GENFlex2

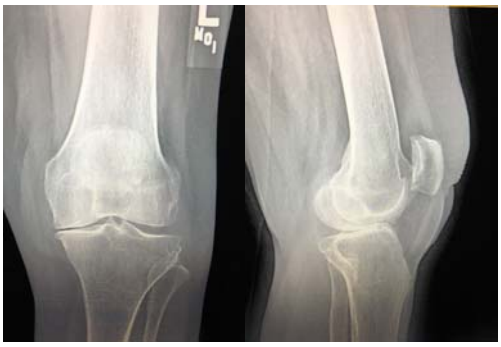
Surgical Technique

StelKast

Table of Contents

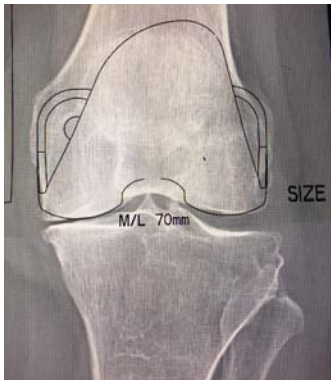
Preoperative Planning

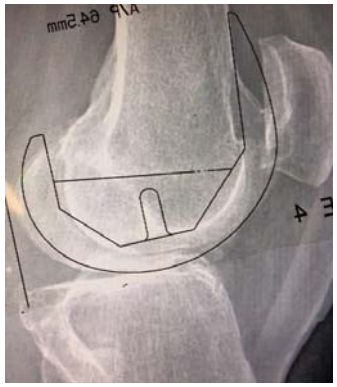
IMPORTANT NOTE: *All resection slots are designed for use with a .050" (1.27mm) thick saw blade, 19mm or less in width.*

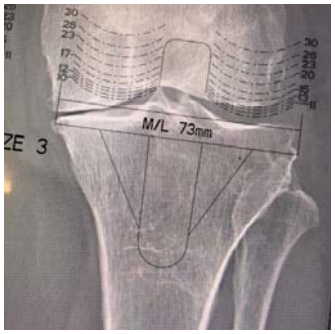


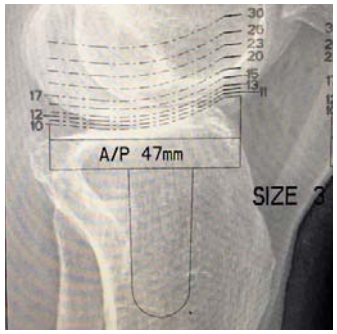
In order to assess bone stock and potential ligament instability, and to determine the mechanical and anatomical axes of the limb, preoperative long leg standing X-rays are recommended. The angle between the mechanical and anatomical axes is determined, assuring the distal femoral cut is perpendicular to the mechanical axis.

Femoral and tibial component size is estimated preoperatively by using lateral and anteroposterior (AP) view X-rays and radiographic templates. Selection of the appropriate size femoral and tibial components is critical to the restoration of normal knee kinematics and quadriceps function. The appropriate size components are confirmed intraoperatively.









Anterior Referencing Femoral Preparation

IMPORTANT NOTE: *All resection slots are designed for use with a .050" (1.27mm) thick saw blade,19mm or less in width.*

Either the tibia or the femur can be prepared first. Femoral preparation is presented here first.

Distal Femoral Resection

Prepare Femoral Canal

8mm IM Drill Bit

5 to 10 mm anterior to the intercondylar notch, use the 8mm IM Drill Bit to locate and enter the midline of the femoral canal. Over-ream the entry point to allow for adequate decompression of the medullary contents during insertion of the T-Handle IM Rod.

Insert the T-Handle IM Rod into the canal and remove.

T-Handle IM Rod

Anterior Referencing
Femoral Preparation (cont.)

10mm Distal Femoral Cut Block

Distal Femoral Resection Body

Distal Femoral Alignment Block

Assemble Distal Cut Guide and Insert into Femoral Canal

For anterior referencing a 10mm Distal Femoral Cut Block is provided. Assemble the 10mm Femoral Distal Cut Block to the Distal Femoral Resection Body.

Choose the appropriate Distal Femoral Alignment Block to match the pre-operatively determined valgus angle. A 5° Distal Femoral Alignment Block is provided as standard. Other options are available.

Assemble the 10mm Distal Femoral Cut Block and Distal Femoral Resection Body assembly to the Distal Femoral Alignment Block by inserting the two Distal Femoral Resection Body posts into the Distal Femoral Alignment Block holes. Assure that the appropriate (Left or Right) joint side marking is visible on the face of the Distal Femoral Alignment Block (LEFT SHOWN BELOW).

Insert the Distal Cut Guide Assembly into the femoral canal using the T-Handle IM Rod until the Distal Femoral Alignment Block is flush with the distal femur.

Distal Cut Guide Assembly

Position Femoral Distal Cut Block and Pin

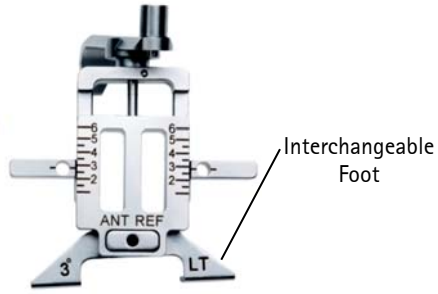
Set the 10mm Distal Femoral Cut Block flush against the anterior femur. Pin the 10mm Distal Femoral Cut Block to the femur using the holes labeled 0. The distal femoral resection depth may be checked with the Resection Locator Guide. If needed, the 10mm Distal Femoral Cut Block can be adjusted to take an additional 2mm of bone by moving the cut block proximally to the 2mm pin holes. Once the Distal Femoral Cut Block is in the correct position then place a pin in the oblique holes (X-pinholes) for additional stability.

