

INSPIREMD, INC.

FORM 8-K (Current report filing)

Filed 11/02/16 for the Period Ending 11/01/16

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 & Distribution

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): November 1, 2016

InspireMD, Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-35731	26-2123838
(State or other jurisdiction	(Commission	(IRS Employer
of incorporation)	File Number)	Identification No.)
321 Columb Boston		02116
(Address of principa	l executive offices)	(Zip Code)
Registr	ant's telephone number, including area code: (857) 305	5-2410
(For	rmer name or former address, if changed since last repo	ort)
Check the appropriate box below if the Fort following provisions:	m 8-K filing is intended to simultaneously satisfy the	e filing obligation of the registrant under any of the
[] Written communications pursuant to Rule 425 under	er the Securities Act (17 CFR 230.425)	
[] Soliciting material pursuant to Rule 14a-12 under the	ne Exchange Act (17 CFR 240.14a-12)	
[] Pre-commencement communications pursuant to R	ule 14d-2(b) under the Exchange Act (17 CFR 240.14d	-2(b))
[] Pre-commencement communications pursuant to R	ule 13e-4 (c) under the Exchange Act (17 CFR 240.13e	e-4(c))

Item 7.01 Regulation FD Disclosure.

Attached hereto as Exhibit 99.1 is a PowerPoint presentation with respect to the 12-month follow-up data from PARADIGM-101 study that Professor Piotr Musialek, MD, DPhil, FESC, presented on November 1, 2016, at the Transcatheter Cardiovascular Therapeutics (TCT) 2016 scientific symposium, taking place from October 29 to November 2, 2016, in Washington, D.C.

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 November 1, 2016, InspireMD, Inc. issued a press release announcing that 12-month follow up data from PARADIGM-101 study were presented in two presentations at the TCT 2016 scientific symposium. A copy of such press release is attached hereto as Exhibit 99.2 and is hereby incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Description
016 TCT Presentation
ress release dated November 1, 2016

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: November 2, 2016 By: /s/ Craig Shore

Name: Craig Shore
Title: Chief Financial Officer



TCT 2016 Featured Research





Twelve-month Safety and Efficacy of CGuard™ MicroNet–covered Embolic Prevention Stent Routine Use to Perform Carotid Revascularization: PARADIGM All-Comer Prospective Academic Study

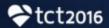
P. MUSIALEK¹, A. MAZUREK¹, M. TRYSTULA², A. BORRATYNSKA³, A. LESNIAK-SOBELGA¹, M. URBANCZYK⁴, RP. BANYS⁴, A. KOZANECKI¹, P. WILKOLEK¹, A. BRZYCHCZY², L. PARTYKA⁵, W. ZAJDEL⁶, K. ZMUDKA⁶, P. PODOLEC¹

(1) Jagiellonian University Deptartment of Cardiac & Vascular Diseases; (2) Dept Vascular Surgery; (3) Neurology Outpatient Dept; (4) Dept Radiology, John Paul II Hospital; (5) KCRI, Krakow; (6) Dept Interventional Cardiology, John Paul II Hospital, Krakow



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





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.

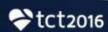
Affiliation/Financial Relationship

- Grant/Research Support
- Consulting Fees/Honoraria
- Major Stock Shareholder/Equity
- Royalty Income
- Ownership/Founder
- Intellectual Property Rights
- Other Financial Benefit

Company

- Abbott
- Abbott, Balton, InspireMD, Medtronic
- no
- no
- no
- no
- no

NB. PARADIGM is an Investigator-Initiated, Non-Industry Funded, Academic study supported by the Jagiellonian University Medical College and 'For the Heart' Foundation in Krakow, Poland



The Problem of Conventional Carotid Stents

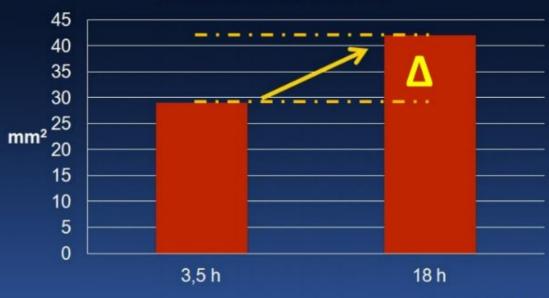




Image courtesy Dr Joan Rigla, MD PhD Perceptual Imaging Lab, Univerity of Barcelona

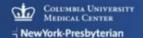
Post-procedural Embolization with conventional carotid stents DW-MRI post CAS

