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STS Intermacs

Quarterly Quality Assurance Report (2021 Q2) - All Patients

HOSPX - DEMO SITE REPORT

Implant and event dates: June 23, 2006 to June 30, 2021

09/30/2021

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CONFIDENTIAL: This information is only intended for: HOSPX - DEMO SITE REPORT

About This Report

The "Cumulative" version of the Quality Assurance report focuses on the complete cohort of patients. This report includes all patients enrolled in Intermacs within the report coverage window.

The "All Patients" version of the report includes all patients enrolled at your center whose first device was implanted within the report coverage window.

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.

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This quarterly report includes clinical information from 806 patients receiving implants between June 23, 2006 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 MCSD 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 PATEINTS 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 and select 'Intermacs Appendices', Appendix M/User's Guide'.

The summary statistics for continous 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).

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.

	IMPL	ANT DATE PE	RIOD	
Device	< 2014	2014 - 2017	2018 - 2021 (Jan-Jun)	TOTAL
	n	n	n	n
Primary Device	242	301	263	806
2nd Device	30	38	6	74
3rd Device	5	2	0	7
4th Device	0	0	0	0
5th Device	0	0	0	0

GROUP=HOSPX-9999

GROUP=STS Intermacs

	IMPL	ANT DATE PE	RIOD	
Device	< 2014	2014 - 2017	2018 - 2021 (Jan-Jun)	TOTAL
	n	n	n	n
Primary Device	11100	11943	10698	33741
2nd Device	1764	1771	528	4063
3rd Device	314	306	53	673
4th Device	45	42	4	91
5th Device	6	4	1	11

II.A. Pre-Implant Summaries - Demographics

Exhibit 2: Age Group

				HOSP	X-9999							STS Int	ermacs			
AGE GROUP (yr)	< 2	014	2014 - 2017		2018 - 2021 (Jan-Jun)		то	ΓAL	< 2	014	2014	- 2017	2018 - (Jan-	-	то	ΓAL
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
19-39	26	10.7 %	42	13.9 %	26	9.8 %	94	11.6 %	1415	12.7 %	1479	12.3 %	1326	12.3 %	4220	12.5 %
40-59	108	44.6 %	122	40.5 %	112	42.5 %	342	42.4 %	4769	42.9 %	5019	42.0 %	4274	39.9 %	14062	41.6 %
60-79	108	44.6 %	135	44.8 %	123	46.7 %	366	45.4 %	4857	43.7 %	5376	45.0 %	5051	47.2 %	15284	45.2 %
80+			2	0.6 %	2	0.7 %	4	0.4 %	59	0.5 %	69	0.5 %	47	0.4 %	175	0.5 %
TOTAL	242	100.0 %	301	100.0 %	263	100.0 %	806	100.0 %	11100	100.0 %	11943	100.0 %	10698	100.0 %	33741	100.0 %

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

II.A. Pre-Implant Summaries - Demographics

Exhibit 3: Gender

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

				HOSP	X-9999							STS Int	ermacs			
GENDER	< 2	014	2014 - 2017		2018 - 2021 (Jan-Jun)		то	FAL	< 2	014	2014 -	2017	2018 (Jan	- 2021 -Jun)	то	ΓAL
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Female	52	21.4 %	73	24.2 %	47	17.8 %	172	21.3 %	2349	21.1 %	2592	21.7 %	2402	22.4 %	7343	21.7 %
Male	190	78.5 %	228	75.7 %	216	82.1 %	634	78.6 %	8750	78.8 %	9333	78.1 %	8293	77.5 %	26376	78.1 %
Unspecified				-				-	1	0.0 %	18	0.1 %	3	0.0 %	22	0.0 %
TOTAL	242	100.0 %	301	100.0 %	263	100.0 %	806	100.0 %	11100	100.0 %	11943	100.0 %	10698	100.0 %	33741	100.0 %

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.

				HOSP	X-9999							STS Inte	ermacs			
RACE	< 2014		2014 -	- 2017		2018 - 2021 (Jan-Jun)		TOTAL		014	2014 -	2017	2018 - (Jan-	-	тот	AL
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
African American	71	29.3 %	115	38.2 %	95	36.1 %	281	34.8 %	2444	22.0 %	3013	25.2 %	3115	29.1 %	8572	25.4 %
Other, Unknown, Undisclosed	45	18.5 %	45	14.9 %	53	20.1 %	143	17.7 %	945	8.5 %	1189	9.9 %	1054	9.8 %	3188	9.4 %
White	126	52.0 %	141	46.8 %	115	43.7 %	382	47.3 %	7711	69.4 %	7741	64.8 %	6529	61.0 %	21981	65.1 %
TOTAL	242	100.0 %	301	100.0 %	263	100.0 %	806	100.0 %	11100	100.0 %	11943	100.0 %	10698	100.0 %	33741	100.0 %

II.A. Pre-Implant Summaries - Demographics

Exhibit 5: Hispanic Ethnicity

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

				HOSP	X-9999							STS Int	ermacs			
HISPANIC ETHNICITY	< 2	014	2014 - 2017			- 2021 -Jun)	то	TAL	< 2	014	2014 ·	- 2017	2018 (Jan-	- 2021 -Jun)	то	ΓAL
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Non-Hispanic	205	84.7 %	253	84.0 %	197	74.9 %	655	81.2 %	10389	93.5 %	10818	90.5 %	9632	90.0 %	30839	91.3 %
Unknown			15	4.9 %	33	12.5 %	48	5.9 %	1	0.0 %	260	2.1 %	356	3.3 %	617	1.8 %
Hispanic	37	15.2 %	33	10.9 %	33	12.5 %	103	12.7 %	710	6.3 %	865	7.2 %	710	6.6 %	2285	6.7 %
TOTAL	242	100.0 %	301	100.0 %	263	100.0 %	806	100.0 %	11100	100.0 %	11943	100.0 %	10698	100.0 %	33741	100.0 %

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.

IPLANT SA	< 2014	2014 - 2017	2018 - 2021 (Jan-Jun)	TOTAL
Ν	239	299	262	800
Mean	2.04	2.00	2.06	2.03
Std	0.29	0.35	0.32	0.33
Min	1.12	0.98	1.01	0.98
Max	3.11	3.05	2.98	3.11

GROUP=HOSPX-9999

GROUP=STS Intermacs

 IPLANT SA	< 2014	2014 - 2017	2018 - 2021 (Jan-Jun)	TOTAL
Ν	10975	11890	10662	33527
Mean	2.08	2.07	2.09	2.08
Std	0.30	0.32	0.32	0.31
Min	0.70	0.46	0.47	0.46
Max	3.44	3.62	3.89	3.89

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.

				HOSP	X-9999							STS Inte	ermacs			
PRE-IMPLANT DEVICE STRATEGY	< 2	014	2014 -	- 2017	2018 · (Jan-	- 2021 Jun)	то	ΓAL	< 2	014	2014	- 2017	2018 (Jan	- 2021 -Jun)	то	TAL
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
BTT - Listed	55	22.7 %	52	17.2 %	29	11.0 %	136	16.8 %	3141	28.2 %	3186	26.6 %	1171	10.9 %	7498	22.2 %
BTT - Likely	54	22.3 %	33	10.9 %	18	6.8 %	105	13.0 %	2570	23.1 %	1656	13.8 %	857	8.0 %	5083	15.0 %
BTT - Moderate	34	14.0 %	34	11.2 %	10	3.8 %	78	9.6 %	1138	10.2 %	1002	8.3 %	874	8.1 %	3014	8.9 %
BTT - Unlikely	11	4.5 %	8	2.6 %	3	1.1 %	22	2.7 %	369	3.3 %	274	2.2 %	269	2.5 %	912	2.7 %
Destination Therapy	86	35.5 %	173	57.4 %	198	75.2 %	457	56.6 %	3696	33.2 %	5730	47.9 %	7333	68.5 %	16759	49.6 %
Bridge to Recovery	-	-	1	0.3 %	5	1.9 %	6	0.7 %	116	1.0 %	50	0.4 %	87	0.8 %	253	0.7 %
Rescue Therapy	2	0.8 %	-	-			2	0.2 %	66	0.5 %	39	0.3 %	27	0.2 %	132	0.3 %
Other		•							4	0.0 %	6	0.0 %	80	0.7 %	90	0.2 %
TOTAL	242	100.0 %	301	100.0 %	263	100.0 %	806	100.0 %	11100	100.0 %	11943	100.0 %	10698	100.0 %	33741	100.0 %

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.

				HOSP	X-9999							STS Inte	ermacs			
PRE-IMPLANT PATIENT PROFILE	< 2	014	2014 -	- 2017	2018 - (Jan-	- 2021 Jun)	то	AL	< 2	014	2014 -	- 2017	2018 - (Jan-		тот	AL
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
1 Critical Cardiogenic Shock	48	19.8 %	36	11.9 %	39	14.8 %	123	15.2 %	2121	19.1 %	2307	19.4 %	2011	18.7 %	6439	19.1 %
2 Progressive Decline	89	36.7 %	73	24.2 %	88	33.4 %	250	31.0 %	4203	38.0 %	4091	34.4 %	3528	32.9 %	11822	35.1 %
3 Stable but Inotrope Dependent	73	30.1 %	175	58.1 %	122	46.3 %	370	45.9 %	2795	25.2 %	3998	33.6 %	3822	35.7 %	10615	31.5 %
4 Resting Symptoms	24	9.9 %	16	5.3 %	11	4.1 %	51	6.3 %	1425	12.8 %	1251	10.5 %	1118	10.4 %	3794	11.2 %
5 Exertion Intolerant	6	2.4 %	-	-	-		6	0.7 %	290	2.6 %	165	1.3 %	113	1.0 %	568	1.6 %
6 Exertion Limited	2	0.8 %	-	-	1	0.3 %	3	0.3 %	141	1.2 %	51	0.4 %	49	0.4 %	241	0.7 %
7 Advanced NYHA Class 3			1	0.3 %	2	0.7 %	3	0.3 %	79	0.7 %	25	0.2 %	57	0.5 %	161	0.4 %
TOTAL	242	100.0 %	301	100.0 %	263	100.0 %	806	100.0 %	11054	100.0 %	11888	100.0 %	10698	100.0 %	33640	100.0 %

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.

	HOSPX-9999													
IV INOTROPES		< 2014		2	014 - 201	7	2018 -	2021 (Ja	n-Jun)					
	Ν	Yes	%	N	Yes	%	Ν	Yes	%					
Dobutamine	201	77	38.3%	274	141	51.5%	219	103	47.0%					
Dopamine	201	16	8.0%	274	6	2.2%	219	5	2.3%					
Milrinone	201	169	84.1%	274	219	79.9%	219	173	79.0%					
Levosimendan	201	0	0.0%	274	0	0.0%	219	1	0.5%					
Epinephrine	201	8	4.0%	274	22	8.0%	219	24	11.0%					
Norepinephrine	201	18	9.0%	274	12	4.4%	219	16	7.3%					
Isoproterenol	201	0	0.0%	274	0	0.0%	219	0	0.0%					
Other Specify	201	6	3.0%	274	0	0.0%	219	6	2.7%					
Unknown	201	0	0.0%	274	0	0.0%	219	2	0.9%					

				ST	S Interma	ICS			
IV INOTROPES		< 2014		2	014 - 201	7	2018 -	2021 (Ja	n-Jun)
	N	Yes	%	Ν	Yes	%	Ν	Yes	%
Dobutamine	8980	3545	39.5%	9951	3715	37.3%	8932	3321	37.2%
Dopamine	8980	1080	12.0%	9951	780	7.8%	8932	401	4.5%
Milrinone	8980	6674	74.3%	9951	7636	76.7%	8932	6795	76.1%
Levosimendan	8980	14	0.2%	9951	7	0.1%	8932	8	0.1%
Epinephrine	8980	563	6.3%	9951	952	9.6%	8932	970	10.9%
Norepinephrine	8980	557	6.2%	9951	803	8.1%	8932	791	8.9%
Isoproterenol	8980	23	0.3%	9951	11	0.1%	8932	12	0.1%
Other Specify	8980	307	3.4%	9951	105	1.1%	8932	87	1.0%
Unknown	8980	11	0.1%	9951	5	0.1%	8932	12	0.1%

IV INOTROPES	HOSPX-9999			STS Intermacs		
IV INCTROPES	Ν	Yes	%	N	Yes	%
Dobutamine	694	321	46.3%	27863	10581	38.0%
Dopamine	694	27	3.9%	27863	2261	8.1%
Milrinone	694	561	80.8%	27863	21105	75.7%
Levosimendan	694	1	0.1%	27863	29	0.1%
Epinephrine	694	54	7.8%	27863	2485	8.9%
Norepinephrine	694	46	6.6%	27863	2151	7.7%
Isoproterenol	694	0	0.0%	27863	46	0.2%

(Continued)

II.A. Pre-Implant Summaries - Clinical Characteristics

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

IV INOTROPES	H	OSPX-9999		STS Intermacs		
IV INUTROPES	N	Yes	%	N	Yes	%
Other Specify	694	12	1.7%	27863	499	1.8%
Unknown	694	2	0.3%	27863	28	0.1%

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	HOSP	X-9999	STS Intermacs	
	N	%	Ν	%
Currently using	113	14.5	6489	19.8
Known previous use (within past year)	164	21.0	6872	21.0
No	325	41.6	16488	50.4
Unknown	180	23.0	2853	8.7
TOTAL	782	100	32702	100

ALDOSTERONE ANTAGONIST	HOSPX-9999		STS Intermacs	
ANTAGONIST	N	%	N	%
Currently using	276	35.3	11883	36.3
Known previous use (within past year)	177	22.6	5607	17.1
No	226	28.9	13089	40.0
Unknown	103	13.2	2123	6.5
TOTAL	782	100	32702	100

	HOSP	X-9999	STS Intermacs		
	N	%	N	%	
Currently using	66	10.0	3350	12.5	
Known previous use (within past year)	24	3.6	954	3.6	
No	381	57.6	19606	73.2	
Unknown	191	28.9	2870	10.7	
TOTAL	662	100	26780	100	

AMIODARONE	HOSP	X-9999	STS Intermacs	
	N	%	N	%
Currently using	295	37.7	13037	39.9
Known previous use (within past year)	64	8.2	2224	6.8
No	311	39.8	15403	47.1
Unknown	112	14.3	2038	6.2
TOTAL	782	100	32702	100

Exhibit 9b. Medications - History and Current Use

ANGIOTENSIN RECEPTOR BLOCKER	HOSPX-9999		STS Intermacs	
RECEPTOR BLOCKER	Ν	%	N	%
Currently using	48	6.1	3090	9.4
Known previous use (within past year)	96	12.3	4188	12.8
No	446	57.0	22047	67.4
Unknown	192	24.6	3377	10.3
TOTAL	782	100	32702	100

ANTIPLATELET THERAPY DRUG	HOSPX-9999		STS Intermacs	
THERAPT DRUG	N	%	N	%
Currently using	325	41.6	17649	54.0
Known previous use (within past year)	125	16.0	4612	14.1
No	239	30.6	8858	27.1
Unknown	93	11.9	1583	4.8
TOTAL	782	100	32702	100

BETA BLOCKERS	HOSP	X-9999	STS Intermacs		
	N	%	N	%	
Currently using	289	37.0	14444	44.2	
Known previous use (within past year)	222	28.4	9535	29.2	
No	175	22.4	7319	22.4	
Unknown	96	12.3	1404	4.3	
TOTAL	782	100	32702	100	

WARFARIN (COUMADIN)	HOSPX-9999		STS Intermacs	
(COOMADIN)	N	%	Ν	%
Currently using	83	10.6	5054	15.5
Known previous use (within past year)	124	15.9	5729	17.5
No	439	56.1	19503	59.6
Unknown	136	17.4	2416	7.4
TOTAL	782	100	32702	100

II.A. Pre-Implant Summaries - Clinical Characteristics

Exhibit 9b. Medications - History and Current Use

NESIRITIDE	HOSP	X-9999	STS Intermacs		
	N	%	Ν	%	
No	692	90.1	30211	94.4	
Unknown	72	9.4	1259	3.9	
Yes	4	0.5	541	1.7	
TOTAL	768	100	32011	100	

NITRIC OXIDE	HOSP	X-9999	STS Intermacs		
	N	%	N	%	
No	698	89.3	30371	92.9	
Unknown	69	8.8	1277	3.9	
Yes	15	1.9	1054	3.2	
TOTAL	782	100	32702	100	

LOOP DIURETICS	HOSP	X-9999	STS Intermacs		
LOOP DIORETICS	N	%	N	%	
No	93	11.9	4879	14.9	
Unknown	51	6.5	416	1.3	
Yes	638	81.6	27407	83.8	
TOTAL	782	100	32702	100	

II.A. Pre-Implant Summaries - Clinical Characteristics

Exhibit 9b. Medications - History and Current Use

PRE-IMPLANT LOOP DIURETIC TYPE⁺		HOSPX-9999				
TTPE	N	Yes	%	N	Yes	%
Furosemide	498	339	68.07%	21249	12536	59.00%
Torsemide	498	59	11.85%	21249	4112	19.35%
Bumetanide	498	101	20.28%	21249	4787	22.53%
Other	498	0	0.00%	21249	94	0.44%

	HOSP	X-9999	STS Int	ermacs
THERAPY (CRT)⁺	Ν	%	Ν	%
No	435	67.1	17615	67.6
Unknown	93	14.4	1670	6.4
Yes	120	18.5	6758	25.9
TOTAL	648	100	26043	100

METALOZONE / THIAZIDE ⁺	HOSP	X-9999	STS Intermacs			
INAZIDE	N	%	Ν	%		
No	458	69.2	22658	84.7		
Unknown	134	20.2	992	3.7		
Yes	70	10.6	3101	11.6		
TOTAL	662	100	26751	100		

METALOZONE / THIAZIDE - FREQUENCY*	HOSP	X-9999	STS Int	ermacs
FREQUENCT	N	%	Ν	%
Regular	31	44.3	1299	41.9
Intermittent	39	55.7	1801	58.1
TOTAL	70	100	3100	100

Exhibit 10. Laboratories

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

		HOSPX-9999	STS Intermacs
Sodium (mEq/L)	Ν	782	32636
	Mean	134.59	135.02
	Std	5.19	4.88
	Min	117.00	110.00
	Max	154.00	161.00
Potassium (mEq/L)	Ν	782	32632
	Mean	4.16	4.07
	Std	0.48	0.48
	Min	2.60	2.00
	Max	6.10	7.00
BUN (mg/dL)	Ν	782	32581
	Mean	31.19	29.59
	Std	19.45	18.04
	Min	1.11	0.70
	Max	336.00	336.12
Creatinine (mg/dL)	Ν	782	32624
	Mean	1.48	1.41
	Std	0.74	0.72
	Min	0.50	0.00
	Max	9.10	15.00
Alanine Aminotransferase/ALT (u/L)	Ν	705	30999
	Mean	69.29	70.14
	Std	178.12	229.68
	Min	4.00	1.00
	Max	2395.00	9930.00
Aspartate Aminotransferase/AST (u/L)	Ν	704	30992
	Mean	60.47	62.59
	Std	185.22	243.64
	Min	2.00	2.00
	Max	3982.00	10000.00
LDH (µkat/L), (U/L)	Ν	406	16615
	Mean	515.30	405.02
	Std	534.95	466.09
	Min	19.00	0.00
	Max	6454.00	18345.00
All	N	806	33741

Exhibit 10. Laboratories

PRE-IMPLANT LABORATORI	HOSPX-9999	STS Intermacs	
Total Bilirubin (mg/dL)	704	30949	
	Mean	1.48	1.42
	Std	1.89	1.91
	Min	0.10	0.08
	Max	27.20	52.00
Albumin (g/dL)	Ν	681	30576
	Mean	3.55	3.39
	Std	0.68	0.65
	Min	0.37	0.00
	Max	8.00	8.00
Pre-albumin (mg/dL)	Ν	423	17254
	Mean	18.40	18.29
	Std	7.88	7.36
	Min	3.00	3.00
	Max	55.00	60.00
Total Cholesterol (mg/dL)	N	515	18408
	Mean	127.08	128.76
	Std	42.31	100.30
	Min	51.40	50.00
	Max	410.00	7413.13
Brain Natriuretic Peptide (pg/mL)	N	12	14073
Brain Natriuretic Peptide (pg/mL)	Mean	2014.75	1240.22
	Std	1459.63	1142.53
	Min	91.00	1.00
	Max	4253.00	7500.00
Pro Brain Natriuretic Peptide (pg/mL	.) N	522	8278
	Mean	6847.37	6885.73
	Std	7146.15	8036.55
	Min	27.00	26.00
	Max	60000.00	60000.00
White Blood Cell Count (x10/µL)	Ν	775	32570
	Mean	9.30	8.86
	Std	4.61	4.25
	Min	2.50	1.00
	Max	68.00	96.00
Hemoglobin (g/dL)	N	777	32571
	Mean	10.80	11.09
	Std	2.22	2.18
	Min	0.78	0.10
	Мах	19.70	20.00
All	N	806	33741

Exhibit 10. Laboratories

PRE-IMPLANT LABOR	ATORIES	HOSPX-9999	STS Intermacs
Platelets (x10/µL)	Ν	778	32553
	Mean	200.43	194.80
	Std	89.07	82.14
	Min	13.00	0.00
	Mean Std Min Max Mean Std Min Std Min Std Min Std Min Max Sg/L) N Mean Std Std Std Std Std Min Std	738.00	800.00
INR	Ν	754	31288
	Mean	1.32	1.32
	Std	0.61	0.52
	Min	0.90	0.50
	Max	13.70	15.00
Sensitivity CRP (mg/L)	Ν	131	8768
	Mean	45.09	23.66
	Std	62.34	46.92
	Min	0.10	0.00
	Max	300.00	800.00
All	Ν	806	33741

PRE-IMPLANT LUPUS ANTICOAGULANT STATUS⁺	HOSPX-9999		STS Int	ermacs
STATUS	N	%	N	%
Negative	9	1.4	2664	9.9
Positive	3	0.5	336	1.3
Unknown	650	98.2	23801	88.8
TOTAL	662	100	26801	100

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 MCSD 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.