Resect Distal Femur

Remove the T-Handle IM Rod from femoral canal. Remove the Distal Femoral Resection Body and Distal Femoral Alignment Block assembly from the 10mm Distal Femoral Cut Block pinned to the femur. Make the distal cut through the cut slot. Remove the 10mm Distal Femoral Cut Block and pins.

Anterior Referencing Femoral Preparation (cont.)

Sizing the Femur



Anterior Referencing A/P Sizer

Assemble the Anterior Referencing (AR) A/P Sizer

To set external or neutral rotation of the femoral component, either the interchangeable 3-degree "right" or "left"; or neutral foot should be placed on the Anterior Referencing (AR) A/P sizing guide.

Size the Femur

Place the AR A/P Sizer flush against the resected distal femur with the feet under the posterior condyles. Place the telescoping stylus slightly lateral to the midline on the anterior cortex. To avoid notching the anterior cortex, ensure the AR A/P Sizer remains flush against the distal femur and is not biased in flexion. The telescoping stylus may also be adjusted for the size indicated on the face of the AR A/P Sizer. If the AR A/P Sizer indicates between sizes, the smaller size is selected to avoid overstuffing the knee in flexion.

A/P Sizer Telescoping Stylus

Drill Holes for Anterior Referencing (AR) 4 in 1 Cut Block

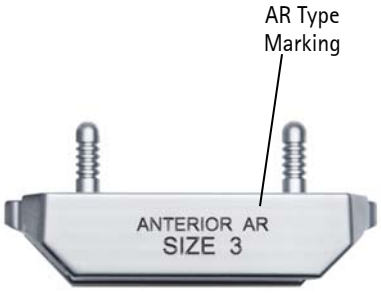
Use the AR A/P Sizer Drill Bit to drill through the AR A/P Sizer guide holes, which prepares the holes in the distal femur for the fixation pins on the corresponding AR 4 in 1 Cut Block. Remove the AR A/P sizer.

AR A/P Sizer Drill Bit

Anterior Referencing Femoral Preparation (cont.)

Anterior and Posterior Resections

Select the appropriate Anterior Referencing (AR) 4 in 1 Cut Block that corresponds to the size indicated by the AR A/P sizer. The medial/lateral (M/L) width of the AR 4 in 1 Cut Block corresponds to the M/L width of the femoral implant and can be used as another method to determine size.



AR 4 in 1 Cut Block—Anterior Face

The size and referencing type (AR) is indicated on the anterior face of the AR 4 in 1 Cut Block. Be sure to orient the AR 4 in 1 Cut Block accordingly.

Insert AR 4 in 1 Cut Block and Check Resections

Insert the AR 4 in 1 Cut Block into the prepared holes until flush against the distal femur. Insert the Resection Locator Guide through the anterior resection slot to assure an adequate cut without notching. Insert the Resection Locator Guide through the posterior resection slots to assure adequate bone is cut. To resect additional posterior bone, the AR 4 in 1 Cut Block can be down sized without taking additional anterior bone.


AR 4 in 1 Cut Block

Secure the AR 4 in 1 Cut Block to Distal Femur and Resect

Pin the AR 4 in 1 Cut Block to the femur using the M/L holes. Make the posterior and anterior cuts. The posterior chamfer and anterior chamfer cuts may be made now, or after checking flexion and extension gaps.

Remove the AR 4 in 1 Cut Block

Pull the pins and remove the AR 4 in 1 Cut Block from the prepared femur. If needed, a slap-hammer adapter can be used. Assemble the Cam Extractor Adapter to the Slap Hammer, insert into the AR 4 in 1 Cut Block extraction hole, give 1/2 turn to engage, and use the slap hammer to extract.

Posterior Referencing Femoral Preparation

IMPORTANT NOTE: *All resection slots are designed for use with a .050" (1.27mm) thick saw blade,19mm or less in width.*

Either the tibia or the femur can be prepared first. Femoral preparation is presented here first.

Distal Femoral Resection

Prepare Femoral Canal

8mm IM Drill Bit

5 to 10 mm anterior to the intercondylar notch, use the 8mm IM Drill Bit to locate and enter the midline of the femoral canal. Over-ream the entry point to allow for adequate decompression of the medullary contents during insertion of the T-Handle IM Rod.

Insert the T-Handle IM Rod into the canal and remove.

T-Handle IM Rod

Posterior Referencing
Femoral Preparation (cont.)

8 &10mm Distal Femoral Cut Block


Distal Femoral Resection Body


Distal Femoral Alignment Block

Distal Cut Guide Assembly

Assemble Distal Cut Guide and Insert into Femoral Canal

For Posterior referencing an 8 &10mm Distal Femoral Cut Block is provided. Assemble the 8 &10mm Femoral Distal Cut Block to the Distal Femoral Resection Body.

Choose the appropriate Distal Femoral Alignment Block to match the pre-operatively determined valgus angle. A 5° Distal Femoral Alignment Block is provided as standard. Other options are available.

