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(71) Applicant: **POLY-MED, INC.** [US/US]; 51 Technology Drive, Anderson, SC 29625 (US).

(72) Inventors: **TAYLOR, Michael, Scott;** 214 Andalusian Trail, Anderson, SC 29621 (US). **MCCULLEN, Seth, Dylan;** 2107 East North Street, Greenville, SC 29607 (US). **SHALABY, David;** 1093 Clayton Mill Road, Southfield, MA 01259 (US).

(74) Agent: **LAHEY, Seann;** Mcnair Law Firm, P.A., P.O. Box 447, Greenville, SC 29602-0447 (US).

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[Continued on next page]

(54) Title: TIME-DEPENDENT SYNTHETIC BIOLOGICAL BARRIER MATERIAL

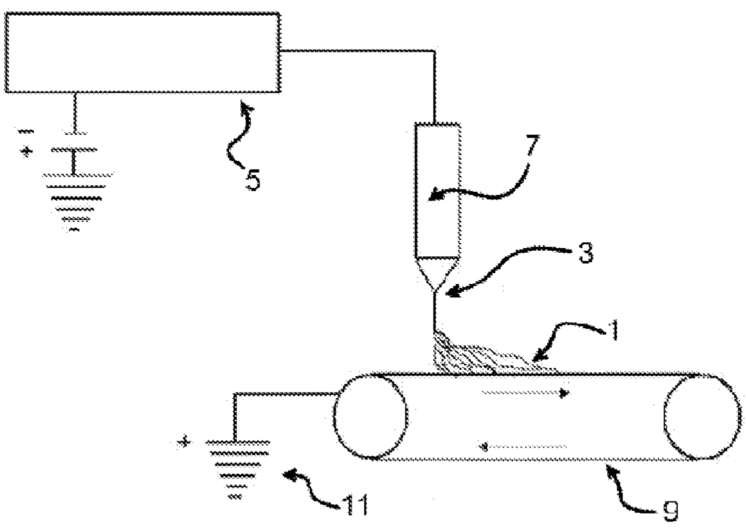

FIG. 1

(57) Abstract: Thermally stable absorbable fiber populations, i.e. fiber populations that do not undergo thermally induced crystallization, can be intermixed to yield a stabilizing effect without altering morphological properties of a first fiber system. By addition of a stabilizing fiber population one may minimize thermally induced shrinkage and maintain physical properties of electrospun materials in the as-formed state. In one particular abstract, medical barrier materials may be formed from the electrospun materials to provide improved medical barriers for treatments.

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TIME-DEPENDENT SYNTHETIC BIOLOGICAL BARRIER MATERIAL

BACKGROUND OF THE INVENTION

[0001] Fibrous materials are capable of providing a barrier for a range of membrane applications including: tissue separation, hernia repair, peritoneum replacement, dura mater replacement, and pelvic floor reconstruction, amongst others. Of these types of tissue replacement, hernia repair is one of the most frequently performed surgical operations in the United States with approximately one million procedures conducted annually.

[0002] The vast majority of these membrane applications, including hernia repairs, employ synthetic surgical meshes that are comprised of various arrangements of absorbable and non-absorbable films, fibers, and yarns, and are primarily based on traditional knit and woven structures. These materials have reduced the frequency of hernia recurrence. Unfortunately, recurrence rates remain high, with up to 15% recurrence reported for inguinal and incisional hernia repair.

[0003] In addition, long-term complications such as chronic pain, increased abdominal wall stiffness, fibrosis, and mesh contraction persist following the use of current surgical meshes. These complications dramatically affect patient quality of life. To counteract these complications, medical device technology has moved toward development of synthetic repair meshes consisting of 100% absorbable materials. To date, no significant clinical data is available to determine the viability of such absorbable meshes.

[0004] A benefit of absorbable meshes is that they would not need to be removed following surgery and do not disrupt new tissue formation of collagen upon healing. However, preliminary studies with completely absorbable hernia meshes indicate that the replacement collagen layer is not strong enough to prevent hernia recurrence and often results in catastrophic failure. This is most likely due to the relatively fast degradation profile of meshes such as VICRYL knitted mesh, available from Ethicon Inc., a subsidiary of Johnson and Johnson. These meshes degrade in approximately three to four weeks. However, the collagen remodeling process may take several months for it to mature and gain normal or pre-injury strength.

[0005] Synthetic barrier materials such as hernia meshes are largely comprised of nondegradable fibrous arrays constructed from either knitted, woven, or nonwoven methodologies. Recently, the electrospinning method has generated significant interest in medical device applications. The process can produce micro-fibrous materials with a topography and size-scale similar to the native extracellular matrix. Electrospun materials are advantageous for a range of applications in the medical device field for tissue replacement, augmentation, drug delivery, among other applications.

[0006] During the electrospinning process, a polymer is dissolved in solution and is metered at a controlled flow rate through a capillary or orifice. By applying a critical voltage to overcome the surface tension of the polymer solution, along with sufficient molecular chain entanglement in solution, fiber formation can occur. Application of a critical voltage induces a high charge density forming a Taylor cone, the cone observed in electrospinning, electrospraying and hydrodynamic spray processes, from which a jet of charged particles emanates above a threshold voltage, at the tip of the orifice.

[0007] Emerging from the Taylor cone, a rapid whipping instability, or fiber jet, is formed moving at approximately 10 m/s from the orifice to a distanced collector. Due to the high velocity of the fiber jet, fiber formation occurs on the order of milliseconds due to the rapid evaporation of the solvent (i.e., solution electrospinning), inhibiting polymer crystallization. Typically, the ejected jets from the polymer solution is elongated more than 10,000 draw ratio in a time period of 0.05s. This high elongation ratio is driven by the electric force induced whipping instability, and the polymer chains remain in an elongated state after fiber solidification due to this high elongation and chain confinement within micron-sized fibers.

[0008] For semi-crystalline polymers, retarded crystallization may be observed as fast solidification of the stretched polymer chains do not allow time to organize into suitable crystal registration, and is also inhibited by the small fiber diameters. The formation process may impart a significant amount of internal stresses into the resulting fibers. As a result, these materials can undergo both morphological and mechanical property changes when exposed to heat due to cold crystallization as well as stress relief via application of heat. Polymers that display a glass transition temperature (Tg) near or at body temperature (37°C) are unstable for biological applications due to the uncontrolled transition between a glassy and amorphous state. Exposing

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