



US009180277B2

(12) **United States Patent**
Erskine

(10) **Patent No.:** **US 9,180,277 B2**
(45) **Date of Patent:** **Nov. 10, 2015**

(54) **RELEASE MECHANISM FOR USE WITH
NEEDLE SHIELDING DEVICES**

USPC 604/263
See application file for complete search history.

(75) Inventor: **Timothy J. Erskine**, Sister Bay, WI
(US)

(56) **References Cited**

(73) Assignee: **Erskine Medical LLC**, High Falls, NY
(US)

U.S. PATENT DOCUMENTS

2,798,487 A 7/1957 Ferguson
3,459,183 A 8/1969 Ring et al.

(Continued)

(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 203 days.

FOREIGN PATENT DOCUMENTS

(21) Appl. No.: **13/997,973**

CN 1145813 A 3/1997
CN 1547493 A 11/2004

(22) PCT Filed: **Dec. 2, 2011**

(Continued)

(86) PCT No.: **PCT/US2011/063118**

OTHER PUBLICATIONS

§ 371 (c)(1),
(2), (4) Date: **Jun. 25, 2013**

Erskine, Australian IP Examination Report No. 2 dated Feb. 25, 2010,
Reference No. 30355386/MRF/TLG/tzs, Application No.
2006220690, 2 pages.

(87) PCT Pub. No.: **WO2012/075421**

(Continued)

PCT Pub. Date: **Jun. 7, 2012**

(65) **Prior Publication Data**

US 2014/0046272 A1 Feb. 13, 2014

Primary Examiner — Jason Flick

(74) *Attorney, Agent, or Firm* — Hoffman Warnick LLC

Related U.S. Application Data

(60) Provisional application No. 61/419,005, filed on Dec.
2, 2010.

(51) **Int. Cl.**

A61M 5/00 (2006.01)

A61M 25/06 (2006.01)

(Continued)

(52) **U.S. Cl.**

CPC **A61M 25/0618** (2013.01); **A61M 25/0009**
(2013.01); **A61M 5/3273** (2013.01); **A61M**
2005/325 (2013.01); **Y10T 29/49826** (2015.01)

(58) **Field of Classification Search**

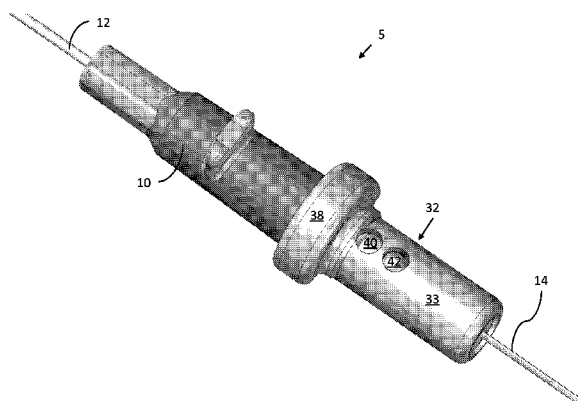
CPC A61M 25/0009; A61M 25/0618;
A61M 2005/325; A61M 5/3273; Y10T
29/49826

(57)

ABSTRACT

A needle-based medical device and method of manufacturing the same are disclosed. A needle device includes a hub having a longitudinal axis; a needle having a sharp distal tip; and a needle shield assembly associated with the needle and moveable from a non-shielding position to a shielding position. In the shielding position, the sharp distal tip is covered by at least part of the needle shield assembly. A latch is further provided for engaging with the hub when the needle shield assembly is in the non-shielding position; as well as a locking member operably connected to the needle shield assembly, and located at least partially within the hub when the needle shield assembly is in the non-shielding position. The latch and locking member lock the latch to the hub, such that when the needle shield assembly moves into the shielding position, the locking member moves generally proximally, unlocking the latch.

26 Claims, 15 Drawing Sheets



Page 2

[illegible]

(56)

References Cited

FOREIGN PATENT DOCUMENTS

WO	2010101573	A1	9/2010
WO	2010110789	A1	9/2010
WO	2012075402	A1	6/2012

OTHER PUBLICATIONS

Erskine, Canadian Application No. 2,599,943, Office Action dated Nov. 20, 2009, 2 pages.

Erskine, Chinese Application No. 200680007590, Office Action dated May 21, 2010, 4 pages.

Erskine, Australian Application No. 2006220691, Notice of Acceptance dated Jun. 9, 2010, 2 pages.

Erskine, Canadian Application No. 2,599,945, Office Action dated Nov. 13, 2009, 2 pages.

Erskine, Chinese Application No. 200680007484, Notification to Grant Patent Right dated Jun. 11, 2010, 4 pages.

Patent Cooperation Treaty, PCT/US06/07911, PCT International Search Report and Written Opinion, dated Jun. 23, 2006, 8 pages.

Patent Cooperation Treaty, PCT/US06/07911, PCT International Preliminary Report on Patentability, dated Feb. 12, 2007, 4 pages.

Erskine, U.S. Appl. No. 11/817,891, Office Communication dated Jun. 11, 2010, 11 pages.

Erskine, Australian Application No. 2006220692, Examiners First Report on Patent Application dated Oct. 21, 2008, 2 pages.

Erskine, Canadian Application No. 2,599,955, Office Action dated Mar. 5, 2010, 2 pages.

Erskine, Chinese Application No. 200680007485.0, Office Action dated Jun. 19, 2008, 6 pages.

Erskine, Chinese Application No. 200680007485.0, Notification to Grant Patent Right dated Jun. 4, 2010, 5 pages.

Erskine, Japanese Application No. P2008-500805, Office Action dated Apr. 20, 2010, 4 pages.

Erskine, Malaysia Application No. PI 20071465, Substantive Examination Report dated Apr. 30, 2010, 3 pages.

Patent Cooperation Treaty, PCT/US06/07912, PCT International Preliminary Report on Patentability, dated Sep. 20, 2007, 5 pages.

Patent Cooperation Treaty, PCT/US06/07912, PCT International Search Report and Written Opinion, dated Jun. 26, 2006, 8 pages.

Erskine, Taiwanese Application No. 095107584, Decision to Grant Patent dated Mar. 4, 2009, 5 pages.

Erskine, U.S. Appl. No. 11/817,687, Office Communication dated Jun. 30, 2010, 8 pages.

Erskine, U.S. Appl. No. 11/817,687, Office Communication dated Jan. 21, 2010, 9 pages.

Erskine, Australian Application No. 2006220689, Examiners First Report on Patent Application dated Jan. 15, 2009, 3 pages.

Erskine, Australian Application No. 2006220689, Patent Granted dated Jun. 18, 2010, 3 pages.

Erskine, Canadian Application No. 2,599,938, Office Action dated Feb. 23, 2010, 2 pages.

Erskine, Chinese Application No. 200680007548.2, Office Action dated Sep. 4, 2009, 4 pages.

Erskine, Chinese Application No. 200680007548.2, Notification to Grant Patent Right dated Jun. 12, 2010, 4 pages.

Erskine, Australian Application No. 2006220690, Notice of Acceptance dated Jun. 15, 2010, 3 pages.

Erskine, Japanese Application No. P2008-500802, Office Action dated Jun. 29, 2010, 6 pages.

Erskine, Malaysia Application No. PI 20071468, Substantive Examination Report dated Apr. 16, 2010, 2 pages.

Patent Cooperation Treaty, PCT/US06/07910, PCT International Preliminary Report on Patentability, dated Jul. 3, 2007, 20 pages.

Patent Cooperation Treaty, PCT/US06/07909, PCT International Search Report and Written Opinion, dated Jun. 26, 2006, 8 pages.

Erskine, Taiwanese Application No. 095107593, Decision to Grant Patent dated Dec. 11, 2009, 5 pages.

Patent Cooperation Treaty, PCT/US09/036197, PCT International Search Report and Written Opinion dated Apr. 28, 2009, 14 pages.

Patent Cooperation Treaty, PCT/US09/038246, PCT International Search Report and Written Opinion dated May 20, 2009, 11 pages.

Erskine, U.S. Appl. No. 11/817,891, Office Communication dated Oct. 19, 2009, 10 pages.

Erskine, Australian Application No. 2006220690, Examiner's First Report on Patent dated Nov. 11, 2008, 3 pages.

Erskine, Chinese Application No. 200680007590, Office Action (Translation) dated Aug. 21, 2009, 11 pages.

Erskine, European Application No. EP06737126, Supplementary European Search Report dated Feb. 11, 2010, 4 pages.

Patent Cooperation Treaty, PCT/US06/07910, PCT International Search Report and Written Opinion, dated Jul. 5, 2006, 8 pages.

OMGBA, Office Action Communication for U.S. Appl. No. 13/114,589 dated Sep. 14, 2012, 39 pages.

Shamsudin, Substantive/Modified Substantive Examination and Search Report, Application No. PI 20071467, Mar. 15, 2013, 4 pages.

Ehrsam, Supplementary European Search Report, Application No. EP 09 84 1250, Feb. 26, 2013, 5 pages.

OMGBA, Office Action Correspondence, U.S. Appl. No. 13/114,589, Apr. 10, 2013, 15 pages.

Desanto, Office Action Communication for U.S. Appl. No. 11/817,890 dated Jun. 6, 2013, 19 pages.

Patent Cooperation Treaty, International Preliminary Report on Patentability for PCT/US2011/063081 dated Jun. 4, 2013, 7 pages.

Patent Cooperation Treaty, International Preliminary Report on Patentability for PCT/US2011/063118 dated Jun. 4, 2013, 8 pages.

European Patent Office, Intention to Grant for EP Application No. 06 737 126.0 dated Jun. 17, 2013, 92 pages.

Canadian Patent Office, Notice of Allowance for CA Application No. 2,599,943 dated Jul. 3, 2013, 1 page.

Price, U.S. Appl. No. 11/817,891, Non-Final Office Action, Sep. 16, 2014, 94 pgs.

Desanto, Notice of Allowance and Fee(s) Due for U.S. Appl. No. 11/817,890 dated Sep. 17, 2013, 17 pages.

Matney, Office Action Communication for U.S. Appl. No. 13/254,163 dated Oct. 15, 2013, 81 pages.

OMGBA, Office Action Communication for U.S. Appl. No. 13/114,589 dated Oct. 31, 2013, 19 pages.

Patent Cooperation Treaty, Preliminary Report on Patentability and Written Opinion of the International Searching Authority for PCT/US2012/032578 dated Oct. 8, 2013, 10 pages.

Patent Cooperation Treaty, Notification of Transmittal of the International Search Report and the Written Opinion of the International Searching Authority, or the Declaration for PCT/US2011/063118 dated Apr. 3, 2012, 17 pages.

Patent Cooperation Treaty, Notification of Transmittal of the International Search Report and the Written Opinion of the International Searching Authority, or the Declaration for PCT/US2011/063081 dated Mar. 22, 2012, 10 pages.

Desanto, Office Action Communication for U.S. Appl. No. 11/817,890 dated Apr. 30, 2012, 14 pages.

Patent Cooperation Treaty, Notification of Transmittal of the International Search Report and the Written Opinion of the International Searching Authority, or the Declaration for PCT/US12/32578 dated Aug. 3, 2012, 26 pages.