Assemble the 8 &10mm Distal Femoral Cut Block and Distal Femoral Resection Body assembly to the Distal Femoral Alignment Block by inserting the two Distal Femoral Resection Body posts into the Distal Femoral Alignment Block holes. Assure that the appropriate (Left or Right) joint side marking is visible on the face of the Distal Femoral Alignment Block (LEFT SHOWN BELOW).

Insert the Distal Cut Guide Assembly into the femoral canal using the T-Handle IM Rod until the Distal Femoral Alignment Block is flush with the distal femur.

Position Femoral Distal Cut Block and Pin

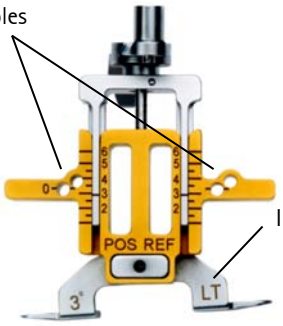
Set the 8 &10mm Distal Femoral Cut Block flush against the anterior femur. Pin the 8 &10mm Distal Femoral Cut Block to the femur using the holes labeled 0. The distal femoral resection depth may be checked with the Resection Locator Guide. Depending on surgeon preference and technique to match the flexion gap, either the 8 or 10mm cut slot is used. If needed, the 8 &10mm Distal Femoral Cut Block can be adjusted to take an additional 2mm of bone by moving the cut block proximally to the 2mm pin holes. Once the block is in the correct position then place a pin in the oblique holes (X-pinholes) for additional stability.

Resect Distal Femur

Remove the T-Handle IM Rod from femoral canal. Remove the Distal Femoral Resection Body and Distal Femoral Alignment Block assembly from the 8 &10mm Distal Femoral Cut Block pinned to femur. Make the distal cut through the appropriate 8 or 10mm cut slot. Remove the 8 &10mm Distal Femoral Cut Block and pins.

Posterior Referencing
Femoral Preparation (cont.)

Sizing the Femur



Posterior Referencing A/P Sizer

Assemble the Posterior Referencing (PR) A/P Sizer

To set external or neutral rotation of the femoral component, either the interchangeable 3-degree "right" or "left"; or neutral feet should be placed on the Posterior Referencing (PR) A/P sizing guide. The PR A/P Sizer has both 0 and 2mm drill holes. The 2mm drill holes allow for the corresponding PR 4 in 1 Cut Block to directly resect additional posterior and less anterior bone.

Size the Femur

A/P Sizer Telescoping Stylus

Place the PR A/P Sizer flush against the resected distal femur with the feet under the posterior condyles. Place the telescoping stylus slightly lateral to the midline on the anterior cortex. To avoid notching the anterior cortex, ensure the PR A/P Sizer remains flush against the distal femur and is not biased in flexion. The telescoping stylus may also be adjusted for the size indicated on the face of the PR A/P Sizer.

1/8" Drill Bit

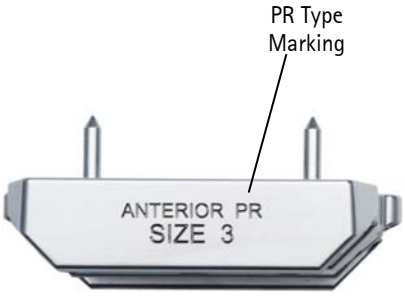
Drill Holes for Posterior Referencing (PR) 4 in 1 Cut Block

Use the 1/8" Drill Bit to drill through the appropriate 0 or 2mm PR A/P Sizer guide holes which prepares the holes in the distal femur for the fixation pins on the corresponding PR 4 in 1 Cut Block. Remove the PR A/P sizer.

Posterior Referencing
Femoral Preparation (cont.)

Anterior and Posterior Resections

Select the appropriate Posterior Referencing (PR) 4 in 1 Cut Block that corresponds to the size indicated by the PR A/P sizer. The medial/lateral (M/L) width of 4 in 1 Cut Block corresponds to the M/L width of the femoral implant and can be used as another method to determine size.

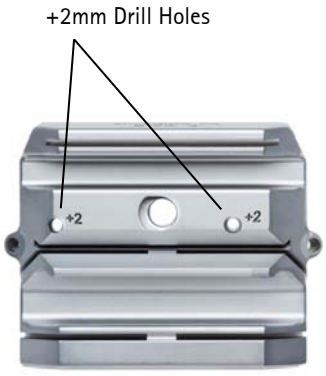


PR 4 in 1 Cut Block—Anterior Face

The size and referencing type (PR) is indicated on the anterior face of the PR 4 in 1 Cut Block. Be sure to orient the PR 4 in 1 Cut Block accordingly.

Insert PR 4 in 1 Cut Block and Check Resections

Insert the PR 4 in 1 Cut Block into the prepared holes until flush against the distal femur. Insert the Resection Locator Guide through the anterior resection slot to assure an adequate cut without notching. Insert the Resection Locator Guide through the posterior resection slots to assure adequate bone is cut. To resect additional anterior bone, or to down size the femoral component, the PR 4 in 1 Cut Block may be down sized without taking additional posterior bone. To resect less anterior bone and additional posterior bone, the PR 4 in 1 Cut Block may be moved anteriorly by drilling through the +2mm holes, removing the 4 in 1 Cut Block, and repositioning in the drilled holes.



