

# 1 Month Followup - Intermacs

## Followup Status

Select one of the following

- Inpatient  
 Outpatient  
 Other Facility  
 Unable to obtain follow-up information

Follow-up date

Facility Type

- Nursing Home/Assisted Care  
 Hospice  
 Another hospital  
 Rehabilitation Facility  
 Unknown

State reason why you are unable to obtain follow-up information

- Patient didn't come to clinic  
 Not able to contact patient  
 Not addressed by site

Was patient intubated since implant? (This includes all time since last follow-up.)

- Yes  
 No  
 Unknown

Was patient on dialysis since implant? (This includes all time since last follow-up.)

- Yes  
 No  
 Unknown

## Pump Change

Pump Exchange

- Yes  
 No  
 Unknown

Pump Exchange Reason

- Thrombus not associated with hemolysis  
 Change in hemodynamics  
 Clinical status  
 Device parameters (please enter Device Malfunction Form)  
 Upsizing device because of patient growth status

Was there a Console Change? (For TAH or Berlin Heart Consoles)

- Yes  
 No  
 Unknown

Date of console change

ST=  Unknown

Original Console Name

New Console Name

**Medical Condition**

NYHA Class

- Class I: No limitation of physical activity; physical activity does not cause fatigue, palpitation or shortness of breath.
- Class II: Slight limitation of physical activity; comfortable at rest, but ordinary physical activity results in fatigue, palpitations or shortness of breath.
- Class III: Marked limitation of physical activity; comfortable at rest, but less than ordinary activity causes fatigue, palpitation or shortness of breath.
- Class IV: Unable to carry on minimal physical activity without discomfort; symptoms may be present at rest.
- Unknown

**ZONES****Hemolysis Zone**

Please enter the peak Plasma-free hemoglobin (PFH) since the last visit:

ST=  Unknown  
 Not Done

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

ST=  Unknown  
 Not Done

Please enter the peak serum lactate dehydrogenase (LDH) since the last visit:

ST=  Unknown  
 Not Done

What is your hospital's upper limit of the normal range of LDH?

ST=  Unknown  
 Not Done

Enter the Maximum and Minimum HCT or HGB since the last visit.

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 since the last visit:**ST=  Unknown Not Done**Has the following been present at any time since the last visit?****Physical Findings:****Hemoglobinuria (Tea-Colored Urine)?** Yes No Unknown**Pump malfunction and/or abnormal pump parameters?** Yes No Unknown**Right Heart Failure Zone****Clinical Findings – Since the last visit.****CVP or RAP > 16 mmHg?** Yes No Unknown Not Done**Dilated Vena Cava with absence of Inspiratory Variation by Echo (If absence of Inspiratory Variation is not documented, Check No)?** Yes No Unknown Not Done**Clinical findings of elevated jugular venous distension at least half way up the neck in an upright patient (If  $\geq 6$  cm, Check Yes)?** Yes No Unknown**Peripheral Edema (If  $\geq 2$ , Check Yes)?** Yes No Unknown**Ascites?** Yes No Unknown**Has the patient been on Inotropes since the last visit?** Yes No Unknown

If yes, select all that apply:

- Dopamine
- Dobutamine
- Milrinone
- Isoproterenol
- Epinephrine
- Norepinephrine
- Levosimendan
- Unknown

Nesiritide?

- Yes
- No
- Unknown

Did the patient have an RVAD implanted since the last follow-up?

- Yes
- No
- Unknown

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

- Yes
- No
- Unknown

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

**Modified Rankin Scale**

- 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**

- 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

# 1 Month Followup - Intermacs

## Hemodynamics

### General Hemodynamics

**Heart rate**  beats per min

ST=  Unknown  
 Not done

**Systolic blood pressure**  mmHg

ST=  Unknown  
 Not done

**Diastolic blood pressure**  mmHg

ST=  Unknown  
 Not done

**Doppler Opening Pressure**

ST=  Unknown  
 Not done  
 Not applicable

**ECG rhythm**

- Sinus  
 Atrial fibrillation  
 Atrial Flutter  
 Paced: Atrial pacing  
 Paced: Ventricular pacing  
 Paced: Atrial and ventricular pacing  
 Not done  
 Unknown  
 Other, specify

**Weight**  lbs

kg

ST=  Unknown  
 Not done

### Echo Findings

**Mitral regurgitation**

- 0 (none)  
 1 (mild)  
 2 (moderate)  
 3 (severe)  
 Not Recorded or Not Documented

**Tricuspid regurgitation**

- 0 (none)  
 1 (mild)

- 2 (moderate)
- 3 (severe)
- Not Recorded or Not Documented

**Aortic regurgitation**

- 0 (none)
- 1 (mild)
- 2 (moderate)
- 3 (severe)
- Not Recorded or Not Documented

**LVEF**

- > 50 (normal)
- 40-49 (mild)
- 30-39 (moderate)
- 20-29 (moderate/severe)
- < 20 (severe)
- Not Recorded or Not Documented
- Unknown

If a number or range is available, check the number range that best applies. For example, a reported ejection fraction of 30-35 would be entered as 30-40. Occasionally the LVEF may be described only as "left ventricular function" or "systolic function" in words. "Mild impairment, mildly reduced, or mild decrease" would all be characterized as "mild".

**LVEDD**
 cm

 ST=  Not Recorded or Not Documented
**RVEF**

- Normal
- Mild
- Moderate
- Severe
- Not Done
- Not Applicable
- Unknown

RV Function is generally NOT measured in numbers, as it is difficult to quantify. It may be described as "right ventricular function" or "right ventricular contractility". "Mild impairment, mildly reduced, or mild decrease" would all be characterized as "mild". Again, mild-moderate would be recorded as moderate, and moderate-severe would be recorded as "severe".

**Swan Hemodynamics****Pulmonary artery systolic pressure**
 mmHg

 ST=  Unknown  
 Not done
**Pulmonary artery diastolic pressure**
 mmHg

 ST=  Unknown  
 Not done
**Mean RA Pressure**
 mmHg

 ST=  Unknown  
 Not done

**Central venous pressure (CVP)** mmHgST=  Unknown  
 Not done**Mean Pulmonary artery wedge pressure** mmHgST=  Unknown  
 Not done**Cardiac Index** L/min/M<sup>2</sup> (by Swan)ST=  Unknown  
 Not done**Was Cardiac Index Measured by Fick or Thermodilution?** Yes  
 No  
 Unknown**Choose Method** Fick  
 Thermodilution**Cardiac output** Liters/minST=  Unknown  
 Not done**Was Cardiac Output Measured by Fick or Thermodilution?** Yes  
 No  
 Unknown**Choose Method** Fick  
 Thermodilution

# 1 Month Followup - Intermacs

## Medications

**Hydralazine**  Yes  
 No  
 Unknown

**Calcium channel blockers**  Yes  
 No  
 Unknown

**Angiotensin receptor blocker drug**  Yes  
 No  
 Unknown

**Amiodarone**  Yes  
 No  
 Unknown

**ACE inhibitors**  Yes  
 No  
 Unknown

**Thrombolytic**  Yes  
 No  
 Unknown

**Beta-blockers**  Yes  
 No  
 Unknown

**Aldosterone antagonist**  Yes  
 No  
 Unknown

**Low molecular weight heparin  
(Lovenox, Fragmin, Innohep)**  Yes  
 No  
 Unknown

**UFH: Unfractionated Heparin**  Yes  
 No  
 Unknown

**Warfarin (coumadin)**  Yes  
 No  
 Unknown

**Arixtra (fondaparinux)**  Yes  
 No  
 Unknown



**Antiplatelet therapy drug**

- Yes
- No
- Unknown

**Select drug(s)**

- Aspirin
- Dextran
- Dipyridamole
- Clopidogrel
- Ticlopidine
- Unknown
- Other, specify

---

**Nitric oxide**

- Yes
- No
- Unknown

---

**Phosphodiesterase inhibitor**

- Yes
- No
- Unknown

---

**Digoxin**

- Yes
- No
- Unknown

---

**Loop diuretics**

- Yes
- No
- Unknown

**If yes, enter dosage:**

 mg/day

ST=  Unknown

**Type of Loop Diuretic:**

- Furosemide
- Torsemide
- Bumetanide
- Other

# 1 Month Followup - Intermacs

## Laboratory

**Sodium**  mEq/L  
 mmol/L  
 ST=  Unknown  
 Not done

**Potassium**  mEq/L  
 mmol/L  
 ST=  Unknown  
 Not done

**Blood urea nitrogen**  mg/dL  
 mmol/L  
 ST=  Unknown  
 Not done

**Creatinine**  mg/dL  
 umol/L  
 ST=  Unknown  
 Not done

**SGPT/ALT (alanine aminotransferase/ALT)**  u/L  
 ST=  Unknown  
 Not done

**SGOT/AST (aspartate aminotransferase/AST)**  u/L  
 ST=  Unknown  
 Not done

**LDH**  units/L, U/L, ukat/L  
 ST=  Unknown  
 Not done

**Total bilirubin**  mg/dL  
 umol/L  
 ST=  Unknown  
 Not done

**Bilirubin direct**  mg/dL  
 umol/L  
 ST=  Unknown  
 Not Done

**Bilirubin indirect** mg/dL  
 umol/LST=  Unknown  
 Not Done**Albumin** g/dL  
 g/LST=  Unknown  
 Not done**Pre-albumin** mg/dL  
 mg/LST=  Unknown  
 Not done**Total Cholesterol** mg/dL  
 mmol/LST=  < 50 mg/dL  
 Unknown  
 Not done**Brain natriuretic peptide BNP** pg/ml  
 ng/LST=  > 7500 pg/mL  
 Unknown  
 Not done**NT pro brain natriuretic peptide Pro-BNP** pg/ml  
 ng/LST=  Unknown  
 Not done**White blood cell count** x10<sup>3</sup>/uL  
 x10<sup>9</sup>/LST=  Unknown  
 Not done**Reticulocyte count** %ST=  Unknown  
 Not Done**Hemoglobin** g/dL  
 g/L  
 mmol/LST=  Unknown  
 Not done

**Hemoglobin A1C** % mmol/mol**Estimated Average Glucose (eAG):** mg/dL mmol/LST=  Unknown Not Done**Platelets** x10<sup>3</sup>/uL x10<sup>9</sup>/LST=  Unknown Not done**INR** international unitsST=  Unknown Not done**Plasma-free hemoglobin** mg/dL g/LST=  Unknown Not Done**Positive antiheparin/platelet antibody (HIT)** Yes No Unknown**If Yes, are they on direct thrombin inhibitors** Yes No Unknown**If Yes, Enter Drugs:** Plavix Heparin Coumadin Direct thrombin inhibitors (ex: arg, lip, val...) Aspirin Dipyridamole**Was a TEG done?** Yes No Unknown**ThrombElastoGraph Hemostasis System (TEG) profile, MA k** max amplitude in kaolinST=  Unknown Not Done**ThrombElastoGraph Hemostasis System (TEG) profile, R k** reaction time in kaolinST=  Unknown Not Done

**ThrombElastoGraph  
HemostasisSystem (TEG) profile, R  
h**

reaction time w/heparinase

- ST=  Unknown  
 Not Done

**CRP or hs-CRP**

mg/dL

- ST=  Unknown  
 Not done

**Lupus Anticoagulant**

- Positive  
 Negative  
 Unknown

**Uric acid**

mg/dL

umol/L

- ST=  <1 mg/dL  
 Unknown  
 Not done

# 1 Week Followup - Intermacs

## Followup Status (1 Week Followup (+/- 3 days))

Select one of the following

- Inpatient  
 Outpatient  
 Other Facility  
 Unable to obtain follow-up information

Follow-up date

Facility Type

- Nursing Home/Assisted Care  
 Hospice  
 Another hospital  
 Rehabilitation Facility  
 Unknown

State reason why you are unable to obtain follow-up information

- Patient didn't come to clinic  
 Not able to contact patient  
 Not addressed by site

Was patient intubated since implant? (This includes all time since last follow-up.)

- Yes  
 No  
 Unknown

Was patient on dialysis since implant? (This includes all time since last follow-up.)

