

INSPIREMD, INC.

FORM 8-K (Current report filing)

Filed 09/10/13 for the Period Ending 09/10/13

Address	321 COLUMBUS AVENUE BOSTON, MA 02116
Telephone	(857) 453-6553
CIK	0001433607
Symbol	NSPR
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment & Supplies
Sector	Healthcare
Fiscal Year	12/31

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 10, 2013

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other
jurisdiction
of incorporation)

001-35731
(Commission File Number)

26-2123838
(IRS Employer
Identification No.)

800 Boylston Street, Suite 16041
Boston, Massachusetts
(Address of principal executive offices)

02199
(Zip Code)

Registrant's telephone number, including area code: (857) 453-6553

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4 (c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure.

Attached hereto as Exhibit 99.1 is a PowerPoint presentation that InspireMD, Inc. (the “Company”) will present on September 10, 2013 at the Rodman & Renshaw Global Investment Conference in New York City.

The information furnished in this Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Rodman & Renshaw Global Investment Conference Presentation

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

InspireMD, Inc.

Date: September 10, 2013

By: /s/ Craig Shore
Name: Craig Shore
Title: Chief Financial Officer



NYSE MKT: NSPR

September 2013

Disclaimer

Forward-Looking Statements:

This presentation contains "forward-looking statements." Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the control of InspireMD, Inc. (the "Company"), and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) market acceptance of the Company's existing and new products, (ii) negative clinical trial results or lengthy product delays in key markets, (iii) an inability to secure regulatory approvals for the sale of the Company's products, (iv) intense competition in the medical device industry from much larger, multi-national companies, (v) product liability claims, (vi) the Company's limited manufacturing capabilities and reliance on subcontractors for assistance, (vii) insufficient or inadequate reimbursement by governmental and other third party payors for the Company's products, (viii) the Company's efforts to successfully obtain and maintain intellectual property protection covering its products, which may not be successful, (ix) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (x) the Company's reliance on single suppliers for certain product components, (xi) the fact that the Company will need to raise additional capital to meet its business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain and (xii) the fact that the Company conducts business in multiple foreign jurisdictions, exposing it to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements are set forth in the Company's filings with the Securities and Exchange Commission, including the Company's Transition Report on Form 10-K/T and its quarterly reports on Form 10-Q. Investors and security holders are urged to read these reports free of charge on the Securities and Exchange Commission's web site at www.sec.gov. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

An emerging medical device company developing and commercializing advanced stent technology for interventional cardiology and other vascular procedures

- NYSE MKT: NSPR
- Stock Price (9/3/13): \$2.12
- Shares Outstanding: 34.3 Million
- Total Cash (3/31/13): \$2.5 Million
 - Does not include net proceeds of \$14.1 million from capital raise in April 2013

Investment Highlights

- Appointed new, experienced management and Board members with proven track records
- Proprietary platform technology addressing the multi-billion dollar global stent market
 - Initially targeting AMI market (i.e. heart attacks)
 - MGuard™ is the only stand alone stent technology proven to demonstrate a positive effect on STEMI patients in a randomized clinical trial
 - Broad pipeline in development for multiple indications
- Pivotal 12-month clinical data to be released Oct 30, 2013 for the MASTER trial
 - Achieved primary endpoint with sustained mortality benefit at 30 days and 6 months
- Commercialization:
 - 12 month MASTER data to provide clinical platform to accelerate sales activities in key international markets
 - U.S. sales pending FDA approval and completion of MASTER II trial



Novel Technology

- Current stent technology:
 - Targets the Stable Angina patient (i.e. general chest pain from poor blood flow through the blood vessels in the heart)
 - Unstable Angina patients (i.e. AMI) represent complex clinical problem not addressed by current stent technologies
- InspireMD's MGuard™ is a game changing platform technology
 - Reduces mortality rate*
 - Reduces myocardial damage associated with AMI*
 - Based on proprietary MicroNet™ technology

* Per the 6-month follow-up results from the MASTER trial

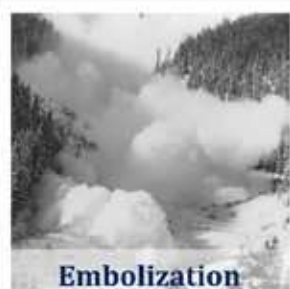


Suboptimal Standard of Care

Treating AMI



Pre Procedure



Embolization



Post Procedure

Minor heart attack treated with a Bare Metal Stent (BMS) or Drug Eluting Stent (DES) implant

Causes:

Debris can flow down stream, occluding small arteries
"Distal Embolization"

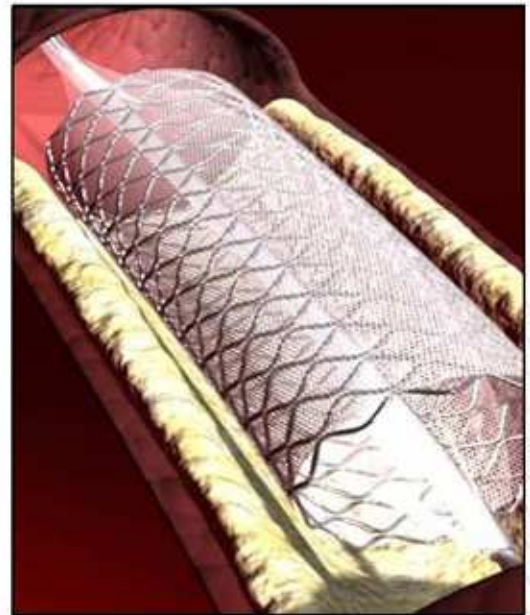
Leading To:

