STS Pedimacs

Pediatric Registry for Mechanically Assisted Circulatory Support

Quality Assurance Quarterly Report (2020 Q1) - Recent Year

Hospital X - (Random 50 Patients)

Implant and event dates: April 1, 2019 to March 31, 2020

06/01/2020

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

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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 "Recent Year" version of the Quality Assurance report includes data on all prospective patients receiving a device at your site. This report includes patients implanted in the most recent completed calendar year (2019) and any patients implanted in the current calendar year (2020).

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.

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This quarterly report includes clinical information from 50 patients receiving prospective implants between April 1, 2019 and March 31, 2020 at Hospital X - (Random 50 Patients).

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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 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.

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

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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.

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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

SITE: Hospital X - (Random 50 Patients)

Section 1 - All Patients

Exhibit 1: Patient Counts

All Patients

Support Type	HOSPX-8888 (n=50)	Pedimacs (n=169)
Durable	29	107
Temp Only	21	62

Device Class for First Durable Support

Device Class	HOSPX-8888 (n=29)	Pedimacs (n=107)
Implantable Continuous	20	64
Paracorporeal Pulsatile	9	43

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

Device Class	HOSPX-8888 (n=21)	Pedimacs (n=62)
Paracorporeal Continuous	17	53
Percutaneous	4	9

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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=50)

DEVICE #	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Primary Device	11	19	9	11	50
2nd Device	1	6	0	1	8
3rd Device	0	2	0	1	3
4th Device	0	2	0	1	3
5th Device	0	2	0	0	2

Pedimacs (n=169)

DEVICE #	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Primary Device	42	55	36	36	169
2nd Device	5	9	7	2	23
3rd Device	2	3	1	2	8
4th Device	0	3	0	1	4
5th Device	0	2	0	0	2

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Section 2 - Patients Recieving 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=29)

DEVICE #	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Primary Device	6	10	7	6	29
2nd Device	0	3	1	0	4
3rd Device	0	1	1	0	2
4th Device	0	1	1	0	2
5th Device	0	1	1	0	2

Pedimacs (n=107)

DEVICE #	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Primary Device	24	33	27	23	107
2nd Device	1	5	6	1	13
3rd Device	1	2	2	0	5
4th Device	0	2	1	0	3
5th Device	0	1	1	0	2

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Section 2 - Patients Recieving a Durable Device

Exhibit 2: Patient Demographics

HOSPX-8888 (n=29)

DEMOGRAPHICS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	6	10	7	6	29
Age Group					
< 1 yr	0%	40%	0%	16%	17%
1-5 yr	16%	30%	0%	0%	13%
6-10 yr	16%	10%	57%	0%	20%
11-18 yr	66%	20%	42%	83%	48%
Gender					
Female	50%	80%	42%	50%	58%
Male	50%	20%	57%	50%	41%
Race					
African American	16%	10%	0%	33%	13%
White	66%	60%	71%	50%	62%
Other, Unknown, Undisclosed	16%	30%	28%	16%	24%
Ethnicity					
Non-Hispanic	83%	50%	71%	100%	72%
Unknown	16%	0%	0%	0%	3%
Hispanic	0%	50%	28%	0%	24%

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Section 2 - Patients Recieving a Durable Device

Exhibit 2: Patient Demographics

Pedimacs (n=107)

DEMOGRAPHICS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	24	33	27	23	107
Age Group					
< 1 yr	20%	33%	18%	8%	**21%**
1-5 yr	12%	24%	11%	34%	**20%**
6-10 yr	12%	12%	25%	21%	**17%**
11-18 yr	54%	30%	44%	34%	**40%**
Gender					
Female	33%	54%	37%	43%	**42%**
Male	66%	45%	62%	56%	**57%**
Race					
African American	8%	18%	25%	30%	**20%**
White	75%	60%	48%	52%	**58%**
Other, Unknown, Undisclosed	16%	21%	25%	17%	**20%**
Ethnicity					
Non-Hispanic	70%	81%	85%	86%	**81%**
Unknown	8%	0%	0%	0%	**1%**
Hispanic	20%	18%	14%	13%	**16%**

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Section 2 - Patients Recieving a Durable Device

Exhibit 3: Weight (kg)

HOSPX-8888 (n=29)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	6	10	7	6	29
Weight (kg)					
Missing	0%	0%	0%	16%	**3%**
< 5 kg	0%	10%	0%	0%	**3%**
5-20 kg	33%	70%	42%	16%	**44%**
> 20 Kg	66%	20%	57%	66%	**48%**

Pedimacs (n=107)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	24	33	27	23	107
Weight (kg)					
Missing	0%	0%	0%	4%	**0%**
< 5 kg	8%	12%	0%	0%	**5%**
5-20 kg	29%	51%	40%	34%	**40%**
> 20 Kg	62%	36%	59%	60%	**53%**

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Section 2 - Patients Recieving a Durable Device

Exhibit 4: Primary Diagnosis

HOSPX-8888 (n=29)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	**6**	**10**	**7**	**6**	**29**
Primary Diagnosis					
Congenital Heart Disease – Biventricular	16%	0%	14%	0%	**6%**
Congenital Heart Disease – Single Ventricle	0%	20%	42%	0%	**17%**
Dialated Cardiomyopathy	83%	70%	42%	83%	**68%**
Restrictive Cardiomyopathy	0%	0%	0%	0%	**0%**
#Valvular Heart Disease#	0%	0%	0%	0%	**0%**
Other	0%	10%	0%	16%	**6%**

Pedimacs (n=107)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	**24**	**33**	**27**	**23**	**107**
Primary Diagnosis					
Congenital Heart Disease – Biventricular	12%	12%	7%	0%	**8%**
Congenital Heart Disease – Single Ventricle	16%	24%	14%	8%	**16%**
Dialated Cardiomyopathy	62%	60%	74%	78%	**68%**
Restrictive Cardiomyopathy	0%	0%	3%	4%	**1%**
#Valvular Heart Disease#	4%	0%	0%	4%	**1%**
Other	4%	3%	0%	4%	**2%**

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Section 2 - Patients Recieving a Durable Device

Exhibit 5: Patient Profile Levels

HOSPX-8888 (n=29)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	**6**	**10**	**7**	**6**	**29**
Patient Profile					
1 Critical Cardiogenic Shock	16%	20%	0%	33%	**17%**
2 Progressive Decline	66%	70%	71%	50%	**65%**
3 Stable but Inotrope Dependent	16%	10%	28%	16%	**17%**
4 Resting Symptoms	0%	0%	0%	0%	**0%**
5 Exertion Intolerant	0%	0%	0%	0%	**0%**
7 Advanced NYHA Class 3 or Ross Class II	0%	0%	0%	0%	**0%**

Pedimacs (n=107)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	**24**	**33**	**27**	**23**	**107**
Patient Profile					
1 Critical Cardiogenic Shock	12%	9%	18%	26%	**15%**
2 Progressive Decline	62%	75%	66%	52%	**65%**
3 Stable but Inotrope Dependent	20%	9%	14%	21%	**15%**
4 Resting Symptoms	4%	0%	0%	0%	**0%**
5 Exertion Intolerant	0%	3%	0%	0%	**0%**
7 Advanced NYHA Class 3 or Ross Class II	0%	3%	0%	0%	**0%**

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Section 2 - Patients Recieving a Durable Device

Exhibit 6: Device Strategy

HOSPX-8888 (n=29)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	**6**	**10**	**7**	**6**	**29**
Current Device Strategy					
BTT - Listed	50%	60%	28%	16%	**41%**
BTT - Likely	50%	20%	42%	50%	**37%**
BTT - Moderate	0%	10%	28%	33%	**17%**
BTT - Unlikely	0%	0%	0%	0%	**0%**
Destination Therapy	0%	10%	0%	0%	**3%**
Bridge to Recovery	0%	0%	0%	0%	**0%**

Pedimacs (n=107)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	**24**	**33**	**27**	**23**	**107**
Current Device Strategy					
BTT - Listed	54%	54%	44%	43%	**49%**
BTT - Likely	37%	24%	33%	39%	**32%**
BTT - Moderate	4%	12%	11%	8%	**9%**
BTT - Unlikely	0%	0%	3%	0%	**0%**
Destination Therapy	4%	6%	3%	0%	**3%**
Bridge to Recovery	0%	3%	3%	8%	**3%**

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Section 2 - Patients Recieving a Durable Device

Exhibit 7: Medications

HOSPX-8888 (n=29)

MEDICATIONS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
Patients (n)	6	10	7	6	29
IV Inotropes at Implant	100%	100%	100%	100%	100%
Pre-implant Loop Diuretics	67%	100%	57%	83%	79%

Pedimacs (n=107)

MEDICATIONS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
Patients (n)	24	33	27	23	107
IV Inotropes at Implant	96%	97%	96%	100%	97%
Pre-implant Loop Diuretics	79%	91%	81%	83%	84%

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Section 2 - Patients Recieving a Durable Device

Exhibit 8: Laboratories

HOSPX-8888 (n=29)

PRE-IMPLANT LABORATORIES		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients	n	6	10	7	6	29
Sodium (mEq/L)	Mean	134.17	138.30	137.43	139.00	137.38
	Std	3.31	5.23	4.08	4.24	4.54
	Missing	0	0	0	0	0
Potassium (mEq/L)	Mean	3.92	4.04	3.84	3.75	3.91
	Std	0.51	0.70	0.48	0.59	0.57
	Missing	0	0	0	0	0
BUN (mg/dL)	Mean	15.17	26.92	21.29	34.85	24.77
	Std	4.96	17.73	6.70	32.69	18.76
	Missing	0	0	0	0	0
Creatinine (mg/dL)	Mean	0.37	0.35	0.63	1.26	0.61
	Std	0.11	0.18	0.30	1.41	0.72
	Missing	0	0	0	0	0
Alanine Aminotransferase/ALT (u/L)	Mean	197.40	72.30	46.67	137.83	104.33
	Std	391.96	156.77	25.29	225.99	212.54
	Missing	1	0	1	0	2
Aspartate Aminotransferase/AST (u/L)	Mean	220.40	79.90	55.50	172.83	121.15
	Std	424.12	65.18	30.88	172.13	197.95
	Missing	1	0	1	0	2
LDH (µkat/L), (U/L)	Mean	558.40	608.20	633.14	1611.00	832.73
	Std	454.03	477.93	574.66	2352.15	1190.96
	Missing	1	5	0	1	7
Total Bilirubin (mg/dL)	Mean	0.80	1.34	1.78	5.25	2.15
	Std	0.80	1.43	1.19	8.99	4.22
	Missing	1	2	1	1	5
Albumin (g/dL)	Mean	3.57	3.80	3.50	3.20	3.57
	Std	0.68	0.56	0.63	0.16	0.58
	Missing	0	0	0	1	1
Pre-albumin (mg/dL)	Mean	19.00	16.70	23.00	13.90	19.77
	Std			5.46		5.20
	Missing	5	9	4	5	23

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Section 2 - Patients Recieving a Durable Device

Exhibit 8: Laboratories

HOSPX-8888 (n=29)

PRE-IMPLANT LABORATORIES		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Total Cholesterol (mg/dL)	Mean		154.00	169.00		**164.00**
	Std			1.41		**8.72**
	Missing	*6*	*9*	*5*	*6*	**26**
Brain Natriuretic Peptide (pg/mL)	Mean	1784.50	1945.00	1680.33	2054.00	**1826.65**
	Std	2086.38	2022.35	1285.77	2211.83	**1637.18**
	Missing	*2*	*5*	*1*	*4*	**12**
Pro Brain Natriuretic Peptide (pg/mL)	Mean	6104.50	24232.67	9061.00	8954.00	**13984.50**
	Std	3713.02	20619.37		637.81	**14033.77**
	Missing	*4*	*7*	*6*	*4*	**21**
White Blood Cell Count (x10/µL)	Mean	8.77	11.04	9.21	16.29	**11.21**
	Std	2.22	6.08	4.63	9.11	**6.32**
	Missing	*0*	*0*	*0*	*0*	**0**
Hemoglobin (g/dL)	Mean	11.37	12.45	12.01	10.35	**11.69**
	Std	1.33	2.70	2.12	1.46	**2.16**
	Missing	*0*	*0*	*0*	*0*	**0**
Platelets (x10/µL)	Mean	200.33	199.10	242.14	230.50	**216.24**
	Std	95.84	100.01	71.55	114.84	**93.15**
	Missing	*0*	*0*	*0*	*0*	**0**
INR	Mean	1.30	1.41	1.77	1.35	**1.47**
	Std	0.32	0.35	1.19	0.13	**0.65**
	Missing	*0*	*0*	*0*	*2*	**2**

Pedimacs (n=107)

PRE-IMPLANT LABORATORIES		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients	n	**24**	**33**	**27**	**23**	**107**
Sodium (mEq/L)	Mean	136.79	137.24	137.52	138.22	**137.42**
	Std	4.21	5.43	5.75	6.49	**5.46**
	Missing	*0*	*0*	*0*	*0*	**0**
Potassium (mEq/L)	Mean	3.83	3.95	3.85	3.81	**3.87**
	Std	0.45	0.60	0.58	0.81	**0.61**
	Missing	*0*	*0*	*0*	*0*	**0**

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Section 2 - Patients Recieving a Durable Device

Exhibit 8: Laboratories

Pedimacs (n=107)

PRE-IMPLANT LABORATORIES		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
BUN (mg/dL)	Mean	16.21	24.18	19.47	29.01	**22.22**
	Std	6.43	16.54	7.59	28.92	**17.34**
	Missing	0	1	0	0	**1**
Creatinine (mg/dL)	Mean	0.52	0.45	0.57	0.84	**0.58**
	Std	0.28	0.27	0.29	0.97	**0.53**
	Missing	0	0	1	0	**1**
Alanine Aminotransferase/ALT (u/L)	Mean	87.27	89.75	76.54	102.82	**88.67**
	Std	192.02	206.59	133.54	162.01	**175.27**
	Missing	2	1	1	1	**5**
Aspartate Aminotransferase/AST (u/L)	Mean	113.05	100.09	60.31	107.00	**94.24**
	Std	214.12	195.09	64.26	125.07	**160.96**
	Missing	2	1	1	1	**5**
LDH (µkat/L), (U/L)	Mean	625.77	698.80	729.73	1109.92	**778.46**
	Std	460.95	626.19	598.42	1472.11	**845.70**
	Missing	11	13	12	10	**46**
Total Bilirubin (mg/dL)	Mean	1.52	1.24	1.30	2.34	**1.56**
	Std	2.24	1.09	1.26	5.01	**2.69**
	Missing	3	6	6	4	**19**
Albumin (g/dL)	Mean	3.48	3.61	3.57	3.57	**3.56**
	Std	0.64	0.68	0.64	0.95	**0.72**
	Missing	0	0	1	1	**2**
Pre-albumin (mg/dL)	Mean	17.64	17.77	20.11	15.08	**18.05**
	Std	5.84	7.76	5.29	3.58	**5.81**
	Missing	17	27	19	19	**82**
Total Cholesterol (mg/dL)	Mean	118.50	104.00	143.67	119.25	**120.08**
	Std	52.77	35.65	38.48	20.25	**40.04**
	Missing	18	25	21	19	**83**
Brain Natriuretic Peptide (pg/mL)	Mean	1622.70	1888.44	1929.88	2780.86	**2067.10**
	Std	1280.57	1850.02	1052.62	1747.26	**1555.64**
	Missing	14	15	10	9	**48**

(Continued)

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Section 2 - Patients Recieving a Durable Device

Exhibit 8: Laboratories

Pedimacs (n=107)

PRE-IMPLANT LABORATORIES		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Pro Brain Natriuretic Peptide (pg/mL)	Mean	13024.00	17735.75	10621.29	8860.80	**13026.03**
	Std	18288.12	21361.64	12323.41	6881.09	**16119.15**
	Missing	*15*	*25*	*20*	*18*	**78**
White Blood Cell Count (x10/μL)	Mean	10.20	10.26	9.64	13.01	**10.68**
	Std	5.80	4.55	5.40	8.57	**6.12**
	Missing	*0*	*0*	*0*	*0*	**0**
Hemoglobin (g/dL)	Mean	11.69	12.20	11.49	11.17	**11.68**
	Std	3.16	2.32	1.48	3.00	**2.52**
	Missing	*0*	*0*	*0*	*0*	**0**
Platelets (x10/μL)	Mean	210.58	220.72	213.77	234.57	**219.71**
	Std	89.48	78.58	87.09	90.75	**85.17**
	Missing	*0*	*1*	*1*	*0*	**2**
INR	Mean	1.38	1.43	1.46	1.27	**1.39**
	Std	0.34	0.42	0.83	0.17	**0.51**
	Missing	*2*	*1*	*3*	*5*	**11**