Mean total lesion area

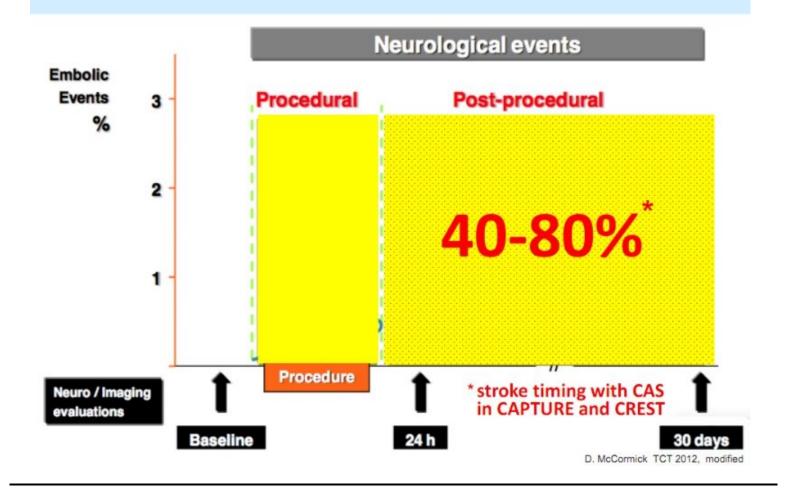


Schofer J et al, JACC Cardiovasc interv 2008

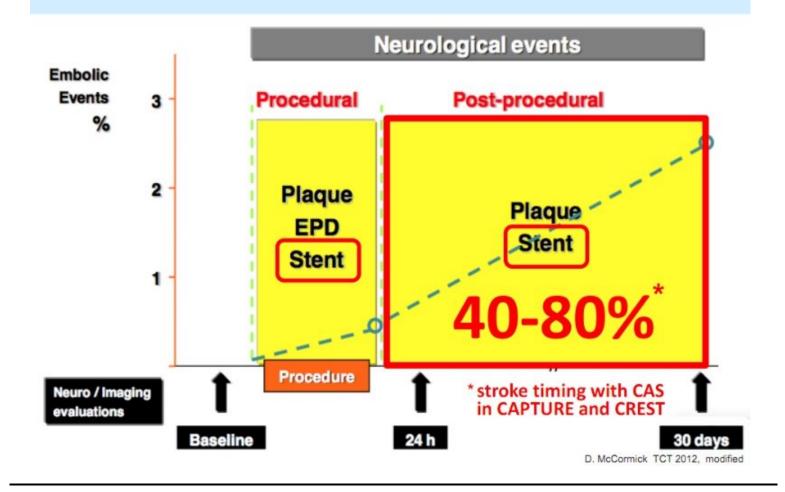




Timing of neuro-embolic events after CAS



Timing of neuro-embolic events after CAS





CEA excludes the plaque



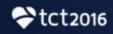


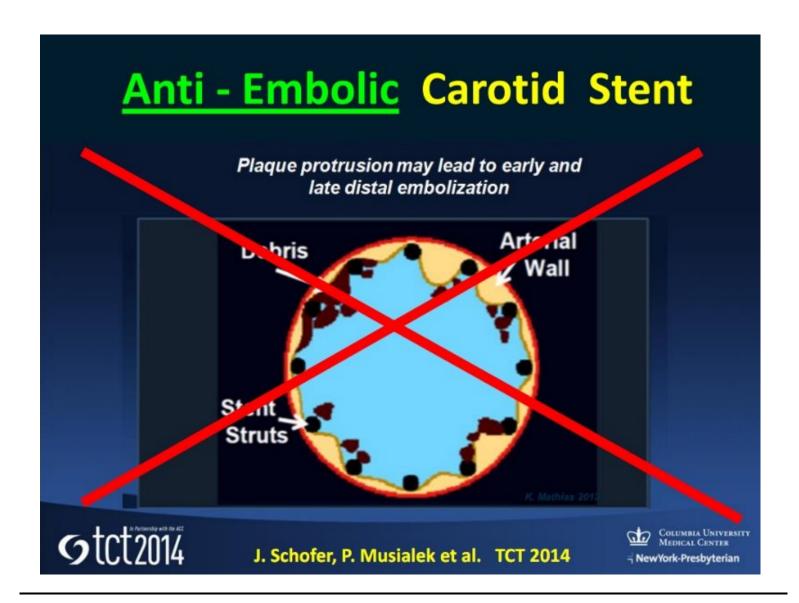
- CEA excludes the plaque
- In CAS, the <u>stent should</u> exclude the plaque too



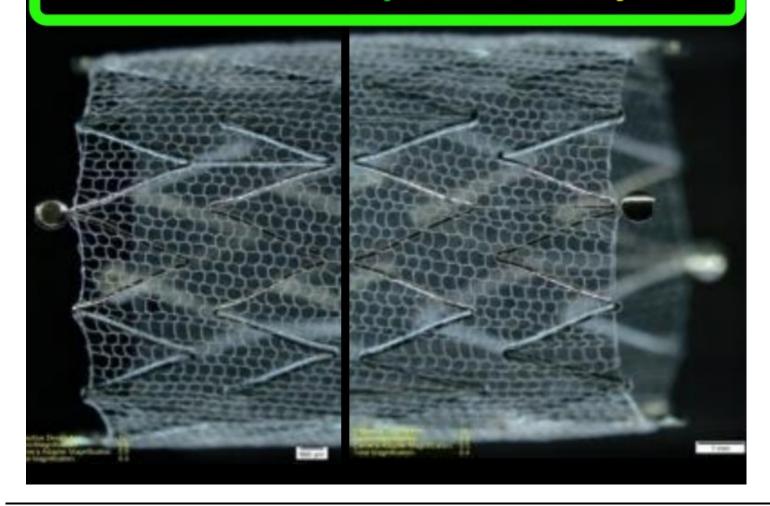


an unmet clinical need





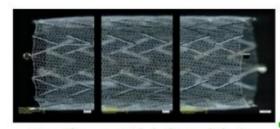
CGuard™ embolic prevention system



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	



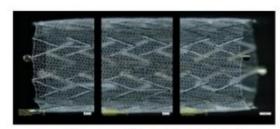


Specific, carotid-dedicated design

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	





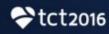
Specific, carotid-dedicated design



Nitinol frame open cell area ≈ 21 mm² MicroNet cell area ≈ 0.3mm² LARGEST SMALEST



CGuardTM CAS:





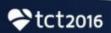
 Intra-procedural cerebral embolization is minimized



J. Schofer, P. Musialek, et al. JACC Interv 20152015;8:1229-1234



- Intra-procedural cerebral embolization is minimized
- Post-procedural procedural cerebral embolization is nearly-eliminated



J. Schofer, P. Musialek, et al. JACC Interv 20152015;8:1229-1234

http://dx.doi.org/10.1016/j.jcin.2015.04.016

A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent



The CGuard CARENET Trial

(Carotid Embolic Protection Using MicroNet)

Joachim Schofer, MD,* Piotr Musiałek, MD, DPHIL,† Klaudija Bijuklic, MD,* Ralf Kolvenbach, MD,‡ Mariusz Trystula, MD,† Zbigniew Siudak, MD,†§ Horst Sievert, MD||

ABSTRACT

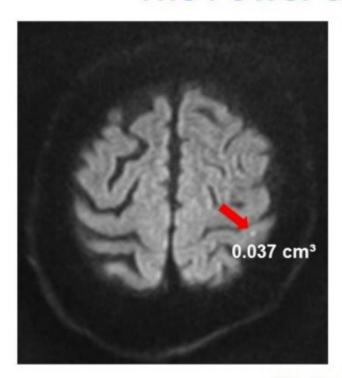
Per-Protocol DW-MRI cerebral imaging at B/L, 24-48h after CAS, and at 30 days

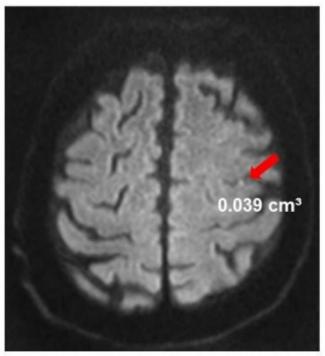
OBJECTIVES This study sought to evaluate the feasibility of the CGuard Carotid Embolic Protective Stent system—a novel thin strut nitinol stent combined with a polyethylene terephthalate mesh covering designed to prevent embolic events from the target lesion in the treatment of carotid artery lesions in consecutive patients suitable for carotid artery stenting.

BACKGROUND The risk of cerebral embolization persists throughout the carotid artery stenting procedure and remains during the stent healing period.

METHODS A total of 30 consecutive patients (age 71.6 \pm 7.6 years, 63% male) meeting the conventional carotid artery stenting inclusion criteria were enrolled in 4 centers in Germany and Poland.

The Power of DW-MRI...





