

The Artisse™ Intracranial Device is Indicated for the Treatment of Wide-neck Bifurcating Intracranial Aneurysms (IAs).

NCT02998229

Status	RECRUITING
Phase	Not Applicable
Sponsor	Medtronic Neurovascular Clinical Affairs
Enrollment	300 participants

Key Eligibility Criteria

Inclusion (14)

- Subject or subject's Legally Authorized Representative (LAR) has provided written informed consent using the Institutional Review Board/Ethics Committee (IRB/EC) approved Informed Consent Form (ICF). Health Insurance Portability and Accountability Act (HIPAA)/data protection authorization has been provided and signed by the subject or subject's LAR.
- Subject is 18-75 years of age at the time of consent.
- Subject has a single unruptured or ruptured IA requiring treatment. If the patient has an additional IA, the additional IA must not be deemed to require treatment within 1-year of the index procedure.
- The target aneurysm must have the following characteristics:
- Saccular morphology
- ... and 9 more (see full listing online)

Exclusion (13)

- During treatment planning, it is determined that subject may need an adjunctive implant device in addition to the Artisse™ Intracranial Device. (Subjects who need unplanned adjunctive implant devices are not excluded.)
- Subject's target aneurysm was previously treated with other devices/implants (e.g., coils) or parent artery has a stent or other obstruction that could interfere with the correct placement of the Artisse™ Intracranial Device.
- Subject has a known active systemic bacterial infection.
- Subject has anatomy or physiology considered unsuitable (e.g., vessel anomaly or disease) for endovascular treatment with the Artisse™ Intracranial Device by the treating physician.
- Subject has a mRS score ≥ 2 (i.e., mRS scores of 3 to 5) prior to procedure (in case of unruptured IA) or prior to rupture (in case of ruptured IA).
- ... and 8 more (see full listing online)

Locations (19 total)

Yale New Haven Hospital, New Haven, Connecticut, United States
Baptist Medical Center Jacksonville, Jacksonville, Florida, United States
Tampa General Hospital, Tampa, Florida, United States
... and 16 more locations

<https://clinicaltrials.gov/study/NCT02998229>

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