



STS National Database™
Trusted. Transformed. Real-Time.

Pedimacs

STS Pedimacs

Pediatric Registry for Mechanically Assisted Circulatory Support

**Quality Assurance Quarterly Report (2020 Q1) - Cumulative
Hospital X - (Random 50 Patients)**

Implant and event dates: September 19, 2012 to March 31, 2020

06/01/2020

Prepared by:

Intermacs Data Warehouse and Analytics Center
University of Alabama at Birmingham

James K. Kirklin, MD
Betsy Blume, MD
Craig Collum, MPH
Ryan S. Cantor, PhD
Nick Timkovich, MSHI
Maceo Cleggett

**CONFIDENTIAL: This information is only intended for:
Hospital X - (Random 50 Patients)**

About This Report

STS Pedimacs is the pediatric portion of STS Intermacs which was launched on 9/19/2012. While STS Intermacs has always included durable devices implanted in pediatric patients, STS Pedimacs has been developed to focus on capturing data elements unique to pediatric patients. STS Pedimacs evaluates special issues in the pediatric population receiving Mechanical Circulatory Support Device (MCSD) therapy, differences in devices available, and the particular pediatric population for whom this therapy may be most effective. Elizabeth Blume, M.D. from the Children's Hospital Boston, is the Pedimacs Chair.

The “Cumulative” version of the Quality Assurance report includes data on all prospective patients receiving a device at your site.

Confidential

This report is intended only for STS Pedimacs 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 Pedimacs site administrator and physician representative. The STS Pedimacs aggregate data in this report may not be distributed to anyone outside of your hospital. STS Pedimacs has a separate mechanism for the creation and distribution of STS Pedimacs aggregate data.

Disclaimer

STS Pedimacs has attempted to create a high quality report that is a direct result of the data submitted by the STS Pedimacs hospitals. However, STS Pedimacs makes no warranties or representations, either expressed or implied, about the content of this report. STS Pedimacs further disclaims any and all liability whatsoever in any information, material, or content of this report. Any reference in this report to any specific commercial product, service, manufacturer, or company does not constitute its endorsement or recommendation by STS Pedimacs or its employees or agents. None of the material, information or content from this report shall serve as or create a contract between STS Pedimacs and any person or entity accessing and using this report. The recipient of this report agrees to abide by the confidentiality laws of the United States, all other applicable federal and state laws, and applicable policies and guidelines of STS Pedimacs. Comments involving information perceived as inaccurate, misleading, or inappropriate should be directed to: Maceo Cleggett with the Data Warehouse and Analytics Center at INTERMACS-Reports@uabmc.edu.

This quarterly report includes clinical information from 48 patients receiving prospective implants between September 19, 2012 and March 31, 2020 at Hospital X - (Random 50 Patients).

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**
 - Section 1 - All Patients**
 - Patient and Device Counts**
 - Section 2 - Patients Receiving a Durable Device**
 - 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
 - Hospital Days
 - 30 Day Readmission
 - Functional Capacity
 - D. Post Implant Outcomes**
 - Survival
 - Competing Outcomes
 - Section 3 - Patients Receiving Temporary Devices Only**
 - A. Pre-implant Summaries**
 - Demographics
 - Clinical Characteristics
 - Concerns and Contraindications
 - Hemodynamics
 - Functional Capacity and Quality of Life
 - Additional Interventions
 - B. Post Implant Outcomes**
 - Survival
 - Competing Outcomes
- III. Registry Compliance**
- IV. Excluded Patients**
- V. Glossary**

I. Introduction and Methods

I.A. Purpose of this Report

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

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

These reports will provide information in the following areas:

Pedimacs Quality Assurance (QA) Report - this report

- Statistical Summaries and Benchmarks for Quality Assurance
- Registry Compliance

Pedimacs Data Quality (DQ) Report

- Patient Level Data
- Data Quality Queries

I.B. Source of Data and Limitations

The data in this report are based on all data entered into the STS Pedimacs web-based data entry application (WBDE) through March 31, 2020. Patient enrollment in STS Pedimacs began on September 19, 2012. Your institution may have joined STS Pedimacs 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 Pedimacs is a registry that strives to meet the data quality standards of a prospective clinical trial. STS Pedimacs 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 March 31, 2020 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 Pedimacs 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 Pedimacs 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 Pedimacs 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 with data entry.

I.E. Future Reports

This report is a major step in greatly expanded quarterly reports from STS Pedimacs. 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.

Probably the most important future enhancement will be risk adjusted evaluation of major outcomes for each hospital. This will occur after the creation of a Pedimacs task force that will address the process to produce multivariable risk factor analyses and will address the statistical methodology to translate the risk factors into risk adjusted comparisons.

I.F. Report Coverage - Patient Selection

The Quality Assurance Report contains information from your site compared to the overall STS Pedimacs experience. To facilitate this comparison only patients receiving at least one durable device is analyzed.

Exclusion reasons from the QA report include:

- a) Retrospective patients (implanted prior to site activation)
- b) Patients receiving at only temporary devices

Transfer patients and their subsequent experience are analyzed in the report for the site that implanted the primary implant.

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

II. Statistical Summaries and Benchmarks for Quality Assurance

The first part of this section contains summary statistics of patients implanted (and enrolled in STS Pedimacs) at your hospital. As a benchmark, the corresponding summary statistics for the entire STS Pedimacs registry are also provided. For explanations and/or definitions of the data elements go to the STS Pedimacs User's Guide www.uab.edu/medicine/intermacs/pedimacs and select Pedimacs Appendices', Appendix M / User's Guide. The summary statistics for continuous variables includes N (the number of patients with data), MEAN (the average value), STD (standard deviation), MIN (the smallest value), and MAX (the largest value).

Starting 2020 Q1, the statistical summaries and benchmarks for quality assurances portion of this report is organized in 3 section:

- Section 1 – All Patients
- Section 2 – Patients Receiving Durable Support - Patient details and outcomes based on the patients first durable device implanted and subsequent follow-up
- Section 3 – Patients Receiving Only Temporary Support - Patient details and outcomes based for patients reviewing only temporary devices based on the first temporary device implanted and subsequent follow-up

COVERAGE: September 19, 2012 - March 31, 2020***SITE: Hospital X - (Random 50 Patients)*****Section 1 - All Patients*****Exhibit 1: Patient Counts*****All Patients**

Support Type	HOSPX-8888 (n=48)	Pedimacs (n=907)
Durable	31	680
Temp Only	17	227

Device Class for First Durable Support

Device Class	HOSPX-8888 (n=31)	Pedimacs (n=680)
Implantable Continuous	21	400
Paracorporeal Pulsatile	9	275
TAH	1	5

Device Class for First Temporary Device for Patients Receiving Only Temporary Support

Device Class	HOSPX-8888 (n=17)	Pedimacs (n=227)
Paracorporeal Continuous	16	187
Percutaneous	1	40

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)**COVERAGE: September 19, 2012 - March 31, 2020****SITE: Hospital X - (Random 50 Patients)****Section 1 - All Patients****Exhibit 2: Primary and Subsequent Device Counts**

The following tables list the number of implants at your site and STS Pedimacs overall by device sequence (primary, secondary, etc.). NOTE: Subsequent analysis in this section evaluate only primary devices unless specified otherwise.

HOSPX-8888 (n=48)

DEVICE #	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Primary Device	20	25	3	48
2nd Device	4	5	0	9
3rd Device	1	2	0	3
4th Device	0	1	0	1
5th Device	0	0	0	0

Pedimacs (n=907)

DEVICE #	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Primary Device	385	486	36	907
2nd Device	55	73	2	130
3rd Device	19	16	2	37
4th Device	9	6	1	16
5th Device	3	3	0	6

COVERAGE: September 19, 2012 - March 31, 2020**SITE: Hospital X - (Random 50 Patients)****Section 2 - Patients Receiving a Durable Device****Exhibit 1: Primary and Subsequent Device Counts**

The following tables list the number of implants at your site and STS Pedimacs overall by device sequence (primary, secondary, etc.). NOTE: Subsequent analysis in this section evaluate only primary devices unless specified otherwise.

HOSPX-8888 (n=31)

DEVICE #	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Primary Device	14	15	2	31
2nd Device	2	2	0	4
3rd Device	0	1	0	1
4th Device	0	1	0	1
5th Device	0	0	0	0

Pedimacs (n=680)

DEVICE #	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Primary Device	313	344	23	680
2nd Device	36	40	1	77
3rd Device	13	12	0	25
4th Device	8	6	0	14
5th Device	2	3	0	5

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 2: Patient Demographics

HOSPX-8888 (n=31)

DEMOGRAPHICS	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	14	15	2	31
Age Group				
< 1 yr	14%	6%	0%	9%
1-5 yr	7%	33%	50%	22%
6-10 yr	7%	13%	50%	12%
11-18 yr	71%	46%	0%	54%
Gender				
Missing	0%	6%	0%	3%
Female	21%	26%	50%	25%
Male	78%	66%	50%	70%
Race				
African American	21%	20%	50%	22%
White	71%	40%	50%	54%
Other, Unknown, Undisclosed	7%	40%	0%	22%
Ethnicity				
Non-Hispanic	85%	66%	50%	74%
Unknown	0%	6%	0%	3%
Hispanic	14%	26%	50%	22%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 2: Patient Demographics

Pedimacs (n=680)

DEMOGRAPHICS	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	313	344	23	680
Age Group				
< 1 yr	16%	21%	8%	18%
1-5 yr	17%	20%	34%	19%
6-10 yr	16%	16%	21%	16%
11-18 yr	48%	41%	34%	44%
Gender				
Missing	0%	0%	0%	0%
Female	39%	45%	43%	42%
Male	60%	53%	56%	56%
Race				
African American	22%	22%	30%	22%
White	58%	58%	52%	58%
Other, Unknown, Undisclosed	18%	18%	17%	18%
Ethnicity				
Non-Hispanic	78%	77%	86%	78%
Unknown	2%	3%	0%	2%
Hispanic	18%	18%	13%	18%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 3: Weight (kg)

HOSPX-8888 (n=31)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	14	15	2	31
Weight (kg)				
Missing	0%	0%	0%	0%
< 5 kg	7%	0%	0%	3%
5-20 kg	14%	46%	50%	32%
> 20 Kg	78%	53%	50%	64%

Pedimacs (n=680)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	313	344	23	680
Weight (kg)				
Missing	0%	0%	4%	0%
< 5 kg	6%	9%	0%	7%
5-20 kg	28%	36%	34%	32%
> 20 Kg	64%	54%	60%	59%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 4: Primary Diagnosis

HOSPX-8888 (n=31)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	14	15	2	31
Primary Diagnosis				
Congenital Heart Disease – Biventricular	21%	13%	0%	16%
Congenital Heart Disease – Single Ventricle	7%	33%	0%	19%
Dilated Cardiomyopathy	57%	53%	100%	58%
Restrictive Cardiomyopathy	7%	0%	0%	3%
Post Transplant/Graft Dysfunction	7%	0%	0%	3%
#Cancer#	0%	0%	0%	0%
#Valvular Heart Disease#	0%	0%	0%	0%
#None#	0%	0%	0%	0%
Other	0%	0%	0%	0%

Pedimacs (n=680)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	313	344	23	680
Primary Diagnosis				
Congenital Heart Disease – Biventricular	8%	7%	0%	7%
Congenital Heart Disease – Single Ventricle	9%	13%	8%	11%
Dilated Cardiomyopathy	70%	71%	78%	71%
Restrictive Cardiomyopathy	4%	1%	4%	2%
Post Transplant/Graft Dysfunction	2%	1%	0%	1%
#Cancer#	0%	0%	0%	0%
#Valvular Heart Disease#	0%	1%	4%	1%
#None#	0%	1%	0%	0%
Other	2%	2%	4%	2%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 5: Patient Profile Levels

HOSPX-8888 (n=31)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	14	15	2	31
Patient Profile				
1 Critical Cardiogenic Shock	7%	26%	0%	16%
2 Progressive Decline	64%	46%	100%	58%
3 Stable but Inotrope Dependent	14%	26%	0%	19%
4 Resting Symptoms	0%	0%	0%	0%
5 Exertion Intolerant	0%	0%	0%	0%
7 Advanced NYHA Class 3 or Ross Class II	0%	0%	0%	0%
Missing	14%	0%	0%	6%

Pedimacs (n=680)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	313	344	23	680
Patient Profile				
1 Critical Cardiogenic Shock	26%	19%	26%	22%
2 Progressive Decline	55%	61%	52%	58%
3 Stable but Inotrope Dependent	10%	18%	21%	15%
4 Resting Symptoms	1%	0%	0%	1%
5 Exertion Intolerant	0%	0%	0%	0%
7 Advanced NYHA Class 3 or Ross Class II	0%	0%	0%	0%
Missing	3%	0%	0%	1%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 6: Device Strategy

HOSPX-8888 (n=31)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	14	15	2	31
Current Device Strategy				
BTT - Listed	50%	46%	100%	51%
BTT - Likely	35%	40%	0%	35%
BTT - Moderate	7%	13%	0%	9%
BTT - Unlikely	7%	0%	0%	3%
Destination Therapy	0%	0%	0%	0%
Bridge to Recovery	0%	0%	0%	0%
Rescue Therapy	0%	0%	0%	0%

Pedimacs (n=680)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	313	344	23	680
Current Device Strategy				
BTT - Listed	62%	50%	43%	55%
BTT - Likely	26%	33%	39%	30%
BTT - Moderate	5%	10%	8%	7%
BTT - Unlikely	1%	0%	0%	0%
Destination Therapy	2%	1%	0%	1%
Bridge to Recovery	0%	3%	8%	2%
Rescue Therapy	0%	0%	0%	0%

COVERAGE: September 19, 2012 - March 31, 2020**SITE: Hospital X - (Random 50 Patients)****Section 2 - Patients Recieving a Durable Device****Exhibit 7: Medications****HOSPX-8888 (n=31)**

MEDICATIONS	2012 - 2016	2017 - 2019	2020Q1	Total
Patients (n)	14	15	2	31
IV Inotropes at Implant	100%	93%	100%	97%
Pre-implant Loop Diuretics	79%	87%	100%	84%

Pedimacs (n=680)

MEDICATIONS	2012 - 2016	2017 - 2019	2020Q1	Total
Patients (n)	313	344	23	680
IV Inotropes at Implant	93%	95%	100%	94%
Pre-implant Loop Diuretics	77%	83%	83%	80%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 8: Laboratories

HOSPX-8888 (n=31)

PRE-IMPLANT LABORATORIES		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients	n	14	15	2	31
Sodium (mEq/L)	Mean	137.79	138.50	135.00	137.93
	Std	4.21	5.35	2.83	4.67
	Missing	0	1	0	1
Potassium (mEq/L)	Mean	3.67	3.83	3.05	3.70
	Std	0.43	0.49	0.35	0.48
	Missing	0	1	0	1
BUN (mg/dL)	Mean	20.36	22.27	17.00	21.03
	Std	9.45	14.72	4.24	11.83
	Missing	0	1	0	1
Creatinine (mg/dL)	Mean	0.69	0.56	0.34	0.61
	Std	0.35	0.33	0.17	0.34
	Missing	0	1	0	1
Alanine Aminotransferase/ALT (u/L)	Mean	197.71	69.36	24.00	126.23
	Std	514.14	73.68	16.97	354.53
	Missing	0	1	0	1
Aspartate Aminotransferase/AST (u/L)	Mean	180.50	98.00	32.50	132.13
	Std	533.19	156.19	0.71	375.17
	Missing	0	1	0	1
LDH (µkat/L), (U/L)	Mean	1109.40	500.88	1262.00	805.20
	Std	1473.37	236.38	509.12	884.57
	Missing	9	7	0	16
Total Bilirubin (mg/dL)	Mean	2.04	1.43		1.76
	Std	2.07	1.05		1.68
	Missing	1	4	2	7
Albumin (g/dL)	Mean	3.57	3.46	3.70	3.52
	Std	0.65	0.83	0.28	0.71
	Missing	1	1	0	2
Pre-albumin (mg/dL)	Mean	16.91	16.00	11.50	16.25
	Std	9.31	6.09		7.88
	Missing	5	10	1	16

(Continued)

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Receiving a Durable Device

Exhibit 8: Laboratories

HOSPX-8888 (n=31)

PRE-IMPLANT LABORATORIES		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Total Cholesterol (mg/dL)	Mean	104.86	107.00	93.00	104.36
	Std	25.85	23.26		22.90
	Missing	7	12	1	20
Brain Natriuretic Peptide (pg/mL)	Mean	1794.25	1984.40	3042.50	2024.07
	Std	1066.65	1294.13	229.81	1109.08
	Missing	6	10	0	16
Pro Brain Natriuretic Peptide (pg/mL)	Mean	5566.33	13553.00		10558.00
	Std	3721.34	16130.62		13027.91
	Missing	11	10	2	23
White Blood Cell Count (x10/ μ L)	Mean	11.47	9.70	9.51	10.51
	Std	5.47	2.67	1.51	4.19
	Missing	0	1	0	1
Hemoglobin (g/dL)	Mean	11.04	12.08	10.20	11.47
	Std	1.87	2.36	0.14	2.11
	Missing	0	1	0	1
Platelets (x10/ μ L)	Mean	211.50	192.21	291.50	207.83
	Std	126.35	101.81	16.26	111.44
	Missing	0	1	0	1
INR	Mean	1.39	1.39	1.30	1.38
	Std	0.27	0.28	0.14	0.26
	Missing	0	1	0	1

Pedimacs (n=680)

PRE-IMPLANT LABORATORIES		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients	n	313	344	23	680
Sodium (mEq/L)	Mean	137.29	137.32	138.22	137.34
	Std	6.49	5.57	6.49	6.04
	Missing	1	2	0	3
Potassium (mEq/L)	Mean	3.78	3.89	3.81	3.83
	Std	0.60	0.63	0.81	0.62
	Missing	1	2	0	3

(Continued)

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 8: Laboratories

Pedimacs (n=680)

