Cleveland Clinic Innovations

False Lumen Occluder (FLO) Device

Eric Roselli, MD

PRODUCT

False Lumen Occluder (FLO) Device for Treating Aortic Dissections

INDICATION

Cardiology, Endovascular procedure, Aortic dissection, Marfan Syndrome, Bicuspid aortic valve

VALUE PROPOSITION

- Designed to match the diseased anatomy.
- FLO's crescent shape permits plugging of residual leaks.
- Enables more widespread treatment of aortic dissection.

DEVELOPMENT STAGE

- Prototype available
- Active business development

INTELLECTUAL PROPERTY

US Patent: 10,524,800

CONTACT INFORMATION

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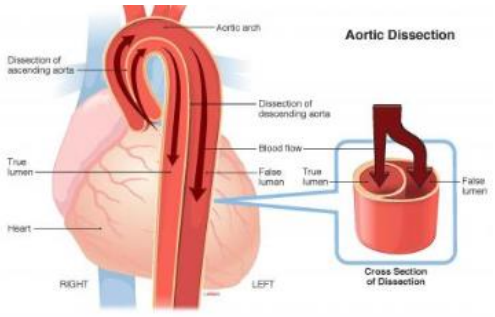
IDF:2015-029

UNMET NEED

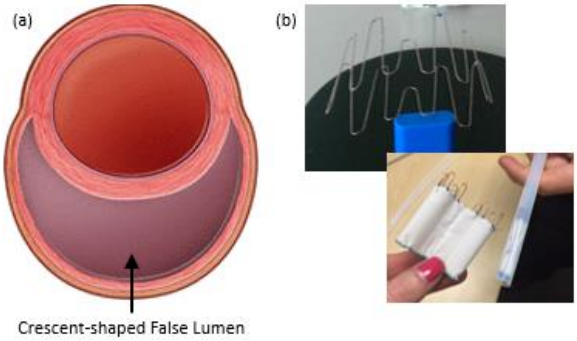
Aortic dissection is caused when the aorta tears, causing the layers of the aorta to separate. As the layers of the aorta separate, blood flows into a new space, creating what is known as a "false lumen" (FL) which can lead to life-threatening events: (i) the FL can develop into an aneurysm that can rupture, or (ii) the FL can compress the regular opening of the aorta ("true lumen") causing decreased blood flow to organs. In acute aortic dissection cases, the mortality rate is ~50% if left untreated for 24 hours. Even after intervention, distal tears do not heal, leading to poor long-term prognoses due to the continued risk for aortic rupture and need for further intervention. Patients with high blood pressure and existing aneurysms are most at risk for developing aortic dissections. Additional risk factors include connective tissue diseases (such as Marfan Syndrome), genetic conditions (such as bicuspid aortic valve), and traumatic injury. It is estimated that 13,000 cases of aortic dissection occur annually in the U.S., but this under-estimates the true incidence, as many patients die before hospital admission.

SOLUTION

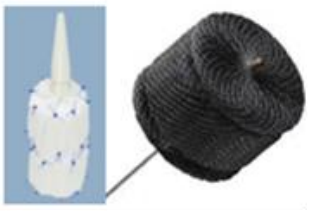
The FLO device is based on clinical measurements, using CT images of diseased anatomy to understand the geometry of the false lumen. Made from Nitinol and containing a graft coating, the crescent shaped frame opposes the false lumen, conforms to its surroundings, and plugs any residual leaks. The FLO device can be compressed and delivered via a transcatheter approach. Unlike current off-label devices that are used to treat aortic dissection, which are round and/or too small and make occlusion difficult, this device would provide physicians with a tool that is specific to this disease for a population that is at serious risk.



Depiction of Aortic Dissection



(a) Crescent shape of the false lumen
(b) Cleveland Clinic Invention: Frame design and graft coating of prototype



Currently used off-label devices