Neurologic Outcome Following Implantation of a Neuro-Spinal Scaffold™ into the Lesion Cavity in Acute Thoracic Complete Spinal Cord Injury: Results of a Pilot Study

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Disclosures

- Globus Medical: Consultant, royalties
- Depuy/Synthes: Royalties
- Stryker: Royalties
- DOD: Research Support
- Barrow Neurological Foundation: Research Support
Neuro-Spinal Scaffold™ - Designed to Act as a Physical Substrate to Promote Neural Repair

Highly porous device

Composition:
- PLGA is the inert biodegradable base
- Poly-L-Lysine promotes cellular adhesion

Promotes the formation of remodeled tissue that supports neural regeneration

Laminin / β3-tubulin
The Neuro-Spinal Scaffold™ Preserves Macroscopic Spinal Cord Architecture

Rat Acute Spinal Cord Contusion Model 3 Months After Injury

<table>
<thead>
<tr>
<th>Cyst Reduction</th>
<th>White Matter Sparing</th>
<th>Remodeled Tissue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>Control</td>
<td>Control</td>
</tr>
<tr>
<td></td>
<td>4.0</td>
<td>0.6</td>
</tr>
<tr>
<td>Neuro-Spinal Scaffold</td>
<td>2.0</td>
<td>0.4</td>
</tr>
</tbody>
</table>

*C* indicates *P*<0.05
First-in-Human Implantation of the Neuro-Spinal Scaffold™
All Subjects Exhibited an Acute Necrotic Cavity Allowing for Neuro-Spinal Scaffold™ Implantation

Select intraoperative images from 4 Neuro-Spinal Scaffold implantsations
# Clinical Outcome of Patients Implanted with the Neuro-Spinal Scaffold™ - ISNCSCI

<table>
<thead>
<tr>
<th>Patient</th>
<th>Gender</th>
<th>Age</th>
<th>NLI</th>
<th>AIS Admission</th>
<th>Time to Surgery (hr)</th>
<th>Neurologic Outcome to Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>25</td>
<td>T11</td>
<td>A</td>
<td>7</td>
<td>Converted to AIS C at 1 month Δ LEMS = +18 at 12 months</td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>22</td>
<td>T7</td>
<td>A</td>
<td>42</td>
<td>Remains AIS A but with marked bowel and bladder improvement by 12 months</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>55</td>
<td>T4</td>
<td>A</td>
<td>81</td>
<td>Converted to AIS B at 1 month</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>28</td>
<td>T3</td>
<td>A</td>
<td>50</td>
<td>Remains AIS A at 6 months</td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>18</td>
<td>T8</td>
<td>A</td>
<td>66</td>
<td>Converted to AIS B at 6 months</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>21</td>
<td>T10</td>
<td>A</td>
<td>10</td>
<td>Has not had follow-up clinical exams</td>
</tr>
</tbody>
</table>
Pilot Study Conclusions & Future Clinical Development (INSPIRE Study)

**Conclusions**
- No SAE’s related to the *Neuro-Spinal Scaffold™* or surgical procedure for implantation
- Preliminary clinical findings are promising
- Further investigation is required to better understand therapeutic benefit

**The INSPIRE Study**
- Aiming to enroll up to 20 patients, inclusive of the 5 patients in the Pilot study
- Enrollment is open at 18 active U.S. clinical sites

*InVivo Study of Probable Benefit of the Neuro-Spinal Scaffold™ for Safety and Neurologic Recovery in Subjects with Complete Thoracic AIS A Spinal Cord Injury*