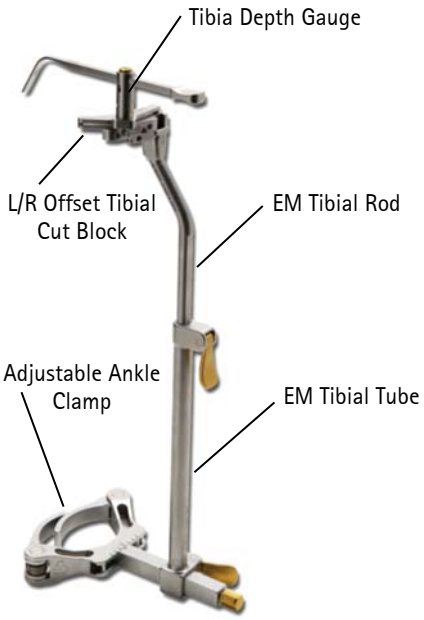
PR 4 in 1 Cut Block

Secure the PR 4 in 1 Cut Block to Distal Femur and Resect

Pin the PR 4 in 1 Cut Block to the femur using the M/L holes. Make the posterior and anterior cuts. The posterior chamfer and anterior chamfer cuts may be made now, or after checking flexion and extension gaps.

Remove the PR 4 in 1 Cut Block

Pull the pins and remove the PR 4 in 1 Cut Block from the prepared femur. If needed, a slap-hammer adapter can be used. Assemble the Cam Extractor Adapter to the Slap Hammer, insert into the PR 4 in 1 Cut Block extraction hole, give 1/2 turn to engage, and use the slap hammer to extract.



EM Tibial Alignment Guide Assembly

Positioning EM Tibial Alignment Guide and Offset Tibia Cut Block

Tibial Preparation

IMPORTANT NOTE: *All resection slots are designed for use with a .050" (1.27mm) thick saw blade,19mm or less in width.*

Assemble the Extramedullary (EM) Tibial Alignment Guide

- Attach the appropriate Left or Right (L/R) Offset Tibial Cut Block to the EM Tibial Rod. A 0° EM Tibial Rod is provided as standard. Other options are available.
- Insert the EM Tibial Rod into the EM Tibial Tube.
- Attach the EM Tibial Tube to the Adjustable Ankle Clamp.
- Assemble the Tibia Depth Gauge by selecting the appropriate 3 or 10mm Tibial Stylus to the Tibial Stylus Body. 3 and 10mm depth gage styluses are standard. Other optional depth gauge styluses are available.

Position Tibial Alignment Guide and Tibial Cut Block

It is recommended that the tibia be resected with a neutral tibial slope. The PS and CR tibial inserts incorporate a 6° posterior slope.

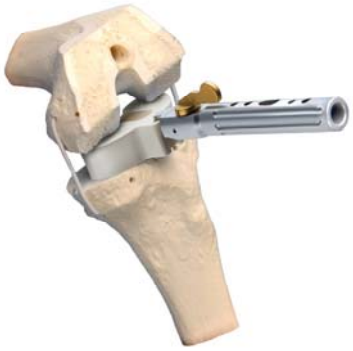
Place the Adjustable Ankle Clamp over the distal tibia so that the clamp is just proximal to the malleolus.

Proximally position the Offset Tibial Cut Block against the anterior tibia. Adjust the EM Tibial Alignment Guide assembly so that it is positioned parallel to the long axis of the tibia. Attach the Tibia Depth Gauge to the Offset Tibia Cut Block and determine the resection depth using either the 10mm stylus on the lowest level of the least affected area on the tibial plateau, or the 3mm stylus on the most affected area.

Secure Offset Tibial Cut Block to Proximal Tibia and Resect

Secure the Offset Tibial Cut Block with pins through the neutral holes. Insert the Resection Locator Guide through the resection slot to assure that enough tibial bone is resected. If the resection depth needs to be adjusted, the Offset Tibial Cut Block can be positioned +2mm. Once the block is in the correct position a pin may be placed through the oblique hole (X-pinhole) for additional stability. Make the proximal tibia cut through the slot. Pull the pins and remove the Offset Tibial Cut Block from the prepared tibia.

Note: The tibial tray and 10mm insert have a combined thickness of 10mm.



Flexion / Extension Block and
Tibial Trial Tray Handle

Flexion/Extension Gap Check

After making the tibial and femoral resections, optional Flexion/ Extension Blocks can be used to check if adequate bone was resected. Attach the 10mm Flexion/Extension Block to the Tibial Trial Tray Handle. If needed, additional spacer blocks can be added to the 10mm Flexion/Extension Block to facilitate measuring the flexion and extension gaps.

If the block is difficult to insert in both flexion and extension, consider resecting additional tibial bone. If the gap is uneven and (1) tight in flexion, consider resecting additional posterior femoral bone; or (2) tight in extension, consider resecting additional distal femoral bone.

If not done so during femoral preparation, the posterior chamfer and anterior chamfer cuts may be made now.

Trial Tibial Template
& Tibial Trial Tray Handle

Tibial Sizing and Positioning

CAUTION: The tibial tray size must be compatible with the tibial insert and matching femoral component size selected. Ensure compatibility of the tibial tray size with the tibial insert and femur size by referring to the Knee System Sizing Chart (see page 18).

Select the Trial Tibial Template size that provides the optimal proximal tibial bone coverage. The Tibial Trial Tray Handle can be assembled to the mating dovetail of the Trial Tibial Template to aid in placement on the resected tibia. To check alignment with the ankle, insert the alignment rod through the Tibial Trial Tray Handle. Evaluate coverage of the tibia.

After ensuring adequate coverage and rotation, Final TibialPreparation can be performed now or after Trial Reduction.