	HOSPX-9999										
Cardiothoracic issues	< 2014		2014 - 2017			2018 - 2021 (Jan-Jun)					
	Ν	Yes	%	Ν	Yes	%	N	Yes	%		
Frequent ICD Shocks	122	4	3.3%	301	13	4.3%	232	4	1.7%		
Chronic Lung Disease	237	27	11.4%	301	12	4.0%	236	16	6.8%		
Pulmonary Hypertension	127	42	33.1%	301	28	9.3%	236	48	20.3%		
Recent Pulmonary Embolus	123	2	1.6%	301	0	0.0%	236	1	0.4%		
History of Atrial Arrhythmia	122	22	18.0%	301	48	15.9%	233	38	16.3%		
Thoracic Aortic Disease	122	1	0.8%	301	2	0.7%	235	6	2.6%		

	STS Intermacs									
Cardiothoracic issues		< 2014		2014 - 2017			2018 - 2021 (Jan-Jun)			
	Ν	Yes	%	Ν	Yes	%	N	Yes	%	
Frequent ICD Shocks	5498	327	5.9%	11942	606	5.1%	9631	393	4.1%	
Chronic Lung Disease	10941	1264	11.6%	11942	1081	9.1%	9631	860	8.9%	
Pulmonary Hypertension	5937	1791	30.2%	11942	2402	20.1%	9627	1754	18.2%	
Recent Pulmonary Embolus	5514	108	2.0%	11942	195	1.6%	9650	132	1.4%	
History of Atrial Arrhythmia	5499	1170	21.3%	11942	2431	20.4%	9639	1840	19.1%	
Thoracic Aortic Disease	5506	68	1.2%	11942	159	1.3%	9640	60	0.6%	

Cardiothoracic issues	H	OSPX-999	99	STS Intermacs			
Cardiothoracic issues	N	Yes	%	Ν	Yes	%	
Frequent ICD Shocks	647	21	3.2%	26370	1295	4.9%	
Chronic Lung Disease	655	36	5.5%	26750	2467	9.2%	
Pulmonary Hypertension	651	113	17.4%	26395	5394	20.4%	
Recent Pulmonary Embolus	651	2	0.3%	26390	415	1.6%	
History of Atrial Arrhythmia	648	107	16.5%	26378	5309	20.1%	
Thoracic Aortic Disease	650	9	1.4%	26379	270	1.0%	

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

Exhibit 11. Pre-Implant Comorbidities

				H	OSPX-999	99						
Nutritional/GI issues	< 2014			2	014 - 201	7	2018 -	2021 (Jar	021 (Jan-Jun)			
	Ν	Yes	%	Ν	Yes	%	Ν	Yes	%			
Severe Diabetes	177	59	33.3%	301	48	15.9%	239	33	13.8%			
Malnutrition/Cachexia	128	6	4.7%	301	1	0.3%	238	4	1.7%			
History GI Ulcers	122	0	0.0%	301	0	0.0%	233	1	0.4%			
Liver Dysfunction	5	0	0.0%	290	2	0.7%	232	12	5.2%			
Hepatitis	234	30	12.8%	301	1	0.3%	236	1	0.4%			

				ST	S Interma	CS						
Nutritional/GI issues		< 2014			014 - 201	7	2018 -	2021 (Ja	2021 (Jan-Jun)			
	Ν	Yes	%	Ν	Yes	%	Ν	Yes	%			
Severe Diabetes	7560	1766	23.4%	11943	1135	9.5%	9656	1004	10.4%			
Malnutrition/Cachexia	5589	256	4.6%	11943	323	2.7%	9641	277	2.9%			
History GI Ulcers	5499	71	1.3%	11943	73	0.6%	9642	68	0.7%			
Liver Dysfunction	316	7	2.2%	11169	505	4.5%	9642	362	3.8%			
Hepatitis	10782	365	3.4%	11943	147	1.2%	9642	113	1.2%			

Nutritional/GI issues	Н	OSPX-99	99	STS Intermacs				
Nutritional/GLISSues	Ν	Yes % N Yes		Yes	%			
Severe Diabetes	656	107	16.3%	26543	2707	10.2%		
Malnutrition/Cachexia	654	6	0.9%	26390	769	2.9%		
History GI Ulcers	648	1	0.2%	26382	203	0.8%		
Liver Dysfunction	527	14	2.7%	21023	872	4.1%		
Hepatitis	656	3	0.5%	26740	352	1.3%		

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

Exhibit 11. Pre-Implant Comorbidities

	HOSPX-9999										
Vascular issues	< 2014			2	014 - 201	7	2018 -	2021 (Jai	า-Jun)		
	Ν	Yes	%	Ν	Yes	%	Ν	Yes	%		
Heparin-induced Thrombocytopenia	122	1	0.8%	301	2	0.7%	234	2	0.9%		
Chronic Coagulopathy	122	1	0.8%	301	1	0.3%	233	0	0.0%		
Cerebrovascular Disease	239	42	17.6%	301	15	5.0%	237	12	5.1%		
Major Stroke	235	19	8.1%	301	10	3.3%	224	9	4.0%		
Peripheral Arterial Disease	234	13	5.6%	301	2	0.7%	238	6	2.5%		

	STS Intermacs										
Vascular issues		< 2014		2	014 - 201	7	2018 -	2021 (Ja	n-Jun)		
	Ν	Yes	%	Ν	Yes	%	N	Yes	%		
Heparin-induced Thrombocytopenia	5536	125	2.3%	11942	118	1.0%	9621	103	1.1%		
Chronic Coagulopathy	5499	52	0.9%	11942	154	1.3%	9625	98	1.0%		
Cerebrovascular Disease	11045	1394	12.6%	11942	678	5.7%	9648	535	5.5%		
Major Stroke	10883	662	6.1%	11899	447	3.8%	9016	368	4.1%		
Peripheral Arterial Disease	10956	591	5.4%	11942	514	4.3%	9642	385	4.0%		

Vascular issues	H	OSPX-99	99	ST	S Intermacs		
vascular issues	Ν	Yes	%	Ν	Yes	%	
Heparin-induced Thrombocytopenia	649	5	0.8%	26361	300	1.1%	
Chronic Coagulopathy	648	2	0.3%	26364	300	1.1%	
Cerebrovascular Disease	657	37	5.6%	26770	1608	6.0%	
Major Stroke	644	27	4.2%	26058	1047	4.0%	
Peripheral Arterial Disease	657	16	2.4%	26762	1171	4.4%	

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

Exhibit 11. Pre-Implant Comorbidities

	HOSPX-9999									
Oncology/infection issues	< 2014			2	014 - 201	7	2018 -	2021 (Jar	า-Jun)	
	Ν	Yes	%	Ν	Yes	%	Ν	Yes	%	
History Solid Organ Cancer	130	8	6.2%	301	14	4.7%	238	10	4.2%	
Currently has Cancer v6	0			0			12	0	0.0%	
History of Solid Organ Transplant v6	0			0			14	0	0.0%	
History of Bone Marrow Transplant (BMT)	122	0	0.0%	301	0	0.0%	239	0	0.0%	
HIV	122	1	0.8%	300	0	0.0%	225	2	0.9%	

	STS Intermacs										
Oncology/infection issues	< 2014			2	014 - 201	7	2018 -	2021 (Jai	า-Jun)		
	Ν	Yes	%	Ν	Yes	%	Ν	Yes	%		
History Solid Organ Cancer	5927	489	8.3%	11942	541	4.5%	9656	478	5.0%		
Currently has Cancer v6	38	0	0.0%	44	0	0.0%	720	13	1.8%		
History of Solid Organ Transplant v6	38	0	0.0%	44	0	0.0%	734	5	0.7%		
History of Bone Marrow Transplant (BMT)	5500	3	0.1%	11943	11	0.1%	9652	16	0.2%		
HIV	5497	16	0.3%	11892	36	0.3%	8953	51	0.6%		

Oncelon/infection issues	H	OSPX-99	99	ST	S Interma	ics
Oncology/infection issues	N	Yes	%	Ν	Yes	%
History Solid Organ Cancer	653	28	4.3%	26426	1302	4.9%
Currently has Cancer v6	12	0	0.0%	798	13	1.6%
History of Solid Organ Transplant v6	14	0	0.0%	812	5	0.6%
History of Bone Marrow Transplant (BMT)	654	0	0.0%	26392	30	0.1%
HIV	639	3	0.5%	25642	101	0.4%

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.

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.

				н	OSPX-999	99			
Potential Barriers to Heart Transplant		< 2014		2	014 - 201	7	2018 -	2021 (Ja	n-Jun)
	Ν	Yes	%	Ν	Yes	%	N	Yes	%
Advanced Age	240	29	12.1%	301	45	15.0%	239	23	9.6%
Frailty	240	5	2.1%	301	19	6.3%	236	8	3.4%
Patient Does Not Want Transplant	240	8	3.3%	301	1	0.3%	234	2	0.9%
Musculoskeletal Limitation to Ambulation	240	0	0.0%	301	0	0.0%	236	0	0.0%
Contraindications to Immunosuppression	240	0	0.0%	301	0	0.0%	235	0	0.0%
Allosensitization	240	0	0.0%	301	0	0.0%	234	3	1.3%
Chronic Renal Disease	240	28	11.7%	301	14	4.7%	236	4	1.7%
Large BMI	240	18	7.5%	301	36	12.0%	239	25	10.5%
Chronic Infectious Concerns	240	0	0.0%	301	0	0.0%	234	1	0.4%

				ST	S Interma	CS			
Potential Barriers to Heart Transplant		< 2014			014 - 201	7	2018 - 2021 (Jan-Jun)		
	Ν	Yes	%	Ν	Yes	%	Ν	Yes	%
Advanced Age	10949	1371	12.5%	11943	1479	12.4%	9633	1457	15.1%
Frailty	10950	404	3.7%	11943	594	5.0%	9615	562	5.8%
Patient Does Not Want Transplant	10949	208	1.9%	11943	199	1.7%	9550	178	1.9%
Musculoskeletal Limitation to Ambulation	10950	42	0.4%	11943	42	0.4%	9615	43	0.4%
Contraindications to Immunosuppression	10950	59	0.5%	11942	37	0.3%	9596	42	0.4%
Allosensitization	10950	78	0.7%	11942	56	0.5%	9570	83	0.9%
Chronic Renal Disease	10949	940	8.6%	11943	904	7.6%	9621	721	7.5%
Large BMI	10949	1065	9.7%	11943	1352	11.3%	9635	1419	14.7%
Chronic Infectious Concerns	10950	76	0.7%	11942	102	0.9%	9615	94	1.0%

Detential Revuiers to Meant Transplant	HOSPX-9999 STS Intern			S Interma	ICS	
Potential Barriers to Heart Transplant	Ν	Yes	%	N	Yes	%
Advanced Age	659	89	13.5%	26746	3705	13.9%
Frailty	656	28	4.3%	26729	1352	5.1%
Patient Does Not Want Transplant	654	8	1.2%	26664	493	1.8%
Musculoskeletal Limitation to Ambulation	656	0	0.0%	26729	106	0.4%
Contraindications to Immunosuppression	655	0	0.0%	26709	110	0.4%
Allosensitization	654	3	0.5%	26683	180	0.7%

(Continued)

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

Exhibit 12. Pre-Implant Potential Barriers to Heart Transplant

Detential Derviews to Heart Transplant	Н	OSPX-999	99	STS Intermacs			
Potential Barriers to Heart Transplant	N	Yes	%	Ν	Yes	%	
Chronic Renal Disease	656	30	4.6%	26734	2030	7.6%	
Large BMI	659	71	10.8%	26748	3288	12.3%	
Chronic Infectious Concerns	654	1	0.2%	26728	229	0.9%	

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 GENERAI HEMODYNAMICS	HOSPX-9999	STS Intermacs	
Heart Rate	Ν	781	32482
	Mean	92.04	90.00
	Std	17.37	17.89
	Min	55.00	31.00
	Мах	175.00	198.00
Diastolic Blood Pressure (mmHg)	Ν	763	31903
	Mean	65.44	65.65
	Std	11.85	11.75
	Min	25.00	20.00
	Мах	110.00	120.00
Systolic Blood Pressure (mmHg)	Ν	768	32019
	Mean	105.44	105.20
	Std	16.77	16.40
	Min	53.00	44.00
	Мах	163.00	193.00
All	Ν	806	33741

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.

PRE-IMPLANT LVEDD (cm)		< 2014	2014 - 2017	2018 - 2021 (Jan-Jun)	TOTAL
LVEDD (CIII)		× 2014	2014 - 2017	(Jan-Jun)	TOTAL
	Ν	199	273	217	689
	Mean	6.57	6.83	6.66	6.70
	Std	1.21	1.07	1.10	1.13
	Min	1.10	3.74	3.21	1.10
	Max	10.00	10.10	9.50	10.10

GROUP=HOSPX-9999

GROUP=STS Intermacs

PRE-IMPLANT LVEDD (cm)		< 2014	2014 - 2017	2018 - 2021 (Jan-Jun)	TOTAL		
N	1	7699	9416	7877	24992		
N	<i>l</i> lean	6.79	6.78	6.73	6.77		
S	Std	1.18	1.13	1.08	1.13		
N	/lin	1.00	1.20	1.60	1.00		
N	lax	10.00	20.00	15.00	20.00		

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.

	HOSPX-9999							STS Intermacs								
PRE-IMPLANT LVEF	< 2014		2018 - 20 2014 - 2017 (Jan-Ju					< 2014		2014 - 2017		2018 - 2021 (Jan-Jun)		TOTAL		
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
> 50 (normal)	1	0.4 %	2	0.6 %	-	-	3	0.3 %	67	0.6 %	33	0.2 %	26	0.2 %	126	0.3 %
40-49 (mild)	1	0.4 %	2	0.6 %	-	-	3	0.3 %	60	0.5 %	59	0.4 %	36	0.3 %	155	0.4 %
30-39 (moderate)	22	9.6 %	9	2.9 %	8	3.3 %	39	5.0 %	431	4.2 %	415	3.4 %	314	3.2 %	1160	3.6 %
20-29 (moderate/severe)	77	33.9 %	68	22.5 %	52	21.7 %	197	25.6 %	2332	22.7 %	2911	24.3 %	2360	24.4 %	7603	23.8 %
< 20 (severe)	113	49.7 %	205	68.1 %	177	74.0 %	495	64.5 %	6819	66.5 %	7932	66.4 %	6520	67.5 %	21271	66.7 %
Not Recorded or Not Documented	12	5.2 %	10	3.3 %	2	0.8 %	24	3.1 %	478	4.6 %	531	4.4 %	367	3.7 %	1376	4.3 %
Unknown	1	0.4 %	5	1.6 %			6	0.7 %	57	0.5 %	62	0.5 %	36	0.3 %	155	0.4 %
TOTAL	227	100.0 %	301	100.0 %	239	100.0 %	767	100.0 %	10244	100.0 %	11943	100.0 %	9659	100.0 %	31846	100.0 %

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.

				HOSP	X-9999							STS Int	ermacs			
PRE-IMPLANT RVEF	< 2	014	2014 -	2017	2018 - (Jan-		то	TAL	< 2	014	2014	- 2017	2018 (Jan-	- 2021 Jun)	тот	ſAL
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Normal	27	11.8 %	71	23.5 %	63	26.3 %	161	20.9 %	1461	14.2 %	2457	20.5 %	2171	22.4 %	6089	19.1 %
Mild	15	6.6 %	76	25.2 %	81	33.8 %	172	22.4 %	1380	13.4 %	2664	22.3 %	2331	24.1 %	6375	20.0 %
Moderate	37	16.2 %	75	24.9 %	61	25.5 %	173	22.5 %	1909	18.6 %	2854	23.8 %	2324	24.0 %	7087	22.2 %
Severe	21	9.2 %	34	11.2 %	12	5.0 %	67	8.7 %	1214	11.8 %	1535	12.8 %	1223	12.6 %	3972	12.4 %
Not Done	65	28.6 %	17	5.6 %	4	1.6 %	86	11.2 %	2745	26.7 %	1512	12.6 %	933	9.6 %	5190	16.2 %
Not Applicable (v4)	-		2	0.6 %	2	0.8 %	4	0.5 %	-		25	0.2 %	24	0.2 %	49	0.1 %
Unknown	62	27.3 %	26	8.6 %	16	6.6 %	104	13.5 %	1535	14.9 %	896	7.5 %	653	6.7 %	3084	9.6 %
TOTAL	227	100.0 %	301	100.0 %	239	100.0 %	767	100.0 %	10244	100.0 %	11943	100.0 %	9659	100.0 %	31846	100.0 %

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.

		HOSPX-9999								STS Intermacs							
PRE-IMPLANT MITRAL REGURGITATION	< 2	014	2014 ·	2017	2018 (Jan	- 2021 -Jun)	то	FAL	< 2	014	2014	- 2017	2018 - (Jan-		то	ΓAL	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	
0 (none)	15	6.6 %	28	9.3 %	28	11.7 %	71	9.2 %	783	7.6 %	873	7.3 %	743	7.6 %	2399	7.5 %	
1 (mild)	94	41.4 %	103	34.2 %	83	34.7 %	280	36.5 %	3341	32.6 %	3892	32.5 %	3260	33.7 %	10493	32.9 %	
2 (moderate)	75	33.0 %	93	30.8 %	63	26.3 %	231	30.1 %	3229	31.5 %	3653	30.5 %	2939	30.4 %	9821	30.8 %	
3 (severe)	33	14.5 %	52	17.2 %	51	21.3 %	136	17.7 %	2224	21.7 %	2652	22.2 %	2028	20.9 %	6904	21.6 %	
Not Recorded or Not Documented	10	4.4 %	25	8.3 %	14	5.8 %	49	6.3 %	578	5.6 %	873	7.3 %	689	7.1 %	2140	6.7 %	
~Unknown~			-			•			89	0.8 %					89	0.2 %	
TOTAL	227	100.0 %	301	100.0 %	239	100.0 %	767	100.0 %	10244	100.0 %	11943	100.0 %	9659	100.0 %	31846	100.0 %	

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.

				HOSP	X-9999				STS Intermacs							
PRE-IMPLANT AORTIC REGURGITATION	< 2	< 2014 2014 - 2017			2018 - 2021 (Jan-Jun)		то	TOTAL		014	2014 - 2017		2018 - 2021 (Jan-Jun)		тот	ſAL
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
0 (none)	136	59.9 %	165	54.8 %	88	36.8 %	389	50.7 %	5982	58.3 %	6484	54.2 %	5168	53.5 %	17634	55.3 %
1 (mild)	63	27.7 %	71	23.5 %	61	25.5 %	195	25.4 %	2524	24.6 %	3291	27.5 %	2805	29.0 %	8620	27.0 %
2 (moderate)	7	3.0 %	12	3.9 %	5	2.0 %	24	3.1 %	338	3.2 %	410	3.4 %	338	3.4 %	1086	3.4 %
3 (severe)	1	0.4 %	2	0.6 %	3	1.2 %	6	0.7 %	69	0.6 %	66	0.5 %	65	0.6 %	200	0.6 %
Not Recorded or Not Documented	20	8.8 %	51	16.9 %	82	34.3 %	153	19.9 %	1331	12.9 %	1692	14.1 %	1283	13.2 %	4306	13.5 %
TOTAL	227	100.0 %	301	100.0 %	239	100.0 %	767	100.0 %	10244	100.0 %	11943	100.0 %	9659	100.0 %	31846	100.0 %

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.

