INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 10/24/12 for the Period Ending 10/24/12

Address	321 COLUMBUS AVENUE
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Telephone	(857) 453-6553
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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): October 24, 2012

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware	000-54335	26-2123838
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4 Menorat Hamaor St. Tel Aviv, Israel	67448
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: 972-3-691-7691

(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.

On October 24, 2012, Gregg W. Stone M.D., the chairman of InspireMD, Inc.'s MASTER *(**M** Guard for **A** cute **ST E** levation **R** eperfusion)* trial and Director Cardiovascular Research and Education Center for Interventional Vascular Therapy at New York Presbyterian Hospital/Columbia University Medical Center, will present results of the trial at the Late Breaking Trials Session at the 24th Annual Transcatheter Cardiovascular Therapeutics (TCT) scientific meeting in Miami, Florida at 11:39 a.m. Eastern Time.

InspireMD, Inc. issued a press release announcing this presentation on October 24, 2012. A copy of the press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is hereby incorporated by reference herein. A copy of the presentation is attached as Exhibit 99.2 to this report.

The information in this Current Report and the accompanying exhibits is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), or 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.

Certain statements contained in the press release and the presentation constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and involve a number of risks and uncertainties. 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 InspireMD, Inc.'s control, 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 our 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 our products, (iv) intense competition in the medical device industry from much larger, multi-national companies, (v) product liability claims, (vi) our limited manufacturing capabilities and reliance on subcontractors for assistance, (vii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (viii) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (ix) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (x) our reliance on single suppliers for certain product components, (xi) the fact that we will need to raise additional capital to meet our business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain and (xii) the fact that we conduct business in multiple foreign jurisdictions, exposing us 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 is set forth in the Company's filings with the Securities and Exchange Commission, including the Company's Transition Report on Form 10-KT For the transition period from January 1, 2012 to June 30, 2012 and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's web site at http://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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated October 24, 2012.
99.2	Slide show presentation dated October 24, 2012.

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: October 24, 2012

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release dated October 24, 2012.
99.2	Slide show presentation dated October 24, 2012.

Exhibit 99.1

Reported At TCT 2012:

InspireMD MGuard Stent Meets Primary Endpoint Of MASTER Trial,
Significantly Improving Prospects Of Heart Attack Survival

MGuard™ Embolic Protection Stent (EPS) Shows a Significant 29 Percent Improvement in Complete ST Resolution Compared to Bare Metal or Drug Eluting Stents

MIAMI, FL, OCT 24, 2012 – InspireMD, Inc. (OTC: NSPR) ("InspireMD" or the "Company"), announced its proprietary MGuard™ Embolic Protection Stent (EPS) was shown to be significantly superior when compared to standard bare metal and drug eluting stents in achieving complete ST resolution and restoring normal blood flow in a major study of 432 randomized patients undergoing em-ergency coronary intervention for potentially fatal heart attacks.

The data was reported at the Late Breaking Trials Session at the 24th Annual Transcatheter Cardiovascular Therapeutics (TCT) scientific meeting in Miami, FL today by Gregg W. Stone M.D., the study's chairman and the Director of the Cardiovascular Research and Education Center for Interventional Vascular Therapy at New York-Presbyterian Hospital/Columbia University Medical Center.

The findings show the novel MGuard EPS provides a significant acute advantage an d, as a result, may hold the potential to lower the incidence of adverse sequela and prolong survival of heart attack victims.

The study met its primary endpoint (proportion of patients with ST segment resolution of≥ 70%, measured at 60 to 90 minutes post procedure), showing the MGuard EPS was significantly superior to the control arm of bare metal and drug eluting stents in the treatment of heart attack patients.

●Significantly more patients treated with the MGuard EPS achieved complete ST resolution (a measure of blood flow restoration to the heart muscle) compared to control arm (57.8% vs. 44.7%, P=0.008), a relative improvement of 29 percent.

●When compared to control, the MGuard EPS showed a significant improvement in coronary artery blood flow, including: (1) superior rates of restoring normal blood flow (TIMI-3 flow) (91.7% vs. 82.9%, P=0.006, a relative improvement of 10.6%); and (2) significantly less incomplete blood flow (TIMI-0/1 flow) post PCI (1.8% vs. 5.6%, P=0.01, a relative improvement of 67.9%).

• The trial showed a trend toward lower mortality (0% vs. 1.9%, P=0.06) at 30 days and smaller infarct size as measured by post procedure cardiac MRI (17.1gr vs. 22.3gr, p=0.27) in the MGuard EPS arm versus control.

