

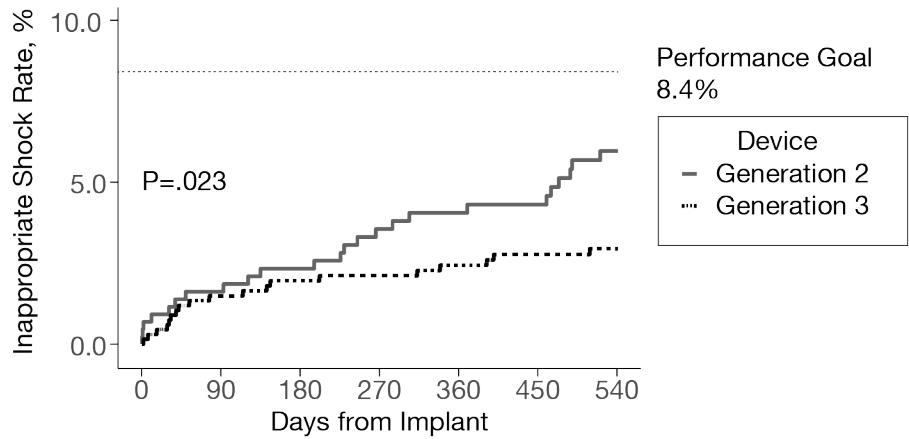
SUPPLEMENTAL MATERIAL

Supplemental Table 1. Pooling Analysis

Endpoint Details					Permanent AF	No Permanent AF	Pooling Analysis (Likelihood Ratio Test: Chi-square with 1 d.f.)	
Endpoint Type	Description	Analysis Type	Time Frame	Performance Goal	N	N	Baseline Covariates	P-value
Primary	Primary Endpoint - Inappropriate Shock Free Rate	Intent to Treat	18 months	> 91.6%	24	1087	Anticoagulants, Antiplatelets, Monomorphic VT, Other VT Arrhythmias	0.4867
Primary	Primary Endpoint - Inappropriate Shock Free Rate	Per Protocol	18 months	> 91.6%	24	1087	Anticoagulants, Antiplatelets, Monomorphic VT	0.5300
Secondary	All-Cause Shock Free Rate	Intent to Treat	18 months	> 85.8%	24	1087	Anticoagulants, Digitalis, Monomorphic VT, Ventricular Fibrillation, Other VT Arrhythmias, LVEF (%), Weight (lb), Body Mass Index (kg/m ²)	0.6555
Secondary	All-Cause Shock Free Rate	Per Protocol	18 months	> 85.8%	24	1087	Anticoagulants, Digitalis, Monomorphic VT, Ventricular Fibrillation, LVEF (%), Weight (lb)	0.7915
Secondary	Complication Free Rate	N/A	30 days	> 93.8%	24	1092	Nitrates, Statins, Weight (lb)	0.3365

Supplemental Figure 1. Inappropriate Shock Rate by Device Type.

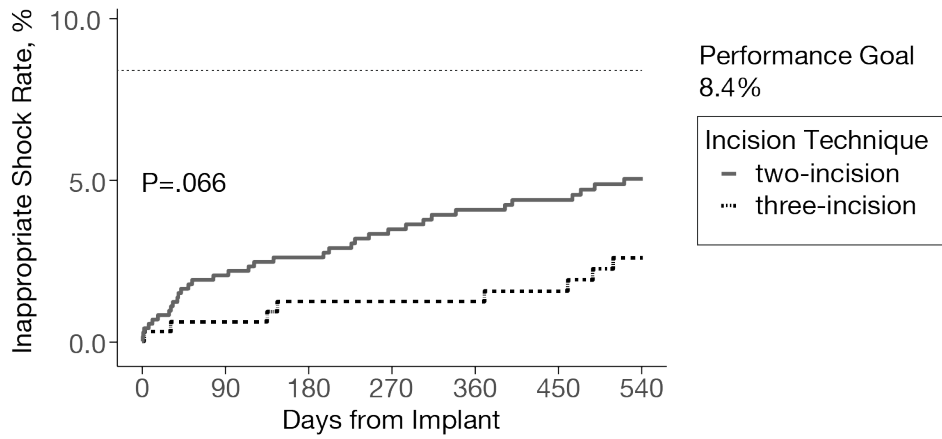
Kaplan-Meier Post-Hoc Analysis: Risk of IAS by Device Type



Subjects at Risk				
	0	90	180	270
Generation 2	436	408	376	312
		(2.3)	(4.1)	(6.0)
Generation 3	675	630	591	497
		(2.0)	(2.4)	(2.9)

Supplemental Figure 2 Inappropriate Shock Rate by Incision Technic.

