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(12) **United States Patent**
Cote et al.

(10) **Patent No.: US 7,731,691 B2**
(45) **Date of Patent: Jun. 8, 2010**

(54) **SUBCUTANEOUS INFUSION DEVICE AND DEVICE FOR INSERTION OF A CANNULA OF AN INFUSION DEVICE AND METHOD**

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(73) Assignee: **Smiths Medical ASD, Inc.**, Rockland, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 630 days.

(21) Appl. No.: **10/705,719**

(22) Filed: **Nov. 10, 2003**

(65) **Prior Publication Data**

US 2005/0101932 A1 May 12, 2005

(51) **Int. Cl.**
A61M 5/178 (2006.01)

(52) **U.S. Cl.** **604/158**

(58) **Field of Classification Search** 604/506, 604/158, 136, 164.01, 131, 134, 500
See application file for complete search history.

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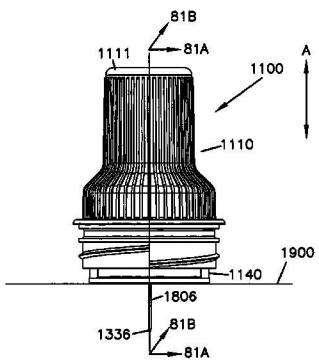
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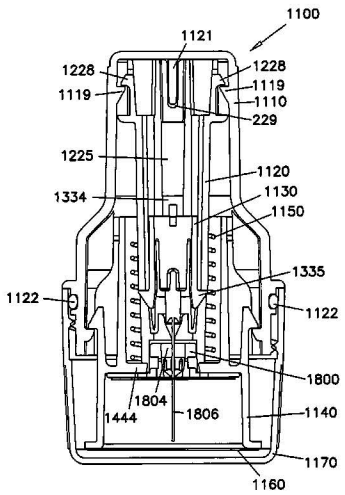
Primary Examiner—Nicholas D Lucchesi
Assistant Examiner—Christopher D Koharski
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(57) **ABSTRACT**

An infusion device including a site and a set for delivery of a substance to a patient. The site can include a cannula that is introduced into a subcutaneous layer of skin of the patient. The set can be coupled to the site by placing the set over the site and moving the set from an unlocked to a locked position. The set can be oriented at multiple rotational orientations with respect to the site, and can be coupled and uncoupled with the site multiple times. Also included is a device for inserting a subcutaneous infusion device into a subcutaneous layer of skin of a patient. Some devices automatically retract a needle used to introduce the cannula. Upon full introduction of the needle and associated cannula of the subcutaneous infusion device into a subcutaneous layer of skin of a patient, the device can move the needle into a retracted state.

8 Claims, 36 Drawing Sheets





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FIG.1

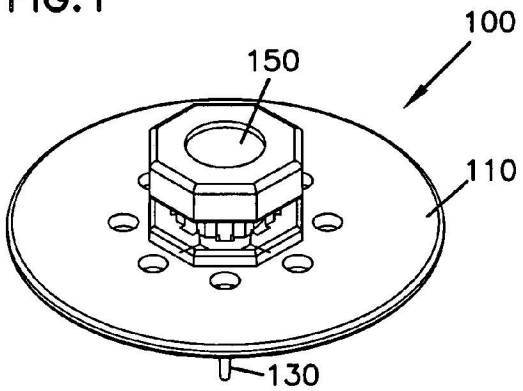


FIG.2

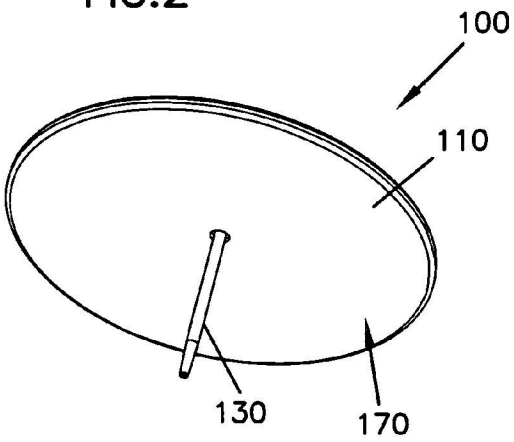


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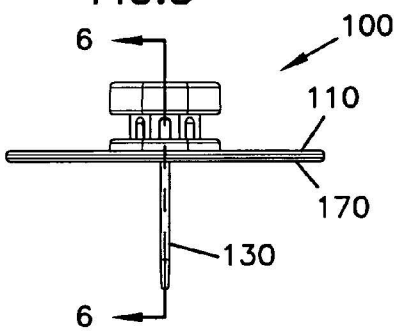


FIG.4

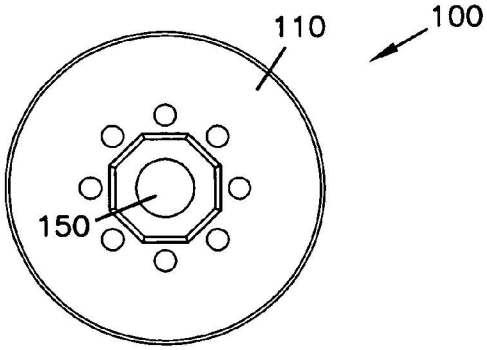
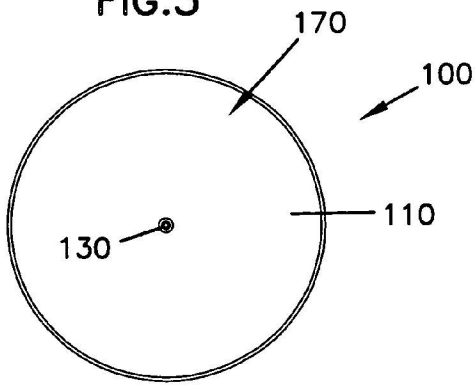


FIG.5



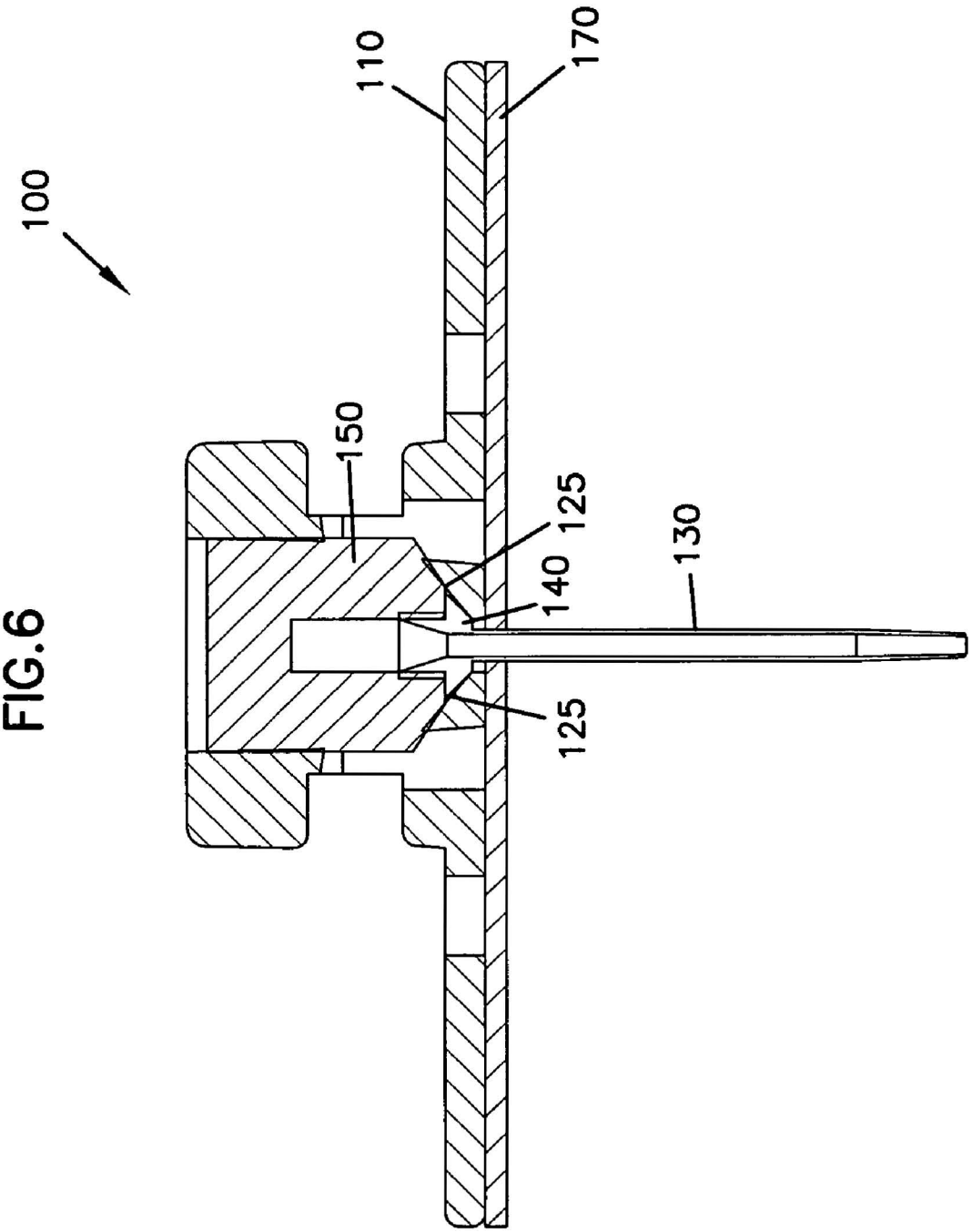


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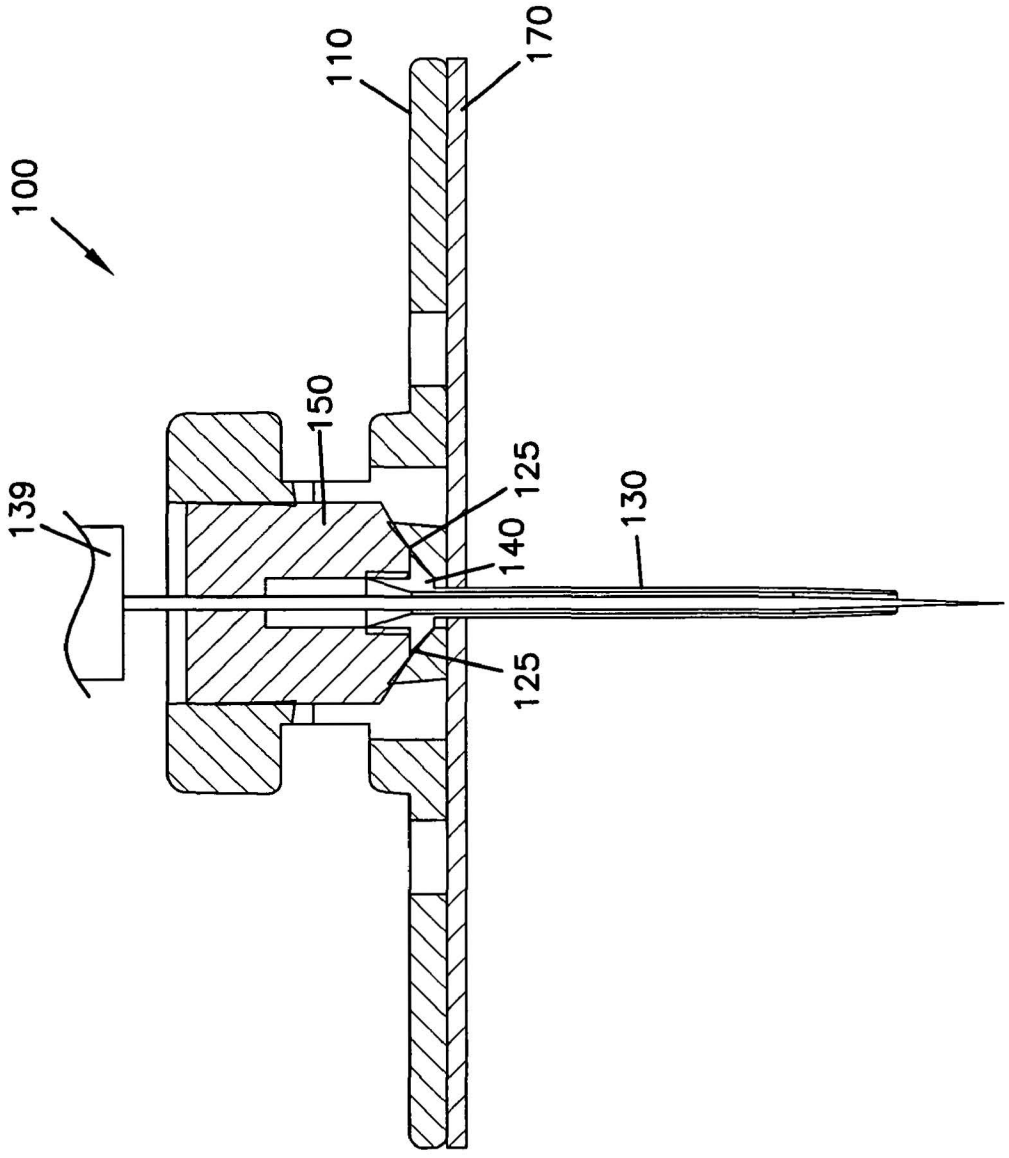


FIG.6A

FIG.7

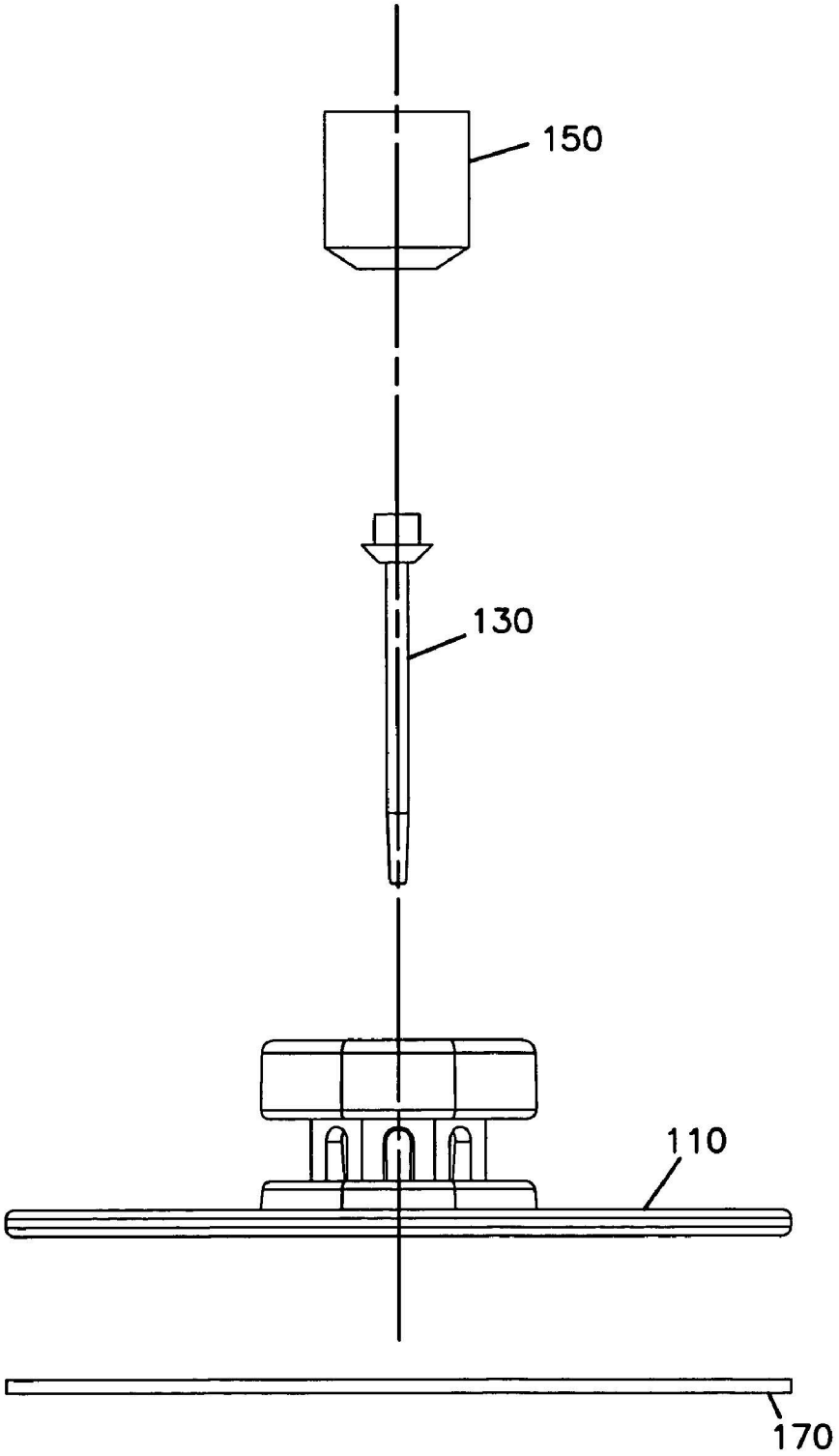


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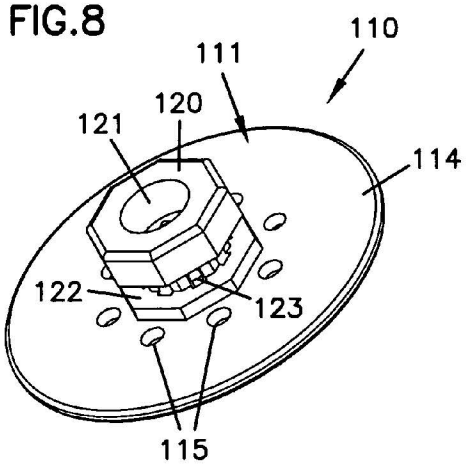


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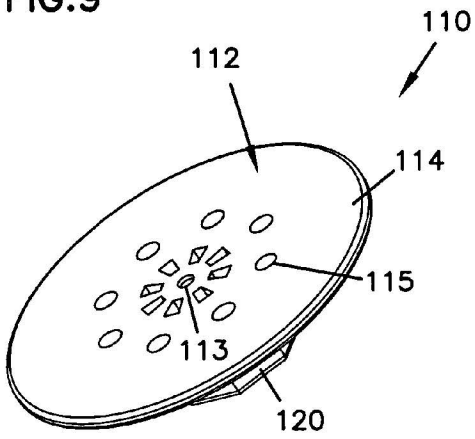


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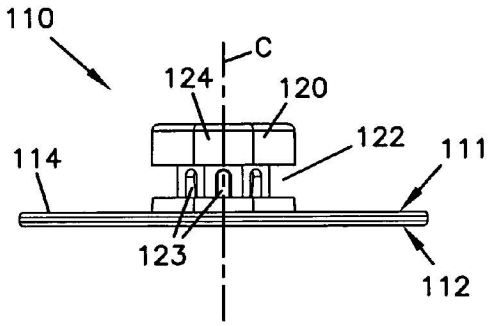


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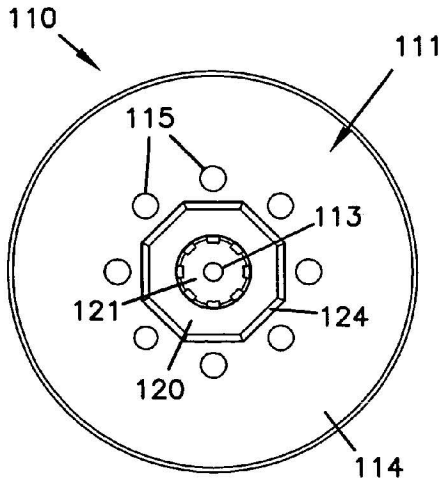


