KURZPROTOKOLL
CONFIDENCE

Öffentlicher Titel	Register zu Herzklappenimplantation
Wissenschaftl. Titel	CONtrolled delivery For ImproveD outcomEs with cliNiCal Evidence
Kurztitel	CONFIDENCE
Studienart	multizentrisch, prospektiv, offen/unverblindet, einarmig, Pharma-Studie
Studienphase	nicht zutreffend
Erkrankung	Herz und Kreislauf: Herzklappenstenose
Einschlusskriterien	- Subjects who are >18 years of age or legal age in host country and have been identified as a candidate for a Portico™ valve implant - Subjects who have been informed of the nature of the study, agree to its provisions and have provided written informed consent as approved by the Ethics Committee (EC) of the respective clinical center
Ausschlusskriterien	- Candidates will be excluded if any of the following conditions are present: - Have sepsis, including active endocarditis - Have any evidence of left ventricular or atrial thrombus - Have vascular conditions (i.e. caliber, stenosis, tortuosity, or severe calcification) that make insertion and endovascular access to the aortic valve improbable - Have a non-calcified aortic annulus - Have congenital bicuspid or unicuspid leaflet configuration - Are unable to tolerate antiplatelet/anticoagulant therapy - Are pregnant at the time of signing informed consent - Are currently participating in a drug or device study that may impact the registry (unless prior sponsor approval for co-enrollment is granted)
Alter	18 - 100 Jahre
Sponsor	Abbott
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03752866 (primäres Register)