associated with contamination due to manual filling a syringe with flush solution or medicament from a vial. Generally speaking, the single use device of the present invention capable of delivering sterile solution to the female luer connection of a VAD. In general, the device comprises a deformable container with a male luer connector capable of holding between 0.5mL and 10mL of sterile and a clip element that collapses the deformable container to expel the solution within. The deformable container includes a male luer connector that enables secure connection to the female luer connector within a VAD. The clip element contains a pivot which is activated by pressing the moveable sides together to expel the solution from the deformable container.

[0038] Referring to Figure 1, a single use pre-filled delivery device **10** according to the present invention generally comprises a deformable container **20** including a side wall **21** having an inside surface **22** defining a chamber **23** for retaining fluid, a clip element **30**, and a locking element **40**. In operation, delivery device **10** is attached to a patient's catheter via a patient's vascular access device (VAD). The deformable container **20** further comprises a closed proximal end **24** and an open distal end **25** including a male luer tip **26** having a passageway **27** therethrough providing fluid communication with the chamber **23**. The male luer tip **26** may be removably connectable to a female luer connection of a vascular access device. Thus, the delivery device of the present invention is capable of a generating a secure connection with a receiving needleless female vascular access connector. The clip element **30** comprises a distal end **31**, proximal end **32**, and a pivot **33** located between the distal end **31** and the proximal end **32** of the clip element **30** for collapsing the deformable container **20** to drive fluid out of the chamber **23** by movement of the proximal end **32** towards the distal end **31**. In one or more embodiments, the pivot 33 may be a hinge, which may be in the form of a living hinge. The deformable container **20** may be attached to the clip element **30**. The locking element 40 may be disposed on the clip element **30**.

[0039] One advantage of the present invention over prior is that the clip element **30** of the present invention improves control of fluid delivery from the deformable container **20**.

[0040] In one or more embodiments, the single use pre-filled delivery device **10** further includes a tip cap **45** that is releasably connected to the male luer tip **26** of the deformable container **20** for sealing the passageway 27. Figures 8-17 show an embodiment of the single use pre-filled delivery device **10** of the present invention having a tip cap **45**.

[0041] In one or more embodiments, the vascular access device is a syringe, extension set, intravenous set, stop cock, tubing, high pressure extension tubing, or needleless connector.

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[0051] In one or more embodiments, the clip element **30** further includes at least one protrusion for removing one or more air bubbles from the delivery device **10** and controlling the delivery of fluid from the delivery device **10**.

[0052] There are several embodiments of the orientation of the clip element **30**. As shown in Figure 1, the delivery device 10 comprises one pivot 33 positioned opposite of the male luer tip of the deformable container **20** between the proximal end and distal end of the clip element 30. As shown in Figure 1, the delivery device 10 comprises a locking element 60 having a forked tip on the proximal end of the clip element which engages the distal end of the clip element near the male luer tip upon activation. As shown in Figure 2, the delivery device 10 comprises a V-shaped clip element having one pivot 33 positioned mid-way along the clip element near of the male luer tip of the deformable container **20.** The delivery device 10 may include a frangible seal 51 to close the passageway of the chamber 23. As shown in Figure 2, the delivery device 10 comprises a locking element 40 having a protrusion on the distal end of the clip element which engages a cavity on the proximal end of the clip element. As shown in Figures 3-5, the delivery device comprises a deformable container positioned in between a V-shaped clip element, said V-shaped clip element comprising two flat longitudinal surfaces **70** connected by pivot 33 positioned perpendicular to the male luer tip located on the distal end of the deformable container. As shown in Figure 3, in one embodiment, the locking element includes a protrusion **80** on one longitudinal end of the clip element which engages a corresponding cavity **90** located on the opposite end of the clip element. As shown in Figure 4, in one embodiment, the locking element includes a plurality of teeth **92** on one longitudinal end of the clip element which engages a corresponding catch **94** located on the opposite end of the clip element. As shown in Figure 5, in one embodiment, the locking element includes detents or a tab 98 on one longitudinal end of the clip element which engages a corresponding slot or cavity 99 located on the opposite end of the clip element. The embodiments of Figures 1-5 are activated by pressing the moveable distal and proximal ends of the clip element together to activate the device and deliver the contents.