Trial Tibial Template
& Cemented Keel Drill

Trial Tibial Template
& Cemented Keel Punch

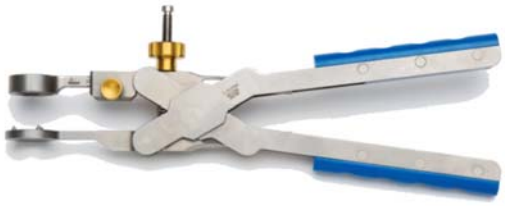
Final Tibial Preparation

Place the Trial Tibial Template onto the proximal tibia as determined during Tibia Sizing and Positioning. Use Headed Pins to secure the Trial Tibial Template to the proximal tibia. Insert the Cemented Keel Drill into the Trial Tibial Template. Drill until the stop is flush with the Trial Tibial Template. Remove the Cemented Keel Drill. Slide the appropriate Cemented Keel Punch through the Trial Tibial Template. Impact until the Cemented Keel Punch is fully seated. Remove the Cemented Keel Punch and pinned Trial Tibial Template.

Patella Preparation

Optional Patella Resection Guide

Three Peg Patella Drill &
Patella Drill Guide



Patella Clamp/Drill Guide &
Modular Drill Guide Head

Resect and Size Patella

The patella may be resected free hand or using an optional Patella Resection Guide. Using a caliper, measure the patella thickness by referencing the highest point of the articular surface. The patella should measure this thickness when the implant is in place. Resect the patella. It is suggested that a minimum of 10mm of patellar bone should remain after resection. Patella Drill Guides for each diameter size are provided to evaluate coverage and also indicate the thickness of each size included here for reference.

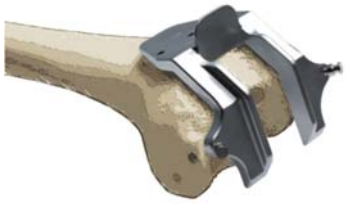
Diameter Size	Thickness
26mm	7mm
29mm	7mm
32mm	8mm
35mm	8mm
38mm	10mm
41mm	11mm

Prepare Patella

Select the appropriate size Patella Drill Guide, place on the resected patella. The implant peg holes are drilled using either the Patella Drill Guide or the modular Patella Drill Guide Head assembled to the Patella Clamp/Drill Guide. Use the 3 holes in the triangular pattern for the 3-peg patella, or the 1 center hole for the optional single peg patella, with the corresponding Three Peg Patella Drill or optional Single Peg Patella Drill.

Note: All diameter patellae are interchangeable with all femur sizes.

Box Cut (PS Knee Only)



PS Box Cut Guide

Position PS Box Cut Guide and Pin

Place the appropriate size PS Box Cut Guide corresponding to the size PS femur selected onto the prepared femur. Determine the medial/lateral (M/L) position of the PS Box Cut Guide. The M/L distance between the distal pin holes corresponds to the implant M/L width. Use this reference to aid in determining the final position of the PS femur. Secure the PS Box Cut Guide with pins through the distal pin holes. Pins may also by placed through one of the anterior holes for additional stability.

Resect Femur for PS Box

Make the box cut with a narrow oscillating saw. Remove the PS Box Cut Guide and pins.

Trial Reduction

Place the selected size Trial Femur onto the prepared femur. A Femoral Inserter/Extractor may be used to assist in positioning. Insert the selected size and thickness Trial Tibial Insert into the selected size Trial Tibial Template.

CAUTION: Ensure compatibility of the tibial tray size with the tibial insert and femur size by referring to the Knee System Sizing Chart (see page 18).

Position the selected size Patellar Trial. Perform the trial reduction and check for the following:

- Stability in flexion and extension
- Range of motion
- Patella tracking

Make any necessary soft tissue releases at this time.

Final Femur Preparation

CR Trial Femur & CR Condyle Peg Drill

After trial reduction, with the selected size CR or PS Trial Femur in the correct medial/lateral position, the implant condyle peg holes are drilled into the distal femur through the holes in the CR or PS Trial Femur using the corresponding CR or PS Condyle Peg Drill.

PS Condyle Peg Drill

Implant Selection and Implantation

Implant Selection

Select the implants corresponding to the trials used during Trial Reduction. Remove the trial components and begin to construct the final implants.

CAUTION: The femoral component size must match the size of the tibial insert. Ensure compatibility of the tibial insert size with the tibial tray size by referring to the Knee System Sizing Chart (see page 18).

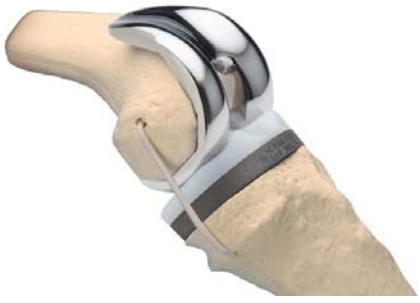
Packaging of the implants is color coded to assist in determining size interchangeability. The color coding of the femur, insert, and tibial tray must match.

All diameter patellae are interchangeable with all femur sizes.

Tibial Tray Impactor

Implantation

Apply cement to the components. To assist in positioning the femoral implant a Femoral Inserter/Extractor may be used. Assemble the femoral implant to the Femoral Inserter/Extractor and impact the implant to the prepared bone. Secondary 3 in 1 (PS) and 2 in 1 (CR) Impactors are also provided. Using the Tibial Tray Impactor impact the tibial tray implant to the prepared tibia. Use the Patella Clamp/Drill Guide and modular cementing head to cement the all-poly patella in place. Remove all excess cement.