European Patent Office, European Search Report for EP12169737 dated Jul. 25, 2012, 4 pages.

European Patent Office, European Search Report for EP12169713 dated Jul. 26, 2012, 5 pages.

European Patent Office, Supplementary European Search Report for EP09842422 dated Aug. 27, 2012, 7 pages.

Desanto, Office Action Communication for U.S. Appl. No. 11/817,890 dated Oct. 11, 2012, 26 pages.

Becamel, International Application No. PCT/US2009/036197, PCT International Preliminary Report on Patentability and Written Opinion of the International Searching Authority, Sep. 15, 2011, 10 pages.

Price, Office Action Communication for U.S. Appl. No. 11/817,892 dated Oct. 6, 2011, 14 pages.

Patent Cooperation Treaty, International Preliminary Report on Patentability and Written Opinion of the International Searching Authority for PCT/US2009/038246 dated Oct. 6, 2011, 7 pages.

Canadian Intellectual Property Office, Office Action for Application No. 2,599,943 dated Oct. 13, 2011, 2 pages.

(56)

References Cited

OTHER PUBLICATIONS

IP Australia, Examiners First Report on Patent Application No. 2010203121 dated Nov. 4, 2011, 2 pages.
 Erskine, Office Communication for U.S. Appl. No. 11/817,687 dated Dec. 9, 2010, 19 pages.
 Erskine, Mexican Application No. MX/a/2007/010944, Office Action dated Mar. 11, 2011, 4 pages.
 Erskine, Japanese Application No. JP07-5616-XY, Decision to Grant a Patent, dated Apr. 5, 2011, 6 pages.
 Erskine, Taiwan Application No. 095107585, Office Action, dated Mar. 17, 2011, 3 pages.
 Erskine, Mexican Application No. MX/a/2007/010946, Office Action, dated Apr. 2011, 2 pages.
 Erskine, Japan Application No. P2008-500802, Notice of Reasons for Rejection, dated Apr. 5, 2011, 4 pages.
 Erskine, China Application No. 201010109122.6, Office Action, dated Apr. 1, 2011, 11 pages.
 Erskine, Office Action Communication for U.S. Appl. No. 11/817,892 dated Apr. 28, 2011, 25 pages.
 Patent Cooperation Treaty, PCT Notification of Transmittal of International Preliminary Report on Patentability for PCT Application No. PCT/US06/07909 dated Aug. 16, 2007, 13 pages.
 Erskine, Malaysia Application No. PI20071466, Office Action, dated Aug. 30, 2010, 3 pages.
 Erskine, Taiwanese Application No. 095107587, Office Action dated Oct. 12, 2009, 12 pages.
 Erskine, Australian Application No. 2006220691, Examiner's First Report on Patent dated Jan. 19, 2009, 2 pages.
 Erskine, Chinese Application No. 200680007484, Office Action dated Aug. 21, 2009, 13 pages.
 Erskine, Taiwanese Application No. 095107585, Office Action dated Apr. 6, 2009, 9 pages.
 Erskine, Taiwanese Application No. 095107585, Office Action dated Oct. 15, 2009, 7 pages.
 European Patent Office, European Search Report for Application No. EP06737125, dated Feb. 10, 2010, 7 pages.
 Erskine, Canadian Application No. 2,599,943, Office Action dated Dec. 30, 2010, 2 pages.

Erskine, Canadian Application No. 2,599,945, Notice of Allowance dated Nov. 25, 2010, 1 pages.
 Erskine, Canadian Application No. 2,599,955, Office Action dated Dec. 21, 2010, 3 pages.
 Erskine, Canadian Application No. 2,599,938, Office Action dated Dec. 20, 2010, 2 pages.
 Erskine, Japanese Application No. P2008-500805, Final Office Action dated Jan. 25, 2011, 25 pages.
 Erskine, Japanese Application No. P2008-500804, Notice to Grant dated Feb. 2, 2011, 6 pages.
 Desanto, Office Action Communication for U.S. Appl. No. 11/817,890 dated Aug. 31, 2011, 33 pages.
 Osinski, Notice of Allowance & Fee(s) Due for U.S. Appl. No. 11/817,687 dated Jun. 30, 2011, 8 pages.
 Erskine, Mexican Application No. MX/a/2007/010943, Office Action dated Jun. 10, 2011, 2 pages.
 State Intellectual Property Office of the the People's Republic of China, Notification of the First Office Action for Application No. CN 201180066317 dated Oct. 27, 2014, 19 pages.
 Price, Notice of Allowance and Fee(s) Due for U.S. Appl. No. 11/817,892 dated Dec. 19, 2014, 71 pages.
 Flick: U.S. Appl. No. 13/259,715, filed Dec. 2, 2011, Office Action Dec. 17, 2012, 42pgs.
 Final Office Action for U.S. Appl. No. 11/817,891, dated Jun. 9, 2015, 14 pages.
 Office Action for JP Application No. 2014-504040, dated Jun. 30, 2015, 6 pages.
 Office Action for CN Application No. 201180066317, dated Jun. 17, 2015, 5 pages.
 Office Action for U.S. Appl. No. 13/997,969, dated Jul. 16, 2015, 85 pages.
 Notice of Allowance and Fee(s) Due for U.S. Appl. No. 11/817,891, dated Aug. 25, 2015, 14 pages.
 Communication Pursuant to Article 94(3) EPC for EP Application No. 12169713.0, dated Aug. 4, 2015, 5 pages.
 Second Office Action for CN Application No. 201180066325.4, dated Jun. 16, 2015, 7 pages.

