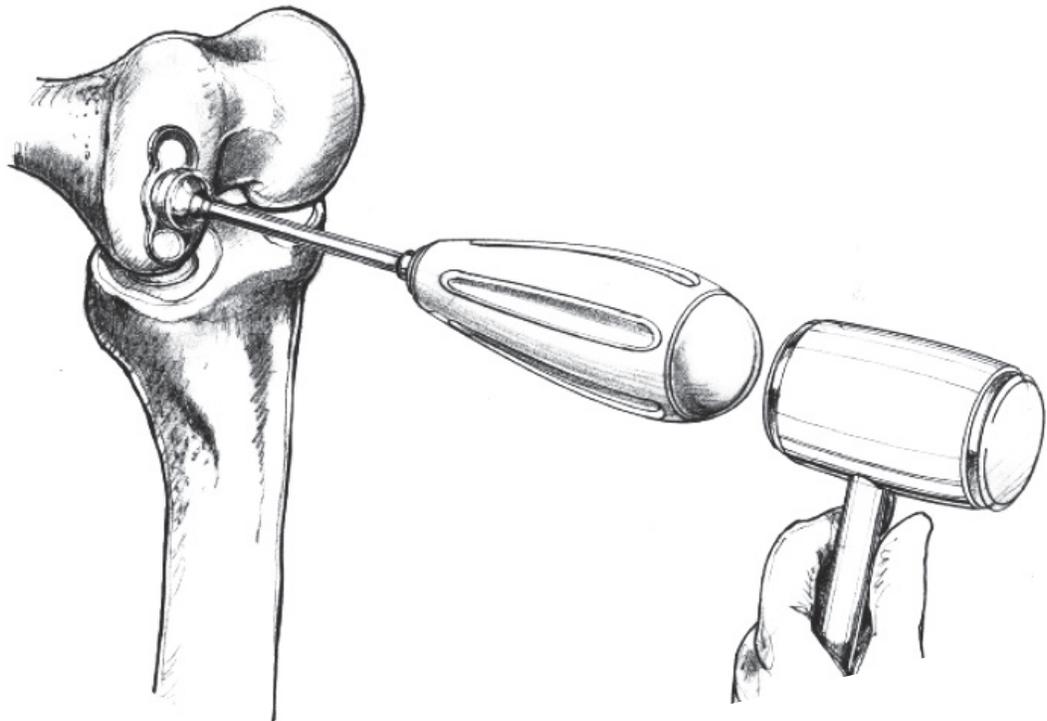


13. Insert the **Taper Post** into the **Sizing Trial Handle**. Attach the **Handle** and **Taper Post** assembly onto the **Femoral Sizing Trial**. Insert the **Hex Driver** into the **Handle** and advance the **Taper Post** into the bone. Stop advancing the **Hex Driver** when the raised stop on the **Driver Shaft** contacts the top of the **Sizing Trial Handle** and the **Femoral Sizing Trial** is flush with the surrounding cartilage. Remove the **Femoral Sizing Trial**.



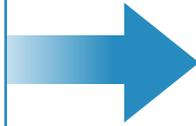
NOTE: Complete implantation of **Tibial Component** (p. 24)

14. Apply pea-sized balls of bone cement to underside of the **Femoral Component**. Position the **Femoral Component** and use a slight tap on the **Impactor** to mate **Femoral Component** to the **Taper Post**.

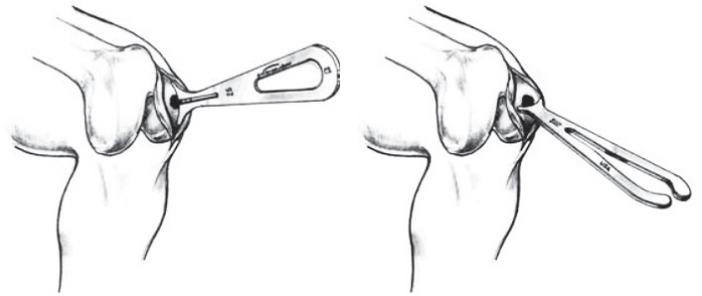


Surgical Technique (UniCAP Small Femoral Component)

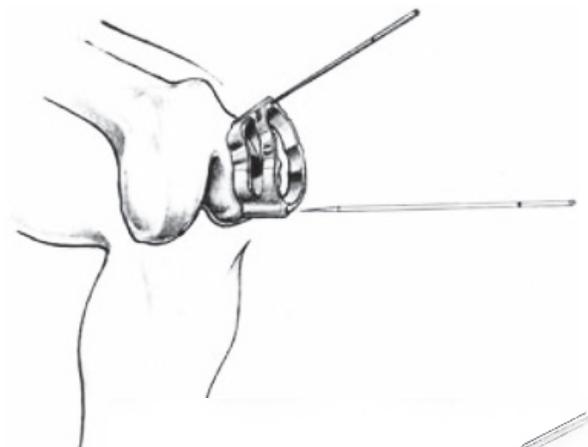
NOTE: Before implanting the **Femoral Component**, complete the implantation of **Tibial Component** (p. 21)



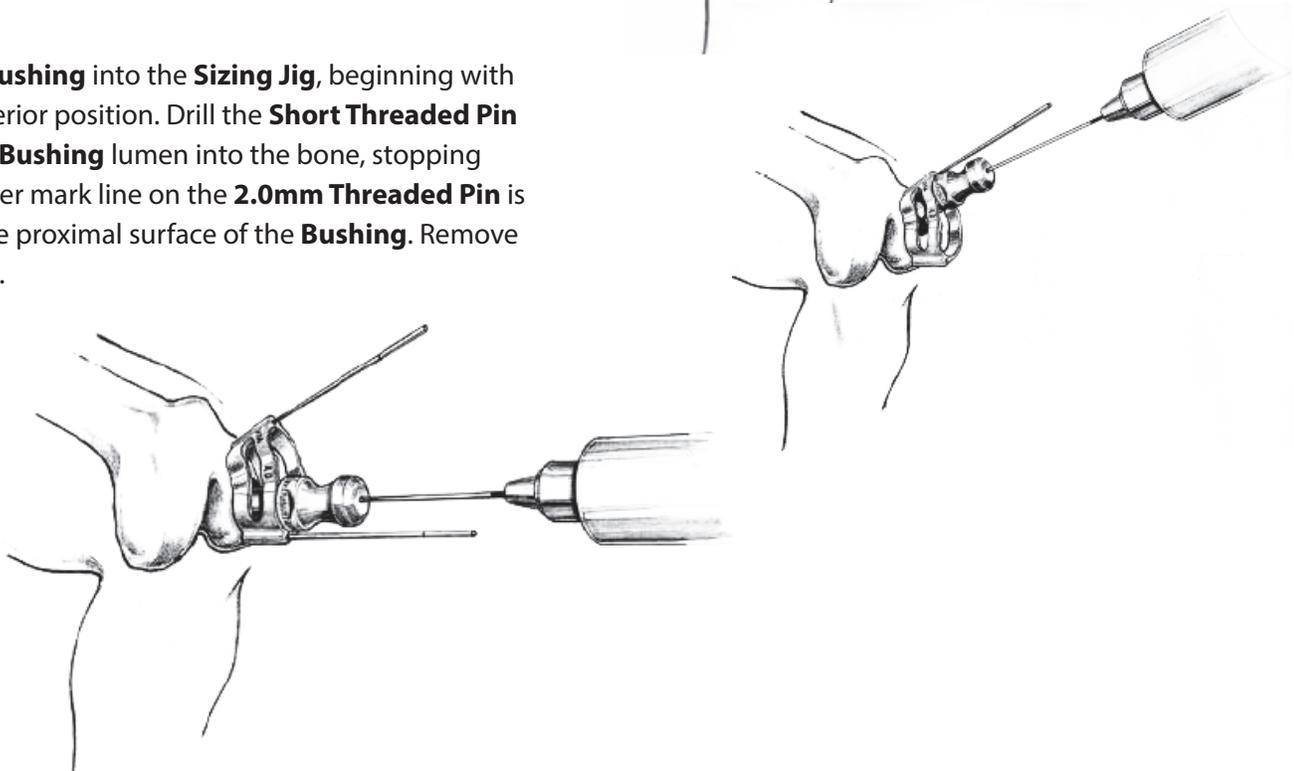
1. With the knee at 90 degrees of flexion and working through an anteromedial incision, determine the anterior/posterior and medial/lateral curvatures of the condyle using the **Templates**.



