Interventional heart failure technologies in development

by technology type

Innovation booklet
Source: cvPipeline, April 2016

Monitoring Technologies

Company	Product	Technology	Description	Status
CardioLogic	pEI	External Monitor	A technology for non-invasive evaluation of lung fluid by assessing lung resistivity	FIM study underway OUS
Endotronix	PAP Monitor	Internal Monitor	Wireless, batteryless implanted biosensor that measures PAP; it is delivered to the artery via a minimally invasive catheterization procedure	U.S. Preclinicals underway, CE Mark approval submitted
Intersection Medical	IMED-4	External Monitor	A non-invasive monitoring technology to measure lung fluid status by assessing how wet or dry the lungs are	U.S. Clinical study underway
ISSYS	Titan	Internal Monitor	Wireless, battery-less implantable pressure sensor for monitoring intracardiac pressure; FIM was for use in adult cardiac surgery	U.S. preclinicals completed, FIM study underway OUS
RSMM	Edema Guard Monitor	External Monitor	A device that derives net lung impedance from measured transthoracic impedance	FIM study completed
Sensible Medical	ReDS	External Monitor	A vest worn by the patient for monitoring CHF by assessing lung water; measures dielectric properties of tissues; provides absolute rather than a relative measure of lung water density	510(k) cleared, CE Mark approval gained

Monitoring Technologies

Company	Product	Technology	Description	Status
St. Jude	CardioMEMS	Internal Monitor	Implantable, wireless, un-powered, permanently implantable pressure monitor; patient pressures are uploaded by telephone to the Internet, allowing patients to be treated remotely based on their pulmonary pressures	FDA approved, CE Mark approval submitted
toSense	CoVa	External Monitor	A necklace that serves as a sensor for at-home monitoring of fluid levels, respiration rate, heart rate, respiration rate, heart rate variability, stroke volume, cardiac output, single-lead ECG, and posture	U.S. clinical study underway
Vectorius	Vectorius Monitor	Internal Monitor	Micro-sized wireless sensor configured for measuring LVEDP directly	Preclinicals underway
Zoll	uCor	External Monitor	Non-invasive system using RF technology for remote monitoring of CHF patients; designed to accurately measure fluid trends in the thoracic region, along with other vital signs	U.S. Feasibility study underway, CE Mark approval gained
Zoll	uCor SubQ	Internal Monitor	Minimally invasive, fully implantable subcutaneous device for direct, accurate monitoring of thoracic fluid	Preclinicals underway

Neurostimulation Technologies

Company	Product	Technology	Description	Status
BioControl	CardioFit	Neurostim-ulation	Implantable stimulator with feedback control to target a pre-set heart rate; includes a vagus nerve stimulation lead	U.S. pivotal study terminated (due to futility for efficacy endpoint), CE Mark approval gained
Boston Scientific	Precision	Neurostim-ulation	Vagus nerve stimulation cuff electrode and neurostimulator for use in HF	OUS FIM study complete; program status unknown
Cardionomic	Cardionomic device	Neurostim-ulation	A neuromodulation approach to improve LV contractility in hospitalized patients with acute decompensated HF; technology licensed from the Cleveland Clinic	International feasibility study underway
CVRx	Barostim neo	Neurostim-ulation	2nd-gen implantable device that provides low-level electrical stimulation to the baroreflex system based in the carotid arteries	U.S. pivotal study underway, CE Mark approval gained
Enopace	Harmony	Neurostim-ulation	Intra-aortic scaffold with a wireless transmission for performing aortic baroreceptor activation (LivaNova is an investor in the company)	CE Mark trial underway
Impulse Dynamics	Optimizer	Neurostim-ulation	Implantable device that delivers non-excitatory electrical impulses to the heart to modify heart cell function and enhance contractility	U.S. confirmatory study underway, CE Mark approval gained

Neurostimulation Technologies

Company	Product	Technology	Description	Status
Kenergy	Kenergy CHF device	Neurostim-ulation	Vagus nerve stimulation using vascular implanted devices for the treatment of CHF	Intellectual property developed
LivaNova	ART+D	Neurostim-ulation	Integrated autonomic regulation therapy system combining vagus nerve stimulation with an ICD in a single implantable pulse generator	In development
LivaNova	VITARIA	Neurostim-ulation	Continuously cyclic, low-intensity, natural-frequency autonomic regulation therapy	U.S. preclinicals underway, CE Mark approval gained
Medtronic	Prime ADVANCED	Neurostim-ulation	Modulation of the autonomic system using a spinal cord stimulator; designed for HF patients not indicated for CRT	U.S. Feasibility study completed, CE Mark trial completed; program status unknown
Medtronic	Transvenous VNS	Neurostim-ulation	Stimulation of the cervical vagus nerve from within the internal jugular vein	OUS FIM study completed; program status unknown
Nephera	RenaSense	Neurostim-ulation	Device that provides renal sympathetic activity inhibition in order to break the cycle of cardio-renal infection in acute HF patients	U.S. Preclinicals underway, OUS Clinical study planned