PRE-IMPLANT LABORATORIES		2012 - 2016	2017 - 2019	2020Q1	TOTAL
BUN (mg/dL)	Mean	26.18	24.68	29.01	25.52
	Std	20.89	17.29	28.92	19.49
	Missing	1	5	0	6
Creatinine (mg/dL)	Mean	0.76	0.60	0.84	0.68
	Std	0.48	0.53	0.97	0.53
	Missing	1	4	0	5
Alanine Aminotransferase/ALT (u/L)	Mean	194.68	101.25	102.82	144.67
	Std	631.26	215.39	162.01	459.24
	Missing	9	15	1	25
Aspartate Aminotransferase/AST (u/L)	Mean	212.35	98.03	107.00	151.55
	Std	809.80	224.36	125.07	577.63
	Missing	9	17	1	27
LDH (µkat/L), (U/L)	Mean	657.02	665.09	1109.92	686.12
	Std	871.19	644.43	1472.11	794.07
	Missing	227	201	10	438
Total Bilirubin (mg/dL)	Mean	1.54	1.42	2.34	1.51
	Std	1.91	1.85	5.01	2.05
	Missing	32	51	4	87
Albumin (g/dL)	Mean	3.47	3.42	3.57	3.45
	Std	0.72	0.75	0.95	0.74
	Missing	7	16	1	24
Pre-albumin (mg/dL)	Mean	17.67	18.25	15.08	17.87
	Std	7.62	7.70	3.58	7.58
	Missing	203	259	19	481
Total Cholesterol (mg/dL)	Mean	111.30	116.01	119.25	113.81
	Std	34.88	43.05	20.25	38.88
	Missing	222	250	19	491
Brain Natriuretic Peptide (pg/mL)	Mean	1971.20	1807.02	2780.86	1922.96
	Std	1659.77	1388.68	1747.26	1538.43
	Missing	175	183	9	367

(Continued)

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 8: Laboratories

Pedimacs (n=680)

PRE-IMPLANT LABORATORIES		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Pro Brain Natriuretic Peptide (pg/mL)	Mean	11963.36	14004.20	8860.80	13018.81
	Std	11338.58	13294.08	6881.09	12398.04
	Missing	230	234	18	482
White Blood Cell Count (x10/ μ L)	Mean	10.90	10.70	13.01	10.87
	Std	5.47	4.95	8.57	5.36
	Missing	1	3	0	4
Hemoglobin (g/dL)	Mean	11.69	11.51	11.17	11.58
	Std	1.91	2.25	3.00	2.13
	Missing	1	2	0	3
Platelets (x10/ μ L)	Mean	221.20	228.79	234.57	225.48
	Std	113.20	112.62	90.75	112.15
	Missing	3	5	0	8
INR	Mean	1.43	1.40	1.27	1.41
	Std	0.54	0.87	0.17	0.72
	Missing	21	25	5	51

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 8: Laboratories

HOSPX-8888 (n=31)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	14	15	2	31
Lupus Anticoagulant				
Negative	28%	0%	0%	12%
Positive	0%	0%	0%	0%
Unknown	71%	100%	100%	87%

Pedimacs (n=680)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	313	344	23	680
Lupus Anticoagulant				
Negative	32%	7%	4%	18%
Positive	0%	0%	0%	0%
Unknown	66%	91%	95%	80%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Receiving a Durable Device

Exhibit 9: Pre-Implant Concerns

HOSPX-8888 (n=31)

PRE-IMPLANT CONCERNS	2012 - 2016	2017 - 2019	2020Q1	Total
Patients (n)	14	15	2	31
Patient/Family Does Not Want Transplant	0%	0%	0%	0%
Musculoskeletal Limitation	0%	7%	0%	3%
Contraindication to Immunosuppression	0%	0%	0%	0%
Allosensitization	0%	7%	0%	3%
Frailty	0%	0%	0%	0%
Chronic Renal Disease	0%	7%	0%	3%
Frequent ICD Shocks	0%	0%	0%	0%
Pulmonary Disease	0%	0%	0%	0%
Pulmonary Hypertension	14%	7%	0%	10%
Recent Pulmonary Embolus	7%	0%	0%	3%
History of Atrial Arrhythmia	7%	7%	0%	6%
Unfavorable Mediastinal Anatomy	21%	13%	0%	16%
Thoracic Aortic Disease	0%	0%	0%	0%
Tracheostomy	0%	0%	0%	0%
Plastic Bronchitis	0%	0%	0%	0%
Large BMI	14%	13%	0%	13%
Severe Diabetes	0%	0%	0%	0%
Malnutrition/Cachexia	0%	7%	0%	3%
History of GI Ulcers	0%	0%	0%	0%
History of Hepatitis	0%	0%	0%	0%
Liver Dysfunction	7%	0%	0%	3%
Anasarca	0%	0%	0%	0%
Protein Losing Enteropathy	0%	0%	0%	0%
Genetic Syndrome	0%	7%	0%	3%
Heparin-induced Thrombocytopenia	0%	0%	0%	0%
Chronic Coagulopathy	14%	0%	0%	10%
Major Stroke	0%	7%	0%	3%
Other Cerebrovascular Disease	0%	0%	0%	0%
Peripheral Vascular Disease	0%	0%	0%	0%
History of Solid Organ Cancer	14%	0%	0%	6%
History of Lymphoma, Leukemia	0%	0%	0%	0%
History of Bone Marrow Transplant (BMT)	7%	0%	0%	3%

(Continued)

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 9: Pre-Implant Concerns

HOSPX-8888 (n=31)

PRE-IMPLANT CONCERNS	2012 - 2016	2017 - 2019	2020Q1	Total
History of HIV	0%	0%	0%	0%
Chronic Infectious Concerns	0%	13%	0%	6%
Limited cognition/understanding	0%	0%	0%	0%
Limited social support	14%	0%	0%	6%
Repeated non-compliance	0%	0%	0%	0%
History of illicit drug use	0%	7%	0%	3%
History of alcohol abuse	0%	0%	0%	0%
Narcotic dependence	0%	0%	0%	0%
History of smoking	0%	0%	0%	0%
Currently smoking	0%	7%	0%	3%
Severe depression	0%	0%	0%	0%
Other major psychiatric diagnosis	0%	0%	0%	0%
Neurological/developmental abnormalities	0%	7%	0%	3%
Other co-morbidity	7%	0%	0%	3%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 9: Pre-Implant Concerns

Pedimacs (n=680)

PRE-IMPLANT CONCERNS	2012 - 2016	2017 - 2019	2020Q1	Total
Patients (n)	313	344	23	680
Patient/Family Does Not Want Transplant	0%	1%	0%	0%
Musculoskeletal Limitation	3%	2%	4%	2%
Contraindication to Immunosuppression	0%	1%	0%	0%
Allosensitization	3%	1%	0%	2%
Frailty	3%	6%	22%	5%
Chronic Renal Disease	3%	2%	4%	3%
Frequent ICD Shocks	2%	1%	0%	1%
Pulmonary Disease	2%	2%	0%	2%
Pulmonary Hypertension	7%	5%	4%	6%
Recent Pulmonary Embolus	0%	0%	0%	0%
History of Atrial Arrhythmia	6%	6%	9%	6%
Unfavorable Mediastinal Anatomy	7%	6%	0%	6%
Thoracic Aortic Disease	0%	0%	4%	0%
Tracheostomy	0%	0%	0%	0%
Plastic Bronchitis	0%	0%	0%	0%
Large BMI	9%	6%	0%	7%
Severe Diabetes	0%	0%	0%	0%
Malnutrition/Cachexia	3%	5%	13%	4%
History of GI Ulcers	0%	0%	0%	0%
History of Hepatitis	0%	0%	0%	0%
Liver Dysfunction	5%	2%	4%	4%
Anasarca	0%	1%	0%	1%
Protein Losing Enteropathy	0%	0%	0%	0%
Genetic Syndrome	4%	3%	0%	3%
Heparin-induced Thrombocytopenia	1%	0%	0%	1%
Chronic Coagulopathy	2%	0%	0%	1%
Major Stroke	3%	3%	0%	3%
Other Cerebrovascular Disease	1%	0%	0%	0%
Peripheral Vascular Disease	0%	0%	0%	0%
History of Solid Organ Cancer	3%	1%	0%	2%
History of Lymphoma, Leukemia	1%	1%	0%	1%
History of Bone Marrow Transplant (BMT)	1%	0%	0%	0%

(Continued)

COVERAGE: September 19, 2012 - March 31, 2020**SITE: Hospital X - (Random 50 Patients)****Section 2 - Patients Recieving a Durable Device****Exhibit 9: Pre-Implant Concerns****Pedimacs (n=680)**

PRE-IMPLANT CONCERNS	2012 - 2016	2017 - 2019	2020Q1	Total
History of HIV	0%	0%	0%	0%
Chronic Infectious Concerns	1%	1%	0%	1%
Limited cognition/understanding	4%	1%	0%	2%
Limited social support	5%	3%	0%	4%
Repeated non-compliance	2%	1%	0%	1%
History of illicit drug use	1%	3%	0%	2%
History of alcohol abuse	0%	0%	0%	0%
Narcotic dependence	0%	0%	0%	0%
History of smoking	1%	1%	0%	1%
Currently smoking	0%	1%	0%	0%
Severe depression	1%	0%	0%	1%
Other major psychiatric diagnosis	1%	1%	0%	1%
Neurological/developmental abnormalities	5%	4%	0%	4%
Other co-morbidity	4%	3%	0%	4%

COVERAGE: September 19, 2012 - March 31, 2020**SITE: Hospital X - (Random 50 Patients)****Section 2 - Patients Receiving a Durable Device****Exhibit 10: General Hemodynamics**

The following table compare pre-implant general hemodynamics for patients receiving durable devices at your site and STS Pedimacs overall.

HOSPX-8888 (n=31)

PRE-IMPLANT GENERAL HEMODYNAMICS		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients	n	14	15	2	31
Heart Rate	Mean	123.20	106.17		113.91
	Std	25.94	37.12		32.20
	Missing	9	9	2	20

Pedimacs (n=680)

PRE-IMPLANT GENERAL HEMODYNAMICS		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients	n	313	344	23	680
Heart Rate	Mean	115.69	116.56	141.00	116.42
	Std	24.73	26.50	12.36	25.54
	Missing	153	208	19	380

COVERAGE: September 19, 2012 - March 31, 2020**SITE: Hospital X - (Random 50 Patients)****Section 2 - Patients Recieving a Durable Device****Exhibit 11: Echo Hemodynamics**

The following table compare pre-implant LVEDD for patients receiving durable devices at your site and STS Pedimacs overall.

HOSPX-8888 (n=31)

		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients	n	14	15	2	31
LVEDD	Mean	5.86	6.00	6.42	5.95
	Std	1.61	1.58	2.09	1.55
	Missing	2	9	0	11

Pedimacs (n=680)

		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients	n	313	344	23	680
LVEDD	Mean	5.78	5.63	6.24	5.72
	Std	1.79	1.77	1.25	1.77
	Missing	120	149	10	279

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Receiving a Durable Device

Exhibit 11: Echo Hemodynamics

The following tables summarize pre-implant RVEF at your site and STS Pedimacs.

HOSPX-8888 (n=31)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	14	15	2	31
RVEF				
Normal	7%	6%	0%	6%
Mild	14%	0%	0%	6%
Moderate	7%	6%	0%	6%
Severe	35%	13%	100%	29%
Not Done	14%	46%	0%	29%
Not Applicable	7%	6%	0%	6%
Unknown	14%	20%	0%	16%
Aortic Regurgitation				
0 (none)	57%	13%	50%	35%
1 (mild)	21%	40%	50%	32%
2 (moderate)	7%	6%	0%	6%
3 (severe)	0%	0%	0%	0%
Not Recorded or Not Documented	14%	40%	0%	25%

Pedimacs (n=680)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	313	344	23	680
RVEF				
Normal	15%	16%	8%	16%
Mild	10%	12%	8%	11%
Moderate	24%	19%	13%	21%
Severe	20%	15%	17%	17%
Not Done	15%	18%	34%	17%
Not Applicable	1%	4%	4%	3%
Unknown	11%	13%	13%	12%
Aortic Regurgitation				
0 (none)	49%	50%	52%	50%
1 (mild)	27%	24%	30%	25%
2 (moderate)	2%	2%	4%	2%
3 (severe)	0%	0%	0%	0%
Not Recorded or Not Documented	20%	21%	13%	20%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 12: Swan Hemodynamics

HOSPX-8888 (n=31)

SWAN HEMODYNAMICS		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients	n	14	15	2	31
Pulmonary Artery Systolic Pressure (mmHg)	Mean	49.00	49.00	53.50	49.75
	Std	25.18	41.01	4.95	23.70
	Missing	6	13	0	19
Pulmonary Artery Diastolic Pressure (mmHg)	Mean	29.38	36.50	26.50	30.08
	Std	14.68	26.16	2.12	14.49
	Missing	6	13	0	19
Mean RA Pressure (mmHg)	Mean	13.50	17.00	8.50	13.79
	Std	12.29	5.60	4.95	9.90
	Missing	6	11	0	17
Pulmonary Artery Wedge Pressure (mmHg)	Mean	22.56	24.00	21.50	22.80
	Std	7.76	13.44	6.36	8.76
	Missing	5	11	0	16
Cardiac Index	Mean	2.04	1.87		2.00
	Std	0.78	2.22		1.04
	Missing	7	13	2	22

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 12: Swan Hemodynamics

Pedimacs (n=680)

SWAN HEMODYNAMICS		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients	n	313	344	23	680
Pulmonary Artery Systolic Pressure (mmHg)	Mean	47.51	41.75	50.00	45.33
	Std	19.85	18.13	19.23	19.31
	Missing	177	249	14	440
Pulmonary Artery Diastolic Pressure (mmHg)	Mean	28.32	25.15	28.22	27.08
	Std	13.13	10.99	8.41	12.25
	Missing	177	252	14	443
Mean RA Pressure (mmHg)	Mean	13.00	12.56	11.00	12.76
	Std	6.55	6.38	5.74	6.45
	Missing	157	230	14	401
Pulmonary Artery Wedge Pressure (mmHg)	Mean	23.08	21.78	22.50	22.51
	Std	8.02	9.27	8.43	8.57
	Missing	193	251	15	459
Cardiac Index	Mean	2.22	2.37	2.36	2.29
	Std	0.89	1.08	0.90	0.97
	Missing	200	258	16	474

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 13: ECG Cardiac Rhythm

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

HOSPX-8888 (n=31)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	14	15	2	31
ECG Rhythm				
Sinus	71%	60%	0%	61%
Atrial fibrillation	7%	0%	0%	3%
Atrial Flutter	0%	0%	0%	0%
Not done	0%	0%	0%	0%
Paced: Atrial pacing	0%	0%	0%	0%
Paced: Ventricular pacing	7%	6%	50%	9%
Paced: Atrial and ventricular pacing	7%	6%	0%	6%
Unknown	0%	6%	0%	3%
Other, specify	7%	20%	50%	16%

Pedimacs (n=680)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	313	344	23	680
ECG Rhythm				
Sinus	73%	77%	73%	75%
Atrial fibrillation	0%	0%	4%	0%
Atrial Flutter	0%	0%	0%	0%
Not done	0%	0%	0%	0%
Paced: Atrial pacing	1%	2%	0%	1%
Paced: Ventricular pacing	2%	4%	4%	3%
Paced: Atrial and ventricular pacing	2%	3%	8%	3%
Unknown	1%	1%	0%	1%
Other, specify	16%	11%	8%	13%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Receiving a Durable Device

Exhibit 14: VAD Indication

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

HOSPX-8888 (n=31)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	14	15	2	31
VAD Indication				
Failure to wean from CPB	0%	0%	0%	0%
Post Cardiac Surgery	0%	6%	0%	3%
None	92%	86%	100%	90%
Failure to Wean from ECMO	7%	6%	0%	6%

Pedimacs (n=680)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	313	344	23	680
VAD Indication				
Failure to wean from CPB	0%	0%	0%	0%
Post Cardiac Surgery	1%	2%	0%	2%
None	84%	84%	91%	84%
Failure to Wean from ECMO	13%	12%	8%	12%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 15: Device Type

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

HOSPX-8888 (n=31)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	14	15	2	31
Device Type				
LVAD	92%	86%	100%	90%
RVAD	0%	6%	0%	3%
BiVAD	0%	6%	0%	3%
TAH	7%	0%	0%	3%

Pedimacs (n=680)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	313	344	23	680
Device Type				
LVAD	83%	84%	82%	83%
RVAD	1%	2%	0%	2%
BiVAD	13%	12%	17%	13%
TAH	1%	0%	0%	0%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Receiving a Durable Device

Exhibit 16: Previous Cardiac Operations

This table lists the cardiac operations that the patient had prior to MCS implantation.

HOSPX-8888 (n=31)

PREVIOUS CARDIAC OPERATIONS	2012 - 2016	2017 - 2019	2020Q1	Total
Patients (n)	14	15	2	31
None	50%	40%	50%	45%
CABG	0%	0%	0%	0%
Aneurysmectomy (DOR)	0%	0%	0%	0%
Aortic Valve replacement / repair	0%	7%	0%	3%
Mitral Valve replacement / repair	7%	0%	0%	3%
Tricuspid replacement /repair	0%	20%	0%	10%
Congenital card surgery	21%	33%	50%	29%
LVAD	14%	13%	0%	13%
RVAD	7%	0%	0%	3%
TAH	0%	0%	0%	0%
Previous heart transplant	7%	0%	0%	3%
Previous ECMO	0%	20%	0%	10%
Other, specify	14%	13%	0%	13%

Pedimacs (n=680)

PREVIOUS CARDIAC OPERATIONS	2012 - 2016	2017 - 2019	2020Q1	Total
Patients (n)	313	344	23	680
None	58%	61%	61%	60%
CABG	1%	1%	0%	1%
Aneurysmectomy (DOR)	0%	0%	0%	0%
Aortic Valve replacement / repair	3%	3%	4%	3%
Mitral Valve replacement / repair	3%	3%	0%	3%
Tricuspid replacement /repair	2%	2%	0%	2%
Congenital card surgery	14%	17%	22%	16%
LVAD	6%	7%	4%	6%
RVAD	2%	1%	0%	1%
TAH	0%	0%	0%	0%
Previous heart transplant	4%	2%	0%	3%
Previous ECMO	16%	14%	9%	15%
Other, specify	11%	9%	13%	10%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Receiving a Durable Device

Exhibit 17: Clinical Events and Interventions during Implant Hospitalization

This table lists the interventions that occurred during the implant hospitalization.

