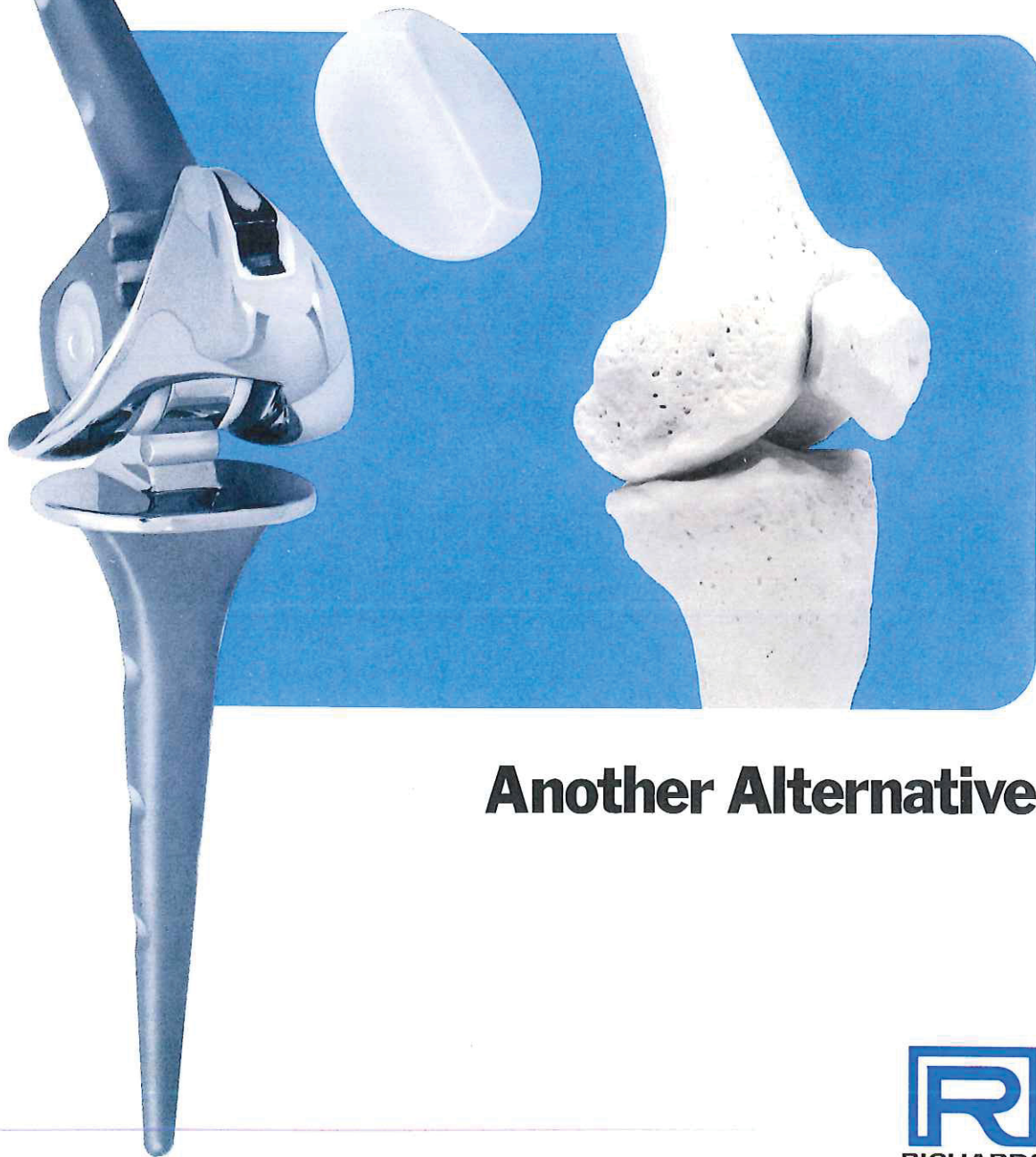


Richards Intracondylar Knee



Another Alternative



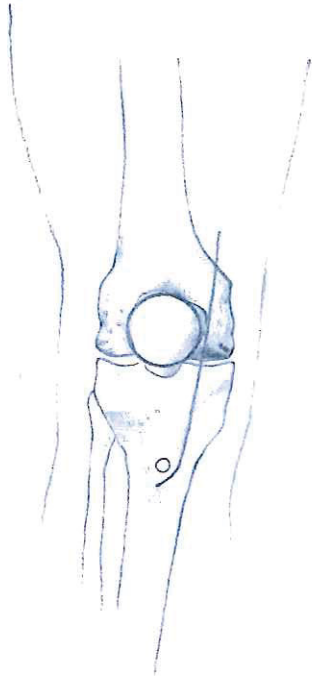
S&N 1020

Richards Intracondylar Knee

Technique as described by Charles O. Bechtol, M.D., Los Angeles, California



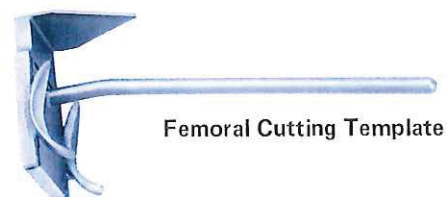
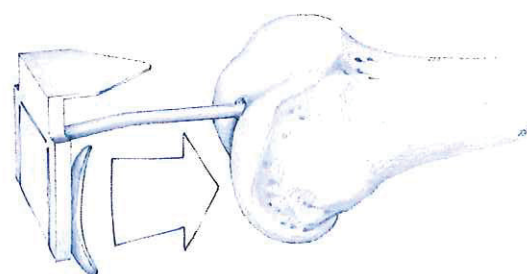
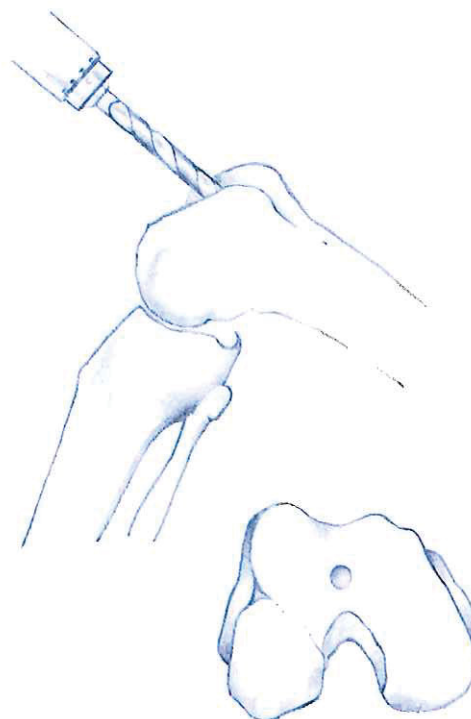
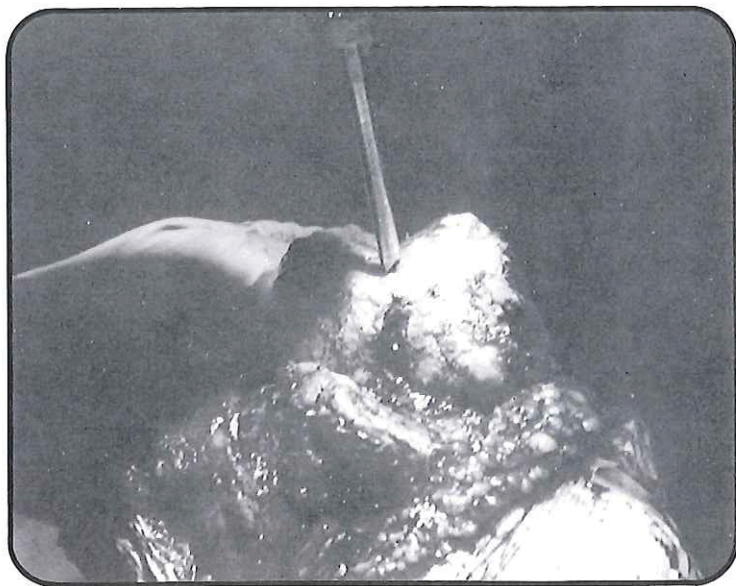
1. After routine skin preparation, the leg is draped in the usual manner. If a tourniquet is used, the leg is exsanguinated with a Tourniwrap™; with the knee in 60° to 90° flexion, the tourniquet is inflated. A median para-patellar incision is recommended.