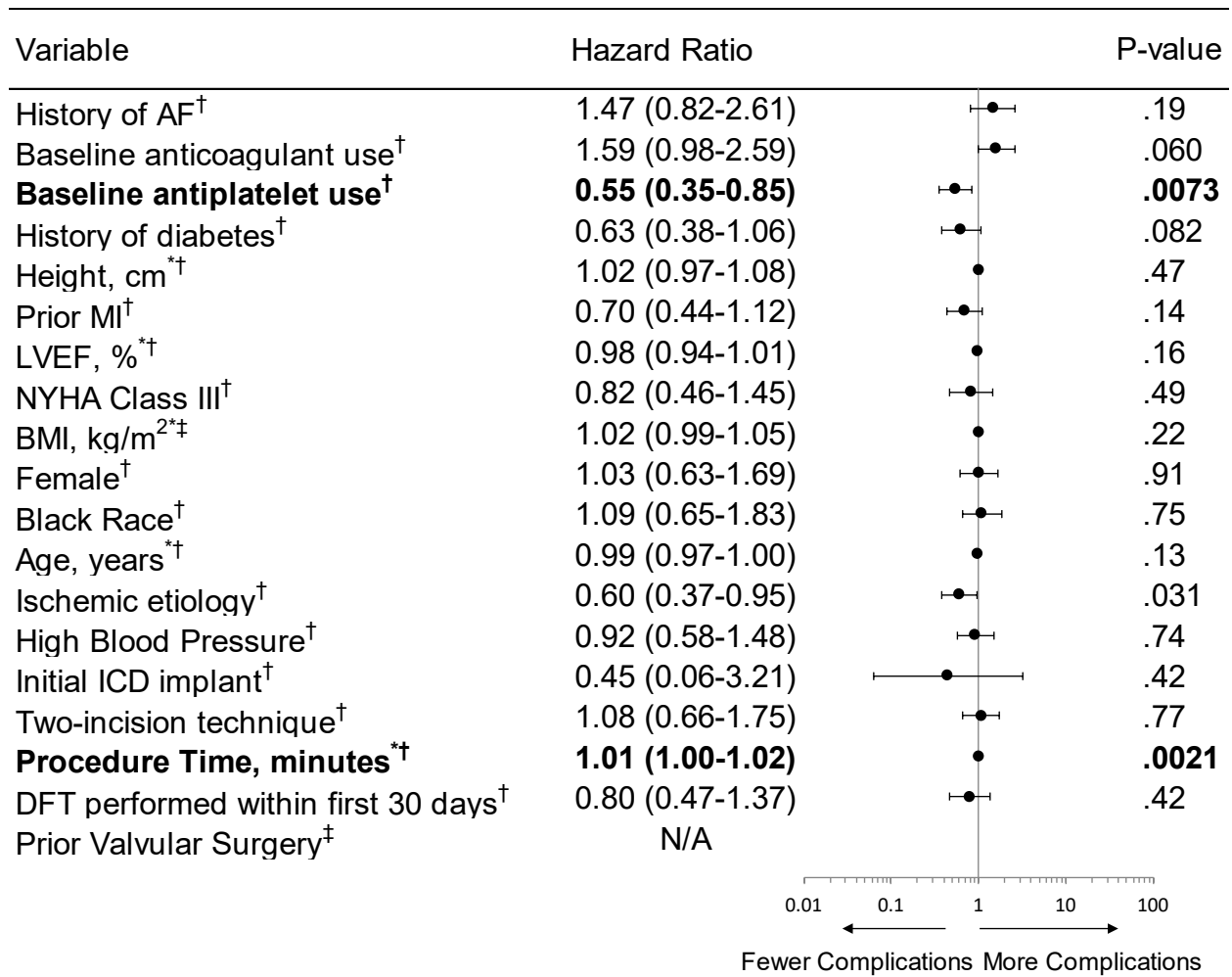
Kaplan-Meier Post-Hoc Analysis: Risk of IAS by Incision Technique