Once the cement is cured, a trial reduction can be performed with a trial insert to verify the correct thickness.

Ensure that the tibial tray is clean and free of soft tissue that could prevent the tibial insert from locking. Slide the tibial insert from the anterior to posterior until the posterior tabs of the tibial insert engage the posterior undercuts of the tibial tray. With finger pressure, press the anterior edge of the tibial insert to engage the locking mechanism. (If an impactor is used, avoid damaging the locking mechanism by lightly tapping the impactor.) Complete seating of the tibial insert is verified by circumferential inspection of the tibial tray.

Close the incision using standard techniques.

Knee System Sizing Chart

Femur		Insert		Tibia Implant
Black 1	→	Black 1	→	Tibia (1T-1F) Tibia (2T-1F)
Bone 1.5	→	Bone 1.5		
Blue 2	→	Blue 2	→	Tibia (1T-2F) Tibia (2T-2F) Tibia (3T-2F)
Yellow 2.5	→	Yellow 2.5		
Brown 3	→	Brown 3	→	Tibia (2T-3F) Tibia (3T-3F) Tibia (4T-3F)
Red 3.5	→	Red 3.5		
Green 4	→	Green 4	→	Tibia (3T-4F) Tibia (4T-4F) Tibia (5T-4F)
Orange 4.5	→	Orange 4.5		
Purple 5	→	Purple 5	→	Tibia (4T-5F) Tibia (5T-5F) Tibia (6T-5F)
Gray 6	→	Gray 6	→	Tibia (5T-6F) Tibia (6T-6F)

Product Specifications

- Implant designs allow the freedom and range of motion expected by today's active patients
- 10 femoral sizes address diverse patient population
- Implant fit optimized using StelKast's extensive bone database combined with advanced simulation and virtual implantation
- Insert thicknesses in 1mm increments for precision gap balancing
- EX*p* Blended Vitamin E polyethylene options for tibial inserts and patella components
- Anterior flange angle enables downsizing of femur for gap balancing while reducing the incidence of femoral notching
- Comprehensive total knee system allows efficient flow from primary to revision knee conversion
- Multiple instrumentation options accommodate various surgical techniques

Catalog #	Description	Offerings
SC3749	Posterior Stabilized (PS) Femur, Left	Sizes 1*, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6
SC3750	Posterior Stabilized (PS) Femur, Right	Sizes 1*, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6
SC3751	Cruciate Retaining (CR) Femur, Left	Sizes 1*, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6
SC3752	Cruciate Retaining (CR) Femur, Right	Sizes 1*, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6
SC3753	PS Insert	Sizes 1* thru 6 10, 11, 12, 13, 15, 17, 20, 23*, 26*, 30*mm
SC3754	CR Insert	Sizes 1* thru 6 10, 11, 12, 13, 15, 17, 20mm
SC3802	EX*p* PS Insert	Sizes 1* thru 6 10, 11, 12, 13, 15, 17, 20, 23*, 26*, 30*mm
SC3803	EX*p* CR Insert	Sizes 1* thru 6 10, 11, 12, 13, 15, 17, 20mm
SC3915	CR Ultracongruent Insert	Sizes 1* thru 6 10, 11, 12, 13, 15, 17, 20, 23*, 26*, 30*mm
SC3916	EX*p* CR Ultracongruent Insert	Sizes 1* thru 6 10, 11, 12, 13, 15, 17, 20, 23*, 26*, 30*mm
SC1584	Tibial Tray	1T1F, 1T2F, 2T1F, 2T2F, 2T3F, 3T2F, 3T3F, 3T4F, 4T3F, 4T4F, 4T5F, 5T4F, 5T5F, 5T6F, 6T5F, 6T6F
SC1591	3 Peg Patella	26, 29, 32, 35, 38, 41mm
SC1592	1 Peg Patella	26, 29, 32, 35, 38, 41mm
SC3454	EX*p* 3 Peg Patella	26, 29, 32, 35, 38, 41mm
SC3426	EX*p* 1 Peg Patella	26, 29, 32, 35, 38, 41mm

* *Indicates Special Order.*

Indications for Use

GENERAL PRODUCT INFORMATION

Through the advancement of partial and total knee joint replacement, the surgeon has been provided with a means of restoring mobility, correcting deformity, and reducing pain for many patients. While the prostheses used are largely successful in attaining these goals, it must be recognized that they are manufactured from metal and plastic materials and that any joint replacement, therefore, cannot be expected to withstand activity levels and loads as would normal healthy bone. In addition, the system will not be as strong, reliable, or durable as a natural human joint.

INDICATIONS FOR USE

Stelkast Company knee implant components are indicated for single use only in skeletally mature Individuals undergoing reconstruction of severely disabled and/or very painful joints. Stelkast Knee System components are indicated for total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis, and/or post-traumatic degenerative problems, revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present, and for cemented use only.

CONTRAINDICATIONS

Stelkast Company knee implant components are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, patients without sufficient soft tissue integrity to provide adequate stability, muscle laxity or inadequate soft tissue for proper function and healing, any pathological conditions that would interfere with the performance of the system and in patients with either mental or neuromuscular disorders that do not allow control of the affected joint, and in patients whose weight, age or activity level might cause extreme loads and early failure of the system.

