J-MACS
Japanese registry for Mechanically Assisted Circulatory Support

Japanese registry for Mechanically Assisted Circulatory Support (J-MACS) Registry Update

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International Society of Heart and Lung Transplantation

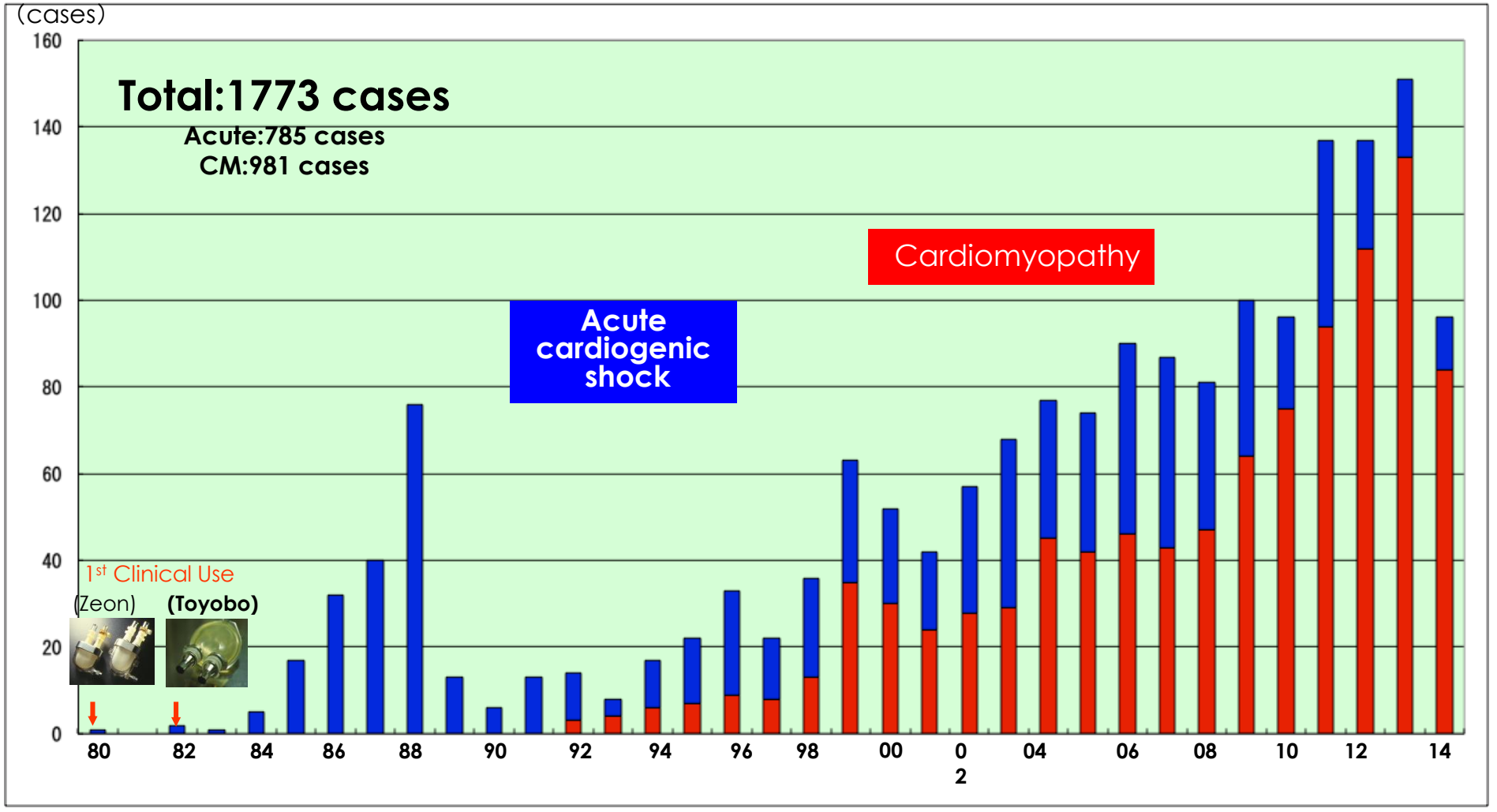
COI Disclosure

Takeshi Nakatani, MD, PhD

The author have no financial conflicts of interest to disclose concerning the presentation.

Clinical application of VAD by year in Japan

(1980 – 2014/8)



Japanese Association for Clinical Ventricular Assist Systems (JACVAS)

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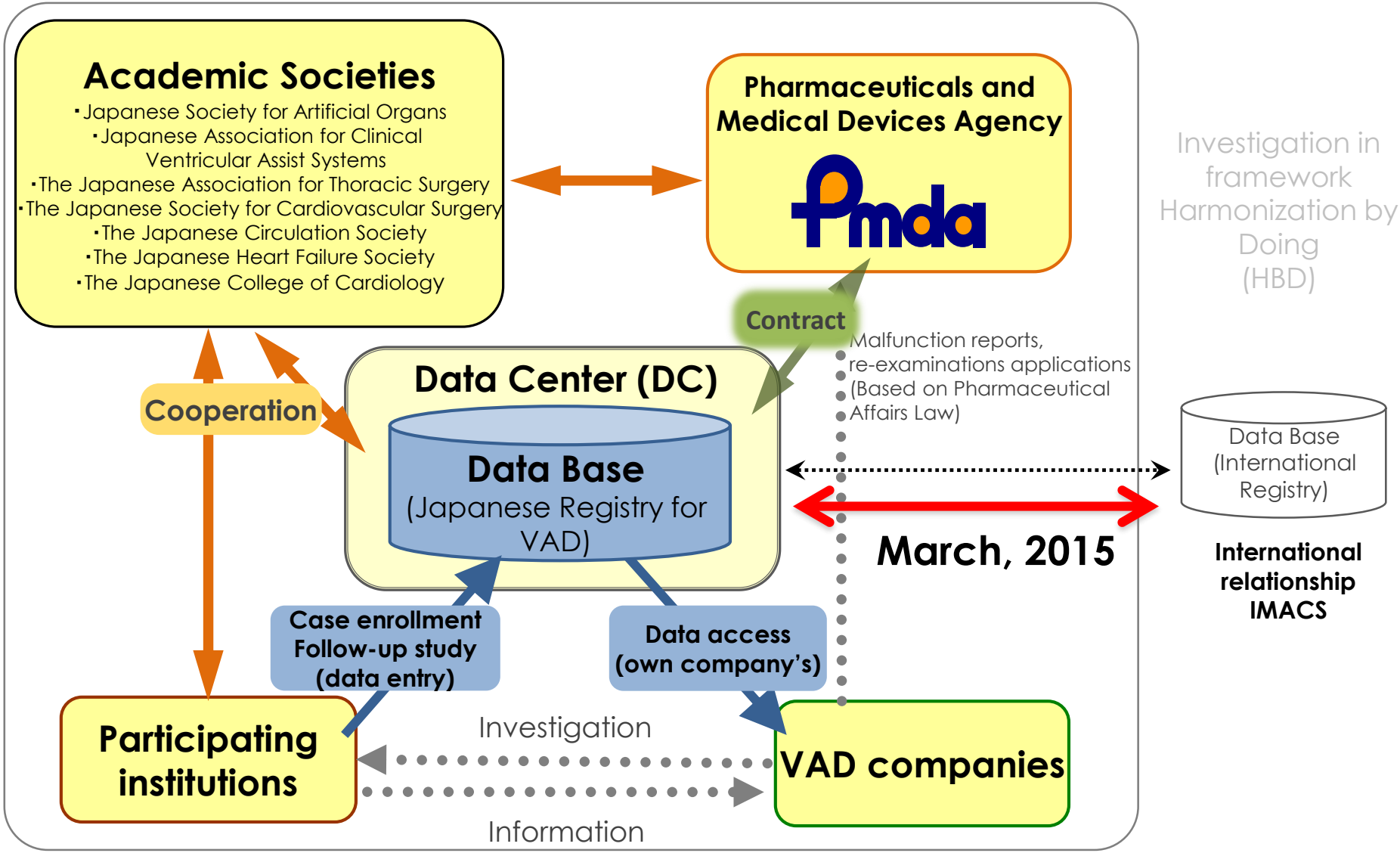
Framework of J-MACS