●There was no difference between the groups in the secondary endpoint of myocardial blush grade (MBG), which is an angiographic measure of blood flow to the cardiac muscle (MBG2/3 83.9% vs. 84.7%, P=0.81).

"I was impressed with the performance of the MGuard Embolic Protection Stent in the MASTER trial," said Dr. Stone. "Compared to standard stents, the MGuard is the first stent in a randomized trial shown to restore complete ST-segment resolution in a higher proportion of patients, a key predictor of myocardial salvage and long-term survival in STEMI (ST segment elevation myocardial infarction) patients."

The MGuard EPS is integrated with a precisely engineered micro net mesh that prevents the unstable arterial plaque and thrombus (clots) that caused the heart attack blockage from breaking off.

Results Published In *Journal of American Cardiology*

T he MASTER *(**M** Guard for **A** cute **ST E** levation **R** eperfusion)* trial randomized 432 patients to MGuard EPS (217) and to either bare metal or drug eluting stents (216). Fifty centers in nine countries participated in the trial. Patients are being followed for one year.

Details of the MASTER trial were published online today in the *Journal of American College of Cardiology* (JACC).

The authors concluded that "among patients with acute STEMI undergoing emergent PCI enrolled in the present multicenter, randomized, controlled trial, the MGuard EPS micro net covered stent compared to standard metallic stents resulted in superior rates of epicardial coronary flow and complete STR, with trends present toward reduced microvascular obstruction, infarct size and mortality."

About Stenting And MGuard EPS

Stenting is a routine procedure for heart attack patients. It opens up the clogged artery that caused the attack.

Standard stents weren't engineered for heart attack patients. They were designed for treating stable angina patients whose occlusion is different from that of an occlusion in a heart attack patient.

In acute heart attack patients the plaque or thrombus is unstable and often breaks up as the stent is implanted causing downstream blockages (some of which can be fatal) in a significant portion of heart attack patients.

InspireMD's solution is the MGuard EPS, a metal stent that's secured inside a proprietary knitted net made of micro polymer fibers, each thinner than a human hair.

The Micronet™ is designed to hold plaque or thrombus in place against the blocked artery's wall, preventing debris from entering the blood stream.

While offering superior performance relative to standard stents in STEMI patients, the MGuard EPS requires no change in current physician practice – an important factor in promoting acceptance and general use in time-critical emergency settings.

MGuard™ EPS is CE Mark approved.

About TCT

Dr. Stone's presentation, titled "A Prospective, Randomized Trial of PET Micronet Mesh-Covered Stent vs. Standard Stents in Patients with ST-Segment Elevation Myocardial Infarction, took place this morning in Miami, FL in the main arena of the TCT.

TCT (Transcatheter Cardiovascular Therapeutics) is the annual scientific symposium of the Cardiovascular Research Foundation. TCT gathers leading medical researchers and clinicians from around the world to present and discuss the latest developments in the field.

The Cardiovascular Research Foundation (CRF) is an independent, academically focused nonprofit organization dedicated to improving the survival and quality of life for people with cardiovascular disease through research and education. Since its inception in 1991, CRF has played a major role in realizing dramatic improvements in the lives of countless numbers of patients by establishing the safe use of new technologies, drugs and therapies in interventional cardiovascular medicine. For more information about CRF, visit www.crf.org .

About InspireMD, Inc.

InspireMD is a medical device company focusing on the development and commercialization of its proprietary stent system technology, MGuard ™ . InspireMD intends to pursue applications of this technology in coronary, carotid and peripheral artery procedures. InspireMD's common stock is quoted on the OTC under the ticker symbol NSPR

About MGuard™ Embolic Protection Coronary Stent

MGuard™ EPS combines a coronary stent merged with an embolic protection specifically designed for acute MI patients. The embolic protection is comprised of an ultra-thin polymer micron net that is integrated with the stent. The MGuard EPS is designed to provide outstanding and lifelong embolic protection, without affecting deliverability. MGuard EPS is CE Mark approved. MGuard™ is not approved for sales in the U.S. by the U.S. Food and Drug Administration at this time.

Forward-looking Statements:

This press release 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 Company's control, 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 our 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 our products, (iv) intense competition in the medical device industry from much larger, multi-national companies, (v) product liability claims, (vi) our limited manufacturing capabilities and reliance on subcontractors for assistance, (vii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (viii) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (ix) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (x) our reliance on single suppliers for certain product components, (xi) the fact that we will need to raise additional capital to meet our business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain and (xii) the fact that we conduct business in multiple foreign jurisdictions, exposing us 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 is set forth in the Company's filings with the Securities and Exchange Commission, including the Company's Annual Report on Form 10-K, its Transition Report on From 10-K/T and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's web site at http://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.