2. After dissection and joint debridement, the knee is flexed to 90°. All osteophytes on the tibia, femur and patella should be removed. The medial and lateral collateral ligaments should be divided at their origin from the femur. The cruciate ligaments should be divided. This allows improved exposure of both tibial and femoral surfaces. The capsule must be freed laterally and posteriorly to allow good mobility of both femur and tibia.

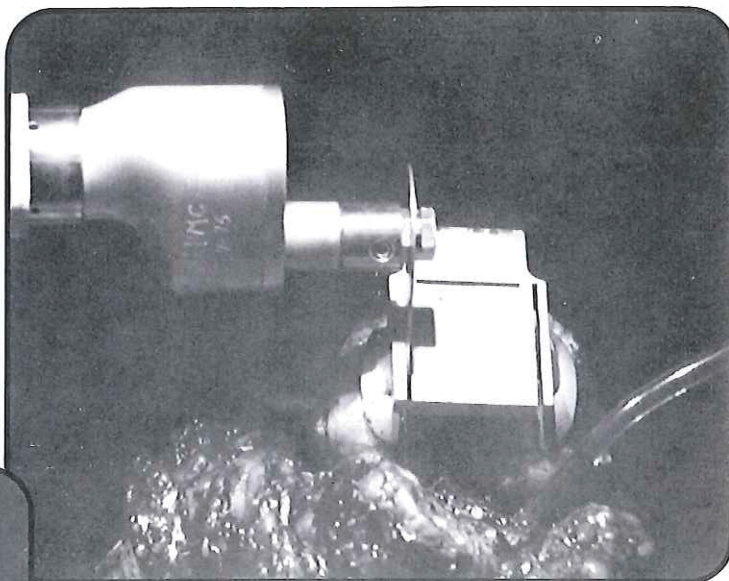
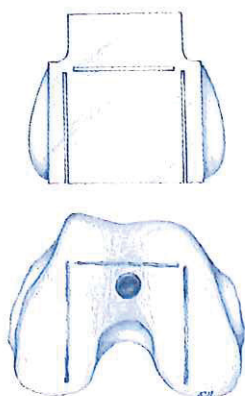


3. A 5/16" diameter hole is drilled directly up into the femoral shaft through the central patellar facet of the femur.

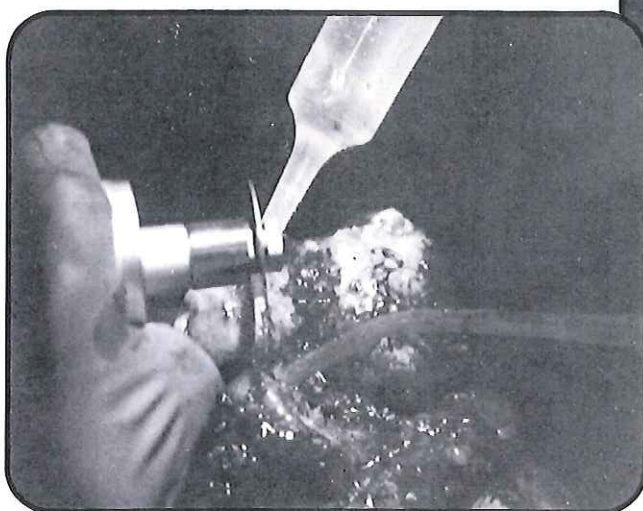


4. The Femoral Cutting Guide is inserted completely into the hole with the V-shaped portion of the guide positioned anteriorly on the femur.

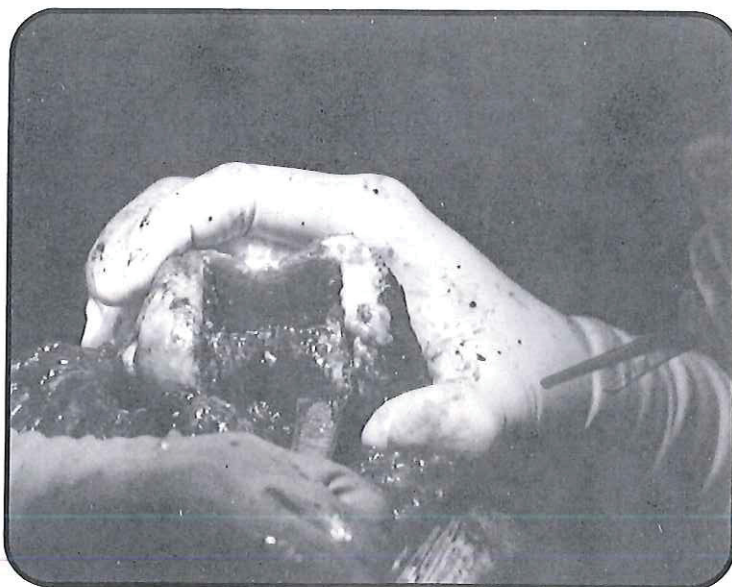
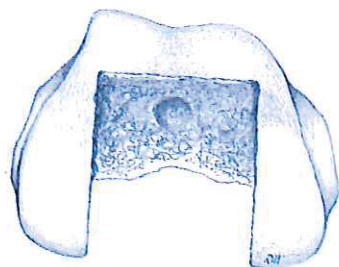
5. The Femoral Cutting Guide has cutting slots to guide a power saw or thin-bladed osteotome. The slots are spaced apart the same width as the femoral component.



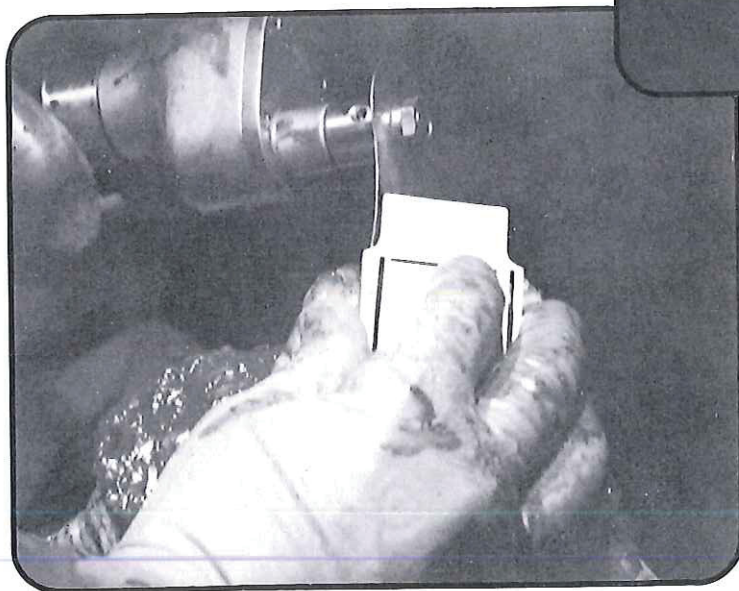
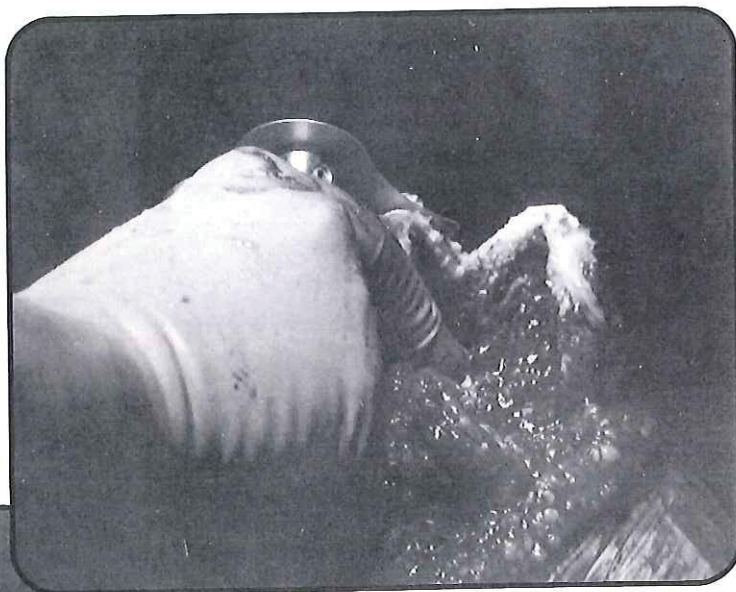
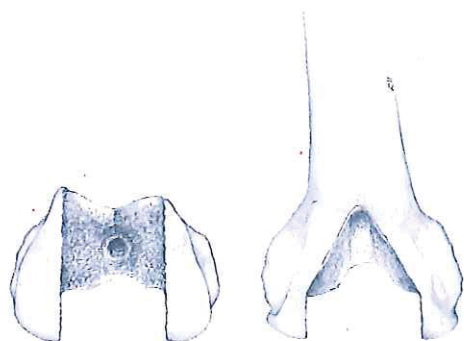
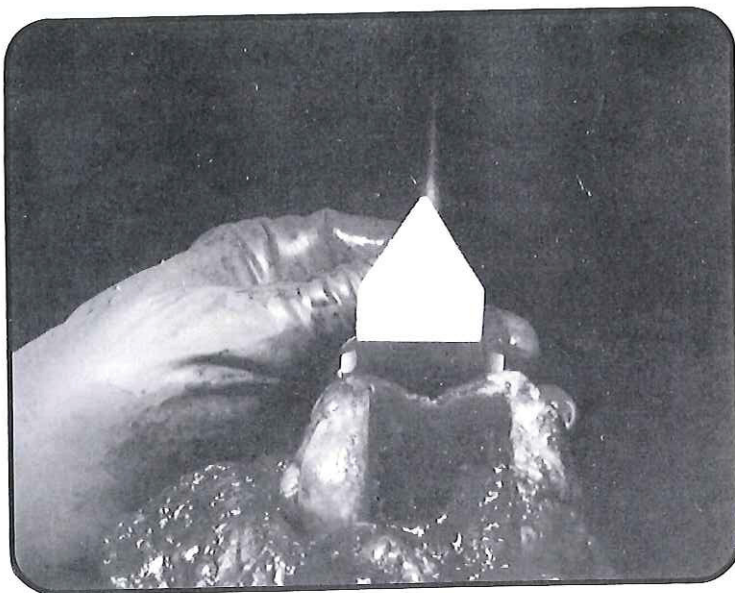
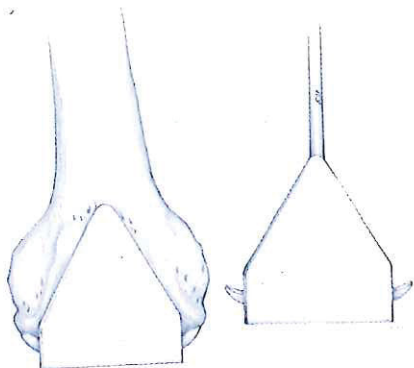
6. Once the initial cuts have been made, the Femoral Cutting Guide is removed and the cuts are completed. The saw blade should be kept cool with saline.



