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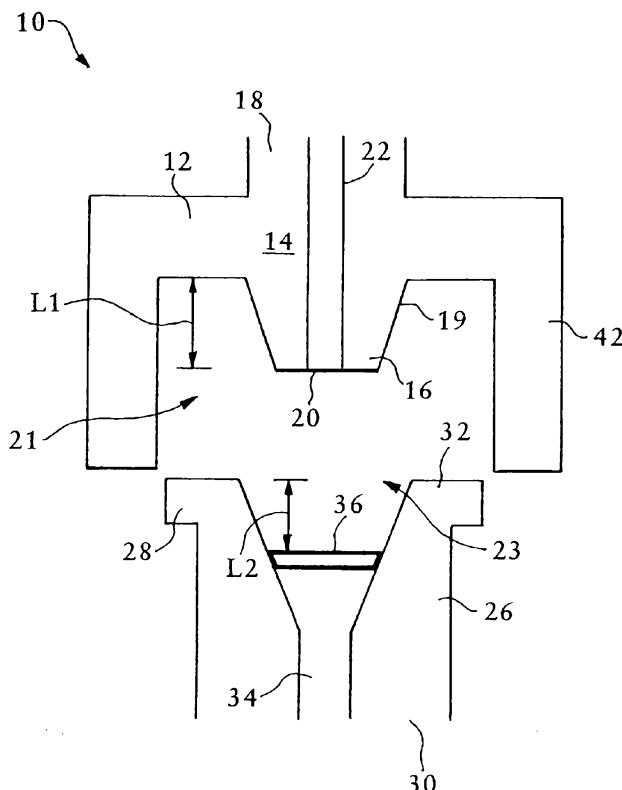
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[Continued on next page]

(54) Title: SAFETY LUER CONNECTION



WO 2008/157788 A3

FIG. 1

(57) Abstract: A connection device has a male connector and a female connector. The female connector will only accommodate the dedicated male connector, thereby prohibiting a misconnection with the wrong male connector. In certain embodiments, a member prohibits male connectors, other than a dedicated male connector, from being inserted into the female connector. In certain other embodiments, a post prohibits male connectors, other than a dedicated male connector including a slot, from being inserted into the female connector. In still certain other embodiments, a series of prongs in the male connector and corresponding grooves in the female connector ensure the proper connection. Once the male connector is inserted and secured within the female connector, a fluid-tight seal is formed between the male connector and the female connector.



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SAFETY LUER CONNECTION

Technical Field

5

The disclosed embodiments relate to a medical connection device, and more particularly, to a male and female connection device, which can be used in conjunction with fluid administration, such as intravenous fluid administration.

10 Luer connections are the typical mechanisms for attaching various medical devices such as syringes, catheters, and intravenous lines to one another. These lines are then generally connected to a patient via a catheter. In a typical luer connection, male and female connectors are mated together to form and secure the connection. Luer connections are widely used in the medical industry because they are quick and easy to assemble.

15 However, with this ease of use comes a high risk of error. For example, in high risk connections, such as epidural lines, the connection of an incorrect line can have serious consequences, including death, for the patient. There is a high risk of accidentally connecting the wrong lines because standard luer connectors are used for both intravenous fluid and epidural infusions. Also, additional lines are commonly found near bedsides of patients seeking medical care for a variety of ailments. Thus, a male connector intended for use with 20 an intravenous line could be easily confused for one intended for use with an epidural line. This confusion can lead to a misconnection, resulting in medication or air erroneously being delivered into an unintended site, leading to serious complications.

25 Currently, precautions for misconnections include double-checking the connection prior to connecting the luers. Alternatively, the different connectors and their attached lines may be specially labeled. Labeling may be accomplished by placing colored tape on the tubing, or placing a color-coded marker on the connectors themselves.

30 While these precautionary measures attempt to solve the problems of misconnections, all of these precautions require an active, mitigating step. This can be problematic and impractical for nurses and doctors who are often working in emergency situations and do not have the luxury of performing time-consuming cautionary steps.

Thus, there is a need for a safety luer connection, in which there is minimal or no risk of disconnecting male and female luers, and in which no additional steps are required by hospital personnel to avoid misconnections.

The above and other needs are met by the disclosed embodiments which provide a connection device comprising a male connector, which includes a body with a distal end and a proximal end, and a projection. The projection has an opening located at a distal end of the projection. The opening is in fluid communication with a fluid passageway located within the body. The projection has a length L1. The connection device further comprises a female connector, comprising a body, a distal end, and a proximal end. A fluid passageway is located within the body. The female connector includes a member perpendicular to the fluid passageway within the body and positioned a length L2 from the proximal end of the female connector and blocking insertion of the projection past the member. The length L1 is approximately equal to L2, such that only a male connector with a projection having the length L1 is fully insertable into the female connector. This will prevent the insertion of typical male connectors.

Other needs are met by disclosed embodiments which provide a connection device comprising a male connector including a projection with a slot. The connection device also includes a female connector comprising a post perpendicular to the fluid passageway within the body. The post is configured to engage the corresponding slot of the projection during insertion of the male connector into the female connector and block insertion of a projection of a male connector without a slot into the female connector.

The earlier stated needs and others are met by still other disclosed embodiments which provide a connection device comprising a male connector, which includes a body with at least one prong. The male connector further includes a tubing pocking with standoffs. The standoffs are configured to permit fluid to flow through a periphery path of the tubing pocket. The male connector also includes at least one attachment piece. The connection device also comprises a female connector, including a body with at least one groove. The groove corresponds to the prong of the male connector, and aligns the male connector upon its insertion into the female connector. The female connector includes a ridge, which cooperates with the attachment piece of the male connector to secure the male connector within the female connector. The female connector further includes a tubing pocket with standoffs.