WARNINGS AND PRECAUTIONS

Familiarity with and attention to appropriate surgical technique for knee joint arthroplasty and the Stelkast implant system is essential for success of the procedure. Improper position of the components could result in dislocation. Only surgeons who have reviewed the literature regarding knee surgery and have had training in the technique should utilize the device. Patient selection is based on age, bone stock and size. The surgeon or his designee should instruct patients in the limitations of the prosthesis, and these patients should be taught to govern their activities accordingly. Patient lifestyles must be evaluated by the physician, and patient properly advised of any required modifications.

Knee implant components must not be reused. The surgeon must not allow damage to polished bearing surfaces because this may accelerate wear of the components. Any alteration or damage to a component may reduce fatigue strength and could result in failure under load. Any prostheses so damaged must not be used.

Components of Stelkast Company knee implants should not be used with those of another manufacturer since articular and dimensional compatibility cannot be assured.

The Stelkast knee implant has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Stelkast knee implant in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Indications for Use (cont.)

ADVERSE EVENTS

As with all knee joint implant systems, potential adverse effects include infection, loosening of the components, breakage, bending or disassembly of the components, or change in position of the components. There have been reports of sensitivity reactions to the implant components. Other potential adverse effects of knee implant joint surgery include neurovascular damage, dislocation, thromboembolic disease, component failure and wear debris and other less common adverse effects. On rare occasions, amputations have been necessary.

STERILITY AND HANDLING

Each Stelkast Company knee implant component is supplied sterile in double sealed containers maintaining double sterile barriers. If the seals or containers are breached, then the component should not be used. The components are not represented to be "pyrogen-free."

Metal parts as well as polyethylene (UHMWPe) parts and/or components containing polyethylene are supplied exposed to a minimum of 2.5 Mrad of gamma irradiation or Ethylene Oxide sterilization and must be kept unopened in the double protective packaging until implantation. The sterilization method used is listed on the respective component label. The sterile container is to be checked for possible damage. Do not use any component if the packages have been breached.

② **Resterilization by any method is ruled out.**

Care should be utilized in the handling of the components to minimize contamination of the component surfaces. Do not allow porous surfaces to come in contact with cloth or other fiber releasing materials. In using cement for fixation, the surgeon should use care to ensure complete cement support on all parts of the prosthesis embedded in bone cement.

UTILIZATION AND IMPLANTATION

Selection of Stelkast Company knee implant components depends on the judgment of the surgeon with regard to the relationship to the requirements of the patient. The surgeon should become thoroughly familiar with the technique of implantation of the prostheses by: (1) appropriate reading of the literature, and (2) training in the operative skills and techniques required for knee joint arthroplasty surgery.

MATERIALS USED

The materials used are listed on the respective product label.

INFORMATION

For any further information, please contact the supplier. Please be sure to refer to the Catalog Number designated with REF.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Cleaning and Sterilization of StelKast Instruments

DESCRIPTION

Stelkast reusable surgical instruments are designed for durability and are produced from stainless steel and/or polymeric materials. Surgical instruments are non-sterile and must be cleaned and sterilized before each use. Instrument cases are produced from aluminum or polymeric materials and are provided to hold surgical instrumentation in place and for protection during handling and storage. Instruments cases also serve to facilitate sterilization of instrument sets. The cases are perforated to allow sterilization of the contents to occur in a steam autoclave utilizing a sterilization cycle and drying cycle that has been validated by the user facility. Instrument cases do not provide a sterile barrier and must be used in conjunction with a sterilization wrap to maintain sterility.

Stelkast has verified through laboratory testing that its instrument cases are suitable for the specific sterilization methods and cycles for which they have been tested. Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in a particular health care facility. Testing should be conducted in the health care facility to ensure that conditions essential to sterilization can be achieved. Stelkast does not accept responsibility or liability arising from a lack of cleanliness or sterility of any medical devices supplied by Stelkast that should have been properly cleaned and/or sterilized by the end user.

CARE AND HANDLING OF INSTRUMENTS

Surgical instruments and instrument cases are susceptible to damage for various reasons including prolonged use, misuse, rough or improper handling. Care must be taken to avoid compromising their exacting performance. To minimize damage, the following should be done:

a) Only use an instrument for its intended purpose.
b) Inspect instrument cases and instruments for damage when received and after each use and cleaning. Incompletely cleaned instruments should be re-cleaned.
c) After cleaning, any disassembled instruments should be reassembled and placed in their proper locations in the instrument case where appropriate.
d) Instruments in need of repair should be returned to Stelkast. Stelkast does not accept responsibility or liability for any instrument or component part upon which repairs or modifications have been made or attempted except as performed by Stelkast. Instruments returned to Stelkast should be cleaned and sterilized prior to shipment. ANSI/AAMI ST35 Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings provides guidance for return.

CLEANING AND DECONTAMINATION

Surgical instruments should be cleaned prior to initial sterilization and as soon as possible after use. Do not allow blood or debris to dry on the instruments. If cleaning must be delayed, place groups of instruments in a covered container with appropriate detergent or enzymatic solution to delay drying. Clean all instruments whether or not they were used or inadvertently came into contact with blood or saline solution. The effectiveness of the decontamination processes depends on prior removal of gross soil from the instrument. Gross soil should be removed under running water using a mechanical aid such as a brush with rigid nylon bristles. Care should be taken to avoid splashing and generating aerosols by holding instruments below the surface of the water in a sink into which water is running and continuously draining. Instruments should not be held under a running tap, as this is likely to result in splashing. Individuals cleaning instruments should be properly gowned with appropriate gloves and personal protective equipment including goggles. Care should be taken to avoid penetrating or cutting injuries. Particular attention should be taken to remove debris from all cannulations and blind holes in the instruments.