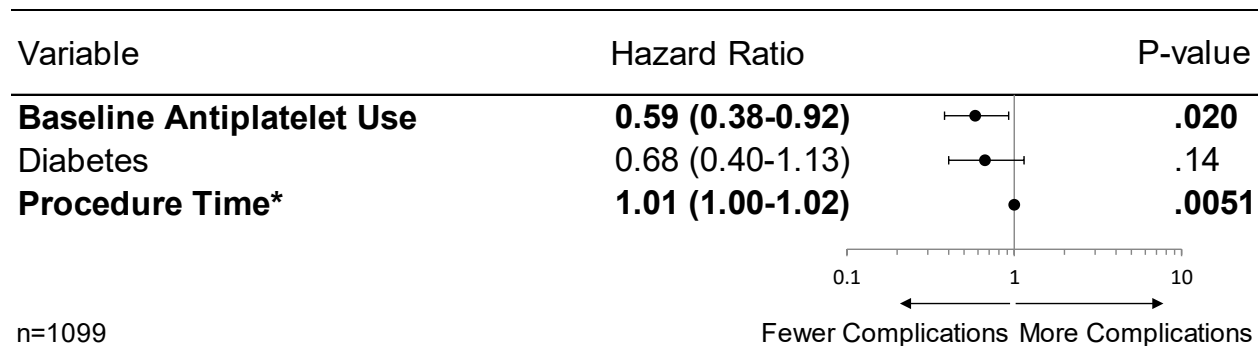
Subjects at Risk				
two-incision	343	328	312	268
		(2.5)	(3.9)	(4.9)
three-incision	768	710	656	563
		(1.2)	(1.2)	(2.5)

Supplemental Figure 3 Predictors of Complications

A. Univariable



B. Multivariable



n=1099

Predictors of complications at 18 months based on hazard analysis. A: Univariable model. BMI and prior valvular surgery were the only variables that failed the proportional hazards assumption. B: Multivariable model. AF = atrial fibrillation; BMI = body mass index; DFT = defibrillation testing; Gen 3 = Generation 3 device; LVEF = left ventricular ejection fraction; MI = myocardial infarction; NYHA = New York Heart Association.

*Continuous variable

†Satisfied the proportional hazard assumption

‡Proportional hazard assumption not verified

Supplemental Table 2

Table of Complications

Classification	Events	N (%)
Sub-optimal position/movement	12	11 (1.0)
Suboptimal electrode position	3	3 (0.3)
Electrode migration/revision	5	5 (0.4)
Electrode movement	1	1 (0.1)
Electrode erosion	1	1 (0.1)
PG erosion	1	1 (0.1)
PG migration	1	1 (0.1)
Sensing/device function	12	12 (1.1)
Inappropriate therapy / Oversensing	7	7 (0.6)
Device shocked 5 times before conversion	1	1 (0.1)
Premature cell battery depletion – PG	3	3 (0.3)
Random component failure – Therapy available	1	1 (0.1)
Conversion test-related	10	10 (0.9)
Out of Range shock impedance – Electrode	1	1 (0.1)
Unable to convert VT/VF with S-ICD	9	9 (0.8)
Device system infection	12	12 (1.1)
Device system infection (acute)	8	8 (0.7)
Device system infection (>30d post implant)	4	4 (0.4)
Post-op healing / pain management	23	23 (2.1)
Electrode suture discomfort	1	1 (0.1)
Device system discomfort	4	4 (0.4)
Post-surgical wound discomfort PG site	4	4 (0.4)
Incisional/Superficial infection	5	5 (0.4)
Suspected infection – Incisional/Superficial	1	1 (0.1)
Hematoma – PG pocket	4	4 (0.4)
Inadequate healing of incision site	2	2 (0.2)
Physical trauma	2	2 (0.2)
Other procedure-related	12	12 (1.1)
Adverse reaction – Respiratory	1	1 (0.1)
Adverse reaction – Hypotension	3	3 (0.3)
Adverse reaction – Medication/Anaphylactic shock	1	1 (0.1)
Adverse reaction – HF symptoms	1	1 (0.1)
Acute blood loss	1	1 (0.1)
postoperative urinary retention	1	1 (0.1)
Hemodynamic instability – DFT testing	1	1 (0.1)
Fascial defect closure	1	1 (0.1)
Suture revision	1	1 (0.1)
Syncope	1	1 (0.1)
Other patient-related	2	2 (0.2)
Outcome of elective MV and LAA closure surgery	1	1 (0.1)
Weight loss	1	1 (0.1)