7. It is necessary to remove the posterior cortex layer of the femoral condyles the same width as the guiding cuts.



8. The guide is reinserted and the V-shaped portion of the guide is designed to guide the power saw to prepare the anterior femur to accept the patellar groove.



9. Any osteophytes are removed and the femoral condyles are trimmed to fit the Femoral Trial Component.

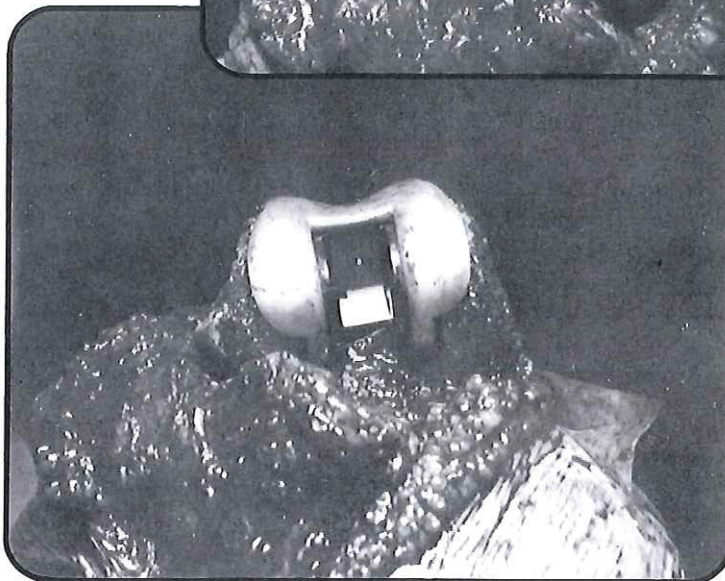
10. After the preparatory work and broaching of the femur is complete, the appropriate Femoral Trial Component (left, right or neutral) is inserted.

A full length X-ray of the femur is necessary to determine if the femur has an abnormal bow or maybe deformed due to previous injury.



Femoral Trial

11. The Femoral Trial Component should seat firmly in the prepared site and the femoral trial flanges should seat on the trimmed femoral condyles. If the trial component does not seat correctly, additional shaping of bone must be done until the trial prosthesis fits properly.



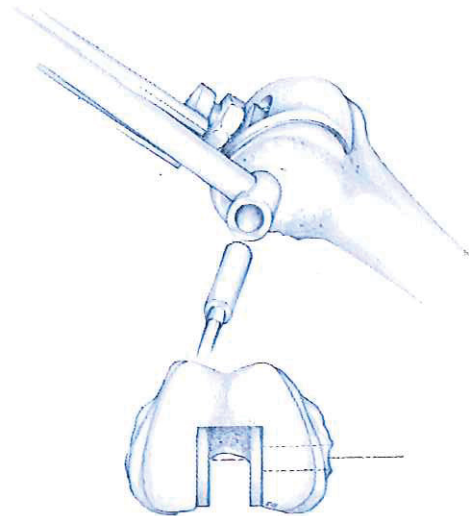
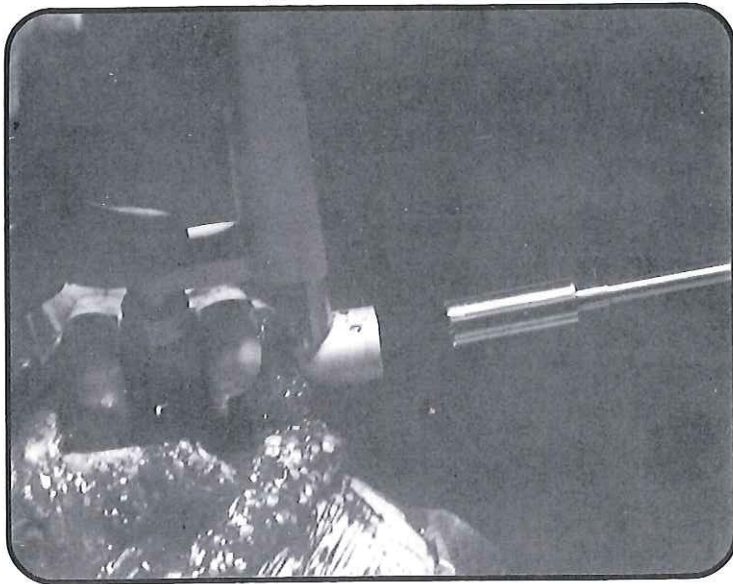
12. The femoral component must first be fully seated in the femoral canal. The Trephine Guide is inserted into the trial femoral prosthesis. It must be fully engaged. The trephine hole is made only into the medial femoral condyle.



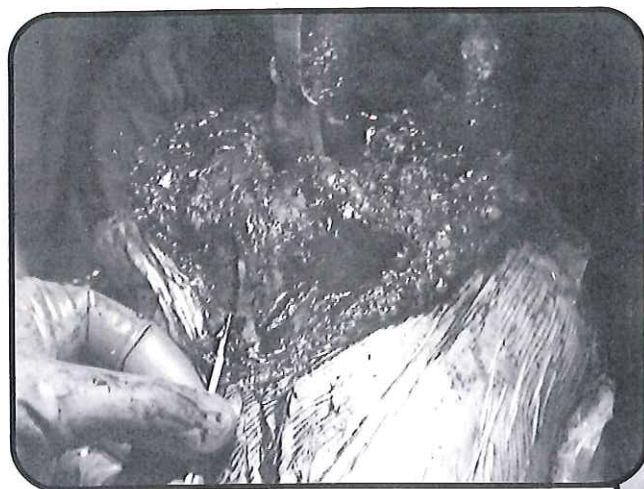
Trephine Guide Assembly



13. Using the Trephine Guide, the hole for the supporting axle is then bored, utilizing the Trephine Cutting Head. The circle saw should be inserted until it stops. The bone removed by the saw is not suitable for a bone graft later.



