CLAIMS

1. A tangential flow filtration (TFF) ~~cassette~~system, comprising:

a flexible isolation plate;

at least one of a gasket and a filter plate; and

a TFF cassette disposed between the flexible isolation plate and the gasket or filter plate, the TFF cassette including a plurality ~~a stack~~ of interleaved layers defining at least one feed channel and at least one filtrate channel, the plurality of interleaved layers comprising:

a filtrate channel spacer defining an open interior volume bounded by an inner perimeter and including one or more fluid ports;

a ~~non-flexible~~ feed channel spacer defining an open interior volume bounded by an inner perimeter and including one or more fluid ports;

a membrane disposed between the filtrate channel spacer and the feed channel spacers; and~~, optionally,~~

~~a pressure sensitive adhesive binding together the membrane and one of the filtrate channel spacer and the feed channel spacer, said thin film of pressure sensitive adhesive having a thickness of less than 50% of height of an adjacent channel;~~

wherein ~~(a)~~ the flexible isolation plate comprises a flexible rubber or ~~polymer or a thermoplastic~~ elastomer and is bonded to a first surface of the plurality ~~stack~~ of interleaved layers to ensure sealing therebetween, the flexible isolation plate arranged and configured to flex to accommodate any irregularities in the first surface to septically seal and isolate the TFF cassette thereby preventing contamination of the TFF cassette; and

wherein the flexible isolation plate is bonded to the first surface via one of a pressure-sensitive adhesive (PSA) material, a thermosetting adhesive, and a multi-part adhesive formulation.

2. The TFF ~~cassette~~ system of claim 1, wherein the at least one of the gasket and the filter plate comprises the gasket, wherein the ~~a~~ gasket is bonded to a second surface of the plurality of interleaved layers~~stack~~ and comprises ~~, the gasket comprising separate~~ fluid ports in fluid communication with the at least one feed channel and the at least one filtrate channel~~for the feed and filtrate channels~~.

3. The TFF system~~cassette~~ of claim 2, wherein the at least one of the gasket and the filter plate further comprises the filter plate, wherein the ~~a~~ filter plate is bonded to the gasket, the filter plate comprising a fluid manifold wherein a feed port of the filter plate is aligned with a feed port of the gasket, and a filtrate port of the filter plate is aligned with a filtrate port of the gasket.

4. The TFF system~~cassette~~ of any of the foregoing claims, further comprising a tab or an engraving on a sidewall of the TFF cassette to identify the TFF cassette by an identifier selected from the group consisting of ~~one or more of~~ a stock keeping unit (SKU) number, a lot number, a serial number, a capacity, a number of feed and/or filtrate channels, and a number of membranes.

5. The TFF systemcassette of any of the foregoing claimsclaim 4, wherein the tab or engraving comprises a barcode.

6. The TFF systemcassette of any of the foregoing claims, wherein the TFF cassette is disposable after use.

7. The TFF systemcassette of any of the foregoing claims, wherein the TFF cassette comprises a sealed edge to isolate the TFF cassette from the environment.

8. The TFF systemcassette of any of the foregoing claims, wherein the at least one feed channel comprises a feed screen disposed within a space defined by the feed channel spacer.

9. The TFF systemcassette of claim 8, wherein the feed screen comprises a woven or extruded polymer mesh.

10. The TFF systemcassette of any of the foregoing claims, wherein the at least one filtrate channel comprises a filtrate screen disposed within a space defined by the filtrate channel spacer.

11. The TFF systemcassette of claim 10, wherein the filtrate screen comprises a woven or extruded polymer mesh.

12. A TFF cassette comprising a plurality of filtrate channels, each filtrate channel comprising, from top to bottom a first filter membrane; a middle comprising a polymer screen disposed within a cured-in-place urethane perimeter seal; and one of a second filter membrane or a flat plastic member, wherein each of the first filter membrane and the second filter membrane or flat plastic member comprise a feed port, and wherein the middle optionally comprises a cured-in-place urethane seal separating the polymer screen from at least one feed port.

13. The TFF cassette of claim 12, further comprising a plurality of feed channels disposed in an alternating manner with the filtrate channels, each feed channel comprising a channel spacer disposed within the urethane perimeter seal, and the channel spacer optionally comprise first and

~~second pressure-sensitive adhesive (PSA) layers for bonding the channel spacer to the first filter membrane and the second filter membrane or flat plastic member.~~

~~14. The TFF cassette of claim 13, wherein the first and second PSA layers are between 0.002 inches and 0.005 inches in thickness.~~

~~15. The TFF cassette of any of any of claims 12-14, wherein the flat plastic member is between 0.010 inches and 0.030 inches in thickness.~~

~~16. A system for shipping a tangential flow filtration (TFF) cassette, comprising a TFF cassette disposed in a sealed package, wherein the system is configured to be sterilized by gramma irradiation.~~

~~17. The system of claim 16, wherein the package comprises a plurality of layers.~~

~~18. The system of any of claims 16 and 17, wherein the package comprises thermoplastic polyurethane, ethylene vinyl acetate, SBS block copolymers, polyester elastomers, or a combination thereof.~~

~~19. The system of any of claims 16-18, wherein the package comprises a sheet formed into a heat-shrink sleeve.~~

~~20. The system of any of claims 16-19, wherein the TFF cassette comprises: a flexible isolation plate; at least one of a gasket and a filter plate; and a plurality of interleaved layers disposed between the flexible isolation plate and the gasket or filter plate, the plurality of interleaved layers defining at least one feed channel and at least one filtrate channel.~~

12. The TFF system of claim 1, further comprising a pressure sensitive adhesive binding together the membrane and one of the filtrate channel spacer and the feed channel spacer, the thin film of pressure sensitive adhesive having a thickness of less than 50% of height of an adjacent channel.