- Yes  
 No  
 Unknown

## Pump Change

Pump Exchange

- Yes  
 No  
 Unknown

Pump Exchange Reason

- Thrombus not associated with hemolysis  
 Change in hemodynamics  
 Clinical status  
 Device parameters (please enter Device Malfunction Form)  
 Upsizing device because of patient growth status

Was there a Console Change? (For TAH or Berlin Heart Consoles)

- Yes  
 No  
 Unknown

Date of console change

ST=  Unknown

Original Console Name

New Console Name

**Medical Condition****NYHA Class**

- Class I: No limitation of physical activity; physical activity does not cause fatigue, palpitation or shortness of breath.
- Class II: Slight limitation of physical activity; comfortable at rest, but ordinary physical activity results in fatigue, palpitations or shortness of breath.
- Class III: Marked limitation of physical activity; comfortable at rest, but less than ordinary activity causes fatigue, palpitation or shortness of breath.
- Class IV: Unable to carry on minimal physical activity without discomfort; symptoms may be present at rest.
- Unknown

**ZONES****Hemolysis Zone**

Please enter the peak Plasma-free hemoglobin (PFH) since Post-Op Day 4:

ST=  Unknown  
 Not Done

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

ST=  Unknown  
 Not Done

Please enter the peak serum lactate dehydrogenase (LDH) since Post-Op Day 4:

ST=  Unknown  
 Not Done

What is your hospital's upper limit of the normal range of LDH?

ST=  Unknown  
 Not Done

**Enter the Maximum and Minimum HCT or HGB since the Post-Op Day 4.**

**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 since Post-Op Day 4:**ST=  Unknown Not Done**Has the following been present at any time since Post-Op Day 4?  
Physical Findings:****Hemoglobinuria (Tea-Colored Urine)?** Yes No Unknown**Pump malfunction and/or abnormal pump parameters?** Yes No Unknown**Right Heart Failure Zone****Clinical Findings – Since the last visit.****CVP or RAP > 16 mmHg?** Yes No Unknown Not Done**Dilated Vena Cava with absence of Inspiratory Variation by Echo (If absence of Inspiratory Variation is not documented, Check No)?** Yes No Unknown Not Done**Clinical findings of elevated jugular venous distension at least half way up the neck in an upright patient (If  $\geq 6$  cm, Check Yes)?** Yes No Unknown**Peripheral Edema (If  $\geq 2$ , Check Yes)?** Yes No Unknown**Ascites?** Yes No Unknown**Has the patient been on Inotropes since the last visit?** Yes No Unknown



If yes, select all that apply:

- Dopamine
- Dobutamine
- Milrinone
- Isoproterenol
- Epinephrine
- Norepinephrine
- Levosimendan
- Unknown

Nesiritide?

- Yes
- No
- Unknown

Did the patient have an RVAD implanted since the last follow-up?

- Yes
- No
- Unknown

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

- Yes
- No
- Unknown

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

**Modified Rankin Scale**

- 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**

- 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

# 1 Week Followup - Intermacs

## Hemodynamics

### General Hemodynamics

**Heart rate**  beats per min

ST=  Unknown  
 Not done

**Systolic blood pressure**  mmHg

ST=  Unknown  
 Not done

**Diastolic blood pressure**  mmHg

ST=  Unknown  
 Not done

**Doppler Opening Pressure**

ST=  Unknown  
 Not done  
 Not applicable

**ECG rhythm**

- Sinus  
 Atrial fibrillation  
 Atrial Flutter  
 Paced: Atrial pacing  
 Paced: Ventricular pacing  
 Paced: Atrial and ventricular pacing  
 Not done  
 Unknown  
 Other, specify

**Weight**  lbs

kg

ST=  Unknown  
 Not done

### Echo Findings

**Mitral regurgitation**

- 0 (none)  
 1 (mild)  
 2 (moderate)  
 3 (severe)  
 Not Recorded or Not Documented

**Tricuspid regurgitation**

- 0 (none)  
 1 (mild)

- 2 (moderate)
- 3 (severe)
- Not Recorded or Not Documented

**Aortic regurgitation**

- 0 (none)
- 1 (mild)
- 2 (moderate)
- 3 (severe)
- Not Recorded or Not Documented

**LVEF**

- > 50 (normal)
- 40-49 (mild)
- 30-39 (moderate)
- 20-29 (moderate/severe)
- < 20 (severe)
- Not Recorded or Not Documented
- Unknown

If a number or range is available, check the number range that best applies. For example, a reported ejection fraction of 30-35 would be entered as 30-40. Occasionally the LVEF may be described only as "left ventricular function" or "systolic function" in words. "Mild impairment, mildly reduced, or mild decrease" would all be characterized as "mild".

**LVEDD**

cm

ST=  Not Recorded or Not Documented

**RVEF**

- Normal
- Mild
- Moderate
- Severe
- Not Done
- Not Applicable
- Unknown

RV Function is generally NOT measured in numbers, as it is difficult to quantify. It may be described as "right ventricular function" or "right ventricular contractility". "Mild impairment, mildly reduced, or mild decrease" would all be characterized as "mild". Again, mild-moderate would be recorded as moderate, and moderate-severe would be recorded as "severe".

**Swan Hemodynamics**

**Pulmonary artery systolic pressure**

mmHg

ST=  Unknown  
 Not done

**Pulmonary artery diastolic pressure**

mmHg

ST=  Unknown  
 Not done

**Mean RA Pressure**

mmHg

ST=  Unknown  
 Not done

**Central venous pressure (CVP)** mmHgST=  Unknown Not done**Mean Pulmonary artery wedge pressure** mmHgST=  Unknown Not done**Cardiac Index** L/min/M<sup>2</sup> (by Swan)ST=  Unknown Not done**Was Cardiac Index Measured by Fick or Thermodilution?** Yes No Unknown**Choose Method** Fick Thermodilution**Cardiac output** Liters/minST=  Unknown Not done**Was Cardiac Output Measured by Fick or Thermodilution?** Yes No Unknown**Choose Method** Fick Thermodilution

# 1 Week Followup - Intermacs

## Medications

**Angiotensin receptor blocker drug**  Yes  
 No  
 Unknown

**Amiodarone**  Yes  
 No  
 Unknown

**ACE inhibitors**  Yes  
 No  
 Unknown

**Thrombolytic**  Yes  
 No  
 Unknown

**Beta-blockers**  Yes  
 No  
 Unknown

**Aldosterone antagonist**  Yes  
 No  
 Unknown

**Low molecular weight heparin  
(Lovenox, Fragmin, Innohep)**  Yes  
 No  
 Unknown

**UFH: Unfractionated Heparin**  Yes  
 No  
 Unknown

**Warfarin (coumadin)**  Yes  
 No  
 Unknown

**Arixtra (fondaparinux)**  Yes  
 No  
 Unknown

**Antiplatelet therapy drug**  Yes  
 No  
 Unknown

**Select drug(s)**

- Aspirin
- Dextran
- Dipyridamole
- Clopidogrel
- Ticlopidine
- Unknown
- Other, specify

---

**Nitric oxide**

- Yes
- No
- Unknown

---

**Phosphodiesterase inhibitor**

- Yes
- No
- Unknown

---

**Digoxin**

- Yes
- No
- Unknown

---

**Loop diuretics**

- Yes
- No
- Unknown

**If yes, enter dosage:**

 mg/day

ST=  Unknown

**Type of Loop Diuretic:**

- Furosemide
- Torsemide
- Bumetanide
- Other

# 1 Week Followup - Intermacs

## Laboratory

**Sodium**

mEq/L

mmol/L

ST=  Unknown  
 Not done

**Potassium**

mEq/L

mmol/L

ST=  Unknown  
 Not done

**Blood urea nitrogen**

mg/dL

mmol/L

ST=  Unknown  
 Not done

**Creatinine**

mg/dL

umol/L

ST=  Unknown  
 Not done

**SGPT/ALT (alanine aminotransferase/ALT)**

u/L

ST=  Unknown  
 Not done

**SGOT/AST (aspartate aminotransferase/AST)**

u/L

ST=  Unknown  
 Not done

**LDH**

units/L, U/L, ukat/L

ST=  Unknown  
 Not done

**Total bilirubin**

mg/dL

umol/L

ST=  Unknown  
 Not done

**Bilirubin direct**

mg/dL

umol/L

ST=  Unknown  
 Not Done

**Bilirubin indirect**
 mg/dL  
 umol/L

 ST=  Unknown  
 Not Done
**Albumin**
 g/dL  
 g/L

 ST=  Unknown  
 Not done
**Pre-albumin**
 mg/dL  
 mg/L

 ST=  Unknown  
 Not done
**Total Cholesterol**
 mg/dL  
 mmol/L

 ST=  < 50 mg/dL  
 Unknown  
 Not done
**Brain natriuretic peptide BNP**
 pg/ml  
 ng/L

 ST=  > 7500 pg/mL  
 Unknown  
 Not done
**NT pro brain natriuretic peptide Pro-BNP**
 pg/ml  
 ng/L

 ST=  Unknown  
 Not done
**White blood cell count**
 x10<sup>3</sup>/uL  
 x10<sup>9</sup>/L

 ST=  Unknown  
 Not done
**Reticulocyte count**
 %

 ST=  Unknown  
 Not Done
**Hemoglobin**
 g/dL  
 g/L  
 mmol/L

 ST=  Unknown  
 Not done



**Hemoglobin A1C** % mmol/mol**Estimated Average Glucose (eAG):** mg/dL mmol/LST=  Unknown Not Done**Platelets** x10<sup>3</sup>/uL x10<sup>9</sup>/LST=  Unknown Not done**INR** international unitsST=  Unknown Not done**Plasma-free hemoglobin** mg/dL g/LST=  Unknown Not Done**Positive antiheparin/platelet antibody (HIT)** Yes No Unknown**If Yes, are they on direct thrombin inhibitors** Yes No Unknown**If Yes, Enter Drugs:** Plavix Heparin Coumadin Direct thrombin inhibitors (ex: arg, lip, val...) Aspirin Dipyridamole**Was a TEG done?** Yes No Unknown**ThrombElastoGraph Hemostasis System (TEG) profile, MA k** max amplitude in kaolinST=  Unknown Not Done**ThrombElastoGraph Hemostasis System (TEG) profile, R k** reaction time in kaolinST=  Unknown Not Done

**ThrombElastoGraph  
HemostasisSystem (TEG) profile, R  
h**

reaction time w/heparinase

- ST=  Unknown  
 Not Done

**CRP or hs-CRP**

mg/dL

- ST=  Unknown  
 Not done

**Lupus Anticoagulant**

- Positive  
 Negative  
 Unknown

**Uric acid**

mg/dL

umol/L

- ST=  <1 mg/dL  
 Unknown  
 Not done



# 1 Year Post Cessation of Mechanical Support

## Enter Information you are reporting

Date of Event

## Death

Is the patient deceased ?

- Yes  
 No

Death Date

Primary cause of death

- Respiratory: Venous Thromboembolism Event
- Respiratory: Respiratory Failure
- 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

**Cancer**

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

---

**Specify support withdrawn**

**Specify**

**Transplant**

---

**Was the patient transplanted ?**

- Yes
- No

---

**Transplant date**

## 3 Month Followup - Intermacs

### Followup Status (3 Month Followup (+/- 1 month))

Select one of the following

- Inpatient  
 Outpatient  
 Other Facility  
 Unable to obtain follow-up information

Follow-up date

Facility Type

- Nursing Home/Assisted Care  
 Hospice  
 Another hospital  
 Rehabilitation Facility  
 Unknown

State reason why you are unable to obtain follow-up information:

- Patient didn't come to clinic  
 Not able to contact patient  
 Not addressed by site

Was patient intubated since implant? (This includes all time since last follow-up.)

- Yes  
 No  
 Unknown

Was patient on dialysis since implant? (This includes all time since last follow-up.)

- Yes  
 No  
 Unknown

Current Device Strategy

- Bridge to Recovery  
 Rescue Therapy  
 Bridge to Transplant (patient currently listed for transplant)  
 Possible Bridge to Transplant - Likely to be eligible  
 Possible Bridge to Transplant - Moderate likelihood of becoming eligible  
 Possible Bridge to Transplant - Unlikely to become eligible  
 Destination Therapy (patient definitely not eligible for transplant)  
 Other, specify

List Date for Transplant

ST=  Unknown

### Pump Change

Pump Exchange

- Yes  
 No  
 Unknown

**If yes, Please select the Pump Exchange Reason:**

- Thrombus not associated with hemolysis
- Change in hemodynamics
- Clinical status
- Device parameters (please enter Device Malfunction Form)
- Upsizing device because of patient growth status

**Was there a Console Change? (For TAH or Berlin Heart Consoles)**

- Yes
- No
- Unknown

**Date of console change**

ST=  Unknown

**Original Console Name**

**New Console Name**

## ZONES

### Hemolysis Zone

**Please enter the peak Plasma-free hemoglobin (PFH) since the last follow-up visit:**

ST=  Unknown  
 Not Done

**What is your hospital's upper limit of the normal range of peak PFH:**

ST=  Unknown  
 Not Done

**Please enter the peak serum lactate dehydrogenase (LDH) since the last follow-up visit:**

ST=  Unknown  
 Not Done

**What is your hospital's upper limit of the normal range of LDH:**

ST=  Unknown  
 Not Done

**Enter the Maximum and Minimum HCT or HGB since the last Follow-up visit:**

**Min. HCT:**

ST=  Unknown  
 Not Done

**Max. HCT:**

ST=  Unknown  
 Not Done

Min. HGB:

ST=  Unknown Not Done

Max. HGB:

ST=  Unknown Not DoneHighest Total Bilirubin since the last  
Follow-up period:ST=  Unknown Not Done

Has the following been present at any time since the last Follow-up period?

