Virginia-Maryland College of Veterinary Medicine

Virginia Polytechnic Institute and State University
Veterinary Teaching Hospital
Address: 245 Duck Pond Dr., Blacksburg, Virginia 24061-0443
Phone: 540-231-4621 | Fax: 540-231-9354

Clinical Research Project
Client Consent Form

Study Title: 6 Month Evaluation of the Cupless Hip System
Principal Investigator: Otto Lanz, DVM, DACVS; Noelle Muro, DVM
540-231-4621; olanz@vt.edu, nmuro13@vt.edu

One of the missions of the Virginia-Maryland College of Veterinary Medicine is to create, disseminate and apply medical knowledge through discovery, learning, and engagement. You are invited to participate in this mission by enrolling your animal in a clinical research study. Your participation is entirely voluntary, and you may withdraw your animal from the study at any time by notifying the Principal Investigator. There is no penalty if you choose not to participate.

Study Purpose:
The purpose of this study is to evaluate the outcome of the cupless hip system in clinical patients. The traditional total hip system consists of a prosthetic ball and cup implant to fully replace the ball and socket joint of the hip. Although this technique can have an excellent outcome in terms of comfort and function, there is risk for significant complications. In addition, the total hip replacement implants are expensive, have the potential to wear out over time, and the procedure itself requires extensive specialty surgical training. The cupless hip system represents an alternative to the total hip replacement, which uses the patient's own bone for the "cup" instead of an implant. This significantly decreases the cost and difficulty of the procedure, so it can afford good function and comfort without the same complications or expense. It has been successfully performed in 5 clinical cases so far with very positive outcomes and high owner satisfaction.

Study Design/Procedures
This is a prospective clinical trial in which eligible canine patients will be treated using the cupless hip system. To be included in the study, a patient must be diagnosed with unilateral or bilateral hind limb lameness secondary to hip dysplasia by orthopedic exam and with radiographs of the pelvis. Pre-anesthetic bloodwork must be within normal limits to be enrolled. Eligible patients will have the cupless hip performed on the most affected hip. Patients will be dropped off the day prior to surgery or the day of surgery if applicable, and remain in hospital the night after the procedure to be discharged the following day as deemed appropriate by the attending clinician. Patients will have pelvic radiographs taken immediately post-operatively and will be evaluated in hospital prior to discharge. Patients must return in 6 months for a full orthopedic exam and recheck radiographs, and owners will be given a questionnaire to fill out both prior to surgery and at the 6 month recheck. If any complications are suspected prior to 6 months, patients should be evaluated sooner as necessary and any complications recorded.

Risks and Benefits:
The risks associated with participation in this study are consistent with those for any orthopedic surgery, including but not limited to anesthesia, infection, and implant failure. These will be discussed in detail on an individual basis. The cupless hip system does not represent increased surgical risk compared to other surgical options for canine hip dysplasia. The benefit is the potential for a surgical option at decreased cost with potentially decreased complication rate overall without sacrificing comfort and function.

Study Costs and Compensation:
The estimated cost for the cupless hip system is $3000-3500 per side, which includes bloodwork, hospitalization, anesthesia, surgery, implants, and post-operative radiographs. This estimate does not include the recheck visit or unforeseen complications. The cost of the 6 month recheck visit will be approximately $250-350, and includes recheck exam, sedation, and radiographs. If patients return for the 6 month recheck radiographs as prescribed, the costs of the implants will be partially rebated by the company (Kyon Veterinary Surgical Products).

Confidentiality:
The data collected in the course of this study is confidential. In any publication or presentation of the study data, we will not include information that would make it possible to identify a research participant. Research records will be kept in a

secure location; only researchers will have access to the records. Study data will be made accessible to the sponsoring company (Kyon Veterinary Surgical Products), but no personal information will be shared.

Statement of Consent:
In giving my consent by signing this form, I acknowledge that I have been informed of the purpose and nature of this study and its associated procedures, as well as any possible side effects.

I have read and understood the above information. I have been given the opportunity to ask questions and receive answers, and I consent to participate in the study. I further certify that I am the owner (or duly authorized agent of the owner) of _____ .
(Animal's name)

Owner or Agent Signature: _____ Date: _____

Attending Clinician Signature: _____ Date: _____

Please don't hesitate to contact us if you have any questions or concerns about this study.
The research and procedures have been reviewed and approved by the Virginia Tech Institutional Animal Care and Use Committee and the Virginia-Maryland College of Veterinary Medicine Veterinary Teaching Hospital Board.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researchers, please contact:

Hospital Director,
Veterinary Teaching Hospital
Virginia-Maryland College of Veterinary Medicine
Address: 245 Duck Pond Dr., Blacksburg, Virginia 24061-0443
Phone: 540-231-4621

You will be given a copy of this form to keep for your records.