INSPIREMD, INC.

FORM 8-K
(Current report filing)

Filed 01/27/15 for the Period Ending 01/27/15

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): January 27, 2015

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-35731	26-2123838
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

321 Columbus Avenue Boston, Massachusetts	02116
(Address of principal executive offices)	(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 Professor Piotr Musiałek presented on January 27, 2015, at the LINC (**L** eipzig **I** nterve **N** tional **C** ourse) meeting in Leipzig, Germany, with respect to the six month follow-up data from its CGuard ™ CARENET (**CAR** otid **E** mbolic protection Study using micro **NET**) trial.

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 8.01 Other Events.

On January 27, 2015, InspireMD, Inc. (the "Company") issued a press release announcing that the Company received CE mark approval for its new CGuard RX rapid exchange system for its MicroNet ™ covered carotid stent technology and that the six month follow-up data from its CGuard ™ CARENET trial were presented at the LINC meeting in Leipzig, Germany on January 27, 2015.

A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	2015 LINC Presentation
99.2	Press release dated January 27, 2015

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: January 27, 2015

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

Exhibit 99.1

The **CARENET** all-comer trial using the **CGuard™** micronet-covered **carotid embolic prevention stent**

6 month data

Piotr Musialek, MD DPhil FESC

Jagiellonian University Dept. of Cardiac & Vascular Diseases
John Paul II Hospital, Krakow, Poland

Disclosures

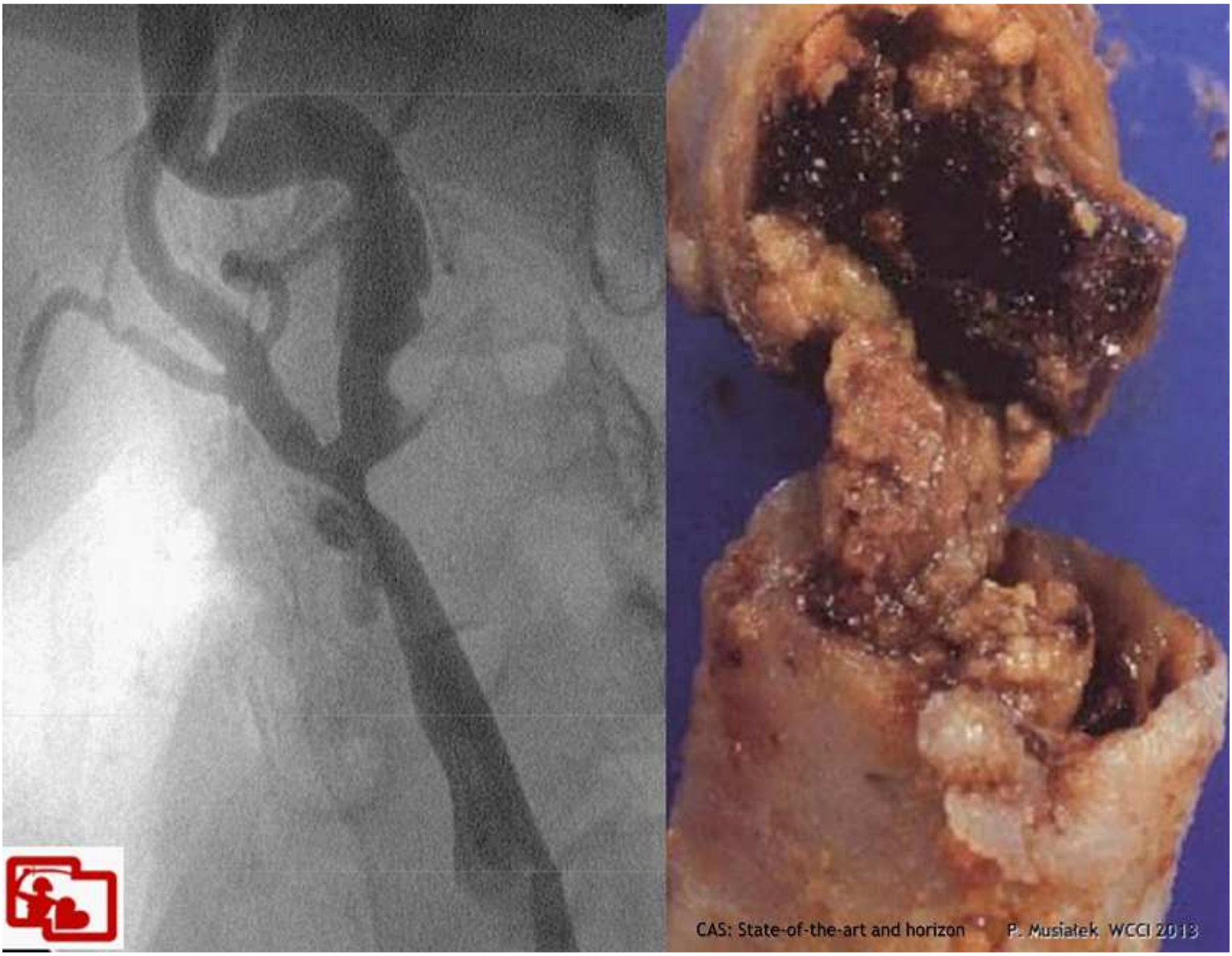
Research / Consulting / Speaker Beureau

Abbott

Cardio3 Biosciences

InspireMD

Medtronic


CAS: State-of-the-art and horizon
P. Musiałek WCCI 2013

CAS (and CEA) are –and will remain– emboli-generating procedures

Effect of the Distal-Balloon Protection System on Microembolization During Carotid Stenting

Nadim Al-Mubarak, MD; Gary S. Roubin, MD, PhD; Jiri J. Vitek, MD, PhD; Sriram S. Iyer, MD; Gishel New, MD; Martin B. Leon, MD

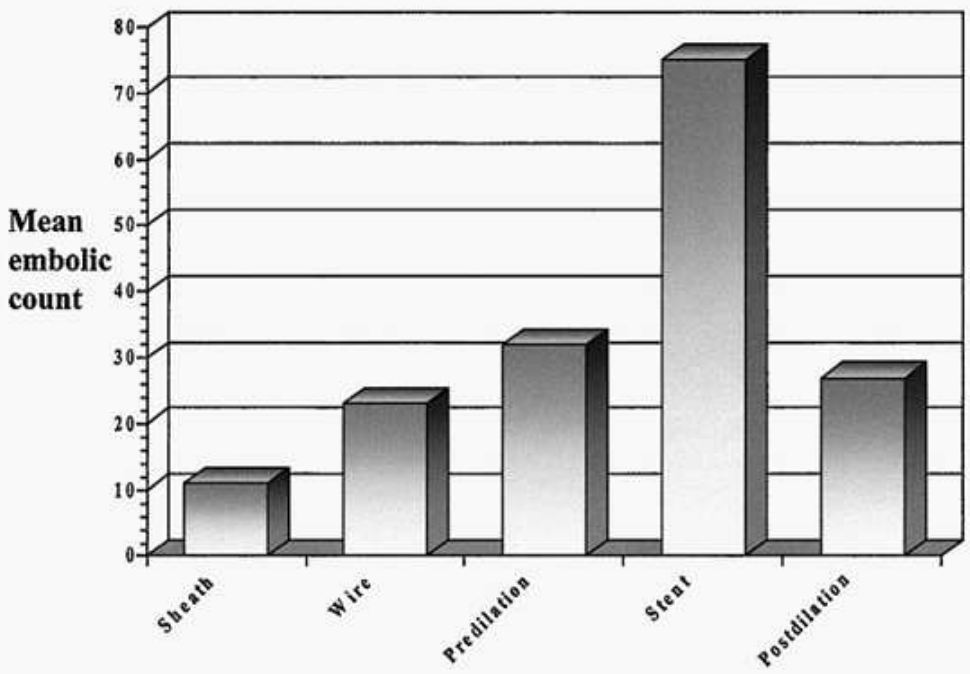


Figure 1. Microembolic profile during unprotected CAS. The mean MES counts during various phases of the procedure are displayed.

Circulation. 2001;104:1999-2002

Does Free Cell Area Influence the Outcome in Carotid Artery Stenting?

M. Bosiers,[1*] G. de Donato,[2] K. Deloose,[1] J. Verbist,[3] P. Peeters,[3]
F. Castriota,[4] A. Cremonesi[4] and C. Setacci[4]

Overview of event rates related to the different stents n = 3179 consecutive CAS patients

	Total population			Symptomatic population			Asymptomatic population		
	Patients	All events	Post-procedural events	Patients	All events	Post-procedural events	Patients	All events	Post-procedural events
Stent name									
X-act		1.9%	1.9%		2.2%	2.2%		1.7%	1.7%
Nexstent		3.3%	3.3%		0.0%	0.0%		4.2%	4.2%
Wallstent		2.3%	1.2%		2.3%	1.2%		2.3%	1.2%
Precise		4.1%	3.1%		6.3%	4.9%		2.0%	1.3%
Protégé		3.0%	3.0%		6.7%	6.7%		1.4%	1.4%
Acculink		4.2%	3.7%		7.7%	7.1%		1.7%	1.2%
Exponent		11.8%	5.9%		9.1%	9.1%		13.0%	4.3%
Total	3179	2.83%	1.9%		3.6%	2.73%	1862	2.25%	1.3%

2/3
CAS neuro events (stroke, TIA) are POST-procedural

Eur J Vasc Endovasc Surg Vol 33, February 2007

LEIPZIG INTERVENTIONAL COURSE
LINC 2015

FREE CELL AREA drives CAS neurologic adverse event (and majority are those during stent healing !)