[0053] As shown in Figure 6, the delivery device 10 comprises two pivots 33 and 34 to create a three-fold clip element comprising portions A, B and C. Pivot 33 connects portions A and B. Pivot 34 connects portions B and C. Deformable container 20 is attached to portion A. Upon activation, portion B folds upon the proximal end of portion A via pivot 33 to serve a priming function for the removal of air bubbles from deformable container 20. Portion C folds upon portion A via pivot 34 for the expulsion of fluid from deformable container 20.

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What is claimed is:

1. A single use pre-filled delivery device comprising:

a deformable container including a side wall having an inside surface defining a chamber for retaining fluid, a closed proximal end and an open distal end including a male luer tip having a passageway therethrough providing fluid communication with said chamber; said male luer tip removably connectable to a female luer connection of a vascular access device; and

a clip element for collapsing the deformable container having a distal end and proximal end comprising a pivot located between the distal end and the proximal end for driving fluid out of said chamber by movement of the proximal end towards the distal end, the clip element comprising a distal portion and a proximal portion, said deformable container being attached to the clip element; and

a locking element disposed on the clip element.

2. The single use pre-filled delivery device of claim 1, wherein the pivot is a hinge.

3. The single use pre-filled delivery device of claim 2, wherein the hinge is a living hinge.

4. The single use pre-filled delivery device of claim 1, further including a tip cap releasably connected to said male luer tip of said deformable container for sealing said passageway.

5. The single use pre-filled delivery device of claim 1, wherein the vascular access device is a syringe, extension set, intravenous set, stop cock, tubing, high pressure extension tubing, or needleless connector.

6. The single use pre-filled delivery device of claim 1, further comprising a pre-selected amount of sterile fluid in the chamber.

7. The single use pre-filled delivery device of claim 6, wherein the pre-selected amount of fluid in the chamber is from 0.5ml to 10 ml.

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8. The single use pre-filled delivery device of claim 6, wherein the fluid comprises a sterile flush solution.

9. The single use pre-filled delivery device of claim 8, wherein the flush solution is saline, heparin, water or a combination thereof.

10. The single use pre-filled delivery device of claim 6, wherein the fluid comprises a medicament or drug.

11. The single use pre-filled delivery device of claim 1, wherein the locking element minimizes reflux of solution in the passageway.

12. The single use pre-filled delivery device of claim 1, wherein the locking element provides confirmation to the user of solution delivery.

13. The single use pre-filled delivery device of claim 1, wherein the locking element comprises at least one protrusion and at least one corresponding cavity.

14. The single use pre-filled delivery device of claim 13, wherein the at least one protrusion is disposed on the proximal end of the clip element and the at least one corresponding cavity is disposed on the distal end of the clip element.

15. The single use pre-filled delivery device of claim 13, wherein the at least one protrusion is disposed on the distal end of the clip element and the at least one corresponding cavity is disposed on the proximal end of the clip element.

16. The single use pre-filled delivery device of claim 13, wherein the locking element is arranged to be manually activated by a user after the protrusion engages to the corresponding slot after the fluid has been expelled from the deformable container.

17. The single use pre-filled delivery device of claim 1, wherein the locking element comprises detents.

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18. The single use pre-filled delivery device of claim 1, wherein the locking element comprises a racheting mechanism having a plurality of teeth and a catch.

19. The single use pre-filled delivery device of claim 18, wherein the catch is disposed on the proximal end of the clip element and the plurality of teeth is disposed on the distal end of the clip element.

20. The single use pre-filled delivery device of claim 18, wherein the catch is disposed on the distal end of the clip element and the plurality of teeth is disposed on the proximal end of the clip element.

21. The single use pre-filled delivery device of claim 18, wherein the locking element is arranged to be manually activated by a user after the catch engages to one or more of the plurality of teeth.

