Note: Please refer to the Product Insert (Instructions for Use) for important information pertaining to the product description and handling, indications for use, warnings and precautions, possible adverse effects, and contraindications.
Indications for Use:
The APEX Knee™ System is intended for use as a primary or revision total knee replacement. This prosthesis may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed

The porous coated femoral component may be used cemented or uncemented (biological fixation). The porous coated tibial baseplate component may be used uncemented (biological fixation). All other femoral, tibial baseplate, and patellar components are indicated for cemented use only.

The APEX Knee Modular System Tibial Augments are intended to be bolted to the Tibia Baseplate and cemented to the prepared tibia. The APEX Revision™ Knee System femoral augments are intended to be bolted to the femoral component and cemented to the prepared femur.

Contraindications
Absolute contraindications include:

- Infection or sepsis or osteomyelitis;
- Insufficient bone structure or quality which may affect the stability of the implant;
- Rapid joint destruction or bone absorption;
- Skeletal immaturity;
- Muscular, ligamentous, neurological, vascular deficiencies or poor skin coverage, which may compromise the affected extremity;
- Alcoholism or other addictions;
- Sensitivity to the implant materials;
- High levels of physical activity (e.g. competitive sports, heavy physical labor)
- Obesity can produce loads on the prosthesis, which can lead to fixation failure or prosthesis breakage or fracture

Relative contraindications include:

- Uncooperative patient or a patient with neurological disorders and incapable of following instruction;
- Metabolic disorders which may impair bone formation or bone quality;
- Distant foci of infection.
PREOPERATIVE PLANNING

High-quality templates and radiographs are essential for accurate preoperative planning. The templates are overlaid on the x-ray films, in order to approximate the size of the femoral component to be implanted.

The size of the femoral component in lateral view is of particular importance since under-sizing may result in laxity in flexion as well as greater potential for notching of the anterior femoral cortex. Over-sizing can create tightness in flexion and increase the potential for increased excursion of the quadriceps mechanism.

In addition, given the particular configuration of concordances of the APEX Knee™ System, the size of the polyethylene tibial insert must always coincide with the numerical size of the femoral component (including the “plus” sizes). This allows high levels of joint conformity, minimizing stress on the insert and reducing polyethylene wear. For this reason, great care must be taken when selecting the size of the tibial insert to be implanted. The following chart describes which tibial inserts are used with each femoral size in the APEX Revision™ Knee System (Fig. 1).

The APEX Revision Knee System offers the ability to use femoral stems for additional stability. X-ray templates can be used to predetermine the potential length and diameter of the stem to fit the femoral canal.

Augments are also available to cover any gaps in femoral coverage between the implant and bone. If there is a measurable gap between the distal or posterior aspect of the bone and implant, augments of 5, 10, and 15mm thicknesses are available to better fit the component.

<table>
<thead>
<tr>
<th>Femur</th>
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fig. 1
**FEMORAL PREPARATION**

**Joint Line Positioning**
Accurate positioning of the joint line and precise femoral component rotation are essential to ensure the success of revision knee arthroplasty. The Joint Line Handle and attached Joint Line Rod are key in placing the joint line in the appropriate position.

Once both components have been attached, as shown in Figures 2a and 2b, position the inner aspect of the Joint Line Handle at the most distal portion of the condyles of the femoral component to be removed.

*Note:* Care must be taken to prevent hyperextension or flexion of the assembly as this could shift the position by a few millimeters.

From the frontal plane, femoral rotation must be established by aligning the Joint Line Handle with the epicondyles.

The assembly must now be adjusted in such a way that the tip of the Short Joint Line Rod is placed on the anterior femoral cortex (Fig. 3).

Finally, a reference mark must be made at the point at which the Short Joint Line Rod hits the cortex (Fig. 4).

If there is no implant in place, the joint line may be identified and marked according to the guide on the following page.
Femoral Distal Alignment Guide

Revision Distal Cuts
1. Establish Joint Line
2. Mark Femur
3. Using Femur Mark, Locate cutting guide
4. Make Distal Cut

Primary Distal Cuts
Use adapter KS-67049, Rest Alignment Guide on Femur Make Distal Cut
FEMORAL PREPERATION

Removal of the Femoral Component and the Tibial Insert

Remove the femoral component and tibial insert and perform a debridement of the distal femur.

