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# STS Intermacs

## Quarterly Quality Assurance Report (2021 Q2) - Prior VAD Patients

### HOSPX - DEMO SITE REPORT

*Implant and event dates: January 1, 2020 to June 30, 2021*

09/30/2021

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HOSPX - DEMO SITE REPORT**

## **About This Report**

The “Recent” version of the Quality Assurance report focuses on a contemporary cohort of patients. This report includes patients whose initial VAD was implanted within the previous 6 quarters.

The “Prior VAD Patients” version of the report is limited to patients whose first device pre-implant form indicates prior VAD support.

## **Confidential**

This report is intended only for STS Intermacs personnel at the hospital named on the cover of this report. Distribution of the report to other personnel within the hospital is left to the discretion of the STS Intermacs site administrator and physician representative. The STS Intermacs data in this report may not be distributed to anyone outside of your hospital. STS Intermacs has a separate mechanism for the creation and distribution of STS Intermacs aggregate data.

## **Disclaimer**

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**This quarterly report includes clinical information from 7 patients receiving implants between January 1, 2020 and June 30, 2021 at HOSPX - DEMO SITE REPORT.**

## Table of Contents

- I. Introduction and Methods**
  - A. Purposes of this Report**
  - B. Source of Data and Limitations**
  - C. Statistical Summaries and Benchmarks for Quality Assurance**
  - D. Registry Compliance**
  - E. Future Reports**
  - F. Report Coverage - Patient Selection**
- II. Statistical Summaries and Benchmarks for Quality Assurance**
  - A. Pre-implant Summaries**
    - Demographics
    - Clinical Characteristics
    - Concerns and Contraindications
    - Hemodynamics
    - Functional Capacity and Quality of Life
    - Additional Interventions
  - B. Implant Summaries**
  - C. Post Implant Summary**
    - Adverse Event Rates
    - Adverse Event Timing
      - Time to First Device Malfunction and/or Thrombus
      - Time to First Infection
      - Time to First Neurological Dysfunction
    - Hospitals Days
    - 30 Day Readmission Rates
    - Functional Capacity
    - Quality of Life
  - D. Post Implant Risk Adjusted Outcomes**
  - E. Post Implant Outcomes**
    - Survival
    - Competing Outcomes
- III. Zone Conditions: Hemolysis, Hypertension, and Right Heart Failure**
  - Hemolysis
  - Hypertension
  - Right Heart Failure
- IV. Registry Compliance**
- V. Glossary**

Topics in **grey** are not part of this report, but will become part of future reports.

## **I. Introduction and Methods**

### **I.A. Purpose of this Report**

As specified by the STS InterMACS Leadership, the primary goals of the registry are:

- Facilitate the refinement of patient selection to maximize outcomes with current and new device options.
- Identify predictors of good outcomes as well as risk factors for adverse events after device implantation.
- Develop consensus best practice guidelines to improve clinical management by reducing short and long term complications of MCS therapy.
- Guide clinical application and evolution of next generation devices.
- Utilize Registry information to guide improvements in technology, particularly as next generation devices evolve.

Consistent with these goals, we have greatly expanded our site reports to move towards these goals at the hospital and patient level. Specifically, these reports will provide information in the following areas:

- Statistical Summaries and Benchmarks for Quality Assurance
- Patient Level Data
- Registry Compliance
- Data Quality Queries

## **I.B. Source of Data and Limitations**

The data in this report are based on all data entered into the STS Intermacs web-based data application through June 30, 2021. Patient enrollment in STS Intermacs began on June 23, 2006 and retrospective entry of patients with implants after March 1, 2006 was allowed. Your institution may have joined STS Intermacs at a later date and therefore your patient enrollment may have begun at a later date. This report is restricted to your patients who were implanted after your enrollment date and received a primary implant.

STS Intermacs is a registry that strives to meet the data quality standards of a prospective clinical trial. STS Intermacs is an on-going registry and therefore data quality efforts will always have an associated lag time.

As you review the data from your hospital that are contained in this report, you may find some information that appears incorrect or inconsistent. Please remember that this report is a direct function of the data that has been entered at your hospital. Therefore, please check any data issues with your online submitted data. The only caveat to this is that any corrections that you have made to your data since June 30, 2021 will not appear in this report. They will appear in the next quarterly report.

A registry that collects data on mechanical circulatory assist devices is necessarily complex. This complexity is the result of the support that the device provides (left ventricular support, right ventricular support, biventricular support, total heart support) and the potential for multiple exchanges within a patient. The major outcomes are just as complex because the standard outcome of death must be considered in the presence of transplantation and explant due to recovery of the heart. We have organized this report so that the pre-implant data represents all prospective device implants of LVAD, BiVAD or TAH. This is based on the organization of the STS Intermacs web-based data entry and will allow a complete picture of the patients and devices entered for your hospital.

## **I.C. Statistical Summaries and Benchmarks for Quality Assurance**

A primary purpose of this report is to provide statistical summaries of patients enrolled at the local hospital and to provide side-by-side comparisons of the hospital data with the data from the entire STS Intermacs Registry. Therefore these reports will provide the data information component of quality assurance where the hospital can compare both their patient mix with a national standard and will also be able to compare their outcomes after device implant with national results.

STS Intermacs is a valuable source of benchmarking according to what is occurring across the country in the MCSD community. This benchmark is not intended to imply good practice or bad practice but rather allows the hospital to compare the characteristics of their implanted patients with the patients from a national database.

## **I.D. Registry Compliance**

Each hospital is evaluated for compliance and data entry.

## **I.E. Future Reports**

As previously stated, this report is a major step in greatly expanded quarterly reports from STS InterMACS. We will continue expansion of this report which will be the results of our pre-specified plans and feedback from the MCSd community.

Some of our specific plans include statistical summaries according to primary and secondary implants and also according to adult and pediatric patients. We also plan to add a section that summarizes the results of the initial screening log. This will include a frequency of the reasons for failing to obtain informed consent and a comparison to the national experience.

## **I.F. Report Coverage - Inclusion / Exclusion Criteria**

Starting 2020 Q4 the INTERMACS reports have been restructured to provide information from ALL patients enrolled in INTERMACS. To organize the information a series of reports is provided to compare patient characteristics and outcomes of different kinds of patients at your site with the aggregate INTERMACS cohort. The following report versions are created:

- Cumulative - All Patients
- Cumulative - Primary Patients
- Cumulative – Prior VAD Patients
- Recent - All Patients
- Recent - Primary Patients
- Recent – Prior VAD Patients

The CUMULATIVE report versions includes patients enrolled throughout the entire registry and is intended to provide a comprehensive set of long term outcomes. The RECENT report is limited to patients enrolled within the last rolling 6 quarters and provides information on contemporary patients.

The versions of the reports generated for ALL PATIENTS include all patients implanted within the report coverage dates. The PRIMARY PATIENTS versions are limited to patients that do not have a history of prior VAD reported on the pre-implant form of their first INTERMACS enrolled implant. The PRIOR VAD PATIENTS reports are limited to patients in which a prior VAD is indicated on their first enrolled pre-implant form.

There are a few administrative scenarios in which patients are excluded from the CUMULATIVE – ALL PATIENTS Report in order facilitate accurate comparisons to the aggregate INTERMACS data. The following patients are removed from all analyses:

- Retrospective Patients – the patient’s initial implant date is prior to your site’s activation in INTERMACS
- Implant, Pre-Implant, or Patient form not validated – patients missing a fully submitted implant, pre-implant, or patient form are not included because key data elements used in the reporting may be missing.
- Patient Implant Date Outside of Report Coverage Patients implanted prior to the start of data collection June 23, 2006 or after the report coverage stop date December 31, 2020 are not include in the report.
- Pediatric Patients (Age <19 years at implant

Patients that meet these exclusion criteria are listed in “Exhibit 49: Patients Implanted at your Center but Excluded from the Cumulative - All Patient Report

The accompanying Data Quality Report lists all patients enrolled in STS Intermacs at your site.

Transfer patients and their subsequent experience are analyzed in the report for the site that implanted the patients first device enrolled in INTERMACS.



## **II. Statistical Summaries and Benchmarks for Quality Assurance**

The first part of this section contains summary statistics of patients implanted (and enrolled in STS Intermacs) at your hospital. As a benchmark, the corresponding summary statistics for the entire Intermacs Registry are also provided. For explanations and/or definitions of the data elements go to the STS Intermacs User's Guide [www.intermacs.org](http://www.intermacs.org) and select 'Intermacs Appendices', Appendix M/User's Guide'.

The summary statistics for continuous variables includes N (the number of patients with data), MEAN (the average value), STD (standard deviation), MIN (the smallest value), and MAX (the largest value).

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients****COVERAGE: January 1, 2020 - June 30, 2021****SITE: HOSPX - DEMO SITE REPORT*****Exhibit 1: Device Counts for Patients in this Report***

The following tables list the number of implants received by patients meeting the inclusion criteria for this report. Subsequent exhibits are based on a patient level analysis. Characteristics are reported at the time of first implant. Unless noted otherwise, outcomes and follow-up include all information reported to INTERMACS for the patient.

NOTE: For most patients a second device indicates a device exchange. However, this count also includes the patients who receive a subsequent RVAD.

**GROUP=HOSPX-9999**

Device	IMPLANT DATE PERIOD			TOTAL
	2020 Q3	2020 Q4	2021 Q2	
	n	n	n	
Primary Device	1	3	3	7
2nd Device	0	0	0	0
3rd Device	0	0	0	0
4th Device	0	0	0	0
5th Device	0	0	0	0

**GROUP=STS Intermacs**

Device	IMPLANT DATE PERIOD						TOTAL
	2020 Q1	2020 Q2	2020 Q3	2020 Q4	2021 Q1	2021 Q2	
	n	n	n	n	n	n	
Primary Device	66	64	78	91	109	88	496
2nd Device	2	4	3	4	6	2	21
3rd Device	0	1	0	1	1	0	3
4th Device	0	0	0	0	0	0	0
5th Device	0	0	0	0	0	0	0

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Demographics**

**Exhibit 2: Age Group**

The following tables summarize age groups at your site and STS InterMACS over time.

AGE GROUP (yr)	HOSPX-9999							
	2020 Q3		2020 Q4		2021 Q2		TOTAL	
	n	%	n	%	n	%	n	%
19-39	1	100.0 %	.	.	.	.	1	14.2 %
40-59	.	.	1	33.3 %	.	.	1	14.2 %
60-79	.	.	2	66.6 %	3	100.0 %	5	71.4 %
80+	.	.	.	.	.	.	.	.
TOTAL	1	100.0 %	3	100.0 %	3	100.0 %	7	100.0 %

AGE GROUP (yr)	STS InterMACS													
	2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		2021 Q2		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
19-39	9	13.6 %	12	18.7 %	12	15.3 %	12	13.1 %	12	11.0 %	7	7.9 %	64	12.9 %
40-59	27	40.9 %	28	43.7 %	25	32.0 %	43	47.2 %	53	48.6 %	35	39.7 %	211	42.5 %
60-79	29	43.9 %	23	35.9 %	41	52.5 %	36	39.5 %	44	40.3 %	45	51.1 %	218	43.9 %
80+	1	1.5 %	1	1.5 %	.	.	.	.	.	.	1	1.1 %	3	0.6 %
TOTAL	66	100.0 %	64	100.0 %	78	100.0 %	91	100.0 %	109	100.0 %	88	100.0 %	496	100.0 %

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT****II.A. Pre-Implant Summaries - Demographics****Exhibit 3: Gender**

The following tables summarize gender at your site and STS Intermacs over time.

GENDER	HOSPX-9999							
	2020 Q3		2020 Q4		2021 Q2		TOTAL	
	n	%	n	%	n	%	n	%
Female	.	.	1	33.3 %	.	.	1	14.2 %
Male	1	100.0 %	2	66.6 %	3	100.0 %	6	85.7 %
TOTAL	1	100.0 %	3	100.0 %	3	100.0 %	7	100.0 %

GENDER	STS Intermacs													
	2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		2021 Q2		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Female	18	27.2 %	11	17.1 %	16	20.5 %	15	16.4 %	31	28.4 %	24	27.2 %	115	23.1 %
Male	48	72.7 %	53	82.8 %	62	79.4 %	76	83.5 %	78	71.5 %	64	72.7 %	381	76.8 %
TOTAL	66	100.0 %	64	100.0 %	78	100.0 %	91	100.0 %	109	100.0 %	88	100.0 %	496	100.0 %

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT****II.A. Pre-Implant Summaries - Demographics****Exhibit 4: Race**

The following tables summarize race at your site and STS InterMACS over time. The coordinator may check all that apply.

RACE	HOSPX-9999							
	2020 Q3		2020 Q4		2021 Q2		TOTAL	
	n	%	n	%	n	%	n	%
African American	1	100.0 %	1	33.3 %	.	.	2	28.5 %
Other, Unknown, Undisclosed	.	.	.	.	.	.	.	.
White	.	.	2	66.6 %	3	100.0 %	5	71.4 %
TOTAL	1	100.0 %	3	100.0 %	3	100.0 %	7	100.0 %

RACE	STS InterMACS													
	2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		2021 Q2		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
African American	17	25.7 %	17	26.5 %	17	21.7 %	20	21.9 %	29	26.6 %	31	35.2 %	131	26.4 %
Other, Unknown, Undisclosed	6	9.0 %	5	7.8 %	9	11.5 %	20	21.9 %	11	10.0 %	7	7.9 %	58	11.6 %
White	43	65.1 %	42	65.6 %	52	66.6 %	51	56.0 %	69	63.3 %	50	56.8 %	307	61.8 %
TOTAL	66	100.0 %	64	100.0 %	78	100.0 %	91	100.0 %	109	100.0 %	88	100.0 %	496	100.0 %

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT****II.A. Pre-Implant Summaries - Demographics****Exhibit 5: Hispanic Ethnicity**

The following tables summarize Hispanic ethnicity at your site and STS Intermacs over time.

HISPANIC ETHNICITY	HOSPX-9999							
	2020 Q3		2020 Q4		2021 Q2		TOTAL	
	n	%	n	%	n	%	n	%
Non-Hispanic	.	.	3	100.0 %	3	100.0 %	6	85.7 %
Unknown	.	.	.	.	.	.	.	.
Hispanic	1	100.0 %	.	.	.	.	1	14.2 %
TOTAL	1	100.0 %	3	100.0 %	3	100.0 %	7	100.0 %

HISPANIC ETHNICITY	STS Intermacs													
	2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		2021 Q2		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Non-Hispanic	59	89.3 %	60	93.7 %	66	84.6 %	76	83.5 %	96	88.0 %	80	90.9 %	437	88.1 %
Unknown	2	3.0 %	1	1.5 %	2	2.5 %	7	7.6 %	2	1.8 %	1	1.1 %	15	3.0 %
Hispanic	5	7.5 %	3	4.6 %	10	12.8 %	8	8.7 %	11	10.0 %	7	7.9 %	44	8.8 %
TOTAL	66	100.0 %	64	100.0 %	78	100.0 %	91	100.0 %	109	100.0 %	88	100.0 %	496	100.0 %

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT****II.A. Pre-Implant Summaries - Clinical Characteristics****Exhibit 6. BSA**

The following tables summarize body surface area (BSA) at your site and STS Intermacs over time. BSA is a variable that is calculated based on the patient's height and weight. The Boyd calculation is used in this analysis.

**GROUP=HOSPX-9999**

PRE-IMPLANT BSA		2020 Q3	2020 Q4	2021 Q2	TOTAL
	<b>N</b>	1	3	3	7
	<b>Mean</b>	2.14	2.19	2.02	2.11
	<b>Std</b>	.	0.47	0.16	0.30
	<b>Min</b>	2.14	1.87	1.91	1.87
	<b>Max</b>	2.14	2.73	2.20	2.73

**GROUP=STS Intermacs**

PRE-IMPLANT BSA		2020 Q1	2020 Q2	2020 Q3	2020 Q4	2021 Q1	2021 Q2	TOTAL
	<b>N</b>	66	63	78	90	109	88	494
	<b>Mean</b>	2.12	2.13	2.08	2.08	2.09	2.13	2.10
	<b>Std</b>	0.33	0.37	0.32	0.28	0.33	0.28	0.32
	<b>Min</b>	1.50	1.03	1.40	1.47	0.98	1.57	0.98
	<b>Max</b>	3.07	3.05	2.95	2.76	2.88	2.89	3.07

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT****II.A. Pre-Implant Summaries - Clinical Characteristics****Exhibit 7. Device Strategy**

The following tables summarize pre-implant device strategy at your site and STS Intermacs over time.

PRE-IMPLANT DEVICE STRATEGY	HOSPX-9999							
	2020 Q3		2020 Q4		2021 Q2		TOTAL	
	n	%	n	%	n	%	n	%
BTT - Listed	.	.	.	.	.	.	.	.
BTT - Likely	.	.	1	33.3 %	.	.	1	14.2 %
BTT - Moderate	.	.	.	.	.	.	.	.
BTT - Unlikely	.	.	.	.	.	.	.	.
Destination Therapy	1	100.0 %	2	66.6 %	3	100.0 %	6	85.7 %
Bridge to Recovery	.	.	.	.	.	.	.	.
Rescue Therapy	.	.	.	.	.	.	.	.
Other	.	.	.	.	.	.	.	.
<b>TOTAL</b>	<b>1</b>	<b>100.0 %</b>	<b>3</b>	<b>100.0 %</b>	<b>3</b>	<b>100.0 %</b>	<b>7</b>	<b>100.0 %</b>

PRE-IMPLANT DEVICE STRATEGY	STS Intermacs													
	2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		2021 Q2		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
BTT - Listed	8	12.1 %	2	3.1 %	4	5.1 %	4	4.3 %	8	7.3 %	7	7.9 %	33	6.6 %
BTT - Likely	3	4.5 %	5	7.8 %	6	7.6 %	4	4.3 %	5	4.5 %	7	7.9 %	30	6.0 %
BTT - Moderate	3	4.5 %	3	4.6 %	4	5.1 %	8	8.7 %	9	8.2 %	10	11.3 %	37	7.4 %
BTT - Unlikely	.	.	1	1.5 %	1	1.2 %	1	1.0 %	2	1.8 %	.	.	5	1.0 %
Destination Therapy	49	74.2 %	52	81.2 %	62	79.4 %	70	76.9 %	83	76.1 %	63	71.5 %	379	76.4 %
Bridge to Recovery	.	.	1	1.5 %	.	.	.	.	.	.	.	.	1	0.2 %
Rescue Therapy	1	1.5 %	.	.	1	1.2 %	2	2.1 %	.	.	.	.	4	0.8 %
Other	2	3.0 %	.	.	.	.	2	2.1 %	2	1.8 %	1	1.1 %	7	1.4 %
<b>TOTAL</b>	<b>66</b>	<b>100.0 %</b>	<b>64</b>	<b>100.0 %</b>	<b>78</b>	<b>100.0 %</b>	<b>91</b>	<b>100.0 %</b>	<b>109</b>	<b>100.0 %</b>	<b>88</b>	<b>100.0 %</b>	<b>496</b>	<b>100.0 %</b>



COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Clinical Characteristics**

**Exhibit 8. Patient Profile Levels**

The following tables summarize pre-implant STS InterMACS patient profile levels at your site and STS InterMACS over time.

PRE-IMPLANT PATIENT PROFILE	HOSPX-9999							
	2020 Q3		2020 Q4		2021 Q2		TOTAL	
	n	%	n	%	n	%	n	%
1 Critical Cardiogenic Shock	.	.	1	33.3 %	.	.	1	14.2 %
2 Progressive Decline	.	.	1	33.3 %	2	66.6 %	3	42.8 %
3 Stable but Inotrope Dependent	.	.	.	.	1	33.3 %	1	14.2 %
4 Resting Symptoms	.	.	.	.	.	.	.	.
5 Exertion Intolerant	.	.	.	.	.	.	.	.
6 Exertion Limited	.	.	.	.	.	.	.	.
7 Advanced NYHA Class 3	1	100.0 %	1	33.3 %	.	.	2	28.5 %
TOTAL	1	100.0 %	3	100.0 %	3	100.0 %	7	100.0 %

PRE-IMPLANT PATIENT PROFILE	STS InterMACS													
	2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		2021 Q2		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
1 Critical Cardiogenic Shock	31	46.9 %	34	53.1 %	32	41.0 %	38	41.7 %	52	47.7 %	33	37.5 %	220	44.3 %
2 Progressive Decline	21	31.8 %	23	35.9 %	27	34.6 %	31	34.0 %	36	33.0 %	29	32.9 %	167	33.6 %
3 Stable but Inotrope Dependent	9	13.6 %	5	7.8 %	12	15.3 %	16	17.5 %	12	11.0 %	18	20.4 %	72	14.5 %
4 Resting Symptoms	3	4.5 %	1	1.5 %	5	6.4 %	2	2.1 %	6	5.5 %	4	4.5 %	21	4.2 %
5 Exertion Intolerant	.	.	.	.	.	.	1	1.0 %	.	.	1	1.1 %	2	0.4 %
6 Exertion Limited	1	1.5 %	.	.	.	.	1	1.0 %	.	.	1	1.1 %	3	0.6 %
7 Advanced NYHA Class 3	1	1.5 %	1	1.5 %	2	2.5 %	2	2.1 %	3	2.7 %	2	2.2 %	11	2.2 %
TOTAL	66	100.0 %	64	100.0 %	78	100.0 %	91	100.0 %	109	100.0 %	88	100.0 %	496	100.0 %

COVERAGE: January 1, 2020 - June 30, 2021

SITE: HOSPX - DEMO SITE REPORT

## II.A. Pre-Implant Summaries - Clinical Characteristics

## Exhibit 9a. Medications - IV Inotropes Within 48 Hours of Implant

The following tables summarize IV inotrope therapy within 48 hours prior to implant at your site and STS Intermacs over time.

IV INOTROPES	HOSPX-9999								
	2020 Q3			2020 Q4			2021 Q2		
	N	Yes	%	N	Yes	%	N	Yes	%
Dobutamine	0	.	.	3	0	0.0%	3	2	66.7%
Dopamine	0	.	.	3	0	0.0%	3	0	0.0%
Milrinone	0	.	.	3	2	66.7%	3	3	100.0%
Levosimendan	0	.	.	3	0	0.0%	3	0	0.0%
Epinephrine	0	.	.	3	1	33.3%	3	1	33.3%
Norepinephrine	0	.	.	3	0	0.0%	3	1	33.3%
Isoproterenol	0	.	.	3	0	0.0%	3	0	0.0%
Other Specify	0	.	.	3	1	33.3%	3	0	0.0%
Unknown	0	.	.	3	0	0.0%	3	0	0.0%

IV INOTROPES	STS Intermacs																	
	2020 Q1			2020 Q2			2020 Q3			2020 Q4			2021 Q1			2021 Q2		
	N	Yes	%	N	Yes	%	N	Yes	%	N	Yes	%	N	Yes	%	N	Yes	%
Dobutamine	48	20	41.7%	54	22	40.7%	61	25	41.0%	65	34	52.3%	84	37	44.0%	71	31	43.7%
Dopamine	48	1	2.1%	54	4	7.4%	61	2	3.3%	65	2	3.1%	84	4	4.8%	71	6	8.5%
Milrinone	48	30	62.5%	54	32	59.3%	61	37	60.7%	65	39	60.0%	84	55	65.5%	71	44	62.0%
Levosimendan	48	0	0.0%	54	0	0.0%	61	0	0.0%	65	0	0.0%	84	1	1.2%	71	0	0.0%
Epinephrine	48	6	12.5%	54	9	16.7%	61	16	26.2%	65	18	27.7%	84	20	23.8%	71	21	29.6%
Norepinephrine	48	6	12.5%	54	10	18.5%	61	13	21.3%	65	6	9.2%	84	27	32.1%	71	16	22.5%
Isoproterenol	48	0	0.0%	54	0	0.0%	61	0	0.0%	65	0	0.0%	84	0	0.0%	71	0	0.0%
Other Specify	48	0	0.0%	54	0	0.0%	61	0	0.0%	65	1	1.5%	84	0	0.0%	71	1	1.4%
Unknown	48	0	0.0%	54	0	0.0%	61	0	0.0%	65	1	1.5%	84	0	0.0%	71	0	0.0%

IV INOTROPES	HOSPX-9999			STS Intermacs		
	N	Yes	%	N	Yes	%
Dobutamine	6	2	33.3%	383	169	44.1%
Dopamine	6	0	0.0%	383	19	5.0%
Milrinone	6	5	83.3%	383	237	61.9%
Levosimendan	6	0	0.0%	383	1	0.3%
Epinephrine	6	2	33.3%	383	90	23.5%
Norepinephrine	6	1	16.7%	383	78	20.4%
Isoproterenol	6	0	0.0%	383	0	0.0%

(Continued)

**COVERAGE: January 1, 2020 - June 30, 2021**

***SITE: HOSPX - DEMO SITE REPORT***

***II.A. Pre-Implant Summaries - Clinical Characteristics***

***Exhibit 9a. Medications - IV Inotropes Within 48 Hours of Implant***

IV INOTROPES	HOSPX-9999			STS InterMACS		
	N	Yes	%	N	Yes	%
Other Specify	6	1	16.7%	383	2	0.5%
Unknown	6	0	0.0%	383	1	0.3%

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

***SITE: HOSPX - DEMO SITE REPORT***

**II.A. Pre-Implant Summaries - Clinical Characteristics**

***Exhibit 9b. Medications - History and Current Use***

The following tables compare the history and current use of specific medications prior to implant at your site and STS InterMACS.

ACE INHIBITORS	HOSPX-9999		STS InterMACS	
	N	%	N	%
Currently using	1	25.0	23	6.7
Known previous use (within past year)	2	50.0	65	19.0
No	.	.	210	61.4
Unknown	1	25.0	44	12.9
TOTAL	4	100	342	100

ALDOSTERONE ANTAGONIST	HOSPX-9999		STS InterMACS	
	N	%	N	%
Currently using	1	25.0	82	24.0
Known previous use (within past year)	2	50.0	81	23.7
No	.	.	149	43.6
Unknown	1	25.0	30	8.8
TOTAL	4	100	342	100

ALLOPURINOL*	HOSPX-9999		STS InterMACS	
	N	%	N	%
Currently using	1	25.0	27	7.9
Known previous use (within past year)	.	.	14	4.1
No	2	50.0	266	77.8
Unknown	1	25.0	35	10.2
TOTAL	4	100	342	100

AMIODARONE	HOSPX-9999		STS InterMACS	
	N	%	N	%
Currently using	2	50.0	152	44.4
Known previous use (within past year)	.	.	42	12.3
No	2	50.0	129	37.7
Unknown	.	.	19	5.6
TOTAL	4	100	342	100

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Clinical Characteristics**

**Exhibit 9b. Medications - History and Current Use**

ANGIOTENSIN RECEPTOR BLOCKER	HOSPX-9999		STS InterMACS	
	N	%	N	%
Currently using	.	.	26	7.6
Known previous use (within past year)	.	.	79	23.1
No	3	75.0	204	59.6
Unknown	1	25.0	33	9.6
TOTAL	4	100	342	100

ANTIPLATELET THERAPY DRUG	HOSPX-9999		STS InterMACS	
	N	%	N	%
Currently using	4	100	209	61.1
Known previous use (within past year)	.	.	49	14.3
No	.	.	69	20.2
Unknown	.	.	15	4.4
TOTAL	4	100	342	100

BETA BLOCKERS	HOSPX-9999		STS InterMACS	
	N	%	N	%
Currently using	2	50.0	92	26.9
Known previous use (within past year)	1	25.0	127	37.1
No	.	.	95	27.8
Unknown	1	25.0	28	8.2
TOTAL	4	100	342	100

WARFARIN (COUMADIN)	HOSPX-9999		STS InterMACS	
	N	%	N	%
Currently using	2	50.0	35	10.2
Known previous use (within past year)	1	25.0	37	10.8
No	1	25.0	243	71.1
Unknown	.	.	27	7.9
TOTAL	4	100	342	100

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

***SITE: HOSPX - DEMO SITE REPORT***

**II.A. Pre-Implant Summaries - Clinical Characteristics**

***Exhibit 9b. Medications - History and Current Use***

NESIRITIDE	HOSPX-9999		STS InterMACS	
	N	%	N	%
No	1	100	208	91.2
Unknown	.	.	19	8.3
Yes	.	.	1	0.4
TOTAL	1	100	228	100

NITRIC OXIDE	HOSPX-9999		STS InterMACS	
	N	%	N	%
No	2	50.0	296	86.5
Unknown	.	.	30	8.8
Yes	2	50.0	16	4.7
TOTAL	4	100	342	100

LOOP DIURETICS	HOSPX-9999		STS InterMACS	
	N	%	N	%
No	.	.	83	24.3
Unknown	1	25.0	12	3.5
Yes	3	75.0	247	72.2
TOTAL	4	100	342	100

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Clinical Characteristics**

**Exhibit 9b. Medications - History and Current Use**

PRE-IMPLANT LOOP DIURETIC TYPE*	HOSPX-9999			STS Intermacs		
	N	Yes	%	N	Yes	%
Furosemide	3	3	100.0%	242	112	46.28%
Torsemide	3	0	0.00%	242	61	25.21%
Bumetanide	3	0	0.00%	242	71	29.34%
Other	3	0	0.00%	242	0	0.00%

CARDIAC RESYNCHRONIZATION THERAPY (CRT)*	HOSPX-9999		STS Intermacs	
	N	%	N	%
No	.	.	164	72.2
Unknown	1	100	14	6.2
Yes	.	.	49	21.6
TOTAL	1	100	227	100

METALOZONE / THIAZIDE*	HOSPX-9999		STS Intermacs	
	N	%	N	%
No	2	50.0	264	77.2
Unknown	2	50.0	24	7.0
Yes	.	.	54	15.8
TOTAL	4	100	342	100

METALOZONE / THIAZIDE - FREQUENCY*	STS Intermacs	
	N	%
Regular	16	29.6
Intermittent	38	70.4
TOTAL	54	100

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Clinical Characteristics**

**Exhibit 10. Laboratories**

The following tables summarize pre-implant laboratories at your site and STS InterMACS.

