KURZPROTOKOLL
Cardioplexol

Öffentlicher Titel	Beobachtungsstudie zu einer Anwendungsschulung einer cardioplegischen Lösung
Wissenschaftl. Titel	Eine multizentrische, offene Beobachtungsstudie mit einer Behandlungsgruppe zur Untersuchung der Auswirkungen einer Schulung zur Anwendung der cardioplegischen Lösung Cardioplexol
Kurztitel	Cardioplexol
Studienart	multizentrisch, prospektiv, einarmig, Pharma-Studie, einfach verblindet
Studienphase	Phase III
Erkrankung	Herz und Kreislauf: Herzklappenstenose Gefäße: Artherienverkalkung (Atherosklerose)
Einschlusskriterien	- Male or female patients between 18 and 80 years of age - The patient's preoperative evaluation indicates the need for a primary elective cardiac coronary artery bypass graft (CABG) operation and/or a cardiac valve repair/replacement - The operation will be carried out via a full or a hemi sternotomy, under cardiac arrest and under the assistance of a heart lung machine - Patients who provide signed written informed consent
Ausschlusskriterien	- Pre-operative EF of less than 30% - Pre-operative IABP - Pre-operative catecholamine support - History of myocardial infarction within less than 7 days - Previous history of cardiac surgery, including the implantation of a pace maker or an ICD - Active myocarditis and/or endocarditis - Aortic valve insufficiency severity grade > 1 - Under dialysis - Pre-operative serum creatinine value of more than 2.0 mg/dl - Known hematologic disorder - Previous therapeutic treatment with anti-vitamin K within 5 days before surgery, or with thrombin inhibitors or factor Xa Inhibitors within 3 days before surgery - History of HIT - Participating in a concomitant research study of an investigational product - Pregnant or lactating - Intravenous drug user, alcohol abuser, prisoner, institutionalized, or is unable to give informed consent
Alter	18 - 80 Jahre
Sponsor	Swiss Cardio Technoligies AG
Registrierung in anderen Studienregistern	EudraCT 2018-002311-10