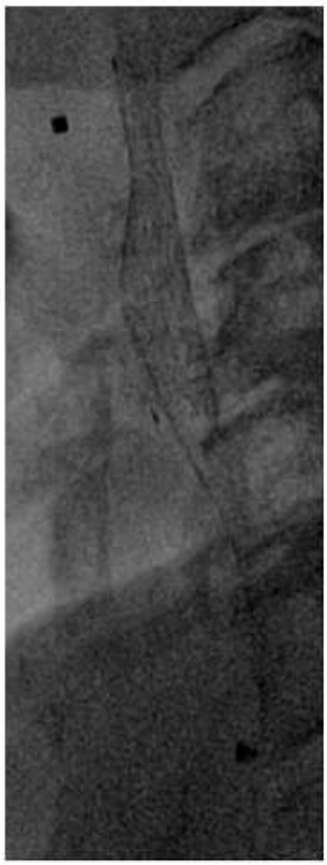
LEIPZIG INTERVENTIONAL COURSE LINC 2015

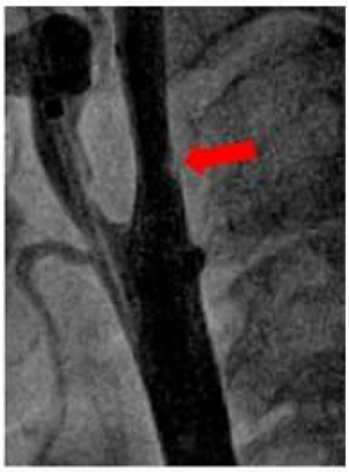
Free cell area	Total population		Symptomatic population	
	All events	Post-procedural events	All events	Post-procedural events
<2.5 vs [2.5, 5]	1.00	1.00	1.00	1.00
<2.5 vs [5, 7.5]	0.054	0.072	0.048	0.024
<2.5 vs >7.5	0.27	0.006	0.0006	$2.8\ 10^{-6}$

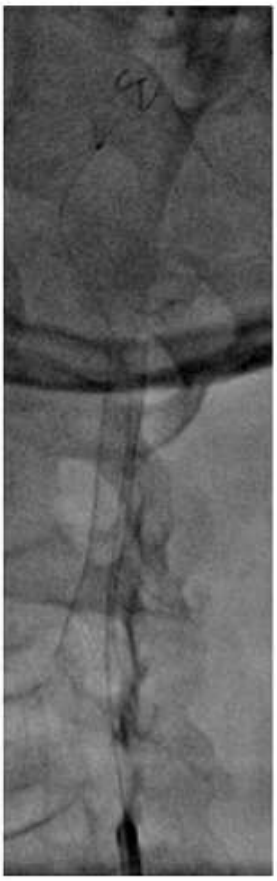
Eur J Vasc Endovasc Surg Vol 33, February 2007

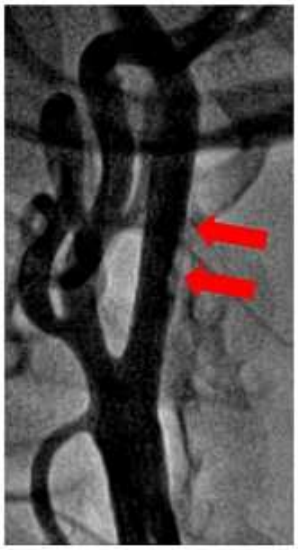
conventional best-in-class
Hybrid stent
('open-close-open')

conventional
best-in-class
Closed-cell stent







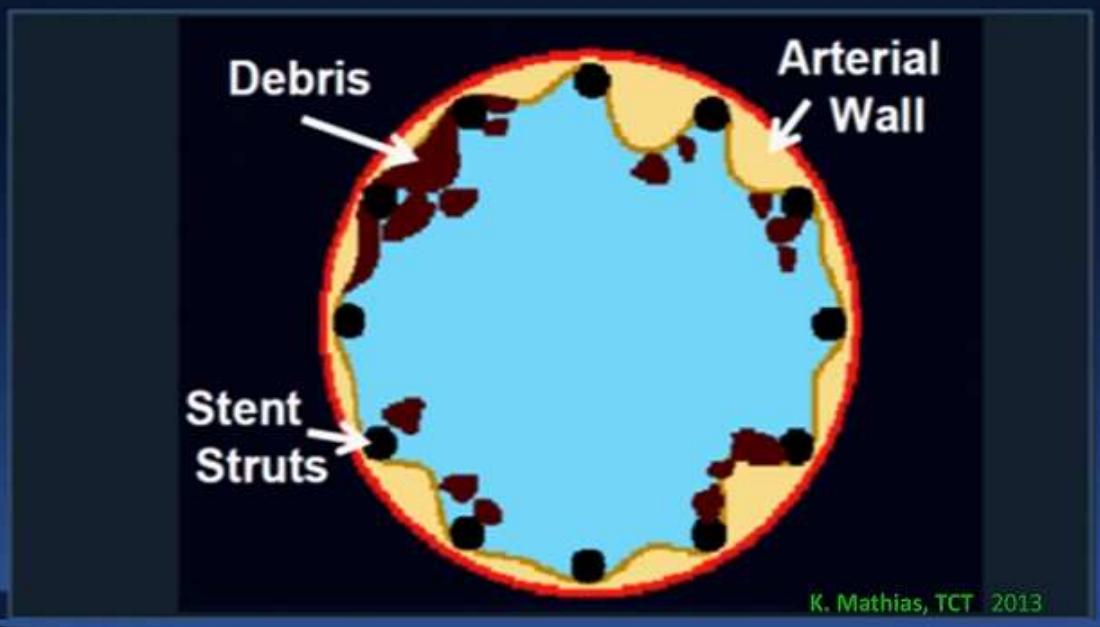


P Musialek, LINC 2015

Rationale of Technology

Conventional Carotid Stent

Plaque protrusion may lead to early and late distal embolization



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LINC 2015

ANY data on incidence of PLAQUE PROLAPSE in conventional carotid stents?

P Musialek, LINC 2015

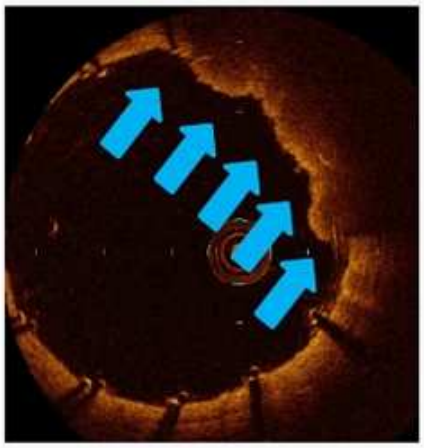
Post-procedural **PLAQUE PROLAPSE** through **conventional stent** struts

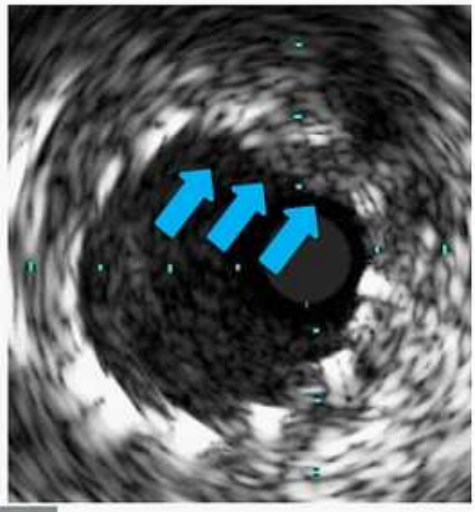
Suzuki M et al.
ESC 2014
Presentation
www.escardio.org

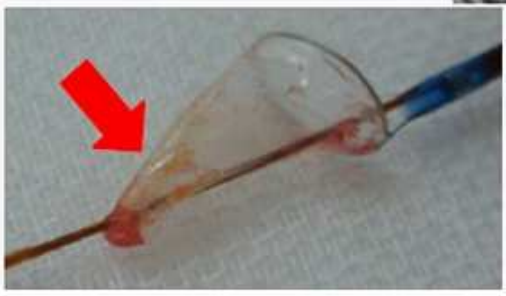
30.7%

1/3 stents = **Precise**
2/3 stents = **Carotid Wallstent**

81 y.o. Female, Symptomatic







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LINC
2015

Images: Dr M. Suzuki
ESC 2014
www.escardio.org

Eur Heart J. 2014;35(Abstr Suppl):178

LEIPZIG INTERVENTIONAL COURSE

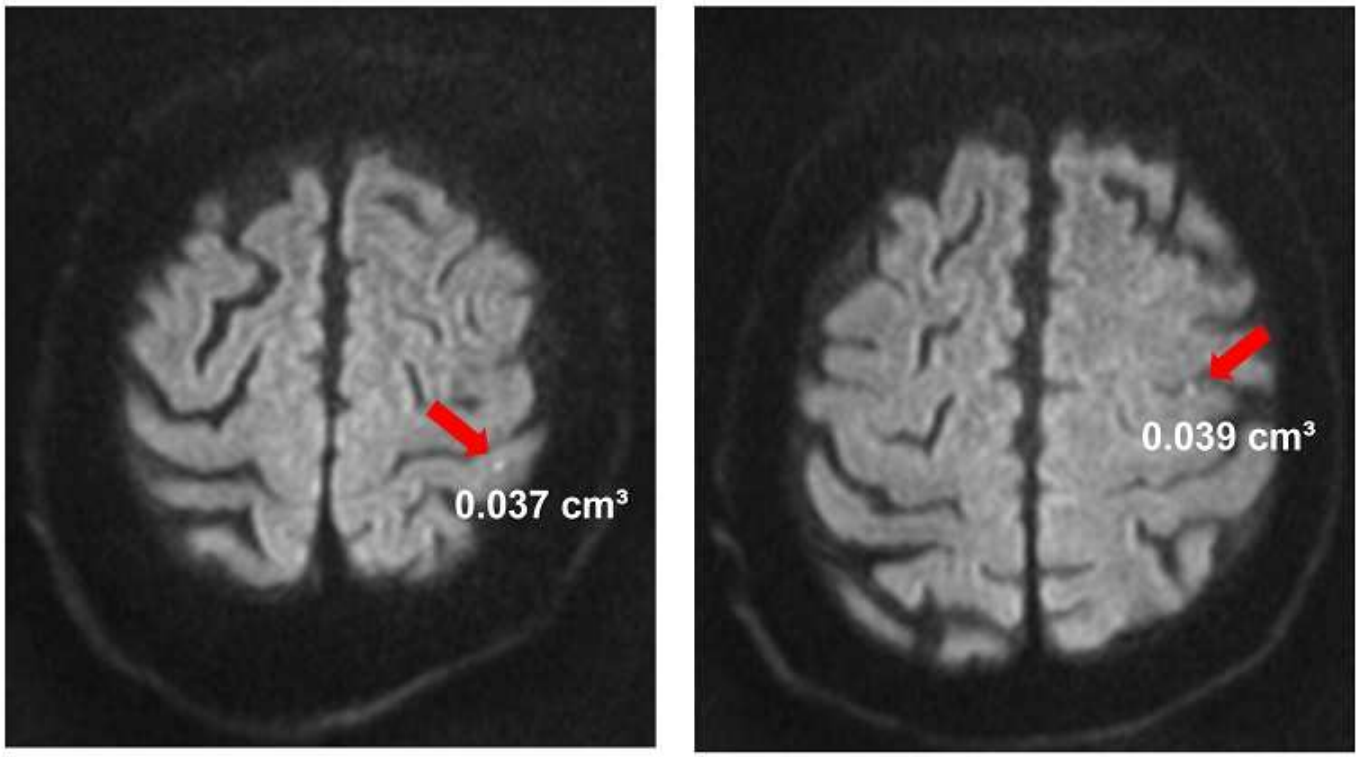
LINC 2015

DW-MRI:

the unforgiving testimony of what you've done to the TARGET ORGAN...