		HOSPX-9999	STS InterMACS
Sodium (mEq/L)	N	4	342
	Mean	138.50	135.17
	Std	1.91	4.99
	Min	137.00	122.00
	Max	141.00	152.00
Potassium (mEq/L)	N	4	342
	Mean	3.88	4.09
	Std	0.36	0.46
	Min	3.60	2.90
	Max	4.40	5.80
BUN (mg/dL)	N	4	342
	Mean	28.25	29.67
	Std	12.42	17.11
	Min	10.00	5.00
	Max	37.00	138.00
Creatinine (mg/dL)	N	4	342
	Mean	1.39	1.37
	Std	0.70	0.71
	Min	0.91	0.30
	Max	2.42	5.17
Alanine Aminotransferase/ALT (u/L)	N	4	339
	Mean	26.25	50.62
	Std	25.88	91.87
	Min	8.00	3.00
	Max	64.00	1233.00
Aspartate Aminotransferase/AST (u/L)	N	4	338
	Mean	23.00	59.38
	Std	5.42	94.34
	Min	19.00	2.00
	Max	31.00	1094.00
LDH (μkat/L), (U/L)	N	4	308
	Mean	1355.00	620.11
	Std	1698.95	620.65
	Min	296.00	39.00
	Max	3892.00	5579.00
All	N	7	496



**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Clinical Characteristics**

**Exhibit 10. Laboratories**

PRE-IMPLANT LABORATORIES		HOSPX-9999	STS InterMACs
Total Bilirubin (mg/dL)	N	4	339
	Mean	2.23	1.73
	Std	2.04	2.02
	Min	0.60	0.10
	Max	5.00	15.60
Albumin (g/dL)	N	4	338
	Mean	3.73	3.12
	Std	0.30	0.65
	Min	3.40	0.20
	Max	4.10	6.50
Pre-albumin (mg/dL)	N	4	190
	Mean	22.50	15.56
	Std	9.87	7.17
	Min	15.00	3.90
	Max	37.00	41.00
Total Cholesterol (mg/dL)	N	4	204
	Mean	120.00	117.40
	Std	26.75	40.87
	Min	94.00	53.00
	Max	157.00	284.00
Brain Natriuretic Peptide (pg/mL)	N	0	128
	Mean	.	1401.70
	Std	.	1218.59
	Min	.	2.00
	Max	.	7319.00
Pro Brain Natriuretic Peptide (pg/mL)	N	2	143
	Mean	3299.50	8576.15
	Std	463.15	9106.04
	Min	2972.00	106.00
	Max	3627.00	51420.00
White Blood Cell Count (x10 <sup>6</sup> /μL)	N	4	342
	Mean	7.58	10.29
	Std	1.46	4.41
	Min	5.60	3.09
	Max	9.00	30.50
Hemoglobin (g/dL)	N	4	342
	Mean	8.98	9.19
	Std	0.58	1.75
	Min	8.20	0.85
	Max	9.60	15.50
All	N	7	496

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Clinical Characteristics**

**Exhibit 10. Laboratories**

PRE-IMPLANT LABORATORIES		HOSPX-9999	STS Intermacs
Platelets (x10/ $\mu$ L)	N	4	342
	Mean	185.75	164.70
	Std	66.51	73.44
	Min	122.00	10.00
	Max	272.00	497.00
INR	N	4	326
	Mean	1.28	1.31
	Std	0.29	0.36
	Min	1.02	0.90
	Max	1.70	3.35
Sensitivity CRP (mg/L)	N	0	112
	Mean	.	37.37
	Std	.	52.73
	Min	.	0.09
	Max	.	246.60
All	N	7	496

PRE-IMPLANT LUPUS ANTICOAGULANT STATUS*	HOSPX-9999		STS Intermacs	
	N	%	N	%
Negative	.	.	39	11.4
Positive	.	.	8	2.3
Unknown	4	100	295	86.3
TOTAL	4	100	342	100

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT****II.A. Pre-Implant Summaries - Comorbidities and Potential Barriers to Heart Transplant****Exhibit 11. Pre-Implant Comorbidities**

The following tables compares pre-implant comorbidities at the time of durable MCS/D implant between your site and STS InterMACS over time. This section was revised during the v6.0 launch (11/24/20) and includes mapped data from patients implanted 2012 and later. Information on Prior Sternotomy and History of Hematopoietic Cancer is currently being mapped and will be available in the reports starting next quarter.

Cardiothoracic issues	HOSPX-9999								
	2020 Q3			2020 Q4			2021 Q2		
	N	Yes	%	N	Yes	%	N	Yes	%
Frequent ICD Shocks	1	0	0.0%	2	0	0.0%	0	.	.
Chronic Lung Disease	1	0	0.0%	3	1	33.3%	0	.	.
Pulmonary Hypertension	1	0	0.0%	3	2	66.7%	0	.	.
Recent Pulmonary Embolus	1	0	0.0%	2	0	0.0%	0	.	.
History of Atrial Arrhythmia	1	0	0.0%	2	0	0.0%	0	.	.
Thoracic Aortic Disease	1	0	0.0%	3	0	0.0%	0	.	.

Cardiothoracic issues	STS InterMACS																	
	2020 Q1			2020 Q2			2020 Q3			2020 Q4			2021 Q1			2021 Q2		
	N	Yes	%	N	Yes	%	N	Yes	%	N	Yes	%	N	Yes	%	N	Yes	%
Frequent ICD Shocks	65	1	1.5%	64	2	3.1%	77	2	2.6%	86	8	9.3%	48	2	4.2%	0	.	.
Chronic Lung Disease	65	2	3.1%	64	5	7.8%	77	8	10.4%	86	11	12.8%	47	6	12.8%	0	.	.
Pulmonary Hypertension	65	10	15.4%	64	8	12.5%	75	10	13.3%	84	24	28.6%	46	23	50.0%	0	.	.
Recent Pulmonary Embolus	65	2	3.1%	64	1	1.6%	77	2	2.6%	85	5	5.9%	49	2	4.1%	0	.	.
History of Atrial Arrhythmia	65	14	21.5%	64	13	20.3%	76	13	17.1%	84	30	35.7%	49	23	46.9%	0	.	.
Thoracic Aortic Disease	65	0	0.0%	64	0	0.0%	76	1	1.3%	85	1	1.2%	49	1	2.0%	0	.	.

Cardiothoracic issues	HOSPX-9999			STS InterMACS		
	N	Yes	%	N	Yes	%
Frequent ICD Shocks	3	0	0.0%	340	15	4.4%
Chronic Lung Disease	4	1	25.0%	339	32	9.4%
Pulmonary Hypertension	4	2	50.0%	334	75	22.5%
Recent Pulmonary Embolus	3	0	0.0%	340	12	3.5%
History of Atrial Arrhythmia	3	0	0.0%	338	93	27.5%
Thoracic Aortic Disease	4	0	0.0%	339	3	0.9%

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Comorbidities and Potential Barriers to Heart Transplant**

**Exhibit 11. Pre-Implant Comorbidities**

Nutritional/GI issues	HOSPX-9999								
	2020 Q3			2020 Q4			2021 Q2		
	N	Yes	%	N	Yes	%	N	Yes	%
Severe Diabetes	1	0	0.0%	3	1	33.3%	0	.	.
Malnutrition/Cachexia	1	0	0.0%	3	1	33.3%	0	.	.
History GI Ulcers	1	0	0.0%	3	1	33.3%	0	.	.
Liver Dysfunction	1	0	0.0%	2	0	0.0%	0	.	.
Hepatitis	1	0	0.0%	3	0	0.0%	0	.	.

Nutritional/GI issues	STS InterMACS																	
	2020 Q1			2020 Q2			2020 Q3			2020 Q4			2021 Q1			2021 Q2		
	N	Yes	%	N	Yes	%	N	Yes	%	N	Yes	%	N	Yes	%	N	Yes	%
Severe Diabetes	65	5	7.7%	64	9	14.1%	77	14	18.2%	87	17	19.5%	47	10	21.3%	0	.	.
Malnutrition/Cachexia	65	0	0.0%	64	2	3.1%	76	3	3.9%	85	7	8.2%	49	7	14.3%	0	.	.
History GI Ulcers	65	0	0.0%	64	0	0.0%	77	0	0.0%	85	3	3.5%	48	3	6.3%	0	.	.
Liver Dysfunction	65	1	1.5%	64	3	4.7%	77	5	6.5%	85	9	10.6%	49	4	8.2%	0	.	.
Hepatitis	65	0	0.0%	64	0	0.0%	77	1	1.3%	87	1	1.1%	48	2	4.2%	0	.	.

Nutritional/GI issues	HOSPX-9999			STS InterMACS		
	N	Yes	%	N	Yes	%
Severe Diabetes	4	1	25.0%	340	55	16.2%
Malnutrition/Cachexia	4	1	25.0%	339	19	5.6%
History GI Ulcers	4	1	25.0%	339	6	1.8%
Liver Dysfunction	3	0	0.0%	340	22	6.5%
Hepatitis	4	0	0.0%	341	4	1.2%

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Comorbidities and Potential Barriers to Heart Transplant**

**Exhibit 11. Pre-Implant Comorbidities**

Vascular issues	HOSPX-9999								
	2020 Q3			2020 Q4			2021 Q2		
	N	Yes	%	N	Yes	%	N	Yes	%
Heparin-induced Thrombocytopenia	1	0	0.0%	3	0	0.0%	0	.	.
Chronic Coagulopathy	1	0	0.0%	3	0	0.0%	0	.	.
Cerebrovascular Disease	1	0	0.0%	3	0	0.0%	0	.	.
Major Stroke	0	.	.	1	0	0.0%	0	.	.
Peripheral Arterial Disease	1	0	0.0%	3	0	0.0%	0	.	.

Vascular issues	STS Intermacs																	
	2020 Q1			2020 Q2			2020 Q3			2020 Q4			2021 Q1			2021 Q2		
	N	Yes	%	N	Yes	%	N	Yes	%	N	Yes	%	N	Yes	%	N	Yes	%
Heparin-induced Thrombocytopenia	65	2	3.1%	64	2	3.1%	77	5	6.5%	83	4	4.8%	41	0	0.0%	0	.	.
Chronic Coagulopathy	65	1	1.5%	64	1	1.6%	76	2	2.6%	84	3	3.6%	40	1	2.5%	0	.	.
Cerebrovascular Disease	65	3	4.6%	64	9	14.1%	77	4	5.2%	86	6	7.0%	48	11	22.9%	0	.	.
Major Stroke	65	3	4.6%	63	6	9.5%	67	1	1.5%	39	5	12.8%	11	10	90.9%	0	.	.
Peripheral Arterial Disease	65	3	4.6%	64	4	6.3%	76	3	3.9%	87	4	4.6%	47	6	12.8%	0	.	.

Vascular issues	HOSPX-9999			STS Intermacs		
	N	Yes	%	N	Yes	%
Heparin-induced Thrombocytopenia	4	0	0.0%	330	13	3.9%
Chronic Coagulopathy	4	0	0.0%	329	8	2.4%
Cerebrovascular Disease	4	0	0.0%	340	33	9.7%
Major Stroke	1	0	0.0%	245	25	10.2%
Peripheral Arterial Disease	4	0	0.0%	339	20	5.9%

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Comorbidities and Potential Barriers to Heart Transplant**

**Exhibit 11. Pre-Implant Comorbidities**

Oncology/infection issues	HOSPX-9999								
	2020 Q3			2020 Q4			2021 Q2		
	N	Yes	%	N	Yes	%	N	Yes	%
History Solid Organ Cancer	1	0	0.0%	3	1	33.3%	0	.	.
Currently has Cancer v6	1	0	0.0%	2	0	0.0%	0	.	.
History of Solid Organ Transplant v6	1	0	0.0%	2	0	0.0%	0	.	.
History of Bone Marrow Transplant (BMT)	1	0	0.0%	3	0	0.0%	0	.	.
HIV	0	.	.	1	0	0.0%	0	.	.

Oncology/infection issues	STS InterMACS																	
	2020 Q1			2020 Q2			2020 Q3			2020 Q4			2021 Q1			2021 Q2		
	N	Yes	%	N	Yes	%	N	Yes	%	N	Yes	%	N	Yes	%	N	Yes	%
History Solid Organ Cancer	65	2	3.1%	64	3	4.7%	77	4	5.2%	86	3	3.5%	49	4	8.2%	0	.	.
Currently has Cancer v6	0	.	.	2	0	0.0%	11	0	0.0%	53	1	1.9%	48	2	4.2%	0	.	.
History of Solid Organ Transplant v6	0	.	.	2	0	0.0%	11	1	9.1%	53	0	0.0%	49	0	0.0%	0	.	.
History of Bone Marrow Transplant (BMT)	65	0	0.0%	64	0	0.0%	77	0	0.0%	87	0	0.0%	49	0	0.0%	0	.	.
HIV	65	1	1.5%	62	0	0.0%	66	0	0.0%	35	0	0.0%	0	.	.	0	.	.

Oncology/infection issues	HOSPX-9999			STS InterMACS		
	N	Yes	%	N	Yes	%
History Solid Organ Cancer	4	1	25.0%	341	16	4.7%
Currently has Cancer v6	3	0	0.0%	114	3	2.6%
History of Solid Organ Transplant v6	3	0	0.0%	115	1	0.9%
History of Bone Marrow Transplant (BMT)	4	0	0.0%	342	0	0.0%
HIV	1	0	0.0%	228	1	0.4%

*COVERAGE: January 1, 2020 - June 30, 2021*

***SITE: HOSPX - DEMO SITE REPORT***

***II.A. Pre-Implant Summaries - Comorbidities and Potential Barriers to Heart Transplant***

***Exhibit 11. Pre-Implant Comorbidities***

Data collection for the psychosocial issues section changed structure as a part of the v6.0 release. Mapping of this data is underway and this information will be available in the reports starting next quarter.

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Comorbidities and Potential Barriers to Heart Transplant**

**Exhibit 12. Pre-Implant Potential Barriers to Heart Transplant**

The following tables compare pre-implant potential barriers to heart transplant at your site and STS Intermacs over time. This section was revised during the v6.0 launch (11/24/20) and includes mapped data from patients implanted 2012 and later.

Potential Barriers to Heart Transplant	HOSPX-9999								
	2020 Q3			2020 Q4			2021 Q2		
	N	Yes	%	N	Yes	%	N	Yes	%
Advanced Age	1	0	0.0%	3	0	0.0%	0	.	.
Frailty	1	0	0.0%	2	0	0.0%	0	.	.
Patient Does Not Want Transplant	1	0	0.0%	2	0	0.0%	0	.	.
Musculoskeletal Limitation to Ambulation	1	0	0.0%	2	0	0.0%	0	.	.
Contraindications to Immunosuppression	1	0	0.0%	2	0	0.0%	0	.	.
Allosensitization	1	0	0.0%	2	0	0.0%	0	.	.
Chronic Renal Disease	1	0	0.0%	3	0	0.0%	0	.	.
Large BMI	1	0	0.0%	3	1	33.3%	0	.	.
Chronic Infectious Concerns	1	0	0.0%	3	1	33.3%	0	.	.

Potential Barriers to Heart Transplant	STS Intermacs																	
	2020 Q1			2020 Q2			2020 Q3			2020 Q4			2021 Q1			2021 Q2		
	N	Yes	%	N	Yes	%	N	Yes	%	N	Yes	%	N	Yes	%	N	Yes	%
Advanced Age	65	6	9.2%	64	8	12.5%	76	7	9.2%	87	15	17.2%	45	2	4.4%	0	.	.
Frailty	65	4	6.2%	64	5	7.8%	76	4	5.3%	83	13	15.7%	43	8	18.6%	0	.	.
Patient Does Not Want Transplant	65	2	3.1%	64	0	0.0%	75	0	0.0%	78	1	1.3%	40	1	2.5%	0	.	.
Musculoskeletal Limitation to Ambulation	65	1	1.5%	64	1	1.6%	76	0	0.0%	83	1	1.2%	44	2	4.5%	0	.	.
Contraindications to Immunosuppression	65	0	0.0%	64	0	0.0%	76	0	0.0%	82	0	0.0%	40	0	0.0%	0	.	.
Allosensitization	65	1	1.5%	64	1	1.6%	75	1	1.3%	78	0	0.0%	39	0	0.0%	0	.	.
Chronic Renal Disease	65	4	6.2%	64	8	12.5%	76	6	7.9%	86	14	16.3%	44	7	15.9%	0	.	.
Large BMI	65	9	13.8%	64	11	17.2%	76	10	13.2%	87	16	18.4%	47	12	25.5%	0	.	.
Chronic Infectious Concerns	65	2	3.1%	64	2	3.1%	76	2	2.6%	85	4	4.7%	43	4	9.3%	0	.	.



COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Comorbidities and Potential Barriers to Heart Transplant**

**Exhibit 12. Pre-Implant Potential Barriers to Heart Transplant**

Potential Barriers to Heart Transplant	HOSPX-9999			STS InterMACS		
	N	Yes	%	N	Yes	%
Advanced Age	4	0	0.0%	337	38	11.3%
Frailty	3	0	0.0%	331	34	10.3%
Patient Does Not Want Transplant	3	0	0.0%	322	4	1.2%
Musculoskeletal Limitation to Ambulation	3	0	0.0%	332	5	1.5%
Contraindications to Immunosuppression	3	0	0.0%	327	0	0.0%
Allosensitization	3	0	0.0%	321	3	0.9%
Chronic Renal Disease	4	0	0.0%	335	39	11.6%
Large BMI	4	1	25.0%	339	58	17.1%
Chronic Infectious Concerns	4	1	25.0%	333	14	4.2%

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Hemodynamics**

**Exhibit 13. General Hemodynamics**

The following table summarizes pre-implant heart rate, systolic BP and diastolic BP at your site and STS InterMACS.

PRE-IMPLANT GENERAL HEMODYNAMICS		HOSPX-9999	STS InterMACS
Heart Rate	N	4	341
	Mean	96.00	93.21
	Std	4.55	17.17
	Min	90.00	48.00
	Max	101.00	151.00
Diastolic Blood Pressure (mmHg)	N	3	320
	Mean	68.67	69.79
	Std	7.02	12.01
	Min	62.00	35.00
	Max	76.00	109.00
Systolic Blood Pressure (mmHg)	N	3	323
	Mean	101.33	101.25
	Std	17.62	17.23
	Min	87.00	57.00
	Max	121.00	176.00
All	N	7	496

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT****II.A. Pre-Implant Summaries - Hemodynamics****Exhibit 14a. Echo Hemodynamics - LVEDD**

The following tables summarizes pre-implant LVEDD at your site and STS Intermacs over time.

**GROUP=HOSPX-9999**

PRE-IMPLANT LVEDD (cm)		2020 Q3	2020 Q4	2021 Q2	TOTAL
	<b>N</b>	1	3	0	4
	<b>Mean</b>	8.10	6.21	.	6.69
	<b>Std</b>	.	1.16	.	1.34
	<b>Min</b>	8.10	4.90	.	4.90
	<b>Max</b>	8.10	7.10	.	8.10

**GROUP=STS Intermacs**

PRE-IMPLANT LVEDD (cm)		2020 Q1	2020 Q2	2020 Q3	2020 Q4	2021 Q1	2021 Q2	TOTAL
	<b>N</b>	59	52	61	66	40	0	278
	<b>Mean</b>	6.48	6.38	6.31	6.41	6.56	.	6.42
	<b>Std</b>	1.32	1.07	1.04	1.10	0.99	.	1.11
	<b>Min</b>	3.69	3.50	3.70	3.78	4.10	.	3.50
	<b>Max</b>	9.80	8.71	8.35	10.50	8.80	.	10.50

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Hemodynamics**

**Exhibit 14b. Echo Hemodynamics - LVEF**

The following tables summarizes pre-implant LVEF at your site and STS InterMACs over time.

PRE-IMPLANT LVEF	HOSPX-9999					
	2020 Q3		2020 Q4		TOTAL	
	n	%	n	%	n	%
30-39 (moderate)	.	.	.	.	.	.
20-29 (moderate/severe)	.	.	1	33.3 %	1	25.0 %
< 20 (severe)	1	100.0 %	2	66.6 %	3	75.0 %
Not Recorded or Not Documented	.	.	.	.	.	.
Unknown	.	.	.	.	.	.
<b>TOTAL</b>	1	100.0 %	3	100.0 %	4	100.0 %

PRE-IMPLANT LVEF	STS InterMACs											
	2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%
30-39 (moderate)	3	4.6 %	3	4.6 %	3	3.8 %	3	3.4 %	2	4.0 %	14	4.0 %
20-29 (moderate/severe)	22	33.8 %	9	14.0 %	15	19.4 %	20	22.9 %	10	20.4 %	76	22.2 %
< 20 (severe)	37	56.9 %	51	79.6 %	56	72.7 %	61	70.1 %	36	73.4 %	241	70.4 %
Not Recorded or Not Documented	3	4.6 %	.	.	2	2.5 %	3	3.4 %	1	2.0 %	9	2.6 %
Unknown	.	.	1	1.5 %	1	1.2 %	.	.	.	.	2	0.5 %
<b>TOTAL</b>	65	100.0 %	64	100.0 %	77	100.0 %	87	100.0 %	49	100.0 %	342	100.0 %

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT****II.A. Pre-Implant Summaries - Hemodynamics****Exhibit 14c. Echo Hemodynamics - RVEF**

The following tables summarizes pre-implant RVEF at your site and STS Intermacs over time.

PRE-IMPLANT RVEF	HOSPX-9999					
	2020 Q3		2020 Q4		TOTAL	
	n	%	n	%	n	%
Normal	.	.	2	66.6 %	2	50.0 %
Mild	.	.	.	.	.	.
Moderate	1	100.0 %	1	33.3 %	2	50.0 %
Severe	.	.	.	.	.	.
Not Done	.	.	.	.	.	.
Unknown	.	.	.	.	.	.
TOTAL	1	100.0 %	3	100.0 %	4	100.0 %

PRE-IMPLANT RVEF	STS Intermacs											
	2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%
Normal	13	20.0 %	18	28.1 %	14	18.1 %	17	19.5 %	13	26.5 %	75	21.9 %
Mild	20	30.7 %	16	25.0 %	21	27.2 %	19	21.8 %	11	22.4 %	87	25.4 %
Moderate	9	13.8 %	9	14.0 %	13	16.8 %	22	25.2 %	9	18.3 %	62	18.1 %
Severe	12	18.4 %	13	20.3 %	16	20.7 %	8	9.1 %	11	22.4 %	60	17.5 %
Not Done	5	7.6 %	6	9.3 %	8	10.3 %	9	10.3 %	2	4.0 %	30	8.7 %
Unknown	6	9.2 %	2	3.1 %	5	6.4 %	12	13.7 %	3	6.1 %	28	8.1 %
TOTAL	65	100.0 %	64	100.0 %	77	100.0 %	87	100.0 %	49	100.0 %	342	100.0 %

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Hemodynamics**

**Exhibit 14d. Echo Hemodynamics - Mitral Regurgitation**

The following tables summarizes pre-implant mitral regurgitation at your site and STS InterMACS over time.

PRE-IMPLANT MITRAL REGURGITATION	HOSPX-9999					
	2020 Q3		2020 Q4		TOTAL	
	n	%	n	%	n	%
0 (none)	.	.	.	.	.	.
1 (mild)	1	100.0 %	2	66.6 %	3	75.0 %
2 (moderate)	.	.	.	.	.	.
3 (severe)	.	.	1	33.3 %	1	25.0 %
Not Recorded or Not Documented	.	.	.	.	.	.
TOTAL	1	100.0 %	3	100.0 %	4	100.0 %

PRE-IMPLANT MITRAL REGURGITATION	STS InterMACS											
	2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%
0 (none)	8	12.3 %	11	17.1 %	9	11.6 %	6	6.8 %	2	4.0 %	36	10.5 %
1 (mild)	21	32.3 %	27	42.1 %	30	38.9 %	40	45.9 %	12	24.4 %	130	38.0 %
2 (moderate)	18	27.6 %	19	29.6 %	25	32.4 %	21	24.1 %	13	26.5 %	96	28.0 %
3 (severe)	14	21.5 %	4	6.2 %	8	10.3 %	15	17.2 %	19	38.7 %	60	17.5 %
Not Recorded or Not Documented	4	6.1 %	3	4.6 %	5	6.4 %	5	5.7 %	3	6.1 %	20	5.8 %
TOTAL	65	100.0 %	64	100.0 %	77	100.0 %	87	100.0 %	49	100.0 %	342	100.0 %

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Hemodynamics**

**Exhibit 14e. Echo Hemodynamics - Aortic Regurgitation**

The following tables summarizes pre-implant aortic regurgitation at your site and STS Intermacs over time.

PRE-IMPLANT AORTIC REGURGITATION	HOSPX-9999					
	2020 Q3		2020 Q4		TOTAL	
	n	%	n	%	n	%
0 (none)	.	.	2	66.6 %	2	50.0 %
1 (mild)	1	100.0 %	.	.	1	25.0 %
2 (moderate)	.	.	.	.	.	.
3 (severe)	.	.	.	.	.	.
Not Recorded or Not Documented	.	.	1	33.3 %	1	25.0 %
TOTAL	1	100.0 %	3	100.0 %	4	100.0 %

PRE-IMPLANT AORTIC REGURGITATION	STS Intermacs											
	2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%
0 (none)	20	30.7 %	25	39.0 %	24	31.1 %	34	39.0 %	16	32.6 %	119	34.7 %
1 (mild)	33	50.7 %	23	35.9 %	32	41.5 %	33	37.9 %	17	34.6 %	138	40.3 %
2 (moderate)	3	4.6 %	4	6.2 %	5	6.4 %	4	4.5 %	4	8.1 %	20	5.8 %
3 (severe)	1	1.5 %	.	.	1	1.2 %	1	1.1 %	.	.	3	0.8 %
Not Recorded or Not Documented	8	12.3 %	12	18.7 %	15	19.4 %	15	17.2 %	12	24.4 %	62	18.1 %
TOTAL	65	100.0 %	64	100.0 %	77	100.0 %	87	100.0 %	49	100.0 %	342	100.0 %

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Hemodynamics**

**Exhibit 14f. Echo Hemodynamics - Tricuspid Regurgitation**

The following tables summarizes pre-implant tricuspid regurgitation at your site and STS Intermacs over time.

