Patients and device selection for Left Ventricular Assist Device

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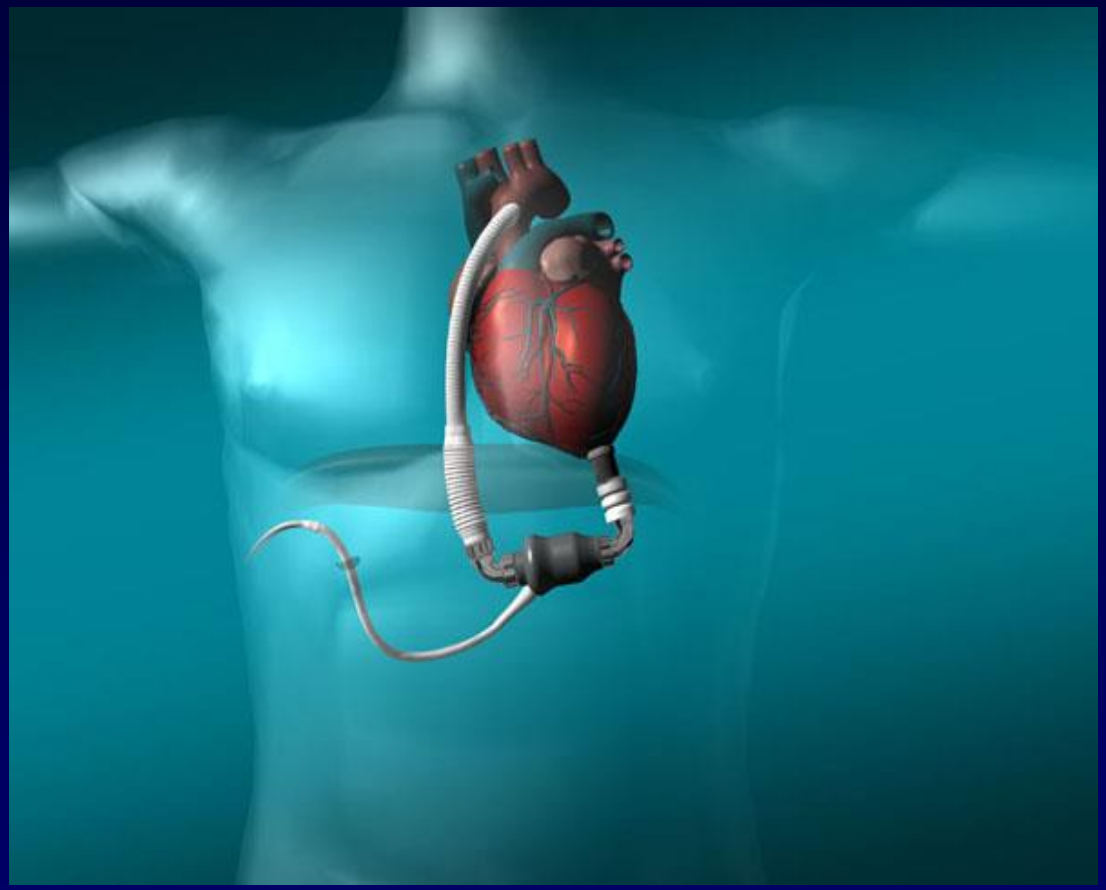
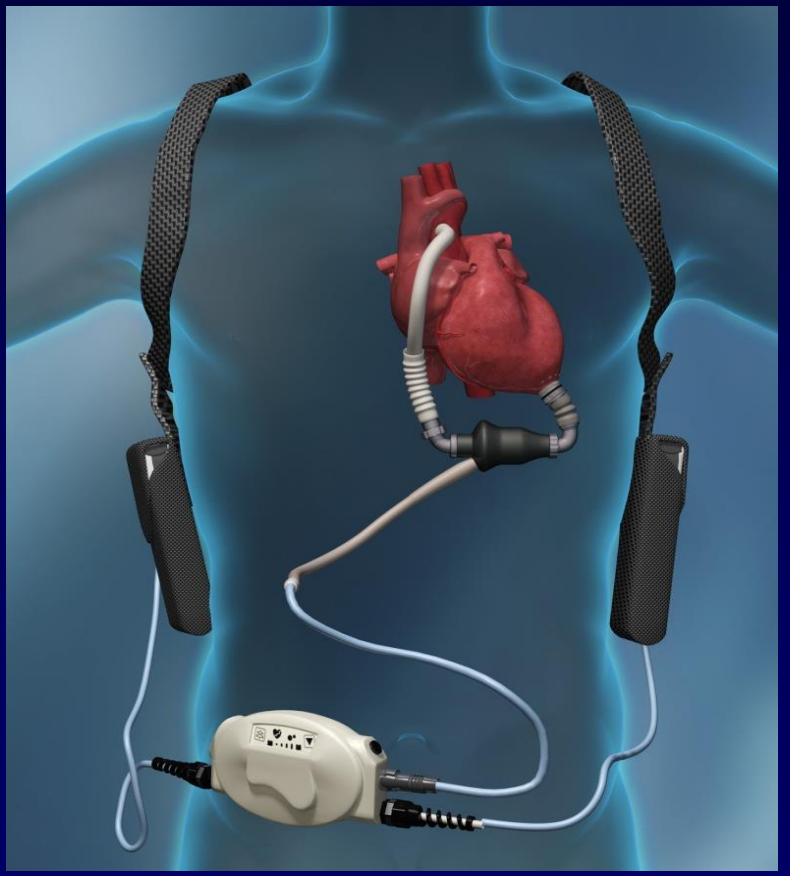
INDICATIONS FOR MECHANICAL CIRCULATORY SUPPORT

