



# AxoMax<sup>®</sup>: A Novel Conduit for Long-Gap Nerve Repair

## Clinical Need

Injuries resulting in facial paralysis significantly affect a patient both physiologically and psychosocially. The standard of care for nerve injury requiring surgical repair is nerve autograft, which is suboptimal for various reasons. While several nerve guides are commercially available for regeneration of nerve gaps <3cm, those for use in large nerve gaps (>3cm) are not. Furthermore, despite the available interventions, current cases of nerve autografting or allografting result in insufficient functional recovery, where ~50% of patients are unable to return to pre-injury employment one year post-operation.

## Solution

Kacey Marra, PhD, and her team at the University of Pittsburgh have developed a novel conduit for long-gap nerve repair, named AxoMax<sup>®</sup>. AxoMax<sup>®</sup> consists of a degradable poly(caprolactone) nerve guide capable of controlled local delivery of drugs for nerve regeneration. Evaluation of the AxoMax<sup>®</sup> in a 5cm median nerve defect model showed ~80% return to function after 1 year as compared to ~70% for an autograft, the standard of care.

## Competitive Advantage

Unlike decellularized technologies, AxoMax<sup>®</sup> elutes factors essential to nerve growth for several months, rendering it biologically similar to an autograft, the standard of care, without the need for a surgery to harvest the graft, thereby avoiding comorbidities associated with such procedures. The elimination of the harvesting procedure spares the patient from lifelong loss of sensation, as well as in an operating room time saving in excess of 60 minutes per case.



**Kacey Marra, PhD**  
University of Pittsburgh

*“This technology has the potential to revolutionize treatment of long gap nerve repair.”*

<http://www.mirm.pitt.edu/our-people/faculty-staff-bios/kacey-g-marra-phd/>

## How the ITP Program Supports this Project

With the ultimate goal of commercialization of AxoMax<sup>®</sup> for bridging craniofacial nerve defects, the work to be supported by the ITP program includes continued market validation and biocompatibility testing in support of a Q-submission to the FDA.

## Clinical Translation Pathway

### Publication:

Incorporation of double-walled microspheres into polymer nerve guides for the sustained delivery of glial cell line-derived neurotrophic factor. *Biomaterials*, 2010. 31 (8): p. 2313-22. (<https://www.ncbi.nlm.nih.gov/pubmed/19969346>)

Sustained Growth Factor Delivery Promotes Axonal Regeneration in Long Gap Peripheral Nerve Repair. *Tissue Engineering, Part A*, 2011, 17(9-10):1263-75. (<https://www.ncbi.nlm.nih.gov/pubmed/21189072>)

### Intellectual Property:

US 9,498,221 Implantable medical devices having double walled microspheres. (<https://patents.google.com/patent/US9498221B2/en11>)

For more information about this technology, please visit: [http://bit.ly/MPWRM\\_AxoMax](http://bit.ly/MPWRM_AxoMax)

### Commercialization Strategy:

New company formation in development

### Regulatory Pathway:

In development with the MPWRM Regulatory Core

### Product Launch Strategy:

In development with the MPWRM Commercialization/ Market Needs Core

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