		HOSPX-9999								STS Intermacs								
PRE-IMPLANT TRICUSPID REGURGITATION	< 2	014	2014 ·	- 2017	2018 · (Jan·	- 2021 -Jun)	то	FAL	< 2	014	2014	- 2017	2018 - (Jan-	-	тот	TAL		
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%		
0 (none)	23	10.1 %	26	8.6 %	32	13.3 %	81	10.5 %	1046	10.2 %	978	8.1 %	962	9.9 %	2986	9.3 %		
1 (mild)	115	50.6 %	120	39.8 %	111	46.4 %	346	45.1 %	4182	40.8 %	5358	44.8 %	4263	44.1 %	13803	43.3 %		
2 (moderate)	69	30.3 %	89	29.5 %	65	27.1 %	223	29.0 %	2991	29.1 %	3279	27.4 %	2590	26.8 %	8860	27.8 %		
3 (severe)	10	4.4 %	43	14.2 %	17	7.1 %	70	9.1 %	1240	12.1 %	1370	11.4 %	1064	11.0 %	3674	11.5 %		
Not Recorded or Not Documented	10	4.4 %	23	7.6 %	14	5.8 %	47	6.1 %	639	6.2 %	958	8.0 %	780	8.0 %	2377	7.4 %		
~Unknown~									146	1.4 %					146	0.4 %		
TOTAL	227	100.0 %	301	100.0 %	239	100.0 %	767	100.0 %	10244	100.0 %	11943	100.0 %	9659	100.0 %	31846	100.0 %		

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)	Ν	678	27114
	Mean	49.60	49.53
	Std	14.25	14.90
	Min	1.00	0.00
	Max	90.00	100.00
Pulmonary Artery Diastolic Pressure (mmHg)	Ν	678	26980
	Mean	24.25	24.94
	Std	8.09	8.85
	Min	2.00	0.00
	Max	60.00	60.00
~Mean RA Pressure (mmHg)~	Ν	543	20736
	Mean	20.32	13.11
	Std	12.17	8.32
	Min	0.00	-4.00
	Мах	54.00	55.00
Mean Pulmonary Artery Capillary Wedge Pressure (mmHg)	Ν	500	21197
	Mean	24.12	24.86
	Std	9.61	9.27
	Min	2.00	0.00
	Мах	50.00	50.00
Cardiac Index	Ν	581	21955
	Mean	2.39	2.19
	Std	1.21	1.47
	Min	0.60	0.17
	Мах	17.00	176.00
Cardiac Output (L/min)	Ν	651	25379
	Mean	4.49	4.24
	Std	1.60	1.45
	Min	0.40	0.33
	Мах	13.10	15.01
All	Ν	806	33741

II.A. Pre-Implant Summaries - Hemodynamics

Exhibit 16. ECG Cardiac Rhythm

				HOSP	X-9999							STS Int	ermacs			
ECG CARDIAC RHYTHM	< 2	014	2014 -	2017		- 2021 -Jun)	тот	ΓAL	< 2	014	2014	- 2017	2018 - (Jan-	- 2021 Jun)	то	ΓAL
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Sinus	109	45.0 %	127	42.1 %	141	58.9 %	377	48.2 %	4708	42.4 %	5855	49.0 %	5300	54.8 %	15863	48.5 %
Atrial fibrillation	19	7.8 %	32	10.6 %	17	7.1 %	68	8.6 %	993	8.9 %	994	8.3 %	662	6.8 %	2649	8.1 %
Atrial Flutter	1	0.4 %	5	1.6 %	2	0.8 %	8	1.0 %	107	0.9 %	121	1.0 %	103	1.0 %	331	1.0 %
Not done	2	0.8 %	3	0.9 %	2	0.8 %	7	0.8 %	160	1.4 %	194	1.6 %	126	1.3 %	480	1.4 %
Atrial Paced, Ventricular Sensed	3	1.2 %	2	0.6 %	5	2.0 %	10	1.2 %	89	0.8 %	246	2.0 %	192	1.9 %	527	1.6 %
Atrial Sensed, Ventricular Paced	21	8.6 %	70	23.2 %	28	11.7 %	119	15.2 %	693	6.2 %	2096	17.5 %	1535	15.8 %	4324	13.2 %
Atrial Paced, Ventricular Paced	5	2.0 %	20	6.6 %	24	10.0 %	49	6.2 %	331	2.9 %	1177	9.8 %	857	8.8 %	2365	7.2 %
Junctional (v6)				-									1	0.0 %	1	0.0 %
Unknown	4	1.6 %	5	1.6 %	3	1.2 %	12	1.5 %	293	2.6 %	275	2.3 %	204	2.1 %	772	2.3 %
Other, specify	78	32.2 %	37	12.2 %	17	7.1 %	132	16.8 %	3726	33.5 %	985	8.2 %	679	7.0 %	5390	16.4 %
TOTAL	242	100.0 %	301	100.0 %	239	100.0 %	782	100.0 %	11100	100.0 %	11943	100.0 %	9659	100.0 %	32702	100.0 %

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

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.

		HOSPX-9999								STS Intermacs							
PRE-IMPLANT NYHA CLASS	< 2	014	2014 ·	- 2017	2018 - (Jan-	- 2021 Jun)	то	AL	< 2	014	2014 ·	- 2017	2018 - (Jan-	-	то	ΓAL	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	
Class I					1	0.4 %	1	0.1 %	13	0.1 %	14	0.1 %	24	0.2 %	51	0.1 %	
Class II	1	0.4 %	2	0.6 %	7	2.9 %	10	1.2 %	46	0.4 %	108	0.9 %	138	1.4 %	292	0.8 %	
Class III	40	16.5 %	39	12.9 %	21	8.7 %	100	12.7 %	1889	17.0 %	1696	14.2 %	1216	12.5 %	4801	14.6 %	
Class IV	186	76.8 %	251	83.3 %	205	85.7 %	642	82.0 %	8195	73.8 %	9656	80.8 %	8083	83.6 %	25934	79.3 %	
Unknown	15	6.1 %	9	2.9 %	5	2.0 %	29	3.7 %	953	8.5 %	468	3.9 %	198	2.0 %	1619	4.9 %	
TOTAL	242	100.0 %	301	100.0 %	239	100.0 %	782	100.0 %	11096	100.0 %	11942	100.0 %	9659	100.0 %	32697	100.0 %	

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)	Ν	17	2840
	Mean	11.81	17.99
	Std	6.61	97.07
	Min	4.00	0.00
	Max	35.00	2800.00
All	Ν	806	33741

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

VO2 MAX - Reason for Incomplete	HOSP	X-9999	STS Intermacs					
incomplete	N	%	N	%				
Not Done: Other	374	48.9	13283	44.5				
Not Done: Too Sick	235	30.7	13205	44.2				
Unknown	156	20.4	3373	11.3				
TOTAL	765	100	29861	100				

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 PEAK		HOSPX-9999	STS Intermacs
Peak R (%)	Ν	14	1730
	Mean	6.27	5.74
	Std	13.80	15.02
	Min	1.00	0.70
	Max	52.00	132.00
All	Ν	806	33741

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	HOSP	X-9999	STS Int	ermacs
incomplete	N	%	Ν	%
Not Done	557	72.5	26934	87.0
Unknown	211	27.5	4037	13.0
TOTAL	768	100	30971	100

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 WAL	K	HOSPX-9999	STS Intermacs
Six Minute Walk (ft)	Ν	140	6077
	Mean	759.09	829.14
	Std	333.02	1485.67
	Min	0.00	0.00
	Max	1500.00	110892.00
All	Ν	806	33741

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	HOSP	X-9999	STS Int	ermacs
Incomplete	N	%	N	%
Not Done: Other	209	32.6	8947	33.6
Not Done: Too Sick	337	52.5	16112	60.5
Unknown	96	15.0	1565	5.9
TOTAL	642	100	26624	100

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

Exhibit 18a. Quality of Life - EQ-5D Mobility

				HOSP	X-9999							STS Int	ermacs			
EQ-5D Mobility	< 20	<u> </u>		- 2017		- 2021 -Jun)	то	ΓAL	< 20	014	2014	- 2017		- 2021 -Jun)	тот	ΓAL
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
I have no problems in walking about	29	19.8 %	74	44.8 %	23	32.3 %	126	32.9 %	1616	28.0 %	1978	32.4 %	1628	35.4 %	5222	31.7 %
I have some problems in walking about	87	59.5 %	74	44.8 %	36	50.7 %	197	51.5 %	3157	54.7 %	3172	52.0 %	2269	49.4 %	8598	52.2 %
I am confined to bed	29	19.8 %	16	9.6 %	11	15.4 %	56	14.6 %	916	15.8 %	819	13.4 %	543	11.8 %	2278	13.8 %
Unknown	1	0.6 %	1	0.6 %	1	1.4 %	3	0.7 %	76	1.3 %	124	2.0 %	151	3.2 %	351	2.1 %
TOTAL	146	100.0 %	165	100.0 %	71	100.0 %	382	100.0 %	5765	100.0 %	6093	100.0 %	4591	100.0 %	16449	100.0 %

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

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.

				HOSP	X-9999							STS Int	ermacs			
EQ-5D Self Care	< 2			2017		- 2021 -Jun)	то	ſAL	< 20	014	2014 -	2017	2018 - (Jan-	- 2021 Jun)	тот	AL
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
I have no problems with self-care	73	50.0 %	96	58.1 %	39	54.9 %	208	54.4 %	3136	54.3 %	3427	56.2 %	2598	56.5 %	9161	55.6 %
I have some problems washing or dressing myself	49	33.5 %	48	29.0 %	20	28.1 %	117	30.6 %	1856	32.1 %	1899	31.1 %	1370	29.8 %	5125	31.1 %
I am unable to wash or dress myself	22	15.0 %	20	12.1 %	11	15.4 %	53	13.8 %	696	12.0 %	651	10.6 %	472	10.2 %	1819	11.0 %
Unknown	2	1.3 %	1	0.6 %	1	1.4 %	4	1.0 %	77	1.3 %	116	1.9 %	151	3.2 %	344	2.0 %
TOTAL	146	100.0 %	165	100.0 %	71	100.0 %	382	100.0 %	5765	100.0 %	6093	100.0 %	4591	100.0 %	16449	100.0 %

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.

				HOSP	X-9999							STS Int	ermacs			
EQ-5D Usual Activities	< 2	014	2014	- 2017	2018 (Jan-	- 2021 -Jun)	то	AL	< 2	014	2014 ·	2017	2018 - (Jan-	- 2021 Jun)	тот	TAL
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
I have no problems with performing my usual activities	24	16.4 %	43	26.0 %	14	19.7 %	81	21.2 %	1021	17.7 %	1109	18.2 %	1033	22.5 %	3163	19.2 %
I have some problems with performing my usual activities	72	49.3 %	73	44.2 %	30	42.2 %	175	45.8 %	2720	47.1 %	2961	48.5 %	2154	46.9 %	7835	47.6 %
I am unable to perform my usual activities	49	33.5 %	49	29.6 %	25	35.2 %	123	32.1 %	1940	33.6 %	1867	30.6 %	1228	26.7 %	5035	30.6 %
Unknown	1	0.6 %			2	2.8 %	3	0.7 %	84	1.4 %	156	2.5 %	176	3.8 %	416	2.5 %
TOTAL	146	100.0 %	165	100.0 %	71	100.0 %	382	100.0 %	5765	100.0 %	6093	100.0 %	4591	100.0 %	16449	100.0 %

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.

				HOSP	X-9999							STS Int	ermacs			
EQ-5D Pain/Discomfort	< 2			- 2017		- 2021 -Jun)	то	ſAL	< 2	014	2014 ·	2017	2018 - (Jan-	- 2021 Jun)	тот	AL
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
I have no pain or discomfort	53	36.3 %	73	44.2 %	33	46.4 %	159	41.6 %	2439	42.3 %	2599	42.6 %	1943	42.3 %	6981	42.4 %
I have moderate pain or discomfort	72	49.3 %	77	46.6 %	29	40.8 %	178	46.5 %	2789	48.3 %	2864	47.0 %	2144	46.7 %	7797	47.4 %
I have extreme pain or discomfort	20	13.6 %	13	7.8 %	8	11.2 %	41	10.7 %	460	7.9 %	495	8.1 %	325	7.0 %	1280	7.7 %
Unknown	1	0.6 %	2	1.2 %	1	1.4 %	4	1.0 %	77	1.3 %	135	2.2 %	179	3.8 %	391	2.3 %
TOTAL	146	100.0 %	165	100.0 %	71	100.0 %	382	100.0 %	5765	100.0 %	6093	100.0 %	4591	100.0 %	16449	100.0 %

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.

				HOSP	X-9999							STS Int	ermacs			
EQ-5D Anxiety	< 2			- 2017		- 2021 -Jun)	то	ſAL	< 2	014	2014 -	- 2017	2018 - (Jan-	- 2021 Jun)	тот	AL
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
I am not anxious or depressed	68	46.5 %	94	56.9 %	36	50.7 %	198	51.8 %	2627	45.5 %	2795	45.8 %	2115	46.0 %	7537	45.8 %
I am moderately anxious or depressed	63	43.1 %	63	38.1 %	32	45.0 %	158	41.3 %	2618	45.4 %	2683	44.0 %	1986	43.2 %	7287	44.3 %
I am extremely anxious or depressed	13	8.9 %	6	3.6 %	2	2.8 %	21	5.4 %	431	7.4 %	449	7.3 %	300	6.5 %	1180	7.1 %
Unknown	2	1.3 %	2	1.2 %	1	1.4 %	5	1.3 %	89	1.5 %	166	2.7 %	190	4.1 %	445	2.7 %
TOTAL	146	100.0 %	165	100.0 %	71	100.0 %	382	100.0 %	5765	100.0 %	6093	100.0 %	4591	100.0 %	16449	100.0 %

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

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

The following table compares the EQ-5D Visual Analog Scale domain between your site and STS Intermacs.

GROUP=HOSPX-9999

D - VAS core	< 2014	2014 - 2017	2018 - 2021 (Jan-Jun)	TOTAL
Ν	146	157	67	370
Mean	39.07	49.64	44.06	44.46
Std	28.02	26.47	24.51	27.11
Min	0.00	0.00	0.00	0.00
Max	100.00	100.00	92.00	100.00

 D - VAS core	< 2014	2014 - 2017	2018 - 2021 (Jan-Jun)	TOTAL
Ν	5591	5818	4265	15674
Mean	43.25	46.37	48.52	45.84
Std	24.82	23.76	24.06	24.31
Min	0.00	0.00	0.00	0.00
Max	100.00	100.00	100.00	100.00

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.

				HOSP	K-9999							STS Inte	ermacs			
Patient Reasons for Incomplete EQ-5D	< 20	014	2014	- 2017	2018 (Jan-		тот	ſAL	< 20	014	2014	- 2017	2018 - (Jan-		тот	'AL
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Too sick (ex., intubated/sedated, critically ill, on short-term VAD)	53	56.9 %	67	52.3 %	58	35.8 %	178	46.4 %	2252	45.0 %	2524	47.2 %	1735	39.3 %	6511	44.1 %
Too tired	4	4.3 %	3	2.3 %	10	6.1 %	17	4.4 %	141	2.8 %	174	3.2 %	120	2.7 %	435	2.9 %
Too stressed, anxious, and/or depressed			11	8.5 %	1	0.6 %	12	3.1 %	159	3.1 %	251	4.6 %	193	4.3 %	603	4.0 %
No time / too busy	1	1.0 %	2	1.5 %	19	11.7 %	22	5.7 %	243	4.8 %	375	7.0 %	379	8.5 %	997	6.7 %
Too much trouble / don't want to be bothered / not interested			13	10.1 %	8	4.9 %	21	5.4 %	40	0.7 %	111	2.0 %	81	1.8 %	232	1.5 %
Can't concentrate	2	2.1 %	2	1.5 %			4	1.0 %	39	0.7 %	45	0.8 %	34	0.7 %	118	0.7 %
Unwilling to complete instrument, no reason given	1	1.0 %	12	9.3 %	9	5.5 %	22	5.7 %	60	1.1 %	162	3.0 %	115	2.6 %	337	2.2 %
Unable to read English and/or illiterate	3	3.2 %			2	1.2 %	5	1.3 %	42	0.8 %	61	1.1 %	40	0.9 %	143	0.9 %
Administrative (check specific reason below)	7	7.5 %	18	14.0 %	55	33.9 %	80	20.8 %	957	19.1 %	1638	30.6 %	1717	38.8 %	4312	29.2 %
Other/Unknown	22	23.6 %					22	5.7 %	1069	21.3 %					1069	7.2 %
TOTAL	93	100.0 %	128	100.0 %	162	100.0 %	383	100.0 %	5002	100.0 %	5341	100.0 %	4414	100.0 %	14757	100.0 %

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.

				HOSP	X-9999							STS Inte	ermacs			
Administrative Reasons for Incomplete EQ-5D	< 2	< 2014		- 2017	2018 (Jan		тот	ΓAL	< 20	014	2014	- 2017	2018 - (Jan-	-	тот	AL
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Urgent/emergent implant, no time to administer QOL instruments			5	26.3 %	5	9.0 %	10	11.6 %	30	2.2 %	137	8.3 %	117	6.8 %	284	6.0 %
Coordinator too busy or forgot to administer QOL instruments	7	58.3 %	9	47.3 %	48	87.2 %	64	74.4 %	479	35.3 %	866	52.7 %	913	53.1 %	2258	47.8 %
Unable to contact patient (ie., not hospitalized or no clinic visit) within the window for QOL instr					1	1.8 %	1	1.1 %	52	3.8 %	51	3.1 %	113	6.5 %	216	4.5 %
Other reason (describe)	5	41.6 %	5	26.3 %	1	1.8 %	11	12.7 %	793	58.5 %	589	35.8 %	574	33.4 %	1956	41.4 %
TOTAL	12	100.0 %	19	100.0 %	55	100.0 %	86	100.0 %	1354	100.0 %	1643	100.0 %	1717	100.0 %	4714	100.0 %

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.

ailmaking Time(s)	< 2014	2014 - 2017	2018 - 2021 (Jan-Jun)	TOTAL
Ν	116	104	35	255
Mean	167.09	152.85	136.49	157.08
Std	100.09	77.54	66.42	87.62
Min	3.00	58.00	46.00	3.00
Мах	560.00	545.00	342.00	560.00

GROUP=HOSPX-9999

iilmaking Time(s)	< 2014	2014 - 2017	2018 - 2021 (Jan-Jun)	TOTAL
Ν	4488	4165	2841	11494
Mean	149.25	136.34	144.65	143.43
Std	121.14	96.66	130.72	115.62
Min	1.00	4.00	6.00	1.00
Max	3600.00	3480.00	3600.00	3600.00

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.

	HOSP	X-9999	STS Intermacs		
VAD INDICATION	N	%	N	%	
Failure to wean from Cardio Pumonary Bypass	26	3.3 %	439	1.3 %	
Persistent Heart Failure Following Cardiac Surgery	12	1.5 %	482	1.5 %	
None	730	95.0 %	31093	97.1 %	
Total Patients	768	100.0 %	32014	100.0 %	

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.

		HOSP	X-9999				STS Intermacs									
Device Type	< 2	014	2014 ·	- 2017	2018 - (Jan-	- 2021 Jun)	то	TAL	< 2	014	2014 ·	2017	2018 - (Jan-	-	тот	AL
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
LVAD	227	93.8 %	288	95.6 %	251	95.4 %	766	95.0 %	10110	91.0 %	11191	93.7 %	10106	94.4 %	31407	93.0 %
RVAD	1	0.4 %					1	0.1 %	21	0.1 %	11	0.0 %	10	0.0 %	42	0.1 %
BiVAD	14	5.7 %	11	3.6 %	10	3.8 %	35	4.3 %	703	6.3 %	539	4.5 %	507	4.7 %	1749	5.1 %
ТАН			2	0.6 %	2	0.7 %	4	0.4 %	266	2.3 %	202	1.6 %	75	0.7 %	543	1.6 %
TOTAL	242	100.0 %	301	100.0 %	263	100.0 %	806	100.0 %	11100	100.0 %	11943	100.0 %	10698	100.0 %	33741	100.0 %

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.

		HOSPX-9999		STS Intermacs				
ADDITIONAL INTERVENTIONS	N	Yes	%	N	Yes	%		
IABP	769	132	17.17%	32018	6373	19.90%		
Dialysis	769	9	1.17%	32018	588	1.84%		
Ultrafiltration	769	6	0.78%	32018	249	0.78%		
Ventilator	769	41	5.33%	32018	2021	6.31%		
Feeding Tube	769	6	0.78%	32018	577	1.80%		
ECMO	769	15	1.95%	32018	1033	3.23%		
None	769	598	77.76%	32018	22991	71.81%		
CABG+	769	2	0.26%	32018	53	0.17%		
Aortic Valve Replacement/Repair+	769	1	0.13%	32018	45	0.14%		
Mitral Valve Replacement/Repair+	769	0	0.00%	32018	19	0.06%		
Congenital Cardiac Surgery+	769	0	0.00%	32018	5	0.02%		
LVAD+	769	1	0.13%	32018	580	1.81%		
RVAD+	769	2	0.26%	32018	160	0.50%		
TAH+	769	0	0.00%	32018	6	0.02%		
Aneurysmectomy+	769	0	0.00%	32018	3	0.01%		

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

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.