Cardiac Mortality and Morbidity

InspireMD

Technology Overview

- Combines stent and embolic protection in a single device
 - Reduces risk of embolization by capturing potentially harmful debris against the artery wall
 - Micro-particles then slowly re-enter the artery in a non-harmful way over approximately 30 days
 - MicroNet™ acts as safety net by offering greater surface area coverage to prevent large debris flow



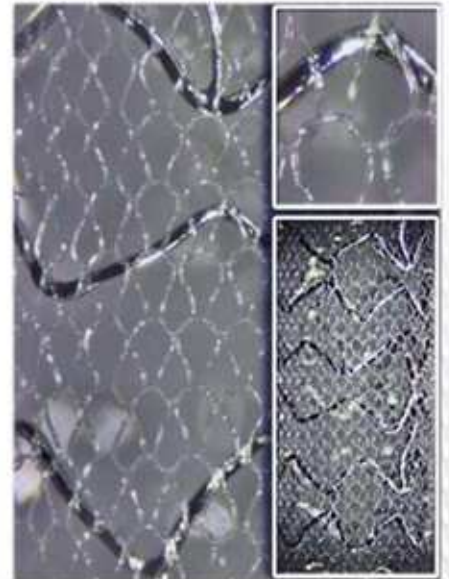
After MGuard™
Particulate trapped behind mesh

MicroNet™ Technology

Proprietary circular knitted mesh wraps around stent to protect patient from plaque debris flowing downstream upon deployment

Advantages of MicroNet™:

- Made of a single fiber from a biocompatible polymer, widely used in medical implantations
- Flexible structure
- Does not promote thrombosis



InspireMD

InspireMD Pipeline

	Target Indication	Stage of Development	Market Size
Commercial	Coronary STEMI / AMI	<ul style="list-style-type: none"> 12-month data to be released in October Commercialization prep ongoing in anticipation of 12-month data CE mark received Seeking FDA approval by 2016 	<ul style="list-style-type: none"> AMI Segment: \$1.7B
	Coronary Drug Eluting	<ul style="list-style-type: none"> Planned product 	<ul style="list-style-type: none"> Total Drug Eluting: \$4.0B
Developing	Carotid	<ul style="list-style-type: none"> CE mark received 	<ul style="list-style-type: none"> Total Carotid: \$250M
	Peripheral Vasculature	<ul style="list-style-type: none"> CE mark anticipated in H1 2014 	<ul style="list-style-type: none"> Total Peripheral: \$2B+
	Aneurysmal	<ul style="list-style-type: none"> Planned product 	<ul style="list-style-type: none"> Total Aneurysm: \$350M+
	Renal	<ul style="list-style-type: none"> Planned product 	<ul style="list-style-type: none"> Total Renal: \$100M+



MGuard™ Clinical Overview

Coronary EPS

- 6 single-center studies in Europe and South America
 - Consistent positive clinical outcomes
- MASTER Trial (**M**Guard™ for **A**cute **ST** **E**levation **R**eperfusion)
 - Multi-center, randomized clinical trial
 - Improved mortality, results confirmed*
- MASTER II (for FDA approval)
 - Began enrollment in July 2013
 - Enrollment expected to conclude in Q4 2014



* Per the 6-month follow-up results from the MASTER trial



The MASTER Trial

MGuard™ for Acute ST Elevation Reperfusion

STEMI with symptom onset within 12 hours at
432 patients | 50 sites | 9 countries

PCI with BMS or DES

PCI with MGuard™

Recruitment: 7/2011 – 5/2012
Follow-up: 30 days, 6 months, 1 year
Primary endpoint: ST-segment resolution at 60-90 minutes
Top Line Data: 8/2012
Detailed Data: 10/2012

Substudies

Cardiac MRI: 60 patients (30 in each arm) at 3-5 days
Angio FU: 50 patients in MGuard arm at 13 months



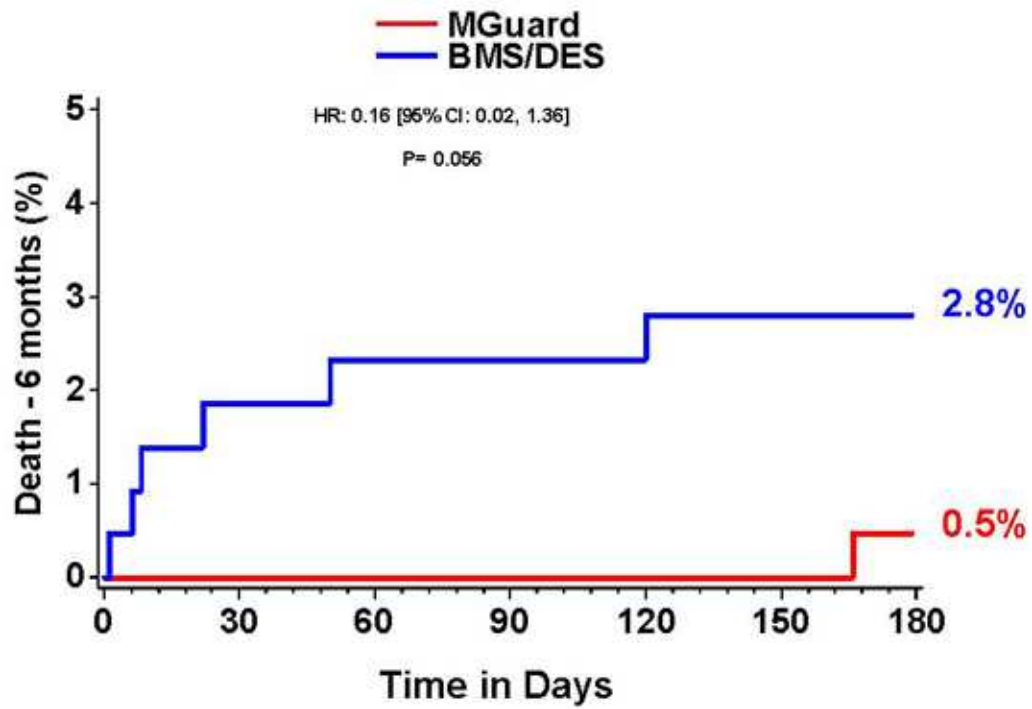
MASTER Trial Highlights

- Achieved primary end point
 - Superiority in ST Resolution – 57.8% vs. 44.7%
- Reduction in mortality rate at 6-months:
 - Occurred in 1/217 (0.5%) patients with MGuard™
 - Occurred in 6/216 (2.8%) patients with BMS or DES
- Reduced Infarct size*
 - 17.1gm (MGuard™) vs 22.3gm (BMS/DES)

