PreImplant

The Pre-implant Form should be collected at time of implant or closest to implant date within 60 days pre-implant but not in the OR. The Quality of Life surveys need to be collected within 30 days pre-implant.

PreImplant Status

Demographics

Height

Enter the height of the patient at the time of implantation in inches or centimeters. The height must fall between 10 and 96 inches or 25 and 244 centimeters.

_____ in
_____ cm
ST= ○Unknown
○Not Done

Weight

Enter the weight of the patient at the time of implantation in the appropriate space, in pounds or kilograms. The weight must fall between 5 and 600 pounds or 2 and 273 kilograms.

_____ 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
_____

This should be determined in conjunction with the heart failure cardiologist and surgeon at the time of the implant. This determination will be re-visited and recorded at 3 months, 6 months, and every 6 months thereafter.

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

The length of time that the patient had any known cardiac diagnosis. For example, the time since the patient had a myocardial infarction, congenital heart disease was noted or the patient was noted to have heart failure.

Number of cardiac hospitalizations

○0-1

in the last 12 months

- ○2-3
- ○4 or more
- ○Unknown

Cardiac diagnosis / Primary

Check one primary reason for cardiac dysfunction

- ○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: Sarciodosis
- ○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

Select all that apply. Secondary reasons for cardiac dysfunction.

- ☐ 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: Sarciodosis
- [ ] 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

If the patient has had an endomyocardial or direct myocardial biopsy, select from the diagnoses listed in the drop down. If the patient has had more than one biopsy (within their lifetime), the one closest to implantation date should be listed it is okay to use cardiac biopsy removed during the implant operation. If no biopsy is known, select "no biopsy known".

Previous cardiac operation

Select all cardiac operations that the patient has had prior to MCSD implantation.

- [ ] None
- [ ] CABG
- [ ] Aneuryomectomy (DOR)
- [ ] Aortic Valve replacement / repair
- [ ] Mitral valve replacement / repair
- [ ] Triscuspid 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)

Pertaining to this implant hospitalization

☐ 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
☐ Aneursyomectomy (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 the patient has gone to the operating room for the purpose of the implant and is on intravenous inotropes of any sort, the answer should be Yes. If an agent is known to have been used but discontinued within 48 hours prior to arriving in the operating room, Yes should also be checked.

If Yes, IV inotrope therapy agents:

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

Interventions within 48 hours of implant

Select all 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
- [ ] Aneursyomectomy (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

INTERMACS® Patient Profile at time of implant

Select one. These profiles will provide a general clinical description of the patients receiving primary LVAD or TAH implants. If there is significant clinical change between the initial decision to implant and the actual implant procedure, then the profile closest to the time of implant should be recorded. Patients admitted electively for implant should be described by the profile just prior to admission.

- ○ 1 "Critical cardiogenic shock" describes a patient who is "crashing and burning", in which a patient has life-threatening hypotension and rapdily 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

This modifier can modify any profile. Recurrent ventricular tachyarrhythmias that have recently contributed substantially to the overall clinical course. This includes frequent shocks from ICD or requirement for external defibrillator, usually more than twice weekly.

TCS –Temporary Circulatory Support.

○ Yes
○ No
○ Unknown

This modifier can modify only patients who are confined to the hospital, Patient Profiles 1, 2, and 3 (a patient who is listed as Patient Profile 3 stable on inotropes who has been at home until elective admission for implantable VAD cannot have a TCS modifier); support includes, but is not limited to, IABP, ECMO, TandemHeart, Levitronix, BVS 5000 or AB5000, Impella.

FF – Frequent Flyer Home.

○ Yes
○ No
○ Unknown

This modifier is designed for Patient Profiles 4, 5, and 6. This modifier can modify Patient Profile 3 if usually at home (frequent admission would require escalation from Patient Profile 7 to Patient Profile 6 or worse). Frequent Flyer is designated for a patient requiring frequent emergency visits or hospitalizations for intravenous diuretics, ultrafiltration, or brief inotropic therapy. Frequent would generally be at least two emergency visits/admissions in the past 3 months or 3 times in the past 6 months. Note: if admissions are triggered by tachyarrhythmias or ICD shocks then the modifier to be applied to would be A, not FF.

FF – Frequent Flyer.

○ Yes
○ No
○ Unknown

This modifier is designed for Patient Profiles 4, 5, and 6. This modifier can modify Patient Profile 3 if usually at home (frequent admission would require escalation from Patient Profile 7 to Patient Profile 6 or worse). Frequent Flyer is designated for a patient requiring frequent emergency visits or hospitalizations for intravenous diuretics, ultrafiltration, or brief inotropic therapy. Frequent would generally be at least two emergency visits/admissions in the past 3 months or 3 times in the past 6 months. Note: if admissions are triggered by tachyarrhythmias or ICD shocks then the modifier to be applied to would be A, not FF.

