The Neuroguard IEP® 3-in-1 Carotid Stent and Post-Dilation Balloon System with Integrated Embolic Protection

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☒ Stockholder of a healthcare company
☒ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Higher Minor Stroke During CAS vs CEA
Importance of Micro-Embolization

Integrated Embolic Protection (IEP)™

- The first device that combines an embolic protection filter and balloon/stent
- Platform designed for ease of use, enhanced safety and efficiency
- Only filter that allows physicians to adjust filter size and optimize wall apposition
- Patented filter design maximizes embolic capture and side branch protection
- Reduces hospital inventory costs
Cognitive Impairment Due to Embolization
Importance of Micro-Embolization

Diffusion-weighted lesions after carotid artery stenting are associated with cognitive impairment

Maggio, P.a, Altamura, C.a, Landi, D.a, Migliore, S.a, Lupoi, D.b, Moffa, F.c, Quintiliani, L.a, Vollaro, S.a, Palazzo, P.a, Altavilla, R.a, Pasqualetti, P.de, Errante,

CONCLUSIONS:
Our study showed that peri-procedural brain microembolic load impacts negatively on cognitive functions, independently from the influence of patients-related variables. © 2013 Elsevier B.V.

Volume of subclinical embolic infarct correlates to long-term cognitive changes after carotid revascularization.


CONCLUSIONS:
Cognitive assessment of procedure-related subclinical microemboli is challenging. Volumes of embolic infarct correlate with long-term cognitive changes, suggesting that microembolization should be considered a surrogate measure for carotid disease management. Published by Elsevier Inc.
Proven Superior Capture Efficiency

The Paladin System has the Highest Capture Efficiency of 4 Embolic Filters Tested

Paladin filter captured 100% of 75-90 µm embolic particles

Data on file at Contego Medical
24 filters collected for analysis of emboli count and size

The majority of particles captured were less than 100 microns
From 23 paired samples, the Paladin filter collected on average 95% more particles by COUNT and 120% more particles between 40-10 microns than the primary filter.

*Number of Embolic Particles Collected in Paladin vs. Primary Filter*

- Distal
- Proximal

<table>
<thead>
<tr>
<th>Particle Average Length Range (microns)</th>
<th>Count</th>
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<tbody>
<tr>
<td>40-100</td>
<td>4053</td>
</tr>
<tr>
<td>101-200</td>
<td>53332</td>
</tr>
<tr>
<td>201-400</td>
<td>1042</td>
</tr>
</tbody>
</table>

p<0.0001 using the t-test
Slow Flow after Mesh-Covered Stenting
The Paladin filter and Roadsaver captured

- 68% more particles by COUNT and
- 69% more particles between 40-10 microns

than the primary filter the Roadsaver stent

\[ p=0.13 \text{ using the t-test} \]
Asymptomatic delayed stent occlusion after dual layer micromesh stent treatment for high grade carotid artery stenosis

Struffert T., Engelhorn T., Gölitz P., Lücking H., Dörfler A., University of Nuremberg, Erlangen, GERMANY
Filter Histology in Patient Treated with Mo.MA and Paladin

Procedure performed in Leipzig, Germany with Medtronic Mo.MA proximal protection system

Courtesy: Dr. Andrej Schmidt

<table>
<thead>
<tr>
<th>Particle Size</th>
<th>40-99</th>
<th>199</th>
<th>299</th>
<th>&gt;300</th>
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<tbody>
<tr>
<td>Particle Count</td>
<td>2599</td>
<td>136</td>
<td>25</td>
<td>7</td>
</tr>
</tbody>
</table>

![Graph showing particle count and size]
How can we further improve the carotid stenting procedure?