Neurostimulation Technologies

Company	Product	Technology	Description	Status
NeuroTronik	NeuroTronik Neuro-modulation System	Neurostim-ulation	Catheter system for neuromodulation to treat acute HF (spun out of Synecor)	U.S. Preclinicals underway; program status unknown
Respicardia	remede	Neurostim-ulation	Implantable system that provides chronic unilateral transvenous phrenic nerve therapy; stimulation of the phrenic nerve can be accomplished from 1 of 2 locations: the left pericardial phrenic vein or the right brachiocephalic vein	U.S. pivotal study enrollment complete, CE Mark approval gained
RMX	RMX Stimulation	Neurostim-ulation	Stimulation method designed to treat obstructive, central, and mixed apneas; stimulation methods using respiratory system to assist cardiac function and offload the heart	Intellectual property developed
St. Jude	Eon Mini	Neurostim-ulation	Implantable, rechargeable pulse generator initially designed for chronic pain management and now being studied for heart failure treatment	OUS FIM study completed; program status unknown

Ventricular Assist Technologies

Company	Product	Technology	Description	Status
ABIOMED	Impella CP+	Ventricular Assist Device	Next-generation version of Impella CP with a flow rate of >4.5 L/min; delivered on the standard 9 Fr catheter and 14 Fr pump; features improved inflow design and “smart” sensor technology	U.S. preclinicals underway
ABIOMED	Impella ECP	Ventricular Assist Device	A percutaneous catheter pump that offers >3 liters of flow per minute; delivered on the standard Impella 9 Fr catheter and will include an 18 Fr expandable inflow in the left ventricle	U.S. and OUS preclinicals underway
ABIOMED	Impella 2.5	Ventricular Assist Device	Active left ventricular unloading catheter implanted percutaneously for supporting heart up to 5 days; features microaxial programmable pump	PMA approved, CE Mark approval gained
ABIOMED	Impella CP	Ventricular Assist Device	Impella CP is a percutaneous, left-side support platform that is similar to Impella 2.5 but that offers a higher flow rate (appx. 4 L/min)	PMA approved, CE Mark approval gained
ABIOMED	Impella Pediatric Pump	Ventricular Assist Device	Catheter-based 12 Fr blood pump based on Impella 2.5 technology that can operate either as a pulsatile or a continuous flow device; designed to provide left ventricular support to small pediatric patients (5 to 9 years old, 15 to 25 kg)	Preclinicals underway
ABIOMED	Impella RP	Ventricular Assist Device	Percutaneous, catheter-based axial flow pump designed for right heart failure; flows up to 4 L/min; designed for support duration of up to 14 days; delivered through femoral vein and directed over a guide wire across the right heart into the pulmonary artery	HDE approved, CE Mark approval gained

Ventricular Assist Technologies

Company	Product	Technology	Description	Status
Boston Scientific	Percutaneous Pump	Ventricular Assist Device	While Boston Scientific has not publicly discussed a percutaneous pump for hemodynamic support, the company is developing intellectual property in this area	Intellectual property developed; program status unknown
CardiacAssist	TandemHeart	Ventricular Assist Device	Percutaneous extracorporeal, centrifugal VAD designed to provide rapid ventricular offloading and increased systemic perfusion; features a 22 Fr venous cannula	510(k) cleared, CE Mark approval gained
CardioBridge	Reitan	Ventricular Assist Device	A percutaneously (transfemorally) placed pump for temporary cardiac assist; features a foldable impeller that is continuously rotated with no need for heart synchronization	OUS Clinical study underway
Corlife	corVAD	Ventricular Assist Device	Catheter-based technique for implanting a ventricular assist device	In development
HeartWare	CircuLite IC	Ventricular Assist Device	Endovascular micro-pump platform for partial support that does not require a major surgery	In development
MinVasc	MinVasc Pump	Ventricular Assist Device	A percutaneous continuous-flow pump; the whole pump sits in the left atrium and will pump 2 to 3 liters of left atrial blood into the axillary artery	U.S. Preclinicals underway
NuCardia	NuCardia Pump	Ventricular Assist Device	Expandable impeller that can be used in percutaneously insertable blood pumps	Intellectual property developed