Femoral Sizing

In revision surgery, the posterior condyles cannot usually be used as a reference to determine the size of the femoral component to be implanted. This precludes the use of traditional femoral sizing techniques and makes it necessary to resort to an instrument that allows precise sizing.

Thus, attach the Revision Femur Sizer to the Universal Handle (Figs. 5a and 5b) and superimpose it on the explanted femoral component in order to gain an approximate idea of the size of the revision component to be implanted (Fig. 6).

Alternatively, the Femur Sizer can be superimposed on the remaining femoral bone (Fig. 7).
Canal Preparation

In revision surgery, the intramedullary canal is often the only landmark available to guide instrument placement. For this reason, the canal must be reamed at the beginning of the procedure.

Note: The intramedullary canal can be reamed either manually or using a power tool, depending on the surgeon's preference.

It is recommended to start reaming with the 8mm reamer. Reamer diameter should be progressively increased until stable contact is made with the femoral cortex (Fig. 8).

Straight femoral stems are available in lengths of 75, 100, and 150 mm. Offset stems are available in 75, 100, 125, and 150 mm. These lengths are indicated by means of circular markings on the shaft of each of the reamers (Fig. 9).

Once the desired diameter has been achieved, reaming must cease and the last reamer used must be left inside the intramedullary canal (Fig. 10).

Note: Lavage and suction of the intramedullary canal may reduce the incidence of fat embolism.
**Distal Cut**

Prior to distal femoral resection, slide the 6 Degree Bushing on the Femoral Locking Device. The inscriptions “Right” or “Left” on the Bushing (on the superior face) must coincide with the side being operated (Fig. 11a-Fig. 11c).

Attach the Revision Distal Cutting Block (Fig. 12a) to the Femoral Locating Device, using the two-guide-peg locking system and a clamp (Fig. 12b).
FEMORAL BONE CUTS

Slide the instrument assembly through the 6 Degree Bushing on the Reamer located inside the femoral canal (Fig. 13a and 13b).

Attach the Short Joint Line Rod to the upper portion of the Femoral Locking Device, so that the tip of the Joint Line Rod is aligned with the marking made on the anterior cortex during Joint Line Positioning (Fig. 14).

In the presence of femoral bone defects, or if there is a hip prosthesis in place, it may be necessary to perform an extramedullary alignment check. To do this, attach a Universal Handle to the upper portion of the Revision Distal Cutting Block, and introduce the Alignment Check Rod through the hole at the most distal portion of the holes in the Cutting Block. The cutting Block is deemed to be correctly oriented when the Alignment Check Rod is directed toward the patient’s femoral head (Fig. 15).
Once correct alignment is assured, secure the Revision Distal Cutting Block by driving two pins through the holes located along the central line indicated as "0". Next, slide the Cutting Block until you come as close as possible to the bone (Fig. 16).

**Note:** For additional stability the Revision Distal Cutting Block has holes for converging pins intended to minimize Cutting Block motion during femoral resection.

In order to determine the amount of bone to be resected, insert the Angel Wing through the slots of the Revision Distal Cutting Block (Fig. 17).

Remove the whole assembly with the exception of the Revision Distal Cutting Block and carry out the required distal femoral cut (Fig. 18).
FEMORAL BONE CUTS

The Revision Distal Cutting Block allows the use of a minimal standard resection to refresh the bone surface (Fig. 19a). The Block is also provided with a series of slots for preparation of the bone surfaces in cases where 5, 10 or 15 mm Distal Augments are needed (Fig. 19b).

**Note:** To maximize accuracy of the bone cut, the thickness of the saw blade used must match the thickness of the slot (1.27 mm or 0.049 inches).

The height of the cut may be adjusted in 1 mm intervals from -2 to +4, with respect to the initial 0 mm position. These adjustments can be made by simply moving the Cutting Block to different hole locations. Figures 20a and 20b exemplify the change from position 0 mm to position +1 mm.

**Note:** Once the cut has been completed, make sure that the resected surfaces are coplanar. If necessary, smoothing of the resected surfaces should be performed.

Remove the Revision Distal Cutting Block. If the reamer has been removed, it should be reinserted into the intramedullary canal.
Femoral 4-in-1 Cut Block

Attach the 6°x0 mm Femoral Alignment Locating Guide to the corresponding Revision 4 in 1 Cutting Block so that, on the anterior face, the inscriptions "Right" or "Left" on the 6°x0 mm Femoral Alignment Locating Guide coincide with the side being operated (Figs 21a and 21b).