	Н	OSPX-99	99	ST	S Interm	acs
	Events	Patients	Patient Percent	Events	Patients	Patient Percent
Arterial Non-CNS Thromboembolism	6	6	0.7%	490	441	1.3%
Bleeding	400	226	28.0%	34548	14255	42.2%
Cardiac Arrhythmia	209	155	19.2%	16002	9609	28.5%
Device Malfunction and/or Pump Thrombosis	165	127	15.8%	13273	7989	23.7%
Hepatic Dysfunction	15	14	1.7%	1890	1712	5.1%
Infection	644	351	43.5%	39728	17445	51.7%
Myocardial Infarction	4	4	0.5%	229	206	0.6%
Neurological Dysfunction	219	173	21.5%	11916	8506	25.2%
Other Serious Adverse Event	230	130	16.1%	20799	10324	30.6%
Pericardial Drainage	20	18	2.2%	1602	1428	4.2%
Psychiatric Episode	19	14	1.7%	3264	2551	7.6%
Rehospitalization	2328	594	73.7%	121070	25055	74.3%
Renal Dysfunction	82	74	9.2%	6644	5509	16.3%
Respiratory Failure	142	110	13.6%	9912	7414	22.0%
Venous Thromboembolism	17	16	2.0%	1353	1247	3.7%
Wound Dehiscence	10	9	1.1%	625	557	1.7%

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	HOSPX-9999	STS Intermacs
Patient exposure during the first 3 months post implant (months)	2156	91725
Patient exposure after the first 3 months post implant (months)	15313	686498
Number of Patients	806	33741

II.C. Post Implant Summary - Adverse Event Rates

Exhibit 23c. Adverse Event Rates

			HOSP	X-9999		
	(During th	Early e First Thre	e Months)	(After the	Late First Three	Months)
	Episodes	Patient %	Rate (per 100 pt month)	Episodes	Patient %	Rate (per 100 pt month)
Arterial Non-CNS Thromboembolism	4	0.5%	0.19	2	0.2%	0.01
Bleeding	204	18.2%	9.46	196	14.6%	1.28
Cardiac Arrhythmia	120	13.2%	5.57	89	8.1%	0.58
Device Malfunction and/or Pump Thrombosis	32	3.3%	1.48	133	13.0%	0.87
Hepatic Dysfunction	10	1.1%	0.46	5	0.6%	0.03
Infection	202	19.4%	9.37	442	31.0%	2.89
Myocardial Infarction	3	0.4%	0.14	1	0.1%	0.01
Neurological Dysfunction	78	8.8%	3.62	141	14.1%	0.92
Other Serious Adverse Event	158	11.8%	7.33	72	5.8%	0.47
Pericardial Drainage	19	2.2%	0.88	1	0.1%	0.01
Psychiatric Episode	11	1.1%	0.51	8	0.7%	0.05
Rehospitalization	393	36.4%	18.23	1935	64.5%	12.64
Renal Dysfunction	60	6.8%	2.78	22	2.6%	0.14
Respiratory Failure	97	9.9%	4.50	45	4.7%	0.29
Venous Thromboembolism	14	1.6%	0.65	3	0.4%	0.02
Wound Dehiscence	10	1.1%	0.46			

GROUP=HOSPX-9999

			STS Int	ermacs		
	(During th	Early e First Thre	e Months)	(After the	Late First Three	Months)
	Episodes	Patient %	Rate (per 100 pt month)	Episodes	Patient %	Rate (per 100 pt month)
Arterial Non-CNS Thromboembolism	305	0.8%	0.33	185	0.5%	0.03
Bleeding	14585	26.8%	15.90	19963	25.0%	2.91
Cardiac Arrhythmia	8975	19.6%	9.78	7027	12.7%	1.02
Device Malfunction and/or Pump Thrombosis	2595	6.5%	2.83	10678	19.4%	1.56
Hepatic Dysfunction	929	2.6%	1.01	961	2.6%	0.14
Infection	13607	27.5%	14.83	26121	35.7%	3.80
Myocardial Infarction	88	0.3%	0.10	141	0.4%	0.02
Neurological Dysfunction	4193	10.8%	4.57	7723	16.4%	1.12
Other Serious Adverse Event	10447	19.2%	11.39	10352	16.7%	1.51
Pericardial Drainage	1540	4.1%	1.68	62	0.2%	0.01
Psychiatric Episode	1765	4.8%	1.92	1499	3.4%	0.22
Rehospitalization	18824	36.4%	20.52	102246	66.8%	14.89
Renal Dysfunction	3941	10.7%	4.30	2703	6.5%	0.39
Respiratory Failure	6927	16.5%	7.55	2985	7.2%	0.43
Venous Thromboembolism	1074	3.0%	1.17	279	0.8%	0.04
Wound Dehiscence	442	1.2%	0.48	183	0.5%	0.03

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.

			HOSP	X-9999			
	(During th	Early e First Thre	e Months)	Late (After the First Three Months)			
	Episodes	Patient %	Rate (per 100 pt month)	Episodes	Patient %	Rate (per 100 pt month)	
GI	12	1.4%	0.56	11	1.1%	0.07	
Line Sepsis	9	1.1%	0.42	9	0.9%	0.06	
Mediastinum	8	0.9%	0.37	1	0.1%	0.01	
Other Specify	26	3.2%	1.21	52	5.5%	0.34	
Peripheral Wound	2	0.2%	0.09	10	1.0%	0.07	
Positive Blood Cultures	39	4.5%	1.81	72	6.9%	0.47	
Pulmonary	57	6.5%	2.64	37	4.3%	0.24	
Pump/Related - Drive Line	37	4.6%	1.72	237	18.9%	1.55	
Pump/Related - Exit Cannula	2	0.2%	0.09	6	0.6%	0.04	
Pump/Related - Pump Interior	1	0.1%	0.05	7	0.7%	0.05	
Pump/Related - Pump Pocket	2	0.2%	0.09	7	0.9%	0.05	
Unknown	4	0.5%	0.19	8	0.9%	0.05	
Urinary Tract	38	4.2%	1.76	52	5.6%	0.34	

GROUP=HOSPX-9999

			STS Int	ermacs			
	(During th	Early e First Thre	e Months)	Late (After the First Three Months)			
	Episodes	Patient %	Rate (per 100 pt month)	Episodes	Patient %	Rate (per 100 pt month)	
GI	1063	2.9%	1.16	1311	3.3%	0.19	
Line Sepsis	428	1.2%	0.47	562	1.5%	0.08	
Mediastinum	591	1.6%	0.64	447	1.1%	0.07	
Other Specify	1916	5.1%	2.09	3548	8.2%	0.52	
Peripheral Wound	414	1.2%	0.45	670	1.7%	0.10	
Positive Blood Cultures	2767	7.3%	3.02	7076	14.1%	1.03	
Pulmonary	4167	10.5%	4.54	3467	7.9%	0.51	
Pump/Related - Drive Line	1228	3.4%	1.34	9247	16.4%	1.35	
Pump/Related - Exit Cannula	39	0.1%	0.04	216	0.6%	0.03	
Pump/Related - Pump Interior	39	0.1%	0.04	136	0.4%	0.02	
Pump/Related - Pump Pocket	354	1.0%	0.39	900	2.2%	0.13	
Unknown	410	1.1%	0.45	525	1.4%	0.08	
Urinary Tract	2541	6.6%	2.77	3270	6.8%	0.48	

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.

			HOSP	K-9999		
	(During th	Early e First Thre	e Months)	(After the	Late First Three	e Months)
	Episodes	Patient %	Rate (per 100 pt month)	Episodes	Patient %	Rate (per 100 pt month)
Device anastamosis	1	0.1%	0.05	•		
ENT / Dental	9	0.9%	0.43	23	1.5%	0.16
GI OVERALL: upper, lower, unknown	79	8.5%	3.80	137	11.7%	0.92
GI: Lower gastrointestinal (colon, rectum, and anus)	23	2.6%	1.11	32	3.6%	0.22
GI: Upper gastrointestinal (esophagus, stomach, duo	42	4.9%	2.02	57	5.7%	0.38
GI: unknown, but guaiac positive stools	17	2.1%	0.82	52	5.8%	0.35
Intra-abdominal	3	0.4%	0.14	2	0.3%	0.01
Mediastinal: Unspecified	20	2.2%	0.96	-		
Mediastinal: chest wall	5	0.6%	0.24	1	0.1%	0.01
Mediastinal: coagulopathy with no surgical site	4	0.5%	0.19	-		
Mediastinal: inflow conduit	1	0.1%	0.05	-		
Mediastinal: other surgical site	2	0.3%	0.10	-		
Mediastinal: outflow-aorta anastomosis	2	0.3%	0.10	-		
Other	40	4.8%	1.93	22	2.2%	0.15
Pleural space	9	1.2%	0.43	1	0.1%	0.01
Pulmonary	1	0.1%	0.05	4	0.4%	0.03
Pump Pocket	8	0.9%	0.39	1	0.1%	0.01
Retroperitoneal	4	0.5%	0.19	2	0.3%	0.01
Urinary tract	4	0.5%	0.19	4	0.5%	0.03

GROUP=HOSPX-9999

			STS Int	ermacs		
	(During th	Early e First Thre	e Months)	(After the	Late First Three	Months)
	Episodes	Patient %	Rate (per 100 pt month)	Episodes	Patient %	Rate (per 100 pt month)
Device anastamosis	113	0.3%	0.13	105	0.2%	0.02
ENT / Dental	595	1.6%	0.67	1204	2.5%	0.18
GI OVERALL: upper, lower, unknown	5775	12.5%	6.54	13768	18.8%	2.06
GI: Lower gastrointestinal (colon, rectum, and anus)	1716	4.3%	1.94	3367	7.0%	0.50
GI: Upper gastrointestinal (esophagus, stomach, duo	2912	6.8%	3.30	6954	11.7%	1.04
GI: unknown, but guaiac positive stools	1486	3.9%	1.68	4008	7.5%	0.60
Intra-abdominal	171	0.5%	0.19	276	0.8%	0.04
Mediastinal: Unspecified	1779	4.7%	2.01	92	0.2%	0.01
Mediastinal: aortic-venous cannulation site	34	0.1%	0.04	2	0.0%	0.00
Mediastinal: chest wall	1059	3.0%	1.20	88	0.3%	0.01
Mediastinal: coagulopathy with no surgical site	287	0.8%	0.32	14	0.0%	0.00
Mediastinal: inflow conduit	38	0.1%	0.04	5	0.0%	0.00
Mediastinal: other surgical site	349	1.0%	0.40	59	0.2%	0.01
Mediastinal: outflow conduit	73	0.2%	0.08	18	0.1%	0.00

II.C. Post Implant Summary - Adverse Event Rates

Exhibit 23e. Bleeding Rates by Source

GRO	UP=	STS	Intermacs	
UNU	01-	515	multimats	

	STS Intermacs						
	(During th	Early e First Thre	e Months)	Late (After the First Three Months)			
	Episodes Patient % Rate (per 100 pt month)			Episodes	Patient %	Rate (per 100 pt month)	
Mediastinal: outflow-aorta anastomosis	117	0.3%	0.13	11	0.0%	0.00	
Other	2936	7.0%	3.32	3715	8.4%	0.56	
Pleural space	656	1.8%	0.74	65	0.2%	0.01	
Pulmonary	291	0.8%	0.33	134	0.3%	0.02	
Pump Pocket	276	0.8%	0.31	76	0.2%	0.01	
Retroperitoneal	134	0.4%	0.15	150	0.4%	0.02	
Urinary tract	179	0.5%	0.20	319	0.8%	0.05	

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).

HOSPX-9999 Early Late (During the First Three Months) (After the First Three Months) Rate Rate (per 100 pt (per 100 pt **Episodes** Patient % **Episodes** Patient % month) month) 0.7% 0.35 4.6% 0.32 **Device Malfunction** 5 29 Pump Thrombosis 13 1.9% 0.91 45 6.3% 0.50

GROUP=HOSPX-9999

	STS Intermacs							
	(During th	Early e First Thre	e Months)	Late (After the First Three Months)				
	Episodes	Patient %	Rate (per 100 pt month)	Episodes	Patient %	Rate (per 100 pt month)		
Device Malfunction	636	2.6%	1.09	2516	8.4%	0.65		
Pump Thrombosis	853	3.4%	1.46	2494	8.6%	0.65		

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).

	HOSPX-9999								
	(During th	Early e First Thre	e Months)	Late (After the First Three Months)					
	Episodes	bisodes Patient % Rate (per 100 pt month)			Patient %	Rate (per 100 pt month)			
CVA	37	4.3%	2.06	Episodes 64	7.4%	0.52			
Confusion	4	0.5%	0.22	13	1.4%	0.11			
Encephalopathy	7	0.9%	0.39	9	1.0%	0.07			
Seizure	13 1.6%		0.73	6	0.5%	0.05			
TIA	3	0.4%	0.17	17	1.9%	0.14			

GROUP=HOSPX-9999

	STS Intermacs								
	(During th	Early e First Thre	e Months)	Late (After the First Three Months)					
	Episodes	odes Patient % Rate (per 100 pt month)			Patient %	Rate (per 100 pt month)			
CVA	2021	5.4%	2.73	3884	9.2%	0.73			
Confusion	262	0.7%	0.35	516	1.3%	0.10			
Encephalopathy	464	1.3%	0.63	434	1.1%	0.08			
Seizure	266	0.8%	0.36	332	0.8%	0.06			
TIA	326	0.9%	0.44	785	2.0%	0.15			
Unspecified	•	•		1	0.0%	0.00			

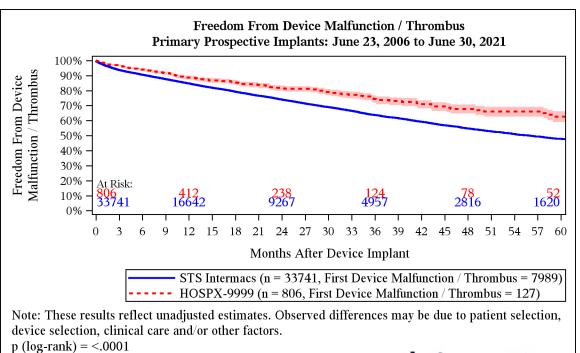


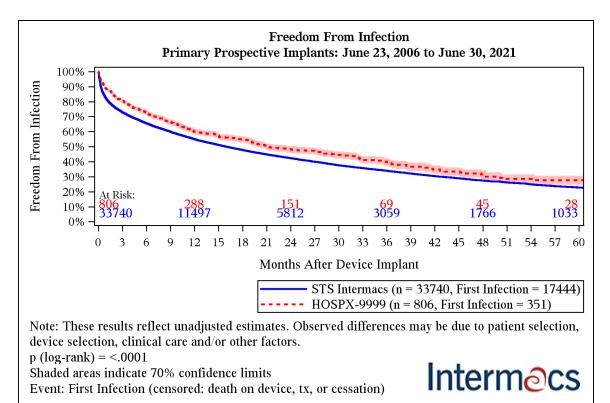
Exhibit 24a. Time to First Device Malfunction / Thrombus

Shaded areas indicate 70% confidence limits Event: First DM / Throm (censored death on device, tx, or cessation)

Months after Device Implant	STS Intermacs	HOSPX-9999
1	97.2% (97.1%-97.3%)	98.5% (97.9%-98.8%)
3	93.7% (93.6%-93.9%)	96.8% (96.1%-97.4%)
6	90.5% (90.4%-90.7%)	94.1% (93.1%-94.9%)
9	87.6% (87.4%-87.8%)	91.7% (90.5%-92.7%)
12	84.7% (84.5%-85.0%)	88.7% (87.3%-89.9%)
24	74.0% (73.7%-74.3%)	81.8% (80.0%-83.6%)
36	63.8% (63.4%-64.2%)	74.3% (71.7%-76.6%)
48	54.8% (54.3%-55.3%)	67.8% (64.7%-70.8%)
60	47.8% (47.2%-48.4%)	62.7% (59.0%-66.2%)

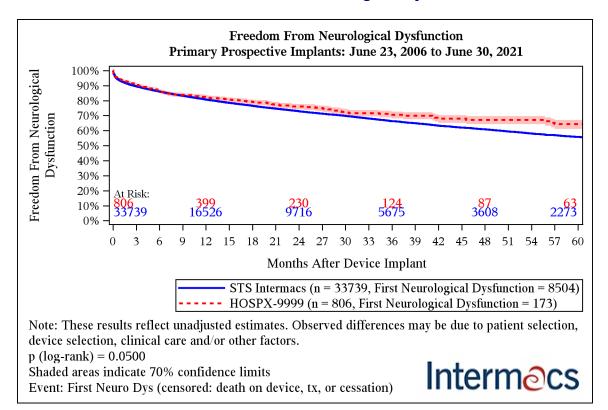
Interm_@cs

Exhibit 24b. Time to First Infection



Months after Device Implant	STS Intermacs	HOSPX-9999
1	81.9% (81.7%-82.1%)	88.5% (87.4%-89.6%)
3	73.0% (72.7%-73.2%)	80.7% (79.2%-82.1%)
6	65.6% (65.3%-65.9%)	72.6% (70.9%-74.3%)
9	60.0% (59.7%-60.3%)	66.5% (64.6%-68.3%)
12	54.9% (54.6%-55.2%)	59.9% (57.9%-61.9%)
24	42.3% (42.0%-42.6%)	48.2% (46.0%-50.5%)
36	33.9% (33.5%-34.2%)	39.5% (36.9%-42.1%)
48	27.5% (27.1%-27.9%)	31.4% (28.5%-34.3%)
60	22.7% (22.3%-23.2%)	27.6% (24.6%-30.6%)

Exhibit 24c. Time to First Neurological Dysfunction



Months after Device Implant	STS Intermacs	HOSPX-9999
1	93.1% (93.0%-93.2%)	94.0% (93.1%-94.8%)
3	89.5% (89.3%-89.7%)	90.8% (89.7%-91.8%)
6	86.1% (85.9%-86.3%)	86.6% (85.3%-87.8%)
9	83.2% (83.0%-83.5%)	83.7% (82.2%-85.0%)
12	80.7% (80.5%-80.9%)	82.3% (80.7%-83.7%)
24	72.9% (72.6%-73.2%)	76.0% (74.1%-77.8%)
36	66.3% (66.0%-66.7%)	70.5% (68.2%-72.7%)
48	60.8% (60.4%-61.3%)	67.1% (64.4%-69.7%)
60	55.8% (55.3%-56.3%)	64.3% (61.2%-67.2%)

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.

	AL DAYS CHARGED		HOSP	X-9999			STS Intermacs			
PATI	ENTS	< 2014	2014 - 2017	2018 - 2021 (Jan-Jun)	TOTAL	< 2014	2014 - 2017	2018 - 2021 (Jan-Jun)	TOTAL	
All	Ν	215	265	215	695	9658	10367	9250	29275	
	Mean	28.25	25.23	28.48	27.17	27.59	25.64	26.79	26.65	
	Std	48.22	19.77	23.57	32.24	33.14	26.23	28.19	29.29	
	Median	18	18	21	19	20	19	20	20	
	Min	8	0	8	0	0	0	0	0	
	Max	581	154	179	581	1492	1131	916	1492	
BiVAD	N	6	8	6	20	395	299	316	1010	
	Mean	60.33	44.25	64.83	55.25	55.07	47.31	48.19	50.62	
	Std	32.14	34.26	57.13	40.63	42.57	38.16	44.33	42.00	
	Median	49	36	44	44	44	37	38	40	
	Min	32	0	29	0	0	0	0	0	
	Max	113	98	179	179	400	433	396	433	
LVAD	N	209	257	208	674	9162	9988	8902	28052	
	Mean	27.33	24.64	27.10	26.23	25.51	24.70	25.91	25.35	
	Std	48.35	18.95	20.78	31.52	28.04	25.09	26.92	26.67	
	Median	18	18	21	19	20	19	20	19	
	Min	8	7	8	7	0	0	0	0	
	Max	581	154	141	581	1492	1131	916	1492	
RVAD	Ν					14	7	3	24	
	Mean					56.43	34.14	22.00	45.63	
	Std			-		42.04	33.22	18.03	38.72	
	Median					48	22	17	32	
	Min			-		8	13	7	7	
	Max			-		156	106	42	156	
TAH	Ν			1	1	87	73	29	189	
	Mean			98.00	98.00	117.43	65.05	61.86	88.67	
	Std					136.84	44.92	57.95	102.71	
	Median			98	98	76	51	54	58	
	Min			98	98	25	14	16	14	
	Max			98	98	916	212	331	916	

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.

