GENESIS®

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MODULAR UNICOMPARTMENTAL KNEE SYSTEM

EXTRAMEDULLARY ALIGNMENT INSTRUMENTATION

SURGICAL TECHNIQUE

S&N 1018

GENESIS UNICOMPARTMENTAL KNEE SYSTEM

Designed in Conjunction With:

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Nota Bene: The technique description herein is made available to the healthcare professional to illustrate the authors' suggested treatment for the uncomplicated procedures. In the final analysis, the preferred treatment is that which addresses the needs of the specific patient.

U.S. Patents #4,950,298; 5,053,037; and 5,100,408. Other Patents Pending. GENESIS is a registered trademark of Smith & Nephew Richards Inc.

INTRODUCTION

The key point to appreciate about the GENESIS Knee System is its flexibility. From primary to revision knee arthroplasty, it is generally not possible to ascertain all details until the knee is actually opened. Although the GENESIS System is an outstanding design for operations in which "all goes as expected," it is in addressing the unexpected that the System's flexibility, in sizes and fit, makes it remarkably useful to the surgeon and beneficial to the patient.

As a unicompartmental knee system, GENESIS recognizes that quality bone stock is important to preserve, and bone resection to match component size may not be a viable option. The GENESIS Unicompartmental Knee System's modularity allows the surgeon to customize a knee prosthesis that suits the needs of each patient.

This flexibility alone would make GENESIS a system worth examining. However, the design of the GENESIS Unicompartmental Knee System makes it an optimal choice for many procedures. Its asymmetric, titanium alloy tibial tray is more anatomically correct, and is available in sizes that offer better fit, thus relieving the surgeon from the unpleasant choice between "overhang" and "underhang,"

The tibial implants feature an aluminum oxide grit-blast surface with cement grooves, a medial fin, and tibial boss, which can accommodate various supplemental fixation options. Tibial component thickness options allow adjustments from 8 mm to 12 mm in 1 mm increments. Minimum polyethylene thickness is 6 mm. It is recommended that 8 mm tibial components be used with low activity patients and a 10 to 12 mm component be used for overweight patients. Although the tibial base is asymmetric for optimal coverage, universal-shaped articular inserts allow insertion on the left or right and between two sizes of implant bases, minimizing inventory.

The resurfacing design of the cobalt chromium alloy (ASTM F75) femoral component involves minimal bone removal, preserving the hard subchondral bone for long-term fixation. A contoured femoral anterior aspect minimizes patellar impingement. Web-like structures have been strategically placed in the component to enhance cement fixation at the component/cement interface. Implant stability is further maximized with an anti-rotation fin and modular fixation peg. Overall, the femoral geometry and anatomic posterior condyle allow flexion to 130°.

The GENESIS Unicompartmental Knee System incorporates instrumentation and techniques which help preserve bone stock, accurately restore the joint line, and ensure precise, reproducible cuts. The instrumentation offers two distinct advantages to the surgeon – minimal bone resection and full trial capacity before drilling for the final implant. Also, a unique femoral reaming system makes the preparation for the GENESIS femoral component reproducible, eliminating the need for freehand preparation. Extramedullary tibial alignment instruments can also be crossed over from the GENESIS Total Knee System.

The surgical technique that follows has been developed as a guide for using the GENESIS Unicompartmental Knee System. It will also demonstrate that the GENESIS design combines superior fit with an effective, reproducible technique. It can be a most useful addition to your practice.

DESIGN FEATURES

Contoured anterior femoral aspect (to minimize patellar

impingement).



Modular inserts allow tibial tbickness adjustments in 1 mm increments, from 8 mm.

Supplemental fixation compression / screws (screw threads through the baseplate, minimizing screw backout).

PREOPERATIVE REQUIREMENTS

As described by Philippe Cartier, M.D.

Preoperative X-Ray Calculation

A careful preoperative X-ray is necessary to obtain a precise idea of the defects and angular deviation.

Three types of X-rays are necessary:

- A full length anteroposterior radiograph of the lower limb made at 4 meters in full weight bearing to calculate the different anatomic and mechanical axis of the limb (*Figure 1*).
- Two knee A-P X-rays in varus and valgus views forced to calculate the thickness of the remaining cartilage. Generally, the magnification is at 15% (Figure 2).
- A weight bearing X-ray of the knee with a lateral view. In weight bearing and with the knee at full extension, determine the anterior tibial subluxation (*Figure 3*).