1. Bridge to transplantation
2. Bridge to recovery
3. Destination therapy

- ✓ **Short term devices**
- ✓ **Long term devices**

HeartMate II LVAD






Newport Bay Regatta
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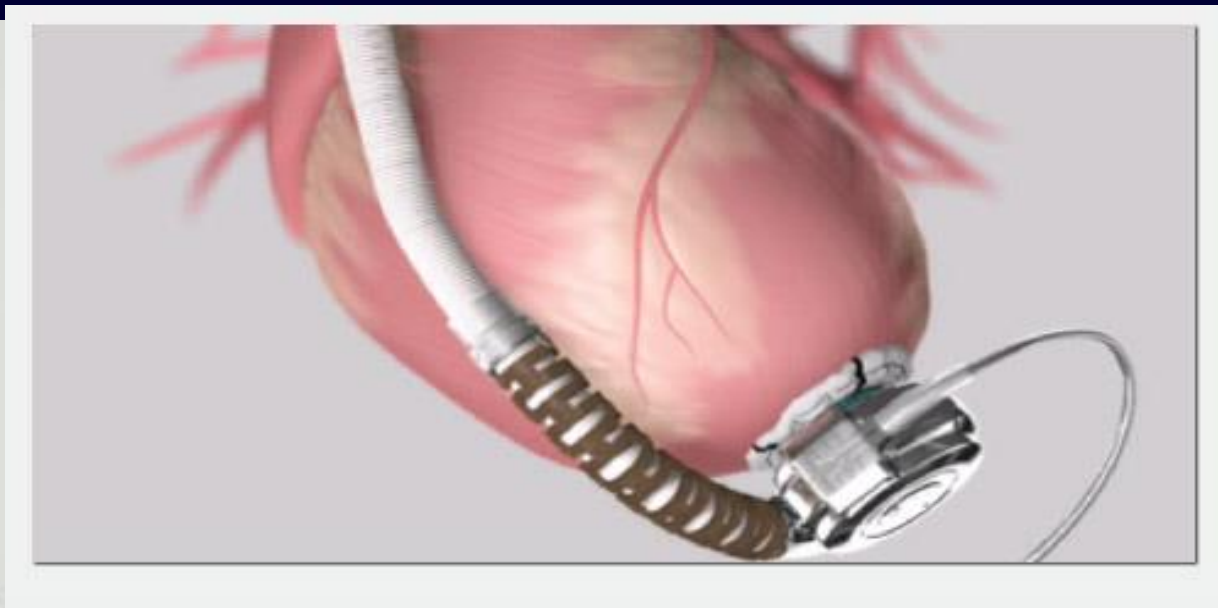
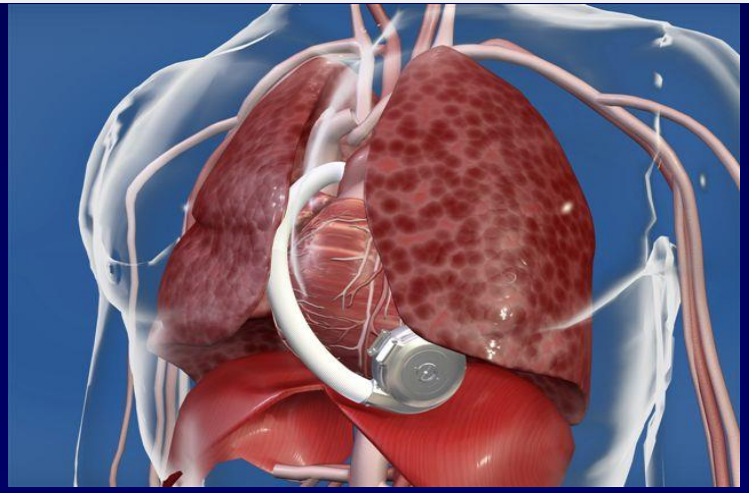
ASSOCIATION

HeartWare LVAD





ELSEVIER

The Journal of Heart and Lung Transplantation
http://www.jhltonline.org

The 2013 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support: Executive Summary

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J Heart Lung Transplant 2013;32:157–187

Recommendation for risk stratification for consideration of MCS

Class IIa:

1. Long-term MCS for patients who are in acute cardiogenic shock should be reserved for the following:
   a. Patients whose ventricular function is deemed unrecoverable or unlikely to recover without long-term device support.

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1. Long-term MCS for patients who are in acute cardiogenic shock should be reserved for the following:
   a. Patients whose ventricular function is deemed unrecoverable or unlikely to recover without long-term device support.
   b. Patients who are deemed too ill to maintain normal hemodynamics and vital organ function with temporary MCSDs, or who cannot be weaned from temporary MCSDs or inotropic support.

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   c. Patients with the capacity for meaningful recovery of end-organ function and quality of life.

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   b. Patients who are deemed too ill to maintain normal hemodynamics and vital organ function with temporary MCSDs, or who cannot be weaned from temporary MCSDs or inotropic support.
   c. Patients with the capacity for meaningful recovery of end-organ function and quality of life.
   d. Patients without irreversible end-organ damage.

Level of evidence: C.

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Recommendation for risk stratification for consideration of MCS

Class IIa:

2. Patients who are inotrope-dependent should be considered for MCS because they represent a group with high mortality with ongoing medical management.

Level of evidence: B.

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2. Patients who are inotrope-dependent should be considered for MCS because they represent a group with high mortality with ongoing medical management.

Level of evidence: B.

3. Patients with end-stage systolic heart failure who do not fall into recommendations 1 and 2 above should undergo routine risk stratification at regular intervals to determine the need for and optimal timing of MCS. This determination may be aided by risk assessment calculators and cardiopulmonary stress testing.

Level of evidence: C.

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Recommendations for management of patients with decompensated heart failure

Class I:

1. Short-term mechanical support, including extracorporeal membrane oxygenation, should be used in acutely decompensated patients who are failing maximal medical therapy.

Level of evidence: C.

Class I:

1. The use of temporary mechanical support should be strongly considered in patients with multiorgan failure, sepsis, or on mechanical ventilation to allow successful optimization of clinical status and neurologic assessment prior to placement of a long-term MCSD.

Level of evidence: C.

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INTERMACS

Interagency Registry for Mechanically Assisted Circulatory Support

Quarterly Statistical Report
2012 4th Quarter

Implant dates: June 23, 2006 – December 31, 2012

Prepared by:

The Data Collection and Analysis Center
University of Alabama at Birmingham

Exhibit 6: Patient Profile at Time of Implant by Implant Period

Patient profile status provides a general clinical description of the patients at the time of implantation.

PATIENT PROFILE AT TIME OF IMPLANT	IMPLANT DATE PERIOD						TOTAL	
	< 2010		2010-2011		2012			
	n	%	n	%	n	%	n	%
1 Critical Cardio Shock	652	29.2 %	535	14.8 %	321	15.3 %	1508	19.0 %
2 Progressive Decline	953	42.7 %	1425	39.6 %	788	37.6 %	3166	40.0 %
3 Stable but Inotrope dependent	333	14.9 %	952	26.4 %	596	28.4 %	1881	23.7 %
4 Resting Symptoms	201	9.0 %	480	13.3 %	284	13.5 %	965	12.1 %
5 Exertion intolerant	42	1.8 %	112	3.1 %	63	3.0 %	217	2.7 %
6 Exertion limited	25	1.1 %	65	1.8 %	26	1.2 %	116	1.4 %
7 Advanced NYHA Class 3	21	0.9 %	25	0.6 %	15	0.7 %	61	0.7 %
TOTAL	2227	100.0 %	3594	100.0 %	2093	100.0 %	7914	100.0 %

Recommendations for patients with acute myocardial infarction

Class IIb:

1. If possible, permanent MCS should be delayed in the setting of an acute infarct involving the left ventricular (LV) apex.

