

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 - Repair (no valve closure)
- Aortic Valve Surgery - Repair with valve closure
- Aortic Valve Surgery - Replacement - Biological
- Aortic Valve Surgery - Replacement - Mechanical
- 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
- Pulmonary Valve Surgery - Repair
- Pulmonary Valve Surgery – Replacement - Biological
- Pulmonary Valve Surgery – Replacement - Mechanical
- Unknown
- Other, specify

Type of procedure (non cardiac surgical procedure)

Other procedure

- Intubation and Vent support
- Dialysis
- Bronchoscopy
- Other, specify

Type of Invasive Cardiac Procedure (Other than Heart Cath)

Enter PA systolic pressure mmHgST= Unknown Not Done**Enter PA diastolic pressure** mmHgST= Unknown Not Done**Enter PCW pressure** mmHgST= Unknown Not Done**Enter Cardiac output** L/minST= Unknown Not Done

Clinical Observations

Systolic blood pressure

(millimeters of mercury)

 mmHgST= Unknown Not done**Diastolic blood pressure**

(millimeters of mercury)

 mmHgST= Unknown Not done**Doppler Opening Pressure**

Record the pressure on the BP cuff at the time of sound on the Doppler as the cuff is released and this is the Doppler opening pressure which may correspond to the MAP.

ST= Unknown Not done Not applicable

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

 Yes No Unknown

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

If yes, you may enter either the Modified Rankin Scale and/or the NIH Stroke Scale.

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

ST= Not Documented
 Not Done

NIH Stroke Scale

Please [click here](#) for further instruction on administering the NIHSS in Appendix I.

- 0: No Stroke
 - 1-4: Minor Stroke
 - 5-15: Moderate Stroke
 - 16-20: Moderate to Severe Stroke
 - 21-42: Severe Stroke
- ST= Not Documented
 Not Done

Intermacs

Adverse Event

Infection

Was there a major infection?

- Yes
 No
 Unknown

Date of onset

MM/DD/YYYY

ST= Unknown**Did this infection contribute to death?**

- Yes
 No
 Unknown

Location of patient

- In hospital
 Out of hospital
 Unknown

Location of infection

Check all that apply

- Pump / related - Drive Line
 Pump / related - Exit Cannula
 Pump / related - Pump Pocket
 Pump / related - Pump Interior
 Positive Blood cultures
 Line Sepsis
 Pulmonary
 Urinary Tract
 Mediastinum
 Peripheral Wound
 GI
 Unknown
 Other, specify

Type of infection

- Bacterial
 Fungal
 Viral
 Protozoan
 Unknown

Was drug therapy an intervention for this AE?

- Yes
 No
 Unknown

If yes, what was the route?

- IV
 Oral
 Topical
 Unknown

Was surgery an intervention for this AE?

- Yes
 No
 Unknown

Is this a Device Related Event?

If this event was caused by the device then please check yes, only complete a device malfunction form if it meets the device malfunction definition.

- Yes
 No

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 (select all that apply):

- Hydroxychloroquine
 Azithromycin
 Immunoglobulin
 Anti-viral therapy
 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

Date of bleeding episode onset

MM/DD/YYYY

ST= Unknown**Location of patient**

- In hospital
 Out of hospital
 Unknown

Did the major bleeding episode result in one or more of the following?

Check all that apply

- Episode resulted in Death
 Episode resulted in re-operation
 Episode resulted in rehospitalization
 Episode resulted in transfusion

Total units PRBCST= Unknown**Date of first transfusion for this episode**

MM/DD/YYYY

ST= Unknown**Source/cause/location of bleeding**

Check all that apply

- Mediastinal: chest wall
 Mediastinal: outflow-aorta anastomosis
 Mediastinal: outflow conduit
 Mediastinal: inflow conduit
 Mediastinal: aortic-venous cannulation site
 Mediastinal: coagulopathy with no surgical site
 Mediastinal: other surgical site
 Pump pocket
 Mediastinal: Unspecified
 Pleural space
 Intra-abdominal
 Retroperitoneal
 Pulmonary
 Device anastomosis
 Urinary 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

INR

ST= Unknown
 Not Done

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

Is this a Device Related Event?

If this event was caused by the device then please check yes, only complete a device malfunction form if it meets the device malfunction definition.

- Yes
- No

Intermacs

Adverse Event

Neurological Dysfunction

Was there a neurological dysfunction?

- Yes
 No
 Unknown

Date of onset

MM/DD/YYYY

ST= Unknown

Location of patient

- In hospital
 Out of hospital
 Unknown

Neurological dysfunction categories

- TIA
 Confusion
 CVA
 Seizure
 Encephalopathy

Type of CVA

- Ischemic / Embolism
 Hemorrhagic
 Other

Stroke severity

- Left sided weakness
 Right sided weakness
 Left sided paralysis
 Right sided paralysis
 Speech deficit
 Altered mental status
 Coma
 Other, specify

Is this a device related event?

If this event was caused by the device then please check yes, only complete a device malfunction form if it meets the device malfunction definition.

- Yes
 No

Seizure Type

- Generalized
 Focal

Encephalopathy type

- Metabolic
 Anoxic
 Traumatic
 Other

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

- Yes
 No
 Unknown

Location of CNS event

Check all that apply

- Right hemisphere: frontal
- Right hemisphere: temporal
- Right hemisphere: occipital
- Right hemisphere: parietal
- Right hemisphere: unspecified
- Left hemisphere: frontal
- Left hemisphere: temporal
- Left hemisphere: occipital
- Left hemisphere: parietal
- Left hemisphere: unspecified
- Bilateral: frontal
- Bilateral: temporal
- Bilateral: occipital
- Bilateral: parietal
- Occipital
- Brain stem
- Cerebellar
- Thalamic
- Unknown
- Other, specify

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

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

- Yes
- No
- Unknown

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

If yes, you may enter either the Modified Rankin Scale and/or the NIH Stroke Scale.