For additional information:
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212 926-1733
203 222-7399
inspiremd@redingtoninc.com

Exhibit 99.2

The MASTER Trial

A Prospective, Randomized, Multicenter Evaluation of a PET Micronet Mesh Covered Stent (MGuard) in STEMI

Gregg W. Stone, MD

Columbia University Medical Center
NewYork-Presbyterian Hospital
Cardiovascular Research Foundation

Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Consulting Fees/Honoraria	• Abbott Vascular, Boston Scientific, Medtronic, InspireMD, Atrium

Background

- Suboptimal myocardial reperfusion after PCI in STEMI is common, and results in increased infarct size and mortality
- The MGuard Embolic Protection Stent (EPS) s a novel thin-strut metallic stent with a PET micronet covering designed to trap and exclude thrombus and friable atheromatous debris to prevent distal embolization

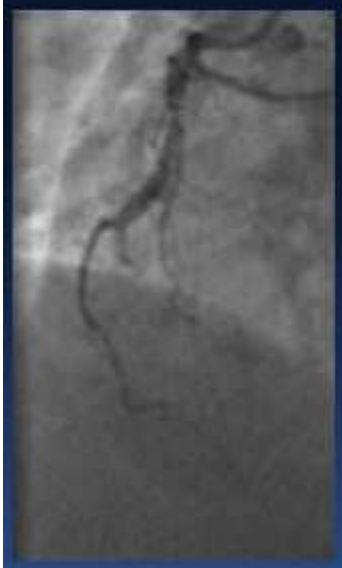
The MGuard and MGuard Prime Embolic Protection Stent (EPS)

	MGuard	MGuard Prime
Metallic frame	316L stainless steel	L605 cobalt chromium
Strut width	100 µm	80 µm
Crossing profile	1.1 – 1.3 mm	1.0 – 1.2 mm
Shaft dimensions	0.65 – 0.86 mm	0.65 – 0.86 mm
Mesh sleeve	PET**	PET**
- Fiber width	20 µm	20 µm
- Net aperture size	150 - 180 µm	150 - 180 µm

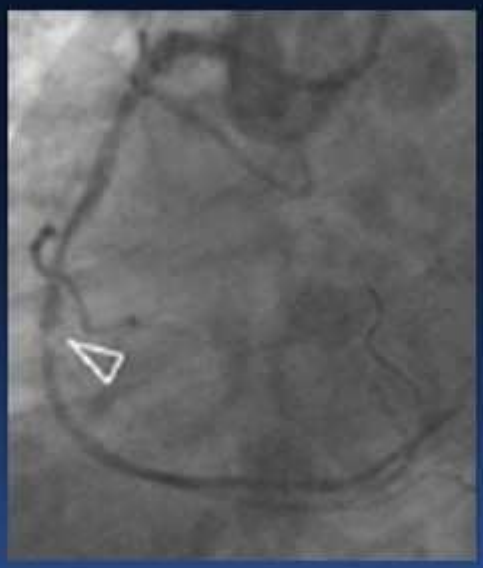
TCT2012

*InspireMD, Tel Aviv, Israel; **Polyethyleneterephthalate

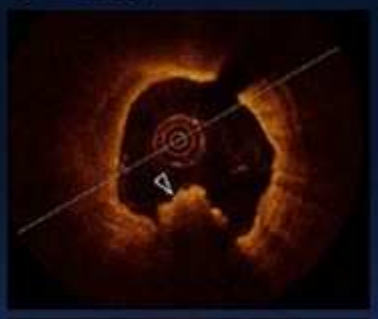
Thrombus Entrapment by the MGuard in STEMI