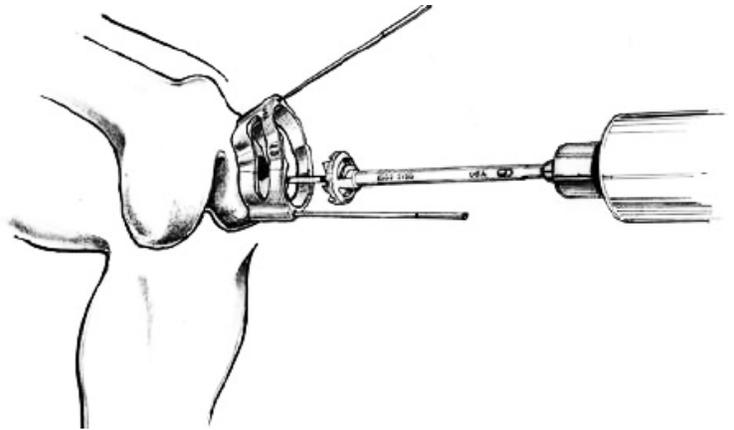
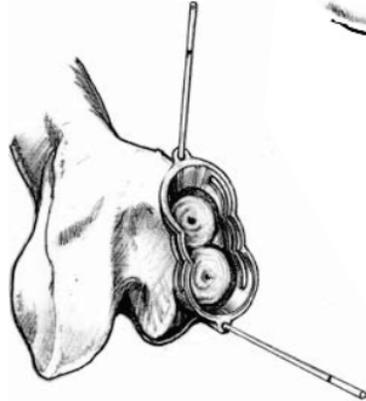
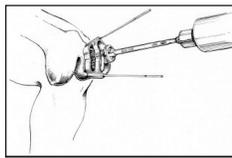
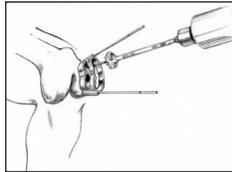
2. Select the **Sizing Jig** based on the determined anterior/posterior curvature. Position and secure the **Sizing Jig** on the condyle using the **2.0mm Short Pins**.



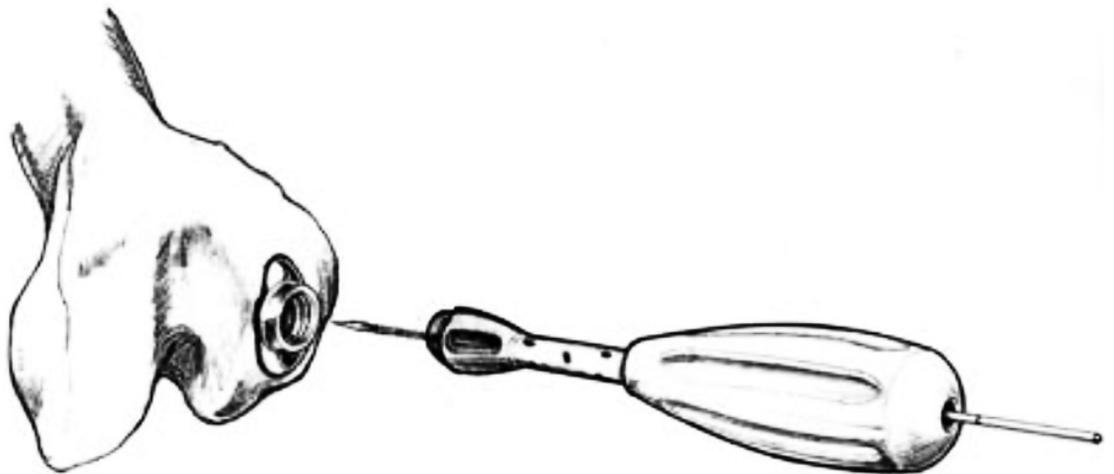
3. Center the **Bushing** into the **Sizing Jig**, beginning with the most inferior position. Drill the **Short Threaded Pin** through the **Bushing** lumen into the bone, stopping when the laser mark line on the **2.0mm Threaded Pin** is level with the proximal surface of the **Bushing**. Remove the **Bushing**.



4. Advance the **17.5mm Reamer** over the **Threaded Pin** until it contacts the stop in the slotted proximal window of the **Reamer**. Repeat steps 3 and 4 for the remaining two positions in the **Sizing Jig**.



5. Select the appropriately sized **Femoral Trial**, attach to the **Sizing Trial Handle** and place into position. Confirm fit at anterior/posterior margins and medial/lateral margins of the **Femoral Trial**. The **Femoral Trial** should be seated so the edges are slightly recessed (approximately 1mm) relative to the surrounding cartilage.

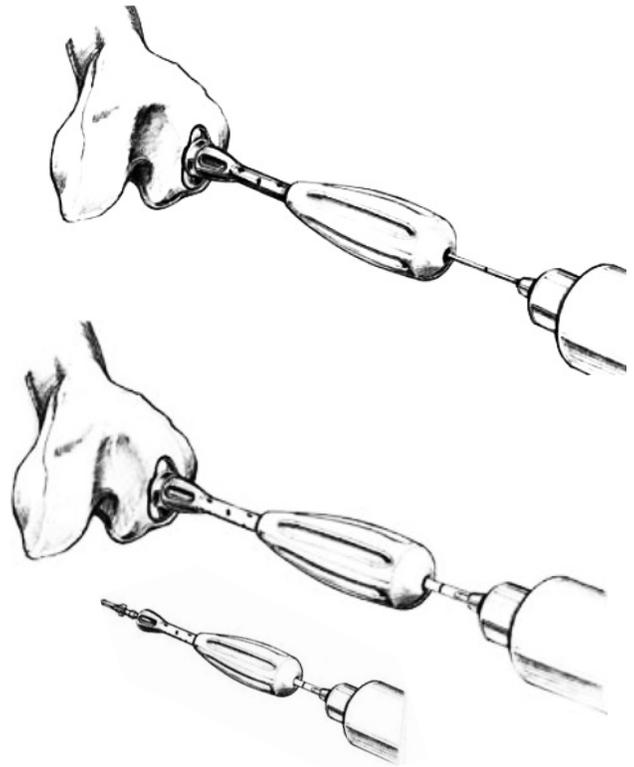


6. Confirm the position of the **Femoral Trial** before preparing the pilot hole for the **Taper Post**. Advance the **4.7mm Pilot Drill** through the **Sizing Trial Handle** until the laser mark is flush with the end of the handle and leave it in position. Replace the **2.0mm Pin** through the **4.7mm Pilot Drill**.

7. Remove the **Sizing Trial Handle** and **4.7mm Pilot Drill**, leaving **2.0mm Pin** in position. Place the **Step Drill** over the **2.0mm Pin** and reposition the **Sizing Trial Handle**. Advance the **Step Drill** until the laser mark is flush with the end of the handle.

