# 2.1
# Physician Labeling

# NEXGEN™ LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEMS
# (United States Version)

Before using this product, the operating surgeon should study carefully the following recommendations, warnings and instructions, as well as the available product-specific information (e.g., product literature, written surgical technique).

All Components Are Provided Sterile.

## DESCRIPTION

The LPS-Flex Mobile Bearing Knee and LPS-Mobile Bearing Knee are both semi-constrained, non-linked, posterior-stabilized, rotating platform mobile bearing knee prostheses that are part of the *NexGen* Complete Knee Solution, *Legacy*™ Knee – Posterior Stabilized (LPS) system. The *NexGen* LPS Mobile Bearing Knee systems consist of the following four main components:

- LPS femoral component *
- LPS-Mobile tibial articular surface component
- Fluted Stem Mobile tibial baseplate component
- All-Poly patella component

*** The only difference between the two knee systems is in the design of the femoral components.** The LPS-Flex Mobile Bearing Knee System utilizes the *NexGen* LPS-Flex non-porous femoral component and the LPS-Mobile Bearing Knee System utilizes the *NexGen* LPS non-porous femoral component.

LPS-Flex femoral components are designed to accommodate increased flexion capability. They are designed for use when both cruciate ligaments are excised and when load bearing range of motion is expected to be less than or equal to 155 degrees.

LPS femoral components are designed for use with both cruciate ligaments excised and when load bearing range of motion is expected to be less than or equal to 120 degrees.

The femoral and mobile tibial baseplate components are made from *Zimaloy*™ Cobalt-Chromium-Molybdenum alloy and the mobile articular surface components are made from ultra-high molecular weight polyethylene (UHMWPE). A variety of stem extensions are available. LPS-Mobile articular surfaces are available in multiple thicknesses to facilitate soft tissue tensioning and joint line restoration.

Fluted Stem Mobile tibial baseplate components are available in uncoated (Option) and polymethyl methacrylate [PMMA] precoat styles. The tibial baseplate components are designed to allow ± 25 degrees of rotational movement.

## INDICATIONS

- This device is indicated for patients with severe knee pain and disability due to:
  - Osteoarthritis.
  - Primary and secondary traumatic arthritis.
  - Avascular necrosis of the femoral condyle.
  - Moderate valgus, varus, or flexion deformities (i.e., valgus/varus deformity of ≤ 15°, fixed flexion deformity of ≤ 10°).

- **This device is intended for cemented use only.**

## CONTRAINDICATIONS

- Contraindications include:
  - Previous history of infection in the affected joint and/or local/systemic infection that may affect the prosthetic joint.
  - Insufficient bone stock on femoral or tibial surfaces.
  - Skeletal immaturity.
  - Neuropathic arthropathy.
  - Osteoporosis or any loss of musculature or neuromuscular disease that compromises the affected limb.
  - A stable, painless arthrodesis in a satisfactory functional position.
  - Severe instability secondary to the absence of collateral ligament integrity.
- Total knee arthroplasty is contraindicated in patients who have rheumatoid arthritis (RA) and an ulcer of the skin or a history of recurrent breakdown of the skin because their risk of postoperative infection is greater. RA patients using steroids may also have increased risk of infection. Late infections in RA patients have been reported 24+ months postoperative.

## WARNINGS

- Do not reuse. This device is for single patient use only.
- Avoid notching, scratching, or striking the device. Improper preoperative or intraoperative implant handling or damage (e.g., scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear.
- Prior to closure of the surgical site, thoroughly cleanse the site of bone chips, bone cement, and any other debris. Foreign particles at the articular interface may cause excessive wear.
- Do not use:
  - This product for other than labeled indications.
  - Any component, if damage is found or caused during setup or insertion.
  - Components from other knee systems (and vice versa) unless expressly labeled for such use. Premature wear or loosening may develop and may require surgical explantation.
  - *NexGen* CR, CRA or CR-Flex femoral components with LPS-Mobile articular surfaces. They were not designed to be compatible.
  - The LPS-Mobile articular surfaces with **porous** LPS-Flex femoral components or **porous** LPS femoral components as these femoral components are not approved for use with the *NexGen* LPS Mobile Bearing Knee systems.
- **All LPS-Mobile 17 and 20mm tibial articular surfaces require a locking screw to fasten the articular surface to the Fluted Stem Mobile tibial baseplate.** Failure to use the locking screw may result in premature failure of the components (e.g., separation) due to the greater moment (i.e., forces) acting on these thicker components.
- Use only LPS-Mobile tibial articular surfaces with the Fluted Stem Mobile tibial baseplates (and vice versa) as they are not compatible with other components.
- Use only *NexGen* all-polyethylene patellas with these femoral components. Patellas made for other systems may demonstrate excessive wear when used with these femoral components.
- Avoid improper positioning and alignment of the implant components. The risk of implant failure is higher with inaccurate component alignment or positioning due to unusual stress conditions which may occur, leading to a reduction in the service life of the implant components. Please refer to the surgical technique manual for information specific to positioning of these implant systems.
- Soft tissues should be balanced and components positioning confirmed to minimize edge loading.
- Consider venting the femur or tibia. Fat embolism risk is increased with intramedullary instrumentation and/or cement pressurization.
- Release leg tourniquets ten minutes apart in simultaneous bilateral knee surgery, to lessen any lung insult that may occur.

## PRECAUTIONS

- LPS-Flex/LPS-Mobile components are sized by matching the femoral component letters and the tibial baseplate component numbers to the articular surface label. Ignore any color codes. A knee implant size matching chart is available to supplement these instructions (See the *NexGen* Complete Knee Solution Component Matching Flowchart in the surgical technique manual). Mismatching may result in poor surface contact and could produce pain, decrease wear resistance, produce instability of the implant, or otherwise reduce implant life.
- Use only instruments and provisional trials specifically designed for use with these devices to help ensure accurate surgical implantation, soft tissue balancing, and evaluation of knee function. Please refer to the accompanying Surgical Techique Manual.
- Thicker polyethylene components may be needed if the patient is young, heavy, and/or physically active.
- The potential for deep sepsis can be minimized by using biocontamination controls. Continued surveillance for new or recurrent sources of infection should be continued as long as the device is in place.
- **The safety and effectiveness of this device has <u>not</u> been established in patients with rheumatoid arthritis, collagen disorders, polyarthritis, or pseudogout; or in patients who need a revision total knee replacement.**

## POTENTIAL ADVERSE EFFECTS ASSOCIATED WITH TOTAL KNEE ARTHROPLASTY

- Loosening of the prosthetic knee components
- Fracture/damage of the prosthetic knee components
- Removal and/or replacement of the device system or its components
- Soft tissue impingement or damage
- Dislocation and/or joint instability
- Malalignment of the prosthetic knee components
- Bone fracture
- Nerve damage
- Infection
- Swelling
- Leg length discrepancies
- Poor range of motion
- Delayed wound healing
- Temporary or permanent neuropathies
- Pain
- Cardiovascular disorders including venous thrombosis, pulmonary embolism or myocardial infarction
- Histological reactions resulting in Inflammation
- Metal sensitivity
- Corrosion of metal components
- Excessive wear secondary to damage of mating wear surfaces and/or debris that can initiate osteolysis which may result in loosening of the implant
- Death

## POTENTIAL ADVERSE EFFECTS ASSOCIATED WITH THE *NEXGEN* LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEMS

- Excessive wear secondary to damage of multiple mating wear surfaces that can initiate osteolysis which may result in loosening of the implant
- Tibiofemoral bearing disassembly
- Tibiofemoral subluxation
- Dislocation and/or joint instability
- Knee stiffness

## ADVERSE EVENTS REPORTED IN THE CLINICAL STUDY OF THE *NEXGEN* LPS-FLEX MOBILE BEARING KNEE

In this clinical study, 388 knees in 374 patients were implanted with either the treatment *NexGen* LPS-Flex Mobile Bearing Knee (n=201) or the control LPS-Flex Fixed Bearing Knee (n=187). All general postoperative adverse events (e.g., systemic, non-device related, etc.) reported during the clinical study on all randomized procedures performed (i.e., All Analyzable procedures) are listed in Table 1. Numbers are cumulative through the 2-year postoperative study endpoint. A time-course distribution of all localized adverse events related to the knee replacement surgey and reported in the clinical study is listed in Table 2.

Postoperatively, only complication rates for knee stiffness requiring manipulation differed statistically (Fisher's exact p = 0.01) between the treatment group (7.0%) and the control group (1.6%).

**Table 1. General Postoperative Complication Rates for All Analyzable Procedures**

| *General Postoperative Complication* | *LPS Flex Mobile (N=201)* | *Control Device (N=187)* | *Fisher's Exact Test P-value* |
|---|---|---|---|
| Anemia | 17 (8.5%) | 9 (4.8%) | 0.16 |
| Cardiac Arrhythmia | 4 (2.0%) | 5 (2.7%) | 0.74 |
| Congestive Heart Failure | 0 | 2 (1.1%) | 0.23 |
| Death | 5 (2.5%) | 3 (1.6%) | 0.73 |
| Infection (contralateral knee cellulitis, following prostectomy, postop - not specified) | 1 (0.5%) | 2 (1.1%) | 0.61 |
| Hemathrosis | 5 (2.5%) | 1 (0.5%) | 0.22 |
| Ileus | 2 (1.0%) | 1 (0.5%) | >0.99 |
| Myocardial Infarction | 2 (1.0%) | 0 | 0.50 |
| Nerve Injury (lumbar spine issues and associated with the surgical procedure) | 0 | 2 (1.1%) | 0.23 |
| Pulmonary Embolism | 1 (0.5%) | 0 | >0.99 |
| Respiratory Infection | 3 (1.5%) | 5 (2.7%) | 0.49 |
| Stroke | 0 | 1 (0.5%) | 0.48 |
| Urinary Retention | 1 (0.5%) | 4 (2.1%) | 0.20 |
| Urinary Tract Infection | 3 (1.5%) | 2 (1.1%) | >0.99 |
| Other General Complications | 221 (73.4%) | 197 (70.6%) | 0.46 |

The numbers and rates for general complications were determined independently for each complication type. General complications for bilateral patients were handled on a case level for each individual patient.

**Table 2. Time Course Distribution of Knee-Related Postoperative Complications and Overall Knee-Related Complication Rates for All Analyzable Procedures**

| Knee-Related Postoperative Complication | Preop | | 6 weeks | | 6 months | | 1 year | | 2 year | | LPS Flex Mobile (N=201) | Control Device (N=187) | Fischer's Exact Test P-value |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Mobile | Control | Mobile | Control | Mobile | Control | Mobile | Control | Mobile | Control | | | |
| Deep Wound Infection < 6 weeks | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.5%) | 0.48 |
| Deep Vein Thrombosis | 0 | 0 | 10 | 9 | 0 | 1 | 0 | 0 | 0 | 0 | 10 (5.0%) | 10 (5.3%) | >0.99 |
| Delayed Wound Healing | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.5%) | 0 | >0.99 |
| Device Clicking | 0 | 0 | 2 | 4 | 0 | 2 | 1 | 1 | 1 | 0 | 4 (2.0%) | 7 (3.7%) | 0.37 |
| Dislocation (poly only, relocated spontaneously) | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.5%) | 0 | >0.99 |
| Effusion | 0 | 0 | 3 | 7 | 2 | 2 | 4 | 1 | 0 | 3 | 9 (1.3%) | 13 (6.9%) | 0.38 |
| Flexion Contracture | 0 | 0 | 1 | 4 | 0 | 1 | 0 | 0 | 0 | 0 | 1 (0.5%) | 5 (2.7%) | 0.11 |
| Fracture of Femur | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.5%) | 0.48 |
| Fracture of Patella | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 (0.5%) | 1 (0.5%) | >0.99 |
| Hematoma | 0 | 0 | 1 | 4 | 0 | 1 | 0 | 0 | 0 | 0 | 1 (0.5%) | 5 (2.7%) | 0.11 |
| Heterotopic Ossification-Femur | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 (0.5%) | 0 | >0.99 |
| Nerve Deficit | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 (0.5%) | 1 (0.5%) | >0.99 |
| Nerve Injury (lumbar spine, not related to implant or procedure; peroneal nerve palsy, related to procedure)) | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 (1.1%) | 0.23 |
| Patella Clunk | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 (0.5%) | 0.48 |
| Patellofemoral Crepitus | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 (1.1%) | 0.23 |
| Patellofemoral Subluxation | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 1 (0.5%) | 1 (0.5%) | >0.99 |
| Stiff Knee Resulting in Manipulation (4 were done under anesthesia) | 0 | 0 | 14 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 14 (7.0%) | 3 (1.6%) | 0.01 |
| Superficial Infection | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4 (2.1%) | 0.05 |
| Tibial Base Plate Loosening | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 1 (0.5%) | 1 (0.5%) | >0.99 |
| Tibial Pain | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 (0.5%) | 0 | >0.99 |
| Wound Dehiscence | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.5%) | 0 | >0.99 |
| Wound Drainage | 0 | 0 | 3 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 3 (1.5%) | 3 (1.6%) | >0.99 |
| Other Knee Related Complications | 0 | 2 | 30 | 26 | 10 | 15 | 17 | 12 | 8 | 10 | 65 (30.1%) | 63 (31.7%) | 0.75 |

## CLINICAL STUDY

A prospective clinical study was conducted to evaluate the safety and effectiveness of the *NexGen* LPS-Flex Mobile Bearing Knee.

### Clinical Study Design

The study was an open, randomized, multi-center, concurrently controlled, non-inferiority clinical trial that compared the safety and effectiveness of the *NexGen* LPS-Flex Mobile Bearing knee system (treatment group) to the non-mobile bearing *NexGen* LPS-Flex Fixed Bearing Knee (control group) at the 2 year postoperative endpoint. Clinical study endpoints included pain, function, radiographic parameters, device survivorship, and complications. The study was conducted at 15 centers and included 388 procedures in 374 patients. This 388 All Analyzable procedures cohort (i.e., all randomized procedures performed) consisted of 201 cases in the treatment group and 187 cases in the control group.

The study included patients 21-80 years of age presenting with severe knee pain and disability due to degenerative joint disease, including:

- Osteoarthritis
- Avascular necrosis of the femoral condyle
- Posttraumatic arthritis

Per study protocol, the primary study analysis cohort excluded bilateral cases and rheumatoid arthritis cases. However, a large number of patients (n=82), failed to meet all protocol inclusion criteria (e.g., pain and function assessment of less than 60 points on the Knee Society Score (KSS)), but were enrolled into the study. As a result, the primary analysis cohort used to evaluate study success was based on the "As Treated" patients (i.e., excluded bilateral cases and rheumatoid arthritis cases, and included protocol inclusion critieria deviations) instead of the "Per-Protocol" patients. The "As Treated" cohort consisted of 341 cases, with 173 in the treatment group and 168 in the control group.

The efficacy of the LPS-Flex Mobile Knee was determined by comparing the survivorship, Knee Society Assessment and Function scores, and selected radiographic parameters, of the treatment group to the control group in the primary study cohort.

The safety of the LPS-Flex Mobile Bearing Knee in patients was evaluated by monitoring the difference in cumulative rates of severe knee related complications and unanticipated adverse device effects (UADE's) between the treatment group and the control group in the primary study cohort.

### Clinical Patient Assessment

Each patient was evaluated 6 weeks, 6 months, 12 months and 24 months after surgery which included pain, function, quality of life, and radiographic evaluations. At two year intervals thereafter, patients were evaluated until the last patient enrolled completed a two-year follow-up evaluation. An independent radiologist reviewed the 6 week and 24 month radiographs by standardized criteria to eliminate potential variability and bias

Clinical success is a composite measure of the primary safety and effectiveness endpoints, and was determined separately for each individual patient. To be considered a clinical success a patient had to meet the success criteria for all five primary study endpoints as noted in Table 3.

Table 3: Success Criteria for Primary Study Endpoints at 2 Years

| Primary Clinical Endpoints | Success Criteria |
|---|---|
| Knee Society Assessment (pain) Score | Knee Society Assessment (pain) Score ≥ 70 |
| Knee Society Function Score | Knee Society Function Score ≥ 70 |
| Adverse Events / Complications | Absence of Severe Knee Related AE's and UADE's |
| Radiographic Parameters | < 2mm Radiolucencies and < 2mm Implant Position Change |
| Survivorship / Revision | No component/device revision or removal |

There were a total of 748 complications reported on the All Analyzable procedures dataset (see Tables 1 and 2). Of these complications, 386 (51.6%) involved the treatment group, and 362 (48.4%) involved the control group.

The percentage of cases experiencing at least one postoperative complication was similar between the two study device groups. In the treatment group, there were 154/201 (76.6%) cases experiencing at least one postoperative complication, and in the control group there were 143/183 (76.5%). These rates did not differ statistically between the device groups.

Postoperatively, only complication rates for knee stiffness requiring manipulation differed statistically (Fisher's exact p = 0.01) between the treatment group (7.0%) and the control group (1.6%). Otherwise, general and knee related complication rates were similar and did not differ statistically between the device groups.

## ***Results***

### Demographics

The primary AsTreated cohort of 341 cases included 199 females (treatment group = 94, control group = 105), and 142 males (treatment group = 79, control group = 63). Preoperative diagnoses consisted of 1 case with avascular necrosis (treatment group), 333 cases with osteoarthritis (treatment group = 168, control group = 165), and 7 cases with post-traumatic arthritis (treatment group = 4, control group = 3).

Results suggest that there were no significant differences (p=0.05) between study devices in key baseline, demographic, or operative variables, such as age, gender, operative side, preoperative diagnosis, preoperative KSS pain and function scores, or operating time, specified in the study protocol.

At two years, patient follow-up was greater than 95% for both study groups. There were eight deaths for reasons unrelated to the surgery or the device (treatment group = 5, control group = 3).

### Safety and Effectiveness Data

Safety and effectiveness results for the primary As Treated study cohort (i.e., 341 cases - 173 treatment group, 168 control group) at two years post-operatively are provided below.

### Safety Results

Adverse Events

The adverse events related to total knee replacement surgery for *all* procedures performed in the clinical study are listed in Tables 1 and 2.

Severe Knee Related Complications & Unanticipated Adverse Device Effects

The results for the primary safety endpoint of severe knee related complications and unanticipated adverse device effects at 2 years, which represent a clinical safety failure, are given in Table 4.

**Table 4. Primary Safety Endpoint Analysis – Available As Treated Endpoints**

| Primary Study Endpoint | LPS Flex Mobile (N=173) | Control Device (N=168) | Difference (98% CI) ¤ [δ = delta]* | Fisher's Exact Test p-value^ (Lt tail) |
|---|---|---|---|---|
| Severe Knee Related Complications & UADEs – N (%) | 3/173 (1.7%) | 5/168 (3.0%) | -1.2% (-5.1%, 2.6%) [8.9%] | 0.87 |

* δ *is the small, maximum clinically acceptable, pre-specified non-inferiority margin.*

¤ *The 98% two-sided confidence limit is presented as it provides the 99% one-sided lower (upper) limit when the upper (lower) bound is ignored, as required to assess non-inferiority.*

^ *Since the p-value was 0.87, a value which is greater than the alpha (Type I error) level of 1 percent (p=0.01) pre-specified for the one-sided test of the primary safety endpoint, we can declare the LPS-Flex Mobile Bearing Knee does not differ from the LPS-Flex Fixed Knee with any clinical significance at 2 years.*

The results for the primary safety endpoint of cumulative incidence of severe knee related complications and unanticipated adverse device effects demonstrate that the treatment group does not differ with any clinical significance from the control group at the 2 year study endpoint.

There were a total of two device revisions reported during this study.

There were no unanticipated adverse device effects reported in the study.

## Efficacy Results

The results for the for the individual primary efficacy endpoints of pain, function, radiographic parameters, and survivorship at 2 years are given in Table 5.

**Table 5. Primary Efficacy Endpoints Analysis – Available As Treated Endpoints**

| Primary Study Endpoint | LPS Flex Mobile (N=173) | Control Device (N=168) | Difference (98% CI) $^{\pi}$ [δ = delta]* | Fisher's Exact Test p-value^ (Lt tail) |
|---|---|---|---|---|
| Knee Society Assessment (pain) Score<br>N<br>Mean (Std Dev)<br>(Min, Max) | <br>165<br>87.9 (12.89)<br>(49, 100) | <br>165<br>88.0 (14.10)<br>(37.6, 100) | <br>-0.16 points<br>(-3.64, 3.31)<br>[-5.7 points] | |
| Knee Society Function Score<br>N<br>Mean (Std Dev)<br>(Min, Max) | <br>172<br>79.7 (22.04)<br>(0, 100) | <br>168<br>80.5 (20.38)<br>(5, 100) | <br>-0.80 points<br>(-6.2, 4.5)<br>[-8.2 points] | |
| Radiolucency ≥ 2mm and/or Implant Component Position Change ≥ 2mm<br>%<br>(n/N) | <br>1.2%<br>(2/172) | <br>2.4%<br>(4/164) | <br>1.3%<br>(-4.7%, 2.1%)<br>[5.7%] | <br>0.90[1] |
| Revision/Removal of Study Device or Component<br>%<br>(n/N) | <br>0.6%<br>(1/173) | <br>0%<br>(0/168) | <br>0.6%<br>(-0.8%, 1.9%)<br>[4.1%] | <br>0.51[2] |

* *δ is the small, maximum clinically acceptable, pre-specified non-inferiority margin. A negative sign was added to the value specified in the clinical protocol to indicate the direction of the limit for interpretation.*

$^{\pi}$ *The 98% two-sided confidence limit is presented as it provides the 99% one-sided lower (upper) limit when the upper (lower) bound is ignored as required to assess non-inferiority*

[1] *Since the p-value was 0.90, a value which is greater than the alpha (Type I error) level of 1 percent (0.01) pre-specified for the one-sided test of the primary radiographic endpoint, we can declare the LPS-Flex Mobile Bearing Knee does not differ from the control device with any clinical significance at 2 years.*

[2] *Since the p-value was 0.51, a value which is greater than the alpha (Type I error) level of 1 percent (0.01) pre-specified for the one-sided test of the primary survival endpoint, we can declare the LPS-Flex Mobile Bearing Knee does not differ from the control device with any clinical significance at 2 years.*

Knee Society Assessment Scores

The results for the primary efficacy endpoint of pain, as measured by the KSS Assessment (pain) Score, demonstrate that the treatment group does not differ with any clinical significance from the control group at the 2 year study endpoint.

Knee Society Function Scores

The results for the primary efficacy endpoint of function, as measured by the KSS Function Score, demonstrate that the treatment group does not differ with any clinical significance from the control group at the 2 year study endpoint.

Radiographic Data

The results for the primary efficacy endpoint of radiographic parameters, as measured by the presence of radiolucency(ies) ≥ 2 millimeters and/or implant component position change ≥ 2 millimeters, which represent radiographic failure, demonstrate that the treatment group does not differ with any clinical significance from the control group at the 2 year study endpoint.

Implant Survivorship

The results for the primary efficacy endpoint of implant survivorship, as measured by the cumulative revisions/removals of the device, which represents implant failure, demonstrate that the treatment group does not differ with any clinical significance from the control group in cumulative number of revisions at the 2 year study endpoint.

There were two device revisions reported during this study. One patient (treatment group) was revised with a new femoral component after 21 months, prior to the 2 year study endpoint. One bilateral patient (control group) was revised with a new articular surface after 31 months, subsequent to the 2 year study endpoint, and does not appear in the data tables.

## Clinical Success

Table 6 displays the proportion of patients that met the success criteria for each of the five individual study endpoints at 2 years post-operatively.

**Table 6: Individual Success Criteria Results at 2 Years**

| Success Criteria | LPS Flex Mobile (N= 173) | Control Device (N=168) |
|---|---|---|
| Knee Society assessment (pain) score ≥ 70 | 92% (152/165) | 88% (145/165) |
| Knee Society function Score ≥ 70 | 79.7% (137/172) | 80.5% (135/168) |
| Absence of severe knee related AE's and UADE's | 98.3% (170/173) | 97% (163/168) |
| < 2mm radiolucencies and < 2mm subsidence for all views | 98.8% (170/172) | 97.6% (160/164) |
| No component/device removal | 99.4% (172/173) | 100% (168/168) |

A secondary analysis of the composite measure of clinical success was also performed. That is, the proportion of patients from each group that met the success criteria for **all** five primary study endpoints were compared. Table 7 displays the composite clinical success rates for the treatment group in comparison to the control group.