PRE-IMPLANT TRICUSPID REGURGITATION	HOSPX-9999					
	2020 Q3		2020 Q4		TOTAL	
	n	%	n	%	n	%
0 (none)	1	100.0 %	.	.	1	25.0 %
1 (mild)	.	.	2	66.6 %	2	50.0 %
2 (moderate)	.	.	1	33.3 %	1	25.0 %
3 (severe)	.	.	.	.	.	.
Not Recorded or Not Documented	.	.	.	.	.	.
TOTAL	1	100.0 %	3	100.0 %	4	100.0 %

PRE-IMPLANT TRICUSPID REGURGITATION	STS Intermacs											
	2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%
0 (none)	7	10.7 %	8	12.5 %	11	14.2 %	11	12.6 %	2	4.0 %	39	11.4 %
1 (mild)	27	41.5 %	27	42.1 %	34	44.1 %	38	43.6 %	14	28.5 %	140	40.9 %
2 (moderate)	20	30.7 %	12	18.7 %	19	24.6 %	19	21.8 %	17	34.6 %	87	25.4 %
3 (severe)	8	12.3 %	8	12.5 %	4	5.1 %	9	10.3 %	8	16.3 %	37	10.8 %
Not Recorded or Not Documented	3	4.6 %	9	14.0 %	9	11.6 %	10	11.4 %	8	16.3 %	39	11.4 %
TOTAL	65	100.0 %	64	100.0 %	77	100.0 %	87	100.0 %	49	100.0 %	342	100.0 %



**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Hemodynamics**

**Exhibit 15. Swan Hemodynamics**

The following table summarizes pre-implant hemodynamics derived from a Swan-Ganz catheter at your site and STS InterMACS.

PRE-IMPLANT SWAN HEMODYNAMICS		HOSPX-9999	STS InterMACS
Pulmonary Artery Systolic Pressure (mmHg)	N	3	281
	Mean	36.00	46.76
	Std	8.89	14.68
	Min	29.00	12.00
	Max	46.00	94.00
Pulmonary Artery Diastolic Pressure (mmHg)	N	3	279
	Mean	18.67	22.97
	Std	4.73	8.22
	Min	15.00	4.00
	Max	24.00	44.00
~Mean RA Pressure (mmHg)~	N	1	129
	Mean	26.00	12.78
	Std	.	7.19
	Min	26.00	1.00
	Max	26.00	35.00
Mean Pulmonary Artery Capillary Wedge Pressure (mmHg)	N	2	208
	Mean	14.50	25.08
	Std	0.71	9.34
	Min	14.00	4.00
	Max	15.00	50.00
Cardiac Index	N	3	259
	Mean	3.26	2.35
	Std	0.64	0.89
	Min	2.80	0.90
	Max	3.99	6.30
Cardiac Output (L/min)	N	3	259
	Mean	6.62	4.73
	Std	1.06	1.79
	Min	5.40	1.80
	Max	7.35	13.03
All	N	7	496

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Hemodynamics**

**Exhibit 16. ECG Cardiac Rhythm**

The following tables summarizes pre-implant ECG cardiac rhythm at your site and STS Intermacs.

ECG CARDIAC RHYTHM	HOSPX-9999					
	2020 Q3		2020 Q4		TOTAL	
	n	%	n	%	n	%
Sinus	.	.	2	66.6 %	2	50.0 %
Atrial fibrillation	.	.	.	.	.	.
Atrial Flutter	.	.	.	.	.	.
Not done	.	.	.	.	.	.
Atrial Paced, Ventricular Sensed	.	.	.	.	.	.
Atrial Sensed, Ventricular Paced	.	.	1	33.3 %	1	25.0 %
Atrial Paced, Ventricular Paced	.	.	.	.	.	.
Unknown	.	.	.	.	.	.
Other, specify	1	100.0 %	.	.	1	25.0 %
TOTAL	1	100.0 %	3	100.0 %	4	100.0 %

ECG CARDIAC RHYTHM	STS Intermacs											
	2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%
Sinus	41	63.0 %	44	68.7 %	51	66.2 %	57	65.5 %	32	65.3 %	225	65.7 %
Atrial fibrillation	6	9.2 %	2	3.1 %	8	10.3 %	8	9.1 %	4	8.1 %	28	8.1 %
Atrial Flutter	1	1.5 %	.	.	3	3.8 %	.	.	.	.	4	1.1 %
Not done	1	1.5 %	2	3.1 %	.	.	1	1.1 %	.	.	4	1.1 %
Atrial Paced, Ventricular Sensed	.	.	1	1.5 %	2	2.5 %	2	2.2 %	1	2.0 %	6	1.7 %
Atrial Sensed, Ventricular Paced	7	10.7 %	10	15.6 %	6	7.7 %	9	10.3 %	7	14.2 %	39	11.4 %
Atrial Paced, Ventricular Paced	7	10.7 %	2	3.1 %	1	1.2 %	7	8.0 %	4	8.1 %	21	6.1 %
Unknown	.	.	.	.	1	1.2 %	2	2.2 %	.	.	3	0.8 %
Other, specify	2	3.0 %	3	4.6 %	5	6.4 %	1	1.1 %	1	2.0 %	12	3.5 %
TOTAL	65	100.0 %	64	100.0 %	77	100.0 %	87	100.0 %	49	100.0 %	342	100.0 %

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT****II.A. Pre-Implant Summaries - Functional Capacity and Quality of Life****Exhibit 17a. Functional Capacity - NYHA Class**

The following table summarizes the pre-implant NYHA Class at your site and STS Intermacs over time.

PRE-IMPLANT NYHA CLASS	HOSPX-9999					
	2020 Q3		2020 Q4		TOTAL	
	n	%	n	%	n	%
Class I	.	.	.	.	.	.
Class II	1	100.0 %	.	.	1	25.0 %
Class III	.	.	.	.	.	.
Class IV	.	.	2	66.6 %	2	50.0 %
Unknown	.	.	1	33.3 %	1	25.0 %
TOTAL	1	100.0 %	3	100.0 %	4	100.0 %

PRE-IMPLANT NYHA CLASS	STS Intermacs											
	2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%
Class I	1	1.5 %	.	.	1	1.2 %	.	.	.	.	2	0.5 %
Class II	1	1.5 %	2	3.1 %	3	3.8 %	4	4.5 %	.	.	10	2.9 %
Class III	7	10.7 %	1	1.5 %	3	3.8 %	6	6.8 %	2	4.0 %	19	5.5 %
Class IV	52	80.0 %	58	90.6 %	69	89.6 %	75	86.2 %	44	89.7 %	298	87.1 %
Unknown	4	6.1 %	3	4.6 %	1	1.2 %	2	2.2 %	3	6.1 %	13	3.8 %
TOTAL	65	100.0 %	64	100.0 %	77	100.0 %	87	100.0 %	49	100.0 %	342	100.0 %

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Functional Capacity and Quality of Life**

**Exhibit 17b. Functional Capacity - VO2 Max**

The following table summarizes the pre-implant VO2 max at your site and STS InterMACS.

VO2 MAX		HOSPX-9999	STS InterMACS
VO2 Max (mL/kg/min)	N	0	12
	Mean	.	12.01
	Std	.	4.00
	Min	.	6.30
	Max	.	17.50
All	N	7	496

The following table summarizes the reasons the pre-implant VO2 max was incomplete at your site and STS InterMACS.

VO2 MAX - Reason for Incomplete	HOSPX-9999		STS InterMACS	
	N	%	N	%
Not Done: Other	3	75.0	114	34.5
Not Done: Too Sick	1	25.0	192	58.2
Unknown	.	.	24	7.3
TOTAL	4	100	330	100

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

***SITE: HOSPX - DEMO SITE REPORT***

***II.A. Pre-Implant Summaries - Functional Capacity and Quality of Life***

***Exhibit 17c. Functional Capacity - R Value at Peak***

The following table summarizes the pre-implant R value at peak at your site and STS InterMACS.

R VALUE AT PEAK		HOSPX-9999	STS InterMACS
Peak R (%)	N	0	8
	Mean	.	14.31
	Std	.	20.24
	Min	.	1.07
	Max	.	55.00
All	N	7	496

The following table summarizes the reasons the pre-implant R value at peak was incomplete at your site and InterMACS.

R VALUE AT PEAK - Reason for Incomplete	HOSPX-9999		STS InterMACS	
	N	%	N	%
Not Done	4	100	312	93.4
Unknown	.	.	22	6.6
TOTAL	4	100	334	100

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Functional Capacity and Quality of Life**

**Exhibit 17d. Functional Capacity - Six Minute Walk**

The following table summarizes the pre-implant six minute walk at your site and STS InterMACS.

6 MINUTE WALK		HOSPX-9999	STS InterMACS
Six Minute Walk (ft)	N	0	28
	Mean	.	724.54
	Std	.	484.89
	Min	.	5.00
	Max	.	2000.00
All	N	7	496

The following table summarizes the reasons the pre-implant six minute walk was incomplete at your site and STS InterMACS.

6 MINUTE WALK - Reason for Incomplete	HOSPX-9999		STS InterMACS	
	N	%	N	%
Not Done: Other	3	75.0	66	21.0
Not Done: Too Sick	1	25.0	236	75.2
Unknown	.	.	12	3.8
TOTAL	4	100	314	100

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT****II.A. Pre-Implant Summaries - Functional Capacity and Quality of Life****Exhibit 18a. Quality of Life - EQ-5D Mobility**

The following table compares the EQ-5D Mobility domain between your site and STS InterMACS.

EQ-5D Mobility	HOSPX-9999				STS InterMACs											
	2020 Q4		TOTAL		2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
I have no problems in walking about	1	100.0 %	1	100.0 %	8	30.7 %	6	30.0 %	4	17.3 %	17	45.9 %	7	35.0 %	42	33.3 %
I have some problems in walking about	.	.	.	.	12	46.1 %	9	45.0 %	12	52.1 %	17	45.9 %	8	40.0 %	58	46.0 %
I am confined to bed	.	.	.	.	4	15.3 %	4	20.0 %	7	30.4 %	3	8.1 %	4	20.0 %	22	17.4 %
Unknown	.	.	.	.	2	7.6 %	1	5.0 %	.	.	.	.	1	5.0 %	4	3.1 %
TOTAL	1	100.0 %	1	100.0 %	26	100.0 %	20	100.0 %	23	100.0 %	37	100.0 %	20	100.0 %	126	100.0 %

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT****II.A. Pre-Implant Summaries - Functional Capacity and Quality of Life****Exhibit 18b. Quality of Life - EQ-5D Self Care**

The following table compares the EQ-5D Self Care domain between your site and STS Intermacs.

EQ-5D Self Care	HOSPX-9999				STS Intermacs											
	2020 Q4		TOTAL		2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
I have no problems with self-care	.	.	.	.	8	30.7 %	7	35.0 %	7	30.4 %	19	51.3 %	9	45.0 %	50	39.6 %
I have some problems washing or dressing myself	1	100.0 %	1	100.0 %	10	38.4 %	11	55.0 %	13	56.5 %	12	32.4 %	7	35.0 %	53	42.0 %
I am unable to wash or dress myself	.	.	.	.	7	26.9 %	2	10.0 %	3	13.0 %	6	16.2 %	3	15.0 %	21	16.6 %
Unknown	.	.	.	.	1	3.8 %	.	.	.	.	.	.	1	5.0 %	2	1.5 %
<b>TOTAL</b>	1	100.0 %	1	100.0 %	26	100.0 %	20	100.0 %	23	100.0 %	37	100.0 %	20	100.0 %	126	100.0 %



COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT****II.A. Pre-Implant Summaries - Functional Capacity and Quality of Life****Exhibit 18c. Quality of Life - EQ-5D Usual Activities**

The following table compares the EQ-5D Usual Activities domain between your site and STS InterMACS.

EQ-5D Usual Activities	HOSPX-9999				STS InterMACS											
	2020 Q4		TOTAL		2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
I have no problems with performing my usual activities	.	.	.	.	5	19.2 %	3	15.0 %	1	4.3 %	12	32.4 %	4	20.0 %	25	19.8 %
I have some problems with performing my usual activities	.	.	.	.	8	30.7 %	6	30.0 %	11	47.8 %	14	37.8 %	11	55.0 %	50	39.6 %
I am unable to perform my usual activities	1	100.0 %	1	100.0 %	12	46.1 %	11	55.0 %	10	43.4 %	10	27.0 %	4	20.0 %	47	37.3 %
Unknown	.	.	.	.	1	3.8 %	.	.	1	4.3 %	1	2.7 %	1	5.0 %	4	3.1 %
<b>TOTAL</b>	1	100.0 %	1	100.0 %	26	100.0 %	20	100.0 %	23	100.0 %	37	100.0 %	20	100.0 %	126	100.0 %

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT****II.A. Pre-Implant Summaries - Functional Capacity and Quality of Life****Exhibit 18d. Quality of Life - EQ-5D Pain/Discomfort**

The following table compares the EQ-5D Pain/Discomfort domain between your site and STS Intermacs.

EQ-5D Pain/Discomfort	HOSPX-9999				STS Intermacs											
	2020 Q4		TOTAL		2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
I have no pain or discomfort	1	100.0 %	1	100.0 %	12	46.1 %	5	25.0 %	5	21.7 %	19	51.3 %	7	35.0 %	48	38.0 %
I have moderate pain or discomfort	.	.	.	.	12	46.1 %	11	55.0 %	12	52.1 %	14	37.8 %	11	55.0 %	60	47.6 %
I have extreme pain or discomfort	.	.	.	.	1	3.8 %	3	15.0 %	4	17.3 %	4	10.8 %	1	5.0 %	13	10.3 %
Unknown	.	.	.	.	1	3.8 %	1	5.0 %	2	8.6 %	.	.	1	5.0 %	5	3.9 %
<b>TOTAL</b>	1	100.0 %	1	100.0 %	26	100.0 %	20	100.0 %	23	100.0 %	37	100.0 %	20	100.0 %	126	100.0 %

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT****II.A. Pre-Implant Summaries - Functional Capacity and Quality of Life****Exhibit 18e. Quality of Life - EQ-5D Anxiety/Depression**

The following table compares the EQ-5D Anxiety/Depression domain between your site and STS Intermacs.

EQ-5D Anxiety	HOSPX-9999				STS Intermacs											
	2020 Q4		TOTAL		2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
I am not anxious or depressed	1	100.0 %	1	100.0 %	9	34.6 %	5	25.0 %	10	43.4 %	16	43.2 %	13	65.0 %	53	42.0 %
I am moderately anxious or depressed	.	.	.	.	14	53.8 %	13	65.0 %	10	43.4 %	14	37.8 %	5	25.0 %	56	44.4 %
I am extremely anxious or depressed	.	.	.	.	2	7.6 %	2	10.0 %	2	8.6 %	7	18.9 %	1	5.0 %	14	11.1 %
Unknown	.	.	.	.	1	3.8 %	.	.	1	4.3 %	.	.	1	5.0 %	3	2.3 %
<b>TOTAL</b>	<b>1</b>	<b>100.0 %</b>	<b>1</b>	<b>100.0 %</b>	<b>26</b>	<b>100.0 %</b>	<b>20</b>	<b>100.0 %</b>	<b>23</b>	<b>100.0 %</b>	<b>37</b>	<b>100.0 %</b>	<b>20</b>	<b>100.0 %</b>	<b>126</b>	<b>100.0 %</b>

**Exhibit 18f. Quality of Life - EQ-5D Visual Analog Scale**

**GROUP=HOSPX-9999**

**GROUP=STS Intermacs**

[illegible]

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Functional Capacity and Quality of Life**

**Exhibit 18g. Quality of Life - EQ-5D Incomplete - Patient Reasons**

The following table compares the Patient Reasons the EQ-5D was not completed.

Patient Reasons for Incomplete EQ-5D	HOSPX-9999					
	2020 Q3		2020 Q4		TOTAL	
	n	%	n	%	n	%
Too sick (ex., intubated/sedated, critically ill, on short-term VAD)	.	.	1	50.0 %	1	33.3 %
Too tired	.	.	.	.	.	.
Too stressed, anxious, and/or depressed	.	.	.	.	.	.
No time / too busy	.	.	1	50.0 %	1	33.3 %
Can't concentrate	.	.	.	.	.	.
Unwilling to complete instrument, no reason given	.	.	.	.	.	.
Administrative (check specific reason below)	1	100.0 %	.	.	1	33.3 %
<b>TOTAL</b>	<b>1</b>	<b>100.0 %</b>	<b>2</b>	<b>100.0 %</b>	<b>3</b>	<b>100.0 %</b>

Patient Reasons for Incomplete EQ-5D	STS Intermacs											
	2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%
Too sick (ex., intubated/sedated, critically ill, on short-term VAD)	20	58.8 %	27	64.2 %	28	57.1 %	37	74.0 %	15	57.6 %	127	63.1 %
Too tired	2	5.8 %	.	.	.	.	.	.	1	3.8 %	3	1.4 %
Too stressed, anxious, and/or depressed	1	2.9 %	1	2.3 %	5	10.2 %	1	2.0 %	.	.	8	3.9 %
No time / too busy	1	2.9 %	.	.	1	2.0 %	2	4.0 %	.	.	4	1.9 %
Can't concentrate	.	.	.	.	1	2.0 %	1	2.0 %	.	.	2	0.9 %
Unwilling to complete instrument, no reason given	2	5.8 %	.	.	1	2.0 %	.	.	.	.	3	1.4 %
Administrative (check specific reason below)	8	23.5 %	14	33.3 %	13	26.5 %	9	18.0 %	10	38.4 %	54	26.8 %
<b>TOTAL</b>	<b>34</b>	<b>100.0 %</b>	<b>42</b>	<b>100.0 %</b>	<b>49</b>	<b>100.0 %</b>	<b>50</b>	<b>100.0 %</b>	<b>26</b>	<b>100.0 %</b>	<b>201</b>	<b>100.0 %</b>

COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT****II.A. Pre-Implant Summaries - Functional Capacity and Quality of Life****Exhibit 18h. Quality of Life - EQ-5D Incomplete - Administrative Reasons**

The following table compares the Administrative Reasons the EQ-5D was not completed.

Administrative Reasons for Incomplete EQ-5D	HOSPX-9999				STS InterMACS											
	2020 Q3		TOTAL		2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Urgent/emergent implant, no time to administer QOL instruments	1	100.0 %	1	100.0 %	1	12.5 %	.	.	2	15.3 %	1	11.1 %	.	.	4	7.4 %
Coordinator too busy or forgot to administer QOL instruments	.	.	.	.	7	87.5 %	8	57.1 %	7	53.8 %	5	55.5 %	3	30.0 %	30	55.5 %
Unable to contact patient (ie., not hospitalized or no clinic visit) within the window for QOL instr	.	.	.	.	.	.	2	14.2 %	3	23.0 %	1	11.1 %	3	30.0 %	9	16.6 %
Other reason (describe)	.	.	.	.	.	.	4	28.5 %	1	7.6 %	2	22.2 %	4	40.0 %	11	20.3 %
<b>TOTAL</b>	1	100.0 %	1	100.0 %	8	100.0 %	14	100.0 %	13	100.0 %	9	100.0 %	10	100.0 %	54	100.0 %

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.A. Pre-Implant Summaries - Functional Capacity and Quality of Life**

**Exhibit 19. Trailmaking**

Trailmaking Test time is the number of seconds required to complete the test.

**GROUP=HOSPX-9999**

Trailmaking Time(s)		2020 Q3	2020 Q4	2021 Q2	TOTAL
	<b>N</b>	0	1	0	1
	<b>Mean</b>	.	110.00	.	110.00
	<b>Std</b>	.	.	.	.
	<b>Min</b>	.	110.00	.	110.00
	<b>Max</b>	.	110.00	.	110.00

**GROUP=STS Intermacs**

Trailmaking Time(s)		2020 Q1	2020 Q2	2020 Q3	2020 Q4	2021 Q1	2021 Q2	TOTAL
	<b>N</b>	13	13	18	16	12	0	72
	<b>Mean</b>	156.62	116.62	128.50	135.19	205.17	.	145.69
	<b>Std</b>	78.03	44.31	51.10	72.11	285.63	.	128.83
	<b>Min</b>	73.00	54.00	69.00	52.00	54.00	.	52.00
	<b>Max</b>	324.00	179.00	233.00	333.00	1093.00	.	1093.00

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

***SITE: HOSPX - DEMO SITE REPORT***

***II.B. Implant Summaries***

***Exhibit 20. VAD Indication***

The following table summarizes additional implant reasons that necessitated the placement of a VAD at your site and STS InterMACS.

VAD INDICATION	HOSPX-9999		STS InterMACS	
	N	%	N	%
Failure to wean from Cardio Pulmonary Bypass	.	.	5	2.1 %
Persistent Heart Failure Following Cardiac Surgery	.	.	17	7.2 %
None	1	100.0 %	213	90.6 %
Total Patients	1	100.0 %	235	100.0 %



COVERAGE: January 1, 2020 - June 30, 2021

**SITE: HOSPX - DEMO SITE REPORT****II.B. Implant Summaries****Exhibit 21. Device Type**

The following tables summarizes the implant side (location) of VADs at your site and STS InterMACs over time.

Device Type	HOSPX-9999							
	2020 Q3		2020 Q4		2021 Q2		TOTAL	
	n	%	n	%	n	%	n	%
LVAD	1	100.0 %	3	100.0 %	3	100.0 %	7	100.0 %
BIVAD	.	.	.	.	.	.	.	.
TAH	.	.	.	.	.	.	.	.
TOTAL	1	100.0 %	3	100.0 %	3	100.0 %	7	100.0 %

Device Type	STS InterMACs													
	2020 Q1		2020 Q2		2020 Q3		2020 Q4		2021 Q1		2021 Q2		TOTAL	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
LVAD	58	87.8 %	57	89.0 %	73	93.5 %	86	94.5 %	99	90.8 %	82	93.1 %	455	91.7 %
BIVAD	7	10.6 %	6	9.3 %	5	6.4 %	5	5.4 %	10	9.1 %	6	6.8 %	39	7.8 %
TAH	1	1.5 %	1	1.5 %	.	.	.	.	.	.	.	.	2	0.4 %
TOTAL	66	100.0 %	64	100.0 %	78	100.0 %	91	100.0 %	109	100.0 %	88	100.0 %	496	100.0 %

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.B. Implant Summaries**

***Exhibit 22. Additional Interventions within 48 Hours of Implant***

This table lists the interventions that occurred during the 48 hours prior to implant. A patient can have more than 1 additional intervention.

ADDITIONAL INTERVENTIONS	HOSPX-9999			STS InterMACS		
	N	Yes	%	N	Yes	%
IABP	2	0	0.00%	230	8	3.48%
Dialysis	2	0	0.00%	230	8	3.48%
Ultrafiltration	2	0	0.00%	230	1	0.43%
Ventilator	2	1	50.00%	230	12	5.22%
Feeding Tube	2	0	0.00%	230	9	3.91%
ECMO	2	0	0.00%	230	7	3.04%
None	2	1	50.00%	230	148	64.35%
CABG+	2	0	0.00%	230	0	0.00%
Aortic Valve Replacement/Repair+	2	0	0.00%	230	2	0.87%
Mitral Valve Replacement/Repair+	2	0	0.00%	230	0	0.00%
Congenital Cardiac Surgery+	2	0	0.00%	230	0	0.00%
LVAD+	2	0	0.00%	230	53	23.04%
RVAD+	2	0	0.00%	230	10	4.35%
TAH+	2	0	0.00%	230	0	0.00%
Aneurysmectomy+	2	0	0.00%	230	0	0.00%

Note: + = variable collected post relaunch (5/2/2012)

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Adverse Event Rates**

***Exhibit 23a. Patient Percent Experiencing Each Adverse Event Type***

For each adverse event type, the percent of patients with a least one event of that type reported is presented at for your site and STS-INTERMACS overall.

Patient percent experiencing a specific adverse event = number of unique patients with reported event / number of patients at your site \* 100

While useful, this measure does not take into consideration the varying amount of time on support for each patient (exposure time) or the timing of the adverse events. Subsequent exhibits use adverse event rates that more accurately compare adverse events reported at your site to the overall cohort.

	HOSPX-9999			STS InterMACS		
	Events	Patients	Patient Percent	Events	Patients	Patient Percent
Arterial Non-CNS Thromboembolism	.	.	.	2	2	0.4%
Bleeding	.	.	.	173	106	21.4%
Cardiac Arrhythmia	2	2	28.6%	108	88	17.7%
Device Malfunction and/or Pump Thrombosis	.	.	.	10	10	2.0%
Hepatic Dysfunction	.	.	.	15	14	2.8%
Infection	1	1	14.3%	248	164	33.1%
Neurological Dysfunction	.	.	.	67	57	11.5%
Other Serious Adverse Event	.	.	.	138	86	17.3%
Pericardial Drainage	.	.	.	18	17	3.4%
Psychiatric Episode	.	.	.	18	14	2.8%
Rehospitalization	1	1	14.3%	391	183	36.9%
Renal Dysfunction	.	.	.	71	64	12.9%
Respiratory Failure	1	1	14.3%	89	77	15.5%
Venous Thromboembolism	.	.	.	17	14	2.8%
Wound Dehiscence	.	.	.	12	12	2.4%

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Adverse Event Rates**

***Exhibit 23b. Adverse Event Exposure***

The following table summarizes the total time patients receiving primary prospective implants have been followed at your site and STS InterMACS overall. The total follow-up time is divided into an early period (less than or equal to three months) and late period (more than three months). These totals are the accrued exposure time for each patient group and are used as the denominators in the following rate calculations.

Patient Follow-Up	STS	
	HOSPX-9999	InterMACS
Patient exposure during the first 3 months post implant (months)	14	1222
Patient exposure after the first 3 months post implant (months)	14	1969
Number of Patients	7	496

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Adverse Event Rates**

**Exhibit 23c. Adverse Event Rates**

**GROUP=HOSPX-9999**

	HOSPX-9999		
	Early (During the First Three Months)		
	Episodes	Patient %	Rate (per 100 pt month)
Cardiac Arrhythmia	2	28.6%	14.53
Infection	1	14.3%	7.27
Rehospitalization	1	14.3%	7.27
Respiratory Failure	1	14.3%	7.27

**GROUP=STS Intermacs**

	STS Intermacs					
	Early (During the First Three Months)			Late (After the First Three Months)		
	Episodes	Patient %	Rate (per 100 pt month)	Episodes	Patient %	Rate (per 100 pt month)
Arterial Non-CNS Thromboembolism	2	0.4%	0.16	.	.	.
Bleeding	125	17.9%	10.23	48	6.3%	2.44
Cardiac Arrhythmia	92	16.3%	7.53	16	2.6%	0.81
Device Malfunction and/or Pump Thrombosis	6	1.2%	0.49	4	0.8%	0.20
Hepatic Dysfunction	11	2.0%	0.90	4	0.8%	0.20
Infection	167	25.4%	13.67	81	12.7%	4.11
Neurological Dysfunction	51	9.1%	4.17	16	3.0%	0.81
Other Serious Adverse Event	110	15.5%	9.00	28	3.8%	1.42
Pericardial Drainage	18	3.4%	1.47	.	.	.
Psychiatric Episode	14	2.4%	1.15	4	0.8%	0.20
Rehospitalization	126	19.6%	10.31	265	26.6%	13.46
Renal Dysfunction	65	12.1%	5.32	6	1.2%	0.30
Respiratory Failure	81	14.1%	6.63	8	1.6%	0.41
Venous Thromboembolism	15	2.6%	1.23	2	0.2%	0.10
Wound Dehiscence	12	2.4%	0.98	.	.	.

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Adverse Event Rates**

**Exhibit 23d. Infection Rates by Location**

The following table compares infection rates according to location at your site and STS InterMACS. Every infection location reported is counted in the table.

**GROUP=HOSPX-9999**

	HOSPX-9999		
	Early (During the First Three Months)		
	Episodes	Patient %	Rate (per 100 pt month)
Pulmonary	1	14.3%	7.27

**GROUP=STS InterMACS**

	STS InterMACS					
	Early (During the First Three Months)			Late (After the First Three Months)		
	Episodes	Patient %	Rate (per 100 pt month)	Episodes	Patient %	Rate (per 100 pt month)
GI	16	3.2%	1.31	4	0.8%	0.20
Line Sepsis	1	0.2%	0.08	.	.	.
Mediastinum	12	2.2%	0.98	2	0.4%	0.10
Other Specify	29	5.8%	2.37	12	2.2%	0.61
Peripheral Wound	7	1.4%	0.57	2	0.4%	0.10
Positive Blood Cultures	40	7.3%	3.27	22	4.4%	1.12
Pulmonary	52	9.1%	4.26	13	2.6%	0.66
Pump/Related - Drive Line	21	4.0%	1.72	31	5.0%	1.57
Pump/Related - Exit Cannula	.	.	.	2	0.4%	0.10
Pump/Related - Pump Interior	1	0.2%	0.08	1	0.2%	0.05
Pump/Related - Pump Pocket	1	0.2%	0.08	.	.	.
Unknown	2	0.4%	0.16	.	.	.
Urinary Tract	29	5.6%	2.37	6	1.0%	0.30

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Adverse Event Rates**

***Exhibit 23e. Bleeding Rates by Source***

The following table compares bleeding rates according to source at your site and STS InterMACS. Every bleed source reported is counted in the table.