Ventricular Assist Technologies

Company	Product	Technology	Description	Status
Procyrion	Aortix	Ventricular Assist Device	Intra-aortic cardiorenal support device intended to provide partial support; unloads the heart and perfuses the kidneys	U.S. Preclinicals underway, FIM study planned
Procyrion	Aortix-Pediatric	Ventricular Assist Device	Modified version of the adult Aortix device for use in children born with single ventricle heart defects	In development
PlugMed	FeedCor	Ventricular Assist Device	Percutaneous osseointegrated connector that is designed to power VADs; expected to reduce episodes of infection related to mechanical circulatory support	In development
Pulsecath	iVAC 2L	Ventricular Assist Device	A short-term, fully percutaneous 17 Fr transfemoral LVAD that generates blood flow up to 2 liters per minute; targeted at the high-risk PCI market	CE Mark approval gained
St Jude	HeartMate PHP	Ventricular Assist Device	Catheter-based axial flow pump inserted through a low-profile introducer sheath; it is expandable to appx. 24 Fr, with an elastomeric, collapsible impeller and nitinol cannula driven by an external motor via a flexible drive shaft	U.S. pivotal study underway, CE Mark approval gained
Xenios	i-cor	Ventricular Assist Device	Extracorporeal, percutaneous pulsatile cardiac assist device; uses synchronized pulses that are superimposed over the patient's weakened heartbeats	CE Mark approval gained

Ventricular Support/Reshaping Technologies

Company	Product	Technology	Description	Status
Bellerophon	BCM	Ventricular Support/ Reshaping	Biodegradable alginate polymer scaffold designed for injection into old scar tissue after myocardial infarction to prevent cardiac remodeling	CE Mark trial completed (failed primary endpoint); development on hold
Bioventrix	Revivent-Percutaneous	Ventricular Support/ Reshaping	Sternal-sparing, percutaneous version of Revivent; designed to perform ventricular reconstruction and reduce the size of the heart	Preclinicals underway
CardioKinetix	Parachute	Ventricular Support/ Reshaping	Device made of an ePTFE membrane stretched over a nitinol frame; deployed into the apex of the left ventricle to partition off non-contractile damaged myocardium to reduce LV volume (Edwards is an investor in the company)	U.S. pivotal study underway, CE Mark approval gained
CorMend	CorMend Device	Ventricular Support/ Reshaping	A mechanical method to treat heart failure by reinforcing “regional” segments of the heart’s wall/muscle, resulting in enhanced cardiac output and an interrupted progression of HF	Intellectual property developed
Ventrix	VentriGel	Ventricular Support/ Reshaping	Off-the-shelf biomaterial scaffold for cardiac repair after MI; designed to mimic extracellular matrix in the heart	U.S. feasibility study underway, OUS Clinical studies planned

Implantable Counterpulsation Technology

Company	Product	Technology	Description	Status
NovaPump	PERKAT	Implantable counter-pulsation device	A right heart assist device; it is integrated into a standalone IABP apparatus to increase pumping volume in the treatment of acute care cases	Preclinicals underway OUS

Interatrial Implant Technologies

Company	Product	Technology	Description	Status
Corvia Medical	IASD	Interatrial implant	Open interatrial septal defect system for use in patients with HF and preserved ejection fraction	U.S. feasibility study underway, CE Mark trial completed
V-Wave	V-Wave Shunt	Interatrial implant	Unidirectional interatrial shunt implant designed to selectively unload the left heart in a pressure-dependent manner in chronic, NYHA Class III/IV heart failure patients	U.S. study planned, OUS FIM study underway

Intracardiac Implant Technologies

Company	Product	Technology	Description	Status
D.H.S.	DHS Diastole Device	Intracardiac implant	Device for treating diastolic HF by trimming the diastole	Intellectual property developed
Magenta	Magenta device	Intracardiac implant	A device placed in the renal veins to provide an acute treatment for HF by reducing venous pressure within the renal vein relative to central venous pressure	Preclinicals underway
Miracor	PICSO	Intracardiac implant	A pressure-controlled, intermittent coronary sinus occlusion device designed to improve cardiac blood flow following MI or in patients with CHF	CE Mark approval gained

Notes

Notes

Notes

Interventional heart failure technologies in development

by technology type

Innovation booklet
Source: cvPipeline, April 2016