APPENDIX 1: INCLUSION/EXCLUSION CRITERIA

Study population	Subjects with unruptured or ruptured (> 30 days since occurrence), wide-necked (neck ≥ 4 mm or dome to neck ratio < 2) intracranial, saccular aneurysms (≥ 4 mm and < 20 mm maximum diameter in any plane) arising from a parent vessel with a diameter ≥ 2.0 mm and ≤ 4.5 mm who are candidates for endovascular coil embolization were consented.
Inclusion Criteria:	Subjects for this study must meet ALL of the following criteria: • Subject whose age is ≥18 and ≤75 years; • Subject with an unruptured or ruptured (> 30 days since occurrence), wide-necked (neck ≥ 4 mm or dome to neck ratio < 2) intracranial, saccular aneurysms (≥ 4 mm and < 20 mm maximum diameter in any plane) arising from a parent vessel with a diameter ≥ 2.0 mm and ≤ 4.5 mm who are candidates for endovascular coil embolization; • Subject or his/her Legally Authorized Representative understands the nature of the procedure, consents to participation in the study and provides a signed informed consent form; • Subject (woman of child-bearing potential) with a current negative pregnancy test who has agreed to an appropriate method of contraception throughout the trial; • Subject lives at a permanent address within commuting range of the investigational site and will be residing at that address during their 12 months of study participation; • Subject is willing to return to the investigational site for the 30-day, 6-month and 12-month follow-up evaluations.

Exclusion Criteria:

Subjects shall be excluded from the study if ANY of the following conditions exist:

- Subject who presents with ruptured aneurysm, unless rupture occurred 30 days or more prior to screening;
- Subject who presents with an intracranial mass (other than a meningioma) or currently undergoing radiation therapy for carcinoma or sarcoma of the head or neck region;
- Subject with significant extracranial or intracranial stenosis of the parent artery (>50%) proximal to the target aneurysm;
- Subject with an irreversible bleeding disorder, a platelet count of less than 100,000/ml (<100x103 cells/mm3) or known platelet dysfunction or a contraindication to or inability to tolerate anticoagulants and/or antiplatelet agents;
- Subject with serum creatinine level > 3.0 mg/dL at time of enrollment (this will restrict the use of contrast) and not on dialysis;
- Subject with known allergies to nickel-titanium metal; jewelries
- Subject with known allergies or contraindications to required antiplatelet and/or heparin medications required for treatment;
- Subject with a life-threatening allergy to radiographic contrast (unless treatment for allergy is tolerated or can be managed medically);
- Subject with a contraindication to CT (Computed Tomography) and MRI (Magnetic Resonant Imaging);
- Subject who has a known cardiac disorder, likely to be associated with cardioembolic symptoms such as AFIB (atrial fibrillation);
- Subject with any condition which in the opinion of the treating physician would place the Subject at a high risk of embolic stroke;
- Subject who is currently participating in another clinical research study with a conflicting protocol;
- Subject who has had a previous intracranial stenting procedure associated with the target aneurysm;
- Subject who is unable to complete the required follow-up;
- Subject who is pregnant or breastfeeding;
- Subject who has participated in a drug study within the last 30 days.

Subjects who are enrolled in the study but subsequently meet the exclusion criteria above will not be treated with the LVIS Device and will be considered enrolled but not treated. These Subjects will be replaced with another subject for the purposes of this study and will not be counted towards the ITT population or included in the data for the analysis of protocol endpoints.

Angiographic Exclusion Criteria

- Subject has a cerebral diagnostic angiogram that demonstrates an aneurysm that is not appropriate for endovascular treatment;
- Subject has a fusiform or dissecting aneurysm;
- Subject is harboring more than one aneurysm with each aneurysm requiring treatment within 30 days;

Subject has an arteriovenous malformation (AVM) in the territory of the target aneurysm.

APPENDIX 2: Pivotal US LVIS Trial Investigators

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