HOSPX-8888 (n=31)

IMPLANT HOSPITALIZATION EVENTS	2012 - 2016	2017 - 2019	2020Q1	Total
Patients (n)	14	15	2	31
None	14%	13%	50%	16%
CABG	0%	0%	0%	0%
Aortic Valve replacement / repair	0%	0%	0%	0%
Mitral Valve replacement / repair	0%	0%	0%	0%
Congenital cardiac surgery	0%	0%	0%	0%
Other surgical procedures	7%	7%	0%	6%
IABP	0%	0%	0%	0%
ECMO	7%	20%	0%	13%
LVAD	14%	7%	0%	10%
RVAD	7%	7%	0%	6%
TAH	0%	0%	0%	0%
Dialysis	7%	0%	0%	3%
Ultrafiltration	7%	0%	0%	3%
Feeding Tube	36%	13%	0%	23%
Intubation	57%	33%	0%	42%
Major MI	0%	0%	0%	0%
Major infections / Positive blood cultures	21%	7%	0%	13%
Escalation to CPAP	7%	13%	0%	10%
Arrhythmia	36%	20%	50%	29%
Previous ECMO	0%	20%	0%	10%
Previous heart transplant	7%	0%	0%	3%
Treatment of Rejection	7%	0%	0%	3%
Peritoneal Drain	0%	0%	0%	0%
Non-cardiac procedure	14%	7%	0%	10%

Pedimacs (n=680)

IMPLANT HOSPITALIZATION EVENTS	2012 - 2016	2017 - 2019	2020Q1	Total
Patients (n)	313	344	23	680
None	25%	30%	13%	27%
CABG	0%	0%	0%	0%
Aortic Valve replacement / repair	0%	1%	4%	1%

(Continued)

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Receiving a Durable Device

Exhibit 17: Clinical Events and Interventions during Implant Hospitalization

Pedimacs (n=680)

IMPLANT HOSPITALIZATION EVENTS	2012 - 2016	2017 - 2019	2020Q1	Total
Mitral Valve replacement / repair	1%	1%	0%	1%
Congenital cardiac surgery	3%	4%	9%	4%
Other surgical procedures	6%	5%	0%	5%
IABP	2%	1%	0%	1%
ECMO	23%	22%	26%	23%
LVAD	7%	10%	13%	9%
RVAD	2%	1%	0%	2%
TAH	0%	0%	0%	0%
Dialysis	6%	2%	17%	5%
Ultrafiltration	3%	1%	4%	2%
Feeding Tube	25%	22%	43%	24%
Intubation	44%	40%	39%	42%
Major MI	1%	2%	0%	1%
Major infections / Positive blood cultures	11%	8%	13%	10%
Escalation to CPAP	5%	9%	13%	7%
Arrhythmia	29%	22%	35%	26%
Previous ECMO	4%	4%	4%	4%
Previous heart transplant	2%	1%	0%	1%
Treatment of Rejection	3%	1%	0%	2%
Peritoneal Drain	1%	1%	0%	1%
Non-cardiac procedure	2%	5%	13%	4%

COVERAGE: September 19, 2012 - March 31, 2020**SITE: Hospital X - (Random 50 Patients)****Section 2 - Patients Recieving a Durable Device*****Exhibit 18a: Adverse Event Exposure***

The following table summarizes the total time patients receiving primary prospective implants have been followed at your site and STS Pedimacs 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-8888	STS Pedimacs
Patient exposure during the first 3 months post implant (months)	130	1456
Patient exposure after the first 3 months post implant (months)	195	1895
Number of Patients	62	711

COVERAGE: September 19, 2012 - March 31, 2020**SITE: Hospital X - (Random 50 Patients)****Section 2 - Patients Recieving a Durable Device****Exhibit 18b: Adverse Event Counts**

The following table includes overall counts and percentages for each type of adverse event reported at your site and STS Pedimacs overall. These totals are based on adverse events reported for primary prospective patients.

Adverse Events	STS Pedimacs	
	Episodes	%
Arterial Non-CNS Thromboembolism	4	0.1 %
Bleeding	380	13.8 %
Cardiac Arrhythmia	86	3.1 %
Device Malfunction	9	0.3 %
Device Malfunction and/or Pump Thrombosis	417	15.2 %
Hepatic Dysfunction	22	0.8 %
Infection	438	16.0 %
Neurological Dysfunction	291	10.6 %
Other Serious Adverse Event	298	10.8 %
Pericardial Drainage	41	1.4 %
Psychiatric Episode	39	1.4 %
Rehospitalization	433	15.8 %
Renal Dysfunction	89	3.2 %
Respiratory Failure	174	6.3 %
Venous Thromboembolism	9	0.3 %
Wound Dehiscence	5	0.1 %
Total Events	2735	100.0 %

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 18c: Adverse Event Rates

	STS Pedimacs			
	Early (During the First Three Months)		Late (After the First Three Months)	
	Episodes	Rate (per 100 pt month)	Episodes	Rate (per 100 pt month)
Arterial Non-CNS Thromboembolism	4	0.27		
Bleeding	338	23.22	42	2.22
Cardiac Arrhythmia	73	5.01	13	0.69
Device Malfunction	7	0.48	2	0.11
Device Malfunction and/or Pump Thrombosis	319	21.91	98	5.17
Hepatic Dysfunction	17	1.17	5	0.26
Infection	316	21.71	122	6.44
Neurological Dysfunction	244	16.76	47	2.48
Other Serious Adverse Event	244	16.76	54	2.85
Pericardial Drainage	41	2.82		
Psychiatric Episode	34	2.34	5	0.26
Rehospitalization	99	6.80	334	17.63
Renal Dysfunction	81	5.56	8	0.42
Respiratory Failure	158	10.85	16	0.84
Venous Thromboembolism	9	0.62		
Wound Dehiscence	5	0.34		

COVERAGE: September 19, 2012 - March 31, 2020**SITE: Hospital X - (Random 50 Patients)****Section 2 - Patients Recieving a Durable Device****Exhibit 18d: Infection Rates by Location**

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

	STS Pedimacs			
	Early (During the First Three Months)		Late (After the First Three Months)	
	Episodes	Rate (per 100 pt month)	Episodes	Rate (per 100 pt month)
GI	23	1.58	11	0.58
Line Sepsis	19	1.31	8	0.42
Mediastinum	20	1.37	3	0.16
Other Specify	50	3.43	15	0.79
Peripheral Wound	11	0.76	5	0.26
Positive Blood Cultures	69	4.74	24	1.27
Pulmonary	92	6.32	19	1.00
Pump/Related - Drive Line	25	1.72	35	1.85
Pump/Related - Exit Cannula	10	0.69	6	0.32
Pump/Related - Pump Interior	2	0.14	0	0.00
Pump/Related - Pump Pocket	2	0.14	2	0.11
Unknown	20	1.37	3	0.16
Urinary Tract	34	2.34	10	0.53

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 19: Hospital Days for Discharged Patients

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

HOSPITAL DAYS FOR DISCHARGED PATIENTS		HOSPX-8888 (n=31)	Pedimacs (n=680)
All	Patients	9	229
	Mean	39.00	48.40
	Std	26.60	50.53
	Min	14	2
	Max	100	423
BiVAD	Patients		10
	Mean		96.50
	Std		116.51
	Min		6
	Max		406
LVAD	Patients	8	208
	Mean	31.38	44.52
	Std	14.52	41.37
	Min	14	2
	Max	61	423
RVAD	Patients		9
	Mean		48.78
	Std		21.07
	Min		22
	Max		91
TAH	Patients	1	2
	Mean	100.00	209.50
	Std		154.86
	Min	100	100
	Max	100	319

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 20: 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 Pedimacs overall. Percentages are listed by device type and discharge year.

HOSPX-8888

30 DAY REDMISSION		2012 - 2016	2017 - 2019	2020Q1	TOTAL
LVAD	Patients Discharged Alive on Device (n)	3	2	0	5
	% With 30 day Readmission	0%	0%		0%
RVAD	Patients Discharged Alive on Device (n)	0	0	0	0
	% With 30 day Readmission				
BiVAD	Patients Discharged Alive on Device (n)	0	0	0	0
	% With 30 day Readmission				
TAH	Patients Discharged Alive on Device (n)	0	0	0	0
	% With 30 day Readmission				

STS Pedimacs

30 DAY REDMISSION		2012 - 2016	2017 - 2019	2020Q1	TOTAL
LVAD	Patients Discharged Alive on Device (n)	96	91	8	195
	% With 30 day Readmission	21%	23%	13%	22%
RVAD	Patients Discharged Alive on Device (n)	4	5	0	9
	% With 30 day Readmission	0%	80%		44%
BiVAD	Patients Discharged Alive on Device (n)	3	1	2	6
	% With 30 day Readmission	33%	0%	50%	33%
TAH	Patients Discharged Alive on Device (n)	1	0	0	1
	% With 30 day Readmission	0%			0%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 21: NYHA Class

The following tables summarize NYHA completion status and values at your site and Pedimacs 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-8888

VISIT	Patients (n)	COMPLETION STATUS				NYHA Class				
		Not Done: Other/Unknown		Complete						
	N	N	%	N	%	Mean	Std	Median	Min	Max
Pre-Implant	31	9	29.0	22	71.0	3.9	0.4	4.0	3.0	4.0
3 Month	13	5	38.5	8	61.5	2.3	0.9	2.0	1.0	4.0
6 Month	4	1	25.0	3	75.0	2.7	1.2	2.0	2.0	4.0
1 Year	4	1	25.0	3	75.0	2.3	1.5	2.0	1.0	4.0
2 Year	2	1	50.0	1	50.0	1.0		1.0	1.0	1.0

GROUP=STS Pedimacs

VISIT	Patients (n)	COMPLETION STATUS				NYHA Class				
		Not Done: Other/Unknown		Complete						
	N	N	%	N	%	Mean	Std	Median	Min	Max
Pre-Implant	680	202	29.7	478	70.3	3.7	0.6	4.0	1.0	4.0
3 Month	289	117	40.5	172	59.5	2.3	1.0	2.0	1.0	4.0
6 Month	139	57	41.0	82	59.0	2.2	1.0	2.0	1.0	4.0
1 Year	54	20	37.0	34	63.0	2.3	1.1	2.0	1.0	4.0
2 Year	14	7	50.0	7	50.0	1.9	1.1	2.0	1.0	4.0
3 Year	5	1	20.0	4	80.0	2.5	1.3	2.5	1.0	4.0
4 Year	3	2	66.7	1	33.3	2.0		2.0	2.0	2.0
5 Year	3	3	100.0							

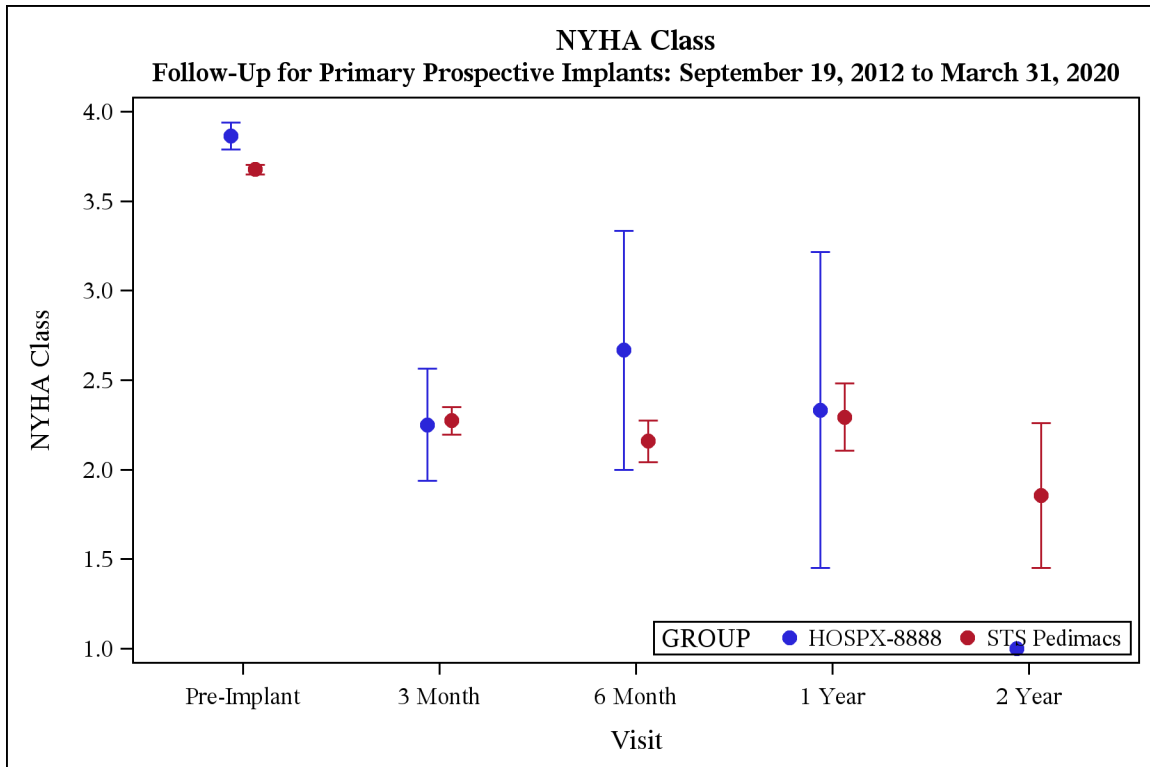
COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 21: NYHA Class

The following figure summarize NYHA Class values your site and Pedimacs 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.



COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

II.D. 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 STS Pedimacs. 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.

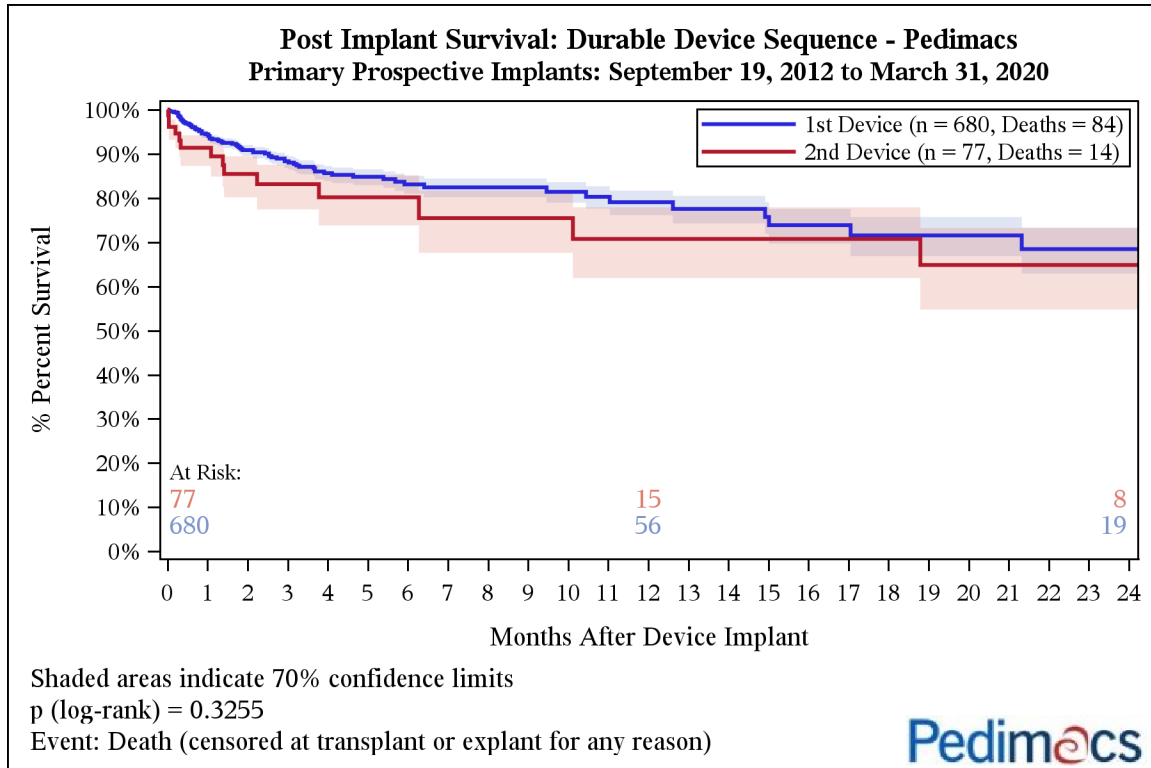
Note: If your site did not report any patients within a specified group, only the overall STS Pedimacs data will be displayed.

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Exhibit 22a: Post Implant Survival - Durable Device Sequence - Pedimacs

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.



