Intermacs

Adverse Event

Adverse Event Status

Please enter the date of the event you are reporting:	
Please enter a label describing this event:	

Intermacs

Adverse Event

Rehospitalization

Was there an occurrence of rehospitalization?
- Yes
- No

Is this rehospitalization at your hospital?
- Yes
- No

Date of admission
MM/DD/YYYY

ST= ○ Unknown

Discharge Date
MM/DD/YYYY
Date of transplant, death or explant for recovery will be considered the date of discharge.

ST= ○ Unknown

Primary reason for rehospitalization
- ○ Anticoagulation adjustment
- ○ Arterial Non-CNS Thrombo-embolism
- ○ Cardiac Arrhythmia
- ○ Cardiac Tamponade
- ○ Catastrophe (i.e. weather)
- ○ Device Malfunction
- ○ Diagnostic Procedure
- ○ Explant
- ○ Fever without known cause
- ○ Fluid Overload
- ○ Gastroenteritis
- ○ GI Disorder
- ○ Hematological
- ○ Hematoma
- ○ Hemolysis
- ○ Hepatic Dysfunction
- ○ Hypertension
- ○ Limb vascular complication
- ○ Major Bleeding
- ○ Major Infection
- ○ Metabolic/Electrolyte Disturbance
- ○ Myocardial Infarction
- ○ Neurological Dysfunction
- ○ Pericardial Fluid Collection
- ○ Planned medical management
- ○ Planned Procedure
- ○ Pneumonia
- ○ Psychiatric Episode
- ○ Pulmonary Embolism/Hemorrhage
- ○ Pulmonary, Other
- ○ Renal Dysfunction
- ○ Respiratory Failure
- ○ Right Heart Failure
- ○ Syncope without known cause
- ○ Transplant

- ◯ Trauma/Accident
- ◯ Venous Thromboembolic Event
- ◯ Wound Complication
- ◯ Wound Dehiscence
- ◯ Unknown
- ◯ Other, specify

Rehospitalization intervention

- ☐ Surgical Procedure
- ☐ Heart Cath
- ☐ Invasive Cardiac Procedures (Other than Heart Cath)
- ☐ Transplantation
- ☐ None
- ☐ Unknown
- ☐ Other

Type of surgical procedure

- ☐ Device related operation
- ☐ Other Cardiac Surgical Procedure
- ☐ Non Cardiac Surgical Procedure
- ☐ Other procedure
- ☐ Unknown

Type of other cardiac procedure

- ☐ Reoperation for Bleeding within 48 hours of implant
- ☐ Reoperation for Bleeding and/or tamponade > 48 hours
- ☐ Surgical Drainage of pericardial effusion
- ☐ Aortic Valve Surgery - Replacement - Biological
- ☐ Aortic Valve Surgery - Replacement - Mechanical
- ☐ Aortic Valve Procedure
- ☐ Mitral Valve Surgery - Repair
- ☐ Mitral Valve Surgery - Replacement - Biological
- ☐ Mitral Valve Surgery - Replacement - Mechanical
- ☐ Tricuspid Valve Surgery - Repair - DeVega
- ☐ Tricuspid Valve Surgery - Repair - Ring
- ☐ Tricuspid Valve Surgery - Repair - Other
- ☐ Tricuspid Valve Surgery – Replacement - Biological
- ☐ Tricuspid Valve Surgery – Replacement - Mechanical
- ☐ Tricuspid Valve Surgery – Excision
- ☐ Pulmonary Valve Surgery - Repair
- ☐ Pulmonary Valve Surgery – Replacement - Biological
- ☐ Pulmonary Valve Surgery – Replacement - Mechanical
- ☐ Aneursyomectomy
- ☐ Mitraclip
- ☐ TAVR
- ☐ Arrhythmia Surgery (Ablation)
- ☐ Ligation of Left Atrial Appendage
- ☐ Unknown
- ☐ Other, specify

Type of procedure (non cardiac surgical procedure)

Type of Invasive Cardiac Procedure (Other than Heart Cath)

Enter PA systolic pressure

mmHg

ST= ◯ Unknown

◯ Not Done

Enter PA diastolic pressure

mmHg

ST= ○ Unknown

○ Not Done

Enter PCW pressure

mmHg

ST= ○ Unknown

○ Not Done

Enter Cardiac output

L/min

ST= ○ Unknown

○ Not Done

Other procedure

- ☐ Intubation/Ventilator
- ☐ Dialysis
- ☐ Bronchoscopy
- ☐ Ultrafiltration
- ☐ Other, specify

Clinical Observations

Systolic blood pressure
(millimeters of mercury)

mmHg

ST= ○ Unknown

○ Not done

Diastolic blood pressure
(millimeters of mercury)

mmHg

ST= ○ Unknown

○ Not done

Mean arterial blood pressure

ST= ○ Unknown

○ Not done

○Not applicable

Has the patient experienced a Neurological Event since time of implant?

Note: This applies only to patients who have had a CVA, TIA or Anoxic Brain Injury.

- ○ Yes
- ○ No
- ○ Unknown

Modified Rankin Scale:

Please click here for further instruction on administering the Modified Rankin Scale in Appendix I.

- ○ 0 – No symptoms at all
- ○ 1 - No Significant disability: despite symptoms: able to carry out all usual duties and activities
- ○ 2 - Slight disability: unable to carry out all previous activities but able to look after own affairs without assistance
- ○ 3 - Moderate disability: requiring some help, but able to walk without assistance.
- ○ 4 - Moderately severe disability: unable to walk without assistance, and unable to attend to own bodily needs without assistance.
- ○ 5 - Severe disability: bedridden, incontinent and requiring constant nursing care and attention.
- ○ 6 - Dead
- ○ Not Documented

Not Done

Intermacs

Adverse Event

Infection

Was there a major infection?
- Yes
- No

Date of onset
MM/DD/YYYY

ST= Unknown

Is this a MCS related or Non-MCS related infection?
- MCS related
- Non-MCS related

Type of MCS infection
- Bacterial
- Fungal
- Viral
- Protozoan
- Unknown

MCS Bacterial
Select all that apply
- Gram positive
- Gram negative
- Other, Specify
- Unknown

MCS Gram positive
- Enterococcus
- Staphylococcus, Methicillin Resistant
- Staphylococcus, Methicillin Sensitive
- Streptococcus
- Other, Specify

MCS Gram negative
- Citrobacter
- Enterobacter
- Enterobacteriaceae
- Escherichia
- Haemophilus
- Klebsiella
- Moraxella
- Pseudomonas
- Serratia
- Other, Specify

Type of Non-MCS infection
- Bacterial
- Fungal
- Viral
- Protozoan
- Unknown

Non-MCS Bacterial
Select all that apply
- Gram positive
- Gram negative
- Other, Specify

Unknown

Non-MCS Gram positive

- Enterococcus
- Staphylococcus, Methicillin Resistant
- Staphylococcus, Methicillin Sensitive
- Streptococcus
- Other, Specify

Non-MCS Gram negative

- Citrobacter
- Enterobacter
- Enterobacteriaceae
- Escherichia
- Haemophilus
- Klebsiella
- Moraxella
- Pseudomonas
- Serratia
- Other, Specify

MCS Related Infections: Select all that apply

- Percutaneous lead site infection
- Infection of external surfaces of an implantable component A positive culture from the tissue surrounding the external housing of a pump or one of its components implanted within the body (including device components such as controllers, batteries, etc.), when there is clinical evidence of infection such as pain, fever, drainage, erythema, or leukocytosis coupled with the need to treat with anti-microbial therapy
- Infection of blood-contacting surfaces of an implantable component (device endocarditis) Infection of blood-contacting internal surfaces of the MCS device including inflow/outflow grafts: documented by positive blood cultures or radiographic or echocardiographic evidence of vegetation in blood flow path of the pump coupled with the need to treat with anti-microbial therapy
- Unknown
- Other, Specify

Percutaneous lead site infection: Select one

- Superficial percutaneous lead infection A positive culture from the skin surrounding the percutaneous lead when there is clinical evidence of infection such as pain, fever, drainage, erythema, or leukocytosis coupled with the need to treat with anti-microbial therapy. The percutaneous lead exit site is pre-served. The gram stain of the skin specimen at the driveline exit site will contain white blood cells (i.e. positive sign for inflammation)
- Deep percutaneous lead infection A positive culture from the driveline exit site deep to the epithelium, when there is clinical evidence of infection such as pain, fever, drainage, erythema, or leukocytosis coupled with the need for microbial therapy
- Unknown

