

# AxoMax:® Incorporation of double-walled microspheres into polymer nerve guides for the sustained delivery of neurotrophic factors

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Long gap peripheral nerve injuries (i.e., gaps >3cm) remain a clinical challenge. When there is a long gap nerve injury, the standard of care is transplanting a nerve from one place in the body to the area where the defect is, a technique known as autografting. The use of an autograft requires a second surgical site resulting in longer operating times, and typically a sensory nerve is used to replace a motor/sensory nerve, which leaves an area of the body with permanent numbness. There are a handful of nerve guides on the market available to regenerate nerve gaps less than 3cm. However, there are no synthetic guides available having an FDA-approved indication for use in nerve gaps greater than three centimeters. Our patented technology utilizes a biodegradable tube containing a controlled drug delivery system supplying the cues necessary to promote the growth of nerves over large gaps, thus fulfilling this clinical unmet need.

#### **Technology Description**

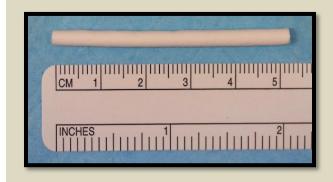
We have developed a biodegradable polymer nerve guide (AxoMax) which locally delivers bioactive neurotropic factors in the proper concentration to cross from the proximal to distal nerve stump. Delivery of a drug that can enhance nerve regeneration is used to overcome the current limitations in nerve repair across large defects.

#### **Advantages**

- There are no commercially available nerve guides to treat long gap (>3cm) nerve injuries.
- We utilize our patented slow delivery system to release drugs over 2-3 months during nerve regeneration.
- In a pivotal large animal model, AxoMax performed better than the standard of care (autograft) in a 5cm nerve defect.

### **Applications**

- Traumatic injuries to peripheral nerves, including battlefield injuries.
- · Brachial plexus repair after shoulder injury.
- · Nerve repair after tumor removal, such as prostatectomy.
- · Post-Neuroma repair.



## **Stage of Development**

Completed large preclinical studies; currently initiating GMP manufacturing and regulatory approval, and preparing for clinical trials.

#### **IP Status**

2 Patents have been issued:

US 9,750,851

US 9,498,221

US patent application 15/668,959 in prosecution