FIG. 12

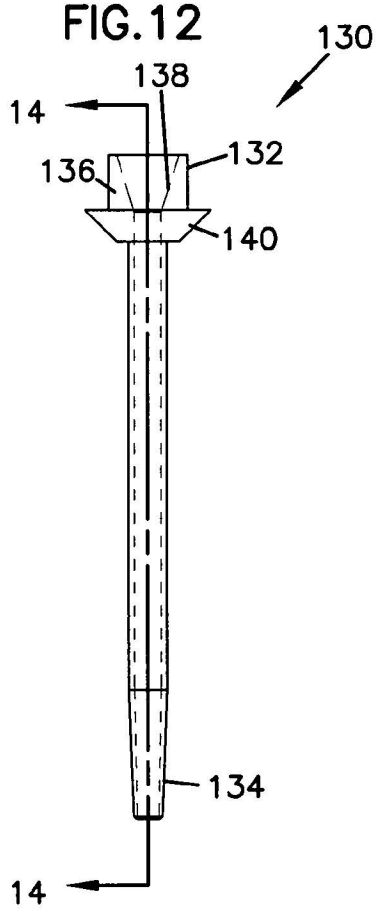


FIG. 13

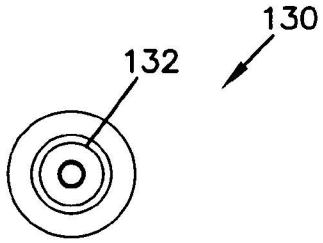


FIG. 14

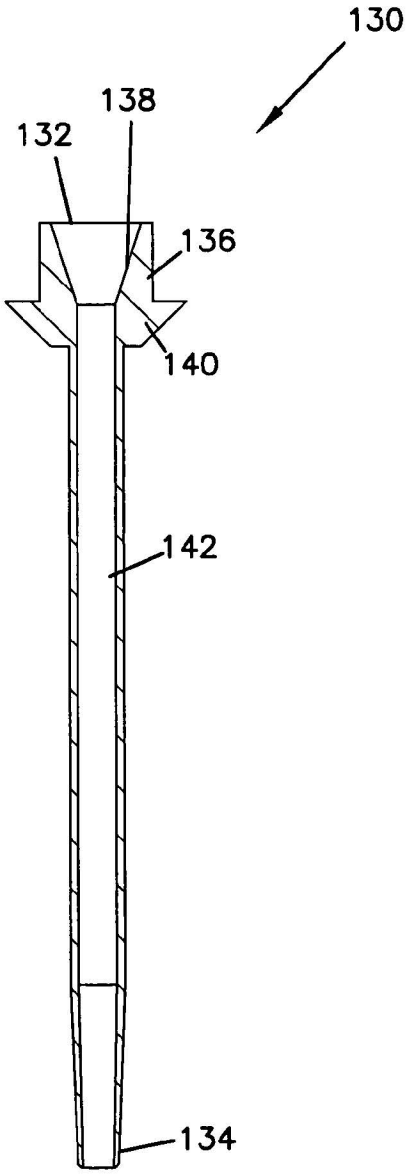


FIG.15

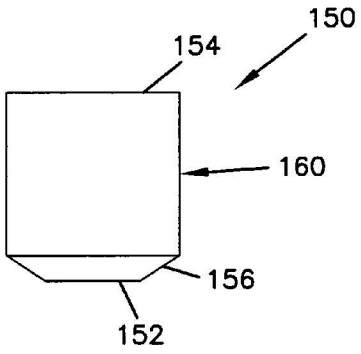


FIG.16

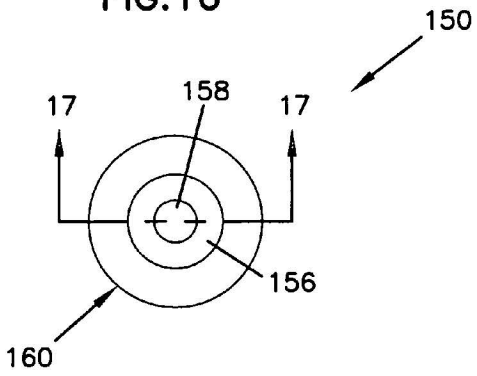


FIG.17

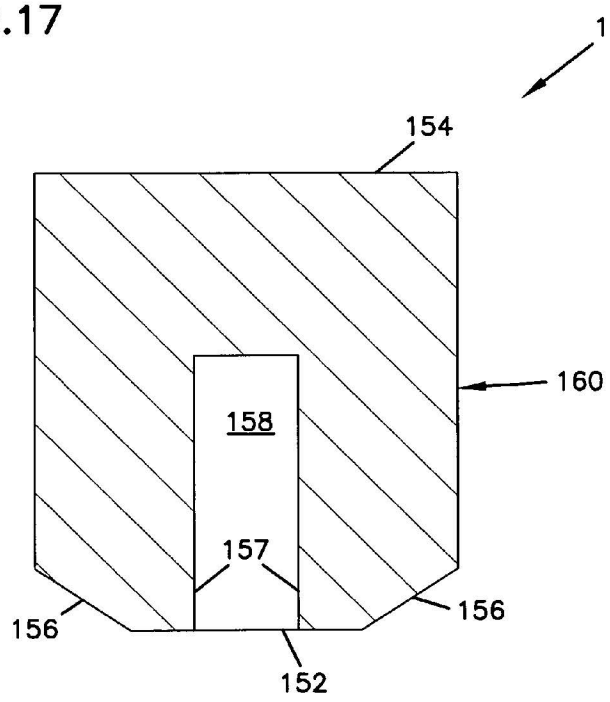


FIG.18

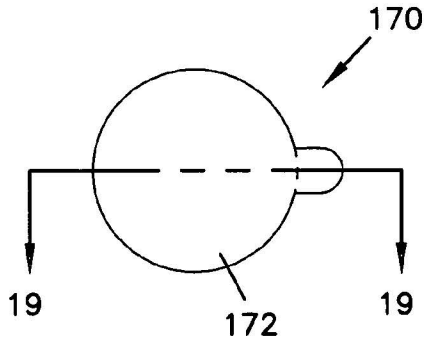


FIG.19

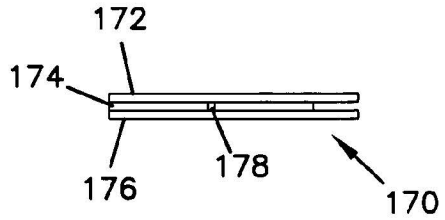


FIG.20

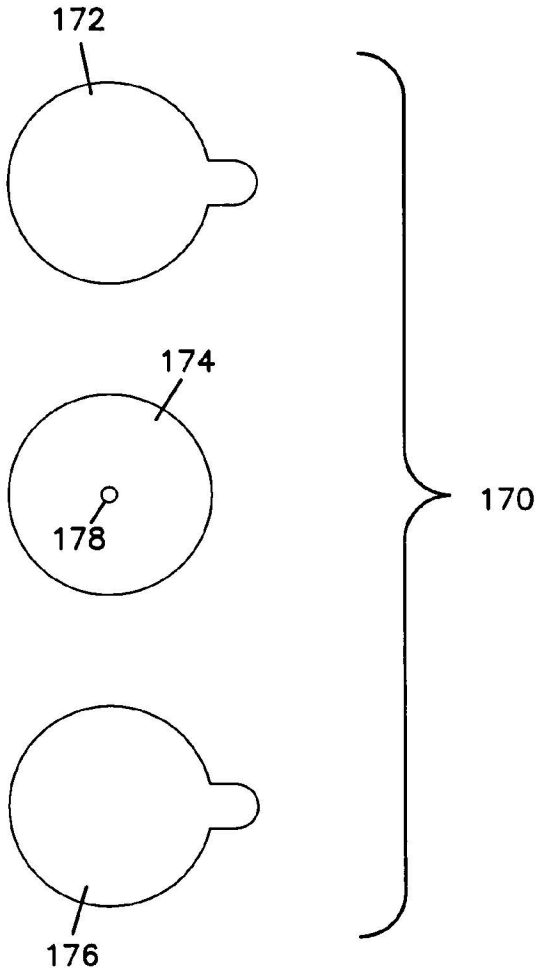


FIG.21

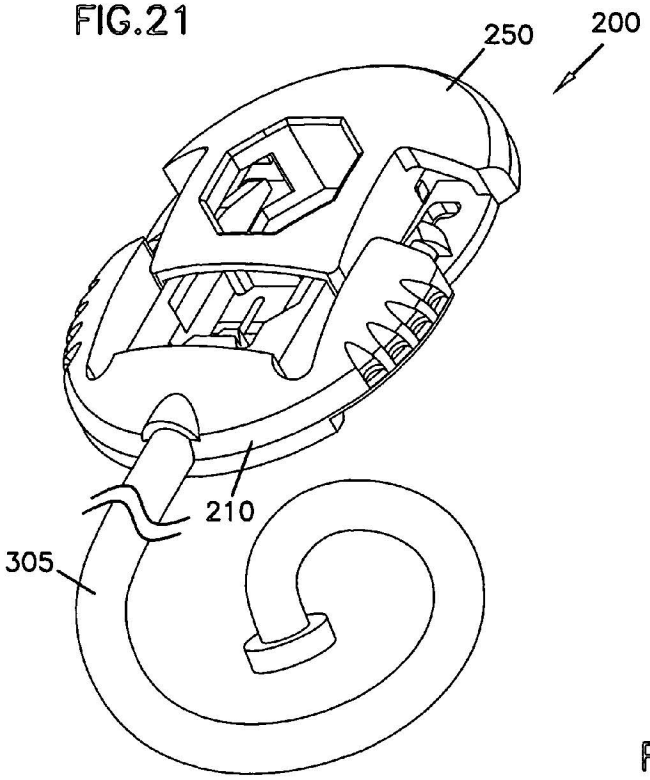


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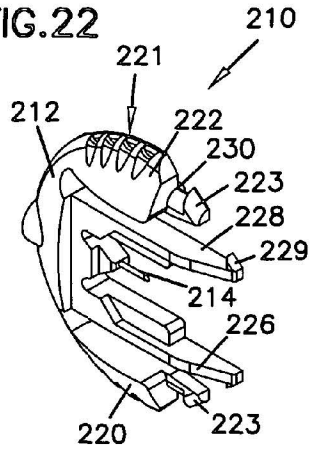


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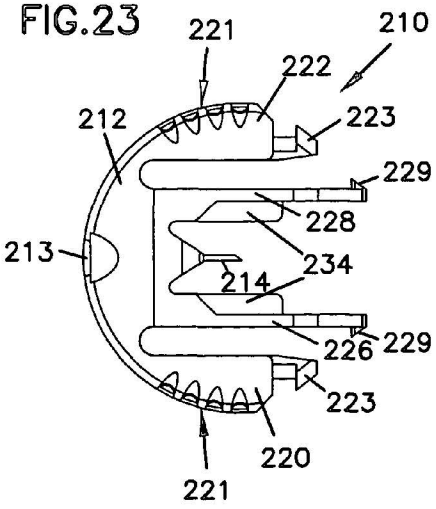


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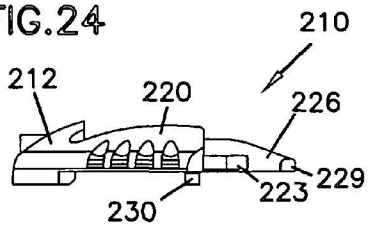


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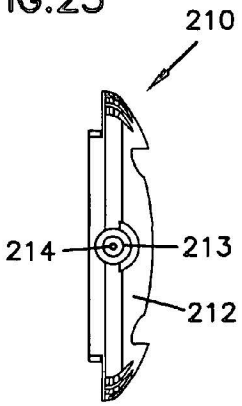
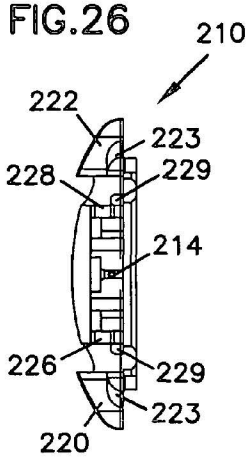


FIG.26



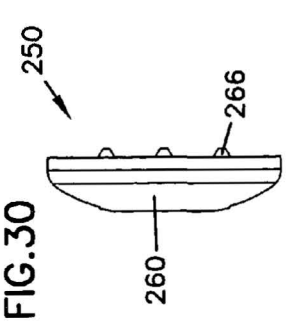


FIG.30

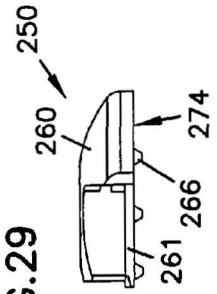


FIG.29

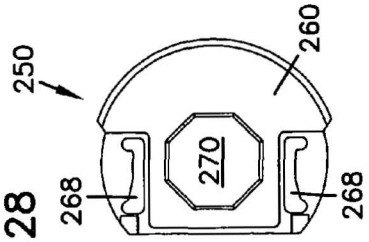


FIG.28

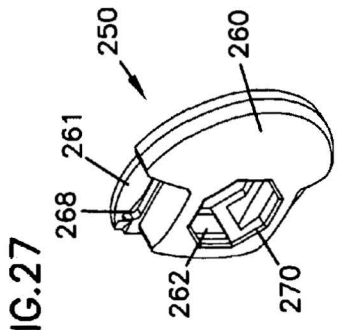


FIG.27

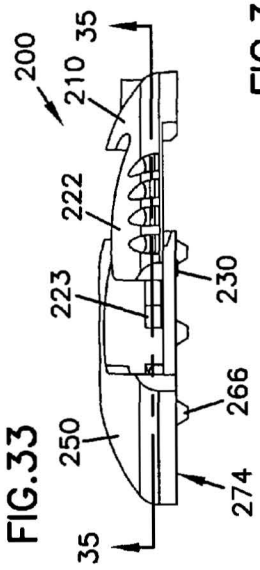


FIG.33

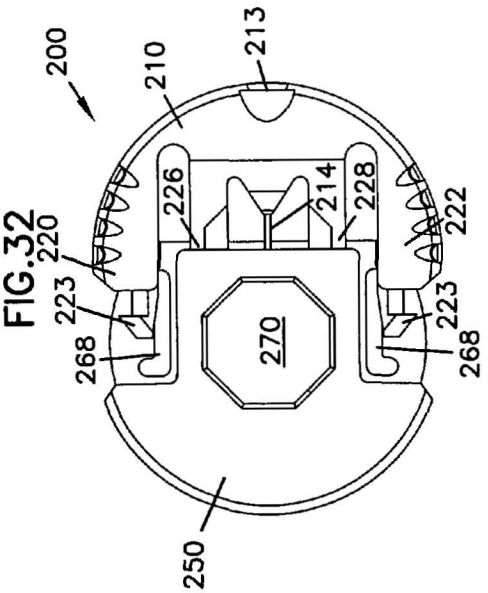


FIG.32

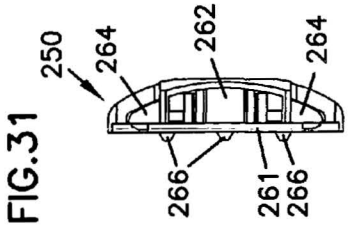


FIG.31

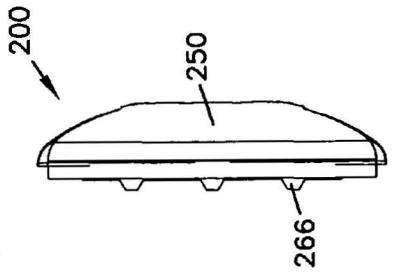


FIG.34

FIG.35

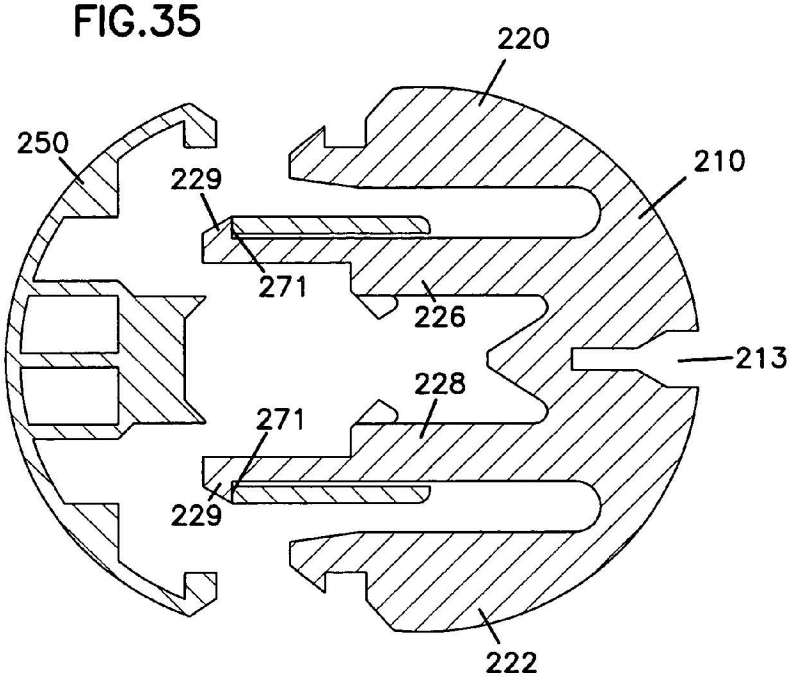


FIG.36

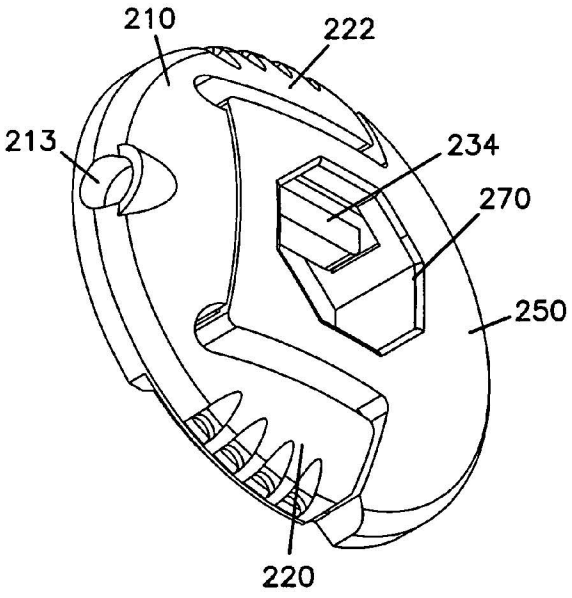


FIG.37

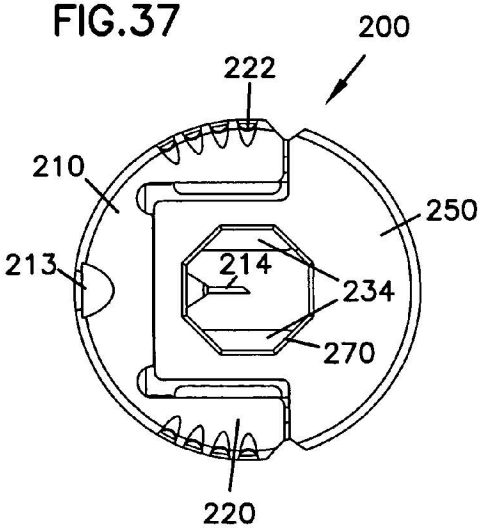


FIG.38

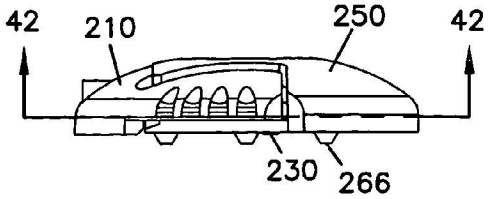


FIG.39

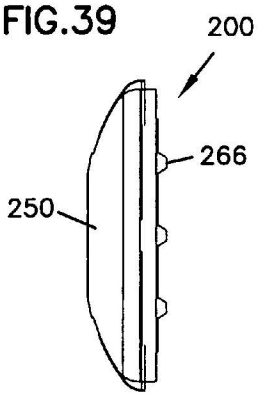


FIG.40

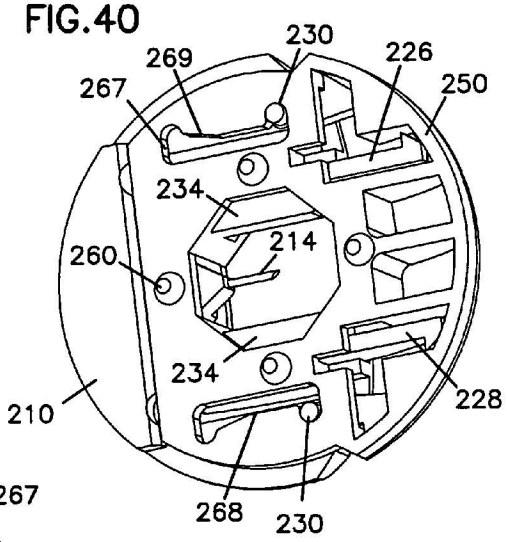


FIG.41

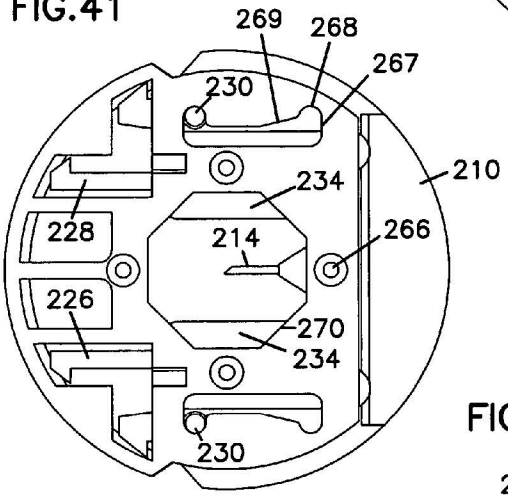


FIG.42

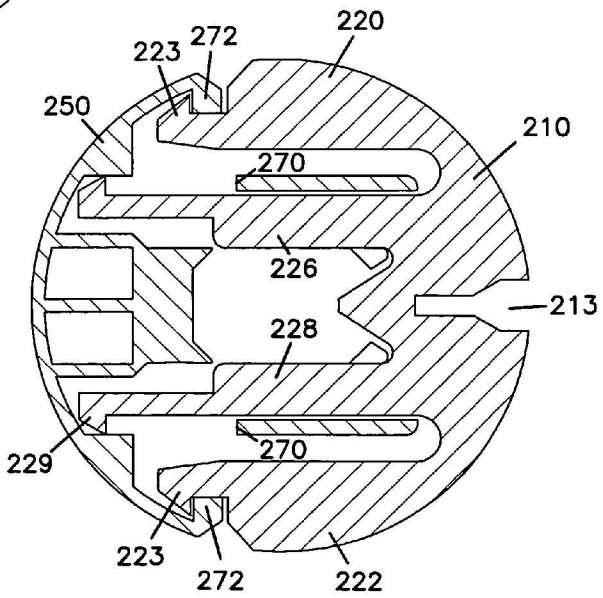


FIG.43

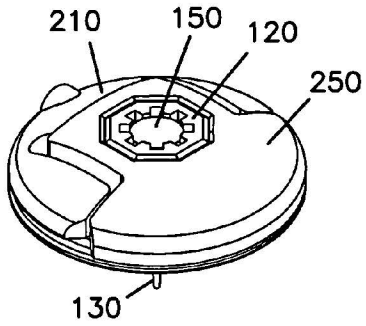


FIG.44

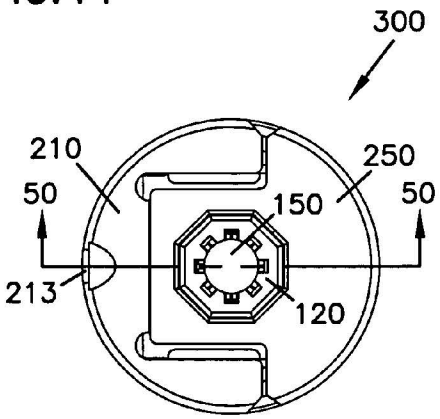


FIG.45

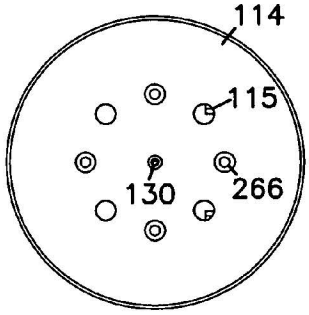


FIG.46

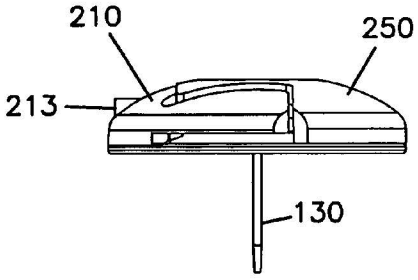


FIG.47

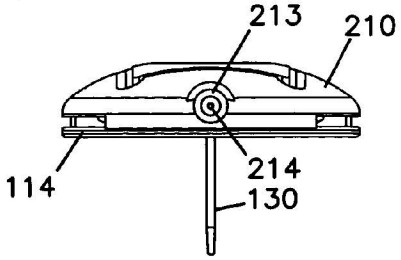


FIG.48

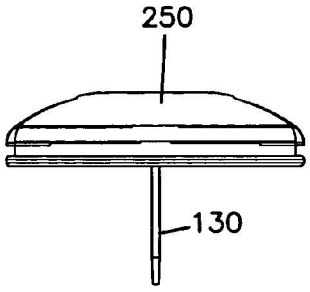


FIG.49

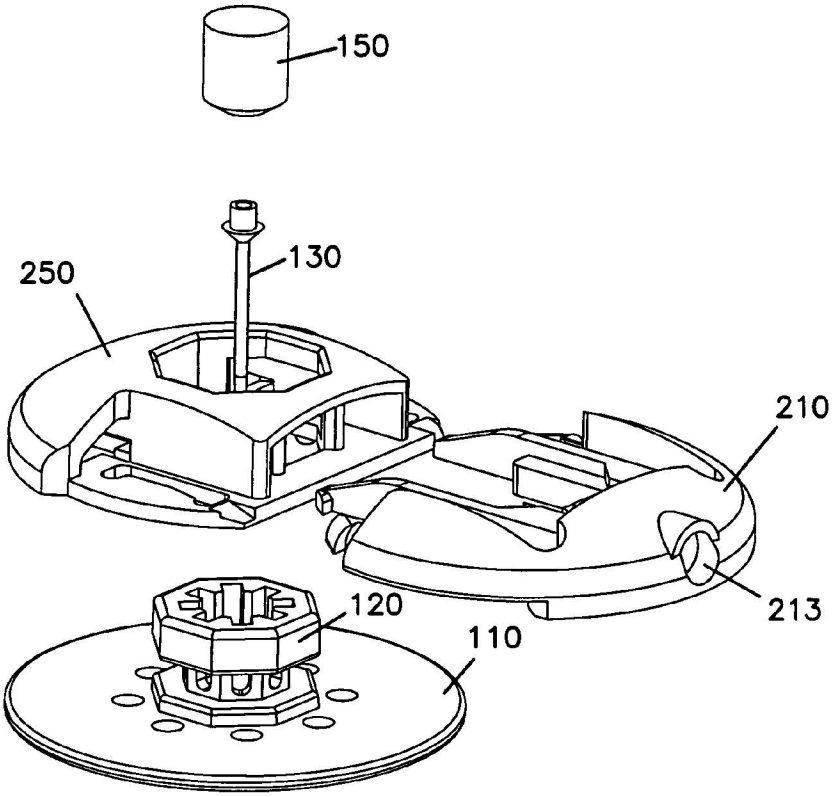
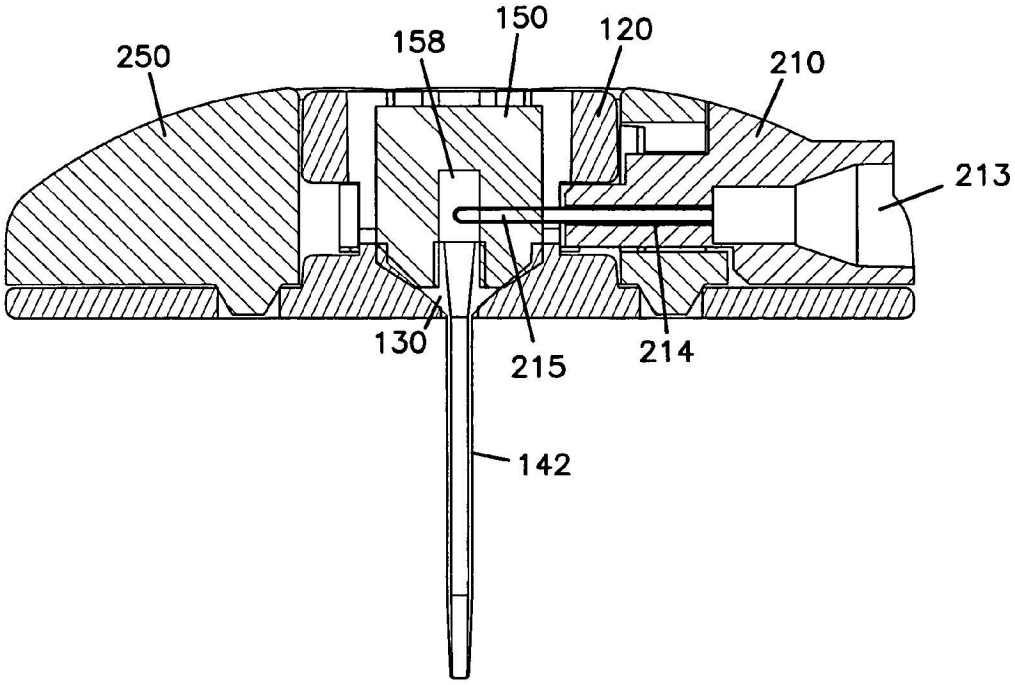

