Exhibit A

Application

Prospective Randomized Single Center Clinical Evaluation of THA Surgical Techniques Comparing the Direct Anterior Approach to the Posterior Approach

1.0 Objective

Total Hip Replacement remains one of the most cost effective procedures in the U.S. for the treatment of discomfort and dysfunction associated with osteoarthritis of the hip. The objectives of this study are to compare the clinical and functional outcomes of subjects in the early post-operative follow-up period (up to 5 years) comparing an anterior to a posterior surgical approach.

2.0 Overview

While several very successful surgical techniques exist and are widely used, there are two recent large studies using the Anterior intramuscular approach (Keggi 2004, Siguier 2004) that have reported excellent results. This technique will be one of two surgical techniques being utilized in this study with the other being the posterior approach.

This is a randomized, prospective, single center clinical evaluation of two different surgical techniques. Pre and post operative protocols, pain management, physical therapy, and implant selection will be standardized for both treatment groups in an attempt to isolate any post-operative functional outcome differences to the surgical approach used during the THA procedure.

The surgical approaches used in this study will be limited to the direct anterior approach, which utilizes a fracture table with the patient placed supine, both feet in boots for proper positioning. An anterior skin incision between 12-14 cm is used. An inter-muscular plane is utilized to access the anterior hip capsule. The hip capsule is opened anteriorly, a femoral neck osteotomy is performed based on pre-op templating and the femoral head is removed. Acetabular retractors are placed and reaming of the acetabulum in commenced. This is done under direct visualization with C-arm confirmation for positioning. The acetabular component is inserted with a press-fit technique using ancillary screw fixation as needed. The femoral side is then visualized with the aid of the traction table. Broaching of the femoral canal is started and proceeds up the appropriate size. A trial reduction is performed. The length and offset are checked manually and with C-arm confirmation. The trial components are removed and the real femoral component placed with press-fit fixation. Routine closure is performed.

The second surgical technique used in the study will be the posterior approach. This approach uses a standard OR table with the patient placed in the lateral decubitus position. A 12-14cm skin incision is utilized over the posterior-lateral corner of the hip. The gluteus maximus muscle is split in line with its fibers and the posterior capsule is opened. The hip is dislocated posteriorly and a femoral neck osteotomy is performed. The acetabular and femoral components are inserted in the same manner as is done with the anterior approach with press-fit fixation utilized. The posterior approach is well described in all major texts on Orthopedic Surgery. To minimize selection bias the surgical technique will be determined by a randomization schedule.

Radiographs and clinical data will be gathered for each qualifying patient in the manner outlined in the Study Procedures below. Harris Hip Evaluation scoring will be used to evaluate pain, function, activity levels, deformity, and range of motion. The HOOS patient reported outcomes will be used to evaluate function and pain relief.

Deaths, device, and procedure related complications will be reported.

Data to be collected includes, but is not limited to that specified in Section 5.2 below.

The primary focus of the study is to compare the short-term safety, efficacy and return to function of patients undergoing primary total hip arthroplasty utilizing an anterior approach vs a posterior approach. Upon completion of the study, a summary of the results will be submitted for publication.

3.0 Device Descriptions

The device to be studied is a commercially available and will be implanted according to its approved labeling.

3.1 Femoral stem –The Corail Stem is made of forged titanium for increased strength, utilizes an extensive hydroxyapatite coating with a groove and ridge surface design. A self locking double taper design improves implant stability. Reduced neck geometry with high offset improves hip stability. It is implanted with compaction broaching.

3.2 Acetabular Component – The Pinnacle cup is composed of titanium and utilizes the Porocoat Porous Coating. The Pinnacle Sector are allowed for use in this investigation. The outside diameters range in size from 48mm to 66mm in 2mm increments.

3.3 Acetabular Liner – The AltrX polyethylene liners start with a base resin bar stock of GUR 1020 and is then moderately cross-linked at 7.5 megards, resulting in a material that is mechanically tough while providing 92% reduction in wear and resistance to oxidation. The liners will be limited in this study to 32mm and 36mm.

