SUMMARY

[0005] The terms “invention,” “the invention,” “this invention” and “the present invention,” as used in this document, are intended to refer broadly to all of the subject matter of this patent application and the claims below. Statements containing these terms should be understood not to limit the subject matter described herein or to limit the meaning or scope of the patent claims below. Covered examples of the invention are defined by the claims, not this summary. This summary is a high-level overview of various aspects of the invention and introduces some of the concepts that are further described in the Detailed Description section below. This summary is not intended to identify key or essential features of the claimed subject matter, nor is it intended to be used in isolation to determine the scope of the claimed subject matter. The subject matter should be understood by reference to appropriate portions of the entire specification, any or all drawings, and each claim.

[0006] The present disclosure provides devices and methods for encapsulating cells for insertion into a patient as biological therapy. The devices include a cell encapsulating pouch formed from a membrane or membrane composite that surrounds the cells and through which the cells can receive nutrients from and provide biological therapy to a host body. The devices further include a tensioning member or members that maintain the designed structure of the cell encapsulating pouch and cell bed.

[0006a] In one aspect, the present disclosure refers to a cell encapsulation device comprising: a cell encapsulating pouch comprising a first layer sealed along a portion of its periphery to a second layer along a portion of its periphery to define an interior volume between the first and second layers, wherein the interior volume comprises a first interior surface and an opposing second interior surface spaced apart from the first interior surface; at least one tensioning member disposed within the interior volume and contacting at least two opposing portions of the cell encapsulating pouch to maintain an average distance between the first interior surface and the second interior surface; and a reservoir space for receiving cells within the interior volume between the first and second interior surfaces.

[0007] In some examples, a cell encapsulation device described herein includes a cell encapsulating pouch including a first layer sealed along a portion of its periphery to a second layer along a portion of its periphery to define an interior volume between the first and second layers, where the interior volume includes a first interior surface and an opposing second interior surface spaced apart from the first interior surface. The interior volume includes the entire volume inside the cell encapsulating pouch whether empty or occupied by a structural element. At least one tensioning member can be disposed within the interior volume and can contact at least two opposing portions of its periphery to maintain an average distance between the first interior surface and the second interior surface. The cell encapsulating device further includes a reservoir space for receiving cells within the interior volume between the first

and second interior surfaces and inward from the tensioning member(s). The reservoir space is only the portion of the interior volume that is available for receiving cells and does not include volume occupied by structural elements. Optionally, the cell encapsulation device may further include at least one port in fluid communication with the reservoir space.

[0008] In some examples, the first and second layers of a cell encapsulating pouch comprise top and bottom portions of a single tube-shaped membrane or membrane composite that is at least partially flattened, and where the first layer is sealed to the second layer at least at one end of the tube-shaped membrane or membrane composite. In other examples, the first and second layers of a cell encapsulating pouch comprise two separate membranes or membrane composites.

[0009] In some examples, a cell encapsulation device described herein may comprise at least one cell displacing core within the interior volume. In other examples, a cell encapsulating device described herein may comprise a plurality of structural spacers within the interior volume.

[0010] The tensioning member of a cell encapsulation device described herein may be in fluid communication with the reservoir space or alternatively may be isolated from the reservoir space. For example, the first layer may be sealed to the second layer between the tensioning member and the reservoir space to isolate the tensioning member from the reservoir space. The seal may comprise a thickness that defines the average thickness between the first interior surface and the second interior surface.

[0011] In some examples of a cell encapsulation device described herein, the tensioning member exerts opposing lateral forces away from the reservoir space. Optionally, the tensioning member(s) may be a shape memory elastomer or a shape memory polymer. Optionally, the tensioning member may be a frame including opposing ends that are non-linear and opposing sides that are linear to provide uniform tension across a length of the cell encapsulating pouch. The tensioning member(s) may adjustable between a deformed configuration and an undeformed configuration such that a distance between at least two opposing sides of the tensioning member(s) is adjustable. For example, the distance between the at least two opposing sides in the

deformed configuration may be less than the distance between the at least two opposing sides in the undeformed configuration.

[0012] In some examples of a cell encapsulation device described herein, the average distance between the first interior surface and the second interior surface is at least a thickness of the tensioning member(s). In other examples, the average distance between the first interior surface and the second interior surface is less than a thickness of the tensioning member(s).

[0013] Optionally, a cell encapsulating pouch described herein may comprise a vascularizing layer. Optionally, the cell encapsulating pouch is a multilayered membrane or membrane composite including an outer vascularizing layer and an inner cell retentive layer adjacent to the outer vascularizing layer.

[0014] In some examples, a cell encapsulation device described herein comprises a plurality of interconnected containment tubes, where each of the containment tubes comprises a first end, a second end opposite the first end, and interior volume or reservoir space located within each containment tube for retaining the cells. The containment tubes may optionally be interconnected by welds, quilting, adhesive, or structural supports. The device may further comprise a tensioning member disposed around at least a portion of a perimeter of the plurality of containment tubes, where the tensioning member maintains an average thickness of each of the containment tubes. Optionally, the tensioning member may comprise at least two arcuate portions including alternating concavities positioned at the first end and/or at the second end of each of the containment tubes. At least a portion of the tensioning member may be attached to one or more containment tubes with an adhesive. Additionally or alternatively, a portion of the tensioning member may be retained within each of the two outermost containment tubes at opposing ends of the cell encapsulation device.

