

**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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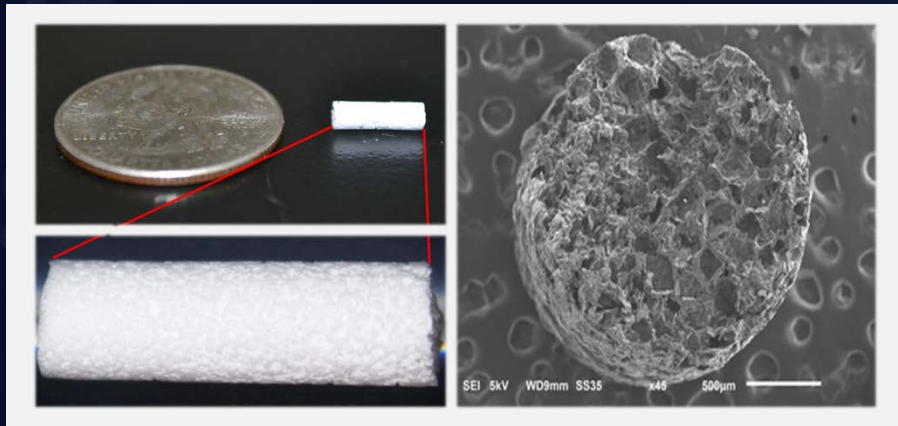
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Kee Kim, MD, UC Davis

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



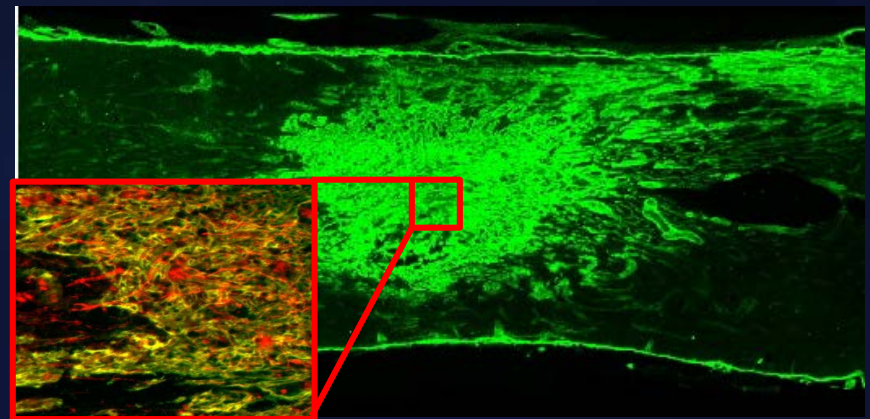
Highly porous device

Composition:

PLGA is the inert biodegradable base

Poly-L-Lysine promotes cellular adhesion

Promotes the formation of remodeled tissue that supports **neural regeneration**



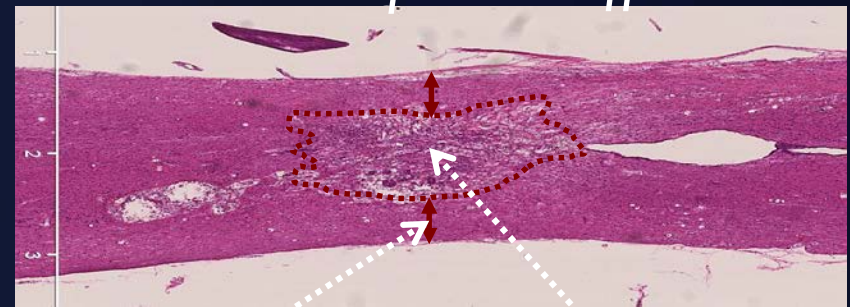
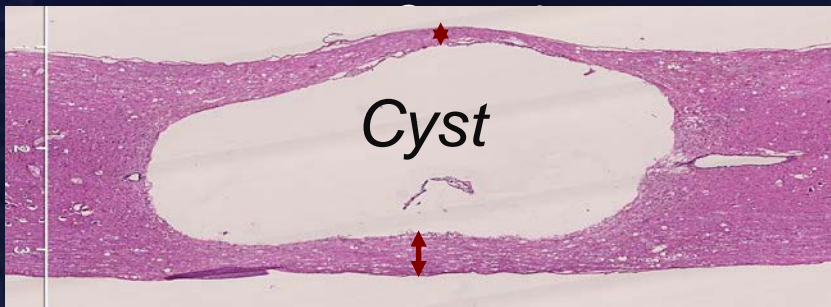
Laminin / β 3-tubulin