48h after LICA-CAS

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



CARENET DW-MRI analysis*

DW-MRI an	alysis @ 48 h	ours	
	CARENET (n=27)	PROFI (all)	ICSS [†] (n=56)
Incidence of new ipsilateral lesions	37.0%	66.2%	68.0%
Average lesion volume (cm³)	0.039	0.375	12
Maximum lesion volume (cm³)	0.4 5	1	



>10-fold reduction in cerebral lesion volume

*External Core Lab analysis (US)

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

J. Schofer, P. Musialek et al. JACC Intv 2015;8:1229-34



CARENET DW-MRI analysis*

All but one peri-procedural ipsilateral lesions

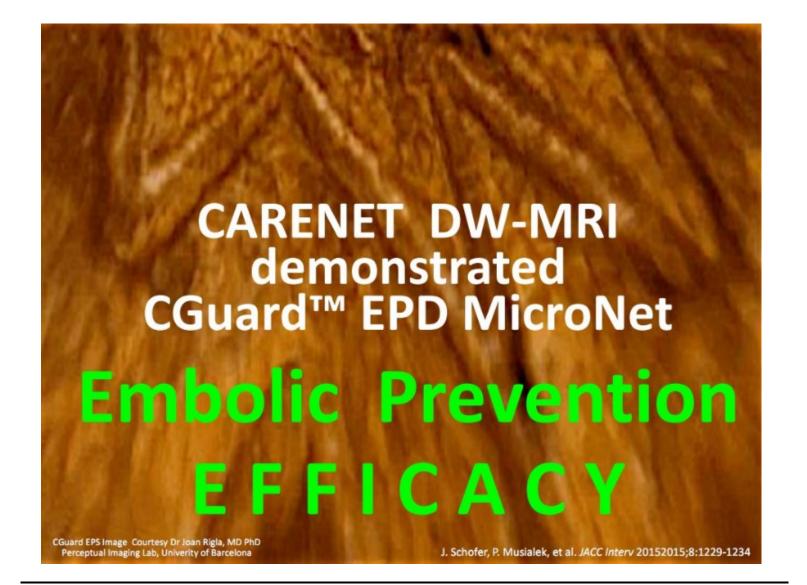
RESOLVED

DW-MRI analysis @ 30 days*		
Incidence of new ipsilateral lesions	1	
Average lesion volume (cm³)	0.08 ± 0.00	
Permanent lesions at 30 days	1	

^{*}External Core Lab analysis (US)

J. Schofer, P. Musialek et al. JACC Intv 2015;8:1229-34







A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent



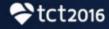
The CGuard CARENET Trial (Carotid Embolic Protection Using MicroNet)

Joachim Schofer, MD,* Piotr Musiałek, MD, DPm., | Klaudija Bijuklic, MD,* Ralf Kolvenbach, MD,; Mariusz Trystula, MD,† Zbigniew Siudak, MD,† Horst Sievert, MD|

RESULTS The primary combined endpoint was the procedure success of the CGuard system and the number and volume of new lesions on the ipsilateral side assessed by diffusion-weighted magnetic resonance imaging at 4.6 h post-procedure and at 30 days. The secondary endpoint was 30-day major adverse cardiac or cerebrovascular events (death, stroke, or myocardial infarction). Protection devices were used in all procedures. Procedure success was 100%, with 0% procedural complications. The 30-day major adverse cardiac or cerebrovascular events rate was 0%. New ipsilateral ischemic lesions at 48 h occurred in 37.0% of patients and the average lesion volume was 0.039 ± 0.08 cm². The 30-day diffusion-weighted magnetic resonance imaging showed complete resolution of all but 1 periprocedural lesion and only 1 new minor (0.116 cm²) lesion in relation to the 48-h scan.

CONCLUSIONS The use of the CGuard system in patients undergoing carotid artery stenting is feasible. In addition, the benefit of using CGuard may extend throughout the stent healing period. (J Am Coll Cardiol Intv 2015;8:1229-34)

 large for routine DW-MRI at 3 time points in relation to CAS





A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent



The CGuard CARENET Trial (Carotid Embolic Protection Using MicroNet)

Joachim Schofer, MD,* Piotr Musiałek, MD, DPm., | Klaudija Bijuklic, MD,* Ralf Kolvenbach, MD,; Mariusz Trystula, MD,† Zbigniew Siudak, MD,† Horst Sievert, MD|

RESULTS. The primary combined endpoint was the procedure success of the CGuard system and the number and volume of new lesions on the ipsilateral side assessed by diffusion-weighted magnetic resonance imaging at 4.6 h post-procedure and at 30 days. The secondary endpoint was 30-day major adverse cardiac or cerebrovascular events (death, stroke, or myocardial infarction). Protection devices were used in all procedures. Procedure success was 100%, with 0% procedural complications. The 30-day major adverse cardiac or cerebrovascular events rate was 0%. New ipsilateral ischemic lesions at 48 h occurred in 37.0% of patients and the average lesion volume was 0.039 ± 0.08 cm³. The 30-day diffusion-weighted magnetic resonance imaging showed complete resolution of all but 1 periprocedural lesion and only 1 new minor (0.116 cm²) lesion in relation to the 48-h scan.

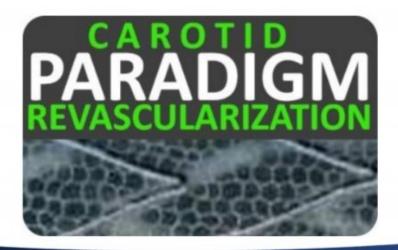
CONCLUSIONS The use of the CGuard system in patients undergoing carotid artery stenting is feasible. In addition, the benefit of using CGuard may extend throughout the stent healing period. (J Am Coll Cardiol Intv 2015;8:1229-34)

- large for routine DW-MRI at 3 time points in relation to CAS
- uderpowered for clinical endpoints or any potential device-related events

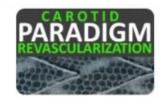


Prospective evaluation of All-comer perRcutaneous cArotiD revascularization In symptomatic and increased-stroke-risk asymptomatic carotid artery stenosis using the CGuard™ MicroNet – covered embolic prevention stent system:

The **PARADIGM** study







Objective

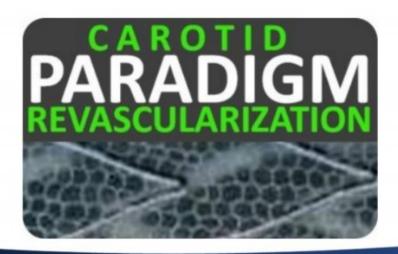
 to evaluate feasibility and outcome of <u>routine</u> anti-embolic stent system use in <u>unselected</u>, <u>consecutive</u> patients referred for carotid revascularization (<u>'all-comer</u>' study)



The PARADIGM study



100 consecutive CAS pts / 12mo*





* determined by typical yearly volume



Study questions:

- (1) feasibility of routine use of CGuard MN-EPS in an all-comer carotid stenosis requiring revasc.
- ?
- (2) CGuard EPS device/procedure acute success rate
- ?
- (3) safety clinical efficacy @30-days and @12 months
 - s ?
- (4) proportion of all-comer carotid stenosis patients that can be treated through the endovascular route
- (5) feasibility of MN-EPS post-dilatation optimization (full endo reconstuction; "CEA-like" effect of CAS)





Methods:

- academic cardio-vascular centre
- investigator-initiated study
- not industry-funded
- all-comer inclusion (target = 101 consecutive patients)
- no exclusion critera, all referrals tracked
- routine consultation and management pathways
- qualitative and quantitative lesion & stent evaluation
- investigator-independent neurological and angiographic evaluation, and external study data verification

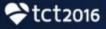


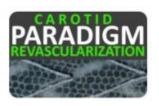


Methods (cont'd):

- ASYMPTOMATIC patients treated interventionally only if at /stroke risk
- established lesion-level increased-risk crieria used:
 - thrombus-containing
 - documented progressive
 - irregular and/or ulcerated
 - contralateral ICA occlusion/stroke
 - asymptomatic ipsilateral brain infarct

AbuRahma A et al. *Ann Surg*. 2003;238:551-562. Ballotta E et al. *J Vasc Surg* 2007;45:516-522. Kakkos SK et al. (ACSRS) *J Vasc Surg*. 2009;49:902-909. Lovett JK et al. *Circulation* 2004;110:2190-97 Nicolaides AN et al. *J Vasc Surg* 2010;52:1486-96. Taussky P et al. *Neurosurg Focus* 2011;31:6-17.