NOTE: These rates are reported for patients receiving a implant starting in March 2009.

**GROUP=STS InterMACS**

	STS InterMACS					
	Early (During the First Three Months)			Late (After the First Three Months)		
	Episodes	Patient %	Rate (per 100 pt month)	Episodes	Patient %	Rate (per 100 pt month)
ENT / Dental	8	1.2%	0.65	7	1.0%	0.36
GI OVERALL: upper, lower, unknown	53	9.9%	4.34	35	4.4%	1.78
GI: Lower gastrointestinal (colon, rectum, and anus)	9	1.8%	0.74	7	1.4%	0.36
GI: Upper gastrointestinal (esophagus, stomach, duod)	18	3.2%	1.47	15	1.8%	0.76
GI: unknown, but guaiac positive stools	27	5.2%	2.21	14	2.6%	0.71
Intra-abdominal	2	0.4%	0.16	1	0.2%	0.05
Mediastinal: Unspecified	2	0.4%	0.16	.	.	.
Mediastinal: chest wall	12	2.0%	0.98	.	.	.
Mediastinal: coagulopathy with no surgical site	5	1.0%	0.41	.	.	.
Mediastinal: inflow conduit	1	0.2%	0.08	.	.	.
Mediastinal: other surgical site	4	0.8%	0.33	.	.	.
Mediastinal: outflow conduit	1	0.2%	0.08	.	.	.
Mediastinal: outflow-aorta anastomosis	3	0.6%	0.25	.	.	.
Other	41	6.3%	3.36	8	1.2%	0.41
Pleural space	5	1.0%	0.41	1	0.2%	0.05
Pulmonary	7	1.0%	0.57	.	.	.
Retroperitoneal	4	0.8%	0.33	.	.	.
Urinary tract	1	0.2%	0.08	2	0.4%	0.10

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Adverse Event Rates**

***Exhibit 23f. Device Malfunction and/or Pump Thrombosis by type***

The following table compares Device Malfunction and/or Pump Thrombosis rates according to type at your site and STS InterMACS.

NOTE: These rates are reported for patients receiving implant starting with Version 4.0 (June 2, 2014).

**GROUP=STS InterMACS**

	STS InterMACS					
	Early (During the First Three Months)			Late (After the First Three Months)		
	Episodes	Patient %	Rate (per 100 pt month)	Episodes	Patient %	Rate (per 100 pt month)
Device Malfunction	1	0.2%	0.08	3	0.6%	0.15
Pump Thrombosis	4	0.8%	0.33	1	0.2%	0.05



**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Adverse Event Rates**

***Exhibit 23g. Neurological Dysfunction by Category***

The following table compares neurological dysfunction rates according to category at your site and STS InterMACS.

NOTE: These rates are reported for patients receiving implant starting with Version 3.0 (May 2, 2012).

**GROUP=STS InterMACS**

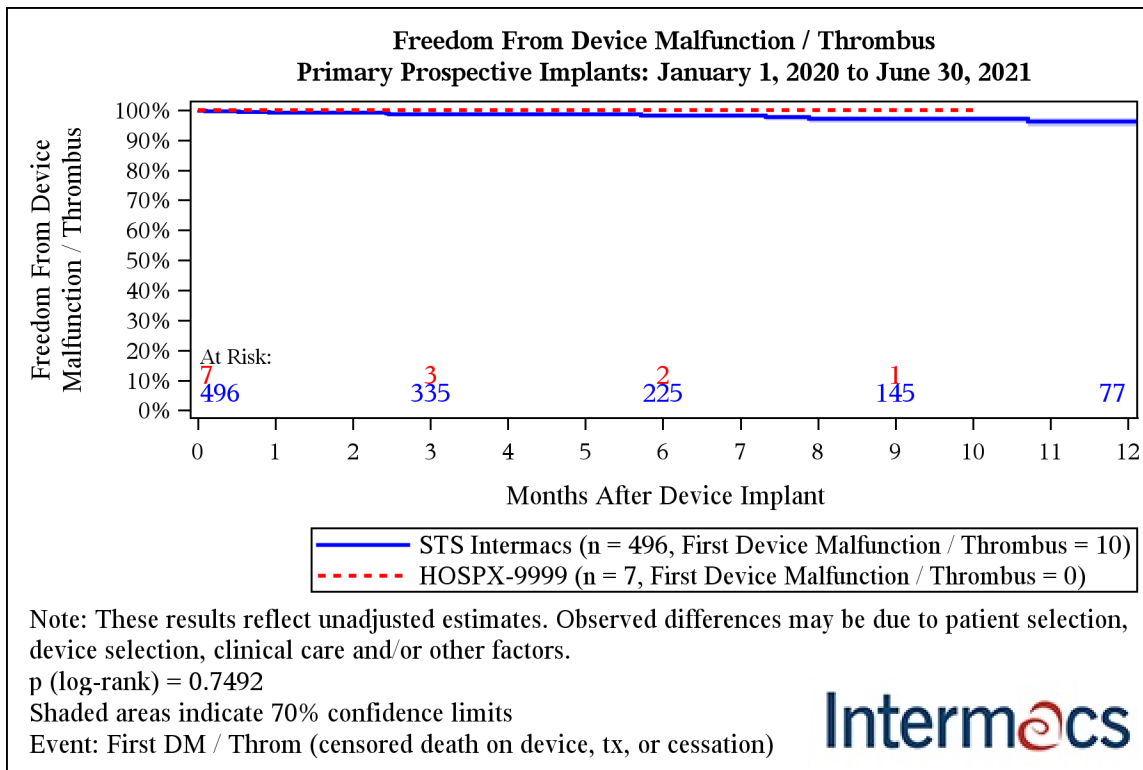
	STS InterMACS					
	Early (During the First Three Months)			Late (After the First Three Months)		
	Episodes	Patient %	Rate (per 100 pt month)	Episodes	Patient %	Rate (per 100 pt month)
CVA	23	4.4%	1.88	10	2.0%	0.51
Confusion	12	2.2%	0.98	1	0.2%	0.05
Encephalopathy	9	1.8%	0.74	2	0.4%	0.10
Seizure	4	0.8%	0.33	1	0.2%	0.05
TIA	3	0.6%	0.25	2	0.2%	0.10

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**Exhibit 24a. Time to First Device Malfunction / Thrombus**



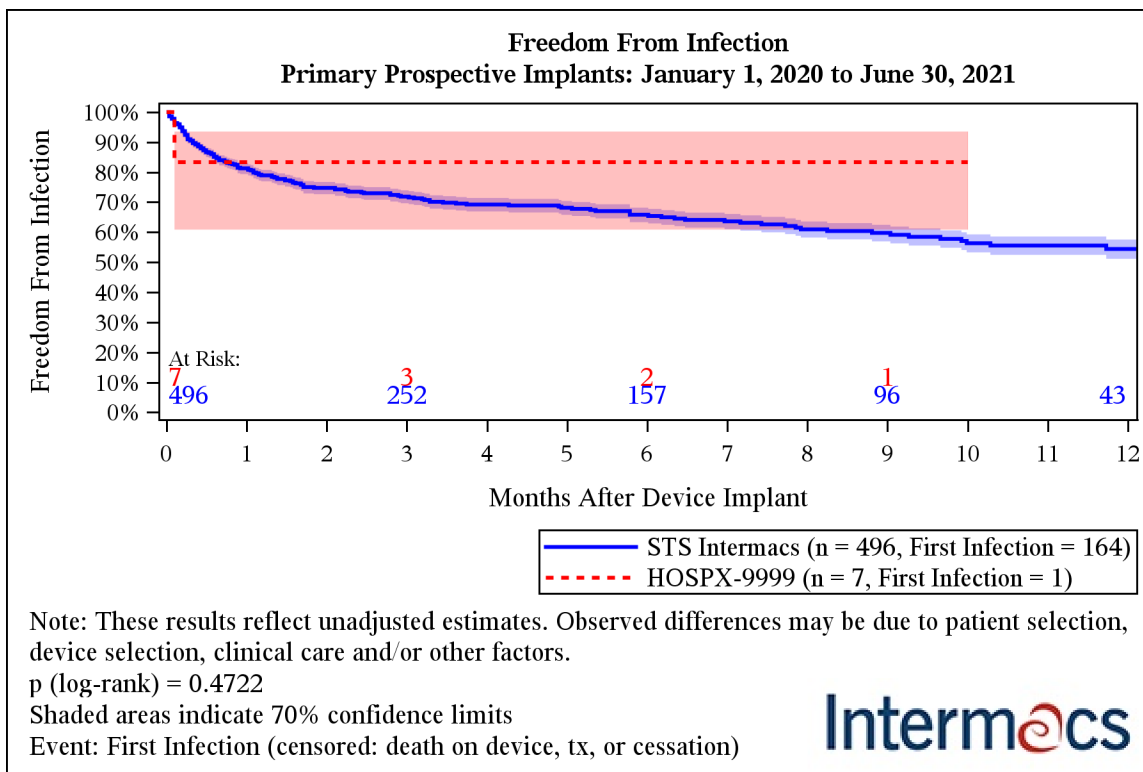
Months after Device Implant	STS Intermacs	HOSPX-9999
1	99.1% (98.6%-99.5%)	100.0% (100.0%-100.0%)
3	98.6% (97.9%-99.1%)	100.0% (100.0%-100.0%)
6	98.2% (97.3%-98.8%)	100.0% (100.0%-100.0%)
9	97.1% (95.9%-98.0%)	100.0% (100.0%-100.0%)
12	96.2% (94.6%-97.3%)	

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**Exhibit 24b. Time to First Infection**



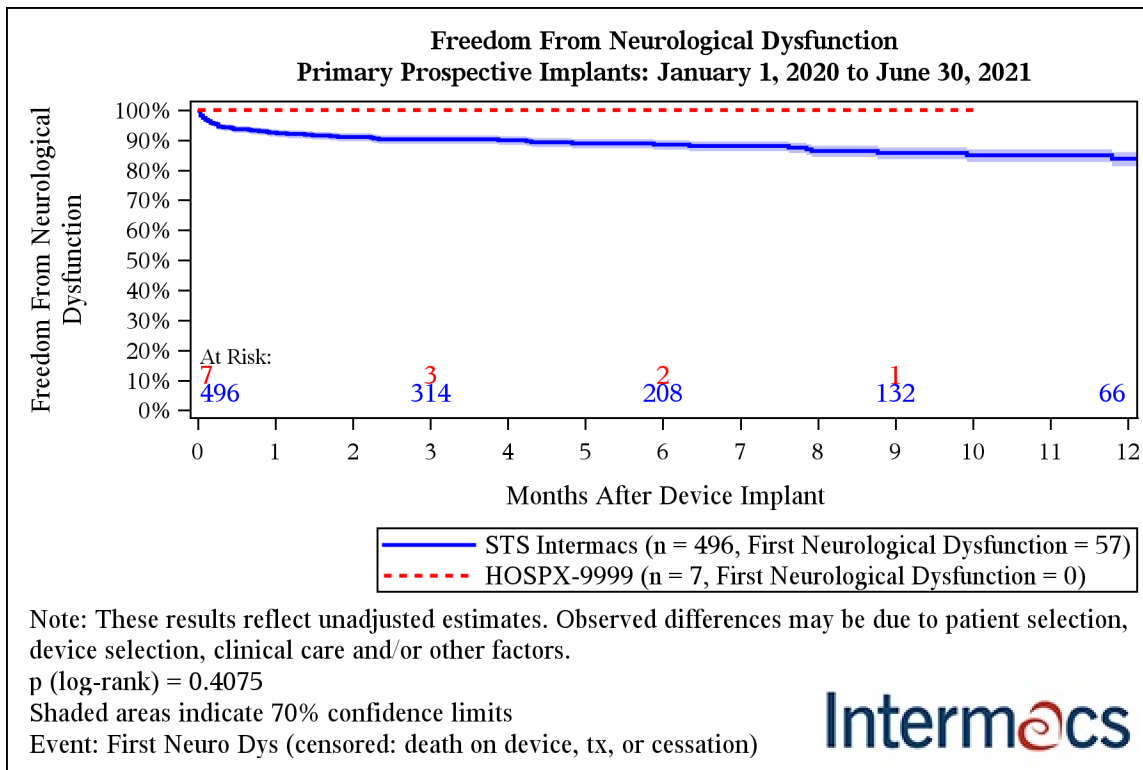
Months after Device Implant	STS Intermacs	HOSPX-9999
1	81.3% (79.4%-83.0%)	83.3% (60.9%-93.5%)
3	71.9% (69.6%-73.9%)	83.3% (60.9%-93.5%)
6	65.8% (63.4%-68.2%)	83.3% (60.9%-93.5%)
9	59.8% (57.0%-62.5%)	83.3% (60.9%-93.5%)
12	54.4% (51.2%-57.6%)	

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**Exhibit 24c. Time to First Neurological Dysfunction**



Months after Device Implant	STS Intermacs	HOSPX-9999
1	92.5% (91.2%-93.6%)	100.0% (100.0%-100.0%)
3	90.3% (88.8%-91.6%)	100.0% (100.0%-100.0%)
6	88.5% (86.8%-90.0%)	100.0% (100.0%-100.0%)
9	85.7% (83.7%-87.6%)	100.0% (100.0%-100.0%)
12	83.8% (81.3%-86.0%)	

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

***Exhibit 25. Hospital Days for Discharged Patients***

This table compares hospital days (initial hospitalization) from implant date to discharge date for patients with submitted discharge forms. For most patients this is the date they were discharged alive on a device but for patients that died or were transplanted in the implantation hospitalization it is the death date or transplant date, respectively. The first section (All) compares overall hospital days. The remaining sections compare hospital days by each device type, LVAD, Bi-VAD and TAH respectively.

HOSPITAL DAYS FOR DISCHARGED PATIENTS			HOSPX-9999			STS Intermacs						
						2020 Q3	2020 Q4	TOTAL	2020 Q1	2020 Q2	2020 Q3	2020 Q4
All		N	1	3	4	58	53	69	72	89	56	397
		Mean	15.00	20.33	19.00	32.62	42.15	27.62	31.79	25.60	19.59	29.46
		Std	.	0.58	2.71	23.89	56.84	17.15	19.71	15.97	11.82	27.28
		Median	15	20	20	25	29	24	27	21	17	22
		Min	15	20	15	7	8	0	0	1	7	0
		Max	15	21	21	123	378	88	96	85	67	378
BiVAD		N	.	.	.	4	4	2	2	8	1	21
		Mean	.	.	.	66.50	129.00	12.50	35.00	45.50	16.00	59.86
		Std	.	.	.	40.44	167.06	17.68	0.00	21.19	.	77.68
		Median	.	.	.	58	58	13	35	41	16	35
		Min	.	.	.	27	23	0	35	22	16	0
		Max	.	.	.	123	378	25	35	77	16	378
LVAD		N	1	3	4	54	49	67	70	81	55	376
		Mean	15.00	20.33	19.00	30.11	35.06	28.07	31.70	23.63	19.65	27.76
		Std	.	0.58	2.71	20.69	32.81	17.06	19.98	14.06	11.92	20.24
		Median	15	20	20	22	28	24	26	20	17	21
		Min	15	20	15	7	8	0	0	1	7	0
		Max	15	21	21	84	210	88	96	85	67	210

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - 30 Day Readmission**

**Exhibit 26. 30 Days Readmission**

The following tables present the counts and percentages of patients that were discharged alive on a device that were readmitted within 30 days for your site and for STS Intermacs overall. Percentages are listed by device type and discharge year.

**GROUP=HOSPX-9999**

30 Day Readmission		Device Type			TOTAL		
		LVAD					
		Patients Discharged Alive on Device (n)	Patients with 30 day Readmission	% With 30 day Readmission	Patients Discharged Alive on Device (n)	Patients with 30 day Readmission	% With 30 day Readmission
Discharge Year							
	2020Q4	3	0	0.0%	3	0	0.0%
	2021Q1	1	1	100.0%	1	1	100.0%
	TOTAL	4	1	25.0%	4	1	25.0%

**GROUP=STS Intermacs**

30 Day Readmission		Device Type						TOTAL		
		LVAD			BiVAD					
		Patients Discharged Alive on Device (n)	Patients with 30 day Readmission	% With 30 day Readmission	Patients Discharged Alive on Device (n)	Patients with 30 day Readmission	% With 30 day Readmission	Patients Discharged Alive on Device (n)	Patients with 30 day Readmission	% With 30 day Readmission
Discharge Year										
	2020Q1	37	5	13.5%	2	0	0.0%	39	5	12.8%
	2020Q2	48	10	20.8%	2	0	0.0%	50	10	20.0%
	2020Q3	63	17	27.0%	3	2	66.7%	66	19	28.8%
	2020Q4	65	10	15.4%	2	0	0.0%	67	10	14.9%
	2021Q1	84	15	17.9%	5	1	20.0%	89	16	18.0%
	2021Q2	74	11	14.9%	6	1	16.7%	80	12	15.0%
	TOTAL	371	68	18.3%	20	4	20.0%	391	72	18.4%

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Functional Capacity**

**Exhibit 27a. 6 Minute Walk - Overall**

The following tables summarize Six Minute Walk completion status and values at your site and STS InterMACs at select follow-up visits. Only follow-up data for patients first devices are considered for this summary. Unlikely values have been categorized as outliers and are listed in the accompanying data quality report.

**GROUP=HOSPX-9999**

VISIT	Patients (n)	COMPLETION STATUS										
		Not Done: Other/Unknown		Not Done: Too Sick		Complete						
	N	%	N	%	N	%	Mean	Std	Median	Min	Max	
Pre-Implant	7	6	85.7	1	14.3	.	.	.	.	.	.	.
3 Month	2	1	50.0	.	.	1	50.0	900.0	.	900.0	900.0	900.0
6 Month	1	1	100.0	.	.	.	.	.	.	.	.	.

**GROUP=STS InterMACs**

VISIT	Patients (n)	COMPLETION STATUS												
		Not Done: Other/Unknown		Not Done: Too Sick		Outlier		Complete						
		N	%	N	%	N	%	N	%	Mean	Std	Median	Min	Max
Pre-Implant	496	232	46.8	236	47.6	.	.	28	5.6	724.5	484.9	781.0	5.0	2000.0
3 Month	308	209	67.9	26	8.4	.	.	73	23.7	1048.4	377.3	1050.0	227.0	1800.0
6 Month	197	120	60.9	11	5.6	1	0.5	65	33.0	1018.6	413.8	955.0	78.0	2017.0
1 Year	60	35	58.3	2	3.3	.	.	23	38.3	1036.7	506.7	1096.0	3.0	2133.0

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

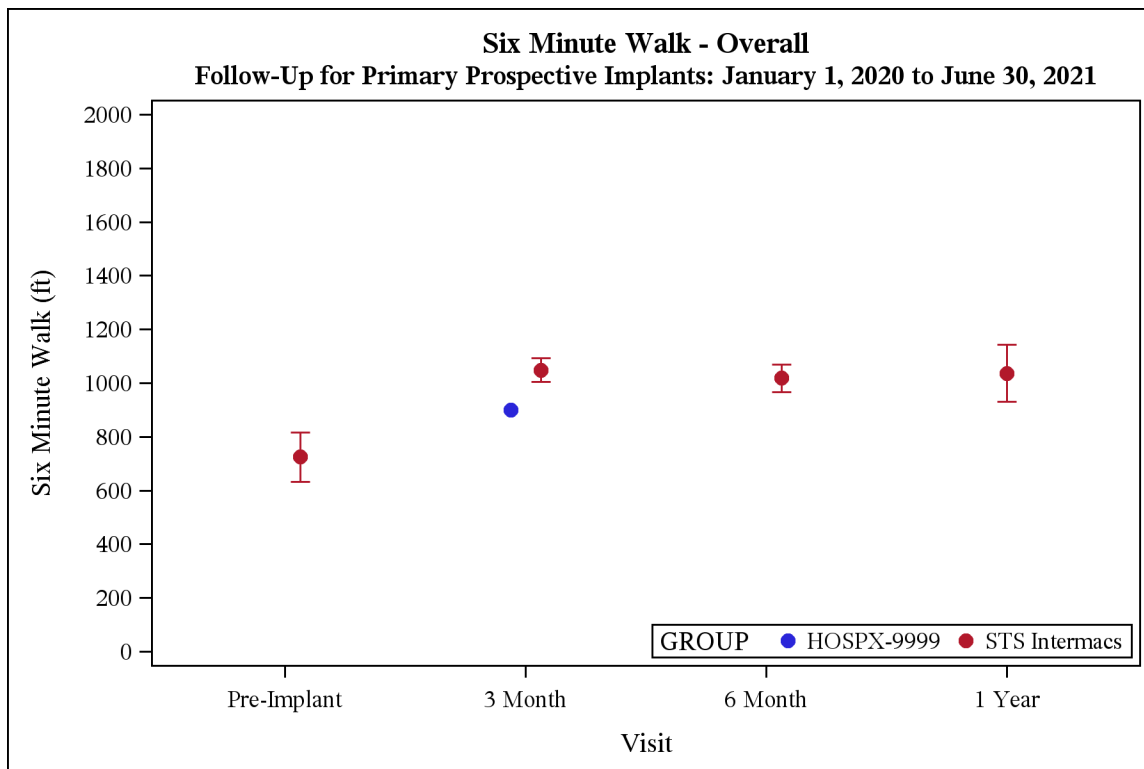
**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Functional Capacity**

**Exhibit 27a. 6 Minute Walk - Overall**

The following figure summarize Six Minute Walk - Overall values your site and STS Intermacs at select follow-up visits. Only follow-up data for patients' first devices are considered for this summary. The dots represent average values and the error bars are the standard errors.





**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Functional Capacity**

**Exhibit 27b. 6 Minute Walk - LVAD**

The following tables summarize Six Minute Walk completion status and values at your site and STS InterMACs at select follow-up visits. Only follow-up data for patients first devices are considered for this summary. Unlikely values have been categorized as outliers and are listed in the accompanying data quality report.

**GROUP=HOSPX-9999**

VISIT		COMPLETION STATUS										
		Not Done: Other/Unknown		Not Done: Too Sick		Complete						
	Patients (n)	Not Done: Other/Unknown		Not Done: Too Sick		Complete		Six Minute Walk (ft)				
	N	N	%	N	%	N	%	Mean	Std	Median	Min	Max
Pre-Implant	7	6	85.7	1	14.3	.	.	.	.	.	.	.
3 Month	2	1	50.0	.	.	1	50.0	900.0	.	900.0	900.0	900.0
6 Month	1	1	100.0	.	.	.	.	.	.	.	.	.

**GROUP=STS InterMACs**

VISIT	Patients (n)	COMPLETION STATUS												
		Not Done: Other/Unknown		Not Done: Too Sick		Outlier		Complete						
		N	%	N	%	N	%	N	%	Mean	Std	Median	Min	Max
Pre-Implant	455	214	47.0	214	47.0	.	.	27	5.9	746.7	479.5	787.0	5.0	2000.0
3 Month	287	194	67.6	22	7.7	.	.	71	24.7	1060.2	375.3	1054.0	227.0	1800.0
6 Month	188	114	60.6	10	5.3	1	0.5	63	33.5	1029.2	415.1	974.0	78.0	2017.0
1 Year	55	32	58.2	2	3.6	.	.	21	38.2	1026.7	529.5	1096.0	3.0	2133.0

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

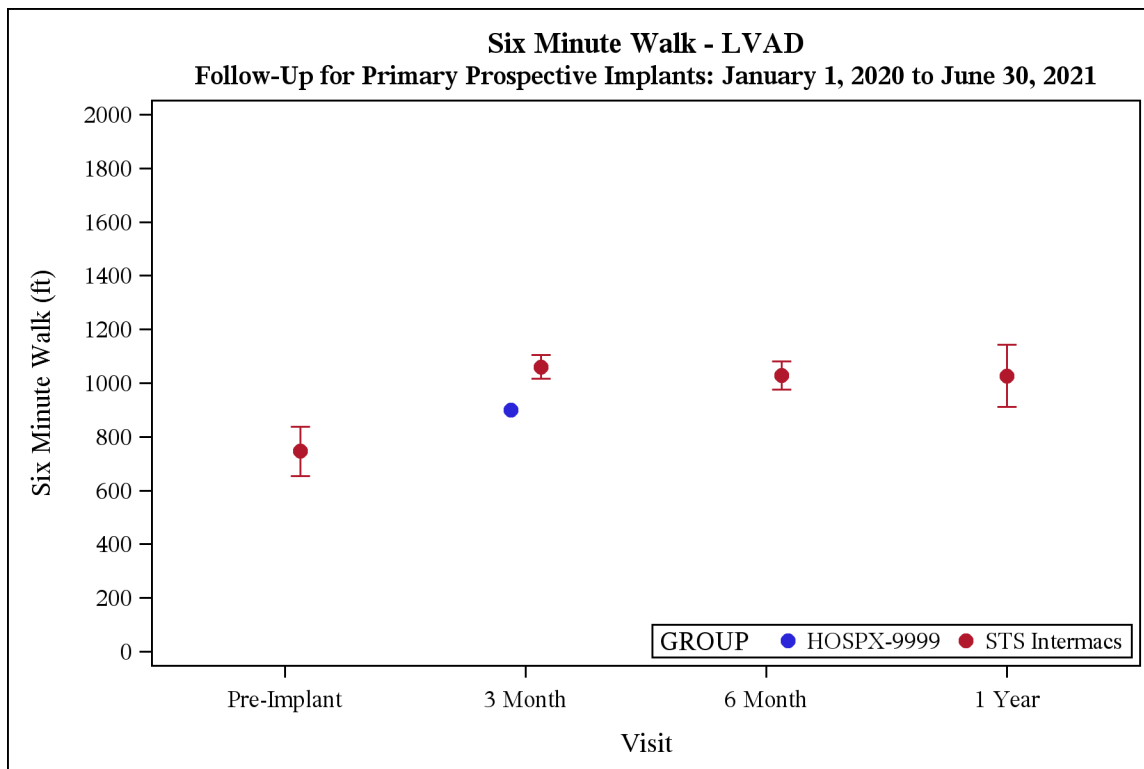
**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Functional Capacity**

**Exhibit 27b. 6 Minute Walk - LVAD**

The following figure summarize Six Minute Walk - LVAD values your site and STS InterMACS at select follow-up visits. Only follow-up data for patients' first devices are considered for this summary. The dots represent average values and the error bars are the standard errors.



**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Functional Capacity**

**Exhibit 27c. 6 Minute Walk - BiVAD**

The following tables summarize Six Minute Walk completion status and values at your site and STS InterMACS at select follow-up visits. Only follow-up data for patients first devices are considered for this summary. Unlikely values have been categorized as outliers and are listed in the accompanying data quality report.