*MRI Substudy – 60 patients



All Cause Mortality at 6 Months



MASTER II Trial

- **Status:** First patient recruited in July 2013
- **Objective:** Evaluate safety and efficacy of MGuard™ Prime Coronary vs. BMS and DES in STEMI
- **Co-Primary Endpoints:**
 - Efficacy: Superiority in complete ST Resolution
 - Safety: Non inferiority in death and Target Vessel MI
- **Design:** Multi-center (70 sites), randomized trial
- **Population:** 1,100, STEMI Randomized 1:1 vs. FDA approved BMS or DES
- **PI's:**
 - Gregg Stone, M.D. FACC, Columbia University
 - Jose Henriques, M.D., University of Amsterdam



MGuard™ EPS Commercialization

- Received CE Mark for AMI indication; expect to submit for FDA approval post-MASTER II trial
- Establishing Embolic Protection Stent (EPS) as a new stent category as the preferred solution for STEMI patients
- Developing sales infrastructure to support a focused and phased selling approach in select high-volume markets
 - Sales activities to accelerate after 12-month MASTER trial data revealed
 - HealthLink Europe to support logistics and distribution capabilities



MGuard™ EPS Sales Strategy

Selectively scaling global reach and frequency

Tier 1

- Mix of direct sales representatives, agents and distributors, with focus on KOL's/high-volume AMI centers
- 14-18 countries, primarily Europe and Brazil

Tier 2

- Country or regional partnerships with high quality local distributors or Strategic partners with regional AMI focused strategies

Tier 3

- United States - Pending successful clinical trial outcomes
- Japan - Pending successful clinical trial outcomes