Level of evidence: C.

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Recommendations for aortic valve disease

Class I:

1. Functioning bioprosthetic valves do not require removal or replacement at the time of implant.

Level of evidence: C.

2. Replacement of a pre-existing aortic mechanical valve with a bioprosthetic valve or oversewing the aortic valve at the time of implantation is recommended.

Level of evidence: C.

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Recommendations for aortic valve disease

Recommendations for aortic regurgitation:

Class I:

1. More than mild aortic insufficiency should prompt consideration for surgical intervention during device implantation.

Level of evidence: C

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Recommendations for aortic valve disease

Recommendations for aortic stenosis:

Class I:

1. Patients with aortic stenosis of any degree that is accompanied by more than mild aortic insufficiency should prompt consideration for a bioprosthetic aortic valve replacement during MCS implant.

Level of evidence: C.

Class IIb:

1. Patients with severe aortic stenosis may be considered for aortic valve replacement, regardless of the degree of concomitant aortic insufficiency.

Level of evidence: C.

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Recommendations for mitral valve

Class IIb:

1. Severe mitral insufficiency is not a contraindication to MCS and does not routinely require surgical repair or valve replacement, unless there is expectation of ventricular recovery.

Level of evidence: C.

Class III:

1. Routine mitral valve repair or replacement for severe mitral regurgitation is not recommended.

Level of evidence: C.

Recommendations for tricuspid valve regurgitation

Class IIa:

1. Moderate or greater tricuspid regurgitation should prompt consideration of surgical repair at the time of implant.

Level of evidence: C.

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Recommendations for arrhythmia therapy

Class IIa:

1. Patients with treatment-refractory recurrent sustained ventricular tachycardia (VT) or ventricular fibrillation (VF) in the presence of untreatable arrhythmogenic pathologic substrate (eg, giant cell myocarditis, scar, sarcoidosis), should not be considered for LV support alone, but rather biventricular support or a total artificial heart.

Level of evidence: C.

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Recommendations for psychologic and psychiatric evaluation

Class III:

1. MCS should not be performed in patients who are unable to physically operate their pump or respond to device alarms. In addition, an inability to report signs and symptoms of device malfunction or other health care needs to the MCS team, or patients who live in an unsafe environment are all contraindications to implantation.

Level of evidence: C.

2. MCS is not recommended in patients with active psychiatric illness that requires long-term institutionalization or who have the inability to care for or maintain their device.

Level of evidence: C.

Recommendations for management of RV dysfunction

Class I:

1. Pre-operatively, patients with evidence of RV dysfunction should be admitted to the hospital for aggressive management, which may include diuresis, ultrafiltration, inotropes, intra-aortic balloon pump, or other short-term mechanical support. Once optimized, RV function should be reassessed.

Level of evidence: C.

2. RV dysfunction post-MCS should be managed with diuresis, inotropes, and pulmonary vasodilators, including nitric oxide or inhaled prostacyclin. RV dysfunction refractory to medical management may require placement of a short-term or long-term mechanical RV support device.

Level of evidence: C.