**Table 7. Secondary Endpoint Analysis for Clinical Success – Available As Treated Endpoints**

| Secondary Study Endpoint | LPS Flex Mobile (N=173) | Control Device (N=168) | Difference (90% CI) [δ = delta]* |
|---|---|---|---|
| Composite Measure of Achieving Clinical Success – % (n/N) | 69.1% (114/165) | 67.7% (109/161) | 1.4% (-7.1%, 9.9%) [10.0%] |

* *δ is the small, maximum clinically acceptable, pre-specified non-inferiority margin. A negative sign was added to the value specified in the clinical protocol to indicate the direction of the limit for interpretation.*

π *The 90% two-sided confidence limit is presented as it provides the 95% one-sided upper limit when the lower bound is ignored as required to assess non-inferiority*

The results demonstrate that the treatment group does not differ with any clinical significance from the control group in terms of the composite measure of clinical success.

## STERILITY

- Gamma irradiation is indicated by the "Sterile-R" symbol on the labeling. These devices remain sterile as long as the package integrity has not been violated.
- Inspect each package prior to use and do not use the component if any seal or cavity is damaged or breached or if the expiration date has been exceeded.
- Once opened, the component must be used, discarded, or resterilized.

## RESTERILIZATION INFORMATION

These resterilization instructions are consistent with AORN and ANSI/AAMI/ISO guidelines. They should be used only for sterile items that were opened but unused. **Do not resterilize single use only components that have been contaminated with body fluids or debris or previously implanted or exceed their expiration date.**

*Zimaloy* alloy and PMMA-coated metal implants may be steam resterilized as follows:

| Type | Minimum Temperature | Minimum Exposure Time |
|---|---|---|
| Gravity Displacement | 121°C (250°F) | 30 minutes |
| Gravity Displacement | 132°C (270°F) | 15 minutes |
| Pre-vacuum | 132°C (270°F) | 4 minutes |

UHMWPE implants may be 100% Ethylene Oxide (EO) resterilized as follows:

| Gas Concentration | Temperature | Exposure Time | Relative Humidity |
|---|---|---|---|
| 725mg/L EO | 55°C (131°F) | 60 minutes | 70% |

The recommended aeration period for EO is a minimum of 12 hours at 54°C (130°F) in a heated mechanical aerator.

UHMWPE implants may also be resterilized using the following STERRAD gas plasma parameters:

| Gas Concentration | Temperature | Exposure Time |
|---|---|---|
| 6 mg/L (59% hydrogen peroxide) | 45°C (113°F) | 65 minutes |

- Do not use the original plastic cavities or lids for resterilization.
- Do not expose polyethylene components or components made exclusively from polymethyl methacrylate (PMMA) to steam sterilization. The high temperatures may cause softening, warping, cracking, or dimensional and material property changes. PMMA-coated metal components may be steam sterilized.
- Before resterilization of PMMA-coated metal components, each item must be rinsed with USP purified water to remove any lint or debris and enclosed in a lint-free sterilization wrap. Do not allow contact of any PMMA surface with the wrap or sterilization tray holding devices because the coating softens slightly during sterilization and might be damaged. Very fine lines may develop in the coating during sterilization. This will not affect the bonding between the PMMA and the bone cement. Cool resterilized PMMA components naturally. Do not force cooling by immersion in room temperature water or saline.

- Additional resterilization information is available upon request. In the USA, call 1-800-348-2759. For calls outside the USA, call the local international access code +1-574-267-6131.

**PATIENT COUNSELING INFORMATION**

Complications and/or failure of total knee prostheses are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients, and/or with patients that fail to follow through with the required rehabilitation program. Not all patients with LPS-Flex components will achieve 155 degrees of flexion. Excessive physical activity and injury can result in loosening, wear, and/or fracture of the knee implant. The patient must be instructed about all postoperative restrictions, particularly those related to occupational and sports activities and about the possibility that the implant or its components may wear out, fail, or need to be replaced. Please refer them to the Patient Labeling Brochure. The implant may not, and is not guaranteed to, last the rest of the patient's life. Because prosthetic joints are not as strong, reliable, or durable as natural, healthy joints, all prosthetic knees may need to be replaced at some point.

**℞** only

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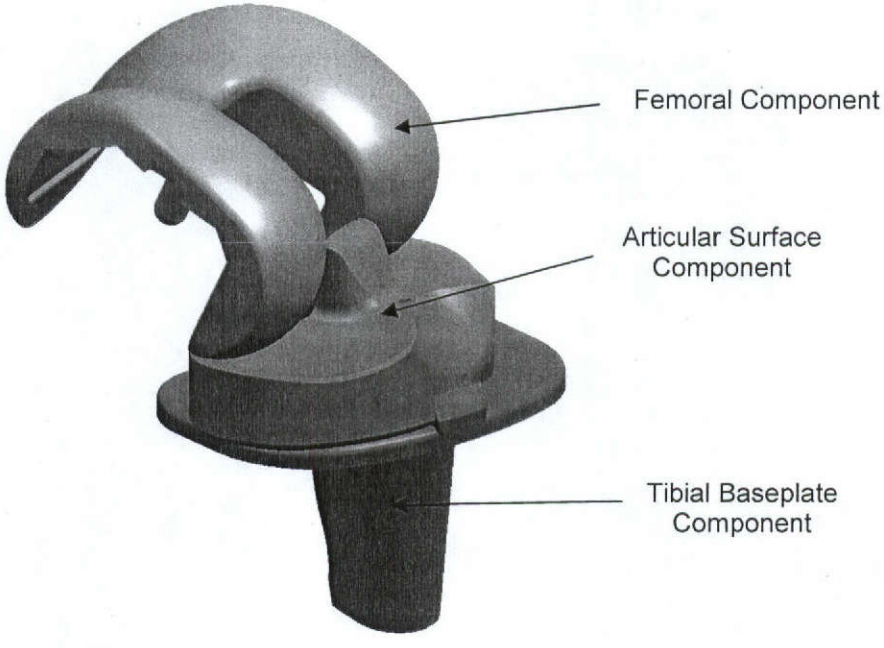
# 2.2
# Patient Labeling

# Zimmer® NexGen®
# LPS-Flex Mobile and LPS-Mobile Bearing Knees
Important Patient Information

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## What Are The *NexGen* LPS-Flex Mobile and LPS-Mobile Bearing Knees?

The *NexGen* LPS-Flex Mobile and LPS-Mobile Bearing knee systems are total knee replacements that are designed to both bend and rotate.

Each system includes a metal femoral component that replaces the end of the thigh bone (femur), a metal tibial base plate that replaces the top of the shin bone (tibia), and a plastic articular surface component that is loosely attached to the tibial base plate and serves as artificial cartilage between the femoral component and the tibial base plate. The femoral component and tibial base plate are implanted using bone cement.

As in most total knee implant systems, the femoral component of a mobile bearing knee rides on top of the articular surface component to provide the knee's bending movement. A mobile bearing knee design allows the articular surface component to rotate on the tibial baseplate to allow free movement as needed.

The only difference between the LPS-Flex Mobile and LPS-Mobile Bearing Knees is in the femoral component that replaces the end of the thigh bone. The LPS-Flex Mobile femoral components are designed to accommodate an increased range of motion for the knee. The range of motion for the LPS-Flex femoral component is designed to range from 0° to 155° whereas the range of motion for the LPS-Mobile femoral component is designed to range from 0° to 120°.

Your physician will discuss with you which femoral component option is appropriate for your total knee replacement.

## What Happens During Total Knee Replacement Surgery?

The surgical procedure involves removing the diseased or damaged portions of your natural knee and replacing them with artificial devices (implants). The *NexGen* LPS-Flex Mobile and LPS-Mobile Bearing knee systems are designed for use when both cruciate ligaments have been removed.

The surface of the thigh bone is replaced with a rounded metal component (femoral component) that comes very close to matching the curve of your natural bone. The upper surface of the shin bone is replaced with a flat metal component (tibial base plate). The articular surface component is inserted on top of the tibial base plate and serves as a replacement for your cartilage. The articular surface is very smooth, like cartilage, and is made from ultra-high-molecular-weight polyethylene, which is a very strong, medical grade plastic. The undersurface of the kneecap may also be replaced with an implant made of the same polyethylene plastic.

**How Are The *NexGen* LPS-Flex Mobile and LPS-Mobile Bearing Knees Used (Indications For Use)?**

These devices are used to replace the knee joints of patients with severe knee pain and disability due to:

- Deterioration of the knee joint cartilage (osteoarthritis)
- Arthritis resulting from physical injury to the knee joint (traumatic arthritis)
- Moderate bowlegged, knock-kneed or bending abnormality
- A loss of blood supply to the lower portion of the thigh bone that leads to tiny breaks within the bone and possible bone collapse (avascular necrosis)

These devices must be implanted using bone cement.

**When Should These Devices Not Be Used (Contraindications)?**

Your doctor may decide that knee replacement surgery is not appropriate if:

- You have an infection or a history of infection
- You do not have enough bone or the bone is not strong enough to support your new knee
- You have injured nerves in your knee area
- You have injured or non-functional knee muscles
- Your knee is severely unstable
- Your bones are not fully grown or developed
- You have noticeable bone loss or a severe decrease in bone mass (osteoporosis)
- Your knee joint has been previously fused and is stable, functional and painless
- You have rheumatoid arthritis and active/history of skin lesions (due to increased risk of infection)

**What Warnings Apply To These Devices?**

WARNING:
You should avoid excessive physical activities, such as impact sports (running, jogging, football, etc.) or activities that place too much stress on the knee joint (downhill skiing, mountain climbing, singles tennis, etc.). These activities significantly increase the chance of complications and/or failure of the knee components (such as breakage, excessive wear or dislocation). Your chances of success with this knee increase if you limit your activity.

WARNING:
Avoid trauma to your knee and weight gain as these could cause premature failure of the implant by loosening, fracture and/or wear. Loosening of the implants can result in increased production of wear particles, as well as damage to the bone making successful revision surgery more difficult.

**What Precautions Apply To These Devices?**

PRECAUTION:
Listen to your doctor. Your doctor will provide you with important postoperative instructions. You will be advised of the limitations of the prosthesis and the need for protection of the implant until adequate healing has occurred. Your failure to follow these postoperative care and rehabilitation instructions will reduce your success with this knee.

PRECAUTION:
Inform your doctor if any symptoms of infection occur. These may include, but are not limited to, localized pain, increased temperature, and redness near the surgical site, or increased general patient temperature. Infection usually requires treatment and can lead to implant failure or removal.

PRECAUTION:
The safety and effectiveness of this device has not been established in patients with rheumatoid arthritis, collagen disorders, polyarthritis, or pseudogout; or in patients who need a revision total knee replacement.

**What Are The Risks/Benefits For These Devices?**

While there can be no guarantee of success, benefits can include pain relief and return of normal use of the knee.

The risks and complications associated with knee replacement using the *NexGen* LPS-Flex Mobile and LPS-Mobile Bearing Knees are expected to be similar to those of other knee replacements. Each of the following reactions or complications can occur during and after surgery and may require medical attention (such as further surgery) and implant removal.

- The bone next to the knee implant may break down (osteolysis) due to your body's reaction to particles that may be caused by:

  - Direct contact of the metal and plastic components
  - Contact between the knee components and the bone cement
  - Contact between the knee components and your natural bone

  Particles that exist between the knee's moving parts can cause more particles or damage to the implant components.

- Implant fracture has been reported following total knee replacement. This is typically caused by:

  - Patients with unrealistic performance expectations
  - Heavy patients
  - Physically active patients

  To minimize the possibility for implant fracture, it is important to follow medical instructions and to avoid excessive or inappropriate activity.

- Removal and/or replacement of the device system or its components may be necessary at some point in the future.

- Although rare, metal allergy reactions from knee implants have been reported. Inform your doctor if you have any allergy symptoms.

- Dislocation can result from improper positioning of the implant components.

- Implant components can loosen or move due to improper cementing, or shock from falls or collisions.

- Cardiovascular disorders associated with the use of bone cement include blood clots, decreased blood pressure, heart attack, and in rare instances death.

- Infection is a risk in any surgical procedure.

**Have These Devices Undergone Clinical Studies?**

A clinical investigation of the *NexGen* LPS-Flex Mobile Knee involving 173 patients (201 knees) was performed in the United States to determine its safety and effectiveness.

- At 2 years following surgery, 155 out of 172 patients (90%) experienced either mild or no pain with 97 of these patients (56%) experiencing no pain at anytime.

- At 2 years after surgery, 152 out of 172 patients (88%) required no support when walking.

- Within two years of the initial surgery, one of the 201 knees (0.5%) were removed or replaced.

## What Complications Might Occur During Surgery Or Later (Adverse Events)?

Adverse events occurring in this clinical investigation of the *NexGen* LPS-Flex Mobile Knee in the United States were similar to those reported for other commercially available knee components. Adverse events reported out of 201 knees were:

| **Complication (n = 201)** | **# Reported** |
|---|---|
| Accumulation of blood in the joint (hemathrosis) | 5 |
| Vein blood clot (deep vein thrombosis) | 10 |
| Delayed wound healing | 1 |
| Device clicking | 4 |
| Dislocation | 2 |
| Accumulation of excessive amount of fluid in the joint space (effusion) | 9 |
| Decrease in ability to flex the leg (flexion contracture) | 1 |
| Fracture of the knee cap (patella) | 1 |
| Local blood clot (hematoma) | 1 |
| Unanticipated thigh bone formation (heterotropic ossification - femur) | 1 |
| Nerve damage (neural deficit) | 1 |
| Doctor bends the stiff knee joint (stiff knee resulting in manipulation by doctor) | 14 |
| Tibial base plate loosening | 1 |
| Tibial pain | 1 |
| Wound splitting open (dehiscence) | 1 |
| Wound drainage | 3 |

## What Might Increase The Risk Of Failure?

- Patients who are unable or unwilling to follow instructions given by medical professionals
- Noticeable bone loss, severe decreased bone mass (osteoporosis)
- Heavy patients
- Impact sports, such as running, jogging, downhill skiing and singles tennis
- Softening of the bones (osteomalacia)
- Metal allergies
- Infection

## What Is My Role As A Patient?

There are limits to what you can do after you receive your new knee. You will need to avoid placing your full weight on your knee implant until adequate healing has occurred. Ask your doctor about when it is safe to place full weight on your knee. Even after full healing, any excessive activity (such as contact sports or activities that provide a twisting or impact force) can cause broken bones, loosening, excessive wear or breakage of the knee implants. Loosening and excessive wear can also result in increased number of loose particles around the implant, which can make another surgery necessary and more difficult.

Please read and obey any instructions given to you by your doctor or health care professional.

## When Should I Contact My Doctor?

When any of the following occur or as your doctor instructs:

- Redness, swelling, or drainage from the incision
- An unexplained fever (temperature over 100° Fahrenheit or 38° Centigrade) or chills that last more than a day
- Severe knee pain that is not relieved by pain medication
- Any unusual shortening or turning (rotation) of the leg
- Any unusual noise coming from the knee implant
- A feeling that "something isn't right"
- Any sudden swelling in the thigh or calf
- Any shortness of breath
- Any chest pressure

## What Alternatives Do I Have?

Depending upon your situation, alternative procedures may include the use of other total knee replacement components or non-surgical treatments such as reduced activity or pain medications. They may also include other surgical and medical treatments that do not involve the use of an implant.

**What About My Knee Implant And Airport Security?**

It is possible that your implant will be detected by an electronic security device at airports. If concerned about privacy, ask the security officer to be discreet when assisting you through the screening process. Although not required, if your doctor has issued you an implant ID card, it may speed the inspection process if you show this card to the security officer. Usually, the security officer will offer you a private screening after being informed that you have a metal implant device. Security officers will need to resolve all alarms associated with metal implants. Most alarms will be able to be resolved during a pat-down, therefore it will not be necessary to remove or lift clothing as part of the inspection process.

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# 2.3
# Operator's Manual

# Zimmer® NexGen® LPS-Flex Mobile and LPS-Mobile Bearing Knees

Surgical Technique



Designed for rotation and safe high flexion

zimmer
Confidence in your hands®

# Zimmer NexGen LPS-Flex Mobile and LPS-Mobile Bearing Knees Surgical Technique

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## Introduction

Successful total knee arthroplasty depends in part on re-establishment of normal lower extremity alignment, proper implant design and orientation, secure implant fixation, adequate soft tissue balancing and stability.

The LPS-Flex Mobile and LPS-Mobile Bearing Knees are posterior stabilized prostheses designed to accommodate greater range of motion for appropriate patients, such as those who are physically capable or whose cultural customs or recreational/work activities require deep flexion.

The development of the LPS-Mobile Bearing Knee Systems is the result of an analysis of a knee prosthesis as it undergoes deep flexion beyond 120°. For example, the interaction of the posterior condyles on the articular surface was carefully studied. As a result, efforts have been made to optimize the contact area as the posterior condyles roll back to flexion angles up to 155° (Fig. 1). This is addressed by thickening the posterior condyles, thereby extending the radius.

**Fig. 1** Contact area at 155°

The tibial articular surface was also considered in the design. In deep flexion, the extensor mechanism experiences a high level of stress as the soft tissues are stretched and pulled tightly against the anterior tibia and distal femur. The LPS-Mobile Bearing Knee Systems are designed to help relieve these stresses through a larger, deeper anterior cutout on the articular surface (Fig. 2). This cutout accommodates the extensor mechanism in deep flexion.

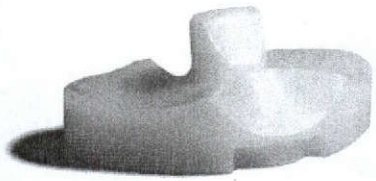

Fig. 2

Additionally, the cam/spine mechanism has been modified to provide greater jump height as the knee prosthesis undergoes deep flexion between 120° and 155°. The cam/spine mechanism induces mechanical rollback while inhibiting posterior subluxation of the tibia.

These design features accommodate high-flexion activities and, together with proper patient selection, surgical technique, and rehabilitation, increase the potential for greater range of motion. The LPS-Flex Mobile and LPS-Mobile Bearing Knee Components can be implanted using any of the *NexGen*® Knee Instrument Systems.

The surgical approach to the LPS-Mobile Knee is the same as for a fixed bearing knee. Intraoperatively, the only variation is the tibial preparation. The decision of fixed or mobile can be made intraoperatively.

When implanting the LPS-Flex Mobile femoral component, the gold Femoral Finishing Guide is used. When implanting the LPS 'non-Flex' femoral component, the (silver colored) MIS Femoral Finishing Guide is used. (Reference page 27 "Option 1 – Posterior Referencing Technique" and page 30 "Option 2 – Anterior Referencing Technique")

### Multi-Reference® 4-in-1 Instruments

*Multi-Reference* 4-in-1 Instruments are designed to help the surgeon accomplish the goals of total knee arthroplasty by combining optimal alignment accuracy with a simple, straight-forward technique. The instruments promote accurate cuts to help ensure secure component fixation.

The *Multi-Reference* 4-in-1 Instruments provide a choice of either anterior or posterior referencing techniques for making the femoral finishing cuts. The anterior referencing technique uses the anterior cortex to set the A/P position of the femoral component. The posterior condyle cut is variable. The posterior referencing technique uses the posterior condyles to set the A/P position of the femoral component. The variable cut is made anteriorly. The posterior referencing technique will help provide a consistent flexion gap. Femoral rotation is determined using the posterior condyles or epicondylar axis as a reference.

The instruments and technique assist the surgeon in restoring the center of the hip, knee, and ankle to lie on a straight line, establishing a neutral mechanical axis. The femoral and tibial components are oriented perpendicular to this axis (Fig. 3). Use the template overlay (available through your Zimmer representative) to help determine the angle between the anatomic axis and the mechanical axis of the femur. This angle should be reproduced intraoperatively.

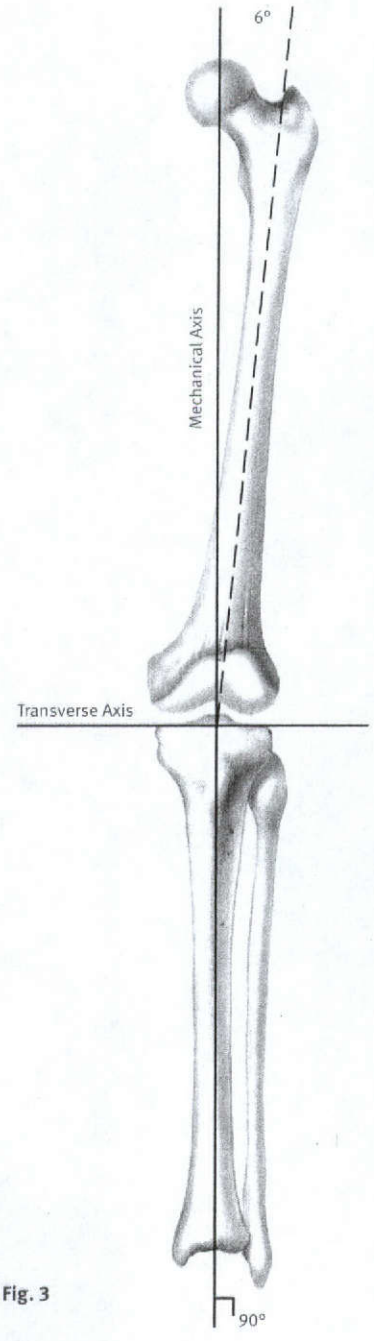


Fig. 3

A common view among orthopaedic surgeons is that certain patients have greater potential for achieving higher flexion after knee replacement. Patients with good flexion preoperatively tend to get better motion postoperatively. To optimize use of the high-flexion design elements of the LPS-Flex Mobile Bearing Knee, the following criteria should be considered:

- The patient should have a need and desire to perform deep-flexion activities. This need may be dictated by cultural or social customs where practices such as frequent kneeling, sitting "cross-legged," and squatting are common. Also, activities specific to daily living, leisure and recreation, or job performance may require high-flexion capability.
- The patient should be capable of reaching 110° of flexion preoperatively with a reasonable probability of achieving a range of 125° postoperatively.
- It may also be important to consider the length of time the patient has not performed high-flexion activities.
- The patient should have a thigh-calf index of less than 90° (Fig. 4).
- The patient should have stable and functional collateral ligaments.
- If the patient has an angular deformity, it should be less than 20°. Keep in mind that it is more difficult to achieve ligament balance in these patients. And, in patients with severe deformity, consider the patient expectation for achieving high flexion.

The LPS-Flex Mobile Bearing Knee is designed to accommodate high flexion, and not create high flexion.

If using a minimally invasive technique, it is suggested that the patient criteria include non-obese patients with preoperative flexion greater than 90°. Patients with varus or valgus deformities greater than 15° are typically candidates for a standard arthrotomy technique.

Patients with severe deformity or instability may not be suitable candidates for a mobile bearing implant.

See the back section of surgical technique for package insert.

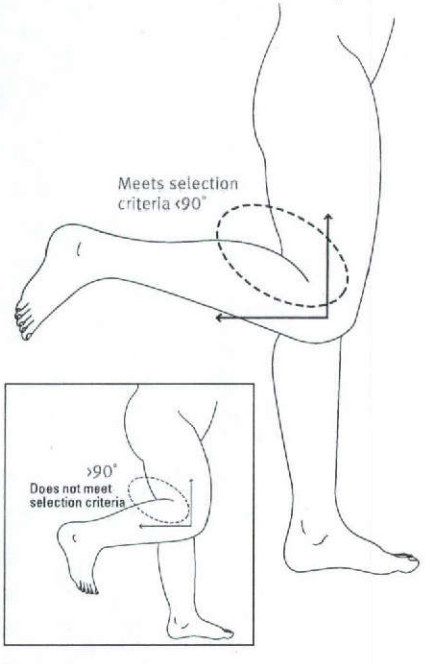


Fig. 4 Thigh-calf angle

## Preoperative Planning

This surgical technique helps the surgeon ensure that the distal femur will be cut perpendicular to the mechanical axis and, after soft tissue balancing, will be parallel to the resected surface of the proximal tibia.