In cases where resections have been performed for Distal Femoral Augments, Cutting Block stability is ensured by attaching 5, 10 or 15 mm Augment Spacers, as appropriate, to the posterior aspect of the Block (Fig. 22a-Fig. 22d).

The assembly is placed on the reamer located in the intramedullary canal, through the 6°x0 mm Femoral Alignment Locating Guide (Figs. 23a and 23b), making sure that, on the anterior face, the inscriptions "Right" or "Left" coincide with the side being operated (Fig. 23c).
Offset Stem Positioning

If appropriate A/P location cannot be achieved using the Neutral (6°x0 mm) Femoral Locating Guide, an Offset Locating Guide (6°x2 mm or 6°x4 mm) must be used. The Offset Locating Guides can be adjusted by pushing in on the adjustment knob and turning the knob until the Cutting Block is positioned correctly. (Fig. 24a)

Releasing the knob will lock the guide into 1 of 12 positions. An Angel Wing can be placed through the anterior saw capture to verify no notching will occur. (Fig. 24b)

This position of the knob must be noted as it will be referenced when positioning the Revision Box Cutting Guide, as well as trialing and final stem positioning.
FEMORAL BONE CUTS

Femoral Rotation

Prior to performing the cuts, femoral rotation must be determined. To do this, the surgeon must visually identify the transepicondylar axis and align the Cutting Block with it.

An alternative is to attach the Universal Handle by way of the Revision Femur Alignment Tower (Fig. 25a) to the superior aspect of the Revision 4 in 1 Cutting Block. The Alignment Check Rod is inserted through one of the holes in the Universal Handle.

The Cutting Block will be adequately aligned if the Alignment Check Rod is directed towards the center of the femoral head (Fig. 25b).

Once femoral rotation has been established and the Cutting Block has been accurately oriented, the Block can be secured with two pins.

Note: Should the stability of the Cutting Block need to be reinforced, attach two Universal Handles to it, one on each side (Fig. 26).
4-in-1 Femoral Cuts

With the Revision 4 in 1 Cutting Block in place, remove both the Femoral Alignment Locating Guide and the Reamer.

The existence of areas of bone loss must be identified. In the absence of bone defects, refresh the bone through the slots (Fig. 27a).

If bone loss affects just one of the posterior condyles, perform the bone resection through the slots for 5 mm or 10 mm Augments, on the appropriate side (Fig. 27b).

If bone loss affects both posterior condyles, make a cut on both sides of the Cutting Block through the appropriate slots in order to refresh both bone surfaces.
FEMORAL BONE CUTS

4-in-1 Femoral Cuts
Perform the anterior femoral cut (Fig. 27c), as well as those corresponding to the anterior (Fig. 27d) and posterior (Fig. 27e) chamfers through the dedicated slots on the Cutting Block.

Note: To maximize resection accuracy, the thickness of the saw blade used must match the thickness of the slot (1.27 mm or 0.049 inches).
CONICAL REAMING

Attach the Conical Reamer Tower to the anterior aspect of the Cutting Block (Fig. 28a), so that from the surgeon’s position the inscriptions “Right” or “Left” on the Conical Reamer Tower coincide with the side being operated (Fig. 28b).

Note: The Conical Reamer is provided with a series of circular markings on the shaft, which indicate the reaming depth required according to the size of the femoral component used (Fig. 29).

Introduce the Conical Reamer and start reaming through the Conical Reamer Tower until the circular marking on the shaft coincides with the size of the femoral component to be implanted (Fig. 30).

Note: The APEX Revision™ Knee System offers the possibility to complete this stage once the femoral box resection has been finalized.
FEMORAL BOX PREPARATION

a.) If conical reaming has been performed, remove the Revision 4 in 1 Cutting Block and Conical Reamer Tower, leaving the Conical Reamer in place.

Attach the Conical Reamer Tower to the Revision Box Cutting Guide, slide the assembly through the Conical Reamer and fix the Guide in place (Page 24).

b.) If conical reaming has not yet been carried out, remove the Revision 4 in 1 Cutting Block.

The Revision Box Cutting Guide will be used to prepare the femoral box cut. The same Femoral Alignment Locating Guide (Neutral, +2 mm, or +4 mm) used for the 4:1 cuts is attached to the Box Cutting Guide (Fig. 31a and Fig. 31b) and the assembly is slid along the reamer (Fig. 32).

