KURZPROTOKOLL
JenaValve AR German

Öffentlicher Titel	Untersuchung des transfemoralen JenaValve-Perikard-TAVR-Systems bei symptomatischer schwerer Aorteninsuffizienz
Wissenschaftl. Titel	JenaValve AR German Study: An Feasibility Study to Assess Safety and Effiacy of the Transapical and Transfemoral JenaValve Pericardial TAVR System in the Treatment of Patients with Symptomatic Severe Aortic Regurgitation
Kurztitel	JenaValve AR German
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig, Pharma-Studie
Studienphase	nicht zutreffend
Erkrankung	Herz und Kreislauf: Herzklappeninsuffizienz
Einschlusskriterien	- Patient with severe aortic regurgitation (AR) - Patient at high risk for open surgical valve replacement - Patient symptomatic according to NYHA functional class II or higher - The study patient has been informed of the nature of the study, agrees to its provisions and has provided written informed consent as approved by the Institutional Review Board (IRB)/ Ethics Committee (EC) of the respective clinical site
Ausschlusskriterien	- Congenital uni or bicuspid aortic valve morphology - Previous prosthetic aortic valve (bioprosthesis or mechanical) implant - Endocarditis or other active infection - Need for urgent or emergent TAVR procedure for any reason - Cardiogenic shock or hemodynamic instability requiring inotropic support or ventricular assist device - Severe mitral regurgitation
Alter	18 Jahre und älter
Sponsor	Jena Valve Technology GmbH
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02732704