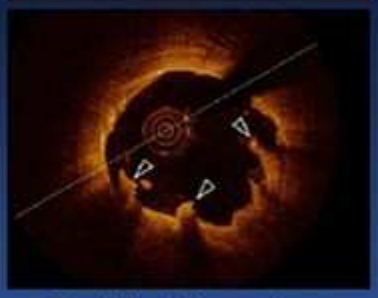


Pre



Post aspiration



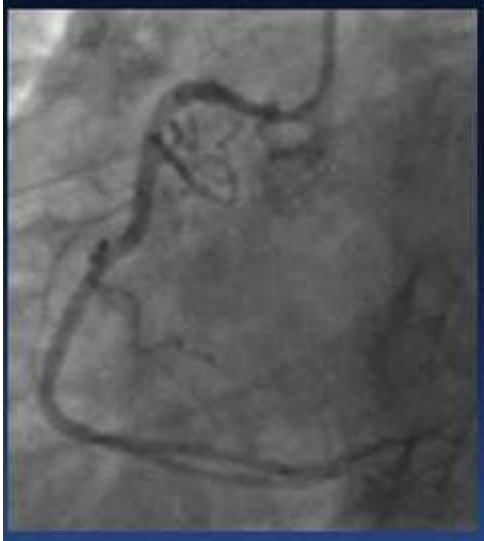


Residual thrombus

TCT2012

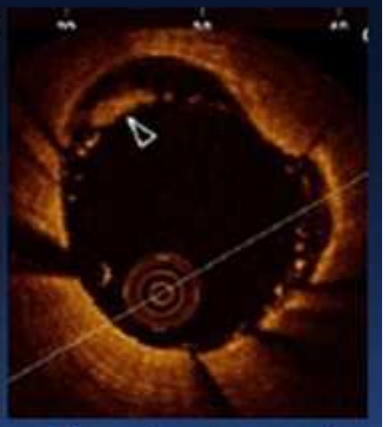
Jain AK and Rothman MT. JACC 2011;58;e39

Thrombus Entrapment by the MGuard in STEMI



Post MGuard

Mesh



Thrombus trapped behind mesh

Jain AK and Rothman MT. JACC 2011;58;e39

MGUARD for Acute ST Elevation Reperfusion
The MASTER Trial

STEMI with symptom onset within 12 hours at
432 pts at 50 sites in 9 countries

R

Stratified by infarct vessel
and thrombus aspiration

PCI with BMS or DES

PCI with MGuard

Follow-up: 30 days, 6 months, 1 year

Primary endpoint: ST-segment resolution at 60-90 minutes

Substudies:

Cardiac MRI: 60 pts (30 pts in each arm) at 3-5 days

Angio FU: 50 pts in MGuard arm at 13 months

TCT2012

Principal Inclusion Criteria

- Symptoms consistent with STEMI within 12 hours of symptom onset
- ≥2 mm of ST-segment elevation in ≥2 contiguous leads
- PCI of a single de novo lesion with RVD ≥3.0 to ≤4.0 mm and length ≤33 mm (capable of being covered by a single study stent)

Principal Exclusion Criteria

- LBBB, paced rhythm, etc.
- Prior PCI within 6 months or prior CABG anytime
- LVEF ≤20%, cardiogenic shock or CPR
- ≥50% left main stenosis present
- Infarct lesion ostial or bifurcation with ≥2.0 mm sidebranch
- Target vessel or infarct lesion excessively tortuous, angulated or with moderate to heavy calcification
- Prior stent proximal or w/i 10 mm distal to the target

Primary Endpoint and Power

- Primary endpoint: Complete ST-segment resolution (STR), defined as ≥70% reduction in the summed 12-lead extent of ST-segment elevation from the baseline to the post-procedure (60-90') ECG as determined by a blinded, independent electrocardiographic core laboratory
- Power: With 412 pts, 80% power is present to demonstrate a 21.7% relative improvement in complete STR from 60% to 73% (2-sided α=0.05)
  - Assuming 95% evaluable paired ECGs, enrollment was planned for 432 pts

Study Organization

Principal investigators:	Alexandre Abizaid, Dariusz Dudek, Sigmund Silber
Study chairman:	Gregg W. Stone
Executive committee:	GW Stone, A Abizaid, D Dudek, S Silber, C Lotan, MB Leon, E Bar, E Yaacoby, M Ivenshitz
Data monitoring:	KCRI, Poland; MedPass Int, France; CRC, Brazil; Tal Yerushalmi, Israel; Modestas Jarutis, Ireland; Adele Liebenberg and Brendalynne Bezuidenhout, South Africa
Data management:	InspireMD, Tel Aviv, Israel.
Data analysis and biostatistics:	Cardiovascular Research Foundation (CRF), NY, NY; Helen Parise (Director), Ovidiu Dressler
Event adjudication:	Cardiovascular Research Center (CRC), Sao Paulo, Brazil; Andrea Abizaid, MD (Director)
STR and MRI core labs:	CRF; S Wolff, A Maehara, E Cristea, P Genereux (Directors)
Angio core labs:	CRC; Ricardo Costa (Director), and CRF; Sorin J. Brener (myocardial blush analysis)
DSMB:	B Gersh (Chair), D Faxon, S Pocock
Sponsor and funding:	InspireMD, Tel Aviv, Israel

Top 12 Enrolling Sites

Between July 22, 2011 and May 29, 2012,
433 pts were randomized at 50 sites in 9 countries

