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NEXGEN® LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEMS (UNITED STATES VERSION)

zimmer

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Rx only

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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 (standard and *Prolong*® Highly Crosslinked Polyethylene)
- Fluted Stem Mobile tibial baseplate component or MIS LPS-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) or *Prolong* Highly Crosslinked Polyethylene. 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. MIS LPS-Mobile tibial baseplate components are available in the poly(methyl methacrylate) [PMMA] precoat style. 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.
  - LPS or LPS-Flex femoral components with *Prolong* LPS-Mobile articular surfaces unless the part number of the femoral component has a 51 or 52 part number suffix. Use of other suffix LPS and LPS-Flex femoral components may increase the risk of articular surface fracture.
- **All LPS-Mobile 17 and 20mm tibial articular surfaces require a locking screw to fasten the articular surface to the Fluted Stem Mobile and MIS LPS-Mobile tibial baseplates.** Failure to use the locking screw may result in premature failure of the components (e.g., separation) due to the greater movement (i.e., forces) acting on these thicker components.
- Use only LPS-Mobile tibial articular surfaces with the Fluted Stem Mobile and MIS LPS-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.**

In the event of exposure to foreseeable environmental conditions, such as magnetic fields, the user and/or patient should be informed of the following precautions:

- This device has not been evaluated for safety and compatibility in the MR environment.
- This device has not been tested for heating or migration in the MR environment.
- There is a potential for heating and migration in the MR environment.
- There is the potential for metal implants to create MR imaging artifacts in the vicinity of the implant.

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

* *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 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.

STERILITY

- Gamma irradiation is indicated by the STERILE R symbol on the labeling. Where available, STERRAD gas plasma sterilization is indicated by the STERILE GP symbol on the label. 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	Minimum Dry Time
Gravity Displacement	121°C (250°F)	30 minutes	15 minutes – Varies by load configuration and sterilizer type.
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.
- Solid metal implants with an articulating surface may be resterilized only once for immediate use. Solid metal implants without an articulating surface may be resterilized multiple times.
- Solid metal implants may be resterilized only once for immediate use, in the event of inadvertent loss of sterility while preparing for surgery.
- 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.