8. Remove the **Sizing Trial Handle** and **Step Drill**, leaving **2.0mm Pin** in position. Feed proximal end of **Tap** into distal opening of **Sizing Trial Handle**, place unit over the **2.0mm Pin** and reposition the **Sizing Trial Handle**. Couple the **Tap Handle** to the **Tap** and advance the **Tap** until the laser mark is flush with the end of the handle.

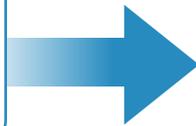
9. Insert the **Taper Post** into the **Sizing Trial Handle**. Attach the **Handle** and **Taper Post** assembly onto the **Femoral Sizing Trial**. Insert the **Hex Driver** into the **Handle** and advance the **Taper Post** into the bone. Stop advancing the **Hex Driver** when the raised stop on the **Driver Shaft** contacts the top of the **Sizing Trial Handle** and the **Femoral Sizing Trial** is flush with the surrounding cartilage. Remove the **Sizing Trial**.



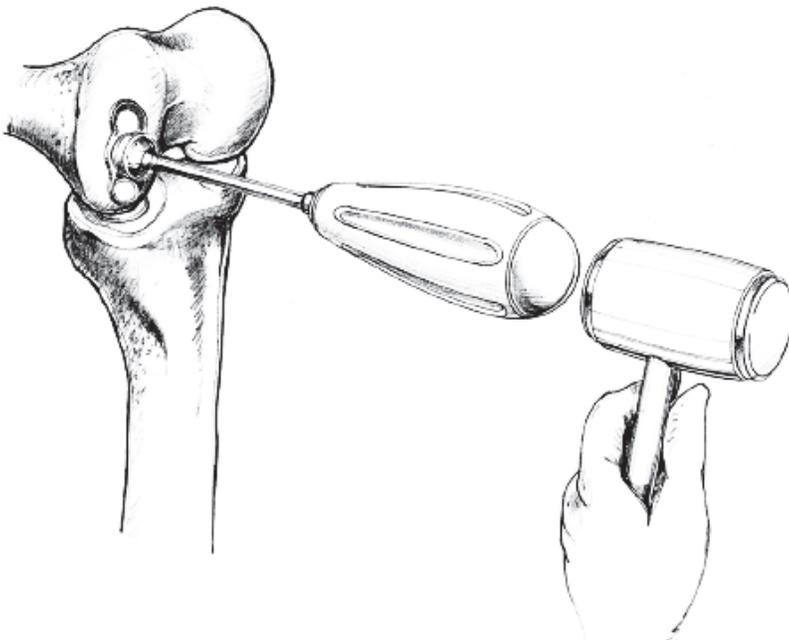
10. Insert the **Taper Post** into the **Sizing Trial Handle**. Attach the **Handle** and **Taper Post** assembly onto the **Femoral Sizing Trial**. Insert the **Hex Driver** into the **Handle** and advance the **Taper Post** into the bone. Stop advancing the **Hex Driver** when the raised stop on the **Driver Shaft** contacts the top of the **Sizing Trial Handle** and the **Femoral Sizing Trial** is flush with the surrounding cartilage. Remove the **Sizing Trial**.

11. Use the **Final Placement Gauge** in combination with the **Femoral Trial** to confirm the proper depth placement of the **Taper Post** (with the **Femoral Trial** in position, and with the **Final Placement Gauge** coupled to the **Taper Post**). A very small separation (less than .5mm) should be seen between the components. If no gap is visible, the **Taper Post** is set too deep and should be raised. If a large gap is visible, the **Taper Post** is set too shallow and should be lowered.

NOTE: Complete implantation of **Tibial Component** (p. 24)



12. Apply pea-sized balls of bone cement to underside of the **Femoral Component**. Position the **Femoral Component**. Use a slight tap on the **Impactor** to mate the **Femoral Component** to the **Taper Post**.



Sizing Card (UniCAP Classic Femoral Component)

arthrosurface®
Uni Femoral

A
P

Sizing Card

fill in all 4 circles

1. Maximum AP _____

Maximum ML

2. Select Femoral UniCAP™ offset values
If no match is found, use the next highest offset value

- 6.0 x 2.0 x 1.0 mm
- 6.0 x 3.0 x 1.0 mm
- 7.0 x 2.0 x 1.0 mm
- 7.0 x 3.0 x 1.0 mm
- 8.0 x 2.0 x 1.0 mm
- 8.0 x 3.0 x 1.0 mm
- 9.0 x 2.0 x 1.5 mm
- 9.0 x 3.0 x 1.5 mm
- 10.0 x 2.0 x 1.5 mm
- 10.0 x 3.0 x 1.5 mm

3. Select Femoral Surface Reamer size
Choose the Surface Reamer that matches the maximum ML offset value.

P/N K001-1040 Rev A

Sizing Card (UniCAP Small Femoral Component)

arthrosurface®
Uni, Small

A
P

Sizing Card

fill in all 4 circles

1. AP _____

ML

2. Select Femoral UniCAP™ offset values
If no match is found, use the next highest offset value

- 2.5 mm x 1.0 mm
- 2.5 mm x 2.0 mm
- 3.0 mm x 1.0 mm
- 3.0 mm x 2.0 mm
- 3.5 mm x 1.0 mm
- 3.5 mm x 2.0 mm
- 4.0 mm x 1.0 mm
- 4.0 mm x 2.0 mm

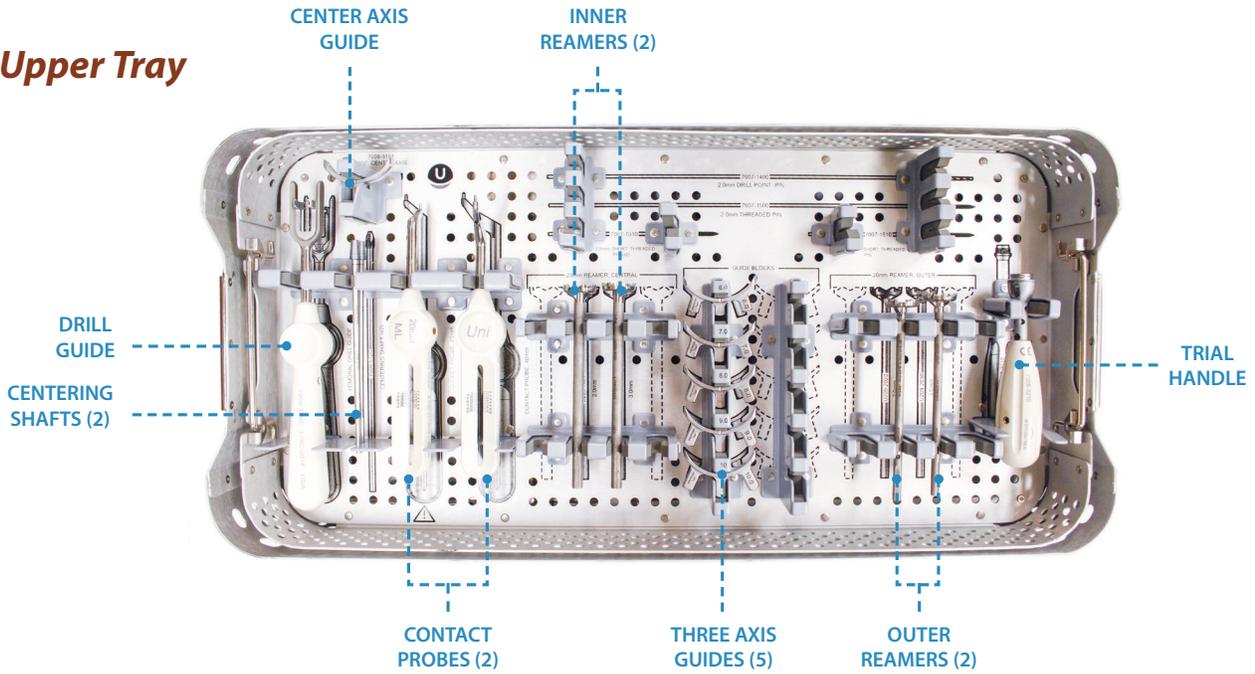
3. Select Femoral Guide Block based on AP offset value.