Methods: The CAS Procedure

- EPD use mandatory; EPD selection according to the 'Tailored CAS' algorithm*
- Liberal postdilatation accepted in order to maximize potential for 'endovascular full reconstruction' (minimizing residual stenosis)
 - NB. 1. DWI evidence of effective MicroNet prevention against cerebral embolization (CARENET/PROFI)
 - Residual stenosis after CAS as independent predictor of in-stent restenosis

Van Laanen J et al. *J Cardiovasc Surg*Cosottini M et al. *Stroke Res*Musialek P et al. *J Endovasc Ther*Wasser K et al. *J Neurol*

*Pieniazek P, Musialek P et al. J Endovasc Ther 2008;15:249-62. Cremonesi A et al. EuroInervention 2009;5:589-98. Pieniazek P, Musialek P et al. J Endovasc Ther 2009;16:744-51.



P. Musialek, A. Mazurek et al. *EuroIntervention* 2016;12:e658-70 (PARADIGM design and 30-day outcome data)



PARADIGM: investigator – independent

external source data verification KCRI



Excellence in clinical research

external angiographic analysis



external statistical analysis





P. Musialek, A. Mazurek et al. *EuroIntervention* 2016;12:e658-70 (PARADIGM design and 30-day outcome data)

PARADIGM

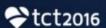


Study endpoints:

PRIMARY a composite of death, stroke (major/minor) and MI
in the peri-procedural period, at 30 days, and up to 12 months

SECONDARY

- (1) acute study device success defined as ability to treat the index carotid lesion using the study device (CGuard MN-EPS) successfully delivered and deployed at the lesion site, obtaining residual diameter stenosis <30% by QA (2) procedural success defined as device success in absence of any vascular
- (3) in-stent velocities/patency (Duplex)
- (4) long-term clinical efficacy: stroke and stroke-related death
- 30 days
- every 12 months up to 5y



P. Musialek, A. Mazurek et al. EuroIntervention 2016;12:e658-70 (PARADIGM design and 30-day outcome data)

complication that would require interventional management

PARADIGM study: referrals flow chart 139 carotid stenosis patient referrals





Neuro Vascular Team

- Neurologist
- Interventional angiologist
- Vascular surgeon
- Cardiologist

for carotid revascularisation 108 patients NOT for carotid revascularisation 31 patients

n=24: increased stroke risk and/or lesion severity criteria not met

n=2: ICA totally occluded on verification

n=2: ICA functional occluded + h/o prior ipsilateral large cerebral infarct with haemorrhagic transformation

n=1: major post-stroke disability, ICA functionally occluded

n=1: severe circulatory failure (ICA stenosis asympt.)

n=1: malignancy with limited life expectancy (ICA stenosis asympt.)

P. Musialek, A. Mazurek et al. EuroIntervention 2016;12:e658-70

⇔tct2016

PARADIGM study: revascularisation flow chart 108 patients for carotid revascularisation



(93%)

(1%)

(6%)

CAS in n=100 patients (bilateral in 5)

CAS+CEA in n=1 patient (LICA-CEA and RICA-CAS)

hybrid management

in n=7
patients

n=1 eGRF 14 → no contrast

n=2 hostile access

n=1 major ICA kink/loop

n=1 severe aortic valve disease +calcific LICA (AVR+CEA)

n=1 floating thrombus in CCA

n=1 ICA diameter <2.0 mm

+contralateral ICA occlusion

106 ICAs treated endovascularly in 101 patients

using exclusively the MicroNet-covered embolic prevention stent system

♦ tct2016

lusialek, A. Mazurek et al. EuroIntervention 2016;12:e658-70

Table 1. Clinical characteristics of the study patients (n=101).

Age, mean±SD (min-max)	69±7 (51-86)
Male, % (n)	70% (71)
Symptomatic, % (n)	55% (55)
Symptomatic ≤14 days, % (n)	22%* (12)
Acutely symptomatic (emergent CAS), % (n)	14%* (9)
Index lesion (CAS), % (n)	
RICA	51% (52)
LICA	49% (49)
RICA+LICA	5% (5)
CAD, % (n)	63% (64)
h/o MI, % (n)	32% (32)
CABG or PCI in the past, % (n)	40% (40)
PCI as bridge to CAS, % (n)	18% (18**)
AFib (h/o or chronic), % (n)	9% (9)
Diabetes, % (n)	41% (41)
h/o neck or chest radiotherapy, % (n)	6% (6)
*proportion of symptomatic nationts: **simultaneou	is (one-stage)



EuroIntervention 2016;12:e658-70



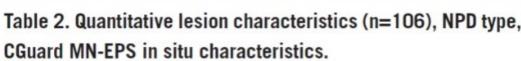
Table 1. Clinical characteristics of the study patients (n=101).

Age, mean±SD (min-max)	69±7 (51-86)	
Male, % (n)	70% (71)	
Symptomatic, % (n)	55% (55)	
Symptomatic ≤14 days, % (n)	22%* (12)	
Acutely symptomatic (emergent CAS), % (n)	14%* (9)	
Index lesion (CAS), % (n)		
RICA	51% (52)	
LICA	49% (49)	
RICA+LICA	5% (5)	
CAD, % (n)	63% (64)	
h/o MI, % (n)	32% (32)	
CABG or PCI in the past, % (n)	40% (40)	
PCI as bridge to CAS, % (n)	18% (18**)	
AFib (h/o or chronic), % (n)	9% (9)	
Diabetes, % (n)	41% (41)	
h/o neck or chest radiotherapy, % (n) 6% (6		
*proportion of symptomatic nationts, **simultaneous	is (one stage)	





EuroIntervention 2016;12:e658-70





external Corelab

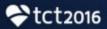
	All (n=106 lesions)	Symptomatic n=55	Asymptomatic n=51	<i>p</i> -value
Before CAS	A		T 7	
PSV, m/s	3.7±1.2	3.7±1.1	3.7±1.2	0.964
EDV, m/s	1.2±0.5	1.1±0.5	1.2±0.5	0.268
Diameter stenosis % (QA)	83±9	80±9	86±9	0.002
CAS				
EPD type				
Proximal	46% (49)	56% (31)	35% (18)	0.030
Distal	54% (57)	44% (24)	65% (33)	

ICA reference diameter 4.99 ± 0.36mm (from 4.27 to 6.02 mm)

Lesion length 19.9 ± 5.8mm (from 8.19 to 30.25 mm)

Direct (primary) stenting in 9 (8.5%); predilatation in 97 (91.5%) lesions Postdil. balloon: \emptyset 4.5mm (n=9); \emptyset 5.0mm (n=55); \emptyset 5.5mm (n=37); \emptyset 6.0mm (n

EuroIntervention 2016;12:e658-70



Emboshield (n=11); FilterWire (n=15); Spider (n=31)
 # Gore FlowReversal (n=6) or flow reversal with MoMa (n=43); (mean flow reversal time was 6min 35s, from 3min 51s to 11min 2s)

Table 2.(cont'd) CGuard MN-EPS in situ characteristics.