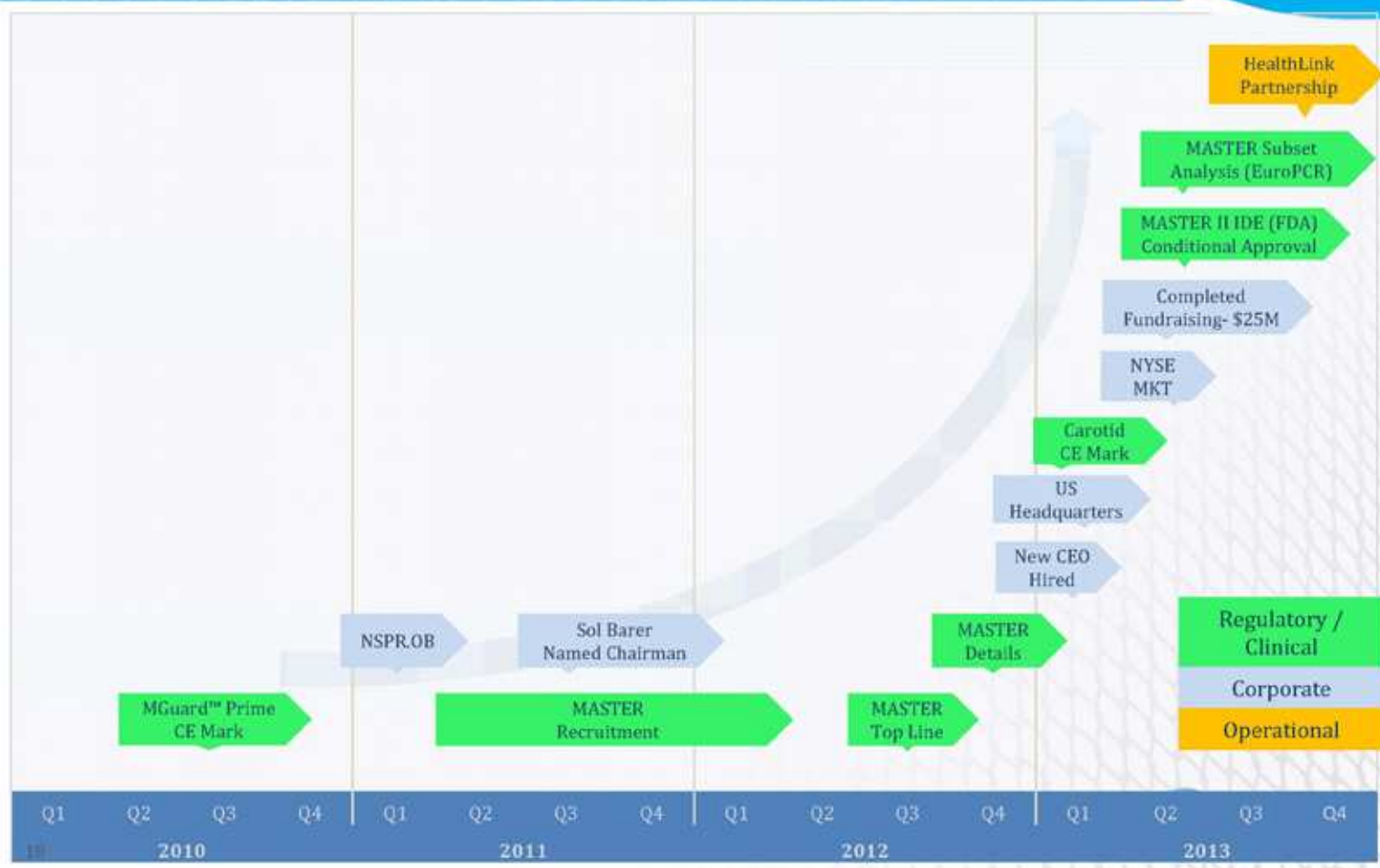


MGuard™ Manufacturing

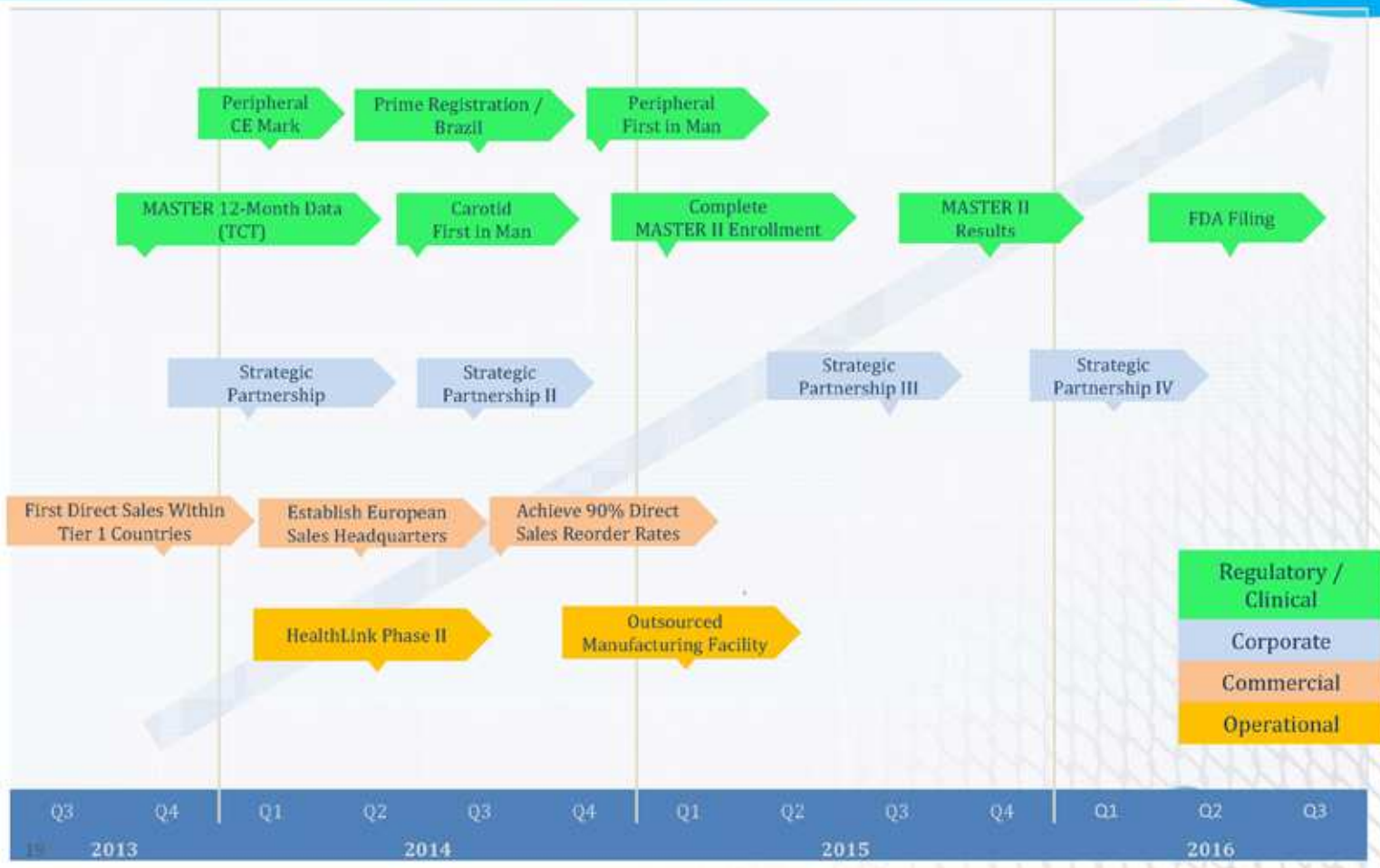
- Platform technology (MicroNet™) produced in-house
- Bare metal stent and catheter manufactured by third-party
- Final product assembled at InspireMD facility, including attachment of proprietary mesh sleeve to the stent
- Recently consolidated facilities to capture additional margin
- Additional manufacturing expected to be fully outsourced



Milestones To-Date



Anticipated Future Milestones



Intellectual Property

- 7 Patent Families
- Filings in U.S. and overseas
- 37 patents
 - 6 granted (1 USA), 31 pending
- Stent platform: U.S. Freedom to Operate legal opinion

IP Protects Key Attributes of MicroNet™ Technology

Anchoring

Drug Delivery

Macro
Structure

Fiber Width



Experienced Leadership Team



Sol Barer, PhD
Chairman of the Board
 • Former Chairman and CEO, Celgene, (NASDAQ: CELG)



Alan Milinazzo
President & CEO
 • Orthofix
 • Medtronic
 • Boston Scientific



Campbell Rogers, PhD
Director
 • CMO, Heartflow
 • CSO, Cordis/JNJ
 • Associate Professor, Harvard School of Medicine
 • Recipient of grants from NIH and AHA



