Clinical Research Project
Client Consent Form

Study Title: Minimally Invasive Mitral Valve Repair in Dogs
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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:
To establish the long-term effects of a procedure to repair the mitral valve in dogs with naturally occurring, advanced chronic valvular degeneration using a minimally-invasive surgical approach.

Study Design/Procedures:
Dogs will undergo echocardiography, thoracic radiographs, ECG, complete blood count and blood chemistry the day before the procedure to confirm eligibility for the study. Eligible dogs will be anesthetized and the investigational biomedical device will be introduced into the heart in order to repair the mitral valve. Dogs will be hospitalized for the initial post-procedural recovery period. Echocardiographic rechecks will be performed to assess function of the mitral valve after the repair. The study has a total duration of 24 months from the time of enrollment. Your dog will be re-assessed every three months for two years following the procedure. The aims of the procedure are: to reduce the amount of mitral regurgitation present, to alleviate clinical signs, and potentially, increase life expectancy and quality of life.

Risks and Benefits:
This procedure is investigational, and is proposed as an alternative to conventional medical symptomatic treatment. The procedure is associated with risks of minor complications (e.g. transient cardiac rhythm abnormalities, mild mitral valve stenosis) and major complications (e.g. device failure, perforation of the heart, and bleeding related to administration of anticoagulants) that could lead to death. Your dog will be monitored by expert personnel for the entire duration of the procedure and will be discharged from the hospital only when judged to be fully recovered from the procedure. The owner will continue administration of one or more medications as prescribed by the investigators.

Study Costs and Compensation:
Enrolled dogs will receive, at no cost to the owner, a physical examination/office visit, blood work, thoracic radiographs, complete echocardiographic examination, the repair procedure and post procedure hospitalization. Cardiac rechecks at 3, 7, 15, 30 and 60 days post procedure are also included at no cost. The costs of an initial screening exam may be waived for patients that are likely to be eligible.

Confidentiality:
The data collected in the course of this study are 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 and the sponsor of the study project will have access to the records and study data.

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)
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.