150
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FIG.50


250
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214
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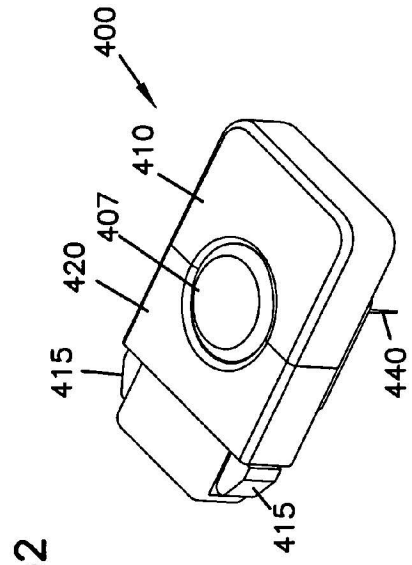


FIG.52

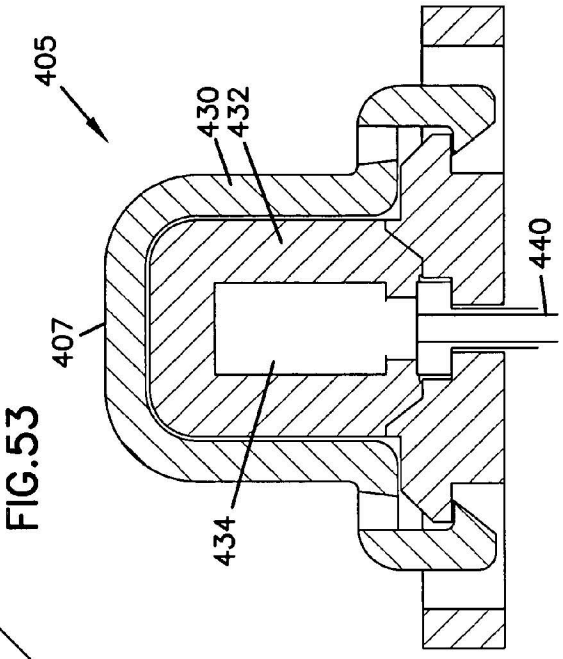


FIG.53

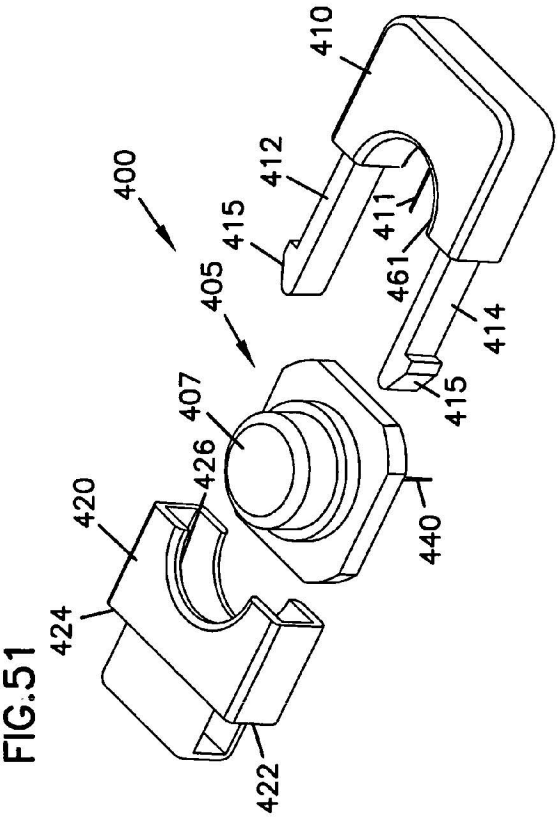


FIG.51

FIG.54

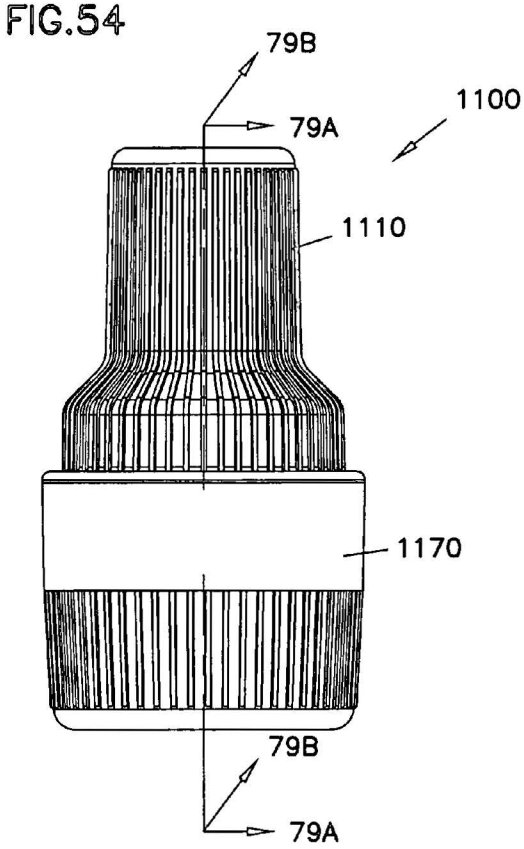
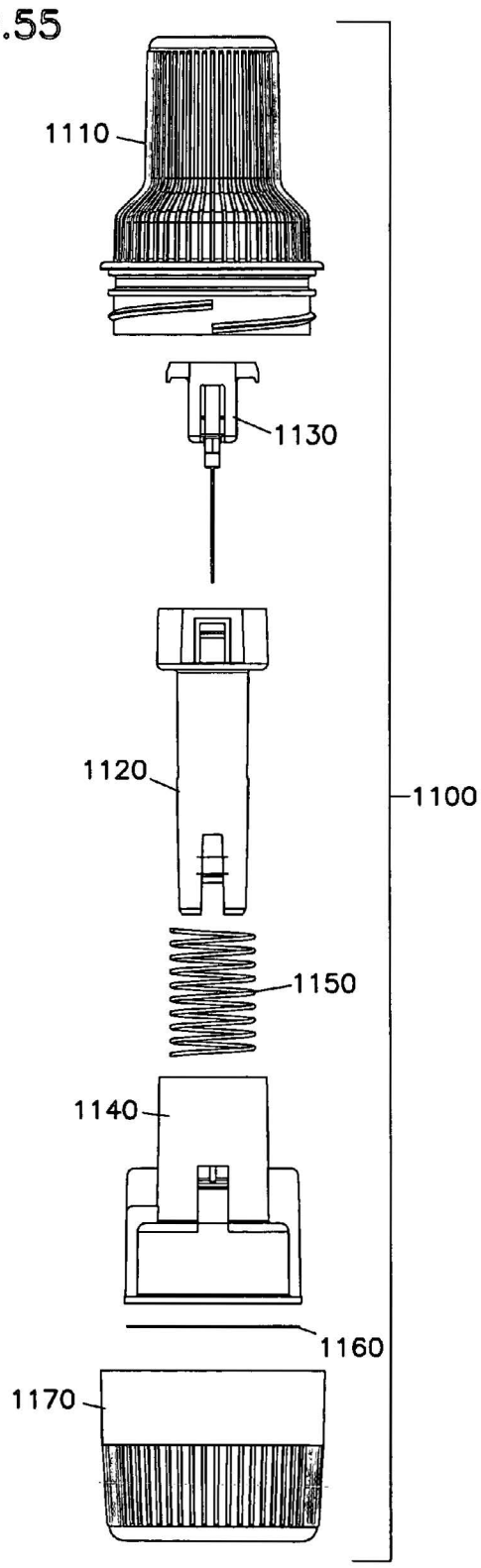
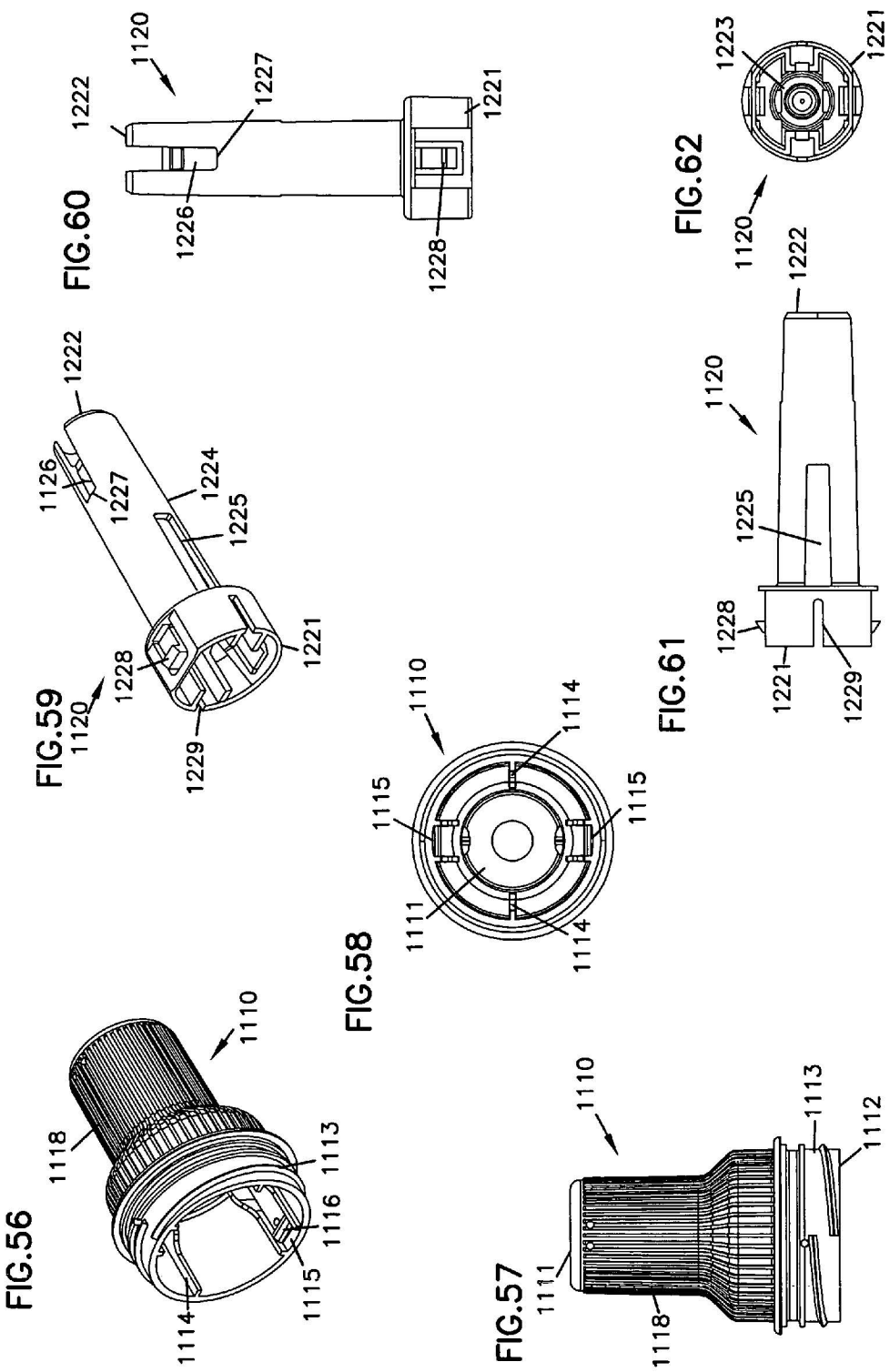

79B
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1100
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79B
79A

FIG.55


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FIG.56
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FIG.57
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FIG.58
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FIG.59
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FIG.60
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FIG.61
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FIG.62
1223
1221
1120

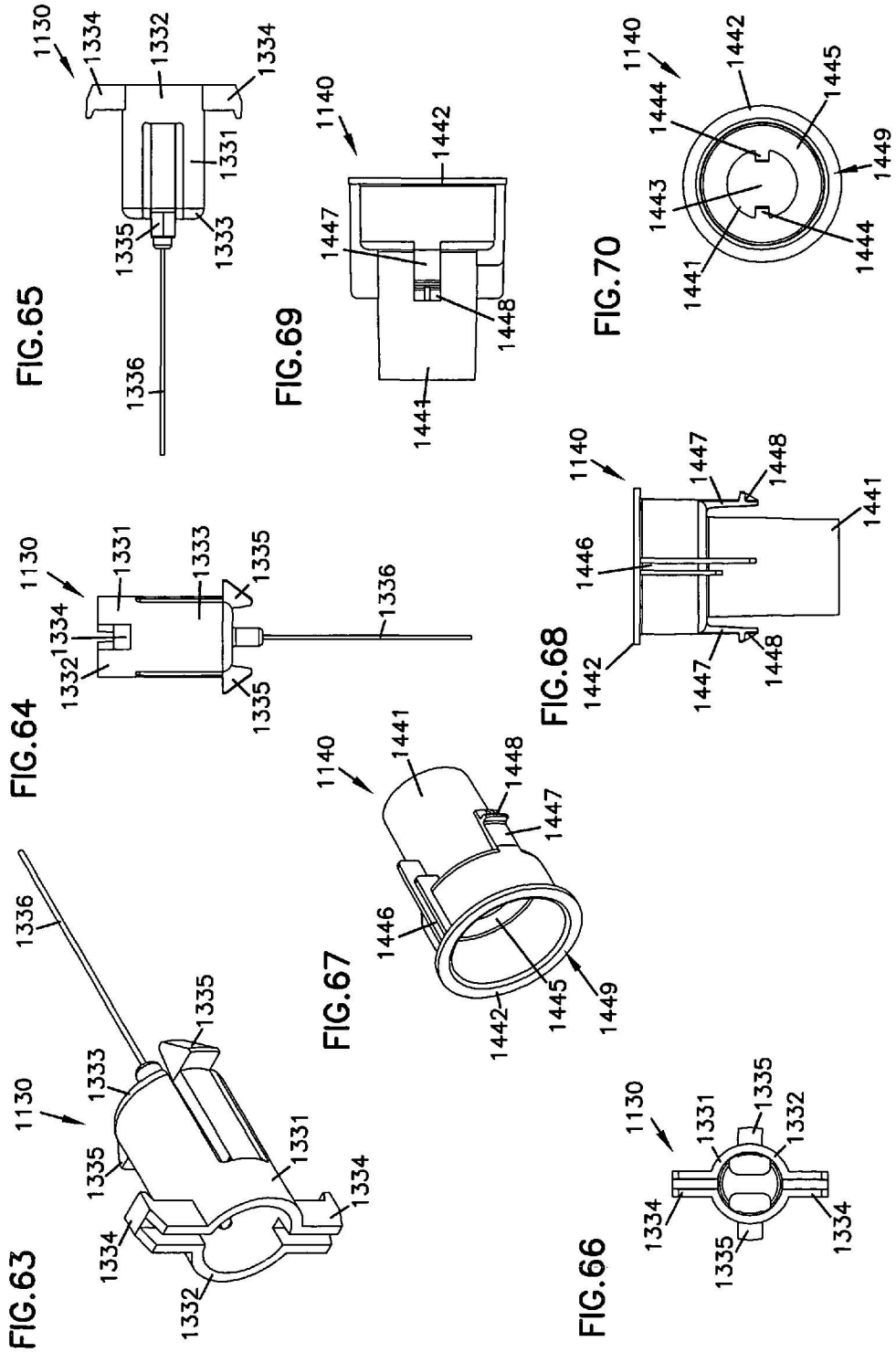

1130
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FIG.65
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FIG.69
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FIG.70
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FIG.64
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FIG.68
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FIG.67
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FIG.63
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1334
1335
1334
FIG.66

FIG.71

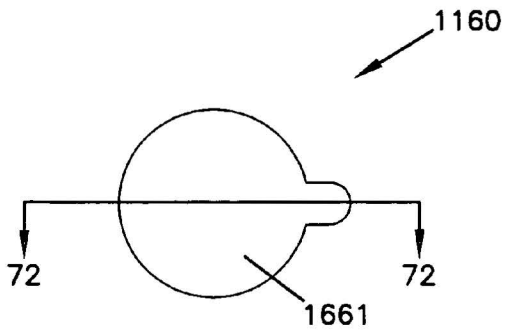


FIG.72

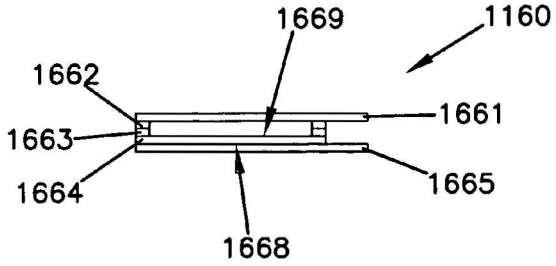


FIG.73

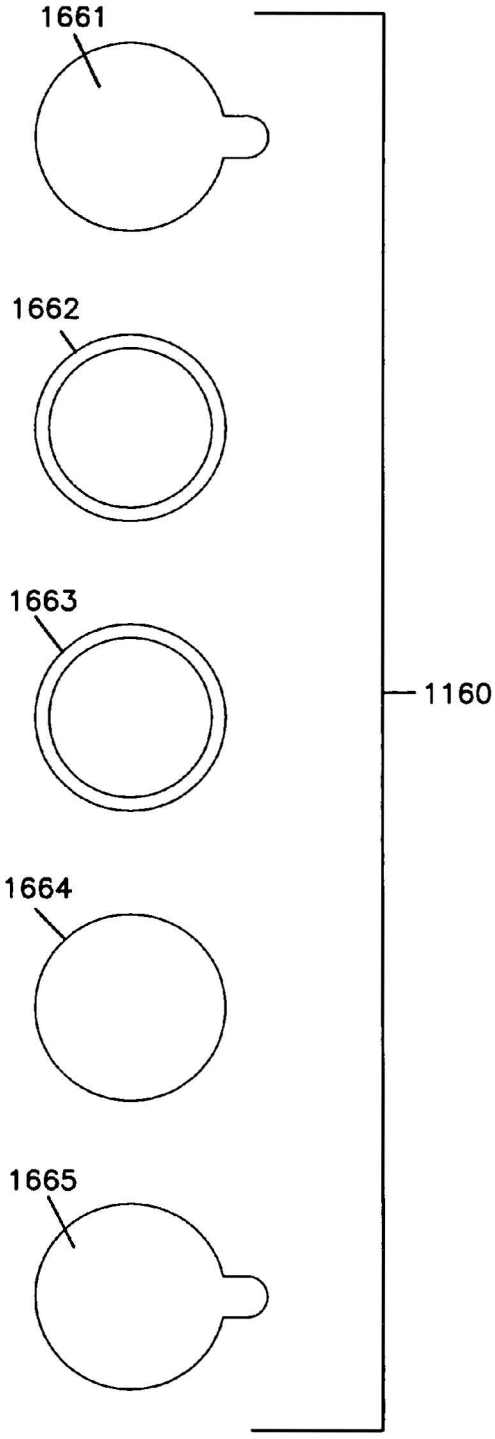


FIG.74

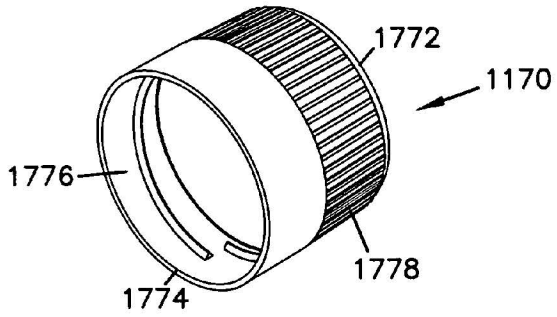


FIG.75

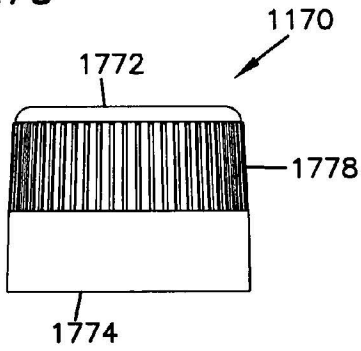


FIG.76

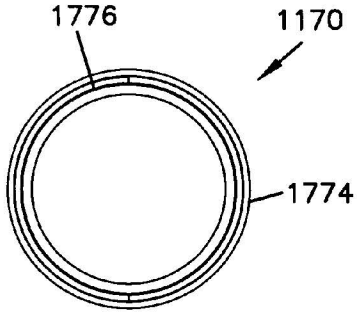


FIG.77

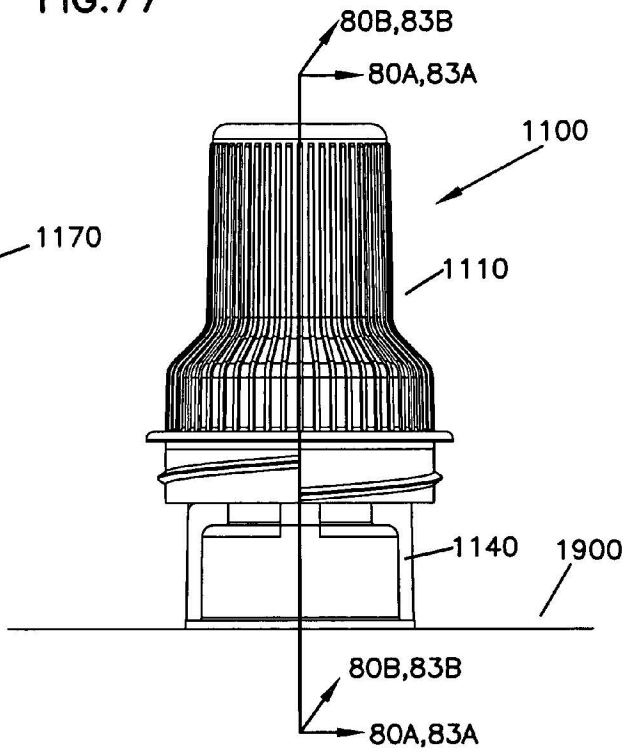
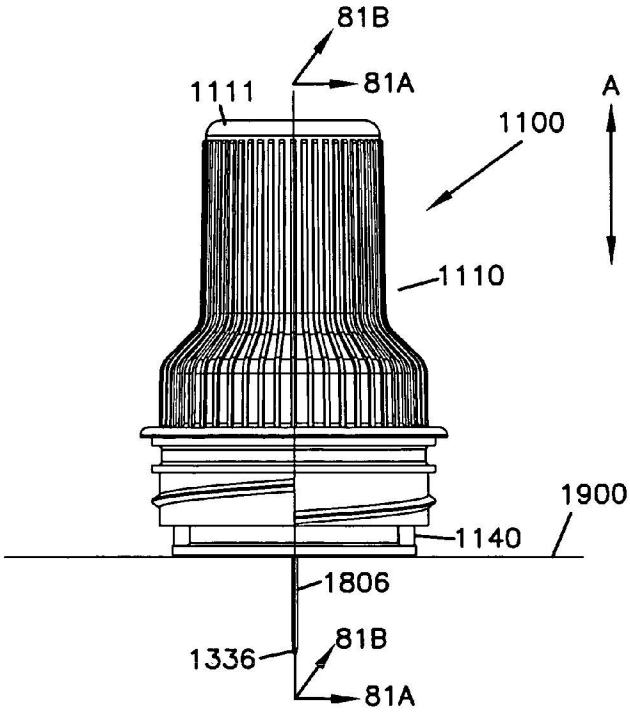


