sterility can be maintained throughout the process, even if certain components are removed during processing, for example through the use of valves, clamps, and heat seals. Furthermore, any or all of the steps can be automated or manually accomplished, according to the specific needs of the application or the user.

[0006] Thus, in one aspect, the present disclosure relates to a tissue mincing tool. The tissue mincing tool includes a compartment for a tissue sample, a solid member actuatable by a handle and moveable within the compartment, a cutting surface at one end of the compartment, and a sterile, sealed container. The compartment is arranged to position the tissue sample between the solid member and the cutting surface and actuation of the handle in one direction causes the solid member to move only towards the cutting surface. The cutting surface separates the compartment from the sterile, sealed container, such that a tissue sample that ~~passes~~ is pressed, via the solid member, into contact with and through the cutting surface can be deposited as a minced tissue within the container. The cutting surface can be dimensioned to mince the tissue sample into fragments having an average cross-section no greater than four square millimeters. For example, the number of square millimeters may be no greater than 3, 2, 1, 0.5, 0.3, 0.2, 0.1, or 0.05 in various embodiments of the present disclosure. The tissue mincing tool can also include a second cutting surface for further reducing the average cross-section of the fragments. The cutting surface of the tissue mincing tool can include an automated cutting system. For example, the cutting surface may include semi-automatic scissors. One or more mincer screens may be positioned in proximity to the cutting surface. The tissue mincing tool may further include a suction cup for stabilizing the tool during operation thereof. The tissue mincing tool also or alternatively can include a fluid conduit in communication with the sterile, sealed container, and a separator unit such as one or more filters within the fluid conduit. The sterile, sealed container optionally includes at least one sealed access port permitting the sterile introduction of a fluid into the container.

[0007] In the tissue mincing tool, the compartment for the tissue sample can incorporate one or more features to facilitate the application of a force to the tissue sample, impelling it beyond the cutting surface and into the sterile, sealed container. For example, a portion of the compartment can be shaped to receive a solid member to press the tissue sample. Such a solid member can optionally be included with the tissue mincing tool, whether connected to it or provided as a separate component.

[0008] In one embodiment, a portion of the compartment near the cutting surface has a substantially constant cross-section, such that a comparably shaped solid member may be introduced into the compartment and fill that portion, while pressing the tissue sample into or

through the cutting surface. In another embodiment, the compartment near the cutting surface has a tapered or cone-shaped end. In some embodiments, an interior surface of the compartment is threaded, such that a threaded solid member may be guided into the compartment. In some embodiments, the compartment also includes a gasket, which can provide an improved seal when a solid member is introduced into the compartment. In yet another embodiment, the tissue mincing tool includes a shaft crank for moving the cutting surface towards the tissue sample.

[0009] In an ~~aspect~~embodiment, the present disclosure provides a kit comprising: a tissue mincing tool as disclosed herein; and a solid member shaped to mate with and to fill the portion of the compartment, the solid member being movable within the portion of the compartment to impel the tissue sample therein through the cutting surface. The present disclosure also provides methods of using any of the above-described tissue mincing tools by impelling the tissue sample through the cutting surface of the tool. The present disclosure provides methods of mincing a tissue sample and optionally injecting an enzyme into the sterile, sealed container, such that the enzyme enhances the digestion of the minced tissue. In an aspect, the present disclosure provides a method of mincing a tissue sample positioned between the solid member and the cutting surface of the tissue mincing tool as disclosed above, the method comprising: ~~impelling~~ pressing the tissue sample, via the solid member, into contact with and through the cutting surface of ~~a~~ the tissue mincing tool ~~as disclosed herein~~. In another aspect, the present disclosure provides a method of digesting a tissue sample, the method comprising: mincing the tissue sample as disclosed herein and, optionally, transferring the minced tissue to a second sterile, sealed container; and injecting an enzyme ~~into the sterile, sealed container~~, whereby the enzyme digests the minced tissue. In yet another aspect, the present disclosure provides a method of separating cells from a tissue sample, the method comprising: ~~digesting~~ mincing the tissue sample as disclosed herein, and removing undigested tissue. The enzyme can be a protease, such as collagenase, hyaluronidase, or dispase, separately or in combination. These steps can optionally be incorporated into a method of separating cells from the tissue sample by mincing and/or digesting the tissue sample and removing fragments larger than about 40 microns (*e.g.* fragments retained by a filter having a pore size of about 500 microns, or fragments retained by a filter having a pore size of about 300 microns, or fragments retained by a filter having a pore size of about 250 microns, or fragments retained by a filter having a pore size of about 150 microns, or fragments retained by a filter having a pore size of about 100 microns, or fragments retained by a filter having a pore size of about 70 microns, or fragments retained by a filter having a pore size of about 40 microns). These larger fragments, referred to herein as "undigested tissue," can be removed by filtering or sedimentation. These methods are effective for purifying cells from any of a variety of

solid tissues. For example, the methods described herein can separate cells, such as stem cells, from fat tissue or afterbirth tissue, such as placental or umbilical cord tissue or, more specifically, a tissue comprising Wharton's Jelly. In some embodiments, the tissue sample is substantially free of blood vessels, which can optionally be dissected from a tissue before the tissue is placed in the compartment.

