
GLOSSARY

“active pharmaceutical ingredient” or “API”	active pharmaceutical ingredient, the substance in a pharmaceutical drug that is biologically active
“aneurysm embolization”	aneurysm is the enlargement of an artery caused by weakness in the arterial wall, and at risk of rupture. In aneurysm embolization procedure, physicians use image guidance to place small, soft metal coils within the aneurysm, where it helps block the flow of blood and prevent rupture of the aneurysm
“anti-restenotic”	prevention of the re-narrowing (restenotic) of blood vessels
“anti-thrombotic”	prevention of blood clot formation (thrombus)
“anticoagulants”	a medicine that helps prevent blood clots and to reduce risk of strokes and heart attacks due to formation of clots
“aortic regurgitation”	a condition where the heart aortic valve is not able to close completely, causing a backflow of blood from the aorta into the left ventricle
“aortic stenosis”	the narrowing of aortic valve opening, restricting blood flow from left ventricle to the aorta
“aorto-(bi)femoral bypass”	a surgery to redirect blood around narrowed or blocked vessels in the belly or groin, to increase blood flow to the legs
“arteriovenous fistula”	an irregular connection between an artery and a vein
“aspiration thrombectomy”	a catheter that is used for removal of thrombus/blood clots from blood vessel via suction
“atherosclerosis”	the buildup of fatty material/plaque inside the blood vessel, causing it to be narrowed and hence limiting the blood flow
“ATM”	the standard atmosphere, a unit of pressure
“balloon angioplasty/stent”	a catheter procedure to restore blood flow of a blocked arteries by using a balloon or a stent

GLOSSARY

“balloon rewrap”	to wrap again the balloon that has been inflated so that profile of the balloon is good for re-crossing
“bare metal stent”	a stent with delivery system but without any drug, polymer, or antibody coating on it
“beta-blocker”	a class of medications that are predominantly used to manage abnormal heart rhythms, treat chest pain and reduce high blood pressure
“carotid artery stents”	a procedure to implant a stent in the narrowed carotid artery to open it up to improve blood flow and prevent risk of stroke
“chronic total occlusion” or “CTO”	100% occlusion of a coronary artery for a duration of at least three months based on angiographic evidence
“compliant balloon”	balloon of which diameter increases as the inflation pressure increases, which usually have lower nominal and rated burst pressure compared to non-compliant balloon
“coronary artery atherosclerosis”	a disease in which the plaque/fatty material builds up inside the coronary arteries
“coronary artery bypass grafting”, or “CABG”	a surgical procedure that diverts/bypass blood around the narrowed/blockage of blood vessels to improve blood flow and oxygen supply to the heart by grafting a blood vessel between the aorta and a point along the coronary artery, past the narrowed area
“coronary artery dissection”	a tear in the blood vessel of the heart
“coronary artery patency”	heart vessel being open or unobstructed
“coronary artery spasm”	a temporary tightening (constriction) of the muscles in the wall of one of the arteries that send blood to the heart. A spasm can decrease or completely block blood flow to part of the heart
“critical limb ischaemia” or “CLI”	severe blockage in the arteries of the lower extremities, which markedly reduces blood flow. It is a serious form of peripheral arterial disease

GLOSSARY

"crossability"	the ability of a catheter to cross a lesion in a vessel that has been narrowed or occluded
"CTO balloon"	balloon catheter specifically designed for crossing a totally blocked vessel (CTO-chronic total occlusion)
"DAPT"	dual antiplatelet therapy, usually combination of aspirin with one of the following ADP/PZY inhibitors, clopidogrel or prasugrel or ticagrelor, which is typically prescribed after percutaneous coronary intervention
"diuretics"	also known as water pills, which help rid the body of salt and water
"drug-coated balloon"	balloon catheter coated with anti-proliferative medicine to reduce re-narrowing of the blood vessel and hence reduce repeat procedure for the patient
"drug eluting balloon"	conventional semi-compliant angioplasty balloons covered with drug which is released into the vessel wall during inflation of the balloon, usually at nominal pressures with a specific minimal inflation time
"drug-eluting stents"	a stent with delivery system and usually with polymer or well to hold anti proliferative drug
"ECMO"	extracorporeal membrane oxygenation, is a machine to provide prolonged cardiac and respiratory support to a person whose heart and lungs are unable to provide an adequate amount of gas exchange or perfusion to sustain life
"endothelial progenitor cells" or "EPCs"	EPCs are thought to originate from bone marrow, mobilize in response to ischemia, and home to sites of vascular injury. EPCs are believed to promote vascular regeneration
"EU Emissions Allowances"	allowances or credits in the EU Emissions Trading System which allow the holders of such allowances or credits to emit greenhouse gas emissions
"extra-anatomical bypass"	an arterial bypass that does not follow the normal anatomic pathway

GLOSSARY

“general anesthetic (GA)”	a state of controlled unconsciousness. During GA, medicine is used to put patient to sleep, so, patient do not move or feel pain during the procedure
“hydrophilic coating”	a coating that is being used to reduce surface friction and enhance lubricity. Hydrophilic means that it has an affinity for water (water loving)
“hypotube shaft”	a long metal tube with micro-engineered features along its length
“intracranial stenosis”	a narrowing of an artery in the brain
“intravenous thrombolysis”, or “IVT”	an injection of clot-busting drugs through an intravenous line to dissolve blood clots that have blocked blood vessels and pose serious life or life threatening implications
“ischemia”	an inadequate supply of blood to an organ or part of the body that is due to narrowing of a blood vessel
“ischemic heart diseases”, or “IHDs”	a condition of recurring chest pain or discomfort that occurs due to narrowed heart arteries
“ischemic stroke”	a condition occurs when a blood clot blocks or narrows an artery leading to the brain
“ISO 13485:2016”	a quality standard established by the International Organization for Standardization which specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements
“LDL cholesterol”	low density lipoprotein cholesterol. When LDL is high, it caused deposition in the walls of blood vessels caused it to be narrowed and reducing blood flow
“lesion”	a term used for plaque buildup in the wall of the arteries
“lumen”	an opening -can refer to the central space in an artery, vein or capillary. It can also refer to the channel within a catheter or tubing