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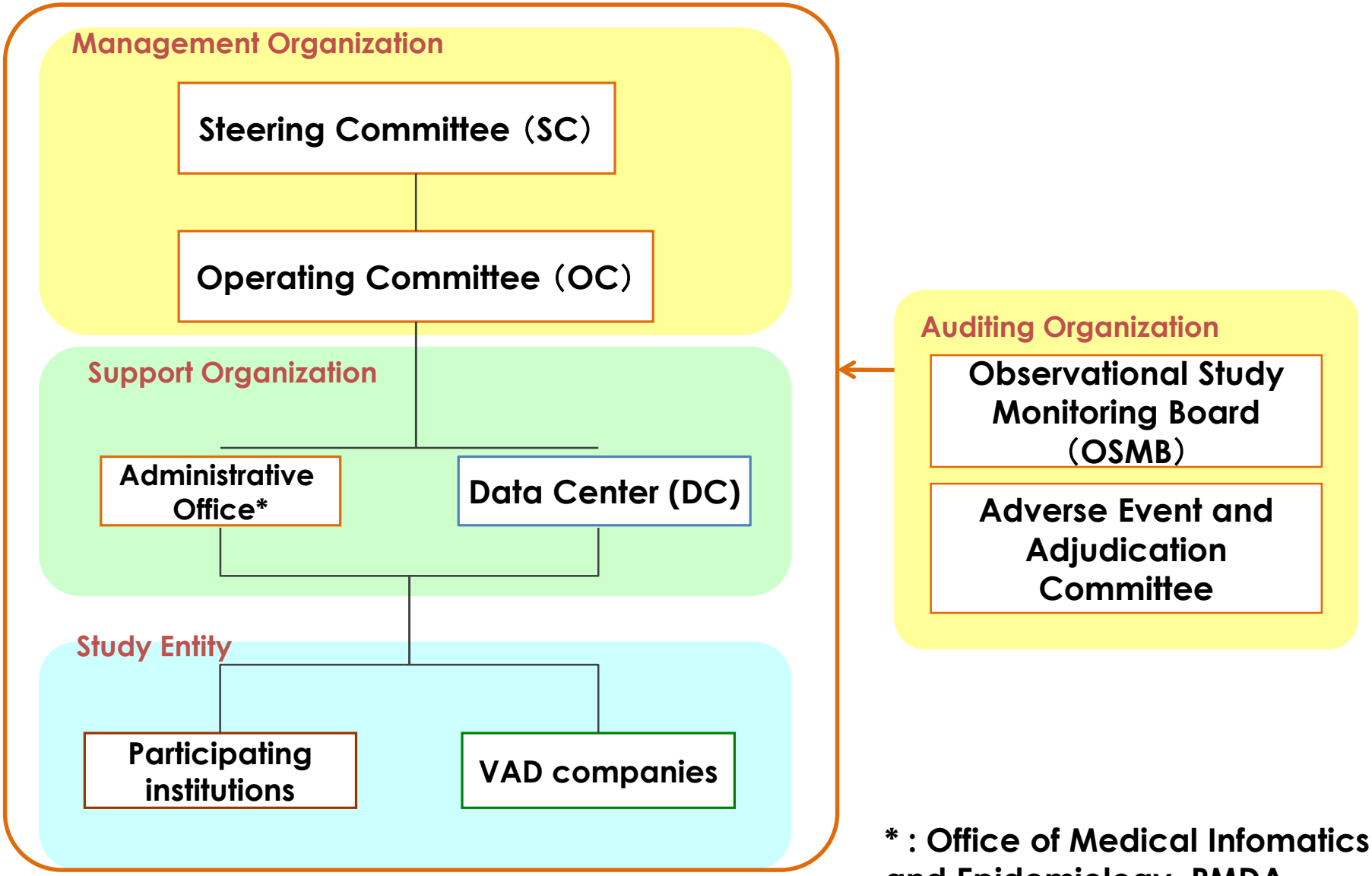
Organization of J-MACS



* : Office of Medical Infomatics and Epidemiology, PMDA

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Steering Committee Members

Members	affiliation
Hirokuni Arai	Tokyo Medical and Dental University
Mitsuaki Isobe	Tokyo Medical and Dental University
Takashi Inai	The Japan Federation of Medical Devices Associations
Hiroaki Oshiyama	Japan Medical Devices Manufacturers Association
Minoru Ono	Tokyo University
Soichiro Kitamura	National Cerebral and Cardiovascular Center
Shunei Kyo	Tokyo Metropolitan Geriatric Hospital and Institute of Gerontology
Yoshikatsu Saiki	Tohoku University
Satoshi Saito	Tokyo Women's Medical University
Yasushi Sakata	Osaka University
Kazuhiro Sase	Juntendo University
Yoshiki Sawa	Osaka University
Ryuji Tominaga	Kyushu University
Takeshi Nakatani	National Cerebral and Cardiovascular Center
Hikaru Matsuda	Higashi Takarazuka Satoh Hospital

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Operating Committee Members

	Members	affiliation
	Masatoshi Akiyama	Tohoku University
*	Hiroaki Oshiyama	Japan Medical Devices Manufacturers Association / TERUMO HEART K.K.
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	Yoshihisa Tanoue	Kyushu University
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	Masao Horie	NIPRO CORPORATION
	Masanobu Yanase	National Cerebral and Cardiovascular Center
	Shunichi Yamazaki	SUN MEDICAL TECHNOLOGY RESERCH CORP.