[0010] In another ~~aspect~~embodiment, the present disclosure relates to a cell collection method including sedimenting cells in a cell collection device. The cell collection device includes a sterile container for a fluid including cells and a fluid passageway in communication with the sterile container. The fluid passageway includes a cell capture zone, such that the volume of the cell capture zone can be less than 5% of the volume of the sterile container and the sterile container

and the cell capture zone can be configured such that sedimentation of the cells from the fluid in the sterile container concentrates the cells in the cell capture zone. This ~~aspect~~ embodiment or any of the following ~~aspects~~ embodiments can have any of the following embodiments. The cell collection device further includes a second sterile container in communication with the fluid passageway and/or a removable clamp to regulate passage of material into the second sterile container. The second sterile container can be heat-sealable and/or a bag. The cell collection method can also include centrifuging the cell collection device to accelerate sedimentation of the cells, and the cells can be Wharton's Jelly stem cells. The fluid includes mechanically minced and/or enzymatically digested umbilical cord tissue. The cell collection method can further include adding a cryoprotectant to the cells; the cryoprotectant includes DMSO, albumin, and/or dextran. The method can also include adding autologous plasma to the cells.

[0011] In still another ~~aspect~~embodiment, the present disclosure relates to a cell collection device having a fluid including cells, a sterile container for housing the cells, and a fluid passageway in communication with the sterile container. The fluid passageway includes a cell capture zone, wherein the volume of the cell capture zone can be less than 5% of the volume of the sterile container and the sterile container and the cell capture zone can be configured such that sedimentation of the cells from the fluid in the sterile container concentrates the cells in the cell capture zone. This embodiment~~aspect~~ or any of the following embodiments ~~aspects~~ can have any of the following embodiments. The cell collection device also or alternatively includes a second sterile container in communication with the fluid passageway and/or a removable clamp to regulate passage of material into the second sterile container. The second sterile container can be heat-sealable and/or a bag.

[0012] In yet another embodiment~~aspect~~, the present disclosure relates to a cell collection device having a sterile container for a fluid comprising cells, such that the sterile container can be adapted for use in sedimentation, and a fluid passageway in communication with the sterile container. The fluid passageway includes first and second valves defining a cell capture zone therebetween, such that the volume of the cell capture zone can be less than 5% of the volume of the sterile container and the sterile container and the cell capture zone can be configured such that sedimentation of the cells from the fluid in the sterile container concentrates the cells in the cell capture zone. This embodiment ~~aspect~~ or any of the following embodiments ~~aspects~~ can have any of the following embodiments. The sterile container can be adapted for use in centrifugation. The cell collection device also or alternatively includes a second sterile container in communication

with the second valve and/or a removable clamp to regulate passage of material into the second sterile container. The second sterile container can be heat-sealable and/or a bag.

[0013] In still yet another embodimentaspect, the present disclosure relates to a cell collection device having a sterile container for housing the cells, a fluid passageway in communication with the sterile container, and a second sterile container in communication with the fluid passageway. The fluid passageway includes a cell capture zone, such that the volume of the cell capture zone is less than 5% of the volume of the sterile container and the sterile container and the cell capture zone can be configured such that sedimentation of the cells from the fluid in the sterile container concentrates the cells in the cell capture zone. The second sterile container includes an element selected from the group consisting of a bag, a heat-sealable container, and a removable clamp.

[0014] In another embodimentaspect, the present disclosure relates to cell collection device that includes a compartment for receiving a tissue; a cutting surface dimensioned to mince the tissue sample into fragments having an average cross-section no greater than four square millimeters; a sterile, sealed container for holding a suspension of the minced tissue, the sterile container having a volume at least ten times greater than the volume of the compartment for receiving a tissue; a filter bag in fluid communication with the sterile, sealed container; and a sedimentation bag in fluid communication with the filter bag. The filter bag contains at least one filter having a pore size sufficiently small to retain particles larger than about 250 μm. The sedimentation bag includes a tapered portion to promote the concentration of sedimented cells.