• Stent deployment in most current procedures is still protected by a distal filter
• Distal filters may not be well opposed to the vessel wall
• Distal filters have > 100 micron pores
• The number of steps in CAS is >9
• Number of steps increases risk of procedure
Neuroguard IEP 3-in-1 System
Neuroguard IEP Carotid Stent

Neuroguard IEP
3-in-1 Carotid Stent and Post-Dilation Balloon System
Neuroguard IEP Carotid Stent
Stent Design

- Asymmetrical tapered design
- Flared ends

Stent Lengths (30, 40 mm)
Mid Stent OD (6, 7 mm)
Neuroguard IEP Carotid Stent

Closed Cell Design
No kinking to >270°

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Result</th>
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<tbody>
<tr>
<td>Stent deployment accuracy</td>
<td>&lt;1 mm</td>
</tr>
<tr>
<td>Maximum stent foreshortening</td>
<td>14%</td>
</tr>
<tr>
<td>Kink Resistance</td>
<td>278 degrees</td>
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<tr>
<td>Conformability</td>
<td>278 degrees</td>
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</table>
Neuroguard IEP Carotid Stent

Radial Force

<table>
<thead>
<tr>
<th>Stent Type</th>
<th>Radial Force (N/mm)</th>
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<tbody>
<tr>
<td>Contego</td>
<td>0.50</td>
</tr>
<tr>
<td>Abbott Xact</td>
<td>0.38</td>
</tr>
<tr>
<td>Boston Sci Wallstent</td>
<td>0.20</td>
</tr>
</tbody>
</table>

The figure shows the comparison of radial force for different stent models and sizes, with the Contego Neuroguard 7 mm model having the highest radial force, followed by the Abbott Xact 7 mm model, and the Boston Sci Wallstent 6 mm model having the lowest radial force.
Neuroguard IEP Carotid Stent

Optimized Flexibility/Conformability

Abbott Xact® Stent

Neuroguard IEP
PERFORMANCE I

• **Protection against Emboli during carotid stenting using a 3-in-1 delivery system comprising of a Post-dilation balloon, integrated Embolic filter and Novel Carotid Stent I**

  – A European feasibility trial of the Neuroguard IEP Carotid Stent System beginning in Q1 2018
  – Approximately 100 subjects, with preliminary analysis performed at 56
  – The primary endpoint is the 30-day rate of MAE, defined as the cumulative incidence of any periprocedural (≤ 30 days post-procedure) death, stroke or MI.

<table>
<thead>
<tr>
<th>Investigators</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prof. Alberto Cremonesi</td>
<td>Cotignola, Italy</td>
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<td>Prof. Sasko Kedev</td>
<td>Skopje, Macedonia</td>
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<tr>
<td>Prof. Ivo Petrov</td>
<td>Sofia, Bulgaria</td>
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<td>Prof. Dierk Scheinert</td>
<td>Leipzig, Germany</td>
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<td>Dr. Ralf Langhoff</td>
<td>Berlin, Germany</td>
</tr>
<tr>
<td>Dr. Zoran Milosevic</td>
<td>Ljubljana, Slovenia</td>
</tr>
</tbody>
</table>
PERFORMANCE II

• A US multicenter clinical study to evaluate the safety and efficacy of the Neuroguard IEP Carotid Stent System

• Approximately 300 subjects will be enrolled, and will be followed through 36 months post-procedure

• The primary endpoint is the 30-day rate of major adverse event (MAE), defined as death, stroke or myocardial infarction (MI) within 30 days of the index carotid stenting procedure, and ipsilateral stroke at 12 months of procedure.

• Start Date Q3 2018

• PI: Dr. William Gray
Summary

• The biggest risk of stroke is due to inadequate embolic protection during index procedure, especially during post-dilation

• Micro embolization < 100 micron particles is important and causes minor stroke

• Trans-femoral or trans-radial stenting with experienced operators using the Neuroguard IEP system may be a good option and will be investigated further via the PERFORMACE Series of Trials
Thank you!
The Neuroguard IEP® 3-in-1 Carotid Stent and Post-Dilation Balloon System with Integrated Embolic Protection

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