Percent Survival [% (70% CI)]

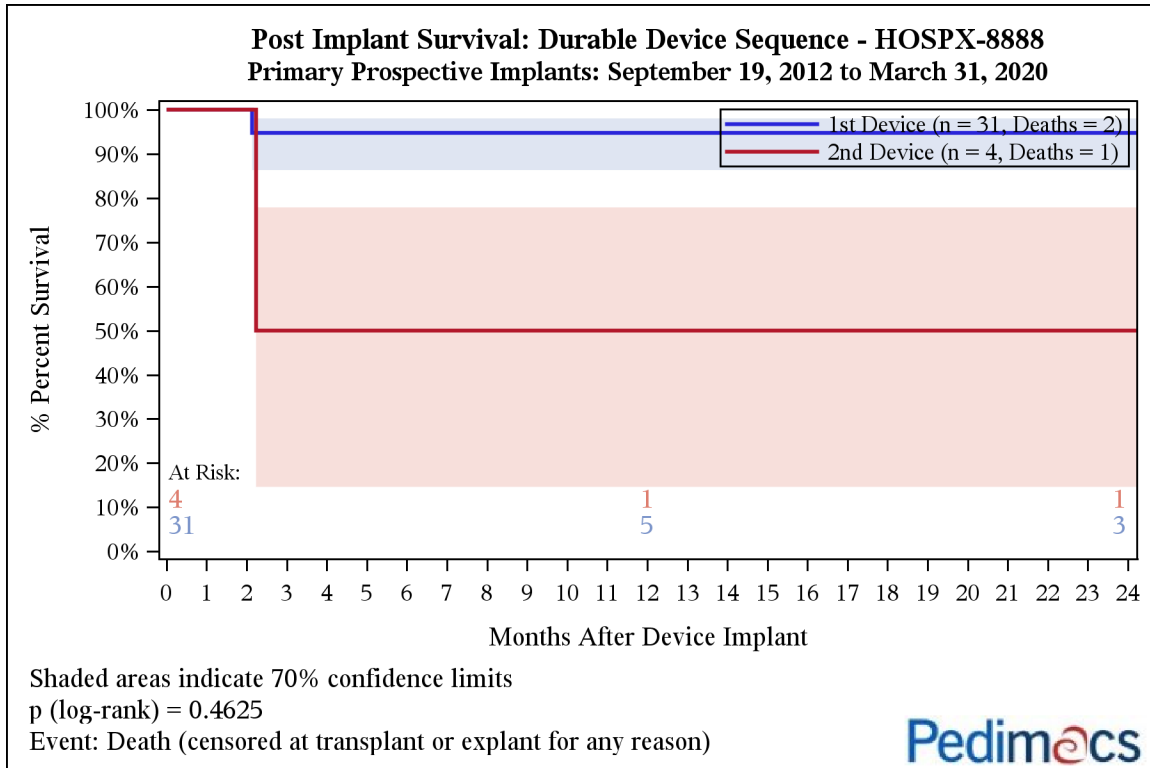
Months after Device Implant	1st Device	2nd Device
1	94.4% (93.4%-95.3%)	91.4% (87.3%-94.2%)
3	88.3% (86.8%-89.7%)	83.1% (77.4%-87.5%)
6	83.1% (81.0%-85.0%)	80.2% (73.8%-85.1%)
12	79.1% (76.1%-81.7%)	70.7% (61.9%-77.9%)
24	68.4% (62.9%-73.3%)	64.8% (54.8%-73.2%)

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Exhibit 22b: Post Implant Survival - Durable Device Sequence - HOSPX-8888

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.



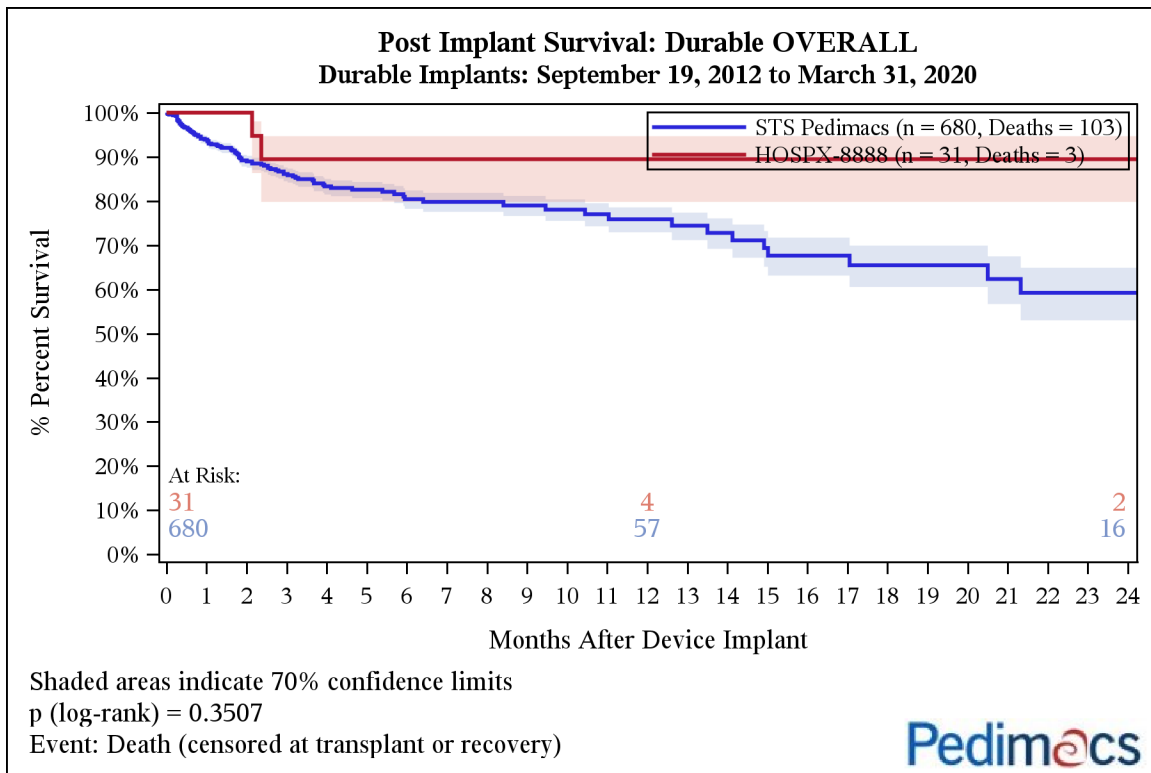
Percent Survival [% (70% CI)]

Months after Device Implant	1st Device	2nd Device
1	100.0% (100.0%-100.0%)	100.0% (100.0%-100.0%)
3	94.7% (86.3%-98.0%)	50.0% (14.6%-77.9%)
6	94.7% (86.3%-98.0%)	50.0% (14.6%-77.9%)
12	94.7% (86.3%-98.0%)	50.0% (14.6%-77.9%)
24	94.7% (86.3%-98.0%)	50.0% (14.6%-77.9%)

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Exhibit 23: Post Implant Survival - Durable OVERALL



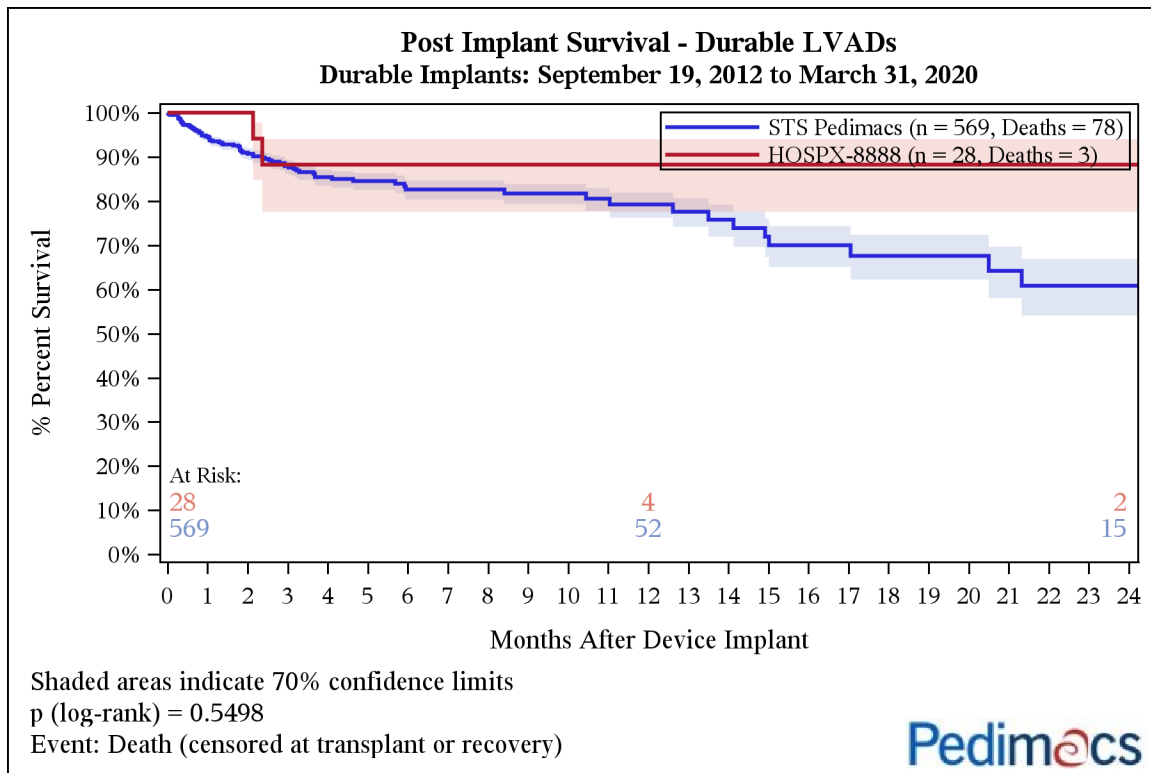
Percent Survival [% (70% CI)]

Months after Device Implant	STS Pedimacs	HOSPX-8888
1	93.9% (92.9%-94.8%)	100.0% (100.0%-100.0%)
3	86.1% (84.5%-87.6%)	89.5% (79.8%-94.7%)
6	80.4% (78.3%-82.4%)	89.5% (79.8%-94.7%)
12	75.9% (72.9%-78.5%)	89.5% (79.8%-94.7%)
24	59.2% (53.0%-64.9%)	89.5% (79.8%-94.7%)

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

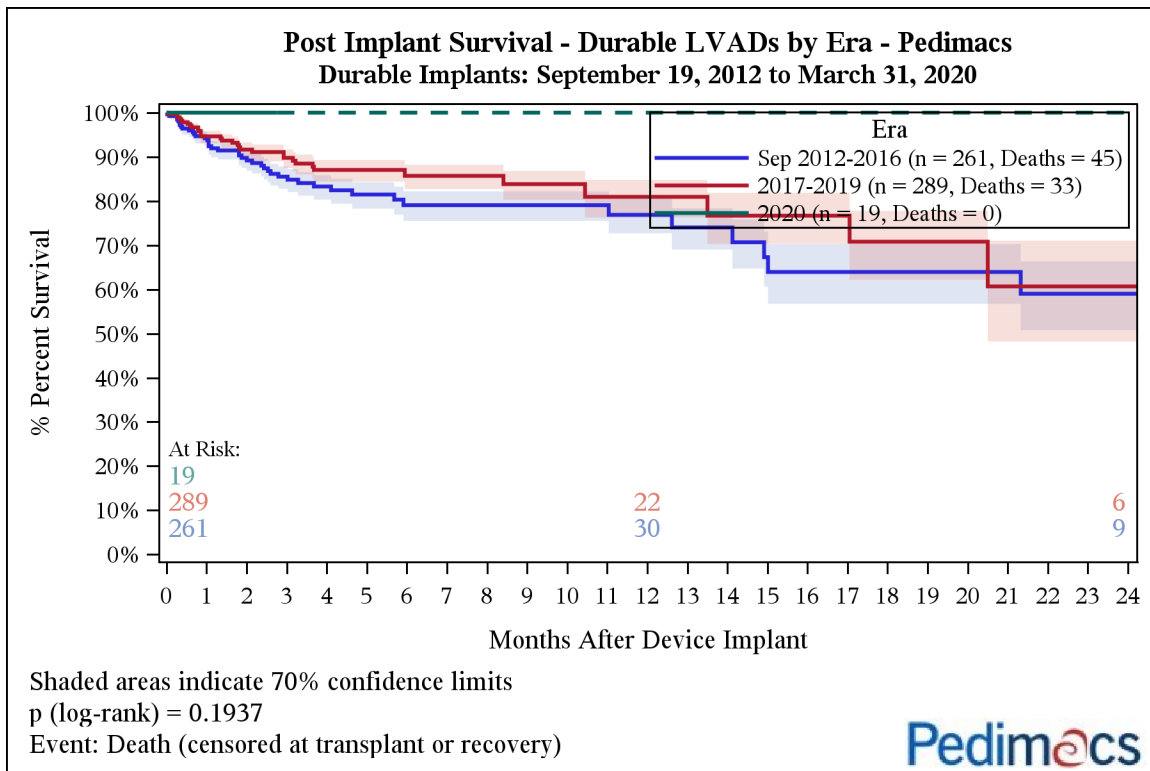
Exhibit 24: Post Implant Survival - Durable LVADs



Percent Survival [% (70% CI)]

Months after Device Implant	STS Pedimacs	HOSPX-8888
1	94.6% (93.5%-95.5%)	100.0% (100.0%-100.0%)
3	87.9% (86.2%-89.4%)	88.2% (77.6%-94.0%)
6	82.6% (80.3%-84.7%)	88.2% (77.6%-94.0%)
12	79.2% (76.2%-81.9%)	88.2% (77.6%-94.0%)
24	60.8% (54.1%-66.9%)	88.2% (77.6%-94.0%)

Exhibit 25a: Post Implant Survival - Durable LVADs by Era - Pedimacs



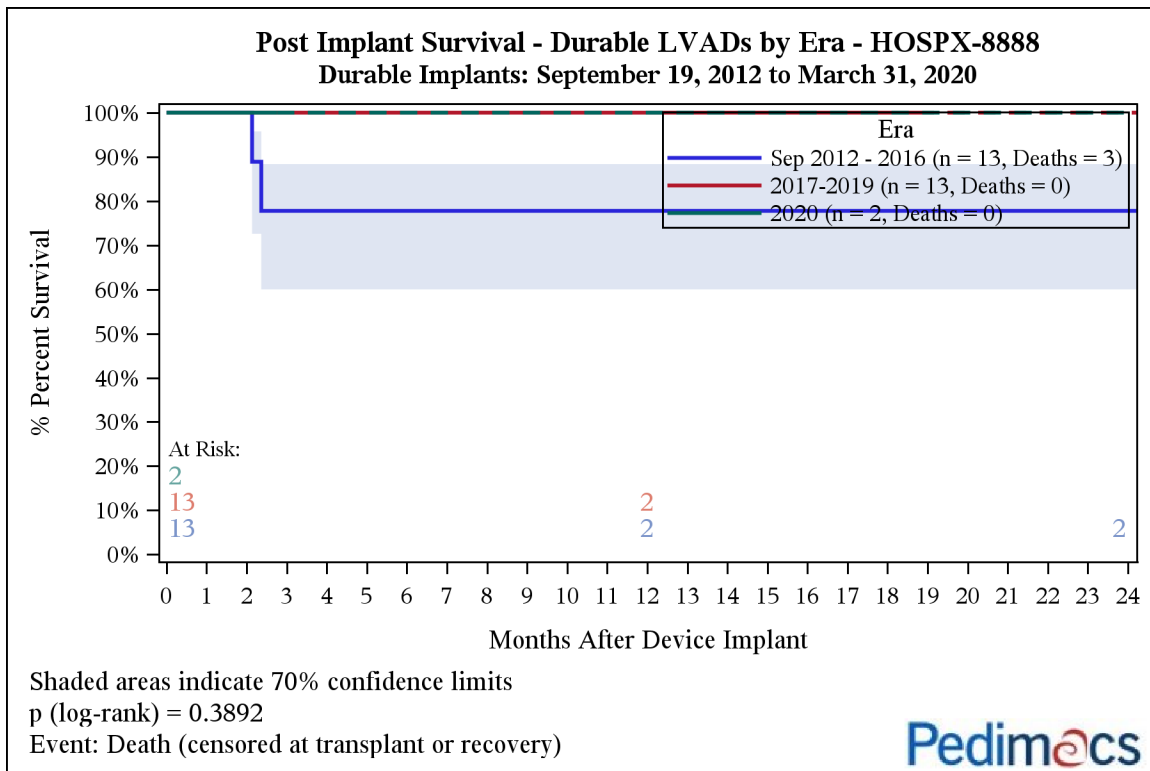
Percent Survival [% (70% CI)]

Months after Device Implant	Sep 2012-2016	2017-2019	2020
1	94.2% (92.5%-95.6%)	94.6% (93.0%-95.9%)	100.0% (100.0%-100.0%)
3	85.5% (82.8%-87.8%)	89.8% (87.5%-91.7%)	
6	79.1% (75.5%-82.2%)	85.7% (82.7%-88.2%)	
12	76.9% (72.7%-80.5%)	80.9% (76.3%-84.8%)	
24	59.0% (50.8%-66.4%)	60.7% (48.2%-71.0%)	

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Exhibit 25b: Post Implant Survival - Durable LVADs by Era - HOSPX-8888



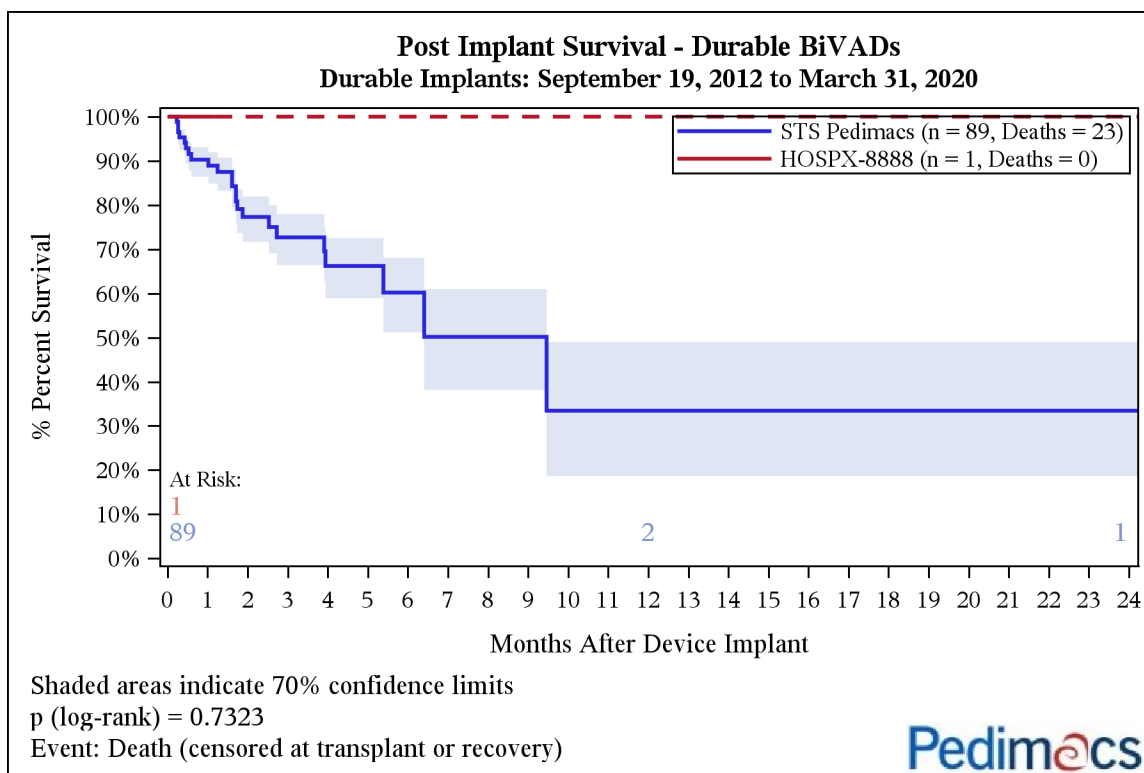
Percent Survival [% (70% CI)]

