**Long-Term In-Vivo Experience with Lumee Oxygen Platform**

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**Unmet Clinical Need**

There is a need for a tissue oxygen monitoring method that is minimally invasive, sensitive, and provides rapid, continuous measurements intra- and post-operatively in PAD patients to aid clinical decision making.

**Lumee Hydrogel Demonstrated Biocompatibility**

ISO 10993 is an internationally recognized standard which provides test protocols designed to address biocompatibility in new medical devices and to ensure product safety. Based on this standard, the following tests were performed on the Lumee Hydrogel:

- **Cytotoxicity**: Determine the potential to cause cytotoxicity
  - Grade 0, no cytotoxicity was observed

- **Irritation**: Evaluate the local dermal irritation following intracutaneous injection in rabbits
  - No signs of erythema or edema were noted

- **Acute Systemic Toxicity**: Evaluate the acute systemic toxicity following injection in mice
  - No evidence of systemic toxicity was noted

- **Genotoxicity**: Evaluate whether the test article extract would cause mutagenic changes
  - Test articles were nonmutagenic for tester strains

- **Subchronic Toxicity**: Evaluate potential toxicity following subcutaneous implantation in rats
  - 30-day toxicity study in 6 animals; the test articles were well tolerated with no adverse effects noted

- **Chronic Toxicity Implantation**: Evaluate potential toxicity following subcutaneous implantation in rabbits
  - 180-day implantation and chronic toxicity study in 5 animals; the test articles were well tolerated with no adverse effects noted

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**Lumee Hydrogel Showed Chemical Integrity**

Chemical characterization of the Lumee Hydrogel was performed per ISO 10993-18. An exhaustive extraction was performed on hydrogels using purified water and hexane, followed by analytical characterization including ICP-MS, GC-MS, UP/LC, IR, and IC. No detectable elements or compounds above quantitation limits were identified, suggesting no extractables or leachables were present.

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**Lumee Hydrogel Functioned as Designed in Animals**

Assess performance by occlusion:

1. Lumee Hydrogels in a porcine model, 29 Days post-injection
2. Hydrogels reported decrease and increase in $O_2$ in under 1 minute

A total of 177 hydrogels have been studied pre-clinically in 17 animals to-date, for up to 542 days of implantation duration. 97% of hydrogels responded to inhaled $O_2$ modulation, when tested at 3 months post-injection.

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**Future Work**

Further clinical investigation to determine its potential for intra-operative decision making and post-operative surveillance will be conducted in 2016.

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**Example Data**

- Normalized $[O_2]$
- Time (min)

1. 100%
2. 15%
3. 100%