Preoperative templates are also helpful to evaluate the size of the implant needed for the particular patient.





Figure 3



Figure 4



Figure 5

PATIENT PREPARATION AND SURGICAL APPROACH

Positioning

Position the leg on a knee support to allow easy mobilization of the knee from 0° to 130° of flexion.

Surgical Incision

Make a straight longitudinal incision just medial to the midline of the knee through the skin (*Figures 4 and 5*). The muscular incision is medial, or lateral when performing a lateral compartment replacement.

Exposition

Release, at a minimum, the proximal edge of the corresponding tibial plateau just enough to insert a small "smillie" type retractor. Any more extensive release could lead to reduced joint stability and may not guarantee the hypocorrection at the end of the surgery.

Exploration

Remove a sample of the synovial fluid for bacterial testing.

Examine carefully the condition of the synovial tissue, the meniscus, and the contralateral cartilage. Inspection, palpation, and needle-probing will be necessary to determine the exact condition of the joint.

Excise all the osteophytes on the operative side on the femur and the tibia (Figure 6).

Examine the femoral condyles, the cruciate ligaments, and open the intracondylar notch and remove anterior tibial bony block which may be responsible for flexion contracture.

Remove the meniscus and any foreign body. Synovectomy may be necessary.

TIBIAL CUT

Flex the knee at 90° and, according to X-ray calculations, mark the level of the horizontal cut directly on the bone with a cautery knife or methylene blue marker while following the ridge of the Extramedullary Tibial Cutting Guide.

There are two types of extramedullary tibial cutting guides. One is an evolution of the Cartier Guide, and the other is a modified GENESIS Cutting Guide (shown in technique). The cut is performed along the tibial spine of the A.C.L. The vertical cut is performed with a reciprocating saw in the exact A-P plane from the top of the guide to the mark made on the bone. Secure the Cutting Guide at the required level with one or two bone spikes and begin the horizontal cut with an oscillating saw.

Generally the cut in the M-L plane is always perpendicular to the mechanical axis and the vertical cut should never be less than 90° (Figure 7). However, there is one exception.



Figure 6





In cases of bowed varus tibia (Figure 8), the cut is made perpendicular to the metaphyseal axis of the tibial shaft. This is perpendicular to the line joining the center of the spine and the mid-part of the chord joining the remaining mark of the growing cartilage which is easily seen on the front of the X-ray. In this case, the cut will be slightly oblique going up to the tibial spine in flexion, but will be horizontal when the knee is in extension. If the bow is too important, an osteotomy for realignment will be necessary before or during the surgery.

In the A-P plane and according to the anatomy, the cut will have a 5° to 10° A-P slope (*Figure 9*). When the cut has been performed, check again with the cutting guide to assure that the cut is in the correct A-P and M-L planes and that the cut is perfectly flat.



TIBIAL CUTTING

Extramedullary Alignment

The following describes the extramedullary alignment technique.

Using the proximally spiked rod, slide the rod through the non-slotted tibial cutting block. The rod is then inserted in the alignment sleeve which is attached to the ankle clamp. After locking the ankle clamp in the open position, place the assembly over the anterior crest of the tibia with the ankle clamp over the ankle (*Figure 10*). The distal portion of the tibial assembly should lie over the center of the tibia, which is medial to the center of the ankle. To secure the ankle clamp, depress the button on either side of the ankle clamp.

The ankle clamp allows the surgeon to offset the distal end of the alignment guide up to 8 mm toward the medial side to allow alignment over the center of the talus. An offset of 8 mm minimizes the chance for a varus cut. Extend the proximal portion of the tibial assembly up over the proximal tibia. Impact the long spike into the proximal tibia at a point just anterior to the tibial spine. Adjust the position of the distal portion of the rod assembly until the rod is parallel to the mid-coronal plane of the tibia, to ensure that the tibial cut is perpendicular to the tibial axis in all planes.