FIG.78



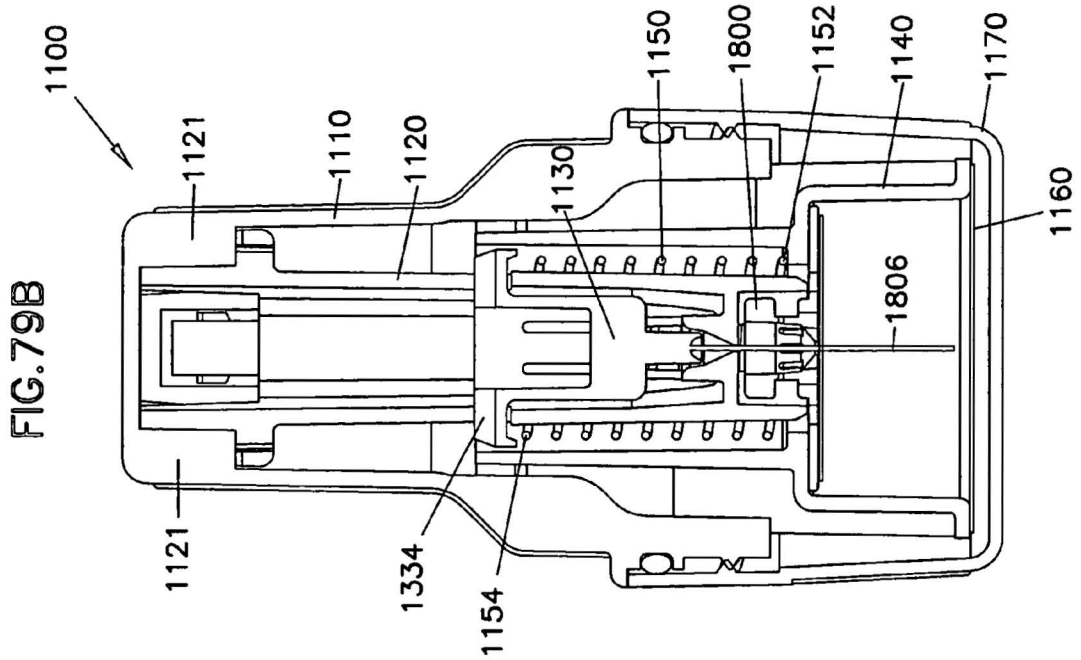


FIG.79B

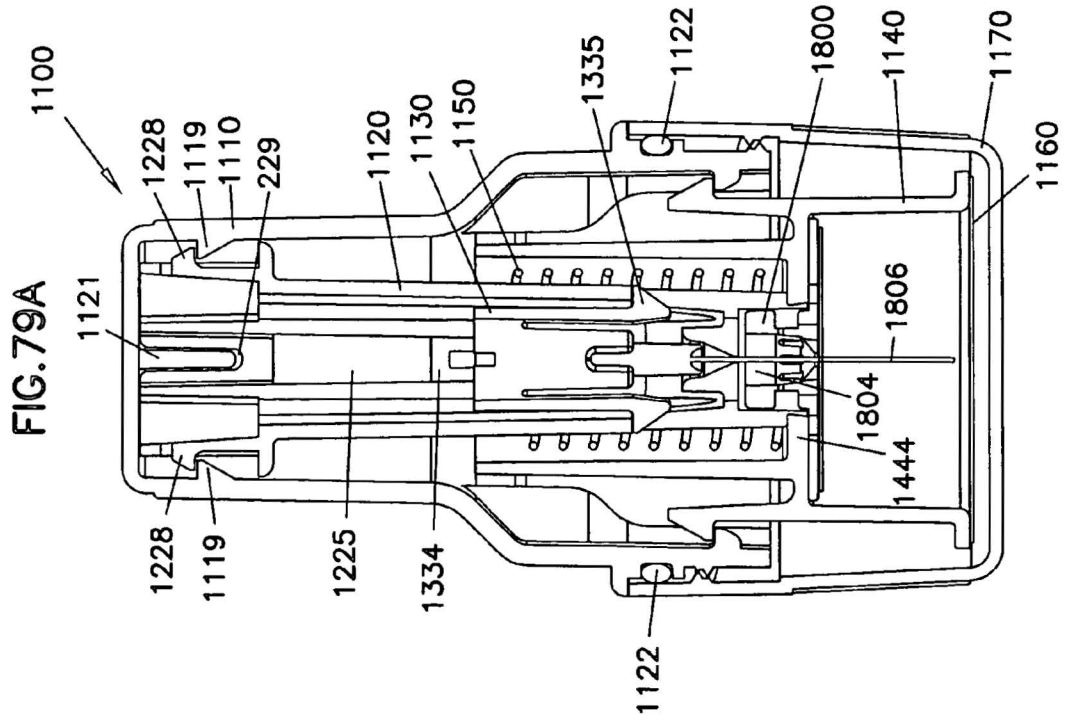


FIG.79A

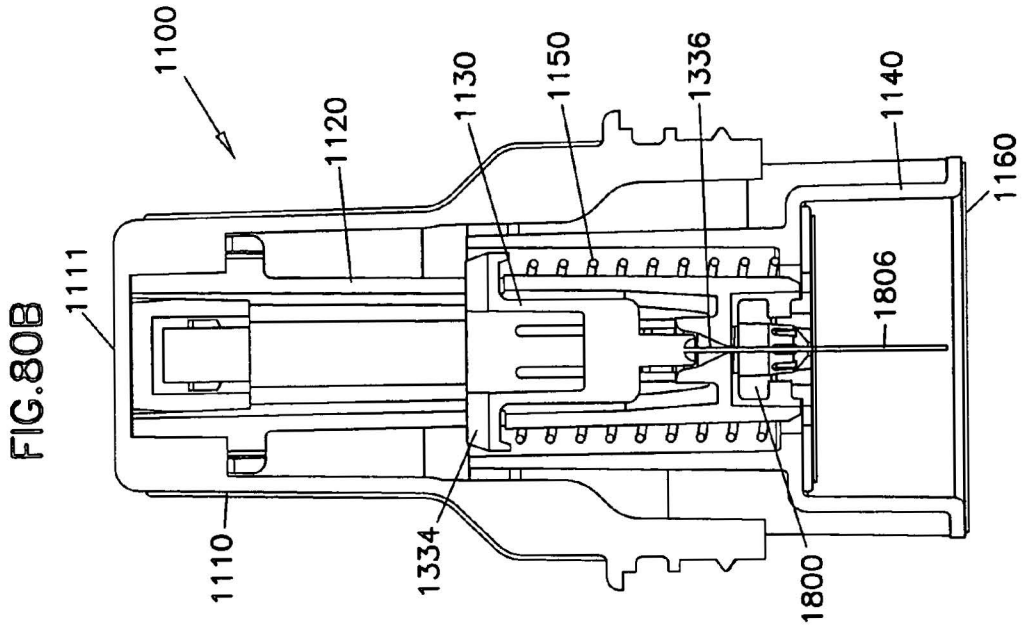


FIG.80B

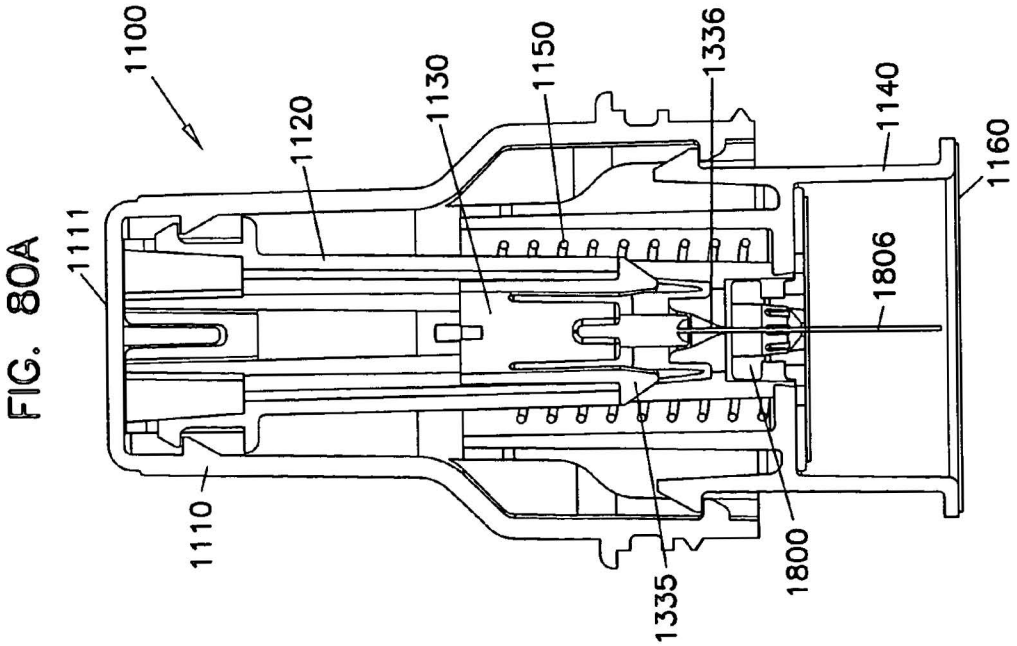


FIG. 80A

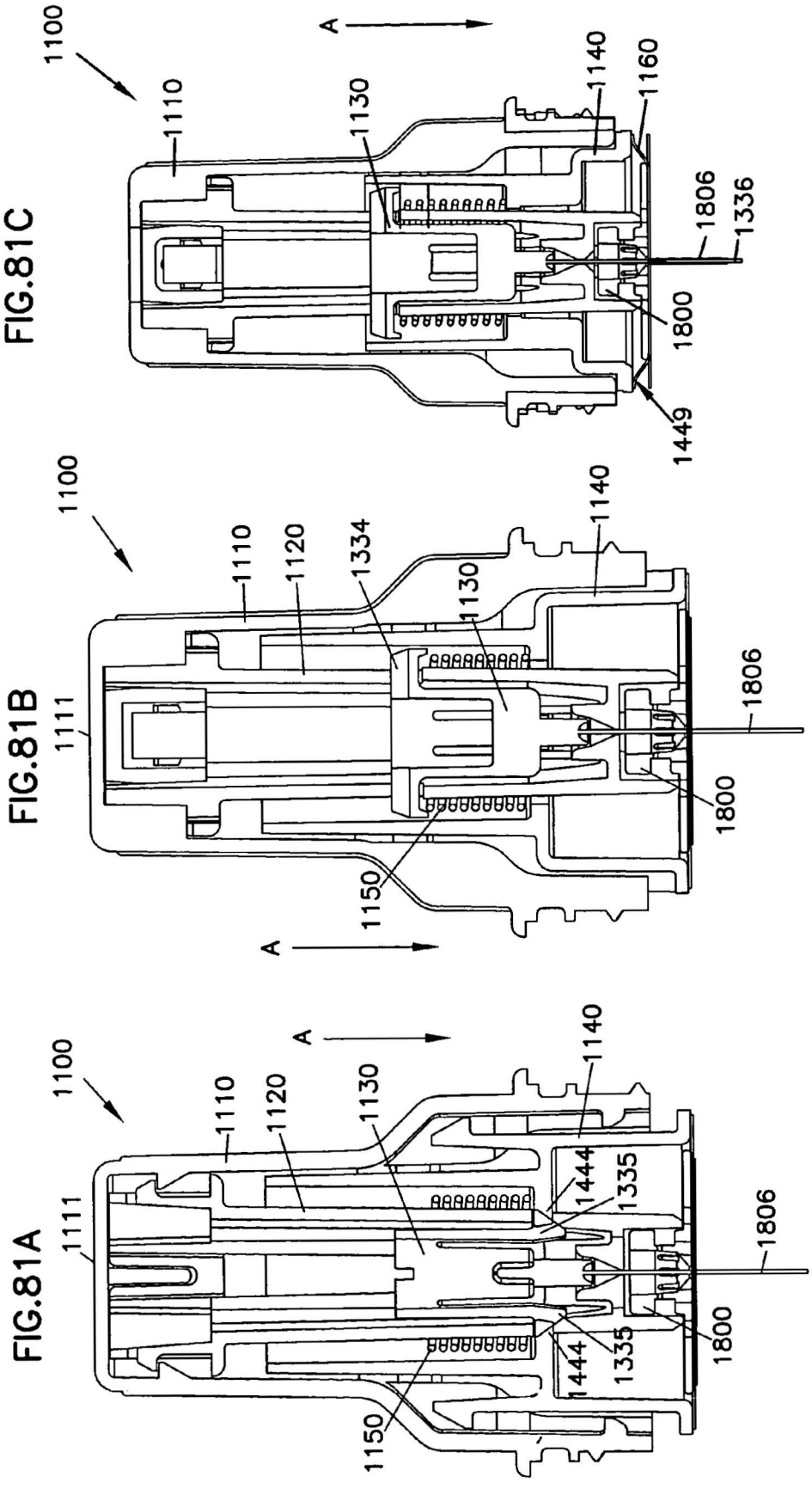

FIG.81A
1100
1110
1120
1130
1140
1111
1444
1335
1806
1800
1150
A
FIG.81B
1100
1110
1120
1334
1130
1140
1111
1806
1800
1150
A
FIG.81C
1100
1110
1130
1140
1160
1806
1336
1800
1449
A

FIG.82B

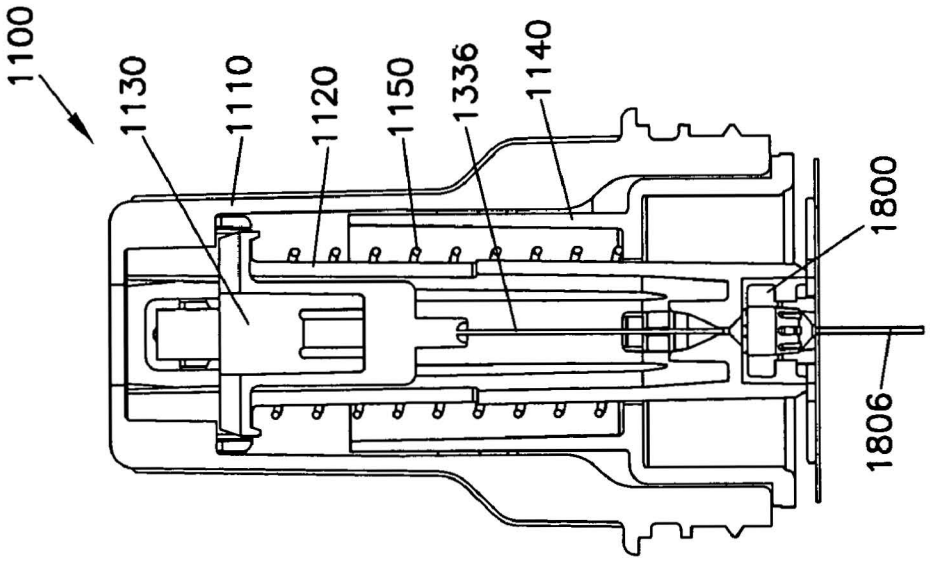


FIG.82A

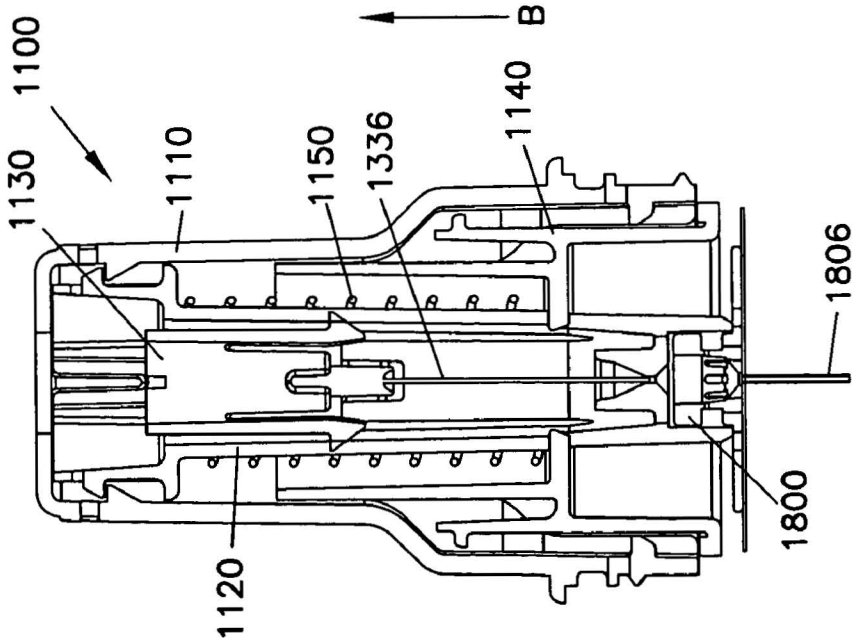


FIG.84

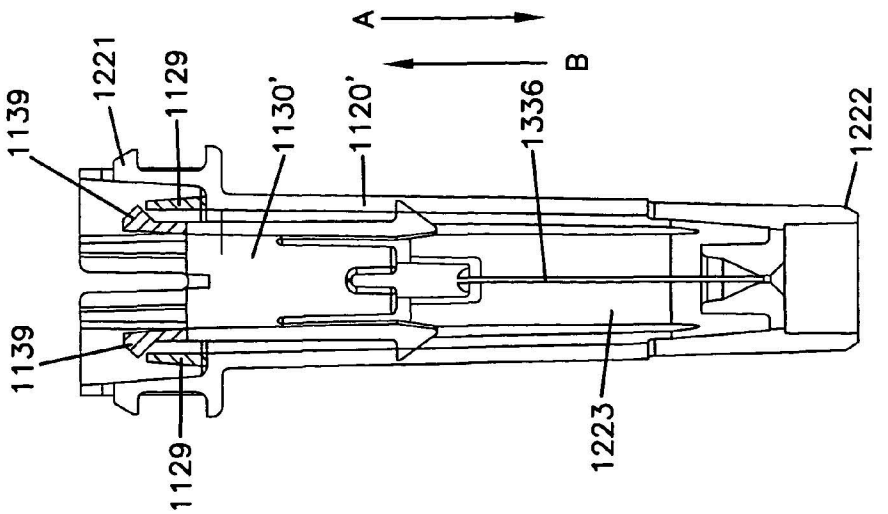


FIG.83B

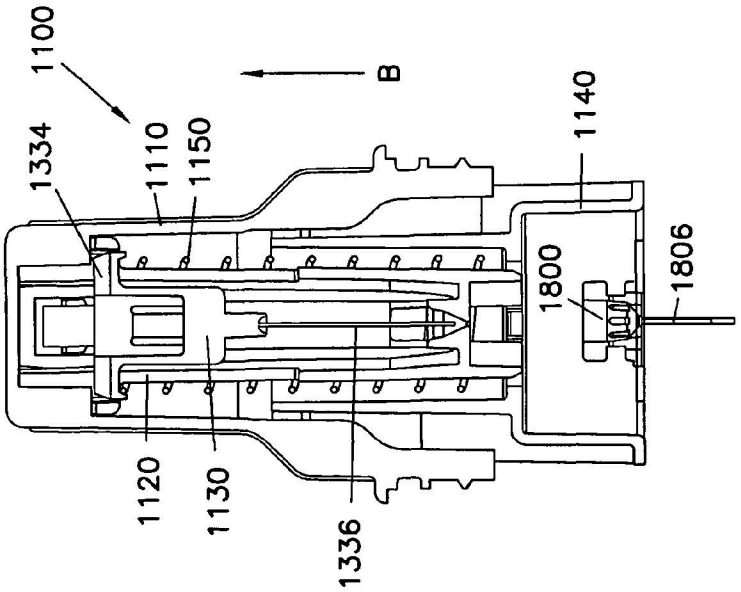
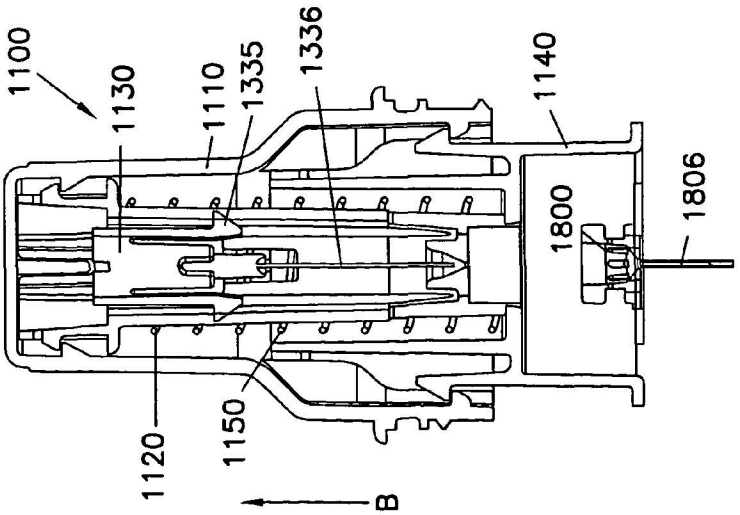