P Musialek, LINC 2015

The Power of DW-MRI...



48h after LICA-CAS

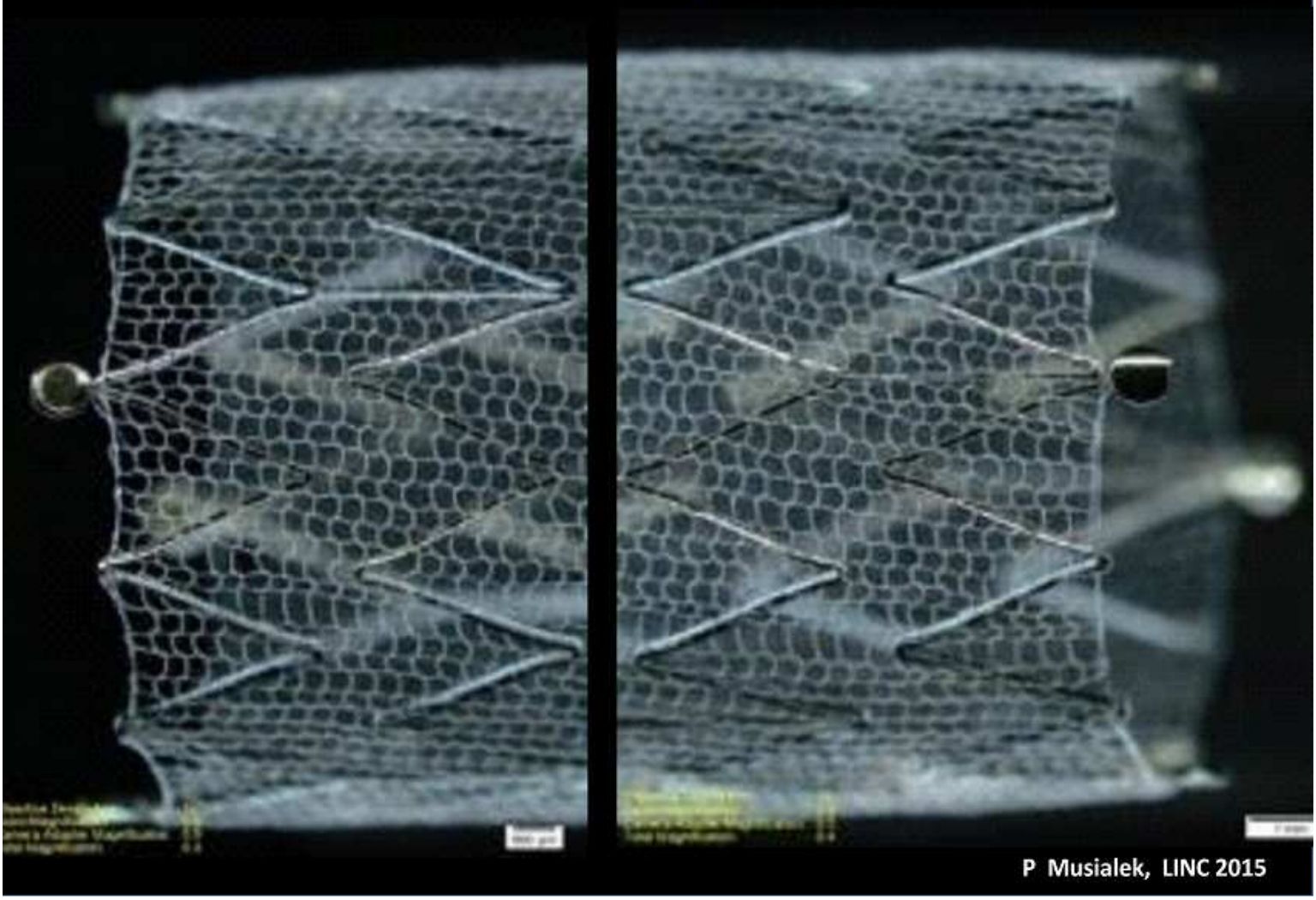
M. Urbanczyk, P. Banys, Dept. Radiology, JP2 Hospital, Krakow, Poland

Post-procedural Embolization with conventional carotid stents

DW-MRI post CAS

Schofer J et al, JACC Cardiovasc interv 2008

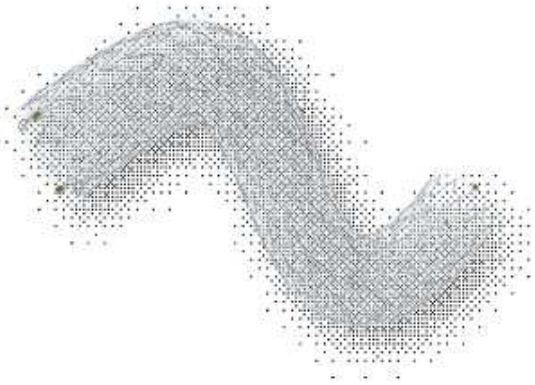
CGuard ™ embolic prevention stent

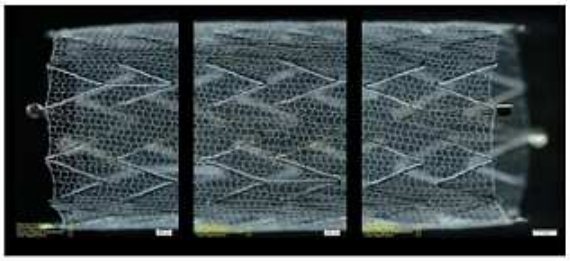


P Musialek, LINC 2015

CGuard™– Carotid Embolic Prevention System

System specifications	
Stent type	Nitinol – self expanding
Micronet aperture size	150-180 μm
Guidewire	0.014”
Sizes - Diameter - Length	 6-10mm 20-60mm





LEIPZIG INTERVENTIONAL COURSE
LINC
2015

Evaluation of PET Mesh Covered Stent in Patients with Carotid Artery Disease

The CARENET-Trial

(CARotid Embolic protection using microNET)

Joachim Schofer (PI)
Piotr Musialek (Co-PI)
On behalf of the CARENET Investigators

Joachim Schofer, MD,PhD, Hamburg University CardiovascularCenter, Hamburg Germany
Piotr Musialek, MD, PhD, Jagiellonian University Medical College at John Paul II Hospital, Krakow, Poland,
Ralf Kolvenbach, MD, PhD, Augusta Hospital, Dusseldorf, Germany,
Horst Sievert, MD, PhD, Cardiovascular Center Frankfurt, Frankfurt, Germany

In Partnership with the ACC
tct2014

Columbia University Medical Center
NewYork-Presbyterian

CARENET – Study Design

Study Design:

Prospective, multi-center, single arm, all-comer

Objectives:

To evaluate the periprocedural safety and efficacy of the CGuard stent in the treatment of carotid lesions in thirty consecutive patients with symptomatic and asymptomatic carotid artery stenosis, suitable for CAS

Sites:

- *Joachim Schofer,* Hamburg University Cardiovascular Center
- *Piotr Musialek,* Jagiellonian University Medical College
- *Ralf Kolvenbach,* Augusta Hospital
- *Horst Sievert,* Cardiovascular Center Frankfurt

Primary Endpoint:

30 day MACCE (death, stroke, MI)

CARENET – Baseline Characteristics

Baseline characteristics	
	CARENET (n=30)
Age (years)	71.6 ±7.6
Male	63.4%
Symptomatic	33.3 (10)
BMI	26.4 ±3.9
Hypertension	83.3% (25)
Hyperlipidemia	90% (27)
Diabetes mellitus	23.3% (7)
Cigarette smoking, current	13.4% (4)
Prior myocardial infarction	26.7% (8)

LEIPZIG INTERVENTIONAL COURSE
LINC 2015

J. Schofer, P. Musialek et al. 2015
(manuscript at review)

CARENET – Procedure Results

Target vessel - Left ICA - Right ICA	 33.3% (10) 66.6% (20)
Protection used -Distal filter protection -Proximal balloon protection	 96.6% (29) 3.4% (1)
Pre dilatation	70.9% (22)
Post dilatation	77.4% (24)
Post dilatation Pressure (ATM)	13.6 ±4.5
Stent deployed	100% (30)
Procedure success	100% (30)
Stent diameter (Mean)	8.23mm ± 0.8
Stent length (Mean)	34.8 mm ± 5.0
Second stent used	3.33% (1)

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LINC 2015

J. Schofer, P. Musialek et al. 2015
(manuscript at review)

CARENET – Procedure Results

Angiographic assessment, CARENET (n=30)		
	Baseline	**Final**
Lesion location in left/right ICA	33/67%	-
Lesion length [mm]	16.94±4.7	-
MLD [mm]	1.25±0.34	4.82±0.60
% Diameter stenosis	79.9±5.0	16.9±6.5
TIMI III flow in the ECA	100%	100%