Use the various templates to approximate the appropriate component sizes. The final sizes will be determined intraoperatively; therefore, larger and smaller sizes should be available during surgery. Plan appropriately to have a fixed bearing system available if a femoral/tibial mismatch exists.

Verify that the femoral and tibial component sizes approximated will be compatible by cross-referencing the femoral and tibial sizes on the Interchangeability Chart.

**Note: If a femoral/tibial mismatch exists, a fixed bearing system should be used.**

| | | Femoral Size | | | | | |
|---|---|---|---|---|---|---|---|
| | | AB | C | D | E | F | G |
| Tibial Size | 1 | AB/1-3 | | | | | |
| | 2 | AB/1-3 | C/2-4 | | | | |
| | 3 | AB/1-3 | C/2-4 | D/3-5 | | | |
| | 4 | | C/2-4 | D/3-5 | E/4-6 | | |
| | 5 | | | D/3-5 | E/4-6 | F/5-7 | |
| | 6 | | | | E/4-6 | F/5-7 | G/6-8 |
| | 7 | | | | | F/5-7 | G/6-8 |
| | 8 | | | | | | G/6-8 |
| Patella Size | Use standard size Patellas with all LPS and LPS-Flex Femoral Components<br>26mm (inset only)† 32mm† 38mm<br>29mm† 35mm 41mm | | | | | | |

† For G & H Femoral Components, the 26, 29 and 32mm patellar components must be inset.

## Preoperative Conditioning

To prepare the patient for surgery, it may be helpful for the patient to perform mobility exercises to prepare the ligaments and muscles for the postoperative rehabilitation protocol.

## Surgical Technique

Surgical technique is an important factor to consider when attempting to maximize range of motion in total knee arthroplasty (TKA). Close attention must be paid to balancing the flexion and extension gaps, clearing posterior osteophytes, releasing the posterior capsule, and reproducing the joint line.

Although the joint line often changes as a result of a posterior cruciate substituting procedure, it is important that an attempt be made to maintain the joint line when high flexion is a priority. Depending on the degree, altering the joint line can cause patellofemoral issues and limit the degree of flexion. An elevated joint, for example, can cause tibiofemoral tightness in roll-back and thus restrict flexion.[1]

When using the gap technique, it is possible that the joint line may be moved proximally, especially if there is a preoperative flexion contracture or if the selected femoral component is smaller than the A/P dimension of the femur. The alteration of the joint line can be minimized by accurately measuring for the femoral component size and performing a posterior capsulotomy to correct flexion contractures.

## Patient Preparation

To prepare the limb for total knee arthroplasty, adequate muscle relaxation is required. This will facilitate the eversion of the patella, if desired, and minimize tension in the remaining quadriceps below the level of the tourniquet. **It is imperative that the muscle relaxant be injected prior to inflation of the tourniquet. Alternatively, spinal or epidural anesthesia should produce adequate muscle relaxation.**

If using a tourniquet, apply the proximal thigh tourniquet and inflate it with the knee in hyperflexion to maximize that portion of the quadriceps that is below the level of the tourniquet. This will help minimize restriction of the quadriceps and ease patellar eversion.

Once the patient is draped and prepped on the operating table, determine the landmarks for the surgical incision with the leg in extension.

## Incision and Exposure

The incision may be made with the leg in extension or flexion depending on surgeon preference. The surgeon can choose a midvastus approach, a subvastus approach, or a medial parapatellar arthrotomy. Also, depending on surgeon preference, the patella can be either everted or subluxed.

The length of the incision is dependent on the size of the femoral component needed. Although the goal of a minimally invasive technique is to complete the surgery with an approximately 10cm-14cm incision, it may be necessary to extend the incision if visualization is inadequate. If the incision must be extended, it is advisable to extend it gradually and only to the degree necessary.

Make a slightly oblique parapatellar skin incision, beginning approximately 2cm proximal and medial to the superior pole of the patella, and extend it approximately 10cm to the level of the superior patellar tendon insertion at the center of the tibial tubercle (Fig. 5). Be careful to avoid disruption of the tendon insertion. This will facilitate access to the vastus medialis obliquus, and allow a minimal split of the muscle. It will also improve visualization of the lateral aspect of the joint obliquely. The length of the incision should be about 50% above and 50% below the joint line. If the length of the incision is not distributed evenly relative to the joint line, it is preferable that the greater portion be distal.

Divide the subcutaneous tissue to the level of the retinaculum.

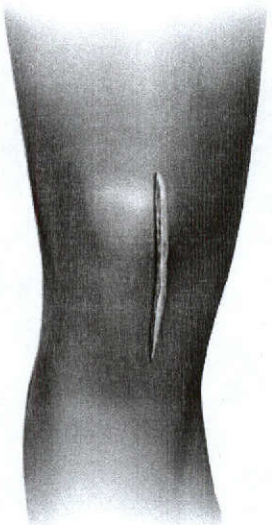

Fig. 5

## MIS Midvastus Approach

Developed in conjunction with Luke M. Vaughan, M.D.

Make a medial parapatellar incision into the capsule, preserving approximately 1cm of peritenon and capsule medial to the patellar tendon. This is important to facilitate complete capsular closure.

Split the superficial enveloping fascia of the quadriceps muscle percutaneously in a proximal direction over a length of approximately 6cm. This will mobilize the quadriceps and allow for significantly greater lateral translation of the muscle while minimizing tension on the patellar tendon insertion.

Split the vastus medialis obliquus approximately 1.5cm-2cm (Fig. 6).

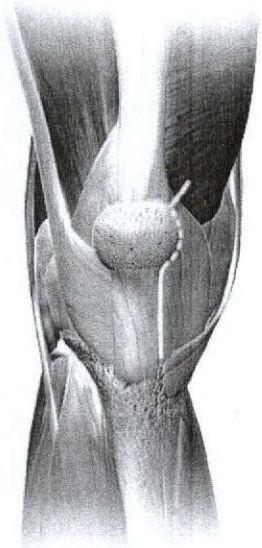

Fig. 6

Use blunt dissection to undermine the skin incision approximately 1cm-2cm around the patella.

Slightly flex the knee and remove the deep third of the fat pad. The patella can be either everted or subluxed. If everting the patella, release the lateral patellofemoral ligament to facilitate full eversion and lateral translation of the patella. Then use hand-held three-pronged or two-pronged hooks to begin to gently evert the patella. Be careful to avoid disrupting the extensor insertion. To help evert the patella, slowly flex the joint and externally rotate the tibia while applying gentle pressure. Once the patella is everted, use a standard-size Hohmann retractor or two small Hohmann retractors along the lateral flare of the tibial metaphysis to maintain the eversion of the patella and the extensor mechanism.

**Note: It is imperative to maintain close observation of the patellar tendon throughout the procedure to ensure that tension on the tendon is minimized, especially if everting the patella and when positioning the patient.**

Remove any large patellar osteophytes.

Release the anterior cruciate ligament, if present. Perform a subperiosteal dissection along the proximal medial and lateral tibia to the level of the tibial tendon insertion. Then perform a limited release of the lateral capsule (less than 5mm) to help minimize tension on the extensor mechanism.

## MIS Subvastus Approach

Developed in conjunction with
Russell G. Cohen, M.D.

Becoming accustomed to operating through a small incision and adopting the concept of a mobile window may be facilitated by starting with a shortened medial parapatellar arthrotomy. This will help to improve visualization of the anatomy during the initial stages of becoming familiar with an *MIS* approach.

When comfortable with the MIS medial parapatellar approach, performing the arthrotomy through a midvastus approach will help preserve the quadriceps tendon and a portion of the medial muscular attachment. As this procedure becomes more familiar, the level of the midvastus incision should be lowered to maintain more muscle attachment.

The subvastus arthrotomy provides excellent exposure through an *MIS* incision. The oblique portion of the incision starts below the vastus medialis obliquus (VMO) attachment and will preserve all the medial muscle attachments, including the retinacular attachment to the medial patella. A key aspect of the subvastus approach is that it is not necessary to evert the patella. This helps avoid tearing of the muscle fibers and helps maintain muscle contraction soon after surgery.

The longitudinal incision should extend only to the point of insertion of the VMO inferiorly, not to the proximal pole. Begin the arthrotomy at the medial edge of the tubercle and extend it along the border of the retinaculum/tendon to a point on the patella corresponding to 10 o'clock on a left knee or 2 o'clock on a right knee. Then continue the incision obliquely 1cm-2cm just below and in line with the VMO fibers (Fig. 7). Do not extend the oblique incision beyond this point as it creates further muscle invasion without providing additional exposure.

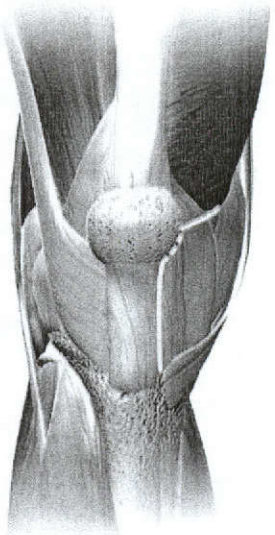

Fig. 7

Perform a medial release according to surgeon judgment, depending on the degree of varus or valgus deformity. To facilitate a medial release, place the knee in extension with a rake retractor positioned medially to provide tension that will assist in developing this plane. For valgus deformities, consider performing a more conservative medial release to avoid over-releasing an already attenuated tissue complex.

With the knee in extension and a rake retractor positioned to place tension on the patella, remove the retropatellar fat pad. Then excise a small piece of the capsule at the junction of the longitudinal and oblique retinacular incisions. This release allows the patella to retract laterally. Undermine the suprapatellar fat pad, but do not excise it. This helps ensure that the Femoral A/P Measuring Guide will be placed directly on bone rather than inadvertently referencing off soft tissue, which may increase the femoral size measurement.

Placement of a lateral retractor is very important for adequate retraction of the patella. With the knee extended, slip the retractor into the lateral gutter and lever it against the retinaculum at the superomedial border of the patella. As the knee is flexed, the patella is retracted laterally to provide good visualization of the joint.

## MIS Medial Parapatellar Arthrotomy

Developed in conjunction with Giles R. Scuderi, M.D.

Minimally invasive total knee arthroplasty can be performed with a limited medial parapatellar arthrotomy. Begin by making a 10cm-14cm midline skin incision from the superior aspect of the tibial tubercle to the superior border of the patella. Following subcutaneous dissection, develop medial and lateral flaps, and dissect proximally and distally to expose the extensor mechanism. This permits mobilization of the skin and subcutaneous tissue as needed during the procedure. In addition, with the knee in flexion, the incision will stretch 2cm-4cm due to the elasticity of the skin, allowing broader exposure.

The goal of minimally invasive surgery is to limit the surgical dissection without compromising the procedure. The medial parapatellar arthrotomy is used to expose the joint, but the proximal division of the quadriceps tendon should be limited to a length that permits only lateral subluxation of the patella without eversion (Fig. 8). Incise the quadriceps tendon for a length of 2cm-4cm initially. If there is difficulty displacing the patella laterally or if the patellar tendon is at risk of tearing, extend the arthrotomy proximally along the quadriceps tendon until adequate exposure is achieved.

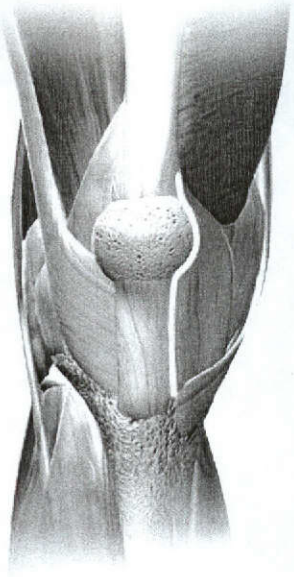

Fig. 8

## PCL Resection

Removing the PCL will make it easier to balance the collateral ligaments. Because the LPS-Flex Mobile Bearing Knee Prosthesis is a posterior cruciate ligament substituting design, it is necessary to completely resect the PCL. Any residual stump of the PCL may impinge in the cam/spine mechanism causing pain and limited motion. Resection of the PCL may influence the height of the flexion and extension gaps. Check for symmetry and balance of the flexion and extension gaps. Any differences in the gaps must be addressed.

## Soft Tissue Releases

The objective of this procedure should be to distribute contact stresses across the artificial joint as symmetrically as possible.[2] This requires the creation of equal and symmetrical flexion and extension gaps.

**Caution: Do not release the popliteal tendon, as this may cause instability.**

## Varus Release

To correct most fixed varus deformities (Fig. 9), progressively release the tight medial structures until they reach the length of the lateral supporting structures. The extent of the release can be monitored by inserting laminar spreaders within the femorotibial joint and judging alignment with a plumb line. To facilitate the release, excise osteophytes from the medial femur and tibia. These osteophytes tent the medial capsule and ligamentous structures, and their removal can produce a minimal correction before beginning the soft tissue release. Posteromedial osteophytes may need to be removed after the proximal tibia is resected.

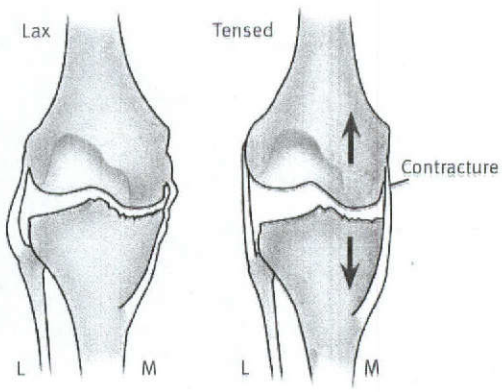


Fig. 9

With the knee in extension, elevate a subperiosteal sleeve of soft tissue from the proximal medial tibia, including the deep medial collateral ligament, superficial medial collateral ligament, and insertion of the pes anserinus tendons. Continue the elevation with a periosteal elevator to free the posterior fibers. To improve exposure during the release, retract this subperiosteal sleeve using a Homan retractor.

Release the insertion of the semimembranosus muscle from the posteromedial tibia, and concurrently remove posterior osteophytes.

Continue the release distally on the anteromedial surface of the tibia for 8cm-10cm and strip the periosteum medially from the tibia. This should be sufficient for moderate deformities. For more severe deformities, continue subperiosteal stripping posteriorly and distally.

When varus malalignment is present with a flexion contracture, it may be necessary to release or transversely divide the of the posterior capsule.

### Valgus Release

Approach the valgus knee (Fig. 10) in a similar fashion to that described for the varus knee; however, to provide better visualization, the bone cuts are usually made before the ligament release.

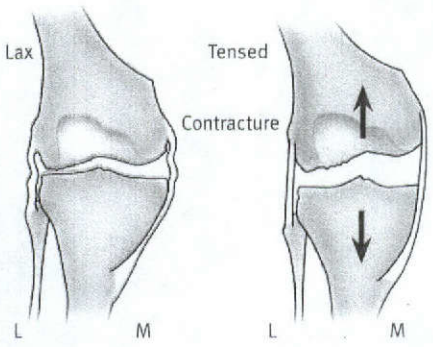


**Fig. 10**

By comparison with that of a varus release, the principle of a valgus release is to elongate the contracted lateral structures to the length of the medial structures. Though lateral osteophytes may be present and should be removed, they do not bowstring the lateral collateral ligament in the same way as osteophytes on the medial side.

This is because the distal insertion of the lateral collateral ligament into the fibular head brings the ligament away from the tibial rim.

For a valgus release, a "piecrust" technique may be preferable. This technique allows lengthening of the lateral side while preserving a continuous soft tissue sleeve, as well as, preserving the popliteus tendon, which ensures stability in flexion.

With the knee in extension and distracted with a laminar spreader, use a 15 blade to transversely cut the arcuate ligament at the joint line. **Be careful not to cut or detach the popliteus tendon.** Then use the 15 blade to pierce the iliotibial band and the lateral retinaculum in a "piecrust" fashion, both proximally above the joint and distally within the joint. Following the multiple punctures, use a laminar spreader to stretch the lateral side. This should elongate the lateral side and create a rectangular extension space. Use spacer blocks to confirm ligament balance in flexion and extension

For more severe valgus deformities, strip the lateral femoral condyle of its soft-tissue attachments proximally for about 9cm, and then divide the periosteum, the iliotibial tract, and the lateral intramuscular septum transversely from inside out. Be sure that any part of the lateral intramuscular septum that remains attached to the distal femur is free to slide.

## Step One
# Resect Proximal Tibia

### Introduction

The Extramedullary/Intramedullary TibialResector provides a choice of techniques for tibial resection. Each of the techniques offers anumber of options to accommodate various anatomical conditions and surgeon preferences. To facilitate the handling of bone defects in the proximal tibia, both the extramedullary and if preferred the distal femur may be resected first.
See page 22.

### Extramedullary Technique Option 1: Using the Cut Guide

### Step One

**Assemble Alignment Guide**

Slide the Ankle Clamp onto the dovetail at the bottom of the Distal Telescoping Rod. Turn the knob opposite the dovetail to temporarily hold the clamp in place (Fig. 11a). The mediolateral position of the rod can be adjusted by loosening this knob. When the final position is determined, the knob can be fully tightened to secure it in place.

The system includes a 7-degree Cut Guide.

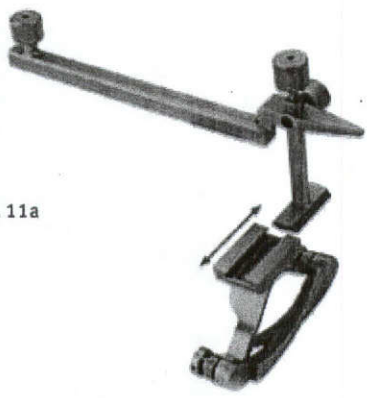

**Fig. 11a**

Place the Cut Guide onto the dovetail of the proximal portion of the Cut Guide Telescoping Rod. Tighten the knob to secure the position (Fig. 11b). Fig. 11a Arrows are etched onto both the Cut Guide Telescoping Rod and the Distal Telescoping Rod to indicate the correct orientation during assembly (Fig. 11c). Insert the Cut Guide Telescoping Rod into the Distal Telescoping Rod.

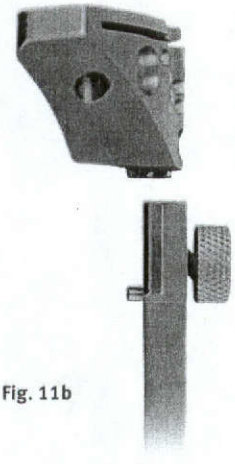

Fig. 11b

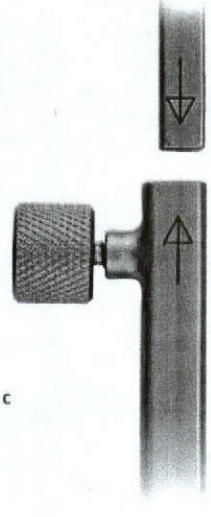

Fig. 11c

## Step Two

**Position Alignment Guide**

To improve the exposure of the tibial surface, use the Tibial Retractor to lever the tibia anteriorly. This instrument should be carefully positioned against the posterior cortex of the tibia subperiosteally to prevent neurovascular injury.Use the Patellar Retractor to retract the patella laterally. Adjust the telescoping rod to the approximate length of the tibia and turn the knob on the shaft of the rod to temporarily maintain the length. Place the spring arms of the Ankle Clamp around the ankle proximal to the malleoli (Fig. 12a) and loosen the knob that provides mediolateral adjustment at the ankle.

Fig. 12a

Position the Cut Guide at the proximal tibia. Loosen the knob in the middle of the telescoping rod and adjust the length of the rod until the Cut Guide is proximal to the tibial tubercle. Align the rod with the medial third of the tibial tubercle (Fig. 12b) or just medial to the tubercle.

Adjust the slide at the foot of the rod mediolaterally so the guide is aligned with the mechanical axis of the tibia (Fig. 12c). The longitudinal axis of the rod will usually lie just medial to the mid-point of the tibial tubercle and be centered in line with the intercondylar eminence. The foot of the rod should be positioned about 5mm-10mm medial to the midpoint between the palpable medial and lateral malleoli. The tip should point to the second toe. When the proper mediolateral position is achieved, tighten the knob to secure the Ankle Clamp to the rod. The posterior cortex of the tibia can also be used as a rotational check. In the sagittal plane, align the rod so it is parallel to the anterior tibial shaft by using the slide adjustment at the distal end of the rod. Tighten the knob for the adjustment. If there is a bulky bandage around the ankle, adjust the rod to accommodate the bandage. This will help ensure that the tibia will be cut with the proper slope.

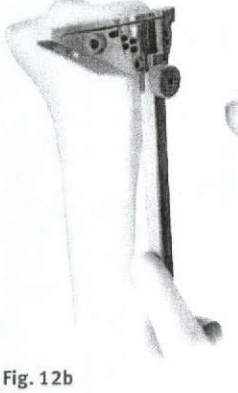

Fig. 12b

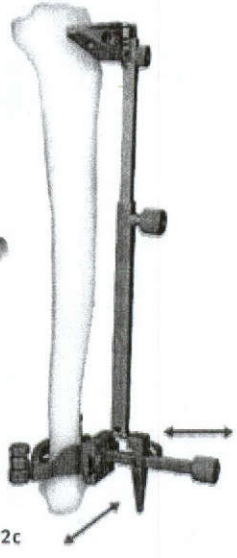

Fig. 12c

## Step Three

**Set Resection Level**

Each tip of the Tibial Depth Resection Stylus indicates a different depth. The 2mm tip is used to check the depth from the defective tibial condyle for a minimal cut. The 10mm tip is used to check the depth from the least involved tibial condyle for an anatomic cut. Insert the Tibial Depth Resection Stylus into the top of the Cut Guide, using the hole that corresponds to the defective tibial condyle (Fig. 13a).


Fig. 13a

The stylus will snap into the hole (Figs. 13b & 13c). Confirm that it is fully seated and properly oriented. The 2mm tip should rest on the tibial condyle (Fig. 13d). This positions the slot of the Cut Guide to remove 2mm of bone below the tip of the stylus.

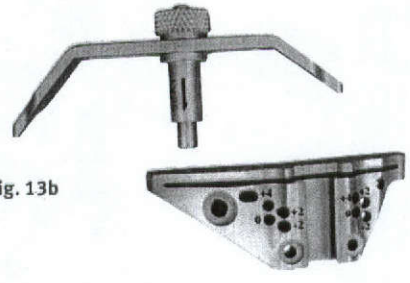

Fig. 13b

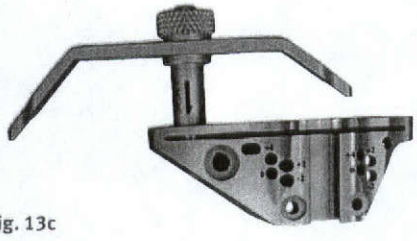

Fig. 13c

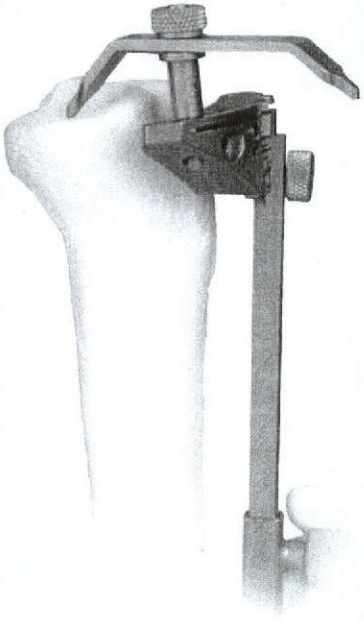

Fig. 13d

Alternatively, rest the 10mm tip of the stylus on the cartilage of the least involved condyle (Fig. 13e).