Infection of external surfaces of an implantable component: Select all that apply

- Pump / related - Exit Cannula
- Pump / related - Pump Pocket
- Pump / related - transcutaneous power element
- Pump / related - implantable battery
- Unknown

Infection of external surfaces of an implantable component: Was the patient

- Yes
- No
- Unknown

treated with anti-microbial therapy?	
If yes, select route	☐ IV ☐ Oral ☐ Topical ☐ Unknown
Percutaneous lead site infection: Was the patient treated with anti-microbial therapy?	○ Yes ○ No ○ Unknown
If yes, select route	☐ IV ☐ Oral ☐ Topical ☐ Unknown
Infection of blood-contacting surfaces of an implantable component (device endocarditis): Was the patient treated with anti-microbial therapy?	○ Yes ○ No ○ Unknown
If yes, select route	☐ IV ☐ Oral ☐ Topical ☐ Unknown
MCS related - Other, specify: Was the patient treated with anti-microbial therapy?	○ Yes ○ No ○ Unknown
If yes, select route	☐ IV ☐ Oral ☐ Topical ☐ Unknown
Non-MCS Related Infections: Select all that apply	☐ Infective Endocarditis Non-MCS related (Positive blood cultures and echocardiography findings for mass or vegetation only on native valves, ICD, or pacemaker leads) ☐ Bloodstream Infection Positive blood cultures with no other source identified; Bloodstream infection: non-VAD site or central venous catheter-related (definition from the Centers for Disease Control/National Healthcare Safety Network) ☐ Mediastinitis ☐ Sepsis Life-threatening organ dysfunction caused by a dysregulated host response to infection with: Evidence of systemic involvement by infection, manifested by need to treat with anti-microbial therapy and positive blood cultures and/or two of the following: (PaO2/FIO2 < 400 or respiratory rate = 22/min or ventilated respiratory support, Hypotension with systolic BP < 100 mmHg or MAP = 65 mmHg, Platelet count < 150 or elevated prothrombin time or fibrinogen degradation products, Bilirubin (serum) > 50% above baseline, Altered mental status (Glasgow score < 15), Creatinine (serum) > 50% above baseline, Need for intravenous vasoconstricting agents) ☐ Localized non-MCS infection Infection localized to a site not involving the MCS device or components (e.g., pneumonia, urinary tract infection, cholecystitis, diverticulitis, dental abscess) coupled with the need to treat with anti-microbial therapy. A positive culture from the infected site or organ should be present unless strong clinical evidence indicates the need for treatment despite negative cultures ☐ Other, Specify

	☐ Unknown
Infective Endocarditis: Was the patient treated with anti-microbial therapy?	○ Yes ○ No ○ Unknown
If yes, select route	☐ IV ☐ Oral ☐ Topical ☐ Unknown
BSI: Was the patient treated with anti-microbial therapy?	○ Yes ○ No ○ Unknown
If yes, select route	☐ IV ☐ Oral ☐ Topical ☐ Unknown
Mediastinitis: Select subtype	○ Procedure-related mediastinitis ○ Non-MCS related mediastinitis Mediastinitis definitively owing to another cause e.g., esophageal perforation during endoscopy, contiguous with empyema ○ Superficial mediastinal or thoracotomy wound infection Infection involving only skin, subcutaneous fat, and muscle of implant incision ○ Unknown
Procedure-related mediastinitis: Select one	○ Deep sternal wound infection (isolated) ○ Deep sternal wound infection involving MCS device components Continuous with mediastinum or already situated in the mediastinum. May be contiguous with implanted components of the MCS device ○ Unknown
Mediastinitis: Was the patient treated with anti-microbial therapy?	○ Yes ○ No ○ Unknown
If yes, select route	☐ IV ☐ Oral ☐ Topical ☐ Unknown
Sepsis: Was the patient treated with anti-microbial therapy?	○ Yes ○ No ○ Unknown
If yes, select route	☐ IV ☐ Oral ☐ Topical ☐ Unknown
Localized non-MCS Infection: Select all that apply	☐ Pneumonia ☐ Tracheobronchitis ☐ Urinary Tract ☐ Thoracotomy incision ☐ Peripheral Wound

- [ ] GI
- [ ] Other, Specify
- [ ] Unknown

Localized non-MCS device infection: Was the patient treated with anti-microbial therapy?

- ( ) Yes
- ( ) No
- ( ) Unknown

If yes, select route

- [ ] IV
- [ ] Oral
- [ ] Topical
- [ ] Unknown

Non-MCS related - Other, specify: Was the patient treated with anti-microbial therapy?

- ( ) Yes
- ( ) No
- ( ) Unknown

If yes, select route

- [ ] IV
- [ ] Oral
- [ ] Topical
- [ ] Unknown

Did this infection contribute to death?

- ( ) Yes
- ( ) No
- ( ) Unknown

The association of the infection event should be classified as

- ( ) Patient related e.g., non-adherence or poor management of driveline exit site or indwelling catheters, IV drug abuse, aspiration
- ( ) Management related e.g., improper tunneling, contamination of the intraoperative site, prolonged intubation
- ( ) Device related e.g., device endocarditis diagnosed by radiological examination or detection of pannus within the conduits or device
- ( ) No association identified

Location of patient

- ( ) In hospital
- ( ) Out of hospital
- ( ) Unknown

Was surgery an intervention for this AE?

- ( ) Yes
- ( ) No
- ( ) Unknown

Did the patient test positive for COVID-19?

- ( ) Yes
- ( ) No
- ( ) Unknown

If yes, select all symptoms that apply

- [ ] Cough
- [ ] Diarrhea
- [ ] Fever
- [ ] Anosmia (loss of sense of smell)
- [ ] Sore Throat
- [ ] Difficulty Breathing
- [ ] None
- [ ] Other, Specify

If yes, select all interventions that apply

- [ ] Intubation
- [ ] New Inotropes
- [ ] ECMO
- [ ] Dialysis
- [ ] RVAD
- [ ] None
- [ ] Other, Specify

If yes, select all therapies the patient received

- [ ] Hydroxychloroquine
- [ ] Azithromycin
- [ ] Immunoglobulin
- [ ] Anti-viral therapy
- [ ] Steroids
- [ ] Convalescent Plasma
- [ ] Interlukin 6 inhibitor
- [ ] None
- [ ] Other, Specify

Anti-viral therapy, specify:

If yes, did the patient have an associated bacterial lung infection?

- ○ Yes
- ○ No
- ○ Unknown

Intermacs

Adverse Event

Bleeding

Transfusions for anemia and hemolysis are not considered bleeding events

Was there a major bleeding event?

- ○ Yes
- ○ No
- ○ Unknown

If yes, Select Type

- ○ Type 1 Bleeding that is not actionable and does not cause the patient to seek unscheduled performance of studies, hospitalization, or treatment by a healthcare professional; may include episodes leading to self-discontinuation of medical therapy by the patient without consulting a healthcare professional. This type is not relevant during a hospitalization
- ○ Type 2 Any overt, actionable sign of hemorrhage (e.g., more bleeding than would be expected for a clinical circumstance, including bleeding found by imaging alone) that does not fit the criteria for Type 3, 4, or 5 but does meet at least one of the following criteria (1. Requiring non-surgical, medical intervention by a healthcare professional, 2. Leading to hospitalization or increased level of care, 3. Prompting evaluation)
- ○ Type 3a Overt bleeding accompanied by hemoglobin drop of 3 to < 5g/dl or (1.86-3.1 mmol/liter SI units) (provided hemoglobin drop is related to bleed)
- ○ Type 3b Overt bleeding plus hemoglobin drop 5 g/dl (3.1 mmol/liter) or greater (provided hemoglobin drop is related to bleed)
- ○ Type 4 VAD implantation-related bleeding (includes concomitant cardiac or non-cardiac surgical procedures)
- ○ Type 5 Fatal bleeding

Type 2: select all that apply

- ☐ Requiring non-surgical, medical intervention by a healthcare professional
- ☐ Leading to hospitalization or increased level of care
- ☐ Prompting evaluation

Type 3b: select all that apply

- ☐ Cardiac tamponade
- ☐ Bleeding requiring surgical intervention for control (excluding dental/nasal/skin/hemorrhoid)
- ☐ Bleeding requiring intravenous vasoactive agents
- ☐ Other, Specify