* cited by examiner

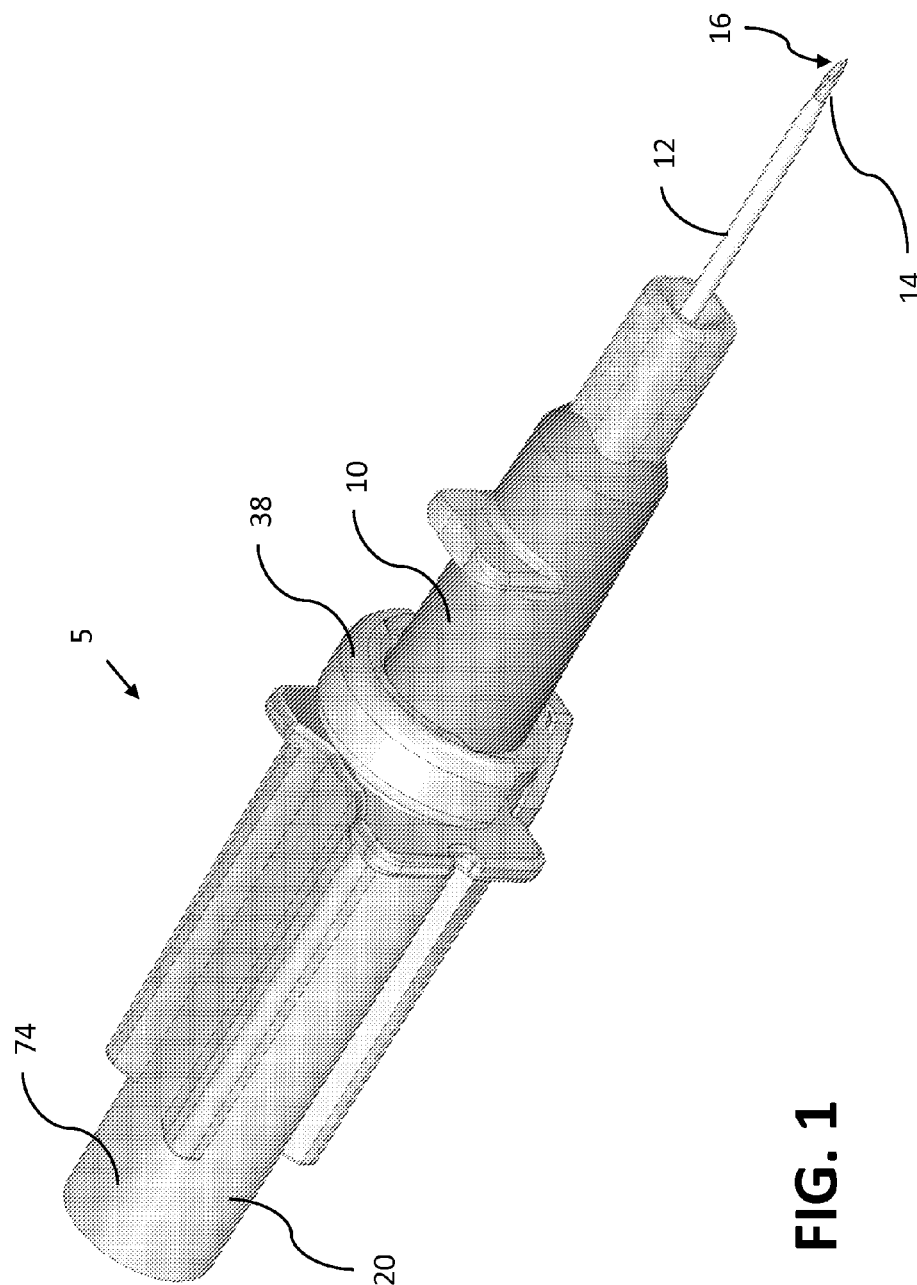


FIG. 1

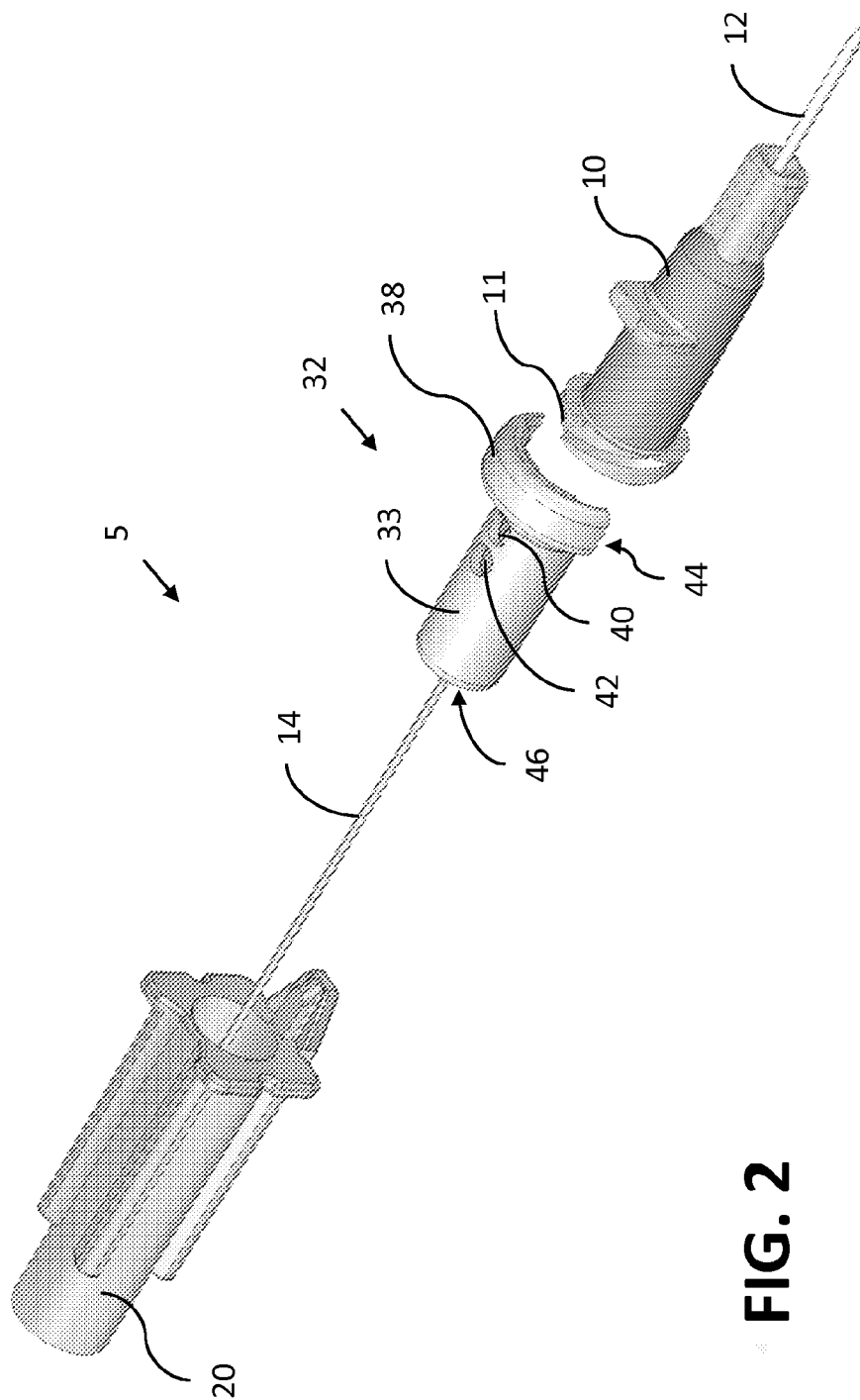
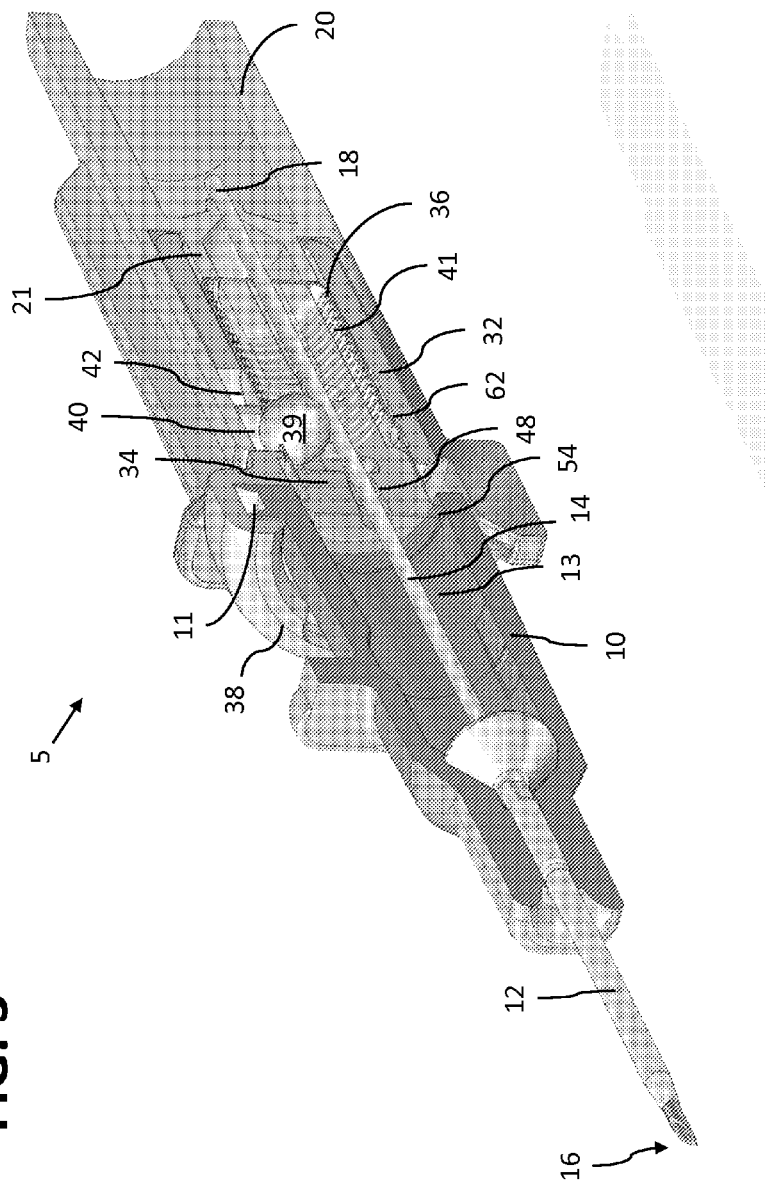


