Unicondylar Knee System

OPTETRAK®
UNICONDYLAR KNEE

THE RIGHT TRACK.
It's not just a road we're on,
it's a trail we're blazing.

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The Optetrak Unicondylar Knee System Operative Technique was developed in consultation with:

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INTRODUCTION

The Optetrak Unicondylar Knee System provides for bone preservation through proper joint spacing. Low Profile Instrumentation (LPI) provides for optimized surgical exposures while featuring biomechanically inspired articular geometry and exclusive net-molded polyethylene to facilitate restoration of knee function.

The shaded area represents a "live" zone, which is surrounded by a rim with a decreased radius to provide constraint at extreme ranges of motion.

DESIGN RATIONALE

Low Profile Instrumentation
The Optetrak Uni instrumentation, part of the Exactech family of Low Profile Instrument systems, is designed for minimal soft tissue disturbance.

Femoral/Tibial Coverage
Comprehensive femoral/tibial coverage is achieved through a broad sizing scope and implant positioning instrumentation. Easy-to-use instruments are integral to the technique. Joint-spacing and tensioning guides the tibial resection, providing for a bone-preserving cut.

Biomechanically Inspired
The all-polyethylene tibial component features a two-stage articular surface. Primary articulation occurs in the central "live" zone. This area is surrounded by a rim with a decreased radius to provide constraint at extreme ranges of motion. This design allows articular sliding with a soft stop that approximates typical knee function with four intact ligaments. The system includes six symmetrical femoral components and six asymmetrical tibial components.

OPERATIVE TECHNIQUE OVERVIEW

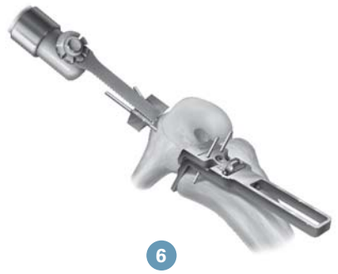
1
Tidemark reference

2
Tibial rough-cut resection

3
Femoral sizing

4
Joint Space Assessment

5
Femoral Distal Resection Guide attachment



6
Femoral distal resection

7
Final tibial resection

8
Femoral Posterior Chamfer Resection

9
Posterior femoral peg hole completion

10
Tibial punch completion

11
Final component implantation

DETAILED OPERATIVE TECHNIQUE

EXPOSURE

Open the joint using a midline or a medial parapatellar incision. When using a limited incision, it is important to undermine the skin and soft tissues. Undermining will help in the exposure of the compartment and retraction of the patella. Taking a little extra time in the beginning of the exposure will make visualization much better later in the procedure. A medial arthrotomy is then completed. A vastus medialis obliquus (VMO) snip is an option that will help mobilize the patella laterally and does very little trauma to the quadriceps tendon. The distal portion of the incision aids in the balancing of the knee. Peeling the periosteum off the medial tibial plateau will aid in the soft tissue balancing similar to a total knee replacement. The medial meniscus can be excised at this time. Osteophytes from behind the tibia and the medial femoral condyle are now removed. Care should be taken to remove the osteophytes behind the medial collateral ligament. Prior to exposure of the compartment, with the knee in approximately 30 degrees of flexion, the patellofemoral and lateral compartments can be inspected for any degenerative changes. Another option is to perform a diagnostic arthroscopy for examination of the compartments prior to opening the joint. Now, with appropriately placed retractors, the compartment is exposed.

EXTENSION REFERENCE POINT (OPTIONAL)

With the knee in extension, mark the point where the anterior edge of the tibia articulates with the femoral condyle *(Figure 1)*. This mark will be used later in the procedure to indicate the amount of distal femoral coverage needed to achieve full extension.

Note: This mark is typically coincident with the anatomical tidemark and is simply used as a reference later in the procedure.

INITIAL TIBIAL RESECTION AND EXTRA-MEDULLARY BASELINE

The initial tibial resection is a "rough cut" that is meant to provide a baseline flat surface for the extra-medullary instrumentation to follow in the procedure.

Step 1
Assemble the **Extra-Medullary Tibial Resector Ankle Clamp, Adjustable Tibial Resector** and the **LPI Beta Tibial Resection Guide**. Clamp the resection guide assembly to the patient's ankle and align the resector shaft parallel to the patient's tibia *(Figure 2)*.