*: Principal and Vice principal investigator

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Device List for J-MACS

(Product approval)

- **Nipro-Toyobo** (April 1990)
- **HeartMate XVE** (November 2009)
- **EVAHEART** (December 2010)
- **DuraHeart** (December 2010)
- **Heartmate II** (November 2012)
- **Jarvik 2000** (November 2013)

Nipro-Toyobo Extracorporeal type
Intended long-term use as BTT
Covered by medical insurance

Implantable non-pulsatile type

EVAHEART

DuraHeart

Heartmate II

Jarvik 2000

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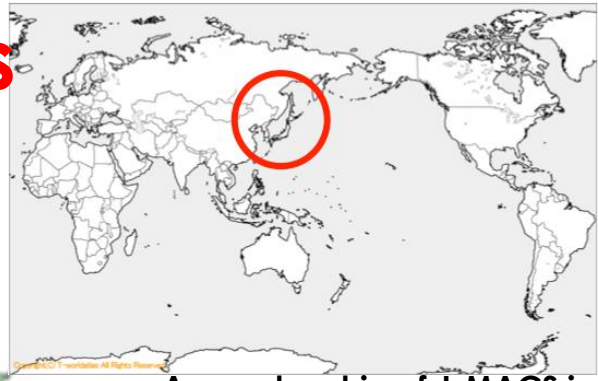
Participating hospitals



As of April 2015,
40 hospitals are participating and of those **7 hospitals** are new members from this year.
At start: 6 hospitals

A membership of J-MACS is one of the essential conditions for authorized hospitals to use of implantable LVAD under medical insurance.

Hokkaido University
Hirosaki University
Jichi Medical University
Dokkyo Medical University
Gunma Cardiovascular Center
Saku Central Hospital Advanced Care Center
Shinshu University
Fukui CardioVascular Center
Kinki University
Kyoto University
National Cerebral and Cardiovascular Center
Osaka University
Sakurabashi Watanabe Hospital
Hyogo College of Medicine
Higashi Takarazuka Satoh Hospital
Tottori University
Ehime University
Kyushu University
Saga University
Kurume University
Nagasaki University
Oita University
Nagoya University
Nagoya Tokushukai General Hospital
Japanese Red Cross Nagoya Daini Hospital
Akita University
Tohoku University
Saitama Cardiovascular and Respiratory Center
Saitama Medical Center Jichi Medical University
Saitama International Medical Center
Nihon University Itabashi Hospital
Tokyo Women's Medical University
Tokyo Medical and Dental University
Mitsui Memorial Hospital
The University of Tokyo
Teikyo University
Chiba University
Kitasato University
University of the Ryukyus
Okinawa Prefectural Nambu Medical Center & Children's Medical Center

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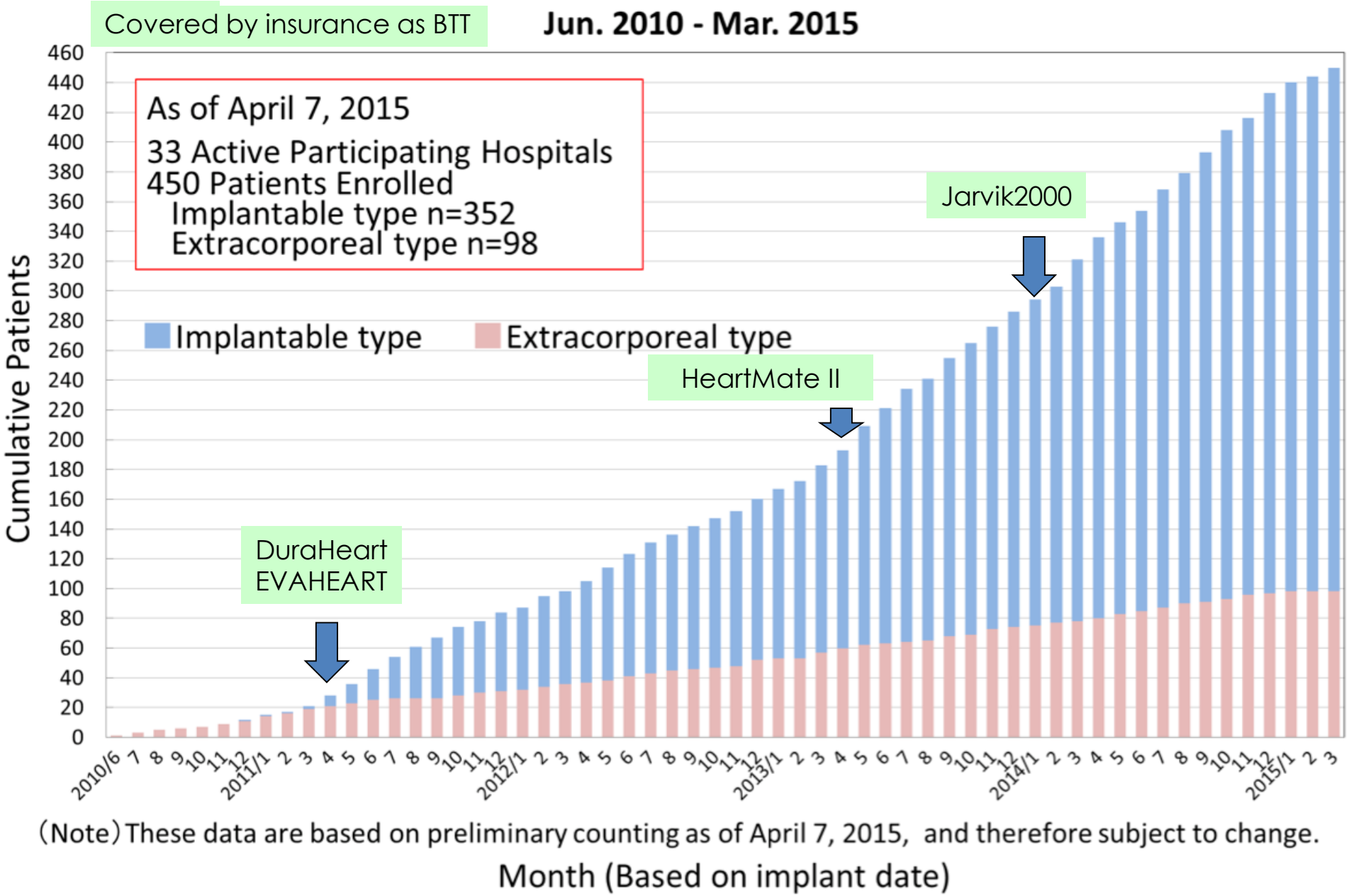
J-MACS: The number of Patient Enrollment



(Note) These data are based on preliminary counting as of April 7, 2015, and therefore subject to change.

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Statistical Summary

Patients included in this analysis

The data of the total 384 patients who had been implanted with VAD between June 2010 and which were available as of December 7, 2014, were extracted.

Of those, 272 patients who met the following criteria (Primary LVAD population) at the time of enrollment in J-MACS were included in this analysis.