The extramedullary alignment tower and rod can be used as a method of checking this alignment. (If the cutting plane is in varus or valgus, the distal 8 mm offset can be fine tuned at this time to ensure correct alignment of the tibial cut.) If a posterior sloped cut is desired, adjust the position of the distal portion of the assembly to the desired angle. Impact the shorter spike on the proximal portion of the assembly into the tibia, or secure the position with a 3.2 mm drill bit in the proximal oblique hole (*Figure 11*).

Figure 10 Figure 11

11-4661





11-4660



11-4667

11-i861



Attach the desired proximal tibial stylus and tighten the stylus down by its knurled knob. Four different stylus levels are available: 0, 2, 4, and 6 mm. Using the 0 mm stylus, the level of cut will be even with the end of the stylus gauge. When using the 2 mm stylus, the level of cut is 2 mm below the end of the stylus gauge, and so on.

There are two holes in the tibial block on either side of the alignment rod. Insert a 1/8" pin into one hole on each side of the tibial rod assembly to fix the cutting block to the anterior surface of the tibia (Figure 12). Optional 45" angle holes on either side of the block may be used for additional stability. Take care to retract the patellar ligament distally, so that it is not impaled by a drill.

Once the block is securely fixed to the tibia, the tibial stylus and alignment assembly can be removed leaving the tibial cutting block. Attach the L-resection guide and adjust for desired resection. The vertical cut should come close to the anterior cruciate ligament insertion (Figure 13). If it appears that too little bone is going to be removed, the block can be adjusted to remove 2 mm more or less hone (Figure 14). Once the correct height of the cutting block has been selected, check the orientation of the cutting block in the varus-valgus plane. This can be done by attaching the tower to the cutting block and placing a long alignment rod through the tower. The rod should center on the center of the talus in both the coronal and sagittal planes. If the orientation of the cutting block is correct, the tibia is ready to be cut.



11-4672 11-4675



Using a GENESIS saw blade and an oscillating saw, cut the horizontal tibial plateau (*Figure 15*). Keep the saw blade flush with the cutting block to ensure a flat cut. Using a reciprocating saw, make the vertical cut (*Figure 16*). Cut carefully so that the bone can be taken out in one piece. The remaining bone can be removed with a rongeur to allow seating of the tibial component. Check the cut surface of the tibia to be sure that it is flat using a straight edge. Level any high spots with a rasp.









POSITIONING OF THE TIBIAL TRIAL

Using the A-P Tibial Sizing Device, check the A-P dimension of the tibial plateau (Figure 17).

Select the most appropriate tibial base trial. There are six sizes ranging from extra-small to magnum with the same design for medial and lateral compartments. Position the base with the straight part along the tibial spine and the narrow end anteriorly. Choose the tibial base with optimum coverage and no overhang. The anterior part of the trial base should be exactly in line with the anterior cortical edge. When the trial is in place, secure its position with one short 3.2 mm drill bit in one of the anterior holes (Figure 18). The final size may be different from the size shown on the A-P tibial sizing guide. In that case, you have to choose the one selected with the trial tibial base. If the trial is smaller than the dimension shown on the sizing guide, adapt the A-P position of the trial to be sure that it is not too anterior. If the trial is bigger than the dimension shown on the sizing guide, check if you have cut enough on the tibial spine and if you have removed the lateral tibial osteophytes.

Position the tibial trial articular insert corresponding to the tibial base size with the adequate polyethylene thickness. There are three sizes (one for two bases) and five different thicknesses (8 mm to 12 mm) (*Figure 19*). In some very tight knees, extend the knee at 20° to 30° of flexion with slight varus or valgus to open the joint and try again. If there is not enough room, a thinner insert should be selected or the posterior condyle should be resected slightly.







71-8108 (etc.)

FEMORAL PREPARATION

In order to locate the center of the femoral condyle at the anterior articular limit in extension, extend the knee with the trial plateau still in place (*Figure 20*). With the knee extended without flexion or hyperextension, mark on the condyle the projection of the anterior edge of the tibial insert and also the projection of the center of the tibial insert. (The center of the tibial insert is outlined by a groove made on the plastic). If you can't get full extension, make the mark 1 mm or 2 mm over the projection of the anterior edge of the tibial insert.

By doing this, the condyle will be exactly over the center of the tibial insert during the walking position. When the knee is flexed, this mark may appear too lateral or even too medial, however, it is the appropriate landmark position (*Figure 21*).