Figure 1
Tidemark reference

Figure 2
Tibial resection instrument set-up

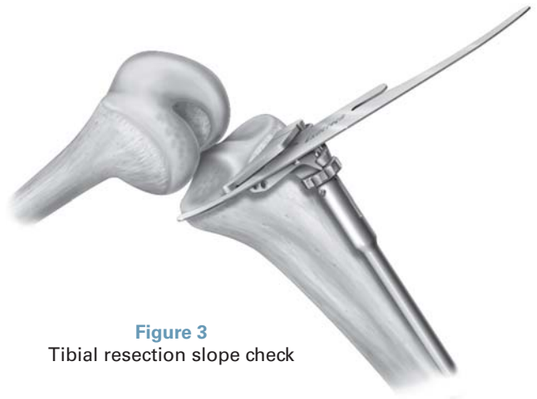


Figure 3
Tibial resection slope check

Figure 4
Tibial resection depth check

Step 2
Referencing the tibial plateau close to the collateral ligament, replicate the anatomic posterior slope or choose a custom slope by adjusting the **Extra-Medullary Tibial Resector Ankle Clamp**. The **Cut Line Predictor** may be used to better visualize the tibial slope *(Figure 3)*.

Step 3
Insert the **Sliding Tibial Stylus** into the LPI Tibial Resection Guide and adjust the resection level *(Figure 4)*. Pin the resection block with the headless holding pins. Perform a minimal tibial rough-cut using an oscillating saw with a .047in (1.19mm) by 13mm blade *(Figure 5)*. Remove the extramedullary resection assembly.

Note: The Stylus creates a 5mm resection from the tip. It is critical to avoid excessive tibial bone resection (often by referencing the low point of the defect). The depth of the cut may be varied depending on the amount of wear in the medial tibial plateau. If there is damage to the tibial plateau, reduce the resection level to minimize the tibial resection. Avoid undermining the tibial eminence.

Figure 5
Tibial rough-cut resection

Step 4
Select the Tibial Template size that provides the best coverage of the resected tibial plateau by aligning the central edge of the template with the medial edge of the anterior collateral ligament (ACL) insertion point *(Figure 6)*.

Note: The transverse resection may be fine-tuned utilizing the cutting teeth on the Tibial Template.

Step 5
With the Tibial Template still in the slot of the resected tibia, slide the **Sagittal Cut Alignment Guide** over the handle *(Figure 7)*. The Cut Line Predictor or a saw blade may be used to estimate the position of the sagittal resection. Using a reciprocating saw, perform the resection *(Figure 8)*. Remove the resected bone.

Step 6
Place the hook on the **Tibial Punch Template** on the posterior cortex of the resected tibial plateau and confirm the tibial component size *(Figure 9)*.

Step 7
Assemble the **Uni Multi-Tool** to the appropriately sized 8 mm Tibial Trial and place it on the resected tibial surface to assess the flexion and extension space *(Figure 10)*. If the fit is satisfactory, no additional tibial resection will be necessary. If the fit is too tight, a secondary resection will be made later in the final tibial preparation.