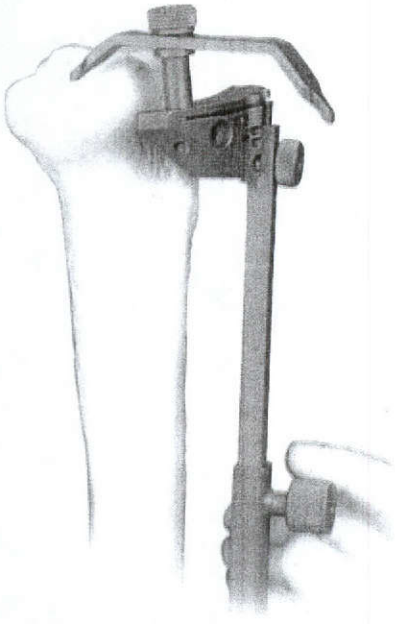

Fig. 13e

This will allow the removal of the same amount of bone that the thinnest tibial component would replace.

These two points of resection will usually not coincide. The surgeon must determine the appropriate level of resection based on patient age, bone quality, and the type of prosthetic fixation planned.

Adjust the Cut Guide to the desired depth by adjusting the length of the alignment guide assembly. Then retighten the telescoping rod, and insert a 48mm Headless Screw Pin or 75mm Headless Holding Pin into the hole marked "0" on the lateral side first of the Cut Guide.

To confirm alignment, insert the ExtramedullaryAlignment Arch into the Cut Guide and insert the Alignment Rod with Coupler through the arch, passing it distally toward the ankle (Fig.13f). The distal end of the rod should point to the second toe.

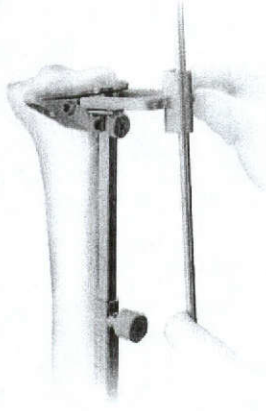

Fig. 13f

Insert a second 75mm Headless Holding Pin into the other hole marked "0" (Fig. 13g).

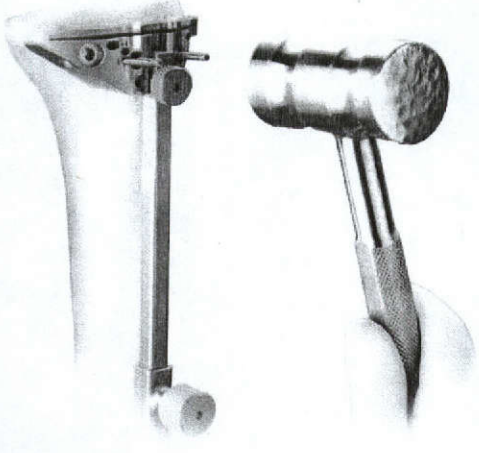

Fig. 13g

## Step Four

**Resect the Proximal Tibia**

Loosen the knob that has secured the Cut Guide onto the Cut Guide Telescoping Rod and remove the entire assembly, leaving the Cut Guide in place on the bone. The entire assembly can be left in place for additional fixation during resection.

Additional 2mm adjustments may be made by using the sets of holes marked -2, +2, and +4. The markings on the Cut Guide indicate, in millimeters, the amount of bone resection each will yield relative to the standard tibial resection set by the Cut Guide and Tibial Depth Resection Stylus. Once the tibial resection has been determined, use the Hex-head Holding Pins, 48mm Headed Screw Pins, or Silver Spring Pins to further stabilize the guide. Use a .050-inch oscillating saw blade through

the slot on the Cut Guide to cut the proximal surface of the tibia flat (Fig. 14a). Then remove the Cut Guide.

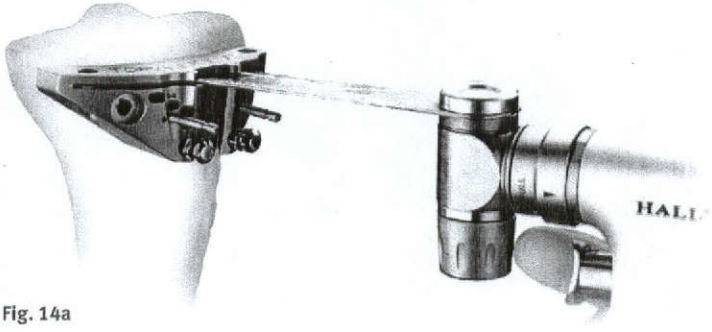

Fig. 14a

**Optional Technique**

*If desired, the cut can be made from the top surface of the Cut Guide. The top surface of the guide is 4mm above the slot (Fig. 14b), so the position of the guide must be adjusted to account for this difference. The adjustment can be made after the alignment guide assembly is removed by lifting the Cut Guide off the headless pins, which were inserted through the holes marked "0," and reinserting the guide through the holes marked "+4" (Fig. 14c).*

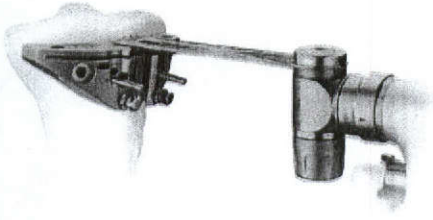

Fig. 14b

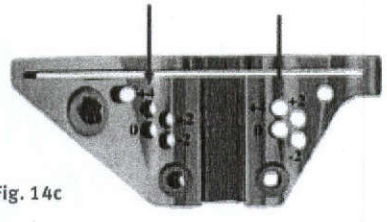

Fig. 14c

## Extramedullary Technique Option 2: Using the Spike Arm

### Step One

**Assemble Alignment Guide**

Slide the Ankle Clamp onto the dovetail at the bottom of the Distal Telescoping Rod. Turn the knob opposite the dovetail to temporarily hold the clamp in place (Fig. 15a). The mediolateral position of the rod can be adjusted by loosening this knob. When the final position is determined, the knob can be fully tightened to secure it in place.

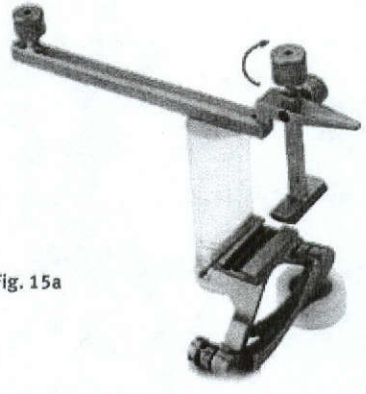

Fig. 15a

Slide the Spike Arm onto the dovetail at the top of the Spike Arm Telescoping Rod and temporarily secure it by turning the knob at the top of the rod (Fig. 15b).

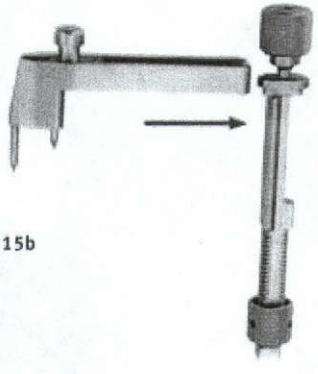

Fig. 15b

The system includes a 7-degree Cut Guide in left and right configurations.

Lower the adjustment knob in the middle of the Spike Arm Telescoping Rod to the bottom of the threaded portion. Insert the Cut Guide over the threaded portion of the rod above the adjustment knob and slide it all the way up on the dovetail (Fig. 15c). To hold the Cut Guide in place, advance the adjustment knob to the upper end of its range of travel. This will allow for space adjustment after the alignment guide assembly has been secured in position.

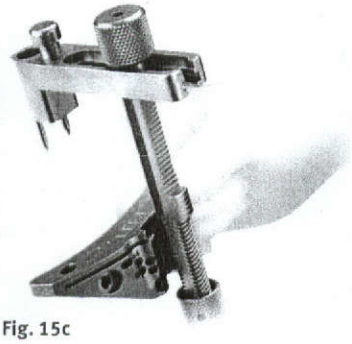

Fig. 15c

Arrows are etched onto both the Spike Arm Telescoping Rod and the Distal Telescoping Rod to indicate the correct orientation during assembly (Fig. 15d). Insert the Spike Arm Telescoping Rod into the Distal Telescoping Rod.

Fig. 15d

### Step Two

**Position Alignment Guide**

To improve exposure of the tibial surface, use the Tibial Retractor to lever the tibia anteriorly. This instrument should be carefully positioned against the posterior cortex of the tibia subperiosteally to prevent neurovascular injury. Use the Patella Retractor to retract the patella laterally.

Adjust the telescoping rod to the approximate length of the tibia and turn the knob on the shaft to temporarily maintain the length.

Place the spring arms of the Ankle Clamp around the ankle proximal to the malleoli (Fig. 16a) and loosen the knob that provides mediolateral adjustment at the ankle.

Fig. 16a

Position the Cut Guide at the proximal tibia. Loosen the knob in the middle of the telescoping rod and adjust the length of the rod until the long spike on the Spike Arm just contacts the tibial plateau. The Cut Guide should be proximal to the tibial tubercle. Center the long spike mediolaterally on the bone surface anterior to the tibial spine. This should align the rod with the medial third of the tibial tubercle. Stabilize the Alignment Guide by tapping the Spike Arm until only the long spike engages the tibial plateau. Do not drive the long spike in too far (Fig. 16b).

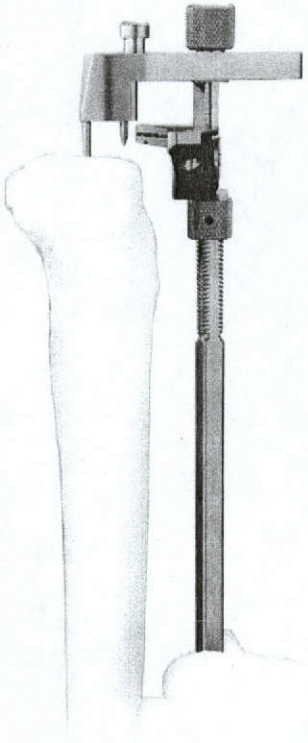

Fig. 16b

Adjust the slide at the foot of the rod mediolaterally so the guide is aligned with the mechanical axis of the tibia. The longitudinal axis of the rod will usually lie just medial to the mid-point of the tibial tubercle and be centered over the intercondylar eminence. The foot of the rod should be positioned about 5mm-10mm medial to the midpoint between the palpable medial and lateral malleoli. The tip should point to the second toe. When the proper mediolateral position is achieved, tighten the knob to secure the Ankle Clamp to the rod.

In the sagittal plane, align the rod so it is parallel to the anterior tibial shaft by using the slide adjustments at both the proximal and distal ends of the rod (Fig. 16c). Then tighten the knobs for both adjustments. If there is a bulky bandage around the ankle, adjust the rod to accommodate the bandage. This will help ensure that the tibia will be cut with the proper slope.

Set the final position of the extramedullary alignment guide assembly by tapping the Spike Arm until both the long and short spikes are fully impacted in the proximal tibia (Fig. 16d). Then tighten the knob in the middle of the telescoping rod assembly.

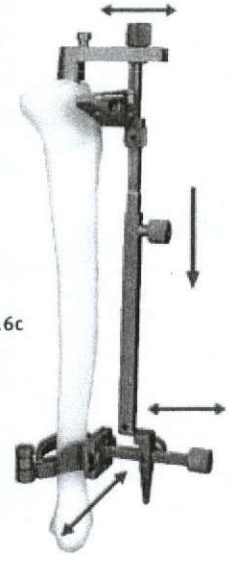

Fig. 16c

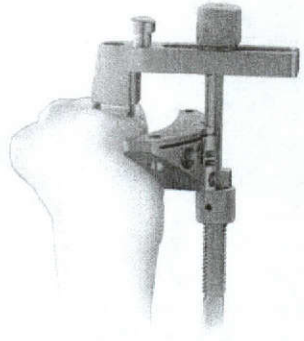

Fig. 16d

## Step Three

### Set Resection Level

Each tip of the Tibial Depth Resection Stylus indicates a different depth. The 2mm tip is used to check the depth from the defective tibial condyle for a minimal cut. The 10mm tip is used to check the depth from the least involved tibial condyle for an anatomic cut. Insert the Tibial Depth Resection Stylus into the top of the Cut Guide, using the hole that corresponds to the defective tibial condyle (Fig. 17a).


Fig. 17a

The stylus will snap into the hole (Figs. 17b & 17c). Confirm that it is fully seated and properly oriented. The 2mm tip should rest on the tibial condyle (Fig. 17d). This positions the slot of the Cut Guide to remove 2mm of bone below the tip of the stylus.

Fig. 17b

Fig. 17c

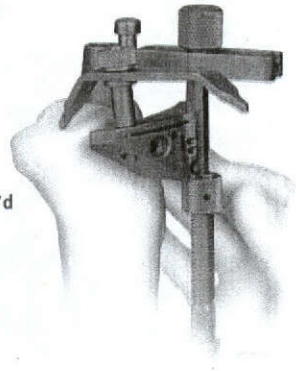

Fig. 17d

Alternatively, rest the 10mm tip of the stylus on the cartilage of the least involved condyle (Fig. 17e).

Fig. 17e

This will allow the removal of the same amount of bone that the thinnest tibial component would replace.

These two points of resection will usually not coincide. The surgeon must determine the appropriate level of resection based on patient age, bone quality, and the type of prosthetic fixation planned.

Adjust the Cut Guide to the desired depth by turning the adjustment knob. Then insert a 75mm Headless Holding Pin or a 48mm Headless Screw Pin into the hole marked "0" on the lateral side of the guide (Fig. 17f).

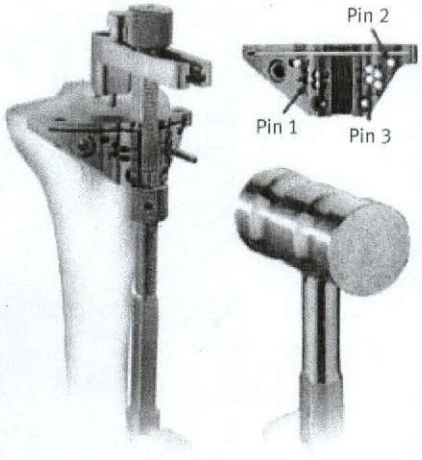


Fig. 17f

To confirm alignment, insert the Extramedullary Alignment Arch onto the Cut Guide and insert the Alignment Rod with Coupler through the arch, passing it distally toward the ankle. The distal end of the rod should point to the second toe (Fig. 17g).

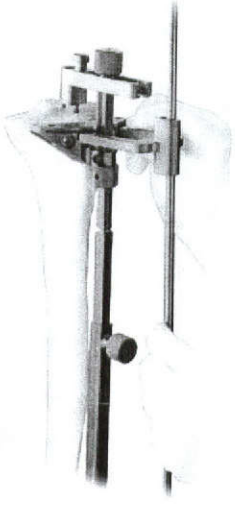

Fig. 17g

Insert a second 75mm Headless Holding Pin into the medial hole marked "0." Once the tibial resection has been determined, use the Hexhead Holding Pins, or 48mm Headed Screw Pins, or Silver Spring Pins to further stabilize the guide.

The extramedullary alignment arch can be left attached to the tibial cut guide for added stability. A 0.050" reciprocating saw blade can be used to make the medial and lateral tibial plateau cuts. Then remove alignment tower to finish tibial cuts.

## Step Four

### Resect the Proximal Tibia

Loosen the adjustment knob below the Cut Guide until the knob is at the bottom of the threaded portion of the rod. Then loosen the knob on the telescoping rod. Use a slaphammer to disengage the spikes on the Spike Arm. Raise the telescoping rod until the dovetail disengages the Cut Guide. Then open the arms of the Ankle Clamp and remove the entire assembly, leaving the Cut Guide in place on the bone.

If desired, the Alignment Arch and Alignment Rod with Coupler can be used on the Cut Guide again to check alignment.

2mm adjustments may be made by using the sets of holes marked -2, +2, and +4. The markings on the Cut Guide indicate, in millimeters, the amount of bone resection each will yield relative to the standard tibial resection set by the Cut Guide and Tibial Depth Resection Stylus.

Use a .050-inch oscillating saw blade through the slot on the Cut Guide to cut the proximal surface of the tibia flat (Fig. 18a). Then remove the Cut Guide.

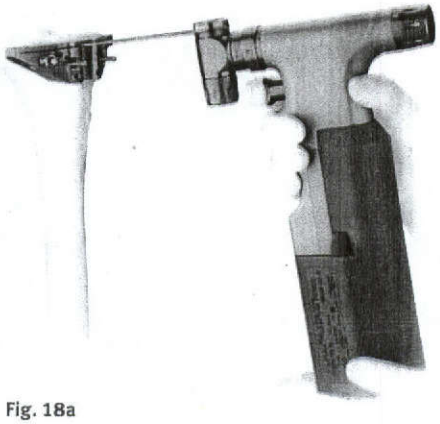

Fig. 18a

**Optional Technique**

*If desired, the cut can be made from the top surface of the Cut Guide. The top surface of the guide is 4mm above the slot (Fig. 18b), so the position of the guide must be adjusted to account for this difference. The adjustment can be made when the Cut Guide is first positioned by using the etch lines, which are in 2mm increments, at the top of the Spike Arm Telescoping Rod (Fig. 18c).*

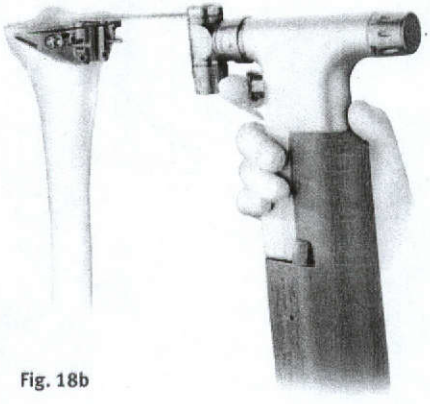

Fig. 18b

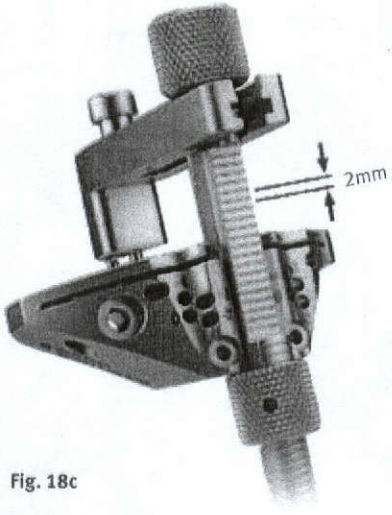


Fig. 18c

Alternatively, the adjustment can be made after the alignment guide assembly is removed by lifting the Cut Guide off the headless pins, which were inserted through the holes marked "0," and reinserting the guide through the holes marked "+4" (Fig. 18d).

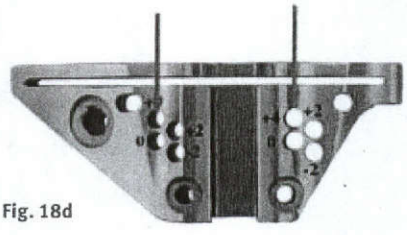

Fig. 18d

## Intramedullary Technique Option 1: Using the Cut Guide

To improve exposure of the tibial surface, use the Tibial Retractor to lever the tibia anteriorly. This instrument should be carefully positioned against the posterior cortex of the tibia subperiosteally to prevent neurovascular injury. Use the Patella Retractor to retract the patella laterally.

A preoperative radiograph of the tibia is necessary to make sure that the tibial shaft is straight and will accept the Tibial IM Rod. Some tibias are bowed or have too small a canal and will not accept the rod. The acetate template used for femoral planning can be inverted and used on the tibia.

### Step One

**Position IM Alignment Guide**

Use the Universal Handle to start a hole in the proximal tibia just anterior to the anterior cruciate ligament insertion and centered mediolaterally (Fig. 19a). This may seem too far anterior; however, it is the straight proximal extension of the tibial medullary canal. If a hole is started further posteriorly, excessive posterior slope may be cut into the proximal tibia.

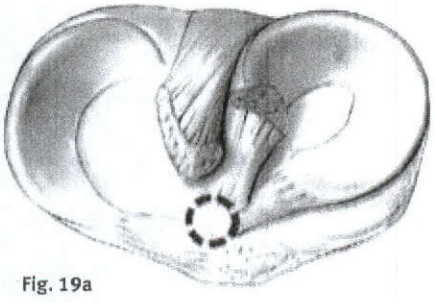

Fig. 19a

Drill a hole using the 8mm IM Drill. Suction the canal to remove medullary contents.

Slowly insert the Tibial IM Rod (00-5977-044-00) into the canal. The flutes on the rod will aid decompression of the canal during insertion.

Attach the 7-degree Revision Tibial Boom (00-5787-010-00) to the rod (Fig. 19b). This boom is needed to provide the appropriate cut for the posterior slope of the tibial plate.

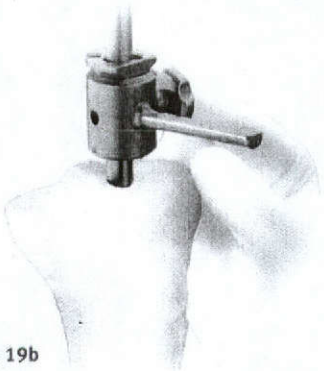

Fig. 19b

Lower the adjustment knob on the IM Alignment Guide to the bottom of the threaded portion. Insert the 0-degree Cut Guide over the threaded portion of the alignment guide above the adjustment knob and slide it up until it just engages the dovetail (Fig. 19c). This will allow for final adjustment after the alignment guide has been secured in position. To hold the Cut Guide in place, advance the adjustment knob until it contacts the underside of the guide.

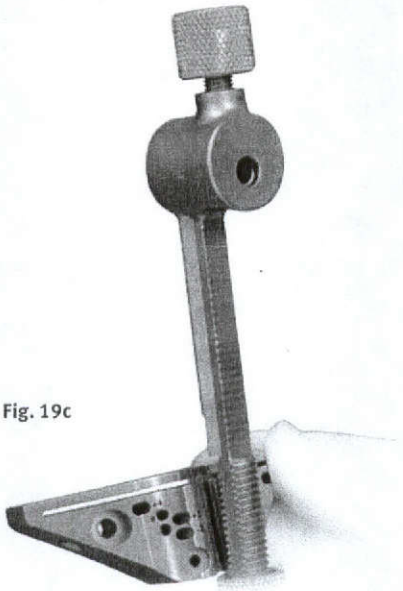

Fig. 19c

*Only the 0-degree Cut Guide will fit onto the IM Alignment Guide. The 7-degree Cut Guide will not fit onto the IM Alignment Guide. Using the 0-degree Cut Guide with the 7-degree Revision Tibial Boom will give you a 7-degree cut.*

Slide the barrel of the IM Alignment Guide onto the boom, making sure that the locking knob has been adjusted to allow free access (Fig. 19d). Rotate the boom on the rod until the Cut Guide is properly positioned mediolaterally on the anterior tibia. Use the medial third of the tibial tubercle as a landmark. Then slightly secure the knob on the boom.

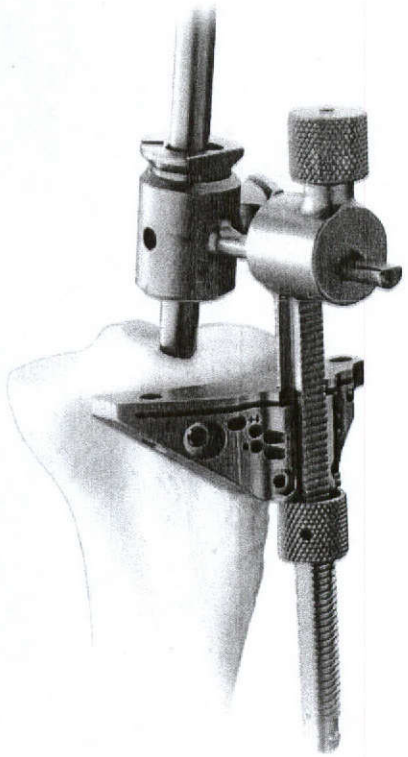

Fig. 19d

To determine varus/valgus alignment, insert the Extramedullary Alignment Arch onto the Cut Guide and insert the Alignment Rod with Coupler through the arch, passing it distally toward the ankle (Fig. 19e). The distal end of the rod should point to the second toe.

