

PROTECT AF Post Approval Study Proposal – Long Term Study

Title	WATCHMAN® Left Atrial Appendage System for Embolic PROTECTION in Patients with Atrial Fibrillation (PROTECT AF)
Protocol Number	[REDACTED]
Sponsor	Atritech, Inc 3750 Annapolis Lane, Suite 105 Plymouth, MN 55447
Device	WATCHMAN Left Atrial Appendage Closure Technology WATCHMAN Device: 21mm, 24mm, 27mm, 30mm, 33mm ACCESS SYSTEM: Double, Single and Reverse Curve Transseptal Access Sheaths
Study Rationale	To fulfill the post-market study requirement, the long-term safety and effectiveness of the WATCHMAN device will be further characterized by following the subjects successfully implanted in the PROTECT AF pivotal trial for 5 years. Development of a new post approval protocol is not warranted as the PROTECT AF protocol already requires a 5 year follow-up and subjects have provided consent for this term. Completion of the PROTECT AF protocol as designed will provide sufficient information on the long-term safety, efficacy and functionality of the device. This plan represents the least burdensome approach to collecting long-term device data. As described in Attachment 2, we will also conduct an acute safety study in a cohort of 300 separate patients to characterize procedural and device related complications.
PROTECT AF Study Design	Multicenter, prospective randomized study stratified by center, with 2 patients randomized to the WATCHMAN group for each control patient, descriptively comparing the WATCHMAN device to long-term Warfarin therapy. Only subjects successfully implanted with the WATCHMAN device will participate in study post approval of the device.
PROTECT AF Primary Endpoints	Primary Effectiveness: All stroke (including ischemic and hemorrhagic), cardiovascular death (limited to any cardiovascular and unexplained), and systemic embolism. Primary Safety: Life-threatening events as determined by the Clinical Events Committee which would include events such as device embolization requiring retrieval and bleeding events e.g., pericardial effusion requiring drainage, cranial bleeding events due to any source, gastrointestinal bleeds requiring transfusion, and any bleeding related to the device or procedure that necessitates an operation.
Study Scope	Up to 60 centers in the U.S. and Europe which have successfully implanted subjects will continue to participate in the study after market approval of the WATCHMAN device. Up to 485 subjects who were successfully implanted with the WATCHMAN device in the PROTECT AF study will be followed per protocol through 5 years post implant. Enrollment into the PROTECT AF study concluded June 2008. It is expected that follow-up will continue until July 2013.

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Follow-up Schedule	Implanted subjects will complete follow-up assessments and adverse event reporting through 5 years post implant.
Post-Approval Reporting	Reports will be submitted according to “Guidance for Industry and FDA staff: Procedures for Handling Post-Approval Studies Imposed by PMA Order”. Atritech will submit an Interim Post-Approval Study Status Report to FDA at 6 month intervals for the first 2 years after market approval of the device, and annually thereafter until the post approval study is complete. The Final Post-Approval Study Status Report will be submitted to FDA within 3 months of collection of all study data. The Final Report is anticipated for completion October 2013.