

Cayenne Medical AperFix(R) System Shows Successful Outcomes For PCL Reconstruction

Clinical Study Reports Restoration of Knee Stability and Range of Motion at Six-Months

SCOTTSDALE, Ariz., April 8 /PRNewswire/ -- Cayenne Medical, Inc. (Cayenne), a privately held sports medicine device company, announced that a new independent clinical study published in the February 2010 issue of *Orthopedics* reports Cayenne's AperFix® System provides a safe, efficient and secure means of arthroscopic reconstruction of the posterior cruciate ligament (PCL) due to traumatic injury.

The AperFix System is a femoral and tibial fixation device originally designed for soft tissue anterior cruciate ligament (ACL) reconstruction. AperFix is proven to restore native knee kinematics through a simple, single incision, "all-inside" technique that allows the implant to be inserted transtibially, or anteromedially, through a single-tunnel, and eliminates the need to drill through the femoral cortex.

The study, titled "Arthroscopic PCL Reconstruction with a Novel All-Inside Femoral Fixation Device: A Single-Incision Technique," is authored by John W. Uribe, M.D. and Luis Vargas, M.D. of UHZ Sports Medicine Institute, Coral Gables, FL, and Brian M. Leo, M.D. of Cleveland Clinic Florida, Weston, FL.

"PCL reconstruction with the AperFix System is designed to alleviate the challenges some surgeons may experience with conventional BTB (bone-tendon-bone) allografts or soft tissue grafts utilizing cortical fixation techniques," said James W. Hart, President and CEO of Cayenne Medical. "This study not only highlights the flexibility of the system as a solution for multiple ligament reconstructions, it also shows the novel procedure provides superior fixation and knee stability for patients and ease-of-use for surgeons due to aperture fixation."

In the study, six active PCL injury patients successfully underwent PCL reconstruction surgery using the AperFix System. At six months, all patients achieved restored knee stability and full, symmetric range of motion, allowing them to return to their previous level of activity. Full recovery following PCL reconstruction surgery typically requires six to 12 months.(i)

Study authors concluded that the AperFix System's single-incision all-inside femoral fixation technique efficiently performs arthroscopic soft tissue PCL reconstruction. Authors cited benefits compared to traditional methods, which include reduced bone and soft tissue injury, eliminated

need for patient repositioning during surgery and a simplified passage of the allograft through the posterior aspect of the tibia.

The AperFix System originally received market clearance from the U.S. Food and Drug Administration (FDA) for soft tissue ACL reconstruction in 2007. In March 2009, AperFix Femoral and Tibial Implants received 510K clearance for extended indications, including a wide variety of tenodesis procedures such as PCL, MCL, LCL and MPFL reconstruction. AperFix implants are made of polyetheretherketone (PEEK™) and provide surgeons with aperture fixation, superior pullout strength and active, circumferential tendon compression.

About the Study

The study examined clinical outcomes of six active PCL reconstruction patients (mean age = 36 years) who underwent soft tissue PCL reconstruction using Cayenne's AperFix System single-incision all-inside approach, with an average length of time from injury to surgical reconstruction of 19.5 months. The indications for surgery were an acute PCL rupture diagnosed clinically and by magnetic resonance imaging (MRI). All arthroscopic procedures were performed by Dr. John W. Uribe of UHZ Sports Medicine Institute, Coral Gables, FL.

Patients were evaluated at six months (6 patients) and one year (3 patients) postoperatively. At six months all patients were pleased with their surgical outcome, had returned to their pre-injury level of activity and achieved full, symmetric range of motion. There were no complications resulting from the procedure.

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About Cayenne Medical, Inc.:

Based in Scottsdale, Arizona, Cayenne Medical is a privately held medical device company defining new technology for the soft tissue reconstruction segment of the sports medicine market. The company was founded in 2005 and is focused on leading the transformation of traditional ACL, PCL, and meniscal repair procedures, by applying advanced technology through minimally invasive techniques. For more information, go to www.cayennemedical.com.

(i) American Orthopaedic Society for Sports Medicine via <http://orthoinfo.aaos.org/topic.cfm?topic=a00420>

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