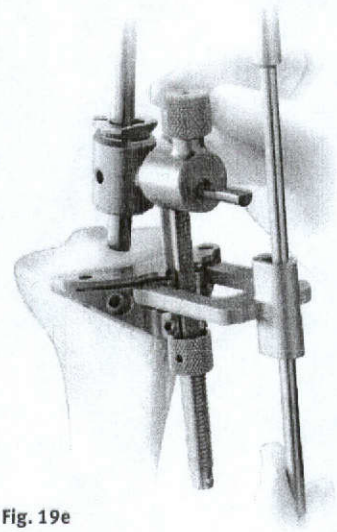

Fig. 19e

If the surgeon would like to set the Cut Guide at a 90-degree angle to the Tibial IM Rod, tighten the knob at the top of the IM Alignment Guide clockwise in the "90°" direction as etched on top of the knob (Fig. 19f). Do not overtighten the knob.

If the alignment check suggests a varus/valgus adjustment, rotate the barrel of the IM Alignment Guide on the boom to align the Alignment Rod to the second toe. When the appropriate varus/valgus alignment is achieved, tighten the knob at the top of the IM Alignment Guide counterclockwise in the "Var-Valg" direction as etched on top of the knob (Fig. 19g). This will hold the varus/valgus position of the Cut Guide. Do not overtighten the knob.

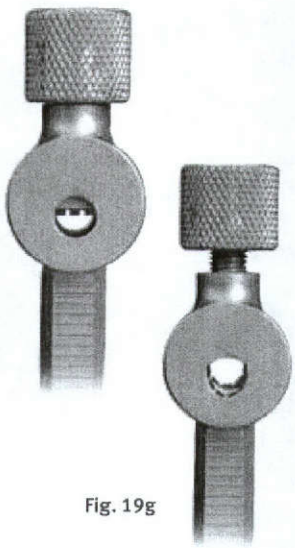

Fig. 19f

Fig. 19g

## Step Two

### Set Resection Level

Each tip of the Tibial Depth Resection Stylus indicates a different depth. The 2mm tip is used to check the depth from the defective tibial condyle for a minimal cut. The10mm tip is used to check the depth from the least involved tibial condyle for an anatomic cut. Insert the Tibial Depth Resection Stylus into the top of the Cut Guide, using the hole that corresponds to the defective tibial condyle (Fig. 20a). The stylus will snap into the hole (Figs. 20b & 20c). Confirm that it is fully seated and properly oriented. The 2mm tip should rest on the tibial condyle (Fig. 20d). This positions the slot of the Cut Guide to remove 2mm of bone below the tip of the stylus.


Fig. 20a

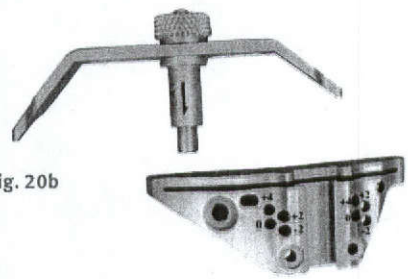

Fig. 20b

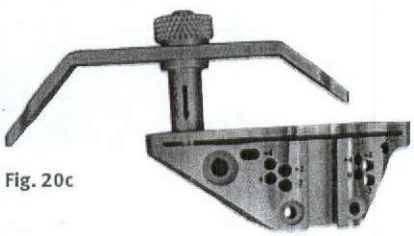

Fig. 20c

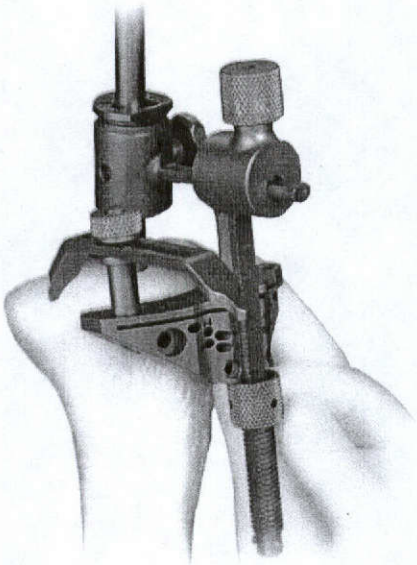

Fig. 20d

Alternatively, rest the 10mm tip of the stylus on the cartilage of the least involved condyle (Fig. 20e). This will allow the removal of the same amount of bone that the thinnest tibial component would replace.

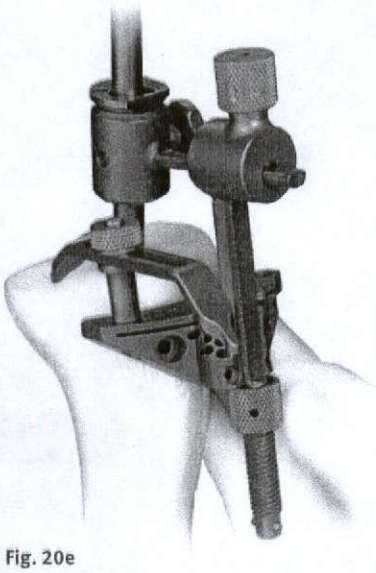

Fig. 20e

These two points of resection will usually not coincide. The surgeon must determine the appropriate resection based on patient age, bone quality, and the type of prosthetic fixation planned.

Adjust the Cut Guide to the desired depth by turning the adjustment knob. Then insert 48mm Headless Pin, or 75mm Headless Holding Pins into the holes marked "0" lateral side first (Fig. 20f).

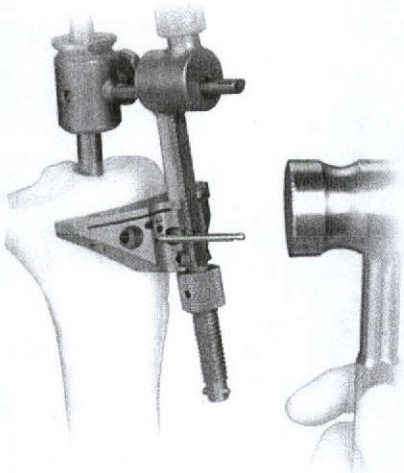

Fig. 20f

## Step Three

### Resect the Proximal Tibia

Loosen the adjustment knob below the Cut Guide until the knob is at the bottom of the threaded portion of the rod. Loosen the varus/valgus adjustment knob on the IM Alignment Guide. Use a slaphammer to raise the IM Rod until the dovetail portion of the IM Alignment Guide disengages from the Cut Guide. Remove the alignment assembly, leaving the Cut Guide in place on the bone.

If desired, the Alignment Arch and Alignment Rod with Coupler can be used on the Cut Guide again to check alignment.

Additional 2mm adjustments may be made by using the sets of holes marked -2, +2, and +4. The markings on the Cut Guide indicate, in millimeters, the amount of bone resection each will yield relative to the standard tibial resection set by the Cut Guide and Tibial Depth Resection Stylus. Once the tibial resection has been determined, use the Hex-head Holding Pins, 48mm Headed Screw Pins, or Silver Spring Pins to further stabilize the guide.

Use a .050-inch oscillating saw blade through the slot on the Cut Guide to cut the proximal surface of the tibia flat (Fig. 21a). Then remove the Cut Guide.

Fig. 21

**Optional Technique**

*If desired, the cut can be made from the top surface of the Cut Guide. The top surface of the guide is 4mm above the slot (Fig. 21b), so the position of the guide must be adjusted to account for this difference. The adjustment can be made when the Cut Guide is first positioned by using the etch lines, which are in 2mm increments, on the IM Alignment Guide (Fig. 21c).*

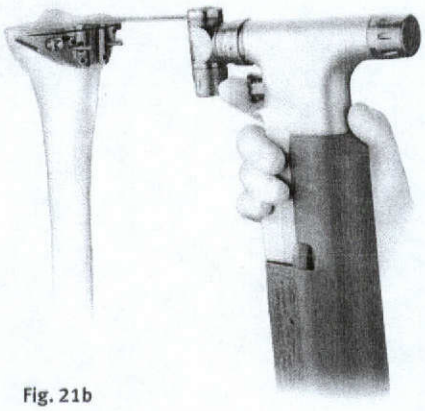

Fig. 21b

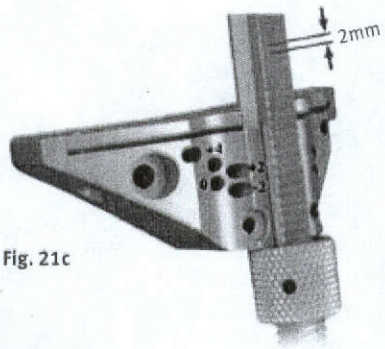


Fig. 21c

*Alternatively, the adjustment can be made after the IM Alignment Guide is removed by lifting the Cut Guide off the headless pins, which were inserted through the holes marked "0," and reinserting the guide through the holes marked "+4" (Fig. 21d).*

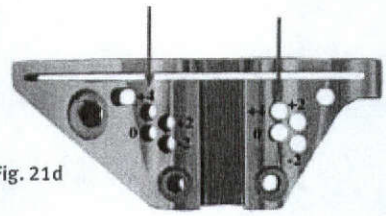

Fig. 21d

## Intramedullary Technique Option 2: Using the Spike Arm

To improve exposure of the tibial surface, use the Tibial Retractor to lever the tibia anteriorly. This instrument should be carefully positioned against the posterior cortex of the tibia subperiosteally to prevent neurovascular injury. Use the Patella Retractor to retract the patella laterally.

A preoperative radiograph of the tibia is necessary to make sure that the tibial shaft is straight and will accept the Tibial IM Rod. Some tibias are bowed or have too small a canal and will not accept the rod. The acetate template used forfemoral planning can be inverted and used on the tibia.

### Step One

**Insert IM Rod**

Use the Universal Handle to start a hole in the proximal tibia just anterior to the anterior cruciate ligament insertion and centered mediolaterally (Fig. 22a). This may seem too far anterior; however, it is the straight proximal extension of the tibial medullary canal. If a hole is started further posteriorly, excessive posterior slope may be cut into the proximal tibia. Drill a hole using the 8mm IM Drill. Suction the canal to remove medullary contents. Slowly insert the Tibial IM Rod (00-5977-044-00) into the canal. The flutes on the rod will aid decompression of the canal during insertion.

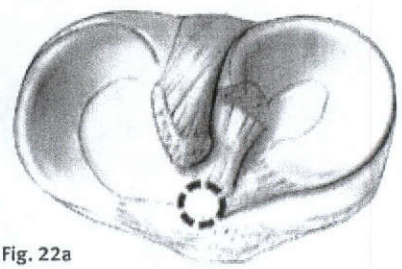

Fig. 22a

## Step Two

### Position Cut Guide

The system includes a 7-degree Cut Guide in left and right configurations.

Slide the Spike Arm onto the top of the Spike Arm Telescoping Rod and secure it temporarily by turning the knob at the top of the rod (Fig. 23a).

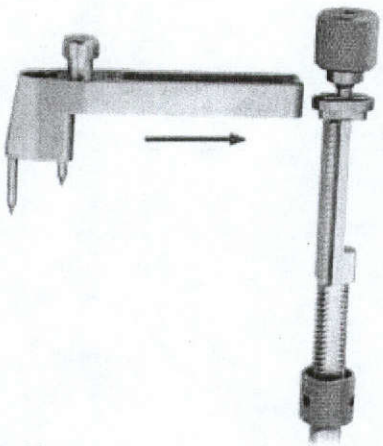

Fig. 23a

Lower the adjustment knob in the middle of the Spike Arm Telescoping Rod to the bottom of the threaded portion. Insert the Cut Guide over the threaded portion of the rod above the adjustment knob and slide it all the way up on the dovetail (Fig. 23b). To hold the Cut Guide in place, advance the adjustment knob to the end of its range of travel. This will allow for final adjustment after the alignment assembly has been secured in position.

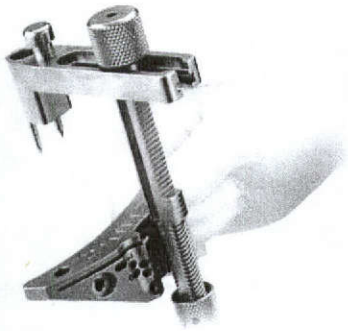

Fig. 23b

Slide the Spike Arm assembly over the IM Rod (Figs. 23c, 23d & 23e). Lower the assembly until the long spike engages the tibial surface. Adjust the assembly to the correct rotation. Impact the Spike Arm until both the long and short spikes are fully engaged in bone. Loosen the knob at the top of the Spike Arm Telescoping Rod, and slide the rod and Cut Guide toward the anterior tibial surface. Then tighten the knob.

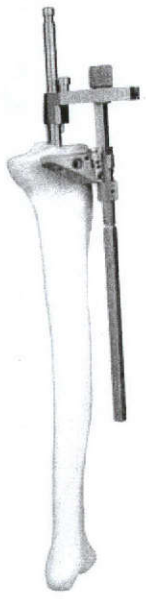

Fig. 23c

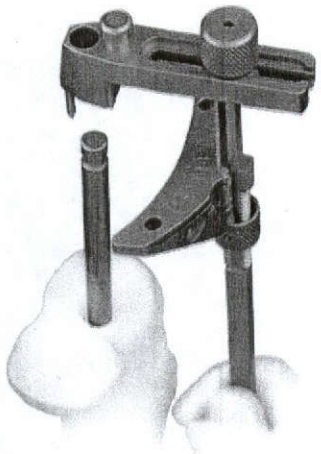

Fig. 23d

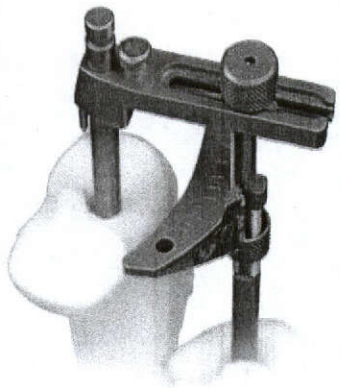

Fig. 23e

To confirm alignment, insert the Extramedullary Alignment Arch onto the Cut Guide and insert the Alignment Rod with Coupler through the arch, passing it distally toward the ankle. The distal end of the rod should point to the second toe.

## Step Three

**Set Resection Level**

Each tip of the Tibial Depth Resection Stylus indicates a different depth. The 2mm tip is used to check the depth from the defective tibial condyle for a minimal cut. The 10mm tip is used to check the depth from the least involved tibial condyle for an anatomic cut.

Insert the Tibial Depth Resection Stylus into the top of the Cut Guide, using the hole that corresponds to the defective tibial condyle (Fig. 24a). The stylus will snap into the hole (Figs. 24b & 24c). Confirm that it is fully seated and properly oriented. The 2mm tip should rest on the tibial condyle (Fig. 24d). This positions the slot of the Cut Guide to remove 2mm of bone below the tip of the stylus.


Fig. 24a

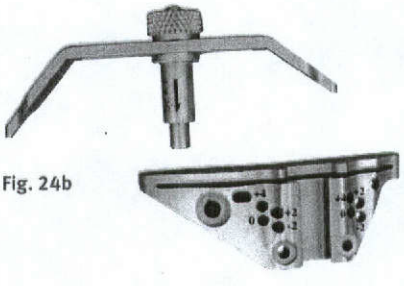

Fig. 24b

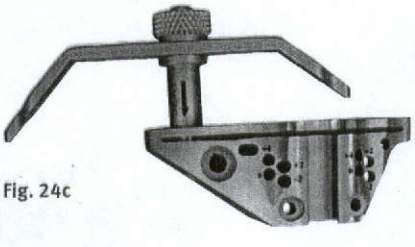

Fig. 24c

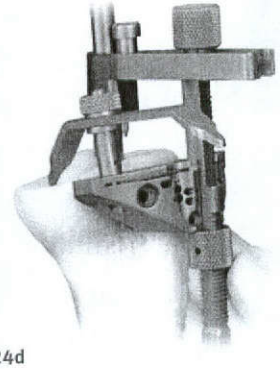

Fig. 24d

Alternatively, rest the 10mm tip of the stylus on the cartilage of the least involved condyle (Fig. 24e). This will allow the removal of the same amount of bone that the thinnest tibial component would replace.

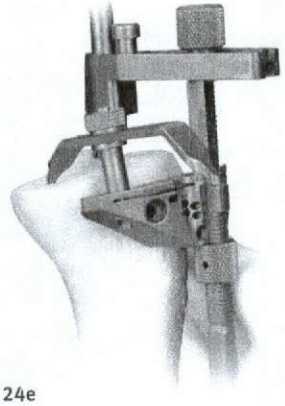

Fig. 24e

These two points of resection will usually not coincide. **The surgeon must determine the appropriate resection based on patient age, bone quality, and the type of prosthetic fixation planned.**

Adjust the Cut Guide to the desired depth by turning the adjustment knob. Then insert 48mm Headless Screw Pins or 75mm Headless Holding Pins into the holes marked "0" lateral side first.

## Step Four

**Resect the Proximal Tibia**

Loosen the adjustment knob below the Cut Guide until the knob is at the bottom of the threaded portion of the rod. Use a slaphammer to raise the IM Rod and Spike Arm assembly until the dovetail portion of the IM Alignment Guide disengages from the Cut Guide. Remove the alignment assembly, leaving the Cut Guide in place on the bone.

If desired, the Alignment Arch and Alignment Rod with Coupler can be used on the Cut Guide again to check alignment.

Additional 2mm adjustments may be made by using the sets of holes marked -2, +2, and +4. The markings on the Cut Guide indicate, in millimeters, the amount of bone resection each will yield relative to the standard tibial resection set by the Cut Guide and Tibial Depth Resection Stylus. Once the tibial resection has been determined, use the Hex-head Holding Pins, Silver Spring Pins, or 48mm Headed Screw Pins to further stabilize the guide.

Use a .050-inch oscillating saw blade through the slot on the Cut Guide to cut the proximal surface of the tibia flat (Fig. 25a). Then remove the Cut Guide.

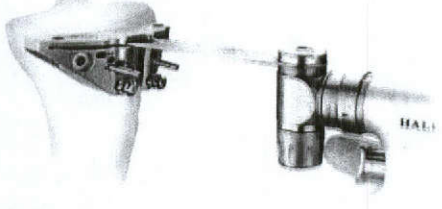

Fig. 25a

**Optional Technique**
If desired, the cut can be made from the top surface of the Cut Guide. The top surface of the guide is 4mm above the slot (Fig. 25b), so the position of the guide must be adjusted to account for this difference. The adjustment can be made when the Cut Guide is first positioned by using the etch lines, which are in 2mm increments, on the Spike Arm Telescoping Rod (Fig. 25c).

Alternatively, the adjustment can be made after the alignment assembly is removed by lifting the Cut Guide off the headless pins, which were inserted through the holes marked "0," and reinserting the guide through the holes marked "+4" (Fig. 25d).

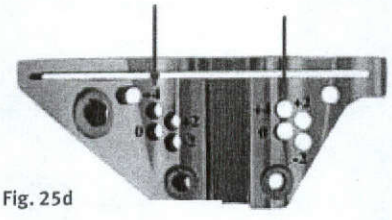

Fig. 25d

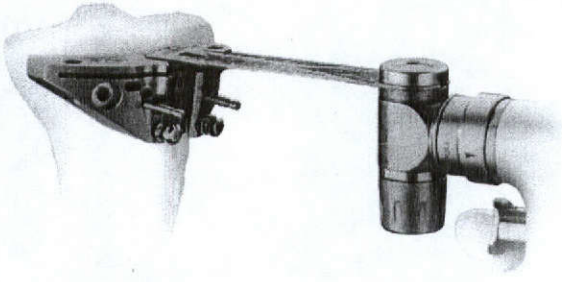

Fig. 25b

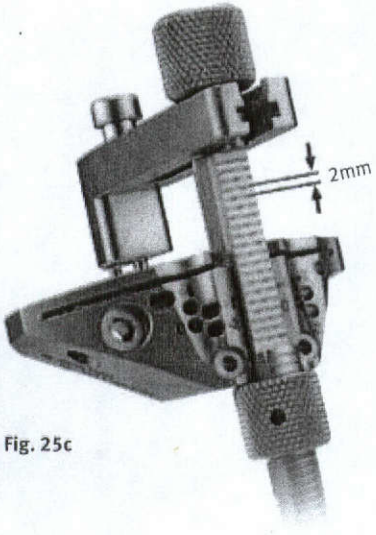


Fig. 25c

## Step Two
## Establish Femoral Alignment

Use the 8mm IM Drill w/Step to drill a hole in the center of the patellar sulcus of the distal femur (Fig. 26a) making sure that the drill is parallel to the shaft of the femur in both the anteroposterior and lateral projections. The hole should be approximately one-half to one centimeter anterior to the origin of the posterior cruciate ligament. Medial or lateral displacement of the hole may be needed according to preoperative templating of the A/P radiograph.

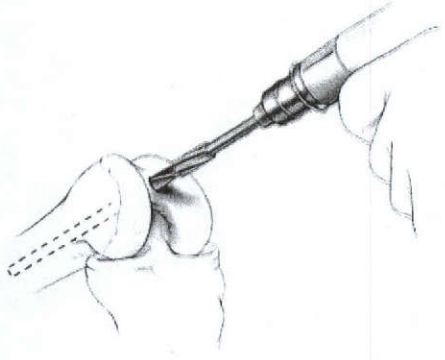

Fig. 26a

The step on the drill will enlarge the entrance hole on the femur to 12mm. This will reduce intramedullary pressure during placement of subsequent IM guides. Suction the canal to remove medullary contents.

The Adjustable IM Alignment Guide is available with two intramedullary rod lengths. The rod on the standard instrument is 229mm (9in) long and the rod on the short instrument is 165mm (6.5in). Choose the length best suited to the length of the patient's leg which will provide the most accurate reproduction of the anatomic axis. If the femoral anatomy has been altered, as in a femur with a long-stem hip prosthesis or with a femoral fracture malunion, use the short Adjustable IM Alignment Guide and use the extramedullary alignment technique.

**Note: It is preferable to use the longest intramedullary rod to guarantee the most accurate replication of the anatomic axis.**

Set the Adjustable IM Alignment Guide to the proper valgus angle as determined by preoperative radiographs. Check to ensure that the proper "Right" or "Left" indication (Fig. 26b) is used and engage the lock mechanism (Fig. 26c).

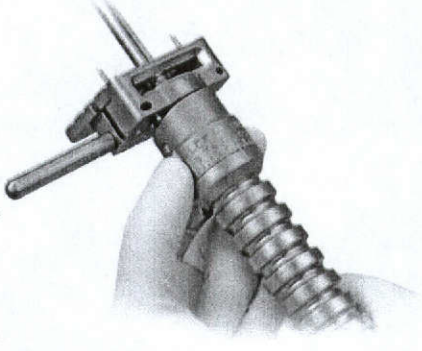

Fig.26b

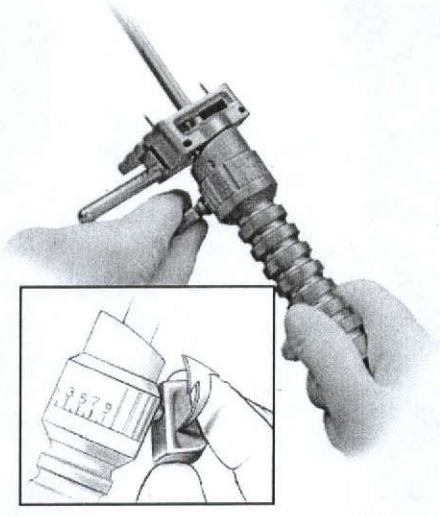

Fig. 26c

The Standard Cut Plate must be attached to the Adjustable IM Alignment Guide for a standard distal femoral resection (Fig. 26d).

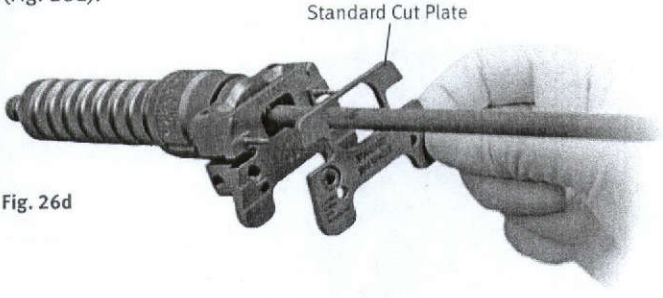


Fig. 26d

Use a hex-head screwdriver to tighten the plate (Fig.26e) on the guide prior to use. The screws must be loosened and the plate removed for sterilization.