**GROUP=STS InterMACS**

VISIT	Patients (n)	COMPLETION STATUS										
		Not Done: Other/Unknown		Not Done: Too Sick		Complete						
		N	%	N	%	N	%	Mean	Std	Median	Min	Max
Pre-Implant	39	18	46.2	20	51.3	1	2.6	126.0	.	126.0	126.0	126.0
3 Month	20	15	75.0	3	15.0	2	10.0	626.5	150.6	626.5	520.0	733.0
6 Month	9	6	66.7	1	11.1	2	22.2	683.5	207.2	683.5	537.0	830.0
1 Year	5	3	60.0	.	.	2	40.0	1142.5	130.8	1142.5	1050.0	1235.0

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

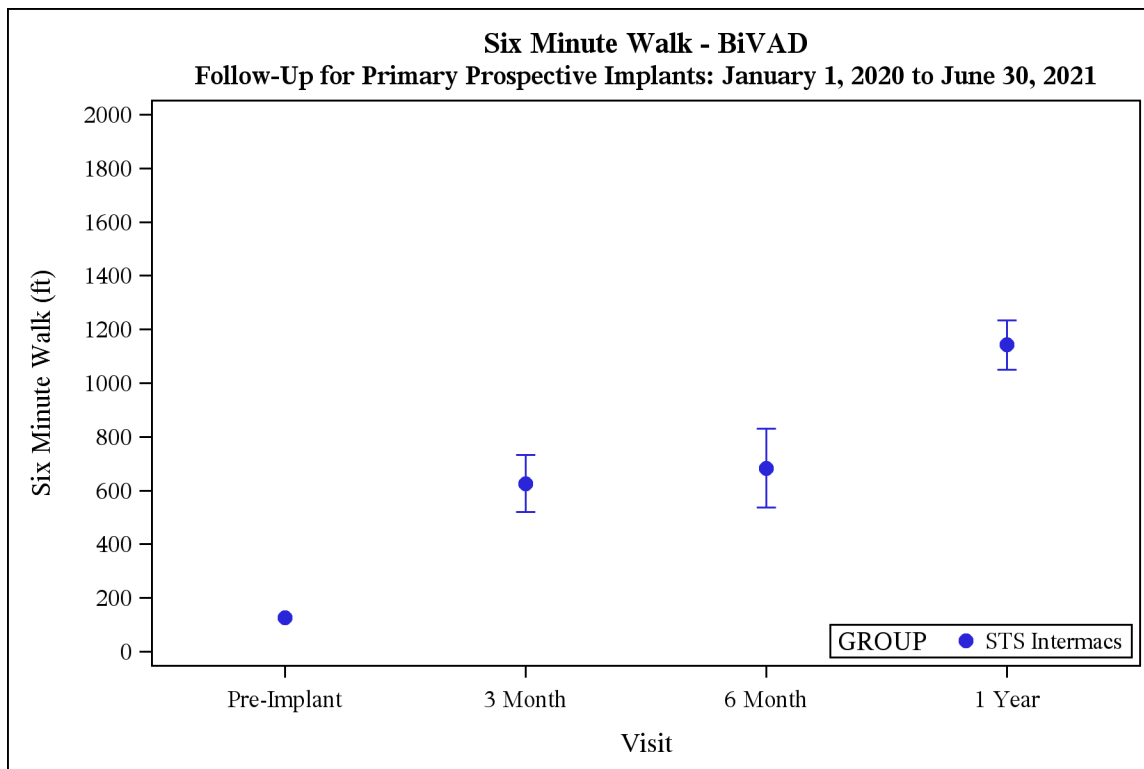
**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Functional Capacity**

**Exhibit 27c. 6 Minute Walk - BiVAD**

The following figure summarize Six Minute Walk - BiVAD values your site and STS InterMACS at select follow-up visits. Only follow-up data for patients' first devices are considered for this summary. The dots represent average values and the error bars are the standard errors.



**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Functional Capacity**

**Exhibit 27d. 6 Minute Walk - TAH**

The following tables summarize Six Minute Walk completion status and values at your site and STS InterMACS at select follow-up visits. Only follow-up data for patients first devices are considered for this summary. Unlikely values have been categorized as outliers and are listed in the accompanying data quality report.

**GROUP=STS InterMACS**

VISIT	Patients (n)	COMPLETION STATUS		Six Minute Walk (ft)				
		Not Done: Too Sick						
	N	N	%	Mean	Std	Median	Min	Max
Pre-Implant	2	2	100.0	.	.	.	.	.
3 Month	1	1	100.0	.	.	.	.	.

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

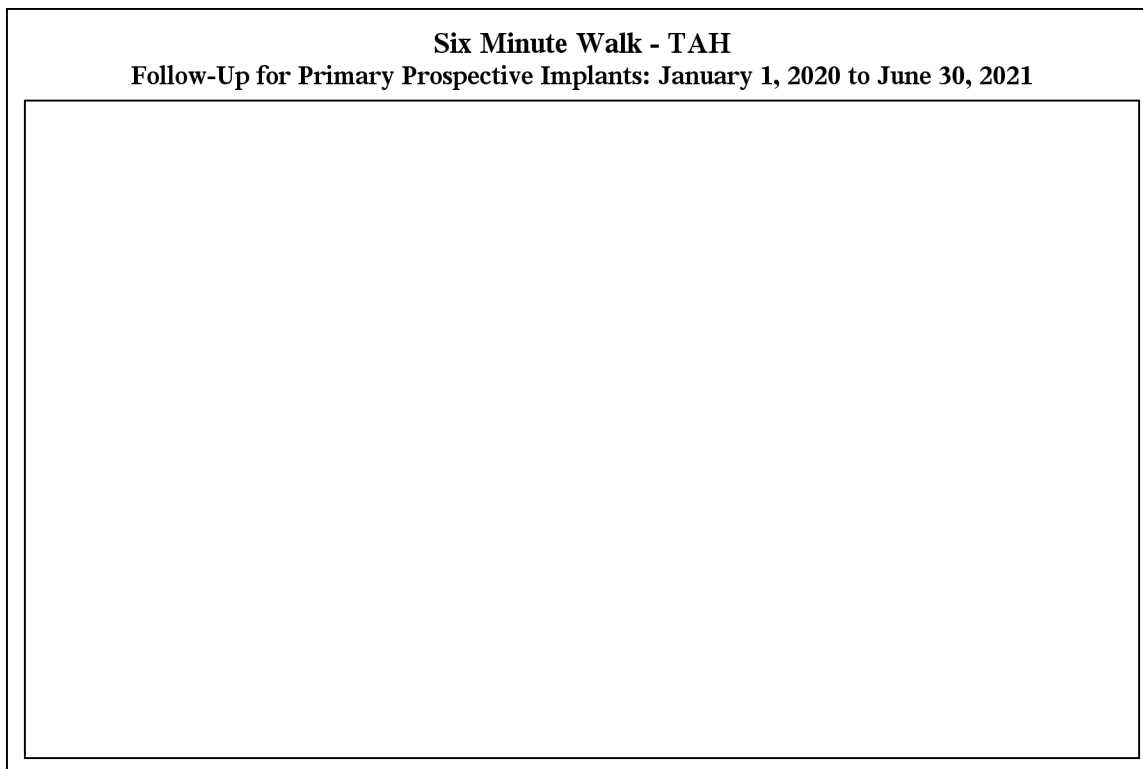
**COVERAGE: January 1, 2020 - June 30, 2021**

***SITE: HOSPX - DEMO SITE REPORT***

***II.C. Post Implant Summary - Functional Capacity***

***Exhibit 27d. 6 Minute Walk - TAH***

The following figure summarize Six Minute Walk - TAH values your site and STS InterMACS at select follow-up visits. Only follow-up data for patients' first devices are considered for this summary. The dots represent average values and the error bars are the standard errors.



**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Functional Capacity**

**Exhibit 28. VO2 Max**

The following tables summarize VO2 Max completion status and values at your site and STS InterMACs at select follow-up visits. Only follow-up data for patients first devices are considered for this summary. Unlikely values have been categorized as outliers and are listed in the accompanying data quality report.

**GROUP=HOSPX-9999**

VISIT	Patients (n)	COMPLETION STATUS								
		Not Done: Other/Unknown		Not Done: Too Sick						
		N	N	%	N	%	Mean	Std	Median	Min
Pre-Implant	7	6	85.7	1	14.3	.	.	.	.	.
3 Month	2	2	100.0	.	.	.	.	.	.	.
6 Month	1	1	100.0	.	.	.	.	.	.	.

**GROUP=STS InterMACs**

VISIT	Patients (n)	COMPLETION STATUS										
		Not Done: Other/Unknown		Not Done: Too Sick		Complete						
		N	%	N	%	N	%	Mean	Std	Median	Min	Max
Pre-Implant	496	292	58.9	192	38.7	12	2.4	12.0	4.0	13.2	6.3	17.5
3 Month	308	289	93.8	18	5.8	1	0.3	10.7	.	10.7	10.7	10.7
6 Month	197	186	94.4	9	4.6	2	1.0	15.0	4.4	15.0	11.9	18.1
1 Year	60	58	96.7	1	1.7	1	1.7	17.4	.	17.4	17.4	17.4

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

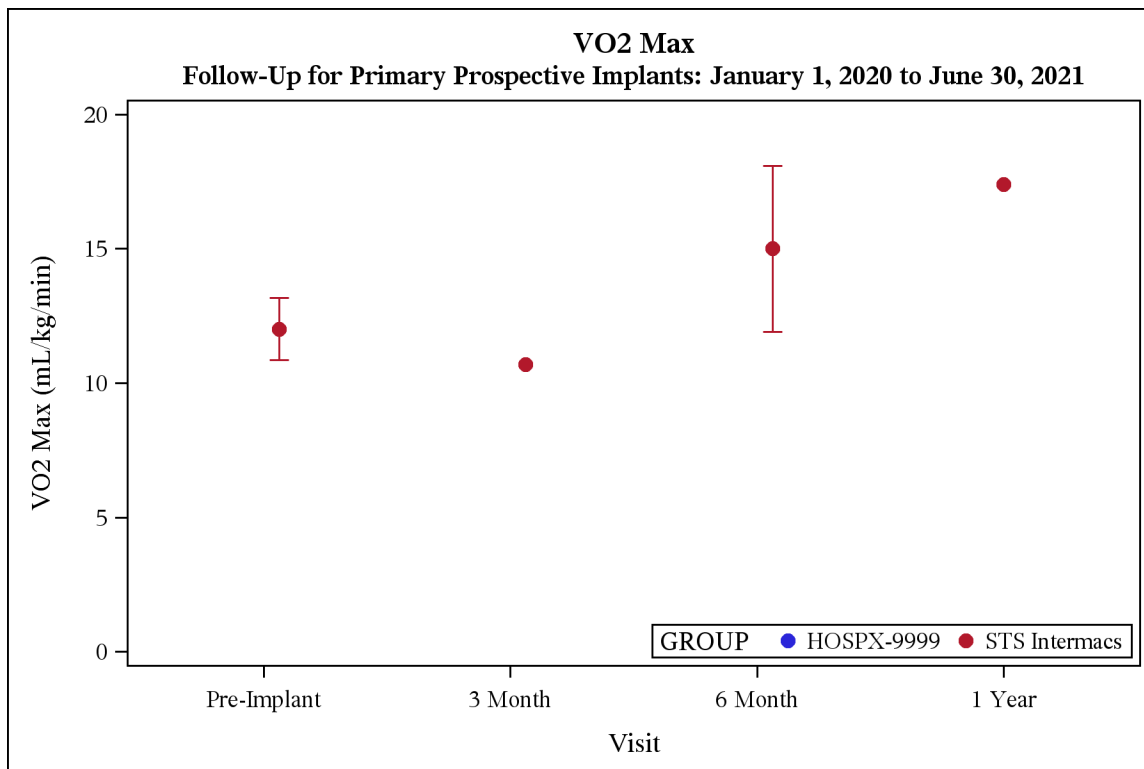
**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Functional Capacity**

**Exhibit 28. VO2 Max**

The following figure summarize VO2 Max values your site and STS InterMACS at select follow-up visits. Only follow-up data for patients' first devices are considered for this summary. The dots represent average values and the error bars are the standard errors.





**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Functional Capacity**

**Exhibit 29. Peak R**

The following tables summarize Peak R completion status and values at your site and STS InterMACS at select follow-up visits. Only follow-up data for patients first devices are considered for this summary. Unlikely values have been categorized as outliers and are listed in the accompanying data quality report.

**GROUP=HOSPX-9999**

VISIT	Patients (n)	COMPLETION STATUS		Peak R (%)				
		Not Done: Other/Unknown						
	N	N	%	Mean	Std	Median	Min	Max
Pre-Implant	7	7	100.0	.	.	.	.	.
3 Month	2	2	100.0	.	.	.	.	.
6 Month	1	1	100.0	.	.	.	.	.

**GROUP=STS InterMACS**

VISIT	Patients (n)	COMPLETION STATUS						Peak R (%)				
		Not Done: Other/Unknown		Outlier		Complete						
	N	N	%	N	%	N	%	Mean	Std	Median	Min	Max
Pre-Implant	496	488	98.4	3	0.6	5	1.0	1.1	0.0	1.1	1.1	1.2
3 Month	308	307	99.7	.	.	1	0.3	1.1	.	1.1	1.1	1.1
6 Month	197	194	98.5	2	1.0	1	0.5	1.1	.	1.1	1.1	1.1
1 Year	60	59	98.3	.	.	1	1.7	1.1	.	1.1	1.1	1.1

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

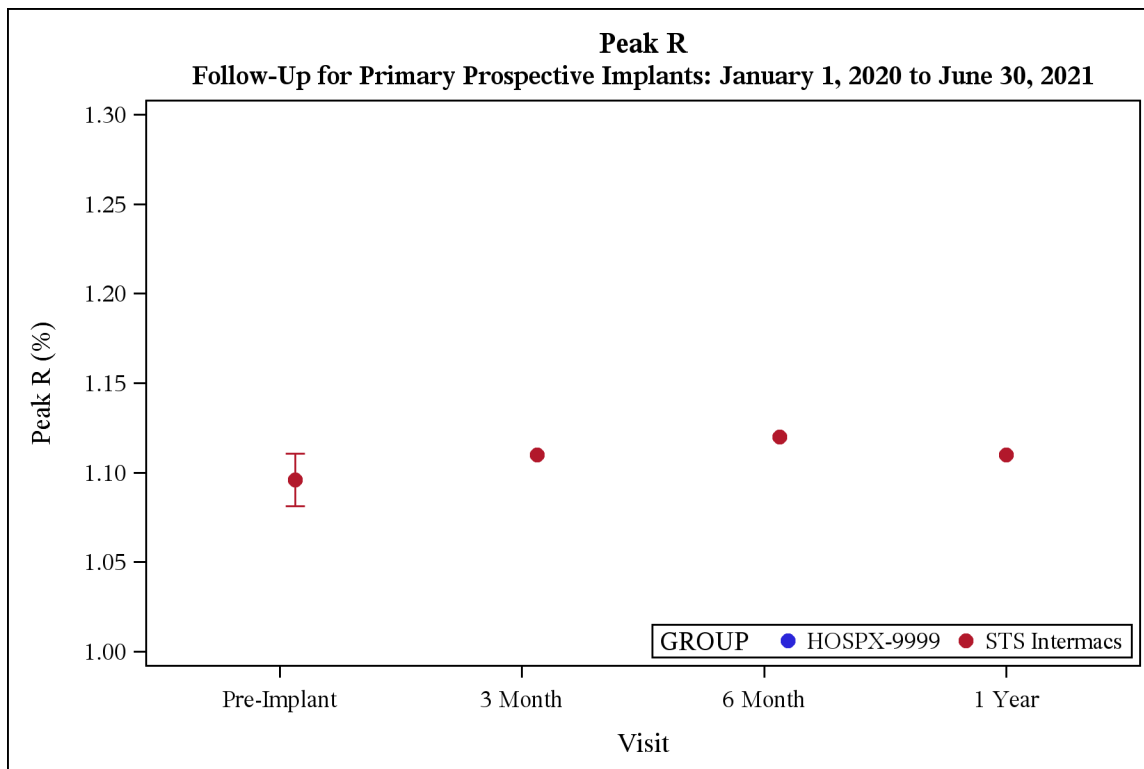
**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Functional Capacity**

**Exhibit 29. Peak R**

The following figure summarize Peak R values your site and STS Intermacs at select follow-up visits. Only follow-up data for patients' first devices are considered for this summary. The dots represent average values and the error bars are the standard errors.



**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Functional Capacity**

**Exhibit 30. Gait Speed**

The following tables summarize Gait Speed completion status and values at your site and STS InterMACs at select follow-up visits. Only follow-up data for patients first devices are considered for this summary. Unlikely values have been categorized as outliers and are listed in the accompanying data quality report.

**GROUP=HOSPX-9999**

VISIT	Patients (n)	COMPLETION STATUS										
		Not Done: Other/Unknown		Not Done: Too Sick		Complete						
		N	%	N	%	N	%	Mean	Std	Median	Min	Max
Pre-Implant	7	6	85.7	1	14.3	.	.	.	.	.	.	.
3 Month	2	1	50.0	.	.	1	50.0	3.0	.	3.0	3.0	3.0
6 Month	1	1	100.0	.	.	.	.	.	.	.	.	.

**GROUP=STS InterMACs**

VISIT	Patients (n)	COMPLETION STATUS								Gait Speed (Feet/Sec) - DV				
		Not Done: Other/Unknown		Not Done: Too Sick		Outlier		Complete						
		N	%	N	%	N	%	N	%	Mean	Std	Median	Min	Max
Pre-Implant	496	266	53.6	225	45.4	1	0.2	4	0.8	2.4	1.4	1.8	1.5	4.5
3 Month	308	242	78.6	23	7.5	.	.	43	14.0	3.6	1.3	3.6	1.0	7.5
6 Month	197	152	77.2	9	4.6	.	.	36	18.3	3.6	1.2	3.5	2.1	7.5
1 Year	60	46	76.7	1	1.7	.	.	13	21.7	3.7	1.5	3.8	0.9	5.8

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

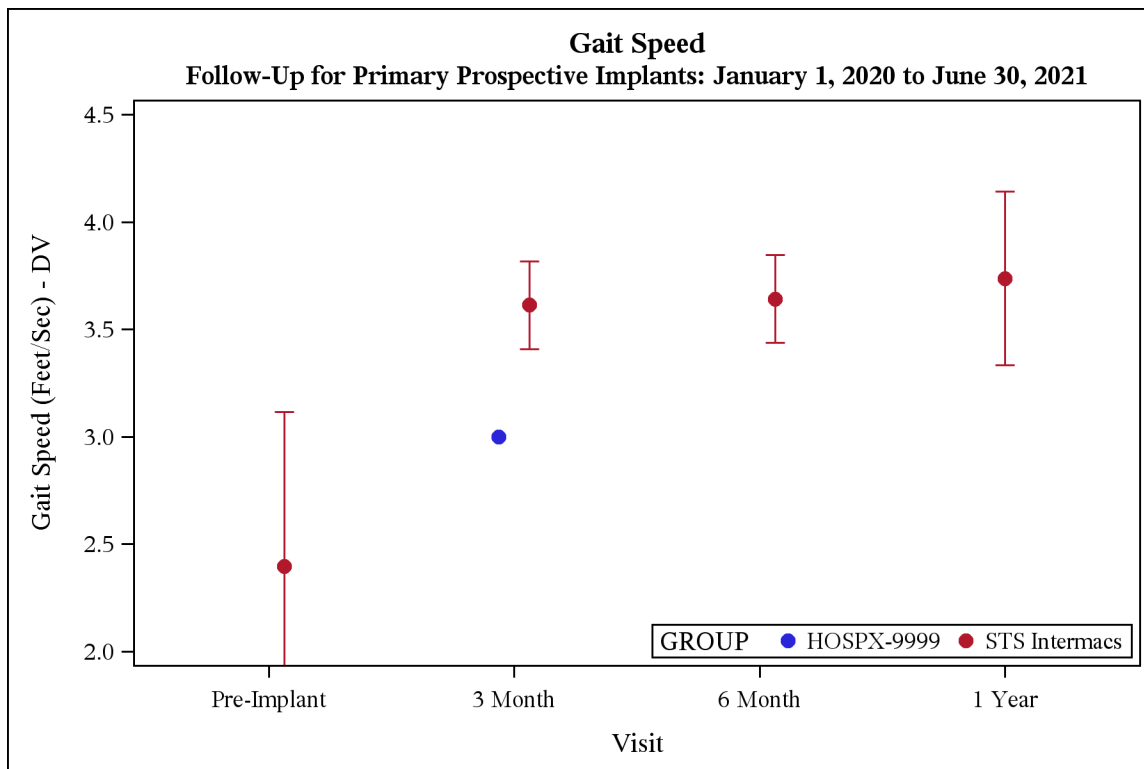
**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Functional Capacity**

**Exhibit 30. Gait Speed**

The following figure summarize Gait Speed values your site and STS InterMACS at select follow-up visits. Only follow-up data for patients' first devices are considered for this summary. The dots represent average values and the error bars are the standard errors.



**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Functional Capacity**

**Exhibit 31. Trailmaking**

The following tables summarize Trailmaking completion status and values at your site and STS InterMACS at select follow-up visits. Only follow-up data for patients first devices are considered for this summary. Unlikely values have been categorized as outliers and are listed in the accompanying data quality report.

**GROUP=HOSPX-9999**

VISIT	Patients (n)	COMPLETION STATUS				Trailmaking Time (sec)				
		Incomplete		Complete						
	N	N	%	N	%	Mean	Std	Median	Min	Max
Pre-Implant	7	6	85.7	1	14.3	110.0	.	110.0	110.0	110.0
3 Month	2	1	50.0	1	50.0	158.0	.	158.0	158.0	158.0
6 Month	1	1	100.0	.	.	.	.	.	.	.

**GROUP=STS InterMACS**

VISIT	Patients (n)	COMPLETION STATUS				Trailmaking Time (sec)				
		Incomplete		Complete						
	N	N	%	N	%	Mean	Std	Median	Min	Max
Pre-Implant	496	424	85.5	72	14.5	145.7	128.8	118.5	52.0	1093.0
3 Month	308	220	71.4	88	28.6	113.1	69.7	92.0	36.0	450.0
6 Month	197	132	67.0	65	33.0	98.6	41.3	92.0	4.0	238.0
1 Year	60	38	63.3	22	36.7	114.4	47.1	97.0	38.0	200.0

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

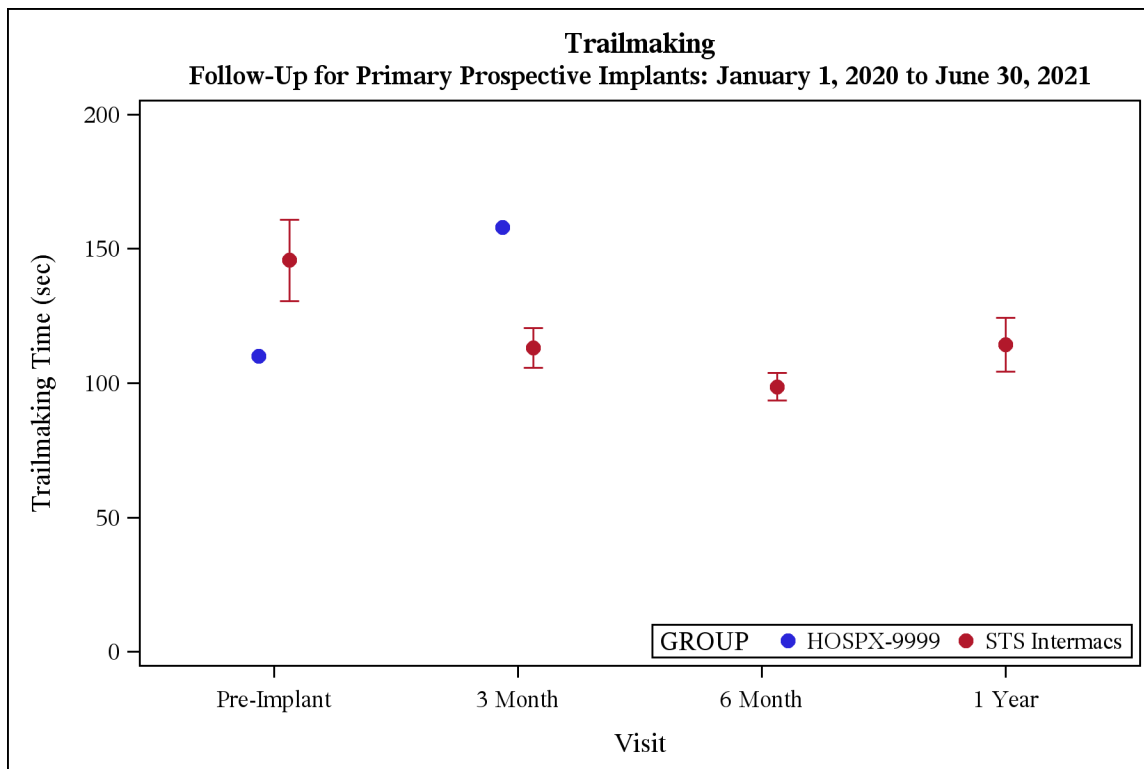
**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Functional Capacity**

**Exhibit 31. Trailmaking**

The following figure summarize Trailmaking values your site and STS InterMACS at select follow-up visits. Only follow-up data for patients' first devices are considered for this summary. The dots represent average values and the error bars are the standard errors.



**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Functional Capacity**

**Exhibit 32. NYHA Class**

The following tables summarize NYHA completion status and values at your site and STS InterMACs at select follow-up visits. Only follow-up data for patients first devices are considered for this summary. Unlikely values have been categorized as outliers and are listed in the accompanying data quality report.

**GROUP=HOSPX-9999**

VISIT	Patients (n)	COMPLETION STATUS				NYHA Class				
		Not Done: Other/Unknown		Complete						
	N	N	%	N	%	Mean	Std	Median	Min	Max
Pre-Implant	7	4	57.1	3	42.9	3.3	1.2	4.0	2.0	4.0
3 Month	2	.	.	2	100.0	3.0	1.4	3.0	2.0	4.0
6 Month	1	.	.	1	100.0	2.0	.	2.0	2.0	2.0

**GROUP=STS InterMACs**

VISIT	Patients (n)	COMPLETION STATUS				NYHA Class				
		Not Done: Other/Unknown		Complete						
	N	N	%	N	%	Mean	Std	Median	Min	Max
Pre-Implant	496	167	33.7	329	66.3	3.9	0.5	4.0	1.0	4.0
3 Month	308	59	19.2	249	80.8	2.5	0.8	2.0	1.0	4.0
6 Month	197	30	15.2	167	84.8	2.3	0.8	2.0	1.0	4.0
1 Year	60	10	16.7	50	83.3	2.1	0.8	2.0	1.0	4.0

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

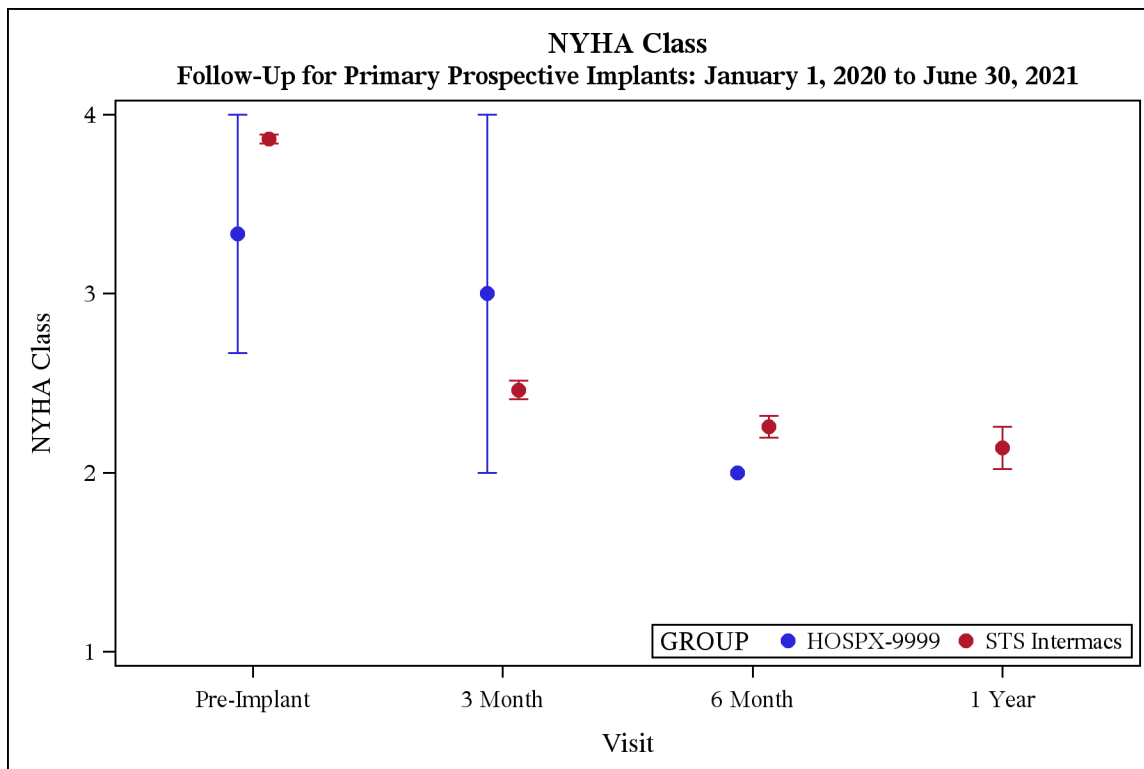
**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Functional Capacity**

**Exhibit 32. NYHA Class**

The following figure summarize NYHA Class values your site and STS Intermacs at select follow-up visits. Only follow-up data for patients' first devices are considered for this summary. The dots represent average values and the error bars are the standard errors.