Figure 6
Tibial sizing

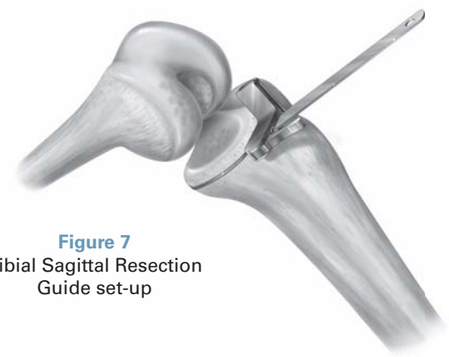


Figure 7
Tibial Sagittal Resection Guide set-up

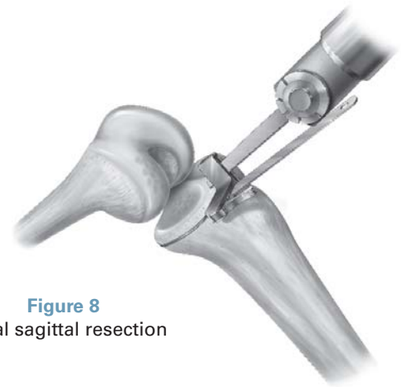


Figure 8
Tibial sagittal resection

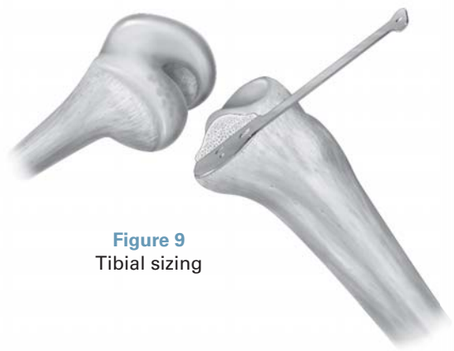


Figure 9
Tibial sizing

Figure 10
Preliminary trial

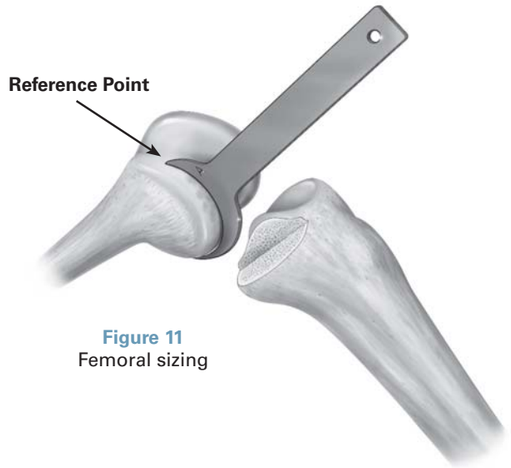


Figure 11
Femoral sizing

Figure 12
Joint space assessment

JOINT IN EXTENSION AND ALIGNMENT

Step 1
With the knee in flexion, slide a Femoral Template around the condyle to assess the femoral size *(Figure 11)*. The handle of the Femoral Template should be almost parallel to the femoral axis. When the best fit is obtained, note the previous reference mark and the tide mark described earlier. The best indication of component size is when the reference points and the anterior tip of the sizing template are aligned and the handle is roughly parallel to the femoral axis.

Note: The posterior portion of the template should extend to the end of the posterior condyle to ensure coverage in flexion. The reference mark will be used in the distal resection step, and it is critical in establishing the proper femoral flexion/extension rotation.

Step 2
Return the knee to full extension and position the **Spacer Alignment Guide** between the tibia and femur. Place it flat against the resected tibial surface *(Figure 12)*. Adjust the Spacer Alignment Guide to achieve the desired joint space. If desired, the Spacer Alignment Guide may be pinned to the tibia after the proper joint space has been achieved.

Note: The Spacer Alignment Guide compensates for space created by existing damage to the tibia and optimizes the space for an 8mm tibial insert (Figure 13).

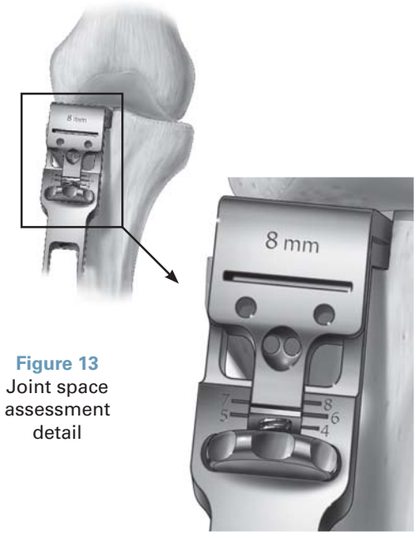


Figure 13
Joint space assessment detail

DISTAL FEMORAL RESECTION AND FINAL PROXIMAL TIBIAL RESECTION

Step 1
Fully extend the knee and place a blade flat on the proximal surface of the Spacer Alignment Guide *(Figure 14)*. Adjust knee flexion until the blade tip intersects the reference mark. This is the starting point for the distal femoral cut.

Note: The knee should be in full extension during this step in order to avoid placing the femoral component in flexion.

Step 2
Place the Distal Femoral Resection Guide on the magnetic proximal surface of the Spacer Alignment Guide *(Figure 15)*. Position the Distal Femoral Resection Guide so that the pins are placed toward the medial side of the condyle and not in the trochlear groove.

Step 3
Affix the Distal Femoral Resection Guide by securing a pin in the proximal hole and one or two pins in the distal pin hole *(Figure 16)*. Securing fixation of the cutting block to the femur is critical. Misalignment of this cutting block could result in excessive resection of the distal femur.