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LINC 2015

J. Schofer, P. Musialek et al. 2015
(manuscript at review)

CARENET Clinical Events

	30 days (n=30)	6 months (n=28*)
MACCE (MI, stroke, death)	(0) 0.0%	(1) 3.6%
MI	(0) 0.0%	(0) 0.0%
stroke	(0) 0.0%	(0) 0.0%
death	(0) 0.0%	(1) 3.6%

Comparative data from other CAS trials

	30 days** (14 trials)	6 months† (3 trials)
MACCE (MI, stroke, death)	5.72%	8.09%

* See patient fluxogram

** Trials included in analysis: ARCHeR pooled, ARMOUR, BEACH, CABERNET, CREATE, EMPIRE, EPIC, MAVErIC 1+2, MAVErIC International, PRIAMUS, SAPPHIRE, SECURITY, PROFI, ICSS

† Values extrapolated from event curves

J. Schofer, P. Musialek et al. 2015 (manuscript at review)

LEIPZIG INTERVENTIONAL COURSE

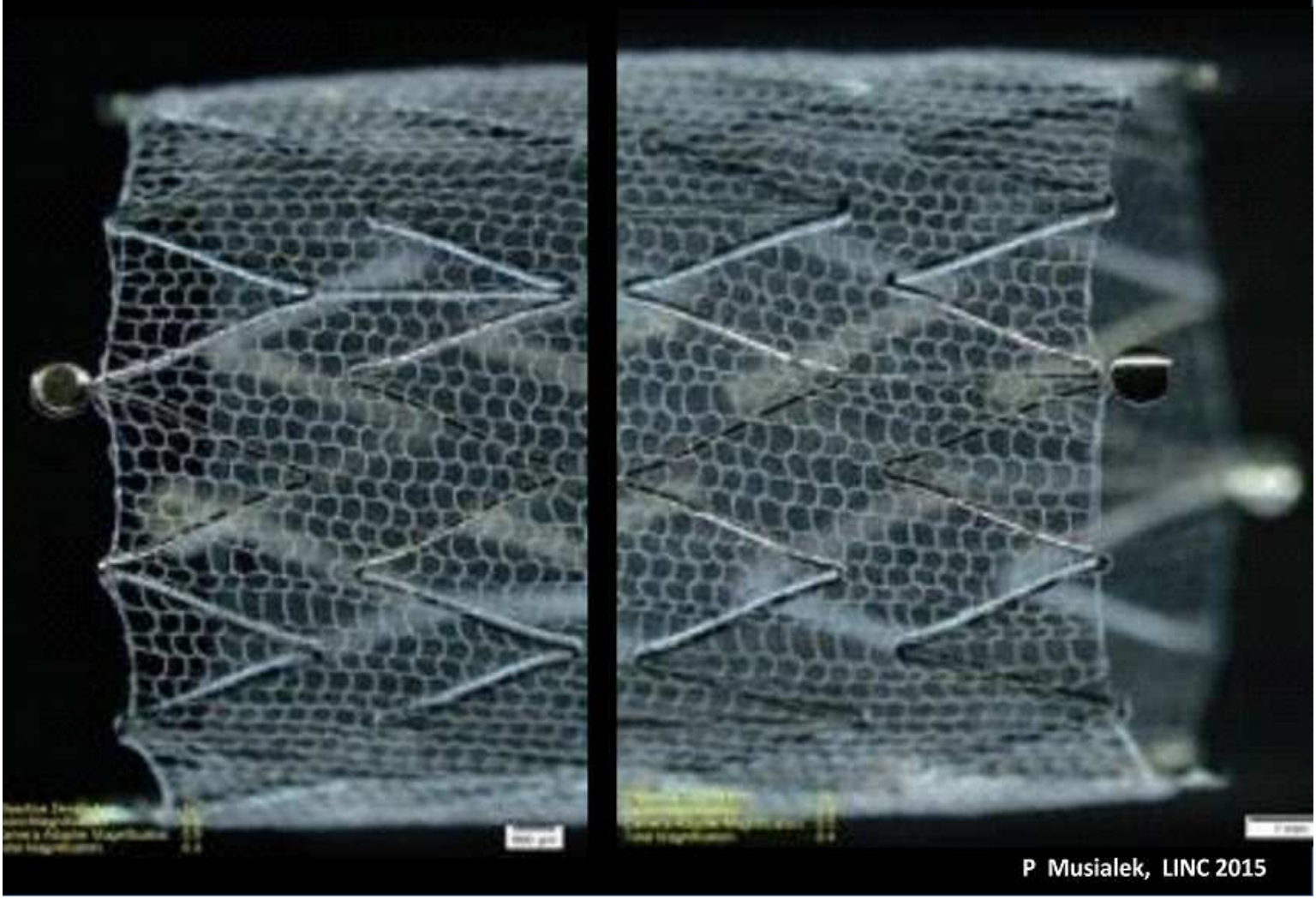
LINC 2015

DW-MRI:

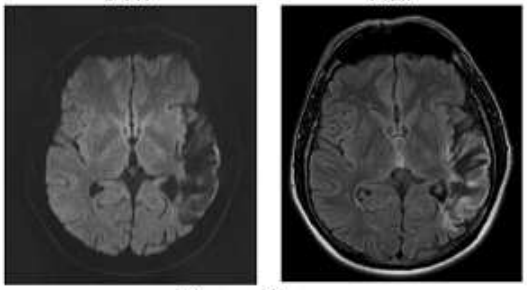
the unforgiving testimony of what you've done to the TARGET ORGAN...

P Musialek, LINC 2015

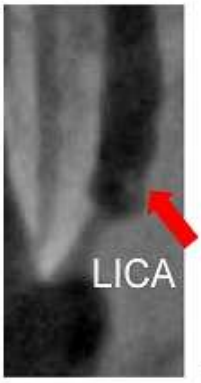
CGuard ™ embolic prevention stent



P Musialek, LINC 2015



CARENET
PJ, **03-007**
(Krakow)



LEIPZIG INTERVENTIONAL COURSE
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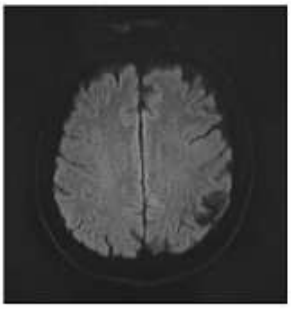
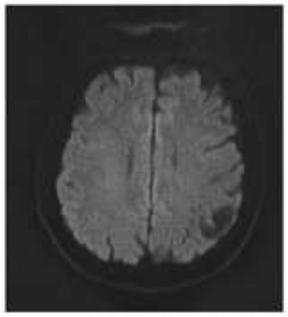
Baseline
Prior to CAS

24h after CAS

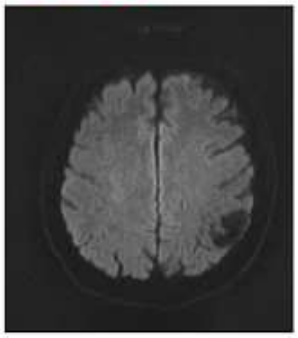
30 days after CAS

DWI



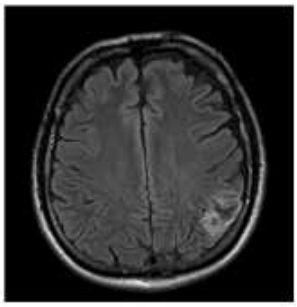


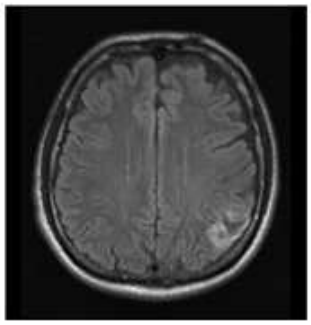
No new CAS-related lesions

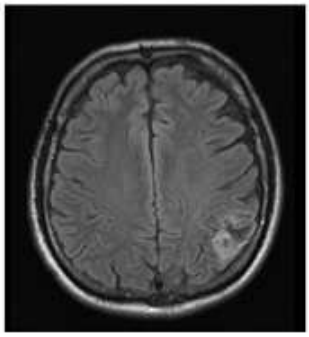


No new lesions between 24h and 30d

Flair







External, blinded CoreLab MRI image analysis and quantification (USA)

CARENET DW-MRI analysis *

DW-MRI analysis @ 48 hours			
	CARENET (n=27)	**PROFI (all)** (n=62)	**ICSS†** (n=56)
Incidence of new ipsilateral lesions	**37.0%**	**66.2%**	68.0%
Average lesion volume (cm^3)	0.039 ± 0.08	.375	-
Maximum lesion volume (cm^3)	0.445		

≈50% reduction

in new ipsilateral lesion **incidence**

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LINC
2015

***External Core Lab analysis (US)**

Bijuklic et al. *JACC*, 2012; Bonati et. al, *Lancet Neurol* 2010
† bilateral lesions

J. Schofer, P. Musialek et al. 2015
(manuscript at review)

CARENET DW-MRI analysis *

DW-MRI analysis @ 48 hours			
	CARENET (n=27)	**PROFI (all)** (n=62)	**ICSS†** (n=56)
Incidence of new ipsilateral lesions	37.0%	66.2%	68.0%
Average lesion volume (cm^3)	**0.039**	**0.375**	-
Maximum lesion volume (cm^3)	0.415		