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Section 2 - Patients Recieving a Durable Device

Exhibit 8: Laboratories

HOSPX-8888 (n=29)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	6	10	7	6	29
Lupus Anticoagulant					
Negative	0%	0%	14%	0%	**3%**
Unknown	100%	100%	85%	100%	**96%**

Pedimacs (n=107)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	24	33	27	23	107
Lupus Anticoagulant					
Negative	0%	0%	11%	4%	**3%**
Unknown	100%	100%	88%	95%	**96%**

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
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SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 9: Pre-Implant Concerns

HOSPX-8888 (n=29)

PRE-IMPLANT CONCERNS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
Patients (n)	6	10	7	6	29
Patient/Family Does Not Want Transplant	0%	10%	0%	0%	3%
Musculoskeletal Limitation	0%	10%	0%	0%	3%
Contraindication to Immunosuppression	0%	0%	14%	0%	3%
Allosensitization	0%	0%	14%	0%	3%
Frailty	0%	0%	0%	17%	3%
Chronic Renal Disease	0%	0%	14%	0%	3%
Frequent ICD Shocks	0%	0%	0%	0%	0%
Pulmonary Disease	0%	0%	0%	0%	0%
Pulmonary Hypertension	0%	0%	29%	0%	7%
Recent Pulmonary Embolus	0%	0%	0%	0%	0%
History of Atrial Arrhythmia	0%	30%	14%	17%	17%
Unfavorable Mediastinal Anatomy	0%	0%	29%	0%	7%
Thoracic Aortic Disease	0%	0%	0%	0%	0%
Tracheostomy	0%	0%	0%	0%	0%
Plastic Bronchitis	0%	0%	0%	0%	0%
Large BMI	0%	0%	14%	0%	3%
Severe Diabetes	0%	0%	0%	0%	0%
Malnutrition/Cachexia	0%	0%	0%	0%	0%
History of GI Ulcers	0%	0%	0%	0%	0%
History of Hepatitis	0%	0%	0%	0%	0%
Liver Dysfunction	0%	0%	0%	0%	0%
Anasarca	0%	0%	0%	0%	0%
Protein Losing Enteropathy	0%	0%	0%	0%	0%
Genetic Syndrome	0%	0%	0%	0%	0%
Heparin-induced Thrombocytopenia	0%	0%	0%	0%	0%
Chronic Coagulopathy	0%	0%	0%	0%	0%
Major Stroke	0%	10%	14%	0%	7%
Other Cerebrovascular Disease	0%	0%	0%	0%	0%
Peripheral Vascular Disease	0%	0%	0%	0%	0%
History of Solid Organ Cancer	0%	0%	0%	0%	0%
History of Lymphoma, Leukemia	0%	0%	0%	0%	0%
History of Bone Marrow Transplant (BMT)	0%	0%	0%	0%	0%

(Continued)

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 9: Pre-Implant Concerns

HOSPX-8888 (n=29)

PRE-IMPLANT CONCERNS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
History of HIV	0%	0%	0%	0%	**0%**
Chronic Infectious Concerns	0%	0%	0%	0%	**0%**
Limited cognition/understanding	0%	0%	0%	0%	**0%**
Limited social support	0%	10%	0%	0%	**3%**
Repeated non-compliance	0%	0%	0%	0%	**0%**
History of illicit drug use	0%	0%	0%	0%	**0%**
History of alcohol abuse	0%	0%	0%	0%	**0%**
Narcotic dependence	0%	0%	0%	0%	**0%**
History of smoking	0%	0%	0%	0%	**0%**
Currently smoking	0%	0%	0%	0%	**0%**
Severe depression	0%	0%	0%	0%	**0%**
Other major psychiatric diagnosis	0%	0%	0%	0%	**0%**
Neurological/developmental abnormalities	0%	10%	0%	0%	**3%**
Other co-morbidity	17%	0%	0%	0%	**3%**

SITE: *Hospital X - (Random 50 Patients)*

Section 2 - Patients Recieving a Durable Device

Exhibit 9: Pre-Implant Concerns

Pedimacs (n=107)

PRE-IMPLANT CONCERNS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
Patients (n)	**24**	**33**	**27**	**23**	**107**
Patient/Family Does Not Want Transplant	0%	3%	0%	0%	**1%**
Musculoskeletal Limitation	0%	3%	0%	4%	**2%**
Contraindication to Immunosuppression	0%	0%	7%	0%	**2%**
Allosensitization	0%	3%	4%	0%	**2%**
Frailty	0%	3%	4%	22%	**7%**
Chronic Renal Disease	0%	3%	4%	4%	**3%**
Frequent ICD Shocks	0%	0%	0%	0%	**0%**
Pulmonary Disease	0%	0%	0%	0%	**0%**
Pulmonary Hypertension	4%	6%	11%	4%	**7%**
Recent Pulmonary Embolus	0%	0%	0%	0%	**0%**
History of Atrial Arrhythmia	0%	9%	7%	9%	**7%**
Unfavorable Mediastinal Anatomy	4%	0%	19%	0%	**6%**
Thoracic Aortic Disease	0%	0%	0%	4%	**1%**
Tracheostomy	0%	0%	0%	0%	**0%**
Plastic Bronchitis	0%	0%	0%	0%	**0%**
Large BMI	4%	6%	7%	0%	**5%**
Severe Diabetes	0%	0%	0%	0%	**0%**
Malnutrition/Cachexia	0%	3%	4%	13%	**5%**
History of GI Ulcers	0%	0%	0%	0%	**0%**
History of Hepatitis	0%	0%	0%	0%	**0%**
Liver Dysfunction	0%	0%	0%	4%	**1%**
Anasarca	4%	0%	0%	0%	**1%**
Protein Losing Enteropathy	0%	0%	0%	0%	**0%**
Genetic Syndrome	4%	0%	0%	0%	**1%**
Heparin-induced Thrombocytopenia	0%	0%	0%	0%	**0%**
Chronic Coagulopathy	0%	0%	0%	0%	**0%**
Major Stroke	0%	3%	7%	0%	**3%**
Other Cerebrovascular Disease	0%	0%	0%	0%	**0%**
Peripheral Vascular Disease	0%	0%	0%	0%	**0%**
History of Solid Organ Cancer	0%	0%	4%	0%	**1%**
History of Lymphoma, Leukemia	0%	0%	0%	0%	**0%**
History of Bone Marrow Transplant (BMT)	0%	0%	0%	0%	**0%**

(Continued)

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
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SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 9: Pre-Implant Concerns

Pedimacs (n=107)

PRE-IMPLANT CONCERNS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
History of HIV	0%	0%	0%	0%	**0%**
Chronic Infectious Concerns	0%	3%	0%	0%	**1%**
Limited cognition/understanding	0%	0%	0%	0%	**0%**
Limited social support	0%	6%	4%	0%	**3%**
Repeated non-compliance	0%	0%	0%	0%	**0%**
History of illicit drug use	4%	0%	0%	0%	**1%**
History of alcohol abuse	0%	0%	0%	0%	**0%**
Narcotic dependence	0%	0%	0%	0%	**0%**
History of smoking	4%	0%	0%	0%	**1%**
Currently smoking	0%	0%	0%	0%	**0%**
Severe depression	0%	0%	0%	0%	**0%**
Other major psychiatric diagnosis	9%	0%	0%	0%	**2%**
Neurological/developmental abnormalities	4%	3%	0%	0%	**2%**
Other co-morbidity	8%	0%	4%	0%	**3%**

Section 2 - Patients Recieving 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=29)

PRE-IMPLANT GENERAL HEMODYNAMICS		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients	n	6	10	7	6	29
Heart Rate	Mean	78.00	116.25	111.75	151.00	117.45
	Std		7.76	16.38	2.83	22.22
	Missing	5	6	3	4	18

Pedimacs (n=107)

PRE-IMPLANT GENERAL HEMODYNAMICS		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients	n	24	33	27	23	107
Heart Rate	Mean	97.13	123.92	107.91	141.00	114.97
	Std	28.29	31.86	25.86	12.36	30.13
	Missing	16	20	16	19	71

COVERAGE: April 1, 2019 - 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=29)

		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients	n	6	10	7	6	29
LVEDD	Mean	6.62	5.13	9.52	5.65	6.30
	Std	1.46	0.92		2.05	1.74
	Missing	1	7	6	4	18

Pedimacs (n=107)

		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients	n	24	33	27	23	107
LVEDD	Mean	6.01	5.41	6.11	6.24	5.93
	Std	1.80	1.22	2.19	1.25	1.62
	Missing	9	19	16	10	54

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
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SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 11: Echo Hemodynamics

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

HOSPX-8888 (n=29)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	**6**	**10**	**7**	**6**	**29**
RVEF					
Normal	16%	20%	14%	0%	**13%**
Mild	16%	0%	0%	33%	**10%**
Moderate	0%	10%	0%	33%	**10%**
Severe	16%	30%	42%	16%	**27%**
Not Done	33%	40%	14%	16%	**27%**
Not Applicable	0%	0%	14%	0%	**3%**
Unknown	16%	0%	14%	0%	**6%**
Aortic Regurgitation					
0 (none)	66%	60%	42%	50%	**55%**
1 (mild)	16%	20%	14%	50%	**24%**
2 (moderate)	0%	0%	0%	0%	**0%**
Not Recorded or Not Documented	16%	20%	42%	0%	**20%**

Pedimacs (n=107)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	**24**	**33**	**27**	**23**	**107**
RVEF					
Normal	16%	6%	22%	8%	**13%**
Mild	8%	15%	7%	8%	**10%**
Moderate	25%	12%	7%	13%	**14%**
Severe	8%	12%	18%	17%	**14%**
Not Done	20%	27%	22%	34%	**26%**
Not Applicable	8%	3%	3%	4%	**4%**
Unknown	12%	24%	18%	13%	**17%**
Aortic Regurgitation					
0 (none)	54%	57%	48%	52%	**53%**
1 (mild)	33%	21%	14%	30%	**24%**
2 (moderate)	0%	3%	3%	4%	**2%**
Not Recorded or Not Documented	12%	18%	33%	13%	**19%**

COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving a Durable Device

Exhibit 12: Swan Hemodynamics

HOSPX-8888 (n=29)

SWAN HEMODYNAMICS		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients	n	6	10	7	6	29
Pulmonary Artery Systolic Pressure (mmHg)	Mean	68.00	44.00	32.67	66.50	47.89
	Std		29.87	23.69	31.82	26.83
	Missing	5	7	4	4	20
Pulmonary Artery Diastolic Pressure (mmHg)	Mean	45.00	29.67	24.67	37.00	31.33
	Std		22.14	13.43	5.66	14.86
	Missing	5	7	4	4	20
Mean RA Pressure (mmHg)	Mean	22.00	15.33	15.00	13.00	15.86
	Std		2.08	7.07		4.22
	Missing	5	7	5	5	22
Pulmonary Artery Wedge Pressure (mmHg)	Mean	49.00	20.00	13.00	30.00	26.40
	Std		5.66			14.29
	Missing	5	8	6	5	24
Cardiac Index	Mean		1.67	0.30	1.63	1.31
	Std				0.33	0.70
	Missing	6	9	6	4	25

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
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Section 2 - Patients Recieving a Durable Device

Exhibit 12: Swan Hemodynamics

Pedimacs (n=107)

SWAN HEMODYNAMICS		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients	n	24	33	27	23	107
Pulmonary Artery Systolic Pressure (mmHg)	Mean	60.40	42.62	32.86	50.00	45.18
	Std	23.61	18.69	14.26	19.23	19.94
	Missing	19	20	20	14	73
Pulmonary Artery Diastolic Pressure (mmHg)	Mean	38.80	26.00	20.43	28.22	27.36
	Std	12.87	11.12	8.94	8.41	11.30
	Missing	19	21	20	14	74
Mean RA Pressure (mmHg)	Mean	12.78	15.73	15.33	11.00	14.00
	Std	7.48	5.48	6.78	5.74	6.36
	Missing	15	18	18	14	65
Pulmonary Artery Wedge Pressure (mmHg)	Mean	34.60	20.45	20.17	22.50	23.30
	Std	10.64	4.50	12.38	8.43	9.67
	Missing	19	22	21	15	77
Cardiac Index	Mean	1.92	2.75	1.61	2.36	2.30
	Std	0.32	1.42	1.02	0.90	1.10
	Missing	17	22	23	16	78

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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=29)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	**6**	**10**	**7**	**6**	**29**
ECG Rhythm					
Sinus	100%	90%	57%	66%	**79%**
Atrial fibrillation	0%	0%	0%	16%	**3%**
Paced: Ventricular pacing	0%	0%	14%	0%	**3%**
Paced: Atrial and ventricular pacing	0%	0%	0%	16%	**3%**
Other, specify	0%	10%	28%	0%	**10%**

Pedimacs (n=107)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	**24**	**33**	**27**	**23**	**107**
ECG Rhythm					
Sinus	83%	84%	77%	73%	**80%**
Atrial fibrillation	0%	0%	0%	4%	**0%**
Paced: Ventricular pacing	0%	6%	3%	4%	**3%**
Paced: Atrial and ventricular pacing	4%	0%	3%	8%	**3%**
Other, specify	12%	9%	14%	8%	**11%**

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Section 2 - Patients Recieving 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=29)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	6	10	7	6	29
VAD Indication					
Post Cardiac Surgery	0%	0%	0%	0%	0%
None	100%	80%	100%	83%	89%
Failure to Wean from ECMO	0%	20%	0%	16%	10%

Pedimacs (n=107)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	24	33	27	23	107
VAD Indication					
Post Cardiac Surgery	0%	3%	3%	0%	1%
None	87%	87%	88%	91%	88%
Failure to Wean from ECMO	12%	9%	7%	8%	9%

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SITE: Hospital X - (Random 50 Patients)

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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=29)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	6	10	7	6	29
Device Type					
LVAD	83%	70%	57%	66%	**68%**
RVAD	0%	20%	28%	0%	**13%**
BiVAD	16%	10%	14%	33%	**17%**

Pedimacs (n=107)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	24	33	27	23	107
Device Type					
LVAD	79%	84%	70%	82%	**79%**
RVAD	8%	6%	7%	0%	**5%**
BiVAD	12%	9%	22%	17%	**14%**

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SITE: Hospital X - (Random 50 Patients)

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Section 2 - Patients Recieving a Durable Device

Exhibit 16: Previous Cardiac Operations

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

HOSPX-8888 (n=29)

PREVIOUS CARDIAC OPERATIONS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
Patients (n)	6	10	7	6	29
None	100%	30%	14%	50%	45%
CABG	0%	0%	14%	0%	3%
Aneuryomectomy (DOR)	0%	0%	0%	0%	0%
Aortic Valve replacement / repair	0%	0%	14%	0%	3%
Mitral Valve replacement / repair	0%	0%	14%	0%	3%
Triscuspid replacement /repair	0%	0%	0%	0%	0%
Congenital card surgery	0%	30%	71%	17%	31%
LVAD	0%	20%	14%	17%	14%
RVAD	0%	0%	14%	0%	3%
TAH	0%	0%	0%	0%	0%
Previous heart transplant	0%	10%	0%	0%	3%
Previous ECMO	0%	30%	14%	17%	17%
Other, specify	0%	20%	0%	33%	14%

Pedimacs (n=107)

PREVIOUS CARDIAC OPERATIONS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
Patients (n)	24	33	27	23	107
None	63%	42%	59%	61%	55%
CABG	0%	0%	4%	0%	1%
Aneuryomectomy (DOR)	0%	0%	0%	0%	0%
Aortic Valve replacement / repair	8%	3%	4%	4%	5%
Mitral Valve replacement / repair	4%	0%	7%	0%	3%
Triscuspid replacement /repair	0%	3%	4%	0%	2%
Congenital card surgery	17%	39%	26%	22%	27%
LVAD	8%	9%	7%	4%	7%
RVAD	0%	0%	4%	0%	1%
TAH	0%	0%	0%	0%	0%
Previous heart transplant	0%	3%	0%	0%	1%
Previous ECMO	8%	15%	7%	9%	10%
Other, specify	13%	9%	4%	13%	9%

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

Section 2 - Patients Recieving 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=29)