- Patients who have never used VAD at the time of enrollment in J-MACS
- Patients who were assisted only by LVAD at the time of enrollment in J-MACS
- Patients who were 19 years of age or older at the time of implantation of LVAD

[Reference] http://www.pmda.go.jp/english/safety/surveillance-analysis/0003.html

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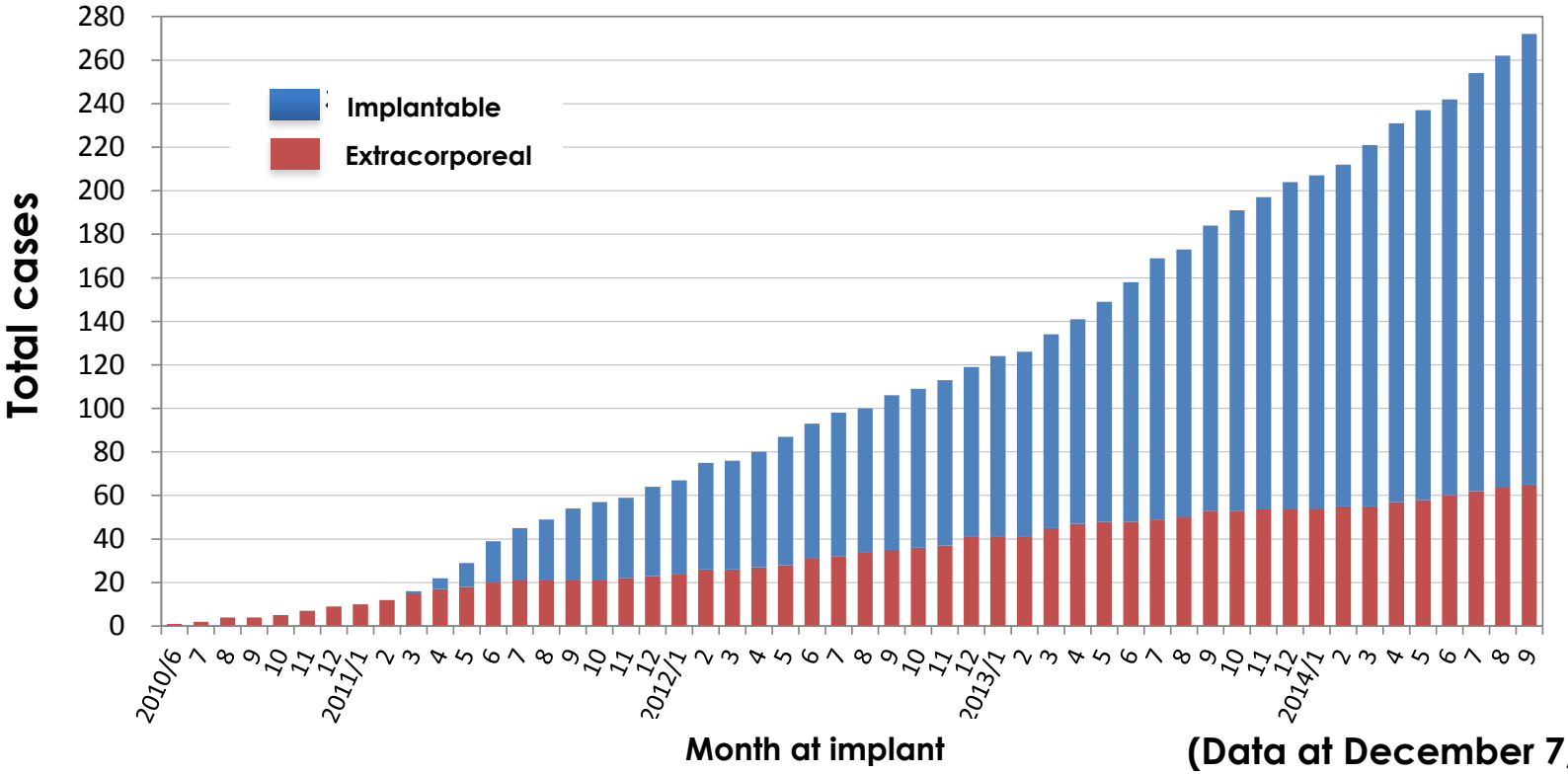
Number of patient enrollment for Statistical analysis

Primary LVAD
(June, 2010 – September,2014)

Device	Cases (%)
Implantable	207（76）
Extracorporeal*	65（24）
Total	272

* :24 cases were converted to implantable type



(Data at December 7, 2014)

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Patients demographics (Primary LVAD population)

Gender

Gender	Total(%)	Implantable(%)	Extracorporeal(%)
Male	220(81)	172(83)	48(74)
Female	52(19)	35(17)	17(26)
Total	272	207	65

Age

Age	Total	Implantable	Extracorporeal
Mean±SD	42.0±12.4	43.3±12.1	38.1±12.4

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Patients demographics (Primary LVAD population)

Pre-Implant patient profile

Profile	Total (%)	Implantable (%)	Extracorporeal (%)
Level 1: Critical cardiogenic shock	41 (15)	6 (3)	35 (54)
Level 2 : Progressive decline	133 (49)	105 (51)	28 (43)
Level 3 : Stable but inotrope dependent	89 (33)	87 (42)	2 (3)
Level 4 : Recurrent advanced HF	9 (3)	9 (4)	0 (0)
Level 5-7 *	0 (0)	0 (0)	0 (0)
Total	272	207	65