FIG.83A



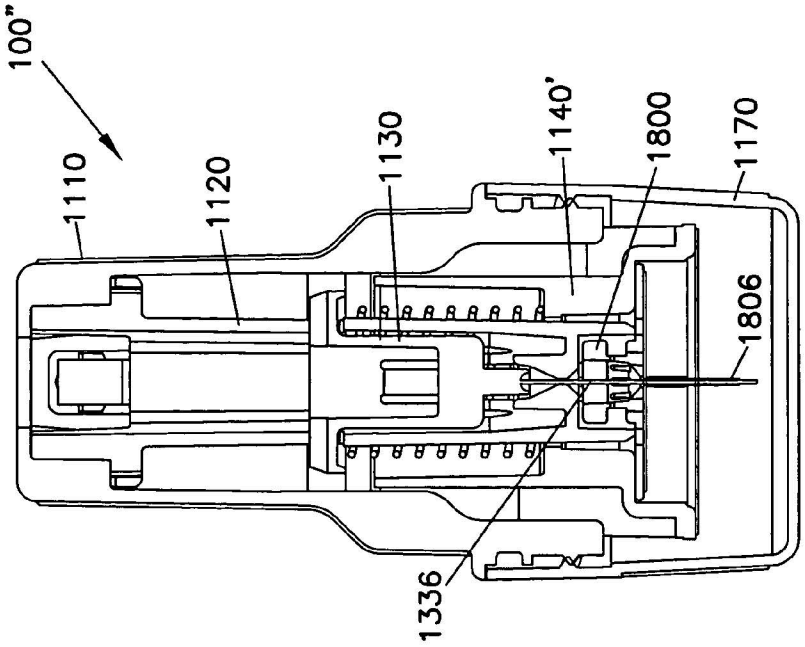


FIG.85B

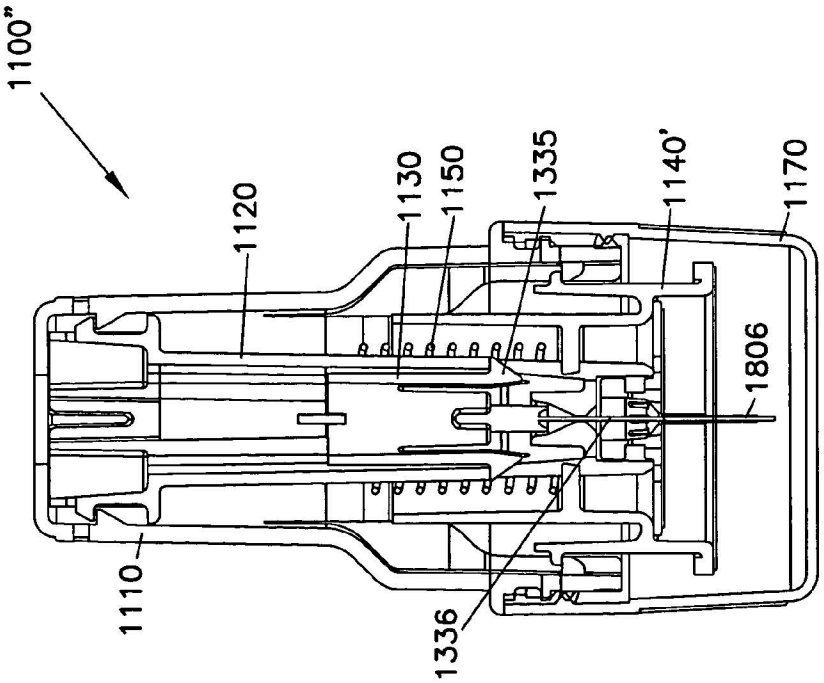


FIG.85A

FIG.86B

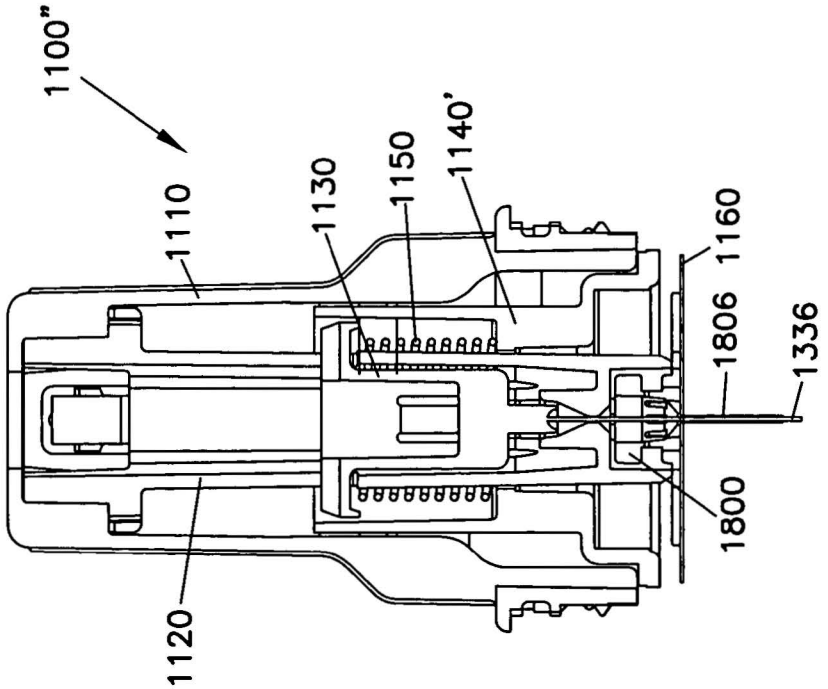


FIG.86A

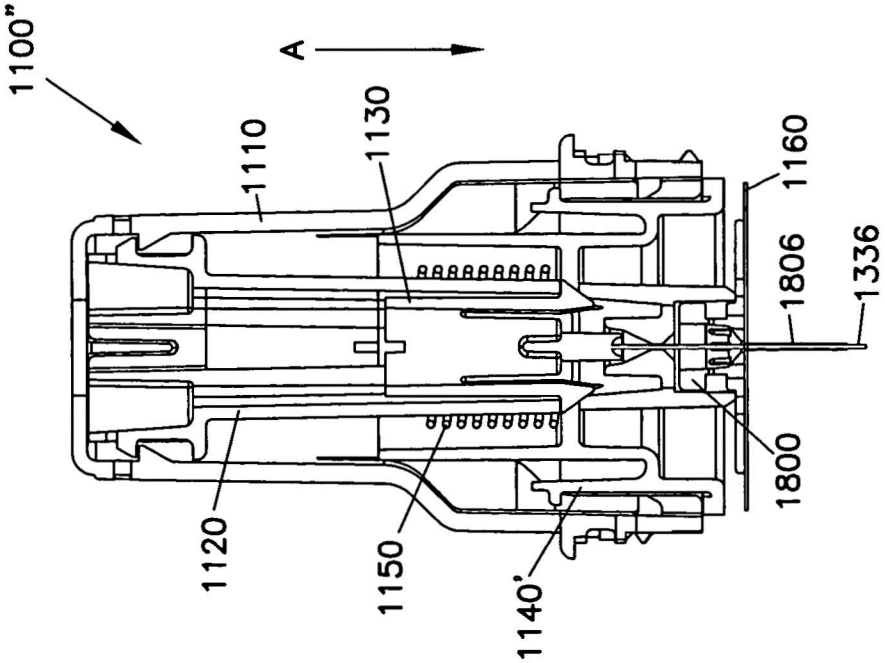


FIG.87B

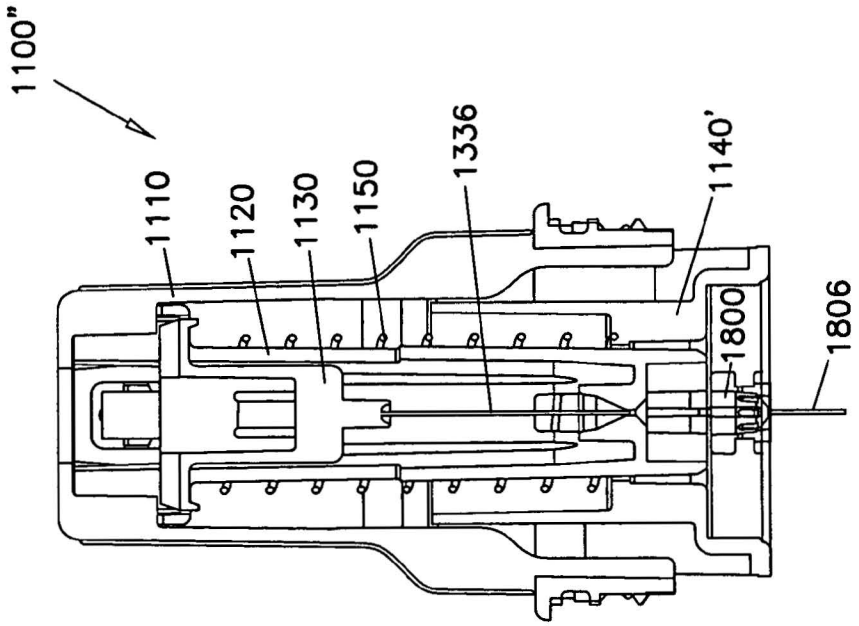
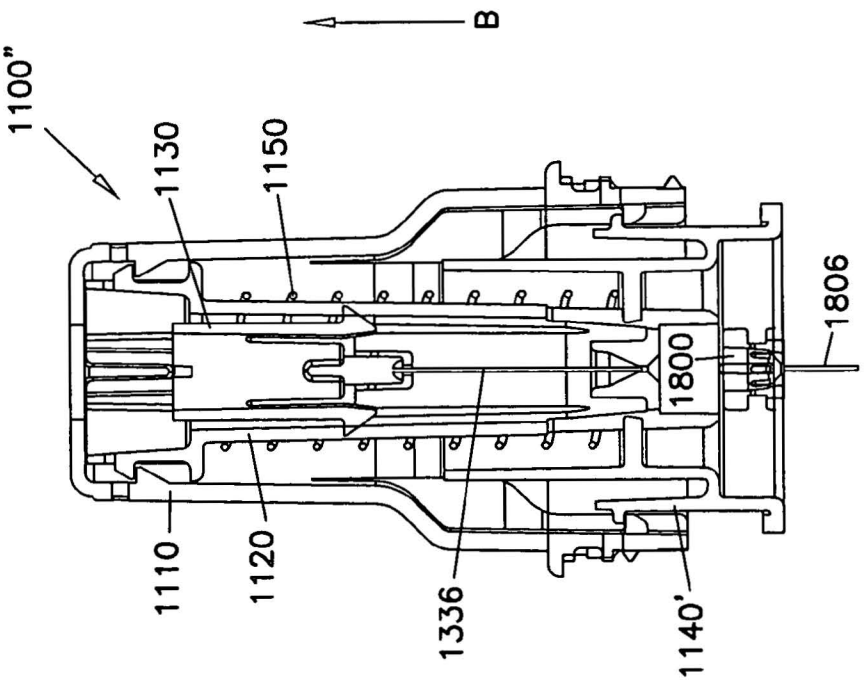