IMPLANT HOSPITALIZATION EVENTS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
Patients (n)	6	10	7	6	29
None	50%	0%	29%	17%	21%
CABG	0%	0%	0%	0%	0%
Aortic Valve replacement / repair	0%	0%	0%	0%	0%
Mitral Valve replacement / repair	0%	0%	0%	0%	0%
Congenital cardiac surgery	0%	10%	0%	17%	7%
Other surgical procedures	17%	0%	43%	0%	14%
IABP	0%	0%	0%	0%	0%
ECMO	17%	30%	29%	50%	31%
LVAD	17%	20%	14%	33%	21%
RVAD	0%	0%	14%	0%	3%
TAH	0%	0%	0%	0%	0%
Dialysis	0%	0%	0%	17%	3%
Ultrafiltration	0%	0%	0%	0%	0%
Feeding Tube	0%	60%	14%	50%	34%
Intubation	17%	70%	29%	67%	48%
Major MI	0%	0%	0%	0%	0%
Major infections / Positive blood cultures	0%	20%	29%	17%	17%
Escalation to CPAP	0%	10%	0%	17%	7%
Arrhythmia	17%	30%	57%	17%	31%
Previous ECMO	0%	0%	0%	17%	3%
Previous heart transplant	0%	0%	0%	0%	0%
Treatment of Rejection	0%	10%	0%	0%	3%
Peritoneal Drain	0%	0%	0%	0%	0%
Non-cardiac procedure	0%	20%	0%	33%	14%

Pedimacs (n=107)

IMPLANT HOSPITALIZATION EVENTS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
Patients (n)	24	33	27	23	107
None	46%	36%	22%	13%	30%
CABG	0%	0%	0%	0%	0%
Aortic Valve replacement / repair	4%	0%	0%	4%	2%

(Continued)

Section 2 - Patients Recieving a Durable Device

Exhibit 17: Clinical Events and Interventions during Implant Hospitalization

Pedimacs (n=107)

IMPLANT HOSPITALIZATION EVENTS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
Mitral Valve replacement / repair	0%	0%	4%	0%	**1%**
Congenital cardiac surgery	4%	9%	4%	9%	**7%**
Other surgical procedures	8%	0%	11%	0%	**5%**
IABP	0%	0%	4%	0%	**1%**
ECMO	21%	18%	19%	26%	**21%**
LVAD	17%	12%	15%	13%	**14%**
RVAD	0%	0%	4%	0%	**1%**
TAH	0%	0%	0%	0%	**0%**
Dialysis	0%	0%	0%	17%	**4%**
Ultrafiltration	0%	0%	0%	4%	**1%**
Feeding Tube	8%	33%	26%	43%	**28%**
Intubation	38%	42%	41%	39%	**40%**
Major MI	0%	0%	0%	0%	**0%**
Major infections / Positive blood cultures	4%	6%	22%	13%	**11%**
Escalation to CPAP	0%	9%	7%	13%	**7%**
Arrhythmia	13%	18%	33%	35%	**24%**
Previous ECMO	4%	3%	0%	4%	**3%**
Previous heart transplant	0%	0%	0%	0%	**0%**
Treatment of Rejection	0%	3%	0%	0%	**1%**
Peritoneal Drain	0%	0%	0%	0%	**0%**
Non-cardiac procedure	8%	6%	4%	13%	**7%**

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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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)	121	259
Patient exposure after the first 3 months post implant (months)	43	99
Number of Patients	58	136

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - 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 %

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - 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	1.55		
Bleeding	338	130.7	42	42.24
Cardiac Arrhythmia	73	28.23	13	13.08
Device Malfunction	7	2.71	2	2.01
Device Malfunction and/or Pump Thrombosis	319	123.4	98	98.57
Hepatic Dysfunction	17	6.57	5	5.03
Infection	316	122.2	122	122.7
Neurological Dysfunction	244	94.36	47	47.27
Other Serious Adverse Event	244	94.36	54	54.31
Pericardial Drainage	41	15.86		
Psychiatric Episode	34	13.15	5	5.03
Rehospitalization	99	38.29	334	335.9
Renal Dysfunction	81	31.33	8	8.05
Respiratory Failure	158	61.10	16	16.09
Venous Thromboembolism	9	3.48		
Wound Dehiscence	5	1.93		

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - 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	8.89	11	11.06
Line Sepsis	19	7.35	8	8.05
Mediastinum	20	7.73	3	3.02
Other Specify	50	19.34	15	15.09
Peripheral Wound	11	4.25	5	5.03
Positive Blood Cultures	69	26.68	24	24.14
Pulmonary	92	35.58	19	19.11
Pump/Related - Drive Line	25	9.67	35	35.20
Pump/Related - Exit Cannula	10	3.87	6	6.03
Pump/Related - Pump Interior	2	0.77	0	0.00
Pump/Related - Pump Pocket	2	0.77	2	2.01
Unknown	20	7.73	3	3.02
Urinary Tract	34	13.15	10	10.06

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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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=29)	Pedimacs (n=107)
All	**Patients**	10	24
	Mean	39.10	44.58
	Std	21.13	28.81
	Min	18	18
	Max	91	134
BiVAD	**Patients**	1	2
	Mean	34.00	43.00
	Std		12.73
	Min	34	34
	Max	34	52
LVAD	**Patients**	7	19
	Mean	30.71	42.89
	Std	10.52	30.15
	Min	18	18
	Max	47	134
RVAD	**Patients**	2	3
	Mean	71.00	56.33
	Std	28.28	32.33
	Min	51	27
	Max	91	91

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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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 age listed by device type and discharge year.

HOSPX-8888

	30 DAY REDAMISSION	2019 Q3	2019 Q4	2020 Q1	TOTAL
LVAD	Patients Discharged Alive on Device (n)	1	0	4	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	1	1
	% With 30 day Readmission			0%	0%

STS Pedimacs

	30 DAY REDAMISSION	2019 Q3	2019 Q4	2020 Q1	TOTAL
LVAD	Patients Discharged Alive on Device (n)	5	4	8	17
	% With 30 day Readmission	0%	0%	13%	6%
RVAD	Patients Discharged Alive on Device (n)	1	0	0	1
	% With 30 day Readmission	100%			100%
BiVAD	Patients Discharged Alive on Device (n)	0	0	2	2
	% With 30 day Readmission			50%	50%

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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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	29	6	20.7	23	79.3	3.6	0.7	4.0	2.0	4.0
3 Month	10	4	40.0	6	60.0	3.0	0.6	3.0	2.0	4.0
6 Month	1	1	100.0							

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	107	39	36.4	68	63.6	3.5	0.7	4.0	2.0	4.0
3 Month	33	19	57.6	14	42.4	2.8	1.0	3.0	1.0	4.0
6 Month	8	4	50.0	4	50.0	2.8	1.3	3.0	1.0	4.0

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.

NYHA Class
Follow-Up for Primary Prospective Implants: April 1, 2019 to March 31, 2020
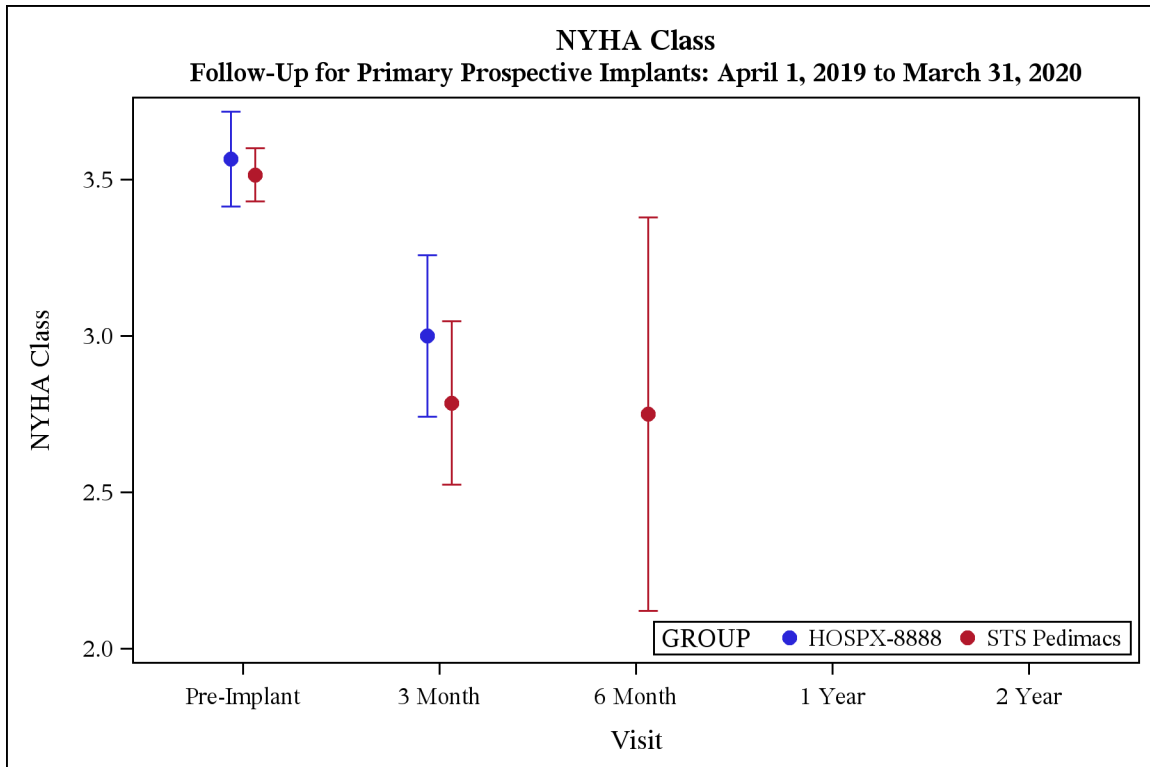
STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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.

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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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.
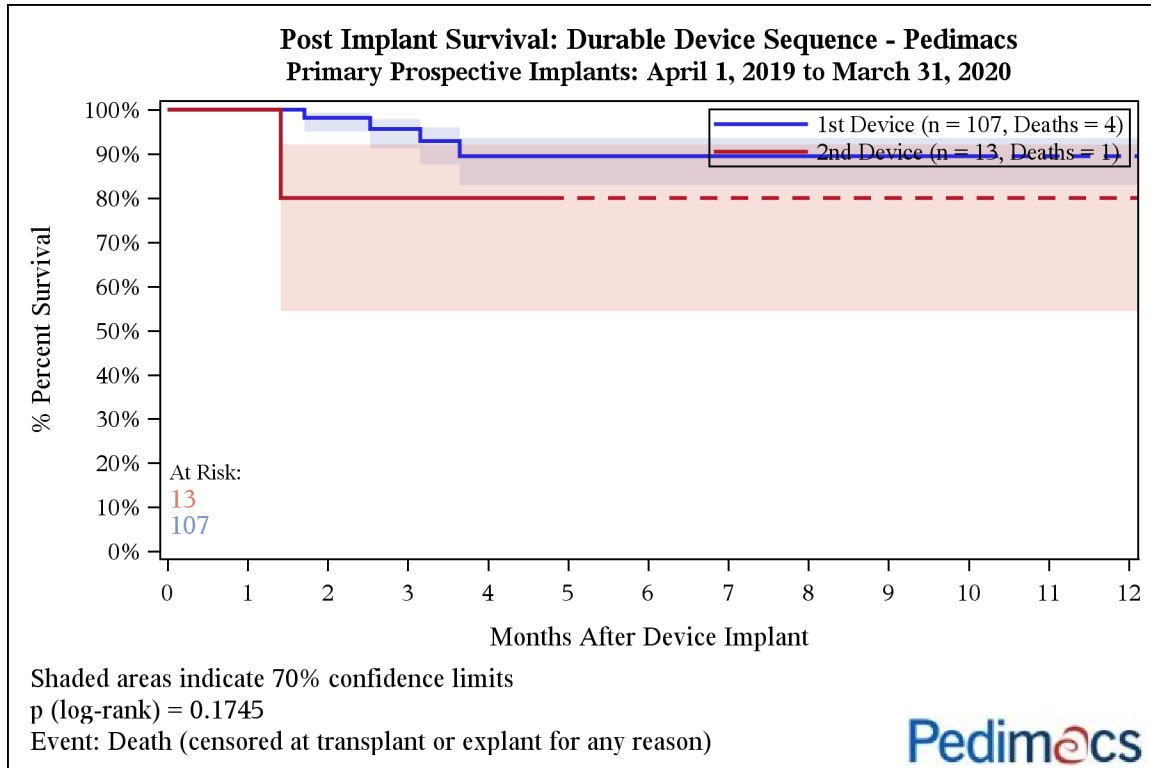
Post Implant Survival: Durable Device Sequence - Pedimacs
Primary Prospective Implants: April 1, 2019 to March 31, 2020

1st Device (n = 107, Deaths = 4)
2nd Device (n = 13, Deaths = 1)

At Risk:
13
107

Shaded areas indicate 70% confidence limits
p (log-rank) = 0.1745
Event: Death (censored at transplant or explant for any reason)

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	95.6% (91.3%-97.8%)	80.0% (54.5%-92.1%)
6	89.5% (83.0%-93.6%)	

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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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.
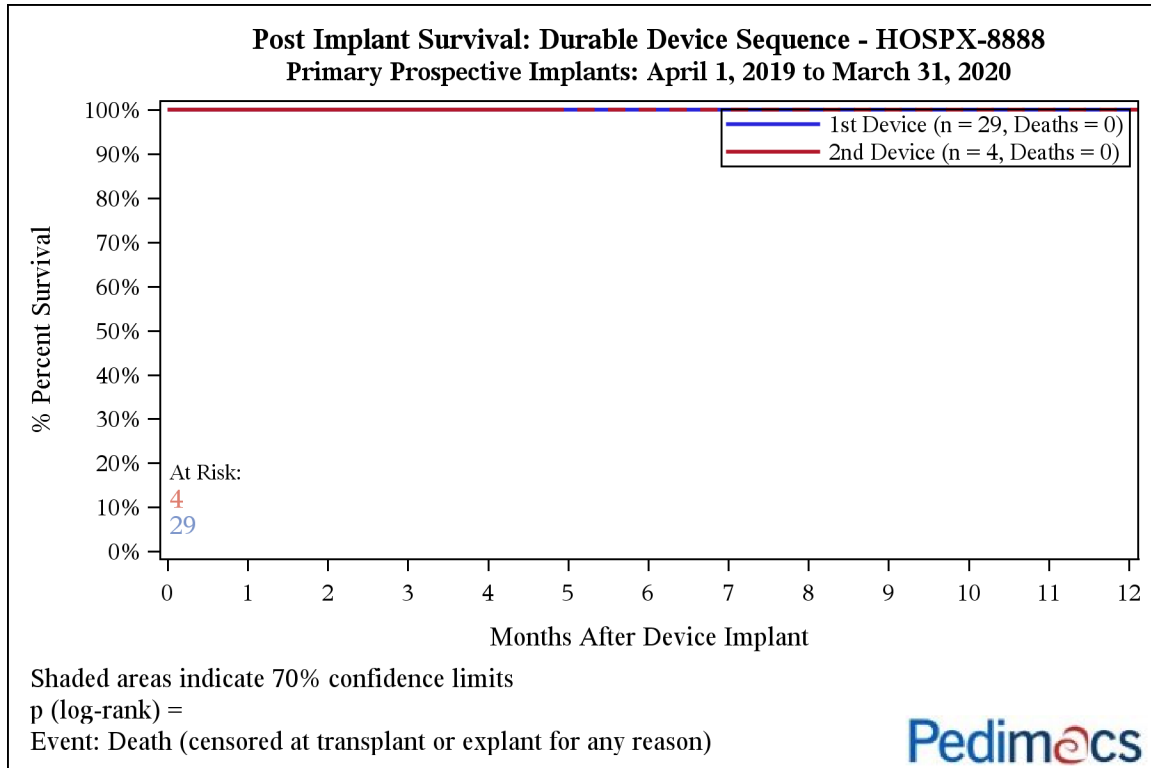
Post Implant Survival: Durable Device Sequence - HOSPX-8888
Primary Prospective Implants: April 1, 2019 to March 31, 2020

1st Device (n = 29, Deaths = 0)
2nd Device (n = 4, Deaths = 0)

At Risk:
4
29

Shaded areas indicate 70% confidence limits
p (log-rank) =
Event: Death (censored at transplant or explant for any reason)

Pedimacs

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	100.0% (100.0%-100.0%)	100.0% (100.0%-100.0%)
6	100.0% (100.0%-100.0%)	