22. The single use pre-filled delivery device of claim 1, wherein the locking element comprises a snap fit element to connect the distal end of the clip element to the proximal end of the clip element upon the release.

23. The single use pre-filled delivery device of claim 1, wherein the pivot is positioned on the proximal end of the deformable container.

24. The single use pre-filled delivery device of claim 1, wherein the pivot is positioned on the distal end of the deformable container.

25. The single use pre-filled delivery device of claim 1, wherein the pivot is oriented in a perpendicular position with respect to the pivot.

26. The single use pre-filled delivery device of claim 1, wherein the locking element provides feedback to the user to confirm delivery of a desired volume of fluid from the chamber.

27. The single use pre-filled delivery device of claim 1, wherein the feedback is tactile, visual or audible.

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28. The single use pre-filled delivery device of claim 1, wherein the deformable container is made of thermoplastic elastomers, polyolefin, polyester or other injection moldable or formable resin.

29. The single use pre-filled delivery device of claim 1, wherein the clip element further includes at least one protrusion for removing one or more air bubbles from the delivery device and controlling the delivery of fluid from the deformable container.

30. A single use pre-filled delivery device comprising:

a deformable container including a side wall having an inside surface defining a chamber for retaining fluid, a closed proximal end and an open distal end including a male luer tip having a passageway therethrough providing fluid communication with said chamber; said male luer tip removably connectable to a female luer connection of a vascular access device; and

a three-fold clip element having a first portion, a second portion and third portion,

said deformable container being attached to said first portion of the clip element,

said second portion being attached to the first portion by a first pivot, said second portion of the clip element being foldable over the first portion of the clip element for removing one or more air bubbles from the deformable container;

said third portion being attached to the second portion by a second pivot, said third portion of the clip element being foldable over the first portion of the clip element for driving fluid out of said chamber; and

a locking element disposed on the first and third portion of the clip element.

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associated with contamination due to manual filling a syringe with flush solution or medicament from a vial. Generally speaking, the single use device of the present invention capable of delivering sterile solution to the female luer connection of a VAD. In general, the device comprises a deformable container with a male luer connector capable of holding between 0.5mL and 10mL of sterile solution and a clip element that collapses the deformable container to expel the solution within. The deformable container includes a male luer connector that enables secure connection to the female luer connector within a VAD. The clip element contains a pivot which is activated by pressing the moveable sides together to expel the solution from the deformable container.

[0038] Referring to Figure 1, a single use pre-filled delivery device **10** according to the present invention generally comprises a deformable container **20** including a side wall **21** having an inside surface **22** defining a chamber **23** for retaining fluid, a clip element **30**, and a locking element **40**. In operation, delivery device **10** is attached to a patient's catheter via a patient's vascular access device (VAD). The deformable container **20** further comprises a closed proximal end **24** and an open distal end **25** including a male luer tip **26** having a passageway **27** therethrough providing fluid communication with the chamber **23**. The male luer tip **26** may be removably connectable to a female luer connection of a vascular access device. Thus, the delivery device of the present invention is capable of a generating a secure connection with a receiving needleless female vascular access connector. The clip element **30** comprises a distal end **31**, proximal end **32**, and a pivot **33** located between the distal end **31** and the proximal end **32** of the clip element **30** for collapsing the deformable container **20** to drive fluid out of the chamber **23** by movement of the proximal end **32** towards the distal end **31**. In one or more embodiments, the pivot 33 may be a hinge, which may be in the form of a living hinge. The deformable container **20** may be attached to the clip element **30**. The locking element 40 may be disposed on the clip element **30**.

[0039] One advantage of the present invention over prior is that the clip element **30** of the present invention improves control of fluid delivery from the deformable container **20**.

[0040] In one or more embodiments, the single use pre-filled delivery device **10** further includes a tip cap **45** that is releasably connected to the male luer tip **26** of the deformable container **20** for sealing the passageway 27. Figures 8-17 show an embodiment of the single use pre-filled delivery device **10** of the present invention having a tip cap **45**.

