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 exerting opposing tensioning forces on the cell encapsulation pouch in an X-Y plane, wherein the at least one tensioning member contacts~~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, wherein the reservoir space has a thickness in the Z-dimension.

[0006b] In one aspect, the present disclosure refers to a method of encapsulating cells comprising providing the cell encapsulation device as disclosed herein, wherein 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.

[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

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 exerting opposing tensioning forces on the cell encapsulation pouch in an X-Y plane, wherein the at least one tensioning member contacts~~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,

wherein the reservoir space has a thickness in the Z-dimension.

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~~.~~; or

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

~~4~~3. The cell encapsulation device of claim 1, further comprising at least one cell displacing core within the interior volume; and optionally~~.~~

~~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~~4. The cell encapsulation device of claim 1, further comprising a plurality of structural spacers within the interior volume; and optionally~~.~~

~~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~~5. The cell encapsulation device of claim 1, wherein the at least one tensioning member is isolated from the reservoir space.

~~9~~6. 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; and optionally

~~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~~7. The cell encapsulation device of claim 1, wherein the at least one tensioning member exerts opposing lateral forces away from the reservoir space; or~~.~~

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

~~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~~8. The cell encapsulation device of claim 1, wherein the device comprises at least two tensioning members.

~~15~~9. 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~~10. The cell encapsulation device of claim 1, wherein the average distance is at least a thickness of the at least one tensioning member; or~~.~~

~~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~~11. The cell encapsulation device of claim 1, wherein the cell encapsulating pouch comprises a vascularizing layer; or 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~~12. The cell encapsulation device of claim 1, further comprising a plurality of biological moieties disposed within the reservoir space; or~~.~~

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

13. The cell encapsulation device of claim 1, wherein the at least one tensioning member maintains an average distance between the first interior surface and the second interior surface.

14. A method of encapsulating cells comprising

providing the cell encapsulation device of claim 1, wherein 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.

15. The cell encapsulation device of claim 1

wherein the 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 membrane or membrane composite; and

wherein the reservoir space is in fluid communication with the tensioning member.

16. 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.

17. The cell encapsulation device of claim 16, wherein the seal comprises a thickness that defines the average thickness between the first interior surface and the second interior surface; or further comprising a plurality of structural spacers within the interior volume inward from the seal, wherein the structural spacers define the average thickness between the first interior surface and the second interior surface.

18. The cell encapsulation device of claim 16, wherein the at least one tensioning member contacts at least two opposing portions of the cell encapsulation pouch to

maintain an average distance between the first interior surface and the second interior surface.

19. The cell encapsulation device of claim 16, wherein the cell encapsulation device has a planar structure.

20. The cell encapsulation device according to claim 1,

wherein the at least one tensioning member contacts the 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 further comprising

a cell displacing core within the interior volume, wherein the cell displacing core defines the average thickness between the first interior surface and the second interior surface; and

wherein the reservoir space for receiving cells within the interior volume is disposed between the first and second interior surfaces and adjacent to at least a portion of the cell displacing core.

21. The cell encapsulation device of claim 20, wherein the at least one tensioning member comprises two tensioning members embedded in opposite sides of the cell displacing core.