If an Offset Locating Guide was used, be sure that the rotation position is consistent with prior steps.
The Revision Box Cutting Guide must now be secured by placing pins through the holes on the medial and lateral sides of the distal aspect of the Guide (Fig. 33).

Note: If use one or two Distal Femoral Augments are required, Augment Trials can be assembled to the Guide's posterior face (Fig. 34).
The femoral cuts are performed with the help of an oscillating saw, using the Revision Box Cutting Guide (Fig. 35a-Fig. 35c).

**Note:** On its medial and lateral sides, the Revision Box Cutting Guide is provided with three slots for the 5, 10 or 15 mm Distal Femoral Augments. The Angel Wing can be inserted through the slots in order to ascertain that the cuts have been performed at the same height as the augment to be implanted. If this is not the case, the cuts must be cleaned up.
FEMORAL BOX PREPARATION

It is possible to attach the Conical Reamer Tower to the anterior portion of the Revision Box Cutting Guide, if the Conical Reaming had yet to be performed. (Fig. 36a-Fig. 36d).

PREPARATION OF THE PATELLA

When required, patellar preparation should follow the procedure in the APEX Knee™ System Surgical Technique.
Femoral Trial Components

The Revision Femur Trial makes it possible to assess the fit and function of the Revision Femoral Component, the Femoral Stem and the Distal and Posterior Femoral Augments.

Choose the Revision Femur Trial of the same size as previously determined, that corresponds to the knee to be operated. (Fig 37a & 37b)

Note: It must be remembered that both the trial and final Distal Augments are grouped by operated side. Augments that bear the indication “Left” or “L”, must be used for left knees, either on the medial or the lateral side, and Augments designated as “Right” or “R” must be used for right knees, either medially or laterally.
Femoral Augment Trial
If distal and/or posterior resections have been performed for Femoral Augments, trials must now be attached to the Revision Femur Trial.

To avoid difficulty when attaching the Femoral Augment Trials, it is recommended to attach the Distal Augment Trials prior to attaching the Posterior Trials as indicated in Figure 38a and 38b.

Note: Figure 39 shows the possible combinations of Femoral Augments of different heights (shown in millimeters) in the APEX Revision™ Knee System.

Should it be necessary to remove one of the Femoral Augment Trials, the System provides a dedicated Augment Removal Handle, shown in Fig. 40a and 40b.
Assemble the Revision Pilot Stem Coupler to the post on the box of the Revision Femur Trial. There are 3 different couplers, one for neutral stem position, one for 2mm Offset Stem positions, and the third for 4mm Offset Stem positions.

When using the Offset Stem Couplers, refer to the stem position determined on pages 14-15. Rotate the coupler so that the offset marking is aligned with the mark on the Femoral Trial box at the same offset used on the Femoral Locating Guide.

To secure the construction, introduce the Revision Pilot Stem Coupler Bolt through the distal portion of the Revision Femoral Trial and adjust it so that the Pilot Stem Coupler is tightly fixed to the post on the box of the femoral component (Fig. 41a and 41b).

Choose the corresponding Pilot Stem to be used. The Pilot Stem length and diameter must correspond to the reaming depth and the diameter of the last reamer used for reaming the intramedullary canal (Fig. 42).

Note: It must be remembered that during trial reduction the total length of the Pilot Stem is the length of the Pilot Stem itself plus the length of the Revision Pilot Stem Coupler.
Once the Revision Femoral Trial has been attached to the Stem and to any Augment Trials needed, place it on the femur using the Femoral Inserter (Figs. 43a and 43b).

Alternatively (or for final insertion) the construction can be implanted using the Femoral Impactor Pad attached to the Impactor Handle (Fig. 44).

Finally, leave the Femoral Trial in place while positioning the Tibial Insert Trial.
Placement of the Tibial Insert Trial
A Revision Tibial Insert Trial of the same numerical size (including “plus” sizes) as the corresponding Revision Femur Trial must now be placed on the Tibial Tray Trial using the Tray Trial Forceps (Figs. 45a and 45b).

Placement of the Patellar Trial
Preparation of the patella for implantation of a patellar component should be carried out in accordance with the procedure described in the Surgical Technique for the APEX Knee™ System.
**Stability Check**
Knee stability must be checked in both flexion and extension.