1. Bela Merkely, Semmelweis University, Budapest, Hungary	37
2. Dariusz Dudek, University Hospital in Krakow, Krakow, Poland	33
3. Ran Kornowski, Rabin Medical Center, Petach Tiqva, Israel	31
4. Roman Wojdyła, Krakow Center of Invasive Cardiology, Electrotherapy and Angiology, Krakow, Poland	23
5. Dezső Apró, State Hospital for Cardiology, Balatonfured, Hungary	19
6. Haim Danenberg, Hadassah U Medical Center, Jerusalem, Israel	19
7. Itzhak Herz, Laniado Hospital, Netanya, Israel	18
8. Bogdan Januś, E. Szczeklik Specialized Hospital, Tarnow, Poland	16
9. Marc A. Ohlow, Zentralklinik Bad Berka, Bad Berka, Germany	15
10. Krystrof Żmudka, John Paul II Hospital, Krakow, Poland	15
11. Jacek Legutko, INTERCARD, Nowy Targ, Nowy Targ, Poland	15

Baseline Characteristics

	MGuard stent (n=217)	Control stent (n=216)
Age (years)	60 [52, 68]	58 [51, 67]
Male	75.1%	76.9%
Hypertension	42.3%	47.4%
Hyperlipidemia	27.4%	27.1%
Diabetes mellitus	12.0%	18.1%
Cigarette smoking	55.3%	46.8%
Prior MI	3.7%	8.8%
Prior PCI	3.7%	5.6%
Symptoms to device, mins	207 [156, 308]	240 [140, 383]
Infarct artery = LAD	40.1%	40.3%
Baseline TIMI flow = 0/1	66.5%	74.0%
Baseline RVD, mm	3.15 [2.87, 3.38]	3.06 [2.87, 3.40]
Baseline DS %	100 [85, 100]	100 [88, 100]

Procedural Medications

	MGuard stent (n=217)	Control stent (n=216)	*P* value
Anti-platelet agents, peri-procedural			
– Aspirin	98.6%	99.1%	1.0
– ADP antagonists	95.4%	95.8%	0.82
– Clopidogrel	72.9%	70.0%	0.51
– Ticlopidine	0.5%	0.0%	1.0
– Prasugrel	21.7%	20.8%	0.81
– Ticagrelor	4.8%	9.2%	0.08
Anticoagulation, peri-procedural			
– Unfractionated heparin	96.8%	96.3%	0.79
– Glycoprotein IIb/IIIa inhibitor	82.9%	83.3%	0.92
– Bivalirudin	11.1%	12.5%	0.64

Procedures

	MGuard stent (n=217)	Control stent (n=216)	*P* value
Aspiration performed	65.9%	67.1%	0.79
Balloon pre-dilatation performed	50.2%	44.9%	0.27
Direct stenting	12.0%	10.6%	0.66
≥1 stent implanted	99.5%	100.0%	1.0
≥2 stents implanted	12.9%	10.6%	0.47
Stent type			
– MGuard	96.3%*	0.5%	<0.0001
– Bare metal stent	1.4%	59.7%	<0.0001
– Drug-eluting stent	2.3%	39.8%	<0.0001
Total stent length, mm	19 [15, 24]	20 [15, 24]	0.64
Post stent dilatation performed	36.4%	30.6%	0.20
Maximal device size, mm	3.5 [3.0, 3.5]	3.5 [3.0, 3.5]	0.78
Maximal dilatation pressure, atm	16 [14, 18]	16 [14, 18]	0.02**