**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Quality of Life**

**Exhibit 33a. EQ-5D Index**

The following tables summarize EQ-5D Index completion status and values at your site and STS InterMACS at select follow-up visits. Only follow-up data for patients first devices are considered for this summary. Unlikely values have been categorized as outliers and are listed in the accompanying data quality report.

**GROUP=HOSPX-9999**

VISIT	Patients (n)	COMPLETION STATUS										
		Not Done: Other/Unknown		Not Done: Too Sick		Complete						
		N	%	N	%	N	%	Mean	Std	Median	Min	Max
Pre-Implant	7	5	71.4	1	14.3	1	14.3	0.6	.	0.6	0.6	0.6
3 Month	2	.	.	.	.	2	100.0	0.9	0.1	0.9	0.9	1.0
6 Month	1	.	.	.	.	1	100.0	1.0	.	1.0	1.0	1.0

**GROUP=STS InterMACS**

VISIT	Patients (n)	COMPLETION STATUS										
		Not Done: Other/Unknown		Not Done: Too Sick		Complete						
		N	%	N	%			N	%	Mean	Std	Median
Pre-Implant	496	250	50.4	127	25.6	119	24.0	0.6	0.3	0.6	-0.1	1.0
3 Month	308	165	53.6	12	3.9	131	42.5	0.8	0.2	0.8	0.1	1.0
6 Month	197	93	47.2	4	2.0	100	50.8	0.8	0.2	0.8	0.4	1.0
1 Year	60	28	46.7	1	1.7	31	51.7	0.8	0.2	0.8	0.1	1.0

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

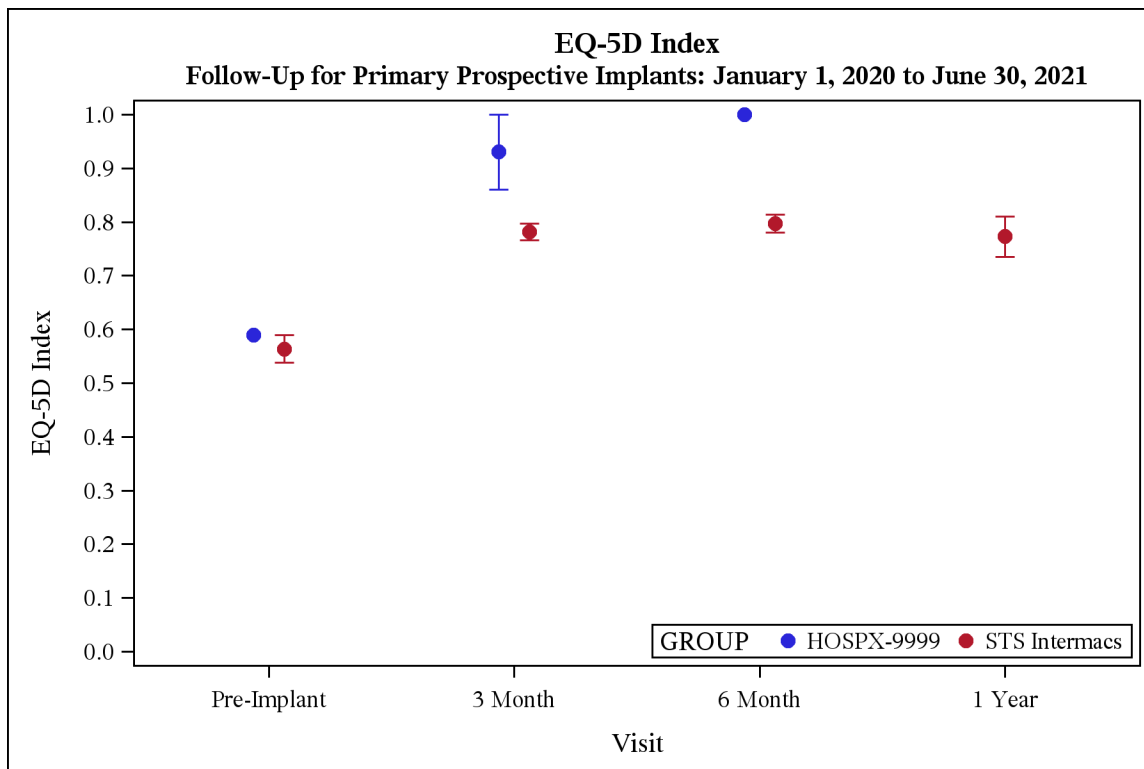
**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Quality of Life**

**Exhibit 33a. EQ-5D Index**

The following figure summarize EQ-5D Index values your site and STS Intermacs at select follow-up visits. Only follow-up data for patients' first devices are considered for this summary. The dots represent average values and the error bars are the standard errors.



**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Quality of Life**

**Exhibit 33b. EQ-5D Visual Analog Scale**

The following tables summarize EQ-5D Visual Analog Scale completion status and values at your site and STS InterMACS at select follow-up visits. Only follow-up data for patients first devices are considered for this summary. Unlikely values have been categorized as outliers and are listed in the accompanying data quality report.

**GROUP=HOSPX-9999**

VISIT	Patients (n)	COMPLETION STATUS						VAS: Own Health State				
		Not Done: Other/Unknown		Not Done: Too Sick		Complete						
		N	%	N	%	N	%	Mean	Std	Median	Min	Max
Pre-Implant	7	5	71.4	1	14.3	1	14.3	15.0	.	15.0	15.0	15.0
3 Month	2	.	.	.	.	2	100.0	95.0	7.1	95.0	90.0	100.0
6 Month	1	.	.	.	.	1	100.0	70.0	.	70.0	70.0	70.0

**GROUP=STS InterMACS**

VISIT	Patients (n)	COMPLETION STATUS										
		Not Done: Other/Unknown		Not Done: Too Sick		Complete						
		N	%	N	%	N	%	Mean	Std	Median	Min	Max
Pre-Implant	496	255	51.4	127	25.6	114	23.0	47.3	26.7	50.0	0.0	100.0
3 Month	308	168	54.5	12	3.9	128	41.6	69.4	20.5	72.5	8.0	100.0
6 Month	197	94	47.7	4	2.0	99	50.3	75.9	17.6	80.0	0.0	100.0
1 Year	60	31	51.7	1	1.7	28	46.7	75.7	19.4	80.0	25.0	100.0

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

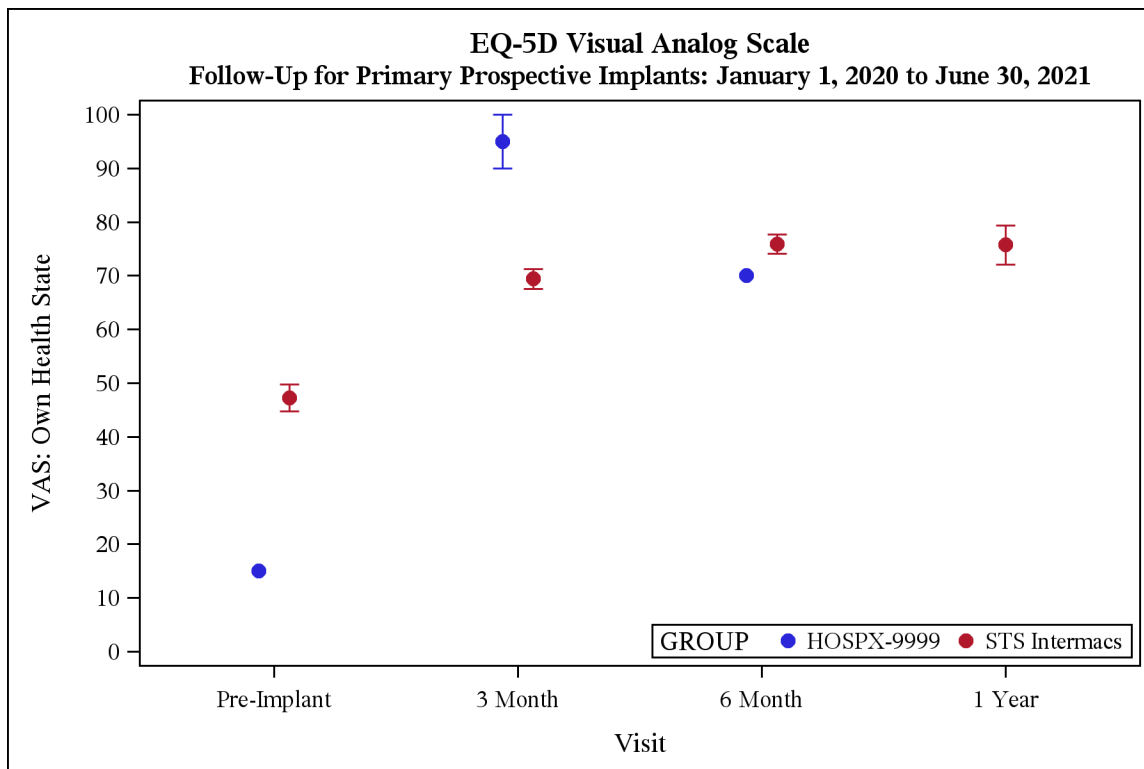
**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Quality of Life**

**Exhibit 33b. EQ-5D Visual Analog Scale**

The following figure summarize EQ-5D Visual Analog Scale values your site and STS InterMACS at select follow-up visits. Only follow-up data for patients' first devices are considered for this summary. The dots represent average values and the error bars are the standard errors.



**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Quality of Life**

**Exhibit 33c. KCCQ-12 - Scored**

The following tables summarize KCCQ-12 - Scored completion status and values at your site and STS InterMACs at select follow-up visits. Only follow-up data for patients first devices are considered for this summary. Unlikely values have been categorized as outliers and are listed in the accompanying data quality report.

**GROUP=HOSPX-9999**

VISIT	Patients (n)	COMPLETION STATUS											
		Not Done: Other/Unknown		Not Done: Too Sick		Complete							
		N	%	N	%	N	%	Mean	Std	Median	Min	Max	
Pre-Implant	7	5	71.4	1	14.3	1	14.3	24.5	.	24.5	24.5	24.5	
3 Month	2	.	.	.	.	2	100.0	79.2	10.3	79.2	71.9	86.5	
6 Month	1	.	.	.	.	1	100.0	68.8	.	68.8	68.8	68.8	

**GROUP=STS InterMACs**

VISIT	Patients (n)	COMPLETION STATUS										
		Not Done: Other/Unknown		Not Done: Too Sick		Complete						
		N	%	N	%	N	%	Mean	Std	Median	Min	Max
Pre-Implant	496	237	47.8	134	27.0	125	25.2	32.0	21.7	27.1	0.0	96.9
3 Month	308	147	47.7	12	3.9	149	48.4	58.6	20.5	57.3	13.9	100.0
6 Month	197	86	43.7	4	2.0	107	54.3	61.5	21.4	60.9	17.2	100.0
1 Year	60	27	45.0	1	1.7	32	53.3	65.7	19.1	68.3	19.3	96.4

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

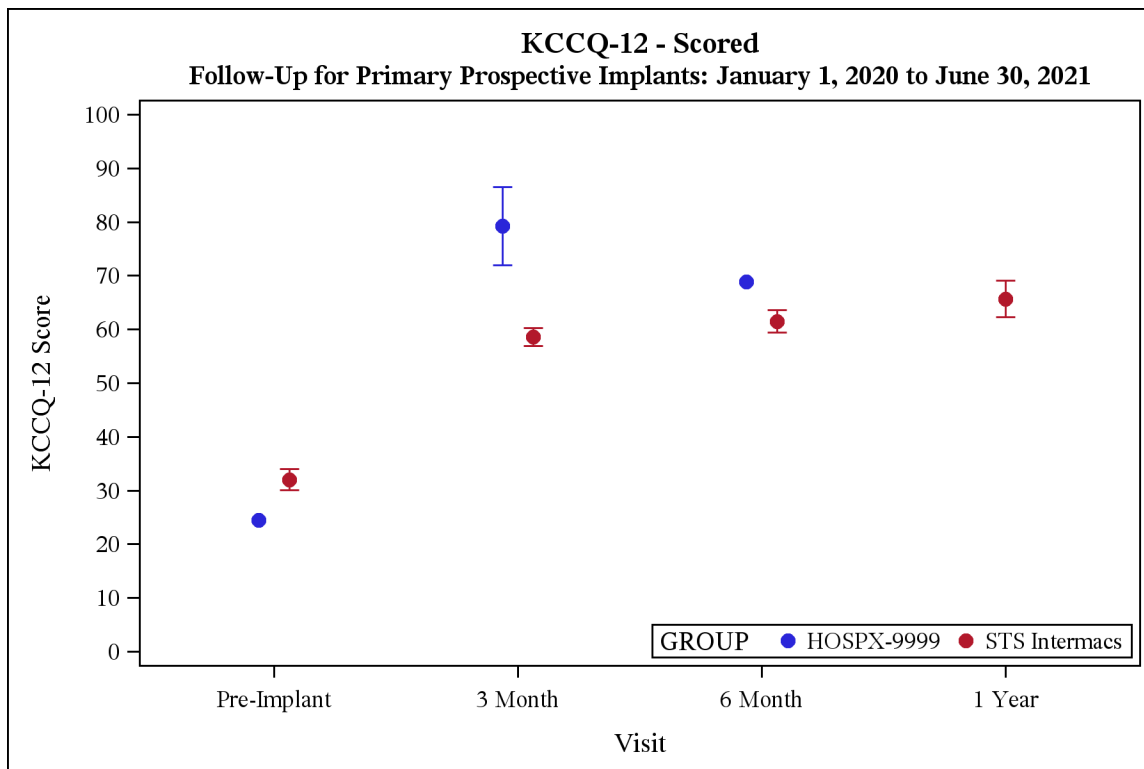
**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**II.C. Post Implant Summary - Quality of Life**

**Exhibit 33c. KCCQ-12 - Scored**

The following figure summarize KCCQ-12 - Scored values your site and STS InterMACS at select follow-up visits. Only follow-up data for patients' first devices are considered for this summary. The dots represent average values and the error bars are the standard errors.



***STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients******COVERAGE: January 1, 2020 - June 30, 2021******SITE: HOSPX - DEMO SITE REPORT******II.E. Post Implant Outcomes***

This section provides statistical summaries of outcomes after VAD implant. These depictions include all patients who received a primary device at your institution and compares it with the equivalent group in InterMACS. The p-values are a univariate comparison (log-rank test) of survival at your institution with survival for the entire registry. Univariate comparisons are well known to be limited in value because no adjustment is made for differing patient characteristics in the groups. Nevertheless, these comparisons can provide an initial comparison of unadjusted results. Future version of this report will provide risk adjusted comparisons.

Note: If your site did not report any patients within a specified group, only the overall STS InterMACS data will be displayed.

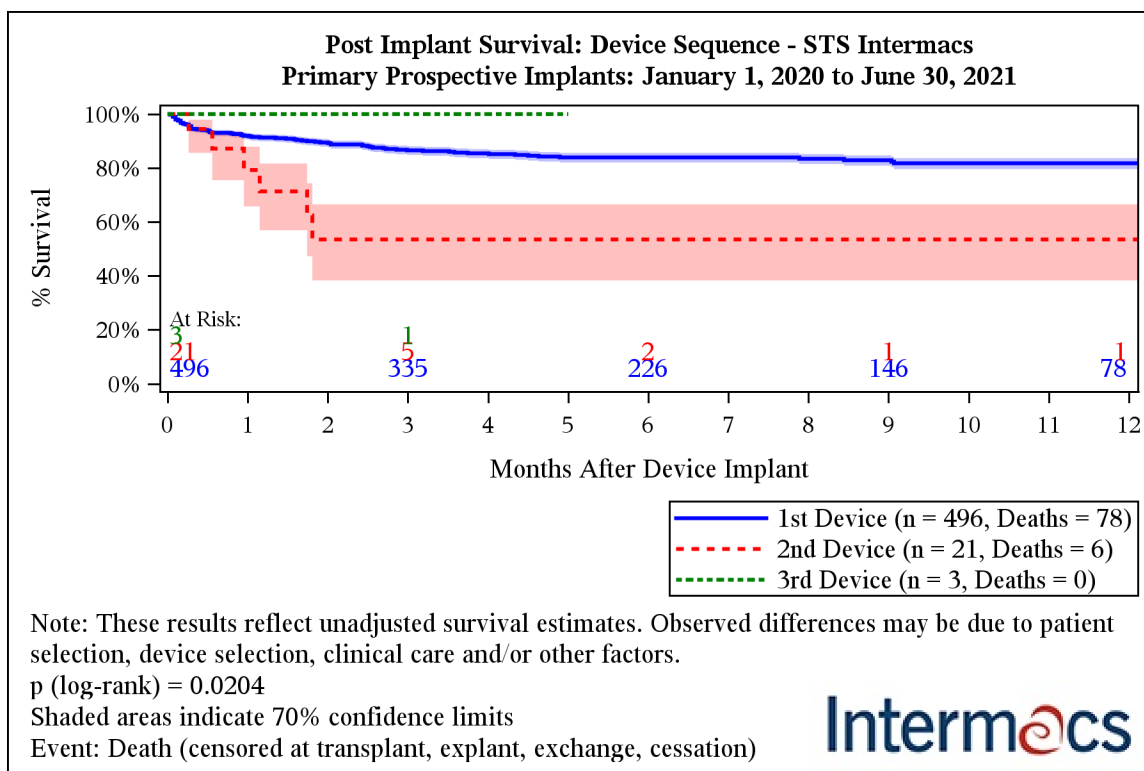
# STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients

COVERAGE: January 1, 2020 - June 30, 2021

SITE: HOSPX - DEMO SITE REPORT

## Exhibit 34a. Post Implant Survival - Device Sequence - STS InterMACs

The following figure compares survival time on specific devices based on device sequence for all of STS InterMACs. Each curve represents survival from the time the device was implanted until death. Patients are censored at time of transplant, explant for any reason, or the device was turned off.



Months after Device Implant	1st Device	2nd Device	3rd Device
1	92.0% (90.6%-93.1%)	79.3% (65.8%-87.9%)	100.0% (100.0%-100.0%)
3	86.5% (84.8%-88.0%)	53.5% (38.3%-66.5%)	100.0% (100.0%-100.0%)
6	83.9% (82.0%-85.6%)	53.5% (38.3%-66.5%)	
9	82.9% (80.9%-84.7%)	53.5% (38.3%-66.5%)	
12	81.7% (79.6%-83.7%)	53.5% (38.3%-66.5%)	



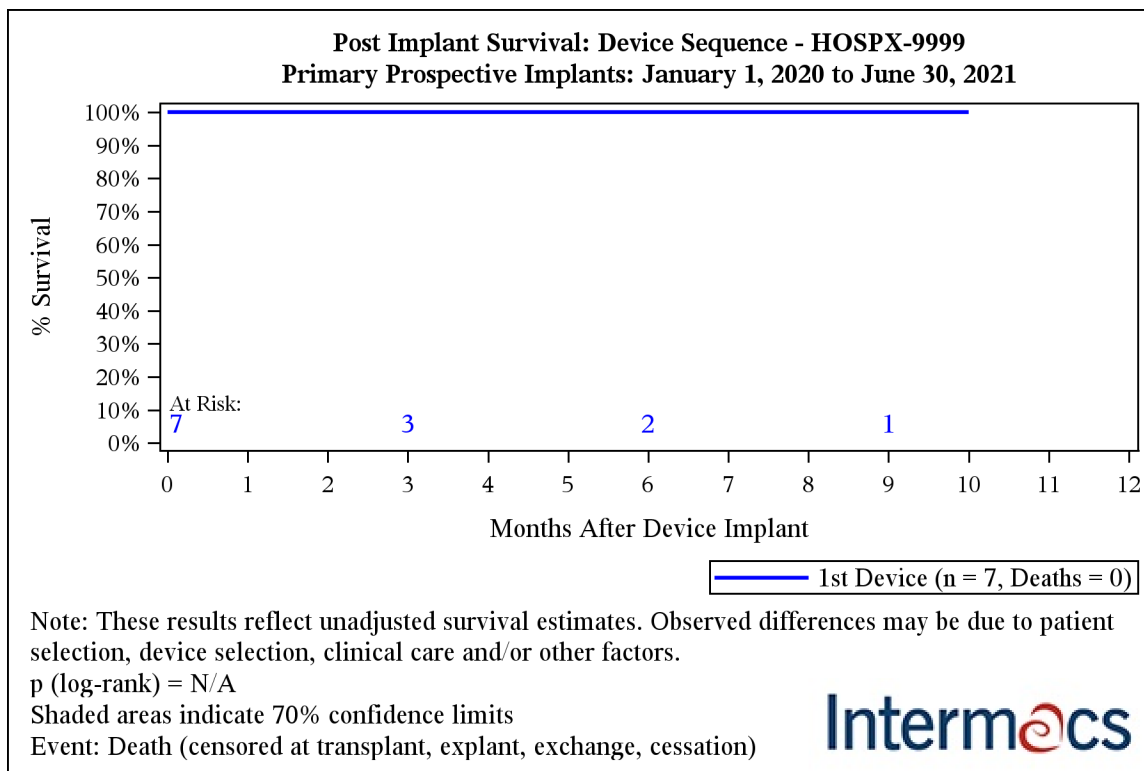
**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**Exhibit 34b. Post Implant Survival - Device Sequence - HOSPX-9999**

The following figure compares survival time on specific devices based on device sequence for your site. Each curve represents survival from the time the device was implanted until death. Patients are censored at transplant, explant for any reason, or the device was turned off.



Months after Device Implant	1st Device
1	100.0% (100.0%-100.0%)
3	100.0% (100.0%-100.0%)
6	100.0% (100.0%-100.0%)
9	100.0% (100.0%-100.0%)

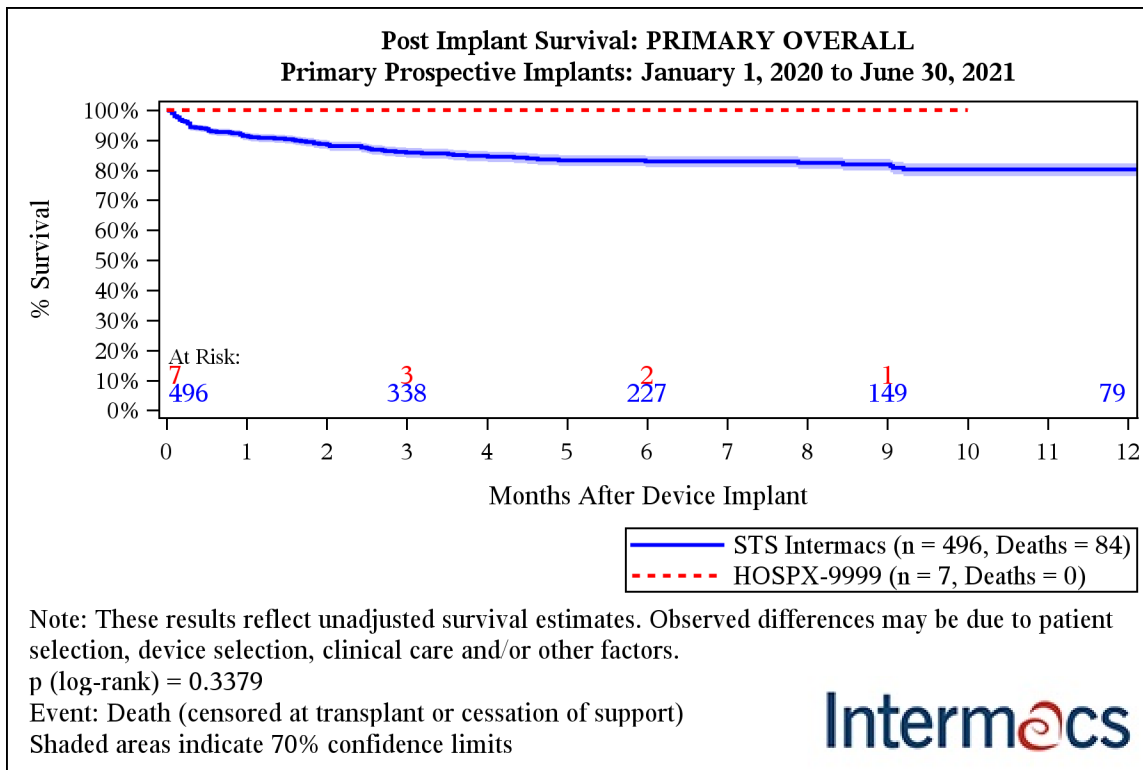
**Intermacs**

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**Exhibit 35. Post Implant Survival - PRIMARY OVERALL**



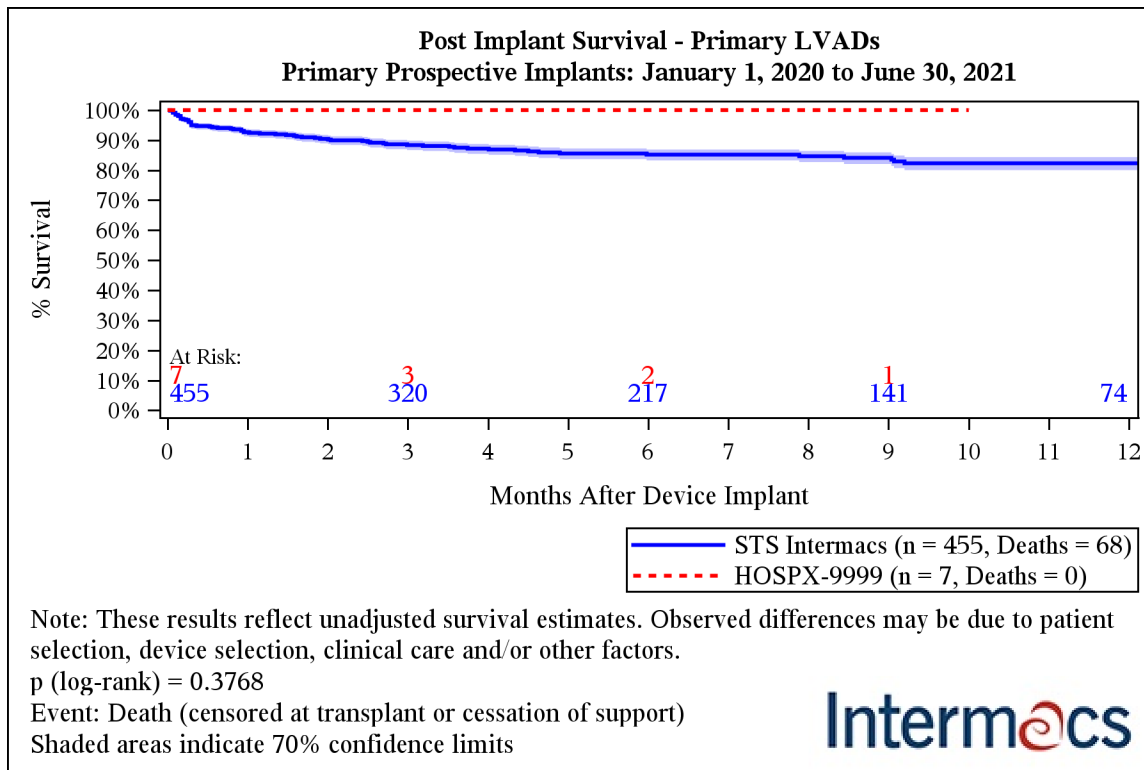
Months after Device Implant	STS InterMACS	HOSPX-9999
1	91.4% (90.0%-92.6%)	100.0% (100.0%-100.0%)
3	85.8% (84.1%-87.4%)	100.0% (100.0%-100.0%)
6	82.9% (81.0%-84.6%)	100.0% (100.0%-100.0%)
9	81.9% (79.9%-83.7%)	100.0% (100.0%-100.0%)
12	80.2% (78.0%-82.3%)	

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**Exhibit 36. Post Implant Survival - Primary LVADs**