The *Neuro-Spinal Scaffold*TM Preserves Macroscopic Spinal Cord Architecture

Rat Acute Spinal Cord Contusion Model 3 Months After Injury

Control

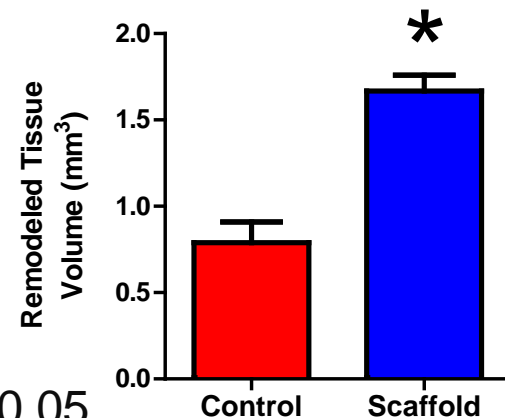
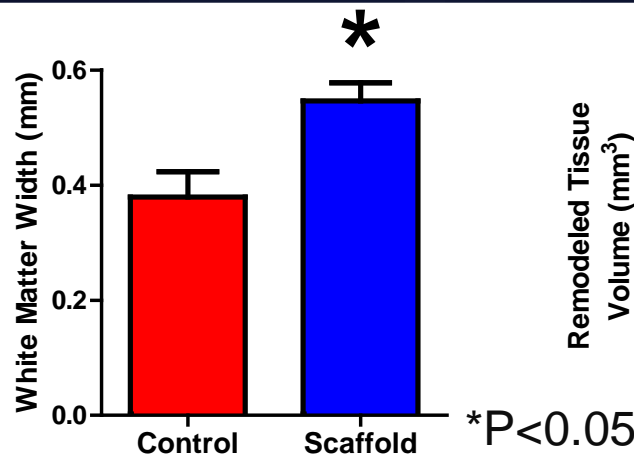
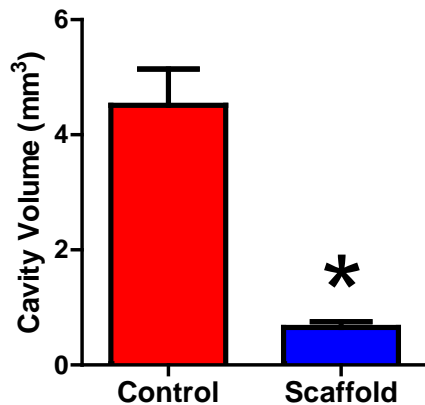
Neuro-Spinal Scaffold