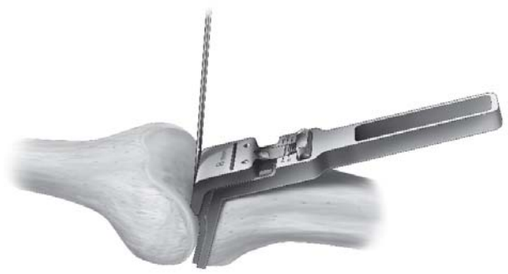


Figure 14
Distal femoral resection check

Figure 15
Distal Femoral Resection Guide set-up

Figure 16
Distal Femoral Resection Guide attachment

Figure 17
Distal femoral resection check

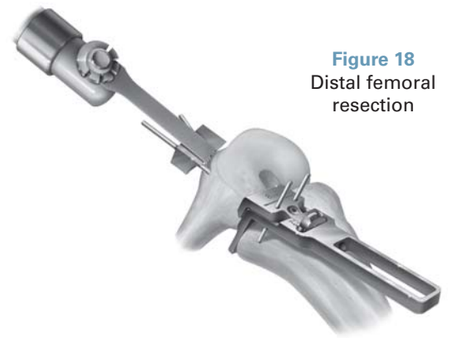


Figure 18
Distal femoral resection

Step 4
Separate the Distal Femoral Resection Guide from the Spacer Alignment Guide by placing the knee into flexion. Check the alignment of the Distal Femoral Resection Guide by using the Cut Line Predictor *(Figure 17)*.The resection should be no more than 7mm and the plane of the cutting block should be perpendicular to the anatomic axis of the femur.

Step 5
Perform the distal femoral resection using the flat distal surface of the Distal Femoral Resection Guide *(Figure 18)*.

Note: Take care to keep the saw blade flat against the cutting plane of the cutting block to avoid misalignment.

Step 6
If required, perform the final resection of the proximal tibia using an oscillating saw. The transverse resection should stop at the existing sagittal cut line.

Note: Slide a saw blade or the Cut Line Predictor in the tibial resection slot of the Spacer Alignment Guide to evaluate the amount of tibial resection (Figure 19).

a) If the Cut Line Predictor touches bone in the slot, a final tibial resection will need to be performed.

b) If the Cut Line Predictor touches metal in the slot, a final tibial resection will not be required, and trial reduction may be performed with 8 mm or 10mm trials to determine which thickness gives an optimal fit after femoral preparation.

Figure 19
Final tibial resection

JOINT TENSION IN FLEXION AND FINAL FEMORAL RESECTION

Step 1
To assemble the Posterior Chamfer Guide, insert the peg on the bottom of the appropriate **Posterior Chamfer Resector** into the **Posterior Chamfer Tensor**. Assemble the Uni Multi-Tool to the Posterior Chamfer Tensor. Place the **Nominal Posterior Tension Spacer** onto the magnet of the Posterior Chamfer Plate. This assembly will resect 7mm of posterior femoral condyle, which will match the thickness of the posterior femoral implant.

With the knee in 90 degrees flexion, place the Posterior Chamfer Guide assembly flat against the distal femoral resection and flat on the resected tibia surface *(Figure 20)*. Position the cutting guide on the distal femoral resection such that optimal medial-lateral coverage is obtained.

Note: The posterior tensor can be rotated in the medial lateral view to create an anatomic replication of the condyle.

If the joint space is too tight, remove the spacer for an additional 1mm resection, which will loosen the joint space. If the flexion space is too loose, remove the Nominal Posterior Tension Spacer and replace it with the **+1mm Posterior Tension Spacer**. This spacer will decrease the resection and add 1mm to the joint space.

Step 2
Pin the cutting guide to the femur using the 1 1/8in Headed Fixation Pins in the oblique pin holes and a Mini-Headed Fixation Pin in the anterior distal hole *(Figure 21)*. Perform the chamfer cut *(Figure 22)*, then the posterior femoral cut *(Figure 23)*. Remove the Posterior Chamfer cutting guide.

Figure 20
Femoral Posterior Chamfer Guide set-up

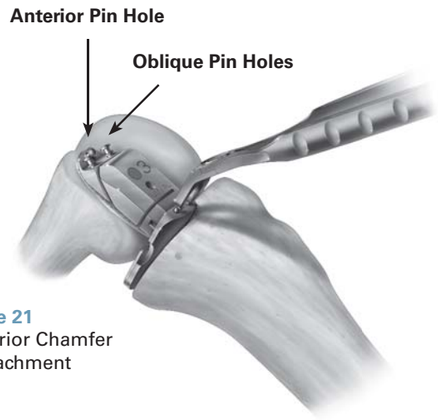


Figure 21
Femoral Posterior Chamfer Guide attachment

Figure 22
Anterior femoral chamfer resection

Figure 23
Posterior femoral resection

FEMORAL PEG HOLE PREPARATION

Step 1
Clamp the Uni Multi-Tool on the medial side of the anterior lughole of the **Femoral Drill Guide** and place the assembly on the prepared femur *(Figure 24)*. Position the guide to maximize femoral coverage. The guide may be pinned to the femur if desired. Drill the anterior femoral peg hole.