James Barry, PhD
Director
 • EVP and COO, Arsenal Medical
 • VP, Corporate Research and Advanced Technology Development at Boston Scientific
 • Howmedica Division of Pfizer



Michael Berman, MBA
Director
 • Pres. Boston Scientific/Scimed
 • Aetherworks
 • Apnex
 • Benechill
 • Cardiosonic



Craig Shore, MBA
CFO
 • Pfizer, Bristol Myers Squibb, and Dunn and Bradstreet, General Electric
 • RIT Technologies (NASDAQ)



Eli Bar, BSc
CTO
 • Product development
 • R&D infrastructure
 • Fully implantable VAD patent



Chaim Lotan, M.D., F.A.C.C. F.E.S.C
Medical Director
 • Hebrew University
 • Hadassah Medical Center



Scientific Advisory Board



Prof. Gregg Stone

- Professor of Medicine at the Columbia University Medical Center
- Director of Cardiovascular Research and Education at the Center for Interventional Vascular Therapies at New York-Presbyterian Hospital, and CRF in New York, NY



Prof. Antonio Colombo

- Director of the Cardiac Catheterization Laboratory at Columbus Hospital
- Chief of Invasive Cardiology at San Raffaele Hospital, both in Milan, Italy



Prof. Dariusz Dudek

- Executive Board of the Working Group on Invasive Cardiology of the Polish Cardiac Society
- Associate professor of the Jagiellonian University, Krakow, Poland



Dr. Yaron Almagor

- Director of Cardiac Catheterization and Interventional Cardiology Laboratories at Jesselson Heart Center, Shaare Zedek Medical Center; Jerusalem, Israel



Prof. Elazer Edelman M.D., Ph.D., F.A.C.C

- Professor of Health Sciences and Technology at MIT. Cardiologist at the Brigham and Women's Hospital in Boston
- Directs the Harvard-MIT Biomedical Engineering Center (BMEC)



Dr. Martin B. Leon

- Director, Center for Interventional Vascular Therapy Columbia University Medical Center / New York-Presbyterian Hospital, New York, NY
- Professor of Medicine Columbia University College of Physicians and Surgeons New York, NY



Prof. Alexandre A. Abizaid

- Chief of Coronary Interventions at Institute Dante Pazzanese de Cardiologia in São Paulo, Brazil
- Associate-director of TCT (Columbia University, U.S.)



Prof. Eberhard Grube

- Professor of Medicine, Chief of the Department of Cardiology and Angiology at Siegburg Heart Centre, Germany



Dr. Edo Kaluski, MD, FACC, FESC

- Director of Cardiac Catheterization Laboratories and Invasive Cardiology at the University Hospital in Newark, New Jersey
- Co-founder of InspireMD



Prof. Chaim Lotan

- Head of The Heart Institute Hadassah University Medical Center.
- Chairman of the Ministry of Health Committee for Certification & Licensing of Coronary Stents

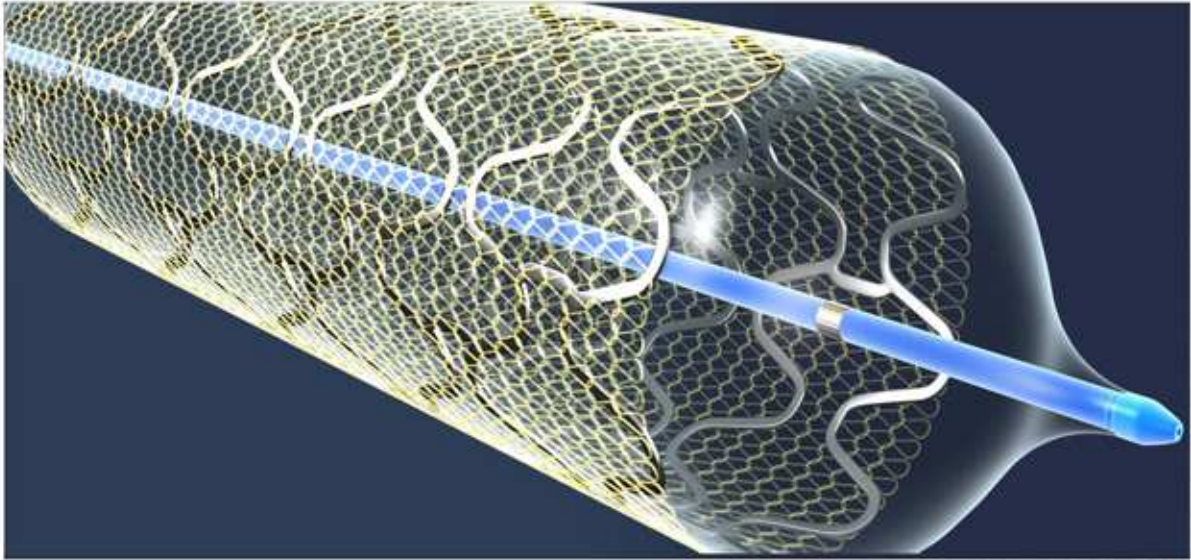
InspireMD

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Thank You



InspireMD

Appendix

MASTER Trial

Detailed Analysis

MASTER, although not powered for non primary endpoint measurements, showed statistical significance and positive trends for key measurements.