Trephine Cutting Head



14. With the knee flexed 90° and the patella retracted laterally, the tibia will externally rotate from the plane of the femur. To prevent misalignment of the trial and final components, the tibial tubercle may be marked with methylene blue as a guide.

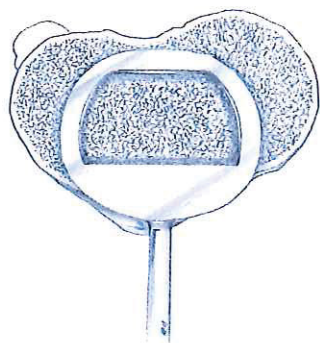
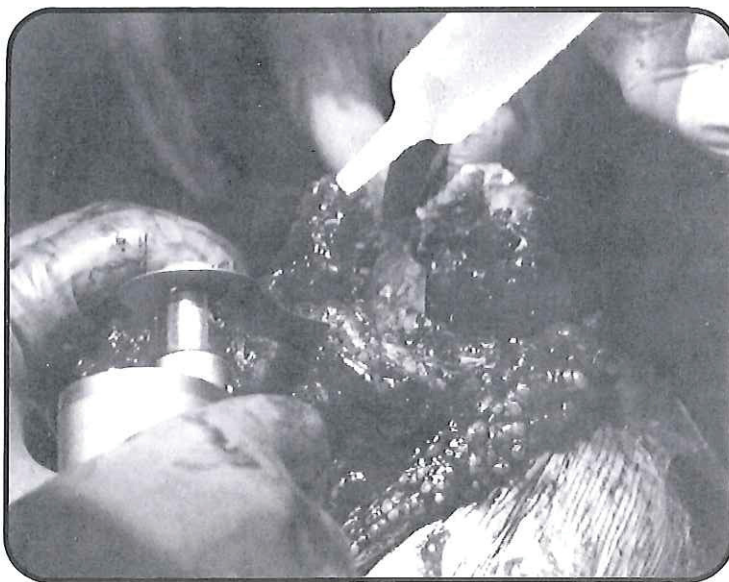
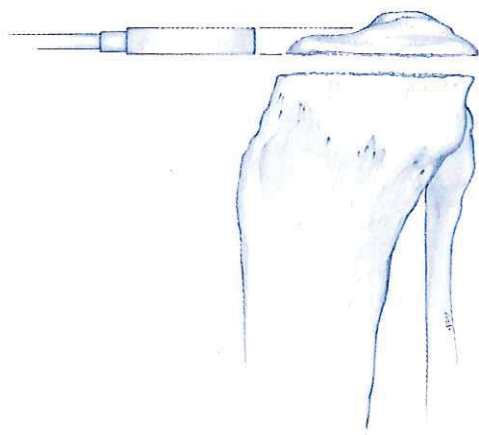
15. The Spacer Template indicates both the thickness of bone to be removed from the tibial plateaus and the outline of bone to be removed for the stem of the Tibial Component.



Spacer Template

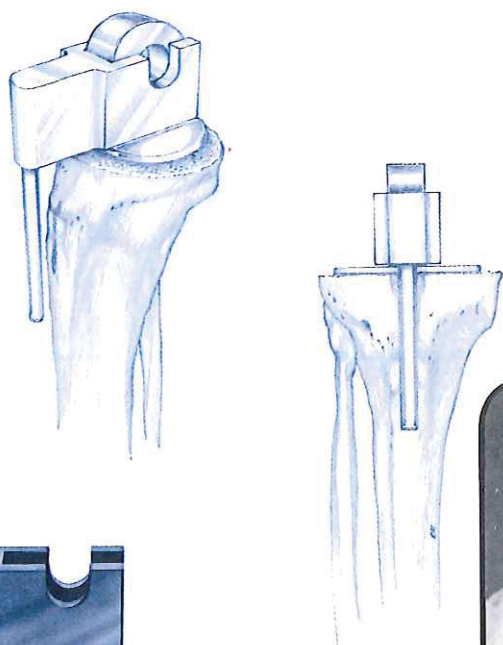
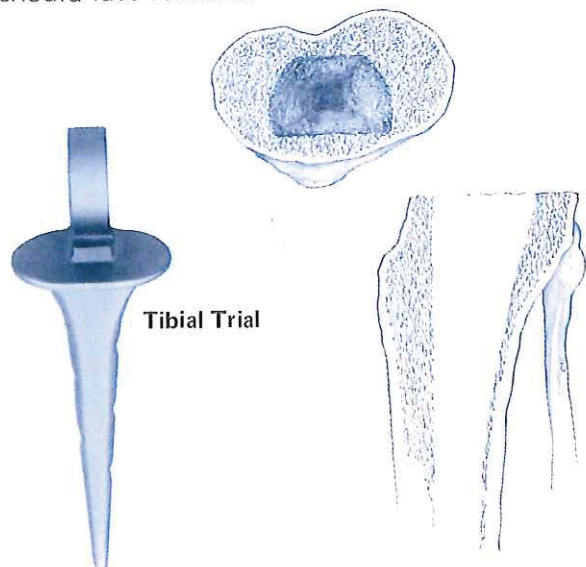


16. The head of the tibia should be resected an amount equal to the thickness of the Spacer Template. If one tibial plateau is destroyed below the thickness of the template, the defect should be filled with bone and/or cement.

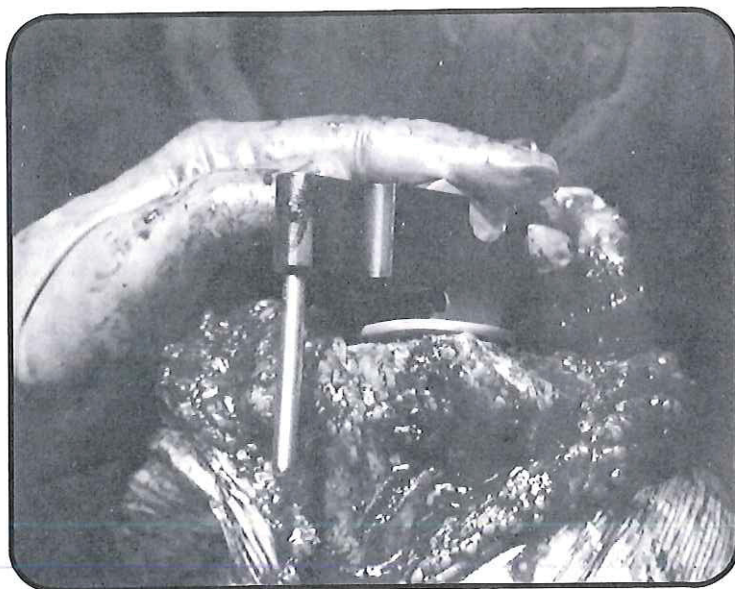


17. The proximal tibia is prepared by inscribing a methylene blue line around the inner portion of the tibial Spacer Template, with the template aligned properly with the tibial tubercle to allow for rotation of the tibia.

18. After drilling an appropriate size hole into the tibia and curetting away an appropriate amount of spongy bone from the medullary canal, a Trial Tibial Prosthesis is inserted. The plastic hyperextension stop should face forward.



19. The Tibia Alignment Guide is then inserted over the Tibial Trial with the metal shaft aligned with the tibial tubercle for correct rotary alignment.