## Physical Findings:

Hemoglobinuria (Tea-Colored  
Urine)? Yes No UnknownPump malfunction and/or abnormal  
pump parameters? Yes No Unknown

## Right Heart Failure Zone

## Clinical Findings – Since the last followup.

CVP or RAP &gt; 16 mmHg?

 Yes No Unknown Not DoneDilated Vena Cava with absence of  
Inspiratory Variation by Echo (If  
absence of Inspiratory Variation is  
not documented, Check No)? Yes No Unknown Not DoneClinical findings of elevated jugular  
venous distension at least half way  
up the neck in an upright patient (If  
≥ 6 cm, Check Yes)? Yes No UnknownPeripheral Edema (If ≥ 2, Check  
Yes)? Yes No Unknown

Ascites?

 Yes No Unknown

**Has the patient been on Inotropes since the last Follow-up?**

- Yes  
 No  
 Unknown

**If yes, select all that apply:**

- Dopamine  
 Dobutamine  
 Milrinone  
 Isoproterenol  
 Epinephrine  
 Norepinephrine  
 Levosimendan  
 Unknown

**Nesiritide?**

- Yes  
 No  
 Unknown

**Did the patient have an RVAD implanted since the last follow-up?**

- Yes  
 No  
 Unknown

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

- Yes  
 No  
 Unknown

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

**Modified Rankin Scale**

- 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**

- 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



# 3 Month Followup - Intermacs

## Hemodynamics

### General Hemodynamics

**Heart rate**  beats per min

ST=  Unknown  
 Not done

**Systolic blood pressure**  mmHg

ST=  Unknown  
 Not done

**Diastolic blood pressure**  mmHg

ST=  Unknown  
 Not done

**Doppler Opening Pressure**

ST=  Unknown  
 Not done  
 Not applicable

**ECG rhythm**

- Sinus  
 Atrial fibrillation  
 Atrial Flutter  
 Paced: Atrial pacing  
 Paced: Ventricular pacing  
 Paced: Atrial and ventricular pacing  
 Not done  
 Unknown  
 Other, specify

**Weight**  lbs

kg

ST=  Unknown  
 Not done

### Echo Findings

**Mitral regurgitation**

- 0 (none)  
 1 (mild)  
 2 (moderate)  
 3 (severe)  
 Not Recorded or Not Documented

**Tricuspid regurgitation**

- 0 (none)  
 1 (mild)

- 2 (moderate)
- 3 (severe)
- Not Recorded or Not Documented

**Aortic regurgitation**

- 0 (none)
- 1 (mild)
- 2 (moderate)
- 3 (severe)
- Not Recorded or Not Documented

**LVEF**

- > 50 (normal)
- 40-49 (mild)
- 30-39 (moderate)
- 20-29 (moderate/severe)
- < 20 (severe)
- Not Recorded or Not Documented
- Unknown

If a number or range is available, check the number range that best applies. For example, a reported ejection fraction of 30-35 would be entered as 30-40. Occasionally the LVEF may be described only as "left ventricular function" or "systolic function" in words. "Mild impairment, mildly reduced, or mild decrease" would all be characterized as "mild".

**LVEDD**
 cm

 ST=  Not Recorded or Not Documented
**RVEF**

- Normal
- Mild
- Moderate
- Severe
- Not Done
- Not Applicable
- Unknown

RV Function is generally NOT measured in numbers, as it is difficult to quantify. It may be described as "right ventricular function" or "right ventricular contractility". "Mild impairment, mildly reduced, or mild decrease" would all be characterized as "mild". Again, mild-moderate would be recorded as moderate, and moderate-severe would be recorded as "severe".

**Swan Hemodynamics****Pulmonary artery systolic pressure**
 mmHg

 ST=  Unknown  
 Not done
**Pulmonary artery diastolic pressure**
 mmHg

 ST=  Unknown  
 Not done
**Mean RA Pressure**
 mmHg

 ST=  Unknown  
 Not done

**Central venous pressure (CVP)**

 mmHg

- ST=  Unknown  
 Not done

**Mean Pulmonary artery wedge pressure**

 mmHg

- ST=  Unknown  
 Not done

**Cardiac Index**

 L/min/M<sup>2</sup> (by Swan)

- ST=  Unknown  
 Not done

**Was Cardiac Index Measured by Fick or Thermodilution?**

- Yes  
 No  
 Unknown

**Choose Method**

- Fick  
 Thermodilution

**Cardiac output**

 Liters/min

- ST=  Unknown  
 Not done

**Was Cardiac Output Measured by Fick or Thermodilution?**

- Yes  
 No  
 Unknown

**Choose Method**

- Fick  
 Thermodilution

## 3 Month Followup - Intermacs

### Medications

**Hydralazine**

Yes  
 No  
 Unknown

**Calcium channel blockers**

Yes  
 No  
 Unknown

**Angiotensin receptor blocker drug**

Yes  
 No  
 Unknown

**Amiodarone**

Yes  
 No  
 Unknown

**ACE inhibitors**

Yes  
 No  
 Unknown

**Thrombolytic**

Yes  
 No  
 Unknown

**Beta-blockers**

Yes  
 No  
 Unknown

**Aldosterone antagonist**

Yes  
 No  
 Unknown

**Low molecular weight heparin  
(Lovenox, Fragmin, Innohep)**

Yes  
 No  
 Unknown

**UFH: Unfractionated Heparin**

Yes  
 No  
 Unknown

**Warfarin (coumadin)**

Yes  
 No  
 Unknown

**Arixtra (fondaparinux)**

Yes  
 No  
 Unknown

**Antiplatelet therapy drug**

- Yes
- No
- Unknown

**Select drug(s)**

- Aspirin
- Dextran
- Dipyridamole
- Clopidogrel
- Ticlopidine
- Unknown
- Other, specify

---

**Nitric oxide**

- Yes
- No
- Unknown

---

**Phosphodiesterase inhibitor**

- Yes
- No
- Unknown

---

**Digoxin**

- Yes
- No
- Unknown

---

**Loop diuretics**

- Yes
- No
- Unknown

**If yes, enter dosage:**

 mg/day

ST=  Unknown

**Type of Loop Diuretic:**

- Furosemide
- Torsemide
- Bumetanide
- Other

## 3 Month Followup - Intermacs

### Laboratory

**Sodium**  mEq/L  
 mmol/L  
 ST=  Unknown  
 Not done

**Potassium**  mEq/L  
 mmol/L  
 ST=  Unknown  
 Not done

**Blood urea nitrogen**  mg/dL  
 mmol/L  
 ST=  Unknown  
 Not done

**Creatinine**  mg/dL  
 umol/L  
 ST=  Unknown  
 Not done

**SGPT/ALT (alanine aminotransferase/ALT)**  u/L  
 ST=  Unknown  
 Not done

**SGOT/AST (aspartate aminotransferase/AST)**  u/L  
 ST=  Unknown  
 Not done

**LDH**  units/L, U/L, ukat/L  
 ST=  Unknown  
 Not done

**Total bilirubin**  mg/dL  
 umol/L  
 ST=  Unknown  
 Not done

**Bilirubin direct**  mg/dL  
 umol/L  
 ST=  Unknown  
 Not Done

**Bilirubin indirect**  mg/dL  
 umol/L  
ST=  Unknown  
 Not Done

**Albumin**  g/dL  
 g/L  
ST=  Unknown  
 Not done

**Pre-albumin**  mg/dL  
 mg/L  
ST=  Unknown  
 Not done

**Total Cholesterol**  mg/dL  
 mmol/L  
ST=  < 50 mg/dL  
 Unknown  
 Not done

**Brain natriuretic peptide BNP**  pg/ml  
 ng/L  
ST=  > 7500 pg/mL  
 Unknown  
 Not done

**NT pro brain natriuretic peptide Pro-BNP**  pg/ml  
 ng/L  
ST=  Unknown  
 Not done

**White blood cell count**  x10<sup>3</sup>/uL  
 x10<sup>9</sup>/L  
ST=  Unknown  
 Not done

**Reticulocyte count**  %  
ST=  Unknown  
 Not Done

**Hemoglobin**  g/dL  
 g/L  
 mmol/L  
ST=  Unknown  
 Not done

**Hemoglobin A1C**

 % mmol/mol

**Estimated Average Glucose (eAG):**

 mg/dL mmol/L

ST=  Unknown  
 Not Done

**Platelets**

 x10<sup>3</sup>/uL x10<sup>9</sup>/L

ST=  Unknown  
 Not done

**INR**

 international units

ST=  Unknown  
 Not done

**Plasma-free hemoglobin**

 mg/dL g/L

ST=  Unknown  
 Not Done

**Positive antiheparin/platelet antibody (HIT)**

- Yes
- No
- Unknown

**If Yes, are they on direct thrombin inhibitors**

- Yes
- No
- Unknown

**If Yes, Enter Drugs:**

- Plavix
- Heparin
- Coumadin
- Direct thrombin inhibitors (ex: arg, lip, val...)
- Aspirin
- Dipyridamole

**Was a TEG done?**

- Yes
- No
- Unknown

**ThrombElastoGraph Hemostasis System (TEG) profile, MA k**

 max amplitude in kaolin

ST=  Unknown  
 Not Done

**ThrombElastoGraph Hemostasis System (TEG) profile, R k**

 reaction time in kaolin

ST=  Unknown  
 Not Done



**ThrombElastoGraph  
HemostasisSystem (TEG) profile, R  
h**

reaction time w/heparinase

- ST=  Unknown  
 Not Done

**Sensitivity CRP**

mg/L

- ST=  Unknown  
 Not done

**Lupus Anticoagulant**

- Positive  
 Negative  
 Unknown

**Uric acid**

mg/dL

umol/L

- ST=  <1 mg/dL  
 Unknown  
 Not done

### 3 Month Followup - Intermacs

#### Device Flow Chart

##### Device Function

---

**Pump Flow**  LPM  
ST=  Unknown

**Pulsality Index**   
ST=  Unknown

---

**Pump Power**  Watts  
ST=  Unknown

##### Device Parameters

---

**Pump Speed**  RPM  
ST=  Unknown

**Low Speed**  RPM  
ST=  Unknown

##### Device Inspection

---

**Auscultation**  Abnormal  
 Normal  
 Not Applicable

**Driveline**  Abnormal  
 Normal  
 Not Applicable

##### Device Funtion (RVAD)

**Pump Flow (RVAD)**  LPM  
ST=  Unknown

##### Device Parameters (RVAD)

**Pump Speed (RVAD)**  RPM  
ST=  Unknown

##### Device Inspection (RVAD)

---

**Depositions**  Abnormal  
 Normal  
 Not Applicable

### 3 Month Followup - Intermacs

#### Device Flow Chart

##### Device Function

---

**Pump Flow**  LPM  
ST=  Unknown

**Pulsality Index**   
ST=  Unknown

---

**Pump Power**  Watts  
ST=  Unknown

##### Device Parameters

---

**Pump Speed**  RPM  
ST=  Unknown

**Low Speed**  RPM  
ST=  Unknown

##### Device Inspection

---

**Auscultation**  Abnormal  
 Normal  
 Not Applicable

**Driveline**  Abnormal  
 Normal  
 Not Applicable

### 3 Month Followup - Intermacs

#### Device Flow Chart

##### Device Function

---

**Left Flow**  LPM  
ST=  Unknown

**Right Flow**  LPM  
ST=  Unknown  
 Not Applicable

**Left Fill Volume:**  ml  
ST=  Unknown

**Right Fill Volume**  ml  
ST=  Unknown  
 Not Applicable

##### Device Parameters

---

**Pump Rate**  BPM  
ST=  Unknown

**Vacuum Pressure**  mm Hg  
ST=  Unknown  
 Not Applicable

**Left Drive Pressure**  mm Hg  
ST=  Unknown  
 Not Applicable

**Right Drive Pressure**  mm Hg  
ST=  Unknown  
 Not Applicable

##### Device Inspection

---

**Auscultation**  Abnormal  
 Normal  
 Not Applicable

### 3 Month Followup - Intermacs

#### Device Flow Chart

##### Device Function

---

**Pump Flow**  LPM  
ST=  Unknown

**Pump Power**  Watts  
ST=  Unknown

##### Device Parameters

**Pump Speed**  RPM  
ST=  Unknown

##### Device Inspection

**Auscultation**  Abnormal  
 Normal  
 Not Applicable

**Driveline**  Abnormal  
 Normal  
 Not Applicable

## 3 Month Followup - Intermacs

### Exercise Function and Trailmaking Data

**6 minute walk**

feet

ST=  Not done: too sick

Not done: other

Unknown

This requires an inside hall for which distances (in FEET) should be measured, preferably as long as possible to avoid frequent turns. Patients are instructed to walk steadily to cover as much distance as possible during the 6 minutes. They are advised that they may stop if necessary during the 6 minutes. The staff member performing the test should walk behind the patient to avoid undue influence on the pace. The distance covered during the 6 minutes in feet will be recorded here. **NOTE: You may use the time from the first 15 feet of the 6minute walk for the Gait speed test listed below (please see instructions for the gait speed test below.)**