Supplemental Table 3

Causes of Death

Cause of Death	Number of Patients
Cardiac	28
<i>Arrhythmic</i>	4
<i>Ischemic etiology, N (%)</i>	2
<i>Pump Failure</i>	14
<i>Unknown</i>	8
Non Cardiac	21
Unknown	8
Total	57

Supplemental Table 4

Tipping point analyses

Endpoint	Rate Among Subjects with Complete Data	Tipping Point	Total Subjects with Incomplete Data	P (observe events>Tipping point), given Rate Among Subjects with Complete Data
Primary: Inappropriate Shocks in 18 months	41/826 (5.0%)	37	286	<.0001
Secondary: All Cause Shocks in 18 months	94/844 (11.1%)	45	268	<.0001
Secondary: 30 day complications	47/1109 (4.2%)	>7	7	N/A

In regards the 30-day complication endpoint, the tipping point is greater than the total subjects with incomplete data, thus the probability of missing the endpoint if we had data from these patients is zero.

Supplemental Table 5

Study Sites and Investigators

Investigational Site	Primary Investigator
The Toledo Hospital	Johan Aasbo, Timothy Phelan
William Beaumont Hospital	Hazim Al-Ameri
Genesis Healthcare System	Abdulhay Albirini
Albany Medical Center	Rizwan Alimohammad
Hospital Virgen De La Salud	Miguel Arias
Hospital de la Pitie-Salpetriere	Nicolas Badenco
Russells Hall Hospital	Craig Barr
CHU Dijon	Geraldine Bertaux
Methodist Hospital of Indianapolis	Deepak Bhakta
Good Samaritan Hospital - San Jose	Sanjay Bindra
CHRU Nancy Brabois	Hugues Blangy
St. Antonius Ziekenhuis	Lucas Boersma
Clinique Pasteur	Serge Boveda
University Hospital Odense	Johansen Brock
CorVita Science Foundation	Martin Burke
Universitaetsmedizin Greifswald	Mathias Busch
Hospital Miguel Servet	Naiara Calvo
Blackpool Victoria NHS Trust Direct	Christopher Cassidy
CHU de Strasbourg	Michel Chauvin, Halim Marzak
Long Island Jewish Medical Center	Jason Chinitz
Sentara Norfolk General Hospital	Allen Ciuffo
Yale University School of Medicine	Jude Clancy
North Mississippi Medical Center	Karl Crossen
Azienda Ospedaliera Papa Giovanni XXIII	Paolo De Filippo
CHU La Timone Hospital	Jean-Claude Deharo
Lutheran Medical Group	Fausto Devecchi, Sreekanth Karanam
Heart Center Research, LLC	Jay Dinerman
University of Southern California Hospital	Rahul Doshi
University Hospital of Muenster	Lars Eckardt
Salem Hospital	Matthew Fedor
University of Utah Hospital and Clinics	Roger Freedman
University of North Carolina Hospital	Anil Gehi
Clinique Saint-Jean	Peter Goethals
Universitaetsklinik Eppendorf	Nils Gosau
Abington Memorial Hospital	Charles Gottlieb
HealthEast St. Joseph's Hospital	Gregory Granrud
St. Joseph Mercy Hospital	Radmira Greenstein