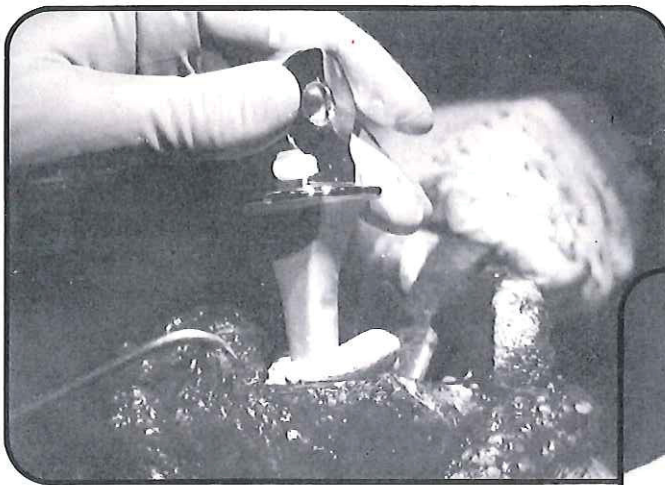
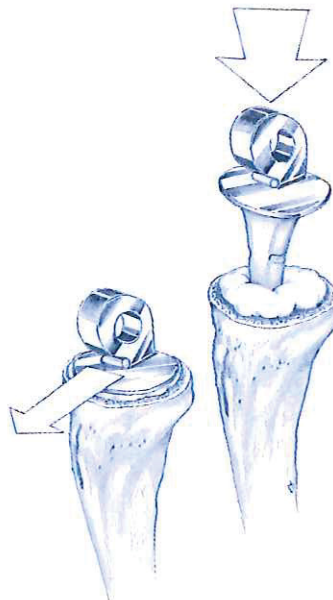
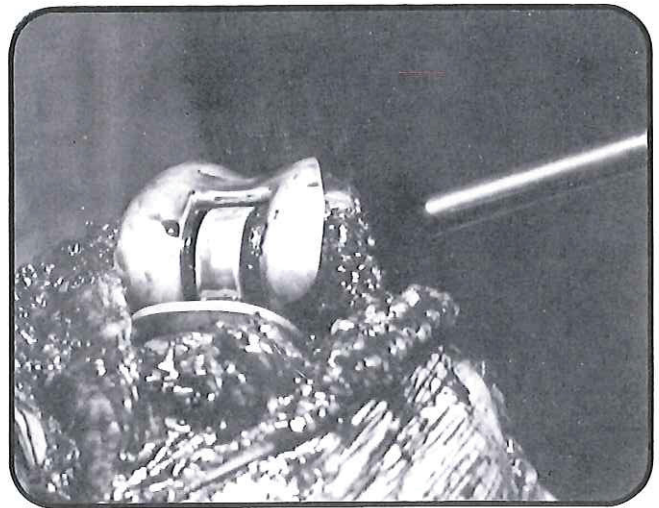
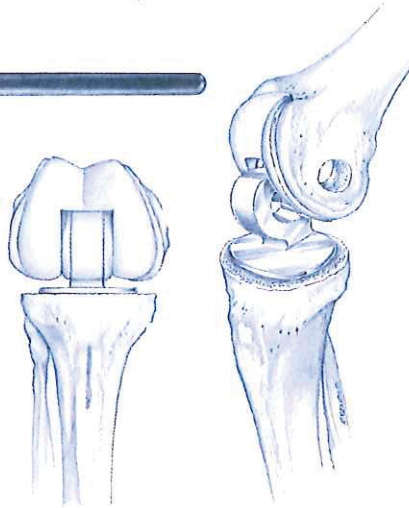


20. With the knee flexed beyond 90°, both the femoral and tibial trial components are inserted. The joint is reduced and the black trial axis pin is inserted. A trial reduction and necessary adjustments should be made at this time. Complete extension and flexion to at least 90° should be possible. Correct alignment of 7° (average) valgus should be present. The trephine hole should be inspected to be sure that it is free of bone chips and its alignment with the axle hole is still correct.

IMPORTANT: Before cementing in the components, the tourniquet should be released; all bleeders can then be visualized and controlled. The leg is again exsanguinated with a Tourniwrap™ and the tourniquet reinflated.

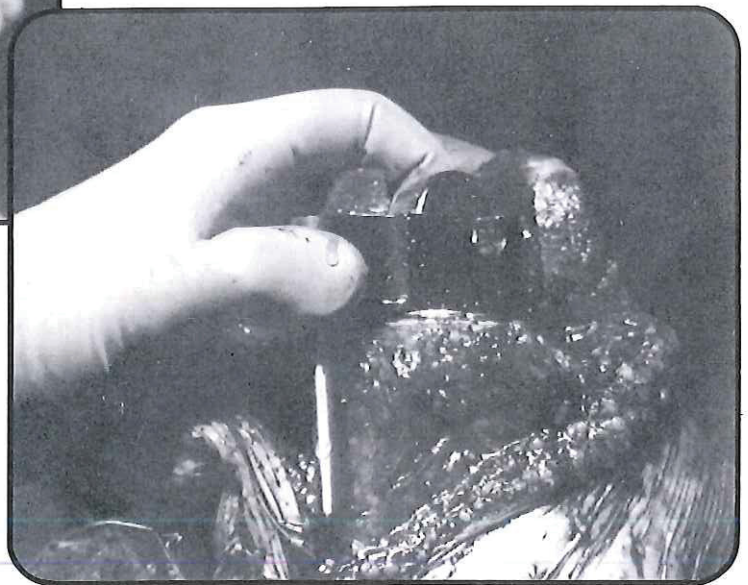


Trial Axis Instrument

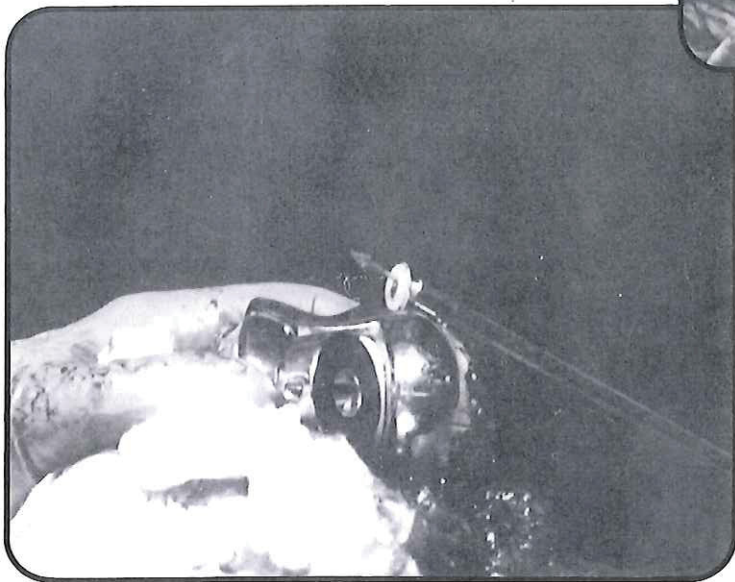
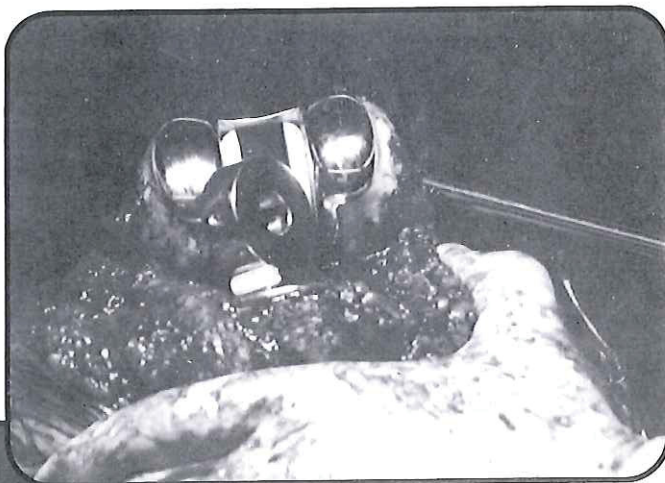


21. One unit of cement is prepared for the tibial component and is inserted with the Jet-Vac™ Cement Dispenser. The tibial component is then inserted, with the polyethylene bumper again facing anteriorly.

22. The Tibia Alignment Guide is again inserted over the tibia. The metal shaft is aligned with the tibial tubercle and alignment of the component is checked before the cement is set, and adjusted if necessary.

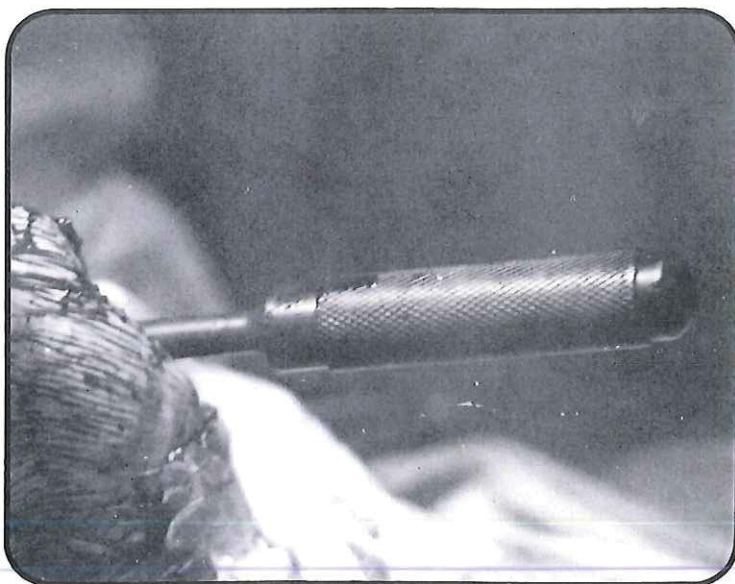


23. Implantation of the Femoral Component is next. 1 to 2 units of cement should be used. The surgeon removes cement from the hole bored in the medial condyle while the cement is still soft. Any cement entering the notch of the femoral component should be carefully curetted away with a plastic Sculp™ instrument. Then the Cement Restrictor Retriever instrument is used to retrieve the poly plug on the medial Femoral Component. Failure to thoroughly immobilize the femur and tibia (Step 2) will make Step 23 difficult.