Step 2
After drilling, place the Femoral Drill Guide peg in the drilled hole to stabilize the guide as the second peg hole is drilled *(Figure 25)*. Unpin and remove the guide.

Figure 24
Anterior femoral peg hole

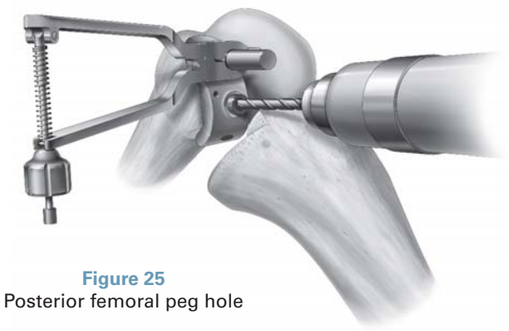


Figure 25
Posterior femoral peg hole

FINAL FEMORAL AND TIBIAL PREPARATION AND TRIALING

Step 1
Install the femoral trial using the **Locking Femoral Inserter** *(Figure 26)*. Remove the Locking Femoral Inserter and seat the Trial Femoral Component with the **Femoral Impactor**.

Step 2
Install Tibial Trial using the Uni Multi-Tool *(Figure 27)*. Evaluate the tibial space in flexion and extension.

Step 3
Complete the final preparation of the tibia by placing the hook on the Tibial Punch Template on the posterior cortex of the resected tibial plateau *(Figure 28)*. A holding pin may be used to secure the template to the tibia.

Step 4
Assemble the **Modular Tibial Punch Handle** to the appropriate size Tibial Tamp. Align the pegs of the Modular Tibial Punch Handle assembly with the slots in the Tibial Punch Template and impact the punch to create the peg and keel holes simultaneously *(Figure 29)*.

Step 5
Prior to cementation, assemble the Uni Multi-Tool to the tibial implant and place it into the prepared tibial bone to confirm the proper depth of the peg holes *(Figure 30)*.

Note: The implant must be wiped off and dry prior to final implantation.

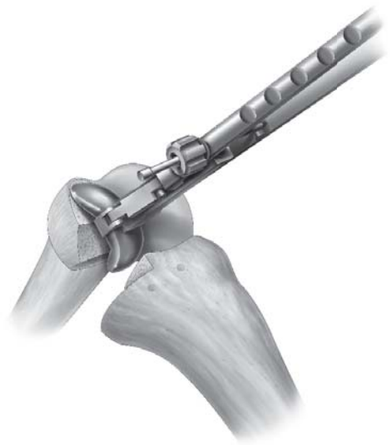


Figure 26
Trial femoral component installation

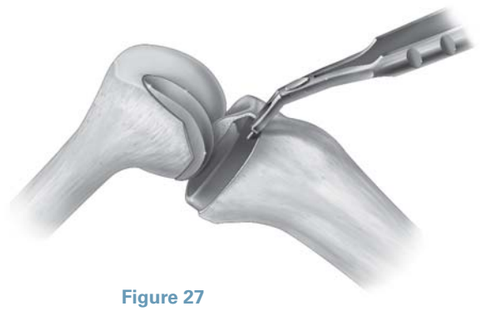


Figure 27
Trial tibial component installation

Figure 28
Tibial Punch Template set-up

Figure 29
Tibial Punch

Figure 30
Tibial peg hole check

FINAL IMPLANTATION

Step 1
Apply cement to the backside of the tibial component and to the top of the tibia. Use the Uni Multi-Tool to place the tibial implant into the prepared tibial bone *(Figure 31)*.

Note: It is helpful to identify the location of the two peg holes by indenting the cement layer with a pin that is pushed into the holes.

Step 2
Place the tibial impactor face on the tibial component and sharply strike the tibial impactor to firmly seat the implant *(Figure 32)*. Remove excess cement.