>10-fold reduction

in cerebral lesion **volume**

LEIPZIG INTERVENTIONAL COURSE
LINC 2015

***External Core Lab analysis (US)**

Bijuklic et al. *JACC*, 2012; Bonati et. al, *Lancet Neurol* 2010

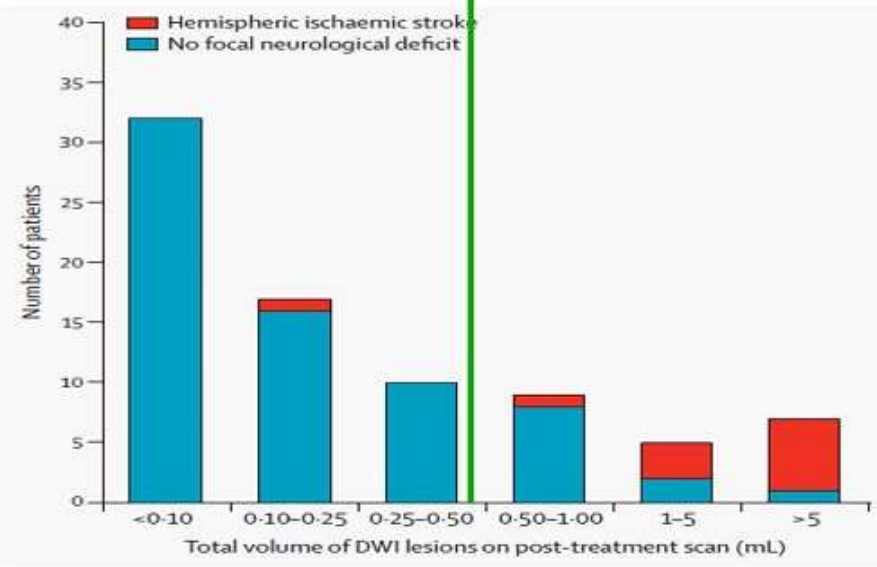
† bilateral lesions

J. Schofer, P. Musialek et al. 2015
(manuscript at review)

CARENET – DW-MRI analysis

DW-MRI analysis @ 48 hours			
	CARENET (n=27)	**PROFI (all)** (n=62)	**ICSS†** (n=56)
Incidence of new ipsilateral lesions	37.0%	66.2%	68.0%
Average lesion volume (cm^3)	0.039 ± 0.08	0.375	-
Maximum lesion volume (cm^3)	**0.445**		

ICSS



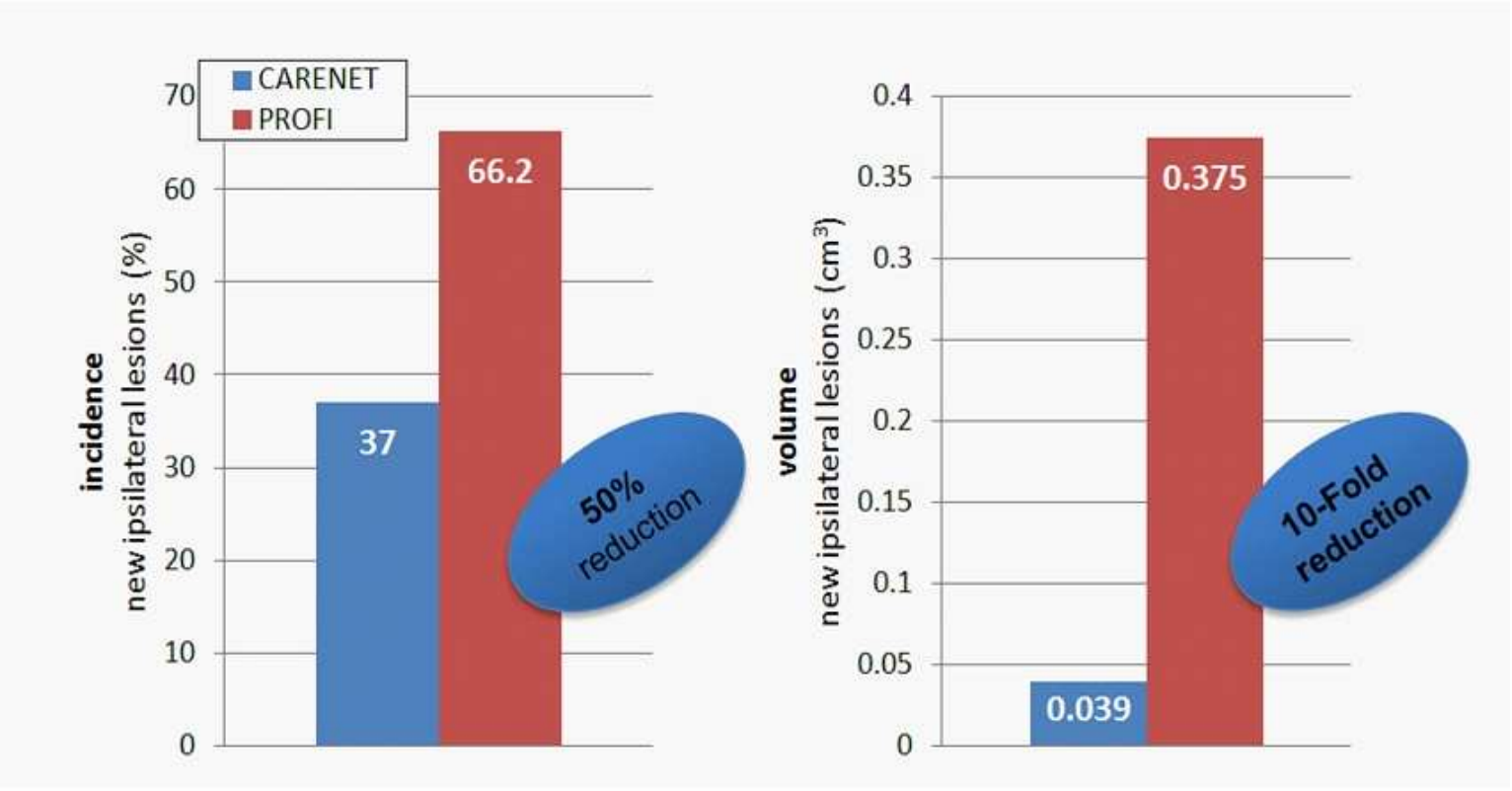
Bijuklic et al. *JACC*, 2012; Bonati et. al, *Lancet Neurol* 2010

† bilateral lesions

LEIPZIG INTERVENTIONAL COURSE
LINC
2015

CARENET: DW-MRI analysis

DW-MRI analysis @ 48 hours*

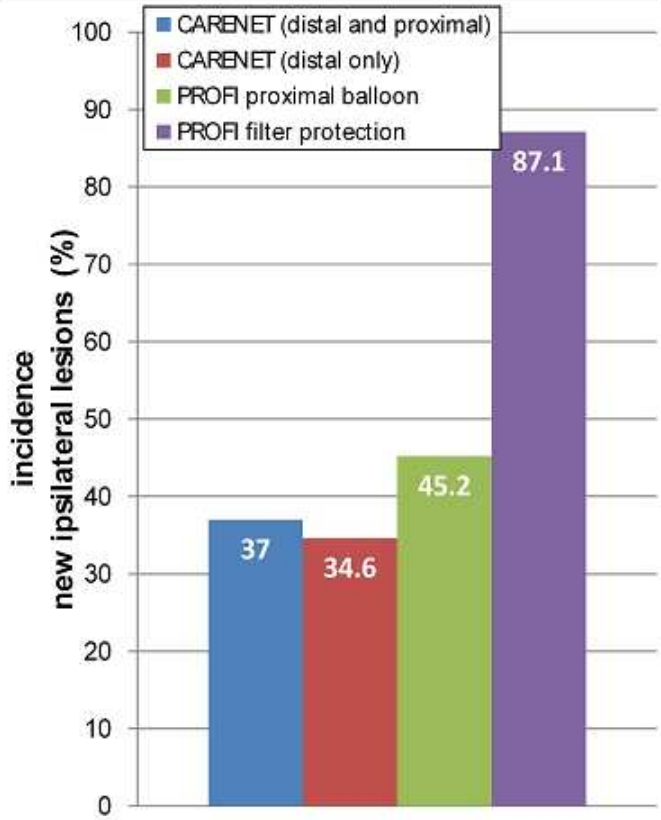


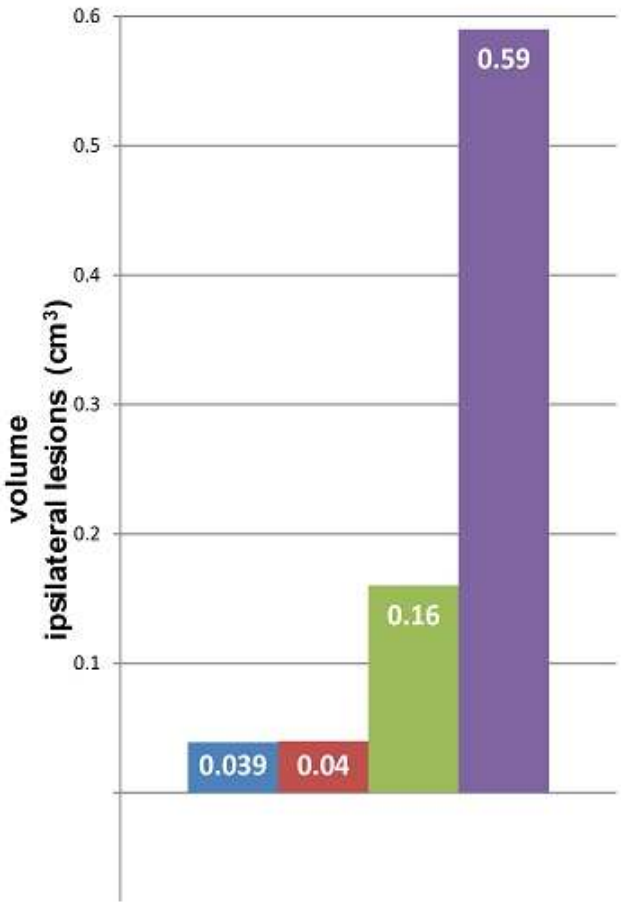
* see patient fluxogram

Bijuklic et al. *JACC*, 2012;59

CARENET vs. PROFI

DW-MRI analysis @ 48 hours*





* See patient fluxogram

Bijuklic et al. *JACC*, 2012;59

CARENET: **30-day** DW-MRI analysis*

All but one peri-procedural ipsilateral lesions

RESOLVED

DW-MRI analysis @ 30 days*	
Incidence of new ipsilateral lesions	1
Average lesion volume (cm^3)	0.08 ± 0.00
Permanent lesions at 30 days	1

***External Core Lab analysis (US)**

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* see patient fluxogram

J. Schofer, P. Musialek et al. 2015
(manuscript at review)

CGuard: Long-term Stent Evaluation

- **Routine Duplex Doppler ultrasound**
  at discharge, 30 days, 6 and 12 months and then yearly
- **(Intravascular ultrasound)**
- **(CT angiography)**