3.4 Femoral Head – Cobalt chrome 28mm, 32mm and 36mm heads will be used in this study

4.0 Patient Selection

4.1 Inclusion Criteria

1. Subject is able to or capable of providing consent to participate in the clinical investigation.
2. Subject is between the ages of 20-75 years, inclusive.
3. Subject requires a cementless, primary total hip arthroplasty for non-inflammatory degenerative joint disease (NIDJD)
4. Subject has sufficient bone stock for the hip replacement device.
5. Subject is a suitable candidate for the devices specified in the clinical investigation plan and is willing to be randomized to either surgical approach.

4.2 Exclusion Criteria

1. Subject in the opinion of the Investigator has an existing condition that would compromise his/her participation and follow-up in this investigation.
2. Subject has had previous surgery on the affected hip.
3. Subject has significant osteoarthritis of the contra-lateral hip requiring a total hip arthroplasty within 12 months.
4. Subject has significant osteoarthritis of either knee requiring a knee replacement within 12 months.
5. Subject has inflammatory arthritis (e.g. rheumatoid arthritis).
6. Subject has active or recent joint sepsis.
7. Subject with marked atrophy or deformity in the upper femur.
8. Subject with a neuromuscular disease where the loss of musculature would affect functional outcome.
9. Subject with known, active metastatic or neoplastic disease.
10. Subject is known to be pregnant, a prisoner, mentally incompetent, and or alcohol or drug abuser.
11. Subject is currently involved in any personal injury litigation, medical legal or worker's compensation claims.

5.0 Data Collection

5.1 Pre-operative Data Collection

Subject ID
Date of Birth
Gender
Height
Weight
BMI
Left or right hip
Diagnosis

Harris Hip Score Elements
Set of x-rays
Pre-op hematocrit and hemoglobin
Timed walking test

5.2 Operative Detail Data
Date of Surgery
Operative side
American Society of Anesthesiologists (ASA) grade
Surgical Approach
Operative time
Surgical blood loss
Implant catalog and lot numbers for all components
Complications

5.3 Post-operative Data
Pain scores pre and post administration of pain meds
Amount of pain medication required
Blood loss from drains over 36 hours post op
Hemaglobin / hematocrit on POD # 1&2
Functional activities (distance walked, transfers and assistive devices used)
Length of hospital stay
Harris Hip Score Elements
HOOS
Timed walking tests
Complications/Patient Withdrawal/Revision/Deaths (as applicable)

5.4 Radiographic Evaluation
Pre-op and post-op (6 weeks, 12 months, 24 months and 60 months)
AP pelvis and Lauenstein lateral radiographs will be analyzed for:
Cup inclination, anteversion, and fixation of the cup
Stem alignment and fixation
Limb length / offset

Patient Consent
In compliance with FDA regulations, no Subject shall be enrolled in an investigation without provision of adequate informed consent. Documentation of the informed consent process is obtained by the use of an Informed Patient Consent (IPC) Form. A copy of a sample IPC is provided as Exhibit 4. The IPC form must be written in each Subject's primary language. All translated consent forms must have the approval of the IRB. Due to specific institution requirements, all eligible consented Subjects should sign a Health Insurance Portability & Accountability Act (HIPPA) statement, which is typically included with the IPC form. Many Institutional Review Boards (IRB) &/or Ethics

Committees (EC) require modifications to the IPC be made to satisfy specific institutional requirements. In some cases the institution's consent form must be substituted for the one provided by the Sponsor. Use of a modified or substituted consent form is permitted provided it meets the requirements of 21 CFR part 50, however Sponsor approval must be obtained prior to use in this investigation.

The investigator or qualified designee will solicit the informed consent of all Subjects meeting the selection criteria and will thoroughly explain and discuss the following features of the investigation to the Subject:
The purpose of the investigation.
The difference between the two treatment groups and potential risks and benefits of each treatment.
Possibility of device failure and subsequent treatment(s).
Alternative procedures.
Assignment of treatment/randomization.
Requirements of the investigation (follow-up visits).
All of the Subject's rights as a participant in the clinical investigation.

The investigator will offer to answer any questions the Subject may have. If the Subject agrees to participate in the investigation, then the Subject must sign and date the IPC form prior to the day of surgery. However, if the IPC is signed on the day of surgery, then the source document must state that the Subject was given adequate time prior to the time of surgery to review and give consent. In such a case, the time the Subject signed the IPC form must be documented.