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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Exhibit 23: Post Implant Survival - Durable OVERALL
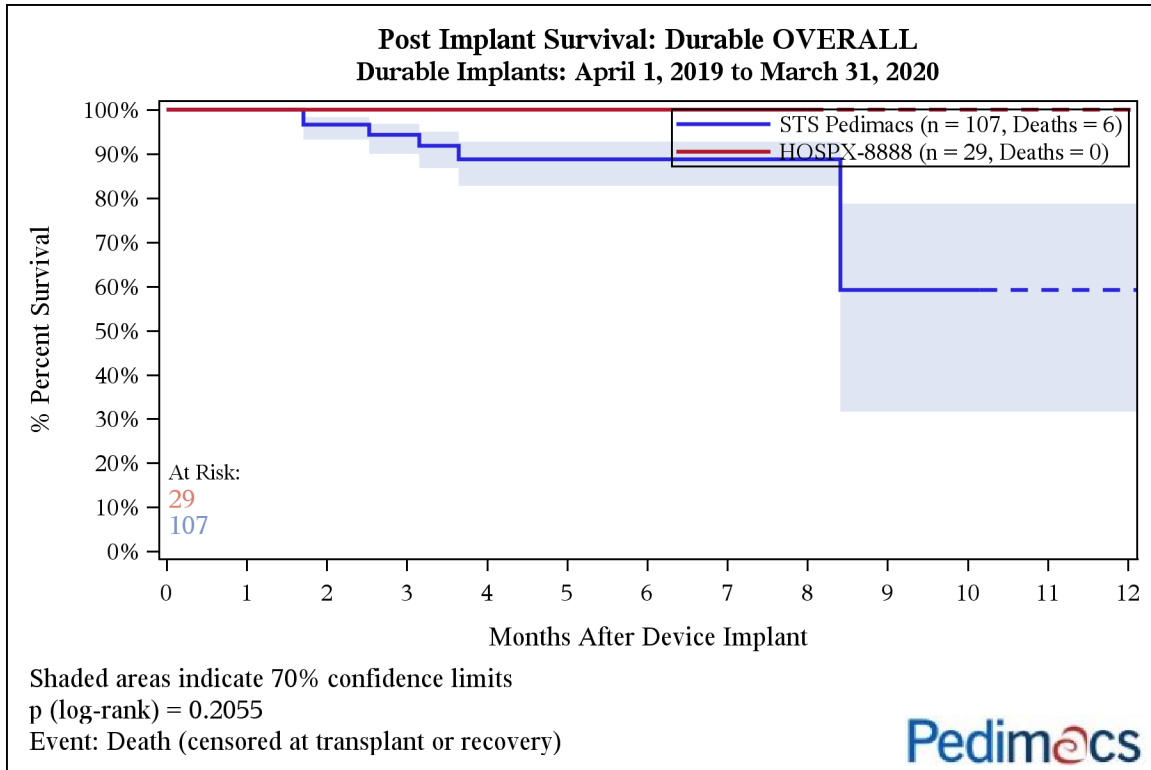
Post Implant Survival: Durable OVERALL
Durable Implants: April 1, 2019 to March 31, 2020

STS Pedimacs (n = 107, Deaths = 6)
HOSPX-8888 (n = 29, Deaths = 0)

At Risk:
29
107

Shaded areas indicate 70% confidence limits
p (log-rank) = 0.2055
Event: Death (censored at transplant or recovery)

Percent Survival [% (70% CI)]

Months after Device Implant	STS Pedimacs	HOSPX-8888
1	100.0% (100.0%-100.0%)	100.0% (100.0%-100.0%)
3	94.3% (90.0%-96.8%)	100.0% (100.0%-100.0%)
6	88.8% (82.8%-92.8%)	100.0% (100.0%-100.0%)

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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Exhibit 24: Post Implant Survival - Durable LVADs
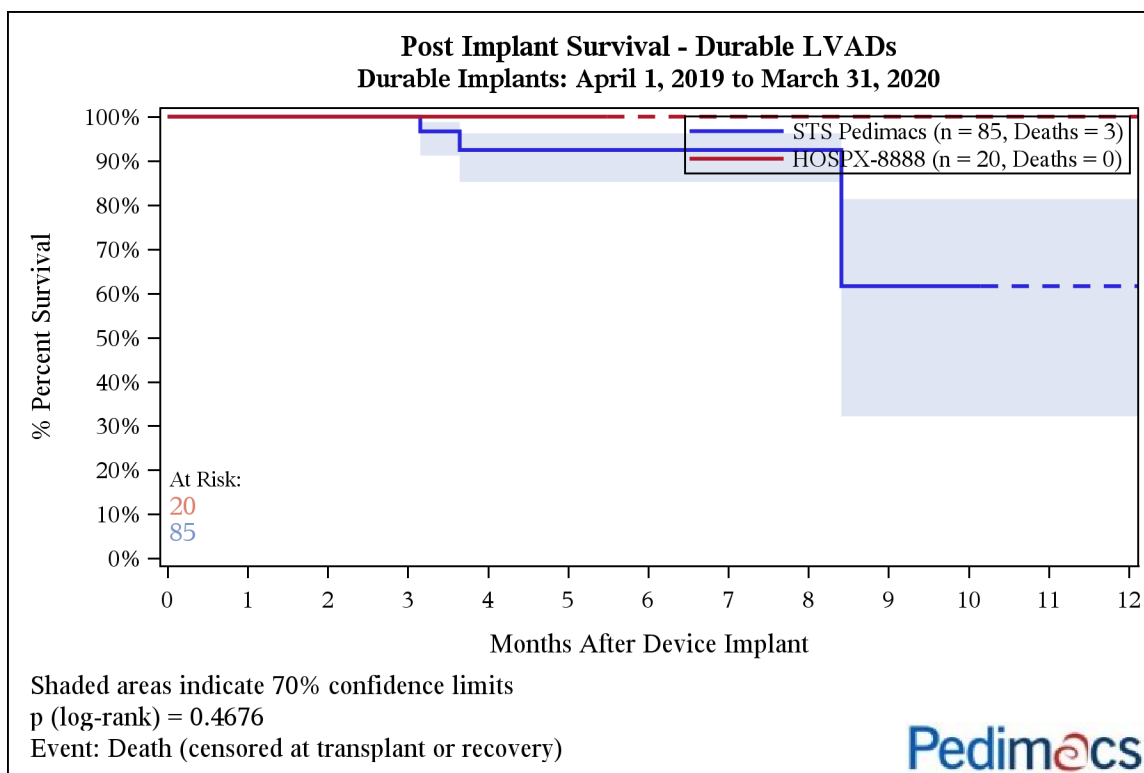
Post Implant Survival - Durable LVADs
Durable Implants: April 1, 2019 to March 31, 2020

STS Pedimacs (n = 85, Deaths = 3)
HOSPX-8888 (n = 20, Deaths = 0)

At Risk:
20
85

Y-axis: % Percent Survival
X-axis: Months After Device Implant

Shaded areas indicate 70% confidence limits
p (log-rank) = 0.4676
Event: Death (censored at transplant or recovery)

Pedimacs

Percent Survival [% (70% CI)]

Months after Device Implant	STS Pedimacs	HOSPX-8888
1	100.0% (100.0%-100.0%)	100.0% (100.0%-100.0%)
3	100.0% (100.0%-100.0%)	100.0% (100.0%-100.0%)
6	92.5% (85.2%-96.2%)	

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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

Post Implant Survival - Durable LVADs by Era - Pedimacs
Durable Implants: April 1, 2019 to March 31, 2020

Era — 2019-2020 (n = 85, Deaths = 3)

At Risk: 85

Shaded areas indicate 70% confidence limits
p (log-rank) = N/A
Event: Death (censored at transplant or recovery)

Pedimacs

Percent Survival [% (70% CI)]

Months after Device Implant	2019-2020
1	100.0% (100.0%-100.0%)
3	100.0% (100.0%-100.0%)
6	92.5% (85.2%-96.2%)

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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

Post Implant Survival - Durable LVADs by Era - HOSPX-8888
Durable Implants: April 1, 2019 to March 31, 2020

Era —— 2019 - 2020 (n = 20, Deaths = 0)

At Risk:
20

% Percent Survival

Months After Device Implant

Shaded areas indicate 70% confidence limits
p (log-rank) = N/A
Event: Death (censored at transplant or recovery)

Pedimacs

Percent Survival [% (70% CI)]

Months after Device Implant	2019 - 2020
1	100.0% (100.0%-100.0%)
3	100.0% (100.0%-100.0%)

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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Exhibit 26: Post Implant Survival - Durable BiVADs

Post Implant Survival - Durable BiVADs
Durable Implants: April 1, 2019 to March 31, 2020

STS Pedimacs (n = 16, Deaths = 3)
HOSPX-8888 (n = 5, Deaths = 0)

At Risk:
5
16

Shaded areas indicate 70% confidence limits
p (log-rank) = 0.2872
Event: Death (censored at transplant or recovery)

Percent Survival [% (70% CI)]

Months after Device Implant	STS Pedimacs	HOSPX-8888
1	100.0% (100.0%-100.0%)	100.0% (100.0%-100.0%)
3	62.2% (42.0%-77.1%)	100.0% (100.0%-100.0%)

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)
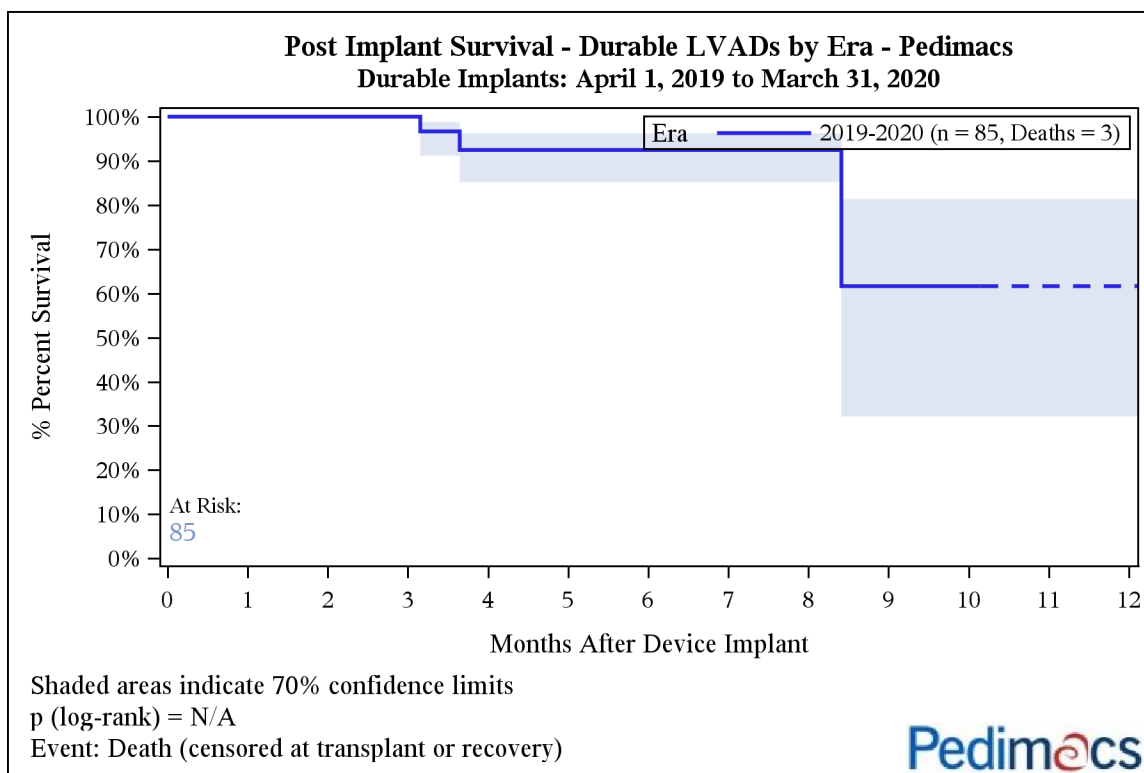
Exhibit 27: Post Implant Survival - Durable TAHs

Percent Survival [% (70% CI)]

Months after Device Implant

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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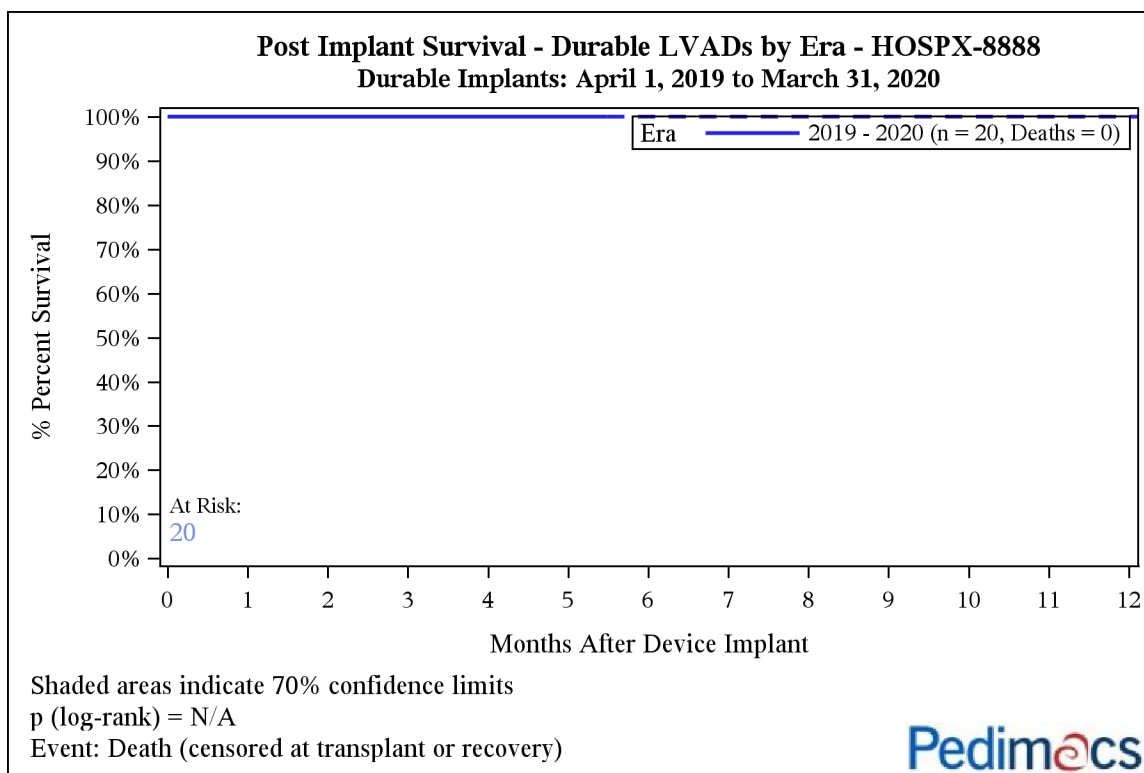
Exhibit 28: Post Implant Survival - Durable LVADs - PULSATILE FLOW
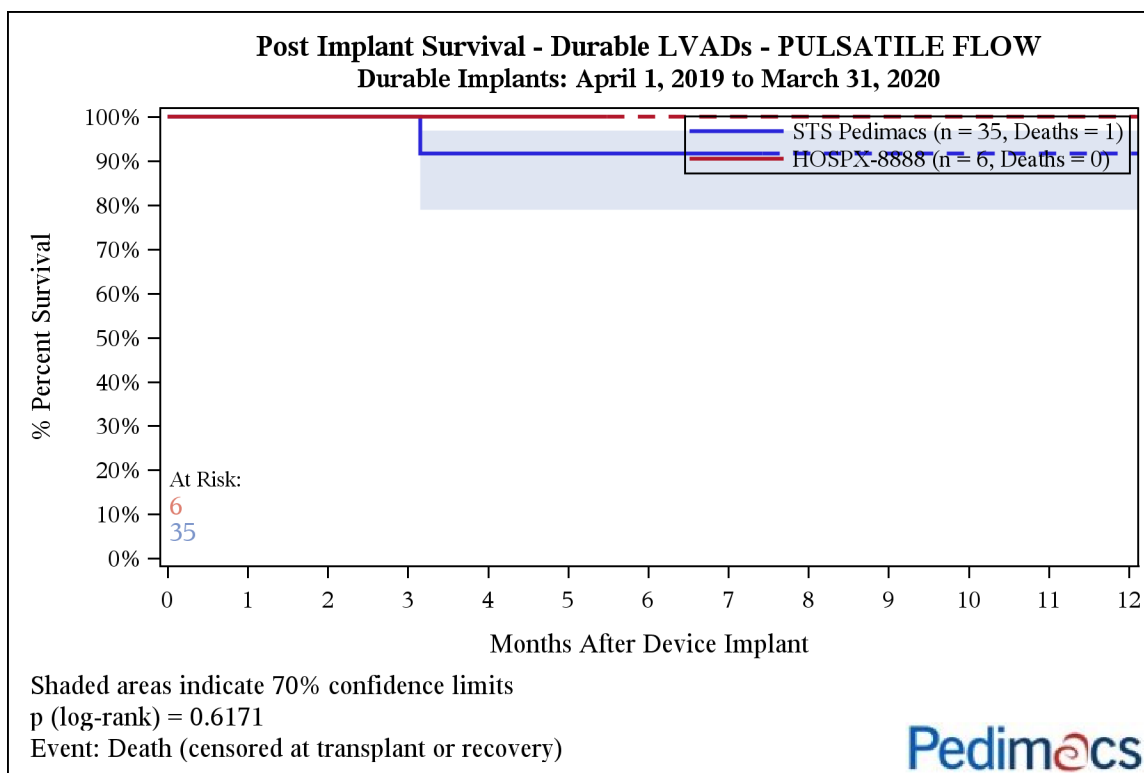
Post Implant Survival - Durable LVADs - PULSATILE FLOW
Durable Implants: April 1, 2019 to March 31, 2020