Months after Device Implant	Sep 2012 - 2016	2017-2019	2020
1	100.0% (100.0%-100.0%)	100.0% (100.0%-100.0%)	100.0% (100.0%-100.0%)
3	77.8% (60.0%-88.4%)	100.0% (100.0%-100.0%)	
6	77.8% (60.0%-88.4%)	100.0% (100.0%-100.0%)	
12	77.8% (60.0%-88.4%)	100.0% (100.0%-100.0%)	
24	77.8% (60.0%-88.4%)		

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Exhibit 26: Post Implant Survival - Durable BiVADs



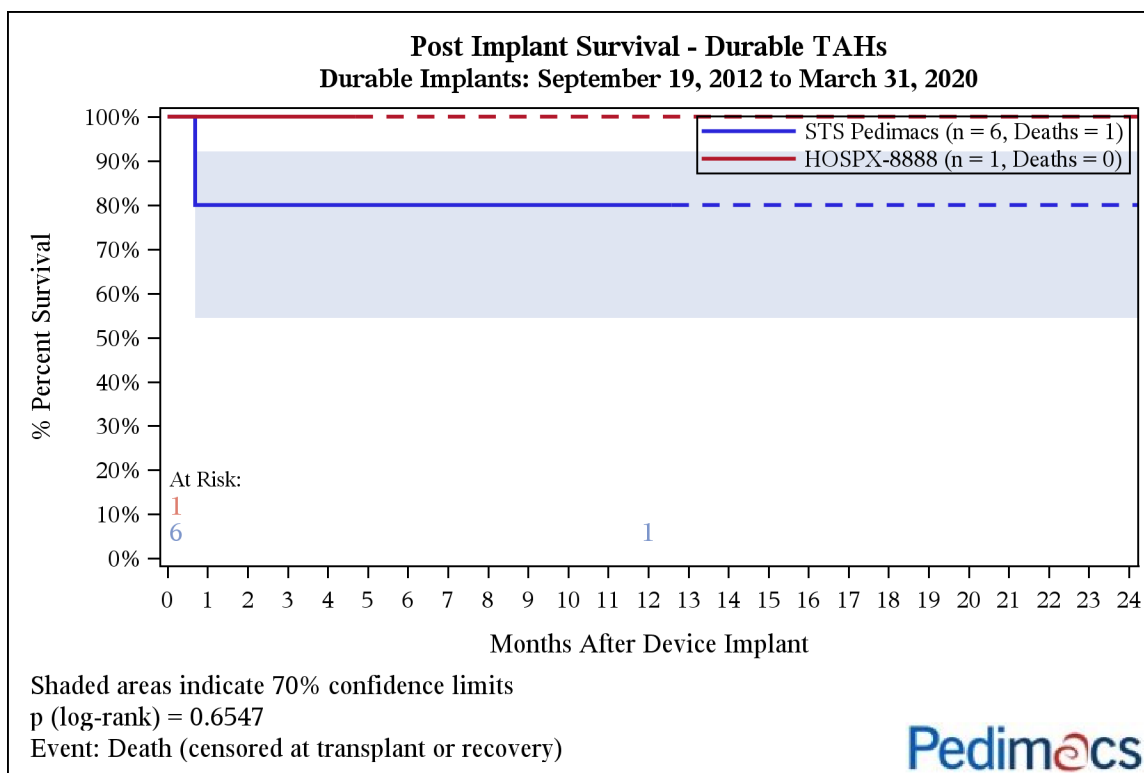
Percent Survival [% (70% CI)]

Months after Device Implant	STS Pedimacs	HOSPX-8888
1	90.3% (86.4%-93.1%)	100.0% (100.0%-100.0%)
3	72.7% (66.4%-78.0%)	
6	60.2% (51.2%-68.0%)	
12	33.4% (18.6%-49.0%)	
24	33.4% (18.6%-49.0%)	

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Exhibit 27: Post Implant Survival - Durable TAHs



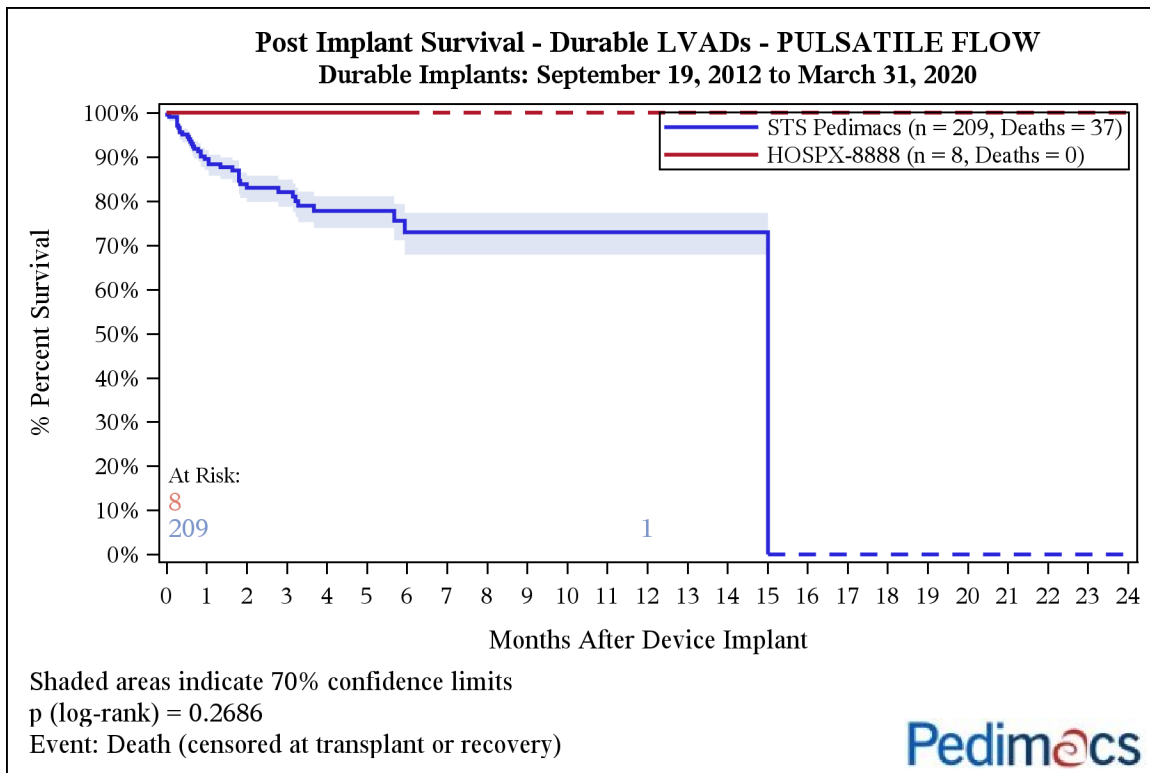
Percent Survival [% (70% CI)]

Months after Device Implant	STS Pedimacs	HOSPX-8888
1	80.0% (54.5%-92.1%)	100.0% (100.0%-100.0%)
3	80.0% (54.5%-92.1%)	100.0% (100.0%-100.0%)
6	80.0% (54.5%-92.1%)	
12	80.0% (54.5%-92.1%)	

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Exhibit 28: Post Implant Survival - Durable LVADs - PULSATILE FLOW



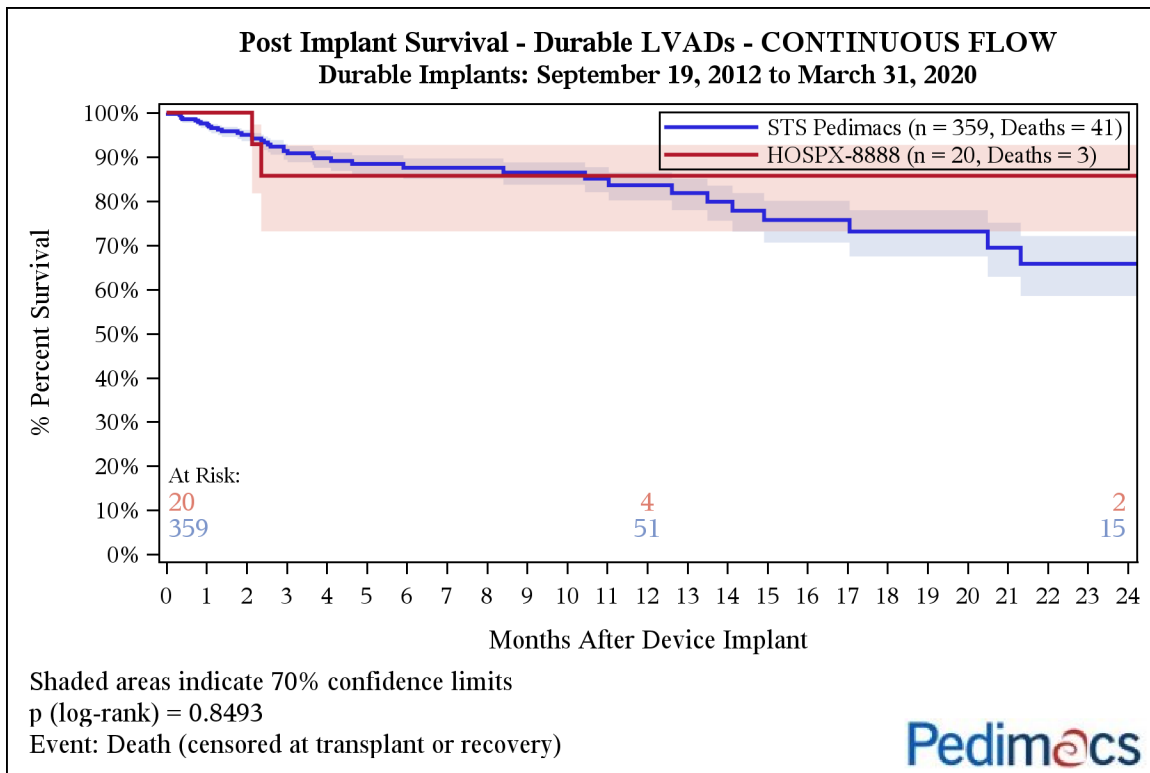
Percent Survival [% (70% CI)]

Months after Device Implant	STS Pedimacs	HOSPX-8888
1	89.5% (87.0%-91.5%)	100.0% (100.0%-100.0%)
3	82.0% (78.7%-84.9%)	100.0% (100.0%-100.0%)
6	72.9% (67.9%-77.3%)	
12	72.9% (67.9%-77.3%)	

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Exhibit 29: Post Implant Survival - Durable LVADs - CONTINUOUS FLOW



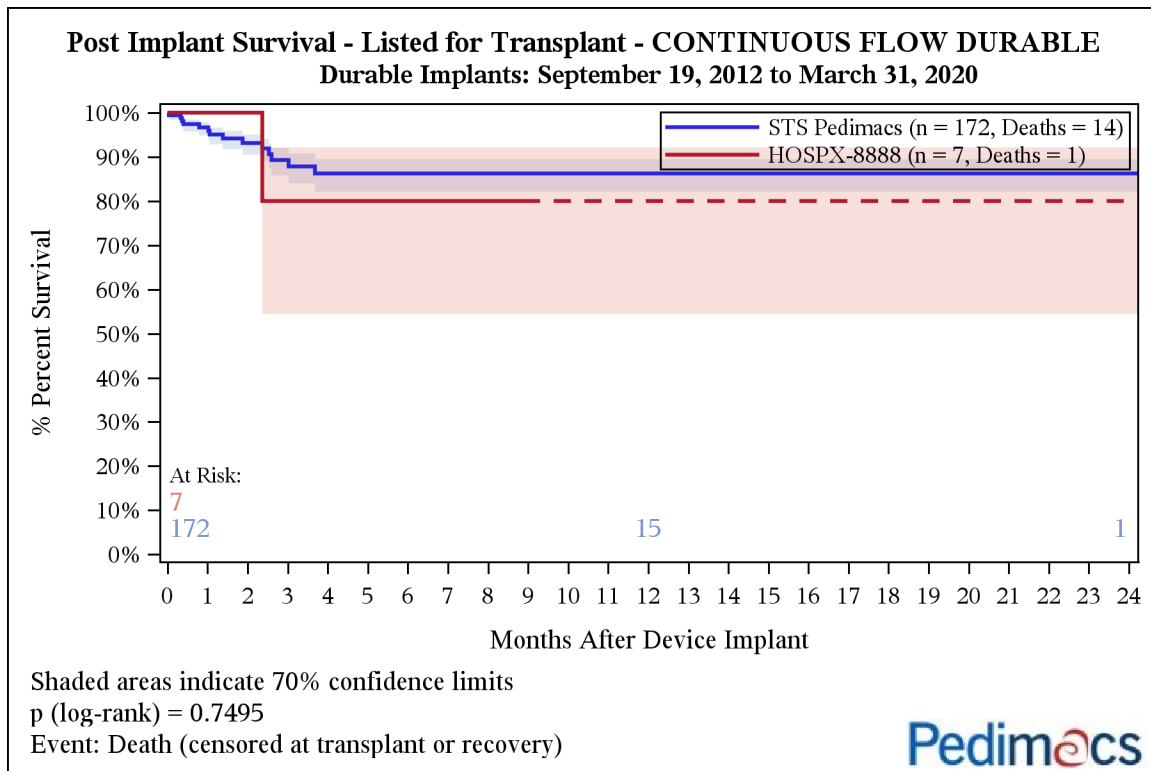
Percent Survival [% (70% CI)]

Months after Device Implant	STS Pedimacs	HOSPX-8888
1	97.6% (96.5%-98.3%)	100.0% (100.0%-100.0%)
3	91.3% (89.4%-92.9%)	85.7% (73.1%-92.7%)
6	87.5% (85.0%-89.6%)	85.7% (73.1%-92.7%)
12	83.6% (80.2%-86.5%)	85.7% (73.1%-92.7%)
24	65.8% (58.5%-72.1%)	85.7% (73.1%-92.7%)

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Exhibit 30: Post Implant Survival - Listed for Transplant - CONTINUOUS FLOW DURABLE



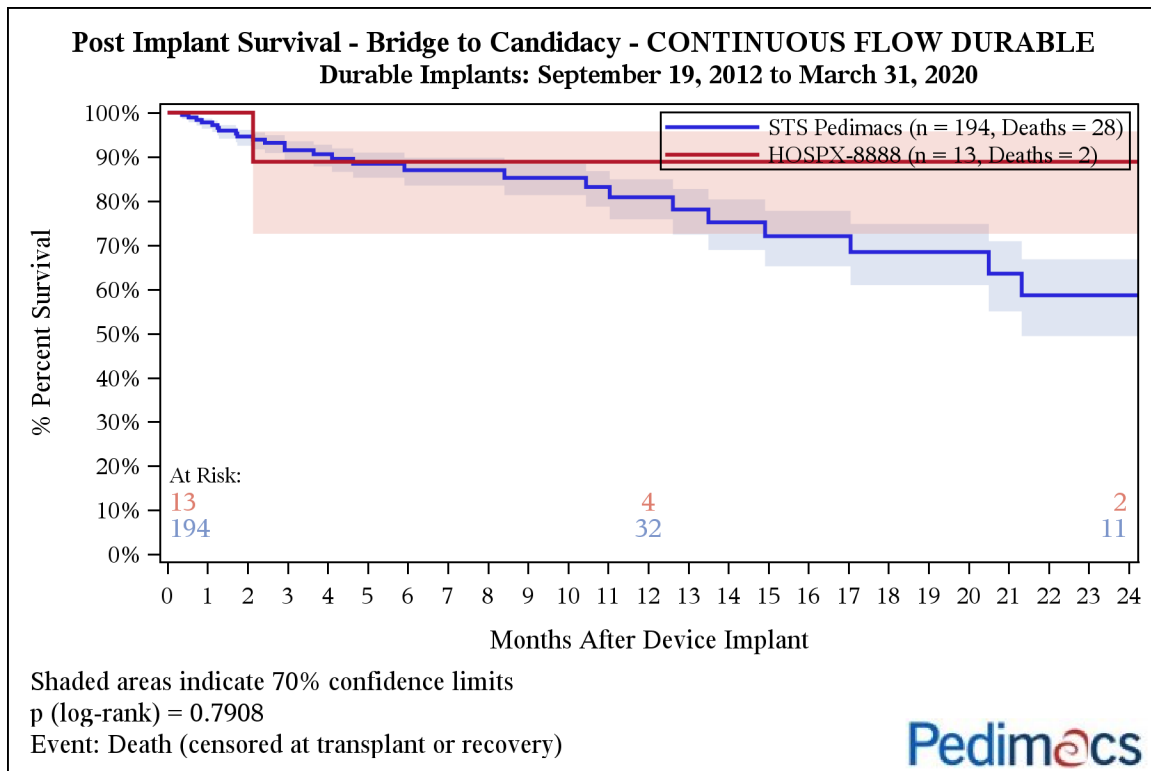
Percent Survival [% (70% CI)]

Months after Device Implant	STS Pedimacs	HOSPX-8888
1	96.7% (94.8%-97.9%)	100.0% (100.0%-100.0%)
3	89.3% (85.8%-92.0%)	80.0% (54.5%-92.1%)
6	86.2% (82.1%-89.5%)	80.0% (54.5%-92.1%)
12	86.2% (82.1%-89.5%)	
24	86.2% (82.1%-89.5%)	