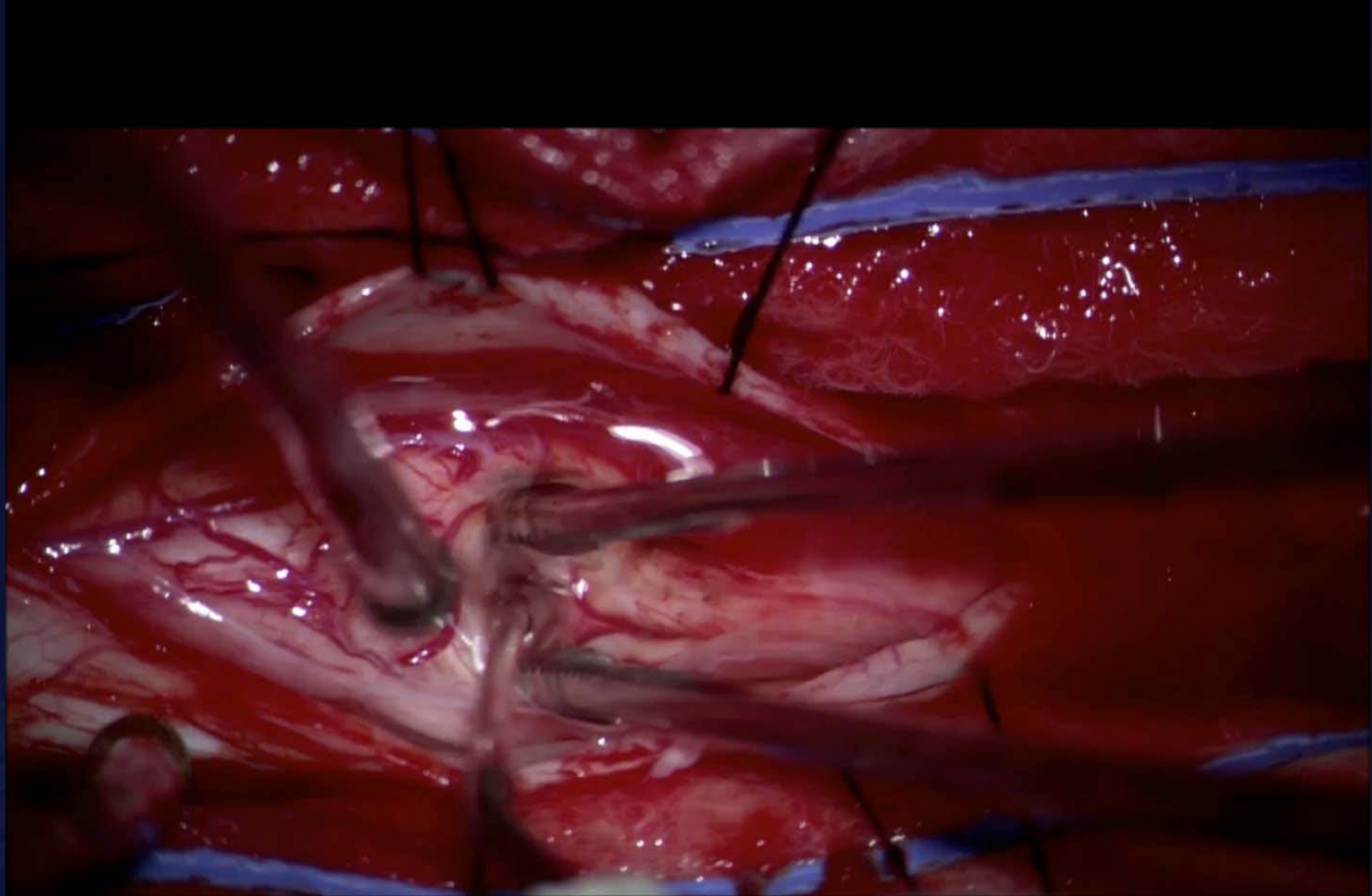
Cyst Reduction

White Matter Sparing

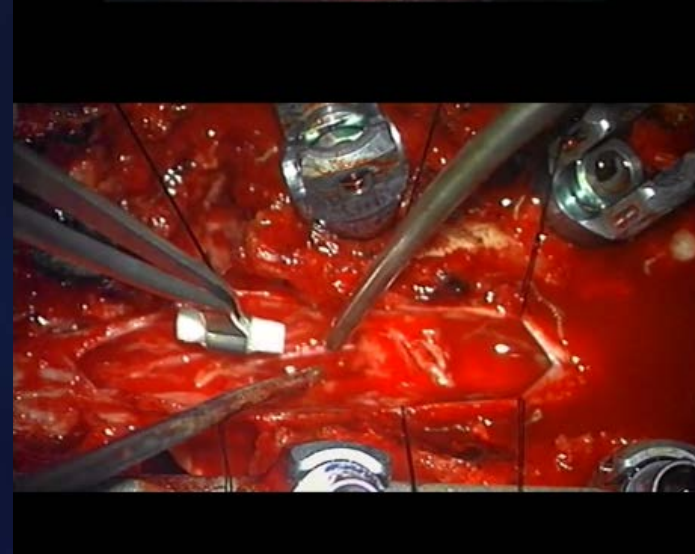
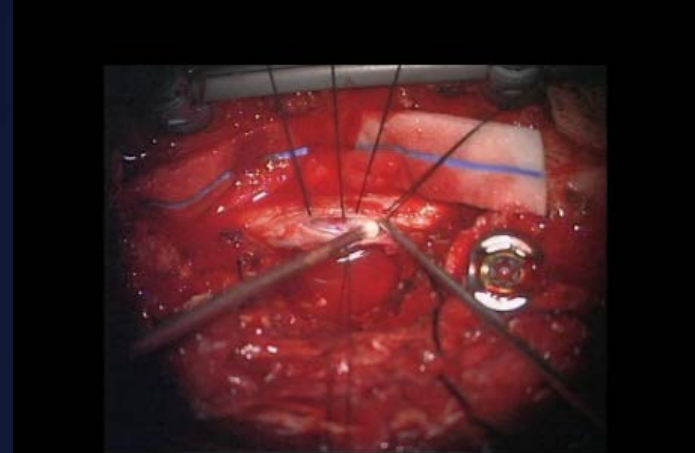
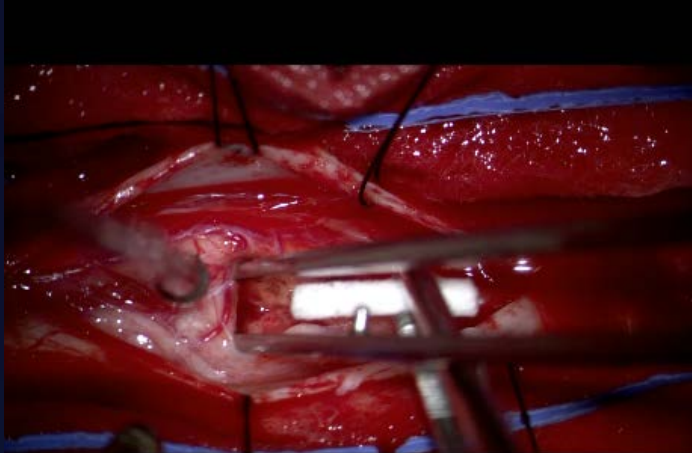
Remodeled Tissue



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* implantations

Clinical Outcome of Patients Implanted with the *Neuro-Spinal Scaffold*TM - ISNCSCI

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

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 **Re**covery in Subjects with Complete Thoracic AIS A Spinal Cord Injury