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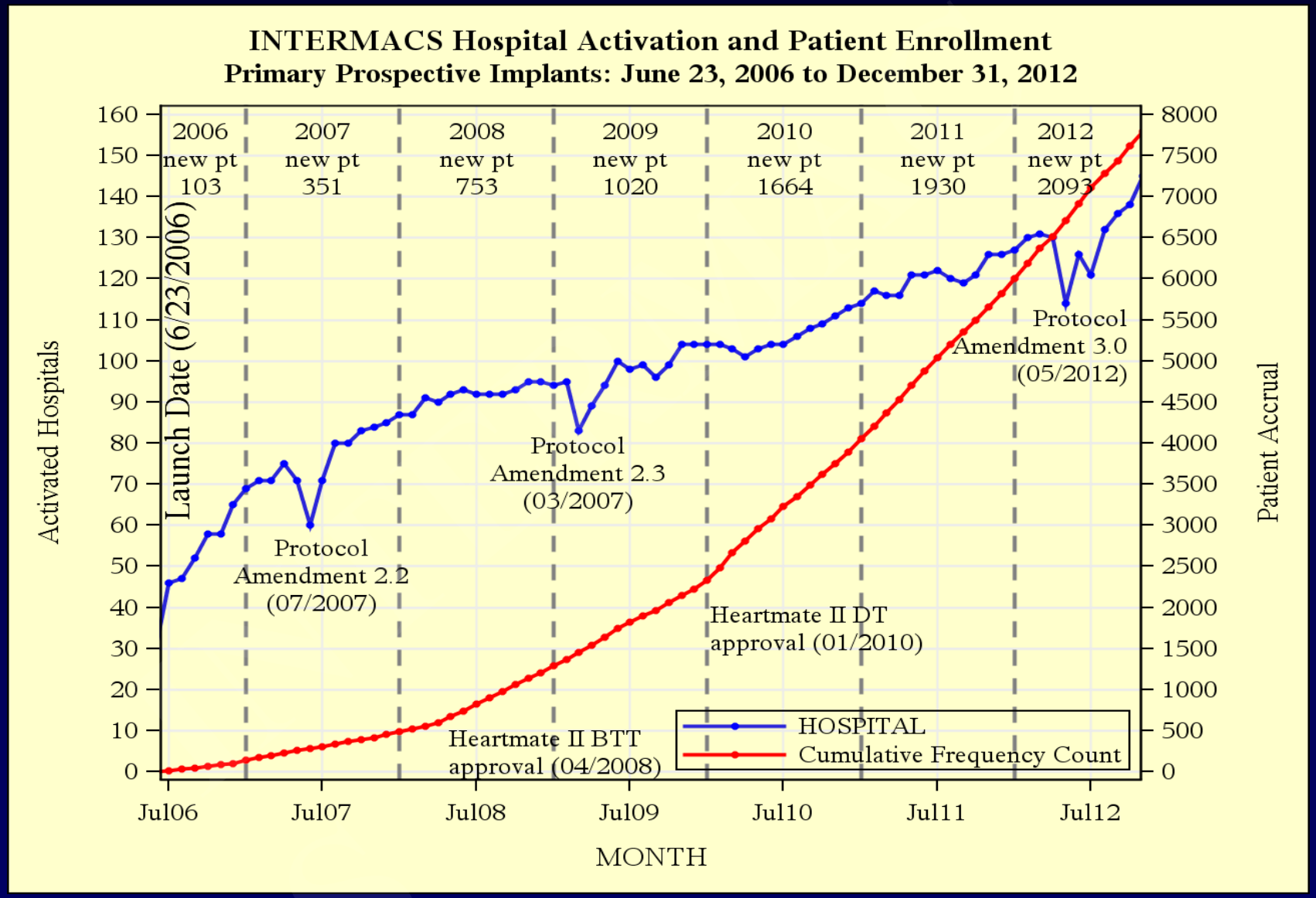
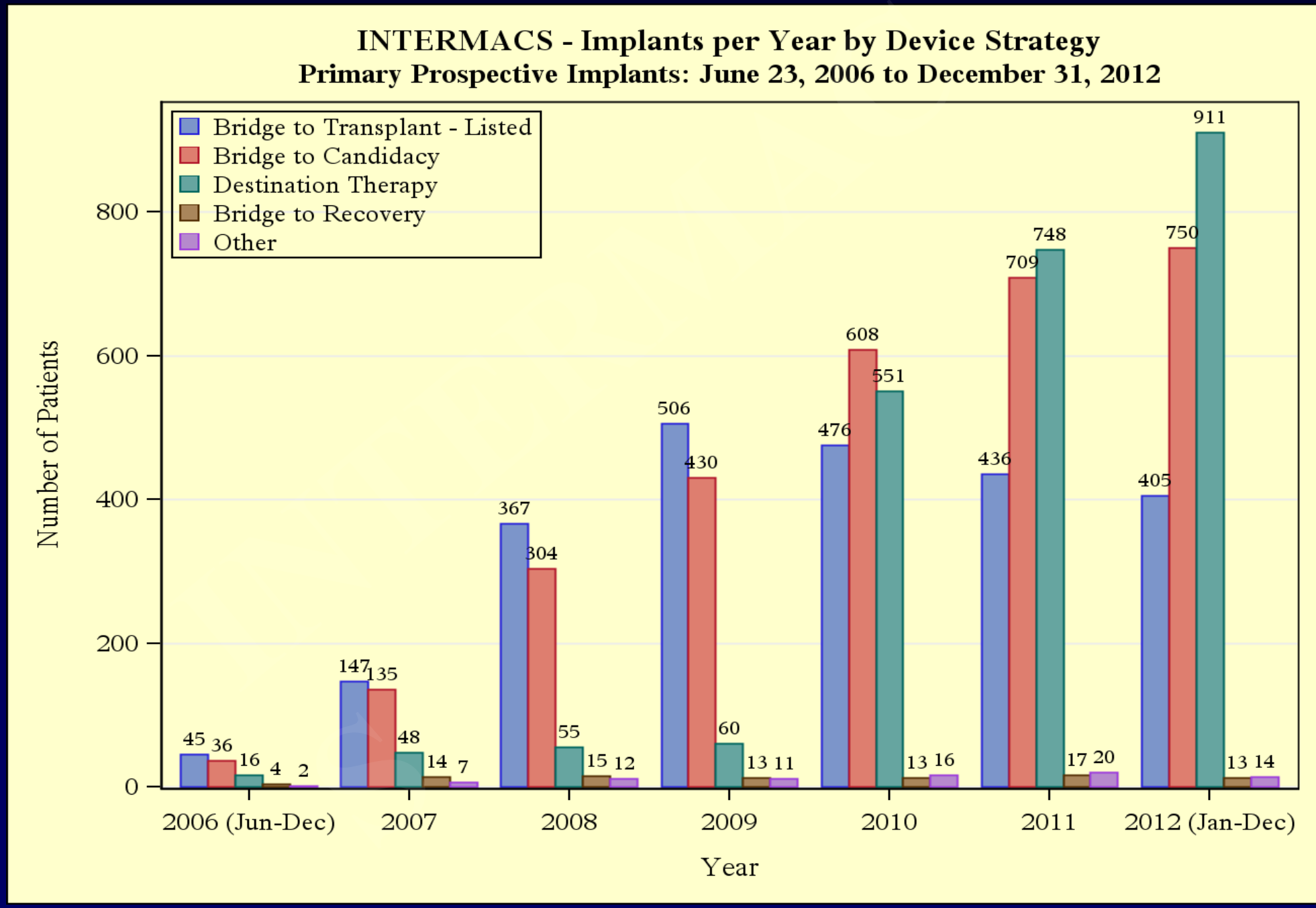
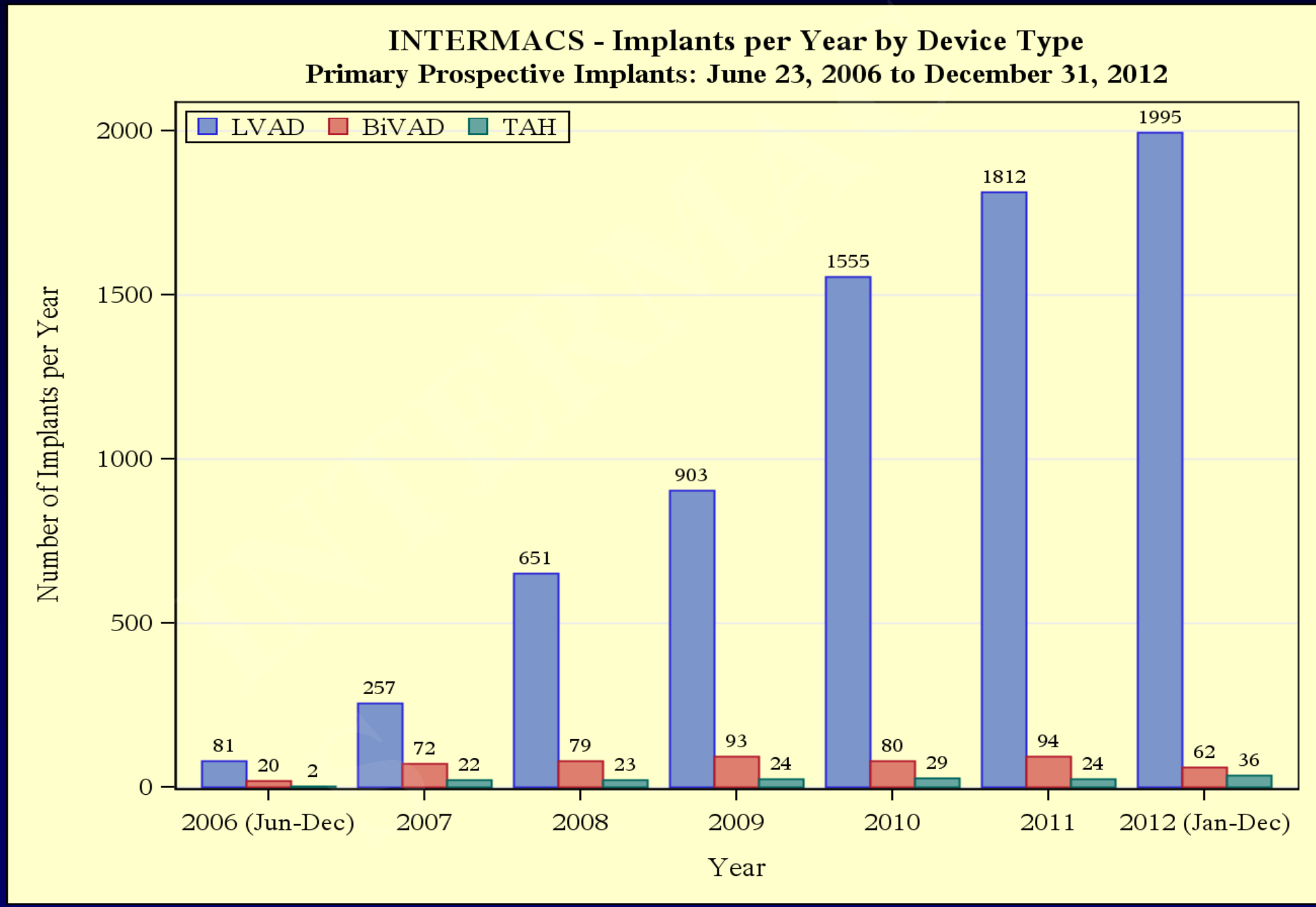