P/N K001-1022 Rev A

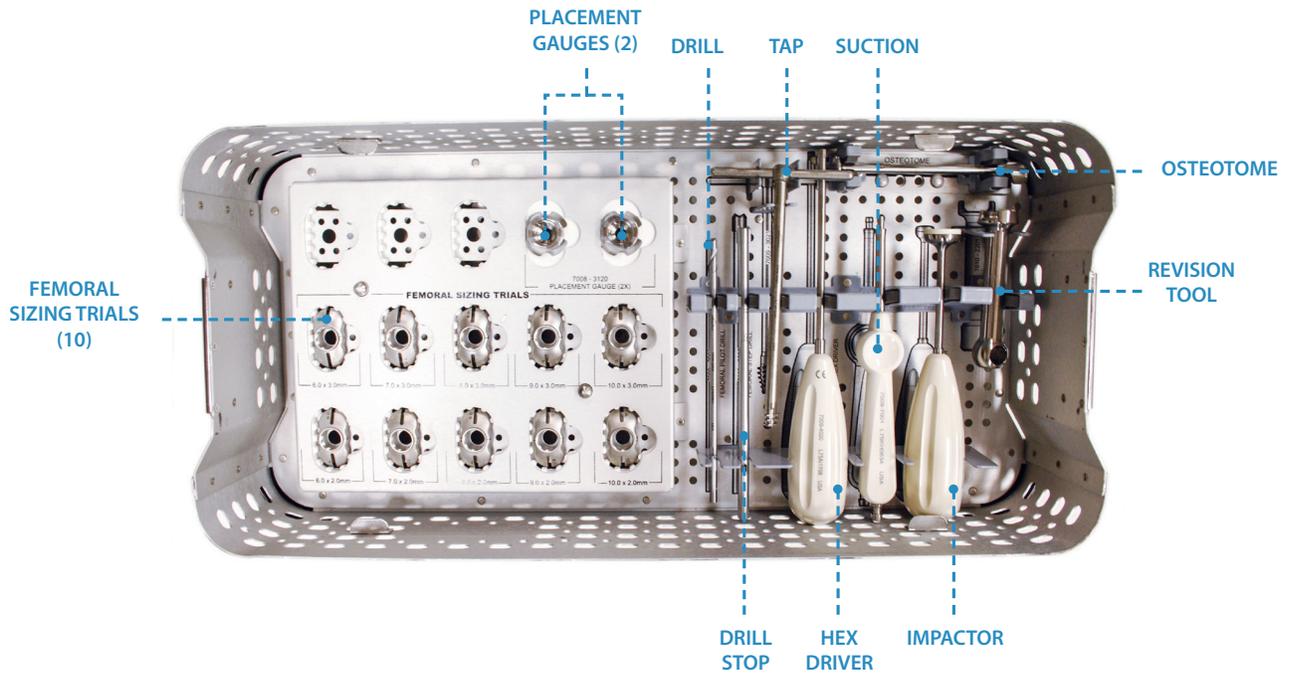
Instrumentation

UniCAP Classic Femoral Component

Upper Tray



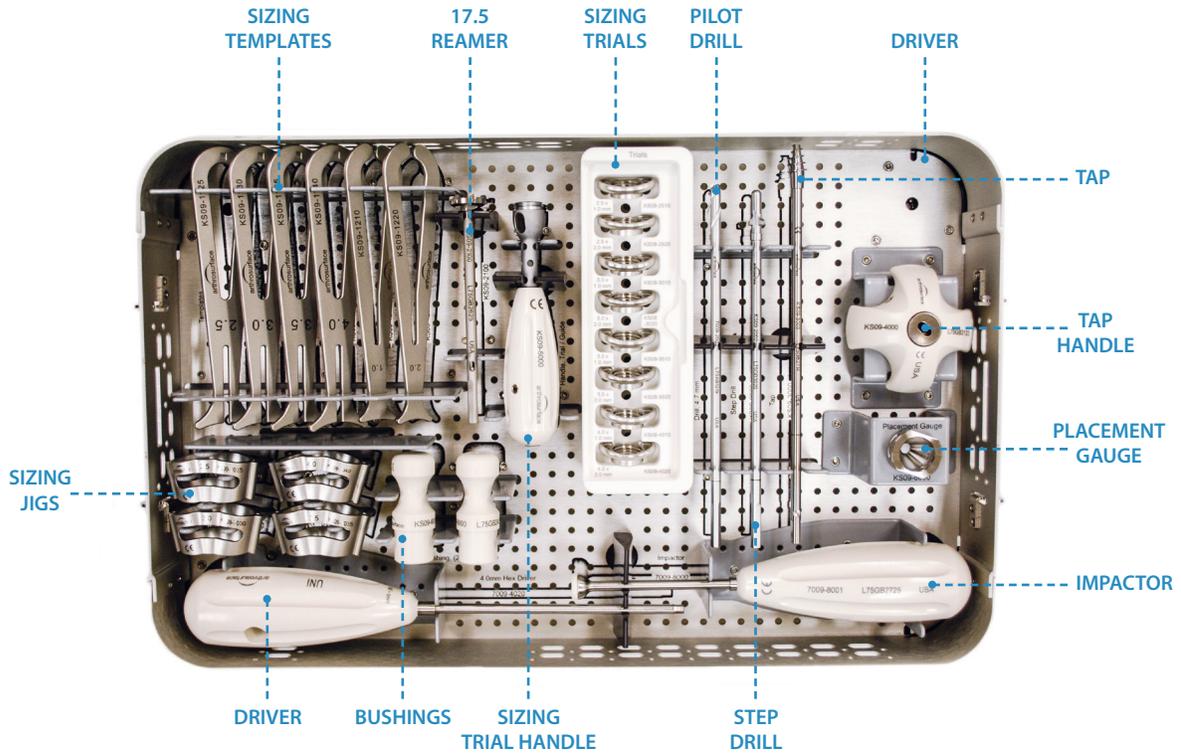
Lower Tray



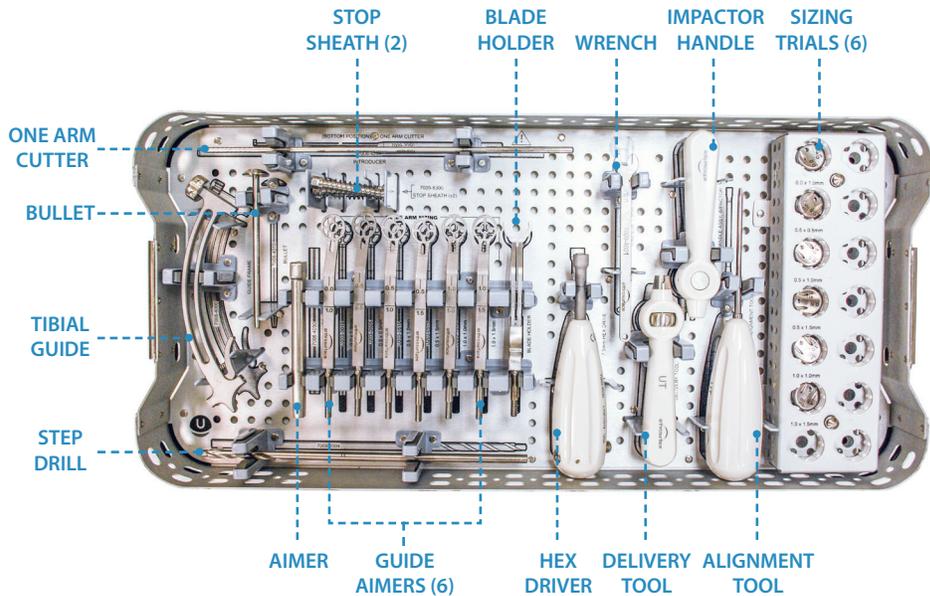
Instrumentation

UniCAP Small Femoral Component

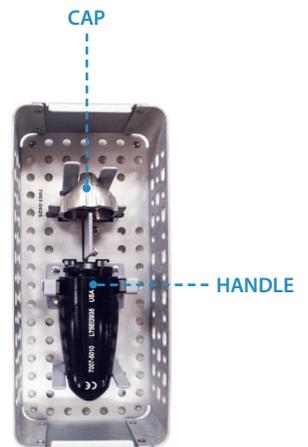
Femoral Tray



Tibial Tray



Cement Dispenser



System Catalog

Instrumentation System

U000-4000	UniCAP Femoral Instrumentation Kit
U000-2000	UniCAP Tibial Instrumentation Kit
U000-0500	Cement Dispenser Kit