Remove the short drill bit, trial base, and insert. Then flex the knee at 90".



Figure 20



Figure 21

FEMORAL COMPONENT SIZING

There are six sizes for the femoral trial. To determine the appropriate size, the femoral sizing device is used. After completely removing the posterior osteophytes, position the sizing device with the posterior part in contact with the posterior aspect of the condyles. The author's preference is to position the guide along the lateral aspect of the condyle with the anterior portion at the level of the anterior mark. The proper size will be the one which seems to be the most appropriate to the condyle shape. The handle should be parallel to the tibial cut when the knee is at 90° to 100° of flexion.

The correct sizing device will correspond exactly with the anterior mark made previously on the condyle (*Figure 22*). If it was necessary to slightly cut the posterior condyle to position the trial insert, measure the thickness removed and allow a corresponding gap between the posterior aspect of the condyle and the posterior aspect of the sizing device.

FEMORAL REAMER GUIDE POSITIONING

Select the reamer guide corresponding to the selected femoral sizing guide (*Figure 23*). There are three reamer guides, each one addressing two femoral sizes (X-Small/Small, Medium/Large, and X-Large/Magnum). Then attach the

reamer guide handles to the block, and set the corresponding plastic collet on the upper hole. 71-1001 through 71-1006





Figure 23

11 - 4890

Position the guide with the inner anterior edge of the plastic bushing placed in the collet in line with the landmark made on the condyle (*Figure 24*). Using two handles (or one if there is not enough space) placed parallel to the plane of the condyle taking into account the obliquity you want to correct, set the position by using a 3.2 mm long drill bit in the upper hole. While oriented vertically, secure the position of the guide with one or two additional 3.2 mm drill bits. The guide should be in perfect contact at the upper part of the underside of the condyle, at least in the most superior and inferior parts.



FEMORAL REAMING



71-2534

71-2556

71-2112

Select the femoral reamer size corresponding to the previously determined femoral size. Select the depth of reaming you need (0 mm to 4 mm) according to the thickness of the remaining cartilage in contact with the reamer guide. Place the bushing into the posterior position of the femoral reamer guide first and begin to ream until the drill stop is in contact with the guide (Figure 25). The appropriate reaming depth can easily be adjusted by loosening the thread (clockwise) on the femoral reamer and placing the depth ring into the appropriately marked position (Figure 25A). Then tighten the thread counter-clockwise to secure the depth position prior to reaming. -

Figure 25





Remove the reamer and check the depth of the reaming. The right depth is reached when the subchondral bone is starting to bleed (Figure 26). If you are not deep enough, ream 1 mm more until you reach the subchondral bone. Keeping the same thickness, clean the bone debris and move the bushing to the upper hole and ream (Figure 27). Remove all material and, if necessary, smooth the edges of the reamed recess with an oscillating rasp, chisel, or file (Figure 28). Both upper and lower reaming must be at the same depth. If not, ream again the more offset side with the reamer, ensuring that the rearning depth position has not changed. Be careful not to over ream.



11-4894

Figure 26

Figure 27

Figure 28



POSTERIOR FEMORAL CUTS

Select the appropriate femoral cutting block and position the anterior part exactly in the middle of the most anterior point of the previous mark made on the condyle. In a few cases, if you can't raise the posterior cutting guide to the level of the mark, check if the recess is anterior enough. If not, make a more anterior recess at the level of the mark with a chisel. Also, check if you have removed posterior osteophytes and at least cut a little from the posterior condyle when you are in between two sizes (*Figure 29*). The handle should be vertical and the posterior part is exactly in contact with the posterior aspect of the condyle.

With the most anterior edge of the cutting block aligned on the tide mark, secure the block with two bone spikes (*Figure 30*). Ensure that the block is well fixed to the condyle. If the cutting block moves posteriorly, the posterior condyle will be too thick and the knee will be tight in flexion. It may be helpful to remove all remaining cartilage from the posterior condyle before seating the femoral cutting block.



Figure 29

Figure 30

11-0088

71-3001

Make the two posterior femoral cuts (*Figures 304 and 30B*) with a narrow oscillating saw. Then, using a 3.2 mm drill bit, drill the two holes 1 cm to facilitate the placement of the femoral finishing trial (*Figure 30C*). Remove the cutting block, finish the cut, if necessary, and remove the bone chips.