To assess stability in extension, the knee must be slightly flexed so that the posterior capsule is completely relaxed. From this position, it should be possible to fully extend the knee.

Assessment of knee flexion should be carried out with the knee flexed at 90°. If stability is appropriate, medial and lateral joint space gapping following application of a varus and valgus stress, respectively, is similar to that of the normal knee.

**Mobility Check**
Knee flexion and extension should be possible without the application of force.

To test knee flexion, the surgeon must raise the thigh and allow the knee to flex as a result of gravity. The degree of flexion obtained in this way is the best indication of the flexion to be eventually gained by the patient.

Assessment of knee extension should allow full extension of the knee.

**Patellar Tracking Check**
The surgeon must make sure that it is possible to slide the patella smoothly along the patellar groove without applying any pressure to its lateral border and without the need to stabilize it medially.
ASSEMBLY OF COMPONENTS

Attach any Femoral Augments as may be needed to the Revision Femoral Component, using the Femoral Augment Bolt(s). Apply a torsion of 100 in-lbs (Figs. 46a and 46b) with the provided Torque Wrench.

Note: One size Femoral Augment Bolt is used regardless of Augment height and position.
The Femoral Stem must now be attached to the post of the box of the Femoral Component.

If an offset stem is used, the final position must correspond with the position selected in the prior steps. Align the marking on the femoral post with the aforementioned numerical position and set the Stem into place.

The tip of the Stem should be protected with a sterile dressing during impaction. (Figs. 47a and 47b).

Impact the Stem onto the Femoral Component so that both components are snugly attached.
Implanting the Femoral Component

Apply a layer of cement on the resected femoral areas and on the areas of the Revision Femoral Component that will be in contact with the bone.

Note: Only a limited amount of cement should be applied onto the posterior aspect of the Femoral Component in order to prevent excessive cement extrusion. The Femoral Stem should not be cemented.

Guide the final Revision Femoral Component to its position using the Femoral Inserter (fig 49a).

Impact the Revision Femoral Component with the Femoral Impactor Pad attached to the Impactor Handle (Fig. 49b).

Note: Carefully remove any cement debris from the surface and the edges of the femoral component.
Place the corresponding Revision Tibial Insert Trial on the Tray Trial. With the knee in extension, push the foot toward the hip until the cement on the Femoral Component sets.

**Implanting the Tibial Insert**

Once the required Tibial Insert thickness has been determined, the Revision Tibial Tray can be implanted (Fig. 50).

For more information on the Revision Tibia implantation, please reference the Revision Tibia Surgical Technique (KL-019)

With the help of the Tray Trial Forceps, slide the corresponding Revision Tibial Insert Trial along two rails of the Tibial Component in the anterior to posterior direction (Fig. 51a-Fig. 51c).
Replace the Tibial Insert Trial with a Revision Tibial Insert of appropriate thickness and slide it along the two rails on the Tibial Tray in the anterior to posterior direction until it reaches the desired position (Figs. 52a and 52b).

**Note:** Given the particular configuration of concordances of the APEX Revision™ Knee System, the size of the polyethylene tibial insert must always coincide with the numerical size of the Femoral Component (including the “plus” sizes). This allows high levels of joint conformity, minimizing stress on the insert and reducing polyethylene wear.

**Implanting the Retaining Bolt**

Insert the Revision Insert Retaining Bolt through the central hole in the Insert and the Tibial Tray and secure it using the Torque Wrench (Fig. 53).

**Note:** Do not apply final tightening torque to the bolt until the cement has cured.

**Note:** Should you experience problems threading the Retaining Bolt into place, check that the Tibial Insert is fully seated on the Tibial Tray. Also check that there are no residues preventing proper Bolt insertion.
Implanting the Patellar Component

Implantation of a Patellar Component should be carried out in accordance with the procedure described in the Surgical Technique for the Primary APEX Knee™ System.

Final Tightening of the Insert Retaining Bolt

Once the cement has set, final tightening of the Insert Retaining Bolt can be carried out. With the knee in flexion, turn the Torque Wrench until the line on its handle aligns with the line marked 60 in-lbs (Fig. 54).

fig. 54
Kinematic Assessment

Appropriate alignment, stability, range of motion and patellar tracking must be checked before closure (Fig. 55).

Note: Remove any cement debris from the area.