Type 4: select all that apply

- ☐ Reoperation after the closure of incision or incisions used to implant the VAD to control bleeding
- ☐ >= 50 kg: >= 4U PRBC within any 48 hours during the first 7 days post-implant
- ☐ < 50 kg: >= 20 cm3/kg PRBC within any 24 hours during the first 7 days post-implant
- ☐ Chest tube output > 2 liters within 24 hours

Type 5: select one

- ○ Type 5a: Probable fatal bleeding; no autopsy or imaging confirmation but clinically suspicious
- ○ Type 5b: Definite fatal bleeding; overt bleeding or autopsy or imaging confirmation
- ○ Unknown

Source/cause/location of bleeding

- ☐ Mediastinal: chest wall
- ☐ Mediastinal: outflow-aorta anastomosis

- Mediastinal: outflow conduit
- Mediastinal: inflow conduit
- Mediastinal: cardio-pulmonary bypass cannulation site
- Mediastinal: coagulopathy with no surgical site
- Mediastinal: other surgical sites
- Pump or implanted component pocket (battery or controller)
- Mediastinal: Unspecified
- Pleural space
- Intra-abdominal
- Retroperitoneal
- Pulmonary
- Genitourinary tract
- GI: Upper gastrointestinal (esophagus, stomach, duodenum, small bowel)
- GI: Lower gastrointestinal (colon, rectum, and anus)
- GI: unknown, but guaiac positive stools
- ENT/Dental
- Other, specify

Date of bleeding episode onset

ST= ○Unknown

Location of patient

- In hospital
- Out of hospital
- Unknown

Anticoagulant therapy at time of event

Select all that apply

- Warfarin
- Heparin
- Lovenox
- Aspirin
- Dipyridamole
- Clopidogrel (plavix)
- Argatroban
- Bivalirudin
- Fondaparinux
- Dextran
- Ticlopidine
- Hirudin
- Lepirudin
- Ximelagatran
- None
- Other, specify

The association of the bleeding event should be classified as

Select one

- Patient related e.g., coagulopathy unrelated to surgical technique such as non-adherence with anti-coagulation medication resulting in an inappropriately high level of anti-coagulation, hepatic failure
- Management related e.g., related to surgical technique; hypertension; bleeding in the setting of inappropriate levels of anti-coagulation or to mismanagement of anti-coagulants
- Device related e.g., bleeding from the outflow graft, apical connector, or other internal components
- No association identified

Intermacs

Adverse Event

Neurological Dysfunction

Was there a neurological dysfunction?

- ○ Yes
- ○ No
- ○ Unknown

Select type

- ○ Type 1 - Overt CNS injury Acutely symptomatic brain or spinal cord injury
- ○ Type 2 - Covert CNS injury Acutely asymptomatic brain or spinal cord injury detected by neuroimaging
- ○ Type 3 - Neurologic dysfunction (acutely symptomatic) without CNS injury Include seizures here

Type 1: select subtype

- ☐ Type 1a - Ischemic stroke Sudden onset of neurologic signs or symptoms fitting a focal or multifocal vascular territory within the brain, spinal cord, or retina
- ☐ Type 1ah - Ischemic stroke with hemorrhagic conversion Ischemic stroke includes hemorrhagic conversions
- ☐ Type 1b - Symptomatic intracerebral hemorrhage Rapidly developing neurologic signs and symptoms (focal or global) caused by an intraparenchymal, intraventricular, spinal cord, or retinal collection of blood, not caused by trauma
- ☐ Type 1c - Symptomatic subarachnoid hemorrhage Rapidly developing neurologic signs or symptoms (focal or global) and/or headache caused by bleeding into the sub-arachnoid space, not caused by trauma
- ☐ Type 1d - Stroke, not otherwise specified An episode of acute focal neurologic signs or symptoms and/or headache presumed to be caused by CNS ischemia or CNS hemorrhage, persisting 24 hours or until death, but without sufficient evidence to be classified as one of the above (i.e., no neuroimaging performed)
- ☐ Type 1e - Symptomatic hypoxic-ischemic injury Non-focal (global) neurologic signs or symptoms due to diffuse brain, spinal cord, or retinal cell death (confirmed by pathology or neuroimaging) in a non-vascular distribution, attributable to hypotension and/or hypoxia
- ☐ Type 1f - Symptomatic subdural hemorrhage An episode of acute focal neurologic signs or symptoms and/or headache accompanied by evidence of bleeding into the subdural space: not caused by an accident or trauma.
- ☐ Type 1g– Traumatic Brain Injury Intracerbral, Subarachnoid or subdural- A brain bleed due to an injury. Examples: Falls, Motor Vehicle accident
- ☐ Unknown

Type 2: select subtype

- ○ Type 2a - Covert CNS infarction Brain, spinal cord or retinal cell death attributable to focal or multifocal ischemia on the basis of neurological imaging or pathologic evidence of CNS infarction, without a history of acute neurologic symptoms consistent with the lesion location
- ○ Type 2ah - Covert CNS infarction with hemorrhagic conversion
- ○ Type 2b - Covert CNS hemorrhage Neuroimaging or pathologic evidence of CNS hemorrhage within the brain parenchyma, subarachnoid space, subdural space, ventricular system
- ○ Unknown

Type 3: select subtype

- ○ Type 3a - TIA Transient focal neurologic signs or symptoms (lasting < 24 hours presumed to be owing to the focal brain, spinal cord, or retinal ischemia, but without evidence of acute infarction by neuroimaging or pathology (or in the absence of imaging)
- ○ Type 3b - Delirium without CNS injury Transient non-focal global neurologic signs or symptoms (variable duration) without evidence of cell death

by neuroimaging or pathology injury
- Seizure
- Unknown

Type 1a: select one

- Persist for 24 hours or until death With pathology or neuroimaging evidence that demonstrates either (a) CNS infarction in the corresponding vascular territory (with or without hemorrhage) or (b) Absence of other apparent causes (including hemorrhage), even if no evidence of acute ischemia in the corresponding vascular territory is detected
- Symptoms lasting < 24 hours With pathology or neuroimaging confirmation of CNS infarction in the corresponding vascular territory. Note: when CNS infarction location does not match the transient symptoms, the event would be classified as covert CNS infarction (Type 2a) and a TIA (Type 3a), but not an ischemic stroke. Signs and symptoms consistent with stroke typically include an acute onset of one of the following: focal weakness and/or numbness, impaired language production or comprehension, homonymous hemianopia or quadrantanopia, diplopia, altitudinal monocular blindness, hemispatial neglect, dysarthria, vertigo, or ataxia. For pediatric patients, generalized symptoms such as seizure, irritability, or altered wakefulness may be accepted as confirmation of acute stroke if imaging or pathology demonstrates previously undocumented CNS infarction
- Unknown

Type 1ah: select one

- Class A Petechial (non-space-occupying) hemorrhage: Petechiae or confluent petechiae within the infarction or its margins, but without a space-occupying effect.
- Class B Confluent (space-occupying) hemorrhage: Confluent hemorrhage or hematoma originating from within the infarcted area with space-occupying effect.

Note: This only applies to patients who have a CVA, TIA, or Anoxic Brain Injury.
You must complete this section at the time of event and throughout the patient's complete STS Intermacs® lifespan.

Modified Rankin Scale

Please click here for further instruction on administering the Modified Rankin Scale in Appendix I.

- 0 - No symptoms at all
- 1 - No Significant disability: despite symptoms: able to carry out all usual duties and activities
- 2 - Slight disability: unable to carry out all previous activities but able to look after own affairs without assistance
- 3 - Moderate disability: requiring some help, but able to walk without assistance.
- 4 - Moderately severe disability: unable to walk without assistance, and unable to attend to own bodily needs without assistance.
- 5 - Severe disability: bedridden, incontinent and requiring constant nursing care and attention.
- 6 - Dead
- Not Documented
- Not Done

NIH Stroke Scale

Please click here for further instruction on administering the NIHSS in Appendix I.

- 0-5
- 6-14
- 15+
- Not Documented
- Not Done

Date of onset

MM/DD/YYYY

ST= ◯Unknown

Location of patient

- In hospital
- Out of hospital
- Unknown

Did this neurological dysfunction adverse event contribute to the patient's death?

