

# University of Pittsburgh

Featured Inventors: Daniel Hachim, Aimon Iftikhar PI: Dr. Bryan Brown

# Layer Up

Drug Eluting Coating Technology for Implantable Devices and Biomaterials

#### **Value Proposition**

For patients implanted with surgical mesh, Layer Up is a drug-eluting coating for implants that prevents complications and rejection of the implant. Unlike conventional coatings, Layer Up releases anti-inflammatory agents from the coating to improve the body's response against the implant, promoting a good integration of the implant into the patient.

## **Market Opportunity**

Many mesh companies are under litigation due to the increased number of complications in patients after implantation. The FDA has issued many warnings along with reclassifying mesh as a Class III device.

There are over 600,000 surgical mesh procedures each year with an average cost of \$4200 - \$6200 per surgery. Between 10 – 20 % of those patients have further complications which leads to 2-3 more surgical procedures. Currently, the size of the surgical mesh market is US\$ 4 Billion, and based on surgeries involving surgical mesh only, our market revenue is estimated to reach US\$ 90 million each year.

## **Competitive Landscape**

Currently, there is no completely safe and effective solution for surgical mesh implantation. Traditional competing technologies using the "hide the implant from the immune system" approach have been studied and tested in clinical trials; however, performance has not improved, and in some cases is worse than conventional meshes. Our Layer Up coating technology has the advantage of using the immune system to promote the integration of the implant in the patient's body, and therefore prevent implant failure and complications. Beyond mesh, the present coating technology is applicable to many types of biomaterial implants.



Body's response against a conventional surgical mesh and a mesh coated with LayerUp

## Technology

Layer Up is a multilayered drug-eluting coating, capable of controlled release of bioactive agents. Surgical meshes will use Layer Up technology to control the immune response against the mesh implant. The released anti-inflammatory molecules will prevent the symptoms associated with the failure of the implant. The implant is recognized and accepted by the body, preventing any complications. Therefore, Layer Up is making mesh implantation safer, effective and long-lasting.

#### **Stage of Development**

Pre-clinical studies on small animals have shown that Layer Up was successful preventing an inflammatory response to the implant and was associated with improved integration in the body in the long term. Currently, we are up-scaling the technology to perform a clinically relevant large animal preclinical study, required for licensing the technology to mesh companies.

#### Funding

NIH R21GM107882 - US\$ 275K.

#### **IP** Landscape

Layer By Layer Coated Mesh For Local Release Of Bio-Active Proteins. U.S. Patent Application No.: 62/308,574

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# **FEATURED INVENTORS:**

# Daniel Hachim

Daniel Hachim is a Ph.D. Candidate in Bioengineering and McGowan Institute for Regenerative Medicine. In 2010, he graduated in Pharmaceutical Chemistry in the Pontifical Catholic University of Chile, and became an assistant researcher and instructor professor in pharmaceutical technology for two years. In 2012, he was awarded with a Fulbright and a Chile Governmental Fellowship to pursue his graduate studies in the United States. During all his past experience and current research under the mentoring of Dr. Brown, Mr. Hachim has gained significant expertise in the field of drug delivery, tissue engineering, devices, surface engineering and the host response against biomaterials, all of them highly relevant to develop our proposed technology.

#### **Education**

Bioengineering Ph.D. Candidate at University of Pittsburgh (2012 - Present).

B.S. in Chemistry and Pharmaceutical Sciences at Pontifical Catholic University of Chile (2004 – 2009).

#### **Publications**

- 1. Daniel Hachim, Samuel T. LoPresti, Bryan N. Brown. Shifts in macrophage phenotype at the biomaterial interface via IL-4 eluting coatings are associated with improved implant integration. Biomaterials (Recently accepted for publication in Biomaterials, an international journal covering the science and clinical application of biomaterials).
- 2. Hachim D, Lopresti ST, Mani D and Brown BN (2016). Improvements in the resolution of the foreign body reaction by the modulation of macrophage polarization towards an M2 phenotype at the tissueimplant interface by local release of IL-4 from layer by layer coated polypropylene meshes. Front. Bioeng. Biotechnol. Conference Abstract: 10th World Biomaterials Congress. doi: 10.3389/conf.FBIOE.2016.01.0221

# Aimon Iftikhar

Aimon Iftikhar is a Ph.D. student in Bioengineering and McGowan Institute for Regenerative Medicine. She graduated from UConn with her B.S. in Biomedical Engineering in 2013, and completed her M.S. the year after at Carnegie Mellon University. Her research following her Master's thesis was involved in the formation of a startup company, Ancure, funded both through NSF iCorps and SBIR grants. Currently, Ms. Iftikhar is working with Mr. Hachim and Dr. Brown on further development of the proposed technology. These research endeavors have allowed her to gain insight and expertise in the field of biomaterials, foreign body reactions, fabrication of devices, and drug delivery.

## Education

Bioengineering Ph.D. Student at University of Pittsburgh (2015-present).

M.S. in Biomedical Engineering at Carnegie Mellon University (2013-2014)

B.S. in Biomedical Engineering (Honors Program) at University of Connecticut with minors in Materials Science & Engineering and Mathematics (2009 – 2013).

#### **Publications**

- 1. Ninh, C., Iftikhar, A., Cramer, M., Bettinger, C., Diffusion-reaction models of genipin incorporation into fibrin networks. Journal of Materials Chemistry B, 2015. 3(22):p. 4607-4615.
- 2. Iftikhar, A., Cramer, M., Bettinger, C., Enzymatic Resistance and Mechanical Stability of Genipin-Crosslinked Films. Conference Abstract: Society for **Biomaterials 2015**
- 3. Iftikhar A., Bettinger, C., Genipin-Crosslinked Polymeric Networks for Vascular Tissue Engineering Grafts. Journal of Materials Chemistry (In Preparation)

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