**Gait Speed (1st 15 foot walk)**

seconds

ST=  Not done: too sick

Not done: other

Unknown

Instructions: Record the time (seconds) required for the patient to walk the first 15 feet of the 6 minute walk. The "starting" line and the 15 foot line should be clearly marked. Record the time to the first footfall at 0 feet and ends with the first footfall at 15 feet in the nearest. 0.1 sec with a stopwatch. **NOTE: You may use the time from the first 15 feet of the 6 minute walk for the Gait speed test.**

**Peak VO2 Max**

mL/kg/min

ST=  Not done: too sick

Not done: other

Unknown

Maximum volume of oxygen the body can consume during exercise (mL/kg/min) is the ml/kg/min of oxygen consumed during symptom-limited exercise testing either on a bicycle or treadmill. The values recorded during the bicycle are usually 1-2 ml/min lower than for the treadmill, but it is assumed that most institutions will use only one instrument. If both are available, the bicycle is preferable as the mode easiest to standardize.

**R Value at peak**

%

ST=  Unknown

Not done

R Value at peak is the respiratory quotient of carbon dioxide production divided by oxygen consumption, and is used as an index of how vigorously the patient exercised. A value above 1.05 is generally considered to represent an adequate effort.

### Trailmaking

**Status**

Completed

Attempted but not completed

Not attempted

Completed but invalid (scores not entered)

**Time**

seconds

### Medical Condition

**NYHA Class**

Class I: No limitation of physical activity; physical activity does not cause fatigue, palpitation or shortness of breath.

- Class II: Slight limitation of physical activity; comfortable at rest, but ordinary physical activity results in fatigue, palpitations or shortness of breath.
- Class III: Marked limitation of physical activity; comfortable at rest, but less than ordinary activity causes fatigue, palpitation or shortness of breath.
- Class IV: Unable to carry on minimal physical activity without discomfort; symptoms may be present at rest.
- Unknown

## 3 Month Followup - Intermacs

### Concerns and Contraindications

Concerns / Contraindications	Is condition present?		Limitation for transplant listing?		
	Yes	No	Yes	No	
<b>Overall Status:</b>					
Advanced age	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Frailty	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Patient does not want transplant	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Musculoskeletal limitation to ambulation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Contraindication to immunosuppression	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Allosensitization	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Chronic Renal Disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
<b>Cardiothoracic issues</b>	<b>Yes</b>	<b>No</b>	<b>Yes</b>	<b>No</b>	
Frequent ICD Shocks	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Pulmonary Disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Pulmonary Hypertension	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Recent Pulmonary Embolus	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
History Of Atrial Arrhythmia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Unfavorable Mediastinal Anatomy (includes sternotomies, sternal resection, radiation, flail chest, etc)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Thoracic Aortic Disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
<b>Nutritional/GI</b>	<b>Yes</b>	<b>No</b>	<b>Yes</b>	<b>No</b>	
Large BMI	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Severe Diabetes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Malnutrition Cachexia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
History Of GI Ulcers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
History Of Hepatitis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Liver Dysfunction	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
<b>Vascular issues</b>	<b>Yes</b>	<b>No</b>	<b>Yes</b>	<b>No</b>	
Heparin Induced Thrombocytopenia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Chronic Coagulopathy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Major Stroke	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Other Cerebrovascular Disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Peripheral Vascular Disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
<b>Oncology/infection issues</b>	<b>Yes</b>	<b>No</b>	<b>Unknown</b>	<b>Yes</b>	<b>No</b>



History Of Solid Organ Cancer	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
History Of Lymphoma Leukemia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
History Of Bone Marrow Transplant BMT	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
History Of HIV	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Chronic Infectious Concerns	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

<b>Psychosocial issues</b>	<b>Yes</b>	<b>No</b>	<b>Yes</b>	<b>No</b>
Limited Cognition/Understanding	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Limited Social Support	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Repeated Noncompliance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
History Of Illicit Drug Use	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
History Of Alcohol Abuse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Narcotic Dependence	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
History Of Smoking	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Currently Smoking	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Severe Depression	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other Major Psychiatric Diagnosis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other Comorbidity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

If history of HIV is present, answer the HIV questions below:

**HIV Diagnosis Date**

ST=  Unknown  
 Not Done

**Plasma HIV-1 RNA (Viral load) - Closest to implant**

ST=  Not Done

**CD4 T-Cell Count - Closest to implant**

ST=  Not Done

**Erythrocyte Sedimentation Rate (ESR)**

ST=  Not Done

**C-Reactive Protein (CRP)**  mg/L

ST=  Not Done

- Antiretroviral Therapy (Select all that apply)**
- Abacavir (ABC) / Ziagen
  - Atripla (FTC/EDV/TDF)
  - Atazanavir (ATV) / Reyataz
  - Combivir (3TC/ZDV)
  - Complera (FTC/RPV/TDF)
  - Darunavir (DRV) / Prezista
  - Delavirdine (DLV) / Rescriptor

- Didanosine (ddl) / Videx EC
- Dolutegravir / Tivicay
- Efavirenz (EFV) / Sustiva
- Emtricitabine (FTC) / Emtriva
- Enfuvirtide (T20) / Fuzeon
- Epzicom (3TC/ABC)
- Etravirine (ETR) / Intelence
- Fosamprenavir (FPV) / Lexiva
- Indinavir (IDV) / Crixivan
- Kaletra (LPV/r)
- Lamivudine (3TC) / Eпивir
- Maraviroc (MVC) / Selzentry
- Nelfinavir (NFV) / Viracept
- Nevirapine (NVP) / Viramune / Viramune XR
- Raltegravir (RAL) / Isentress
- Rilpivirine (RPV) / Edurant
- Ritonavir (RTV) / Norvir
- Saquinavir (SQV) / Invirase
- Stavudine (d4T) / Zerit
- Stribild (FTC/EVG/COBI/TDF)
- Tenofovir Disoproxil Fumarate (TDF) / Viread
- Tipranavir (TPV) / Aptivus
- Trizivir (3TC/ZDV/ABC)
- Truvada (FTC/TDF)
- Zidovudine (ZDV) / Retrovir
- Unknown
- None

**Infection Prophylaxis (Select all that apply)**

- Atovaquone
- Azithromycin
- Dapsone
- Fluconazole
- Pentamidine, aerosolized
- Trimethoprim-sulfamethoxazole (TMP-SMX)
- Unknown
- None

**Has patient had an opportunistic infection since last follow-up?**

- Yes
- No
- Unknown

If yes, enter infection date:

- ST=  Unknown  
 Not Done

If yes, enter Type of Infection (select all that apply)

- Cryptococcosis
- Cytomegalovirus (CMV)
- Epstein Barr virus (EBV)
- Esophageal candidiasis
- Histoplasmosis
- Kaposi's sarcoma
- Mycobacterium avium complex (MAC), disseminated
- Pneumocystis jiroveci (carinii) pneumonia (PCP)
- Toxoplasmosis
- Tuberculosis

**History of Hepatitis B**

- Positive

Negative

ST=  Unknown

Not Done

---

**History of Hepatitis C**

Positive

Negative

ST=  Unknown

Not Done

## 3 Month Followup - Intermacs

### Quality Of Life

(QOL surveys cannot be administered after the visit date)

#### EuroQol (EQ-5D)

Did the patient complete a EuroQol form?

Yes  
 No  
 Unknown

How was the test administered?

Self-administered  
 Coordinator administered  
 Family member administered

Mobility:

I have no problems in walking about  
 I have some problems in walking about  
 I am confined to bed  
 Unknown

Self care

I have no problems with self-care  
 I have some problems washing or dressing myself  
 I am unable to wash or dress myself  
 Unknown

Usual Activities (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities  
 I have some problems with performing my usual activities  
 I am unable to perform my usual activities  
 Unknown

Pain/discomfort

I have no pain or discomfort  
 I have moderate pain or discomfort  
 I have extreme pain or discomfort  
 Unknown

Anxiety/depression

I am not anxious or depressed  
 I am moderately anxious or depressed  
 I am extremely anxious or depressed  
 Unknown

Patient Visual Analog Status (VAS)  (0-100) 0=Worst, 100=Best  
 ST=  Unknown

Which of the following best describes your \*one\* main activity?

Actively working  
 Retired  
 Keeping house  
 Student  
 Seeking work  
 Too sick to work (disabled)

Unknown Other

Is this "one" main activity considered

 Full time Part time Unknown

How many of your close friends or relatives do you see in person, speak to on the telephone or contact via the internet at least once a month? (please count each person 1 time)?

ST=  Unknown

Have you unintentionally lost more than 10 pounds in the last year?

 Yes No Unknown

Do you currently smoke cigarettes?

 Yes No Unknown

If Yes, How many cigarettes are you currently smoking, on average?

 Half a pack or less per day More than half to 1 pack per day 1 to 2 packs per day 2 or more packs per day

Do you currently smoke e-cigarettes?

 Yes No Unknown

Please enter a number from 1 to 10 for the questions below.

How much stress related to your health issues do you feel you've been under during the past month?

ST=  Unknown

How well do you feel you've been coping with or handling your stress related to your health issues during the past month?

ST=  Unknown

How confident are you that you can do the tasks and activities needed to manage your ventricular assist device so as to reduce how much having a ventricular assist device affects your everyday life?

ST=  Unknown

How satisfied are you with the outcome of your ventricular assist device surgery, during the past 3 months?

ST=  Unknown

If you had to do it all over again, would you decide to have a

**ventricular assist device knowing what you know now?**

- Definitely No
- Probably No
- Not Sure
- Probably Yes
- Definitely Yes
- Unknown

**If No, Please select a reason why the EuroQol (EQ-5D) was not completed:**

- Too sick (ex., intubated/sedated, critically ill, on short-term VAD)
- Too tired
- Too stressed, anxious, and/or depressed
- Can't concentrate
- No time/too busy
- Too much trouble/don't want to be bothered/not interested
- Unwilling to complete instrument, no reason given
- Unable to read English and/or illiterate
- Administrative (check specific reason below)

**If Administrative, select a specific reason**

- Urgent/emergent implant, no time to administer QOL instruments
- Coordinator too busy or forgot to administer QOL instruments
- Unable to contact patient (ie., not hospitalized or no clinic visit) within the window for QOL instrument completion
- Other reason (describe)

### Kansas City Cardiomyopathy Questionnaire

**Did the patient complete a KCCQ form?**

- Yes
- No

**How was the test administered?**

- Self-administered
- Coordinator administered
- Family member administered

**Heart Failure affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by heart failure (shortness of breath or fatigue) in your ability to do the following activities over the past 2 weeks.**

**Showering/Bathing**

- Extremely limited
- Quite a bit limited
- Moderately limited
- Slightly limited
- Not at all limited
- Limited for other reasons or did not do the activity
- Unknown

**Walking 1 block on level ground**

- Extremely limited
- Quite a bit limited
- Moderately limited
- Slightly limited
- Not at all limited
- Limited for other reasons or did not do the activity
- Unknown

**Hurrying or jogging  
(as if to catch a bus)**

- Extremely limited
- Quite a bit limited
- Moderately limited
- Slightly limited
- Not at all limited
- Limited for other reasons or did not do the activity
- Unknown

**Over the past 2 weeks, how many  
times did you have swelling in your  
feet, ankles or legs when you woke  
up in the morning?**

- Every morning
- 3 or more times a week, but not every day
- 1-2 times a week
- Less than once a week
- Never over the past 2 weeks
- Unknown