BRIEF DESCRIPTION OF THE FIGURES

[0015] Other features and advantages of the present invention, as well as the invention itself, can be more fully understood from the following description of the various embodiments, when read together with the accompanying drawings, in which:

[0016] FIG. 1 schematically depicts a tissue mincing tool, according to an embodiment of the invention;

[0017] FIG. 2 is a schematic perspective view of a solid member of a tissue mincing tool, according to an embodiment of the invention;

[0018] FIG. 3 is a schematic perspective view of the solid member of FIG. 2;

1. A tissue mincing tool comprising:

a compartment for a tissue sample;

a solid member actuatable by a handle and moveable within the compartment;

a cutting surface at one end of the compartment; and

a sterile, sealed container,

wherein the compartment is arranged to position the tissue sample between the solid member and the cutting surface and actuation of the handle in one direction causes the solid member to move only towards the cutting surface,

and further wherein the cutting surface separates the compartment from the sterile, sealed container, such that a tissue sample that ~~passes~~ is pressed, via the solid member, into contact with and through the cutting surface is deposited as a minced tissue within the sterile, sealed container.

2. The tissue mincing tool of claim 1, wherein the cutting surface is dimensioned to mince the tissue sample into fragments having an average cross-section no greater than four square millimeters.

3. The tissue mincing tool of claim 2, wherein the average cross-section is no greater than one square millimeter.

4. A tissue mincing tool according to any one of the preceding claims, further comprising a second cutting surface for reducing the average cross-section of the fragments.

5. A tissue mincing tool according to any one of the preceding claims, wherein the cutting surface comprises an automated cutting system.

6. ~~A~~ The tissue mincing tool of claim 5, wherein the automated cutting system comprises semi-automatic scissors.

7. A tissue mincing tool according to any one of the preceding claims, further comprising at least one mincer screen positioned in proximity to the cutting surface.

8. The tissue mincing tool of claim 7, wherein the at least one mincer screen is moveable towards the tissue sample.

~~8~~9. A tissue mincing tool according to any one of the preceding claims, further comprising a suction cup for stabilizing the tissue mincing tool during operation thereof.

~~9~~10. A tissue mincing tool according to any one of the preceding claims, further comprising a fluid conduit in communication with the sterile, sealed container, and a filter disposed within the fluid conduit.

~~10~~11. A tissue mincing tool according to any one of the preceding claims, wherein the sterile, sealed container comprises at least one sealed access port permitting the sterile introduction of a fluid into the container.

~~11~~12. A tissue mincing tool according to any one of the preceding claims, wherein an interior surface of the compartment is threaded.

~~12~~13. A tissue mincing tool according to any one of the preceding claims, further comprising a gasket for sealing the compartment.

~~13~~14. A tissue mincing tool according to any one of the preceding claims, wherein a portion of the compartment near its end has a substantially constant cross-section.

~~14~~15. A tissue mincing tool according to any one of the preceding claims, wherein a portion of the compartment near its end is tapered or cone-shaped.

~~15~~16. The tissue mincing tool according to claim ~~13 or 14, further comprising a~~ 14 or 15, wherein the solid member is shaped to mate with and to fill the portion of the compartment~~, the solid member being movable within the portion of the compartment to impel the tissue sample disposed therein through the cutting surface.~~

~~16~~17. The tissue mincing tool of claim 1, further comprising a shaft crank for moving the cutting surface towards the tissue sample.

~~17. A kit comprising:~~

~~a tissue mincing tool according to any one of claims 1-14; and~~

~~a solid member shaped to mate with and to fill the portion of the compartment, the solid member being movable within the portion of the compartment to impel the tissue sample therein through the cutting surface.~~

18. The tissue mincing tool of claim 1, wherein the cutting surface is rotatable.

19. The tissue mincing tool of claim 1, wherein the cutting surface is moveable towards the tissue sample.

20. The tissue mincing tool of claim 1, wherein the tissue mincing tool comprises a series of cutting surfaces at the one end of the compartment.

~~18~~21. A method of mincing a tissue sample positioned between the solid member and the cutting surface of the tissue mincing tool of claim 1, the method comprising:

~~impelling~~ pressing the tissue sample, via the solid member, into contact with and through the cutting surface of ~~a~~ the tissue mincing tool ~~according to any one of the preceding claims~~.

~~19~~22. A method of digesting a tissue sample, the method comprising:

mincing the tissue sample according to the method of claim ~~18~~21 and, optionally, transferring the minced tissue to a second sterile, sealed container; and

injecting an enzyme ~~into the sterile, sealed container~~, whereby the enzyme digests the minced tissue.

~~20~~23. The method of claim ~~19~~22, wherein the enzyme is a collagenase.

~~21~~24. A method of separating cells from a tissue sample, the method comprising:

~~digesting~~ mincing the tissue sample according to the method of claim ~~19 or 20~~,21; and

removing undigested tissue.

~~22~~25. The method of claim ~~21~~,24, further comprising diluting the tissue sample, wherein the undigested tissue is subsequently removed by filtering.

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26. The method of claim 25, further comprising sedimenting a filtrate generated by the filtering.

27. The method of claim 26, further comprising re-suspending sedimented cells and filtering the re-suspended sedimented cells.