	All (n=106 lesions)	Symptomatic n=55	Asymptomatic n=51	<i>p</i> -value
After CAS				
Stent length (QA, CoreLab) [§]				N/A
Nominal 30 mm	29.82±0.68	29.83±0.76	29.80±0.59	
(min-max)	(27.83-32.62)	(27.83-32.62)	(28.83-31.89)	
Nominal 40 mm	39.89±0.59	39.80±0.70	39.97±0.51	
(min-max)	(38.88-41.43)	(38.88-41.43)	(39.14-41.01)	
Residual diameter stenosis	6.7±5%	6.1±5%	7.8±5%	0.262
In-stent PSV, m/s	0.68±0.29	0.64±0.26	0.72±0.31	0.121
in-stent EDV, m/s	0.18±0.08	0.16±0.07	0.19±0.08	0.087



 $^{^{5}}$ In three cases two overlapping stents were used to cover the whole lesion length; these are not included in the in situ stent length evaluation. N/A: not applicable



EuroIntervention 2016;12:e658-70



Table 2.(cont'd) CGuard MN-EPS in situ characteristics.

	All (n=106 lesions)	Symptomatic n=55	Asymptomatic n=51	<i>p</i> -value
After CAS				
Stent length (QA, CoreLab) [§]				N/A
Nominal 30 mm	29.82±0.68	29.83±0.76	29.80±0.59	
(min-max)	(27.83-32.62)	(27.83-32.62)	(28.83-31.89)	
Nominal 40 mm	39.89±0.59	39.80±0.70	39.97±0.51	
(min-max)	(38.88-41.43)	(38.88-41.43)	(39.14-41.01)	
Residual diameter stenosis	6.7±5%	6.1±5%	7.8±5%	0.262
In-stent PSV, m/s	0.68±0.29	0.64±0.26	0.72±0.31	0.121
in-stent EDV, m/s	0.18±0.08	0.16±0.07	0.19±0.08	0.087

not included in the in situ stent length evaluation. N/A: not applicable

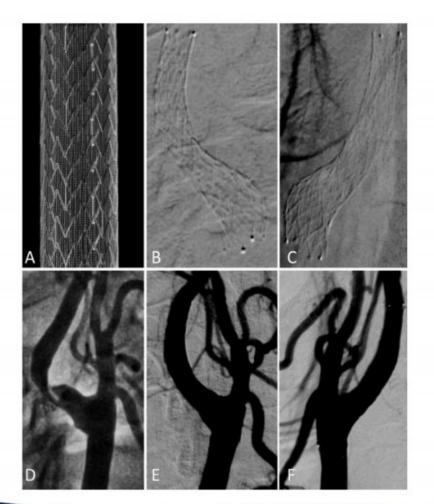


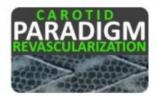
analy



EuroIntervention 2016;12:e658-70

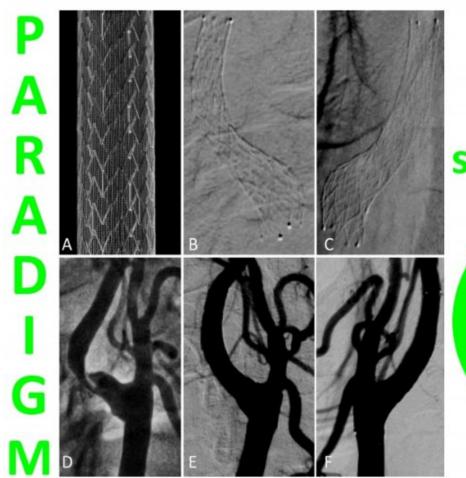








EuroIntervention 2016;12:e658-70





systematic





EuroIntervention 2016;12:e658-70

PARADIGM



 CAS feasibility using the study-tested MicroNet-covered embolic prevention stent system 100% CAS (n= 106)

(ie, no cross-over to other stents or other carotid stent use during the whole study period)

 Device success 	99.1%	(n=105)*
 Procedure success 	99.1%	$(n=105)^*$
 Transient dopamine infusion 	15.1%	(n = 16)
 Debris in EPD 	17.9%	(n = 19)
 Vascular plug closure 	53.8%	(n = 57)
 Access site complications 	0%	(n = 0)

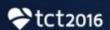
^{*} in 1 case no stent post-dilatation was performed due to profound bradycardia-asystole, and 46% residual diameter stenosis was left (ie, above the Protocol-defined threshold <30% DS for "device success")

ECA patency data

6/106 (5.6%) ECAs were occluded on the index side prior to CAS 3/100 (3.0%), with severe stenosis prior to CAS, occluded at CAS NO ECA occlusion occurred between CAS and 30 days

=> no concern

30-day neurological, duplex, and cardiologic follow up was executed in 100% patients (101) and arteries (106)



PARADIGM: 30 days



Clinical Results (MACNE)

O peri-procedural death/major stroke/MI 0%

• 1 peri-procedural minor stroke* 0.9%

0 new clinical events by 30 days
 (100% follow-up, independent neuro evaluation)

^{*} One patient, with symptomatic RICA stenosis (minor right-hemispheric stroke 2 months prior to CAS), had hypotonia and transient, fluctuating cognitive dysfunction at 24-48h after CAS. The patient had additional neurologic evaluation on discharge (day 7) that showed no change in NIH-SS [=3] and no change in modified Rankin scale [=1] against 48h (and baseline) evaluation.

CT scan on day 2 showed no new cerebral lesions but day 6 CT indicated an extension of the prior lesion in the right hemisphere.

The event, in absence of right haemispheric symptoms and in absence of any clinical sequelae, was CEC—adjudicated as 'minor stroke in relation to CAS'.