* Level 5,6,7 : Exertion intolerant, Exertion limited, Advanced NYHA class III

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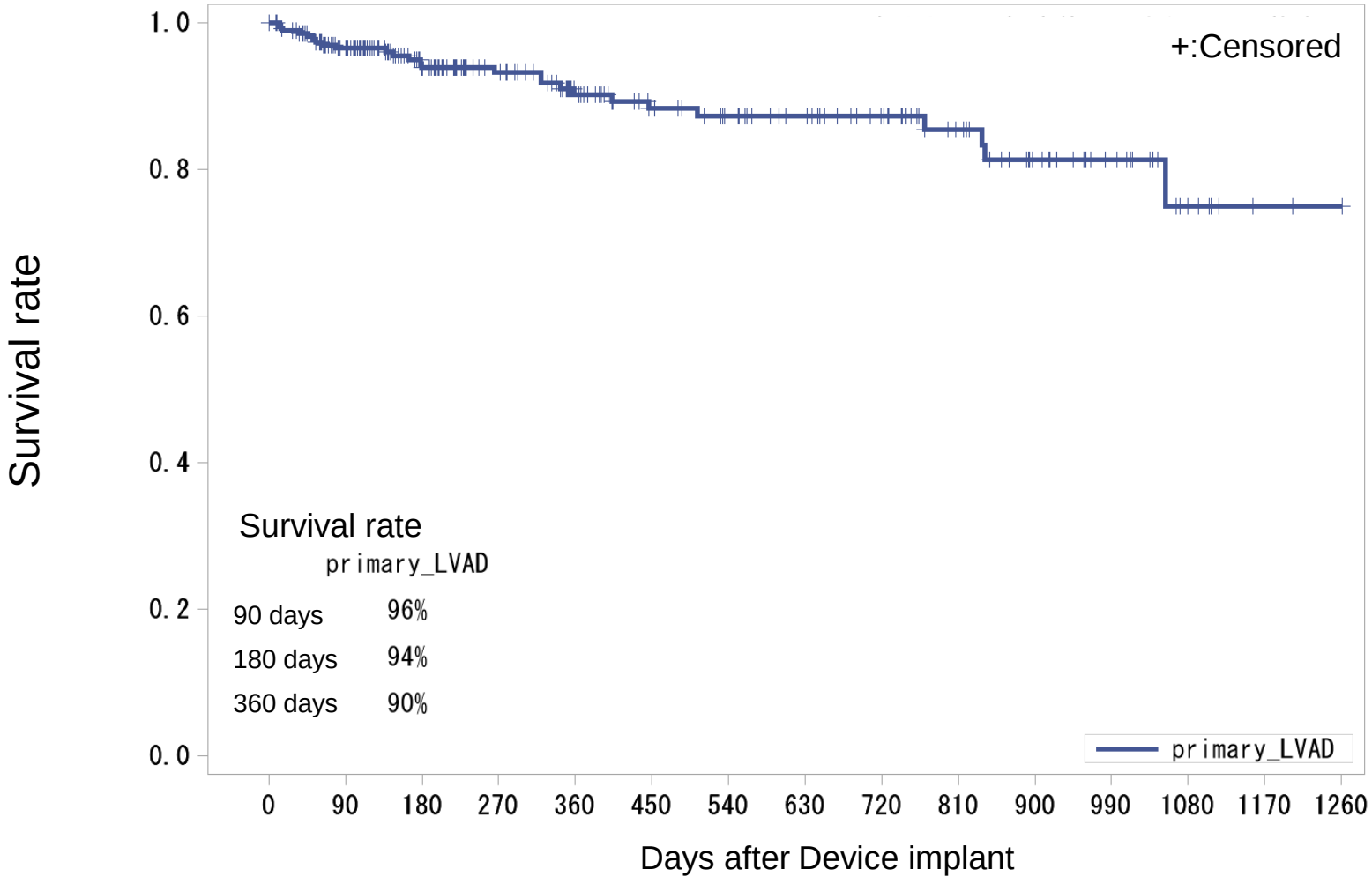
Actuarial survival

Primary LVAD
Kaplan-Meier Plot



Patients at risk (cases)

primary_LVAD	272	228	171	138	113	87	78	70	60	45	30	20	8	2	1

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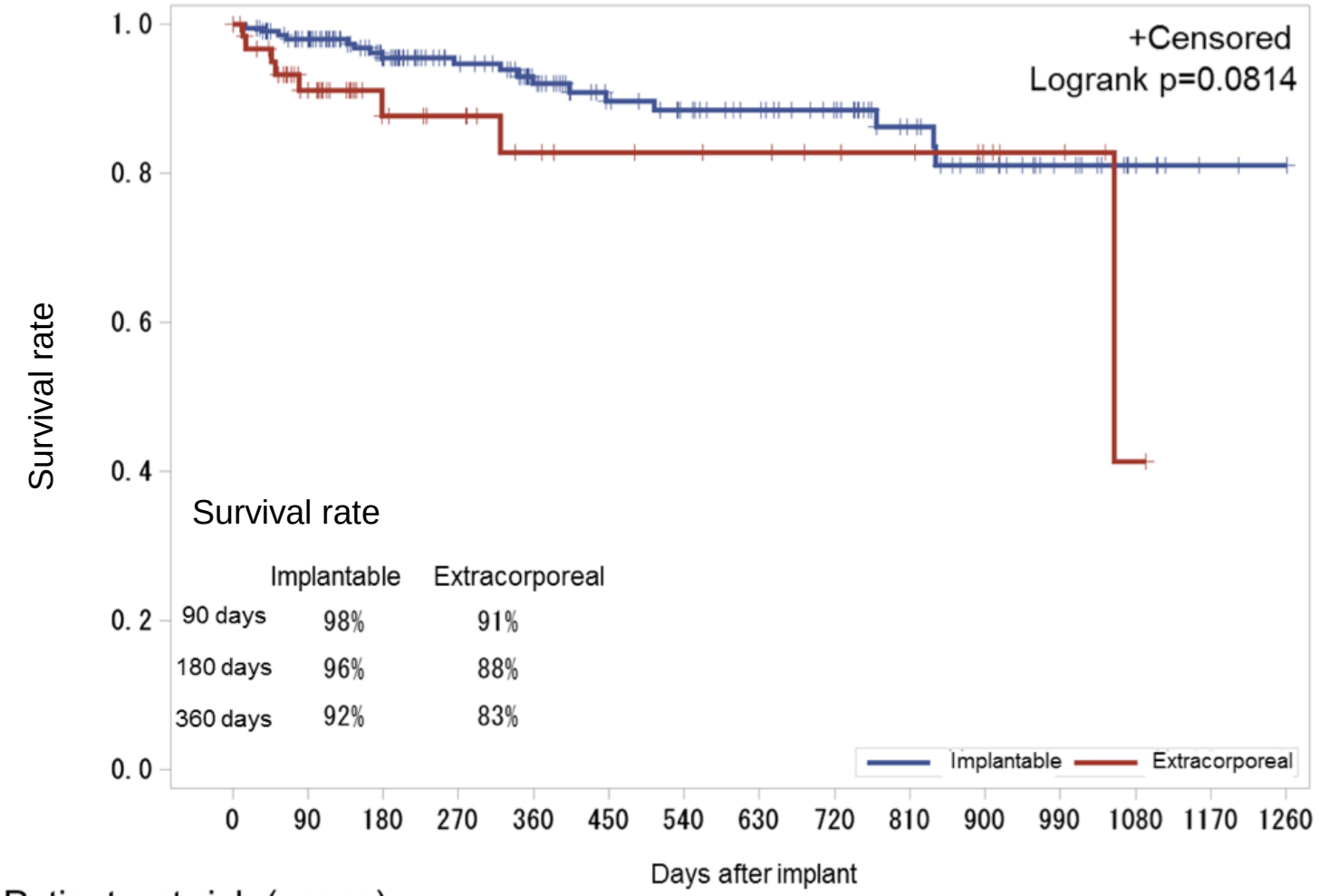
Actuarial survival

Primary LVAD（Implantable/Extracorporeal)



Patients at risk (cases)

Implantable	207	186	147	117	97	73	65	58	50	36	24	16	7	2	1
Extracorporeal	65	42	24	21	16	14	13	12	10	9	6	4	1	0	