*191 MGuard, 26 MGuard Prime
**Marginally higher in the MGuard group

Device Success

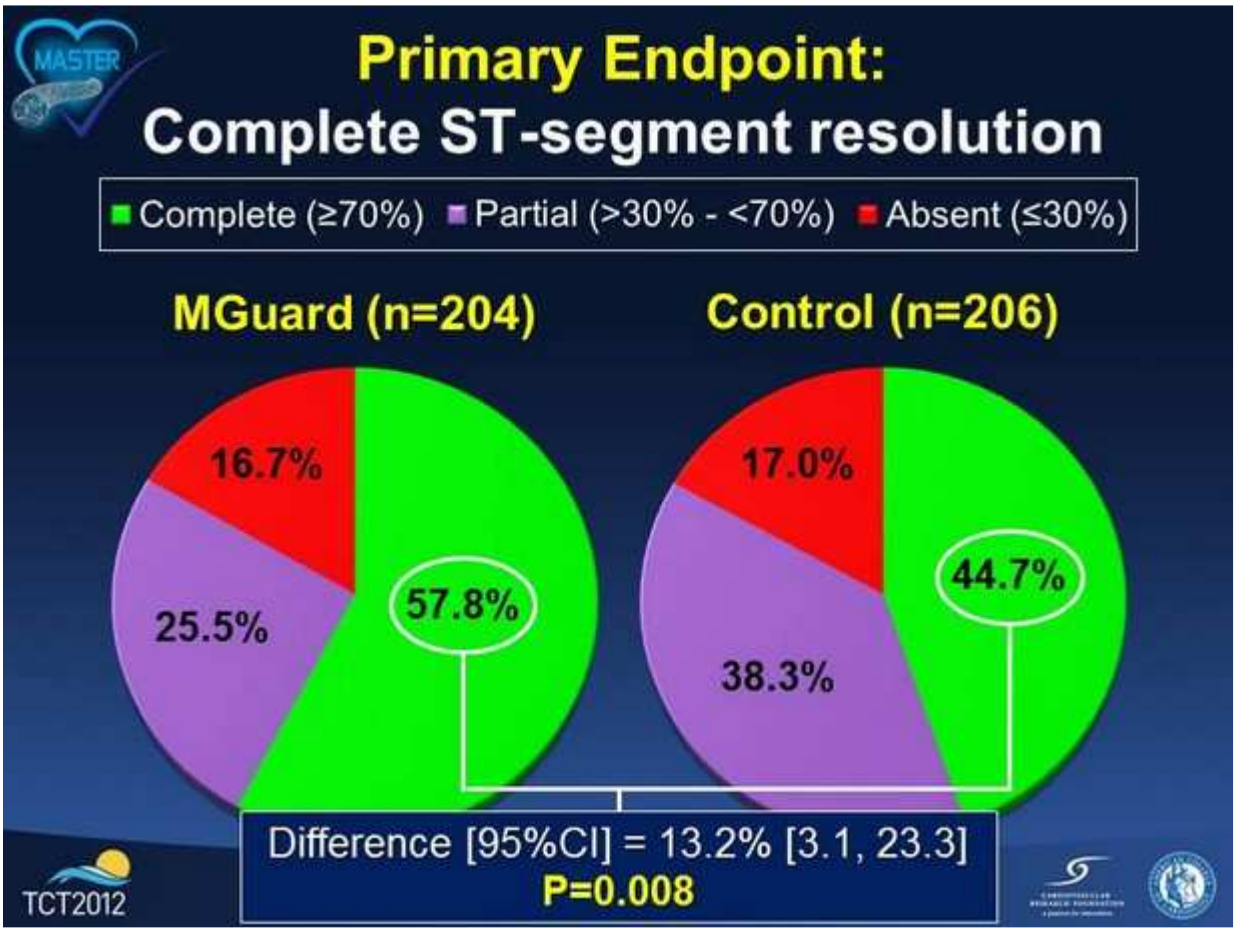
Device success: <50% final residual stenosis using only the randomized stent
Lesion success: <50% final residual stenosis using any percutaneous method
Angiographic success: <50% final residual stenosis and final TIMI 3 flow

*9/217 cases (4.1%), including 9/191 (4.7%) and 0/26 (0%) cases in which the original MGuard and MGuard Prime devices were used, respectively

Procedural Results

	MGuard stent (n=217)	Control stent (n=216)	*P* value
TIMI flow = 3	91.7%	82.9%	0.006
TIMI flow = 2	6.5%	11.6%	0.06
TIMI flow = 0/1	1.8%	5.6%	0.01
Corrected TIMI frame count	17 [12, 23]	18 [13,22]	0.23
Myocardial blush = 2/3	83.9%	84.7%	0.81
IPTE	21.7%	22.3%	0.87
RVD, mm	3.20 [2.90, 3.46]	3.16 [2.91, 3.46]	0.99
MLD, in-stent, mm	2.99 [2.73, 3.25]	2.99 [2.69, 3.31]	0.91
MLD in-lesion, mm	2.64 [2.40, 2.96]	2.64 [2.36, 2.95]	0.82
DS%, in-stent	6.9 [4.2, 10.5]	6.4 [3.9, 10.3]	0.56
DS%, in-lesion	15.3 [9.6, 21.2]	15.4 [10.8, 21.2]	0.66

IPTE = intraprocedural thrombotic events


Primary Endpoint:
Complete ST-segment resolution
Complete (≥70%)
Partial (>30% - <70%)
Absent (≤30%)
MGuard (n=204)
Control (n=206)
16.7%
25.5%
57.8%
17.0%
38.3%
44.7%
Difference [95%CI] = 13.2% [3.1, 23.3]
P=0.008
TCT2012