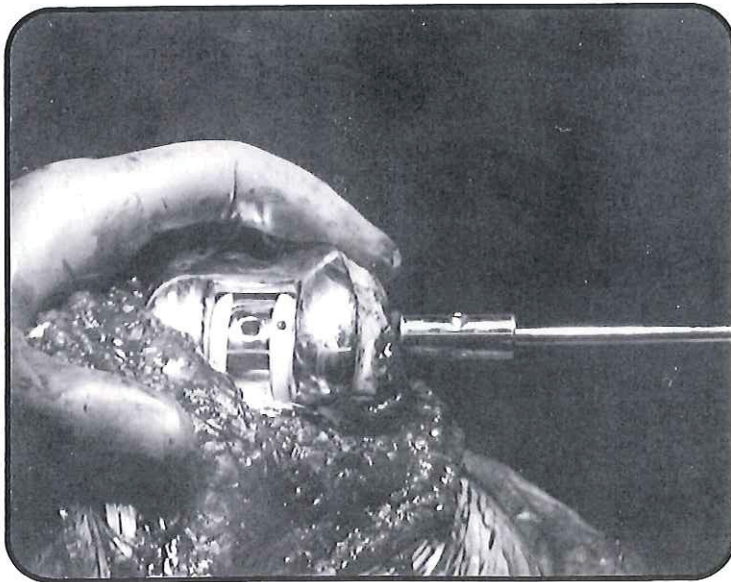
Cement Restrictor Retriever

24. The retriever is inserted in the bored hole and the restrictor membrane is punctured. The instrument is then twisted 90° and is pulled out of the bored hole. The poly plug in the lateral side should not be removed.



Trial Axis Instrument

25. The prosthesis is reduced, and the Black Delrin® Trial Axis instrument is inserted through the bored hole. The tibial and femoral components are then aligned. Motion and alignment are again checked. Any excess cement should be carefully chipped away.



26. After aligning the components, the Trial Axis instrument is removed and the final metal axle (Trunion Pin) is placed using the threaded Axis Pin Positioner.

Trunion Pin

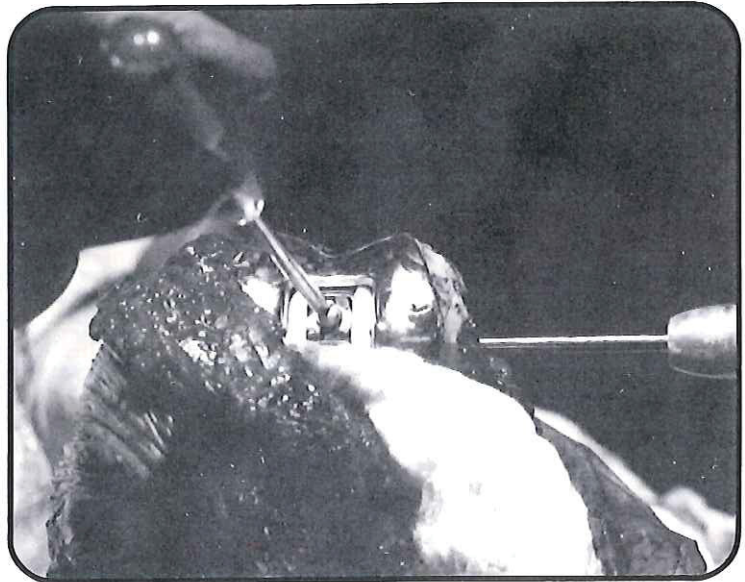


Alignment Indicator Mark



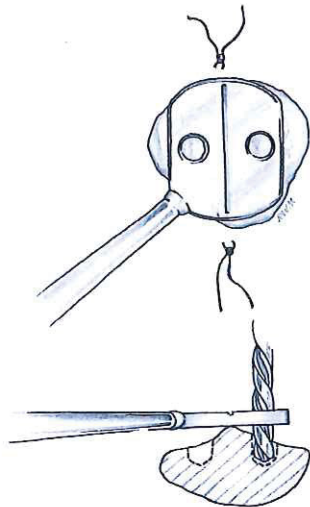
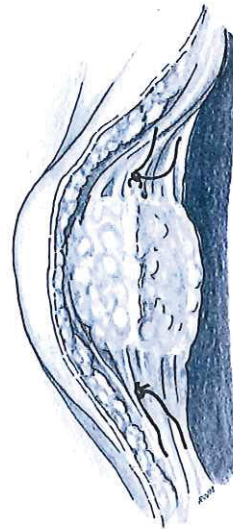
Axis Pin Positioner

27. The recessed hole of the axis is then aligned with the tapped hole of the Tibial Component. The metal set screw is inserted and the polyethylene lock screw is placed securely. The trephine hole in the medial femoral condyle is packed full of cancellous bone. Bone from the top of the tibia is suitable. Exposed raw bone areas should be covered with a thin layer of bone wax to prevent new bone formation.



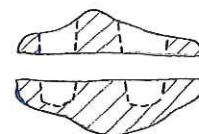
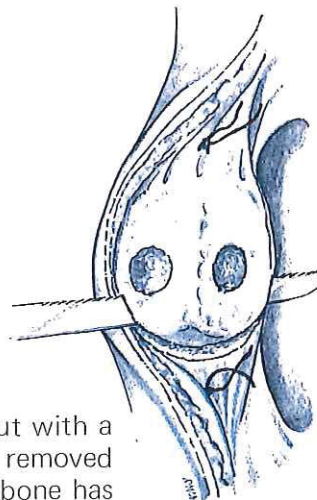
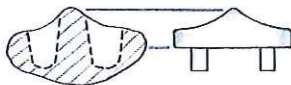
Patellar Preparation

The patella is then prepared for implantation of the patellar component, if the surgeon deems patellar replacement necessary. With the leg in full extension and the patella retracted laterally, the border of the patella is cleared of soft tissue and all osteophytes are removed. A heavy dark suture is placed in the substance of the tendon at either end of the patellar crest. The sutures will identify the original position of the patellar crest after it has been osteotomized. This procedure is crucial to correct orientation of the plastic Patellar Component.



The Patellar Drill Jig is aligned over the crest and two 1/4" diameter drill holes are started through the guide holes in the jig. The jig is then removed and the holes are deepened until they reach the outer cortex of the patella. The drill should not penetrate the cortex. The holes are enlarged by rocking the drill slightly from side to side. Final deepening should be done with the small McElroy Curette, as this will not penetrate the cortex.

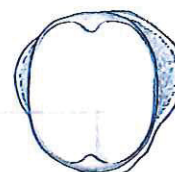
A black plastic Trial Patellar Component of the size closest to the natural patella is selected. The level of the patellar osteotomy should correspond to the thickness of the trial component. The correct level is marked with methylene blue around the entire border of the patella.



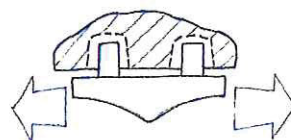
The osteotomy is then carried out in a single straight cut with a reciprocating saw or an osteotome. The portion of bone removed is compared to the trial component to be sure enough bone has been removed.

The trial is put in place on the remaining patella and the cut surface is checked to see that it is even to insure that the crest aligns with the sutures identifying the line of the natural crest.

The fixation pegs on the Trial Patellar Component should fit loosely into the fixation holes to allow for minor adjustment of the Final Patellar Component while the cement is soft.