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Exhibit 31: Post Implant Survival - Bridge to Candidacy - CONTINUOUS FLOW DURABLE



Percent Survival [% (70% CI)]

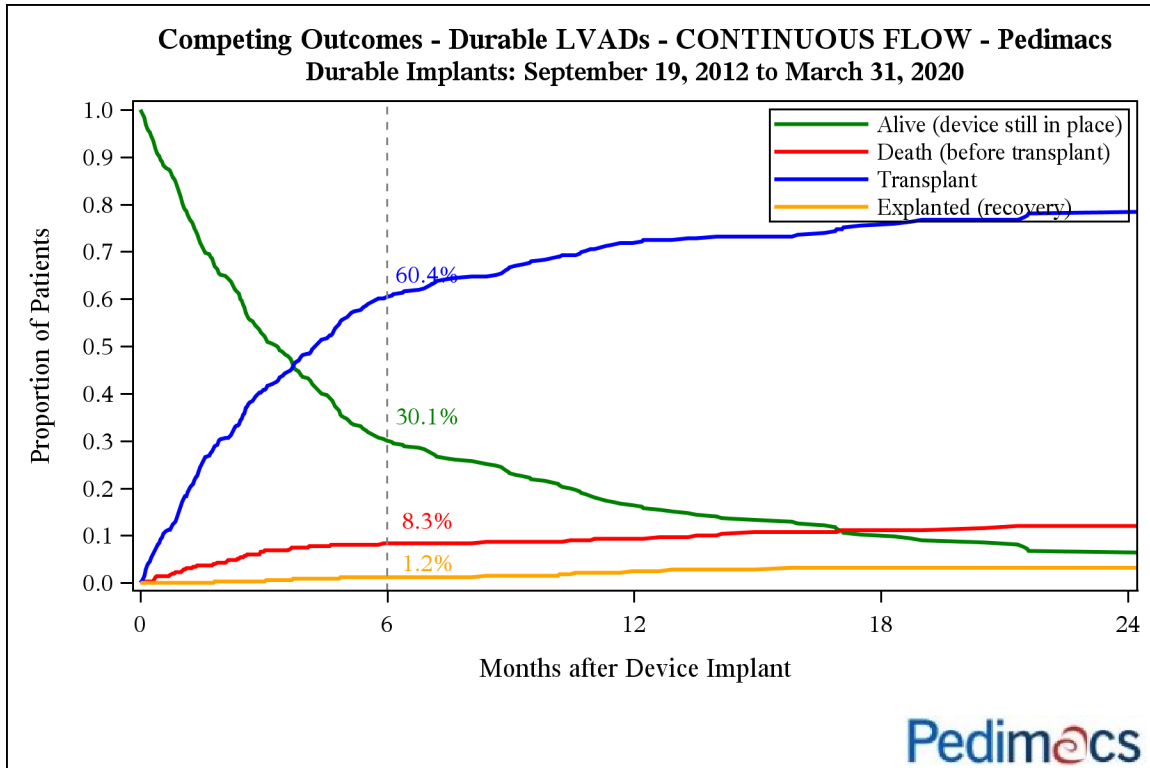
Months after Device Implant	STS Pedimacs	HOSPX-8888
1	97.8% (96.4%-98.7%)	100.0% (100.0%-100.0%)
3	91.5% (88.9%-93.5%)	88.9% (72.6%-95.8%)
6	87.0% (83.5%-89.8%)	88.9% (72.6%-95.8%)
12	80.9% (75.9%-84.9%)	88.9% (72.6%-95.8%)
24	58.7% (49.4%-66.8%)	88.9% (72.6%-95.8%)

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Exhibit 32a: Competing Outcomes - Durable LVADs - CONTINUOUS FLOW - Pedimacs

This figure estimates the simultaneous probability across time of a patient moving from alive (with a device in place) to one of the following terminal events: transplanted, dead, or recovery (due to device removal). This depiction is for all primary LVADs in STS Pedimacs.



Number of Patients at Risk

Month			
0	12	24	36
359	52	16	7

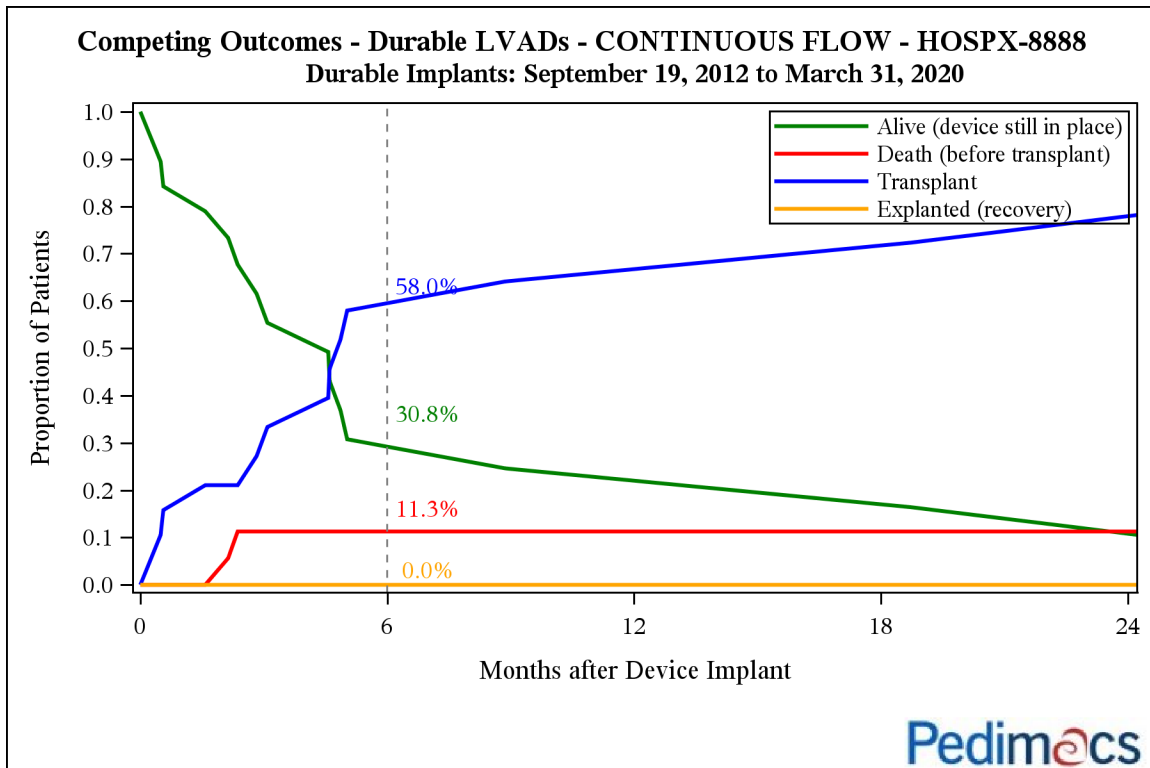
COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Exhibit 32b: Competing Outcomes - Durable LVADs - CONTINUOUS FLOW - HOSPX-8888

This figure estimates the simultaneous probability across time of a patient moving from alive (with a device in place) to one of the following terminal events: transplanted, dead, or recovery (due to device removal). This depiction is for all primary LVADs at your hospital.

Competing outcomes results for sites with low numbers of patients (e.g. < 20) may be extremely jagged and/or suppressed in this display and comparisons with Pedimacs competing outcome results will have limited value.



Number of Patients at Risk

Month		
0	12	24
20	5	3

COVERAGE: September 19, 2012 - March 31, 2020**SITE: Hospital X - (Random 50 Patients)****Section 3 - Patients Receiving only Temporary Devices****Exhibit 1: Primary and Subsequent Device Counts**

The following tables list the number of implants at your site and STS Pedimacs overall by device sequence (primary, secondary, etc.). NOTE: Subsequent analysis in this section evaluate only primary devices unless specified otherwise.

HOSPX-8888 (n=17)

DEVICE #	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Primary Device	6	10	1	17
2nd Device	0	0	0	0
3rd Device	0	0	0	0
4th Device	0	0	0	0
5th Device	0	0	0	0

Pedimacs (n=227)

DEVICE #	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Primary Device	72	142	13	227
2nd Device	4	6	1	11
3rd Device	1	0	1	2
4th Device	0	0	1	1
5th Device	0	0	0	0

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Receiving only Temporary Devices

Exhibit 2: Patient Demographics

HOSPX-8888 (n=17)

DEMOGRAPHICS	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	6	10	1	17
Age At Implant - BDV				
< 1 yr	66%	30%	100%	47%
1-5 yr	16%	50%	0%	35%
6-10 yr	16%	10%	0%	11%
11-18 yr	0%	10%	0%	5%
Gender				
Female	50%	60%	0%	52%
Male	50%	40%	100%	47%
Race				
African American	16%	0%	100%	11%
White	50%	60%	0%	52%
Other, Unknown, Undisclosed	33%	40%	0%	35%
Ethnicity				
Non-Hispanic	66%	60%	100%	64%
Unknown	16%	10%	0%	11%
Hispanic	16%	30%	0%	23%

Pedimacs (n=227)

DEMOGRAPHICS	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	72	142	13	227
Age At Implant - BDV				
< 1 yr	34%	45%	38%	41%
1-5 yr	29%	26%	23%	26%
6-10 yr	13%	8%	0%	9%
11-18 yr	22%	20%	38%	22%
Gender				
Female	44%	45%	53%	45%
Male	55%	54%	46%	54%
Race				
African American	23%	21%	46%	23%
White	52%	50%	23%	49%
Other, Unknown, Undisclosed	23%	28%	30%	26%

(Continued)

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 2: Patient Demographics

Pedimacs (n=227)

DEMOGRAPHICS	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Ethnicity				
Non-Hispanic	77%	75%	84%	76%
Unknown	4%	6%	7%	5%
Hispanic	18%	18%	7%	17%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 3: Weight (kg)

HOSPX-8888 (n=17)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	6	10	1	17
Weight (kg)				
Missing	0%	0%	0%	0%
< 5 kg	16%	20%	0%	17%
5-20 kg	66%	70%	100%	70%
> 20 Kg	16%	10%	0%	11%

Pedimacs (n=227)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	72	142	13	227
Weight (kg)				
Missing	2%	0%	0%	0%
< 5 kg	16%	27%	15%	23%
5-20 kg	44%	45%	46%	44%
> 20 Kg	36%	27%	38%	30%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Receiving only Temporary Devices

Exhibit 4: Primary Diagnosis

HOSPX-8888 (n=17)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	6	10	1	17
Primary Diagnosis				
<i>Congenital Heart Disease – Biventricular</i>	16%	0%	0%	5%
<i>Congenital Heart Disease – Single Ventricle</i>	33%	20%	0%	23%
<i>Dilated Cardiomyopathy</i>	50%	60%	100%	58%
<i>Restrictive Cardiomyopathy</i>	0%	0%	0%	0%
<i>Post Transplant/Graft Dysfunction</i>	0%	20%	0%	11%
#None#	0%	0%	0%	0%
<i>Other</i>	0%	0%	0%	0%

Pedimacs (n=227)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	72	142	13	227
Primary Diagnosis				
<i>Congenital Heart Disease – Biventricular</i>	12%	7%	7%	9%
<i>Congenital Heart Disease – Single Ventricle</i>	30%	33%	7%	31%
<i>Dilated Cardiomyopathy</i>	41%	44%	61%	44%
<i>Restrictive Cardiomyopathy</i>	1%	0%	0%	0%
<i>Post Transplant/Graft Dysfunction</i>	6%	7%	0%	6%
#None#	5%	0%	0%	2%
<i>Other</i>	1%	6%	23%	5%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Receiving only Temporary Devices

Exhibit 5: Patient Profile Levels

HOSPX-8888 (n=17)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	6	10	1	17
Patient Profile				
1 Critical Cardiogenic Shock	50%	50%	100%	52%
2 Progressive Decline	33%	30%	0%	29%
3 Stable but Inotrope Dependent	16%	10%	0%	11%
4 Resting Symptoms	0%	0%	0%	0%
7 Advanced NYHA Class 3 or Ross Class II	0%	10%	0%	5%

Pedimacs (n=227)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	72	142	13	227
Patient Profile				
1 Critical Cardiogenic Shock	43%	47%	53%	46%
2 Progressive Decline	47%	40%	46%	43%
3 Stable but Inotrope Dependent	9%	9%	0%	8%
4 Resting Symptoms	0%	1%	0%	0%
7 Advanced NYHA Class 3 or Ross Class II	0%	0%	0%	0%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Receiving only Temporary Devices

Exhibit 6: Device Strategy

HOSPX-8888 (n=17)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	6	10	1	17
Current Device Strategy				
Bridge to Recovery	16%	20%	0%	17%
Bridge to Transplant (patient currently listed for transplant)	50%	30%	0%	35%
Possible Bridge to Transplant - Likely to be eligible	16%	20%	100%	23%
Possible Bridge to Transplant - Moderate likelihood of becoming eligible	0%	0%	0%	0%
Possible Bridge to Transplant - Unlikely to become eligible	0%	0%	0%	0%
Destination Therapy (patient definitely not eligible for transplant)	0%	0%	0%	0%
Rescue Therapy	16%	30%	0%	23%

Pedimacs (n=227)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	72	142	13	227
Current Device Strategy				
Bridge to Recovery	30%	19%	23%	23%
Bridge to Transplant (patient currently listed for transplant)	34%	30%	23%	31%
Possible Bridge to Transplant - Likely to be eligible	18%	19%	7%	18%
Possible Bridge to Transplant - Moderate likelihood of becoming eligible	5%	12%	15%	10%
Possible Bridge to Transplant - Unlikely to become eligible	0%	2%	0%	1%
Destination Therapy (patient definitely not eligible for transplant)	0%	0%	7%	0%
Rescue Therapy	11%	14%	23%	14%

COVERAGE: September 19, 2012 - March 31, 2020**SITE: Hospital X - (Random 50 Patients)****Section 3 - Patients Receiving only Temporary Devices****Exhibit 7: Medications****HOSPX-8888 (n=17)**

MEDICATIONS	2012 - 2016	2017 - 2019	2020Q1	Total
Patients (n)	6	10	1	17
IV Inotropes at Implant	100%	80%	100%	88%
Pre-implant Loop Diuretics	67%	70%	0%	65%

Pedimacs (n=227)

MEDICATIONS	2012 - 2016	2017 - 2019	2020Q1	Total
Patients (n)	72	142	13	227
IV Inotropes at Implant	92%	95%	100%	94%
Pre-implant Loop Diuretics	68%	72%	69%	70%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Receiving only Temporary Devices

Exhibit 8: Laboratories

HOSPX-8888 (n=17)

PRE-IMPLANT LABORATORIES		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients	n	6	10	1	17
Sodium (mEq/L)	Mean	142.50	140.50	136.00	140.94
	Std	5.68	2.99		4.21
	Missing	0	0	0	0
Potassium (mEq/L)	Mean	3.94	4.07	4.10	4.03
	Std	1.22	0.58		0.81
	Missing	0	0	0	0
BUN (mg/dL)	Mean	23.17	32.70	8.00	27.88
	Std	13.61	22.87		19.99
	Missing	0	0	0	0
Creatinine (mg/dL)	Mean	0.77	0.59	0.33	0.64
	Std	0.70	0.48		0.55
	Missing	0	0	0	0
Alanine Aminotransferase/ALT (u/L)	Mean	1670.33	295.89	175.00	803.75
	Std	3515.81	756.99		2215.27
	Missing	0	1	0	1
Aspartate Aminotransferase/AST (u/L)	Mean	1953.17	709.89	634.00	1171.38
	Std	3991.12	1889.81		2757.89
	Missing	0	1	0	1
LDH (ukat/L) , (U/L)	Mean	1575.33	1472.60	4858.00	1883.00
	Std	2099.14	1467.59		1850.84
	Missing	3	5	0	8
Total Bilirubin (mg/dL)	Mean	0.94	1.11	1.30	1.07
	Std	0.78	0.89		0.81
	Missing	1	0	0	1
Albumin (g/dL)	Mean	3.70	3.04	2.60	3.25
	Std	0.41	0.55		0.59
	Missing	0	0	0	0
Pre-albumin (mg/dL)	Mean	21.80	13.10		17.45
	Std	1.13	5.52		5.98
	Missing	4	8	1	13

(Continued)

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Receiving only Temporary Devices

Exhibit 8: Laboratories

HOSPX-8888 (n=17)

PRE-IMPLANT LABORATORIES		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Total Cholesterol (mg/dL)	Mean	105.50	110.00		107.75
	Std	48.79	12.73		29.23
	Missing	4	8	1	13
Brain Natriuretic Peptide (pg/mL)	Mean	2664.00	3210.00	2812.00	2779.67
	Std	3374.83			2623.29
	Missing	2	9	0	11
Pro Brain Natriuretic Peptide (pg/mL)	Mean	22599.00	32014.00		29660.25
	Std		28818.25		23996.28
	Missing	5	7	1	13
White Blood Cell Count (x10 ³ /uL)	Mean	14.81	11.68	7.30	12.53
	Std	5.06	4.00		4.59
	Missing	0	0	0	0
Hemoglobin (g/dL)	Mean	12.60	11.05	17.50	11.98
	Std	1.48	1.96		2.33
	Missing	0	0	0	0
Platelets (x10 ³ /uL)	Mean	238.17	204.40	36.00	206.41
	Std	158.14	139.19		144.60
	Missing	0	0	0	0
INR	Mean	1.36	1.94	1.82	1.76
	Std	0.70	1.64		1.35
	Missing	1	0	0	1

Pedimacs (n=227)

PRE-IMPLANT LABORATORIES		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients	n	72	142	13	227
Sodium (mEq/L)	Mean	140.01	139.83	141.54	139.99
	Std	7.10	5.67	4.65	6.09
	Missing	2	0	0	2
Potassium (mEq/L)	Mean	3.77	3.99	4.06	3.92
	Std	0.73	0.84	0.63	0.80
	Missing	2	0	0	2

(Continued)

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Receiving only Temporary Devices

Exhibit 8: Laboratories

Pedimacs (n=227)