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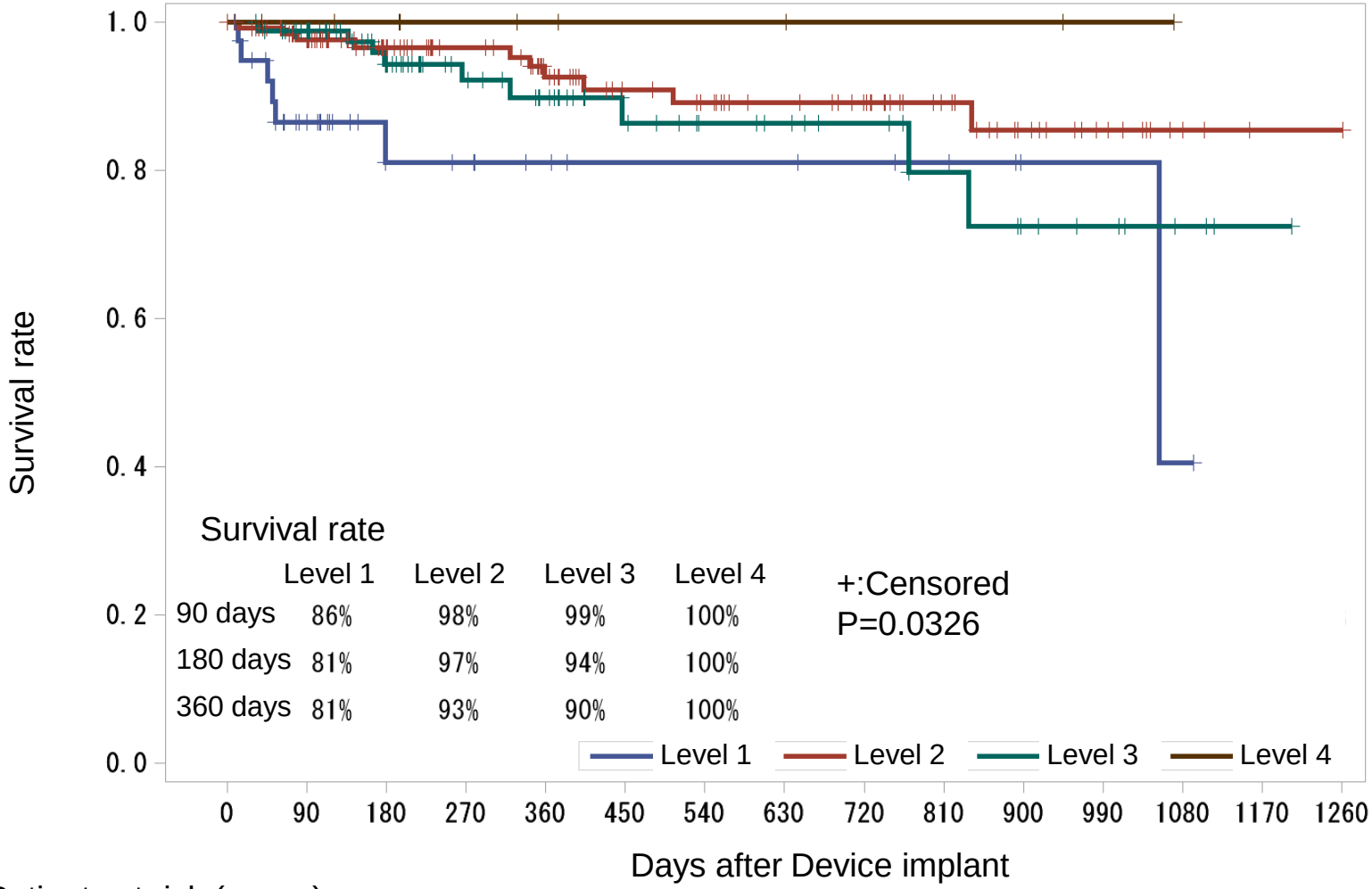
Actuarial survival

Primary LVAD（Patient profile）
Kaplan-Meier Plot



Patients at risk (cases)

Level 1	41	25	14	13	9	7	7	7	6	5	2	2	1	0
Level 2	133	115	91	77	64	52	48	42	37	27	18	11	4	1	1
Level 3	89	80	59	43	36	25	20	18	15	11	8	6	3	1	0
Level 4	9	8	7	5	4	3	3	3	2	2	2	1	0		

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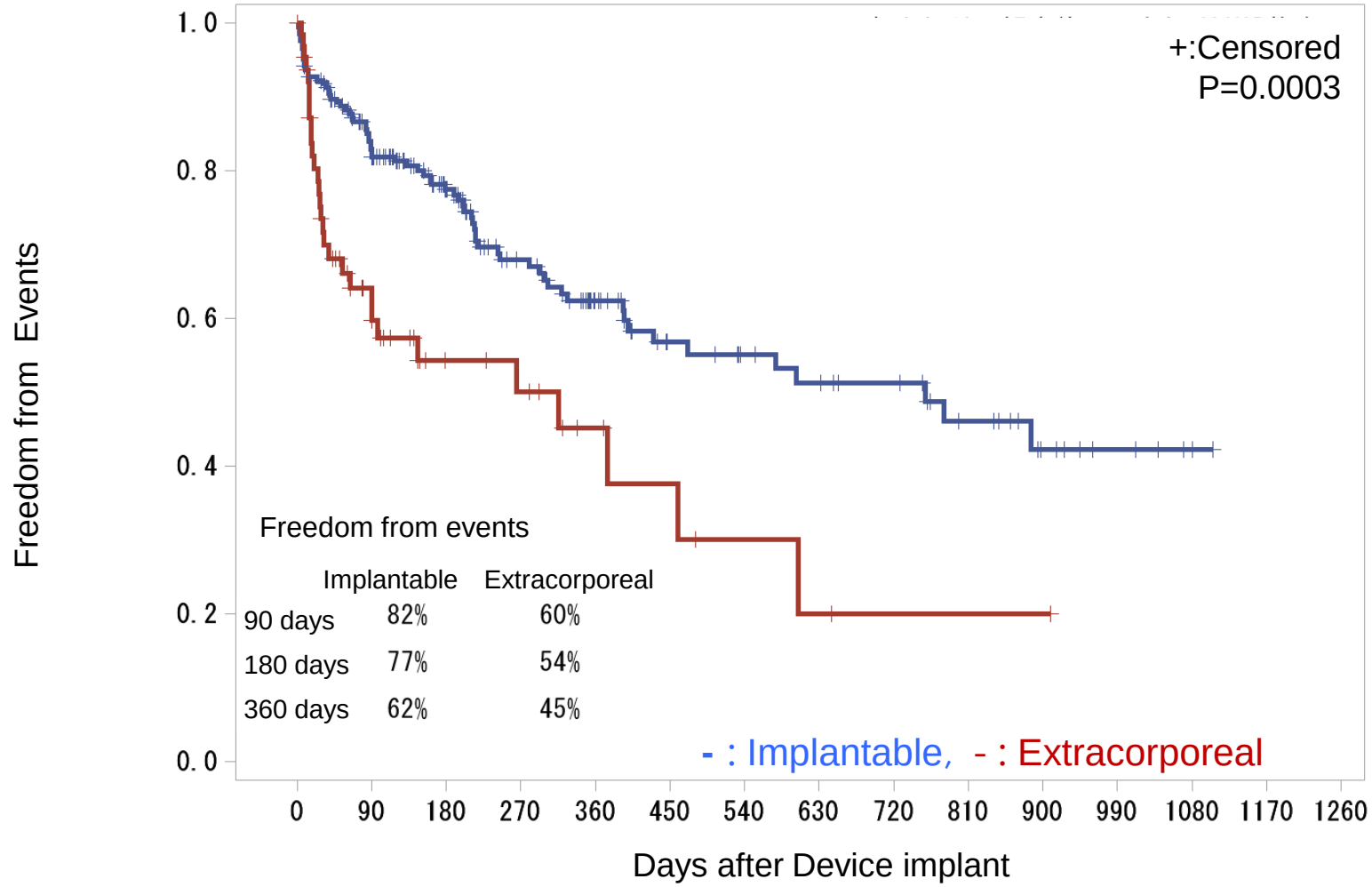
Actual freedom from malfunction