FIG. 2

FIG. 3



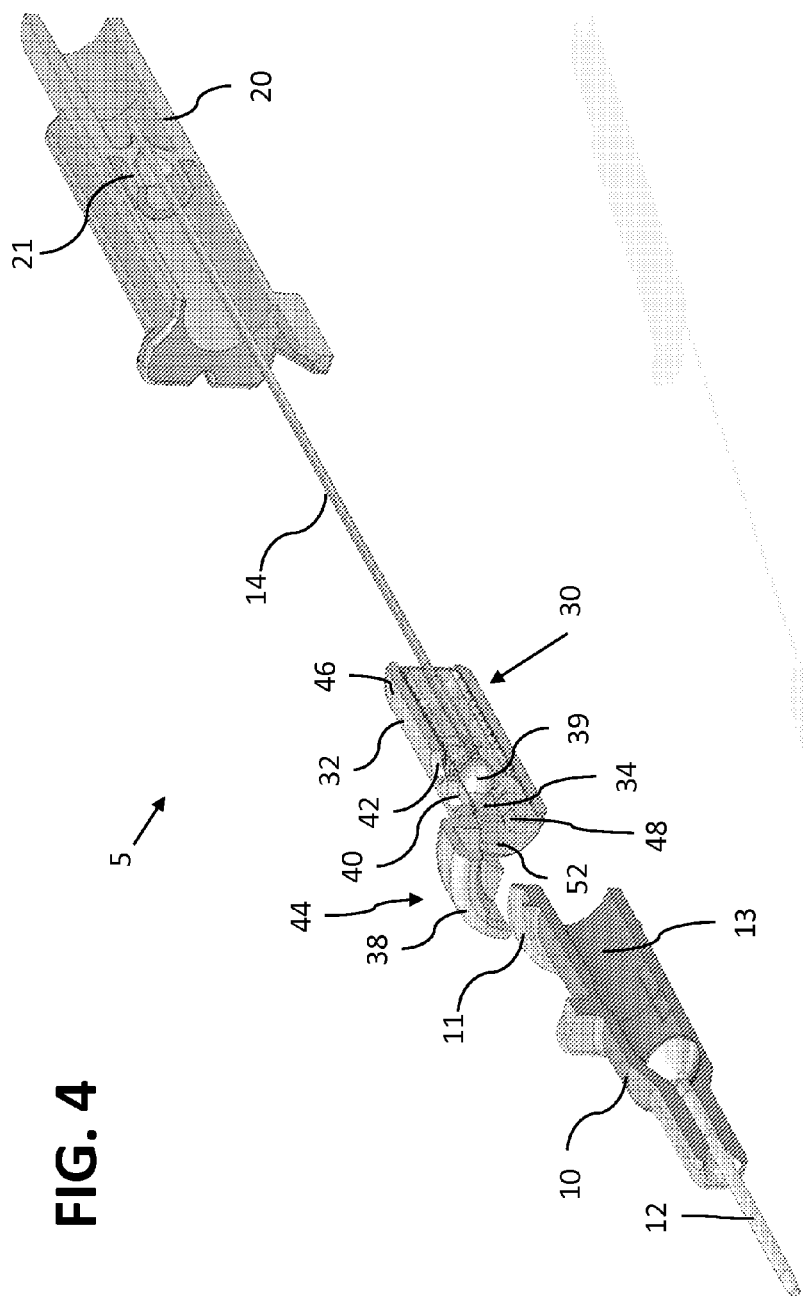


FIG. 5

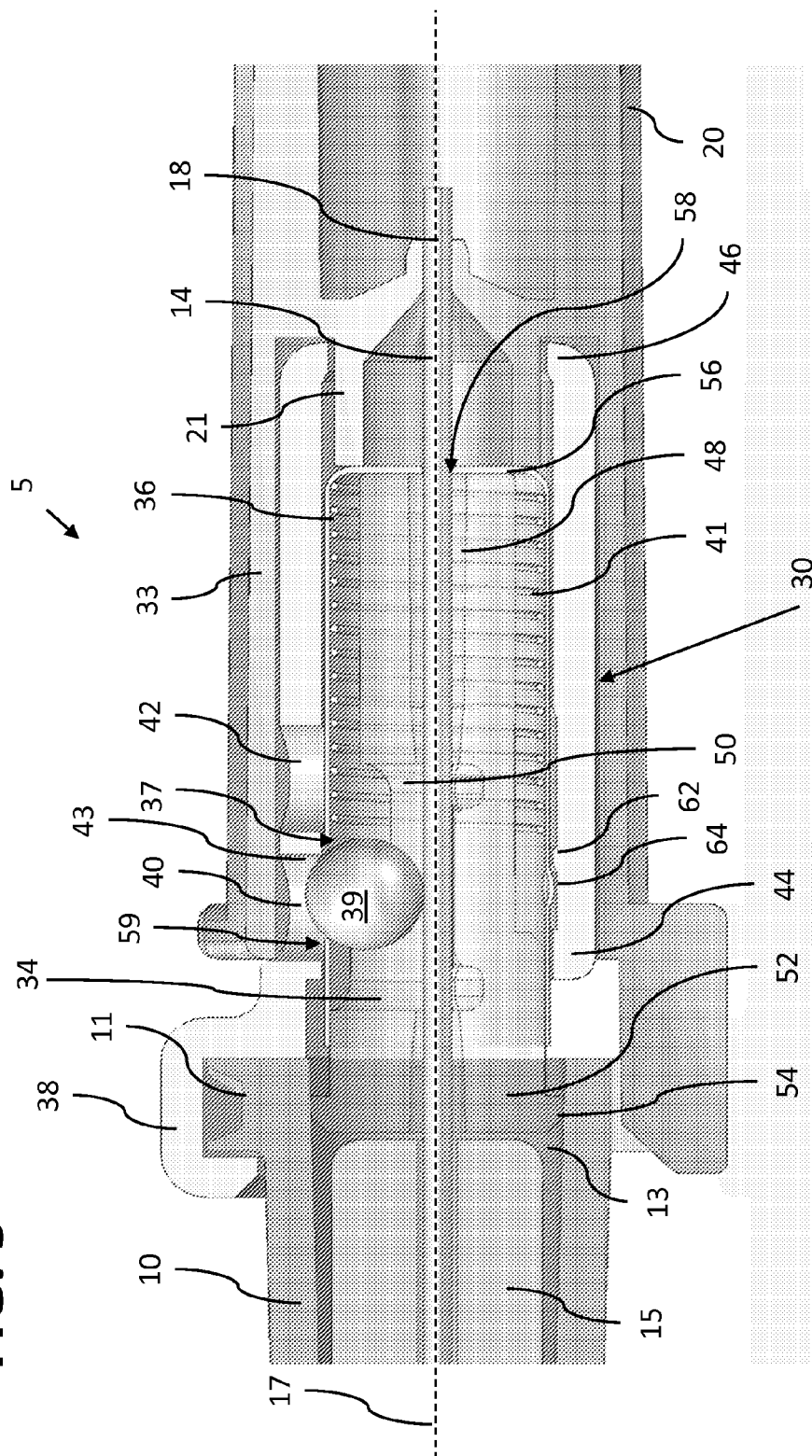


FIG. 7

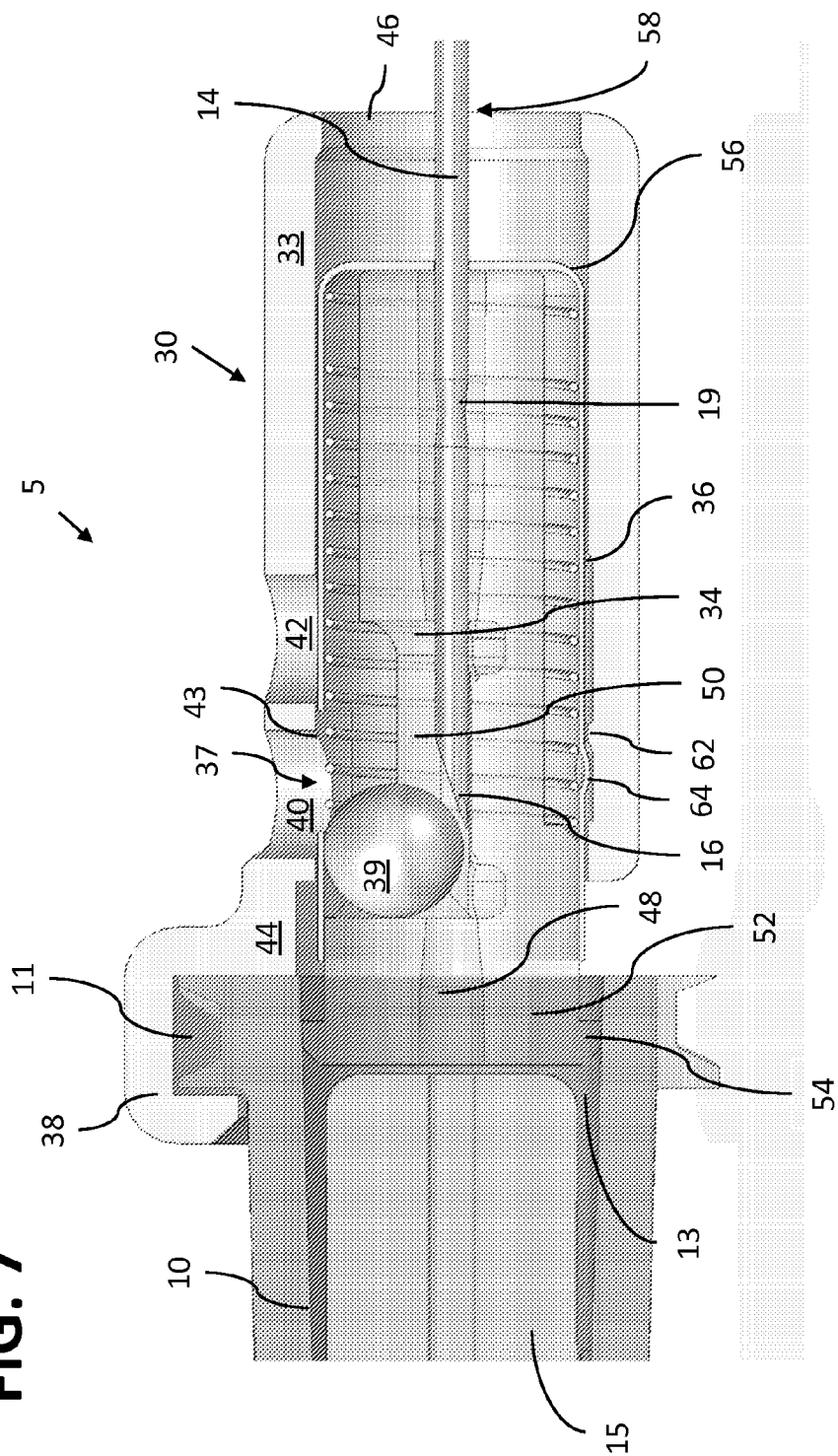
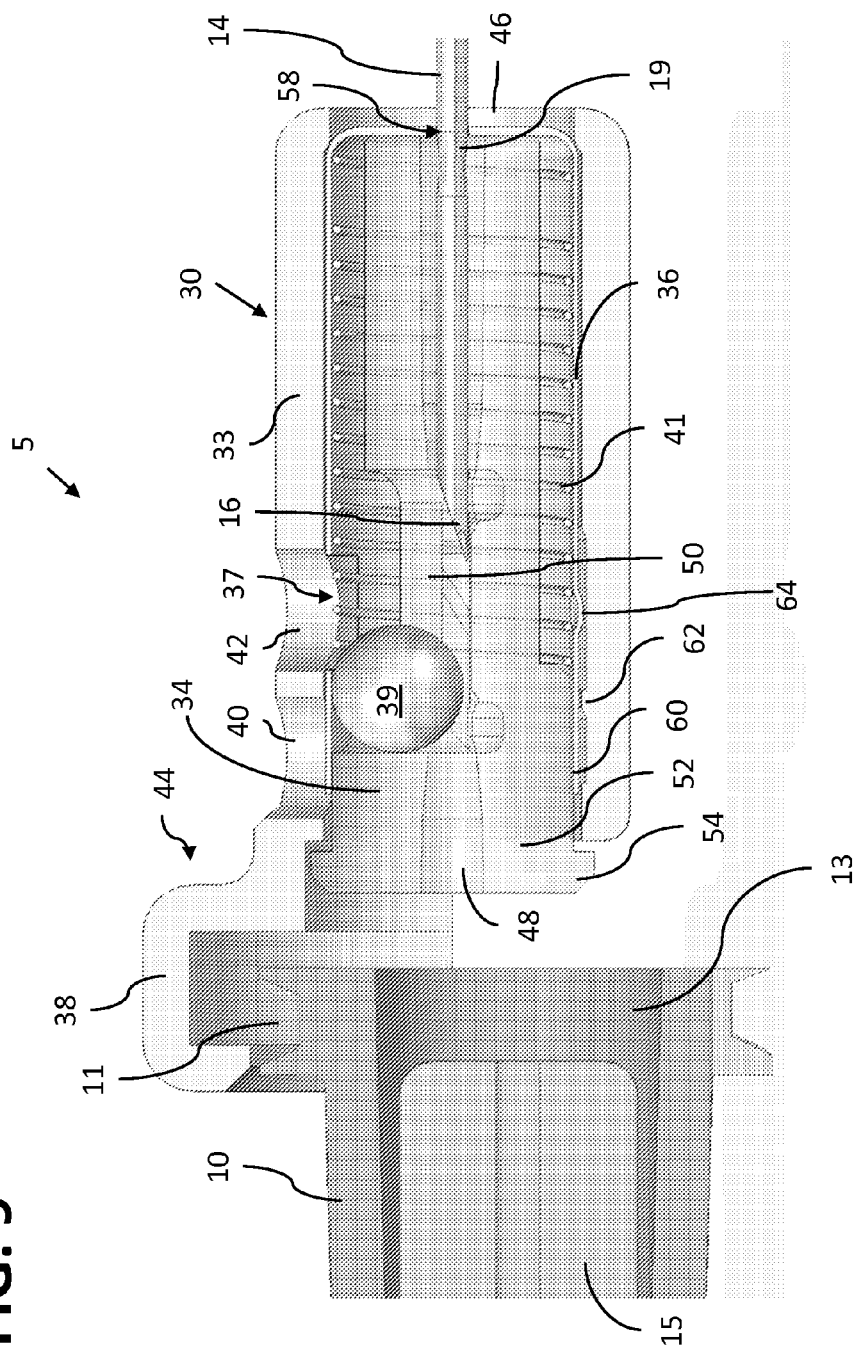