Figure 31
Tibial component implantation

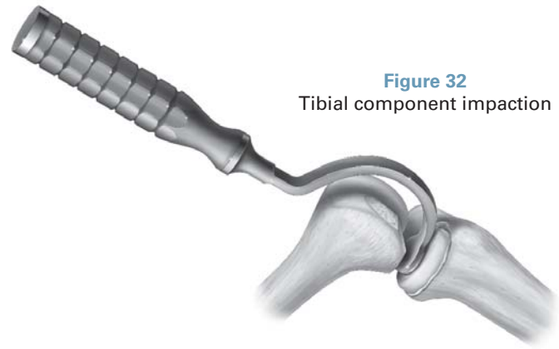


Figure 32
Tibial component impaction

Step 3
Assemble the femoral component to the inserter, and apply cement to the backside of the femoral component. Apply cement to the distal and chamfer surfaces of the femoral bone, but not the posterior surface. Install the femoral component *(Figure 33)*.

Note: This may require applying a valgus stress to the knee to open the joint space. Align the pegs with the holes drilled previously, starting at approximately 100 degrees of flexion and increase the flexion angle to insert the component fully. Do not use the Locking Femoral Inserter to impact the femoral component.

Step 4
Use the femoral impactor to firmly seat the implant *(Figure 34)*. Take care to remove all excess cement. Hold the knee stable and apply pressure to both implants while cement is curing. It is recommended that separate batches of cement be used to implant the tibial and femoral component. Remove excess cement.

Figure 33
Femoral component implantation

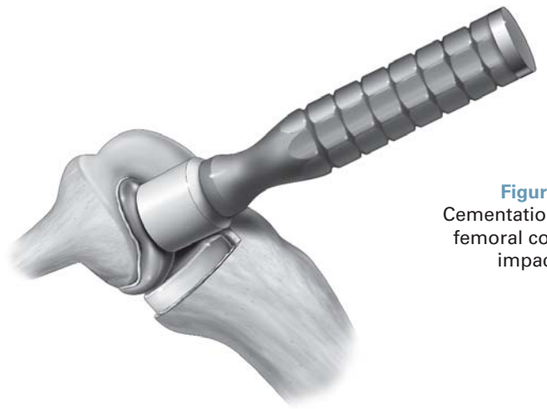


Figure 34
Cementation and final femoral component impaction

INSTRUMENT LISTING

201-45-00	Pin Drill	
201-78-05	Mini Headed Fixation Pin	
201-46-10	Headless Holding Pin, 3in	
201-52-00	Extra-Medullary Tibial Resector Ankle Clamp	
201-52-01	Adjustable Tibial Resector	
201-69-01	Pin Puller	
201-77-00	Cut Line Predictor	
201-78-19	Headed Fixation Pin, 1 1/8”	

209-69-00 CC Pin Puller/Driver

213-73-07 LPI Beta Tibial Resection Guide, Right
213-73-08 LPI Beta Tibial Resection Guide, Left

251-00-00 Femoral Drill Guide

251-00-01
251-00-02
251-00-03
251-00-04
251-00-05
251-00-06 Femoral Template, Sizes 1 through 6

251-01-01
251-01-02
251-01-03
251-01-04
251-01-05
251-01-06 Femoral Trial, Sizes 1 through 6

251-01-20 Distal Femoral Resection Guide

251-01-21 Wide Femoral Tibial Resection Guide

251-02-01
251-02-02
251-02-03
251-02-04
251-02-05
251-02-06 Posterior Chamfer Resector, Left, Sizes 1 through 6

251-03-01
251-03-02
251-03-03
251-03-04
251-03-05
251-03-06 Posterior Chamfer Resector, Right, Sizes 1 through 6

251-02-13 Posterior Chamfer Tensor

251-02-14 Nominal Posterior Tension Spacer
251-02-15 +1mm Posterior Tension Spacer

251-04-01
251-04-02
251-04-03
251-04-04
251-04-05
251-04-06 Femoral Drill Guide, Sizes 1 through 6

251-05-01 Uni Multi-Tool

251-07-00	Femoral Impactor	
251-07-01	Locking Femoral Inserter	
251-08-00	Femoral Extractor	
251-11-00	Spacer Alignment Guide	
253-02-00	Sliding Tibial Stylus, 5mm	
253-11-01 253-11-02 253-11-03 253-11-04 253-11-05 253-11-06	Tibial Template, Sizes 1 through 6	
253-11-21 253-11-22 253-11-23 253-11-24 253-11-25 253-11-26	Tibial Punch Template, Sizes 1 through 6	

