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Disclosures
Consultant to:
Contego Medical
W.L. Gore

Gore Embolic Filter (GEF)

Gore Embolic Filter: High Capture Efficiency

30 day outcomes

Use of a novel embolic filter in carotid artery stenting: 30-Day results from the EMBOLDEN Clinical Study

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<table>
<thead>
<tr>
<th>Outcome</th>
<th>Octogenarians: 51/10 MAE 3.4%</th>
<th>Non-octogenarians: 3.2%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status</td>
<td>30 day</td>
<td>30 day</td>
</tr>
<tr>
<td>Stent</td>
<td>30 day</td>
<td>30 day</td>
</tr>
<tr>
<td>Proximal</td>
<td>30 day</td>
<td>30 day</td>
</tr>
<tr>
<td>Distal</td>
<td>30 day</td>
<td>30 day</td>
</tr>
<tr>
<td>Total</td>
<td>30 day</td>
<td>30 day</td>
</tr>
</tbody>
</table>
The Neuroguard System (Contego)

The first device that combines an embolic protection filter and balloon/stent
- 40 micron pore size allows micro-embolic capture
- Filter size can be adjusted to suit each patient’s unique anatomy

The PALADIN Study

- Objective: To evaluate the procedural safety and technical success of the Paladin System in subjects with carotid artery stenosis
- Co-Principal Investigators: Profs. Horst Sievert MD and Thomas Zeller MD

5 Sites in Germany:
- Universitätsklinikum Leipzig, Leipzig, Prof. Dietrich Scheinert MD
- Cardiovasculäres Zentrum, Frankfurt, Prof. Horst Sievert MD
- Meyle-Schroeder Clinic, Cardiovascular Center Hamburg, Prof. Joachim Schofer MD
- Universitätsklinikum Bad Kissingen, Freiberg, Prof. Thomas Zeller MD
- Sankt Gertrauden-Krankenhaus, Berlin, Dr. Ralf Langhoff

The Solution:
Integrated Embolic Protection (IEP)™
- The first device that combines an embolic protection filter and balloon/stent
- 40 micron pore size allows micro-embolic capture
- Filter size can be adjusted to suit each patient’s unique anatomy

30 Day Clinical Results
Paladin Study demonstrates excellent results for CAS independent of type of carotid stent used

PALADIN Registry
Post-Procedural and 30-Day Outcomes
% (N/105)
- Stroke, Death and MI: 0.00 (0)
- MI: 0.00 (0)
- Stroke and Death: 0.05 (1)

- 106 subjects enrolled at 5 sites in Germany
- 99% Technical Success
- No Deaths, strokes, MI or other Major Adverse Events (MAE) through discharge
- 1 stroke at day 12 due to stent thrombosis of a mesh-covered stent

DW-MRI Results from a Single Center

MRI DATA
Incidence and Size of New Lesions on MRI Were Significantly Lower Than Other Technologies

<table>
<thead>
<tr>
<th>Comparative DW-MRI Results</th>
<th>Paladin (n=33)</th>
<th>PROFI (n=37)</th>
<th>ICSS (n=32)</th>
<th>CARENET (n=26)</th>
<th>CGuard (n=26)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence of New Lesions</td>
<td>21.2%</td>
<td>45%</td>
<td>87%</td>
<td>73%</td>
<td>48%</td>
</tr>
<tr>
<td>Mean number of lesions per pt.</td>
<td>0.24 1.0 +/- 1.4</td>
<td>3.6 +/- 3.2</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Mean Lesion Volume (cm³)</td>
<td>0.005 0.18</td>
<td>0.59 NA 0.05</td>
<td></td>
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</tr>
</tbody>
</table>

Data courtesy Joachim Schofer MD et al.

DW-MRI performed in 33 patients

# of subjects with new ischemic lesions 7

% of subjects with new ischemic lesions 21.2%

Total number of new ischemic lesions 8

Mean Lesion Volume – Only patients with new lesions 0.004 cm³

Mean Lesion Volume – All Patients 0.003 cm³

* A lesion was one patient, and a single lesion was observed in the remaining 6 patients.
Filter Histological Analysis: Particle Size

Filters in a subset of 23 subjects were collected for histopathological analysis to evaluate size and number of particles in both Paladin and primary IEP/EPU filter.

![Graph showing particle frequency and size distribution.]

Filter Histological Analysis: Major Points

- >90% of particles captured were less than 100 microns in size
- These are NOT captured by current filters, but ARE captured by PALADIN
- Consistent with MRI findings

Neuroguard IEP 3-in-1 System

Neuroguard IEP Carotid Stent

Thank you