

Ancure, LLC

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Technology

Indication: Intracranial cerebral aneurysms (ICA) are arterial saccular dilatations in which a weakening of a major blood vessel in the brain is susceptible to rupture. The incidence of these lesions in human autopsy studies is ~5%. Most aneurysms are asymptomatic because of the low rupture rate of 1%. However, the mortality rate after rupture is very high (30-60%). **Standard of Care:** Current treatment options for both ruptured and unruptured aneurysms include surgical clipping (exovascular therapy) and catheter-based intervention (endovascular therapy). The latter often includes the placement of foreign materials (e.g. platinum coils) into the aneurysm. **Current Challenges:** The primary mechanisms for recurrence in endovascular coiling procedures are recanalization of the clot (via enzymatic digestion) and mechanical compaction of coils within the sac (due to blood flow). Enzymatic remodeling of the newly formed clot, via fibrinolytic and thrombolytic pathways, reduces the mechanical integrity of the protein network. The weakened clot is susceptible to mechanical compaction, recanalization, and recurrence. **Innovation:** Ancure, LLC proposes to deliver a bioactive agent locally within the aneurysm sac that will induce additional covalent crosslinking to stabilize the nascent clot and then (Fig. 1).

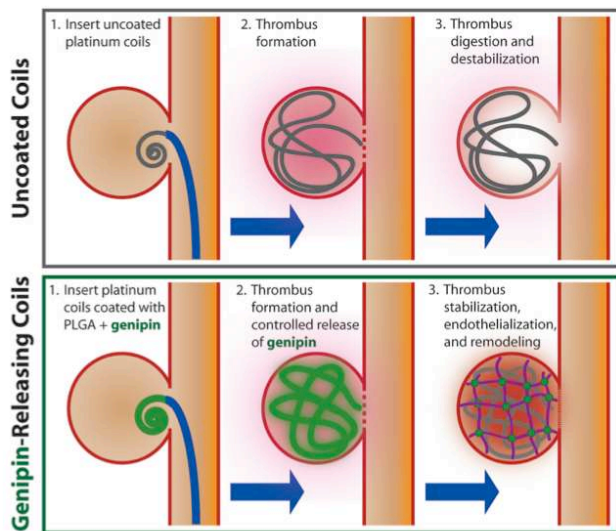


Fig. 1. Controlled release of genipin from platinum coils within intracranial aneurysms to stabilize nascent clots, prevent remodeling/digestion, and reduce the rate of recurrence.

Market

The Pt coil embolization market is >\$500MM in the US and is growing at 20% YoY (Fig. 2). Coatings attempt to increase the filling fraction (e.g. HydroCoil, Microvention Therapeutics) or induce a more robust clotting response (e.g. Cerecyte™, Trufill™, Axiom™,

Codman). Many coating strategies may improve the initial stability of clots in vivo. However, the long-term stability of these clots could be improved[81]. Furthermore, amplified clotting cascades can lead to complications. Endovascular coils with bioactive coatings are widely accepted as effective approaches for improved outcomes via embolization. However, there is a fundamental limitation to the current strategies. Ancure, LLC is well-positioned to build on the widespread clinical adoption of coated-coil technologies. Additionally, the innovative genipin-releasing coils will address mechanisms that lead to recanalization.



Fig. 2. Platinum embolization coils are an expanding market in the treatment of intracranial aneurysms.

Commercialization Strategy

We anticipate that the regulatory approval process will be expedited due to several strategic design considerations for genipin-releasing coated Pt coils. **Translation Strategy:** The proposed treatment strategy is compatible with standardized surgical procedures and uses materials and biologics of known risk. The biocompatibility profiles of PLGA are well characterized. Furthermore, genipin is a cost-effective (<\$100/g) and naturally occurring biologic that PLGA matrices (GRAS material) and naturally occurring biologic will expedite clinical translation. **Regulatory:** This product could potentially be classified as a Class II device that can be approved under the 510(k) mechanism. The predicate device in this scenario will be MatrixCoil™, a PLGA-coated Pt that was studied in human trials. **Reimbursement:** This transformative approach could increase the rate of successful outcomes in endovascular coiling procedures for treating ICAs. There is a clear path for reimbursement for this technology. Pt@PLGA+Gen will reduce costs associated with CPT code 437.3, a code assigned to procedures that diagnose and treat subarachnoid hemorrhages (CPT code 430) via aneurysm. Specifically, this technology will reduce the cost associated with revision surgeries, which are also associated with CPT code 437.3.