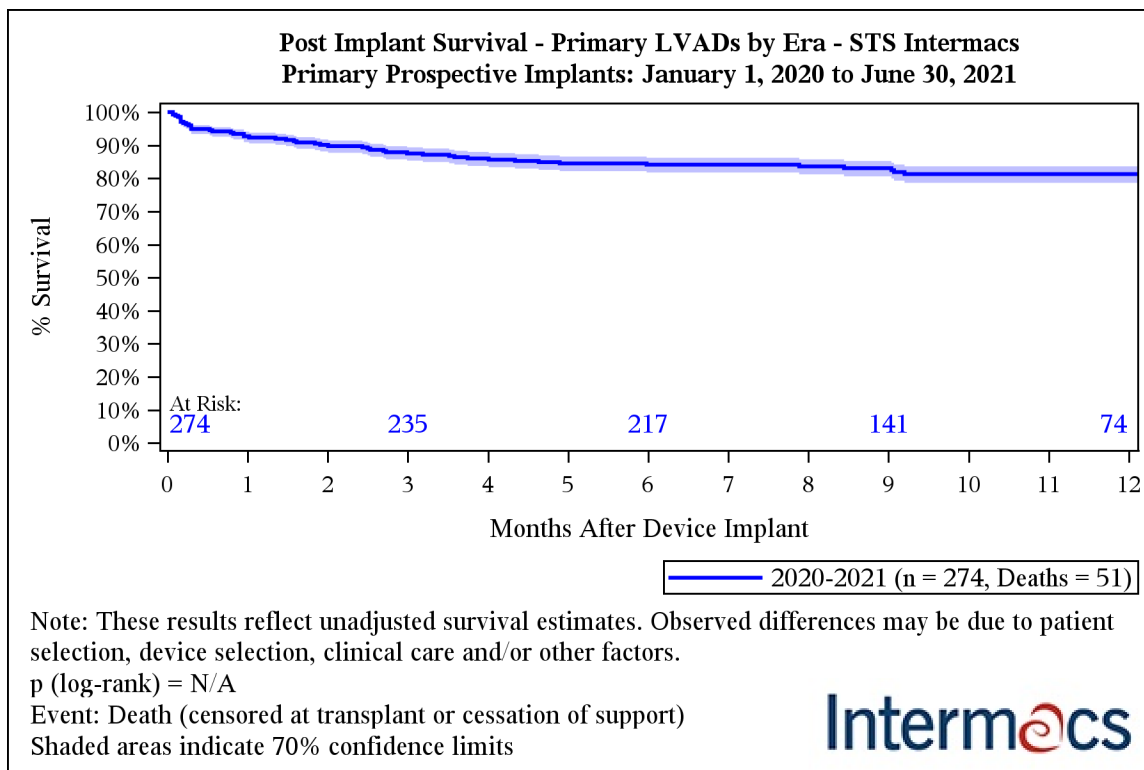
Months after Device Implant	STS InterMACS	HOSPX-9999
1	92.6% (91.3%-93.8%)	100.0% (100.0%-100.0%)
3	88.3% (86.7%-89.8%)	100.0% (100.0%-100.0%)
6	85.2% (83.3%-86.9%)	100.0% (100.0%-100.0%)
9	84.1% (82.1%-85.9%)	100.0% (100.0%-100.0%)
12	82.3% (80.0%-84.3%)	

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**Exhibit 37a. Post Implant Survival - Primary LVADs by Era - STS Intermacs**



**Intermacs**

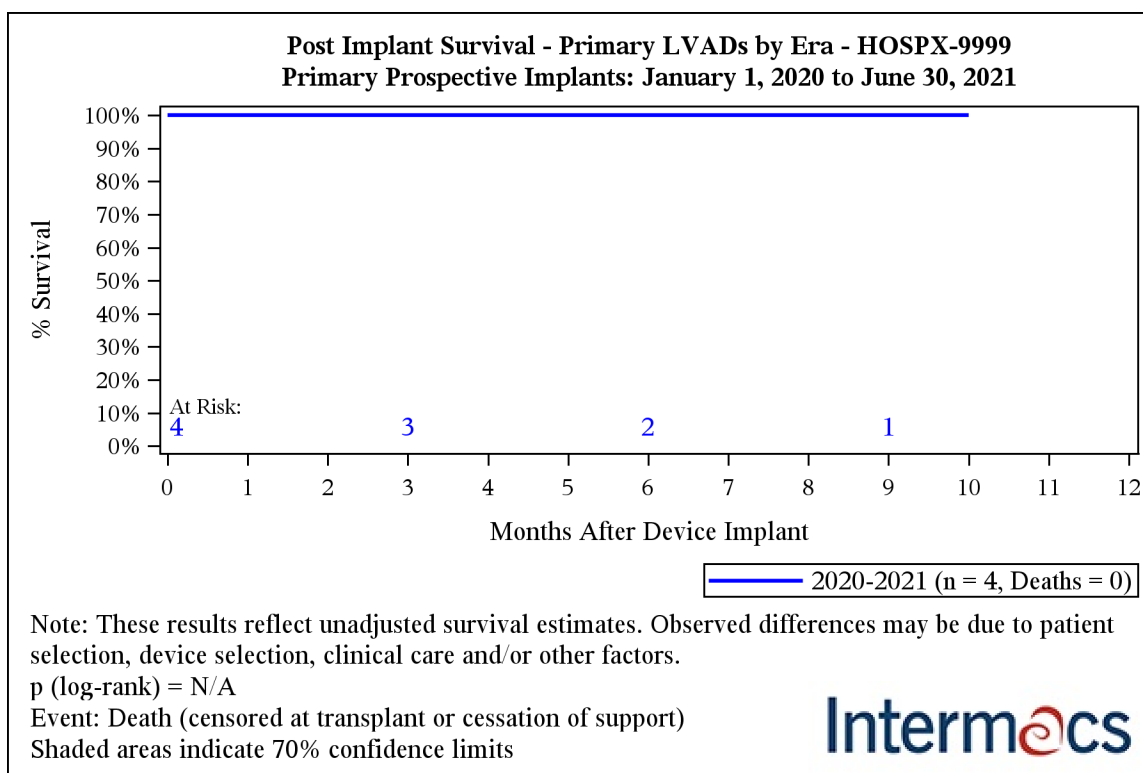
Months after Device Implant	2020-2021
1	92.7% (90.9%-94.1%)
3	87.5% (85.3%-89.4%)
6	84.1% (81.7%-86.2%)
9	83.1% (80.6%-85.2%)
12	81.3% (78.6%-83.6%)

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**Exhibit 37b. Post Implant Survival - Primary LVADs by Era - HOSPX-9999**



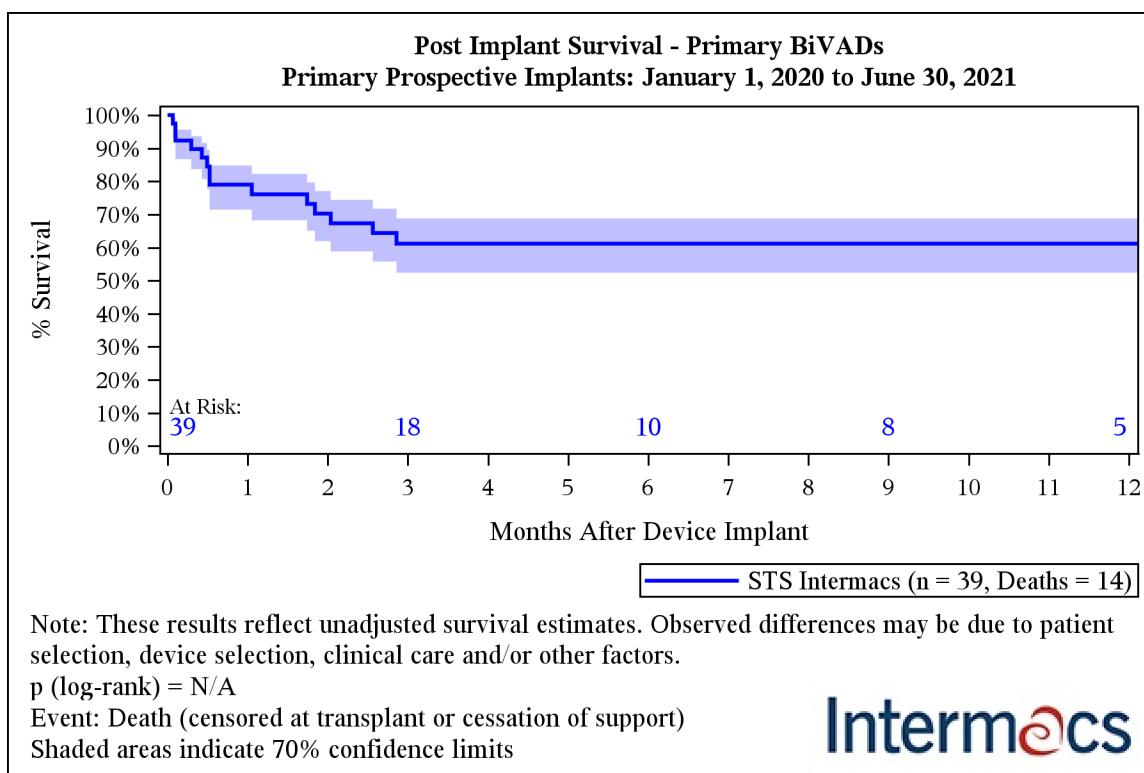
Months after Device Implant	2020-2021
1	100.0% (100.0%-100.0%)
3	100.0% (100.0%-100.0%)
6	100.0% (100.0%-100.0%)
9	100.0% (100.0%-100.0%)

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**Exhibit 38. Post Implant Survival - Primary BiVADs**



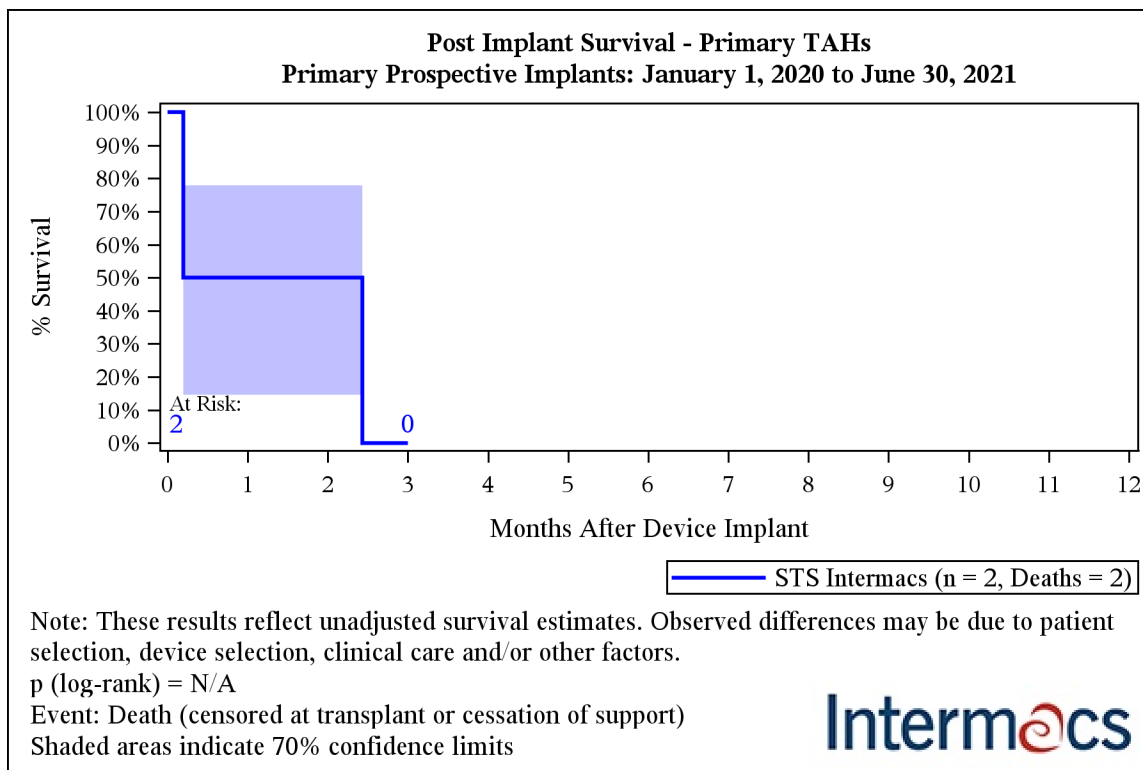
Months after Device Implant	STS Intermacs
1	79.0% (71.5%-84.8%)
3	61.2% (52.4%-68.8%)
6	61.2% (52.4%-68.8%)
9	61.2% (52.4%-68.8%)
12	61.2% (52.4%-68.8%)

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**Exhibit 39. Post Implant Survival - Primary TAHs**



Months after Device Implant	STS InterMACS
1	50.0% (14.6%-77.9%)
3	0.0% (0.0%-0.0%)

***STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients***

***COVERAGE: January 1, 2020 - June 30, 2021***

***SITE: HOSPX - DEMO SITE REPORT***

***Exhibit 40. Post Implant Survival - Primary LVADs - PULSATILE FLOW***

Not enough patients or events to produce exhibit

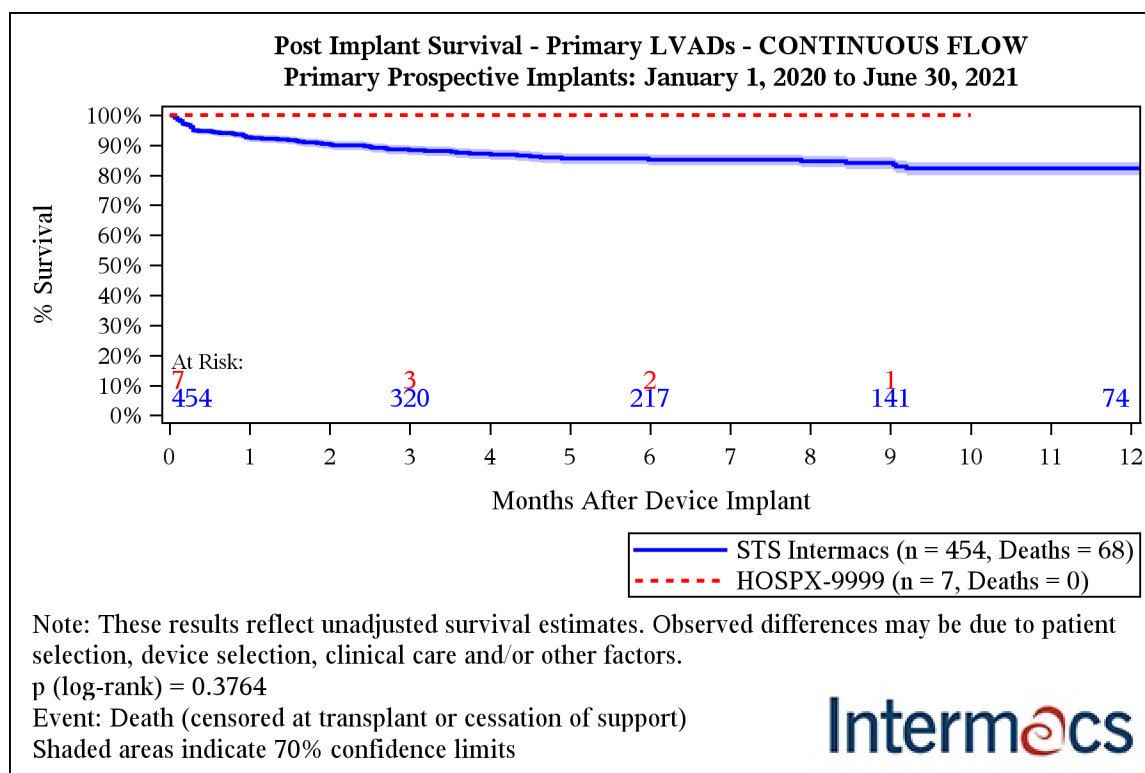


**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**Exhibit 41. Post Implant Survival - Primary LVADs - CONTINUOUS FLOW**



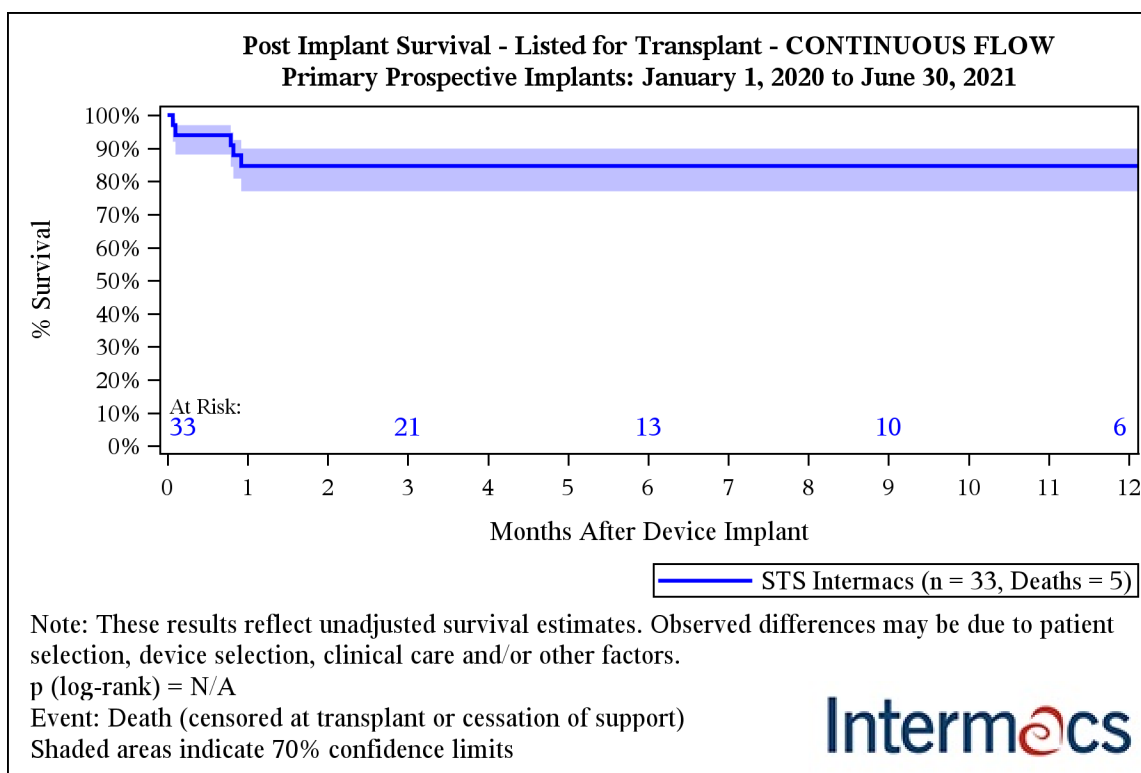
Months after Device Implant	STS InterMACS	HOSPX-9999
1	92.6% (91.3%-93.8%)	100.0% (100.0%-100.0%)
3	88.3% (86.7%-89.8%)	100.0% (100.0%-100.0%)
6	85.1% (83.2%-86.8%)	100.0% (100.0%-100.0%)
9	84.1% (82.0%-85.9%)	100.0% (100.0%-100.0%)
12	82.3% (80.0%-84.3%)	

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**Exhibit 42. Post Implant Survival - Listed for Transplant - CONTINUOUS FLOW**



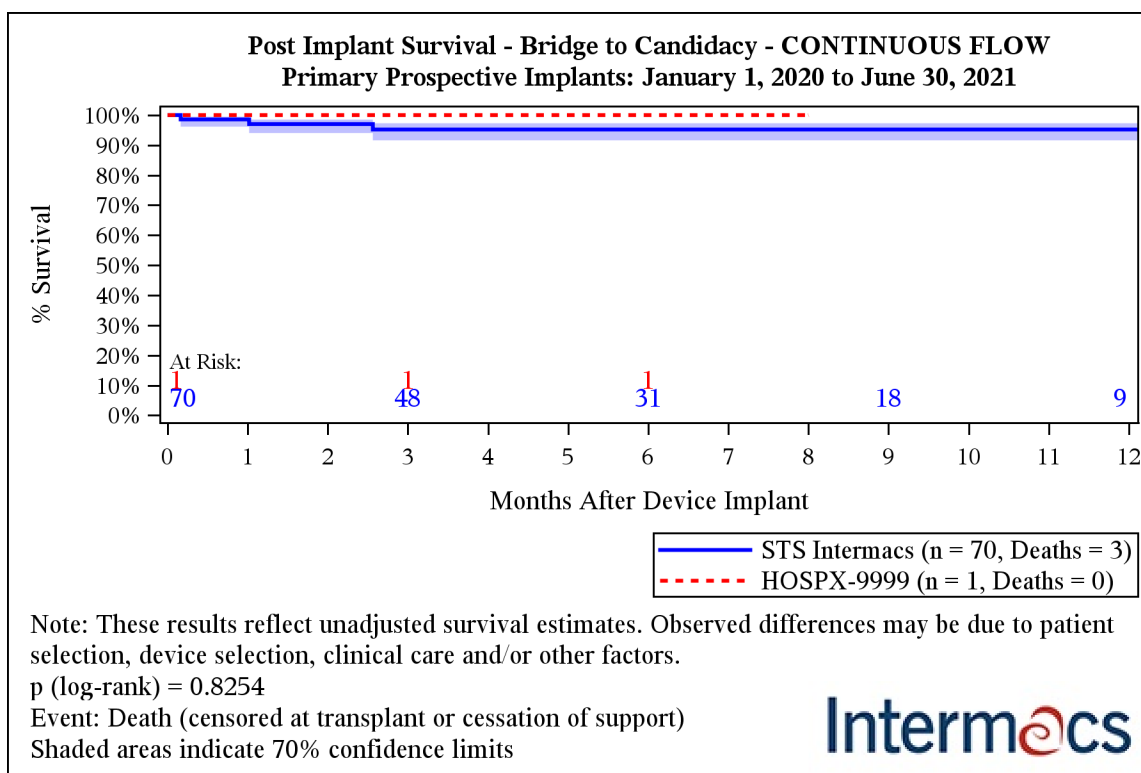
Months after Device Implant	STS Intermacs
1	84.6% (77.0%-89.9%)
3	84.6% (77.0%-89.9%)
6	84.6% (77.0%-89.9%)
9	84.6% (77.0%-89.9%)
12	84.6% (77.0%-89.9%)

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**Exhibit 43. Post Implant Survival - Bridge to Candidacy - CONTINUOUS FLOW**



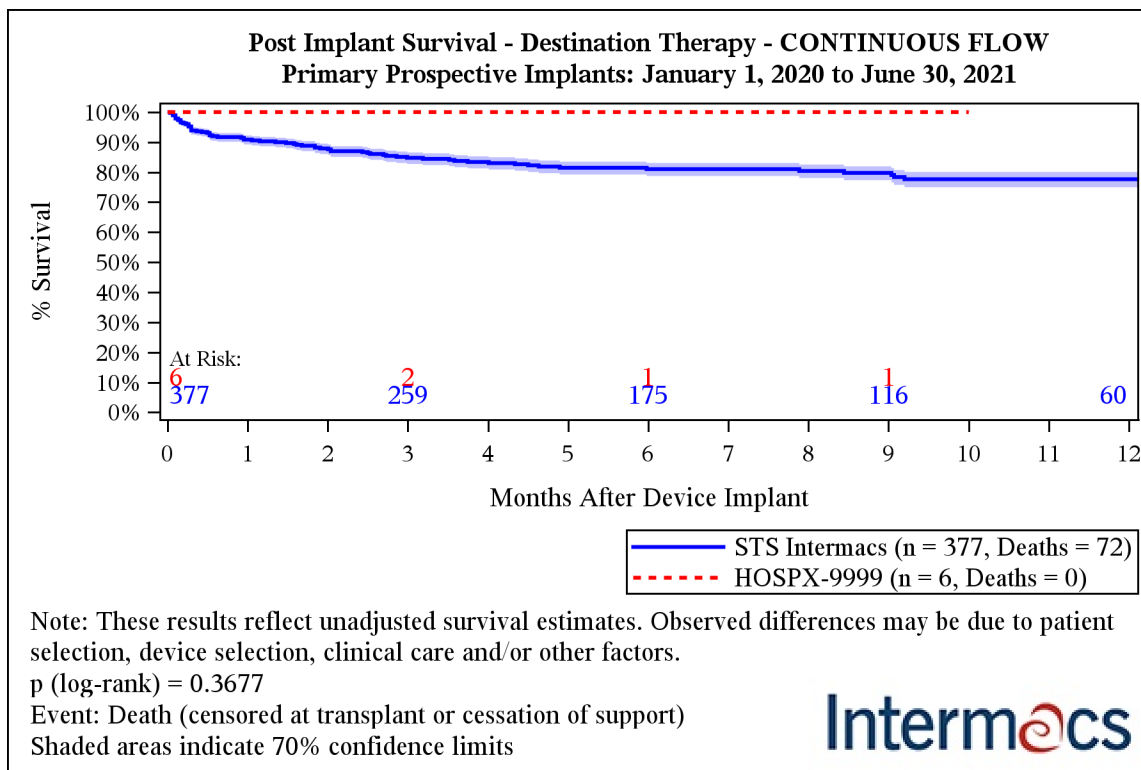
Months after Device Implant	STS Intermacs	HOSPX-9999
1	98.6% (96.2%-99.5%)	100.0% (100.0%-100.0%)
3	95.2% (91.6%-97.3%)	100.0% (100.0%-100.0%)
6	95.2% (91.6%-97.3%)	100.0% (100.0%-100.0%)
9	95.2% (91.6%-97.3%)	
12	95.2% (91.6%-97.3%)	

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**Exhibit 44. Post Implant Survival - Destination Therapy - CONTINUOUS FLOW**



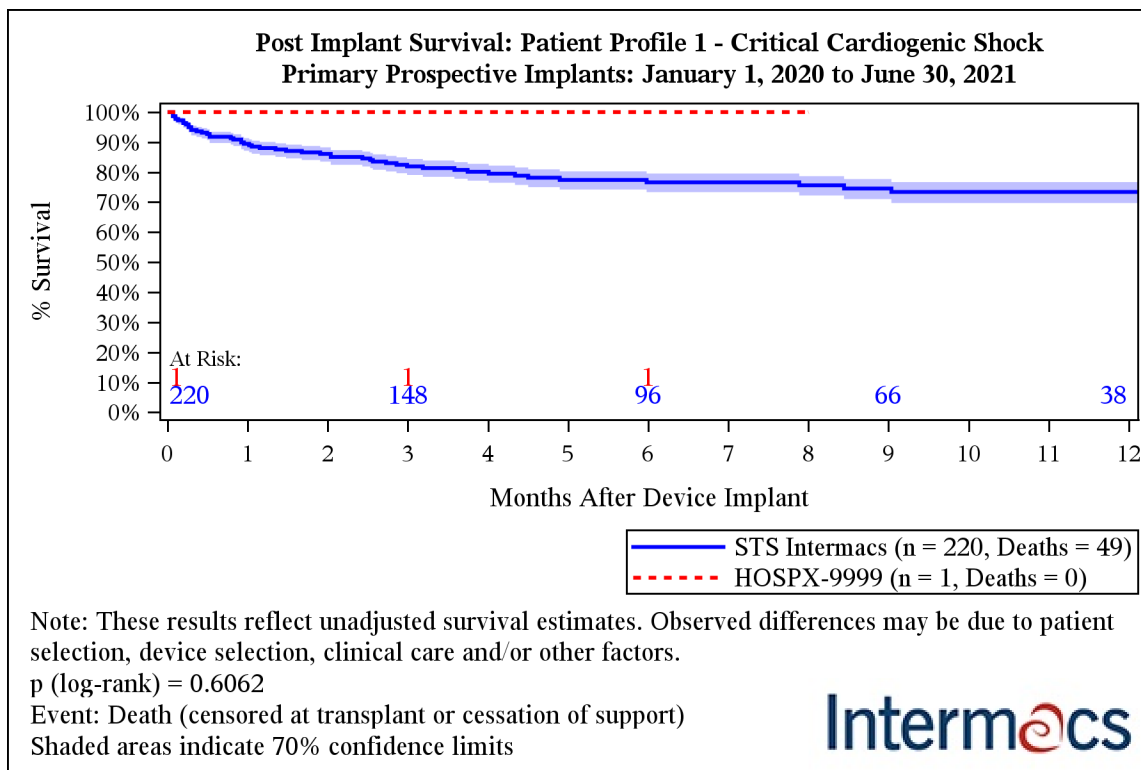
Months after Device Implant	STS InterMACS	HOSPX-9999
1	90.8% (89.2%-92.2%)	100.0% (100.0%-100.0%)
3	84.8% (82.7%-86.6%)	100.0% (100.0%-100.0%)
6	81.0% (78.7%-83.1%)	100.0% (100.0%-100.0%)
9	79.8% (77.3%-82.0%)	100.0% (100.0%-100.0%)
12	77.7% (75.0%-80.1%)	

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**Exhibit 45a. Post Implant Survival: Patient Profile 1 - Critical Cardiogenic Shock**