FIG. 9



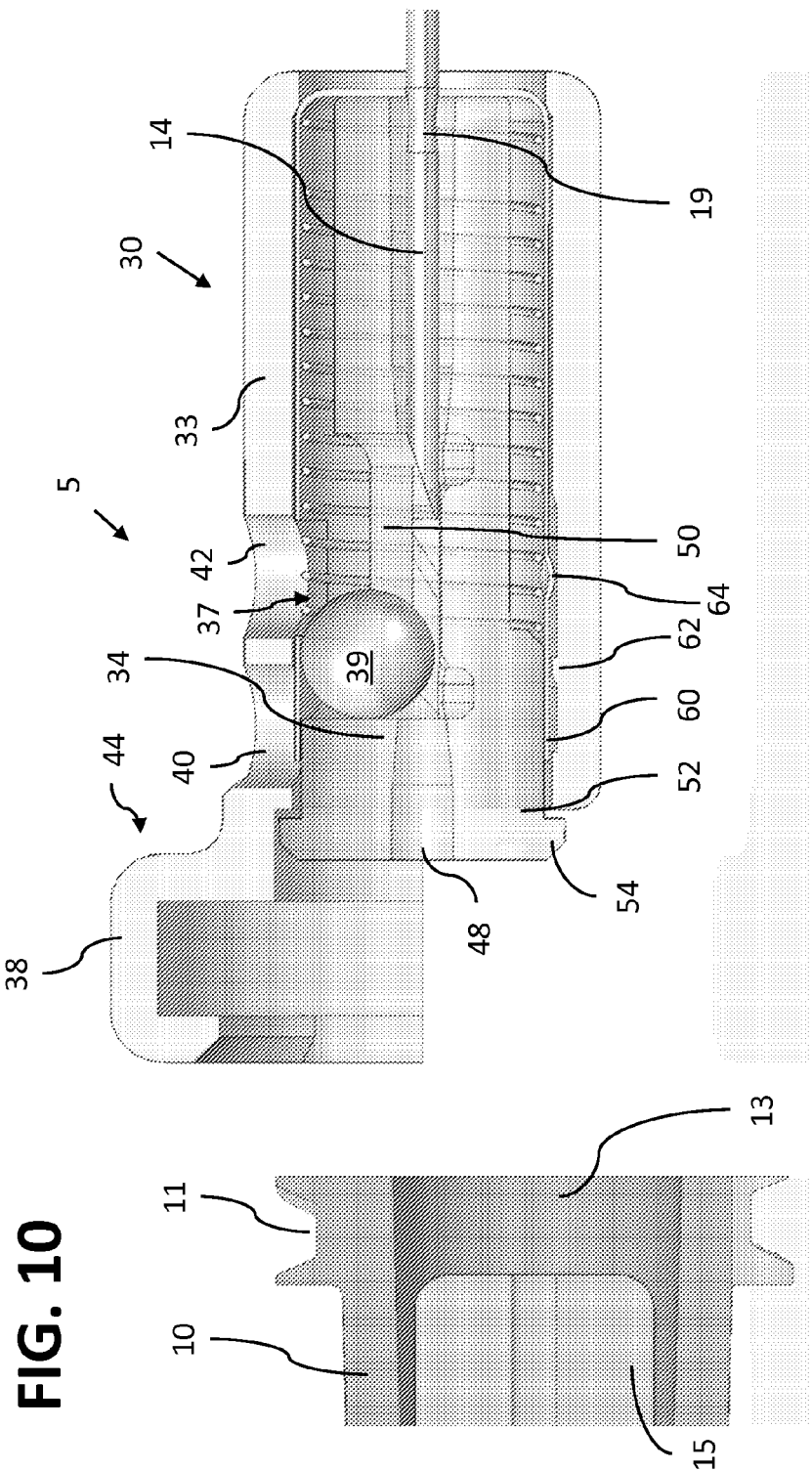


FIG. 10

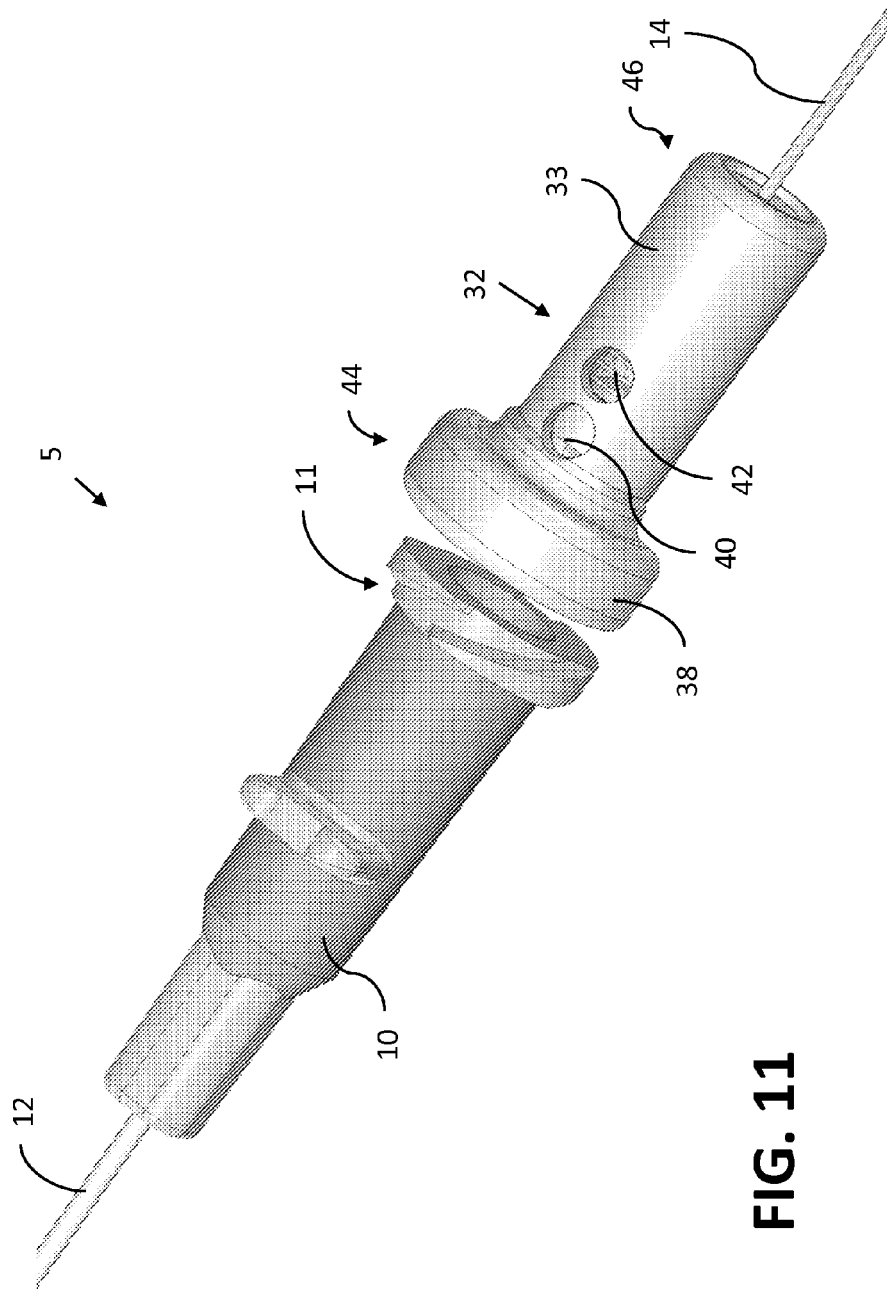


FIG. 11

FIG. 13

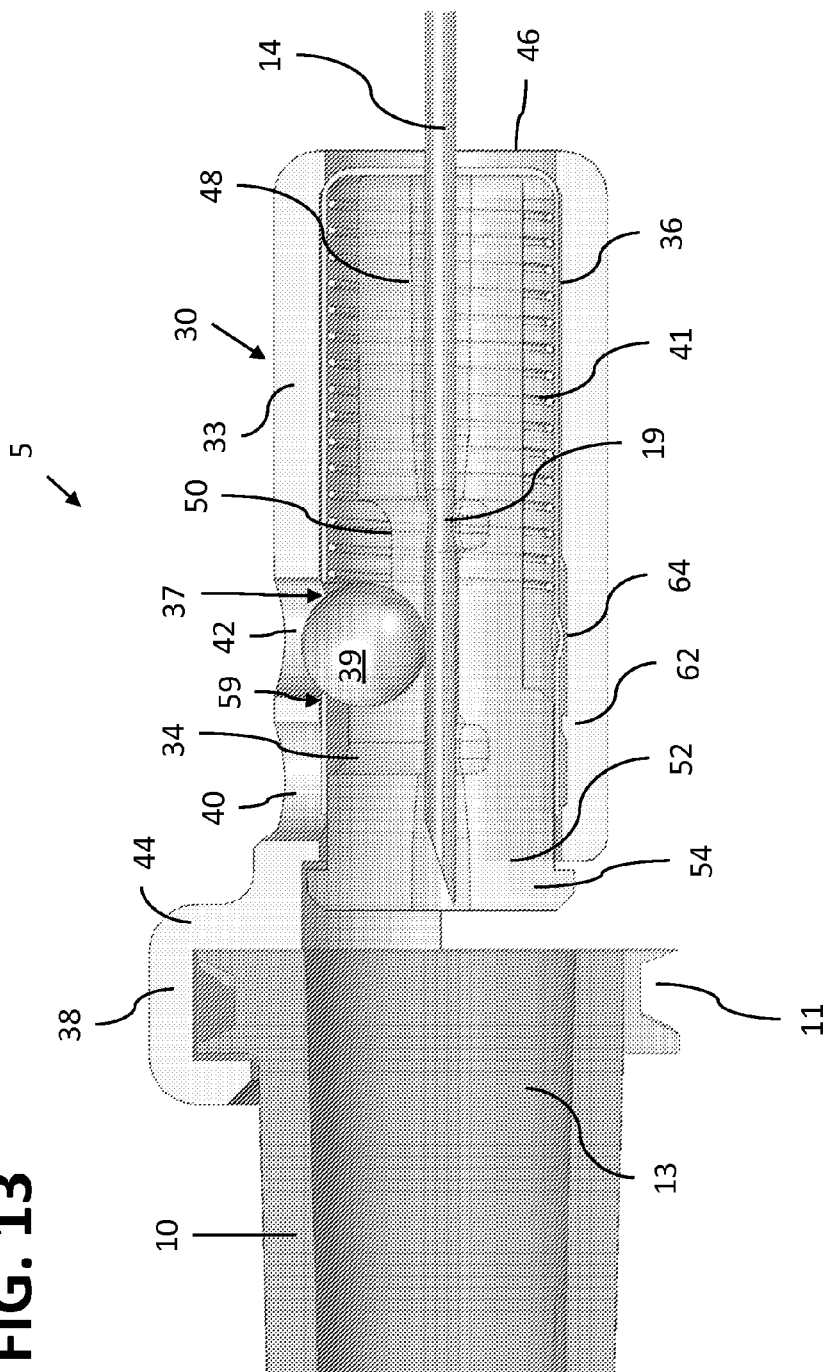
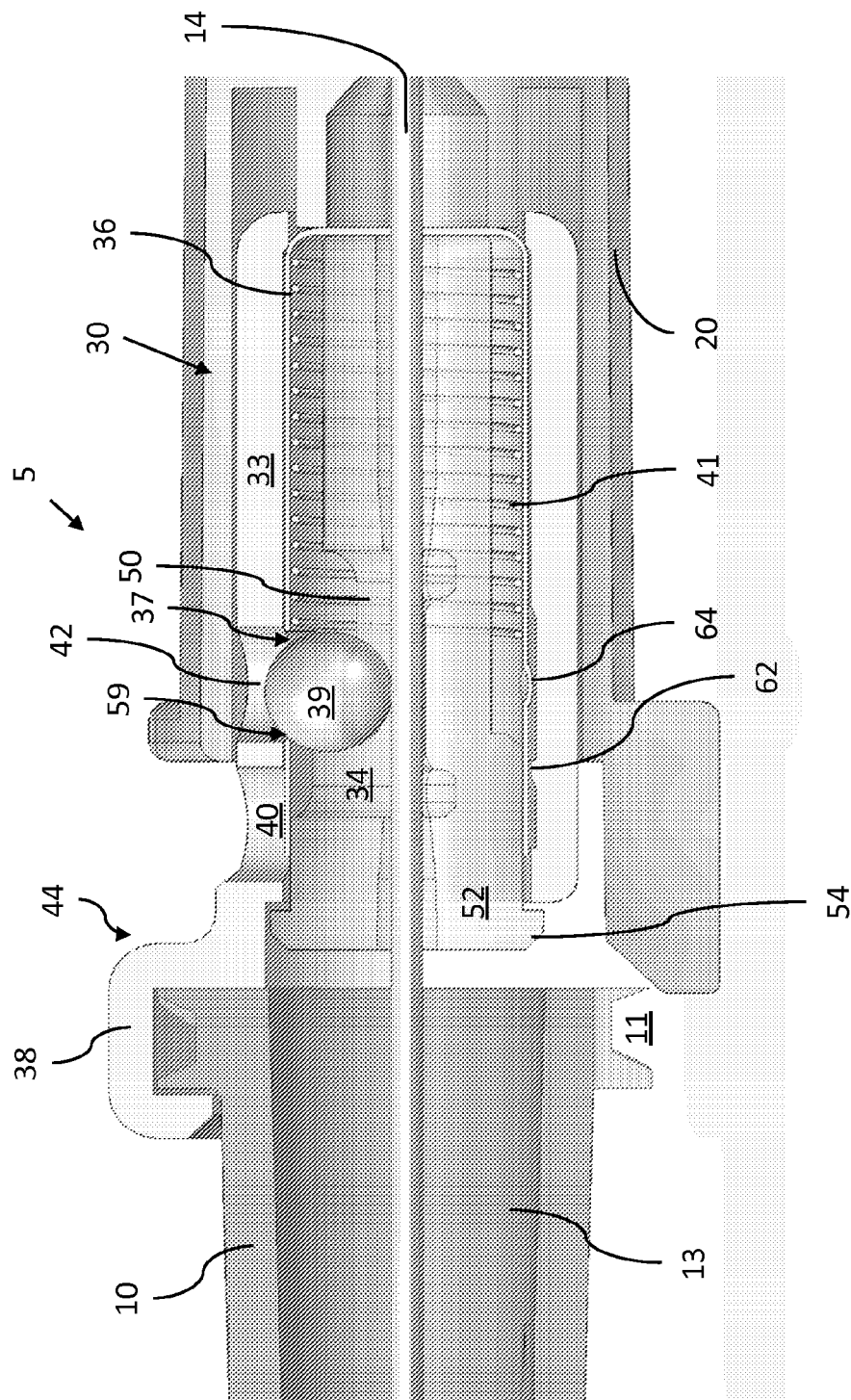