STS Pedimacs (n = 35, Deaths = 1)
HOSPX-8888 (n = 6, Deaths = 0)

At Risk:
6
35

Shaded areas indicate 70% confidence limits
p (log-rank) = 0.6171
Event: Death (censored at transplant or recovery)

Percent Survival [% (70% CI)]

Months after Device Implant	STS Pedimacs	HOSPX-8888
1	100.0% (100.0%-100.0%)	100.0% (100.0%-100.0%)
3	100.0% (100.0%-100.0%)	100.0% (100.0%-100.0%)
6	91.7% (78.9%-96.9%)	

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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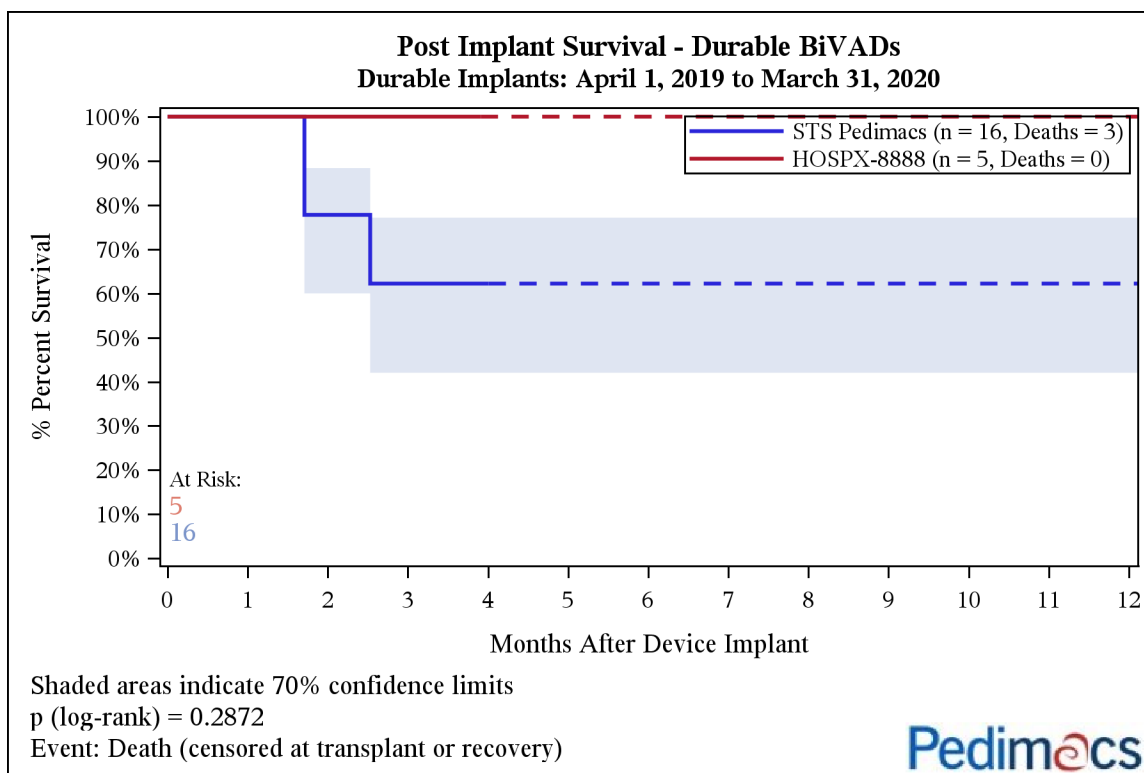
Exhibit 29: Post Implant Survival - Durable LVADs - CONTINUOUS FLOW
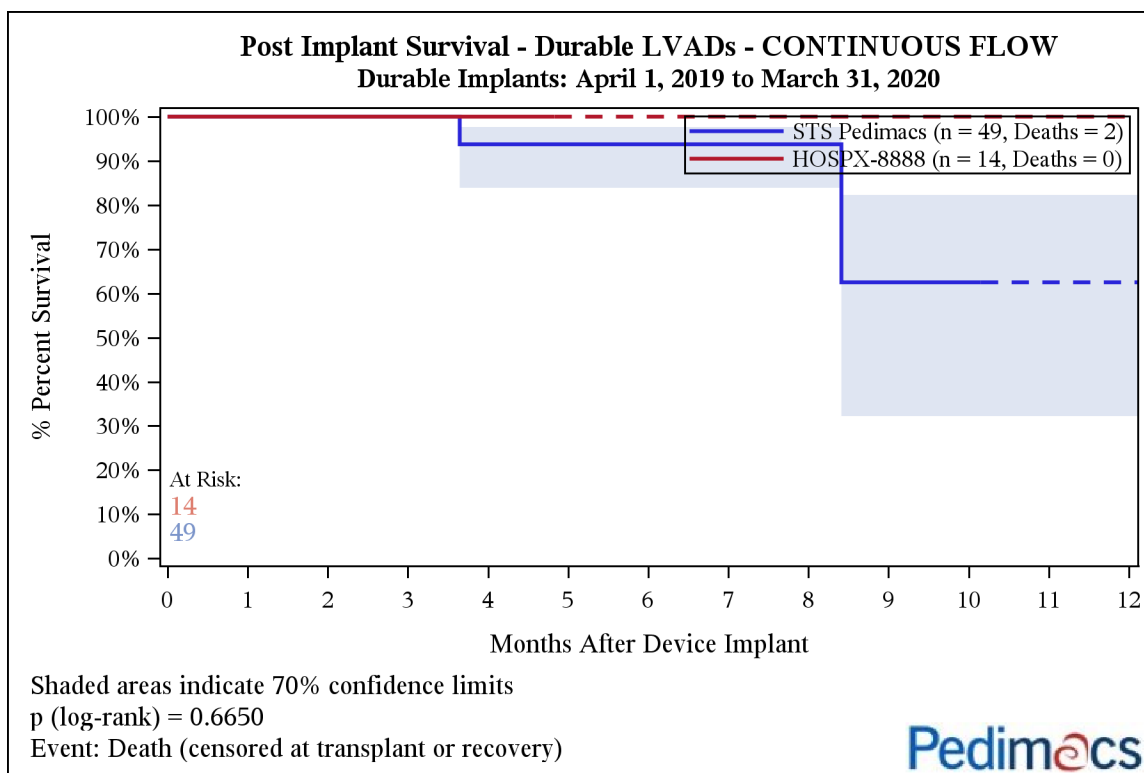
Post Implant Survival - Durable LVADs - CONTINUOUS FLOW
Durable Implants: April 1, 2019 to March 31, 2020

STS Pedimacs (n = 49, Deaths = 2)
HOSPX-8888 (n = 14, Deaths = 0)

At Risk:
14
49

Shaded areas indicate 70% confidence limits
p (log-rank) = 0.6650
Event: Death (censored at transplant or recovery)

Pedimacs

Percent Survival [% (70% CI)]

Months after Device Implant	STS Pedimacs	HOSPX-8888
1	100.0% (100.0%-100.0%)	100.0% (100.0%-100.0%)
3	100.0% (100.0%-100.0%)	100.0% (100.0%-100.0%)
6	93.8% (83.9%-97.7%)	

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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Exhibit 30: Post Implant Survival - Listed for Transplant - CONTINUOUS FLOW DURABLE
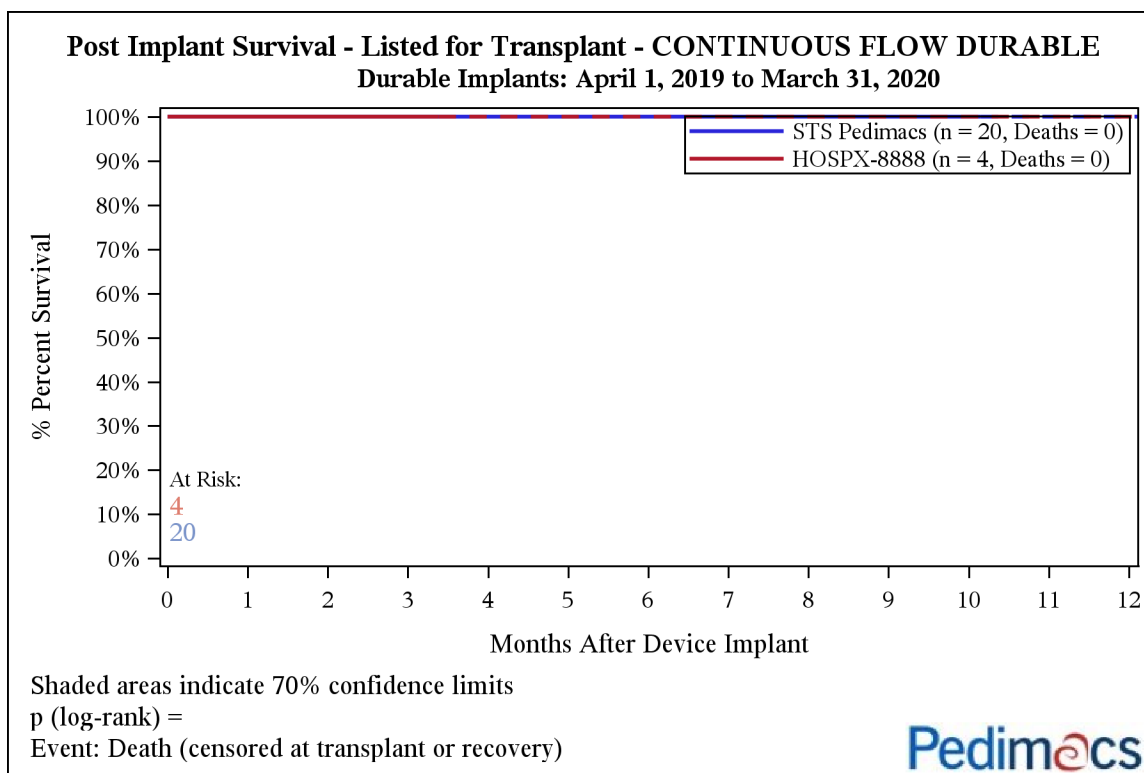
Post Implant Survival - Listed for Transplant - CONTINUOUS FLOW DURABLE
Durable Implants: April 1, 2019 to March 31, 2020

STS Pedimacs (n = 20, Deaths = 0)
HOSPX-8888 (n = 4, Deaths = 0)

At Risk:
4
20

Shaded areas indicate 70% confidence limits
p (log-rank) =
Event: Death (censored at transplant or recovery)

Percent Survival [% (70% CI)]

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

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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Exhibit 31: Post Implant Survival - Bridge to Candidacy - CONTINUOUS FLOW DURABLE
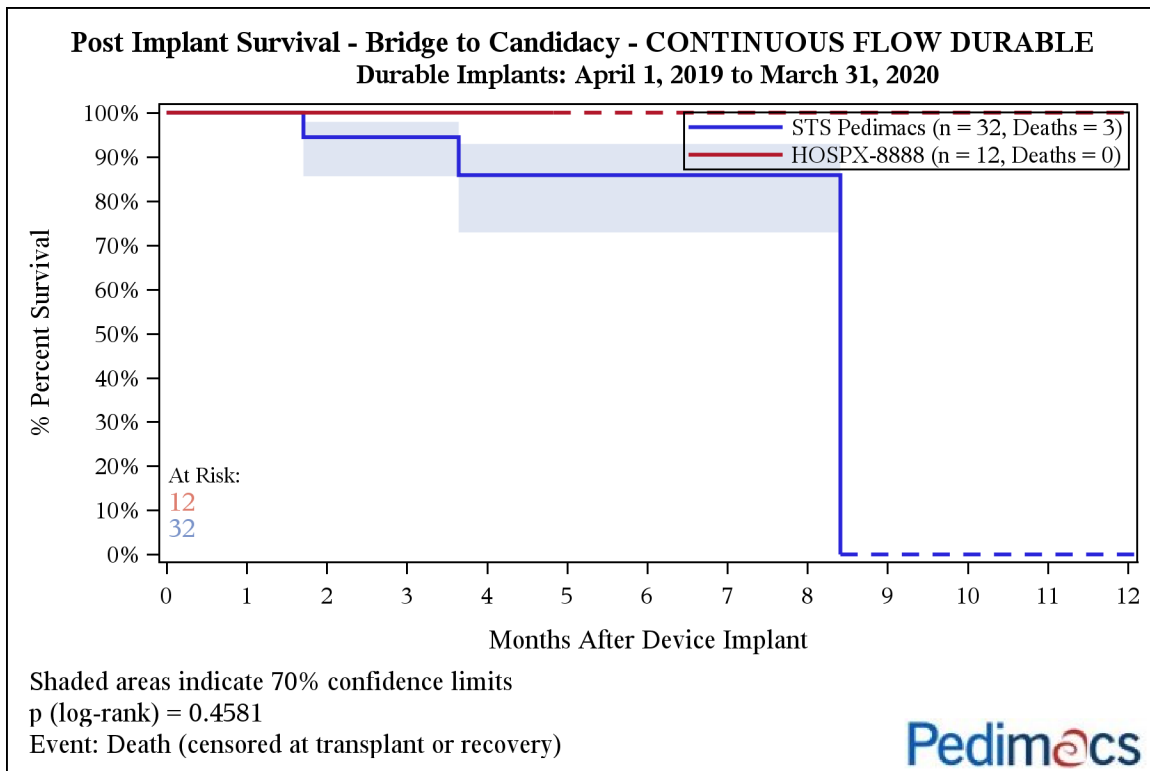
Post Implant Survival - Bridge to Candidacy - CONTINUOUS FLOW DURABLE
Durable Implants: April 1, 2019 to March 31, 2020

STS Pedimacs (n = 32, Deaths = 3)
HOSPX-8888 (n = 12, Deaths = 0)

At Risk:
12
32

Shaded areas indicate 70% confidence limits
p (log-rank) = 0.4581
Event: Death (censored at transplant or recovery)

Percent Survival [% (70% CI)]

Months after Device Implant	STS Pedimacs	HOSPX-8888
1	100.0% (100.0%-100.0%)	100.0% (100.0%-100.0%)
3	94.4% (85.6%-97.9%)	100.0% (100.0%-100.0%)
6	85.9% (72.9%-92.9%)	

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: *April 1, 2019 - March 31, 2020*
SITE: Hospital X - (Random 50 Patients)

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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.

Competing Outcomes - Durable LVADs - CONTINUOUS FLOW - Pedimacs
Durable Implants: April 1, 2019 to March 31, 2020

Number of Patients at Risk

Month
0
49

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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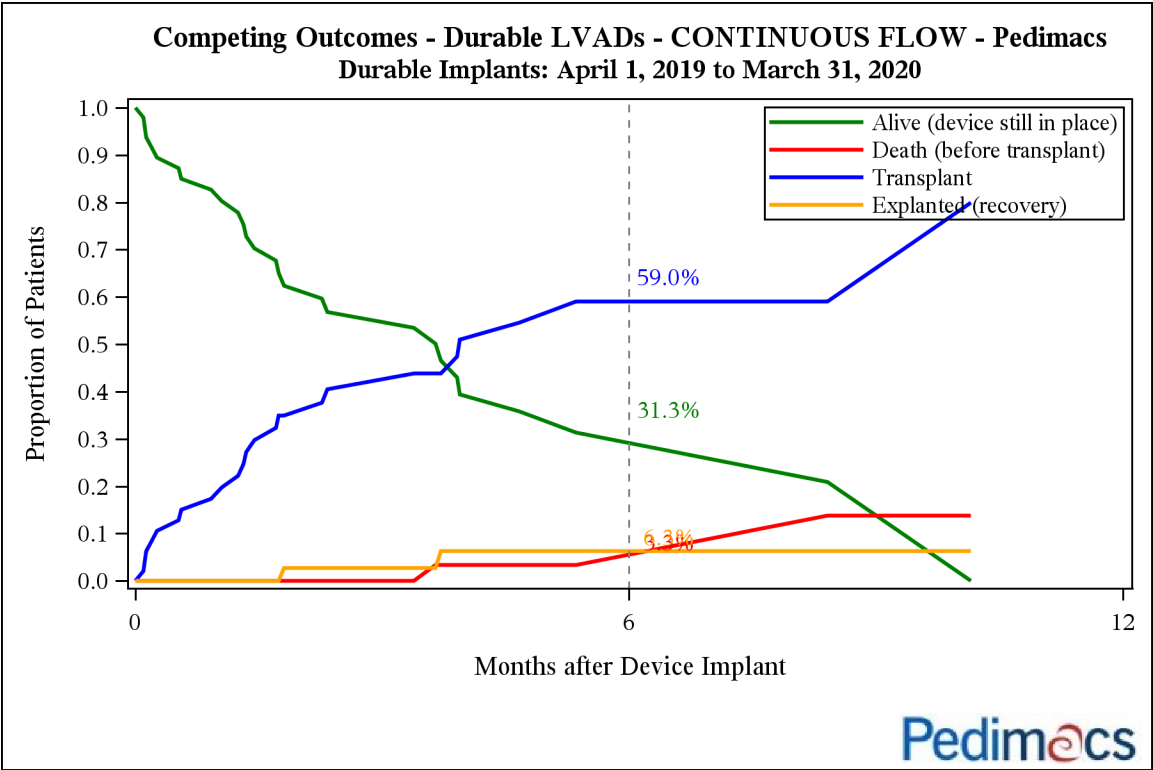
Exhibit 32b: Competing Outcomes - Durable LVADs - CONTINUOUS FLOW - HOSPX-8888

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.