The original IPC form remains with the clinical investigator (i.e., within the CRF booklet or clinic chart) and a copy is provided to the Subject. The IPC is not forwarded to the Sponsor. Instead, the Investigator will complete the "Assurance of Investigator" form documenting that informed consent has been properly obtained and then submit a copy to the Sponsor. Once a Subject has executed the IPC documentation, they are considered a study Subject.

Post-operative visit schedule will consist of the following: pre-op, operative, and post-operatively at 2 weeks, 4-6 weeks, 3 months, 6-months ,12-months, 24 months and 60 months.

Time	**Data Collected**
2 weeks (7-21 days)	Average Pain Score (VAS) Amount of pain MED use/day Walking Distance Use of Assistive Device

4-6 weeks (22-45 days)	Average Pain Score (VAS) Average pain MED use/day Walking distance Assistive Device X-ray Protocol cup position stem position limb length offset Return to work/Activity/Driving Timed Walking Test Harris Hip Score HOOS
3 months (60-120 days)	Pain Score (VAS) Average pain MED use/day Walking distance Assisted device Timed Walking Test Harris Hip Score HOOS
6 months (130-240 days)	Average Pain Score (VAS) Harris Hip Score HOOS
12 months (270-425 days)	Average Pain Score (VAS) Harris Hip Score X-ray Protocol HOOS
24 months (426-1460)	Average Pain Score (VAS) Harris Hip Score X-ray Protocol
60 months (1461-2737)	Average Pain Score (VAS) Harris Hip Score X-ray Protocol

6.0 Statistical Methodology

Treatment Assignment
Treatment assignment will be determined with the use of a randomization schedule that will utilize blocks to ensure approximate treatment balance at any time during the study enrollment phase.

Sample Size Determination

Sample size was determined with the use of historical unpublished data of Harris Hip parameters at 6 weeks post-operatively from patients who underwent the primary THA using the anterior surgical approach. The percentage of patients at 6 week post-operative that had the ability to climb stairs normally, and walk unlimited, were 37%, and 40% respectively. Using a 2-tailed Fisher's Exact test and assuming a difference in clinical results of 30% and statistical power of 85% the required sample size for this study is 40 patients per treatment group. To account for 10% attrition the sample size was increased to 44 patients per treatment group (88 patients total).

Primary Endpoint

The proportion of patients with the ability to climb stairs normally or walk unlimited at 6 weeks post-operatively is the primary endpoint in this study. However, the HOOS patient self-assessment dimensions of Pain, Symptoms, Activities of Daily Living, Sport & Recreation, and Quality of Life will be important secondary endpoints. Six minute walk test distances and VAS Pain scores are also secondary endpoints

Analysis Populations

The Intent-to-Treat population will be analyzed.

Interim Analyses

No formal interim analyses will be conducted.

Analyses Planned

Demographics of the 2 treatment groups and pre-operative Harris Hip Evaluation sub-scores and HOOS sub-scores will be compared using appropriate statistical methodologies to determine comparability of treatment groups pre-operatively.

The proportion of patients able to climb stairs normally or walk unlimited as evaluated with the Harris Hip Evaluation at 6 weeks post-operatively will be compared using a 2-tailed Fisher's Exact test. Potentially covariates (e.g. age, BMI, gender) will be assessed using logistic regression techniques.

HOOS sub-scores of Pain, Symptoms, Activities of Daily Living, Sport & Recreation, and Quality of Life will be scored according to the HOOS Users Guide and will be compared using parametric or non-parametric techniques (as appropriate) at 6 weeks, 3, 6 and 12 months post-operatively to determine if there is a difference between treatment groups and at what time points the difference are detected.

Six minute walk test distances at 6 weeks and 3 months and VAS Pain scores will also be compared using parametric or non-parametric techniques (as appropriate) at 6 weeks, 3, 6, 12 months, 24 months and 60 months post-operatively to determine if there is a difference between treatment groups and at what time points the difference are detected.

The prevalence of both inter-operative and post-operative complications and adverse advents such as dislocation, hospital re-admission, revision operation, and other postoperative events not normally associated with THA will be compared between groups using a Fisher's Exact (2-tailed) test, with $p \leq 0.05$ being considered significant.