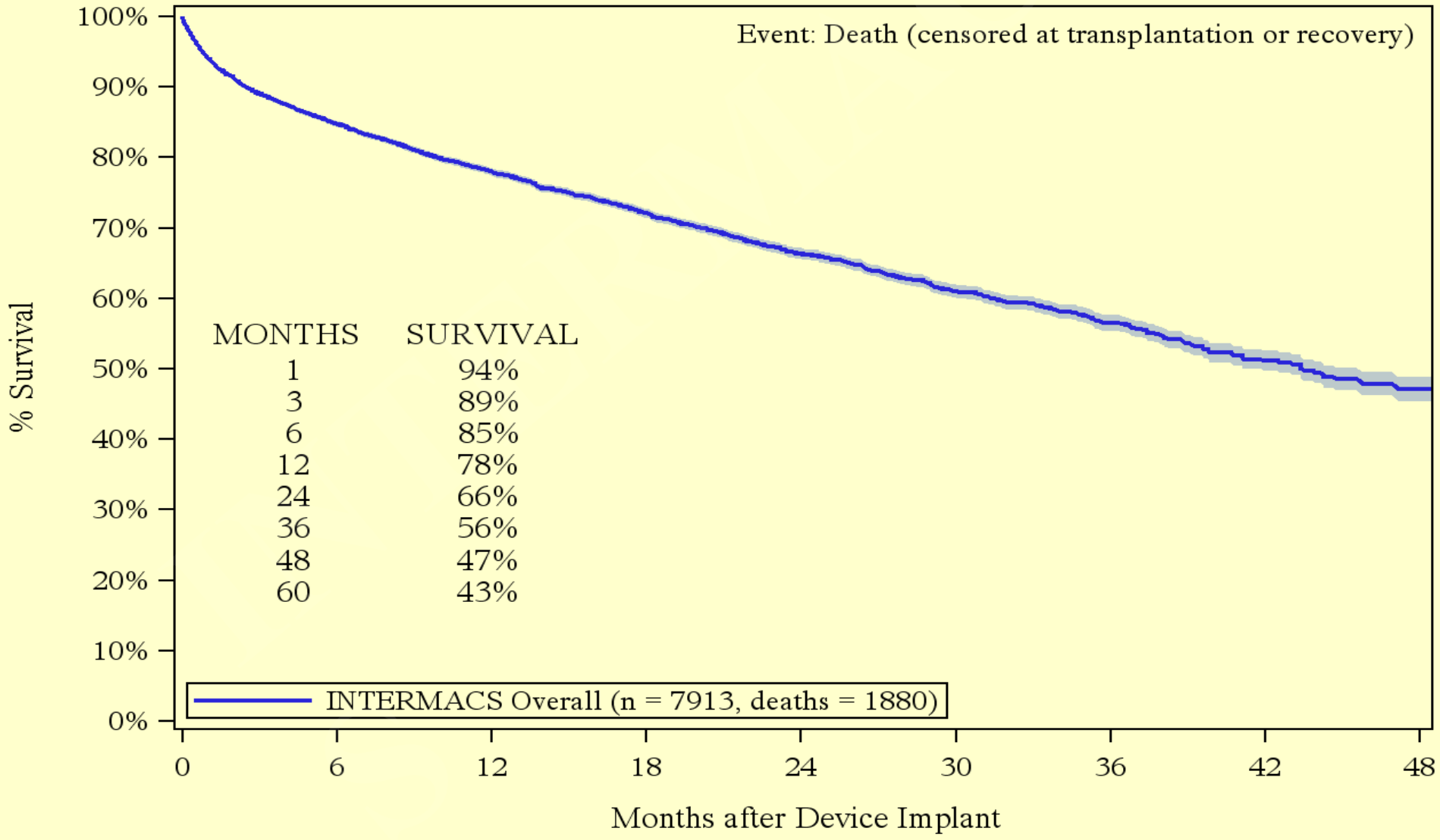
Between June 23, 2006 and December 31, 2012, 148 hospitals participated in INTERMACS and, of these, 138 hospitals actively contributed information on a total of 7914 patients. Cumulative patient accrual and the number of participating hospitals over this time period are displayed below.


