




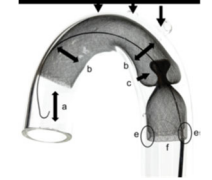

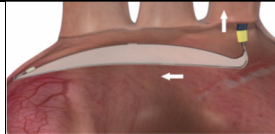
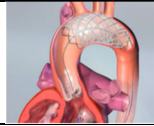







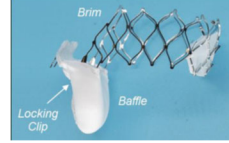
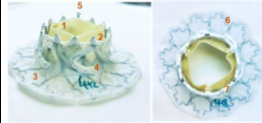
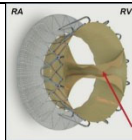
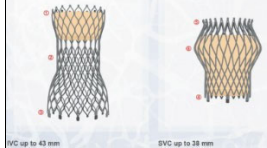







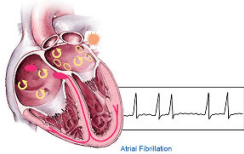









## Ongoing Clinical Trials

Trial Name	Valve Disease	Company	Purpose	Device Description	Image	Leadership
<i>Aortic Valve Disease</i>						
ACURATE NEO & PRIME	Aortic Stenosis	Boston Scientific	Transcatheter Aortic Valve Replacement in Low and Intermediate Risk Patients	Transfemoral TAVR		Site PI: Isaac George, Tamim Nazif
ALIGN AR	Aortic Regurgitation	JenaValve	Transcatheter Aortic valve replacement in high risk patients	Transfemoral TAVR that captures leaflets		National Co-PI: Torsten Vahl  Site PI: Isaac George, Susheel Kodali
ALLIANCE & ALLIANCE AVIV	Aortic Stenosis	Edwards Lifesciences	Transcatheter Aortic Valve Replacement for in all risk patients	Transfemoral TAVR using the Sapien X4 System		National Co-PI: Tamim Nazif  Site PI: Tamim Nazif, Isaac George
COMPLETE	Aortic Stenosis and Coronary Disease	Independent Funding	Transcatheter Aortic Valve Replacement and PCI in patients with AS and Coronary disease	Transfemoral TAVR+PCI of all lesions		Site PI: Vivian Ng
DURA AVR	Aortic Stenosis	Anteris Technologies Ltd.	Transcatheter Aortic Valve Replacement for in all risk patients	Transfemoral TAVR using the DurAVR THV system		Site PI: Isaac George
PROTECT-H2H	Aortic Stenosis	Emboline	Embolic Protection during Transcatheter Aortic Valve Replacement	Emboliner CEPD device		Site PI: Tamim Nazif

PROTEMBO	Aortic Stenosis	Protembis	Embolic Protection during Transcatheter Aortic Valve Replacement			National Co-PI: Susheel Kodali Site PI: Torsten Vahl
ENCOMPASS F2	Aortic Stenosis	EnCompass Technologies	Embolic Protection during Transcatheter Aortic Valve Replacement			Site PI: Vivian Ng
PATCH	Percutaneous catheter- based interventional procedures	Vivasure Medical	Vascular Closure Device Patients Undergoing Percutaneous Transcatheter Procedures			Site PI: Vivian Ng
Inspiris Resilia VIV	Bioprosthetic Aortic Valve Stenosis	Edwards Lifesciences	Transcatheter Aortic Valve-in-Valve Replacement After Surgical Aortic Valve Replacement	Transfemoral TAVR		Site PI: Hiroo Takayama
<b>Mitral Valve</b>						
PRIMARY	Degenerative Mitral Regurgitation	CTSN	Surgical MV Repair vs. Mitraclip	N/A		National Co-PI: Martin Leon Site PI: Isaac George
APOLLO-INTREPID	Mitral Regurgitation	Medtronic	Transcatheter Mitral valve Replacement in high risk surgical patients	Transapical catheter valve		National Co-PI: Martin Leon Site PI: Isaac George, Martin Leon
CORCINCH HFrEF	Heart Failure	Ancora	Left ventricular support system to prevent heart dilatation	Transcatheter approach with ventricular hooks and band		Site PI: Gabe Sayer
REPAIR-MR	Mitral Regurgitation in degenerative disease	Abbott	Transcatheter mitral valve repair vs surgery in intermediate risk patients	Transseptal approach using clip applied to both anterior and posterior mitral valve leaflets vs open surgical repair		Site PI: Isaac George, Susheel Kodali

