

TITLE: Protocol for a Prospective Multi-site Registry of Real-world Experience of Catheter Ablation for the Treatment of Symptomatic Paroxysmal and Persistent Atrial Fibrillation: REAL AF

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Tables for Supplement:

Supplement I:

Inclusion Criteria
Symptomatic PAF or PsAF deemed to be candidates for ablation by the treating physician
18 years of age or older
De Novo ablation procedure unless it is a repeat for a patient whose index procedure is also in the registry
Able and willing to participate in baseline and follow up evaluations for the full length of the registry
Willing and able to provide informed consent, if applicable

Exclusion Criteria
Enrolled in an investigational drug or device clinical trial, or any trial that dictates the treatment plan
Long-standing persistent AF (AF greater than one year's duration)
Having a repeat ablation, unless the subject's index ablation procedure is also included in the registry
In the opinion of the investigator, any known contraindication to an ablation procedure

Supplement II- Definitions of Adverse Events

Reportable Event	Criteria/ Definitions
Atrioesophageal Fistula:	Documentation in the medical record of esophageal erosion combined with evidence of a fistulous connection to the atrium, such as air emboli, an embolic event, or direct observation at the time of surgical repair.
Bleeding	Within the first 72 hours post procedure and requires and/or is treated with transfusion or results in a 20% or greater fall in hematocrit or a 2 gram or greater fall in hemoglobin.
Cardiac Perforation/Tamponade:	Pericardial effusion during or within 30 days of undergoing the AF ablation procedure resulting in hemodynamic compromise, elective or urgent pericardiocentesis, or results in a 1 cm or more pericardial effusion as documented by echocardiography.
Esophageal Injury:	An erosion, ulceration, or perforation of the esophagus
Pericarditis:	Report as AE if it leads to hemodynamic compromise or requires pericardiocentesis, prolongs hospitalization by more than 48 hours, requires hospitalization, or persists for more than 30 days and/or requires escalation of treatment following the ablation procedure.
Phrenic Nerve Injury/Paralysis:	Absent phrenic nerve function confirmed by appropriate diagnostic testing.
Pulmonary Vein Stenosis:	Reduction of the diameter of a PV or PV branch and further categorized as mild <50%, moderate 50-70% and severe > 70%.

Stroke or TIA:

Transient Ischemic Attack: new focal neurological deficit with rapid symptom resolution within 24 hours and no new evidence of injury on neuroimaging

Stroke: Rapid onset neurologic signs/ symptoms consistent with stroke with duration lasting > 24 hours or < 24 hours with therapeutic intervention, or neuroimaging showing a new hemorrhage or infarct or other neurologic deficit resulting in death. No identifiable alternative non-stroke explanation. Confirmation must be obtained by either a neurology/ neurosurgical specialist, neuroimaging procedure, or lumbar puncture.

Vagal Nerve Injury:

Vagus nerve injury resulting in esophageal dysmotility or gastroparesis with ongoing symptoms for more than 30 days following the ablation procedure, need for hospitalization, or prolongation of a hospitalization.

Vascular Access Complication:

Includes a hematoma, AV Fistula or pseudoaneurysm that requires intervention (i.e thrombin injection, evacuation or surgical repair or transfusion)

Death from causes not listed above and occurring prior to the 12- month follow up

e.g.. cancer, accident, myocardial infarction

Other:

Any other event the investigator considered serious and related to the ablation procedure.