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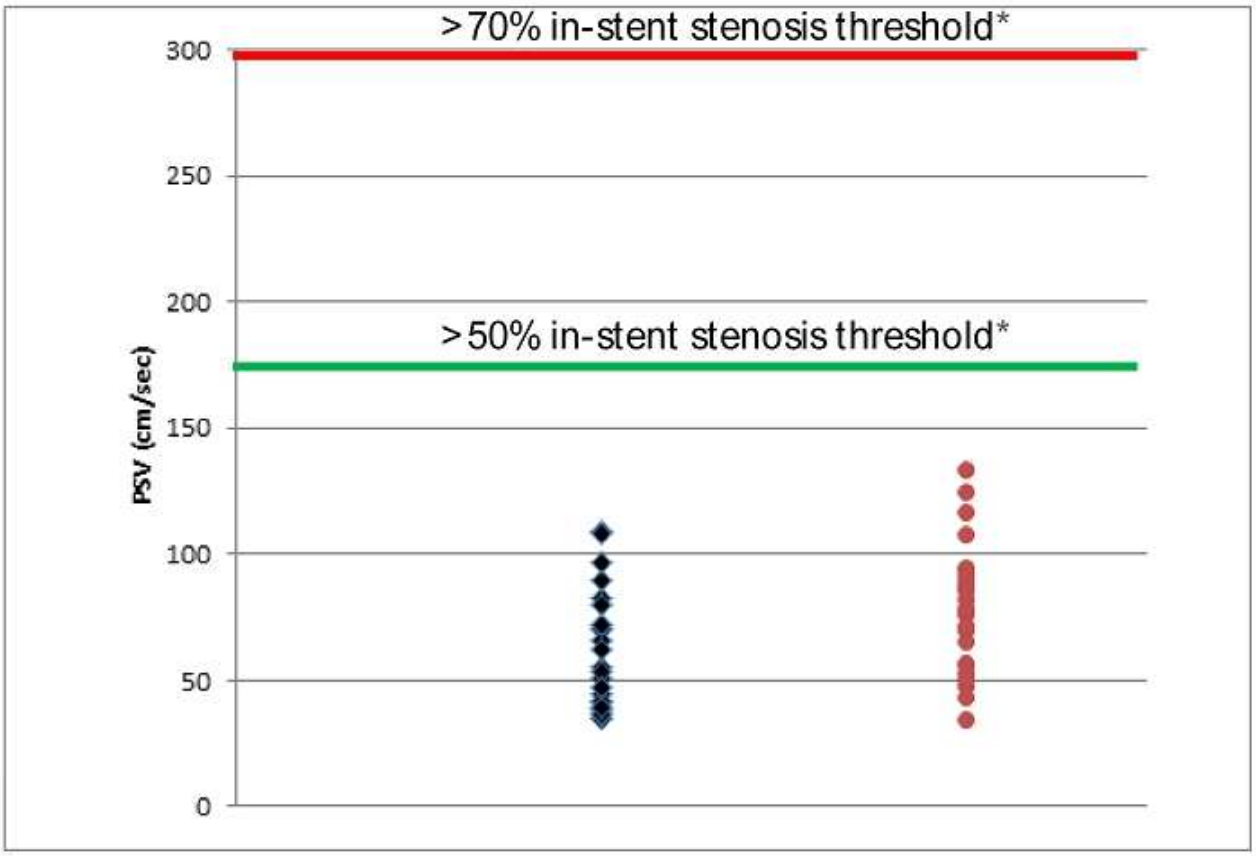
J. Schofer, P. Musialek et al. 2015
(manuscript at review)

CARENET in-stent Peak Systolic Velocities



NB. in one patient 6 mo ultrasound data pending

(NB. ECA patency 100% @6mo)

* Setacci et. al, Grading Carotid Intrastent Restenosis of 814 CAS patients *Stroke*. 2008

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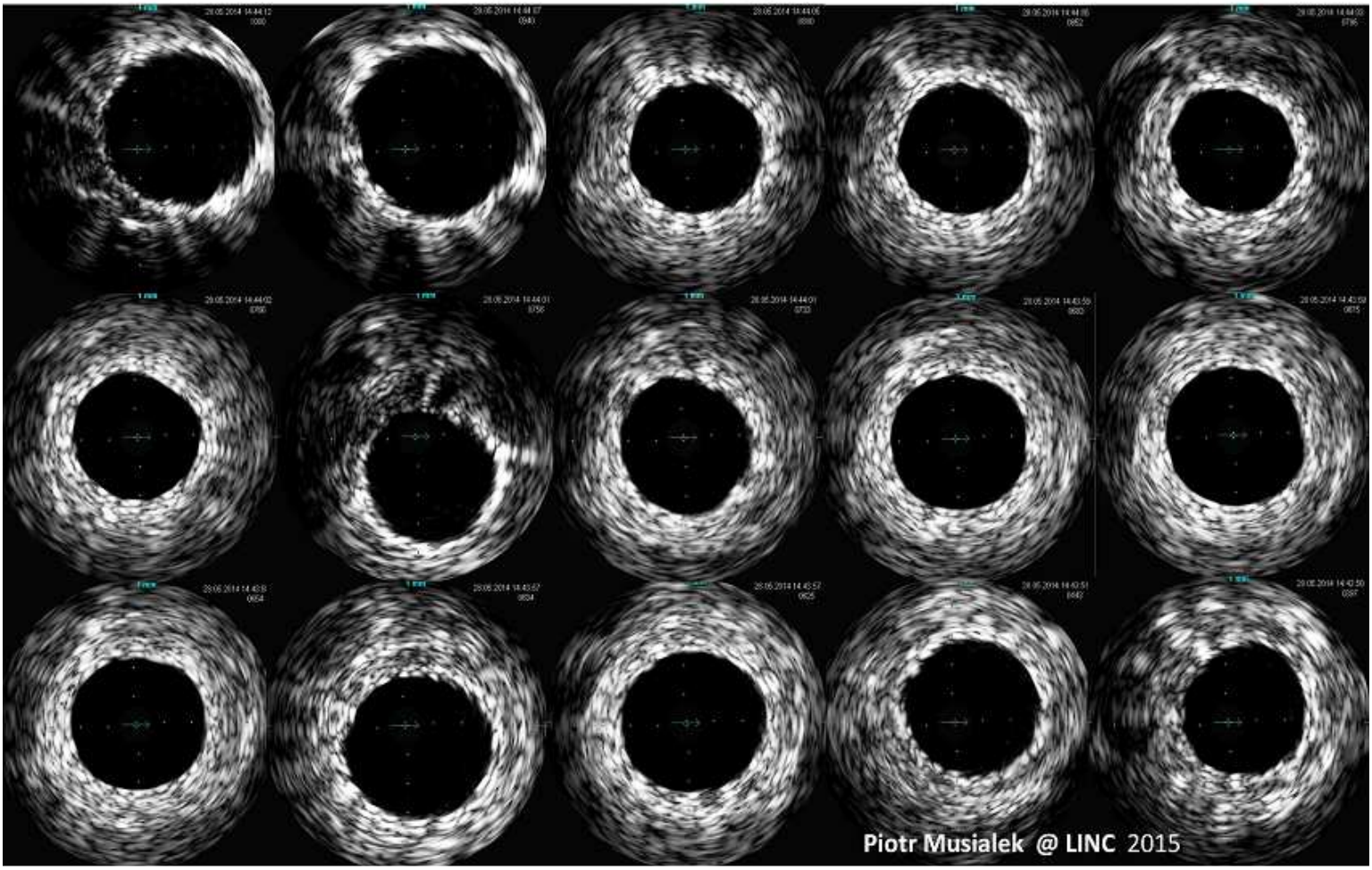
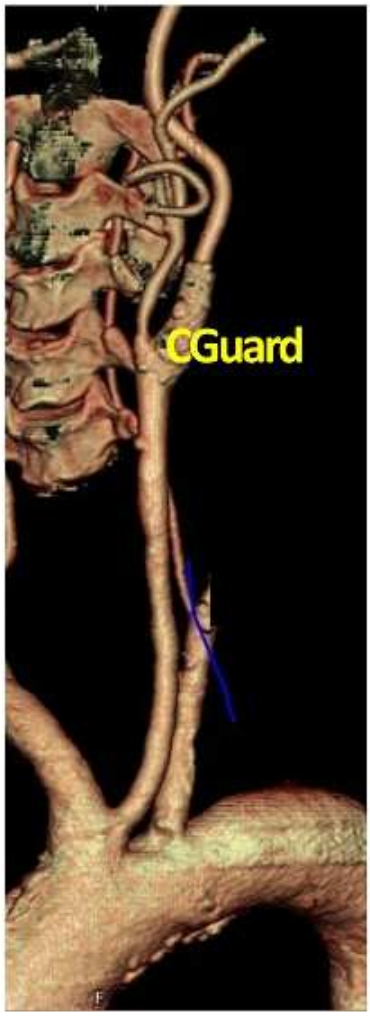
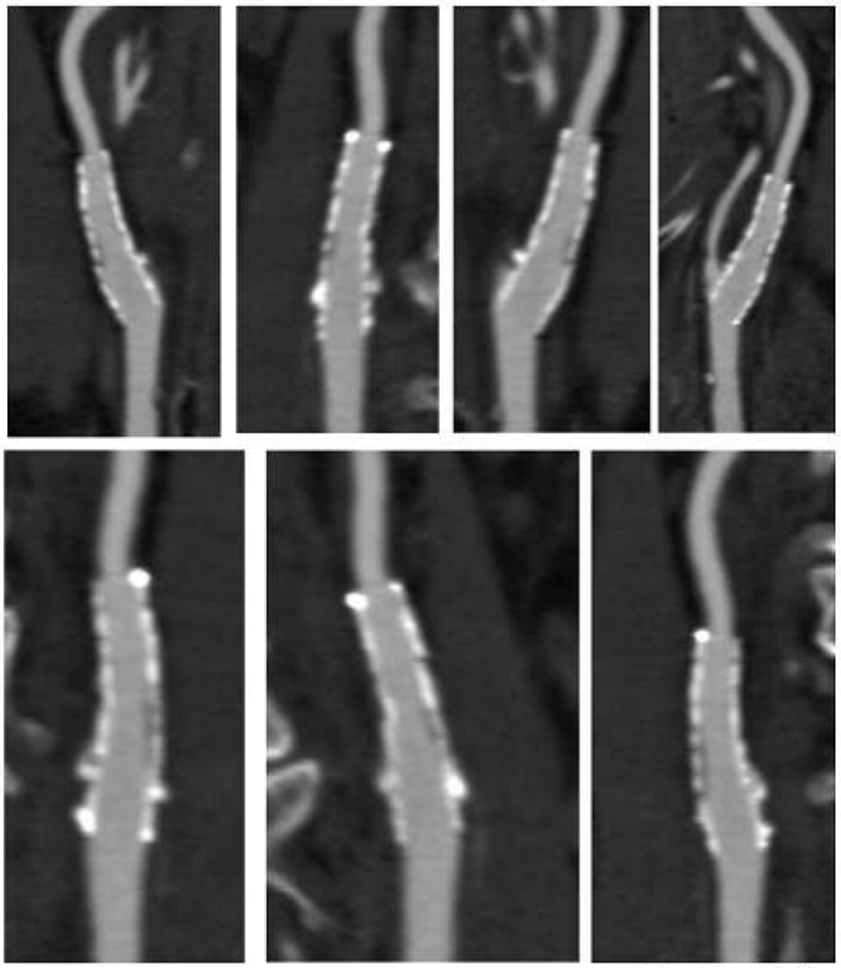
Initial series of IVUS CGuard™ studies suggests...