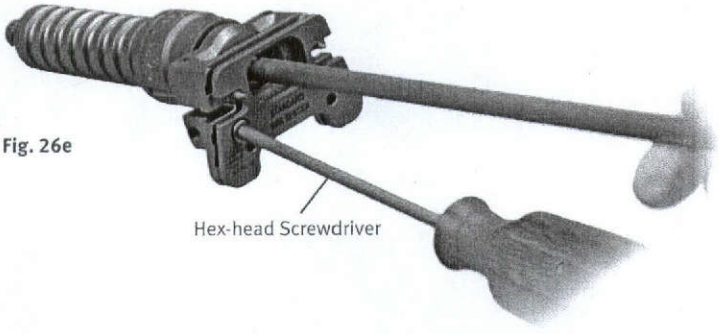


Fig. 26e

If preferred, remove the Standard Cut Plate if a significant flexion contracture exists. This will allow for an additional 3mm of distal femoral bone resection (Fig. 26f).

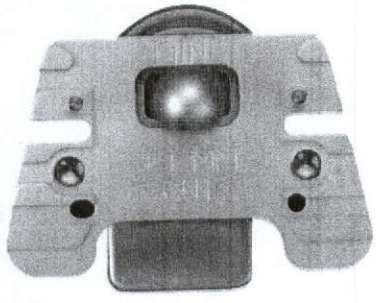

Fig. 26f

Insert the IM guide into the hole in the distal femur. If the epicondyles are visible, the epicondylar axis may be used as a guide in setting the orientation of the Adjustable IM Alignment Guide. If desired, add the Threaded Handles to the guide and position the handles relative to the epicondyles. This does not set rotation of the femoral component, but keeps the distal cut oriented to the final component rotation.

Once the proper orientation is achieved, impact the IM guide until it seats on the most prominent condyle. After impacting, check to ensure that the valgus setting has not changed. Ensure that the guide is contacting at least one distal condyle. This will set the proper distal femoral resection.

***Optional Technique:*** *An Extramedullary Alignment Arch and Alignment Rod can be used to confirm the alignment. If this is anticipated, identify the center of the femoral head before draping. If extramedullary alignment will be the only mode of alignment, use a palpable radiopaque marker in combination with an A/P x-ray film to ensure proper location of the femoral head.*

## Step Three
## Cut the Distal Femur

While the Adjustable IM Alignment Guide is being inserted by the surgeon, the scrub nurse should attach the Mini Distal Femoral Cutting Guide to the 0° Distal Placement Guide (Fig. 27a). A 3° Distal Placement Guide is available which will resect the femur in 3° of flexion.

Fig. 27a

Ensure that the attachment screw is tight.

Insert the Distal Placement Guide with the cutting guide into the Adjustable IM Alignment Guide until the cutting guide rests on the anterior femoral cortex (Fig. 27b). The Mini Distal Femoral Cutting Guide is designed to help avoid soft tissue impingement.

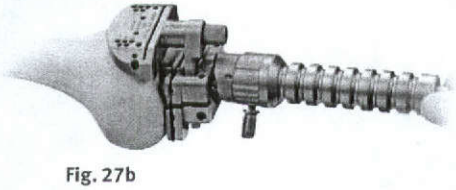

Fig. 27b

Using the 3.2mm drill bit, drill holes through the two standard pin holes marked "0" in the anterior surface of the Mini Distal Femoral Cutting Guide, and place Headless Holding Pins through the holes (Fig. 27c).

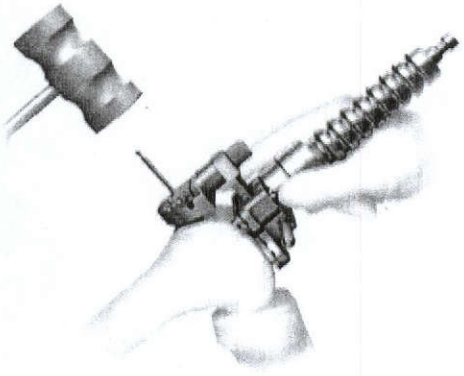

Fig. 27c

Additional 2mm adjustments may be made by using the sets of holes marked -4, - 2, +2, and +4. The markings on the cutting guide indicate, in millimeters, the amount of bone resection each will yield relative to the standard distal resection set by the Adjustable IM Alignment Guide and Standard Cut Plate.

If more fixation is needed, use two 3.2mm Headed Screws or predrill and insert two Hex-head Holding Pins in the small oblique holes on the Mini Distal Femoral Cutting Guide, or Silver Spring Pins may be used in the large oblique holes (Fig. 27d).

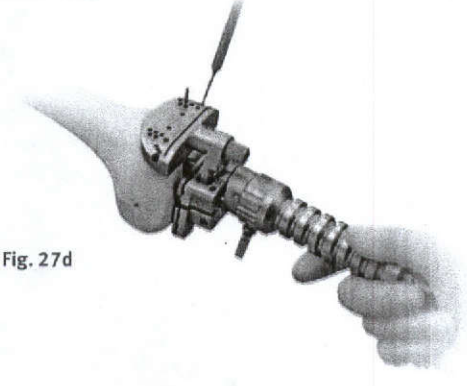

Fig. 27d

Completely loosen the attachment screw (Fig. 27e) in the Distal Placement Guide. Then use the Slaphammer Extractor to remove the IM Alignment Guide and the Distal Placement Guide.

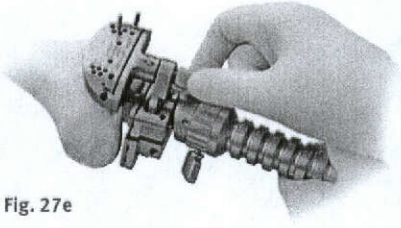

Fig. 27e

Cut the distal femur through the cutting slot in the cutting guide using a 1.27mm (0.050-in.) oscillating saw blade (Fig. 27f). Then remove the cutting guide.

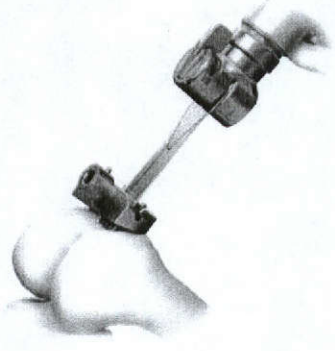

Fig. 27f

Check the flatness of the distal femoral cut with a flat surface. If necessary, modify the distal femoral surface so that it is completely flat. This is extremely important since this cut guides the placement of all subsequent guides and to help assure proper fit of the implant.

## Step Four
## Check Extension Gap

After the proximal tibia and distal femur have been resected, the extension gap is evaluated using spacer blocks or a tensioning device.

With the knee in flexion, position the Spacer/Alignment Guides or *MIS* Spacer/Alignment Guides on top of the resected proximal tibia. Drop the Alignment Rod with Coupler into the Spacer/Alignment Guide. Check the flatness, slope and alignment of the tibial cut.

Position the knee in full extension. Apply varus and valgus stress for optimal ligament balancing. Ligament releases should be performed until the extension gap is rectangular. This can be achieved with appropriate ligament releases.

Use the Spacer/Alignment Guides to check the extension gap, insert the thinnest appropriate Spacer/Alignment Guide between the resected surfaces of the femur and tibia. (Fig. 28). If necessary insert progressively thicker Spacer/Alignment Guides until the proper soft tissue tension is obtained.

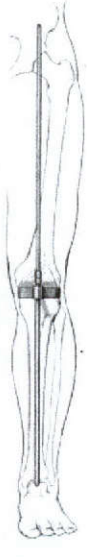

Fig. 28

When the extension gap is balanced, proceed to size femur, establish external rotation and finish the femoral cuts.

### Step Five
## Size Femur and Establish External Rotation

Flex the knee to 90°. Attach the *MIS* Threaded Handle to the medial side of the Mini A/P Sizing Guide, and place the guide flat onto the smoothly cut distal femur (Fig. 29a). Apply the guide so that the flat surface of the Mini A/P Sizing Guide is flush against the resected surface of the distal femur and the feet of the Mini A/P Sizing Guide are flush against the posterior condyles.

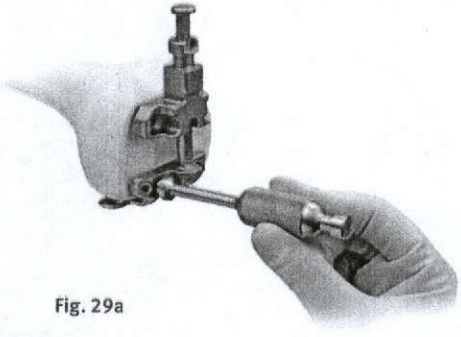

Fig. 29a

Slide the body of the Mini A/P Sizing Guide along the shaft to the level of the medullary canal. Position the guide mediolaterally, and check the position by looking through both windows of the guide to ensure that the medullary canal is not visible through either.

**Note: Remove any osteophytes that interfere with instrument positioning.**

While holding the Mini A/P Sizing Guide in place, secure the guide to the resected distal femur using a short 3.2mm (1/8-inch) Headed Screw or predrill and insert a Short-head Holding Pin into the lateral hole in the lower portion of the guide.

**Note: Remove the Threaded Handle before using the Screw Inserter/ Extractor. Then remove the Threaded Handle and insert a 3.2mm (1/8-inch) Headed Screw or predrill and insert a Short-head Holding Pin into the medial hole in the lower portion of the guide. Do not over tighten or the anterior portion will not slide on the distal femur.**

Slightly extend the knee and retract soft tissues to expose the anterior femoral cortex. Clear any soft tissue from the anterior cortex. Ensure that the leg is in less than 90° of flexion (70°-80°). This will decrease the tension of the patellar tendon to facilitate placement of the guide.

Attach the *MIS* Locking Boom to the Mini A/P Sizing Guide. Ensure that the skin does not put pressure on the top of the boom and potentially change its position. The position of the boom dictates the exit point of the anterior bone cut and the ultimate position of the femoral component. When the boom is appropriately positioned, lock it by turning the knurled knob (Fig. 29b).

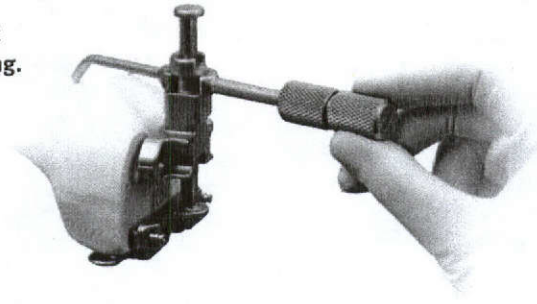

Fig.29b

Read the femoral size directly from the guide between the engraved lines on the sizing tower (Fig. 29c). There are eight sizes labeled "A" through "H". With the breadth of sizes available, if the indicator is between two sizes, the size closest to the indicator is typically chosen.

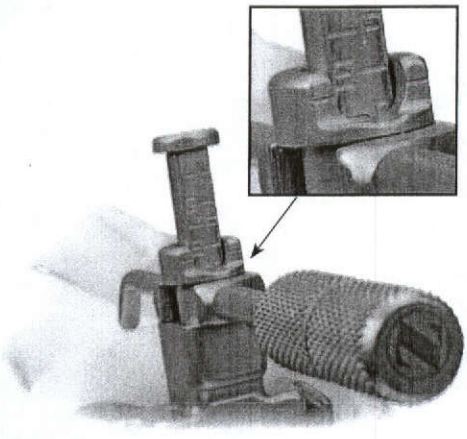

Fig. 29c

If a posterior referencing technique is preferred, remove the Mini A/P Sizing Guide and go to page 27, "STEP SIX Finish the Femur - Posterior Referencing". If a blended technique is preferred, proceed to set external rotation and make final determination of posterior resection using the Posterior Referencing option.

There are four External Rotation Plates: 0°/3° Left, 0°/3° Right, 5°/7° Left, and 5°/7° Right. Choose the External Rotation Plate that provides the desired external rotation for the appropriate knee. The 0° option can be used when positioning will be determined by the A/P axis or the epicondylar axis. Use the 3° option for varus knees. Use the 5° option for knees with a valgus deformity from 10° to 13°.

Attach the selected plate to the Mini A/P Sizing Guide (Fig. 29d).

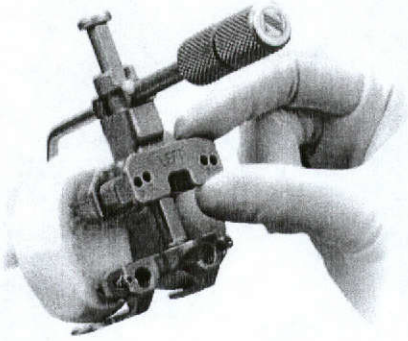

Fig. 29d

Use a 3.2mm drill to drill through the two holes that correspond to the desired external rotation. Position two Headless Holding Pins, and impact them into the guide (Fig. 29e). Leave the head of the pin proud. If preferred, the *MIS* Headless Screws may be used. This will establish the desired external rotation from the posterior condyles.

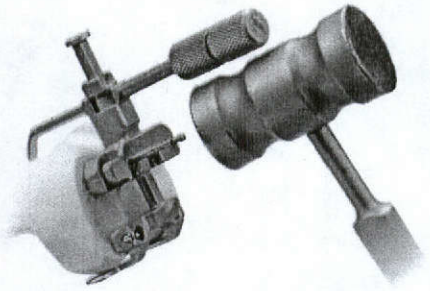

Fig. 29e

**Note: Do not impact the Headless Holding Pins flush with the External Rotation Plate.**

Careful attention should be taken when placing the headless pins into the appropriate External Rotation Plate as these pins also set the A/P placement for the *MIS* Femoral Finishing Guide in the next step of the procedure. It is important to monitor the location of the anterior boom on the anterior cortex of the femur to ensure the anterior cut will not notch the femur. Positioning the anterior boom on the "high" part of the femur by lateralizing the location of the boom can often lessen the likelihood of notching the femur.

Unlock and rotate the boom of the guide medially until it clears the medial condyle. Then remove the guide, but leave the two Headless Holding Pins. These pins will establish the A/P position and rotational alignment of the Femoral Finishing Guide.

## Step Six
## Finish the Femur

**Option 1**
Posterior Referencing Technique
*preferred technique for LPS-Flex Mobile*

**Option 2**
Anterior Referencing Technique, page 30

### Option 1
Posterior Referencing Technique

Select the appropriate size *MIS* Femoral Finishing Guide (silver-colored for standard LPS femoral component) or MIS Flex Femoral Finishing Guide (gold-colored for LPS-Flex femoral component) as determined by the measurement from the A/P Sizing Guide. Additional bone is removed from the posterior condyles when using the flex finishing guide. Attach the Posterior Reference/Rotation Guide to the selected femoral finishing guide (Fig. 30a).

When implanting the LPS-Flex Mobile femoral component, the gold Femoral Finishing Guide is used. When implanting the LPS 'non-Flex' femoral component, the (silver colored) MIS Femoral Finishing Guide is used. (Reference page 27 "Option 1 – Posterior Referencing Technique" and page 30 "Option 2 – Anterior Referencing Technique")

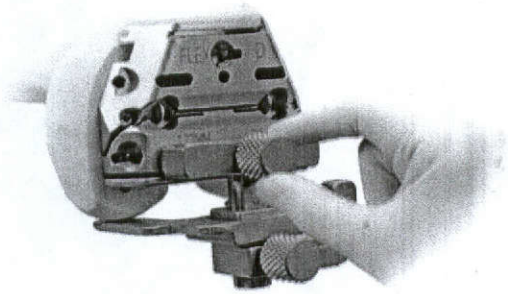

Fig. 30a

Lock the femoral position locator on the rotation guide to the zero position (Fig. 30b). This zero setting ensures that, when the feet are flush with the posterior condyles, the amount of posterior bone resection will average 9mm when using the standard *MIS* Femoral Finishing Guides, and approximately 11mm when using the *MIS* Flex Femoral Finishing Guides.

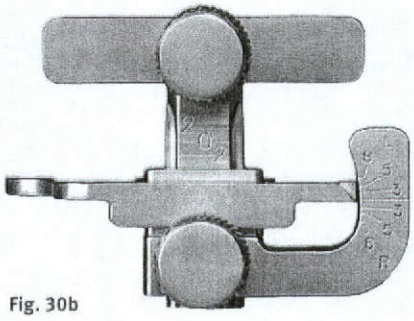

Fig. 30b

***Technique Tip:*** *If between sizes and you don't want to go to larger size, you may shift the femoral cutting block 2mm anterior using the +2mm setting to reduce chance of notching the femur.*

Place the finishing guide on the distal femur, bringing the feet of the rotation guide flush against the posterior condyles of the femur (Fig. 30c).

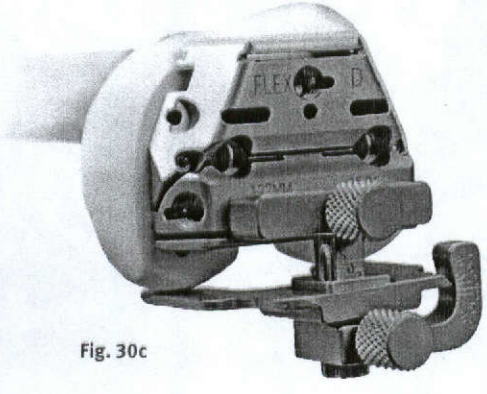

Fig. 30c

Set the rotation of the finishing guide parallel to the epicondylar axis. Check the rotation of the guide by reading the angle indicated by the Posterior Reference/Rotation Guide. The epicondylar line is rotated externally 0°-8°, (4°±4°), relative to the posterior condyles. The external rotation angle can also be set relative to the posterior condyles, lining up the degrees desired.

Remove any lateral osteophytes that may interfere with guide placement. Position the MIS Femoral Finishing Guide mediolaterally. The width of the MIS Femoral Finishing Guide replicates the width of the *NexGen* CR and CRA femoral component which are 3-4mm wider than standard LPS femoral components (sizes C-G). The width of the MIS Flex Femoral Finishing Guide replicates the width of the *NexGen* LPS-Flex femoral components. Lateralization of the femoral component is desired. Note that mediolateral widths of the size B MIS Femoral Finishing Guide and size B MIS Flex Finishing Guide replicate the widths of standard LPS and LPS-Flex femoral components.

When the proper rotation and the mediolateral and anteroposterior position are achieved, secure the finishing guide to the distal femur. Use the Screw Inserter/Extractor to insert a 3.2mm Headed Screw or predrill and insert a Hex-head Holding Pin through the superior pinhole on the beveled medial side of the Femoral Finishing Guide (Fig. 30d). Then secure the lateral side in the same manner.

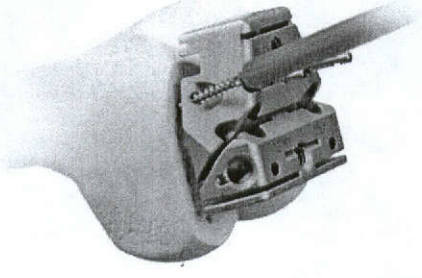

Fig. 30d

For additional fixation, drill the post holes using the Patellar/Femoral Drill Bit (Fig. 30e). Then insert 6.5mm x 35mm Periarticular Bone Screws through the post holes.

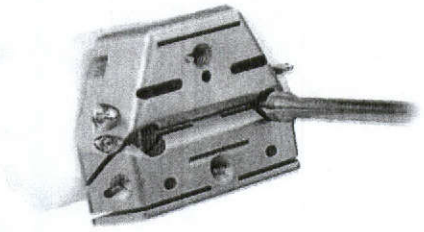

Fig. 30e

**If a size A or B femoral component is chosen, do not drill the distal femoral post holes at this time.** Size A and B femoral components have smaller pegs. The holes should be drilled using the size A/B Femoral Peg Drill and the Notch Guide.

If additional stability is needed, predrill and insert two Short-head Holding Pins through the inferior holes on one or both sides of the guide.

Use the Resection Guide through the anterior cutting slot of the finishing guide, and check the medial and lateral sides to be sure the cut will not notch the anterior femoral cortex (Fig. 30f).

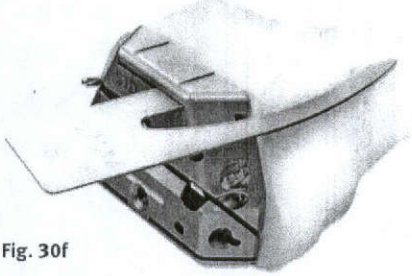

Fig. 30f

Alternatively, the *MIS* Locking Boom Attachment can be attached to the face of the femoral finishing guide. Use the *MIS* Locking Boom or Telescoping Locking Boom to check the location of the anterior cut and determine if notching will occur (Fig. 30g). The boom tip indicates where the anterior femoral cut will exit the bone.

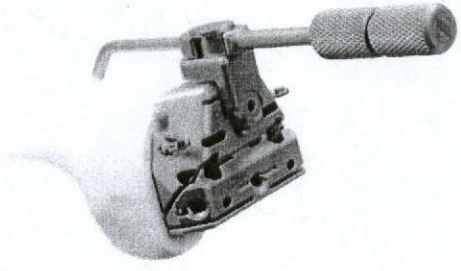

Fig. 30g

Use a 1.27mm (0.050-in.) narrow, oscillating saw blade to cut the femoral profile in the following sequence for optimal stability of the finishing guide (Fig. 30h):

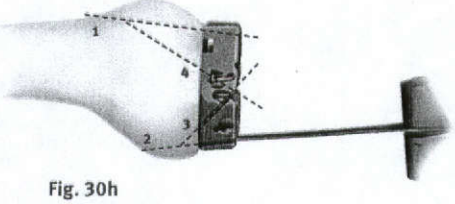


Fig. 30h

1) Anterior condyles
2) Posterior condyles
3) Posterior chamfer
4) Anterior chamfers

Use the Patellar/Femoral Drill Bit to drill the post holes if not done previously.

Use the 1.27mm (0.050-in.) narrow, reciprocating saw blade to cut the base of the trochlear recess (Fig. 30i) and score the edges (Fig. 30j). Remove the finishing guide to complete the trochlear recess cuts and complete any remaining bone cuts.

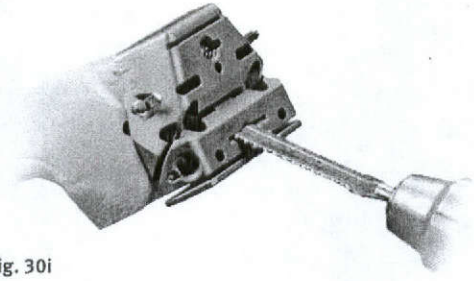

Fig. 30i

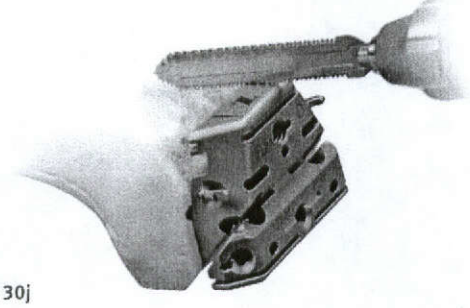

Fig. 30j

## Option 2

Anterior Referencing Technique

Select the correct size *MIS* Femoral Finishing Guide (silver colored for standard LPS femoral component) or *MIS* Flex Femoral Finishing Guide (gold colored for LPS-Flex femoral component) as determined by the measurement from the A/P Sizing Guide. An additional 2mm (approximately) of bone is removed from the posterior condyles when using the Flex Femoral Finishing Guide.

When implanting the LPS-Flex Mobile femoral component, the gold Femoral Finishing Guide is used. When implanting the LPS 'non-Flex' femoral component, the (silver colored) MIS Femoral Finishing Guide is used. (Reference page 27 "Option 1 – Posterior Referencing Technique" and page 30 "Option 2 – Anterior Referencing Technique")

Place the finishing guide onto the distal femur, over the headless pins (Fig. 30k). This determines the A/P position and rotation of the guide. Remove any lateral osteophytes that may interfere with guide placement. Position the finishing guide mediolaterally by sliding it on the headless pins. The width of the *MIS* Femoral Finishing Guide replicates the width of the *NexGen* LPS femoral component which are 3-4mm wider than standard LPS femoral components (sizes C-G). The width of the *MIS* Flex Femoral Finishing Guide replicates the width of the *NexGen* LPS-Flex femoral components (sizes C-G). Lateralization of the femoral component is desired. Note that the mediolateral widths of the size B MIS Femoral Finishing Guide and size B MIS Flex Finishing Guide replicate the widths of CR, CR-Flex, standard LPS, and LPS-Flex femoral components.