PRE-IMPLANT LABORATORIES		2012 - 2016	2017 - 2019	2020Q1	TOTAL
BUN (mg/dL)	Mean	27.92	29.54	26.63	28.88
	Std	16.52	19.78	15.17	18.55
	Missing	2	0	1	3
Creatinine (mg/dL)	Mean	0.69	0.65	0.55	0.66
	Std	0.48	0.62	0.28	0.57
	Missing	2	0	1	3
Alanine Aminotransferase/ALT (u/L)	Mean	264.51	175.54	114.92	198.37
	Std	1125.33	435.14	119.21	705.40
	Missing	9	7	0	16
Aspartate Aminotransferase/AST (u/L)	Mean	367.51	255.38	284.69	291.35
	Std	1337.38	707.23	346.83	929.28
	Missing	9	11	0	20
LDH (ukat/L) , (U/L)	Mean	1733.47	1188.35	2951.00	1396.17
	Std	2224.83	1706.70	2628.47	1898.85
	Missing	55	77	8	140
Total Bilirubin (mg/dL)	Mean	2.62	2.90	2.57	2.80
	Std	5.32	6.25	5.47	5.93
	Missing	17	18	3	38
Albumin (g/dL)	Mean	3.19	3.08	3.19	3.12
	Std	0.84	0.68	0.41	0.72
	Missing	8	5	2	15
Pre-albumin (mg/dL)	Mean	15.77	16.44	14.00	15.95
	Std	5.88	7.16	3.14	6.29
	Missing	58	125	10	193
Total Cholesterol (mg/dL)	Mean	110.69	117.19		114.71
	Std	45.12	38.06		40.35
	Missing	59	121	13	193
Brain Natriuretic Peptide (pg/mL)	Mean	2369.87	1787.90	2511.00	2045.71
	Std	1851.70	1558.52	2234.94	1716.45
	Missing	41	94	8	143

(Continued)

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)

71

COVERAGE: September 19, 2012 - March 31, 2020**SITE: Hospital X - (Random 50 Patients)****Section 3 - Patients Receiving only Temporary Devices****Exhibit 8: Laboratories****Pedimacs (n=227)**

PRE-IMPLANT LABORATORIES		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Pro Brain Natriuretic Peptide (pg/mL)	Mean	20521.71	23579.98	26314.67	23321.08
	Std	16865.78	20188.26	29837.50	19937.10
	Missing	65	101	10	176
White Blood Cell Count (x10 ³ /uL)	Mean	13.66	12.53	14.26	12.98
	Std	8.04	5.69	7.14	6.57
	Missing	4	1	0	5
Hemoglobin (g/dL)	Mean	12.32	11.53	11.36	11.76
	Std	1.96	2.31	2.30	2.23
	Missing	3	0	0	3
Platelets (x10 ³ /uL)	Mean	210.46	200.35	218.54	204.54
	Std	115.44	143.20	145.95	134.90
	Missing	3	1	0	4
INR	Mean	1.48	1.55	1.32	1.52
	Std	0.53	0.91	0.37	0.80
	Missing	20	11	2	33

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Receiving only Temporary Devices

Exhibit 8: Laboratories

HOSPX-8888 (n=17)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	6	10	1	17
Lupus Anticoagulant				
Negative	0%	0%	0%	0%
Positive	0%	0%	0%	0%
Unknown	100%	100%	100%	100%

Pedimacs (n=227)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	72	142	13	227
Lupus Anticoagulant				
Negative	22%	5%	0%	10%
Positive	0%	1%	0%	0%
Unknown	77%	92%	100%	88%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Receiving only Temporary Devices

Exhibit 9: Pre-Implant Concerns

HOSPX-8888 (n=17)

PRE-IMPLANT CONCERNS	2012 - 2016	2017 - 2019	2020Q1	Total
Patients (n)	6	10	1	17
Concern: Patient Does Not Want Transplant	0%	0%	0%	0%
Concern: Musculoskeletal Limitation	17%	0%	0%	6%
Concern: Contraindications to Immunosuppression	0%	0%	0%	0%
Concern: Allosensitization	0%	0%	0%	0%
Concern: Frailty	17%	10%	0%	12%
Concern: Chronic Renal Disease	0%	0%	0%	0%
Concern: Frequent ICD Shocks	0%	0%	0%	0%
Concern: Pulmonary Disease	0%	0%	0%	0%
Concern: Pulmonary Hypertension	0%	0%	0%	0%
Concern: Recent Pulmonary Embolus	0%	0%	0%	0%
Concern: History Atrial Arrhythmia	0%	0%	0%	0%
Concern: Unfavorable Mediastinal Anatomy	0%	10%	0%	6%
Concern: Thoracic Aortic Disease	0%	0%	0%	0%
Concern: Tracheotomy	0%	0%	0%	0%
Concern: Plastic Bronchitis	0%	0%	0%	0%
Concern: Large BMI	0%	10%	0%	6%
Concern: Severe Diabetes	0%	0%	0%	0%
Concern: Malnutrition/Cachexia	0%	0%	0%	0%
Concern: History GI Ulcers	0%	0%	0%	0%
Concern: History Hepatitis	0%	0%	0%	0%
Concern: Liver Dysfunction	17%	0%	0%	6%
Concern: Anasarca	0%	0%	0%	0%
Concern: Protein Losing Enteropathy	0%	0%	0%	0%
Concern: Genetic Syndrome	0%	0%	0%	0%
Concern: Heparin Induced Thrombosis	0%	0%	0%	0%
Concern: Chronic Coagulopathy	0%			0%
Concern: Major Stroke	0%	10%	0%	6%
Concern: Other Cerebrovascular Disease	0%	0%	0%	0%
Concern: Peripheral Vascular Disease	0%	0%	0%	0%
Concern: History Solid Organ Cancer	0%	0%	0%	0%
Concern: History Lymphoma Leukemia	0%	0%	0%	0%
Concern: History Bone Marrow Transplant	0%	0%	0%	0%

(Continued)

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Receiving only Temporary Devices

Exhibit 9: Pre-Implant Concerns

HOSPX-8888 (n=17)

PRE-IMPLANT CONCERNS	2012 - 2016	2017 - 2019	2020Q1	Total
Concern: History HIV	0%	0%	0%	0%
Concern: Chronic Infectious Concerns	0%	0%	0%	0%
Concern: Limited Cognitive Understanding	17%	0%	0%	6%
Concern: Limited Social Support	17%	10%	0%	12%
Concern: Repeated Non Compliance	0%	0%	0%	0%
Concern: History Drug Use	0%	0%	0%	0%
Concern: History Alcohol Abuse	0%	0%	0%	0%
Concern: Narcotic Dependence	0%	0%	0%	0%
Concern: History Smoking	0%	0%	0%	0%
Concern: Currently Smoking	0%	0%	0%	0%
Concern: Severe Depression	0%	0%	0%	0%
Concern: Other Major Psychological Diagnosis	0%	0%	0%	0%
Concern: Neuro Abnormal	17%	0%	0%	6%
Concern: Other Co-Morbidity	17%	0%	0%	6%

Pedimacs (n=227)

PRE-IMPLANT CONCERNS	2012 - 2016	2017 - 2019	2020Q1	Total
Patients (n)	72	142	13	227
Concern: Patient Does Not Want Transplant	1%	0%	0%	0%
Concern: Musculoskeletal Limitation	6%	1%	0%	3%
Concern: Contraindications to Immunosuppression	0%	0%	0%	0%
Concern: Allosensitization	3%	1%	0%	1%
Concern: Frailty	10%	9%	8%	9%
Concern: Chronic Renal Disease	0%	1%	8%	1%
Concern: Frequent ICD Shocks	0%	1%	0%	0%
Concern: Pulmonary Disease	3%	4%	0%	3%
Concern: Pulmonary Hypertension	6%	4%	0%	4%
Concern: Recent Pulmonary Embolus	1%	1%	0%	1%
Concern: History Atrial Arrhythmia	7%	3%	8%	4%
Concern: Unfavorable Mediastinal Anatomy	7%	9%	0%	8%
Concern: Thoracic Aortic Disease	1%	1%	0%	1%
Concern: Tracheotomy	3%	1%	0%	2%
Concern: Plastic Bronchitis	0%	0%	0%	0%

(Continued)

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Receiving only Temporary Devices

Exhibit 9: Pre-Implant Concerns

Pedimacs (n=227)

PRE-IMPLANT CONCERNS	2012 - 2016	2017 - 2019	2020Q1	Total
Concern: Large BMI	0%	2%	0%	1%
Concern: Severe Diabetes	0%	1%	0%	0%
Concern: Malnutrition/Cachexia	8%	4%	0%	5%
Concern: History GI Ulcers	0%	1%	0%	0%
Concern: History Hepatitis	0%	1%	0%	0%
Concern: Liver Dysfunction	4%	5%	0%	4%
Concern: Anasarca	3%	1%	0%	2%
Concern: Protein Losing Enteropathy	0%	0%	0%	0%
Concern: Genetic Syndrome	4%	4%	0%	4%
Concern: Heparin Induced Thrombosis	1%	1%	0%	1%
Concern: Chronic Coagulopathy	4%	4%	0%	4%
Concern: Major Stroke	1%	6%	0%	4%
Concern: Other Cerebrovascular Disease	1%	1%	0%	1%
Concern: Peripheral Vascular Disease	1%	0%	0%	0%
Concern: History Solid Organ Cancer	1%	0%	0%	0%
Concern: History Lymphoma Leukemia	0%	1%	0%	1%
Concern: History Bone Marrow Transplant	0%	0%	0%	0%
Concern: History HIV	0%	0%	0%	0%
Concern: Chronic Infectious Concerns	1%	1%	0%	1%
Concern: Limited Cognitive Understanding	3%	4%	8%	4%
Concern: Limited Social Support	7%	4%	0%	5%
Concern: Repeated Non Compliance	1%	1%	0%	1%
Concern: History Drug Use	0%	0%	0%	0%
Concern: History Alcohol Abuse	0%	0%	0%	0%
Concern: Narcotic Dependence	0%	0%	0%	0%
Concern: History Smoking	0%	0%	0%	0%
Concern: Currently Smoking	0%	0%	0%	0%
Concern: Severe Depression	0%	0%	0%	0%
Concern: Other Major Psychological Diagnosis	1%	1%	0%	1%
Concern: Neuro Abnormal	4%	4%	0%	4%
Concern: Other Co-Morbidity	7%	5%	0%	5%

COVERAGE: September 19, 2012 - March 31, 2020**SITE: Hospital X - (Random 50 Patients)****Section 3 - Patients Receiving only Temporary Devices****Exhibit 10: General Hemodynamics**

The following table compare pre-implant general hemodynamics for patients receiving durable devices at your site and STS Pedimacs overall.

HOSPX-8888 (n=17)

PRE-IMPLANT GENERAL HEMODYNAMICS		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients	n	6	10	1	17
Heart Rate	Mean	117.00	124.00	184.00	141.67
	Std				36.83
	Missing	5	9	0	14

Pedimacs (n=227)

PRE-IMPLANT GENERAL HEMODYNAMICS		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients	n	72	142	13	227
Heart Rate	Mean	123.26	124.47	148.60	125.53
	Std	20.64	24.59	34.59	24.43
	Missing	45	91	8	144

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 11: Echo Hemodynamics

The following table compare pre-implant LVEDD for patients receiving durable devices at your site and STS Pedimacs overall.

HOSPX-8888 (n=17)

		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients	n	6	10	1	17
LVEDD	Mean	4.52	3.70		3.93
	Std	1.30	1.35		1.33
	Missing	3	2	1	6

Pedimacs (n=227)

		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients	n	72	142	13	227
LVEDD	Mean	4.62	4.01	4.89	4.20
	Std	1.24	1.43	0.96	1.39
	Missing	47	76	10	133

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Receiving only Temporary Devices

The following tables summarize pre-implant RVEF at your site and STS Pedimacs.

HOSPX-8888 (n=17)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	6	10	1	17
RVEF				
Normal	16%	20%	0%	17%
Mild	33%	20%	0%	23%
Moderate	0%	30%	0%	17%
Severe	16%	10%	0%	11%
Not Done	33%	10%	0%	17%
Not Applicable	0%	10%	0%	5%
Unknown	0%	0%	100%	5%
Aortic Regurgitation				
0 (none)	0%	40%	0%	23%
1 (mild)	50%	20%	100%	35%
2 (moderate)	16%	0%	0%	5%
3 (severe)	0%	20%	0%	11%
Not Recorded or Not Documented	33%	20%	0%	23%

Pedimacs (n=227)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	72	142	13	227
RVEF				
Normal	12%	17%	15%	15%
Mild	12%	9%	7%	10%
Moderate	9%	16%	7%	13%
Severe	25%	23%	15%	23%
Not Done	16%	14%	15%	15%
Not Applicable	6%	5%	0%	5%
Unknown	16%	12%	38%	15%
Aortic Regurgitation				
0 (none)	37%	43%	15%	40%
1 (mild)	29%	27%	69%	30%
2 (moderate)	2%	1%	0%	1%
3 (severe)	0%	2%	0%	1%
Not Recorded or Not Documented	30%	25%	15%	26%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Receiving only Temporary Devices

Exhibit 12: Swan Hemodynamics

HOSPX-8888 (n=17)

SWAN HEMODYNAMICS		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients	n	6	10	1	17
Pulmonary Artery Systolic Pressure (mmHg)	Mean		30.00		30.00
	Std		12.73		12.73
	Missing	6	8	1	15
Pulmonary Artery Diastolic Pressure (mmHg)	Mean		15.50		15.50
	Std		6.36		6.36
	Missing	6	8	1	15
Mean RA Pressure (mmHg)	Mean	10.00	9.33	7.00	9.17
	Std	2.83	4.04		3.06
	Missing	4	7	0	11
Pulmonary Artery Wedge Pressure (mmHg)	Mean	21.00	16.00		17.67
	Std		8.49		6.66
	Missing	5	8	1	14
Cardiac Index	Mean	2.60	4.84		3.72
	Std				1.58
	Missing	5	9	1	15

Pedimacs (n=227)

SWAN HEMODYNAMICS		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients	n	72	142	13	227
Pulmonary Artery Systolic Pressure (mmHg)	Mean	38.80	34.06		35.85
	Std	18.52	21.52		20.39
	Missing	52	109	13	174
Pulmonary Artery Diastolic Pressure (mmHg)	Mean	22.81	21.39		21.96
	Std	11.91	10.18		10.82
	Missing	51	111	13	175
Mean RA Pressure (mmHg)	Mean	11.10	11.60	7.00	11.36
	Std	6.01	4.81		5.25
	Missing	43	94	12	149
Pulmonary Artery Wedge Pressure (mmHg)	Mean	18.81	17.25		17.92
	Std	8.93	7.46		8.07
	Missing	51	114	13	178

(Continued)

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)

80

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 12: Swan Hemodynamics

Pedimacs (n=227)

SWAN HEMODYNAMICS		2012 - 2016	2017 - 2019	2020Q1	TOTAL
Cardiac Index	Mean	2.65	3.41		3.12
	Std	1.04	2.47		2.07
	Missing	53	111	13	177

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Receiving only Temporary Devices

Exhibit 13: ECG Cardiac Rhythm

The following tables summarize pre-implant ECG cardiac rhythm at your site and STS Pedimacs.

HOSPX-8888 (n=17)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	6	10	1	17
ECG Rhythm				
Sinus	33%	50%	100%	47%
Atrial fibrillation	0%	0%	0%	0%
Atrial Flutter	0%	0%	0%	0%
Not done	0%	10%	0%	5%
Paced: Atrial pacing	0%	0%	0%	0%
Paced: Ventricular pacing	16%	0%	0%	5%
Paced: Atrial and ventricular pacing	0%	0%	0%	0%
Unknown	16%	20%	0%	17%
Other, specify	33%	20%	0%	23%

Pedimacs (n=227)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	72	142	13	227
ECG Rhythm				
Sinus	66%	67%	76%	67%
Atrial fibrillation	0%	0%	0%	0%
Atrial Flutter	0%	0%	0%	0%
Not done	0%	1%	7%	1%
Paced: Atrial pacing	2%	0%	0%	1%
Paced: Ventricular pacing	8%	1%	0%	3%
Paced: Atrial and ventricular pacing	4%	2%	7%	3%
Unknown	4%	4%	0%	4%
Other, specify	13%	19%	7%	17%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Receiving only Temporary Devices

Exhibit 14: VAD Indication

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

HOSPX-8888 (n=17)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	6	10	1	17
VAD Indication				
<i>Failure to wean from CPB</i>	0%	10%	0%	5%
<i>Post Cardiac Surgery</i>	0%	0%	0%	0%
<i>None</i>	66%	60%	0%	58%
<i>Failure to Wean from ECMO</i>	33%	30%	100%	35%

Pedimacs (n=227)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	72	142	13	227
VAD Indication				
<i>Failure to wean from CPB</i>	1%	4%	0%	3%
<i>Post Cardiac Surgery</i>	9%	7%	7%	8%
<i>None</i>	58%	55%	69%	57%
<i>Failure to Wean from ECMO</i>	30%	32%	23%	31%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 15: Device Type

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

HOSPX-8888 (n=17)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	6	10	1	17
Device Type				
LVAD	83%	70%	100%	76%
RVAD	0%	10%	0%	5%
BiVAD	16%	20%	0%	17%
TAH	0%	0%	0%	0%

Pedimacs (n=227)

	2012 - 2016	2017 - 2019	2020Q1	TOTAL
Patients (n)	72	142	13	227
Device Type				
LVAD	76%	73%	84%	74%
RVAD	5%	14%	0%	10%
BiVAD	18%	11%	15%	14%
TAH	0%	0%	0%	0%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Receiving only Temporary Devices

Exhibit 16: Previous Cardiac Operations

This table lists the cardiac operations that the patient had prior to MCS implantation.