- ○ Yes
- ○ No
- ○ Unknown

The association of the neurologic event should be classified as

- ○ Patient related e.g., documentation of previous carotid or cerebrovascular disease, coagulopathy unrelated to surgical technique such as non-adherence with anti-coagulation medication resulting in an inappropriately high level of anticoagulation, related to illicit drug use, non-adherence with other medications, trauma, associated with sepsis
- ○ Management related e.g., over anti-coagulation or associated with the use of accessory assist device, hypotension or hypertension-related to surgical procedure
- ○ Device related e.g. secondary to pump thrombosis or device malfunction
- ○ No association identified

Method of diagnosis of CNS event

- ○ CT
- ○ MRI
- ○ Angiogram
- ○ Clinical
- ○ Unknown
- ○ Other, specify

Anticoagulant therapy at time of event

Check all that apply

- ☐ Warfarin
- ☐ Heparin
- ☐ Lovenox
- ☐ Aspirin
- ☐ Dipyridamole
- ☐ Clopidogrel (plavix)
- ☐ Argatroban
- ☐ Bivalirudin
- ☐ Fondaparinux
- ☐ Dextran
- ☐ Ticlopidine
- ☐ Hirudin
- ☐ Lepirudin
- ☐ Ximelagatran
- ☐ None
- ☐ Other, specify

Intermacs

Adverse Event

Device Malf/Failure and/or Pump Thrombus

Was there a device malfunction / failure and / or a pump thrombus?
- ○ Yes
- ○ No

Was there a device malfunction?
A device malfunction occurs when any component of the MCSD system ceases to operate to its designed performance specifications or otherwise fails to perform as intended. Performance specifications include all claims made in the instructions for use. Device malfunctions are further defined as major or minor.
- ○ Yes
- ○ No
- ○ Unknown

If yes, select type
- ○ Major Device Malfunction
- ○ Minor Device Malfunction
- ○ Unknown

If Major Device Malfunction, check all criteria that apply
- ☐ Death
- ☐ Hospitalization Emergency room visit or prolongation of hospitalization, or escalation of the level of care in an ongoing hospitalization (i.e., transfer to the intensive care unit)
- ☐ Life-threatening event i.e. stroke or TIA, cardiac arrest, heart failure, syncope or near syncopal event, arrhythmia, etc.
- ☐ Results in significant disability or incapacity
- ☐ Requires an intervention to prevent impairment/injury Urgent transplantation listing (immediate urgent listing for the transplant), Pump replacement, Pump explant, Pump deactivation without explant or partial explant of components, Breach of integrity of percutaneous lead requiring repair, Operation to repair or replace any internal component of the circulatory support system, Procedure to repair or stent an outflow graft
- ☐ Unknown

Requires an intervention to prevent impairment/injury, check all criteria that apply
- ☐ Urgent transplantation listing (immediate urgent listing for the transplant)
- ☐ Pump replacement (please enter explant form and add new device to record exchange)
- ☐ Pump explant (please complete explant form)
- ☐ Pump deactivation without explant or partial explant of components (please complete explant form and select explant reason: turned off (decommissioned))
- ☐ Breach of integrity of percutaneous lead requiring repair
- ☐ Operation to repair or replace any internal component of the circulatory support system
- ☐ Procedure to repair or stent an outflow graft
- ☐ Unknown

Date of Device Malfunction onset
MM/DD/YYYY

Device Type

Location of patient
- ○ In hospital
- ○ Out of hospital
- ○ Unknown

Description of Malfunction
Please briefly describe this device malfunction including what happened, what component was involved, method of diagnosis, intervention(s) if any, and the result.

Pump
- ○ Yes
- ○ No

Pump Component(s)
- ☐ Pump Body (including bearings and rotor)
- ☐ Driveline
- ☐ Inflow Cannula
- ☐ Outflow Graft (including bend relief)

Implantable component(s)
- ○ Yes
- ○ No

Implantable component(s)
Check all that apply
- ☐ Percutaneous driveline
- ☐ Implantable batteries
- ☐ Other, Specify

Controller
- ○ Yes
- ○ No

Controller Component(s)
- ☐ Primary System Failure (running in backup mode)
- ☐ Complete System Failure (primary and backup failure)
- ☐ Power Cable (attached to controller)
- ☐ Power Connectors (attached to controller)
- ☐ Other, Specify

Peripherals
- ○ Yes
- ○ No

Peripheral Component(s)
- ☐ External Battery
- ☐ Cell Battery (in controller)
- ☐ Power Module
- ☐ Patient Cable
- ☐ System Monitor / Display
- ☐ Battery Charger
- ☐ Battery Clip

Pump (RVAD)
- ○ Yes
- ○ No

Pump Component(s) (RVAD)
- ☐ Pump Body (including bearings and rotor)
- ☐ Driveline
- ☐ Inflow Cannula
- ☐ Outflow Graft (including bend relief)

Implantable component(s) (RVAD)
- ○ Yes
- ○ No

Implantable component(s) (RVAD)
- ☐ Percutaneous driveline
- ☐ Implantable batteries

- [ ] Other, Specify

Controller (RVAD)

- ( ) Yes
- ( ) No

Controller Component(s) (RVAD)

- [ ] Primary System Failure (running in backup mode)
- [ ] Complete System Failure (primary and backup failure)
- [ ] Power Cable (attached to controller)
- [ ] Power Connectors (attached to controller)
- [ ] Other, Specify

Peripherals (RVAD)

- ( ) Yes
- ( ) No

Peripheral Component(s) (RVAD)

- [ ] External Battery
- [ ] Cell Battery (in controller)
- [ ] Power Module
- [ ] Patient Cable
- [ ] System Monitor / Display
- [ ] Battery Charger
- [ ] Battery Clip

Was there a device thrombus?

Device thrombus: Intracorporeal device thrombus represents a special case of major device malfunction and can be categorized as a suspected device thrombus or confirmed device thrombus. Device thrombus will be classified as suspected (see definition below) on the basis of clinical, biochemical, or hemodynamic findings or confirmed (see definition below) on the basis of device inspection or incontrovertible radiologic studies or absence of appropriate Doppler flow signals that confirm thrombus within the device or its conduits that results in or could potentially induce circulatory failure.

- ( ) Yes
- ( ) No
- ( ) Unknown

If yes, select type (suspected or confirmed).

- ( ) Suspected device thrombus A device-related malfunction in which clinical or MCSD parameters suggest thrombus on the blood-contacting components of the pump, cannula, or grafts
- ( ) Confirmed device thrombus A major device-related malfunction in which thrombus is confirmed within the blood-contacting surfaces of device inflow cannula or outflow conduit or grafts. This can be reported through direct visual inspection or by incontrovertible contrast radiographic evidence or by the absence of an appropriate Doppler flow signal that results in or could potentially induce circulatory failure or result in thromboembolism

If suspected device thrombus, check all signs and symptoms that apply

- [ ] Presence of major hemolysis Including elevation of biochemical markers of hemolysis; i.e., lactate dehydrogenase or plasma-free hemoglobin, or clinical evidence of hemolysis; i.e., hemoglobinuria
- [ ] Presence of heart failure not explained by structural heart disease
- [ ] Abnormal pump parameters consistent with diminished pump output/pump efficiency/pump performance
- [ ] Unknown

If suspected device thrombus, check all events/interventions that apply:

- [ ] Death (please complete death form)
- [ ] Stroke or TIA (please complete neuro dysfunction adverse event)
- [ ] Arterial non-CNS thromboembolism (please complete adverse event form)
- [ ] De-novo need for inotrope therapy

- ☐ Treatment with intravenous anti-coagulation (i.e., heparin), intravenous thrombolytics (i.e., tPA), or intravenous anti-platelet therapy (i.e., eptifibatide, tirofiban)
- ☐ Pump replacement (please enter explant form and add new device to record exchange)
- ☐ Pump explantation with or without exchange (please complete explant form)
- ☐ Pump deactivation without pump removal (please complete explant form and select explant reason: turned off (decommissioned))
- ☐ Operation to repair or replace any internal component of the circulatory support system
- ☐ Urgent transplantation listing Immediate urgent listing for transplant
- ☐ Unknown

If confirmed device thrombus, check all criteria that apply

- ☐ Death
- ☐ Hospitalization, emergency room visit or prolongation of hospitalization, or escalation of the level of care in an ongoing hospitalization i.e. transfer to the intensive care unit
- ☐ Life-threatening event i.e., stroke or TIA, cardiac arrest, heart failure, syncope or near syncopal event, arrhythmia, etc.
- ☐ Results in significant disability or incapacity
- ☐ Requires an intervention to prevent impairment/injury Urgent transplantation listing (immediate urgent listing for the transplant), Pump replacement, Pump explant, Pump deactivation without explant or partial explant of components, Breach of integrity of percutaneous lead requiring repair, Operation to repair or replace any internal component of the circulatory support system, Procedure to repair or stent an outflow graft
- ☐ Unknown