EuroIntervention 2016;12:e658-70

Novel PARADIGM in Carotid Revascularization:



Clinical & Duplex US
Outcome Data

@ 12 months

TCT 2016

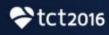




- 106 index arteries / 101 study subjects
- no patient withdrawals by 12 months
- 100% - clinical

- neurological - 12 month follow up

- Duplex US





12month data

- 106 index arteries / 101 study subjects
- no patient withdrawals by 12 months
- 100%
- clinical

- neurological - 12 month follow up

- Duplex US

ZERO Stroke Deaths ZERO Strokes @ 12mo

Per-Protocol independent neurological evaluation





- 106 index arteries / 101 study subjects
- no patient withdrawals by 12 months
- 100% - clinical

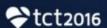
- neurological - 12 month follow up

- Duplex US

ZERO Stroke Deaths ZERO Strokes 30d-12mo

Per-Protocol independent neurological evaluation

- 1 cardiac death @ 11mo (man 68y, heart failure death)
- 3 non-cardiac deaths @ 3mo, 5mo, 11mo
 - urosepsis (woman 73y)
 - pulmonary embolism (woman 67y)
 - microcellular pulmonary cancer (man 71y)





0% stroke

•0% TIA

•0% MI

between 30 days and 12 months

in n=101 /stroke-risk patients (55% symptomatic)