- Excellent stent expansion and apposition √
- ZERO tissue protrusion though mesh-and-struts √



5 months follow-up





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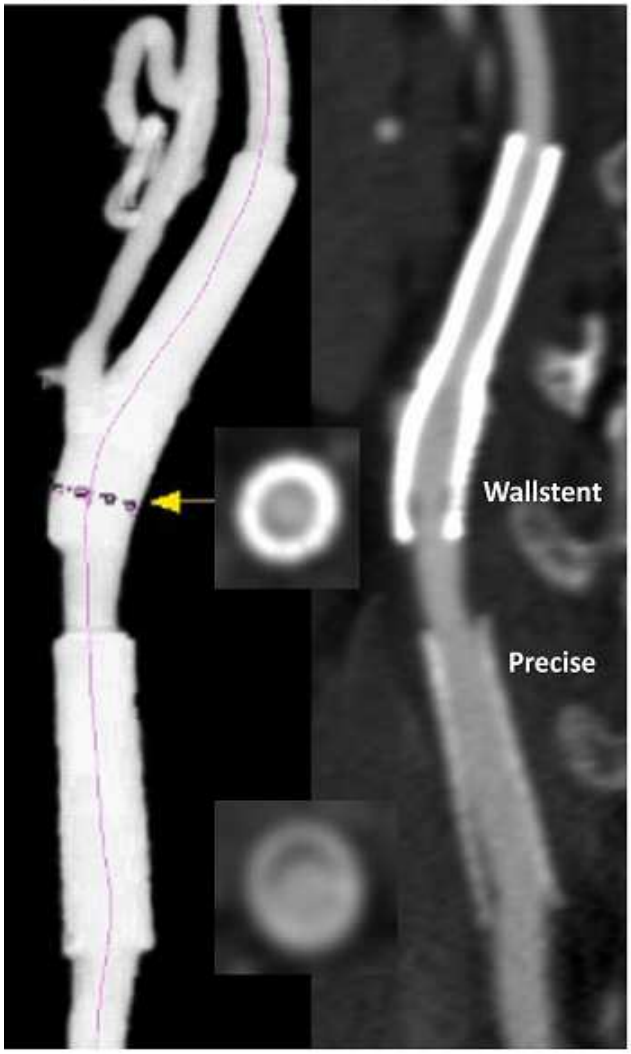
RCCA & RICA



LICA CGuard

5 months follow-up

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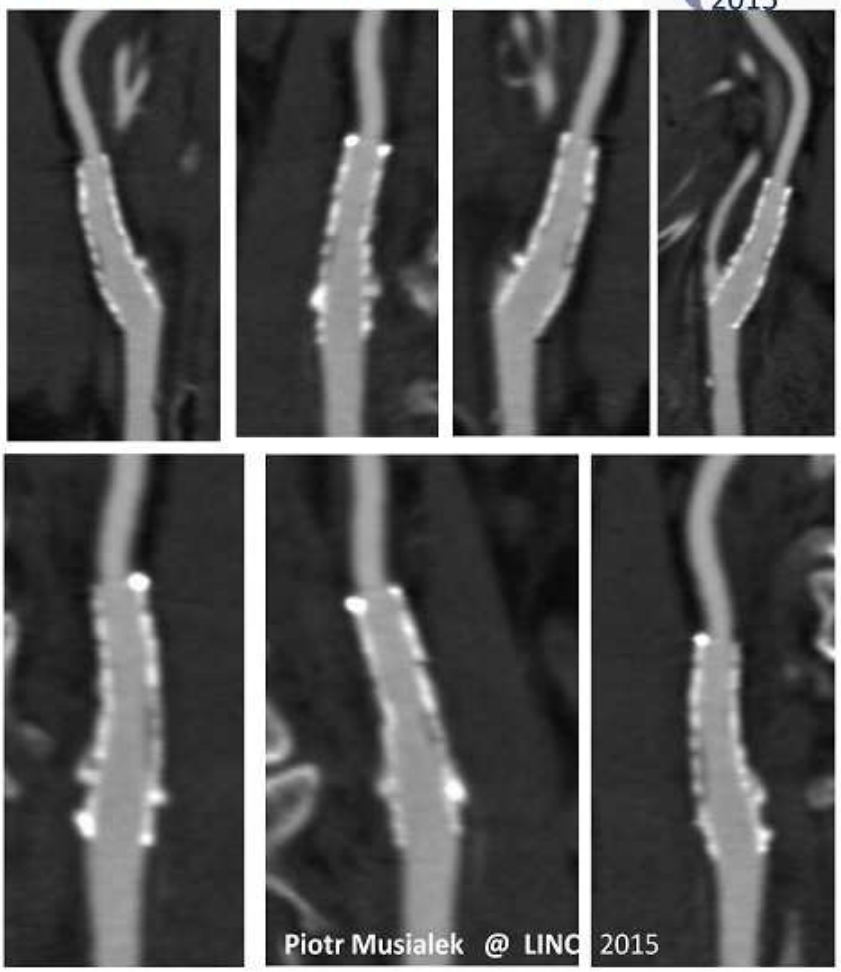
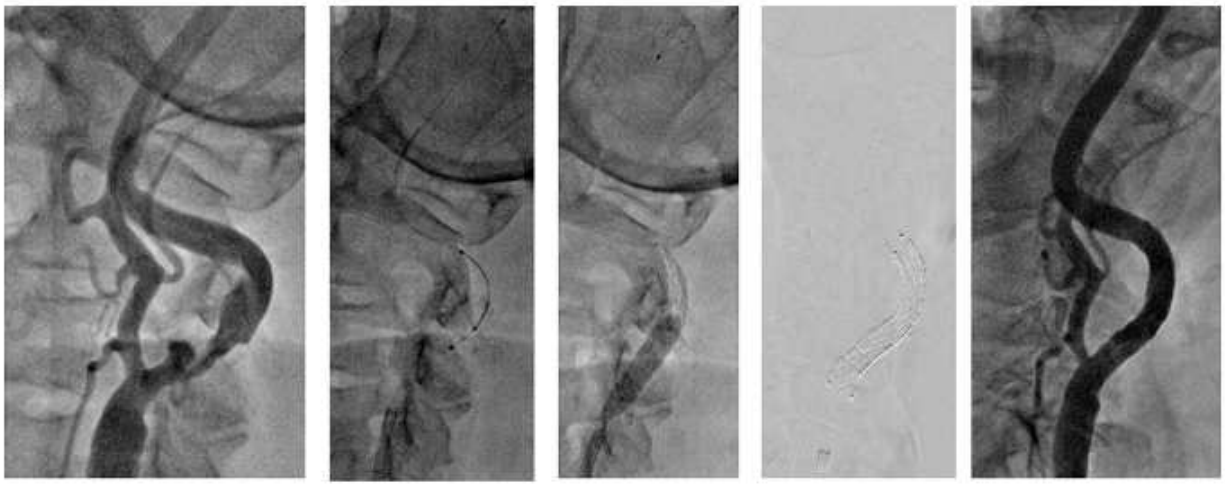
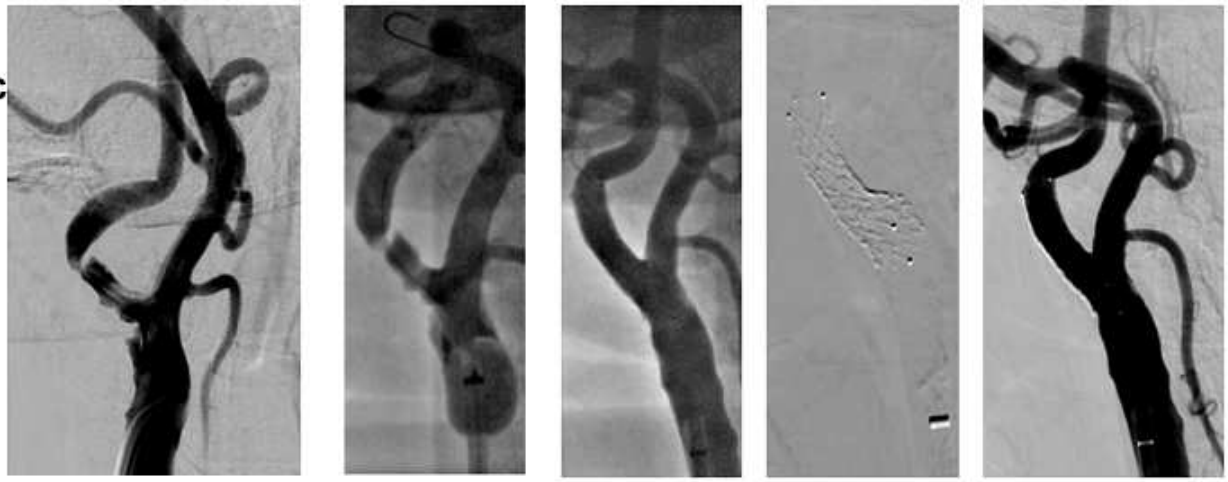