71-4001 through 71-4006

FINISHING TRIAL

Select the appropriate size femoral finishing trial based on the previous steps, attach the handle, and impact it on the femur in the previously prepared holes (*Figure 31*). Make certain that the anterior edge does not overlap the tide mark (*Figure 32*). Remove the handle, reinsert the tibial trials, and begin the range of motion/stabilizing testing.



71-4011



Figure 31 Figure 32



Figure 33

TRIALING

The tibial insert must remain perfectly stable without any tilting from 0° to 130° of flexion with the foot in 5" to 10" of external rotation (Figure 33). In slight flexion (15"), when you apply pressure in forced varus (medial compartment) or in valgus (lateral compartment), the femoral condyle does not have to be in contact with the tibial spine.

In slight flexion (15"), you should have to keep a small remaining laxity on the side of the concavity to avoid over correction problems. This test is accurate unless you have done an excessive release. In full extension, be careful to avoid any contact between the spine and the intracondylar notch (Figure 34). If contact occurs, open more of the notch and remove, if necessary, any remaining osteophytes on the medial part of the condyle with a rongeur.



MAIN CAUSES OF TILTING

With the GENESIS Uni and the precise instrumentation, tilting is no longer a frequent problem. Nevertheless, it could be helpful to know the seven main causes of tilting:

- Patella is Not Replaced: Recheck after replacing patella (*Figure 35*).
- Residual Posterior Obstacle: Remove the tibial trial and check for any remaining meniscus or bone that may be obscuring the trial and hindering good positioning. Also check to see that any remaining posterior condyle is causing an obstacle (*Figure 36*).



Figure 35



Figure 36

- Anteroposterior Malpositioning: Change the A-P position of the base and check again (*Figure 37*).
- 4. Tibial Cut is Not Flat: Flatten the cut (Figure 38).
- Condylar Obliquity: Remove the trial and reposition the condyle correctly (*Figure 39*).



Figure 39



- Impingement of the Condyle on the Spine in Valgus/Varus Force: Move the trial laterally or cut more of the tibial spine (*Figure 40*).
- Everything Looks Good, But Tilting Remains: Increase the posterior slope of the tibial cut or cut more distal femur and move down to a smaller femoral size (*Figure 41*).

CONTROL OF HYPOCORRECTION

- For the varus knee, a check may be performed easily on the medial compartment. Along the vertical cut on the tibial spine, check to ensure that the upper portion of the trial insert is never over the difference between the cancellous and cortical bone.
- 2. For both the varus and valgus knee, reference the opposite compartment and check to determine if the contralateral cartilage is thick enough. Then spike a needle in the center of the cartilage. Using the tibial trial, check that the upper, anterior portion of the trial insert is not over the level of the needle. If the cartilage was found thin, spike the long needle at the upper level of the cartilage and duplicate the technique.
- For both the varus and valgus knee, always check that there is a slight laxity at about 15° of flexion on the side of the deformity.



Figure 40

Figure 41

FINAL TIBIAL AND FEMORAL PREPARATION

If the trials are not satisfactory, you should be able to easily move the position of either the tibial plateau or the femoral finishing trial without destroying any bone. When the trials give an excellent result, secure the tibial base position with one or two bone spikes. Replace the femoral handle on the marking template and using the femoral peg drill, drill the hole for the peg (*Figure 42*). Using a narrow oscillating saw, prepare the slot for the femoral fins taking into account that the anterior fin is smaller than the posterior which goes until the beginning of the most posterior cut (*Figure 43*).

Figure 42

Figure 43

71-4012

Fix, with two bone spikes, the position of the tibial base at the exact position determined during the trials and tests. (In some cases where the bone is very hard, the



28-2771





71-9100 71-9110



71-9120



During drilling, it is mandatory to check that the drill guide remains flat and in perfect contact with the tibial base. The boss drill will only prepare for the boss extension on the undersurface of the tibial implant (*Figure 46*). If screw fixation is desired, select the combination boss/lag screw drill, but always use the boss drill first.

Figure 46







CEMENT PREPARATION

Remove femoral and tibial trials.