[0015] In some examples, a method of encapsulating cells includes providing a cell encapsulation device as described herein where the tensioning member is in a first deformed configuration that provides tension across the cell encapsulating pouch; deforming the tensioning member from the first deformed configuration to a second deformed configuration that is more deformed than the first deformed configuration,

whereby the tension on the cell encapsulating pouch is lessened; inserting cells into the reservoir space; and releasing the tensioning member to the first deformed configuration.

[0016] In some examples, a method of inserting a cell encapsulation device into a patient includes providing a cell encapsulation device as described herein, where the cell encapsulation device further comprises cells disposed in the reservoir space, and where the tensioning member is in a first deformed configuration that provides tension across the cell encapsulating pouch; deforming the tensioning member from the first deformed configuration to a second deformed configuration that is more deformed than the first deformed configuration, whereby the tension on the cell encapsulating pouch is lessened; implanting the cell encapsulation device into a tissue bed of a patient; and releasing the tensioning member to the first deformed configuration.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The accompanying drawings are included to provide a further understanding of the disclosure and are incorporated in and constitute a part of this specification, illustrate embodiments, and together with the description serve to explain the principles of the disclosure.

[0018] FIG. 1A is a top view of a cell encapsulation device according to embodiments described herein.

[0019] FIG. 1B is a schematic of a cross-section of the cell encapsulation device of FIG. 1A taken along line 1B – 1B in FIG. 1A.

[0020] FIG. 1C is a top view of the tensioning member of the cell encapsulation device of FIG. 1A.

[0021] FIG. 2 is a schematic of a cross-section of a cell encapsulation device according to embodiments described herein.

[0022] FIG. 3A is a top view of a cell encapsulation device according to embodiments described herein.

[0023] FIG. 3B is a schematic of a cross section of the cell encapsulation device of FIG. 3A taken along line 3B-3B in FIG. 3A.

CLAIMS

That which is claimed:

1. A cell encapsulation device comprising:

a cell encapsulating pouch comprising a first layer sealed along a portion of its periphery to a second layer along a portion of its periphery to define an interior volume between the first and second layers, wherein the interior volume comprises a first interior surface and an opposing second interior surface spaced apart from the first interior surface;

at least one tensioning member disposed within the interior volume and contacting at least two opposing portions of the cell encapsulating pouch to maintain an average distance between the first interior surface and the second interior surface; and

a reservoir space for receiving cells within the interior volume between the first and second interior surfaces.

2. The cell encapsulation device of claim 1, wherein the first and second layers comprise top and bottom portions of a single tube-shaped membrane or membrane composite that is at least partially flattened, and wherein the first and second layers are sealed along the portion of their peripheries at least at one end of the tube-shaped membrane or membrane composite.

3. The cell encapsulation device of claim 1, wherein the first and second layers comprise two separate membranes or membrane composites.

4. The cell encapsulation device of claim 1, further comprising at least one cell displacing core within the interior volume.

5. The cell encapsulation device of claim 4, wherein the cell displacing core defines the average thickness between the first interior surface and the second interior surface.

6. The cell encapsulation device of claim 1, further comprising a plurality of structural spacers within the interior volume.

7. The cell encapsulation device of claim 6, wherein the first layer is sealed to the second layer between the tensioning member and the structural spacers, and wherein the structural spacers define the average thickness between the first interior surface and the second interior surface.

8. The cell encapsulation device of claim 1, wherein the at least one tensioning member is isolated from the reservoir space.

9. The cell encapsulation device of claim 1, wherein the first layer is sealed to the second layer between the tensioning member and the reservoir space to isolate the tensioning member from the reservoir space

10. The cell encapsulation device of claim 9, wherein the seal comprises a thickness that defines the average thickness between the first interior surface and the second interior surface.

11. The cell encapsulation device of claim 1, wherein the at least one tensioning member exerts opposing lateral forces away from the reservoir space.

12. The cell encapsulation device of claim 1, wherein the at least one tensioning member comprises a shape memory alloy or an elastomer.

13. The cell encapsulation device of claim 1, wherein the at least one tensioning member is a frame comprising opposing ends that are non-linear and opposing sides that are linear to provide uniform tension across a length of the cell encapsulating pouch.

14. The cell encapsulation device of claim 1, wherein the device comprises at least two tensioning members.

15. The cell encapsulation device of claim 1, wherein the at least one tensioning member is adjustable between a deformed configuration and an undeformed configuration such that a distance between at least two opposing sides of the at least one tensioning member is adjustable, wherein the distance between the at least two opposing sides in the deformed configuration is less than the distance between the at least two opposing sides in the undeformed configuration.

16. The cell encapsulation device of claim 1, wherein the average distance is at least a thickness of the at least one tensioning member.

17. The cell encapsulation device of claim 1, wherein the average distance is less than a thickness of the at least one tensioning member.

18. The cell encapsulation device of claim 1, wherein the cell encapsulating pouch is a membrane composite comprising an outer porous layer and an inner porous layer adjacent to the outer porous layer, and wherein a porosity of the inner porous layer is less than a porosity of the outer porous layer.

19. The cell encapsulation device of claim 1, further comprising a plurality of biological moieties disposed within the reservoir space.

20. The cell encapsulation device of claim 1, further comprising at least one port in fluid communication with the reservoir space.