**Over the past 2 weeks, on average,  
how many times has fatigue limited  
your ability to do what you want?**

- All of the time
- Several times per day
- At least once a day
- 3 or more times per week but not every day
- 1-2 times per week
- Less than once a week
- Never over the past 2 weeks
- Unknown

**Over the past 2 weeks, on average,  
how many times has shortness of  
breath limited your ability to do  
what you wanted?**

- All of the time
- Several times per day
- At least once a day
- 3 or more times per week but not every day
- 1-2 times per week
- Less than once a week
- Never over the past 2 weeks
- Unknown

**Over the past 2 weeks, on average,  
how many times have you been  
forced to sleep sitting up in a chair  
or with at least 3 pillows to prop you  
up because of shortness of breath?**

- Every night
- 3 or more times a week, but not every day
- 1-2 times a week
- Less than once a week
- Never over the past 2 weeks
- Unknown

**Over the past 2 weeks, how much  
has your heart failure limited your  
enjoyment of life?**

- It has extremely limited my enjoyment of life
- It has limited my enjoyment of life quite a bit
- It has moderately limited my enjoyment of life
- It has slightly limited my enjoyment of life
- It has not limited my enjoyment of life at all
- Unknown

**If you had to spend the rest of your  
life with your heart failure the way it  
is right now, how would you feel  
about this?**

- Not at all satisfied
- Mostly dissatisfied
- Somewhat satisfied
- Mostly satisfied

- Completely satisfied
- Unknown

**How much does your heart failure affect your lifestyle? Please indicate how your heart failure may have limited your participation in the following activities over the past 2 weeks?**

**Hobbies, recreational activities**

- Severely limited
- Limited quite a bit
- Moderately limited
- Slightly limited
- Did not limit at all
- Does not apply or did not do for other reasons
- Unknown

**Working or doing household chores**

- Severely limited
- Limited quite a bit
- Moderately limited
- Slightly limited
- Did not limit at all
- Does not apply or did not do for other reasons
- Unknown

**Visiting family or friends out of your home**

- Severely limited
- Limited quite a bit
- Moderately limited
- Slightly limited
- Did not limit at all
- Does not apply or did not do for other reasons
- Unknown

**If No, Please select a reason why the KCCQ was not completed:**

- Too sick (ex., intubated/sedated, critically ill, on short-term VAD)
- Too tired
- Too stressed, anxious, and/or depressed
- Can't concentrate
- No time / too busy
- Too much trouble / don't want to be bothered / not interested
- Unwilling to complete instrument, no reason given
- Unable to read English and/or illiterate
- Administrative (check specific reason below)

**If Administrative, select a specific reason**

- Urgent/emergent implant, no time to administer QOL instruments
- Coordinator too busy or forgot to administer QOL instruments
- Unable to contact patient (ie., not hospitalized or no clinic visit) within the window for QOL instrument completion
- Other reason (describe)



# Adverse Event - Intermacs

## Adverse Event Status

---

Please enter the date of the event you  
are reporting:

---

Please enter a label describing this  
event:

## Adverse Event - Intermacs

### Rehospitalization

Was there an occurrence of rehospitalization?  Yes  
 No

Is this rehospitalization at your hospital?  Yes  
 No

Date of admission

ST=  Unknown

Discharge Date

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  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

### Clinical Observations

Systolic blood pressure  mmHg

ST=  Unknown  
 Not done

Diastolic blood pressure  mmHg

ST=  Unknown  
 Not done

Doppler Opening Pressure

ST=  Unknown  
 Not done  
 Not applicable

Has the patient experienced a  
Neurological Event since time of  
implant?  Yes  
 No  
 Unknown

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

**Modified Rankin Scale:**

- 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**

- 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

# Adverse Event - Intermacs

## Infection

- Was there a major infection?**
- Yes  
 No  
 Unknown

**Date of onset**

ST=  Unknown

- Did this infection contribute to death?**
- Yes  
 No  
 Unknown

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

- Location of infection**
- 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?**

- Yes
- No

## Adverse Event - Intermacs

### 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**

ST=  Unknown

**Location of patient**

In hospital  
 Out of hospital  
 Unknown

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

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

**Total units PRBC**

ST=  Unknown

**Date of first transfusion for this episode**

ST=  Unknown

**Source/cause/location of bleeding**

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**

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

---

**Is this a Device Related Event?**

- Yes
- No

# Adverse Event - Intermacs

## Neuro

**Was there a neurological dysfunction?**

Yes  
 No  
 Unknown

**Date of onset**

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?**

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**

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**

- 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

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

**Modified Rankin Scale**

- 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**

- 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

# Adverse Event - Intermacs

## Device Malf/Failure and/or Pump Thrombus

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

- Yes  
 No  
 Unknown

Date of onset

Device Type

Location of patient

- In hospital  
 Out of hospital  
 Unknown

Description of Malfunction

## 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?

- 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?

- 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:

- Imaging Study  
 Visual Inspection  
 Manufacturer's Report

**Was there a device Malfunction?**

- 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**

---

**Patient Outcome**

- 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**

- 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

## Adverse Event - Intermacs

### Additional Adverse Events

Were there any additional adverse events?  Yes  
 No

Cardiac Arrhythmia  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  Yes  
 No  
 Unknown

Event Date

ST=  Unknown

Signs of tamponade  Yes  
 No  
 Unknown

Method of drainage  Surgical intervention  
 Cath  
 Unknown

Hepatic Dysfunction  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

ST=  Unknown



**Myocardial Infarction**  Yes  
 No  
 Unknown

**Event Date**   
ST=  Unknown

**Psychiatric Episode**  Yes  
 No  
 Unknown

**Event Date**   
ST=  Unknown

**Renal Dysfunction**  Yes  
 No  
 Unknown

**Event Date**   
ST=  Unknown

**Dialysis duration**  days  
ST=  Unknown  
 Not Done  
 Ongoing

**Peak creatinine measurement**  mg/dL  
ST=  Unknown  
 Not Done

**Respiratory Failure**  Yes  
 No  
 Unknown

**Event Date**   
ST=  Unknown  
 Ongoing

**Intubation duration**  days  
ST=  Unknown  
 Ongoing

**Was a tracheotomy performed?**  Yes  
 No  
 Unknown

**Arterial Non-CNS Thromboembolism**  Yes  
 No  
 Unknown

**Date**

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

---

**Venous Thromboembolism Event**  Deep Vein thrombosis  
 Pulmonary Embolis  
 Other, specify  
 Unknown  
 None

**Enter deep vein thrombosis date**   
ST=  Unknown

**Enter pulmonary embolus date**   
ST=  Unknown

**Enter other date**   
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**

- Yes
- No
- Unknown

**Date**

ST=  Unknown

**Enter location:**

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

---

**Other Events**

- Yes
- No
- Unknown

**Description**

**Event Date**

ST=  Unknown

## Adverse Event - Intermacs

### 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**

- 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
- No
- Unknown

**Evidence of Pump Thrombosis?**

- Yes
- No
- Unknown

**Transplant date**

ST=  Unknown

**Waitlist ID**

## Adverse Event - Intermacs

### Death

Did the patient die?  Yes  
 No

Death date

ST=  Unknown

Was device functioning normally?  Yes  
 No  
 Unknown

Associated Operation  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

**Primary cause of death**

- Respiratory: Venous Thromboembolism Event
- Respiratory: Respiratory Failure
- 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**



## Demographics - Intermacs

First Name

Middle Name

Last Name

Medical record number

SSN (last 5 digits)

ST=  Not Assigned

Undisclosed

Health Insurance Claim Number  
(HICN):

ST=  Unknown

Date of Birth

Gender

Male

Female

Unspecified

Ethnicity: Hispanic or Latino

Yes

No

Unknown

Race

American Indian or Alaska Native

Asian

African-American or Black

Hawaiian or other Pacific Islander

White

Unknown / Undisclosed

Other / none of the above

Marital Status

Single

Married

Domestic Partners

Divorced/Separated

Widowed

Unknown

Highest education level

None

Grade school (0-8)

High school (9-12)

Attended college/technical school

Associate/bachelor degree

Post-college graduate degree

- Not Applicable
- Unknown

**Working for income**

- Yes
- No
- Unknown

**If yes:**

- Working Full Time
- Working Part Time due to Demands of Treatment
- Working Part Time due to Disability
- Working Part Time due to Insurance Conflict
- Working Part Time due to Inability to Find Full Time Work
- Working Part Time due to Patient Choice
- Working Part Time Reason Unknown
- Working, Part Time vs. Full Time Unknown

**If No, Not Working Due To:**

- Disability
- Demands of Treatment
- Insurance Conflict
- Inability to Find Work
- Patient Choice - Homemaker
- Patient Choice - Student Full Time/Part Time
- Patient Choice - Retired
- Patient Choice - Other
- Not Applicable - Hospitalized
- Unknown

**Is patient involved in a VAD related study?**

- Yes
- No
- Unknown

**What is the name of the study?**

**Is this an industry sponsored post approval study?**

- Yes
- No
- Unknown

## Implant Discharge - Intermacs

**During the implant hospitalization was the patient?**

- Discharged alive with a device in place
- Died during the implant hospitalization
- Transplanted during the implant hospitalization
- Explanted due to recovery during the implant hospitalization
- Patient has device exchange (excluding RVAD exchange)

**Patient discharged to**

- Home - residential setting
- Nursing Home / Assisted Care
- Hospice
- Another hospital
- Rehabilitation Facility
- Unknown

**Implant Discharge or LVAD Exchange Date**

ST=  Unknown

**Acute care (ICU / CCU) duration of post-implant stay**

 days

ST=  Unknown

**Intermediate / step-down care - duration of post-implant stay**

 days

ST=  Unknown

**Date of approximate discontinuation of inotropes**

- < 1 week
- 1-2 weeks
- 2-4 weeks
- > 4 weeks
- Ongoing
- Unknown
- Not applicable

**Interventions since implant**

- Transplant
- Invasive Cardiac Procedures (Other than Heart Cath)
- Unknown
- None

**Surgical Procedures:**

- Device Related Operation
- Surgical Procedure - Non Cardiac Surgical Procedure
- Surgical Procedure - Other Procedure
- Surgical Procedure - Unknown

**Cardiac Surgical Procedures:**

- 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
- Other Cardiac Surgical Procedure
- Cardiac Surgical Procedure - Unknown

**Other Procedures:**

- Reintubation due to Respiratory Failure
- Dialysis
- Bronchoscopy
- Other, specify

**Was there a pump exchange of a para- or extra- corporeal pump? (Example PVAD, Berlin Heart)**

- Yes
- No
- Unknown

**If yes, Please select the Pump Exchange Reason:**

- Thrombus not associated with hemolysis
- Change in hemodynamics
- Clinical status
- Device parameters (please enter Device Malfunction Form)
- Upsizing device because of patient growth status

**Was there a Console Change? (For TAH or Berlin Heart Consoles)**

- Yes
- No
- Unknown

**Date of console change**

ST=  Unknown

**Original Console Name**

**New Console Name**

# Implant Form - Intermacs

Implant date

Did you obtain consent from the patient?