Clinical Events at 30 Days		
	MGuard (n=217)	Control (n=216)
MACE	4 (1.8%)	5 (2.3%)
- Cardiac mortality ⁽¹⁾	0 (0.0%)	4 (1.9%)
- Reinfarction	3 (1.4%)	2 (0.9%)
- TLR, ischemia-driven	4 (1.8%)	1 (0.5%)

3-5 Day MRI Substudy Results		
	MGuard (n=30)	Control (n=29)
Infarct mass, grams	17.1 [10.0,30.0]	22.3 [15.7,30.1]
Infarct mass (% total LV mass)	13.3 [7.9,25.0]	16.6 [10.0,22.6]
Total MVO, grams	0.3 [0.0,1.6]	1.0 [0.2, 2.8]
MVO (% total LV mass) ⁽²⁾	0.4 [0.0,1.4]	0.8 [0.2,1.9]
LVEF (%)	48.3 [44.5,52.3]	47.3 [42.0,54.5]

Measurement of Blood Flow		
	MGuard (n=217 ⁽⁴⁾)	Control (n=216)
Aspiration Performed	65.9%	67.1%
Stent Type		
- BMS		59.7%
- DES		39.8%
TIMI Flow = 3 ⁽³⁾	91.7%	82.9%
TIMI Flow = 2 ⁽³⁾	6.5%	11.6%
TIMI Flow = 0/1 ⁽³⁾	1.8%	5.6%
Myocardial Blush = 2/3	83.9%	84.7%

- (1) Data showing a positive trend
 (2) MVO = microvascular obstruction
 (3) Data is statistically significant
 (4) 191 MGuard, 26 MGuard Prime



MGuard™

Clinical Results Summary

Clinical Trials	ST Resolution	Death		MACE	
		30 days	1 year	30 days	1 year
MAGICAL	61.00%	0.00%	1.80%	0.00%	1.80%
Piscione	90.00%	2.20%	4.50%	N/A	5.60%
Weerakody	N/A	0.00%	0.00%	N/A	6.00%
iMOS	N/A	2.00%	N/A	2.80%	6.80%
Gaul	58.00%	N/A	N/A	N/A	N/A
MICAMI	N/A	0.00%	N/A	0.00%	N/A
MASTER	57.8%	0.00%	N/A	1.8%	N/A

Acute and 30 Day results:

- Superior ST Segment resolution
- Improved TIMI 3 Flow/ reduced TIMI 0-1 occurrence
- Trend toward reduced infarct size measured by MRI
- Trend towards lower mortality with 0 deaths in treatment group vs. 4 deaths in control arm
- **What impact over time?**

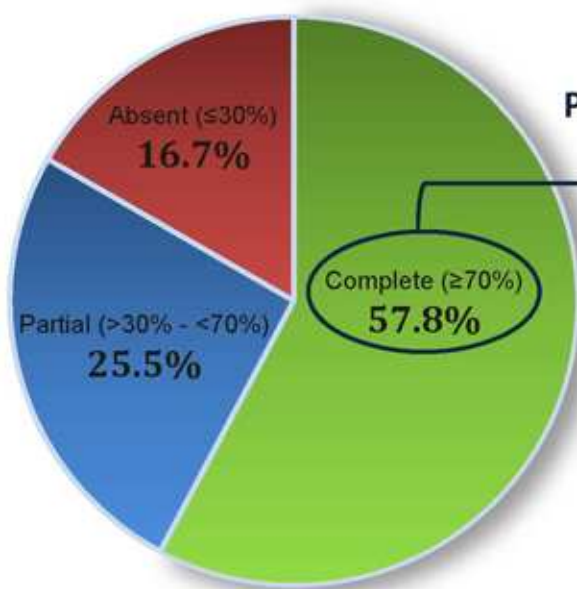
6 Month Clinical Results*

	MGUARD (N=217)	CONTROL BMS / DES (N=216)	P Value
MACE	11 (5.2%)	7 (3.4%)	0.34
All cause mortality	1 (0.5%)	6 (2.8%)	0.06
Cardiac death	1 (0.5%)	5 (2.3%)	0.10
Reinfarction	3 (1.4%)	2 (0.9%)	0.66
TLR, ischemia-driven	10 (4.8%)	2 (1.0%)	0.02
TVR, ischemia-driven	13 (6.2%)	2 (1.0%)	<0.01
Stent Thrombosis			
Definite or Probable	4 (1.8%)	2 (0.9%)	0.42
Definite	4 (1.8%)	1 (0.5%)	0.18
Stroke	1 (0.5%)	0 (0.0%)	0.32
TIMI Bleeding			
Major or Minor	5 (2.30%)	5 (2.3%)	0.99
Major	4 (1.8%)	4 (1.3%)	0.71

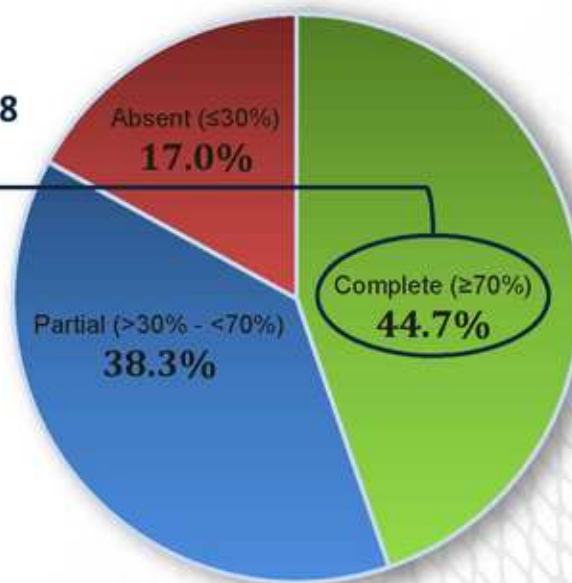
Master Trial - Primary Endpoint

Complete ST Segment Resolution

MGuard (n=204)



Control (n=206)