The foregoing and other features, aspects and advantages of the disclosed embodiments will become more apparent from the following detailed description and accompanying drawings.

FIG. 1 is a cross-sectional view of the male connector and female connector of one embodiment of the connection device, in an unconnected state;

FIG. 2 is a cross-sectional view of the male connector and female connector of the connection device of FIG. 1, in a connected state;

5 FIG. 3 is a cross-sectional view of the female connector of the connection device of FIG. 1 and a typical male luer;

FIG. 4 is a cross-sectional view of the male connector and female connector of another embodiment of the connection device, in an unconnected state;

10 FIG. 5 is a cross-sectional view of the male connector and female connector of the connection device of FIG. 4, in a partially connected state;

FIG. 6 is a cross-sectional view of the male connector and female connector of the connection device of FIG. 4, in a connected state;

FIG. 7 is a close-up partial-perspective view of the slot and post of the connection device of FIG. 4, in a partially connected state;

15 FIG. 8 is a perspective view of the male connector of another embodiment of the connection device;

FIG. 9 is a side view of FIG. 8;

FIG. 10 is a cross-sectional view of FIG. 9;

20 FIG. 11 is a perspective view of the female connector of the connection device of FIG. 8;

FIG. 12 is a cross-sectional view of FIG. 12;

25 FIG. 13 is a cross-sectional view of the male and female connectors of FIGS. 8 and 11, in a connected state;

FIG. 14 is a perspective view of the male connector of another embodiment of the connection device;

30 FIG. 15 is a perspective view of the female connector of the connection device of FIG. 14; and

FIG. 16 is a cross-sectional view of the male and female connectors of FIGS. 14 and 15, in a connected state.

It is contemplated that the subject matter described herein may be embodied in many forms. Accordingly, the embodiments described in detail below are the presently preferred 5 embodiments, and are not to be considered as limitations.

The disclosed embodiments address problems related to the misconnection of male and female luer connection devices and the dire consequences misconnections may cause in time critical situations. The disclosed embodiments solve these problems, at least in part, by providing a connection device comprising a male connector, which includes a body with a 10 distal end and a proximal end, and a projection from the body having an opening located at a distal end of the projection. The opening is in fluid communication with a fluid passageway located within the body. The projection has a length L1. The connection device further comprises a female connector comprising a body with a distal end and a proximal end, a fluid passageway located within the body, and a member perpendicular to the fluid passageway 15 within the body. The member is positioned a length L2 from the proximal end of the female connector and blocks insertion of the projection past the member, with L1 approximately equal to L2, such that only a male connector with a projection having the length L1 is fully insertable into the female connector. This will prevent the insertion of typical male connectors.

20 The problems are also addressed by disclosed embodiments which provide a connection device comprising a male connector including a projection with a slot. The connection device also includes a female connector comprising a post perpendicular to the fluid passageway within the body. The post is configured to engage the corresponding slot of the projection during insertion of the male connector into the female connector and block 25 insertion of a projection of a male connector without a slot into the female connector a connection device comprising a male connector including a slot. The connection device also includes a female connector comprising a post. The post is configured to engage the corresponding slot of the male connector. The post is located so as to only allow full insertion of the dedicated male connector into the female connector.

30 Other disclosed embodiments provide a connection device comprising a male connector, which includes a body with at least one prong. The male connector further includes a tubing pocking with standoffs. The standoffs are configured to permit fluid to

flow through a periphery path of the tubing pocket. The male connector also includes at least one attachment piece. The connection device also comprises a female connector, including a body with at least one groove. The groove corresponds to the prong of the male connector, and aligns the male connector upon its insertion into the female connector. The female 5 connector includes a ridge, which cooperates with the attachment piece of the male connector to secure the male connector within the female connector. The female connector further includes a tubing pocket with standoffs.

FIG. 1 shows a connection device 10. The device comprises a male connector 12, that includes a body 14. The body 14 has a distal end 16 and a proximal end 18. It should be 10 noted that “distal” refers to the direction toward the patient. “Proximal” refers to the direction away from the patient, or toward the syringe or other collection or dispensing device, such as an intravenous (IV) bag. The male connector 12 has a generally cup-shaped design, as seen in FIG. 1, with a recess 21 configured to mate with a female connector. A projection 19 extends within the recess 21 towards the distal end 16 of the body 14. The 15 projection 19 is received within a mating portion of a female connector, as will be further described. The projection 19 includes an opening 20 in fluid communication with a fluid passageway 22. Thus, fluid may flow unobstructed through the fluid passageway 22 and out of the opening 20.

The male connector 12 is configured to mate securely with the female connector 26 20 depicted in FIG. 1, with other male connectors not being able to be securely mated. As shown in FIG. 1, the connection device 10 further comprises a female connector 26. The female connector 26 includes a body 28. The body 28 has a distal end 30 and a proximal end 32. A fluid passageway 34 is located within the body 28. The male connector 12 of FIG. 1 25 may be inserted into the female connector 26 such that the fluid passageways 22, 34 are aligned with one another. The fluid passageways 22, 34 are sized to accommodate typical sized intravenous tubing. However, other types of male connectors will not be able to be fully inserted into the female connector 26.

The female connector 26 includes a member 36. The member 36 is fixedly positioned 30 perpendicular to the fluid passageway 34 of the female connector 26. The member 36 is shallowly located, such that it is not immediately proximate to the distal end 30 of the female connector 26. The member 36 is positioned within the fluid passageway 34 so that only the dedicated male connector 12 may be fully inserted into the female connector 26, as shown in

FIG. 2. The length L1 of the projection 19 is substantially equal to the length L2 between the proximal opening 23 of the female connector 26 and the member 36. Typical male connectors include projections that are longer, such that the projections extend to the distal end of the male connector.