- Yes  
 No

Payor

- Government Health Insurance  
 Commercial Health Insurance  
 Health Maintenance Organization  
 Non-U.S. Insurance  
 None / Self  
 Unknown

Government:

- Medicare  
 Medicaid  
 State-Specific Plan  
 Correctional Facility

Health Insurance Claim Number (HIC):

ST=  Unknown

- Medicare Fee For Service  
 Military Health Care  
 Indian Health Service  
 Not Applicable  
 Other, specify

## National Provider Identifier (NPI) Information

Operator First Name

ST=  Unknown

Operator Middle Name

ST=  Unknown

Operator Last Name

ST=  Unknown

Operator NPI

ST=  Unknown

Additional indication for VAD

- Failure to wean from CPB  
 Post Cardiac Surgery  
 None

- Device type**
- LVAD
  - RVAD
  - BIVAD
  - TAH

- Device brand**
- Berlin Heart EXCOR (paracorporeal)
  - HeartWare HVAD
  - HeartMate II LVAS
  - HeartMate III
  - HeartMate IP
  - HeartMate VE
  - HeartMate XVE
  - Micromed DeBaKey VAD - Child
  - Novacor PC
  - Novacor PCq
  - Thoratec IVAD
  - Thoratec PVAD
  - Other, Specify

**Specify brand:**

- Surgical Approach**
- Sternotomy
  - Thoracotomy
  - Subcostal
  - Unknown
  - Other, specify
- 

**LVAD: Serial Number**

ST=  Unknown

- LVAD: cannulae location-inflow**
- LA appendage
  - LA interatrial groove
  - LV apex
  - LV diaphragmatic surface
  - Unknown
  - Other, specify
- 

- LVAD: cannulae location-outflow**
- Ascending aorta
  - Descending thoracic aorta
  - Abdominal aorta
  - Unknown
  - Subclavian
  - Other, Specify
- 

**Device brand (RVAD)**

**Specify brand (RVAD):**

RVAD: Serial Number

ST=  Unknown

RVAD: cannulae location-inflow

- RA  
 RV  
 Unknown

RVAD: cannulae location-outflow

- MPA (main pulmonary artery)  
 LPA (left pulmonary artery)  
 RPA (right pulmonary artery)  
 Conduit  
 Other, Specify

TAH: Serial Number

ST=  Unknown

Associated findings

- PFO / ASD  
 Aortic Insufficiency  
 Tricuspid Insufficiency  
 None

Aortic Insufficiency

- Mild  
 Moderate  
 Severe

Tricuspid Insufficiency

- Mild  
 Moderate  
 Severe

Concomitant surgery

- None  
 ASD closure  
 PFO closure  
 RVAD Implant  
 RVAD Explant  
 ECMO Decannulation  
 CABG  
 VSD closure  
 IABP Removal  
 Congenital cardiac surgery, other  
 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

Other, specify

---

**Was the patient put on Cardio Bypass Pump?**

Yes

No

**CPB Time**

 minutes

ST=  Unknown

Not Done

---

**Surgery Time**

 minutes

ST=  Unknown

---

**Was cross clamp used?**

Yes

No

Unknown

**Enter duration of the cross clamp time in minutes**

ST=  Unknown

Not Done



# PreImplant - InterMACs

## PreImplant Status

### Demographics

**Height**  in  
 cm  
 ST=  Unknown  
 Not Done

**Weight**  lbs  
 kg  
 ST=  Unknown  
 Not Done

**Blood Type**  O  
 A  
 B  
 AB  
 Unknown

### Medical Support Status

**Current Device Strategy at time of implant**

- Bridge to Recovery
- Rescue Therapy
- Bridge to Transplant (patient currently listed for transplant)
- Possible Bridge to Transplant - Likely to be eligible
- Possible Bridge to Transplant - Moderate likelihood of becoming eligible
- Possible Bridge to Transplant - Unlikely to become eligible
- Destination Therapy (patient definitely not eligible for transplant)
- Other, specify

**List Date for Transplant**   
 ST=  Unknown

**Current ICD device in place?**  Yes  
 No  
 Unknown

**Time since first cardiac diagnosis**

- < 1 month
- 1 month - 1 year
- 1-2 years
- > 2 years
- Unknown

**Number of cardiac hospitalizations in the last 12 months**

- 0-1
- 2-3
- 4 or more
- Unknown

**Cardiac diagnosis / Primary**

- Cancer
- Congenital Heart Disease: Biventricular: CAVC/VSD/ASD
- Congenital Heart Disease: Biventricular: Congenitally Corrected Transposition (l-TGA) (CC-TGA)
- Congenital Heart Disease: Biventricular: Ebstein's Anomaly
- Congenital Heart Disease: Biventricular: Kawasaki Disease
- Congenital Heart Disease: Biventricular: Left Heart Valve/Structural Hypoplasia
- Congenital Heart Disease: Biventricular: TOF/TOF Variant
- Congenital Heart Disease: Biventricular: Transposition of the Great Arteries (d-TGA)
- Congenital Heart Disease: Biventricular: Truncus Arteriosus
- Congenital Heart Disease: Single Ventricle: Heterotaxy / Complex CAVC
- Congenital Heart Disease: Single Ventricle: Hypoplastic Left Heart
- Congenital Heart Disease: Single Ventricle: Other
- Congenital Heart Disease: Single Ventricle: Pulmonary Artesia with IVS
- Congenital Heart Disease: Single Ventricle: Pulmonary Artesia with IVS (RVDC)
- Congenital Heart Disease: Single Ventricle: Unspecified
- Coronary Artery Disease
- Dilated Myopathy: Adriamycin
- Dilated Myopathy: Alcoholic
- Dilated Myopathy: Familial
- Dilated Myopathy: Idiopathic
- Dilated Myopathy: Ischemic
- Dilated Myopathy: Myocarditis
- Dilated Myopathy: Other, Specify
- Dilated Myopathy: Post Partum
- Dilated Myopathy: Viral
- Hypertrophic Cardiomyopathy
- Restrictive Myopathy: Amyloidosis
- Restrictive Myopathy: Endocardial Fibrosis
- Restrictive Myopathy: Idiopathic
- Restrictive Myopathy: Other, specify
- Restrictive Myopathy: Sarcoidosis
- Restrictive Myopathy: Sec to Radiation/Chemotherapy
- Valvular Heart Disease
- Unknown
- None

**Dilated Myopathy: Other, Specify:**

**Restrictive Myopathy: Other, Specify:**

**Congenital Heart Disease: Single Ventricle: Other, Specify:**

**Cardiac diagnosis / Secondary**

- Cancer
- Congenital Heart Disease: Biventricular: CAVC/VSD/ASD
- Congenital Heart Disease: Biventricular: Congenitally Corrected Transposition (l-TGA) (CC-TGA)
- Congenital Heart Disease: Biventricular: Ebstein's Anomaly
- Congenital Heart Disease: Biventricular: Kawasaki Disease
- Congenital Heart Disease: Biventricular: Left Heart Valve/Structural Hypoplasia
- Congenital Heart Disease: Biventricular: TOF/TOF Variant
- Congenital Heart Disease: Biventricular: Transposition of the Great Arteries (d-TGA)
- Congenital Heart Disease: Biventricular: Truncus Arteriosus
- Congenital Heart Disease: Single Ventricle: Heterotaxy / Complex CAVC
- Congenital Heart Disease: Single Ventricle: Hypoplastic Left Heart
- Congenital Heart Disease: Single Ventricle: Other
- Congenital Heart Disease: Single Ventricle: Pulmonary Artesia with IVS
- Congenital Heart Disease: Single Ventricle: Pulmonary Artesia with IVS (RVDC)
- Congenital Heart Disease: Single Ventricle: Unspecified
- Coronary Artery Disease
- Dilated Myopathy: Adriamycin
- Dilated Myopathy: Alcoholic
- Dilated Myopathy: Familial
- Dilated Myopathy: Idiopathic
- Dilated Myopathy: Ischemic
- Dilated Myopathy: Myocarditis
- Dilated Myopathy: Other, Specify
- Dilated Myopathy: Post Partum
- Dilated Myopathy: Viral
- Hypertrophic Cardiomyopathy
- Restrictive Myopathy: Amyloidosis
- Restrictive Myopathy: Endocardial Fibrosis
- Restrictive Myopathy: Idiopathic
- Restrictive Myopathy: Other, specify
- Restrictive Myopathy: Sarcoidosis
- Restrictive Myopathy: Sec to Radiation/Chemotherapy
- Valvular Heart Disease
- Unknown
- None

**Dilated Myopathy: Other, Specify:**

**Restrictive Myopathy: Other, Specify:**

**Congenital Heart Disease: Single Ventricle: Other, Specify:**

**Known Cardiac biopsy**

- Other, specify
- No biopsy known
- Sarcoidosis
- Giant cell myocarditis
- Eosiniphilic myocarditis
- Other myocarditis
- Hemochromatosis
- Mitochondrial myopathy

**Previous cardiac operation**

- None
- CABG
- Aneurysmectomy (DOR)
- Aortic Valve replacement / repair
- Mitral valve replacement / repair
- Tricuspid replacement /repair
- Congenital cardiac surgery
- LVAD
- RVAD
- TAH
- Previous heart transplant
- Previous ECMO
- Other, specify (INCLUDE ONLY OPERATIONS ACTUALLY PERFORMED ON HEART OR GREAT VESSELS)

**Congenital cardiac surgery,  
Check all that apply**

- Congenitally Corrected Transposition Repair (double switch)
- Congenitally Corrected Transposition Repair (classic)
- PA Banding
- TOF/DORV/RVOTO Repair
- Ebstein's Anomaly Repair
- VSD Repair
- Norwood Stage I
- Glenn, Bi-directional
- Glenn, Classical
- Fontan Procedure
- d- Transposition of the Great Vessels Repair – arterial switch operation
- d- Transposition of the Great Vessels Repair – atrial switch (Senning/Mustard)
- Truncus Arteriosus Repair
- Complete AV Septal Defect Repair
- AP Shunt
- ASD Repair
- Damus Kaye Stansel (DKS)
- Other, specify

**Admitting Diagnosis or Planned  
Implant**

- Heart failure
- Cardiac surgery
- Non-cardiac medical problem
- VAD Placement
- TAH Placement
- Other cardiology
- Acute MI
- Non-cardiac surgery
- Unknown

**Clinical Events and Interventions  
this hospitalization (Pre-implant)**

- Cardiac arrest
- Dialysis
- Intubation
- Major MI
- Cardiac surgery, other
- Positive blood cultures
- Other surgical procedures
- Major Infections
- Unknown
- None
- IABP
- Ultrafiltration
- Ventilator
- Feeding tube
- ECMO
- CABG
- Aortic Valve replacement / repair
- Mitral valve replacement / repair
- Congenital cardiac surgery
- LVAD
- RVAD
- TAH
- Aneurysmectomy (DOR)

**Select Type of infection:**

- Bacterial
- Fungal
- Viral
- Protozoan
- Unknown

**Select Location of infection:**

- Blood
- Endocarditis, native
- Line Sepsis
- Mediastinum
- Pneumonia
- Urine
- Unknown
- Other

**Congenital cardiac surgery,  
Select all that apply:**

- Congenitally Corrected Transposition Repair (double switch)
- Congenitally Corrected Transposition Repair (classic)
- PA Banding
- TOF/DORV/RVOTO Repair
- Ebstein's Anomaly Repair
- VSD Repair
- Norwood Stage I
- Glenn, Bi-directional
- Glenn, Classical
- Fontan Procedure
- d- Transposition of the Great Vessels Repair – arterial switch operation
- d- Transposition of the Great Vessels Repair – atrial switch (Senning/Mustard)
- Truncus Arteriosus Repair
- Complete AV Septal Defect Repair
- AP Shunt
- ASD Repair
- Damus Kaye Stansel (DKS)
- Other, specify

**IV inotrope therapy within 48 hours  
of implant**

- Yes
- No
- Unknown

**If Yes, IV inotrope therapy agents:**

- Dobutamine
- Dopamine
- Milrinone
- Levosimendan
- Epinephrine
- Norepinephrine
- Isoproterenol
- Other, Specify
- Unknown

**Interventions within 48 hours of  
implant**

- IABP
- Dialysis
- Ultrafiltration
- Ventilator
- Feeding tube
- ECMO
- None
- CABG
- Aortic Valve replacement / repair
- Mitral valve replacement / repair
- Congenital card surg
- LVAD
- RVAD
- TAH
- Aneurysmectomy (DOR)

**Congenital Cardiac Surgery  
Select all that Apply:**

- Congenitally Corrected Transposition Repair (double switch)
- Congenitally Corrected Transposition Repair (classic)
- PA Banding
- TOF/DORV/RVOTO Repair
- Ebstein's Anomaly Repair
- VSD Repair
- Norwood Stage I
- Glenn, Bi-directional
- Glenn, Classical
- Fontan Procedure
- d- Transposition of the Great Vessels Repair – arterial switch operation
- d- Transposition of the Great Vessels Repair – atrial switch (Senning/Mustard)
- Truncus Arteriosus Repair
- Complete AV Septal Defect Repair
- AP Shunt
- ASD Repair
- Damus Kaye Stansel (DKS)
- Other, specify

**Is this implant the primary MCSD  
(LVAD or TAH) for this patient?**

- Yes
- No

**The INTERMACS® Patient Profiles are required at pre-implant and at all times when an implant occurs even if this is NOT the primary LVAD or TAH implant.**

