

KURZPROTOKOLL
PROTECTED TAVR

Öffentlicher Titel	Studie zu Sentinel bei Transkatheter-Aortenklappenersatz
Wissenschaftl. Titel	PROTECTED TAVR: Stroke PROTECTION with SEntinel During Transcatheter Aortic Valve Replacement
Kurztitel	PROTECTED TAVR
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, zweiarmig
Studienphase	nicht zutreffend
Erkrankung	Herz und Kreislauf: Schlaganfall / Hirninfarkt
Einschlusskriterien	- Subject has documented aortic valve stenosis and is treated with an approved TAVR device via transfemoral access - Subject has the recommended artery diameter at the site of filter placement per the Sentinel® Cerebral Protection System Instructions For Use: 9-15 mm for the brachiocephalic artery and 6.5-10 mm in the left common carotid artery - Subject (or legal representative) provides written informed consent
Ausschlusskriterien	- Subject has arterial stenosis >70% in either the left common carotid artery or the brachiocephalic artery - Subject's brachiocephalic or left carotid artery reveals significant stenosis, ectasia, dissection, or aneurysm at the aortic ostium or within 3 cm of the aortic ostium - Subject has compromised blood flow to the right upper extremity - Subject has access vessels with excessive tortuosity - Subject has uncorrected bleeding disorders - Subject is contraindicated for anticoagulant and antiplatelet therapy
Alter	Keine Altersbegrenzung
Sponsor	Boston Scientific Corporation
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT04149535 (primäres Register)