FIG. 14



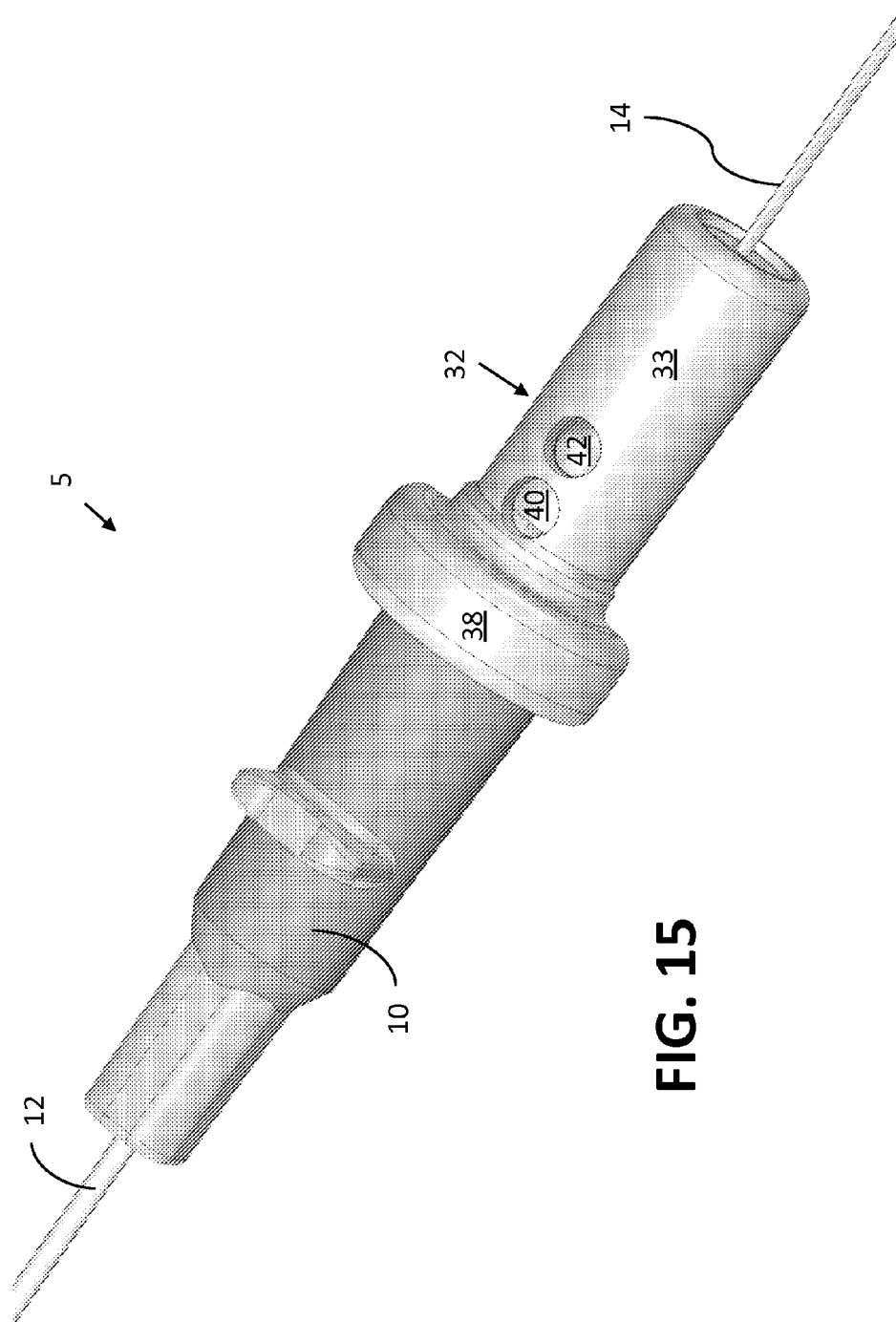


FIG. 15

1

RELEASE MECHANISM FOR USE WITH NEEDLE SHIELDING DEVICES

CROSS REFERENCE TO RELATED APPLICATION

This patent application claims the benefit of U.S. Provisional Patent Application Ser. No. 61/419,005, filed Dec. 2, 2010.

BACKGROUND OF THE INVENTION

The invention relates generally to needle-based medical devices. More particularly, the invention relates to a passive safety shield for a needle of a needle-based medical device which shields the needle prior to releasing from a device. Needle shielding devices come in a variety of forms that do not allow for easy and passive activation and disconnection from a hub, such as a catheter introducer hub. Furthermore, needle shielding devices protrude into the catheter introducer hub and occupy the volume of the female luer connector, thereby interfering with hemostatic valves and seals.

BRIEF DESCRIPTION OF THE INVENTION

A first aspect of the disclosure provides a needle device comprising a hub having a longitudinal axis; a needle having a sharp distal tip; a needle shield assembly associated with the needle and moveable from a non-shielding position to a shielding position in which the sharp distal tip is covered by at least part of the needle shield assembly; a latch engaging with the hub when the needle shield assembly is in the non-shielding position; and a locking member operably connected to the needle shield assembly, and located at least partially within the hub when the needle shield assembly is in the non-shielding position, thereby locking the latch to the hub, and such that when the needle shield assembly moves into the shielding position, the locking member moves generally proximally, thereby unlocking the latch.

A second aspect of the disclosure provides a needle device comprising: a hub comprising a luer connector with a luer thread and having a longitudinal axis; a needle having a sharp distal tip; a needle shield assembly associated with the needle and moveable from a non-shielding position to a shielding position in which the sharp distal tip is covered by at least part of the needle shield assembly; a latch engaging with the luer thread of the hub when the needle shield assembly is in the non-shielding position, a locking member operably connected to the needle shield assembly and located at least partially in the luer connector when the needle shield assembly is in the non-shielding position, thereby locking the latch to the hub, and such that when the needle shield assembly moves into the shielding position, the locking member moves axially.

A third aspect of the disclosure provides a method of manufacturing a needle assembly comprising: placing a blocking object in a carrier, wherein the carrier includes a flange disposed on a distal end thereof; inserting the carrier into a shroud; inserting the shroud into a housing until the proximal end of the shroud abuts a reduced diameter portion at a proximal end of the housing, wherein the housing includes a hooked member circumferentially extending from a portion of a distal end of the housing, and a first, distal opening and a second, proximal opening are provided through a wall of the housing; inserting a proximal end of a needle into an axial lumen of the carrier, thereby displacing the blocking object such that it protrudes at least partially through the proximal,

2

second opening in the housing; affixing the proximal end of the needle to a needle hub; threading a catheter hub and a cannula over a distal end of the needle, wherein the catheter hub has a flanged proximal end; and engaging the hooked member with the flanged proximal end of the catheter hub, and inserting the flange disposed on the distal end of the carrier into the catheter hub, wherein the engaging and inserting the flange causes the blocking object to move distally such that it protrudes from the first, distal opening in the housing.

These and other aspects, advantages and salient features of the invention will become apparent from the following detailed description, which, when taken in conjunction with the annexed drawings, where like parts are designated by like reference characters throughout the drawings, disclose embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a perspective view of a needle device including a needle shield assembly in a non-shielding position according to embodiments of the invention.

FIG. 2 shows an exploded perspective view of a needle device including a needle shield assembly according to embodiments of the invention.

FIG. 3 shows a cutaway perspective view of a needle device including a needle shield assembly in a non-shielding position according to embodiments of the invention.

FIG. 4 shows an exploded cutaway perspective view of a needle device including a needle shield assembly in a non-shielding position according to embodiments of the invention.

FIG. 5 shows a detailed cross-sectional view of the needle shield assembly and hub in a non-shielding position according to embodiments of the invention.

FIG. 6 shows a detailed cross-sectional view of the needle shield assembly in an intermediate non-shielding position according to embodiments of the invention.

FIG. 7 shows a detailed cross-sectional view of the needle shield assembly in an intermediate shielding position according to embodiments of the invention.

FIG. 8 shows a detailed cross-sectional view of the needle shield assembly in an intermediate shielding position according to embodiments of the invention.

FIG. 9 shows a detailed cross-sectional view of the needle shield assembly in an intermediate shielding position according to embodiments of the invention.

FIG. 10 shows a detailed cross-sectional view of the needle shield assembly in a shielding position according to embodiments of the invention.

FIG. 11 shows an exploded perspective view of a needle device including a needle shield assembly according to embodiments of the invention.

FIG. 12 shows a detailed cross-sectional view of the needle shield assembly in an intermediate non-shielding position according to embodiments of the invention.

FIG. 13 shows a detailed cross-sectional view of the needle shield assembly in an intermediate step of manufacturing the device in accordance with embodiments of the invention.

FIG. 14 shows a detailed cross-sectional view of the needle shield assembly and hub in an intermediate step of manufacturing the device in accordance with embodiments of the invention.

FIG. 15 shows a perspective view of a needle device including a needle shield assembly according to embodiments of the invention.

It is noted that the drawings of the disclosure are not necessarily to scale. The drawings are intended to depict only

3

typical aspects of the disclosure, and therefore should not be considered as limiting the scope of the disclosure. In the drawings, like numbering represents like elements between the drawings.

DETAILED DESCRIPTION OF THE INVENTION

As noted, a needle-based medical device including a needle shield **30** (FIG. **5**) will be described with reference to FIGS. **1-15**. At least one embodiment of the present invention is described below in reference to its application in connection with a needle-based medical device in the form of a catheter introducer. Although embodiments of the invention are illustrated relative to a needle-based medical device in the form of a catheter introducer, it is understood that the teachings are equally applicable to other needle-based medical devices including, but not limited to, syringes, blood collection devices, and other types of devices. Further, at least one embodiment of the present invention is described below in reference to a nominal size and including a set of nominal dimensions. However, it should be apparent to those skilled in the art that the present invention is likewise applicable to any suitable needle-based device. Further, it should be apparent to those skilled in the art that the present invention is likewise applicable to various scales of the nominal size and/or nominal dimensions.