5 FIG. 3 shows an attempt to insert a typical male luer into the female connector 26. If an incorrect male connector is inserted into the female connector 26, the member 36 will prevent the connectors 12, 26 from properly mating. By contrast, with the connection made in FIG. 2 employing the dedicated male connector 12 and female connector 26, a fluid-tight seal may be formed once the male and female connectors 12, 26 are secured. The member 36 ensures an incorrect male connector cannot be fully inserted, which could be a potentially 10 fatal situation for the patient.

15 In certain embodiments, the male connector 12 includes a threaded locking hub 42 and the body 28 of the female connector 26 is also threaded. Hence, the locking hub 42 may be screwed onto and around the female connector body 26, securing the male and female connectors 12, 26.

As discussed above, the member 36 of the female connector 26 prohibits insertion of an incorrect male connector 12. In addition, the female connector 26 is visually devoid of the typical locking tabs that are found on typical female connectors. This should be an additional indication that the female connector 26 disclosed is not to be used with typical male luers.

20 In certain other embodiments, as shown by FIGS. 4-7, the male connector 12 includes a slot 38. The slot 38 may be rotatably cut-out around the exterior of the body 14 of the male connector 12. As shown in FIGS. 4-7, the female connector 26 includes a post 40, which may be cylindrically shaped, or may assume other shapes configured to interact with the slot. The post 40 is configured to engage the slot 38 of the male connector 12, upon insertion of 25 the male connector 12 into the female connector 26.

As shown by FIGS. 5-7, as the male connector 12 is inserted into the female connector 26, the post 40 engages the end of the slot 38. The post 40 is shallowly located on the female connector 26. The location of the post 40 prevents full insertion and engagement of a typical male luer. The location of the post 40 is such that it engages the slot 38 when the 30 male connector 12 is only partially inserted, shown by FIG. 5. The male connector 12 is then rotated as it is fully inserted into the female connector 26, such that the post 40 travels up and further into the slot 38, shown in direction A in FIGS. 6 and 7.

FIGS. 8-10 show a connection device 10 comprising the male connector 12, in which the body 14 has at least one prong 44. As shown in FIG. 8, the male connector 12 includes a tubing pocket 46 with standoffs 48. The standoffs 48 are configured to permit fluid passing through the male connector 12 to flow through a periphery path 50 of the tubing pocket 46.

5 Thus, the fluid will take a more direct path through the male connector 12. The male connector 12 further includes at least one attachment piece 52. The attachment piece 52 may be a snapping piece 52 of a snap-fit connection.

The connection device 10 further includes the female connector 26, shown in FIGS. 11-12, in which the female connector 26 includes at least one groove 54 (FIG. 12). The 10 groove 54 is formed between a plurality of ribs 66 located within the female connector 26. The groove 54 corresponds to the prong 44 of the male connector 12. Upon insertion of the male connector 12 into the female connector 26, the groove 54 and prong 44 matingly engage, aligning the male connector 12 within the female connector 26, shown in FIG. 13. The groove 54 is tapered so that the prong 44 will align easier with the groove 54. The male 15 connector 12 may be rotated until the prong 44 engages the groove 54. While only one prong 44 may be present, it is contemplated that the male connector 12 comprises a plurality of prongs 44 that engage a plurality of corresponding grooves 54. The presence of the prong 44 and groove 54 prevents the connection device 10 from being compatible with typical ISO male and female luer connectors. Thus, the connection device ensures that an incorrect 20 connector, and line, will not be attached to a patient.

The female connector 26 also includes a ridge 56, shown in FIGS. 11 and 12. The ridge 56 cooperates with the snapping piece 52 of the male connector 12, seen in FIG. 8. Thus, as shown in FIG. 13, to secure the male and female connectors 12, 26, the snapping piece 52 snaps onto the ridge 56. This secures the connectors 12, 26 together and may form a 25 fluid-tight seal. The bodies 14, 28 of the male and female connectors 12, 26 are generally cylindrically shaped such that they may easily be mated. However, the bodies 14, 28 may be shaped in other geometries as well.

As shown in FIG. 12, the female connector 26 further includes a tubing pocket 58 with standoffs 60. The tubing pockets 46, 58 are sized to receive typical sized intravenous 30 tubing. The standoffs 48, 60 prevent the tubing within the tubing pockets 46, 58 from forming a seal at the base of the tubing pocket. This would prevent flow of the fluid through the connection device 10 and to the patient or fluid receptacle.

The male connector 12 may also include at least one wing 62, and the body 14 may have a notch 64. The wing 62 is shaped to extend outwardly from the body 14, as seen in FIGS. 8-10. The notch 64 provides for independent flexibility of the wing 62. Compressing the wing 62 disengages the snapping piece 52 of the male connector 12. The notch 64 allows 5 the wing 62 to flex open and away from the body 14 of the male connector 12. This allows for removal of the male connector 12 from the female connector 26. It is contemplated that a plurality of wings 62 may be included on the male connector 12.

The attachment piece 52 of the male connector 12 may be threaded, and the ridge 56 of the female connector 26 may be threaded. Thus, to secure the male and female connectors 10 12, 26, the male connector 12 may be screwed onto the female connector 26.

In another embodiment, shown in FIGS. 14-16, the prong 44 of the male connector 12 may be circumferential. The prong 44, shown in FIG. 16, may be hollow inside its circumference such that it may still engage the groove 54 of the female connector 26. The groove 54, shown in FIG. 15, of the female connector 26 may then also be circumferential in 15 shape so that it may receive the prong 44 of the male connector 12. Additionally, as shown in FIGS. 14-15, the attachment piece 52 of the male connector 12 may be threaded, and the ridge 56 of the female connector 26 may be threaded. Thus, to secure the male and female connectors 12, 26, the male connector 12 may be screwed onto the female connector 26, as shown in FIG. 16.