				Devic	е Туре					
20 D			LVAD			BiVAD		TOTAL		
Disc		Alive on	Patients with 30 day Readmission	% With 30 day Readmission	Alive on	Patients with 30 day Readmission	With 30 day	Alive on	Patients with 30 day Readmission	% With 30 day Readmission
Discharge Year										
	2006	2	0	0.0%				2	0	0.0%
	2007	3	1	33.3%		-	-	3	1	33.3%
	2008	16	4	25.0%		-	-	16	4	25.0%
	2009	21	2	9.5%	1	0	0.0%	22	2	9.1%
	2010	27	7	25.9%	2	1	50.0%	29	8	27.6%
	2011	29	10	34.5%	2	2	100.0%	31	12	38.7%
	2012	44	13	29.5%	1	1	100.0%	45	14	31.1%
	2013	62	19	30.6%		-	-	62	19	30.6%
	2014	58	17	29.3%	2	1	50.0%	60	18	30.0%
	2015	84	19	22.6%		-	-	84	19	22.6%
	2016	80	22	27.5%	3	1	33.3%	83	23	27.7%
	2017	34	11	32.4%	3	0	0.0%	37	11	29.7%
	2018	65	15	23.1%	1	1	100.0%	66	16	24.2%
	2019	85	18	21.2%	4	2	50.0%	89	20	22.5%
	2020	49	12	24.5%				49	12	24.5%
	2021	13	4	30.8%	1	0	0.0%	14	4	28.6%
	TOTAL	672	174	25.9%	20	9	45.0%	692	183	26.4%

GROUP=HOSPX-9999

II.C. Post Implant Summary - 30 Day Readmission

Exhibit 26. 30 Days Readmission

GROUP=STS	Intermacs
------------------	-----------

						Device Type					
20 0	21/		LVAD			RVAD		BiVAD			
30 Day Readmission		Patients Discharged Alive on Device (n)	Patients with 30 day Readmission	% With 30 day Readmission	Alive on	Patients with 30 day Readmission	With 30 day	Alive on	Patients with 30 day Readmission	% With 30 day Readmission	
Discharge Year											
	2006	60	17	28.3%				5	2	40.0%	
	2007	188	46	24.5%	4	2	50.0%	31	11	35.5%	
	2008	540	136	25.2%		-	-	42	15	35.7%	
	2009	795	185	23.3%		-	-	52	16	30.8%	
	2010	1415	357	25.2%	2	0	0.0%	68	19	27.9%	
	2011	1666	472	28.3%	1	1	100.0%	61	17	27.9%	
	2012	1999	567	28.4%	2	1	50.0%	53	16	30.2%	
	2013	2389	769	32.2%	3	0	0.0%	63	16	25.4%	
	2014	2417	694	28.7%	2	1	50.0%	83	21	25.3%	
	2015	2694	804	29.8%	4	3	75.0%	69	23	33.3%	
	2016	2552	725	28.4%		-	-	72	18	25.0%	
	2017	2188	651	29.8%		-	-	62	23	37.1%	
	2018	2612	722	27.6%		-	-	85	19	22.4%	
	2019	2900	753	26.0%				96	36	37.5%	
	2020	2453	595	24.3%	1	0	0.0%	92	25	27.2%	
	2021	1053	237	22.5%		-		51	11	21.6%	
	TOTAL	27921	7730	27.7%	19	8	42.1%	985	288	29.2%	

30 Day Readmission			Device Type TAH		TOTAL			
		Patients Discharged Patients with Alive on 30 day		% With 30 day Readmission	Alive on	Patients with 30 day	% With 30 day Readmission	
Discharge Year								
	2006	-			65	19	29.2%	
	2007	3	0	0.0%	226	59	26.1%	
	2008	1	0	0.0%	583	151	25.9%	
	2009		-	-	847	201	23.7%	
	2010	2	1	50.0%	1487	377	25.4%	
	2011	14	3	21.4%	1742	493	28.3%	
	2012	16	6	37.5%	2070	590	28.5%	
	2013	16	4	25.0%	2471	789	31.9%	
	2014	23	10	43.5%	2525	726	28.8%	
	2015	18	6	33.3%	2785	836	30.0%	
	2016	17	8	47.1%	2641	751	28.4%	
	2017	16	7	43.8%	2266	681	30.1%	
	2018	8	4	50.0%	2705	745	27.5%	
	2019	14	4	28.6%	3010	793	26.3%	
	2020	5	4	80.0%	2551	624	24.5%	
	2021	2	1	50.0%	1106	249	22.5%	
	TOTAL	155	58	37.4%	29080	8084	27.8%	

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.

COMPLETION STATUS Not VISIT Done: Patients Not Done: Тоо **Other/Unknown** Sick Outlier Complete Six Minute Walk (ft) (n) Ν % Ν % Ν % % Mean Std Median Min Max Ν Ν 329 337 41.8 Pre-Implant 806 40.8 140 17.4 759.1 333.0 750.0 0.0 1500.0 3 Month 614 301 49.0 52 8.5 1 0.2 260 42.3 949.0 369.7 1000.0 42.0 1850.0 6 Month 528 374 70.8 21 4.0 3 0.6 130 24.6 974.6 360.1 1020.0 50.0 2130.0 297 2.8 1 Year 391 76.0 11 83 21.2 1013.6 322.6 1050.0 335.0 1620.0 996.8 363.6 220 171 77.7 4 45 20.5 1000.0 200.0 1700.0 2 Year 1.8 3 Year 106 98 92.5 3 2.8 5 4.7 1216.0 255.9 1200.0 840.0 1500.0 71 65 6 8.5 1022.8 223.9 1057.5 672.0 1300.0 4 Year 91.5 5 Year 31 25 80.6 3 9.7 3 9.7 898.3 517.5 900.0 380.0 1415.0

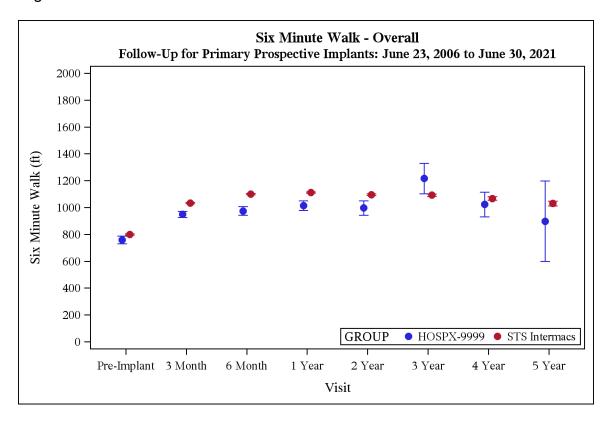
GROUP=HOSPX-9999

			COM	IPLETI	ON S	ΤΑΤ	US							
VISIT	Patients (n)	Not D Other/U		Not D Too S		Out	lier	Com	plete		Six Mi	nute Wa	lk (ft)	
	N	Ν	%	Ν	%	Ν	%	Ν	%	Mean	Std	Median	Min	Мах
Pre-Implant	33741	11552	34.2	16112	47.8	15	0.0	6062	18.0	799.9	374.9	800.0	0.0	2388.0
3 Month	27048	15419	57.0	2666	9.9	20	0.1	8943	33.1	1033.3	369.0	1060.0	1.0	2400.0
6 Month	23486	13148	56.0	1749	7.4	38	0.2	8551	36.4	1100.2	375.2	1131.0	1.0	2400.0
1 Year	17258	9917	57.5	1144	6.6	20	0.1	6177	35.8	1111.5	378.7	1150.0	1.0	2400.0
2 Year	9794	5869	59.9	693	7.1	8	0.1	3224	32.9	1096.3	373.5	1130.0	14.0	2400.0
3 Year	5539	3481	62.8	419	7.6	2	0.0	1637	29.6	1092.1	372.5	1106.0	15.0	2359.0
4 Year	3244	2124	65.5	257	7.9	2	0.1	861	26.5	1068.0	379.7	1100.0	5.0	2320.0
5 Year	1915	1277	66.7	151	7.9	3	0.2	484	25.3	1030.2	404.6	1068.0	0.0	2145.0

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.



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.

COMPLETION STATUS Not VISIT Done: Patients Not Done: Тоо **Other/Unknown** Sick Outlier Complete Six Minute Walk (ft) (n) Ν % Ν Ν % % Mean Std Median Min Max Ν % Ν 310 40.5 Pre-Implant 766 316 41.3 140 18.3 759.1 333.0 750.0 0.0 1500.0 3 Month 590 290 49.2 46 7.8 1 0.2 253 42.9 956.9 366.1 1000.0 42.0 1850.0 6 Month 511 368 72.0 18 3.5 3 0.6 122 23.9 986.1 352.3 1034.5 80.0 2130.0 376 289 2.7 1 Year 76.9 10 77 20.5 1018.9 311.4 1060.0 335.0 1620.0 212 168 79.2 4 40 18.9 1017.0 331.4 1007.5 200.0 1700.0 2 Year 1.9 3 Year 105 97 92.4 3 2.9 5 4.8 1216.0 255.9 1200.0 840.0 1500.0 70 64 91.4 6 8.6 1022.8 223.9 1057.5 672.0 1300.0 4 Year 5 Year 30 24 80.0 3 10.0 3 10.0 898.3 517.5 900.0 380.0 1415.0

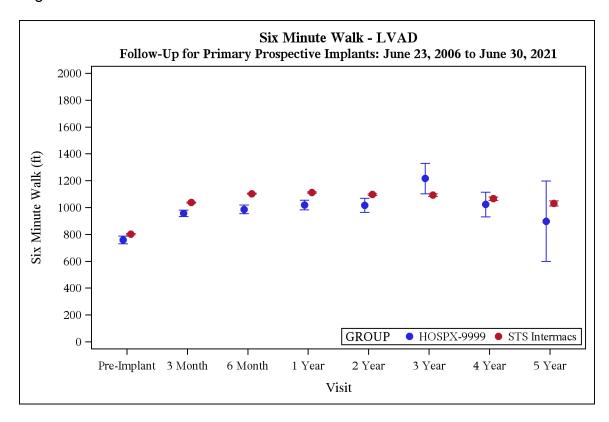
GROUP=HOSPX-9999

			COM	IPLETI	ON S	TAT	US							
VISIT	Patients (n)	Not D Other/U		Not D Too S		Out	lier	Com	plete		Six Mi	nute Wa	lk (ft)	
	Ν	N			%	Ν	%	Ν	%	Mean	Std	Median	Min	Max
Pre-Implant	31407	11084	35.3	14421	45.9	15	0.0	5887	18.7	801.7	374.8	800.0	0.0	2388.0
3 Month	25727	14729	57.3	2362	9.2	17	0.1	8619	33.5	1037.4	368.3	1067.0	1.0	2400.0
6 Month	22588	12675	56.1	1619	7.2	38	0.2	8256	36.6	1103.2	374.1	1135.0	1.0	2400.0
1 Year	16700	9587	57.4	1106	6.6	20	0.1	5987	35.9	1112.0	378.9	1150.0	1.0	2400.0
2 Year	9555	5724	59.9	673	7.0	8	0.1	3150	33.0	1097.0	373.9	1130.0	14.0	2400.0
3 Year	5421	3407	62.8	413	7.6	2	0.0	1599	29.5	1092.9	370.9	1108.0	15.0	2359.0
4 Year	3186	2089	65.6	255	8.0	2	0.1	840	26.4	1066.8	379.8	1100.0	5.0	2320.0
5 Year	1874	1253	66.9	149	8.0	3	0.2	469	25.0	1030.5	406.2	1066.0	0.0	2145.0

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.



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.

		С	OMPLET	ION	STA	TUS						
VISIT	Patients (n))one: nknown	Do T	lot one: oo ick	Com	plete		Six N	linute W	alk (ft)	
	Ν	Ν				Ν	%	Mean	Std	Median	Min	Max
Pre-Implant	35	12	34.3	23	65.7							
3 Month	21	10	47.6	4	19.0	7	33.3	662.7	416.3	825.0	175.0	1103.0
6 Month	16	6	37.5	2	12.5	8	50.0	798.8	453.5	875.0	50.0	1450.0
1 Year	15	8	53.3	1	6.7	6	40.0	945.5	475.8	907.5	373.0	1600.0
2 Year	8	3	37.5			5	62.5	835.0	588.9	825.0	200.0	1450.0
3 Year	1	1	100.0									
4 Year	1	1	100.0									
5 Year	1	1	100.0									

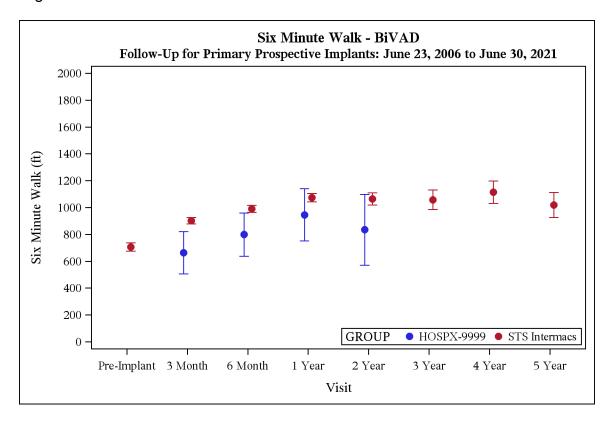
GROUP=HOSPX-9999

			сом	PLET		тат	ับร							
VISIT	Patients (n))one: nknown	No Doi Too	ne:	Out	lier	Com	plete		Six M	inute Wa	alk (ft)	
	Ν	N	382 21.8		%	Ν	%	Ν	%	Mean	Std	Median	Min	Max
Pre-Implant	1749	382	21.8	1237	70.7			130	7.4	706.6	357.0	671.0	100.0	1800.0
3 Month	988	538	54.5	216	21.9	2	0.2	232	23.5	902.7	362.9	912.5	15.0	2283.0
6 Month	722	387	53.6	105	14.5		•	230	31.9	991.6	398.6	1050.0	3.0	1871.0
1 Year	477	290	60.8	33	6.9		•	154	32.3	1074.0	373.7	1090.0	15.0	1951.0
2 Year	220	134	60.9	18	8.2		•	68	30.9	1064.0	368.5	1091.0	150.0	1738.0
3 Year	110	68	61.8	5	4.5			37	33.6	1058.2	443.0	1043.0	220.0	1774.0
4 Year	54	31	57.4	2	3.7			21	38.9	1115.0	383.2	1176.0	370.0	1721.0
5 Year	40	23	57.5	2	5.0			15	37.5	1019.7	361.4	1087.0	336.0	1570.0

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.



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=HOSPX-9999

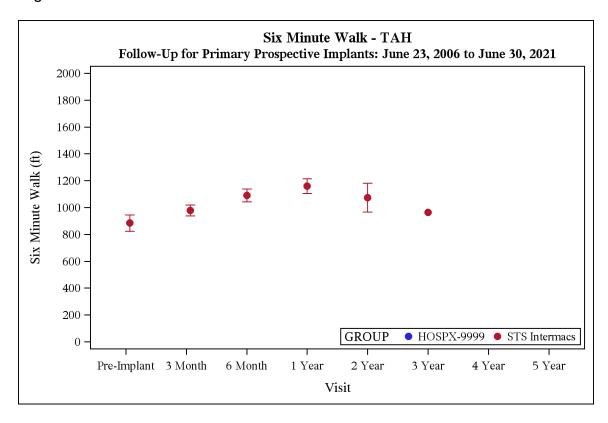
		СС	MPL	ETION S	TATUS					
VISIT	Patients (n)	Do To	ot ne: oo ick	Not E Other/U)one: nknown	Si	ix Mi	nute Wa	lk (ft)
	Ν	Ν	%	Ν	%	Mean	Std	Median	Min	Мах
Pre-Implant	4	3	75.0	1	25.0					
3 Month	2	1	50.0	1	50.0					-

			COMF	PLET		STA	TUS							
VISIT	Patients (n)	Not D Other/U		Do T	lot one: oo ick	Out	tlier	Com	nlete		Six M	inute Wa	alk (ft)	
	N	N	%	N	%	N	%	N	%	Mean		Median	Min	Мах
Pre-Implant	543	76	14.0	426	78.5			41	7.6	884.6	385.0	879.0	141.0	1947.0
3 Month	316	144	45.6	84	26.6	1	0.3	87	27.5	978.3	384.0	1018.0	50.0	2100.0
6 Month	165	78	47.3	24	14.5			63	38.2	1091.4	378.2	1126.0	300.0	2289.0
1 Year	76	36	47.4	5	6.6			35	46.1	1160.0	325.5	1182.0	100.0	1876.0
2 Year	17	9	52.9	2	11.8			6	35.3	1073.5	263.6	1093.5	667.0	1359.0
3 Year	6	4	66.7	1	16.7			1	16.7	965.0		965.0	965.0	965.0
4 Year	3	3	100.0											

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.



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.

		с	OMPLET	ION	STA	TUS						
VISIT				Do	ot ne: oo							
	Patients (n)		Not Done: Other/Unknown N %			Com	plete	vo	2 M	ax (mL/k	g/mir	1)
	Ν	Ν				Ν	%	Mean	Std	Median	Min	Max
Pre-Implant	806	554	235	29.2	17	2.1	11.8	6.6	10.5	4.0	35.0	
3 Month	614	580	32	5.2	2	0.3	12.0	2.8	12.0	10.0	14.0	
6 Month	528	507	19	3.6	2	0.4	10.5	2.1	10.5	9.0	12.0	
1 Year	391	382	97.7	8	2.0	1	0.3	9.0	•	9.0	9.0	9.0
2 Year	220	217	98.6	3	1.4				•	-	•	
3 Year	106	104							•	-	•	
4 Year	71	71	100.0									
5 Year	31	29	93.5	2	6.5							

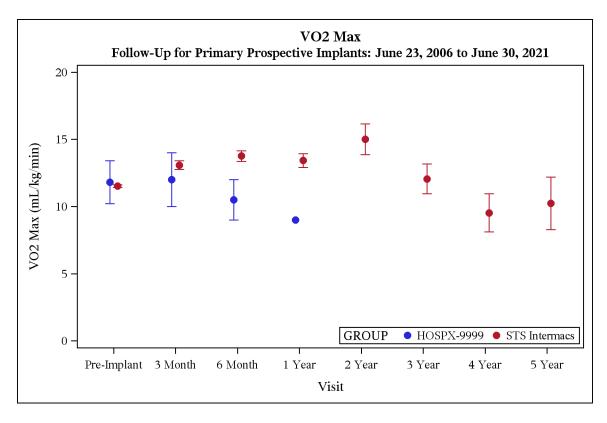
GROUP=HOSPX-9999

			CON	IPLETI	ON S	ТАТ	US	-						
VISIT	Patients (n)	Not D Other/U		Not D Too S		Out	lier	Com	plete	vo)2 M	ax (mL/k	g/mi	n)
	Ν	N			%	Ν	%	Ν	%	Mean	Std	Median	Min	Max
Pre-Implant	33741	17696	52.4	13205	39.1	35	0.1	2805	8.3	11.5	5.0	11.0	0.0	73.0
3 Month	27048	24854	91.9	1943	7.2	32	0.1	219	0.8	13.1	4.8	13.0	1.1	43.0
6 Month	23486	21999	93.7	1208	5.1	29	0.1	250	1.1	13.8	6.1	13.0	1.0	63.0
1 Year	17258	16349	94.7	745	4.3	22	0.1	142	0.8	13.4	6.1	13.0	1.0	53.0
2 Year	9794	9314	95.1	406	4.1	7	0.1	67	0.7	15.0	9.4	13.0	0.8	58.0
3 Year	5539	5292	95.5	223	4.0	5	0.1	19	0.3	12.1	4.8	11.2	5.7	24.5
4 Year	3244	3108	95.8	120	3.7	5	0.2	11	0.3	9.5	4.7	10.2	0.9	17.0
5 Year	1915	1829	95.5	76	4.0	3	0.2	7	0.4	10.2	5.2	11.6	0.0	17.0

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.



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.

		C	OMPLET	ION	STA	TUS						
VISIT	Patients (n)	Not E Other/U		Out	lier	Com	plete		P	eak R (%	5)	
	N	N	N % 792 98.3			Ν	%	Mean	Std	Median	Min	Max
Pre-Implant	806	792	98.3	3	0.4	11	1.4	1.1	0.1	1.1	1.0	1.3
3 Month	614	613	99.8	•		1	0.2	1.1		1.1	1.1	1.1
6 Month	528	526	99.6			2	0.4	1.2	0.0	1.2	1.2	1.2
1 Year	391	391	100.0									
2 Year	220	220	100.0									
3 Year	106	106	100.0									
4 Year	71	71	100.0									
5 Year	31	31	100.0									

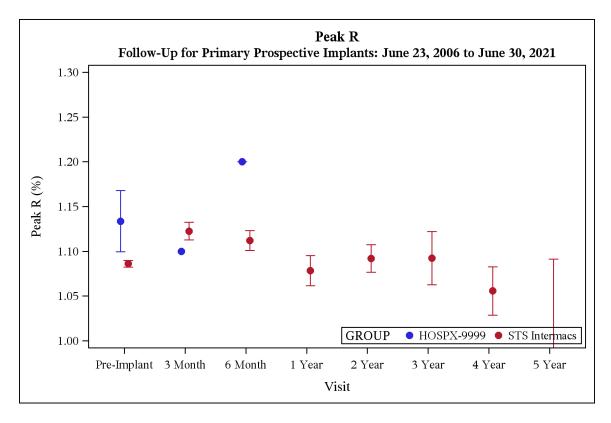
GROUP=HOSPX-9999

		C	OMPLET	ION	STA	TUS						
VISIT	Patients (n)	Not D Other/U		Out	lier	Com	plete		Р	eak R (%	5)	
	N	N			%	Ν	%	Mean	Std	Median	Min	Max
Pre-Implant	33741	32011	94.9	197	0.6	1533	4.5	1.1	0.2	1.1	0.7	3.4
3 Month	27048	26888	26888 99.4			150	0.6	1.1	0.1	1.1	0.8	1.4
6 Month	23486	23300				174	0.7	1.1	0.1	1.1	0.2	1.5
1 Year	17258	17143	99.3	9	0.1	106	0.6	1.1	0.2	1.1	0.0	1.4
2 Year	9794	9738	99.4	7	0.1	49	0.5	1.1	0.1	1.1	0.8	1.5
3 Year	5539	5521	99.7	1	0.0	17	0.3	1.1	0.1	1.1	0.9	1.4
4 Year	3244	3237	99.8		•	7	0.2	1.1	0.1	1.1	1.0	1.2
5 Year	1915	1908	99.6			7	0.4	0.9	0.4	1.1	0.0	1.2

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.