Requires an intervention to prevent impairment/injury, check all criteria that apply

- ☐ Urgent transplantation listing (immediate urgent listing for the transplant)
- ☐ Pump replacement (please enter explant form and add new device to record exchange)
- ☐ Pump explant (please complete explant form)
- ☐ Pump deactivation without explant or partial explant of components (please complete explant form and select explant reason: turned off (decommissioned))
- ☐ Breach of integrity of percutaneous lead requiring repair
- ☐ Operation to repair or replace any internal component of the circulatory support system
- ☐ Procedure to repair or stent an outflow graft
- ☐ Unknown

If confirmed device thrombus, check all signs and symptoms and events/interventions that apply

*Note: Para conduit device thrombus represents a special case of device malfunction whereby thrombus obstructs the outflow graft from the pump. This should be classified as major if the thrombus directly interferes with pump function by obstructing flow and if the pump is replaced because of the thrombus. The event should be classified as minor if there is visible thrombus with the preserved function of the pump but requires surgical intervention. In all instances, visual confirmation of the thrombus is sufficient for confirmation. **Note: If a suspected device thrombus event is ultimately confirmed through visual inspection following pump replacement, urgent transplantation or on autopsy following death, the event may be reclassified to confirmed device thrombus.

- ☐ Presence of major hemolysis including elevation of biochemical markers of hemolysis; i.e., lactate dehydrogenase or plasma-free hemoglobin, or clinical evidence of hemolysis; i.e., hemoglobinuria
- ☐ Presence of heart failure not explained by structural heart disease
- ☐ Abnormal pump parameters consistent with diminished pump output/pump efficiency/pump performance.
- ☐ Arterial non-CNS thromboembolism (please complete adverse event form)
- ☐ De-novo need for inotrope therapy
- ☐ Treatment with intravenous anti-coagulation i.e., heparin
- ☐ Intravenous thrombolytics i.e., tPA
- ☐ Intravenous anti-platelet therapy i.e., eptifibatide, tirofiban
- ☐ Unknown

Date of device thrombus onset

MM/DD/YYYY

Please select method of confirmation:
Check all that apply

- ☐ Imaging Study
- ☐ Visual Inspection
- ☐ Manufacturer's Report

The association of the device malfunction / thrombus event should be classified as:

- ○ Patient related i.e. non-adherence with care of device or instructions for use, or its peripheral components, non-adherence with the anti-coagulation regimen, pro-coagulation abnormalities
- ○ Management related i.e. surgical protocol deviation, sub-optimal anti-coagulation
- ○ Device related i.e. detected in a device at explant or on contrast studies or associated with hemolysis or other controller data consistent with device malfunction
- ○ No association identified

Intermacs

Adverse Event

Other Adverse Events

Were there any additional adverse events?
- ○ Yes
- ○ No

Cardiac Arrhythmia
Did a documented arrhythmia result in clinical compromise?
- ○ Yes
- ◉ No
- ○ Unknown

Date of event
MM/DD/YYYY

ST= ○ Unknown

Cardiac arrhythmia, select type
Any documented arrhythmia that results in clinical compromise (e.g., abnormal VAD function [e.g., diminished VAD flow or suction events], oliguria, pre-syncope or syncope, angina, dyspnea), or requires hospitalization or treatment (drug therapy, defibrillation, cardioversion, ICD therapy (e.g., shock or anti-tachycardia pacing) or arrhythmia ablation procedure). Cardiac arrhythmias are classified as 1 of 2 types:
- ○ Sustained ventricular arrhythmia resulting in clinical compromise, or requiring hospitalization or drug treatment, defibrillation, cardioversion, ICD therapy, or arrhythmia ablation procedure
- ○ Sustained supraventricular arrhythmia resulting in clinical compromise, or requiring hospitalization or drug treatment, cardioversion, ICD therapy, or arrhythmia ablation procedure
- ○ Unknown

The association of the cardiac arrhythmia event should be classified as follows:
- ○ Patient related e.g., recurrence of pre-operative arrhythmia non-adherence with medications
- ○ Management related e.g., related to uncorrected electrolyte imbalance, Swan Ganz malposition, secondary to cardiac tamponade
- ○ Device related e.g., pump malfunction, malposition of pump, or inflow cannula
- ○ No association identified

Respiratory Failure
Impairment of respiratory function requiring reintubation, tracheostomy, or the inability to discontinue ventilatory support within 6 days (144 hours) post-VAD implant since last STS Intermacs report/last followup. This excludes intubation for reoperation or temporary intubation for diagnostic or therapeutic procedures.
- ○ Yes
- ◉ No
- ○ Unknown

Date of event
MM/DD/YYYY

ST= ○ Unknown
○ Ongoing

Was this a prolonged intubation (patient intubated greater than 144 hours)?
Cumulative duration of intubation. Any reintubation except procedures should be documented here. Initial implant intubation including any subsequent intubation will be considered the initial procedure intubation. Begin counting intubation hours when patient is in the unit.
- ○ Yes
- ○ No
- ○ Unknown

Number of days of intubation

ST: ○ Unknown
○ Ongoing

Was there a need for reintubation?
Extubated within the first 6 days (144 hours) and then re-intubated. Any reintubation except procedure should be documented here.

- ○ Yes
- ○ No
- ○ Unknown

Date of reintubation
MM/DD/YYYY

ST= ○ Unknown

Was there a need for a tracheostomy?

- ○ Yes
- ○ No
- ○ Unknown

Date of tracheostomy
MM/DD/YYYY

ST= ○ Unknown

The association of the respiratory failure event should be classified as follows:

- ○ Patient related e.g., non-adherence to medical therapy resulting in respiratory failure
- ○ Management related e.g., inadequate diuretic therapy resulting in respiratory dysfunction
- ○ Device related e.g., device failure resulting in respiratory dysfunction
- ○ No association identified

Evidence of Venous Thromboemoblic event

- ☐ Deep Vein thrombosis
- ☐ Pulmonary Embolis
- ☐ Other, specify

☐ Unknown
☑ None

Enter deep vein thrombosis date
MM/DD/YYYY

ST= ○ Unknown

Enter pulmonary embolus date
MM/DD/YYYY

ST= ○ Unknown

Enter other date
MM/DD/YYYY

ST= ○ Unknown

Anticoagulant therapy at time of event

- ☐ Warfarin
- ☐ Heparin
- ☐ Lovenox
- ☐ Aspirin
- ☐ Dipyridamole
- ☐ Clopidogrel (plavix)
- ☐ Argatroban
- ☐ Bivalirudin
- ☐ Fondaparinux
- ☐ Dextran
- ☐ Ticlopidine
- ☐ Hirudin
- ☐ Lepirudin
- ☐ Ximelagatran
- ☐ None
- ☐ Other, specify

Wound Dehiscence
Disruption of the apposed surfaces of a surgical incision, excluding infectious etiology, and requiring surgical repair.

- ○ Yes
- ◉ No
- ○ Unknown

Date of event
MM/DD/YYYY

ST= ○ Unknown

Enter Location

- ○ Sternum
- ○ Driveline Sites
- ○ Site of thoracotomy
- ○ Other, specify

Arterial non-CNS Thromboembolism
An acute systemic arterial perfusion deficit in any non-cerebrovascular organ system due to thromboembolism confirmed by 1 or more of the following: This definition excludes neurologic events. 1) standard clinical and laboratory testing 2) operative findings and 3) autopsy findings

- ○ Yes
- ◉ No
- ○ Unknown

Date of event
MM/DD/YYYY

ST= ○ Unknown

Location

- ○ Pulmonary
- ○ Renal
- ○ Hepatic
- ○ Splenic
- ○ Limb
- ○ Other
- ○ Unknown

Confirmation source

- ○ Standard clinical and laboratory testing
- ○ Operative findings
- ○ Autopsy finding
- ○ Other
- ○ Unknown

Anticoagulant therapy at time of event

- ☐ Warfarin
- ☐ Heparin
- ☐ Lovenox
- ☐ Aspirin
- ☐ Dipyridamole
- ☐ Clopidogrel (plavix)
- ☐ Argatroban
- ☐ Bivalirudin
- ☐ Fondaparinux
- ☐ Dextran
- ☐ Ticlopidine
- ☐ Hirudin
- ☐ Lepirudin
- ☐ Ximelagatran
- ☐ None

Other, specify

Hypertension
New-onset blood pressure elevation greater than or equal to 140 mm Hg systolic or 90 mm Hg diastolic (pulsatile pump) or 110 mm Hg mean pressure (rotary pump).

