## Team Members

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# A Participant Introduction *to the* Intelligent Spine Interface

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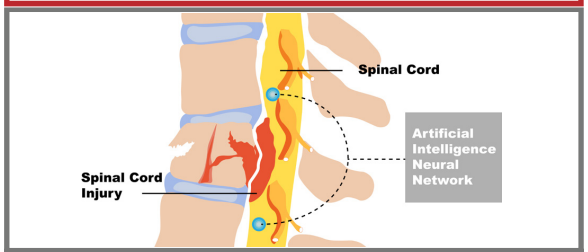
## What It Is

Our Intelligent Spine Interface (ISI) will interpret neural information from above a spinal cord lesion and transfer that information, via an artificial neural network-based interpreter, to sites below the lesion. Our study is focused on restoration of bi-directional sensing and control of the legs for voluntary locomotion and stance, as well as understanding bladder function in spinal cord injury. This is our concept, though as of now there is no known clinical benefit.

Participants enrolled in the study will undergo two surgical procedures: implantation of the ISI device and removal of the ISI device. The surgical procedure itself will only be performed by the site principal investigator assisted by the surgical sub-investigators to ensure procedure consistency.

There is a dedicated state-of-the-art neurosurgery spinal cord injury laboratory for functional restoration, the Center for Innovative Neuro-technology for Neural Repair (CINNR).

The benefit of this ISI study is potentially groundbreaking. We hope that this research will be used to develop a fully implantable device that can lead to improved locomotor function, amongst other functional measures.

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## Inclusion Criteria

### Inclusion

- Adults (men or women) between the ages of 18 and 65 years old.
- Complete or Incomplete Spinal Cord Injury (SCI) with AIS (American Spinal Injury Association Impairment Scale) grade of A or B between the levels of C7/T1 and T10 (level and degree of injury based on the international standards for neurological classification of SCI (ISNCSCI)).
- Focal area of SCI due to trauma.
- Date of SCI injury is at least 1 year prior to enrollment.
- Completed prior SCI rehabilitation program.
- Ability to use both upper extremities to ambulate (move) with a wheelchair or crutches.
- Distance between the conus medullaris (lower end of the spinal cord) and site of injury must be greater than 4cm.
- The ability to participate in intensive physical therapy and research for at least 4 hours per day for 2 weeks.
- Must provide informed consent prior to study participation.

### Exclusion

- Presence of co-existing lower extremity neuropathy or disorders of the cauda equina (a bundle of spinal nerves consisting of the 2-5th lumbar nerve pairs).
- Presence of non-traumatic spinal cord pathology.
- Significant cognitive impairment or decreased level of consciousness.

## Exclusion Criteria

- Presence of an intrathecal baclofen or morphine pump.
- Presence of a cardiac defibrillator or pacemaker.
- Presence of a deep brain stimulator device.
- Participant who has any contraindication to having a MRI performed.
- Severe or disabling joint contractures in the lower extremities.
- Presence of hematologic disorder or medication related coagulopathy that would preclude surgery.
- Lower extremity congenital or acquired deformities.
- Women who are pregnant or who are unwilling to use contraception during the study period.
- Body mass index greater than 30.
- Cardiopulmonary comorbidities that preclude participation in intensive physical therapy.
- Known or suspected participant non-compliance during the study period and at follow up.
- Participant life expectancy less than 12 months.
- Presence of participant comorbidities or spinal anatomy that would preclude participation in the study per investigators' recommendation.