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.

		С	OMPLET	ION	STA	TUS						
VISIT	Defierate			Do	ot ne: oo							
	Patients (n)		Not Done: Other/Unknown N %			Com	plete	Gait	Spee	d (Feet/	Sec)	- DV
	Ν	Ν				Ν	%	Mean	Std	Median	Min	Max
Pre-Implant	806	575	71.3	206	25.6	25	3.1	2.0	0.6	2.1	0.7	3.0
3 Month	614	494	80.5	40	6.5	80	13.0	3.8	1.5	3.8	1.0	7.9
6 Month	528	436	82.6	16	3.0	76	14.4	3.9	1.6	3.8	1.5	9.9
1 Year	391	330	84.4	11	2.8	50	12.8	4.1	1.4	4.0	1.5	8.0
2 Year	220	181	82.3	5	2.3	34	15.5	4.0	1.4	4.1	0.8	6.8
3 Year	106	100	94.3	2	1.9	4	3.8	3.8	2.3	2.8	2.5	7.1
4 Year	71	64	90.1	1	1.4	6	8.5	3.5	0.8	3.4	2.5	4.8
5 Year	31	24	77.4	3	9.7	4	12.9	3.1	1.1	3.4	1.5	3.8

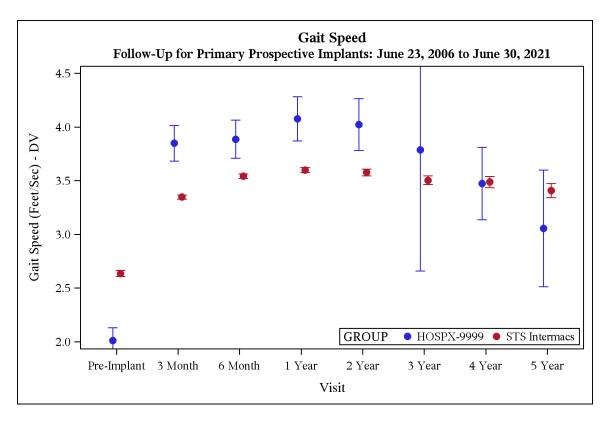
GROUP=HOSPX-9999

			CON	IPLETI	ON S	ТАТ	US							
VISIT	Patients (n)	Not D Other/U		Not D Too S		Out	lier	Com	plete	Gait	Spee	ed (Feet/	Sec)	- DV
	N	Ν			%	Ν	%	Ν	%	Mean	Std	Median	Min	Max
Pre-Implant	33741	19727	58.5	11833	35.1	32	0.1	2149	6.4	2.6	1.3	2.5	0.0	10.0
3 Month	27048	20288	75.0	2113	7.8	20	0.1	4627	17.1	3.3	1.3	3.2	0.0	10.0
6 Month	23486	17514	74.6	1393	5.9	15	0.1	4564	19.4	3.5	1.4	3.5	0.0	10.0
1 Year	17258	12850	74.5	937	5.4	15	0.1	3456	20.0	3.6	1.4	3.6	0.0	10.0
2 Year	9794	7217	73.7	612	6.2	14	0.1	1951	19.9	3.6	1.3	3.5	0.0	9.6
3 Year	5539	4131	74.6	374	6.8	4	0.1	1030	18.6	3.5	1.3	3.5	0.0	9.4
4 Year	3244	2461	75.9	224	6.9	2	0.1	557	17.2	3.5	1.2	3.5	0.0	8.3
5 Year	1915	1489	77.8	131	6.8	2	0.1	293	15.3	3.4	1.1	3.3	0.3	8.3

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.



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.

VISIT	Patients (n)		LETIO	N ST/ Com								
	N	N	%	N	%	Mean		Median	· ·	Max		
Pre-Implant	806	551	68.4	255	31.6	157.1	87.6	133.0	3.0	560.0		
3 Month	614	259	42.2	355	57.8	140.1	99.9	117.0	30.0	840.0		
6 Month	528	230	43.6	298	56.4	128.7	77.2	111.5	30.0	640.0		
1 Year	391	184	47.1	207	52.9	119.7	66.1	109.0	25.0	417.0		
2 Year	220	100	45.5	120	54.5	121.2	81.6	103.0	42.0	584.0		
3 Year	106	57	53.8	49	46.2	135.0	87.5	109.0	36.0	506.0		
4 Year	71	52	73.2	19	26.8	115.0	50.7	110.0	43.0	250.0		
5 Year	31	21	67.7	10	32.3	101.4	40.8	91.0	57.0	169.0		

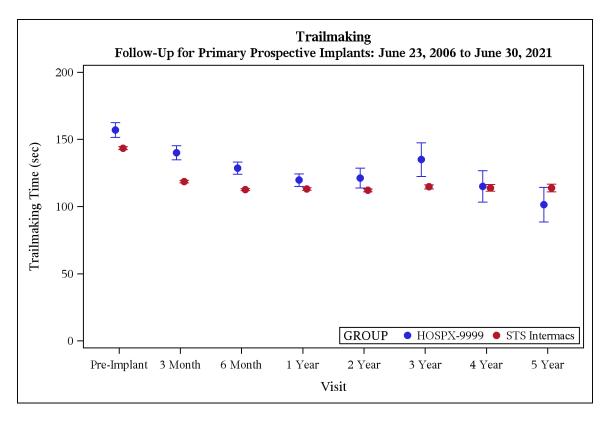
GROUP=HOSPX-9999

VISIT	Patients	_		ON STA		_			,	
_	(n)	Incom	plete	Comp	blete		railma	king Tin	ie (se	ec)
	Ν	Ν	%	Ν	%	Mean	Std	Median	Min	Max
Pre-Implant	33741	22247	65.9	11494	34.1	143.4	115.6	120.0	1.0	3600.0
3 Month	27048	16421	60.7	10627	39.3	118.6	90.0	100.0	1.0	3479.0
6 Month	23486	13530	57.6	9956	42.4	112.6	69.8	95.0	1.0	1360.0
1 Year	17258	9944	57.6	7314	42.4	113.1	75.8	95.0	5.0	2134.0
2 Year	9794	5908	60.3	3886	39.7	112.1	66.0	96.0	2.0	919.0
3 Year	5539	3520	63.5	2019	36.5	114.7	70.6	97.0	1.0	960.0
4 Year	3244	2170	66.9	1074	33.1	113.9	82.4	96.0	3.0	1848.0
5 Year	1915	1334	69.7	581	30.3	113.8	69.6	96.0	20.0	680.0

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.



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.

		COMP	LETION	STAT	US					
VISIT	Patients (n)	Not E Other/U		Com	plete		N	HA Clas	s	
	Ν	Ν	%	Ν	%	Mean	Std	Median	Min	Мах
Pre-Implant	806	53	6.6	753	93.4	3.8	0.4	4.0	1.0	4.0
3 Month	614	69	11.2	545	88.8	2.2	1.0	2.0	1.0	4.0
6 Month	528	67	12.7	461	87.3	2.0	0.9	2.0	1.0	4.0
1 Year	391	47	12.0	344	88.0	1.8	0.8	2.0	1.0	4.0
2 Year	220	31	14.1	189	85.9	1.8	0.8	2.0	1.0	4.0
3 Year	106	9	8.5	97	91.5	1.9	0.8	2.0	1.0	4.0
4 Year	71	8	11.3	63	88.7	1.9	0.8	2.0	1.0	4.0
5 Year	31	2	6.5	29	93.5	2.0	0.9	2.0	1.0	4.0

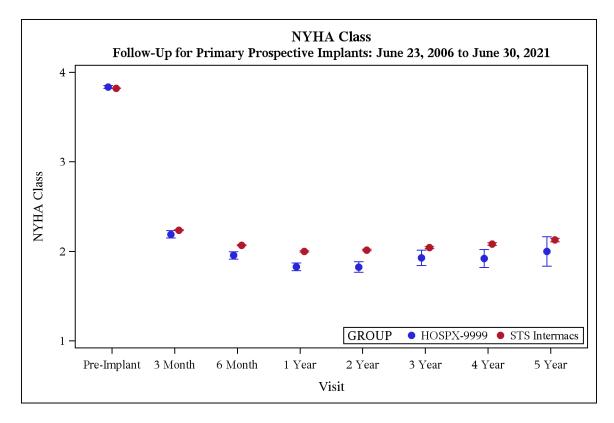
GROUP=HOSPX-9999

		сомі	PLETION	STATI	JS					
VISIT	Patients (n)		Not Done: Other/Unknown Complete				N	(HA Clas	S	
	N	N	%	Ν	%	Mean	Std	Median	Min	Max
Pre-Implant	33741	2663	7.9	31078	92.1	3.8	0.4	4.0	1.0	4.0
3 Month	27048	5132	19.0	21916	81.0	2.2	0.8	2.0	1.0	4.0
6 Month	23486	3967	16.9	19519	83.1	2.1	0.8	2.0	1.0	4.0
1 Year	17258	2683	15.5	14575	84.5	2.0	0.8	2.0	1.0	4.0
2 Year	9794	1441	14.7	8353	85.3	2.0	0.8	2.0	1.0	4.0
3 Year	5539	825	14.9	4714	85.1	2.0	0.8	2.0	1.0	4.0
4 Year	3244	464	14.3	2780	85.7	2.1	0.8	2.0	1.0	4.0
5 Year	1915	275	14.4	1640	85.6	2.1	0.8	2.0	1.0	4.0

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.



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.

		С	OMPLET	ION	STA	TUS						
VISIT	Patients	Not D)000:	Do	ot ne: oo							
	(n)	Other/U		-	ick	Com	plete		EC	Q-5D Inde	ex	
	Ν	Ν	%	Ν	%	Ν	%	Mean	Std	Median	Min	Max
Pre-Implant	806	254	31.5	178	22.1	374	46.4	0.6	0.3	0.7	-0.1	1.0
3 Month	614	153	24.9	24	3.9	437	71.2	0.8	0.2	0.8	0.1	1.0
6 Month	528	139	26.3	11	2.1	378	71.6	0.8	0.2	0.8	-0.1	1.0
1 Year	391	127	32.5	3	0.8	261	66.8	0.8	0.2	0.8	-0.0	1.0
2 Year	220	64	29.1	1	0.5	155	70.5	0.8	0.2	0.8	0.2	1.0
3 Year	106	44	41.5	2	1.9	60	56.6	0.8	0.2	0.8	0.3	1.0
4 Year	71	39	54.9			32	45.1	0.8	0.1	0.8	0.5	1.0
5 Year	31	16	51.6	2	6.5	13	41.9	0.8	0.2	0.8	0.3	1.0

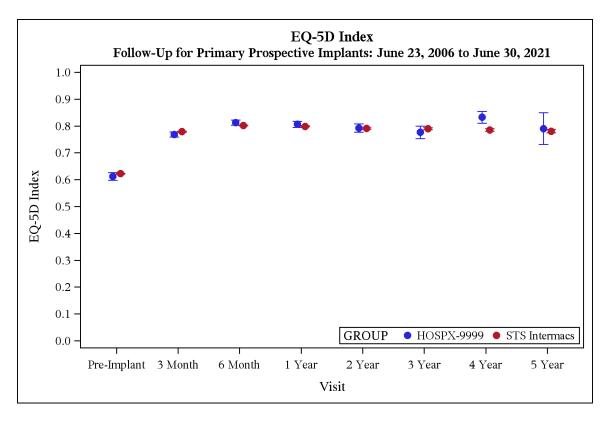
GROUP=HOSPX-9999

			COMPLE	TION	STA	rus						
VISIT	Patients (n)	Not E Other/U)one: nknown	No Doi Too	ne:	Comp	olete		EC	2-5D Inde	эх	
	N	Ν	%	Ν	%	Ν	%	Mean	Std	Median	Min	Max
Pre-Implant	33741	11518	34.1	6511	19.3	15712	46.6	0.6	0.3	0.7	-0.1	1.0
3 Month	27048	12362	45.7	1032	3.8	13654	50.5	0.8	0.2	0.8	-0.1	1.0
6 Month	23486	10064	42.9	525	2.2	12897	54.9	0.8	0.2	0.8	-0.1	1.0
1 Year	17258	7330	42.5	309	1.8	9619	55.7	0.8	0.2	0.8	-0.1	1.0
2 Year	9794	4339	44.3	155	1.6	5300	54.1	0.8	0.2	0.8	-0.1	1.0
3 Year	5539	2607	47.1	96	1.7	2836	51.2	0.8	0.2	0.8	-0.0	1.0
4 Year	3244	1610	49.6	50	1.5	1584	48.8	0.8	0.2	0.8	-0.1	1.0
5 Year	1915	1022	53.4	37	1.9	856	44.7	0.8	0.2	0.8	-0.0	1.0

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.



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.

		С	OMPLET	ION	STA ⁻	TUS						
VISIT	Patients (n)	Not E Other/U)one: nknown	Do To	ot ne: oo ck	Com	plete	VA	NS: O	wn Heal	th Sta	ate
	N	Ν	%	N	%	Ν	%	Mean	Std	Median	Min	Max
Pre-Implant	806	258	32.0	178	22.1	370	45.9	44.5	27.1	45.0	0.0	100.0
3 Month	614	146	23.8	24	3.9	444	72.3	71.8	22.3	80.0	3.0	100.0
6 Month	528	139	26.3	11	2.1	378	71.6	75.7	18.9	80.0	0.0	100.0
1 Year	391	123	31.5	3	0.8	265	67.8	76.3	18.4	80.0	10.0	100.0
2 Year	220	64	29.1	1	0.5	155	70.5	74.7	19.8	80.0	10.0	100.0
3 Year	106	43	40.6	2	1.9	61	57.5	70.3	20.7	80.0	10.0	100.0
4 Year	71	41	57.7			30	42.3	72.7	18.9	72.5	20.0	100.0
5 Year	31	16	51.6	2	6.5	13	41.9	72.6	27.6	80.0	0.0	100.0

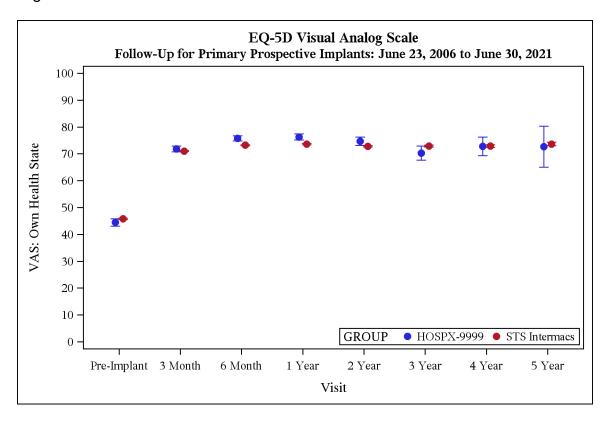
GROUP=HOSPX-9999

			COMPLE	TION	STA	TUS						
VISIT	Patients (n)	Not E Other/U		No Doi Too	ne:	Comp	olete	VA	S: 0	wn Healt	th Sta	ate
	Ν	N	%	Ν	%	Ν	%	Mean	Std	Median	Min	Max
Pre-Implant	33741	11557	34.3	6511	19.3	15673	46.5	45.8	24.3	45.0	0.0	100.0
3 Month	27048	12452	46.0	1032	3.8	13564	50.1	71.0	19.9	75.0	0.0	100.0
6 Month	23486	10204	43.4	525	2.2	12757	54.3	73.2	19.4	75.0	0.0	100.0
1 Year	17258	7490	43.4	309	1.8	9459	54.8	73.6	19.1	78.0	0.0	100.0
2 Year	9794	4421	45.1	155	1.6	5218	53.3	72.8	19.9	75.0	0.0	100.0
3 Year	5539	2649	47.8	96	1.7	2794	50.4	72.9	19.4	75.0	0.0	100.0
4 Year	3244	1610	49.6	50	1.5	1584	48.8	72.9	19.4	75.0	0.0	100.0
5 Year	1915	1026	53.6	37	1.9	852	44.5	73.7	19.0	80.0	0.0	100.0

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.



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.

		с	OMPLET	ION	STA ⁻	TUS						
VISIT	Patients	Not D)one:	Do	ot ne: oo							
	(n)		nknown	-	ick	Com	plete		ксо	CQ-12 Sc	ore	
	Ν	N	%	Ν	%	Ν	%	Mean	Std	Median	Min	Max
Pre-Implant	806	334	41.4	153	19.0	319	39.6	35.8	21.5	33.9	0.0	100.0
3 Month	614	224	36.5	20	3.3	370	60.3	62.7	21.7	66.7	0.0	100.0
6 Month	528	193	36.6	10	1.9	325	61.6	67.2	20.9	69.8	4.2	100.0
1 Year	391	149	38.1	3	0.8	239	61.1	66.7	21.4	69.3	10.4	100.0
2 Year	220	77	35.0			143	65.0	64.8	22.4	68.2	4.9	100.0
3 Year	106	43	40.6	2	1.9	61	57.5	62.0	23.1	66.1	9.4	100.0
4 Year	71	38	53.5			33	46.5	67.2	21.2	71.9	22.4	100.0
5 Year	31	16	51.6	2	6.5	13	41.9	65.4	28.2	74.0	6.3	100.0

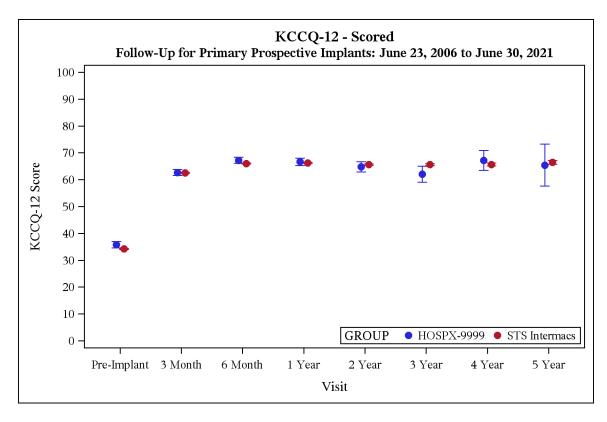
GROUP=HOSPX-9999

			COMPLE	TION	STA	TUS						
VISIT	Patients (n)	Not E Other/U)one: nknown	No Doi Too	ne:	Comp	olete		ксо	Q-12 Sc	ore	
	Ν	N	%	Ν	%	Ν	%	Mean	Std	Median	Min	Max
Pre-Implant	33741	15347	45.5	5257	15.6	13137	38.9	34.2	21.6	30.9	0.0	100.0
3 Month	27048	14109	52.2	860	3.2	12079	44.7	62.5	20.6	64.6	0.0	100.0
6 Month	23486	11250	47.9	440	1.9	11796	50.2	66.0	20.5	68.8	0.0	100.0
1 Year	17258	7985	46.3	267	1.5	9006	52.2	66.3	20.8	68.8	0.0	100.0
2 Year	9794	4305	44.0	147	1.5	5342	54.5	65.6	21.0	67.7	0.0	100.0
3 Year	5539	2496	45.1	96	1.7	2947	53.2	65.6	21.2	67.7	0.0	100.0
4 Year	3244	1495	46.1	52	1.6	1697	52.3	65.7	21.2	68.2	0.0	100.0
5 Year	1915	957	50.0	39	2.0	919	48.0	66.4	21.2	68.8	6.3	100.0

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.



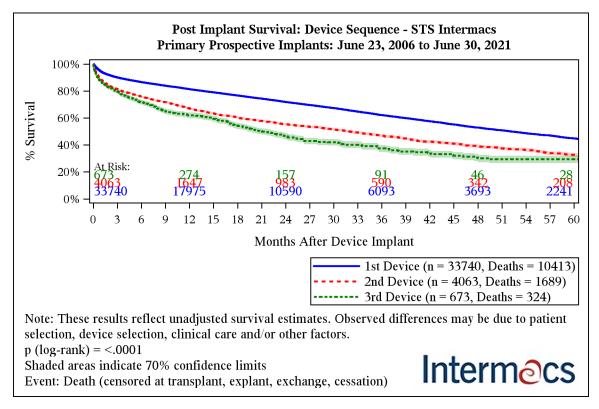
II.E. Post Implant Outcomes

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.