Yes
No
Unknown

Date of event

ST= Unknown

Hepatic Dysfunction
An increase in any two of the following hepatic laboratory values (total bilirubin, AST, and ALT) to a level greater than 3 times the upper limit of normal for the hospital, beyond 14 days post-implant (or if hepatic dysfunction is the primary cause of death).

Yes
No
Unknown

Date of event
MM/DD/YYYY

ST= Unknown

Total bilirubin measurement

ST: Unknown
Not Done

SGOT // AST measurement

ST: Unknown
Not Done

SGPT // ALT measurement

ST: Unknown
Not Done

Psychiatric Episode
Disturbance in thinking, emotion or behavior that causes substantial impairment in functioning or marked subjective distress and requires intervention. Intervention is the addition of new psychiatric medication, hospitalization, or referral to a mental health professional for treatment. Suicide is included in this definition.

Yes
No
Unknown

Date of event
MM/DD/YYYY

ST= Unknown

The psychiatric event should be classified according to the DSM 5 classification: (select one)

Axis I: Clinical disorders, including anxiety disorders, mood disorders, schizophrenia and other psychotic disorders.
Axis II: Personality disorders and mental retardation.
Axis III: General medical conditions.
Axis IV: Psychosocial and environmental problems.
Unknown

Pericardial Effusion
Did a pericardial effusion that required drainage occur?

Yes
No
Unknown

Date of event

ST= ◯ Unknown

Signs of tamponade

- Yes
- No
- Unknown

Method of drainage

- Surgical intervention
- Cath
- Unknown

Myocardial Infarction

Did a myocardial infarction occur?

- Yes
- No
- Unknown

Date of event

ST= ◯ Unknown

Other events

Did any other major serious adverse event occur?

- Yes
- No
- Unknown

Description

Other Major Serious Adverse Event. An event that causes clinically relevant changes in the patient's health (e.g. cancer).

Date of event

MM/DD/YYYY

ST= ◯Unknown

Intermacs

Adverse Event

Explant

Was device explanted for any reason (includes exchanges or "turned off")?
- ○ Yes
- ○ No

Explant date

ST= ○ Unknown

Device explanted
- ○ LVAD

Did patient suffer major hemolysis related solely to this device?
- ○ Yes
- ○ No
- ○ Unknown

Patient's Home Street Address

ST= ○ Unknown
- ○ Undisclosed

Patient's Home City

ST= ○ Unknown
- ○ Undisclosed

Patient's Home State/Territory/Province
- ○ Alabama
- ○ Alaska
- ○ American Samoa
- ○ Arizona
- ○ Arkansas
- ○ California
- ○ Colorado
- ○ Connecticut
- ○ Delaware
- ○ District of Columbia
- ○ Federated States of Micronesia
- ○ Florida
- ○ Georgia
- ○ Guam
- ○ Hawaii
- ○ Idaho
- ○ Illinois
- ○ Indiana
- ○ Iowa
- ○ Kansas
- ○ Kentucky
- ○ Louisiana
- ○ Maine
- ○ Marshall Islands
- ○ Maryland
- ○ Massachusetts
- ○ Michigan

- ◯ Minnesota
- ◯ Mississippi
- ◯ Missouri
- ◯ Montana
- ◯ Nebraska
- ◯ Nevada
- ◯ New Hampshire
- ◯ New Jersey
- ◯ New Mexico
- ◯ New York
- ◯ North Carolina
- ◯ North Dakota
- ◯ Northern Mariana Islands
- ◯ Ohio
- ◯ Oklahoma
- ◯ Oregon
- ◯ Palau
- ◯ Pennsylvania
- ◯ Puerto Rico
- ◯ Rhode Island
- ◯ South Carolina
- ◯ South Dakota
- ◯ Tennessee
- ◯ Texas
- ◯ Utah
- ◯ Vermont
- ◯ Virgin Islands
- ◯ Virginia
- ◯ Washington
- ◯ West Virginia
- ◯ Wisconsin
- ◯ Wyoming
- ◯ Alberta
- ◯ Ontario
- ◯ Nova Scotia
- ◯ British Columbia
- ◯ Manitoba
- ◯ Quebec
- ◯ New Brunswick
- ◯ Prince Edward Island
- ◯ Saskatchewan
- ◯ Newfoundland and Labrador
- ◯ Unknown

Patient's Home Zip Code

ST= ◯ Unknown

Was the patient on ECMO at any time since implant of their durable LVAD?

- ◯ Yes
- ◯ No
- ◯ Unknown

Total number of days on ECMO

ST= ◯ Unknown

If death or transplant occurred post cessation of MCSD support please complete the 1 year post cessation form.

Explant reason

- ○ Explant - Death
- ○ Explant - Transplanted
- ○ Explant - Exchange
- ○ Explant - No new device
- ○ Turned off (decommissioned)

Explant reasons
Check all that apply

- ☐ Device Malfunction: Elective (Please fill out Device Malfunction/Thrombus form)
- ☐ Device Malfunction: Emergent (Please fill out Device Malfunction/Thrombus form)
- ☐ Device Thrombosis: Elective (Please fill out Device Malfunction/Thrombus form)
- ☐ Device Thrombosis: Emergent (Please fill out Device Malfunction/Thrombus form)
- ☐ Infection: Elective (Please fill out Infection form)
- ☐ Infection: Emergent (Please fill out Infection form)
- ☐ Other

Exchanged Device FDA IDE Trial
If device was exchanged, was the new device part of an FDA IDE trial?

- ○ Yes
- ○ No
- ○ Unknown

Name of FDA IDE Trial

Explant reasons
Check all that apply

- ☐ Recovery
- ☐ Withdrawal of Support
- ☐ Device Malfunction: Elective (Please fill out Device Malfunction/Thrombus form)
- ☐ Device Malfunction: Emergent (Please fill out Device Malfunction/Thrombus form)
- ☐ Device Thrombosis: Elective (Please fill out Device Malfunction/Thrombus form)
- ☐ Device Thrombosis: Emergent (Please fill out Device Malfunction/Thrombus form)
- ☐ Infection: Elective (Please fill out Infection form)
- ☐ Infection: Emergent (Please fill out Infection form)
- ☐ Other

Reasons
Check all that apply

- ☐ Recovery
- ☐ Withdrawal of Support
- ☐ Device Malfunction: Elective (Please fill out Device Malfunction/Thrombus form)
- ☐ Device Malfunction: Emergent (Please fill out Device Malfunction/Thrombus form)
- ☐ Device Thrombosis: Elective (Please fill out Device Malfunction/Thrombus form)
- ☐ Device Thrombosis: Emergent (Please fill out Device Malfunction/Thrombus form)
- ☐ Infection: Elective (Please fill out Infection form)
- ☐ Infection: Emergent (Please fill out Infection form)
- ☐ Other

Evidence of Pump Thrombosis?

- ○ Yes

If yes, please fill out the Device Malfunction/Thrombosis form

- ○ No
- ○ Unknown

Evidence of Pump Thrombosis?

If yes, please fill out the Device Malfunction/Thrombosis form

- ○ Yes
- ○ No
- ○ Unknown

Transplant date

ST= ○Unknown

Waitlist ID

May enter '99999', when the waitlist ID number is not known.