20 In sum, a connection device having a male connector and a female connector is provided. The female connector will only accommodate the dedicated male connector, thereby prohibiting a misconnection with the wrong male connector. In certain embodiments, a member prohibits male connectors other than a dedicated male connector from being fully inserted into the female connector. In certain other embodiments, a post prohibits male luers, 25 other than a dedicated male connector including a slot, from being fully inserted into the female connector. In yet certain other embodiments, a series of prongs in the male connector and corresponding grooves in the female connector ensure the proper connection. Once the male connector is inserted and secured within the female connector, a fluid-tight seal is formed between the male connector and the female connector. The disclosed embodiments 30 therefore prevent the misconnection of male and female luer connectors without requiring medical personnel to take additional precautionary steps.

Although the disclosed embodiments have been described and illustrated in detail, it is to be clearly understood that the same is by way of illustration and example only and is not to be taken by way of limitation.

5 In the claims which follow and in the preceding description of the invention, except where the context requires otherwise due to express language or necessary implication, the word "comprise" or variations such as "comprises" or "comprising" is used in an inclusive sense, i.e. to specify the presence of the stated features but not to preclude the presence or addition of further features in various embodiments of the
10 invention.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A connection device comprising:

5 a male connector comprising a body with a distal end and a proximal end, and a projection from the body having an external conical surface with a Luer taper and an opening located at a distal end of the projection, the opening in fluid communication with a fluid passageway located within the male connector body, the projection having a length L1; and

10 a female connector comprising a body with a distal end and a proximal end and an internal fluid passageway, having an internal conical surface with a Luer taper configured to sealingly mate with the external conical surface of the male connector and a member projecting into the internal fluid passageway at a point intermediate to a proximal end and a distal end of the internal conical surface, the member positioned a length L2 from the proximal end of the female connector and blocking insertion of the projection past the member, with L1 = L2, such that an external conical surface of a male Luer connector with a projection having a length greater than the length L1 cannot sealingly mate with the internal conical surface of the female connector.

15 2. The connection device of claim 1, wherein the member is a bar horizontally positioned within the fluid passageway of the female connector.

20 3. The connection device of claim 2, wherein the projection extends from the body less than the distal end of the body.

25 4. A connection device comprising:

a male connector comprising a body with a threaded locking hub, a distal end, and a proximal end, a projection with an opening located at the distal end of the body, the opening in fluid communication with a fluid passageway located within the body, the projection having a slot; and

30 a female connector comprising a body, a distal end, and a proximal end, a fluid passageway located within the body, the female connector further comprising a post perpendicular to the fluid passageway within the body, the

post engaging the slot of the projection during insertion of the male connector into the female connector.

5. The connection device of claim 4, wherein the slot of the male connector is a rotational cut-out around the projection of the male connector.

5 6. The connection device of claim 5, wherein the rotational cut-out is configured such that as the male connector is inserted into the female connector, the male connector is rotated such that the post of the female connector travels up the slot.

10 7. The connection device of claim 6, wherein the slot of the male connector is mirrored at 180°, and the post of the female connector is cylindrically shaped, such that the post engages the slot.

15 8. The connection device of any one of claims 4 - 7, wherein the post of the female connector is positioned within the fluid passageway such that the post engages the slot of the male connector upon partial insertion of the male connector into the female connector.

9. The connection device of any one of claims 4 - 8, wherein the position of the post within the fluid passageway of the female connector prevents engagement of a male connector.

20 10. The connection device of any one of claims 4 - 9, wherein the male and female connectors are Luer connectors.

11. A connection device comprising:

25 a male connector comprising a body with at least one prong, the male connector further comprising a tubing pocket with standoffs, the standoffs configured to permit fluid to flow through a periphery path of the tubing pocket when the male connector is fully coupled with a female connector, the male connector including at least one attachment piece; and

a female connector comprising a body with at least one groove, the groove corresponding to the prong of the male connector and aligning the male

connector upon its insertion into the female connector, the female connector further including a ridge, wherein the ridge cooperates with the attachment piece of the male connector to secure the male connector within the female connector, the female connector including a tubing pocket with standoffs.

5 12. The connection device of claim 11, wherein the body of the male connector further comprises at least one wing, and further comprises a notch in the body, the notch providing for independent flexibility of the wing.

10 13. The connection device of claim 12, wherein the attachment piece of the male connector is a snap, which engages the ridge of the female connector by snapping onto the ridge.

14. The connection device of claim 13, wherein compressing the wing disengages the snap of the male connector from the ridge of the female connector, thereby allowing for removal of the male connector from the female connector.

15 15. The connection device of any one of claims 12 - 14, wherein the body of the male connector comprises a plurality of wings.

16. The connection device of any one of claims 11 – 15, wherein the attachment piece of the male connector is threaded and engages the ridge of the female connector, which is also threaded, by screwing onto the threaded ridge.

20 17. The connection device of any one of claims 11 – 16, wherein a plurality of prongs of the male connector engages a plurality of corresponding grooves on the female connector.

25 18. The connection device of any one of claims 11 – 17, wherein the tubing pockets of the male connector and female connector are sized to receive typical intravenous tubing.

19. The connection device of claim 18, wherein the standoffs of the male connector and female connector prevent the intravenous tubing from forming a seal at the base of the tubing pockets of the male and female connectors.

20. The connection device of any one of claims 11 – 19, wherein the male connector is rotatable within the female connector until the grooves are aligned with the prongs.

5 21. The connection device of any one of claims 11 – 20, wherein the body of the male connector and the body of the female connector are generally cylindrically shaped.