Aultman Hospital	Firas Hamdan
Beth Israel Medical Center	Sam Hanon
Sharp Grossmont Hospital	Alborz Hassankhani
AnMed Health	Rick Henderson
University Hospital Frankfurt	Stefan Hohnloser
Strong Memorial Hospital of the University of Rochester	David Huang
CH Annecy	Didier Irles
Virginia Commonwealth University Health System	Gautham Kalahasty
Deborah Heart and Lung Center	Pedram Kazemian
Tallahassee Memorial Hospital	Farhat Khairallah
St. Joseph Hospital	Brian Kim
Evergreen Hospital Medical Center	Edward Kim
Deutsches Herzzentrum Berlin	Christoph Klein
Northwestern Memorial Hospital	Bradley Knight
Academisch Medisch Centrum	Reinoud Knops
HealthCare Partners Cardiology	Niuton Koide
Centra Stroobants Cardiovascular Center	Richard Kuk
St. Bartholomews Hospital	Pier Lambiase
CHRU Hopital Pontchaillou	Christophe Leclercq
Alta Bates Summit Medical Center	Michael Lee
Mercy Research	Shang-Chiun Lee
Unfallkrankenhaus Berlin Marzahn	Corinna Lenz
Northern General Hospital	Nigel Lewis
Durham VA Medical Center	Robert Lewis
Cardiovascular Associates of the Delaware Valley	George Mark
CHRU de Lille	Christelle Marquie
St. Mary's Madison	Kelly McDonnell
Glendale Adventist Medical Center	John Mckenzie
Emory University Hospital	Faisal Merchant
Rex Hospital	Sameh Mobarek
Cardiocentro Ticino	Tiziano Moccetti
Institut universitaire de Cardiologie et de Pneumologie de Quebec	Franck Molin, Francois Philliopon
Azienda Ospedaliera Universitaria Integrata di Verona	Giovanni Morani
Ochsner Clinic Foundation	Daniel Morin
Glenfield Hospital	G. Ng
Peninsula Cardiology Associates	Emmanuel Nsah
South Texas Veterans Health Care System	Manoj Panday
CHU Montpellier	Jean-Luc Pasquie
Hospital Clinico San Carlos	Nicasio Castellano Perez
Hospital San Lucas	Francisco Perez-Gil
Centralny Szpital Kliniczny Uniwersytetu Medycznego	Pawel Ptaszynski

Alabama Cardiovascular Group	Anil Rajendra
University of Iowa Hospitals and Clinics	Troy Rhodes
Southampton University Hospital	Paul Roberts
Cox Health	Steven Rowe
Cooper Hospital - University Medical Center	Andrea Russo
University of Pittsburgh Medical Center	Samir Saba
Baptist Medical Center	Venkata Sagi
Cardiology Physicians PA	Brian Sarter
Centracare Heart and Vascular Center	John Schoenhard
St. Vincent's Hospital	John Schutzman
Mayo Clinic Phoenix	Luis Scott
CHI Franciscan Health System	Nathan Segerson
AdventHealth Orlando	Naushad Shaik
CardioVascular Institute of Michigan P.C.	Ali Shakir
Memorial Mission Hospital	Matthew Smelley
University Hospital Zurich	Jan Steffel
Medical University of South Carolina	J. Lacy Sturdivant
Heartland Cardiology	Ghiyath Tabbal
Mercy Gilbert Medical Center	Drory Tandler
Erasmus MC - University Medical Center Rotterdam	Dominic Theuns
Universitair Ziekenhuis Gent	Liesbeth Timmers
Sacred Heart Medical Center at Riverbend	Matthew Trojan
The Nebraska Medical Center	Shane Tsai
University of Chicago Hospital	Gaurav Upadhyay
University Hospital Augusta	Santosh Varkey
Azienda Ospedaliero Universitaria Pisana	Stefano Viani
Christus Trinity Mother Frances Health System	Stanislav Weiner
Ohio State University Medical Center	Raul Weiss
Advanced Cardiovascular Specialists	Sherman Wiggins
Liverpool Heart and Chest Hospital	David Wright
Harbor UCLA Medical Center	Andrew Zadeh
Universitaetsklinikum Heidelberg	Edgar Zitron