Intermacs

Adverse Event

Death

Did the patient die?
- ○ Yes
- ○ No

Death date
MM/DD/YYYY

ST= ○ Unknown

Patient's Home Street Address

ST= ○ Unknown
○ Undisclosed

Patient's Home City

ST= ○ Unknown
○ Undisclosed

Patient's Home State/Territory/Province
- ○ Alabama
- ○ Alaska
- ○ American Samoa
- ○ Arizona
- ○ Arkansas
- ○ California
- ○ Colorado
- ○ Connecticut
- ○ Delaware
- ○ District of Columbia
- ○ Federated States of Micronesia
- ○ Florida
- ○ Georgia
- ○ Guam
- ○ Hawaii
- ○ Idaho
- ○ Illinois
- ○ Indiana
- ○ Iowa
- ○ Kansas
- ○ Kentucky
- ○ Louisiana
- ○ Maine
- ○ Marshall Islands
- ○ Maryland
- ○ Massachusetts
- ○ Michigan
- ○ Minnesota
- ○ Mississippi
- ○ Missouri
- ○ Montana
- ○ Nebraska
- ○ Nevada
- ○ New Hampshire

- ◯ New Jersey
- ◯ New Mexico
- ◯ New York
- ◯ North Carolina
- ◯ North Dakota
- ◯ Northern Mariana Islands
- ◯ Ohio
- ◯ Oklahoma
- ◯ Oregon
- ◯ Palau
- ◯ Pennsylvania
- ◯ Puerto Rico
- ◯ Rhode Island
- ◯ South Carolina
- ◯ South Dakota
- ◯ Tennessee
- ◯ Texas
- ◯ Utah
- ◯ Vermont
- ◯ Virgin Islands
- ◯ Virginia
- ◯ Washington
- ◯ West Virginia
- ◯ Wisconsin
- ◯ Wyoming
- ◯ Alberta
- ◯ Ontario
- ◯ Nova Scotia
- ◯ British Columbia
- ◯ Manitoba
- ◯ Quebec
- ◯ New Brunswick
- ◯ Prince Edward Island
- ◯ Saskatchewan
- ◯ Newfoundland and Labrador
- ◯ Unknown

Patient's Home Zip Code

ST= ◯ Unknown

Was device functioning normally?

- ◯ Yes
- ◯ No
- ◯ Unknown

Associated Operation

Was there an operation associated with the device malfunction?

- ◯ Yes
- ◯ No
- ◯ Unknown

Was the patient on ECMO at any time since implant of their durable LVAD?

- ◯ Yes
- ◯ No
- ◯ Unknown

Total number of days on ECMO

ST= ◯ Unknown

Post mortem device explant?
- Yes
- No
- Unknown

Did the device go to the manufacturer?
- Yes
- No
- Unknown

Location of death
- In hospital
- Out of hospital
- Unknown

Timing of death
- Expected
- Unexpected
- Unknown

Did COVID-19 contribute to death?
- Yes
- No
- Unknown

Primary cause of death
- ◯ Respiratory: Venous Thromboembolism Event
- ◯ Respiratory: Respiratory Failure
- ◯ Respiratory: COVID-19
- ◯ Respiratory: Pulmonary: Other, specify
- ◯ Circulatory: Arterial Non-CNS Thromboembolism
- ◯ Circulatory: Myocardial Infarction
- ◯ Circulatory: Myocardial Rupture
- ◯ Circulatory: Ruptured Aortic aneurysm
- ◯ Circulatory: Right Heart Failure
- ◯ Circulatory: Major Bleeding
- ◯ Circulatory: Cardiac Arrhythmia
- ◯ Circulatory: Hemolysis
- ◯ Circulatory: Hypertension
- ◯ Circulatory: Other, Specify
- ◯ Circulatory: Sudden unexplained death
- ◯ Circulatory: CHF
- ◯ Circulatory: Heart Disease
- ◯ Circulatory: End Stage Cardiomyopathy
- ◯ Circulatory: End Stage Ischemic Cardiomyopathy
- ◯ Circulatory: Pericardial Fluid Collection (effusion)
- ◯ Digestive (Intestinal or GI/GU): Hepatic Dysfunction
- ◯ Digestive (Intestinal or GI/GU): Renal Dysfunction
- ◯ Digestive (Intestinal or GI/GU): GI Disorder
- ◯ Digestive (Intestinal or GI/GU): Fluid/Electrolyte Disorder
- ◯ Digestive (Intestinal or GI/GU): Pancreatitis
- ◯ Nervous System: Neurological Dysfunction
- ◯ Psychiatric Episode/Suicide
- ◯ Major Infection
- ◯ Device Malfunction
- ◯ Multiple System Organ Failure (MSOF)
- ◯ Withdrawal of Support, specify
- ◯ Cancer
- ◯ Wound Dehiscence
- ◯ Trauma/accident, specify
- ◯ Endocrine
- ◯ Hematological
- ◯ Other, specify

Select type of cancer

- ○ CNS
- ○ GI
- ○ Lymph
- ○ ENT
- ○ Pulmonary
- ○ Renal
- ○ Breast
- ○ Reproductive
- ○ Skin
- ○ Other
- ○ Unknown

Specify support withdrawn

Specify

Intermacs

Adverse Event

Extracorporeal / Paracorporeal Pump Change

Exchange of extracorporeal/paracorporeal pumps and pump components. Please use this form when only extracorporeal/paracorporeal pump components (i.e. cannulaes, and pumps) are exchanged. If components/pump are exchanged in the surgery suite and/or the pump is exchanged to a different device brand (i.e Maquet to Berlin Heart) then please fill out the device explant form and enter a new device and do not fill out this form.

Was there an extracorporeal pump/component exchange?
- ○ Yes
- ○ No

Pump/Component Exchange Date:
Enter exchange date in MMDDYYYY format.

ST= ○ Unknown

Device Type:
- ○ LVAD
- ○ RVAD
- ○ BIVAD

Component Exchanged:
Select all that apply. Note: not all components are applicable to all devices.
- ☐ Pump
- ☐ Inflow Cannula Parts (not requiring OR visit)
- ☐ Outflow Cannula Parts (not requiring OR visit)
- ☐ Driving Tube Connector
- ☐ Other, specify

RVAD Component Exchanged:
Select all that apply. Note: not all components are applicable to all devices.
- ☐ Pump
- ☐ Inflow Cannula Parts (not requiring OR visit)
- ☐ Outflow Cannula Parts (not requiring OR visit)
- ☐ Driving Tube Connector
- ☐ Other, specify

Reason for Exchange
Select one of the following.
- ○ Thrombus NOT associated with hemolysis
- ○ Change in hemodynamics
- ○ Clinical status
- ○ Device parameters (please enter Device Malfunction Form)
- ○ Upsizing device because of patient growth status
- ○ Other, specify

Intermacs

Adverse Event

Hemolysis

Must be within 30 days of event

Was there a hemolysis adverse event?

- ○ Yes
- ○ No

If yes, select type

- ○ Minor Hemolysis A plasma-free hemoglobin value greater than 20 mg/dl or a serum LDH level greater than two and one-half times the upper limits of the normal range at the implanting center occurring after the first 72 hours post-implant in the absence of clinical symptoms or findings of hemolysis or abnormal pump function (see Major Hemolysis for a list of symptoms and findings) and thought not attributable to laboratory error.
- ○ Major Hemolysis A plasma-free hemoglobin value greater than 20 mg/dl or a serum LDH level greater than two and one-half times the upper limits of the normal range at the implanting center occurring after the first 72 hours post-implant and associated with clinical symptoms or findings of hemolysis or abnormal pump function.

If major hemolysis, select condition

Major Hemolysis requires the presence of at least one of these conditions Note: Isolated LDH elevations should not be reported as hemolysis if attributable to laboratory error, hepatic or pulmonary dysfunction. If suspected, confirmatory testing of LDH, LDH isoenzymes and plasma-free hemoglobin within 24 hours should be obtained to rule out laboratory error. All causes of hemolysis should be reported regardless of whether they are thought attributable to the device or not.

- ☐ Hemoglobinuria tea-colored urine
- ☐ Anemia hematocrit <= 25 or hemoglobin <= 8 not explained by chronic illness or usual post-VAD state
- ☐ Hyperbilirubinemia total bilirubin above 2 mg/dl, with predominately indirect component
- ☐ Pump malfunction and/or abnormal pump parameters as per section on device malfunction

The association of the hemolysis event should be classified as (select one):

- ○ Patient related e.g., hematologic abnormalities
- ○ Management related e.g., drug related, secondary pump or IABP related, pump malposition
- ○ Device related e.g., related to pump thrombosis or device malfunction
- ○ No association identified

Date of Event

MM/DD/YYYY

ST= ○ Unknown

Please enter the peak Plasma-free hemoglobin (PFH).

ST: ○ Unknown

○ Not Done

What is your hospital's upper limit of the normal range for peak PFH?