Remove the tibial trials. Before cementing, it is important to check that the implant positioning is correct. Then place the cement on the bone, but don't put any in the boss hole. Keep the plastic cap on the base and impact with the tibial impactor. Remove any excess cement.

If you are using a screw, remove the plastic cap in the boss of the tibial base and tap through the base component with the screw tap. Then insert the 16 mm or 22 mm screw. Remove any remaining cement.

71-9191



To set the insert in place, slide it between the femoral component and the tibial base and towards the medial part first. Then push down laterally until you hear a "click" or check a perfect insertion (Figure 47A). In order to have a better view and more space to set the insert in place, it is easier to place the knee in 20° or 30° of flexion with a slight forced valgus (medial side) or varus (lateral side). If you have any difficulty seating the insert, remove it and check if the vertical cut is at 90° or more from the horizontal tibial cut (Figure 47B). If not, correct the cut with a reciprocating saw or rasp and then reseat the insert.

Special Note For Cementing the Tibia:

The use of the screw is optional. When cementing the tibial base without a screw, place a flexible tube, which is slightly smaller than the prepared hole, into the drilled boss hole. Use a small drill to create some holes on the cut tibial surface to improve cement penetration. Place cement on the prepared tibial surface and in the boss hole around the inserted tube. The use of the slightly undersized plastic tube allows cement to penetrate the bone around the boss, but prevents cement from accumulating under the boss hole.



Figure 47A



Figure 47B

72-5558 72-5559



72-8108 (etc.)

When cementing the tibial base with a screw, be sure to cover the drilled boss hole completely while applying cement on the tibial surface. This will prevent cement from migrating into the boss hole area and eliminate the chance of soft cement creep into the tibial base. No drill holes on the tibial surface are necessary since the compression screw provides enough cement interdigitation. NOTE: It is recommended that the screw option be utilized only with the medium through magnum size tibial bases. The x-small and small tibial bases should be cemented without the screw option to ensure adequate cement coverage.

For the femoral component, put a small amount of cement on the condyle, but do not put any in the peg hole or posterior aspect of the femoral condyle. Carefully place the femoral component on the prepared condyle. The femoral peg and fin will direct the implant into the proper position and orientation. Then seat it with the femoral impactor, remove any excess cement, and then impact again. Remove remaining cement and place the leg in full extension until the cement is fully dry.

Clean and wash carefully.

CLOSURE

Verify flexion is obtained at 0° to 130°. Perform closure after irrigation and suction with the flexed knee between 30° and 60°. Suture the quadriceps first. Carefully repair the medial patellar retinaculum (for medial procedures only). Verify absence of patella snapping after closure of the soft tissues. Do not suture the patellar retinaculum in lateral procedures. Place two suction drainage tubes; one intra-articularly and the other subcutaneously or juxta-articularly.

POSTOPERATIVE CARE

The patient should be allowed to fully bear weight, with crutches, on the first days after surgery. Initiate isometric contraction of the quadriceps and begin gentle therapy with a CPM machine. Remove the knee dressing on the third day postoperatively. Check the knee dressing on the eighth day and initiate physical therapy. In certain instances, physical therapy may start on the fourth or fifth day. Advise the patient to walk with a crutch for at least one month after the surgery.

IMPLANTS









FEMORAL COMPONENT

Cat. No.	Description	
72-5001	Extra Small	
72-5002	Small	
72-5003	Medium	
72-5004	Large	
72-5005	Extra Large	
72-5006	Magnum	

TIBIAL COMPONENT

(Right Medial/Left Lateral)

Cat. No.	Description
72-7100	Extra Small
72-7101	Small
72-7202	Medium
72-7203	Large
72-7304	Extra Large
72-7305	Magnum

TIBIAL COMPONENT

(Left Medial/Right Lateral)

Cat. No.	Description	
72-6100	Extra Small	
72-6101	Small	
72-6202	Medium	
72-6203	Large	
72-6304	Extra Large	
72-6305	Magnum	

TIBIAL ARTICULAR INSERT

Extra Small/	/ Medium/	Extra Large/	
Small	Large	Magnum	Size
72-8108	72-8208	72-8308	8 mm
72-8109	72-8209	72-8309	9 mm
72-8110	72-8210	72-8310	10 mm
72-8111	72-8211	72-8311	11 mm
72-8112	72-8212	72-8312	12 mm