Competing Outcomes - Durable LVADs - CONTINUOUS FLOW - HOSPX-8888
Durable Implants: April 1, 2019 to March 31, 2020

Number of Patients at Risk

Month
0
14

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving 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=21)

DEVICE #	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Primary Device	5	8	3	5	21
2nd Device	0	1	0	1	2
3rd Device	0	0	0	1	1
4th Device	0	0	0	1	1
5th Device	0	0	0	0	0

Pedimacs (n=62)

DEVICE #	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Primary Device	18	21	10	13	62
2nd Device	1	1	0	1	3
3rd Device	0	0	0	1	1
4th Device	0	0	0	1	1
5th Device	0	0	0	0	0

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 2: Patient Demographics

HOSPX-8888 (n=21)

DEMOGRAPHICS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	5	8	3	5	21
Age At Implant - BDV					
< 1 yr	40%	62%	33%	20%	**42%**
1-5 yr	60%	12%	33%	40%	**33%**
6-10 yr	0%	12%	0%	0%	**4%**
11-18 yr	0%	12%	33%	40%	**19%**
Gender					
Female	40%	62%	66%	60%	**57%**
Male	60%	37%	33%	40%	**42%**
Race					
African American	20%	25%	0%	40%	**23%**
White	20%	50%	100%	20%	**42%**
Other, Unknown, Undisclosed	60%	25%	0%	40%	**33%**
Ethnicity					
Non-Hispanic	80%	87%	33%	80%	**76%**
Unknown	20%	12%	0%	20%	**14%**
Hispanic	0%	0%	66%	0%	**9%**

Pedimacs (n=62)

DEMOGRAPHICS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	18	21	10	13	62
Age At Implant - BDV					
< 1 yr	50%	61%	20%	38%	**46%**
1-5 yr	33%	23%	30%	23%	**27%**
6-10 yr	11%	4%	20%	0%	**8%**
11-18 yr	5%	9%	30%	38%	**17%**
Gender					
Female	27%	52%	70%	53%	**48%**
Male	72%	47%	30%	46%	**51%**
Race					
African American	11%	28%	20%	46%	**25%**
White	55%	57%	50%	23%	**48%**
Other, Unknown, Undisclosed	33%	14%	30%	30%	**25%**

(Continued)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 2: Patient Demographics

Pedimacs (n=62)

DEMOGRAPHICS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Ethnicity					
Non-Hispanic	77%	80%	80%	84%	**80%**
Unknown	5%	4%	0%	7%	**4%**
Hispanic	16%	14%	20%	7%	**14%**

Section 3 - Patients Recieving only Temporary Devices

<div align="center">

Exhibit 3: Weight (kg)

</div>

HOSPX-8888 (n=21)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	5	8	3	5	21
Weight (kg)					
< 5 kg	0%	62%	33%	0%	**28%**
5-20 kg	100%	12%	33%	60%	**47%**
> 20 Kg	0%	25%	33%	40%	**23%**

Pedimacs (n=62)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	18	21	10	13	62
Weight (kg)					
< 5 kg	22%	47%	20%	15%	**29%**
5-20 kg	66%	38%	40%	46%	**48%**
> 20 Kg	11%	14%	40%	38%	**22%**

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 4: Primary Diagnosis

HOSPX-8888 (n=21)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	**5**	**8**	**3**	**5**	**21**
Primary Diagnosis					
Congenital Heart Disease – Biventricular	0%	0%	0%	20%	**4%**
Congenital Heart Disease – Single Ventricle	40%	37%	0%	20%	**28%**
Dialated Cardiomyopathy	40%	62%	66%	40%	**52%**
Post Transplant/Graft Dysfunction	0%	0%	33%	0%	**4%**
#None#	0%	0%	0%	0%	**0%**
Other	20%	0%	0%	20%	**9%**

Pedimacs (n=62)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	**18**	**21**	**10**	**13**	**62**
Primary Diagnosis					
Congenital Heart Disease – Biventricular	5%	4%	10%	7%	**6%**
Congenital Heart Disease – Single Ventricle	44%	52%	20%	7%	**35%**
Dialated Cardiomyopathy	38%	38%	50%	61%	**45%**
Post Transplant/Graft Dysfunction	0%	0%	10%	0%	**1%**
#None#	0%	4%	0%	0%	**1%**
Other	11%	0%	10%	23%	**9%**

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 5: Patient Profile Levels

HOSPX-8888 (n=21)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	5	8	3	5	21
Patient Profile					
1 Critical Cardiogenic Shock	40%	75%	33%	60%	**57%**
2 Progressive Decline	60%	12%	66%	40%	**38%**
3 Stable but Inotrope Dependent	0%	12%	0%	0%	**4%**
4 Resting Symptoms	0%	0%	0%	0%	**0%**

Pedimacs (n=62)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	18	21	10	13	62
Patient Profile					
1 Critical Cardiogenic Shock	38%	71%	70%	53%	**58%**
2 Progressive Decline	50%	23%	20%	46%	**35%**
3 Stable but Inotrope Dependent	11%	4%	0%	0%	**4%**
4 Resting Symptoms	0%	0%	10%	0%	**1%**

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 6: Device Strategy

HOSPX-8888 (n=21)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	**5**	**8**	**3**	**5**	**21**
Current Device Strategy					
Bridge to Recovery	40%	12%	0%	40%	**23%**
Bridge to Transplant (patient currently listed for transplant)	20%	12%	33%	20%	**19%**
Possible Bridge to Transplant - Likely to be eligible	20%	37%	33%	0%	**23%**
Possible Bridge to Transplant - Moderate likelihood of becoming eligible	0%	12%	0%	20%	**9%**
Possible Bridge to Transplant - Unlikely to become eligible	0%	0%	0%	0%	**0%**
Destination Therapy (patient definitely not eligible for transplant)	0%	0%	0%	0%	**0%**
Rescue Therapy	20%	25%	33%	20%	**23%**

Pedimacs (n=62)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	**18**	**21**	**10**	**13**	**62**
Current Device Strategy					
Bridge to Recovery	27%	4%	30%	23%	**19%**
Bridge to Transplant (patient currently listed for transplant)	33%	28%	20%	23%	**27%**
Possible Bridge to Transplant - Likely to be eligible	27%	28%	10%	7%	**20%**
Possible Bridge to Transplant - Moderate likelihood of becoming eligible	5%	14%	10%	15%	**11%**
Possible Bridge to Transplant - Unlikely to become eligible	0%	4%	0%	0%	**1%**
Destination Therapy (patient definitely not eligible for transplant)	0%	0%	0%	7%	**1%**
Rescue Therapy	5%	19%	30%	23%	**17%**

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 7: Medications

HOSPX-8888 (n=21)

MEDICATIONS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
Patients (n)	5	8	3	5	21
IV Inotropes at Implant	100%	100%	100%	100%	**100%**
Pre-implant Loop Diuretics	60%	75%	67%	80%	71%

Pedimacs (n=62)

MEDICATIONS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
Patients (n)	18	21	10	13	62
IV Inotropes at Implant	100%	100%	90%	100%	**98%**
Pre-implant Loop Diuretics	72%	71%	50%	69%	**68%**

Section 3 - Patients Recieving only Temporary Devices

Exhibit 8: Laboratories

HOSPX-8888 (n=21)

PRE-IMPLANT LABORATORIES		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients	n	5	8	3	5	21
Sodium (mEq/L)	Mean	140.60	140.38	138.00	141.80	**140.43**
	Std	3.13	5.13	1.73	4.09	**4.02**
	Missing	0	0	0	0	**0**
Potassium (mEq/L)	Mean	4.06	3.85	4.00	3.86	**3.92**
	Std	0.80	0.40	0.87	0.48	**0.56**
	Missing	0	0	0	0	**0**
BUN (mg/dL)	Mean	32.20	22.25	34.33	24.87	**26.97**
	Std	24.44	9.07	14.22	13.68	**15.19**
	Missing	0	0	0	0	**0**
Creatinine (mg/dL)	Mean	0.49	0.76	0.67	0.56	**0.64**
	Std	0.37	0.91	0.26	0.34	**0.60**
	Missing	0	0	0	0	**0**
Alanine Aminotransferase/ALT (u/L)	Mean	21.75	53.71	60.33	133.40	**69.00**
	Std	8.18	24.40	66.38	108.09	**71.04**
	Missing	1	1	0	0	**2**
Aspartate Aminotransferase/AST (u/L)	Mean	40.75	93.14	64.33	455.00	**172.79**
	Std	13.99	57.84	58.02	456.03	**279.57**
	Missing	1	1	0	0	**2**
LDH (ukat/L) , (U/L)	Mean	802.25	1079.25	1093.00	3627.00	**1443.00**
	Std	441.08	725.72		3973.94	**1725.97**
	Missing	1	4	2	3	**10**
Total Bilirubin (mg/dL)	Mean	0.88	1.23	0.73	0.86	**0.97**
	Std	0.38	0.82	0.84	0.44	**0.63**
	Missing	1	2	0	1	**4**
Albumin (g/dL)	Mean	3.28	3.10	3.57	3.40	**3.28**
	Std	0.79	0.51	0.46	0.42	**0.55**
	Missing	0	0	0	1	**1**
Pre-albumin (mg/dL)	Mean	23.10		9.20	12.90	**14.53**
	Std				3.54	**6.32**
	Missing	4	8	2	3	**17**

(Continued)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 8: Laboratories

HOSPX-8888 (n=21)

PRE-IMPLANT LABORATORIES		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Total Cholesterol (mg/dL)	Mean			119.00		**119.00**
	Std					
	Missing	*5*	*8*	*2*	*5*	**20**
Brain Natriuretic Peptide (pg/mL)	Mean	250.00	2824.00	2183.00	1157.00	**1943.43**
	Std		3077.33	892.12		**1646.76**
	Missing	*4*	*6*	*0*	*4*	**14**
Pro Brain Natriuretic Peptide (pg/mL)	Mean	47903.00	35220.50		9472.00	**27457.60**
	Std		5029.65		8860.05	**17953.42**
	Missing	*4*	*6*	*3*	*3*	**16**
White Blood Cell Count (x10^3/uL)	Mean	10.44	9.32	9.46	16.08	**11.21**
	Std	3.44	4.32	5.22	6.92	**5.40**
	Missing	*0*	*0*	*0*	*0*	**0**
Hemoglobin (g/dL)	Mean	10.66	11.99	11.20	10.82	**11.28**
	Std	1.17	1.54	2.75	0.76	**1.52**
	Missing	*0*	*0*	*0*	*0*	**0**
Platelets (x10^3/uL)	Mean	236.60	102.13	365.33	261.80	**209.76**
	Std	141.50	43.51	164.20	171.84	**149.64**
	Missing	*0*	*0*	*0*	*0*	**0**
INR	Mean	2.22	1.30	1.27	1.20	**1.50**
	Std	2.34	0.14	0.06	0.25	**1.16**
	Missing	*0*	*1*	*0*	*0*	**1**

Pedimacs (n=62)

PRE-IMPLANT LABORATORIES		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients	n	18	21	10	13	62
Sodium (mEq/L)	Mean	137.94	141.00	138.00	141.54	**139.74**
	Std	5.84	5.83	3.46	4.65	**5.42**
	Missing	*0*	*0*	*0*	*0*	**0**
Potassium (mEq/L)	Mean	3.94	4.08	3.91	4.06	**4.01**
	Std	0.53	0.95	0.65	0.63	**0.72**
	Missing	*0*	*0*	*0*	*0*	**0**

(Continued)

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 8: Laboratories

Pedimacs (n=62)

PRE-IMPLANT LABORATORIES		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
BUN (mg/dL)	Mean	26.17	27.96	23.66	26.63	**26.46**
	Std	17.88	17.94	11.99	15.17	**16.24**
	Missing	0	0	0	1	**1**
Creatinine (mg/dL)	Mean	0.49	0.58	0.48	0.55	**0.53**
	Std	0.25	0.64	0.21	0.28	**0.42**
	Missing	0	0	0	1	**1**
Alanine Aminotransferase/ALT (u/L)	Mean	144.88	157.22	116.20	114.92	**136.91**
	Std	427.40	362.73	199.16	119.21	**314.06**
	Missing	2	3	0	0	**5**
Aspartate Aminotransferase/AST (u/L)	Mean	208.25	212.67	222.44	284.69	**229.70**
	Std	582.08	521.66	276.44	346.83	**463.50**
	Missing	2	3	1	0	**6**
LDH (ukat/L) , (U/L)	Mean	844.25	880.30	1047.67	2951.00	**1211.36**
	Std	828.91	706.34	499.71	2628.47	**1357.13**
	Missing	6	11	4	8	**29**
Total Bilirubin (mg/dL)	Mean	3.16	1.77	4.09	2.57	**2.73**
	Std	7.03	2.75	8.24	5.47	**5.73**
	Missing	2	4	2	3	**11**
Albumin (g/dL)	Mean	3.27	3.01	3.25	3.19	**3.16**
	Std	0.67	0.48	0.83	0.41	**0.60**
	Missing	0	0	0	2	**2**
Pre-albumin (mg/dL)	Mean	23.10		9.20	14.00	**14.86**
	Std				3.14	**5.52**
	Missing	17	21	9	10	**57**
Total Cholesterol (mg/dL)	Mean	99.50	128.00	119.00		**111.50**
	Std	31.82				**23.30**
	Missing	16	20	9	13	**58**
Brain Natriuretic Peptide (pg/mL)	Mean	731.20	2389.57	1645.71	2511.00	**1852.42**
	Std	897.21	2042.51	1219.84	2234.94	**1718.59**
	Missing	13	14	3	8	**38**

(Continued)

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 8: Laboratories

Pedimacs (n=62)

PRE-IMPLANT LABORATORIES		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Pro Brain Natriuretic Peptide (pg/mL)	Mean	17610.13	35771.80	14334.00	26314.67	**24295.18**
	Std	18227.93	21192.48		29837.50	**20961.85**
	Missing	*10*	*16*	*9*	*10*	**45**
White Blood Cell Count (x10^3/uL)	Mean	12.35	9.60	10.29	14.26	**11.49**
	Std	6.46	3.80	3.53	7.14	**5.62**
	Missing	*0*	*0*	*0*	*0*	**0**
Hemoglobin (g/dL)	Mean	11.81	11.71	11.78	11.36	**11.68**
	Std	2.61	3.18	2.61	2.30	**2.70**
	Missing	*0*	*0*	*0*	*0*	**0**
Platelets (x10^3/uL)	Mean	238.78	181.76	188.70	218.54	**207.15**
	Std	184.02	161.16	156.23	145.95	**162.31**
	Missing	*0*	*0*	*0*	*0*	**0**
INR	Mean	1.59	1.47	1.32	1.32	**1.45**
	Std	1.22	0.39	0.39	0.37	**0.75**
	Missing	*0*	*3*	*0*	*2*	**5**

Section 3 - Patients Recieving only Temporary Devices

Exhibit 8: Laboratories

HOSPX-8888 (n=21)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	5	8	3	5	21
Lupus Anticoagulant					
Negative	0%	0%	0%	0%	0%
Unknown	100%	100%	100%	100%	100%

Pedimacs (n=62)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	18	21	10	13	62
Lupus Anticoagulant					
Negative	5%	0%	0%	0%	1%
Unknown	94%	100%	100%	100%	98%

COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 9: Pre-Implant Concerns

HOSPX-8888 (n=21)

