SUPPLEMENTAL MATERIAL

Shape memory polymer technology in peripheral vascular embolization

Study inclusion criteria:

1. Study participant is ≥18 years of age and ≤75 years of age;
2. Study participant is considered a candidate for arterial or venous embolization of the peripheral vasculature;
3. Study participant has a target vessel >2 mm and <9 mm in diameter, measured during angiographic imaging.

Study exclusion criteria:

1. Study participant has an inability to provide written informed consent;
2. Study participant is unable or unwilling to fulfill the study protocol follow-up requirements;
3. Study participant has known significant vascular disease that will prohibit safe femoral artery/vein access and access to the target vessel(s);
4. Study participant has inappropriate anatomy of the vasculature for the safe access and/or the deployment of the investigational product, including, but not limited to, inappropriate sizing, significant tortuosity, insufficient landing zone to deploy the investigational product, determined by any pre-procedural imaging;
5. Study participant has a target vessel diameter outside the recommended diameter range of the investigational product, measured during any pre-procedural imaging;
6. Study participant has known hypersensitivity or contraindication to nickel or nitinol;
7. Study participant has a condition that inhibits radiographic visualization during the implantation procedure;
8. Study participant has a history of allergy to contrast medium that cannot be managed medically;
9. Study participant has an uncontrolled co-morbid medical condition, including mental health issues, that would adversely affect participation in the study;
10. Study participant is pregnant or a lactating female. For females of child-bearing potential, a positive pregnancy test within 7 days of the day of procedure or refusal to use a medically accepted method of birth control for the duration of the study;
11. Study participant is enrolled in a concurrent clinical study of a study device or drug that has not yet reached its primary endpoint;
12. Study participant is a prisoner or member of other vulnerable population.

Supplementary Figure. Left testicular vein embolization. Right internal jugular vein and renal vein approach. (a) Diagnostic venogram with pelvic compression illustrating venous incompetence and dilation. (b) Deployment of the anchor coil of the device, where the radiolucent shape memory polymer (white arrow) and proximal marker (black arrow) are still in the catheter. (c) Post unsheathing of the shape memory polymer into the vessel. (d) Completion venogram illustrating complete occlusion and stasis of contrast in the vein above the device.