Exhibit 34a. Post Implant Survival - Device Sequence - STS Intermacs

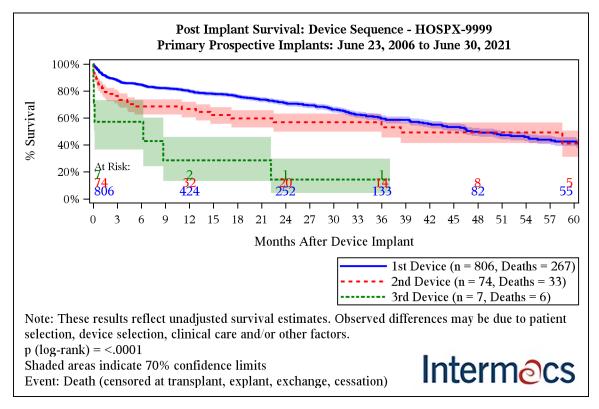
The following figure compares survival time on specific devices based on device sequence for all of STS Intermacs. Each curve represents survival from the time the device was implanted until death. Patients are censored at time of transplant, explant for any reason, or the device was turned off.



Months after Device Implant	1st Device	2nd Device	3rd Device
1	94.4% (94.2%-94.5%)	88.2% (87.7%-88.7%)	87.1% (85.7%-88.4%)
3	90.1% (89.9%-90.2%)	81.4% (80.7%-82.0%)	79.8% (78.1%-81.3%)
6	86.6% (86.4%-86.8%)	75.9% (75.2%-76.6%)	71.8% (69.9%-73.6%)
9	83.9% (83.7%-84.1%)	71.7% (70.9%-72.5%)	65.2% (63.2%-67.2%)
12	81.4% (81.1%-81.6%)	67.1% (66.2%-67.9%)	62.0% (59.9%-64.0%)
24	71.9% (71.6%-72.2%)	55.2% (54.2%-56.2%)	46.7% (44.4%-49.0%)
36	62.2% (61.8%-62.5%)	46.9% (45.8%-48.0%)	37.4% (34.9%-39.9%)
48	52.9% (52.5%-53.3%)	38.9% (37.7%-40.1%)	30.6% (28.0%-33.3%)
60	44.8% (44.3%-45.3%)	32.6% (31.3%-33.9%)	29.3% (26.6%-32.0%)

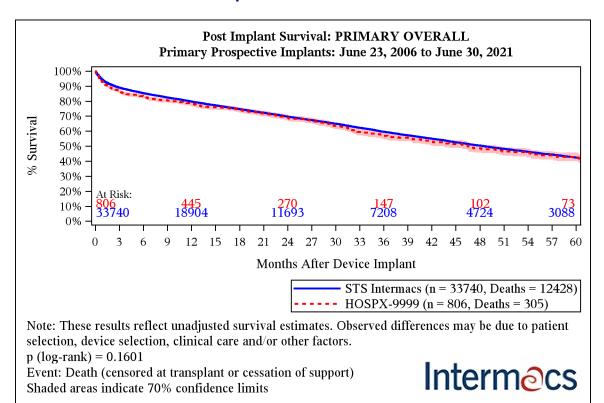
Exhibit 34b. Post Implant Survival - Device Sequence - HOSPX-9999

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.



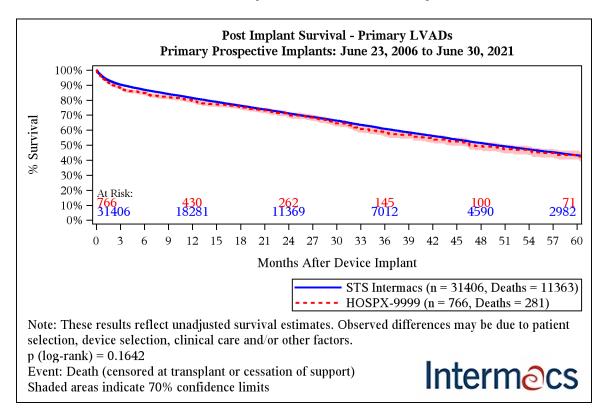
Months after Device Implant	1st Device	2nd Device	3rd Device
1	93.6% (92.7%-94.4%)	83.5% (78.6%-87.4%)	57.1% (36.6%-73.2%)
3	87.9% (86.6%-89.0%)	76.4% (70.9%-81.0%)	57.1% (36.6%-73.2%)
6	84.6% (83.2%-85.9%)	68.6% (62.6%-73.8%)	57.1% (36.6%-73.2%)
9	82.2% (80.8%-83.6%)	68.6% (62.6%-73.8%)	28.6% (13.3%-46.0%)
12	79.9% (78.3%-81.3%)	66.6% (60.5%-72.0%)	28.6% (13.3%-46.0%)
24	71.1% (69.2%-73.0%)	56.8% (49.8%-63.2%)	14.3% (4.4%-29.8%)
36	59.5% (57.0%-61.9%)	53.0% (45.5%-60.0%)	14.3% (4.4%-29.8%)
48	49.7% (46.7%-52.7%)	49.3% (41.4%-56.6%)	
60	42.5% (39.3%-45.8%)	41.0% (31.2%-50.7%)	

Exhibit 35. Post Implant Survival - PRIMARY OVERALL



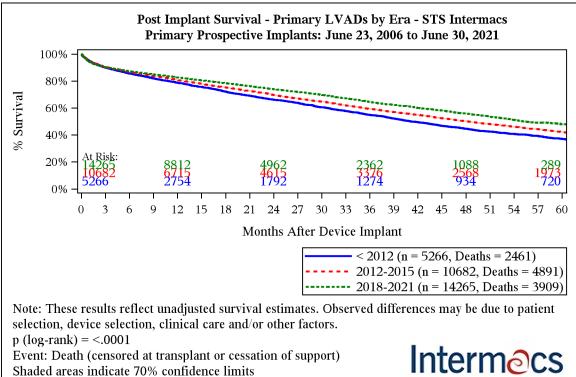
Months after Device Implant	STS Intermacs	HOSPX-9999
1	93.7% (93.6%-93.9%)	92.8% (91.8%-93.6%)
3	89.0% (88.8%-89.1%)	86.5% (85.3%-87.7%)
6	85.3% (85.1%-85.5%)	83.1% (81.7%-84.4%)
9	82.4% (82.2%-82.6%)	80.5% (79.0%-81.9%)
12	79.7% (79.5%-79.9%)	78.1% (76.5%-79.6%)
24	69.7% (69.4%-69.9%)	69.0% (67.0%-70.9%)
36	59.6% (59.2%-59.9%)	56.9% (54.4%-59.2%)
48	50.4% (50.0%-50.8%)	48.5% (45.7%-51.2%)
60	42.4% (41.9%-42.8%)	42.8% (39.9%-45.7%)

Exhibit 36. Post Implant Survival - Primary LVADs



Months after Device Implant	STS Intermacs	HOSPX-9999
1	94.7% (94.5%-94.8%)	94.1% (93.2%-94.9%)
3	90.3% (90.2%-90.5%)	88.0% (86.8%-89.2%)
6	86.8% (86.6%-87.0%)	84.6% (83.2%-85.9%)
9	84.0% (83.8%-84.3%)	82.0% (80.5%-83.4%)
12	81.4% (81.1%-81.6%)	79.5% (77.9%-81.0%)
24	71.1% (70.8%-71.4%)	70.4% (68.4%-72.3%)
36	60.9% (60.5%-61.2%)	58.1% (55.6%-60.5%)
48	51.4% (51.0%-51.9%)	49.4% (46.6%-52.1%)
60	43.2% (42.7%-43.6%)	43.5% (40.5%-46.4%)

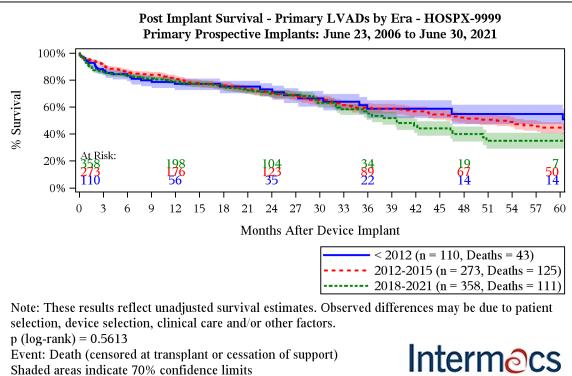
Exhibit 37a. Post Implant Survival - Primary LVADs by Era - STS Intermacs



Shaded areas indicate 70% confidence limits

Months after Device Implant		< 2012	2	012-2015	2	018-2021
1	94.9%	(94.6%-95.2%)	95.0%	(94.7%-95.2%)	94.4%	(94.2%-94.6%)
3	90.0%	(89.6%-90.4%)	90.5%	(90.2%-90.8%)	90.2%	(90.0%-90.5%)
6	85.5%	(85.0%-86.0%)	86.8%	(86.5%-87.1%)	87.3%	(87.0%-87.5%)
9	82.0%	(81.4%-82.5%)	83.8%	(83.4%-84.1%)	84.9%	(84.6%-85.2%)
12	78.7%	(78.1%-79.3%)	80.7%	(80.3%-81.1%)	82.6%	(82.3%-83.0%)
24	66.2%	(65.4%-67.0%)	69.7%	(69.2%-70.2%)	74.0%	(73.5%-74.4%)
36	54.9%	(54.0%-55.8%)	59.4%	(58.8%-59.9%)	64.5%	(64.0%-65.1%)
48	44.6%	(43.6%-45.5%)	50.2%	(49.6%-50.8%)	55.9%	(55.2%-56.6%)
60	37.1%	(36.1%-38.0%)	42.1%	(41.5%-42.7%)	47.9%	(46.9%-48.9%)

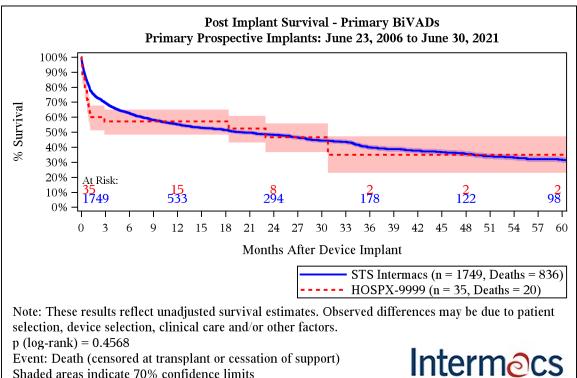
Exhibit 37b. Post Implant Survival - Primary LVADs by Era - HOSPX-9999



Event: Death (censored at transplant or cessation of support) Shaded areas indicate 70% confidence limits

Months after Device Implant		< 2012	2	012-2015	2	018-2021
1	94.5%	(91.9%-96.3%)	95.6%	(94.2%-96.7%)	92.7%	(91.2%-94.0%)
3	87.2%	(83.6%-90.0%)	91.1%	(89.2%-92.7%)	85.9%	(83.9%-87.6%)
6	83.2%	(79.2%-86.5%)	86.4%	(84.1%-88.4%)	83.5%	(81.4%-85.4%)
9	79.7%	(75.4%-83.4%)	83.9%	(81.4%-86.0%)	81.1%	(78.9%-83.1%)
12	77.2%	(72.6%-81.1%)	81.2%	(78.6%-83.5%)	78.9%	(76.5%-81.0%)
24	73.0%	(67.7%-77.6%)	70.5%	(67.3%-73.4%)	69.8%	(66.8%-72.6%)
36	58.7%	(51.8%-65.0%)	59.5%	(55.9%-62.9%)	55.1%	(50.6%-59.4%)
48	54.8%	(47.2%-61.7%)	52.1%	(48.3%-55.8%)	39.9%	(34.3%-45.5%)
60	54.8%	(47.2%-61.7%)	44.7%	(40.6%-48.6%)	34.9%	(29.1%-40.8%)

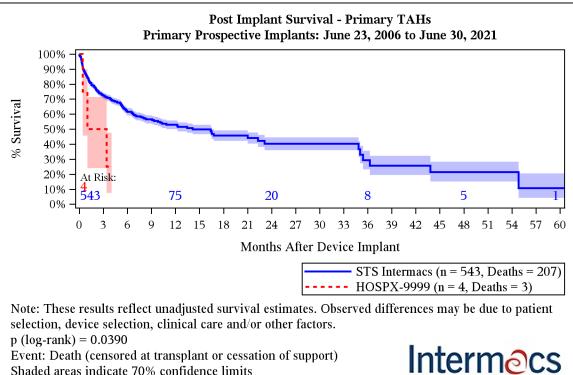




Shaded areas indicate 70% confidence limits

Months after Device Implant	STS Intermacs	HOSPX-9999
1	80.1% (79.1%-81.0%)	65.7% (57.0%-73.1%)
3	69.5% (68.4%-70.6%)	57.1% (48.3%-65.0%)
6	62.7% (61.5%-63.9%)	57.1% (48.3%-65.0%)
9	58.1% (56.8%-59.4%)	57.1% (48.3%-65.0%)
12	55.2% (53.8%-56.5%)	57.1% (48.3%-65.0%)
24	48.2% (46.7%-49.6%)	46.6% (36.7%-55.8%)
36	39.8% (38.1%-41.5%)	34.9% (22.9%-47.2%)
48	35.4% (33.6%-37.3%)	34.9% (22.9%-47.2%)
60	31.7% (29.8%-33.6%)	34.9% (22.9%-47.2%)

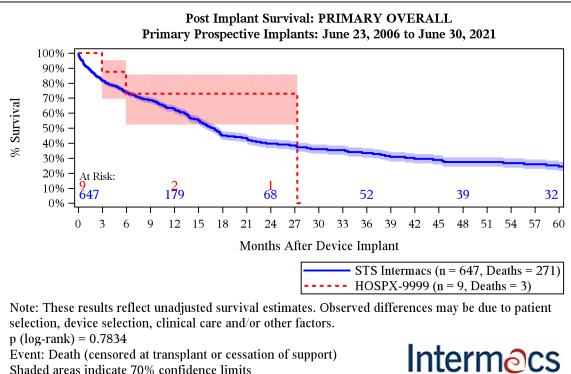
Exhibit 39. Post Implant Survival - Primary TAHs



Shaded areas indicate 70% confidence limits

Months after Device Implant	STS Intermacs	HOSPX-9999
1	85.0% (83.3%-86.4%)	75.0% (45.6%-90.0%)
3	72.3% (70.3%-74.3%)	50.0% (24.0%-71.4%)
6	61.5% (59.0%-64.0%)	
9	56.5% (53.8%-59.2%)	
12	52.9% (50.0%-55.8%)	
24	40.3% (36.0%-44.5%)	
36	29.3% (23.2%-35.6%)	
48	21.3% (15.1%-28.3%)	
60	10.7% (4.2%-20.5%)	

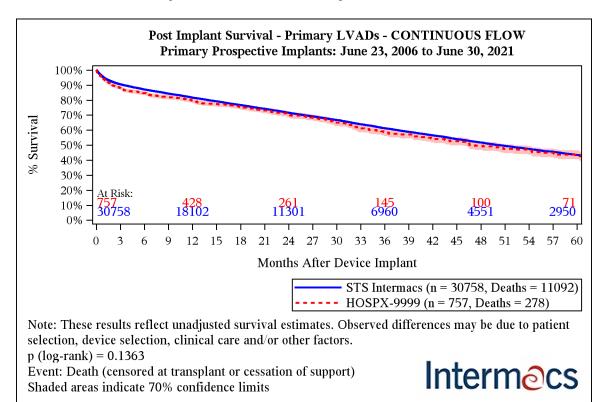
Exhibit 40. Post Implant Survival - Primary LVADs - PULSATILE FLOW



Event: Death (censored at transplant or cessation of support) Shaded areas indicate 70% confidence limits

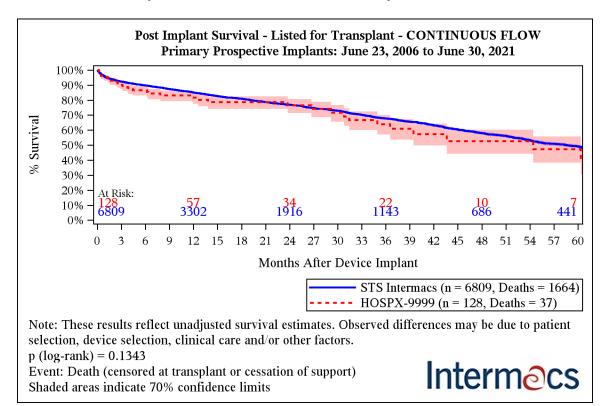
Months after Device Implant	STS Intermacs	HOSPX-9999
1	91.0% (89.8%-92.1%)	100.0% (100.0%-100.0%)
3	81.7% (80.0%-83.2%)	87.5% (69.5%-95.2%)
6	73.7% (71.7%-75.6%)	72.9% (52.4%-85.7%)
9	68.6% (66.4%-70.6%)	72.9% (52.4%-85.7%)
12	62.7% (60.3%-65.0%)	72.9% (52.4%-85.7%)
24	39.7% (36.7%-42.6%)	72.9% (52.4%-85.7%)
36	33.4% (30.3%-36.5%)	
48	27.4% (24.3%-30.6%)	
60	24.4% (21.4%-27.6%)	

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



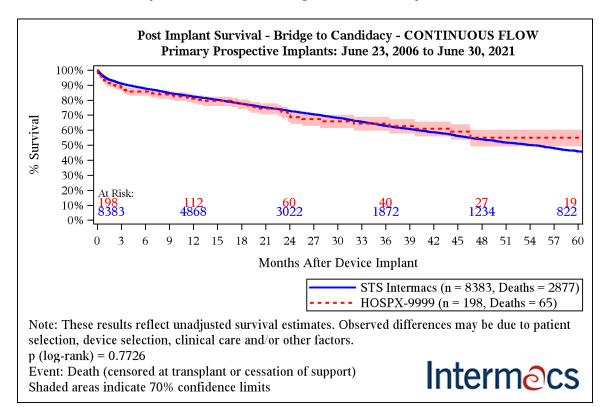
Months after Device Implant	STS Intermacs	HOSPX-9999
1	94.7% (94.6%-94.9%)	94.0% (93.1%-94.8%)
3	90.5% (90.3%-90.7%)	88.0% (86.8%-89.2%)
6	87.1% (86.9%-87.3%)	84.7% (83.3%-86.0%)
9	84.3% (84.1%-84.5%)	82.1% (80.6%-83.5%)
12	81.7% (81.4%-81.9%)	79.6% (78.0%-81.1%)
24	71.6% (71.3%-71.9%)	70.4% (68.5%-72.3%)
36	61.3% (60.9%-61.6%)	58.4% (55.9%-60.8%)
48	51.8% (51.4%-52.2%)	49.6% (46.8%-52.4%)
60	43.4% (43.0%-43.9%)	43.7% (40.7%-46.7%)

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



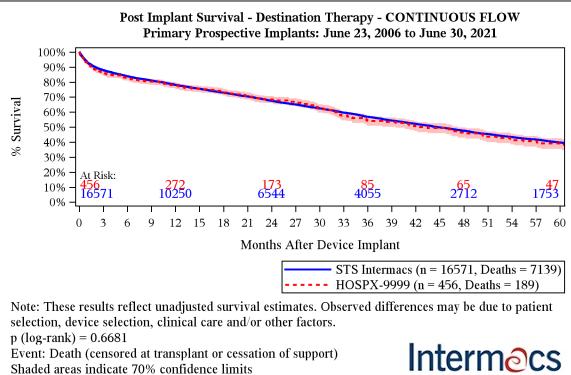
Months after Device Implant	STS Intermacs	HOSPX-9999
1	95.4% (95.1%-95.6%)	95.3% (93.0%-96.8%)
3	92.3% (92.0%-92.6%)	90.2% (87.2%-92.6%)
6	89.7% (89.3%-90.1%)	86.5% (83.0%-89.4%)
9	87.3% (86.9%-87.8%)	83.2% (79.2%-86.4%)
12	85.1% (84.6%-85.6%)	81.7% (77.6%-85.2%)
24	76.8% (76.2%-77.5%)	76.4% (71.4%-80.7%)
36	67.8% (67.0%-68.7%)	64.0% (57.2%-70.0%)
48	58.0% (57.0%-59.1%)	52.6% (44.2%-60.3%)
60	49.3% (48.0%-50.5%)	47.3% (38.3%-55.8%)