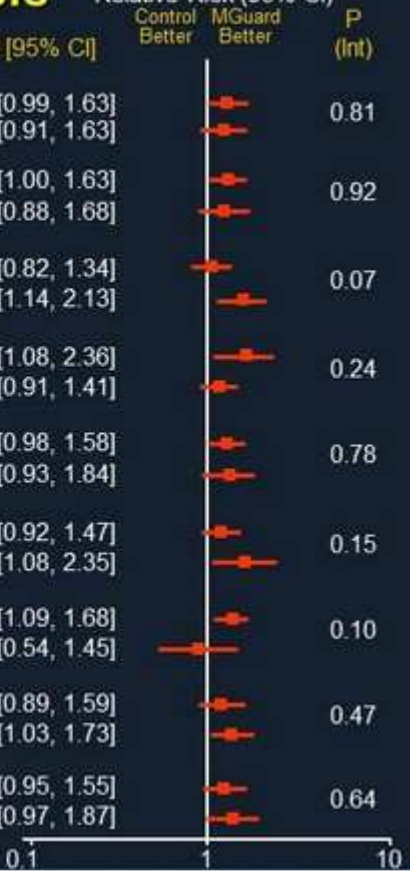
Primary Endpoint:
Complete ST-segment resolution
Multivariable predictors

	OR (95%CI)	P value
MGuard vs. control	1.73 (1.14 - 2.62)	0.01
Age (yrs)	1.03 (1.00 - 1.05)	0.02
Male	0.42 (0.25 - 0.71)	0.001
Current smoking	2.07 (1.31 - 3.27)	0.002

Variables: age, male, BMI, hypertension, hyperlipidemia, diabetes, current smoking, congestive heart failure, prior angina, prior MI, prior PCI, randomized group

Complete STR: Subgroup Analysis

Group	MGuard	Control	RR [95% CI]	P (Int)
Sex				
Male	80/163 (49.1%)	64/166 (38.6%)	1.27 [0.99, 1.63]	0.81
Female	38/54 (70.4%)	29/50 (58.0%)	1.21 [0.91, 1.63]	
Age				
≤65 years	78/149 (52.3%)	63/154 (40.9%)	1.28 [1.00, 1.63]	0.92
>65 years	40/68 (58.8%)	30/62 (48.4%)	1.22 [0.88, 1.68]	
Symptom onset to balloon time				
<Median (220 min)	63/114 (55.3%)	54/102 (52.9%)	1.04 [0.82, 1.34]	0.07
>Median	55/102 (59.2%)	39/113 (34.5%)	1.56 [1.14, 2.13]	
Infarct vessel				
LAD	41/87 (47.1%)	26/88 (29.5%)	1.60 [1.08, 2.36]	0.24
Non-LAD	77/130 (59.2%)	67/128 (52.3%)	1.13 [0.91, 1.41]	
Aspiration				
Used	77/143 (53.8%)	63/145 (43.4%)	1.24 [0.98, 1.58]	0.78
Not used	41/74 (59.2%)	30/71 (42.3%)	1.31 [0.93, 1.84]	
Initial TIMI flow				
0/1	74/143 (51.7%)	71/159 (44.7%)	1.16 [0.92, 1.47]	0.15
2/3	43/72 (59.7%)	21/56 (37.5%)	1.59 [1.08, 2.35]	
Vessel diameter				
<3.5 mm	102/179 (57.0%)	74/176 (42.0%)	1.36 [1.09, 1.68]	0.10
≥3.5 mm	16/38 (42.1%)	19/40 (47.5%)	0.89 [0.54, 1.45]	
Lesion length				
≤Median (7.8 mm)	54/109 (49.5%)	45/108 (41.7%)	1.19 [0.89, 1.59]	0.47
<Median	64/108 (59.3%)	48/108 (44.4%)	1.33 [1.03, 1.73]	
Maximum device size				
≤3.5 mm	73/135 (54.1%)	60/135 (44.4%)	1.22 [0.95, 1.55]	0.64
<3.5 mm	45/82 (54.9%)	33/81 (40.7%)	1.35 [0.97, 1.87]	



Clinical Events at 30 Days

	MGuard stent (n=217)	Control stent (n=214)	*P* value
MACE	4 (1.8%)	5 (2.3%)	0.75
– Cardiac mortality*	0 (0.0%)	4 (1.9%)	0.06
– Reinfarction	3 (1.4%)	2 (0.9%)	1.00
– TLR, ischemia-driven	4 (1.8%)	1 (0.5%)	0.37
TVR, ischemia-driven	6 (2.8%)	1 (0.5%)	0.12
Stent thrombosis, def/prob	3 (1.4%)	2 (0.9%)	1.00
Stroke	1 (0.5%)	0 (0.0%)	1.00
TIMI bleeding, major/minor	4 (1.8%)	4 (1.9%)	1.00