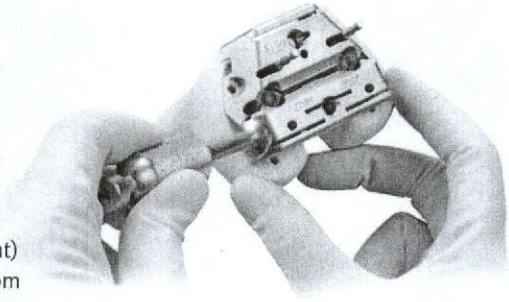

Fig. 30k

When the proper rotation and the mediolateral and anteroposterior position are achieved, secure the finishing guide to the distal femur. Use the Screw Inserter/Extractor to insert a 3.2mm Headed Screw or predrill and insert a Hex-head Holding Pin through the superior pinhole on the beveled medial side of the Femoral Finishing Guide (Fig. 30l). Then secure the lateral side in the same manner.

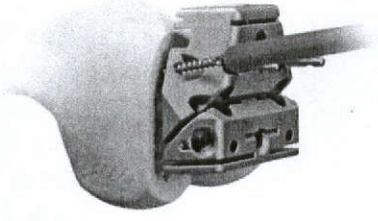

Fig. 30l

For additional fixation, drill the post holes using the Patellar/Femoral Drill Bit (Fig. 30m). Then insert 6.5mm x 35mm Periarticular Bone Screws through the post holes.

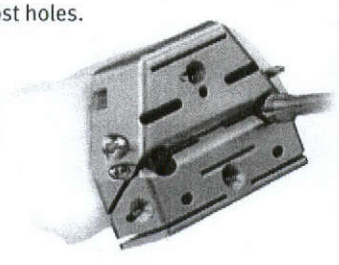

Fig. 30m

If additional stability is needed, predrill and insert two Short-head Holding Pins through the inferior holes on one or both sides of the guide.

Use the Resection Guide through the anterior cutting slot of the finishing guide, and check the medial and lateral sides to be sure the cut will not notch the anterior femoral cortex (Fig. 30n).

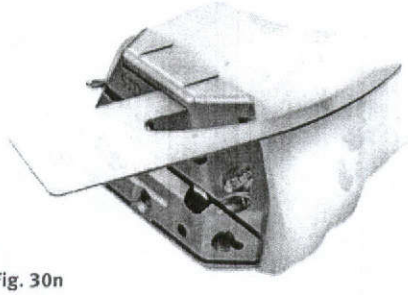

Fig. 30n

Alternatively, the MIS Locking Boom Attachment can be attached to the face of the femoral finishing guide. Use the MIS Locking Boom or Telescoping Locking Boom to check the location of the anterior cut and determine if notching will occur (Fig. 30o). The boom tip indicates where the anterior femoral cut will exit the bone.

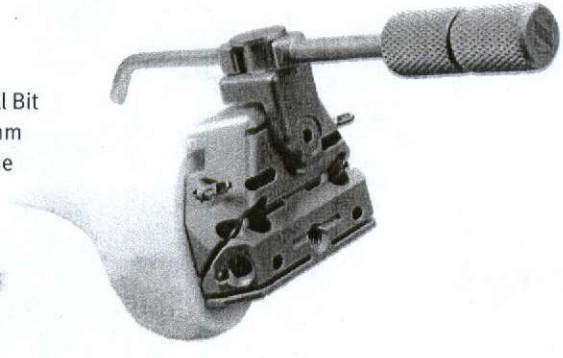

Fig. 30o

Remove the Headless Holding Pins from the Femoral Finishing Guide (Fig. 30p) with the Headless Pin Puller.

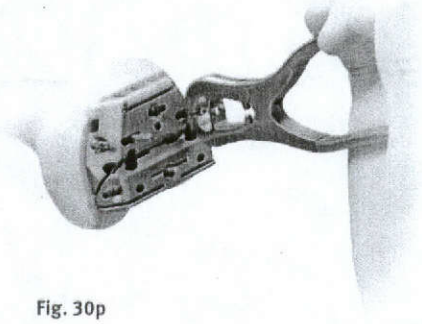

Fig. 30p

Use a 1.27mm (0.050-in.) narrow, oscillating saw blade to cut the femoral profile in the following sequence for optimal stability of the finishing guide (Fig. 30q):

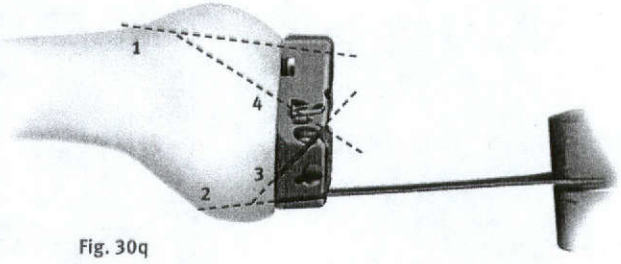


Fig. 30q

1) Anterior condyles
2) Posterior condyles
3) Posterior chamfer
4) Anterior chamfers

Use the Patellar/Femoral Drill Bit to drill the post holes if not done previously.

Use the 1.27mm (0.050-in.) narrow, reciprocating saw blade to cut the base of the trochlear recess (Fig. 30r) and score the edges (Fig. 30s). Remove the finishing guide to complete the trochlear recess cuts and complete any remaining bone cuts.

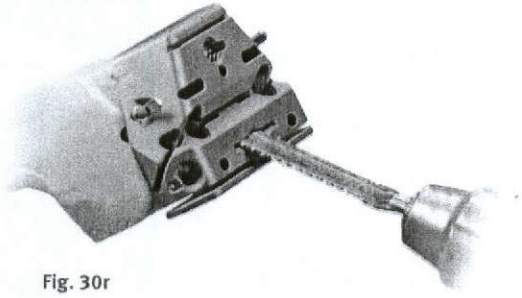

Fig. 30r

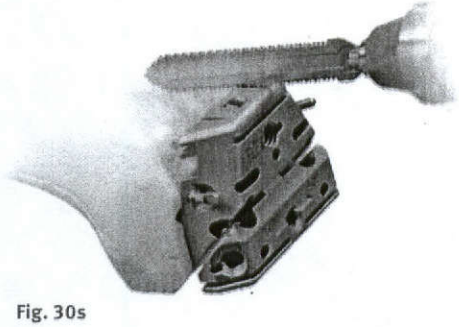

Fig. 30s

The critical goal is to create a rectangular and symmetrical flexion gap between the femur and tibia.

When establishing the mediolateral position of the femoral component, it is recommended to lateralize the component to help improve patellar tracking. Avoid positioning the component where it overhangs the bone as this may restrict flexion.

With the knee in flexion, remove posterior osteophytes with a 3/4-inch curve-on-flat osteotome (Fig. 30t). Use a laminar spreader and the Posterior Femoral Retractor to improve exposure (Fig. 30u).

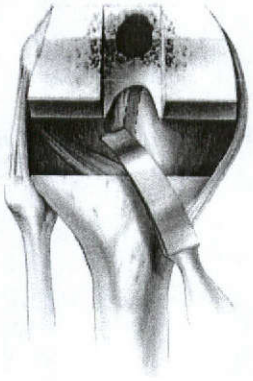

Fig. 30t

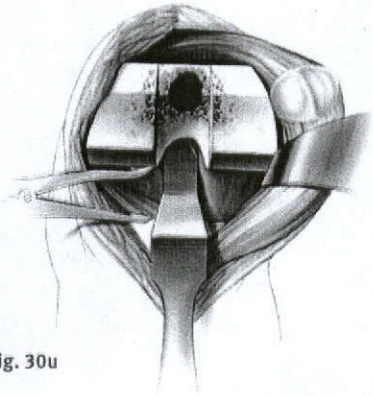

Fig. 30u

### Step Seven
## Check Flexion Gap

*Knee in 90° flexion*

Use the Spacer/Alignment Guides or *MIS* Spacer/Alignment Guides to check ligament balance and joint alignment in flexion. Insert the Alignment Rod with Coupler into the guide and check the alignment of the tibial resection (Fig. 31). Then check ligament balance. If necessary insert progressively thicker Spacer Blocks until the proper soft tissue tension is obtained. When using the *MIS* Flex Femoral Finishing Guide, the flexion gap will be greater than the extension gap. **Use the LPS-Flex Spacer Block Adapter to simulate the LPS-Flex component posterior condyle dimension for sizes C-G.**

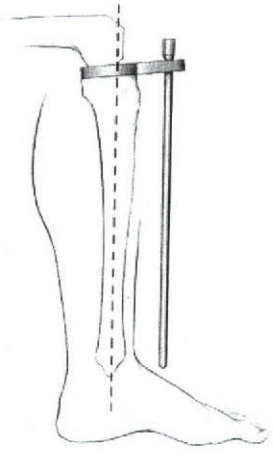

Fig. 31

**Note: Do not use the CR-Flex Spacer Block Adapter since it simulates the CR-Flex component posterior condyle dimension and will result in inaccurate representation of the LPS-Flex flexion gap.**

### Balance Flexion/Extension Gaps

*Knee in extension*

Attach the Alignment Rod to the Alignment Rod with Coupler. Check ligament balance and limb alignment in extension.

If the tension is significantly greater in extension than in flexion, re-cut the distal femur using the appropriate instrumentation. This will enlarge the extension space.

If the tension is significantly less in extension than in flexion, either use a minus-size femur or perform additional ligament releases.

### Step Eight
## Patellar Preparation

**Note: If the surgeon determines that the condition of the patient's patella is satisfactory, it is not necessary to resurface the patella. The geometry, depth, and length of the patellar groove on the *NexGen* Femoral Component accommodate the unresurfaced patella.**

Using the desired patella preparation technique, resurface the articular surface of the patella. Be sure to determine the appropriate patella thickness. When drilling the peg holes for the patellar component, position the Patellar Drill Guide so as to medialize the patellar implant. (When the patella is everted, this means placing the guide on the lateral border.)

### Step Nine
## Finishing the Tibia

Select the proper size Tibial Sizing/ Positioning Plate that provides the desired tibial coverage. Be sure that one of the three femoral component sizes designated on the anterior surface of the plate matches the femoral provisional size.

The tibia can be finished before the trial reduction if the implant position will be chosen based on anatomic landmarks. Alternatively, the sizing plate and provisionals can be used to perform a trial range of motion to aid in tibial positioning.

### Step Ten
## Position Based on Anatomic Landmarks

Attach the Mobile Bearing Knee Tibial Holding Clamp to the selected sizing plate by placing the cutout of the clamp over the anterior rail of the plate. Secure it by tightening the thumb screw (Fig. 32a).

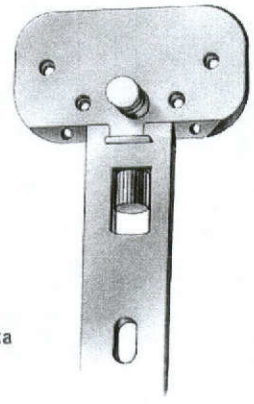

Fig. 32a

Align the handle of the holding clamp with the anterior aspect of the tibia. Use the Alignment Rod to aid in confirming varus/valgus alignment and posterior slope. Position the plate so the handle of the holding clamp points at, or slightly medial to, the midpoint of the tibial tubercle. Then pin the plate in place with two Small-head Holding Pins. Ensure that the sizing plate remains in the proper position when pinning.

Proceed to Page 34 (2nd column) to complete tibial preparation.

### Optional Technique:
Position Based on Trial Range of Motion

Insert the proper Femoral Provisional, Tibial Sizing/Positioning Plate, and Articular Surface Provisional. Ensure that soft tissue balance is appropriate.

Insert a Small-head Holding Pin through the anterior hole on the rail of the sizing plate (Fig. 32b). This will hold the Articular Surface Provisional in a fixed central position on the sizing plate.

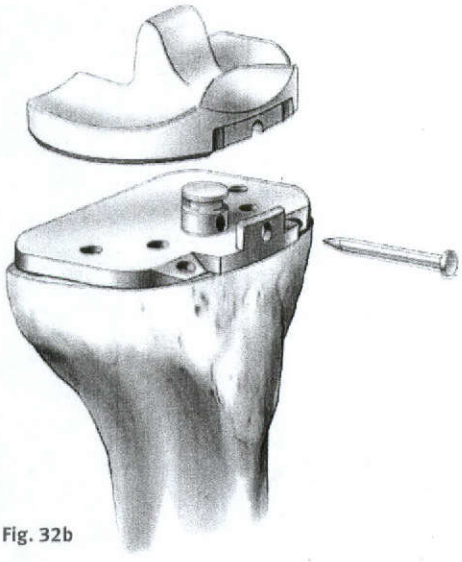

Fig. 32b

Flex and extend the knee with the provisionals in place (Fig. 32c).

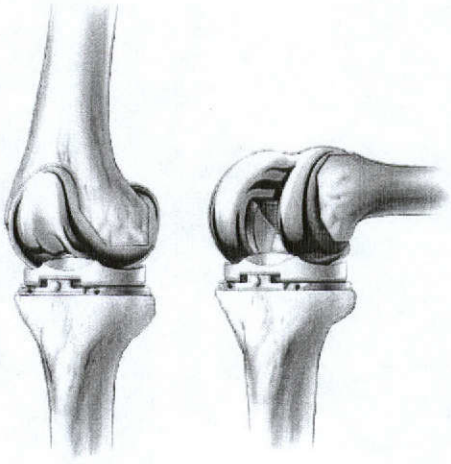

Fig. 32c

If the Articular Surface Provisional lifts off anteriorly during flexion, check the resected bone surface and remove any bony protrusions. If this lift-off occurs and the resected bone surface is smooth, perform an additional release of the posterior capsule. Flex and extend the knee again with the provisionals in place to determine the location of the plate. Once proper soft tissue balancing is complete, the tibial component tends to seat itself in the position where it best articulates with the femur.

After the location of the plate has been determined, insert the temporary Small-head Holding Pins through the angled holes on the front rail of the sizing plate (Fig. 32d).

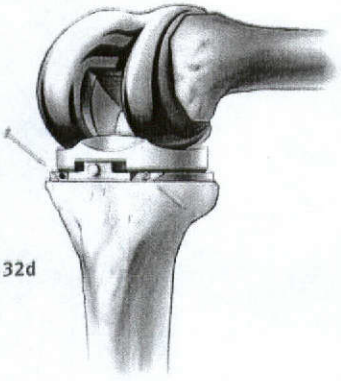

Fig. 32d

Remove the Small-head Holding Pin, the Articular Surface Provisional, and the Femoral Provisional. Then insert Short-head Holding Pins through the holes in the top of the Tibial Sizing/Positioning Plate to mark the location of the plate when using the broaching plate in the next step (Fig. 32e).

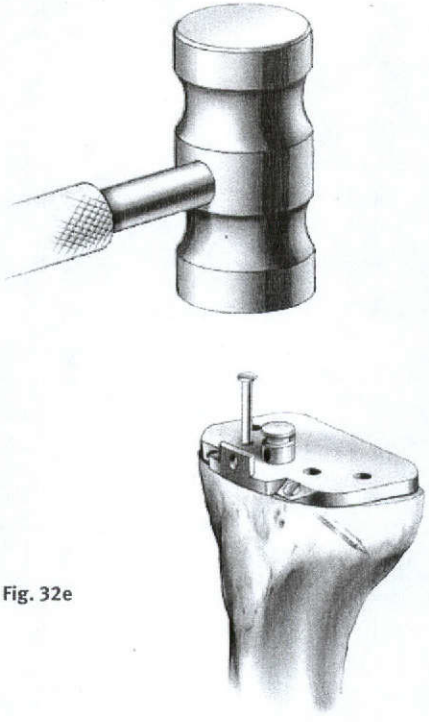

Fig. 32e

Remove any pins and the Tibial Sizing/Positioning Plate. Place the same size Fluted Stem Tibial Broach Plate onto the tibial surface. Use the holes created by the Small-head Holding Pins that secured the Tibial Sizing/Positioning Plate to determine the proper location of the Fluted Stem Tibial Broach Plate. Secure the plate with Short-head Holding Pins through the existing holes.

Place the Tibial Drill Guide on the sizing plate and drill for the stem with the 15mm Drill (Fig. 32f). Drill until the first engraved line on the drill is in line with the top of the drill sleeve. Then remove the Tibial Drill Guide.

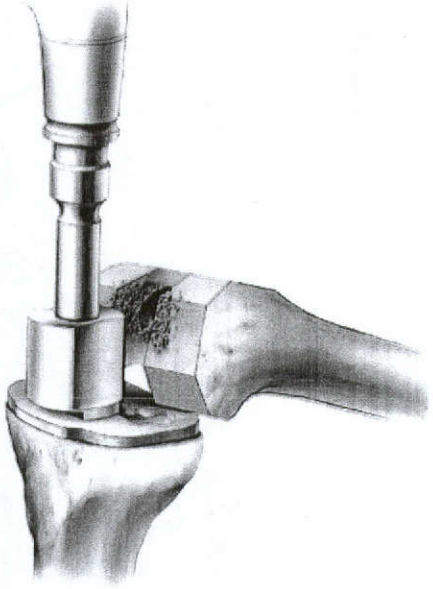

Fig. 32f

Assemble the proper size Fluted Stem Tibial Broach to the Broach Impactor (Fig. 32g).

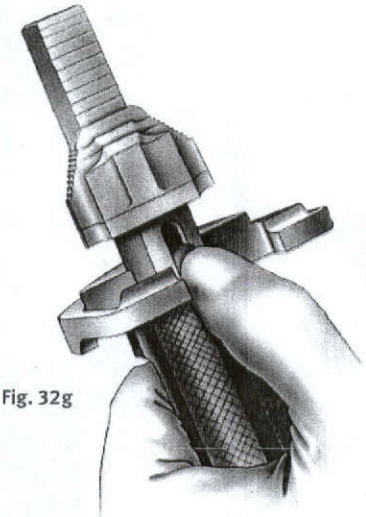

Fig. 32g

The broach can be assembled only from the front. Seat the impactor on the broach plate and impact the broach to the proper depth indicated by the etched groove on the shaft aligning with the impactor handle. The broach has a built-in stop so it cannot be over impacted (Fig. 32h).

Fig. 32h

Remove the impactor assembly using the built-in slaphammer, then remove the Fluted Stem Broach Plate. Use the correct size tibial plate provisional to ensure proper fit before implanting the final components.

## Step Eleven
## Trial Reduction

Place the Femoral Provisional, the Tibial Plate Provisional, the Articular Surface Provisional, and the Patellar Provisional if needed onto the prepared bone surfaces.

With all the provisional components in place, perform a complete range of motion. Observe patellar tracking and tilt. If necessary, perform a lateral retinacular release.

## Step Twelve
## Implantation

After the implants have been chosen, make one last check to ensure that the femoral, tibial, and articular surface components match. The femoral letter must match one of the letters on the articular surface carton. The tibial plate number must match one of the three numbers indicated on the articular surface carton as indicated by the interchangeability chart.

If desired, a Straight or Offset Stem Extension can be used with the Precoat Fluted Stem Mobile Tibial Base Plate. The locking mechanism between the mobile tibial implant and the stem extension implant is a combination of a Morse-type taper and a set-screw. Remove the stem extension locking screw from the stem extension and discard. The stem extension locking screw is not used with the mobile tibial component.

The LPS-Flex Mobile and LPS-Mobile Bearing Knee Systems are compatible with all available sizes of NexGen stem, extensions, which consist of the following designs:

- Straight Stem
- Straight Stem - Long
- Offset Stem
- Offset Stem - Long
- Sharp Fluted Stem
- Sharp Fluted Stem - Long
- Cemented Stem

Check to ensure that the set-screw has not migrated into the mobile tibial stem base taper prior to inserting the stem extension. Insert the stem extension into the stem-base of the mobile tibial component. When using the Offset Stem Extension, line up the stem location number with the etched line on the posterior stem base housing. The stem extension should be "snug" in the tibial component stem base. If toggle exists, back out the set-screw one half turn. When a snug fit is achieved, wrap the mobile tibial component in a cloth and place it on a surgical cart to provide a rigid surface for taper impaction. While protecting the stem extension, strike it solidly one time with a two-pound mallet.

**Note: Hitting the stem more than once may loosen the taper connection.**

After seating the Morse-type taper, tighten the set-screw located on the posterior aspect of the mobile tibial base plate stem (Fig. 33a) using a standard 3.5mm hex screwdriver.

**Note: If, in the surgeon's opinion, a stem is not needed, then the set-screw should be removed before implanting the tibial base plate.**

Insert the appropriate size femoral and tibial components. Then insert the appropriate tibial articular surface onto the plate.

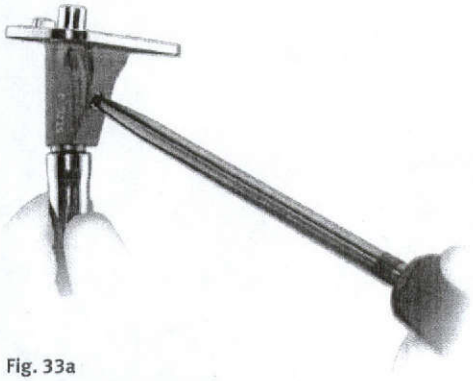

Fig. 33a

### Techniques for 17mm and 20mm Articular Surface Assembly

**A secondary locking screw is required for the 17mm- and 20mm-thick articular surface components** (Fig. 33b). Either of two assembly techniques can be used.

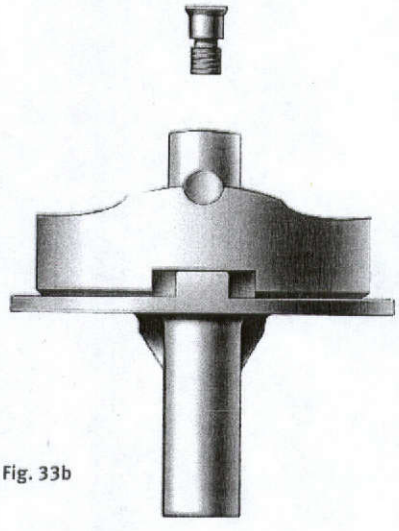

Fig. 33b

### Intraoperative Technique:

Implant the tibial base plate and wait for the bone cement to completely cure. Then insert the articular surface onto the trunnion of the base plate. Place the secondary locking screw (packaged with the articular surface) through the hole in the articular surface.

Select the Tibial Plate Wrench which has the tibial plate size that matches the implant size to be assembled. Place the end of the wrench over the tibial plate. Ensure that the wrench is in line with the base of the tibial plate. Attach the Deflection Beam Torque Wrench to the 4.5mm Hex Driver Bit. Apply 95 in.-lbs. of torque with the wrench.
**Do not-over or under-torque.**

### Optional Back-Table Technique:

The tibial plate may be placed onto the holding fixture, which is an integral part of the instrument case. Assemble the articular surface onto the trunnion of the tibial plate. Insert the secondary locking screw through the hole in the articular surface.

Attach the Deflection Beam Assembly Wrench to the 4.5mm Hex Driver Bit. Apply 95 in.-lbs. of torque with the wrench.
**Do not over or under torque.**

## Closure

Close the capsule and perform a "drop and dangle" test to predict the range of motion for the patient (Fig. 33c).

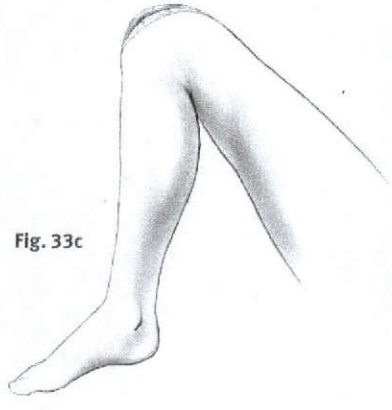

Fig. 33c

Position the knee in flexion to continue closing the layers (Fig. 33d).