INTERMACS - Implants per Year by Device Strategy
Primary Prospective Implants: June 23, 2006 to December 31, 2012
Bridge to Transplant - Listed
Bridge to Candidacy
Destination Therapy
Bridge to Recovery
Other
Number of Patients
0
200
400
600
800
45 36 16 4 2
147 135 48 14 7
367 304 55 15 12
506 430 60 13 11
476 608 551 13 16
436 709 748 17 20
405 750 911 13 14
2006 (Jun-Dec)
2007
2008
2009
2010
2011
2012 (Jan-Dec)
Year


INTERMACS - Implants per Year by Device Type
Primary Prospective Implants: June 23, 2006 to December 31, 2012
LVAD
BiVAD
TAH
Number of Implants per Year
2000
1500
1000
500
0
81
20
2
257
72
22
651
79
23
903
93
24
1555
80
29
1812
94
24
1995
62
36
2006 (Jun-Dec)
2007
2008
2009
2010
2011
2012 (Jan-Dec)
Year

INTERMACS - Kaplan-Meier Survival for INTERMACS Overall

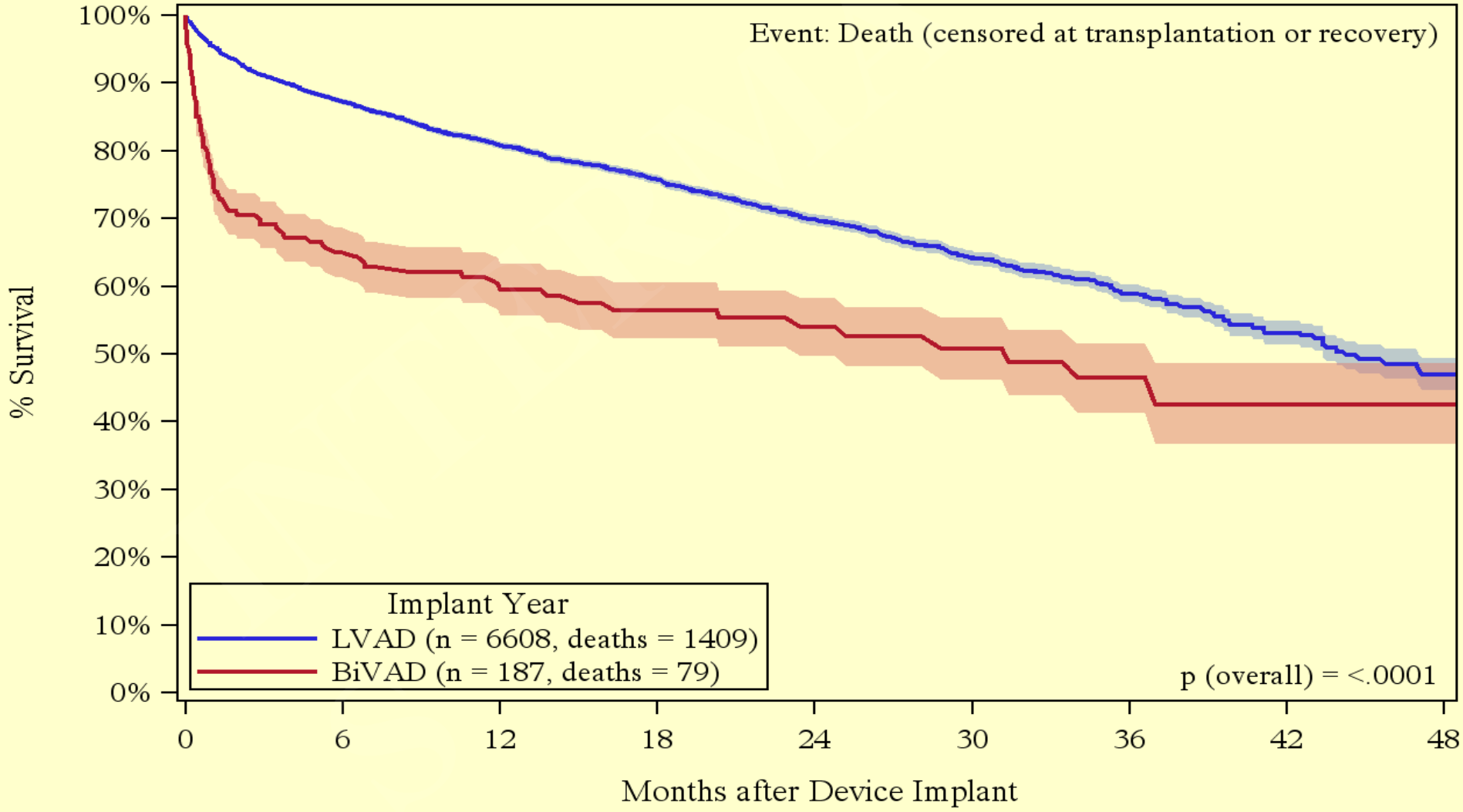
Primary Prospective Implants: June 23, 2006 to December 31, 2012



Shaded areas indicate 70% confidence limits

INTERMACS - Kaplan-Meier Survival for Continuous Flow LVADs (with or without RVAD implant at time of LVAD operation) by Device Type

