Supplementary Table 2. Definitions of comorbidities and adverse outcomes [17-26]

	Definition
Comorbidities	
Ischemic heart disease	Significant coronary artery disease, defined as the presence of any epicardial coronary vessels with ≥ 75% stenosis or any history of myocardial infarction or coronary revascularization, accompanied by depressed myocardial contractility
Severe diabetes mellitus	Type 2 diabetes mellitus with hemoglobin A1c ≥ 8.0% or requiring insulin therapy
Chronic renal disease	Kidney damage or glomerular filtration rate (GFR) < 60 mL/min/1.73 m^2 for 3 months or more, irrespective of cause
Chronic lung disease	Chronic respiratory symptoms with persistent airflow limitation confirmed by spirometry (post-bronchodilator forced expiratory volume in 1 second [FEV1]/forced vital capacity [FVC] ratio < 0.70)
Peripheral arterial disease	Hypoperfusion symptoms and signs of the lower extremities such as claudication or ischemic wound, accompanied by an ankle-brachial index (ABI) ≤ 0.9 or vascular imaging (e.g., Doppler ultrasonography or invasive and noninvasive angiography)
Major stroke	An episode of acute neurological dysfunction presumed to be caused by ischemia or hemorrhage and persists ≥ 24 hours or until death Ischemic stroke: An episode of neurological dysfunction caused by focal cerebral, spinal, or retinal infarction Hemorrhagic stroke: Rapidly developing clinical signs of neurological dysfunction attributable to a focal collection of blood within the brain parenchyma, ventricular system, or subarachnoid space
Major adverse events	
Major bleeding	An episode of suspected internal or external bleeding that results in one or more of the following: (a) Death, (b) Reoperation, (c) Hospitalization, (d) Transfusion of red blood cells as follows: If transfusion is selected, then apply the following rules: During first 7 days post-implant: • ≥ 50 kg: ≥ 4U packed red blood cells (PRBC) within any 24-hour period during first 7 days post-implant • < 50 kg: ≥ 20 cc/kg PRBC within any 24-hour period during the first 7 days post-implant After 7 days post-implant*: • Any transfusion of PRBC after 7 days following implant with the investigator recording the number of units given (record number of units given per 24-hour period) Major bleeding: Bleeding occurring > 7 days after implant, events requiring 2 units of packed red blood cells within a 24-hour period, and death from bleeding Note: Hemorrhagic stroke is considered a neurological event and not as a separate bleeding event *Any transfusion of ≥ 2 U PRBC after 7 days following implant will be considered a serious bleed
Cardiac arrhythmia	Any documented arrhythmia that results in clinical compromise (e.g., diminished VAD flow, oliguria, pre-syncope, or syncope) that requires hospitalization or occurs during a hospital stay
Device thrombosis	Device thrombosis is an event in which the pump or its conduits contain a thrombus that results in or could potentially induce circulatory failure Suspected device thrombus is an event in which clinical or mechanical circulatory support device (MCSD) parameters suggest thrombus on the blood contacting components of the pump, cannulae, or grafts. Signs and symptoms should include at least 2 of the 3 following criteria: presence of hemolysis, worsening heart failure or inability to decompress the left ventricle, abnormal pump parameters Confirmed device thrombus is an event in which thrombus is confirmed by sponsor-returned product analysis to be found within the blood contacting surfaces of device inflow cannula or outflow conduit or grafts
Hemolysis	A plasma-free hemoglobin value that is greater than 40 mg/dL, concomitant with a rise in serum LDH above three times the upper limit of normal, in association with clinical signs associated with hemolysis (e.g., anemia, low hematocrit, hyperbilirubinemia) occurring after the first 72 hours post-implant