FIG.87A



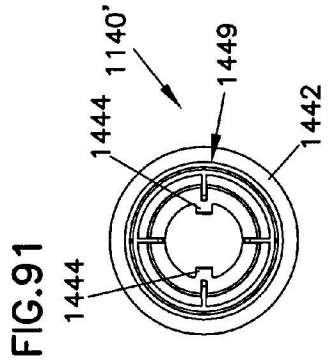


FIG.91

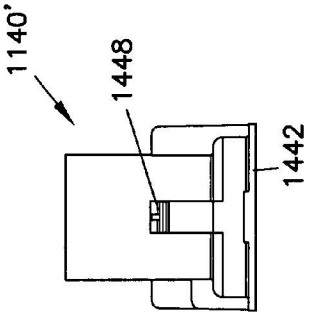


FIG.90

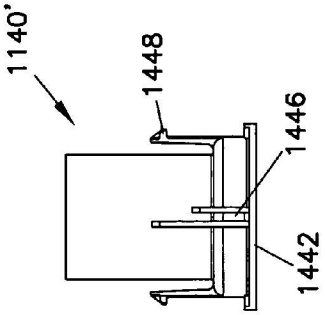


FIG.89

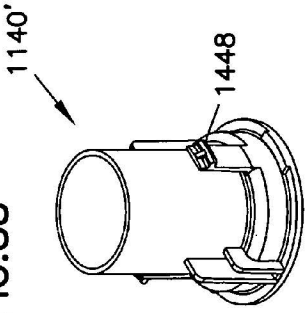


FIG.88

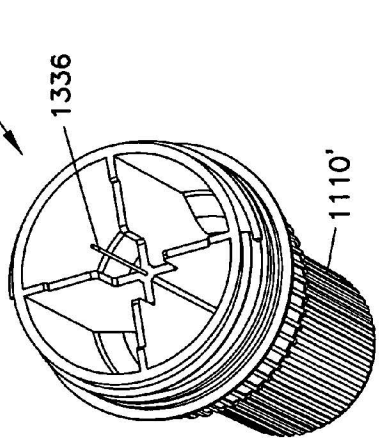


FIG.93

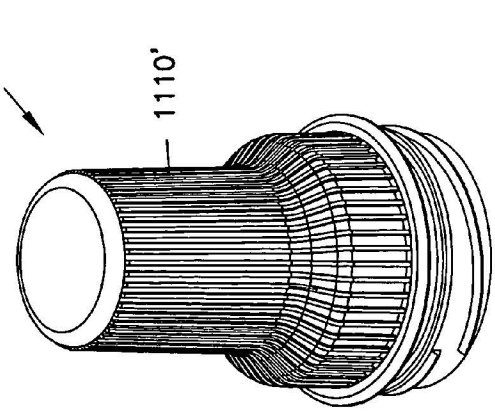


FIG.92

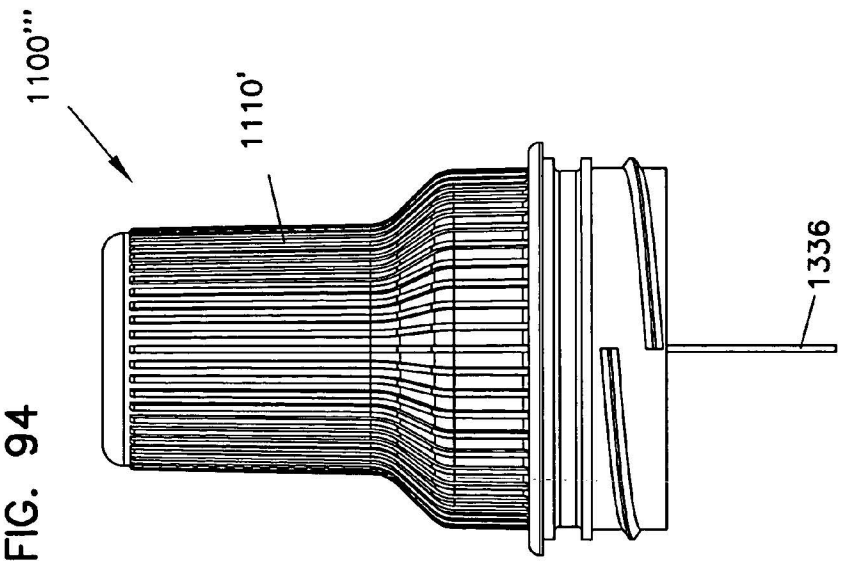


FIG. 94

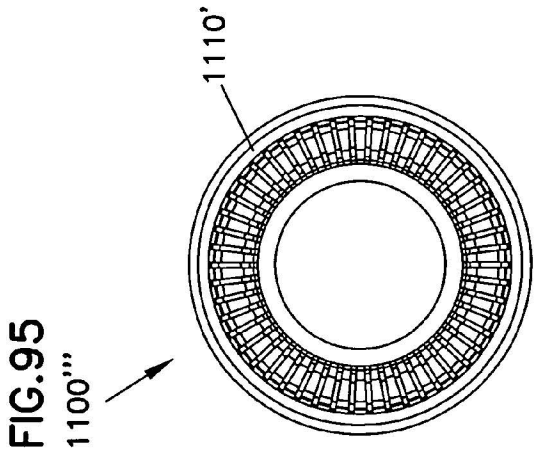


FIG.95

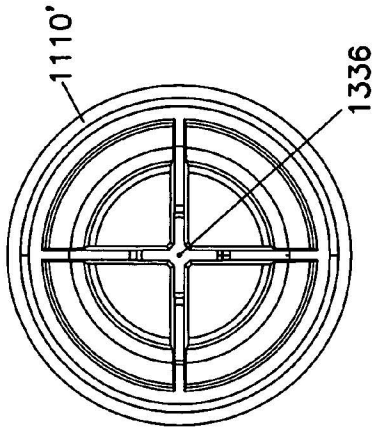


FIG.96

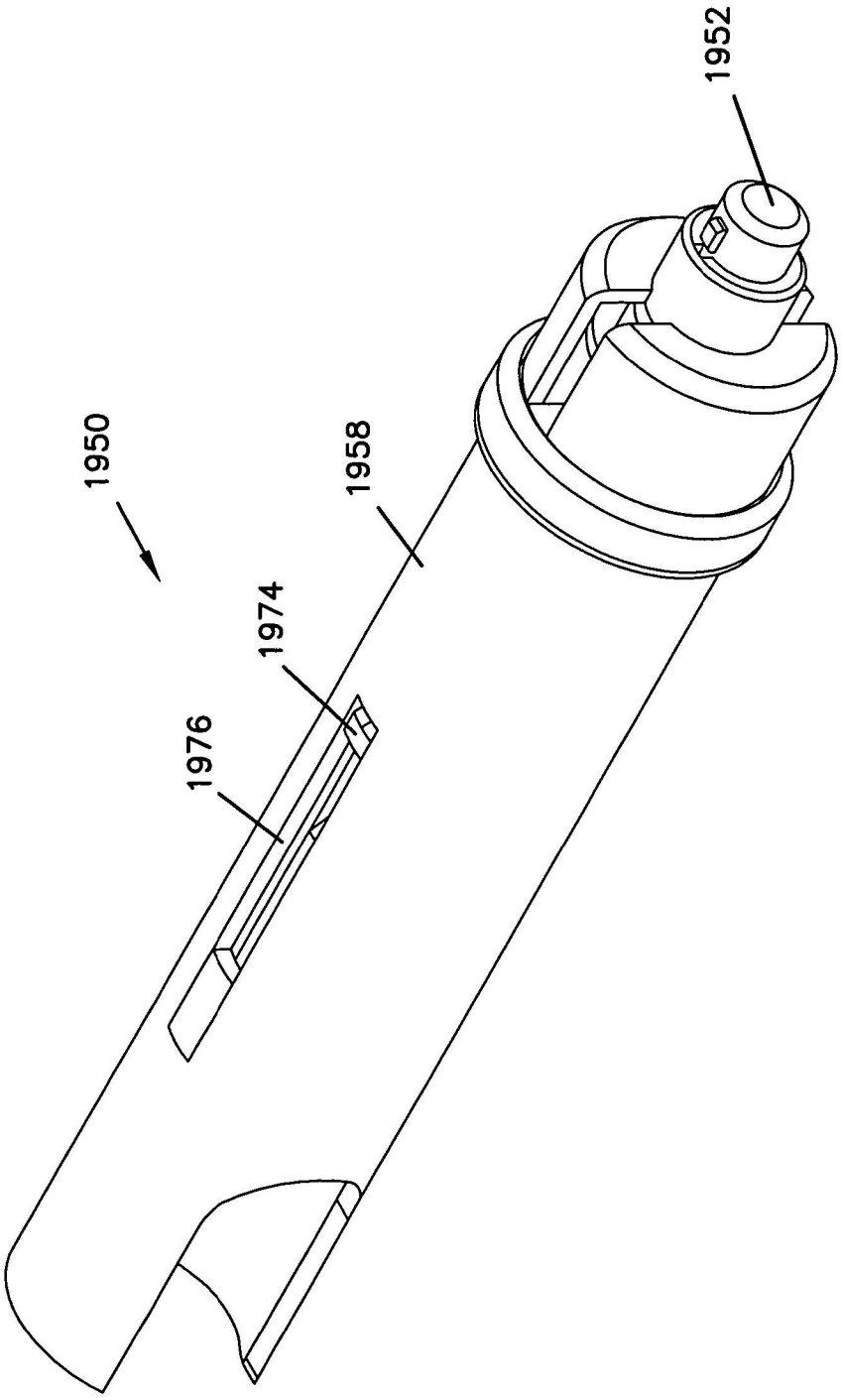


FIG.97

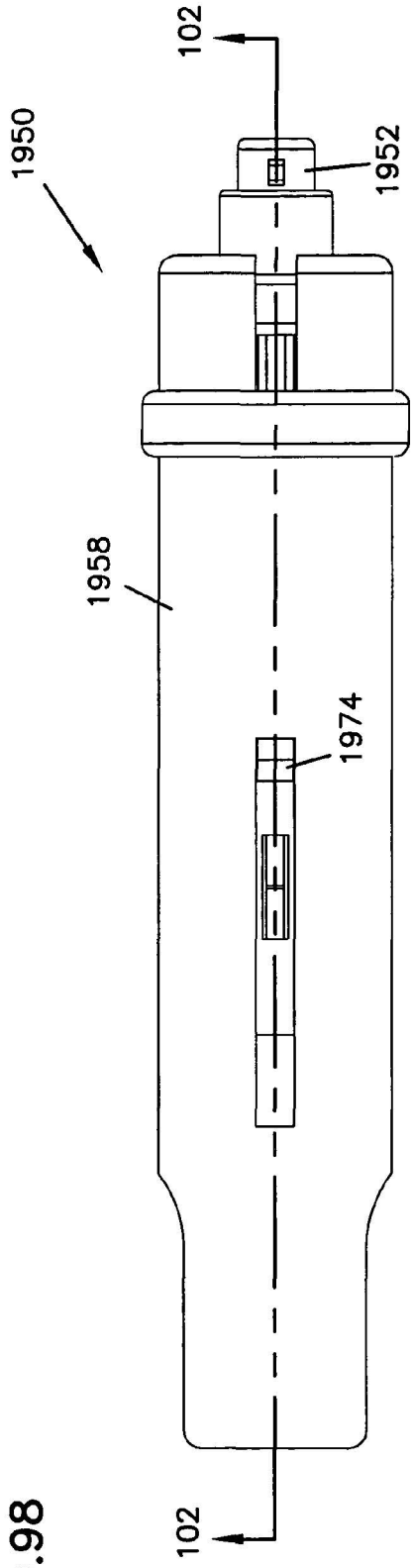


FIG.98

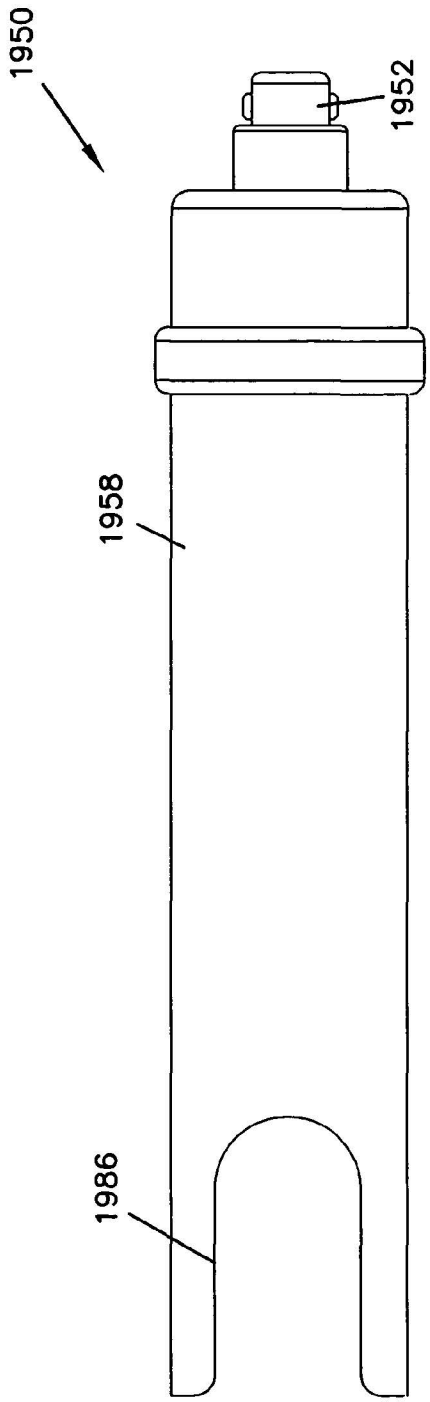


FIG.99

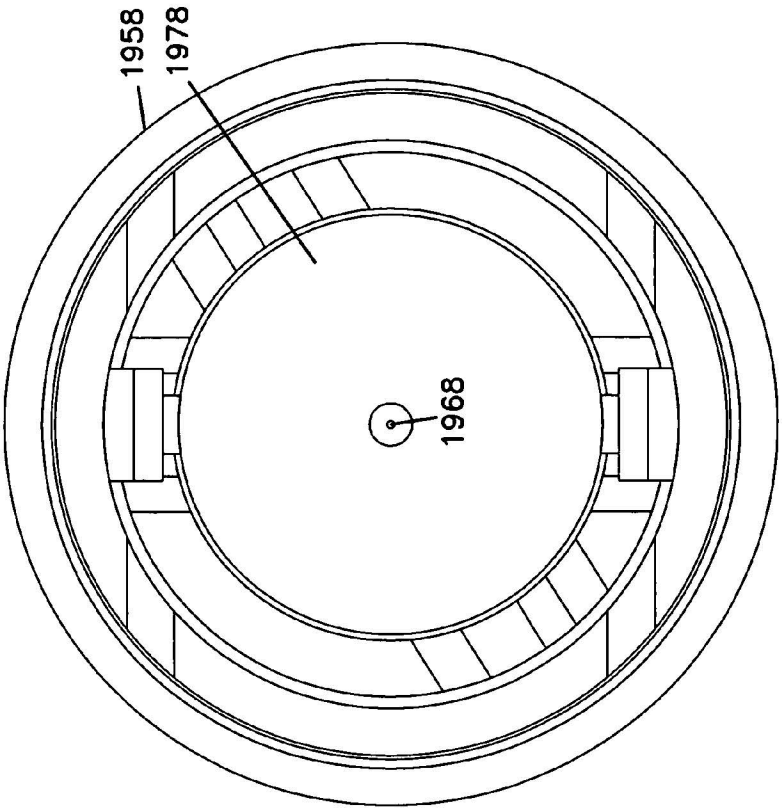


FIG.101

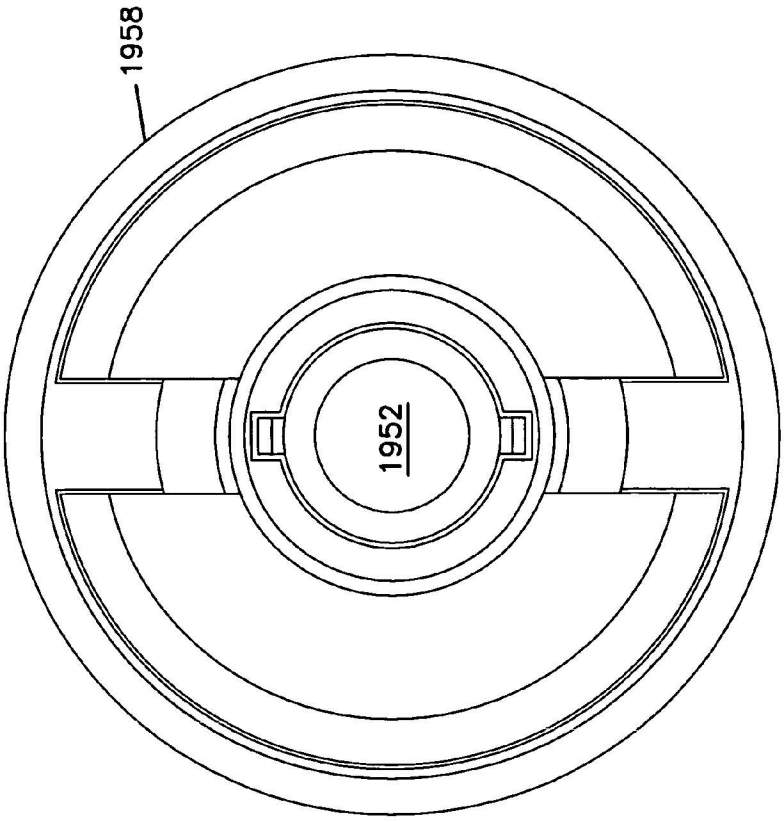


FIG.100

FIG. 102

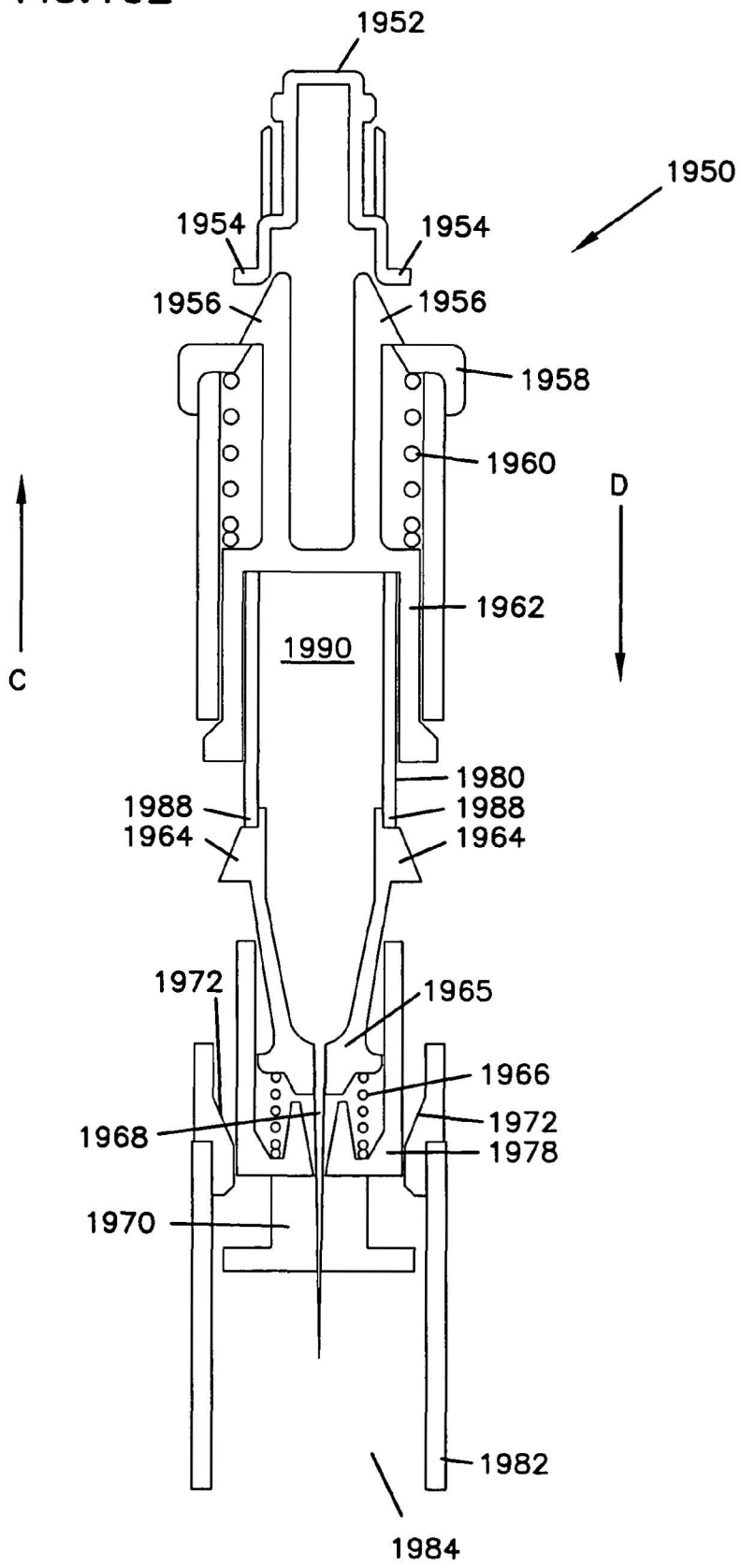

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FIG.104

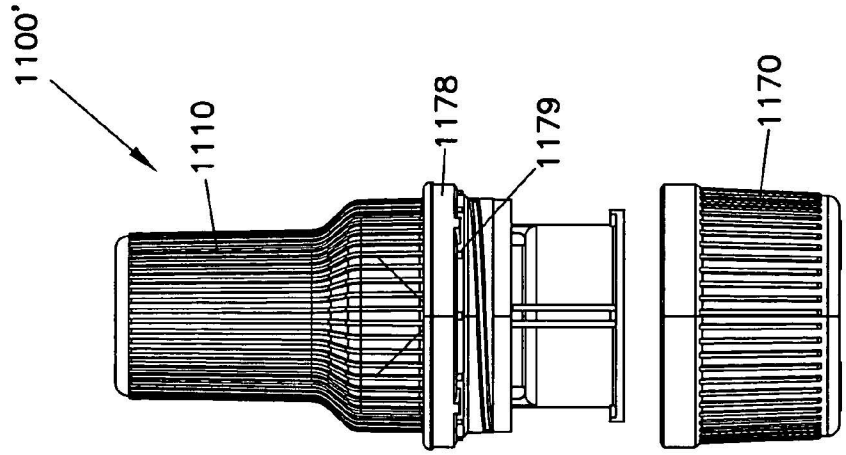
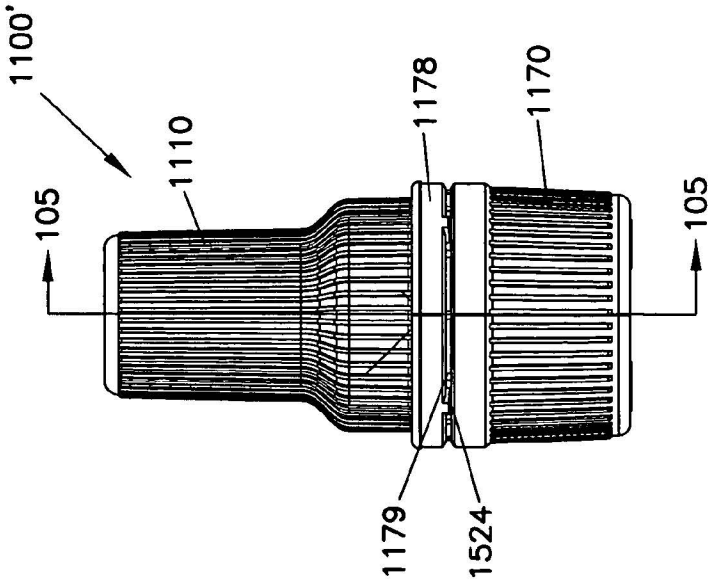


FIG.103



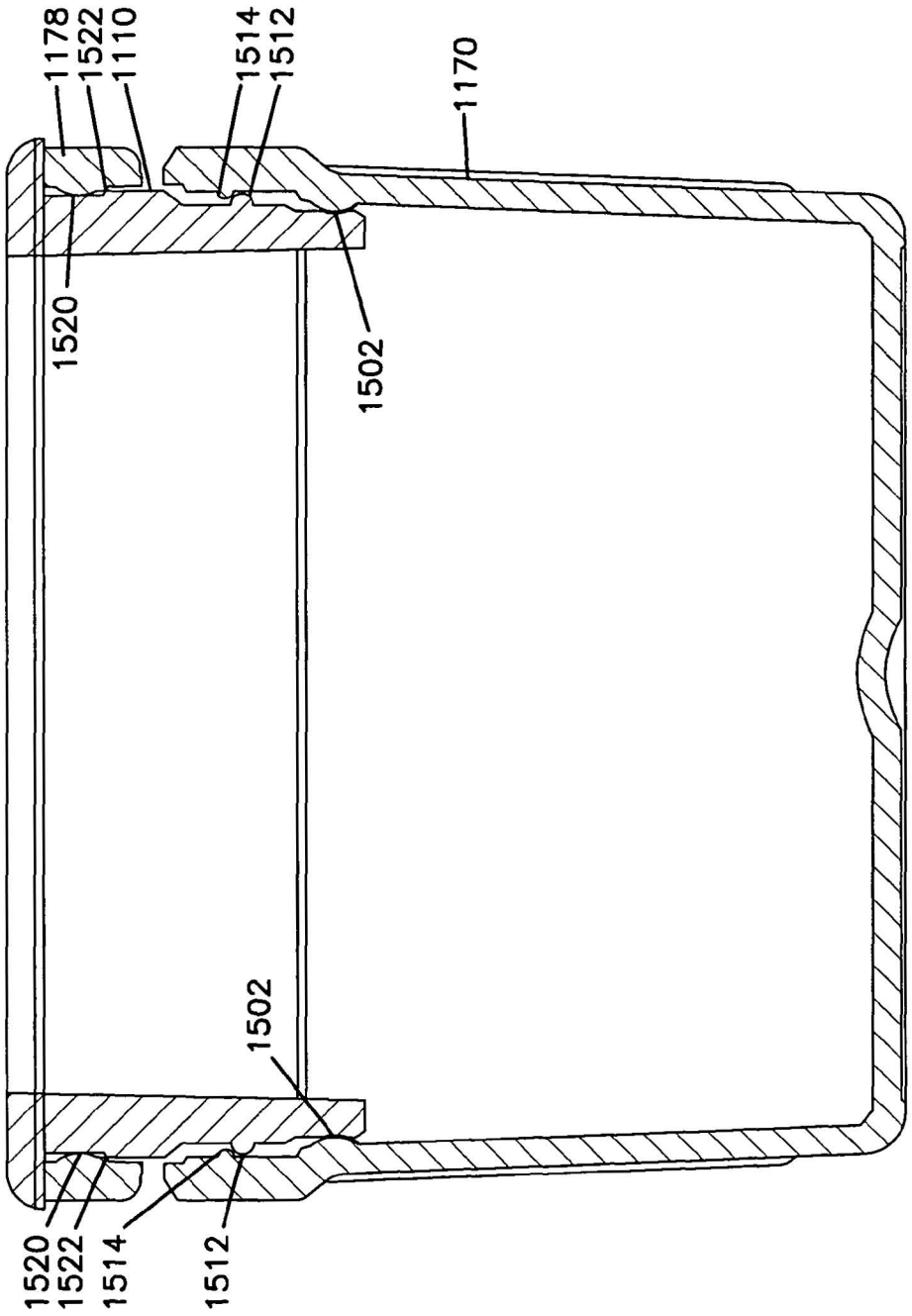

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FIG.105

SUBCUTANEOUS INFUSION DEVICE AND DEVICE FOR INSERTION OF A CANNULA OF AN INFUSION DEVICE AND METHOD

TECHNICAL FIELD

The present invention relates to an infusion device for delivery of a substance to a patient. The present invention also relates to a device for assisting in the introduction of a cannula of an infusion device into the skin of a patient.

BACKGROUND

Infusion devices are used to deliver substances such as medications into the subcutaneous layer of skin of a patient. Typically, an infusion device includes a cannula that is introduced into the skin, as well as a tube extending from the infusion device to, for example, an infusion pump to deliver the substance.

In current designs, it is typically necessary to introduce a cannula of the infusion device into the skin while maintaining the device at a given orientation so that the tubing extends in a direction towards the infusion pump. Further, once the infusion device is placed on the skin, there is typically no way to reorient the device and associated tubing, or to remove the tubing from the body without removing the cannula from the skin of the patient. In addition, the profile of infusion devices can be undesirably high, making placement and concealment of the infusion device difficult and uncomfortable to wear. Also, introduction of the infusion device into the skin can be complicated and require two hands to accomplish.

In addition, devices for assisting in insertion of the cannula of an infusion device into the skin of the patient are known. For example, some devices utilize springs to automatically drive a needle into the skin of a patient to introduce the cannula of the infusion device into the subcutaneous layer.

Because a needle is used to introduce the cannula of the infusion device into the subcutaneous layer of skin, there is a risk associated with inadvertent exposure to the needle. Further, patients may react adversely to viewing the needle prior to insertion and may, for example, be reluctant to place the needle into the skin. Prior devices may not adequately shroud this needle prior to and/or after introduction of the infusion device.

Other issues of concern in the design and use of insertion devices include ease of use by the patient and sterilization. For example, some patients may have difficulty loading the infusion device into the insertion device.

It is therefore desirable to provide new designs for infusion devices and devices used to assist in the introduction of an infusion device into the skin of a patient to deliver a substance into the skin.

SUMMARY

Embodiments made in accordance with the present invention are related to infusion devices for delivery of a substance to a patient. Embodiments made in accordance with the present invention also include devices that can be used to assist in the introduction of the cannula of an infusion device into the skin of a patient for delivery of a substance to the patient.

In one embodiment, an infusion device can include a site and a set. The site can include a cannula that is introduced into a subcutaneous layer of skin of the patient. The set can be coupled to the site by, for example, placing the set over the site and moving the set from an unlocked to a locked position. A substance can then be delivered through the set to the site and from the site into the patient through the cannula.

The set can preferably be oriented at multiple rotational orientations with respect to the site, and can preferably be coupled and uncoupled with the site multiple times.

In another embodiment, a device includes a needle used to insert the cannula of an infusion device into the skin of a patient. Once the cannula of the infusion device is inserted into the skin, the device moves the needle to a retracted state within the device.

In another embodiment, a device is configured to move a needle and associated cannula of an infusion device from a delivery state to a trigger state at which the cannula of the infusion device is inserted into the skin of a patient. Upon full insertion of the cannula at the trigger state, the device is then configured to move the needle to a retracted state within the device.

In another embodiment, a device includes a needle that can be used to insert a cannula of a site into the skin of a patient. Upon insertion of the cannula, the needle can be removed from the skin. In one embodiment, a cap is provided that can be placed onto the device prior to and after use of the device to provide a sterile environment and/or to reduce exposure to the needle.

In other embodiments, a subcutaneous infusion device and device for introduction of a cannula of the infusion device can be combined to introduce the cannula into the skin and deliver a substance into the skin.

The above summary of the present invention is not intended to describe each disclosed embodiment or every implementation of the present invention. Figures in the detailed description that follow more particularly exemplify embodiments of the invention. While certain embodiments will be illustrated and described, the invention is not limited to use in such embodiments.

DESCRIPTION OF THE DRAWINGS

FIG. **1** is a top perspective view of an example embodiment of a site made in accordance with the present invention.

FIG. **2** is a bottom perspective view of the site of FIG. **1**.

FIG. **3** is a side view of the site of FIG. **1**.

FIG. **4** is a top view of the site of FIG. **1**.

FIG. **5** is a bottom view of the site of FIG. **1**.

FIG. **6** is a cross-sectional view taken along line **6-6** of the site of FIG. **3**.

FIG. **6A** is a cross-sectional view taken along line **6-6** of the site of FIG. **3** including a needle used to insert the site.

FIG. **7** is an exploded view of the site of FIG. **1**.

FIG. **8** is a top perspective view of a base of the site of FIG. **1**.

FIG. **9** is a bottom perspective view of the base of FIG. **8**.

FIG. **10** is a side view of the base of FIG. **8**.

FIG. **11** is a top view of the base of FIG. **8**.

FIG. **12** is a side view of a cannula of the site of FIG. **1**.

FIG. **13** is an end view of the cannula of FIG. **13**.

FIG. **14** is cross-sectional view taken along line **14-14** of the cannula of FIG. **12**.

FIG. **15** is a side view of a diaphragm of the site of FIG. **1**.

FIG. **16** is an end view of the diaphragm of FIG. **15**.

FIG. **17** is a cross-sectional view taken along line **17-17** of the diaphragm of FIG. **16**.

FIG. **18** is a top view of an adhesive portion of the site of FIG. **1**.

FIG. **19** is a cross-sectional view taken along line **19-19** of the adhesive portion of FIG. **18**.

FIG. **20** is an exploded view of the adhesive portion of FIG. **18**.

FIG. **21** is a top perspective view of an example embodiment of a set in an unlocked position made in accordance with the present invention.

FIG. **22** is a top perspective view of a first member of the set of FIG. **21**.

FIG. **23** is a top view of the first member of FIG. **22**.

FIG. **24** is a side view of the first member of FIG. **22**.

FIG. **25** is an end view of the first member of FIG. **22**.

FIG. **26** is another end view of the first member of FIG. **22**.

FIG. **27** is a top perspective view of a second member of the set of FIG. **21**.

FIG. **28** is a top view of the second member of FIG. **27**.

FIG. **29** is a side view of the second member of FIG. **27**.

FIG. **30** is an end view of the second member of FIG. **27**.

FIG. **31** is another end view of the second member of FIG. **27**.

FIG. **32** is a top view of the set of FIG. **21** in an unlocked position.

FIG. **33** is a side view of the set of FIG. **32**.

FIG. **34** is an end view of the set of FIG. **32**.

FIG. **35** is a cross-sectional view taken along line **35**-**35** of the set of FIG. **32** with portions of the set removed for clarity.

FIG. **36** is a top perspective view of the set of FIG. **21** in a locked position.

FIG. **37** is a top view of the set of FIG. **36**.

FIG. **38** is a side view of the set of FIG. **36**.

FIG. **39** is an end view of the set of FIG. **36**.

FIG. **40** is a bottom perspective view of the set of FIG. **36**.

FIG. **41** is a bottom view of the set of FIG. **36**.

FIG. **42** is a cross-sectional view taken along line **42**-**42** of the set of FIG. **38** with portions of the set removed for clarity.

FIG. **43** is a perspective view of the site of FIG. **1** and the set of FIG. **21** coupled to one another.

FIG. **44** is a top view of the site and set of FIG. **43**.

FIG. **45** is a bottom view of the site and set of FIG. **43**.

FIG. **46** is a side view of the site and set of FIG. **43**.

FIG. **47** is an end view of the site and set of FIG. **43**.

FIG. **48** is another end view of the site and set of FIG. **43**.

FIG. **49** is an exploded perspective view of the site and set of FIG. **43**.

FIG. **50** is a cross-sectional view taken along line **50**-**50** of the site and set of FIG. **44**.

FIG. **51** is an exploded perspective view of another example embodiment of an infusion device including a site and set made in accordance with the present invention.

FIG. **52** is a perspective view of the infusion device of FIG. **51** in a locked position.

FIG. **53** is a cross-sectional view of the site of FIG. **51**.

FIG. **54** is a side view of an example embodiment of a device used to introduce a cannula of an infusion device into a patient made in accordance with the present invention.

FIG. **55** is an exploded side view of the device of FIG. **54**.

FIG. **56** is a perspective view of a housing of the device of FIG. **54**.

FIG. **57** is a side view of the housing of FIG. **56**.

FIG. **58** is an end view of the housing of FIG. **56**.

FIG. **59** is a perspective view of a cylinder hub of the device of FIG. **54**.

FIG. **60** is side view of the cylinder hub of FIG. **59**.

FIG. **61** is another side view of the cylinder hub of FIG. **59**.

FIG. **62** is an end view of the cylinder hub of FIG. **59**.

FIG. **63** is a perspective view of a needle hub of the device of FIG. **54**.

FIG. **64** is a side view of the needle hub of FIG. **63**.

FIG. **65** is another side view of the needle hub of FIG. **63**.

FIG. **66** is an end view of the needle hub of FIG. **63**.

FIG. **67** is a perspective view of a sleeve of the device of FIG. **54**.

FIG. **68** is a side view of the sleeve of FIG. **67**.

FIG. **69** is another side view of the sleeve of FIG. **67**.

FIG. **70** is an end view of the sleeve of FIG. **67**.

FIG. **71** is a top view of an adhesive portion of the device of FIG. **54**.

FIG. **72** is a cross-sectional view taken along line **72**-**72** of the adhesive portion of FIG. **71**.

FIG. **73** is an exploded view of the adhesive portion of FIG. **71**.

FIG. **74** is a perspective view of a cap of the device of FIG. **54**.

FIG. **75** is a side view of the cap of FIG. **74**.

FIG. **76** is an end view of the cap of FIG. **74**.

FIG. **77** is a side view of the device of FIG. **54** with the cap removed.

FIG. **78** is a side view of the device of FIG. **77** in a trigger state.

FIG. **79**A is a cross-sectional view taken along line **79**A-**79**A of the device of FIG. **54** in a ship state.

FIG. **79**B is a cross-sectional view taken along line **79**B-**79**B of the device of FIG. **54** in the ship state.

FIG. **80**A is a cross-sectional view taken along line **80**A-**80**A of the device of FIG. **77** in a delivery state.

FIG. **80**B is a cross-sectional view taken along line **80**B-**80**B of the device of FIG. **77** in the delivery state.

FIG. **81**A is a cross-sectional view taken along line **81**A-**81**A of the device of FIG. **78** in a trigger state.

FIG. **81**B is a cross-sectional view taken along line **81**B-**81**B of the device of FIG. **78** in the trigger state.

FIG. **81**C is a cross-sectional view of the device of FIG. **81**B illustrating the adhesive portion being sheared from a surface of the sleeve.

FIG. **82**A is a cross-sectional view of the device of FIG. **81**A with the needle hub retracted.

FIG. **82**B is a cross-sectional view of the device of FIG. **81**B with the needle hub retracted.

FIG. **83**A is a cross-sectional view taken along line **83**A-**83**A of the device of FIG. **77** in a retracted state.

FIG. **83**B is a cross-sectional view taken along line **83**B-**83**B of the device of FIG. **77** in the retracted state.

FIG. **84** is a cross-sectional view of a portion of another example embodiment of a device used to introduce an infusion device into a patient made in accordance with the present invention.

FIG. **85**A is a cross-sectional view of another example embodiment of a device used to introduce an infusion device into a patient in a ship state made in accordance with the present invention.

FIG. **85**B is a cross-sectional view along a perpendicular plane of the device of FIG. **85**A.

FIG. **86**A is a cross-sectional view of the device of FIG. **85**A in a delivery state.

FIG. **86**B is a cross-sectional view of the device of FIG. **85**B in the delivery state.