Primary LVAD（Implantable/Extracorporeal）

Kaplan-Meier Plot



Patients at risk (cases)

Implantable	207	156	114	76	55	34	29	26	23	16	9	5	2	0
Extracorporeal	65	29	14	12	7	5	3	2	1	1	1	0		

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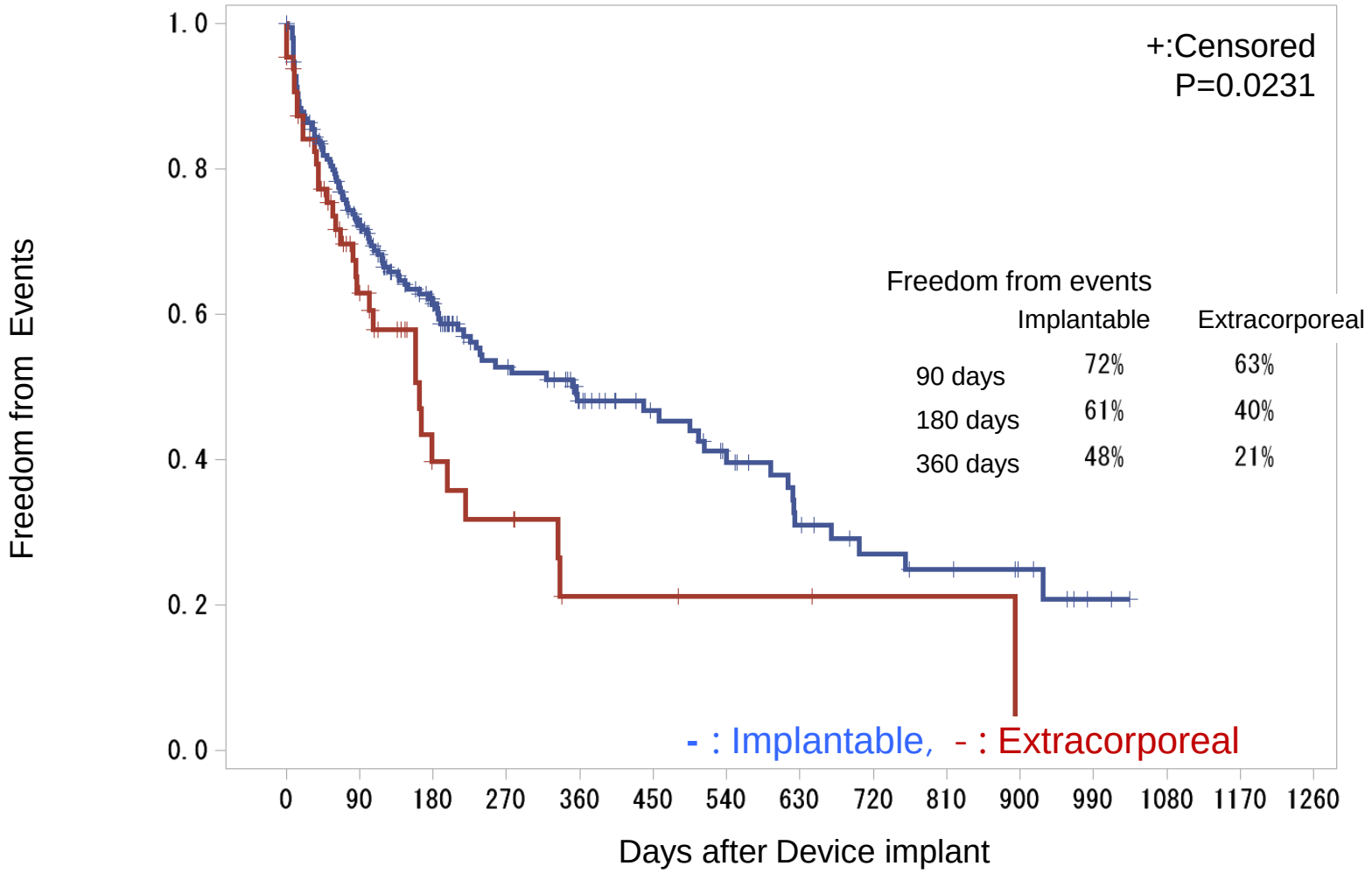
Actual freedom from infection

Primary LVAD（Implantable/Extracorporeal）

Kaplan-Meier Plot



Patients at risk (cases)

Implantable	207	139	93	62	45	34	27	18	13	11	7	2	0
Extracorporeal	65	28	10	8	3	3	2	2	1	1	0		