Supplementary Table 2. Continued

	Definition
Hepatic dysfunction	An increase in any two of the following hepatic laboratory values (total bilirubin, aspartate aminotransferase [AST] and alanine aminotransferase [ALT]) to a level greater than three times the upper limit of normal for the hospital, beyond 14 days post-implant (or if hepatic dysfunction is the primary cause of death)
Major infection	A clinical infection accompanied by pain, fever, drainage and/or leukocytosis that is treated by anti-microbial agents (non-prophylactic). A positive culture from the infected site or organ should be present unless strong clinical evidence indicates the need for treatment despite negative cultures. The general categories of infection are listed below: Localized non-device infection: Infection localized to any organ system or region without evidence of systemic involvement, ascertained by standard clinical methods and either associated with evidence of bacterial, viral, fungal or protozoal infection, and/or requiring empirical treatment Percutaneous site, driveline and/or pocket infection: A positive culture from the skin and/or tissue surrounding the drive line or from the tissue surrounding the external housing of a pump implanted within the body, coupled with the need to treat with antimicrobial therapy, when there is clinical evidence of infection such as pain, fever, drainage, or leukocytosis. Internal pump component, inflow or outflow tract infection: Infection of blood-contacting surfaces of the LVAD documented by positive site culture (Sepsis: Evidence of systemic involvement by infection, manifested by positive blood cultures and/or hypotension) ISHLT standardization of definition of infection in LVAD patients [26] VAD-specific infections: Infections that are specific to patients with VADs, are related to the device hardware, and do not occur in non-VAD patients; for example, pump and cannula infections, pocket infections, and percutaneous driveline infections VAD-related infections: Infections that can also occur in patients who do not have VADs; however, there may be unique considerations in patients with VADs with respect to making the correct diagnosis or determining the cause-and-effect relationship (e.g., mediastinitis and IE) Non-VAD infections: Infections essentially not affected by the presence of the VAD, and are unlikely related to the VAD presence but are included to encourage comprehensive and comparable data recording of all infections in this patient population to facilitate multi-center review
Neurologic dysfunction	Transient ischemic attack: As an acute transient neurological deficit conforming anatomically to arterial distribution cerebral ischemia, which resolves in < 24 hours and is associated with no infarction on brain imaging (head CT performed > 24 hours after symptom onset; or MRI) Ischemic stroke: A new acute neurologic deficit of any duration associated with acute infarction on imaging corresponding anatomically to the clinical deficit, or a clinically covert ischemic stroke seen by surveillance imaging, without clinical findings of stroke or at the time of event recognition. Hemorrhagic stroke: A new acute neurologic deficit attributable to intracranial hemorrhage (ICH), or a clinically covert ICH seen by surveillance imaging, without clinical findings of ICH at the time of event recognition Encephalopathy: Acute new encephalopathy due to hypoxic-ischemic injury (HIE), or other causes, manifest as clinically evident signs or symptoms, or subclinical electrographic seizures found by complete neurological diagnostic evaluation to be attributable to acute global or focal hypoxic, or ischemic brain injury not meeting one of ischemic stroke or ICH events as defined above Seizure of any kind
Renal dysfunction	Acute renal dysfunction: Abnormal kidney function requiring dialysis (including hemofiltration) in subjects who did not require this procedure prior to implant, or a rise in serum creatinine of greater than 3 times baseline or greater than 5 mg/dL sustained for over 48 hours Chronic renal dysfunction: An increase in serum creatinine of 2 mg/dL or greater above baseline, or requirement for hemodialysis sustained for at least 90 days
Respiratory failure	Impairment of respiratory function requiring reintubation, tracheostomy or (the inability to discontinue ventilatory support within 6 days (144 hours) post-VAD implant. This excludes intubation for reoperation or temporary intubation for diagnostic or therapeutic procedures

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Supplementary Table 2. Continued

	Definition
Right heart failure	Symptoms and signs of persistent right ventricular dysfunction requiring RVAD implantation, or requiring inhaled nitric oxide or inotropic therapy for a duration of more than 1 week at any time after LVAD implantation
Device malfunction	Either directly causes or could potentially induce a state of inadequate circulatory support (low cardiac output state) or death. A failure that was iatrogenic or recipient-induced will be classified as an iatrogenic/recipient-induced failure Device failure should be classified according to which components fails as follows: Pump failure (blood contacting components of pump and any motor or other pump actuating mechanism that is housed with the blood contacting components). In the special situation of pump thrombosis, thrombus is documented to be present within the device or its conduits that result in or could potentially induce circulatory failure Non-pump failure (e.g., external pneumatic drive unit, electric power supply unit, batteries, controller, interconnect cable, compliance chamber)

VAD, ventricular assist device; LDH, lactate dehydrogenase; LVAD, left ventricular assist device; ISHLT, International Society for Heart and Lung Transplantation; IE, lactate dehydrogenase; CT, computed tomography; MRI, magnetic resonance imaging; RVAD, right ventricular assist device.