**INTERMACS® Patient Profile at time  
of implant**

- 1 "Critical cardiogenic shock" describes a patient who is "crashing and burning", in which a patient has life-threatening hypotension and rapidly escalating inotropic pressor support (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, INTERMACS Patient Profiles for more details)
- 2 "Progressive decline" describes a patient who has been demonstrated "dependent" on inotropic support but nonetheless shows signs of continuing deterioration (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, INTERMACS Patient Profiles for more details)
- 3 "Stable but inotrope dependent" describes a patient who is clinically stable on mild-moderate doses of intravenous inotropes (or has a temporary circulatory support device) after repeated documentation of failure to wean without symptoms (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, INTERMACS Patient Profiles for more details)
- 4 "Resting symptoms" describes a patient who is at home on oral therapy but frequently has symptoms of congestion at rest or with ADL. (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, INTERMACS Patient Profiles for more details)
- 5 "Exertion Intolerant" describes a patient who is comfortable at rest but unable to engage in any activity, living predominantly within the house or household (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, INTERMACS Patient Profiles for more details)
- 6 "Exertion Limited" also describes a patient who is comfortable at rest without evidence of fluid overload, but who is able to do some mild activity (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, INTERMACS Patient Profiles for more details)
- 7 "Advanced NYHA Class 3" describes a patient who is clinically stable with a reasonable level of comfortable activity, despite history of previous decompensation that is not recent (see the Site Users Guide, Section II. 2.4 Pre-Implant Form, INTERMACS Patient Profiles for more details)

**MODIFIERS of the INTERMACS® Patient Profiles**

**A - Arrhythmia.**

- Yes
- No
- Unknown

**TCS –Temporary Circulatory Support.**

- Yes
- No
- Unknown

**FF – Frequent Flyer Home.**

- Yes
- No
- Unknown

**FF – Frequent Flyer.**

- Yes
- No
- Unknown



# PreImplant - Intermacs

## Hemodynamics

### General Hemodynamics

**Heart rate**  beats per min

ST=  Unknown  
 Not done

**Systolic blood pressure**  mmHg

ST=  Unknown  
 Not done

**Diastolic blood pressure**  mmHg

ST=  Unknown  
 Not done

**Doppler Opening Pressure**

ST=  Unknown  
 Not done  
 Not applicable

**Peripheral edema**

Yes  
 No  
 Unknown

**Ascites**

Yes  
 No  
 Unknown

**ECG rhythm**

Sinus  
 Atrial fibrillation  
 Atrial Flutter  
 Paced: Atrial pacing  
 Paced: Ventricular pacing  
 Paced: Atrial and ventricular pacing  
 Not done  
 Unknown  
 Other, specify

### Echo Findings

**Mitral regurgitation**

0 (none)  
 1 (mild)  
 2 (moderate)  
 3 (severe)  
 Not Recorded or Not Documented

- Tricuspid regurgitation**
- 0 (none)
  - 1 (mild)
  - 2 (moderate)
  - 3 (severe)
  - Not Recorded or Not Documented

- Aortic regurgitation**
- 0 (none)
  - 1 (mild)
  - 2 (moderate)
  - 3 (severe)
  - Not Recorded or Not Documented

- LVEF**
- > 50 (normal)
  - 40-49 (mild)
  - 30-39 (moderate)
  - 20-29 (moderate/severe)
  - < 20 (severe)
  - Not Recorded or Not Documented
  - Unknown

If a number or range is available, check the number range that best applies. For example, a reported ejection fraction of 30-35 would be entered as 30-40. Occasionally the LVEF may be described only as "left ventricular function" or "systolic function" in words. "Mild impairment, mildly reduced, or mild decrease" would all be characterized as "mild".

**LVEDD**  cm  
 ST=  Not Recorded or Not Documented

- RVEF**
- Normal
  - Mild
  - Moderate
  - Severe
  - Not Done
  - Not Applicable
  - Unknown

RV Function is generally NOT measured in numbers, as it is difficult to quantify. It may be described as "right ventricular function" or "right ventricular contractility". "Mild impairment, mildly reduced, or mild decrease" would all be characterized as "mild". Again, mild-moderate would be recorded as moderate, and moderate-severe would be recorded as "severe".

**Swan Hemodynamics**

**Pulmonary artery systolic pressure**  mmHg  
 ST=  Unknown  
 Not done

**Pulmonary artery diastolic pressure**  mmHg  
 ST=  Unknown  
 Not done

**Mean Pulmonary artery wedge pressure**  mmHg  
 ST=  Unknown

Not done

**Mean RA Pressure**

mmHg

ST=  Unknown

Not done

**Central venous pressure (CVP)**

mmHg

ST=  Unknown

Not done

**Cardiac Index**

L/min/M2 (by Swan)

ST=  Unknown

Not done

**Was Cardiac Index Measured by Fick or Thermodilution?**

Yes

No

Unknown

**Choose Method**

Fick

Thermodilution

**Cardiac output**

L/min

ST=  Unknown

Not done

**Was Cardiac Output Measured by Fick or Thermodilution?**

Yes

No

Unknown

**Choose Method**

Fick

Thermodilution

# Prelimplant - InterMACs

## Laboratory

**Sodium**  mEq/L  
 mmol/L  
 ST=  Unknown  
 Not done

**Potassium**  mEq/L  
 mmol/L  
 ST=  Unknown  
 Not done

**Blood urea nitrogen**  mg/dL  
 mmol/L  
 ST=  Unknown  
 Not done

**Creatinine**  mg/dL  
 umol/L  
 ST=  Unknown  
 Not done

**SGPT/ALT (alanine aminotransferase/ALT)**  u/L  
 ST=  Unknown  
 Not done

**SGOT/AST (aspartate aminotransferase/AST)**  u/L  
 ST=  Unknown  
 Not done

**LDH**  units/L, U/L, ukat/L  
 ST=  Unknown  
 Not done

**Total bilirubin**  mg/dL  
 umol/L  
 ST=  Unknown  
 Not done

**Albumin**  g/dL  
 g/L  
 ST=  Unknown  
 Not done

**Pre-albumin**

mg/dL  
 mg/L

ST=  Unknown  
 Not done

**Total Cholesterol**

mg/dL  
 mmol/L

ST=  < 50 mg/dL  
 Unknown  
 Not done

**Brain natriuretic peptide BNP**

pg/mL  
 ng/L

ST=  > 7500 pg/mL  
 Unknown  
 Not done

**NT pro brain natriuretic peptide Pro-BNP**

pg/mL  
 ng/L

ST=  Unknown  
 Not done

**White blood cell count**

x10<sup>3</sup>/uL  
 x10<sup>9</sup>/L

ST=  Unknown  
 Not done

**Hemoglobin**

g/dL  
 g/L  
 mmol/L

ST=  Unknown  
 Not done

**Hemoglobin A1C**

%  
 mmol/mol

**Estimated Average Glucose (eAG):**

mg/dL  
 mmol/L

ST=  Unknown  
 Not Done

**Platelets**

x10<sup>3</sup>/uL  
 x10<sup>9</sup>/L

ST=  Unknown  
 Not done

**INR**  international units

ST=  Unknown  
 Not done

---

**Sensitivity CRP  
(C Reactive Protein)**  mg/L

ST=  Unknown  
 Not done

---

**Lupus Anticoagulant**  Positive  
 Negative  
 Unknown

---

**Uric acid**  mg/dL

umol/L

ST=  <1 mg/dL  
 Unknown  
 Not done

---

**Lymphocyte Count**  %

x10<sup>3</sup> cells/ $\mu$ L

x10<sup>9</sup> cells/liter

ST=  Unknown  
 Not done  
 <2%

# PreImplant - Intermacs

## Concerns and Contraindications

Concerns / Contraindications	Is condition present?		Limitation for transplant listing?		
	Yes	No	Yes	No	
<b>Overall Status</b>					
Advanced age	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Frailty	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Patient does not want transplant	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Musculoskeletal limitation to ambulation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Contraindication to immunosuppression	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Allosensitization	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Chronic Renal Disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
<b>Cardiothoracic issues</b>	<b>Yes</b>	<b>No</b>	<b>Yes</b>	<b>No</b>	
Frequent ICD Shocks	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Pulmonary Disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Pulmonary Hypertension	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Recent Pulmonary Embolus	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
History Of Atrial Arrhythmia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Unfavorable Mediastinal Anatomy (includes sternotomies, sternal resection, radiation, flail chest, etc)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Thoracic Aortic Disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
<b>Nutritional/GI</b>	<b>Yes</b>	<b>No</b>	<b>Yes</b>	<b>No</b>	
Large BMI	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Severe Diabetes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Malnutrition Cachexia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
History Of GI Ulcers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
History Of Hepatitis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Liver Dysfunction	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
<b>Vascular issues</b>	<b>Yes</b>	<b>No</b>	<b>Yes</b>	<b>No</b>	
Heparin Induced Thrombocytopenia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Chronic Coagulopathy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Major Stroke	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Other Cerebrovascular Disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Peripheral Vascular Disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
<b>Oncology/infection issues</b>	<b>Yes</b>	<b>No</b>	<b>Unknown</b>	<b>Yes</b>	<b>No</b>

History Of Solid Organ Cancer	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
History Of Lymphoma Leukemia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
History Of Bone Marrow Transplant BMT	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
History Of HIV	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Chronic Infectious Concerns	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

<b>Psychosocial issues</b>	<b>Yes</b>	<b>No</b>	<b>Yes</b>	<b>No</b>
Limited Cognition/Understanding	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Limited Social Support	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Repeated Noncompliance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
History Of Illicit Drug Use	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
History Of Alcohol Abuse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Narcotic Dependence	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
History Of Smoking	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Currently Smoking	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Severe Depression	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other Major Psychiatric Diagnosis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other Comorbidity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**HIV History**

**HIV Diagnosis Date**

ST=  Unknown  
 Not Done

**Plasma HIV-1 RNA (Viral load) -  
 Closest to implant**

 copies/ml

ST=  Not Done

**CD4 T-Cell Count - Closest to  
 implant**

 cells/mm3

ST=  Not Done

**Erythrocyte Sedimentation Rate  
 (ESR)**

 mm/hr

ST=  Not Done

**C-Reactive Protein (CRP)**

 mg/L

ST=  Not Done

**Antiretroviral Therapy**

- Abacavir (ABC) / Ziagen
- Atripla (FTC/EDV/TDF)
- Atazanavir (ATV) / Reyataz
- Combivir (3TC/ZDV)
- Complera (FTC/RPV/TDF)
- Darunavir (DRV) / Prezista
- Delavirdine (DLV) / Rescriptor
- Didanosine (ddI) / Videx EC
- Dolutegravir / Tivicay
- Efavirenz (EFV) / Sustiva



- Emtricitabine (FTC) / Emtriva
- Enfuvirtide (T20) / Fuzeon
- Epzicom (3TC/ABC)
- Etravirine (ETR) / Intelence
- Fosamprenavir (FPV) / Lexiva
- Indinavir (IDV) / Crixivan
- Kaletra (LPV/r)
- Lamivudine (3TC) / EpiVir
- Maraviroc (MVC) / Selzentry
- Nelfinavir (NFV) / Viracept
- Nevirapine (NVP) / Viramune / Viramune XR
- Raltegravir (RAL) / Isentress
- Rilpivirine (RPV) / Edurant
- Ritonavir (RTV) / Norvir
- Saquinavir (SQV) / Invirase
- Stavudine (d4T) / Zerit
- Stribild (FTC/EVG/COBI/TDF)
- Tenofovir Disoproxil Fumarate (TDF) / Viread
- Tipranavir (TPV) / Aptivus
- Trizivir (3TC/ZDV/ABC)
- Truvada (FTC/TDF)
- Zidovudine (ZDV) / Retrovir
- Unknown
- None

**Infection Prophylaxis**

- Atovaquone
- Azithromycin
- Dapsone
- Fluconazole
- Pentamidine, aerosolized
- Trimethoprim-sulfamethoxazole (TMP-SMX)
- Unknown
- None

**History of Opportunistic Infection**

- Cryptococcosis
- Cytomegalovirus (CMV)
- Epstein Barr virus (EBV)
- Esophageal candidiasis
- Histoplasmosis
- Kaposi's sarcoma
- Mycobacterium avium complex (MAC), disseminated
- Pneumocystis jiroveci (carinii) pneumonia (PCP)
- Toxoplasmosis
- Tuberculosis
- None

**History of Hepatitis B**

- Positive
- Negative
  
- ST=  Unknown
- Not Done

**History of Hepatitis C**

- Positive
- Negative
  
- ST=  Unknown
- Not Done

# PreImplant - InterMACs

## Medications

- Allopurinol**
- Currently using
  - Known previous use (within past year)
  - No
  - Unknown

- Angiotensin receptor blocker drug**
- Currently using
  - Known previous use (within past year)
  - No
  - Unknown

- Amiodarone**
- Currently using
  - Known previous use (within past year)
  - No
  - Unknown

- ACE inhibitors**
- Currently using
  - Known previous use (within past year)
  - No
  - Unknown

- Beta-blockers**
- Currently using
  - Known previous use (within past year)
  - No
  - Unknown

- Aldosterone antagonist**
- Currently using
  - Known previous use (within past year)
  - No
  - Unknown

- Warfarin (coumadin)**
- Currently using
  - Known previous use (within past year)
  - No
  - Unknown

- Antiplatelet therapy drug**
- Currently using
  - Known previous use (within past year)
  - No
  - Unknown

- Nesiritide**
- Yes
  - No
  - Unknown

- Nitric oxide**
- Yes

- No
- Unknown

**Loop diuretics**

- Yes
- No
- Unknown

**If yes, enter dosage**

 mg/day

ST=  Unknown

**Type of Loop Diuretic:**

- Furosemide
- Torsemide
- Bumetanide
- Other

**Outpatient (prior to admission)  
inotrope infusion:**

- Yes
- No
- Unknown

**Cardiac Resynchronization Therapy  
(CRT)**

- Yes
- No
- Unknown

**Is patient on Metalozone/Thiazide?**

- Yes
- No
- Unknown

**If yes, then select (check one):**

- Regular
- Intermittent

**Is patient on Phosphodiesterase  
inhibitors?**

- Yes
- No
- Unknown

# PreImplant - InterMACs

## Quality Of Life

(QOL surveys cannot be administered after the visit date)

### EuroQol (EQ-5D)

Did the patient complete a EuroQol form?