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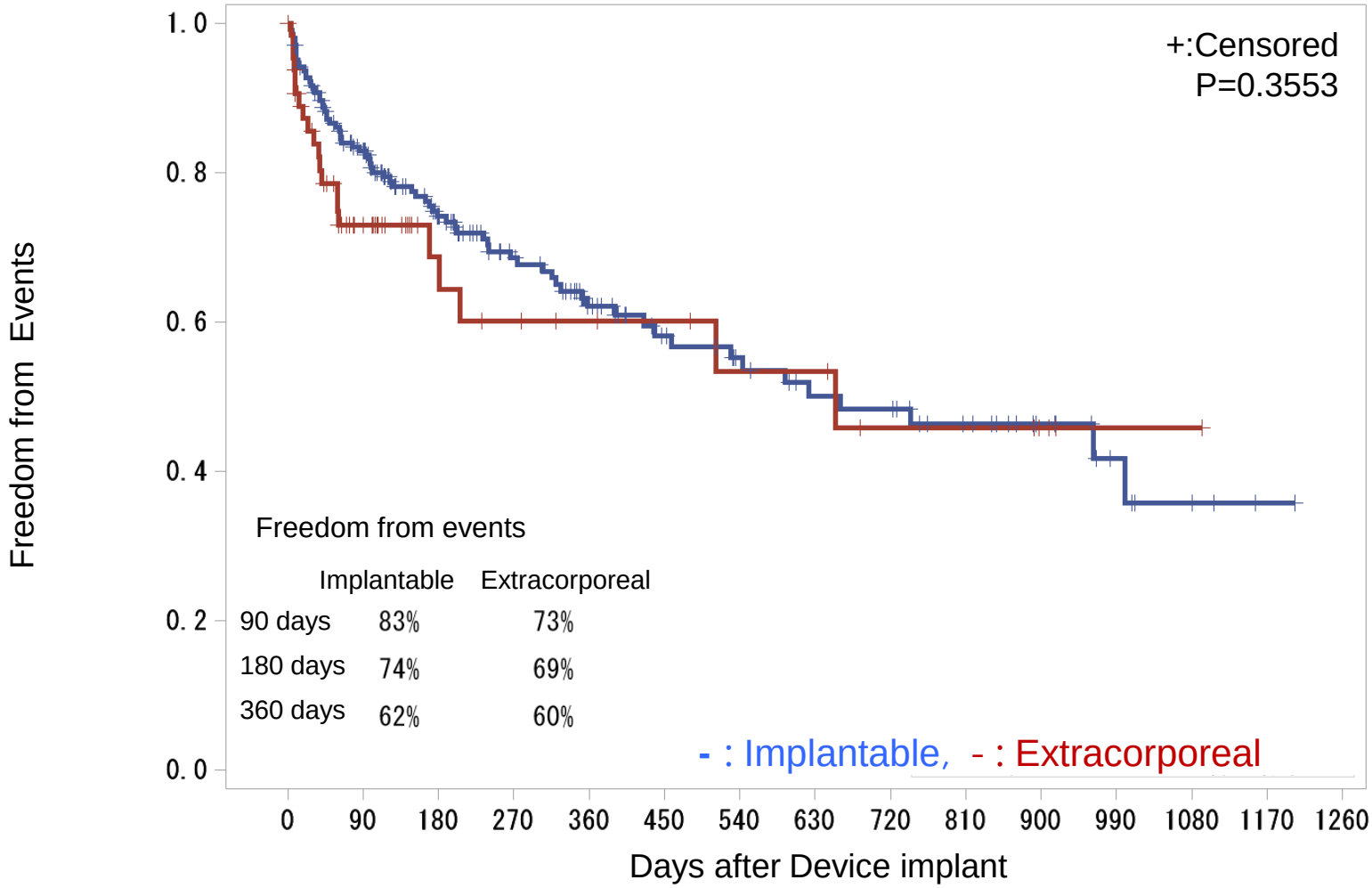
Actual freedom from neurological events

Primary LVAD（Implantable/Extracorporeal）

Kaplan-Meier Plot



Patients at risk (cases)

Implantable	207	153	107	79	58	41	34	28	27	20	13	7	4	1	0
Extracorporeal	65	32	16	13	11	10	8	8	5	5	3	1	1	0	

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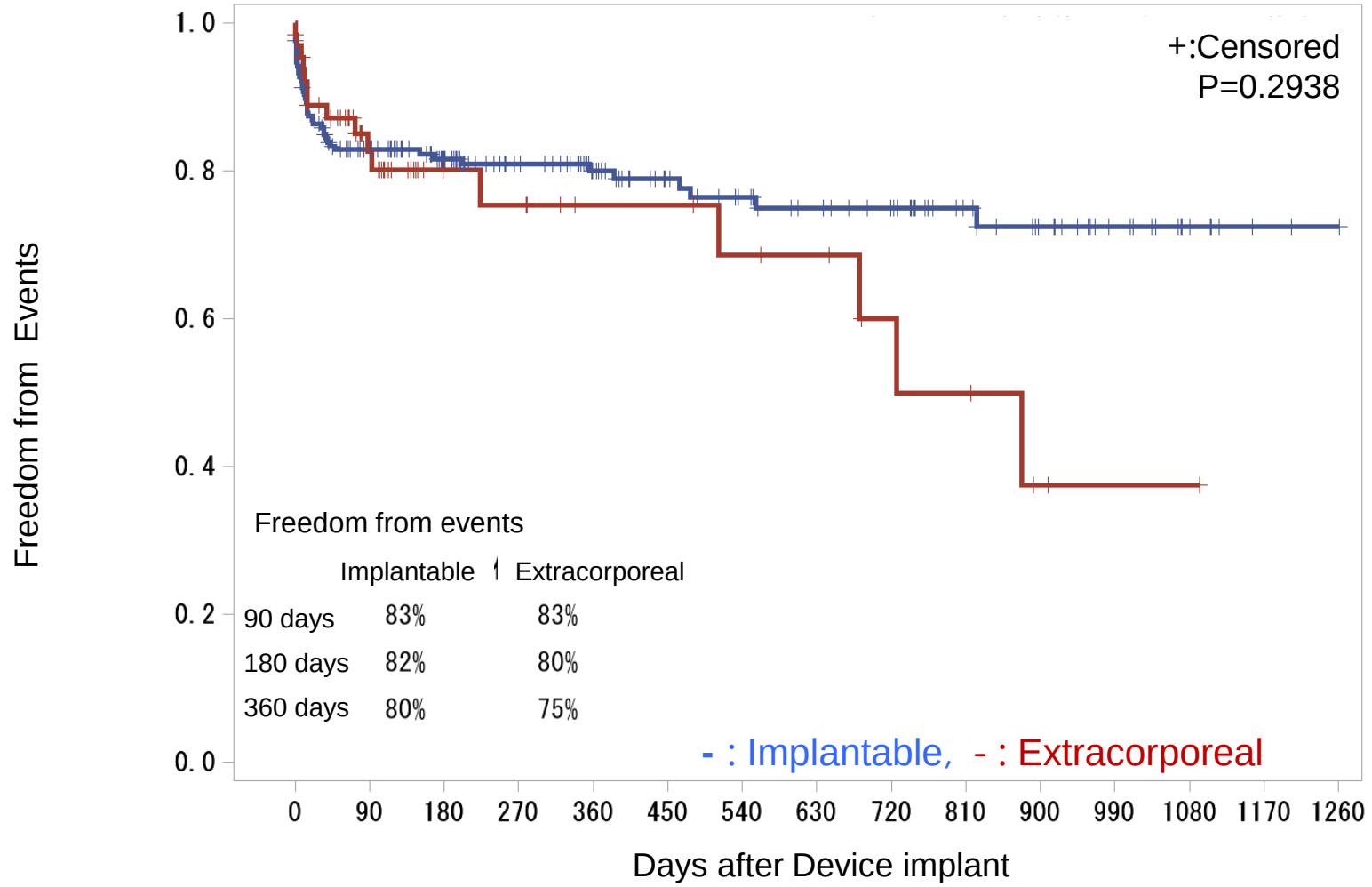
Actuarial freedom from bleeding

Primary LVAD（Implantable/Extracorporeal）
Kaplan-Meier Plot



Patients at risk (cases)

Implantable	207	156	126	101	84	63	55	49	44	31	23	15	7	2	1
Extracorporeal	65	35	17	16	12	12	10	9	6	5	2	1	1	0	

Summary

J-MACS is useful for better clinical management and development of new VADs, while, the collected data are beneficial for assuring the safety of new devices.

Continuity of J-MACS is future task.