253-12-00	Sagittal Cut Alignment Guide	
253-14-01 253-14-02 253-14-03 253-14-04 253-14-05 253-14-06	Tibial Trial Spacer, Sizes 1 through 6	
253-17-00	Modular Tibial Punch Handle	
253-17-11 253-17-12 253-17-13 253-17-14 253-17-15 253-17-16	Tibial Tamp, Sizes 1 through 6	
253-20-00	Tibial Impactor	
253-22-01 253-22-02 253-22-03 253-22-04 253-22-05 253-22-06	Tibial Trials, Left Medial, Sizes 1 through 6	
253-23-01 253-23-02 253-23-03 253-23-04 253-23-05 253-23-06	Tibial Trials, Right Medial, Sizes 1 through 6	

PACKAGE INSERT

OPTETRAK® UNICONDYLAR KNEE

DESCRIPTION

The Exactech Optetrak® Unicondylar Knee System is intended for partial replacement of the medial or lateral articulating surface of the knee joint.

The system is asymmetrically designed for left/right orientation and includes femoral and tibial components in a range of sizes to fit varying anatomical requirements.

A complete instrumentation system including trial implants and pre-operative planning templates is available to assist in size selection and component implantation.

For a more detailed description of the implants, instruments and their utilization, please refer to the surgical technique, or contact your sales representative.

Implants are supplied sterile and are intended for cemented use only.

Component	Material
Femoral Components	Cobalt Chromium Alloy (CoCr); ASTM F75
All-Poly Tibial Component (left/right)	Ultra High Molecular Weight Polyethylene (UHMWPE) ASTM F648
Molded Metal Backed Tibial Component (left/right)	Cobalt Chromium Alloy (CoCr); ASTM F75; Ultra High Molecular Weight Polyethylene (UHMWPE); ASTM F648
Modular Tibial Tray Insert Component	Titanium Alloy (Ti6Al4V); ASTM F136
Modular Tibial Tray Insert Component (left/right)	Ultra High Molecular Weight Polyethylene (UHMWPE); ASTM F648

INDICATIONS FOR USE

The Exactech Optetrak® Unicondylar Knee System may be indicated for replacement of the medial or lateral joint compartment in skeletally mature patients with the following clinical conditions:

1) non-inflammatory osteoarthritis, osteonecrosis and/or traumatic arthritis
2) functional deformity
3) tibial condyle or plateau fractures that are not manageable by other techniques
4) traumatic bone and/or cartilage lesions

CONTRAINDICATIONS

The Exactech Optetrak® Unicondylar Knee System is contraindicated for the following clinical conditions:

1) Patella-femoral or contralateral compartment disease or injury
2) Insufficient soft tissue integrity (e.g. ligaments, muscles, tendons)
3) Cartilage degradation due to rheumatoid arthritis
4) Osteomyelitis, a systemic infection or a secondary remote infection is suspected or confirmed
5) Inadequate or malformed bone structure precludes adequate support and fixation of the prosthesis
6) Poor bone quality (as in osteoporosis, osteomalacia and rapid joint destruction) could cause the prosthesis to migrate or to fracture host bone
7) Localized bone tumors
8) For correction of excessive varus or valgus deformities
9) For revision of previous failed arthroplasty procedures
10) Neuromuscular disorders that do not allow control of the joint
11) A patient's weight, age or activity level might cause extreme loads or early failure of the system
12) The patient is unwilling or unable to comply with the post-operative care instructions
13) Alcohol, drug or other substance abuse
14) Any disease state that could adversely affect the function or longevity of the implant

ADVERSE EFFECTS

The following serious adverse effects may be associated with use of the device. Although some effects are not directly attributable to the device itself, the surgeon should be aware of these potential complications and be ready to treat the patient accordingly.

General Surgical Risks	Total Joint Surgery Risks	Total Joint Surgery Risks
venous thrombosis	damage to blood vessels	component loosening
transitory hypotension	nerve damage	device breakage
myocardical infarction	bone bed damage	disassociation of modular components
pulmonary embolism	arthrofibrosis	difficulty removing the device
arrhythmias	phlebitis, thrombophlebitis	subluxation
delayed wound healing	hematoma	subluxation
wound healing problems	extensive blood loss the use of bone cement such as precipitous blood pressure drop	iatrogenic fracture
extensive blood loss		leg length discrepancy sensitivity reactions to implant materials

WARNINGS AND PRECAUTIONS

Preoperative:

Only qualified surgeons knowledgeable in anatomy, biomechanics and reconstructive surgery should utilize these devices.