Yes  
 No  
 Unknown

How was the test administered?

Self-administered  
 Coordinator administered  
 Family member administered

**Mobility:**

I have no problems in walking about  
 I have some problems in walking about  
 I am confined to bed  
 Unknown

**Self care:**

I have no problems with self-care  
 I have some problems washing or dressing myself  
 I am unable to wash or dress myself  
 Unknown

**Usual Activities (e.g. work, study, housework, family or leisure activities)**

I have no problems with performing my usual activities  
 I have some problems with performing my usual activities  
 I am unable to perform my usual activities  
 Unknown

**Pain/discomfort:**

I have no pain or discomfort  
 I have moderate pain or discomfort  
 I have extreme pain or discomfort  
 Unknown

**Anxiety/depression:**

I am not anxious or depressed  
 I am moderately anxious or depressed  
 I am extremely anxious or depressed  
 Unknown

**Patient Visual Analog Status (VAS):**  (0-100) 0=Worst, 100=Best  
 ST=  Unknown

**Which of the following best describes your \*one\* main activity?**

Actively working  
 Retired  
 Keeping house  
 Student  
 Seeking work  
 Too sick to work (disabled)

Unknown

Other

**Is this \*one\* main activity considered:**

Full time

Part time

Unknown

**How many of your close friends or relatives do you see in person, speak to on the telephone or contact via the internet at least once a month? (please count each person 1 time)?**

ST=  Unknown

**Have you unintentionally lost more than 10 pounds in the last year?**

Yes

No

Unknown

**Do you currently smoke cigarettes?**

Yes

No

Unknown

**If Yes, How many cigarettes are you currently smoking, on average?**

Half a pack or less per day

More than half to 1 pack per day

1 to 2 packs per day

2 or more packs per day

**Do you currently smoke e-cigarettes?**

Yes

No

Unknown

**Please enter a number from 1 to 10 for the questions below:**

**How much stress related to your health issues do you feel you've been under during the past month?**

ST=  Unknown

**How well do you feel you've been coping with or handling your stress related to your health issues during the past month?**

ST=  Unknown

**How confident are you that you can do the tasks and activities needed to manage your heart failure so as to reduce how much having heart failure affects your everyday life?**

ST=  Unknown

**How satisfied are you with the outcome of your therapy for heart failure during the past 3 months?**

ST=  Unknown

**If No, Please select a reason why the EuroQol (EQ-5D) was not completed:**

Too sick (ex., intubated/sedated, critically ill, on short-term VAD)

Too tired

- Too stressed, anxious, and/or depressed
- Can't concentrate
- No time/too busy
- Too much trouble/don't want to be bothered/not interested
- Unwilling to complete instrument, no reason given
- Unable to read English and/or illiterate
- Administrative (check specific reason below)

**If Administrative: Select a specific reason:**

- Urgent/emergent implant, no time to administer QOL instruments
- Coordinator too busy or forgot to administer QOL instruments
- Unable to contact patient (ie., not hospitalized or no clinic visit) within the window for QOL instrument completion
- Other reason (describe)

**Kansas City Cardiomyopathy Questionnaire**

**Did the patient complete a KCCQ form?**

- Yes
- No

**How was the test administered?**

- Self-administered
- Coordinator administered
- Family member administered

**Heart Failure affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by heart failure (shortness of breath or fatigue) in your ability to do the following activities over the past 2 weeks.**

**Showering/Bathing**

- Extremely limited
- Quite a bit limited
- Moderately limited
- Slightly limited
- Not at all limited
- Limited for other reasons or did not do the activity
- Unknown

**Walking 1 block on level ground**

- Extremely limited
- Quite a bit limited
- Moderately limited
- Slightly limited
- Not at all limited
- Limited for other reasons or did not do the activity
- Unknown

**Hurrying or jogging (as if to catch a bus)**

- Extremely limited
- Quite a bit limited
- Moderately limited
- Slightly limited
- Not at all limited
- Limited for other reasons or did not do the activity
- Unknown

**Over the past 2 weeks, how many times did you have swelling in your feet, ankles or legs when you woke up in the morning?**

- Every morning
- 3 or more times a week, but not every day
- 1-2 times a week
- Less than once a week
- Never over the past 2 weeks
- Unknown

**Over the past 2 weeks, on average, how many times has fatigue limited your ability to do what you want?**

- All of the time
- Several times per day
- At least once a day
- 3 or more times per week but not every day
- 1-2 times per week
- Less than once a week
- Never over the past 2 weeks
- Unknown

**Over the past 2 weeks, on average, how many times has shortness of breath limited your ability to do what you wanted?**

- All of the time
- Several times per day
- At least once a day
- 3 or more times per week but not every day
- 1-2 times per week
- Less than once a week
- Never over the past 2 weeks
- Unknown

**Over the past 2 weeks, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of shortness of breath?**

- Every night
- 3 or more times a week, but not every day
- 1-2 times a week
- Less than once a week
- Never over the past 2 weeks
- Unknown

**Over the past 2 weeks, how much has your heart failure limited your enjoyment of life?**

- It has extremely limited my enjoyment of life
- It has limited my enjoyment of life quite a bit
- It has moderately limited my enjoyment of life
- It has slightly limited my enjoyment of life
- It has not limited my enjoyment of life at all
- Unknown

**If you had to spend the rest of your life with your heart failure the way it is right now, how would you feel about this?**

- Not at all satisfied
- Mostly dissatisfied
- Somewhat satisfied
- Mostly satisfied
- Completely satisfied
- Unknown

**How much does your heart failure affect your lifestyle? Please indicate how your heart failure may have limited your participation in the following activities over the past 2 weeks?**

**Hobbies, recreational activities**

- Severely limited
- Limited quite a bit
- Moderately limited
- Slightly limited
- Did not limit at all
- Does not apply or did not do for other reasons
- Unknown

**Working or doing household chores**

- Severely limited
- Limited quite a bit
- Moderately limited
- Slightly limited
- Did not limit at all
- Does not apply or did not do for other reasons
- Unknown

**Visiting family or friends out of your home**

- Severely limited
- Limited quite a bit
- Moderately limited
- Slightly limited
- Did not limit at all
- Does not apply or did not do for other reasons
- Unknown

**If No, Please select a reason why the KCCQ was not completed:**

- Too sick (ex., intubated/sedated, critically ill, on short-term VAD)
- Too tired
- Too stressed, anxious, and/or depressed
- Can't concentrate
- No time / too busy
- Too much trouble / don't want to be bothered / not interested
- Unwilling to complete instrument, no reason given
- Unable to read English and/or illiterate
- Administrative (check specific reason below)

**If Administrative: Select a specific reason:**

- Urgent/emergent implant, no time to administer QOL instruments
- Coordinator too busy or forgot to administer QOL instruments
- Unable to contact patient (ie., not hospitalized or no clinic visit) within the window for QOL instrument completion
- Other reason (describe)



# PreImplant - InterMACs

## Exercise Function and Trailmaking Data

**6 minute walk**

feet

ST=  Not done: too sick

Not done: other

Unknown

This requires an inside hall for which distances (in FEET) should be measured, preferably as long as possible to avoid frequent turns. Patients are instructed to walk steadily to cover as much distance as possible during the 6 minutes. They are advised that they may stop if necessary during the 6 minutes. The staff member performing the test should walk behind the patient to avoid undue influence on the pace. The distance covered during the 6 minutes in feet will be recorded here. **NOTE: You may use the time from the first 15 feet of the 6minute walk for the Gait speed test listed below (please see instructions for the gait speed test below.)**

**Gait Speed (1st 15 foot walk)**

seconds

ST=  Not done: too sick

Not done: other

Unknown

Instructions: Record the time (seconds) required for the patient to walk the first 15 feet of the 6 minute walk. The "starting" line and the 15 foot line should be clearly marked. Record the time to the first footfall at 0 feet and ends with the first footfall at 15 feet in the nearest. 0.1 sec with a stopwatch. **NOTE: You may use the time from the first 15 feet of the 6 minute walk for the Gait speed test.**

**Peak VO2 Max**

mL/kg/min

ST=  Not done: too sick

Not done: other

Unknown

Maximum volume of oxygen the body can consume during exercise (mL/kg/min) is the ml/kg/min of oxygen consumed during symptom-limited exercise testing either on a bicycle or treadmill. The values recorded during the bicycle are usually 1-2 ml/min lower than for the treadmill, but it is assumed that most institutions will use only one instrument. If both are available, the bicycle is preferable as the mode easiest to standardize.

**R Value at peak**

%

ST=  Unknown

Not done

R Value at peak is the respiratory quotient of carbon dioxide production divided by oxygen consumption, and is used as an index of how vigorously the patient exercised. A value above 1.05 is generally considered to represent an adequate effort.

## Trailmaking

**Status:**

Completed

Attempted but not completed

Not attempted

Completed but invalid (scores not entered)

**Time:**

seconds

## Medical Condition

**NYHA Class**

Class I: No limitation of physical activity; physical activity does not cause fatigue, palpitation or shortness of breath.

- Class II: Slight limitation of physical activity; comfortable at rest, but ordinary physical activity results in fatigue, palpitations or shortness of breath.
- Class III: Marked limitation of physical activity; comfortable at rest, but less than ordinary activity causes fatigue, palpitation or shortness of breath.
- Class IV: Unable to carry on minimal physical activity without discomfort; symptoms may be present at rest.
- Unknown

# Screening Log - Intermacs

Implant Date

## Inclusion: Patient must meet all inclusion criteria:

- Patient receives a durable mechanical circulatory support device (MCS) which is FDA approved
- Implanted on or after March 1, 2006 (The device does not need to be the first implant for the patient)
- Patient signed informed consent for the registry

## Exclusion: Any exclusion will disqualify the patient for entry into INTERMACS®

- Patient receives a durable mechanical circulatory support device (MCS) which is not FDA approved
- Patient is incarcerated (prisoner)
- Patient did not sign the informed consent

Device type

- LVAD
- RVAD
- Both (LVAD + RVAD in the same OR visit)
- Total Artificial Heart

Device brand

- Berlin Heart EXCOR (paracorporeal)
- HeartWare HVAD
- HeartMate II LVAS
- HeartMate III
- HeartMate IP
- HeartMate VE
- HeartMate XVE
- Micromed DeBakey VAD - Child
- Novacor PC
- Novacor PCq
- Thoratec IVAD
- Thoratec PVAD
- Other, Specify

Specify brand

Device brand (RVAD)

Specify brand (RVAD)

Age Range

- 19 to 39
- 40 to 59
- 60 to 79
- 80+

**Race**

- American Indian or Alaska Native
- Asian
- African-American or Black
- Hawaiian or other Pacific Islander
- White
- Unknown / Undisclosed
- Other / none of the above

**Ethnicity: Hispanic or Latino**

- Yes
- No
- Unknown

**Gender**

- Male
- Female
- Unspecified

**Did death occur within 2 days post implant?**

- Yes
- No

**Is this VAD an investigational device?**

- Yes
- No

**Is patient involved in a VAD related study?**

- Yes
- No
- Unknown

**What is the name of the study?****Is this an industry sponsored post approval study?**

- Yes
- No
- Unknown

# Transfer Form - Intermacs

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**Transferred Care to another hospital**

- Yes
- No

**Date transferred care**

ST=  Unknown

## Withdraw Consent - Intermacs

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**Did the patient withdraw consent?**

- Yes
- No

**Date of withdrawn consent:**