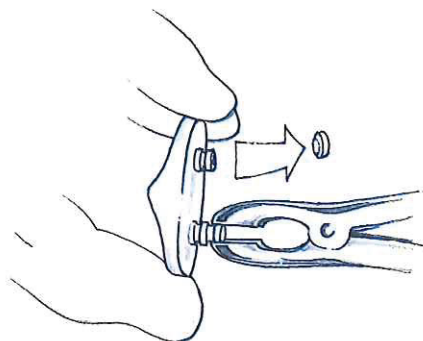


The flat underside of the Trial should fit flush against the cut surface of the bone. Any necessary adjustments to the bone should be made at this time.*



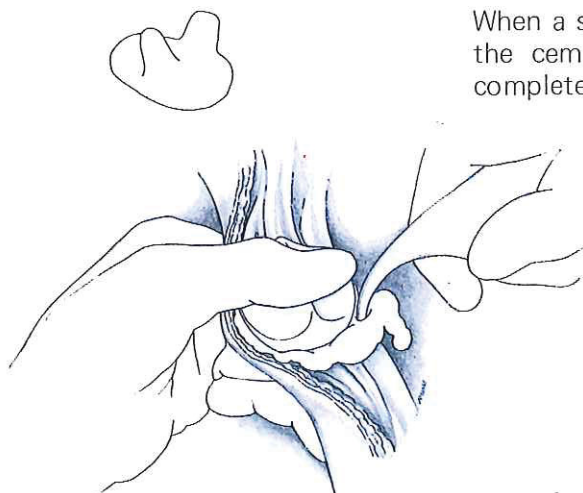
When bony preparation has been completed, the Tibial Patellar Component is inserted and the patella is reduced with the implanted femoral and tibial components. The knee is carried through a full range of flexion-extension. The patellar component should glide smoothly through the complete range of joint motion. In valgus knees, the patella is frequently displaced laterally and there is an associated contracture of the lateral patellar retinaculum. A release of the retinaculum should be done. A vastus lateralis release may occasionally be necessary.

*Some very small patellas will not be of sufficient thickness to allow the Trial Component to lie flush against the bone. This can be compensated for before implantation of the Final Patellar Component by removing the last segment of each fixation peg with a rongeur. If this step is necessary, the final implant should be prepared and used as a trial for the final testing and preparation stage.



The surgeon should attempt to visualize the patellar component during flexion-extension to insure that the component is tracking in the center of the femoral groove throughout its travel. Minor tracking adjustments may be made by enlarging the drill holes in the patella.

When a satisfactory trial reduction and testing has been achieved, the cement is pressed on the prepared surface of the patella, completely filling all holes.



The plastic Patellar Component is pushed firmly in position of the patella. Excess cement is cleared from around the edges of the implant. The patella is reduced (while the cement is still soft) and the knee is carried through 60° of flexion-extension with the surgeon exerting firm pressure on the top of the patella. This aids final seating of the component. With the surgeon still maintaining pressure on the patella, the knee is then brought into full extension and held firmly until the cement sets.

Range of motion is again tested, both with the patella dislocated and reduced. Sometimes motion will be found to be greater with the patella dislocated. The limited motion with the patella reduced to the proper position is caused by a contracture of the quadriceps muscle. The decision to correct the contracture will depend upon its severity. It may be done at this time or as a secondary procedure.

A thorough inspection of the entire joint is made (with X-ray assistance if necessary) to identify and remove any loose cement or bone debris. Any ectopic bone, bony spurs, or excess cement around the periphery of the implant components should be removed.

Closure is then accomplished with interrupted sutures in the capsule. After each 2 or 3 sutures are put in place, the knee should be flexed to 90° to insure that the sutures are properly in position and will not pull out. Wound suction tubes are then put in place and the closure of the wound completed. A pressure dressing is applied.

Post Operative Care

The patient is maintained in bed for three to five days, being allowed to turn freely as pain allows. The compression bandage is then removed and a small, sterile bandage applied. Mobilization of the knee should then be initiated by the physical therapist. It is imperative that full extension and 90° or more of flexion be obtained during the following seven days, if at all possible. In patients sensitive to pain, it is advisable to give them hypodermic medication (such as Demerol®), and follow this by passive motion of the knee when medication becomes effective, one-half to two hours later. Manipulation of the knee under general anesthesia is usually of little value. If it is necessary, it should be done with great caution.

Ambulation with crutches can be started from the fifth to the seventh day. Weight-bearing on the affected leg should be limited to about 10 percent of body weight. When progress is satisfactory, the patient may be given bathroom privileges. Training on the stairs with the aid of crutches and a railing should be started when coordination is satisfactory. The patient can usually be discharged from the hospital ten to fourteen days postoperative. Weight-bearing should be restricted to 10 percent for at least six weeks from date of surgery. At that time, X-rays are obtained and if satisfactory healing has occurred, increased weight-bearing may be started. If healing is unsatisfactory, a further period of 10 percent weight-bearing should follow (rheumatoid arthritis or severe osteoporosis should require at least 12 weeks of limited weight-bearing). When the patient is dismissed from the hospital, a program of passive and active stretching should be started. Muscle conditioning exercises should be delayed until the patient has progressed to full weight-bearing.

IMPLANTS

Richards Intracondylar Knee, Neutral
12-9700

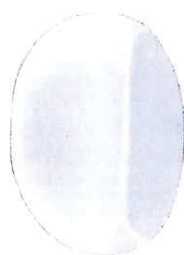
Richards Intracondylar Knee, Left
12-9701

Richards Intracondylar Knee, Right
12-9702

Patella Component, Large
12-0750

Patella Component, Medium
12-0751

Patella Component, Small
12-0752

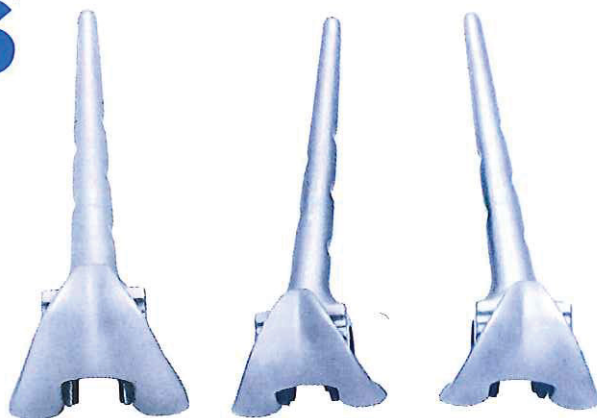


TRIALS

Femoral Trial, Neutral
11-3000

Femoral Trial, Left
11-3001

Femoral Trial, Right
11-3002



Tibial Trial
11-3010

Patella Trial, Large
11-1875

Patella Trial, Medium
11-1876

Patella Trial, Small
11-1877



INSTRUMENTATION



Trephine Guide Assembly
11-3003



Trephine Cutting Head
11-3004



Tibial Alignment Guide
11-3005



Spacer Template
11-3006



Femoral Cutting Template
11-3007



Cement Restrictor Retriever
11-3009



Trial Axis Instrument
11-3011



Axis Pin Positioner
11-0260



Screwdriver
11-0264



Patella Drill Jig
11-1892



5/16'' Stainless Steel Twist Drill
21-0454

IMPORTANT MEDICAL INFORMATION

WARNINGS AND PRECAUTIONS RICHARDS INTRACONDYLAR KNEE

IMPORTANT NOTE

The total knee implant operation is a remarkably successful procedure. Its success, however, probably cannot reach 100 percent, and even in an uncomplicated case, there is some risk. The patient and physician must realize that any of the circumstances listed under the relevant categories, below, may reduce the chance of a successful outcome and an increased percentage of risk must be accepted.

The goals of the total knee replacement are to decrease pain, increase function and increase mobility. To accomplish these goals, patients should be selected: (1) who have and will maintain adequate bone support, (2) who are able and willing to follow their physician's directions generally, and particularly with respect to no or minimal weight-bearing in postoperative care. Provide substantial and even cement support for the prosthesis and have support for the cement. Patients should be cautioned against heavy labor, active sports or any activity which places heavy or abrupt loads on implanted prostheses.

DESCRIPTION OF PROSTHESIS

The Richards Intracondylar Total Knee Prosthesis is a hinge-style total knee replacement for those cases which present uncorrectable ligamentous instability or other surgical considerations preventing the use of a more conservative prosthesis. The prosthesis provides a posteriorly placed axis and a femoral patellar facet. While providing substantial strength, the stem design permits minimal removal of cortical bone for hinge-style low-friction arthroplasty. Available in left and right styles with an anatomical 7° angulation of the femoral component, as well as a neutral style.