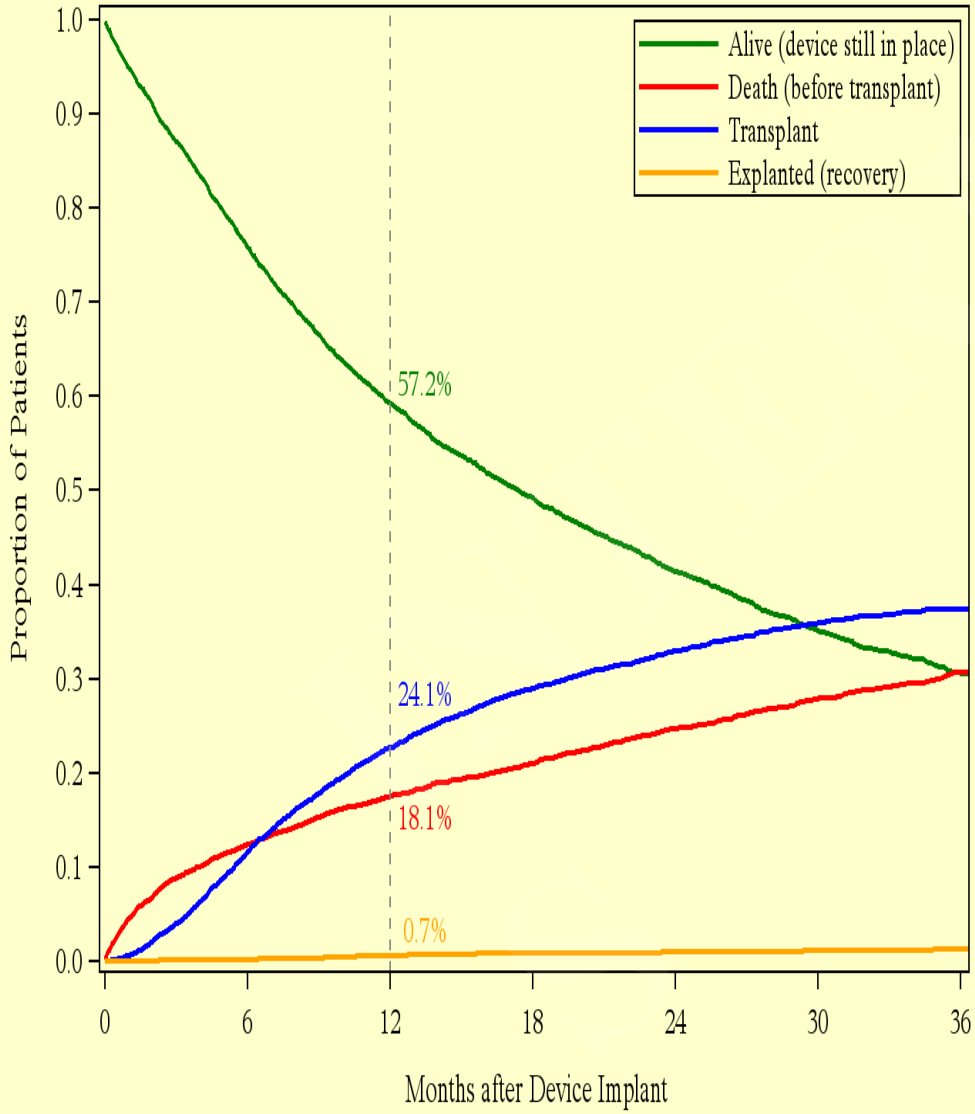
Primary Prospective Implants: June 23, 2006 to December 31, 2012



Shaded areas indicate 70% confidence limits

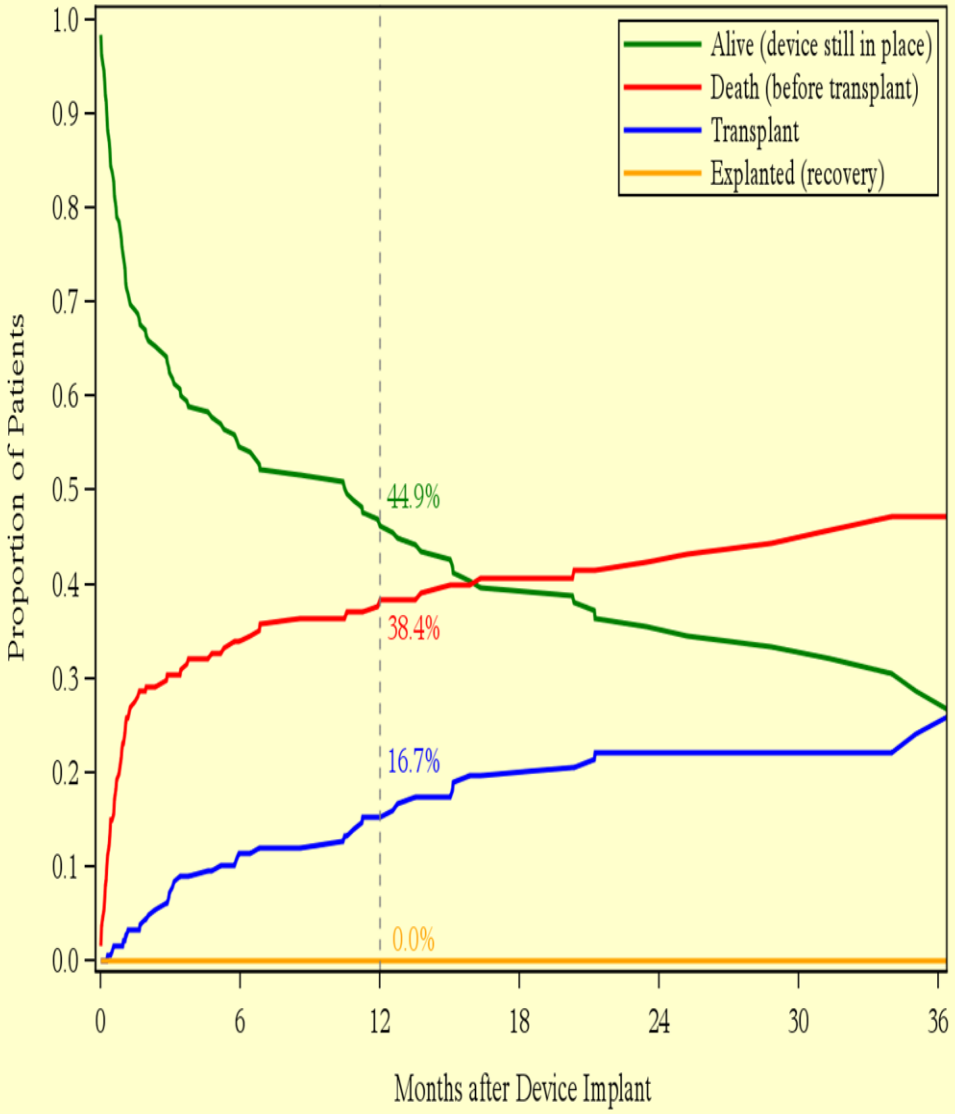
INTERMACS - Competing Outcomes for Continuous Flow LVADs (without RVAD implant at time of LVAD operation)

Primary Prospective Implants: June 23, 2006 to December 31, 2012



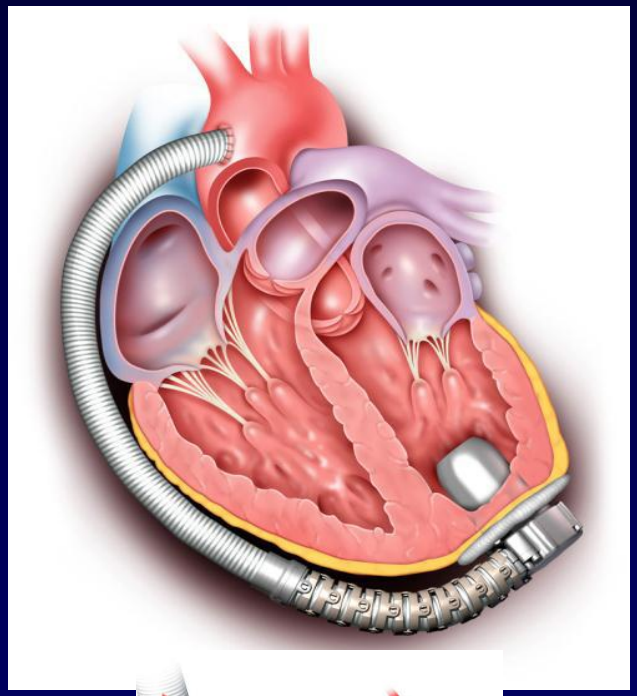
INTERMACS - Competing Outcomes for Continuous Flow LVADs (with RVAD implant at time of LVAD operation)