PRE-IMPLANT CONCERNS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
Patients (n)	**5**	**8**	**3**	**5**	**21**
Concern: Patient Does Not Want Transplant	0%	0%	0%	0%	**0%**
Concern: Musculoskeletal Limitation	0%	0%	0%	0%	**0%**
Concern: Contraindications to Immunosuppression	0%	0%	0%	0%	**0%**
Concern: Allosensitization	0%	0%	0%	0%	**0%**
Concern: Frailty	0%	13%	0%	0%	**5%**
Concern: Chronic Renal Disease	0%	0%	0%	0%	**0%**
Concern: Frequent ICD Shocks	0%	0%	0%	0%	**0%**
Concern: Pulmonary Disease	0%	0%	0%	0%	**0%**
Concern: Pulmonary Hypertension	0%	0%	0%	0%	**0%**
Concern: Recent Pulmonary Embolus	0%	0%	0%	0%	**0%**
Concern: History Atrial Arrhythmia	0%	0%	0%	0%	**0%**
Concern: Unfavorable Mediastinal Anatomy	0%	0%	33%	0%	**5%**
Concern: Thoracic Aortic Disease	20%	0%	0%	0%	**5%**
Concern: Tracheotomy	0%	0%	0%	0%	**0%**
Concern: Plastic Bronchitis	0%	0%	0%	0%	**0%**
Concern: Large BMI	0%	0%	33%	0%	**5%**
Concern: Severe Diabetes	0%	0%	0%	0%	**0%**
Concern: Malnutrition/Cachexia	0%	0%	0%	0%	**0%**
Concern: History GI Ulcers	0%	0%	0%	0%	**0%**
Concern: History Hepatitis	0%	0%	0%	0%	**0%**
Concern: Liver Dysfunction	0%	0%	0%	0%	**0%**
Concern: Anasarca	0%	0%	0%	0%	**0%**
Concern: Protein Losing Enteropathy	0%	0%	0%	0%	**0%**
Concern: Genetic Syndrome	0%	0%	0%	0%	**0%**
Concern: Heparin Induced Thrombosis	0%	0%	0%	0%	**0%**
Concern: Chronic Coagulopathy		0%			**0%**
Concern: Major Stroke	0%	13%	0%	0%	**5%**
Concern: Other Cerebrovascular Disease	0%	0%	0%	0%	**0%**
Concern: Peripheral Vascular Disease	0%	0%	0%	0%	**0%**
Concern: History Solid Organ Cancer	0%	0%	0%	0%	**0%**
Concern: History Lymphoma Leukemia	0%	0%	0%	0%	**0%**
Concern: History Bone Marrow Transplant	0%	0%	0%	0%	**0%**

(Continued)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 9: Pre-Implant Concerns

HOSPX-8888 (n=21)

PRE-IMPLANT CONCERNS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
Concern: History HIV	0%	0%	0%	0%	**0%**
Concern: Chronic Infectious Concerns	0%	0%	0%	0%	**0%**
Concern: Limited Cognitive Understanding	0%	0%	0%	0%	**0%**
Concern: Limited Social Support	0%	0%	33%	0%	**5%**
Concern: Repeated Non Compliance	0%	0%	33%	0%	**5%**
Concern: History Drug Use	0%	0%	0%	0%	**0%**
Concern: History Alcohol Abuse	0%	0%	0%	0%	**0%**
Concern: Narcotic Dependence	0%	0%	0%	0%	**0%**
Concern: History Smoking	0%	0%	0%	0%	**0%**
Concern: Currently Smoking	0%	0%	0%	0%	**0%**
Concern: Severe Depression	0%	0%	0%	0%	**0%**
Concern: Other Major Psychological Diagnosis	0%	0%	0%	0%	**0%**
Concern: Neuro Abnormal	0%	0%	0%	0%	**0%**
Concern: Other Co-Morbidity	0%	0%	0%	0%	**0%**

Pedimacs (n=62)

PRE-IMPLANT CONCERNS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
Patients (n)	**18**	**21**	**10**	**13**	**62**
Concern: Patient Does Not Want Transplant	0%	0%	0%	0%	**0%**
Concern: Musculoskeletal Limitation	0%	0%	0%	0%	**0%**
Concern: Contraindications to Immunosuppression	0%	0%	0%	0%	**0%**
Concern: Allosensitization	0%	0%	0%	0%	**0%**
Concern: Frailty	0%	10%	0%	8%	**5%**
Concern: Chronic Renal Disease	0%	0%	0%	8%	**2%**
Concern: Frequent ICD Shocks	0%	0%	0%	0%	**0%**
Concern: Pulmonary Disease	6%	5%	10%	0%	**5%**
Concern: Pulmonary Hypertension	0%	0%	10%	0%	**2%**
Concern: Recent Pulmonary Embolus	0%	0%	0%	0%	**0%**
Concern: History Atrial Arrhythmia	0%	0%	0%	8%	**2%**
Concern: Unfavorable Mediastinal Anatomy	17%	5%	20%	0%	**10%**
Concern: Thoracic Aortic Disease	6%	0%	0%	0%	**2%**
Concern: Tracheotomy	0%	0%	0%	0%	**0%**
Concern: Plastic Bronchitis	0%	0%	0%	0%	**0%**

(Continued)

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 9: Pre-Implant Concerns

Pedimacs (n=62)

PRE-IMPLANT CONCERNS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
Concern: Large BMI	0%	5%	10%	0%	3%
Concern: Severe Diabetes	0%	0%	0%	0%	0%
Concern: Malnutrition/Cachexia	0%	0%	0%	0%	0%
Concern: History GI Ulcers	0%	0%	0%	0%	0%
Concern: History Hepatitis	0%	0%	0%	0%	0%
Concern: Liver Dysfunction	0%	5%	0%	0%	2%
Concern: Anasarca	0%	0%	0%	0%	0%
Concern: Protein Losing Enteropathy	0%	0%	0%	0%	0%
Concern: Genetic Syndrome	6%	5%	0%	0%	3%
Concern: Heparin Induced Thrombosis	0%	0%	0%	0%	0%
Concern: Chronic Coagulopathy	33%	0%	0%	0%	9%
Concern: Major Stroke	17%	10%	0%	0%	8%
Concern: Other Cerebrovascular Disease	0%	5%	0%	0%	2%
Concern: Peripheral Vascular Disease	0%	0%	0%	0%	0%
Concern: History Solid Organ Cancer	0%	0%	0%	0%	0%
Concern: History Lymphoma Leukemia	0%	0%	0%	0%	0%
Concern: History Bone Marrow Transplant	0%	0%	0%	0%	0%
Concern: History HIV	0%	0%	0%	0%	0%
Concern: Chronic Infectious Concerns	0%	0%	0%	0%	0%
Concern: Limited Cognitive Understanding	6%	0%	0%	8%	3%
Concern: Limited Social Support	0%	5%	10%	0%	3%
Concern: Repeated Non Compliance	0%	0%	10%	0%	2%
Concern: History Drug Use	0%	0%	0%	0%	0%
Concern: History Alcohol Abuse	0%	0%	0%	0%	0%
Concern: Narcotic Dependence	0%	0%	0%	0%	0%
Concern: History Smoking	0%	0%	0%	0%	0%
Concern: Currently Smoking	0%	0%	0%	0%	0%
Concern: Severe Depression	0%	0%	0%	0%	0%
Concern: Other Major Psychological Diagnosis	6%	0%	0%	0%	2%
Concern: Neuro Abnormal	6%	5%	0%	0%	3%
Concern: Other Co-Morbidity	6%	0%	0%	0%	2%

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

<div align="center">*Exhibit 10: General Hemodynamics*</div>

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

HOSPX-8888 (n=21)

PRE-IMPLANT GENERAL HEMODYNAMICS		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients	n	5	8	3	5	21
Heart Rate	Mean		130.67		125.67	128.17
	Std		4.04		20.50	13.50
	Missing	5	5	3	2	15

Pedimacs (n=62)

PRE-IMPLANT GENERAL HEMODYNAMICS		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients	n	18	21	10	13	62
Heart Rate	Mean	111.20	132.22	135.67	148.60	131.64
	Std	18.25	12.00	42.62	34.59	26.26
	Missing	13	12	7	8	40

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=21)

		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients	n	5	8	3	5	21
LVEDD	Mean	4.19	4.49	4.27		4.36
	Std	2.21	2.68	0.70		2.06
	Missing	2	2	0	5	9

Pedimacs (n=62)

		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients	n	18	21	10	13	62
LVEDD	Mean	3.92	3.89	5.14	4.89	4.32
	Std	1.60	2.35	1.35	0.96	1.83
	Missing	13	12	5	10	40

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

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

HOSPX-8888 (n=21)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	5	8	3	5	21
RVEF					
Normal	20%	25%	0%	20%	**19%**
Mild	0%	12%	33%	20%	**14%**
Moderate	20%	12%	66%	0%	**19%**
Severe	0%	12%	0%	20%	**9%**
Not Done	20%	12%	0%	0%	**9%**
Not Applicable	20%	25%	0%	0%	**14%**
Unknown	20%	0%	0%	40%	**14%**
Aortic Regurgitation					
0 (none)	60%	50%	66%	20%	**47%**
1 (mild)	0%	37%	0%	80%	**33%**
2 (moderate)	0%	0%	0%	0%	**0%**
3 (severe)	20%	0%	0%	0%	**4%**
Not Recorded or Not Documented	20%	12%	33%	0%	**14%**

Pedimacs (n=62)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	18	21	10	13	62
RVEF					
Normal	11%	19%	20%	15%	**16%**
Mild	5%	9%	20%	7%	**9%**
Moderate	11%	14%	30%	7%	**14%**
Severe	16%	23%	10%	15%	**17%**
Not Done	33%	14%	0%	15%	**17%**
Not Applicable	16%	14%	0%	0%	**9%**
Unknown	5%	4%	20%	38%	**14%**
Aortic Regurgitation					
0 (none)	61%	42%	40%	15%	**41%**
1 (mild)	11%	33%	20%	69%	**32%**
2 (moderate)	0%	4%	0%	0%	**1%**
3 (severe)	5%	0%	0%	0%	**1%**
Not Recorded or Not Documented	22%	19%	40%	15%	**22%**

SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 12: Swan Hemodynamics

HOSPX-8888 (n=21)

SWAN HEMODYNAMICS		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients	**n**	**5**	**8**	**3**	**5**	**21**
Pulmonary Artery Systolic Pressure (mmHg)	**Mean**	21.00	19.00	39.00		**24.50**
	Std		4.24			**10.02**
	Missing	*4*	*6*	*2*	*5*	**17**
Pulmonary Artery Diastolic Pressure (mmHg)	**Mean**	11.00	14.00	20.00		**14.75**
	Std		4.24			**4.50**
	Missing	*4*	*6*	*2*	*5*	**17**
Mean RA Pressure (mmHg)	**Mean**	10.00	7.75	13.00		**9.00**
	Std		2.99			**3.16**
	Missing	*4*	*4*	*2*	*5*	**15**
Pulmonary Artery Wedge Pressure (mmHg)	**Mean**	10.00	14.50	22.00		**15.25**
	Std		0.71			**4.99**
	Missing	*4*	*6*	*2*	*5*	**17**
Cardiac Index	**Mean**		4.35			**4.35**
	Std		0.70			**0.70**
	Missing	*5*	*6*	*3*	*5*	**19**

Pedimacs (n=62)

SWAN HEMODYNAMICS		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients	**n**	**18**	**21**	**10**	**13**	**62**
Pulmonary Artery Systolic Pressure (mmHg)	**Mean**	20.20	34.83	23.33		**27.14**
	Std	4.66	32.66	13.80		**22.26**
	Missing	*13*	*15*	*7*	*13*	**48**
Pulmonary Artery Diastolic Pressure (mmHg)	**Mean**	13.75	23.00	16.67		**18.69**
	Std	2.63	13.31	4.16		**9.84**
	Missing	*14*	*15*	*7*	*13*	**49**
Mean RA Pressure (mmHg)	**Mean**	9.50	8.75	13.75	7.00	**9.95**
	Std	2.43	2.96	5.38		**3.78**
	Missing	*12*	*13*	*6*	*12*	**43**
Pulmonary Artery Wedge Pressure (mmHg)	**Mean**	11.50	15.25	17.00		**14.10**
	Std	3.87	4.19	7.07		**4.68**
	Missing	*14*	*17*	*8*	*13*	**52**

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STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 12: Swan Hemodynamics

Pedimacs (n=62)

SWAN HEMODYNAMICS		2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Cardiac Index	**Mean**	3.15	4.13	2.18		**3.48**
	Std	0.49	1.69	0.11		**1.40**
	Missing	*14*	*15*	*8*	*13*	**50**

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
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SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 13: ECG Cardiac Rhythm

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

HOSPX-8888 (n=21)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	**5**	**8**	**3**	**5**	**21**
ECG Rhythm					
Sinus	40%	62%	66%	100%	**66%**
Atrial fibrillation	0%	0%	0%	0%	**0%**
Not done	20%	0%	0%	0%	**4%**
Paced: Ventricular pacing	0%	0%	0%	0%	**0%**
Paced: Atrial and ventricular pacing	0%	12%	0%	0%	**4%**
Unknown	20%	0%	0%	0%	**4%**
Other, specify	20%	25%	33%	0%	**19%**

Pedimacs (n=62)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	**18**	**21**	**10**	**13**	**62**
ECG Rhythm					
Sinus	66%	71%	60%	76%	**69%**
Atrial fibrillation	0%	0%	10%	0%	**1%**
Not done	5%	0%	0%	7%	**3%**
Paced: Ventricular pacing	0%	4%	0%	0%	**1%**
Paced: Atrial and ventricular pacing	0%	4%	0%	7%	**3%**
Unknown	5%	4%	0%	0%	**3%**
Other, specify	22%	14%	30%	7%	**17%**

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving 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=21)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	5	8	3	5	21
VAD Indication					
Failure to wean from CPB	0%	0%	0%	0%	**0%**
Post Cardiac Surgery	0%	0%	0%	20%	**4%**
None	60%	25%	100%	80%	**57%**
Failure to Wean from ECMO	40%	75%	0%	0%	**38%**

Pedimacs (n=62)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	18	21	10	13	62
VAD Indication					
Failure to wean from CPB	0%	0%	10%	0%	**1%**
Post Cardiac Surgery	22%	0%	0%	7%	**8%**
None	55%	47%	70%	69%	**58%**
Failure to Wean from ECMO	22%	52%	20%	23%	**32%**

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
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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=21)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	5	8	3	5	21
Device Type					
LVAD	80%	100%	66%	80%	85%
RVAD	20%	0%	0%	0%	4%
BiVAD	0%	0%	33%	20%	9%

Pedimacs (n=62)

	2019 Q2	2019 Q3	2019 Q4	2020 Q1	TOTAL
Patients (n)	18	21	10	13	62
Device Type					
LVAD	72%	90%	70%	84%	80%
RVAD	22%	9%	20%	0%	12%
BiVAD	5%	0%	10%	15%	6%

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
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SITE: Hospital X - (Random 50 Patients)

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Section 3 - Patients Recieving only Temporary Devices

Exhibit 16: Previous Cardiac Operations

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

HOSPX-8888 (n=21)

PREVIOUS CARDIAC OPERATIONS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
Patients (n)	5	8	3	5	21
None	40%	50%	67%	20%	43%
CABG	0%	0%	0%	0%	0%
Aneuryomectomy (DOR)	0%	0%	0%	0%	0%
Aortic Valve replacement / repair	0%	0%	0%	0%	0%
Mitral Valve replacement / repair	0%	0%	0%	0%	0%
Triscuspid replacement /repair	0%	0%	0%	0%	0%
Congenital card surgery	20%	38%	33%	40%	33%
LVAD	20%	0%	0%	20%	10%
RVAD	20%	0%	0%	0%	5%
TAH	0%	0%	0%	0%	0%
Previous heart transplant	20%	0%	33%	0%	10%
Previous ECMO	40%	25%	0%	40%	29%
Other, specify	20%	13%	0%	0%	10%

Pedimacs (n=62)

PREVIOUS CARDIAC OPERATIONS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
Patients (n)	18	21	10	13	62
None	33%	38%	50%	38%	39%
CABG	0%	0%	0%	0%	0%
Aneuryomectomy (DOR)	0%	0%	0%	0%	0%
Aortic Valve replacement / repair	0%	0%	0%	0%	0%
Mitral Valve replacement / repair	0%	5%	0%	0%	2%
Triscuspid replacement /repair	6%	0%	0%	0%	2%
Congenital card surgery	28%	48%	30%	23%	34%
LVAD	6%	0%	0%	15%	5%
RVAD	6%	0%	0%	0%	2%
TAH	0%	0%	0%	0%	0%
Previous heart transplant	6%	0%	10%	0%	3%

(Continued)

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
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SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 16: Previous Cardiac Operations

Pedimacs (n=62)