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



Months after Device Implant	STS Intermacs	HOSPX-9999
1	95.1% (94.9%-95.3%)	92.9% (90.9%-94.5%)
3	90.9% (90.6%-91.2%)	88.3% (85.8%-90.4%)
6	87.7% (87.3%-88.0%)	85.7% (82.9%-88.0%)
9	84.7% (84.3%-85.1%)	83.7% (80.8%-86.2%)
12	82.3% (81.8%-82.7%)	81.0% (77.8%-83.7%)
24	72.8% (72.3%-73.4%)	69.7% (65.4%-73.6%)
36	62.8% (62.1%-63.5%)	64.4% (59.6%-68.7%)
48	53.9% (53.1%-54.7%)	55.0% (49.3%-60.3%)
60	45.8% (44.9%-46.7%)	55.0% (49.3%-60.3%)

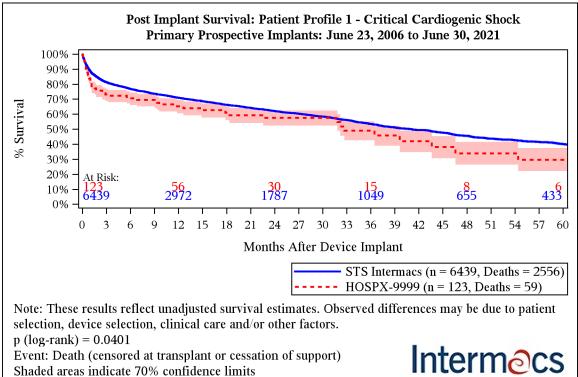
Exhibit 44. Post Implant Survival - Destination Therapy - CONTINUOUS FLOW



Event: Death (censored at transplant or cessation of support) Shaded areas indicate 70% confidence limits

Months after Device Implant	STS Intermacs	HOSPX-9999
1	93.2% (93.0%-93.4%)	93.1% (91.9%-94.2%)
3	87.9% (87.7%-88.2%)	86.2% (84.5%-87.7%)
6	83.9% (83.6%-84.2%)	82.9% (81.0%-84.6%)
9	81.0% (80.7%-81.3%)	80.3% (78.3%-82.1%)
12	78.1% (77.8%-78.5%)	77.8% (75.7%-79.8%)
24	67.5% (67.1%-67.9%)	68.5% (65.9%-70.8%)
36	56.9% (56.4%-57.4%)	54.1% (50.9%-57.1%)
48	47.7% (47.1%-48.2%)	46.5% (43.0%-49.9%)
60	39.7% (39.1%-40.3%)	39.1% (35.5%-42.7%)

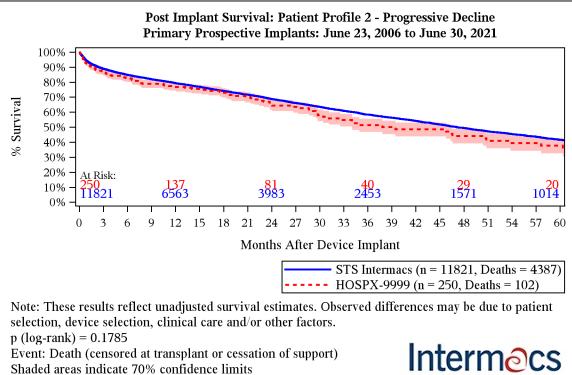
Exhibit 45a. Post Implant Survival: Patient Profile 1 - Critical Cardiogenic Shock



Shaded areas indicate 70% confidence limits

Months after Device Implant	STS Intermacs	HOSPX-9999
1	88.6% (88.2%-89.0%)	83.7% (80.1%-86.8%)
3	81.3% (80.8%-81.8%)	73.1% (68.9%-76.9%)
6	76.8% (76.3%-77.4%)	70.5% (66.1%-74.4%)
9	73.6% (73.0%-74.2%)	69.5% (65.1%-73.5%)
12	70.9% (70.3%-71.5%)	65.2% (60.6%-69.5%)
24	62.0% (61.3%-62.8%)	57.6% (52.3%-62.5%)
36	53.5% (52.6%-54.3%)	48.9% (42.5%-55.1%)
48	45.5% (44.5%-46.5%)	33.8% (26.3%-41.6%)
60	40.0% (38.9%-41.0%)	29.6% (22.0%-37.5%)

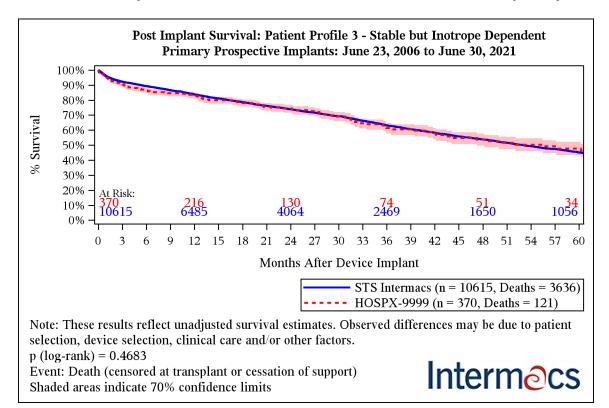
Exhibit 45b. Post Implant Survival: Patient Profile 2 - Progressive Decline



Shaded areas indicate 70% confidence limits

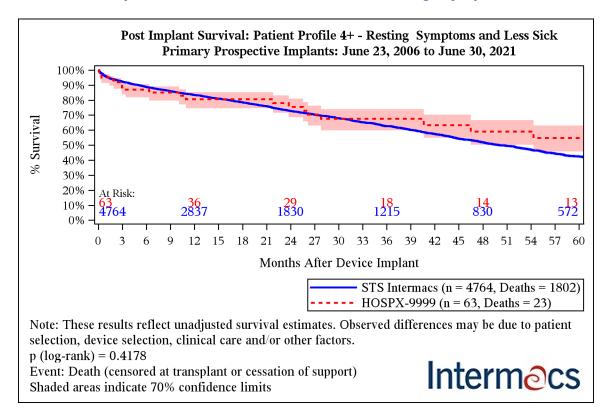
Months after Device Implant	STS Intermacs	HOSPX-9999
1	93.9% (93.6%-94.1%)	92.4% (90.5%-93.9%)
3	88.9% (88.6%-89.2%)	86.7% (84.3%-88.7%)
6	84.8% (84.5%-85.1%)	82.7% (80.2%-85.0%)
9	81.9% (81.5%-82.3%)	78.9% (76.0%-81.4%)
12	79.3% (78.9%-79.7%)	77.3% (74.4%-79.9%)
24	68.7% (68.2%-69.2%)	65.2% (61.5%-68.7%)
36	58.4% (57.8%-59.0%)	51.3% (46.9%-55.6%)
48	49.5% (48.8%-50.1%)	44.0% (39.1%-48.8%)
60	41.6% (40.8%-42.4%)	37.6% (32.5%-42.6%)

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



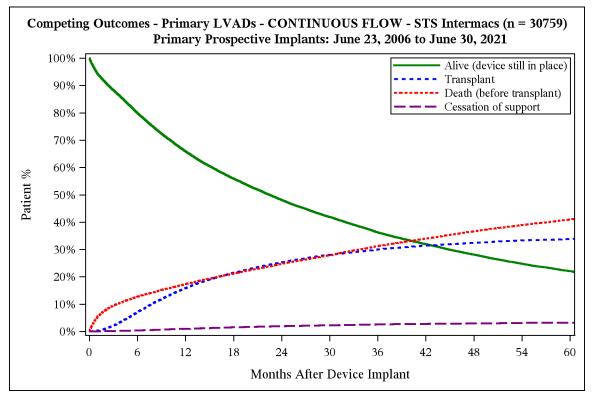
Months after Device Implant	STS Intermacs	HOSPX-9999
1	95.9% (95.7%-96.1%)	95.6% (94.4%-96.6%)
3	92.2% (92.0%-92.5%)	90.6% (88.9%-92.0%)
6	89.3% (89.0%-89.6%)	87.0% (85.0%-88.7%)
9	86.6% (86.3%-86.9%)	84.6% (82.5%-86.4%)
12	83.8% (83.4%-84.1%)	82.7% (80.5%-84.7%)
24	73.9% (73.4%-74.4%)	74.4% (71.6%-76.9%)
36	63.1% (62.5%-63.8%)	61.3% (57.6%-64.8%)
48	53.8% (53.1%-54.5%)	53.7% (49.6%-57.6%)
60	45.1% (44.3%-45.9%)	47.8% (43.4%-52.1%)

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



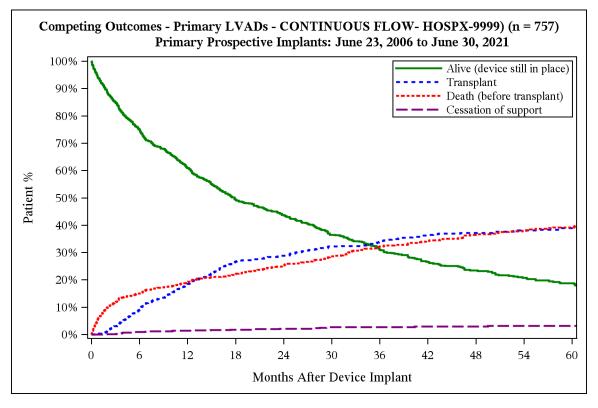
Months after Device Implant	STS Intermacs	HOSPX-9999
1	95.6% (95.3%-95.9%)	95.2% (91.5%-97.3%)
3	92.2% (91.8%-92.6%)	88.5% (83.7%-92.0%)
6	88.7% (88.2%-89.1%)	86.9% (81.8%-90.6%)
9	86.0% (85.5%-86.5%)	85.0% (79.7%-89.0%)
12	83.4% (82.8%-83.9%)	80.6% (74.5%-85.3%)
24	72.8% (72.0%-73.5%)	75.4% (68.7%-80.9%)
36	62.7% (61.8%-63.6%)	67.4% (59.9%-73.9%)
48	51.9% (50.9%-53.0%)	59.0% (50.2%-66.7%)
60	42.5% (41.3%-43.6%)	54.8% (45.7%-63.0%)

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



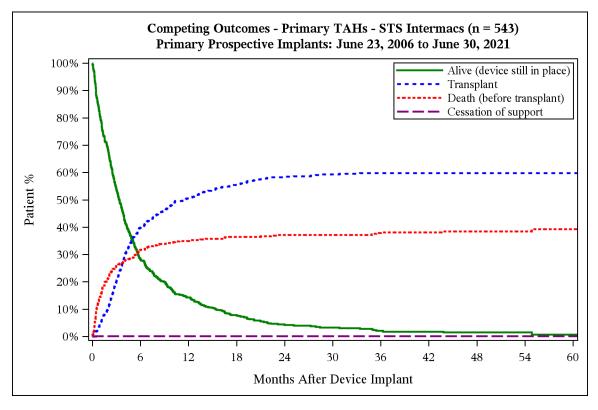
Outcome	Months After Device Implant									
Outcome	1	3	6	9	12	24	36	48	60	
Alive (device still in place)	94.4%	88.3%	79.9%	72.4%	65.9%	48.1%	36.2%	28.1%	22.0%	
Transplant	0.3%	2.1%	7.0%	11.8%	15.8%	25.3%	30.0%	32.4%	33.8%	
Death (before transplant)	5.2%	9.5%	12.7%	15.1%	17.3%	24.7%	31.2%	36.6%	40.9%	
Cessation of support	0.0%	0.2%	0.4%	0.7%	1.0%	1.9%	2.6%	2.9%	3.2%	
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%	

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



Outcome	Months After Device Implant									
Outcome	1	3	6	9	12	24	36	48	60	
Alive (device still in place)	93.6%	84.9%	75.1%	68.0%	60.9%	43.7%	31.0%	23.4%	18.8%	
Transplant	0.4%	3.1%	8.9%	13.5%	18.5%	28.8%	34.1%	37.2%	38.9%	
Death (before transplant)	6.0%	11.9%	15.0%	17.2%	19.2%	25.4%	32.2%	36.5%	39.2%	
Cessation of support	0.0%	0.1%	1.0%	1.2%	1.4%	2.1%	2.7%	2.9%	3.1%	
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%	





Outcome	Months After Device Implant									
Outcome	1	3	6	9	12	24	36	48	60	
Alive (device still in place)	80.1%	53.5%	28.2%	20.0%	14.4%	4.2%	2.1%	1.5%	0.8%	
Transplant	5.0%	20.5%	39.8%	46.0%	50.5%	58.5%	59.8%	59.8%	59.8%	
Death (before transplant)	14.8%	25.8%	31.8%	33.8%	35.0%	37.1%	37.9%	38.5%	39.2%	
Cessation of support	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%	

Exhibit 47b. Competing Outcomes - Primary TAHs - HOSPX-9999 Not enough patients or events to produce exhibit

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.

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.

Follow-up Visit	All	Unat		Con	Iluation Idition Iluated		
	Ν	N %		Ν	%		
3 Month	387			387	100.00		
6 Month	337	2	0.59	335	99.41		
1 Year	248	1	0.40	247	99.60		
2 Year	131	2	1.53	129	98.47		

GROUP=HOSPX-9999

F . U		Hem	Hemolysis Evaluation							
Follow-up Visit	All	Unat Eval	ole to uate	Condition Evaluated						
	Ν	N %		Ν	%					
3 Month	17132	868	5.07	16264	94.93					
6 Month	14969	762	5.09	14207	94.91					
1 Year	11008	450	4.09	10558	95.91					
2 Year	5969	237	3.97	5732	96.03					

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.

Follow-up		Hemolysis Condition							
Visit	All	Μ	ajor	Μ	inor	-	No		
	Ν	Ν	%	N %		Ν	%		
3 Month	387	17	4.39	60	15.50	310	80.10		
6 Month	335	9	2.69	39	11.64	287	85.67		
1 Year	247	9	3.64	29	11.74	209	84.62		
2 Year	129	5	3.88	21	16.28	103	79.84		
3 Year	49	2	4.08	7	14.29	40	81.63		
4 Year	36	1	2.78	9	25.00	26	72.22		
5 Year	14	2	14.29	3	21.43	9	64.29		

GROUP=HOSPX-9999

Follow-up		Hemolysis Condition							
Visit	All	Ма	ijor	Mi	nor	N	0		
	Ν	Ν	%	N %		Ν	%		
3 Month	16264	610	3.75	2729	16.78	12925	79.47		
6 Month	14207	392	2.76	2260	15.91	11555	81.33		
1 Year	10558	386	3.66	1892	17.92	8280	78.42		
2 Year	5732	204	3.56	968	16.89	4560	79.55		
3 Year	2928	121	4.13	530	18.10	2277	77.77		
4 Year	1499	70	4.67	268	17.88	1161	77.45		
5 Year	740	30	4.05	135	18.24	575	77.70		

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.

Follow-up		Hypertension Evaluation					
Visit	All		ble to luate	Condition Evaluated			
	Ν	Ν	%	Ν	%		
3 Month	387	168	43.41	219	56.59		
6 Month	337	139	41.25	198	58.75		
1 Year	248	120	48.39	128	51.61		
2 Year	131	80	61.07	51	38.93		

GROUP=HOSPX-9999

		Hypertension Evaluation						
Follow-up Visit	All	Unable to Evaluate		Condition Evaluated				
	Ν	Ν	%	Ν	%			
3 Month	17132	4277	24.96	12855	75.04			
6 Month	14969	3649	24.38	11320	75.62			
1 Year	11008	2703	24.55	8305	75.45			
2 Year	5969	1524	25.53	4445	74.47			

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.

Follow-up		Hypertension Condition						
Visit	All	H	ITN	No	HTN			
	Ν	Ν	%	Ν	%			
3 Month	219	8	3.65	211	96.35			
6 Month	198	11	5.56	187	94.44			
1 Year	128	8	6.25	120	93.75			
2 Year	51	11	21.57	40	78.43			
3 Year	21			21	100.00			
4 Year	18	5	27.78	13	72.22			
5 Year	3	1	33.33	2	66.67			

GROUP=HOSPX-9999

Follow-up		Hypertension Condition						
Visit	All	H	TN	No I	HTN			
	Ν	Ν	%	Ν	%			
3 Month	12855	624	4.85	12231	95.15			
6 Month	11320	596	5.27	10724	94.73			
1 Year	8305	448	5.39	7857	94.61			
2 Year	4445	268	6.03	4177	93.97			
3 Year	2258	110	4.87	2148	95.13			
4 Year	1163	72	6.19	1091	93.81			
5 Year	538	26	4.83	512	95.17			

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.

		RHF Evaluation							
Follow-up Visit	AII	Unat Eval		Condition Evaluated					
	Ν	Ν	%	Ν	%				
3 Month	387	15	3.88	372	96.12				
6 Month	337	9	2.67	328	97.33				
1 Year	248	9	3.63	239	96.37				
2 Year	131	4	3.05	127	96.95				

GROUP=HOSPX-9999

		R	RHF Evaluation					
Follow-up Visit	All	Unat Eval	ole to uate	Condition Evaluated				
	Ν	Ν	%	Ν	%			
3 Month	17132	713	4.16	16419	95.84			
6 Month	14969	513	3.43	14456	96.57			
1 Year	11008	346	3.14	10662	96.86			
2 Year	5969	137	2.30	5832	97.70			

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.

Follow-up Visit			RHF Condition 4. RHF 5. RHF 3. RHF (Inotropic (RVAD							
VISIC	All	1. N	lo RHF		lild)	(Support)		
	Ν	Ν	%	Ν	%	Ν	%	Ν	%	
3 Month	372	352	94.62	9	2.42	10	2.69	1	0.27	
6 Month	328	317	96.65	7	2.13	3	0.91	1	0.30	
1 Year	239	228	95.40	10	4.18	1	0.42			
2 Year	127	126	99.21	1	0.79					
3 Year	49	48	97.96	1	2.04					
4 Year	36	36	100.00							
5 Year	14	13	92.86			1	7.14			

GROUP=HOSPX-9999

		RHF Condition										
Follow-up Visit	All	1. No	RHF	3. RHF (Mild)				(4. RHF 5. RH (Inotropic (RVAI Support) Support		'AD
	Ν	Ν	%	Ν	%	Ν	%	Ν	%			
3 Month	16419	14573	88.76	840	5.12	967	5.89	39	0.24			
6 Month	14456	13203	91.33	694	4.80	545	3.77	14	0.10			
1 Year	10662	9666	90.66	607	5.69	385	3.61	4	0.04			
2 Year	5832	5349	91.72	288	4.94	189	3.24	6	0.10			
3 Year	2988	2756	92.24	137	4.59	93	3.11	2	0.07			
4 Year	1542	1403	90.99	84	5.45	54	3.50	1	0.06			
5 Year	748	681	91.04	34	4.55	33	4.41					

Exhibit 49: Patients Implanted at your Center but Excluded from the Cumulative - All Patient Report

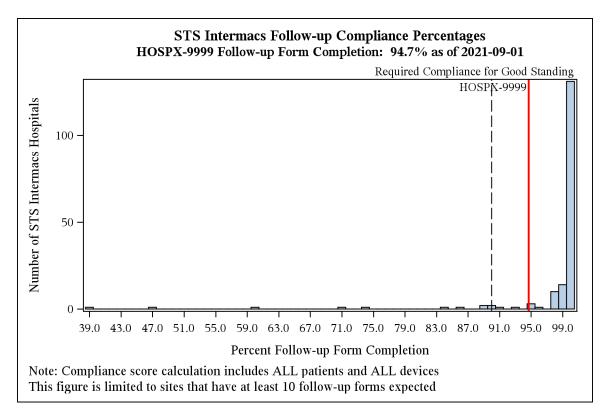
Excluded		
Patient	Furthering Descent	Implant
	Exclusion Reason	Year
	Retrospective Patient	2006
	Pediatric Patient (Age<19)	2007
	Patient Implant Date Outside of Report Coverage	2006
4756	Pediatric Patient (Age<19)	2011
5048	Pediatric Patient (Age<19)	2011
5561	Retrospective Patient	2010
5590	Retrospective 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 validate	d 2020
125722	Implant, Pre-Implant, or Patient form not validate	d 2020
126037	Implant, Pre-Implant, or Patient form not validate	d 2020
126223	Implant, Pre-Implant, or Patient form not validate	d 2020
126245	Implant, Pre-Implant, or Patient form not validate	d 2020
126375	Implant, Pre-Implant, or Patient form not validate	d 2020
126411	Implant, Pre-Implant, or Patient form not validate	d 2020
126738	Implant, Pre-Implant, or Patient form not validate	d 2021
126823	Implant, Pre-Implant, or Patient form not validate	d 2021
126928	Implant, Pre-Implant, or Patient form not validate	d 2021
127069	Implant, Pre-Implant, or Patient form not validate	d 2021
	Implant, Pre-Implant, or Patient form not validate	
	Implant, Pre-Implant, or Patient form not validate	
	Implant, Pre-Implant, or Patient form not validate	
	Implant, Pre-Implant, or Patient form not validate	
	Implant, Pre-Implant, or Patient form not validate	
	Implant, Pre-Implant, or Patient form not validate	
	Implant, Pre-Implant, or Patient form not validate	
	Implant, Pre-Implant, or Patient form not validate	-
	Implant, Pre-Implant, or Patient form not validate	

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 cumumlative 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.



V. Glossary

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