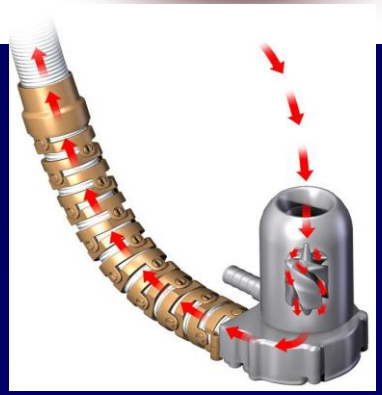
Primary Prospective Implants: June 23, 2006 to December 31, 2012



FUTURE DEVICES

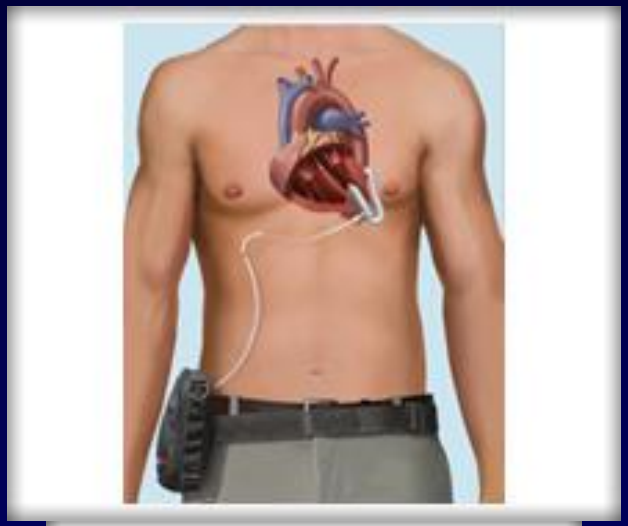
HEARTWARE MVAD





THORATEC HEARTMATE X

WORLDHEART MiFlow



MICROMED HEART ASSIST 5


It is a bit freaky with this wireless technology
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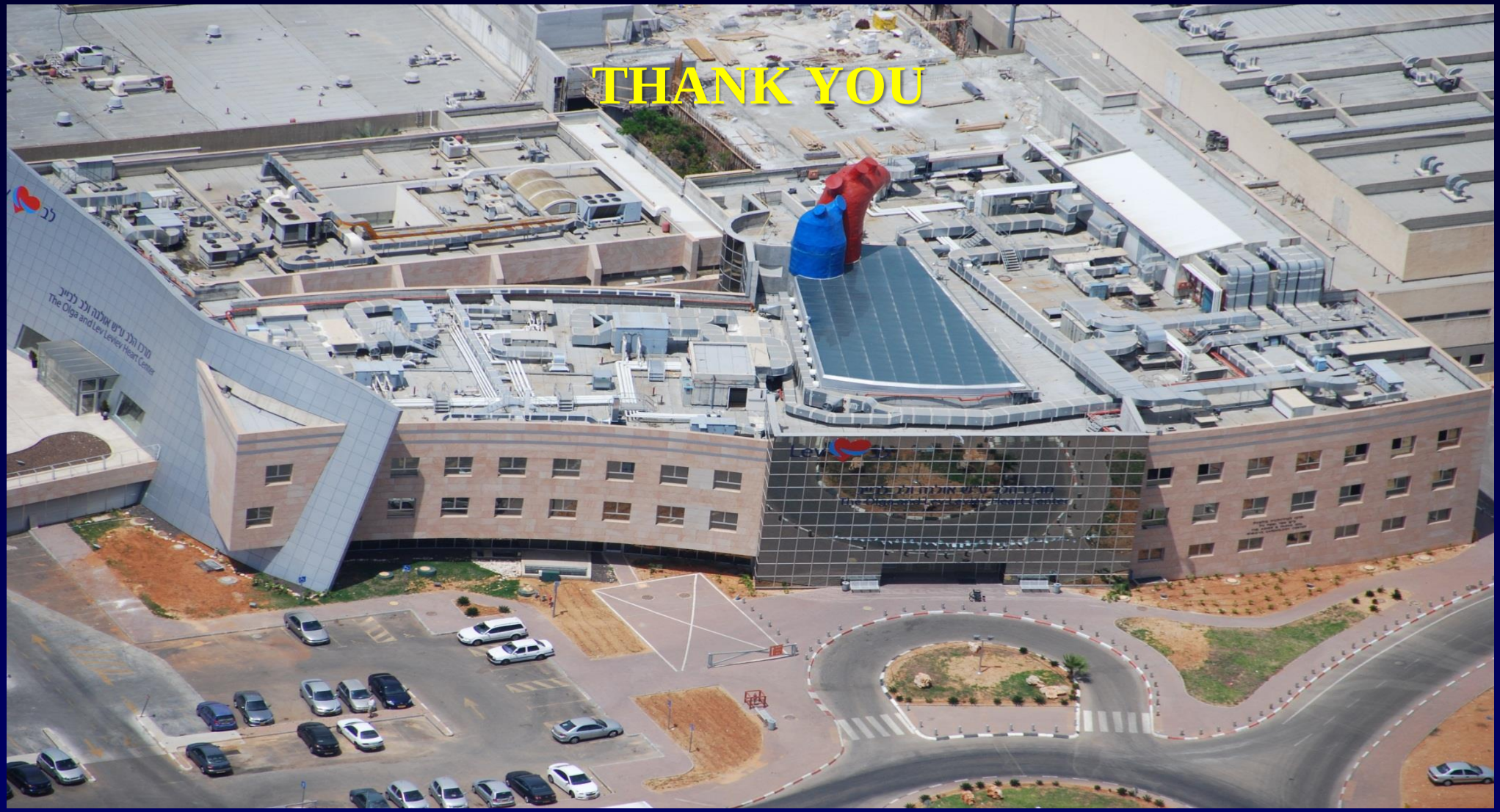

Leviev Heart Center
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