ST: ○ Unknown

○ Not Done

Please enter the peak serum lactate dehydrogenase (LDH)

ST: ○ Unknown

○ Not Done

What is your hospital's upper limit of the normal range of LDH?	ST: ○ Unknown ○ Not Done
Min. HCT	ST: ○ Unknown ○ Not Done
Max. HCT	ST: ○ Unknown ○ Not Done
Min. HGB	ST: ○ Unknown ○ Not Done
Max. HGB	ST: ○ Unknown ○ Not Done
Highest Total Bilirubin	ST: ○ Unknown ○Not Done

Intermacs

Adverse Event

Right Heart Failure

Was there a Right Heart Failure Adverse Event?
- ○ Yes
- ○ No

Date of Diagnosis
MM/DD/YYYY

ST= ○Unknown

If yes, select type
- ○ Early Acute RHF Need for implantation of a temporary or durable RVAD (including ECMO) concomitant with LVAD implantation (RVAD implanted before the patient leaving the operating room). REMINDER: Only check this option if the RVAD was implanted during the LVAD implantation procedure
- ○ Early post-implant RHF NOTE: Does NOT include RVAD/BiVAD placed during LVAD implantation
- ○ Late RHF

Early post-implant RHF: Select category
- ○ Need for implantation of a temporary or durable RVAD (including ECMO) within 30 days following LVAD implantation for any duration of time
- ○ Initiation or continuation of inotropic or vasopressor support or inhaled nitric oxide after 14 days following LVAD implantation or having to initiate this support within 30 days of implant for a duration of at least 14 days
- ○ Death occurring in patients within 30 days of LVAD implant who have not received an RVAD but who remain on inotropes or vasopressors at the time of death and meet criteria for the diagnosis of RHF The contribution of early post-implant RHF to the death (primary or secondary) will be made by the clinical care team.

If late RHF, select category
- ○ Need for implantation of an RVAD (including ECMO) greater than 30 days after an LVAD implantation This may occur within the index hospitalization for LVAD implant or during subsequent rehospitalization for any diagnosis which resulted in a need for temporary or permanent right-sided mechanical assist devices
- ○ Hospitalization that occurs greater than 30 days post-implant and which requires intravenous diuretics or inotropic support for at least 72 hours

The primary diagnosis of right heart failure is made by the presence of at least two of the following clinical findings or is associated with at least one of the following manifestations

Initiation or continuation of inotropic or vasopressor support clinical findings
Check all that are present
- ☐ Ascites
- ☐ Functionally limiting peripheral edema >= 2
- ☐ Elevated estimated jugular venous pressure (>= 6cm) at least half way up the neck in an upright patient or hepatomegaly (> 3cm below costal margin)
- ☐ Elevated measured central venous pressure (CVP) or right atrial pressure (RAP) (>= 16mmHg)
- ☐ Other, Specify

Initiation or continuation of inotropic or vasopressor support manifestations
Check all that are present
- ☐ Renal failure with serum creatinine > 2x baseline values
- ☐ Liver injury with an elevation of at least 2x upper limit normal in AST/ALT or total bilirubin > 2.0
- ☐ SvO2 < 50%
- ☐ Cardiac index < 2.2 liter/min/m2

- [ ] Reduction in pump flow of > 30% from the previous baseline in the absence of mechanical causes such as cardiac tamponade or tension pneumothorax
- [ ] Elevated lactate > 3.0 mmol/liter
- [ ] Other, Specify

Death clinical findings
Check all that are present

- [ ] Ascites
- [ ] Functionally limiting peripheral edema >= 2
- [ ] Elevated estimated jugular venous pressure (>= 6cm) at least half way up the neck in an upright patient or hepatomegaly (> 3cm below costal margin)
- [ ] Elevated measured central venous pressure (CVP) or right atrial pressure (RAP) (>= 16mmHg)
- [ ] Other, Specify

Death manifestations
Check all that are present

- [ ] Renal failure with serum creatinine > 2x baseline values
- [ ] Liver injury with an elevation of at least 2x upper limit normal in AST/ALT or total bilirubin > 2.0
- [ ] SvO2 < 50%
- [ ] Cardiac index < 2.2 liter/min/m2
- [ ] Reduction in pump flow of > 30% from the previous baseline in the absence of mechanical causes such as cardiac tamponade or tension pneumothorax
- [ ] Elevated lactate > 3.0 mmol/liter
- [ ] Other, Specify

Hospitalization clinical findings
Check all that are present

- [ ] Ascites
- [ ] Functionally limiting peripheral edema >= 2
- [ ] Elevated estimated jugular venous pressure (>= 6cm) at least half way up the neck in an upright patient or hepatomegaly (>3 cm below costal margin)
- [ ] Elevated measured central venous pressure (CVP) or right atrial pressure (RAP) (>= 16mmHg)
- [ ] Other, Specify

Hospitalization manifestations
Check all that are present

- [ ] Renal failure with serum creatinine > 2x baseline values
- [ ] Liver injury with an elevation of at least 2 x upper limit normal in AST/ALT or total bilirubin > 2.0
- [ ] SvO2 < 50%
- [ ] Cardiac index < 2.2 liter/min/m2
- [ ] Reduction in pump flow of > 30% from the previous baseline in the absence of mechanical causes such as cardiac tamponade or tension pneumothorax
- [ ] Elevated lactate > 3.0 mmol/liter
- [ ] Other, Specify

The association of the RHF event should be classified as

- ( ) Patient related e.g., pre-implant RHF, volume overload secondary to non-adherence with medical management, severe aortic regurgitation, cardiorenal syndrome, arrhythmia induced, pulmonary disease, elevated pulmonary vascular resistance
- ( ) Management related e.g., related to implant surgery, volume overload, inotropic agent withdrawal

- Device related e.g., associated with Pump malfunction, outflow graft compromise
- No association identified

Intermacs

Adverse Event

Renal Dysfunction

If the patient has acute renal failure diagnosis prior to the implant, do not enter an acute renal failure ae for that patient. If the acute renal failure escalates to chronic after the VAD implant, then document as chronic renal failure

Was there a Renal Dysfunction adverse event?
- ○ Yes
- ○ No

If yes, select type
- ○ Acute Renal Dysfunction
- ○ Chronic Renal Dysfunction An increase in serum creatinine of 2 mg/dl or greater above baseline, or requirement for renal replacement therapy, either of which is sustained for at least 90 days

If acute, select stage
- ○ Stage 1 Increase in serum creatinine to 150% to 199% (1.5 to 1.99x increase compared with baseline) or increase of > 0.3 mg/dl (> 26.4 mmol/liter) or urine output < 0.5 ml/kg/h for > 6 but < 12 hours
- ○ Stage 2 Increase in serum creatinine to 200% to 299% (2.0 to 2.99x increase compared with baseline) or urine output < 0.5 ml/kg/h for > 12 but < 24 hours
- ○ Stage 3 Increase in serum creatinine to > 300% (> 3x increase compared with baseline) or serum creatinine of > 4.0 mg/dl (> 354 mmol/liter) with an acute increase of at least 0.5 mg/dl (44 mmol/liter) or urine output < 0.3 ml/kg/h for > 24 hours or anuria for > 12 hours or need for renal replacement therapy (includes dialysis or ultrafiltration) regardless of above criteria

If stage 1, Select all that apply
- ☐ Increase in serum creatinine to 150% to 199% (1.5 to 1.99x increase compared with baseline)
- ☐ Increase of > 0.3 mg/dl (> 26.4 mmol/liter)
- ☐ Urine output < 0.5 ml/kg/h for > 6 but < 12 hours

If stage 2, Select all that apply
- ☐ Increase in serum creatinine from 200% to 299% (2.0 to 2.99x increase compared with baseline)
- ☐ Urine output < 0.5 ml/kg/h for > 12 but < 24 hours

If stage 3, Select all that apply
- ☐ Increase in serum creatinine to > 300% (> 3x increase compared with baseline)
- ☐ Serum creatinine of > 4.0 mg/dl (>354 mmol/liter) with an acute increase of at least 0.5 mg/dl (44 mmol/liter)
- ☐ Urine output <0.3 ml/kg/h for >24 hours
- ☐ Anuria for >12 hours
- ☐ Need for renal replacement therapy (includes dialysis or ultrafiltration) regardless of above criteria

Date of event
MM/DD/YYYY

ST= ○Unknown

The association of the renal dysfunction event should be classified as follows	○ Patient related e.g., non-adherence to medical therapy resulting in renal dysfunction ○ Management related e.g., overprescribing of diuretic therapy or administration of renal toxic drugs or contrast agents that result in renal dysfunction ○ Device related e.g., device failure resulting in renal dysfunction ○ No association identified