

**Continued Access PROTECT AF Post Approval Study Proposal – Acute Study**

<b>Title</b>	Continued Access PROTECT AF Post Approval Study
<b>Protocol Number</b>	██████████
<b>Sponsor</b>	Atritech, Inc. 3750 Annapolis Lane, Suite 105 Plymouth, MN 55447
<b>Device</b>	WATCHMAN Left Atrial Appendage Closure Technology WATCHMAN Device: 21mm, 24mm, 27mm, 30mm, 33mm ACCESS SYSTEM: Double, Single and Reverse Curve Transseptal Access Sheaths
<b>Study Rationale</b>	This study is an acute evaluation of the WATCHMAN device to further characterize implant related complications. Subjects will be followed for 45 days post device implant to collect data on procedural and device related complications. The results of the pivotal study concluded that procedure and device related events, such as pericardial effusion and device embolization, occur within the first month following implantation. These rates decreased over time based on procedural modifications and training enhancements implemented throughout the study. This acute evaluation will provide additional information on complications to demonstrate that lower rates will be sustained in a commercial use environment. The study will consist of subjects enrolled in the Continued Access PROTECT AF Registry Rev4, IDE #G020312, up to the time of market release of the WATCHMAN device, as well as prospectively enrolled subjects. Up to 300 subjects will be enrolled, implanted, and followed for 45 days.
<b>Study Design</b>	Non- randomized, open label, multi-center post market approval study for acute experience with the WATCHMAN LAA Closure Technology
<b>Primary Endpoint</b>	45-day serious procedure and device related adverse event free rate following successful WATCHMAN implantation
<b>Secondary Endpoints</b>	<ul style="list-style-type: none"> <li>• Device implant success, defined as successful delivery and release of the WATCHMAN implant into the LAA</li> <li>• Freedom from life-threatening events, to include device embolization requiring retrieval, pericardial effusion requiring drainage, cranial bleeding, gastrointestinal bleeds requiring transfusion and any bleeding related to the device or procedure that necessitates an operation</li> <li>• Other individual complication rates including, but not limited to MI, TIA, and death</li> </ul>
<b>Number of Centers</b>	Up to 40 centers may participate in the study; including up to 30 investigative centers worldwide who participated in the PROTECT AF trial, and 10 additional centers in the U.S. who do not have prior experience with the WATCHMAN device.

<b>Number of Subjects</b>	Up to 300 subjects will be implanted with the WATCHMAN device, with a minimum of 100 subjects enrolled in the 10 new (non-PROTECT AF) centers
<b>Study Scope</b>	<p>Approximately 90 subjects at 15 centers have been enrolled into the Continued Access PROTECT AF study to date. It is anticipated that about 20 subjects will be enrolled per month once all centers have completed requirements to initiate enrollment.</p> <p>Enrollment is expected to be completed by October 2010, and follow-up visit completion is anticipated by January 2011.</p> <p>It is expected that at least 90% of subjects will complete their participation through the 45 day follow-up visit.</p>
<b>Subject Population</b>	<p>Subjects enrolled in this acute post approval study will include those enrolled into the previous IDE version of the CAP Registry protocol and prospective subjects enrolled after market release of the device.</p> <p>The inclusion and exclusion criteria are in accordance with the current labeling of the WATCHMAN device.</p>
<b>Follow-up Schedule</b>	Implanted subjects will complete follow-up assessments and adverse event reporting through 45 days post implant.
<b>Analysis</b>	<p>Descriptive statistics for adverse event rates and other data will be presented. No formal hypothesis test will be performed.</p> <p>If the observed percentage of subjects experiencing a serious pericardial effusion is equal to that observed in the PROTECT AF trial (5%), the two-sided exact 95% confidence interval for this percentage based on 300 subjects would be 2.8% - 8.1%. This would provide reasonable characterization of the incidence of serious pericardial effusions, or other acute adverse events, in the post-approval study.</p> <p>New sites will enroll a minimum of 100 subjects. This will provide reasonable characterization of the incidence of serious pericardial effusions, or other acute adverse events, at new sites. For example, if the observed percentage of subjects experiencing a serious pericardial effusion at new sites is equal to that observed in the PROTECT AF trial (5%), the two-sided exact 95% confidence interval for this percentage based on 100 subjects would be 1.6% - 11.3%.</p>
<b>Post-Approval Reporting</b>	<p>Atritech will submit an Interim Post-Approval Study Status Report to FDA at 6 month intervals for the first 2 years of the study, or until the study is complete. The Final Post-Approval Study Status Report will be submitted to FDA within 3 months of collection of all study data.</p> <p>Reports will be submitted according to “Guidance for Industry and FDA staff: Procedures for Handling Post-Approval Studies Imposed by PMA Order”.</p> <p>Considering the expected enrollment projection, it is anticipated two Interim Reports will be necessary, and the Final Report may be completed by October 2010.</p>