[0041] In one or more embodiments, the vascular access device is a syringe, extension set, intravenous set, stop cock, tubing, high pressure extension tubing, or needleless connector.

[0051] In one or more embodiments, the clip element **30** further includes at least one protrusion for removing one or more air bubbles from the delivery device **10** and controlling the delivery of fluid from the delivery device **10**.

[0052] There are several embodiments of the orientation of the clip element **30**. As shown in Figure 1, the delivery device 10 comprises one pivot 33 positioned opposite of the male luer tip of the deformable container **20** between the proximal end and distal end of the clip element 30. As shown in Figure 2, the delivery device 10 comprises a locking element 60 having a forked tip on the proximal end of the clip element which engages the distal end of the clip element near the male luer tip upon activation. As shown in Figure 2, the delivery device 10 comprises a V-shaped clip element having one pivot 33 positioned mid-way along the clip element near of the male luer tip of the deformable container **20.** The delivery device 10 may include a frangible seal 51 to close the passageway of the chamber 23. As shown in Figure 2, the delivery device 10 comprises a locking element 40 having a protrusion on the distal end of the clip element which engages a cavity on the proximal end of the clip element. As shown in Figures 3-5, the delivery device comprises a deformable container positioned in between a V-shaped clip element, said V-shaped clip element comprising two flat longitudinal surfaces **70** connected by pivot 33 positioned perpendicular to the male luer tip located on the distal end of the deformable container. As shown in Figure 3, in one embodiment, the locking element includes a protrusion **80** on one longitudinal end of the clip element which engages a corresponding cavity **90** located on the opposite end of the clip element. As shown in Figure 4, in one embodiment, the locking element includes a plurality of teeth **92** on one longitudinal end of the clip element which engages a corresponding catch **94** located on the opposite end of the clip element. As shown in Figure 5, in one embodiment, the locking element includes detents or a tab 98 on one longitudinal end of the clip element which engages a corresponding slot or cavity 99 located on the opposite end of the clip element. The embodiments of Figures 1-5 are activated by pressing the moveable distal and proximal ends of the clip element together to activate the device and deliver the contents.

[0053] As shown in Figure 6, the delivery device 10 comprises two pivots 33 and 34 to create a three-fold clip element comprising portions A, B and C. Pivot 33 connects portions A and B. Pivot 34 connects portions B and C. Deformable container 20 is attached to portion A. Upon activation, portion B folds upon the proximal end of portion A via pivot 33 to serve a priming function for the removal of air bubbles from deformable container 20. Portion C folds upon portion A via pivot 34 for the expulsion of fluid from deformable container 20.

Claims

1. A single use pre-filled delivery device comprising:

a deformable container including a side wall having an inside surface defining a chamber for retaining fluid, a closed proximal end and an open distal end including a male luer tip having a passageway therethrough providing fluid communication with said chamber; said male luer tip removably connectable to a female luer connection of a vascular access device; and

a two-fold clip element for collapsing the deformable container having a distal end and proximal end comprising a pivot located between the distal end and the proximal end for driving fluid out of said chamber by movement of the proximal end towards the distal end, the clip element comprising a distal first portion and a proximal second portion, said deformable container being attached to the clip element, wherein the clip element further includes at least one protrusion for removing one or more air bubbles from the delivery device and controlling the delivery of fluid from the deformable container, wherein the first portion moves along the pivot in a counterclockwise direction to remove one or more air bubbles and the first portion moves along the pivot in a clockwise direction to expel a fluid from the chamber; and

a locking element disposed on the clip element wherein the locking element comprises at least one protrusion and at least one corresponding cavity, the at least one protrusion and the at least one corresponding cavity being on opposite ends of the clip element.

2. The single use pre-filled delivery device of claim 1, wherein the pivot is a hinge.

3. The single use pre-filled delivery device of claim 2, wherein the hinge is a living hinge.

4. The single use pre-filled delivery device of claim 1, further including a tip cap releasably connected to said male luer tip of said deformable container for sealing said passageway.