Femoral Articular Components (UniCAP Classic)

U202-0621	6.0mm x 2.0mm Offset
U202-0631	6.0mm x 3.0mm Offset
U202-0721	7.0mm x 2.0mm Offset
U202-0731	7.0mm x 3.0mm Offset
U202-0821	8.0mm x 2.0mm Offset
U202-0831	8.0mm x 3.0mm Offset
U202-0925	9.0mm x 2.0mm Offset
U202-0935	9.0mm x 3.0mm Offset
U202-1025	10.0mm x 2.0mm Offset
U202-1035	10.0mm x 3.0mm Offset

Femoral Articular Components (UniCAP Small)

US02-2510	2.5mm x 1.0mm Offset
US02-2520	2.5mm x 2.0mm Offset
US02-3010	3.0mm x 1.0mm Offset
US02-3020	3.0mm x 2.0mm Offset
US02-3510	3.5mm x 1.0mm Offset
US02-3520	3.5mm x 2.0mm Offset
US02-4010	4.0mm x 1.0mm Offset
US02-4020	4.0mm x 2.0mm Offset

Taper Post, Femoral (UniCAP Classic)

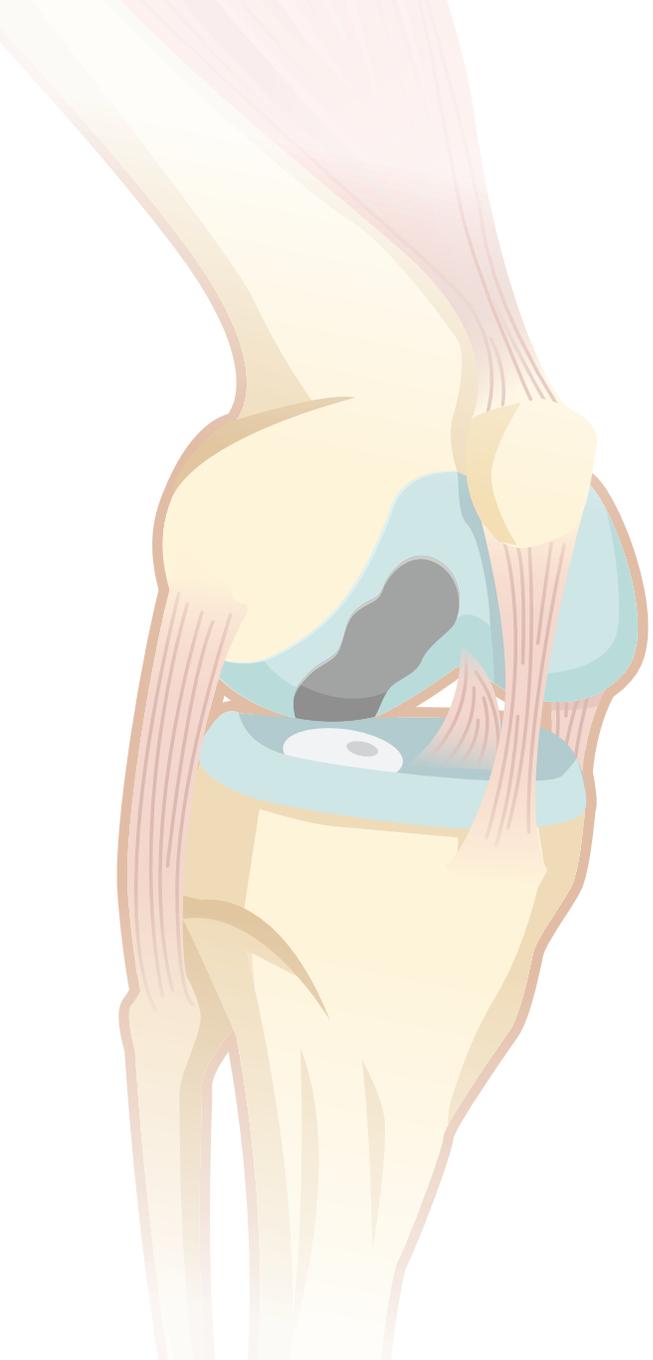
U110-0218	11mm x 22mm
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Taper Post, Femoral (UniCAP Small)

US11-0205	10.6mm Taper Post, Uni, Small
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Tibial Articular Components

U205-0010	0.0mm x 1.0mm Offset
U205-0505	0.5mm x 0.5mm Offset
U205-0510	0.5mm x 1.0mm Offset
U205-0515	0.5mm x 1.5mm Offset
U205-1010	1.0mm x 1.0mm Offset
U205-1015	1.0mm x 1.5mm Offset



Accessories

U000-0100	Tibial Cutter Kit
U000-0510	Cement Cartridge Kit
U000-0200	Pin Kit includes: 2.0mm Drill Tip Pin 2.0mm Threaded Pin (2) 2.0mm Short Threaded Pin

UniCAP[®]

Tibial Component



KEY FEATURES:

Minimal bone removal maintains future options

Only tibial component to preserve the meniscus

*Designed for localized defects and early
intervention*

Description

The Unicompartmental Knee Resurfacing Prosthesis (UniCAP®) incorporates a low-profile femoral articular component that mates to a taper post via a taper interlock. The femoral component articulates against an all-polyethylene tibial component. The UniCAP® implants allow resurfacing of the compartment utilizing the undisturbed compartmental structures and soft-tissues.

Materials

Articular Component:	Cobalt-Chromium Alloy (Co-Cr-Mo)
Surface Coating:	Titanium (CPTi)
Taper Post:	Titanium Alloy (Ti-6Al-4V)
Tibial Component:	Ultra-High-Molecular Weight Polyethylene (UHMWPE)

Indications

Partial replacement of the articulating surfaces of the knee when only one side of the joint is affected due to the compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty. This device is intended to be used with bone cement.

