Biologic Hydrogel Material for Combatting Intervertebral Disc Degeneration (2015-048)

Provides Early-Stage Intervention for Intervertebral Disc Degeneration via a Biomimetic Nucleus Pulposus Scaffold

Market Overview
This hydrogel scaffold can be used as an early-stage intervention for combatting intervertebral disc (IVD) degeneration (IDD). Lower back pain is a significant burden that affects nearly 85 percent of all people, 40 percent of which are attributed to IDD. IVDs reside between the bones of the spine and contain the nucleus pulposus (NP) which is a resilient hydrogel core that generates intradiscal pressure to support compressive loading. IDD has been shown to initiate in the NP and results in IVD tissue disorganization, loss of intradiscal pressure and IVD height. Current treatments only mitigate pain and currently available biomaterials do not contain, nor do they mimic native the NP extracellular matrix (ECM) biochemistry or mechanical properties. Patients with early-stage IDD have no choice but to wait for degeneration to progress before warranting IVD replacement or fusion. Clemson University researchers have developed a biomaterial that mimics the structure and function of human NP to mitigate or halt progression of IDD.

Technical Summary
The biomimetic hydrogel scaffolds were created by decellularizing the NP isolated from cow tail IVDs utilizing chemical and physical methods. Cow NPs were used due to their similar geometry, size, and biochemical components as compared to the human NP. The decellularized NP has no residual bovine DNA, yet retains a significant amount of natural NP ECM, including both collagen type II and

Application
Early-stage intervention of IVD degeneration

Development Stage
Preliminary Prototype; Large Animal Model Studies

Advantages
• Utilizes biomaterial formed from decellularized cow NP tissue via the application of tissue-specific decellularization solution and procedure, resulting in a hydrogel that maintains bulk biochemical and mechanical properties similar to human NP
• Supports human cell viability, mitigating or halting IDD progression
• Can be produced via simple, repeatable, low cost batch process
aggrecan, comparable to human NP. Additionally, the biomaterial has similar static and dynamic compressive properties as compared to healthy human NP tissue. This biomaterial fills a significant market need for the development of a biologic-based NP replacement targeting the early-stage intervention of IDD.

<table>
<thead>
<tr>
<th>App Type</th>
<th>Country</th>
<th>Serial No.</th>
<th>Patent No.</th>
<th>CURF Ref. No.</th>
<th>Inventors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provisional</td>
<td>United States</td>
<td>62/215,475</td>
<td>NA</td>
<td>2015-048</td>
<td>Jeremy Mercuri, Christopher Fernandez</td>
</tr>
</tbody>
</table>

About the Inventors

**Dr. Jeremy Mercuri**  
Assistant Professor of Bioengineering at Clemson University

Dr. Jeremy Mercuri earned his Ph.D. in Bioengineering from Clemson University. Prior to joining Clemson, he was a senior research engineer at Stryker Orthobiologics and a research engineer at Medtronic Spinal & Biologics. Among his accomplishments, Dr. Mercuri holds two issued patents and several applications in prosecution. He founded the Laboratory of Orthopaedic Tissue Regeneration and Orthobiologics at Clemson in August 2013 where he focuses on the development of regenerative medicine technologies. His research expertise lies in biomaterials development and the application of stem cells towards orthopaedic tissue engineering and regenerative medicine.