The surgeon must be fully knowledgeable of all aspects of the specific surgical technique and use the implants in accordance with the indications and contraindications specified for each component.

The surgeon must become knowledgeable regarding compatibility between system components and use the system accordingly.

Prior to performing the surgery, the surgeon must obtain training on the proper operative technique including the proper use of system instrumentation.

It is essential to implant the devices with the instrumentation specifically designed for this purpose.

This information may be obtained by contacting Exactech, Inc.

As part of the pre-operative assessment, the surgeon must ensure that there are no biological, biomechanical or other factors that might adversely affect the surgery and the postoperative period.

The expected useful life of the device may be reduced in a very large or overweight individual and/or one who has a physically active lifestyle.

Use of smaller components in young, physically active, and/or overweight patients may result in failure that would require revision surgery.

Prior to surgery the patient must be informed of all potential risks and adverse effects contained in the present instructions for use.

Intraoperative:

An appropriate range of sizes must be available at the time of the surgery.

Selection of the appropriate type of implant and the correct size as well as proper positioning of the components is essential for the success of the procedure.

It is recommended to always use the largest component size that will appropriately fit the patient's anatomy.

The surgeon must not allow damage to polished bearing surfaces or damage and/or contamination of modular locking surfaces.

Any alteration or damage to a component will reduce fatigue strength and may result in failure under load.

The wear rate of component contact surfaces is greatly accelerated if loose fragments of bone, bone cement,or other particulate debris become detached and act as an abrasive in the articular and modular interfaces.

Components should be handled with care to minimize contamination of the component surfaces with any material that would interfere with cement fixation procedures.

When using cement for fixation, the surgeon should ensure complete cement support on all parts of the prosthesis embedded in bone cement.

Implants must not be reused.

Any implant, once used, should be discarded even though it may appear undamaged.

Postoperative:

Post-operative counseling and care is important.

The surgeon must inform the patient of the precautions to take in order maximize the life of the implant.

It is recommended that a regular postoperative follow-up be undertaken to detect early signs of component wear, loosening etc., and to consider the action to be taken.

A suitable rehabilitation program must be designed and implemented.

All patients should be instructed on the limitations of the prosthesis and the possibility of subsequent surgery.

Patients should be taught to govern their activities accordingly.

Exactech components must not be used with those of another manufacturer since dimensional compatibility cannot be assured.

Failure to adhere to these recommendations will result in increased probability of poor function, loosening, wear, fracture or premature failure.

Normal wear of the implant in respect of the state of knowledge at the time of its design cannot in any way be considered to constitute a dysfunction or a deterioration in the characteristics of the implant.

USE DURING PREGNANCY

Surgery should be avoided during pregnancy.

This device is indicated for applications in pregnancy only when it is believed impossible to save the joint or preserve the patient's life through other forms of intervention.

USE IN CHILDREN

There are no tests that demonstrate the device is safe to use in children.

The device should only be used in skeletally mature individuals.

UTILIZATION AND IMPLANTATION

Selection of components depends on the judgment of the surgeon with relationship to the requirements of the patient.

The surgeon shall become thoroughly familiar with the technique of implantation of the prostheses by: (1) appropriate reading of the literature, (2) specific training in the operative skills and techniques required for the implant system, and (3) reviewing information regarding use of instrumentation designed for the implant system.

HOW SUPPLIED

Implants are supplied sterile (gamma radiation) to a sterility assurance level (SAL) of 10-6 and are intended for single use only.

Never resterilize an implant. Resterilization may adversely affect implant materials and result in poor function, loosening, wear, fracture or premature failure.

STORAGE AND HANDLING

Store implants in their original sealed packaging in clean, dry conditions.

Do not expose to direct sunlight, ionizing radiation, extreme temperatures or particulate contamination.

In order to ensure sterility, implants must be used before the end of the expiration date indicated on the outer package label.

Prior to use inspect the packaging and labeling for integrity.

If the device is opened, damaged or adulterated in any way, it must not be used.

In order to ensure sterility, observe aseptic surgical procedures when removing the implant from its packaging.

CAUTION

Federal law restricts this device to sale by or on the order of a physician.

INFORMATION

For further product information, please contact Customer Service, Exactech, Inc., Gainesville, Florida 32653, USA. (352) 377-1140, (800) 392-2832 or FAX (352) 378-2617.

US and foreign patents pending

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Some components may not be currently available.
Please contact your sales representative for additional information.

CE 0123

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English

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