Contraindications

Absolute contraindications include:

- 1) Infection, sepsis, or osteomyelitis
- 2) Patients that have a known sensitivity to materials typically used in orthopedic prosthetic devices or bone cements

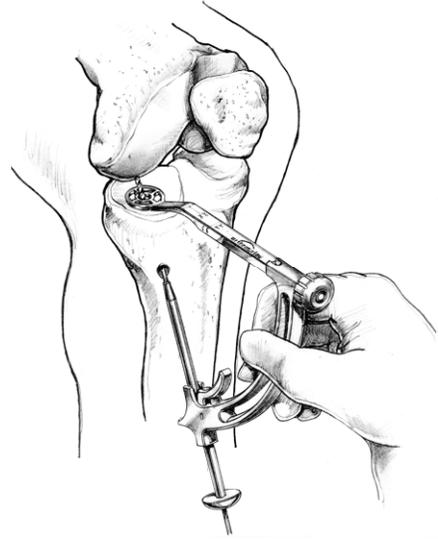
Relative contraindications include:

- 1) Uncooperative patient or patient incapable of following pre-operative and post-operative instructions
- 2) Osteoporosis
- 3) Metabolic disorders which may impair the formation or healing of bone
- 4) Infections at remote sites which may spread to the implant site
- 5) Rapid joint destruction or bone resorption visible on roentgenogram
- 6) Chronic instability or deficient soft tissues and other support structures
- 7) Vascular or muscular insufficiency
- 8) Inadequate skin, musculotendinus or neurovascular system status

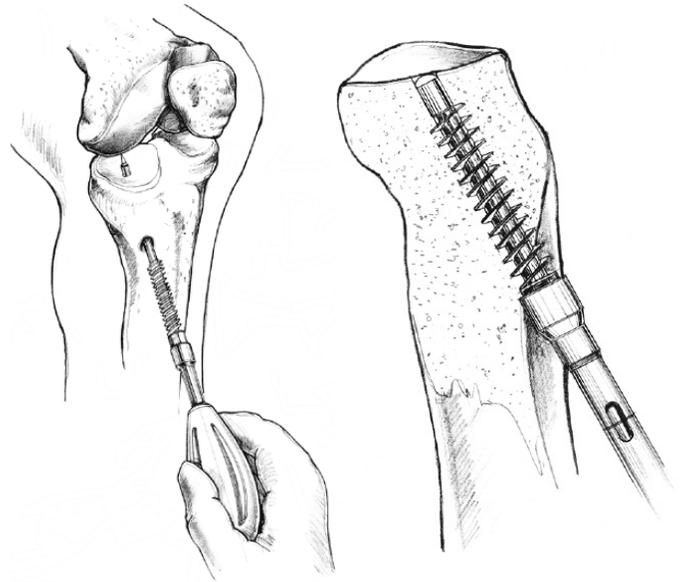


Surgical Technique (Tibial Component)

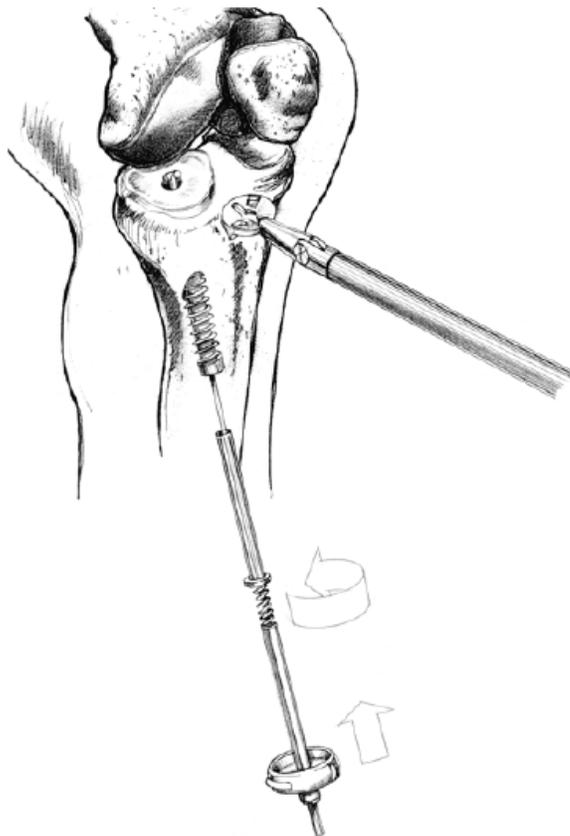
1. The **Tibial Component** may be placed under arthroscopic visualization to ease preparation of the tibial defect. With the knee at 90 degrees of flexion, and working through an anteromedial portal, place a **Tibial Template** central to the damaged area of the tibial plateau surface. The underside of the **Tibial Template** should be in contact with the surface of the tibia. Select the **Tibial Template** that best matches the A/P and M/L surface curvatures of the tibia. Attach the **Tibial Template** to the **Tibial Drill Guide** and **Bullet**. Place the guide so the arm of the **Tibial Template** is parallel to the tibial plateau.



2. Drill the **2.0mm Threaded Pin** through the central axis of the **Tibial Drill Guide** until it reaches the center of the **Tibial Template**. Use a small closed curette to "catch" the tip of the Pin to prevent drilling into the femur. Care must be taken so that excessive torque is not applied to the **Drill Guide** which may cause the pin to miss the target. Confirm that there is a minimum of 5mm of bone from the edge of the **Template** to the front of the tibia to avoid breaking through the anterior tibia during reaming. Bring the knee into extension and probe the underside of the meniscus to ensure complete visualization and proper placement of the **Template**. Remove the **Tibial Drill Guide** and **Bullet**.



3. Drive the **Tibial Pilot Drill** over the **2.0mm Threaded Pin** until it reaches the center of the templated area. Drilling should stop before the larger diameter tip of the **Pilot Drill** breaches the tibial plateau. Remove the **Tibial Pilot Drill** and **2.0mm Pin**.

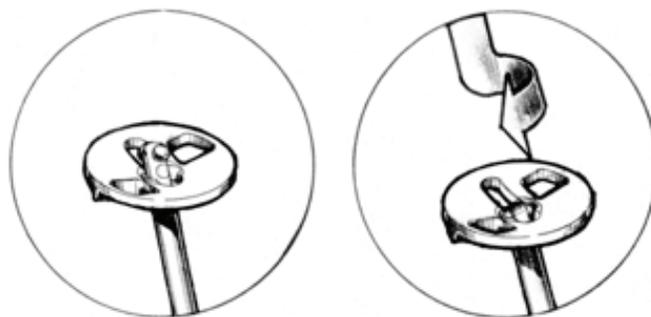


4. Advance the **Introducer** into the prepared tibial tunnel. The proximal tip of the **Introducer** should be flush with the tibial plateau. Begin to advance the threaded **Blade Stop** over the **Introducer** until it begins to screw into the bone. Remove **Introducer** and continue to advance the **Blade Stop** until it is 2/3rds into the tunnel.

- a. Remove the **Driver** handle and reinsert the **Introducer** and **Driver**, continuing to advance as one unit. Stop when the tip of the **Introducer** is flush with the tibial plateau. Confirm that the laser mark on the **Introducer** is in-line with the laser mark in the slotted window of the **Blade Stop Driver**.

- b. The **Blade Stop** is at the correct depth when the tip of the **Introducer** is flush with the tibial plateau and the laser mark lines on the **Driver** and **Introducer** are aligned in the slotted window. Remove the **Blade Stop Driver** and **Introducer**.

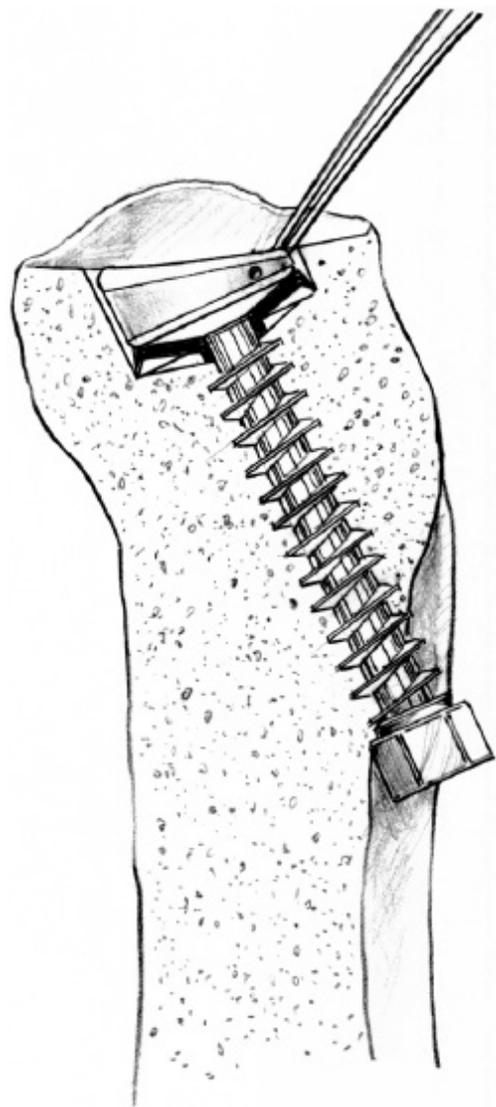
5. Place the **Cutting Blade** into the **Blade Holder** with the long slot facing posteriorly to the joint. Introduce the **Cutting Blade** into the portal. Advance the **Blade Drive Shaft** into the tibial tunnel until it is visible in the joint. Push the tip of the **Drive Shaft** through the center of the **Cutting Blade**.



