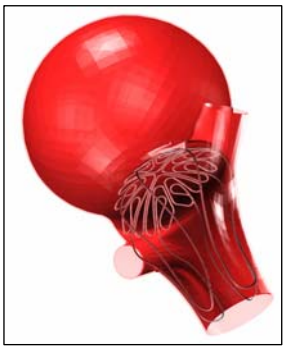
Spherical Cerebral Aneurysm Devices (Sphere)



The MINT team is developing a revolutionary set of flow diverting devices to treat complex cerebral aneurysms, allowing clinicians to offer minimally invasive treatment options to patients who would otherwise require high-risk open surgical procedures.

The Unmet Clinical Need

Each year, approximately 30,000 people in the US suffer from ruptured brain aneurysms and the significant mortality and morbidity associated with this condition. In many more instances, aneurysms may be diagnosed before they rupture and treated with open brain surgery or endovascular interventions, such as placing a stent or coil to prevent aneurysm rupture. Despite recent advances in stent and coil technology, current endovascular devices inadequately treat several cerebral aneurysm types, particularly aneurysms located at vessel bifurcations and aneurysms with wide necks. Clinicians require devices specifically designed to treat these challenging aneurysms.

MINT'S Solution

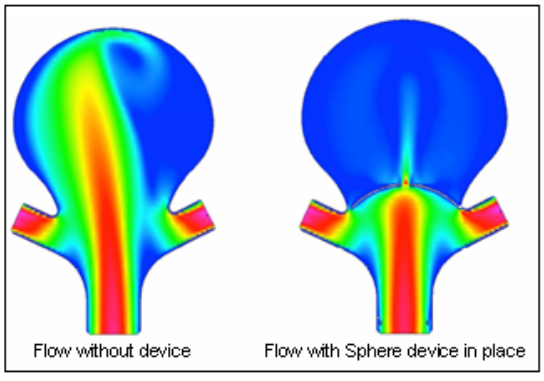
Sphere is a family of spherical-shaped blood flow diverters that significantly decrease the amount of blood entering an aneurysm, allowing the aneurysm to thrombose and heal. Ideally suited to bifurcation and wide-neck aneurysms, Sphere self-seats within blood vessels adjacent to target aneurysms.

The single wire legs anchor Sphere in the blood vessel and allow blood to continue flowing down stream, while the dense face of Sphere is positioned across the aneurysm neck to redirect flow away from the aneurysm. Unlike coils, Sphere is deployed in the blood vessel rather than in the delicate aneurysm dome itself, reducing the risk of rupturing the delicate dome.

Sphere is comprised of a single wire loop, which clinicians can stretch into a catheter and deploy using standard endovascular techniques. When released at the aneurysm site, the device regains its spherical shape and can be precisely positioned against the aneurysm neck to ensure optimal treatment. Sphere can be manufactured in different shapes (ellipsoid vs. sphere, etc.), and with differing face densities to optimize treatment for different types of aneurysms (including side wall aneurysms) and in other locations in the body.

Project Status

Sphere has successfully completed Proof of Concept studies in vitro, demonstrating deployment, precise positioning, and the ability to maintain position in an arterial model when exposed to blood flow simulation.



Extensive Computational Fluid Dynamics (CFD) studies have revealed that Sphere sufficiently reduces aneurysm blood flow to enable thrombosis and healing. These CFD studies are the first step in a comprehensive "virtual clinical trial" where we will test Sphere's ability to treat a series MRI-derived aneurysm models. In parallel, preliminary in vivo experiments will be conducted in the near future. New, alternative device designs are underway to further optimize delivery of the Sphere device as is a novel manufacturing process to cost-effectively produce Sphere for clinical use.

Intellectual Property

MINT has filed 34 patent applications for Sphere in the United States and internationally