PREVIOUS CARDIAC OPERATIONS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
Previous ECMO	33%	10%	20%	38%	**24%**
Other, specify	22%	19%	20%	15%	**19%**

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving 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=21)

IMPLANT HOSPITALIZATION EVENTS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
Patients (n)	5	8	3	5	21
None	20%	0%	33%	0%	10%
CABG	0%	0%	0%	0%	0%
Aortic Valve replacement / repair	0%	0%	0%	0%	0%
Mitral Valve replacement / repair	0%	0%	0%	0%	0%
Congenital cardiac surgery	0%	25%	0%	0%	10%
Other surgical procedures	40%	13%	0%	20%	19%
IABP	0%	0%	0%	0%	0%
ECMO	20%	75%	0%	80%	52%
LVAD	20%	0%	0%	20%	10%
RVAD	20%	0%	0%	0%	5%
TAH	0%	0%	0%	0%	0%
Dialysis	0%	0%	0%	20%	5%
Ultrafiltration	20%	13%	0%	0%	10%
Feeding Tube	0%	50%	0%	60%	33%
Intubation	60%	75%	67%	80%	71%
Major MI	0%	0%	0%	20%	5%
Major infections / Positive blood cultures	20%	13%	0%	20%	14%
Escalation to CPAP	20%	0%	0%	0%	5%
Arrhythmia	20%	38%	0%	20%	24%
Previous ECMO	40%	13%	0%	0%	14%
Previous heart transplant	20%	0%	0%	0%	5%
Treatment of Rejection	0%	0%	33%	0%	5%
Peritoneal Drain	0%	0%	0%	0%	0%
Non-cardiac procedure	0%	25%	0%	0%	10%

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

Section 3 - Patients Recieving only Temporary Devices

Exhibit 17: Clinical Events and Interventions during Implant Hospitalization
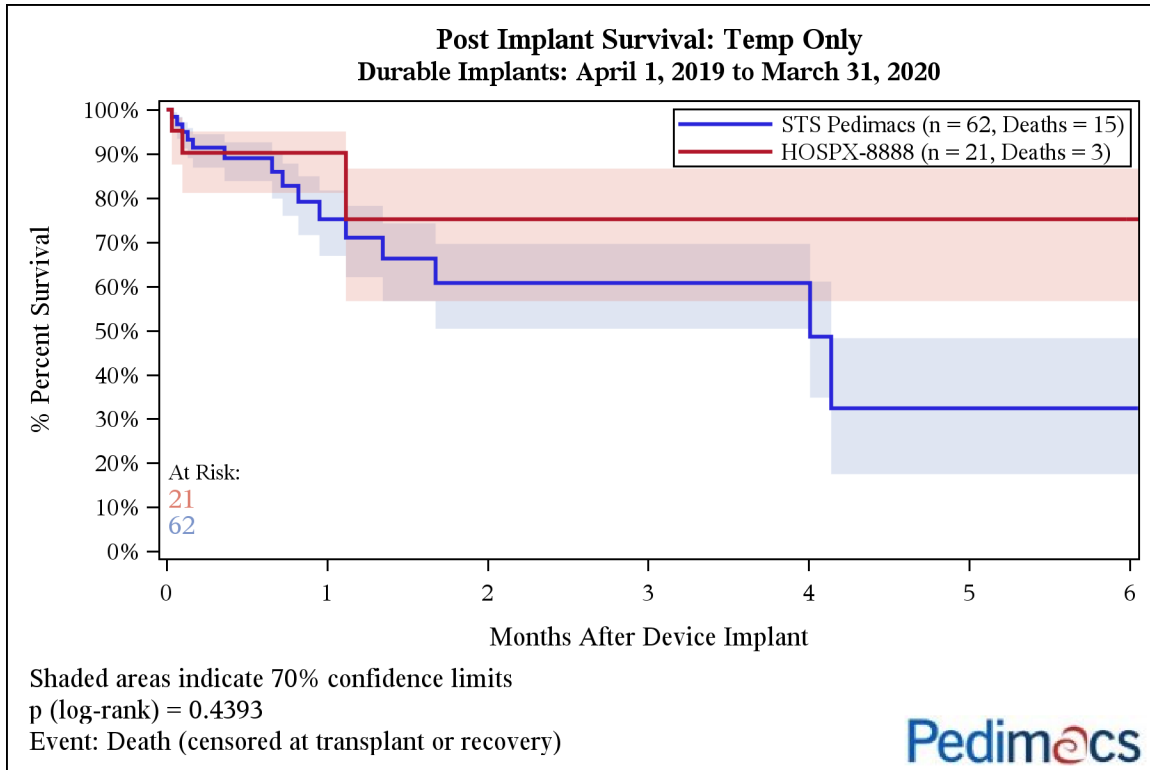
Pedimacs (n=62)

IMPLANT HOSPITALIZATION EVENTS	2019 Q2	2019 Q3	2019 Q4	2020 Q1	Total
Patients (n)	18	21	10	13	62
None	11%	0%	20%	0%	6%
CABG	0%	0%	0%	0%	0%
Aortic Valve replacement / repair	0%	0%	0%	0%	0%
Mitral Valve replacement / repair	0%	5%	0%	0%	2%
Congenital cardiac surgery	6%	24%	0%	15%	13%
Other surgical procedures	17%	5%	10%	8%	10%
IABP	0%	0%	0%	0%	0%
ECMO	33%	52%	40%	77%	50%
LVAD	6%	0%	0%	15%	5%
RVAD	6%	0%	0%	0%	2%
TAH	0%	0%	0%	0%	0%
Dialysis	6%	5%	0%	23%	8%
Ultrafiltration	11%	5%	0%	15%	8%
Feeding Tube	6%	38%	10%	62%	29%
Intubation	72%	86%	70%	77%	77%
Major MI	0%	0%	10%	8%	3%
Major infections / Positive blood cultures	11%	19%	10%	15%	15%
Escalation to CPAP	6%	14%	0%	0%	6%
Arrhythmia	22%	29%	20%	31%	26%
Previous ECMO	17%	5%	0%	0%	6%
Previous heart transplant	6%	0%	0%	0%	2%
Treatment of Rejection	0%	0%	10%	0%	2%
Peritoneal Drain	0%	0%	0%	0%	0%
Non-cardiac procedure	6%	10%	0%	8%	6%

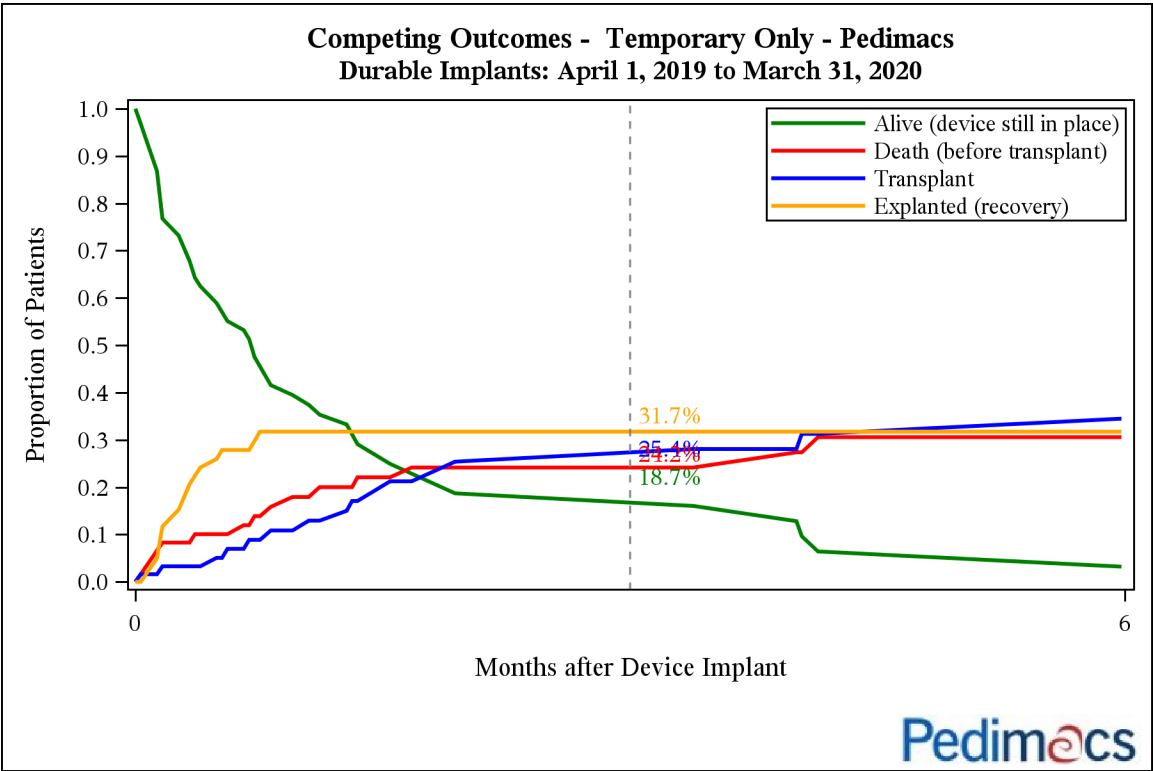*STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)*
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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Section 3 - Patients Recieving only Temporary Devices

Exhibit 18: Post Implant Survival - Temp Only

Post Implant Survival: Temp Only
Durable Implants: April 1, 2019 to March 31, 2020

STS Pedimacs (n = 62, Deaths = 15)
HOSPX-8888 (n = 21, Deaths = 3)

% Percent Survival

At Risk:
21
62

Months After Device Implant

Shaded areas indicate 70% confidence limits
p (log-rank) = 0.4393
Event: Death (censored at transplant or recovery)

Percent Survival [% (70% CI)]

Months after Device Implant	STS Pedimacs	HOSPX-8888
1	75.2% (66.9%-81.7%)	90.2% (81.2%-95.1%)
3	60.8% (50.4%-69.6%)	75.2% (56.7%-86.7%)
6	32.4% (17.5%-48.3%)	

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
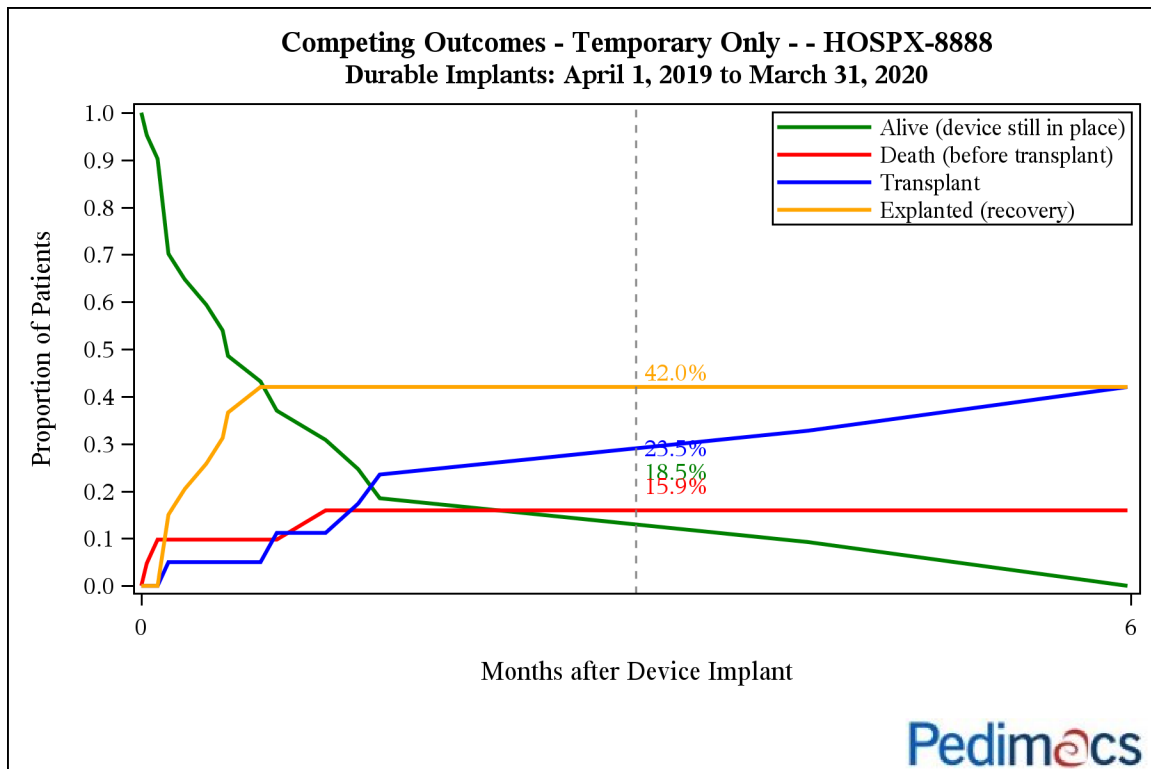*COVERAGE: April 1, 2019 - March 31, 2020*
SITE: Hospital X - (Random 50 Patients)

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
62

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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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.

Competing Outcomes - Temporary Only - - HOSPX-8888
Durable Implants: April 1, 2019 to March 31, 2020

Legend:
- Alive (device still in place)
- Death (before transplant)
- Transplant
- Explanted (recovery)

42.0%
23.5%
18.5%
15.9%

Proportion of Patients — Months after Device Implant

Number of Patients at Risk

Month
0
21

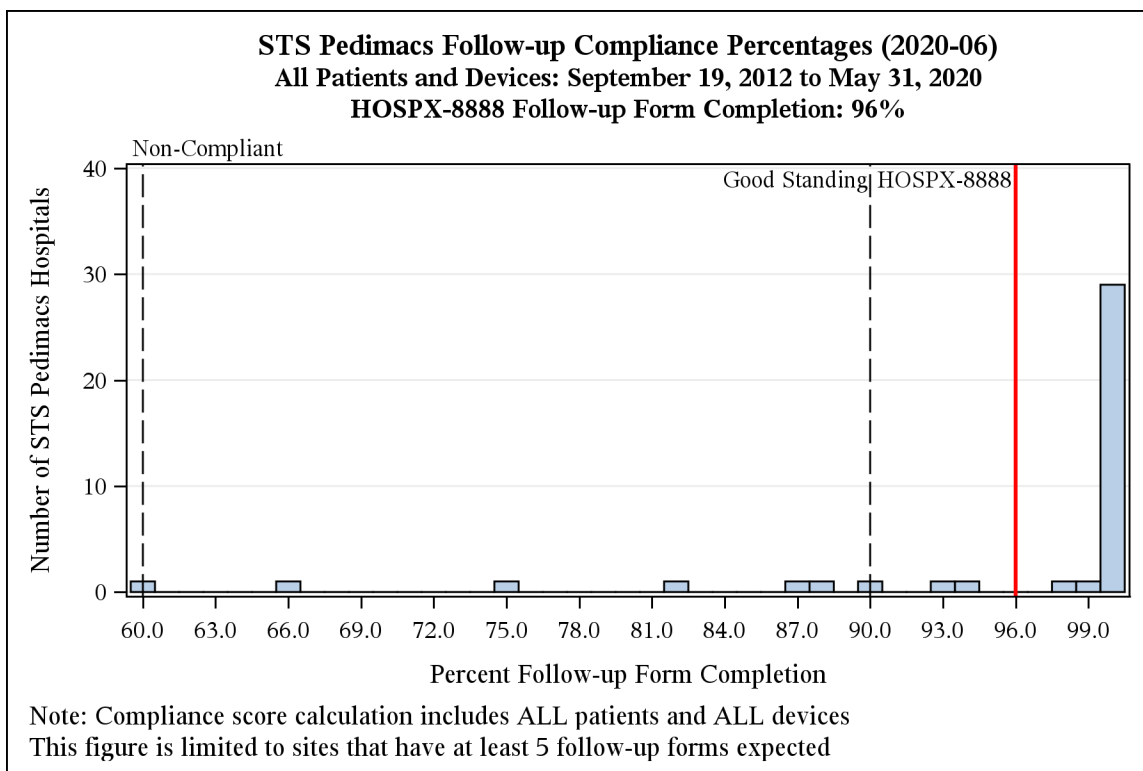*STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)*
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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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.

STS Pedimacs Follow-up Compliance Percentages (2020-06)
All Patients and Devices: September 19, 2012 to May 31, 2020
HOSPX-8888 Follow-up Form Completion: 96%

Note: Compliance score calculation includes ALL patients and ALL devices
This figure is limited to sites that have at least 5 follow-up forms expected

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - 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.

No patients were identified by this check.

STS PEDIMACS QUALITY ASSURANCE QUARTERLY REPORT (2020 Q1)
COVERAGE: April 1, 2019 - March 31, 2020
SITE: Hospital X - (Random 50 Patients)

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