With reference to FIGS. **1-3**, one embodiment is illustrated including a needle device **5** in the form of a catheter introducer assembly including a hub **10**, a catheter cannula **12**, and an introducer needle **14**.

In the embodiment shown in FIG. **2**, hub **10** includes a threaded proximal end **11** to which tubing and the like can be connected. Hub **10** also may include a female luer adapter **13** (FIGS. **3-4**) into which a male component such as a blood sealing device **15** (FIGS. **5-10**) such as a valve or septum can be placed within hub **10**. Although not shown, hub **10** may also include a port. Needle **14** includes a longitudinal axis **17** (FIG. **5**), a sharp distal end **16**, and a proximal end **18** (FIG. **3**).

As shown in FIGS. **3-5**, proximal end **18** of needle **14** is secured to a distal end of needle hub **20**, e.g., by glue using a glue well, which is described in co-pending US patent applications publications No. 2009/0036843A1 and No. 2009/0032185A1, each of which are incorporated herein by reference. Needle hub **20** may be secured at its proximal end to a handle **74**. Needle **14**, hub **10**, cannula **12**, and needle hub **20** may be substantially coaxial.

Referring to FIGS. **3-10**, needle shield assembly **30** and a latch **32** are provided for shielding distal tip **16** of needle **14**. Needle shield assembly **30** includes a needle blocking object **39**, and a carrier **34** for carrying needle blocking object **39**. Needle shield assembly **30** may further include an external shroud **36** disposed about carrier **34** and within latch **32**, and a spring **41** for biasing needle blocking object **39** as described herein.

Needle shield assembly **30** is movable between a non-shielding position (FIGS. **3**, **5-6**) and a shielding position (FIGS. **7-10**). FIGS. **5-10** illustrate one embodiment of progression from the non-shielding position, in which latch **32** and locking member **54** retain the needle shield assembly **30** in engagement with hub **10**, to the shielding position, in which needle shield assembly **30** prevents emergence of sharp distal end **16** of needle **14** therefrom.

With reference to FIG. **5**, needle shield assembly **30** will now be described. Needle shield assembly **30** includes carrier **34**, which may be substantially cylindrical and includes an axial lumen **48** substantially aligned with a longitudinal axis of the device. Axial lumen **48** accommodates needle **14** and

4

allows carrier **34** to slide along needle **14**. Carrier **34** may further include an internal member including a channel **50** or other structure for limiting radial movement of needle blocking object **39** toward the longitudinal axis of needle **14** in the shielding position of needle shield assembly **30**. In the illustrative embodiment, channel **50** is shaped and dimensioned such that needle blocking object **39** can be carried and can moved along channel **50** (FIGS. **5-10**) and dropped into place in the shielding position (FIGS. **7-10**). In the shielding position, needle blocking object lies at least partially across axial lumen **48**, thereby blocking emergence of sharp distal end **16** of needle **14**. In still further embodiments, carrier **34** may include an external shroud **36**. Shroud **36** may be made of metal, and may be substantially cup-shaped, such that it substantially encases carrier **34**, but is open at the distal end **60**. Carrier **34** can thus be inserted into shroud **36** such that a proximal end of the carrier abuts the inside of proximal end **56** of shroud **36**. Carrier **34** also includes a first opening **37** through which a portion of needle blocking object projects **39** while resting in channel **50** in a non-shielding position. In embodiments including shroud **36**, opening **37** extends through a thickness of a wall of shroud **36**.

A spring **41** may further be provided for biasing needle blocking object **39**. Spring **41** may be disposed about carrier **34**, and within shroud **36**, such that it abuts needle blocking object **39**. Spring **41** tends to urge needle blocking object distally and into lumen **48**, toward the axis of the device. Spring **41** may be, for example, a coil spring, although other types of springs may be used as known in the art.

A locking member **54** may be operably coupled to a distal end **52** of carrier **34**, and is dimensioned to engage an internal surface of hub **10** in the non-shielding position. Locking member **54** may be a flange or flanged member. In some embodiments, the engagement between an internal surface of hub **10** and locking member **54** may include insertion of at least a portion of locking member **54** into hub **10** as shown in FIG. **5**. As noted, hub **10** may include a female luer adapter **13**, which engages with a close slip fit with locking member **54**.

In an embodiment, at a proximal end of axial lumen **48**, a hole or opening **58** (FIGS. **5-6**) may be provided in carrier **34** including shroud **36**. Hole **58** is dimensioned to accommodate the outer diameter of needle **14**. Needle **14** may include a crimp **19**, shown in FIG. **6**, which provides an area of needle **14** having enlarged diameter in at least one radial direction. Opening **58** does not accommodate crimp **19**, so that as shown in FIG. **8**, crimp **19** provides a stop which engages an inside of proximal end **56** of shroud **36**. Crimp **19** is positioned along needle **14** such that when crimp **19** reaches proximal end **56** of shroud **36**, sharp distal tip **16** of needle **14** is proximal of needle blocking object **39**, and therefore shielded.

As further shown in FIG. **5**, carrier **34** may be disposed substantially within latch **32**, the latter of which engages hub **10** to needle shield assembly **30** in the non-shielding position. Latch **32** includes a housing **33** having a proximal end **46** and a distal end **44**, the latter of which is coupled to a hooked latch member **38**. Latch member **38** and housing **33** are shown in FIG. **5** as being a single, continuous member, but embodiments in which latch member **38** and housing **33** are separate members that are operably connected are also considered part of the invention.

Latch member **38** is shaped and dimensioned to engage with flanged proximal end **11** of hub **10**. As shown in FIGS. **3** and **12**, latch member **38** includes a hooked leg extending over a flange on flanged proximal end **11** of hub **10**. In one embodiment, hooked latch member **38** includes a first member **81** extending radially outward relative to housing **33**, a

5

second member **82** extending distally from a radially outward end of first member **81** in a direction substantially parallel to housing **33**, and a third member **83** extending radially inward from the distal end of second member **82**, forming a distal restraining surface of latch **32**. In one embodiment, shown in FIG. **5**, second member **82** and third member **83** may be orthogonal. In an alternative embodiment, shown in FIG. **6**, the angle α formed by second member **82** and third member **83** may be other than orthogonal, e.g., about 135° , such that third member **83** provides a beveled edge on the distal restraining surface of latch **32** for releaseably engaging flanged proximal end **11** of hub **10**. With reference to FIG. **12**, in one embodiment, a first distance A between a radially inward end of the leg of latch member **38** and distal end **52** of locking member **54** as positioned within hub **10** is less than a second distance B between a proximal-most point on an internal diameter of hub **10** and a distal-most point on an external diameter of the flange on proximal end **11** of hub **10**. The above-described angled structure may be provided to enable smooth disengagement of hook member **38** and flanged proximal end **11**.

In some embodiments, flanged proximal end **11** of hub **10** may be threaded. Latch member **38** may have an extent that varies between about 90° and 180° circumferentially such that latch **32** can engage hub **10** regardless of position relative to threads on flanged proximal end **11** of hub **10**, and still be able to freely disengage from hub **10** in the shielding position.

Latch **32** further includes a first opening **40** extending through a wall thereof. In the non-shielding position, shown in FIGS. **5-6**, opening **37** in external shroud **36** substantially aligns with first opening **40** in latch **32** in the non-shielding position, such that at least a portion of needle blocking object **39** protrudes through opening **37** and into first opening **40**. The protruding portion of needle blocking object **39** engages a proximal edge **43** of first opening **40** in latch **32** to engage locking member **54** with the internal surface of hub **10** and maintain latch **32** in engagement with hub **10**.

FIGS. **7-10** illustrate the continued progression of movement from the non-shielding position to the shielding position. Upon movement of the needle shield assembly **30** from the non-shielding position to the shielding position, needle blocking object **39** exits first opening **40** in latch **32** and opening **37** in carrier **34**. Needle blocking object **39** does so under a force from spring **41**, which biases needle blocking object **39** distally and toward longitudinal axis **17** of needle **14**. Needle blocking object **39** at least partially enters axial lumen **48**, preventing emergence of sharp distal end **16** of needle **14** from carrier **34**. Locking member **54** disengages from hub **10** and moves proximally within latch **32**, allowing latch **32** to disengage hub **10** from needle shield assembly **30**.

Latch **32** may further include a second opening **42** through a wall of housing **33**. Second opening **42** is disposed proximally of first opening **40**.

In further embodiments, as shown in FIGS. **5-10**, latch **32** may include a first protrusion **62** on an inner surface of housing **33**. A second protrusion **64** may be disposed on an outer surface of carrier **34**. Where carrier **34** includes external shroud **36** encasing carrier **34**, second protrusion **64** may be on, or part of, an outer surface of external shroud **36**. First protrusion **62** interacts with second protrusion **64** as needle shield assembly **30** moves proximally from a non-shielding position to a shielding position such that a pull-out force required to move carrier **34** proximally relative to latch **32** is greater than a frictional force between needle blocking object **39** and needle **14**. This structure prevents wedging of block-

6

ing object **39** and needle **14**, as blocking object **39** can roll under proximal edge **43** of opening **40** in latch **32** and wedge against needle **14**.

As shown in FIGS. **1-5**, needle hub **20** may be disposed about latch **32**. Needle **14** is coupled to needle hub **20** such that when needle hub **20** is pulled in a proximal direction, needle **14** moves proximally toward a shielding position. Needle hub **20** may include a boss **21** that abuts proximal end **56** of shroud **36**.

When the needle shield assembly is in its fully assembled, non-shielding state (FIGS. **5-6**) locking member **54** fits closely into female luer **13** in hub **10**. Latch **32**, and particularly latch member **38**, is hooked over proximal end **11** of hub **10**. The fit between latch member **38** and proximal end **11** of hub **10** is loose, such that the pull-off force is low. Needle blocking object **39** partially protrudes through opening **37** and into first opening **40** in latch **32**. Needle blocking object **39** abuts distal edge **59** of opening **37** and proximal edge **43** of opening **40**, and is held in place by abutment with the outer surface of needle **14**. Locking member **54** cannot escape hub **10** due to needle blocking object **39** abutting with proximal edge **43** of first opening **40**.

When needle shield assembly **30** is deployed (i.e., needle **14** is withdrawn from hub **10** and carrier **34** moves into the shielding position shown in FIGS. **7-10**), the user pulls needle hub **20** in a proximal direction, thus drawing needle **14** along cannula **12** and carrier **34**, until crimp **19** abuts opening **58** in shroud **36**. At that point, sharp distal tip **16** of needle **14** has passed needle blocking object **39**, and needle blocking object **39** has moved into lumen **48**, urged there by spring **41** (turning about distal edge **59** of opening **37** in shroud **36**), thereby blocking the path of sharp distal tip **16** of needle **14**, should needle **14** move in the distal direction. Locking member **54** can now move out of hub **10** and deeper, or proximally, into latch **32**, since needle blocking object **39** is no longer obstructed by proximal edge **43** of first opening **40**. This movement also releases latch member **38**, so it can disengage with proximal end **11** of hub **10**.