22. The connection device of any one of claims 11 – 21, wherein the connection device is incompatible with standard ISO Luer connectors ratio of para-hydrogen to ortho-hydrogen.

10 23. A connection device comprising

15 a male connector comprising a body with a threaded locking hub, a distal end, a proximal end, and a projection with an external conical surface with a Luer taper and an opening located at a distal end of the projection, the opening in fluid communication with a fluid passageway located within the body, the projection having a slot at a point intermediate to a proximal end and the distal end of the external conical surface; and

20 a female connector comprising a body, a distal end, and a proximal end, a fluid passageway located within the body having an internal conical surface with a Luer taper configured to sealingly mate with the external conical surface of the male connector, the female connector further comprising a post projecting into the female connector fluid passageway at a point intermediate to a proximal end and a distal end of the internal conical surface, the post configured to engage the slot of the projection during insertion of the male connector into the female connector,

25 wherein an external conical surface of a male Luer connector without a slot cannot sealingly mate with the internal conical surface of the female connector.

24. A connection device comprising:

5 a male connector comprising a body with a plurality of prongs are configured to collectively form a projection from the body with an external conical surface with a Luer taper with slots separating the prongs for at least a portion of a length of the projection, each prong having an opening at a distal end of the respective prong that is in fluid communication with a fluid passageway located within the male connector body; and

10 a female connector comprising a body with a cavity having an internal conical surface having a Luer taper with a plurality of grooves in the internal conical surface corresponding to the prongs of the male connector, each groove having an opening at a distal end of the respective groove that is in fluid communication with a fluid passageway located within the female connector body, the grooves separated by ribs that fit into the slots of the male connector when the male connector is mated with the female connector such that an 15 external conical surface of a male Luer connector without prongs cannot sealingly mate with the internal conical surface of the female connector.

25. The connection device of claim 1, wherein the member is a rod-shaped bar which is positioned within and across the fluid passageway of the female connector to span the fluid passageway of the female connector.

20 26. A connection device comprising:

25 a male connector with a distal end and a proximal end comprising a first tubing pocket configured to accept a tube at the proximal end and a plurality of prongs at the distal end, the plurality of prongs each having an opening at a distal end that is in fluid communication with the first tube pocket; and

30 a female connector with a distal end and a proximal end and comprising a second tube pocket configured to accept a tube at the distal end and a cavity comprising a plurality of internal grooves configured to matingly engage the plurality of prongs of the male connector at the proximal end, the plurality of grooves each having an opening at a distal end that is in fluid communication with the second tube pocket.