FIG. **87**A is a cross-sectional view of the device of FIG. **85**A in a retracted state.

FIG. **87**B is a cross-sectional view of the device of FIG. **85**B in the retracted state.

FIG. **88** is a perspective view of a sleeve of the device of FIG. **85**A.

FIG. **89** is a side view of the sleeve of FIG. **88**.

FIG. **90** is another side view of the sleeve of FIG. **88**.

FIG. **91** is an end view of the sleeve of FIG. **88**.

FIG. **92** is a perspective view of another example embodiment of a device used to introduce an infusion device into a patient made in accordance with the present invention.

FIG. **93** is another perspective view of the device of FIG. **92**.

FIG. **94** is a side view of the device of FIG. **92**.

FIG. **95** is an end view of the device of FIG. **92**.

FIG. **96** is an opposite end view of the device of FIG. **92**.

FIG. **97** is a perspective view of another example embodiment of a device used to introduce an infusion device into a patient made in accordance with the present invention.

FIG. **98** is a side view of the device of FIG. **97**.

FIG. **99** is another side view of the device of FIG. **97**.

FIG. **100** is an end view of the device of FIG. **97**.

FIG. **101** is another end view of the device of FIG. **97**.

FIG. **102** is a cross-sectional view taken along line **102-102** of the device of FIG. **98**.

FIG. **103** is a side view of another example embodiment of a device used to introduce a cannula of an infusion device into a patient including a tamper-evident seal made in accordance with the present invention.

FIG. **104** is a side view of the device of FIG. **103** with the cap uncoupled and the tamper-evident seal having been broken.

FIG. **105** is a cross-sectional view taken along line **105-105** of a portion of the device of FIG. **103**.

DETAILED DESCRIPTION

Embodiments of the present invention relate to infusion devices for delivering a substance into the subcutaneous layer of skin of a patient. Embodiments of the present invention also relate to devices for assisting in the introduction of an infusion device, specifically a cannula of the infusion device, into the subcutaneous layer of skin of a patient.

Generally, the example infusion devices disclosed herein include a site with a cannula that is introduced into the subcutaneous layer of the skin of a patient to deliver a substance, as well as a set that can be coupled to the site to deliver the substance to the site.

Referring now to FIGS. **1-7**, an example embodiment of a site **100** of an infusion device is depicted in accordance with the present invention. Generally, the site **100** can be used in conjunction with a set (described below) to deliver a substance into a patient.

The site **100** includes a base **110**, a cannula **130**, a diaphragm **150**, and an adhesive portion **170**. The cannula **130** of the site **100** can be introduced into the subcutaneous layer of skin of the patient using a needle (e.g., needle **139**), as shown in FIG. **6**A. The adhesive portion **170** allows the base **110** of the site **100** to be coupled to the skin of the patient. The diaphragm **150** is in fluid communication with the cannula to deliver a substance from the diaphragm **150**, through the cannula **130**, and into the skin of the patient, as described further below.

Referring now to FIGS. **8-11**, the base **110** is shown. The base includes a stand **114** with a top side **111** and a bottom side **112**, and forms a central aperture **113** located at a central axis C of the base **110**. The stand **114** further forms eight positional slots **115** on the top side **111** positioned radially with respect to the central axis C of the site **110** at regular intervals.

The base **110** also includes a member **120** coupled to the stand **114**, the member **120** being positioned about the central aperture **113** of the stand **114** and including eight surfaces **124**. In one preferred embodiment, the member **120** is non-cylindrical in shape. For example, in the embodiment shown the member **120** is octagonal in shape, although other shapes can also be used, as noted below. The non-cylindrical shape of member **120** defines different mounting orientations for a set that can be coupled to the site **100**.

An interior wall of the member **120** forms a cylindrical cavity **121**, and an exterior periphery of the member **120** forms a groove **122** extending about the exterior periphery. In addition, the member **120** forms eight apertures **123** extending from the interior cavity **121** to the groove **122** in the exterior of the member **120**.

Referring now to FIGS. **12-14**, the cannula **130** is illustrated. The cannula **130** includes first and second ends **132** and **134**. The first end **132** of the cannula **130** includes a flange portion **136** having a tapered bottom side **140**, as well as a tapered portion **138** described further below. The cannula **130** also includes a central bore **142** extending from the first end **132** to the second end **134** to allow a substance to be introduced at the first end **132** and delivered out of the second end **134**.

The cannula **130** is positioned within the cavity **121** of the base **110** so that the bottom taper **140** of the cannula **130** engages tapered bottom surfaces **125** of the cavity **121** of the member **120**, and the second end **134** of the cannula **130** extends through the central aperture **113** of the stand **114** at an approximate right angle to the bottom side **112** of the stand **114**. See FIG. **6**. Preferably, the bottom taper **140** of the cannula **130** is positioned adjacent to the stand **114** of the base **110**.

Preferably the cannula **130** is made of fluorinated ethylene propylene (FEP). Other materials can also be used, such as polytetrafluoroethylene (PTFE), or other suitable plastics.

Referring now to FIGS. **15-17**, the diaphragm **150** is shown. Generally, the diaphragm **150** functions as a septum or seal that allows a needle to access an internal portion of the septum to deliver a substance provided, for example, from an infusion device or other similar device to the cannula **130**.

Preferably, the diaphragm **150** is generally cylindrical in shape and includes an open bottom end **152** and a closed top end **154**. The diaphragm **150** also includes a tapered portion **156** adjacent the bottom end **152**, and a central reservoir **158**.

As shown, for example, in FIGS. **6** and **17**, the diaphragm **150** is positioned in the cavity **121** of the member **120** and preferably includes an outer periphery **160** that is sized to frictionally engage the interior cavity wall of the member **120** to retain the diaphragm **150** in the cavity **121**. In addition, the tapered portion **156** of the diaphragm **150** is configured to engage the tapered bottom surfaces **125** of the base **110**. The bottom end **152** engages the first end **132** of the cannula **130** to provide fluid communication between the reservoir **158** and the bore **142** of the cannula **130**.

More specifically, surfaces **157** adjacent to the bottom end **152** of diaphragm **150** preferably are compressed against the first end **132** of the cannula **130** to provide a seal with respect to the cannula **130** so a substance can be delivered from the diaphragm **150**, through the cannula **130**, and into the patient. In alternative embodiments, additional structure such as, for example, an O-ring can also be provided between the diaphragm **150** and cannula **130** to provide additional sealing.

In a preferred embodiment, the diaphragm **150** is made of a silicone elastomer. Other materials can also be used, such as ethylene propylene or other suitable elastomeric materials.

As previously noted, preferably the diaphragm **150** is retained in the cavity **121** of the member **120** of the base **110** through the frictional engagement of the outer periphery **160** of the diaphragm **150** with the walls of the cavity **121**. In alternative embodiments, a retaining member can be fitted over the open top of the member **120** to further retain the

diaphragm **150** in position in the cavity **121**. In other embodiments, the diaphragm **150** can be retained in the cavity **121** through compression by other features of the member **120**, or the diaphragm **150** can have features that mate with features of the member **120**. For example, in one alternative embodiment, the diaphragm **150** can be formed with barbs on the outer periphery **160** positioned and sized to be received within apertures **123** formed in the member **120** to retain the diaphragm **150** in the cavity **120**. Other configurations are also possible.

Referring now to FIGS. **18-20**, the adhesive portion **170** is shown. The adhesive portion includes liners **172** and **176** sandwiching a layer **174**. Preferably, the layer **174** includes an aperture **178** through which the cannula **130** of the site **100** extends, as described below.

The liner **172** can be removed and the layer **174** coupled to the bottom side **112** of the stand **114** of the base **110** using an adhesive. Examples of such adhesives include, without limitation, acrylic adhesive, synthetic rubber-based adhesive, acrylate adhesive, and silicone-based adhesive. In addition, the liner **176** can be removed and an adhesive be provided on a bottom side of the layer **174** to couple the adhesive portion **170** and associated site **100** to another adhesive portion or the skin of the patient, for example.

In a preferred embodiment, layer **174** of the adhesive portion **170** includes films with adhesives thereon, such as and without limitation, 3M™ 1577 tape. Other materials can also be used.

In other alternative embodiments, the adhesive portion **170** can be removed completely, and adhesion between the site **100** and skin of the patient can be provided using film and/or adhesive carried on other structures, such as a device used to insert the site **100** into the body, as described further below. Or, the layer **174** can be replaced or supplemented by one or more layers of other material such as, for example, a Tegaderm™ film manufactured by 3M™ or an IV3000™ film manufactured by Smith & Nephew.

In an alternative embodiment, layer **174** can be provided with a tab (not shown, but preferably similar to tabs shown on liners **172** and **176**) or other similar structure that can assist the patient in removing the layer **174** and associated site **100** from the skin when desired. For example, the tab can extend from an outer periphery of the layer **174** and allow the patient to grasp the tab and thereby peel the layer **174** from the skin to remove the site **100**.

In another alternative embodiment, the layer **174** can include a foam backing or similar additional material can be added adjacent to the layer **174** to provide supplemental cushioning as the site **100** is inserted into the skin of the patient.

Referring now to FIG. **21**, an example embodiment of a set **200** of an infusion device is depicted in accordance with the present invention. As noted generally above and described further below, the set **200** can be used in conjunction with a site (e.g., site **100**) to deliver a substance into a patient.

The set **200** generally includes a first member **210** and a second member **250**. The first member **210** is slideable relative to the second member **250** into an unlocked position (see, e.g., FIGS. **21** and **32-35**) and a locked position (see, e.g., FIGS. **36-42**), described further below.

Referring now to FIGS. **22-26**, the first member **210** is shown. The first member **210** includes a main body **212**, and a port **213** extending through the body **212** and in fluid communication with a hollow needle **214**. The port **213** is preferably coupled to a tube (e.g., tube **305** shown in FIG. **21**) that can be attached, for example, to an infusion pump for the delivery of a substance to the set **200**.

The first member **210** also includes outer arms **220** and **222** with barbs **223** formed on the ends and projections **230** extending below the arms **220**. In addition, the first member **210** includes inner arms **226** and **228** with barbs **229**. As described further below, the outer arms **220** and **222** can be displaced towards one another when force is applied to surfaces **221**.

Referring now to FIGS. **27-31**, the second member **250** is shown. The second member **250** includes a main body **260**, and a central octagonal aperture **270**. The second member **250** also includes opening **262** extending to the central aperture **270**, as well as openings **264** positioned on opposite sides of the main body **260**. The second member **250** also includes projections **266** formed on a bottom surface **274** of a base **261**, as well as slots **268** preferably extending through the base **261** of the main body **260**.

Referring now to FIGS. **21** and **32-35**, the first and second members **210** and **250** of the set **200** are shown in the unlocked position. The first member **210** is slidingly received by the second member **250** such that inner arms **226** and **228** are accepted into opening **262** of the second member **250**. Projections **230** on outer arms **220** and **222** of the first member **210** are received in slots **268** of the second member **250**.

As illustrated by FIG. **35**, in the unlocked position barbs **229** of inner arms **226** and **228** of the first member **210** extend through openings **264** and engage shoulders **271** of the second member **250** such that the first and second members **210** and **250** cannot be further separated.

Referring now to FIGS. **36-42**, the first and second members **210** and **250** of the set **200** are shown in the locked position. To move the set **200** from the unlocked to the locked position, the first and second members **210** and **250** are slid towards one another, and outer arms **220** and **222** of the first member **210** are accepted into the openings **264** of the second member **250**. Likewise, projections **230** on outer arms **220** and **222** slide along slots **268** of the second member **250**. Further, surfaces **234** of the inner arms **226** and **228** partially extend into aperture **270**, as described further below.

As illustrated by FIG. **42**, in the locked position outer arms **220** and **222** extend through openings **264** and engage lips **272** of the second member **250**. In addition, inner arms **226** and **228** of the first member **210** extend further into the second member **250**. In this locked position, the engagement of the barbs **223** with the lips **272** resist allowing the first member **210** from being slid relative to the second member **250**.

In order to slide the first member **210** away from the second member **250** from the locked position back to the unlocked position, the outer arms **220** and **222** are deflected inwardly toward one another by applying pressure on surfaces **221** until the barbs **223** clear the lips **272**, thereby allowing the first member **210** to be slid with respect to the second member **250** back into the unlocked position as shown in FIGS. **21** and **32-35**.

Preferably, slots **268** formed in the second member **250** include a cammed surface **269** so that projections **230** extending below the arms **220** of the first member **210** are biased towards a first end **267** of the slots **268** to thereby bias the first member **210** into the unlocked position. See FIGS. **40** and **41**. In alternative embodiments, other features can be provided to bias the first member **210** into the unlocked position. For example, detents can be provided to engage barbs **229** as inner arms **226** and **228** of the first member **210** are moved towards the locked position to bias the first member **210** into the unlocked position. It can be preferable to bias the set **200** into the unlocked position so that the set **200** can be easily positioned onto and removed from the site **100**, as described further below.

Referring now to FIGS. **43-50**, as previously noted the site **100** and set **200** can be used together to form an infusion device **300** for delivery of a substance to a patient.

One method of use of the infusion device **300** is as follows. Initially, the site **100** is positioned on the skin of a patient with the cannula **130** being introduced into the subcutaneous layer of the skin. This can be accomplished, for example, using a needle (e.g., needle **130** shown in FIG. **6**A) that is extended through the exposed closed end **154** of the diaphragm **150** and through the bore **142** of the cannula **130** and beyond the second end **134**. The tapered portion **138** of the flange portion **136** of the cannula **130** can assist in directing the needle through into the bore **142** of the cannula **130**. In this position, the needle can be used to introduce the cannula **130** of the site **100** into the skin of the-patient. Further, once the cannula **130** is in position, the needle can be removed, leaving the cannula **130** in place in the subcutaneous layer of the skin. As the needle is removed, the closed end **154** of the diaphragm **150** reseals itself to retain the fluid-tight reservoir **158**.

In a preferred embodiment, the site **100** of the infusion device **300** is placed in position on the skin of a patient using one or more of the devices or methods described below with reference to FIGS. **54-105**.

Once the site **100** has been positioned on the skin of a patient (with the cannula **130** having been introduced into the subcutaneous layer), the set **200** can be coupled to the site **100** as follows. With the set **200** in the unlocked position, the set **200** can be placed over the member **120** so that the central octagonal aperture **270** of the set **200** accepts the member **120** into the aperture **270**. The set **200** is lowered onto the site **100** until the bottom surface **274** of the set **200** contacts the stand **114** of the site **100** and projections **266** of the second member **250** are accepted into the positional slots **115** of the stand **114** of the base **110**.

In this position on the site **100**, the first member **210** of the set **200** can be slid from the unlocked to the locked position. As the first member **210** is slid to the locked position, surfaces **234** of the inner arms **226** and **228** (see FIGS. **23**, **36**, and **37**) are accepted by the groove **112** of the member **120** of the base **100**, which locks the set **200** to the site **100** so that the set **200** resists any upward force tending to remove the set **200** from the site **100** when the set **200** is in the locked position. In addition, the shape of the member **120** of the site **100** and the central aperture **270** of the set **200**, as well as projections **266** received in slots **115**, orient the set **200** with respect to the site **100** and function to resist rotation of the set **200** with respect to the site **100** when the set **200** is in the locked position.

In addition, as the first member **210** of the set **200** is moved from the unlocked to the locked position, the needle **214** is advanced through one of the eight apertures **123** formed in the member **120** and into the diaphragm **150** in the cavity **121**. In the fully locked position as shown in FIG. **50**, an end **215** of the needle **214** is positioned within the reservoir **158** of the diaphragm **150**. In this position, the port **213** is fluidly coupled to the cavity **121** of the diaphragm **150** through the hollow needle **214**, and the cavity **121** is in turn fluidly coupled to the skin of the patient through the bore **142** in the cannula **130**. In this manner, a substance can be delivered to the port **213** of the set **200** (by, for example, a tube not shown in the figures), through the needle **214**, into the reservoir **158**, and into the subcutaneous layer of the skin of the patient by the cannula **130**.

If the set **200** is not oriented as desired with respect to the site **100**, or if the patient desires to remove the set **200** from the site **100**, the set **200** can be moved from the locked to the unlocked position by forcing the outer arms **220** and **222** together and sliding the first member **210** away from the second member **250** to the unlocked position. This action removes the surfaces **234** from the groove **122**, as well as the needle **214** from the reservoir **158**. The diaphragm **150** reseals upon removal of the needle **214**. The set **200** can then be removed from the site **100**, leaving the site **100** in place on the skin of the patient. The set **200** can be replaced at another orientation or at a later time.

In the illustrated embodiment of the infusion device **300**, the set **200** can be oriented and fixed in eight different positions with respect to the site **100**. In alternative embodiments, the site **100** and set **200** can be configured to include fewer or more positions as desired. For example, in an alternative embodiment the member **120** of the site **100** and the aperture **270** of the set **200** can be formed in the shape of a square if four orientational positions are desired.

Referring now to FIGS. **51-53**, another example infusion device **400** is shown in accordance with the present invention. The device **400** is similar to the example device **300** described above, except for the details noted below.

The infusion device **400** includes a site **405** with a central portion **407**. The central portion **407** includes a pierceable outer shell **430** made of a material such as a plastic, and a softer inner diaphragm **432** surrounding the outer shell **430**. An inner reservoir **434** of the central portion **407** is fluidly coupled to a cannula **440**. See FIG. **53**.

The infusion device **400** also includes a set with a first member **410** and a second member **420**. The first member **410** includes a needle **411**, and first and second arms **412** and **414** with barbs **415** on ends. The second member **420** includes shoulders **422** and **424**. The first and second members **410** and **420** each form openings **461** and **426**, respectively, that are sized to each receive a portion of the central portion **407** of the site **405**.

The infusion device **400** can be used as follows. First, the site **405** is positioned on the skin of a patient so that the cannula **440** is introduced into the subcutaneous layer. Next, the first member **410** and second member **420** of the site are placed onto the site **405** so that openings **461** and **426** are positioned about the central portion **407**, and the first and second members **410** and **420** are slid towards one another from the unlocked to the locked position. As the set is moved to the locked position, the needle **411** is introduced into the central portion **407** of the site **405**, moving through the outer shell **430** and into the reservoir **434** to become fluidly coupled to the cannula **440**. In addition, the arms **412** and **414** are accepted into the second member **420** until barbs **415** engage the shoulders **422** and **424** in the locked position, as shown in FIG. **52**.

To move the set from the locked position back into the unlocked position, the barbs **415** are pressed inwardly toward one another until they clear the shoulders **422** and **424**, and then the first member **410** is slid away from the second member **420**, thereby removing the needle **411** from the central portion **407** of the site **405**.

As preferably there is no specific structure provided with infusion device **400** for rotationally orienting the set with the site **405**, the set can be oriented at an infinite number of rotational positions with respect to the site **405** as desired. Further, since the central portion **407** of the site and the openings **461** and **426** of the set are preferably circular in shape, the first and second members **410** and **420** of the site can be rotated relative to the site **405** without requiring that the set be completely removed from the site **405**.

Referring now to FIGS. **54-105**, example devices and methods for placing a subcutaneous infusion device, such as site **100**, into a subcutaneous layer of skin of a patient are disclosed.

Referring to FIGS. **54** and **55**, one example embodiment of a device **1100** is shown. The device **1100** is used to introduce a cannula of an infusion device, such as a set, site, or other access device, into the skin of the patient. The set, site, or other access device can then be used to deliver drugs or other fluid to the patient, such as from an infusion pump.

The device **1100** generally includes a housing **1110**, a cylinder hub **1120**, a needle hub **1130**, a sleeve **1140**, a spring **1150**, an adhesive portion **1160**, and a cap **1170**. Each of the components of the device **1100**, described further below, is configured to assist in the introduction of a cannula of an infusion device into the skin of a patient.

Referring now to FIGS. **56-58**, the housing **1110** is shown. The housing **1110** is preferably cylindrical in shape and includes a closed upper end **1111** and an open lower end **1112**. The housing **1110** further preferably includes a portion **1118** with a knurled surface to enhance a patient's grip on the housing **1110**, as well as a threaded portion **1113** positioned adjacent the open lower end **1112**.

Referring now to FIGS. **59-62**, the cylinder hub **1120** is shown in greater detail. The cylinder hub **1120** includes first and second ends **1221** and **1222** and an interior passage **1223**. In addition, two opposing slots **1225** are formed on opposite sides of the cylinder hub **1120** and generally extend from a mid-portion **1224** of the hub **1120** to the first end **1221**. Further, the cylinder hub **1120** includes opposing apertures **1226** formed in the cylinder hub **1120** adjacent the second end **1222**.

The first end **1221** of the cylinder hub **1120** is coupled to the upper end **1111** of the housing **1110** by tabs **1119** on the housing **1110** engaging shoulders **1228** formed by the cylinder hub **1120**. See, for example, FIGS. **59-61**, **79**A, and **79**B. In addition, members **1121** of the housing **1110** are received in slots **1229** of the cylinder hub **1120**. In alternative designs, the housing **1110** and cylinder hub **1120** can be formed as a single unit.

Referring now to FIGS. **63-66**, the needle hub **1130** includes a main body **1331** with first and second ends **1332** and **1333**, and a needle **1336** (hollow or solid) coupled to the main body **1331**. The main body **1331** includes opposing wings **1334** formed at the first end **1332** and opposing barbs **1335** at the second end **1333**.

The needle hub **1130** is positioned in the interior passage **1223** of the cylinder hub **1120** such that the opposing wings **1334** of the needle hub **1130** extend through the opposing slots **1225** of the cylinder hub **1120**. See FIGS. **59**, **61**, **79**B, **80**B, **81**B, **82**B, and **83**B. In addition, the opposing barbs **1335** of the needle hub **1130** extend through the opposing apertures **1226** of the cylinder hub **1120** and engage shoulders **1227** formed by the apertures **1226** so that the needle hub **1130** is held in a fixed position relative to the cylinder hub **1120** and the housing **1110**. See, for example, FIGS. **59**, **61**, **79**A, **80**A, and **81**A.

Referring now to FIGS. **67-70**, the sleeve **1140** is shown. The sleeve **1140** is preferably cylindrical in shape and includes first and second ends **1441** and **1442** and interior passage **1443**. Opposing projections **1444** extend into the passage **1443** adjacent to a shoulder **1445**. On the exterior of the sleeve **1140** channels **1446** are formed, as well as railways **1447** with barbs **1448** formed on ends thereof.

The sleeve **1140** is coupled to the housing **1110** such that the housing **1110** can be moved longitudinally with respect to the sleeve **1140**. Specifically, the railways **1114** of the housing are received in the channels **1446** of the sleeve **1140**. Likewise, the railways **1447** of the sleeve **1140** are received in the channels **1115** of the housing **1110**. Barbs **1448** on the railways **1447** of the sleeve **1140** engage projections **1116** in the channels **1115** of the housing **1110** so that the housing **1110** remains slideably coupled to the sleeve **1140** in opposition to the force exerted by the spring **1150** (described further below).

The spring **1150** includes first and second ends **1152** and **1154**. See, for example, FIG. **79**B. The spring **1150** surrounds a portion of the cylinder hub **1120** and extends within the passage **1443** of the sleeve **1140**. The first end **1152** of the spring **1150** is seated on the shoulder **1445** of the sleeve **1140**, and the second end **1154** of the spring **1150** engages the opposing wings **1334** of the needle hub **1130** extending through the opposing slots **1225** of the cylinder hub **1120**.

The spring **1150** is in a compressed state as shown in FIGS. **79**A, **79**B, **27**A, **27**B, **28**A, and **28**B and therefore applies force against the wings **1334** of the needle hub **1130**, biasing the needle hub **1130** in an upward direction. However, barbs **1335** of the main body **1331** of the needle hub **1130** are engaged against shoulders **1227** of the apertures **1226** of the cylinder hub **1120** to retain the needle hub **1130** in place with respect to the cylinder hub **1120**. See, for example, FIG. **79**A. Likewise, the spring **1150** forces the housing **1110** and the sleeve **1140** apart until barbs **1448** of the sleeve **1140** engage projections **1115** of the housing **1110** to maintain coupling between the housing **1110** and the sleeve **1140**.