The combination of needle blocking object **39**, needle **14**, openings **37** in shroud **36** and first opening **40** in latch **32**, and locking member **54** (on carrier **34**) forms a locking assembly, which secures needle shield assembly **30** to hub **10**. This locking assembly is only released when sharp distal tip **16** of needle **14** has passed needle blocking object **39** and is thus shielded, thereby providing a passive safety shield which cannot disengage from hub **10** prior to shielding sharp distal tip **16** of needle **14**. Needle shield assembly **30** is substantially external of hub **10** in this position, thus providing space within hub **10** for a blood sealing device **15**, for example a septum or a luer-actuated valve, as well as a side port.

The combination of crimp **19** and opening **37** in shroud **36** prevents proximal movement of sharp distal tip **16** of needle **14**. This and other ways of preventing proximal movement of the needle **14** are shown in co-pending US patent applications No. 2008/0119795 A1, No. 2009/0137958 A1 and 2009/0249605 A1, each of which are incorporated herein by reference.

A method of assembling or manufacturing the device will now be described.

With reference to FIG. **13**, a needle blocking object **39** may be placed in carrier **34**. Carrier **34** may include: a locking member **54** on, or engaged with, a distal end **52** thereof, and a channel **50** for carrying needle blocking object **39**. Carrier **34** may be inserted into shroud **36** until a proximal end of carrier **34** abuts proximal end **56** of shroud **36**. Shroud **36** is then inserted into latch **32** until proximal end **56** of shroud **36** abuts a reduced diameter portion at a proximal end of latch **32**.

7

Latch 32 includes a latch member 38 extending from a portion of a distal end 44 of latch 32. Latch 32 further includes a first opening 40 through a wall thereof, and a second opening 42 through a wall thereof, located proximally of first opening 40.

Proximal end 18 of needle 14 is inserted into distal end 52 of axial lumen 48 in carrier 34. Needle 14 displaces needle blocking object 39 such that it protrudes at least partially into second opening 42 in latch 32, as shown in FIG. 13. Proximal end 18 of needle 14 is then affixed to needle hub 20, for example, with glue as shown in FIGS. 3 and 5. Hub 10 may have a flanged proximal end 11. Latch member 38 is engaged with flanged proximal end 11 of hub 10 as shown in FIG. 14. Hub 10 and cannula 12 are then threaded over distal tip 16 of needle 14. Needle shield assembly 30 is then inserted into needle hub 20, causing boss 21 to push locking member 54 distally into hub 10, slip fitting closely into it as shown in FIG. 5.

Hub 10 may include a female luer adapter 13 therein. The foregoing engagement of latching member 38 with flanged proximal end 11 of hub 10, and the insertion of locking member 54 into hub 10 cause needle blocking object 39 to move distally within carrier 34 and out of second opening 42 (FIGS. 14-15), such that it protrudes into first opening 40 in latch 32 as in FIG. 5. Latch 32 may be configured to flex or expand slightly to allow needle blocking object 39 to snap from second opening 42 to first opening 40. Needle shield assembly 30 is thus locked onto hub 10 and is ready for deployment as described herein.

As used herein, the terms “first,” “second,” and the like, do not denote any order, quantity, or importance, but rather are used to distinguish one element from another, and the terms “a” and “an” herein do not denote a limitation of quantity, but rather denote the presence of at least one of the referenced item. The modifier “about” used in connection with a quantity is inclusive of the stated value and has the meaning dictated by the context (e.g., includes the degree of error associated with measurement of the particular quantity). The suffix “(s)” as used herein is intended to include both the singular and the plural of the term that it modifies, thereby including one or more of that term (e.g., the metal(s) includes one or more metals). Ranges disclosed herein are inclusive and independently combinable (e.g., ranges of “up to about 25 mm, or, more specifically, about 5 mm to about 20 mm,” is inclusive of the endpoints and all intermediate values of the ranges of “about 5 mm to about 25 mm,” etc.).

While various embodiments are described herein, it will be appreciated from the specification that various combinations of elements, variations or improvements therein may be made by those skilled in the art, and are within the scope of the invention. In addition, many modifications may be made to adapt a particular situation or material to the teachings of the invention without departing from essential scope thereof. Therefore, it is intended that the invention not be limited to the particular embodiment disclosed as the best mode contemplated for carrying out this invention, but that the invention will include all embodiments falling within the scope of the appended claims.

What is claimed is:

1. A needle device comprising:

a hub having a longitudinal axis;

a needle having a sharp distal tip;

a needle shield assembly associated with the needle and moveable from a non-shielding position to a shielding position in which the sharp distal tip is covered by at least part of the needle shield assembly;

8

a latch engaging with a radially outer surface of the hub when the needle shield assembly is in the non-shielding position; and

a locking member operably connected to the needle shield assembly, and located at least partially within the hub when the needle shield assembly is in the non-shielding position, thereby locking the latch to the hub, and such that when the needle shield assembly moves into the shielding position, the locking member moves generally proximally, thereby unlocking the latch.

2. The needle device of claim 1 wherein, when the needle shield assembly moves proximally out of the hub, the latch moves generally radially outward relative to the longitudinal axis.

3. The needle device of claim 2, wherein the latch comprises a housing coupled to a latch member.

4. The needle device of claim 3, wherein the housing includes a first opening extending through a wall thereof.

5. The needle device of claim 1, wherein the needle shield assembly comprises:

a needle blocking object;

a spring for biasing the needle blocking object distally and toward the longitudinal axis; and

a carrier for carrying the needle blocking object.

6. The needle device of claim 5, wherein the carrier includes:

a channel in which the needle blocking object is carried, an axial lumen slidable on and dimensioned to accommodate the needle, and

an external shroud providing an opening through which a portion of the needle blocking object projects in the non-shielding position,

wherein in the shielding position, the needle blocking object at least partially occupies the axial lumen.

7. The needle device of claim 5, wherein the locking member further comprises a flange coupled to a distal end of the carrier.

8. The needle device of claim 6, wherein the external shroud includes a hole axially aligned with the axial lumen and dimensioned to accommodate the needle,

wherein the needle further includes a crimp having a larger outer diameter than that of the needle,

wherein the hole engages the crimp to provide a stop preventing further proximal movement of the needle, and wherein the sharp distal tip of the needle is shielded by the needle shield assembly when the crimp engages the hole.

9. The needle device of claim 6, wherein the external shroud further comprises a substantially cylindrical member having an open distal end.

10. The needle device of claim 6, wherein the housing further comprises a first protrusion on an inner surface thereof, and the external shroud further comprises a second protrusion on an outer surface thereof,

wherein the first protrusion interacts with the second protrusion as the needle shield assembly moves proximally from the non-shielding position to the shielding position, and wherein a pull-out force required to move the carrier proximally relative to the housing is greater than a frictional force between the needle blocking object and the needle.

11. The needle device of claim 1, wherein the hub comprises a flanged proximal end.

12. The needle device of claim 11, wherein the hub further comprises a threaded flanged proximal end.

9

13. The needle device of claim 3, wherein the latch member extends circumferentially between about 90° and about 180° about a distal end of the housing.

14. The needle device of claim 3, wherein the latch member comprises a hooked leg having:

a first member extending radially outward relative to the housing,

a second member extending distally from a radially outward end of the first member in a direction substantially parallel to the housing, and

a third member extending radially inward from a distal end of the second member, forming a distal restraining surface of the latch,

wherein an angle formed by the second member and the third member is about 135°.

15. The needle device of claim 14, wherein a first distance between a radially inward end of the third member and a distal end of the locking member is less than a second distance between a proximal-most point on an internal diameter of the hub and a distal-most point on an external diameter of a flange on a proximal end of the hub.

16. The needle device of claim 4, wherein the housing further includes a second opening extending through a wall thereof, located proximal of the first opening.

17. The needle device of claim 1, further comprising a needle hub disposed about the needle shield assembly, wherein the needle hub includes a boss abutting a proximal end of the needle shield assembly.

18. The needle device of claim 5, wherein in the non-shielding position,

a portion of the needle blocking object protrudes into a first opening in the latch, and engages a proximal edge of the first opening.

19. The needle device of claim 18, wherein upon movement of the needle shield assembly from the non-shielding position to the shielding position,

the needle blocking object exits the first opening in the latch under a force from the spring and at least partially enters the axial lumen to prevent emergence of the sharp distal end of the needle from the carrier.

20. The needle device of claim 1, wherein the hub further comprises a female luer adapter.

21. The needle device of claim 1, wherein the hub further comprises at least one of: a valve and a septum.

22. A needle device comprising:

a hub comprising a luer connector with a luer thread and having a longitudinal axis;

a needle having a sharp distal tip;

a needle shield assembly associated with the needle and moveable from a non-shielding position to a shielding position in which the sharp distal tip is covered by at least part of the needle shield assembly;

a latch engaging with the luer thread of the hub when the needle shield assembly is in the non-shielding position; and

a locking member operably connected to the needle shield assembly and located at least partially in the luer connector when the needle shield assembly is in the non-shielding position, thereby locking the latch to the hub, and such that when the needle shield assembly moves into the shielding position, the locking member moves axially.

23. The needle device of claim 22, wherein the needle shield assembly comprises a needle blocking member

10

adapted to move from a locking position in which the needle blocking member locks the needle shield assembly to the luer connector and maintains the locking member at least partially in the hub to the shielding position in which the needle blocking member releases the needle shield assembly from the luer connector and releases the locking member so that the locking member unlocks the latch and moves outwards relative to the hub.

24. A needle device comprising:

a hub comprising a luer connector with a luer thread and having a longitudinal axis;

a needle having a sharp distal tip; and

a housing comprising:

a needle shield assembly associated with the needle and operably connected to the housing, the needle shield assembly being moveable from the non-shielding position to a shielding position in which the sharp distal tip is covered by at least part of the needle shield assembly;

a latch engaging with the luer connector of the hub when the needle shield assembly is in a non-shielding position; and

the needle shield assembly further comprising a locking member located at least partially in the hub when the needle shield assembly is in the non-shielding position, thereby locking the latch to the luer connector, and such that when the needle shield assembly moves into the shielding position, the locking member moves axially thereby allowing the latch to move radially relative to the longitudinal axis.

25. The needle device of claim 24, wherein the needle shield assembly further comprises a needle blocking member adapted to move from a locking position in which the needle blocking member locks the needle shield assembly to the housing to a needle blocking position in which the needle blocking member releases the housing, thereby releasing the latch.

26. A method of manufacturing a needle assembly comprising:

placing a blocking object in a carrier, wherein the carrier includes a flange disposed on a distal end thereof;

inserting the carrier into a shroud;

inserting the shroud into a housing until the proximal end of the shroud abuts a reduced diameter portion at a proximal end of the housing, wherein the housing includes a hooked member circumferentially extending from a portion of a distal end of the housing, and a first, distal opening and a second, proximal opening are provided through a wall of the housing;

inserting a proximal end of a needle into an axial lumen of the carrier, thereby displacing the blocking object such that the blocking object protrudes at least partially through the proximal, second opening in the housing; affixing the proximal end of the needle to a needle hub; engaging the hooked member with a flanged proximal end of a hub;

threading the hub and a cannula over a distal end of the needle;

inserting the housing into the needle hub, wherein the engaging and inserting the housing causes the blocking object to move distally such that it protrudes from the first, distal opening in the housing.

* * * * *