27. A connection device substantially as herein described with reference to the accompanying drawings.

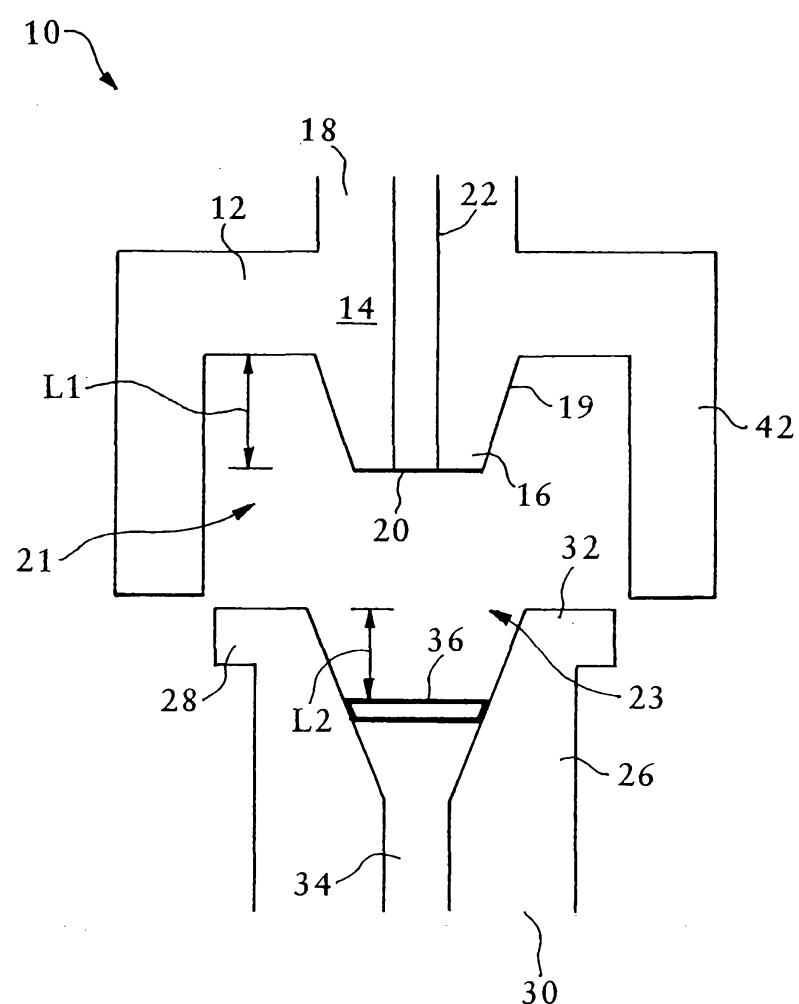


FIG. 1

2/16

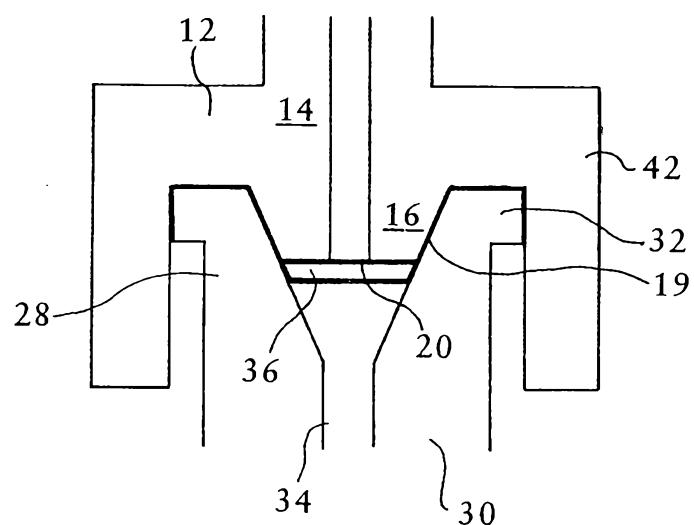


FIG. 2

3/16

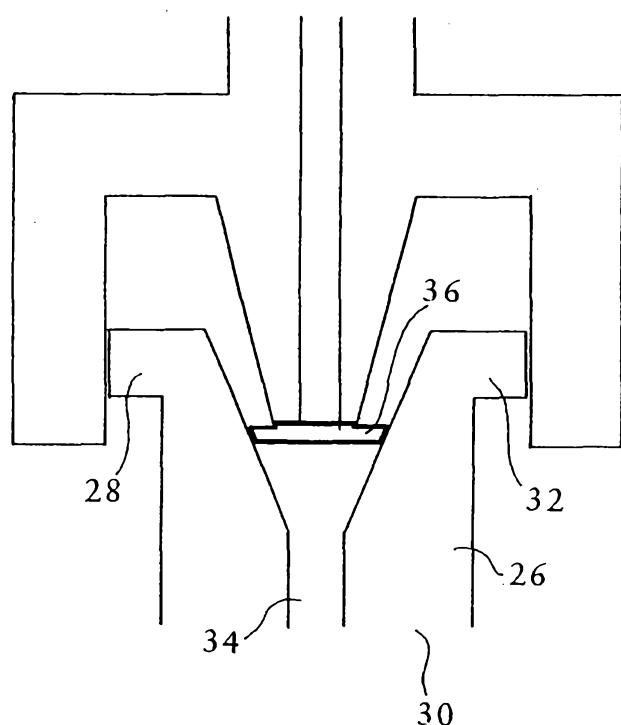


FIG. 3

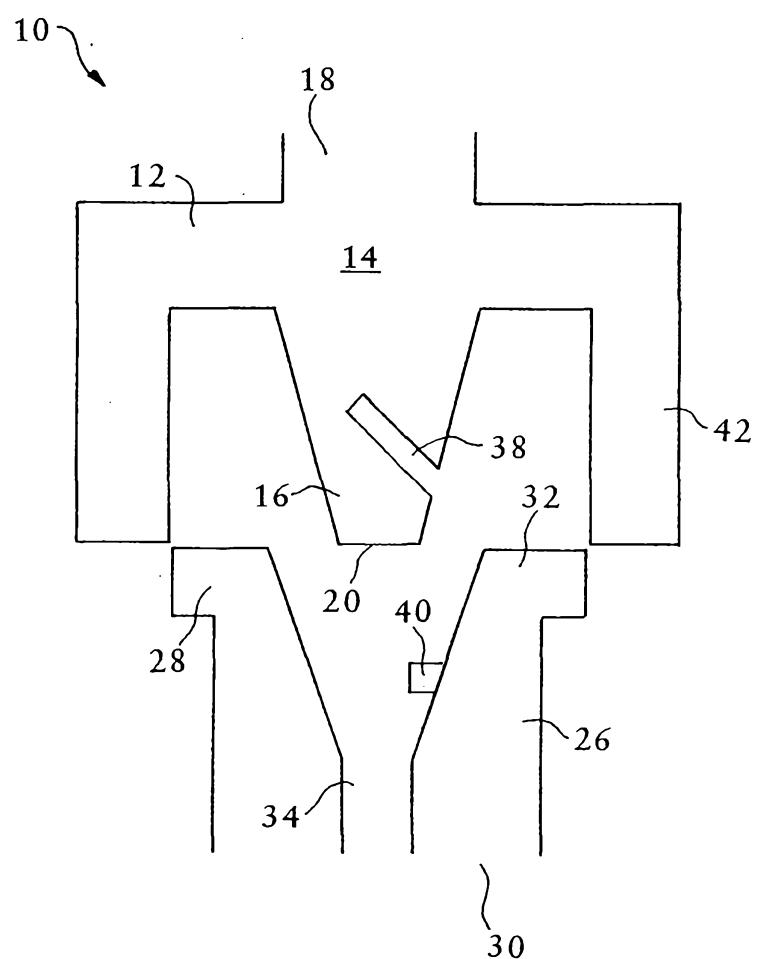


FIG. 4