INDICATIONS, CONTRAINDICATIONS AND ADVERSE EFFECTS

GENERAL: The general principles of patient selection and sound surgical judgment apply to the total knee procedure. Additional Indications and Contraindications are:

INDICATIONS

Patients with the following conditions that in addition, have severe ligamentous instability or conditions not permitting satisfactory use of non-hinged knee replacement:

1. Patient conditions of rheumatoid arthritis, osteoarthritis, post traumatic arthritis and secondary arthritis including, but not limited to:
 - acromegaly
 - ankylosing spondylitis
 - avascular necrosis
 - cancer
 - Gaucher's disease
 - gout
 - Paget's disease
 - systemic lupus erythematosus;
 2. Old, remote osteomyelitis with an extended drainage-free period; in which case, the patient should be warned of an above normal danger of infection;
 3. Unsuccessful osteotomies, hemiarthroplasties, and conservative therapy.
 4. Unsuccessful arthrodesis, or arthrodesis in poor position or with disabling pain.
- Most of the diagnoses listed above and below may also increase the chance of complications and reduce the chance of a satisfactory result.

CONTRAINDICATIONS

1. Patient conditions correctable by use of a non-hinged knee prosthesis.
2. Patient physical condition that would eliminate or tend to eliminate adequate implant and/or cement support, e.g.: (1) blood supply limitations from previous surgery, alcohol agglutination, etc., (2) insufficient quantity or quality of bone resulting from conditions such as: cancer, obesity, osteoporosis, etc., (3) infections or other conditions which lead to reduced fixation.
3. Patient mental or neurological conditions which tend to pre-empt the patient's ability or willingness to restrict activities, especially during the healing period, e.g.:
 - alcohol abuse
 - Charcot's disease
 - drug use
 - mental illness
 - senility
4. Patient conditions or predispositions which tend to place extreme loads on implants, e.g.:
 - active sports
 - claudication
 - heavy labor
 - deficiencies of muscles or ligaments
 - history of falls
 - neurological deficiencies
 - obesity
 - disablement of other joints, e.g., hips and ankles (especially ipsilateral)

5. Severe contractures not corrected by other procedures.

Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.

POSSIBLE ADVERSE EFFECTS

1. 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.
2. Rotation phenomenon, flexion contracture, decreased range of motion, or lengthening or shortening of the leg, caused by improper positioning, looseness of components or extraneous bone or cement.
3. Fractures of the tibia or femur: Postoperative fractures are usually stress fractures. Fractures are usually evidence of defects in the cortex due to prior screw holes, misdirected reaming, and/or inadequacy or maldistribution of cement. Intraoperative fractures are usually associated with revision surgery deformity and/or severe osteoporosis.
4. Infection, both acute post-op wound infection and late deep wound sepsis. Also, low-grade synovitis.
5. Neuropathies: especially common peroneal nerve with valgus deformity.
6. Cardiovascular disorders: Wound hematoma, thromboembolic disease, including venous thrombosis and pulmonary embolus.
7. Tissue reactions: Macrophage and foreign body reaction adjacent to implants, resulting from foreign material in tissues. Also, myositis ossificans, especially in males with hypotrophic arthritis, limited pre-operative range of motion and/or previous myositis. Myositis ossificans is increased with prior surgery or presence of infection.

WARNINGS AND PRECAUTIONS

Loosening, bending, cracking, and/or fracture of implants and other complications may result from failure to observe the following warnings and precautions.

PRE-OPERATIVE

1. Use extreme care in handling and storage of implant components, particularly metal components. Cutting, bending or scratching the surface of components tends to reduce the strength, fatigue resistance and/or wear characteristics of the implant system. These, in turn, may cause cracks and/or internal stresses that are not obvious to the eye and may lead to fracture of the component. Special protection for implants and instruments during storage is recommended when exposed to corrosive environments such as salt air, etc.
2. Extra implant components are recommended, especially if ETO resterilization is required. All packages and implants should be thoroughly inspected prior to surgery for possible damage. Do not steam or dry heat sterilize plastic implants as temperature involved may cause deformation of the material. (See Sterilization section, below.)
3. Patient conditions and/or predispositions such as addressed in Contraindications, above, should be avoided.
4. Allergies and other reactions to device materials, although infrequent, should be considered, tested (if appropriate) and ruled out pre-operatively.
5. Certain special surgical instruments are required to perform this surgery. Review of the use and handling of these instruments is very important.
6. Richards Surgical Technique brochure available upon request at no charge, should be reviewed prior to initial surgery.

INTRA-OPERATIVE

1. The correct selection of the implant is extremely important. The appropriate type must be custom fitted to the patient. Inadequate cement support, or improper positioning may result in loosening, bending, cracking, or fracture of the component, cement and/or bone.
2. Adequate and continuous support of components (particularly tibial) by both cement and bone, are of utmost importance. Layering of cement and inclusion of air or blood should be avoided. Use of a cement injector tends to aid in introduction of a continuous bolus of cement, free of entrapped air, blood or layers.
3. When preparing beds and positioning the tibial component, check for proper tibial alignment and note that the tibia may be displaced or externally rotated by the retraction of the patella.

4. Revision procedures for previous arthroplasty, etc., are technically demanding and difficult to exercise. Common errors include misplacement of the incision, inadequate exposure or mobilization, inadequate removal of ectopic bone, improper positioning of components or inadequate cement support. Increased operative time, blood loss, increased incidence of pulmonary embolus and wound hematoma can be expected with revision procedures.
5. With rheumatoid arthritis, especially for those patients on steroids, bone may be extremely osteoporotic.
6. Care should be taken not to scratch, bend, or cut metal components during surgery for the reasons stated in Number One of the pre-operative section of Warnings and Precautions. Once removed from the patient, implants previously implanted should never be reused, since internal stresses which are not visible may lead to early bending or fracture.
7. During curing of cement, care should be taken to prevent moving implant components. A tight fit of implant to cement and cement to bone is essential to prevent motion which may lead to bone resorption and/or cement cracking.
8. 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. Ectopic bone and/or bone spurs may lead to painful or restricted motion. Range of motion should be thoroughly checked for restricted motion.

POSTOPERATIVE

1. Postoperative directions and warnings to patients by physicians, and patient care are extremely important. Nonweight-bearing after surgery is recommended to allow healing of bone to provide proper bone and cement support. Evidence suggests healing may require six weeks or longer, and a period shorter than this increases the possibility of loosening, bending, cracking, and/or fracture of implants.
2. Patients should be cautioned against unassisted activity, particularly use of toilet facilities, kneeling, and other activities requiring walking.
3. Use extreme care in patient handling. Support should be provided to the operative leg when moving the patient. While placing the patient on bedpans, changing dressings, clothing, and similar activities, precautions should be taken to avoid placing any load on the operative part of the body.
4. Postoperative therapy should be structured to prevent loading of the operative knee.
5. Periodic x-rays are recommended for close comparison with post-op conditions to detect long term evidence of changes in the bone, the cement, or changes in the position or loosening, bending, or cracking of components. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reducing activities and/or early revision considered.

UTILIZATION AND IMPLANTATION

1. With both knee and hip disease, generally operate on hips prior to knees and on the more diseased side of each pair of joints first in order to make rehabilitation more effective.
2. Bone scanning may help identify postoperative problems such as infection, loosening, or ectopic bone formation; however, most postoperative complications can be identified on periodic routine radiographs.

PACKAGING AND LABELING

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

STERILIZATION

The Richards Intracondylar Knee is supplied assembled in a non-sterile condition. The implant should be completely disassembled and sterilized by ethylene oxide gas using techniques recommended by the sterilizer manufacturer. Do not steam or dry heat sterilize plastic components. Recommended aeration time is 48 hours at room temperature or 8 hours at 60-degrees C. to 12 hours at 50-degrees C. with power aeration. Consult recommendations of aerator manufacturer.

INFORMATION

Where further information is desired, please contact the Manager, Customer Service Division, Richards Manufacturing Company, Inc., 1450 Brooks Road, Memphis, Tennessee 38116.



RICHARDS MANUFACTURING COMPANY, INC.

1450 BROOKS RD., MEMPHIS, TENN. 38116 • 396-2121

CALL TOLL FREE: 800-238-7538 (IN TN. 800-582-6282)

IN CANADA, RICHARDS SURGICAL LIMITED, 7524 BATH ROAD, MALTON, ONTARIO, L4T 1L2, (416) 677-9744