Cleaning and Sterilization of StelKast Instruments (cont.)

The cleaning process must be conducted so that all parts of the surgical instrument are exposed as permitted by design. The majority of surgical instruments and trial components are constructed in such a way that they do not require disassembly. Some of the more complex instruments are made of several components and these should be disassembled into their individual parts prior to decontamination. In most cases the method of disassembly is self evident. Loosen and/or disassemble instruments with removable parts.

Ultrasonic Cleaners can be used with hot water per manufacturer's recommended temperature (usually 90°-140°F or 32°-60°C) and specially formulated detergents. Follow manufacturer's recommendations for proper cleaning solution formulated specifically for ultrasonic cleaners. Be aware that loading patterns, instrument cases, water temperature, and other external factors may change the effectiveness of the equipment.

Washer-Decontamination Equipment will wash and decontaminate instruments. Complete removal of soil from crevices and serrations depends on instrument construction, exposure time, pressure of delivered solution, and pH of the detergent solution, and thus may require prior brushing. Be familiar with equipment manufacturers' use and operation instructions. Be aware that loading, detergent, water temperature, and other external factors may change the effectiveness of the equipment.

It is recommended that instruments, disassembled as required, be decontaminated using an automatic washer-disinfection unit utilizing thermal disinfection. This should preferably be of the ultrasonic or continuous tunnel process type. The cabinet type is an acceptable alternative if a continuous process machine is not available. (Typical initial cleaning temperature is at or below 95° F (35°C), followed by a hot water disinfectant rinse where the surface temperature of the instruments should reach a minimum temperature of 160°F (71°C) for a minimum of 3 minutes, 176°F (80°C) for a minimum of 1 minute, or 194°F (90°C) for 1 second.) Compatible detergents and rinse aids may be used as recommended by the manufacturer of the washer-disinfection unit. These detergents and/or rinse aids, however, should be of neutral or near neutral pH. Excessively acidic or alkaline solutions may corrode aluminum instruments or instrument cases.

STERILITY

Unless otherwise indicated, instruments are NOT STERILE and must be thoroughly cleaned and sterilized prior to use. Stelkast instruments can be steam autoclaved. Repeat processing has minimal effects on instrumentation. Below is a recommended minimum cycle for steam sterilization that has been validated by Stelkast under laboratory conditions. Validation was conducted on instrument cases that were double-wrapped in an FDA cleared non-woven medical grade wrapping material.

Steam Sterilization		
Cycle Type	Parameter	Minimum Set Point
Pre-Vacuumed Sterilizer 270°-275°F (132°-135°C)	Exposure Temperature	270°F (132°C)
	Exposure Time	4 minutes
	Drying Time	20 minutes

These recommendations are consistent with AAMI ST79 Table 5 guidelines and have been developed and validated using specific equipment. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your facility. Individual user facilities must validate the cleaning and autoclaving procedures used on-site, including the on-site validation of the recommended minimum cycle parameters.

Cleaning and Sterilization of StelKast Instruments (cont.)

Surgical instruments may be autoclaved using a full cycle. Instruments that have been used in a surgical environment should be thoroughly cleaned prior to autoclaving. Use of ANSI/AAMI ST46 Steam Sterilization and Sterility Assurance in Health Care Facilities is recommended.

RESPONSIBILITIES OF THE USER

Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material is suitable for use in sterilization processing and sterility maintenance.

The health care facility is responsible to insure that conditions essential to safe handling and decontamination can be achieved. ANSI/AAMI ST35 Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings provides guidelines for design and personnel considerations, immediate handling of contaminated items and transportation, decontamination processes, servicing, repair, and process performance.

Users should conduct testing in the health care facility to ensure that conditions essential to sterilization can be achieved and that specific configuration of the container contents is acceptable for the sterilization process and for the requirements at the point of use. ANSI/AAMI ST33 Guidelines for the Selection and Use of Reusable Rigid Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities covers the selection and use of reusable rigid sterilization container systems. Guidelines are provided by this standard for cleaning and decontamination, preparation and assembly, sterilizer loading and unloading, matching the container system to the appropriate sterilization cycle, quality assurance, sterile storage, transport, and aseptic use.

WARNINGS AND PRECAUTIONS

Use extreme caution to avoid injury when handling sharp instruments. Consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.

Unless otherwise indicated, instrument sets are NOT sterile and must be cleaned and sterilized prior to use. Instruments should NOT be flash-autoclaved inside the instrument case. Flash-autoclaving of individual instruments should be avoided. Always double-wrap instrument cases in an FDA-cleared non-woven medical grade wrapping material. Unwrapped instrument cases DO NOT maintain sterility.

STORAGE

Instrument cases that have been processed and wrapped to maintain sterility should be stored in a manner to avoid extremes in temperature and moisture. Care must be exercised in handling of wrapped cases to prevent damage to the sterile barrier. The health care facility should establish a shelf life for wrapped instrument cases based upon the type of sterile wrap used and the recommendations of the sterile wrap manufacturer. The user must be aware that maintenance of sterility is event-related and that the probability of occurrence of a contaminating event increases over time, with handling, and whether woven or non-woven materials, pouches, or container systems are used as the packaging method.

Notes

www.stelkast.com

StelKast FLEXIBILITY IN MOTION℠

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