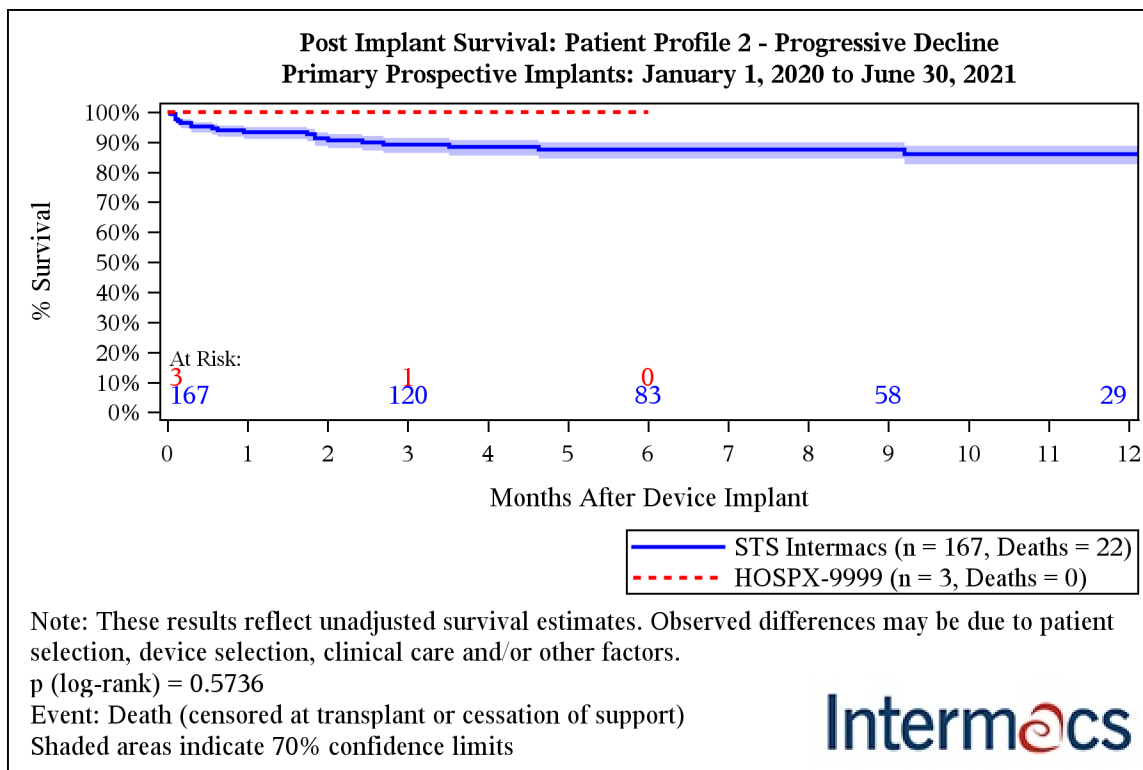
Months after Device Implant	STS Intermacs	HOSPX-9999
1	89.4% (87.2%-91.3%)	100.0% (100.0%-100.0%)
3	81.9% (79.1%-84.4%)	100.0% (100.0%-100.0%)
6	76.6% (73.4%-79.5%)	100.0% (100.0%-100.0%)
9	74.5% (71.0%-77.7%)	
12	73.4% (69.7%-76.7%)	

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**Exhibit 45b. Post Implant Survival: Patient Profile 2 - Progressive Decline**



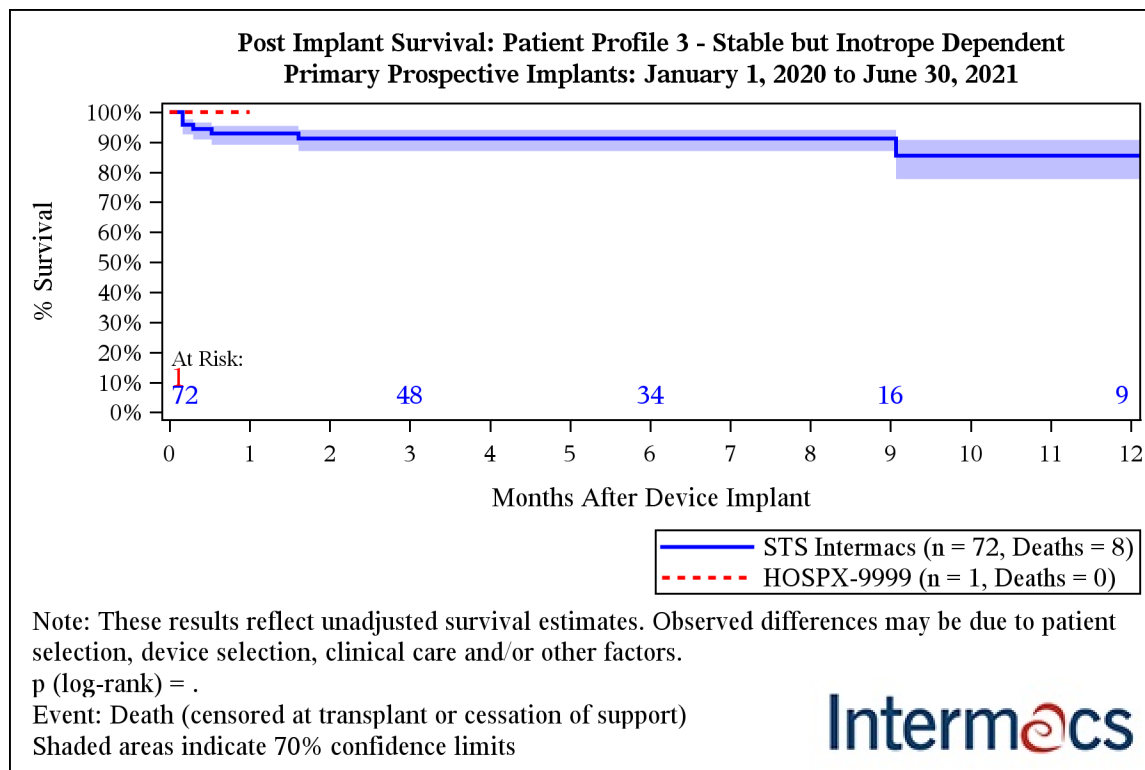
Months after Device Implant	STS Intermacs	HOSPX-9999
1	93.3% (91.1%-95.0%)	100.0% (100.0%-100.0%)
3	89.2% (86.4%-91.4%)	100.0% (100.0%-100.0%)
6	87.5% (84.5%-90.0%)	100.0% (100.0%-100.0%)
9	87.5% (84.5%-90.0%)	
12	86.0% (82.6%-88.8%)	

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**Exhibit 45c. Post Implant Survival: Patient Profile 3 - Stable but Inotrope Dependent**



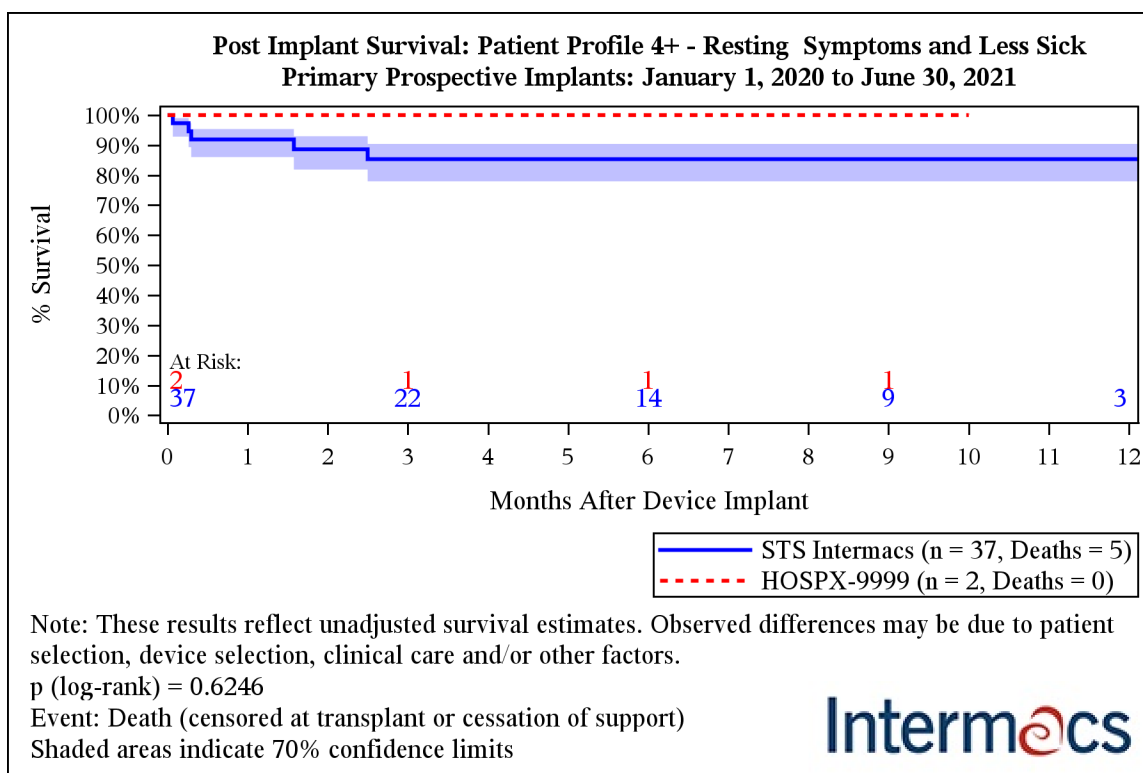
Months after Device Implant	STS Intermacs	HOSPX-9999
1	92.9% (89.1%-95.4%)	100.0% (100.0%-100.0%)
3	91.2% (87.0%-94.1%)	
6	91.2% (87.0%-94.1%)	
9	91.2% (87.0%-94.1%)	
12	85.5% (77.7%-90.7%)	

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**Exhibit 45d. Post Implant Survival: Patient Profile 4+ Resting Symptoms and Less Sick**



Months after Device Implant	STS Intermacs	HOSPX-9999
1	91.9% (86.0%-95.4%)	100.0% (100.0%-100.0%)
3	85.3% (77.9%-90.4%)	100.0% (100.0%-100.0%)
6	85.3% (77.9%-90.4%)	100.0% (100.0%-100.0%)
9	85.3% (77.9%-90.4%)	100.0% (100.0%-100.0%)
12	85.3% (77.9%-90.4%)	

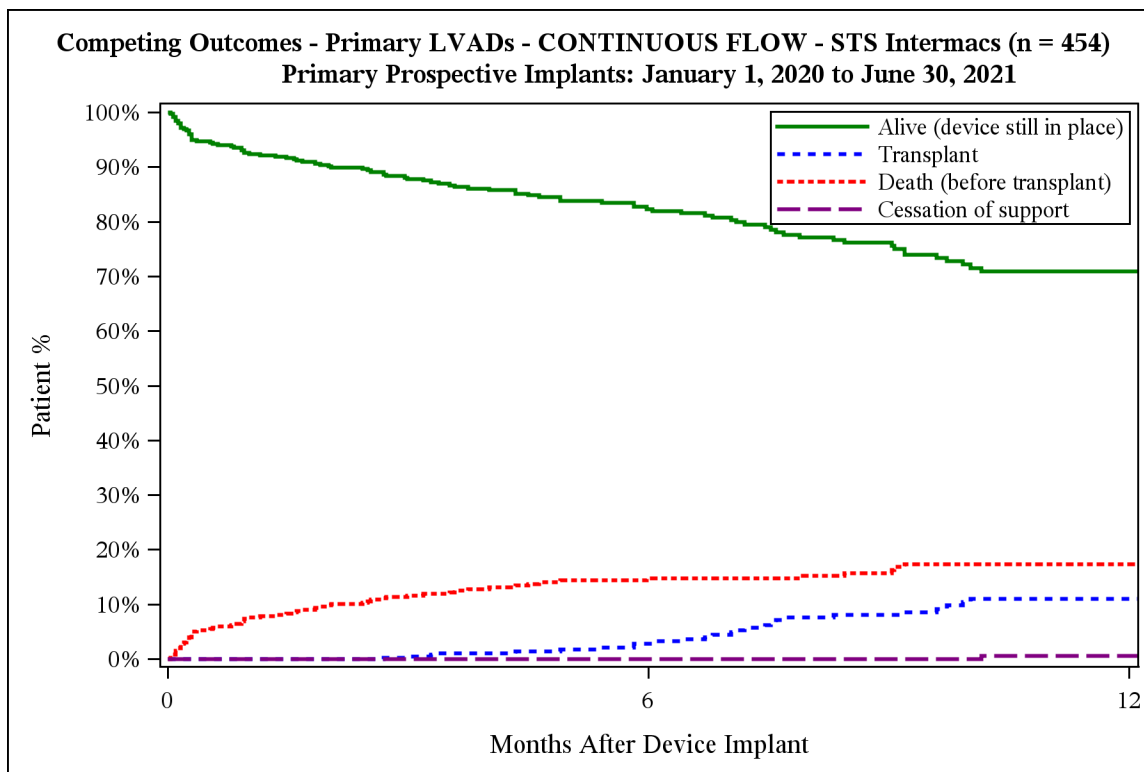


**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**Exhibit 46a. Competing Outcomes - Primary LVADs - CONTINUOUS FLOW - STS Intermacs**



Outcome	Months After Device Implant				
	1	3	6	9	12
Alive (device still in place)	92.6%	87.8%	82.3%	76.1%	70.9%
Transplant	0.0%	0.5%	2.9%	8.1%	11.0%
Death (before transplant)	7.4%	11.7%	14.8%	15.8%	17.4%
Cessation of support	0.0%	0.0%	0.0%	0.0%	0.6%
Total	100%	100%	100%	100%	100%

***STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients***

***COVERAGE: January 1, 2020 - June 30, 2021***

***SITE: HOSPX - DEMO SITE REPORT***

***Exhibit 46b. Competing Outcomes - Primary LVADs - CONTINUOUS FLOW - HOSPX-9999***

Not enough patients or events to produce exhibit

***STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients***

***COVERAGE: January 1, 2020 - June 30, 2021***

***SITE: HOSPX - DEMO SITE REPORT***

***Exhibit 47a. Competing Outcomes - Primary TAHs - STS Intermacs***

Not enough patients or events to produce exhibit

***STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients***

***COVERAGE: January 1, 2020 - June 30, 2021***

***SITE: HOSPX - DEMO SITE REPORT***

***Exhibit 47b. Competing Outcomes - Primary TAHs - HOSPX-9999***

Not enough patients or events to produce exhibit

***STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients******COVERAGE: January 1, 2020 - June 30, 2021******SITE: HOSPX - DEMO SITE REPORT******IV. Zone Conditions: Hemolysis, Hypertension, and Right Heart Failure***

The following Exhibits consist of data collected regarding the three “Zone Conditions”: Hemolysis, Hypertension, and Right Heart Failure. These zones were added to the STS Intermacs released in June of 2014. The zone sections, including data fields and flag calculations, were added to the Web Based Data Entry (WBDE) system. In the WBDE, the flags are calculated on any applicable form that is updated by a user after the release date, and the flags are displayed in the WBDE (on the Patient Summary). The report exhibits on the following pages provide useful, clinical analysis of the flags by adding comparison to the STS Intermacs Aggregate Group, and include some further division into relevant categories, such as classification of severity, and timing.

Note: Further information on the calculation and processing of the Zone Conditions can be found on the Intermacs.org website, in the Reports FAQ section. For any queries about the zone conditions or the exhibits, please don’t hesitate to contact the Intermacs Data Warehouse and Analytics Center.

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

***Exhibit 48a: Hemolysis Evaluation Condition Coverage at Follow-up***

The table below consists of data that was collected in the Hemolysis Zone for each Follow-Up interval. Patients that were implanted with a Primary Device on or after June 2, 2014 are analyzed in this exhibit. In the 'Unable to Evaluate' column, the condition could not be evaluated due to missing variables.

**GROUP=HOSPX-9999**

Follow-up Visit	Hemolysis Evaluation		
	All	Condition Evaluated	
		N	%
3 Month	2	2	100.00
6 Month	1	1	100.00

**GROUP=STS Intermacs**

Follow-up Visit	All	Hemolysis Evaluation			
		Unable to Evaluate		Condition Evaluated	
		N	%	N	%
3 Month	308	15	4.87	293	95.13
6 Month	197	7	3.55	190	96.45
1 Year	60	1	1.67	59	98.33

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

***SITE: HOSPX - DEMO SITE REPORT***

**IV. Zone Conditions: Hemolysis**

***Exhibit 48b: Hemolysis Major and Minor Condition Coverage at Follow-up***

The table below consists of patients who had Major or Minor Hemolysis Conditions for each Follow-Up interval. Patients that were implanted with a Primary Device on or after June 2, 2014 are analyzed in this exhibit.

**GROUP=HOSPX-9999**

Follow-up Visit	Hemolysis Condition		
	All	No	
	N	N	%
<b>3 Month</b>	2	2	100.00
<b>6 Month</b>	1	1	100.00

**GROUP=STS Intermacs**

Follow-up Visit	All N	Hemolysis Condition					
		Major		Minor		No	
		N	%	N	%	N	%
<b>3 Month</b>	293	6	2.05	32	10.92	255	87.03
<b>6 Month</b>	190	3	1.58	10	5.26	177	93.16
<b>1 Year</b>	59	.	.	10	16.95	49	83.05

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

***Exhibit 48c: Hypertension Evaluation Condition Coverage at Follow-up***

The table below consists of data that was collected in the Hypertension Zone for each Follow-Up interval. Patients that were implanted with a Primary Device on or after June 2, 2014 are analyzed in this exhibit. In the 'Unable to Evaluate' column, the condition could not be evaluated due to missing variables.

**GROUP=HOSPX-9999**

Follow-up Visit	Hypertension Evaluation				
	All	Unable to Evaluate		Condition Evaluated	
		N	%	N	%
3 Month	2	1	50.00	1	50.00
6 Month	1	1	100.00	.	.

**GROUP=STS Intermacs**

Follow-up Visit	Hypertension Evaluation				
	All	Unable to Evaluate		Condition Evaluated	
		N	%	N	%
3 Month	308	81	26.30	227	73.70
6 Month	197	42	21.32	155	78.68
1 Year	60	10	16.67	50	83.33



**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

***Exhibit 48d: Hypertension No or Yes Condition Coverage at Follow-up***

The table below consists of patients who did or did not have Hypertension Conditions for each Follow-Up interval. Patients that were implanted with a Primary Device on or after June 2, 2014 are analyzed in this exhibit.

**GROUP=HOSPX-9999**

Follow-up Visit	Hypertension Condition		
	All	No HTN	
	N	N	%
<b>3 Month</b>	1	1	100.00

**GROUP=STS Intermacs**

Follow-up Visit	All	Hypertension Condition			
		HTN		No HTN	
		N	%	N	%
<b>3 Month</b>	227	4	1.76	223	98.24
<b>6 Month</b>	155	5	3.23	150	96.77
<b>1 Year</b>	50	.	.	50	100.00

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

**IV. Zone Conditions: Right Heart Failure**

***Exhibit 48e: Right Heart Failure Evaluation Condition Coverage at Follow-up***

The table below consists of data that was collected in the Right Heart Failure Zone for each Follow-Up interval. Patients that were implanted with a Primary Device on or after June 2, 2014 are analyzed in this exhibit. In the 'Unable to Evaluate' column, the condition could not be evaluated due to missing variables.

**GROUP=HOSPX-9999**

Follow-up Visit	RHF Evaluation		
	All	Condition Evaluated	
		N	%
3 Month	2	2	100.00
6 Month	1	1	100.00

**GROUP=STS Intermacs**

Follow-up Visit	RHF Evaluation				
	All	Unable to Evaluate		Condition Evaluated	
		N	%	N	%
3 Month	308	21	6.82	287	93.18
6 Month	197	9	4.57	188	95.43
1 Year	60	5	8.33	55	91.67

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients**

**COVERAGE: January 1, 2020 - June 30, 2021**

**SITE: HOSPX - DEMO SITE REPORT**

***Exhibit 48f: Right Heart Failure Evaluation Condition Coverage at Follow-up***

The table below consists of patients who Right Heart Failure for each Follow-Up interval, including analysis of severity. Patients that were implanted with a Primary Device on or after June 2, 2014 are analyzed in this exhibit. For full details on how each severity level is calculated, please check the Reports FAQ section on the Intermacs.org website.

**GROUP=HOSPX-9999**

Follow-up Visit	RHF Condition		
	All	1. No RHF	
	N	N	%
3 Month	2	2	100.00
6 Month	1	1	100.00

**GROUP=STS Intermacs**

Follow-up Visit	RHF Condition								
	1. No RHF			3. RHF (Mild)		4. RHF (Inotropic Support)		5. RHF (RVAD Support)	
	All	N	%	N	%	N	%	N	%
3 Month	287	255	88.85	11	3.83	20	6.97	1	0.35
6 Month	188	173	92.02	8	4.26	6	3.19	1	0.53
1 Year	55	50	90.91	4	7.27	1	1.82	.	.

**STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients****COVERAGE: January 1, 2020 - June 30, 2021****SITE: HOSPX - DEMO SITE REPORT****Exhibit 49: Patients Implanted at your Center but Excluded from the Cumulative - All Patient Report**

Excluded Patient ID	Exclusion Reason	Implant Year
452	Retrospective Patient	2006
631	Pediatric Patient (Age<19)	2007
1060	Patient Implant Date Outside of Report Coverage	2006
4756	Pediatric Patient (Age<19)	2011
5048	Pediatric Patient (Age<19)	2011
5561	Retrospective Patient	2010
5590	Retrospective Patient	2010
5591	Retrospective Patient	2010
5593	Retrospective Patient	2010
7012	Pediatric Patient (Age<19)	2012
107122	Retrospective Patient	2015
116990	Retrospective Patient	2018
125366	Implant, Pre-Implant, or Patient form not validated	2020
125722	Implant, Pre-Implant, or Patient form not validated	2020
126037	Implant, Pre-Implant, or Patient form not validated	2020
126223	Implant, Pre-Implant, or Patient form not validated	2020
126245	Implant, Pre-Implant, or Patient form not validated	2020
126375	Implant, Pre-Implant, or Patient form not validated	2020
126411	Implant, Pre-Implant, or Patient form not validated	2020
126738	Implant, Pre-Implant, or Patient form not validated	2021
126823	Implant, Pre-Implant, or Patient form not validated	2021
126928	Implant, Pre-Implant, or Patient form not validated	2021
127069	Implant, Pre-Implant, or Patient form not validated	2021
127251	Implant, Pre-Implant, or Patient form not validated	2021
127334	Implant, Pre-Implant, or Patient form not validated	2021
127727	Implant, Pre-Implant, or Patient form not validated	2021
127743	Implant, Pre-Implant, or Patient form not validated	2021
127744	Implant, Pre-Implant, or Patient form not validated	2021
127829	Implant, Pre-Implant, or Patient form not validated	2021
127830	Implant, Pre-Implant, or Patient form not validated	2021
127984	Implant, Pre-Implant, or Patient form not validated	2021
128045	Implant, Pre-Implant, or Patient form not validated	2021

# STS INTERMACS - Quarterly Quality Assurance Report (2021 Q2) - Recent - Prior VAD Patients

COVERAGE: January 1, 2020 - June 30, 2021

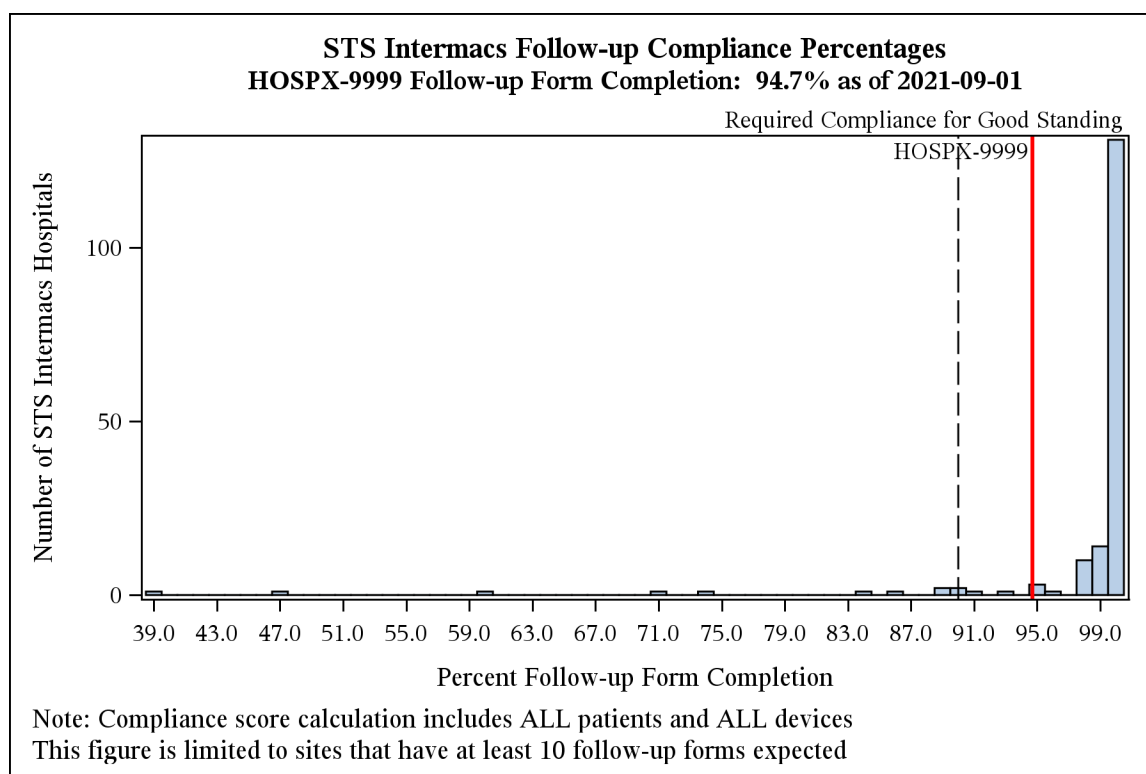
**SITE: HOSPX - DEMO SITE REPORT**

## III. Registry Compliance

### Exhibit 50. Compliance

Site compliance is determined by the percentage of all follow-up forms that are due during this reporting period that have been completed. **This calculation has been updated to include ALL follow-up forms expected for ALL patients and ALL devices.** Only active sites that have at least 10 follow-up forms due are included in this figure (n = 172 sites). This exhibit is the same in both cumulative and recent report. It is based on all follow-up forms.

STS InterMACS has defined required compliance as 90%. If your hospital is below 90%, please examine your patient follow-up table that is contained in the STS InterMACS Data Quality Quarterly Report. This table will identify the exact patients who have a 'past due' follow-up form.



BiVAD: BiVentricular Assist Device  
BMI: Body Mass Index  
BP: Blood Pressure  
BSA: Body Surface Area  
BTC: Bridge to Candidacy  
BUN: Blood Urea Nitrogen  
CMS: Centers for Medicare and Medicaid  
COPD: Chronic Obstructive Pulmonary Disease  
CNS: Central Nervous System  
CRP: C - Reactive Protein  
CVA: Cerebrovascular Accident  
DCC: Data Coordinating Center  
DT: Destination Therapy  
ECMO: Extracorporeal-membrane Oxygenation  
EQ-5D: Euro Quality of Life  
FDA: Federal Drug Administration  
HF: Heart Failure  
IABP: Intra-Aortic Balloon Pump  
IgG: Immunoglobulin G  
INR: International Normalized Ratio  
Intermacs: Interagency Registry for Mechanically Assisted Circulatory Support  
LVAD: Left Ventricular Assist Device  
LVEF: Left Ventricular Ejection Fraction  
LVEDD: Left Ventricular End Diastolic Dysfunction  
LVSF: Left Ventricular Shortening Fraction  
MCSD: Mechanically Circulatory Support Device  
NHLBI: National Heart Lung and Blood Institute  
NT pro brain natriuretic peptide: N-Terminal pro brain Natriuretic peptide  
NYHA: New York Heart Association  
OR: Operating Room  
Regurg: Regurgitation  
RVAD: Right Ventricular Assist Device  
RVEF: Right Ventricular Ejection Fraction  
SAE: Serious Adverse Event  
SGOT-AST: Serum Glutamic Oxaloacetic Transaminase  
SGPT-ALT: Serum Glutamic Pyruvic Transaminase  
STS: Society of Thoracic Surgeons  
TAH: Total Artificial Heart  
TIA: Transient Ischemic Attack  
VAD: Ventricular Assist Device  
VAS: Visual Analog Scale