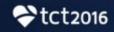






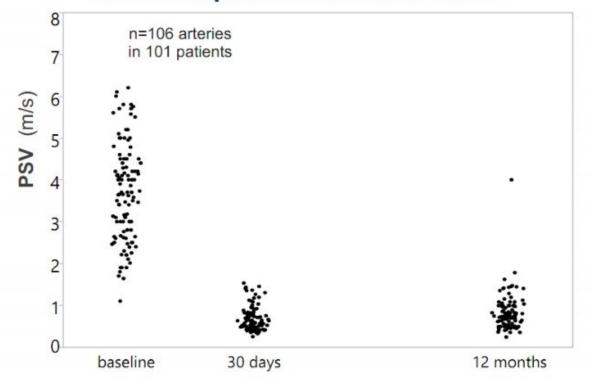
PARADIGM 12 months

- NO device-related adverse events
- NO procedure-related events





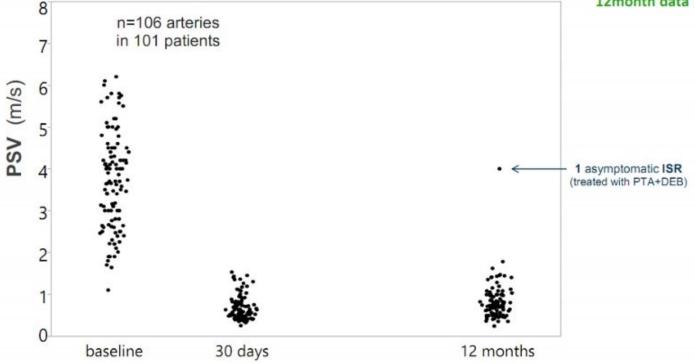
12month data







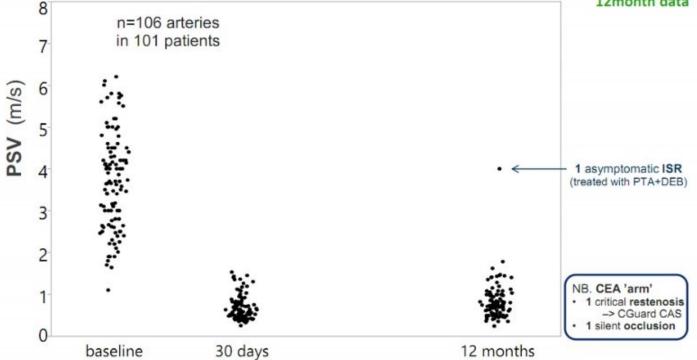
12month data



♦ tct2016



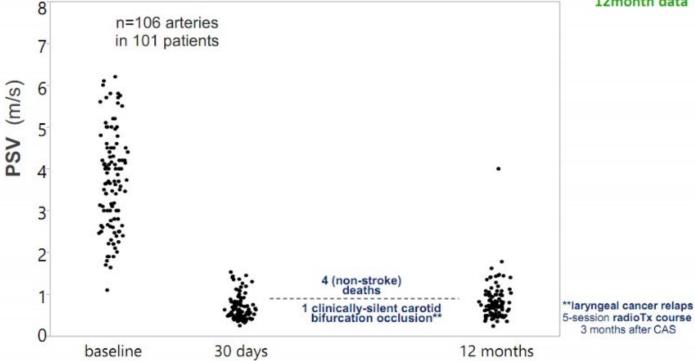


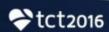






12month data

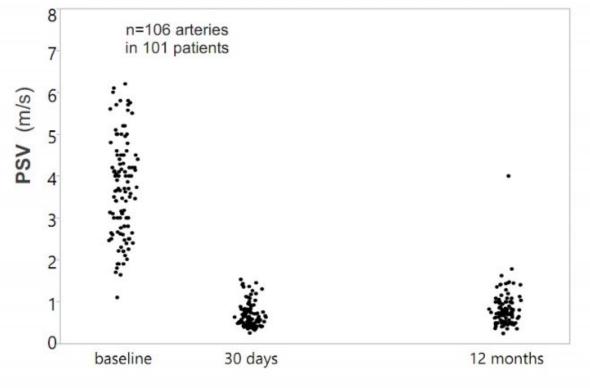


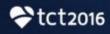


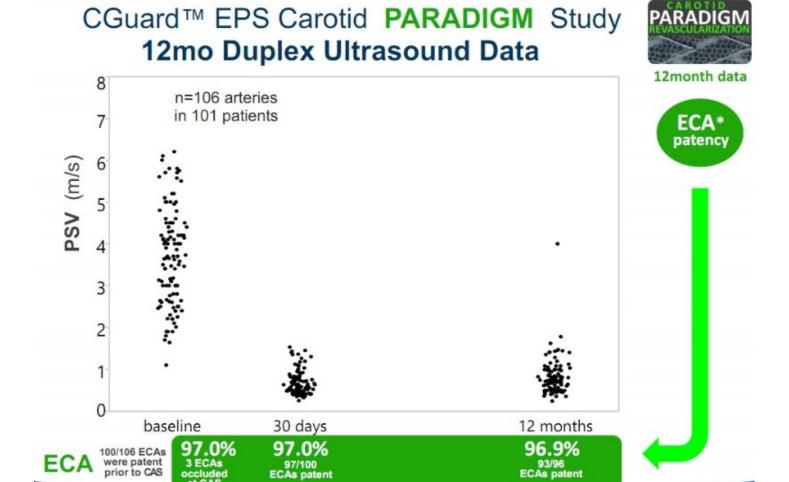




patency





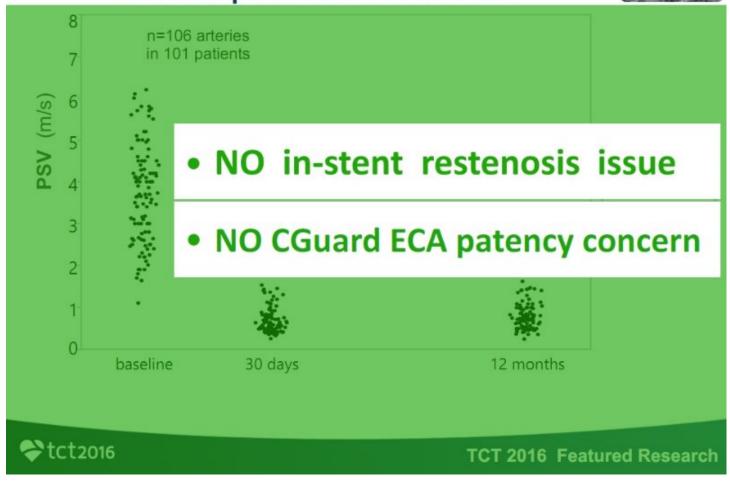


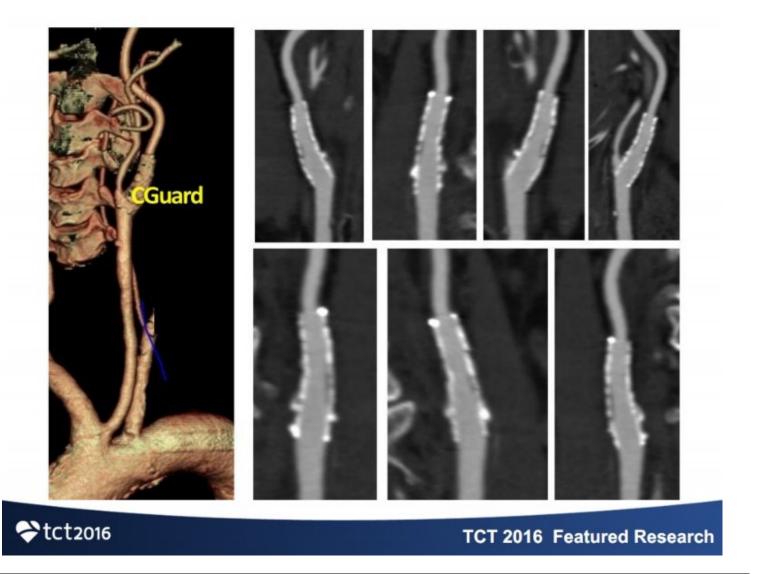
* per stented ICAs/ patent (patient alive)

TCT 2016 Featured Research

tct2016











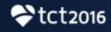
Conclusions





Conclusions

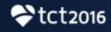
 In the increased-stroke-risk population, including >50% symptomatic patients, CGuard™ EPS demonstrated effective and durable protection against stroke





Conclusions

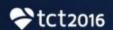
 In the increased-stroke-risk population, including >50% symptomatic patients, CGuard™ EPS demonstrated effective and durable protection against stroke in absence of any device-related adverse events by 12 months





Conclusions

- In the increased-stroke-risk population, including >50% symptomatic patients, CGuard™ EPS demonstrated effective and durable protection against stroke in absence of any device-related adverse events by 12 months
- 12-month Duplex Ultrasound data indicate normal device healing and ECA patency



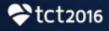
Impact on clinical practice



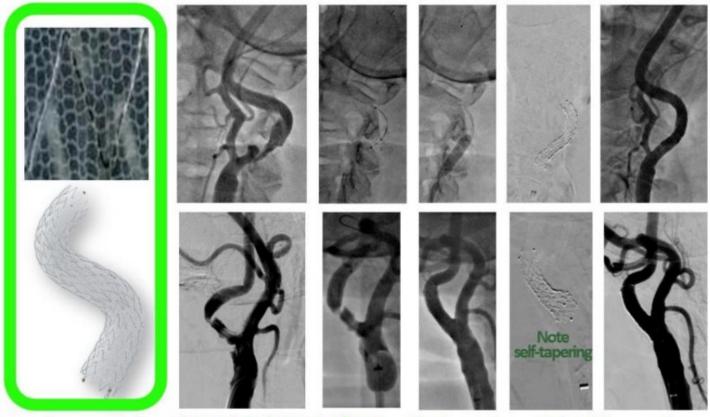
With this novel technology,

The ENDOVASCULAR route of carotid stenosis management in PRIMARY and SECONDARY Stroke Prevention is

- Viable √
- Safe and effective V
- Applicable to routine practice of CAS V
- Applicable to >90% of all-comer patients \checkmark
- Durable in absence of device-related issues

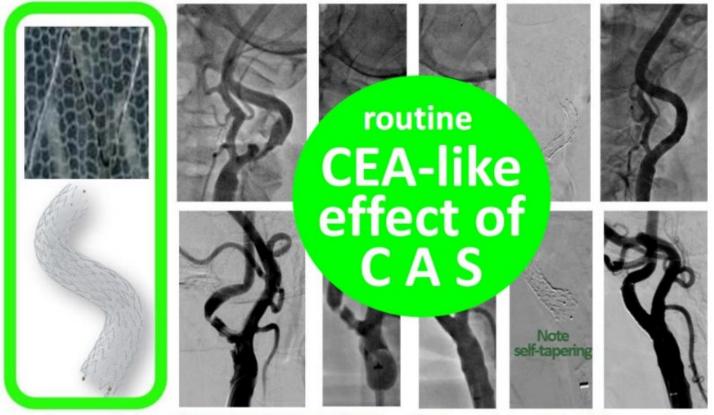


Endovascular Solution for All-Comers

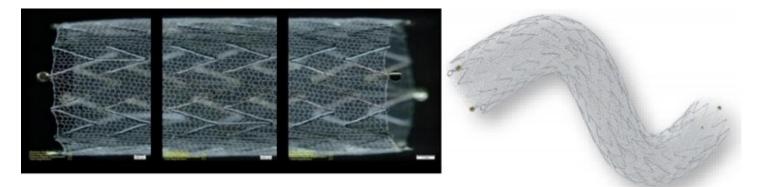


Endovascular Reconstruction of the Carotid Bifurcation Prevention of embolism, Optimal radial force, Conformability

Endovascular Solution for All-Comers



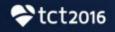
Endovascular Reconstruction of the Carotid Bifurcation Prevention of embolism, Optimal radial force, Conformability

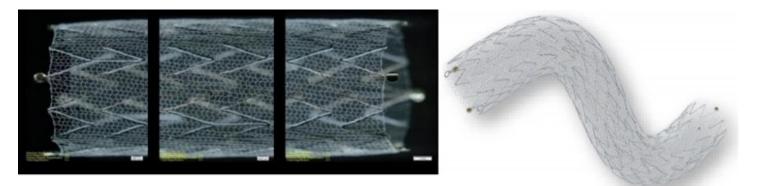


This concept has been desired.

And it works.

This is the future of Carotid Artery Stenting

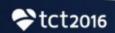


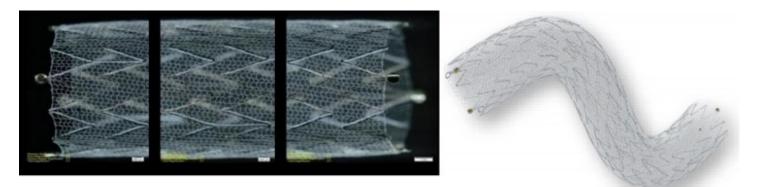


This concept has been desired.

And it works.

This is the future of Carotid Artery Stenting





This concept has been desired.

And it works.





InspireMD CGuard™ Embolic Prevention System 12-Month Clinical Trial Data Further Validate Potential of CGuard™ to Improve Management of Carotid Artery Disease and Prevent Stroke

BOSTON, MA – November 1, 2016 – InspireMD, Inc. (NYSE MKT: NSPR, NSPR.WS) ("InspireMD" or the "Company"), a leader in embolic prevention systems (EPS), neurovascular devices and thrombus management technologies, today announced 12-month follow up data from PARADIGM-101 of the CGuard™ Embolic Prevention System (EPS) which were presented in two presentations at the Transcatheter Cardiovascular Therapeutics (TCT) 2016 scientific symposium, taking place October 29 − November 2 in Washington, D.C. at the Walter E. Washington Convention Center.