~~23~~28. A method according to any one of claims ~~18-22~~21-27, wherein the tissue sample comprises Wharton's Jelly stem cells.

~~24~~29. The method of claim ~~23~~28, wherein the tissue sample is substantially free of blood vessels.

25. A cell collection method comprising sedimenting cells in a cell collection device, wherein the cell collection device comprises:

a sterile container for a fluid comprising cells; and

a fluid passageway in communication with the sterile container, the fluid passageway comprising a cell capture zone, wherein the volume of the cell capture zone is less than 5% of the volume of the sterile container and the sterile container and the cell capture zone are configured such that sedimentation of the cells from the fluid in the sterile container concentrates the cells in the cell capture zone.

26. The cell collection method of the preceding claim, wherein the cell collection device further comprises a second sterile container in communication with the fluid passageway.

27. The cell collection method of the preceding claim, wherein the cell collection device further comprises a removable clamp to regulate passage of material into the second sterile container.

28. A cell collection method according to claim 26 or 27, wherein the second sterile container is heat-sealable.

29. A cell collection method according to any one of claims 26-28, wherein the second sterile container comprises a bag.

30. The cell collection method of claim 25, further comprising centrifuging the cell collection device to accelerate sedimentation of the cells.

31. A cell collection method according to any one of claims 25-30, wherein the cells are Wharton's Jelly stem cells.

32. The cell collection method of claim 31, wherein the fluid comprises minced and/or enzymatically digested umbilical cord tissue.

33. A cell collection method according to any one of claims 25-32, further comprising adding a cryoprotectant to the cells.

34. The cell collection method of claim 33, wherein the cryoprotectant comprises DMSO.

35. The cell collection method of claim 33 or 34, wherein the cryoprotectant comprises albumin.

36. A cell collection method according to any one of claims 33-35, wherein the cryoprotectant comprises dextran.

37. A cell collection method according to any one of claims 25-36, further comprising adding autologous plasma to the cells.

38. A cell collection device comprising:

a fluid comprising cells;

a sterile container for housing the cells; and

a fluid passageway in communication with the sterile container, the fluid passageway comprising a cell capture zone, wherein the volume of the cell capture zone is less than 5% of the volume of the sterile container and the sterile container and the cell capture zone are configured such that sedimentation of the cells from the fluid in the sterile container concentrates the cells in the cell capture zone.

39. The cell collection device of the preceding claim further comprising a second sterile container in communication with the fluid passageway.

40. The cell collection device of the preceding claim further comprising a removable clamp to regulate passage of material into the second sterile container.

41. A cell collection device according to claim 39 or 40, wherein the second sterile container is heat-sealable.

42. A cell collection device according to any one of claims 39-41, wherein the second sterile container comprises a bag.

43. A cell collection device comprising:

a sterile container for a fluid comprising cells, the sterile container being adapted for use in sedimentation; and

a fluid passageway in communication with the sterile container, the fluid passageway comprising a cell capture zone, wherein the volume of the cell capture zone is less than 5% of the volume of the sterile container and the sterile container and the cell capture zone are configured such that sedimentation of the cells from the fluid in the sterile container concentrates the cells in the cell capture zone.

44. The cell collection device of claim 43, wherein the sterile container is adapted for use in centrifugation.

45. A cell collection device according to claim 43 or 44, further comprising a second sterile container in communication with the fluid passageway.

46. The cell collection device of the preceding claim further comprising a removable clamp to regulate passage of material into the second sterile container.

47. A cell collection device according to claim 45 or 46, wherein the second sterile container is heat-sealable.

48. A cell collection device according to any one of claims 45-47, wherein the second sterile container comprises a bag.

49. A cell collection device comprising:

a sterile container for housing the cells;

a fluid passageway in communication with the sterile container, the fluid passageway comprising a cell capture zone, wherein the volume of the cell capture zone is less than 5% of the volume of the sterile container and the sterile container and the cell capture zone are configured such that sedimentation of the cells from the fluid in the sterile container concentrates the cells in the cell capture zone; and

a second sterile container in communication with the fluid passageway, the second sterile container comprising an element selected from the group consisting of a bag, a heat-sealable container, and a removable clamp.

50. A cell collection device comprising:

a compartment for receiving a tissue;

a cutting surface dimensioned to mince the tissue sample into fragments having an average cross-section no greater than four square millimeters;

a sterile, sealed container for holding a suspension of the minced tissue, the sterile container having a volume at least ten times greater than the volume of the compartment for receiving a tissue;

a filter bag in fluid communication with the sterile, sealed container, the filter bag comprising at least one filter having a pore size sufficiently small to retain particles larger than about 250 μm; and

a sedimentation bag in fluid communication with the filter bag, the sedimentation bag comprising a tapered portion to promote the concentration of sedimented cells.