PreImplant

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Hemodynamics

General Hemodynamics (Closest to implant but not in OR)

Heart rate

_____ beats per min

ST= ○Unknown
○Not done

Systolic blood pressure
(millimeters of mercury) should be determined from auscultation or arterial line if necessary.

_____ mmHg

ST= ○Unknown
○Not done

Diastolic blood pressure
(millimeters of mercury) should be determined from auscultation or arterial line if necessary

_____ mmHg

ST= ○Unknown
○Not done

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

_____

ST= ○Unknown
○Not done
○Not applicable

ECG rhythm
(cardiac rhythm)

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

Echo Findings (Closest to implant but not in OR)

Mitral regurgitation
Mitral regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".

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

Tricuspid regurgitation
Tricuspid regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".

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

Aortic regurgitation
Aortic regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".

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

○Not Applicable
○Unknown

LVEF
Left ventricular ejection fraction.

○> 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 (Closest to implant but not in OR)

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

Cardiac output L/min

ST= ○Unknown

○Not done

PreImplant

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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
If value is outside given range please see 'Status (ST=)' drop down field.
If < 50 mg/dl select from the 'status' drop down field.

mg/dL
mmol/L
ST= ○< 50 mg/dL
○Unknown
○Not done

Brain natriuretic peptide BNP
If value is outside given range please see 'status (ST=)' drop down field.
If > 7500 pg/mL select from the 'status' drop down field.

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

$x10^3$/uL
$x10^9$/uL
ST= ○Unknown
○Not done

Hemoglobin

g/dL
g/L
mmol/L
ST= ○Unknown
○Not done

Platelets

$x10^3$/uL
$x10^9$/uL
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= ○Unknown
○Not done

Lymphocyte Count

%

x10^3 cells/µL

x10^9 cells/liter

ST= ○Unknown
○Not done

PreImplant

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Concerns and Contraindications

Checking any of these contraindications/co-morbidities/concerns does not necessarily mean that a condition is a contraindication or concern for the patient. No specific thresholds are provided for these concerns or contraindications. They should represent the results of formal discussion with the medical and surgical transplant team prior to the decision for device implantation. If there are no contraindications or concerns specified then select No.

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

History Of Lymphoma Leukemia	○	○	○	○
History Of Bone Marrow Transplant BMT	○	○	○	○
History Of HIV	○	○	○	○
Chronic Infectious Concerns	○	○	○	○

Psychosocial issues	**Yes**	**No**	**Yes**	**No**
Limited Cognition/Understanding	○	○	○	○
Limited Social Support	○	○	○	○
Repeated Noncompliance	○	○	○	○
History Of Illicit Drug Use	○	○	○	○
History Of Alcohol Abuse	○	○	○	○
Narcotic Dependence	○	○	○	○
History Of Smoking	○	○	○	○
Currently Smoking	○	○	○	○
Severe Depression	○	○	○	○
Other Major Psychiatric Diagnosis	○	○	○	○
Other Comorbidity	○	○	○	○

HIV History

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

HIV Diagnosis Date
MM/DD/YYYY

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
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 (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
- ☐ Tipranivir (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
- ☐ Trimethroprim-sulfamethoxazole (TMP-SMX)
- ☐ Unknown
- ☐ None

History of Opportunistic 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
- ☐ None

History of Hepatitis B

- ○ Positive
- ○ Negative

ST= ○Unknown
○Not Done

History of Hepatitis C

- ○ Positive
- ○ Negative

ST= ○Unknown
○Not Done

PreImplant

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Medications

Currently using - At the time of VAD placement.

Known previous use within the past year - Is intended to capture the adequacy of medical therapy prior to determining heart failure to be refractory. For instance, ACEI, beta blockers, and diuretics are considered standard necessary therapy for heart failure but may be stopped due to hypotension or renal failure during a hospitalization for severely decompensated heart failure. If patients are known to have received these agents within the past year, please check known previous use.

No (not being used) - If there is no reason to believe that they have taken those agents, and reasonable certainty that information is accurate, check No.

Unknown - If it is not known whether the patient has taken those agents within the previous year, check Unknown.

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
Enter the total daily dose the patient received at home before hospitalization.

_____ 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?
Please enter only for the indication of Pulmonary Hypertension or Right Heart Failure
- ○ Yes
- ○ No
- ○ Unknown

PreImplant

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Quality Of Life

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
○Unknown

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?
(1-10) 1=No Stress, 10=Very Much Stress

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?
(1-10) 1=Coping very poorly, 10=Coping very well

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?
(1-10) 1=Not at all confident, 10=Totally confident

ST= ○Unknown

How satisfied are you with the outcome of your therapy for heart failure during the past 3 months?
(1-10) 1=Not satisfied, 10=Very satisfied

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 indiciate how your heart failure may have limited your participation in the following activites 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)

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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
New York Heart Association Class for heart failure

○ 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