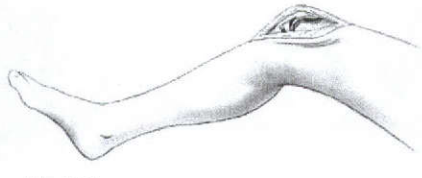

Fig. 33d

## Rehabilitation Protocol

An equally important factor in gaining or maintaining high flexion after successful total knee arthroplasty is early and/or aggressive rehabilitation of the patient. Many of the standard rehabilitation protocols used in western-style hospitals today are aimed at restoring knee motion and function between 90° and 110°, which is sufficient for the TKA patient to get into or out of a chair or a car. Those patients undergoing TKA who are able and willing to flex and wish to maintain preoperative flexibility may be better off with earlier and/or relatively more aggressive rehabilitation exercises.

### References

1 Whiteside LA. Factors affecting range of motion in total knee arthroplasty. J Jpn Orthop Assoc. 1991;65:193-194.

2 Insall JN. Surgery of the Knee. 3rd ed. New York, NY: Churchill Livingston; 2001:1553.

# Package Insert

## NexGen® LPS-Flex Mobile and LPS-Mobile Bearing Knee Systems (United States Version)

### Indications

- This device is indicated for patients with severe knee pain and disability due to:
  - Osteoarthritis.
  - Primary and secondary traumatic arthritis.
  - Avascular necrosis of the femoral condyle.
  - Moderate valgus, varus, or flexion deformities (i.e., valgus/varus deformity of ≤ 15°, fixed flexion deformity of ≤ 10°).
- **This device is intended for cemented use only.**

### Contraindications

- Contraindications include:
  - Previous history of infection in the affected joint and/or local/systemic infection that may affect the prosthetic joint.
  - Insufficient bone stock on femoral or tibial surfaces.
  - Skeletal immaturity.
  - Neuropathic arthropathy.
  - Osteoporosis or any loss of musculature or neuromuscular disease that compromises the affected limb.
  - A stable, painless arthrodesis in a satisfactory functional position.
  - Severe instability secondary to the absence of collateral ligament integrity.
- Total knee arthroplasty is contraindicated in patients who have rheumatoid arthritis (RA) and an ulcer of the skin or a history of recurrent breakdown of the skin because their risk of postoperative infection is greater. RA patients using steroids may also have increased risk of infection. Late infections in RA patients have been reported 24+ months postoperative.

### Warnings

- Do not reuse. This device is for single patient use only.
- Avoid notching, scratching, or striking the device. Improper preoperative or intraoperative implant handling or damage (e.g., scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear.
- Prior to closure of the surgical site, thoroughly cleanse the site of bone chips, bone cement, and any other debris. Foreign particles at the articular interface may cause excessive wear.
- Do not use:
  - This product for other than labeled indications.
  - Any component, if damage is found or caused during setup or insertion.
  - Components from other knee systems (and vice versa) unless expressly labeled for such use. Premature wear or loosening may develop and may require surgical explantation.
  - *NexGen* CR, CRA or CR-Flex femoral components with LPS-Mobile articular surfaces. They were not designed to be compatible.
  - The LPS-Mobile articular surfaces with porous LPS-Flex femoral components or porous LPS femoral components as these femoral components are not approved for use with the *NexGen* LPS Mobile Bearing Knee systems.
- **All LPS-Mobile 17 and 20mm tibial articular surfaces require a locking screw to fasten the articular surface to the Fluted Stem Mobile tibial baseplate.** Failure to use the locking screw may result in premature failure of the components (e.g., separation) due to the greater moment (i.e., forces) acting on these thicker components.
- Use only LPS-Mobile tibial articular surfaces with the Fluted Stem Mobile tibial baseplates (and vice versa) as they are not compatible with other components.
- Use only *NexGen* all-polyethylene patellas with these femoral components. Patellas made for other systems may demonstrate excessive wear when used with these femoral components.
- Avoid improper positioning and alignment of the implant components. The risk of implant failure is higher with inaccurate component alignment or positioning due to unusual stress conditions which may occur, leading to a reduction in the service life of the implant components. Please refer to the surgical technique manual for information specific to positioning of these implant systems.
- Soft tissues should be balanced and components positioning confirmed to minimize edge loading.
- Consider venting the femur or tibia. Fat embolism risk is increased with intramedullary instrumentation and/or cement pressurization.
- Release leg tourniquets ten minutes apart in simultaneous bilateral knee surgery, to lessen any lung insult that may occur.

## Precautions

- LPS-Flex/LPS-Mobile components are sized by matching the femoral component letters and the tibial baseplate component numbers to the articular surface label. Ignore any color codes. A knee implant size matching chart is available to supplement these instructions (See the *NexGen* Complete Knee Solution Component Matching Flowchart in the surgical technique manual). Mis matching may result in poor surface contact and could produce pain, decrease wear resistance, produce instability of the implant, or otherwise reduce implant life.
- Use only instruments and provisional trials specifically designed for use with these devices to help ensure accurate surgical implantation, soft tissue balancing, and evaluation of knee function. Please refer to the accompanying Surgical Techique Manual.
- Thicker polyethylene components may be needed if the patient is young, heavy, and/or physically active.
- The potential for deep sepsis can be minimized by using biocontamination controls. Continued surveillance for new or recurrent sources of infection should be continued as long as the device is in place.
- **The safety and effectiveness of this device has not been established in patients with rheumatoid arthritis, collagen disorders, polyarthritis, or pseudogout; or in patients who need a revision total knee replacement.**

## Potential Adverse Effects associated with Total Knee Arthroplasty

- Loosening of the prosthetic knee components
- Fracture/damage of the prosthetic knee components
- Removal and/or replacement of the device system or its components
- Soft tissue impingement or damage
- Dislocation and/or joint instability
- Malalignment of the prosthetic knee components
- Bone fracture
- Nerve damage
- Infection
- Swelling
- Leg length discrepancies
- Poor range of motion
- Delayed wound healing
- Temporary or permanent neuropathies
- Pain
- Cardiovascular disorders including venous thrombosis, pulmonary embolism or myocardial infarction
- Histological reactions resulting in Inflammation
- Metal sensitivity
- Corrosion of metal components
- Excessive wear secondary to damage of mating wear surfaces and/or debris that can initiate osteolysis which may result in loosening of the implant
- Death

## Potential Adverse Effects associated with the *NexGen* LPS-Flex Mobile and LPS-Mobile Bearing Knee Systems

- Excessive wear secondary to damage of multiple mating wear surfaces that can initiate osteolysis which may result in loosening of the implant
- Tibiofemoral bearing disassembly
- Tibiofemoral subluxation
- Dislocation and/or joint instability
- Knee stiffness

## Adverse Events Reported in the Clinical Study of the *NexGen* LPS-Flex Mobile Bearing Knee

In this clinical study, 388 knees in 374 patients were implanted with either the treatment *NexGen* LPS-Flex Mobile Bearing Knee (n=201) or the control LPS-Flex Fixed Bearing Knee (n=187). All general postoperative adverse events (e.g., systemic, non-device related, etc.) reported during the clinical study on all randomized procedures performed (i.e., All Analyzable procedures) are listed in Table 1. Numbers are cumulative through the 2-year postoperative study endpoint. A time-course distribution of all localized adverse events related to the knee replacement surgey and reported in the clinical study is listed in Table 2.

Postoperatively, only complication rates for knee stiffness requiring manipulation differed statistically (Fisher's exact p = 0.01) between the treatment group (7.0%) and the control group (1.6%).

Table 1. General Postoperative Complication Rates for All Analyzable Procedures

| *General Postoperative Complication* | *LPS Flex Mobile (N=201)* | *Control Device (N=187)* | *Fisher's Exact Test P-value* |
|---|---|---|---|
| Anemia | 17 (8.5%) | 9 (4.8%) | 0.16 |
| Cardiac Arrhythmia | 4 (2.0%) | 5 (2.7%) | 0.74 |
| Congestive Heart Failure | 0 | 2 (1.1%) | 0.23 |
| Death | 5 (2.5%) | 3 (1.6%) | 0.73 |
| Infection (contralateral knee cellulitis, following prostectomy, postop - not specified) | 1 (0.5%) | 2 (1.1%) | 0.61 |
| Hemathrosis | 5 (2.5%) | 1 (0.5%) | 0.22 |
| Ileus | 2 (1.0%) | 1 (0.5%) | >0.99 |
| Myocardial Infarction | 2 (1.0%) | 0 | 0.50 |
| Nerve Injury (lumbar spine issues and associated with the surgical procedure) | 0 | 2 (1.1%) | 0.23 |
| Pulmonary Embolism | 1 (0.5%) | 0 | >0.99 |
| Respiratory Infection | 3 (1.5%) | 5 (2.7%) | 0.49 |
| Stroke | 0 | 1 (0.5%) | 0.48 |
| Urinary Retention | 1 (0.5%) | 4 (2.1%) | 0.20 |
| Urinary Tract Infection | 3 (1.5%) | 2 (1.1%) | >0.99 |
| Other General Complications | 221 (73.4%) | 197 (70.6%) | 0.46 |

The numbers and rates for general complications were determined independently for each complication type. General complications for bilateral patients were handled on a case level for each individual patient.

**Table 2. Time Course Distribution of Knee-Related Postoperative Complications and Overall Knee-Related Complication Rates for All Analyzable Procedures**

| Knee-Related Postoperative Complication | Preop | | 6 weeks | | 6 months | | 1 year | | 2 year | | LPS Flex Mobile (N=201) | Control Device (N=187) | Fischer's Exact Test P-value |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Mobile | Control | Mobile | Control | Mobile | Control | Mobile | Control | Mobile | Control | | | |
| Deep Wound Infection < 6 weeks | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.5%) | 0.48 |
| Deep Vein Thrombosis | 0 | 0 | 10 | 9 | 0 | 1 | 0 | 0 | 0 | 0 | 10 (5.0%) | 10 (5.3%) | >0.99 |
| Delayed Wound Healing | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.5%) | 0 | >0.99 |
| Device Clicking | 0 | 0 | 2 | 4 | 0 | 2 | 1 | 1 | 1 | 0 | 4 (2.0%) | 7 (3.7%) | 0.37 |
| Dislocation (poly only, relocated spontaneously) | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.5%) | 0 | >0.99 |
| Effusion | 0 | 0 | 3 | 7 | 2 | 2 | 4 | 1 | 0 | 3 | 9 (1.3%) | 13 (6.9%) | 0.38 |
| Flexion Contracture | 0 | 0 | 1 | 4 | 0 | 1 | 0 | 0 | 0 | 0 | 1 (0.5%) | 5 (2.7%) | 0.11 |
| Fracture of Femur | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.5%) | 0.48 |
| Fracture of Patella | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 (0.5%) | 1 (0.5%) | >0.99 |
| Hematoma | 0 | 0 | 1 | 4 | 0 | 1 | 0 | 0 | 0 | 0 | 1 (0.5%) | 5 (2.7%) | 0.11 |
| Heterotopic Ossification-Femur | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 (0.5%) | 0 | >0.99 |
| Nerve Deficit | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 (0.5%) | 1 (0.5%) | >0.99 |
| Nerve Injury (lumbar spine, not related to implant or procedure; peroneal nerve palsy, related to procedure)) | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 2 (1.1%) | 0.23 |
| Patella Clunk | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 (0.5%) | 0.48 |
| Patellofemoral Crepitus | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 (1.1%) | 0.23 |
| Patellofemoral Subluxation | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 1 (0.5%) | 1 (0.5%) | >0.99 |
| Stiff Knee Resulting in Manipulation (4 were done under anesthesia) | 0 | 0 | 14 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 14 (7.0%) | 3 (1.6%) | 0.01 |
| Superficial Infection | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4 (2.1%) | 0.05 |
| Tibial Base Plate Loosening | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 1 (0.5%) | 1 (0.5%) | >0.99 |
| Tibial Pain | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 (0.5%) | 0 | >0.99 |
| Wound Dehiscence | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (0.5%) | 0 | >0.99 |
| Wound Drainage | 0 | 0 | 3 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 3 (1.5%) | 3 (1.6%) | >0.99 |
| Other Knee Related Complications | 0 | 2 | 30 | 26 | 10 | 15 | 17 | 12 | 8 | 10 | 65 (30.1%) | 63 (31.7%) | 0.75 |

## Clinical Study

A prospective clinical study was conducted to evaluate the safety and effectiveness of the *NexGen* LPS-Flex Mobile Bearing Knee.

### Clinical Study Design

The study was an open, randomized, multi-center, concurrently controlled, non-inferiority clinical trial that compared the safety and effectiveness of the *NexGen* LPS-Flex Mobile Bearing knee system (treatment group) to the non-mobile bearing *NexGen* LPS-Flex Fixed Bearing Knee (control group) at the 2 year postoperative endpoint. Clinical study endpoints included pain, function, radiographic parameters, device survivorship, and complications. The study was conducted at 15 centers and included 388 procedures in 374 patients. This 388 All Analyzable procedures cohort (i.e., all randomized procedures performed) consisted of 201 cases in the treatment group and 187 cases in the control group.

The study included patients 21-80 years of age presenting with severe knee pain and disability due to degenerative joint disease, including:

- Osteoarthritis
- Avascular necrosis of the femoral condyle
- Posttraumatic arthritis

Per study protocol, the primary study analysis cohort excluded bilateral cases and rheumatoid arthritis cases. However, a large number of patients (n=82), failed to meet all protocol inclusion criteria (e.g., pain and function assessment of less than 60 points on the Knee Society Score (KSS)), but were enrolled into the study. As a result, the primary analysis cohort used to evaluate study success was based on the "As Treated" patients (i.e., excluded bilateral cases and rheumatoid arthritis cases, and included protocol inclusion critieria deviations) instead of the "Per-Protocol" patients. The "As Treated" cohort consisted of 341 cases, with 173 in the treatment group and 168 in the control group.

The efficacy of the LPS-Flex Mobile Knee was determined by comparing the survivorship, Knee Society Assessment and Function scores, and selected radiographic parameters, of the treatment group to the control group in the primary study cohort.

The safety of the LPS-Flex Mobile Bearing Knee in patients was evaluated by monitoring the difference in cumulative rates of severe knee related complications and unanticipated adverse device effects (UADE's) between the treatment group and the control group in the primary study cohort.

### Clinical Patient Assessment

Each patient was evaluated 6 weeks, 6 months, 12 months and 24 months after surgery which included pain, function, quality of life, and radiographic evaluations. At two year intervals thereafter, patients were evaluated until the last patient enrolled completed a two-year follow-up evaluation. An independent radiologist reviewed the 6 week and 24 month radiographs by standardized criteria to eliminate potential variability and bias.

Clinical success is a composite measure of the primary safety and effectiveness endpoints, and was determined separately for each individual patient. To be considered a clinical success a patient had to meet the success criteria for all five primary study endpoints as noted in Table 3.

**Table 3: Success Criteria for Primary Study Endpoints at 2 Years**

| Primary Clinical Endpoints | Success Criteria |
|---|---|
| Knee Society Assessment (pain) Score | Knee Society Assessment (pain) Score ≥ 70 |
| Knee Society Function Score | Knee Society Function Score ≥ 70 |
| Adverse Events / Complications | Absence of Severe Knee Related AE's and UADE's |
| Radiographic Parameters | < 2mm Radiolucencies and < 2mm Implant Position Change |
| Survivorship / Revision | No component/device revision or removal |

There were a total of 748 complications reported on the All Analyzable procedures dataset (see Tables 1 and 2). Of these complications, 386 (51.6%) involved the treatment group, and 362 (48.4%) involved the control group.

The percentage of cases experiencing at least one postoperative complication was similar between the two study device groups. In the treatment group, there were 154/201 (76.6%) cases experiencing at least one postoperative complication, and in the control group there were 143/183 (76.5%). These rates did not differ statistically between the device groups.

Postoperatively, only complication rates for knee stiffness requiring manipulation differed statistically (Fisher's exact p = 0.01) between the treatment group (7.0%) and the control group (1.6%). Otherwise, general and knee related complication rates were similar and did not differ statistically between the device groups.

## Results

Demographics

The primary As Treated cohort of 341 cases included 199 females (treatment group = 94, control group = 105), and 142 males (treatment group = 79, control group = 63). Preoperative diagnoses consisted of 1 case with avascular necrosis (treatment group), 333 cases with osteoarthritis (treatment group = 168, control group = 165), and 7 cases with post-traumatic arthritis (treatment group = 4, control group = 3).

Results suggest that there were no significant differences (p=0.05) between study devices in key baseline, demographic, or operative variables, such as age, gender, operative side, preoperative diagnosis, preoperative KSS pain and function scores, or operating time, specified in the study protocol.

At two years, patient follow-up was greater than 95% for both study groups. There were eight deaths for reasons unrelated to the surgery or the device (treatment group = 5, control group = 3).

Safety and Effectiveness Data

Safety and effectiveness results for the primary As Treated study cohort (i.e., 341 cases - 173 treatment group, 168 control group) at two years post-operatively are provided below.

## Safety Results

Adverse Events

The adverse events related to total knee replacement surgery for all procedures performed in the clinical study are listed in Tables 1 and 2.

Severe Knee Related Complications & Unanticipated Adverse Device Effects

The results for the primary safety endpoint of severe knee related complications and unanticipated adverse device effects at 2 years, which represent a clinical safety failure, are given in Table 4.

**Table 4. Primary Safety Endpoint Analysis – Available As Treated Endpoints**

| Primary Study Endpoint | LPS Flex Mobile (N=173) | Control Device (N=168) | Difference (98% CI) ¤ [δ = delta]* | Fisher's Exact Test p-value^ (Lt tail) |
|---|---|---|---|---|
| Severe Knee Related Complications & UADEs – N (%) | 3/173 (1.7%) | 5/168 (3.0%) | -1.2% (-5.1%, 2.6%) [8.9%] | 0.87 |

* *δ is the small, maximum clinically acceptable, pre-specified non-inferiority margin.*

¤ *The 98% two-sided confidence limit is presented as it provides the 99% one-sided lower (upper) limit when the upper (lower) bound is ignored, as required to assess non-inferiority.*

^ *Since the p-value was 0.87, a value which is greater than the alpha (Type I error) level of 1 percent (p=0.01) pre-specified for the one-sided test of the primary safety endpoint, we can declare the LPS-Flex Mobile Bearing Knee does not differ from the LPS-Flex Fixed Knee with any clinical significance at 2 years.*

The results for the primary safety endpoint of cumulative incidence of severe knee related complications and unanticipated adverse device effects demonstrate that the treatment group does not differ with any clinical significance from the control group at the 2 year study endpoint.

There were a total of two device revisions reported during this study.

There were no unanticipated adverse device effects reported in the study.

## Efficacy Results

The results for the for the individual primary efficacy endpoints of pain, function, radiographic parameters, and survivorship at 2 years are given in Table 5.

**Table 5. Primary Efficacy Endpoints Analysis – Available As Treated Endpoints**

| Primary Study Endpoint | LPS Flex Mobile (N=173) | Control Device (N=168) | Difference (98% CI) [π] [δ = delta]* | Fisher's Exact Test p-value^ (Lt tail) |
|---|---|---|---|---|
| Knee Society Assessment (pain) Score<br>N<br>Mean (Std Dev)<br>(Min, Max) | <br>165<br>87.9 (12.89)<br>(49, 100) | <br>165<br>88.0 (14.10)<br>(37.6, 100) | <br>-0.16 points<br>(-3.64, 3.31)<br>[-5.7 points] | |
| Knee Society Function Score<br>N<br>Mean (Std Dev)<br>(Min, Max) | <br>172<br>79.7 (22.04)<br>(0, 100) | <br>168<br>80.5 (20.38)<br>(5, 100) | <br>-0.80 points<br>(-6.2, 4.5)<br>[-8.2 points] | |
| Radiolucency ≥ 2mm and/or Implant Component Position Change ≥ 2mm<br>%<br>(n/N) | <br>1.2%<br>(2/172) | <br>2.4%<br>(4/164) | <br>1.3%<br>(-4.7%, 2.1%)<br>[5.7%] | <br>0.90[1] |
| Revision/Removal of Study Device or Component<br>%<br>(n/N) | <br>0.6%<br>(1/173) | <br>0%<br>(0/168) | <br>0.6%<br>(-0.8%, 1.9%)<br>[4.1%] | <br>0.51[2] |

* *δ is the small, maximum clinically acceptable, pre-specified non-inferiority margin. A negative sign was added to the value specified in the clinical protocol to indicate the direction of the limit for interpretation.*

π *The 98% two-sided confidence limit is presented as it provides the 99% one-sided lower (upper) limit when the upper (lower) bound is ignored as required to assess non-inferiority*

1 *Since the p-value was 0.90, a value which is greater than the alpha (Type I error) level of 1 percent (0.01) pre-specified for the one-sided test of the primary radiographic endpoint, we can declare the LPS-Flex Mobile Bearing Knee does not differ from the control device with any clinical significance at 2 years.*

2 *Since the p-value was 0.51, a value which is greater than the alpha (Type I error) level of 1 percent (0.01) pre-specified for the one-sided test of the primary survival endpoint, we can declare the LPS-Flex Mobile Bearing Knee does not differ from the control device with any clinical significance at 2 years.*

Knee Society Assessment Scores
The results for the primary efficacy endpoint of pain, as measured by the KSS Assessment (pain) Score, demonstrate that the treatment group does not differ with any clinical significance from the control group at the 2 year study endpoint.

Knee Society Function Scores
The results for the primary efficacy endpoint of function, as measured by the KSS Function Score, demonstrate that the treatment group does not differ with any clinical significance from the control group at the 2 year study endpoint.

Radiographic Data
The results for the primary efficacy endpoint of radiographic parameters, as measured by the presence of radiolucency(ies) ≥ 2 millimeters and/or implant component position change ≥ 2 millimeters, which represent radiographic failure, demonstrate that the treatment group does not differ with any clinical significance from the control group at the 2 year study endpoint.

Implant Survivorship
The results for the primary efficacy endpoint of implant survivorship, as measured by the cumulative revisions/removals of the device, which represents implant failure, demonstrate that the treatment group does not differ with any clinical significance from the control group in cumulative number of revisions at the 2 year study endpoint.

There were two device revisions reported during this study. One patient (treatment group) was revised with a new femoral component after 21 months, prior to the 2 year study endpoint. One bilateral patient (control group) was revised with a new articular surface after 31 months, subsequent to the 2 year study endpoint, and does not appear in the data tables.

## Clinical Success

Table 6 displays the proportion of patients that met the success criteria for each of the five individual study endpoints at 2 years post-operatively.

**Table 6: Individual Success Criteria Results at 2 Years**

| Success Criteria | LPS Flex Mobile (N= 173) | Control Device (N=168) |
|---|---|---|
| Knee Society assessment (pain) score ≥ 70 | 92% (152/165) | 88% (145/165) |
| Knee Society function Score > 70 | 79.7% (137/172) | 80.5% (135/168) |
| Absence of severe knee related AE's and UADE's | 98.3% (170/173) | 97% (163/168) |
| < 2mm radiolucencies and < 2mm subsidence for all views | 98.8% (170/172) | 97.6% (160/164) |
| No component/device removal | 99.4% (172/173) | 100% (168/168) |

A secondary analysis of the composite measure of clinical success was also performed. That is, the proportion of patients from each group that met the success criteria for all five primary study endpoints were compared. Table 7 displays the composite clinical success rates for the treatment group in comparison to the control group.

**Table 7. Secondary Endpoint Analysis for Clinical Success – Available As Treated Endpoints**

| Secondary Study Endpoint | LPS Flex Mobile (N=173) | Control Device (N=168) | Difference (90% CI) [δ = delta]* |
|---|---|---|---|
| Composite Measure of Achieving Clinical Success – % (n/N) | 69.1% (114/165) | 67.7% (109/161) | 1.4% (-7.1%, 9.9%) [10.0%] |

* *δ is the small, maximum clinically acceptable, pre-specified non-inferiority margin. A negative sign was added to the value specified in the clinical protocol to indicate the direction of the limit for interpretation.*

\# *The 90% two-sided confidence limit is presented as it provides the 95% one-sided upper limit when the lower bound is ignored as required to assess non-inferiority*

The results demonstrate that the treatment group does not differ with any clinical significance from the control group in terms of the composite measure of clinical success.

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