TIBIAL COMPRESSION SCREW

Cat. No.	Description
72-5558	16 mm
72-5559	22 mm

TRIALS

FEMORAL COMPONENT FINISHING TRIAL

Cat.	Description	
71-4001	Extra Small	
71-4002	Small	
71-4003	Medium	
71-4004	Large	
71-4005	Extra Large	
71-4006	Magnum	
	3	

FEMORAL COMPONENT FINAL TRIAL

Cat. No.	Description
71-5001	Extra Small
71-5002	Small
71-5003	Medium
71-5004	Large
71-5005	Extra Large
71-5006	Magnum

E



TIBIAL COMPONENT TRIAL

(Right Medial/Left Lateral and Left Medial/Right Lateral)

Left Medial/Right Lateral)

Cat. No.	Description	
71-7100	Extra Small	
71-7101	Small	
71-7202	Medium	
71-7203	Large	
71-7304	Extra Large	
71-7305	Magnum	



TIBIAL ARTICULAR INSERT TRIAL

Extra Small/	Medium/	Extra Large/	
Small	Large	Magnum	Size
71-8108	71-8208	71-8308	8 mm
71-8109	71-8209	71-8309	9 mm
71-8110	71-8210	71-8310	10 mm
71-8111	71-8211	71-8311	11 mm
71-8112	71-8212	71-8312	12 mm





C









INSTRUMENTS

Femoral Sizing Guide

Cat. No.	Description	
71-1001	Extra Small	
71-1002	Small	
71-1003	Medium	
71-1004	Large	
71-1005	Extra Large	
71-1006	Magnum	

Femoral Reamer Guide

Cat. No.	Description
71-2012	Extra Small/Small
71-2034	Medium/Large
71-2056	Extra Large/Magnum

Femoral Reamer Bushing

Cat. No.	Description
71-2112	Extra Small/Small
71-2134	Medium/Large
71-2156	Extra Large/Magnum

Femoral Reamer

Cat. No.	Description
71-2512	Extra Small/Small
71-2534	Medium/Large
71-2556	Extra Large/Magnum

Femoral Cutting Block

Cat. No.	Description
71-3001	Extra Small
71-3002	Small
71-3003	Medium
71-3004	Large
71-3005	Extra Large
71-3006	Magnum

Femoral Finishing Trial Handle Cat. No. 71-4011

Femoral Peg Drill Cat. No. 71-4012



Femoral Impactor Cat. No. 11-2241



Handles (2 included) Cat. No. 11-4890

Tibial Fin Punch Cat. No. Description 71-9100 RM/LL 71-9110 LM/RL

Tibial Drill Guide Cat. No. 71-9120

Baby Lane Forceps Cat. No. 28-2771











Tibial Boss Drill Cat. No. 71-9130

Tibial Boss/Screw Drill Cat. No. 71-9140

Tibial Trial Handle/Sizing Guide Cat. No. 71-9160



Tibial L-Resection Guide Cat. No. 71-9170



Tibial Impactor Cat. No. 71-9180



Tibial Screw Tap Sleeve Cat. No. 71-9190

Tibial Screw Tap Cat. No. 71-9191

Ankle Clamp and Alignment Sleeve Cat. No. 11-4660



Spiked Fixation Rod Cat. No. 11-4661

Tibial Cutting Block Cat. No. 11-4663

Extramedullary Alignment Tower Cat. No. 11-4667

Extramedullary Alignment Rod Cat. No. 11-4861

Tibial Stylus

Cat. No.	Description
11-4668	0 mm
11-4671	2 mm
11-4672	4 mm
11-4673	6 mm







Straight Screwdriver Cat. No. 11-5035

Bone Spikes Cat. No. 11-0088

Tibial File Cat. No. 11-4894

Drill Bits

Cat. No.	Description
11-4969	3.2 mm x 76 mm
21-0442	3.2 mm x 127 mm

Femoral Instrument Tray Cat. No. 71-0002

Tibial Instrument Tray Cat. No. 71-0004

IMPORTANT MEDICAL INFORMATION

Warnings and Precautions

GENESIS[®] Unicompartmental Knee System

MATERIALS:

GENESIS femoral components are Cobalt Chromium Alloy (ASTM F 75). GENESIS tibial component bases are titanium, 6AI-4V Alloy (ISO 5832/III). GENESIS tibial component articular inserts are ultra-high molecular weight polyethylene (ASTM F 648). The GENESIS Unicompartmental Knee System is designed as a system and DOES NOT ALLOW THE SUBSTITUTION OF COMPONENTS FROM OTHER SYSTEMS.

INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EFFECTS

The general principles of good patient selection and sound surgical judgment apply to the total knee procedure. Preoperative planning and meticulous surgical technique are essential to achieve optimum results. Considerations of anatomic loading, soft-tissue condition, and component placement are critical to minimize a variety of postoperative complications.

Indications:

- Post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result.
- 2. Failed osteotomies.

Contraindications:

- Rheumatoid arthritis, which is confined to only one or two compartments of the knee.
- Inadequate bony support or cement support.
- 3. Previous intra-articular infections.
- Mental or neurologic conditions that tend to preempt the patient's ability or willingness to restrict activities.
- Neuropathic joint (Charcot).
- Conditions that tend to place increased loads on implants such as age, weight, and activity level, which are incompatible with a satisfactory long-term result.

Possible Adverse Effects:

 Loosening, bending, cracking, or fracture of femoral or tibial components. Usually attributable to one or more factors included in Contraindications (above) and/or Warnings and Precautions (below).

- Dislocation, subluxation, rotation phenomenon, flexion contracture, decreased range of motion, lengthening or shortening of the leg, looseness of components, or extraneous bone or ligament laxity.
- 3. Tibial or femoral fractures.
- Acute post-surgical wound infection, late deep wound sepsils and/or low-grade synovitis.
- 5. Neuropathies.
- Cardiovascular disorders: wound hematoma, thromboembolic diseases including venous thrombosis and pulmonary embolus.
- Tissue reactions: macrophage and foreign body reaction. Also, myositis ossificans.
- 8. Skin sloughs or delayed wound healing.

WARNING AND PRECAUTIONS

Preoperative:

- Use care in handling and storing of implant components. Cutting, bending, or scratching the surfaces of components can significantly reduce the strength, fatigue resistance, and/or wear characteristics of the implant system. These in turn may induce internal stresses that are not obvious to the eye and may lead to fracture of the component.
- Richards Surgical Technique Brochure is available upon request. The surgeon should be familiar with the technique.
- An adequate inventory of implant sizes should be available at the time of surgery.

Operative:

- Adequate and continuous support of components by cement and/or bone, and proper component size are important.
- Proper alignment, axially and rotationally, is important.
- During curing of cement, care should be taken to prevent moving of the implant components.
- Prior to closure, the surgical site should be thoroughly cleaned of bone chips, extraneous cement, ectopic bone, etc. Foreign particles at the metal/plastic interface may cause excessive wear and/or friction.

Postoperative:

- Postoperative patient care, and directions and warnings to patients by physicians, are extremely important. Protected weight bearing with external support is recommended for a period of time to allow healing.
- 2. Use extreme care in patient handling.
- Postoperative therapy should be structured to prevent excessive loading of the operative knee and to encourage bone healing.
- Patients should be cautioned to limit their activities as directed by their surgeon.

Packaging and Labeling:

GENESIS Unicompartmental implants are sterilized products and should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact.

STERILIZATION

All components have been sterilized by a minimum of 2.5 megarads of gamma irradiation and are supplied in protective trays. Inspect packages for punctures or other damage prior to surgery.

RESTERILIZATION

During resterilization, protect components from contact with metal or other hard objects. Polyethylene or polyethylene/metal components can only be resterilized by ethylene oxide gas, using the sterilizer manufacturer's instructions. Suggested aeration time is 48 hours at room temperature or 8 hours at 60°C to 12 hours at 50°C with power aeration. Consult aerator manufacturer for more specific instructions. In addition to resterilization by ethylene oxide gas, using the sterilizer manufacturer's instructions, GENESIS Unicompartment all metallic components can also be resterilized by steam autoclaving in appropriate protective wrapping, after removal of all the original packaging and labeling.

INFORMATION

For further information, please contact the Manager, Customer Service Department, Smith & Nephew Richards Inc., 1450 Brooks Road, Memphis, TN 38116.



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