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

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Disclosure

Speaker name:

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
How can we further improve the carotid stenting procedure?

- Minor stroke remains a the Achilles Heal of CAS
- Worldwide, most CAS procedures are are protected by one distal filter
- Most commercially available distal filters may not be well opposed to the vessel wall and have > 100 micron pores
- This allows microembolization
- The number of steps in CAS is >9
- Number of steps increases risk of procedure
Strategies to Protect Against Microembolization During CAS

- Mesh Covered Stents
- Proximal Occlusion
Comparison of Particle Counts in CAS with Mesh-Covered Stents vs Non-Mesh Covered Stents

- **Paladin Filter + Roadsaver Stent**: N=13, P=0.13 using the t-test
- **Paladin Filter + Non-mesh covered stents**: N=10, 1784 (40-100 microns), 3014 (101-200 microns), 117 (201-400 microns), 149 (101-200 microns), 16 (201-400 microns), 52 (101-200 microns)
Slow Flow after Mesh-Covered Stenting
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
Neuroguard IEP 3-in-1 System
Neuroguard IEP Carotid Stent

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

Contego Medical
INTEGRATED EMBOLIC PROTECTION®
Neuroguard IEP Carotid Stent
Neuroguard IEP Carotid Stent
Stent Design

• Closed Cell
• Asymmetrical hourglass design
• Flared ends
• Optimized Radial Strength and Flexibility

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

Kink Resistance to $> 270^\circ$
Neuroguard IEP Carotid Stent

Optimized Flexibility/Conformability

Abbott Xact® Stent

Neuroguard IEP
Neuroguard IEP Carotid Stent

Radial Force

<table>
<thead>
<tr>
<th>Stent Type</th>
<th>Diameter</th>
<th>Radial Force</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neuroguard 7 mm</td>
<td></td>
<td>0.5</td>
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<tr>
<td>Abbott Xact 7 mm</td>
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<td>0.4</td>
</tr>
<tr>
<td>Neuroguard 6 mm</td>
<td></td>
<td>0.6</td>
</tr>
<tr>
<td>Boston Sci Wallstent 6 mm</td>
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<td>0.2</td>
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</table>
# Neuroguard IEP Carotid Stent

## Stent Free Cell Area

<table>
<thead>
<tr>
<th>Stent Type</th>
<th>Stent Design</th>
<th>Free Cell Area (mm$^2$)</th>
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</thead>
<tbody>
<tr>
<td>Wallstent</td>
<td>Closed cell</td>
<td>1.08</td>
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<tr>
<td>Xact</td>
<td>Closed cell</td>
<td>2.74</td>
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<tr>
<td><strong>Neuroguard</strong></td>
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<td>Nexstent</td>
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<td>Precise</td>
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<td>Protégé</td>
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<td>20.71</td>
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<tr>
<td>Acculink</td>
<td>Open cell</td>
<td>11.48</td>
</tr>
</tbody>
</table>
Neuroguard IEP Carotid Stent
400 Million Cycle Fatigue Testing

No breakage was observed on any of the test articles following 400,000,000 cycles
Neuroguard IEP Carotid Stent
MRI Compatibility

Non-clinical testing demonstrated that the Neuroguard Carotid Stent is MR Conditional. A patient with this device can be scanned safely in an MR system.

T1 Weighted, spin echo pulse sequence
6-Month Porcine Study

6-Month Histopathology Results

- There was no procedural injury in the stented vessels.
- The Neuroguard stent was fully biocompatible at 6 months.
- The stented segments showed no stenotic response.
- The filter deployment region showed no neointima formation.
- The downstream tissues were normal.
Summary

• The biggest risk of stroke is due to inadequate embolic protection during index procedure.

• Micro embolization is important and causes minor stroke.

• The Neuroguard IEP has been developed to address this issue in a safe and efficient manner.

• Will be studied in detail in the PERFORMACE I and II Trials (400 patients total).
Thank you!