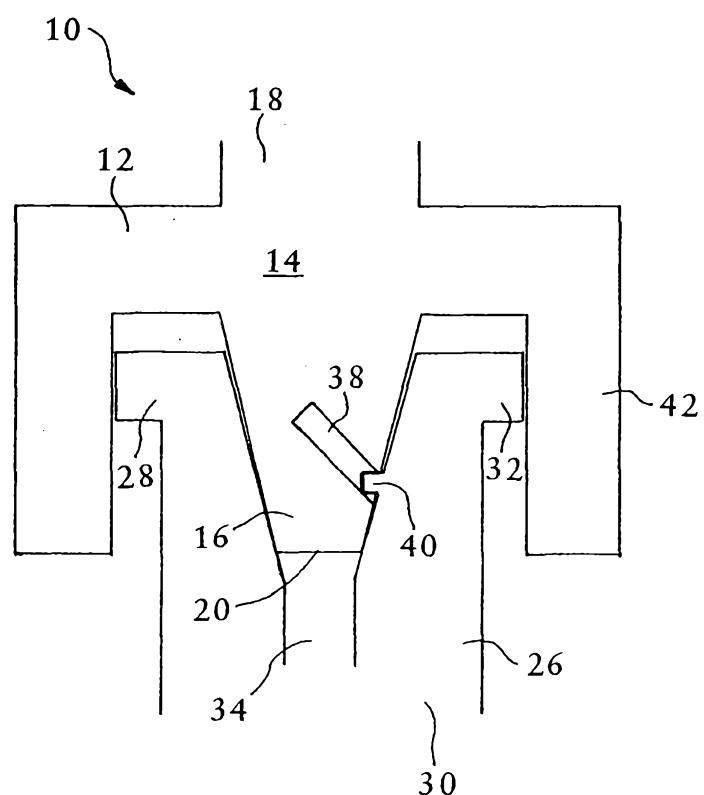


FIG. 5

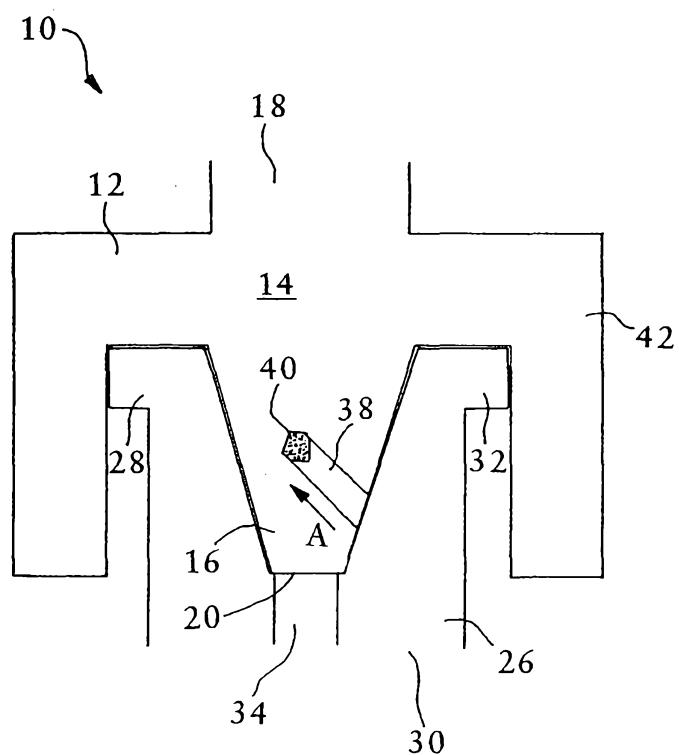


FIG. 6

7/16

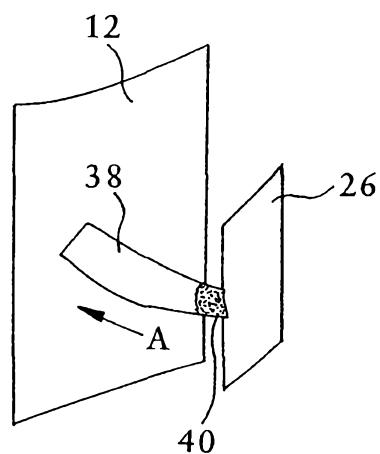


FIG. 7

8/16

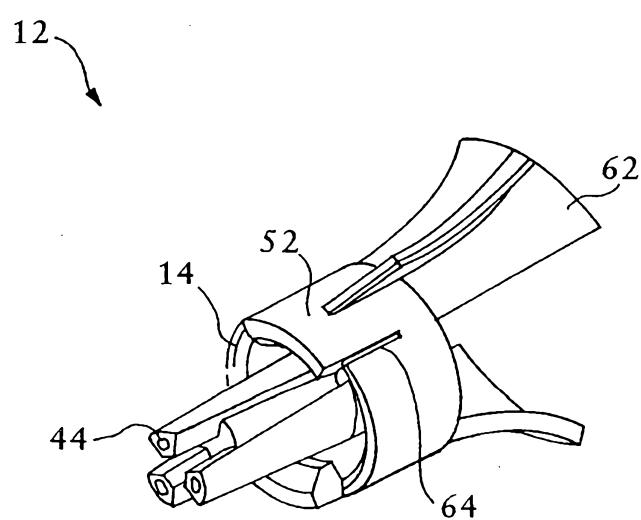


FIG. 8

9/16

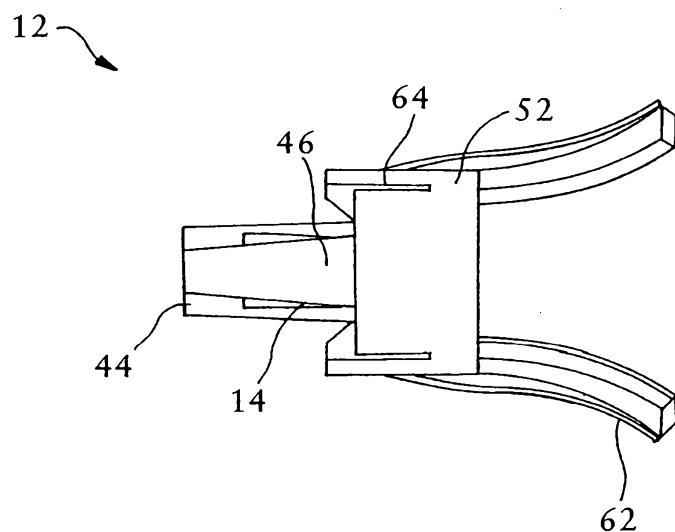


FIG. 9

10/16

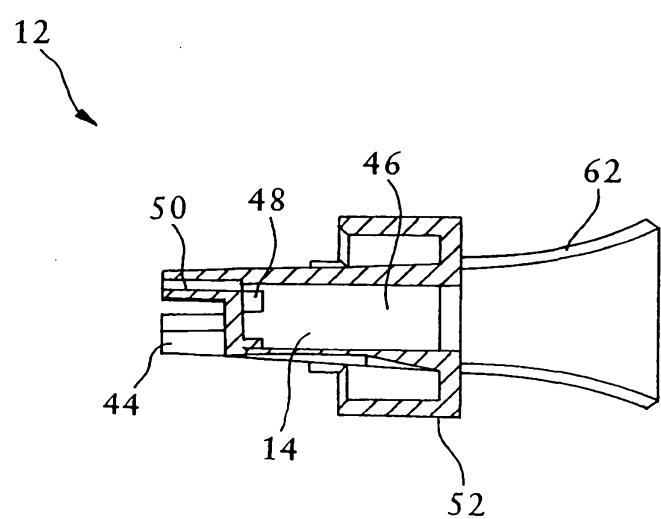


FIG. 10

11/16