GLOSSARY

“mitral regurgitation”	a condition where the heart mitral valve is leaky. The mitral valve does not close completely, causing a backflow of blood from the left ventricle into the left atrium
“mitral stenosis”	the narrowing of the heart’s mitral valve. The valve doesn’t open properly, obstructing the blood flow into the left ventricle
“myocardial infarction”	MI or heart attack. MI happens when one or more areas of the heart muscle don’t get enough oxygen due to narrowed coronary arteries
“NAI”	no action indicator, which means no observations are found during the onsite inspection of factories by the FDA
“non-compliant balloon”	balloon with very little growth in diameter versus the pressure increase, and a higher nominal and rated burst pressure as compared to a compliant balloon
“over-the-wire”	a type of catheter design where the entire length of the catheter traverses over a guidewire to access the desired anatomy
“paclitaxel particle abscission”	a process of removal/separation of paclitaxel particle
“paclitaxel-carrying balloons”	a balloon that is coated with paclitaxel drug
“Paris Course for Revascularization” or “PCR”	a renowned medical device conference with the objectives of sharing knowledge, experience and practice in cardiovascular interventional medicine
“percutaneous coronary intervention” or “PCI”	a minimally invasive procedure to open narrowed coronary arteries to restore blood to the heart
“percutaneous pulmonary valve implantation” or “PPVI”	a minimally invasive procedure to replace a pulmonary valve via catheterization through a vein
“percutaneous transluminal angioplasty” or “PTA”	a minimally invasive procedure to open a blocked blood vessel using a balloon catheter to restore the blood flow
“peripheral vascular intervention”	a minimally invasive procedure used to treat peripheral (outside of heart) artery disease

GLOSSARY

“PMA”	premarket approval, issued to Class III medical devices which have a large impact on human health and as such, their evaluation undergo more thorough scientific and regulatory processes to determine their safety and effectiveness
“post stent dilatation”	a balloon is dilated inside the stent to further open the stent area post stent deployment
“pre-dilatation balloon catheter”	balloons that are used to open the narrowed blood vessel to allow stent to cross and be deployed
“pro-healing”	the promotion of the restoration of a complete and functional endothelial cellular layer which lines inside the heart and blood vessels
“rated burst pressure”	the operating pressure where a balloon catheter has been shown to operate repeatably and reliably
“resistant lesion”	a lesion that requires high pressure balloon dilatation and sometimes cannot be opened up using a normal balloon catheter but require other device like scoring balloon or atherectomy
“restenosis”	a renarrowing of the blood vessel
“sirolimus”	a macrolide compound used to coat coronary stents to prevent renarrowing of the stented vessel
“smooth muscle cells (SMC) proliferation”	rapid increase of SMC
“scoring balloon”	a balloon catheter with scoring wire to help to crack the plaque via controlled manner
“standard balloon”	a balloon catheter that is used for dilating a narrowed blood vessel
“stenosis”	a term used when the plaque buildup caused narrowing or blockage of the arteries
“thrombectomy”	a procedure of removing a blood clot from arteries or veins. It can be surgical or minimally invasive procedure

GLOSSARY

“thrombus”	a blood clot
“trackability”	the ability of a catheter to track along the vessel that not always straight but has some tortuosity
“transcatheter aortic valve replacement”, or “TAVR”	a minimally invasive procedure using a catheter-based technique to replace the diseased aortic valve with a new aortic valve
“transcatheter cardiovascular therapeutics”, or “TCT”	TCT is organized by Cardiovascular Research Foundation (CRF) and one of the world largest cardiovascular educational conference for physicians and industry held in USA
“transcatheter edge-to-edge mitral valve repair”, or “TEER”	TEER is a minimally invasive procedure that treats severe leakage of the mitral valve in patients deemed to be at prohibitive risk by a heart team
“transcatheter intervention”	a minimally invasive procedure that is catheter-based
“transcatheter mitral valve implantation”, or “TMVI”	a minimally invasive procedure using a catheter-based technique to replace the diseased mitral valve with a new mitral valve
“tricuspid regurgitation”	a condition where the tricuspid valve is not able to close completely, causing a backflow of blood from the right ventricle to the right atrium
“tricuspid stenosis”	a narrowing of the tricuspid valve opening that slows blood flow from the right atrium to the right ventricle
“TricValve” or “TricValve Bicaval System”	TricValve is a bicaval transcatheter tricuspid valve implantation system, which includes the transcatheter bicaval valve for superior vena cava and the transcatheter bicaval valve for inferior vena cava. The TricValve transcatheter bicaval valves are already pre-mounted into the delivery system
“valvular heart disease”	a category of diseases where any valve in the heart is narrowed or does not close properly
“vasodilators”	medications that promotes the dilatation of blood vessels, so blood flows easily through the blood vessels

GLOSSARY

“ventricular abnormalities”	ventricular abnormalities or ventricular arrhythmias are abnormal heartbeats that originates in the lower heart chambers (the ventricles), cause the heart to beat too fast, which prevent oxygen rich blood from circulating to the brain and body and may result in cardiac arrest
“Zero Observation” or “No Action Indicated”	meaning no objectionable conditions or practices were found during an inspection by the U.S. FDA (or the significance of the documented objectionable conditions found does not justify further action)