CLASP IID/F: PASCAL	Mitral Regurgitation	Edwards Lifesciences	Transcatheter Mitral Valve Repair	Transseptal clip applied to both anterior and posterior leaflets independently		Site PI: Isaac George, Susheel Kodali
MITRAL II	Calcific mitral valve disease	Physician Led Mayo Clinic Hospital	Transcatheter in MAC in high surgical risk patients with symptomatic mitral valve disease.	Edwards SAPIEN 3 and SAPIEN 3 Ultra valves with Commander delivery system		Site PI: Susheel Kodali
HALF MOON	Mitral Regurgitation	Half Moon	Transcatheter Mitral valve Repair in high risk surgical patients			Site PI: Susheel Kodali
TWIST	Mitral Regurgitation	Innovalve Bio Medical Ltd.	Transcatheter Mitral valve Replacement in elevated (STS PROM risk calculator >6%) risk surgical patients			Site PI: Susheel Kodali Study Chairman: Martin Leon
<b>Tricuspid Valve</b>						
TRISOL	Tricuspid Regurgitation	Trisol	Transcatheter Tricuspid Valve Replacement	Bileaflet valve delivered from transcatheter transvenous route		National PI: Isaac George Site PI: Susheel Kodali
TRI VALVE	Tricuspid Regurgitation	P&F	Bicaval valves to prevent venous congestion in high-risk patients with severe TR	Transcatheter, one way valves in the SVC and IVC		Site PI: Isaac George, Susheel Kodali
CLASP TR- PASCAL	Tricuspid Regurgitation	Edwards Lifesciences	Transcatheter Tricuspid Valve Repair	Transcatheter approach to clip applied to tricuspid valve leaflets		National PI: Martin Leon Site PI: Susheel Kodali, Isaac George
TANDEM II	Tricuspid Regurgitation	CroValve Ltd.	Transcatheter Tricuspid valve Replacement in high risk surgical patients	Transcatheter Tricuspid Coaptation Valve System		Site PI: Susheel Kodali,

INTREPID	Tricuspid Regurgitation	Medtronic	Transcatheter Tricuspid valve Replacement in high risk surgical patients	Transcatheter Tricuspid Valve Replacement		Site PI: Isaac George, Susheel Kodali
<b><i>Surgical Trials</i></b>						
PRIMARY	Degenerative Mitral Regurgitation	CTSN	Surgical MV Repair vs. Mitraclip	N/A		National Co-PI: Martin Leon Site PI: Isaac George
GUARDIAN	Heart Preservation	Paragonix	Heart preservation device for adult and pediatric heart transplants. Registry.	SherpaPak Cardiac Transport System		Site PI: Koji Takeda
OHP Registry II	Heart Preservation/Perfusion	Transmedics	Heart preservation device for adult transplants, specifically pertaining to hearts outside of normal acceptance criteria.	Transmedics OCS (Organ Care System) Heart		Site PI: Koji Takeda
MOMENTIS	Mitral Regurgitation	Edwards Lifesciences	Surgical replacements of the mitral valve using bovine pericardial tissue valve.	MITRIS RESILIA Mitral Valve, Model 11400M		Site PI: Hiroo Takayama
PACeS	Post-operative Atrial Fibrillation	CTSN	OAC + Aspirin vs. Aspirin only in patients with new on-set post-operative atrial fibrillation.	N/A		Site PI: Michael Argenziano
ROMA (Women)	Coronary Artery Disease	Weill Cornell	Single Arterial Graft vs. Multiple Arterial Graft in women with significant coronary artery disease in two or more vessels.	N/A		Site PI: Koji Takeda

IMPACT	Severely reduced LV function	Abiomed	Peri-operative usage of Impella 5.5 in high-risk cardiac patients with low EF.	Impella 5.5 with SmartAssist System		Site PI: Yuji Kaku
PERSEVERE	Acute DeBakey Type I Aortic Dissection	Artivion	Insertion of AMDS device to treat patients with acute DeBakey Type I Dissection.	AMDS Hybrid Prosthesis		Site PI: Hiroo Takayama
COMMENCE	Aortic Regurgitation/ Mitral Regurgitation	Edwards Lifesciences	Replacement of Aortic or Mitral valve using the Edwards Pericardial Aortic Bioprosthesis or Edwards Pericardial Mitral Bioprosthesis	Edwards Pericardial Aortic Bioprosthesis or Edwards Pericardial Mitral Bioprosthesis		Site PI: Hiroo Takayama
RESILIENCE	Aortic Regurgitation	Edwards Lifesciences	Aortic Valve Replacement using Edwards Aortic bioprosthesis valve with RESILIA tissue.	INSPIRIS RESILIA Aortic Valve		Site PI: Hiroo Takayama
EMPRO	High-risk Valve Surgery	CTSN	Embolic protection during high-risk valve surgery. CardioGard Embolic Protection Cannula vs. standard aortic cannula.	CardioGard Embolic Protection Cannula		Site PI: Isaac George
XVIVO Heart PRESERVE	Heart Preservation	XVIVO Perfusion	Non-ischemic heart perfusion of extended criteria donor heart using the XVIVO Heart Preservation System.	XVIVO Heart Preservation System (XHPS)		Site PI: Koji Takeda