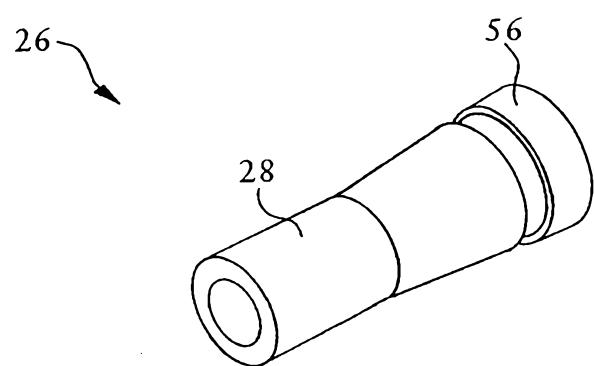


FIG. 11

12/16

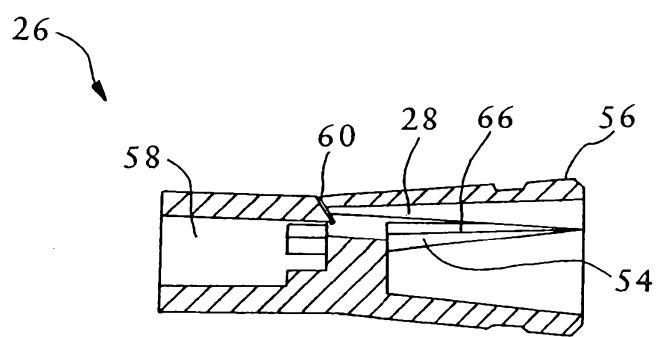


FIG. 12

13/16

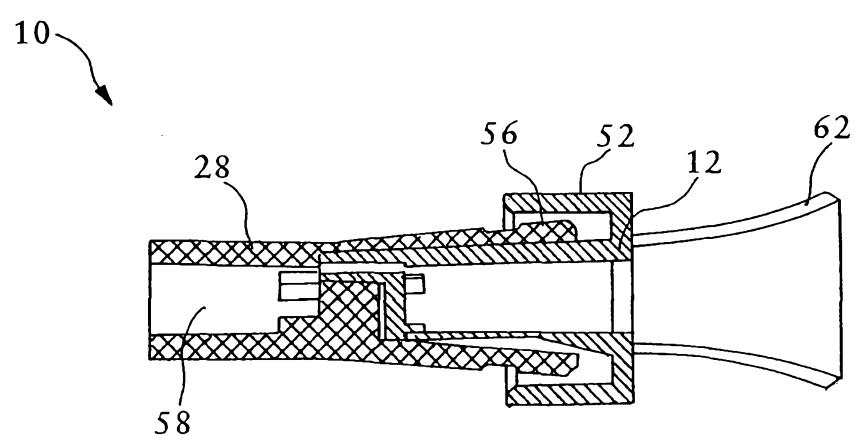


FIG. 13

14/16

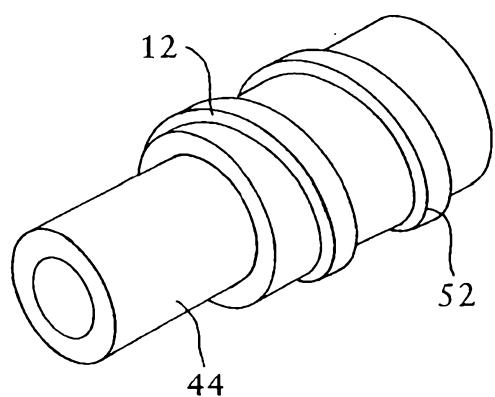


FIG. 14

15/16

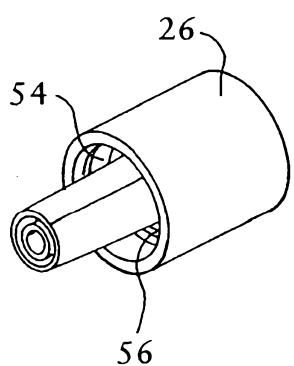


FIG. 15

16/16

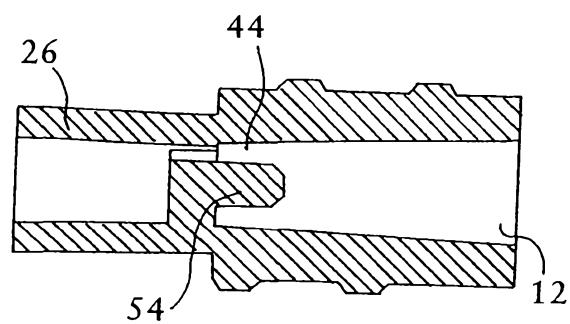


FIG. 16