HOSPX-8888 (n=17)

PREVIOUS CARDIAC OPERATIONS	2012 - 2016	2017 - 2019	2020Q1	Total
Patients (n)	6	10	1	17
None	33%	50%	100%	47%
CABG	0%	0%	0%	0%
Aneurysmectomy (DOR)	0%	0%	0%	0%
Aortic Valve replacement / repair	0%	0%	0%	0%
Mitral Valve replacement / repair	0%	0%	0%	0%
Tricuspid replacement /repair	0%	0%	0%	0%
Congenital card surgery	50%	30%	0%	35%
LVAD	0%	10%	0%	6%
RVAD	0%	20%	0%	12%
TAH	0%	0%	0%	0%
Previous heart transplant	0%	30%	0%	18%
Previous ECMO	0%	30%	0%	18%
Other, specify	17%	0%	0%	6%

Pedimacs (n=227)

PREVIOUS CARDIAC OPERATIONS	2012 - 2016	2017 - 2019	2020Q1	Total
Patients (n)	72	142	13	227
None	33%	41%	38%	38%
CABG	0%	0%	0%	0%
Aneurysmectomy (DOR)	0%	0%	0%	0%
Aortic Valve replacement / repair	3%	0%	0%	1%
Mitral Valve replacement / repair	1%	1%	0%	1%
Tricuspid replacement /repair	4%	2%	0%	3%
Congenital card surgery	33%	30%	23%	31%
LVAD	3%	4%	15%	4%
RVAD	1%	1%	0%	1%
TAH	0%	0%	0%	0%
Previous heart transplant	6%	10%	0%	8%

(Continued)

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Receiving only Temporary Devices

Exhibit 16: Previous Cardiac Operations

Pedimacs (n=227)

PREVIOUS CARDIAC OPERATIONS	2012 - 2016	2017 - 2019	2020Q1	Total
Previous ECMO	19%	23%	38%	22%
Other, specify	26%	18%	15%	21%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Receiving only Temporary Devices

Exhibit 17: Clinical Events and Interventions during Implant Hospitalization

This table lists the interventions that occurred during the implant hospitalization.

HOSPX-8888 (n=17)

IMPLANT HOSPITALIZATION EVENTS	2012 - 2016	2017 - 2019	2020Q1	Total
Patients (n)	6	10	1	17
None	0%	20%	0%	12%
CABG	0%	0%	0%	0%
Aortic Valve replacement / repair	0%	0%	0%	0%
Mitral Valve replacement / repair	0%	0%	0%	0%
Congenital cardiac surgery	33%	10%	100%	24%
Other surgical procedures	0%	10%	0%	6%
IABP	0%	0%	0%	0%
ECMO	33%	40%	100%	41%
LVAD	17%	10%	0%	12%
RVAD	17%	20%	0%	18%
TAH	0%	0%	0%	0%
Dialysis	33%	0%	0%	12%
Ultrafiltration	17%	10%	0%	12%
Feeding Tube	33%	0%	0%	12%
Intubation	67%	60%	100%	65%
Major MI	0%	0%	0%	0%
Major infections / Positive blood cultures	0%	10%	100%	12%
Escalation to CPAP	0%	10%	0%	6%
Arrhythmia	17%	30%	0%	24%
Previous ECMO	0%	10%	0%	6%
Previous heart transplant	0%	10%	0%	6%
Treatment of Rejection	0%	10%	0%	6%
Peritoneal Drain	0%	0%	0%	0%
Non-cardiac procedure	17%	10%	0%	12%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Receiving only Temporary Devices

Exhibit 17: Clinical Events and Interventions during Implant Hospitalization

Pedimacs (n=227)

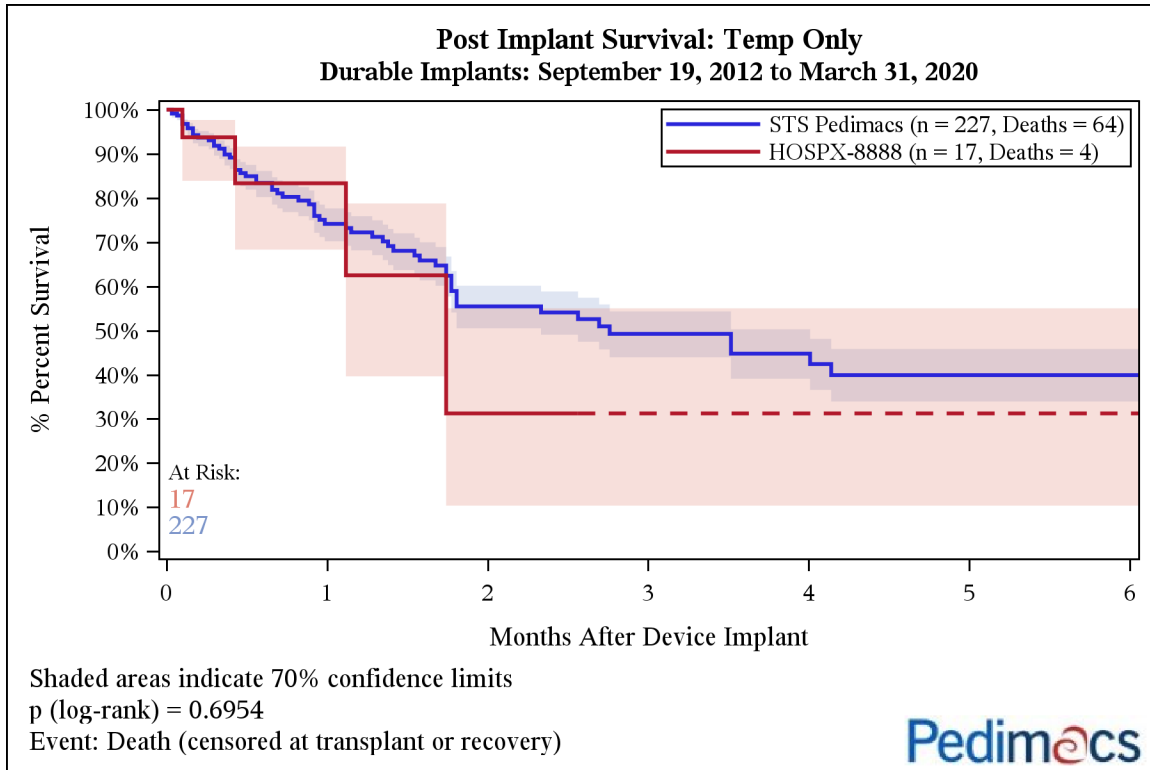
IMPLANT HOSPITALIZATION EVENTS	2012 - 2016	2017 - 2019	2020Q1	Total
Patients (n)	72	142	13	227
None	7%	9%	0%	8%
CABG	0%	0%	0%	0%
Aortic Valve replacement / repair	0%	0%	0%	0%
Mitral Valve replacement / repair	3%	1%	0%	2%
Congenital cardiac surgery	21%	14%	15%	16%
Other surgical procedures	14%	11%	8%	11%
IABP	0%	1%	0%	0%
ECMO	38%	43%	77%	43%
LVAD	3%	5%	15%	5%
RVAD	3%	3%	0%	3%
TAH	0%	0%	0%	0%
Dialysis	17%	8%	23%	11%
Ultrafiltration	3%	5%	15%	5%
Feeding Tube	29%	32%	62%	33%
Intubation	72%	72%	77%	72%
Major MI	3%	2%	8%	3%
Major infections / Positive blood cultures	15%	18%	15%	17%
Escalation to CPAP	6%	8%	0%	7%
Arrhythmia	29%	27%	31%	28%
Previous ECMO	6%	8%	0%	7%
Previous heart transplant	4%	7%	0%	6%
Treatment of Rejection	4%	4%	0%	4%
Peritoneal Drain	3%	0%	0%	1%
Non-cardiac procedure	4%	6%	8%	5%

COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Receiving only Temporary Devices

Exhibit 18: Post Implant Survival - Temp Only



Percent Survival [% (70% CI)]

Months after Device Implant	STS Pedimacs	HOSPX-8888
1	74.1% (70.2%-77.6%)	83.3% (68.3%-91.6%)
3	49.2% (43.9%-54.3%)	
6	39.9% (33.9%-45.8%)	

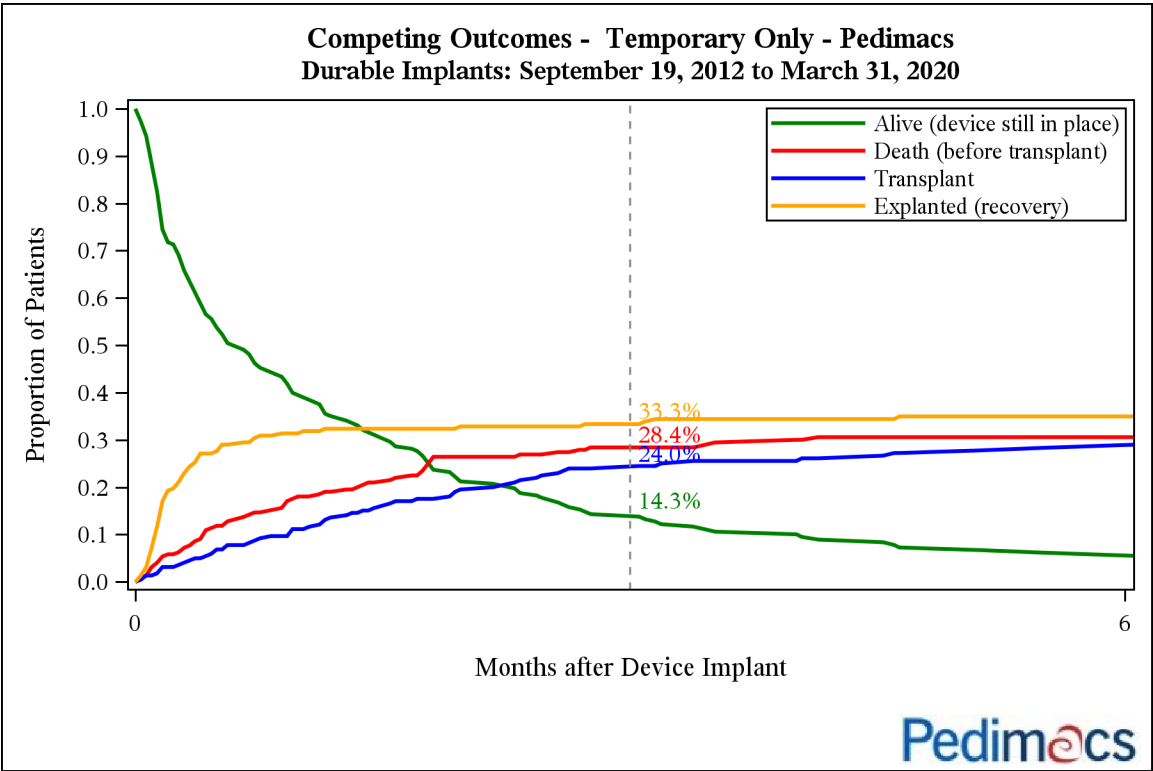
COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 19a: Competing Outcomes - Temporary Only - Pedimacs

This figure estimates the simultaneous probability across time of a patient moving from alive (with a device in place) to one of the following terminal events: transplanted, dead, or recovery (due to device removal). This depiction is for all primary LVADs in STS Pedimacs.



Number of Patients at Risk

Month
0
227

COVERAGE: September 19, 2012 - March 31, 2020

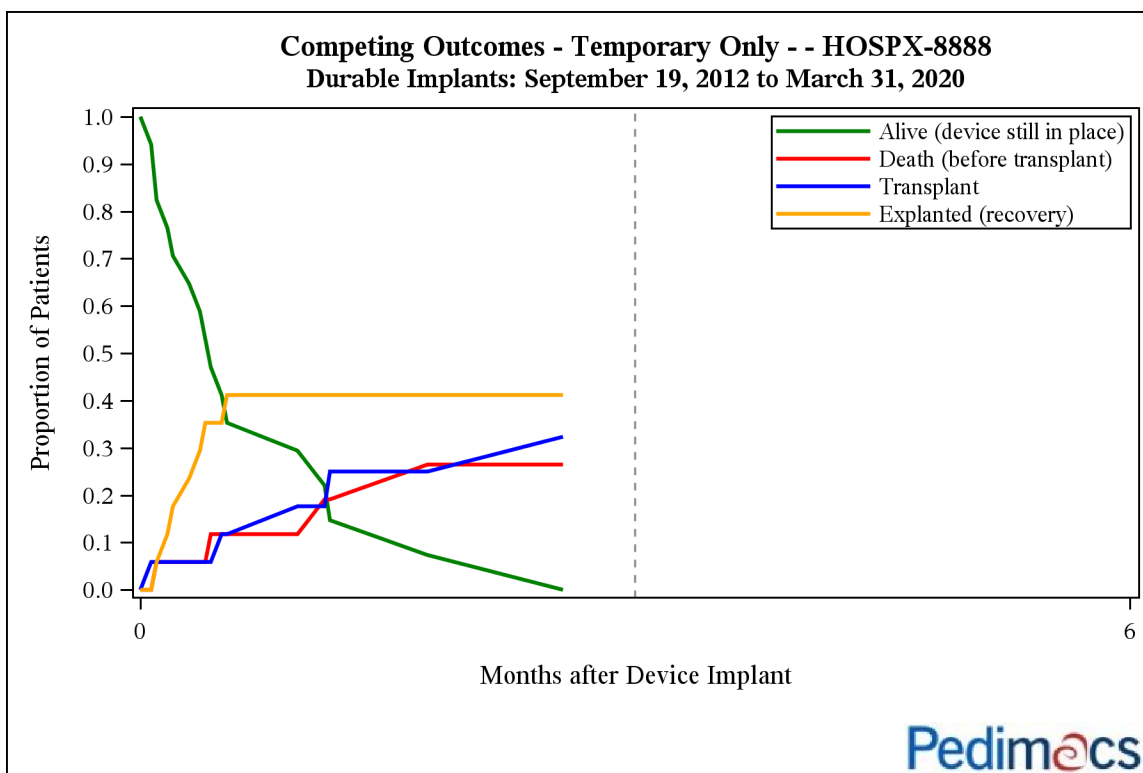
SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 19b: Competing Outcomes - Temporary Only - HOSPX-8888

This figure estimates the simultaneous probability across time of a patient moving from alive (with a device in place) to one of the following terminal events: transplanted, dead, or recovery (due to device removal). This depiction is for all primary LVADs at your hospital.

Competing outcomes results for sites with low numbers of patients (e.g. < 20) may be extremely jagged and/or suppressed in this display and comparisons with Pedimacs competing outcome results will have limited value.



Number of Patients at Risk

Month
0
17

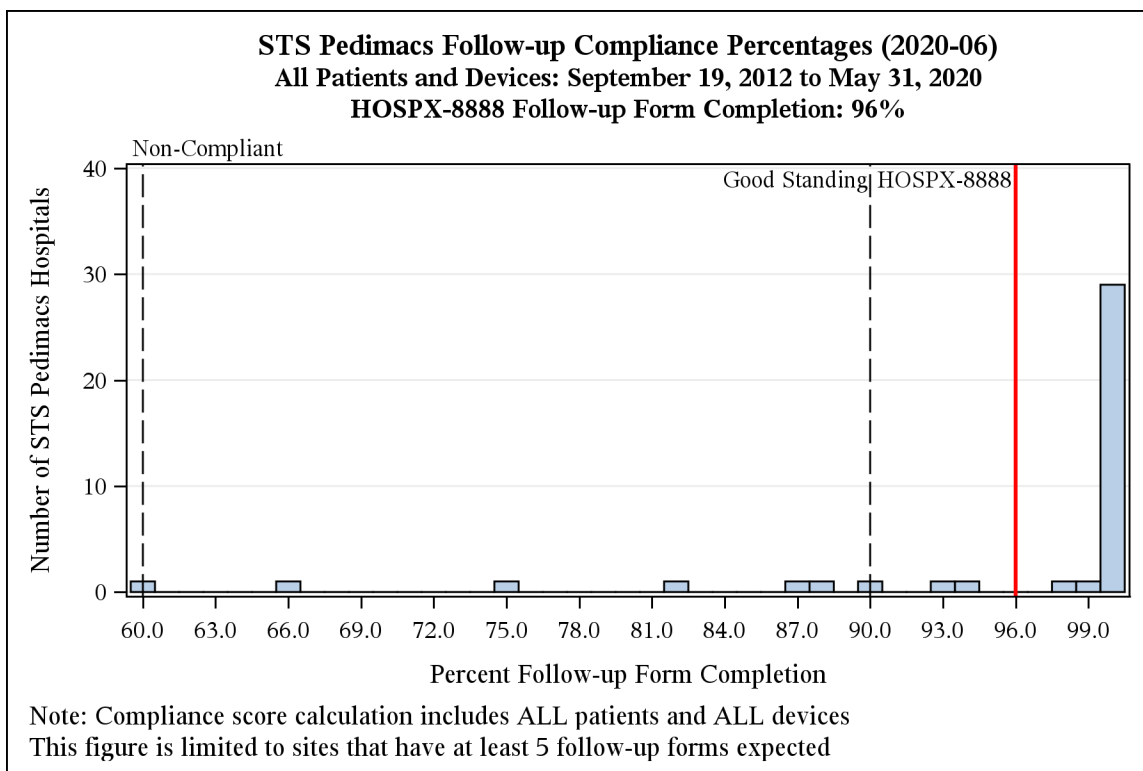
COVERAGE: September 19, 2012 - March 31, 2020

SITE: Hospital X - (Random 50 Patients)

III. Registry 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 5 follow-up forms due are included in this figure (n = 40 sites).

STS Pedimacs has defined required compliance as 90%. If your hospital is below 90%, please examine your patient follow-up table that is contained in the Pedimacs Data Quality Quarterly Report. This table will identify the exact patients who have a 'past due' follow-up form. If your hospital is below 70% compliance. All sites below 60% compliance will be put on probationary status and will be deemed Non-Compliant.



COVERAGE: September 19, 2012 - March 31, 2020**SITE: Hospital X - (Random 50 Patients)****IV. Excluded Patients**

The following table lists patients at your site that are excluded from the analysis in this report. These patients include: 1) patients receiving only temporary support, 2) patients that have transferred to your site, 3) patients with missing implant dates.

Obs	Excluded Patient ID
1	100032
2	100068

IV. 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
ECG: Electrocardiogram
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
Pedimacs: Pediatric arm of INTERMACS
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