In an oral presentation today in the Featured Clinical Research Session titled "Twelve-month Safety and Efficacy of CGuardTM Micronet-Covered Embolic Prevention Stent System: Routine Use to Perform Carotid Revascularization in Symptomatic and Increased Stroke Risk Asymptomatic Patients: The PARADIGM All-Comer Prospective Academic Study," Prof. Piotr Musialek, MD, DPhil, FESC, from the Jagiellonian University Department of Cardiac & Vascular Diseases, in Krakow, Poland, reported 12-month follow up data from PARADIGM-101. PARADIGM-101 is an investigator-led clinical study evaluating the use of CGuardTM EPS in 101 consecutive patients with carotid artery stenosis. Key findings from the presentation included:

- Zero device-related adverse events at 12 months
- CGuard TM EPS device and procedure success were each 99.1%. The device showed excellent placement precision, and there was no foreshortening or elongation
- Vessel narrowing was reduced from 83±9% to only 6.7±5% (p<0.001) by independent core lab analysis
- Peri-procedural death/major stroke/myocardial infarction (MI) was 0%.
- One peri-procedural event was adjudicated by the Clinical Events Committee as a minor stroke (0.9%), with no change in NIH Stroke Scale or modified Ranking scale and no clinical sequel
- At 12 months the device showed a normal healing profile, and the patency of the external carotid artery was normal

"These data further reinforce the strong safety and efficacy profiles reported in previous trials of the CGuard TM EPS, and validate the system as an important option for endovascular management of patients with carotid artery disease," said Prof. Musialek. "Importantly, the very low incidence of peri- or post-procedural complications and stroke create a positive risk-benefit profile for CGuard TM EPS in patients with asymptomatic carotid artery disease. These patients are frequently denied intervention due to fear of the complications associated with conventional intervention, and are left with a substantial risk of stroke when treated only with medication. Our study found that CGuard TM EPS is applicable in up to 90% of all-comer patients with carotid stenosis. These data indicate that CGuard TM EPS may fundamentally alter the paradigm for managing patients with carotid artery disease, whether they have symptoms or not."

In addition, a poster titled "Highly Calcific Carotid Lesions Endovascular Revascularizaton Using a Novel Dual-layer Carotid Stent System CGuardTM: Analysis from the PARADIGM Study," was presented by Adam Mazurek, MD, also from the Jagiellonian University Department of Cardiac & Vascular Diseases. Dr. Mazurek's study described the use of CGuard TM EPS to treat highly calcific carotid stenosis. Because patients with highly calcified carotid lesions are typically contraindicated for endovascular intervention due to suboptimal procedural outcomes with conventional stents, CGuard provides an important new treatment solution.

Key findings from Dr. Mazurek's presentation included:

- 16 of the 101 patients in PARADIGM-101 had hepatocellular carcinoma (HCC) lesions
- No difference in procedural success rates with CGuard TM EPS between highly calcified lesions and other lesions treated in this trial
- Use of CGuard TM EPS in management of highly calcified lesions was safe, with no neurologic or cardiac events during the procedure and during the stent healing period
- Highly calcified lesions treated with CGuard TM EPS showed no restenosis at 12 months

"Highly calcified lesions are particularly difficult to manage with conventional endovascular intervention due to the difficulty in achieving optimal procedure results on one hand, and the risk of carotid artery rupture or perforation on the other. Patients with these lesions remain at risk of stroke, and they require a safe treatment," said Dr. Mazurek. "The results of this study show that the design and mechanical properties of CGuard TM EPS enable safe and effective endovascular management and revascularization of highly calcified lesions. I believe CGuard TM EPS has significant potential as a new approach to managing these difficult lesions and reducing the risk of stroke in patients with highly calcified lesions. Additional studies of CGuard EPS TM in this patient population should further validate common use of this innovative embolic prevention stent system to improve the treatment and outcomes of carotid artery disease."

The data presented at TCT add to a growing body of clinical evidence validating the use of the CGuard as a proven treatment for both symptomatic and asymptomatic patients with carotid artery disease.

About PARADIGM

PARADIGM is an investigator-initiated **P** rospective evaluation of All-comer pe **R** cutaneous c **A** roti **D** revascularization **I** n symptomatic and increased-risk asymptomatic carotid artery stenosis, using C **G** uardTM **M** esh-covered embolic prevention stent system. Dr. Musialek previously presented data from the first cohort in the PARADIGM study, which comprised 71 CGuardTM EPS procedures in unselected all-comer patients, at EuroPCR 2015. The early outcome data in the target cohort of 101 patients were presented as a Late-Breaking Clinical Trial at EuroPCR 2016 and were simultaneously published in EuroIntervention. These data showed a 100% success rate for the CGuard Embolic Prevention System during the placement procedure. Importantly, there were no procedure-related complications during CGuard TM EPS placement and at 30 days post procedure. Similarly, there were no major adverse cardiac or neurological events, as determined by operator-independent neurologist and non-invasive cardiologist evaluation. The new data presented at TCT are important because they confirm safety and durability of the CGuard TM EPS innovative treatment over 12 months.

About CGuard™ EPS

The CGuardTM EPS is designed to prevent peri-procedural and late embolization by trapping potential emboli against the arterial wall while maintaining excellent perfusion to the external carotid artery.

MicroNetTM is a bio-stable mesh woven from a single strand of 20 micron Polyethylene Terephthalate (PET).

CGuard™ EPS is CE Marked and not approved for sale in the U.S. by the U.S. Food and Drug Administration at this time.

Carotid stenosis is a narrowing of the carotid arteries, the major arteries that supply blood and oxygen to the brain. This narrowing results from a buildup of plaque inside the blood vessel and reduces blood flow to the brain. The presence of plaque in the blood vessel can also cause the development of blood clots, which may also reduce blood flow to the brain. In some cases, plaque may rupture or dislodge from the vessel wall and block smaller downstream arteries. Patients with carotid stenosis have an increased risk of stroke as a result of cerebral embolism and decreased blood flow to the brain.

Patients with symptomatic carotid stenosis are typically treated by placement of a stent inside the blood vessel in order to re-open the carotid artery and improve blood flow to the brain. InspireMD's CGuard TM EPS uses the company's patented MicroNetTM technology to provide the revascularization benefits of a stent with a mesh "safety net" that secures the plaque against the blood vessel's arterial wall and thereby prevents plaque and other debris from flowing through the stent's scaffold.

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MicroNet TM 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 TM), neurovascular, and peripheral artery procedures. InspireMD's common stock is quoted on the NYSE MKT under the ticker symbol NSPR and certain warrants are quoted on the NYSE MKT under the ticker symbol NSPR.WS.

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 forwardlooking 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 Annual Report on Form 10-K 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.

Investor Contacts:

InspireMD, Inc.

Craig Shore Chief Financial Officer

Phone: S 1-888-776-6804 FREE

Email: craigs@inspiremd.com

Lazar Partners

David Carey Investor Relations Phone: (212) 867-1768

Email: dcarey@lazarpartners.com