CGuard: Endovascular Solution For All-comers

61 yo symptomatic LICA



72 yo asymptomatic RICA



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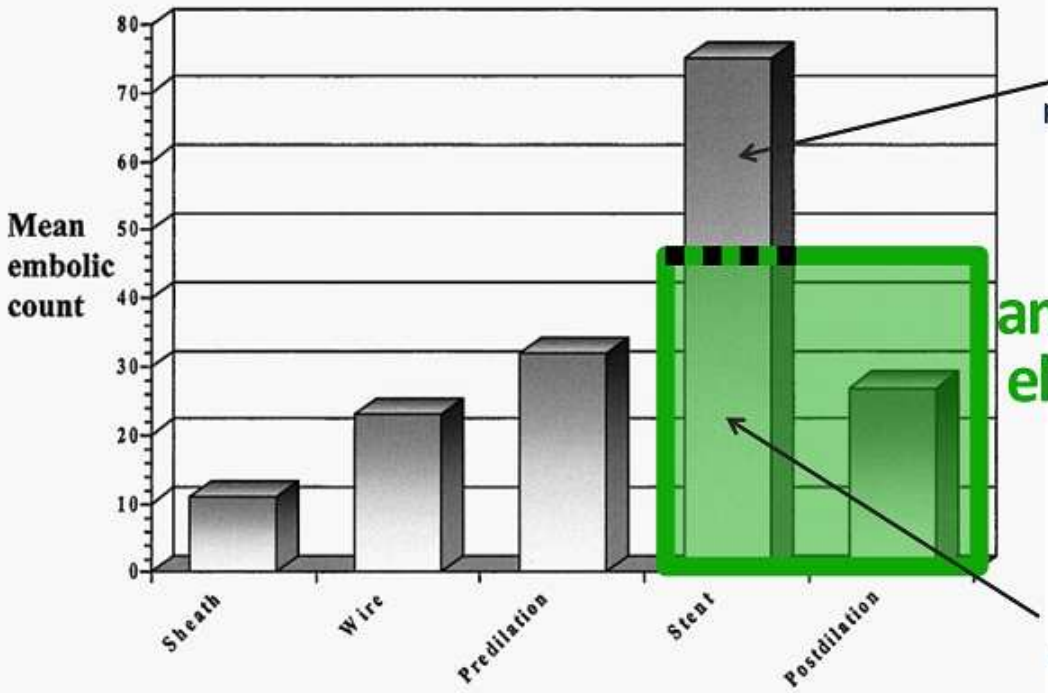
Piotr Musialek @ LINC 2015

CAS (and CEA) are –and will remain– emboli-generating procedures

Effect of the Distal-Balloon Protection System on Microembolization During Carotid Stenting

Nadim Al-Mubarak, MD; Gary S. Roubin, MD, PhD; Jiri J. Vitek, MD, PhD; Sriram S. Iyer, MD; Gishel New, MD; Martin B. Leon, MD



amenable to elimination with mesh

Figure 1. Microembolic profile during unprotected CAS. The mean MES counts during various phases of the procedure are displayed. *Circulation.* 2001;104:1999-2002

P Musialek @ LINC 2015

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JOURNAL OF VASCULAR SURGERY
November 2010

CAS: 2010 Vision

Kosmas I. Paraskevas, MD,[a] Dimitri P. Mikhailidis, MD, FFPM, FRCPath, FRCP,[b] and Frank J. Veith, MD, FACS,[c,d] *Athens, Greece; London, United Kingdom; Cleveland, Ohio; and New York, NY*

Improved technology for CAS — better EPDs (flow reversal and proximal occlusion) and better stents (membrane-covered, ultra-closed cell, and biodegragable). Several issues may improve CAS outcomes, such as the introduction of new and better stents. An ex vivo study showed that use of a polyurethane membrane-covered stent resulted in lower cerebral embolization rates.[69] Membrane-covered stents also have the potential to reduce the incidence of late embolization, that is, after the removal of the EPD.[70] Furthermore, proximal EPDs (such as the Mo.Ma flow interruption device [Invatec, Roncadelle, Italy][71] or the Parodi flow reversal Anti-Emboli System [W.L. Gore, Flagstaff, AZ])[72] offer the advantage of cerebral protection during most of the procedure.

JOURNAL OF VASCULAR SURGERY
Volume 52, Number 5

CGuard embolic prevention stent system

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- Compatible with ALL EPD types √
- Deliverable in hard-access anatomies √
- Optimal visibility √
- Reliable, predictable, and extremely precise placement √
- No indication of foreshortening √
- Radial strength sufficient for v. hard lesions √

CGuard embolic prevention stent system

- **Full respect of the carotid bifurcation anatomy**
  -> 'endovascular anatomic reconstruction' √

- **Optimal performance across all lesion subsets (including high calcium/thrombus/string)** √

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CARENET Conclusions

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- CARENET Trial demonstrated unprecedented safety of the CGuard stent, with 30-day MACCE rate of 0%.
- The CGuard device success and procedure success rate were 100%.
- Majority of patients treated with CGuard have zero ipsilateral lesions on post-procedural DWI.

CARENET Conclusions

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- 10-fold reduction in average lesion volume when compared to conventional carotid stents.
- All but one peri-procedural lesion had resolved completely by 30 days.
- 6 month ultrasound analysis is indicative of normal stent healing without any restenosis concern and with normal ECA flow.
- CARENET data indicates that CGuard may offer **unique clinical benefits** for patients undergoing CAS – with unprecedented safety.

Exhibit 99.2

InspireMD Receives CE Mark Approval for Its New CGuard RX and Announces Positive Six Month Follow-Up CARENET Trial Data at LINC 2015

The New CGuard ™ RX Rapid Exchange System Receives CE Mark Approval

Six-Month Ultrasound Analysis Confirms Widely Patent Internal and External Carotid Arteries When Compared to Conventional Carotid Stents

BOSTON, MA – January 27, 2015 — InspireMD, Inc. (NYSE MKT: NSPR) ("InspireMD" or the "Company"), a leader in embolic protection systems ("EPS"), today announced that it received CE mark approval for its new CGuard RX rapid exchange system for its MicroNet ™ covered carotid stent technology. Concurrently, the Company announced positive 6 month follow up data from its CGuard ™ CARENET (**CAR** otid **E** mbolic protection Study using micro **NET**) trial at the LINC (**L** eipzig **I** nterve **N** tional **C** ourse) meeting in Leipzig, Germany.

The Company announced today that it received CE mark approval for its new CGuard ™ RX rapid exchange delivery system for its MicroNet ™ covered embolic prevention system. The new state- of- the- art RX delivery system will enable clinicians to place the CGuard technology using an easy-to-use, and familiar, delivery system. The CGuard MicroNet mesh covered carotid stent remains unchanged.

Also today, Prof. Piotr Musiałek, Co- Principal Investigator for the CARENET study, from Jagiellonian University Medical College at John Paul II Hospital, Krakow, Poland, presented the CARENET 6 month data at a late breaking trial session at the LINC Meeting. There was one MACCE (major adverse cardiac and cerebrovascular) event reported at 6 months which was not device related. This 6 month MACCE rate is substantially lower than MACCE rates reported in other conventional carotid stenting trials. The duplex ultrasound analysis performed at 6 months confirmed widely patent carotid arteries, which were stented with the CGuard as determined by flow measurements indicating no sign of vessel narrowing, consistent with historical data of conventional carotid artery stenting. Importantly, the external carotid artery showed unimpeded flow in 100% of cases demonstrating that the MicroNet allows excellent blood flow into bifurcated arteries. The reduction in both the incidence and the volume of new ischemic lesions, as well as this 6 month data showing minimal restenosis concern, and 100% patent internal and external carotid arteries, indicates that the therapeutic benefits of the CGuard ™ MicroNet technology may extend well beyond the acute procedural period.

Alan Milinazzo, CEO of InspireMD, commented, "We are very pleased to have received the CE mark approval for our CGuard RX rapid exchange system. This is an important milestone for the Company as it creates significant near term commercial opportunities for us." He stated, "Physicians continue to be impressed with the superior clinical data and our 6 month results further validate that CGuard with MicroNet may represent a superior next generation of stenting technology. We plan to use the new clinical data and the RX approval to expand our commercial launch activities starting immediately."

About CGuard EPS
The proprietary CGuard EPS uses the same MicroNet technology featured on the MGuard™ and MGuard Prime™ coronary embolic protection systems. The MicroNet technology is a single fiber knitted mesh wrapped on an open cell stent platform designed to trap debris that can dislodge and travel downstream after a patient is treated with traditional stenting methods. This technology seeks to protect patients from plaque debris and blood clots breaking off and which can lead to life threatening strokes. The size, or aperture, of the MicroNet 'pore' is only 150-180 microns in order to maximize protection against the potentially dangerous plaque and thrombus within the carotid artery.

CGuard EPS is CE Mark approved. CGuard EPS, however, is not approved for sales in the U.S. by the U.S. Food and Drug Administration at this time.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MGuard™ with MicroNet ™ technology to make its products the industry standard for embolic protection and to provide a superior solution to the key clinical issues of current stenting in patients with a high risk of distal embolization, no reflow and major adverse cardiac events.

InspireMD intends to pursue applications of this MicroNet technology in coronary, carotid (CGuard ™) and peripheral artery procedures. InspireMD's common stock is quoted on the NYSE MKT under the ticker symbol NSPR.

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, multinational companies, (v) product liability claims, (vi) product malfunctions, (vii) our limited manufacturing capabilities and reliance on subcontractors for assistance, (viii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (ix) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (x) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (xi) our reliance on single suppliers for certain product components, (xii) 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 (xiii) 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 (SEC), including the Company's Transition Report on Form 10-KT 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.

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