6. Connect the **Cutting Blade** to the **Blade Drive Shaft** by turning the **Drive Shaft** 90 degrees and pull distally to engage the blade. To lock the **Tibial Cutting** system, push the sheath in an upward motion and rotate 90 degrees so the **Lock Indicator** on the **Blade Drive Shaft** is positioned over the **Dowel Pin** and **Laser Mark** line. Release to lock the **Cutting Blade** into position. Attach the cannulated powered drill to the laser mark indicated on the distal end of the **Drive Shaft**.

7. Using a cannulated powered drill, begin rotation counterclockwise to normalize the blade to the tibial plateau. This will help ensure even cutting engagement of the **Cutting Blade** into the plateau. Care should be taken to avoid the meniscus. Begin to prepare the inlay implant socket using a clockwise blade rotation. Drilling is complete when the **Cutting Blade** comes in contact and stops on the proximal end of the **Blade Stop**.

8. With the **Cutting Blade** remaining in place, insert the appropriate **Sizing Trial** based on the mapping (determined by using the **Tibial Template**). Confirm fit at anterior/posterior and medial/lateral margins of the **Sizing Trial**. If the **Trial** is proud at the margins, use the **Blade Stop Wrench** to rotate the **Blade Stop** clockwise. Each 90 degree turn of the **Blade Stop** using the **Blade Stop Wrench** lowers the **Blade Stop** 1mm. Reattach the cannulated powered drill and re-ream to the new depth. This will lower the implant depth in the tibial socket.

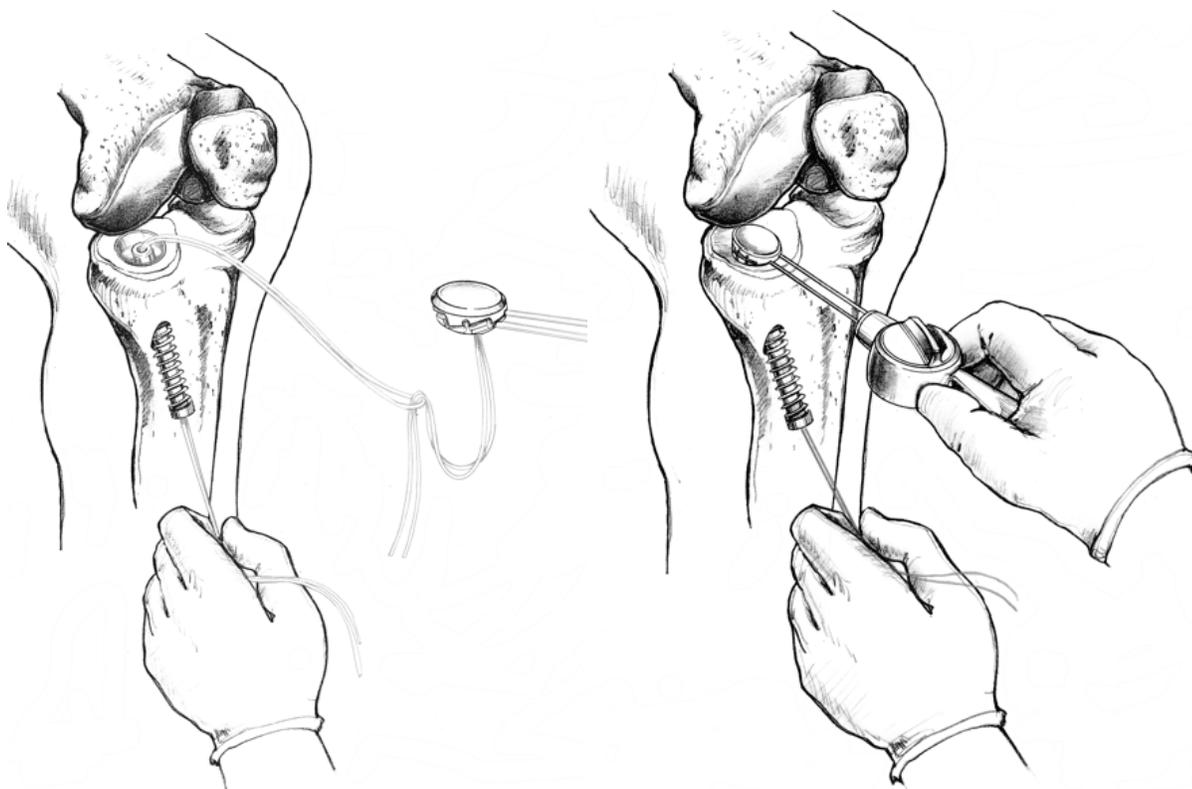


9. With the **Sizing Trial** set at the appropriate height, begin removing the instrumentation. Raise the **Drive Shaft** so the **Cutting Blade** can be grasped for removal. To unlock and remove the **Cutting Blade**, push the sheath in an upward motion and rotate 90 degrees counterclockwise so the **Unlock Indicator** on **Blade Drive Shaft** is positioned over the **Dowel Pin**. Release to unlock **Cutting Blade**. Push **Drive Shaft** upwards to free it from the **Cutting Blade** and turn the **Drive Shaft** 90 degrees. Pull distally on the **Drive Shaft** and remove from the tibial tunnel. Use a grasper to remove the **Cutting Blade**.

NOTE: Prepare **Femoral Component (UniCAP Classic p. 5 / UniCAP Small p. 11)** prior to final placement of **Tibial Component**.

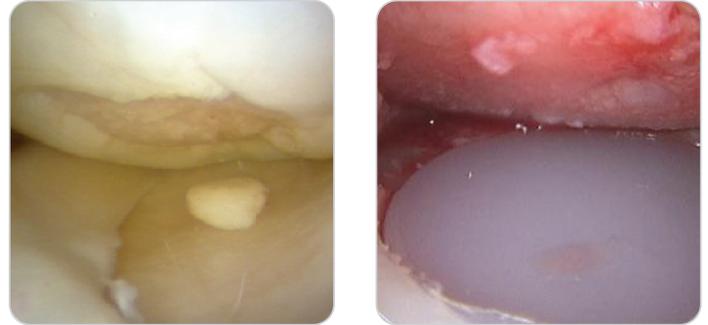


10. Open **Tibial Component Kit**. Using the **Suture Retriever**, capture the suture and pull the suture through and out of the distal tibial drill hole. Introduce the **Tibial Component** into the tibial socket using the **Delivery Tool**.



11. Advance the **Slot Driver** into the tibial tunnel to rotate the **Tibial Component** (via the distal slot on the bottom of the component) to its optimal orientation if needed.