5. The single use pre-filled delivery device of claim 1, wherein the vascular access device is a syringe, extension set, intravenous set, stop cock, tubing, high pressure extension tubing, or needleless connector.

6. The single use pre-filled delivery device of claim 1, further comprising a pre-selected amount of sterile fluid in the chamber.

7. The single use pre-filled delivery device of claim 6, wherein the pre-selected amount of fluid in the chamber is from 0.5ml to 10 ml.

8. The single use pre-filled delivery device of claim 6, wherein the fluid comprises a sterile flush solution.

9. The single use pre-filled delivery device of claim 8, wherein the flush solution is saline, heparin, water or a combination thereof.

10. The single use pre-filled delivery device of claim 6, wherein the fluid comprises a medicament or drug.

11. The single use pre-filled delivery device of claim 1, wherein the locking element minimizes reflux of solution in the passageway.

12. The single use pre-filled delivery device of claim 1, wherein the locking element provides confirmation to the user of solution delivery.

13. The single use pre-filled delivery device of claim 12, wherein the at least one protrusion is disposed on the proximal end of the clip element and the at least one corresponding cavity is disposed on the distal end of the clip element.

14. The single use pre-filled delivery device of claim 12, wherein the at least one protrusion is disposed on the distal end of the clip element and the at least one corresponding cavity is disposed on the proximal end of the clip element.

15. The single use pre-filled delivery device of claim 12, wherein the locking element is arranged to be manually activated by a user after the protrusion engages to the corresponding slot after the fluid has been expelled from the deformable container.

16. The single use pre-filled delivery device of claim 1, wherein the locking element comprises detents.

17. The single use pre-filled delivery device of claim 1, wherein the locking element comprises a racheting mechanism having a plurality of teeth and a catch.

18. The single use pre-filled delivery device of claim 17, wherein the catch is disposed on the proximal end of the clip element and the plurality of teeth is disposed on the distal end of the clip element.

19. The single use pre-filled delivery device of claim 17, wherein the catch is disposed on the distal end of the clip element and the plurality of teeth is disposed on the proximal end of the clip element.

20. The single use pre-filled delivery device of claim 17, wherein the locking element is arranged to be manually activated by a user after the catch engages to one or more of the plurality of teeth.

21. The single use pre-filled delivery device of claim 1, wherein the locking element comprises a snap fit element to connect the distal end of the clip element to the proximal end of the clip element upon the release.

22. The single use pre-filled delivery device of claim 1, wherein the pivot is positioned on the proximal end of the deformable container.

23. The single use pre-filled delivery device of claim 1, wherein the pivot is positioned on the distal end of the deformable container.

24. The single use pre-filled delivery device of claim 1, wherein the pivot is oriented in a perpendicular position with respect to the distal end of the deformable container pivot.

25. The single use pre-filled delivery device of claim 1, wherein the locking element provides feedback to the user to confirm delivery of a desired volume of fluid from the chamber.

26. The single use pre-filled delivery device of claim 25, wherein the feedback is tactile, visual or audible.

27. The single use pre-filled delivery device of claim 1, wherein the deformable container is made of thermoplastic elastomers, polyolefin, polyester or other injection moldable or formable resin.

28. A single use pre-filled delivery device comprising:

a deformable container including a side wall having an inside surface defining a chamber for retaining fluid, a closed proximal end and an open distal end including a male luer tip having a passageway therethrough providing fluid communication with said chamber; said male luer tip removably connectable to a female luer connection of a vascular access device; and

a three-fold clip element having a first portion, a second portion and third portion,

said deformable container being attached to said first portion of the clip element,

said second portion being attached to the first portion by a first pivot, said second portion of the clip element being foldable over the first portion of the clip element for removing one or more air bubbles from the deformable container wherein the second portion further includes at least one protrusion for removing one or more air bubbles from the delivery device and controlling the delivery of fluid from the deformable container;

said third portion being attached to the second portion by a second pivot, said third portion of the clip element being foldable over the first portion of the clip element for driving fluid out of said chamber; and

a locking element disposed on the first and third portion of the clip element.