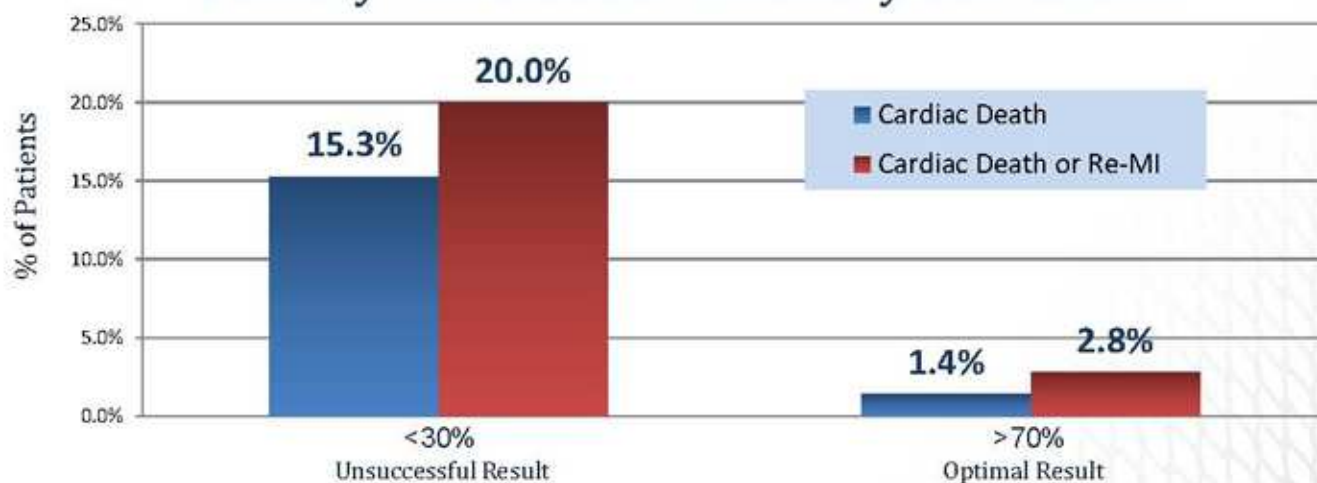


P value = 0.008

Relative Improvement: 29.3% (absolute - 13.2%)

Clinical Significance of ST Segment Resolution

TAPAS: Thrombus Aspiration During Primary Percutaneous Coronary Intervention

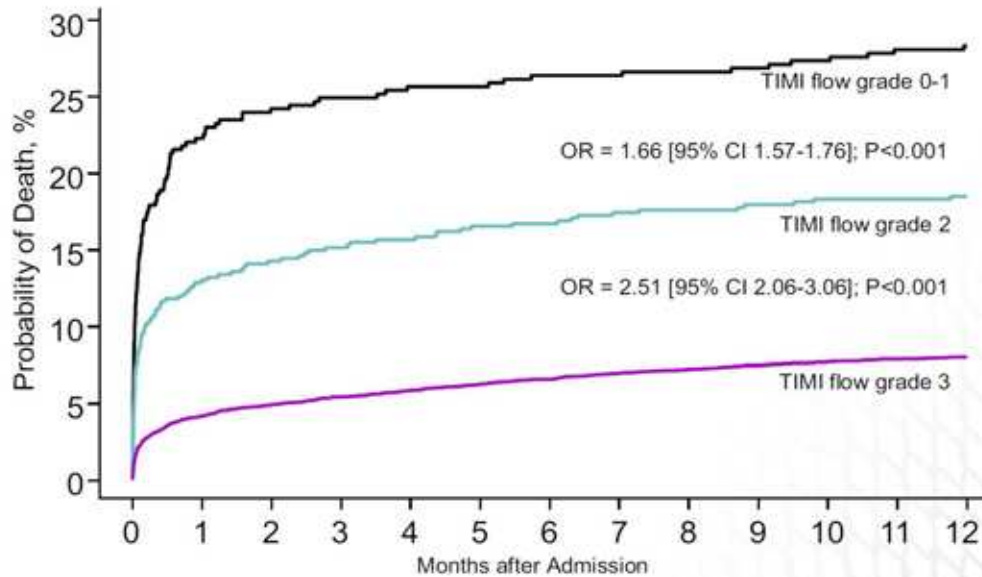


In STEMI, occurrence of major clinical events at 1 year is significantly related to ST resolution*



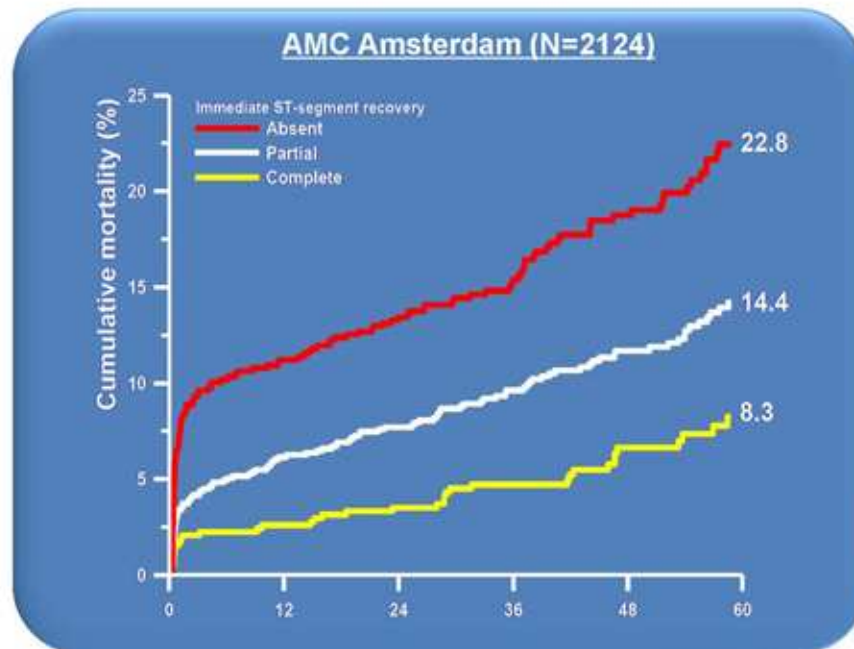
STEMI Reperfusion

Goal: Achieve 90% TIMI 3 flow within 90'