Modified Rankin Scale

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NIH Stroke Scale

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- Not Done

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Adverse Event

Device Malf/Failure and/or Pump Thrombus

Was there a device malfunction / failure and / or a pump thrombus?

- Yes
 No
 Unknown

Date of 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.

Thrombus Event

Did the patient experience a thrombus event (suspected or confirmed)?

- Yes
 No
 Unknown

Was the suspected or confirmed thrombus associated with one or more of the following signs or symptoms?

Check all that apply

- Hemolysis
 Heart Failure
 Abnormal Pump Parameters
 Stroke
 TIA
 Arterial Non-CNS Thromboembolism
 None
 Other, Specify

Did the patient have one or more of the following?

Check all that apply

- Treatment with intravenous anticoagulation (e.g. heparin)
 Intravenous thrombolytic (e.g. TPA)
 Intravenous antiplatelet therapy (e.g. eptifibatide)
 Other, Specify

Was the thrombus event confirmed?

- Yes
 No
 Unknown

Please select method of confirmation:

Check all that apply

- Imaging Study
 Visual Inspection
 Manufacturer's Report

Was there a device Malfunction?

Did the patient experience a device malfunction (failure of one or more of the components of the MCS D system which either directly causes or could potentially induce a state of inadequate circulatory support or death)?

- Yes
 No
 Unknown

Please select all of the components that apply

Pump

- Yes
 No

Pump Component(s)

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

Controller

- Yes
 No

Controller

- 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)

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
-

Outcomes of Device Adverse Event

Malfunction / Failure and/or Pump Thrombus

Patient Outcome

Check all that apply

- Death
 - Serious Injury
 - Urgent Transplantation
 - Explant Without Replacement
 - Exchange
 - Breach of Integrity of Drive Line that Required Repair
 - Other Surgical Procedure
 - None of the Above
-

Causative or contributing factors to the Device Malfunction

Check all that apply

- Patient Accident
 - Patient Non-Compliance
 - Sub Therapeutic Anticoagulation
 - Prothrombotic States
 - End of Component Expected Life
 - Technical and/or Procedural Issues (e.g. cannula or graft malposition or kinking)
 - No Cause Identified
-

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Adverse Event

Additional Adverse Events

Were there any additional adverse events?

- Yes
 No

Cardiac Arrhythmia

Did a documented arrhythmia result in clinical compromise?

- Yes
 No
 Unknown

Event Date

ST= Unknown

Type of cardiac arrhythmia

- Sustained ventricular arrhythmia requiring defibrillation or cardioversion
 Sustained supraventricular arrhythmia requiring drug treatment or cardioversion
 Unknown

Pericardial Effusion

Did a pericardial effusion that required drainage occur?

- Yes
 No
 Unknown

Event Date

MM/DD/YYYY

ST= Unknown

Signs of tamponade

- Yes
 No
 Unknown

Method of drainage

- Surgical intervention
 Cath
 Unknown

Hepatic Dysfunction

Did Clinical evidence of liver dysfunction occur beyond 14 days post-implant?

- Yes
 No
 Unknown

Total bilirubin measurement

 mg/dL

ST= Unknown
 Not Done

SGOT // AST measurement

 u/L

ST= Unknown
 Not Done

SGPT // ALT measurement

 u/L

ST= Unknown
 Not Done

Event Date

MM/DD/YYYY

ST= Unknown**Myocardial Infarction**

Did a myocardial infarction occur?

- Yes
 No
 Unknown

Event Date

MM/DD/YYYY

ST= Unknown**Psychiatric Episode**

Did a disturbance in thinking, emotion or behaviour that required intervention occur in patient?

- Yes
 No
 Unknown

Event Date

MM/DD/YYYY

ST= Unknown**Renal Dysfunction**

Did renal dysfunction (by definition) occur?

- Yes
 No
 Unknown

Event Date

MM/DD/YYYY

ST= Unknown**Dialysis duration**

days

- ST= Unknown
 Not Done
 Ongoing

Peak creatinine measurement

mg/dL

- ST= Unknown
 Not Done

Respiratory Failure

Did an impairment of respiratory function requiring re-intubation, tracheostomy, or the inability to discontinue ventilator support within six days (144 hours) post-VAD implant occur? (Intubation for re-operation or temporary intubation for procedures is excluded).

- Yes
 No
 Unknown

Event Date

MM/DD/YYYY

- ST= Unknown
 Ongoing

Intubation duration

days

- ST= Unknown
 Ongoing

Was a tracheotomy performed?

- Yes
 No
 Unknown

Arterial Non-CNS Thromboembolism

Did an acute perfusion deficit in any non-cerebrovascular organ system occur?

- Yes
 No
 Unknown

Date
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

Check all that apply

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

Venous Thromboembolism Event

Evidence of Venous Thromboembolic event
Check all that apply

- Deep Vein thrombosis
 Pulmonary Embolism
 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**

Check all that apply

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

Wound Dehiscence

Did a disruption of the apposed surfaces of surgical incision require surgical repair?

- Yes
 No
 Unknown

Date

MM/DD/YYYY

ST= Unknown**Enter location:**

- Sternum
 Driveline Sites
 Site of thoracotomy
 Other, specify

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).

Event Date

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

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?

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

- Yes
- 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.

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Adverse Event

Death

Did the patient die? Yes
 No

Death date

MM/DD/YYYY

ST= Unknown

Was device functioning normally? Yes
 No
 Unknown

Associated Operation

Was there an operation associated with the device malfunction?

Yes
 No
 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