Referring now to FIGS. **71-73**, an adhesive portion **1160** is positioned on a surface **1449** at the second end **1442** of the sleeve **1140** (see FIGS. **67** and **70**). The surface **1449** preferably acts as a framework that stabilizes the adhesive portion **1160** prior to placement on the patient. In a preferred embodiment shown, the adhesive portion **1160** includes layers **1662**, **1663**, and **1664**, as well as liners **1661** and **1665**. Liners **1661** and **1665** also preferably include tabs **1666** and **1667** that allow for removal of the liners **1661** and **1665** as described below.

The adhesive portion **1160** can be coupled to the surface **1449** of sleeve **1140** in a variety of manners. In a preferred embodiment, the liner **1661** is removed, and layer **1662** is coupled to the surface **1449** using an adhesive. In addition, as described further below, in a preferred embodiment a top surface **1669** of layer **1664** and/or a lower end of the infusion device includes an adhesive to couple the infusion device to the adhesive portion **1160** as the infusion device is moved into contact with the adhesive portion. See FIGS. **81**A, **81**B, and **81**C.

In addition, the liner **1665** is preferably removed, and a lower surface **1668** of the layer **1664** includes an adhesive to couple the adhesive portion **1160** to the skin of the patient.

Preferably, the site is loaded into the device **1100** prior to application of the adhesive portion **1160** onto the device **1100**, and preferably both liners **1661** and **1665** are removed as described above prior to attachment of the adhesive portion to the sleeve **1140** and coupling of the cap **1170** to the housing **1110**. In this manner, the patient preferably does not need to remove any liners prior to application of the adhesive portion **1160** to the skin and introduction of the site into the skin.

Preferably, the layer **1664** does not include any holes, but instead is pierced by the needle **1336** as the needle **1336** is advanced towards the skin, as described further below. This configuration can enhance the fit between the adhesive portion **1160** and the skin of the patient.

In a preferred embodiment, the adhesive portion **1160** includes adhesive on one or more of surfaces **1668** and **1669** to allow the adhesive portion **1160** to be coupled to the sleeve **1140**, site, and/or to the skin of the patient. Typical adhesives that can be used on the adhesive portion **1160** include, without limitation, acrylic adhesive, synthetic rubber-based adhesive, acrylate adhesive, and silicone-based adhesive.

In example embodiments, the adhesive portion **1160** includes films with adhesives thereon, such as a Tegaderm™ film manufactured by 3M™ or an IV3000™ film manufactured by Smith & Nephew. For example, in the preferred embodiment shown, the tape layer **1662** is 3M™ 9731 tape, and layers **1663** and **1664** are 3M™ Tegaderm™ p/n 9842.

Referring now to FIGS. **74-76**, the cap **1170** is illustrated. The cap **1170** includes a closed first end **1772** and an open second end **1774**. The cap **1170** preferably includes an exterior with a knurled surface **1778** to enhance the patient's grip on the cap **1170**. In addition, the interior of the cap **1170** includes a threaded portion **1776** positioned adjacent the open second end **1774** so that the threaded portion **1776** can be threaded onto the threaded portion **1113** of the housing **1110** to seal the device **1100**. See FIGS. **54**, **79**A, and **79**B.

In a preferred embodiment, a gasket **1122** is provided on the threaded portion **1113** of the housing **1110** to create a seal between the cap **1170** and the housing **1110** as the cap **1170** is threaded onto the housing **1110**. See FIGS. **79**A and **79**B. In this manner, the internal components of the device **1100** (e.g., needle **1336** and site **1800**) can be maintained in a substantially sterile state prior to removal of the cap **1170**. Further, the cap **1170** can function to maintain the device **1100** in a ship state (i.e., the housing **1110** can not be moved relative to the sleeve **1140**) prior to removal of the cap **1170** from the housing **1110**.

In alternative embodiments, the cap **1170** and/or housing **1110** can be formed to provide a tamper-evident seal so that the patient can determine when the cap **1170** has been previously uncoupled from the housing **1110**. For example, in an alternative embodiment of the device **1100'** shown in FIGS. **103-105**, a tamper-evident band **1178** is shown. The band **1178** includes tabs **1179** that are coupled to the cap **1170** as shown in FIG. **103**. As the cap **1170** is removed from the housing **1110** (i.e., threads **1514** on cap **1170** are unthreaded from threads **1512** on housing **1110**), the tabs **1179** break away from the cap **1170**, and the seal **1178** remains coupled to the housing **1110**, as shown in FIG. **104**. If the cap **1170** is later threaded back onto the device **1100'**, the breaks between the tabs **1179** and the cap **1170** are evident, allowing the patient to identify that the cap **1170** of the device **1100'** has been previously removed.

The cap **1170** and band **1178** can be placed on the device **1100'** during manufacturing as a single unit. For example, as shown in FIG. **105**, the cap **1170** and band **1178** can be pushed onto the device **1100'** (note that threads **1512** and **1514** can be rounded to allow the cap **1170** to be pressed onto the device **1100'**) so that portion **1520** of the band **1178** passes over and engages shoulder **1522** of the housing **1110** to retain the band **1178** on the housing **1110** when the cap **1170** is unthreaded and tabs **1179** are broken. In addition, notches **1524** formed periodically along the band **1178** prevent the cap **1170** from bottoming out against the band **1178** as the cap **1170** and band **1178** are pushed onto the device **1100'** so that the tabs **1179** remain intact. A portion **1502** extending along an interior circumference of the cap **1170** can also be formed to engage the outer surface of the housing **1110** to create a seal between the housing **1110** and the cap **1170**.

It can be desirable to provide a tamper-evident seal, for example, so that the patient can assure that the device **1100'** is has not been previously opened and is sterile prior to use. Other methods of indicating tampering can also be used.

As previously noted, device **1100** can be used to insert a cannula **1806** of an infusion device, such as site **1800**, into the subcutaneous layer of skin of a patient. In preferred embodiments, the site **1800** is configured in a manner similar to sites **100** or **450** described above.

Referring now to FIGS. **54** and **67-83**, the device **1100** is illustrated in various states of use. As shown in FIGS. **54**, **79**A, and **79**B, the device **1100** is in a ship state prior to use. As shown in FIGS. **77**, **80**A, and **80**B, the device **1100** is in a delivery state ready to deliver the cannula of an infusion device into the skin of the patient. As shown in FIGS. **78**, **81**A, **81**B, and **81**C the device **1100** is in a trigger state, or the state at which the needle **1336** and the cannula of the site **1800** have been fully inserted into the subcutaneous layer of skin of the patient, and the needle hub **1130** and associated needle **1336** are about to be retracted. As shown in FIGS. **82**A and **82**B, the device **1100** is in a retracted state with the needle hub **1130** and associated needle **1336** having been retracted into the device **1100**. As shown in FIGS. **83**A and **83**B, the device **1100** is in a fully retracted state with the housing **1110** and sleeve **1140** returned to an uncompressed position relative to one another.

An example method of use of the device **1100** is as follows. The device **1100** is provided to a patient with the cap **1170** coupled to the housing **1110**, as shown in FIGS. **54**, **79**A, and **79**B. Preferably, the site **1800** has been previously loaded (i.e., preloaded) into the device **1100** during, for example, the manufacturing process for the device **1100**.

For example, the site **1800** can be preloaded by introducing the site **1800** onto the needle **1336**. More particularly, a diaphragm of the site **1800** is positioned on the needle **1336**, and the site **1800** is moved further onto the needle **1336** so that the needle **1336** extends through the cannula **1806**. With the site **1800** positioned on the needle **1336**, the cap **1170** can be coupled to the device **1100**.

Referring back to the method of using the device **1100**, the cap **1170** is then unthreaded from the housing **1110**, and the sleeve **1140** of the device **1100** is positioned so that the adhesive portion **1160** (i.e., surface **1668**) contacts the skin **1900** of the patient. See FIGS. **77**, **80**A, and **80**B.

Next, in the illustrated preferred embodiment, the patient applies pressure to the upper end **1111** of the housing **1110** to move the housing **1110** and associated structures including the cylinder hub **1120** and needle hub **1130** (including needle **1336** and site **1800**) in a direction A with respect to the sleeve **1140** and toward the skin **1900** of the patient. As the needle **1336** of the needle hub **1130** and associated site **1800** are moved in the direction A, the needle **1336** and the cannula **1806** of the site **1800** are introduced into the skin **1900** of the patient. In addition, as the needle hub **1130** is moved toward the sleeve **1140**, the spring **1150** is further compressed.

Once the needle **1336** and cannula **1806** of the site **1800** have been fully inserted into the skin **1900**, the device **1100** is in a trigger state, as illustrated in FIGS. **78**, **81**A, **81**B, and **81**C. In this state, the barbs **1335** that couple the needle hub **1130** to the cylinder hub **1120** are biased inwardly through contact with the projections **1444** formed by the sleeve **1140**.

As the housing **1110**, cylinder hub **1120**, and needle hub **1130** are displaced further in the direction A, it is preferable that the needle hub **1130** is positioned so that a lower portion of the site **1800** travels slightly beyond the second end **1442** of the sleeve **1140** as shown in FIG. **81**C. This "over-travel" assures that the adhesive portion **1160** is properly sheared away from the surface **1449** of the sleeve **1140** and allows for the coupling of the site **1800** to the adhesive portion **1160**.

For example, in preferred embodiments, the lower portion of the site **1800** travels beyond the second end **1442** of the sleeve **1140** by between 50 to 100 thousandths of an inch, more preferably approximately 70 thousandths of an inch. Adhesive can be provided on the adhesive portion **1160** of the device **1100** and/or the site **1800** to couple the site **1800** to the adhesive portion **1160**.

In addition, as the housing **1110**, cylinder hub **1120**, and needle hub **1130** are displaced further in the direction A as described above, barbs **1335** of the needle hub **1130** are forced inwardly by the projections **1444** of the sleeve **1140**, and the barbs **1335** are thereby uncoupled from engagement with the cylinder hub **1120**. Once the barbs **1335** of the needle hub **1130** are released from the cylinder hub **1120**, the needle hub **1130** is free to move longitudinally within the passage **1223** of the cylinder hub **1120** in a direction B opposite to that of the direction A. The spring **1150**, which has been compressed through the movement of the housing **1110** in the direction A, propels the needle hub **1130** and associated needle **1336** in the direction B up through the cylinder hub **1120** into the upper end **1111** of the housing **1110**, while the site **1800** and associated cannula **1806** are held on the skin **1900** of the patient, as shown in FIGS. **82**A and **82**B.

Once the patient removes pressure from the upper end **1111** of the housing **1110**, the spring **1150** causes the housing **1110** and cylinder hub **1120** to move in the direction B as shown in FIGS. **83**A and **83**B to a fully retracted state.

Finally, the sleeve **1140** is removed from contact with the skin **1900**, and the cap **1170** can be replaced onto the threaded portion **1113** of the housing **1110** of the device **1100**. Subsequently, the device **1100** can be discarded.

Many alternative designs for the device can be provided. For example, in FIG. **84** a portion of an alternative device is shown including cylinder hub **1120'** and needle hub **1130'**. The cylinder hub **1120'** and needle hub **1130'** are similar to cylinder hub **1120** and needle hub **1130** described above, except that the cylinder hub **1120'** includes projections **1129** formed near the first end **1221** of the cylinder hub **1120'**, and the needle hub **1130'** includes barbs **1139** formed on the first end **1332**. The barbs **1139** are configured to ride inside the interior passage **1223** of the cylinder hub **1120'** during retraction of the needle **1336** in the direction B until the barbs **1139** extend beyond the projections **1129** of the cylinder hub **1120'**. Once this occurs, the barbs **1139** expand outward slightly. In this configuration as shown in FIG. **84**, the barbs **1139** prevent the needle hub **1130'** and associated needle **1336** from being moved back in the direction A. In this manner, the barbs **1129** lock the needle hub **1130'** in the retracted position. This configuration can be beneficial, used separately or in conjunction with the force of the spring **1150** forcing the needle hub **1130'** in the direction B, to further reduce the possibility of inadvertent exposure to the needle **1336** after retraction.

According to another alternative embodiment, a device **1100"** is illustrated in FIGS. **85-91**. Device **1100"** is similar to device **1100** described above, except that the sleeve (e.g., sleeve **1140**) is replaced with a trigger **1140'**. In device **1100"**, the trigger **1140'** (see FIGS. **88-91**) does not function as sleeve **1140** to shroud the needle **1336** prior to insertion, but instead trigger **1140'** functions to cause retraction of the needle **1336** upon full insertion, as described further below.

In this embodiment of device **1100"**, once the cap **1170** has been removed, needle **1336** is exposed as shown in FIGS. **86**A and **86**B. In this configuration, instead of moving the housing **1110**, cylinder hub **1120**, and needle hub **1130** longitudinally with respect to the housing, the patient simply inserts the needle **1336** and associated cannula **1806** of the site into the skin by grasping the housing **1110** and introducing the exposed needle **1336** into the skin.

As the needle **1336** and cannula **1806** reaches full insertion, the trigger **1140'** contacts the skin and thereby causes the needle hub **1130** including the needle **1336** to be retracted into the housing **1110**, leaving the site **1800** in place on the skin. In the illustrated embodiment, the trigger **1140'** is automatic, in that the trigger **1140'** is configured to cause barbs **1335** of the needle hub **1130** to be displace inwardly to release the needle hub **1130** from the cylinder hub **1120**, and the spring **1150** can thereupon move the needle hub **1130** and associated needle **1336** in the direction B into an upper portion of the housing **1110** as shown in FIGS. **87**A and **87**B.

In alternative embodiments, the trigger **1140'** can be configured to be manually actuated by the patient to cause retraction of the needle hub **1130** and associated needle **1336** once the cannula **1806** has been fully inserted.

Referring now to FIGS. **92-96**, another embodiment of a device **1100'"** is shown. The device **1100'"** is a manual device in that the device **1100'"** includes only a housing **1110'**, needle **1336**, and cap (not shown) that can be threaded onto the housing **1110'**. Preferably, a site (not shown) can be preloaded onto the needle **1336** and the cap placed on the housing **1110'** to create a sterile environment prior to use. To use device **1100'"**, the patient preferably removes the cap from the housing **1110'** and, holding the housing **1110'** inserts the needle and associated cannula of the site into the skin. Once the cannula is completely inserted, the patient moves the housing **1110'** in the opposite direction to remove the needle from the skin while leaving the site in place. Finally, the patient preferably reapplies the cap to the housing **1110'** to reduce the chance for further inadvertent exposure to the needle **1336**. The device **1100'"** can then be discarded or reused as desired.

Referring now to FIGS. **97-102**, another example embodiment of a device **1950** for assisting in the introduction of a site **1970** is shown. The device **1950** differs from the device **1100**. For example, while the device **1100** can be manually driven by the patient to insert the needle and cannula of the site into the skin, the device **1950** is automated in that a spring **1960** is used to drive the needle and cannula of the site into the skin of the patient.

The device **1950** includes a housing **1958**, cap **1952**, lock member **1962**, needle hub **1965**, main body **1980**, retainer body **1978**, and sleeve **1982**. Also included are the first spring **1960** and a second spring **1966**.

The device **1950** functions as follows. The lock member **1962**, needle hub **1964**, and retainer body **1978** are moveable longitudinally with respect to the housing **1958** and sleeve **1982** of the device **1950**. The lock member **1962** is positioned so that needle **1968** of the needle hub **1965** is accessible from open end **1984** of the device **1950**. The site **1970** can then be loaded onto the needle **1968** by threading the cannula of the site **1970** onto the needle **1968**. Openings **1986** are formed by the housing **1958** to accommodate sites **1970** of various sizes (e.g., wings formed on sites).

Once the site **1970** has been loaded onto the needle **1968**, the lock member **1962** is moved in a direction C by the patient using projections **1974** that are accessible through slot **1976** of housing **1958** until barbs **1956** of the lock member **1962** engage an outer surface of the housing **1958**, as shown in FIG. **102**. In this position, the device **1950** is ready to insert the site **1970** into the skin of the patient.

Next, the sleeve **1982** of the device **1950** is placed against the skin of the patient. To initiate insertion of the site **1970**, the cap **1952** is pressed by the patient. Once pressed, shoulders **1954** on an opposite end of the cap **1952** engage and push the barbs **1956** of the lock member **1962** toward one another to disengage the barbs **1956** from the housing **1958**. When the barbs **1956** clear the housing **1958**, the lock member **1962**, main body **1980**, needle hub **1965**, retainer body **1978**, and associated site **1970** are moved by the first spring **1960** a the direction D.

The device **1950** continues to move the site **1970** towards the skin, thereby introducing the needle **1968** and cannula of the site **1970** into the skin. As the cannula of the site **1970** is

fully inserted into the skin, barbs **1964** of the needle hub **1965** engage ramped surfaces **1972** of the sleeve **1982**, causing the barbs **1964** to be forced toward one another. When the cannula of the site **1970** is fully inserted into the skin, the barbs **1964** have been forced inwardly by the surfaces **1972** sufficiently to clear ends **1988** of the main body **1980**, and the second spring **1966** moves the needle hub **1965** in the direction C into a passage **1990** formed by the main body **1980**.

As the needle hub **1965** is moved by the second spring **1966** into the main body **1980**, the needle **1968** is removed from the site **1970**, leaving the site **1970** in place on the skin. In addition, the retainer body **1978** remains in a position adjacent the open end **1984** of the sleeve **1982** so that once the device **1950** is removed from the skin of the patient, the retainer body **1978** protects the patient from further contact with the needle **1968**.

Infusion devices made in accordance with the principles described herein can be advantageous for various reasons. For example, the set can be coupled in various selectable rotational orientations with respect to the site. In some embodiments, a plurality of orientations can be provided. This allows a patient to rotationally orient the set (and associated tube coupled to the set) as desired so that the tube can extend, for example, towards an infusion pump regardless of where the site is placed on the body of the patient.

In addition, the set and associated tube can be removed from the site multiple times while leaving the site on the skin. This can be desirable if the patient wants to reorient the set with respect to the site, or if the patient wants to remove the set from the site for a period of time, such as if the patient wishes to shower and then replace the set onto the site. Further, the site is preferably configured to have a low profile to be unobtrusive to the patient.

The engagement of the set with the site and sliding action of the set from the unlocked to locked position can also be advantageous in that a patient can preferably accomplish orientation and coupling of the set to the site using a single hand. This can be preferable, for example, if the site has been placed on a portion of the body of the patient that is not easily reached using two hands, or cannot easily be seen by the patient (e.g., if the site is placed on the back of the patient).

Further, the configuration of the set functions to protect the patient from inadvertent contact with the hollow needle (e.g., needles **214** and **411**) used to pierce the diaphragm and deliver the substance to the site. For example, the outer arms **220** and **222** and the inner arms **226** and **228** of the first member **210** of the set **200** generally surround the needle **214** and function to reduce the chance that the patient will inadvertently contact the needle.

Also, the configuration of the diaphragm in the site can be preferable in that a single diaphragm can function to both allow introduction of the cannula of the site into the body using one needle, as well as coupling of the set with the site using a second needle. In addition, the diaphragm can preferably be held within the site through frictional engagement between the diaphragm and the site without requiring additional structure to retain the diaphragm in the site.

Although examples of infusion devices have been described herein, various modifications can be made to the devices. For example, as noted above the member **120** of the site **100** and the aperture **270** of the set **200** can be formed in a variety of shapes to allow the set **200** to be oriented in multiple positions with respect to the site **100**. In addition, a retaining member can be fitted over the open top of the member **120** to further retain the diaphragm **150** in position in the cavity **121**

In another alternative embodiment, the second member **250** of the site **200** can be constructed to include a cover portion extending from the main body **260** so that when the set **200** is moved to the locked position the cover extends over the closed end **154** of the diaphragm **150** to reduce exposure of the set and site to outside contaminants.

Devices used to insert infusion devices made in accordance with the principles described herein can be advantageous for various reasons. For example, each device can provide ease in placement of the site on the skin, preferably allowing the user to place the site with the device where desired on the body using a single hand to operate the device.

Further, several embodiments disclosed herein include structures that cover or hide the needle prior to insertion of the site, and also cause the needle to be retracted into the device after insertion to protect against inadvertent contact with the needle.

In addition, several embodiments of the devices disclosed herein can automatically retract the needle while leaving the site placed on the skin, thereby reducing the patient's contact with the exposed needle. Preferably, this retraction is automatic in that once the device reaches the trigger state there is no further action required by the patient to cause the needle to be retracted. The automatic retraction of the needle also limits the dwell time of the needle in the patient, increasing comfort for the patient.

In addition, the action of inserting the needle into position on the skin using the devices disclosed herein can function to hold the site on the surface of the skin during needle retraction. This can assist in adherence of the adhesive portion to the skin and reduce the chances of separation between the adhesive portion and site and the skin during needle retraction.

In addition, the housing and cap of several of embodiments of the devices disclosed herein allow the various components of the devices including the needle and infusion device to be delivered to the patient in a self-contained, sterile environment prior to use. The configuration further minimizes the need for packaging surrounding the devices, reducing manufacturing cost and increasing ease in use of the devices. The configuration also allows the housing and cap to protect and maintain the site on the needle of the device. The configuration and disposable nature of the devices further allow ease in discarding of the devices after use.

Also, the configuration of several embodiments of the devices disclosed herein can allow the site to be preloaded into the device, thereby providing ease of use for the patient and reducing the patient's exposure to the needle. For example, single-use embodiments disclosed herein preferably do not require that the patient load the site into the device prior to insertion, but instead provide the device with the site preloaded.

Some embodiments of the devices allow for both automatic delivery of the site and withdrawal of the needle, thereby automating the entire introduction process for the patient.

While single use devices are preferred, reusable devices wherein the needle retracts but can be reloaded are also anticipated.

The above specification, examples and data provide a complete description of the manufacture and of the invention. Since many embodiments of the invention can be made without departing from the spirit and scope of the invention, the invention resides in the claims hereinafter appended.

What is claimed is:

1. A method for introducing an infusion device into a subcutaneous layer of skin of a patient, comprising:

providing an infusion device preloaded onto a needle of an insertion device so that the needle extends through a cannula of the infusion device, and a sleeve coupled to a housing of the insertion device that hides the needle

prior to retraction, wherein the needle is coupled to the housing of the insertion device so that, as the housing is moved relative to the sleeve, the needle is moved relative to the sleeve;

positioning the insertion device adjacent to the skin of the patient;

allowing a patient to manually introduce the cannula of the infusion device into a subcutaneous layer of skin of the patient by manually moving the housing and the needle of the insertion device relative to the sleeve from a retracted position to an extended position, wherein manually moving the needle is accomplished by allowing the patient to move the housing relative to the sleeve towards the skin of the patient; and

upon full manual insertion of the cannula by the insertion device and the insertion device reaching a trigger state, automatically moving the needle of the insertion device from the extended position to the retracted position while leaving the sleeve in contact with the skin of the patient.

2. The method of claim **1**, wherein the step of providing an infusion device further comprises coupling a cap to the insertion device.

3. The method of claim **2**, further comprising removing the cap prior to introducing the cannula into the subcutaneous layer of skin of the patient.

4. The method of claim **1**, wherein the infusion device includes a site having the cannula, and a set, and the method further comprises coupling the set to the site of the infusion device positioned on the skin of the patient.

5. The method of claim **4**, wherein the step of coupling the set to the site of the infusion device further comprises:

positioning the set in an unlocked position over the site;

positioning the set onto the site; and

moving the set from the unlocked position to a locked position to couple the set to the site and to introduce a needle of the set into a reservoir defined by the site.

6. The method of claim **5**, wherein the step of moving further comprises sliding a first member of the set relative to a second member of the set to move the set from the unlocked position to the locked position.

7. The method of claim **5**, further comprising moving the set from the locked position to the unlocked position.

8. The method of claim **7**, further comprising:

reorienting the set rotationally relative to the site; and

moving the set from the unlocked position to the locked position to recouple the set to the site and to reintroduce a needle of the set into a reservoir defined by the site.

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