STEMI Reperfusion:

ST-Resolution after PCI in STEMI



ST-Resolution immediately post PCI is a strong predictor of long term mortality

STEMI Reperfusion

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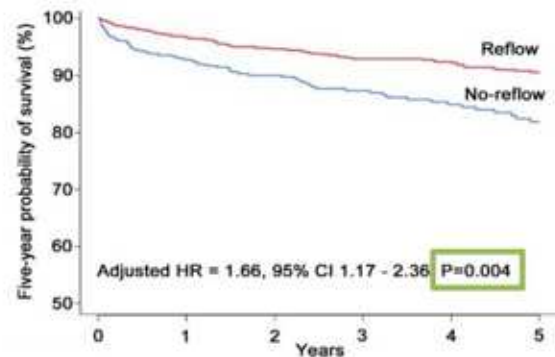
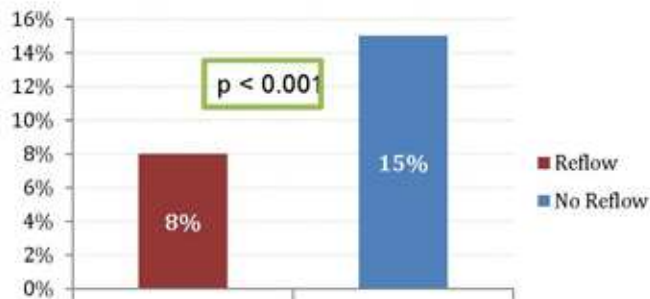
5-Year Prognostic Value of No-Reflow Phenomenon After Percutaneous Coronary Intervention in Patients With Acute Myocardial Infarction

Gjin Ndrepepa, MD,* Klaus Tirosch, MD,* Maximiliano Finazzo, MD,* Dritan Keta, MD,* Melchior Seyfarth, MD,* Robert A. Byrne, MD,* Jürgen Pache, MD,* Patricia Alger, MD,* Julinda Mehilli, MD,* Albert Schömig, MD,*† Adnan Kastrati, MD*

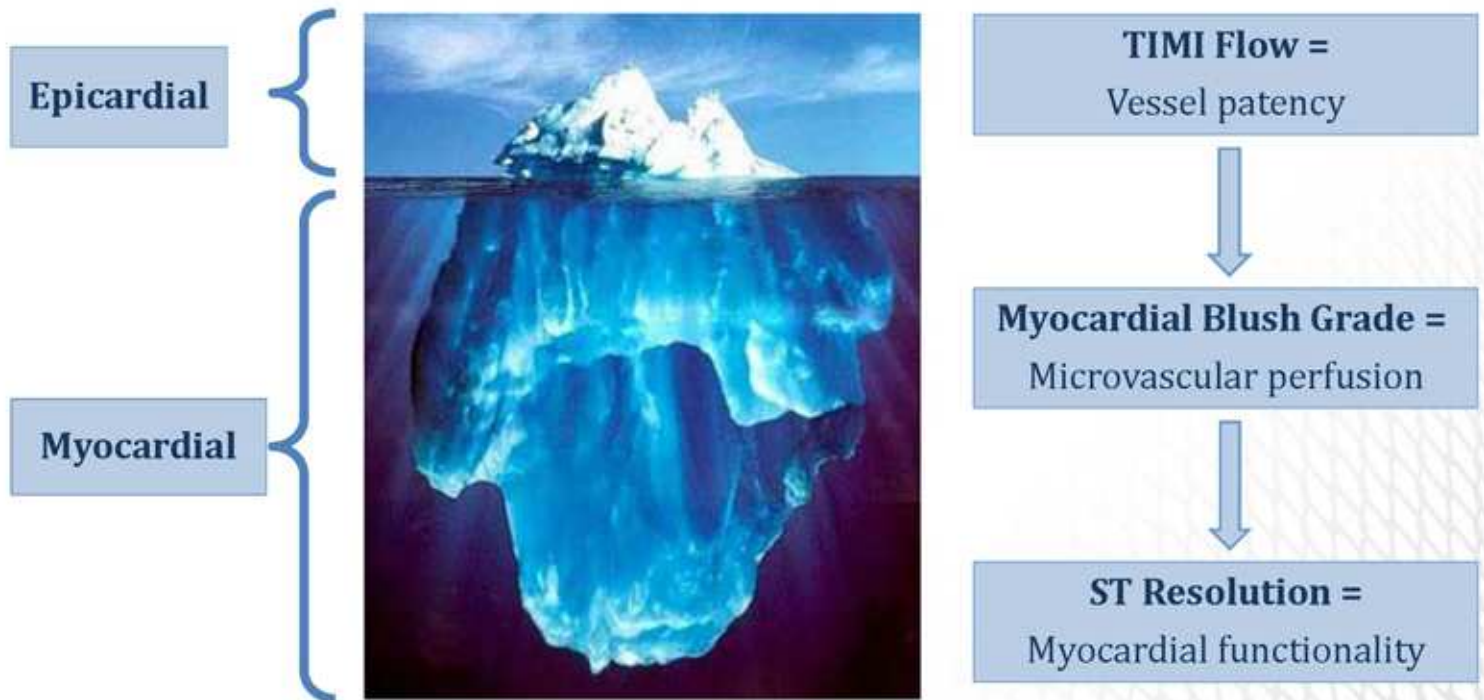
Munich, Germany

No Reflow increases infarct size and mortality

Infarct Size



STEMI Reperfusion



Reperfusion will have impact on Infarct Size