Mortality at 30 days occurred in 0/211 pts with complete STR and in 4/198 pts with partial or absent STR (0% vs 2.0%, p=0.05)

* There were no non-cardiac mortalities

3-5 Day MRI Substudy Results

	MGuard stent (n=30)	Control stent (n=29)	*P* value
Total LV myocardial mass, gms	141 [117, 163]	147 [118, 174]	0.41
Infarct mass, grams	17.1 [10.0, 30.0]	22.3 [15.7, 30.1]	0.27
Infarct mass (% total LV mass)	13.3 [7.9, 25.0]	16.6 [10.0, 22.6]	0.48
Total MVO, grams	0.3 [0.0, 1.6]	1.0 [0.2, 2.8]	0.14
MVO (% total LV mass)	0.4 [0.0, 1.4]	0.8 [0.2, 1.9]	0.39
Abnormal wall motion score	22.5 [20.0, 26.0]	25.0 [21.0, 27.0]	0.48
LVEF (%)	48.3 [44.5, 52.3]	47.3 [42.0, 54.5]	0.79

MVO = microvascular obstruction

Limitations

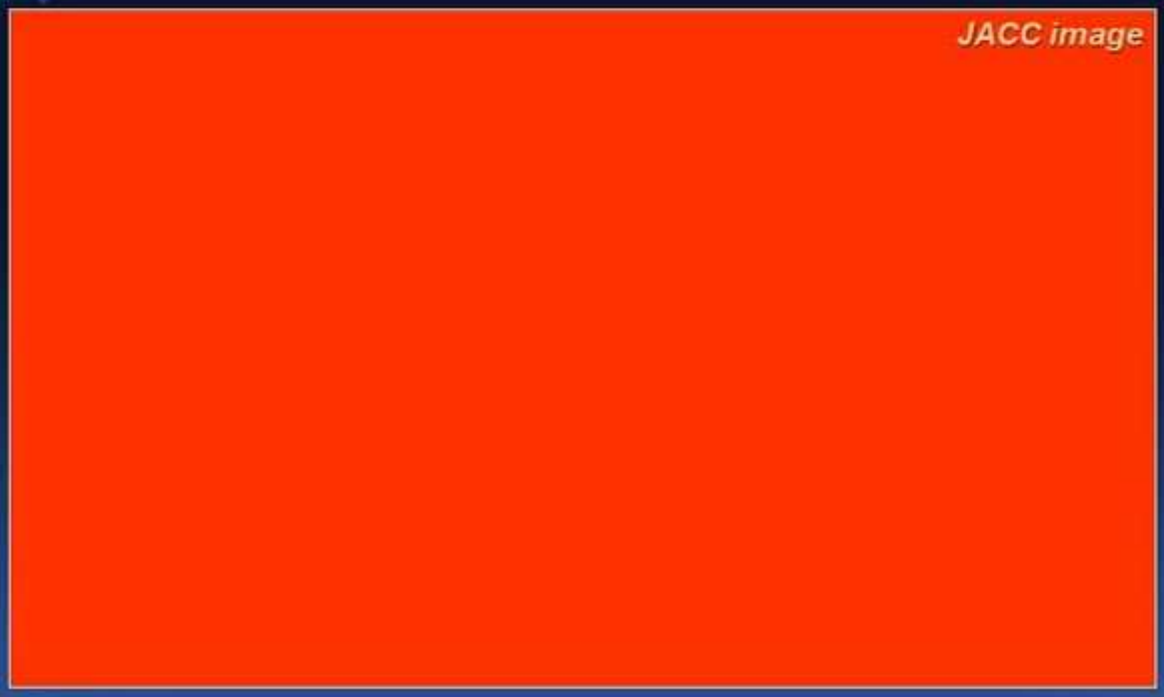
- Single-blind only
- Underpowered for infarct size and clinical events, and subgroup analyses should be considered hypothesis-generating.
- More experience with the MGuard Prime in STEMI is required
- Long-term clinical and angiographic follow-up is ongoing
- Discordance between TIMI flow, STR, infarct size, and death (improvement) vs. blush and IPTE (no significant change) is noted

Conclusions and Implications

- Among pts with acute STEMI undergoing emergent PCI, the MGuard micronet mesh covered stent compared to conventional metallic stents resulted in superior rates of epicardial coronary flow and complete STR
- A larger randomized trial is warranted to verify these findings, and determine whether these benefits result in reduced infarct size and/or improved clinical outcomes (MASTER II)

The MASTER Trial

JACC image



Stone GW et al. J Am Coll Cardiol 2012;

TCT2012