12. Implant the **Tibial Component** with cement using the **Arthrosurface® Cement Ejector**. When discharging cement, allow the back pressure from the cement extraction to lift the implant up 2mm and then continue to back fill the tibial tunnel with cement. Utilize the **Tibial Template** through the portal to apply downward pressure onto the **Tibial Component** to seat it in its final position. This will allow for optimal cement integration.



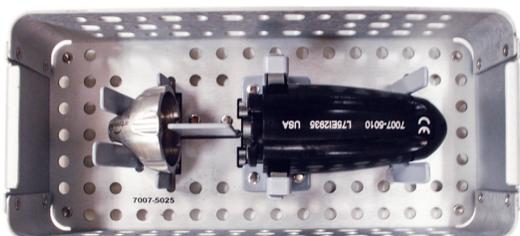
Before & After Tibial Component

*** Implant Femoral Component:**

*Apply pea-sized balls of bone cement to underside of the **Femoral Component**. Position the **Femoral Component** and use a slight tap on the **Impactor** to mate **Femoral Component** to the **Taper Post**.*

Cement Ejector Assembly

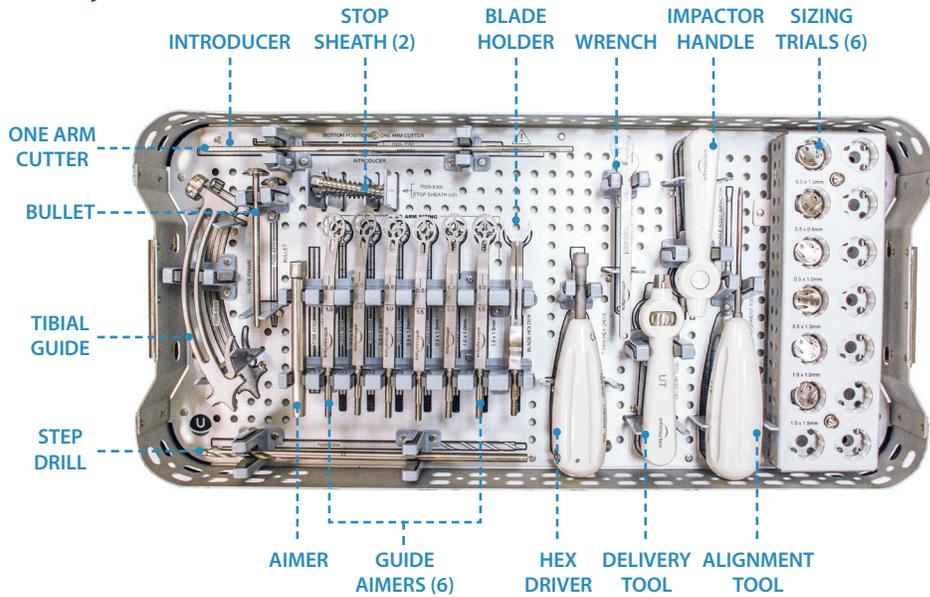
- a. Mix low viscosity cement according to manufacturers' directions.
- b. Place cement into the **Delivery Syringe**. Remove **Funnel** when **Delivery Syringe** is full.
- c. Insert **Plunger** into **Delivery Syringe**. Insert into **Ejector Handle**.
- d. Attach **Drive Rod** onto **Ejector Handle**.
- e. Place **Threaded Sheath** into tibial tunnel to prevent cement extrusion.
- f. A cannulated powered drill with Jacobs chuck is used to advance the **Drive Rod**.
- g. Deliver cement to undersurface of implant through tibial tunnel and draw **Cement Ejector** retrograde as tibial tunnel is filled.



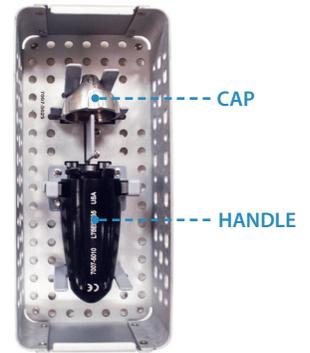
Cement Dispenser

Instrumentation (Tibial Component)

Tibial Tray



Cement Dispenser



System Catalog

Tibial Articular Components

U205-0010	0.0mm x 1.0mm Offset
U205-0505	0.5mm x 0.5mm Offset
U205-0510	0.5mm x 1.0mm Offset
U205-0515	0.5mm x 1.5mm Offset
U205-1010	1.0mm x 1.0mm Offset
U205-1015	1.0mm x 1.5mm Offset

Instrumentation System

U000-2000	UniCAP Tibial Instrumentation Kit
U000-0500	Cement Dispenser Kit

Accessories

U000-0100	Tibial Cutter Kit
U000-0510	Cement Cartridge Kit

Warnings

Improper selection, placement, positioning, alignment, and fixation of the implant components may reduce the service life of the prosthetic components. Inadequate preparation and cleaning of the implant components mating surfaces may result in improper fixation of the device. Improper handling of the implants can produce scratches, nicks or dents that may have adverse clinical effects on mating joint surfaces. Do not modify implants. The surgeon shall be thoroughly familiar with the implants, instruments, and surgical technique prior to performing surgery.

When defining offsets of articular surfaces, care should be taken to ensure that instruments are properly aligned and mated with taper in Taper Post. Visually confirm distal tip of contact probe is making contact on articular surfaces and free from any soft tissue structures to ensure accuracy. Use light pressure on contact probe to slightly indent articular surface at each offset point, ensuring that the selected implant will be flush or slightly recessed with the articular surface.

Prior to placing implant, carefully trim articular cartilage debris around prepared margin. Remove bone particles and lavage thoroughly. To ensure mechanical interlock of the Taper Post and implant, carefully clean Taper Post taper with provided instruments. All drilling or reaming should be done with vigorous lavage to minimize heat effects to adjacent bone and cartilage tissues.

Accepted practices in post operative care should be used. The patient is to be instructed and monitored to ensure a reasonable degree of compliance to post operative instructions and activity restrictions. Excessive activity, impact, and weight gain have been implicated in the reduction of the benefit and service life of prosthetic devices.

Precautions

These implants are intended to be fitted and installed with the matched instrument set. Use of instruments from other systems may result in improper implant selection, fitting, and placement which could result in implant failure or poor clinical outcome. The instrument set should be regularly inspected for any signs of wear or damage. Do not reuse implants or disposable instruments.

Possible Adverse Effects

- 1) Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions. Particulate wear debris and mild tissue discoloration from metallic components have been noted in other prosthetic devices constructed of similar materials. Some types of wear debris have been associated with osteolysis and implant loosening.
- 2) Infection or allergic reaction.
- 3) Loosening, migration or loss of fixation of implant.
- 4) Fretting and crevice corrosion can occur at the interface between the implant components.
- 5) Fatigue fracture of the implants as a result of bone resorption around the implant components.
- 6) Wear and damage to the implant articulating surface.
- 7) Wear and damage to the adjacent and opposed articular cartilage surfaces or soft tissue support structures.
- 8) Intraoperative or postoperative bone fracture.

UniCAP®

UniCAP Classic Femoral Components



UniCAP Small Femoral Components



Tibial Components



The Arthrosurface Resurfacing Systems are also available for the following joints:

- Shoulder
- Great Toe
- 2nd MTP
- Talus (*Available in most International markets via CE mark*)
- Patello-Femoral
- Hip
- Femoral Condyle (*Available in most International markets via CE mark and as a part of a IDE study in the U.S.*)

This product is covered by one or more of U.S. Patent Nos. 6,520,964; 6,610,067; 6,679,917; 7,163,541; 7,029,479 and other patents pending. UniCAP® and HemiCAP® are trademarks of Arthrosurface, Inc. U.S. © 2020 Arthrosurface, Inc. All rights reserved. Printed in U.S.A.



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This pamphlet and information is intended for markets where regulatory approval has been granted.